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SELF-ASSESSED VISUAL FUNCTION IN CATARACT SURGERY USING CATQUEST-9SF

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THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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The thesis will be defended in public at the auditorium, St. Erik Eye Hospital, Stockholm, Dec 1st 2023 at 9:00 am.

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Popular science summary of the thesis

The lens of the human eye refracts, or bends light focusing it on the retina. An undisrupted passage of light though the lens is a requirement for clear vision. During life the lens of the eye changes. From being clear, permitting rays of light passing through it undisturbed, the lens with age becomes cloudy, blurring the vision, eventually leading to blindness. This is the cataract disease. The incidence of cataract increases with age and as life expectancy increases, so does the number of cataract patients. In fact, cataract is the leading cause of preventable blindness worldwide.

The only treatment is surgery in which the cloudy lens is removed from inside the eye and replaced by a plastic lens in the eye. Luckily, cataract surgery is available in many parts of the world and this operation is the most common surgery performed in humans worldwide. Large resources are spent to treat cataract but even after a successful surgery about one in ten patients do not experience any benefit from surgery.

The Swedish National Cataract Register (NCR) has data from more than two million eyes undergoing cataract surgery. The Register also uses a patient questionnaire, Catquest-9SF, which is completed by the patient before and again three months after cataract surgery. The questionnaire has nine questions concerning the patient´s own self-assessed visual function.

In **paper 1** we used data from the NCR together with data from thousands of Catquest-9SF questionnaires to find that other diseases of the eye at the time of cataract surgery affect the patients' vision after cataract surgery, even when we controlled for visual acuity.

Paper 2 shows that difficulties during the surgery itself can affect the patients' vision after surgery, this association got weaker for most difficulties when controlled for visual acuity.

We also wanted to make sure that the patients' answers in Catquest-9SF do not depend on chance, that the reliability is high. In **paper 3** we assessed the reliability by giving Catquest-9SF twice to the same cataract patients, within one to two weeks in between, before cataract surgery, a so-called test-retest study. We found that most patients gave the same answers to the questions and could conclude that the test-retest reliability of Catquest-9SF is very high.

When analyzing data from NCR together with data from Catquest-9SF on factors that might affect the visual function, the result is presented in a unit called logit. There has been a lack of knowledge on how large a logit change has to be to be important to the patient, the minimum important difference (MID). Our aim in **paper 4** was to estimate MID of Catquest-9SF. To calculate the MID, we sent an extra anchor question to patients on how their vision changed after cataract surgery and compared the answer to the result of the Catquest-9SF questionnaires. The MID was also estimated on the basis of mathematical calculation. We found credible values of MID, and also that the MID differ depending on how the patients' vision was before surgery.

This project has added new knowledge on some factors that do affect the patients' self-assessed vision after cataract surgery and some factors that do not. The novel data on the test-retest reliability of Catquest-9SF ensures that the quality of data is high and supports continued use of Catquest-9SF in assessing the quality and outcome in cataract surgery. The estimations of MID of Catquest-9SF enable even more precise high-quality evaluation of the outcome and benefit of cataract surgery.

Populärvetenskaplig sammanfattning

Linsen i människans öga bryter ljuset, eller böjer ljusets strålar, så att en skarp bild fokuseras på näthinnan längst bak i ögat. Vägen för ljuset genom ögat fram till näthinnan får inte innebära något hinder. Linsen förändras under människans liv, från att ha varit helt klar blir den med åldern grumlig, vilket försämrar synen och leder till slut till blindhet. Denna sjukdom kallas för katarakt, eller grå starr. Många drabbas vid hög ålder och med ökande medellivslängd ökar också antalet kataraktpatienter. Katarakt är den vanligaste orsaken till behandlingsbar blindhet i världen.

Den enda behandlingen av katarakt är en operation då man byter ut den grumliga linsen i ögat till en ny lins gjord av plast. Lyckligtvis är modern och säker kataraktkirurgi tillgänglig i stora delar av världen och detta är den vanligaste operationen på människokroppen. Stora resurser läggs ner på att behandla katarakt, men studier har visat att nästan en av tio patienter inte upplever någon förbättring av synen efter sin kataraktoperation. I det här arbetet undersöker vi vad som påverkar resultatet av kataraktoperation. Vi undersöker också den metod som används för att utvärdera resultatet.

Svenska Nationella Kataraktregistret (NCR) har data från mer än två miljoner kataraktoperationer. Registret använder även ett frågeformulär, Catquest-9SF, som fylls i av patienten innan och tre månader efter operationen. Formuläret har nio frågor som rör patientens egen upplevelse av sin synfunktion.

I det här projektets **delarbete 1** analyserade vi data från NCR tillsammans med tusentals Catquest-9SF-formulär och kunde konstatera att om ögat som opereras för katarakt samtidigt har en eller flera andra specifika ögonsjukdomar, så påverkar detta resultatet negativt. Detta stämde även när vi kontrollerat för, eller kompenserat för, patientens synskärpa innan och efter operationen.

I **delarbete 2** hittade vi också stöd för att svårigheter eller komplikationer under själva operationen påverkade resultatet negativt, denna påverkan var oftast mindre betydelsefull när vi kontrollerat för synskärpan.

Vi ville också undersöka om tillförlitligheten i formuläret Catquest-9SF är tillräckligt hög, d.v.s. att patientens svar inte är slumpmässiga. Detta gjorde vi i **delarbete 3** genom en så kallad test-retest-studie där patienter som skulle opereras för katarakt fick fylla i Catquest-9SF två gånger innan operationen, med minst en och maximalt två veckor mellan formulären. Vi analyserade sedan i hur stor utsträckning patienterna hade givit samma svar i de båda formulären. Resultaten visade att tillförlitligheten är mycket hög.

När vi analyserar data från NCR tillsammans med data från Catquest-9SF avseende faktorer som kan påverka synfunktionen efter kataraktoperationen får vi resultatet i enheten logit. Det har saknats kunskap om hur stor förändring i logits som krävs för att det ska ha betydelse för patienten, den så kallade minimum important difference (MID). För att beräkna värdet på MID skickade vi i **delarbete 4** ett formulär med en enda ankar-fråga till patienterna om hur deras synfunktion förändrades av kataraktoperationen och jämförde svaret med resultatet av Catquest-9SF-formulären. Vi beräknade också värden på MID med hjälp av en matematisk modell. Vi fick fram värden för MID och kunde också visa att MID är beroende av patientens synfunktion innan operationen.

Det här projektet har tillfört ny kunskap om några faktorer som påverkar synfunktionen vid kataraktoperation och också påvisat några faktorer som är av mindre betydelse. Vi har också kunnat visa att Catquest-9SF har en hög test-retest-tillförlitlighet och därmed att kvalitén på data från Catquest-9SF kan fortsätta att användas för att utvärdera kataraktkirurgins kvalitet och resultat. Beräkningarna för MID möjliggör mer precis och högkvalitativ utvärdering av resultatet och nyttan av kataraktkirurgi.

Abstract

The cataract disease is the leading cause of preventable blindness in high-income countries alone as well as globally despite the groundbreaking technological advancements in recent years and steadily increasing number of cataract operations. Even when the clouded lens of the eye has been successfully removed during cataract surgery and been replaced by a plastic intra-ocular lens (IOL) a significant number of patients experience no benefit from cataract surgery. There is an ongoing quest to find factors that affect the result and to monitor and ensure high-quality cataract surgery. The Swedish National Cataract Register (NCR) collection of data on more than 2 million cataract surgeries is a great aid in this challenge. In 2009 the NCR introduced Catquest-9SF, recently proven to be a state-of-the-art questionnaire. We used Catquest-9SF to investigate factors that might affect the outcome of cataract surgery using the patient self-assessed visual function perspective. We also studied the reliability of Catquest-9SF and the minimum important difference (MID) of the results.

In **Paper I** we investigated how other simultaneous diseases of the eye in addition to cataract affect the patient self-assessed outcome of cataract surgery using the Catquest-9SF in a prospective nationwide, multicenter study including more than 10,000 patients. This comorbidity study showed that several other ocular diseases at the time of cataract surgery affect the patient´s self-assessed visual function after cataract surgery despite inclusion of the preoperative corrected distance visual acuity (CDVA) and postoperative CDVA in the analyses.

Paper II assessed how challenging characteristics of the eye and difficulties during surgery as well as the feared complication of posterior capsular tear affect the outcome of cataract surgery in a prospective study including almost 11,000 patients from 42 Swedish surgical ophthalmology units. Several of the studied intraoperative difficulties and complications were significantly associated to the patient-reported outcome in cataract surgery. Including the preoperative CDVA and postoperative CDVA in the analyses reduced the impact of the intraoperative difficulties.

