Original Investigation

A Proposed Minimum Standard Set of Outcome Measures for Cataract Surgery

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IMPORTANCE Aligning outcome measures for cataract surgery, one of the most frequently performed procedures globally, may facilitate international comparisons that can drive improvements in the outcomes most meaningful to patients.

OBJECTIVE To propose a minimum standard set of outcome measures for cataract surgery that enables global comparisons.

DESIGN, SETTING, AND PARTICIPANTS A working group of international experts in cataract outcomes and registries was convened, along with a patient advocate, to agree on a consensus of outcome measures for cataract surgery. In a modified Delphi process, the group met regularly between November 10, 2012, and November 21, 2013, to discuss which outcomes to include in a standard set. Included factors were based on extant literature, existing registries, and the experience of group members. Similarly, a series of consensus discussions were held to determine a set of risk factors to be gathered for each patient. The final shortlist was compiled into a standard set. Analysis was performed from November 22, 2013, to April 5, 2014.

MAIN OUTCOMES AND MEASURES Development of a recommended standard set encompassing preoperative metrics including patient risk factors, intraoperative factors including surgical complications, and postoperative cataract surgery outcomes.

RESULTS The recommended standard set encompasses all patients treated for cataracts by 1 of 4 surgical approaches (phacoemulsification, sutured manual extracapsular cataract extraction, sutureless manual extracapsular cataract extraction, or intracapsular cataract extraction). The recommended metrics to be recorded preoperatively include demographics, ocular history and comorbidities, preoperative visual acuity, and patient-reported visual function. The recommended outcomes were split into intraoperative and postoperative metrics. Intraoperative outcomes include capsule-related problems, dislocation of lens nucleus fragments into the vitreous, and other complications. Postoperative outcomes include visual acuity, refractive error, patient-reported visual function, and early and late complications of surgery. The suggested follow-up for collection of postoperative outcomes is up to 3 months.

CONCLUSIONS AND RELEVANCE A minimum standard set of outcome measures for cataract surgery is important for meaningful comparison across contexts. The proposed data set is a compromise between all useful data and the practicalities of data collection.

Invited Commentary
page 1253

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Cataract, a progressive opacity of the ocular lens, is the single largest cause of reversible blindness worldwide. The only effective treatment for cataract is surgical extraction, for which several techniques exist. Despite its effectiveness, rates of cataract surgery vary substantially between countries. In developed countries, operations are increasingly performed on cataracts in the early stage, whereas in developing countries, 90% of cases of blindness are attributable to untreated cataracts.[1,2] Cataract surgery has become the most common elective surgical procedure in many countries,[3,4] and rates of this surgery are likely to continue increasing as access improves in developing countries.[5-8]

The need for systematic measurement of outcomes after cataract surgery is greater than ever. Despite marked improvements in quality throughout the years, life-altering complications of cataract surgery, such as blindness, still occur.[9-13] With increasing numbers of patients undergoing cataract surgery,[7] the need to adequately balance these risks with the expected benefit is paramount.[14]

Since the first cataract registry was established in Sweden,[4] numerous registries have systematically collected outcome data after cataract surgery (such as the Malaysian National Eye Database,[15] the European Registry of Quality Outcomes for Cataract and Refractive Surgery,[16] the National Eye Outcomes Network in the United States,[17] the Aravind Cataract Registry in India,[18] and the United Kingdom's Cataract National Data Set[19]). To compare outcomes between countries and thereby learn and improve processes, a common data set with common definitions is needed.

To encourage the broader measurement of outcomes and collaboration on global outcome comparisons, the International Consortium for Health Outcomes Measurement (ICHOM) formed a working group to develop a global standard set of outcomes for cataract surgery that we recommend all health care professionals who perform cataract surgery track. The resultant set is presented here.

At a Glance

- The purpose of this study was to develop an outcomes framework for cataract surgery that can be used worldwide.
- Cataract surgery is one of the most frequently performed surgical procedures worldwide.
- Patient outcomes for cataract surgery vary greatly between health care professionals and contexts; therefore, existing registries have begun to gather outcomes information.
- This article describes the development of a recommended standard set of outcome measures that can be tracked for cataract surgery worldwide.
- This standard set may enable global comparisons and help to drive improvements in outcomes that are relevant to patients.

