Optimizing the Patient Journey in Cataract and Refractive Surgery

Joukje Wanten

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Optimizing the Patient Journey in Cataract and Refractive Surgery

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List of abbreviations

AAO	American Academy of Ophthalmology
ACD	anterior chamber depth
AE	adverse event
AEMPS	Agencia Española de Medicamentos y Productos Santarios
AGREE II	Appraisal of Guidelines for Research and Evaluation II
AI	artificial intelligence
AIOL	accommodative intraocular lens
AL	axial length
AMD	age-related macular degeneration
ANSI	American National Standards Institute
ASCRS	American Society of Cataract and Refractive Surgery
AS-OCT	anterior segment optical coherence tomography
ATR	against-the-rule
BOCA	Bayer Ophthalmic Care Award
BOOST	better operative outcome software tool
BU-II	Barrett Universal-II
CCS	conventional cataract surgery
CDG	constituting guideline development group
CDVA	corrected distance visual acuity
CE	Conformity Européenne
CI	confidence interval
CME	cystoid macular edema
CNVA	corrected near visual acuity
CTA	corneal topographic axis
D	diopter
DCIVA	distance-corrected intermediate visual acuity
DCNVA	distance-corrected near visual acuity
DED	dry eye disease
DEQ	defocus equivalent
DOFi	depth of field
DSBCS	delayed sequential bilateral cataract surgery
DSR	delayed surgical recovery
ECD	endothelial cell density
EDF / EDOF	extended depth-of-focus
epi-LASIK	epithelial laser-assisted in situ keratomileusis
EQ-5D-5L	EuroQol 5-dimension 5-level
ERM	epiretinal membrane
ESCRS	European Society of Cataract and Refractive Surgeons
ETDRS	early treatment diabetic retinopathy study
EUREQUO	European Registry of Quality Outcomes for Cataract and Refractive Surgery
FDA	Food and Drug Administration
FLACS	femtosecond laser-assisted cataract surgery
FVR	functional visual range
GDG	guideline development group
GEE	generalized estimating equation
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICER	incremental cost-effectiveness ratio

ICL	implantable collamer lens
IFIS	intraoperative floppy iris syndrome
IOL	intraocular lens
IOP	intraocular pressure
IPCL	implantable phakic contact lens
ISBCS	immediate sequential bilateral cataract surgery
ISO	International Organization for Standardization
IVI	intravitreal injection
KLEx	keratorefractive lenticule extraction
KSR	Kleijnen Systematic Reviews
LAL	light adjustable lens
LASEK	laser-assisted subepithelial keratectomy
LASIK	laser-assisted in situ keratomileusis
LE	left eye
LFU	lost to follow-up
LoA	limits of agreement
logMAR	logarithm of the minimum angle of resolution
MGD	meibomian gland dysfunction
mIOL	multifocal intraocular lens
MMAS-8	Morisky Medication Adherence Scale
Mono-EDF	monofocal intraocular lens with enhanced depth of focus
MRSE	manifest refraction spherical equivalent
MTF	modulation transfer function
MUMC+	Maastricht University Medical Center+
NA	not applicable
NEI-VFQ-25	National Eye Institute Visual Function Questionnaire-25
NIOIC	Nederlandse Intraoculaire Implant Club
NOG	Nederlands Oogheelkundig Gezelschap
NPS	Net Promoter Score
NR	not reported
NSAID	nonsteroidal anti-inflammatory drug
OCT	optical coherence tomography
OR	odds ratio
PA	pupillary axis
PCO	posterior capsule opacification
PE	prediction error
PEX	pseudoexfoliation syndrome
PICO	Population Intervention Comparators Outcome
pIOL	phakic intraocular lens
PRK	photorefractive keratectomy
PROM	patient-reported outcome measurement
PVD	posterior vitreous detachment
QALY	quality-adjusted life year
QoL	quality of life
QoV	Quality of Vision questionnaire
RCT	randomized controlled trial
RE	right eye
RK	radial keratotomy
RLE	refractive lens exchange
SAE	serious adverse event

SAI	State Anxiety Inventory
SD	standard deviation
SE	standard error
SE / SEQ	spherical equivalent
SIA	surgically induced astigmatism
SMS	short message service
SS-OCT	swept-source optical coherence tomography
SUS	System Usability Scale
SVL	simultaneous vision lenses
TASS	toxic anterior segment syndrome
TBUT	tear break-up time
TK	total keratometry
TUQ	Telehealth Usability Questionnaire
UDVA	uncorrected distance visual acuity
UIVA	uncorrected intermediate visual acuity
UNVA	uncorrected near visual acuity
UV	ultraviolet
VA	visual acuity / visual axis
VEGF	vascular endothelial growth factor
WHO	World Health Organization
WTR	with-the-rule



CHAPTER 1

Introduction

Introduction

The ability to see is a fundamental aspect of our daily life. It enables us to perceive the world around us and interact with the people we love. Research conducted in the United Kingdom has identified vision as the most valued sense.[1] Vision impairment is significantly associated with reduced quality of life and is considered one of the most detrimental health conditions, with a greater impact on daily functioning than the loss of speech, hearing, or a limb.[2,3] Moreover, vision loss is associated with an increased risk of all-cause mortality. Individuals experiencing severe vision impairment or blindness face a higher risk compared to those with normal vision or mildly impaired vision.[4] Given the significant impact of vision on quality of life and longevity, ophthalmology plays an important role in medicine, focusing on delivering the highest standard of care to achieve optimal visual outcomes, ensure patient satisfaction, and promote long-term well-being.

The aim of this thesis is to explore potential improvements in the patient journey for cataract and refractive surgery, from the initial consultation to postoperative assessments.

The optical pathway

To understand potential improvements in cataract and refractive surgery, it is essential to understand the anatomical and optical mechanisms that underlie optimal vision. Optimal vision depends on the entire optical system, beginning with the projection of light onto the fovea in a healthy eye. **Figure 1.1** shows the anatomy of the eye, including the refractive components that contribute to this process. Incoming light is subsequently refracted by the tear film, cornea, and crystalline lens before reaching the retina, where photoreceptors (rods and cones) detect it. The photoreceptors convert light into electrical signals, which are transmitted through the optic nerve to the visual cortex in the brain for further processing and perception.[5]

Any imperfections or impairments in the optical components, such as refractive errors and cataract, disrupt this refractive pathway and can significantly affect visual acuity. A refractive error is an eye condition that arises from abnormalities in the eye's shape or length, causing blurred vision at various distances. In contrast, cataract is an age-related disease characterized by clouding of the crystalline lens, which scatters light and reduces visual clarity.[6] Patients with cataract may report symptoms such as blurred vision, difficulty seeing in low light conditions, increased visual disturbances, and faded colors.[7] Currently, both these conditions are the leading causes of moderate to severe vision impairment worldwide, significantly impacting the quality of life for many individuals.[6-9]

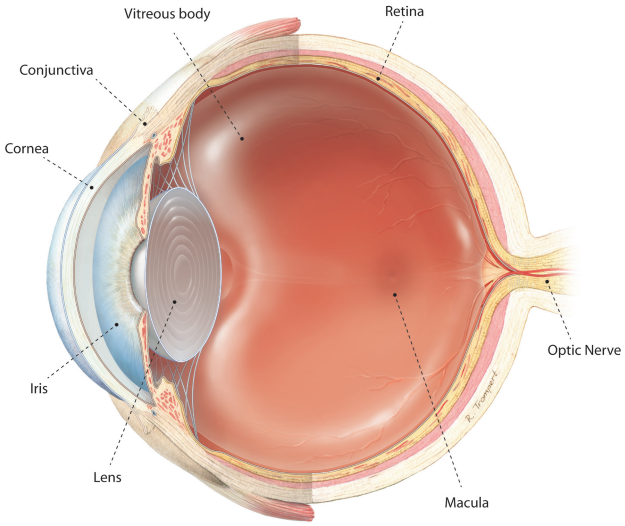

Figure 1.1. Anatomy of the eye.

Initial assessment

The journey of patients seeking cataract and refractive surgery begins with a visit to the ophthalmologist, where common complaints include reduced visual acuity and difficulties performing daily tasks such as reading, driving, or recognizing faces. During this initial assessment, both the overall health of the eye and the patient's visual goals are evaluated. Understanding the refractive state of the eye is crucial for offering personalized medical advice and determining the most suitable non-surgical or surgical approach.

The refractive state of the eye describes how light is focused by the cornea and lens onto the retina. In emmetropia, light rays entering the eye are perfectly focused on the retina, as shown in **Figure 1.2**. Ametropia, the presence of a refractive error, encompasses three main types: myopia, hyperopia, and astigmatism. In myopia (nearsightedness), the focal point of parallel light rays lies in front of the retina, whereas in hyperopia (farsightedness), it lies behind the retina. Astigmatism is characterized by cylindrical refractive errors that lead to irregular light projections onto the retina and result in blurred or distorted vision. This condition can occur independently or in combination with myopia or hyperopia. The different types of refractive errors are illustrated in **Figure 1.3**. The magnitude of a refractive error is expressed in Diopters (D), the reciprocal of the focal distance in meters.

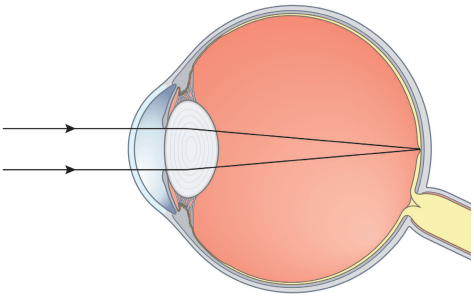

Figure 1.2. Pathway of parallel light rays in an emmetropic eye.

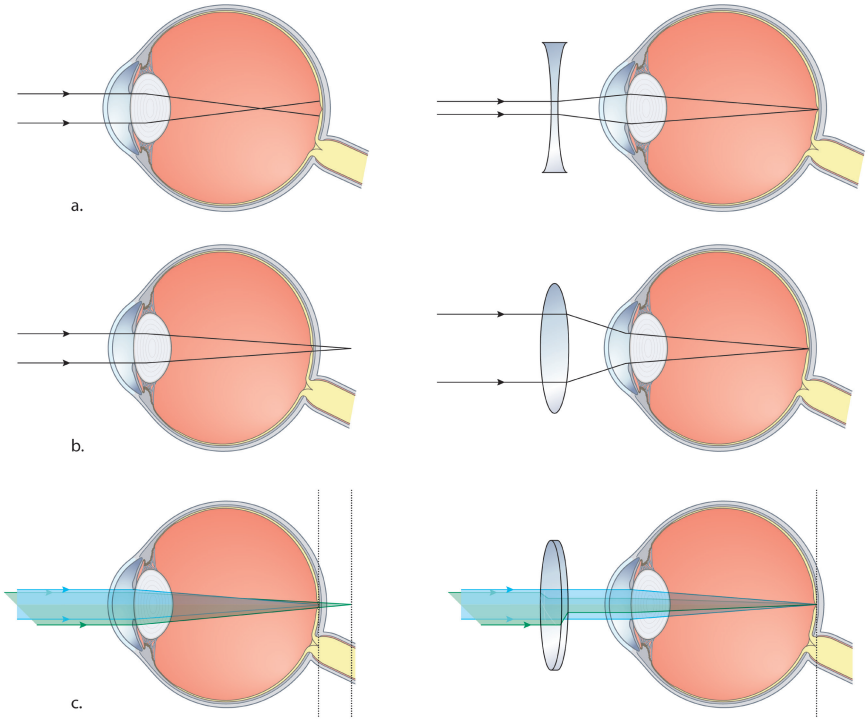

Figure 1.3. Natural pathway of parallel light rays and their pathway after correction with a convex, concave, or toric lens in a myopic (a), hyperopic (b), and astigmatic eye.

In addition to refractive errors, presbyopia represents another important common visual condition that must be assessed during the preoperative evaluation. Presbyopia is not classified as a refractive error, but as an age-related visual condition that is characterized by a gradual decline in the eye's capacity to accommodate. Accommodation refers to the ability of the crystalline lens to adjust the refractive power by increasing its convexity, enabling the eye to focus on near objects. With advancing age, the crystalline lens becomes sclerotic and loses its flexibility, resulting in diminished accommodative capacity and the onset of presbyopia.[10,11] This condition impairs the ability to see clearly at near distances and is significantly associated with a reduced quality of life.[12,13] Presbyopia often coexists with cataract, which represents the leading cause of irreversible vision loss worldwide.[6] Understanding these visual impairments is essential for determining appropriate solutions to restore or optimize visual acuity.[14] Unlike refractive errors, cataract has no non-invasive treatment options; surgical intervention is the only effective method to restore vision. After fully characterizing the patient's ocular condition and considering available treatment options, the next step is to evaluate eligibility and carefully plan the appropriate intervention.

Decision-making

When cataract or refractive surgery is being considered, a systematic screening is conducted to evaluate the patient's eligibility for specific procedures. This assessment includes measuring eye dimensions such as axial length and anterior chamber depth through biometry, evaluating corneal characteristics using techniques like keratometry and corneal topography, and assessing other critical eye parameters such as lens opacity and intraocular pressure.[15] Absolute contraindications rule out a surgical procedure, while relative contraindications require shared decisions between patient and surgeon.[14-19] These assessments and discussions ensure that treatment decisions align with the patient's ocular health and visual goals.

For patients with refractive errors and/or presbyopia, but without cataract, non-invasive methods such as the use of spectacles or contact lenses are typically recommended as first-line treatment. These options are effective for patients who seek visual correction without undergoing surgery. However, if a patient desires independence from spectacles or contact lenses, or if non-invasive options do not fully meet their needs, invasive surgical methods become necessary for the long-term correction of the refractive error. For patients with a cataractous lens though, cataract surgery remains the only effective method to restore visual acuity by removing the cloudy lens and replacing it with an

intraocular lens (IOL).

Shared decision-making is a core element of patient-centered care, ensuring active involvement of both the patient and surgeon in the treatment process.[20] This approach supports aligning the treatment plan with the patient's desires, expectations, and lifestyle. The decision-making process includes thorough discussions about the potential benefits, risks, and outcomes of the various treatment options. Both the patient and surgeon must reach a consensus on the approach, with the patient being fully informed about the potential outcomes and limitations of each option. Ultimately, these decisions are driven by the patient's perspective on how their refractive conditions or cataract affect their quality of life, as well as the feasibility and limitations of the available treatment options.

Cataract Surgery

For patients diagnosed with cataract, once the decision to proceed with surgery is made, cataract extraction is the standard approach to restore visual function. This procedure is among the most frequently performed surgeries worldwide and is recognized for its high effectiveness and safety.[7] In the Netherlands, over 180.000 cataract surgeries are performed annually.[21] The current standard procedure is phacoemulsification under topical anesthesia, which begins with the creation of a small corneal incision. This is followed by the formation of a capsulorhexis to access the cataractous lens. Hydrodissection is performed to separate the lens from the capsule, facilitating its removal. Then the lens is fragmented and removed using ultrasonic energy, after which an artificial IOL is implanted in into the capsular bag. These surgical steps are illustrated in **Figures 1.4 and 1.5**.[10]

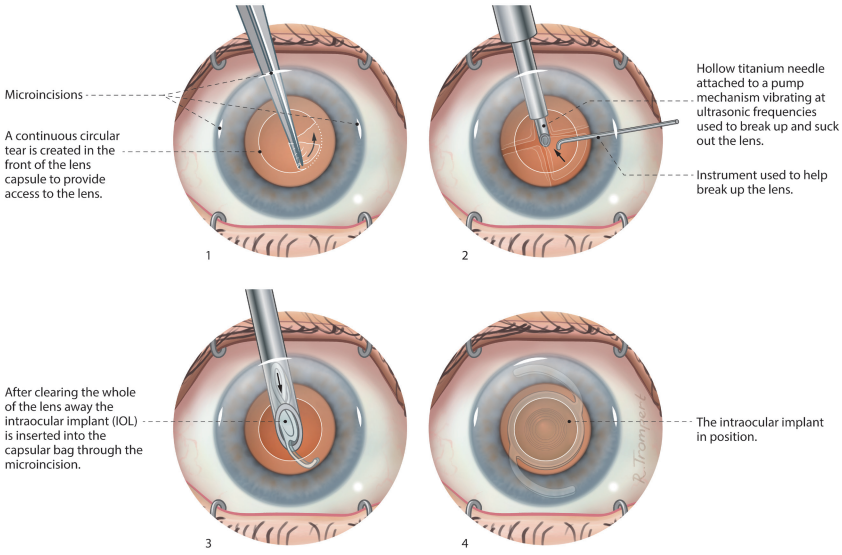

Figure 1.4. Main steps of cataract surgery, including creating a capsulorhexis (1), fragmentation and removal of the cataractous lens, placement of the introcular lens (3), with finally the intraocular lens in situ in the capsular bag (4).

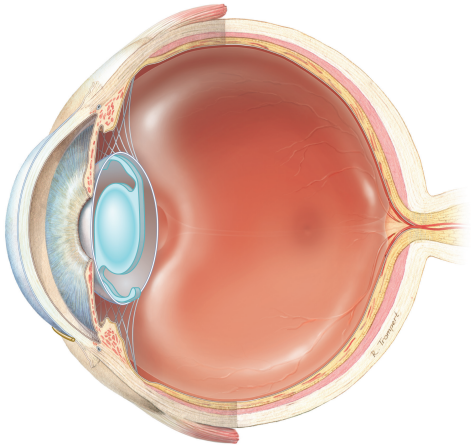

Figure 1.5. Eye after IOL implantation in the capsular bag.

When a decision for cataract surgery is made and the surgeon has evaluated relevant ocular characteristics and any comorbidities that may affect the procedure or postoperative outcomes, the next step is selecting the appropriate target refraction and IOL. This decision is based on both objective clinical criteria and the patient's visual preferences, which are influenced by various aspects, including the patient's occupation, daily activities,

and the desire for spectacle independence. By considering all these factors, the surgeon can recommend an IOL and target refraction that best aligns with the patient's specific requirements and needs, ensuring a personalized approach to treatment.[22-24]

Target refraction

Before determining the appropriate IOL type, selecting the desired target refraction is a fundamental aspect of preoperative decision-making. The main options include emmetropia, myopia, monovision, and mini-monovision. Generally, most patients choose an emmetropic target, aiming for optimal uncorrected visual acuity at distance.[25] Yet, this approach may not address the specific needs of every patient. Some individuals prefer to keep their myopic target to reduce their dependence on reading glasses for near vision, as they have been familiar with during their lifetime. Monovision – targeting emmetropia in the dominant eye and myopia in the non-dominant eye (typically ranging from -1.0 to -2.0 D) – can increase spectacle independence. However, this method of inducing anisometropia can result in reduced stereopsis and can require neuroadaptive processes for the brain to adjust to using each eye for different visual tasks: the dominant eye for distance vision and non-dominant eye for near vision.[11,26-30] A variation of this technique, mini-monovision, involves a smaller refractive difference between the eyes, targeting the dominant eye for emmetropia and the non-dominant eye for myopia ranging from -0.25 D to -0.75 D. This approach offers a more balanced compromise by reducing binocular reading distance while maintaining the quality and quantity of binocular distance vision. Nevertheless, mini-monovision generally does not result in complete spectacle independence, as most patients still require reading glasses for near tasks.[31-33]

Intraocular lens classifications

Understanding the characteristics of different IOLs is crucial for healthcare providers to effectively inform patients and facilitate shared decision-making, thereby enhancing the overall patient experience. IOLs can be classified using various systems. One common method categorizes them based on optical technologies, primarily distinguishing between refractive and diffractive optics. Refractive optics bend the incoming light, while diffractive optics split the light into multiple directions or focal points, creating multifocality, as shown in **Figure 1.6**.[11,34] Some IOL designs integrate both refractive and diffractive elements.

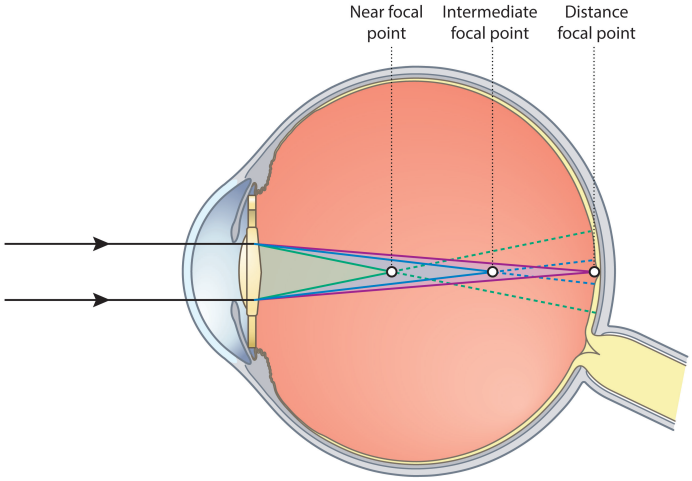

Figure 1.6. Principle of multifocality in an eye implanted with a multifocal (trifocal) intraocular lens.

An alternative classification categorizes IOLs based on the number of focal points they provide, including multifocal (bifocal, trifocal, quadrifocal), Extended Depth-of-Focus (EDF), monofocal with enhanced depth-of-focus, and conventional monofocal IOLs as presented in **Figure 1.7**. Monofocal IOLs offer high optical quality and a low risk for visual disturbances, yet limited spectacle independence.[11] In contrast, multifocal IOLs provide focus at multiple distances, increasing spectacle independence. However, they may reduce contrast sensitivity and have an increased risk of optical phenomena such as glare and halos due to their optic design.[34,35] EDF IOLs are designed to provide a continuous range of vision from far through intermediate, serving as a compromise between monofocal and multifocal IOLs. While they increase spectacle independence, they maintain a disturbance profile similar to monofocal IOLs. Importantly, patients who receive EDF IOLs typically still require reading glasses for near tasks.[34,36-38]

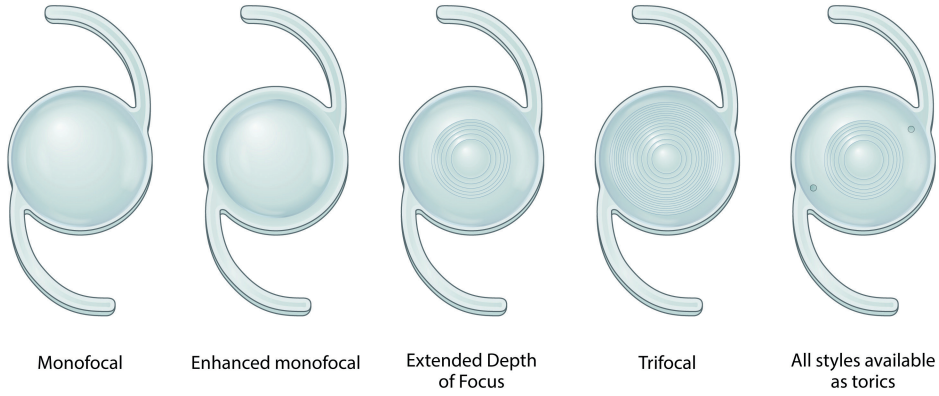

Figure 1.7 Classification of intraocular lenses based on the number of focal points.

The International Organization for Standardization (ISO) categorizes IOLs into four primary types based on their optical design and clinical features: monofocal, toric, simultaneous vision lenses (SVL), and accommodating IOLs.[39] Among these, SVLs are non-accommodative IOLs that provide simultaneous vision at multiple distances and can be further subdivided into multifocal, EDF, and full visual range (FVR) IOLs.

To better understand how IOLs perform across different visual demands, defocus curves are used to assess visual acuity over a range of simulated distances by introducing varying amounts of defocus, providing valuable insights into the optical performance of IOLs.[40] Recently, a functional classification has been developed to assess IOLs based on their depth of field (DOFi) in the monocular distance-corrected defocus curve at 0.2 logMAR visual acuity and based on the improvement of visual acuity from intermediate to near distances (see chapter 2).[41,42] This classification has a more patient-centered approach as it focuses on visual acuity outcomes across multiple distances, which is most relevant to patients. However, it is important to note that this functional classification solely focuses on visual acuity achieved along the DOFi and does not account for other functional outcomes, such as dysphotopsia, contrast sensitivity, and patient-reported outcomes, all of which should also be considered during the IOL selection process.

Refractive surgery

In contrast to cataract surgery, which focuses on improving vision through the removal of the cataractous lens and implantation of an IOL, refractive surgery addresses refractive errors in patients without cataract formation. The primary objective of refractive surgery is to achieve spectacle or contact lens independence. Refractive surgery encompasses a variety of surgical techniques, including both cornea and lens-based surgical procedures. Over the last decades, advances in technology have significantly improved the precision and safety of these procedures, thereby expanding their applicability to a broader patient population seeking freedom from spectacles or contact lenses.

Cornea-based procedures

Cornea-based refractive procedures consist of laser techniques that reshape the cornea to correct refractive errors. These techniques are divided into surface and intracorneal ablative approaches. Surface ablative methods– such as photorefractive keratectomy (PRK), Laser-Assisted Subepithelial Keratectomy (LASEK), and Epithelial Laser-Assisted in Situ Keratomileusis (epi-LASIK)–require removal or loosening of the corneal epithelium to expose the stroma for laser ablation as shown in **Figure 1.8**. Intracorneal laser procedures include Laser-Assisted in Situ Keratomileusis (LASIK), and Keratorefractive Lenticule Extraction (KLEx). In LASIK, a lamellar flap is created using either a mechanical microkeratome or a femtosecond laser. The flap is then lifted to allow ablation of the underlying stromal bed, and once ablation is complete, the flap is repositioned, as illustrated in **Figure 1.9**. In KLEx, a femtosecond laser creates an intrastromal lenticule, which is extracted through a small corneal incision, presented in **Figure 1.10**. The removal of this lenticule alters the corneal curvature to correct the refractive error.[16,43,44]

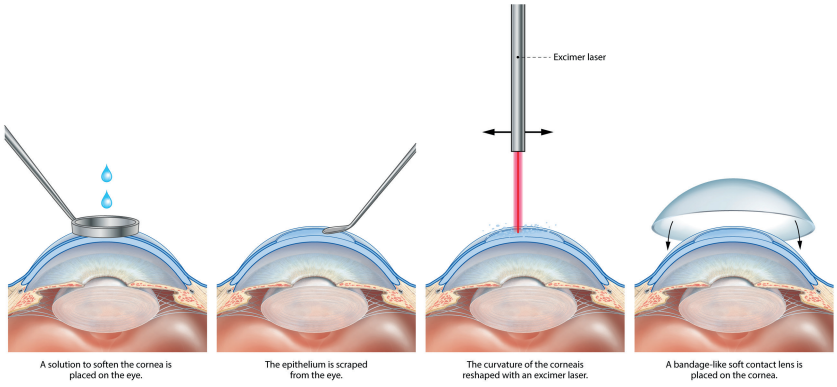

Figure 1.8. Photorefractive keratectomy (PRK).

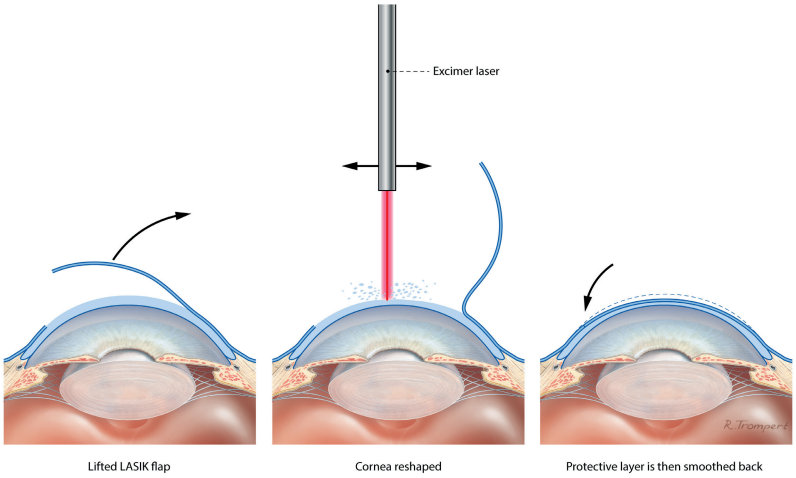

Figure 1.9. Laser-Assisted in Situ Keratomileusis (LASIK).

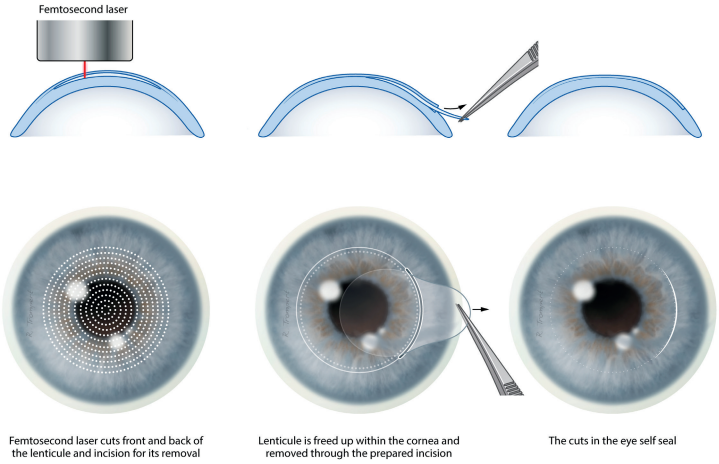

Figure 1.10. Keratorefractive Lenticule Extraction (KLEx).

Lens-based procedures

Lens-based procedures can be categorized into two types: crystalline lens-sparing procedures such as phakic intraocular lens (pIOL) implantation, and crystalline lens-extraction procedures, also known as refractive lens exchange (RLE).[16,43,44] In pIOL implantation, an artificial lens is implanted in the eye, positioned in front of the patient's crystalline lens. There are two types of pIOLs, classified by their positioning within the

eye, including the anterior and posterior chamber pIOLs. Anterior chamber pIOLs are iris-fixated IOLs with "lobster claws", as shown in **Figure 1.11**, while posterior chamber pIOLs are implanted in the sulcus, the space between the crystalline lens and the iris.[45,46] RLE involves the removal of the crystalline lens and its replacement with an IOL. This procedure follows similar steps to those of cataract surgery, but is performed electively before cataract formation.[43,44] The decision-making process regarding the selection of the IOL and target refraction is similarly personalized, taking into account factors such as the patient's age, ocular parameters, visual needs, and preferences.[43]

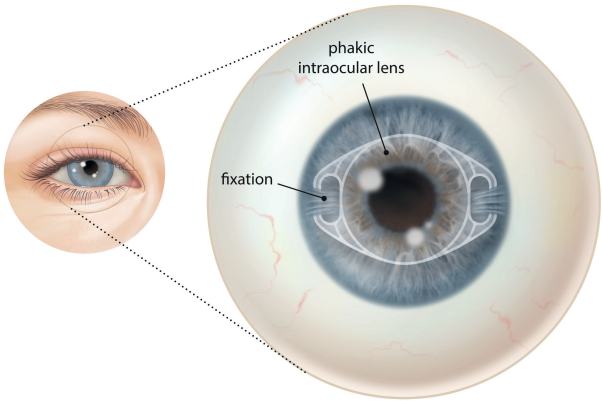

Figure 1.11. Implanted iris-fixated phakic intraocular lens.

Refractive surgery for presbyopia correction

Most patients seeking refractive surgery are under the age of 40, accounting for 59% of the total patient population, with 36% aged between 40 and 60. Among those under 40, 70% proceed with surgery, compared to only 40% in the 40 to 60 age group. This difference is largely due to the onset of presbyopia, which generally occurs around the age of 40.[47] Several procedures exist to address presbyopia, however, no single technique has emerged as superior, as patient suitability varies widely between methods.[13,48,49] Consequently, presbyopia correction remains one of the last challenges in refractive surgery.

Cornea-based options for presbyopia correction are available but have not gained widespread popularity among patients and surgeons.[44,50] Many corneal inlays have been associated with biocompatibility issues, such as corneal haze, and their long-term performance has been limited by regression, as observed in procedures like laser thermal keratoplasty.[51] Newer approaches, including intrastromal implantation of human corneal tissue—particularly for high hyperopia—are currently under investigation.[52,53] In addition,

advanced excimer and femtosecond laser algorithms for presbyopic correction, such as those integrated in the platforms of Zeiss and Schwind, represent evolving options.[54,55] Among lens-based strategies, refractive lens exchange with presbyopia-correcting IOLs remains a popular choice. Nevertheless, this procedure poses specific challenges in patients with moderate to high myopia, particularly due to their relatively young age and increased axial length, which elevate the risk of retinal detachment.[56,57] For these patients, presbyopia-correcting pIOLs may offer a safer alternative by preserving the crystalline lens and reducing the risk of retinal complications.[45,50] Phakic IOLs are well-established for correcting myopia and myopic astigmatism, and are commonly used in patients with high myopia and thin corneas.[45,48] The novel concept of a presbyopia-correcting pIOL has the potential to broaden the spectrum of patients who can achieve spectacle independence.[58-61]

Surgical outcomes and patient satisfaction

The success of surgical interventions has traditionally been assessed using objective clinical measures. While this approach remains important, there is an increasing emphasis on subjective outcomes, particularly patient satisfaction. Such subjective outcomes offer valuable insights into the patient's overall experience, quality of life, and well-being following surgery. By considering both objective and subjective outcomes, a more comprehensive understanding of surgical success can be achieved, highlighting the need for a holistic approach to patient care.

Objective outcomes

Cataract and refractive surgeries are both effective and safe in improving visual acuity and overall visual function.[10,43] Standard objective clinical assessments after surgery include monitoring for complications, measuring visual acuity, and evaluating refractive outcomes. When results are suboptimal, further investigation is required to identify the underlying causes, such as ocular comorbidities or problems related to the IOL. Precise IOL alignment is critical for optimal performance. Ideally, the optical center should be aligned with the eye's visual axis. Misalignment in the form of tilt (the angular deviation between the visual axis and the IOL plane) or decentration (the lateral displacement between them) can adversely affect IOL function.[62-64] Additional diagnostic tests, such as wavefront aberrations, contrast sensitivity, stray light, and binocular vision assessment, may be necessary to evaluate other factors contributing to reduced visual acuity or quality.[65]

Subjective outcomes

Subjective outcomes, which reflect various aspects of the patient experience, are fundamental in evaluating the success of a cataract and refractive surgery. These outcomes, including functional vision, spectacle independence, and the presence of visual disturbances, are major determinants of patient satisfaction. While overall satisfaction rates for these procedures are generally high, some patients may experience dissatisfaction, often due to mismatches between preoperative expectations and postoperative outcomes.[22] Expectations are influenced by multiple factors, including patient beliefs, attitudes, and anticipated results, all of which affect their perception of the care they receive.[66] Other common contributors to dissatisfaction may include ocular comorbidities, residual refractive errors, and unrealistic patient expectations. Preoperative assessment of patient expectations is therefore paramount, given the complex relationship between expectations, clinical results, and patient satisfaction.[67-70] By aligning surgical outcomes with patient expectations, overall satisfaction and the patient experience during the cataract and refractive surgery pathway can be improved. It is essential to acknowledge that the patient plays a central role in the optimization of these aspects, thereby supporting a comprehensive, patient-centric approach throughout their journey in ophthalmologic care.

Postoperative care

Effective postoperative care is necessary to achieve optimal objective and subjective outcomes following cataract and refractive surgery. It promotes recovery and reduces the risk of postoperative inflammation or infection. Standard treatment typically includes antibiotics, corticosteroids, and nonsteroidal anti-inflammatory drugs (NSAIDs), with regimens adapted to the specific surgical procedure performed.[71-75] Clear and effective patient education is essential to ensure correct use of postoperative eye drops and to support understanding of expected postoperative symptoms, such as mild discomfort, some redness, and temporary visual fluctuations.[76,77]

Although both cataract and refractive surgeries have a high safety profile, the nature and likelihood of postoperative complications can differ. Cataract surgery follow-up usually spans several weeks and includes multiple hospital visits at predefined intervals. These visits focus on detecting complications such as infection, intraocular pressure spikes, cystoid macular edema, or retinal detachment. Assessments typically include a review of symptoms (pain, redness, floaters, flashing lights), as well as objective measurements

such as visual acuity, refraction, and slit lamp biomicroscopy. In contrast, refractive surgery requires a more intensive follow-up in the early postoperative phase. The main emphasis is on monitoring corneal wound healing and addressing procedure-specific issues such as flap-related complications, epithelial ingrowth, haze formation, or severe dry eye. While long-term follow-up is generally less extensive than in cataract surgery, the early postoperative period is more critical, with shorter intervals between visits to allow timely detection and intervention.[44,78,79]

As the demand for cataract surgery rises due to the aging population, optimizing postoperative care pathway becomes increasingly important. Given this rising demand, a study conducted in the United States estimates that by 2035, the ophthalmology workforce will fall short, potentially impacting not only access to care but also the quality of services provided due to staff shortages.[80] To address this challenge, remote and digital care options could offer scalable, efficient solutions while maintaining high standards of safety and quality. The World Health Organization (WHO) defines digital health interventions as "a discrete functionality of digital technology that is applied to achieve health objectives and is implemented within digital health applications and ICT systems, including communication channels such as text messages".[81] These interventions can encompass a variety of tools and technologies, including telemedicine consultations, mobile health applications, wearable devices, and remote monitoring systems. Telehealth services are increasingly employed across various medical fields, with evidence demonstrating that these solutions can be equally effective, or even superior, to traditional care in some contexts.[82]

In ophthalmology, telemedicine can be used for a broad range of conditions, including diabetic retinopathy, glaucoma, and cataract care.[83] For cataract surgery, remote care has the potential to transform traditional care pathways by reducing the need for in-person visits. This is achieved primarily through tools such as video or telephone consultations, improving both clinical efficiency and resource allocation.[83,84] In addition, the implementation of digital innovations can empower patients to take an active role in their healthcare, providing them with valuable insights into their own health and enhancing their decision-making processes.[85,86] However, despite this promising potential, current evidence on remote and digital interventions in cataract surgery is limited. Furthermore, the Dutch Cataract Guideline indicates that these approaches can currently only partially substitute in-person postoperative visits, underscoring the need for further research and development to integrate remote care effectively into clinical practice.[87-89] Beyond clinical performance, the cost-effectiveness of remote care will be a key determinant for its sustainable integration into routine practice. Recent developments in the Netherlands,

such as the decision to postpone the introduction of a structural reimbursement framework for primary care optometry pending further policy exploration, highlight the financial and policy challenges that may impede long-term adoption. Nevertheless, with the rapid advancement of artificial intelligence, the potential for personalized, data-driven remote care in cataract surgery is expanding, offering new opportunities to improve postoperative outcomes and overall patient care.

Aims and outline of the thesis

This thesis aims to evaluate potential improvements in the patient journey for cataract and refractive surgery, focusing on advancements in lens technologies, clinical outcomes, patient satisfaction, and digital and remote care innovations. The primary objective is to provide evidence-based insights to enhance the standard of care for future cataract and refractive surgery patients.

Chapter 2 presents evidence-based recommendations for high-quality cataract care, covering essential diagnostic and therapeutic steps. This guideline supports clinicians in optimizing patient selection, conducting preoperative assessments, and effectively implementing perioperative and postoperative care. Additionally, we explore recent advancements in lens technology, aimed at improving spectacle independence and visual quality. In **chapter 3**, we prospectively compare the visual outcomes of two EDF IOLs in a single center randomized controlled trial, assessing their efficacy in enhancing distance to intermediate vision, while maintaining contrast sensitivity and minimizing optical disturbances. **Chapter 4** provides an evaluation of the efficacy and safety of a novel iris-fixated multifocal presbyopia-correcting phakic IOL in an international multicenter prospective clinical trial. Both studies aim to provide insights into the impact of innovative lens designs on visual performance and patient satisfaction. **Chapter 5** introduces our custom-developed software for analyzing postoperative IOL tilt and decentration using Swept-Source Optical Coherence Tomography (SS-OCT) data. We evaluate the impact of IOL tilt and decentration on the corrected distance visual acuity (CDVA). This chapter contributes to the enhancement of postoperative assessments and thereby patient-specific care. In **chapter 6**, we evaluate patient satisfaction following EDF IOL implantation to identify reasons for dissatisfaction. This study aims to provide insights for improvements in patient outcomes and enhance overall patient satisfaction. **Chapters 7 to 11** investigate remote and digital care interventions within the postoperative cataract management. **Chapter 7** presents a systematic review of digital tools and remote care modalities for postoperative cataract patients, evaluating the evidence and highlighting

the areas requiring further research. In **chapter 8,** we validate a web-based tool for visual acuity assessment in patients who underwent cataract surgery. **Chapter 9** outlines the rationale and design of the multicenter randomized controlled trial, which investigates the feasibility of using this tool to facilitate remote follow-up visual acuity and refraction assessments. The results of this trial are presented in **chapter 10**, where we compare outcomes between web-based self-assessment follow-ups and traditional in-person follow-up after cataract surgery. In **chapter 11**, we examine the clinical safety and effectiveness of an artificial intelligence-based follow-up call system, evaluating its ability to identify patients in the Netherlands who may require further clinical assessment after cataract surgery. This thesis concludes with **chapter 12 and 13. Chapter 12** discusses the main findings and limitations of our work, and **chapter 13** reflects on the broader clinical impact and future implications, offering insights into potential advancements in patient care pathways for cataract and refractive surgery.

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CHAPTER 2

European Society of Cataract and Refractive Surgeons Guideline for Cataract Surgery 2024

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Abstract

Cataract is a leading cause of visual impairment globally, with surgery as the only effective treatment. Management involves a care pathway, including screening, patient selection, preoperative assessment, surgery, and postoperative care. The European Society of Cataract and Refractive Surgeons (ESCRS) developed evidence-based guidelines to aid decision-making for patients, clinicians, and stakeholders. A multidisciplinary panel, supported by methodologists using the Grading of Recommendations, Assessment, Development, and Evaluations approach, addressed 32 key clinical questions. Recommendations include intracameral antibiotics to prevent endophthalmitis, topical anesthesia as the preferred technique, and toric intraocular lenses for corneal astigmatism ≥1.0 D. Conventional and femtosecond laser-assisted surgeries are comparably safe and effective. NSAID eye drops, alone or with corticosteroids, are recommended to reduce inflammation and prevent cystoid macular edema. Additional guidance includes shared decision-making for lens selection, safe use of immediate sequential bilateral cataract surgery, and potential of remote postoperative care to enhance healthcare efficiency. These guidelines aim to improve outcomes, patient experience, and care delivery.

Introduction

Cataract is a significant cause of blindness, which is currently only reversible by surgery. As age advances, the prevalence of cataracts increases significantly. The prevalence of cataracts ranges from 3.9% among individuals aged 55-64 years to as high as 92.6% among those aged 80 years and older. It is projected that by 2025, the worldwide population of individuals affected by cataract blindness will increase to 40 million.[1] Cataract surgery is the most commonly performed surgical procedure worldwide, with 7 million cases each year in Europe, 3.7 million cases in the USA, and 20 million worldwide.[2]

The purpose of the ESCRS Cataract Surgery Guidelines is to address the value of diagnostic and therapeutic steps for various stakeholders in the patient cataract care pathway. The guideline aims to apply to all healthcare workers (e.g., ophthalmologists, residents, general practitioners, nurses, optometrists, opticians, health care decision takers, patient societies, and health care insurance companies) and patients interested in cataract management. It provides explicit, evidence-based recommendations and insights that healthcare providers should follow to deliver high-quality care. The clinical recommendations are crucial for supporting clinical decision-making and promoting better care, transparency, and reduced unwanted practice variation. While they are not prescriptive regulations, healthcare providers may deviate from these recommendations in complex cases where the patient's circumstances differ significantly from the "average patient." The physician must exercise his/her judgment on the suitability of the care provided to a particular patient, considering all the circumstances presented by the patient. However, any deviation should be documented in the patient's record and be supported by clear reasoning. This documentation requirement is not intended to limit clinical autonomy, but rather reflects standard medico-legal practice in many European countries and serves to document the shared decision-making process between physician and patient. These guidelines are developed within the European regulatory and medicolegal framework; therefore, the recommendations reflect current approvals and standards of care applicable in Europe.

This manuscript represents a condensed summary of the ESCRS Cataract Surgery Guidelines and therefore includes only selected recommendations. Readers are strongly encouraged to consult the comprehensive version of the guidelines in **Supplementary Material 2.1** for a detailed discussion of the evidence base, methodology, and full set of recommendations and considerations.

Methodology

This guideline was developed according to the comprehensive quality criteria as described in the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument.[3] The guideline development group (GDG) consisted of 18 ophthalmologists, and the constituting guideline development group (CDG) of two PhD candidates and a supervising methodologist. All clinical members possessed expertise in diagnosing and treating cataracts, and they were geographically distributed to cater to diverse regions. Review questions were formulated according to the PICO framework. Outcome parameters were selected based on importance for decision-making in the clinical setting. Literature searches were performed, using KSR evidence, CDSR, Medline, Embase, and Central as resources to identify relevant systematic reviews and randomized controlled trials for each review question, in total 5744 articles were found. The two PhD candidates performed selection of the articles supervised by the methodologist. Critical appraisal of available systematic reviews was performed based on the Risk of Bias assessment Tool ROBIS by reviewers at KSR Ltd.[4] The quality of the relevant evidence was summarized using the GRADE approach.[5] According to the GRADE approach, the evidence is classified as high (++++), moderate (+++), low (++) or very low (+). These classifications are accompanied by a specific formulation of the recommendations, using the wording “must”, “should”, “could”, “may”, “may not”, and “can be considered”. Considering high-level evidence, the term “must” was used in the recommendations of this guideline. In the case of moderate evidence, “should” or “could” were used. For low-graded evidence, “could” or “may” are applicable, and lastly, when there was very low evidence implemented in the recommendations, “can be considered” was used.[4-6]

Summary of Recommendations

The structure of this guideline is according to the patient cataract care pathway, and includes following sections: screening and patient selection, preoperative assessment, perioperative procedure, postoperative care, and complications.

Screening and patient selection

What are the indications for cataract surgery? (Question 4.1)

A cataract may be initially suspected or identified by optometrists or other eye care providers, but the formal clinical diagnosis is made by an ophthalmologist at the slit lamp

examination. The decision to proceed with cataract surgery should be made jointly by the patient and ophthalmologist and documented in the patient's medical record (GRADE +).

Important aspects to be considered for the indication for cataract surgery are the presence and appearance of cataract, a patient's visual acuity and function (visual acuity and quality of vision), the subjective disability of the patient and the expected benefits of the cataract surgery (GRADE +).

Co-morbidities and the surgical risk profile should be considered and discussed with the patient prior to the surgery. Documentation of this process in the patient file is mandatory The use of validated patient satisfaction questionnaires and Patient-Reported Outcome Measures (PROMs) may be considered to evaluate the outcomes of cataract surgery and support quality improvement or benchmarking, but their use can be adapted according to local practice and regulatory requirements (GRADE +).

Will the presence versus absence of (characteristic A) impact efficacy and safety outcomes in patients for whom cataract surgery is considered? (Question 4.2)

The presence of patient characteristics and comorbidities can have an impact not only on the outcome in vision but also on the risks of surgery and postoperative complications. These should be discussed with the patient so that they are fully informed, and expectations are realistic (GRADE +).

Significant ocular comorbidities, such as diabetic retinopathy, glaucoma, maculopathies, uveitis, and strabismus should be identified during the preoperative evaluation since its presence can affect the postoperative visual acuity and function (GRADE +).

In addition, certain risk factors can lead to a higher complication rate during cataract surgery including: pseudoexfoliation syndrome, Fuchs endothelial dystrophy, shallow anterior chambers, white and brunescent cataracts, small pupils, and eyes with an extreme axial length (<22 mm or >26 mm). In patients who previously underwent refractive surgery, specific precautions should be taken to prevent a refractive surprise. (see Question: Which formula(e) for calculating the intraocular lens in patients who have undergone refractive surgery is/are preferred?).

Regarding eyes with "active disease" (such as uveitis, proliferative diabetic retinopathy, neovascular age-related macular degeneration (AMD), herpetic keratitis), these may be more susceptible to complications when performing cataract surgery.

It is recommended to perform the surgery when the disease is in a quiet phase. Customizing the postoperative follow-up based on the presence of ocular comorbidities is essential for

ensuring comprehensive and effective care. Furthermore, it is crucial to provide patients with thorough information about potential risks to ensure realistic expectations (GRADE +).

Table 2.1 presents recommendations for patient characteristics and comorbidities associated with increased risk of surgical complications or suboptimal visual outcomes.

Table 2.1. Patient characteristics and comorbidities with an increased risk for complications during or after cataract surgery, and a suboptimal visual outcome.

Comorbidity	Recommendation
Macular degeneration	Cataract surgery in patients with macular degeneration improves visual function in all severity grades of AMD, at least in the short-term (GRADE +).
	It is recommended to perform cataract surgery in a period of quiescence of neovascular AMD, but timing for cataract surgery must be individualized according to the patient's needs (GRADE +).
	Maculopathies should be identified before cataract surgery. The long-term effects of AMD after cataract surgery are still unclear (GRADE +).
Glaucoma/ Ocular hypertension	Intraocular pressure should be monitored short-term after cataract surgery in glaucoma patients (GRADE ++).
Diabetic Retinopathy	The presence of active diabetic retinopathy or diabetic macular edema increases the risks of intraoperative and postoperative complications, such as macular edema (GRADE +).
	Cataract surgery can be considered when the underlying retinal disease is stabilized or when the presence of the cataract impedes with the evaluation and treatment of the retinal disease (GRADE +).
Dry eye disease (DED)	Preoperative dry eye has an impact not only on preoperative examinations but also on postoperative outcomes. DED management should be optimized prior to surgery (see preoperative examinations) and the patients should be informed that DED symptoms often become worse after surgery (although often temporary) (GRADE +).
Fuchs Endothelial Corneal Dystrophy	The severity of Fuchs' endothelial dystrophy should be evaluated for cataract surgery decision-making, based on the clinical presentation and the visual symptoms (GRADE +).
Amblyopia	Preoperative orthoptic examination may be necessary to assess binocular vision and detect possible amblyopia (GRADE +).
Corneal opacities	Patients should be advised on the impact of the opacities on outcomes and the risk of additional medical or surgical management (GRADE +).
Macular pucker/ epiretinal membrane (ERM)	Compared to eyes without ERM, higher rates of cystoid macular edema and a reduced postoperative gain in visual acuity can be noted (GRADE +).

Comorbidity	Recommendation
Previous refractive surgery	In cataract patients who previously underwent refractive surgery, special preoperative examinations such as corneal topography and tomography may be of added value (GRADE +).
	The impact of previous surgery on refractive outcome prediction should be discussed as well as the need for further refractive correction (GRADE +).
Shallow anterior chamber	Patients with a shallow anterior chamber should be informed about the increased risk of peri- and postoperative complications such as iris prolapse and corneal endothelial cell loss (GRADE +).
Pseudoexfoliation syndrome (PEX)	PEX is an important risk factor in phacoemulsification because of complications such as poor pupillary dilatation, zonular weakness inducing intra- or postoperative lens dislocation, vitreous loss, postoperative IOP spikes, capsular phimosis, prolonged inflammation, and postoperative corneal decompensation. Patients should be counselled accordingly (GRADE +).
White/ Brunescent cataract	Surgical adaptions such as using trypan blue for capsular bag staining and decompression/ aspiration, or “milking” of the cortical material should be performed to reduce the risk of capsular tear (GRADE +).
	High cohesive viscoelastics and intravenous mannitol may be used to reduce the risk of tear out (GRADE +).
	Anterior segment ocular tomography (OCT) may be performed to grade lens intumescence (GRADE +).
Small Pupil/ Intraoperative floppy iris syndrome (IFIS)	The use of pupil expansion strategies should be considered in cases with small pupils that cannot be dilated pharmacologically (GRADE +).
	A staged approach of viscodilation, pupil expansion devices, including rings and iris hooks, should be considered and these devices should be available in the operating room (GRADE +).
	In cases of IFIS a combination of strategies including appropriate phacoemulsification fluidic parameters, pharmacological agents, longer corneal tunnels and dispersive viscoelastics should be considered (GRADE +).
Eyes with extreme axial length	Long eyes can be defined as eyes with an axial length of over 26 mm, while short eyes are generally defined as eyes with an axial length of under 22 mm.
	Patients should be informed about the increased risk of refractive surprise and complications with postoperative refraction being non-coherent with target refraction (GRADE +).

Comorbidity	Recommendation
Uveitis	Patients with uveitis will have visual improvement after cataract surgery but are also at more risk for the development of macular edema and a recurrence of uveitis (GRADE +). Active inflammation should be controlled prior to surgery, which means that the inflammation is sufficiently controlled, where possible (GRADE +). Pre-existing corneal, anterior, and posterior segment pathological changes such as corneal scarring, band keratopathy, iris atrophy, vascular fragility, anterior and posterior synechiae, pupillary and cyclic membrane formation, macular scarring, optic nerve inflammation, ischemia, atrophy and retinal vascular disease should be considered (GRADE +).
History of herpes keratitis	Antiviral prophylaxis with acyclovir or valacyclovir should be considered (GRADE +).
Vascular occlusions	Patients with preoperative history of central retinal vein occlusions should be informed about the possible limitations on their visual outcomes after cataract surgery compared to other patients without retinal diseases (GRADE +).

AMD=age-related macular degeneration; DED=dry eye disease; ERM=epiretinal membrane, GRADE=Grading of Recommendations, Assessment, Development and Evaluations; IFIS=intraoperative floppy iris syndrome; PEX=pseudoexfoliation syndrome

What mental health factors must be considered when preparing for cataract surgery? (Question 4.3)

Cataract surgery has a beneficial effect on cognitive and mental health. Cataract extraction can be considered in patients at higher risk for cognitive decline and impaired vision due to cataracts (GRADE +/++).

The timing of the surgery with regard to the course of the mental illness and the potential application of immediate sequential bilateral cataract surgery (ISBCS) may be of benefit for these patients (GRADE +/++).

What information about surgery, target refraction and complications should be given to the patient before cataract surgery? (Question 4.4)

The ophthalmic surgeon should ensure that the following information is verbally provided to the patient before obtaining informed consent and performing cataract surgery:

- The option of not undergoing surgery
- Purpose and nature of the cataract surgery
- Surgery process overview
- Risk for (serious) complications during and after the surgery

- Patient-specific additional risks
- Surgery on one or both eyes
- Target refraction and expected vision improvement after surgery
- Treatment options: IOL types, including discussion of the potential needs for spectacles after surgery, regardless of IOL choice
- The financial implications of the surgical and IOL choices
- In cases of bilateral cataract surgery: delayed sequential or immediate bilateral surgery
- Type of anesthesia
- A clear means to reach the surgeon or delegated assistant in case of emergencies

Targeted interventions improve patients' satisfaction with cataract surgery and the accompanying postoperative care (GRADE +).

In addition to verbal information, patients undergoing cataract surgery should be provided with written information and, if possible, audio-visual material. It is important to consider national informed consent guidelines and adapt the information provided to local best practices and legal frameworks (GRADE +).

In patients needing cataract surgery, what are the effects of immediate bilateral surgery compared with delayed sequential surgery and what is the minimum time between cataract surgery on the first and second eye? (Question 4.5)

ISBCS is effective and safe, has a high degree of patient satisfaction and can be considered in patients without complication-inducing ocular comorbidities (GRADE +).

There are comparable clinical outcomes of DSBCS (delayed sequential bilateral cataract surgery) and ISBCS. Therefore, either technique can be considered (GRADE +/+++ (for endophthalmitis)).

Bilateral cataract surgery on the same day allows rapid patient rehabilitation and helps avoid suboptimal visual function while waiting for second-eye surgery. However, there was no extra long-term benefit of self-assessed visual function compared with cataract surgery in one eye at a time (GRADE +).

Specific relative contraindications must be considered if bilateral simultaneous cataract surgery is planned:

- The ISBCS should be reconsidered if there is an increased risk of peri- or postoperative complications.
- Second-eye surgery should generally be deferred in the event of major intraoperative

complications in the first eye. Minor complications may allow second-eye surgery if judged safe by the surgeon.

If bilateral simultaneous cataract surgery is planned, it should be considered and treated as two entirely separate procedures, according to the principal practice guideline for bilateral surgery. These guidelines can be found at: https://www.rcophth.ac.uk/wp-content/uploads/2020/09/Immediate-Sequential-Bilateral-Cataract-Surgery-Guidance.pdf [7]

Do pseudophakic presbyopia correcting IOLs have a better postoperative outcome than monofocal IOLs with a monovision target? (Question 4.6)

Detailed patient information must be given to choose the correct IOL type for patients undergoing cataract surgery with pseudophakic correcting presbyopia IOLs (GRADE +). A comparison of visual outcomes, spectacle dependence, dysphotopsia risk, and associated costs for multifocal IOLs, EDF IOLs, and monovision is provided in **Table 2.2**.

Table 2.2. Overview of visual performance, spectacle dependence, dysphotopsia risk, and cost for multifocal IOLs, EDF IOLs, and monovision.

Multifocal IOLs	EDF	Monovision
Good near, intermediate and distance visual acuity	Good intermediate and distance visual acuity	Good intermediate and distance visual acuity
Spectacle independence	Spectacles for near vision needed in most cases	Spectacles for near vision needed in most cases
Higher probability of dysphotopsia, reduced contrast sensitivity	Reduced probability of dysphotopsia	Low probability of dysphotopsia
Increased costs (depending on IOL/clinic)	Increased costs (depending on IOL/clinic)	Mostly covered by insurance

EDF=extended depth of focus; IOL=intraocular lens

Multifocal IOLs should be considered in patients who desire a high chance of spectacle independence for far, near and intermediate vision, as multifocal IOLs show better results than standard monofocal IOLs in uncorrected near and intermediate vision (low certainty evidence for bifocal vs. trifocal).

Thoughtful use of multifocal IOLs is recommended, as unwanted visual phenomena such as halos, glare, and starbursts are more common with multifocal IOLs than with monofocal IOLs (GRADE ++).

EDF IOLs or pseudophakic monovision can be considered for patients seeking improved intermediate vision. Some designs of EDF IOLs may be associated with less dysphotopsia than multifocal IOLs, although this is not consistent across all designs (GRADE +).

Do toric IOLs give a better postoperative outcome than non-toric IOLs in cataract surgery? From which magnitude of corneal astigmatism is a toric IOL indicated? (Question 4.7)

Current recommendations are based on studies performed using anterior keratometry:

In the case of regular corneal astigmatism, toric IOLs may be considered for implementation (GRADE ++).
Toric IOLs should be considered in eyes with a degree of corneal astigmatism of 1.0 D or more. The greatest clinical effectiveness is observed in eyes with corneal astigmatism >2.0 D, with meaningful visual benefits also observed from 1.5 D and above. While toric IOLs may offer benefits in eyes with astigmatism ≥1.0 D, the supporting evidence is more limited (GRADE ++ for ≥2.0 D; GRADE + for ≥1.5 D).

New insights rely on predictions of postoperative astigmatism, making it imperative to use these predictions as a basis for decision-making in cases with corneal astigmatism.

What type of anesthesia is indicated for the patient? (Question 4.8)

There are several accepted and safe anesthesia techniques available for patients who undergo cataract surgery. Topical anesthesia appears to be the most commonly used anesthesia technique during cataract surgery (GRADE ++/+++).

For further reducing pain during the cataract surgery, additional intracameral lidocaine can be instilled (GRADE ++/+++).

The choice for a specific type of anesthesia during cataract surgery should be made together with the surgeon and patient (GRADE +).

Nevertheless, other techniques have also gained acceptance and have demonstrated safety during cataract surgery. The decision-making process regarding the choice of anesthesia should be a collaborative effort involving the ophthalmic surgeon and the patient. The anesthesia technique may vary from surgeon to surgeon, influenced by their experience and individual preferences. Additionally, patient-specific considerations, such as medical history, anxiety levels, and comfort, are vital in determining the most suitable anesthesia approach.

Under certain conditions, preoperative fasting and intravenous sedation can be

considered. When general anesthesia is needed, preoperative health tests and blood samples might be necessary.

Preoperative assessment

What kind of diagnostics and preoperative assessment of the patient should be done? In patients who will undergo cataract surgery, what are the effects of diagnostic A versus no diagnostic A or versus diagnostic B on efficacy and safety outcomes? (Question 5.1)

Prior to cataract surgery, a series of essential preoperative examinations must be conducted to ensure a comprehensive understanding of the patient's ocular health and overall medical condition.

In general, for preoperative assessment prior to cataract surgery the following diagnostic measures are recommended: refraction, visual acuity, slit lamp assessment, dilated fundus examination, optical biometry and tonometry (GRADE ++).

In the presence of refractive astigmatism additional measurements with tomography/ topography are recommended (GRADE +).

It is recommended to provide patient with detailed information (see Question: What information about surgery, target refraction and complications should be given to the patient before cataract surgery?) and use cataract-specific checklists adapted to the clinic of practice, since checklist use is associated with improvement of patient safety by reducing surgical morbidity and mortality (GRADE +).

In addition to diagnostic measurements, providing detailed patient information is crucial. This includes discussing target refraction, potential visual outcomes, the possibility of needing spectacles after surgery, and postoperative instructions with the patient. Equally essential is providing a detailed explanation of the surgical process and potential complications.

What kind of diagnostics and preoperative assessments of patients who previously underwent refractive surgery should be done? (Question 5.2)

It is recommended to perform corneal tomography or topography in patients who previously underwent corneal refractive surgery (GRADE +).

In post-radial keratotomy (RK) eyes, a corneal tomography/ topography should be performed for assessment of corneal astigmatism and corneal irregularities (GRADE +).

A slightly myopic target refraction should be considered (GRADE +). Patients should be

informed about the possibility of a refractive surprise and that spectacles may still be required for certain tasks after surgery (GRADE +).

It is recommended to choose a slightly myopic target refraction in eyes with anterior and posterior phakic IOLs (GRADE +). An anterior segment OCT may be used for anterior chamber depth measurements in anterior phakic IOLs (GRADE +). Endothelial cell count should be done in patients with anterior phakic IOLs prior to cataract surgery (GRADE +).

In which patients with an indication for cataract surgery is posterior segment OCT indicated? (Question 5.3)

In general, posterior segment OCT in cataract surgery should be used when there is a clinical indication, such as AMD, diabetic retinopathy, glaucoma, uveitis, an epiretinal membrane, or when the visual acuity is worse than expected (GRADE +).

OCT is more effective in detecting optic nerve or macular pathologies than a regular fundus examination (GRADE +).

Posterior segment OCT may be used in routine cataract cases and can be considered at least in the following situations (GRADE +):

- In case of increased risk or medical history of macular abnormalities that could adversely affect the postoperative visual outcome, such as AMD, diabetic retinopathy, glaucoma, uveitis, or an epiretinal membrane
- Where the visual acuity is worse than expected and cannot be fully explained by the degree of cataract
- In case of considering presbyopia correction IOLs

In which patients with an indication for cataract surgery is ultrasonography (A- or B-scan) indicated? (Question 5.4)

Ultrasound biometry (A- and/or B-scan) should be used when there is low visibility of the posterior segment, such as in mature and dense cataracts when optical biometry is not applicable or feasible (GRADE +). An A-scan provides valuable information about the axial length, while B-scan offers imaging of the posterior segment, enabling the detection of some underlying ocular conditions that may impact surgical planning and outcomes.

