

Patient-Reported Outcome Measures in Cataract Surgery

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Statement of Originality

*This is to certify that to the best of my knowledge, the content of this thesis is my own work.
This thesis has not been submitted for any degree or other purposes.*

*I certify that the intellectual content of this thesis is the product of my own work and that all
the assistance received in preparing this thesis and sources have been acknowledged.*

Rachel Xuan

Statement of authorship attribution

Professor Andrew Chang and Associate Professor Constantinos Petsoglou have provided expert advice throughout all aspects of the research including the study design and revision of the thesis. Joanna McCulloch assisted with the overall execution of the study described in Chapter 3.

The research in Chapter 2 was presented at the Sydney Eye Hospital Alumni Meeting in Sydney and the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) 54th Annual Scientific Congress in Perth. The abstract was published in the journal, *Clinical and Experimental Ophthalmology*.

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As the supervisors of the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

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Validation of the Catquest-9SF compared to Priquest questionnaire in an Australian cataract population. Poster Abstracts. *Clinical and Experimental Ophthalmology*. 2024 (in press).

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List of Abbreviations

ACI	Agency for Clinical Innovation
ACSQHC	Australian Commission for Safety and Quality in Health Care
ADVS	Activities of Daily Vision Scale
AIOLIS	Assessment of IntraOcular Lens Implant Symptoms
AMD	Age-related macular degeneration
ANCHOR	Anti-vascular endothelial growth factor antibody for the Treatment of Predominantly Classic Choroidal Neovascularisation in AMD
BRAVO	BRAnch Retinal Vein Occlusion study
Catquest-9SF	Catquest 9-Short Form
CCCS	Cataract Clinical Care Standard
CIHI	Canadian Institute of Health Information
CMS	Centers for Medicare and Medicaid Services
CRUISE	Treatment of Macular Edema after Central Retinal Vein Occlusion Study: Evaluation of Efficacy and Safety study
DIF	Differential item functioning
DSBCS	Delayed sequential bilateral cataract surgery
EAGLE	Effectiveness in Angle Closure of Lens Extraction
EQ-5D	EuroQol-5D
EQ-5D-5L	EuroQol-5D 5 Levels
eMR	Electronic Medical Record
ePROM	electronic Patient-Reported Outcome Measures
ES	Effect size
ESCRS	European Society of Cataract and Refractive Surgeons
EUREQUO	European Registry of Quality Outcomes for Cataract and Refractive Surgery
HOPE	Health Outcomes and Patient Experience

HOS	Health Outcome Survey
HQIP	Health Quality Improvement Partnership
HUI	Health Utility Index
HURON	Chronic Uveitis evaluation of the intravitreal dexamethasone implant
ICC	Intraclass correlation coefficient
ICHOM	International Consortium for Health Outcomes Measurement
ISBCS	Immediate sequential bilateral cataract surgery
IT	Information technology
IVAN	Inhibition of VEGF in Age-related choroidal Neovascularisation
LE	Left eye
LHDs	Local Health Districts
MARINA	Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular Age-Related Macular Degeneration
MID	Minimal Important Difference
MNSQ	Mean squares
NED	National Eye Database
NCR	National Cataract Register
NQRs	National Quality Registries
NSW	New South Wales
OECD	Organisation for Economic Co-operation and Development
PCA	Principal component analysis
PCORI	Patient-Centred Outcomes Research Institute
PPEP	PROMs, PREMs, and Effectiveness Programme
PR	Person Reliability
PREM(s)	Patient-Reported Experience Measure(s)

PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PRO	Patient-reported outcome
PROE	Patient Reported Outcome Extension
PROMIS	Patient-Reported Outcomes Measurement Information System
PROM(s)	Patient-Reported Outcome Measure(s)
PSI	Person Separation Index
QALY	Quality-adjusted life-year
QIRC	Quality of Life Impact of Refractive Correction
QOL	Quality of Life
NICE	National Institute of Health and Care Excellence
NIKE	Nationell Indikationsmodell for Kataraktextraktion
NOD	National Ophthalmology Database
NHS	National Health Service
RCOphth	Royal College of Ophthalmologists
RE	Right eye
SES	Socioeconomic status
SF-36	Short Form-36
SF-6D	Short-Form Six-Dimension
SHNs	Specialty Health Networks
TAGS	Treatment of Advanced Glaucoma
UK	United Kingdom
USA	United States of America
VA	Visual Acuity
VBHC	Value-Based Healthcare
VBHCAT	Value-Based Healthcare in Cataract Surgery

VDA	Visual Disability Assessment
VEGF	Vascular endothelial growth factor
VF-14	Visual Functioning 14
WHO	World Health Organisation
WHOQOL-BREF	World Health Organisation Quality Of Life Brief Version
ZSTD	Z-score

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1. Introduction

1.1 Transforming Healthcare with Patient-Reported Outcome Measures

In recent years, clinical practice and research trials have seen a shift away from exclusively relying on conventional outcome metrics to embracing patient-reported outcome measures (PROMs).¹ Traditionally, landmark ophthalmology trials focused on parameters such as visual acuity, intraocular pressure and anatomic outcomes to assess the safety and efficacy of treatments.²⁻⁴ Whilst these clinical parameters are important, they may not reflect the impact of disease on patients' lives.^{5,6} In response, there has been a growing focus on the patient's perspective and experience within clinical care.⁷

Whilst the use of PROMs has grown, with increasing incorporation into ophthalmic clinical trials⁸⁻¹⁰, its application in routine ophthalmology practice remains limited.^{5,11-14} In Australia, PROMs has yet to be embedded into routine care at regional, or national levels.¹⁵ However, health systems around the world have adopted, or are developing, routine and consistent PROMs within clinical practice. For example, in the UK, patient-reported outcome assessments are standard pre-operatively and post-operatively in various surgical specialities including hernia, hip, knee and varicose vein surgery in the National Health Service (NHS).¹⁶⁻¹⁸ Elsewhere, PROMs have been incorporated into national quality registries to guide patient-reported quality improvements in healthcare with. The Swedish healthcare system has achieved up to 87% inclusion rates of some form of PROM.^{19,20}

In Australia, PROMs are an emerging method to inform the improvement of quality of care. Within the last decade, the Australian Commission for Safety and Quality in Health Care (ACSQHC) has actively promoted the integration of PROMs at a national level to drive patient-centred quality changes. This chapter outlines the use of PROMs within international health systems, thus forming the foundation of this thesis which focuses on the implementation of PROMs in an Australian cataract population within a broader, international context.

PROMs comprise a series of structured questions to report on the *“status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else”*.²¹ PROMs are usually paper- or electronic-based questionnaires with data showing higher compliance rates associated with electronic delivery.²² PROM questions are referred to as 'items' for which there may be two or more answer options. They can be generic in nature and measure aspects of health status and quality of life or, tailored to a specific condition such as symptom severity.^{23,24}

Generic PROMs assess the wider aspects of health status by calculating the quality-adjusted life-year (QALY) to quantify the impact of the disease or healthcare treatment. As a result, clinicians can estimate incremental effectiveness and cost-associations especially when comparing multiple interventions with similar clinical effectiveness.⁷ These questionnaires generally include outcomes such as physical functioning, psychological symptoms or pain. The more commonly used generic PROMs in ophthalmology are EQ-5D (EuroQol-5D)²⁵, HUI (Health Utility Index)²⁶ and versions of the Short Form-36 (SF-36)²⁷. However, the use of generic PROMs alone lacks sensitivity to assess disease-specific symptoms.²⁸ Over the last three decades, these instruments and their dimension have performed variably for different health conditions hence care must be taken in the selection of an appropriate PROMs.²⁹⁻³¹

On the other hand, vision-related PROMs focus more on ocular symptoms or the impact of vision impairment on daily activities and social function as reported by patients. Most PROMs, in ophthalmology, were developed to assess these health aspects except for some – the Ocular Surface Disease Index is used to evaluate pain associated with dry eye disease.³² Condition-specific PROMs are used to for patients with a single disease for example, the Glaucoma Quality of Life -15 (QOL)³³ for patients with glaucoma or Catquest-9SF (short-form) for patients with cataract.³⁴

In research, PROMs may be used as primary outcomes to assess treatment effectiveness however it has more traditionally been used to complement a clinical parameter. Table 1 highlights some examples of select recent ophthalmic RCTs where PROMs were used as primary outcome measures.¹

In recent years, ophthalmic subspecialties including glaucoma^{35,36}, medical retina³⁷ and cataract³⁸⁻⁴⁰ have actively explored the integration of PROMs into routine practice. However, in other subspecialties such as neuro-ophthalmology⁴¹ and oculoplastic⁴², PROMs are still at early stages of development with current preference for generic instruments for assessment. With over 160 patient-reported outcome (PRO) instruments in ophthalmology⁴³, careful consideration is required for the selection of an appropriate questionnaire with regards to the content and its relevance to the patient group.^{43,44} The psychometric properties used to determine the appropriateness is discussed in Chapter 2.

Table 1. Selected recent ophthalmic RCTs in which PROMs were evaluated as primary outcome measures.

Subject	Name of the study	Intervention	PRO measures	Impact	Reference
Neovascular AMD	IVAN (Inhibition of VEGF in Age-related choroidal Neovascularisation)	Intravitreal ranibizumab vs bevacizumab	EQ-5D, Macular Disease Dependent Quality of Life Macular Disease Treatment Satisfaction Questionnaire (MacTSQ)	No significant difference in all three PRO measures by drug or treatment regime	Chakravarthy et al ⁴⁵
Branch Retinal Vein Occlusion/ Central Retinal Vein Occlusion	BRAVO (BRANch Retinal Vein Occlusion study)	Intravitreal ranibizumab (0.3mg or 0.5mg) vs sham injection	Visual Function Questionnaire-25 (VFQ-25)	Significant meaningful visual function measured by PRO tool for patients who received ranibizumab	Campochiaro et al ⁴
	Treatment of Macular Edema after Central Retinal Vein Occlusion Study: Evaluation of Efficacy and Safety study (CRUISE study)	Intravitreal ranibizumab (0.3mg or 0.5mg) vs sham injection	VFQ-25	Improvement from baseline mean VFQ-25	Brown et al ⁴⁶
Glaucoma	EAGLE	Lens extraction vs laser peripheral iridotomy and topical medical therapy	VFQ-24, EQ-5D, Glaucoma Utility Index	Greater efficacy and more cost-effective	Azuara-Blanco et al ⁴⁷
	Treatment of Advanced Glaucoma (TAGS)	Medical therapy vs augmented trabeculectomy	NEI-VFQ, EQ-5D-5L (EuroQoL-5D 5 Levels), HUI-3 and Glaucoma Utility Index	No significant difference at 5 years	King et al ⁴⁸
	Glaucoma Australia Educational Study	Glaucoma education vs control	Auckland Glaucoma Knowledge Questionnaire	Significant reduction in anxiety in intervention group	Skalicky et al ⁴⁹
	Tube vs Trabeculectomy Study	Baerveldt tube shunt vs trabeculectomy with Mitomycin C	NEI-VFQ composite score and Minimal important difference (MID)	No significant difference at baseline or annual review for 5 years	Kotecha et al ⁵⁰
Diabetic macular oedema	RESTORE	Ranibizumab monotherapy vs combined with laser vs laser alone	VFQ-25	Visual acuity improvements associated with significant gains in VFQ-25 scores	Mitchell et al ⁵¹
Uveitis	HURON (cHronic Uveitis evaluation of the intravitreal dexamethasone implant)	Ozurdex implant vs sham	NEI-VFQ, SF-36, Short-Form Six-Dimension (SF-6D), EuroQoL-5D	Significant differences were identified for uveitis participants vs general population, except with SF-36 physical component and EQ-5D	Naik et al ⁵²

1.2 Unlocking the Potential of PROMs: Promoting Safety and Quality in Healthcare

The use of PROMs has the potential to inform stakeholders and enhance patient-centred care through the evaluation of healthcare delivery and quality improvement initiatives at a multi-level approach (Figure 1).^{18,53-55}

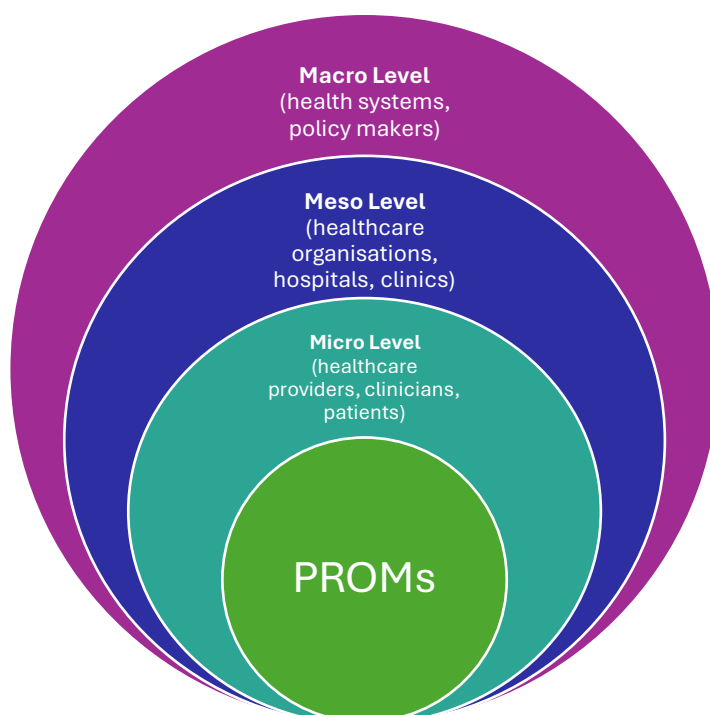


Figure 1. Multilevel approach to PROMs in healthcare.

At the micro level, the collected information can be used to further understanding of interactions between patients and their healthcare providers to guide shared-decisions made about treatment.⁵⁶ At the meso level, PROMs data within an organisation can be used to understand factors that influence outcomes and thus be used in clinical research to compare effectiveness of interventions or, to study patterns of care and evaluate healthcare services.⁵⁷

At the macro level, PROMs that are collected can provide aggregated data to guide healthcare improvements at a system level which includes evaluating health policies. This can be performed across different jurisdictions, spanning across multiple regions whilst ensuring that these changes include consumer perspectives and priorities.⁵⁸ At this level, PROMs have an important role in international reporting of the performance of health systems and benchmarking activities.

There are two main international projects that are integral to the development of PROMs for cross-country comparisons, the International Consortium for Health Outcomes Measurement (ICHOM) and Organisation for Economic Co-operation and Development (OECD).⁵⁹ The

ICHOM is responsible for the development of at least 26 health outcome standard measurement sets using both generic and disease or condition-specific measures. The ICHOM collaborates with multiple international, individual health agencies to promote awareness and the use of standard measurement sets in benchmarking outcomes.

In 2018, the ICHOM, the Commonwealth Fund and the OECD instigated the Patient-Reported Indicators Survey initiative dedicated to developing PROMs and Patient-Reported Experience Measures (PREMs) that were suitable for international comparisons.⁶⁰ Other organisations such as the World Health Organisation (WHO) have also been involved in developing leading generic PROMs such as the World Health Organisation Quality Of Life Brief Version (WHOQOL-BREF) short version which is widely used in population health research.⁶¹ These international initiatives have been monumental in driving the movement of incorporating routine PROMs into health systems.

Several international registries have been established to facilitate global comparisons of cataract surgery outcomes. To standardise these efforts, in 2015, the ICHOM developed a minimum standard set of outcome measures for cataract surgery. Parameters included pre-operative assessment, surgical details and post-operative outcomes.⁶² The Catquest-9SF questionnaire was recommended as the preferred PROMs tool to measure patient-reported visual functioning and quality of life after surgery.

In 2016, the first analysis using the ICHOMs' cataract standards (10 metrics) involved eye hospitals from Australia, the United Kingdom (UK), Sweden, Singapore, India and the United States of America (USA).⁶³ However, there was minimal alignment between the reported metrics and proposed ICHOM measures. Furthermore, none of the hospitals included patient-reported outcome measures. Since then, there has been a growing recognition of the importance of PROMs with an increasing number of healthcare institutions now adopting ICHOM standards.⁶⁴

Chapter 1.3 represents a snapshot of the international approaches to PRO data collection and benchmarking activities with much of this information synthesised from grey literature, consisting mostly of government documents and websites, and supplemented by published reviews.

1.3 Global Tapestry of PROMs Benchmarking: Insights and innovations

1.3.1 United Kingdom

Both the National Institute for Health and Care Excellence (NICE) cataract surgery guideline and the Royal College of Ophthalmologists (RCOphth) Cataract Commissioning Guide (2015) recommend using PROMs for cataract surgery.⁶⁵ In line with this, the RCOphth has adopted the Cat-PROM5, a PROM specifically developed in the UK, for integration into the National Ophthalmology Database (NOD) National Cataract Audit. The Cat-PROM5 was created to address the high demand for cataract surgeries and the challenges posed by limited NHS resources.⁶⁶ The NOD audit now includes about 70% of cataract surgeries conducted in England, Wales and Guernsey.⁶⁷

Furthermore, the NOD allows surgeons to benchmark their performance against peers on a national scale, with key measures being risk-adjusted. This process not only promotes consistency and standardisation in the quality of cataract surgery but also recognises the challenges of managing complex cases. NOD data gathered from 177 centres has demonstrated a 57% reduction in posterior capsule rupture since 2010, and this has translated into an estimated £3.5 million in financial savings for the NHS.⁶⁸ This showcases the dual impact of data-driven quality improvement in improving patient outcomes whilst reducing costs to healthcare.

Since April 2009, the NHS in UK has implemented a world-leading initiative, the National PROMs Programme which details the mandatory collection of patient-reported outcomes for certain elective surgeries.^{69,70} Although cataract PROMs are not currently included in this program, significant progress has been made in incorporating cataract surgery data into the NOD audit with 196 centres participating in 2023.⁶⁸ The audit also identified that most centres collected relevant data as part of routine clinical activity. Notably, the audit found that all participating centres submitted data using electronic medical records or in-house databases. This aligns with the NHS's broader digital agenda aimed to encourage electronic-driven processes in ophthalmology.

In NHS Wales, the collection of PROMs and PREMs was initially conducted through small, local initiatives which limited opportunities for standardisation.⁷¹ In 2016, the Welsh PROMs, PREMs, and Effectiveness Programme (PPEP) was launched to facilitate a unified, national platform that was centrally managed.⁷¹ Importantly, the data is integrated into electronic patient records which enables clinicians to access this information during consultations and facilitates real-time, data-informed discussions with patients.⁷² The PPEP has prioritised the electronic implementation of the Welsh-translated Cat-PROM5 into their cataract services across Wales. In 2018, the RCOphth commissioned the Health Quality Improvement Partnership (HQIP) to report on the feasibility of digital data collection using the Cat-PROM5, before and after cataract surgery.⁷³ The NHS Wales is also developing a digital platform known as the National Data Resource, a multi-provider benchmarking hub that allows open reporting across research and clinics across Wales.⁷⁴

1.3.2 Scandinavia – Sweden, Denmark, Norway

Sweden has set a global benchmark for the integration of PROMs into healthcare, particularly through its National Quality Registries (NQRs).⁷⁵ These registries are renowned for their comprehensiveness, and many are certified at Level 2 of 3 due to their inclusion of PROMs.⁷⁶

In 1992, the Swedish National Cataract Register (NCR) was established to collect data on pre-operative surgical outcomes for cataract surgery. The first generation Catquest PROM was created in 1994 and was later refined into the Catquest-9SF in 2007.⁷⁷ By combining patient-reported data with clinical outcomes, the NCR has generated critical insights into the impacts of cataract surgery. These include categories of patients who reported no benefit following surgery, coexisting ocular diseases were associated with poorer visual outcomes after surgery and implications associated with anisometropia.⁷⁸ Consequently, new protocols have been developed to implement more precise criteria for surgery eligibility, ensuring complex cases are handled by experienced surgeons and reducing the interval between surgeries on both eyes to minimise the visual impact of anisometropia on patients.²⁰ Although the NCR is voluntary, it captured data from 93.5% of cataract surgeries, from most surgical centres across the country, performed over a nine year period.⁷⁷ The extensive coverage

ensures a comprehensive and accurate representation for cataract surgery outcomes and trends, making it a valuable tool for understanding the broader implications of surgery.