In **Paper III** our aim was to estimate the reliability of the Catquest-9SF questionnaire. In patient reported outcome measurement (PROM) it is fundamental that the patients' answers are repeatable, that they do not depend on chance, that the reliability is high. This test-retest study of the reliability of the Catquest-9SF, including 144 patients, showed an intraclass correlation of 0.93, thus we can conclude that the reliability of the Swedish Catquest-9SF is very high. Together with previous knowledge, our findings support continued use of the Catquest-9SF in assessing the quality and outcome in cataract surgery.

Our most recent study was reported in **Paper IV** in which we assessed the minimum important difference (MID) of Catquest-9SF. The large set of data in the NCR has a statistical power large enough to find even rather small significant associations. Our purpose was to assess how large the change measured in logit has to be to be significant to the patient, that is the MID. The assessment of MID of Catquest-9SF in this study adds detailed knowledge of MID and shows that MID differs depending on the baseline visual function. The findings enable even more precise high-quality evaluation of the outcome and benefit of cataract surgery.

List of scientific papers

I. Grimfors M, Mollazadegan K, Lundström M, Kugelberg M. Ocular comorbidity and self-assessed visual function after cataract surgery. J Cataract Refract Surg. 2014 Jul;40(7):1163-9. doi: 10.1016/j.jcrs.2013.11.033. PMID: 24957436.

II. Grimfors M, Lundström M, Höijer J, Kugelberg M. Intraoperative difficulties, complications and self-assessed visual function in cataract surgery. Acta Ophthalmol. 2018 Sep;96(6):592-599. doi: 10.1111/aos.13757. Epub 2018 Mar 25. PMID: 29575808.

III. Grimfors M, Lundström M, Hammar U, Kugelberg M. Patient-reported visual function outcome in cataract surgery: test-retest reliability of the Catquest-9SF questionnaire. Acta Ophthalmol. 2020 Dec;98(8):828-832. doi: 10.1111/aos.14461. Epub 2020 May 14. PMID: 32406609.

IV. Grimfors M, Lundström M, Kugelberg M. Self-assessed visual function outcome in cataract surgery: minimum important difference of the Catquest-9SF questionnaire. Eye Vis (Lond). 2022 Dec 6;9(1):46. doi: 10.1186/s40662-022-00318-x. PMID: 36494767; PMCID: PMC9733057.

Contents

List of abbreviations

CDVA	corrected distance visual acuity
CTR	capsular tension ring
DR	diabetic retinopathy
ECCE	extracapsular cataract extraction
ICC	intraclass correlation coefficient
IFIS	intraoperative floppy iris syndrome
IOL	intraocular lens
MID	minimum important difference
NCR	Swedish National Cataract Register
OR	odds ratio
OVD	ophthalmic viscosurgical device
PA	percentage agreement
PROM	patient reported outcome measurement
RD	retinal detachment
VA	visual acuity

1 INTRODUCTION

Cataract is when the lens of the eye has become cloudy, disturbing the rays of light, limiting vision. Cataract is common and the leading cause of blindness both globally[1, 2, 3] and in high-income countries alone.[4] Globally, 15,2 million people were estimated to be blind because of cataract in 2020,[5] and the number of people suffering from cataract blindness is rising.[6] The only treatment is removal of the lens and insertion of a plastic lens. The number of operations is steadily increasing and as the population is aging, this development is likely to continue. More than 150,000 operations were performed in 2022 in Sweden alone.[7] The technology used in cataract surgery has evolved immensely, making surgery today safe, where available. However, one in ten patients reports unchanged or worse vision after surgery.[8] There is an ongoing quest to find factors that affect the result and to monitor and ensure high-quality cataract surgery.

2 THE EYE AND CATARACT

During life the lens of the eye often changes. From being clear, permitting rays of light passing through it undisturbed, the lens can become opaque, blurring the vision. This is the cataract disease. The incidence of cataract increases with age and as the life expectancy increases, so does the number of cataract patients. In fact, cataract is the leading cause of preventable blindness worldwide.[1, 9]

2.1 THE EYE, LENS AND VISION

The eye is a receiver of light rays that are projected on the retina. The retina converts the light rays to nerve signals that are sent to the brain. The lens refracts, or bends light rays, focusing them on the retina. An undisrupted passage of light though the lens is a requirement for clear vision. The anatomy of the human eye is displayed in figure 1.

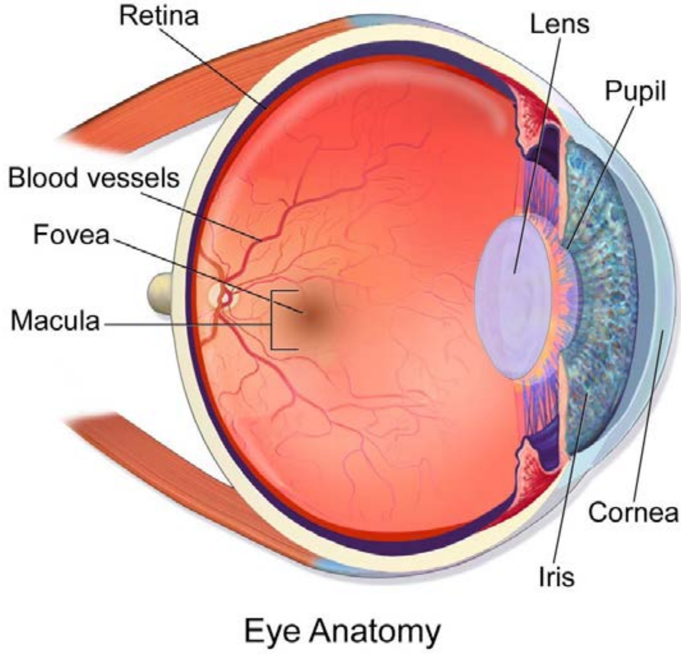


Figure 1. Anatomy of the human eye.

Reproduced from Blausen.com staff (2014). "Medical gallery of Blausen Medical 2014". WikiJournal of Medicine 1 (2). DOI:10.15347/wjm/2014.010. ISSN 2002-4436.
https://commons.wikimedia.org/w/index.php?curid=29025015

2.1.1 Microanatomy of the lens

The lens is located behind the iris, suspended to the ciliary body by fibrous strands called the zonules.(figure 2) The zonules are about 1–2 µm in diameter.[10] The zonules are attached to the lens capsule near the equator in the periphery of the lens. This part of the lens capsule is the thickest, 28 µm, the capsule being thinnest near the posterior pole with only 2 µm.[11] The lens capsule is an elastic, transparent basement membrane composed of collagen. The cells of the lens epithelium are located under the lens capsule in the anterior and equatorial region of the lens (figure 3). These epithelial cells are the most metabolically active cells of the lens. The cells pump ions that entered the lens from the poles along with nutrients back into the aqueous humor to maintain appropriate osmotic balance in the lens. The cells of the lens epithelium are also responsible for the lifelong growth of the lens by undergoing a process which transform them to lens fibers that migrates centrally to form the lens nucleus.[12]

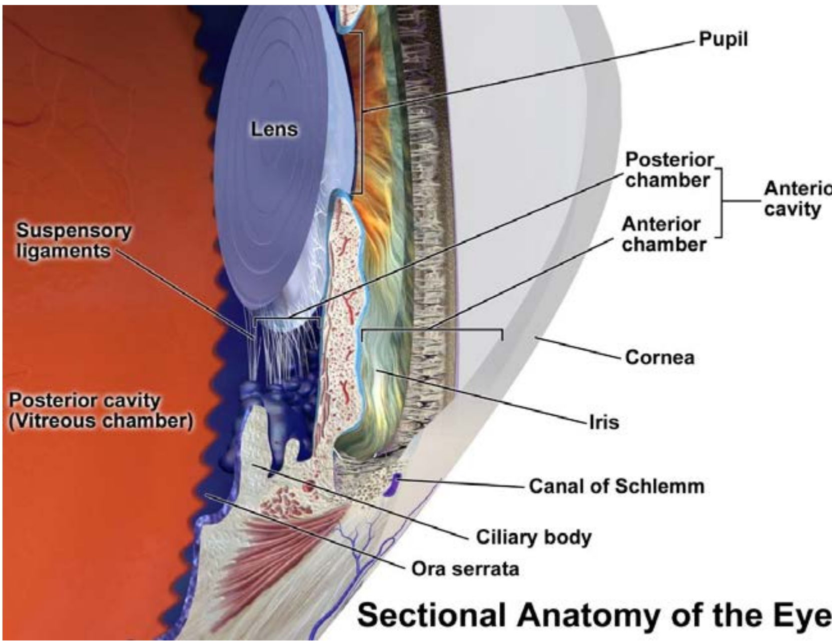


Figure 2. Anatomy of the anterior segment of the eye.

