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CAN USING THE BOOST APP IMPROVE CATARACT SURGICAL OUTCOMES? A Prospective Study

Research Study Protocol

26 October 2018, Ref: 18/48v2

PROJECT SUMMARY

Background:
Unoperated cataract is the leading cause of blindness worldwide.[1] A cataract causes a clouding of the normally clear lens of the eye and can affect either or both eyes. Cataract blindness can only be treated by surgically removing the cataract and inserting an intraocular lens (IOL). The provision of high-quality, effective cataract surgical services is critical to ensuring that patients with cataracts can have their sight restored.

Traditionally, success in cataract surgery has been assessed by measuring post-operative visual acuity in the operated eye 4 to 6 weeks after operation.[6] In many low and middle-income countries, postoperative follow-up rates are very low (20-30% in some cases)[9] due to poor transportation and other costs, and low motivation of patients to return for follow up care. A landmark study published in 2014 however demonstrated that measuring vision immediately after surgery is a valid indicator of surgical outcomes at 4 to 6 weeks.[11]

Capitalising on the opportunity to use outcome data collected immediately following surgery, and to address the challenges of measuring and reporting cataract surgical outcomes in low-resource settings, a consortium of eye health stakeholders has developed Cataract BOOST (Better Operative Outcomes Software Tool). BOOST is a simple, free and easy to use software tool that can be accessed via a smartphone app and desktop program. It therefore supports surgeons in low resource settings to record, assess, benchmark, and improve the outcomes of cataract surgery. Now developed, BOOST requires validation as a tool that can effectively capture outcome data, is acceptable to potential users, can be integrated into routine surgical care, and can act to enhance surgeon performance.

Aim: To determine whether BOOST can improve cataract surgical outcomes and be effectively integrated into routine surgical care.

Study design: A pragmatic trial involving cataract surgeons and managers of cataract surgical services.

Time frame: November 2018 – August 2019.

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RATIONALE & BACKGROUND

Un-operated cataract remains the leading cause of blindness worldwide. More than one third (35%) of the 36 million global cases of blindness are due to cataracts.[1] While significant efforts to increase cataract surgery rates have reduced prevalence in many regions of the world,[2] a large backlog in cataract cases remains, particularly in developing countries. This is due in part to the continued growth and overall ageing of the world's population,[1] and inadequate access to cataract surgery in low resource settings.

In addition to the issue of surgical rates not keeping pace with need, the quality of surgeries performed is also a concern. Cataract can be treated with a relatively simple, low cost surgical procedure that can restore vision in more than 90% of cases.[3] Despite this potential, outcomes remain sub-optimal in many areas[4] due to inappropriate case selection and pre-existing eye disease, surgical complications, co-morbidity of uncorrected refractive error and post-operative sequelae.[5] Monitoring and responding to causes of poor surgical outcomes is critical to improving surgical results. The World Health Organization (WHO)[6] recommends that 80% patients should have uncorrected visual acuity of ≥6/18 in the operated eye following cataract surgery. Actual reporting and benchmarking varies widely across surgical centres internationally[7] and many countries where data is available fall well below this benchmark.[8]

Another key challenge has been low rates of patient follow-up. In many low and middle income countries (LMICs), postoperative follow-up rates are very low (20-30% in some cases), because of the challenges (from transport through to patient motivation) of getting patients to return to surgical sites several weeks following their procedure.[9] Visual acuity after cataract surgery has traditionally been measured 6 to 8 weeks after the operation, [10] since wound healing can change glasses power and substantially improves vision. Increasingly however, widespread use of smaller, sutureless wounds now means that visual outcomes can be assessed soon after surgery, before patients are discharged home. The PRECOG study demonstrated that 1 to 3 day post-operative outcomes are predictive of 6 to 8 week post-operative outcomes.[11]

A key strategy for improving cataract surgical quality is the strengthening of continuous quality improvement processes and accountability measures within surgical centres. Several challenges however exist, including the availability of effective, low cost, easy to use data collection and reporting tools, secure data management systems, and surgeon resistance.[11]