PROMs have further been incorporated into value-based healthcare payment initiatives. In Sweden, a national project called SVEUS that involves seven Swedish regions with support from the Ministry of Social Affairs and more than 50 organisations oversaw the development of value-based, reimbursement systems.⁷⁹ This reform encouraged patient choice and a bundled payment model that successfully reduced rates of adverse events, following hip replacement surgery, including complication rates and duration of admission as well as costs whilst maintaining a constant, functional outcome.⁸⁰

Denmark does not currently have a national or regional system dedicated to the collection of PROMs. Instead, cataract surgeries and related complications are recorded in the Danish National Patient Registry. However, a lack of registration of cataract surgery limits its value for quality assurance monitoring and benchmarking purposes.⁸¹ The National Health Data Authority has initiated a working program aimed at establishing a nationwide system for routine PROMs collection. Additionally, of the 19 national registries in Norway with some including PROMs data, there is no dedicated national cataract registry at present.

The Danish health care relationship to PROMs is retraceable to the Program PRO that was launched alongside the National Quality Programme (2016) which recommended nationwide application of PROMs. This laid the foundation for the 2017 Transparency Reform which accelerated the widespread standardisation and implementation of PROMs in eight clinical areas.⁸² The Danish model further illustrates the importance of accessibility and actionability of PROM data using electronic Patient-Reported Outcome Measures (ePROM). For example, WestChronic is a web and paper system that enables clinicians to access and view collected PRO data to support clinical decision-making.⁸³

1.3.3 United States of America

In 1992, the International Cataract Surgery Outcomes Study began to assess and compare cataract management, surgical outcomes and quality of care in four countries: the USA, Canada, Barcelona and Spain.⁸⁴ The study highlighted issues related to quality assessment, benchmarking and the challenges of establishing national database registries. One of its most important findings was controlling for case-mix variables to allow for meaningful benchmarking. This has now been widely accepted and incorporated into databases such as the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) system.^{85,86}

In the United States, significant efforts have been made to integrate PROMs into healthcare to guide clinical decision-making and improve cost-effectiveness. Despite their success in other areas of healthcare, standardised PROMs have yet to be widely adopted in routine cataract surgery pathways.^{87,88} The American Academy of Ophthalmology initiated a cataract surgery registry in 1996 which allowed ophthalmologists to collect data on postoperative patient satisfaction with visual outcomes and care.⁸⁹

A major milestone in PROM development came in 2004 with the National Institutes of Health's PROMIS (Patient-Reported Outcomes Measurement Information System).⁹⁰ PROMIS created a robust, psychometrically sound PRO measurement tool for health outcomes through large item banks and computerised adaptive testing.^{91,92} Initially research-

focused, PROMIS has since expanded to clinical practice by translating questionnaires, facilitating uptake into clinical practice and educating users as well as engaging with stakeholders to secure partnerships to sustain the software.⁹² This model could be adapted for cataract surgery to track patient progress and inform population health assessments.

Additionally, the Patient-Centred Outcomes Research Institute (PCORI), established to emphasise patient needs in research, has set minimum standards for the development and use of PROMs.⁹³ PCORI initiatives reflect a shift toward patient-centred healthcare, as does the integration of PROMs into the Health Outcome Survey (HOS) by the Centers for Medicare and Medicaid Services (CMS) in 1998. This was the first national, longitudinal survey to measure self-reported quality of life and functional status among Medicare beneficiaries.⁹⁴ Currently, the HOS does not include PROMs that survey the impact of cataract on QOL.⁹⁵

1.3.4 Asia – Singapore, Malaysia, Korea

In 2002, Malaysia's Ministry of Health launched the National Cataract Surgery Registry to collect data on cataract surgeries. Initially, it relied on a paper-based system, but this was soon discontinued due to intensive efforts required to manage the paper records. Five years later, the registry evolved into a web-based system as part of the National Eye Database (NED).⁹⁶ The NED, which includes the Cataract Surgery Registry, is focused on monitoring key performance indicators such as surgical outcomes and variance in performance among hospitals.⁹⁷

The Malaysian Cataract Registry is one of the most comprehensive in the world, covering almost all cataract surgeries performed in public hospitals and more than half of procedures nationwide. However, despite its extensive coverage, the registry does not yet include PROMs.⁹⁸

Countries such as Korea and Singapore have made progress in collecting PREMs data but have more limited integration of PROMs.⁹⁹ For instance, Singapore's National University Hospital introduced the Value Driven Outcome Program for cataract surgery. While this program assesses ten quality outcome measures, nine are clinical (e.g. surgical complications), and only one relates to patient experience.

This comparison underscores a global disparity with some countries excelling in clinical data and patient experience measures, PROMs are still underutilised. Expanding PROMs inclusion in registries like Malaysia's could enhance the evaluation of cataract surgery outcomes by balancing clinical success with real-world patient impact.

1.3.4 Europe – France, Netherlands, Portugal, Germany, Belgium

In 2007, the EUREQUO was launched by the European Society of Cataract and Refractive Surgeons (ESCRS) and 11 national societies. It is a web-based registry that collects cataract and refractive data, and PROMs that are easily accessible by surgeons to monitor their results and anonymously compare with others across Europe. This benchmarking has led to more stringent cataract surgery guidelines. In 2022, data from 17 countries contributed to the EUREQUO.¹⁰⁰

The ESCRS Steering Group has also initiated the PROMs Task Force to support the development of registries to focus on developing and validating PROMs tools that can be incorporated in the healthcare system. The ESCRS also funds patient-centred outcomes

research such as the Patient Reported Outcome Extension (PROE) project.⁷¹ It aims to link PROMs to clinical outcome data using the Catquest-9SF questionnaire for patients undergoing cataract surgery.

The Portugal Cataract Registry is a component of the Health Cluster Portugal Project and includes both public and private sectors. Interestingly, and importantly, analysis of the registry data revealed that for 10% of patients, clinicians rated excellent post-operative outcomes while the patients did not. This example highlights the importance of incorporation patients' perspectives of outcomes following cataract surgery for a true representation of the quality of care.

The Dutch National Cataract Registry reports coverage on half of all the cataract surgeries performed in the Netherlands.⁹⁸ The Dutch Institute for Clinical Audit in the Netherlands includes the use of PROMs in 19 of 23 national registries.¹⁰¹ However, cataract surgery is not one of the listed areas where PROMs are currently being used, suggesting that their use in cataract surgery registries have not yet been implemented in the Netherlands.

Historically, countries such as Germany, France and Belgium have focused more on the implementation of PREMs rather than PROMs. They have adopted national systems for the routine collection of PREMs based on voluntary participation of hospitals. Survey reports are publicly disclosed to allow comparison and benchmarking between both public hospitals and private practices⁹⁹. In 2015, the French National Authority for Health developed the e-Satis Initiative to observe patient satisfaction indicators which were made public available on hospital accreditation record.¹⁰¹ Similarly, the National Health Survey employed in Belgium informs the overall health status of the population with PREM questionnaires administered via a computer.^{102,103}

Recently, EUREQUO expanded to include the PromCAT France national cataract registry which uses advanced technology to collect and analyse PROMs data more efficiently. The European collaboration between PromTime – a health data science pioneer in value-based healthcare (VBHC) – and the ESCRS is a unique partnership that standardises a digital tool to compare real-life PROMS adjusted to severity profiles.⁷¹ The electronic platform uses the French-translated Catquest-9SF PROM tool to digitise clinical data. This allows the ESCRS to audit the data with an algorithm enabling risk-adjusted PROMs comparisons. Furthermore, the initiative promotes a transparency model whereby clinicians are encouraged to share health gains with stakeholders including patients.¹⁰⁴

1.3.5 Canada

The Canadian Institute of Health Information (CIHI) identified several provincial-level initiatives that used PROMs however this was not standardised in relation to collection or reporting.¹⁰⁵ The CIHI formed the National PROMs Advisory Committee which led to the development of PROMs collection in joint arthroplasty, however this has yet to make its way to cataract surgery.¹⁰⁶ Due to limited leadership and coordination, there have been few national initiatives with PROMs being predominantly used for independent research projects. Canada has regional and local PROMs collection initiatives however systematic use of PROMs on a national level remains at early stages of development.

1.3.6 Oceania - Australia, New Zealand

In Australia, PROMs have been largely used within a research context. The ACSQHC (Australian Commission of Safety and Quality in Health Care) is at the forefront of advising a national approach to the use of routine PROMs in local health systems. Several clinical registries in Australia collect and report on PROMs: Australian Stroke Clinical Registry, Victoria Severe Trauma Registry and the Arthroplasty Clinical Outcomes Registry in New South Wales. However, the absence of an established and standardised interval change in PROMs scores achieved by a health intervention prevents health care improvements.¹⁰⁷ National programs in other areas of health, such as cancer care, have adopted the use of standardised and validated PRO assessment tools in routine clinical practice both for benchmarking purposes and to formally evaluate interventions.¹⁰⁸ The collected data is publicly reported at an aggregate level and sent to participating sites for comparison between clinical practices.¹⁰⁹ As already noted previously, there is continued efforts to implement routine PROMs across the health sector.¹¹⁰

In New South Wales (NSW), the Agency for Clinical Innovation (ACI) is leading PROMs Program across NSW Health. Initially involving four local health districts, it grew to include 14 sites across hospital, community and primary health care. Patient cohorts included people living with chronic conditions, diabetes, renal disease, skin cancer and drug and alcohol issues, as well as people over the age of 65.¹¹¹

In 2021, three local health districts implemented collection of PROMs via a web-based platform (HOPE, Health Outcomes and Patient Experience). The HOPE platform is a digital platform designed by the ACI (Agency of Clinical Innovation) in collaboration with eHealth NSW, NSW Ministry of Health, consumers, clinicians and managers across NSW.¹¹² The platform now hosts the Catquest-9SF questionnaire, a widely used PROM for cataract surgery. This technology streamlines data collection and ensures secure access whilst supporting more patient-centred care by providing health professionals timely insights into patients' perspectives. Despite its capabilities, the HOPE platform has not been widely adopted for the routine monitoring of cataract surgery outcomes in either the public or private healthcare sectors.

The New Zealand Ministry of Health has been piloting a national surgical prioritisation program to drive timely access to elective surgical procedures.¹¹³ The program involves using the Clinical Prioritisation Tool which collects multifaceted health data including the locally developed Impact on Life Questionnaire, a PROM tool designed to assess the needs and benefits of surgical procedures from the patient's perspective. There has been limited uptake of the questionnaire as patients' assessment of their health condition does not always match their clinicians' severity assessment.

New Zealand has set the benchmark for using PROMs within Indigenous populations by developing culturally specific tools that ensure inclusivity and relevance. For example, the Hua Oranga tool was created to collect data from three perspectives: the consumer (patient), clinician and whānau member (significant other), reflecting a holistic approach tailored to Māori culture.¹¹⁴ Other similar culturally specific initiatives are available through the Te Pou, an organisation supporting New Zealand's mental health workforce. These efforts highlight New Zealand's leadership in creating PROMs that respect and integrate Indigenous cultural values.

1.4 Navigating the Challenges in the Implementation of PROMs in Clinical Practice

Barriers related to the use of PROM questionnaires exist whether they are used in clinical practice, research or health policy.^{18,115-117} To successfully incorporate PROMs into healthcare systems and maximise potential benefits, these challenges must be addressed.

On a micro-level, there exists technical barriers related to the practical use of questionnaires and perceptual barriers from the patient or clinician's perspective. Patient-reported difficulties have included time burden associated with long questionnaires, inability to read or understand items, technological barriers or not understanding the purpose of PROMs. Therefore, each stage of the PROM development process should be undertaken with the involvement of consumers to improve readability.¹¹⁸ Suggested recommendations include questionnaires that avoid technical jargon, use consistent terminology and short, simple sentences as well as providing patients with a friendly user-interface if electronic platforms are being considered.¹¹⁹

In clinical practice, PROMs must be implemented in a way that patients find acceptable and perceived to have value to patients.¹²⁰ Other reported challenges manifest as concerns regarding the confidentiality of PROMs, the potential effect on their relationship with healthcare providers as well as cultural insensitivity or disabilities (visual impairment) that limit their capacity to complete questionnaires. Furthermore, repeated questionnaires are required to monitor trajectory of treatment outcomes which can further add to patients' response burden and consequently affect the feasibility of obtaining follow-up questionnaires.¹²¹ A reduced compliance rate and high rates of missing data can result in poor data quality which cannot be used to inform regulatory decision-making or clinical care.¹²²

Barriers to uptake amongst clinicians have included time burden, lack of support and familiarity with the appropriate PROM, increased staff workload, mismatch between patient versus clinician's assessment of disease severity affecting their relationship and the potential use of such measures limiting access to health services.^{120,123} Many reviews have highlighted that a lack of awareness among professionals about PROMs and their objectives, and an uncertainty of how to collect, interpret and act on PROMs data were key barriers to implementation.^{56,124-127} Thus, adequate training opportunities must be provided for staff which includes piloting the use of PROMs before more widespread implementation.^{117,128} Arguably, one of the most significant facilitator of PROMs by healthcare professionals, is their perception of their role in its implementation and clinical value.¹²⁶ Choosing PROMs that are not only user friendly but clinically valid and reliable can influence clinician's view of PROMs. Additionally, easy access to the data collected at the individual patient level is valuable to guide and improve individualised patient care.^{56,124,125}

At a meso-level, health care systems are responsible for ensuring that relevant stakeholders can access the PROMs data in a timely and efficient manner. Proposed solutions that tackle systems-associated barriers include easy-to-interpret aggregate data presentation and providing adequate administrative support.^{129,130} Aligning data collection with scheduled appointments or linking PROM results to patient health records have found to be major enablers.¹³¹ Health systems are encouraged to invest in electronic and web-based data management to enable real-time feedback of results to optimise patient-clinician engagement.^{132,133} Studies are being conducted to validate non-paper-based alternatives such

as computers, telecommunication systems with interactive voice-response and hand-held electronic devices.¹³⁴ Published reviews have also found that a mix of electronic and paper questionnaires may facilitate higher response rates due to the adaptability to individual patient circumstances.¹³⁵

Challenges on a national level largely involve data- and instrument-related validity and reliability. Case-mix adjustment is vital for standardised public reporting however many countries struggle with this due to a lack of robustness of data. Canadian policy survey results have further demonstrated that other barriers to international comparability include appropriate selection of PROM tools, lack of standardised measures and indicators for comparison, absence of single data storage database for international comparisons, varying local and sociocultural aspects of health and different collection protocols.¹³¹ This is similarly reflected in England's policy survey response which identified the issue of standardisation of PROMs items and responses, especially across different cultures.

Another barrier is the selection of an appropriate PROMs instrument that is specific and sensitive to change which is key in ensuring collected data is accurate, reliable and valid. However, the development of high-quality questionnaires that have been psychometrically validated and applicable to different cultural context requires extensive engagement with patients and pilot studies. One solution is the use of item-banking with validated subsets of questions in various diseases and patient populations. The Eye-tem Bank project aims to provide technologically efficient and comprehensive PROMs tools across thirteen ophthalmic conditions through the use of item banking.⁴³ Its implementation via computer-adaptive testing will further address the shortcomings easily where outdated items are targeted using the dynamic responses of each individual.¹

At the macro-level, a primary challenge in the implementation of PROMs in Australia is the cooperation between state, territory, and federal government to ensure that the financial means for a common electronic recording infrastructure are available across Australia. A lack of information technology (IT) and digital health infrastructures, data privacy regulations and guidance for best practice at a regional or national level are common challenges faced by those trying to incorporate PROMs in daily clinical practice and on a wider scale.^{136,137}

2. A Comprehensive Review of Catquest-9SF Validation Across Diverse Cataract Populations

Synopsis

Chapter 2 of the thesis provides a comprehensive synthesis of evidence from published literature to evaluate the Catquest-9SF, one of the more widely used PROMs in cataract surgery. The chapter focuses on examining the psychometric properties of the questionnaire assessed through Rasch analysis, a robust statistical method for evaluating measurement tools. The findings demonstrate that the Catquest-9SF is a valid and reliable questionnaire that can be used to assess visual function in patients with cataracts, making it an effective tool for monitoring outcomes in various populations. This systematic review underscores its applicability across diverse cataract populations and highlights its utility in both clinical and research settings.

2.1 Introduction: The Evolution of PROMs in Cataract Surgery

The continual evolution of cataract surgery and improved technology are achieving excellent results in traditional objective outcomes including best-corrected visual acuity (BCVA) and refraction.¹³⁸ However, these outcomes do not always correlate with improvements to patients' day-to-day life.¹³⁹ In current practice, it has become increasingly recognised to monitor patient-reported outcome measures (PROMs) to ensure that interventions lead to patient-centred improvements.¹⁴⁰ Additionally, PROM data used in clinical research can be used to compare the effectiveness of interventions, understand factors that influence patient outcomes and evaluate healthcare services.⁵⁷

There are multiple visual disability questionnaires available including the National Eye Institute Visual Function Questionnaire (NEI-VFQ)¹⁴¹, Visual Functioning 14 (VF-14)²⁸, Visual Disability Assessment (VDA)¹⁴², Activities of Daily Vision Scale (ADVS)¹⁴³, Cat-PROM5^{66,144} and the Catquest-9SF¹⁴⁵. However, the ADVS^{146,147}, NEI-VFQ¹⁴⁸ and VF-14¹⁴⁸ have been shown to exhibit poor psychometric properties as analysed by the Rasch model.

McAlinden et al (2011) compared 16 vision-specific questionnaires and demonstrated that the Catquest-9SF was the most sensitive to clinical changes after cataract surgery.⁴⁰ Additionally, the Catquest-9SF is a shorter questionnaire with nine items compared to the ADVS with 16 questions or the NEI-VFQ consisting of 25 questions. This makes it an attractive choice for clinicians and patients.

Since 1995, The Swedish National Cataract Register has used the original Catquest questionnaire to monitor PROMs for cataract surgery.¹⁴⁹ It initially contained 19 questions covering four aspects of health and vision: 7 items on frequency of performing activities, 8 items on difficulty with activities of daily living, 2 items about patient's satisfaction with vision and general difficulties, and 2 items on cataract associated symptoms. Each item has four possible answers corresponding to the level of perceived difficulty. However, Lundstrom and Pesudovs (2008) found that a combination of the 7 disability items and 2 global assessment items produced the greatest measurement precision, thus forming the shorter, abridged version, the Catquest-9SF.¹⁴⁵

Classically, the development of measurement scales employed Likert-type scoring which involved adding the scores from patients' choice of response options and producing an interval scale. However, this method of summing scores assumes that the distance between each raw score is equal, without considering the item difficulty.¹⁴⁵ By comparison, the Rasch analysis uses a model that takes into consideration an individual's response to an item as well as the item difficulty, thereby producing a statistically calculated interval scale.¹⁴⁵

Questionnaires are sample dependent as different populations vary in demographic characteristics and sociocultural aspects of health. Hence, it is important for studies to investigate the performance of different vision-specific questionnaires prior to implementing into routine clinical care.⁸ Since 2008, the Catquest-9SF questionnaire has been validated in several different languages,^{140,145,150-152} in an abbreviated version¹⁵³ and electronically¹⁵⁴. It has further been used in cataract surgery appropriateness and prioritisation studies in Canada.^{155,156}

The psychometric robustness of a patient-reported outcome (PRO) tool is calculated by a pre-determined criteria that assess validity, reliability and responsiveness.¹¹ Multiple studies have demonstrated that the Catquest-9SF questionnaire has excellent performance measures in all

three criteria.^{140,152,157,158} Subsequently, the questionnaire has been incorporated into cataract clinical care standards such as the ICHOM¹⁵⁹, the EUREQUO¹⁶⁰ and the ACSQHC.¹⁶¹

Kabanovski et al (2019) summarised thirteen studies to demonstrate that the Catquest-9SF is a psychometrically robust questionnaire when used to measure patient-reported visual functioning in cataract surgery.¹⁶² Since then, there have been further studies conducted to validate the Catquest-9SF in new populations with different translations, abridged and electronic versions. The aim of the review is to reassess the reliability and validity of the Catquest-9SF questionnaire amongst different cataract populations worldwide.

2.2 Study Methodology

2.2.1 Search strategy and Data extraction

Five electronic databases were searched (Cochrane, PubMed, EMBASE, Scopus and Medline) using the keyword “catquest” and “cataract”. The initial search was conducted on 18th March 2023, and the search was last updated on 12th October 2024. Appendix 1 contains the full search strategy.

The systematic review included studies that employed Rasch analysis to assess the psychometric properties of the Catquest-9SF questionnaire. Exclusion criteria included studies that evaluated other questionnaires, original Catquest or in a non-cataract population. Multiple articles identified during initial screening used the Catquest-9SF as a PRO tool rather than assessing psychometric properties of the questionnaire and hence, were also excluded.

