

**TELEMONITORING IN
OPHTHALMOLOGY**

JANNEAU CLAESSENS

Telemonitoring in Ophthalmology

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Conflicts of Interest

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Chapter I

General introduction and thesis outline

INTRODUCTION TO THIS THESIS

Digital technologies have transformed the healthcare system. Over the past decades, they changed the way health information is accessed by patients and how doctors and patients communicate. This thesis focuses on technologies for assessing and monitoring ophthalmic patients remotely, placing emphasis on vision self-assessment tools.

Telemonitoring: a brief overview

“Telemonitoring” refers to the use of digital technologies to monitor patients at a distance.¹ This remote patient monitoring involves collecting individual health data at one location, most commonly a patient’s home, and transmitting these data for assessment and recommendations to healthcare providers in a different location.^{2,3} The design of the technologies and the role of the patient may vary, depending on the context. Data may be captured and transmitted automatically, e.g. by wearable devices for monitoring of vital signs, or require the patient to actively submit their own health data, e.g. through a secured website or smartphone app.³

Telemonitoring finds its origin in space aviation, when in the early 1960s the first manned spaceflights were performed and astronauts were equipped with sensors to monitor cardiovascular parameters. The biometric data collected in space were transferred these back to Earth.^{4,5} Today’s world sees more easily accessible telemonitoring initiatives, driven by the increased access and use of the Internet and mobile devices. Examples of telemonitoring applications today include management of chronic diseases such as hypertension, diabetes, or various cardiopulmonary conditions^{1,6-9}; and monitoring of maternal and fetal health during pregnancy.^{10,11}

Receiving care from the comfort of their home-environment could benefit patients by saving time, efforts and expenditures related to clinic visits. It greatly improves accessibility of healthcare services for those in geographically remote or underserved areas. Moreover, empowering and encouraging patients to actively participate in their own health management fits today’s society of acknowledging the central role of patients as informed and engaged partners in clinical-decision making.¹² As telemonitoring fosters the active role of patients in their health, it has the potential to give patients better insights into their disease.¹³⁻¹⁶ Its effectiveness has been underlined by the significantly reduced number of clinic visits and hospitalizations observed after introducing telemonitoring in several chronic diseases such as inflammatory bowel disease, chronic heart failure, chronic obstructive pulmonary disease or Parkinson’s disease.¹⁶⁻¹⁹ Here, telemonitoring provided ground for safely deferring outpatient visits of stable patients, and importantly, facilitated the timely identification of deterioration, enabling the initia-

tion of interventions at an early stage to avert potential complications. This way, digital health solutions are increasingly recognized as an integral part to alleviate the current strain on the healthcare system and comply with the increasing demands and costs in our ageing society.^{20,21}

Terminology

Different terms referring to the use of digital technologies in health care are being used interchangeably. The definitions of the terminology we use in our thesis are explicated for clarity:

“E-health”, sometimes referred to as **“telehealth”**, is a widely used umbrella term referring to health services and information delivered or enhanced through the Internet and related technologies.²²

“Digital Health” is a term recently adopted by the World Health Organization (WHO) to expand the concept of E-health by including the growing role of artificial intelligence (AI) and big data, and the wider range of smart devices.²³ Thereby, this broader scope not only focuses on obtaining and transmitting data by electronic means, but also on enhancing care through intelligent processing of traditional, clinical data.²⁴

“Telemonitoring” is the modality of digital health that we will focus on in this thesis and defined as the use of digital technologies to monitor patients at a distance.¹

Telemonitoring in ophthalmology

It is important to point out that the advantages and effectiveness of telemonitoring may vary across different healthcare contexts and patient populations. This thesis focuses on ophthalmology. Not all parameters of an ophthalmic examination can be obtained remotely, as some assessments require specialized office-based equipment. A routine ophthalmic examination at the clinic consists of an anamnesis, an assessment of the eye’s function by vision testing, and a microscopic examination of the eye’s anatomical structures (i.e. slit lamp examination and/or funduscopy). Depending on the context, additional assessments using advanced diagnostic modalities may be indicated; such as the visualization of the layers of the retina and optic nerve by optical coherence tomography (OCT), fluorescein angiography, corneal topography, visual field testing, or wavefront aberrometry. Emerging technologies offer potential avenues for obtaining

some of these assessments remotely. Examples include home-based OCT devices or smartphone-based applications for corneal topography, autorefractometry or visual field screening.²⁵⁻²⁸

This thesis will particularly focus on applications for web-based vision testing, performed independently by ophthalmic patients at home. An abundance of tools for this purpose can be found on the internet and in mobile app stores, though most lack clinical validation and certification, or have only been examined in controlled environments organized by test manufacturers, owners or patent-holders.^{29,30} Therefore, this thesis sought to provide the lacking scientific evidence on the performance of vision self-assessment tools in ophthalmic patient populations and determine the implications for clinical practice. A specific patient pathway that is being explored in depth is cataract care. Cataract, the clouding of the eye's natural lens, is the leading cause of reversible visual impairment worldwide.³¹ The only treatment for cataract is surgery: replacing the eye's natural lens with an artificial intraocular lens implant. Currently, millions of cataract surgeries are performed around the world, of which approximately 180,000 surgeries annually in the Netherlands.³² As the condition is most commonly age-related, the future demands for surgeries will keep on increasing in our ageing society. The surgery is usually performed in day care and patients are followed up in the subsequent weeks to assess postoperative visual outcomes and detect complications. Cataract surgery has evolved to small-incisional surgery with rapid visual recovery, good visual outcomes, and minimal complications due to advancements in technology and surgical techniques.³³ The high volume of patients and the low complication rates make cataract surgery follow-up an interesting domain for telemonitoring.

Assessing visual acuity and refractive error

Visual acuity (VA) and refractive error are two important outcome measures obtained by the vision self-assessment tools explored in this thesis.

Visual acuity

VA refers to the eye's ability to see fine detail by discerning two high-contrast separate points.³⁴ Most commonly it is assessed by charts that display optotypes (i.e. letters, numbers or symbols), which patients should recognize at a certain distance, aiming to identify the smallest optotype that can be read. Various charts employing different optotypes exist, though all of these adhere to strict geometric principles, outlined in the ISO Standard 'Ophthalmic Optics' (8596:2017).³⁵

Standardized methods for assessing VA date back to the 19th century, when the first chart was introduced by the Dutch ophthalmologist Herman Snellen, who was later

appointed Professor of Ophthalmology at Utrecht University in 1877.³⁶ Modern adaptations of the Snellen chart remain popular today due to their familiarity and ease-of-use.³⁷ LogMAR charts, first introduced by Bailey and Lovie in 1976, offer higher accuracy and consistency and are therefore preferred in research settings, though their longer test time and complex scoring system limit their use in clinical practice.³⁷⁻³⁹

Different reporting standards for VA are used interchangeably. Traditionally, Snellen VA is scored as a fraction. The numerator represents the distance from the chart, typically 6 meters (or 20 feet), while the denominator represents the distance at which the thickness of the separable lines, and the spaces in between, subtend one minute of arc (i.e. a unit of angular measurement).³⁴ In most European countries this fraction is reported as a decimal score. A VA score of 6/6 (i.e. 1.0 or 20/20) indicates an ability to resolve details at an angle of 1 minute of arc at 6 meters.³⁷ LogMAR charts score VA based on the logarithm of the minimum angle of resolution (MAR). One who resolves details at an angle of 1 minute of arc (MAR = 1) then scores logMAR 0, since the base-10 logarithm of 1 is 0.

In this thesis, VA scores will be presented in logMAR units. If Snellen chart assessments were performed, these scores were converted to logMAR using a standardized formula: $\log\text{MAR} = -\log(\text{Snellen decimal})$.^{40,41} Table 1 provides an overview of how the presented logMAR scores can be converted to other reporting standards of VA.

Table 1. Conversion table for logMAR notation⁴²

logMAR	MAR	Snellen decimal	Snellen fraction (meters)	Snellen fraction (foot)
1.0	10	0.10	6/60	20/200
0.9	8	0.13	6/48	20/160
0.8	6.3	0.16	6/38	20/125
0.7	5	0.20	6/30	20/100
0.6	4	0.25	6/24	20/80
0.5	3.2	0.32	6/18	20/63
0.4	2.5	0.40	6/15	20/50
0.3	2.0	0.50	6/12	20/40
0.2	1.6	0.63	6/9.5	20/32
0.1	1.25	0.80	6/7.5	20/25
0.0	1	1.00	6/6	20/20
-0.1	0.8	1.25	6/4.8	20/16
-0.20	0.63	1.60	6/3.8	20/12.5
-0.30	0.5	2.00	6/3	20/10

Refractive error

The eye's refractive state refers to its ability to bend light rays passing through the eye to project an image on the retina.³⁴ *Emmetropia* is the optimal state a sharp image is projected, while *ametropia* refers to the state where refractive errors, such as myopia (focal points fall in front of the retina) or hyperopia (focal points fall behind the retina), lead to blurred vision. Astigmatism refers to the state in which the light rays do not bend evenly in every meridian as a result of an unevenly curved eye, resulting in a distorted image.

Refractive errors can be assessed objectively or subjectively.³⁴ Objective refraction, obtained without patient feedback, often utilizes autorefractors (computerized systems using sensors to detect reflections of infrared light cones). Subjective refraction involves a manual assessment with patient responses, using a phoropter or trial frame while changing lenses based on patient feedback.

Refractive errors are corrected by spectacles, such as glasses or contacts, and reported as the prescription that is required for this correction. This prescription comprises three components: spherical power (i.e. sphere), cylindrical power (i.e. cyl), and cylindrical axis. Myopia is corrected with diverging (-) lenses, while hyperopia requires converging (+) lenses. The cylindrical component corrects astigmatism, with the lens having zero power in one meridian (the axis) and maximal or minimal power in the perpendicular meridian.⁴³ Spherical and cylindrical powers are measured in diopters (D), and the axis is measured in degrees (1 to 180). The components of sphere, cylinder and axis are dependent on each other and may therefore not be treated as independent variables.⁴³ In this thesis, refractive outcomes are reported as spherical equivalent (SEQ), a compound measure combining sphere and cylinder using the formula: $SEQ = Sphere + (Cylinder / 2)$.⁴³

THESIS OUTLINE

In this thesis, our goal was to explore the role which digital technology can play in assessing and monitoring ophthalmic patients remotely, with a particular focus on vision self-assessments. The **first section** elaborates on digital technologies for remotely assessing ophthalmic patients in general. The **second section** specifically focuses on cataract care, by introducing and evaluating remote, web-based follow-up after cataract surgery.

Section 1: Development and evaluation of digital tools for remotely assessing ophthalmic patients

In **chapter 2** we provide an overview of available digital tools for self-assessing visual function and discuss how these compare to conventional assessments at the clinic. In **chapter 3** and **chapter 4**, we evaluate the accuracy of a certified vision self-assessment, when performed independently by ophthalmic patients in their home environment. **Chapter 5** introduces and evaluates an innovative approach to reduce outpatient waiting lists by clinical decision making based on health information gathered by phone, available in the electronic health records, and/or obtained by remote vision testing; a practical implementation of telemonitoring.

Section 2: Remote follow up after cataract surgery

In **chapter 6** we evaluate the accuracy of the certified vision self-assessment in cataract patients; a pilot study conducted at the clinic to assess if older-aged adults were able to perform the self-assessment independently. In **chapter 7** we describe the rationale and design of employing this specific tool in a randomized controlled trial on remote monitoring after cataract surgery. The main findings of this study are discussed in **chapter 8**, while the patient perspectives were captured in a separate paper, presented in **chapter 9**.

Section 3: Synthesis

A summary of these findings and the clinical implications are discussed In **chapter 10**.

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Section I

**Development and evaluation of digital tools for
remotely assessing ophthalmic patients**



Chapter 2

Digital tools for the self-assessment of visual acuity: a systematic review

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Digital Tools for the Self-Assessment of Visual Acuity: A Systematic Review.
Ophthalmol Ther. 2021 Dec;10(4):715-730. doi: 10.1007/s40123-021-00360-3.

ABSTRACT

Purpose: Numerous digital tools to self-assess visual acuity have been introduced. The recent COVID-19 pandemic underlined the need for high-quality remote care. This review gives a current overview of digital tools for remotely assessing visual function and reports on their accuracy.

Methods: We searched the databases of Embase and Pubmed, and systematically reviewed the literature, conform PRISMA guidelines. Two preliminary papers were added from medRxiv.org. The main outcome was the agreement of the digital tools with conventional clinical charts, as expressed by mean differences and 95% Limits of Agreement (95% LoA).

Results: Seventeen included studies reported on 13 different digital tools. Most of the tools focus on distance visual acuity. The mean differences of the digital tools ranged from -0.08 to 0.10 logMAR, when compared to traditional clinical assessments. The 95% LoA differed considerably between studies: from ± 0.08 logMAR to ± 0.47 logMAR, though the variability was less pronounced for higher visual acuities.

Conclusion: The low mean differences between digital visual acuity assessments and reference charts suggest clinical equivalence, though the wide 95% LoA identify a lower precision of digital self-assessments. This effect diminishes in individuals with better visual acuities; a common feature of visual acuity assessments. There is great potential for the digital tools to increase access to eye care and we expect the accuracy of the current tools to improve with every iteration in technology development.

INTRODUCTION

Digital tools are of great value for enhancing access to health care. In ophthalmology, numerous tools for self-assessing visual function have been developed over the last decade. These tools enable laypersons to self-measure aspects of visual acuity (VA) at home, or at school, using applications on smartphones, tablets and/or computers.

VA testing is the most commonly performed examination of visual function.¹ In clinical practice, it is most commonly carried out using a Snellen chart, which utilizes black letters or symbols (optotypes) of a range of sizes set on a white chart.² This chart was developed in 1862 and has been globally adopted as the standard VA test, despite some considerations regarding its design.^{3,4} The most important issues with this chart are the irregular progression of the size of the letters. Alternative charts have been introduced. LogMAR charts are the standard method in research as they are considered the most accurate.² The Snellen chart retains its popularity in clinical practice, due to familiarity, cost, smaller chart size and, most importantly, the short time taken to perform the test.⁵ Notwithstanding, traditional VA testing with Snellen or logMAR charts requires the patient to physically attend a clinic. Figure 1 shows a visualization of the Snellen chart (left) and the alternative ETDRS chart, a well-established logMAR chart (right).

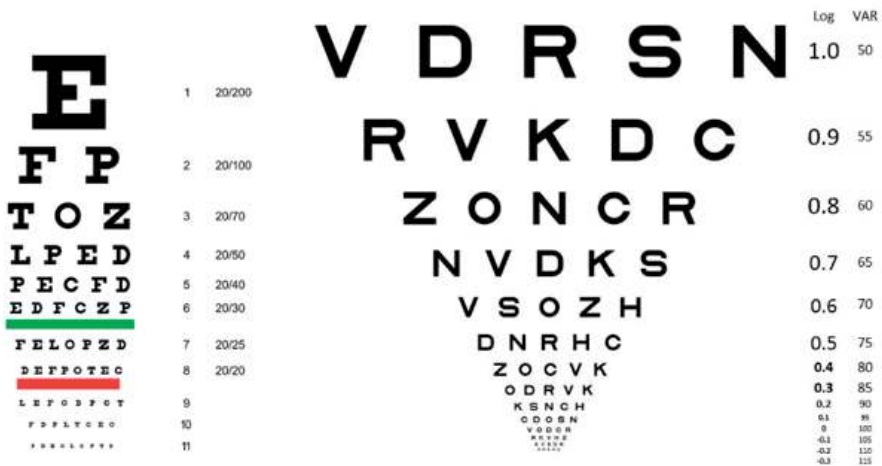


Figure 1. Left: Snellen visual acuity chart; Right: LogMAR visual acuity chart. Images are not to scale.

An urgent need for high-quality remote care was brought about during the COVID-19 pandemic in 2020, when most hospital care was globally suspended or postponed. Digital tools for self-assessment of VA increase the access to eye care and avoid the burden for patients in quarantine, with poor mobility, or without means of transportation.

A plethora of digital tools is available on the internet and in mobile app stores, which impedes choosing which tools are the most effective and reliable.⁶ Before a digital self-testing tool can successfully be used in hospital care, extensive validation research and certification is needed.⁷ The aim of this literature review is to provide an overview of the available scientific evidence for remote testing of visual function, and to critically appraise and report on the validity, quality and effectiveness of the available tools.

METHODS

Protocol and registration

A review protocol was developed based on the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) statement.⁸ The systematic review was registered in the international prospective register of systematic reviews (PROSPERO) on August 28, 2020 (ID: CRD42020201421). In accordance with Dutch law, no institutional ethical review board approval was required.

Search strategy

A search was conducted in PubMed and Embase, including literature published up to the 1st of April 2021. The syntax included synonyms for the words 'assessment' and 'digital', as well as the keywords: 'refractive error', 'visual field', 'color vision' and 'visual acuity'. We deliberately used more keywords than 'visual acuity' as we did not want to miss out on tools that were not primarily developed to assess VA, but had the ability to do so. The full syntax can be found in the supplementary file. Articles published before 2010 were excluded because of the rapidly changing environment of digital tools and smartphones. No further limitations or filters were applied.

Study selection

Titles and abstracts were screened for relevance independently by two reviewers (JC and JG). The reviewers were blinded and initial title/abstract screening focused on the use of digital tools in the field of ophthalmology in the broadest sense. Articles with a different topic were excluded. Subsequently, additional screening of titles/abstracts and full texts was performed to exclude papers about digital tools that did not include a VA assessment (i.e. different outcome) or were not self-assessments. We defined self-assessment

tools as applications on a smartphone, computer or tablet that can be used without assistance of a healthcare professional. References of reviews and included studies were screened for additional citations. Articles were excluded if the full text was not available.

Our outcome of interest was measurement accuracy of the digital tools, compared to conventional clinical charts, expressed as mean differences of VA and 95% Limits of Agreement (95% LoA). The mean difference can be interpreted as the systematic difference between the measurements (i.e. bias) and the 95% LoA as the range within 95% of the differences between one measurement and the other are included (i.e. random error). This methodology was first introduced by Bland and Altman and is commonly used in method comparison studies.⁹ If the 95% LoA was not directly reported in the original article, it was derived from the plots or calculated manually from the mean difference and the SD using the following standard formula: $95\%LoA = \text{mean difference} \pm 1.96 * SD$.

In parallel to writing the current review, our group investigates a specific remote eye exam in various patient populations: in a sample of 100 keratoconus eyes and a sample of 98 uveitis eyes. To illustrate how the accuracy of one digital tool varies for different VA ranges these preliminary study data were included in this review as well. The pre-prints have been published on medRxiv.org.^{10,11}

Quality assessment

All included studies were assessed for methodological quality according to the QUADAS-2 tool by two reviewers independently.¹² Disagreements were solved in consensus. 'Bias' is scored in terms of patient selection, blinding of outcomes during assessment with index test or reference test and the timing of the assessments (i.e. whether both tests were done sequentially within a short interval). Applicability focuses on whether there are concerns that the patient population, index tests or reference tests match the review question.

Data extraction and synthesis

Two reviewers (JC and JG) independently extracted the relevant data. From each included study, we retrieved information on study and patient characteristics, type of the index test, reference test and relevant statistics including mean difference, 95% LoA, and/or standard deviation (SD) of the mean difference.

If multiple comparisons were presented in one article, we only recorded the measurements that were assessed in controlled experimental settings, as these represent the agreement in the most optimal settings. Two studies compared a near vision tool with both a near VA card and a distance chart.^{13,14} Another study used both types of reference

charts for evaluating a distance tool.¹⁵ We only present the comparisons using the reference chart with the closest resemblance to the original tool, as we consider these as the best representation for the measurement accuracy. One study reported VA in ETDRS letters, which we manually converted to logMAR using standard conversion charts.¹³ For the included study by our own research group, the mean difference and 95% LoA were calculated manually since we had access to the study database.¹⁶ If the reported 95% LoA were inconsistent in different sections of the original article¹⁷, we could not report these numerical data.

The individual studies all differed greatly with regards to the studied digital tools, reference standards and study populations. This high between-study heterogeneity precluded a meta-analysis of these outcomes, as the generalizability of a possible pooled estimate was expected to be low.

Additional subgroup analyses for different visual acuity ranges

Subgroup analyses illustrate how measurement accuracy of a similar tool can differ for different VA ranges. Two of the included studies reported outcomes of subgroup analyses in the original article.^{10,18} We had access to the databases of the included studies by our own research group and used these data for additional subgroup analyses.^{10,16} Subgroups were based on achieved VA of ≤ 0.5 logMAR (≥ 0.3 Snellen) and VA > 0.5 logMAR (< 0.3 Snellen). This is the cut-off value for low vision by the World Health Organization.¹⁹

Data on test-retest variability of visual acuity assessments

Variation between two assessments of VA is common, partly owing to the psychophysical nature of the test. This is demonstrated when an individual is assessed twice within a short time-interval, using the same chart, and further confounds the outcomes when different charts are compared.²⁰ Therefore, to put in perspective the agreement between the digital tools and the clinical charts, we will also report outcomes of studies regarding repeatability (test-retest variabilities) of the conventional Snellen and ETDRS charts. A comprehensive literature search identified relevant papers.^{1,21–25}

Statement of ethics compliance

This systematic review is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

RESULTS

Search strategy and study selection

The study flow chart can be found in Figure 2. Our search resulted in 679 Embase and 408 PubMed citations. After removal of duplicates, 903 were screened for relevance by titles and abstract, followed by full-text screening of 40 potentially eligible articles. Subsequently, 32 articles were excluded based on criteria depicted in the flow chart. Two articles were added from the medRxiv preprint server and seven articles were added after manual screening of references.

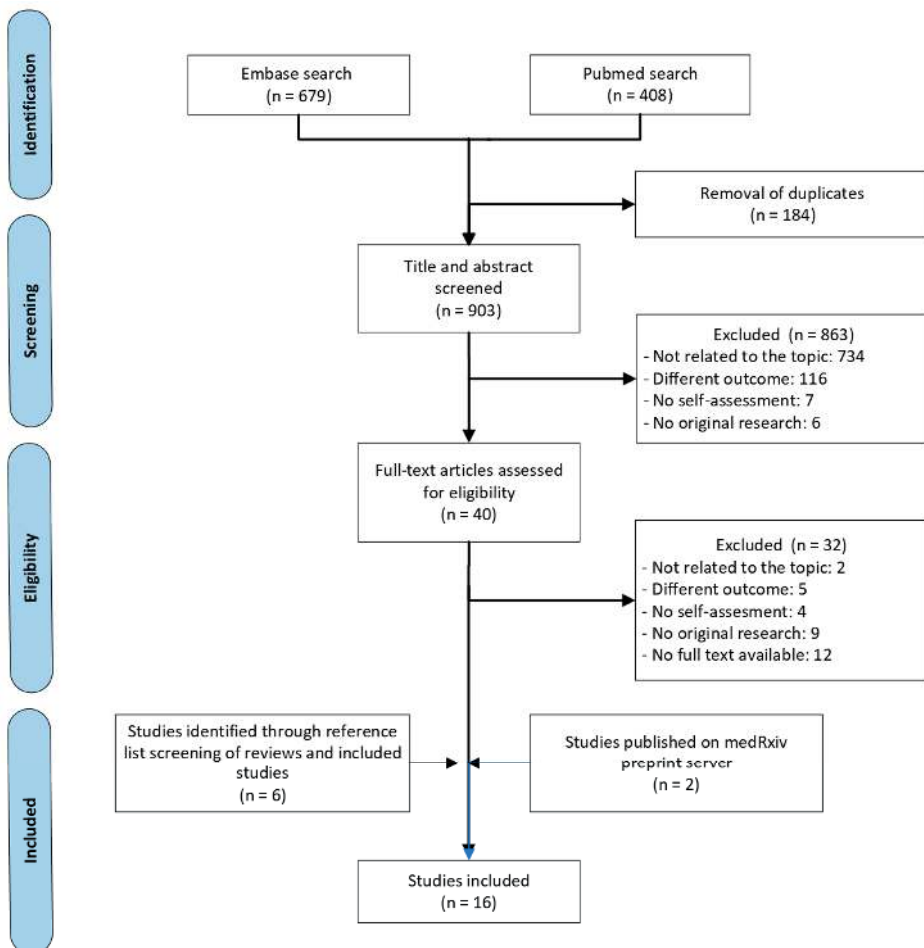


Figure 2. Study flow diagram based on PRISMA Guidelines.⁸

Quality assessment

The evaluation of the risk of bias and applicability of the included studies is depicted in Figure 3. In terms of risk of bias, most striking are concerns regarding the blinding of participants and/or researchers. Some studies explicitly reported on blinding, i.e. performing the index test (digital tool) without knowledge of the score of the reference test (conventional chart) and vice versa. For some studies it was unclear whether the researcher and/or subject had been blinded. Concerning patient selection, patients were mostly recruited consecutively. One study, Nik Azis et al.²⁶, reported a convenience sampling method for recruitment, by excluding children who were deemed uncooperative. Overall, there were no concerns regarding applicability for any of the studies: all studies matched the review question.



Figure 3. Risk of bias and applicability concerns summary. Scores are based on the QUADAS-2 tool.¹²

Data extraction

An overview of the study characteristics can be found in Table 1. The 17 identified studies have examined 13 different tools. A total of 3,591 eyes have been included. There is a large heterogeneity among the included studies; participants differed in age, nationality and medical history. The majority of studies examined a population with a wide age range. Four studies focused on testing VA in children. Some studies examined only healthy participants, other studies examined patients or a mixed group of both.

Seven unique evaluated tools have been developed to test distance vision^{15-18,26-30}, and four unique tools specifically focus on near vision testing.^{13,14,30-32} One tool assesses both.³³ Most of the studies assessed corrected VA, meaning that study subjects wore their habitual correction (i.e. glasses/contacts), if applicable. The digital tools involve different devices, including smartphones, tablets and computers. Most digital tools are available as an application for smartphones and tablets. Two tools are web-based and do not need installation of an app. Most of the publications were validation studies in experimental controlled environments. One study evaluated a smartphone-based near vision test to assess VA at an emergency department.³⁴ For one study, the digital tool was assessed unsupervised by subjects in their own home environment.¹¹ Different reference standards were used to assess agreement.

Table 1. Study characteristics of the 15 included peer-reviewed studies and 2 pre-print publications

Author, year, country	Name of test	No. of Eyes, Study population	Age (in years)	study objectives	Platform, device	Optotypes index test	Reference standard
Zhang 2013, China ¹⁶	Eye Chart Pro	240, patients	27-80 (mean 47)	Uncorrected VA (logMAR)	App, smartphone and tablet	Tumbling E	Standard tumbling E light box
Gounder 2014, Australia ²⁷	EyeSnellen app	122, patients	19-89 (mean 57)	Corrected VA (logMAR)	App, smartphone and table	Snellen chart	Snellen light box
Bastawrous 2015, Kenya ²⁸	Peek Acuity	544, patients	>55	Corrected VA (logMAR)	App, smartphone	ETDRS tumbling E	ETDRS tumbling E chart and Snellen chart
Tofigh 2015, USA ³²	EyeHandBook*	100, patients	18-89	Near VA with corrective lenses if applicable (logMAR)	App, smartphone	Tool-specific optotypes	Rosenbaum near card
Jan-Bond 2015, Malaysia ¹⁷	REST application	202, patients and staff	5-75 (mean 37)	VA (logMAR) [unknown whether uncorrected or corrected]	App, smartphone or tablet	Tumbling E	ETDRS tumbling E chart
Phung 2016, USA ¹³	Sightbook*	238, unknown population	25-93 (mean 67)	Corrected VA (approx.ETDRS)	App, smartphone or tablet	Tool-specific optotypes	Rosenbaum near card (near vision) and Snellen chart (distance vision)
Pathipati 2016, USA ⁴	Sightbook*	Phase 1: 57, Phase 2: 51, patients presenting at emergency department	Adults (mean 48.5)	Corrected VA (logMAR)	App, smartphone or tablet	Tool-specific optotypes	Phase 1: Snellen chart Phase 2: Rosenbaum near card
Calabrèse 2018, USA ³¹	MNREAD iPad application*	330 (normal vision) and 86 (low vision) [binocular assessments, so 165 and 43 comparisons, respectively]	Normal vision: 8-72 (mean 28) Low vision: 22-93 (mean 60)	- Maximum Reading Speed - Reading Acuity - Critical Printing Size - Reading Accessibility Index	App, iPad	MNREAD chart	Printed MNREAD chart
Nik Azis 2019, Malaysia ²⁶	AAPOS Vision Screening app	390, patients and healthy participants	5 and 6	Corrected VA (logMAR)	App, iPad	LEA Symbols	LEA symbols light box

Han 2019, China/ Australia ³³	Vision @Home* 100 (adolescent Chinese), 100 (elderly Chinese), and 126 (Australian) patients and non-patients	Elderly Chinese: 50-79 Adolescent Chinese: 13-26 Australian: 8-91	Corrected VA (logMAR)	Website or app, smartphone	Tumbling E	ETDRS tumbling E chart (distance vision) and ETDRS near chart (near vision)
Wisse 2019, the Netherlands ¹⁶	Easee 200, healthy participants	18-40 (mean 25.4)	Refractive error, uncorrected VA (logMAR)	Website, smartphone and computer or tablet	Tumbling E and tool-specific optotypes	ETDRS chart
Brucker 2019, France ¹⁴	Odysight* 120, patients	24-92 (mean 64.7)	Corrected VA (logMAR) Contrast sensitivity	App, smartphone	ETDRS, Tumbling E	Sloan ETDRS chart (near vision) and ETDRS chart (distance)
Ansell 2020, United Kingdom ²⁹	Eye Chart 24, students	18-27 (mean 20.1)	Corrected VA (logMAR)	App, smartphone	Snellen chart	ETDRS chart
Tiraset 2021, Thailand ¹⁵	Eye Chart 295, patients	18-85 (mean 64)	Corrected VA (logMAR)	App, smartphone	Snellen chart or Tumbling E	ETDRS chart (distance vision) and Rosenbaum near card (near vision)
Satgunam 2021, India ³⁰	Peek Acuity Smart Optometry* 68, healthy participants (employees of the institute) 24, presbyopic subgroup of the abovementioned population (in A)	20-60 (median 31) 37-60 (median 50)	Uncorrected VA (logMAR) Uncorrected VA (logMAR)	App, smartphone or tablet App, smartphone or tablet	ETDRS Tumbling E Tumbling E	COMLog presenting Tumbling E Reduced Snellen near vision chart with tumbling E
Muijzer 2021, the Netherlands ¹⁰	Easee 100, keratoconus patients	18-40 (mean 25.6)	Refractive error, uncorrected VA (logMAR)	Website, smartphone and computer/tablet	Tumbling E and tool-specific optotypes	ETDRS chart
Claessens 2021, the Netherlands ¹¹	Easee 98, uveitis patients	Adults (mean 46.5)	Corrected VA (logMAR)	Website, smartphone and computer/tablet	Tumbling E and tool-specific optotypes	Snellen light box

VA = Visual acuity. Corrected = with habitual correction (if worn).
* Digital tool assesses near visual acuity (i.e. visual acuity measured at 40cm distance)

Comparisons of distance visual acuity assessments

Overall measurement accuracy

An overview of the comparisons of the distance VA assessments can be found in Figure 4.^{10,11,15,16,18,26–30,33} Most articles reported outcomes for different subgroups or per eye, resulting in 18 comparisons. The mean differences between the digital tools and the reference standards (i.e. bias) range from -0.08 to 0.10 logMAR. Most of the digital tools provide a slightly worse VA-score (i.e. higher logMAR score) than the actual VA as measured by the reference standard. The distribution of the differences between the two tests (i.e. random error), as expressed by the 95% LoA, varies greatly between the studies. It ranges from ± 0.08 logMAR (lowest variability) to ± 0.47 logMAR (highest variability) from the mean difference. Separate comparisons per eye were mostly comparable within studies.