What are the indications for specific assessment examinations for patients with corneal comorbidities? (Question 5.5)

Pre-existing corneal comorbidities, including dry eye disease, Fuchs endothelial dystrophy

and corneal scars and opacities are crucial to identify before performing cataract surgery since this may influence the outcomes.

Dry eye disease management should be optimized prior to surgery, and patients should be informed that symptoms of dry eye disease may worsen temporarily after surgery. Patients with pre-existing dry eye disease should be recognized and diagnosed before cataract surgery by using questionnaires, testing the tear breakup time, corneal fluorescein staining or Schirmer test (GRADE +).

The severity of Fuchs endothelial dystrophy should be evaluated for cataract surgery decision-making, based on the clinical presentation and the visual symptoms (GRADE +).

Identifying corneal opacities before cataract surgery is essential for estimating potential visual improvement. Ideally, corneal transplantation should be performed first to allow accurate biometry and optimal visual outcomes after healing. Cataract surgery may be considered prior to keratoplasty in selected cases—for example, when the cataract is dense and visual impairment from the cornea is uncertain, or when corneal transplantation is delayed due to donor availability or medical factors. Each case must be evaluated individually, with careful assessment of the benefits, risks, and timing of interventions for both cataract and corneal disease (GRADE +).

What are the indications for specific assessment examinations for patients with keratoconus? (Question 5.6)

In keratoconus patients, stabilizing procedures before cataract surgery should be considered if the patient is at risk of progression (GRADE +).

When evaluating astigmatism in this patient population, the anterior, posterior and total corneal astigmatism should be assessed to perform the most accurate IOL power calculations (GRADE +).

What preoperative assessment is necessary for presbyopia correcting IOLs? (Question 5.7)

Patient selection for pseudophakic presbyopia correcting IOLs should be based on the desire for spectacle independence, and realistic patient expectations. Patients with additional ocular pathologies may not be ideal candidates for pseudophakic presbyopia correcting IOLs (GRADE +).

For the preoperative assessment before implantation of a presbyopia correcting IOL additional assessments can be considered including evaluation of dry eye symptoms,

stereopsis assessment, corneal topography/tomography, posterior segment OCT, and pupillometry (GRADE +).

What preoperative assessment is necessary for toric IOLs? (Question 5.8)

In the case of implantation of a toric IOL the preoperative assessment should encompass not only general mandatory evaluations but also corneal topography and/or tomography (GRADE +). Methods which include measurements of factors such as the additional posterior corneal astigmatism and effective lens position are preferred for toric IOL calculation (GRADE +).

IOL power calculation

In general, new formulae appear annually and therefore it may take some time before evidence-based value of these formulae has been established.

Which formula(e) for calculating lens power should be considered? (Question 6.1)

There is a tendency towards improved outcomes with newer-generation formulae as they show less trend error, meaning that they appear more consistent along the range of axial lengths. Traditional formulae can still be considered an acceptable option where newer formulae are not available (GRADE +).

The ESCRS IOL Calculator can be considered for comparing different formulae. Please find the corresponding link: https://iolcalculator.escrs.org

Which formula(e) for calculating lens power in specific conditions should be considered? (Question 6.2)

Specific IOL formulae are recommended for eyes with certain conditions to ensure accurate outcomes. In extreme long and short eyes, new-generation formulae are recommended (GRADE +).

In eyes with keratoconus, all formulae tend to overestimate the IOL power, which may result in a hyperopic refractive outcome if not carefully planned. It is recommended to avoid traditional formulae other than SRK/T and to use keratoconus-specific formulae for more accurate outcomes. The Barrett True-K and Kane formulae for keratoconus appear to provide more accurate results, especially in more advanced stages. A slightly myopic target refraction is generally preferred over risking an unintended hyperopic refractive outcome (GRADE +).

In patients with steep (>46 D) or flat corneas (<42 D), the Barrett Universal II (Total Keratometry (TK)) and EVO (TK) formulae may be considered (GRADE +).

The Haigis formula should be considered for patients with an ACD >3.5 mm, while the Hoffer Q formula is suggested for a shallow anterior chamber (ACD <2.5 mm) (GRADE +).

Which formula(e) for calculating the intraocular lens in patients who have undergone refractive surgery is/are preferred? (Question 6.3)

When performing IOL calculations in patients who have undergone refractive surgery, designated formulas and methods should be used such as those in the American Society of Cataract and Refractive Surgery (ASCRS) post-refractive surgery calculator.

The ESCRS calculator is available at: https://iolcalculator.escrs.org/

Which target refraction is preferred in patients who will undergo cataract surgery? (Question 6.4)

The selection of a specific target refraction highly depends on the selected IOL, expectations and preferences of the patient. The patient and ophthalmologist should take the shared decision for IOL target selection (GRADE ++).

Perioperative procedure

What are the differences between femtosecond assisted laser cataract surgery (FLACS) and conventional phacoemulsification cataract surgery? (Question 7.1)

Both conventional cataract surgery (CCS) and femtosecond laser assisted cataract surgery (FLACS) can be used as:

- They are both safe and effective procedures (GRADE +/++).
- Visual acuity and refractive outcomes are comparable (GRADE +/++).
- Overall intraoperative and postoperative complication rates are low and appear similar for both conventional phacoemulsification and femtosecond laser assisted cataract surgery (GRADE +/++).

FLACS may be considered in patients with dense cataract or low endothelial counts reflecting a short-term benefit without evidence of sustained long-term superiority (GRADE +/++).

What is the role of femtosecond laser in astigmatism control during cataract surgery? (Question 7.2)

Femtosecond-laser assisted (FLACS) as well as manual corneal incisions (e.g. opposite clear corneal incisions, limbal relaxing incisions and astigmatic keratotomies) are safe and effective options for astigmatism control during cataract surgery (GRADE +).

Femtosecond lasers can be used to perform corneal incisions specifically designed to correct corneal astigmatism (e.g. intrastromal and penetrating femtosecond laser astigmatism keratotomies). These are more precisely performed than when done by hand (GRADE +).

What are the differences between different marking techniques for patients receiving toric IOLs? (Question 7.3)

Digital marking may result in less axis misalignment, a smaller difference vector and less postoperative astigmatism than manual marking, but there are no clinically significant differences in visual and refractive outcomes between the two techniques (GRADE +).

What prophylaxis should be administered during cataract surgery to minimize the risk of postoperative endophthalmitis? (Question 7.4)

Intracameral antibiotic therapy should be used because it is effective and safe for preventing endophthalmitis after cataract surgery. The use of intracameral antibiotics significantly reduces the risk of endophthalmitis (GRADE +).

An intracameral injection should be used (cefuroxime 1 mg in 0.1 ml.) at the end of the cataract surgery to lower the risk for postoperative endophthalmitis (GRADE +++).

Adequate antisepsis can be achieved by applying povidone-iodine 5-10% 3 minutes before commencing cataract surgery on the periocular skin, while lower concentrations (0.3- 0.5%) are used for application to the conjunctival fornix. In cases of povidone-iodine allergy, chlorhexidine (0.02%) can be used as an alternative (GRADE +).

These recommendations reflect the current European regulatory framework; intracameral antibiotics approved and commonly used in other regions may demonstrate acceptable safety and efficacy but are not addressed as formal recommendations within these guidelines.

What prophylaxis should be used in cataract surgery to minimize the risk of post-operative inflammation? (Question 7.5)

- *What is the most effective treatment to reduce post-operative inflammation after cataract surgery and reduce the risk of cystoid macular edema (CME)?*
- *Is perioperative inflammatory prophylaxis (dropless cataract surgery) equally effective as a postoperative anti-inflammatory eye drop regimen?*

For the prevention of CME after routine cataract surgery in non-diabetic patients, topical NSAID eye drops or combination therapy with a corticosteroid can be used, as both have similar clinical effectiveness in uncomplicated cases (GRADE +/++). Economic considerations may favor combination therapy in certain settings.

Potential adverse effects of topical NSAIDs, including their use in patients with severe dry eye disease or collagen vascular disorders have to be considered (GRADE +).

It is currently unclear whether dropless inflammatory prophylaxis is as safe and effective as topical inflammatory prophylaxis to prevent CME and inflammation after cataract surgery (GRADE +/++).

What are the optimal intra- and postoperative medication for patients with other ocular pathologies who undergo cataract surgery? (Question 7.6)

Specific postoperative treatments should be considered for patients with certain ocular comorbidities following cataract surgery.

In diabetic patients without diabetic retinopathy, it is recommended to use a combination of corticosteroid and non-steroidal anti-inflammatory drug (NSAID) eye drops to prevent cystoid macular edema (GRADE +/++).

In patients with diabetic retinopathy, a supplementary subconjunctival depot of triamcinolone should be considered to reduce this risk. Intraocular pressure must be monitored postoperatively when using a triamcinolone depot (GRADE +).

Literature reports discrepancies concerning the effect of anti-vascular endothelial growth factor (VEGF) intravitreal therapy in preventing CME after cataract surgery in patients with diabetes (GRADE +/++).

In patients with retinal diseases, topical NSAIDs should be used, and only in selected cases intravitreal anti-VEGF injections could be considered (GRADE +).

In patients with uveitis, an increased frequency and prolonged topical steroid treatment is suggested. Oral steroids should be reserved for cases with severe or active intraocular

inflammation, involvement of the posterior segment, or when topical therapy alone is insufficient to control inflammation pre- and postoperatively (GRADE +).

Glaucoma patients should receive carbonic anhydrase inhibitors or topical agents postoperatively to minimize the potential increase in intraocular pressure (IOP) after surgery (GRADE +).

Oral acetazolamide administration postoperatively can be considered to reduce IOP elevation after cataract surgery (GRADE +).

Patients should be screened for risk factors for dry eye disease (DED), particularly for meibomian gland dysfunction. DED patients should use artificial tears both before and after surgery to manage symptoms and optimize ocular surface health (GRADE +/++).

Postoperative care

What precautions does the patient have to consider after the surgery? When should the next follow-up visit take place? (Question 8.1)

The following precautions have to be considered after surgery: the patient should take the eye drops as instructed and seek medical attention if vision decreases after prior improvement, or if there is sudden onset of black dots, flashing lights, increased pain, or redness of the operated eye. Patients should not rub the eye, and should not drive after surgery until cleared in line with national driving regulations (GRADE +).

New glasses can be prescribed after 4-6 weeks, earlier refraction may be appropriate in selected patients once refractive stability is achieved. Uncomplicated cases can defer follow-up visits by up to two weeks without safety reduction (GRADE +).

What is the preferred postoperative medication that should be administered to treat inflammation and CME after cataract surgery? (Question 8.2)

This section addresses the management of CME once it has developed, rather than strategies for its prevention.

The incidence of clinically significant CME following cataract surgery has been reported to be as high as 2%. In many cases, the CME is a self-limiting condition that resolves spontaneously without causing any visual impairment.[8] Nevertheless, there are instances where CME may persist or may lead to deterioration of the visual function, necessitating treatment. The primary treatment options for CME after cataract surgery are topical NSAIDs or steroids. Currently, there is insufficient evidence to determine an optimal

treatment strategy for this condition. This highlights the importance of conducting future research to further explore and clarify the most effective strategies for managing CME following cataract surgery (GRADE ++).

No definitive conclusions can be drawn regarding the clinical effectiveness of injectable medications (including intravitreal injection of anti-VEGF, sub-Tenon steroid injections and intravitreal steroid implants) for the treatment of CME (GRADE +).

When is remote care after cataract surgery indicated for patients? (Question 8.3)

Postoperative remote care following cataract surgery may serve as an alternative to short-term clinical examinations, potentially improving resource allocation and enhancing time and cost efficiency in surgical centers. However, the accuracy and validity of remote care and telemonitoring still require evaluation (GRADE +).

Screening has to be performed prior to allocating patients to a certain group that will receive remote care. Patients at an increased risk of complications or patients with comorbidities which may adversely affect their postoperative outcome should be prioritized for traditional postoperative hospital care (GRADE +).

Complications

The complications included were therefore limited to the most common and clinically relevant events, based on available evidence and expert consensus. We acknowledge that less frequent or highly specific complications, while clinically important, are not comprehensively listed.

What kind of (serious) complications can occur during cataract surgery? (Question 9.1 and 9.2)

Cataract surgery is generally regarded as a safe procedure with a low incidence of complications. However, intraoperative complications can occur and may vary in severity. Serious adverse events include anterior and posterior capsule rupture, dropped nucleus, zonular dialysis without vitreous loss, iris or intraocular lens (IOL) damage, and suprachoroidal hemorrhage. Other intraoperative complications may include anterior capsule tear and iris trauma.

What kind of (serious) adverse events can occur after cataract surgery? (Question 9.3 and 9.4)

Postoperative complications may also vary in severity and timing. Serious adverse events include intraocular inflammation (such as cystoid macular edema), endophthalmitis, toxic anterior segment syndrome (TASS), retinal detachment, pseudophakic bullous keratopathy, retained lens fragments, and IOL-related issues such as dislocation, luxation, malposition, damage, opacification, calcification, residual refractive error, and photic phenomena. Other postoperative complications may involve posterior capsular opacification (PCO), capsular contraction syndrome, elevated intraocular pressure, persistent inflammation, corneal edema, binocular imbalance, diplopia, dry eye symptoms, and refractive surprise.

Cost-effectiveness

What is the cost-effectiveness of specific cataract surgery-related decisions? (Question 10)

A cost-effectiveness overview is provided in chapter 10 of **Supplemenatry Material 2.1**, including the following topics: endophthalmitis prevention, prevention of inflammation/CME after cataract surgery, toric IOLs, ISBCS, and femtosecond laser assisted surgery. The main findings are summarized below:

Endophthalmitis prevention: Prophylactic intracameral cefuroxime significantly reduces the risk of endophthalmitis and is cost-effective compared with no antibiotic use. The incremental cost-effectiveness ratio (ICER) was €2,427 per Quality Adjusted Life-Year (QALY).[9]

Inflammation and CME prevention: In non-diabetic patients, combination therapy with bromfenac and dexamethasone is cost-effective compared to monotherapy, with an ICER of €6,544 per QALY.[10] In diabetic patients, subconjunctival triamcinolone alone is more cost-effective than combination therapy with triamcinolone and intravitreal bevacizumab, with an ICER of €321,984 per QALY for the combination therapy.[11]

Toric intraocular lenses: Bilateral toric IOL implantation in patients with corneal astigmatism was associated with slightly lower QALYs and was not considered cost-effective compared to monofocal IOLs, with reported ICERs ranging from €2,500 to €20,000 per QALY.[12]

Femtosecond laser-assisted cataract surgery (FLACS): FLACS does not offer clinical or economic advantage over conventional phacoemulsification, with reported ICERs

showing higher costs and no added benefit (ICER: £167,120/QALY).[13]

Immediate sequential bilateral cataract surgery (ISBCS): ISBCS demonstrates superior cost-effectiveness compared to Delayed Sequential Bilateral Cataract Surgery (DSBCS), with ICERs ranging from €2,500 to €80,000/QALY.[14]

Cost-effectiveness analyses are inherently dependent on country-specific pricing, reimbursement structures, and healthcare systems, and therefore relate to the specific interventions evaluated in the underlying studies. As a result, these findings cannot be generalized to entire drug classes or universally applied across different healthcare settings.

Limitations and implementation considerations

The aim of this guideline is to provide comprehensive and evidence-based recommendations for managing cataract surgery. However, it is important to acknowledge certain limitations. Primarily, there are persistent evidence gaps in specific areas, which may necessitate careful interpretation of certain recommendations. The ESCRS has supported various clinical studies, including the Endophthalmitis Study and PREMED Study, but further research projects are needed to address the knowledge gaps identified in this guideline. Moreover, it is crucial to recognize that the guideline primarily focuses on routine cataract patients. Cases involving severe comorbidities may require individualized decision-making regarding outcomes or the surgery itself. Additionally, the implementation of these recommendations may face barriers due to the variability in clinical practices and workflows. It is important to acknowledge these potential barriers, as they may require tailored approaches in certain instances. Despite these limitations, this guideline serves as a valuable resource for all stakeholders involved in cataract care, providing evidence-informed guidance for cataract management.

Conclusion

This guideline presents valuable insights and practical recommendations for healthcare professionals engaged in cataract care, achieved through a rigorous review of evidence and expert consensus. By adhering to these evidence-based guidelines, clinicians can elevate the quality of care they deliver to patients, thereby enhancing outcomes and overall health. We urge stakeholders to integrate this guideline into their clinical decision-

making processes, recognizing its capacity to instigate positive changes in healthcare practice and patient outcomes. It is important to note that this document is dynamic and can be adapted as new evidence emerges. The ESCRS has played a crucial role in optimizing future cataract care by providing a transparent, evidence-based guideline, and supporting clinical studies in the field.

The extended version of the guidelines and all critical appraisals, and the comments overview can be found in **Supplementary Material 2.1, 2.2, and 2.3.**

Key recommendations

The principal recommendations of this guideline are summarized below, structured by the corresponding level of evidence:

1. An intracameral injection should be used (e.g. cefuroxime 1 mg in 0.1 ml.) at the end of the cataract surgery to lower the risk for postoperative endophthalmitis (GRADE +++).
2. Topical anesthesia appears to be the most used commonly used anesthesia technique during cataract surgery, if suitable for the patient (GRADE ++/+++). For further reducing pain during the cataract surgery, an additional intracameral lidocaine can be instilled (GRADE ++/+++). For further reducing pain during the cataract surgery, additional intracameral lidocaine injection can be considered (GRADE ++/+++).
3. Toric IOLs should be considered in eyes with a degree of corneal astigmatism of 1.0 D or more. The greatest clinical effectiveness is observed in eyes with corneal astigmatism >2.0 D, with meaningful visual benefits also observed from 1.5 D and above. While toric IOLs may offer benefits in eyes with astigmatism ≥1.0 D, the supporting evidence is more limited (GRADE ++ for ≥2.0 D; GRADE + for ≥1.5 D).
4. The selection of a specific target refraction highly depends on the selected IOL, expectations and preferences of the patient. The patient and ophthalmologist should take the shared decision for IOL target selection (GRADE ++).
5. The use of NSAIDs eye drops, either in combination with corticosteroid eye drops or as monotherapy is effective to use after routine cataract surgery to prevent inflammation and CME. However, there is a lack of sufficient evidence to establish the optimal treatment approach for this condition (GRADE +/++).
6. Both conventional cataract surgery (CCS) and femtosecond laser assisted cataract surgery (FLACS) can be used, as they are both safe and effective procedures (GRADE

+/++).. They give comparable visual acuity and refractive outcomes and overall intraoperative and postoperative complication rates (GRADE +/++).

7. In diabetic patients without diabetic retinopathy, it is recommended to use a combination of corticosteroid and non-steroidal anti-inflammatory drug (NSAID) eye drops to prevent cystoid macular edema (GRADE +/++). In patients with diabetic retinopathy, a supplementary depot of triamcinolone should be considered to reduce this risk. Intraocular pressure must be monitored postoperatively when using a triamcinolone depot (GRADE +).
8. ISBCS is effective and safe, has a high degree of patient satisfaction and can be considered in patients without complication-inducing ocular comorbidities (GRADE +).
9. EDF IOLs or pseudophakic monovision can be considered for patients seeking improved intermediate vision. Some designs of EDF IOLs may be associated with less dysphotopsia than multifocal IOLs, although this is not consistent across all designs (GRADE +).
10. In general, posterior segment OCT in cataract surgery should be used when there is a clinical indication, such as age-related macular degeneration, diabetic retinopathy, glaucoma, uveitis, an epiretinal membrane, or when the visual acuity is worse than expected (GRADE +).
11. Patient selection for pseudophakic presbyopia correcting IOLs should be based on the desire for spectacle independence, and realistic patient expectations. Patients with additional ocular pathologies may not be ideal candidates for pseudophakic presbyopia correcting IOLs (GRADE +).
12. In the case of implantation of a toric IOL, the preoperative assessment should encompass not only general mandatory evaluations but also corneal topography and/or tomography (GRADE +). Methods which include measurements of factors such as the additional posterior corneal astigmatism and effective lens position are preferred for toric IOL calculation (GRADE +).
13. Specific IOL formulae are recommended for eyes with certain conditions to ensure accurate outcomes. In extreme long and short eyes, new-generation formulae are recommended (GRADE +).
14. Postoperative remote care following cataract surgery may serve as an alternative to short-term clinical examinations, potentially improving resource allocation and enhancing time and cost efficiency in surgical centers. However, the accuracy and validity of remote care and telemonitoring still require evaluation (GRADE +).

Plans for updating these guidelines

The ESCRS aims to update its guidelines periodically, every 5 years. This process will involve conducting update searches and assessing any relevant research in relation to the current recommendations and considerations. The project team will evaluate whether modifications or revisions to the recommendations are warranted in light of emerging evidence or evolving best practices.

Definitions

Definitions of target refraction

Prior to cataract surgery, patients should be consulted regarding the desired target refraction. This guideline covers the following target refraction goals:

- **Emmetropia:** Emmetropia refers to the condition in which there are no refractive errors present. When the eyes are in an emmetropic state, objects located at infinity are sharply focused on the retina without any need for accommodation. In practice, a refraction ranging between +0.25 diopters (D) and -0.25 D is defined as emmetropia.[15]
- **Mini-monovision:** Mini-monovision refers to the condition where one eye (usually the dominant eye) is targeted for emmetropia while the other eye (usually the non-dominant eye) is targeted for slight myopia ranging between -0.25 D and -0.75 D in order to increase spectacle independence.[16]
- **Monovision:** Monovision refers to the condition when one eye is targeted for distance vision while the other eye is targeted for near vision. The range of diopters for monovision correction may vary according to the specific needs of the patient and discretion of the surgeon. In practice, monovision ranges from -1.00 D to -2.00 D.[17]

Definitions of different types of astigmatism

Grading

- Low astigmatism (0.25 to 1.5 D)
- Moderate astigmatism (1.5 to 3.0 D)
- High astigmatism (above 3.0 D)
- Myopic / hyperopic / mixed astigmatism[18]

Regular astigmatism

- With-the-rule astigmatism: Steep axis of the cylinder is vertical or within 30 degrees of the 90 degrees of vertical meridian (60-120 degrees)
- Against-the-rule astigmatism: Steep axis of the cylinder is horizontal or within 30 degrees of the horizontal meridian (0-30 or 150-180 degrees)
- Oblique astigmatism: Steep axis of the cylinder is not within 30 degrees of the horizontal or vertical meridians (31-59 degrees and 121-149 degrees)

Irregular astigmatism

- Where the two main axes of astigmatism are not symmetric and/ or do not lie 90 degrees apart (orthogonal)
- Irregular or pathological astigmatism treatment is beyond the scope of these guidelines (e.g., those caused by corneal dystrophies, trauma, degeneration, ocular surface disease, corneal ectatic diseases such as keratoconus, and prior corneal surgery)

Definitions of different IOLs

Classifying intraocular lens (IOL) technologies is not an easy task, primarily due to the various categories that can be integrated into a classification. Some of these categories represent different characteristics that may be inappropriately combined in an attempt to create a simplified taxonomy, which is not always feasible. Therefore, when defining an IOL, it is crucial to differentiate between various categories and avoid mixing them, to prevent confusion for the user.

Optical Technologies

Two main types of optical technologies, diffractive and refractive, have historically been used to classify IOLs, depending on the optical principles utilized for focusing light.[19] Diffraction and refraction can be achieved through distinct optical structures or optical features.[20,21] Diffraction can be accomplished with small optical apertures and diffractive gratings, while refraction can be achieved by varying the asphericity and radius of an optical surface or through zones and sectors.[19,21] However, some designs may combine some of the previously described optical features or mechanisms, thus controversies are likely to occur forcing to assign an IOL to one optical classification.[19,22,23]

According to the shape and number of foci, a taxonomy with five categories has been described in the literature: multifocal intraocular lenses (including bifocal, and trifocal), with the first trifocal lens commercially introduced in 2010,[24] extended depth of focus

lenses (EDF), which emerged in 2014,[22,25] monofocal IOLs with enhanced depth of focus (Mono-EDF) for which the first Conformité Européenne (CE) mark was granted in 2019,[19,26,27] and conventional monofocal aspherical and finally spherical IOLs.

Standard Terms and Definitions

According to the International Organization for Standardization (ISO 11979-7, 2024), there are four main categories of IOLs that are determined by optical design and/or clinical characteristics or performance.[28] Monofocal, Toric, Simultaneous Vision Lens (SVL) and Accommodating IOLs. From these, SVL are those non-accommodative lenses that provide simultaneous vision at multiple distances and can be subclassified in three types:

- Multifocal (MIOL): lens implants that emphasize optical and functionally useful acuity levels at far, but when compared to the monofocal control lens, also have improved optical and clinical performances at near focal distances;
- Extended Depth of Focus (EDF): lens implants that emphasize optical and functionally useful acuity levels at far but also from far through intermediate focal distances;
- Full Visual Range (FVR): lens implants that emphasize optical and functionally useful acuity levels at far but also from far through intermediate and up to near focal distances.

Evidence-Based Functional Classification

A functional classification has been developed considering the end-points described in the standards, especially those referring to the DOFi measured through monofocal visual acuity defocus curves with the best distance correction.[29] The functional classification can be gound in **Figure 2.1**. This classification has been qualified as evidence-based because the scientific method (cluster analysis) has been the pillar during the development.

The methodology and metrics used for the cluster analysis are described in the extended version of the Guidelines (**Supplementary Material 2.1**).

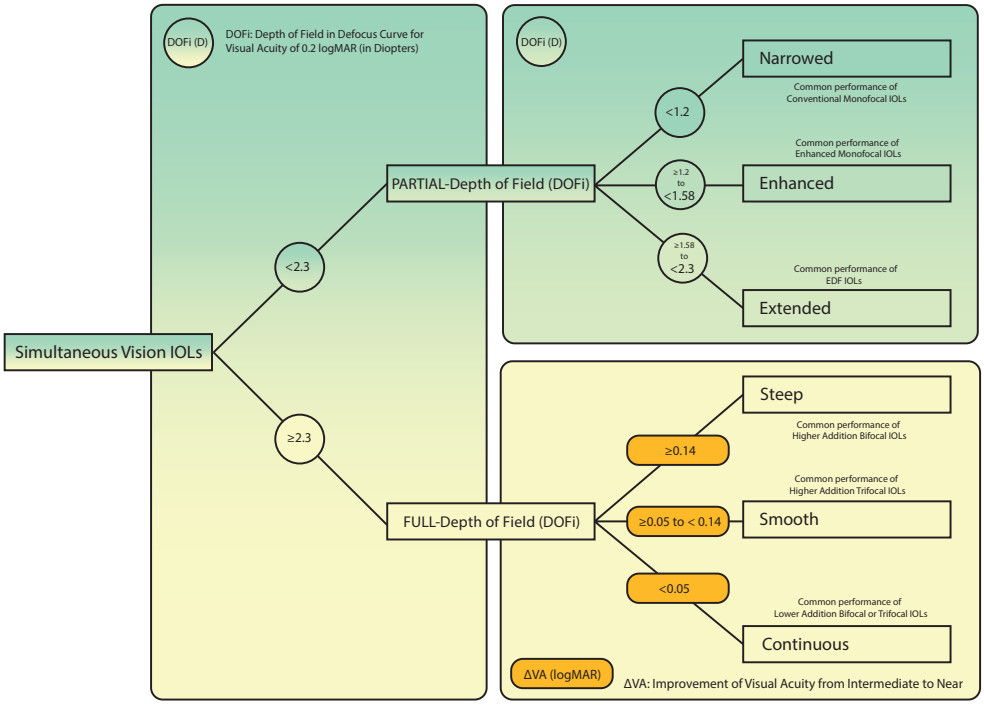

Figure 2.1. Diagram of functional classification depending on (1) the DOFi achieved in the monocular defocus curve with best correction at distance at the 0.20 logMAR VA level and (2) the improvement of VA from intermediate to near (Δ VA). Adapted from Ribeiro et al., J Cataract Refract Surg. 2024;50(8):794 798. DOFi = depth of field; Δ VA = VA increase from intermediate to near.

Conclusion

This IOL classification has been proposed by members of this ESCRS guideline development group. Historical terminologies used for classifying IOLs have been reviewed, and a functional classification has been introduced to enhance understanding, focusing on the visual acuity that patients achieve across the visual range. The importance of separating classification categories is emphasized, as different optical technologies could produce similar functional outcomes.

Supplements

The supplementary material can be found using the QR code:

Supplementary Material 2.1. Extended version of the European Society of Cataract and Refractive Surgeons Guideline for Cataract Surgery 2024.

Supplementary Material 2.2. Critical appraisals of included evidence.

Supplementary Material 2.3. Comments of stakeholders and responses of cataract surgery working group.

Supplementary Material 2.4. Declarations of interest for all authors.

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CHAPTER 3

Two Novel Extended Depth-of-Focus Intraocular Lenses Targeted for Mini-Monovision: a Prospective Randomized Controlled Trial

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American Journal of Ophthalmology. 2025 Aug;276:286-296.

Abstract

Purpose: To compare the visual outcomes of two extended depth-of-focus (EDOF) intraocular lenses (IOLs).

Design: Single-center prospective randomized controlled trial.

Methods: Patients undergoing bilateral cataract surgery were randomly assigned to receive either the Acunex Vario IOL (Teleon Surgical B.V., Spankeren, The Netherlands) or the AcrySof IQ Vivity IOL (Alcon Laboratories Inc., Fort Worth, United States of America); both Vario-group and Vivity-group were targeted for mini-monovision. The primary outcome was the uncorrected intermediate visual acuity (UIVA, measured at 66 cm). Secondary outcome parameters were uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), defocus curves, reading speed, contrast sensitivity, spectacle independence and quality of vision.

Setting: University Eye Clinic, Maastricht University Medical Center+, the Netherlands.

Results: A total of 31 subjects (62 eyes) were included, 16 patients were enrolled into the Vario-group and 15 patients into the Vivity-group. At three months postoperatively, no statistically significant differences were found for the binocular visual acuities between the groups after adjustment for covariates. The mean and standard deviation for the binocular UIVA was 0.04 ± 0.11 and 0.15 ± 0.11 logMAR (adjusted-p=0.264) for the Vario-group and Vivity-group, respectively. The binocular UDVA was 0.00 ± 0.14 and 0.08 ± 0.10 logMAR (adjusted-p=0.753), and UNVA was 0.22 ± 0.17 and 0.31 ± 0.14 logMAR (adjusted-p=0.235), for both groups, respectively. While the Vario-group had a larger range of defocus, no significant differences were found for patient satisfaction and spectacle independence. Contrast sensitivity and reading speed were comparable, and there were no statistically significant differences in optical side effects between the groups.

Conclusion: Bilateral implantation of the Acunex Vario IOL and the AcrySof IQ Vivity IOL targeted for mini-monovision had comparable results for binocular visual acuity outcomes, contrast sensitivity, optical side effects, and reading speed. The Vario-group showed a larger continuous range of defocus.

Introduction

Ideally, cataract surgery should provide perfect vison at all distances without optical complaints. Advances in intraocular lens (IOL) technology using multifocal designs offer expanding possibilities for achieving spectacle independence after cataract surgery. Although multifocal IOLs (mIOLs) may offer good visual performance at all distances, they carry risks of contrast sensitivity loss and photic phenomena.[1] Recently, extended-depth-of-focus (EDOF) IOLs have been developed that primarily focus on good uncorrected distance and intermediate vision.[2] The range of vision with EDOF IOLs can be increased by targeting for mini-monovision, wherein the dominant eye is targeted for emmetropia and the non-dominant eye targeted for -0.25 to -0.75 D, improving the binocular uncorrected near visual acuity and thus increasing spectacle independency.[3,4] Furthermore, recent reports demonstrated that EDOF IOLs have an optical disturbance profile similar to monofocal IOLs, which assumedly contributes to the shifting popularity from multifocal to EDOF IOLs.[2,5] Various EDOF IOLs are available, either with a small aperture, aspherical continuous, refractive zonal or diffractive optical design.[6] For the current study the Acunex Vario IOL AN6V (+1.5 D addition) (Teleon Surgical B.V., Spankeren, the Netherlands), and the AcrySof IQ Vivity IOL DFT015 (Alcon Laboratories Inc., Fort Worth, United States of America) are explored.[2,3,7] The purpose of this study was to evaluate and compare the visual outcomes of these two EDOF IOLs when targeting for mini-monovision.

Methods

For this study, patients with bilateral cataracts were invited for participation if they expressed an unsolicited interest in an EDOF IOL, had a power calculation between +10.0 Diopters (D) and +30.0 D, and an expected postoperative refractive astigmatism of ≤1.0 D. Exclusion criteria were previous eye surgery, any significant ocular pathology that would limit the postoperative visual acuity <0.3 logMAR, extensive visual field loss, and cognitive or concentration disorders. Between May and December 2022, 32 participants from the University Eye Clinic of the Maastricht University Medical Center+ were enrolled. All patients signed informed consent before enrollment. This study was approved by the local medical ethics committee and executed in accordance with the principles of the Helsinki Declaration. The trial registration can be accessed at ClinicalTrials.gov under the identifier NCT05335408. We used the CONSORT checklist when writing our report.[8]

Patients were randomized for bilateral implantation of the AN6V (Vario-group; intervention) or bilateral implantation of the DFT015 (Vivity-group; control). The randomization was

performed using the algorithm of the data management platform (Castor, Amsterdam, the Netherlands) in blocks of 2 and 4. Patients and clinicians performing the postoperative assessments were blinded. Both IOLs are one-piece, foldable EDOF IOLs made of hydrophobic acrylic with a diopter range between +10.0 and +30.0 D. The AN6V optic offers the extended depth of focus by a sector-shaped near vision segment of +1.5 D located on the inferior IOL surface. The DFT015 provides extended depth of focus by its wavefront-shaping design. Power calculations were performed using the IOLMaster700 optical biometry (Carl Zeiss, Jena, Germany), the Barrett Universal-II (BU-II) formula, and the manufacturer recommended lens factor. All patients were targeted for mini-monovision, with the postoperative refraction in the dominant eye aimed closest to emmetropia and the non-dominant eye targeted for 0.25 to 0.75 D of myopia.

Surgeries were performed by three experienced surgeons using a standard divide-and-conquer phacoemulsification technique or by performing femtosecond laser-assisted cataract surgery, with a 2.2 mm clear corneal incision. For cases of with-the-rule (WTR) astigmatism, the corneal incision was made superiorly, while for against-the-rule (ATR) astigmatism, the corneal incision was made temporally. The choice between immediate sequential bilateral or delayed sequential bilateral cataract surgery was based on the patient's preference.[9]

Preoperatively, patients underwent routine ophthalmological examination, including manifest subjective refraction, visual acuity measurements, slit lamp and funduscopy, optical biometry, and corneal topography (Pentacam HR, Oculus, Wetzlar, Germany). Postoperative assessments were planned at one week, one month, and three months. The three-month postoperative visit included a comprehensive ophthalmological assessment, with manifest refraction, uncorrected and corrected monocular and binocular visual acuities for distance (UDVA and CDVA), intermediate (UIVA and DCIVA), and near (UNVA and DCNVA). Visual acuity measurements were performed using the Early Treatment Diabetic Retinopathy Study (ETDRS) charts, at distances of 4 m, 66 cm, and 40 cm. The last attempted line on the ETDRS chart was determined, until no further optotypes could be distinguished. The logMAR score was identified by adding the total number of correctly identified optotypes added to the score of the last attempted line. Functional vision assessment included binocular uncorrected and distance-corrected defocus curves, ranging from +2.0 D to -4.0 D with +0.50 D increments, in photopic conditions. The defocus equivalent (DEQ) was calculated using:|Sphere + ½*Cylinder|+|½*Cylinder|. Contrast sensitivity was measured using the CSV-1000 (Greenville, Ohio, United States of America) in photopic and mesopic conditions, with and without glare. Reading speed (binocular uncorrected) was tested at 40 cm with the Radner reading chart in photopic conditions.[10]

Aberrometry measurements were conducted with the KR-1W Wavefront analyser (Topcon, Tokyo, Japan), and tilt and decentration analyses with the CASIA2 (Tomey Corp., Nagoya, Japan). At three months postoperatively, patient satisfaction, spectacle independence, and optical complaints were assessed using the Catquest-9SF, IOLSAT (Alcon Laboratories Inc., Fort Worth, United States of America), and Quality of Vision (QoV) questionnaires with Likert scales ranging from zero (none/never) to four (severe/always).[11,12] Questionnaires were completed by patients at home, without involvement from surgeons or researches, to minimize bias.

Sample size and statistical analyses

A sample size of 32 participants was determined based on the assumption of no UIVA difference in logMAR at three months postoperatively, with an expected standard deviation (SD) of 0.09 logMAR and a non-inferiority margin of 0.10 logMAR. A significance level of 0.05, power of 90%, and a 10% loss to follow-up were used in this calculation. Data analysis was conducted using SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY).

Qualitative variables were summarized as frequencies and percentages, while descriptive statistics, including mean and SD, were calculated for quantitative variables. Preoperative keratometric astigmatism, postoperative corneal astigmatism, and tilt and decentration measurements were analyzed using vector analysis. The comparison of vector values between the study groups were performed using Hotelling's T-squared test. The binocular visual acuity outcomes were assessed for non-inferiority (Vario-group – Vivity-group), with a 90% confidence interval (CI). For postoperative analyses of the quantitative outcomes, linear regression analyses were carried out. Logistic regression analyses were performed to compare the qualitative outcomes between the two study groups. A significance level of ≤0.05 was applied.

Results

A total of 32 patients (64 eyes) were randomly assigned to the Vario-group or Vivity-group. One patient withdrew from the study because of anxiety for the cataract surgery. In total, 22 patients underwent immediate sequential bilateral cataract surgery (ISBCS) and 9 underwent delayed sequential bilateral cataract surgery (DSBCS). The Vario-group comprised 16 patients (8 males and 8 females) and the Vivity-group comprised 15 patients (3 males and 12 females). **Table 3.1** presents baseline characteristics. Baseline

imbalances were observed for age, IOL power, and preoperative keratometric values of the dominant eye. In the statistical analyses of postoperative outcomes, age and IOL power were found to significantly influence the results and were included as covariates. Consequently, all p-values were adjusted for these covariates and reported as adjusted p-values (adjusted-p).

Table 3.1. Baseline characteristics of the study groups.

		Vario-Group (n=16, 32 eyes) Mean ± SD	**Vivity-Group (n=15, 30 eyes) Mean ± SD**
Age (y)	All patients	64.1 ± 9.6	71.7 ± 7.6
CDVA (LogMAR)	Dominant eyes	0.27 ± 0.18	0.19 ± 0.14
	Non-dominant eyes	0.27 ± 0.33	0.21 ± 0.23
SEQ (D)	Dominant eyes	0.10 ± 2.20	-1.61 ± 3.01
	Non-dominant eyes	0.98 ± 2.91	0.00 ± 3.38
AL (mm)	Dominant eyes	23.46 ± 1.02	24.35 ± 1.43
	Non-dominant eyes	23.51 ± 1.05	24.23 ± 1.43
ACD (mm)	Dominant eyes	3.16 ± 0.41	3.25 ± 0.47
	Non-dominant eyes	3.14 ± 0.42	3.30 ± 0.48
Keratometric astigmatism[a] (D)	Dominant eyes	0.40 ± 0.56	0.20 ± 0.75
	Non-dominant eyes	0.22 ± 0.69	0.16 ± 0.70
Target (D)	Dominant eyes	-0.02 ± 0.10	-0.04 ± 0.11
	Non-dominant eyes	-0.35 ± 0.09	-0.41 ± 0.13
IOL Power (D)	Dominant eyes	22.1 ± 3.1	18.7 ± 4.3
	Non-dominant eyes	22.5 ± 3.3	19.7 ± 4.2

Vectors, marked with [a], are calculated using vector analyses.

ACD=anterior chamber depth; AL=axial length; CDVA=corrected distance visual acuity; D=diopter; IOL=intraocular lens; SD=standard deviation; SEQ=spherical equivalent

Table 3.2 summarizes the refraction and visual acuity outcomes at three months postoperatively subdivided into dominant and non-dominant eyes. The unstandardized B-coefficients, including standard error (SE) represent the difference between the two study groups after adjusting for covariates. The primary outcome parameter, UIVA, was non-inferior, with a 90%CI of -0.026 to 0.091. All other binocular visual acuity outcomes showed non-inferior outcomes as well, the 90% CI levels can be found in **Supplementary Table 3.1**. The postoperative refractive astigmatism was analyzed using double-angle plots shown in **Figure 3.1**. An additional analysis of the monocular and binocular uncorrected visual acuity outcomes was conducted, shown in **Table 3.3**, comparing the

data excluding the outlier eyes with a postoperative corneal astigmatism >1.0 D. This sensitivity analysis showed non-inferior binocular uncorrected visual acuity outcomes for the Vario-group compared to the Vivity-group.

Table 3.2. Refractive state and visual acuity outcomes at three months postoperatively.

Binocular outcomes					
	Vario-Group (n=16) Mean ± SD [range]	**Vivity-Group (n=15) Mean ± SD [range]**	**p**	**Unstandardized coefficient B (SE (B))***	**Adjusted-p***
UDVA (logMAR)	0.00 ± 0.14 [-0.20, 0.34]	0.08 ± 0.10 [-0.06, 0.22]	0.056	-0.014 (0.045)	0.313
UIVA (logMAR)	0.04 ± 0.11 [-0.10, 0.24]	0.15 ± 0.11 [-0.02, 0.36]	0.011	-0.052 (0.045)	0.264
UNVA (logMAR)	0.22 ± 0.17 [-0.10, 0.50]	0.31 ± 0.14 [0.14, 0.60]	0.104	-0.086 (0.071)	0.235
CDVA (logMAR)	-0.07 ± 0.09 [-0.20, 0.12]	0.00 ± 0.10 [-0.16, 0.18]	0.059	-0.028 (0.037)	0.459
DCIVA (logMAR)	0.06 ± 0.12 [-0.08, 0.34]	0.14 ± 0.14 [-0.04, 0.40]	0.105	-0.042 (0.056)	0.453
DCNVA (logMAR)	0.26 ± 0.12 [-0.10, 0.42]	0.35 ± 0.14 [0.12, 0.64]	0.055	-0.061 (0.059)	0.313
Monocular outcomes: dominant eyes					
	Vario-Group (n=16) Mean ± SD [range]	**Vivity-Group (n=15) Mean ± SD [range]**	**p**	**Unstandardized coefficient B (SE (B))***	**Adjusted-p***
Sphere (D)	0.09 ± 0.38 [-0.75, 0.75]	0.57 ± 0.51 [-0.25, 1.50]	0.006	-0.452 (0.197)	0.030
Cylinder[a] (D)	-0.27 ± 0.54 [-1.25, 0.00]	-0.73 ± 0.79 [-1.75, 0.00]	0.001	NA	0.008
SEQ (D)	-0.12 ± 0.44 [-1.12, 0.75]	0.10 ± 0.48 [-0.50, 0.88]	0.181	-0.360 (0.202)	0.086
DEQ (D)	0.48 ± 0.46 [0.00, 1.50]	0.87 ± 0.31 [0.50, 1.50]	0.012	-0.110 (0.141)	0.442
UDVA (logMAR)	0.01 ± 0.09 [-0.16, 0.20]	0.18 ± 0.12 [0.04, 0.50]	<0.001	-0.104 (0.044)	0.027

CDVA (logMAR)	-0.02 ± 0.08 [-0.16, 0.14]	0.03 ± 0.09 [-0.16, 0.16]	0.106	-0.022 (0.033)	0.499
Prediction error (D)	0.11 ± 0.45 [-0.73, 1.12]	-0.14 ± 0.44 [-0.85, 0.50]	0.121	0.443 (0.192)	0.029
Monocular outcomes: non-dominant eyes					
	Vario-Group (n=16) Mean ± SD [range]	**Vivity-Group (n=15) Mean ± SD [range]**	**p**	**Unstandardized coefficient B (SE (B))***	**Adjusted-p***
Sphere (D)	-0.03 ± 0.35 [-0.75, 0.75]	0.05 ± 0.45 [-0.75, 1.00]	0.576	-0.111 (0.176)	0.535
Cylinder[a] (D)	-0.15 ± 0.57 [-1.25, 0.00]	-0.67 ± 0.84 [-1.75, -0.25]	0.006	NA	0.141
SEQ (D)	-0.22 ± 0.33 [-0.75, 0.63]	-0.42 ± 0.41 [-1.25, 0.13]	0.131	0.072 (0.158)	0.651
DEQ (D)	0.50 ± 0.37 [0.00, 1.25]	0.95 ± 0.46 [0.25, 2.00]	0.005	-0.207 (0.166)	0.221
UDVA (logMAR)	0.04 ± 0.14 [-0.14, 0.34]	0.20 ± 0.12 [0.04, 0.48]	0.002	-0.088 (0.052)	0.098
CDVA (logMAR)	-0.02 ± 0.10 [-0.16, 0.22]	0.06 ± 0.11 [-0.08, 0.34]	0.039	-0.063 (0.046)	0.178
Prediction error (D)	-0.14 ± 0.34 [-1.02, 0.29]	0.01 ± 0.36 [-0.58, 0.72]	0.246	0.016 (0.145)	0.915

Vectors, marked with [a], are calculated using vector analyses and further analyzed using Hotelling's T-squared tests. The outcomes are corrected for the covariates age and IOL power, offering the unstandardized coefficient B, standard error, and adjusted p-value marked with an asterisk (*).

CDVA=corrected distance visual acuity; D=diopter; DCIVA=distance corrected intermediate visual acuity; DCNVA=distance corrected near visual acuity; DEQ=defocus equivalent, IOL=intraocular lens; SD=standard deviation; SE=standard error; SEQ=spherical equivalent; UDVA=uncorrected distance visual acuity; UIVA=uncorrected intermediate visual acuity; UNVA=uncorrected near visual acuity

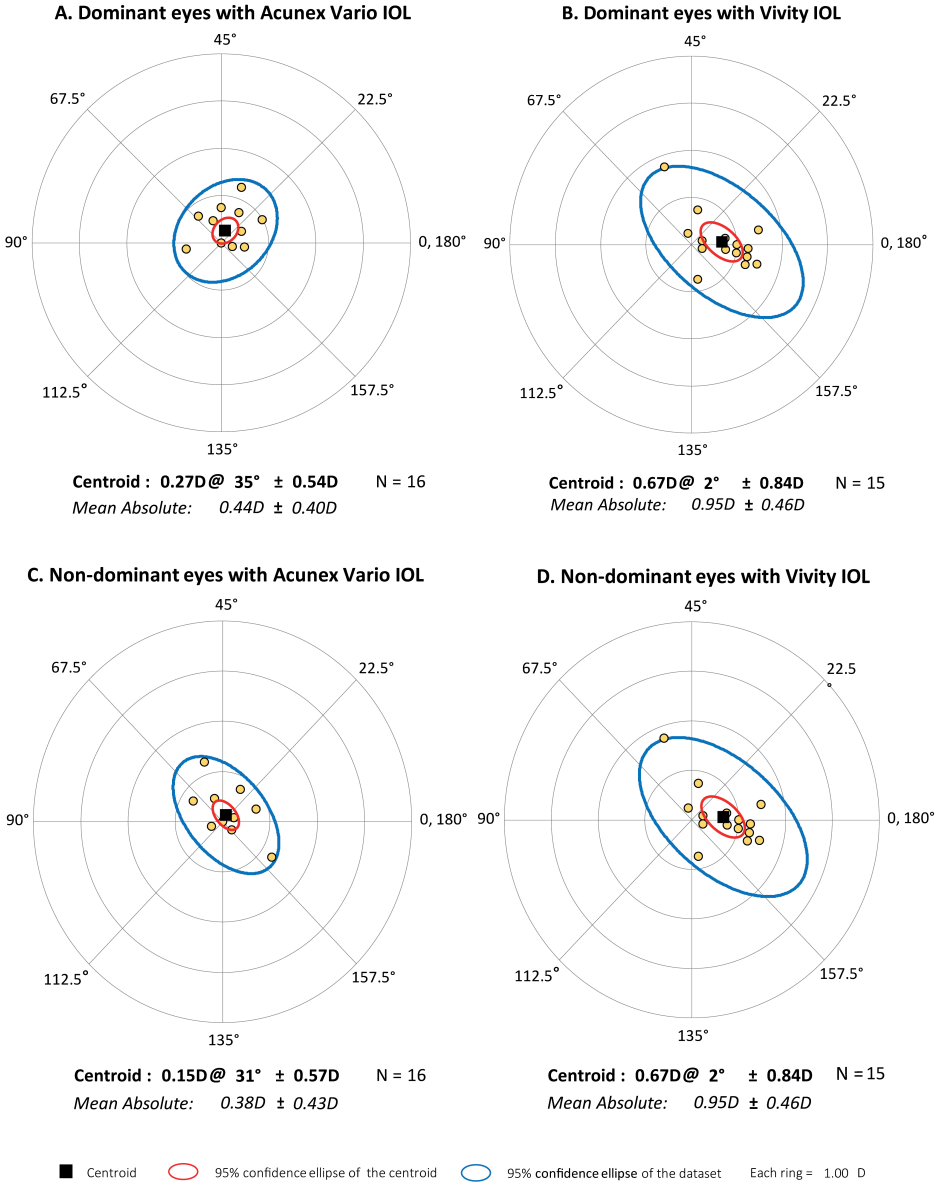


Figure 3.1. Double angle plots of postoperative refractive astigmatism at three months postoperatively.

The centroid is represented by the black square, the red ellipse encompasses the 95% confidence interval of the centroid. The blue ellipse represents the 95% confidence interval of the entire dataset. Each concentering ring in the double angle plot corresponds to a 1.0 D increment.

D=diopter

Table 3.3. Sensitivity analysis visual acuity outcomes.

	Vario-Group Mean ± SD (n=Eyes)	Vivity-Group Mean ± SD (n=Eyes)	p	Unstandardized coefficient B (SE (B))*	Adjusted-p*
Binocular outcomes					
UDVA (logMAR)	-0.03 ± 0.11 (28)	0.01 ± 0.07 (14)	0.241	-0.013 (0.049)	0.794
UIVA (logMAR)	0.05 ± 0.11 (28)	0.07 ± 0.06 (14)	0.273	-0.003 (0.052)	0.956
UNVA (logMAR)	0.24 ± 0.17 (28)	0.23 ± 0.11 (14)	0.460	-0.010 (0.087)	0.911
Monocular outcomes					
UDVA (logMAR) dominant eyes	0.00 ± 0.08 (15)	0.14 ± 0.08 (10)	<0.001	-0.092 (0.036)	0.018
UDVA (logMAR) non-dominant eyes	0.02 ± 0.12 (14)	0.15 ± 0.09 (9)	0.013	-0.069 (0.053)	0.215

Sensitivity analysis of uncorrected monocular and binocular visual outcomes at three months postoperatively. Outlier-eyes with a corneal astigmatism >1.0 D were excluded before analysis. The outcomes are corrected for covariates age and IOL power, offering the unstandardized coefficient B, standard error (SE), and adjusted p-value marked with an asterisk (*). For binocular visual acuity outcomes, one-sided p-values are given and for monocular visual acuity outcomes two-sided p-values are used.

SD=standard deviation; SE=standard error; UDVA=uncorrected distance visual acuity; UIVA=uncorrected intermediate visual acuity; UNVA=uncorrected near visual acuity

The postoperative prediction error (PE) was statistically significantly different between the two study groups for the dominant eyes. The percentage of dominant eyes within ± 0.50 D of the target was 82% for the Vario-group and 73% for the Vivity-group at three months postoperatively. For the non-dominant eyes these values were respectively 88% and 80%. Vector analyses were performed for all operated eyes using preoperative and postoperative Scheimpflug topography scans. Mean surgically induced astigmatism (SIA) for the Vario-group and the Vivity-group of the dominant eyes was 0.19 ± 0.38 D at 5° and 0.19 ± 0.37 D at 30° (adjusted-p=0.673), and for the non-dominant eyes 0.35 ± 0.39 D at 2° and 0.128 ± 0.34 D at 10° (adjusted-p=0.453).

Figure 3.2 shows the binocular UDVA defocus curve and binocular UDVA defocus curve without the outlier eyes with a postoperative residual astigmatism >1.0 D. The Vario-group showed significantly better results for the uncorrected defocus curve at -2.0 D (adjusted-p=0.034; B=0.118; SE(B)=0.053), -2.5 D (adjusted-p=0.024; B=0.241; SE(B)=0.068), -3.0 D (adjusted-p=0.003; B=0.257; SE(B)=0.077), and -3.5 D (adjusted-p<0.001; B=0.251; SE(B)=0.066). The defocus curve without outliers showed no differences between the two study groups. The binocular CDVA defocus curve can be found in **Supplementary Figure 3.1**.

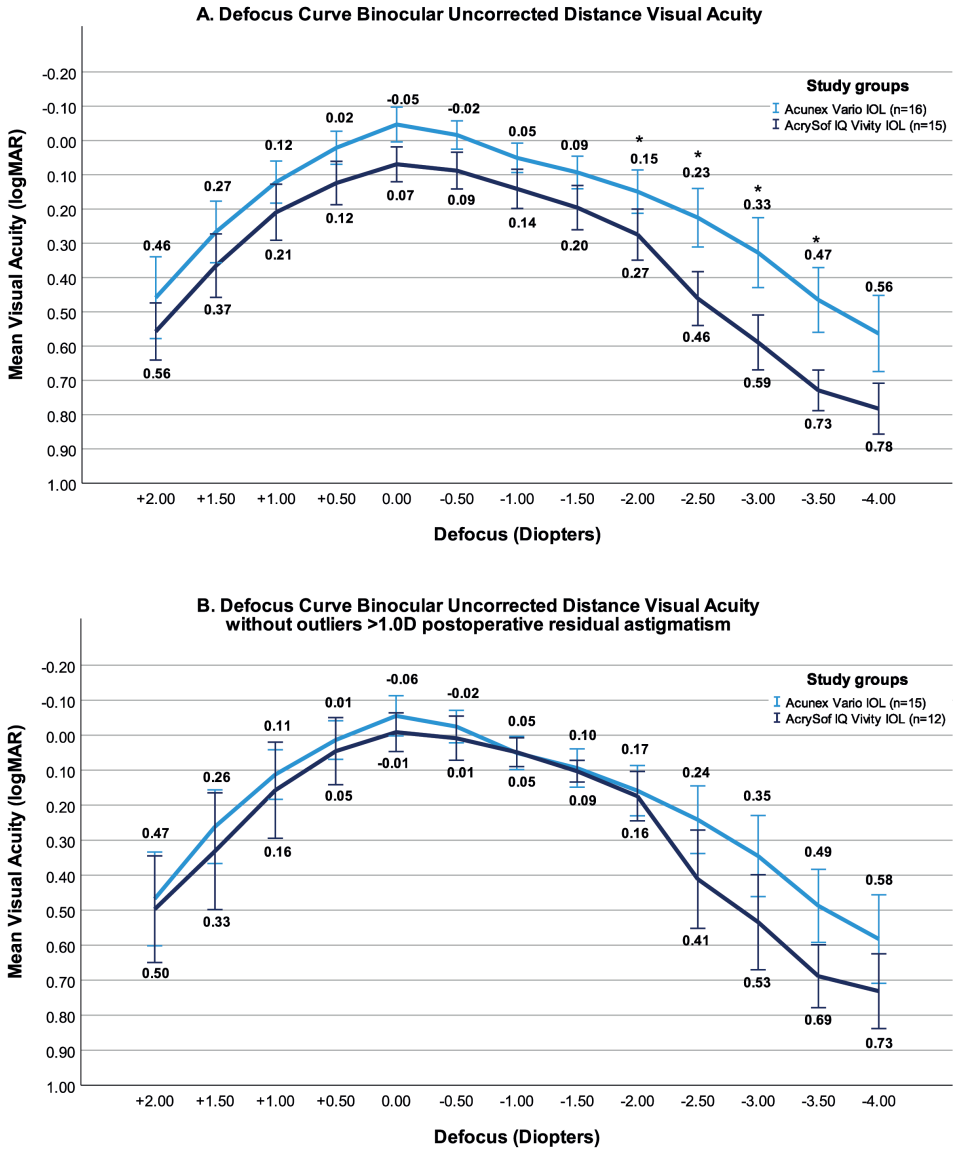


Figure 3.2. Binocular defocus curves at three months postoperatively.

A. Binocular UDVA defocus curve. B. Binocular UDVA defocus curve without outliers having >1.0 D postoperative residual astigmatism. The statistically significant differences between group, after adjusting for the covariates age and IOL power, are denoted by an asterisk (*).

D=diopter; IOL=intraocular lens; UDVA=uncorrected distance visual acuity

Tilt and decentration analyses were performed at one month postoperatively, showing a mean tilt for the dominant eyes of 3.4 ± 3.6° for the Vario-group and 4.4 ± 2.3° for the Vivity-

group (adjusted-p=0.079). The non-dominant eyes had values of 3.5 ± 3.2° and 4.5 ± 2.1° for the Vario-group and Vivity-group, respectively (adjusted-p=0.0124). Mean decentration for the dominant eyes was 0.11 ± 0.16 mm for the Vario-group and 0.06 ± 0.20 mm for the Vivity-group (adjusted-p=0.718). Non-dominant eyes had a decentration of 0.13 ± 0.18 mm for the Vario-group and 0.02 ± 0.20 mm for the Vivity-group (adjusted-p=0.667).

Both study groups had comparable reading speed scores in relation to visual acuity in logRAD. Contrast sensitivities are presented in **Figure 3.3**. Only at 12cpd in mesopic conditions with glare there was significant difference in favor of the Vario-group (adjusted-p=0.024; B=0.124, SE(B)=0.052).

At three months postoperatively, the total higher-order aberrations were measured in pupils of 4 mm and 6 mm, respectively. For dominant eyes with 4 mm pupils, values were 0.19 ± 0.11 µm and 0.16 ± 0.05 µm for the Vario-group and Vivity-group, respectively (adjusted-p=0.366). In 6 mm pupils, the values were 0.49 ± 0.21 µm and 0.47 ± 0.11 µm (adjusted-p=0.334). Non-dominant eyes of the Vario-group and Vivity-group showed values of 0.23 ± 0.16 µm and 0.17 ± 0.04 µm in 4 mm pupils (adjusted-p=0.430) and 0.52 ± 0.17 µm of and 0.49 ± 0.09 µm in 6 mm pupils (adjusted-p=0.651), respectively.

No statistically significant difference in patient satisfaction was found between the groups with 93.8% (n=15) in the Vario-group and 86.7% (n=13) in the Vivity-group being satisfied. Similarly, the Catquest-9SF questionnaire outcomes did not reveal significant differences between the groups (detailed results available in **Supplementary Figure 3.2**. The presence of photic phenomena and the spectacle independence at three months postoperatively can be found in **Supplementary Figure 3.3** and **Supplementary Table 3.2**, where the results were comparable between the study groups. In bright light conditions, 93.8% of the Vario-group and 86.7% of the Vivity-group never or rarely used glasses. For near vision, reading glasses were required by 62.5% of patients in the Vario-group and 73.3% in the Vivity-group. Patients reported halos, glare, and starbursts never or only sometimes in 75% (n=12), 75% (n=12), and 81% (n=13) of cases in the Vario-group and 93% (n=14), 86% (n=13), and 93% (n=14) in the Vivity-group, respectively. Two patients in the Vario-group reported bothersome halos and glare, while one experienced starburst complaints. In the Vivity-group, one patient reported bothersome glare.

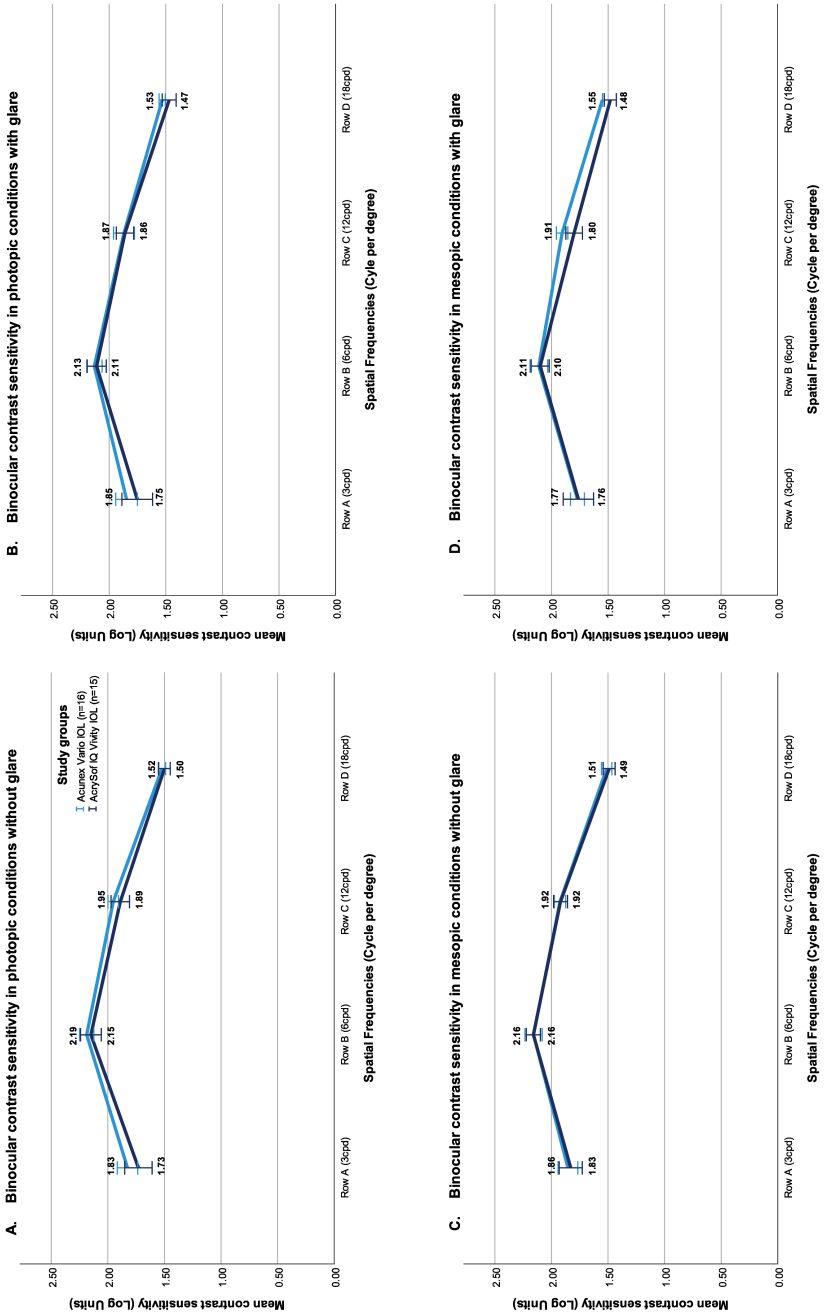


Figure 3.3. Binocular contrast sensitivity outcomes at three months postoperatively in different conditions.

A. Photopic conditions without glare; B. Mesopic conditions without glare; C. Photopic conditions with glare; D. Mesopic conditions with glare.