Methods

Assembly of the Working Group

A working group of leading experts in the fields of cataract surgery and outcome measurement was convened under the leadership of the previous director of the Swedish National Cataract Register and clinical director of the European Registry of Quality Outcomes for Cataract and Refractive Surgery project (M.L.). Working group members were selected on the basis of their prior experience with outcomes measurement in cataract surgery or involvement in clinical registries. They were drawn from a wide range of international backgrounds, including the United States (S.P. and C.S.), Great Britain (T.K., I.M., and J.M.S.), India (A.H.), Sweden (A.B. and M.L.), Australia (N.M. and K.P.), and Malaysia (P.P.G.). The group included ophthalmologists, an optometrist, an executive at an eye hospital, and an experienced patient advocate who had recently undergone cataract surgery. A project leader from ICHOM (T.K.) managed the effort, and an ICHOM research fellow (I.M.) supported the content development. Institutional review board approval was not required because the study did not involve patient or registry data.

Compilation of Standard Set

A modified Delphi technique was used to develop the standard set. Between November 10, 2012, and November 21, 2013, the working group met every 4 to 6 weeks by teleconference to discuss outcomes and risk factors for inclusion in the standard set. Using existing registries and published data as a starting point, a long list of measures was collated and refined through consensus discussions steered by the leader of the working group. Definitions of measures were then refined to prioritize ease of interpretation and data collection across a variety of contexts. Following teleconferences, members submitted their feedback and final votes on the content of the standard set through electronic surveys. The group used a threshold of two-thirds of the members in agreement to identify when a particular point could be decided. In cases in which that threshold was not met, that point was revisited during the next teleconference and on the following survey. The final standard set (**Table**) was approved unanimously by all members of the working group. Analysis was performed from November 22, 2013, to April 5, 2014.

Results

Treatment Approaches Covered

Continued innovation in cataract surgery has led to a wide spectrum of surgical variables, including type of anesthesia, incision size, lens disassembly technique, use of ultrasound phacoemulsification, intraocular lens material, implantation position (capsular bag vs sulcus vs anterior chamber), and femtosecond laser–assisted surgery. In addition, innovations in intraocular lenses include toric intraocular lenses to correct astigmatism and multifocal or accommodating intraocular lenses to address presbyopia. The result is an almost infinite variety of unique surgical approaches. We have developed a pragmatic compromise; namely, to limit the initial data set to the minimum number of broad categories chosen to be sufficiently discriminatory to warrant separation: phacoemulsification, sutured manual extracapsular cataract extraction, su-

Table. Summary of Standard Set of Outcomes for Cataract Surgery[a]

Timing	Measure	Details
Preoperative	Demographics	
	Age,y	
	Sex	
	Baseline visual status	
	Visual acuity (distance)	Uncorrected and best corrected; record in local format (eg, Snellen, logMAR)
	Target refraction	Spherical equivalent
	Patient-reported visual function	Rasch-calibrated score from Catquest-9SF or other Rasch-calibrated PROM
	Ocular comorbidities[b]	
	Glaucoma	
	Macular degeneration	
	Diabetic eye disease	Diabetic retinopathy and/or diabetic macular edema
	Amblyopia	
	Other	Any other diagnosis likely to effect outcome
	Prior ophthalmic interventions	
	Previous cataract surgery (fellow eye)	
	Previous corneal refractive surgery	
	Previous vitrectomy	
	Other	Any other prior intervention likely to effect outcome
Intraoperative	Surgical technique	Select intended technique at outset of operation
	Technical factors	
	Dense brown or white cataract	
	Corneal opacities	
	Pseudoexfoliation	
	Pupil problems	Miosis, floppy iris syndrome
	Complications	
	Capsule problems	Any surgical communication between anterior segment and vitreous, including capsular breach and/or zonular dehiscence
	Dropped nucleus or lens fragment into vitreous	Any clearly visible part of the lens material that enters the vitreous, regardless of whether removed or not
	Other	Complication prolonging surgery or causing change in procedure that may effect outcome
Postoperative	Visual outcomes	
	Visual acuity (distance)	Surgical eye and fellow eye assessed independently
	Refractive error	Surgical eye
	Patient-reported visual function	Rasch-calibrated score from Catquest-9SF or other Rasch-calibrated PROM
	Complications	
	Return to operating theater	Any return within 3 mo of surgery caused by intraoperative or postoperative complication
	Endophthalmitis	
	Persistent corneal edema	
	Other	Any postoperative complication within 3 mo requiring treatment or compromising outcome

Abbreviation: PROM, patient-reported outcome measure.