The study by Bastawrous et al demonstrates that the accuracy of the same digital tool (Peek acuity) varies when compared to different reference charts. Han et al. reported on different study populations, illustrating how test accuracy slightly differs when various groups are assessed similar conditions. The studies by our own study group (Wisse et al.,¹⁶ Muijzer et al.¹⁰ and Claessens et al.¹¹) all focus on the same digital tool (Easee). Interestingly, the random error is much higher for *uncorrected* VA assessments in healthy individuals (of whom some have refractive errors) and keratoconus patients, than for *corrected* VA assessments in uveitis patients.

Subgroup analyses for different visual acuity ranges

The subgroup analyses illustrate how the measurement accuracy of a similar tool can differ for different VA ranges, see Figure 4. In all of these comparisons, the measurement accuracy appears lower in the poorer VA subgroups, illustrated by the higher mean differences and, most notably, the wider 95% LoA. In better VA ranges, these 95% LoA are smaller.

Test-retest variability of clinical wall charts

Test-retest variabilities of logMAR and Snellen charts have been added as a reference in Figure 4.^{1,21–25} Test-retest variability of logMAR charts ranges from ± 0.07 to ± 0.18 logMAR (from the mean difference). Snellen charts are less consistent, with reported ranges from ± 0.18 to ± 0.34 logMAR. Especially the line assignment, often used in clinical practice, shows a great variation when measurements are repeated.

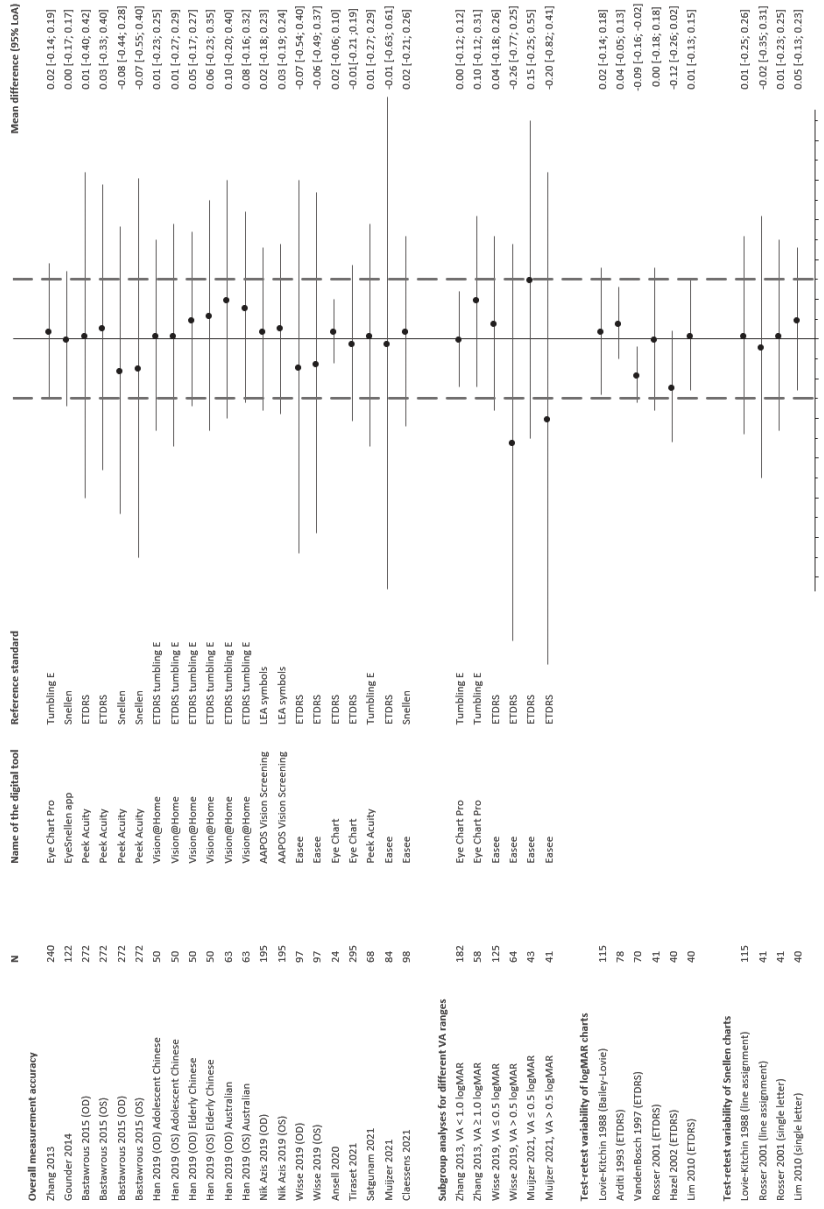


Figure 4. Mean differences between distance visual acuity assessments (digital tool minus reference standard) and 95% limits of agreement in logMAR. Some articles reported separate comparisons per subgroup or per eye. The dashed lines represent ± 0.15 logMAR, a difference that has been suggested in literature to be clinically acceptable.²⁰

Abbreviations: N = number of paired observations; 95% LoA = 95% Limits of Agreement

Comparisons of near vision assessments

For the comparisons focusing on near VA assessments, the mean differences range from -0.03 to 0.09 logMAR.^{13,30,32,33} The 95% LoA range from ± 0.17 to ± 0.35 logMAR from the mean difference. One study examined the Sightbook tool in clinical practice, at an emergency department.³⁴ This self-administered tool provided a more accurate representation of the VA recorded by consulted ophthalmologic residents (using Rosenbaum near cards) when compared to a distance Snellen chart assessed by non-ophthalmologic personnel at the emergency department [mean difference 0.06 ± 0.40 logMAR (Sightbook app) vs 0.21 ± 0.35 logMAR (Snellen chart)].

DISCUSSION

Many digital tools are available to self-test VA, though a clinical validation is often lacking. This systematic review presents the 17 publications on 13 different tools for the self-assessment of VA currently available.

Our systematic review identified low mean differences of the digital tools when compared to reference standards for assessing distance VA, suggesting a low systematic bias. The mean differences ranged from -0.08 to 0.10 logMAR. The digital tools only slightly underestimate the VA-score of the patients and we consider these low values to be negligible in clinical practice. The 95% LoA are varying between studies, ranging from ± 0.08 logMAR to ± 0.47 logMAR from the mean difference. Most of the 95% LoA are rather wide, suggesting considerable variability of the VA assessments of the digital tools. As stated before, there is always a certain variation in repeated measurements in the same person.^{1,20} A study on the variability of VA assessments in a large eye clinic, reported a test-retest variability of ± 0.15 logMAR, when different charts and different examiners assessed the same patient's VA within a short time interval.²⁰ The authors conclude that, in general, differences of less than 0.15 logMAR (i.e. 1.5 lines) are considered measurement variation and should therefore not be considered as indicative of an actual clinical change. Surprisingly, despite the different chart designs and examiners that are compared in this study, this reported variability does not substantially differ from the test-retest variability of same-chart measurements. The test-retest variability of Snellen charts is actually even wider, as depicted in Figure 4. This figure also illustrated that the 95% LoA of most digital tools exceed the 95% LoA reflecting test-retest variability of traditional VA charts. Based on these findings, the digital tools appear less precise than traditional VA charts. Obviously, as with any medical technological device, quality differences of the different tools affect performance. Importantly, these technologies

are developing continuously and an improvement in accuracy is attained with every design iteration.

The accuracy of the near vision tests seems better than the distance VA assessments, expressed by the smaller 95% LoA. The near vision cards and the assessments using tablets are very comparable in nature, which might explain the good agreement. Although near vision testing has a remarkably smaller role in clinical practice, these tools are very easy-to-use. It has been proven effective to have patients do a self-test by handing over a tablet at an emergency unit.³⁴ Especially in an emergency setting, convenience and time-effectiveness outweighs accuracy.

To the best of our knowledge, this is the first systematic review that focusses on clinically validated digital tools for self-assessing VA. We conducted a comprehensive literature search and reviewed all reference lists of included studies using PRISMA guidelines. Two reviewers independently performed the literature screening, data extraction and risk of bias assessment. The bias analysis identified concerns regarding blinding of the subject and researcher for the outcome of the tests in nine studies. We do not consider this a major problem since VA tests report an objective outcome which can be recorded without interpretation. In addition, the two compared tests were different, so learning effects are not expected. One study, Nik Azis et al.²⁶, reported a convenience sampling method for recruitment, by excluding children who were deemed uncooperative. This may have negatively affected generalizability of the outcomes.

When comparing VA assessments two factors are important to consider. First the used type of chart significantly affects the obtained VA outcome.⁴ Consequently, this affects the observed differences between the digital tools and the reference charts. There is always variation when two different VA charts are compared, and one should be careful when using charts interchangeably.⁵ This also explains the difference in agreement of the Peek Acuity tool, as studied by Bastawrous et al, when different reference charts are used (Snellen vs. ETDRS, see Figure 4).²⁸

Secondly, the precision of the assessment depends strongly on the achieved VA of the tested subject. When examining the Bland Altman plots of individual studies, we noticed that the accuracy of the tests improves for patients with better VA-scores. This was also demonstrated in the subgroup analyses in Figure 4. For the study by Zhang et al, the variability of the difference was remarkably smaller for subjects with an achieved VA <1.0 logMAR, than for the ≥ 1.0 logMAR subgroup (± 0.12 vs. ± 0.22). From our own study data, we also learned that the measurement accuracy of one specific tool (Easee) differed for various VA ranges and study populations. For example, the additional subanalysis of the

data of Wisse et al revealed an evidently smaller 95%LoA for the healthy individuals with higher VA scores (e.g. 95%LoA of 0.00;0.58 for visual acuities ≤ 0.5 logMAR, versus 95% LoA of -0.75;-0.25 for visual acuities > 0.5 logMAR).¹⁶ More importantly, the measurements of this specific digital tool were substantially more accurate when assessing *corrected* VA (in uveitis patients), compared to assessing *uncorrected* VA (in healthy individuals and keratoconus patients, with refractive errors).^{10,11,16} The digital self-assessments provide less accurate results for poorer VA ranges, regardless of underlying ocular comorbidities. Thus, wide 95% LoA do not necessarily imply inadequate testing conditions, or a low technical quality of the studied digital tools, but can be largely attributed to the poor vision of the tested population. A lower accuracy in poorer ranges is a common feature of VA assessments. A recurrent clinical reason is that the person administering the conventional test, might terminate the assessment too early. Especially the Snellen chart shows a poorer precision in lower VA ranges and the differences between Snellen and ETDRS increase in this range.²¹ This can be explained by the chart design. When testing Snellen acuity, the tester uses a line assignment method. The poor vision lines usually contain only 1 or 2 letters. Thus, missing a letter on these lines can make a huge difference in this range.⁵ In clinical practice, both time and convenience are essential, and therefore Snellen charts remain popular. We suggest that the accuracy of the digital VA self-assessments in poorer VA ranges could be improved by extending the initial assessment of individuals with poor scores for retesting (i.e. performing another assessment with different optotypes for internal validation and adjustment of the initial VA-score).

Two studies show a remarkable narrow 95% LoA: Ansell et al.²⁹ and Zhang et al.¹⁸ in the subgroup with VA better than 0.1 Snellen. These papers show a better agreement than well executed test-retest studies of VA wall charts, evaluated in controlled, experimental settings.

Future research should focus on the performance of the digital tools in unsupervised conditions. Some of the included studies reported specifically that tests were performed at fixed distances, for example with the head of the participant leaning against an ophthalmologic chin piece and the smartphone or chart fixed on a desk (Brucker et al.¹⁴) We expect the accuracy to be different in real-world, less controlled, conditions. We encourage stratifying for different VA ranges when evaluating agreement between VA charts. We strongly recommend using logMAR charts as reference charts as they are the most accurate and consistent. For follow-up purposes, good repeatability (test-retest reliability) of the tools is important. This creates excellent opportunities for follow-up and signaling worsening of vision, as obtaining baseline measurements will allow future vision comparisons. Only two of the included validation studies reported on repeatability.^{13,28}

Digital testing with mobile technology has many important advantages that outweigh accuracy. Traditional in-hospital VA testing requires patients to physically attend a clinic and consumes substantial hospital resources. The former might be particularly difficult for patients from rural areas, the elderly and immobilized patients. With the increasing digitization and availability of mobile devices, the digital tools have the potential to identify the most important cause of visual impairment worldwide: uncorrected refractive errors. Visual impairment has a negative impact on school performance, employability and quality of life in general. Strikingly, 53% of the visually impaired people have poor vision that can be prevented or remedied by glasses or contacts.³⁵ For screening of visual impairment, one is mostly interested in identifying a low VA range, rather than determining an exact value. When looking at the accuracy of the Peek Acuity tool (Bastawrous et al.²⁸) in the forest plot, the 95% LoA are wider than the previously discussed test-retest studies of traditional charts. Notwithstanding, the tool has been successfully implemented in school screening programs for identifying visual impairment. This has been investigated among various study populations around the globe.³⁶⁻³⁸ Sensitivity, specificity and predictive value varied among the studies, but included some promising results. A screening study in the USA illustrated how sensitivity differed per age category and found the highest sensitivity for detecting decreased vision in 3-5 years old (93-100%).³⁸ In a study in Kenya, the sensitivity (77%) was reported to be similar to the conventional screening method: standard E-card assessments by school teachers.³⁷ Importantly, when visual impairment was detected by the smartphone application, personalized SMS reminders to attend the hospital were sent to the children's parents or guardians, increasing adherence to hospital referral. Specificity of the digital screening was a bit lower compared to the conventional method (91% vs. 97%). The authors of the original article suggested testing strategies to reduce the false positive rate, including retesting the children who tested positive at first and a local triage service to review all children who initially screened positive.

Our systematic review indicates that the low rate of bias makes digital tools for self-assessment of VA a promising avenue for delivering eye care remotely. The precision of most tools seems lower than traditional VA charts, though these differences diminish when assessing individuals with better VA. There is a great potential of these self-assessments of visual function for screening purposes, particularly to increase access to eye care, acutely relevant in the current COVID-19 pandemic. The landscape of digital medicine has been rapidly changing, especially over the last years: we expect the accuracy of the current tools to improve with every iteration and new tools to be introduced in the upcoming years.

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SUPPLEMENTARY DATA

Search strategy Pubmed and Embase:

((online) AND (assessment) OR (web-based) AND (assessment) OR (digital) AND (assessment) OR (smartphone) AND (assessment) OR (online) AND (tool) OR (web-based) AND (tool) OR (digital) AND (tool) OR (smartphone) AND (tool) AND (online) AND (test) OR (web-based) AND (test) OR (digital) AND (test) OR (smartphone) AND (test)) AND (((((((refractive error) OR (visual field)) OR (visual acuity)) OR (color vision)) OR (refractive error[MeSH Terms])) OR (visual field[MeSH Terms])) OR (color vision[MeSH Terms])) OR (visual acuity[MeSH Terms]))



Chapter 3

Evaluating a web-based visual acuity self-assessment tool in adult ophthalmic patients

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The Accuracy of a Web-Based Visual Acuity Self-assessment Tool Performed Independently by Eye Care Patients at Home: Method Comparison Study.
JMIR Form Res. 2023 Jan 25;7:e41045. doi: 10.2196/41045.

ABSTRACT

Background: Telehealth solutions can play an important role in increasing access to eye care. Web-based eye tests can enable individuals to self-assess their visual function remotely without the assistance of an eye care professional. A web-based tool for self-assessing visual acuity (VA) has previously been studied in controlled, supervised conditions. The accuracy of this tool when performed independently by patients in their home environment, using their own devices, has not yet been examined.

Objective: The objective of this paper was to examine the accuracy of a web-based tool with respect to measuring VA in ophthalmic patients in their home environment, compared with a conventional in-hospital assessment using a Snellen chart (the gold standard).

Methods: From April through September 2020, consecutive adult patients with uveitis at the University Medical Center Utrecht, the Netherlands, performed the web-based VA test at home (the index test) before their upcoming conventional VA assessment at the hospital (the reference test). The agreement between the 2 tests was assessed by the Bland-Altman analysis. Additional analyses were performed to investigate associations between clinical characteristics and the accuracy of the web-based test.

Results: A total of 98 eyes in 59 patients were included in the study. The difference in VA between the index and reference tests was not significant, with a mean difference of 0.02 (SD 0.12) logMAR ($P=.09$) and 95% limits of agreement of -0.21 to 0.26 logMAR. The majority of the differences (77%) fell within the predetermined acceptable deviation limit of 0.15 logMAR. In addition, no patient characteristics or clinical parameters were found to significantly affect the accuracy of the web-based test.

Conclusions: This web-based test for measuring VA is a valid tool for remotely assessing VA, also when performed independently by patients at home. Implementation of validated web-based tools like this in the health care system may represent a valuable step forward in revolutionizing teleconsultations and can provide individual patients with the opportunity to self-monitor changes in VA. This is particularly relevant when the patient's access to ophthalmic care is limited. Future developments should focus on optimizing the testing conditions at home to reduce outliers.

INTRODUCTION

The sharp and sudden decrease in health care access during the COVID-19 pandemic underlined the importance of telehealth services for remote patient monitoring. But also in the postpandemic world, telehealth can play an important role in achieving universal health access.^{1,2} Considering eye care, web-based eye tests can enable individuals to self-assess their visual function remotely using their own electronic devices, without the assistance of an eye care professional. Several research teams around the globe have been evaluating and implementing a smartphone-based eye test in community- or school-based screening for visual impairment.³⁻⁸ But also in eye care practices, web-based eye tests are of great value, as they can enrich teleconsultations by providing eye care professionals and patients with a quantifiable measurement of visual function without a clinic visit.⁹

Visual acuity (VA) is the ability of the eye to correctly distinguish details of an object at a given distance.¹⁰ It is one of the key parameters of an ophthalmic (ie, eye care) patient's evaluation and is conventionally assessed at a clinic using a white chart displaying black optotypes—typically letters or symbols—that patients should correctly identify from a standardized distance.¹¹ Multiple tools for self-assessing VA have been introduced over the last decade, though many lack clinical validation.^{12,13} Before implementing a telehealth tool in clinical practice, validation research and certification is needed.¹⁴ The medtech company Easee B.V. (Amsterdam, the Netherlands) developed the world's first Conformité Européenne–certified web-based assessment of refractive error and VA, in collaboration with our clinical specialists (RW). The accuracy of this web-based test at assessing VA has been previously validated in controlled, supervised settings in healthy individuals 25 (SD 5) years of age¹⁵, and in a relatively young cohort of keratoconus (a disease affecting the structure of the eye's cornea) patients 26 (SD 5) years of age⁹, with robust results, particularly in the higher VA range. We hypothesize that this self-assessment of VA can serve as a reliable and feasible substitute for a conventional in-hospital assessment, including in older patients and patients with limited mobility. Nevertheless, the ability of this web-based test to provide reliable estimates of VA when performed by patients in unsupervised, in-home settings has not yet been examined. This study evaluates the accuracy of the web-based VA test when performed independently by ophthalmic patients at home.

METHODS

Ethical approval

This study was approved by the local medical ethics committee (METC Utrecht, the Netherlands; review number: 21-072) and performed in accordance with Dutch privacy laws and the Declaration of Helsinki. A study invitation letter, informed consent form, and return envelope were sent by mail. The letter contained comprehensive information about the study, including a statement that there was no (financial) compensation for, or benefits related to, participation. Contact details of the research team were given to discuss any questions or concerns. Written informed consent was obtained from all participants in this study: patients were instructed to sign the informed consent form and send it using the provided return envelope when willing to participate. All study data were coded and stored in a database only accessible to the research team. Data collected by Easee B.V. were stored on General Data Protection Regulation-compliant and Health Insurance Portability and Accountability Act-compliant servers located within the European Union. This paper was written in adherence to the STARD 2015 guidelines for reporting diagnostic accuracy studies.¹⁶

Study design and patient recruitment

This method comparison study was conducted at the University Medical Center Utrecht, the Netherlands, from April through September 2020. In this period, many nonurgent outpatient visits were either rescheduled or postponed. We therefore focused on recruiting patients with uveitis (an inflammatory eye condition), as their outpatient visits were considered essential and not likely to be canceled. In addition, a large number of these patients previously provided consent to be approached for participation in future research.

All consecutive adult patients scheduled to visit our uveitis clinic were invited. Those who were willing to participate were requested to perform the web-based test at home before their hospital visit. We instructed patients to reperform the web-based test, or reach out to the study team, whenever they experienced a change in VA before their hospital visit. For this study, we excluded patients who did not perform an in-hospital test within 14 days of completing their web-based test and patients who changed their glasses or contact lens prescription or who reported a change in their VA between the web-based and in-hospital tests without repeating the web-based eye test.

Web-based VA assessment (index test) and conventional VA assessment (reference test)

Patients were instructed to perform the web-based test in their home 1 to 14 days before their hospital visit. This test is accessible via a dedicated URL via the institution's patient portal, and users must have a computer or tablet, a smartphone, and an internet connection to perform the test. In brief, the smartphone serves as a remote control through which the users submit their input a distance of 3 m from the computer or tablet screen (Figure 1). Audio instructions guide them through the test. During the test, the computer or tablet screen displays a sequence of optotypes—varying in size—that the patients must correctly identify (Figure 2). A calibration step in the setup phase of the tool reassures that the displayed optotypes are correctly sized, regardless of the screen dimensions of the patient's own device. The VA score will be determined based on the answers provided by the user.

Before the test starts, one can manually select which eye to measure. Users will be requested to cover the contralateral eye with their hand during the assessment. All participants were instructed to complete the web-based eye test once for each eye and wear their standard spectacles or contact lenses for distance vision, if applicable, while performing the assessment. If the web-based test was performed multiple times, we collected the most recent outcomes only.

Conventional VA measurements were performed during the hospital visit by an eye care professional using a Snellen chart at 6 m (the standardized distance for this chart). During this assessment, the patients also wore their standard spectacles or contact lenses, if applicable, and the clinical staff were blinded with respect to the outcomes of the patient's previously performed web-based test.

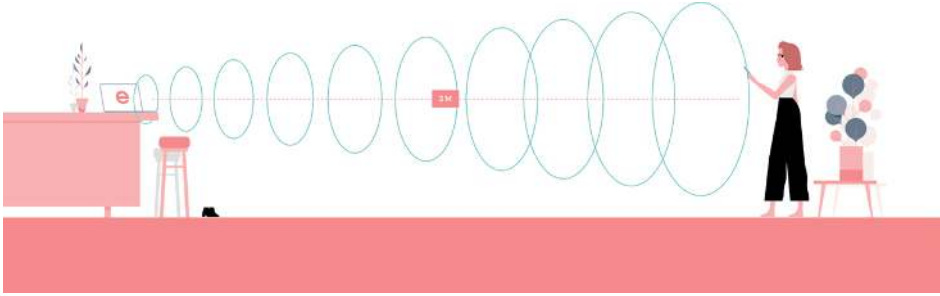


Figure 1. Schematic diagram depicting the web-based test (not to scale). During the test, the patient is instructed to stand 3 m away from the screen and use the smartphone to control the test.

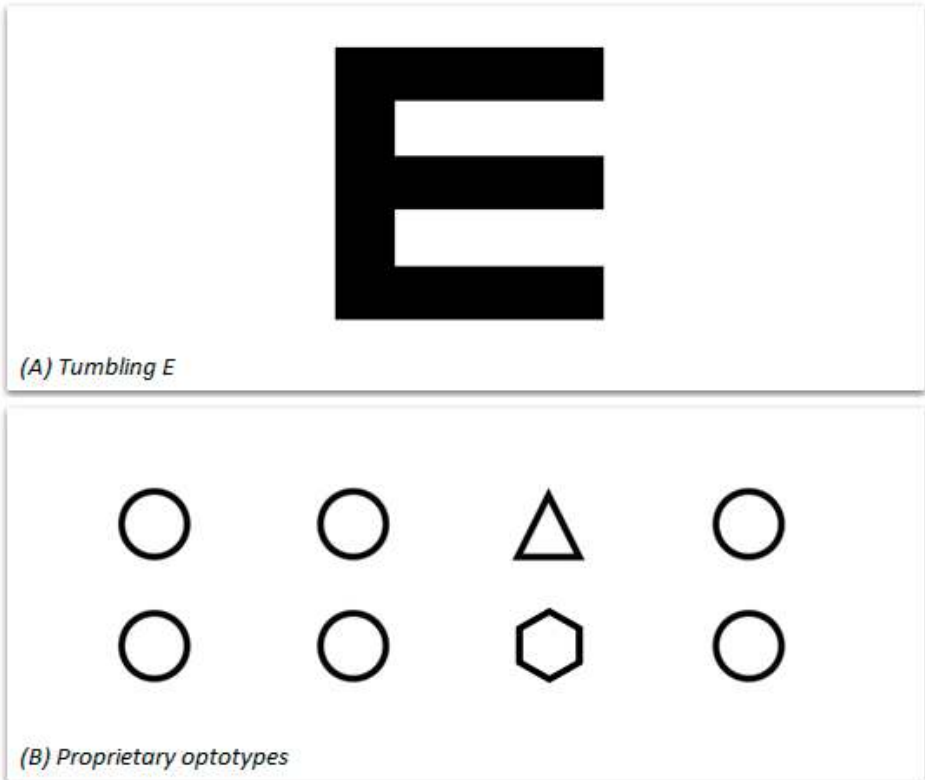


Figure 2. Different optotypes presented on the computer or tablet screen during the test. (A) Four kinds of rotations of this optotype will be displayed on the smartphone screen. The patient will be asked to select the one that is identical to the optotype presented on the computer or tablet screen. (B) A row of 4 numbers (1-4) will be displayed on the smartphone screen. The patient will be asked which of the 4 optotypes presented on the computer or tablet screen is different.

Data collection

The outcomes of the web-based test were collected by Easee B.V., the developer of the test. The following clinical data were collected from the patient's electronic health record: sex, age, ophthalmic diagnosis, medical history, use of medication, and VA measurements; in addition, because we included patients with uveitis, we also collected their uveitis classification and symptoms associated with active uveitis. All ophthalmologists at our ophthalmology clinic use the Standardization of Uveitis Nomenclature (SUN) classification criteria.¹⁷ Specifically, uveitis disease activity was classified based on vitreous haze (VH), anterior chamber cell count (ACC), optical coherence tomography, and fluorescent angiography and dichotomized as "inactive" (both ACC and VH ≤ 0.5 and not considered active by a specialist) or "active" (ACC > 0.5 , VH > 0.5 , or considered active by a specialist).

Statistical analysis

Our main outcome was the accuracy of the web-based test for measuring VA, compared with the conventional in-hospital VA assessment performed within 14 days. The patient's web-based VA was reported in logarithm of the minimum angle of resolution (logMAR) units, and the in-hospital Snellen decimal score was converted to logMAR units. Measurement accuracy is expressed as the mean difference between the 2 assessments, with 95% limits of agreement (95% LoA; ie, the range within 95% of the differences between the 2 assessments is included). This methodology was first introduced by Bland and Altman and is commonly used to evaluate the agreement between 2 measurements on a continuous scale.¹⁸ Varying outcomes are common when repeatedly performing a VA test in an individual patient.¹⁹⁻²¹ In line with an authoritative cross-sectional study performed in a large eye clinic using various charts and observers, we considered an absolute difference between tests > 0.15 logMAR to be clinically relevant.¹⁹

The minimum VA score that can be measured using the web-based test is 0.05 Snellen decimal (1.3 logMAR); thus, scores lower than this value are reported as " < 0.05 Snellen decimal (> 1.3 logMAR)." Because the exact VA in these patients was unknown, patients with a VA score > 1.3 logMAR were not included in the Bland-Altman analysis but were descriptively analyzed as a subgroup.

We also performed a subgroup analysis to investigate the possible association between clinical characteristics and agreement between the index and reference test outcomes. Specifically, we analyzed patients with an absolute difference > 0.15 logMAR (ie, "under-performance" of the web-based test) versus patients with an absolute difference ≤ 0.15 logMAR (ie, "good performance" of the web-based test). Differences between these groups were analyzed using the chi-square test or independent-sample Student's *t* test.

A multivariable generalized estimating equation (GEE) model was used to assess the association between clinical variables and the VA outcome of both tests. The GEE model was designed to correct for bilateral disease, age, sex, use of a mydriatic agent, ocular comorbidity that can affect VA, symptoms associated with uveitis activity, and the interval (in days) between the index and reference tests.

RESULTS

Included patients

A total of 59 patients met all of the inclusion criteria. Our analysis included 98 eyes (20 patients performed the web-based assessment for only 1 eye). Patient recruitment is depicted in Supplementary Figure 1, and a participation bias toward younger patients is appreciated (mean age of patients not willing to participate vs included patients: 53, SD 19 vs 47, SD 15 years). The clinical characteristics of the study population are summarized in Tables 1 and 2. Consistent with our overall uveitis population, approximately two-thirds (68%) of the participants were female. The mean interval between the index test and the reference test was 4.8 (SD 2.7) days. At the time of their visit to our ophthalmology clinic, 27% of eyes had symptoms of potentially active uveitis, including ocular pain, floaters, photophobia, and vision loss. On the basis of the SUN classification,¹⁷ 73% of patients had nonanterior uveitis and 97% had a chronic disease course. At the time of their visit, 25% of eyes were classified as having “active inflammation” of uveitis, whereas the other 75% were classified as “inactive.”

Table 1. Clinical characteristics of the study population (patients: N=59)

Clinical characteristics		Values
Age (years), mean (SD)		47 (15)
Sex, n (%)	Male	19 (32)
	Female	40 (68)
Interval between tests (days), mean (SD)		4.8 (2.7)
Ophthalmic medication ^a , n (%)	Mydriatics	4 (7)
	Other	45 (76)
Uni- or bilateral uveitis, n (%)	Unilateral	16 (27)
	Bilateral	43 (73)
Anatomical classification ^b , n (%)	Anterior	16 (27)
	Non-anterior	43 (73)
Uveitis course ^b , n (%)	Acute	2 (3)
	Chronic	57 (97)

^a Use of ophthalmic medication at the time of the in-hospital appointment.