The systematic review was registered at PROSPERO CRD42023408662. Two authors (RX, CP) independently screened titles and abstract first, followed by full text article reviews. The web-based systematic review platform Covidence (available at <https://www.covidence.org/>) was used to keep track of the articles that were screened. Any conflicts during the screening stage were resolved through discussions. If the authors could not reach a consensus, a third author (AC) was available to review. The screening process has been summarised in Figure 2. Data was extracted by a single investigator (RX). Data extracted included baseline and demographic data for the study population of included studies (Table 2).

2.2.2 The Catquest-9SF Questionnaire

The Catquest-9SF questionnaire contains seven questions regarding performance of daily living activities (C1-7) and two global questions (Ca and Cb) assessing general difficulties and satisfaction with vision. Response options for eight items include no difficulty, some difficulty, great difficulty, very great difficulty and cannot say. The responses to Question Cb include very dissatisfied, rather dissatisfied, fairly dissatisfied, very satisfied and cannot say. The response option “cannot say” is treated as missing data according to the guidelines that pertains to the original Catquest questionnaire.³⁷ This method of handling missing data is considered accurate as the missing data is considered unnecessary if the raw data fits the Rasch model.¹⁶³

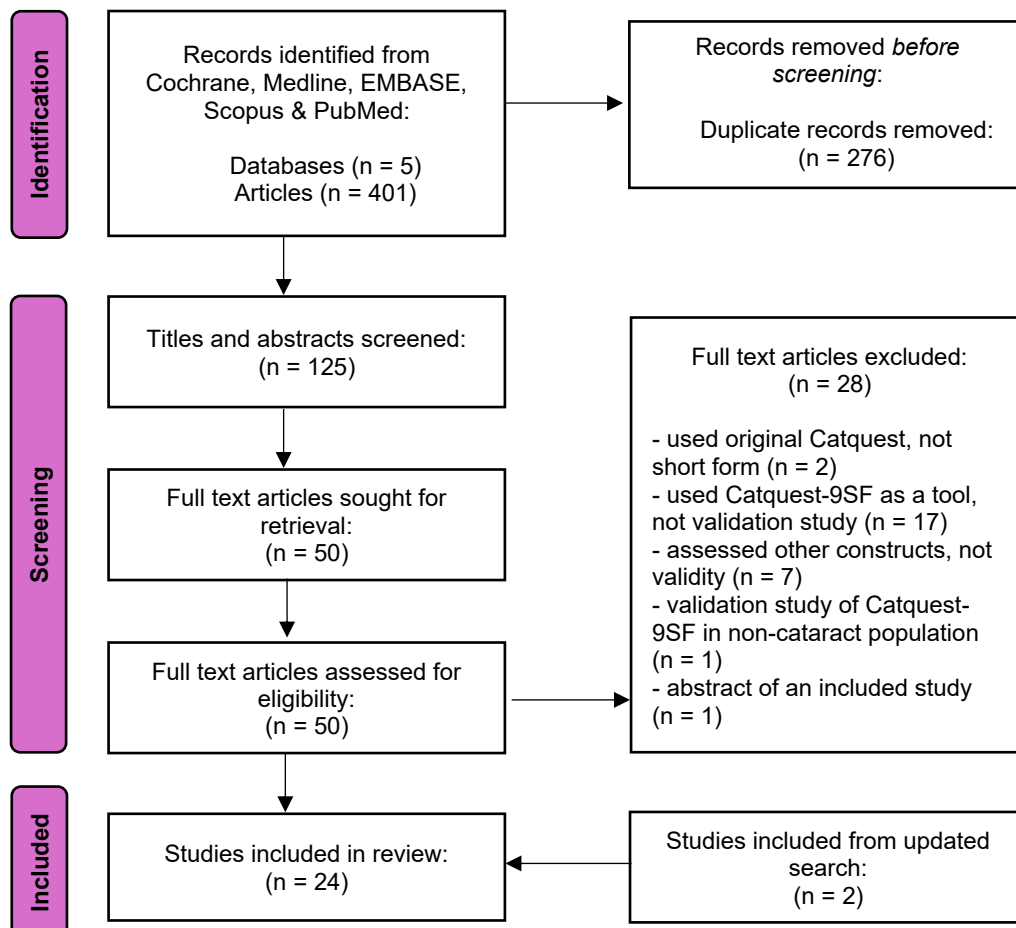


Figure 2. Flow diagram of search strategy.

2.2.3 Rasch analysis

Rasch analysis assesses the questionnaire's effectiveness in determining how well items fit the underlying trait being measured and evaluates the questionnaire's effectiveness in differentiating respondents based on their ability levels.¹⁶⁴ This method estimates two key parameters: item difficulty (the level of challenge associated with completing a specific task) and person ability (the person's capability to complete the task). These are measured on a linear scale and expressed in logit units. Higher person ability or greater item difficulty corresponds to more negative logit values, with lower logits indicating better visual function.¹⁵³

Category threshold order. Category threshold ordering is analysed first during psychometric assessments of a questionnaire as the presence of ordered, compared to disordered, response categories can influence other metric properties of items.^{165,166} In a well-fitting model, respondents with more visual impairment should consistently select higher response options (such as 3 or 4) while those with better vision should consistently select lower response options (such as 1 or 2). In Rasch analysis, the item probability curve is used to depict the sequential arrangement of response thresholds corresponding to each item. The threshold denotes the point at which two consecutive categories intersect, resulting in an equal probability of choosing either category.¹⁶⁷ These thresholds are expected to exhibit a monotonically increasing response pattern, wherein, with increasing visual disability, the likelihood of choosing a higher response category should increase.

A questionnaire that fits the Rasch model requires ordered response thresholds. As the respondent's ability increases, the probability of selecting higher response categories follows a logical sequence. For example, the point where the likelihood of choosing category 1 transitions to category 2 occurs before the transition from category 2 to category 3 and so on. This ordering ensures that the response categories function as intended, reflecting an increasing level of the underlying trait being measured such as visual function. However, disordering may occur (i.e., threshold 3 being located between 1 and 2) when respondents have difficulty differentiating between categories, categories are not frequently chosen or if category definitions are ambiguous. In these situations, reorganisation of the categories by combining them is often performed.¹⁶⁸

Fit statistics. Infit and outfit mean squares (MNSQ) indicate how accurately the data aligns with the Rasch model. Infit is particularly attuned to inliers and are thus sensitive to the response patterns of items targeted at the respondent's ability.¹⁶⁹ For example, a high infit value (indicating underfit) can be due to an individual with moderate visual function inaccurately responding to a moderately difficult item, experiencing either significant difficulties or none at all. Conversely, a low infit value (suggesting overfit) may result from cumulative patterns where several items elicit the same information.¹⁷⁰

Outfit is outlier-sensitive and assesses responses to items far from the respondent's ability. For example, an underfit outfit value could arise when an individual with higher visual function inaccurately responds with great difficulty to an easy item or when an individual person with greater visual disability selects a higher response category corresponding to a difficult item. An overfit outfit value can be due to imputed responses.

The expected value for infit and outfit MNSQ values is 1.0, indicating perfect fit. The optimal range is between 0.7 and 1.3, which suggests a good fit with minimal noise in the data. An acceptable range is between 0.5 to 1.50 accommodating minor deviations that may still be considered reasonable. Values outside these ranges suggest potential misfit, where items or responses might not align well with the underlying trait being measured.¹⁵⁰

Unidimensionality. In Rasch analysis, evaluating fit statistics alone is insufficient to confirm that the data meets the assumption of unidimensionality; Principal Component Analysis (PCA) of the residuals must also be conducted. Unidimensionality is a key assumption which posits that a single latent trait – visual function – is sufficient to explain the performance of the items in the questionnaire.¹⁷¹ PCA of the residuals helps test this assumption by analysing the unexplained variance (residuals) after the primary trait has been accounted for. If patterns in the residuals reveal groups of items with similar unexpected responses, it might indicate the presence of an additional latent trait, thus challenging the unidimensionality of the scale.¹⁷²

In a unidimensional questionnaire, the results of the data analysed can be accounted for by the latent trait which renders the residuals, or unexplained part of the data, random noise.¹⁷² Conversely, in a non-unidimensional questionnaire, the unexplained part of the data reflects shared patterns of unexpectedness among questionnaire items, indicating the presence of a secondary trait.

PCA is assessed by examining two key aspects: the variance explained by the measures and by first contrast. The variance explained by the measures, which represents the primary latent

trait being measured should ideally exceed 60% with a value of 50% considered acceptable. This indicates that the majority of the variability in the data is attributed to the intended trait, minimising the likelihood of other underlying components influencing the results. On the other hand, variance explained by the first contrast reflects unexplained variance or potential additional dimensions in the data. A value less than 2.0 eigenvalue units suggests random noise rather than representing a meaningful secondary dimension.^{172,173}

Measurement precision. The evaluation of measurement precision involves the consideration of the Person Separation Index (PSI) and Person Reliability (PR). PSI is a measure of the questionnaire's capacity to distinguish respondents with varying levels of the underlying trait being measured.¹⁷⁴ A higher person separation value corresponds to increased questionnaire precision. A PSI exceeding 2.0 is deemed the minimum threshold for the questionnaire to effectively discriminate among respondents with at least three levels of abilities, such as mild, moderate, and severe.

Meanwhile, PR shares similarities with Cronbach's alpha, serving as a metric for the internal consistency of the questionnaire and estimating the degree of replicability of a person's responses across other questionnaires measuring the same trait.¹⁷⁴ Reliability may range from 0 to 1 with coefficients greater than 0.8 representing 'good' and greater than 0.9 indicating 'excellent' reliability.^{167,174}

Targeting. Targeting assesses the alignment between item difficulty and individual ability, as depicted graphically on the person-item map.^{175,176} An effectively targeted instrument requires the mean of person ability to be centred on the same mean as the item difficulty, with a target difference of 0 indicating perfect alignment of the scale.¹⁷⁷ Significant mistargeting is identified when the difference between the average item difficulty and the average person ability is equal to or greater than 1 logit, indicating a substantial misalignment. Conversely a difference of less than 1 logit suggests that the targeting is satisfactory, meaning the items are appropriately aligned with the abilities of the respondents. A negative mistargeting value indicates that the items are too easy for the respondents whilst a positive value suggests the opposite.

Clustering of Questions. The convergence of items in proximity on person-item maps implies item redundancy. To assess whether specific groups of items in a questionnaire exhibit clustering and potential redundancy, item calibration and location are examined. Items placed on the same line indicate clustering. In a prior review, a cut-off value of equal to or less than 0.25 in the difference of item calibration values for two items was employed to identify clustering.¹⁶² In this review, the mean range of item calibration reported in the included studies was 2.95 making a value of 0.25 equivalent to less than a 10% difference. Therefore, a difference of equal to or less than 0.25 was also adopted in this review for consistency. In instances where item calibration values were not reported, estimates were derived from the person-item maps, and items positioned on the same line were considered indicative of clustering.

Differential item functioning (DIF). DIF helps to ascertain whether an item measures a latent construct in a consistent manner across different subgroups. DIF occurs when respondents from different subgroups but with similar visual function answer differently to a particular item. The studies included in this review examined DIF parameters, encompassing factors like age, gender, pre-operative visual acuity, socioeconomic status, right versus left

eye, presence of systemic or ocular comorbidities, surgery on the first or second eye, and the administration of the questionnaire preoperatively versus postoperatively.

The DIF contrast refers to the difference in how a particular item performs between two groups in a study. This difference is measured using logits. A logit difference of less than 0.5 indicates that the difference is small or absent. A difference between 0.5 and 1.0 is considered minimal and a difference greater than 1.0 is regarded as significant.¹⁴⁵ A p-value of less than 0.05 is deemed statistically significant. An absence of DIF suggests that the items in the questionnaire are not biased across subgroups. DIF is considered benign for intrinsic differences between subgroups (i.e., one subgroup performing the task more frequently thus affecting responses). Conversely, DIF is considered adverse if it is caused by item bias, such as poor wording of the items.¹⁶⁴

Responsiveness to surgery. Responsiveness refers to a questionnaire's ability to detect clinically important changes in the measured trait over time. Determining the MID which represents the smallest score difference perceived as beneficial by the individual, is crucial in assessing the magnitude of change.¹¹ MID, often expressed as effect size (ES), becomes particularly relevant when comparing data for two time point within the same patient population.¹⁷⁸

In several of the studied included, the responsiveness of the questionnaire was evaluated by comparing pre- and post-operative scores. Cohen's classification of standardised effect size (ES) is used to represent this change.¹⁷⁹ According to Cohen's classification, an ES of less than 0.2 is considered a trivial effect, between 0.2 and 0.5 as small, between 0.5 and 0.8 as moderate and greater than 0.8 is large.¹⁷⁹

Reliability. Reliability refers to the degree of repeatability for any noteworthy results derived from a questionnaire. These tests assess three aspects of reliability: test-retest reliability, internal consistency, and inter-rater reliability.¹⁸⁰ Test-retest reliability measures the consistency of questionnaire results as completed by the same individuals at different timepoints. Internal consistency examines how consistently the items within the questionnaire measure the same underlying construct. Inter-rater reliability assesses the agreement between different respondents. Reliability results of the Catquest-9SF were only reported in some of the included studies.

2.3 Results

A total of 24 validation studies, conducted from 2009 to 2024, were included in the analysis, encompassing a sample size ranging from 41 to 42,023 (n=60,251). These studies were carried out in 18 countries and 13 languages, with a summary provided in Table 2. Of these, 17 studies (71%) administered post-operative Catquest-9SF questionnaires, and five studies excluded participants with low vision. The mean age across all studies was 70 (range 62 to 78), and gender distribution was similar. However, other demographic characteristics exhibited variations among the studies. Detailed psychometric properties of each study are presented in Table 3 and 4.

Table 2. Overview of included studies.

Study No.	Author	Year	Country (language)	Setting	N	Age	% Female	BCVA	1 st , 2 nd eye or both (%)	% ocular comorbidity	Excluded low vision	Post-op collected (months)
1	Adnan et al ¹⁸¹	2018	Malaysia (Malay) (Chinese)	3 Centres	236 202	63 68	54.7 54	45.8% 47.5%	N/A	26.7 36.6	No	No
2	Li et al ¹⁵⁴	2019	New Zealand (English)	1 Centre	41	78	49	0.45	N/A	N/A	No	Yes (3)
3	Seth et al ¹⁸²	2022	Australia (English)	1 Centre	61	73	62.2	N/A	1 st (47.5) 2 nd (52.4)	N/A	No	Yes (3)
4	Khadka et al ¹⁵³	2016	China (Mandarin)	1 Centre	247	70	49	0.60	1 st (49.8) 2 nd (13.8) Both (36.4)	49	Yes	Yes (12) Follow up rate: 30%
5	Sparrow et al ¹⁴⁴	2018	England (English)	4 Centres	822	76	58	N/A	1 st (67) 2 nd (33)	N/A	No	Yes (N/A)
6	Gothwal et al ¹⁵²	2009	Australia (English)	1 Centre	217	75	58.1	0.22	1 st (41.1) 2 nd (58.9)	57.1	No	No
7	Lundstrom et al ³⁴	2020	Sweden (Swedish)	1 Registry	42023	75	60.4	0.21	1 st (60.7) 2 nd (39.3)	36.8	No	Yes (1) Follow up rate: 65%
8	Lundstrom et al ¹⁴⁵	2009	Sweden (Swedish)	58 Surgical Units	10886	76	65.8	0.27	1 st (62.6) 2 nd (37.4)	33.8	No	Yes (6)
9	Harrer et al ¹⁸³	2013	Austria Germany (German)	2 Centres	120 90	74 74	58 60	N/A	1 st (12.9) 2 nd (5.2) Both (72.4)	13-14	Yes	Yes (3)
10	Xu et al ¹⁸⁴	2018	China (Chinese)	1 community	104	67	59	N/A	N/A	N/A	Yes	No
11	Lundstrom et al ¹³⁹	2011	Sweden (Swedish)	6 Surgical Units	846	76	63.7	0.25	1 st (58.2) 2 nd (41.8)	31.8	No	Yes (6)
12	Nielsen et al ¹⁴⁰	2019	Denmark (Danish)	1 Centre	250	75	55.7	0.45	Both (93)	23-25	No	Yes (3)
13	Lin et al ¹⁸⁵	2014	China (Chinese)	1 Centre	102	70	46.9	68.6%	N/A	N/A	No	No

14	Lundstrom et al ¹⁸⁶	2016	Spain (Spanish)	1 Centre	301	62	62.1	0.20	One eye (16.3) Both (83.7)	5.4*	Yes	Yes (3)
15	Visser et al ¹⁸⁷	2017	The Netherlands (Danish)	1 Centre	657	70	56	N/A	One eye (49) Both (51)	N/A	No	Yes (3) Follow up rate: 70%
16	Katz et al ¹⁵¹	2021	France (French)	2 Centres	848	72	61	N/A	One eye (46) Both (54)	N/A	No	Yes (3)
17	Antunes et al ¹⁸⁸	2023	Brazil (Portuguese)	1 Centre	101	70	53.5	0.6	1 st (89.1) 2 nd (10.9)	N/A	Yes	No
18	Skiadaresi et al ¹⁵⁸	2016	Italy (Italian)	1 Centre	209	74	58.4	0.36	1 st (50.7) 2 nd (49.3)	25.4	No	Yes (3)
19	Bando et al ¹⁸⁹	2022	Brazil (Portuguese)	1 Centre	133	66	52	0.84	N/A	Excluded ⁺	No	Yes (3) Follow up rate: 76%
20	To et al ¹⁹⁰	2020	Vietnam (Vietnamese)	2 Centres	347	65 [^]	62	N/A	1 st (100)	Excluded	No	No
21	Nanos et al ¹⁵⁰	2022	Greece (Greek)	2 Centres	100	72	45	0.15	1 st (59) 2 nd (41)	49	No	Yes (2)
22	Schlenker et al ¹⁶⁴	2020	Canada (English)	4 Centres	313	69	56.5	52.8	1 st (100)	N/A	No	No
23	Negre et al ¹⁹¹	2023	Philippines (Filipino)	1 Centre	61	63	63.9	1.3	N/A	16.4	No	Yes
24	Kabanovs ki et al ¹⁹²	2023	Canada (English)	3 Centres	934	72	51.7	0.29	N/A	N/A	N/A	Yes

Corrected visual acuity column: reported as mean/median binocular or better eye LogMAR; or % of subjects with visual impairment.

Excluded significant ocular comorbidities or low vision (<6/60)

*% of participants with ocular comorbidities was reported only for the group that had bilateral surgery

[^]50.4% of participants were older than 65 years

⁺Excluded participants with glaucoma, ocular hypertension, using eye drops or medications that could possibly alter the corneal surface, self-referred diagnosis of depression or other psychiatric changes, previous eye surgeries

Table 3. Psychometric properties of Catquest-9SF.

