Fundamental Virtual Reality Simulation for Manual Small Incision Cataract Surgery Validity: Evaluation, Efficacy and Acceptability Study in Bangladesh, China, Ethiopia, India, Mongolia, Togo, United Kingdom and United States of America.

A Prospective Multi-Centre Mixed Methods Study.

STUDY PROTOCOL

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Collaborating Institutions:

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3. Queen's University Belfast, Northern Ireland, UK
4. FundamentalVR, London, UK
5. Chittagong Eye Infirmary and Training Complex, Chittagong, Bangladesh
6. Addis Ababa University, department of Ophthalmology, Menelik II Hospital, Addis Ababa, Ethiopia
7. University of Gondar, Gondar, Ethiopia
8. Dr. Shroff's Charity Eye Hospital (SCEH), New Delhi, India
9. H.V. Desai Eye Hospital, Pune, India
10. The First Central Hospital, Ulaanbaatar, Mongolia
11. Shenyang He Eye Specialist Hospital, China.
12. Lumiere Devine Eye Hospital, Lome, Togo
13. Emory Eye Center, Atlanta, GA USA

This protocol describes the Orbis-FVR Study, and provides information about procedures for selecting participants, training involved, and the methods for validation.

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

Questions relating to this educational-intervention study should be referred, in the first instance, to the primary investigators Dr William Dean: will.dean@lshtm.ac.uk or Amelia Geary: Amelia.geary@orbis.org

This trial will adhere to the principles outlined in the International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines, and all applicable local and training program regulations.

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Glossary of Abbreviations

ACGME	Accreditation Council for Graduate Medical Education
CCC	Continuous curvilinear capsulorrhexis
ECCE	Extracapsular cataract extraction
FRCOphth	Fellow of the Royal College of Ophthalmologists (UK)
FVR	Fundamental VR
GCP	Good Clinical Practice
IAPB	International Agency for the Prevention of Blindness
ICEH	International Centre for Eye Health
INO	Instituto Nacional de Oftalmología
IRO	Instituto Regional de Oftalmología
LSHTM	London School of Hygiene & Tropical Medicine
MD	Doctor of Medicine
MEd	Masters in Education
MSICS	Manual small incision cataract surgery
OASIS	Objective assessment of skills in intra-ocular surgery
OSSCAR	Ophthalmic Simulated Surgical Competency Assessment Rubric
PCR	Posterior capsule rupture
PhD	Doctor of Philosophy
PI	Principal investigator
QUB	Queen's University Belfast
RCOphth	The Royal College of Ophthalmologists, UK
SCEH	Shroff's Charity Eye Hospital
UK	United Kingdom
USA	United States of America
VA	Visual acuity
VL	Vitreous loss
VR	Virtual reality
WHO	World Health Organization

Keywords

Virtual reality, Simulation, Surgical Education, Cataract

General Information

Project Title

Fundamental Virtual Reality Simulation for Manual Small Incision Cataract Surgery Validity: Evaluation, Efficacy and Acceptability Study in Bangladesh, China, Ethiopia, India, Mongolia, Togo, United Kingdom and United States of America.

Identifying numbers
LSHTM Application Reference Number:

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12. Lumiere Devine Eye Hospital, Lome, Togo
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Study Sponsor

London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

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Study Funders

- Orbis International

Study Summary

Title	Fundamental Virtual Reality Simulation for Manual Small Incision Cataract Surgery Validity: Evaluation, Efficacy and Acceptability Study in Bangladesh, China, Ethiopia, India, Mongolia, Togo, United Kingdom and United States of America.
Design	Prospective Pre-Post single-masked education-intervention randomized controlled study of intense virtual reality (VR) simulation-based surgical education of ophthalmologists in Bangladesh, China, Ethiopia, India, Mongolia, Togo, UK and USA. Construct validity study of assessment scores generated by the VR simulator for novices versus experts. Qualitative study of face validity of VR simulator, and acceptability questionnaire survey of users.
Aims	To investigate the efficacy of intense VR simulation-based surgical education using the Orbis-FVR simulator. To examine whether it improves competence; is acceptable and has validity. To assess the construct validity of the VR simulator's assessment capacity.
Intervention	The 'intervention training' is a structured course of training using the Orbis-FVR MSICS simulator. ***This training is in addition to, and an enhancement of the trainees' normal current standard conventional training, and not designed to replace it.***
Outcome measures	Assessments and follow-up time points are at baseline and 1 month. ***Primary outcome measure****:* mean specific simulated surgical competency assessment score at one-month post-training intervention between groups (assessed using Sim-OSSCAR) (Appendix 4).[1] ***Secondary outcome measures:*** • Assessment scores generated by Orbis-FVR Simulator pre- and post-intervention. • Step-specific analysis: mean differences in Sim-OSSCAR score for the seven interactive steps assessed (incision, tunnel, AC entry, CCC, mobilization, removal and IOL). Total possible score 14. • Self-reported confidence ratings (10-point Likert scale) in MSICS skills, and ophthalmic surgical skills ***Further Exploratory Analysis:*** • Construct validity study comparing scores generated by Orbis-FVR simulator between two cohorts of novice and expert MSICS surgeons. • Face validity study subjectively assessing a group of expert MSICS surgeons' views of the Orbis-FVR simulator as representing MSICS • Qualitative study of the acceptability and utility of the Orbis-FVR simulator as a training or assessment tool.

Population

The VR simulation surgical training, construct and face validity studies will be conducted in ophthalmology institutions in the Americas, Europe, Africa, and Asia. Participants will have follow-up assessments in their home training or work institutions in Bangladesh, China, Ethiopia, India, Mongolia, Togo, UK and USA.

Eligibility

Inclusion criteria for trainee:

- Trainee ophthalmologist (year 1, 2, or 3) in collaborating institution.
- Agree to undertake simulation procedure assessments
- Agree to undertake and complete the intense VR simulation training course.
- Performed 0 MSICS as primary surgeon and assisted or part-performed less than 10 MSICS cases

Exclusion Criteria (trainee)

- Performed 1 or more MSICS cataract surgeries as primary surgeon; and assisted or part-performed 10 or more.