^b According to the Standardization of Uveitis Nomenclature classification.¹⁷

Table 2. Uveitis characteristics of the study population

Uveitis characteristics (per eye)	Eyes (N=98), n (%)	
Activity of uveitis	Inactive ^a	73 (75)
	Active ^b	24 (25)
	Not known	1 (1)
Visual acuity influencing comorbidities, at time of appointment ^c	30 (31)	
Anamnestic symptoms of active uveitis ^d	26 (27)	

^a When anterior chamber cell count (ACC) and vitreous haze (VH) is ≤ 0.5 and not called active by the ophthalmologist.

^b When ACC or VH is ≥ 1 or called active by the ophthalmologist.

^c Including (secondary) cataract, keratitis, scleritis, corneal lesion, or history of pars plana vitrectomy.

^d Symptoms associated with active uveitis: ocular pain, floaters, photophobia, and visual loss.

Accuracy of the web-based VA test

The mean VA measured using the web-based test was 0.12 (SD 0.25) logMAR (0.86, SD 0.37 Snellen decimal), which was similar to the conventional in-clinic assessment (0.10, SD 0.25 logMAR; 0.89, SD 0.32 Snellen decimal; mean difference: 0.02, SD 0.12 logMAR, $P=.09$). The Bland-Altman plot (Figure 3A) summarizes the difference between the 2 tests for 91 eyes with a web-based VA of ≥ 0.05 Snellen decimal. The 95% LoA ranged from -0.21 to 0.26 logMAR, with no indication of a proportional bias. Overall, 70 of these 91 eyes (77%) fell within the predetermined acceptable deviation limit of ± 0.15 logMAR. As shown in Figure 3B, a distribution histogram of the difference between VA values reveals that the peak difference was close to zero (ie, virtually no difference between test results). We found similar results when we performed a Bland-Altman analysis on the left eyes only (mean difference 0.01, SD 0.13 logMAR; 95% LoA -0.23 to 0.26 logMAR) and on the right eyes only (mean difference 0.03, SD 0.11 logMAR; 95% LoA -0.19 to 0.25). Finally, an indication of the reliability of the web-based test is found in the concordance of 2 separate measurements within the same individual: subjects who performed the web-based test for both eyes ($n=39$ patients) showed a similar accuracy for both separate monocular measurements.

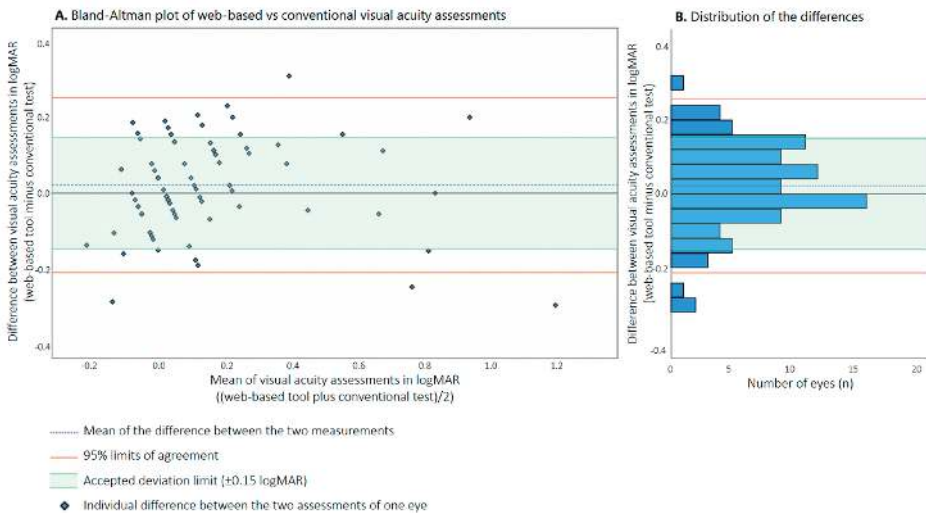


Figure 3. (A) Bland-Altman plot comparing the results of the web-based VA test and the results of the conventional VA test. Each symbol indicates an individual eye. (B) Distribution histogram summarizing the data shown in panel A.

| logMAR: logarithm of the minimum angle of resolution; VA: visual acuity |

Subgroup analysis of patients with a poor web-based VA score

Seven eyes had a VA score below the minimum detectable limit of the web-based test (ie, <0.05 Snellen decimal). For 6 of these eyes, however, VA was indeed measured correctly using the web-based test, as the corresponding VA measured using the conventional reference test was also <0.05 Snellen decimal. Remarkably, one eye with a VA score <0.05 Snellen decimal based on the index test was found to have a VA of 0.4 Snellen decimal based on the conventional test; upon inquiry, however, the patients reported that the web-based test was difficult to perform, indicating that the VA measured using the web-based test likely did not represent their actual VA.

Subgroup analysis of good performance versus underperformance on the Web-based test

The results of our subgroup analysis comparing eyes in which the web-based test had good performance (n=70 eyes) and eyes in which the web-based test underperformed (n=21) are shown in Table 3. We found no significant difference between subgroups with respect to any of the clinical characteristics analyzed.

Table 3. Subgroup analysis of “good performance” vs “underperformance” of the web-based test

Characteristics		Overall	logMAR ^a difference ≤0.15 'good performance'	logMAR ^a difference >0.15 'underperformance'	P-value
Number of eyes		91	70	21	N.A. ^b
Age, mean (SD)		45 (15)	44 (15)	48 (15)	.24
Sex	Male	31 (34)	23 (33)	8 (38)	.66
	Female	60 (66)	47 (67)	13 (62)	
Interval between tests (days), mean (SD)		4.6 (2.6)	4.6 (2.8)	4.7 (2.0)	.89
Visual acuity influencing comorbidities ^c		26 (29)	17 (24)	9 (43)	.10
Anamnestic symptoms at time of appointment ^d		23 (25)	17 (24)	6 (29)	.69
Ophthalmic medication use	Mydriatic	7 (8)	6 (9)	1 (5)	.53
	Other	69 (76)	54 (77)	15 (71)	
	None	15 (17)	10 (14)	5 (24)	
Uveitis anatomical classification ^e	Anterior	27 (30)	24 (34)	3 (14)	.08
	Non- anterior	64 (70)	46 (66)	18 (86)	
Uveitis course	Acute	2 (2)	2 (3%)	0 (0)	.43
	Chronic	89 (98)	68 (97)	21 (100)	
Activity of uveitis at time of appointment	Inactive ^f	68 (75)	50 (71)	18 (86)	.19
	Active ^g	23 (25)	20 (29)	3 (14)	

^a logMAR: logarithm of the minimum angle of resolution.

^b N/A: not applicable.

^c Including (secondary) cataract, keratitis, scleritis or corneal lesions at time of appointment, or history of pars plana vitrectomy.

^d Symptoms associated with uveitis: ocular pain, floaters, sensitivity to light, and visual loss.

^e According to the Standardization of Uveitis Nomenclature classification.¹⁷

^f When anterior chamber cell count (ACC) and vitreous haze (VH) ≤0.5 and not called active by the ophthalmologist.

^g When ACC or VH is ≥1 or called active by the ophthalmologist.

Generalized estimating equation analysis

The GEE analysis revealed no significant association between VA and any of the clinical variables examined (Supplementary Table 1). Specifically, we found no clinical factors—uveitis-related or otherwise—that appeared to affect VA measured using both tests or either test individually.

DISCUSSION

Principal findings

In this study, we examined the accuracy of a web-based tool for self-assessing VA when performed remotely by ophthalmic patients. Our results indicate that ophthalmic patients can use this web-based tool to estimate VA independently in their own home, which is particularly advantageous when access to the clinic is limited. We found a clinically negligible mean difference of 0.02 (SD 0.12) logMAR between the web-based test results and in-hospital chart assessments, and the majority of the comparisons (77%) fell within the conventional and predetermined acceptable deviation limit of 0.15 logMAR.¹⁹ 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 distribution of the differences (indicated by the 95% LoA) slightly exceeded the predetermined acceptable limit, pointing out that some of the patients had a larger difference between the 2 assessments than expected based on normal measurement variation. Subgroup analyses did not identify clinical characteristics that affected agreement between the 2 tests.

For this study, we focused on patients with uveitis. Importantly, however, tools for measuring VA are considered to be universally applicable, regardless of any underlying ocular conditions. It is therefore reasonable to speculate that the web-based tool's accuracy observed in patients with uveitis will be similar when used by similar-aged (ie, similarly digitally proficient) and similarly visually proficient patients with other ocular conditions.

When comparing between different tests of VA, 2 important phenomena should be taken into account. First, a certain degree of variability is inevitable when repeatedly measuring VA in the same eye, even in the absence of any clinical changes between tests, due to the psychophysical nature of VA testing. Outlier measurements occur even in controlled in-hospital settings, owing to patients' behavioral factors such as concentration, fatigue, and a low intrinsic motivation. Studies that focused on test-retest variability using Snellen VA charts reported that 95% LoA ranged from ± 0.18 logMAR (using the single-letter method) to ± 0.33 logMAR (using the line assignment method) from the mean difference.^{20,22} The line assignment method (in which the test is terminated when at last half of the letters are misread) remains the most popular method in clinical practice, despite the introduction of more reliable alternatives such as the Early Treatment Diabetic Retinopathy Study (ETDRS) chart.^{21,23,24} Based on the 95% LoA values (± 0.24 logMAR from the mean difference), the precision of the remote web-based test used in our study appears to be fairly similar to the precision of conventional VA testing using Snellen charts. Secondly, differences in VA are inevitable when using 2

different types of VA charts.^{19,25,26} In the web-based test, patients were presented with a combination of tumbling E optotypes and proprietary optotypes (Figure 2), whereas for the conventional examination, a Snellen letter chart was used. Thus, a conversion effect may have contributed—at least in part—to the observed differences in VA between the web-based test and the conventional test.

Comparison with prior work

We previously examined the accuracy of the web-based VA test in healthy individuals and in patients with keratoconus.^{9,15} Compared with our previous results, the distribution of differences in VA was smaller. We attribute this to measuring corrected (better) VA in this study, whereas our previous studies measured uncorrected (poorer) VA. Measurement accuracy is known to be suboptimal in these poorer VA ranges, particularly when using a Snellen chart.²¹ Interestingly, this was the first time the web-based tool was used by patients in a completely unsupervised situation, namely the patient's own home in which lighting and test conditions were controlled exclusively by the patient. We believe that this greatly increases the generalizability of the outcomes of our study. Notably, the fact that the test was unsupervised did not appear to affect its overall accuracy.

There are many other telehealth tools for self-assessing visual function available in app stores or on the World Wide Web, though many of these have not been validated.^{12,13} A well-established tool is the “Peek Acuity” smartphone app, which was first introduced by Bastawrous et al in 2015.²⁵ This tool has been evaluated by various research teams.^{3–6,27} In a recent validation study, conducted among hospital employees, a mean difference of 0.01 logMAR (95% LoA: –0.27 to 0.29 logMAR) was reported when compared with a conventional clinical chart. Another application that has been evaluated multiple times is the “EyeChart” app.^{28,29} Tiraset et al evaluated the “EyeChart” application in ophthalmic patients and reported similar results (mean difference: 0.01 logMAR; 95% LoA: –0.21 to 0.19 logMAR) as our study.²⁹ Overall, our findings with respect to the web-based tool developed by Easee are similar to the mean differences and 95% LoA observed using these other VA self-assessment tools. Importantly, note that these other tools were evaluated in controlled settings. In addition, these tools require a person to hold the smartphone or tablet (presenting the optotypes) and submit answers on the touch screen, while the patient stands at a distance from this screen. The present study focuses on the self-administration of a web-based VA test at home. The Easee eye test is highly intuitive, and a paired smartphone is used as a remote control, negating the need for assistance.

Future perspectives

Our results indicate that an unsupervised, remote web-based VA test can serve as a validated option for measuring VA in ophthalmic patients who are both willing and

able to perform the self-test, including patients with a complex ocular disease such as uveitis. Hence, the web-based test can enrich teleconsultations in ophthalmic care and create opportunities for patients with a chronic condition to self-assess their VA at home when they suspect that their visual function might be deteriorating. We learned from our clinic's patient board that patients consider this form of self-control to be important. We do not claim that this web-based tool can fully replace a comprehensive ophthalmic examination, nor do we claim that it by itself is sufficient for adequately following all ophthalmic patients. Based on our subgroup analyses, it is not possible to use clinical parameters to preselect patients for whom the web-based test is considered unsuitable.

It is important to note that some of the included patients performed poorly on the web-based test. We did not identify clinical factors, such as uveitis activity, that affect measurement accuracy. Interestingly, we found that most patients performed the web-based test with equal reliability for both eyes. It is therefore reasonable to speculate that the test's performance is affected the most by behavioral factors such as the patient's competence using digital devices, their intrinsic motivation, and the environmental conditions when performing the test such as lighting and setup. Given these factors, we strongly recommend introducing telehealth tools for self-assessing visual function on an individual level and in close consultation with the patient. Adequate patient instructions (and compliance with these instructions) are essential to the tool's success, especially in unsupervised settings. The web-based test flow is highly intuitive, though future changes to the tool should focus on optimizing the testing conditions at home, for example, by using the webcam to provide feedback regarding lighting conditions and the patient's distance from the screen. Still, outlier measurements might occur, as these also occur in in-hospital settings using conventional charts. We propose that whenever web-based test outcomes are suspected to be invalid, patients should be instructed to retest under optimal testing conditions. This is not different from what we would do in an in-hospital setting using conventional charts.

Limitations

Several considerations warrant further discussion. First, we included only patients who were willing and able to perform the web-based eye test at home. As the participation flow demonstrates (Supplementary Figure 1), this study design resulted in a participation bias in favor of younger patients, who are potentially more comfortable using digital devices. The accuracy of the web-based test may be poorer in patients who are less competent or comfortable using digital devices, as tests may be performed incorrectly. However, it is important to note that successful completion of the web-based test does not necessarily indicate adequate performance. In our study, we included poorly performing patients in our analyses, as information regarding outliers is important for

interpreting the web-based test's accuracy and identifying patient characteristics that may be correlated with poor performance. Notwithstanding, we strongly recommend that future studies evaluate the performance of the web-based tool in older, less digitally competent patient populations. Second, all patients were first-time users of the web-based test. We recommend future studies to determine whether directions of variations within patients are similar when repeating web-based self-assessments at different time points. It is important to understand the test-retest variability of the web-based test and to identify whether learning effects can be appreciated, indicated by a better accuracy when repeatedly performing the test.

Conclusions

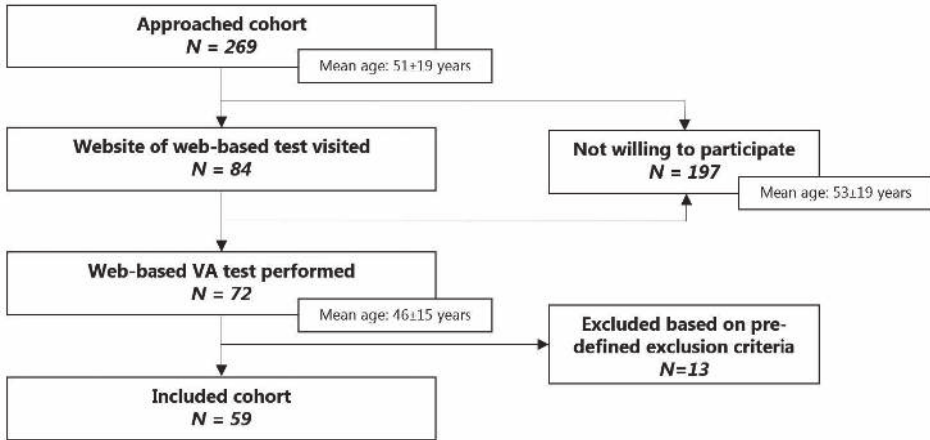
In summary, we report that the web-based VA test, performed unsupervised and independently at home, provided a reliable measure of VA in the majority of patients in our study. The in-home assessment appears a feasible substitute for a conventional Snellen chart assessment at the clinic. Implementing this web-based test into the health care system enriches teleconsultations by providing patients with the tools they need for self-monitoring, which is particularly valuable when access to hospital care is limited. We found no clinical characteristics that significantly affected the accuracy of the web-based test. Outliers beyond the clinically acceptable range of -0.15 to $+0.15$ logMAR were identified, which we consider a common feature of VA testing and attributed to behavioral and environmental factors. Future developments of the web-based test should focus on optimizing testing conditions at home to reduce the potential effects of these factors.

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SUPPLEMENTARY DATA



Supplementary Figure 1. Flowchart showing patient recruitment, including the mean (\pm SD) ages of the indicated groups. A total of 269 patients were invited to participate. Of the 84 patients who visited the website, 72 successfully completed the test (reasons for not completing the test included the requirement to create an account on the company's website in order to collect and store the data). Note that the 72 patients who performed the test successfully were significantly younger than the 197 patients who were not willing to participate ($p=0.005$).

Supplementary Table 1. Multivariable GEE analysis to investigate the associations between clinical variables and the visual acuity outcomes in logMAR

Characteristics	Difference between the VA scores of the web-based and conventional test, in logMAR ^a		VA score of the web-based assessment, in logMAR		VA score of the conventional test, in logMAR	
	B	95% confidence interval	P-value ^b	B	95% confidence interval	P-value ^b
Sex ^c	0.02	-0.01 to 0.06	0.65	-0.04	-0.14 to 0.07	0.49
Age	0.00	0.00 to 0.00	0.87	0.00	-0.00 to 0.01	0.13
Use of mydriatics	-0.03	-0.10 to 0.04	0.41	0.15	-0.20 to 0.49	0.41
Visual acuity influencing comorbidities ^d	0.01	-0.02 to 0.05	0.70	0.06	-0.07 to 0.18	0.39
Symptoms at time of appointment ^e	0.02	-0.03 to 0.10	0.28	0.10	-0.02 to 0.21	0.11
Interval ^f	0.00	-0.00 to 0.01	0.37	0.00	-0.02 to 0.02	0.81
				0.00	-0.01 to 0.02	0.00

B: beta value; VA = visual acuity

^a absolute difference between the two VA assessments in logMAR

^b analyzed using a Generalized Estimating Equations to correct for inclusion of two eyes of one patient

^c female as reference

^d visual acuity influencing comorbidities such as: (secondary) cataract, keratitis, scleritis, corneal lesion or history of pars plana vitrectomy

^e symptoms associated with active uveitis at time of the hospital consultation; pain, floaters, photophobia, visual loss

^f interval in days between the web-based assessment and conventional assessment



Chapter 4

Evaluating a web-based visual acuity and refractive error self-assessment tool in myopic children

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ABSTRACT

Introduction: Demands for myopia management are rising. A web-based tool that allows home-performed self-assessments of visual acuity (VA) and refractive error may enable hybrid care pathways and aid in identifying those with deteriorating visual performance. The tool has been validated in adult populations, but has yet to be evaluated in children. This study compares home-performed VA and refraction self-assessments to conventional measurements obtained at the clinic in a population of myopic children.

Methods: Myopic children aged ≥ 6 years old were invited to perform web-based eye tests at home, assisted by a parent. At two myopia control clinics, they also underwent measurements of VA using a Snellen chart, and refractive error using cycloplegic autorefraction. Agreement between the tests, repeatability of the web-based test, and associations between clinical characteristics and web-based test accuracy were evaluated.

Results: A total of 116 children (51% male; mean age 13 ± 3 years; mean spherical equivalent refraction (SEQ) -5.58 ± 3.05) performed the web-based tests at home. Overall, the home-performed VA self-assessment and the Snellen chart assessment at the clinic agreed equally (mean difference 0.03 ± 0.11 logMAR). A significant proportional bias was identified, indicating underestimated web-based VA scores when the child's vision declined (β 0.65, $P < 0.001$). The sensitivity to detect VA poorer than 0.1 logMAR was 94% (sensitivity); the specificity was 71%. The web-based refractive error algorithm measured more myopia progression than what was observed at the clinic (mean difference SEQ 0.40 ± 0.51 dioptres). Age, sex or use of atropine drops were not significantly associated with test accuracy.

Conclusions: The web-based test for self-assessing vision, performed at home by children in assistance of their parent, yielded VA scores with a precision similar to Snellen chart testing conducted in a clinical setting. However, the web-based refractive error algorithm overestimated myopia progression and requires a recalibration for this specific age group.

INTRODUCTION

The prevalence of myopia has been increasing globally at an alarming rate. In East Asia, the rise of myopia has been unprecedented. Sixty years ago, 10-20% of the Chinese population was myopic, whereas 90% of today's teenagers are.¹ Other parts of the world also see tremendous increases; in both the United States and Europe the prevalence of myopia doubled over half a century, with now half of all young adults being myopic.¹ This increasing prevalence puts an escalating number of children at risk of developing high myopia (defined by a spherical equivalent (SEQ) of -6 dioptres (D) or more and an axial length >26 mm).² This carries significant clinical and economic implications, mainly due to the burden of the associated sight-threatening complications such as retinal damage, cataract and glaucoma.³ Important risk factors for high myopia include an early age of onset and long duration of the myopia progression.⁴⁻⁶ Early detection and initiation of interventions to decelerate its progression during childhood and adolescence are considered imperative to prevent irreversible complications later in life.^{7,8}

Due to the increasing prevalence, demands for myopia management are ever-increasing. Innovative solutions are necessary to comply with these increasing demands, in a health landscape dictated with limited resources and shortage of qualified staff. Web-based self-assessments performed at home have the potential to optimize staff time and increase productivity as a greater volume of patients can be managed with similar resources.⁹ Over the past decade, several E-health tools for self-assessing visual function have been introduced.¹⁰ Empowering children to perform self-assessments in the comfort of their home under parental supervision, could yield valuable insights into the child's vision without requiring the presence of an eye care professional nor a time-consuming visit to the clinic. A reliable self-assessment tool could play a crucial role in patient prioritization by identifying the myopic children with rapidly deteriorating vision who require urgent clinical attention. Another important advantage of this approach is its potential to revolutionize teleconsultations, thereby alleviating the burden of clinic visits for both children and their families.

The tool investigated in this study is the first CE-marked e-health tool for self-assessing both visual acuity (VA) and refractive error. Previous validation research of this tool has been limited to adult populations.¹¹⁻¹⁴ The aim of this study is to evaluate the performance of a remote web-based eye test for self-assessing VA and refractive error in myopic children at home.

METHODS

Study design

This study was performed at the Erasmus Medical Center Rotterdam and the Radboud UMC Nijmegen, both located in the Netherlands. The Medical Ethics Review Committee Erasmus MC approved the study (MEC-2021-0816). Written informed consent was obtained from all participating children and, if aged <16 years old, from their parent(s) or guardian(s).

Myopic children aged 6 to 18 years old scheduled at the myopia control clinic between January 27 2022, and June 30 2023 were invited to participate in this study. Children with ocular comorbidities (such as congenital retinal disorders or amblyopia) were excluded from participation. An internet connection and access to a smartphone and a computer or tablet were required in order to perform the web-based test at home. No other exclusion criteria were applied.

At the clinic, a standardized ophthalmological examination was performed at baseline. Presenting VA was assessed by a Snellen chart at 6 meters distance, while children wore their current glasses or contacts. Refractive error was measured by a Topcon autorefractor (KR8900), after two drops of cyclopentolate 1% with 5 min interval and a minimum waiting time of 45 min after the first drop. In case of atropine 0.5 and 1% interventions, cycloplegia was considered already present. Informed consent was recorded during this clinic visit and a personalized link to access the studied web-based test was then sent via e-mail, with instructions to perform this test one day later at home. Participants enrolled after September 1 2022 were also invited to perform a *second* exam 5 days after their first home test, allowing to assess repeatability. Although the web-based assessment can be performed individually, all participants in this study were instructed to be assisted by their parent or another adult relative.

The web-based test for self-assessing VA and refractive error at home was developed by *Easee BV* (Amsterdam, the Netherlands). *Easee* employed an ISO 13485 Quality Measurement System and the tool was classified as *Conformité Européenne* (CE) class 2A medical device according to the Medical Device Regulation 2017/745.¹⁵ The tool was accessed via a website on a tablet or computer. A smartphone was connected by scanning a QR-code or by entering a code sent by SMS. Participants were instructed to stand or sit at 3 meters from the computer or tablet screen and cover one eye. The smartphone functioned as a remote control for submitting answers to questions regarding the optotypes and astigmatic dials that were presented on the computer or tablet screen. A calibration

step reassured that the optotypes were correctly sized, regardless of the device screen dimensions. Figure 1 depicts the optotypes and astigmatic dials used in the test.

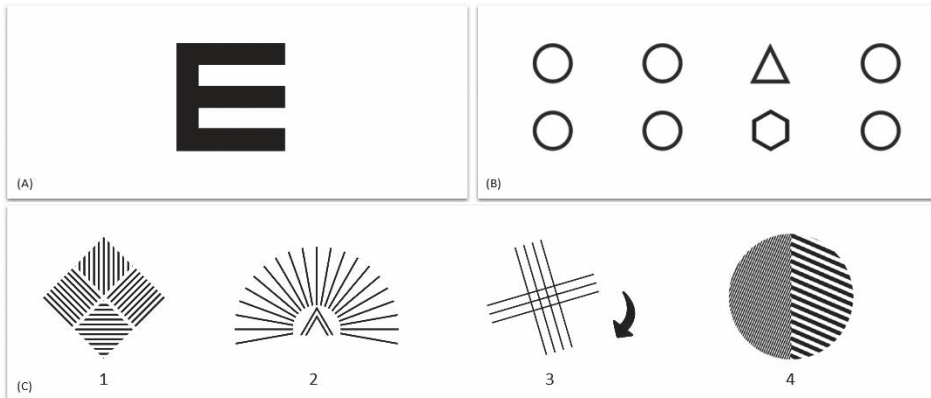


Figure 1. Optotypes and astigmatic dials presented on the computer or tablet screen. [A] Tumbling E. [B] Two variations of proprietary optotypes: triangles and hexagons (users are asked to select which of the 4 symbols is different). [C] Astigmatic dials to detect astigmatism (1), and to determine the cylindrical axis (2+3) and power (4).

Similar to the VA assessment at the clinic, the web-based test at home was performed while wearing their current existing glasses or contacts, effectively assessing the habitual or presenting VA. For clarity, VA thus refers to *presenting VA*. The web-based VA assessment consists of three parts, each with a different optotype (Tumbling E's, triangles and hexagons, see Figure 1A and 1B). The recorded VA was based on the average of the scores of the three scores for each optotype. If two of the three individual scores differed more than 0.2 logMAR, the within-test variation was considered unacceptable and these cases were analyzed separately. The web-based algorithm transposes VA into a power error (SEQ), and combined with the proprietary cylinder test (Figure 1C), it induces a spherical power and a cylindrical power. Noteworthy, it assumes any VA poorer than -0.1 logMAR (i.e. 1.25 Snellen decimal) to be caused by a refractive error. The refractive error was measured while wearing one's glasses or contacts, thus effectively performing an over-refraction. In this study – whilst performing over-refraction in a myopic population without vision impacting comorbidities - we considered the web-based refractive error outcomes a proxy of myopia progression. For clarity, when referring to myopia progression assessed at home, this is derived from the *over-refraction outcomes* as assessed with the web-based test. The true myopia progression was calculated by subtracting the current prescription from the cycloplegic autorefraction: *myopia progression at the clinic* = SEQ cycloplegic autorefraction – SEQ current prescription.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows version 29.0 (Armonk, NY, USA). Snellen decimal scores of clinic VA assessments were converted to logMAR using a standardized formula.^{16,17} Refractive error outcomes were converted to spherical equivalent (SEQ).¹⁸ To ease interpretability of the comparisons, both myopic progression outcomes (SEQ) were converted to absolute values and presented as such. Web-based assessments were compared to conventional assessments by paired t-tests and visualized by Bland-Altman plots, the gold standard for method comparison studies.¹⁹ Mean differences can be interpreted as the systematic difference between the assessments (i.e. bias) and the 95% limits of agreement (95%LoA) as the range within 95% of the differences are distributed (i.e. random error). Linear regression was performed to determine the existence of proportional bias (i.e. the methods do not agree equally through the range of measurements). Repeatability and learning effects were analyzed by paired t-tests. A multivariable generalized estimating equation (GEE) model correcting for bilaterality was used to assess the association between baseline characteristics and the outcome of both tests. For all analyses, a $P < .05$ was considered statistically significant.

The sample size calculation was based on the evaluation of the accuracy of the refractive error assessment, and determined as described by Lu et. al in 2016.²⁰ We assumed no difference between the two assessments, an accepted difference of 0.5 D, and a standard deviation(SD) of 0.2 D (based on repeatability of autorefractor assessments²¹). With an alpha of 0.05 and a power of 80%, 109 paired observations were required.

RESULTS

Informed consent was obtained from 147 patients (and their parents), of whom 116 performed the web-based test. The 116 responders were slightly younger than the 31 non-responders (13.0 vs. 14.3 years respectively, $P=0.03$). No differences in other baseline characteristics were identified. All exams were completed and no technical errors were noted.

The baseline characteristics of the 116 participants who completed the web-based test are presented in Table 1.

Table 1. Baseline characteristics of study participants who completed web-based test (n=116 patients)

Clinical characteristics		Values
Age (years), mean (SD)		12.9 (2.9)
Sex, n (%)		
- Male		59 (50.9)
- Female		57 (49.1)
Spherical equivalent refraction (dioptres), mean (SD) ^a		-5.58 (3.05)
Presenting visual acuity at the clinic (logMAR), mean (SD)		0.04 (0.11)
Current eye wear, n (%)	Glasses	58 (50.0)
	Contact lenses	54 (46.6)
	Unaided ^b	4 (3.5)
Atropine use, n (%)		
- High dose atropine		70 (6.0)
- Low dose atropine		30 (25.8)
- No atropine (i.e. other myopia control intervention)		16 (13.8)
Axial length (mm), mean (SD)		25.73 (1.29)

^a Based on current prescription at baseline

^b Three patients wore Ortho-K and one patient refused wearing glasses or contacts

Assessment of visual acuity (VA)

As previously mentioned, the web-based VA assessment consists of 3 separate VA tests per eye (Figures 1A and B). For 34 monocular assessments (of 31 patients) the within-test variation between the 3 separate tests was considered unacceptable (i.e. scores differed > 0.2 logMAR), and these cases are reported separately.

The comparison between the web-based VA assessment and conventional VA assessment of the remaining 198 monocular assessments showed a mean difference of 0.03 logMAR (SD 0.11), with 95%LoA ranging from -0.18 to 0.25 logMAR. These outcomes are visually represented in Figure 2A and 2B. A significant proportional bias was identified, with underestimated web-based VA scores when the child's vision declined (β 0.65, $P < 0.001$).

Similar distributions of differences were found when comparing the left or right eyes only. Participants performed the web-based test with equal accuracy for both eyes, with insignificant differences between the agreement of the right and left eyes (mean difference 0.02 logMAR, $P = 0.062$).