Reproduced from Blausen.com staff (2014). "Medical gallery of Blausen Medical 2014". WikiJournal of Medicine 1 (2). DOI:10.15347/wjm/2014.010. ISSN 2002-4436. https://commons.wikimedia.org/w/index.php?curid=29025013

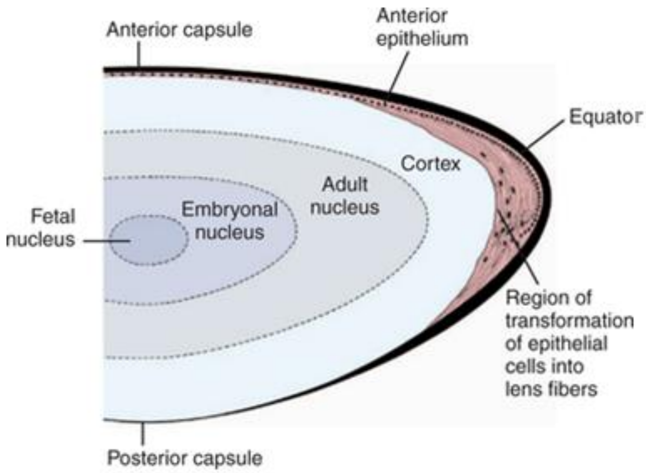


Figure 3. Anatomy of the human lens.

Reproduced from Hogan MJ, Alvarado JA, Wedell JE. Histology of the Human Eye: An atlas and textbook, 1st ed. Philadelphia: Saunders; 1971. © Reproduced with permission from Elsevier Science & Technology Journals.

2.2 **CATARACT DISEASE**

2.2.1 Causes of cataract

Cataracts can be classified into three groups depending on the cause; age-related cataracts, cataracts secondary to other causes and pediatric cataracts. The most common type is age-related cataract and the clouding of the lens is caused by oxidative stress and other changes to the lens proteins.[13, 14, 15] The pathophysiology of cataract differs depending on the location of the opacity within the lens; nuclear, cortical or subcapsular. Of the pediatric cataracts one third are inherited, one third combined with other ocular anomalies or part of a syndrome and one third unknown causes.[16] Drugs can cause cataract, for example long term use of corticosteroids is associated with formation of subcapsular cataract.[17] Other causes are mechanical trauma or other injury, ultraviolet radiation, chronic uveitis or certain systemic diseases.

2.2.2 Symptoms of cataract

The clouded lens disturbs light rays causing a reduction of the visual function. Perhaps the most common impairment is reduced visual acuity. Other important visual symptoms are blinding, for example by the headlights of oncoming car when driving in the dark or reduced contrast sensitivity resulting in the need for extra lighting when reading. The assessment of distance can also be disturbed, resulting in problems walking in stairs or on uneven ground.

3 CATARACT SURGERY AND OUTCOME

3.1 HISTORY OF CATARACT TREATMENT

The earliest known method to treat cataract is called couching, from the French word “coucher” which means “put to bed” dated to the 5th century BC. In couching, a sharp needle is used to pierce the eye and remove the lens from the visual axis, usually into the vitreous.[18] Unfortunately, in spite of poor outcome, this technique is still used in remote parts of some countries in western Africa.[19] Another early technique was a primitive extracapsular cataract extraction (ECCE) from 600 BC by an Indian surgeon named Sushruta.[20] A sharp needle is used in the same manner as described in couching, but the lens capsule is punctured with the needle followed by extraction of the lens by the patient´s valsalva with closed nostrils. Nevertheless, couching remained the standard procedure until mid-18th century when French surgeon Jacques Daviel introduced a somewhat more sophisticated method of ECCE compared to Sushruta´s method, performing better than couching, but still had significant complications.[21] Another method first described in 1753 by Samuel Sharp, just seven years after Daviel performed ECCE, was intracapsular cataract extraction (ICCE). ICCE involves removing the lens and it´s capsule in one piece allowing vitreous prolapse into the anterior chamber with subsequent complications. In spite of complications, ICCE was the primary intervention in cataract in the United States until 1970s and is still practiced in developing countries.[18]

Perhaps the most important function of the lens is to refract the waves of light so that they are focused on the retina. Even though the cloudy lens is removed from the visual axis as in the ECCE technique, heavy high-powered spectacles were required which rarely gave satisfactory visual quality. During World War II, Dr Harold Ridley noticed that a Royal Airforce pilot that had suffered shrapnel ocular trauma from his airplane windshield was largely asymptomatic for years, despite having a plastic intraocular foreign body. In 1949 Ridley performed the first intraocular lens (IOL) operation at St. Thomas Hospital in London, using an IOL made of polymethylmethacrylate (PMMA), the same plastic used in airplane windshields at the time.[18]

3.2 MODERN CATARACT SURGERY

Since Ridley, foldable IOLs have evolved as well as surgical techniques, topical anesthesia and ophthalmic viscosurgical devices (OVDs) have been introduced. An OVD is a gel-like substance injected into the anterior chamber during surgery to prevent deflation and maintain space. This development has gradually improved the safety of cataract surgery. Phacoemulsification, often referred to as “phaco”, was introduced by Charles Kelman in 1967.[22, 23] The phaco handpiece is a multifunction instrument the size of a thin pen. The phaco tip maintains intraocular pressure by irrigation of a saline solution. The phaco tip also emulsifies the lens by ultrasound and aspirates it, removing it from the eye. Perhaps the greatest challenge of cataract surgery is removing the lens while keeping the lens capsule and the zonules intact. After removal of lens material, the IOL is inserted into the capsular bag. The evolution of phaco has led to a reduction of the main incision size from about 10 mm in ECCE to 2 mm in phaco, resulting in significant less induced astigmatism, faster healing and reduced risk of bacterial infection. Thanks to inventions and advances in technology cataract surgery can now be very safe.

3.3 PATIENT REPORTED OUTCOME MEASUREMENT

The high and steadily increasing number of patients with cataract calls for high quality evaluation of the outcome and benefit of cataract surgery. Measuring the entirety of the complex human visual function is challenging. Visual acuity is perhaps the most common and accessible measure of vision, but it is not sufficient and a more advanced tool is needed for a complete evaluation. Arguably the most appropriate procedure is letting the patient assess her visual function before and after cataract surgery.[24] The evolution of questionnaires used for this assessment has been significant, this kind of instruments are called patient reported outcome measurement, PROM.[25, 26]

The Swedish National Cataract Register (NCR) was introduced in 1992.[27] The NCR began to use the original Catquest questionnaire in 1995 to collect data on patient-reported visual function.[28] Questionnaires at this time were often based on classical test theory which has certain limitations.[29] Primarily, the psychometric properties were not fully assessed and the scoring did not render a continuous interval-level measurement. In 2009, the questionnaire was revised using Rasch analysis, resulting in the current version: Catquest-9SF (Figure 4).[30, 31] Several questionnaires concerning visual function have been assessed using Rasch analysis, some resulting in improved versions.[32, 33, 34, 35, 36, 37, 38] Catquest-9SF measures activity limitations in daily life due to reduced visual function. Activity limitations in daily life is a domain within the concept of quality of life, as described by the World Health Organization. The Rasch model, used to revise Catquest and create Catqueat-9SF, is based on the probabilistic relationship between person (patient) and item (visual ability described by the questions). The ordinal (raw) psychometric data on individual visual ability obtained from the Catquest-9SF are converted to an interval level measurement (a logit unit).[39] Early PROM instruments were scored by simple algebraic sum of the raw rank values given to the response categories across all the items. However, such scores provide steps along the measurement continuum that are not the same size which is the case in true interval level measurement. Interval level measurement is one of two essential features of a high-quality PROM instrument, the other one being unidimensionality, meaning that the scale only measures a single underlying construct.[40] For example, it should measure visual function only, not being influenced by the person´s balance or general physical health. A large number of criteria determines the quality of a PROM instrument. To which extent a

PROM instrument measures what it is supposed to measure is called validity. Reliability refers to the repeatability of the measurement, that the same patient would give the same answer repeatedly under unchanged conditions. Patients undergoing cataract surgery are expected to experience change in their visual function, the ability of the PROM to detect this change is called responsiveness. Precision is the PROM ability to distinguish between different levels of patients´ abilities. Targeting is to which extent item (question) difficulty matches with the level of participants´ visual abilities. Catquest-9SF has been successfully tested on its validity in measuring visual disability outcomes in cataract surgery in several different populations: Swedish,[30] Australian,[41] German and Austrian,[42] Malay and Chinese,[43, 44] Italian,[45] Spanish,[46] Dutch,[47] English,[48] Danish,[49] New Zealander,[50], Vietnamese,[51], Canadian[52] and Greek.[53] Recently, a systematic review of the mentioned validation reports could conclude that Catquest-9SF is a reliable and valid instrument that can be used on cataract patients in several populations to measure self-assessed vision.[54] The Catquest-9SF was found to be short, highly responsive to cataract surgery, and a good measure of visual function outcomes in a comparison with other tools.[55] Catquest-9SF was the recommended questionnaire for version 2.0.1 of the ICHOM Cataracts Data Collection Guide in 2017.[56] Several instruments measuring visual function have been developed worldwide. A review of the quality of 17 patient-reported cataract outcome instruments concluded that the Catquest-9SF demonstrated superior psychometric properties as well as high responsiveness, and should be considered the recommended instrument for cataract surgery.[57] However, as noted in that review, further studies are needed regarding the reliability of the Swedish Catquest-9SF, the inception report in 2009[30] did not report on the reliability.