Inclusion Criteria (Expert)

1. Participants in the construct validity study are two cohorts: novice MSICS surgeons having performed 0 MSICS procedures as primary surgeon and assisted in less than 10. The second cohort is expert MSICS surgeons having performed a minimum of 1,000 MSICS procedures as primary surgeon.
2. Participants in face validity study are expert MSICS surgeons with over 1,000 MSICS procedures performed.

Duration

The anticipated overall project duration is one year. The fieldwork will take about nine months.

Executive Summary

Cataract is the leading cause of blindness, representing 35% of global blindness.[2] There is a huge need to perform high volumes of cataract surgery globally, to tackle the backlog of cataract cases. There is a great need to train many eye surgeons safely, efficiently, effectively, and to an acceptable level of competence.

Currently, surgical training is often conducted using the traditional "apprentice model", where a trainee observes a qualified surgeon and learns from them, and then the surgeon supervises the trainee performing surgery on a patient. We believe that this conventional model has substantial limitations and drawbacks, making surgical training less efficient and less safe. Simulation-based surgical education in cataract and glaucoma surgery has been shown to be effective in improving competence and confidence of trainee eye surgeons.[3 4] However, the role of an immersive haptic virtual reality learning environment has not been established for manual small incision cataract surgery.

We will test the hypothesis that intense virtual reality (VR) simulation-based ophthalmic surgical training impacts initial acquisition of competence in key stages of MSICS. Orbis International has partnered with FundamentalVR and expert cataract surgeons to create a MSICS simulator, using virtual reality software combined with existing gaming technology. The result is a VR simulator available at a fraction of the cost of cataract surgical simulators currently on the market.[5 6] We are proposing a pilot randomized multi-country study evaluating the efficacy and acceptability of the simulator training, using simulation alone. This mix method study will combine qualitative and quantitative data collection; no patients are involved.

All the training within the 'educational intervention' of this study will be performed using simulation. There is no testing or interventional surgical training on patients. When three anonymized and non-identifiable recordings of supervised cataract surgical procedures are video recorded (at one month), no patients are involved, and these assessments are, as for the baseline assessments, using validated artificial model eyes and assessment rubric.[1 3]

The results of this study will inform the design of a future multi-center randomized-controlled clinical trial.

Background

Cataract and Cataract Surgery globally

Globally there are 36 million people who are blind and a further 219 million with moderate or severe vision impairment (MSVI).[2] Cataract remains the most common cause of blindness. Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in low- and middle-income countries (LMIC). Only around half of the 230,000 ophthalmologists in the world perform surgery, and regions with the greatest burden have the lowest ratios of ophthalmologists to population.[7] One reason for having surgeons who do not perform surgery is that they are inadequately trained to perform it. For example, in India and China, consultants do not trust their novice apprentices to perform safe surgery leading to residents performing fewer than a dozen independent surgeries in their entire training. Ophthalmologists who have graduated with inadequate surgical skills find fewer opportunities to practice their skills after graduation.

The procedure of manual small-incision cataract surgery (MSICS) is the most commonly performed cataract surgery procedure in many regions of the world and is the main standard of care.[8 9] It is the commonest technique of cataract surgery taught in residency training programs in South Asia.[10] The technique uses a smaller wound compared to the older technique of sutured extra-capsular cataract extraction (ECCE).[11] There is less post-operative astigmatism, and fewer suture-related problems for SICS versus ECCE. The surgical and visual outcomes of phacoemulsification cataract surgery and MSICS are comparable.[12-14] MSICS is an appropriate, safe, and affordable technique for blindness prevention.

Simulation in Ophthalmic Surgical Training

A recent randomized controlled trial (RCT) of intense simulation-based surgical education for MSICS using artificial eyes showed a rapid and sustained increase in competence, a 72% reduction in complication rates, and a doubling of confidence in participants.[3] An RCT of simulation-based surgical education in glaucoma has also illustrated a rapid and sustained increase in surgical competence as well as confidence.[4]

The use of computerized simulation models has been validated for cataract[15-17] and retinal surgery.[18] Three computerized simulators have been used for cataract surgical training in ophthalmology: the Eyesi (VRMagic Holding AG, Mannheim, Germany), MicroVisTouch (ImmersiveTouch, Chicago, USA), and PhacoVision (Melerit Medical, Linkoping, Sweden).

A simulation-based performance test and certification for phacoemulsification cataract surgery has been established for use with the Eyesi simulator. The test showed evidence of validity, and appeared to be a useful and reliable assessment tool, both for cataract procedure-specific as well as general micro-surgical skills.[19] HelpMeSee (New York, USA) recently launched a full-immersion surgical training simulator for the use within high capacity surgical education programs for small-incision cataract surgery.[5] This was launched in November 2020.[20] However, the simulator is currently unavailable in full, and the cost per unit is around US$250,000.[6]

Development of the Training Curriculum

Table 1: Training Course Curriculum & Objectives

Pre-Course	• Study information and consent • Video of procedure (MSICS) • Introduction video to Orbis-FVR simulator
Course Curriculum	• Video of procedure (MSICS) • Surgical procedure specifics • Orbis Fundamentals of MSICS course • Detailed illustration of Orbis-FVR simulator and instruction course • Intense Orbis-FVR simulator training: Course completion to minimum 5 sequential benchmarked score.

Methodology

Design Summary

This research program involves a prospective, single-masked education-intervention randomized controlled study of intense virtual reality (VR) simulation-based surgical education of ophthalmologists in Bangladesh, China, Ethiopia, India, Mongolia, Togo, UK and USA. Participants will be randomized, and simulation surgical competency will be assessed at baseline and 1-month between groups. Competency will be assessed at using artificial model eyes: both groups will perform three full MSICS cases using model eyes at baseline. At one-month post intervention, both groups will again perform three full MSICS using model eyes (primary outcome).

