

# **A Randomized Controlled Trial of Low-Cost Model Eyes for Cataract Surgical Training of Rural Chinese Ophthalmologists: The China OLIMPICS (Ophthalmic Learning & Improvement Initiative in Cataract Surgery) Trial**

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This protocol describes the China-OLIMPICS\* Trial, and provides information about procedures for selecting participants and the training involved.

The protocol should not be used as a replacement curriculum for current surgical training.

Questions relating to this educational-intervention study should be referred, in the first instance, to the primary investigators: Dr Will Dean, Profs Wang Ningli, Nathan Congdon, & Matthew Burton.

This trial will adhere to the principles outlined in the guidelines and protocol of the International Conference on Harmonisation Good Clinical Practice (ICH GCP) and all applicable local and training programme regulations.

*\*Ophthalmic learning & improvement initiative in cataract surgery*

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## Glossary of Abbreviations

BOOST	Better Operative Outcomes Software Tool
CF	Counting fingers
COS	Chinese Ophthalmic Society
CPD	Continuing professional development
CSR	Cataract surgical rate
FRCOphth	Fellow of the Royal College of Ophthalmologists (UK)
GCP	Good Clinical Practice
IAPB	International Agency for the Prevention of Blindness
ICEH	International Centre for Eye Health
ICC	Intraclass correlation coefficient
ICO	International Council of Ophthalmology
ITT	Intention-to-treat
LSHTM	London School of Hygiene & Tropical Medicine
LOCS	Lens opacities classification system
LMIC	Low & middle income countries
MD	Medical Doctor
MEd	Masters in Education
MOH	Ministry of Health
MOU	Memorandum of Understanding
MPH	Masters in Public Health
NEI	National Eye Institute
NY	New York
OLIMPICS	Ophthalmic Learning & Improvement Initiative in Cataract Surgery
OSCAR	Ophthalmology Surgical Competency Assessment Rubric
OSSCAR	Ophthalmic Simulated Surgical Competency Assessment Rubric
PCR	Posterior capsule rupture
PI	Principal investigator
POD	Post-operative Day
QUB	Queen's University Belfast
PRECOG	Prospective Review of Early Cataract Outcomes and Grading Study
RCT	Randomised controlled trial
SDP	Sustained deliberate practice
SICS	Small-incision cataract surgery
SOS	Simulated ocular surgery
STEER	Orbis/Chinese Ophthalmic Society Rural Training Program
TREE	Translational Research for Equitable Eyecare
UK	United Kingdom
USA	United States of America
VA	Visual acuity
VFQ	Visual Functioning Questionnaire
VL	Vitreous loss
WHO	World Health Organisation

## Keywords

Simulation, Surgical Education, Training, China, Cataract, Ophthalmic, Randomized Trial, Model Eye

## General Information

### Project Title

A Randomized Trial of Low-Cost Model Eyes for Cataract Surgical Training of Rural Chinese Ophthalmologists: The China OLIMPICS (Ophthalmic Learning & Improvement Initiative in Cataract Surgery) Trial

### Identifying numbers

Beijing Tongren Hospital Research Ethics Committee: **TRECKY2017-046**

Queen's University Belfast Research Ethic Committee:

London School of Hygiene & Tropical Medicine:

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Sichuan Provincial People's Hospital, Chengdu, Sichuan, China

Jinan Hospital, Jinan, Shandong, China

Hebei Provincial Eye Hospital, Hebei, China

### Study Sponsor

Queen's University Belfast is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Governance, Ethics & Integrity Team, Queens University, University Road, Belfast, BT7 1NN, Northern Ireland, UK

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### Study Funders

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## Executive Summary

The leading cause of blindness in China and the world more generally is un-operated cataract. Despite notable efforts on the part of the Chinese government, China's cataract surgical rate (1400/million/year in 2015) remains lower than that of many of its poorer neighbours, such as India (6500)<sup>1</sup> and Vietnam (2250)<sup>2</sup>. An important reason is the unavailability of trained surgeons. Although China has over 36,000 ophthalmologists, only a third are capable of performing independent cataract surgery. This shortfall is due in large part to a lack of hands-on training opportunities. For instance, a recent survey of residents at China's top-ranked resident training programs found that the median number of independent cataract surgeries performed was actually zero.<sup>3</sup> The problem persists after formal training is completed and looks set to worsen as experienced surgeons retire: in recent years, <5% of cataract surgeries were performed by doctors aged 24-43 years. The problem is particularly acute in rural areas, where hands-on training opportunities for young ophthalmic surgeons are even rarer. One reason is safety concerns on the part of patients and senior doctors in entrusting operations to young surgeons.

New training models for cataract surgery are needed which can safely and efficiently support trainees during the transition from novice to competent surgeon. Simulation-based surgical training, using high-fidelity, inexpensive, re-usable model eyes have been successfully piloted. We now propose to study these in a randomized trial comparing a programme that combines training using these model eyes and training using traditional techniques versus traditional training alone, to assess the impact on quality of surgery (assessed by masked grading of videos using the ICO OSCAR system), visual acuity and cost-utility outcomes. We hypothesize that the hands-on training with the model eyes will be a valuable addition to the more didactic standard training.

The costs of our research will be minimised by piggybacking on an on-going collaborative program between Orbis International, the Chinese Ministry of Health (MOH), Chinese National Blindness Prevention Committee and Tongren Hospital (one of China's largest and best-respected eye hospitals), which will train 120 rural cataract surgeons at 60 county hospitals in 6 provinces. Our collaboration involves internationally-respected vision research teams at ICEH, Queen's University Belfast and Tongren; while offering opportunities for scale-up and engagement with Chinese policy makers at the highest level. This collaboration provides an excellent setting to assess whether model eye training can contribute to standard surgical training.

A successful trial proving the training benefits of inexpensive model eyes will make a unique contribution to building the capacity to manage China's leading cause of blindness, thus furthering the aims of SightFirst and the Chinese MOH, while improving the lives of Chinese people dwelling in low-resource areas.

## Background Literature Review

Some 90% of preventable blindness occurs in the developing world,<sup>4</sup> and with the aging of populations globally, there is a rapidly increasing demand for well-trained ophthalmic personnel. Data from the International Council of Ophthalmology (ICO) reveal a shortage of ophthalmologists, with a shortfall predicted in both low income and developed areas.<sup>5</sup>

China accounts for 18% of the world's blind, with an estimated 5 million people who have lost the ability to self-care, half of them due to un-operated cataract.<sup>6,7</sup> The Chinese Ministry of Health has made it a priority to tackle preventable blindness nationally, but the estimated number of cataract operations performed annually (360,000) falls short of the number of people becoming blind each year from cataract (400,000).<sup>6</sup> The cataract surgical rate (CSR) is the number of cataract operations per million population per year. China's cataract surgical rate of 1400 is far lower than that of India (6500)<sup>1</sup> and Vietnam (2250),<sup>2</sup> both of whom have lower per capita incomes.<sup>8</sup>

In addition to the lack of access to affordable rural eye care<sup>9</sup> and the aging Chinese population,<sup>10</sup> an important cause of China's cataract problem is the lack of qualified ophthalmologists. Fewer than one third of the estimated 36,000 ophthalmologists in China perform cataract surgery,<sup>11</sup> most concentrated in urban settings. Surgical quality among those who do operate is not always optimal, especially in rural areas.<sup>12</sup>

The lack of hands-on training opportunities is an important barrier to achieving the Chinese government's goal of increasing cataract surgical capacity. A recent survey of residents at top-ranked training programs in China and Hong Kong found that the median number of cataract procedures performed during residency by Chinese trainees was 0 (compared to 100 for Hong Kong)<sup>3</sup>; falling well below mandated training minimums for other countries, such as 80-90 for Singapore and the United States and 350 for the United Kingdom. This problem of inadequate training opportunities persists after formal residency training is completed: in recent years, doctors aged 24-43 years performed <5% of operations across several specialities including ophthalmology, with two-thirds to three-quarters done by doctors over 50 years of age.<sup>13</sup> The need to train a new cadre of young eye surgeons is particularly compelling in view of the fact that doctors at most of China's largest hospitals are civil servants, with a mandatory retirement age of 60. The problem has been ascribed in part to the unwillingness of senior physicians to accept responsibility for complications caused by junior surgeons.<sup>13</sup>

Alternative training models that can safely build capacity among younger cataract surgeons are sorely needed. The problem is particularly profound in underserved rural areas. The Chinese Ministry of Health and Chinese Ophthalmic Society (COS) recently invited Orbis International to collaborate with Tongren Hospital, one of China's leading training centres, to carry out a project establishing a training curriculum for rural surgeons, which will include cataract surgical training for 120 rural doctors at 60 county hospitals in 6 provinces. Because of the opportunities it offers for scale-up and engagement with policy makers at the highest level, this Orbis-COS project has been chosen as the platform for the proposed research.