A. Do you experience that your present vision is giving you difficulty in any way in your everyday life?

Yes, very great difficulties	Yes, great difficulties	Yes, some difficulties	No, no difficulties	Cannot decide
☐	☐	☐	☐	☐

B. Are you satisfied or dissatisfied with your present vision?

Very dissatisfied	Rather dissatisfied	Fairly satisfied	Very satisfied	Cannot decide
☐	☐	☐	☐	☐

C. Do you have difficulty with the following activities because of your vision? If so, how much? In each row, mark only one cross, in the square you think agrees best with reality.

	Yes, very great difficulties	Yes, great difficulties	Yes, some difficulties	No, no difficulties	Cannot decide
Reading text in the daily paper	☐	☐	☐	☐	☐
Recognise the faces of people you come across	☐	☐	☐	☐	☐
See prices when shopping	☐	☐	☐	☐	☐
Seeing to walk on uneven ground	☐	☐	☐	☐	☐
See to do handwork, woodworking, etc.	☐	☐	☐	☐	☐
Reading text on TV	☐	☐	☐	☐	☐
See to carry on an activity/hobby you are interested in	☐	☐	☐	☐	☐

Many thanks for your help!

Figure 4. The English version of Catquest-9SF

3.4 FACTORS ASSOCIATED WITH THE OUTCOME OF CATARACT SURGERY

The evolution of technology in cataract surgery has improved the outcome of cataract surgery immensely during the last decades. Nevertheless, up to 10 percent of patients report that they experience no benefit from surgery. Efforts have been made to identify and evaluate causes of poor patient-reported outcome after cataract surgery.[58] It is known that certain factors such as ocular comorbidity, gender and age are associated to the outcome.[59, 60, 61, 62, 63, 64, 65] Several relatively small studies have investigated the association between ocular comorbidity and the outcome with varying results.[66, 67, 68, 69, 70, 71, 72, 73] Some studies do only have CDVA or IOP as outcome, not considering the subjective visual function.[71, 74, 75, 76]. There has been a need of a large study measuring the impact of ocular comorbidity on the patient self-assessed visual function in cataract surgery.

In addition to comorbidity, there are several characteristics that usually can be identified by the surgeon preoperatively that suggest an increased risk of difficulties and complications intraoperatively.[77] Often measures are taken to overcome the difficulties. A small pupil in spite of dilating eye drops, intraoperative floppy iris syndrome (IFIS), a white cataract without visible red reflex, a movable lens capsule and weakness of the zonules are difficulties that can be identified. Clinical experience as well as previous studies have shown that a small pupil or IFIS,[78, 79, 80, 81, 82, 83] absence of a red reflex due to a white cataract,[84, 85, 86] or an unstable capsular bag[87, 88, 89, 90, 91, 92, 93, 94] intraoperatively increase the risk of damage to important structures and complications. Capsular tension rings (CTRs), devices for mechanical stretching of the pupil and OVD, trypan blue dye,[86, 95]and capsular hooks can be used in these challenging situations to avoid complications. There is a lack of studies on to what extent patients with these challenging characteristics have worse outcome in visual function, despite compensatory measures, compared to patients without these characteristics.

As described above, use of the Rasch model, in which the ordinal (raw) data from Catquest-9SF are converted to an interval level measurement, yields a result expressed in the unit logit. Studies using extensive data from the NCR, often with more than 10,000 patients in each study, increase chance of finding statistically significant associations. Nevertheless, it is not obvious how to interpret the results. An association, even if statistically significant, can be small, due to the high power gained through the large amount of data. It remains unclear if these associations are of clinical importance to the patient, that is; what value of the unit logit is significant to the patient. In other words; what is the minimum important difference (MID)?

4 RESEARCH AIMS AND ETHICS

4.1 RESEARCH AIMS

Paper I — To study the association between ocular comorbidities and the change in patient reported visual function, postoperative patient reported visual function, and patient visual satisfaction after cataract surgery.

Paper II — To investigate associations between intraoperative difficulties and changes in patient self-assessed visual function, postoperative visual function and patient visual satisfaction after cataract surgery.

Paper III — To study the test–retest reliability of the Catquest-9SF questionnaire in cataract surgery.

Paper IV — The purpose of this study was to explore the minimum important difference (MID) of the Catquest-9SF questionnaire in cataract surgery.

4.2 ETHICAL CONSIDERATIONS

The studies are based on questionnaire surveys. The participating patients answer questions in questionnaires, thus there is no risk of physical injury, pain or discomfort. The study participants were well informed of the purpose of the investigation which was given on the questionnaire together with information on responsible researcher with contact details. If the patients did not want to participate they could simply refrain from completing the questionnaire. Based on this, we believe that the gain of knowledge by these studies exceeds the risks and discomfort of the patients.

The NCR has been reviewed by the Swedish Data Inspection Board and the collection of data in the NCR has been approved by an ethics vetting board. Study III and IV was approved by the Stockholm Regional Ethical Review Board (reference number 2017/130-31/2).

5 MATERIALS AND METHODS

5.1 PAPER I

5.1.1 Patient enrolment

Patients with cataract who underwent cataract surgery during March each year from 2008 to 2011 were included. 41 Swedish ophthalmology units participated and a total of 10,364 patients were included after exclusion of 615 patients, missing data being the main reason for exclusion.

5.1.2 Method and statistical analysis

The patients completed the Catquest-9SF before surgery and 3 months postoperatively. Several ocular comorbidities are registered in the NCR, these are glaucoma, macular degeneration, diabetic retinopathy (DR), cornea guttata, and "other ocular comorbidities" (e.g., amblyopia, retinal detachment [RD]). Based on clinical experience and previous findings all these ocular comorbidities were selected as predictive factors that may affect the outcome of cataract surgery. Rasch analysis was performed with three response variables. All analyses were based on multivariate statistics using SPSS software (version 20.0, International Business Machines Corp. Software Group). Multiple regression analyses were used for the continuous response variables (changes in visual function and postoperative visual function). The change in the patient-perceived visual function was calculated by subtracting the preoperative Rasch person score from the postoperative Rasch person score. The second response variable measures the postoperative visual function, i.e. the Rasch person score from the postoperative questionnaire only. General satisfaction with visual function postoperatively was the third response variable based on this single question from the postoperative questionnaire. The risk ratios of being generally satisfied and dissatisfied were calculated after dichotomization of the general satisfaction level into general satisfaction or general dissatisfaction. Logistic regression was used to calculate the risk ratios. A P value less than 0.05 was considered statistically significant. We performed the analyses both with and without the preoperative corrected distance visual acuity (CDVA) and the postoperative CDVA as covariates.

5.2 PAPER II

5.2.1 Patient enrolment

Patients with cataract who underwent cataract surgery during March each year from 2008 to 2011 were included. 42 Swedish ophthalmology units participated and a total of

10,979 patients were included initially, missing data was the main reason for later exclusion.

5.2.2. Method and statistical analysis

The patients completed the Catquest-9SF before surgery and 3 months postoperatively. The NCR contains data on the use of certain surgical instruments that reflect intraoperative difficulties. Posterior capsular tear is also registered. The instruments included as covariates in the analyses were capsular tension ring (CTR), mechanical pupillary stretching, trypan blue dye and capsular hooks. Posterior capsular tear was also a covariate. Rasch analysis was performed with three response variables similar to Paper I; change in subjective visual function after cataract surgery, mean subjective visual function (postoperative Rasch person score) and risk ratios of general satisfaction instead of general dissatisfaction. As in paper I we performed the analyses both with and without the preoperative CDVA and the postoperative CDVA as covariates. All analyses are based on multiple regression analyses using STATA version 13.1 (StataCorp LP, College Station, TX, USA). We used multiple linear regression analyses for the continuous response variables (changes in visual function and postoperative visual function). Poisson regression was used to calculate the risk ratios and the relative risk of posterior capsular tears. Multiple ordinal logistic regression was used to calculate the odds ratios (ORs) of the postoperative CDVA. A p value less than 0.05 was considered statistically significant.

5.3 PAPER III

5.3.1 Patient enrolment

Patients scheduled for cataract surgery at St. Erik Eye Hospital completed the Catquest-9SF twice before surgery. 247 patients completed the first questionnaire of whom 41 did not answer the second questionnaire and were therefore excluded. Only patients with 7-14 days between the two questionnaires were included in this test-retest study according to an appropriate interval in measuring test-retest reliability described earlier.[96] To meet this requirement another 56 patients were excluded along with 6 more due to other reasons. A total of 144 patients were included in the analyses.