The study will assess the construct validity study of assessment scores generated by the VR simulator for novices versus experts. Both Novices and Experts will perform three full VR cases using the simulator. The first score will be disregarded to allow for familiarization with the hardware, and the mean of the second and third cases will be recorded.

Qualitative study of face validity of VR simulator, and acceptability questionnaire survey of users. An anonymous survey administered to experts and novices, using a Likert scale.

Study Setting

This is a multi-center study. We will enroll trainee ophthalmologists (doctors who have graduated from medical school and are currently undergoing ophthalmology specialist training) in 9 ophthalmology training institutions in in Bangladesh, China, Ethiopia, India, Mongolia, Togo, UK and USA.

Study Duration

The training will be conducted during 2021 and 2022.

Study Participants

Current trainees (between January 2021 and June 2022) in all 9 training institutions will be selected according to the inclusion and exclusion criteria.

Inclusion / Exclusion Criteria

Orbis-FVR Training Study:

Inclusion Criteria (trainee participant)

- Trainee ophthalmologist (year 1, 2 or 3) in collaborating institution.
- Agree to undertake simulation surgical procedure assessments.
- Agree to undertake and complete the intense VR simulation training course.
- Performed 0 MSICS as primary surgeon and assisted or part-performed less than 10.

Exclusion Criteria (trainee)

- Performed 1 or more MSICS cataract surgeries as primary surgeon and assisted or part-performed 10 or more.

Inclusion Criteria (Expert)

3. Participants in the construct validity study are two cohorts: novice MSICS surgeons having performed 0 MSICS procedures as primary surgeon and assisted in less than 10. The second cohort is expert MSICS surgeons having performed a minimum of 1000 MSICS procedures
4. Participants in face validity study are expert MSICS surgeons with over 1,000 MSICS procedures performed.

Informed Consent

Potential participant trainees will be informed of the training opportunity and the study. Heads of Department will be involved in the process. Trainee participants will be informed in detail about the nature of the education-intervention study; that the training offered offers no official qualification and will not be recorded in their annual review of clinical national training evaluation. All surgeons participating will be free to leave the study at any time. See Appendices 1 to 2 for detailed Information and Consent Forms.

Withdrawal Criteria

Trainee 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. Data collected up to the point of withdrawal of consent will have been anonymized and securely stored and will still be held and included in data analysis.

Baseline Data

Resident Trainees

- Age
- Sex
- Year of training
- Training Institution
- Number of MSICS surgeries performed as primary surgeon
- Number of MSICS surgeries assisted in or part performed
- Total number of other ophthalmic surgeries performed (disaggregated by type)

Attending Consultants (experts)

- Sex
- Training institution
- Number of MSICS surgeries performed as primary surgeon

Randomisation

Sequence generation

The randomization sequences will be computer generated and administered centrally by a statistician based at the QUB who is independent of all other aspects of the trial. We will use block randomization (block size 2 or 4), with a separate sequence for each of the ten recruitment sites, to ensure balance. The statistician will generate the code / sequence (as a block of 2 or 4).

Allocation Concealment

The statistician will not have access to information about subsequent allocation, and the individual potential participants. The PI, co-investigators, and participants will have no prior access to the random sequence.

Randomization Implementation

Trainees within the same training institution, who have met the appropriate inclusion and exclusion (as detailed previously), will be eligible for randomization to the 'intervention' or 'control' arm. Each group of four trainee participants will be agreed by the Head of Training Program or Department.

For example (Blocks will be in groups of 4, 6 or 8 depending on the institution and the number of residents that meet the inclusion criteria):

A block of four potential participants is identified in Chittagong Eye Institute Training Center (CEITC), Bangladesh. Cards with the allocation or a block of four (two intervention and two control) were printed and placed in sealed opaque envelopes. Physically, in Bangladesh, a block of four identical envelops (e.g. block number 11) will be selected. Participants will be invited by the Head of Department to pick one of the four envelops. In this example, CEITC randomization block 11 allocation might be:

IRO1101	Intervention
IRO1102	Control
IRO1103	Control
IRO1104	Intervention

Table 2: Orbis-FVR Training Program

Pre-Learning (one month in advance)

- Surgical video review

Pre-Course Assignment (one week in advance)

- Complete and record three full MSICS cases using the Philips Studio MSICS model eye[21] and following the steps of the Sim-OSSCAR (Appendix 4).
- Upload the 3 recorded simulated surgical procedures to the Cybersight platform

The Orbis-FVR Virtual Reality MSICS simulator has 19 steps in total. Currently, 10 steps are animated and 9 are **interactive**, as follows:

1. *Patient Preparation – Animated Step*
2. *Conjunctival Peritomy – Animated Step*
3. *Paracentesis – Aminated Step*
4. *Formation of the AC – Animated Step*
5. *Anterior Chamber Maintainer – Animated Step*
6. **Marking the Scleral Incision – Interactive Step**
7. **Scleral Incision – Interaction Step**
8. **Sclerocorneal tunnel – Interactive Step**
9. **Anterior Chamber (AC) Entry – Interactive Step**
10. **Continuous Curvilinear Capsulorrhexis (CCC) – Interactive Step**
11. *Hydrodissection – Animated Step*
12. **Mobilization of the nucleus – Interactive Step**
13. *Releasing the nucleus – Animated Step*
14. **Nucleus removal – Interactive Step**
15. *Cortex removal – Animated Step*
16. **IOL insertion – Interactive Step**
17. **IOL Dialing and Implantation – Interactive Step**
18. *Inspection of the wound – Animated Step*
19. *Closure of the wound – Animated Step*

Course Overview

Participants must attend and successfully complete all sessions. All simulator tasks are to be completed in sequential order, in line with the course outline. A required minimum score of 85 points for each interactive step must be reached reliably three times in a row to advance to the next step in the course.

For each step within the simulation the following is recorded:
Step Time - The total time spent on a step including ALL attempts.
Pass / Fail - The interpreted pass or fail result of the last attempt of the step.
Step score - Each step is scored between 0 and 100 points, based on user performance in completing the surgical objective, taking into account any adverse events.