To respond to the demand for a low-cost, user friendly software tool that allows surgeons to measure and compare their surgical results with those of other practitioners, [12] a consortium of eye health stakeholders developed Cataract BOOST (Better Operative Outcomes Software Tool). BOOST is a free, simple-to-use app for Android smartphones, laptops and desktop computers which guides surgeons through two rounds of data collection. Quality assessment is achieved through a two-step process using a mobile or desktop application. During Step I, uncorrected (without glasses) visual acuity (VA) is recorded 1 to 3 days after surgery for 60 consecutive patients. This allows outcome quality (proportion of patients with good [≥6/18] and bad [≤6/60] VA) to be presented alongside benchmarks. During Step 2, surgeons record the causes of poor outcomes (categorising poor outcomes as relating to

refractive problems, surgical complications, or inappropriate case selection/co-morbidities) from at least 20 patients returning for follow-up appointments 6 weeks or more after surgery with presenting VA of 6/60 or less. The app then offers tailored suggestions to surgeons regarding how they might improve their surgical practice in order to address the main issues they are experiencing. The BOOST app is free and available to download from a secure, open-source website in 7 languages, including English, French, Spanish, Russian, Simplified Chinese, Vietnamese and Bahasa Indonesian. Data entered into the BOOST app is stored locally and synchronised across registered devices and a cloud server when connected to the internet.

Aims and objectives

Now developed, BOOST requires validation as a tool that can effectively capture outcome data, is acceptable to potential users, can be integrated into routine surgical care, and can act to enhance surgeon performance. The results of the study will inform further refinements of the tool, and efforts to engage surgeons and surgical centres in the routine practice of cataract outcome measurement.

The following key research questions guide the proposed study:

1. Does use of the BOOST app improve surgeon performance?
2. Are any associations observed between degree of performance improvements and: a) level of surgical experience; b) facility size; c) presence/absence of other BOOST users in the facility; d) volume of surgeries performed; e) site location (rural/urban); f) private vs government facility; g) region?
3. Does (and to what extent) use of BOOST influence engagement of surgeons in the collection and use of cataract surgical outcome data?
4. How does use of BOOST influence surgical practice?
5. What are the relative costs associated with introducing and using BOOST in contrast to existing outcome monitoring systems used within participating sites?
6. Do users of BOOST find it easy/difficult to use, and incorporate into clinical practice?
7. What user, service, contextual factors and engagement strategies influence uptake and use of BOOST?
8. What key improvements to BOOST do users recommend?
9. What data sharing arrangements (at the level of site and surgeon) do users view as acceptable?

The primary outcome will be:

- Change in the average percentage of surgical cases with good outcomes (uncorrected VA >= 6/18) across participating surgeons

Secondary outcomes of interest are:

- reported changes in collection and use of cataract surgical outcome data as a result of using BOOST
- reported changes in surgical practice as a result of using BOOST
- reported costs of using BOOST in contrast to pre-existing cataract outcome monitoring systems; and if possible, relevant cost-effectiveness in terms of cost per proportionate increase in good outcomes from cataract surgery
- reported ease of use and ease of incorporation of BOOST into clinical practice
- reported and observed user, service, and contextual factors, and engagement strategies associated with continued use of BOOST one-two months post-intervention
- suggested areas of improvement to BOOST
- reported preferences with regards to data sharing arrangements

METHODS

Study design

A pragmatic trial engaging cataract surgeons practicing within surgical centres across low and middle income countries. Repeated measures design whereby percentage of surgical cases with good outcomes (uncorrected VA >= 6/18) is observed at baseline and then 3-4 months later.

Study participants and sample size

Study participants fall into two key groups: 1) practicing cataract surgeons; and 2) administrators of cataract surgical centres. The primary participant group is cataract surgeons, with each participating surgeon asked to record de-identified surgical outcome data from a sample of their patients over 35 years presenting with a cataract for the first time. Surgeons will need the support of surgical centre managers to take part in the study, and the perspectives of these managers will be sought during the project. The sample size for the study is presented in the table below.