5.2.3. Method and statistical analysis

Calculating the sample size, we considered an intraclass correlation coefficient (ICC) higher than 0.75 as good correlation[97] and an ICC of 0.82 as the least clinically relevant correlation. Sample size was calculated with the method suggested by Shoukri et al.,[98] using an a-level of 0.05 and a power of 0.8. The sample size was estimated at 188 patients.

A rating scale model[99] was constructed on the basis of the questionnaires from the first measurement. We used this model to generate scores for both the first and second measurements. The ICC, the Pearson correlation and a Bland–Altman plot[100] were calculated to examine the consistency between a patient's score at the first questionnaire and the same patient's score at the second questionnaire. Cronbach's alpha was used to measure internal consistency of the test at each time point. A high internal consistency indicates that all questions are measurements of the same latent construct.

5.4 PAPER IV

5.4.1 Patient enrolment

We randomly selected 400 patients nationwide who were scheduled for cataract surgery and completed the Catquest-9SF before surgery and 3 months postoperatively. An anchor question was sent to the patients 14 days after completing the second Catquest-9SF. This questionnaire contained one single question: "How do you experience your present vision compared to your vision before the cataract surgery?". The anchor question had five response options: "much better", "somewhat better", "no difference", "somewhat worse", and "much worse". Of the 400 patients, 234 responded and 231 were included in the final analyses.

5.4.2 Method and statistical analysis

Rach analysis (Winsteps (www.winsteps.com) M Linacre, Chicago, Il, USA) was performed on the Catquest-9SF questionnaires and the patients were dichotomized based on their preoperative Rasch score. Patients with Rasch scores of -1.50 or lower were placed in Group 1, and those with scores of -1.49 or higher in Group 2. A scatter plot was used to estimate the anchor question-based MID. To increase the accuracy of our estimation the MID was also estimated on the basis of distribution via Cohen's effect size (d).[55] Cohen's effect size is calculated by dividing the difference of the mean postoperative Rasch score and the mean preoperative Rasch score by the standard deviation of the preoperative Rasch score: d = (mean postop Rasch – mean preop Rasch)/SD. The MID is half of Cohen's effect size.

6 RESULTS

6.1 PAPER I

The mean age of the included patients was 74.9 years of whom 61.6% were women. The presence of comorbidities is described in Table 1.

	Patients, n (%)	
Comorbidity	**Present**	**Absent**
Glaucoma	740 (7.1)	9,624 (92.9)
Macular degeneration	1,928 (18.6)	8,436 (81.4)
Diabetic retinopathy	235 (2.3)	10,129 (97.7)
Cornea guttata	97 (0.9)	10,267 (99.1)
Any one other eye disease	700 (6.8)	9,664 (93.2)
More than one other eye disease	412 (4.0)	9,952 (96.0)
Total any comorbidity	4,112 (39.7)	6,252 (60.3)

Table 1. Comorbidities

6.1.1 Changes in patient-reported visual function

Eight covariates were significantly associated with the change in patient-reported visual function, including all six covariates regarding ocular comorbidity. Adding the preoperative and postoperative CDVA as covariates in the analyses reduced the impact of most of the comorbidities. Glaucoma, Macular degeneration and "any 1 other ocular disease" significantly affected the change in visual function despite the inclusion of the preoperative and postoperative CDVA in the regression model. Absence of glaucoma had the lowest logit value; -0.355. The lower the logit value, the larger change to the better in patient-reported visual function.

6.1.2 Postoperative visual function

Eight covariates were significantly associated with the patient-reported postoperative visual function, including all six covariates regarding ocular comorbidity. Even after adding the preoperative CDVA and postoperative CDVA as covariates in the regression model presence of DR, "any 1 other ocular disease", glaucoma, macular degeneration and "more than 1 other eye disease" were significantly associated to worse postoperative visual function. Presence of DR and glaucoma resulted in the worse patient-reported visual function, that is the highest logit values.

6.1.3 Odds ratios of satisfaction and dissatisfaction

Presence of any of all the ocular diseases were significantly associated to the odds ratio (OR) of general satisfaction instead of general dissatisfaction. Highest OR of being generally dissatisfied was seen in the presence of cornea guttata, "any 1 other ocular disease" or macular degeneration. After inclusion of preoperative and postoperative CDVA in the model glaucoma, macular degeneration and "more than 1 other ocular disease" were all significantly associated to higher OR of being generally dissatisfied. The postoperative CDVA was the covariate strongest associated to the level of general satisfaction after cataract surgery.

6.2 PAPER II

The mean age of the included patients was 74.9 years of whom 61.4% were women. The presence of intraoperative difficulties and other covariates in the study participants is described in Table 2.

Table 2. Intraoperative difficulties and other covariates

Intraoperative difficulty	Patients, n (%) Present	Absent
Posterior capsule tear	129 (1.2)	10,822 (98.8)
Capsular tension ring	207 (1.9)	10,745 (98.1)
Mechanical pupillary stretch	453 (4.1)	10,499 (95.9)
Trypan blue dye	344 (3.1)	10,608 (96.9)
Capsular hooks	167 (1.5)	10,785 (98.5)
Any intraoperative difficulty	907 (8.3)	10,045 (91.7)
Ocular comorbidity	3,763 (34.4)	7,189 (65.6)

6.2.1 Changes in patient-reported visual function

Posterior capsular tear and trypan blue dye was significantly associated with the change in subjective visual function as well as other factors. Patients with posterior capsular tear had less improvement, but patients with trypan blue dye had greater improvement in subjective visual function. Including the preoperative CDVA and postoperative CDVA in the model reduced the impact of the intraoperative difficulties.

6.2.2 Patient-reported postoperative visual function

Statistical analysis showed that the preoperative Rasch score was associated with this outcome variable, the postoperative Rasch person score, and therefore was added as a covariate. Posterior capsular tear and capsular hooks were significantly associated with the postoperative visual function, both factors led to worse postoperative visual function. Including the preoperative CDVA and postoperative CDVA in the model showed that trypan blue dye gave significantly better patient-reported postoperative visual function. Also, a lower preoperative CDVA and a higher postoperative CDVA was associated with better postoperative visual function. In contrary, posterior capsular tear led to worse subjective visual function.

6.2.3 Relative risks of patient satisfaction and dissatisfaction

Patients with another ocular disease, who required mechanical pupillary stretching or patients with posterior capsular tear had a higher risk of general dissatisfaction compared to their counterparts. Statistical analysis including the preoperative and postoperative CDVAs showed that only ocular comorbidity and postoperative CDVA was significantly associated to the risk of general satisfaction.

6.2.4 Posterior capsular tear

Patients who required trypan blue dye or capsular hooks had a significantly higher risk of posterior capsular tear.

6.2.5 Postoperative CDVA

The postoperative CDVA, the outcome variable in this analysis, was trichotomized into three levels, and ordinal logistic regression was used to calculate the ORs. Trypan blue dye, capsular hooks and posterior capsular tears were associated significantly with worse postoperative CDVA.

6.3 PAPER III

The gender and age of the included and excluded patients are shown in table 1. The age and visual acuity were similar between the groups. Male patients had a somewhat higher inclusion rate.

Table 1. Gender, age and preoperative visual acuity of the study participants

Patients	Female patients, n (%)	Male patients, n (%)	Mean age	Visual acuity logMar =ns (p=0.62)	Total patients, n
Included	69 (47.9)	75 (52.1)	73.1	0.19	144
Excluded	58 (56.3)	45 (43.7)	73.9	0.17	103
All	127 (51.4)	120 (48.6)	73.4	0.18	247

ns= not significant difference between included and excluded

The proportion of patients who gave the same answer on a specific question at the baseline test and the retest is called the percentage agreement (PA). The PA on each question ranged from 79.6% (question 1) to 63.1% (question 3). Table 2 shows the result on Question 2 on general satisfaction with visual function.

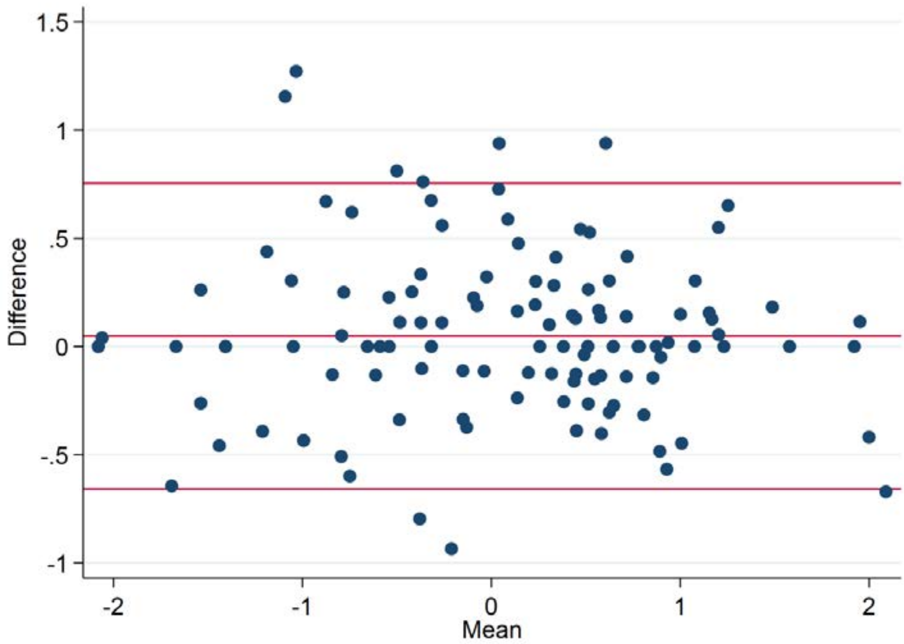
Table 2. Test-retest reliability, question 2: satisfaction with vision

Q2		Retest				
	Answer	1	2	3	4	Total
Test	1	31	14	0	0	45
	2	5	50	8	1	64
	3	0	3	22	1	26
	4	0	0	2	0	2
	Total	36	67	32	2	137

Green: patients who answered the same at test and retest (n = 103; PA = 75.2%). Yellow: patients who answered differently by one response option step (n = 34; 24.8%). Red: patients who answered differently by two steps or more (n = 1; 0.7%).