- Adverse events –For each step, if triggered, all of the adverse events are recorded.
- No. of attempts - The number of attempts (inc. resets) of the step.

Course Content

- Each course will combine autonomous learning and live mentorship.
- Autonomous learning will consist of a series of 15-minute video presentations, which include:
    - Narrated demonstration video of specific VR step(s)
    - PowerPoint presentations

    - Instrument use demonstrations
- Live mentorship will be delivered in two ways:
    - Local mentor who provides in-person mentorship
    - International mentor from technical advisory group provides live tele-mentorship

Content hosting

- All content will be hosted on the Orbis Cybersight Learning Management System platform (cybersight.org)
- Data will be randomized and anonymized by the Cybersight Program manager, who will not be involved in any other aspect of the research study.

Course delivery

Each day:

- Local mentor will facilitate introductions in each morning session. This will cover:
    - An overview of the day's training plan
    - Outlining the learning objectives for the day's training plan
    - Introduction of the content covered in the day's training plan
- Local mentor will also facilitate discussion and answer questions on autonomous content viewed in the morning and midday sessions
- Local mentor will provide periodic check ins throughout the day's session
- International mentor will provide tele-mentorship for the first hour of the 2-5pm session
- Trainees will do self-practice for the remainder of the afternoon session
- Each trainee will complete each interactive step on the VR simulator a minimum of 5 times with a reliability gate (3) and minimum score of 85
- Each trainee will complete at least 5 full cases on the VR simulator with a reliability gate (3) and minimum score of 85

Course outline

Day	Morning 8:00 – 10:30	Midday 11:00 – 1:00	Afternoon 2:00 – 5:00
Monday	Introduction Orientation to simulator. Review of animated steps 1-5	Marking the scleral Incision Scleral Incision Sclerocorneal tunnel	Mentored practice Self-Practice
Tuesday	Introduction Review CCC	AC entry Hydrodissection Releasing the Nucleus Nucleus Removal Cortex Removal	Mentored practice Self-Practice
Wednesday	Introduction Review IOL Insertion IOL Dialling and implantation	Inspection of the wound Closure of the wound	Mentored practice Self-Practice
Thursday	Introduction Review of entire SICS procedure.	Putting it all together: Full Cases	Mentored practice Self-Practice
Friday	Introduction Assessment and Scoring	Final Review	

Attendance to be recorded as follows:

- Confirmation of three simulation video uploads pre-intervention
- Simulator use and assessment logs
- Attendance records taken per daily session
- Confirmation of three simulation video uploads post-intervention

Outcomes

In the Fundamental Virtual Reality MSICS study, participants will be assessed on one occasion after recruitment (in addition to baseline), at one month: three simulation MSICS procedures recorded, anonymized and remotely assessed in a masked fashion (primary outcome). On the baseline and 1-month assessment, simulation MSICS procedures will be recorded (with masked assessment using the Sim-OSSCAR).[1]

Primary Outcome – Orbis-FVR Study

The primary outcome measure of the Orbis-FVR study will be the procedure specific repeated measures analysis of Sim-OSSCAR score performed three times at 1-month. The analysis of the primary outcome measure will be based on the mean differences in the Sim-OSSCAR scores between the intervention and control groups. This score is derived from an assessment matrix or rubric of procedure specific and general microsurgical skill indices (see appendix 4).[1] Each item in the matrix is graded on a modified Dreyfus score (novice, advanced beginner, and competent). The total possible score is 40 points.

Simulation assessment will be recorded using a standard microscope and recording device with all participants wearing similar latex-free surgical gloves. Recordings will be given an anonymous number to give no indication as to in which arm the surgeon is. Assessments of the surgical video will be conducted separately by two masked observers, watching the recorded surgery performed by the trainee at a separate time and place. Both observers are experienced eye surgeons and surgical trainers. Intra- and Inter-observer reliability studies will be conducted.

Secondary Outcomes / Qualitative Outcomes / Additional Exploratory Analysis:

1. Step-specific analysis: Secondary analysis of the primary outcome measure: mean differences in Sim-OSSCAR score for the seven interactive steps assessed (incision, tunnel, AC entry, CCC, mobilization, removal and IOL). Total possible score 14.
2. Assessment scores generated by Orbis-FundamentalVR MSICS simulator for two cohorts of surgeon: novice and expert (construct validity).
3. Self-reported confidence ratings (10-point Likert scale) in MSICS skills, and ophthalmic surgical skills.
4. Face validity assessment of Orbis-FVR simulator by international group of MSICS expert surgeons, performed through survey, using 5-point Likert scale.
5. Further qualitative study including acceptability assessment of Orbis-FVR simulator by international group of MSICS expert surgeons; and subjective improvement analysis and feedback by both experts and trainees.
6. Cost-effectiveness analysis of simulation-based training

Analysis

Statistical analysis

The primary outcome measure (mean Sim-OSSCAR score at 1 month) will be analyzed using a t-test. Performances will be compared between intervention and control groups: these are a continuous variable in each group. We will compare these mean Sim-OSSCAR[1] scores by t-tests (which is unadjusted) and linear regression (adjusting for training center as a fixed effect). An alpha level of $p<0.05$ will be considered statistically significant, and a kappa coefficient of ≥ 0.75 for inter-rater agreement is considered

excellent.[226]

Qualitative analysis

Structured anonymous survey (appendix 8), using a 5-point Likert scale, to assess acceptability of VR simulator by Novice and Expert study participants.

Face validity assessment of Orbis-FVR simulator by international group of MSICS expert surgeons, performed through survey, using 5-point Likert scale.

Cost-effectiveness

Cost effectiveness will be evaluated by calculating the incremental cost-effectiveness ration (for the primary outcome of Sim-OSSCAR scores of surgical competency:

ICER = cost of Orbis-FVR Simulation module per group of trainees divided by the difference in their outcomes (Scores).

Cost-effectiveness will also be assessed against the expense of the VR simulator and model eyes with trainers time, versus trainers time alone; and compared at different safety and learning curves for competency outcomes of participants per group.