Complications and adverse events

Three surgical complications were reported: one case of corneal erosion and partial zonulolysis in the Vario-group, and one posterior capsule rupture necessitating anterior vitrectomy in the Vivity-group. Postoperatively, one patient in the Vario-group developed bilateral uveitis anterior, while one patient in the Vivity-group had bilateral cystoid macular edema, and another had stromal edema. These conditions had all resolved with standard treatment at the final postoperative visit. Thereafter, one patient was scheduled to receive additional laser-assisted sub-epithelial keratectomy (LASEK) to correct the residual ametropia.

Discussion

The purpose of this study was to compare the visual outcomes of two EDOF IOLs (AN6V and DFT015) when targeted for a mini-monovision approach. At three months postoperatively, after correcting for the covariates age and IOL power, non-inferiority was observed for the primary outcome binocular UIVA in the Vario-group compared to the Vivity-group. The correction for these covariates was applied to all quantitative outcomes to mitigate bias arising from the imbalances between the groups at baseline and to ensure the objectivity of our comparisons between the study groups.

The refractive outcomes at three months demonstrated significant differences for sphere, cylinder and UDVA for the dominant eyes between the study groups. These disparities were primarily attributed to higher residual astigmatism outcomes in the Vivity-group compared to the Vario-group. Although our study aimed for a postoperative residual astigmatism of ≤1.0 D, postoperative refractive astigmatism clearly demonstrated higher centroid values and an increased prevalence of outliers (>1.0 D) in the Vivity-group. The sensitivity analysis without these >1.0 D outliers indicated comparable binocular visual acuity outcomes between the groups, which emphasizes the importance of postoperative residual astigmatism <1.0 D on uncorrected visual acuity outcomes. This is in line with previous research showing that residual astigmatism of ≥1.0 D significantly decreases UDVA.[13] In retrospect, targeting a residual astigmatism lower than the ≤1.0 D aim might have been preferable to limit the amount of residual postoperative astigmatism due to the wide range and individual variability of SIA.[14] Therefore, IOL calculations aiming for a residual postoperative astigmatism ≤0.75 D may decrease the number of outliers >1.0 D of astigmatism and reduce the postoperative PE.

For both monofocal and EDOF IOLs, the impact of refractive cylinder on UDVA shows a comparable change of 0.0425 logMAR per 0.25 D cylinder.[15] Furthermore, toric monofocal IOLs in patients with low preoperative corneal astigmatism (0.75-1.5 D) demonstrate significantly reduced postoperative residual astigmatism, leading to improved UDVA outcomes. Therefore, considering the use of a toric IOL is suggested for preoperative astigmatism at or above the 0.75 D threshold.[16] Studies involving presbyopia-correcting IOLs also have recommended astigmatism correction ≥0.75 D to ensure postoperative vision quality.[17] In our study, the IOLs of interest were expected to tolerate ≤1.0 D astigmatism, although scientific validation is lacking for refractive EDOF IOLs. Previous research on the DFT015 has shown that low levels of induced ametropia (up to ± 0.50 D) are tolerated, with no significant difference in visual acuity compared to emmetropia (≤1 line loss).[18] Additionally, another study has demonstrated a tolerance for negative spherical aberrations up to -0.05 µm, which does not impact UDVA and may even provide slight improvements in UNVA and UIVA.[19] Higher levels of ametropia and spherical aberrations have not yet been reported.

Literature on the AN6V (+1.5 D addition) is limited. The precursor of this IOL, the Lentis Comfort M15 IOL (currently Teleon Surgical B.V., Spankeren, The Netherlands), features a sector-shaped near vision zone with a +1.5 D add power. When targeted for emmetropia, this IOL demonstrated monocular UDVA, UIVA and UNVA outcomes at three months postoperatively, with values of 0.12 ± 0.13, 0.16 ± 0.17, and 0.32 ± 0.18 logMAR, respectively.[20] Another study reported bilateral outcomes for UDVA, UIVA, UNVA of 0.07 ± 0.10, 0.21 ± 0.15, and 0.53 ± 0.15 logMAR at three months postoperatively.[21] Long-term results up to 5 years postoperatively showed stable distance and intermediate visual acuity.[22] A prospective study involving the implantation of the AN6V (+1.5 D addition), targeted for emmetropia, reported binocular UDVA, UIVA, and UNVA at three months of -0.08 ± 0.06, -0.03 ± 0.06, and 0.16 ± 0.06 logMAR, respectively. Additionally, the distance-corrected defocus curve demonstrated a visual acuity of 0.20 logMAR or better within +1.50 D to -2.00 D.[23] Our results with the AN6V targeted for mini-monovision, showed superior outcomes on all distances as compared to the previous studies using the Lentis Comfort M15 IOL, but slightly lower visual acuity outcomes and a narrower range of defocus (from +1.00 D to -2.00 D) as compared to the previous prospective AN6V study. The DFT015 has demonstrated good results both when targeting for emmetropia and mini-monovision.[2,3,24-30] In our earlier case series we bilaterally implanted DFT015 IOLs targeted for mini-monovision and reported binocular UDVA of -0.07 ± 0.10, UIVA of 0.04 ± 0.09, and UNVA of 0.23 ± 0.12 logMAR at three months.[3] These results were comparable to those reported in the literature, which indicate that DFT015 implantation for mini-monovision

provides good UDVA and UIVA, as well as functional UNVA.[3,24,27-30] In the present study, the Vivity-group had a higher mean age and postoperative residual astigmatism, which contributed to inferior uncorrected visual acuity outcomes compared to our previous case series. This difference may be attributed to variations in corneal rigidity, which typically increases with age.[31]

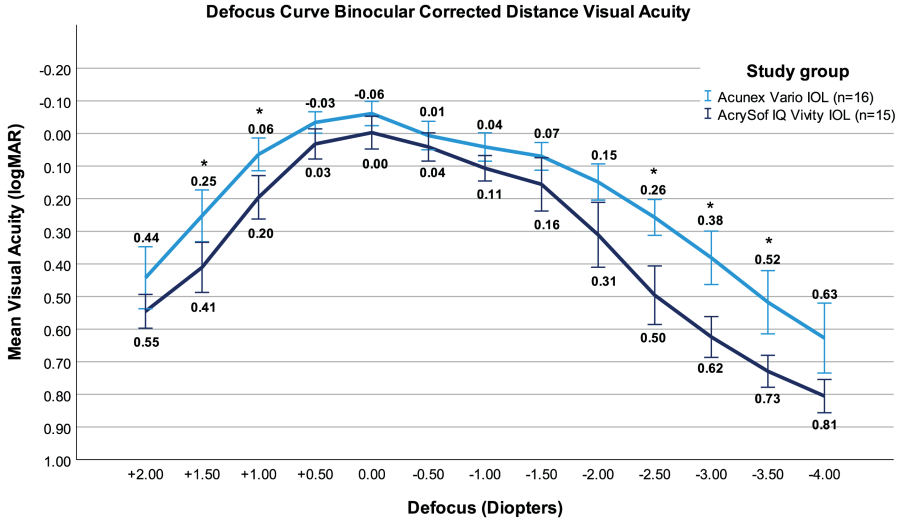
Both study IOLs induced minimal or only occasional optical disturbances. Previous results with the Lentis Comfort M15 IOL showed that 9.1% of the eyes experienced dysphotopsia at three months postoperatively.[21] In an AN6V cohort study, 15% of patients reported halos or starbursts, and 20% reported glare.[23] In our study, the incidence of dysphotopsia in the Vario-group was higher. However, it is important to note that the previous AN6V study used a different questionnaire to assess these disturbances. The results for the DFT015 in the literature were comparable with our findings, reporting an incidence of no halos, and no starbursts ranging from 53% to 94% and 78% to 100%, respectively. Only the incidence of glare in our Vivity-group was higher, with 13% of the patients reporting no glare, compared to 53% to 97% in the literature.[3,5,7,24-26,32-36]

While our study revealed a significantly greater range of defocus in the Vario-group, no difference in spectacle independence was observed between the groups. Both study-groups demonstrated similar results in terms of near spectacle independence. A prospective study involving bilateral AN6V implantation targeted for emmetropia reports that 85% of the patients use reading glasses occasionally or for prolonged reading.[23] After DFT015 implantation, near vision spectacle independence ranges from 33% to 87%.[3,25,26] Following DFT015 implantation targeted for mini-monovision, only 32% of patients report complete spectacle independence. [3] Our findings aligned with those from other EDOF studies, suggesting that while a mini-monovision approach can improve spectacle independence, it does not guarantee complete spectacle independence.[3,36,37] Therefore, patients should be carefully counseled with respect to expectations of achieving full spectacle independency when applying EDOF IOLs.

Despite randomization, the main limitation of this study was the baseline imbalances between the groups, emphasizing the need for age stratification. Moreover, striving for a lower postoperative residual astigmatism by taking into account the wide individual variability in SIA, is crucial to minimize refractive outliers as much as possible. In addition, patients were treated by multiple surgeons, which could have led to bias. Lastly, it is important to note the scarcity of cohorts focused on mini-monovision in the existing EDOF literature, which makes comparisons challenging.

In conclusion, the findings of this randomized controlled trial illustrate that bilateral Acunex Vario IOL (AN6V +1.5 D addition) implantation offers non-inferior visual outcomes compared to bilateral AcrySof IQ Vivity IOL (DFT015) implantation, when targeted for mini-monovision. Furthermore, the study reveals comparable visual quality and high levels of patient satisfaction in both study groups.

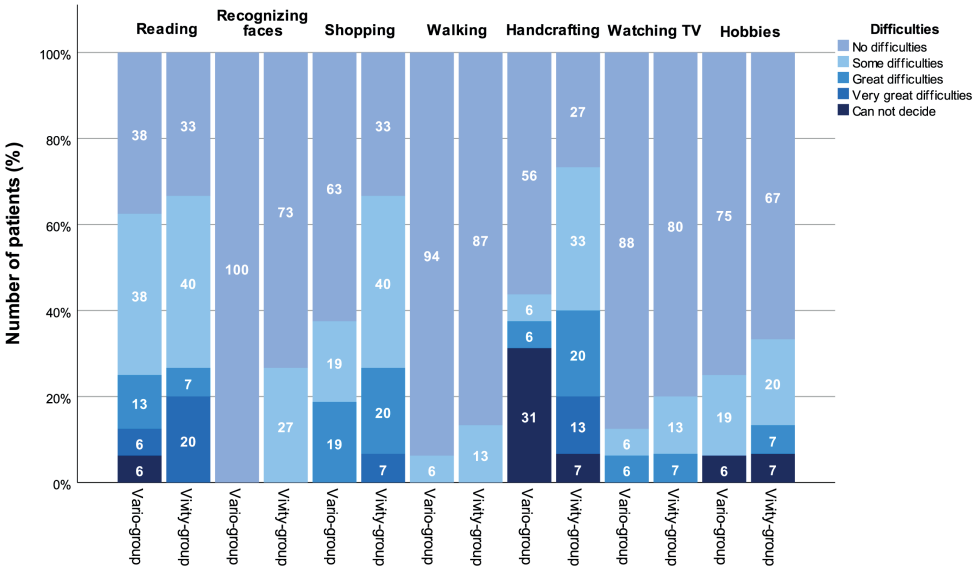
Supplements



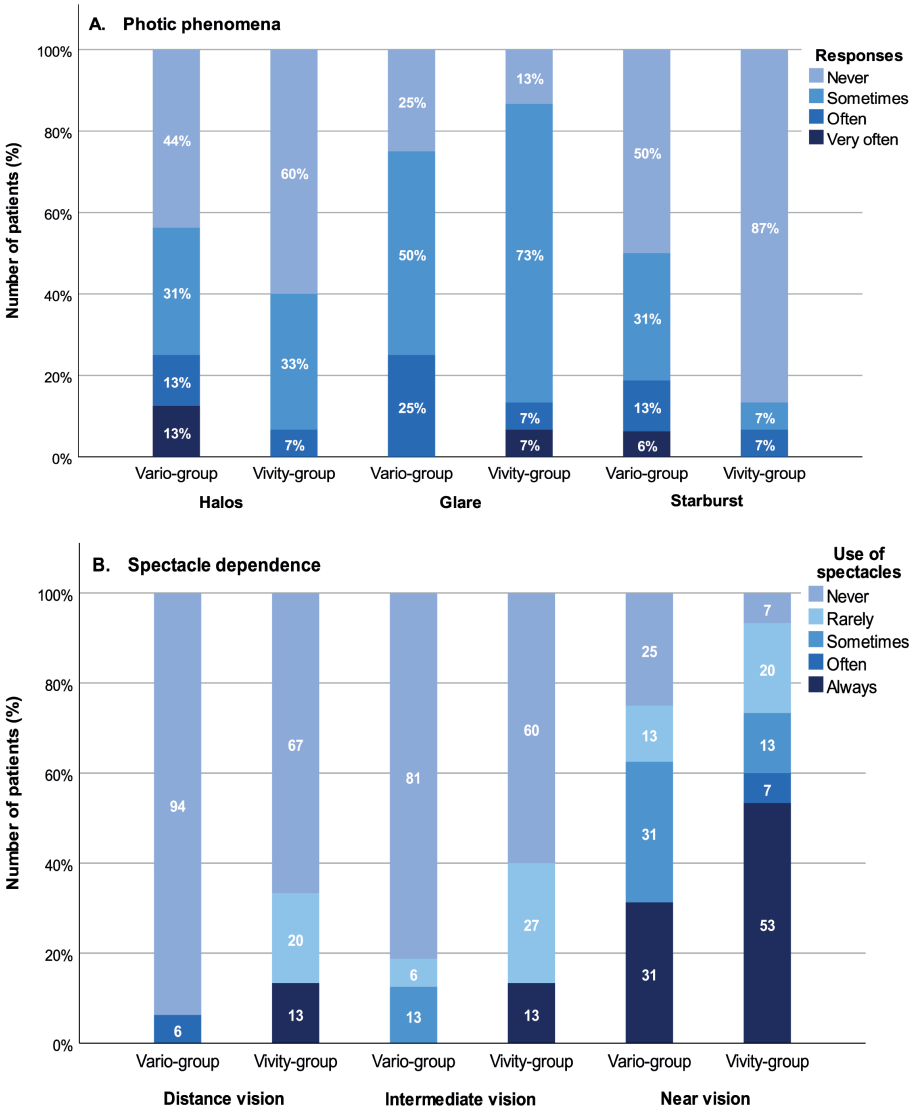
Supplementary Figure 3.1. Binocular CDVA defocus curves at three months postoperatively.

The statistically significant differences between group, after adjusting for the covariates age and IOL power, are denoted by an asterisk (*).

D=diopter; UDVA=uncorrected distance visual acuity



Supplementary Figure 3.2. Outcomes of Catquest questionnaire at three months postoperatively of the Variogroup (n=16) and Vivity-group (n=15).



Supplementary Figure 3.3. Outcomes of questionnaires at three months postoperatively of the Vario-group (n=16) and Vivity-group (n=15).

A. Questionnaire regarding spectacle dependence at photopic conditions; B. Questionnaire regarding photic phenomena.

Supplementary Table 3.1. Confidence intervals binocular visual acuity outcomes.

	90% confidence intervals	
Binocular outcomes	**Lower**	**Upper**
UDVA (logMAR)	-0.062	0.091
UIVA (logMAR)	-0.026	0.129
UNVA (logMAR)	-0.035	0.206
CDVA (logMAR)	-0.035	0.09
DCIVA (logMAR)	-0.052	0.137
DCNVA (logMAR)	-0.04	0.161

90% Confidence Intervals (non-inferiority design) for the binocular visual acuities at three months after surgery.

CDVA=corrected distance visual acuity; D=diopter, DCIVA=distance corrected intermediate visual acuity; DCNVA=distance corrected near visual acuity; UDVA=uncorrected distance visual acuity; UIVA=uncorrected intermediate visual acuity; UNVA=uncorrected near visual acuity

Supplementary Table 3.2. Detailed outcomes IOLSAT questionnaire at three months postoperatively of the Vario-group (n=16) and Vivity-group (n=15).

Rarely or never using glasses	**Vario-group (%)**	**Vivity-group (%)**
Bright light conditions:		
Distance vision “far away”	93.8	86.7
Intermediate vision “arm’s length”	87.6	86.7
Near vision “up close”	37.5	26.7
Dim light conditions:		
Distance vision “far away”	87.5	93.4
Intermediate vision “arm’s length”	93.8	66.6
Near vision “up close”	31.3	26.7

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CHAPTER 4

Six-Month Performance and Safety of an Iris-Fixated Multifocal Intraocular Lens for Presbyopia Correction in Phakic Eyes

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Abstract

Purpose: Purpose: To evaluate the six-month effectiveness and safety of a novel foldable multifocal iris-fixated phakic IOL (pIOL) for presbyopia correction.

Setting: Multicenter study at 7 sites.

Design: Nonrandomized prospective clinical trial.

Methods: Presbyopic patients without cataracts undergoing bilateral multifocal pIOL implantation (Ophtec ArtiPlus) were studied. The primary outcome for efficacy was the visual acuity at distance, intermediate, and near. Secondary outcomes included endothelial cell density (ECD), postoperative refraction, binocular defocus curve, vision quality, spectacle independence, and patient satisfaction.

Results: A total of 49 subjects (98 eyes) were included. At six months, the mean binocular uncorrected distance intermediate, and near visual acuity were -0.05 ± 0.09, -0.02 ± 0.07, and 0.02 ± 0.08 logMAR, respectively. The ECD remained stable with a mean value of 2771 ± 289 cells/mm2 at six months postoperatively. The mean spherical equivalent was -0.42 ± 0.33 diopters (D), with 95% eyes having a prediction error within ± 1.0 D and 77% within ± 0.5 D. The binocular distance-corrected defocus curve showed a visual acuity of 0.20 logMAR or better over a range of +1.0 D to -3.5 D. Patient satisfaction was high, with a mean score of 3.5 on a 4-point scale, and 83% of the patients reported spectacle independence. 47%, 35%, and 96% of patients reported experiencing glare, halos, and starbursts at well-tolerated levels, respectively. Notably, only 2% of patients found halos and starbursts to be very bothersome.

Conclusion: Bilateral ArtiPlus multifocal pIOL implantation demonstrated good visual acuity from distant to near and maintained stable ECD over six months. Patients reported high levels of satisfaction and spectacle independence, despite some optical disturbances.

Introduction

In the past decades, various innovative technologies have been introduced in refractive surgery to address the needs of presbyopic patients seeking spectacle independence. As the prevalence of this age-related condition increases and its associated spectacle dependence significantly reduces quality of life, more presbyopic patients are seeking freedom from corrective eyewear.[1,2] Presbyopia correction is considered the last significant challenge of refractive surgery, with a range of surgical techniques available, including both cornea-based and lens-based procedures. No single technique has emerged as superior, as patient suitability varies based on specific characteristics. Among the lens-based treatment options are refractive lens exchange (RLE) with multifocal intraocular lens (IOL) implantation or multifocal phakic intraocular lens (pIOL) implantation.[2-4] The use of multifocal IOLs has proven effective for achieving complete spectacle independence.[5,6] Multifocal phakic intraocular lens (pIOL) implantation offers a promising alternative. It combines the benefits of reversibility with a lower risk of retinal complications, making it particularly suitable for middle-aged, presbyopic patients.[2,5,6] Previous studies have demonstrated the safety and efficacy of pIOLs in correcting myopia, with outcomes indicating high levels of patient satisfaction and visual acuity.[4,7] The novel multifocal ArtiPlus IOL integrates the platform of the Artiflex Myopia lens with the optical design of the Precizon Presbyopic IOLs, both previously developed by Ophtec, Groningen, The Netherlands. The purpose of this study is to evaluate the effectiveness and safety of the novel multifocal ArtiPlus pIOL in presbyopic adults desiring spectacle independence for all distances.

Methods

This study was a multicenter, prospective clinical trial conducted at four hospitals in Spain (IMO Institutio de Microcirurgía Ocular, Barcelona; Clinica CIMO, Seville; ICQO Instituto Clínico Quirúgico de Oftalmologia, Bilbao; Servicio de Oftalmologia San Rafael, Madrid) and three hospitals in South Korea (Nune Eye Hospital, Daegu; GM St. Mary's Eye clinic, Busan; SU Yonsei Eye Clinic, Seoul). Participants were enrolled from each center. Presbyopic adults without cataract, seeking spectacle independence for distant to near vision, were included if they had a stable refractive spherical equivalent (SE) of ± 0.75 diopters (D) for at least 12 months prior to surgery, and an expected residual postoperative cylindrical refractive error ≤0.75 D and an expected postoperative CDVA of ≤0.2 logMAR. Patients were excluded if the selection criteria for pIOL implantation were

not met according to the instructions for use. Full details about the selection criteria are summarized in **Supplementary Material 4.1**. All patients signed informed consent before enrollment. This study was approved by the Medical Ethics Committee at IMO and 'Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)' in Spain, and the local ethics committee at each site in South Korea. The Korean competent authority, MFDS, also assessed and approved the study. This study adhered to the tenets of the Declaration of Helsinki. The trial was registered at ClinicalTrial.gov (NCT04632784).

Patients were scheduled for bilateral ArtiPlus (Ophtec, Groningen, The Netherlands) pIOL implantation. The ArtiPlus is a foldable anterior chamber iris-fixated multifocal pIOL made of polysiloxane, with a diopter range between -15.0 and +2.0 D and an add-on power of +2.5 D for near vision. This pIOL features an aspherical segmented optic designed with multiple elongated focal points, enabling a seamless transition between distance and near vision. The design includes five segments for far vision and six segments for near vision, as illustrated in **Figure 4.1**. Lens power calculation was performed by Ophtec BV (Groningen, The Netherlands) using the modified Van der Heijde formula targeted for emmetropia.[8] Surgeries were performed by experienced surgeons using a 3.2 mm main incision positioned at 90° from the intended enclavation axis. The pIOL was implanted and fixated to the iris. An iridectomy or iridotomy was performed either during surgery or at least one week prior to pIOL implantation using a Nd:YAG laser. If necessary, a suture was used for wound closure. The surgeries for the first and second eye were performed within a two-week interval.

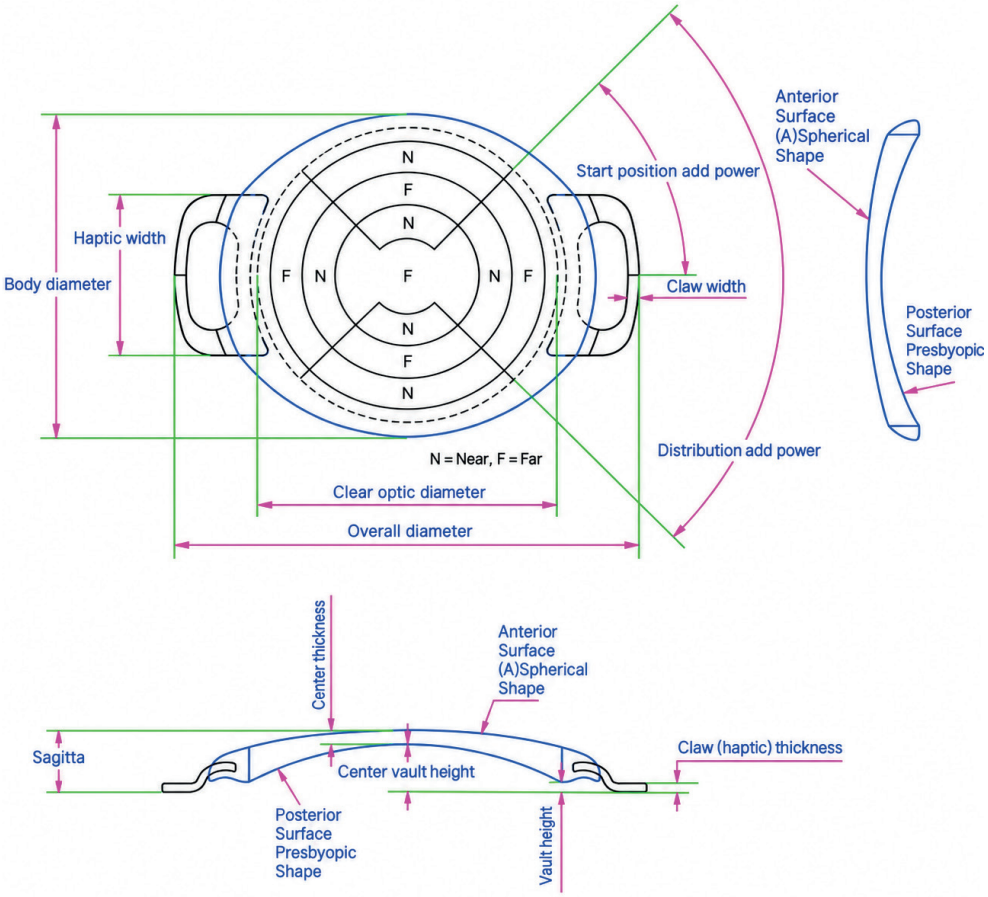


Figure 4.1. The Artiflex Presbyopic IOL design with distribution of the far/near segments.

F=far; N=near

Patients underwent preoperative testing, including manifest subjective and cycloplegic refraction, visual acuity assessments, biometry (IOLMaster, Zeiss Meditec, Jena, Germany; Alladin, Topcon, Tokyo, Japan; Argos, Alcon, Fort Worth, Texas, United States of America), corneal topography and tomography (Pentacam, Oculus, Wetzlar, Germany; Aladdin, Topcon, Tokyo, Japan; Gallilei G4, Ziemer Ophthalmic Systems AG, Brügg, Switzerland), pupillometry, tonometry, gonioscopy, specular microscopy, contrast sensitivity testing (CSV-1000, Vector Vision Inc, Greenville, United States of America), slit lamp and funduscopic examination. Postoperative assessments were performed at 1 day, 1 week, 1 month, 3 months, and 6 months after pIOL implantation. Visual acuity assessments were conducted using the Early Treatment Diabetic Retinopathy Study (ETDRS) charts at 4 m,

80 cm and 40 cm for distant, intermediate and near vision, respectively. The logMAR score was determined by identifying the last attempted line on the ETDRS chart until no further optotypes could be distinguished. This score was obtained by adding the total number of correctly identified optotypes to the score of the last attempted line. A binocular corrected defocus curve was performed six months postoperatively under photopic conditions, with a defocus range of +1.5 D to -5.0 D with 0.50 D increments. Preoperatively and at six months postoperatively, the quality of vision was evaluated using the validated QoV-questionnaire.[9] Patient satisfaction was assessed at six months postoperatively through an unvalidated satisfaction questionnaire, which can be found in the **Supplementary Material 4.2**. Both questionnaires utilize 4-point Likert scales, ranging from zero (representing none/never) to four (indicating severe/always).

Statistical analyses

Data analysis was conducted using SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY). All qualitative variables were summarized as the distribution of frequency, absolute, and percentage. For all quantitative variables, descriptive statistics were calculated. Statistical comparison of endothelial cell density (ECD) and intraocular pressure (IOP) over time were calculated using the ANOVA repeated measures in case of normality. In case of non-normally distributed data, non-parametric tests were used. Comparisons between preoperative and postoperative quality of vision questionnaires were performed using the Wilcoxon Signed-Rank test. Associations between optical side effects and pupillary sizes were tested using ordinal regression analysis. A significance level of ≤0.05 was applied.

Results

From November 2021 to March 2023, a total of 49 patients (98 eyes) were enrolled in the study. The cohort consisted of 22 males (45%) and 27 females (55%), with a mean age of 49 ± 5 years (range: 43-64). The ethnic distribution included 21 Caucasian patients (43%) and 28 Asian patients (57%). **Table 4.1** presents the baseline characteristics. Note that one patient missed the 6-month postoperative visit.

Table 4.1. Baseline characteristics of 49 patients (98 eyes).

Parameter	Mean ± SD	Range
Refraction (Manifest)		
- Sphere (D)	-4.64 ± 2.23	-10.50; 1.75
- Cylinder Magnitude (D)	-0.68 ± 0.42	-2.25; 0.00
- SE (D)	-4.98 ± 2.27	-11.00; 1.50
Refraction (Cycloplegic)		
- Sphere (D)	-4.55 ± 2.26	-9.75; 2.00
- Cylinder Magnitude (D)	-0.67 ± 0.44	-2.50; 0.00
- SE (D)	-4.88 ± 2.30	-10.37; 1.75
CDVA, monocular (logMAR)	0.00 ± 0.08	-0.20; 0.40
IOP (mmHg)	15.0 ± 3.1	9.0; 21.0
AL (mm)	25.68 ± 1.01	23.36; 28.69
ACD (mm)	3.24 ± 0.26	2.83; 3.83
Keratometry (D)	44.23 ± 1.22	41.38; 46.85
ECD (cells/mm^2)	2785 ± 238	2057;3436
Pupillometry		
- Photopic (mm)	3.79 ± 0.76	2.75; 6.20
- Mesopic (mm)	5.51 ± 1.02	3.30; 7.00
- Scotopic (mm)	6.11 ± 0.83	3.10; 7.00
IOL Power (D)	-5.53 ± 2.42	-11.50; 2.00
Target (D)	-0.07 ± 0.18	-0.95; 0.28

ACD=anterior chamber depth; AL=axial length; CDVA=corrected distance visual acuity; D=diopter; ECD=endothelial cell density; IOL=intraocular lens; IOP=intraocular pressure; SD=standard deviation; SE=spherical equivalent

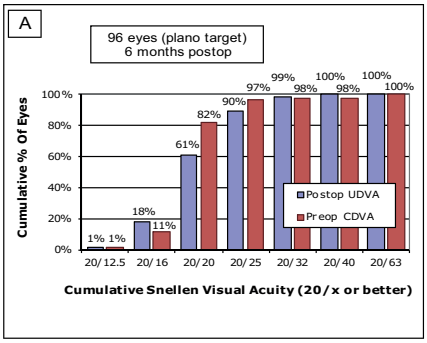
Short-term efficacy

The monocular refractive and visual outcomes at 1, 3, and 6 months postoperatively are detailed in **Table 4.2**. The mean uncorrected and distance-corrected binocular outcomes at 6 months postoperatively were -0.05 ± 0.09 and -0.09 ± 0.06 logMAR for distance (UDVA and CDVA), -0.02 ± 0.07 and 0.00 ± 0.09 logMAR for intermediate (UIVA and DCIVA), and 0.02 ± 0.08 and 0.01 ± 0.06 logMAR for near vision (UNVA, DCNVA), respectively. The binocular corrected near visual acuity (CNVA) was -0.02 ± 0.05 logMAR. The efficacy indices at 1, 3, and 6 months (mean postoperative UDVA/mean preoperative CDVA) were 0.81, 0.91, and 0.99, respectively. The postoperative uncorrected and preoperative corrected visual outcomes for all eyes are displayed in **Figure 4.2A**. **Figure 4.3** shows the binocular distance corrected binocular defocus curve at 6 months postoperatively (n=48). The visual acuity was 0.20 logMAR or better over a range of +1.0 D to -3.5 D.

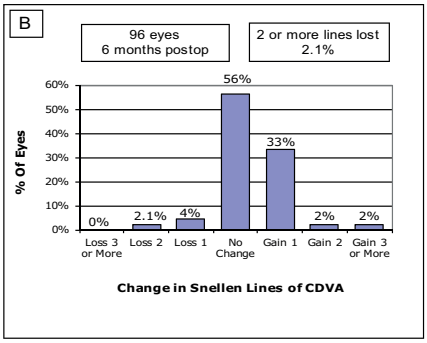
Table 4.2. Monocular refractive and visual acuity outcomes at multiple time points.

	Preop (n=98)	1 month postop (n=98)	3 months postop (n=98)	6 months postop (n=96)
Sphere (D)	-4.64 ± 2.23	-0.27 ± 0.36	-0.22 ± 0.31	-0.21 ± 0.29
Cylinder magnitude (D)	-0.68 ± 0.42	-0.50 ± 0.38	-0.44 ± 0.35	-0.41 ± 0.35
SE (D)	-4.98 ± 2.27	-0.52 ± 0.40	-0.43 ± 0.35	-0.41 ± 0.33
UDVA (logMAR)	0.94 ± 0.25	0.09 ± 0.15	0.04 ± 0.11	0.02 ± 0.09
CDVA (logMAR)	0.00 ± 0.08	0.00 ± 0.10	-0.03 ± 0.07	-0.05 ± 0.06
UIVA (logMAR)	0.73 ± 0.36		0.04 ± 0.10	0.02 ± 0.08
DCIVA (logMAR)	0.08 ± 0.14		0.05 ± 0.12	0.03 ± 0.10
UNVA (logMAR)	0.47 ± 0.42	0.11 ± 0.16	0.10 ± 0.12	0.07 ± 0.09
DCNVA (logMAR)	0.15 ± 0.21		0.10 ± 0.13	0.04 ± 0.08
CNVA (logMAR)	0.01 ± 0.07		0.02 ± 0.06	0.01 ± 0.06

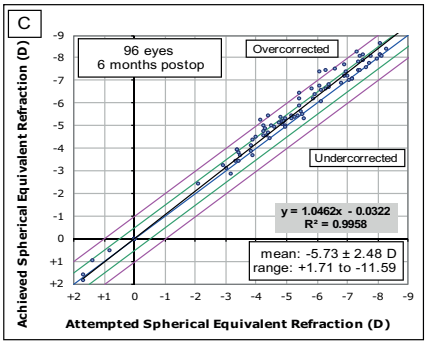
CDVA=corrected distance visual acuity; CNVA=corrected near visual acuity; D=diopters; DCIVA= distance corrected intermediate visual acuity; DCNVA=distance corrected near visual acuity; SE=spherical equivalent; SD=standard deviation; UDVA=uncorrected distance visual acuity; UIVA=uncorrected intermediate visual acuity; UNVA=uncorrected near visual acuity



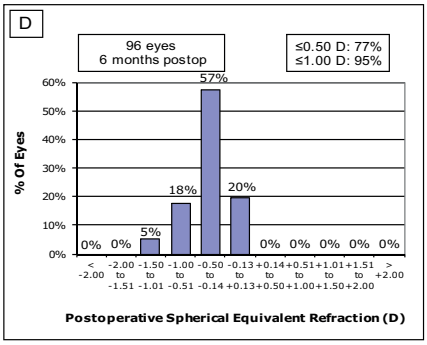
Uncorrected Distance Visual Acuity



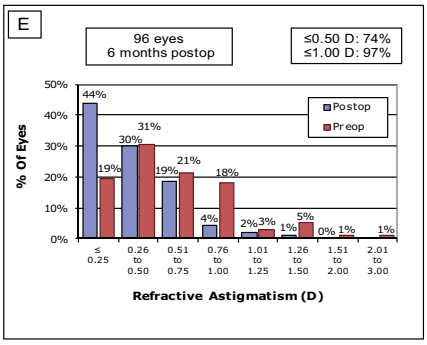
Change in Corrected Distance Visual Acuity



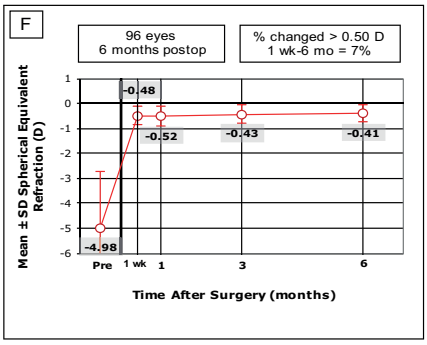
Spherical Equivalent Attempted vs Achieved



Spherical Equivalent Refractive Accuracy



Refractive Astigmatism



Stability of Spherical Equivalent Refraction

Figure 4.2. Visual and refractive outcomes after bilateral implantation of the ArtiPlus phakic IOL. (A) Uncorrected distance visual acuity (UDVA) outcomes. (B) Postoperative UDVA and preoperative corrected distance visual acuity (CDVA). (C) Distribution of achieved spherical equivalent outcomes. The green lines represent outcomes within ± 0.50 D and the pink lines within ± 1.0 D. (D) Spherical equivalent refractive accuracy. (E) Refractive Astigmatism. (F) Spherical equivalent refraction stability.

CDVA=corrected distance visual acuity; D=diopter; UDVA=uncorrected distance visual acuity

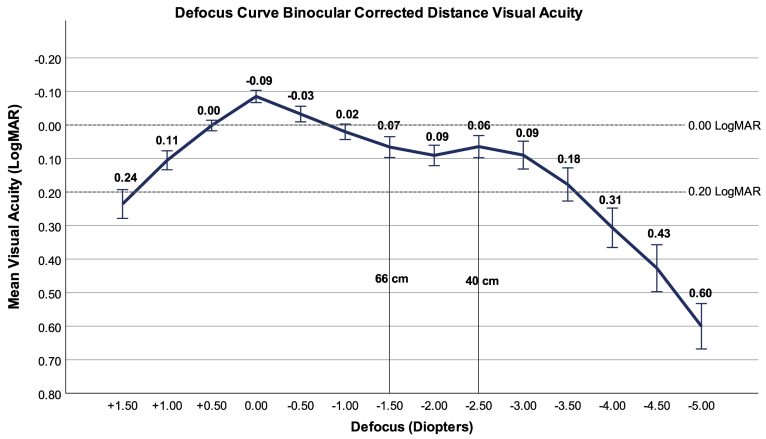


Figure 4.3. Binocular corrected distance visual acuity defocus curve (n=48).

Short-term safety

The safety assessment focused on ECD, with mean values of 2760 ± 225 and 2809 ± 249 cells/mm^2 preoperatively, 2753 ± 265 and 2786 ± 268 cells/mm^2 at one 1 month, and 2750 ± 271 and 2785 ± 309 cells/mm^2 at 6 months postoperatively, for the right and left eyes respectively. The ECD remained stable over the first 6 months postoperatively, with no significant differences observed over time for both the right (p=0.858) and left eyes (p=0.344). At the 6 months follow-up, the IOP had a mean value of 14.2 ± 2.6 mmHg for the right eyes and 14.2 ± 2.8 mmHg for the left eyes. No significant differences were found in IOP over time for the right (p=0.308) and left eyes (p=0.217). The safety indices (ratio of mean postoperative CDVA to mean preoperative CDVA) at 1, 3, and 6 months were 1.00, 1.07, and 1.12, respectively. There was a gain or no change in Snellen lines of CDVA for 94% of the eyes at 6 months postoperatively and 2.1% lost 2 or more lines, displayed in **Figure 4.2B**.

Predictability and stability

The mean prediction error (PE) was -0.42 ± 0.33 D at 6 months postoperatively. The SE of 77% of eyes was within ± 0.5 D and 95% of eyes within ± 1.0 D from the intended target. The mean refractive cylinder magnitude was -0.41 ± 0.35 D, with 74% eyes showing a residual cylinder of ≤0.50 D and 97% of ≤1.00 D. Predictability outcomes are displayed in **Figure 4.2CDE** The SE remained stable over 6 months, with 7% of the eyes exhibiting a change >0.50 D between week 1 and 6 months, as visualized in **Figure 4.2F**.

Complications and adverse events

One month postoperatively, one patient (one eye) was diagnosed with non-lens related optic neuritis, while another patient (both eyes) had elevated intraocular pressure (IOP) due to corticosteroid treatment occurred. Additionally, a third patient (both eyes) had developed cell deposits in the anterior chamber. At 3 months postoperatively, one patient (one eye) had retained cell deposits, and another patient (one eye) was diagnosed with viral conjunctivitis. No other adverse events were reported.

Quality of vision

The postoperative contrast sensitivity (n=31) was comparable in photopic and mesopic conditions, with and without glare. These contrast sensitivities were within normal limits and are presented in **Supplementary Figure 4.1**. The postoperative outcomes of the QoV-questionnaire can be found in **Figure 4.4AB**. Most patients experienced never or only occasionally glare or halos, although starburst were more frequently reported. Starbursts were reported as little bothersome in 54%, quite bothersome in 6%, and very bothersome in 2% of the patients. Overall, visual symptoms remained unchanged for 50% of the patients when compared to the preoperative assessments, improved for 48% and worsened for 2%. There was no difference found between the preoperative and postoperative existence of glare and halos, but for the presence of starbursts there was a significant increase found with a Z-score of 3.26 (p=0.001). Preoperative pupil size under photopic, mesopic or scotopic light conditions did not show a significant association with postoperative optical side effects.

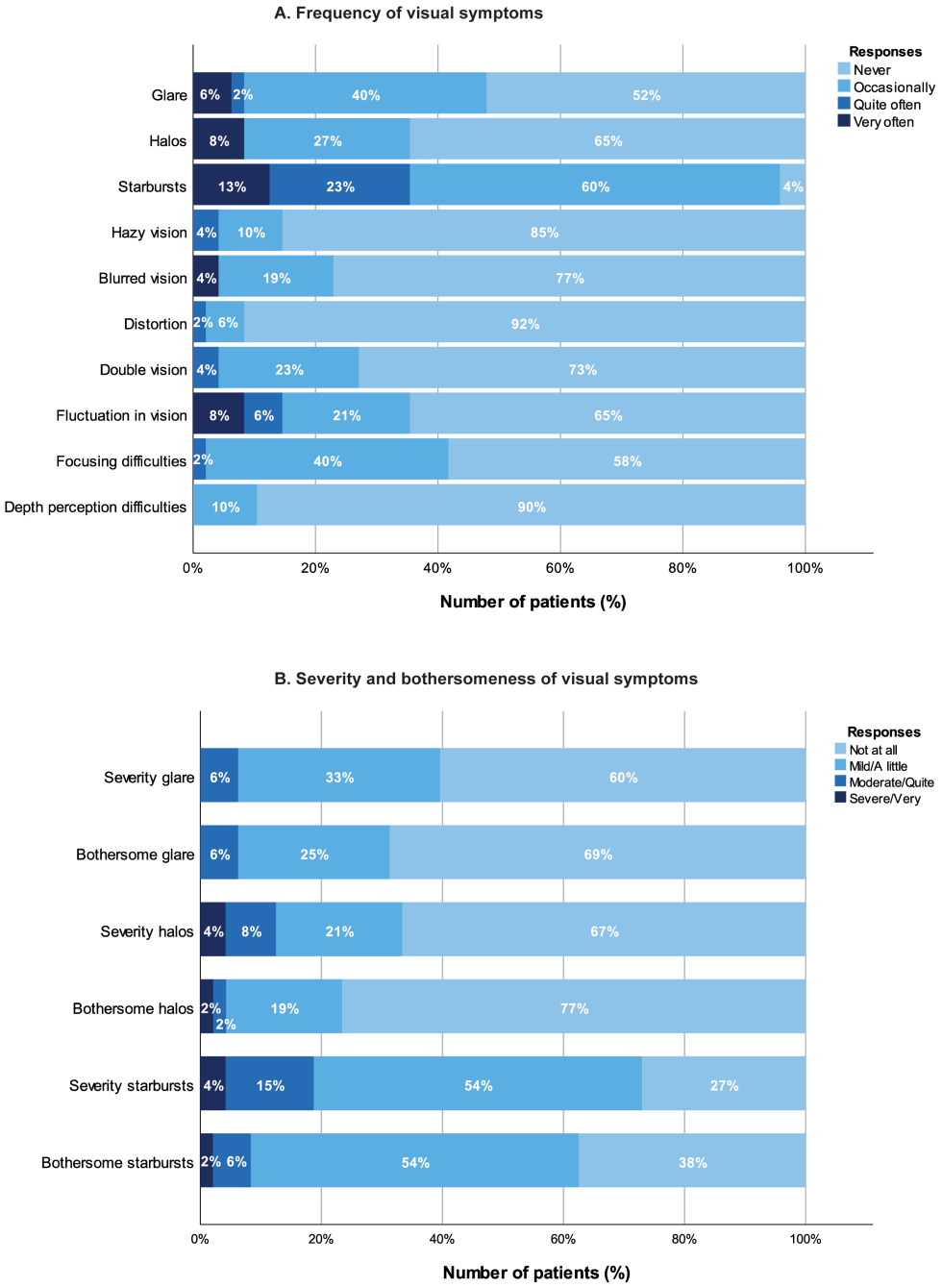


Figure 4.4. Outcomes Quality of Vision (QoV) questionnaire at six months postoperatively (n=48), including A. The frequency of visual symptoms and B. The severity and bothersomeness of the visual symptoms.

Spectacle independence and patient satisfaction

Six months after surgery, the majority of patients (98%) reported to be quite or very satisfied, rating 3 or 4 on a 4-point Likert scale, respectively. One patient reported little satisfaction with the results due to continued spectacle dependence. All patients were satisfied with their distant vision and intermediate vision, except for one patient who expressed only slight satisfaction with intermediate vision. For near vision, five patients indicated little satisfaction (rating 2 on a 4-point Likert scale), while the majority reported being satisfied. In total, 98% of the patients would choose the same procedure again. Regarding spectacle independence, 83% (n=40) reported never using glasses or contact lenses, 15% (n=7) used them occasionally, and one patient reported to use them very often. Those patients who did require glasses primarily needed them for far and near distances.

Discussion

This multicenter prospective trial is the first study to report on the 6 months postoperative performance and safety after bilateral implantation of the iris-fixated multifocal ArtiPlus pIOL. The results demonstrated that the ArtiPlus pIOL is an effective treatment for correcting presbyopia in adult patients without cataract who seek spectacle independence. The study showed predictable and stable outcomes over the first 6 postoperative months. Safety indices were high and the ECD remained stable throughout this period. Additionally, the majority of patients reported high satisfaction with the results, with 83% of patients achieving full spectacle independence.

Previous studies have demonstrated that the implantation of iris-fixated pIOLs (Artiflex pIOL, Ophtec, Groningen, the Netherlands) is effective and safe to correct patients with myopia with or without myopic astigmatism.[10-15] The ArtiPlus pIOL is the only anterior chamber, iris-fixated presbyopia-correcting pIOL which is currently available. In this study, the mean binocular UDVA, UIVA and UNVA at 6 months were excellent, with values of -0.05 ± 0.09, -0.02 ± 0.07, and 0.02 ± 0.08 logMAR. Although all eyes were targeted for emmetropia, the refractive outcomes were slightly more myopic, with a mean SE of -0.41 ± 0.33 D. This myopic outcome may have contributed to enhanced visual acuity at intermediate and near distances. At 6 months, the efficacy index was 0.99 and the binocular corrected defocus curve showed a mean visual acuity better than 0.2 logMAR across a broad defocus range from +1.0 to -3.50 D. These findings are consistent with the reported visual acuity outcomes for distance and efficacy indices following monofocal

Artiflex pIOL implantations.[13,14,16]

Other currently available presbyopia correcting pIOLs include posterior chamber pIOLs – Implantable Collamer Lenses (ICLs) or Implantable Phakic Contact Lenses (IPCLs). However, only limited and short-term data are reported in the literature. The EVO Viva ICL (STAAR Surgical, Monrovia, California, United States of America), designed to extend depth of focus by 2.0 D, has demonstrated a mean binocular UDVA and CDVA of 0.09 ± 0.09 and 0.02 ± 0.03 logMAR after an average follow-up of 8 months. The corresponding SE is -0.61 ± 0.54 D, with 60% of the eyes achieving a refractive outcome within ± 0.50 D and 87.5% within ± 1.00 D of target. The binocular distance-corrected defocus curve shows a visual acuity ≤0.2 logMAR between +2.0 and -2.0 D of defocus. Additionally, the efficacy and safety indices of this ICL are 0.78 and 0.97, respectively.[17] Another EVO+ Visian ICL (STAAR Surgical, Monrovia, California, United States of America) study with 34 patients, also designed to provide up to 2.0 D of extended depth of focus, demonstrates a 6 months postoperatively binocular UDVA, UIVA, and UNVA of 0.07 ± 0.10, -0.01 ± 0.05, and -0.02 ± 0.08 logMAR, respectively. The binocular distance-corrected defocus curve shows a visual acuity ≤0.2 logMAR between +1.5 and -2.5 D of defocus. The majority of patients (91.2%) report being overall satisfied, while there is also a vision related decrease in quality of life due to glare symptoms.[18] Furthermore, two small studies investigating the presbyopia IPCL (Care Group India, Gujarat, India), available with additions from +1.5 to +4.0 D report a postoperative SE of -0.25 ± 0.25 D at 12 months postoperatively. The binocular uncorrected defocus curve demonstrates a visual acuity ≤0.2 logMAR between +0.5 and -3.5 D of defocus.[19,20] Overall, compared to these other available multifocal pIOLs, the ArtiPlus pIOL showed superior visual acuity results.

In this patient cohort, optical disturbances were commonly reported, with 47.9% of patients experiencing glare, 35.4% experiencing halos, and 95.8% experiencing starbursts; however, only 8.3% found these disturbances to be bothersome. A previous study also reported high rates of optical disturbances related to night vision in patients following Artisan pIOL (Ophtec, Groningen, the Netherlands) implantation, with halos and starbursts occurring in 48.8% and starbursts in 41.7% of cases. Furthermore, the study highlights that glare associated with this pIOL varies under different weather conditions, with prevalence rates of 50.8% on sunny days, 42.6% in snowy weather conditions, and 12.5% in foggy weather.[15] Other studies investigating the Artisan pIOL report lower incidence of halos and glare, ranging between 6.0-8.0%.[21,22] Research involving the Artiflex pIOL reports an incidence of mild to moderate glare of 7.0-13.9%, and of mild halos in 4.3-11.3% during the early postoperative period.[23] Furthermore, a comparative study concludes that there is no significant difference in incidence of halos and glare between

Artisan and Artiflex pIOLs.[24]

Our results demonstrated a higher incidence of starbursts, which were reported by nearly all patients. These discrepancies with the existing literature may be attributed to the fact that multifocal lens designs generally carry a higher risk of optical side effects compared to monofocal lens designs.[25] In this cohort, no association with preoperative pupillary size was found to further explain the high incidence of these optical disturbances, and data regarding aberrometry and stray light have not been collected. Literature suggests that in general complaints of positive dysphotopsia may be a result of insufficient neuroadaptation after IOL implantation.[26,27] In our findings, patients who experienced bothersome starbursts often also reported bothersome halos and glare, which could be a result of an insufficient neuroadaptation at 6 months postoperatively. Further long-term studies are necessary to clarify the extent and mechanisms of these optical side effects in patients with multifocal pIOLs.

Although optical disturbances were reported at relatively high rates, they were bothersome to only a small percentage of patients, with the majority (98%) expressing satisfaction with the results. Only one patient reported little satisfaction, which was attributed to bothersome glare, halos, and starbursts, as well as continued spectacle dependence for distant vision. Overall, the spectacle independence after bilateral ArtiPlus implantation was high at all distances, with 83% of the patients being fully spectacle independent for all ranges of vision.

Over the course of 6 months, the ArtiPlus pIOL showed safe and stable results. However, no conclusions can yet be drawn regarding long-term outcomes. The ECD remained stable during this period, but a longer follow-up period is required to assess the long-term impact on ECD. The mean reported survival time of a pIOL is 10-15 years, with ECD loss and cataract formation being the primary reasons for explantation.[28-31] Studies on long-term ECD loss following Artiflex pIOL implantation report an average ECD loss of 0.98-2.0% each year.[14,16,32] Generally, these monofocal pIOLs are implanted in relatively young, healthy patients. The population of the current study is over 40 years of age, which reduces the long-term risks, as the time to cataract surgery is shorter compared to non-presbyopic patients receiving pIOLs.[3] Despite this, strict long-term follow-up, including annual ECD monitoring, is recommended to detect ECD loss at an early stage.[28,30] Also, further research is necessary to evaluate the additional risk of cataract formation in this population.

Limitations of this study were the small sample size and short follow-up time and therefore additional research is essential to investigate the long-term outcomes of this

novel multifocal pIOL. In conclusion, this study demonstrated that binocular implantation of ArtiPlus pIOLs is a safe and effective approach, providing excellent vision across all distances six months postoperatively. This novel pIOL design enabled presbyopic patients to achieve spectacle independence, with high overall satisfaction and an acceptable level of bothersome optical disturbances.

What was known

- Implantation of foldable iris-fixated phakic intraocular lenses (pIOLs) has been proven safe and effective for myopia correction, with or without myopic astigmatism.
- Presbyopia correction remains a significant challenge in refractive surgery, with both cornea-and lens-based techniques available. No single method is universally superior due to patient-specific factors.

What this paper adds

- The novel multifocal iris-fixated pIOL (ArtiPlus) effectively corrects presbyopia in middle-aged patients, achieving high spectacle independence and patient satisfaction.
- Optical disturbances were reported but were generally non-bothersome.
- This study demonstrated that the multifocal pIOL yields safe, predictable, and stable outcomes up to six months postoperatively.

Supplements

Supplementary Figure 4.1. Binocular contrast sensitivity outcomes (n=31) at different conditions, including (A) photopic conditions without glare, (B) photopic conditions with glare, (C) mesopic conditions without glare, and (D) mesopic conditions with glare.

Supplementary Material 4.1. Selection criteria.

Inclusion criteria

- Presbyopic adult
- Potential for binocular vision
- Subject wishes to be spectacle independent for near and far vision
- Refractive error that can be corrected with correction at PIOL plane from +2.0 to -15.0 D
- Subject requiring a presbyopic correction
- Patients with reading glasses of minimum +1 D.
- Stable refraction (± 0.75 D), as expressed by manifest refraction spherical equivalent (MRSE) for a minimum of 12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history
- Expected best corrected visual acuity of 0.2 logMAR (0.63 Snellen decimal) or better after lens implantation
- Current contact lens wearer should demonstrate a stable refraction (± 0.5 D), expressed as subjective refraction spherical equivalent, on two consecutive examination dates performed at least 7 days apart. Before the first refraction, the contact lens wearer should not have worn lenses for at least 2 weeks in case of rigid and toric contact lenses, or 3 days for spherical soft contact lenses.
- Any subject, who is expected to have a residual postoperative cylindrical refractive error of below 0.75 D
- Ability to give informed consent

Availability, willingness and sufficient cognitive awareness and physical ability to comply with examination procedures throughout the entire duration of the study

Exclusion criteria

- Preoperative ocular or systemic condition or medication use that would be expected to present undue risk to the subject, that can predispose for future complications or confound the outcome(s) of the study.
- Previous ocular surgery which might affect the outcome of the study
- Concurrent participation or participation during the last 30 days in another drug or device investigation
- Secondary surgical procedure planned during the first 6 months of the study (e.g. laser treatment to correct astigmatism)
- Amblyopia
- Preoperative anterior chamber depth measurement of below 3.0 mm for subjects < 40 years old and 2.8 mm for subjects > 40 years old. Anterior chamber depth is being measured from corneal endothelium to the anterior pole of the crystalline lens. This will result in a critical distance between PIOL and endothelium of 1.5 mm or more as simulated with anterior

segment imaging.

- White-to-white smaller than 10.5 mm
- Subjects not meeting the age specific minimum preoperative endothelial cell density as defined below:

31 to 35 years of age	2400 cells/mm^2;
36 to 45 years of age	2200 cells/mm^2;
> 45 years of age	2000 cells/mm^2

- Corneas with high rates of polymegethism (a coefficient of variation over 0.40) and pleomorphism (the presence of less than 50% hexagonal cells).
- Abnormal iris (e.g. convex, bulging or volcano shaped iris)
- Crystalline lens rise of 600 µm or more
- Abnormal cornea (keratoconus, opaque cornea, corneal scars, post corneal transplant, corneal dystrophy, or other)
- Ocular surface conditions which might influence the quality of vision and affect the outcome of the study
- Abnormal pupil (e.g. nonreactive, fixed)
- Ectopic pupil
- Pupil in photopic light conditions smaller than 2.6 mm
- Pupil in scotopic light conditions greater than 7.0 mm
- High preoperative intraocular pressure (>21 mmHg)
- Cataract of any grade
- Glaucoma or family history of glaucoma (dependent on the evaluation of physician)
- Diabetes or diabetic retinopathy
- Acute or chronic inflammation
- Chronic or recurrent uveitis or family history of the same condition
- Retinal detachments or family history of retinal detachments
- Corticosteroid responder
- Pregnant or nursing
- Unstable refraction (≥ 0.5 D of variability in refraction over the last 12 months)
- Aged under 18

Supplementary Material 4.2. Unvalidated questionnaire patient satisfaction.

Artiflex Presbyopic (protocol nr AP01000816)

To be filled out by the researcher:

Investigator _____

Patient ID: _____

Investigator's signature: _____

Date: ☐☐/☐☐/☐☐☐☐
(dd/mm/yyyy)

Instructions:

- Answer the questions below about your opinion on the lenses that were implanted in your eyes
- Please respond based on how you feel now
- Be honest, there are no right or wrong answers
- Please place a cross in the checkbox next your answer

Answer the following questions:

1. How satisfied are you with the overall outcome of the procedure?

☐	Not at all
☐	A little
☐	Quite
☐	Very

2. How satisfied are you with your current *uncorrected* vision (without glasses or contact lenses)?

☐	Not at all
☐	A little
☐	Quite
☐	Very

3. How satisfied are you with your near vision (reading distance, approximately 40cm)?

☐	Not at all
☐	A little
☐	Quite
☐	Very

4. How satisfied are you with your intermediate vision (working with a computer, watching TV)?

	Not at all
	A little
	Quite
	Very

5. How satisfied are your far vision (6 meters away and further)?

	Not at all
	A little
	Quite
	Very

6. Did you achieve the quality of vision you expected?

	No
	Maybe
	Quite surely
	Definitely

7. Was taking this lens a good choice?

	Not at all
	A little
	Quite
	Very

8. With your current experience, would you do the procedure again?

	No
	Maybe
	Quite surely
	Definitely

9. Would you recommend implantation of this lens to other people?

	No
	Maybe
	Quite surely
	Definitely

10. How often do you still use glasses or contact lenses?

	Never
	Occasionally

	Quite often
	Very often

11. In case you wear glasses / contact lenses, for which distance is this?

	Not applicable
	Near
	Intermediate
	Far

Thank you for answering this questionnaire!

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CHAPTER 5

Association of Intraocular Lens Tilt and Decentration With Visual Acuity Using SS-OCT-Based Analysis

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Abstract

Purpose: To evaluate the association of postoperative IOL tilt and decentration and corrected distance visual acuity (CDVA) by performing analyses using IOLMaster700 data and custom-developed software.

Setting: University Eye Clinic Maastricht, Maastricht University Medical Center, Maastricht, The Netherlands.

Methods: This case series included patients after cataract surgery who underwent SS-OCT scans using the IOLMaster700 with custom-developed software for tilt and decentration analyses. The outcomes based on our custom-developed software were conducted along the pupillary axis (PA) and corneal topographic axis (CTA). Associations between tilt, decentration and CDVA were evaluated.

Results: A total of 168 eyes (168 patients) were analyzed. The maximum observed IOL tilt was 9.54° along the CTA and 3.69° along the PA. Maximum decentration reached 2.22 mm (CTA) and 2.17 mm (PA). Mean tilt was 1.21 ± 0.69° (PA) and 4.87 ± 1.52° (CTA), while mean decentration was 0.27 ± 0.25 mm (PA) and 0.27 ± 0.26 mm (CTA). Regression analyses showed no statistically significant associations between tilt or decentration and CDVA, irrespective of the reference axis used. For tilt along the PA, the regression coefficient (B) was 0.004 (95%CI -0.011, 0.020; p=0.592), for tilt along the CTA, B was -0.006 (95%CI -0.013, 0.001; p=0.082). For decentration, B was 0.012 (95%CI -0.020, 0.044; p=0.455) and 0.002 (SE=0.018, 95%CI -0.034, 0.037; p=0.925) along the PA and CTA, respectively.

Conclusion: In this cohort, IOL tilt and decentration were generally small, with no detectable association with CDVA. The findings emphasize that different assessment methods should not be used interchangeably, and potential effects cannot be excluded given the limited sample and range of values.

Introduction

Intraocular lens (IOL) tilt and decentration are significant risk factors for suboptimal visual acuity outcomes after cataract surgery in healthy eyes.[1] Tilt refers to the angle between the IOL plane and a reference axis, while decentration indicates the distance between them.[2,3] Commonly reported tilt and decentration outcomes, ranging from 2-3^0 and 0.2-0.3 mm, often go unnoticed by patients.[1] Research suggests that tilt exceeding 5-7^0 or decentration over 0.4-0.5 mm are clinically significant, as they can induce optical aberrations that adversely affect IOL performance.[4-8] However, most of these thresholds are derived from model analyses, and real-world tolerances may vary depending on IOL design.[5-8] Certain designs, such as toric and multifocal IOLs (mIOLs) appear more susceptible to tilt and decentration, which can result in less predictable astigmatism outcomes and altered light distributions between focal points.[9-13] Despite the established clinical significance of tilt and decentration, the exact impact on visual acuity remains controversial in the literature.[1,12,14,15]

Accurately measuring IOL tilt and decentration postoperatively is challenging due to the lack of a universal reference axis. During cataract surgery, the IOL is usually centered by aligning the IOL with the patient's visual axis using the Purkinje reflex. The visual axis is defined as the axis which connects the fixation point with the fovea through the nodal points of the eye, while the optical axis connects the three Purkinje images. However, for postoperative assessment of IOL tilt and decentration, devices such as the IOLMaster700 (Carl Zeiss Meditec, Jena, Germany) that utilize Swept-Source Optical Coherence Tomography (SS-OCT) rely on alternative reference axes, as they cannot precisely determine the visual axis.[16,17] This absence of a universal reference axis has led to the use of different axes in tilt and decentration analyses, raising concerns regarding the comparability of results across studies. **Figure 5.1** shows the axes which are commonly used in practice.[1,15,16,18] The pupillary axis (PA) extends from the corneal surface through the pupillary center, and the corneal topographic axis (CTA) is a perpendicular line through the fixation point that intersects the anterior corneal surface at the corneal vertex.[19]

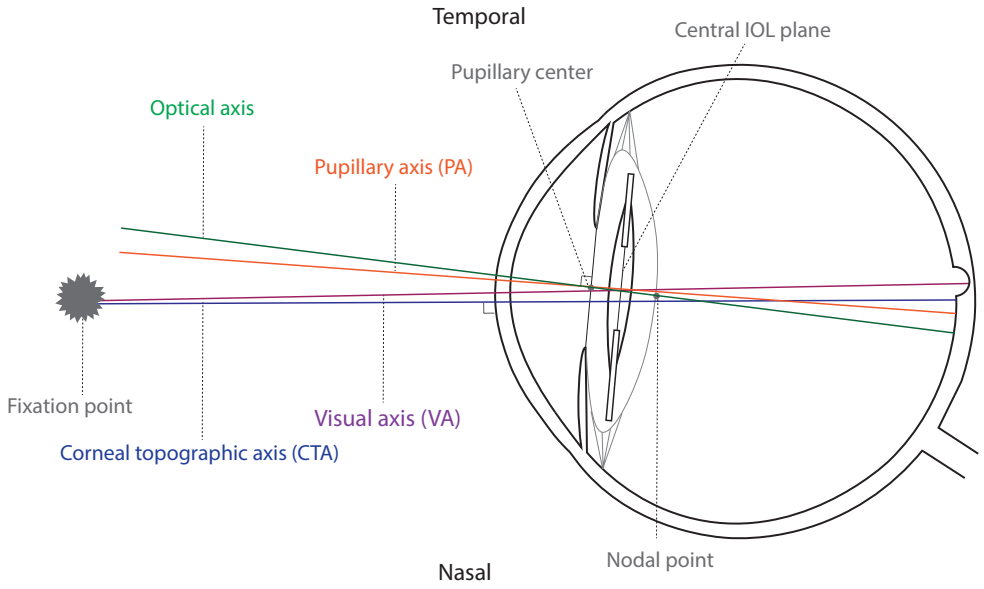

Figure 5.1. Schematic overview of different ocular reference axes, including the optical axis (green), pupillary axis (orange), corneal topographic axis (blue), and visual axis (purple). Angle alpha (α) is defined as the angle between the optical and visual axis. Angle kappa (κ) is defined as the angle between the pupillary and visual axis.