The ICC was 0.93 and the 95% confidence interval was 0.903–0.948, and the Pearson correlation was 0.93. Figure 2 depicts the results as a Bland–Altman plot. The Bland–Altman plot shows the mean of the two scores of each patient (x-axis) plotted against the difference in logits (y-axis), with red lines, also known as limits of agreement, denoting 1.96 standard deviations from the mean. In such a plot, it is desirable that the vast majority of the dots are between the peripheral two red lines, and in addition there should be no trend; that is, aside from some random variation, the difference for high scores should be equal to the difference for low scores. The result calculated from the first and second measurements for Cronbach's alphas were both 0.94.

Figure 2. Bland-Altman plot



6.4 PAPER IV

Of the 400 patients that received the anchor question after having completed both the preoperative and postoperative Catquest-9SF, 234 patients responded. Three patients gave inconclusive answers and were excluded, thus 231 patients with a mean age of 74 years of whom 60 % female were included in the statistical analyses. The mean age of the excluded patients (n=169) of whom n=166 were non-responders was also 74 years and 62 % were female. Rasch analyses was performed and the patients were dichotomized into two groups based on the preoperative Rasch score. Patients with Rasch scores of -1.50 or lower were placed in Group 1, and those with scores of -1.49 or higher in Group 2. Table 1 and table 2 show the results of the anchor question for each group.

Table 1. Mean Rasch score change in Group 1.

Answer anchor question	**Mean Rasch score change (logits)**	**Number of patients (n)**	**Percentage of patients (%)**
1 (Much better)	-2.3551	57	83
2 (Somewhat better)	-1.1756	9	13
3 (No difference)	0.2033	3	4
4 (Somewhat worse)	-	0	0
5 (Much worse)	-	0	0
All	-2.09	69	100

Group 1 comprises patients with a preoperative Rasch score of -1.50 or lower; that is, the group with better preoperative self-assessed visual function.

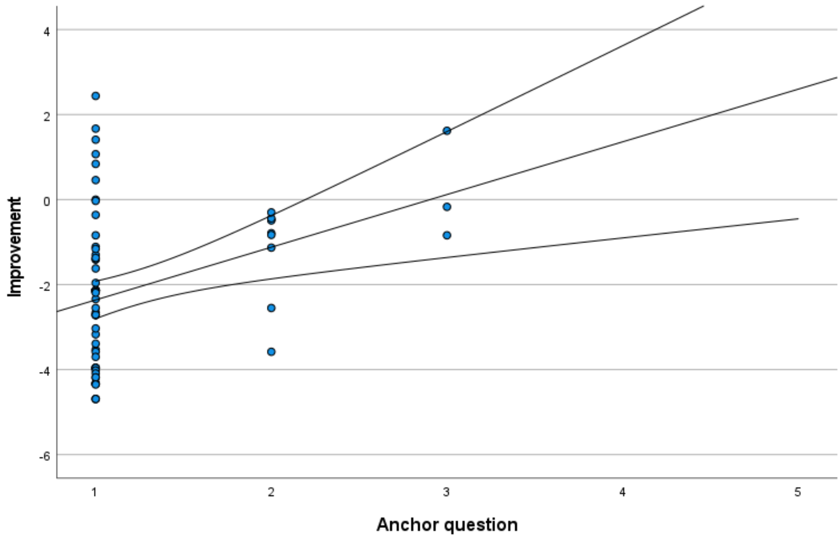
As shown in table 1 patients in Group 1 who experienced "no difference" in their vision after cataract surgery had a mean Rasch score change of 0.2033 to be compared to the mean of -1.1756 in patients who assessed their vision to be "somewhat better" after surgery. As a consequence, the MID of Group 1 was estimated to be between these numbers. The corresponding numbers of the MID range for Group 2 were -0.6250 and -2.6892. A scatter plot was created to calculate a more precise value of MID where the trend line met the value of 2.5 corresponding to the point in the middle between answer 2 ("somewhat better") and answer 3 ("no difference"). As shown in figure 2 and 3, the value of MID in Group 1 was estimated to -0.5 and in Group 2 to -1.80.

Table 2. Mean Rasch score change in Group 2.

Answer anchor question	Mean Rasch score change (logits)	Number of patients (n)	Percentage of patients (%)
1 (Much better)	-4.4669	133	82
2 (Somewhat better)	-2.6892	24	15
3 (No difference)	-0.625	2	1
4 (Somewhat worse)	0.7	3	2
5 (Much worse)	-	0	0
All	-4.0604	162	100

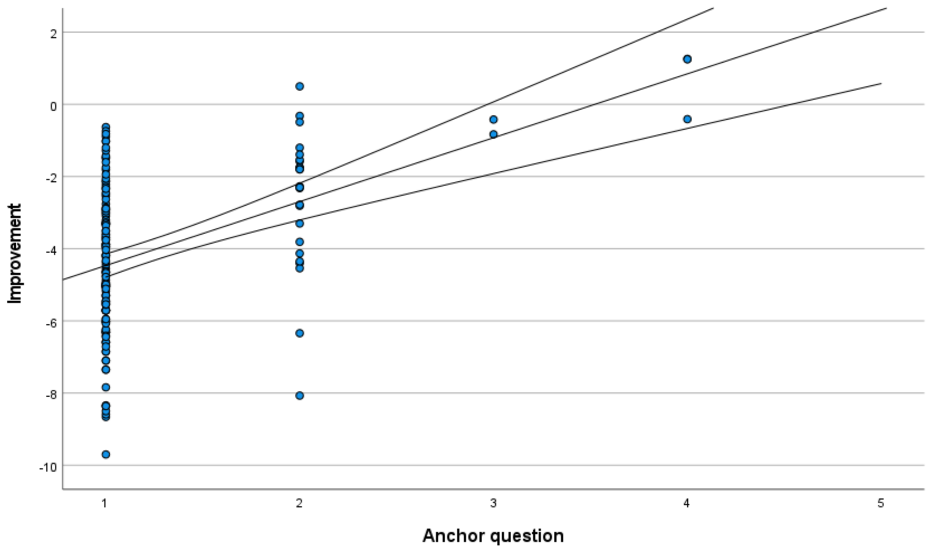
Group 2 comprises patients with a preoperative Rasch score of -1.49 or higher; that is, the group with worse preoperative self-assessed visual function.

Figure 2. Scatter plot showing improvement in Rasch score (logits) and answers to anchor question in Group 1.



Group 1 comprises patients with a pre-operative Rasch score of -1.50 logits or lower.

Figure 3. Scatter plot showing improvement in Rasch score (logits) and answers to anchor question in Group 2.



Group 2 comprises patients with a pre-operative Rasch score of -1.49 logits or higher.

By calculating Cohen´s effect size we estimated MID on the basis of distribution. The results were -1.07 for Group 1 and -1.46 for Group 2. Table 3 shows a summary of the different estimations of MID.

Table 3. Estimations of MID in each group.

Means of MID estimation	**Group 1 (logits)**	**Group 2 (logits)**
Anchor question	-0.5	-1.80
Cohen's effect size	-1.07	-1.46
Approximation of true MID (mean of the above)	-0.79	-1.63

Group 1 comprises patients with a pre-operative Rasch score of -1.50 logits or lower; that is, the group with better preoperative self-assessed visual function. Group 2 comprises patients with a pre-operative Rasch score of -1.49 logits or higher; that is, the group with worse preoperative self-assessed visual function.