### Cataract Surgery

The procedure of sutureless scleral-tunnel small-incision cataract surgery (SICS) is one of the most commonly performed cataract surgery procedure in China, and is a main standard of care. The technique uses a smaller wound compared to the older technique of sutured extra-capsular cataract extraction. There is less post-operative astigmatism, and fewer suture-related problems for SICS. The clinical outcomes of phacoemulsification cataract surgery and sutureless extra-capsular manual SICS are comparable.<sup>14-17</sup> SICS is an appropriate, safe, and affordable technique.

The primary outcome of cataract surgery is an improvement in visual acuity (VA). This can be measured without refractive correction (unaided), or with spectacle correction (best-corrected). It can be measured for distance (usually 6 metres) or near (usually 30cm). It is often very difficult, unrealistic, and expensive to measure post-operative visual acuity a few weeks after cataract surgery in rural LMIC settings due to the logistics of bringing the patient back to the hospital. Furthermore, there is evidence that day-one post-operative VA is a very good predictor of final VA.<sup>18</sup> It is critical for surgeons to collect and analyse their own cataract surgical outcomes, as there is clear evidence that such monitoring and personal reflection improves surgical quality and outcomes.<sup>19</sup> Tools for monitoring the outcomes and quality of cataract surgery have been developed, including post-operative VA, surgical complications,<sup>20</sup> and the ICO OSCAR (Ophthalmology Surgical Competency Assessment Rubric).<sup>21 22</sup>

Complication rates vary for cataract surgery, depending on co-morbidity, the experience of the surgeon, the maturity of the cataract, and the technique used. Rates of complications (posterior capsule rupture (PCR) or vitreous loss (VL)) vary from 1.92% to 6%.<sup>15 16 23</sup> The WHO recommends aiming for a complication rate (PCR rate) of <5%.

## Surgical Education and Simulation

It is of course of benefit to patients, trainees and trainers if simulation in surgical training offers and enables an accessible, safe, and reproducible method of learning surgical skills and procedures outside of the stress of the operating theatre. However, despite these explicit and implicit benefits, and the great enthusiasm surrounding simulation in surgical and certainly ophthalmic surgical training, a question remains: are the skills obtained transferable to theatre? Simply put, does practicing eye surgery on a simulator only make a trainee better at operating on a simulator, or does it make him/her better in the live-surgical setting too? This 'predictive validity', being the transfer of skills learnt in a simulation environment to live surgery, is challenging to measure.

Intensive simulation-based surgical education has been shown to rapidly increase surgical skills, decrease complication rates, provide a safe and relaxed environment to learn in, and enable sustained deliberate practice.<sup>24</sup> However, this has not yet been demonstrated for ophthalmic surgical training in the context of a randomised trial.<sup>25</sup>

Artificial eyes made from plastic and other synthetic materials have been used and developed over the past decade for ophthalmic simulated training. In the UK, Phillips Studio in Bristol have developed artificial eyes for use in training in a number of ophthalmic surgical procedures, including SICS and trabeculectomy.<sup>26</sup> 'Kitaro DryLab' is a tool to teach and learn some steps of cataract surgery, including the capsulorrhexis. It is portable, and can be used

on a desktop, and without the need for an operating microscope (Frontier Vision Co. Ltd., Hyogo, Japan).

In a major systematic review, a team from Denmark screened over a thousand papers, and studied 118 trials involving simulation-based training or assessment of ophthalmic surgical skills among health professionals.<sup>25</sup> They concluded that “using simulation models without knowledge of reliability, validity and efficacy may compromise patient safety, especially if the trained skills do not correlate with the skills needed for real-life performance”. Through the use of state-of-the art frameworks for assessing the quality of trials, including a modern unified framework consisting of five sources of validity and a four-level assessment of the efficacy of simulation training programmes, they found the overall evidence for the use of simulation-based training or assessment in ophthalmology to be poor. Only two of the trials investigated transfer of skills into the operating theatre, and only four evaluated the effect of simulation-based training on clinically-relevant outcomes. More rigorous educational research investigating the validity, reliability and efficacy of simulation-based ophthalmic surgical training is needed.

## Rationale

The leading cause of blindness in China and the world generally is un-operated cataract. Despite notable efforts on the part of the Chinese government, China’s cataract surgical rate (1400/million/year in 2015) remains behind that of many of its poorer neighbours. An important reason is the unavailability of a large enough number of trained surgeons. A recent survey of residents at China’s top-ranked resident training programs found that the median number of independent cataract surgeries performed was zero.<sup>3</sup>

Therefore, the huge need for eye surgery requires effective and efficient methods to meet the need to train eye surgeons. One way to achieve this might be through simulation-based surgical education, which has been shown to rapidly increase the rate of learning of surgical skills, decrease complication rates, and provide a safe and calm environment to learn in.<sup>24</sup> However, this has not yet been robustly tested or proven for ophthalmology surgical training.<sup>25</sup>

## Project aims

The aim of the proposed project is to provide an evidence base for a novel approach to cataract surgical training at the county-hospital level in China: the use of low-cost, high-fidelity model eyes. Thus, project aims are very tightly aligned with key SightFirst priorities in China: improving cataract surgical capacity, developing new training models and strengthening county-level facilities.

## Objectives

This study will assess whether the addition of simulation-based ophthalmic surgical education using bespoke artificial eyes is superior to standard conventional training alone; with regard to the initial acquisition of surgical competence, and surgery-specific outcomes (post-operative visual acuity). The outcomes will include measures of both surgical competence and surgical quality.

The overall purpose of this research is to develop the evidence base to guide efficient, high-quality skills development in ophthalmic surgical training in China, which can then be scaled-up to include other regions. The evidence base to be developed could inform the planning and implementation of ophthalmology surgical training programmes globally.

## Methodology

**Study Design:** Randomized controlled trial of an educational intervention.

**Study Population:** Cataract surgical trainees learning to perform small-incision cataract surgery (SICS) in the Orbis/Chinese Ophthalmic Society Rural Training Program (STEER). (This is a currently funded Orbis project, thus reducing the costs for this randomised trial.)

**Partners:** Orbis International and Queen's University Belfast (Congdon is affiliated with both); Tongren Hospital and the Chinese National Committee for the Prevention of Blindness (Wang heads both); and International Centre for Eye Health at the London School of Hygiene & Tropical Medicine (Dean, Burton)

**Sample Size Calculations:** Based on OSCAR (ophthalmology surgical competency assessment rubric) scores for different surgical steps among SICS trainees at Aravind, India: 14 doctors in each of two groups operating on 10 patients each (total 280 surgeries) would allow for detection of a difference in mean OSCAR scores (across all steps) of 1.0 (point per set) between groups with a power of 0.9, alpha-error of 0.05, a standard deviation of 1.0 for scores, and an ICC of 0.57 for scores across cases within surgeon. The ICC value comes from our review of SICS cataract surgical training assessed using OSCAR in other Orbis training programs. (As this main outcome will be captured during surgery, there is no need to inflate our required sample size estimate to allow for loss to follow-up).

A total of 34 participants has been selected, to allow for a 15% attrition rate.

ICO-OSCAR scores cover 19 categories, with each category score ranging 0 to 5, and therefore with an overall 0 to 95. An example of a 1.0 point difference within the category, "Conjunctival and Corneal Tissue Handling" is for a Competent score (score = 5) the "tissue is not damaged nor at risk by handling," while for an Advanced Beginner score (score = 4), "tissue handling decent but potential for damage exists."

### Surgeon Inclusion Criteria:

- <20 complete SICS cases performed lifetime
- 25-50 years of age
- Completed ophthalmic training
- Will have opportunity to carry out independent SICS surgery after training

### Surgeon Exclusion Criteria:

- Already capable of performing independent intra-ocular surgery of any kind
- No opportunity to perform cataract surgery after training
- Unwillingness to discuss surgical training with colleague from other randomised group

### Patient Enrolment Criteria:

- Cataract in one or both eyes felt to be visually significant in the opinion of the patient and operating ophthalmologist.

### Patient Exclusion Criteria:

- Fellow eye has an irreversible cause of visual impairment
- Any prior ophthalmic surgery in the proposed operative eye
- Any co-morbid condition in the operative eye likely to impact post-operative visual acuity negatively (conditions only detected on post-operative examination would also lead to retrospective exclusion)

**Intervention:** Standard surgical training (as described below for “Control”) plus a new, bespoke simulation-based training scheme using low cost, reusable model eyes combined with practical surgical exercises, developed in Africa by ICEH collaborator Dean. *See page 17.*

**Control:** Standard surgical training (without the bespoke training scheme that uses simulation and model eyes) in the ORBIS-COS administrated STEER project, mentioned above. Trainees complete 2-4 weeks of didactic lectures, surgical observation, and wet-lab training at a provincial training centre with a minimum of 50 pig eye wet-lab simulations per trainee. After observed mastery of wet-lab pig eyes, trainees then perform hands-on training in County level hospitals. The hands-on training pairs a surgeon from the training centre who travels to the county level hospital to mentor the trainee through a minimum of 30 assisted surgeries, and 50 ‘independent’ surgeries under supervision. This project and its cataract surgical training protocol have been approved by the Chinese National Blindness Prevention Committee, who are essential partners.