Of the 60 consecutive participants included after September 1st 2022, 40 performed the second assessment (i.e. re-test) within one week. Non-responders had similar baseline characteristics (data not shown). The web-based test-retest variability closely resembled

the previously mentioned precision level: a mean difference of -0.02 (SD 0.11) logMAR, with 95%LoA ranging from -0.24 to 0.20 logMAR (see Supplementary Figure 1A). Both web-based tests showed a comparable performance and agreed equally to the conventional Snellen chart assessment at the clinic (mean difference -0.01 logMAR, $P=0.415$, see Figure 3). Importantly, an improved precision was found when the test-retest web-based VA scores were averaged, resulting in a mean difference of 0.04 (SD 0.09) logMAR, with narrowed 95%LoA ranging from -0.14 to 0.23 logMAR (see Supplementary Figure 1B).

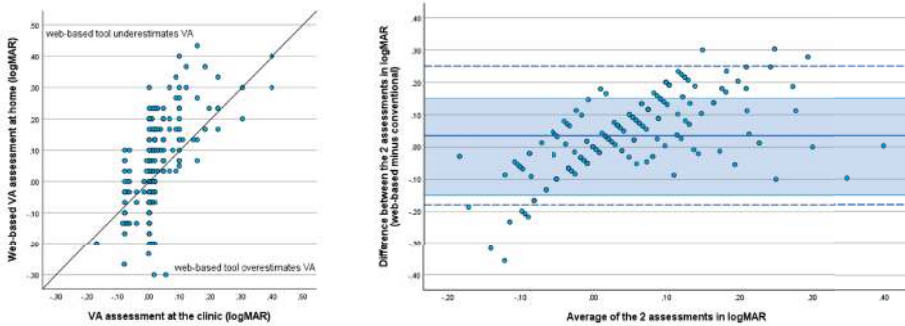


Figure 2. Web-based vs. conventional VA assessments. Each circle depicts a monocular assessment.
 [A] Scatter plot of web-based vs. conventional VA assessment. The black line represents the line of equality (45 degrees)
 [B] Bland-Altman plot of web-based vs. conventional VA assessment. The solid lines depict the mean difference (i.e. bias) and the dashed lines the 95% limits of agreement (i.e. random error). The semi-transparent blue zone in depicts the pre-determined clinically acceptable deviation range of ± 0.15 logMAR.

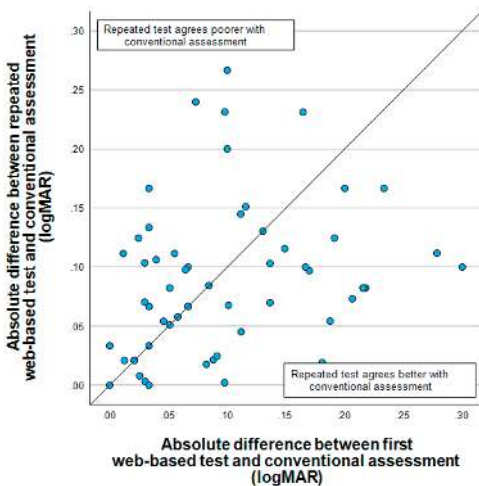


Figure 3. Repeated web-based vs. conventional VA assessments. Scatter plot depicting agreement of the repeated vs. the first web-based test, for subgroup who performed the test twice within one week ($n=40$ participants). Each circle depicts a monocular assessment. The black line represents the line of equality (45 degrees).

Assessment of refractive errors

The visual representation of the comparison between the myopia progression assessment at home and at the clinic are depicted in Figure 4A and 4B. A mean difference in SEQ of 0.40 D (SD 0.51), with 95%LoA ranging from -0.60 to 1.39 D, was identified. Myopia progression $>0.5D$ was observed for 31% of the eyes at the clinic, while this was measured for 76% of the eyes at home.

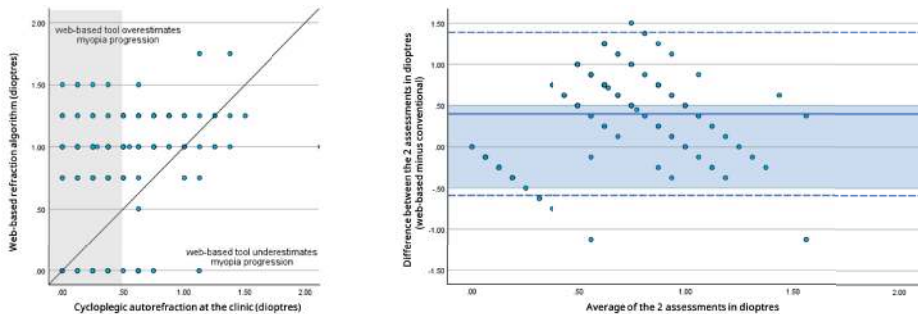


Figure 4. Web-based vs. conventional refraction. Each blue circle depicts a monocular assessment.

[A] Scatter plot of web-based vs. conventional refraction. The black line represents the line of equality (45 degrees). Note that absolute values are presented, meaning that positive values indicate more myopic progression. Myopia progression until 0.5D is not considered clinically relevant (see the semi-transparent grey zone).

[B] Bland-Altman plot of web-based vs. conventional refraction. The solid line depicts the mean difference (i.e. bias) and the dashed lines the 95% limits of agreement (i.e. random error). The semi-transparent blue zone depicts the pre-determined clinically acceptable deviation range of ± 0.50 D. Note that comparisons were based on absolute values. Positive differences (y-axis) indicate that the web-based assessment overestimates the myopia progression.

Determinants of test performance

GEE-analysis did not find age, sex or atropine use to be significantly associated with accuracy of the web-based VA or refraction assessment (i.e. the absolute difference between the home-assessments and clinic assessments, see Supplementary Table 1). For 34 monocular assessments (of 31 patients) the web-based test scores could not reliably be determined due to an unacceptable within-test variation. The presenting VA of these cases was significantly poorer when compared to the remainder (mean 0.11 vs. 0.02 logMAR, $P < 0.0001$). No differences between these groups were found in terms of age, sex or use of atropine drops.

The ability of the tool to detect visual deterioration

For screening purposes, one is primarily interested in identifying a poor VA range, rather than determining an exact value. The tool was able to detect a VA >0.1 logMAR ($<20/25$ Snellen) with a sensitivity of 94% and a specificity of 71%, when compared to the conventional assessments.

DISCUSSION

In this study we evaluated the accuracy of a CE certified web-based assessment of VA and refraction, performed by myopic children at home, assisted by their parent(s). We found a clinically negligible mean difference of 0.03 logMAR (SD 0.11 logMAR) when comparing the web-based VA self-assessment to a conventional Snellen VA obtained by trained staff at the clinic. Still, a significant proportional bias was identified, with a relative underperformance when vision declined (β -0.65). This resulted in an overestimation of the myopic progression as determined by the web-based refraction algorithm, compared to the progression objectified by gold-standard cycloplegic autorefraction. Age, sex or use of atropine drops were not found to be significantly affecting measurement accuracy.

When comparing VA assessments, it is important to note that differences in outcomes are inevitable, even when assessing the same eye and in the absence of any true clinical changes. Different optotypes and scoring criteria will result in different VA outcomes.²² A study comparing multiple VA assessments using different charts and observers concluded that differences up to ± 0.15 logMAR ought to be regarded as normal measurement variation.²² In addition, even when conducting repeated VA assessments using the same chart, fluctuations in scores will occur due to behavioural factors such as fatigue or motivation. The latter has been confirmed by multiple repeatability (i.e. test-retest) studies, where assessments in the same individual are repeated in controlled environments. For the widely used Snellen chart, repeatability studies have reported 95% Limits of Agreement (95%LoA) ranging from ± 0.18 up to ± 0.24 logMAR (from the mean difference) using the single-letter method and up to ± 0.33 logMAR using the line assignment method.^{23,24} These 95%LoA underline that a broad distribution of measurement differences and the occurrence of outlier measurements beyond the aforementioned limit of ± 0.15 logMAR are inevitable when comparing different VA assessments. Based on the 95%LoA reported in this paper (± 0.22 logMAR from the mean difference when comparing the web-based test to the Snellen chart, as well as when assessing the repeatability), the web-based tool yields a precision that is fairly similar to clinical Snellen chart testing. In the subgroup who performed the web-based test twice, we did not objectify a learning effect, as the second web-based VA assessment's accuracy was not significantly better than that the first's. Interestingly, the overall precision did improve when averaging the outcomes of the two tests (± 0.18 logMAR), underlining the added value of repeating tests to enhance accuracy.

The web-based test demonstrated a relative underperformance in poorer VA ranges. It has previously been described that VA assessments generally exhibit more variability in

poorer vision ranges, regardless of the testing method.^{12,14,25} The differences found in this study, however, are predominantly oriented in one direction (an underestimation of VA by the web-based test); an effect we had not observed in our previous study amongst adult ophthalmic patients.¹³ When vision declines, VA assessments become more challenging and more susceptible to the influence of behavioural and environmental factors. In children this influence may be more profound, as they have a more variable or shorter attention span, or may use different criteria in a yes/no paradigm.²⁶ A lack of comprehension or cooperation can pose difficulties in conducting the assessment or result in an earlier termination of the test. The expertise of trained staff may be vital in providing guidance and motivation. Interestingly, despite our study population encompassing a wide age range (7 – 17 years), age did not emerge as a significant factor affecting the accuracy of the home-performed assessment. A limitation is that our participants were recruited from a myopia control clinic and were therefore familiar with vision testing concepts. For naïve children who have not often experienced vision testing before, the performance on the web-based test may differ.

Our findings demonstrate an overestimation of the myopic progression, suggesting that the web-based refraction assessment is not valid in this population. An important factor contributing to this is the variability of the VA assessment; particularly the proportional bias indicating a relative underperformance of the web-based assessments when the child's vision declines. A more precise assessment of VA, especially in these poorer ranges, will undeniably improve the accuracy of the refraction assessment, as the refraction is derived from the VA scores. In addition, the web-based refraction algorithm requires a recalibration for this age group. The current algorithm was trained based on input of young and healthy adults (aged 18-40 years old), with an excellent best corrected VA >20/25 Snellen.¹¹ The algorithm's assumption that any VA poorer than -0.1 logMAR (20/25 Snellen) is attributable to a refractive error might not be valid in a population of children. For (younger) children, the maximum attainable vision may not have yet reached an adult-like level. An authoritative review reports that VA matures between approximately 6 to 10 years.²⁶ The data collected in this initiative will serve as input for iterations aiming to improve the algorithm performance. We recommend future studies to further evaluate the performance of these algorithms. An in-depth evaluation of the different components of the web-based refraction assessment (sphere/cylinder/axis) demands a controlled study environment, assessments without correction, and a paediatric study population with a wide distribution of refractive errors.

It is important to mention that we do not expect accommodation to have impacted the web-based refraction outcome, even though the home refraction is performed without cycloplegia. During conventional refraction assessments, proper accommodation con-

trol is critical to prevent myopic overcorrection. The web-based refraction assessment operates differently. Here, the refraction is derived from the home-assessed corrected distance VA. If myopia has progressed in this population, the optical focal point will fall in front of the retina during the distance VA assessment. An attempt of the eye to accommodate would only blur the vision even more, so the accommodation is expected to be relaxed in the eye's natural state. The concept of fogging during subjective refraction uses the same principle, by using spherical powers to create artificial myopia.

It should be noted that not all children (or parents) may be willing to perform these self-assessments independently at home, indicated by the non-responders in our study. These were considered missing at random, as no evident differences in baseline characteristics were identified. Importantly, completion of the web-based test does not necessarily mean it was performed correctly. In this study, exclusion of monocular assessments due to a high within-test variation was employed as a proxy for poor performance. Yet this was also more common in poorer VA ranges. No other clinical characteristics were identified as significantly affecting measurement accuracy. Interestingly, an equal accuracy was observed when comparing both eyes within the same individual, suggesting that performance is influenced by (external) factors on individual levels, such as behaviour or testing conditions. The tool would greatly benefit from improving performance in the poorer vision ranges. An important step to achieve this would be to gamify the experience: make the self-assessment more fun. The concept of "gamification" aims to improve motivation and engagement of users doing a nongame task and has been introduced in the mobile health industry.²⁷ Incorporating gaming elements into the web-based test may not only boost motivation to complete the test, but also enhance the willingness to exert maximum effort, particularly among children. Furthermore, web-based test updates aim to mitigate the impact of environmental factors at home, e.g. by webcam monitoring of the users and their environment and providing Artificial Intelligence (AI)-guided live feedback to optimize conditions such as room lighting or distance from the screen.

We do not claim that this web-based test can fully deliver all clinical determinants assessed typically during myopia control visits. Particularly, the eye's axial length is considered a primary target of myopia management.²⁸ The assessment of this parameter requires a clinic visit and specialized measurement equipment. Rising healthcare demands will compel us to reconsider follow-up schemes, recognizing that not all patients necessitate the same level of follow-up intensity. Myopia control strategies should become more personalised, based on risk profiles based on lifestyle, family risk, side effects and individual preferences.⁷ The myopic control could be less stringent for some, with fewer face-to-face clinic visits. A valid vision self-assessment increases opportuni-

ties for teleconsultations and reduces the burden for both children and their parents by empowering them to perform vision tests independently, not restricted to time or place. Moreover, it could aid in timely identifying those with rapidly deteriorating vision. In this study, the tool was able to detect patients with VA >0.1 logMAR ($<20/25$ Snellen) with a sensitivity of 94% and a specificity of 71%. The latter indicates that there will be a substantial rate of false positives, meaning that the web-based score will incorrectly report a VA poorer than 0.1 logMAR. This is in line with the aforementioned observed proportional bias; indicating an underperformance of the web-based VA test in poorer VA ranges. Improving the performance of the web-based test by the aforementioned adjustments is expected to improve this specificity. Another option to reduce false positive rates is to automatically request these patients to repeat the test at a later point, so conclusions could be based on more than one assessment. Ideally, this proposition should prospectively be evaluated in patients new to myopia management.

In conclusion, we report that myopic children are able to perform the web-based self-assessment at home, in assistance of a parent. The web-based VA assessment has a precision that is comparable to Snellen chart assessment at the clinic. Repeating the web-based VA test and averaging the scores appeared to further improve precision. We observed a proportional bias with underestimated web-based VA scores when the child's vision declined, resulting in an overestimation of the myopic progression. Future iterations of the web-based test should aim to increase the test accuracy and limit the influence of behavioural and environmental factors.

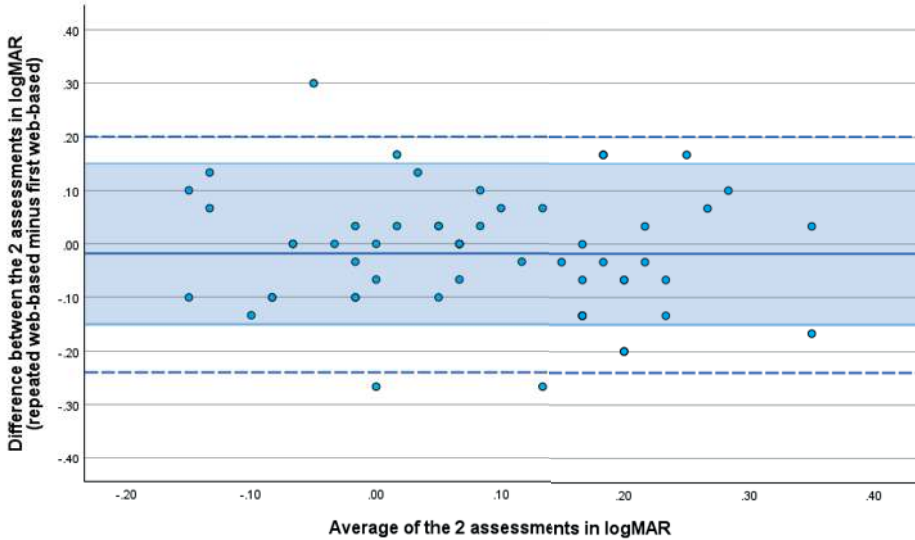
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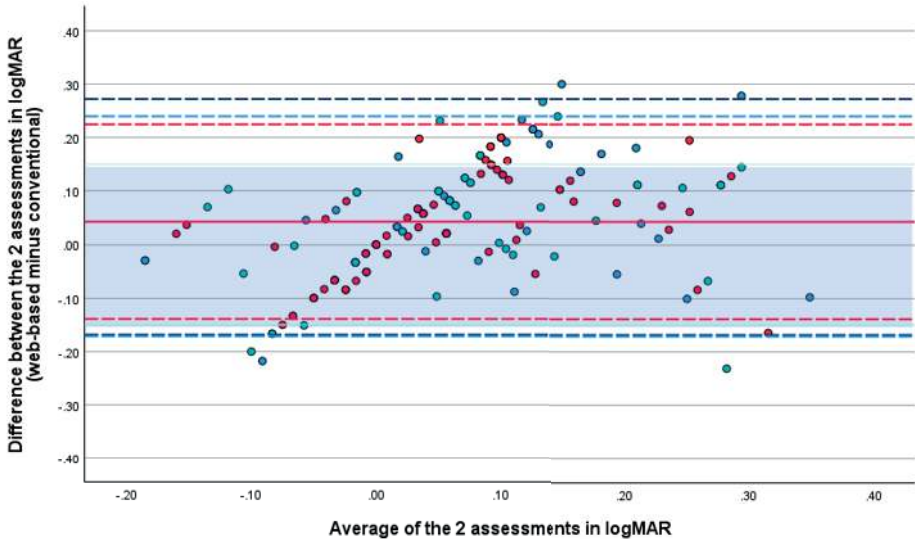
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SUPPLEMENTARY DATA

[A]



[B]



Supplementary Figure 1. Repeatability of the web-based test.

[A] Bland-Altman plot of repeated vs. first web-based test. Each circle depicts a monocular assessment. The solid lines depict the mean difference (i.e. bias) and the dashed lines the 95% limits of agreement (i.e. random error). The semi-transparent blue zone in depicts the pre-determined clinically acceptable deviation range of ± 0.15 logMAR.

[B] Combined Bland-Altman plot of both web-based vs. conventional VA assessments. Each circle depicts a monocular assessment. Dark blue colors depict the comparisons for the first web-based test, light blue for the second web-based test; and red for the average score of the two web-based tests. The red solid line depicts the mean difference (i.e. bias) for the averaged score; and the dashed lines the 95% limits of agreement (i.e. random error) for all 3 comparisons.

Supplementary Table 1. Multivariable GEE analysis to investigate associations between clinical variables and the accuracy of the home-based vision self-assessment

Baseline characteristics	Difference between the VA scores of the web-based and conventional test, in logMAR ^a			Difference between the myopia progression scores of the web-based and conventional test, SEQ in dioptres ^a		
	B	95% CI	P-value ^b	B	95% CI	P-value ^b
Sex ^c	-0.01	-0.03 – 0.01	0.43	-0.04	-0.15 – 0.07	0.43
Age (years) ^c	0.00	-0.00 – 0.00	0.73	-0.11	-0.03 – 0.01	0.25
High dose atropine ^d	0.01	-0.03 – 0.02	0.70	-0.06	-1.70 – 0.05	0.27

VA = visual acuity; SEQ = spherical equivalent; B = beta value; CI = confidence interval

^a absolute difference between the two assessments in logMAR

^b analyzed using a Generalized Estimating Equations to correct for inclusion of two eyes of one patient

^c 'male' as reference

^d 'low dose atropine (<0.5%)' as reference; atropine 0.5% and 1% are considered 'high dose'



Chapter 5

**The TeleTriageTeam, offering continuity of
personalized care through telemedicine:
development and evaluation**

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ABSTRACT

Background: The COVID-19 pandemic taught us how to rethink care delivery. It catalyzed creative solutions to amplify the potential of personnel and facilities. This paper presents and evaluates a promptly introduced triaging solution that evolved into a tool to tackle the ever-growing waiting lists at an academic ophthalmology department, the TeleTriageTeam (TTT). A team of undergraduate optometry students, tutor optometrists, and ophthalmologists collaborate to maintain continuity of eye care. In this ongoing project, we combine innovative interprofessional task allocation, teaching, and remote care delivery.

Objective: In this paper, we described a novel approach, the TTT; reported its clinical effectiveness and impact on waiting lists; and discussed its transformation to a sustainable method for delivering remote eye care.

Methods: Real-world clinical data of all patients assessed by the TTT between April 16, 2020, and December 31, 2021, are covered in this paper. Business data on waiting lists and patient portal access were collected from the capacity management team and IT department of our hospital. Interim analyses were performed at different time points during the project, and this study presents a synthesis of these analyses.

Results: A total of 3658 cases were assessed by the TTT. For approximately half (1789/3658, 48.91%) of the assessed cases, an alternative to a conventional face-to-face consultation was found. The waiting lists that had built up during the first months of the pandemic diminished and have been stable since the end of 2020, even during periods of imposed lockdown restrictions and reduced capacity. Patient portal access decreased with age, and patients who were invited to perform a remote, web-based eye test at home were on average younger than patients who were not invited.

Conclusions: Our promptly introduced approach to remotely review cases and prioritize urgency has been successful in maintaining continuity of care and education throughout the pandemic and has evolved into a telemedicine service that is of great interest for future purposes, especially in the routine follow-up of patients with chronic diseases. TTT appears to be a potentially preferred practice in other clinics and medical specialties. The paradox is that judicious clinical decision-making based on remotely collected data is possible, only if we as caregivers are willing to change our routines and cognitions regarding face-to-face care delivery.

INTRODUCTION

Background

The importance of high-quality remote care was emphasized when most elective hospital care was on hold during the COVID-19 pandemic. The number of regular face-to-face patient consultations were reduced to comply with government-imposed mobility restrictions. Initially, face-to-face in-hospital consultations were considered only when medically urgent. The capacity of our academic outpatient clinic reduced by 90% (from 300 to 30 visitors per day). Before the pandemic, the capacity of ophthalmic care in the Netherlands was already barely sufficient, with accessibility under pressure and ever-growing waiting lists.¹ Future projections offer little perspective, with an estimated increase in national health expenditures from 12.7% of gross national income in 2015 to 19.6% by 2060, owing to our aging society.² To address these immediate and future challenges, we conceptualized and executed a novel telemedicine approach, the TeleTriageTeam (TTT).

The TTT is an ongoing collaboration between the HU University of Applied Sciences Utrecht (HU-UAS) and the University Medical Center Utrecht (UMCU). In this approach, a team of undergraduate (i.e. bachelor's degree) optometry students, tutor optometrists, and ophthalmologists worked together to remotely provide eye care.³ Although originally conceptualized for telephonic triaging and rescheduling appointments during the acute pandemic-related capacity crisis, the approach has evolved into a telemedicine service that included advising patients, refining treatment, or referring patients to other physicians. It appeared highly valuable beyond the acute crisis and is therefore still ongoing. In addition to allowing the continuation of care, the approach created a unique opportunity to continue the training of optometry students during the pandemic while respecting social distancing and quarantining.

Objective

In this paper, we described a novel method of delivering remote care safely and effectively using an innovative approach to interprofessional task allocation and the application of technology for remote vision testing. We aimed to report on the clinical effectiveness of the TTT approach and its impact on waiting lists and discuss its transformation to a sustainable method for delivering remote eye care.

METHODS

Synopsis

The TTT approach included evaluations of current (ocular) health status using semi structured anamneses by telephone conducted by optometry students. If visual acuity was of interest for clinical decision-making, patients were requested to perform a remote, web-based eye test in their home environment. Patients were called back after their cases had been discussed by the supervising ophthalmologists, who were responsible for the clinical decision-making.

Process overview

Eye care delivery before the pandemic

The UMCU is a tertiary clinic and training institution. Most of the patients in the ophthalmology department have complex and multifactorial eye disorders. New cases typically present after referral by ophthalmologists from regional clinics. After diagnosis and treatment, most of the patients will be referred back to the referring ophthalmologist or the general practitioner (GP) once the condition is stable. Exempts from this policy are complex cases in need of indefinite academic care. Teleconsultations that replaced in-office visits were fairly uncommon, and video consultations were not performed.

Eye care delivery during the pandemic

When the COVID-19 pandemic began in March 2020, about 90% of our outpatient capacity had to be reduced, greatly impacting scheduled appointments and waiting lists. Teleconsultations (i.e. telephonic or video-assisted consultations) were preferred to face-to-face in-hospital consultations to limit the number of hospital visitors. Patients were referred to the hospital only when medically urgent (e.g. neovascular age-related macular degeneration, poorly regulated glaucoma, and retinal detachments). To help prioritize scheduled appointments and restructure the waiting lists in our ophthalmologic department, the TTT was conceptualized. This approach was continued throughout the pandemic, during the various stages of lockdowns and subsequent changes in social restrictions. Shortly after its introduction, TeleTriage became a part of the standard curriculum for the optometry training at the HU-UAS. After a 2-day training program that focused on navigating through the electronic health record (EHR), best practices in data handling, and patient communication, students were enrolled in the TTT program for 4 weeks.

TTT workflow

Students of the TTT were assigned patients who were on the waiting list or scheduled for ophthalmology resident clinics. First, the students thoroughly studied and summarized the available information on the EHR. Subsequently, they reached out to the patients by telephone for semi structured anamnesis. A triaging checklist was used to assess the current eye health status and identify any changes in general health or medication use. The primary learning task for the optometry students was to make a triaging proposal based on the gathered information, adhering strictly to the existing clinical protocols. The students were supervised by a qualified tutor optometrist and an ophthalmologist. Under Dutch law, the ophthalmologist is responsible and accountable for the final clinical decision. Triaging decisions for the clinical appointment included the following options: maintain, expedite, postpone, cancel, change into a telephone or video consultation with their physician, or refer regionally. Case summaries were recorded in the EHR, and clinical decisions were relayed back to the patients and, if applicable, to the patients' GPs or the referring ophthalmologists. Figure 1 depicts the workflow of the TTT.

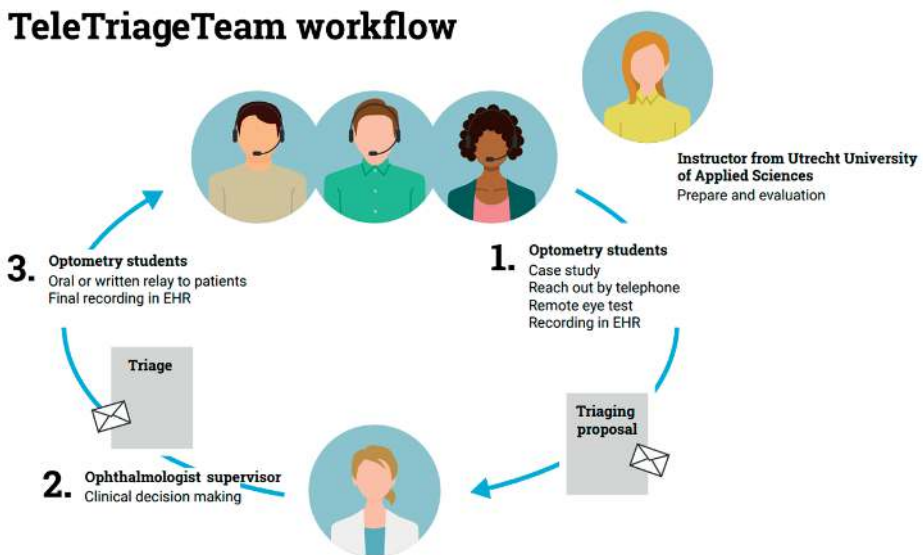


Figure 1. Workflow of the TeleTriageTeam.

Optometry students reach out to patients by telephone and make a triaging proposal. A supervising ophthalmologist will make the final clinical decision. The patient will be informed by the students and the decision will be recorded in the electronic health record (EHR). A tutor optometrist will be on site for overseeing the process, assigning patients to the students, and prediscussing proposal options based on current guidelines.

The remote eye test

In some cases, patients were requested to perform a remote eye test. This web-based Conformité Européenne (CE)–certified application enables individuals to self-assess their visual acuity in their home environment using their own electronic devices. This test was developed by Easee BV in collaboration with the UMCU and extensively studied in various patient populations.⁴⁻⁷ To perform it at home, patients need an internet connection, a smartphone, and a computer or tablet. After entering the test via a website on their computer or tablet, users will be instructed to connect their smartphone by scanning a QR code or entering a code sent by an SMS text message. The patients are instructed to stand or sit 3 m from their screen and cover one eye with their hand while the computer or tablet screen displays a sequence of optotypes that the patient should correctly identify. A calibration step ensures that the displayed symbols are correctly sized, regardless of the screen dimensions of the user’s own devices. The smartphone is used as a remote control to submit the answers. At the end of the test, a visual acuity score will be presented (in Snellen decimal system, the common notation to express this outcome in our clinic).

The remote eye test was available via our clinic’s patient portal website. All patients of our clinic have direct access to their medical records via this secured web-based portal. Access is granted through a government-backed identification system (“DigiD”),⁸ which ensures data safety and privacy of this digital environment. Patients were directed to the portal to open the eye test via a web link and instructed to write down or save their eye test results after completion. Within the portal, a dedicated questionnaire allowed patients to report their outcomes, after which it became available to the health professionals in the EHR. This manual step was required because the data were not automatically transferred between the remote eye test and the EHR.

Study population

This study database included all patients who were assessed by the students as part of the TTT project between April 16, 2020, and December 31, 2021. In principle, all patients on waiting lists or with scheduled appointments at the general resident outpatient clinic of the UMCU were screened for eligibility for teletriaging. Patients scheduled for a subspecialty appointment (e.g., patients with uveitis and patients referred to pediatric ophthalmology or vitreoretinal consultants) were excluded from the project because of the anticipated complexity of the cases. The consultant ophthalmologists were responsible for downscaling their waiting lists, and these cases are not covered in this paper. Ophthalmologists specializing in corneal pathology were involved in supervising the TTT (depicted in Figure 1 as “ophthalmologist supervisor”); hence, a minority of cases

were considered subspecialty cases from the corneal clinic. No further exclusion criteria were applied.

Data collection

We used real-world clinical data and demographics of the TTT project, gathered by the optometry students, registered in Microsoft Excel (version 16.0.4266.1001 for Windows; Microsoft Corp) and the EHR, HiX (version 6.1; Chipsoft). The characteristics included in the database were as follows: age, sex, diagnosis, date of triaging contact, reachability by phone (yes or no), possibility of a video consultation (yes or no), remote eye test offered (yes or no), remote eye test performed (yes or no), triage proposal by the student, and final decision by the ophthalmologist. Free-text variables were recoded into categories before the analysis. Business data on waiting lists and patient portal access were collected from the capacity management team and IT department of our hospital.

Data analysis

The outcomes of this study included the clinical characteristics of the assessed patients, triaging decisions, uptake of the remote eye test, and the effects of triaging on the waiting lists and case mix of our outpatient department. The TTT project had an iterative development to optimize the service. Therefore, interim analyses were performed at different time points during the project, as part of the scheduled project evaluations. This paper presents the synthesis of these analyses.