7 DISCUSSION

7.1 PAPER I

In the comorbidity-study the aim was to increase knowledge on how other simultaneous ocular diseases affect the patient´s self-assessed visual function after cataract surgery. Patients without all studied ocular comorbidities had higher improvement, better postoperative visual function and greater satisfaction after cataract surgery compared to patients with one or more of the other ocular diseases. The impact of all ocular diseases was reduced by including the preoperative and postoperative CDVA in the statistical analyses. This is not surprising because CDVA is a powerful predictor of visual function. Nevertheless, the presence of glaucoma or macular degeneration in our study had a significant impact on all three outcome measures even when the CDVAs were included in the analyses. This implies that presence of any of the two diseases mean that the patient will not benefit as much as their healthier counterparts according to their own self-assessment of the visual function despite taking the powerful predictor of CDVA into account. This knowledge is useful in the preoperative situation when informing the patient about the surgery and the expected outcome.

There was weak association between cornea guttata and the studied outcome measures. This suggests that the presence of cornea guttata has little impact on the visual function. However, the cases of guttata was relatively few in our study and a larger sample might have a different result. Also, there is no grading of the severity of guttata in the NCR, which might result in the inclusion of mild cases with little risk of complications during the study period and this can perhaps dilute the significance.

We found a worse postoperative visual function in patients with DR even when the preoperative and postoperative CDVA were included as covariates. Nevertheless, patients with diabetic retinopathy did not have higher odds ratios of general dissatisfaction with the CDVAs included. It can be discussed why this is the case, one reason might be that these patients are aware of their diabetes disease and subsequent retinopathy making their expectations and personal requirements of what to classify as satisfactory visual function low.

Several previous studies have examined associations between ocular comorbidity and postoperative visual function with varying conclusions. A study of almost 400 patients undergoing cataract surgery found that patients with macular disease, DR or glaucoma had worse outcome in perceived visual function.[67] Another group using the Rasch-analyzed Quality of Vision questionnaire suggested that a study including almost 20 000 patients would be required to find statistical significant difference in improvement in the scores between patients with an ocular comorbidity and their counterparts.[68] A previous study saw increased risk of having no benefit from surgery in patients with ocular comorbidity compared to patients without other ocular disease using the original version of the Catquest questionnaire on 1933 patients.[59]

The severity of the simultaneous ocular comorbidities is not registered in the NCR. It is likely that many cases of mild disease with little or no effect on the visual function are included in this study. If so, these cases dilute the significance of having a comorbidity. It would be interesting to investigate the association between moderate or severe ocular disease and the self-assessed visual function after cataract surgery.

The large number of patients included in the study is a strength that makes it easier to find significant associations. However, some of the significant associations might be rather small and we cannot be sure how large a change in the logit unit has to be to be significant to the patient. That is, the minimum important difference, which was assessed in paper IV.

7.2 PAPER II

In this intraoperative difficulties-study we wanted to to investigate if intraoperative difficulties or complications have an impact on the patient´s benefit of cataract surgery. We looked for associations between intraoperative difficulties or complications and the change in patient reported visual function, postoperative visual function and general satisfaction with vision postoperatively. The results show that the intraoperative difficulties use of trypan blue dye, mechanical pupillary stretching or capsular hooks and posterior capsular tears were all significantly associated to the outcome of visual function. Including the preoperative and postoperative CDVAs in the analysis reduced the influence of the intraoperative difficulties and complications. This is to expect because the known large impact of CDVA on patient-reported visual function. Posterior capsular tear and postoperative CDVA were added as two separate outcomes.

We did not find any association between the use of a CTR and any of the outcome variables. One could argue that this suggests that the use of a CTR is a safe technique to manage weak zonules and unstable capsular bags. There is little knowledge on visual outcome with the use of a CTR. A study from Australia of 84 eyes in which CTRs were inserted intraoperatively reported that compared to the preoperative visual acuity (VA), 73% had a better postoperative VA, 20% remained unchanged and 7% had worse postoperative VA.[88] The study did not report comparative data on eyes without CTR insertion intraoperatively.

The surgeon identifies the need for a CTR and this decision largely depends on the preference of the surgeon which can be quite personal. Implanting the CTR in the capsular bag is also associated to a risk of even more zonular damage. The cost of the CTR instrument is substantial. To gain more precise knowledge a randomized study of CTR use could be useful. An additional outcome with CTR use could be secondary suture of a luxated IOL which would require a follow-up period of several years.

Mechanical pupillary stretching was not associated to the patient-reported improvement of visual function or postoperative visual function. It has been shown earlier that a small pupil or IFIS significantly increases the risk of intraoperative complications.[80, 81, 101, 102] Another study in which experienced surgeons could anticipate IFIS and mechanically stretch the pupil by use of iris retractors or pupillary expansion ring reported a low complication rate.[103] This later study supports the findings in our study that use of mechanical pupillary stretching can compensate for the difficulties implied by a small pupil or IFIS.

Trypan blue dye is used to visualize the anterior capsule in cases of a very dense or white cataract. These white lenses are very likely to have a major negative impact on the visual function. The finding in the current study that use of trypan blue dye is associated to significantly greater improvement in visual function when the CDVA is not included is therefore not surprising. Use of trypan blue dye was also found to be associated to posterior capsular tear a worse postoperative CDVA. The association to posterior capsular tear has been reported earlier.[101, 104]

There was weak or no associations between use of capsular hooks and the outcome. It can be discussed if this could at least partly be interpreted as that use of capsular hooks is a safe measure to handle the difficulties implied by weak zonules or an unstable capsular bag. Another explanation can be connected to the information given to the patient prior to the surgery. If an unstable capsule is noted before surgery and the patient is informed of the increased risk of intraoperative complications it might help the patient to establish realistic expectations and secondly experience higher improvement and lower risk of general dissatisfaction with visual function after cataract surgery.

It has been shown earlier that posterior capsular tear is associated to increased risk of visual loss.[105] Another study showed worse postoperative CDVA in patients with posterior capsular tear compared to patients with no capsular tear.[106] In addition to worse postoperative CDVA, our study showed that posterior capsular tear was significantly associated to all three outcome measures of patient-reported visual function; less improvement, worse postoperative visual function and increased risk of general dissatisfaction.

A weakness of the data collection in the NCR and therefore also in this study is the personal preferences of the surgeon when it comes to choosing additional instruments to handle intraoperative difficulties. Some surgeons might have a low threshold for using e.g. a CTR whereas other surgeons hardly ever use them. There is no grading of the indications for use of an additional instrument in the NCR, for example how many clock hours of zonular weakness that was observed before deciding if to use a CTR or capsular hooks or not, or in the situation with trypan blue dye; how poor is the visualization due to a white lens or dense nuclear sclerosis? One could argue that experienced high-volume surgeons are likely to make similar decisions. The high-volume surgeons contribute to a majority of the cataract operations performed in the NCR.[107] Thus, this weakness has little effect on the results on this study.

7.3 PAPER III

In our test-retest study the aim was to assess the reliability of the Catquest-9SF questionnaire. The result of ICC was 0.93 and Cronbach´s alpha was 0.94, indicating very high reliability. Signs of high reliability was also seen in the Bland-Altman plot as the vast majority of the dots lie within the limits of agreement and as the plot has no visible trend.

There are alternatives to the statistical methods used in this paper. It can be discussed if Cronbach´s alfa is the optimal measure of internal consistency. The data from two identical questionnaires as in Paper III can be treated as paired ordinal data whereas Cronbach´s alfa is primarily for use with continuous data. In a previous study mentioned in our paper, the ordinal alpha method is used to calculate the internal consistency.[108] One can argue that the latter is more correct based on the characteristics of the data. Another concern one might have is the use of ICC for analysing data from questionnaires since ICC demands data on at least interval-level. An alternative that might be favourable is the use of Svensson´s method which was found to be suitable for analysing questionnaire data.[108] Compared to the cited study, we had no reason to expect a systematic change in Paper III, which means that some advantages of Svensson´s method are lost. Also, all items assessed in Paper III are about one single dimension, activity limitations in daily life, which is not the case in the cited study that analysed data from several subscales. When performing statistics, striving to find and use the best suited measure for the data to be analysed is fundamental. Regardless of which of the mentioned statistical methods to use, there is reason to believe that the result in this study would be very similar. When publishing work in international scientific journals reaching researchers and clinicians, it is an advantage to use well known and widely accepted measures.

The original version of Catquest was tested in a test-retest study, testing only the seven disability items focused on the patient-perceived problems in everyday activities due to inadequate visual function.[28] 57 patients completed the questionnaire twice with a mean of 10.6 days interval between the baseline test and the retest (range 6-16 days). High stability and high internal consistency were shown in the results. The revised version, Catquest-9SF, includes the same seven items on disability, so the high reliability seen in the current study is not a surprise.