### Outcomes

**Main outcome:** Mean video grade of the first 10 successive supervised or assisted SICS cases (with patient consent) for each surgeon, using ICO-OSCAR. Two approaches to determine mean video grade will be employed to account for the variation in the number of surgical steps performed by trainees. Variation either arises from individual competence, with the assumption that more competent surgeons are given a larger role during surgery, or from the teaching style of different mentors, with an emphasis on conservative training.

Both approaches are equally significant for determining the main outcome, and differ solely in the number of steps graded.

- Mean video grade across all surgical steps of the first 10 successive supervised or assisted SICS cases (with patient consent) for each trainee surgeon, using ICO-OSCAR. This approach penalizes surgeons for executing less steps, assigning a score of 0 for steps not performed.
- Mean video grade across all trainee-completed steps of the first 10 successive supervised or assisted SICS cases (with patient consent) for each trainee surgeon, using ICO-OSCAR. This approach scores surgeons only on surgical steps they performed in consideration of the variation in mentors’ teaching styles.

The graders are masked to surgeon/patient identity, using a file-sharing platform to transfer videos to graders and collate grading information.<sup>21 22 27</sup> These 10 cases will be the first 10 out of 30 cases completed under the supervision of the STEER trainee.

#### Secondary outcomes:

- Mean presenting logMAR visual acuity on post-operative day (POD) 1 of ten successive cases with patient consent per surgeon (measured using the BOOST [Better Operative Outcome Software Tool] application.<sup>28</sup>
- Mean improvement in lines of visual acuity in operative eye at POD 1.
- Cost per trainee in each group.

#### Informed Consent

Potential participant trainees will be informed of the training opportunity and this research study. Heads of Training Centres will be involved in the process and are co-investigators in the trial.

Surgeon participants will be informed in detail about the nature of the education-intervention study; all surgeons participating will be free to leave the study at any time. See Appendix 1a and 1b for detailed Information and Consent Forms. Surgeons who decline to take part in the study will be offered the standard STEER surgical training package without the bespoke training scheme that uses simulation and model eyes. Each participant eye surgeon attending the 2 to 4-week training and involved in this educational-intervention research will be invited to read and sign a consent form (Appendix 1).

Patient participants will be informed that the outcomes of their surgery will be recorded as per normal good clinical practice and standard care. Informed consent to video record their surgery will be obtained. A standard consent form (Appendix 4), similar to local consent forms that indicates permission to use standard clinical photography will be used. This form will indicate that, as part of an educational randomised control trial, some surgeons received additional training. This form will be read to patients in Chinese, if they are unable to read it; and they will be invited to sign. The individual seeking consent should not know which randomisation group the surgeon is in.

#### Participant Withdrawal

Surgeon participants, in either the 'intervention' or 'control' group, are free to leave the study at any time. If this is the case for any participant, no effort will be made to recover any costs incurred or equipment provided. Data collected up to the point of withdrawal of consent will have been anonymised and securely stored, and will still be held and included in data analysis.

#### Randomisation

##### Pre-randomisation baseline assessment

Following consent, participant surgeons will be evaluated. This will include evaluation of previous surgical experience, and introduction to the ICO OSCAR.<sup>29</sup> They will then be assessed



using the baseline Simulation-OSSCAR (see Appendices 3a and 3b). This will involve three simulation procedures (these will be recorded, anonymised, and remotely assessed using the Simulation-OSSCAR). This provides the baseline score for all participants: intervention and control.

#### Randomisation (stratified blocked randomization):

Participants who have reached the appropriate inclusion and exclusion criteria for the trial will be eligible for randomisation to 'intervention' or 'control'.

Eligible trainees completing baseline data collection will be enrolled into the study and stratified into 10 groups\* according to their training center and hospitals (home facilities). The hospitals with only one participant are combined to form a mixed group. Participants in each of the 10 stratified groups will be assigned at random to one of the study arms as shown in the following figure.

An independent statistician having no contact with participants will generate the randomization sequences (lists) using a computer system that is inaccessible until after recruitment. The random sequence includes three types: (1) A list of the mixed hospitals with only one participant; (2) A number of lists of the hospital with paired participants (3) Individual list(s) of the hospitals with more than two participants. Each random sequence comprises of sequence numbers and their corresponding codes (e.g. two letters plus a 4-digit number). Codes are used to represent the Intervention or Control group; a codebook is created for decoding the group allocations.

To preserve allocation concealment, a two-step procedure will be used for random allocation in each training center.

**Step 1:** Project manager (PM) sends randomization sequences to the Quality Control officer (QCO). QCO assigns a code to each participant from the randomization sequences. QCO update the random lists with participant's names and send it to PM. At the end of this step, neither the QCO or participants know what group the codes refer to.

**Step 2:** As soon as receiving result file from QCO, PM checks the codebook, update the file with participant's names and send it back to QCO. QCO allocates the participants into control and intervention groups and completes the random allocation.

The participants will know their group assignment. However, the staff(s) grading video recordings of assessments will be masked by having a randomized number assigned to each video.

## Baseline data:

- Patient
  - Age/Sex
  - Baseline uncorrected and best-corrected visual acuity in operative eye
  - LOCS III cataract grade
  - Result of full ocular examination including test for afferent pupillary defect and intra-ocular pressure, with subsequent dilation of the pupil and B-scan in the event of inadequate visualization of the fundus
  
- Physician
  - Age/Sex
  - Presenting and best-corrected visual acuity in both eyes (near and distance)
  - Years of ophthalmic practice
  - Previous number of independent cataract surgeries performed (SICS and total)
  - Mean video grade across all steps on 3 successive SICS cases using ICO OSSCAR (Grader masked to surgeon/patient identity)

## The Intervention

All participants in both intervention and control groups will undertake the 2-4 week Orbis-COS STEER training course. This course will consist of didactic training, observation as well as a minimum of:

- 1) wet lab training with 50 pig eyes
- 2) assisting 30 surgeries, finishing one of more steps of the procedure, and
- 3) 50 independent operations under supervision.

Participants in the intervention group will be introduced to a variety of simulation-based surgical training techniques over 2 to 4 weeks. This additional training will involve a total of approximately 16 hours of video-based presentations, practical SICS procedures on model eyes, trainee feedback, and self-assessment of surgical performance using the simulation-OSSCAR scoring system. Specifically, this will involve breaking down the SICS cataract surgery procedure into stages. At each stage surgeons will be presented background knowledge and then practice that stage repeatedly using simulation. This sustained deliberate practice will be an enhancement to the STEER course, and not as a replacement of any part of the educational content. Within the first week of the course, 'intervention' arm participants will be introduced to the artificial eyes, practice the cataract surgery procedure using the Simulation-OSSCAR as a learning tool, and be provided with ongoing feedback. (See also Standard Operating Procedures (SOP) 9 through 19 for Model Eye Training).

It is expected that surgeons will independently complete 8 SICS procedures by the end of the training period. The first two simulation SICS procedures on model eyes will be performed under supervision of the consultant trainer. The fourth and eighth SICS procedure will be recorded, uploaded to Cybersight, and assessed by PI Dr Will Dean who will provide feedback to the trainee.

During this time, trainees in the control group are at liberty to spend time as they please.



## China-OLIMPICS Trial Intervention Objectives and Timetable

Week	Knowledge & Understanding <i>[Hosted online at Cybersight]</i>		Skills <i>[Practical skills learning &amp; practice in wet-lab / dry-lab]</i>		Attitudes & Assessment <i>[Online, video-recording, and reflective learning]</i>	
	Aim	Time / [Outcome]	Aim	Time / [Outcome]	Aim	Time / [Outcome]
1	Learning theory & expertise	20 minutes			Reflective learning	20 minutes
	Scleral tunnelling	20 minutes	Scleral tunnel	2 hours <i>[perform 40 tunnels on apples]</i>		
	Capsulotomy.	20 minutes	Capsulotomy	2 hours <i>[perform 20 capsulotomies on tomatoes, and 10 using Kitaro kit]</i>		
	SICS video.	50 minutes			Introduction to SICS ICO-OSCAR	30 minutes
	Simulation SICS video	20 minutes	Initial artificial eye simulation surgery	2 hours <i>[perform 3 full SICS]</i>	Introduction to SICS Simulation-OSSCAR	20 minutes
2			Scleral tunnel	1 hours <i>[perform 30 tunnels on apples]</i>	Audit / Monitoring of outcomes	20 minutes
	Simulation SICS video	20 minutes	Artificial eye simulation surgery	3 hours <i>[perform 5 full SICS]</i>	SICS Simulation-OSSCAR: self-assessment	2 hours

## Follow-up

*Participant Follow-up schedule:*

*Data collected at follow-up in the County Hospital:*

- Surgical recording of ten live SICS procedures (supervised by the trainer).