Study No.	Country	Fit statistics (MNSQ)			Unidimensionality		Precision		Targeting		Ordered	Cronbach's Alpha (α)
		Infit range	Outfit range	# Misfits (item)	Raw variance	Unexplained variance	PSI	PR	Preop	Preop + Postop		
1	Malaysia (Malay)	0.85-1.26	0.73-1.13	1 (Cb)^	63.5 (63.5)	2.0	2.84	0.89	0.30	N/A	Yes	0.93
	(Mandarin)	0.80-1.51	0.71-1.36	0	60.4 (60.5)	2.0	2.59	0.87	-0.11			
2	New Zealand	0.62-1.13	0.43-0.79	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	Australia	0.65-1.33	0.64-1.31	0	N/A	N/A	2.58	0.87	N/A	N/A	Yes	0.74
4	China	0.76-1.43	0.73-1.42	1 (C5)	60.8 (61.4)	1.7	2.09	N/A	0.50	N/A	Yes	N/A
5	England	0.75-1.32	0.66-1.32	2	64	1.6	N/A	0.88	N/A	N/A	Yes	0.92
6	Australia	0.76-1.22	N/A	0	65.0 (63.7)	1.7	2.28	N/A	-0.86	N/A	N/A	N/A
7	Sweden	0.70-1.08	0.72-1.03	2 (C2, C4)^	N/A	N/A	2.58	0.87	-0.45	-2.06	N/A	N/A
8	Sweden	0.75-1.29	0.70-1.39	0	64.2 (64.2)	1.6	2.65	0.88	-0.34	-1.21	Yes	0.91
9	Austria	0.70-1.40	N/A	0	N/A	N/A	2.74	N/A	-1.36*	-1.69	Yes	N/A
10	China	0.70-1.25	0.68-1.11	0	51.3	2.0	2.00	0.80	-1.39	N/A	Yes	0.85
11	Sweden	0.79-1.40	0.74-1.40	0	62.3 (62.2)	1.8	2.58	0.87	-0.22	-1.95	Yes	0.94
12	Denmark	0.69-1.22	0.73-1.14	2 (C2, C4)	70.4	1.7	2.78	0.89	0.66	-1.69	Yes	N/A
13	China	0.82-1.22	N/A	0	63	1.9	2.94	0.90	-1.61	N/A	Yes	0.86-0.88
14	Spain	0.85-1.25	0.80-1.26	0	62.3	1.9	2.35	0.85	0.28	-1.59	Yes	N/A
15	Netherlands	0.80-1.24	0.80-1.50	0	69.6	0.56	2.56	0.87	-0.56	-1.64	Yes	0.95
16	France	0.70-1.32	0.74-1.25	0	58	1.6	2.32	0.84	-1.12	N/A	Yes	0.87
17	Brazil	0.63-1.24	0.56-1.83	1 (Cb)^	69.3	1.77	3.07	0.90	-0.13	N/A	Yes	N/A
18	Italy	0.84-1.31	0.73-1.34	0	N/A	1.8	2.04	N/A	-1.52	-2.04	Yes	N/A
19	Brazil	N/A	N/A	1 (Q2)^#^	69.9	2.39	2.95	0.9	N/A	N/A	N/A	N/A
20	Vietnam	0.69-1.42	0.69-1.33	0	59.7 (58.6)	1.73	2.51	0.86	0.06	N/A	Yes	N/A
21	Greece	0.66-1.36	0.66-1.37	0	74.3	1.98	3.28	0.92	-0.29	-1.83	Yes	⊗
22	Canada	0.75-1.35	0.83-1.36	0	58.3 (59)	1.7	2.09	0.81	-1.43	N/A	Yes	0.87

23	Philippines	0.66-1.17	0.66-1.49	1 (Cb)	55.3	1.9	2.70	0.88	1.24	-1.53	Yes	>0.90
24	Canada	0.75-1.29	0.74-1.51	1 (Cb)	61.3 (61.7)	1.72	2.01	0.80	-1.07	-2.43	Yes	0.90

PSI, Pearson Separation Index; PR, person reliability; MNSQ mean square.

*This value was obtained from Khadka and co-workers (study 9).

^Item was misfitted (infit or outfit MNSQ value >1.50) but not removed or uncertain if removed from analysis

⊗Study 21 reported an intraclass correlation coefficient of 0.991

#Q2 was misfitted and removed from analysis however study did not specify which item

N/A Values were not provided by the study

Table 4. Differential item functioning of Catquest-9SF.

No.	Person factor										No. of DIF	
	Age	Gender	VA	RE vs LE	SES	Other^	Comorbidities		1 st vs 2 nd	Pre-op vs	≥ 0.5 or	>1.0 or
							Systemic	Ocular	eye surgery	post-op	≤ -0.5	≤ -1.0
1	•	•	•								1	0
3											N/A	0
4	•	•	•				•	•	•	•	N/A	0
5	•	•	•	•	•	•			•	•	2	N/A
6	•	•					•	•	•		2	0
7		•				•					0	0
8	•	•						•	•	•	11	0
11		•						•	•	•	6	0
12	•	•	•					•		•	1	0
13	•	•			•						14	4
15	•	•								•	7	1
16		•									0	0
17	•	•									5	2
18								•	•		0	0
20	•	•							•		1	0
21	•	•	•					•	•	•	N/A	7
22	•	•	•								1	0
24	•	•				•				•	3	0

DIF differential item functioning, VA visual acuity, SES socioeconomic status, RE right eye, LE left eye

Studies that did not conduct DIF: 2, 9, 10, 14, 19, 23

^Other person factors included cycles of study, year of surgery, corneal astigmatism, education, complication

Table 5. Summary of DIF occurrences in all validation studies.

Item	Study	Variable tested	DIF contrast (logits)	p-value	Subgroup which ranked the item as less difficult (or more satisfied for questions Cb)	Subgroup which ranked the item as more difficulty (or more dissatisfied for questions Cb)
Ca “difficulties in daily life”	1	Visual acuity	0.51	0.04	VA \leq 6/18	VA $>$ 6/18
	8	Age	0.57		$>$ 65 years old	$<$ 65-85 years old
	8	Age	0.72	0.07	$<$ 65 years old	$>$ 85 years old
	13	Age	1.00		$>$ 60 years old	\leq 60 years old
	8	Pre-op vs post-op	0.56		Pre-op	Post-op
	15	Pre-op vs post-op	0.74	$<$0.05	Post-op	Pre-op
	21	Pre-op vs post-op	1.01		Pre-op	Post-op
	13	Gender	0.54		Female	Male
	17	Gender	0.78		Male	Female
	13	Education level	0.94	0.21	University-level education	No or primary education
Cb “satisfaction with vision”	6	1 st vs 2 nd eye surgery	0.86	0.03	1 st eye surgery	2 nd eye surgery
	20	1 st vs 2 nd eye surgery	0.50		1 st eye surgery	2 nd eye surgery
	8	Age	0.54		$<$ 65 years old	$>$ 85 years old
	13	Age	1.32	0.07	$>$ 60 years old	\leq 60 years old
	17	Age	1.23		\leq 70 years old	$>$ 70 years old
	8	Pre-op vs post-op	1.02	$>$0.05	Pre-op	Post-op
	11	Pre-op vs post-op	0.99		Pre-op	Post-op
	15	Pre-op vs post-op	1.26		Post-op	Pre-op
	21	Pre-op vs post-op	0.71		Pre-op	Post-op
	13	Education level	1.51		University-level education	No or primary education
	24	Pre-op vs post-op	0.81	$<$0.0001	Post-op	Pre-op
C1 “difficulty reading text in the newspaper”	11	Gender	0.63	0.90	Male	Female
	13	Age	0.93		$>$ 60 years old	\leq 60 years old
	13	Education level	2.02	0.01	University level education	No or primary education
	15	Pre-op vs post-op	0.60	$<$0.05	Pre-op	Post-op
	21	Pre-op vs post-op	2.06		Post-op	Pre-op
21	Pre-op vs post-op	1.13	$<$0.05	Pre-op	Post-op	

C2 “recognising faces”	21	Age	1.09	0.05	N/A	N/A
	21	Gender	1.41	0.005	N/A	N/A
	24	Pre-op vs post-op	0.54	0.001	Post-op	Pre-op
C3 “difficulty seeing prices”	11	Pre-op vs post-op	0.62		Post-op	Pre-op
	15	Pre-op vs post-op	0.66		Pre-op	Post-op
	21	Pre-op vs post-op	0.64	>0.05	Post-op	Pre-op
	21	Gender	1.27	0.008	N/A	N/A
C4 “difficulty seeing to walk on uneven surfaces”	6	Gender	0.50		Female	Male
	8	Gender	0.64		Female	Male
	11	Gender	0.68		Female	Male
	17	Gender	1.26		Female	Male
	8	Age	0.53		65-85 years old	<65 years old
	8	Age	0.89		>85 years old	<65 years old
	17	Age	0.51		>70 years old	≤70 years old
	8	Pre-op vs post-op	0.93	0.23	Pre-op	Post-op
	11	Pre-op vs post-op	0.52		Post-op	Pre-op
	21	Pre-op vs post-op	1.08	>0.05	Pre-op	Post-op
	13	Education level	0.89		University-level education	No or primary education
C5 “difficulty seeing to do handicraft”	8	Gender	0.62		Female	Male
	11	Gender	0.75		Female	Male
	12	Gender	0.54		Female	Male
	15	Gender	0.65		Male	Female
	21	Gender	1.72	0.0006	N/A	N/A
	8	Age	0.56	0.34	>85 years old	<65 years old
	13	Age	0.52	0.26	>60 years old	≤60 years old
	13	Education level	0.90		University-level	No or primary education
	15	Pre-op vs post-op	0.69		Pre-op	Post-op
	21	Pre-op vs post-op	0.64	>0.05	Post-op	Pre-op
	22	Visual acuity	0.56	0.007	Better pre-op visual acuity	Worse pre-op visual acuity
	24	Pre-op vs post-op	0.65	<0.0001	Pre-op	Post-op
13	Age	1.25	0.04	≥60 years old	<60 years old	

C6 “difficulty reading subtitles on television”	13	Gender	0.93	0.03	Female	Male
	15	Gender	0.65		Female	Male
	13	Education level	0.53	0.47	University-level	No or primary education
	15	Pre-op vs post-op	0.55		Post-op	Pre-op
C7 “difficulty engaging in an activity/hobby”	13	Age	0.50	0.42	>60 years old	≤60 years old
	17	Gender	0.67		Female	Male

Category threshold order In nineteen studies, (79%) Rasch analysis demonstrated ordered thresholds with category probability curves.

Fit statistics The majority of studies demonstrated an infit and outfit MNSQ range between 0.50-1.50 except for seven studies; one conducted in a Chinese-speaking Malay population¹⁸¹, one in China¹⁵³, one in Denmark¹⁴⁰, one in Canada¹⁹², one in Philippines⁴¹ and two in Brazil.^{188,189} Six studies revealed misfitting items with an infit/outfit value greater than 1.50; including Cb “satisfaction with vision”, C2 “recognising faces”, C4 “seeing to walk on uneven surfaces” and C5 “seeing to do handicrafts”. Bando et al¹⁸⁹ revealed that Q2 was misfitted however it was not clear whether this referred to the second global or activity of daily living item. Adnan et al¹⁸¹ demonstrated Cb to be misfitting (outfit value = 1.51); Khadka et al¹⁵³ (study 4) removed item C5 (outfit value = 1.74) with slight reduction to measurement precision (Person Separation Index, PSI dropped to 2.09 from 2.15)¹⁵¹; Nielsen et al¹⁴⁰ (study 12) removed item C2 (infit value = 1.55, outfit value = 1.57) and C4 (outfit value = 1.68) from the remainder of the Rasch analysis, revealing a PSI of 2.78; Antunes et al¹⁸⁸ found Cb to be misfitted (outfit value = 1.83); Bando et al¹⁸⁹ (study 19) revealed Q2 was misfitted (outfit value = 2.13) however it is uncertain whether the misfitted item was removed from the analysis; Negre et al¹⁹¹ and Kabanovski et al¹⁹² both removed Cb (outfit value = 1.81; 1.51, respectively) from their analyses.

Ten studies demonstrated slight misfit of six items with an infit and outfit MNSQ range between 1.30 and 1.50: Cb (infit 1.31-1.32, outfit 1.32-1.33), C1 “reading newspapers” (infit=1.36, outfit=1.37), C2 (infit 1.33-1.40, outfit 1.33-1.50), C4 (infit=1.35, outfit 1.36-1.40), C5 (infit=1.42, outfit=1.32) and C6 “reading subtitles on TV” (infit=1.33, outfit=1.31). Harrer et al did not specify individual fit statistics for items but quoted an infit range of 0.70 to 1.40.¹⁸³

Unidimensionality The Catquest-9SF questionnaire demonstrated unidimensionality across all studied populations, as indicated by both fit statistics and principal component analysis, except for one population. Bando et al identified an unexplained variance in the first contrast of 2.39 eigenvalue units, surpassing the threshold of 2.¹⁸⁹ This finding suggests the possibility that items may share a secondary trait beyond visual function. In cases where the questionnaire lacks unidimensionality which suggests that the items share a consistent pattern of unexpectedness, indicating the presence of a secondary trait.

Measurement precision In all published studies, measurement precision was deemed satisfactory with PSI greater than or equal to 2.0 and Person Reliability (PR) greater than or equal to 0.80. Across the studies, the Catquest-9SF demonstrated an average PSI of 2.42 (range 2.00 to 3.28), and average PR of 0.85 (range 0.80 to 0.92). This suggested that the questionnaire was able to differentiate individuals based on their abilities and achieved good reliability in terms of replicating responses across items. Nanos et al demonstrated the highest precision (PSI 3.28, PR 0.92), while Adnan et al showed the lowest precision (PSI 2.00, PR 0.80).^{150,181}

Targeting Lundstrom et al (2009) and Lundstrom et al (2002) had the largest sample size of 10,886 and 42,023, respectively. Both studies exhibited effective targeting in the Swedish population before cataract surgery. However, eight studies (study 9, 10, 13, 16, 18, 22, 23, 24) identified significant mistargeting pre-operatively revealing differences ranging from -1.07 to -1.61. The remaining studies displayed mistargeting ranging from -0.11 to -0.86. Post-

operatively, all studies experienced significant mistargeting, with values ranging from -1.21 to -2.43.

Differential item functioning Of the 19 studies that performed DIF, four studies (study 13, 15, 17, 21) demonstrated significant evidence of DIF >1.0 or <-1.0 (Table 4 and 5). The only statistically notable DIF contrasts reported in the studies were seen for item Ca “difficulties in daily life” (rated easier pre-operatively by 1.01 logits, $p\text{-value}<0.05$), C1 “difficulty reading text in the newspaper” (rated easier by respondents with a university-level education by 2.02 logits, $p\text{-value}=0.01$; and easier pre-operatively by 2.06 logits, $p\text{-value}<0.05$), C2 “recognising faces” (rated easier pre-operatively by 1.13 logits, $p\text{-value}<0.05$; by gender, 1.41 logits, $p\text{ value}=0.005$), C3 “difficulty seeing prices” (by gender, 1.27 logits, $p\text{-value}=0.008$), C5 “difficulty seeing to do handicraft” (by gender, 1.72 logits, $p\text{-value}=0.0006$) and C6 “difficulty reading subtitles on television” (rated easier by respondents ≥ 60 years old by 1.25 logits, $p\text{-value}=0.04$).

Interestingly, respondents found that satisfaction with vision was increased whilst awaiting first-eye surgery compared to second-eye surgery, albeit this was not statistically significant. Similarly, non-statistically significant general trends included men rated the item “seeing to walk on uneven surfaces” more difficult than women and those ≥ 70 years old found it easier “to walk on uneven surfaces” than those <70 years old. No statistically significant patterns were identified among these results.

Item ranking

Figure 3 illustrates item ranking along with the item calibration measured in logits for each item. A negative value represents a more difficult item requiring higher visual function while a positive value represents an easier item requiring lower visual function. Each item is ordered horizontally from most difficult (Cb) to least difficulty (C2). Respondents found item Cb “satisfaction with vision” (1.43 logits) the most difficult to answer in 16 of 19 studies. This was followed by items C1 “reading text in the newspaper” (0.28 logits) and C5 “seeing to do needlework and handicraft” (0.20 logits). Item C2 “recognising faces” (0.89 logits) was ranked the easier question in 11 of 19 studies. This was followed by items C7 “seeing to carry out a hobby” (0.57 logits) and C4 “seeing to walk on uneven ground” (0.57 logits).

Clustering of questions

Clustering of items was identified among two main groups: Ca, C1, C3, C5, C6 and C2, C4, C7. Item Ca clustered with item C1 in seven studies (8, 10, 11, 12, 15, 20, 21), with item C3 in seven studies (1, 4, 10, 12, 15, 17, 18) and with item C6 in seven studies (1, 4, 11, 13, 15, 16, 17, 22). Item C1 clustered with C3 in six studies (1, 6, 10, 11, 12, 15) and with item C6 in five studies (3, 5, 11, 15, 20). Item C3 clustered with item C5 in six studies (1, 11, 13, 15, 16, 21) and with item C6 in seven studies (1, 4, 10, 17, 21, 22, 23). Item C5 clustered with item C6 in five studies (1, 5, 6, 18, 20).

Items C2 clustered with C4 in four studies (1, 4, 15, 21) and with C7 in two studies (4, 21). Item C4 clustered with item C7 in five studies (4, 6, 10, 21, 22). Figure 3 demonstrates the clustering of these two main groups of items, indicating potential redundancy of items.

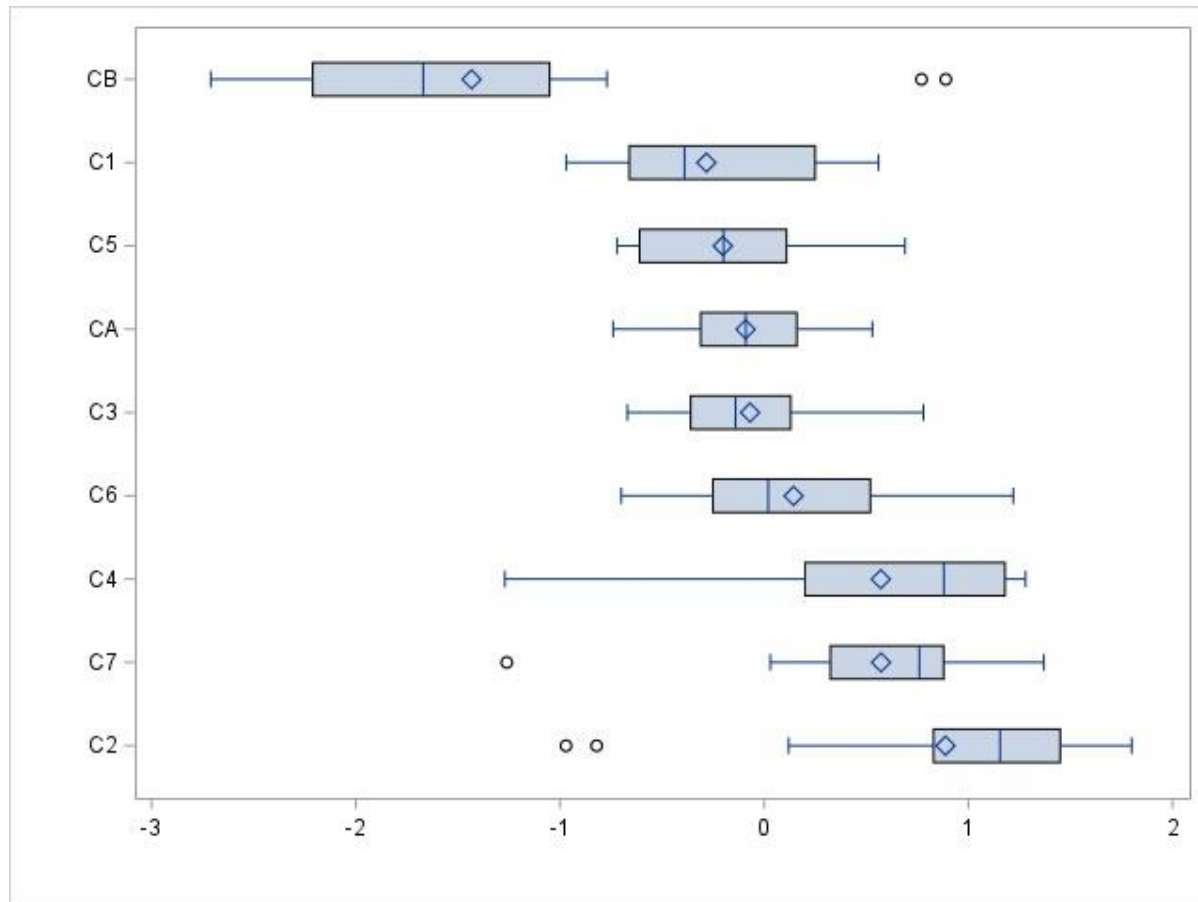


Figure 3. Item ranking measured in logits. Mean ranking is indicated by a diamond in each bar. Box plots ordered horizontally from most difficult (top) to least difficult (bottom).

Responsiveness to surgery

Out of the 17 studies that evaluated pre-operative and post-operative scores, 12 studies identified the Catquest-9SF as responsive to cataract surgery. Six studies demonstrated responsiveness by measuring effect size values of greater than 0.80: 1.58, 1.47, 1.35, 1.8, 1.27, 2.6, 2.55 (studies 4, 5, 8, 11, 15, 16, 23). Nine studies reported a statistically significant overall score improvement measured by logits: 3.07, 3.41 to 3.21 (from 2008 to 2018), 2.89, 3.47, 5.07, 3.89, 2.81, 4.56, 1.47 (studies 4, 7, 8, 11, 12, 14, 15, 16,).

Studies 3, 4, 8, 9, 15 and 18 conducted subgroup analyses to assess the responsiveness of the Catquest-9SF (or modified version) to cataract surgery. Studies 4, 9 and 15 showed that patients who had bilateral cataract surgery demonstrated greatest improvement (ES 2.20, 4.25 logits, 3.32 logits, respectively) compared to first-eye or one-eye (ES 1.57, 2.53 logits; 2.07 logits, respectively). However, study 3 found that mean visual functioning increased in 22% of patients who underwent unilateral surgery compared to 10.4% in bilateral surgery. Similarly study 4 and 18 found that patients who underwent cataract surgery in their first eye experienced greater improvement compared to those who had surgery on their second eye, irrespective of comorbidities. Conversely, study 9 observed that patients found greater visual functioning following second-eye surgery (3.84 vs 2.53 logits).