CTA=corneal topographic axis; PA=pupillary axis; VA=visual axis

This study aims to evaluate the association between IOL tilt and decentration and corrected distance visual acuity (CDVA), using IOLMaster700 data analyzed with custom-developed software. These analyses are conducted along different reference axes to assess their clinical implications. Furthermore, the study offers insight into the range and potential clinical thresholds of postoperative IOL tilt and decentration observed in routine cataract surgery.

Methods

This is a single-center validation and descriptive study in the University Eye Clinic Maastricht of the Maastricht University Medical Centre (MUMC+), the Netherlands. From December 2021 until April 2023 data was collected from patients who underwent cataract surgery on the right eye. The study was approved by the local medical ethics committee and executed in accordance with the principles of the Helsinki Declaration.

Data collection

Patients were included if they were ≥18 years and had finished their last postoperative visit after cataract surgery. Exclusion criteria encompassed sight-threatening comorbidities, cornea opacities, conditions that hindered the patient's ability to focus on the fixation target during the measurements, and poor image quality affecting tilt and decentration analyses. The following variables were collected from electronic medical records: demographics, medical history, surgery data, relevant biometry values, visual acuities, refraction, and IOL design. All eyes included in the study underwent postoperative undilated SS-OCT imaging using the IOLMaster700 with fixation tracked through the device's visualization of the fovea centralis. Consecutive scans were captured from six different angles (0°, 30°, 60°, 90°, 120° and 150°). CDVA was assessed using either a Snellen chart or an Early Treatment Diabetic Retinopathy Study (ETDRS) chart at 4 meters. The last correctly identified line on the chart was recorded, continuing until no further optotypes could be discerned.

Custom-developed software for tilt and decentration analyses

Lens tilt and decentration analyses were performed by custom-developed software using MATLAB (Version 2021b, The Mathworks, Natick, United States of America). Prior to analysis, images were cropped while retaining anterior segment data, underwent noise removal, applying non-local mean denoising, and then underwent sharpening and contrast enhancements.[20] Binary segmentation techniques were employed to identify the cornea, iris, and lens.

To ensure transparency and reproducibility, all data preparation steps were implemented using standardized procedures embedded within the MATLAB code. A detailed description of the software workflow, including data preparation and image processing, is provided in the software manual in **Supplementary Material 5.1.** For a 3D-reconstruction of the IOL, the pupillary center was determined in the six different angles, using the upper and lower halves of the iris in the images. Parabolas were then fitted along the anterior and posterior lens surfaces, defined by the formula: $a(x - x_0)^2 + c$. . To achieve optimal fitting for the IOL thickness, multiple weighted parabolas were utilized and incorporated into a minimized cost function. The parabola with parameter c represented the most optimal fit and carried the highest weight. Any deviation to the left (c-1 and so on) augmented the score, indicating a poorer fit, while deviations to the right (c+1 and so on) diminished the score, albeit to a lesser extent than the original parabola due to the assigned weight. While toric IOLs deviate from a perfect parabolic surface, this approximation was used to

determine lens positioning (tilt and decentration) rather than to capture astigmatic optics. Any systematic error introduced by this simplification is expected to be smaller than the known measurement variability of SS-OCT devices and below thresholds considered clinically relevant.

The analysis of lens tilt entailed the calculation of connecting lines between the parabola intersections for each angle-slice. A central plane was then constructed employing 100 data points for each line, and the normal vector of this plane, in comparison to the reference axis, determined the lens tilt. To assess lens decentration, the center of the lens was used, presuming it to be its thickest point. The thickness, defined as the distance between the anterior and posterior surfaces perpendicular to the line passing through the center of the lens, was calculated at 100 evenly distributed points along this line. A parabola was fitted for each angle in each scan. The thickest point was identified by fitting a paraboloid to these data points using the formula: $a((x - x_0)^2 + (y - y_0)^2) + c$. The thickest point, denoted as (x_0, y_0, c), was then utilized to determine lens decentration by comparing intersections of the reference axis with the central lens plane. The difference in x- and y-coordinates between these intersections and the thickest point delineated the lens' decentration relative to the reference axis. **Figure 5.2** shows an angle-slice, with the corneal and lens surfaces identified using our custom-developed software for tilt and decentration assessment.

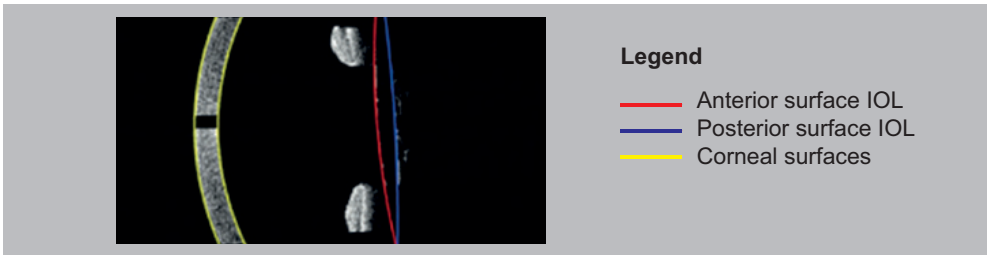

Figure 5.2. Tilt and decentration analysis using our custom-developed software and IOLMaster700 images. This software identifies the corneal surfaces and anterior and posterior lens surface to assess the tilt and decentration.

IOL=intraocular lens

As in clinical practice, tilt and decentration are commonly evaluated with respect to the CTA and PA, and therefore both reference axes are used in our analyses. To ascertain the CTA, the vertex of the anterior cornea was identified using the x_0 and parameters. This axis was established by fitting a paraboloid through the vertex of the anterior corneal parabolas, followed by determination of the tangent plane. The PA was computed by establishing the line connecting the centers of the iris from each slice. Tilt and decentration were then

calculated using the normal vectors of both planes of the reference axes. We assumed that the precise direction of tilt and/or decentration did not affect our results, given the exploratory nature of this study.

Statistical analysis

This study was exploratory in nature, and the sample size was based on all eligible patients who met the inclusion criteria during the study period. No a priori power analysis was performed, as the primary aim was to describe postoperative IOL tilt and decentration in a real-world clinical cohort and to explore potential associations with CDVA.

All statistical analyses were performed using SPSS (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY). Frequencies and descriptive statistics were employed for the analysis of quantitative variables, including mean and standard deviation (SD). Visual acuity outcomes, originally obtained using either Snellen or ETDRS charts, were converted to logMAR units using standard conversion formulas prior to analysis. Associations between IOL tilt or decentration and ocular or surgical factors were first assessed using univariable linear regression. Variables identified as potentially relevant, either clinically or based on a significance level were subsequently included in multivariable linear regression models using the forced entry method. To evaluate the robustness of these models, a backward stepwise regression analysis was also conducted as a sensitivity check.

In case of non-normal distribution, a logarithmic transformation was applied before conducting the regression analyses and model assumptions were carefully assessed. The distribution of residuals was visually inspected using Q-Q plots and histograms to confirm approximate normality. To assess whether the relationship between CDVA and either IOL tilt or decentration differed by IOL type (monofocal or EDOF), additional multivariable regression models were performed including interaction terms (tilt*IOL type or decentration*IOL type), adjusted for age. During model development, lens thickness and IOL power showed high correlation with anterior chamber depth (ACD) and axial length (AL), respectively, and were excluded from the final models to reduce collinearity. The quantification of decentration, and angles alpha and kappa involved the determination of their horizontal and vertical components. The magnitudes of these variables were calculated using the Euclidean distance, which is obtained by taking the square root of the sum of the squares of their respective horizontal and vertical components. A $p \leq 0.05$ was considered statistically significant.

Results

Table 5.1 presents the baseline characteristics of the 168 operated right eyes from 168 patients (82 males, 86 females) included in this study. Patients received either a monofocal intraocular lens (IOL, n=118) or an extended depth-of-focus (EDOF) IOL (n=50). The implanted IOLs included the AcrySof® IQ Monofocal IOL (Alcon, Fort Worth, TX, USA), AcrySof® IQ Vivity IOL (Alcon, Fort Worth, TX, USA), and Acunex® Vario IOL (Teleon Surgical BV, Spankeren, the Netherlands). Both toric and non-toric IOLs were used. Eleven patients underwent an intraocular procedure prior to cataract surgery, with pars plana vitrectomy (PPV) performed in 10 eyes and trabeculectomy in one eye. Six patients underwent cataract surgery combined with either an iStent (Glaukos Corp., Laguna Hills, California, United States of America) implantation for primary open angle glaucoma (n=5) or a PPV for a macular pucker (n=1). Intraoperative complications included three posterior capsular ruptures and one irregular, but continuous curvilinear capsulorhexis, considered relevant factors for post-surgery IOL tilt or decentration.

Table 5.1. Baseline characteristics.

Variable	Mean ± SD	Range
Age (years)	71 ± 11	17; 92
CDVA (logMAR)	0.01 ± 0.07	-0.18; 0.28
SEQ (D)	-0.15 ± 0.62	-3.50; 1.25
Absolute prediction error (D)	0.32 ± 0.30	0.00; 1.63
AL (mm)	24.1 ± 1.5	21.6; 30.2
ACD (mm)	3.16 ± 0.40	2.00; 4.01
WTW (mm)	12.1 ± 0.39	11.1 ± 13.1
Angle alpha (mm)	0.48 ± 0.15	0.10; 1.08
Angle kappa (mm)	0.34 ± 0.16	0.01; 0.92

ACD=anterior chamber depth; AL=axis length; CDVA=corrected distance visual acuity; D=diopter; SD=standard deviation; SEQ=spherical equivalent; WTW=white-to-white

Tilt and decentration along different reference axes

The tilt (n=168) and decentration (n=162) analyses conducted using IOLMaster700 images and our custom-developed software employed different reference axes, including the CTA and PA. Mean tilt outcomes in this cohort along the PA were 1.21 ± 0.69° (range 0.09; 3.69), and along the CTA 4.87 ± 1.52° (range 0.25; 9.54). The decentration outcomes along the PA had a mean value of 0.27 ± 0.25 mm (range 0.02; 2.17), and 0.27 ± 0.26 mm (range 0.02; 2.22) along the CTA.

Associated factors for tilt and decentration

Univariable and multivariable linear regression analyses identified variables associated with tilt and decentration along both reference axes, as shown in **Tables 5.2 and 5.3**. For tilt along the PA, statistically significant associations were found with preoperative angle alpha and combined surgery. For tilt along the CTA, axial length (AL), preoperative angles alpha and kappa, and intraoperative complications emerged as significantly associated factors. Decentration measured along both axes showed a statistically significant association with AL. Additionally, backward stepwise regression, conducted as a sensitivity analysis, confirmed these findings and identified age and intraoperative complications as significantly associated factors with tilt along the PA, complementing those identified in the forced entry analysis.

Table 5.2. Univariable and multivariable linear regression analyses for both tilt and decentration along the pupillary axis.

	Tilt					Decentration				
	Univariable linear regression		Multivariable linear regression			Univariable linear regression		Multivariable linear regression		
Variable	Unstandardized B-coefficient (SE)	p	Unstandardized B-coefficient (SE)	95%CI	p	Unstandardized B-coefficient (SE)	p	Unstandardized B-coefficient (SE)	95%CI	p
Age (year)	0.008 (0.005)	0.113	0.009 (0.005)	-0.001; 0.020	0.087	0.001 (0.003)	0.814	0.003 (0.003)	-0.003; 0.009	0.269
Female sex	0.162 (0.106)	0.128	0.097 (0.110)	-0.120; 0.315	0.377	-0.095 (0.055)	0.086	-0.032 (0.060)	-0.150; 0.086	0.589
AL (mm)	-0.109 (0.035)	0.002	-0.019 (0.046)	-0.109; 0.071	0.684	0.079 (0.018)	<0.001	0.087 (0.026)	0.036; 0.138	<0.001
ACD (mm)	-0.312 (0.133)	0.020	0.002 (0.160)	-0.313; 0.318	0.990	0.176 (0.068)	0.011	0.009 (0.086)	-0.160; 0.178	0.919
WTW (mm)	-0.158 (0.141)	0.263	0.034 (0.151)	-0.266; 0.333	0.825	0.108 (0.072)	0.134	0.010 (0.083)	-0.153; 0.173	0.906
Angle alpha (mm)	1.273 (0.353)	<0.001	1.290 (0.375)	0.549; 2.031	<0.001	-0.466 (0.186)	0.013	-0.138 (0.202)	-0.534; 0.258	0.497
Angle kappa (mm)	0.296 (0.333)	0.408	-0.029 (0.327)	-0.676; 0.618	0.930	-0.300 (0.177)	0.093	-0.164 (0.180)	-0.517; 0.189	0.366
Junior surgeon (yes)	0.136 (0.114)	0.234	0.103 (0.116)	-0.126; 0.333	0.375	0.047 (0.058)	0.419	0.049 (0.062)	-0.073; 0.171	0.432
History of intraocular surgery (yes)	-0.559 (0.211)	0.009	-0.343 (0.237)	-0.811; 0.126	0.150	0.021 (0.111)	0.848	-0.016 (0.125)	-0.261; 0.229	0.901
Underwent combined surgery (yes)	-0.665 (0.283)	0.020	-0.839 (0.295)	-1.422; -0.256	0.005	-0.050 (0.145)	0.732	-0.083 (0.155)	-0.387; 0.221	0.592
Intraoperative complication (yes)	0.557 (0.348)	0.111	0.524 (0.345)	-0.159; 1.206	0.131	0.061 (0.177)	0.732	0.205 (0.182)	-0.152; 0.562	0.263

ACD=anterior chamber depth; AL=axis length; CI=Confidence Interval; SE=Standard Error; WTW=white-to-white

Table 5.3. Univariable and multivariable linear regression analyses for both tilt and decentration along the corneal topographic axis (CTA). Decentration outcomes were log-transformed.

	Tilt					Decentration				
	Univariable linear regression		Multivariable linear regression			Univariable linear regression		Multivariable linear regression		
Variable	Unstandardized B-coefficient (SE)	p	Unstandardized B-coefficient (SE)	95%CI	p	Unstandardized B-coefficient (SE)	p	Unstandardized B-coefficient (SE)	95%CI	p
Age (year)	0.002 (0.011)	0.888	-0.004 (0.009)	-0.022; 0.014	0.722	-0.005 (0.002)	0.025	-0.003 (0.003)	-0.009; 0.003	0.253
Female sex	0.126 (0.235)	0.593	0.003 (0.180)	-0.351; 0.357	0.985	-0.029 (0.051)	0.563	0.003 (0.054)	-0.103; 0.109	0.956
AL (mm)	-0.465 (0.069)	<0.001	-0.358 (0.075)	-0.504; -0.212	<0.001	0.067 (0.016)	<0.001	0.068 (0.023)	0.023; 0.113	0.004
ACD (mm)	-0.792 (0.281)	0.005	0.397 (0.261)	-0.115; 0.909	0.130	0.131 (0.062)	0.036	-0.027 (0.078)	-0.180; 0.126	0.726
WTW (mm)	-0.474 (0.297)	0.113	0.057 (0.247)	-0.427; 0.541	0.817	0.134 (0.064)	0.039	0.043 (0.075)	-0.104; 0.190	0.569
Angle alpha (mm)	6.188 (0.608)	<0.001	5.093 (0.613)	3.890; 6.296	<0.001	-0.368 (0.168)	0.030	-0.144 (0.183)	-0.504; 0.216	0.433
Angle kappa (mm)	2.828 (0.689)	<0.001	1.524 (0.535)	0.476; 2.572	0.005	-0.078 (0.160)	0.625	0.008 (0.163)	-0.312; 0.328	0.962
Junior surgeon (yes)	0.136 (0.244)	0.577	0.078 (0.190)	-0.294; 0.450	0.682	-0.012 (0.053)	0.825	0.027 (0.056)	-0.083; 0.137	0.634
History of intraocular surgery (yes)	-0.144 (0.475)	0.763	0.310 (0.387)	-0.447; 1.067	0.425	0.033 (0.100)	0.741	0.030 (0.114)	-0.193; 0.253	0.795
Underwent combined surgery (yes)	0.717 (0.613)	0.244	-0.083 (0.482)	-1.028; 0.862	0.864	-0.169 (0.131)	0.199	-0.092 (0.141)	-0.369; 0.185	0.512
Intraoperative complication (yes)	1.903 (0.735)	0.010	1.384 (0.564)	0.279; 2.489	0.015	0.005 (0.160)	0.974	0.039 (0.165)	-0.285; 0.363	0.815

ACD=anterior chamber depth; AL=axis length; CI=Confidence Interval; SE=Standard Error; WTW=white-to-white

Association with CDVA

In this cohort, the maximum observed tilt and decentration along the CTA was 9.54° and 2.22 mm, respectively. Along the PA, the maximum values were 3.69° for tilt and 2.17 mm for decentration. Neither tilt nor decentration showed a detectable association with CDVA when adjusted for age, regardless of the reference axis used. For tilt along the PA, the unstandardized regression coefficient (B) was 0.004 (SE=0.008), with a 95% confidence interval (CI) of –0.011 to 0.020 (p=0.592). For tilt along the CTA, B was –0.006 (SE=0.004), CI –0.013 to 0.001 (p=0.082). Regarding decentration, the B-coefficient for the PA axis was 0.012 (SE=0.016), CI –0.020 to 0.044 (p=0.455), and for the CTA axis, 0.002 (SE=0.018), CI –0.034 to 0.037 (p=0.925).

To evaluate whether the relationship between tilt or decentration and CDVA differed by IOL type, a second multivariable model was constructed including IOL type and the corresponding interaction terms. None of the interaction terms reached statistical significance: for tilt along the PA, B =–0.005 (SE=0.018), CI –0.039 to 0.030 (p=0.790); for tilt along the CTA, B=0.003 (SE=0.008), CI –0.069 to 0.092 (p=0.717); for decentration along the PA, B = –0.028 (SE=0.035), CI –0.098 to 0.042 (p=0.430); and for decentration along the CTA, B=–0.052 (SE=0.040), CI –0.131 to 0.028 (p=0.201). These findings indicate no significant effect modification by IOL type on the relationship between either tilt or decentration and CDVA.

Discussion

This study evaluated the association between postoperative IOL tilt and decentration and CDVA in patients who underwent cataract surgery, providing valuable insights into their clinical implications. Using IOLMaster700 data and custom-developed software, our findings suggest that within the limited ranges of tilt and decentration observed, no detectable association with CDVA was found. The tilt values reached a maximum of 3.7° along the PA and 9.5° along the CTA, while mean decentration was 0.27 mm on both axes. In view of reported thresholds suggesting that tilt exceeding 5–7° or decentration beyond 0.4–0.5 mm can adversely affect visual outcomes, it is notable that the majority of eyes in our cohort remained below these levels.[4-8] This restricted range likely explains why no significant association with CDVA was detected in our study. Regression coefficients were close to zero, and the confidence intervals suggest that within the observed ranges, any potential association with CDVA is unlikely to be clinically meaningful. As the study was not powered for equivalence testing, possible effects in cases with larger tilt or decentration

cannot be excluded.

Over the past decades, various methods for analyzing tilt and decentration have been studied, including Purkinje imaging, Scheimpflug imaging, ultrasound biomicroscopy, and anterior segment OCT (AS-OCT), the latter of which remains to be widely used. Among these, AS-OCT using SS-OCT provides high-resolution imaging and greater repeatability for tilt and decentration measurements compared to older techniques.[21] The IOLMaster700 and CASIA2 (Tomey Corp., Nagoya, Japan) are SS-OCT devices commonly used for such analyses. The IOLMaster700 uses custom software and different reference axes can be applied, whereas the CASIA2 employs built-in software for these analyses with the CTA as reference axis. Previous studies have demonstrated a high level of reproducibility of the CASIA2 for assessment of tilt and decentration, and excellent repeatability for tilt analyses of IOLMaster700 data utilizing custom software, using a similar methodology to our custom-developed software.[22,23] This study is the first to analyze decentration with IOLMaster700 data and custom-developed software. By using a whole-eye scanning device, IOL positioning is assessed with reference to the fovea, with the patient fixating the optical axis during the imaging.[2,24] However, while patient fixation is assumed to enhance measurement accuracy, it does not fully ensure alignment of the reference axis with the visual axis.

In this study, different reference axes were employed for tilt and decentration analyses. Although the PA and CTA are often used, there is uncertainty regarding which method best simulates the visual axis. The PA can easily be located but may vary with pupil shape, whereas the CTA is independent of pupil shape but more complex to determine. Furthermore, the literature indicates that there is tilt and decentration of the crystalline lens with respect to the corneal vertex.[15-17,25,26] Another approach for assessing tilt and decentration is the limbus-to-limbus method, which was not employed in this analysis.[27] Our results showed lower tilt outcomes along the PA compared to the CTA, while similar outcomes for decentration were found for both axes. A study using Scheimpflug imaging observes significant differences along the CTA and PA in tilt magnitude and decentration along the 180-degree meridian, but not along the 90-degree meridian. This discrepancy may be attributed to the nasal displacement of the corneal vertex relative to the pupillary center and may explain the differences in tilt outcomes between the PA and CTA in our study.[15] The similar decentration outcomes, which contradict previous findings, could be attributed to the use of Euclidean distances between horizontal and vertical outcomes in the study.

The literature identifies several variables associated with IOL tilt and decentration, yet the results can be influenced by the use of different devices and reference axes. Most studies

focus on the CASIA2 and the CTA as reference axis. Significant positive associations with tilt have been reported for angles alpha and kappa, and previous PPV, whereas negative associations are reported for AL and ACD.[3,23-25,28-30] For decentration, AL and previous PPV show significant positive associations.[3,25,29,31] One study has also found angles alpha and kappa, as well as age, to be positively associated with decentration.[28]

Our analysis confirmed a significant positive association between angle alpha and IOL tilt along both axes, with other associations varying by reference axis. Combined surgery showed a significant negative association with tilt along the PA, whereas for tilt along the CTA positive associations were found with angle kappa and intraoperative complications, and a negative association with AL. However, as only six patients underwent combined surgery, no definitive conclusion can be drawn. Unlike previous studies, we found no association between previous intraocular surgery and tilt or decentration, possibly due to the small sample size. Intraoperative complications in this cohort, including three posterior capsular ruptures, were significantly associated with tilt along the CTA only. Further investigation with a larger sample size is required to assess these associations. For decentration, our analysis only identified a significant positive association with AL along both axes.

The impact of tilt and decentration on CDVA remains uncertain according to existing literature. One study reports that tilt <4° and decentration <1 mm along the PA do not significantly affect CDVA.[17] Conversely, other studies observes a significant correlation between CDVA, intermediate and near visual acuity and decentration towards the temporal and inferior quadrants when measured along the CTA.[15,32,33] In our cohort, tilt and decentration were not significantly associated with CDVA, with observed tilt values reaching up to 3.7° along the PA, and 9.5° along the CTA, and mean decentration outcomes of 0.27 mm along both axes. Even with a maximum decentration exceeding 2.00 mm, one patient still achieved a CDVA of 0.02 logMAR. These findings challenge the existing thresholds for clinically significant tilt and decentration, underlining their dependence on methods and reference axis used for analysis.

When interpreting our results, it is important to note that this cohort primarily consisted of patients with aspheric monofocal IOL designs, along with a group of non-diffractive EDOF IOLs. The literature indicates that the effects of tilt and decentration vary by IOL design.[1,5,6] Studies suggest that correct IOL positioning is particularly important for aspheric, toric, and multifocal IOLs, although reported findings are inconsistent.[6,34,35] A cohort study using adaptive optics has simulated the impact of tilt and decentration on different monofocal IOL designs, reporting a mean CDVA difference of 0.11 logMAR between centered and 0.2 mm decentered IOLs, and a 0.14 logMAR difference for 2° tilt.

Aspheric IOL designs are found to be more sensitive to tilt and decentration with a limited compensating effect on spherical aberrations.[36] In contrast, a Scheimpflug imaging study finds no significant correlation between CDVA and IOL tilt or decentration in patients with monofocal or refractive mIOLs, with mean tilt ranging between 1.09 and 1.44°, and decentration ranging between 0.14 and 0.19 mm, respectively. However, the reference axis used in this study has not been specified.[14] Furthermore, a laboratory evaluation reports significant reductions in modulation transfer function (MTF) for monofocal IOLs only when decentrations exceed 0.75 mm.[37] Additionally, an optical bench study highlights the design-dependent variability of tilt and decentration effects on EDOF IOLs. The Tecnis Eyhance IOL (Johnson & Johnson Vision, Santa Ana, United States of America) shows a high sensitivity to tilt and decentration, while the Vivity (Alcon Laboratories Inc., Forth Worth, United States of America) and LuxSmart (Bausch & Lomb GmbH, Berlin Germany) IOL exhibit greater tolerance to tilt but are notably affected by decentration. The RayOne EMV (Rayner, Worthing, United Kingdom) demonstrates the highest robustness to tilt and decentration for small apertures but deteriorated with larger apertures, with decentration generally having a greater impact than tilt.[38] Another study suggests that a infero-temporal centration relative to the CTA in trifocal IOLs reduces the occurrence of photic phenomena, as measured by the Light Distortion Index.[39] These results emphasize the significant variability in sensitivity to tilt and decentration, driven by differences in IOL design and technology.

This study has several limitations, including a narrow range of tilt and decentration outcomes and a limited selection of IOL designs within the cohort. Orientation-dependent analyses were not conducted due to data constraints. However, we expect that such analyses would not have resulted in statistically significant differences in relation to CDVA. Patients unable to maintain proper fixation were excluded, as compromised fixation could diminish OCT scan quality, though pronounced tilt might itself impair fixation and contribute to selection bias. Additionally, heterogeneity in devices and reference axes used in previous studies complicates direct comparisons with our findings. While these limitations reduce the generalizability of our study, they emphasize the need for standardization of methodologies.

The absence of a statistically significant association between IOL tilt or decentration and CDVA in this cohort may be clinically reassuring, particularly for patients receiving standard aspheric or non-diffractive EDOF lenses. These findings suggest that, within the observed ranges of tilt and decentration, visual outcomes remain stable in an average-risk population. Given that the IOLMaster700 is widely used in clinical practice, our results provide relevant reference data for routine postoperative assessment. However,

the generalizability of these findings is limited, particularly in relation to diffractive multifocal or other premium IOL designs, which may respond differently to variations in IOL positioning. Future studies in more diverse cohorts and lens types are therefore warranted.

In conclusion, tilt and decentration analyses conducted along both the PA and CTA revealed differences in outcomes based on the reference axis applied, which underscore the importance of considering specific devices and reference axes when comparing tilt and decentration outcomes, as the methods of analysis cannot be used interchangeably. Key variables associated with tilt varied depending on the reference axis, whereas decentration consistently demonstrated a positive association with AL along both axes. In this cohort of patients predominantly implanted with monofocal and non-diffractive EDOF lenses, no statistically significant association was found between tilt and decentration and CDVA. These findings may serve as a practical reference for evaluating postoperative IOL position in routine clinical practice.

What was known

- Intraocular lens (IOL) tilt and decentration are generally seen as risk factors for suboptimal visual acuity following cataract surgery.
- Accurately measuring IOL tilt and decentration is challenging due to the lack of a universal reference axis**.**

What this paper adds

- Using SS-OCT and custom software, IOL tilt and decentration were generally small, with no detectable association with corrected distance visual acuity (CDVA) in this cohort.
- IOL tilt and decentration analyses along the pupillary axis (PA) and corneal topographic axis (CTA) showed outcome differences, highlighting different methods of analyses cannot be used interchangeably.

Supplements

The supplementary material can be found using the QR code:

Supplementary Material 5.1. User Manual: Custom Software for Tilt and Decentration Analysis.

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CHAPTER 6

Dissatisfaction after Implantation of EDOF Intraocular Lenses

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Abstract

Purpose: To evaluate the symptoms, etiology, and treatment of patient dissatisfaction after extended depth-of-focus (EDOF) intraocular lens (IOL) implantation.

Setting: University Eye Clinic, Maastricht University Medical Center, the Netherlands.

Design: Retrospective case series.

Methods: For this study, all medical records of patients who received an EDOF IOL from July 2020 to July 2022 were reviewed. Patients were included if they had reported any dissatisfaction after surgery. The main outcome parameters were reasons for dissatisfaction (subjective complaints) and the presumed etiology of the complaints.

Results: Of 202 patients (354 eyes) who underwent EDOF IOL implantation, 83 eyes (22.8%) of 52 dissatisfied patients were included. Blurred vision was the predominant complaint, reported in 78 eyes (94%). Photic phenomena were reported in 21 eyes (25.3%), with 16 eyes (76.2%) experiencing coexisting blurred vision. The major etiologies for dissatisfaction in this cohort were residual ametropia (51.8%), dry eye disease (26.5%), and posterior capsular opacification (12.0%). Treatments were administered to 85.5% of the eyes, including interventions such as artificial tears, spectacles, or refractive surgery enhancement. A small number of patients (n=12; 5.9%) remained dissatisfied despite intervention.

Conclusions: Based on this real-world data study, dissatisfaction after EDOF IOL implantation can be effectively identified and treated in most cases.

Introduction

As the use of digital devices increases, intermediate vision is becoming more and more important in daily life. In cataract surgery, the extended depth-of-focus (EDOF) intraocular lens (IOL) has emerged as a popular option for addressing intermediate vision.[1] EDOF IOLs provide a continuous range of focus from distant to intermediate vision, thereby offering distinct advantages over both monofocal and multifocal IOLs (mIOLs). One commonly used EDOF IOL is the AcrySof IQ Vivity IOL (Alcon Laboratories, Inc.). Patients report high satisfaction with this IOL, providing excellent distance and intermediate vision, and functional near visual acuity. The visual disturbance profile seems comparable with a monofocal IOL, and no significant difference in contrast sensitivity has been reported.[2-5] Applying a mini-monovision approach increases spectacle independence by expanding the range of vision.[6-8] Despite the high overall satisfaction, a number of patients can be dissatisfied postoperatively, which can arise from various factors.[9] In this retrospective study, our aim was to evaluate and classify the symptoms and etiology of dissatisfaction in patients after EDOF IOL implantation.

Methods

This single-center retrospective study evaluated real-world data of dissatisfied patients after EDOF IOL implantation between July 2020 and July 2022 at the University Eye Clinic of the Maastricht University Medical Center, The Netherlands. This study adhered to the tenets of the Declaration of Helsinki. Electronic medical records were reviewed regarding patient dissatisfaction with a low threshold for patient inclusion, including even minor levels of dissatisfaction.

Our routine postoperative ophthalmologic investigations included slit lamp and funduscopic examination, corneal topography and tomography (Pentacam HR, Oculus Optikgeräte GmbH), and optical biometry using the IOLMaster700 (Carl Zeiss Meditec AG); visual acuity was assessed using Snellen charts for distance and Early Treatment of Diabetic Retinopathy Study charts for intermediate and near visual acuity. The mean visual acuity values and SDs were calculated using logMAR data. Postoperative contrast sensitivity (CSV-1000, Vector Vision) and aberrometry assessments (KR-1W Wavefront analyser, Topcon Corp.) were only performed on indication, and therefore not included in this analysis.

All patients of this cohort received the AcrySof IQ Vivity EDOF IOL, providing spectacle

independence for distance to intermediate vision. According to the manufacturer, this single-piece foldable nondiffractive EDOF IOL features a biconvex optic with an aspheric anterior wavefront-shaping design and a spherical posterior surface. The IOL is made of a hydrophobic acrylate–methacrylate copolymer, with an optic diameter of 6.0 mm and a refractive index of 1.55. The spherical power ranges from +10.0 to +30.0 diopters (D) in 0.5 D increments.

The IOL calculations were performed using optical biometry data (IOLMaster700) and the Barrett Universal-II formula. In cases with a history of corneal refractive surgery, the Barrett True-K formula was applied. The target refraction was aimed for either bilateral emmetropia or mini-monovision, with the dominant eye is targeted for emmetropia and the non-dominant eye for residual myopia between −0.25 and −0.75 D, aiming for a difference of 0.50 D between the two eyes. Eye dominance was tested using the Miles Test. Toric IOLs were used if there was an expected postoperative astigmatism >1.0 D. The Verion Image Guided System (Alcon Laboratories, Inc.) was used for toric axis alignment during surgery. All surgeries were performed by three experienced surgeons using a conventional phacoemulsification or femtosecond laser-assisted cataract surgery technique. A standard superior clear corneal incision of 2.2 mm was used. In case of bilateral implantation of the Vivity IOL, either immediate sequential bilateral cataract surgery or delayed sequential bilateral cataract surgery was performed.[10]

The electronic medical records of all included patients were systematically reviewed to classify the (objective) findings in different etiology groups. Residual ametropia as cause of dissatisfaction was based on subjective refractive assessments. Patients with a reduced tear break-up time, positive Schirmer test (<5 mm in 5 minutes), and/or punctate keratopathy at least one month postoperatively were categorized as having dry eye disease (DED). Patients solely reporting subjective complaints of DED were not categorized as such. If a patient had posterior capsule opacification (PCO) or vitreous floaters, this was confirmed during slit lamp examination, and the presence of a maculopathy was confirmed using optical coherence tomography. Waxy vision syndrome was defined as dissatisfaction related to the quality of vision in the absence of a residual refractive error, PCO, or another ocular comorbidity. This syndrome is primarily caused by reduced contrast sensitivity.[11] If patients described resolution of symptoms on correcting the intended ametropia to emmetropia using trial frames or contact lenses, this was classified as mini-monovision intolerance. The complaint of binocular vision dysfunction was confirmed during orthoptic examination. Finally, if patients were dissatisfied without any objective findings and despite meeting the target refraction and achieving visual acuity and quality outcomes consistent with the characteristics of the EDOF IOL, this was

classified as an expectation mismatch.

Statistical analysis

All data were analyzed using SPSS (v. 28, IBM Corp.). Descriptive statistics and frequencies were used to summarize the quantitative and qualitative variables, respectively. Vector analyses were used to evaluate the astigmatism outcomes. In addition, supplementary analysis by artificial intelligence, including Random Forest, Logistic Regression, and ClassiNet2 Rule Induction models, was conducted on preoperative Scheimpflug topography using Orange (v. 3.36.1, Bioinformatics Lab).[12] These analyses aimed to identify predictive patterns associated with patient satisfaction or dissatisfaction after EDOF IOL implantation. The dataset included all data obtained from preoperative Scheimpflug topography, comprising both objective parameters directly measured by the device and data derived from extrapolation or calculation by algorithms within the Scheimpflug topography software. A p-value ≤0.05 was considered statistically significant.

Results

For this study, all 202 patients (364 eyes) who received an EDOF IOL between 2020 and 2022 were screened for dissatisfaction. A total of 52 patients (83 eyes) were included and evaluated because of expressed dissatisfaction with the results. Patient demographics at presentation are given in **Table 6.1**. If a patient underwent bilateral EDOF IOL implantation but had complaints limited to one eye, the analysis solely focused on the affected eye. Overall, 53 eyes (64%) received a non-toric and 30 eyes (36%) received a toric Vivity IOL. A total of 43 patients underwent bilateral IOL implantation, targeting for mini-monovision as the standard approach, while 9 patients had unilateral EDOF IOL implantation targeted for emmetropia. In total, 4 patients underwent refractive lens exchange. Eyes implanted with a phakic IOL (pIOL) underwent a combination procedure of pIOL explantation and cataract surgery followed by EDOF implantation.

Table 6.1 presents the refractive and visual outcomes at the time of presentation. Binocular visual acuities were only included in case of bilateral complaints. Furthermore, visual and refractive outcomes were separately analyzed for both the dominant (n=43) and non-dominant (n=40) eyes. Dominant eyes exhibited a mean sphere of 0.03 ± 0.54 D, cylinder centroid of −0.11 ± 0.79 D, and spherical equivalent (SE) of −0.29 ± 0.48 D, with UDVA and CDVA of 0.17 ± 0.14 and 0.02 ± 0.08 logMAR, respectively. Nondominant eyes showed a mean sphere of −0.22 ± 0.59 D, cylinder centroid of −0.11 ± 0.85D, SE of −0.57

± 0.52 D, with an UDVA and CDVA of respectively, 0.17 ± 0.12 and 0.01 ± 0.06 logMAR. The cumulative percentage of eyes having a postoperative prediction error (PE) within 0.50 D and 1.0 D was 76% and 94%, respectively. In addition, vector analyses were performed by comparing the preoperative and postoperative Scheimpflug topography scans. The mean surgically induced astigmatism (SIA) had a centroid of 0.21 ± 0.38 D for the dominant eyes and 0.09 ± 0.79 D for the non-dominant eyes, respectively.

Table 6.1. Baseline characteristics at first presentation of complaints.

Demographics (n=52) Mean ± SD, [Range]	
Mean age (years)	63 ± 11 [18; 79]
Gender (M/F)	18/34
Time from surgery to presentation (days)	67 ± 81 [6; 400]
Complaints, n (%)	
Bilateral	31 (59.6%)
Unilateral, unilateral IOL	9 (17.3%)
Unilateral, bilateral IOL	12 (23.0%)
Refractive and visual outcomes (monocular n=83, binocular n=30)	
Manifest refraction (D)	
Sphere	-0.09 ± 0.58 [-1.50; 1.00]
Cylinder	-0.07 ± 0.81 [-1.50; 0.00]
Spherical equivalent	-0.42 ± 0.51 [-1.88; 0.75]
Monocular UDVA (logMAR)	0.17 ± 0.13 [-0.07; 0.52]
Monocular CDVA (logMAR)	0.02 ± 0.07 [-0.09; 0.22]
Binocular UIVA (logMAR)	0.14 ± 0.17 [-0.10; 0.40]
Binocular UNVA (logMAR)	0.20 ± 0.15 [-0.10; 0.40]
Eye characteristics (n=83)	
AL (mm)	24.3 ± 1.6 [21.6; 29.5]
ACD (mm)	3.16 ± 0.34 [2.32; 4.18]
Concomitant ocular comorbidities, n (%)	
Previous corneal laser surgery	8 eyes (9.6%)
Previous phakic IOL implantation	5 eyes (6.0%)
Macular atrophy	4 eyes (4.8%)
Epiretinal membrane	1 eye (1.2%)
Fuchs endothelial dystrophy	1 eye (1.2%)
Amblyopia	1 eye (1.2%)
Previous retinal detachment	1 eye (1.2%)

Cylindrical outcomes were calculated using a vector analysis.

ACD=anterior chamber depth; AL=axial length; CDVA=corrected distance visual acuity; D=diopter; IOL=intraocular lens; SD=standard deviation; UDVA=uncorrected distance visual acuity; UIVA=uncorrected intermediate visual acuity; UDVA=uncorrected near visual acuity

Tables 6.2 and 6.3 summarize the presenting symptoms and the etiologies attributed to each eye, respectively. Patients primarily expressed dissatisfaction with blurred vision, particularly affecting distance vision. These complaints were mainly ascribed to residual ametropia (39 eyes), DED (17 eyes), and PCO (10 eyes). The 28 patients (45 eyes) with ametropia-related complaints exhibited a mean sphere of −0.18 ± 0.66 D, a cylinder centroid of −0.12 ± 0.94 D, and a SE of −0.60 ± 0.58 D.

Table 6.2. Presenting symptoms.

Presenting symptom (n=83 eyes)	Eyes, n (%)
Blurred vision	62 (74.7)
Distance only	38 (45.8)
All distances	9 (10.8)
Distance and near	5 (6.0)
Distance and intermediate	4 (4.8)
Intermediate and near	4 (4.8)
Near only	2 (2.4)
Photic phenomena	5 (6.0)
Blurred vision and photic phenomena	16 (19.2)

Table 6.3. Etiologies of dissatisfaction and satisfaction rate after treatment.

Etiology (n=83 eyes)	Eyes, n (%)
Residual ametropia	45 (54.2)
Dry Eye Disease	22 (26.5)
PCO	10 (12.0)
Expectation mismatch	8 (9.6)
Other findings	25 (30.1)
- Waxy vision syndrome	8 (9.6)
- Maculopathies (incl CME)	5 (6.0)
- No identified cause	5 (6.0)
- Vitreous floaters	2 (2.4)
- Minimonovision intolerance	2 (2.4)
- Decompensated exophoria	2 (2.4)
Single contributing finding	59 (71.1)
Multiple contributing findings	24 (28.9)

CME=cystoid macular edema; PCO=posterior capsule opacification

The group of 4 patients (8 eyes) categorized with expectation mismatches were predominantly unsatisfied with their uncorrected near visual acuity (UNVA), with a mean value of 0.30 ± 0.18 logMAR. The mean monocular uncorrected distance visual acuity

(UDVA) of this group was 0.07 ± 0.06 logMAR, with a mean SE of −0.16 ± 0.45 D and a PE of 0.02 ± 0.31 D. Despite the standardized and comprehensive preoperative information about the working mechanism of an EDOF IOL, some patients may have had higher expectations regarding spectacle independence for near vision. Finally, mini-monovision intolerance was diagnosed in one patient.

Among this patient cohort, photic phenomena were reported in 12 patients (21 eyes), yielding an incidence of 5.9% within the total EDOF IOL cohort. Important to note is that only 5 patients exclusively experienced photic phenomena, while the remaining 16 patients reported concurrent blurred vision. The occurrence of photic phenomena was reported in some patients with multiple etiologies, including residual ametropia (6 eyes), DED (6 eyes), waxy vision syndrome (4 eyes), expectation mismatch (4 eyes), PCO (2 eyes), and floaters (1 eye). In 5 eyes, no cause for the dysphotopsia was identified.

Table 6.4 presents the treatments and their effectiveness. Both noninvasive and invasive interventions were used for correction of the residual ametropia. Eyes (n=16) that underwent laser-assisted subepithelial keratectomy (LASEK) enhancement demonstrated an improvement in UDVA from pre-LASEK value of 0.22 ± 0.11 logMAR to 0.03 ± 0.10 logMAR post-LASEK shown in **Figure 6.1**. CDVA remained stable, with mean values of −0.02 ± 0.05 logMAR and −0.02 ± 0.06 logMAR before and after LASEK, respectively. The SE pre-LASEK was −0.57 ± 0.57 D and post-LASEK −0.16 ± 0.30 D. LASEK reduced the postoperative ametropia, primarily by decreasing refractive astigmatism, as shown in **Figure 6.2**. The mean cylinder centroid decreased from 0.42 ± 0.83 D pre-LASEK to 0.12 ± 0.27 D post-LASEK treatment. In most patients (n=12), LASEK was solely performed on the dominant eye, resulting in satisfactory binocular visual acuity. One patient with waxy vision in both eyes underwent an IOL exchange with the implantation of a monofocal IOL in the left eye. Since the patient did not experience symptom improvement after the exchange, we refrained from a similar procedure in the other eye.

Table 6.4. Provided treatments and percentage of eyes with satisfactory outcomes.

Treatment (n=83 eyes)	Eyes, n (%)	Satisfied after treatment, n (%)
Artificial tears	37 (44.6)	24 (64.9)
Reading glasses	22 (26.5)	9 (40.9)
LASEK	16 (19.3)	14 (87.5)
Spectacles/contact lenses	14 (16.9)	13 (92.9)
None	12 (14.5)	6 (50.0)
Nd:YAG capsulotomy	10 (12.0)	5 (50.0)
Brimonidine	3 (3.6)	3 (100)
Other	4 (4.8)	4 (100)
Loss to follow-up	2 (2.4)	
Reoperation		
Realignment	1 (1.2)	1 (100)
Exchange	1 (1.2)	0 (0)
Single modality	48 (57.8)	36 (75.0)
Multiple modalities	35 (42.2)	21 (60.0)

Other treatments include contact lens-trial (n=1), intravitreal injection with corticosteroid (n=2), and floaterectomy (n=1).

LASEK=laser-assisted subepithelial keratectomy

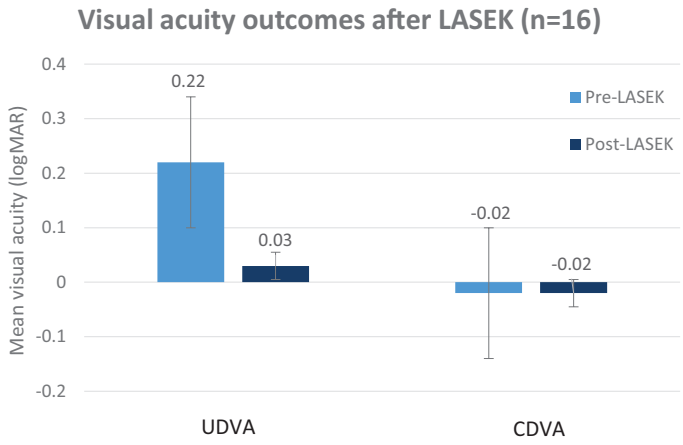

Figure 6.1. Visual acuity outcomes of eyes which underwent LASEK enhancement.

CDVA=corrected distance visual acuity ; LASEK=laser-assisted subepithelial keratectomy; UDVA=uncorrected distance visual acuity

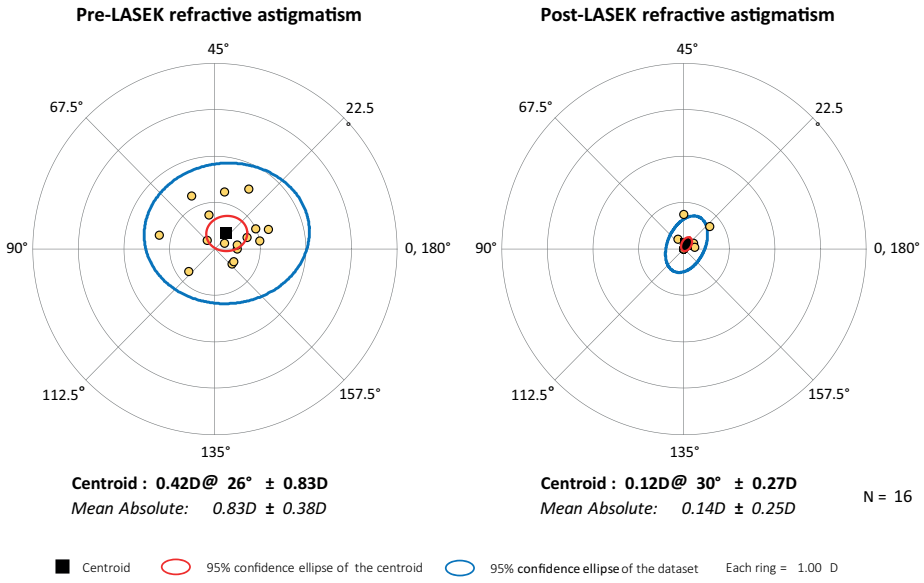

Figure 6.2. Double-angle plots of refractive astigmatism before and after LASEK enhancement.

The centroid is represented by the black square, the red ellipse encompasses the 95% confidence interval of the centroid. The blue ellipse represents the 95% confidence interval of the entire dataset. Each concentering ring in the double-angle plot corresponds to a 1.0 D increment.

D=diopter; LASEK=laser-assisted subepithelial keratectomy

Of the 52 patients (83 eyes) with expressed dissatisfaction, 35 patients (57 eyes, 68.7%) achieved successful treatment, while 12 patients (21 eyes, 25.3%) remained dissatisfied, and 5 patients were lost to follow-up. Patients who did not receive additional treatment were provided with additional explanations regarding the optical function of the EDOF IOL and the expectations regarding visual function with this type of IOL. Among the patients who remained dissatisfied despite treatment, various etiologies were observed, including waxy vision syndrome (6 eyes), DED (6 eyes), and expectation mismatch (4 eyes) being predominant. The incidence of patient dissatisfaction after EDOF IOL implantation in this cohort was 5.9% (12 patients). Of these 12 patients, 2 had preexisting ocular comorbidities, including one with age-related macular degeneration (2 eyes) and another with a history of retinal detachment (one eye). Preoperative Scheimpflug topography of 349 eyes, conducted before EDOF IOL implantation, underwent analysis using AI algorithms aimed at identifying predictive patterns for patient (dis)satisfaction postoperatively. However, no significant predictive pattern emerged.

Discussion

This retrospective case series describes patient dissatisfaction after Vivity IOL implantation. Our results indicated that the majority of these patients experienced complaints of blurred vision, primarily resulting from postoperative residual refractive errors and DED. Photic phenomena were reported in 25.3% of eyes, with a variety of etiologies observed. These findings are consistent with a previous study indicating that DED, glare symptoms, and postoperative binocular UDVA and UNVA are independent factors for satisfaction after EDOF IOL implantation.[13]

The AcrySof IQ Vivity IOL has demonstrated effective performance in providing distance and intermediate vision, along with functional near vision.[2-5,8,14] Reported mean binocular UDVA, uncorrected intermediate visual acuity (UIVA), and UNVA range between −0.07 and 0.00 logMAR, 0.04 and 0.06 logMAR, and 0.21 and 0.23 logMAR, respectively.[2,15,16] Compared with these previous reports, our cohort showed lower UDVA and UIVA, while UNVA outcomes were consistent with previous findings. Factors including residual ametropia, DED, and ocular pathologies or comorbidities may have influenced these visual outcome

Studies investigating patient satisfaction after EDOF and mIOL implantation highlight that blurred vision is the main complaint, leading to dissatisfaction in 67.7% to 94.7% of the cases. Photic phenomena are reported to a lesser extent, ranging from 32.4% to 47.1%.[17-19] Principal etiological factors for dissatisfaction after mIOL implantation include residual ametropia and PCO.[18,19]

The primary cause of dissatisfaction in our cohort was residual ametropia, accounting for 54.2% of the cases. Our patient cohort exhibited a PE distribution consistent with literature findings using the Barrett Universal-II formula, with 76% within ± 0.50 D and 94% within ± 1.0 D.[20] However, the wide range of the SIA introduced high variability in postoperative residual refractive astigmatism, thereby adversely impacting visual acuity outcomes. Previous studies indicate that residual astigmatism ≥1.0 D has a significant impact on visual acuity, affecting spectacle independence by negatively impacting both UDVA and UNVA outcomes.[21-23] Therefore, we aimed to target postoperative residual refractive astigmatism lower than 1.0 D. However, the literature lacks consensus regarding the acceptable level of postoperative refractive astigmatism for specific IOL designs in relation to patient's satisfaction.[23] In general, the amount of postoperative residual astigmatism after toric monfocal, diffractive EDOF, and mIOLs similarly affects UDVA, resulting in a reduction of 0.12 to 0.18 logMAR per 1.0 D of astigmatism.[24] Studies on mIOLs indicate that residual astigmatism has a greater impact on UDVA compared with its effect on UIVA and UNVA, with suggested astigmatism tolerances of 0.75 D for trifocal

and 1.0 D for bifocal IOLs.[25]

Studies on residual refractive error after implantation of the Vivity IOL showed that spherical ametropia up to ± 0.50 D and a combination of −0.25 D spherical and 0.50 D cylindrical error were well-tolerated and resulted in ≤1 line visual acuity loss.[26] Additional studies on induced ocular spherical aberrations have shown acceptable levels up to −0.05 µm in eyes implanted with a Vivity IOL, leading to marginal improvement of UNVA and UIVA.[27] In our study cohort, eyes with residual ametropia causing dissatisfaction had an astigmatism centroid of −0.12 ± 0.94 D and a SE of −0.60 ± 0.58 D. This level of residual ametropia significantly affected visual quality because 26 patients (81.6%) were satisfied with the outcomes after ametropia correction. Based on these findings, it is anticipated that the tolerance of residual refractive astigmatism for EDOF IOLs lies between 0.50 and 0.75 D.

The reported prevalence of photic phenomena is higher in mIOLs cohorts compared with our EDOF IOL cohort.[17-19] After Vivity IOL implantation, photic phenomena have been reported in 9% to 30% of patients.[2,14] In our patient cohort, these symptoms were reported in 12 patients, accounting for 23.1% of the dissatisfied cohort and 5.9% of the total cohort of 202 Vivity patients. Visual disturbances are believed to depend significantly on neuroadaptation within the first 6 months postoperatively.[28,29] With an average time of 67 days from surgery to presentation of complaints, some patients of our cohort were still within this neuroadaptive phase. A study of patients experiencing neuroadaptive difficulties with mIOLs has found that exchanging the mIOL with another mIOL featuring a different optical profile resulted in an increased satisfaction in 80% of the cases.[30] In another case series of patients undergoing IOL exchange after mIOL implantation, reasons for exchange include waxy vision (58%), halos and glare (30%), and blurred distance vision (24%).[31] In our cohort, 1 IOL exchange with a monofocal IOL was performed, but the patient remained dissatisfied with persisting complaints of waxy vision.

Another significant factor contributing to patient dissatisfaction after EDOF IOL implantation was DED. The prevalence of DED after cataract surgery varies over time, but DED is known as a common condition and can be exacerbated by this surgical procedure.[32] In our cohort, 20 patients (37 eyes, 44.6%) were treated with preservative-free artificial tears, while DED (25.3%) was diagnosed in only 21 eyes. This discrepancy might have been caused by the liberal use of lubrication agents aiming for symptom alleviation.

Mini-monovision is a common strategy with EDOF IOLs to increase binocular uncorrected reading vision. Despite applying this strategy, 16 patients (29 eyes) were dissatisfied because of a suboptimal UNVA. This is in line with previous studies, where only 38% of the

patients achieved spectacle independence for reading when the Vivity IOL was targeted for mini-monovision.[2] Furthermore, near vision quality can be negatively affected by different factors such as dry eye or residual astigmatism.[33] Hence, counselling regarding expectations for achieving spectacle independence for near vision is crucial because EDOF IOLs usually do not provide spectacle independency for reading. Notably, mini-monovision intolerance was diagnosed in 1 patient, which has been described earlier.[34] Relief from discomfort and blurred vision was achieved by correcting mini-monovision to emmetropia.

In a subgroup of 4 patients (8 eyes) within our cohort, no objective cause for dissatisfaction was found because all measurable postoperative outcomes aligned with the expected results for an EDOF IOL. This may have resulted from an expectation mismatch despite the extensive counselling process.[35] In addition, since EDOF IOLs are not covered by health insurance in the Netherlands, the necessary copayment may negatively affect the expectation level regarding postoperative outcomes.

Based on the findings of this study, surgeons should exercise caution when implanting EDOF IOLs in patients with DED or other ocular comorbidities. Within our EDOF cohort, the primary etiologies comprised residual ametropia and DED, with DED exhibiting a higher incidence compared with the mIOL cohorts.[17-19,31] For effective expectation management, comprehensive preoperative counselling should be performed.[35] If dissatisfaction arises postoperatively, options include noninvasive (spectacles, artificial tears) or invasive procedures (laser enhancement, Nd:YAG, piggy-back IOL, or as a last resort IOL exchange).[30] Most of the patients is satisfied after receiving the right treatment.

The major limitation of this study is its retrospective nature, which might have caused selection bias or misclassification bias. In addition, since only 1 type of EDOF IOL has been analyzed, these outcomes cannot generally be applied for other EDOF IOLs. In conclusion, after EDOF IOL implantation, the primary reasons for dissatisfied patients were blurred distance vision and to a lesser extent photic phenomena. The main explanations for these complaints are residual ametropia, DED, and PCO. Most dissatisfied patients responded successfully to additional treatment, with 6% remaining dissatisfied.

What was known

- The general satisfaction rate after EDOF IOL implantation is high.
- EDOF IOLs are designed to provide good distance and intermediate vision.

What this paper adds

- Main causes of dissatisfaction after EDOF IOL implantation include residual ametropia, dry eye disease, posterior capsule opacification, dysphotopsia, and expectation mismatches.
- LASEK enhancement is effective to correct residual ametropia after EDOF IOL implantation.
- Treatment of dissatisfied EDOF patients is successful in most cases, with 6% remaining dissatisfied.

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CHAPTER 7

Efficacy of Remote Care in Cataract Surgery: a Systematic Review

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Abstract

Topic: To evaluate the efficacy of currently available digital and remote care applications for postoperative cataract management compared with traditional methods for postoperative clinical measurements.

Clinical relevance: With the increasing demand for ophthalmological services and an anticipated shortage of professionals, innovative approaches are needed to optimize care. Cataract surgery, characterized by its high-safety profile and turnover rate, is well-suited for digital and remote care solutions, which could enhance the postoperative patient pathway, potentially leading to substantial time and cost savings.

Methods: A systematic search was performed in Ovid Embase, Ovid MEDLINE, KSR Evidence, CINAHL, and Cochrane CENTRAL Library for randomized controlled trials (RCTs) and observational studies on digital tools, telemedicine, or remote care in postoperative cataract management. Reported outcomes included patient-reported outcomes, visual acuity, refraction, intraocular pressure, slit lamp and fundus examination, or complication prevalence. The risk of bias was evaluated using the Cochrane Risk-of-Bias Assessment Tool (v. 2) and Joanna Briggs Institute Critical appraisal checklists. Data extraction included both qualitative and quantitative information. The protocol was registered at International Prospective Register of Systematic Reviews (CRD42024505933).

Results: The search identified 11,319 studies of which 14 were included. These comprised 4 RCTs and 10 observational studies involving 2681 patients. Interventions were categorized into telephone consultation, messaging, automated phone calls, and mobile applications/software. Telephone consultations were effective for follow-up screening, and automated phone calls also showed promising results. Messaging was suggested to improve adherence in the early postoperative period. Visual acuity assessment tools showed potential as screening methods, but exhibited variability compared with conventional methods and had wide 95% limits of agreement. All types of interventions were well-accepted by patients.

Conclusion: Early evidence supports a positive impact of implementing digital and remote care tools in the postoperative cataract management pathway, particularly for screening purposes. However, further research is needed to define their roles and develop clinical practice guideline

Introduction

Cataract surgery is one of the most performed surgeries worldwide, characterized by a high-safety profile and low-complication rate. This procedure is highly effective in enhancing patients' vision and thereby improving their quality of life.[1,2] The postoperative care pathway for cataract surgery involves multiple hospital visits to monitor ocular recovery and identify complications. With the growing demand for ophthalmological care and an anticipated shortage in the ophthalmology workforce, there is a pressing need for innovative solutions to optimize care delivery and address this imbalance.[3] The rapid development of new technologies provides opportunities to streamline these processes. Implementing remote care and digital health applications aims to enhance efficiency, save time and costs, and maintain high-quality patient care by minimizing the need for in-person visits.[4,5] Remote care holds promise for managing the postoperative cataract pathway by enabling remote monitoring, improving patient engagement, and facilitating timely interventions, which could potentially reduce the frequency of hospital visits. Given the various components of postoperative cataract care, a range of digital applications and remote care is currently being developed to address the needs of different postoperative stages. This systematic literature review aims to provide a comprehensive overview of digital tools and remote care options for patients in the 3-month postoperative period after cataract surgery. It compares measurements using remote and digital approaches with regular clinical measurements in visual acuity, refraction, intraocular pressure (IOP), slit lamp and fundus examination, and the incidence of complications.

Methods

This systematic review was reported according to the PRISMA statement (available at http://links.lww.com/JRS/B314).[6] The review was registered in the International Prospective Register of Systematic Reviews (registration number: CRD42024505933).

Eligibility criteria

Studies involving patients with postoperative cataract who used digital tools, telemedicine, or remote care for the postoperative management were included. Postoperative management should at least include one assessment of patient-reported outcomes (PROMs), visual acuity, refraction, IOP, slit lamp and fundus examination, or the prevalence of complications. Comparators consisted of regular follow-up procedures after cataract surgery. Randomized controlled trials (RCTs) were prioritized because of

their high level of evidence. However, observational studies were included if RCTs were limited to provide a broader perspective on the topic. All languages were considered, with translations to English performed as needed.

Search Methods

A bibliographic search was performed in Ovid Embase, Ovid MEDLINE, KSR Evidence (Kleijnen Systematic Reviews Ltd.), CINAHL, and Cochrane CENTRAL Library. The search strategy was conducted on February 29, 2024. The search syntax included synonyms for "cataract surgery," "postoperative," "digital tool," "telemedicine," and "remote consultation." References from the included studies were reviewed, and trial registries such as ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform were also checked. Studies published before 2010 were excluded because the field of remote care and digital health technologies has rapidly developed during the past few years, with significant improvements in availability and quality since 2010. The complete strategies are detailed in **Supplementary Material 7.1**.

Study Selection

All references were imported into Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia; available at www.covidence.org) for selection, data extraction, and quality assessment. Title and abstract screening was independently performed by two reviewers (J.C.W., M.H.M.S.) according to the selection criteria. Any disagreements between the reviewers were resolved through discussion. Subsequently, full-text screening was independently performed by the same 2 reviewers, and reasons for exclusion of the full texts were recorded.

Data collection and Risk of Bias assessment

Two researchers (J.C.W., M.H.M.S.) independently assessed the risk of bias and extracted relevant data, including study characteristics, participant demographics, interventions, outcomes, and results. Authors were contacted for missing full texts; data extraction could not be performed if these were unavailable. RCTs were assessed for risk of bias using the Cochrane Risk-of-Bias Assessment Tool (v. 2), covering 5 domains: randomization, deviations from intended interventions, missing outcome data, outcome measurement, and selection of the reported results.[7] Non-RCTs were evaluated with the Joanna Briggs Institute Critical appraisal checklists.[8,9] For cohort studies, 11 domains were assessed, including recruitment, study group exposure, exposure measurement, confounding

factors, strategies for confounding factors, presence of outcome at the start of the study, measurement outcomes, follow-up time, completeness of follow-up, strategies for incomplete follow-up, and statistical analysis.[8] Case series were assessed for 10 domains, including selection criteria, condition measurement, condition identification, consecutive inclusion, inclusion completeness, participant demographics, clinical information of participants, reporting outcomes, reporting site(s)/clinic(s) demographic information, and statistical analysis.[9] The overall risk of bias was determined based on domain-level judgements. A "low" risk required all domains to be rated as "low risk of bias." An "unclear" overall risk was assigned if at least 1 domain was "unclear risk of bias," but none was "high risk of bias." A "high" overall risk required at least 1 domain to be rated "high risk of bias."

Data synthesis and analysis

Qualitative and quantitative data were extracted from the included studies. Owing to the significant heterogeneity of extracted data, a meta-analysis could not be conducted. Therefore, a narrative synthesis was performed, detailing study designs, quality assessments, and primary findings. Effect sizes were calculated where data were sufficient, while a summary of reported results was provided when data were lacking. RCTs and observational studies were analyzed separately.

Results

The study flow chart (PRISMA diagram) is shown in **Figure 7.1**. The search yielded 14,584 results, with 11,319 records remaining after duplicate removal. These records were screened for relevance based on their titles and abstracts, followed by a full-text review of 101 potentially eligible articles. In total, 80 articles were excluded, and 7 papers were either ongoing studies, or provided only protocols or abstracts, precluding data extraction. Fourteen studies were included for data extraction and quality assessment. **Table 7.1** summarizes the study characteristics, including various study designs: 4 RCTs with a total of 471 patients and 10 observational studies involving 2,210 participants.[10-22] The observational studies comprised both comparative and non-comparative designs. The selected studies, published between 2014 and 2024, were conducted at hospitals across different continents. Sample sizes ranged from 46 to 929 participants all of whom underwent uneventful cataract surgery, with a mean age ranging from 58 to 80 years.