Statistical analyses were performed using the SPSS Statistics (version 25; IBM Corp). Demographic data, clinical characteristics, and triaging outcomes were available for all included patients (April 16, 2020, to December 31, 2021). These data are descriptively presented as frequencies and percentages and as means and SDs.

Data on patient portal access and uptake of the remote test were available for all patients included up to May 7, 2021. The data are descriptively presented as frequencies and percentages. The differences in age between active and nonactive patient portal users, invited and uninvited for the remote eye test, and successful and unsuccessful performance of the remote eye test were compared using the independent samples 2-tailed t test. Age differences between the groups were considered statistically significant at a $P < .05$.

Ethical considerations

An anonymized, coded version of the TTT database was used to analyze the clinical data, precluding the research team from tracking patients on an individual level. Analyses were performed in accordance with Dutch privacy laws and the Declaration of Helsinki

in the context of quality control and health care evaluation. According to national regulations (Centrale Commissie Mensgebonden Onderzoek), ethics approval and informed consent are not required when the quality of a novel health care delivery system is investigated for local applications.⁹

RESULTS

Population characteristics

Our database included 3658 registrations of cases that were assessed in this project. The clinical characteristics and demographics of the assessed patients are summarized in Table 1, and this distribution reflects the general outpatient clinic population of our academic hospital. Sex distribution among the patients was equal (female patients: 1902/3658, 52%). The mean patient age was 59 (SD 19) years. The most frequent diagnosis categories were “corneal and conjunctival diseases” (632/2527, 25.01%), “glaucoma” (432/2527, 17.1%), and “screening for ophthalmic disease” (322/2527, 12.74%). The latter included routine screening of patients who had systemic diseases and used chronic medication with an increased risk of ocular disease (e.g., protocolled hydroxychloroquine screening).

Table 1. Demographics and clinical characteristics of patients assessed by the TeleTriageTeam

		Values
All cases (N=3658)^a		
Sex, n (%)	Male	1756 (48)
	Female	1902 (52)
Age (years)	Value, mean (SD)	59 (19)
	Value, range	11-97
First-year cohort (n=2527)^b		
Diagnosis category ^c , n (%)	Corneal and conjunctival diseases	632 (25.01)
	Glaucoma	432 (17.1)
	Screening for ophthalmic disease	322 (12.74)
	Screening for diabetic retinopathy	269 (10.65)
	Cataract and other lens abnormalities	266 (10.53)
	Retinal and macular diseases	225 (8.9)
	Eye lid and orbit pathologies	120 (4.75)
	Neuro-ophthalmological diseases	110 (4.45)
	Other (e.g. refractive errors or unspecified vision loss)	97 (3.84)
	Uveitis	88 (3.48)
	Pathologies of the bulbus, sclera or vitreous	75 (2.97)

^a All consecutive cases assessed between April 16, 2020, and December 31, 2021.

^b All consecutive cases assessed between April 16, 2020, and April 7, 2021.

^c Diagnosis categories are based on "Diagnosis Treatment Combinations" (DTC). The DTC coding is the Dutch registration method for charging health care to the insurer or the patient.

Triaging outcomes

The triage outcomes are presented in Table 2. For approximately half (n=1789, 48.91%) of the 3658 assessed cases, an alternative to the conventional face-to-face consultation was found. The appointment was cancelled in 212 (5.8%) of the cases, or postponed 733 (20.04%) times, with a mean delay of 6 (SD 4) months. Of the total 3658 patients, the face-to-face consultations of 132 (3.61%) patients were changed to teleconsultations with the ophthalmologist. A substantial proportion of patients (492/3658, 13.45%) was dismissed from academic care, as there was no solid ground for specialized follow-up. Other decisions included consulting with other specialists (194/3658, 5.3%).

Table 2. *Triaging outcomes based on the final clinical decision made by ophthalmologists*

Triaging outcomes	All cases (N=3658)^a, n (%)
Consultation unchanged	1869 (51.09)
Consultation postponed ^b	733 (20.04)
Consultation expedited	26 (0.71)
Consultation cancelled	212 (5.8)
Consultation changed to teleconsultation	132 (3.61)
Referral to regional hospital or general practitioner	492 (13.45)
Other	194 (5.3)

^a All consecutive cases assessed between April 16, 2020, and December 31, 2021.

^b Mean delay 6 (SD 4) months.

The other half (1869/3658, 51.09%) of the patients still required the scheduled face-to-face examination at the clinic and were marked as “maintain the consultation.” The consultations of a few patients (26/3658, 0.71%) were expedited after noting warning signs in the telephonic anamnesis.

Access to the patient portal and uptake of the remote eye test

Interim analyses of patient portal access and remote eye test performance were conducted 1 year after the start of the project in May 2021. Most of the assessed patients (1667/2634, 63.3%) up to this date were “active” users of the patient portal, meaning they had logged on to this web service at least once. These active users were, on average, slightly younger than those who did not access (mean age 55, SD 18 years vs mean age 65, SD 18 years, respectively; $P < .001$). Patient portal use decreased with age; 75.7% (390/515) of the patients who were aged <40 years were active users, whereas only 32.1% (97/302) of the patients who were aged ≥ 80 years used the service, as shown in Table 3.

Table 3. Access to the patient portal and remote eye test, stratified per age category^a

	Age (years)						
	All categories (n=2634)	<40 (n=515, 19.6%)	40-49 (n=234, 8.9%)	50-59 (n=409, 15.5%)	60-69 (n=583, 22.1%)	70-79 (n=591, 22.4%)	≥80 (n=302, 11.5%)
Active users of the patient portal, n (% of category total)	1667 (63.3)	390 (75.7)	170 (72.6)	301 (73.6)	395 (67.8)	314 (53.1)	97 (32.1)
Invited to perform the remote eye examination, n (% of active users)	184 (11)	43 (11)	17 (10)	38 (12.6)	52 (13.2)	29 (9.2)	5 (5.2)
Successful completion of the remote eye test, n (% of invited patients)	82 (44.6)	19 (44.2)	7 (41.2)	19 (50)	23 (44.2)	14 (48.3)	0 (0)

^a Cross-sectional analysis based on data from University Medical Center Utrecht IT department in May 2021. The patients who were not actively using the patient portal were, on average, older than the patients who had been using the patient portal (mean age 65, SD 18 years vs mean age 55, SD 18 years; $P < 0.001$).

Table 3 indicates that 11% (184/1667) of the active patient portal users were invited to perform the eye test. The eye test was offered if three conditions were met: (1) patients had access to the patient's portal, (2) patients had access to a smartphone and computer or tablet, and (3) visual acuity was of interest in clinical decision-making. The reasons for not inviting patients to perform the test were not registered. Invited patients were only slightly younger than those who were not invited (mean age 53, SD 18 years vs mean age 59, SD 19 years; $P < .001$). Among the invited patients, there was no significant difference in age between the patients who successfully performed the eye test after the invitation and those who did not ($P = .91$).

Waiting list reduction at the outpatient department

To evaluate the impact of TeleTriage on our clinic's health care delivery, we performed several cross-sectional investigations. Figure 2 illustrates the number of patients on the waiting lists in the outpatient department of the ophthalmology residents at our clinic and the pandemic-related restrictions, as expressed by the clinic capacity and lockdown stringency (as reported using the Oxford COVID-19 Stringency Index).¹⁰ The first blue bar effectively represents the prepandemic status of the waiting list, as the government's lockdown measures were only effective from March 15, 2020, and waiting list effects needed some time to accumulate and materialize. During the following months, the waiting lists grew, peaking in summer 2020 (n=1991, July 2020). TeleTriage assisted tre-

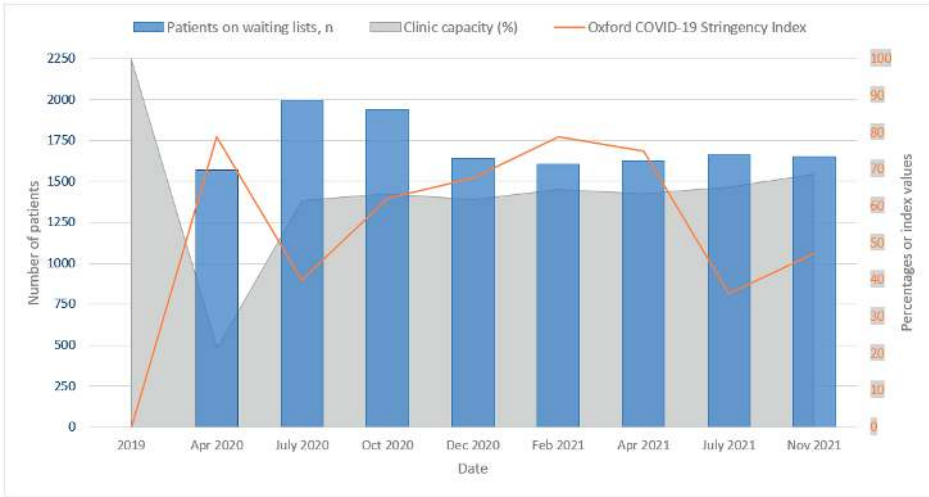


Figure 2. Number of patients on the waiting lists at the outpatient department of the ophthalmology residents and pandemic-related restrictions, as expressed by the clinical capacity (%) and Oxford COVID-19 Stringency Index. The total number of patients on the waiting lists is represented by the blue bars (left y-axis). The gray surface represents the operational clinic capacity (right y-axis), with 2019 data as the index (100). The orange line represents the Oxford COVID-19 Stringency Index (right y-axis), a composite measure based on 9 response indicators including school closures, workplace closures, and travel bans, rescaled to a value from 0 to 100 (100=the strictest).

mendously in the continuation of the most urgent care because the clinic capacity was markedly reduced during this first lockdown (~80%). The lockdown stringency varied over time. Lockdown restrictions were lessened in summer 2020, coupled with a slight normalization of clinic capacity (approximately ~30%).

The team productivity of the TTT peaked in July 2020, when approximately 500 cases were assessed over the month. Productivity mostly relied on the number of optometry students assigned to the project and the number of tutor optometrists. From September 2020 onward, TeleTriage became part of the standard curriculum of the optometry training at the HU-UAS, leading to a stabilized inflow of student optometrists. Naturally, other factors influenced the waiting list, such as the fluctuating number of new referrals or surgical capacity. Both dropped during the first months of the initial COVID-19 lockdown but normalized during 2020, albeit at a slightly lower level than in 2019.¹¹ Since the end of 2020, we have managed to balance the influx of new patients and referrals to our general outpatient clinic with our reduced capacity and the added outflow of patients owing to TeleTriage, even with periods of imposed restrictions (as reflected by the increasing Stringency Index).

Developing TeleTriage into a tool for Value-Based Health Care delivery

During the initial global COVID-19 lockdown, TeleTriage served to retain continuity of care for the most urgent eye care. No patients with an urgent need for eye care were

denied service within the TTT, including retinal detachments, progressive glaucoma, and wet age-related macular degeneration. Within months, our clinic's capacity recuperated, and the TTT allowed us to process the backlog of patients awaiting an appointment (almost 2000 patients at its peak in summer 2020). Patients with lower urgency or complexity were often processed completely remotely and had their face-to-face consultations cancelled or postponed or were referred externally.

Interestingly, TeleTriage offered a potent means to judiciously select patients for non-specialty follow-up with regional ophthalmologists or GPs. Referrals were customized to a high degree, with personal telephone feedback and a tailored written medical summary provided to both patients and caregivers. As a result, our patient population slowly but steadily grew more academic with less protocolled care of higher complexity.

A business analysis showed that the eye care delivered by our outpatient clinic in 2021 better adhered to the parameters of the academic care set in 2019. First, in 2021, registrations of Diagnosis Treatment Combinations fell significantly more often within our defined academic care profile (+15% increase compared with 2019). Second, the care delivered was significantly more often considered a strategic theme of the department (+14% increase compared with 2019). Our academic care profile is defined at the institutional level as tertiary referred care, pertaining to hospital-wide strategic themes, or last-resort care. Strategic themes are defined at the department level and indicate when certain Diagnosis Treatment Combinations are compliant with the vision of our management team and adhere to the spearpoints of the UMCU. Note that TTT only considered the general, glaucoma, and cornea outpatient clinics (25% of total patient volume) and not the other subspecialty clinics such as surgical, medical retina, uveitis or orbit, neuro-ophthalmology, and pediatrics. These analyses could only be made for our eye clinic as a whole, with an average of 8000 patients on the waiting list. Interestingly, the TTT still exerted a substantial effect on our overall case mix, whereas the addressable population was only 25% of our total clinic. Should one hypothetically apply this effect to all eye care patients, the case mix changes are assumed to be even more pronounced.

DISCUSSION

Principal findings

We present a novel method to triage eye care patients remotely, using interprofessional collaboration, teleconsultations, and remote vision testing. This project was conceptualized and catalyzed by the sudden COVID-19 pandemic. Subsequently, we developed it as a tool to deliver value-based health care beyond the primary pandemic setting. This innovation was successful in reducing approximately half of the planned care while providing continuity of care for the most urgent cases and deferring or cancelling consultations judiciously or referring the remaining patients after obtaining a specialist's consideration. The TTT has helped mitigate the backlog of waiting lists that had been built during the initial months of the pandemic. Limited resources were required, and to the best of our knowledge, this telemedicine approach was the first of its kind to actively involve optometry students and remote eye testing in the workflow. Student participation is beneficial for teaching and training, but it can also enable a high turnover without additional staffing. To date, we continue to use this method in our department, as it offers a tool for value-based health care, delivering "the right care in the right place" (*"de juiste zorg op de juiste plek"*¹²), and is timely when relevant and needed. We propose that similar workflows could be conceptualized in other eye clinics with more GP referrals (e.g. regular hospitals and specialized eye clinics), as less-complex pathology appeared easier to triage. However, this could be offset by a lack of available clinical data; in this project, we often had extensive patient charts at our disposal with numerous auxiliary investigations. Other medical specialties could similarly benefit from a working method as described here and contribute to the human capital challenges in both health care delivery and health care education, only if there is availability of technology for remote assessments and delegated personnel to interpret and collect these data.¹³⁻¹⁵ Advanced eHealth technologies are not always required. Our project demonstrated that most triaging decisions were based on the clinical information collected by phone in addition to the data already available in the EHR.

When delivering remote care and triaging services, several ethical considerations and challenges should be considered. One major challenge is to deliver care that is non-inferior to a face-to-face examination in terms of quality and safety. In this project, all optometry students worked under supervision, and none of their decisions were made independently. Although quality and safety aspects could not be examined in our descriptive analyses, we argue that in any form, clinical decision-making on available data by ophthalmologists is of the highest quality and pace when compared with other eye care professionals. Our asynchronous method, in which patients were called back after the case discussion with the supervising ophthalmologist, allowed ample time to thor-

oroughly review patient health records and look into national and international guidelines and peer-reviewed literature. In addition to improving quality of care, this method also creates excellent teaching opportunities with real exposure to patient communication and clinical decision-making. Moreover, a plenary discussion of the case summaries was helpful for our ophthalmology residents. Incidentally, the case review resulted in the planning of additional examinations before the planned consultation, thereby improving the efficiency.

Importantly, our remote triaging arguably increased the safety of our population when compared with no care at all. Although this may sound as clear as day, the latter is an inconvenient reality for patients who spend weeks or months waiting for their appointments. In utopia, without restrictions on the amount of care we can deliver, we would happily invite everyone to our clinic for a specialist examination. In reality, scarcity of time and means demands alternative solutions to deal with the ever-increasing waiting lists for routine eye care that further soared during the pandemic. Access to eye care is of paramount importance, and TeleTriage is a novel approach to improve the access.

The biggest lesson learned during this project is that clinical decision-making is often possible *without* seeing patients in the clinic, especially during the routine follow-up of patients with chronic diseases. A judicious decision to cancel or postpone the consultations or refer patients to specialists could be made frequently based on the patients' history, current complaints, home-assessed visual acuity, and knowledge of disease biology and epidemiology. However, at an almost equal rate, our ophthalmologists concluded that patient safety could be compromised when further delaying care and decided to maintain (or expedite) consultations at the clinic. The most commonly encountered reasons were the nature of the disease (e.g. asymptomatic diseases such as progressive glaucoma), red flags in the case summary (e.g. poorer visual acuity or vision symptoms), a lack of trust in the case summary (e.g. inconsistencies or language barriers), or existing protocols mandating follow-up (e.g. screening for hydroxychloroquine maculopathy or diabetic retinopathy). Naturally, important clinical findings such as ophthalmic examinations, intraocular pressure assessments, and optical coherence tomography imaging can only be assessed in person. For only a small fraction (4%) of the cases, the scheduled face-to-face consultation was changed into a telephonic consultation with their ophthalmologist, although it should be noted that treatment advice or feedback was often delivered via the TTT approach itself. These cases are de facto teleconsultations, paving the way for cancellation or postponement of consultations without compromising quality of care. In this way, while originally conceptualized for triaging, the TTT approach evolved into a telemedicine service that included the full assessments of patients *and* remote health care delivery.

The supposedly decreased *human interaction* between patients and their health care professionals is another ethical concern that is frequently introduced as an argument against telemedicine implementation. In this project, we experienced little resistance and no formal complaints from patients who were contacted by phone. The extraordinary situation of the pandemic eased the acceptance of this project, though we also consider the personalized approaches and tailored communication between the students and the patients a vital reason for success. A few patients opposed the final clinical decisions. This was most frequently encountered when patients had a long-standing relationship with our hospital and were referred to another eye care provider. Invariably, not all patients suitable for referral were referred. The data reported in this study reflect the final management rather than the initially proposed management. Differences between these 2 were not recorded; therefore, the true size of this effect could not be quantified.

Technology adoption is another challenge in the delivery of remote care. Not all patients are willing or able to use telemedicine services. In this project, most clinical decisions were based on the information gathered via phone. More or less all of our patients had access to telephone services, so we did not encounter technical difficulties while collecting these data. In addition, a platform for remote eye examinations was available to the team to collect quantifiable information about the visual function of the patients. As this service requires access to technology and basic digital skills, adoption issues arose. The proportion of internet access in the Netherlands has been reported to be the highest in Europe: 98% of households had direct internet access in 2022.¹⁶ Nevertheless, digital literacy is age associated and related to the technological competencies that were required during the life course.^{17,18} Internet use is less common among the older generations.¹⁹ Most of our ophthalmic population was older. Despite the high internet accessibility and—relatively high—digital literacy rate in the Netherlands compared with other European countries, the uptake of this eHealth application and its role in clinical decision-making was rather low for 2 reasons. First, the students did not invite all patients to perform the eye examination. Obviously, a quantifiable visual acuity outcome is not always essential for clinical decision-making, and unfamiliarity of new team members with the web-based platform reduces *professional adaptation*. More importantly, the lack of patient portal access and initial resistance of some patients to perform the computer-based test were the evident barriers that precluded the students from guiding the patients through the examination. Second, approximately half of the invited patients did not complete the eye examinations. Anecdotal telephonic feedback from patients who did not complete the test was collected by the research team (JC). Patients reported that the clinic's patient portal environment was difficult to navigate. Frequently, there were problems with manually entering the test outcomes into the questionnaire. To a lesser degree, a lack of time or motivation was reported. Interest-

ingly, the instructions for the eye test itself were reported to be clear. This is in line with a recently published study on cataract patients (mean age 70, SD 7 years).²⁰ In-depth interviews and quantitative questionnaires based on Technology Acceptance Models identified an overall positive attitude toward the web-based eye test. We propose that better integration of this test into the patient portal will make it easier for patients to access the tool and, more importantly, will waive the need to manually enter one's outcomes. Positive experiences are expected to increase staff confidence in inviting patients to perform the examination. Engaging patients in self-measurements can promote self-awareness, self-management, and ownership of one's health and well-being. This complies with the transition to patient-centered care models, as reported in a World Health Organization report on eHealth implementation.²¹

Eye care delivery after the pandemic

Changing demographics, increased technical possibilities, and a higher prevalence of systemic disorders with ocular manifestations (e.g. diabetes) are expected to drastically increase the future demand not only for ophthalmic care but also for other domains of health care.^{2,22,23} In the Netherlands, it is estimated that by 2060, one in 3 people should be working in the health care industry to tackle these demands. As this is not feasible, alternative strategies are required to maintain health care accessible for all, such as prioritizing and improving efficiency.² Therefore, we propose that the TTT approach is highly valuable beyond the pandemic setting and of great interest for future purposes.

An important aspect of this project was that the practice pattern was preliminarily introduced within a short period. Our approach could be extended by enriching the remote monitoring platform with options for obtaining images remotely. In the United Kingdom, more evolved triaging workflows have been very successful in reducing hospital visits while maintaining communication, patient safety, and clinical quality, even before the pandemic.^{24–27} Especially for retinal disorders, diagnosis and treatment rely increasingly on optical coherence tomography imaging devices rather than fundoscopy,²⁸ which allows an asynchronous approach to diagnostics and clinical decision-making. Therefore, several eye clinics have started to refer patients to remote community clinics for obtaining these images. As not all screened retinas require treatment or further examination, this significantly reduces the burden of clinic visits. Interestingly, an added beneficial effect was higher attendance of diabetic retinopathy screening based on a telemedicine-based methodology when compared with conventional screening.²⁹ The combined approach of remote diagnostics with centralized asynchronous *augmented intelligence* clinical decision-making certainly holds promise for the future; this TeleTriage project provides important lessons in this regard. We hope that this manuscript inspires (young) colleagues to rethink how eye care is delivered and that it provides

insights into how to become architects of this change. Future studies could focus on further exploring patients' perspectives and cognitions on teletriaging, analyze clinical outcomes and safety aspects, and evaluate the cost-effectiveness of this telemedicine approach.

Conclusions

In conclusion, our novel approach to remotely review cases and prioritize urgency has been successful in maintaining continuity of care despite the COVID-19 pandemic. The project evolved into a telemedicine service of great interest for future purposes, as it aligns with the current trends toward remote care delivery and reduces the burden of hospital visits. The asynchronous triaging allows efficient task allocation without compromising the quality of care, as medical specialists are responsible for the final clinical decisions. The paradox debated in this paper is that judicious clinical decision-making based on remotely collected data actually is possible, only if we as caregivers are willing to change our routines and cognitions regarding face-to-face care delivery. Patient acceptance of this novel method of care delivery is essential for success and is promoted by individual communication and tailored clinical decision-making (i.e. patient-centered care). In addition, the triaging method has been highly valuable for educating future health care professionals in understanding the course of disease, communicating with patients, and clinical decision-making. This project serves as a proving ground for upcoming innovations in remote eye care delivery and could play a comparable role for other clinical domains.

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Section 2

Remote follow up after cataract surgery



Chapter 6

Evaluating a web-based visual acuity self-assessment tool in postoperative cataract patients: a pilot study at the clinic

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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, the Netherlands.

Design: Prospective method comparison study.

Methods: Subjects aged between 18 and 69 years old who underwent cataract surgery on one or both eyes at the Maastricht University Medical Center+ were eligible to participate in this study. The uncorrected (UDVA) and corrected 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: A total of 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 to Snellen 0.92. In total, 73% to 88% of the visual acuity measurement differences were within 0.15 logMAR.

Conclusion: 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. The majority of participants had a positive attitude towards 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 last 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 one or more regular clinical follow-up examinations by telephone consultations.⁴ However, these teleconsultations are only partly applicable in ophthalmologic care, since 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 lowers 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, non-inferiority was shown for refraction measurements of this tool compared to 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 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 is 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 carried out by the web-based tool as compared to the conventional assessments.

METHODS

Test-retest

Firstly, a test-retest analysis was carried out among five healthy volunteers by measuring the right eye UDVA using the Snellen, Early Treatment Diabetic Retinopathy Study' (ETDRS) visual acuity charts and the web-based tool. The measurements were performed at three 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 if they 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 prior to 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 principles of the Helsinki Declaration.

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

Both UDVA and 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, prior to 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 meters 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 1). The smartphone is used as a remote controller to submit the input of the user from a distance of three meters 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 laptop (Dell Latitude 5501, 15.6 inch). The test consisted of three parts with audio and visually instructed guidance: intake, arrangement of the test (calibrating and connecting the screen, placing a chair at 3 meters 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.

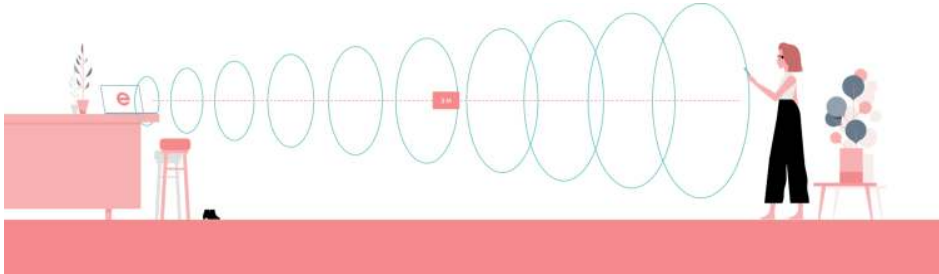


Figure 1. Schematic diagram depicting the web-based test (not to scale). During the test, the patient is instructed to stand 3 m away from the screen and use the smartphone to control the test.

All participants performed the web-based test twice. Firstly, monocular UDVA measurements were carried out 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 above-mentioned sequence. All participants were unaware of their results.

Questionnaires

An exploratory questionnaire was performed to assess pre- and post-test confidence of subjects towards 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 Limits of Agreement (LoA) of 0.01 logMAR and an assumed standard deviation (SD) of 0.02 logMAR.⁸

Statistical analysis

Analyses were performed using SPSS (version 25, IBM, Armonk, NY, USA). 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 one line represented 0.10 logMAR. The Snellen test was measured in decimals and afterwards converted to logMAR. The analysis of variance between the web-based tool, Snellen and ETDRS charts was carried out 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 since this is the usual intraindividual variability in repeated visual acuity measurements.¹⁰⁻¹²

RESULTS

Firstly, a small test-retest sample was carried out among five 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 for 41 operated right eyes and -0.64 ± 1.33 diopters for 34 operated left eyes. The majority of 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

to the reference tests for right UDVA and CDVA, and left CDVA (Table 1). The differences between the visual acuity outcomes of the web-based tool were maximally -0.07 ± 0.10 logMAR ($p < 0.001$) compared to the ETDRS chart and had maximal value of -0.08 ± 0.12 logMAR ($p < 0.001$) compared to the Snellen chart. The correlation ranged from 0.70 to 0.94 and up to 88.2% of the web-based outcomes were within the clinically significant difference cut-off value of ± 0.15 logMAR (Table 2).

Table 1. Outcomes of different visual acuity assessments

Parameter	Visual acuity test	N	Mean \pm SD (logMAR)	Variance P-value
UDVA RE	ETDRS	41	0.15 \pm 0.30	.001
	Snellen	39	0.17 \pm 0.38	
	Web-based	41	0.22 \pm 0.30	
UDVA LE	ETDRS	34	0.14 \pm 0.27	.060
	Snellen	32	0.11 \pm 0.23	
	Web-based	34	0.17 \pm 0.27	
CDVA RE	ETDRS	41	0.03 \pm 0.22	.002
	Snellen	37	-0.04 ± 0.12	
	Web-based	41	0.06 \pm 0.21	
CDVA LE	ETDRS	34	-0.03 ± 0.15	<.001
	Snellen	33	-0.05 ± 0.08	
	Web-based	34	0.02 \pm 0.14	

RE = right eye; LE = left eye.

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

Table 2. Comparison of visual acuity outcomes of different tests

Parameter	Difference between tests	Mean \pm SD (logMAR)	P-value	Pearson correlation ^a	% within ± 0.15 logMAR
UDVA RE	ETDRS: web-based	-0.07 ± 0.10	<.001	0.94	82.9
	Snellen: web-based	-0.04 ± 0.16	.125	0.92	76.9
	ETDRS: Snellen	-0.03 ± 0.13	.172	0.95	76.9
UDVA LE	ETDRS: web-based	-0.04 ± 0.10	.037	0.93	88.2
	Snellen: web-based	-0.04 ± 0.13	.060	0.88	75.0
	ETDRS: Snellen	0.00 \pm 0.11	.925	0.90	87.5
CDVA RE	ETDRS: web-based	-0.03 ± 0.09	.029	0.91	85.4
	Snellen: web-based	-0.08 ± 0.12	<.001	0.70	73.0
	ETDRS: Snellen	0.04 \pm 0.09	.013	0.84	89.2
CDVA LE	ETDRS: web-based	-0.05 ± 0.08	.001	0.84	85.3
	Snellen: web-based	-0.06 ± 0.08	<.001	0.72	81.8
	ETDRS: Snellen	0.01 \pm 0.09	.697	0.68	90.9

RE = right eye; LE = left eye.

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

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 2A and 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 2B and 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 appendix (Supplementary Figures 1 and 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.

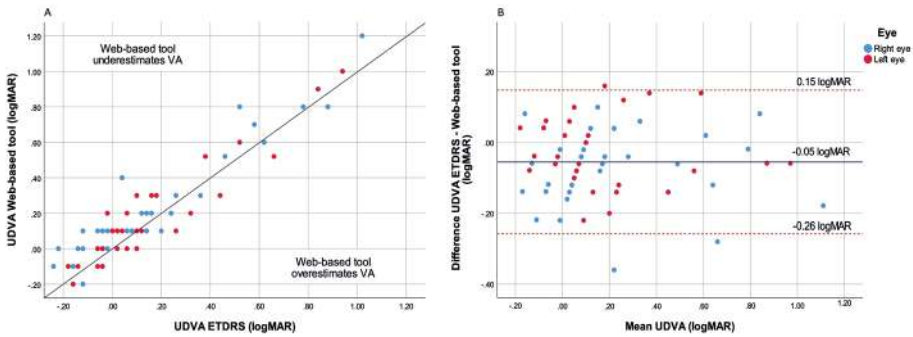


Figure 2. [A] Scatterplot UDVA of the web-based tool and ETDRS chart for the right and left eyes. The line presents the line of equality. [B] Bland-Altman plot of UDVA determined by the web-based and ETDRS chart. The blue line represents the mean value, and the red dashed lines represent the ± 1.96 SD (95% limits of agreement).

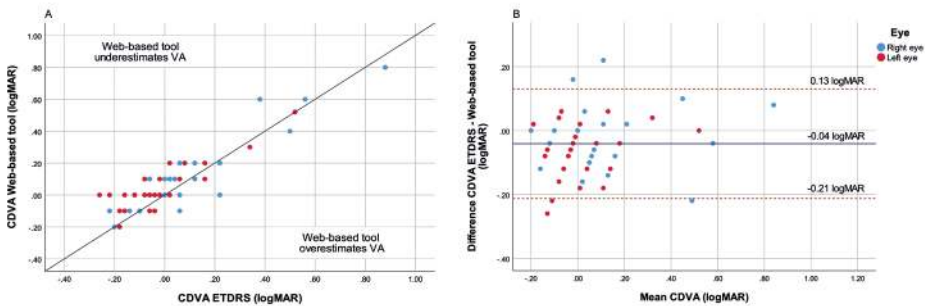


Figure 3. [A] Scatterplot CDVA of the web-based tool and ETDRS chart for the right and left eyes. The line presents the line of equality. [B] Bland-Altman plot of CDVA determined by the web-based and ETDRS chart. The blue line represents the mean value, and the red dashed lines represent the ± 1.96 SD (95% limits of agreement).