Study 18 showed that improvement was greater in patients without comorbidities compared to those with ocular comorbidities, regardless of first or second eye (1st eye, 3.57 vs 1.92; 2nd eye, 2.94 vs 1.44 logits, respectively). However, study 4 showed that patients with comorbidities reported greater improvement than those without (ES 1.69 vs 1.45, respectively).

Study 24 performed an extended analysis for shortened versions of the Catquest-9SF including an 8-, 5- and 3-item subset.¹⁹² However, this resulted in reduced precision when differentiating between three levels of visual function for the 5- and 3-item subset.

Reliability

Majority of the studies (92%) reported good internal consistency of Cronbach's α greater than 0.8 and more than half reported an excellent consistency of greater than 0.9. One study reported an excellent intraclass correlation coefficient of 0.991.¹⁹⁰

2.4 Discussion

The review demonstrated that the Catquest-9SF is a valid questionnaire for measuring PROMs related to visual disability in patients with cataracts. Of the studies that reported on category threshold ordering, all showed ordered thresholds indicating that an individual with lower visual function consistently chose higher category responses representing greater difficulties. Unidimensionality by fit statistics and PCA showed that the Catquest-9SF largely measured a single trait, visual function in this case. Misfitting was found in four items across seven studies. Precision was adequate in all published studies indicating that the instrument was able to distinguish respondents who have different levels of visual function. One third of the studies found significant mistargeting and all studies demonstrated mistargeting post-operatively, suggesting that the questions were too easy. The majority of studies did not identify statistically significant DIF with only some studies suggesting differential item functioning with respect to visual acuity, pre- and post-operative status, and demographic factors such as age, gender, and education level.

Most studies found that the Catquest-9SF was responsive to cataract surgery. Generally, higher visual scores in post-surgery surveys were found in patients with bilateral cataract surgery compared to unilateral, and first eye surgery patients saw larger mean improvements than second eye.¹⁸² However, in this review, the Catquest-9SF did not identify any consistent correlation patterns with contradictory data presented for either subgroup. Studies 4 and 18 also presented differing data in relation to the use of Catquest-9SF to monitor self-assessed visual improvements in patients with ocular comorbidities compared to those without.^{153,158}

Study 4 found that patients with comorbidities reported a greater visual improvement than those without however, the study excluded patients with significant co-existing diseases. Conversely, study 18 included patients with visually significant ocular comorbidities and found that these patients demonstrated less visual gain. Although the severity of the comorbidities is not known, it is likely that patients with more severe co-existing eye diseases do not experience as much self-reported visual improvements due to the presence of their ocular comorbidities. It is also noteworthy that study 4 reported a significant loss to follow up with only 30% of recruited participants returning a post-operative questionnaire, thus introducing possible selection bias.

Some studies demonstrated mistargeting pre-operatively, suggesting that the items were relatively easy for respondents. However, in all eight studies that demonstrated pre-operative mistargeting, the questionnaire demonstrated adequate precision in both PSI and PR values. Post-operative mistargeting is consistent with the visual improvement observed following cataract surgery thus enabling respondents to easily answer items. Katz et al, employed the use of an electronic notepad when administering the questionnaire and found that mistargeting persisted.¹⁵¹ Ergonomic issues associated with the use of notepads were also reported in the study. Previous literature has recommended the use of item banking and computerised adaptive testing to tailor patients' responses thus reduce targeting whilst improving efficiency. This does not yet exist for ophthalmology. Further investigations into the cost-effectiveness, efficiency and workflow process involved in paper-based versus computerised testing is required, especially in a population of mostly elderly patients with poorer visual acuity.

This review found clustering of items that could be broadly categorised by item for near vision forming one cluster (Ca, C1, C3, C5 and C6) and items for distance vision (C2, C4 and C7) forming another cluster. Clustering of items suggest redundancy and therefore could be removed and replaced with items that assess other aspects of visual function. In a Canadian study that investigated a cataract surgery appropriateness and prioritisation instrument, items such as glare, ability to work and care for dependents, ability to run errands and ability to assist others or participate in social life were found to be important predictors in health outcomes.

Four studies demonstrated significant evidence of differential item functioning (13, 15, 17, 21) across six items. Interestingly, three items (Ca, C1 and C2) were rated easier pre-operatively. Possible contributing factors to the DIF could include surgical complications affecting follow up rates, timing of the questionnaire being administered pre- or post- new reading glasses and the various follow up intervals. The task C1, "difficulty reading text in the newspaper," was observed to be less challenging for individuals with higher levels of education. Lin et al hypothesised that participants with university-level education found the task easier to respond as they were more likely to engage in reading newspapers regularly. In

the same study, the investigators reasoned that in China, the men are more likely to read the newspaper than women and the elderly, more likely to watch television than the younger generation. Thus, the DIF observed could potentially be benign. Gender was another variable that demonstrated statistically significant DIF amongst three items C2 “recognising faces”, C3 “difficulty seeing prices” and C5 “needlework and handicraft”. However, it is unclear from the study whether female or males found these tasks easier to perform.

Three abridged versions of the Catquest-9SF were included in this review: and Catquest-8SF-CN in study 4, Catquest-8SF-PH (where “PH” stands for Philippines version) in study 23, Catquest 7SF in study 12. The Danish Catquest-7SF removed items C2 and C4 due to misfitting. Despite its removal, the questionnaire continued to demonstrate poor targeting which was attributed to socio-environmental factors. Similarly, study 12 found misfit and removed item C5 “needlework and handicraft”, attributing the presence of misfitting to ambiguity of linguistic translation. The Catquest-8SF-CN (Chinese version) demonstrated excellent targeting owing to its cultural adaptation to better reflect the impact of the disease in a Chinese cataract population. Populations differ in demographic characteristics, cultural and linguistic aspects hence the performance of a questionnaire will vary, and a targeted algorithm is required to accurately interpret the responses. The Canadian Catquest-8SF, with C4 removed, had no mistargeting, no misfitting item and similar precision in comparison to the Catquest-9SF.¹⁹²

Although the abridged versions of the Catquest-9SF may reduce response burden, the items removed from the questionnaire should maintain acceptable psychometric values. The Filipino Catquest-8SF, which removed misfitting item Cb “satisfaction with vision”, revealed poor targeting as well as multidimensionality.¹⁹¹ The shorter 5- and 3-item subsets in the Kabanovski et al study further showed unacceptable precision values.¹⁹²

The Catquest-9SF also demonstrated a good internal consistency and excellent test re-test reliability which is consistent with other published studies.^{157,190} This suggests that the Catquest-9SF should be used to evaluate patient-reported outcomes in cataract surgery. However, the questionnaire has not been incorporated into routine clinical practice in many centres presumably due to the fact that it is still seen as a research tool rather than a tool to identify patients with impaired visual function.¹⁸⁵

Other studies have demonstrated additional uses of the Catquest-9SF which include guiding the timing of a second cataract operation based on the patients’ needs or optimising appropriateness and prioritisation of cataract surgery.¹⁸² A recent Canadian study (2022) suggested that the Catquest-9SF, alongside visual function scores, could be used to determine cataract surgery especially for patients with the same visual acuity. The investigators proposed that a Catquest-9SF score less than -3 combined with a best-corrected visual acuity in the worse eye of 20/30, or better, indicates a lower priority.¹⁵⁵ However, the study was limited by a population consisting of only English-speaking participants undergoing sequential cataract surgery and the use of a Rasch-scoring algorithm derived from an Australian population.

A limitation of the review was the heterogeneity in how results were interpreted across different studies. This variability arose from differences in the demographic characteristics and outcome measures reported. For instance, some studies assessed visual acuity using the mean or median binocular or better eye visual acuity, while others reported the percentage of participants with visual impairment. Furthermore, the included participants differed greatly

with some including patients with ocular comorbidities whilst others excluded participants with significant co-existing eye diseases, patients who were using eye drops that could possibly alter the corneal surface or were diagnosed with mental health illnesses. Additionally, the psychometric properties were not always reported in the included studies.

2.5 Conclusion

The systematic review in Chapter 2 contributes to the existing literature by highlighting the strong psychometric properties of the Catquest-9SF questionnaire. It showcases the reliability and validity of the questionnaire across various cataract populations and includes evidence from newly developed translations and abridged versions, further supporting its use as a robust tool for assessing patient-reported outcomes in diverse settings.

3. A Comparative Study of the Catquest-9SF vs Priquest questionnaire in an Australian cataract population

Synopsis

Chapter 3 focuses on the process of selecting an appropriate PROM tool for use in monitoring visual functioning of patients undergoing cataract surgery at Sydney and Sydney Eye Hospital, New South Wales, Australia. The Cataract Clinical Care Standard released by the Australia Commission of Quality and Safety in Healthcare (ACQSH), references the Catquest-9SF and Priquest questionnaires which are the primary tools under investigation in this study. Using Rasch analysis, the psychometric properties of these two questionnaires will be rigorously evaluated. The chapter will discuss their respective advantages and limitations of both questionnaires. Additionally, the chapter will address the limitations of the study itself, discussing factors that may affect the generalisability and applicability of the results as well as any potential biases that might influence the conclusions drawn. Finally, the implications of these findings will be explored in the context of cataract surgery in a public hospital in Australia, considering how the choice of PROM tool can impact clinical practice and patient care.

3.1 Introduction: The Pilot Study

Alongside traditional objective metrics including best-correct visual acuity and refraction, PROMs are increasingly acknowledged as key indicators of performance. This is especially significant as traditional objective measures do not always align with improvements in patients' daily lives.¹³⁹ Hence, there has been a global trend towards monitoring PROMs to ensure that medical interventions lead to patient-centred improvements.¹⁴⁰ In Australia, PROMs have been largely used within a research context or benchmarking purposes across state and national levels.

The Rasch model is the gold-standard analysis used for validating the psychometric properties of PROM questionnaires.¹⁹³ The psychometric robustness of a PRO tool is calculated by a pre-determined criteria that assess validity, reliability and responsiveness.¹¹ Lundstrom and Pesudovs (2008) found that a combination of the 7 disability items and 2 global assessment items produced the greatest measurement precision which eventuated in a shorter, abridged version, the Catquest-9SF. Since 2008, the Catquest-9SF has remained unchanged.

The Catquest-9SF and Priquest questionnaires have been recommended by the ACQSH to be incorporated in the cataract service pathway to support patient-centred healthcare.¹⁶¹ The Catquest-9SF is a validated questionnaire for the monitoring of PROMs in cataract surgery.¹³⁹ However, little is known about the psychometric properties of the Priquest. In two studies, the Priquest was used to monitor visual difficulty in the everyday life of patients with cataracts. Charalampidou et al (2011) administered the questionnaire in symptomatic non-advanced cataract populations however only in the capacity of a vision PRO tool rather than to assess the validity of the Priquest.¹⁹⁴ Similarly, Lundstrom et al (2006) used the Priquest as a means to establish a clinical tool for categorising cataract surgery prioritisation.¹⁹⁵ To date, no validation study has been conducted using the Priquest questionnaire.

Questionnaires are sample dependent as different populations vary in demographic characteristics and sociocultural aspects of health. Hence, it is important for studies to investigate the performance of different vision-specific questionnaires in order to validate their relevance, reliability, and robustness prior to implementing into routine clinical care. Since 2008, the Catquest-9SF questionnaire has been validated in several different languages^{140,145,150,151}, in an abbreviated version¹⁵³ and electronically¹⁵¹. Only a minority of these studies were conducted in its English translation.^{154,182} The Catquest-9SF has been shown to have excellent performance measures and subsequently, has been incorporated into cataract clinical care standards such as the ICHOM¹⁵⁹ and the EUREQUO.¹⁶⁰

The aim of this study was to assess the validity of the Catquest-9SF compared to the Priquest questionnaire amongst a diverse Australian cataract population.

3.2 Study Methodology

3.2.1 Implementation of PROMs at the Sydney and Sydney Eye Hospital

The English translations of the Catquest-9SF (Appendix 2) and Priquest (Appendix 3) was employed. The Priquest (Appendix 3) is a twelve-item questionnaire consisting of two cataract symptom questions (B1 and B2) and ten questions on the performance of daily living activities (A1-7, C1-3). The items A1-7 are similar to that of the Catquest-9SF. Response

categories include very great difficulty, great difficulty, some difficulty and no difficulty. Many items in the Priquest questionnaire are identical to those in the Catquest questionnaire.¹⁹⁵ Given the degree of similarity to the Catquest-9SF and to improve comparability, an additional response category was included ‘cannot say’ – similar to that of the Catquest-9SF.

Patients who presented to Sydney and Sydney Eye Hospital, Australia between March and June 2023 were given the Catquest-9SF questionnaire on the day of surgery, prior to surgery and one month post-operatively at their follow up appointment. Following this, the Catquest-9SF questionnaire was substituted with the Priquest questionnaire and administered to patients between June and September 2023. Patients who did not return post-operative questionnaires were followed up by staff to complete the questionnaire via telecommunications.

Whilst the ICHOM recommends collecting PROMs three months after cataract surgery, the current facility only schedules patients for a routine one-month post-operative appointment following uncomplicated surgery.

The questionnaire was completed by patients without involvement from clinical staff and returned on the same day they were administered. Patients diagnosed with a cataract and undergoing cataract surgery were included. Patients were not provided with the questionnaire if they were unable to complete it due to cognitive impairment or inability to visualise the questionnaire. Patients with a co-existing ocular morbidity were included in the study. The study was reviewed and deemed low negligible risk by the review board of South Eastern Sydney Local Health District, Human Research Ethics Committee and followed the tenets of the Declaration of Helsinki.

Pre-operative and post-operative questionnaire responses, demographic and clinical data were collected. This included age, gender, country of birth, first or second eye cataract surgery and follow up time.

3.2.1 Statistical Analysis using the Rasch Model

The psychometric properties of the Catquest-9SF and Priquest data were evaluated using Rasch analysis, a statistical model designed to measure latent traits, such as visual function in this context.

A person-item map provides a visual representation of the hierarchy of item difficulty from the easiest to the most difficult tasks, alongside the distribution of respondent abilities. For example, a respondent positioned at the most negative end of the scale exhibits higher visual function, indicating minimal difficulty performing tasks. Conversely, a person closer to 0 on the scale likely experiences difficulties with some tasks, particularly the more challenging items located further along the scale. The map helps to identify whether the scale is well-targeted to the population being measured.

The outcome measures from Rasch modelling included category threshold order, item fit statistics, unidimensionality, measurement precision, targeting, differential item functioning.¹⁴² Rasch analysis was performed using WINSTEPS software version 5.6.0 (Winsteps.com, Chicago, IL, USA).

3.3 Results

Patient characteristics

A total of 299 and 204 patients completed the Catquest-9SF and Priquest pre-operative questionnaires, respectively. Baseline demographics was comparable between both groups (Table 6). Figure 5 illustrates the country of origin of participants. For the Catquest-9SF group, 35% of patients had pre-existing ocular comorbidity while 30% of patients who completed the Priquest had pre-existing ocular diseases. These included glaucoma, retinal pathologies such as diabetic retinopathy and previous retinal detachments, macular degeneration and corneal disease.

Threshold order

Both questionnaires demonstrated ordered category threshold for all items (Figure 4).

Item Fit Statistics

The overall performance of both the Catquest-9SF and Priquest questionnaires was found to be acceptable as they showed a satisfactory fit to the Rasch model (Table 7 and 8). The fit statistics were within an acceptable range. For the Catquest-9SF, the infit values ranged from 0.78 to 1.26, and the outfit values ranged from 0.74 to 1.33. Similarly, the infit values for the Priquest ranged from 0.78 to 1.45 and the outfit values from 0.67 to 1.26. Falling within the acceptable range of 0.5 to 1.5, both questionnaires demonstrated a good fit to a single overall construct.

Unidimensionality

The Catquest-9SF had acceptable variances explained by the measures (empirical calculation 60%, models expectation 60.2%). Unexplained variance measured by the first contrast was 1.8 eigenvalues. In contrast, the Priquest demonstrated a lower than acceptable level of variance explained by the measures (empirical calculation 45.1%, models' expectation 45%) and a higher than acceptable level of unexplained variance in the first contrast (2.7 eigenvalue units)

Precision

Both questionnaires demonstrated acceptable PSI and PR values (Catquest-9SF: PSI 2.65, PR 0.88, Priquest: PSI 2.56, PR 0.87).

Table 6. Characteristics of the participants.

Characteristics	Catquest-9SF, n (%)	Priquest, n (%)
Participants	299	204
Gender		
Female	156 (52)	100 (49)
Male	143 (48)	104 (51)
Age (mean)	73 years	73 years
1 st vs 2 nd eye surgery		
1st	214 (72)	135 (66)
2nd	85 (28)	69 (34)
Ocular comorbidity		
Yes	104 (35)	62 (30)
No	195 (65)	142 (69)
Mean follow up (days)	47	100

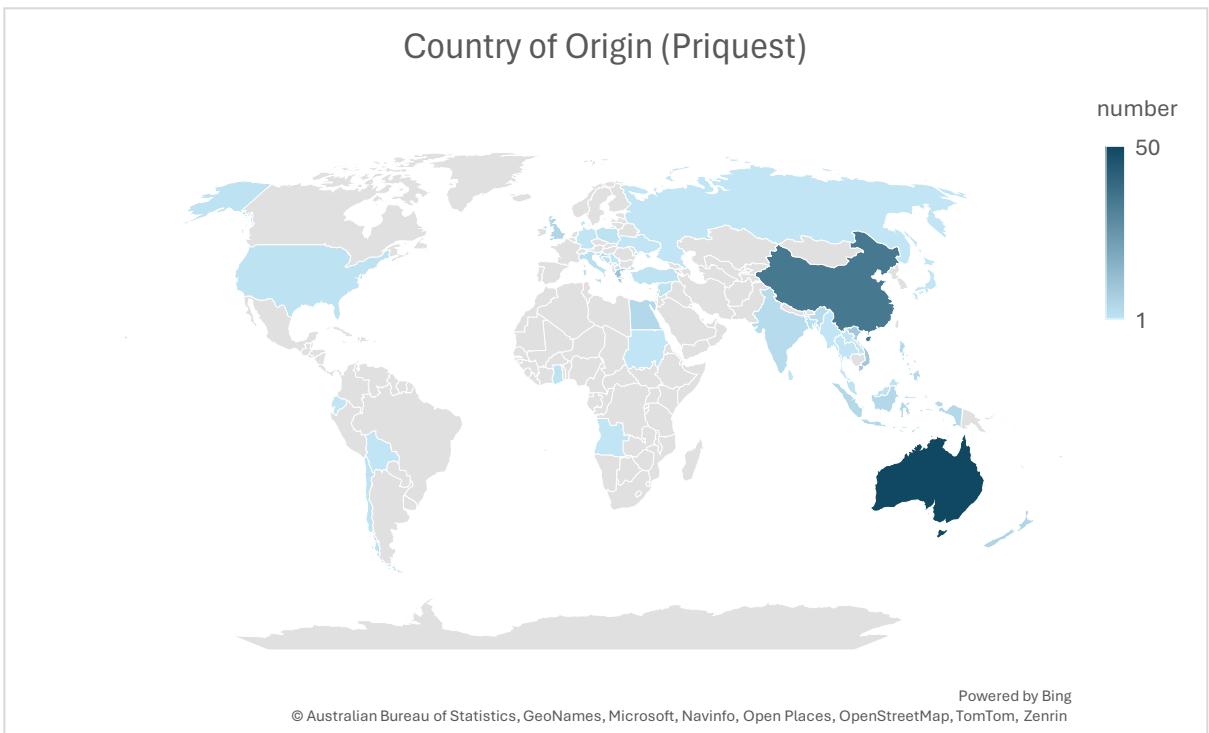
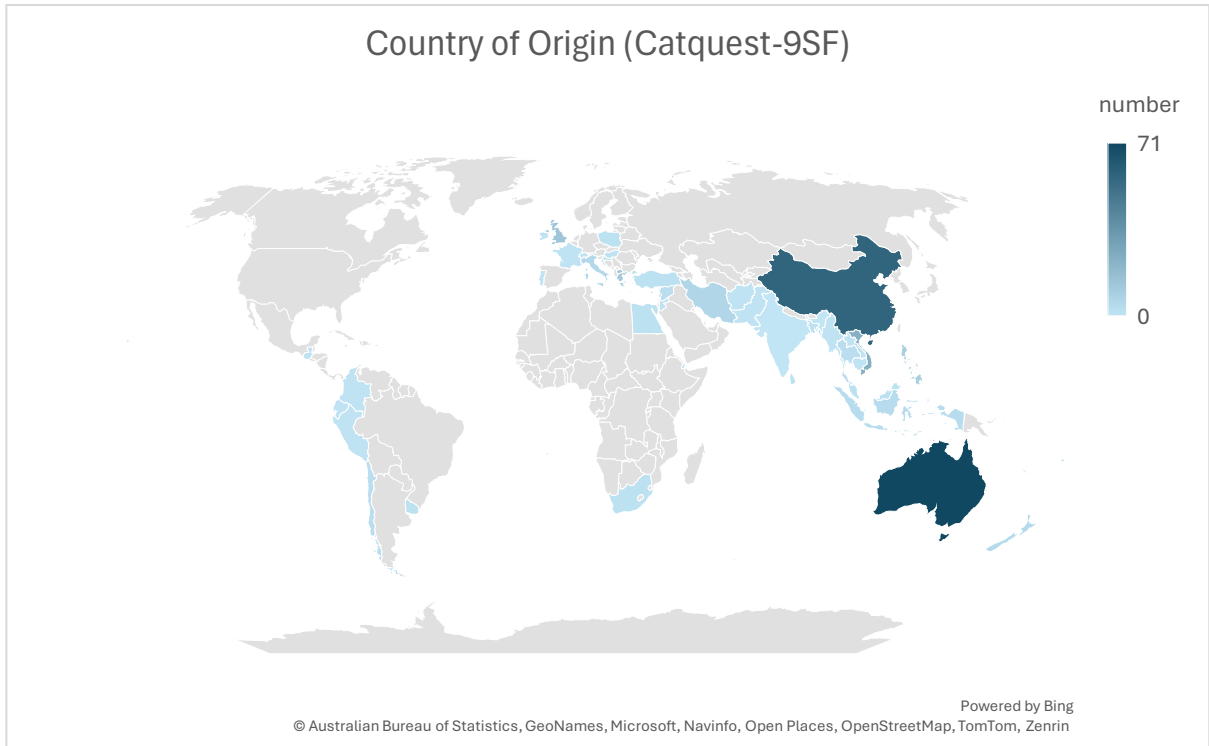