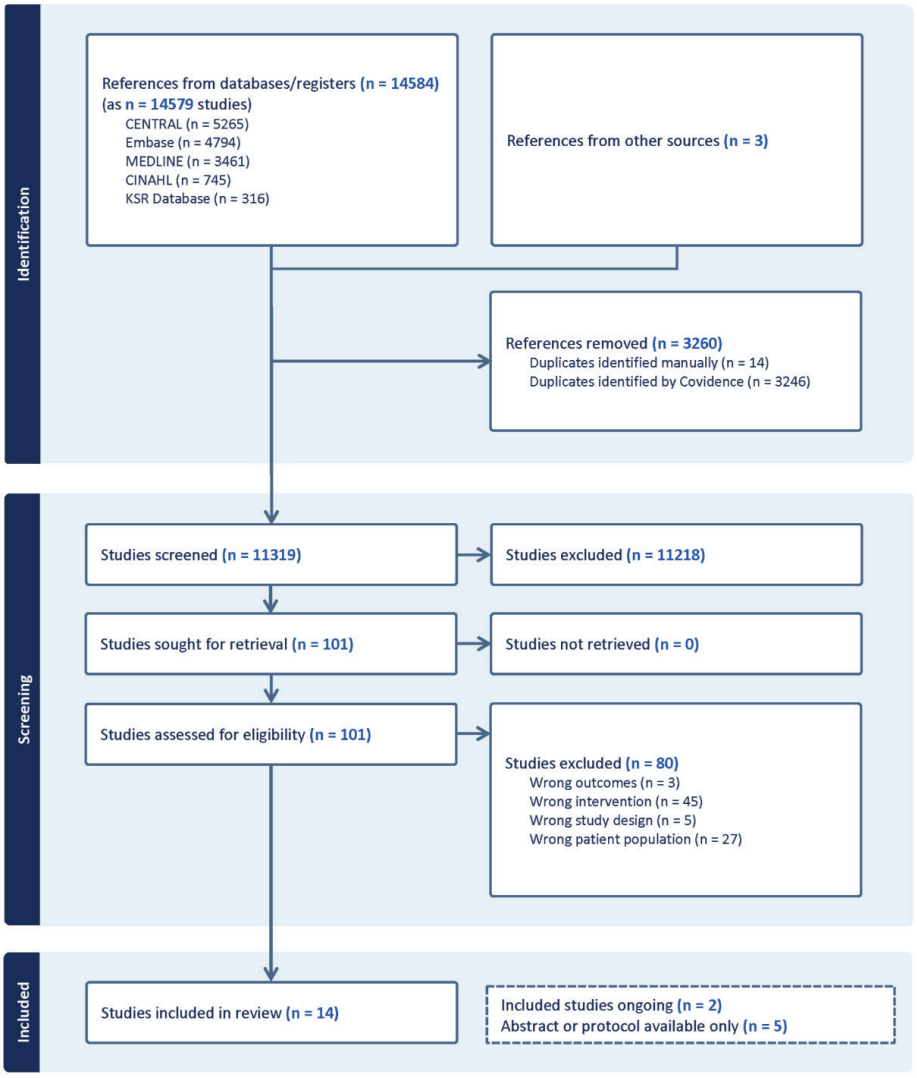

Figure 7.1. Flow diagram of study selection based on PRISMA 2020 statement.[6]

Table 7.1. Study characteristics of the fourteen included studies.

Author	Year	Country	Study design	Intervention type	Equipment needed	Sample size	Comparison	Control group
Hoffman	2016	United Kingdom	Prospective case series	Telephone	Personnel, Telephone	50	No	No
Machado	2020	Brazil	RCT	Telephone	Personnel, Telephone	95	Hospital visit	Yes
Ruiss	2024	Austria	RCT	Telephone	Personnel, Telephone	200	Hospital visit	Yes
Dole	2023	India	Prospective cohort study	Telephone	Smartphone, application	240	Regular care	Yes
Tan	2014	Singapore	Case series	Telephone	Personnel, Telephone	260	No	No
Al-Ani	2023	New Zealand	Retrospective cases series	Telephone	Personnel, Telephone	929	No	No
Wanten	2023	The Netherlands	Case series	Mobile application / software	Computer or tablet, Smartphone, application	46	Conventional visual acuity assessment	No
Gordon	2021	United States of America	Case series	Mobile application / software	Software	59	Conventional visual acuity assessment	No
Claessens	2024	The Netherlands, Germany, Austria	RCT	Mobile application / software	Computer or tablet, Smartphone, application	94	Conventional visual acuity assessment	Yes
Lecumberri	2023	Spain	Prospective case series	Mobile application / software	Smartphone, application	126	No	No
Digin	2022	Turkey	RCT	Messaging	Personnel / Telephone	82	Regular patient education	Yes
Sanguansak	2017	Thailand	Prospective cohort study	Messaging	Smartphone, application	98	Regular patient education	Yes
Khavandi	2023	United Kingdom	Prospective case series	Automated phone calls	Telephone	177	No	No
Meinert	2024	United Kingdom	Prospective case series	Automated phone calls	Telephone	225	No	No

RCT=randomized controlled trial

The main risk of bias outcomes for the included studies are reported in **Table 7.2**. The full assessment can be found in **Supplementary Material 7.2**. The studies were subdivided according to the type of intervention: telephone consultation (6 studies), messaging (2 studies), automated phone calls (2 studies), and mobile applications/software (4 studies).[10-23] The main outcomes of each study are discussed in the text, with a more detailed data synthesis provided in **Supplementary Material 7.3**.

Table 7.2. Risk of bias summary, including the key outcomes of the different domains and overall risk of bias.

Author, year	Study type	Key outcomes domains	Overall Risk of Bias
Claessens, 2024	RCT[a]	No bias assumed in all assessed domains	Low
Digin, 2022	RCT[a]	High bias arising from randomization process, deviations from intended intervention, and measurement of outcome	High
Machado, 2020	RCT[a]	No bias assumed in all assessed domains	Low
Ruiss, 2024	RCT[a]	High bias arising from measurement of the outcome	High
Dole, 2023	Cohort study[b]	High bias arising from measurement of exposure	High
Sanguansak, 2017	Cohort study[b]	High bias arising from incomplete follow-up	High
Al-Ani, 2023	Case series[c]	No bias assumed in all assessed domains	Low
Gordon, 2021	Case series[c]	High bias arising from inclusion process, participant demographics, and reporting of outcomes	High
Hoffman, 2016	Case series[c]	Unclear risk of bias for clinical information of participants, reporting outcomes and clinic demographic information	Unclear
Khavandi, 2023	Case series[c]	Unclear risk of bias for inclusion process and clinic demographic information	Unclear
Lecumberri, 2023	Case series[c]	Unclear risk of bias for selection and inclusion, clinical information of participants, and clinic demographic information	Unclear
Meinert, 2024	Case series[c]	Unclear risk of bias for clinical information of participants	Unclear
Tan, 2014	Case series[c]	Unclear risk of bias for clinical information of participants and clinic demographic information	Unclear
Wanten, 2023	Case series[c]	Unclear risk of bias for completeness of inclusion and clinic demographic information	Unclear

Based on the study type, a specific risk of bias assessment tool was selected: [a]RoB V2 was used, [b]JBI checklist for cohort studies, and [c]JBI checklist for case series.

RCT=randomized controlled trial

Telephone consultation

This intervention involves communication through telephone between healthcare providers and patients, replacing in-hospital visits. During these telephone consultations, healthcare providers assessed postoperative symptoms to ensure the absence of potential complications, primarily focusing on symptoms such as pain, redness, and vision issues. Six studies—3 comparative and 3 non-comparative ones—were identified, all emphasizing safety and/or PROMs.[12-15,17,21] Various healthcare providers, including ophthalmologists, optometrists, residents, and nurses, conducted the calls. Most telephone consultation interventions were performed directly postoperatively or within 1 to 3 days postoperatively.[12-15,21] One study conducted the first telephone consultation 2 to 3 weeks postoperatively.[17] Telephone consultations generally required only a basic telephone. However, in one study, a smartphone was necessary for visual acuity assessment as a secondary outcome.[15] The risk of bias varied, with some studies having a low risk of bias (n=2), and others high (n=2) or unclear (n=2).[12-15,17,21] The studies with an unclear risk of bias both had unclear reporting regarding clinical participant and clinic demographic information.[17,21] One RCT had a high risk of bias due to bias in the outcome measurements, while the cohort study had potentially induced bias in the exposure measurements.[13,15]The comparative studies observed no difference in unplanned visits or additional therapy at 1 week, and no difference in complications at 1 week and 1 month postoperatively.[13,15] One study reported a significantly lower delayed surgical recovery (DSR) at 1 week postoperatively of patients receiving additional telephone calls, compared with regular care only, with a DSR reported in 3 (6.3%) and 17 (36.2%) ($p<0.01$), respectively. No differences were found in DSR either 1 day or 1 month postoperatively.[12] The patient satisfaction with telephone consultations was high, with up to 91% of the patients reporting satisfaction after receiving a phone call directly after surgery, because the calls were perceived to have a calming effect.[13] The overall reported satisfaction—measured on a 5-point scale—was comparable between patients receiving a telephone call, reporting a mean score of 3.74 ± 0.23 (95% CI 3.70-3.78), and patients receiving regular care with a mean score of 3.72 ± 0.27 (95% CI 3.67-3.77).[15] The non-comparative studies stated that telephone consultations are a safe alternative to clinical reviews in patients with low-risk cataract.[14,17,21]. However, these studies report results based solely on observations during the follow-up period, without comparing them with regular care or baseline data. These patients reported a high overall satisfaction rate with this intervention using an unvalidated questionnaire.[17] Notably, the majority of patients expressed preference for telephone follow-up over in-hospital reviews because the telephone consultations were perceived as “more personal than in clinic, with more time to ask questions.”[15,17]

Messaging

Messaging uses digital platforms such as Short Message Service (SMS) or secure messaging applications to provide instructions and reminders. Two comparative studies were identified in which messaging was used alongside regular patient care and compared with a control group that received only regular patient education.[11,20] The intervention started directly or within 1 to 3 days postoperatively, with multiple messages sent throughout the postoperative follow-up. The cohort study used the LINE messaging application (LY Corp.) to deliver preoperative education information, postoperative instructions (such as drop instructions), and appointment reminders. Patients needed a smartphone for this intervention and were followed up to 1 month postoperatively.[20] The other study sent patients only postoperative instructions through SMS, managed by a researcher or clinical nurse, with follow-up lasting up to 1 week postoperatively.[11] Both studies were assessed with a high risk of bias. The RCT had biases related to randomization, deviations from the intended intervention, and outcome measurements.[11] The cohort study lacked clear explanations for the loss to follow-up. The cohort study lacked clear explanations for the loss to follow-up.[20] Reported outcomes included PROMs and safety outcomes. Messaging using the LINE application resulted in significantly higher scores on the Morisky Medication Adherence Scale one week postoperatively for the intervention group, with 47 patients (96%) achieving high adherence compared with 36 (73%) in the control group.[24] There was a statistically significant difference in adherence between patients with high adherence and those with medium or low adherence scores between the study groups (p=0.004). At 30 days postoperatively, 43 patients (88%) in the intervention group maintained high adherence vs 41 (91%) patients in the control group. However, no differences were observed between the intervention and control groups in IOP, with means of 11.71 ± 2.61 mmHg (95% CI 11.00-12.40) and 12.31 ± 3.09 mmHg (95% CI 11.40-13.20), respectively, or in intraocular inflammation, with means of 0.33 ± 0.62 cells/mm2 (95% CI 0.16-0.50) and 0.38 ± 0.53 cells/mm2 (95% CI 0.23-0.53).[20] In the RCT, participants receiving SMS reminders showed comparable difference in State Anxiety Inventory (SAI) scores compared with controls, with a mean difference between preoperative and postoperative SAI scores of 24.9 ± 9.2 (95% limits of agreement [LoA] 6.87-2.93) and 21.5 ± 10.5 (95% LoA 0.92-42.08), respectively.[11,25]

Automated phone calls

Automated phone calls involve telephone communication delivered without human interaction. Two prospective case series used the voice-based conversational assistant Dora (Ufonia Ltd.) for automated phone calls.[18,23] The only equipment required for patients

was a telephone. Calls were conducted 3 to 4 weeks after cataract surgery to assess postoperative symptoms (pain, redness, vision issues, presence of floaters, or flashing lights) and determine if additional review by a clinician was necessary. The risk of bias was deemed unclear in both studies. One study had uncertainties regarding the inclusion process and clinic demographic information, while the other lacked clear clinical details about participants.[18,23] Reported outcomes included PROMs, diagnostic performance, and cost analyses. Diagnostic performance outcomes, evaluated in only one study, assessed the accuracy of symptom recognition and decision-making by the automated phone calls. The sensitivity and specificity of the overall decision-making based on clinical symptoms were 93.75% (95% CI 84.76-98.27) and 86.26% (95% CI 79.16-91.56), respectively.[23] Both studies measured the Net Promotor Score (with scores ranging from −100 to +100) for the automated phone calls, yielding scores of +45 and +51, with a mean score of 8.55 ± 1.67 (95% CI 8.30-8.80) and 8.59 ± 2.05 (95% CI 8.30-8.88), respectively.[18,23] In addition, in both studies, patients completed the Telehealth Usability Questionnaire, which demonstrated high scores in all 5-point scale domains, yielding overall mean scores of 3.96 ± 0.47 (95% CI 3.76-4.16) and 3.79 ± 0.89 (95% CI 3.40-4.18).[26] The System Usability Scale had a mean score of 77.76 ± 17.55 (95% CI 70.10-85.50), and the estimated staff cost savings per patient in UK hospitals were £35.18 compared with standard care.[23,27]

Mobile application/software

Mobile applications and software are digital tools designed to assist patients in postoperative care. Four studies, comprising 1 RCT and 3 noncomparative observational studies, investigated the use of mobile applications/software for visual acuity measurements.[10,16,19,22] The evaluated tools included the Easee web-based tool (Easee BV), Better Operative Outcome Software Tool (BOOST) Cataract app (Aravind Eye Care System-Govel Trust), and DYOP online visual acuity test (Dyop Vision Associates). The Easee tool required a computer or tablet along with a smartphone, while the BOOST app only required a smartphone. The equipment needed for the DYOP test was not specified. The timing of visual acuity assessments varied. One study conducted assessments at multiple time-points up to 3 months postoperatively, while others measured it only once during follow-up.[10] The risk of bias in the RCT was low, whereas 2 observational studies had an unclear risk of bias due to incomplete reporting on inclusion and uncertainty about clinic demographics.[10,19,22] The third observational study had a high risk of bias related to inclusion, patient demographics, and site clinic information.[16] Reported outcomes included visual acuity, refraction, and PROMs. The Easee tool was compared with conventional visual acuity measurements using the Early Treatment Diabetic Retinopathy Study (ETDRS)

chart or Snellen chart in 2 studies. The mean difference in uncorrected distance visual acuity (UDVA) compared with ETDRS ranged from −0.03 ± 0.14 to −0.07 ± 0.10 logMAR, with corresponding 95% LoA of −0.30 to 0.24 and −0.26 to 0.15 logMAR, respectively.[10,22] The DYOP UDVA measurement was compared with the Snellen chart, showing a maximum mean difference of 0.17 ± 0.23 decimal units, with 95% LoA of 0.08 to 0.26 decimal units.[16] Outcomes of the BOOST app were not directly compared with conventional visual acuity measurements, but patient classification based on BOOST outcomes achieved a success rate of 65.6%, the kappa agreement compared with a 6-week postoperative regular UDVA measurement was 0.35 ± 0.07 (95% CI 0.48 to −0.21).[19] Refraction was only assessed using the Easee tool in 1 study, with a mean spherical equivalent difference of −0.32 ± 0.43 D (95% LoA 0.54 to 1.16) compared with conventional manifest spherical equivalent.[10] Both studies involving the Easee tool assessed PROMs using unvalidated questionnaires, showing a generally positive attitude of patients toward this tool. The mean score of a 5-point scale technology acceptability questionnaire was 3.70 ± 0.97 (95% CI 3.29-4.11), and the 5-point scale questionnaire regarding the experience of the tool had a mean score of 4.05 ± 0.39 (95% CI 3.94-4.16).[10,22]

Discussion

This systematic review aimed to provide a comprehensive overview of the efficacy of digital applications and remote interventions within the postoperative cataract care pathway. We identified 14 publications evaluating telephone consultations, messaging, automated phone calls, and mobile applications/software. The primary outcomes assessed included safety, visual acuity, and PROMs, with a variety of methodological approaches and risk of bias across studies.

Telephone consultations, whether human-led or automated, offer a safe alternative for postoperative cataract care, avoiding long travel distances or accommodating systemic diseases that impair travel.[12-15,17,18,21,23] These interventions were both well-received by users. Automated phone consultations have been studied in only 2 prospective case series, demonstrating a high decision-making accuracy of 88.72% and high patient acceptability.[18,23] Automated calls use a standardized set of questions to identify potential complications after cataract surgery, based on symptoms reported by the patient. This method reduces variability in subjective interpretation, compared with human-led consultations. However, despite this, both methods of telephone consultations only capture subjective information and lack objective data on visual acuity and refractive status. This could compromise monitoring over postoperative healing and visual

improvement. Nonetheless, studies indicate that unexpected management changes in asymptomatic patients are rare after uneventful cataract surgery, and effective risk stratification can be achieved using structured clinical questions.[28,29] Hence, although telephone-based care cannot fully replace traditional postoperative care, it can serve as a screening tool during the postoperative follow-up of uneventful cases.

Messaging has primarily been used for patient education and to send out reminders, potentially enhancing adherence and follow-up attendance. Findings indicated that this intervention can be a valuable addition to regular care during the early postoperative period.[11,20] However, two-way messaging may increase workload because of the potential for generating a high volume of responses because patients encounter a low barrier to communication. In this context, an RCT has investigated the effect of home monitoring through a mobile app after ambulatory breast reconstruction surgery. The results show that patients using the app had 0.4 times fewer in-hospital visits while sending more emails to their clinician in the first month after surgery compared with the patients in the in-person follow-up group, with the remote care group reporting that this follow-up method is convenient.[30] These findings suggest that integrating messaging into postoperative care may enhance patient engagement while balancing the workload.

Alongside interventions involving patient communication, visual acuity assessment is another crucial aspect of postoperative cataract management. In general, when performing visual acuity assessments, it is important to recognize that these measurements are characterized by intraindividual variability. Literature indicates that differences of ≥0.15 logMAR are considered clinically irrelevant when 2 tests are repeatedly performed.[31] In addition, visual acuity measured using different methods cannot be used interchangeably. For instance, the ETDRS chart and the Snellen chart have a significant mean difference of 6.5 letters.[32] Such discrepancies complicate the interpretation of results compared with conventional visual acuity tests. In this review, 3 visual acuity tools were identified, including the BOOST app, DYOP chart, and Easee web-based tool. However, the included studies showed some limitations. In the study investigating the BOOST app, no direct comparison of UDVA outcomes with conventional visual acuity assessment was performed because of study design limitations.[19] Furthermore, the outcomes using the DYOP chart were compared with those from the Snellen chart and reported in decimal units. The methods used to calculate these differences and their corresponding 95% CIs were not clearly defined, which limits the applicability of the findings.[16]

The Easee web-based tool has been validated for visual acuity assessment in patients with postoperative cataract.[22] Generally, this application demonstrated lower precision than conventional methods, with broad LoAs.[10,22] However, since the primary aim of

postoperative visual acuity check is the early detection of potential complications, the Easee tool may serve as an useful screening instrument for identifying patients with sight-impacting complications. One study also reported on outcomes of refraction assessments using the Easee tool, with a mean difference of −0.32 ± 0.43 D (95% LoA 0.54 to 1.16) compared with subjective manifest measurement, indicating that the tool may overestimate residual refractive errors.[10] Hence, refractive assessments using the Easee tool do not yet provide reliable postoperative refraction outcomes. Regarding patient attitudes toward digital visual acuity assessments, this aspect was only evaluated in studies involving the Easee tool, which showed an overall positive response.[10,22]

The target population for this review included adult patients who underwent cataract surgery. Most studies excluded patients with intraoperative complications or severe/unstable ocular comorbidities, which limits the generalizability of the findings for more complex cases. In addition, participants were required to effectively use digital or remote care, necessitating access to specific resources (phone or smartphone), digital skills, or assistance from a relative. These criteria may have introduced selection bias, further restricting the applicability to a broader cataract surgery population. To illustrate this, in the RCT assessing the Easee tool, 391 eligible patients were invited to participate. Of these, 293 patients were unwilling or unable to take part in the study. Among the nonparticipants, 141 reported either a lack of access to a smartphone, computer, or tablet, or difficulty performing the demo version of the test.[10] Moreover, patients opposed to digital or remote care may have declined participation, potentially skewing the results toward a more favorable response and limiting the generalizability of the findings to the broader population.

Current evidence does not support a fully remote care pathway for postoperative patients, although digital tools may partially replace follow-up visits, primarily for screening purposes. Integrating different telemedicine approaches could expand opportunities for remote monitoring, especially with anticipated innovations driven by artificial intelligence.[33] These interventions must be tailored to specific clinical settings to ensure patient-centered care all while carefully considering privacy concerns. Furthermore, since the timing of postoperative complications and symptoms can vary, this variability should be considered when designing remote care pathways, alongside the considerable differences in the timing of postoperative check-ups between countries and clinics.[1] Studies indicate that after uneventful cataract surgery, the first follow-up can safely be deferred until at least 2 weeks postoperatively.[34,35] Moreover, another study states that routine postoperative visits may not be necessary in uneventful cases without comorbidities, with personalized follow-up plans recommended only for patients with

comorbidities. To ensure patient understanding and compliance in these cases, effective preoperative counseling and patient education are essential.[36,37] Additionally, it is crucial that patients face no barriers when reaching out with questions, symptoms, or concerns. In this context, remote care could offer an effective solution, as patients using automated telephone calls reported greater convenience and reassurance, ensuring comprehensive follow-up for all patients.[23] Finally, cost-effectiveness is another crucial consideration in adopting remote or digital care. Although early evidence suggests that automated phone calls may yield potential savings, further research is needed to evaluate the overall cost-effectiveness of these approaches.[23] In addition, the implementation of remote or digital care must comply with healthcare quality standards like the obligatory requirement for outcome data input in cataract quality registries because reimbursement policies depend on evidence of cost-effectiveness, which may vary between countries.[38-40]

This review provides a comprehensive synthesis of the existing literature on digital and remote interventions for postoperative cataract care. Although preliminary evidence supports the feasibility of these interventions, the limited amount of published data, along with variable quality and study designs hinder the ability to formulate definitive recommendations for clinical practice. Despite these challenges, the growing interest in digital and remote care indicates a potential shift in cataract care delivery. Clinicians may consider digital remote screening to complement their traditional postoperative follow-up, but further research is essential for validation and to clarify the role of these interventions within the care pathway. Future research should aim to standardize methodologies, enhance comparability, and explore long-term outcomes, cost-effectiveness, and patient satisfaction to clarify the potential of remote care in the postoperative cataract management. Expected advancements in artificial intelligence are likely to expand the impact of digital care within ophthalmology.

Supplements

Supplementary material 7.1. Literature searches.

KSR Database
https://ksrevidence.com

Date searched: 29-02-2024
Records found: 316

1 Cataract* in All text
2 Phaco* in All text
3 lens in All text
4 #1 or #2 or #3 in All text
5 postoperative in All text
6 postop* in All text
7 post- in All text
8 after surg* in All text
9 post surg* in All text
10 #5 or #6 or #7 or #8 or #9 in All text
11 ehealth or internet* or digital* or monitor* or mhealth or remote* or tool* or tele* or app* or virtual* in All text
12 #4 and #10 and #11 in All text Date published: 2010 -

Ovid MEDLINE
Date searched: 29-02-2024
Records found: 3461

1. Exp Phacoemulsification/ or exp Lens Implantation, Intraocular/ or exp Cataract Extraction/ or Cataract/ or cataract surgery.mp.
2. Exp Lenses, Intraocular/ or opacification lens.mp. or exp Capsule Opacification/
3. cataract surg*.mp.
4. phaco*.mp.
5. cataract operation.mp.
6. lens.mp.
7. 1 or 2 or 3 or 4 or 5 or 6
8. Postoperative Period/ or Postoperative Care/ or postoperative.mp.
9. post surg*.mp.
10. after surg*.mp.
11. postop*.mp.
12. post-op*.mp.
13. 8 or 9 or 10 or 11 or 12
14. Telemedicine/
15. ehealth.mp.
16. mhealth.mp.

17. Remote Consultation/
18. medical informatics.mp. or Medical Informatics/
19. internet-based intervention.mp. or Internet/ or Internet-Based Intervention/
20. "Internet of Things"/
21. remote monitoring.mp.
22. mobile-health.mp.
23. videoconsultation.mp.
24. Telenursing/
25. smartphone.mp. or Computers, Handheld/ or Smartphone/
26. social media.mp. or Social Media/
27. application.mp. or Mobile Applications/
28. information technology.mp. or Information Technology/
29. online.mp. or Online Systems/
30. e-consult.mp.
31. remote.mp.
32. tele*.mp.
33. remote*.mp.
34. medical informat*.mp.
35. monitor*.mp.
36. app*.mp.
37. video*.mp.
38. Telephone/ or Text Messaging/
39. mail.mp.
40. e-mail.mp. or Electronic Mail/
41. distant care.mp.
42. e-health solutions.mp.
43. digital tool.mp.
44. connected health devices.mp.
45. Telecommunications/
46. healthcare platform.mp.
47. virtual care.mp.
48. tool*.mp.
49. artificial intelligence.mp. or Artificial Intelligence/
50. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49
51. 7 and 13 and 50
52. exp animals/ not (exp animals/ and humans/)
53. 51 not 52
54. limit 53 to yr="2010 -Current"

Embase (Ovid)
Date searched: 29-02-2024
Records found: 4794

1. cataract surgery.mp. or exp cataract extraction/
2. exp phacoemulsification/ or phacoemulcification.mp.

3. exp cataract/ or cataract.mp.
4. exp lens implantation/ or lens implantation.mp.
5. intraocular lens.mp. or exp lens implant/
6. Exp capsule opacification/ or opacification lens.mp.
7. cataract surg*.mp.
8. phaco*.mp.
9. cataract operation.mp.
10. lens/ or lens.mp.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. postoperative monitoring/ or postoperative period/ or postoperative care/ or postoperative.mp.
13. post surg*.mp.
14. after surg*.mp.
15. postop*.mp.
16. post-op*.mp.
17. 12 or 13 or 14 or 15 or 16
18. telemedicine.mp. or telemedicine/
19. ehealth.mp. or telehealth/
20. mhealth.mp.
21. remote consultation.mp. or teleconsultation/
22. medical informatics.mp. or medical informatics/
23. internet-based intervention.mp. or web-based intervention/
24. "internet of things"/ or Internet/ or internet.mp.
25. remote monitoring.mp.
26. mobile application/ or mobile-health.mp. or mobile health application/
27. videoconsultation.mp. or video consultation/
28. telenursing.mp. or telenursing/
29. smartphone.mp. or smartphone/
30. computer/ or computer.mp.
31. social media.mp. or social media/
32. application.mp.
33. information technology.mp. or information technology/
34. online.mp. or online system/ or online monitoring/
35. e-consult.mp.
36. remote.mp.
37. medical informat*.mp.
38. tele*.mp.
39. remote*.mp.
40. monitor*.mp.
41. app*.mp.
42. video*.mp.
43. telephone.mp. or telephone/
44. text messaging/
45. e-mail/ or mail.mp.
46. electronic mail.mp.
47. distant care.mp.

48. e-health solutions.mp.
49. digital tool.mp.
50. connected health devices.mp. or artificial intelligence/
51. telecommunications.mp. or telecommunication/
52. healthcare platform.mp.
53. virtual care.mp. or telecare/
54. tool*.mp.
55. artificial intelligence.mp.
56. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55
57. 11 and 17 and 56
58. exp animals/ not (exp animals/ and humans/)
59. 57 not 58
60. limit 59 to yr="2010 -Current"

CINAHL

Date searched: 29-02-2024
Records found: 745

S1 (MH "Cataract") OR "cataract" OR (MH "Cataract Extraction+") OR (MH "Phacoemulsification")
S2 (MH "Phacoemulsification") OR "phacoemulsification"
S3 (MH "Lenses, Intraocular") OR "intraocular lens"
S4 (MH "Lenses, Intraocular") OR "lens implantation" OR (MH "Lenses+")
S5 "cataract surgery"
S6 "opacification lens"
S7 "capsule opacification "
S8 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S9 (MH "Postoperative Period") OR (MH "Postoperative Care+") OR "postoperative"
S10 after surg*
S11 postop*
S12 post-op*
S13 post surg*
S14 S9 OR S10 OR S10 OR S12 OR S13
S15 (MH "Telemedicine") OR "telemedicine" OR (MH "Telehealth")
S16 "ehealth"
S17 "mhealth"
S18 (MH "Remote Consultation") OR "remote consultation"
S19 (MH "Medical Informatics") OR "medical informatics" OR (MH "Health Informatics")
S20 (MH "Internet-Based Intervention") OR "internet based intervention"
S21 (MH "Internet") OR "internet" OR (MH "Internet of Things")
S22 "remote monitoring"
S23 "mobile-health"

S24 “videoconsultation”
S25 (MH “Telenursing”) OR “telenursing”
S26 (MH “Smartphone”) OR “smartphone” OR (MH “Text Messaging”) OR (MH “Mobile Applications”) OR (MH “Computers, Hand-Held”) OR (MH “Cellular Phone”)
S27 (MH “Social Media”) OR “social media”
S28 “application”
S29 (MH “Information Technology”) OR “information technology”
S30 “online” OR (MH “Online Systems”)
S31 “e-consult”
S32 tele* OR remote OR medical informat* OR monitor* OR app* OR video*
S33 (MH “Telephone”) OR “telephone”
S34 (MH “Email”) OR (MH “Mail”) OR “mail”
S35 “distant care”
S35 “e-health solutions”
S36 “digital tool”
S37 (MH “Digital Health”)
S38 “connected health devices”
S39 (MH “Telecommunications”) OR “telecommunication”
S40 “healthcare platform”
S41 “virtual care”
S42 (MH “Artificial Intelligence”) OR “artificial intelligence”
S43 tool*
S44 (S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43)
S45 (S8 AND S24 AND S44)

The Cochrane CENTRAL Library
Date searched: 29-02-2024
Records found: 5265

#1	MeSH descriptor: [Cataract] explode all trees
#2	MeSH descriptor: [Cataract Extraction] explode all trees
#3	Cataract surg*
#4	phaco*
#5	cataract operation
#6	lens
#7	#1 or #2 or #3 or #4 or #5 or #6
#8	MeSH descriptor: [Postoperative Care] this term only
#9	MeSH descriptor: [Postoperative Period] this term only
#10	postoperative monitoring or postop* or post-op* or after surg* or post surg*
#11	#8 or #9 or #10
#12	MeSH descriptor: [Telemedicine] this term only
#13	MeSH descriptor: [Telecommunications] this term only
#14	MeSH descriptor: [Remote Consultation] this term only
#15	MeSH descriptor: [Medical Informatics] this term only
#16	MeSH descriptor: [Internet] this term only 5210
#17	MeSH descriptor: [Mobile Applications] this term only
#18	MeSH descriptor: [Internet-Based Intervention] this term only
#19	MeSH descriptor: [Telenursing] this term only
#20	MeSH descriptor: [Computers] this term only
#21	MeSH descriptor: [Smartphone] this term only
#22	MeSH descriptor: [Social Media] this term only
#23	MeSH descriptor: [Electronic Mail] this term only
#24	MeSH descriptor: [Artificial Intelligence] this term only
#25	tele* or Tool* or ehealth or mhealth or remote consultation or teleconsultation or medical informatics or internet or online or remote monitoring or mobile application or mobile-health or telenursing or smarphone or computer or social media or app* or information technology or online monitoring or e-consult or remote or medical informat* or remote* or monitor* or video* or telephone or text messaging or mail or e-mail or distant care or e-health solutions or telecommunication or healthcare platform or virtual care
#26	#12 or #13 or # 14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25
#27	#7 and #11 and #26 with Cochrane Library publication date from Jan 2010 to present

Supplementary material 7.2. Risk of bias assessment tables.

Table A. Quality assessment randomized controlled trials.

		Risk of bias domains RoB2 tool					
		Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall
Study	**Claessens 2024**	Low	Low	Low	Low	Low	Low
	Digin 2022	High	High	Low	High	Unclear	High
	Machado 2020	Low	Low	Low	Low	Low	Low
	Ruiss 2024	Low	Low	Unclear	High	Low	High

Domain 1: Bias arising from the randomization process

Domain 2: Bias due to deviations from the intended intervention

Domain 3: Bias due to missing outcome data

Domain 4: Bias in measurement of the outcome

Domain 5: Bias in selection of the reported result

Table B. Quality assessment cohort studies.

		Risk of bias domains JBI checklist cohort studies											
		1	2	3	4	5	6	7	8	9	10	11	Overall
Study	**Dole 2023**	Unclear	✓	×	✓	Unclear	✓	Unclear	✓	✓	✓	Unclear	High
	Sanguansak 2017	✓	✓	✓	✓	✓	Unclear	✓	✓	×	Unclear	✓	High

Domain 1: Recruitment study groups

Domain 2: Similar exposure in study groups

Domain 3: Measurement of exposure

Domain 4: Confounding factors

Domain 5: Strategies for confounding factors

Domain 6: Presence outcome at start of study

Domain 7: Measurement outcomes

Domain 8: Follow-up time

Domain 9: Complete follow-up

Domain 10: Strategies for incomplete follow-up

Domain 11: Statistical analysis

Table C. Quality assessment case series.

		Risk of bias domains JBI checklist case series										
		1	2	3	4	5	6	7	8	9	10	Overall
Study	**Al-Ani 2023**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Low
	Gordon 2021	✓	✓	✓	×	×	×	Unclear	×	Unclear	Unclear	High
	Hoffman 2016	✓	✓	✓	✓	✓	✓	Unclear	Unclear	Unclear	✓	Unclear
	Khavandi 2023	✓	✓	✓	Unclear	Unclear	✓	✓	✓	Unclear	✓	Unclear
	Lecumberri 2023	Unclear	✓	✓	Unclear	Unclear	✓	Unclear	✓	Unclear	✓	Unclear
	Meinert 2024	✓	✓	✓	✓	✓	✓	Unclear	✓	✓	✓	Unclear
	Tan 2014	✓	✓	✓	✓	✓	✓	Unclear	✓	Unclear	✓	Unclear
	Wanten 2023	✓	✓	✓	✓	Unclear	✓	✓	✓	Unclear	✓	Unclear

Domain 1: Selection criteria

Domain 2: Measurement of condition

Domain 3: Condition identification

Domain 4: Consecutive inclusion

Domain 5: Complete inclusion

Domain 6: Participant demographics

Domain 7: Clinical information participants

Domain 8: Reporting outcomes

Domain 9: Reporting site(s)/clinic(s) demographic information

Domain 10: Statistical analysis

Supplementary material 7.3. Data extraction per intervention type.

Table A. Telephone consultation.

	Comparative study			Non-comparative study		
Author, Year	**Machado, 2020**	**Ruiss, 2024**	**Dole, 2023**	**Al-Ani, 2023**	**Hoffman, 2016**	**Tan, 2014**
Country	Brazil	Austria	India	New Zealand	United Kingdom	Singapore
Study design	Randomized controlled trial	Randomized controlled trial	Prospective cohort-study	Retrospective cases series	Prospective case series	Case series
Type of intervention	Telephone consultation	Telephone consultation	Telephone consultation	Telephone consultation	Telephone consultation	Telephone consultation
Specified	Telephone	Telephone	Telephone, Peek Acuity application	Telephone	Telephone	Telephone
Comparison	Regular care	Regular care	Regular care	No	No	No
Control group	Yes	Yes	Yes	No	No	No
Duration of participation	Up to 1 month	Up to 1 week	Up to 2 months	Up to 1 month	Up to 1 month	Up to 2 weeks
Inclusion criteria	Adults cataract patients	Adults cataract patients	Adult cataract patients	Adult cataract patients	Adult cataract patients	Adult cataract patients
Exclusion criteria	Unable to perform phone-based follow-up (language, hearing, cognitive issues)	Unable to perform phone-based follow-up (language, equipment)	Ocular diseases, Not able to perform phone-based follow-up (language, equipment, skills)	Not able to attend calls or visits, complications, operated by residents	Unable to perform phone-based follow-up (language, equipment, skills), complications, ocular comorbidities	Intraoperative complications
Sample size (n)	95	200	240	930	50	260

	Comparative study						Non-comparative study		
Withdrawals, reason for withdrawals (n)	0		19: LFU (17), Surgery cancelled (2)		0		2: LFU (2)	1: LFU (1)	22: LFU (22)
Group differences	None		None		None		NA	NA	NA
Study groups	Intervention (n=48)	Control (n=47)	Intervention (n=89)	Control (n=92)	Intervention (n=120)	Control (n=120)	Intervention	Intervention	Intervention
Age (mean ± SD)	71		72	73	Median 51-60	Median 51-60	Median 74.2 (IQR 66.5-80.2)	80 ± 8	68
Gender (M/F)	34/61		31/58	44/48	64/56	55/65	337/591	23/27	101/137
Ethnicity/ Roots	NR		NR	NR	NR	NR	NR	NR	Asian
Comorbidities (n)	NR		Corneal pathology (6)	Corneal pathology (6), previous eye surgery (1)	None	None	Glaucoma (15)	None	Retinal (19), Amblyopia (1), Neuropathy (2), Inflammation (3), Glaucoma (1), High myopia (2)
Other treatment received (n)	None		Additional non-surgical therapy (35)	Additional non-surgical therapy (31)	NR	NR	IVI (9)	None	Glaucoma treatment (1)
Period of treatment	Multiple	Multiple	Single	Single	Multiple	Multiple	Single	Single	Single

	Comparative study						Non-comparative study		
Start of intervention	1-3 days	1-3 days	Directly postoperatively (n=46) or within 1-3 days (n=43)	<1 week	1-3 days	<3 months	1-3 days	<1 month	1-3 days
Timing of measurement from start	Up to 1 month	Up to 1 month	Within 1-3 days	Up to 1 week	Within 1-3 days	Within 1-3 days	Within 1-3 days	Up to 1 month	Up to 2 weeks
Resource requirements	Personnel, telephone	Personnel	Personnel, telephone	Personnel	Smartphone, application	Personnel	Personnel, telephone	Personnel, telephone	Personnel, telephone
Test time	<1 h	NR	NR	NR	NR	NR	<15 minutes	<15 minutes	NR
Provider	Ophthal-mologist	Nurse, nursing specialists	Medical staff	Medical staff	NR	NR	Optometrist, Nurse	Resident, Nurse	Nurse
Type of outcomes	Safety		Safety, PROMs		Safety, (Visual Acuity), PROMs		Safety	Safety, PROMs	Safety
Specify measurement	Delayed Surgical Recovery (DSR)		Visits and additional therapy, complaints, satisfaction		(S)AE, (UDVA), Satisfaction (5-point scale)		(S)AE	(S)AE, Satisfaction (10-point scale)	(S)AE
Effectiveness outcome: Safety	DSR (n=48) n (%) Day 1: 0 (0) Day 7: 3 (6.3) Day 30: 2 (4.2)	DSR (n=48) n (%) Day 1: 0 (0) Day 7: 17 (36.2) Day 30: 6 (12.8)	Unplanned control at 1 week (n=89): 6 Additional therapy at 1 week (n=89): 5	Unplanned control at 1 week (n=92): 7 Additional therapy at 1 week (n=92): 9	Complications: (n) Day 1: 39 Day 7: 7 Day 30: 6	Complications: (n) Day 1: 44 Day 7: 7 Day 30: 5	Patients with complication at one month, n (%): 110 (11.2%), including inflammation 62 (6.3%), CME 46 (4.7, and IOP spike 2 (0.2%)	Patients with complaints, n (%): 14 (28%) ocular discomfort, 5 (10%) pain at one month. No complications reported.	Patients with complications, n (%): 1 (0.4%) IOP rise day 1
	Comparison DSR Day 1: p=1.000 Day 7: p=0.000 Day 30: p=0.159		Comparison 1 week Unplanned control: p=1.00 Additional therapy: p=0.561		Comparison complications Day 1: p=0.003 Day 7: p=0.54 Day 30: p=0.32				

	Comparative study			Non-comparative study
Effectiveness outcome: PROMs	Satisfied call Same day: 91% Next day: 84%	Overall satisfaction (n=120): Mean ± SD (95% CI) 3.74 ± 0.23 (3.70;3.78)	Overall satisfaction (n=120): Mean ± SD (95% CI) 3.72 ± 0.27 (3.67;3.77)	Mean overall satisfaction (n=50): 8.9 Preference telephone follow-up n, (%): 38 (75.5%) Telephone follow-up was more convenient n, (%): 40 (81.6%)

CME=cystoid macular edema; DSR=delayed surgical recovery; IOP=intraocular pressure; IQR=interquartile range; IVI=intravitreal injection; LFU=lost to follow-up; NA=not applicable; NR=Not reported; PROM=patient reported outcome measure; (S)AE=(serious) adverse event; SD=standard deviation; UDVA=uncorrected distance visual acuity

Table B. Messaging.

	Comparative study			
Author, Year	**Digin, 2022**		**Sanguansak, 2017**	
Country	Turkey		Thailand	
Study design	Randomized controlled trial		Prospective cohort study	
Type of intervention, specified	Messaging, Short Message Service (SMS)		Messaging, LINE app	
Comparison	Regular patient education		Regular patient education	
Control group	Yes		Yes	
Duration of participation	Up to 1 week		Up to 1 month	
Inclusion criteria	Adult cataract patients		Adult cataract patients	
Exclusion criteria	(History of) psychiatric disease or using psychiatric medication, language, unable to receive messages		No previous eye surgery, unable to use the application, vulnerable population (prisoners, mental illness, pregnant women)	
Sample size (n)	82		98	
Withdrawals, reasons for withdrawal (n)	0		6: NR	
Group differences	Imbalances in people living together vs people living alone		Imbalances in age and surrogate users of LINE app	
Study groups	Intervention (n=41)	Control (n=41)	Intervention (n=49)	Control (n=49)
Age (mean ± SD)	57.2 ± 5.7	58.0 ± 7.2	64	68
Gender (M/F)	13/28	19/22	24/25	29/20
Ethnicity/Roots	NR	NR	NR	NR
Comorbidities (n)	Yes (23), No (18) (Not further specified)	Yes (29), No (12) (Not further specified)	NR	NR
Other treatment received	No	No	NR	NR
Period of treatment	Multiple	Single	Multiple	NA
Start of intervention	1-3 days postoperatively	Directly postoperatively	Directly after surgery	1-3 days postoperatively
Timing of measurement from start	Up to 1 week	Up to 1 week	Up to 1 month	Up to 1 month
Resource requirements	Personnel, Telephone	Personnel	Smartphone, Application	Personnel

	Comparative study			
Test time	NR	NR	NR	NR
Provider	Researcher, Clinical nurse	Nurse	NR	NR
Type of outcomes	PROMs		PROMs, safety	
Specify measurement	State Anxiety Inventory (SAI) Questionnaire (scores ranging between 20-80)		Morisky Medication Adherence Scale Questionnaire (MMAS-8; 8-point scale), (S)AE, visit adherence, visual acuity	
Effectiveness outcome: PROMs	Difference preoperative and postoperative SAI Mean ± SD, (95%LoA) 24.9 ± 9.2 (6.87;42.93)	Difference preoperative and postoperative SAI Mean ± SD, (95%LoA) 21.5 ± 10.5 (0.92;42.08)	MMAS-8 n, (%) 7 days postop high / low and medium score: 47 (96%) / 2 (4%) 30 days postop high / low and medium score: 43 (88%) / 6 (12%) Comparison high score vs. low and medium score at 7 days postop: p=0.004 Comparison high score vs. low and medium score at 30 days postop: p=0.74	MMAS-8 n, (%) 7 days postop high / low and medium score: 36 (73%) / 13 (27%) 30 days postop high / low and medium score: 41 (91%) / 4 (9%)
Effectiveness outcome: Safety Mean ± SD (95% CI)			Outcomes 7 days / 30 days postop Visit adherence: 100% / 100% Visual acuity (logMAR): 0.19 ± 0.25 (0.12;0.26) / 0.19 ± 0.25 (0.12;0.26) IOP (mmHg): 11.71 ± 2.61 (11.00;12.40) / 13.16 ± 3.42 (12.20;14.12) Intraocular inflammation (cells/mm^2): 0.33 ± 0.62 (0.16;0.50) / 0.00 ± 0.00	Outcomes 7 days / 30 days postop Visit adherence: 100% / 88% Visual acuity (logMAR): 0.36 ± 0.43 (0.24;0.48) / 0.36 ± 0.78 (0.14;0.58) IOP (mmHg): 12.31 ± 3.09 (11.40;13.20) / 12.22 ± 3.62 (11.21;13.23) Intraocular inflammation (cells/mm^2): 0.38 ± 0.53 (0.23;0.53) / 0.00 ± 0.00

CI=Confidence Interval; IOP=intraocular pressure; MMAS-8=Morisky Medication Adherence Scale-8; NR=not reported; LoA=limits of agreement; PROM=patient reported outcome measure; (S)AE=(serious) adverse event; SAI=State Anxiety Inventory; SD=standard deviation

Table C. Automated phone calls.

	Non-comparative study	
Author, Year	**Khavandi, 2024**	**Meinert, 2024**
Country	United Kingdom	United Kingdom
Study design	Prospective case series	Prospective case series
Type of intervention, specified	Automated phone calls, Dora	Automated phone calls, Dora
Comparison	No	No
Duration of participation	Up to 1 month	Up to 3 months
Inclusion criteria	Adult patients after uncomplicated routine cataract surgery	Adult patients planned for routine cataract surgery
Exclusion criteria	Unable to perform phone-based follow-up (language, hearing or cognitive issues), combined surgeries, complex ocular comorbidities.	Unable to perform phone-based follow-up (language, hearing or cognitive issues), combined surgeries, complex ocular comorbidities.
Sample size (n)	177	225
Withdrawals, reasons for withdrawal (n)	3: Time burden (3)	30: LFU (14), AE (1), Health-related issue (8), Incomplete call (7)
Group differences	NA	NA
Age (mean ± SD)	Median 76 ± 10	74 ± 8.96
Gender (M/F)	77/100	86/116
Ethnicity/Roots	NR	White (160), Asian (23), Black (11), Other (17)
Other treatment received	None	None
Period of treatment	Single	Single
Start of intervention	<1 month postoperatively	<1 month postoperatively
Timing of measurement from start	Up to 2 months	<1 month
Resource requirements	Telephone	Telephone
Test time	NR	<15 minutes
Provider	Telemedicine providers	Telemedicine providers
Type of outcomes	PROMs	Diagnostic accuracy, PROMs, Costs

	Non-comparative study	
Specify measurement	NPS (10-point scale), Telehealth Usability Questionnaire (TUQ; 5-point scale)	Sensitivity, specificity, Cohens kappa agreement, NPS (10-point scale), System Usability Scale (SUS; 5-point scale), Telehealth Usability Questionnaire (TUQ; 5-point scale), Cost savings
Effectiveness outcome:		Overall decision-making (95%CI)
Diagnostic accuracy, sensitivity, specificity, and Kappa agreement		Accuracy: 88.72% (83.42;92.79) Sensitivity: 93.75% (84.76;98.27) Specificity: 86.26% (79.16;91.56) Kappa agreement: 0.758 (0.664;0.852)
Effectiveness outcome: PROMs Mean ± SD, (95%CI)	NPS (n=170): 8.55 ± 1.67 (8.30;8.80) TUQ (n=21): 3.96 ± 0.47 (3.76;4.16)	NPS (n=195): 8.59 ± 2.05 (8.30;8.88) SUS (n=20): 77.76 ± 17.55 (70.10;85.50) TUQ (n=20): 3.79 ± 0.89 (3.40;4.18)

LFU=Lost to follow-up; NPS=Net Promoter Score; NR=not reported; PROM=patient reported outcome measure; (S)AE=(serious) adverse event; SAI=State Anxiety Inventory; SD=standard deviation; SUS=System Usability Scale; TUQ=Telehealth Usability Questionnaire

Table D. Mobile application/software.

	Comparative study		Non-comparative study		
Author, Year	**Claessens, 2024**		**Wanten, 2023**	**Lecumberri, 2023**	**Gordon, 2021**
Country	The Netherlands, Germany, Austria		The Netherlands	Spain	United States of America
Study design	Randomized controlled trial		Case series	Prospective case series	Case series
Type of intervention	Mobile app/software, Easee VA test		Mobile app/ software, Easee VA test	Mobile app/ software, BOOST VA assessment	Mobile app/ software, DYOP Online VA test
Comparison	ETDRS/Snellen		ETDRS/Snellen	None	Snellen
Control group	Yes		NA	NA	NA
Duration of participation	Up to 3 months		NR	Up to 2 months	NR
Inclusion criteria	Adult patients undergoing bilateral cataract surgery		Adult patients (18-69 years old) after cataract surgery	Patients who underwent cataract surgery	Adult patients (>40 years) undergoing cataract surgery
Exclusion criteria	Combined surgery, comorbidities affecting visual acuity, unable to perform test (language, hearing, cognitive issues)		Unable to perform the test (language)	Absence pupillary light reflex, retinal pathology	Ocular comorbidities
Sample size (n)	94		46	126	59
Withdrawals, reasons for withdrawal (n)	1: LFU (1)		0	4: NR	NR
Group differences	None		NA	NA	NA
Study groups	Intervention (n=44)	Control (n=50)	Intervention	Intervention	Intervention
Age (mean ± SD)	70 ± 6	70 ± 8	62.8 ± 7.1	75.8 ± 12.2	NR
Gender (M/F)	23/21	23/27	24/22	60/66	NR
Ethnicity/Roots	Dutch (34), German (3), Austrian (7)	Dutch (38), German (3), Austrian (9)	NR	NR	NR
Comorbidities (n)	Refractive surgery (3), Strabismus surgery (1)	Strabismus surgery (1)	NR	NR	None

	Comparative study		Non-comparative study		
Other treatment received	None	None	None	NR	NR
Period of treatment	Multiple	Multiple	Single	Single	Single
Start of intervention	<1 week postoperatively	<1 week postoperatively	NR	1-3 days postoperatively	NR
Timing of measurement from start	Up to 3 months	Up to 3 months	NR	1-3 days	NR
Resource requirements	Smartphone/ Laptop, Easee tool	Personnel	Smartphone/ Laptop, Easee tool	Smartphone, BOOST application	DYOP chart
Test time	NR	NR	<15 minutes	NR	NR
Provider	Telemedicine providers	Optometrist	Telemedicine providers	Telemedicine providers	NR
Type of outcomes	Visual acuity, Refraction, Safety, PROMs		Visual acuity, PROMs	Visual acuity	Visual acuity
Specify measurement	UDVA, CDVA, SEQ, (S)AE, Questionnaire of technology acceptance (5-point scale)		UDVA, CDVA, Questionnaire confidence towards tool (5-point scale)	UDVA	UDVA
Effectiveness outcome: visual acuity Mean ± SD	Difference ETDRS UDVA (logMAR) (95%LoA) OD and OS (n=88): -0.03 ± 0.14 (-0.30;0.24)		Difference ETDRS UDVA (logMAR) (95%LoA) OD (n=41): -0.07 ± 0.10 OS (n=34): -0.04 ± 0.10 Overall LoA (-0.26;0.15)		Difference Snellen UDVA (Decimal) (95%CI) OD (n=26): 0.17 ± 0.23 (0.08;0.26)[a] OS (n=24): 0.12 ± 0.20 (0.04;0.20)[a]
Effectiveness outcome: refraction Mean ± SD, (95%CI)	Difference Manifest SEQ (D) OD and OS (n=88): -0.32 ± 0.43 (-0.41;-0.23)				

	Comparative study		Non-comparative study
Effectiveness outcome: diagnostic accuracy	Unexpected consultations intervention/control (n): 7 / 12		Kappa agreement BOOST (day 1) and 6-week regular UDVA Kappa ± SE (95%CI): (n=126) 0.35 ± 0.07 (0.48;-0.21)
Effectiveness outcome: PROMs Mean ± SD, (95%CI)	Questionnaire technology acceptability (n=22) 3.70 ± 0.97 (3.29;4.11)	Questionnaire experiences tool (n=46) 4.05 ± 0.39 (3.94;4.16)	

[a]The methods calculating these outcomes are questionable.

CI=confidence interval; CDVA=corrected distance visual acuity; D=diopter; LFU=lost to follow-up; LoA=limits of agreement; NPS=Net Promoter Score; NR=not reported; PROM=patient reported outcome measure; (S)AE=(serious) adverse event; SAI=State Anxiety Inventory; SUS=System Usability Scale; TUQ=Telehealth Usability Questionnaire; SD=standard deviation; SE=standard error; SEQ=spherical equivalent; UDVA=uncorrected distance visual acuity

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CHAPTER 8

Evaluation of a Visual Acuity eHealth Tool in Patients with Cataract

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Abstract

Purpose: To validate the Easee web-based tool for the assessment of visual acuity in patients who underwent cataract surgery.

Setting: University Eye Clinic Maastricht, Maastricht, the Netherlands.

Design: Prospective method comparison study.

Methods: Subjects aged between 18 and 69 years who underwent cataract surgery on 1 or both eyes at the Maastricht University Medical Center+ were eligible to participate in this study. The uncorrected (UDVA) and corrected distance visual acuity (CDVA) assessments were performed using the web-based tool (index test) and conventional ETDRS and Snellen charts (reference tests). The outcomes of the different tests were expressed in logMAR, and a difference of <0.15 logMAR was considered clinically acceptable.

Results: 46 subjects with 75 operated eyes were included in this study. The difference of the UDVA between the web-based tool and ETDRS or Snellen was -0.05 ± 0.10 logMAR ($p<0.001$ [0.15; -0.26]) and -0.04 ± 0.15 logMAR ($p=0.018$ [0.24; -0.33]), respectively. For the CDVA, these differences were -0.04 ± 0.08 logMAR ($p<0.001$ [0.13; -0.21]) and -0.07 ± 0.10 logMAR ($p<0.001$ [0.13; -0.27]), respectively. The Pearson correlation coefficients between the web-based tool and ETDRS were maximally 0.94 and compared with Snellen 0.92. In total, 73% to 88% of the visual acuity measurement differences were within 0.15 logMAR.

Conclusions: The web-based tool was validated for the assessment of visual acuity in patients who underwent cataract surgery and showed clinically acceptable outcomes in up to 88% of patients. Most of the participants had a positive attitude toward the web-based tool, which requires basic digital skills.

Introduction

Cataract is the world's leading cause of age-related vision loss.[1] During the past few decades, it has become one of the most performed surgeries worldwide and the number of procedures is likely to increase.[2] The corresponding postoperative care includes frequent and rather time-consuming routine check-up appointments. In combination with the low incidence of serious sight-threatening complications, optimizing the postoperative cataract care pathway through eHealth technology is a logical next step in improving the patient journey.

The efficiency of the postoperative care could be enhanced by using remote care using teleconsultation and (online) remote measurements. Over the past few years, organizing remote care has accelerated, partly because of the COVID-19 pandemic.[3] Several clinics have already implemented this kind of care and replaced 1 or more regular clinical follow-up examinations by telephone consultations.[4] However, these teleconsultations are only partly applicable in ophthalmologic care because they lack objective outcome parameters for visual acuity and refractive state. Upcoming eHealth applications which provide the opportunity of self-monitoring and collecting objective outcome parameters may offer a solution. Utilization of these applications will lower the burden on patients after cataract surgery by saving follow-up visits at the outpatient clinic, which may improve efficiency and lower costs. The increased use of digital tools in general supports the implementation of eHealth solutions.

One of these eHealth applications is the Easee web-based tool that allows patients to individually assess their visual acuity and corresponding refraction using a smartphone and computer screen. Recently, noninferiority was shown for refraction measurements of this tool compared with manifest refraction obtained from standard measurements at the outpatient clinic in a healthy study population. Besides, the web-based tool and ETDRS chart showed similar results for the uncorrected distance visual acuity (UDVA) with mean values of 0.33 ± 0.30 logMAR and 0.39 ± 0.39 logMAR (p=0.21), respectively.[5]

The aim of this study was to validate the web-based tool for assessment of the visual acuity in patients who underwent cataract surgery. We hypothesize agreement between the visual acuity measurements performed by the web-based tool as compared with the conventional assessments.

Methods

Test-Retest

Firstly, a test–retest analysis was performed among 5 healthy volunteers by measuring the right eye UDVA using the Snellen, ETDRS visual acuity charts, and the web-based tool. The measurements were performed at 3 different dates by the same individual under the same controlled and optimized circumstances, providing an indication of intraindividual variability of these tests.

Study design and recruitment

From November 2020 to March 2021, a total of 46 participants were recruited from the University Eye Clinic of Maastricht University Medical Center (MUMC+). Subjects were eligible if they were aged between 18 and 69 years, underwent cataract surgery on one or both eyes, and were able to perform the web-based tool in Dutch, German, or English. The age limit of 69 years was selected based on the data of European statistics concerning digital skills to minimize the effects of digital proficiency on study outcomes.[6] All participants were informed about the study in advance and signed an informed consent before enrolment. This hospital-based validation study was approved by the local medical ethics committee and institutional review board of the MUMC+ (Maastricht, the Netherlands). The study was executed in accordance with the tenets of the Declaration of Helsinki.

Conventional (reference tests) and web-based (index-test) assessments

Both UDVA and corrected distance visual acuity (CDVA) were assessed using the Snellen and ETDRS charts as reference tests. The Snellen chart was routinely assessed by an optometrist at the postoperative visit before study enrolment. For the Snellen chart, the line assessment method was used. After study enrolment, visual acuity was assessed using the ETDRS chart by the researcher. The chart was placed 4 m from the subject, and the last attempted line on the ETDRS chart was determined until no optotypes could be distinguished. The total number of correctly identified optotypes was added to the score of the last attempted line to determine a logMAR score. Monocular CDVA measurements were performed using trial frames with the subjective manifest refraction as routinely measured by the optometrist.

The web-based tool (Easee B.V.) is an online visual function test using a computer screen and a smartphone (**Figure 8.1**). The smartphone is used as a remote controller to submit

the input of the user from a distance of 3 m from the computer screen. All participants performed the web-based tool at the outpatient clinic after their (regular) postoperative visit, under controlled and optimized conditions, using a commonly used smartphone (Samsung Galaxy S6) and a laptop (Dell Latitude 5501, 15.6 inch). The test consisted of 3 parts with audio and visually instructed guidance: intake, arrangement of the test (calibrating and connecting the screen, placing a chair at 3 m distance), and performing the test. A short demo video illustrated the purpose of the web-based tool. During the test, a sequence of optotypes (tumbling-E and proprietary optotypes) was displayed that had to be identified correctly by the subject. The application used built-in algorithms to check the consistency of the input.

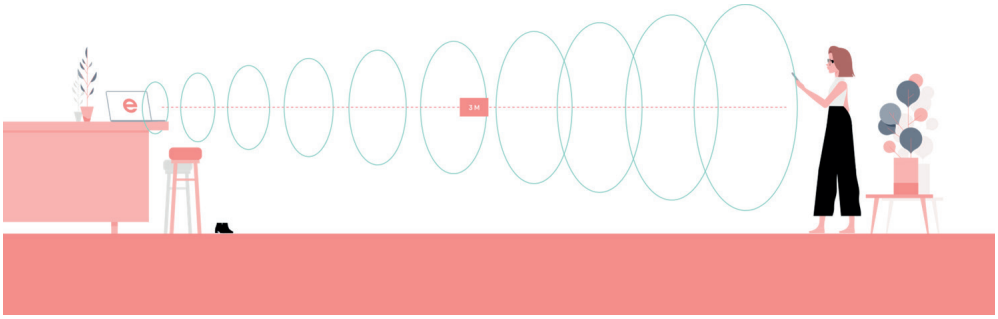


Figure 8.1. The web-based tool is performed by the patient by using a computer, 3 m distance, and a smartphone used as a remote controller.

All participants performed the web-based test twice. Firstly, monocular UDVA measurements were performed and secondly monocular CDVA measurements. CDVA was assessed using trial frames with the subjective manifest refraction as used during the reference tests. Subjects could get assistance in using the smartphone and were reminded to cover up the appropriate eye during the tests. The amount of time the participants needed to perform the web-based tool was collected. Online refractive measurements were not performed in this study.

All assessments were performed using a fixed sequence: All operated eyes were routinely examined performing the Snellen UDVA and CDVA, first left and then the right eye. Subsequently, the researcher conducted the ETDRS measurements followed by measurements using the web-based tool in the same abovementioned sequence. All participants were unaware of their results.

Questionnaires

An exploratory questionnaire was performed to assess pretest and posttest confidence of subjects toward the web-based tool. Questions pertained to the recommendation of the web-based tool to other patients, to the level of confidence of the subjects in their results, and to the amount of assistance during the tests. Outcomes were scored for every individual subject using a Likert scale (ranging from “strongly agree” to “strongly disagree”). In addition, the digital skills indicator survey, derived from the Eurostat survey on ICT usage by individuals, was performed.[7]

Sample size

The sample size calculation of 46 participants was based on a desired limit of agreement (LoA) of 0.01 logMAR and an assumed SD of 0.02 logMAR.[8]

Statistical analysis

Analyses were performed using SPSS (v. 25, IBM Corp.). An outcome was considered statistically significant when the p-value was ≤0.05. Frequencies and descriptive statistics were used to summarize the baseline criteria and analyze the distribution of the variables. Left and right eyes were analyzed both separately and combined.

When using the ETDRS and web-based tool, UDVA and CDVA were expressed in logMAR. Each optotype of the ETDRS chart had a score of 0.02 log units, and 1 line represented 0.10 logMAR. The Snellen test was measured in decimals and afterward converted to logMAR. The analysis of variance between the web-based tool, Snellen, and ETDRS charts was performed using general linear model–repeated measures. Differences between visual acuity outcomes of the individual tests were compared using paired t tests. Data were displayed in scatterplots, and the related Pearson correlation coefficients were calculated. Bland Altman plots were used to visualize the agreement between the web-based tool and the reference tests.[9] A difference ≥0.15 logMAR was considered clinically relevant because this is the usual intraindividual variability in repeated visual acuity measurements.[10-12]

Results

Firstly, a small test–retest sample was performed among 5 healthy volunteers and showed SDs for the ETDRS of 0.05 logMAR, Snellen 0.04 logMAR, and web-based tool of 0.08

logMAR. The study population consisted of 22 women (48%) and 24 men (52%) with a mean age of 62.8 ± 7.1 years (ranging from 26 to 69 years). Bilateral cataract surgery was performed in 29 patients (63%). The manifest refraction spherical equivalent (MRSE) was −0.41 ± 0.84 diopters (D) for 41 operated right eyes and −0.64 ± 1.33 D for 34 operated left eyes. Most of the 44 patients (96%) had basic digital skills.