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 can be found in Figure 4. The distribution of these outcomes was skewed and therefore not suitable for additional analyses.

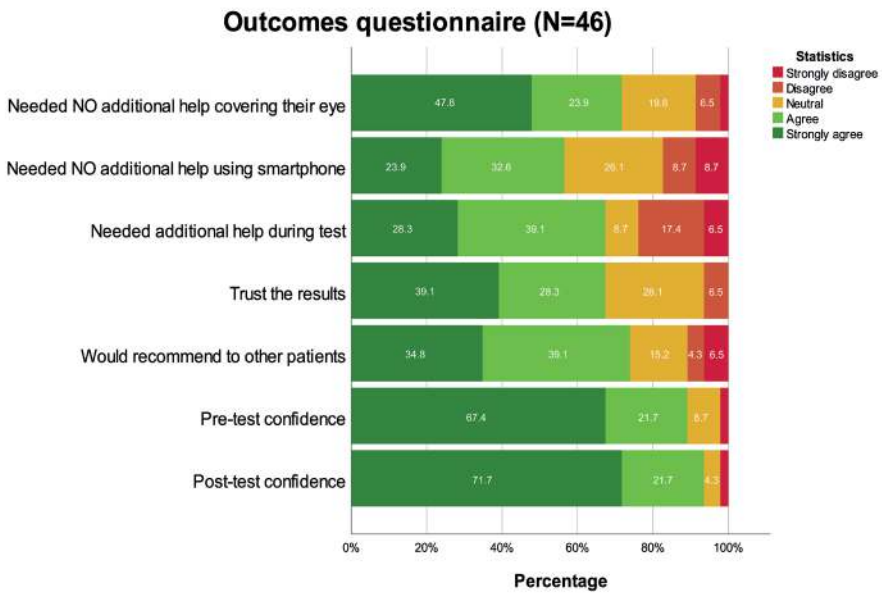


Figure 4. Outcomes of the questionnaire about the attitude and experiences of subjects using the web-based tool. Every questionnaire item was scored using a 5-level Likert scale. The outcomes are given in percentages.

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 cut-off 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, since 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 to -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 to 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 to 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 the majority of participants had a positive attitude towards the web-based tool. The net promotor score for the confidence towards 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 keratoconus patients 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 prior studies compared digital tools to 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 to the ETDRS chart, respectively. The 'Eye Chart' and 'Peek Acuity' were tested among healthy adults, with a mean age of respectively 64 and 65 years. 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, were performed at different testing distances (the 'Peek Acuity' and 'Vision at Home' tool at 2 meters testing distance, and the 'Eye Chart' at 4 feet (1.20 meters) distance), 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 to the Web-based tool in this study. According to a systematic review, digital tools were in general less accurate in measuring visual acuity compared to 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 psycho-physical 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 to a logMAR chart.¹⁹ Concerning the scoring methods, the letter-by-letter method is more accurate compared to 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 seven optotypes in each line instead of five. Above-mentioned characteristics contribute to the general variability between visual acuity tests. If the post-cataract 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 since 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 case of a non-significant 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. Prior studies compared Landolt rings with numbers and showed higher visual acuity outcomes (0.13 ± 0.14 logMAR) using number optotypes. Other confirmed these lower outcomes when using Landolt rings compared with 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. Lastly, 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 carried out once. As a consequence, no test-retest or intraindividual consistency results were obtained from patients, that 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 non-variable interpretation of patient responses by the tool. 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 to the conventional charts. Prior 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 post-cataract users of the web-based tool, further research is necessary. We can conclude that the differences among all three test outcomes in this study confirm the great variability generally observed.

Since the visual acuity assessments were carried out 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 non-randomized 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 in order 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.

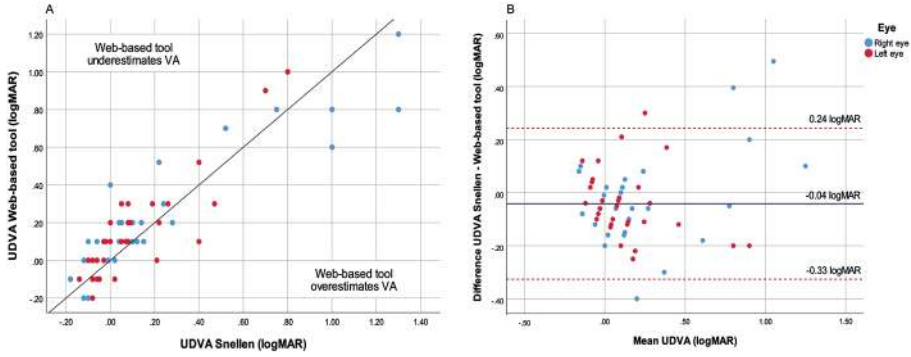
Based on the results of this study, the web-based tool is validated for assessment of the visual acuity in patients who underwent cataract surgery. The web-based tool showed different outcomes compared to the conventional tests for both the UDVA and CDVA, but the vast majority of these differences were 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.

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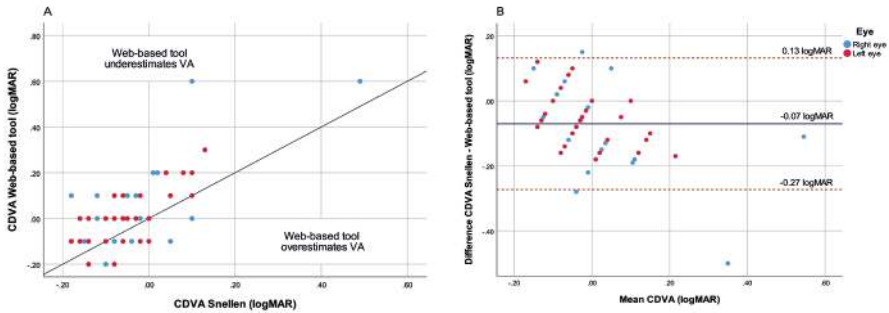
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SUPPLEMENTARY DATA



Supplementary Figure 1. [A] Scatterplot UDVA (Uncorrected Distance Visual Acuity) 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 Standard Deviation (95% Limits of Agreement).



Supplementary Figure 2. [A] Scatterplot CDVA (Corrected Distance Visual Acuity) 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 Standard Deviation (95% Limits of Agreement).



Chapter 7

**Rationale and design of a randomized controlled trial
to evaluate remote monitoring after cataract surgery**

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*Remote follow-up after cataract surgery (CORE-RCT): study protocol of a randomized controlled trial.
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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 in the telemonitoring arm 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 EQ5D-5L questionnaire²¹), 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 questionnaire²⁴), 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 1989²⁵, the model has been extended by multiple research teams, including for utilization in health care settings.²⁶⁻²⁸ 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 acuity²⁹⁻³¹), 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). 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 1.

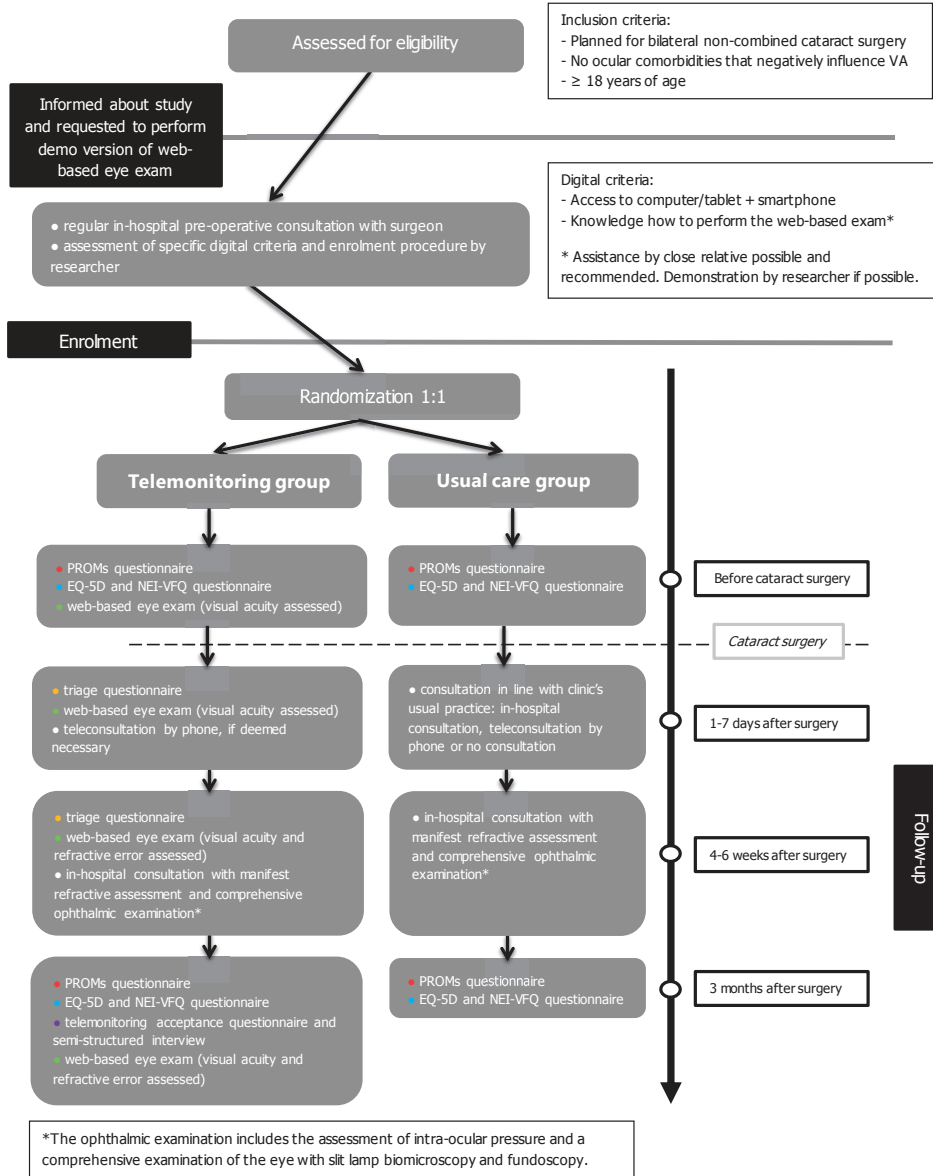


Figure 1. Flowchart of the CORE-RCT study procedures. Overview of study procedures: recruitment, randomization and study measurements.

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.

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 years¹⁴).

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 one 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 metres, 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 centimetres. 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 centres, 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-5L²⁴) and visual function (Catquest-9SF²², NEI-VFQ-25²³). 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 $P < .05$ is considered statistically significant.

Comparisons between the web-based eye exam and the conventional clinical assessments will be analysed according to the Bland-Altman methodology.³² We will compare assessments of distance visual acuity, near visual acuity and refractive error. Furthermore, we will analyse 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 8

Telemonitoring in cataract care: comparing web-based, self-administered follow-up to conventional face-to-face follow-up

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ABSTRACT

Purpose: Comparing 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 cataract patients were randomized into two 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 4-6 week post-surgery 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 good agreement with conventional ETDRS chart testing, with a negligible mean difference (-0.03 ± 0.14 logMAR). The web-based refraction assessment overestimated the postoperative refractive error (mean difference 0.15 ± 0.67 diopters), resulting in a poorer corrected distance VA compared to subjective refraction (mean 0.1 vs. -0.1 logMAR). Rates of adverse events and unscheduled consultations were minimal across both groups. Preoperative and postoperative PROMs questionnaires had a 100% response rate. Vision-related quality of life improved after surgery, yet did not significantly differ between the two groups.

Conclusion: The cataract patients in this study effectively provided postoperative outcome data via a web-interface. Both conventional and web-based follow-ups yielded similar PROMs outcomes and adverse event rates. The home-performed vision self-assessment provides reliable estimates of VA, and with additional training of its refraction assessment, the web-based platform appears a promising tool for telemonitoring after cataract surgery.

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, CO₂ emissions and absenteeism from work.³

Although national protocols vary, conventional cataract surgery follow-up typically involves routine face-to-face examinations to assess post-operative 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 employing 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 to 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; four located in the Netherlands (University Medical Center Utrecht, Maastricht University Medical Center+, Amphia Hospital Breda, Oogcentrum Noordholland), one in Austria (Vienna Institute for Research in Ocular Surgery) and one 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 via a relative), and an internet connection. Prior to enrolment, 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 enrolment, patients were randomly assigned (1:1) to one of the two 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 three distinct points in time: an early assessments within 1-7 days after surgery, a late assessment 4-6 weeks after surgery, and a final assessment at 3 months after surgery. All participants underwent a remote assessment of patient reported outcome measurements (PROMs) before and after surgery, and all participants underwent an in-office postoperative clinical assessment 4-6 weeks after surgery. The telemonitoring group was invited to perform the remote assessments within 5 days prior to the in-office assessment at 4-6 weeks after surgery. As such, a method comparison study design was embedded in the 'telemonitoring' arm, comparing the home-based self-assessment to the conventional in-office clinical assessment of visual acuity and refractive error. An overview of the study assessments can be found in Figure 1. Invitations for questionnaires and/or web-based eye tests were sent via e-mail. Any unexpected consultations or adverse events were recorded for both groups.

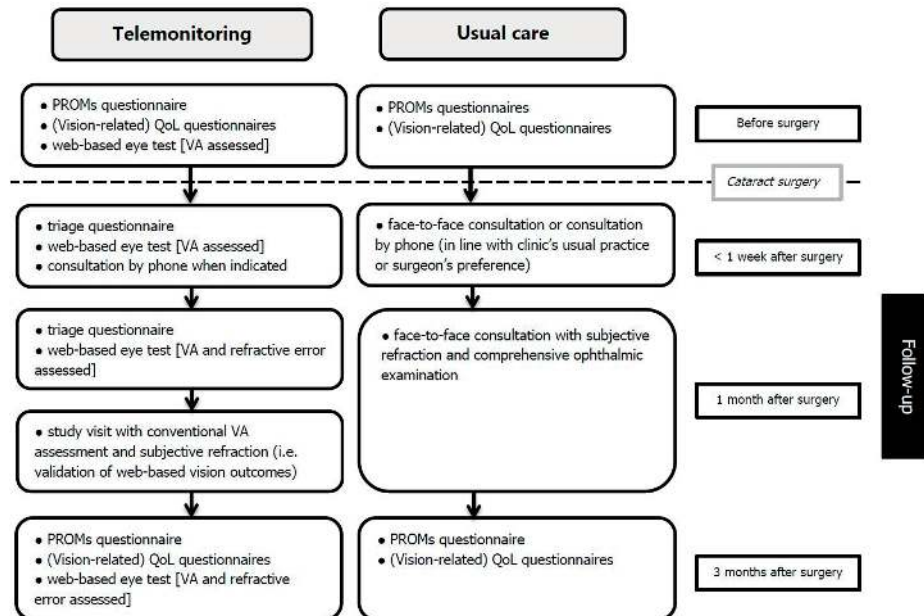


Figure 1. Study assessments. Abbreviations: VA= visual acuity; PROMs = patient reported outcome measurements, assessed by Catquest-9SF questionnaire⁹; (Vision-related) QoL = (vision-related) quality of life, assessed by NEI-VFQ-25¹⁰ and EQ-5D-5L questionnaire¹¹

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) employs an ISO 13485 Quality Measurement System and the tool is classified as Conformité Européenne (CE) class 2A medical device according to the Medical Device Regulation 2017/745.¹² An overview of the test flow and assessed determinants of visual function are found in Figure 2.

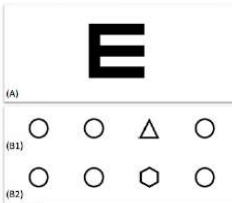
Set-up

- 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

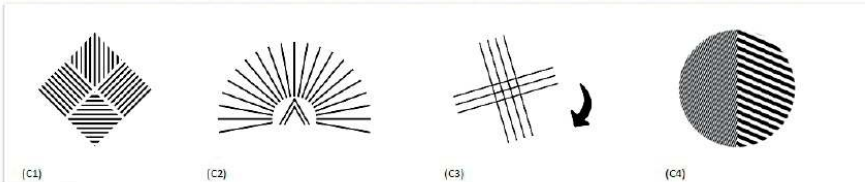
- Patients are requested to sit down on the chair and cover one eye with their hand, while the screen displays a sequence of optotypes and astigmatic dials that the patient must correctly identify with the contralateral eye. Answers are submitted by the patients (or their relative) on the smartphone.
- 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 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 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 4-6 weeks after surgery. 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 after surgery to those obtained 4-6 weeks after surgery. Here, participants were asked whether they had experienced a change in vision prior to 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.¹³⁻¹⁶

The web-based VA assessment consists of three parts. In each part a different optotype is used (see Figure 2). This results in three individual scores that are averaged to calculate the final web-based VA score. A 'human overread' 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 three separate VA tests of one 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 ETDRS charts at 4 meters (distance) and Sloan ETDRS charts at 40 centimeters (near).

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. Signation of the refractive error 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 measurements

Both study groups were sent digital questionnaires about (vision-related) quality of life (NEI-VFQ25¹⁰ and EQ-5D-5L¹¹) and patient-reported outcomes measurements (CatQuest-9SF⁹), preoperatively and 3 months after surgery in the appropriate language.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows version 29.0 (Armonk, NY, USA). All quantitative variables were summarized. The data were tested for normal distribution, and the appropriate (non-)parametric test was used. For all analyses, a $P \leq .05$ 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 (95%LoA, i.e. sampling error) will be 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 equations (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 two 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 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 , $P < .001$).

A total of 94 participants (188 eyes) were enrolled at baseline. Table 1 depicts their baseline characteristics.

Table 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 dioptres), 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 <-0.5 D)	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.

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 4-6 weeks after surgery is depicted in Figure 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 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 1).

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

A graphical comparison between the web-based and subjective refraction outcomes at 4-6 weeks after surgery is depicted in Figure 3B. These comparisons were made within the same subject and only refer to the telemonitoring group. The mean difference in spherical equivalent (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 prior to the web-based test are significantly associated with the accuracy of the SEQ assessment (see Supplementary Table 1), though the extent of these effects (β 0.01 and β 0.17) are not considered clinically relevant.

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. emmetropic patients will falsely be classified as ametropic). The attained mean CDVA achieved with the algorithm's web-based refraction increased compared to the mean pre-operative 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.

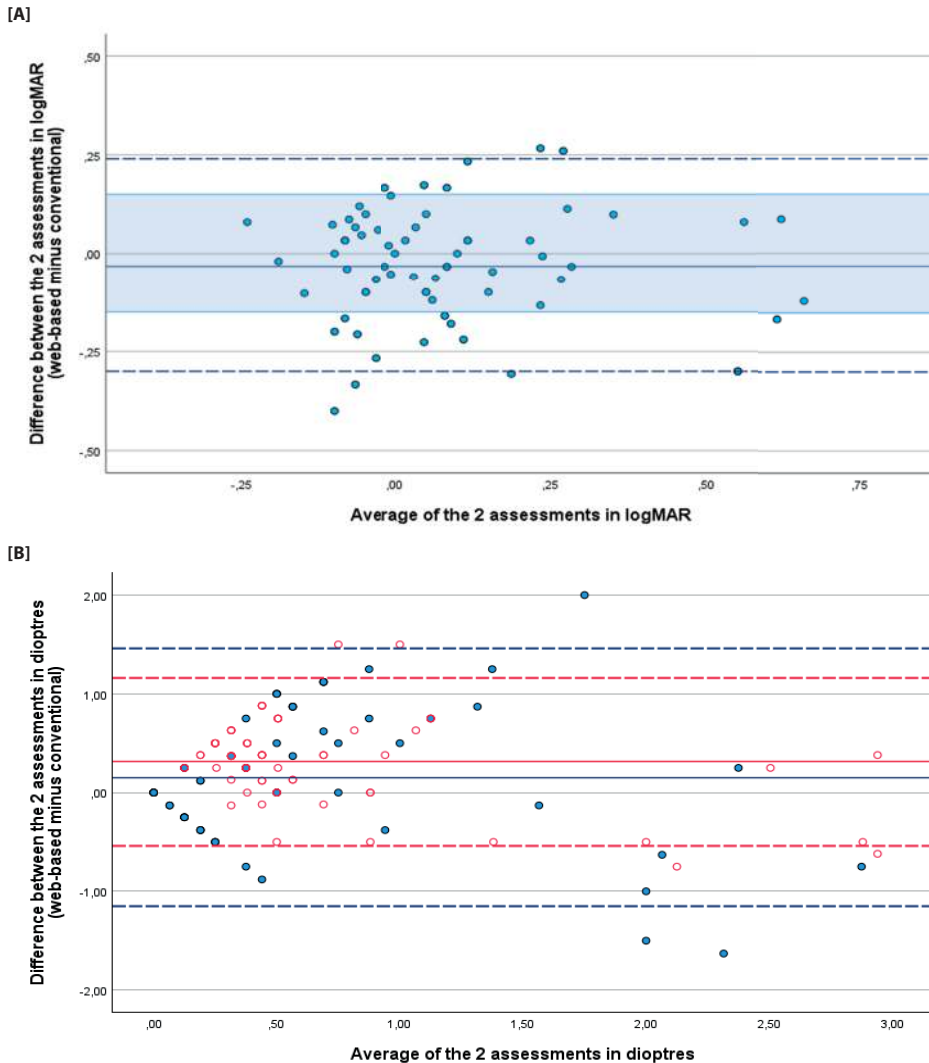


Figure 3. Comparisons of web-based vs. conventional assessments. Each circle depicts a monocular assessment. Please note that these two assessments were compared within the same subject and therefore only refer to the telemonitoring group.

[A] Web-based vs. conventional VA assessment, 4-6 weeks after surgery. The solid lines represents the mean difference; the dashed lines the 95% limits of agreement. The semi-transparent blue zone in depicts the pre-determined clinically acceptable deviation range of ± 0.15 logMAR.

[B] Web-based vs. conventional refraction assessment, 4-6 weeks after surgery. The solid lines represents the mean difference; the dashed lines the 95% limits of agreement. 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 3B represent the original web-based refraction algorithm; the red lines and red circles the updated algorithm.

Human overread

An unacceptable high within-test variation (*i.e.* during the same monocular exam) 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 to 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 due to an interoperative complication, underlining that a poor uncorrected distance visual acuity 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 1).

Safety

Adverse events and postoperative management changes

Most participants did not have a face-to-face consultation in the first week after surgery: 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 (as defined in Figure 1), 12 'usual care' and 7 'telemonitoring' participants contacted or visited the clinic. These unexpected consultations and consecutive management changes are depicted in Table 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 due to intraoperative difficulties. All of these underwent successful reoperations.

Table 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)	<i>Reassurance of patient</i>
Dry eye syndrome or blepharitis, n (%)	5 (42)	1 (14)	<i>Addition of lubricating drops</i>
Postoperative inflammation, n (%)	2 (17)	1 (14)	<i>Addition of anti-inflammatory drops</i>
Intraoperative complication, n (%)	2 (17)	1 (14)	<i>Reoperation</i>

Triage questionnaires

In addition to the web-based eye tests, the telemonitoring participants were asked to fill out triage questionnaires. The reported symptoms are depicted in Table 3.

Table 3. Outcomes of self-reported triage questionnaires

Self-reported symptom in triage questionnaire, n (%)	< 1 week after surgery, Total n= 87 eyes^a	± 1 month after surgery, Total 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 sent 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 can be found in the Supplementary Table 2. Visual functioning (indicated by the Catquest-9SF and NEI-VFQ-25 scores) improved after surgery for all participants (with a mean improvement of -0.80 and 16.70 respectively), and performing vision self-assessments did not materially impact these scores, as there were no significant differences between the two follow-up groups. The effects of cataract surgery on EQ5D-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 good agreement with conventional ETDRS chart testing, with a negligible mean difference of 0.03 ± 0.14 logMAR. The web-based refraction algorithm resulted in an overestimation of the residual refractive error and will falsely indicate a residual refractive error in emmetropic patients. Adverse events were rare and occurred in both groups. Telemonitoring and self-reporting led to a more detailed overview of post-operative symptoms and complaints, while not affecting the rate of unscheduled consultations. Vision-related quality of life improved after surgery with no apparent differences between groups.

The mean difference between the web-based VA assessment and the conventional chart was clinically negligible. However, one is also interested in the distribution of differences. When evaluating the accuracy of a vision assessment tool, 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. An authoritative study comparing repeated VA assessments with various charts and observers concluded that differences up to ± 0.15 logMAR should therefore be considered clinically irrelevant.¹⁴ Notwithstanding, outlier measurements may arise even beyond this limit, in the absence of clinical changes, due to behavioural factors such as fatigue or intrinsic motivation. This phenomenon has been confirmed 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.^{15,18} 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).^{15,18} The wide distribution of measurement differences indicated by the 95%LoA underlines that the occurrence of outlier measurements is an inherent aspect of assessing VA. Based on the 95%LoA, the here-found outcomes (95%LoA: -0.30 to 0.24 logMAR for the primary comparison and -0.25 to 0.29 logMAR for the repeatability) indicate a precision that is comparable to the Snellen chart, the most frequently used chart in clinical practice. Multiple telehealth tools for self-assessing visual function are available on the internet, though many have not been validated.¹⁹ Those that are validated, have mostly been evaluated in controlled settings, prone to observer bias.¹⁸ 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 – 0.15 logMAR).²⁰ Unsupervised home-assessments will arguably be more affected by behavioural and environmental factors than assessments in controlled settings. In the present study, the web-based test was performed independently by patients at home, reflecting a future real-world scenario. Future software updates are aimed at limiting effects of behavioural or environmental factors, such as using webcam images and provide AI-guided live feedback to optimize testing conditions (e.g. lighting and distance to the screen). In addition, high within-test variability could subsequently be addressed by automatically requesting participants to repeat the test at a later point in time under optimal testing conditions, potentially reducing the chance of unacceptable measurement variations.

An improvement in VA is indicative of surgical success. Most cataract guidelines also recommend a refraction assessment after surgery.²¹ Our findings indicate that the web-based refraction assessment requires a recalibration. The algorithm was trained on a population of young adults (aged 18-40 years old), with an excellent VA (>1.25 Snellen decimal)²². VA has been reported to decrease with age, even in healthy eyes, particularly after 55 years of age.²³ 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-aged adults. A dataset 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 (EUREQUO) and will be used to recalibrate the algorithm. An updated and accurate self-assessment of residual refractive errors after surgery 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.²⁴ 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 is 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.^{5,25} Unexpected management changes are unlikely in asymptomatic patients after uncomplicated surgery and a structured set of clinical questions (such as pain, redness, decreased vision etc.) has been proven sufficient to risk-stratify patients.^{21,26} A recent innovation is an automated telephone consultations with AI-driven clinical assistants, combining a low-tech method of delivery with a high-tech *large language model* driven solution²⁷ 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.

Lastly, we would like to underline that conventional follow-up care involving face-to-face visits should always remain accessible. Even though high patient satisfaction rates for remote cataract surgery follow-up, involving (automated) telephone consultations^{28,29} and/or self-assessments of visual function³⁰, have been reported, the recruitment phase of this trial appeared challenging. 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 due to a lack of access to mobile devices or insufficient proficiency to carry out 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.³¹ Internet access has, however, been growing rapidly across Europe over the last decade and we expect the group of digitally skilled cataract patients 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 for complications and postoperative management changes is crucial. This includes patients with known risk factors for endophthalmitis (e.g. blepharitis, ectropion^{32,33}), uncontrolled intraocular pressure elevation (e.g. glaucoma, ocular hypertension^{34,35}) or post-operative 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. 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 cataract patients were able to complete unsupervised self-assessments of visual function, and self-report postoperative outcome measures. Adverse events or (vision-related) quality of life did not differ between the two follow-up groups. The studied web-based test delivers estimates of visual acuity that are as reliable as Snellen chart assessments, but assessed independently by patients at home. The web-based refraction assessment requires a recalibration, with future training building on a normative dataset derived from EUREQUO. 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.

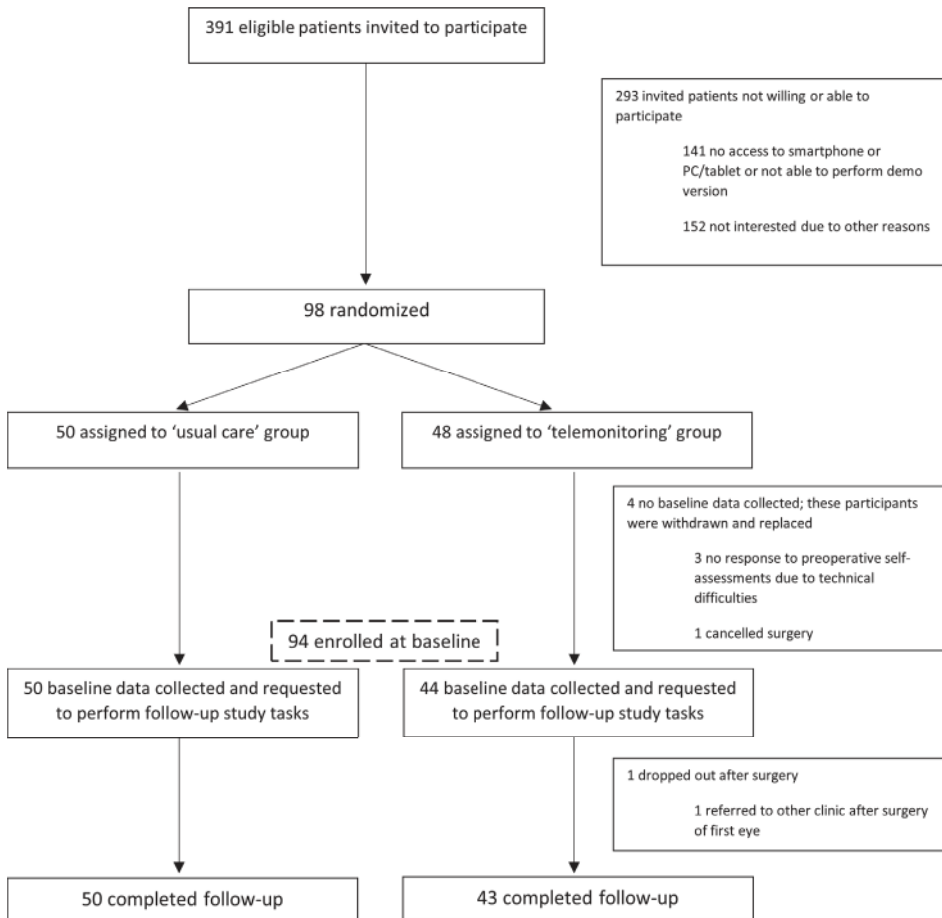
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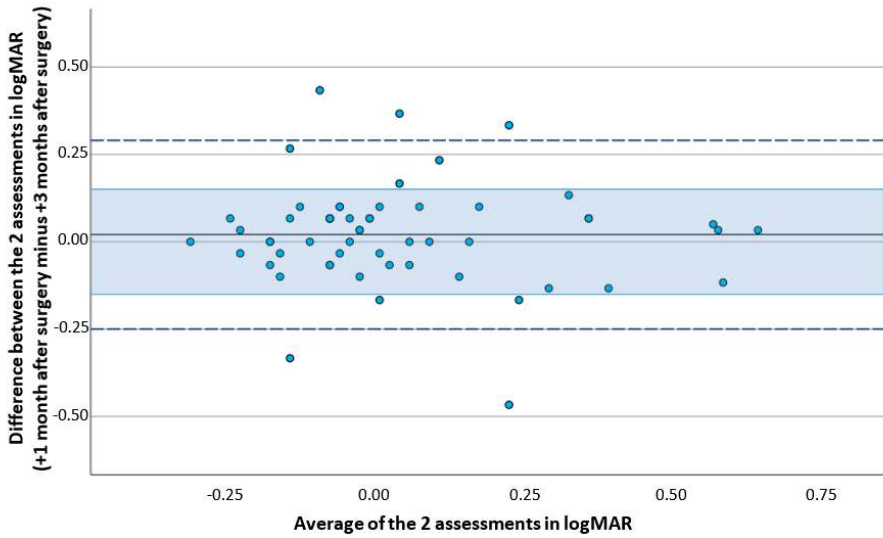
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SUPPLEMENTARY DATA



Supplementary Figure 1. Trial profile.