Willingness-to-pay will be assessed as a crude monetary value per simulator, then per trainee outcome.

Construct Validity

Construct validity essentially assesses the sharpness of a tool, in this context addressing the question: can the simulator be used to discriminate between a novice and an expert. Mean assessment scores generated by Orbis-FundamentalVR MSICS simulator will be compared between two cohorts of surgeon: novice and expert. There will be 5 in each cohort, each performing 3 cases. The first case will be disregarded and the mean of the remaining two cases will be recorded and analyzed.

Participants in the construct validity of assessment scores will be recruited from three centers.

Face Validity

Face Validity will be assessed by survey and response to the questions:

- "Do you think the Orbis-FVR MSICS simulator is an appropriate way for trainees to learn manual small incision cataract surgery?"
- "Do you think the Orbis-FVR MSICS simulator is an appropriate way to assess trainees' MSICS surgical skill?"

Responses will be evaluated on a 5-point Likert scale anchored at '1=strongly disagree' and '5=strongly agree'.

A total of ten experts will be selected as participants in the face validity of the VR simulator. Recruited from all locations participating in the primary randomized control trial (Bangladesh, China, Ethiopia, India, Bangladesh, Togo, UK and USA).

Sample size

Based on pilot and published data we anticipate the mean Sim-OSSCAR score to be 10/40 (standard deviation (SD) 6 points) at baseline. We anticipate an effect size of 2.5 SD in the mean Sim-OSSCAR between groups. We assume a correlation between these observations of 0.8. Variation between clusters (training institutions) will be accounted for with a co-efficient of variation of 0.5.

Therefore, a sample of 52 individuals in total (26 in each arm) would have 80% power and 95% confidence to detect a difference of 15 points (2.5SD). We will recruit 60 participants for the Orbis-FVR training study to provide 8 extra participants as we anticipate a moderate loss to follow-up.

We and our collaborators consider this sample size of 60 participants to be feasible within the available time and financial resources. It would take longer (an extra academic year) if we needed to recruit many more, and if the impact of COVID-19 on training continued throughout the recruitment year.

For the construct validity of the FVR assessment capacity, we will recruit a total of 5 experts and 5 novices from participating centers. Sample sizes of content, face and construct validity study are based on data from recent validation studies of ophthalmic simulation surgical competency assessment rubrics.[1 237] Additionally, as we predict a large differences between the two participating groups, small cohort numbers suffice. For face validity, we will recruit ten experts from multiple centers, likewise, this was determined based on data from similar face validation studies.

Prevention of Bias

It is accepted that there will be variability in individual participants' inherent or natural surgical aptitude. All efforts will be made to standardize the training offered. The intense simulation course will be hosted on the same standardized surgical training platform: Cybersight. All intervention and control participants will wear surgical gloves

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 intervention/control arm.

Observer Bias

Recordings will be converted to an MP4 format, and coded. At CyberSight, the recording will be renamed as a randomly generated seven-digit number (e.g. 6253815). The code sheet will be generated by an independent statistician and only be known to them and the CyberSight administrator. Once assessors are notified that the video is ready for marking, this random number will be the only identifiable information available when the simulation surgical procedure is assessed, thus completely masking the assessor to the participant's intervention/control arm and personal identity.

Benefits of the Study

Benefits to the study participants
Participants are expected to benefit from the additional intense VR simulation training in MSICS, as well as the online educational content of Cybersight.

General benefits
These may include the further validation and refinement of the educational platform, as well as additional evidence to the utility of VR simulation-based ophthalmic surgical education.

Risks and Limitations

There are **no clinical risks** within this study, as all the intervention training is using simulation. No patients are involved in any of the training, or any of the assessments.

There are a number of broad risks in conducting this study.

- Trainees, meeting the inclusion criteria, not being available for enrolment (due to examinations, closure of training institutions, personal reasons).
- Connectivity issues undermining access to the VR software, orientation and training
- New technology: users' comfortability with engaging in new technology
- Civil unrest (including national elections).
- Customs delays in the import of equipment or consumables.

There are expected limitations to this study:

- All training and assessments are using simulation. No patients are involved. Predictive validity (how the simulation training impacts live surgical competence) will not be assessed. A future prospective randomized-controlled educational-intervention clinical trial will be needed.
  .

Study Timetable:

Figure 1. Detailed timeline of recruitment, assessment, and training.

2021/2022:	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Orbis research concept template	X													
Protocol development	X	X												
Collaborating institution MOUs		X	X											
Orbis-FVR simulator training course			X	X										
Equipment procurement & shipping	X	X	X	X										
Ethics submission		X	X											
Recruitment					X	X	X	X	X					
Baseline assessments					X	X	X	X	X	X				
Construct validity study (novices)					X	X	X	X	X	X				
Orbis-FVR simulator training					X	X	X	X	X	X	X			
1-month follow-up assessments						X	X	X	X	X	X	X		
Face validity study							X	X	X	X				
Construct validity study (experts)							X	X	X	X				
Qualitative / acceptability data								X	X	X	X			
Data analysis										X	X	X		
Final report													X	
Presentation & Publication													X	X

Data Management

All recordings of surgeries (either simulated or real) will be anonymized. Recordings will be kept on an encrypted computer hard drive, and a separate back-up encrypted hard drive in a safe in a locked office by the Principal Investigator, and numerically randomized. Any identifiable information (of the performing surgeon) will be kept separately on an encrypted spreadsheet. No patient identifiable information will be recorded at any time, as no patients are involved in the study. Recordings will be transported on an encrypted hard-drive if physical transportation is necessary. If this is not practical (in terms of delivering the videos to a masked assessor), then the videos will be uploaded to the secure CyberSight website. The website will send a notification to the assessor that a video has been uploaded and is ready for assessment, however the assessor will need a login name and password to access the website and video.

Expected Outcomes of the Study

The outcome of this study is to test the Null Hypothesis that there is no association or relationship between the educational intervention of 'intense virtual reality simulation-based surgical education' for manual small incision cataract surgery.