[a] Summary of data included in the minimum standard set to be gathered preoperatively, intraoperatively, and postoperatively. A full explanation of definitions can be requested from the International Consortium for Health Outcomes Measurement website at http://www.ichom.org/medical-conditions/cataracts/.

[b] Documented before or immediately after surgery.

tureless manual extracapsular cataract extraction, and intracapsular cataract extraction.

Visual Outcome

Improved vision is the primary motivation for most patients seeking cataract surgery and is an essential component of any outcome assessment. Visual acuity reflects the established criterion standard of visual function that strongly correlates with quality of life and patient-reported health outcomes. There are many different visual acuity notations used in practice, but they are readily interconverted. We recommend that clinics use their standard notation when recording visual acuity but that these are subsequently transposed into logMAR notations to enable comparison.

Refractive Outcome

Refractive error is important to capture because it affects vision-related quality of life. As postoperative refraction may intentionally deviate from emmetropia (eg, monovision), we suggest capturing the target refraction and the actual postoperative refractive error.

Patient-Reported Visual Functioning

It is increasingly clear that a successful visual outcome, as measured by visual acuity, is not synonymous with improved visual functioning for patients.[20,21] To fully understand the effect of cataract surgery, we must also assess the patients' view of whether their lives have improved. Today, patient-reported outcome measures (PROMs) are less widespread than measurements of visual acuity or refractive error, but implementing regular PROMs as part of routine clinical practice is possible.[5]

Many PROMs exist, and results following cataract surgery vary worldwide.[22] Examples include the Visual Disability Assessment,[23] National Eye Institute Visual Function Questionnaire,[24] and the Catquest-9SF.[22,25] Although we recommend use of a freely available, short, responsive Rasch-calibrated PROM such as the Catquest-9SF, we recognize that a variety of PROM tools are widely adopted and some centers may elect to use fixed scoring instruments. We recommend that centers collect PROM data using an instrument of their preference. By assessing PROMs using cross-talk algorithms at the same time points as recommended in this study, Rasch-

calibrated PROM outcomes can be meaningfully compared between centers tracking the standard set.

Complications

Complications, although uncommon, are of significant concern to patients undergoing cataract surgery. In the developed world, many patients who undergo cataract surgery have only mild impairment in visual functioning and most weigh the improvement in visual function against the small but potentially life-altering concern of a serious complication. We recommend capturing intraoperative and postoperative complications.

The most common, significant intraoperative complications include capsule-related problems and dislocation of lens nucleus fragments or entrance of lens fragments into the vitreous, both of which we recommend be recorded as part of the standard set. Numerous studies have demonstrated poor patient-reported outcomes in cases involving capsule-related surgical complications.[20] Retained cataract fragments are also associated with complicated and prolonged cataract surgery, poorer visual acuity outcomes, longer recovery, increased risk of secondary complications, and poor PROMs. Subsequent vitrectomy surgery is often required to remove the fragments, which may result in poor visual outcomes from mechanical damage to the retina, persistent intraocular inflammation, and/or glaucoma.[26,27]

We also recommend tracking a category of other unnamed complications that may threaten the visual outcome. A high frequency of other complications may prompt investigation of clinical records to identify the sources and may inform inclusion of more detailed measures in later iterations of this standard set.

For postoperative complications, we recommend tracking the incidence of endophthalmitis. Although endophthalmitis occurs rarely, its inclusion in the standard set reflects its potentially devastating effect on visual outcomes and its frequent association with posterior capsule rupture.[5,28-30] Return to the operating theater is included in the standard set to capture several rare but significant early complications that may threaten visual outcome and are often correlated with an inexperienced surgeon.[31] Although we recommend recording this outcome within 3 months postoperatively, we recognize that doing so may present challenges given that these data are not routinely gathered. Persistent corneal edema is another devastating complication included in the list. This complication often leads to a corneal transplantation.[32]

Baseline Characteristics

To make meaningful comparisons of outcomes between patients, it is important to measure certain baseline characteristics to enable appropriate adjustment. The selected demographics, comorbidities, and ocular history (Table) represent the most common characteristics that affect clinical outcomes following cataract surgery.[33-35] Systemic comorbidities, such as hypertension and cardiovascular disease, are not included because they pose little risk to patients undergoing cataract surgery.[36] We also recommend recording factors such as anatomical or pathological variants and intraoperative findings that make surgery more technically challenging. Such findings include dense brown or white cataract, corneal opacities, pseudoexfoliation, and problems with the pupil, as they may increase the risk of an adverse outcome.[37-45] To ensure that patients can be followed up appropriately and diagnoses verified, we recommend that comorbidities and prior ophthalmic interventions recorded in the set be documented within the patient's clinical record before or immediately after surgery.