*Patient Follow-up schedule: Post-op Day 1*

*Data at follow-up:*

- Uncorrected and best-corrected visual acuity in operative eye (post-operative day (POD) 1)
- Ocular examination of operative eye with dilation of pupil to detect any co-morbidity undetected at baseline examination (POD 1)

## Analyses

### Statistical Analysis

- Mean OSCAR grade for 10 consecutive consenting patients for each surgeon, comparing Intervention and Control Groups, with and without adjustment for baseline surgeon and patient factors. Each surgeon will have two mean OSCAR grades, one based off scores on all surgical steps and the other based off scores on trainee-completed steps, and they will be our co-primary outcomes. GEEs (generalised estimating equations) will be used for repeated measures analysis of the OSCAR scores.
- Mean presenting logMAR visual acuity on POD 1 for ten consecutive consenting patients per surgeon, comparing Intervention and Control Groups, with and without adjustment for baseline surgeon and patient factors.
- Mean improvement in lines of visual acuity in operative eye at POD 1, for 10 consecutive consenting patients per surgeon, comparing Intervention and Control Groups, with and without adjustment for baseline surgeon and patient factors.

## Cost Analysis

A cost-utility analysis will be conducted. This will be cost per trainee in each group.

## Prevention of Bias

It is accepted that there will be variability in individual participants' inherent or natural surgical aptitude. In order to attempt to reduce the effects of this, the two groups will be balanced with regard to the baseline OSCAR scores of participants, and their total number of previous surgical cases. This however will only occur in final analysis, and not before randomisation or training.

All efforts will be made to standardise the training offered to the 'Intervention' participants. The intense simulation course will be held in the same Training Centres. The training will be conducted by experienced trainers who have undertaken a specifically designed 'Training the Trainers' course. All recordings of surgical procedures will be performed using the same recording system.

Video recordings of procedures will be allocated a random 7-digit number, and subsequently stored onto an encrypted computer, and a separate encrypted hard drive. This random number will be the only identifiable information available when the simulation/surgical procedure is assessed, thus masking the assessor to the participant's randomised group.

It is recognised that surgical education is complex and multi-faceted. However, every effort will be made to reduce 'contamination' bias. Participants will sign an informed consent form detailing that they will in no way share any of the details of the course or educational intervention with any surgeon who is not known to be in the same randomised group as themselves; for a minimum of six months following the end of the training programme in Tongren.

The PIs and co-investigators declare that they have no financial or other conflicts of interest that are relevant to this randomised trial.

## Potential Harms and Benefits of the Study

### Potential Harms

There are no clinical harms from the study protocol itself, as all the intervention training is using simulation. No patients are involved in any of the training in the intervention group and training in the control group is using standard methods as described above, approved by the Chinese National Blindness Prevention Committee. Patients are involved only as part of regulated and accredited post-graduate clinical and surgical practice within the collaborating tertiary training institutions and County level hospitals, and will undergo a separate, standard surgical informed consent process for any potential harms that might arise from their operations. Operations taking place in the STEER project are part of this

previously-approved service delivery project, and as such are not being done as part of the OLIMPICS research protocol.

With regard to risk of failure of the trial, these include the below possibilities:

- Trainees not being available for enrolment
- No patients being available in hospital
- No or very few patients being enrolled for video assessments

#### Potential Benefits

##### *Benefits to the study participants*

The surgeon participants in both groups (intervention and control) of the randomised trial will receive the Orbis-COS training course. Surgeons who decline to take part in the study will be offered the standard surgical training package without the bespoke training scheme that uses simulation and model eyes.

Participants in the intervention group will also receive simulation-based surgical training. This is not designed to replace any standard training, but to augment it.

An important element of 'training-the-trainers' is included in the study. After the start of the study, trainers from collaborating institutions will be invited to a Training-the-Trainers course, which would benefit them as Surgeon Educators.

##### *General benefits*

The results of a successful trial would have major implications in augmenting and streamlining ophthalmic surgical education, and potentially changing the way ophthalmologists approach initial surgical training. Additionally, this study could reduce patient complications while the trainee eye surgeon moves from 'novice' to 'competent'.

Finally, the evidence provided from this study could influence investment in surgical training units throughout China, and beyond.

## Training Timetable

The GANTT chart below illustrates major milestones and deliverables.



## Project Management

### Study Management

Overall study management responsibility lies with the Principal Investigator. Three monthly Project Update Reports will be circulated to co-investigators. Six monthly reports will be sent to the major funder.

### Trial Steering Committee

The members of the Trial Steering Committee include:

Prof Wang Ningli, COS  
Prof Nathan Congdon, QUB, Orbis  
Dr William Dean, ICEH, LSHTM  
Christopher Magoon  
Prof Hu Ailian, Director China NCPB  
Dr Peter Xu  
Prof Mathew Burton, ICEH, LSHTM  
Dr Wen Qing  
Dr Tang Jianjun  
Prof Ciaran O'Neill  
Prof Mike Clarke  
Catherine Jan

### Department resources, collaborators & contractual arrangements

Orbis International has already entered into a Memorandum of Understanding (MOU) with Beijing Tongren Hospital and the National PBL Committee to support their Rural Eye Health Team Training Program. Queen's University Belfast (QUB) has also completed an MOU with Tongren over on-going research collaborations between Congdon and Wang. These existing relationships, and the various collaborations between Orbis and QUB arising from Congdon's being employed by both organizations, will form the basis for the three-way contractual agreement (Orbis-Tongren-QUB) supporting the current study. Resources of the main project partners are outlined below.

**Orbis International:** ORBIS International has worked in China since 1982, carrying out over 200 projects in 25 regions, which have trained tens of thousands of health care workers and provided hundreds of thousands of sight-saving surgeries. Orbis' particular strength in China lies in the area of surgical instruction, and the current study will capitalize on Orbis' rural surgical training program in collaboration with Tongren and the National PBL Committee, which will equip 120 rural surgeons to perform independent cataract surgery. The project will also benefit from Orbis' unique CyberSight training platform, which will allow surgeries to be



recorded by trainees and graded in masked fashion by experienced surgeons using existing Chinese-language software provided by Orbis.

**Beijing Tongren Hospital:** Tongren is China's leading clinical and research facility in the area of eyecare. Tongren will provide a PhD student under Congdon and Wang's joint supervision to oversee quality control and adherence to the trial protocol in the project, and will also offer support for data entry. A statistician at Tongren will be supervised by Dr Wen Qing at QUB (see below) as part of building local capacity in clinical trials.

**Queen's University Belfast:** Congdon is the Director of Translational Research for Equitable Eyecare (TREE) at QUB, a leading global eye health research centre. This centre includes six senior researchers in eye health, and a staff of statisticians, health economists and program managers fluent in Chinese to support projects in China such as the proposed research. QUB will offer the time of Congdon, statistician Dr Wen Qing and health economist Dr Tang Jianjun in kind to the project. Dr Wen Qing will oversee the randomization, drafting of study forms and protocols and statistical analysis in the project. Dr Tang Jianjun will oversee the health economic analyses (training costs and cost per line of vision gained per patient).

**International Centre for Eye Health (London School of Hygiene and Tropical Medicine):** ICEH is a global leader in research and training for the delivery of high-quality eyecare in low-resource areas. Collaborators Dean and Burton have developed and refined a bespoke training course around low-cost, re-usable, high-fidelity model eyes, which will be the focus of the current research. Their course will have incorporated use of the Orbis CyberSight platform prior to beginning the project in China. Dean will travel to China to supervise translation of the model eye training protocol to a Chinese setting, and provide oversight to the Chinese teams on maintaining quality throughout the training process.

### Project leadership plan (for consortiums)

As PI, Congdon will be responsible for coordination between teams at Orbis, QUB, Tongren and ICEH, and will also supervise the Chinese-speaking statistician Dr Wen Qing at QUB. Wang will be the lead investigator on the Chinese side, co-supervising the Tongren PhD student and statistician responsible for the project. The Orbis China team, led by Dr Peter Xu, will assist in coordinating the research with the existing Orbis-Tongren rural training project. Burton will coordinate work on the model eye training program at ICEH and its translation to the Chinese context.

### Research PI team professional history/biography

*Congdon*, the Ulverscroft Chair at QUB, Professor at Zhongshan Ophthalmic Center in China and Director of Research at Orbis, is an international leader in global eye health research, with over 175 publications in journals including JAMA, BMJ and Lancet Global Health, and an h-index of 35. He has received honours including a Chinese government Thousand Man Plan Award (one of very few non-Chinese recipients) and the Holmes Lecture, one of Asia's highest blindness prevention awards. Congdon has been funded by WHO, World Bank, EC, MRC, the US NIH, USAID and Chinese and Hong Kong governments. His fluency in written and spoken

Chinese, 10-year history of collaboration with Wang, and key roles at both Orbis and QUB will help to cement collaboration in the project.

*Wang*, President of China's top-ranked hospital Beijing Tongren, is the acknowledged leader in public health ophthalmology in China. He has published over 220 SCI papers, and has been funded by nearly every Chinese government health research scheme. He designed and directed the Handan Eye Survey, still the standard reference for understanding blinding disease in rural China, which has led to over 40 publications. Wang is arguably the most influential ophthalmologist in China, as past president of the Chinese Ophthalmic Society and head of the National Blindness Prevention Committee. He has worked closely with Congdon and Orbis since 2006.