If the analyzed data from this study does indeed statistically prove the alternate hypothesis, this study has the potential of proving, and providing the robust data, that simulation-based VR surgical education in MSICS improves competence and has face and construct validity.

Quality Assurance

Data management

All data collected will be anonymized: no participant-identifiable information will be available. The anonymization and randomization data will be kept separately. All data will be backed up weekly on an encrypted external hard drive.

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 Orbis International. Monthly Project Reports will be prepared by the Principal Investigator (LSHTM).

Advisory Panel

The advisory panel are:

Amelia Geary, USA
Professor Nathan Congdon, Northern Ireland
Dr. Hunter Cherwek, USA
Dr Glenn Strauss, USA
Mr John Ferris, UK
Dr Parikshit Gogate, India

Funding

Orbis International

Medical Registration

No medical registration is necessary for participants or collaborators

Data and safety management

All participant information will be randomized, anonymized and encrypted. All patient-related surgical outcomes data will be anonymized and numerated as per local policy. No patient identifiable information will be made available outside of the hospital or training institution or be made available in any form to the PI.

Ethical Considerations

Ethical Approval & Trial Registration

Ethics approval would be obtained from individual institutional review boards per participating institution. Educational ethics are important to consider separately for this study.

Participant / Trainee Informed Consent

Each trainee eye surgeon attending the training and involved in qualitative research will be invited to read and sign a consent form (Appendix 1). It is important to emphasize that 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 anonymized 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.

No assessment or report will be given to any of the participant trainees' colleagues, or surgical or educational supervisors. In other words, this 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' training record.

None of the data collected or reported will be made available to work/training institutions or be used for any future job selection. All and any of the training carries no accreditation, nor official continuous professional development (CPD) points.

Trainee 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.

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

Dissemination of Results and Publication Policy

There will be a number of separate aspects of this research to analyze and develop into articles for submission to international peer-reviewed journals.

Co-authorship of submitted and published articles will be evaluated as per internationally agreed research guidelines:

Authorship credit should 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.

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Appendices

Appendix 1 Participant Consent Form (Orbis-FVR)

Validity and effectiveness of a virtual reality simulator for manual small incision cataract surgery: The Orbis-FundamentalVR MSICS Simulator.

- London School of Hygiene and Tropical Medicine, UK
- Orbis International, New York, USA
- Queen's University Belfast, Northern Ireland, UK
- FundamentalVR, London, UK
- Chittagong Eye Infirmary and Training Complex, Chittagong, Bangladesh
- Addis Ababa University, department of Ophthalmology, Menelik II Hospital, Addis Ababa, Ethiopia
- University of Gondar, Gondar, Ethiopia
- Dr. Shroff's Charity Eye Hospital (SCEH), New Delhi, India
- H.V. Desai Eye Hospital, Pune, India
- The First Central Hospital, Ulaanbaatar, Mongolia
- Shenyang He Eye Specialist Hospital, China.
- Lumiere Devine Eye Hospital, Lome, Togo
- Emory Eye Center, Atlanta, GA USA

I _____ (name) have been invited to participate in a study of surgical training, involving a two day intense training and education course for cataract surgery and ongoing assessment for the following one month. 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 Orbis-FVR study. I have had the opportunity to consider the information, ask questions and have had these answered fully.	☐
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.	☐
3. I give my permission for anonymized 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.	☐
4. I understand that **no personal identifiable information** will be included in any published output.	☐
5. I understand that interviews, opinions, or recordings of the education and training will only be used for academic purposes.	☐
6. I understand that no formal feedback will be given to any of my colleagues or surgical supervisors	☐

7. I understand that no data will be made available to work/training institutions or be used for any future job selection.	☐
8. I agree to anonymized simulation video recording and assessment at baseline, and one month of my surgery	☐

Signed _____ Date: _____

Name _____

Countersigned by collaborating investigator

Principle Investigator Dr William H Dean PhD FRCOphth MEd MBChB BSc
Principle Investigator (Orbis): Amelia Geary

Any queries should be directed in the first instance to the Principal Investigator Dr Will Dean:
Will.Dean@lshtm.ac.uk
Phone: UK +44(0)7899 753 953

Please refer to Participant Information Sheet (Orbis-FVR Version 1.0)

Appendix 2 Participant Information Sheet – Orbis-FVR

Validity and effectiveness of a virtual reality simulator for manual small incision cataract surgery: The Orbis-FundamentalVR MSICS Simulator.

Participant Information Sheet (Orbis-FVR Version 1.0)

- London School of Hygiene and Tropical Medicine, UK
- Orbis International, New York, USA
- Queen's University Belfast, Northern Ireland, UK
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- Chittagong Eye Infirmary and Training Complex, Chittagong, Bangladesh
- Addis Ababa University, department of Ophthalmology, Menelik II Hospital, Addis Ababa, Ethiopia
- University of Gondar, Gondar, Ethiopia
- Dr. Shroff's Charity Eye Hospital (SCEH), New Delhi, India
- H.V. Desai Eye Hospital, Pune, India
- The First Central Hospital, Ulaanbaatar, Mongolia
- Shenyang He Eye Specialist Hospital, China.
- Lumiere Devine Eye Hospital, Lome, Togo
- Emory Eye Center, Atlanta, GA USA

LSHTM Principal Investigator: Dr William Dean PhD FRCOphth MEd MBChB BSc
Orbis Principal Investigator: Amelia Geary. MSc
Orbis Principal Investigator: Professor Nathan Congdon PhD MD

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. Talk to others about the study, including your training program Director, if you wish. Ask us if there is anything that is not clear or if you would like more information.

This form 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 on 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 your Ophthalmology Training Institution course.

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 this 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 your training institution and curriculum.

Study Overview

What is the study about?

Globally there are an estimated 36 million people who are blind and a further 207 million with significant visual impairment. Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in Low- and Middle-Income Countries (LMIC). Age-related cataract accounts for about one-third of this blindness. Manual small incision cataract surgery (MSICS) is a widely accepted, appropriate and affordable procedure with high quality visual outcomes.