Note: 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 protocol⁷).



Supplementary Figure 2. Repeatability of the web-based visual acuity (VA) assessment.

Bland-Altman plot comparing VA assessment 4 to 6 weeks after surgery vs. 3 months after surgery. Each circle depicts a monocular assessment. The solid 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.

Supplementary Table 1. Multivariable GEE analysis to investigate associations between clinical variables and the accuracy of the web-based vision assessments

Characteristics	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 dioptres ^a			Within-test variation > 0.20 logMAR		
	B	95% CI	P-value ^b	B	95% CI	P-value ^b	B	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

VA = visual acuity; SEQ = spherical equivalent; B = beta estimate (on the logit scale); CI = confidence interval

^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 <0.5 dioptres) as reference

^e 'no reported symptoms' as reference (symptoms include photophobia, itchiness, oppressive feeling, gritty feeling, burning sensation or pain)

Supplementary Table 2. Outcomes of self-reported (vision-related) quality of life questionnaires

	Both groups	Telemonitoring group	Usual care group	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
EQ5D-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 Index Value Calculator



Chapter 9

Patient perspectives on a web-based eye test for postoperative telemonitoring in cataract care

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Introducing e-health technology to routine cataract care: patient perspectives on web-based eye test for postoperative telemonitoring.
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ABSTRACT

Purpose: To explore cataract patients' experiences with an e-health tool for self-assessing visual function (i.e. a web-based eye test), and to formulate recommendations for its successful adoption in routine cataract care.

Setting: Clinics in the Netherlands, Germany and Austria.

Design: Mixed-methods study.

Methods: Questionnaires and in-depth semi-structured interviews were conducted alongside a multicenter randomized controlled trial evaluating the validity, safety and cost-effectiveness of remote care after cataract surgery (CORE-RCT). Results were analyzed thematically.

Results: A total of 22 participants were included in this study. In-depth interviews were conducted with 12 of them. Participants reported positively about performing the web-based eye test at home. Four overarching themes were identified in the interviews. First, participants were inventive in overcoming practical barriers encountered while conducting the test. Second, participants desired a clear presentation of test results and their meaning. Third, the ability to self-monitor visual function was appreciated. Fourth, most participants preferred to remain the option to contact their eye care professional postoperatively, especially when experiencing symptoms. Most would be satisfied with a phone consultation or an E-consult.

Conclusions: Participants reported positive experiences with the studied web-based eye test. Barriers for successful adoption were identified, including: insecurity about correctly performing the test, incomplete information on how to interpret test results, and a feeling that in-hospital assessments are superior to remote assessments. We propose recommendations to focus on building trust in remote eye care delivery, and acknowledging the need to retain access to the ECP when medically indicated or deemed necessary by the patient.

INTRODUCTION

The interaction between health care providers and patients is increasingly mediated by a variety of digital technologies, commonly referred to as “e-health”.¹ E-health technology allows remote health monitoring and can contribute to the transition towards patient-centered care by engaging patients in their own health and well-being.²

Several applications for self-assessing visual function have been introduced over the last decade.³ These ‘web-based eye tests’ could enable patients to self-assess visual function at home and provide themselves and their eye care professionals (ECPs) with measurements without visiting a clinic. Thereby, web-based eye testing has the potential to improve efficiency of certain ophthalmic patient journeys, by increasing possibilities for monitoring patients remotely (i.e. telemonitoring). The high volume of surgical procedures and low adverse events rates make routine cataract surgery follow-up particularly interesting. However, it might be challenging to introduce web-based eye tests to cataract patients, as the condition is most commonly age-related. Many older adults face barriers to e-health engagement such as a lack of confidence in (or knowledge of) using digital technology.⁴

For successful adoption of e-health technology, it is crucial to look beyond aspects of validity, safety and cost-effectiveness, and also take the patients’ perspective into account, especially during the development phase.^{5,6} Therefore, this study aims to explore cataract patients’ experiences with a web-based eye test, and to formulate recommendations for its successful adoption in routine cataract surgery follow-up care.

METHODS

This mixed-method study was embedded in a prospective clinical trial: Cataract Online Refraction Evaluation, a Randomized Controlled Trial (CORE-RCT) (ClinicalTrials.gov: NCT04809402). The study was performed in accordance with the Declaration of Helsinki and approved by the METC 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.

Cataract patients without ocular comorbidities, with planned bilateral surgery either immediate or delayed sequential, were invited to participate. Patients were eligible when meeting technical requirements before enrolment, meaning that they should be able to access the studied web-based eye test at home using their own devices without pre-

ceding extensive (onsite) training. After enrolment in the CORE-RCT, participants were randomized into either a “usual care”, or “telemonitoring” group. This mixed-methods study specifically focuses on the latter. These “telemonitoring” participants performed the web-based eye test at four specific time points: prior to the surgery, within one week after the surgery, approximately one month after the surgery, and three months after surgery. A hospital visit was planned at approximately one month after surgery, for the purpose of validating the web-based eye exam outcomes. After the last web-based eye test, participants were asked about their experiences in questionnaires and interviews. In this study, all questionnaire respondents between April 19, 2021 (the trial start date), and November 1, 2022 were included. In addition, semi-structured in-depth interviews were conducted with Dutch-speaking participants only.

The web-based eye test

The studied test has been developed by Easee BV (Amsterdam, the Netherlands). It allows users to self-assess visual acuity or refractive error using their own electronic devices (a computer or tablet, and a smartphone). In this trial, a hyperlink to access the test was sent via e-mail. Though the web-based test can be performed independently, it was recommended to perform it with assistance from a relative, if possible.

The web-based test consists of three phases: set-up, vision assessment, and results. Audio and written instructions guide users through the test. Figure 1 depicts an overview of the different phases. Preoperatively, patients wore their current glasses (if applicable) while performing the test, assessing corrected distance visual acuity. Postoperatively, the test was performed without correction, assessing uncorrected visual acuity (distance and near) and refractive error.

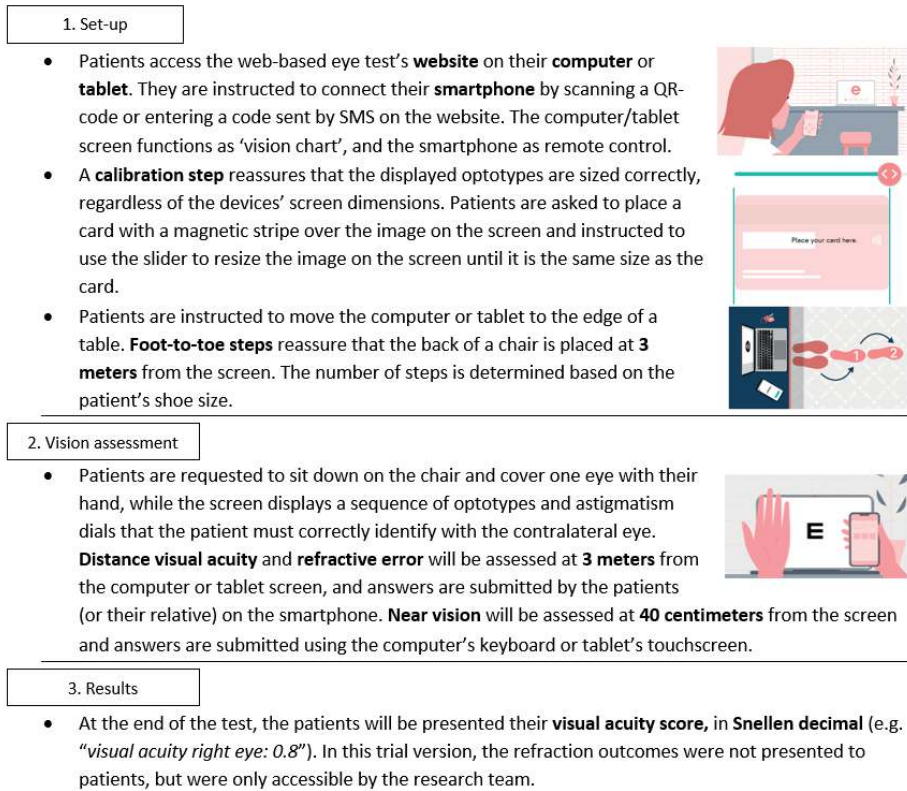


Figure 1. Overview of the three different phases of the studied web-based eye test.

Data collection and analysis

Questionnaires

The questionnaire used in this study is based on the theoretical Technology Acceptance Model; a commonly used model to evaluate and incorporate user experience in the development process of technology.⁷⁻⁹ Since its introduction, multiple research teams have extended this model, including to make it applicable to health care settings.^{5,10,11} These models formed the reference framework for adoption into a questionnaire specific for web-based eye testing.¹² The full study questionnaire can be found in Supplementary Table 1.

Interviews

To deepen the quantitative results, qualitative insights were gathered using the Consolidated Criteria for Reporting Qualitative studies (COREQ).¹³

Semi-structured interviews took place by phone (n=9), or by video call (n=3), as preferred by the participant. JC and EM, both medical doctors with experience in (qualitative) research, conducted the interviews. The interview topic list was based on preliminary questionnaire results. Interviews were conducted until saturation was reached, meaning that new insights were no longer gained. Interview transcripts were imported into NVivo (Release 1.5.1) and analyzed thematically. The initial coding scheme was based on the topic list and extended by additional themes emerging from transcripts analyses.

RESULTS

Participant characteristics

A total of 22 participants were included. In-depth interviews were conducted with 12 of them. The demographics and clinical characteristics are shown in Table 1.

Table 1. Demographics and clinical characteristics

Parameters		All participants (n=22)	Interviewees (n=12)
Age (years), mean (SD)		70 (7)	71 (6)
Sex (male), n (%)		14 (64)	6 (50)
Country, n	The Netherlands	12	12
	Germany	3	0
	Austria	7	0
Best corrected visual acuity score assessed at the clinic, in logMAR, mean (SD)	Preop, right eye	0.27 (0.19)	0.29 (0.22)
	Postop, right eye	-0.03 (0.09)	-0.04 (0.08)
	Preop, left eye	0.25 (0.20)	0.35 (0.23)
	Postop, left eye	-0.05 (0.11)	-0.03 (0.12)
Postop target refraction, n (%) ^a	Emmetropia	18 (82)	8 (67)
	Myopia (-2.00 D)	4 (18)	4 (33)
Vision-related quality of life score (scale 0-100), mean (SD) ^b	Preop	76 (12)	76 (15)
	Postop	91 (5)	94 (4)
General health condition: self-rated health score at baseline (scale: 0-100%), mean (SD) ^c		84 (17)	80 (22)
Self-reported travel distance between home and eye clinic in km, mean (SD)		11 (7)	9 (5)
Assisted by relative while conducting the web-based test, n (%)		6 (27)	3 (25)
Device used for web-based test, n (%)	Desktop computer	10 (46)	4 (33)
	Laptop	10 (46)	7 (58)
	Tablet	2 (9)	1 (8)

^a Postoperative target refraction was similar for both eyes

^b Based on NEI-VFQ-25 questionnaire¹⁴

^c Based on EQ-5D-5L visual analogue scale at baseline¹⁵

Quantitative analysis

Figure 2 depicts responses to a relevant subset of the questionnaire. The full questionnaire outcomes can be found in the Supplementary Table 1.

An overall positive attitude towards the web-based eye exam was identified. The vast majority was willing to use e-health services like the web-based eye exam in the future (mean 4.1/5.0), and considered the web-based eye test useful for self-monitoring visual function (3.9/5.0). The web-based eye exam was reported to be easy to use (3.8/5.0), participants felt adequately capable of using their own electronic devices for e-health services (4.3/5.0), and most participants stated that they would be able to complete the eye test independently, without assistance (3.7/5.0). The web-based eye test was considered trustworthy by almost all participants (4.3/5.0), and participants trust their physician's judgement on the employment of the web-based eye test (4.3/5.0).

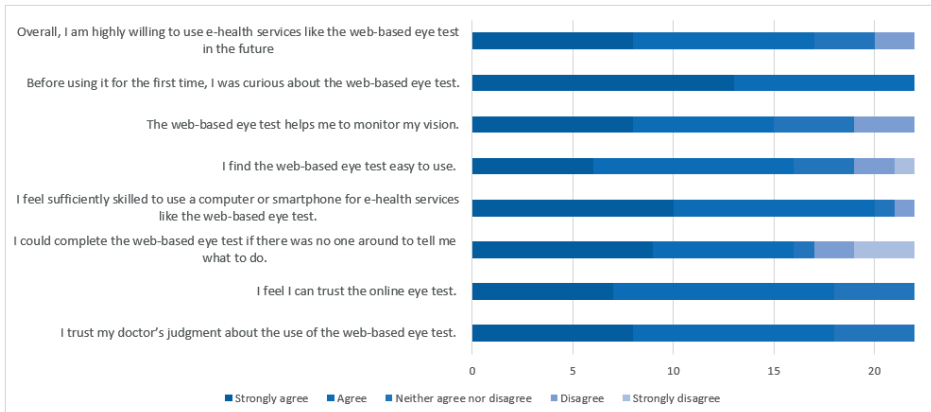


Figure 2. Selection of questionnaire results.

Qualitative analysis

Participants reported positively about performing the web-based eye test. In general, instructions were considered clear and participants were adequately capable to perform the web-based test. One participant explicitly stated that the test was “way too difficult, for older aged adults”.

All participants were first-time users of the web-based eye exam and many stated that, initially, the set-up in their home environment felt odd. Though, their familiarity with the testing environment and the tool itself increased over time. The vast majority executed the test independently, some (n=3) were assisted by a relative, especially for controlling the smartphone during the vision assessment.

Four overarching themes were identified in the data. Relevant quotes are depicted in Table 2.

Table 2. Quotes illustrating interviewee perspectives

Theme	Quote ^a
Interpretation of web-based test results	<p>Q1: Yes, so the number 0.25 is presented to me, and it leaves me thinking: “What am I supposed to do with that? What does it mean?” <i>73-year-old male</i></p> <p>Q2: The instructions were all clear and easy to follow. But trusting myself in terms of thinking: “I am doing this right”, that’s not there yet. It may, however, be possible... but I might be a bit old-fashioned, due to my age. I can image that younger people trust this practice more easily. <i>78-year-old male</i></p>
Value for self-monitoring	<p>Q3: You can print the test results and self-monitor the improvement. I thought that was very interesting. I must admit that I even performed the test one extra time, in between the requested testing. (...) I must also admit that I had my wife perform the test as well, to get an impression of her visual function. <i>57-year-old male.</i></p> <p>Q4: By explaining what’s going to happen and explicating what it means, the test result... the patient says “I am being taken seriously. I execute the test, a result follows, and I also understand what it means.” <i>73-year-old male</i></p>
Need for human interaction	<p>Q5: During the hospital visit, they (i.e. the eye care professionals) do not only assess the visual function. They also look behind the eyes. Maybe they are checking if the lens has been correctly implemented, I don’t know. <i>71-year-old female</i></p>

^a Quotes have been translated from Dutch to English.

Theme 1: Inventiveness to overcome practical barriers

While quantitative results indicated that participants had no difficulty in conducting the test, the interviews revealed that participants did experience some challenges while doing so. Notably, participants were inventive in overcoming these challenges, and their general user experience was not negatively affected. The main challenge reported was controlling the smartphone during the vision assessment, as the postoperative test is performed without glasses and most of the participants require reading glasses for near work activities because their postoperative target refraction was emmetropia. In addition, some mentioned they were not used to controlling their smartphone with one hand, while also holding it (the other hand was covering their eye). Some overcame this by asking a relative to control the smartphone. Others, despite having a relative around, took other steps to complete the test independently. These included increasing the distance between their eyes and smartphone by stretching out their arm, or placing their smartphone on a table and using a pencil-eraser to control the touchscreen. Others increased the smartphone’s font size or intermittently put on reading glasses during the assessment.

Theme 2: Interpretation of web-based test results

At the end of the test, the visual acuity scores were presented in Snellen decimal. Participants' interpretation of these presented test results varied greatly. Some paid little attention to the result page, or reported that they did not know how to interpret the scores. Other participants actively engaged with the presented scores by comparing them to previous web-based or in-hospital visual acuity scores, and actively drew conclusions (e.g., that their eye sight has improved). Regardless of these different interpretations, all participants expressed the desire for being presented a result at the end of the test. Presenting only a numerical score without additional information, was confusing to some. They stressed the need for additional information on how to interpret test results (e.g., "Is the score good/bad?") and whether follow-up actions are required; information that was currently considered incomplete. (Quote 1, Table 2).

Though the quantitative results indicated that most participants 'trust' the web-based test, many reported that their opinion on the test's trustworthiness turned positive only after having seen that the results were fairly similar to in-hospital findings. Participants were explicitly asked if they would trust the web-based test to the same extent, without confirmation of results during an in-hospital consultation. All answered that they consider a conventional in-hospital assessment more trustworthy. Reasons for being hesitant to trust the web-based test revolve around being insecure about correctly performing the test. This was partly due to the absence of feedback on their performance, and the inability to ask questions to get this feedback. Also, participants questioned whether their personal devices were sufficient for the web-based test, and mentioned an unfamiliarity with home-based testing in general. (Quote 2, Table 2).

All participants stated that, one way or another, the web-based test result requires confirmation. Most considered the test trustworthy for future use after a single confirmation of the result, potentially negating the desire for additional in-hospital follow-up. The majority desired confirmation by an ECP during an in-hospital consultation. Others, thought it would be sufficient to receive computerized textual feedback on their performance, or human feedback from an ECP remotely (e.g., by phone).

Theme 3: Value for self-monitoring

Participants who actively engaged with the test results mostly appreciated having access to these themselves. Some reported that 'active' self-testing resulted in greater insights in their visual improvement, as compared to 'passively' being assessed at the hospital. When desired, participants could -and regularly did- repeat the web-based eye test to monitor visual function over time. Some expressed an intention to use the tool again in the future when suspecting a visual deterioration. (Quote 3, Table 2) One

participant remarked that being given the tools for self-monitoring in follow-up care is a sign of 'being taken seriously' and that the patient's input is valued. (Quote 4, Table 2)

Participants were positive about being able to perform the web-based test at moments suitable to them. It was mentioned that self-testing saves time and efforts related to clinic visits, and that this could be beneficial for patients with limited mobility. Yet, this study population did not consider visiting the hospital as an evident barrier.

Theme 4: Need for human interaction

The opinions on interaction between patients and ECPs in remote cataract surgery follow-up varied. The majority of participants wished to maintain the option to contact their ECP, mainly to discuss questions or postoperative symptoms. It was suggested to incorporate a functionality in the web-based test for reporting symptoms. Most would be satisfied with a phone consultation or an E-consult (e.g., via e-mail/chat), while others explicitly appreciate an in-hospital consultation. Some mentioned that they would not require human interaction if web-based test results were good and symptoms or questions absent.

Some participants mentioned that they value in-hospital consultations for being more comprehensive than web-based eye testing, as these consultations usually include slit lamp examinations in addition to the vision assessment. Furthermore, other examinations, such as "scans", could be performed easily when at the clinic. Notably, it was not always clear to participants what in-hospital examinations were performed exactly, yet they valued being examined by an ECP, even in the absence of symptoms. (Quote 5, Table 2)

Apart from medical reasons, some participants appreciated human interaction for its social dimension, namely for expressing gratitude to the surgeon, or sharing experiences regarding the surgery and recovery period. It was specifically mentioned by some that this may be a characteristic of their generation, being of older age and not particularly familiar with digital communication in general.

DISCUSSION

This study analyzed patients' experiences with a web-based test for self-assessing visual function after cataract surgery. Overall, participants reported positively about the test. Instructions were considered clear and even though some practical challenges were encountered while performing the test, participants were inventive in overcoming these and their overall user experience was not negatively affected. Almost all participants were willing to use the test again in the future. Though participants reported being adequately capable of performing the test, several barriers for successful adoption were identified in the interviews. We argue that focusing on these barriers in further improvements of the test facilitates its adoption in cataract care.

The first barrier was insecurity about performing the web-based test correctly. Participants missed feedback on their performance. Furthermore, some questioned whether their own devices were sufficient. This is in line with a study amongst 46 million senior Americans, which identified that many lacked confidence to use electronic devices for online activities.¹⁴ We expect that this insecurity will fade away over time, as usage of internet services is growing rapidly.¹⁵ Future cataract patients will generally be more familiar with technology.

Interestingly, all participants desired a confirmation of the test results, including those who were confident about performing the test correctly. This suggests that the need for confirmation of the test results is not solely dependent on a (generation-specific) unfamiliarity with technology. We acknowledge that patients desiring an in-hospital confirmation after every remote self-assessment would jeopardize the justification of investments in remote eye care. Interestingly, most participants reported that a single confirmation of the test result was sufficient for trusting the test in future attempts. We suppose that granting patients access to the technology prior to surgery, could allow them (and the ECPs) to assess their ability to use this test, and concurrently allows for a confirmation of the result, reassuring them to trust the test in the future.

A second barrier was the inability to interpret web-based test results. Solely reporting a numerical score, without any further information regarding its meaning or additional steps to be taken, was confusing to some participants. In the absence of an ECP, participants expressed a wish to be well-informed about their eye status after completing the test, and which follow-up actions are required (e.g., contacting the clinic). This indicates that patients are motivated to actively participate in follow-up care. By providing patients the opportunity to do so, the web-based eye test recognizes the central role of patients as informed and engaged partners in decisions affecting their own health. This

contributes to promoting patient-centered care, a key element and goal for health care in the 21st century.^{2,16}

Thirdly, some participants expressed the feeling that in-hospital assessments are superior to web-based home-assessments, as more comprehensive examinations can be performed if needed. This line of thought was also captured in a recent study amongst non-ophthalmic patients, evaluating patients' attitudes towards telephone consultations during the COVID-19 pandemic. Here, most patients were worried about the accuracy of their health assessment in the absence of physical examinations and non-verbal communication.¹⁷ It suggests a general feeling that quality of care is reduced when delivered remotely. However, examples are available where remote care appears a feasible and safe alternative to in-hospital assessments.^{18,19} In addition, in the context of cataract surgery follow-up, the value of a comprehensive ophthalmic examination after uneventful surgery is debatable when patients do not experience symptoms, as shown by a large comparative cohort study on cataract follow-up in Finland.²⁰ According to the Dutch national cataract surgery guideline, clinically relevant outcomes indicative of surgical success are the improvement of visual acuity and visual functioning after surgery.²¹ These outcomes can be assessed remotely with the here studied web-based eye test, complemented with patient-reported outcomes (PRO) questionnaires focusing on vision-related daily life activities (such as the Catquest-9SF²²).

Even when the aforementioned barriers are adequately overcome, it should be noted that human interaction remains important. Patients wish to communicate with their ECP to discuss symptoms or ask questions. For some, the social dimension is a fundamental part of (follow-up) care.

Recommendations

Based on the included cataract patients' experiences with the web-based eye test, we formulated the following recommendations to advance its successful adoption in routine cataract surgery follow-up care:

1. New versions of the web-based test should address the patients' need for feedback during the test, e.g. by providing artificial intelligence-guided live feedback during the vision assessment. Furthermore, the result page should include more information on how to interpret test results and which additional actions are required.
2. The web-based eye test should be introduced to patients before surgery, e.g. by providing a brief instruction guide requesting patients to access and perform the test prior to the preoperative consultation. This allows confirmation of the web-based test result during this consultation, thereby both assisting ECPs to assess patients' eligibility and creating patients' trust regarding the test result. Furthermore, 'practic-

- ing' the web-based test preoperatively, fosters the patients' capacity to perform the assessment after surgery.
3. Costly and time consuming training of patients should be avoided. Patients who are unable to complete the web-based eye test after brief instructions, or who do not have a relative that can assist them in achieving this, should not be considered eligible. The web-based eye test is designed to be intuitive and self-explanatory, and those with basic digital skills should be able to complete the test at home without training.
 4. At the preoperative consultation, ECPs should invite patients to contact them post-operatively when experiencing alarm symptoms.
 5. A safety guard should be implemented to ensure that patients with these symptoms are adequately identified and contacted by their ECP, in the case they do not reach out themselves. This could take the form of a self-reported triage questionnaire, as an addition to the web-based vision assessment, linked to an automated warning system.
 6. Naturally, the option for conventional, in-hospital follow-up should remain open to those who are not willing or able to perform the web-based test at home.

Strengths and considerations

The mixed-methods approach allowed for a deeper understanding of patients' experiences with the web-based eye test, as insights gained during the in-depth interviews were supplementary to the quantitative questionnaire results. Interviews were conducted until data saturation was reached, meaning that no longer new insights were gained. This is the most commonly employed concept for determining sample sizes in qualitative research.^{23,24} Sample sizes in qualitative studies, like the present study, are commonly smaller than in clinical studies based on quantitative research.

Interestingly, barriers identified in this study relate to more general themes revolving around remote care, such as the unfamiliarity with technology and the altered human interaction. Therefore, a strength of the present study is that these insights will add to the academic and societal debate on how e-health technology should meet the health-care needs of older adults.

It is important to note that only patients who were willing and able to use the web-based eye test were included. Participants with an innate sense of curiosity and general interest in technology are known to be more likely to engage with e-health.⁴ There is a group of patients whose low digital literacy may restrict them from using this web-based test. Notwithstanding, in this emerging field, the feedback of early technology

adopters is most valuable to improve the web-based eye test and increase the access to remote eye care delivery.

In this research setting, all participants had an in-hospital examination to validate the web-based test. Future research could investigate the web-based eye test without a parallel offering in-hospital consultation. It is important to realize that this setting means that ECPs will have to rely on the patients' own measurements. Self-testing technology shifts tasks and responsibilities to patients.²⁵ For some, this additional burden may be stressful.²⁶ Notwithstanding, this new practice will also have implications for the ECPs. It would be interesting to explore their perspectives on web-based eye testing.

Conclusions

This study evaluated patients' experiences with a web-based test for self-assessing visual function after cataract surgery. Overall, patients reported positively about their experience with the test. Barriers for adoption were identified. To further promote successful adoption of the web-based eye test in cataract surgery follow-up care, recommendations were formulated. These focus on building trust in remote eye care delivery, and acknowledging the need to retain access to the ECP when medically indicated or deemed necessary by the patient.

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SUPPLEMENTARY DATA

Supplementary Table 1. Full study-specific questionnaire outcomes

	Score (mean/5)
Behavioral Intention	
1. Overall, I am highly willing to use e-health services like the web-based eye test in the future	4.0/5 4.6/5
2. Before using it for the first time, I was curious about the web-based eye test.	4.3/5
3. I find it would be good to use a web-based eye test to monitor vision after surgery.	
Performance Expectancy	
1. I find a web-based eye test useful.	4.0/5
2. The web-based eye test helps me to monitor my vision.	3.9/5
Effort Expectancy	
1. The instructions of the web-based eye test are clear and understandable.	4.4/5
2. It was easy for me to learn how to use the web-based eye test.	4.2/5
3. I find the web-based eye test easy to use.	3.8/5
4. Using the web-based eye test does not require me much effort.	3.6/5
Facilitating Conditions	
1. Before participating in the study, I had the resources (smartphone, computer or tablet) available to do the web-based eye test.	4.3/5 4.4/5
2. I feel like I have the knowledge necessary to fully complete the web-based eye test.	4.1/5
3. I believe there is adequate assistance available when encountering problems with the web-based eye test.	
Technology Anxiety	
1. I feel sufficiently skilled to use a computer or smartphone for e-health services like the web-based eye test.	4.3/5 1.8/5
2. I hesitate to use a computer or smartphone (for e-health services like the web-based eye test) for fear of making mistakes.	1.6/5 1.8/5
3. The web-based eye test is somewhat intimidating to me.	
4. Using the web-based eye test makes me feel uncomfortable.	
Self-efficacy	
1. I could complete the web-based eye test if there was no one around to tell me what to do.	3.8/5 2.3/5
2. I need assistance by someone else while using the web-based eye test.	
Trust/reliability	
1. I feel I can trust the web-based eye test.	4.1/5
2. I trust in the data protection and privacy of e-health services like the web-based eye test.	4.2/5
Doctor's opinion	
1. I trust my doctor's judgment.	4.5/5
2. I trust my doctor's judgment about the use of the web-based eye test.	4.2/5

Based on 5-point Likert scale.

5 = strongly agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; 1 = strongly disagree

Section 3

Synthesis



Chapter 10

Summary and discussion

In this thesis, we explored the role of telemonitoring in ophthalmology. This chapter will summarize the main findings of this thesis and address the clinical implications and future perspectives.

SUMMARY

The **first section** of this thesis focused on the development and evaluation of digital technologies for remotely assessing ophthalmic patients, placing emphasis on vision self-assessment tools. We started by reviewing the existing evidence on the accuracy of these tools in **chapter 2**. A plethora of digital tools are available on the Internet and in mobile apps, though clinical validation is often lacking.¹ In our review, we report 17 studies comparing VA scores obtained by self-assessment tools using websites or mobile apps, to scores obtained using traditional wall chart assessments. Although the mean differences between the two methods were minimal, there was a notable variation in scores on individual levels, generally surpassing the variability typically observed in traditional chart testing. Interestingly, we observed varying outcomes when the same tool was studied in different study populations and/or vision ranges. Apparently, VA assessments become more challenging in poorer VA ranges and possibly more susceptible to the influence of behavioural and environmental factors. These external influences may be more profound when assessments are performed independently at home, in the absence of clinical staff for guidance, feedback or motivation. The majority of research has been carried out in controlled environments, with the vision self-assessments tool being administered at the clinic. This emphasizes the need for further research in a real-world setting in which ophthalmic patients perform the self-assessments independently at home.