*Dean*, a UK-trained ophthalmologist, has extensive surgical and training experience in the UK and in low and middle-income countries, having performed over 7000 cataract operations in Africa, the majority of them SICS. He has a Masters in Surgical Education (MEd) degree from Imperial College London, and is a current recipient of the Barry Jones Fellowship funded by the British Council for the Prevention of Blindness, to complete a PhD in simulation-based cataract and glaucoma surgical education in low-income settings in Africa. He led the development, piloting and refining of the simulation-based SICS training course and model eyes used in this current proposed study. His PhD supervisor is Prof *Burton* of ICEH/LSHTM, a leading researcher in alternative service delivery models to promote eye health in low income settings.

## Ethical Considerations

### Ethical Approval

Approval will be sought from ethics committees at Queen's University Belfast and Beijing Tongren Hospital, and Capitol Medical University. It is estimated that the approval process will require 2 months at Tongren and 3 months at QUB. This will be completed in parallel with other preparatory work, including finalization and on-line registration of the trial protocol, and preparation of study forms, and, therefore, will not delay the start of the trial.

### Patient and Surgeon Informed Consent

See above section on "Informed Consent"

### Patient Privacy

Patient participants will be informed that the outcomes of their surgery will be recorded as per normal good clinical practice and standard care. Informed consent to video record their surgery will be obtained. The surgery will be anonymised, and no patient identifiable information will be kept. Patients have the right to refuse consent for video recording, and this in no way will affect their treatment or surgery plan. Photographs or videos of patients are often a part of clinical practice, teaching, telemedicine, or research. Patients will be invited to sign a standard consent form (Appendix 4).

## Participant Information

Each participant eye surgeon attending the six-week training and involved in this educational-intervention research will be invited to read and sign a consent form (Appendix 1). There is no fee for the course and all educational materials are given free of charge.

Participant trainees should understand that the course is for their personal educational benefit, and they give permission for anonymised data from the study to be published in peer-reviewed literature as part of broader research into surgical training techniques.

**No personal identifiable information** will be included at any stage.

Interviews, opinions, video recordings of assessments, and surgical outcome data of the education and training will only be used for academic purposes.

The training is as a boost to ‘standard training’, and not a replacement: none of the results of this study of training will form a part of the participants’ professional records.

Surgeon participants are free to leave the study at any time. If this is the case for any participant, no effort will be made to recover any costs incurred or equipment provided.

Trainee participants in the Control group will be offered exactly the same six-week training course as the Intervention group, only without the use of simulation practice with model artificial eyes.

Patients with cataract are indirectly involved in this study. However, cataract surgery conducted in this study by all participants (in both the intervention and control groups) is part of standard and regulated good clinical practice; and supervised by qualified and registered senior eye surgeons as per normal practice.

Patient outcome data will be anonymised, no personal patient identifiable information will be made public, and **no personal patient identifiable information will be made available** to any of the Investigators outside of China. Patients operated in both the Intervention and Control groups will be during normal standard training, and thus regulated by the Chinese Medical Board.

The research adheres to the tenets of the Declaration of Helsinki.

## Budget and Justification

Appendix 2 shows the associated budget. The project and training involves consumables and equipment, and other administrative costs (including for ethical approval).

## Dissemination of Results and Publication Policy

Publication will be sought for the main trial report in a high-impact factor journal with an open access policy (relevant examples include BMJ, Lancet Global Health and Investigative Ophthalmology and Visual Science), so as to improve access to researchers and policy-makers in low and middle-income countries.

Co-authorship of submitted and published articles will be evaluated as per internationally agreed research guidelines, such that authorship credit will be based on:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Authors should meet conditions 1, 2, *and* 3.

## Appendices

Appendix 1 Informed Consent Forms and Participant Information Sheets

Appendix 2 Budget

Appendix 3 OSCAR and Simulation-OSSCAR

Appendix 4 Patient Consent to Clinical Photography

## Appendix 1a

## Participant Consent Form

The China OLIMPIC (Ophthalmic Learning & Improvement Initiative in Cataract Surgery) Trial: Randomised Controlled Trial Comparing Intense Simulation-Based Surgical Education for Cataract Surgery to Conventional Training Alone in China.

Beijing Tongren Hospital, PRC

Queens University Belfast, UK

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK

I \_\_\_\_\_  
(name) have been invited to participate in a trial of surgical training, involving a six-week intense training and education course for cataract surgery in \_\_\_\_\_ Hospital, and ongoing assessment for the following 6 months. I understand there is no fee for the course, and all educational materials are given free of charge. I understand that the course is for my personal educational benefit.

Study Reference Number:

Please initial box	
1. I confirm that I have read and understand the participant information sheet dated ..... (version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered fully.	<input type="checkbox"/>
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without training or legal rights being affected.	<input type="checkbox"/>
3. I give my permission for anonymised data from this course to be published in peer-reviewed literature as part of broader research into surgical training techniques, including the placement of an anonymized data set in a data repository.	<input type="checkbox"/>
4. I understand that <b>no personal identifiable information</b> will be included in any published output.	<input type="checkbox"/>
5. I understand that interviews, opinions, or recordings of the education and training will only be used for academic purposes.	<input type="checkbox"/>
6. I understand that no formal feedback will be given to any of my colleagues or surgical supervisors or colleagues.	<input type="checkbox"/>
7. I understand that no data will be made available to work/training institutions or be used for any future job selection.	<input type="checkbox"/>
8. I agree to anonymised video recording and assessment for ten surgeries following the training course.	<input type="checkbox"/>
9. I commit to ensuring that <b>all</b> surgical outcome data for patients operated by myself (supervised or other) for SICS, that these data (day 1 VA and complications of PCR) are captured onto a recording sheet (with no patient identifiable data), and reported for ten cases following the training course.	<input type="checkbox"/>

10. I understand, agree, and wholly commit to NOT discussing or sharing any of the details in any way with colleagues in this study who were allocated to the other trial group for at least six months following the training course.

Signed \_\_\_\_\_ Date:

\_\_\_\_\_

Countersigned by Investigator (Christopher Magoon)

Principal Investigator (China) – Prof Wang Ningli <sup>1</sup>

Principal Investigator (Belfast) – Prof Nathan Congdon MD MPH<sup>2</sup>

Principal Investigator (London) – Dr William H Dean FRCOphth MEd MBChB BSc<sup>3,4</sup>

### Co-Investigators

Christopher Magoon<sup>5</sup>

Dr Peter Xu<sup>6</sup>

Dr Wen Qing

Dr Tang Jianjun

Prof Mathew Burton PhD FRCOphth<sup>3</sup>

Any queries should be directed in the first instance to the Principal Investigator Prof Nathan Congdon: [ncongdon1@gmail.com](mailto:ncongdon1@gmail.com)

Phone: UK +44

China +86

***Please refer to Participant Information Sheet (OLIMPICS Version 1.0)***

## **Appendix 1b Participant Information Sheet – SICS Training**

The China OLIMPIC (Ophthalmic Learning & Improvement Initiative in Cataract Surgery)  
Trial: Randomised Controlled Trial Comparing Intense Simulation-Based Surgical Education  
for Cataract Surgery to Conventional Training Alone in China.

### **Participant Information Sheet (OLIMPICS Version 1.0, 2.28.18)**

Beijing Tongren Hospital, PRC  
Queen's University Belfast, UK  
International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK

Principal Investigator (China) – Prof Wang Ningli  
Principal Investigator (Belfast) – Prof Nathan Congdon MD MPH  
Principal Investigator (London) – Dr William H Dean FRCOphth MEd MBChB BSc

#### **Introduction**

You are being invited to take part in an educational-intervention research study. Before you decide whether or not you will be a participant, it is important for you to understand why this research is being done and what it will involve.

Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

This information sheet is designed to tell you everything you need to think about before you decide whether or not you agree to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the study. The decision to join or not join the study will not cause you to lose any of your usual training opportunities within the ORBIS-COS Training Initiative.

You can take a copy of this information sheet to keep. Do not sign the consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing the consent form, you will not give up any legal rights.

#### **Do you have to take part in this study?**

No. You do not have to take part in this study. Even if you do not take part in this study, you will still be offered exactly the same training as per The Orbis-COS curriculum.

#### **Study Overview**

##### **What is the study about?**

The aim of this study is to investigate whether the addition of simulation-based surgical education improves competence and surgical outcomes. All participants in the study will



receive the educational intervention of the six-week Orbis-COS course. Those allocated to the intervention group will receive this training and an additional element of learning and sustained deliberate practice using model eyes and simulation.

### **Why have you been chosen?**

You are being invited to join the study because you are an ophthalmologist at one of the collaborating County level hospitals, and you may meet all the eligibility criteria.

### **How many people are taking part in this trial?**

We plan to recruit 28 eye surgeons in total: 14 for the intervention training group (with model eyes and simulation) and 14 for the standard (control) training group.

## **Procedures**

### **What will we ask you to do?**

#### ***Baseline assessment:***

We will ask you some basic questions about cataract surgery. We will ask you about your previous surgical experience.