It has been acknowledged however that the curriculum-integration of simulation is only in its infancy, as with many ophthalmology training programs around the world. There is no coherent, sustainable, standardized and educationally-underpinned regional training program employing simulation. Furthermore, there is no robust evidence or significant data testing the efficacy of simulation-based surgical education in cataract and glaucoma surgery.

Of the more than 230,000 ophthalmologists in the world, less than half perform cataract surgery. The shortage of expert eye surgeons in low and middle-income settings is well documented in the literature. This leads to a number of challenges, including the amount of time is available for training. There is a need to develop innovative, efficient, well-evidenced, and cost-effective strategies for ophthalmic training in the globally.

This is a prospective, single-masked education-intervention study of intense virtual reality (VR) simulation-based surgical education. The aim is to investigate whether VR simulation-based surgical education improves competence. All participants will receive the educational intervention of 'two-days intense VR simulation-based training'. This training is in addition to the trainees' normal current standard training, and not designed to replace it.

Why have you been chosen?

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

How many people are taking part in this trial?

We plan to recruit 60 trainees in total.

Procedures

What will we ask you to do?

Baseline assessment:

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

Further Baseline assessment:

We will show you some of the basics of the procedure of MSICS, and the performing of a procedure using simulation (artificial eyes). We will then invite you to perform three simulation MSICS procedures using artificial eyes, which we will record (these recordings will be anonymized).

Educational Intervention:

Once you are enrolled, you will receive clear instruction on how the timetable will run. The intervention is an intense virtual reality training program using the Orbis-FundamentalVR simulator.

Follow-up assessments:
We will revisit you at your Training Institution at 1 month after your enrolment to the study and training intervention. We will invite you to perform three further simulation MSICS procedures using model eyes (which again we will record and anonymize).

What is the educational intervention that is being tested?
The surgical education that is being is investigated is intense simulation-based surgical training. This involves an intense 2-day course. No patients are involved in this training. This training is not meant to replace standard training, but to augment it.

Benefits
What benefits are there to taking part in the study?
You will be offered free VR simulation-based surgical training.

Risks
What are the risks of taking part?
There are very low risks associated with participating in this study. You will be away from normal work and training for two days. No patients are involved in the assessments or training.

There is however no risk that this training will affect, or reflect on, your current training course marks, future employment, or be reported to your training program Director.

What will happen to the assessment recordings, interviews, feedback, and surgical outcomes data I give?
The video recordings will be made using the same blue latex-free gloves for all participants, using the same instruments, and the same standard recording equipment. They will also be anonymized so that none of your personal information will be identifiable. These recordings will be stored on an encrypted hard drive. Interviews will be recorded and transcribed, anonymized, and thematized: again, no personal identifiable information will be kept. Once this data is reported, none of your personal related information will be made available. Summarized, anonymized data will be including the placement of an anonymized data set in a data repository.

Are there any other alternative educational interventions available?
There is growing evidence that simulation-based surgical education is a valid way to augment surgical training. It is envisaged that in years to come, there will be further local, national, and regional opportunities to engage in this.

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 were not to 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?
If we find that intense simulation-based surgical training is better than none, we will publish this finding and envisage that it will lead to further funding for such training.

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. 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 funded this study?

The study is funded through Orbis International.

Who has reviewed the study?

This study was reviewed by the advisory panel of international cataract, ophthalmic surgical training, and education experts in India, UK, USA and South Africa.

Who is doing this study?

The study will be coordinated by Dr Will Dean who is an ophthalmology attending consultant who has a PhD from LSHTM and a MEd (Masters in Education) in Surgical Education at Imperial College London; a Fellowship of the Royal College of Ophthalmology (UK); over 20 years of experience in ophthalmology and training ophthalmologists in globally.

Contact Information

If you have any questions please ask us:

- if you have any questions about this study or your part in it, or
- if you have questions, concerns or complaints about the research

Dr. Will Dean at +44 7899 753 953 or will.dean@lshtm.ac.uk

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

Appendix 3. Training Intervention

Pre-Learning (one month in advance)

- Surgical video review

Pre-Course Assignment (one week in advance)

- Complete and record three full MSICS cases using the Philips MSICS model eye and following the steps of the OSSCAR (Appendix 4).
- Upload the 3 recorded simulated surgical procedures to the Cybersight platform

The Orbis-FVR Virtual Reality MSICS simulator has 19 steps in total. Currently, 10 steps are animated and 9 are interactive, as follows:

20. Patient Preparation – Animated Step
21. Conjunctival Peritomy – Animated Step
22. Paracentesis – Aminated Step
23. Formation of the AC – Animated Step
24. Anterior Chamber Maintainer – Animated Step
25. Marking the Scleral Incision – Interactive Step
26. Scleral Incision – Interaction Step
27. Sclerocorneal tunnel – Interactive Step
28. AC Entry – Interactive Step
29. CCC – Interactive Step
30. Hydrodissection – Animated Step
31. Mobilization of the nucleus – Interactive Step
32. Releasing the nucleus – Animated Step
33. Nucleus removal – Interactive Step
34. Cortex removal – Animated Step
35. IOL insertion – Interactive Step
36. IOL Dialling and Implantation – Interactive Step
37. Inspection of the wound – Animated Step
38. Closure of the wound – Animated Step

Course Overview

Participants must attend and successfully complete all sessions. All simulator tasks are to be completed in sequential order, in line with the course outline. A required score of 85 points for each interactive step must be reached reliably three times in a row to advance to the next step in the course.

For each step within the simulation the following is recorded:
Step Time - The total time spent on a step including ALL attempts.
Pass / Fail - The interpreted pass or fail result of the last attempt of the step.
Step score - Each step is scored between 0 and 100 points, based on user performance in completing the surgical objective, taking into account any adverse events.

- Adverse events –For each step, if triggered, all of the adverse events are recorded.
- No. of attempts - The number of attempts (inc. resets) of the step.

Course Content

- Each course will combine autonomous learning and live mentorship.