Participant group	Sample Size	Sample size justification
Cataract Surgeons	76-160	Repeated measures design. 80% power at 2-sided alpha=0.05, to detect a 20% improvement in the Main Outcome
Cataract Surgery Managers	76-160	One per study site recruited

Inclusion and exclusion criteria

Surgeons are eligible to participate if they are: a) currently practicing and will continue to practice consistently over the study period (i.e. breaks from practice of no longer than 4 weeks during the study period); b) practice in a low or middle income country; c) perform more than 6 cataract surgeries per week, on average. Sites are eligible if they have one eligible surgeon.

Study sites and recruitment

Cataract surgery centres collaborating with The Fred Hollows Foundation, Orbis International, SightSavers International, Aravind Hospitals, and Seva Foundation will be approached to participate in the study. The key participant target group for the study is practicing cataract surgeons. The following targets have been identified by region, as a guide for recruitment: East Asia/South East Asia/Oceania (n=26); South Asia/Central Asia (n=26); Africa (n=12); Latin America/Caribbbean (n=12).

Sites will be approached and invited to participate by collaborating organisations (i.e. The Fred Hollows Foundation, Orbis International, SightSavers International, Aravind Hospitals, and Seva Foundation). Collaborating organisations have existing relationships with a large number of cataract surgical centres globally and it is through these existing network that sites will be identified. Please find attached, the Letter of Invitation - Site (Attachment A), and BOOST introductory information (Attachment B). Letters of invitation will be followed up with a phone call or email from a member of the research team.

Sites that agree to participate will be asked to recruit one of their cataract surgeons, and identify a service manager/administrator to act as key contact. Please find attached, the Plain Language Statement and Consent Form – Surgeons (Attachment C). The Plain Language Statement and Consent Form will be translated in languages relevant to the target study sites, including: English, French, Spanish and Simplified Chinese. All translations will be independently verified for accuracy.

Procedure and materials

Recording surgical outcome data. Surgeons are asked to use the BOOST app to record their surgical outcome data. They are required in the first instance to download the app onto their mobile phone. Over the course of the six month trial surgeons continue with their routine clinical care and record in the BOOST app, the surgical outcomes of their patients. Surgeons may choose to record the results of all patients during this time, or the minimum of: a) 1-3 day post surgical data for 60 consecutive patients within the first six weeks; b) 1-3 day post surgical data for 60 consecutive patients in the final six weeks; and c) 6-8 week data for 20 patients returning with a poor outcome, during the first 3 months of the trial period. Surgeons provide permissions within the app, for the research team to access the data they enter. *All patient data recorded by surgeons is de-identified and is collected as part of routine care – patients are not asked to provide any additional information and their experience of care is not effected*. We are interested in observing whether the act of recording and considering the results of their surgeries, acts to improve surgeon performance. No patient level intervention is proposed in this study. Please see Attachment D for a list of data collected within BOOST.

Surgeon surveys and interviews. All participating surgeons are asked a series of questions at commencement of the trial. These questions gather demographic information about the surgeons and their current practice with regards to recording surgical outcome data. At the conclusion of the six month trial period surgeons are asked to complete a second survey gathering details of their experience of using BOOST, and changes they made to their surgical practice during the trial. A sample of participating surgeons (n=40) will be invited to participate in a 30 minute telephone interview at the conclusion of the trial, in which they will asked to provide further details relating to these themes. Please see Attachment E for a copy of the survey questions. The interview will explore the same questions posed in the survey, in greater depth.

Service manager surveys and interviews. All surgical services are asked to identify a service manager to act as key contact during the trial period. These service managers will each be asked to complete a survey at commencement of the trial. This survey will gather information regarding the surgical service and context, and routine practice within the service with regards to the collection and use of surgical outcomes data. At the conclusion of the trial period, managers will be asked to complete a second survey gathering details of their experience of BOOST, and observed changes in surgical practice within the service during the trial. A sample of participating managers (n=10) will be invited to participate in a 30min telephone interview at the conclusion of the trial, in which they will be asked to provide further details relating to these themes. Please see Attachment F for a copy of the survey questions. The interview will explore the same questions posed in the survey, in greater depth.