Measures of patient-reported visual function following cataract surgery are influenced greatly by whether the eye undergoing the procedure is the patient's first or second eye to undergo cataract surgery.[46,47] To account for this influence, we recommend the collection of visual acuity and refractive error data from both eyes along with any history of cataract surgery on the fellow eye. The inclusion of a measure of socioeconomic status (SES) was discussed because it is well documented that SES is inversely linked with cataract severity[48] and that patients of lower SES have more limited access to treatments.[49] However, there is no accepted worldwide standard measure of SES for all contexts. Given the many difficulties in defining and interpreting different SES measures, SES was not included in this initial minimum standard set, although this may change in future iterations.

Follow-up Time

We recommend a universal window of up to 3 months for initial follow-up for simplicity and feasibility. Allowing patient follow-up at any point within 3 months after surgery should give most clinics enough time to record early complications, measure visual acuity and refractive error, and obtain the PROM.

Discussion

The working group set out to develop a minimum set of patient-centered outcomes for cataract surgery that would be practical for all health care professionals to track and that would yield meaningful results for patients wishing to choose their physician and/or health care organization and for health care professionals wishing to objectively assess their performance. The outcome standard set that has been developed includes a patient-reported outcome questionnaire, measures of intraoperative and postoperative complications, and key outcomes including postoperative visual acuity and refractive error. Additional risk factors were collected to ensure that it will be possible to perform meaningful case mix–adjusted comparisons. Of course, measures included in the standard set reflect the need for meaningful and pragmatic data collection that can be incorporated into existing patient pathways in a variety of clinical contexts. Of necessity, the resultant data set is therefore a compromise between all that is useful for comparison and the practicalities of data collection.

Data points that were considered but ultimately excluded for this reason include, but are not limited to, the type of intraocular lens used, surgical time, whether the procedure was inpatient or ambulatory, SES, antibiotic prophy-

laxis, medications, systemic comorbidities, and geographical location. Postoperative visual symptoms, such as positive or negative dysphotopsia, were also considered for inclusion, but the difficulty in defining a solid and indisputable variable to be collected for registry use hampered the incorporation of such symptoms into the standard set at this time. Severe problems with dysphotopsia may be captured by the satisfaction component of PROM instruments.[50] Interested centers should add additional outcomes to meet their specific requirements.

Data on the cost of cataract surgery are of great interest when considering the value of surgery (defined as outcomes per unit cost). These data will be considered in a subsequent analysis focusing on the denominator of the value equation.

We anticipate that the greatest strength of this data set will be consistency across international registries that will allow global comparison of outcomes. However, the infrastructure for data collection varies greatly across countries and health systems. For example, feasibility of follow-up may be difficult in some cases owing to patient volume, geographic distances, and availability of transportation. Also of concern will be issues of data sharing and ownership and patient privacy. These are pervasive issues across data collection registries, particularly in an environment of increased electronic communication and, in many countries, increased regulatory oversight. Nevertheless, this minimum data set is realistic in most settings, and participation and feedback will inform future iterations.

A possible future use of a data set such as this is to form part of an approval process for devices used in cataract surgery. This process has previously been suggested for both the United States and Europe.[51]

Zonular integrity is important for the outcome of cataract surgery. Phacodonesis may be a challenge during surgery, and more discrete zonular deficiency may cause long-term issues, such as intraocular lens dislocation, and present as a late complication. In future revisions we will discuss inclusion of this risk factor as a stand-alone risk factor rather than being included in the pseudoexfoliation variable. Of course, this is the minimum data set, and there is nothing to preclude centers from collecting additional important data such as zonular integrity.

We believe that this data set builds on existing national registries by aligning the metrics used across a larger scale and steering data collection efforts toward outcomes that matter most to patients. As a result, we hope to achieve international alignment on metrics that are most meaningful to patients.

Conclusions

The ICHOM will work with organizations worldwide to encourage adoption of the cataract standard set and is planning to facilitate global comparisons between health care organizations as adoption of the standard set takes place. These comparisons will give surgeons a unique opportunity to learn from global best practice and enable them to provide the best care for their patients. The ICHOM will form a cataract standard set steering committee to review and, if necessary, update this set on an annual basis, ensuring that it remains current and relevant for patients and physicians.

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