- Autonomous learning will consist of a series of 15-minute video presentations, which include:
    - Narrated demonstration video of specific VR step(s)
    - PowerPoint presentations
    - Instrument use demonstrations
- Live mentorship will be delivered in two ways:
    - Local mentor who provides in-person mentorship
    - International mentor from technical advisory group provides live tele-mentorship

Content hosting

- All content will be hosted on the Orbis Cybersight Learning Management System platform. Data will be randomized and anonymized by the Cybersight Program manager, who will not be involved in any other aspect of the research initiative.

Course delivery

Each day:

- Local mentor will facilitate introductions in each morning session. This will cover:
    - An overview of the day's training plan
    - Outlining the learning objectives for the day's training plan
    - Introduction of the content covered in the day's training plan
- Local mentor will also facilitate discussion and answer questions on autonomous content viewed in the morning and midday sessions
- Local mentor will provide periodic check ins throughout the day's session
- International mentor will provide tele-mentorship for the first hour of the 2-5pm session
- Trainees will do self-practice for the remainder of the afternoon session
- Each trainee will complete each interactive step on the VR simulator a minimum of 5 times with a reliability gate (3) and minimum score of 85
- Each trainee will complete at least 5 full cases on the VR simulator with a reliability gate (3) and minimum score of 85

Course outline

Day	Morning 8:00 – 10:30	Midday 11:00 – 1:00	Afternoon 2:00 – 5:00
Monday	Introduction Orientation to simulator. Review of animated steps 1-5	Marking the scleral Incision Scleral Incision Sclerocorneal tunnel	Mentored practice Self-Practice
Tuesday	Introduction Review CCC	AC entry Hydrodissection Releasing the Nucleus Nucleus Removal Cortex Removal	Mentored practice Self-Practice
Wednesday	Introduction Review IOL Insertion IOL Dialling and implantation	Inspection of the wound Closure of the wound	Mentored practice Self-Practice
Thursday	Introduction Review of entire SICS procedure.	Putting it all together: Full Cases	Mentored practice Self-Practice
Friday	Introduction Assessment and Scoring	Final Review	

Attendance to be recorded as follows:

- Confirmation of Three video uploads pre-intervention
- Simulator use and assessment logs
- Attendance records taken per daily session
- Confirmation of Three video uploads post-intervention

Appendix 4. MSICS Sim-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	**Scleral fixation**	No scleral fixation; inappropriate place; tissue trauma	Appropriate position of scleral fixation, but needs to re-grip. Mild tissure trauma	Good position of fixation, no need to re-grip, no trauma	
2	**Paracentesis**	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	**Viscoelastic insertion**	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	**Scleral incision**	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	**Scleral tunnel**	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	**Sclero-corneal tunnel**	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	**Corneal entry**	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	**Capsulotomy / Capsulorrhexis start**	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	**Capsulotomy / Capsulorrhexis completion**	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	**Hydro-dissection: Visible fluid wave and free prolapse of one pole of nucleus**	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	**Injection of visco-elastic**	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	**Prolapse of nucleus partially into AC**	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	**Nucleus extraction**	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	**IOL insertion**	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	
GLOBAL INDICES					
15	**Wound Neutrality and Minimizing Eye Rolling and Corneal Distortion**	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	**Eye Positioned Centrally Within Microscope View**	Constantly requires repositioning.	Mild fluctuation in pupil position.	The pupil is kept centered during the surgery.	
17	**Scleral and Corneal Tissue Handling**	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	**Intraocular Spatial Awareness**	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	**Overall Fluidity of Procedure**	Hesitant, frequent starts and stops, not at all fluid.	Occasional inefficient and/or unnecessary manipulations occur	Inefficient and/or unnecessary manipulations are avoided	
20	**Overall Speed of Procedure**	Case duration more than 15 minutes.	Case duration about 10-15 minutes.	Case duration about 5-10 minutes.	
				TOTAL	

Good Points: _____

Suggestions for development: _____

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

Appendix 5. Acceptability and Utility Survey & Questionnaire

What is your gender?

- Male
- Female
- Other

Level of experience:

- Novice
- Expert

Likert scale statements

1. I was comfortable using the VR simulator
2. I found the VR simulator user friendly
3. I was able to easily use the VR simulator
4. The VR simulator tutorials were helpful
5. I was able to navigate the VR program with ease
6. The VR simulator helped me gain a better understanding of the MSICS procedure
7. The VR simulator improved my knowledge of the MSICS procedure
8. The VR simulator improved my MSICS skills
9. I found the VR simulator hardware user friendly
10. I would recommend training on the VR simulator to others

Responses will be evaluated on a 5-point Likert scale anchored at '1=strongly disagree' and '5=strongly agree'.

User feedback – open ended questions

- What elements of the simulator were most useful? Which steps or resources?
- Which were least useful?
- What change or improvement to the simulator program would you recommend?
- Do you think the VR simulator has a place in cataract surgical training?
- Any other comments?

Pre- and Post-Intervention Confidence Ratings:

1> On a scale of 1-10, how confident are you in your ophthalmic surgical skills?
2> On a scale of 1-10, how confident are you in MSICS skills?
3> What has impacted this confidence? [open question]

Appendix 6. Proposed Budget

Description	Unit cost (USD)	Quantity	Total (USD)
Research Project Costs			
Artificial eyes	250	60	15,000
Shipping for eyes	1	3000	3,000
Customs fees for eyes	14.7	30	441
AV/IT for video recording	5	100	5,000
Cost of grading (outsourced)	5	360	1,800
Course build out on CS	2,500	1	2,500
Cost for data analysis	1	5000	5,000
Publication costs	1	3000	3,000
Technical support	700	12	8,400
Research Project subtotal			**44,141**
Country Support Costs			
Country team support Bangladesh	8,460	1	8,460
Country team support Ethiopia	12,840	1	12,840
Country team off support India	8,063	1	8,063
Country office subtotal			**29,363**
VR Kit Shipping Costs			
Custom fees	3000	6	18,000
Shipping fees	TBD	7	15,000
Shipping Subtotal			**33,000**
TOTAL			**106,504**