Statistical analysis

All of the primary and secondary outcomes are measured at the surgeon and service level. Surgeon performance is measured using percentage of surgical cases with good outcomes (uncorrected VA >= 6/18), at time 1 and time 2. McNemar's test will be used to examine differences in proportions of good (VA ≥ 6/18) and poor (VA ≤ 6/60) outcomes between the first and second rounds of data collection for each surgeon. For users who complete more than two rounds within the study, bivariate logistic regression will be used to test the correlation between length of use and outcomes improvement. Descriptive statistics will be performed to describe changes in data collection and surgical practice as a result of using BOOST, supplemented by thematic analysis of qualitative data to understand the nature, degree and contributors of any reported changes.

Project timetable and responsibilities

Key members of the research team are noted within the following text by their initials as follows:

- Principal Investigator - Prof Nathan Congdon (NC) - QUB
- Co-Investigator - Dr Sarity Dodson (SD) – The Fred Hollows Foundation
- Co-Investigator – Ms Elise Moo (EM) – The Fred Hollows Foundation

- Project statistician – to be advised

The project advisory group – representatives from collaborating organisations (The Fred Hollows Foundation, Orbis International, SightSavers International, Aravind Hospitals, and Seva Foundation) will form the project advisory group.

Service and surgeon recruitment, and commencement survey - Oct to Dec 2018. Sites will be approached and invited to participate by collaborating organisations (i.e. The Fred Hollows Foundation, Orbis International, SightSavers International, Aravind Hospitals, and Seva Foundation). Key contacts from collaborating organisations will send a Letter of Invitation to potential sites, and a member of the research team (EM) will follow up with potential participants by phone or email to ascertain interest in participanting in the study and obtain the consent of service managers. Service managers will supply contact details of potential surgeon participants who will then be approached by email by a member of the research team (EM) and consent obtained. Following receipt of consent from service managers and surgeons, the brief commencement survey will provided for them to complete and return.

Recording surgical outcome data – Nov 2018 to June 2019. Surgeons will record their surgical outcome data using the BOOST app over a 3 to 6 period (depending on volume of surgeries performed). A member of the research team (EM) will act as key contact for any queries from surgeons or service managers over this period. Technical issues will be managed from here by the project's IT support team, clinical questions will be responded to by the project lead (an ophthalmologist; NC), and data management questions will be responded to by co-investigator SD. Engagement in data collection activities will be monitored routinely by the research team and surgeons contacted if issues are detected. Reported issues will be logged by a member of the research team (EM). Surgeons will be supported to withdraw their participation if they express a desire to do so.

Final surveys and interviews – March to June 2019. At the conclusion of the six month trial period surgeons will be asked to complete a second survey. A member of the research team (EM) will contact them with this survey, and to invite their participation in an additional interview. Once all surgeons from a site have completed their survey, service managers will be approached for survey. Interviews will be conducted by EM and SD.

Data analysis and report preparation – July to Aug 2019. The project database will be managed during the data collection period by EM, with oversight from SD and NC. The project statistician (tba) will undertake data cleaning and analysis. The report will be prepared with input from all members of the research team.

Data protection

The data will be collected in electronic (either via BOOST app and/or via Survey Monkey questionnaire) and then entered into a password protected spread sheet. Patient information will be de-identified. Surgeon and service manager data will be re-identifiable to allow information to be contrasted between time 1 and time 2, for the purposes of surgeon interviews, and to allow surgeons and sites to withdraw from the study if they choose. Consent on the behalf of surgeons to participate in an interview at the conclusion of the study will include consent allowing the interviewer to access aggregated surgical outcome data (i.e. not patient level data).

Electronic records of surgeon level data required for analysis (i.e. not patient level data) will be password protected and stored on both The Fred Hollows Foundation and QUB secure servers. Data will remain re-identifiable until after publication of the results (expected in late 2019), after which the data will be de-identified. Data will be retained at QUB for 5 years before being destroyed.

Study Funding Details

Funder: Standard Chartered Bank (SCB), Seeing is Believing Innovation – Scale-Up Funding; awarded June 2018
Funding amount: USD: $61,567; **In-Kind Support:** approx. USD: $50,000 from the BOOST project team

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