A total of 75 operated eyes completed the assessments using the web-based tool and the conventional ETDRS chart. Outcomes of the web-based tool, Snellen, and ETDRS chart showed a significant visual acuity underestimation of the index test, when compared with the reference tests for right UDVA and CDVA, and left CDVA (**Table 8.1**). The differences between the visual acuity outcomes of the web-based tool were maximally −0.07 ± 0.10 logMAR (p<0.001) compared with the ETDRS chart and had a maximal value of −0.08 ± 0.12 logMAR (p<0.001) compared with the Snellen chart. The correlation ranged from 0.70 to 0.94 and up to 88.2% of the web-based outcomes was within the clinically significant difference cutoff value of ± 0.15 logMAR (**Table 8.2**).

Table 8.1. Outcomes of different visual acuity assessments.

	Visual acuity test	N	Mean ± SD (logMAR)	Variance p-value
UDVA RE	ETDRS	41	0.15 ± 0.30	0.001
	Snellen	39	0.17 ± 0.38	
	Web-based	41	0.22 ± 0.30	
UDVA LE	ETDRS	34	0.14 ± 0.27	0.060
	Snellen	32	0.11 ± 0.23	
	Web-based	34	0.17 ± 0.27	
CDVA RE	ETDRS	41	0.03 ± 0.22	0.002
	Snellen	37	-0.04 ± 0.12	
	Web-based	41	0.06 ± 0.21	
CDVA LE	ETDRS	34	-0.03 ± 0.15	<0.001
	Snellen	33	-0.05 ± 0.08	
	Web-based	34	0.02 ± 0.14	

Mean UDVA and CDVA scores of the right and left eyes in logMAR (± SD). The variance (p-values) between the web-based tool, Snellen, and ETDRS charts was assessed using general linear model-repeated measures.

LE=left eye; RE=right eye; SD=standard deviation

Table 8.2. Comparison of visual acuity outcomes of different tests.

	Difference between tests	Mean ± SD (logMAR)	p-value	Pearson Correlation[a]	% within ± 0.15 logMAR
UDVA RE	ETDRS – Web-based	-0.07 ± 0.10	<0.001	0.94	82.9
	Snellen – Web-based	-0.04 ± 0.16	0.125	0.92	76.9
	ETDRS – Snellen	-0.03 ± 0.13	0.172	0.95	76.9
UDVA LE	ETDRS – Web-based	-0.04 ± 0.10	0.037	0.93	88.2
	Snellen – Web-based	-0.04 ± 0.13	0.060	0.88	75.0
	ETDRS – Snellen	0.00 ± 0.11	0.925	0.90	87.5
CDVA RE	ETDRS – Web-based	-0.03 ± 0.09	0.029	0.91	85.4
	Snellen – Web-based	-0.08 ± 0.12	<0.001	0.70	73.0
	ETDRS – Snellen	0.04 ± 0.09	0.013	0.84	89.2
CDVA LE	ETDRS – Web-based	-0.05 ± 0.08	0.001	0.84	85.3
	Snellen – Web-based	-0.06 ± 0.08	<0.001	0.72	81.8
	ETDRS – Snellen	0.01 ± 0.09	0.697	0.68	90.9

Outcomes paired t-tests and Pearson correlations between the different visual acuity tests. [a]All outcomes of the Pearson correlation coefficients had a p-value of <0.001.

CDVA=corrected distance visual acuity; LE=left eye; RE=right eye; SD=standard deviation; UDVA=uncorrected distance visual acuity

The correlation coefficients between the web-based tool and ETDRS chart of both eyes combined for UDVA and CDVA were 0.94 and 0.89, respectively (both p<0.001) (**Figures 8.2A and 8.3A**). The corresponding Bland Altman plots showed 95% LoAs ranging from 0.15 to −0.26 logMAR and 0.13 to −0.21 logMAR, respectively (**Figures 8.2B and 8.3B**). For the comparison between the scores of the web-based tool and Snellen chart, scatterplots and corresponding Bland Altman plots can be found in the **Supplementary Figures 8.1 and 8.2**. The Snellen CDVA score had a statistically significant mean difference of maximally −0.08 ± 0.12 logMAR with the web-based outcomes. The UDVA and CDVA between Snellen and the web-based tool had a correlation coefficient of 0.89 and 0.71 (both p<0.001), respectively. The 95% LoA ranged from 0.24 to −0.33 logMAR for the UDVA and from 0.13 to −0.27 logMAR for the CDVA.

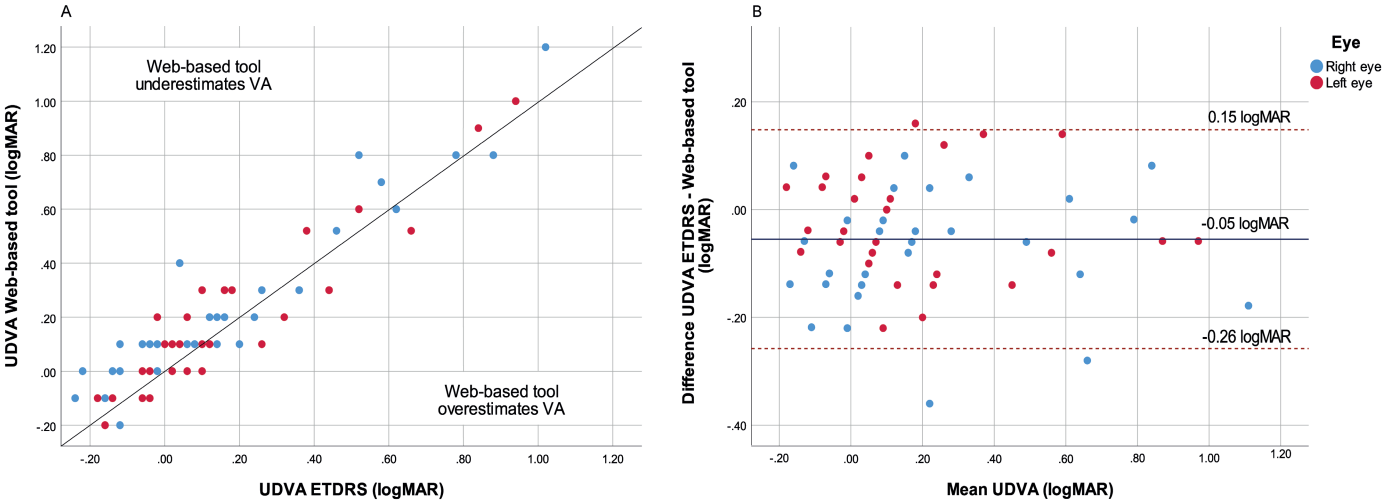


Figure 8.2. Comparison UDVA web-based tool and ETDRS chart.

A. Scatterplot UDVA of the web-based tool and ETDRS chart for the right and left eyes. The line presents the line of equality. B. Bland-Altman plot of UDVA determined by the web-based and ETDRS chart. The blue line represents the mean value, and the red dashed lines represent the ± 1.96 SD (95% limits of agreement).

UDVA=uncorrected distance visual acuity; SD=standard deviation

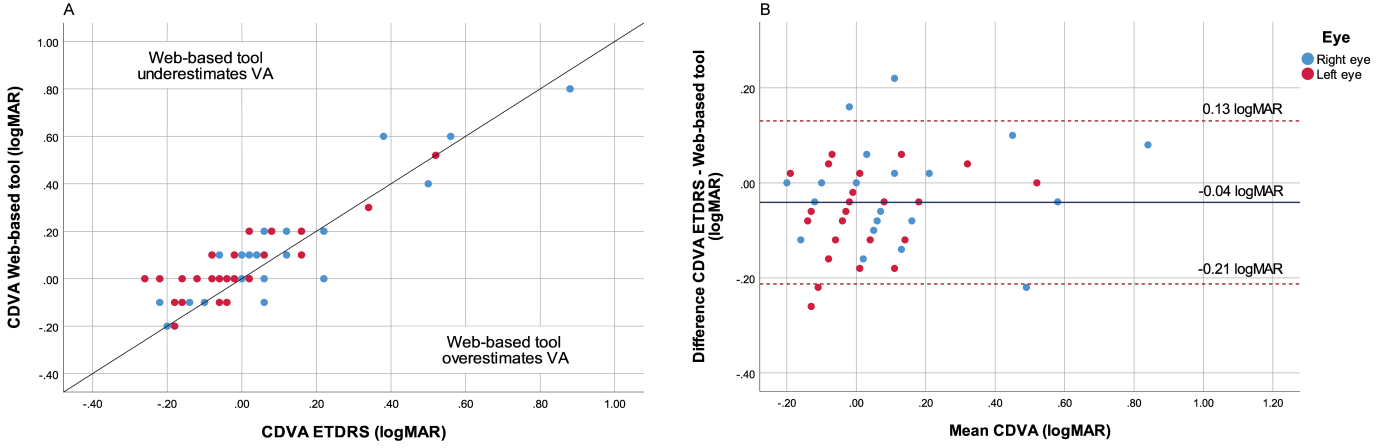


Figure 8.3. Comparison CDVA web-based tool and ETDRS chart.

A. Scatterplot CDVA of the web-based tool and ETDRS chart for the right and left eyes. The line presents the line of equality. B. Bland-Altman plot of CDVA determined by the web-based and ETDRS chart. The blue line represents the mean value, and the red dashed lines represent the ± 1.96 SD (95% limits of agreement).

CDVA=corrected distance visual acuity; SD=standard deviation

The mean time for performing the web-based tool was for the UDVA of the first and second tested eye 98 ± 45 and 88 ± 48 seconds, respectively. The CDVA assessment was completed in 73 ± 43 seconds for the first and 65 ± 22 for the second tested eye. Questionnaire outcomes are shown in **Figure 8.4**. The distribution of these outcomes was skewed and therefore not suitable for additional analyses.

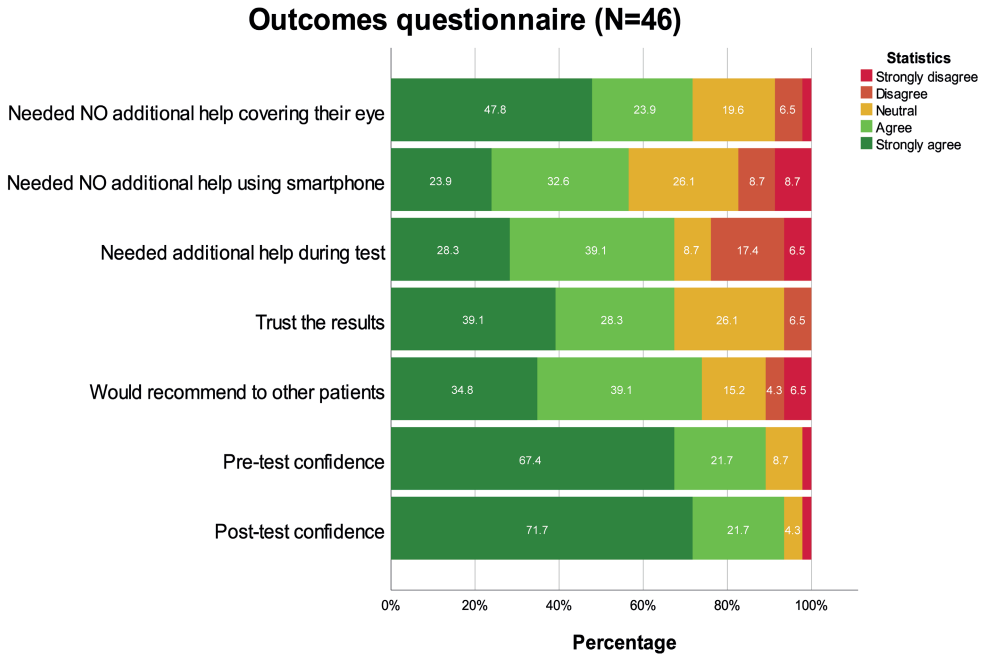


Figure 8.4. Outcomes of the questionnaire about the attitude and experiences of subjects using the web-based tool.

Each questionnaire item was scored using a 5-level Likert scale. The outcomes are given in percentages.

Discussion

The aim of this research was to validate the web-based tool for visual acuity assessment among patients who underwent cataract surgery. This study demonstrates statistically significant differences for both UDVA and CDVA scores between the web-based tool and the gold standard ETDRS chart of maximally −0.07 ± 0.10 logMAR and −0.05 ± 0.08 logMAR, respectively. Apparently, the web-based tool underestimates visual acuity, falling within the clinically acceptable cutoff of 0.15 logMAR. The Pearson correlation coefficients show a good reliability. However, it must be noted that this correlation cannot be defined as agreement because it only measures association.[13] The Bland Altman plots show a wide distribution between these tests, with a 95% LoA maximum variation between 0.15 and −0.26 logMAR. However, up to 88% of the patients' visual acuity outcome differences were within the range of ± 0.15 logMAR. Patients who were out of this range had either higher or worse visual acuity scores. Based on these results, we believe the web-based tool has an acceptable accuracy for clinical application.

Since the Snellen chart is the most commonly used test in daily clinical practice, the web-based outcomes were also compared with those obtained using a Snellen chart. Only the CDVA score showed a statistically significant mean difference of maximally −0.08 ± 0.12 logMAR. The Pearson correlation coefficients showed a reduced reliability compared with the correlation of the web-based tool and ETDRS chart. In total, 82% of the patients had a visual acuity outcome difference within ± 0.15 logMAR. Furthermore, explorative analyses did not reveal any consistent or useful relationships between questionnaire results and visual acuity outcomes.

Questionnaire outcomes showed that most of the participants had a positive attitude toward the web-based tool. The net promotor score for the confidence toward the web-based outcomes was 86.9 before and 91.1 after performing the test. Generally, the amount of time the participants needed to perform the web-based assessment declined over the course of measurements. We observed a learning curve for completing the test in which the last performed measurement was completed the fastest.

A study using the web-based tool indicated this test as a valid and safe method for measuring visual acuity and refraction in healthy eyes. They found no difference between UDVA assessed by the web-based tool and an ETDRS chart, with mean values of 0.33 ± 0.30 and 0.39 ± 0.39 logMAR (p=0.21), respectively.[5] A study among patients with keratoconus showed an UDVA mean difference of −0.01 logMAR (p=0.76), comparing ETDRS and the web-based tool, with a broad distribution including a LoA of −0.63 to 0.60 logMAR, albeit in subjects with a lower visual acuity.[14]

Several previous studies compared digital tools with conventional visual acuity charts, including the "Eye Chart," "Peek Acuity," and "Vision at Home" tool. These tools showed maximal mean differences of −0.01 logMAR (LoA of −0.21 to 0.19), 0.01 logMAR (LoA of −0.40 to 0.42), and 0.06 logMAR (LoA of −0.23 to 0.35) when compared with the ETDRS chart, respectively. The "Eye Chart" and "Peek Acuity" were tested among healthy adults, with a mean age of 64 and 65 years, respectively. The "Vision at Home" tool was performed by adolescents, adults, and elderly. Only the "Peek Acuity" tool was tested in the home and clinical environment, the other tools were tested in the controlled clinical environment. The tests were all performed using (habitual) spectacle correction. In comparison with the web-based tool, these visual acuity tests have an equivalent or better performance but were tested with a different methodology: The digital tests were all smartphone-based and were performed at different testing distances (the "Peek Acuity" and "Vision at Home" tool at 2 m testing distance and the "Eye Chart" at 4 feet [1.20 m] distance), and the visual acuities were scored using different methods (including letter-by-letter and line assignment) and not specifically assessed among patients who previously underwent cataract surgery.[15-17] This might be an explanation for the discrepancies in outcomes compared with the web-based tool in this study. According to a systematic review, digital tools were in general less accurate in measuring visual acuity compared with conventional charts and showed wide distributions.[18]

There is consensus that outcomes of different visual acuity assessments vary.[11] This variability is partly due to the psychophysical origin of the tests. Other reasons can be the design structure of the charts (decimal or logMAR), the optotypes used, the scoring methods, and the conditions under which the test is administered. Previous studies demonstrated that a decimal chart overestimates visual acuity compared with a logMAR chart.[19] Concerning the scoring methods, the letter-by-letter method is more accurate compared with the line assignment method.[20] For this study, the difference in scoring methods is presumably the primary factor that has caused some bias. The ETDRS chart is scored by the letter-by-letter method, the Snellen chart by the line assignment method, and the web-based tool by using an algorithm with a customized letter-by-letter method. Furthermore, the web-based tool has 7 optotypes in each line instead of 5. The abovementioned characteristics contribute to the general variability between visual acuity tests. If the postcataract pathway will represent a combination of both in-hospital and at home visual acuity tests, this should be taken into account. Nevertheless, a combination of these testing procedures can be very helpful because it offers flexibility for both patients and clinicians. Besides, the main aim of visual acuity testing after cataract surgery is a safety check for postoperative complications. In the case of a nonsignificant

complication, an underestimation of the visual acuity up to 1.5 lines would be of lesser clinical relevance. Therefore, the variability of this visual acuity tool does not have a negative influence on the patient pathway but offers an additional screening opportunity.

In addition, the usage of different optotypes in assessments may affect the outcomes as well. Previous studies compared Landolt rings with numbers and showed higher visual acuity outcomes (0.13 ± 0.14 logMAR) using number optotypes.[21] Other confirmed these lower outcomes when using Landolt rings compared with the Snellen (tumbling-)E chart or LEA symbols.[21] In yet another study, there was no significant difference observed between visual acuity outcomes assessed by the Landolt and ETDRS chart among healthy and cataract eyes.[22] These mentioned observations may have contributed to some discrepancies in our results. The web-based tool used tumbling-E optotypes, and the conventional charts had letter optotypes. Finally, the outcomes strongly depend on the achieved visual acuity of the tested subjects. Patients with the better scores tend to have more accurate visual acuity outcomes using the web-based tool.[5] However, our outcomes did not confirm these findings, presumably due to the high overall visual acuity in our study population.

The limitation of this study was the fact that the web-based tool was only performed once. As a consequence, no test–retest or intraindividual consistency results were obtained from patients, which could have (partly) explained the variance between the gold standard and the web-based tool. Nevertheless, the web-based tool is considered to have a high test–retest reproducibility because of the nonvariable interpretation of patient responses by the tool.[5] However, our additional test–retest analysis in healthy volunteers indicates that the variability of the web-based tool is up to twice as high compared with the conventional charts. Previous research showed a mean test–retest variability of the ETDRS and Snellen charts of 0.10 logMAR (LoA of −0.18 to 0.18) and −0.02 logMAR (LoA of −0.35 to 0.31), respectively.[12] For assessing the intraindividual consistency among postcataract users of the web-based tool, further research is necessary. We can conclude that the differences among all 3 test outcomes in this study confirm the great variability generally observed.

Since the visual acuity assessments were performed under ideal conditions, it is expected that when patients perform the web-based tool in their home environment, outcomes may have both a lower reliability and greater variability. Other aspects, which may have influenced the outcomes, are the nonrandomized test sequence and duration of testing. The web-based tool was performed after the ETDRS chart assessment, which could have resulted in less accurate visual acuity outcomes using the web-based tool due to fatigue. In our results, no learning curve pattern could be demonstrated between first and second examined eyes. The subjects were blinded to the results to limit the performance bias.

However, observation bias could not completely be prevented.

For implementation of a digital tool, practical issues must be taken into account. In this study, both UDVA and CDVA were evaluated. When performing an online visual acuity test in the home environment, the CDVA can only be measured after the patient has received his/her newly prescribed spectacles. Hence, directly after cataract surgery, only the UDVA measurements are applicable at home. Furthermore, elderly patients who undergo cataract surgery may not be able to perform digital tests unsupervised in their home environment. The introduction and usage of eHealth must always be in concordance with the patient. In addition, it should be noted that remote visual acuity testing will not completely replace ophthalmologic examination at the outpatient clinic but can enhance the efficiency of cataract care. Our results suggest that the web-based tool is useful in detecting larger changes in visual acuity but is probably not sensitive enough to reliably detect subtle changes.

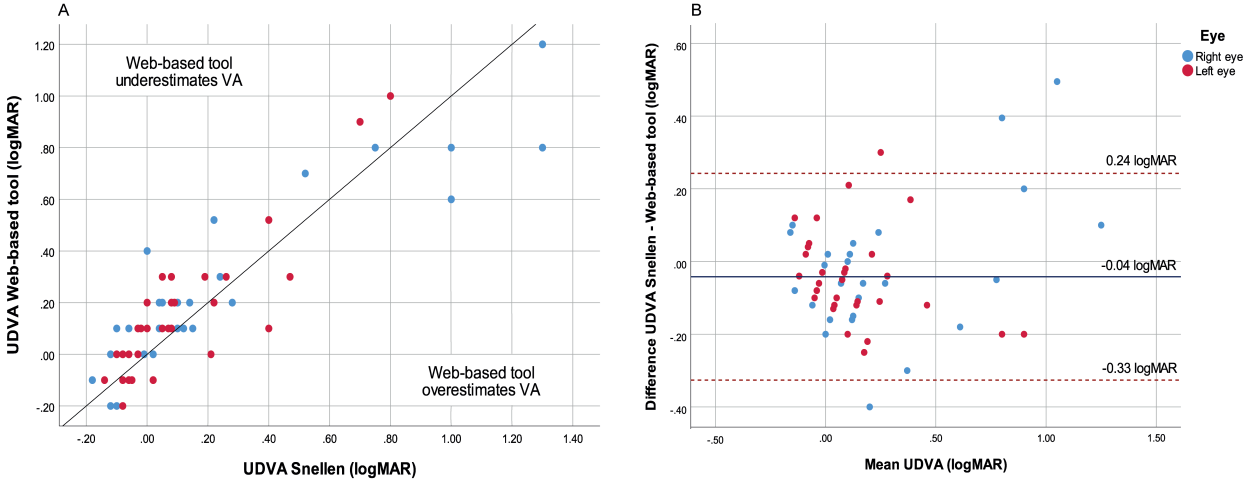
Based on the results of this study, the web-based tool is validated for assessment of the visual acuity in patients who underwent cataract surgery. The web-based tool showed different outcomes compared with the conventional tests for both the UDVA and the CDVA, but most of these differences were within the established clinically acceptable limit of ± 0.15 logMAR. These results are sufficient to introduce the web-based tool as a reliable screening method for detecting significant deterioration or lack of improvement of visual acuity in post-cataract patients. Our results suggest that the test can function as an interim assessment during the postoperative cataract care pathway. However, patients need to have basic digital skills to perform this web-based visual acuity assessment. Future research into this digital tool with a larger study population is necessary.

What was known

- The Easee test has shown promising results for refraction and visual acuity measurements among healthy volunteers and patients with keratoconus.
- This web-based tool was not tested among patients who underwent cataract surgery before.

What this paper adds

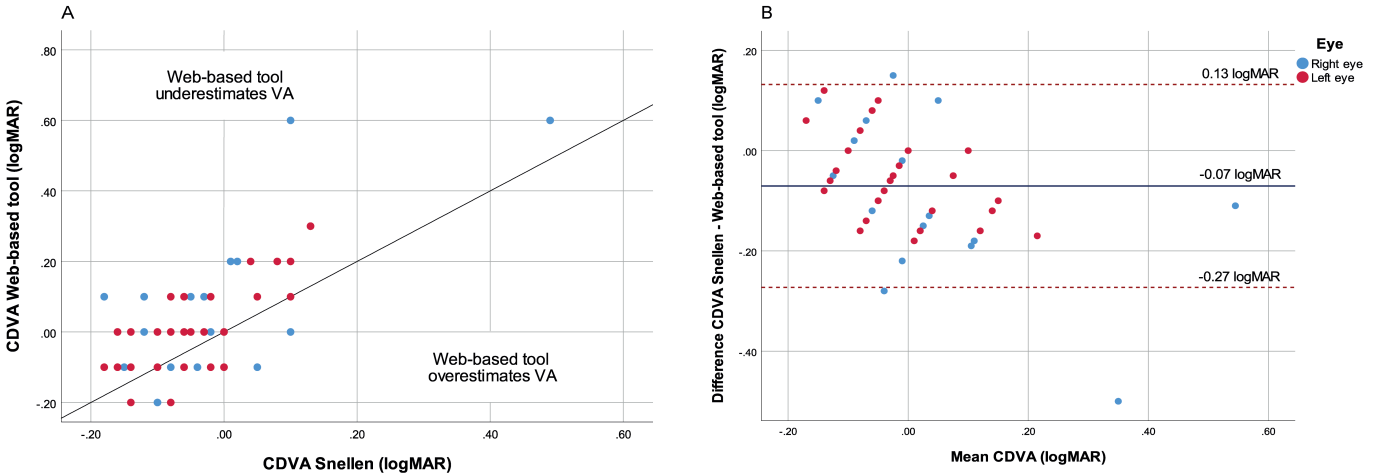
- The web-based tool is validated for assessment of the visual acuity in patients who underwent cataract surgery.
- The test is useful in detecting larger changes in visual acuity but is probably not sensitive enough to detect subtle changes.



Supplementary Figure 8.1. Comparison UDVA web-based tool and Snellen chart.

A. Scatterplot UDVA of the web-based tool and Snellen chart for the right and left eye. The line presents the line of equality. B. Bland Altman Plot of UDVA determined by the web-based and Snellen chart. The blue line represents the mean value and the red dashed lines represent the ± 1.96 SD (95% limits of agreement).

UDVA=uncorrected distance visual acuity



Supplementary Figure 8.2. Comparison CDVA web-based tool and Snellen chart.

A. Scatterplot CDVA of the web-based tool and Snellen chart for the right and left eye. The line presents the line of equality. B. Bland Altman Plot of CDVA determined by the web-based and Snellen chart. The blue line represents the mean value and the red dashed lines represent the ± 1.96 SD (95% limits of agreement).

CDVA=corrected distance visual acuity; SD=standard deviation

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CHAPTER 9

Remote Follow-Up after Cataract Surgery (CORE-RCT): Study Protocol of a Randomized Controlled Trial

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BMC Ophthalmology. 2023 Jan;30;23(1):41.

Abstract

Background: Cataract surgery has become one of the most performed surgical procedures worldwide. Postoperative management consists of routine clinical examinations to assess post-operative visual function and detect possible adverse events. Due to the low incidence of complications, the majority of clinic visits after cataract surgery are uneventful. Nonetheless, valuable time and hospital resources are consumed. We hypothesize that remote post-operative follow-up involving teleconsultations and self-assessments of visual function and health status, could be a valid alternative to face-to-face clinical examinations in selected patient groups. The practice of remote follow-up after cataract surgery has not yet been evaluated. The aim of this study is to investigate the validity, safety and cost-effectiveness of remote cataract surgery follow-up, and to report on the patients' experiences with remotely self-assessing visual function.

Methods: This study is a multicenter, open-label, randomized controlled trial. Patients planned for cataract surgery on both eyes, without ocular comorbidities, are eligible for participation. Participants will be allocated (1:1) into one of the two study groups: "telemonitoring" or "usual care". Participants in the "telemonitoring" group will perform in-home assessments after cataract surgery (remote web-based eye exams and digital questionnaires on their own devices). Participants in the "usual care" group will have regular post-operative consultations, according to the study site's regular practice. Outcome measures include accuracy of the web-based eye exam for assessing visual acuity and refraction, patient-reported outcome measures (visual function and quality of life), adverse events, and cost aspects.

Discussion: Investigating remote follow-up after cataract surgery fits the current trends of digitization of health care. We believe that remote self-care can be a promising avenue to comply with the increasing demands of cataract care. This randomized controlled trial provides scientific evidence on this unmet need and delivers the desired insights on (cost) effectiveness of remote follow-up after cataract surgery.

Trial registration: ClinicalTrials.gov: NCT04809402. Date of registration: March 22, 2021.

Background

Cataract, clouding of the eye's natural lens, is one of the leading causes of blindness and visual impairment worldwide.[1,2] It is most commonly age-related, and therefore a common condition amongst older-aged adults.[2] The main treatment is surgical extraction of the cataract, followed by implantation of a clear artificial lens.[3] Across the European Union member states, cataract surgery is conducted 4.3 million times yearly, making it the most performed surgical procedure.[4] Due to increasing life expectancies and aging of the population, these numbers are expected to keep increasing.

Over the last decades, new technologies and surgical techniques have revolutionized the procedure, making cataract extraction one of the safest surgeries to be performed.[2,5] Based on the latest report of the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO), 98% of the procedures remained uneventful.[6] Infectious endophthalmitis, the most dreaded short-term post-operative complication with a devastating prognosis, only occurred in 0.01% of the cases.[6] Other short-term post-operative consultations include cystoid macular edema (0.46%), persistent corneal edema (0.02%), and uncontrolled elevated intraocular pressure (0.02%).[6]

Cataract surgery is usually performed in day care. A recent innovation is immediate sequential bilateral cataract surgery, further improving the cost-effectiveness of cataract care as both eyes will be operated on the same day.[7] Typical postoperative follow-up consists of a short-term evaluation within a few days after surgery and a long-term evaluation approximately one month after surgery.[8] The main purpose of the short-term postoperative consultation is to ascertain no complications have occurred immediately after surgery, such as an elevated intraocular pressure.[9-12] At approximately one month after surgery, the residual refractive error is determined and routine postoperative cataract care is finished. Due to the low rate of (serious) adverse events, the majority of postoperative examinations after cataract surgery will be uneventful.[5,13,14] Nevertheless, because of the high number of cataract surgeries performed, postoperative follow-up of cataract patients takes up a considerable amount of hospital time and resources. To maximize the efficiency of postoperative cataract care, the clinical examination shortly after surgery is often replaced by a telephone consultation.[15] Notwithstanding, telephone consultations lack quantifiable outcome parameters.

Remote follow-up could be a cost-effective and patient friendly alternative to conventional in-hospital follow-up. A remote monitoring platform that includes assessments of visual function using e-health technology could enable patients to self-monitor their postoperative eye status and remotely provide quantifiable outcome parameters, such as

visual acuity, to their eye care professional.

An e-health tool that can be used for this purpose has been developed by the Amsterdam-based medtech company Easee (https://easee.online). It allows users to self-assess their visual acuity and refractive error via a website, using their own electronic devices (a computer or tablet, and a smartphone). Previous research indicated the refraction assessment of this tool to be non-inferior to a manifest refraction performed by an eye care professional, investigated amongst healthy volunteers with refractive errors, achieving the best outcomes in low myopes.[16] Moreover, studies have shown that visual acuity can be reliably assessed in patients with various ocular conditions.[16-18] Most studies have been targeting relatively younger-aged individuals and we suspect that introducing e-health technology to older-aged generations will be more challenging. Interestingly, a recent study on the performance of the remote assessment in post-operative cataract patients identified that the majority of patients were able to complete the assessment and achieve accurate visual acuity scores.[19] This study was performed in a supervised, controlled setting and only evaluated distance visual acuity assessments. In the present study, the remote exam will be more comprehensive and also include refractive error assessments, as well as near vision. Moreover, examinations will be performed unsupervised by patients at home, using their own smartphones and computers, mimicking a future real-world application of this tool.

In summary, we hypothesize that remote follow-up could be a valid alternative to conventional face-to-face examinations in post-operative cataract care. This randomized controlled trial aims to investigate the validity, safety and cost-effectiveness of remote follow-up after cataract surgery, and provide insights on patients' experiences with remotely assessing visual function.

Methods

Study design and setting

This study will assess the validity of a web-based eye exam, report on patients' experiences with this tool, and evaluate the cost-effectiveness and safety of remote follow-up. Therefore, we will perform a randomized controlled trial to make a comparison between two different methods of post-operative follow-up: "telemonitoring" vs. "usual care". The study is titled the CORE-RCT: Cataract Online Refraction Evaluation – a Randomized Controlled Trial. The protocol for this study was designed according to the SPIRIT 2013 guidelines.[20]

Multiple centers will participate in the trial. The sponsor of this study is the University Medical Center Utrecht, the Netherlands. Participating centers are the Maastricht University Medical Center+, the Netherlands; Amphia Hospital Breda, the Netherlands; Oogcentrum Noordholland, the Netherlands; Vienna Institute for Research in Ocular Surgery, Austria; and Augenklinik Sulzbach, Germany. Each of the participating sites reviewed a copy of the research protocol and provided written approval and agreement to participate in this study. The study has been approved by the Medisch Ethische Toetsingscommissie Utrecht, the Netherlands (NL74625.041.21); the Ethikkommission der Stadt Wien, Austria (EK 20-334-0121); and the Ethikkommission Saarbrücken, Germany (Ha 44/18).

Study objectives

This randomized controlled trial aims to evaluate remote follow-up after cataract surgery. The objectives of this trial can be categorized into four categories: validity, safety, cost-effectiveness, and patients' experiences.

Validity of the web-based eye exam

Validity of the web-based eye exam (developed by Easee B.V.) will be assessed by comparing the web-based outcomes to the clinical findings at the visit scheduled 4-6 weeks after surgery. Our main objective will be to determine if the corrected distance visual acuity (CDVA) achieved with the refraction resulting from the remotely performed web-based refraction assessment is non-inferior to the achieved CDVA with the prescription of the in-hospital manifest refraction. A mean difference between the two scores up to 0.10 logMAR (one ETDRS line) will be considered clinically acceptable (i.e., non-inferior). In addition, we will assess uncorrected distance visual acuity (UDVA) and compare the outcomes of the web-based vs. the in-hospital assessment. Furthermore, we will evaluate the accuracy of the web-based exam for determining refractive error and uncorrected near visual acuity, by comparing these outcomes to the conventional in-hospital assessments. The repeatability of the web-based refractive assessment will be determined by comparing the outcomes 4-6 weeks after surgery to the outcomes 3 months after surgery (on the condition that post-operative complications resulting in a change of visual function are absent).

Safety of remote follow-up

Safety will be evaluated by reporting on the occurrence of (serious) adverse events in both groups. Furthermore we will evaluate to what extent the digital triage questionnaires can

detect alarming symptoms and adverse events.

Cost-effectiveness of remote follow-up

The cost-effectiveness will be evaluated by quality-adjusted life years (QALYs), total costs (societal and hospital costs), and the probability of adverse events or additional clinical examinations. The main outcome measure will be incremental cost-effectiveness ratio (ICER), defined as euros per QALY (based on the EQ-5D-5L questionnaire[21]), and compared between the two study groups.

Patients' perspective

Firstly, we will determine if remotely self-assessing vision influences patient-reported outcome measures of visual function (Catquest-9SF and NEI-VFQ-25 questionnaires[22,23]) and quality of life (EQ-5D-5L questionnaire[24]), by comparing the outcomes between both randomization groups.

Secondly, we will evaluate the user experiences with the web-based tool by a custom quantitative questionnaire, distributed amongst the participants of the telemonitoring group at the end of the study. This questionnaire is based on the theoretical Technology Acceptance Model; a commonly used model to evaluate and incorporate user experiences in the development process of technology. Since its introduction by Davis in 1989, the model has been extended by multiple research teams, including for utilization in health care settings.[25-28] We used the extended models as a reference framework and developed a study-specific questionnaire in cooperation with the University of Twente, the Netherlands. Lastly, the quantitative results are enriched with in-depth qualitative interviews. Dutch-speaking participants of the telemonitoring group will be invited to report on their experiences with the web-based eye exam. Interviews will be conducted by researchers experienced in qualitative interview studies, until data saturation is reached (i.e., when no longer new insights are gained).

Study population and sample size calculation

Patients planned for bilateral cataract surgery without visual acuity influencing comorbidities are eligible for study participation. The surgical procedures can be performed on the same day (i.e., immediate sequential) or on two different days. Exclusion criteria are: cataract surgeries combined with other procedures (including keratoplasty, vitrectomy, glaucoma filter implants), presence of ocular comorbidities that negatively influence post-operative visual acuity (such as amblyopia, age-related macular

degeneration, diabetic retinopathy, glaucoma or uveitis), insufficient command of the Dutch, German or English language, no access to a smartphone and computer/tablet, and inability to successfully perform the demo version of the web-based eye exam.

The sample size calculation is based on determining the validity of the web-based eye exam since calculations based on cost-effectiveness and safety were not feasible. We aim to assess whether the corrected distance visual acuity obtained with the web-based refraction is not significantly worse than the visual acuity obtained with the manifest refraction. We assume no difference between the measurements and consider a difference up to 0.10 logMAR to be non-inferior. With a standard deviation of 0.30 logMAR (a commonly used SD in power calculations on visual acuity), an α of 0.05, a power of 90, 20% loss to follow-up and using a one-sided, one sample t-test, 94 eyes are then required in the telemonitoring group (so 47 participants, as all measurements will be performed bilaterally).[29-31] This results in a total study population of 94 participants (188 eyes) for both study groups.

Study procedures

A flowchart describing the study procedures is depicted in **Figure 9.1**.

Recruitment and informed consent procedure

Eligible patients will be identified by the ophthalmologist or delegated personnel at the outpatient department, when cataract is diagnosed and the cataract surgery will be planned for both eyes. All eligible patients will be provided with written information about the study. Patients who are interested to participate, will be invited to perform a demo version of the web-based eye exam at home. We always recommend assistance by a relative. The demo contains the home set-up phase and a shortened test flow, and aims to assure that the technical requirements and a sufficient level of digital proficiency for study participation are met, preventing a high loss-to-follow-up after enrolment. Patients who fail to access the demo version of the web-based eye exam, will be excluded from randomization. To report on this participation bias, we will keep track of an overview of all invited patients and record reasons for non-participating.

If all inclusion criteria are met and the patient is willing to participate, written informed consent will be obtained. After enrolment, participants can leave the study at any time for any reason if they wish to do so. Participants who have not completed the questionnaires and/or performed the web-based eye exam prior to surgery (i.e., at baseline) will be withdrawn from the study and replaced.

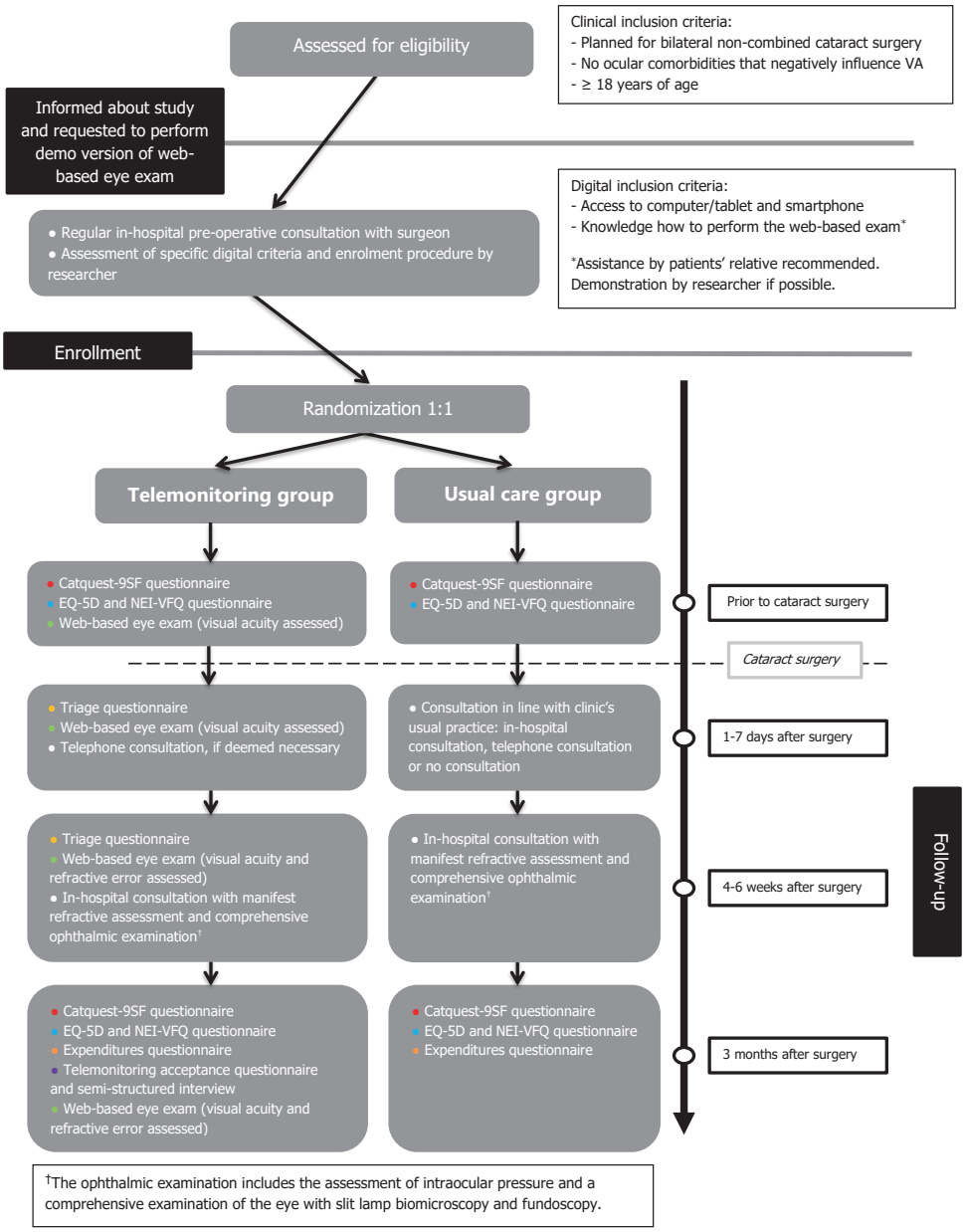

Figure 9.1. Flowchart of the CORE-RCT study procedures, including recruitment, randomization and study measurements.

Randomization

Participants will be randomized 1:1 using a computer-generated block size permuted randomization list (block sizes 2 and 4). The randomization will be stratified for treatment center and age (<69 and ≥69 years). The age stratification is based on prior experiences with the remote monitoring platform regarding age-related digital literacy, and the distribution of cataract incidence among age deciles (mean age in the Netherlands in 2019 was 73 years).[14]

Study measurements

The "telemonitoring" group will have a post-operative follow-up involving web-based eye exams, digital questionnaires and telephone consultations. The invitations for the web-based eye exams and questionnaires will be sent via e-mail at 4 specific time points: prior to surgery, <1 week after the surgery, 4-6 weeks after the surgery and 3 months after surgery. Prior to surgery, visual acuity will be assessed with the participant's current spectacles, if applicable. After surgery, the web-based eye exam will be performed without spectacles. In addition, participants will fill out triage questionnaires to identify any (alarming) symptoms.

Shortly (1-7 days) after surgery, uncorrected distance visual acuity (UDVA) will be assessed remotely, and a telephone consultation will take place if deemed necessary by the surgeon. Approximately 1 month (i.e., 4-6 weeks) after surgery, the web-based tool will assess uncorrected visual acuity (distance and near) and the residual refractive error. After performing this remote assessment at home, participants will have an in-hospital ophthalmic examination with conventional visual acuity and refraction assessments for validity and safety purposes. The observer and participant will be blinded for the web-based refraction outcome during the manifest refraction. At this in-hospital consultation, distance visual acuity will be assessed by an ETDRS chart at 4 m, both uncorrected (UDVA) and corrected (CDVA). The CDVA will be assessed twice: using both the prescriptions of the web-based and the manifest refraction. Near visual acuity will be assessed uncorrected using a Sloan ETDRS chart at 40 cm. Three months after surgery, the web-based assessment will be repeated and participants will be requested to fill out a questionnaire about their experiences with the web-based eye exam. In addition, a sample of the Dutch-speaking participants will be interviewed to further explore their perspective on remote follow-up after cataract surgery.

The "usual care" group will have a post-operative follow-up adhering to the clinic's usual practice. Typically, regular consultations will be planned within 1 week after surgery (i.e., short-term evaluation) and at approximately 4-6 weeks after surgery (i.e., long-

term evaluation). The latter will include a full ophthalmic examination and refraction assessment, to assess post-operative visual outcomes and residual refractive errors. In some of the participating centers, the short-term follow-up evaluation will be a telephone consultation instead of an in-hospital consultation, or no consultation at all, depending on the standard guidelines of this clinic.

For both study groups, all adverse events and additional consultations–at other moments than the specified time points in the study flow chart–will be registered. Prior to (i.e., at baseline) and three months after surgery, participants of both groups will be requested to fill out questionnaires about quality of life (EQ-5D-5L) and visual function (Catquest-9SF, NEI-VFQ-25).[23-25] Three months after surgery, all participants will be requested to fill out a short custom questionnaire about expenditures related to hospital visits (such as costs for transportation and parking).

Statistical analysis

Data will be collected and analyzed preoperative (i.e., at baseline) and at three postoperative time points. All quantitative variables will be summarized. The data will be tested for distribution, and if not normally distributed the corresponding non-parametric test will be used. For all analyses, a $p<0.05$ is considered statistically significant.

Comparisons between the web-based eye exam and the conventional clinical assessments will be analyzed according to the Bland-Altman methodology.[32] We will compare assessments of distance visual acuity, near visual acuity and refractive error. Furthermore, we will analyze independent associations between clinical characteristics and agreement between the web-based exam and the conventional reference tests. Safety of the remote follow-up will be evaluated by comparing the occurrence of adverse events in both study groups. The cost-effectiveness will be assessed by QALYs, total costs, and the probability of adverse events and additional clinical examinations.

Discussion

This is the first study to investigate remote follow-up after cataract surgery including refractive assessments. We believe that remote follow-up fits in the current trends of digitization of health care, and that it can be a promising avenue to tackle the increasing demands of cataract care. The studied population, i.e., cataract patients, is particularly interesting due to the high volume of procedures and low risks. We are aiming to provide a clear overview on validity, safety, cost aspects, and patients' perspectives regarding

remote follow-up after cataract surgery. After completion of the present study, the web-based eye exam test flow will be improved and an iteration in algorithm development will take place, focusing on additional training, recalibrating, and a machine learning approach to better control user-behavior and -environment. We anticipate to amend the current trial with a telemonitoring-only approach to further explore the performance and deliver fine granular data on the (cost-)effectiveness of the updated web-based tool.

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CHAPTER 10

Web-Based Telemonitoring of Visual Function and Self-Reported Postoperative Outcomes in Cataract Care: International Multicenter Randomized Controlled Trial

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Abstract

Purpose: To compare web-based, self-administered follow-up after cataract surgery to conventional face-to-face follow-up.

Setting: Eye clinics in the Netherlands, Austria and Germany.

Design: Randomized controlled trial with an embedded method comparison study [ClinicalTrials.gov: NCT04809402].

Methods: Routine patients with cataract were randomized into 2 groups: The telemonitoring group undertook web-based vision self-assessments and questionnaires from home, while the usual care group received conventional care. All participants had a 4 to 6-week postoperative clinic visit for safety and validation purposes. Outcomes included, the web test's accuracy for assessing postoperative visual acuity (VA) and refractive error, adverse event rates, and patient-reported outcome measurements (PROMs).

Results: 94 participants (188 eyes) were enrolled. Web-based uncorrected distance VA testing demonstrated a negligible mean difference (−0.03 ± 0.14 logMAR) when compared with conventional Early Treatment Diabetic Retinopathy Study chart testing, with 95% limits of agreement ranging from −0.30 to 0.24 logMAR. The web-based refraction assessment overestimated the postoperative refractive error (mean difference in spherical equivalent 0.15 ± 0.67 diopters), resulting in a poorer corrected distance VA compared with subjective refraction (mean 0.1 vs. −0.1 logMAR). Rates of adverse events and unscheduled consultations were minimal across both groups. Preoperative and postoperative PROM questionnaires had a 100% response rate. Visual functioning (Catquest-9SF and National Eye Institute Visual Function Questionnaire-25) improved postoperatively (mean improvement −0.80 and 16.70, respectively) and did not significantly differ between the 2 groups.

Conclusion: The patients with cataract in this study effectively provided postoperative outcome data using a web interface. Both conventional and web-based follow-ups yielded similar PROMs and adverse event rates. Future developments should reduce the variability in the web-based VA test and yield representative refraction outcomes.

Introduction

Cataract surgery stands as the most performed surgical procedure across European member states, with demands continuing to rise in our ageing society.[1] Workloads for eye care professionals are ever-increasing and jeopardize access to ophthalmic care. Solutions that increase efficiency and productivity are, therefore, desired. Optimization of staff time by telehealth and self-management can lead to productivity gains, as a greater volume of patients can be managed with similar resources.[2] Other important advantages are related to the lower frequency of clinic visits and include reduction of travel-related expenditures, carbon dioxide emissions, and absenteeism from work.[3]

Although national protocols vary, conventional cataract surgery follow-up typically involves routine face-to-face examinations to assess postoperative visual function and detect adverse events.[4] Advances in surgical techniques and routine use of intraocular antibiotics have greatly improved safety of this procedure, and most of the postoperative check-ups are uneventful.[5,6] This renders cataract surgery follow-up a compelling field for using telehealth for remote care delivery.

This trial is the first to evaluate cataract surgery follow-up involving remote self-assessments of visual function and self-reported outcome measurements collected at home, compared with conventional clinical practice where those assessments are conducted at clinics and obtained by trained staff.

Methods

Study design

A detailed overview of the study design can be found in the published study protocol.[7] This randomized controlled trial was performed at six eye clinics: 4 located in the Netherlands (University Medical Center Utrecht, Maastricht University Medical Center+, Amphia Hospital Breda, Oogcentrum Noordholland), 1 in Austria (Vienna Institute for Research in Ocular Surgery), and 1 in Germany (Augenklinik Sulzbach). The study was registered at ClinicalTrials.gov, number NCT04809402, and the protocol for this study was designed according to the SPIRIT 2013 guidelines.[8] The study was approved by the Medisch Ethische Toetsingscommissie Utrecht, the Netherlands (NL74625.041.21); the Ethikkommission der Stadt Wien, Austria (EK 20-334-0121); and the Ethikkommission Saarbrücken, Germany (Ha 44/18). Written informed consent was obtained from all participants.

Between April 2021 and January 2023, consecutive patients planned for bilateral cataract

surgery (either delayed sequential or immediate sequential) were invited to participate. Exclusion criteria were cataract surgeries combined with other procedures; presence of ocular comorbidities that negatively influence postoperative visual acuity (VA), such as amblyopia, age-related macular degeneration, diabetic retinopathy, glaucoma, or uveitis; an insufficient command of the Dutch, German, or English language; and not being able to access the web-based eye test (Easee BV, Amsterdam, the Netherlands) at home. The latter required access to a computer or tablet and a smartphone (possibly obtained by a relative) and an internet connection. Before enrollment, all interested patients were requested to try a demo version of the web-based eye test (a shortened test version). Those who were unable to access this demo were excluded from participation. Assistance by a relative was always recommended, though not strictly required.

After enrollment, patients were randomly assigned (1:1) to 1 of the 2 follow-up groups, using a web-based system stratified by center and age (<69 and ≥69 years). Participants of the telemonitoring group performed postoperative self-assessments at home (remote vision self-assessments and questionnaires) while those of the usual care group had conventional postoperative consultations dictated by local preferences and regulations. The postoperative self-assessments were offered at 3 distinct points in time: an early assessment within 1 to 7 days postoperatively, a late assessment 4 to 6 weeks postoperatively, and a final assessment at 3 months postoperatively. All participants underwent a remote assessment of patient-reported outcome measurements pre and postoperatively, and all participants underwent an in-office clinical assessment 4 to 6 weeks postoperatively. The telemonitoring group was invited to perform the remote assessments within 5 days before the in-office assessment at 4 to 6 weeks postoperatively. As such, a method comparison study design was embedded in the telemonitoring arm, comparing the home-based self-assessment with the conventional in-office clinical assessment of VA and refractive error. An overview of the study assessments is presented in **Figure 10.1**. Invitations for questionnaires and/or web-based eye tests were sent through email. Any unexpected consultations or adverse events were recorded for both groups.

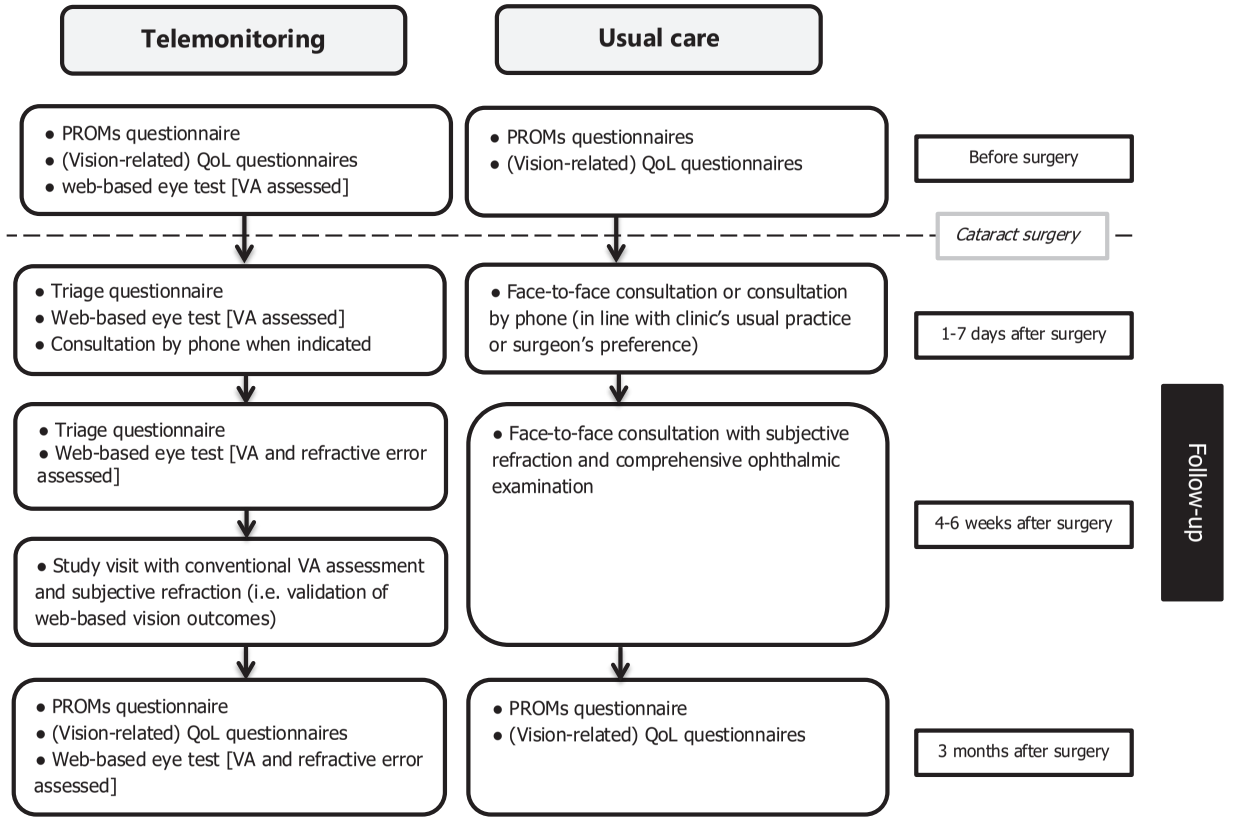


Figure 10.1. Study assessments.

PROM=patient reported outcome measurement, assessed by Catquest-9SF questionnaire; QoL=quality of life, assessed by National Eye Institute Visual Function Questionnaire-25 and EuroQol 5-Dimension 5-level questionnaire; VA=visual acuity

Outcome measures

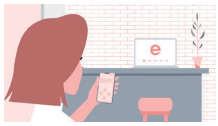
Accuracy of the web-based vision self-assessment (telemonitoring group only)

The web-based eye test evaluated in this study allows self-assessments of visual function at home. Easee (Amsterdam, the Netherlands) uses an ISO 13485 Quality Measurement System, and the tool is classified as Conformité Européenne class 2A medical device according to the Medical Device Regulation 2017/745.[9] An overview of the test flow and assessed determinants of visual function is presented in **Figure 10.2**.

The web-based test's accuracy was evaluated by comparing the home-assessed uncorrected distance VA and refraction to the outcomes obtained by trained staff during the validation visit at 4 to 6 weeks postoperatively. These assessments only refer to the telemonitoring group, and comparisons are made of data acquired in the same subject. Repeatability of the web-based test was evaluated by comparing the outcomes obtained 3 months postoperatively with those obtained 4 to 6 weeks postoperatively. Participants were asked whether they had experienced a change in vision before the start of the final eye test, and if so, these cases were excluded from the analysis. Based on studies on intraindividual variability in repeated VA and refraction assessments, differences between assessments up to 0.15 logMAR or 0.5 diopters (D) were considered normal measurement variation.[10-13]

The web-based VA assessment consists of 3 parts. In each part, a different optotype is used (**Figure 10.2**). This results in 3 individual scores that are averaged to calculate the final web-based VA score. A human over-read was performed after data collection. All web-based assessments were checked on individual levels to detect a within-test variation >0.2 logMAR between the 3 separate VA tests of 1 monocular assessment. As the true web-based test score cannot be reliably determined for these eyes, these were excluded from the comparisons and discussed separately. Conventional VA was assessed by Early Treatment Diabetic Retinopathy Study (ETDRS) charts at 4 meters (distance) and Sloan ETDRS charts at 40 centimeters (near).

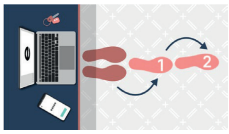
Set-up



- Patients access the web-based eye test's **website** on their **computer** or **tablet**. They are instructed to connect their **smartphone** by scanning a QR-code or entering a code sent by SMS on the website. The computer/tablet screen functions as vision chart; the smartphone as remote control. Audio and written instructions guide them through the test



- A **calibration step** reassures that the displayed optotypes are sized correctly, regardless of the devices' screen dimensions. Patients are asked to place a standard sized (bank) card over the image on the screen and instructed to use the slider to resize the image on the screen until it is the same size as this card.

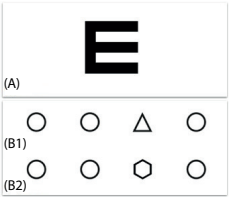


- Patients are instructed to move the computer or tablet to the edge of a table. **Foot-to-toe steps** reassure that the back of a chair is placed at **3 meters** from the screen. The number of steps is determined based on the patient's shoe size.

Vision assessment

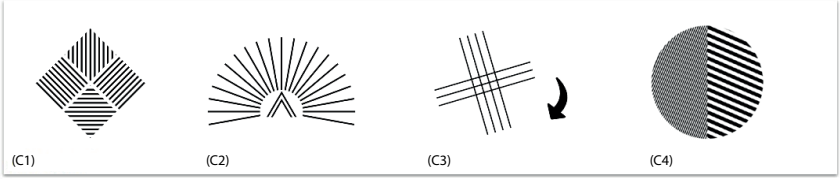


- Patients are requested to sit down on the chair and cover one eye with their hand, while the screen displays a sequence of optotypes and astigmatic dials that the patient must correctly identify with the contralateral eye. Answers are submitted by the patients (or their relative) on the smartphone.
- 3 different optotypes will be used during the VA assessment:



A) Tumbling E. Four kinds of rotations of this optotype will be displayed on the smartphone screen. The patient will be asked to select the one that is identical to the optotype presented on the computer or tablet screen.
B1+B2) Proprietary optotypes: triangles and hexagons. The patient will be asked which of the 4 optotypes presented on the computer or tablet screen is different.

- Different astigmatic dials are used for the detection and quantification of ocular astigmatism.



C1) Detection of ocular astigmatism. The patient is asked whether blurriness moves across the quadrants when tilting the head. If astigmatism is detected, other components are activated.
C2) Axis determination. The patient is asked to rotate the arrow in the direction of the clearest line.
C3) Axis determination. The patient is asked to rotate the figure until the 3 most visible lines appear sharpest.
C4) Cylindrical power determination. Each side of the circle contains a set of black, equally spaced, parallel lines. The patient is asked to adjust the thickness of the right half until both sides are equally blurry.

Figure 10.2. Overview of the web-based test flow.

Collected parameters of the web-based test include corrected/uncorrected visual acuity and refractive error (sphere, cylinder, axis).

The test's algorithm will interpret any VA poorer than −0.1 logMAR (i.e., 1.25 Snellen decimal) to be caused by a refractive error. Astigmatic dials will determine the presence and magnitude of a cylinder. The type of refractive error (myopia or hyperopia) is based on an adapted red/green duochrome test combined with a short questionnaire. Algorithm updates had taken place after the start of the trial, resulting in a new method of calculating the spherical equivalent (SEQ). This updated algorithm performance is reported alongside the performance of the original algorithm. Subjective refraction was obtained at the clinic by trained optometrists masked for the web-based outcomes. After this assessment, corrected distance VA (CDVA) was measured using the prescription of both the subjective refraction and the web-based assessment.

Safety

For both study groups, all adverse events and unexpected consultations were registered. Participants of the telemonitoring group were requested to fill out a triaging questionnaire prior to each web-based vision assessment. Outcomes of these questionnaires were evaluated.

Self-reported outcome measures

Both study groups were sent digital questionnaires about (vision-related) quality of life (National Eye Institute Visual Function Questionnaire [NEI-VFQ]-25 and EuroQol 5-Dimension 5-level [EQ-5D-5L]) and patient-reported outcomes measurements (CatQuest-9SF) preoperatively and 3 months postoperatively in the appropriate language.[14-16]

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows v. 29.0 (IBM Corp.). All quantitative variables were summarized. The data were tested for normal distribution, and the appropriate (non-)parametric test was used. For all analyses, a $p \leq 0.05$ is considered statistically significant. Comparisons between the web-based assessments and the conventional clinical assessments were analyzed with paired t tests and in line with the Bland-Altman methodology.[17] Mean differences (i.e., bias) and 95% limits of agreement (LoA) (i.e., sampling error) were presented. Residual refractive error outcomes were converted to absolute values of the SEQ. Associations between clinical characteristics and accuracy of the web-based test were evaluated by generalized estimating equation (GEE) analysis correcting for bilaterality, age, sex, myopic target refraction, and self-reported vision symptoms. Scores of the self-reported outcome

measurements were calculated using official scoring manuals and conversion sheets. Differences between the 2 follow-up groups regarding these outcomes were evaluated with an independent samples t test.

Results

Recruitment

A total of 391 patients were invited to participate. The participant recruitment is depicted in **Supplementary Figure 10.1**.The willingness and ability of invited patients to enter the study varied between countries: 41% in the Netherlands, 14% in Germany and 9% in Austria. There was no difference in age between those who were willing and able to participate and those who were not (70 ± 7 vs. 71 ± 11, $p<0.001$). A total of 94 participants (188 eyes) were enrolled at baseline. **Table 10.1** presents their baseline characteristics.

Table 10.1. Baseline characteristics.