Figure 5. Distribution of participants by country-of-origin A. Catquest-9SF (above) B. Priquest (below)

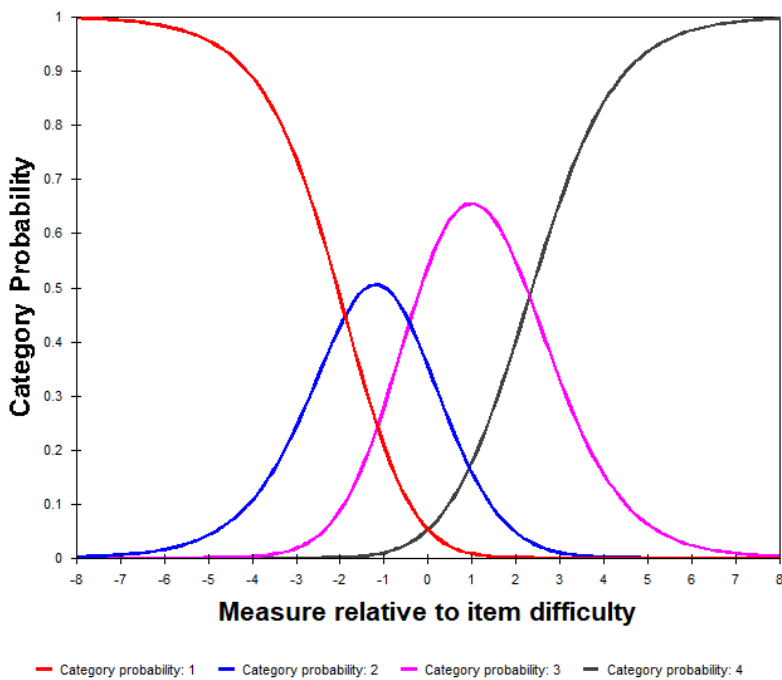
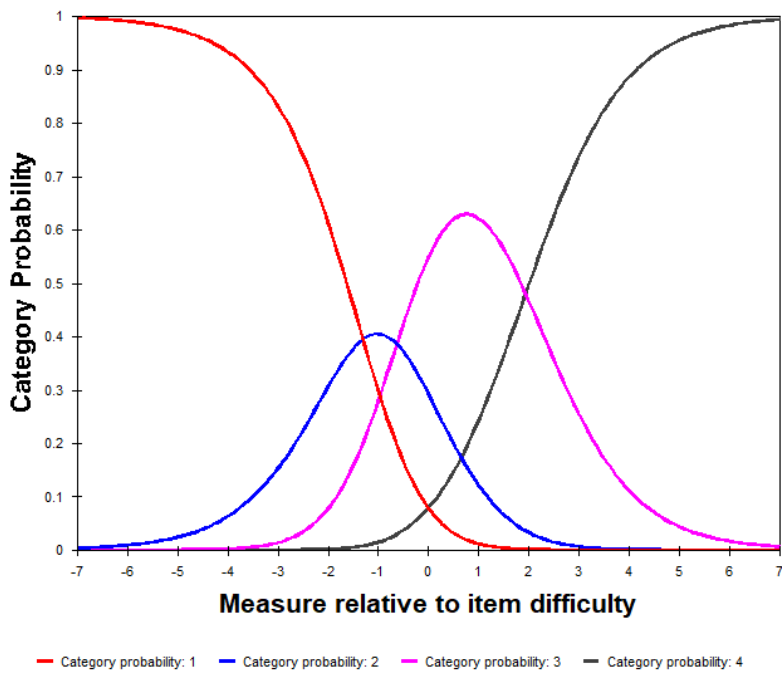


Figure 4. A. Category probability curve for the Prequest (above). B. Category probability curve for the Catquest-9SF (below).

Table 7. The Catquest-9SF questionnaire with infit and outfit mean square (MNSQ) and standardised (ZSTD) fit statistics.

Item	Infit		Outfit	
	MNSQ	ZSTD	MNSQ	ZSTD
Ca Do you experience that your present vision gives you difficulties in any way in your daily life?	1.02	0.25	1.09	1.06
Cb Are you satisfied or dissatisfied with your sight at present?	0.91	-1.09	0.99	-0.08
C1 Reading text in newspapers	0.94	-0.73	0.89	-1.24
C2 Recognising the faces of people you meet	1.26	2.73	1.16	1.33
C3 Seeing the prices of goods when shopping	1.11	1.28	1.04	0.50
C4 Seeing to walk on uneven surfaces e.g. cobblestones	1.14	1.57	1.06	0.63
C5 Seeing to do handicrafts, woodwork etc.	0.96	-0.43	0.91	-1.00
C6 Reading subtitles on TV	0.98	-0.19	0.95	-0.54
C7 Seeing to engage in an activities/hobby that you are interested in	0.78	-2.73	0.74	-3.10

Table 8. The Priquest questionnaire with infit and outfit mean square (MNSQ) and standardised (ZSTD) fit statistics.

Item	Infit		Outfit	
	MNSQ	ZSTD	MNSQ	ZSTD
Because of your vision, do you have difficulty with the following activities?				
A1 Reading newspaper print	0.98	-0.16	1.01	0.13
A2 Recognising the faces of people you meet	1.45	3.60	1.26	1.57
A3 Seeing the prices of goods when you shop	0.89	-1.14	0.88	-1.09
A4 Seeing to walk on uneven ground	0.81	-1.94	0.79	-1.82
A5 Seeing to do needlework	1.17	1.64	1.08	0.74
A6 Reading TV text	1.02	0.19	1.01	0.09
A7 Seeing to carry out preferred activity/hobby	0.89	-1.06	0.85	-1.38
B1 Do you feel that headlights, lamps, sunlight or other lights dazzle you, reducing your vision?	1.12	1.22	1.23	2.07
B2 Do you experience visual disturbances from differences (clarity, colour, poor depth perception) between two eyes?	0.97	-0.25	1.05	0.48
C1 If you have a job, does your present vision cause any problems?	1.03	0.24	1.08	0.60
C2 If you are a car driver, does your present vision cause any difficulties in driving?	0.98	-0.12	0.88	-0.87
C3 If you look after yourself or care for someone at home, does your present vision cause any problems?	0.78	-1.90	0.67	-2.23

Targeting

The person-item maps for the Catquest-9SF and Priquest are shown in Figure 6. The item difficulty for the Catquest-9SF ranged from -1.83 to 1.65 logits, while the patient ability ranged from -5.69 to 6.04 logits. No mistargeting was observed between the patient ability and item difficulty in the pre-operative data suggesting that the questionnaire items were targeted ideally to respondent abilities. Item difficulty for the Priquest ranged from -1.34 to 1.29 whilst patient ability ranged from -5.24 to 5.74. The difference between the item and person means was 0.70 logits indicating the items were also well-targeted to the respondents' abilities. However, following surgery, both questionnaires demonstrated significant mistargeting (Catquest-9SF -3.35 logits; Priquest -3.65 logits).

Figure 6 showed that the two easiest questions in the Catquest-9SF were C2 "recognising the faces of people you meet" and C4 "seeing to walk on uneven surface". The easiest question in the Priquest was C1 "if you have a job, does your present vision cause any problems". The most difficult questions in the Catquest-9SF were Cb "satisfaction with vision" and C1 "reading text in newspapers" whilst in the Priquest was "seeing to do needlework".

Clustering of questions

Figure 6A revealed clustering of Catquest-9SF questions: C3 "seeing the prices of goods when shopping", C5 "seeing to do handicrafts, woodwork etc" and C6 "reading subtitles on TV". The Priquest showed two groups of clustering: A1 "reading newspaper print", A6 "reading TV text" and B1 "do you feel that headlights, lamps, sunlight or other lights dazzle you, reducing your vision" and, A3 "seeing the prices of goods when you shop", A7 "seeing to carry out preferred activity/hobby", B2 "do you feel that headlights, lamps, sunlight or other lights dazzle you, reducing your vision" and C1 "if you have a job, does your present vision cause any problems".

Differential item functioning

Table 9 demonstrates that the Catquest-9SF and Priquest did not contain any statistically significant DIF ($DIF > 1.00$, $p < 0.05$) suggesting that the items performed the same across different subgroups of patients (stratified by gender, age group, number of eye operated and comorbidities).

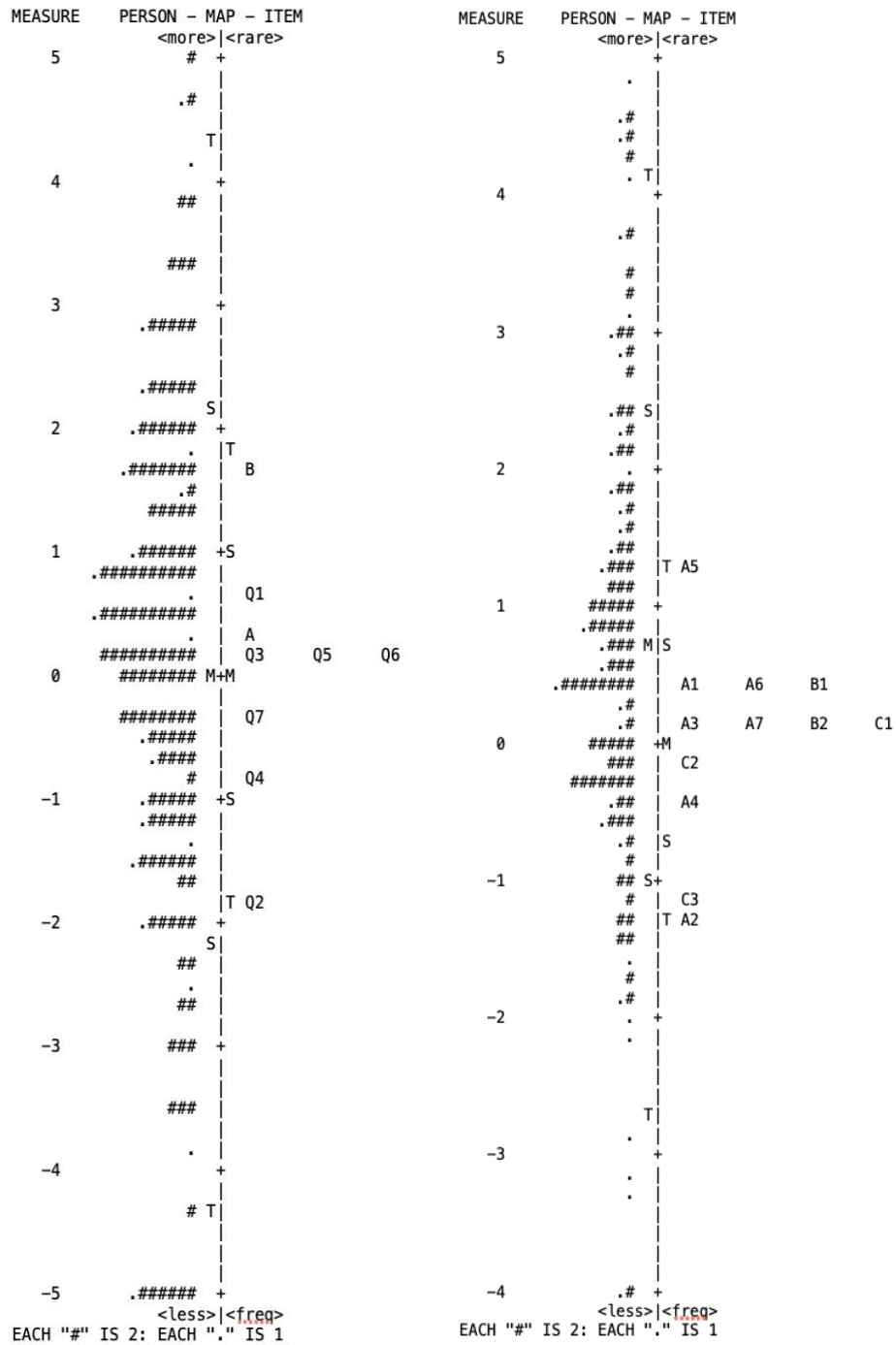
Ceiling and floor effects

Pre-operatively, no ceiling or floor effect was observed for either the Catquest-9SF or Priquest questionnaire. However, there was a significant ceiling effect for both questionnaires, post-operatively. In the Catquest-9SF assessment 66 of the 195 respondents (>15%) and 15 of the 58 respondents (>15%) to the Priquest, achieved the highest possible logit score.

Responsiveness to surgery

In the Catquest-9SF group, pre- and post-operative data demonstrated a marked improvement in the mean person Rasch score from 0.00 [-2.14, 2.14] logits to 3.35 [1.21, 5.49] logits. Effect size was 1.57. Similarly, the pre- and post-operative data for the Priquest demonstrated a significant improvement from 0.70 [-1.74, 2.44] logits to 4.35 [1.89, 6.81] logits. Effect size was 1.71. Overall, patients demonstrated improved visual function post-operatively in both the Catquest-9SF and Priquest across all items (Figure 7 and 8).

Reliability



Cronbach's α was 0.92 for both questionnaires.

Figure 6. A. Person-item map of the Catquest-9SF. B. Person-item map of the Priquest. Distribution of Rasch calibrated participant score (left side in each graph) and item locations (right side in each graph). (M=mean, S = 1 standard deviation, T = 2 standard deviations. Each 'X' is 2. Each "." is 1.

Table 9. Differential item functioning (DIF) by age, gender, eye and comorbidities.

Questionnaire	Item	DIF by age			DIF by gender			DIF by eye			DIB by comorbidities						
		Item difficulty		Diff in logits	p-value	Item difficulty		Diff in logits	p-value	Item difficulty		Diff in logits	p-value				
		≤ 70 years	> 70 years			Male	Female			1st	2nd			No	Yes		
Catquest-9SF	n=	105	194			143	156			214	85			195	104		
	Ca	0.28	0.36	-0.08	0.919	0.43	0.24	0.20	0.562	0.39	0.17	0.22	0.020	0.29	0.41	-0.12	0.699
	Cb	1.68	1.65	0.03	0.943	1.73	1.58	0.15	0.369	1.74	1.46	0.28	0.052	1.56	1.82	-0.26	0.212
	C1	0.61	0.68	-0.07	0.541	0.73	0.59	0.14	0.493	0.65	0.68	-0.02	0.937	0.69	0.58	0.11	0.288
	C2	-1.73	-1.89	0.16	0.335	-1.83	-1.83	0.00	0.963	-2.04	-1.41	-0.63	0.238	-1.83	-1.81	-0.02	0.928
	C3	0.23	0.06	0.16	0.320	-0.01	-0.05	-0.25	0.592	0.08	0.24	-0.16	0.124	0.19	-0.01	0.20	0.964
	C4	-1.03	-0.76	-0.27	0.196	-0.99	-0.73	-0.25	0.011	-0.85	-0.81	-0.04	0.931	-0.95	-0.67	-0.28	0.036
	C5	0.28	0.19	0.08	0.750	0.02	0.40	-0.38	0.188	0.26	0.15	0.10	0.494	0.22	0.19	0.03	0.654
Priquest	n=	69	135			104	100			135	69			142	62		
	A1	0.57	0.37	0.20	0.113	0.44	0.44	0.00	0.091	0.36	0.58	-0.22	0.345	0.44	0.34	0.09	0.514
	A2	-1.26	-1.39	0.13	0.867	-1.58	-1.14	-0.44	0.079	-1.34	-1.34	0.00	0.780	-1.28	-1.56	0.28	0.084
	A3	0.06	0.22	-0.15	0.710	0.09	0.26	-0.17	0.368	0.04	0.44	-0.40	0.240	0.20	0.13	0.07	0.954
	A4	-0.41	-0.48	0.07	0.820	-0.59	-0.34	-0.25	0.749	-0.39	-0.59	0.19	0.092	-0.41	-0.57	0.16	0.034
	A5	1.39	1.24	0.15	0.359	1.37	1.21	0.17	0.359	1.15	1.57	-0.42	0.525	1.24	1.38	-0.14	0.194
	A6	0.24	0.50	-0.26	0.091	0.46	0.35	0.11	0.721	0.49	0.24	0.25	0.065	0.30	0.67	-0.37	0.006
	A7	-0.06	0.14	-0.19	0.252	0.06	0.10	-0.04	0.638	0.08	0.05	0.02	0.208	0.08	0.08	0.00	0.058
	B1	0.68	0.26	0.41	0.200	0.41	0.41	0.00	0.612	0.53	0.16	0.37	0.375	0.41	0.44	-0.03	0.751
	B2	0.30	0.02	0.28	0.192	0.21	0.02	0.19	0.155	0.11	0.11	0.00	0.253	-0.04	0.60	-0.65	0.198
	C1	0.07	0.20	-0.14	0.432	0.43	-0.12	0.55	0.150	0.18	0.07	0.11	0.413	0.21	-0.03	0.24	0.091
	C2	-0.30	-0.05	-0.25	0.555	-0.02	-0.29	0.26	0.500	-0.11	-0.26	0.15	0.270	-0.02	-0.61	0.59	0.084
C3	-1.50	-0.93	-0.58	0.089	-1.34	-0.91	-0.43	0.015	-1.08	-1.21	0.13	0.422	-1.03	-1.41	0.38	0.214	

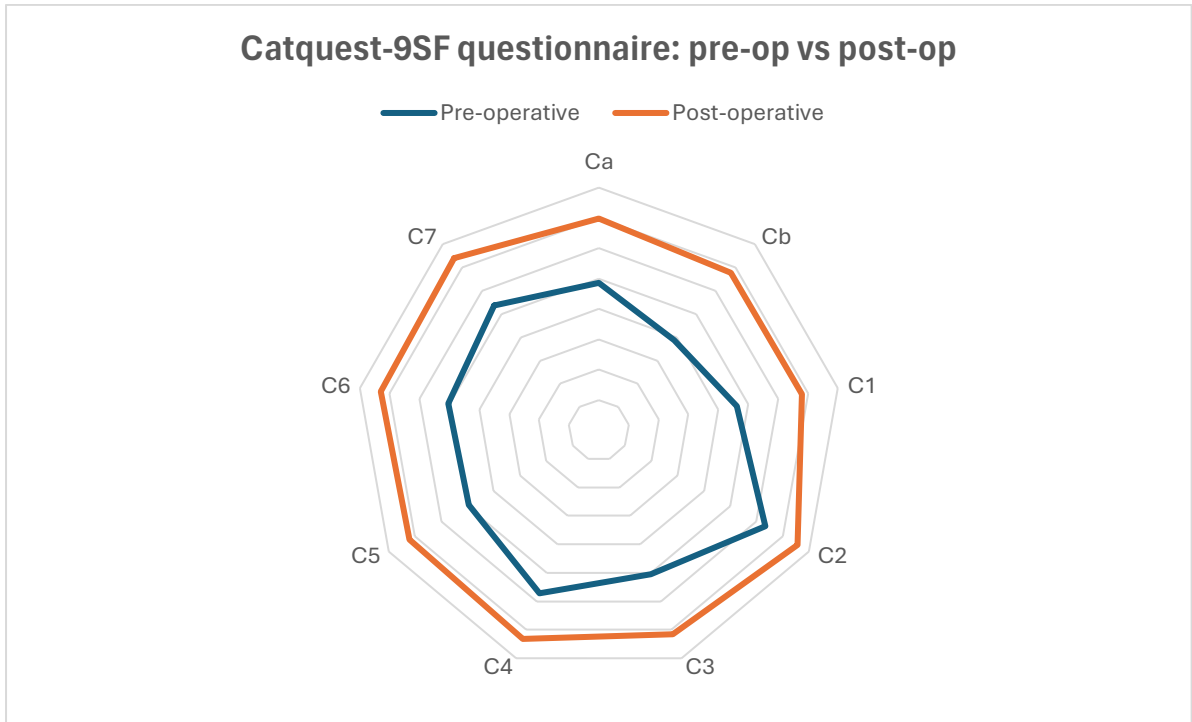


Figure 7. Radar plot of the Catquest-9SF questionnaire comparison between pre-cataract surgery (in orange) and post-cataract surgery (in blue).