Similar results of an ICC of 0.93 was seen in a test-retest study on the Dutch version of Catquest-9SF, the interval between the two preoperative tests being one week.[47]

As explained earlier, it is important for us to know that the patients´ answers to the questions do not rely on chance, that is that the reliability is high. High reliability means that the answers are similar or same when tested repeatedly under consistent conditions in a short period of time. In the current study the first baseline questionnaire was completed by the patient in their home after receiving it by paper mail. The second form, the retest, was delivered to the patient just before cataract surgery in the hospital. It can be discussed if changing the location from the patient´s own home to a hospital setting just before eye surgery violates the rule of consistent

conditions and that this perhaps could have influenced the answers. If this is the case, it can be assumed that the true reliability is even higher than our results show.
We were controlling the interval between tests to be 7-14 days only, excluding a considerable number of patients. This was to make sure the interval is short enough to reduce risk of progress in the cataract disease changing the conditions, but long enough to make sure the patients do not remember their previous answers. This is in line with the requirements stated by McDowell & Newell.[96] Arguably, the strict implementation of these requirements adds to the quality of our study. Table 1 shows that the excluded patients were of similar age and had similar visual acuity compared to the included patients. Men were included at a somewhat higher rate compared to women, this probably is of minor importance to the results.
The considerably large number of exclusions resulted in 144 included patients in the final analyses. One can discuss if the large number of exclusions resulted in a sample size smaller than preferable. To compensate for non-responders and other exclusions, the baseline questionnaire was sent to a significantly higher number of patients than our estimations showed we would need for analyses. The analyses resulted in an ICC of 0.93 with the 95% confidence interval of (0.903-0.948). This narrow confidence interval means that the calculated ICC is robust and that the sample size is large enough for these analyses.

7.4 PAPER IV

Several studies have shown statistically significant associations between preoperative or intraoperative factors and the patient self-assessed outcome in cataract surgery. The large set of data in the NCR has a statistical power large enough to find even rather small significant associations. With this study our purpose was to assess how large the change measured in logit has to be to be significant to the patient, that is the MID. For example, in paper 1, the comorbidity study described above, macular degeneration was found to be significantly associated to the change in patient-reported visual function after cataract surgery by the logit value of -0.205 when the CDVAs were included in the analyses. Comparing this logit value to the results of this MID study finding a MID logit value of -0.79 in Group 1 suggests that the presence of macular degeneration is probably of minor clinical importance.
To add to the accuracy of the estimation of MID in this study we used two separate methods. An effect size of -1.87 corresponding to a MID of -0.935 was found in a previous study that included 846 patients who completed the Catquest-9SF before and after surgery.[31] The value obtained is similar to the result of the current study.
The Rasch score change in cataract surgery differs depending on the baseline Rasch score. Patients with big problems due to visual function (high Rasch score) have a larger scope of improvement compared to patient with few problems (low Rasch score). With this in mind, it is likely that the MID will also differ depending on the baseline Rasch score. Therefore, we dichotomized the patients into two separate groups depending on the baseline Rasch score. Our findings support the dichotomization, showing a significant difference in the MID between the two groups.

Taking the baseline Rasch score into account when evaluation the effect of cataract surgery seems to be important. As in the example above regarding the effect of macular degeneration on the change in patient-reported visual function after cataract surgery, it is fundamental to adjust for the baseline Rasch score when deciding if it is likely that patients with macular degeneration will have a significantly worse clinical outcome of cataract surgery compared to patients without macular degeneration.
It can be discussed if a dichotomization into two groups of patients is enough. Our finding of significant difference in Rasch score change and MID between the two groups suggest that division into more groups would increase the precision of the estimations even further. However, the number of patients included in the current study did not allow further division.
The final number of included patients was 231 after exclusion of 169. The age and gender of the excluded patients were similar to age and gender of the included patients.
The relatively few patients experiencing only a small improvement or no improvement limits the statistical power of the study, as the vast majority assessed their visual function after cataract surgery to "much better" compared to the situation before surgery. It can be discussed if this is a weakness of this study. It is well known from previous studies that few patients experience having no benefit from cataract surgery. Nevertheless, constructing an anchor question with a larger proportion of patients with only mild or no improvement is very difficult. Adding more patients seems to be the only way to increase statistical power and to permit further division into several separate groups instead of just two as in the present study. However, our use of two separate methods to estimate the MID and the subsequent finding that they produce similar results for the MID of Catquest-9SF arguably adds to the precision of the assessment.

8 MAIN CONCLUSIONS

8.1 PAPER I

The comorbidity study shows that several other simultaneous ocular diseases in addition to cataract at the time of cataract surgery affect the patient´s self-assessed visual function after cataract surgery despite inclusion of the preoperative CDVA and postoperative CDVA.

8.2 PAPER II

Several of the studied intraoperative difficulties and complications were significantly associated to the patient-reported outcome in cataract surgery. Including the preoperative CDVA and postoperative CDVA in the analyses reduced the impact of some of the intraoperative difficulties.

8.3 PAPER III

From this test-retest study of the reliability of the Catquest-9SF we can conclude that the reliability of the Swedish Catquest-9SF is very high. Together with previous knowledge, our findings support continued use of the Catquest-9SF in assessing the quality and outcome in cataract surgery.

8.4 PAPER IV

The assessment of MID of Catquest-9SF in the study adds detailed knowledge of MID and shows that MID differs depending on the baseline visual function. The findings enable even more precise high-quality evaluation of the outcome and benefit of cataract surgery.

9 POINTS OF PERSPECTIVE

Information on factors that influence the outcome in cataract surgery can be used by surgeons in deciding the right time to perform surgery. The information can also aid in informing patients of the expected outcome, helping patients to gain realistic expectations. Information obtained from the NCR and Catquest-9SF can also be used by the surgical departments and clinics to monitor the cataract care and to measure the quality of the care and patients´ self-assessed effect on their visual function.

In some countries the possibility to introduce Catquest-9SF as an instrument to grade the indication for surgery is discussed. This may seem as a good idea, considering the questionnaire´s qualities in measuring visual disabilities due to cataract. However, Catquest-9SF score does not consider other factors that may weaken or strengthen the indications for cataract surgery. One factor that may weaken the indication for surgery could be advanced ocular comorbidity. Factors that may strengthen the indication for surgery could be a medical indication, e.g. to reduce intraocular pressure or a social indication; e.g. in cases when cataract limits the patient´s ability to perform her employment. In Sweden, there is a separate indication model for cataract surgery called NIKE[109] that combines the mentioned factors with a cataract symptom scoring questionnaire, Priquest V2.

It would be favorable if data collection in the NCR could be more detailed on disease severity. In the current registration ocular comorbidity, glaucoma for example, is only registered as present or not present. There is no grading on the severity of disease. It is reasonable to assume that we include many cases of very mild disease with limited effect on the self-assessed visual function. The inclusion of mild cases dilutes the results, and it is likely that the effect of clinically significant comorbidity would show larger effect on the postoperative visual function compared to the results in this project. The registration of data in the NCR at the time of surgery is done by the surgeon. To obtain a grading of disease severity in the NCR, the registration process would be more detailed and time consuming, and perhaps discourage surgeons to register. A vast majority of clinics now use digital patient files. An interesting alternative to manual registration by the surgeon would be a system that automatically collects all needed data from the patient´s records into the NCR. This possibility would save time and probably increase the information accuracy of NCR and Catquest-9SF. Presumably, this would require large investments, the diversity of software used for patient records across the country is an obstacle.

Availability and registration of all patient data in the preoperative situation would enable the creation and use of a prognostic instrument that can predict the individualized outcome of cataract surgery for every single patient. This patient data could be run and matched to NCR data on previous results on the effect of cataract surgery. The instrument would deliver an individualized calculated prognostic result to aid the surgeon in the decision on when to recommend to perform cataract surgery and helping the patient to even more precise expectations. However, patients are individuals and an instrument based on statistics would not be able to compensate for personal traits and attitudes and this would limit the accuracy of the instrument. Nevertheless, an instrument like this could be used to identify patients at increased risk of experiencing unchanged or worse visual function after cataract surgery.

Future development of the Catquest-9SF would probably include an effort to adjust the items (i.e. questions) towards the postoperative situation. The item difficulty in the current questionnaire corresponds well to the pre-operative situation, but could be argued to be a bit too easy in the situation after cataract surgery since a vast majority experience few limitations in their daily life due to poor vision after cataract surgery.

Catquest-9SF does not specifically measure the grade of dependence on use of eyeglasses to obtain sufficient vision. Patients' expectations related to eyeglass independence are increasing. Eyeglass independence could be argued to add to quality of life, thus it could be argued that this should be measured in the future.

A less revolutionary improvement compared to introducing a new version of the Catquest questionnaire would be to implement a digital Catquest-9SF that could be completed by the patient on a cellphone, on a computer at home or on a computer tablet in the waiting room in the clinic. This would probably increase participation and reduce the administrative burden.

Future technological developments will probably improve the outcome of cataract surgery. This includes more precise preoperative biometry of the eye that reduces risk of refractive errors in cataract surgery. The IOLs will continue to develop with better materials and new techniques that will improve the results in non-monofocal IOL-surgery in particular. This will probably reduce glare, halos, and other photic phenomena as well as limit the decrease in vision quality due to aberrations.

The greatest challenge for the future is to increase access to high-quality cataract surgery in middle- and low-income countries.

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