#### ***Randomisation:***

Immediately after baseline assessment, we will randomise you to either the SICS “intervention” training group or the SICS “control” training group. “Randomisation” means that you have an equal chance of being in either group, like flipping a coin.

#### ***Educational Intervention:***

Once you are allocated to one of the groups, you will receive clear instruction on how the timetable will run. If you are allocated to the “Intervention” group, then you will be invited to the STEER Training Centre nearest you for a six-week training course (run by Orbis and the COS). If you are allocated to the “Control” group, then you will also be invited to the same Training Centre for a six-week training course (run by Orbis and the COS).

#### ***Follow-up assessments:***

We will revisit you at your hospital after the training course. We will ask you to video record the performance of ten SICS procedures (which we will anonymise). During the period after the course, we will arrange for you and nurses at your hospital to record and report all of the outcomes of ten consecutive SICS surgeries that you perform in your hospital (in terms of day 1 visual acuity, and incidences of peri-operative complications of posterior capsule rupture), using a smartphone app called BOOST which we will provide for free.

It is critically important to emphasise that you should ***not share any of the learning, lessons, materials or experiences in any way between colleagues who are in a different group to you*** for at least the first six months after all training courses have concluded. If you feel this will not be possible, then please to tell us, and we will work with you to try to make this possible or, if necessary, to exclude you from this study.

### **What is the educational intervention that is being tested?**

The surgical education that is being investigated is intense simulation-based surgical training. This involves practicing with model artificial eyes during the six-weeks training course, and subsequent practice back home. No patients are involved in this additional training. This simulation part of training is not meant to replace standard training, but to augment it. Both intervention and control groups will subsequently conduct recorded surgeries on live patients as part of the standard training.

### **Benefits**

#### **What benefits are there to taking part in the study?**

You will be offered free surgical training course. All this training, and the expenses involved will be provided to you free of charge. No study has been done to investigate the efficacy of simulated ophthalmic surgical education for SICS to this level. You will be helping to resolve uncertainty about its potential benefits.

### **Potential harms**

#### **What are the potential harms of taking part?**

There are very low risks associated with participating in this study. You will be away from normal work for 2-4 weeks at the Training Centre. You may have colleagues with whom you will not be able to share (initially for at least six months) the learning from this educational intervention.

#### **What will happen to the assessment recordings, interviews, feedback, and surgical outcomes data you give?**

The video recordings will be made using the same instruments, and the same standard recording equipment. They will also be anonymised so that none of your personal information will be identifiable. These recordings will be stored on an encrypted hard drive in Beijing and Belfast, Northern Ireland, UK. Interviews will be recorded and transcribed, anonymised, and thematised: again, no personal identifiable information will be kept. Surgical outcomes of your SICS procedures that you record for the ten cases will need to be documented in such a way so they do not include any patient-identifying information. Once these data are reported to the research team, none of your personal related information will be made available. Anonymised data will be including the placement of a anonymized data set in a data repository.

### **Withdrawal from the Study**

You have the right to leave a study at any time without penalty. The researchers and sponsor also have the right to stop your participation in this study without your consent if, for example:

- They believe there has been 'contamination' between "Intervention" and "Control" individuals
- You do not agree to any future changes that may be made in the study plan

### **New Information**

#### **What will we do if we find if one educational-intervention is better than the other?**

You will be informed if one training approach is found to be better than the other, and we will publish the results of the study (regardless of our finding) to help people making decisions about surgical training in the future.

### **Payment**

You will not be offered payment for being in this study.

### **Costs**

There will be no costs to you for participating in this study. You will not be charged for any of the research activities. All transport, accommodation, meals, and materials will be provided free of charge. You will not receive any additional payments or per diems for participating, beyond your normal stipend or salary from your training unit.

### **Confidentiality**

#### **What will happen to the records/interview, and videos we keep of your (simulation) operations?**

All the information and videos we collect will be kept confidential. It will be kept securely and only the primary investigator, or expert markers will have access to it. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might identify you will not appear when we present this study or publish its results. No information from this study will be placed into your ophthalmology training record.

### **In Case of Complaint**

#### **What if there is a problem?**

Any complaint about the way you have been treated during the study will be addressed. Please use the addresses below to contact the study coordinators.

### **Who is sponsoring this study?**

The study is sponsored through Beijing Tongren Hospital and Queen's University Belfast.

### **Who has reviewed the study?**

This study was reviewed and approved by the Beijing Tongren Ethics Review Committee, and the Queen's University Belfast Ethics Committee.

### **Who is doing this study?**

The study will be coordinated by Christopher Magoon who is a Yale University graduate, and MD candidate at the University of Pennsylvania Perelman School of Medicine and has extensive experience of working in rural China, and public health. Co-coordinators include Dr Kang Mengtian, a resident trainee in ophthalmology at Tongren, and Tai Stephan, an expert in Monitoring and Evaluation at the Orbis International Beijing office.

Professor Nathan Congdon, the Ulverscroft Chair at Queen's University Belfast, UK, Professor at Zhongshan Ophthalmic Center in China and Director of Research at Orbis, is the Principal Investigator, along with Professor Wang Ningli, of Beijing Tongren, and Dr William Dean, who is completing a PhD in simulation-based cataract surgical education at the International Centre for Eye Health in London, UK.

### **Contact Information**

#### **How can you obtain more information about the study?**

If you have any questions about this study or your part in it, or if you have questions, concerns or complaints about the research more generally, contact Dr. Kang Mengtian, kangmengtian@163.com, +86 13581788600.

**You will be given a copy of the information sheet to keep.  
Thank you for considering taking the time to read this sheet.**

Appendix 2 Budget

Budget Category	Itemised Costs of specific project activities	Budgeted Spend (USD)				
		6 months*	12 months*	18 months*	24 months*	TOTAL
		Target	Target	Target	Target	Target
<b>PERSONNEL (salaries, per diems, honoraria, etc.)</b>						
	Orbis CyberSight development of grading platform	6,000				6,000
	Patient baseline questionnaire collection: \$10/patient * 280 patients	400	1,200	1,200		2,800
	Local post doctoral research coordinator Beijing Tongren (over the full period of project implementation) \$875/mo (CNY6000/mo) * 18 months	1,750	5,250	5,250	3,500	15,750
	Data collection on visual acuity outcomes: \$10/case X 280 cases	400	1,200	1,200		2,800
	Top-up fees for surgery: \$20/case*280 cases	800	2,400	2,400		5,600
	Grading of 280 +56 videos by senior cataract surgeons at \$10/video	960	1,200	1,200		3,360
	Patient endline questionnaire collection: \$10/patient * 280 patients	400	1,200	1,200		2,800

	Data entry for forms: 4 forms/patient*280 patients*\$3/form				3,360	3,360
	Data analysis (Also includes support for form creation, creation of database and randomization process): Statistician \$1300/mo (CNY9,000/mo) * 100%time * 6 months	3,500	800		3,500	7,800
<b>Personnel Sub-total</b>		<b>14,210</b>	<b>13,250</b>	<b>12,450</b>	<b>10,360</b>	<b>50,270</b>
<b>EQUIPMENT (including consumables, rentals, etc.</b>						
	Model eyes (14 surgeons*8 eyes/surgeon*\$60/eye) Phillips	6,720				6,720
	Mannequins and mounts for model eyes Phillips	2,400				2,400
	Kitaro DryLab artificial eye system	2,200				2,200
	Zeiss Stemi 305 ECU microscopes for training on artificial eyes (4 * @ \$2,000)	8,000				8,000
	Video cameras \$800*5 cameras	4,000				4,000
	Laptop@ \$800	800				800
<b>Equipment Sub-total</b>		<b>24,120</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>24,120</b>
<b>TRAVEL</b>						

	Travel to China for investigator Will Dean: \$1500 return fare, \$150 hotel/night and \$50/day food X 10 days	3,500				3,500
	Patients transport: 280 patient*\$15 each	600	1,800	1,800		4,200
	Travel to China for investigator Will Dean: \$1500 return fare, \$150 hotel/night and \$50/day food X 5 days			2,500		2,500
	<i>Travel Sub-total</i>	<b>4,100</b>	<b>1,800</b>	<b>4,300</b>	<b>0</b>	<b>10,200</b>
	<b>TOTAL PROGRAM COSTS</b>	<b>42,430</b>	<b>15,050</b>	<b>16,750</b>	<b>10,360</b>	<b>84,590</b>
	<b>FACILITIES &amp; ADMINISTRATIVE</b>					
	Indirect Costs	2,375	2,375	2,375	2,375	9,500
	<b>TOTALS</b>	<b>44,805</b>	<b>17,425</b>	<b>19,125</b>	<b>12,735</b>	<b>94,090</b>