Clinical characteristics		Telemonitoring group (n=44)	Usual care group (n=50)
Age (years), mean ± SD, [range]		70 ± 6 [54-80]	70 ± 8 [47-87]
Sex, n (%)	Male	23 (52)	23 (46)
	Female	21 (48)	27 (54)
Nationality, n (%)	Dutch	34 (77)	38 (76)
	German	3 (7)	3 (6)
	Austrian	7 (16)	9 (18)
Preoperative presenting visual acuity score at the clinic (in logMAR)[a], mean ± SD		0.28 ± 0.17	0.34 ± 0.26
Preoperative refractive error (SEQ in diopters), mean ± SD		-1.22 ± 2.97	-1.43 ± 3.99
History of eye diseases and/or eye surgeries, n (%)	Refractive surgery	3 (7)	0 (0)
	Blepharoplasty	2 (5)	4 (8)
	Strabismus surgery	1 (2)	1 (2)
Postoperative target refraction, n (%)[b]	Emmetropia	37 (84)	40 (80)
	Myopia (SEQ <-0.5D)	7 (16)	10 (20)
Surgical complicating factors, n (%)[c]	None	40 (91)	50 (100)
	Corneal clouding	0 (0)	0 (0)
	Small pupil	1 (0.02)	0 (0)
	Mature cataract	0 (0)	0 (0)
	Pseudoexfoliation syndrome	1 (0.02)	0 (0)
	Other (e.g. shallow anterior chamber)	2 (0.05)	0 (0)
CatQuest-9SF score (scale -6.00-6.00), mean ± SD		3.03 ± 0.43	3.06 ± 0.62
NEI VFQ-25 composite score (scale 0-100), mean ± SD		75 ± 12	74 ± 15
General health condition: self-rated health score at baseline (scale 0%-100%), mean ± SD		83 ± 12)	82 ± 15
EQ-5D-5L Index Values (scale 0.00-1.00), mean ± SD		0.96 ± 0.06	0.91 ± 0.13

[a] Preoperative visual acuity was assessed with current prescription, if applicable

[b] Target refraction was similar for both eyes

[c] Potentially complicated surgical cases where not explicitly excluded from participation

D=diopter; EQ-5D-5L= EuroQol 5-dimension 5-level; NEI VFQ-25=National Eye Institute Visual Function Questionnaire-25; SD=standard deviation; SEQ=spherical equivalent

Accuracy of web-based vision self-assessment *(telemonitoring group only)*

Comparison of web-based vs. conventional VA assessment

The graphical comparison between the VA assessments at home and at the clinic at 4 to 6 weeks postoperatively is depicted in **Figure 10.3A**. These comparisons were made within the same subject and only refer to the telemonitoring group. The mean difference was -0.03 ± 0.14 logMAR (p=0.07), indicating that there is no systematic under- or overestimation of the VA by the web-based tool. The 95% LoA ranged from -0.30 to 0.24 logMAR, and most assessments fall within the pre-determined acceptable range of ± 0.15 logMAR. Repeatability of the VA assessment showed a fairly similar precision: a mean difference of 0.02 ± 0.14 logMAR (p=0.15), with 95% LoA ranging from -0.25 to 0.29 logMAR (1 vs. 3 months postoperatively, see **Supplementary Figure 10.2**). Six participants were excluded from this repeatability comparison as they had reported a change in vision over the 2-months interval. GEE analysis revealed no associations between any of the examined clinical variables and accuracy of the web-based VA assessment (see **Supplementary Table 10.1**).

Comparison of web-based refraction vs. manifest refraction at the clinic

A graphical comparison between the web-based and subjective refraction outcomes at 4 to 6 weeks postoperatively is depicted in **Figure 10.3B**. These comparisons were made within the same subject and only refer to the telemonitoring group. The mean difference in SEQ was 0.15 ± 0.67 D (p=0.07), with 95% LoA ranging from 1.15 to 1.46 D. The updated algorithm generated a reduced variability, yet with a higher and significant systematic bias: a mean difference of 0.32 ± 0.43 D (p<0.01), with 95% LoA ranging from −0.54 to 1.16 D. GEE analysis revealed that age and the presence of self-reported symptoms in the triage questionnaire before the web-based test are significantly associated with the accuracy of the SEQ assessment, although the extent of these effects (B=0.01 and B=0.17) are not considered clinically relevant (see **Supplementary Table 10.1**).

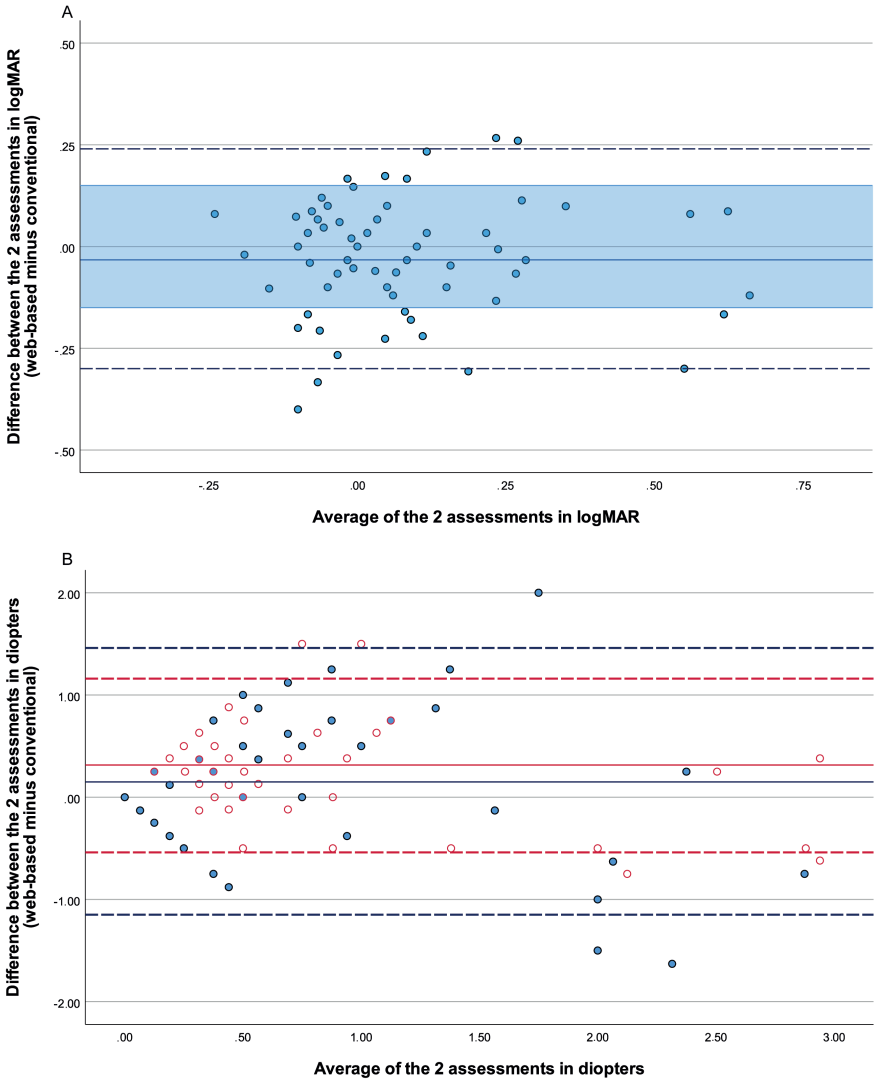


Figure 10.3. Comparisons of web-based versus conventional assessments (telemonitoring patients only).

Please note that these 2 assessments were compared within the same subject and, therefore, only refer to the telemonitoring group. The straight lines represent the mean difference and the dashed lines the 95% limits of agreement. The semitransparent blue zone in A depicts the predetermined clinically acceptable deviation range of ± 0.15 logMAR. Note that an update of the web-based refraction algorithm had taken place after the trial, resulting in a new method of SEQ calculations. The blue lines and blue circles in B represent the original web-based refraction algorithm; the red lines and red circles represent the updated algorithm.

SEQ=spherical equivalent

The data demonstrate that the algorithm tends to overestimate the absolute residual refractive error. The web-based test's ability to determine a residual refractive error >0.5 D has a sensitivity of 88% and specificity of 67%, meaning that there will be a substantial number of false positives (i.e., patients with emmetropia will falsely be classified as ametropic). The attained mean CDVA achieved with the algorithm's web-based refraction increased compared with the mean preoperative CDVA (0.1 vs. 0.3 logMAR), yet was inferior to the mean CDVA achieved with the prescription of the subjective refraction assessed at the clinic: 0.1 vs. −0.1 logMAR (i.e., 0.8 vs. 1.2 Snellen decimal). An improvement of 1 or more lines from the preoperative VA was achieved for 63% of the eyes using the web-based refraction and for 96% of the eyes using the manifest refraction.

Human overread

An unacceptable high within-test variation (i.e., during the same monocular examination) was identified for 15 assessments (in 13 patients); these were excluded from the overall analyses. This subgroup was not evidently different at baseline in terms of age (71 ± 5 years) or sex (46% female) when compared with other telemonitoring participants. Interestingly, 7 of these eyes had a myopic target refraction (i.e., half of all myopic eyes included in the trial) and 1 eye was aphakic because of an interoperative complication; underlining that a poor uncorrected distance VA is associated with a high within-test variation. GEE analysis confirmed this with a positive association between a myopic target refraction and a high within-test variation. No other clinical parameters were identified in this aspect (see **Supplementary Table 10.1**).

Safety

Adverse events and postoperative management changes

Most of the participants did not have a face-to-face consultation in the first week postoperatively: Only 18 participants visited the clinic (36% of the usual care group). These visits had been scheduled preoperatively in line with the clinic's usual practice and were all uneventful.

In addition to the scheduled consultations, 12 usual care and 7 telemonitoring participants contacted or visited the clinic (24% vs. 16% of each group total) (as defined in **Figure 10.1**). These unexpected consultations and consecutive management changes are presented in **Table 10.2**. Three surgical complications were registered: 1 residual cortical lens matter in the anterior chamber, 1 wrong lens implantation, and 1 eye was left aphakic because of intraoperative difficulties. All of these underwent successful reoperations.

Table 10.2. Reasons for unexpected consultations (independent of study scheme).

Reason for consultation	Usual care participants (n=12)	Telemonitoring participants (n=7)	Management change
No pathology, n (%)	3 (25)	4 (57)	Reassurance of patient
Dry eye syndrome or blepharitis, n (%)	5 (42)	1 (14)	Addition of lubricating drops
Postoperative inflammation, n (%)	2 (17)	1 (14)	Addition of anti-inflammatory drops
Intraoperative complication, n (%)	2 (17)	1 (14)	Reoperation

Triage questionnaires

In addition to the web-based eye tests, the telemonitoring participants were asked to fill out triage questionnaires. The reported symptoms are presented in **Table 10.3**.

Table 10.3. Outcomes of self-reported triage questionnaires.

Self-reported symptom in triage questionnaire	< 1 week after surgery, n (%) (n=87 eyes)[a]	± 1 month after surgery, n (%) (n=85 eyes)[a,b]
None	33 (38)	41 (48)
Photophobia	25 (29)	18 (21)
Itchiness	7 (8)	9 (11)
Oppressive feeling	4 (5)	7 (8)
Gritty feeling	4 (5)	11 (13)
Burning sensation	3 (3)	7 (8)
Pain	3 (3), mean score = 2/10	4 (5), mean score = 2/10
Free text: “Tears”	0 (0)	4 (5)
Free text: “Dry eyes”	0 (0)	3 (4)
No response to questionnaire	10 (11)	4 (5)

[a] Surgery cancelled for one eye

[b] One study drop-out after surgery (both eyes)

Self-reported outcome measurements

The response rate of the questionnaires at baseline and 3 months postoperatively was 100%. An overview of the self-reported outcome measurements is presented in the **Supplementary Table 10.2**. Visual functioning (indicated by the Catquest-9SF and NEI-VFQ-25 scores) improved postoperatively for all participants (with a mean improvement of −0.80 and 16.70, respectively), and performing vision self-assessments did not materially affect these scores, as there were no significant differences between the 2 follow-up groups. The effects of cataract surgery on EQ-5D-5L index scores were marginal in both groups.

Discussion

Our study evaluated remote cataract surgery follow-up involving self-assessments of visual function and self-reported outcome measurements using telehealth technology. The studied web-based postoperative VA assessment, performed independently at home, showed a mean difference of 0.03 ± 0.14 logMAR when compared with conventional ETDRS testing. This negligible mean difference indicates that there is no fixed bias, meaning that the web-based test does not systematically over or underestimate VA. The 95% LoA (i.e., the distribution of differences) ranged from −0.30 to 0.24 logMAR, indicating that outlier assessments occurred beyond the predetermined clinical deviation limit of ± 0.15 logMAR. The web-based refraction algorithm resulted in an overestimation of the residual refractive error and will falsely indicate a residual refractive error in patients with emmetropia. Adverse events were rare and occurred in both groups. Telemonitoring and self-reporting led to a more detailed overview of postoperative symptoms and complaints while unscheduled consultations were recorded less often. We acknowledge that the study was not powered on adverse events and postoperative management changes. Vision-related quality of life improved postoperatively with no apparent differences between groups.

The mean difference between the web-based VA assessment and the conventional chart was clinically negligible. However, when evaluating agreement, it is crucial to look into the distribution of differences. It is important to realize that a certain degree of variation is unavoidable when comparing different charts, given the diversity in optotypes and scoring criteria.[11,18] An authoritative study comparing repeated VA assessments with various charts and observers concluded that differences exceeding ± 0.15 logMAR should, therefore, be considered clinically relevant.[11] In our study, we identified outcomes

beyond this range. It should be noted that the occurrence of variation in the absence of clinical changes is a common feature of VA testing, attributed to behavioral factors such as fatigue or intrinsic motivation. This has been demonstrated by repeatability (i.e., test-retest studies) that evaluate repeated VA assessments using the same chart in the same person. For the ETDRS chart, repeatability studies have shown 95% LoA ranging up to ± 0.18 logMAR.[12,19] For the Snellen chart, the variability is higher, with 95% LoA ranging up to ± 0.24 logMAR using the single-letter method and up to ± 0.33 logMAR using the line assignment method (i.e., the test is terminated when half of the letters on the line are misread).[12,19] The wide distribution of measurement variability indicated by the 95% LoA underlines that the occurrence of outlier measurements is an inherent aspect of assessing VA. Notwithstanding, the here-found agreement is subpar to the precision reported in ETDRS test-retest studies, prompting future efforts to increase the measurement precision of the web-based test.

Multiple telehealth tools for self-assessing visual function are available on the internet, although many have not been validated.[20] Those that are validated have mostly been evaluated in controlled settings, prone to observer bias.[19] A previous study evaluated the performance of the here-studied web-based test in a supervised hospital setting and reported a slightly better precision regarding the uncorrected VA assessment after cataract surgery (95% LoA −0.26 to 0.15 logMAR).[21] Unsupervised home assessments will arguably be more affected by behavioral and environmental factors than assessments in controlled settings. In this study, the web-based test was performed independently by patients at home, reflecting a real-world scenario.

Future software updates should be aimed at improving the measurement precision of the web-based test. This involves new technical integrations, for instance, by using webcam images and providing AI-guided live feedback to optimize testing conditions at home (e.g., considering lighting conditions and distance to the screen). Moreover, the ease by which repeated measurements can be performed is an interesting feature of home-based self-assessments, potentially reducing the variability of VA results. The web-based test could benefit from automated detection of within-test inconsistencies indicative of poor performance, with the subsequent functionality to let patients repeat a specific part of the test or to redo the complete test at a later point in time under optimal testing conditions.

It is important to address the suboptimal performance of the web-based refraction assessment in this study population. While an improvement in VA is indicative of surgical success, most cataract guidelines also recommend a refraction assessment postoperatively.[22] Our findings indicate that the current version of the web-based refraction assessment is not able to reliably determine refractive error in this patient population.

The current version has a tendency to falsely identify a residual refractive error in patients with emmetropia. This is an important limitation. The algorithm, therefore, requires a recalibration before it can be useful to collect surgery outcomes for mandatory registries. It was trained on a population of young adults (aged 18 to 40 years) with an excellent VA (>1.25 Snellen decimal).[23] VA has been reported to decrease with age, even in healthy eyes, particularly after 55 years of age.[24] The assumption in the algorithm that any VA poorer than −0.1 logMAR requires a refractive correction will, therefore, by design result in an overestimation of the residual refractive error in older adults. A data set comprising normative best corrected VA scores after uneventful post-cataract surgery (based on 490,240 records) has been obtained from the European Registry of Quality Outcomes for Cataract and Refractive Surgery and will be used to recalibrate the algorithm. An updated and accurate self-assessment of residual refractive errors postoperatively would be an important step for automated data collection and quality registration.

The quality of vision as perceived by the patient may be influenced by parameters other than VA. Patient-reported data on vision-related quality of life have become important indicators for surgical success.[25] These parameters are often under-reported in conventional care. Interestingly, the response rate of these questionnaires in this study was 100%. We believe that collection of self-reported data relies on adequate instructions, a perceived benefit of registration, and a good and accessible digital infrastructure. Therefore, engaging patients in their eye health by self-monitoring their vision might build on this perception of usefulness and lower thresholds to fill out these outcome-related questionnaires. In addition, a well-integrated web-based platform could be of great value for maintaining feedback loops to cataract surgeons, by collecting data that are relevant for quality control and benchmarking.

Public support is of paramount importance for successful adoption of a remote follow-up practice. Some eye care professionals might be reluctant to adopt remote care practices as they fear vision-threatening postoperative complications. Notwithstanding, a substantial body of clinical experience and scientific evidence has demonstrated the safety and efficacy of telephone follow-up alternative to face-to-face visits.[5,26] Unexpected management changes are unlikely in asymptomatic patients after uncomplicated surgery, and a structured set of clinical questions (such as pain, redness, and decreased vision) has been proven sufficient to risk-stratify patients.[22,27] A recent innovation is an automated telephone consultation with AI-driven clinical assistants, combining a low-tech method of delivery with a high-tech large language model–driven solution.[28] A potentially more accessible and scalable alternative could be a self-administered digital questionnaire, as in this study, or a combination of both: an interactive questionnaire providing personalized

feedback based on the responses. Patients could, for instance, be reminded to apply their lubricating drops as most reported symptoms in the triage questionnaires relate to dry eyes. An automated alert system, integrated with the clinic's electronic health record should identify those in need of a follow-up consultation.

Finally, we would like to underline that conventional follow-up care involving face-to-face visits should always remain accessible. Although high patient satisfaction rates for remote cataract surgery follow-up, involving (automated) telephone consultations and/or self-assessments of visual function, have been reported, the recruitment phase of this trial seemed challenging.[29-31] Regional differences in the ability and willingness to participate were identified, with participation rates being highest in the Netherlands. This was mainly rooted in technology adoption barriers. In Germany and Austria, a notable proportion of invited patients could not participate because of a lack of access to mobile devices or insufficient proficiency to perform self-assessments at home. The participant rates align with Eurostats data indicating that the Netherlands surpasses both Germany and Austria by having the highest levels of internet usage and greatest number of citizens possessing basic digital skills in Europe.[32] Internet access has, however, been growing rapidly across Europe over the past decade, and we expect the group of digitally skilled patients with cataract to grow exponentially in the upcoming years. In reality, a group of patients will remain not suitable for remote follow-up. Preoperative counselling and identifying those at risk of complications and postoperative management changes is crucial. This includes patients with known risk factors of endophthalmitis (e.g., blepharitis, ectropion), uncontrolled intraocular pressure elevation (e.g., glaucoma, ocular hypertension), or postoperative inflammation (i.e., uveitis); those who lack the (digital) skills to self-report their own clinical data; or those who are not willing to do so.[33-36] In addition, even when the patient was initially planned for remote follow-up, thresholds for call-backs to the clinic should be low.

In conclusion, our study showed that a group of digitally skilled patients with cataract were able to complete unsupervised self-assessments of visual function and self-report postoperative outcome measures. This underlines the potential of telemonitoring after cataract surgery. Adverse events or (vision-related) quality of life did not differ between the 2 follow-up groups. Future adjustments should aim to further improve the precision of the web-based test. The biggest challenges revolve around the inevitable occurrence of outlier assessments, which could be more frequent when vision assessments are performed unsupervised by patients at home. Software updates of the web-based tool should be aimed at identifying and limiting these outliers, and design automated feedback loops that invite to retest when an outlier is suspected. The current version of the web-

based refraction assessment does not deliver reliable outcomes in this population and requires a recalibration, with future training building on a normative data set derived from the European Registry of Quality Outcomes for Cataract and Refractive Surgery. We believe that remote self-care can be a promising avenue to comply with increasing demands of cataract care, and improvements of technology and public support could make web-based self-collection of postoperative outcome data become a reality.

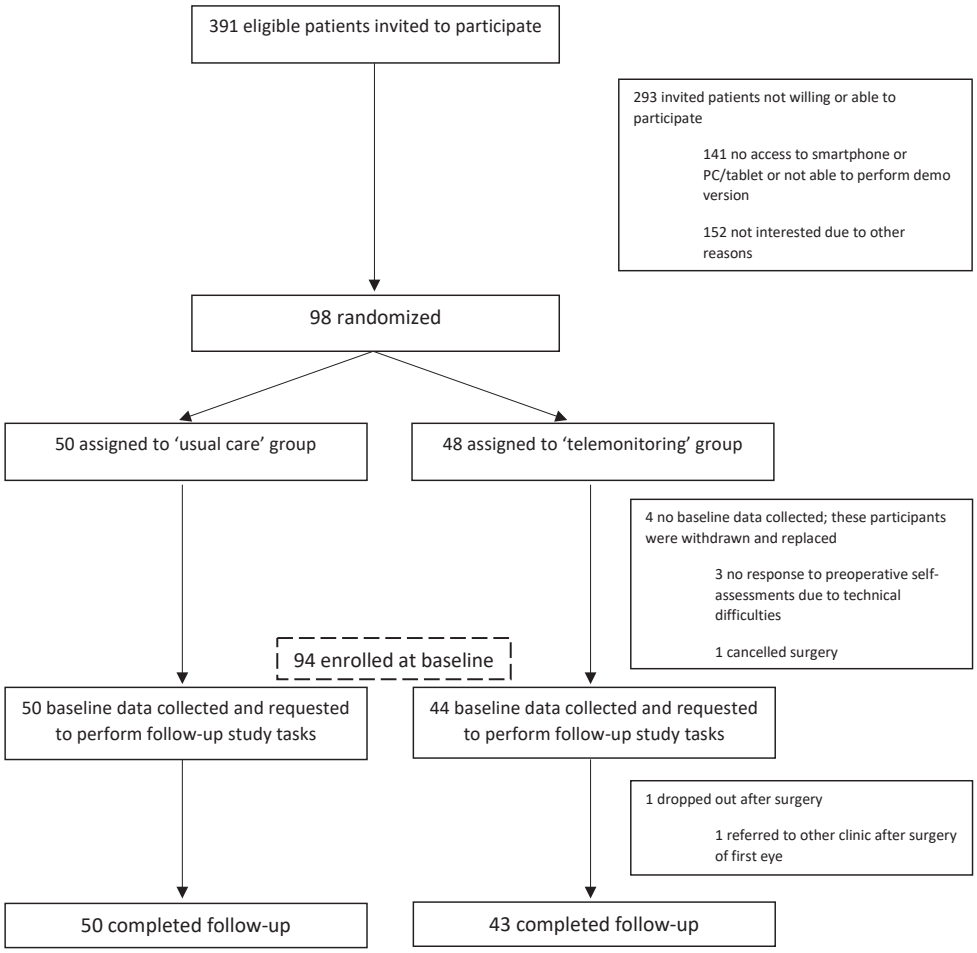
What was known

- Demands for cataract surgery are ever-increasing. Although national protocols vary, conventional cataract surgery follow-up typically consists of routine face-to-face examinations to assess postoperative visual function and detect adverse events
- The high volume of surgical procedures and low adverse event rates make routine cataract surgery follow-up an interesting field for using telehealth for remote care delivery.
- A web-based platform for collecting self-assessments of visual function and self-reported clinical outcome measures has yet to be evaluated.

What this paper adds

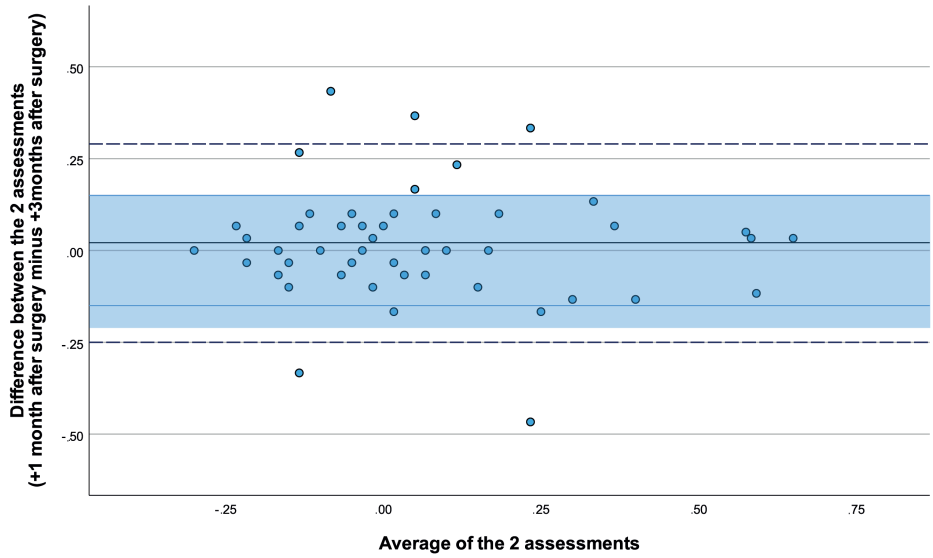
- Digitally skilled patients with cataract are able to complete unsupervised self-assessments of visual function and self-report clinical outcome measures using a web-based platform.
- Both conventional and web-based follow-ups yielded similar patient-reported outcome measurements outcomes and adverse event rates, suggesting less unscheduled clinical visits with web-based follow-ups.
- Future adjustments should aim to further improve the precision of the web-based test. The biggest challenges revolve around the inevitable occurrence of outlier assessments, which could be more frequent when vision assessments are performed unsupervised by patients at home.

Supplements



Supplementary Figure 10.1. Trial profile.

Note that after obtaining informed consent, patients were randomized 1:1. Four patients were withdrawn after randomization and randomly replaced, as no baseline data were collected (in line with the study protocol).



Supplementary Figure 10.2. Repeatability of the web-based visual acuity assessment.

The straight line represents the mean difference and the dashed lines represent the 95% limits of agreement. The semi-transparent blue zone depicts the pre-determined clinically acceptable deviation range of ± 0.15 logMAR.

VA=visual acuity

Supplementary Table 10.1. Multivariable GEE analysis to investigate associations between clinical variables and the accuracy of the web-based vision assessments.

	Difference between the VA scores of the web-based and conventional test, in logMAR[a]			**Difference between the SEQ scores of the web-based and conventional test, in diopters**[a]			**Within-test variation >0.20 logMAR**		
	Unstandardized B coefficient	95% CI	p-value[b]	Unstandardized B coefficient	95% CI	p-value[b]	Unstandardized B coefficient	95% CI	p-value[b]
Sex[c]	0.01	-0.04; 0.06	0.69	-0.18	-0.37; 0.01	0.06	-0.04	-0.20; 0.13	0.68
Age	0.00	0.00; 0.00	0.03	0.01	0.00; 0.03	0.05	0.01	0.00; 0.01	0.30
Myopic target refraction[d]	0.05	-0.04; 0.14	0.27	0.42	0.10; 0.73	0.10	0.23	0.03; 0.42	0.03
Self-reported symptoms prior to assessment[e]	-0.02	-0.06; 0.24	0.40	0.17	0.00; 0.33	0.04	0.06	-0.11; 0.23	0.54

[a] Absolute difference between the two assessments in logMAR, web-based tests with within-test variation >0.20 logMAR were excluded

[b] Analyzed using a Generalized Estimating Equations to correct for inclusion of two eyes of one patient

[c] "Female" as reference

[d] "Emmetropia" (target refraction SEQ >-0.5 or <0.5D) as reference

[e] "No reported symptoms" as reference (symptoms include photophobia, itchiness, oppressive feeling, gritty feeling, burning sensation or pain)

CI=confidence interval; D=diopter; SEQ=spherical equivalent; VA=visual acuity

Supplementary Table 10.2. Outcomes of self-reported (vision-related) quality of life questionnaires.

	Both groups Mean ± SD	Telemonitoring group Mean ± SD	Usual care group Mean ± SD	Difference between groups	p-value
Catquest-9SF score[a]					
Preoperatively	3.05 ± 0.54	3.05 ± 0.53	3.05 ± 0.55	0.00	0.98
Postoperatively	2.25 ± 0.53	2.18 ± 0.55	2.31 ± 0.50	0.13	0.24
Improvement[b]	-0.80 ± 0.75	-0.87 ± 0.77	-0.74 ± 0.72	0.13	0.40
Composite NEI-VFQ-25 score[c]					
Preoperatively	74.49 ± 13.76	75.42 ± 11.89	73.66 ± 15.29	-1.76	0.54
Postoperatively	91.43 ± 6.21	91.51 ± 6.36	91.36 ± 11.89	-0.15	0.91
Improvement	16.70 ± 13.26	15.55 ± 11.23	17.70 ± 14.83	2.15	0.44
EQ-5D-5L score[d]					
Preoperatively	0.93 ± 0.11	0.96 ± 0.13	0.91 ± 0.13	-0.05	0.01
Postoperatively	0.93 ± 0.14	0.97 ± 0.06	0.89 ± 0.17	-0.08	0.02
Improvement	-0.01 ± 0.09	0.01 ± 0.04	-0.02 ± 0.12	-0.03	0.17

[a] Calculated using the official ICHOM EU conversion sheet (Rasch scores)

[b] A shift in a negative direction between the preoperative and postoperative CatQuest-9SF score signifies an improvement

[c] Calculated using the official NEI-VFQ scoring manual

[d] Calculated using the official EuroQol Group EQ-5D-5L Index Value Calculator

EQ-5D-5L= EuroQol 5-dimension 5-level; NEI VFQ-25=National Eye Institute Visual Function Questionnaire-25; SD=standard deviation

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CHAPTER 11

Optimizing the Postcataract Patient Journey Using AI-Driven Teleconsultation: Prospective Case Study

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Abstract

Background: Given the increasing global demand for ophthalmologic care and the anticipated shortage of ophthalmology professionals, innovative solutions are essential for optimizing health care delivery. Digital health technologies offer promising opportunities to efficiently manage high patient volumes. Cataract surgery, with its established safety profile and routine postoperative care, provides an ideal setting for implementing such innovations. Structured clinical questions have proven effective in identifying patients requiring further assessment, supporting the feasibility of follow-up through telephone consultations. To further extend this approach, artificial intelligence–based follow-up systems may offer an opportunity to automate these interactions, reduce clinician workload, and streamline care pathways.

Objective: The aim of the study is to assess the clinical safety and effectiveness of an artificial intelligence–based follow-up call system (Dora-NL1) in identifying patients who require further assessment after cataract surgery in the Netherlands.

Methods: This prospective single-center study was conducted at the University Eye Clinic Maastricht, the Netherlands. Adult patients who underwent uncomplicated cataract surgery were eligible to participate. All patients received a Dora-NL1 follow-up telephone call at 1 and 4 weeks postoperatively in addition to standard care (a clinician-led telephone consultation at week 1 and an in-person hospital visit at week 4). The Dora-NL1 calls used a standard conversational flow to evaluate symptoms and recommend a clinical outcome. The recommended outcomes of Dora-NL1 were based on the symptoms reported by the patient. Clinical safety and accuracy were assessed by comparing Dora-NL1 outcomes to blinded clinician assessments of recorded calls and to standard postoperative care. Patient-reported usability was measured using the Telehealth Usability Questionnaire and Net Promoter Score.

Results: A total of 105 patients with a mean age of 72 (SD 7) years were included in the analysis. Dora-NL1 demonstrated high agreement with clinician-supervised calls, with symptom evaluation accuracy ranging from 89% to 99% (κ=0.390-0.947) and care management decision accuracy between 83% and 88% (κ=0.640-0.753). At week 1, Dora-NL1 showed a sensitivity of 100% and a specificity of 42% compared to standard clinician-led telephone consultations with no missed clinical concerns. At week 4, compared to the in-person follow-up, Dora-NL1 failed to identify 4 (4.1%) patients who required unexpected management changes, including 3 with asymptomatic complications detected only via slit lamp examination and 1 with complaints in the non-operated eye. Patients rated Dora-NL1 positively, with Net Promoter Scores of +13.5 and +12.6 at week 1 and 4, respectively.

The Telehealth Usability Questionnaire was completed by 98 patients, yielding a mean score of 3.19 (SD 1.13) on a 5-point scale, highlighting its simplicity, ease of use, and audibility.

Conclusions: Dora-NL1 is a safe and effective tool for automated postoperative screening following cataract surgery. It offers a safe alternative to clinician-led telephone consultations in routine cases but cannot fully replace in-person examinations.

Introduction

Our health care systems worldwide face increasing challenges, driven in large part by demographic shifts such as population aging and the rising prevalence of chronic diseases. These developments contribute to a growing mismatch between demand for and supply of health care services. In ophthalmology, a field characterized by high patient volumes and an aging patient population, it is expected that, by 2035, the workforce will be insufficient to meet the growing demand for care.[1-3] This trend is expected to intensify the burden on our health care systems. Moreover, the strain extends beyond ophthalmology, with similar challenges observed in most specialties including cardiology, urology, and neurology, underscoring the need for innovative, scalable solutions to maintain the quality and accessibility of care.[2] To mitigate this growing pressure, efficient management of high-volume workloads is essential. eHealth solutions offer promising opportunities to optimize health care delivery, enhance accessibility, and reduce the burden on clinical personnel. The COVID-19 pandemic further accelerated the adoption of such technologies, demonstrating their potential to ensure continuity of care and support remote follow-up.[4,5] In ophthalmology, advances in digital or remote health technologies have facilitated developments in triage, diagnosis, and patient monitoring.[4-6] Cataract care, in particular, is well suited to such innovations, as it is among the most frequently performed procedures worldwide and associated with a high safety profile and predictable recovery.[7,8] Previous studies have shown that structured sets of postoperative clinical questions can reliably identify patients who require further assessment within the first week after surgery. This has enabled safe and feasible alternatives to in-person follow-up during the early postoperative period, such as nurse-led telephone consultations.[9,10] Building on these developments, automated systems offer an additional opportunity to streamline care pathways. One such innovation is the voice-based automated conversational assistant, “Dora” (Ufonia Limited), which uses a machine learning–driven conversational model to conduct follow-up after cataract surgery via telephone. The system applies a standardized script of clinically validated questions to screen for symptoms that may indicate postoperative complications. Only patients who give responses requiring further attention are flagged for clinical review, potentially reducing the need for in-person or clinician-led consultations. Dora has already been validated for use in the United Kingdom, where it has demonstrated safety, feasibility, and high patient acceptability while also reducing the burden on outpatient services.[11] The English Dora system uses a discriminative dialogue mechanism that combines rule-based natural language processing with machine learning components. It uses a Dual Intent and Entity Transformer classifier for intent recognition.[12] This model interprets patient responses by mapping them to predefined “intents,” which

in turn determine the next action in the dialogue flow. These “intents” were carefully designed to capture relevant aspects of postoperative symptomatology and are linked to a rule-based system that ensures that the complete sequence of questions is asked in a clinically appropriate order. Both the conversational flows and response content were developed in close collaboration with specialist clinicians and have been previously described in detail.[11]

In this study, our aim is to validate and evaluate the clinical safety and effectiveness of the first Dutch version (Dora-NL1) in identifying patients who require further assessment after cataract surgery in the Netherlands. We hypothesize that the Dora-NL1 will be a safe and effective tool for early complication screening and a reliable alternative to human-led telephone consultation in routine cataract care.

Methods

Recruitment

Adult patients (≥21 years) who underwent uncomplicated cataract surgery on either 1 or both eyes, with implantation of a monofocal (including toric) intraocular lens (IOL) targeted for emmetropia, were recruited for this study at the University Eye Clinic of the Maastricht University Medical Center+. Patients were excluded if they had serious ocular comorbidities requiring face-to-face postoperative visits, underwent combined procedures (e.g., glaucoma or retinal surgeries), needed follow-up visits within 1 week due to complications, were not able to speak Dutch, or had significant hearing or cognitive impairments.

Ethical Considerations

All patients were informed about the study and signed an informed consent before enrollment. This prospective validation study was approved by the local medical ethics committee (Medisch-ethische toetsingscommissie azM/UM, Maastricht, the Netherlands; approval METC 2022-3258) and executed in accordance with the Declaration of Helsinki. Patient data were anonymized to ensure confidentiality. Participants did not receive financial compensation for their involvement.

Dutch Model Development and Validation

The model for the autonomous cataract follow-up call system, Dora, was originally

developed for English-speaking patients. In this study, the model was adapted for use in Dutch, with the initial Dutch system developed from the pretrained English version. To facilitate this adaptation, an intermediary translation function was integrated into the Dora-NL1 software, translating captured Dutch answers into English, formulating a response, and then converting it back to Dutch for speech output, as presented in **Figure 11.1**. While this is a crucial step, the translation process introduces complexity and the risk of altering the original message. The Dora model has a finite number of potential utterances; thus, it was possible to confirm that these were correctly translated into Dutch. In addition to the translation layer, the system was further adapted to improve its handling of Dutch-language input. Dutch utterances that were not recognized by the English Dora system were translated into English and manually reviewed to assign them to the appropriate intent category. These additions were incorporated into the training data to enhance the model's ability to interpret Dutch responses. All translations and validation of the Dutch utterances were carried out by a bilingual clinician-researcher who was independent of the Dora development team. To ensure the reliability of the Dora-NL1 software, we ran a preliminary investigation before starting the study by looking at the agreement between Dutch (Dora-NL1) and English (Dora-R2) calls. In total, 12 different postoperative scenarios were created, reflecting both the common and most severe outcomes of patients who underwent cataract surgery. These scenarios were simulated by the bilingual clinician-researcher in both languages using a predefined strict script that underwent forward and back-translation and independent expert review to ensure accuracy and consistency. The responses from both models were compared to assess their consistency, defined as acceptable when no statistically significant differences were found in symptom assessment and care management decisions. The questions and responses used for model validation were similar to those used in the trial version of the Dora-NL1. Furthermore, before starting the trial, we recruited volunteers to evaluate the different regional accents and variations in phrasing.

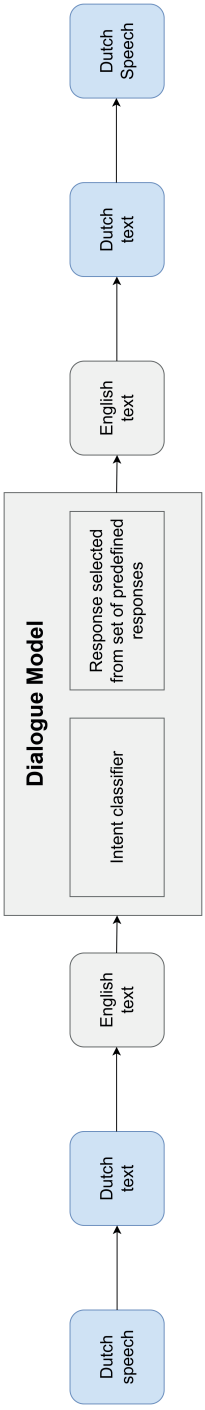


Figure 11.1. Schematic workflow of the Dora-NL1 system.

Postoperative Follow-Up

Patients undergoing bilateral cataract surgery underwent either immediate sequential bilateral or delayed sequential bilateral cataract surgery. For those undergoing unilateral surgery, the postoperative follow-up schedule aligned with that of immediate sequential bilateral cataract surgery. All patients received regular postoperative care in addition to the Dora-NL1 calls, as shown in **Figure 11.2**. One week after the first eye surgery, patients received both a Dora-NL1 call and a regular postoperative telephone consultation with a clinician. During the telephone consultations, a standardized set of questions was used to evaluate the patient's symptoms and identify any necessary management changes. Management changes included deviations from the standard eye drop tapering schedule, the addition of any drops (excluding artificial tears), the need for an additional hospital visit, or the implementation of further interventions (excluding suture removal). Clinicians conducting the telephone consultations were masked to the results of the Dora-NL1 calls. For patients receiving a toric IOL, a 1-week follow-up hospital visit was scheduled instead of a telephone consultation. At 4 weeks postoperatively, another Dora-NL1 call was conducted within 24 hours before the regular outpatient clinic visit. The final postoperative visit at the outpatient clinic consisted of a routine ophthalmological assessment, including evaluation of the refractive status and visual acuity as well as slit lamp and retinal examination.

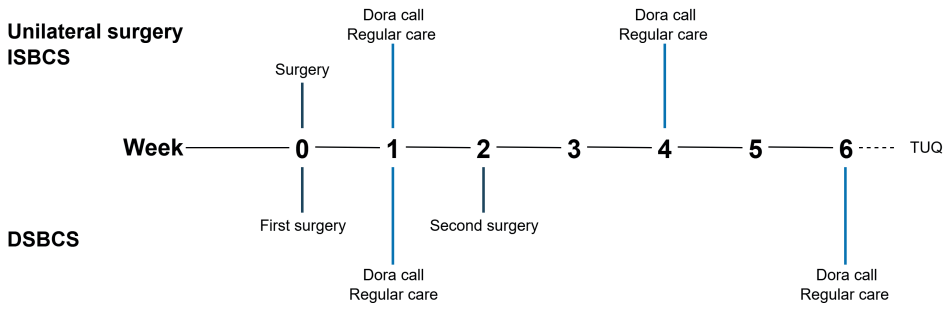


Figure 11.2. Patient pathway.

DSBCS=delayed sequential bilateral cataract surgery; ISBCS=immediate sequential bilateral cataract surgery; TUQ=Telehealth Usability Questionnaire

Dora-NL1 Call

The postoperative Dora-NL1 call followed a structured conversational flow: greeting and introduction, patient identification, symptom evaluation, patient queries, care management decision-making, user-acceptability question, and call closure. The key symptoms that were assessed included redness, pain, reduced vision, flashing lights, and floaters. At the core of this, Dora decision-making is an intent recognition system, a Dual Intent and Entity Transformer–based classifier that classifies the patient responses into predefined categories of intents (such as a "red eye" or "poor vision").[12-14] These intent categories have been developed based on 2 prior clinical studies, and real-world use of Dora in the United Kingdom, with the input of clinicians and system developers.[11,15] For each patient utterance, the classifier assigns a confidence score reflecting the system's certainty in its interpretation. If the confidence score for a response falls below the preset threshold, Dora-NL1 prompts the patient to repeat or rephrase their response—allowing up to 2 attempts—to improve the accuracy of symptom detection.

Dora-NL1 classified each reported symptom as either absent, present without clinical significance, present with clinical significance, or inconclusive due to insufficient information. The thresholds used to flag "potential concerns" were intentionally set to err on the side of caution. These were based on the framework established for the English version and were informed by clinical expertise and relevant literature on symptomatology, with a focus on sensitivity to minimize the risk of missing significant complications. If there was incomplete information regarding a symptom or if the patient asked a question that Dora-NL1 could not address, the overall call outcome defaulted to "potential clinical concerns."

Based on the overall symptom evaluation, Dora-NL1 provided an overall outcome of either "no clinical concerns" or "potential clinical concerns." The decision-making flowchart can be found in **Supplementary Material 11.1**. Depending on the overall call outcome, Dora-NL1 generated a corresponding care management recommendation: either "no review recommended" or "clinician review recommended." All Dora-NL1 calls were recorded and subsequently reviewed by a clinician, who independently assessed symptoms and made clinical decisions based on the audio recordings while masked to Dora-NL1's outputs and the regular care outcomes.

User Acceptability

At the end of each call, Dora asked patients to rate their likelihood of recommending the automated system to others on a scale of 1 to 10. The Net Promoter Score (NPS) was

calculated by subtracting the "%-detractors" (scores of 1 to 6) from the "%-promoters" (scores of 9 or 10). [16] Additionally, after the final postoperative visit, patients were invited to complete the Telehealth Usability Questionnaire (TUQ), translated to Dutch. The TUQ consists of 20 questions that can be answered on a 5-point scale ranging from 1=fully disagree to 5=fully agree.[17]

Sample Size and Statistical Analysis

For this pilot study, a sample size of 100 participants who completed the 1-week call was used. Data analysis was conducted using SPSS (version 28.0; IBM Corp) and Microsoft Excel. Qualitative variables were summarized as frequencies and percentages, while descriptive statistics, including mean and SD, were calculated for quantitative variables. The agreement between the English and Dutch models in the developmental phase was tested using chi-square or Fisher exact tests. The interobserver reliability was calculated using the Cohen κ coefficient. The accuracy of the tool was defined in accuracy, specificity, and sensitivity, including 95% CIs of these proportions calculated using the Wilson score interval. A significance level of ≤.05 was applied.

Results

Preliminary Study Results

The agreement between the Dutch (Dora-NL1) and English (Dora-R2) versions used 12 scenarios. The accuracy in terms of detecting symptoms, including redness, pain, floaters, and flashing lights, was 100%. With respect to reduced vision, the accuracy was 83.3%, affected by 2 missing data points where Dora was unable to collect or understand the patient's response (1 from the English model and 1 from the Dutch model). The accuracy of the care management decisions was 91.7%, with the decrease attributed to these missing data points. There was no statistically significant difference found between the 2 language models (p=0.32). Detailed responses for each scenario are provided in **Supplementary Table 11.1**.

Study Results

Between July 2023 and April 2024, a total of 182 patients who were scheduled for cataract surgery were screened for eligibility. Of these, 168 were suitable for participation, and 111 patients provided informed consent. In total, 105 patients (190 eyes) with a mean age of 72

(SD 7; range 50-84) years were included in the analysis; 100 patients completed the 1-week follow-up with Dora-NL1, and 98 patients completed the 4-week follow-up. The patient flowchart can be found in **Figure 11.3**. The baseline characteristics are summarized in **Table 11.1**.

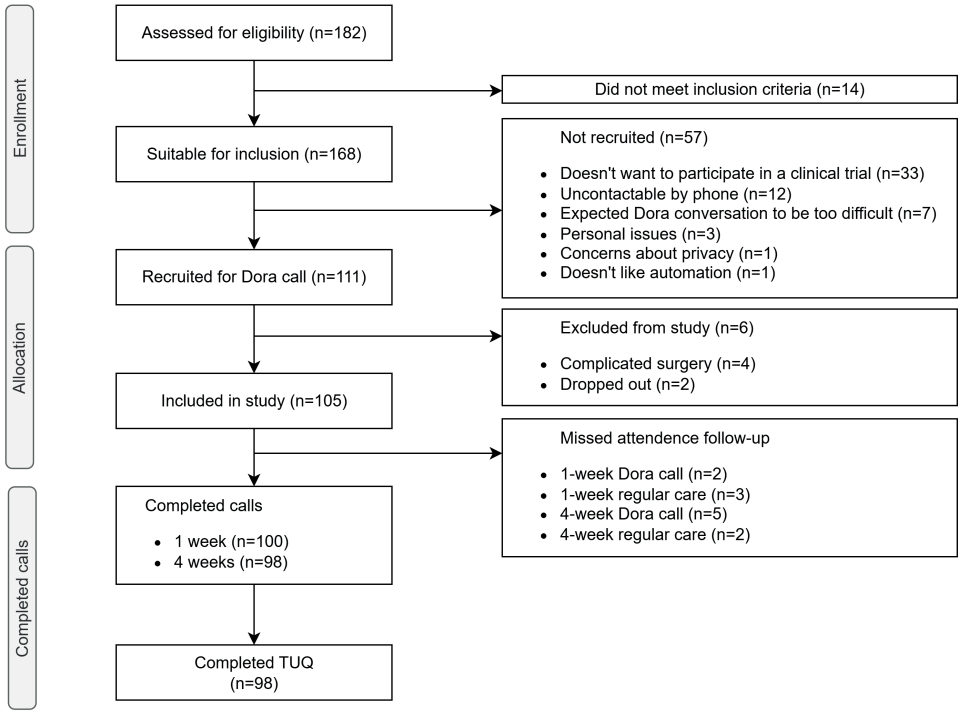


Figure 11.3. Flowchart study.

TUQ=Telehealth Usability Questionnaire

Table 11.1. Baseline characteristics.

Demographics (n=105)	
Gender, n (%)	
Male	44 (41.9)
Female	61 (58.1)
Surgical risk factors, n (%)	
High myopia	3 (2.9)
High hyperopia	3 (2.9)
Glaucoma	2 (1.9)
Corneal pathology	7 (6.7)
Diabetic retinopathy	1 (1.0)
Previous vitrectomy	3 (2.9)
Type of surgery, n (%)	
Unilateral	20 (19.0)
DSBCS	29 (27.6)
ISBCS	56 (53.3)
IOL characteristics (n=190)	
Type of IOL, n (%)	
Monofocal non-toric	169 (88.9)
Monofocal toric	21 (11.1)
IOL Power (D), Mean ± SD	20.0 ± 3.8
Refractive target (D), Mean ± SD	-0.03 ± 0.12

DSBCS=delayed sequential bilateral cataract surgery; ISBCS=immediate sequential bilateral cataract surgery; TUQ=Telehealth Usability Questionnaire; IOL=intraocular lens

Postoperative Week 1

The agreement between the assessments made by Dora-NL1 at week 1 and those made by the clinician reviewing the Dora-NL1 call is shown in **Table 11.2**. The sensitivity ranged from 66.7% to 100%, and specificity ranged from 78.6% to 97.4% in identifying key symptoms and making care management decisions, with κ values ranging from 0.390 to 0.947. Only the detection of new floaters at week 1 showed a sensitivity of 66.67% and a specificity of 96.81%. Sensitivity was reduced because Dora failed to capture 2 patients' initial reports of floaters. In line with this protocol to repeat the question when the input is unclear or not captured by the system, Dora reasked the patients whether they

had floaters. On the second attempt, both responded that they did not, resulting in an incorrect final classification. The agreement between the automated care management decisions made by Dora-NL1 and the regular care is shown in **Table 11.3**. At week 1, only patients who received regular telephone consultations were analyzed, excluding those with toric IOLs (n=13) who were scheduled for routine postoperative hospital visits. At this time, Dora-NL1 demonstrated 100% sensitivity with no false negatives and a specificity of 41.7%, yielding a false positive rate of 57.5%.

Table 11.2. Symptom and outcome accuracy of automated Dora versus supervised Dora call at week 1.

Decision (n=100)	Accuracy (%) [95%CI]	Sensitivity (%) [95%CI]	Specificity (%) [95%CI]	Kappa [95%CI]	p-value
Redness[1]	96.0 [90.12; 98.4]	100 [56.6; 100.0]	95.79 [89.7; 98.4]	0.695 [0.416; 0.973]	<0.001
Pain[2]	97.0 [91.6; 99.0]	100 [20.7; 100.0]	96.97 [91.5; 99.0]	0.390 [-0.149; 0.929]	<0.001
Vision issue[3]	94.0 [87.5; 97.2]	100 [70.1; 100.0]	93.41 [86.4; 96.9]	0.718 [0.508; 0.928]	<0.001
New floaters	95.0 [88.8; 97.9]	66.7 [30.0; 90.3]	96.81 [91.0; 98.9]	0.589 [0.262; 0.916]	<0.001
Flashing lights	98.0 [93.0;99.5]	100 [86.2; 100.0]	97.37 [90.9; 99.3]	0.947 [0.874; 1.000]	<0.001
Outcome	88.0 [80.2; 93.0]	100 [92.0; 100.0]	78.57 [66.2; 87.3]	0.763 [0.641; 0.885]	<0.001

[a]Accuracy=(true positive+true negative)/(true positive+true negative+false positive+false negative)

[b]Amount of cases with “incomplete information”: n=4

[c]Amount of cases with “incomplete information”: n=1

Table 11.3. Accuracy in clinical decision-making between automated Dora versus regular telephone consultation at week 1.[a]

	Decision during the regular telephone consultation		
Dora decision	Potential concerns n, (%)	No clinical concerns n, (%)	Total n, (%)
Potential concerns n, (%)	1 (1.1)	50 (57.5)	51 58.6)
No clinical concerns n, (%)	0 (0.0)	36 (41.4)	36 (41.4)
Total n, (%)	1 (1.1)	86 (98.8)	87 (100)

[a]Sensitivity: 100% (95% CI 20.7-100.0), specificity: 41.9% (95% CI 32.0-52.4), κ: 0.016 (95% CI 0.00-0.398); p=0.39

Postoperative Week 4

Table 11.4 summarizes the agreement between the Dora-NL1 assessments at week 4 and those by the clinician reviewing the Dora-NL1 call, with a 100% sensitivity and specificity ranging from 88.3% to 99% for symptom evaluation. Despite this agreement, 3 asymptomatic patients who were identified as having "no clinical concerns" required an unexpected management change at the 4-week postoperative clinic visit, and 1 patient who had been asymptomatic of visual concerns at the week 1 Dora and clinician calls reported binocular diplopia. The 3 asymptomatic patients all had inflammatory cells detected during slit lamp examination, with 1 of these patients also having a residual lens fragment in the anterior chamber. They received topical corticosteroids and required additional follow-up visits. The fourth patient who reported binocular diplopia was evaluated by an orthoptist, who identified monocular diplopia in the contralateral eye due to postoperative changes after macular pucker peeling.

Table 11.4. Symptom and outcome accuracy of automated Dora versus supervised Dora call at week 4.

Decision (n=98)	Accuracy (%) [95%CI]	Sensitivity (%) [95%CI]	Specificity (%) [95%CI]	Kappa [95%CI]	p-value
Redness[1]	99.0 [94.4;99.8]	100 [34.2; 100.0]	99.0 [94.3; 99.8]	0.795 [0.403; 1.000]	<0.001
Pain[2]	98.0 [92.9; 99.4]	100 [34.2; 100.0]	97.9 [92.7;99.4]	0.657 [0.216; 1.000]	<0.001
Vision issue	96.9 [91.4; 99.0]	100 [56.6; 100.0]	96.8 [90.9; 98.9]	0.754 [0.487; 1.000]	<0.001
New floaters[3]	88.8 [81.0; 93.6]	100 [51.0; 100.0]	88.3 [80.3; 93.3]	0.823 [0.656; 0.990]	<0.001
Flashing lights	94.9 [88.6; 97.8]	100 [77.2; 100.0]	94.1 [87.0; 97.5]	0.809 [0.648; 0.970]	<0.001
Outcome	82.7 [74.0; 88.9]	93.6 [79.3;100.0]	77.6 [66.3; 85.9]	0.640 [0.491; 0.789]	<0.001

[a]Accuracy = (true positive+true negative) /(true positive+true negative+false positive+false negative)

[b]Amount of cases with "incomplete information": n=1

[c]Amount of cases with "incomplete information": n=3

[d]Amount of cases with "incomplete information": n=2

Acceptability and Patient

Patients rated their likelihood of recommending the Dora-NL1 calls, with mean scores of 7.59 (SD 1.77) at week 1 and 7.38 (SD 2.35) at week 4, shown in **Table 11.5**. The corresponding NPSs for these calls were +13.5 and +12.6, respectively. The TUQ (n=98)

had an overall mean score of 3.19 (SD 1.13). High scores were given for aspects such as time savings due to reduced travel (mean 3.80, SD 1.11), simplicity (mean 3.89, SD 0.96), ease of use (mean 3.94, SD 0.88), and audibility (mean 3.97, SD 0.91). However, the user experience of Dora-NL1 was not deemed equivalent to an in-person consultation with a clinician, with a mean score of 2.46 (SD 1.07). Detailed questionnaire results are available in **Supplementary Table 11.2**.

Table 11.5. Net Promoter Scores of Dora-NL calls at 1 and 4 weeks postoperatively.

Net Promoter Score	Week 1 (n=96), n (%)	Week 4 (n=95), n (%)
1	1 (1.0)	3 (3.2)
2	1 (1.0)	3 (3.2)
3	1 (1.0)	3 (3.2)
4	4 (4.2)	3 (3.2)
5	5 (5.2)	6 (6.3)
6	6 (6.3)	7 (7.4)
7	17 (17.7)	13 (13.7)
8	30 (31.3)	20 (21.1)
9	23 (24.0)	22 (23.2)
10	8 (8.3)	15 (15.8)

Discussion

Principal Results

The purpose of this study was to evaluate the clinical safety and effectiveness of the Dutch Dora-NL1 model in identifying patients who require further assessment following uncomplicated cataract surgery. Our findings demonstrated high overall accuracy of Dora-NL1's symptom evaluation and care management decision-making at both 1 and 4 weeks after surgery, when compared to the clinician-supervised Dora-NL1 calls. At week 1, Dora-NL1 exhibited a perfect sensitivity of 100% for care management decision-making when compared to a regular telephone consultation. However, at 4 weeks, clinical issues in four asymptomatic patients were identified during face-to-face consultations, which were not detected by Dora or by the clinician reviewing the calls. In terms of user-acceptability, most patients expressed a positive attitude towards the tool, highlighting its simplicity, ease of use, and audibility.

The Dora-NL1 model was designed to err on the side of caution, thereby ensuring that

patients classified as having “no concerns” by Dora are unlikely to have underlying clinical issues. Additionally, in cases of “incomplete information”, patients were assumed to have potential concerns, which may have increased the rate of false positives and with that, lowered the specificity. The sensitivity and specificity of the automated Dora-NL1 outcomes compared to the supervised Dora-NL1 calls were high both at 1 and 4 weeks. Only the sensitivity for floaters at week 1 was reduced as Dora misunderstood two patients. In addition, the kappa agreement for the symptom “pain” at week 1 was low due to the low prevalence of pain symptoms in this cohort (n=1). When comparing Dora-NL1 to regular care at week 1, no clinical issues were missed by Dora-NL1, resulting in 100% sensitivity, while the specificity was 41.86% due to the high rate of false positives.

Comparison with Prior Work

Previous studies have demonstrated that telephone follow-ups are a safe method for identifying significant issues after cataract surgery.[9,18,19] In this study, 3 patients had inflammatory cells, which required a management change during their 4-week hospital visit. These complications were detected during slit lamp examination, highlighting a limitation of telephone consultations, which may fail to identify such issues in asymptomatic patients. Postoperative inflammatory cells usually peak at day 1 after surgery and may take up to 3 months to resolve.[20] Studies have demonstrated a correlation between prolonged intraocular inflammation and an increased likelihood of developing cystoid macular edema (CME), suggesting a threshold beyond which extended corticosteroid treatment is advisable.[21] However, randomized controlled trials comparing corticosteroid treatments versus placebo for inflammation after cataract surgery have shown that only 2.7% to 3.8% of patients in the placebo groups developed CME within 3 months after surgery versus 1.4% to 3.8% in the corticosteroid-treated groups.[22,23] These findings pose the question of clinical relevance of the presence of inflammatory cells in asymptomatic patients who have no symptoms of red eye or ocular pain or decreased visual acuity due to clinically significant CME. Additionally, another patient in our cohort who required a management change at week 4 erroneously reported experiencing binocular diplopia while there appeared to be monocular diplopia in the contralateral eye. Notably, this symptom was also missed by the clinician-led call at week 1. The cases missed by Dora-NL1 at 4 weeks postoperatively highlight the limitations of this tool in detecting subclinical or asymptomatic complications. While some complications, such as mild inflammation, may resolve without intervention, others, such as retained lens material, could lead to more serious consequences, including chronic inflammation and secondary glaucoma, or corneal decompensation. It should, however, be noted

that the Dora call provides safety net advice for the patient to seek review with new or worsening symptoms. Hence, this tool should be viewed as a complement to, rather than a replacement for, in-person follow-up visits.

The English Dora-R1 model has been investigated in the United Kingdom, showing it to be a safe alternative for cataract surgery follow-up, with automated calls conducted 3-4 weeks postoperatively and reviewed by an ophthalmologist.[11,15] The sensitivity of care management decision-making was 93.75% (95% CI 84.76-98.27), and the specificity was 86.26% (95% CI 79.16-91.56), with an accuracy of 88.72% (95% CI 93.42-92.79).[11] These results are consistent with our findings in **Tables 11.2 and 11.4**. In the UK cohort, 10 patients who had been discharged following a Dora-R1 call—based on both Dora's and the supervising clinician's decision—experienced unexpected management changes at their 4-week routine hospital visit. These patients were either asymptomatic or exhibited mild symptoms that were not reported during the Dora-R1 call. Among them, 3 were diagnosed with CME, 5 presented with inflammatory cells, 1 experienced a refractive surprise, and 1 developed early posterior capsular opacification.[11] These findings are consistent with our results, as the majority of cases not detected via the telephone call were in asymptomatic patients with inflammatory cells in the anterior chamber.

The NPS for Dora-R1 ranged from +45 to +51, with mean scores of 8.55 (SD 1.67) and 8.59 (SD 2.05), respectively. The overall TUQ mean score was 3.96 (SD 0.47; 95% CI 3.76-4.16).[11,15] The mean NPS at 3 weeks for the Dora-R1 was compared with that at 4 weeks postoperatively, yielding a statistically significant mean difference of −1.21 (SD 0.27; $p<0.0001$). Compared to UK studies, both NPS and TUQ scores in our Dutch cohort were lower. Several factors may account for this difference. First, the study design differed: while the UK participants received either only a Dora-R1 call or a Dora-R1 call along with a hospital visit at week 4, all Dutch participants received automated Dora-NL1 calls in addition to standard postoperative care, including telephone consultations and hospital visits. Consequently, patient expectations may have been shaped by direct comparisons between Dora and conventional care, potentially leading to more critical evaluations. Additionally, the Dora-NL1 model was adapted from the pre-trained English version but relied on more limited Dutch natural language processing resources at the time of development. This may have affected the performance of both the text-to-speech and speech-to-text functions, resulting in less fluent and less natural user interactions.[24] Furthermore, cultural attitudes toward artificial intelligence (AI) and digital communication in health care may have contributed. Dutch patients may place a higher value on personal interaction and may be more reserved in expressing satisfaction with automated systems, particularly when these are perceived as less empathetic or less competent communicators. Future cross-

cultural studies using harmonized protocols are needed to clarify the extent to which these differences are attributable to cultural, technical, or methodological factors.

Limitations

Limitations of this study mainly included the potential selection bias. There were eligible patients who decided not to participate due to the expected difficulties of the Dora-NL1 call or who strongly opposed eHealth solutions in general. This population may not represent the broader cataract population, limiting generalizability. In addition, this is a mono-center study, which reduces the applicability to other health care facilities in the Netherlands, as there is a high variability in practice patterns of the postoperative cataract care pathway. Additionally, as all participants received both the Dora-NL1 and standard follow-up (clinician phone calls and in-person visits), the study is subject to performance bias. The awareness of being monitored by multiple systems may have influenced patient behavior, which may have influenced the outcomes.

Moreover, symptom-based systems like Dora-NL1 cannot detect structural or subclinical complications, which may require in-person assessment. Therefore, this tool is suitable as a complementary screening tool, replacing regular telephonic consultations for complication screening, but not as a substitute for in-person postoperative assessments.

Future implementation

Our findings indicated that at the 1-week follow-up, the Dora-NL1 model accurately identified 41.4% (n=36) of patients as having “no clinical concerns.” This suggests that approximately 4 of 10 patients could avoid clinician callbacks, potentially enhancing health care efficiency and reducing costs. Telephone reviews have been shown to be a safe time- and cost-saving alternative to short-term hospital visits after routine surgeries, with high patient satisfaction.[18,19,25] Moreover, automated calls allow clinicians to save time and focus on other care tasks while ensuring a standardized approach to symptom evaluation and decision-making. This consistency reduces variability, improves the quality of patient care, and facilitates the collection and comparison of patient outcomes. In the UK cohort, the average staff cost savings amount to US $47.78 per patient compared to regular care.[11] Further research is necessary to evaluate the potential cost-effectiveness in the Netherlands.