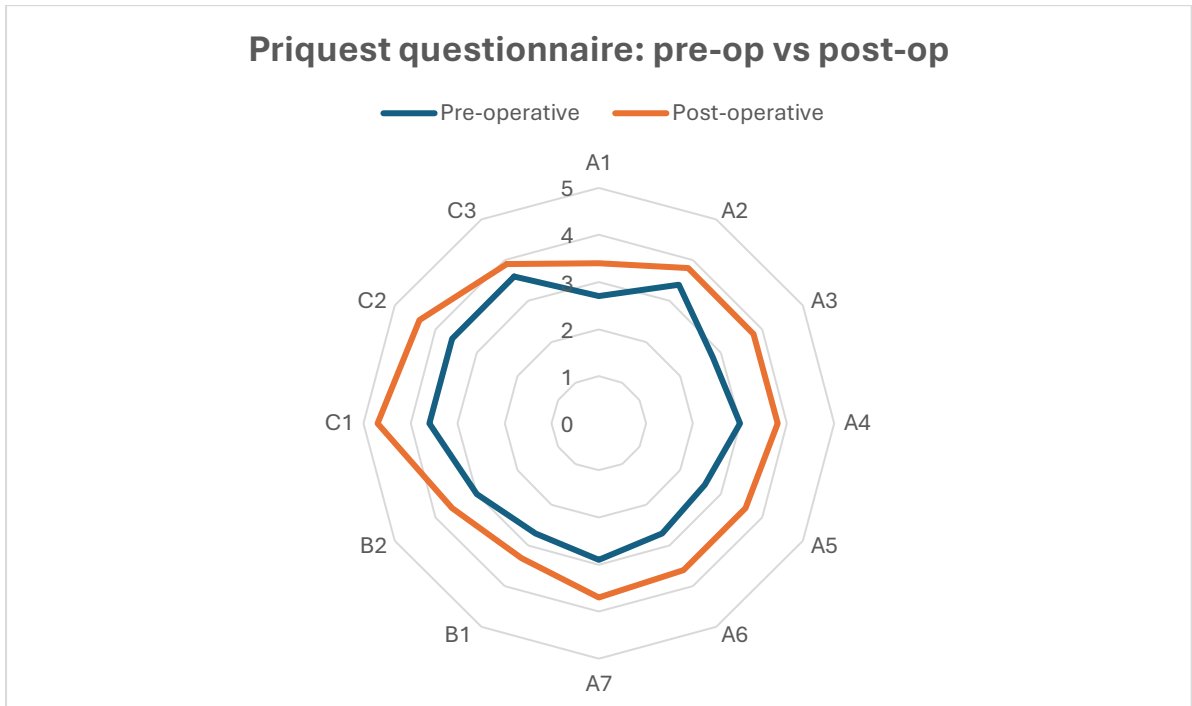


Figure 8. Radar plot of the Priquest questionnaire comparison between pre-cataract surgery (in orange) and post-cataract surgery (in blue).

3.4 Discussion

The study underpinning this thesis supports the findings of the systematic review, confirming that the Catquest-9SF is a valid and reliable tool for assessing visual functioning in patients undergoing cataract surgery. It goes a step further by highlighting that the Catquest-9SF outperforms the Priquest questionnaire in terms of its psychometric properties, particularly for an Australian cataract population.

The Catquest-9SF and Priquest scores demonstrated significant improvements in person measures (3.35 vs 3.65 logits, respectively), emulating that of former studies reporting an overall mean score improvement ranging from 2.81 to 4.56 logits.^{34,139,140,145,151,153,186,187} Moreover, the study demonstrated that both questionnaires are responsive to cataract surgery, with both eliciting large effect sizes (Catquest-9SF 1.57; Priquest 1.71). Current literature report effect sizes of the Catquest-9SF ranging between 1.27 and 2.6 logits.^{139,144,145,151,153,187}

The Catquest-9SF demonstrated a strong unidimensional structure with similar empirical calculation (60%) and model's expectation (60.2%) for the variance explained by the measures. Additionally, the unexplained variance, measured by the first contrast, was 1.8 eigenvalue units which is close to the level typically seen with random data, further supporting the unidimensionality of the questionnaire. In contrast, the Priquest showed a discrepancy in its fit to a unidimensional model. The variance explained by the measures was lower than the acceptable value of 50%. Furthermore, the unexplained variance in the first contrast was a higher value than that seen in the Catquest-9SF. This outcome suggested that the Priquest had multidimensionality whereby items may have shared a secondary trait other than visual function.

With regards to unidimensionality assessment, item fit statistics derived from the present data ranged acceptably for the Catquest-9SF and Priquest. The majority of previous studies that validated the Catquest-9SF demonstrated similar results with only five studies identifying misfitting items which included Cb "satisfaction with vision", C2 "recognising faces", C4 "seeing to walk on uneven surfaces and C5 "seeing to do handicrafts".^{140,153,181,188,189}

Both the Catquest-9SF and Priquest showed good precision and separation ability. Each item for both questionnaires had three ordered response thresholds, demonstrating that the scale is well-structured. Specifically, respondents who selected higher categories – indicating greater difficulty with the item – tended to have lower visual functioning, aligning with the intended meaning of the questions. Moreover, previous studies validating the Catquest-9SF in other languages have consistently shown high precision, with a PSI greater than or equal to 2.0 and PR greater than equal to 0.80.

The person-item maps for the Catquest-9SF and Priquest demonstrated good coverage across the range of person abilities and item difficulties, suggesting that both capture a wide spectrum of visual functioning. The Catquest-9SF showed a slightly wider range than the Priquest. Both questionnaires also exhibited a high level of precision and excellent reliability (Cronbach's $\alpha > 0.9$). However, it is important to note that Cronbach's α is influenced by the number of items and a larger number can naturally lead to a high Cronbach's α .

In high-volume cataract services, the use of a routine PROM questionnaire should take into consideration the potential logistical, personnel burden and costs associated. The Priquest questionnaire has almost twice as many questions as the Catquest. Consequently, shorter questionnaires such as the Catquest-9SF or CatPROM5 have become more widely preferred.^{66,144}

Similar to previous literature, this study found that item C2 “recognising the faces of people you meet” was the easiest item in the Catquest-9SF whilst the most difficult item was “satisfaction with vision”.^{34,152,181,182,185,187,188x}

Clustering was also observed between C3 “seeing the prices of goods when shopping”, C5 “seeing to do handicrafts, woodwork etc” and C6 “reading subtitles on TV”. This has previously been demonstrated in the Malaysian cohort suggesting redundancy of items as clustered items could indicate a similar level of visual function.¹⁸¹ Interestingly, similar questions in the Priquest did not demonstrate the same clustering patterns.

Despite the high degree of item overlap between the Priquest and Catquest-9SF questionnaires, clustering of similar items was not observed in the item map. This may be attributed to evidence of multidimensionality within the Priquest suggesting that the questionnaire may capture a broader or less cohesive latent construct. Furthermore, the inclusion of symptom-based items and potential contextual priming or sequencing effects may have further influenced response patterns, disrupting the expected clustering of functionally similar items.

No statistically significant DIF was identified for any item across both questionnaires. Although DIF with select items were previously observed for the Catquest-9SF, no discernible pattern was detected in this study.

Post-operatively, both questionnaires demonstrated significant mistargeting, as indicated by negative values. These negative values suggest that the difficulty of the tasks was too low relative to the respondents’ abilities. This is consistent with the typical outcome of cataract surgery where improved vision leads to a reduction in difficulty for tasks that were previously challenging. Previous validation studies using the Catquest-9SF also experienced significant mistargeting with values up to -2.06 logits.³⁴

No ceiling or floor effect was identified pre-operatively thus allowing for greater potential for improvements in visual functioning. A significant ceiling effect in the post-operative Catquest-9SF and Priquest data is, again, consistent with the improved visual outcome of patients following cataract surgery hence the items becoming easier to respond post-operatively. It is likely that the cause of this is due to the significant mistargeting that appeared after cataract surgery.

The Catquest-9SF and Priquest both demonstrated a good internal consistency. This has been previously replicated in other studies suggesting that the Catquest-9SF should be used to evaluate patient-reported outcomes in cataract surgery.¹⁵⁷ However, neither questionnaires have been incorporated into routine clinical practice, being used more commonly as a research tool.¹⁸⁵

Overall, the Catquest-9SF performed well in all psychometric properties as assessed by Rasch analysis. However, it is noteworthy that the Priquest contains important screening questions related to driving, employment and caretaking which the Catquest-9SF does not.

Cataract surgery is often prioritised for patients who are affected by the aforementioned activities thus making these items imperative to triaging surgery timing.

The current study is the largest Australian study to assess the Catquest-9SF questionnaire in a diverse Australian population including pre- and post-operative groups to validate its use for assessing visual function in patients with cataract. It is also the first study to compare the psychometric properties of the Catquest-9SF with the Priquest questionnaire to help identify benefits and challenges of one over the other. It is noteworthy that previous studies may have exhibited patient bias as participants being asked to complete the questionnaire prior to a decision being made regarding surgery may lead to exaggeration of poor quality of life in order to obtain surgery. In the present study, the risk of patient bias influencing their responses was minimised by the administration of questionnaires the day of their scheduled surgery thus removing the risk of patient bias influencing their responses.

A notable limitation of the study was handling of post-operative questionnaires. A major contributing reason was due to the varying clinics that follow up appointments were conducted in, especially for patients with co-morbidities as they were reviewed in subspecialty clinics. Additionally, not all staff and clinicians were made aware of the use of routine, post-operative PROMs, particularly the Priquest, which led to a significant poor completion rate of post-operative questionnaires. Low post-operative completion rates of PROMs can result in selection bias as patients may disproportionately represent those with poor outcomes avoiding reviews or those with excellent results who deem no further care required. However, in this study, patients attended their follow-up appointments but did not complete the post-operative questionnaires. This distinction highlights that the issue lies with non-compliance. Addressing the underlying reasons such as time constraints, questionnaire fatigue or lack of administrative staff could help improve compliance rates in future studies.

The shorter follow-up period of this study may also limit the ability to comprehensively track the long-term visual improvements or patient satisfaction. Post-operative outcomes at one month could negatively skew PROMs results due to ongoing post-operative issues such as inflammation or macula oedema. Furthermore, the results cannot be reliably compared to standardised PROMs outcomes. Aligning with the three-month timeframe recommended by ICHOM could provide a more accurate reflection of functional improvement and allow benchmarking.

Although the study was conducted at a single site, the Sydney and Sydney Eye Hospital is a quaternary referral centre hence the profile of the participants are likely to be representative of cataract populations in public hospitals in Australia. Another consideration is that the questionnaires were only administered in their English translations. Although the participants represented a broad range of countries of origin, a certain proficiency in English was required to complete the questionnaires. This may limit the generalisability of the study's findings. Cultural nuances and differing levels of health literacy further impact the accuracy of self-reported outcomes. These factors highlight the importance of culturally appropriate translations, plain language adaptations and support mechanisms to ensure inclusivity and equitable participation in PROMs collection.

3.5 Conclusion

This study concluded that the Catquest-9SF showed better psychometric properties for measuring visual functioning in Australian cataract surgery patients than the Priquest questionnaire.

4. Work in the Pipeline at the Sydney and Sydney Eye Hospital: A Framework and Protocol for Implementing a web-based PROM questionnaire

Synopsis

This thesis has addressed the selection of an appropriate, valid and reliable tool for the monitoring of PROMs in cataract surgery within the Australian healthcare context.

Furthermore, it has also identified a potential solution in addressing some of the challenges encountered with implementing PROMs in routine clinical care – web-based administration.

Chapter 4 details the framework and protocol for the implementation of an electronic method that would enable clinicians to access the results of the questionnaire in real-time during patient consultations.

4.1 Introduction: Modernising PROMs in Healthcare

PROMs that are captured electronically allow patients, or their families and carers, to share their healthcare experiences and outcomes. To facilitate this process, the Health Outcomes and Patient Experience (HOPE) platform was developed – a specialised IT system co-designed in collaboration with consumers, clinicians and healthcare managers across NSW.¹¹² The initiative was created in partnership with the ACI, eHealth NSW and the Ministry of Health ensuring a user-centred and integrated approach to data collection.

Few studies^{196,197} have addressed patient-centred outcomes including quality of life or satisfaction for patients undergoing cataract surgery particularly in Australia.¹⁹⁸ The Sydney Eye Hospital is a quaternary referral unit located in the central business district of Sydney, Australia.¹⁹⁹ The unit performs approximately 300 cataract operations monthly.

At the Sydney and Sydney Eye Hospital, the cataract service pathway recommends the completion of a PROMs questionnaire prior to undergoing cataract surgery.¹⁹⁹ The Cataract Clinical Care Standard has recommended the use of the Catquest-9SF questionnaire. Patients complete a paper-based questionnaire which is filed away in patient records however, this can be lost among paperwork.

A French study by Katz et al (2021) demonstrated that the electronic method of using the Catquest-9SF was not only convenient for patients and but also a valid method of collection.¹⁵¹ The primary aim is to develop a protocol to validate an electronic, routine and systematic method of monitoring PROMs in an Australian cataract surgery population.

4.2 Study Methodology

4.2.1 Establishing the Study Framework at Sydney and Sydney Eye Hospital

This feasibility study will be conducted at a single centre, Sydney Eye Hospital, Sydney NSW. Patients who present to the Cataract Pre-Assessment Clinic, Sydney Eye Hospital for cataract assessment will be provided a mobile, electronic device containing the HOPE platform which houses the Catquest-9SF questionnaire. The questionnaire has been translated to nine languages that the patient can select from. The questionnaire will be completed by patients without involvement from clinical staff and returned on the same day they were administered. The patient is considered to have consented (implied consent) once they have completed and submitted the survey. This will be conducted at patients' one-month post-operative review as well.

The mobile, electronic devices have already been included into the NSW eHealth Mobile Device Management system. As part of the Patient Reported Measures Data Governance and Management Framework data collected will primarily be used to contribute to patient care including indications for cataract surgery and monitor quality of care received. Secondary use of the data will include:

- quality improvement in healthcare service delivery to enable benchmarking between services
- research and preparation of publications
- development of health policy at Sydney and Sydney Eye Hospital
- assist with development of clinical decision support systems and research

Clinical staff – medical, nursing, orthoptics and clerical – will be required to login using their Stafflink Identification number. Patients and/or carers will be able to login if they have a Service NSW account. Educational sessions, such as nursing in-services, will be held prior to the implementation of the electronic Catquest-9SF data collection tool. These sessions aim to prepare staff for the transition to an electronic PROM tool, ensuring they understand its importance and use. Sessions will focus on emphasising the value of patient-focused outcomes to demonstrate how collecting this data benefits care. It will also address resistance from staff by discussing concerns, such as potential interruption to clinic flow, and how these can be mitigated.

Patients, aged 18 or higher, diagnosed with a cataract and undergoing cataract surgery will be included. Patients will not be provided with the questionnaire if they are unable to complete it due to cognitive impairment or inability to visualise the questionnaire. Patients with a co-existing ocular morbidity will be included in the study. The study will be submitted to the review board of South Eastern Sydney Local Health District, Human Research Ethics Committee for approval.

Patients who withdraw their consent will have their data removed from the HOPE platform.

4.2.2 Managing Local Data: Collection, Accessibility and Storage

The HOPE platform is a secure, web-based system designed to manage and store online surveys and patient response data. It serves as a centralised database for capturing PROMs. Clinical staff with a login will invite participants by sending a secure code to patients either via text or email to their mobile phone.¹¹²

Patients must then verify their identity through a Service NSW authentication process which is similar to that employed when renewing a driver's licence. This will ensure secure and reliable user identification. Importantly, no data or information from the HOPE platform will be stored within Service NSW, maintaining the confidentiality and security of patient and survey data.¹¹² HOPE functionality is now available for use in the Electronic Medical Record (eMR) in the majority of Local Health Districts (LHDs) and Specialty Health Networks (SHNs). The data will only be accessible by hospital personnel as part of routine care. Sydney and Sydney Eye Hospital will be the local data custodian and control local collection, use, access, in addition to the privacy and security of the PROMs data.

Participants' privacy will be protected by password and only accessible by personnel employed at the hospital as well as principal investigators. Data collected as part of this study will be stored in electronic format. No individuals will be identified in any published reports. As part of routine cataract care, the data from the questionnaire will be kept on HOPE platform.

4.3 Results

The study protocol will seek ethics approval by the South Eastern Local Health District Human Research Ethics Committee. Study commencement will be delayed due to multiple factors including resistance to the implementation of PROMs in the pre-operative Cataract Pre-Assessment Clinic, owing to concerns regarding additional workload on and time pressure. Additionally, it is expected that some clinical staff will be unaware of the value of using PROMs to incorporate patient perspectives into pre-operative outcome assessments which may hinder progress. The setup process will likely take longer than anticipated, largely

due to administrative requirements including obtaining necessary approvals from Heads of Departments. Furthermore, configuring the Catquest-9SF tool specifically for use at Sydney and Sydney Eye Hospital will require support from the Agency for Clinical Innovation which is expected to contribute to further delays.

4.4 Discussion

This chapter outlined the framework and protocol for the implementation of a web-based platform to administer the Catquest-9SF questionnaire to patients undergoing cataract surgery.

The introduction of the HOPE platform aims to streamline the integration of patient-reported outcome measures into clinical care. The workflow and functionality of the system will address some of the challenges and barriers identified in our study. These include reducing the administrative burden on the clinical team by automating the process of administering, collecting and entering PROMs data. This was typically time-consuming and prone to error. However, the system will link the questionnaire directly to the electronic medical records used at Sydney and Sydney Eye Hospital. This data collected will be readily accessible within the eMR thus allowing clinicians to view the information during pre-operative consultations. This real-time access will promote the integration of the patient's perspective into the decision-making process. One of the system's key features will be its ability to display pre- and post-operative PROMs data side by side which will present a visual summary that enhances efficiency by enabling quick comparisons and insights into patient-reported outcomes.

The HOPE platform already contains the Catquest-9SF questionnaire, translated and validated in nine different languages, which will enhance its accessibility and cultural relevance. The multilingual validation will ensure more accurate and reliable patient responses, improving the questionnaire's ability to capture diverse patient outcomes and generalise findings across various populations.

A notable limitation of paper-based forms reported by patients in our study has been the difficulty patients face in reading small print. This often affects their ability to complete the questionnaire accurately. This issue will be addressed by electronic notepads which allow the font size to be adjusted. By making the text more readable, patients will be able to interact with the questionnaire more comfortably and effectively, ultimately improving the quality and completeness of the data collected.

The proposed protocol will be the first study in Australia to implement an electronic-based PROMs questionnaire to monitor outcomes in patients undergoing cataract surgery. This innovative approach will represent a significant milestone, setting a precedent for the integration of routine PROMs into cataract services nationwide. By demonstrating the feasibility and benefits of electronic PROMs, this study aims to pave the way for widespread adoption, standardising the use of PROMs in cataract care and enhancing the overall quality of patient-centred outcomes monitoring.