## Appendix 3a. ICO SICS OSCAR

ICO-Ophthalmology Surgical Competency Assessment Rubric-SICS (ICO-OSCAR: SICS)					
Date _____ Resident _____	Novice (score = 2)	Beginner (score = 3)	Advanced Beginner (score = 4)	Competent (score = 5)	Not done. Done by preceptor (score= 0)
1 <b>Draping</b>	Unable to start draping without help.	Drapes with minimal verbal instruction. Incomplete lash coverage.	Lashes mostly covered, drape at most minimally obstructing view.	Lashes completely covered and clear of incision site, drape not obstructing view.	
2 <b>Scleral access &amp; Cauterization</b>	Unable to successfully access sclera. Cauterization insufficient or excessive both in intensity and localization.	Accesses sclera but with difficulty and hesitation. Cauterization insufficient or excessive in location or intensity.	Achieves good scleral access with mild difficulty. Adequate cauterization.	Precisely and deftly accesses sclera. Appropriate and precise cauterization.	
3 <b>Sclerocorneal Tunnel</b>	Inappropriate incision depth, location, and size, hesitant dissection. Iris prolapse may occur	One of the following correct: incision depth, location or size. Able to dissect forward but not able to perceive depth	Two of the following are correct: incision depth, location or size. Understands that tunnel depth is incorrect but unable to correct.	Good incision depth, location and size. Tunnel constructed at right plane, if inappropriate plane, able to rectify.	
4 <b>Corneal entry</b>	Hesitant keratome entry into AC. Unable to extend the internal valve. Significant shallowing of anterior chamber. Require wound extension or suturing.	Enters into AC but difficulty in extension. Follows a different plane. Entry either anterior or posterior to dissection site. Mild AC shallowing. Require wound extension or suturing.	Entry at right plane. Able to extend but with repeated use of viscoelastic. Internal valve irregular. Require wound extension or suturing.	Fluently enters in right plane. Wound length adequate with no further need for extension. Retains viscoelastic during extension. Self-sealing, provides good access for surgical transvering.	
5 <b>Paracentesis &amp; Viscoelastic Insertion</b>	Chamber collapses on performing paracentesis. Inappropriate width, length and location. Pierces anterior capsule on entry. Unsure of when, what type and how much viscoelastic to use. Has difficulty accessing anterior chamber through paracentesis.	Appropriate incision width, location or length. Anterior chamber shallows mildly. Requires minimal instruction. Knows when to use but administers incorrect amount or type of viscoelastic.	Inappropriate location, width or length. Anterior chamber almost stable. Requires no instruction. Administers viscoelastic at appropriate time, amount, type, and cannula position.	Wound of adequate length, width, and correct location. Viscoelastics administered in appropriate amount, at appropriate time, with cannula tip clear of lens capsule and endothelium.	
6 <b>Capsulorhexis: Commencement of Flap &amp; follow-through.</b>	Instruction required, tentative, chases rather than controls rhexis, cortex disruption may occur.	Minimal instruction, occasional loss of control of rhexis, cortex disruption may occur.	In control, few awkward or repositioning movements, no cortex disruption.	Delicate approach and confident control of the rhexis, no cortex disruption.	
7 <b>Capsulorhexis: Formation and Circular Completion</b>	Size and position are inadequate for nucleus density, tear may occur.	Size and position are barely adequate for nucleus density, difficulty achieving circular rhexis, tear may occur.	Size and position are almost exact for nucleus density, shows control, and requires only minimal instruction.	Adequate size and position for nucleus density, no tears, rapid, unaided control of radialization, maintains control of the flap and AC depth throughout the capsulorhexis.	
8 <b>Hydrodissection: Visible Fluid Wave and Free prolapse of one pole of nucleus</b>	Hydrodissection fluid not injected in quantity or place to achieve nucleus rotation or prolapse.	Multiple attempts required, able to prolapse nuclear pole after multiple efforts. Manually forces nucleus prolapse before adequate hydrodissection, cheese wiring.	Fluid injected in appropriate location, able to prolapse one pole of nucleus but encounters more than minimal resistance.	Ideally see free fluid wave, adequate for free nuclear hydroprolapse or mechanical prolapse with minimal resistance. Aware of contraindications to hydrodissection.	
9 <b>Prolapse of nucleus completely into AC</b>	Unable to dial nucleus into AC. Hooks anterior or posterior nuclear surface, nucleus rotates in the bag, iris and corneal touch, pupillary constriction, may damage capsule or zonules.	Prolapses nucleus after repeated awkward attempts, needs instruction, cherns cortex causing reduced visibility, iris or corneal touch, no damage to capsule or zonules.	Prolapses nucleus into AC with more than minimal resistance. No corneal touch.	Prolapse with minimal resistance. No damage to pupil and iris.	
10 <b>Nucleus extraction</b>	Damages endothelium, iris or capsule, unable to hold and extract nucleus, movements not coordinated.	Movements coordinated but unable to extract nucleus, iris or corneal damage, unable to assess wound size in relation to nuclear density.	Removes nucleus after repeated attempts, more than one piece, might need wound extension prior to extraction.	Extracts nucleus with one or two attempts, proper wound size in relation to nuclear density.	
11 <b>Irrigation and Aspiration Technique With Adequate Removal of Cortex</b>	Great difficulty introducing the aspiration tip under the capsulorhexis border, aspiration hole position not controlled, cannot regulate aspiration flow as needed, cannot peel cortical material adequately, engages capsule or iris with aspiration port.	Moderate difficulty introducing aspiration tip under capsulorhexis and maintaining hole up position, attempts to aspirate without occluding tip, shows poor comprehension of aspiration dynamics, cortical peeling is not well controlled, jerky and slow, capsule potentially compromised. Prolonged attempts result in minimal residual cortical material.	Minimal difficulty introducing the aspiration tip under the capsulorhexis, aspiration hole usually up, cortex will engage for 360 degrees, cortical peeling slow, few technical errors, minimal residual cortical material. Some difficulty in removing sub incisional cortex	Aspiration tip is introduced under the free border of the capsulorhexis in irrigation mode with the aspiration hole up. Aspiration is activated in just enough flow as to occlude the tip, efficiently removes all cortex. The cortical material is peeled gently towards the center of the pupil, tangentially in cases of zonular weakness. No difficulty in removing subincisional cortex	
12 <b>Lens Insertion, Rotation, and Final Position of Intraocular Lens</b>	Unable to insert IOL.	Difficult insertion, manipulation of IOL, rough handling, unstable anterior chamber. Repeated hesitant attempts placing lower haptic in capsule, repeated attempts rotate upper haptic d into place with excessive force.	Insertion and manipulation of IOL accomplished with minimal anterior chamber instability, the lower haptic is placed with some difficulty, upper haptic is rotated with some stress.	Insertion and manipulation of IOL is performed in a deep, and stable anterior chamber and capsular bag, with incision appropriate for implant type. The lower haptic is smoothly placed inside the capsular bag; the upper haptic is rotated or gently bent and inserted into place without exerting excessive stress to the capsulorhexis or the zonule fibers.	
13 <b>Wound Closure (Including Suturing, Hydration, and Checking Security as Required)</b>	If suturing is needed, instruction is required and stitches are placed in an awkward, slow fashion with much difficulty, astigmatism, bent needles, incomplete suture rotation and wound leakage may result, unable to remove viscoelastics thoroughly, unable to make incision watertight or does not check wound for seal. Improper final IOP.	If suturing is needed, stitches are placed with some difficulty, resuturing may be needed, questionable wound closure with probable astigmatism, instruction may be needed, questionable whether all viscoelastics are thoroughly removed. Extra maneuvers are required to make the incision water tight at the end of the surgery. May have improper IOP.	If suturing is needed, stitches are placed with minimal difficulty tight enough to maintain the wound closed, may have slight astigmatism, viscoelastics are adequately removed after this step with some difficulty. The incision is checked and is water tight or needs minimal adjustment at the end of the surgery. May have improper IOP.	If suturing is needed, stitches are placed tight enough to maintain the wound closed, but not too tight as to induce astigmatism, viscoelastics are thoroughly removed after this step, the incision is checked and is water tight at the end of the surgery. Proper final IOP.	
14 <b>Global Indices Wound Neutrality and Minimizing Eye Rolling and Corneal Distortion</b>	Nearly constant eye movement and corneal distortion.	Eye often not in primary position, frequent distortion folds.	Eye usually in primary position, mild corneal distortion folds occur.	The eye is kept in primary position during the surgery. No distortion folds are produced. The length and location of incisions prevents distortion of the cornea.	
15 <b>Eye Positioned Centrally Within Microscope View</b>	Constantly requires repositioning.	Occasional repositioning required.	Mild fluctuation in pupil position.	The pupil is kept centered during the surgery.	
16 <b>Conjunctival and Corneal Tissue Handling</b>	Tissue handling is rough and damage occurs.	Tissue handling borderline, minimal damage occurs.	Tissue handling decent but potential for damage exists.	Tissue is not damaged nor at risk by handling.	
17 <b>Intraocular Spatial Awareness</b>	Instruments often in contact with capsule, iris, corneal endothelium; blunt second instrument not kept in appropriate position.	Occasional contact with capsule, iris, corneal endothelium; sometimes has blunt second instrument in appropriate position.	Rare contact with capsule, iris, endothelium. Often has blunt second hand instrument in appropriate position.	No accidental contact with capsule, iris, corneal endothelium. Blunt, second hand instrument, is kept in appropriate position.	
18 <b>Iris Protection</b>	Iris constantly at risk, handled roughly.	Iris occasionally at risk. Needs help in deciding when and how to use hooks, ring or other methods of iris protection.	Iris generally well protected. Slight difficulty with iris hooks, ring or other methods of iris protection.	Iris is uninjured. Iris hooks, ring, or other methods are used as needed to protect the iris.	
19 <b>Overall Speed and Fluidity of Procedure</b>	Hesitant, frequent starts and stops, not at all fluid.	Occasional starts and stops, inefficient and unnecessary manipulations common, case duration about 60 minutes.	Occasional inefficient and/or unnecessary manipulations occur, case duration about 45 minutes.	Inefficient and/or unnecessary manipulations are avoided, case duration is appropriate for case difficulty. In general, 30 minutes should be adequate.	
Comments: _____					TOTAL: _____