We therefore evaluated a certified self-assessment tool in this setting, amongst both adults and children, presented in **chapter 3** and **chapter 4**. Mean differences between the VA self-assessments at home and reference assessments at the clinic were clinically negligible. The distribution of differences was fairly similar to the variability commonly observed in Snellen chart testing. We did not identify associations between clinical characteristics and accuracy of the home-assessment in either study. We hypothesize that outlier assessments were mainly attributed to behavioral factors (e.g. intrinsic motivation) and environmental testing conditions (e.g. lighting and distance from the screen). In children, the behavioral influences may be more profound, illustrated by the underestimated home-assessed VA scores in poorer ranges. In this pediatric population, we evaluated the web-based refraction algorithm alongside the VA assessment

and concluded that a recalibration is required, as the refractive changes were highly overestimated.

In **chapter 5**, we explored a novel method for remotely reviewing ophthalmic patient cases at an academic ophthalmology department, known as the TeleTriageTeam (TTT). In this approach, optometry students created case summaries based on phone consultations with patients; the clinical data already available in the electronic health records; and – when indicated – outcomes of home-based visual function self-assessments. Supervising ophthalmologists reviewed these summaries in clinical case conferences, resulting in effective prioritization of patients on waiting lists. Interestingly, the uptake of the web-based vision self-assessment was low. Although a quantifiable visual acuity outcome is not always essential for clinical decision making, the low uptake of the self-assessment tool was also rooted in staff and patient unfamiliarity and further compounded by poor implementation in the digital patient portal. This underscores the need for building trust and ensuring user-friendly remote data collection and transfer.

The **second section** of this thesis focused on a specific patient journey: telemonitoring in cataract care. As a participation bias favoring younger participants had been described in our previous study amongst adult ophthalmic patients, we performed a pilot study to evaluate if older-aged, potentially less digitally competent, patients were able to perform the vision self-assessment in **chapter 6**. The cataract patients in this study were able to adequately complete the web-based test and deliver reliable estimates of VA, highlighting its potential for monitoring vision after cataract surgery. As this study was performed in a controlled setting, we recommended to re-evaluate the tool in this population in an unsupervised home environment. This was carried out in a subsequent multicenter trial, of which the rationale and design are described in **chapter 7**.

In the pivotal **chapter 8** the findings of this trial were presented. Our study showed that cataract patients were able to complete unsupervised self-assessments of visual function, and self-report postoperative outcome measures via a web-interface, provided that they possessed basic digital skills. The studied web-based test delivered estimates of VA assessed independently at home, with a precision similar to Snellen chart testing at the clinic. The web-based refraction assessment requires a recalibration, as the residual refractive error was often overestimated, falsely classifying emmetropes as being ametropic. Uptake of patient reported outcome measurements (PROMs) and vision-related quality of life questionnaires were high. These self-reported parameters improved after surgery, and there were no apparent differences between the groups who had performed the vision self-assessments and those who had not. Adverse event rates and unexpected management changes were low in both groups.

For successful adoption of digital health technologies, we emphasize the importance of considering not only clinical parameters, but also take the patients' perspectives into account. We therefore devoted **chapter 9** on the patients' experiences with web-based testing after cataract surgery. Questionnaires and in-depth semi-structured interviews revealed predominantly positive experiences, but also identified several potential barriers for successful adoption. When performing unsupervised vision self-assessments at home, patients expressed a desire of feedback; both on how to interpret the test result, but also on whether they adequately performed the test. Patients also explicitly wished to communicate with their eye care professional postoperatively to discuss symptoms or ask question. Furthermore, some expressed a feeling that face-to-face care is superior to remote care, as it allows for more comprehensive examinations when needed. These findings highlight the importance of building trust in remote eye care delivery and ensuring access to eye care professionals when medically necessary, or preferred by the patient.

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

Evaluating the studied web-based vision self-assessment

The accuracy of a certified web-based vision self-assessment tool was evaluated in various study populations and settings, by comparing the outcomes to those obtained at the clinic using conventional wall charts. In all of our studies, the mean differences between the two VA assessments were clinically negligible, indicating that the web-based tool does not systematically over- or under-correct VA. Notwithstanding, a certain distribution of differences was identified. It is important to realize that variation is inevitable when comparing two VA assessments in the same individual. Firstly, different charts use distinct optotypes and scoring criteria, leading to varying outcomes.²⁻⁴ Secondly, fluctuations in scores can occur due to behavioral and environmental factors.² When comparing the variability observed in our studies to that reported in test-retest studies, the precision of the web-based tool appears comparable to that of the Snellen chart.^{5,6}

In our studies, the web-based test was mostly performed for both eyes. If one monocular web-based assessment differed greatly from the conventional test, this was usually also the case for the other eye. This suggests that performance is influenced by external factors on individual levels, such as user behavior or the testing environment. Limiting the influence of these factors would be an important target to improve the accuracy of the studied web-based tool. This could include the use of webcam images to assess testing conditions such as room lighting or distance to the screen, or providing Artificial Intelligence (AI)-guided live feedback to optimize these conditions directly. In addition, as the test employs three different optotypes, a high rate of within-test inconsistencies could be addressed automatically by requesting participants to repeat the test later. In children, the behavioral influences may be more profound, illustrated by the underestimated VA scores as vision declined. In the absence of trained staff experienced in providing guidance and motivation, introducing gaming elements (i.e. "gamification"⁷) could be effective in stimulating children to exert maximum effort.

The studied web-based test also employs an algorithm that determines the refraction, which was evaluated amongst the populations of myopic children and cataract patients. The assessment appeared too challenging in both of these study populations. The refraction is derived from the VA and could therefore benefit from an overall improved test precision, particularly in poorer VA ranges. Additionally, the algorithm requires a recalibration for these specific age groups. The current version, trained on young and healthy adults, assumes any VA poorer than -0.1 logMAR (i.e. 1.25 Snellen decimal) to be caused by a refractive error.⁸ The maximum achievable VA is age-related and will be dif-

ferent for older-aged adults or very young children, hence requiring different refraction calculations.^{9,10}

Clinical implications

The majority of the available scientific evidence of vision self-assessment tools is limited to validation studies performed in attendance of trained staff or clinical researchers, often organized by test manufacturers.¹¹ Studies performed in settings that mimic real-world conditions provide better insights for clinical use than studies in unrealistic settings.¹² Our own research demonstrated that even if tools are certified and compliant with international medical device regulations, performance may vary across different contexts. In the next paragraphs we will discuss the clinical implications of our findings. Even though this thesis zoomed in on one specific vision self-assessment tool, we anticipate that most of the conclusions can be generalized to other web-based solutions for remotely assessing visual function.

An essential factor to consider when adopting these vision self-assessment tools in clinical practice is the observed variability, especially the seemingly inevitable occurrence of outlier measurements. This variability is driven by external factors which may be more profound in unsupervised, home settings. In our systematic review we identified that the precision of most digital self-assessment tools is generally poorer than that of conventional clinic assessments. Anticipated technological advances may improve these vision self-assessment tools in the upcoming years, yet it is important to realize that even the most precise tool may still yield outcomes not representative of true clinical changes. Optotype-based vision assessments are psychophysical tests, meaning that the score depend entirely on subjects' responses and are thus highly influenced by behavior and cognition. This subjectivity distinguishes vision self-assessment tools from telemonitoring devices collecting objective biometric data such as heart rate or oxygen saturation, requiring less effort from patients.

The implications of this variability may vary depending on the context. For screening purposes, one is primarily interested in detecting an arbitrary vision range, rather than determining an exact value. Smartphone-based vision tests have been introduced in community- or school-based screening amongst children in several low-income countries, based on this principle.¹³⁻¹⁵ Even if underperformance of these assessments in pediatric populations may result in some false positive cases, the ability of these tools to detect (reversible) visual impairment could be a gamechanger for these countries where regular screening programs are either non-existing or facing accessibility barriers.

The implications for medical eye care practices, however, are different. In a clinical setting, it is crucial to discern whether unexpected outcomes reflect true clinically relevant changes, or whether these are caused by poor patient efforts or performance errors. At clinics, trained staff conducting the vision assessments identify signs of poor cooperation or comprehension and communicate with the patient directly for guidance and motivation. In other words, both the outcome and the performance of the test are taken into account. In contrast, current assessments performed independently at home lack this surveillance and assessment of user performance. The self-assessment tools could therefore benefit from collecting and reporting information on performance adequacy, aiding in the interpretation of test scores and thereby promoting the relevance of the test outcome. In addition, this may benefit patients, who expressed insecurity about correctly performing the test due to the absence of this feedback during our interviews. To the best of our knowledge, none of the available vision self-assessment tools provide any information regarding performance. We propose that metadata on user behavior such as test duration, within-test consistency, or webcam information on room lighting and distance from the screen, could be used as input to present indications of performance alongside the actual VA scores.

Not all patients are willing nor able to perform digital self-assessments independently at home. Additionally, some eye care professionals may not feel comfortable in introducing these tools to their patient. Patient selection based on clinical characteristics may be difficult, as in none of our clinical studies we were able to identify significant associations between these characteristics and the accuracy of the web-based vision assessment. Notwithstanding, all of our studies were subject to a participation bias of patients with a general interest and curiosity in technology, as basic digital skills and access to mobile devices were a requirement to perform the vision self-assessments independently at home. The 80-year-old patient who participated in our study may not be representative for all older-aged adults, as this population is known to face barriers to engaging with digital health technology due to a poorer digital literacy.^{16,17} We expect these technology adoption barriers to diminish over time, driven by the increasing accessibility and utilization of internet and mobile devices. However, there may be other reasons that refrain patients from using these tools. In the end, we recommend introducing vision self-assessment tools to patients on personal levels, especially given the importance of patient compliance due to the influence of behavior.

It should be noted that VA is not the sole parameter of interest in ophthalmic patient assessments. Enriching vision self-assessments with additional subjective information, such as self-reported symptom questionnaires, could provide a more comprehensive overview of the remotely assessed patient. An important lesson learned during our

TeleTriageTeam project was that clinical decision-making did not always require a vision self-assessment outcome in addition to the information gathered by phone or available in the electronic health record. Moreover, some ophthalmic diseases necessitate evaluations using specialized equipment that cannot be self-collected by patients at home, such as slit lamp examinations. Sometimes clinic visits primarily focus on obtaining diagnostic images which do not always necessitate real-time assessment at specialized eye clinics. Consequently, initiatives have emerged around the globe where routine images are collected in local clinics and sent for remote evaluation by eye care professionals, for instance in diabetic retinopathy screening.^{18–20} AI-based automated processing and scoring of the images is expected to further streamline this diagnostic process.^{21,22} These developments underline that the opportunities for assessing ophthalmic patients beyond the walls of the traditional eye clinic, are definitely not limited to remote vision self-assessments.

Telemonitoring in cataract care

The standardized follow-up pathways and the low complication rates make cataract surgery a compelling field for employing technology. In this thesis we learned that a group of digitally skilled cataract patients were willing and able to complete unsupervised self-assessments of visual function and self-report postoperative outcome measures via a web-interface, underlining the potential of using digital health technology for remote follow-up after surgery.

Screening for complications and assessing visual outcomes are the main objectives of cataract surgery follow-up. Furthermore, outcome metrics are increasingly being collected to determine cataract surgery success rates.²³ The European Society of Cataract & Refractive Surgeons (ESCRS) established a multinational registry to record surgical outcomes, with the aim of improving quality of care and enable benchmarking by allowing surgeons to compare their outcomes to a reference database. In some countries, such as the Netherlands, the recording of these outcomes is mandatory.²⁴ Consequently, telemonitoring technology should be able to deliver these.

Screening for complications

In our own experiences, ophthalmologists' reluctance to adopt telemonitoring in cataract care primarily stems from fears of missing complications, thereby reducing the overall quality of care. While in-person check-ups with comprehensive examinations remain necessary for individuals with known risk factors or complex surgeries, there is no global consensus on the need for postoperative ophthalmic follow-up after routine, uneventful cataract surgery in patients without ocular comorbidities.²⁵ With the increasing safety of cataract surgery, these cases constitute the majority of patients. Global

differences in culture, liability, and regulations have resulted in variation in routine follow-up schedules. One large retrospective study claimed that follow-up visits could be completely omitted after uneventful surgery in routine patients without ocular comorbidities.²⁵ Most evidence, however, has been targeted on demonstrating the safety and efficacy of telephone follow-up as an alternative to in-person visits, as most complications manifest with typical symptoms and structured sets of clinical questions have been proven sufficient to risk-stratify patients.²⁶⁻²⁹ This paves way for self-reported questionnaires, or even automated telephone consultations with AI-driven clinical assistants.³⁰ Automated warning systems integrated in the electronic patient record could aid in identifying those in need of in-person consultations.

Assessing visual outcomes

The emerging evidence that in-person consultations may not always be necessary are based on studies evaluating follow-up by telephone consultations, or even no follow-up at all. Both of these strategies will lack the collection of quantifiable data on visual performance, such as VA or refraction; parameters indicative of surgical success and therefore important for quality control. Vision self-assessments tools have the potential to deliver these outcomes.

Improving VA is an important goal of cataract surgery.³¹ An improvement of 1 or more lines from the preoperative distance VA is considered an indicator of surgical success. We expect the currently available vision-self assessments to be able to assess an improvement of VA scores in the majority of patients, although the aforementioned suggestions for improvement of these tools also apply in this setting.

Another outcome of interest is whether the achieved postoperative vision is similar to what was expected. Ideally, the difference between the preoperative target refraction and the actual postoperative manifest refraction should be below 1.0 dioptres.²³ Cataract guidelines therefore recommend a postoperative refraction assessment to determine the residual refractive error once the eye has fully recovered.²⁷ In our study, the refraction algorithm of the vision self-assessment tool was not reliable in this cataract population, resulting in the false identification of refractive errors in emmetropic patients. For now, traditional in-person refraction assessments remain the best way to deliver these outcomes. It could be debatable if an in-person visit at the eye clinic would be justified, should this be the only outcome of interest demanding an in-person assessment. Some countries have shifted the postoperative refraction assessments surgery to community optometrists or opticians.²⁵ A potential risk of this approach would be that follow-up data will be lost, jeopardizing the feedback loops to cataract surgeons and the mandatory collection of these outcomes for the quality registries. Those who are not in-

interested in acquiring any glasses may not attend these practices and more importantly, the transmission of data requires a good (digital) infrastructure, and a motivation by external parties to submit these data in the first place.

Cataract surgery not only aims to improve VA, but also the ability to perform vision-related tasks in daily life. Patient-reported data on the quality of life related to vision have become increasingly important indicators for successful surgery.³² These questionnaires could be easily incorporated in the a telemonitoring platform. Engaging patients in their own health by self-testing might boost the uptake of these questionnaires. In our clinical trial the uptake was 100%, while in our own experience, these outcomes are often underreported in conventional care.

Adoption of telemonitoring in clinical practice

To exert the full potential of telemonitoring in cataract care, we advocate that remote follow-up should extend beyond merely substituting face-to-face consultation with consultations by phone. A comprehensive telemonitoring platform, incorporating vision self-assessment tools and self-reported questionnaires, not only improves efficiency but also enhances the collection of crucial, often underreported parameters indicating surgical success. Our research has shown the potential. To make this a reality, the next steps involve refining the self-assessment tools and establishing a robust platform with secure data transmission directly to electronic health records and/or quality registries.

Adopting telemonitoring in cataract care raises important ethical questions. Firstly, it changes the way eye care professionals and patients interact. While most patients mainly desire communication during symptoms or questions and would be satisfied with digital communication, some value face-to-face interactions for their social aspect. Secondly, shifting tasks and responsibilities to patients through self-testing may be burdensome for some, impacting both patients and eye care professionals accustomed to traditional care approaches.^{33,34} Introducing telemonitoring technology brings new responsibility questions.³⁵ Who will be responsible or accountable if an alert generated by the telemonitoring technology is missed, or if the generated data is of insufficient quality? The patient, the doctor, or the manufacturer? Thirdly, concerns about inclusivity arise as self-testing requires a level of health literacy and may therefore not be suitable for all who wish to benefit from the advantages of performing self-assessments in the convenience of their home environment.³⁵ Considering these ethical aspects is crucial when adopting these new practices.

Lastly, we do not expect nor wish that telemonitoring fully replaces follow-up of all cataract patients. Conventional follow-up at the clinic should always remain an option

when medically indicated, but also for those who are not willing or able to adopt these self-assessment tools. Also in this context, patient support and trust are essential for success. During our interviews we learned that a group of cataract patients are ready to accept these new practice patterns, but these early adopters also stressed the importance of adequate feedback on test performance and interpretation of the outcomes. Excessive patient inquiries for reassurance or clarification could jeopardize the justification for investing in telemonitoring technology. In our own study, we did not observe self-assessments impacting the frequency of patients reaching out to clinics. However, the sample size was limited, and all patients were aware of upcoming clinic visits for study purposes. Future research should further elaborate on evaluating the impact of telemonitoring on health consumption on a larger scale, and in the absence of scheduled clinic visits. Other future challenges will be to establish reimbursement policies and frameworks for these new practice patterns. The Dutch cataract surgery guideline has recently (December 2023) been amended with a module on “remote care”.³⁶ This update permits remote screening for complications and visual deterioration through self-reported questionnaires and vision self-assessments, marking an important step forward in fostering innovation to reshape follow-up care.

Conclusions and future directions

This thesis has shown that a plethora of digital tools for vision self-assessments are available, yet also underlined the importance of research before adopting these tools in clinical practice. The most important clinical implications of vision self-assessments revolve around the subjectivity of VA testing, particularly the influence of external factors. Future self-assessment tools should focus on limiting the influence of these factors and providing information on performance adequacy. Another important lesson learnt is that the collection and representation of the data should be intuitive and easy-to-understand, for both patients and eye care professionals.

While vision self-assessments can enrich teleconsultations with quantifiable estimates of visual function and play an important role in screening, it is important to acknowledge that ophthalmic care typically relies on more than mere VA assessments. Some assessments require office-based specialized technology. Obtaining these assessments at a local optometrist or general practitioner and forwarding these for an asynchronous specialist’s review is another telemonitoring trend that we expect to reshape future eye care. Blending these trends could pave the way for hybrid approaches which combine self-testing, remote assessments at community clinics, and face-to-face examinations at traditional eye clinics.

Cataract surgery follow-up care will most likely be one of the most compelling fields to employ telemonitoring. A robust telemonitoring platform could enable patients to independently assess their vision and self-report surgical outcomes at home, while contributing to the data collection for quality control and benchmarking. The studies in this thesis represent the first steps. Improvements of existing technology and widespread support are crucial to make this a reality. In our studies we demonstrated a readiness of cataract patients to embrace remote follow-up care with self-testing technology and we anticipate this trend to gain momentum in the coming years. Perhaps the biggest challenge will be to convince the eye care professionals, grown accustomed to traditional practice patterns. Large-scale studies performed in real-world conditions, and evaluated by independent research teams, should be at the cornerstone to achieve their support. Importantly, the studies focusing on clinical outcomes should be performed in parallel to stakeholder analyses and cost-effectiveness research. In the end, the development and implementation of digital health technology requires a holistic approach.

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Appendices

Dutch summary
Acknowledgements
Curriculum vitae

DUTCH SUMMARY

Telemonitoring in de oogheelkunde

De laatste decennia hebben digitale technologieën de gezondheidszorg drastisch veranderd. In toenemende mate wordt technologie ingezet om patiënten op afstand te beoordelen of communicatie tussen zorgverleners en patiënten op afstand mogelijk te maken. “Telemonitoring” is het gebruik van digitale technologieën om patiënten op afstand te monitoren. In dit proefschrift hebben we de mogelijke rol van telemonitoring in de oogheelkunde verkend.

De **eerste sectie** van dit proefschrift richtte zich op de ontwikkeling en evaluatie van digitale technologieën voor het op afstand beoordelen van oogheelkundige patiënten, met de nadruk op het zelftesten van het gezichtsvermogen. Er is een overvloed aan digitale toepassingen en apps beschikbaar op het internet, maar klinische validatie ontbreekt vaak. We begonnen met het bespreken van het beschikbare wetenschappelijke bewijs ten aanzien van bestaande digitale toepassingen voor het zelfmeten van de gezichtsscherpte, ook wel “visus” genoemd, in **hoofdstuk 2**. In onze review laten we zien dat de nauwkeurigheid van visus-zelftesten veelal iets lager is dan van traditionele meetmethodes in de kliniek. Ook blijkt er veel variatie te bestaan tussen verschillende studies. Een belangrijke bevinding hierbij is dat de nauwkeurigheid van een visus-zelftest afhankelijk blijkt van de context waarin deze wordt uitgevoerd, bijvoorbeeld in welke populatie. Zo is de zelftest minder nauwkeurig wanneer de proefpersoon slechter ziet. Een belangrijk punt van aandacht is dat in veel studies de zelftesten worden uitgevoerd in een klinische setting. Voor de implementatie in de klinische praktijk, is het echter van uitzonderlijk belang om deze zelftesten ook in de “echte wereld” te onderzoeken, waarbij ze door patiënten zelfstandig in de thuisomgeving worden uitgevoerd.

Om deze reden hebben we een gecertificeerde zelftest onderzocht in een thuis-setting bij zowel volwassenen als kinderen, gepresenteerd in **hoofdstuk 3** en **hoofdstuk 4**. De gemiddelde verschillen tussen de visus-scores van de zelftesten thuis en de referentietesten in het ziekenhuis waren klinisch verwaarloosbaar. De verdeling van de verschillen was vergelijkbaar met de variabiliteit die doorgaans wordt waargenomen bij het herhaaldelijk testen van de visus met een Snellen kaart, de meest gebruikte meetmethode in de kliniek. We vonden geen associaties tussen patiëntkarakteristieken en de nauwkeurigheid van de thuis uitgevoerde zelftest. Onze hypothese is dat sterk afwijkende metingen worden toegeschreven aan gedragsfactoren (bijv. intrinsieke motivatie) of omgevingsfactoren (bijv. de verlichting in de ruimte en de afstand tot het scherm). Bij kinderen zouden deze gedragsinvloeden sterker kunnen zijn, vanwege de geobserveerde onderschattingen van de visus-scores wanneer kinderen slechter zien

(en dus mogelijk meer moeite hebben met de test). In de kinderopulatie hebben we naast de visus-scores ook een algoritme geëvalueerd die de corresponderende brilafwijking, ook wel “refractie” genoemd, bepaalt. Het refractie-algoritme bleek de progressie in brilafwijking sterk te overschatten en dient gekalibreerd te worden.

In **hoofdstuk 5** onderzochten we een nieuwe methode voor het op afstand beoordelen en triëren van oogheelkundige patiëntendossiers in een academisch ziekenhuis, bekend als het TeleTriageTeam (TTT). Optometriestudenten vatten casussen samen op basis van telefonische consulten met patiënten, de klinische gegevens beschikbaar in de elektronische patiëntendossiers; en - indien nodig - de uitkomsten van thuis uitgevoerde visus-zelftesten. Supervisorende oogartsen beoordeelden deze samenvattingen in klinische casusbesprekingen, resulterend in een effectieve prioritering van patiënten op poliklinische wachtlijsten. De visus-zelftest werd weinig ingezet. Hoewel een kwantitatieve visus-uitkomst niet altijd essentieel is voor klinische besluitvorming, was de lage respons vooral ook te wijten aan onwennigheid bij personeel en patiënten, en de slechte implementatie in het digitale patiëntenportaal. Dit onderstreept de noodzaak van het opbouwen van vertrouwen in digitale zelftesten en het waarborgen van een gebruiksvriendelijke omgeving om deze gegevens te verzamelen.

De **tweede sectie** van dit proefschrift richtte zich op een specifiek domein: de patiënt met cataract, ook wel “staar” genoemd. Dit is vertroebeling van de ooglens, een aandoening die vaak mensen van een oudere leeftijd treft. Allereerst voerden we daarom in **hoofdstuk 6** een pilotstudie uit om te evalueren of oudere patiënten, die mogelijk minder digitaal vaardig zijn, ook in staat waren om zelfstandig een visus-zelftest uit te voeren. De proefpersonen in deze studie waren in staat om dit te doen, hetgeen ons motiveerde om de potentiële rol van visus-zelfmonitoring na een staaroperatie verder te exploreren. Aangezien de pilotstudie was uitgevoerd in een experimentele klinische setting, wilden wij deze evaluatie op een grotere schaal nog eens overdoen in een niet-superviseerde thuis-setting. De opzet van deze multicenter studie wordt beschreven in **hoofdstuk 7**. In deze studie kijken we niet alleen naar de zelftesten van visus en refractie, maar ook naar de zelfrapportage van andere belangrijke postoperatieve uitkomstmaten, het voorkomen van ongewenste voorvallen en de ervaringen van de patiënten.

In het belangrijke **hoofdstuk 8** worden bevindingen van deze multicenter studie gepresenteerd. We bevonden dat geselecteerde cataractpatiënten in staat waren om thuis, zonder ondersteuning van een zorgverlener, visus- en refractiezelftesten uit te voeren en postoperatieve uitkomstmaten te rapporteren via een digitaal systeem. Ook hier bleek de visustest een vergelijkbare precisie te hebben als de Snellen kaart in de kliniek, maar

bleek de refractiebepaling nog niet toereikend. Vaak werd de restrefractie na een staaroperatie overschat, waardoor mensen die eigenlijk geen brilcorrectie behoeften wel als zodanig werden geclassificeerd. De respons op PROMs-vragenlijsten (“Patient Reported Outcome Measures”) en andere gezondheidsvragenlijsten was 100%. Een verbetering werd aangetoond wanneer we de scores vóór en na de staaroperatie vergeleken. Er was hierbij geen verschil tussen de studiegroep die wel de zelftesten thuis had uitgevoerd en de studiegroep die dit niet had gedaan. Het aantal ongewenste voorvallen was laag in beide groepen.

Voor een succesvolle toepassing van digitale technologieën in de zorg is het van uitzonderlijk hoog belang om ook het perspectief van de patiënt te belichten. **Hoofdstuk 9** hebben we daarom gewijd aan de ervaringen van de patiënten met de digitale zelftesten na hun staaroperatie. Vragenlijsten en semigestructureerd interviews werden uitgevoerd en alhoewel de ervaring overwegend positief bleken, werden er ook verschillende potentiële belemmeringen voor succesvolle adoptie geïdentificeerd. Patiënten gaven aan feedback te willen wanneer ze zelfstandig een zelftest thuis uitvoeren, zowel over hoe ze het testresultaat moesten interpreteren, maar ook of ze de test goed hebben uitgevoerd. In de kliniek wordt deze feedback geleverd door de zorgverlener, die in de thuisomgeving ontbreekt. Patiënten benadrukten ook expliciet de wens om de *mogelijkheid* tot contact te behouden, voor het geval ze symptomen ervaren of vragen hebben. Bovendien hebben sommigen een algemeen gevoel dat de zorg in het ziekenhuis altijd van hogere kwaliteit zal zijn dan zorg op afstand, omdat er meer onderzoeken mogelijk zijn dan in de thuis-setting. Deze bevindingen benadrukken het belang van het opbouwen van vertrouwen in oogzorg op afstand en het waarborgen van toegang tot oogzorgprofessionals; uiteraard wanneer dit medisch noodzakelijk is, maar ook wanneer de patiënt hier behoefte aan heeft.

In de **algemene discussie** van dit proefschrift plaatsen we de hoofdbevindingen van onze studies in een breder perspectief. Concluderend benadrukt dit proefschrift het belang van grondig onderzoek voordat digitale toepassingen worden geïntegreerd in de klinische praktijk. De subjectiviteit van visusmetingen door de sterke invloed van externe factoren vormen een uitdaging. Toekomstige software-updates moeten erop gericht zijn om deze invloeden te verminderen. Daarnaast dient een duidelijke weergave van de testcores, alsmede een indicatie betreffende de betrouwbaarheid hiervan, gewaarborgd te worden. Hoewel visus-zelftesten zeker een waardevolle toevoeging kunnen zijn bij teleconsulten, of in het kader van screening, vereist de oogzorg vaak ook gespecialiseerde onderzoeken die alleen op locatie kunnen worden uitgevoerd. Wellicht dat een hybride aanpak de toekomstige oogzorg zal hervormen, waarbij telemonitoring initiatieven een deel van de zorg in gespecialiseerde centra vervangen. Denk hierbij aan

thuis uitgevoerde zelftesten, maar ook het verkrijgen van onderzoeken in een 1^e-lijns setting met een beoordeling op afstand in een 2^e- of 3^e-lijns setting. De cataractzorg is één van de interessantste domeinen binnen de oogheelkunde voor de implementatie van telemonitoring. Het kan een uitdaging zijn om de oogzorgprofessionals te overtuigen om deze veranderingen te omarmen. Grootschalige implementatiestudies en stakeholder-analyses zijn vereist om de haalbaarheid te toetsen. Naast de klinische uitkomstmaten dienen ook aspecten als kosteneffectiviteit uit te worden gediept. Uiteindelijk vraagt de ontwikkeling en toepassing van digitale technologie in de zorg om een holistische benadering.

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CURRICULUM VITAE

Janneau Claessens was born on May 11, 1995, in the picturesque city of Maastricht, the Netherlands. Following his graduation from the Porta Mosana College Maastricht in 2013, he moved to Utrecht to study at Utrecht University, where he obtained his master's degree in Medicine in 2019.

Under the expert guidance of prof. dr. S.M. Imhof and dr. R.P.L. Wisse, Janneau commenced his PhD candidacy at the Department of Ophthalmology at the University Medical Center Utrecht. His research endeavors have taken him to various conferences, where he presented his work. This includes the national annual meetings of the Dutch Ophthalmological Society (NOG) and the Dutch Ophthalmology PhD Students (DOPS). International conferences where he presented his work include the International Myopia Conference (Rotterdam, The Netherlands, 2022), the Society of European Ophthalmology (SOE) Congress (Prague, Czech Republic, 2023) and the Congress of the European Society of Cataract and Refractive Surgeons (ESCRS) (Vienna, Austria, 2023).

Janneau's commitment to academic education extends beyond his own work. He undertook multiple courses at the Utrecht University Graduate School of Life Sciences and participated in the 2022 PhD Career Boost Program of the University Medical Center Utrecht. Other extracurricular activities during his PhD candidacy included tutoring medical students and organizing the annual Dutch Ophthalmology PhD Students Congress of 2021.

In January 2024, Janneau took the next step in his career by commencing his residency in ophthalmology at the University Medical Center Utrecht, the Netherlands.

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