The future use of the Catquest-9SF within the ACI-HOPE platform at SSEH pre-operative assessment clinics is intended to be an embedded part of routine clinical workflow. However, to ensure clarity, it is important to note that while the current implementation is focused on feasibility and usability testing the long-term aim will be for PROMS data to be collected

consistently at the pre-operative stage for every patient undergoing cataract surgery. Integration into the ACI-HOPE pathway supports the potential for wider state-level adoption, but this will depend on sustained institutional support, clinical engagement, and infrastructure that enables PROMs data to be systematically reviewed and used during clinical decision-making. Clear protocols for interpreting Catquest-9SF scores and presenting them in a user-friendly, actionable format will be critical to its future success in the SSEH clinical context.

The proposed protocol has several limitations. The primary limitation is that clinicians may face challenges in interpreting the results of the Catquest-9SF questionnaire, potentially limiting its value and integration into clinical decision-making. Secondly, the data collected from the questionnaire is not designed to inform or support the triage process, restricting its utility in prioritising patients for care. Lastly, the successful implementation of the program will depend on securing adequate funding which could pose a barrier to its widespread adoption and sustainability.

Future research in this field should focus on developing a protocol that integrates PROMs data into the triage prioritisation process. By incorporating QoL metrics into waitlist management, this approach could help ensure more timely and equitable access to cataract surgery. Additionally, a hybrid model of care that combines pre-operative visual acuity assessments with PROMs data would be highly impactful. This model could utilise advanced weighting strategies to balance patient-reported outcomes with clinical measures, providing a more comprehensive framework for prioritising care based on both the clinical and personal impact of the condition.

4.5 Conclusion

The successful incorporation of an electronic platform for the routine, systematic monitoring of PROMs within the cataract service pathway at Sydney and Sydney Eye Hospital is poised to establish a national benchmark. This platform will address the gap between the unmet clinical needs of patients and the capabilities of healthcare providers and health systems, ensuring that patient feedback is consistently collected and used to improve quality and safety. By streamlining the integration of PROMs into this process, this initiative will set a precedent for other institutions across the country, helping to enhance patient satisfaction and overall treatment outcomes.

5. Lessons Learned in Shaping the Future of PROMs in Clinical Practice

Synopsis

Chapter 5 of the thesis details the challenges encountered during the implementation of PROMs in the cataract service pathway within a public hospital setting. It identifies the barriers faced during this process, addressing obstacles at the micro, meso and macro levels – from individual patient and provider challenges to organisational and departmental issues, and broader system-level factors. The chapter proposes solutions and discusses the future directions of PROMs in clinical practice. It emphasises how the integration of these tools can evolve to meet the changing needs of patients and healthcare providers. Furthermore, it provides a roadmap for the modernisation of PROMs, ensuring they remain relevant in assessing patient outcomes and improving their utility in healthcare settings.

5.1 Levers to Promote the Widespread use of PROMs in Clinical Practice

The challenges faced during the implementation of PROMs into the cataract service pathway align with those reported in prior government documents and existing literature.

At the micro level, there was initial resistance from healthcare providers as PROMs were perceived as unhelpful and time-consuming. When the Catquest-9SF and Priquest were introduced into clinical care, a notable gap in awareness emerged, specifically concerning the Priquest questionnaire. This lack of awareness likely stemmed from limited exposure, inadequate education, or insufficient communication about the questionnaire's purpose, application, and benefits among clinicians and staff. Addressing this issue could involve targeted training and efforts to integrate the questionnaire more seamlessly into clinical workflows. Furthermore, staff expressed concerns about their limited expertise in discussing the results of PROMs assessments with patients. They reported challenges in interpreting the data, translating it into meaningful conversations, and using it to guide clinical decision-making. This highlights the need for additional training and resources to build confidence in engaging patients in discussions about their PROMs outcomes, ensuring that these assessments contribute to shared decision-making and patient-centred care.

Additionally, barriers such as language differences, cultural nuances, and varying levels of health literacy pose significant challenges to achieving broad patient participation in PROMs collection. Patients with limited proficiency in the primary language of the questionnaire may struggle to understand or accurately respond to the items. Similarly, cultural differences can influence the interpretation of questions or the willingness to engage in self-reporting. Health literacy issues further complicate the process, as some patients may lack the knowledge or confidence to comprehend the purpose or content of PROMs. Addressing these barriers requires culturally appropriate translations, plain language adaptations, and support mechanisms to ensure inclusivity and equitable participation.

At the clinical level, challenges involved practicalities of implementation including training staff to use the new tools effectively, integrating PROMs into existing workflows without disrupting patient care whilst addressing staff resistance due to increased workload or perceived complexity. The use of paper-based forms significantly increased the workload for staff as it required manual handling, including distribution, collection, and data entry into electronic systems, which not only added to personnel burden but also introduced the risk of typographical errors during transcription. Moreover, the data from these paper forms was not readily accessible within electronic patient records, creating inefficiencies in retrieving and utilizing the information. Transitioning to a digital solution could alleviate these challenges by streamlining data collection, reducing the risk of errors, and improving integration with electronic medical record systems, ultimately enhancing workflow efficiency. These hurdles highlight the need for tailored solutions that bridge the gap between high-level planning and on-the-ground execution to ensure successful adoption of PROMs in clinical practice.

Macro-level challenges were primarily driven by the absence of standardized frameworks for digital tools and PROMs, as well as the insufficient integration of healthcare IT systems. Current healthcare registries often fail to incorporate PROMs data, and a lack of interoperability between systems further exacerbates the issue, hindering the seamless sharing and utilization of information. These technical barriers are compounded by insufficient

cooperation among stakeholders across regional, state, and national levels. Misalignment of priorities and fragmented decision-making make it difficult to establish cohesive strategies for implementing PROMs effectively within healthcare systems. Addressing these challenges requires coordinated efforts to standardize processes, enhance IT infrastructure, and promote collaboration among all parties involved. An appropriate system to collect, store, process and report data efficiently, securely and accurately is required for reporting purposes.

Furthermore, PROMs initiatives should detail plans for data linkage with databases or registries to allow for case mix adjustments. This is recommended for obtaining meaningful comparisons across jurisdictions and care providers and thus allow for benchmarking activities.¹⁰⁵ A supportive top-down framework to standardise methodology, allocation of funding as well as independent bodies of auditing is needed to drive the implementation of PROMs.²⁰⁰

Health professionals play a critical role in championing the use of PROMs by highlighting their benefits, including empowering patients to actively participate in their own care, fostering improved doctor-patient communication, and generating valuable data for clinical research and quality improvement. Simultaneously, policymakers must support national efforts to establish a unified framework for PROMs implementation. This involves creating clear standards, providing financial incentives for adoption, and prioritizing investments in the necessary digital infrastructure. Collaborative efforts between healthcare providers and policymakers are essential to ensure PROMs are seamlessly integrated into clinical practice, benefiting both individual patient care and broader healthcare system advancements.

Furthermore, the integration of PROMs should extend beyond specialist care to include community healthcare services, such as general practitioners and optometrists. By involving community healthcare services in PROMs implementation, healthcare systems can ensure a more comprehensive approach to capturing patient-reported outcomes across the continuum of care. This collaborative effort between different levels of care enhances the overall utility of PROMs, making the data more representative and impactful for both individual patient management and population health initiatives.

5.2 The Changing Needs of Consumers, Providers and Stakeholders

5.2.1 Prioritisation for cataract surgery waitlist

While visual acuity is an objective standard of care, it does not necessarily reflect the impact on patients' ability to perform activities of daily living. It is now recognised that both clinical measures and patient-reported measures are to be used in conjunction to optimise the prioritisation of cataract surgery. Quality statement 5 from the Cataract Clinical Care Standard (CCCS – Appendix 4) details the need for prioritisation protocols to consider the severity of the patient's visual impairment and impact on daily activities.

Many systems for cataract surgery indications rely heavily on visual acuity to determine the appropriateness and priority for surgery. However, using the examiner's subjective opinion as the primary method of scoring patient needs is problematic as individual judgement leads to inconsistencies in care.²⁰¹ More developed models have been proposed including the Nationell Indikationsmodell for Kataraktextraktion (NIKE), Manitoba Cataract Waiting List Program and the Cataract Impact Model.^{201,202} The Cataract Impact Model proposed by

McAlinden et al (2012) suggested a Rasch-based model that incorporates both clinical data and patient-reported information from questionnaires to eliminate arbitrary weighting of inputs.²⁰² Despite its better representation of clinical acumen in the prioritisation of patients for cataract surgery, integrating a new system into existing healthcare workflows is challenging. As such, this proof of concept is yet to be implemented in clinical practice.

The NIKE national for indications of cataract extraction used in Sweden has been adopted by all ophthalmology practices in the country. A key feature of this system is that a significant portion of the indication score is derived from patients' responses to the Priquest questionnaire. This approach reduces the impact of examiner variation hence is a more reliably and consistent method of prioritisation for cataract surgery.¹⁹⁵ Patient perspectives remain incompletely captured in the current health system which significantly limits its ability to be applied to clinical practice.

The next step in the application of PROMs is the development and validation of a clinical prioritisation tool to establish levels of indications and category of urgency for cataract surgery. This tool should aim to integrate both traditional clinical assessments including visual acuity of both eyes and patient perspectives of difficulties in performing activities of daily living. Other contextual factors including medical and ophthalmic reasons for surgery should also be factors into the prioritisation process. For instance, cataract surgery may be indicated earlier for patients who require improved visual acuity for work especially related to driving standards or those with caregiving responsibilities. The presence of co-existing ocular comorbidities should be included in determining the level of indication. Certain conditions, such as phacomorphic glaucoma, may require earlier intervention and timely removal of cataract surgery. Conversely, instances where co-existing ocular conditions may limit the potential benefits of cataract surgery, such as advanced optic neuropathy or severe macular degeneration, may result in a lower indication score.

5.2.2 Second eye and immediate sequential bilateral cataract surgery

Determining the appropriate timing of cataract surgery for patients with bilateral cataracts necessitates a collaborative approach through shared decision-making. Beyond assessing the visual impairment caused by the cataracts, it is essential to consider the potential impact of anisometropia after first-eye surgery. Such anisometropia can disrupt binocular vision leading to reduced stereopsis, impaired stereoacuity and an increased risk of falls, particularly in older adults. These functional challenges must be communicated to patients, aligning with Quality Statement 6 of the Cataract Clinical Care Standard. Depending on the patient's circumstances and preferences, management options may include proceeding with no surgery, opting for delayed sequential bilateral cataract surgery (DSBCS) or choosing immediate sequential bilateral cataract surgery (ISBCS).

The use of PROMs for first versus second-eye cataract surgery represents an important area for future research and clinical application. While first-eye surgery often yields substantial improvements in visual function and quality of life, second-eye surgery can further enhance binocular vision, depth perception and overall satisfaction, even if the gains are comparatively smaller. Moreover, evidence suggests that second-eye surgery plays a crucial role in reducing the risk of falls.²⁰³ Recently, NSW Health updated the Clinical Urgency Category recommendation (Appendix 5) for second eye cataract extraction from Category 3 (surgery within 365 days) to Category 2 (surgery within 90 days).²⁰⁴

Emerging evidence indicates that ISBCS versus DSBCS found no difference in achieving target refractive goals nor any patient-reported outcome measures following surgery.²⁰⁵ With increasing trends of ISBCS²⁰⁶, there is a need to invest in PROMs tailored to these patients. However, in doing so, clinicians must also stratify patient groups to determine who may benefit from ISBCS versus those who may be at higher risk for intraoperative or postoperative complications, necessitating a delay in second-eye surgery. For instance, younger patients who prioritize faster visual recovery or those requiring general anaesthesia cataract surgery might be ideal candidates for immediate bilateral procedures.

Future directions for the use of PROMs in cataract surgery might focus on enhancing their sensitivity and specificity to evaluate the outcomes of both DSBCS and ISBCS. Most existing questionnaires were designed to assess the benefits of first-eye cataract surgery or delayed bilateral cataract surgery. However, these tools often fail to capture the nuanced functional improvements that second-eye cataract surgery provides. Postoperative visual function encompasses tasks that may be manageable after surgery in one eye but require binocular vision for optimal performance, highlighting the need for PROMs that can distinguish these differences.²⁰⁷ An example is that of the Priquest questionnaire regarding the ability to drive. Incorporating items that assess patient-specific factors, such as recovery priorities and risk profiles, will aid in personalized surgical planning and improving overall outcomes.

5.2.3 Modern day cataract refractive outcomes

Due to high patient visual demands, cataract surgery is being performed in less advanced cases, at younger ages and with refractive purposes including seeking independence from glasses for distance, intermediate and/or near vision. The introduction of multifocal and extended depth of focus intraocular lenses has added a new dimension to cataract surgery outcomes. As a result, cataract surgery outcomes are no longer solely evaluated based on visual outcome but also on the patient's ability to perform various visual tasks such as reading at near, seeing clearly at intermediate distance such as a computer screen, all alongside traditional distance vision. These new considerations offer more convenience and visual freedom however also present new challenges such as dysphotopsias or a trade-off in sharpness of vision compared to traditional monofocal intraocular lenses. Consequently, outcome assessment tools that focus solely on visual impairment or daily activity limitations may no longer capture the complete patient experience.

In recognition of these changing expectations, professional bodies such as the ESCRS have recommended the use of refractive-specific PROMs, such as the Quality of Life Impact of Refractive Correction (QIRC) questionnaire, for those receiving presbyopia-correcting intraocular lenses.²⁰⁸ Furthermore, several recent PROMs have been developed and validated specifically for this population including the Assessment of IntraOcular Lens Implant Symptoms (AIOLIS) questionnaire.^{209,210} This tool incorporates modern psychometric methods and aims to address the visual and lifestyle outcomes relevant to multifocal and extended depth-of-focus lenses. These newer instruments reflect the growing recognition that cataract surgery must be evaluated not only in terms of safety and acuity outcomes, but also in terms of refractive success and patient satisfaction.

In the annual report released by Portugal Value-Based Healthcare in Cataract Surgery (VBHCAT) Project, multifocal lenses including toric models demonstrated the best visual results, not only by the practitioner's standard but also from the patients' point of view as demonstrated by their post-operative Catquest-9SF scores.²¹¹ There was also a lower proportion of patients with multifocals compared to monofocals reporting more barriers to

performing daily activities after surgery. PROM surveys will also enable the analysis of the cost-benefit ratio for the different lens options available such as multifocals or extended depth of focus lenses.¹⁰⁰

Given these additional factors, it is essential to refine how cataract surgery outcomes are measured, ensuring that patient-reported outcomes reflect the full spectrum of vision-related quality of life. Future PROMs should account for these new lens technologies by including questions about the patient's experience with vision at various distances potential side effects and overall satisfaction with their visual outcomes as determined by their requested visual demands. The use of computerised adaptive testing offers a potential solution to the multitude of refractive outcomes available. Based on the patient's previous responses, the model identifies the correct subset of items applicable to the patient, selected from the full questionnaire. This method of machine learning has shown to produce an accurate outcome measure from fewer number of items.²¹²

5.2.4 Electronic PROM data collection

The use of PROMs can be valuable during patient consultation to help determine the optimal time for intervention, guide refractive outcome discussions and to manage the patient expectations. However, the implementation of PROMs should enable real-time feedback of results and be made readily available to clinicians during consultations to facilitate consumer engagement and improvements. Hence, electronic and web-based data management health systems are encouraged over traditional paper-based methods.^{132,133} Multiple online, cloud-based platforms are commercially available such as the RayPRO (Rayner Surgical Group Limited, United Kingdom) and ZEDOC (The Clinician, New Zealand).

The electronic collection of PROM data for patients with cataracts has been implemented in routine clinical practice in France.¹⁵¹ The use of notepads in collecting data alleviates the time-consuming process of manually transferring the data from paper to electronic. Additionally, the electronic set up is suitable for use by clinicians during consultations as it presents the results of the questionnaire as raw score changes from pre-operative to post surgery. The use of a spider chart allows for a quick comparison of the responses for each item in a single, easy-to-read diagram. Previous literature has recommended the use of item banking and computerised adaptive testing to tailor patients' responses thus reduce targeting whilst improving efficiency.⁴⁰ This does not yet exist in ophthalmology as further investigations into the cost-effectiveness, efficiency and workflow process involved in paper-based versus computerised testing is required.

The HOPE platform is a secure, web-based information technology platform designed by the Agency of Clinical Innovation in collaboration with eHealth NSW, NSW Ministry of Health, consumers, clinicians and managers across NSW which allows both consumers and clinicians to access real-time information.¹¹² The Sydney and Sydney Eye Hospital is currently in the progress of transitioning paper-based PROM questionnaires to implementing the HOPE platform in the cataract pre-operative assessment clinic to improve cataract prioritisation and better inform patient-reported outcome measures. It has the added benefit of being available in multiple translations that have been previously validated.

6. Bridging the Gap: Completing the clinical picture and supporting good professional practice

This body of work has contributed to the understanding of the implementation and implication of PROMs in routine cataract care. PROMs are widely integrated into clinical practice internationally, serving as tools for improving patient care, guiding clinical decisions and supporting health system performance. In contrast, the use of PROMs in Australia remains predominantly focused on research or benchmarking purposes, offering a more limited scope for their integration into routine clinical workflows. This comparison lays the groundwork for exploring the potential for expanding the use of PROMs in Australian healthcare, particularly in the context of cataract surgery. Cataract surgery is one of the most performed surgeries, making it an ideal candidate for the routine integration of PROMs.²¹³

A systematic review of one of the most used cataract PROM questionnaires demonstrated that the Catquest-9SF is a highly reliable and valid PROM with robust psychometric properties across various population groups and language translations. It has been shown to be responsive to clinical changes following cataract surgery, making it a valuable tool for assessing patient outcomes. Additionally, the revised versions of the Catquest-9SF displayed several strengths, including ordered category probability curves, high precision in measuring outcomes, no evidence of item misfit, and confirmation of unidimensionality, ensuring that the questionnaire effectively measures a single construct related to vision-related quality of life.

The primary objective of this thesis was to assess the appropriateness of two PROMs questionnaire as recommended by the CCCS. The study found that the Catquest-9SF exhibited superior psychometric properties compared to the Priquest, demonstrating better validity, reliability and responsiveness to cataract surgery. Furthermore, the findings reinforced that cataract surgery leads to measurable improvements in patient-reported outcomes.

A notable limitation of both the Catquest-9SF and Priquest questionnaires is that they were originally designed for cataract surgery outcomes involving monofocal intraocular lenses for distance vision and near vision corrected with glasses. These questionnaires do not account for advancements in modern cataract surgery, particularly with the increasing use of multifocal IOLs that provide spectacle independence. As such, these tools may not fully capture the experiences and outcomes of patients opting for contemporary refractive cataract surgery options.

Further studies are needed to better tailor PROMs to the diverse cataract surgery pathways that are increasingly common, such as the growing trend of immediate bilateral sequential cataract surgery. Additionally, with patients now having more control over their refractive outcomes, it is essential to account for the different visual targets they may choose, such as achieving distance vision, near vision, or spectacle independence. Research should focus on adapting PROMs to capture the unique patient preferences and surgical experiences across these evolving cataract surgery options.

Investing in PROMs specifically designed for these complex scenarios can provide valuable insights to guide more precise clinical decision-making. These tools can enhance shared decision-making between clinicians and patients by offering a clearer understanding of

patient needs, preferences, and expected outcomes. By tailoring PROMs to the unique challenges of different cataract surgery pathways, this approach has the potential to optimize patient care, improve surgical outcomes, and ensure a more personalized and effective healthcare experience.

The study also provided valuable insights into the challenges and barriers associated with implementing PROMs in clinical practice. As a result, this work led to the development of a comprehensive protocol designed to address these obstacles, facilitating the integration of PROMs into routine cataract care and ultimately improving patient outcomes and service delivery. The secondary aim was to explore potential strategies for integrating PROMs into routine clinical practice. This thesis determined in Chapter 3 that a web-based platform may provide a solution for the barriers to uptake of routine PROMs monitoring.

By adopting these measures universally, Australia could significantly enhance patient-centred care by ensuring that patient experiences and outcomes are consistently considered in treatment decisions. Widespread use of PROMs would also improve the monitoring of surgical outcomes, providing more accurate and comprehensive data to guide clinical practice. Furthermore, aligning cataract surgery practices with global standards, where PROMs are already extensively implemented, would help ensure that Australia remains at the forefront of evidence-based healthcare, optimizing both patient care and surgical results.

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Appendix

Appendix 1. Search strategy

Appendix 2. Catquest-9SF Questionnaire

Appendix 3. Priquest Questionnaire

Appendix 4. Cataract Clinical Care Standard

Appendix 5. Clinical Urgency Category recommendation