To implement automated calls in routine postoperative cataract care, several practical issues must be considered, particularly the significant variability in postoperative care across clinics and countries.[26] In some clinics, patients may not receive follow-up visits,

as research indicates that for those undergoing uncomplicated cataract surgery without pre-existing ocular comorbidities, follow-up can be safely deferred to 2 to 4 weeks after surgery without significant differences in visual outcomes. [27,28] However, automated phone calls for interim check-ups could enhance patients' confidence and reassurance during their recovery without straining health care resources. Despite this potential benefit, the current Dutch cataract guidelines do not yet recommend remote care for the final 4-week postoperative follow-up due to the limited evidence regarding its safety and the necessity of visual acuity and refraction assessments for the mandatory quality registry of cataract surgeries in the Netherlands.[29] Further development of the Dora-NL1 model is expected to improve its accuracy and expand its applicability.

Conclusions

Based on the results of this study, we can conclude that the Dutch AI-based cataract follow-up call system, Dora-NL1, is a safe alternative for telephone consultations in the postoperative cataract care pathway and is suitable as a screening tool for postoperative complications during the follow-up of cataract surgery. However, as this tool only captures subjective information, it is not able to fully replace final 4-week in-person hospital visits after cataract surgery in the Netherlands. Future research is necessary to investigate the practical implications and cost-effectiveness of this AI-driven teleconsultation system.

Supplements

Supplementary Table 11.1. Agreement between Dutch and English models across different patient scenarios.

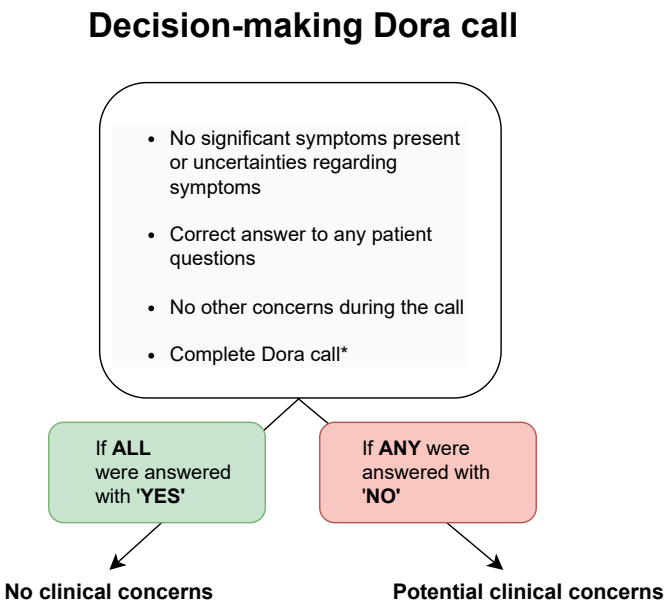
Component	Questionnaire item	Mean ± SD
Usefulness	Q1 "Telehealth improves my access to healthcare services"	3.11 ± 0.87
	Q2 "Telehealth saves me time traveling to a hospital or specialist clinic"	3.80 ± 1.11
	Q3 "Telehealth provides for my healthcare needs"	3.05 ± 0.97
Ease of use & Learnability	Q4 "It was simple to use this system"	3.89 ± 0.96
	Q5 "It was easy to learn to use the system"	3.94 ± 0.88
	Q6 "I believe I could become productive quickly using this system"	2.98 ± 1.00
Interface quality	Q7 "The way I interact with this system is pleasant"	2.99 ± 1.19
	Q8 "I like using the system"	3.00 ± 1.16
	Q9 "The system is simple and easy to understand"	3.74 ± 0.97
	Q10 "The system is able to do everything I would want it to be able to do"	2.72 ± 1.03
Interaction quality	Q11 "I could easily communicate using the telehealth system"	3.10 ± 1.08
	Q12 "I could hear everything clearly using the telehealth system"	3.97 ± 0.91
	Q13 "I felt I was able to express myself effectively"	2.78 ± 1.14
	Q14 "Using the telehealth system, it can see the clinician as well as if we met in person"	2.46 ± 1.07
Reliability	Q15 "I think the visits provided over the telehealth system are the same as in-person visits"	2.79 ± 1.11
	Q16 "Whenever I made a mistake using the system, I could recover easily and quickly"	3.18 ± 0.83
Satisfaction & Future use	Q17 "I feel comfortable communicating with the clinician using the telehealth system"	3.07 ± 1.09
	Q18 "Telehealth is an acceptable way to receive healthcare services"	3.06 ± 1.13
	Q19 "I would use the telehealth services again"	3.05 ± 1.25
	Q20 "Overall, I am satisfied with the telehealth system"	3.13 ± 1.20

Supplementary Table 11.2. Outcomes of the Telehealth Usability Questionnaire.

Scenario/Component	Redness	Pain	Vision issue	New Floaters	Flashing Lights	Decision
1. Asymptomatic						
Answers	No	No	No	No	No	No review
Dutch model	No	No	No	No	No	No review
English model	No	No	*Missing*	No	No	Review
2. Dry eye						
Answers	Yes	No	No	No	No	Review
Dutch model	Yes	No	No	No	No	Review
English model	Yes	No	No	No	No	Review
3. Uveitis						
Answers	Yes	Yes	Yes	No	No	Review
Dutch model	Yes	Yes	Yes	No	No	Review
English model	Yes	Yes	Yes	No	No	Review
4. Vitreoretinal problem						
Answers	No	No	No	Yes	Yes	Review
Dutch model	No	No	No	Yes	Yes	Review
English model	No	No	No	Yes	Yes	Review
5. Endophthalmitis 1						
Answers	Yes	Yes	Yes	Yes	No	Review
Dutch model	Yes	Yes	Yes	Yes	No	Review
English model	Yes	Yes	Yes	Yes	No	Review
6. Endophthalmitis 2						
Answers	Yes	Yes	Yes	No	No	Review
Dutch model	Yes	Yes	Yes	No	No	Review
English model	Yes	Yes	Yes	No	No	Review
7. Macular edema						
Answers	No	No	Yes	No	No	Review
Dutch model	No	No	Yes	No	No	Review
English model	No	No	Yes	No	No	Review
8. Refractive surprise						
Answers	No	No	Yes	No	No	Review
Dutch model	No	No	Yes	No	No	Review
English model	No	No	Yes	No	No	Review

Scenario/Component	Redness	Pain	Vision issue	New Floaters	Flashing Lights	Decision
9. High IOP						
Answers	No	Yes	No	No	No	Review
Dutch model	No	Yes	No	No	No	Review
English model	No	Yes	No	No	No	Review
10. Subconjunctival hemorrhage in corner of the eye						
Answers	No	No	No	No	No	No review
Dutch model	No	No	No	No	No	No review
English model	No	No	No	No	No	No review
11. Corneal edema						
Answers	No	No	Yes	No	No	Review
Dutch model	No	No	Yes	No	No	Review
English model	No	No	Yes	No	No	Review
12. Old floaters						
Answers	No	No	No	No	No	No review
Dutch model	No	No	*Missing*	No	No	No review
English model	No	No	No	No	No	No review

Supplementary Material 11.1. Dora decision algorithm and symptom classification.



*A complete call was defined as completing all clinically relevant sections, including symptom assessments and patient questions.

Symptom classification

Symptom	Not significant	Signficant
Red eye	• No redness • Only red in the corner by the nose • Occasional redness in the eye • Eye was red, but not anymore	• Eye is red all over • Progressively worsening redness
Pain	• No pain • Pain described as gritty or dry eye complaints • Pain has resolved • Pain only when using eye drops	• Painful all the time • Worsening pain • Deep or severe pain
Vision issues	• Patient is satisfied with vision • Good vision • Blurred reading vision, but good distance vision	• Patient has concerns about vision • Worsening vision • Unable to see clearly in the distance • Distorted vision
Flashing lights	• No flashing lights in vision	• Any flashing lights in vision
Floaters	• No floaters • Pre-existing floaters	• Any new floaters

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CHAPTER 12

Discussion

This thesis evaluates innovations aimed at optimizing the cataract and refractive surgery patient journey. By addressing both clinical and technological advancements, it contributes new insights into more precise surgical interventions, better patient outcomes, and more personalized ophthalmic care. Additionally, it considers clinical application of these results and outlines directions for future research. We highlight how the individual studies presented in this thesis contribute to optimization of the patient journey and enhancement of patient-centered care, and how the results reflect on their broader significance for the future of cataract and refractive surgery. This chapter is structured along the patient pathway, beginning with clinical guidelines and preoperative decision-making, continuing through intraoperative considerations, and concluding with postoperative management and follow-up. This framework follows the thematic organization of the thesis.

The discussion begins with the development of the first European cataract surgery guideline (**chapter 2**), which provided evidence-based recommendations across the full spectrum of cataract care, based on a comprehensive review of the existing scientific literature. This process also highlighted uncertainties in key areas of clinical practice. Some of these areas were explored further in this thesis, providing additional insights that contribute to a better understanding of these important topics. The subsequent chapters investigate a range of themes relevant to the cataract and refractive surgery patient journey. Clinical outcomes following implantation of novel intraocular lens (IOL) designs are examined (**chapters 3 and 4**), followed by factors influencing patient satisfaction such as IOL positioning (**chapter 5**), postoperative complaints, and expectation mismatches (**chapter 6**). The focus then shifts to perioperative medication strategies, assessing dropless approaches for the prevention of cystoid macular edema (CME) (**chapter 7**). The final section explores digital and remote care innovations in the postoperative setting, including a tool for visual acuity assessment and an artificial intelligence-based clinical assistant capable of conducting routine follow-ups via telephone (**chapters 8 to 12**). These studies evaluate the feasibility, safety, patient acceptance, and potential integration of digital technologies to complement traditional postoperative care.

Evidence-based guideline in cataract surgery

A fundamental component of modern healthcare is the systematic application of scientific evidence. In this context, the first clinical European guidelines for cataract surgery (**chapter 2**) offered evidence-based recommendations that healthcare providers should follow to ensure high-quality care. By standardizing practices, these guidelines enhance

patient safety, improve outcomes, and foster consistency in care delivery.[1] In developing this guideline, a comprehensive search was conducted for all the review questions, and recommendations were based on a critical appraisal of the best available evidence. This search also revealed existing evidence gaps, which highlight the limitations of the guideline and identify areas where further research is needed to enhance understanding and improve clinical practice. Evidence gaps were found across all domains of the cataract patient journey, including optimal preoperative patient education strategies, the use of (dropless) medication strategies to prevent cystoid macular edema, the astigmatism magnitude for considering toric IOLs, the optimal timing of postoperative follow-up visits, and the safety, efficacy and cost-effectiveness of remote and digital care after cataract surgery.

These findings underscore the limitations of the current guidelines and suggest caution when applying certain recommendations. Moreover, deviations from these recommendations may be necessary when patient-specific factors require adjustments in management. In such cases, the rationale should be clearly communicated and documented, aligning with the growing focus on shared decision-making, where the patient's specific circumstances and preferences guide treatment choices. This reflects the ongoing shift from a paternalistic model to a more patient-centered approach that emphasizes individualized shared decision-making.[2,3] Patients nowadays want to have more insights into their own health and often wish to participate in the self-management of their conditions. However, this extent of patient engagement in self-management varies and is influenced by their individual circumstances.[2,4] As elective procedures, cataract and refractive surgeries offer an opportunity for shared decision-making and active patient self-management. The degree of patient involvement in IOL selection depends on factors such as education, surgical history in the operated eye, and preparedness for decision-making. Additionally, there is a positive association between the preparedness for decision-making, the level of shared decision-making and ultimately, the satisfaction with the decision-making process.[5] To facilitate decision-making, clinicians should first aim to determine and understand patients' expectations. These are shaped by individual beliefs and perceptions of clinical outcomes and directly influence postoperative satisfaction.[6,7] The effective management of these expectations through comprehensive patient education and counseling is, therefore, essential for optimizing satisfaction and evaluating the quality of care received.[8-10]

Building on the foundation of evidence-based clinical guidelines and the emphasis on shared decision-making, a crucial factor in optimizing outcomes in cataract and refractive surgery is the continuous advancement of surgical technology. Over recent decades,

cataract surgery has evolved into a refractive procedure, largely driven by successive innovations in surgical technique, IOL design, and ocular biometry.[11,12] With both cataract and refractive surgeries well-established as safe and effective, the field has entered a new era focused on refining patient care and pushing the boundaries to achieve even better visual outcomes. Technological innovations in lens optics have broadened the range of options for patients and clinicians, allowing more personalized approaches to vision correction and enhancing the overall patient experience. The following section highlights these technological developments, with an emphasis on different lens designs and their effects on visual performance and clinical outcomes.

Advancements in lens design technologies

Advances in lens optics have introduced a variety of IOL options for patients with the goal to further improve safety profiles and patient satisfaction. **Chapter 2** provides a functional classification of IOL designs, offering insight into visual acuity that patients achieve across the visual range. However, it must be noted that this classification only addresses visual acuity along the depth of field (DOFi). Other important factors contributing to the overall quality of vision and patient satisfaction, such as contrast sensitivity and the impact of dysphotopsias, are not encompassed by this classification, despite their relevance to patients when selecting an IOL.[13,14]

Although significant advances have been made in IOL technology, the “perfect” IOL, one that fully replicates the dynamic and multifaceted optical properties of the natural crystalline lens, remains elusive. For patients seeking presbyopia correction, identifying their specific needs regarding spectacle independence and visual quality is essential.[15] The growing demand for spectacle independence has led to a variety of IOL concepts, including bifocal, trifocal, quadrifocal, extended depth of focus (EDF), and accommodating IOLs, each based on different optical principles. Nevertheless, all designs still carry trade-offs, particularly concerning the balance between visual acuity range and overall visual quality.[12] The modulation transfer function (MTF) curve, which visualizes contrast degradation across various spatial frequencies, provides a useful tool for comparing optical performance between IOLs.[16] The MTF of multifocal IOLs typically shows low MTF peaks between focal points, indicating reduced visual performance in these zones. This reflects a diminished ability of the optical system to transmit contrast in the regions between the designated focal points, where the lens is not optimized. As a result, contrast sensitivity is reduced, making low-contrast details harder to discern. Conversely, EDF IOLs tend to maintain a more stable MTF across distances, thereby minimizing contrast

sensitivity loss and providing more consistent visual acuity from distance to intermediate ranges.[16-18]

Several EDF and multifocal IOLs are currently available. Multifocal IOLs, such as trifocal IOLs, provide good distance-to-near vision and aim for spectacle independence. However, multifocal IOLs split incoming light into different focal points, resulting in energy dispersion and reduced image quality at certain distances.[19,20] EDF IOLs, on the other hand, offer optimal vision from distance to intermediate ranges without these main drawbacks of multifocal IOLs. While EDF IOLs do usually not provide complete spectacle independence, their optical design is associated with a lower risk of dysphotopsias when compared to multifocal IOLs.[21] Research indicates that trifocal IOLs yield particularly favorable outcomes for near vision, whereas EDF IOLs demonstrate better performance in the intermediate vision range.[22] Both IOL types offer high levels of patient satisfaction, though EDF IOLs appear to have a broader range of applicability and may be considered as an effective alternative to monofocal IOLs in cases where ocular comorbidities preclude multifocal IOL implantation.[23]

In **chapter 3**, a comparison of two EDF IOLs demonstrated good visual outcomes, with comparable visual quality and overall high patient satisfaction outcomes. All patients were targeted for mini-monovision, a strategy that extends the range of uncorrected binocular vision towards near, thereby enhancing spectacle independence across a broader range. While some patients achieved complete spectacle independence with this approach, the majority still required reading glasses postoperatively. **Chapter 4** showed that bilateral implantation of a multifocal phakic IOL provided good visual acuity from distance to near. Patients reported high levels of satisfaction and spectacle independence, despite occurrence of some optical disturbances. Together, these chapters highlight the specific advantages and disadvantages of different lens designs for presbyopia correction.

Key factors influencing iol implantation outcomes

While innovations in lens design have expanded the range of options available to optimize visual outcomes, successful cataract and refractive surgery depend not only on the choice of IOL but also on factors related to its precise implantation and accurate preoperative biometry. The implantation procedure itself is a standardized surgical procedure to ensure safety, precision, and predictable outcomes.[24] Surgical success is primarily assessed by the absence of complications and improvements in visual function. Among the critical determinants for postoperative success are accurate IOL positioning and minimization of

residual refractive errors. Understanding and controlling these parameters is essential to ensure that the theoretical benefits of advanced lens technologies can be fully realized in clinical practice.

IOL Positioning

Among the various factors influencing surgical success, proper IOL positioning is crucial, especially for toric and presbyopia-correcting lenses, where tilt or decentration can lead to an uneven light distribution, thereby reducing visual acuity and quality of vision.[25-27] Consequently, in cases of suboptimal visual outcomes following IOL implantation surgery, lens positioning should be a primary factor to consider. Although it is established that evident IOL tilt and decentration can negatively affect the lens performance, exact thresholds at which tilt and decentration become clinically significant, specifically in terms of corrected distance visual acuity (CDVA), remain unclear due to conflicting findings in the literature.[28,29] In **chapter 5**, our findings demonstrated that postoperative IOL tilt and decentration, assessed using Swept-Source Optical Coherence Tomography (SS-OCT) images from the IOLMaster700 (Carl Zeiss Meditec, Jena, Germany) and custom-developed software, did not significantly influence the CDVA in our patient cohort. This particular cohort consisted of patients who underwent cataract surgery, with no cases of IOL tilt or decentration detected on slit lamp examination.

Notably, the analyses along different anatomical reference axes, namely the pupillary axis (PA) and corneal topographic axis (CTA), revealed varying results. Tilt reached up to 3.7° along the PA and 9.5° along the CTA, while decentration values were consistent with mean values of 0.27 mm. These discrepancies highlight the critical importance of methodological consistency when interpreting tilt and decentration data, as different approaches may necessitate distinct thresholds for clinical relevance. Furthermore, the current literature shows substantial variability in the devices and methodologies used to assess IOL tilt and decentration, complicating direct comparisons across studies.[25,26,28] For example, while both the CASIA2 (Tomey Corp., Nagoya, Japan) and the IOLMaster700 are SS-OCT devices can be used to measure tilt and decentration with high intraindividual reproducibility, they rely on different software programs, which have not yet been directly compared.[30,31] This methodological diversity underscores the need for standardized approaches to define clinically relevant thresholds for tilt and decentration. These thresholds should be IOL-specific and suitable for integration into routine clinical practice, enabling consistent evaluation, which ultimately contributes to improved patient outcomes.

Residual refractive error and IOL power calculation

In addition to optimal IOL positioning, achieving precise refractive outcomes through accurate IOL power calculation is critical for ensuring satisfactory visual function. Minimizing postoperative residual ametropia is essential for optimal visual acuity outcomes. Even a small residual refractive sphere, as low as -0.25 or +0.50 diopters (D), can significantly reduce the likelihood of achieving a distance visual acuity of ≥20/20.[32] The European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO), which includes over two million cataract procedures, reported that prediction errors within ± 0.50 D and ± 1.00 D were achieved in 72.7% and 93.0% of eyes, respectively. However, this accuracy of refractive outcomes is highly dependent on the pre-operative IOL calculation formula employed.[33] Modern vergence IOL power formulae have reduced systematic errors and improved refractive predictability.[34-36] For instance, the widely used Barrett Universal II formula achieves prediction errors within ± 0.50 D and ± 1.00 D in 80.8% and 97.8% of monofocal IOL cases, respectively.[37] Despite these improvements, no single formula has yet emerged as a universal gold standard. This emphasizes the need to individualize IOL selection and power calculation according to the individual patient's ocular characteristics. Emerging technologies such as ray-tracing and artificial intelligence (AI)-based formulae, promise further refinements in IOL power calculations. These emerging technologies hold promise for enhanced accuracy in complex eyes and may contribute to improved personalized refractive outcomes.

Residual astigmatism and surgically induced astigmatism

Residual astigmatism represents an important form of ametropia that can independently affect visual acuity after lens implantation.[38-40] As demonstrated in **chapter 3**, residual refractive astigmatism has a notable impact on the visual outcomes of EDF IOLs. The ESCRS Cataract Surgery guideline, discussed in **chapter 2**, recommended the use of toric IOLs for patients with corneal astigmatism >1.5 D, with possible benefits for cases >1.0 D. However, supporting evidence for the use of toric IOLs in astigmatism <1.0 D remains limited. Some studies suggest improved uncorrected distance visual acuity (UDVA) outcomes with toric IOLs when postoperative refractive astigmatism is ≥0.75 D.[40-42] Residual astigmatism as low as 0.50 D has been associated with reduced visual acuity. For example, a postoperative cylinder of 0.50 D nearly doubles the odds of not achieving 20/20 UDVA (odds ratio 1.9). This risk increases progressively with higher residual astigmatism: odds ratios of 6.1 for 0.75–1.00 D, 21.1 for 1.25–1.50 D, and even higher for 1.50–2.00 D have been reported.[43]

The tolerance to residual astigmatism appears to differ between IOL designs. While some

studies report similar effects across monofocal and multifocal lenses, others highlight design-specific differences.[38-40] EDF IOLs are generally thought to have a greater tolerance to residual astigmatism compared to multifocal IOLs. The literature suggests clinical thresholds for multifocal IOLs of up to 0.7-1.0 D for with-the-rule astigmatism and up to 0.5-0.7 D for against-the-rule astigmatism to maintain acceptable distance visual acuity. In contrast, EDF IOLs demonstrate a notably higher tolerance at near, with near visual acuity remaining unaffected by residual astigmatism up to 2.0 D in both directions.[44] This enhanced tolerance may be attributed to the lens design of focus elongation, which potentially allows partial compensation for astigmatic blur. Nevertheless, formal clinical thresholds for tolerable residual astigmatism with EDF IOLs have yet to be clearly defined.

Achieving these tolerable levels of residual astigmatism in clinical practice is often influenced by surgically induced astigmatism (SIA), which introduces variability and compromises the predictability of postoperative refractive outcomes. SIA depends on various factors, including incision location, size (width and length), and angle. Larger or more centrally placed incisions tend to cause more flattening, thereby increasing the magnitude of the SIA.[45-47] To minimize residual astigmatism, the corneal incision is most commonly placed temporally, as this location typically induces the lowest SIA. Based on preoperative measurements, the expected SIA and the predicted residual astigmatism, the option to implant a toric IOL is then discussed. This approach is particularly beneficial in patients with <1.5 D of corneal astigmatism. However, research shows that superiorly located incisions are associated with more SIA compared with temporal incisions.[48,49] Furthermore, individual variability in SIA frequently leads to discrepancies between the target refractive astigmatism and clinical outcomes achieved.[50] This was also observed in our EDF cohort in **chapter 3**, where the SIA showed broad standard deviations, resulting in higher residual postoperative astigmatism than expected.

Given that most age-related cataract patients present with against-the-rule astigmatism, and temporal incisions induce less SIA, temporal incisions may be preferred in routine cataract surgery to minimize refractive error.[51-54] Conversely, superior incisions may be more beneficial for cases of with-the-rule astigmatism.[52,55] The optimal incision site for astigmatism correction remains a subject of ongoing debate, and surgeons may need to tailor their approach based on individual patient's corneal profile and refractive goals.

Postoperative evaluation and patient satisfaction

Having identified the principal factors that influence IOL implantation outcomes, it is

crucial to consider their implications for patient satisfaction. While objective measures such as visual acuity offer important insights, a comprehensive evaluation must also encompass patient-reported outcomes, which capture the broader dimensions of visual quality and postoperative quality of life.

Patient-reported outcomes and residual ametropia

Among the various influences on patient-reported outcomes, residual ametropia emerges as a notable contributor to dissatisfaction. Although the direct impact of residual ametropia on the postoperative UDVA is evident, its effect on patient-reported outcomes is more complex, as patient satisfaction is influenced by multiple other factors as well. In our case series in **chapter 6**, one of the main reasons for dissatisfaction after EDF IOL implantation was blurred vision due to residual ametropia, primarily attributed to residual astigmatism. Similar findings have been observed in studies involving dissatisfied patients after multifocal IOL implantation.[56-58] Research indicates that low levels of astigmatism (up to 0.50 D) have a minimal impact on patient satisfaction, whereas astigmatism of 0.75 D or more significantly diminishes satisfaction levels.[43] To further enhance the already high levels of patient satisfaction and strive for (near-)perfect outcomes after cataract and refractive surgery, addressing residual ametropia is essential. This requires a patient-centered approach that takes into account the tolerance to residual astigmatism specific to the IOL designs. The ongoing ESCRS Toric IOL study aims to investigate patient tolerance to residual astigmatism across different IOL designs, which may provide guidance for future optimization of refractive outcomes.

Given the significant impact of residual ametropia on patient satisfaction and visual outcomes, innovative solutions have been developed to address this issue postoperatively. Postoperative refractive errors can arise from various factors during surgery, which traditional methods cannot easily prevent after IOL implantation. To overcome this limitation a novel lens, the so-called light adjustable lens (LAL), has been developed. This lens permits post-implantation adjustments, effectively correcting residual ametropia regardless of its underlying causes, and without requiring additional surgical procedures such as IOL exchange or realignment. The LAL contains an optic of light-sensitive silicone macromers, which can be non-invasively adjusted after implantation using targeted ultraviolet (UV) light. Once the desired refractive change is achieved, a final UV exposure permanently “locks in” the correction.[59,60] The first-generation LALs were approved by the Food and Drug Administration (FDA) in 2017.[12] Long-term results with this first-generation technology demonstrate its effectiveness in providing stable refractive outcomes.[61] However, LALs are associated with certain complications, including UV-related issues

such as unintended refractive changes due to ocular UV exposure before the final "lock-in" procedure, erythropsia or color vision alterations, corneal abrasions from adjustment or "lock-in" procedures, and UV-induced retinal damage.[62] Second-generation LALs have enhanced UV absorbers, offering greater protection against environmental UV exposure and requiring lower peak radiant energy to the retina for a "lock-in" procedure.[63] Further research is necessary to evaluate the long-term outcomes and the cost-effectiveness of this new generation of LALs, as well as to determine whether increasing the proportion of patients achieving a target deviation of ± 0.5 D from the current 80% to 90–95% actually results in meaningful gains in patient satisfaction.

Subjective outcomes after IOL implantation

In the past, the evaluation of surgical success was primarily centered on objective outcomes. While these remain essential, there is now greater recognition of the importance of subjective outcomes, such as patient satisfaction, quality of vision, and spectacle independence. These outcomes reflect broader aspects of quality of life and functional well-being, as perceived by the patient. Although inherently subjective, parameters such as quality of vision and spectacle independence can be quantified by the use of validated questionnaires and partially assessed with objective tools — for example, by contrast sensitivity or straylight testing, aberrometry, or reading performance assessments. Such measurements play an important role in gaining insight into the patient's experience beyond traditional measures of visual acuity. This shift in understanding underscores that achieving optimal visual outcomes alone is insufficient and addressing patient-reported outcomes is equally crucial. [10,64]

To ensure patient satisfaction following IOL implantation, it is essential to understand the factors contributing to dissatisfaction. As discussed in **chapter 6**, in addition to residual ametropia, other key factors identified as leading to dissatisfaction included dry eye disease (DED), posterior capsule opacification (PCO), and expectation mismatches. DED warrants special attention as it can affect both preoperative evaluations and postoperative outcomes, ultimately impacting the success of cataract and refractive surgery.[65] Proactive evaluation and management of DED can therefore directly and indirectly influence the effectiveness of the treatment. Tools such as symptom questionnaires, Tear Break-Up Time (TBUT), Schirmer's test, and fluorescein staining can assist in detecting DED and guiding treatment strategies.[66,67]

PCO, another major factor for dissatisfaction, causes secondary vision loss in a significant proportion of patients after IOL implantation. This condition results from residual lens

epithelial cells on the anterior capsule, which proliferate and migrate posteriorly between the IOL and posterior capsule, eventually impairing visual function. Various factors influence the development of PCO, including IOL design features such as the square-edge IOL optic profile, a feature of modern IOL designs, and surgical techniques such as the bag-in-the-lens approach.[68] When PCO progresses to the point of significantly compromising vision, Nd:YAG laser capsulotomy offers a safe and effective treatment option.[69] Although serious complications of this treatment are rare, surgeons should remain aware of potential risks, including increased intraocular pressure, IOL damage, retinal detachment, CME, or the need for anterior vitrectomy in cases requiring a secondary intraocular lens procedure.[70,71]

Finally, another important factor identified in our research as contributing to patient dissatisfaction was an expectation mismatch. Given the variability of individual expectations, effective communication in the cataract patient journey forms the basis for establishing realistic postoperative goals.[72] However, personality traits such as neuroticism and measures of the Eye Surgery Inventory (ESI) have not been shown to reliably predict satisfaction after multifocal IOL implantation, which highlight the need to focus on patient-reported outcomes and tailored expectation management.[73] Patient satisfaction is closely linked to the alignment between preoperative expectations and postoperative outcomes, a concept illustrated by the “disconfirmation-of-expectations” model. According to this model, when perceived outcomes fall short of initial expectations, negative disconfirmation occurs, which leads to dissatisfaction.[6] The primary drivers of such mismatches are insufficient spectacle independence or suboptimal visual quality.[74] As previously discussed, despite continuous technological innovations, no IOL is without compromise, as each design entails specific benefits and limitations. It is therefore imperative that patients and surgeons are aware of these trade-offs when discussing potential outcomes to set realistic expectations. To facilitate this process, visual aids and decision-support tools are available that provide diagrams, outcome simulations, and comparative information on IOL types. In selected cases, a contact lens trial—used to simulate monovision or multifocality—or the use of advanced simulation technologies may be considered to help patients better understand potential outcomes. Examples include the Vivior Visual Behaviour Monitor (VBM; Vivior), which objectively assesses a patient’s visual behavior in daily life to guide IOL selection, and the Simvis Gekko (2EyesVision), a wearable device that simulates various multifocal lens profiles in real time, allowing patients to experience different optical effects prior to surgery. [75,76]

The pursuit of restoring natural accommodation

The ultimate aim of an IOL is to replicate the full functional range of the natural crystalline lens, offering seamless vision from distance to near, thereby mimicking the natural dynamic process of accommodation.[77] To achieve this, accommodative IOLs (AIOLs) have been developed, incorporating designs such as single-optic, dual-optic, or deformable surface technologies.[78] These lenses dynamically adjust the eye's dioptric power in response to ciliary muscle contraction. Nonetheless, existing research underscores persistent limitations and challenges inherent to each design. At present, no AIOL provides a wide accommodative amplitude without significant compromise. Frequently encountered limitations include a high risk of capsular contraction syndrome, posterior capsule opacification, the need for larger insertion incisions, and insufficient long-term positional stability.[12,79] Ongoing innovation is required to overcome these issues and to ultimately restore the full accommodative function of the crystalline lens.

Procedural innovations and postoperative care models

Improving patient outcomes and satisfaction after cataract surgery requires ongoing advancements beyond lens design and postoperative evaluation. Innovations in surgical procedures, such as dropless cataract surgery and evolving healthcare delivery models, particularly digital and remote postoperative care, continue to enhance patient care pathway. The following section outlines key procedural innovations, followed by an overview of digital solutions in postoperative cataract care.

Innovations in surgical practice

Achieving optimal care and high patient satisfaction requires the effective implementation of procedural innovations and ongoing improvements. To facilitate this, healthcare systems must be optimized to create the necessary resources and infrastructure for the integration of such breakthroughs.[80] This necessitates a re-evaluation of current patient pathways and clinical workflows, aiming to minimize inefficiencies and enhance overall care delivery.

One notable example of procedural innovation is immediate sequential bilateral cataract surgery (ISBCS), which has demonstrated non-inferiority to delayed sequential bilateral cataract surgery (DSBCS) in terms of efficacy, safety, and patient-reported outcomes. Moreover, ISBCS has been associated with cost savings and improved quality-adjusted life

years (QALYs), positioning it as a cost-effective alternative to DSBCS.[81] These findings have contributed to revisions of the Dutch clinical guidelines for cataract surgery, promoting wider acceptance of ISBCS in routine clinical practice where appropriate patient selection criteria are met.[82]

Surgical innovations such as ISBCS show how procedural changes can enhance efficiency and patient outcomes, while also requiring careful consideration of safety, cost-effectiveness, and patient-centered care. Their successful implementation relies on both clinical evidence and structural adaptations within healthcare systems, highlighting the importance of aligning innovation with broader organizational and economic contexts.

Digital and remote postoperative management

In parallel with procedural innovations, the digital transformation of healthcare is becoming a key driver of more efficient, personalized, and scalable models of care. By employing technology, digital health solutions aim to enhance patient-centered approaches and streamline care pathways. Traditionally, remote and telehealth solutions were primarily designed to address the needs of patient populations in remote and rural areas.[80,83] However, the growing interest in and need for a broader application of these technologies was accelerated during the COVID-19 pandemic, which forced healthcare systems to reorganize and adopt more innovative practices to maintain care delivery.[84-87] In ophthalmology, the risk of SARS-CoV-2 transmission was particularly high due to the close face-to-face contact required during patient examinations. Furthermore, the majority of ophthalmologic patients are aged 65 years or older, a group at increased risk of severe outcomes from SARS-CoV-2 infections.[85] These factors stimulated the adoption of digital health solutions, thereby prompting a shift in how care can be delivered. As a result, healthcare systems now stand at crossroads, with remote and digital care becoming increasingly accessible and integrated into clinical practice. While this shift may initially appear to conflict with the personalized, patient-centered care, it fosters a more tailored approach that more effectively and efficiently addresses individual patient needs. Nonetheless, significant financial and policy challenges remain, particularly regarding who will bear the costs of implementing and maintaining these (additional) services. For example, recent developments in the Netherlands, where the introduction of a reimbursement framework for optometric care has been postponed, highlight barriers that may impede sustainable adoption of remote care.

Chapters 7 to 11 of this thesis explored digital and remote care solutions within the postoperative cataract care pathway. **Chapter 7** presents a systematic review of digital

and remote tools for postoperative cataract management. This review demonstrated the feasibility of implementing such innovations, particularly for screening purposes, but also highlighted the limited availability of published data, indicating the need for further research. Another systematic review on virtual follow-ups after cataract surgery suggests that these follow-ups are a safe alternative to in-clinic reviews for uncomplicated cases. However, a key limitation of virtual care remains the absence of direct clinical examination.[88] Furthermore, the financial sustainability of these digital care models is an important consideration, as reimbursement frameworks and cost allocation will influence their broader implementation in clinical practice.

Web-based visual acuity tool

Chapters 8 to 10 focused on a web-based tool for assessing visual acuity in postoperative cataract patients. **Chapter 8** demonstrated differences in outcomes between this tool and conventional visual acuity tests, such as the ETDRS and Snellen charts. However, given the known significant intra-individual variability between visual acuity measurements with commonly observed test-retest differences, discrepancies between methods are to be expected. A difference of ≤0.15 logMAR was therefore generally considered as clinically insignificant.[89-91] Most outcomes obtained with the web-based tool were within this clinically acceptable range, supporting its validity for postoperative visual acuity assessments in cataract patients. Building on these findings, a multicenter trial was designed using the same web-based tool (**chapter 9**), with outcomes reported in **chapter 10**. The trial showed that digitally skilled cataract patients were able to complete unsupervised visual acuity tests at home, which simulates real-world conditions. Although the tool demonstrated clinical utility, its precision was lower than that of conventional methods. The visual acuity measurements showed wide variability and distribution. In addition to visual acuity testing, these patients also performed a refraction measurement at home. However, the tool tended to overestimate residual refractive errors, incorrectly classifying some emmetropic patients as ametropic. This limitation arose because the underlying algorithm was developed using data from young, healthy adults and assumed that visual acuity worse than -0.1 logMAR was attributable to refractive error.[92] As the maximum achievable visual acuity declines with age, this assumption introduced inaccuracies in the older patients within this cohort.[93] These findings indicated that this web-based tool may serve as a feasible screening method for at-home visual acuity in postoperative cataract patients, though refinements are required to improve its refractive measurement accuracy. Two systematic reviews support this potential, reporting that several digital tools demonstrated promise as screening instruments.[94,95] However, most

of the tools have not been specifically validated in cataract populations and were assessed in controlled clinical trial settings, rather than real-world home environments. It is also important to recognize that visual acuity assessments are not directly interchangeable, as they differ in test design, optotypes, and scoring methods.[96-98] Moreover, behavioral and environmental factors can affect test outcomes, which further complicate comparisons across tools.[91] The feedback from participants in the multicenter trial indicated a generally positive experience with the web-based tool. Nevertheless, several barriers for adoption of this tool were identified, such as concerns about correctly performing the test, unclear instructions for result interpretation, and the perception that in-hospital assessments are superior to remote evaluations. For the successful integration of this web-based tool into cataract surgery follow-up, it will be essential to foster trust in remote eye care delivery.[99] These limitations must be carefully considered when integrating remote visual acuity testing into routine clinical practice.

Artificial intelligence clinical assistant for telephone-based patient follow-up

In addition to visual acuity assessments, screening for postoperative complications is another component of postoperative cataract care. Literature suggests that such screening can be achieved using a standardized, structured set of questions.[100] Telephone follow-ups have already been shown to be a safe and effective method for identifying complications in patients following uncomplicated cataract surgery.[88] These consultations offer a reliable alternative to in-person visits, reducing patient travel and improving access to care. Building on this approach, artificial intelligence (AI)-driven conversational agents represent a further advancement, with the potential to reduce clinician workload and triage patients more efficiently by prioritizing those at risk of complications. **Chapter 11** evaluated the first Dutch-language version of a voice-automated telephone conversational agent for screening postoperative complications in cataract patients. This Dutch version was adapted from the validated English version used in the United Kingdom, which demonstrated high levels of patient acceptability.[101,102] The Dutch version of the tool was found to be a safe and effective alternative to human-led telephone consultations for postoperative complication screening. Designed with a safety-first approach, the system errs on the side of caution and is therefore well suited as a screening tool to identify potentially significant postoperative issues. However, this conservative design reduces its specificity, increasing the likelihood of false-positive outcomes and unnecessary follow-up assessments. While patient safety is paramount, an excessive number of false positives burden healthcare resources and compromise efficiency of this tool. Another limitation is

that, as with regular telephone consultations, these automated phone calls rely solely on patient-reported symptoms and do not allow for objective clinical examination. As such, it cannot fully replace face-to-face consultations, particularly in cases requiring detailed clinical assessment. Nevertheless, its integration into postoperative care pathways may offer valuable support in triaging and monitoring patients, especially when combined with other digital tools.

Implementation of digital and remote care

Current evidence does not yet support the implementation of a fully remote postoperative cataract care pathway. However, validated digital tools, such as online visual acuity assessments, can partially substitute in-person follow-up visits. These tools can be effectively combined with telephone follow-ups (whether human-led or automated) to provide both objective and subjective information remotely, making them suitable for screening of uncomplicated cataract cases. The integration of multiple telemedicine approaches has the potential to strengthen remote monitoring capabilities, particularly as artificial intelligence technologies continue to evolve.[84] For new innovations to be successfully adopted, trust from both patients and clinicians is crucial. A lack of confidence in proven healthcare innovations can significantly hinder their uptake.[80,103] Barriers to engagement with digital and remote care remain, especially among individuals with limited digital literacy, which restricts the generalizability of research findings. In this context, selection bias is a relevant concern, as studies exclude patients who are unable or unwilling to use digital tools.[104] However, as newer generations of elderly patients become increasingly comfortable with technology, the acceptance and perceived value of such tools are likely to improve, potentially facilitating a broader adoption in the near future.

To encourage the integration of telehealth in clinical practice, it is important to establish the effectiveness and safety of innovative tools, ensuring that their risks and benefits are clearly understood.[105] According to the World Health organization (WHO) guidelines for digital health, key assessments of healthcare interventions include benefits, harms, acceptability, feasibility, resource use, and accessibility considerations.[106] A key concern is that the use of telemedicine or digital innovations as a substitute for face-to-face ophthalmologic care must not compromise the patient safety due to reduced direct interaction between patients and clinicians.[80] The implementation of eHealth technologies is multifaceted and complex, with challenges ranging from technological barriers, such as the validation and system integration, to data privacy and cybersecurity. In addition, medico-legal issues, such as regulatory inconsistencies, unclear reimbursement models, and financial constraints, pose further obstacles to widespread adoption.[80,83,103,104,107] Addressing these

challenges will require collaborative efforts from all relevant stakeholders, including healthcare providers, policymakers, and technology developers, to create sustainable solutions that prioritize patient safety and equitable access to care.[80,83]

Conclusions and future perspectives

This thesis has provided evidence-based insights into opportunities for optimizing the patient journey in cataract and refractive surgery. The current landscape in these fields has become leaner and meaner, driven by advancements in technology, clinical practices, and logistical efficiencies. The studies presented in this work have contributed to a deeper understanding of how various components of the standard of care may be refined for future patients undergoing cataract and refractive procedures. Specifically, this research has evaluated the available evidence on the cataract care pathway, explored recent advancements in lens technologies and surgical practice, postoperative assessments, patient-reported outcomes, and investigated novel remote and digital care interventions in the postoperative cataract care setting.

Continued innovation remains essential to further enhance ophthalmic care for patients undergoing cataract and refractive surgery. Technological developments, such as EDF IOLs and other presbyopia-correcting IOL designs, together with procedural innovations such as immediate sequential bilateral cataract surgery and dropless cataract surgery, offer promising avenues to improve the safety, accessibility, and efficiency of care delivery. Moreover, the integration of big data and AI has the potential to transform ophthalmic care by enabling predictive modeling, personalized treatment strategies, and early detection of postoperative complications.[108]

Beyond the technological innovations, structural and economic shifts are reshaping the landscape of ophthalmic care. The increasing involvement of private equity in ophthalmology, driven by the aging population and rising demand for ophthalmic services, may influence patient choice, care pathways, and prioritization of treatments.[109-111] Evidence on the effects of this shift remains limited, with both potential benefits and risks reported. On the positive side, the consolidation of practices may enhance patient access, expand care capacity, support technological innovations, and enable more efficient patient management. However, the profit-driven focus of private equity may conflict with the provision of comprehensive, affordable, high-quality care, potentially diminishing physician autonomy and increasing the risk of overtreatment.[109,111,112] These changes will inevitably shape the patient journey, affecting not only access and efficiency but also the

degree to which care aligns with individual patient preferences and the outcomes they value most. Consequently, while private equity may offer certain operational advantages, its overall impact on the patient journey remains uncertain, underscoring the need for careful monitoring to ensure that financial incentives remain aligned with patient-centered care.

In this context, independent academic institutions remain essential. They provide objective research, guide best practices, and serve as benchmarks for training and innovation. Such oversight is crucial to ensure that private equity pressures do not compromise patient outcomes, safety, or evidence-based care, and to guide policymakers and professional societies in safeguarding patient-centered standards. This role contrasts with the actual distribution of cataract procedures across private practices, general hospitals, and top clinical teaching hospitals. As shown in **Table 12.1**, between 2022 and 2024 the majority of cataract surgeries in the Netherlands were performed in private and teaching hospital settings, whereas university medical centers performed a smaller proportion, highlighting that their impact lies not in volume but in maintaining quality, advancing innovation, and shaping the standards of care.[113]

Table 12.1. Cataract surgeries performed in 2022-2024 by institution type in the Netherlands.

Institution type	Cataract surgeries performed each year (n)		
	2022	2023	2024
University medical centers	11,318	10,772	11,690
General hospitals	123,860	122,112	124,824
Private practice/Independent treatment centers	70,152	81,709	75,744
Total surgeries in all institutions	205,330	214,593	212,258

Data were retrieved from the open dataset of Zorginzicht.[113]

Looking further ahead, emerging technologies such as fully autonomous robotic cataract surgery have the potential to redefine who performs cataract procedures. Robot systems may offer enhanced surgical precision, stability, and repeatability, potentially reducing intraoperative complications and improving refractive outcomes, especially in complex cases and with premium IOLs. The role of the surgeon may shift from direct manual performance to supervision, decision-making, and management of complications, as the robot executes the surgical steps autonomously. Also, discussion may arise that trained non-surgeon personnel, such as physician assistants, could operate the system under supervision, which may expand the access to care while maintaining safety standards. Of

course these future perspectives may need a thorough discussion within the ophthalmic community as to warrant the high quality standards of these procedures. However, current systems remain costly, are slower than conventional surgery, and require validation in large clinical trials to confirm their benefit over established techniques.[114-117] The transition to autonomous surgery also raises important considerations regarding training and maintenance of surgical skills, and regulatory and ethical frameworks.

At the same time, femtosecond laser-assisted cataract surgery sometimes erroneously called "robotic cataract surgery", continues to evolve with the potential to further improve refractive accuracy and capsulotomy precision, which could be beneficial when implanting advanced IOL designs. However, while this procedure has been shown to be non-inferior to conventional cataract surgery, its lack of cost-effectiveness remains a barrier to wider adoption.[82,118-121] In the field of intraocular lens technology, innovations such as refractive index shaping IOLs, where the refractive properties of the lens can be modified using laser after implantation, are being developed.[122] Similarly, accommodating IOLs, which are designed to restore the eye's dynamic focusing ability, are an active area of interest in research. Although these technologies have yet to reach widespread clinical adoption, ongoing research and development may bring them closer to practical application in the coming years.

Future research should focus on addressing current knowledge gaps by evaluating the long-term outcomes of these innovations and their real-world (cost)effectiveness. Such efforts are essential to ensure the continued advancement of cataract and refractive surgery, to achieve the highest possible standard of care and to warrant implementation in the cataract care path for all patients. Guided by evidence and designed around patient needs, the next era of cataract and refractive surgery can move beyond restoring sight toward expanding the boundaries of ophthalmic care.

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CHAPTER 13

Impact paragraph

Main findings and relevance

This thesis explored potential improvements to the patient journey in cataract and refractive surgery by examining clinical and digital health innovations. Its primary objective was to generate evidence-based insights that could inform and refine future standards of care. Refractive errors and cataract are the leading causes of moderate to severe vision impairment worldwide. With aging populations driving increasing demand for ophthalmologic services, optimizing care pathways has become a matter of urgency. As visual function is vital to daily life and independence, securing care that is accessible, safe, cost-effective, and patient-centered is essential.

The research is divided into two main parts. The first addresses clinical care, with contributions including the development of the first European evidence-based guideline for cataract surgery initiated by the ESCRS, the evaluation of novel intraocular lens technologies, and the analysis of factors influencing surgical outcomes and patient satisfaction. The second part focuses on digital and remote care innovations, with the validation of tools designed to support or partially replace traditional postoperative consultations. Together, these studies mark initial steps toward a future model of cataract and refractive care that is not only evidence-driven and technologically enhanced, but also responsive to individual patient needs.

The findings presented in this thesis hold both scientific and societal relevance. From a scientific perspective, the development of the first European evidence-based guideline for cataract surgery represents a key milestone in the standardization of clinical practice across Europe. It is designed to reduce unwarranted variations in care, enhance transparency, and support evidence-based decision-making grounded in the best available evidence. Additionally, the evaluations of novel intraocular lens technologies expand our understanding of factors that influence refractive outcomes and patient satisfaction, including the role of specific optical design features. These findings further strengthen the evidence base for the selection of personalized surgical strategies. Furthermore, the validation of digital tools for postoperative monitoring advances the field of teleophthalmology, offering reliable alternatives to in-person follow-up. Our systematic review of digital and remote postoperative cataract care also identified persistent knowledge gaps, providing direction for future research and guiding the responsible development and integration of digital models of care within ophthalmology.

From a societal perspective, this work addresses several challenges faced by modern healthcare systems. The global aging of the population is contributing to a rising demand for cataract surgery and ophthalmological services more broadly. By exploring both

clinical and digital innovations, this thesis contributes to the development of care models that are more scalable, efficient, and accessible. In particular, automated or digital follow-up strategies offer opportunities to streamline the postoperative phase, reduce pressure on healthcare resources, and maintain a high standard of safety and efficacy. By facilitating less resource-intensive approaches, the findings contribute to the long-term sustainability of care delivery. Furthermore, the thesis underscores the importance of patient-centered care and shared decision-making, emphasizing the need to manage expectations and to integrate patient-reported outcomes into routine practice. In addressing these interrelated challenges, this research supports the ongoing transformation of ophthalmic care towards a more inclusive, adaptive, and future-oriented framework.

Target groups

The findings of this thesis are relevant for a wide range of stakeholders involved in ophthalmologic care. The primary audience includes ophthalmologists, clinical researchers, and other healthcare professionals involved in cataract and refractive surgery. These results offer practical guidance for clinical decision-making, surgical planning, and follow-up care. In addition, by identifying key knowledge gaps, this work enhances the understanding of the current state of clinical practice and contributes to the setting of future research priorities. These insights may inform the development of updated clinical guidelines and broader research agendas. Healthcare policymakers and regulatory bodies, including institutions such as the Dutch National Health Care Institute (Zorginstituut Nederland), may find these results valuable when assessing the integration of digital follow-up tools into national healthcare frameworks and reimbursement policies. Moreover, the findings provide a basis for infrastructure planning in ophthalmology by evaluating the feasibility and reliability of digital care solutions. The ophthalmic industry and medical technology sector may also benefit from this work. The clinical insights and identified gaps can guide the development and refinement of intraocular lenses, remote monitoring platforms, and digital health tools tailored to the needs of both patients and clinicians. Finally, and most importantly, the work addresses the perspectives of patients and patient advocacy groups by aiming to improve access, satisfaction, and outcomes through a more personalized, efficient, and responsive healthcare system that meets the needs of those it serves.

Activities and future implementation

The outcomes of this research have been disseminated through publications in peer-reviewed international journals, reaching clinicians, clinical researchers, and stakeholders in the fields of cataract and refractive surgery. Findings have also been presented at multiple national and international congresses, including the annual meetings of the European Society of Cataract and Refractive Surgeons (ESCRS), American Society of Cataract and Refractive Surgery (ASCRS), American Academy of Ophthalmology (AAO), Nederlands Oogheelkundig Gezelschap (NOG), and Nederlandse Intra Oculaire Implant Club (NIOIC). These efforts aim to stimulate continued investigation and development of clinical and technological innovations to improve the cataract and refractive surgery patient pathway. The results of this thesis are relevant for guiding future clinical guidelines and informing healthcare policy. They also provide a foundation for the continued clinical validation of digital and remote care tools and novel surgical strategies. Policymakers may use these results to inform the adoption of sustainable innovations in national healthcare systems. To support shared decision-making and manage patient expectations, it is recommended that the findings be incorporated into preoperative counselling and patient education. Ultimately, we hope this work will foster further research and development in academia and industry towards more sustainable, efficient, and patient-centered ophthalmic care.



ADDENDUM

Summary
Nederlandse samenvatting
Dankwoord
About the author
List of publications

Summary

Refractive errors and cataract are currently the leading causes of moderate to severe vision impairment worldwide, significantly affecting quality of life and longevity. Given this impact of vision on daily functioning, it is crucial to optimize the patient pathway, ensuring that ophthalmological care is both accessible and personalized. This thesis explores technical and clinical innovations designed to improve the cataract and refractive surgery patient journey. The thesis is divided into two parts. The first part focuses on evidence-based cataract care guidelines, advancements in intraocular lens technologies, and clinical outcomes in cataract and refractive surgery. The second part evaluates the potential of digital and remote care options for postoperative management of cataract patients.

Chapter 1 presents the general introduction with the aims and outline of the thesis. This chapter provides background information on the journey of patients seeking cataract or refractive surgery. It covers the optical pathway, different types of refractive errors and cataract, treatment options, postoperative outcome measures, and postoperative remote and digital care.

In **chapter 2**, we provide the first European guideline for cataract surgery management, offering evidence-based recommendations derived from a comprehensive literature review and expert consensus. The guideline covers the entire patient pathway, from diagnosis to therapy, with the goal of standardizing care, improving transparency, and reducing clinical variability. It also highlights persistent knowledge gaps, pointing to areas where research is needed to further enhance clinical practice.

Chapter 3 reports a randomized controlled trial comparing outcomes after bilateral implantation of two extended depth-of-focus (EDOF) intraocular lenses (IOLs), targeted for mini-monovision. Both IOLs demonstrated similar binocular visual acuity, visual quality, and patient satisfaction outcomes. However, the group with the sector-shaped near-vision segment design showed a greater range of defocus. The study also revealed wide variability in surgically induced astigmatism (SIA), which was identified as a critical factor influencing refractive outcomes.

Chapter 4 evaluates the efficacy and safety of a novel multifocal anterior chamber iris-fixated phakic intraocular lens (pIOL) during the first six months after implantation. In this multicenter prospective clinical trial, bilateral implantation of this pIOL resulted in excellent distant to near visual acuity and stable endothelial cell density (ECD). The patient satisfaction levels were found to be high, with 83% of the patients reporting full spectacle independence, despite experiencing some optical disturbances.

Chapter 5 describes the use of swept-source optical coherence tomography (SS-OCT) imaging and custom-developed software to assess IOL tilt and decentration after cataract surgery. The findings of this study indicated that these factors did not significantly affect corrected distance visual acuity, regardless of the reference axis used for analysis.

Chapter 6 reports on reasons for dissatisfaction after EDOF IOL implantation. In this cohort, blurred vision was the most commonly expressed complaint, followed by photopic phenomena. The primary reasons for these complaints were residual ametropia, dry eye disease, posterior capsule opacification, and expectation mismatches. Most patients responded well to additional treatments, with only a small proportion remaining dissatisfied.

The second part of the thesis focuses on digital and remote care innovations for the postoperative cataract management.

Chapter 7 presents a systematic review with a comprehensive overview of digital tools and remote care options, including telephone consultations, messaging, automated phone calls, and mobile applications or software. While current evidence does not yet support the complete replacement of in-person follow-up by remote care, these tools were found to be safe and effective for screening and partially substituting in-person follow-up visits. Clinicians may consider digital or remote care to complement their traditional postoperative cataract follow-up, but further research is necessary to define the roles and develop clinical practice guidelines.

Chapter 8 describes a pilot-study validating a web-based visual acuity tool for post-operative cataract patients. It demonstrated clinically acceptable outcomes in 88% of patients and received a high user-acceptability score. **Chapter 9** outlines the rationale and design of a multicenter randomized controlled trial, and **chapter 10** reports the results of this trial using the web-based tool. Patients using the tool at home for unsupervised assessments achieved reliable, comparable visual acuity outcomes to conventional tests. Future improvements to the tool should aim to reduce variability in assessments and refine recalibration for refractive outcomes.

Chapter 11 evaluates an artificial intelligence-based follow-up phone-call system for complication screening after cataract surgery. This innovative tool was found to be a safe and reliable alternative for postoperative telephone consultations, though it could not fully replace the in-person examinations after cataract surgery. Patients expressed a positive attitude towards the tool, highlighting its simplicity, ease of use, and audibility.

Chapter 12 discusses the main findings and limitations of this research, and offers

perspectives to guide future ophthalmological studies aimed at improving the patient journey in cataract and refractive surgery.

Chapter 13 concludes by reflecting on the broader societal impact of our findings and their potential to inform clinical practice, guide future innovations, and support the development of sustainable, patient-centered care pathways in ophthalmology.

Nederlandse samenvatting

Refractie afwijkingen en cataract zijn momenteel de belangrijkste oorzaken van matige tot ernstige visuele beperkingen wereldwijd, met aanzienlijke gevolgen voor zowel de kwaliteit van leven als de levensverwachting. Aangezien de kwaliteit van het gezichtsvermogen impact heeft op het dagelijks functioneren, is het van essentieel belang om het zorgpad voor deze patiënten te optimaliseren en ervoor te zorgen dat oogheelkundige zorg zowel toegankelijk als gepersonaliseerd is. Dit proefschrift onderzoekt technische en klinische innovaties die zijn gericht op het verbeteren van het zorgpad van patiënten die een cataractoperatie of refractiechirurgie ondergaan. Het proefschrift is opgedeeld in twee delen. Het eerste deel richt zich op evidence-based richtlijnen voor de cataractzorg, verbeteringen in intraoculaire lens technologieën en klinische uitkomsten in cataract- en refractiechirurgie. Het tweede deel evalueert de effectiviteit van digitale en op afstand geleverde zorgopties voor het postoperatieve traject van cataractpatiënten.

Hoofdstuk 1 omvat een algemene inleiding, waarin de doelstellingen en de opzet van dit proefschrift worden beschreven. Dit hoofdstuk biedt achtergrondinformatie over het zorgpad van patiënten die cataract- of refractiechirurgie ondergaan. Hierbij wordt ingegaan op het traject dat licht aflegt door de optische componenten van het oog, verschillende typen refractieafwijkingen en cataract, behandelopties, postoperatieve uitkomstmetingen en digitale zorg na de cataractoperatie, inclusief zorg op afstand.

In **hoofdstuk 2** presenteren we de eerste Europese richtlijn voor het management van cataractchirurgie, met evidence-based aanbevelingen die voortkomen uit een uitgebreide literatuurreview en expertconsensus. De richtlijn bestrijkt het gehele zorgpad, van diagnose tot behandeling, met als doel de zorg te standaardiseren, transparantie te bevorderen en klinische variabiliteit te verminderen. Daarnaast identificeert de richtlijn kennislacunes, waarmee wordt aangeduid op welke terreinen verder onderzoek nodig is om de klinische praktijk verder te verbeteren.

Hoofdstuk 3 rapporteert een gerandomiseerde gecontroleerde studie die de uitkomsten vergelijkt na bilaterale implantatie van twee extended depth-of-focus (EDOF) intra-oculaire lenzen (IOLs), met een mini-monovisie correctie. Beide IOLs toonden vergelijkbare binoculaire gezichtsscherptes, kwaliteit van zien en patiënttevredenheid. De groep met het lensdesign met segmenten voor nabij zicht vertoonde echter een grotere scherptediepte en daardoor een groter visusbereik. De studie onthulde tevens een grote variabiliteit in chirurgisch geïnduceerde astigmatisme (SIA), dat werd geïdentificeerd als een cruciale factor die de refractieve uitkomsten beïnvloedde.

Hoofdstuk 4 evalueert de effectiviteit en veiligheid van een nieuw multifocale iris-gefixeerde phake intraoculaire lens (pIOL) in de voorste kamer tijdens de eerste zes maanden na implantatie. In deze multicenter prospectieve klinische studie resulteerde bilaterale implantatie van deze pIOL in een uitstekende gezichtsscherpte, zowel van veraf als voor dichtbij, met een stabiele endotheelcel dichtheid (ECD). De patiënttevredenheid was hoog, met 83% van de patiënten die volledige brilonafhankelijkheid rapporteerden, ondanks het ervaren van enkele optische verstoringen.

Hoofdstuk 5 beschrijft het gebruik van swept-source optical coherence tomography (SS-OCT) beeldvorming en op maat ontwikkelde software om tilt en decentratie van de IOL na cataractchirurgie te beoordelen. De bevindingen van deze studie toonden aan dat deze factoren de gecorrigeerde vertevisus voor afstand niet significant beïnvloedden, ongeacht de gebruikte referentie-as voor de analyse.

Hoofdstuk 6 rapporteert de redenen voor ontevredenheid na implantatie van EDOF IOLs. In dit cohort was wazig zicht de meest genoemde klacht, gevolgd door dysfotopsieën. De belangrijkste oorzaken voor deze klachten waren residuele ametropie, droge ogen, nastaar en mismatches in verwachtingen. De meeste patiënten reageerden goed op aanvullende behandelingen, met slechts een klein percentage dat ontevreden bleef.

Het tweede deel van het proefschrift richt zich op digitale zorg en zorg op afstand voor de postoperatieve cataractzorg. **Hoofdstuk 7** presenteert een systematische review met een uitgebreid overzicht van digitale hulpmiddelen en op afstand geleverde zorgopties, waaronder telefonische consultaties, berichtgeving, geautomatiseerde telefoongesprekken en mobiele applicaties of software. Hoewel het huidige bewijs nog geen volledig zorgpad met zorg op afstand ondersteunt, werden deze hulpmiddelen als veilig en effectief bevonden voor screening en het gedeeltelijk vervangen van fysieke vervolgafspraken. Klinisch personeel kan digitale of op afstand geboden zorg overwegen als aanvulling op traditionele postoperatieve controles na een cataractoperatie, maar verder onderzoek is noodzakelijk om de exacte rol hiervan te definiëren en richtlijnen voor klinische praktijk te ontwikkelen.

Hoofdstuk 8 beschrijft een pilotstudie die een online visustest valideert voor postoperatieve cataractpatiënten. Deze studie toonde klinisch acceptabele uitkomsten bij 88% van de patiënten en ontving een hoge score voor gebruikersacceptatie. **Hoofdstuk 9** beschrijft de achtergrond en opzet van een multicenter gerandomiseerde gecontroleerde studie, en **hoofdstuk 10** rapporteert de resultaten van deze studie, waarbij de online visustest werd onderzocht. Patiënten die deze online zelftest thuis gebruikten, behaalden betrouwbare en vergelijkbare uitkomsten voor gezichtsscherpte in vergelijking met

conventionele testen. Toekomstige verbeteringen van deze online visustest zouden gericht moeten zijn op het verminderen van de variabiliteit in beoordelingen en het verfijnen van de herkalibratie voor refractie uitkomsten.

Hoofdstuk 11 evalueert een op kunstmatige intelligentie gebaseerd belsysteem voor complicatiescreening na cataractchirurgie. Dit innovatieve hulpmiddel bleek een veilige en betrouwbare alternatieve optie voor postoperatieve telefonische consultaties, hoewel het de fysieke onderzoeken na cataractchirurgie niet volledig kon vervangen. Patiënten hadden een positieve houding ten opzichte van het hulpmiddel en benadrukten de eenvoud, het gebruiksgemak en de hoorbaarheid ervan.

Hoofdstuk 12 bespreekt de belangrijkste bevindingen en beperkingen van dit onderzoek en biedt perspectieven voor toekomstige oogheelkundige studies die gericht zijn op het verbeteren van het zorgpad voor cataract- en refractiechirurgiepatiënten. **Hoofdstuk 13** sluit af met een reflectie op de bredere maatschappelijke impact van onze bevindingen en hun potentieel om de klinische praktijk te informeren, toekomstige innovaties te stimuleren en bij te dragen aan de ontwikkeling van duurzame, patiëntgerichte zorgpaden in de oogheelkunde.

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About the author



Joukje Wanten was born on the 20th of May 1997 in Venray, The Netherlands. After graduating from secondary school (Dendron College, Horst) with the distinction *cum laude*, she started Medical School at the University of Maastricht, developing a special interest in ophthalmology. In 2021, after she obtained her Master's degree in Medicine, she started with her Ph.D. under the supervision of Prof. dr. R.M.M.A. Nuijts and Dr. N.J.C. Bauer at the University Eye Clinic Maastricht. She presented her research at various national and international scientific conferences, was awarded by the Bayer Ophthalmic Care Award in 2023, and received the European Society of Cataract and Refractive Surgeons (ESCRS) the Systematic Research Award in 2023. She was part of the ESCRS clinical guidelines working group and had co-authored a book chapter on refractive surgery during her research. As of October 2025, she has started her residency in Ophthalmology at the University Eye Clinic Maastricht.

List of publications

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Wanten JC, Till V, Findl O, Cochener-Lamard C, Kohnen T, Nuijts R. European Society of Cataract and Refractive Surgeons Guideline for Cataract Surgery 2024: executive summary. *J Cataract Refract Surg. 2026;52*(9):e1-e13. doi:10.1097/j.jcrs.0000000000002012

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