## Appendix 3c. SICS Simulation-OSSCAR

Trainee: \_\_\_\_\_ Evaluator: \_\_\_\_\_ Date: \_\_\_\_\_

Ophthalmic Simulated Surgical Competency Assessment Rubric – Sutureless ECCE (OSSCAR-SICS)					
		Novice (score = 0)	Advanced Beginner (score = 1)	Competent (score = 2)	Score (Not done score = 0)
1	<b>Scleral fixation</b>	No scleral fixation; inappropriate place; tissue trauma	Appropriate position of scleral fixation, but needs to re-grip. Mild tissue trauma	Good position of fixation, no need to re-grip, no trauma	
2	<b>Paracentesis</b>	Chamber collapses on performing paracentesis. Inappropriate width, length and location. Pierces anterior capsule on entry.	Inappropriate location, width or length. Anterior chamber almost stable.	Wound of adequate length, width, and correct location.	
3	<b>Viscoelastic insertion</b>	Unsure of when and how much viscoelastic to use. Has difficulty accessing anterior chamber through paracentesis.	Administers viscoelastic at appropriate time, amount, and cannula position.	Viscoelastics administered in appropriate amount, at appropriate time, with cannula tip clear of lens capsule and endothelium.	
4	<b>Scleral incision</b>	Inappropriate location, shape and size; hesitant incision.	Either one of the incision location, shape or size is incorrect.	Good incision location, shape and size. Firm and stable scleral fixation throughout.	
5	<b>Scleral tunnel</b>	Inappropriate tunnel depth, hesitant dissection. Button-hole and/or premature entry.	Able to dissect forward, and understands that tunnel depth is incorrect but unable to correct.	Tunnel constructed at correct place. If inappropriate place, able to rectify.	
6	<b>Sciero-corneal tunnel</b>	Does not extend into clear cornea. Button-hole and/or premature entry.	Does not extend >1mm into clear cornea. Internal tunnel not wider than external.	Extends tunnel into clear cornea >1mm, wider limbal corneal tunnel than at scleral incision.	
7	<b>Corneal entry</b>	Hesitant keratome entry into AC. Significant shallowing of anterior chamber. Require wound extension or suturing.	Entry at mostly right plane. Able to extend but with repeated use of viscoelastic. Internal valve irregular. Require wound extension or suturing.	Fluently enters in right plane. Wound length adequate with no further need for extension. Retains viscoelastic during extension.	
8	<b>Capsulotomy / Capsulorrhexis start</b>	Tentative; size and position are inadequate for nucleus density, incorrect capsulotomy position.	Mostly in control, slow initial start. Capsulotomy in correct position.	Correct and smooth start to capsulorrhexis. Delicate approach and confident control of cystotome.	
9	<b>Capsulotomy / Capsulorrhexis completion</b>	Tentative; size and position are inadequate for nucleus density, incorrect capsulotomy position. Radial tear	Mostly in control, few awkward or repositioning movements. Capsulotomy in correct position. Radial tear corrected.	Adequate size and position for nucleus density, no tears. AC depth throughout the capsulorrhexis.	
10	<b>Hydro-dissection: Visible fluid wave and free prolapse of one pole of nucleus</b>	Hydrodissection fluid not injected in quantity or place to achieve nucleus rotation or prolapse.	Fluid injected in appropriate location, able to prolapse one pole of nucleus but encounters more than minimal resistance.	Ideally see free fluid wave, adequate for free nuclear hydroprolapse or mechanical prolapse with minimal resistance.	
11	<b>Injection of visco-elastic</b>	Doesn't inject visco-elastic into eye	Injects insufficient visco-elastic. Injects only into PC or AC	Injects adequate visco-elastic into capsule bag behind nucleus, and AC	
12	<b>Prolapse of nucleus partially into AC</b>	Unable to dial nucleus into AC. Hooks anterior or posterior nuclear surface, nucleus rotates in the bag, iris and corneal touch.	Multiple attempts required to prolapse upper equator of nucleus into AC with more than minimal resistance. No corneal touch.	Prolapse of upper equator with minimal resistance. No damage to pupil and iris.	
13	<b>Nucleus extraction</b>	Damages endothelium, iris or capsule, unable to hold and extract nucleus, movements not coordinated. Pierces posterior capsule.	Removes nucleus after repeated attempts, more than one piece, might need wound extension prior to extraction.	Extracts nucleus with one or two attempts; proper wound size in relation to nuclear density.	
14	<b>IOL insertion</b>	Grips IOL incorrectly, inserts IOL incorrectly, multiple attempts.	Hesitant insertion of IOL, more than one attempt to insert	Inserts IOL into capsular bag efficiently, correctly, and in first attempt	
<b>GLOBAL INDICES</b>					
15	<b>Wound Neutrality and Minimizing Eye Rolling and Corneal Distortion</b>	Nearly constant eye movement and corneal distortion.	Eye usually in primary position, mild corneal distortion folds occur.	The eye is kept in primary position during the surgery. No distortion folds are produced. The length and location of incisions prevents distortion of the cornea.	
16	<b>Eye Positioned Centrally Within Microscope View</b>	Constantly requires repositioning.	Mild fluctuation in pupil position.	The pupil is kept centered during the surgery.	
17	<b>Scleral and Corneal Tissue Handling</b>	Tissue handling is rough and damage occurs.	Tissue handling decent but potential for damage exists.	Tissue is not damaged nor at risk by handling.	
18	<b>Intraocular Spatial Awareness</b>	Instruments often in contact with capsule, iris, corneal endothelium; blunt second instrument not kept in appropriate position.	Rare contact with capsule, iris, endothelium. Often has blunt second hand instrument in appropriate position.	No accidental contact with capsule, iris, corneal endothelium. Blunt, second hand instrument, is kept in appropriate position.	
19	<b>Overall Fluidity of Procedure</b>	Hesitant, frequent starts and stops, not at all fluid.	Occasional inefficient and/or unnecessary manipulations occur	Inefficient and/or unnecessary manipulations are avoided	
20	<b>Overall Speed of Procedure</b>	Case duration more than 15 minutes.	Case duration about 10-15 minutes.	Case duration about 5-10 minutes.	
<b>TOTAL</b>					

Good Points: \_\_\_\_\_

Suggestions for development: \_\_\_\_\_

*Based on the International Council of Ophthalmology (ICO)-Ophthalmology Surgical Competency Assessment Rubric-SICS (ICO-OSSCAR: SICS)*

## Appendix 4. Consent to Clinical Photography Form

### Consent to Clinical Photography Form

#### PATIENT INFORMATION

Dear patients:

Hello!

We are working on a scoring system for cataract surgeons' surgery skills and will need your permission to take pictures and videos of your eyes and the operation. By signing this informed consent form, you certify that you agree and know that your clinical information will be taken and recorded.

You can refuse to have photographs or videos taken for any reason other than for your health records. This will not affect your treatment in any way.

You have been asked to have medical video recordings taken. These will be for:

Anonymous assessment of your surgery, as part of ongoing evaluation of eye surgery and surgery training.

The videos of your surgery will not themselves be published or made available in any way to the public.

You will be given information about how the recordings will be used and will be asked to sign a consent form.

**Further Information: If you have any further questions, please speak to your doctor.**

**This leaflet is available in large print and other languages on request.**

**Consent to Clinical Photography/Video and Consent Form**

## Patient Details

Initials .....  
Date of Birth .....  
Hospital No.....

## Health professional statement

I have explained the purpose of clinical photography/recordings to the patient and how the images will be used.

Patient information leaflet has been given.

I am a health professional requesting clinical photography and video recording.

I will ensure that the appropriate video images are taken in a manner as to ensure that the patient **cannot be identified**.


Signature of health professional.....

Print Name .....

Job Title .....

Contact details..... Date..... / ..... / .....

**Patient statement** (please circle your answer) I agree to have clinical video recordings done. The request for these has been explained to me and I fully understand what it entails.

**Yes**

**No**

**Signature of patient** ..... **Date** ...../...../.....

## Statement of Independent Witness / Interpreter

I have interpreted the above information to the patient to the best of my ability and in a way which I believe she or he can understand.

Interpreter's signature .....Name.....Date  
...../...../.....

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