THE OPHTHALMIC LEARNING AND IMPROVEMENT INITIATIVE IN CATARACT SURGERY (OLIMPICS) TRIAL: RANDOMISED-CONTROLLED TRIAL COMPARING INTENSE SIMULATION-BASED SURGICAL EDUCATION FOR CATARACT SURGERY TO CONVENTIONAL TRAINING ALONE IN EAST AND SOUTHERN AFRICA

STUDY PROTOCOL

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This protocol describes the Intense Simulation-Based Ophthalmic Surgical Education vs. Conventional Training Alone study, 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 investigator and trainer, Dr Will Dean: will.dean@lshtm.ac.uk

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

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Glossary of Abbreviations

ACGME	Accreditation Council for Graduate Medical Education
BCPB	British Council for the Prevention of Blindness
CBM	Christian Blind Mission
CEHI	Community Eye Health Institute
COECSA	College of Ophthalmology of Eastern Central & Southern Africa
COSECSA	College of Surgery of Eastern Central and Southern Africa
CPD	Continuing professional development
ESSAT	Eye surgical skills assessment test
FRCOphth	Fellow of the Royal College of Ophthalmologists (UK)
GCP	Good Clinical Practice
GLASS	Glaucoma Simulated Surgery
GMC	General Medical Council
IAPB	International Agency for the Prevention of Blindness
ICEH	International Centre for Eye Health
ICO	International Council of Ophthalmology
ITT	Intention-to-treat
KCMC	Kilimanjaro Christian Medical Centre
LSHTM	London School of Hygiene & Tropical Medicine
LMIC	Low & middle income countries
MCQ	Multiple choice question examination
MEd	Masters in Education
MMed	Masters in Medicine
MURHEC	Mbarara University & Referral Hospital Eye Centre
OASIS	Objective assessment of skills in intra-ocular surgery
OLIMPICS	Ophthalmic Learning & Improvement Initiative in Cataract Surgery
OSACSS	Objective structured assessment of cataract surgical skill
OSCAR	Ophthalmology Surgical Competency Assessment Rubric
OSSCAR	Ophthalmic Simulated Surgical Competency Assessment Rubric
PCR	Posterior capsule rupture
PI	Principal investigator
RCOphth	The Royal College of Ophthalmologists, UK
RCT	Randomised controlled trial
SDP	Sustained deliberate practice
SICS	Small-incision cataract surgery
SOS	Simulated ocular surgery
SSA	Sub-Saharan Africa
STU	Surgery Training Unit
UCT	University of Cape Town
VA	Visual acuity
VL	Vitreous loss
WHO	World Health Organisation

Keywords

Simulation, Surgical Education, Training, Africa, Cataract, Glaucoma, Ophthalmic

General Information

Project Title

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in Southern East Africa.

Identifying numbers
LSHTM Application Reference Number: **11795**
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Mbarara University REC: **13/06-17**
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- Kilimanjaro Christian Medical Centre (KCMC), Moshi, Tanzania.
- Department of Ophthalmology, University of Zimbabwe, Churchill Avenue, Mount Pleasant, Harare, Zimbabwe.
- Division of Ophthalmology, Groote Schuur Hospital and Red Cross Children's Hospital, University of Cape Town (UCT), South Africa.

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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- Queen Elisabeth Diamond Jubilee Trust (London., UK)
- Orbis International (New York, USA)
- L'Occitane Foundation (Paris, France)

Study Summary

Title

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

Design

Prospective, single-masked randomised controlled education-intervention trials of intense simulation-based surgical education versus current standard conventional training alone, of ophthalmologists-in-training in five East and Southern African countries.

Two separate trials:
(1) OLIMPICS*: cataract surgery simulation training vs conventional alone; and
(2) GLASS**: glaucoma surgery simulation training vs conventional training alone.
**Ophthalmic learning & improvement initiative in cataract surgery.*
*** Glaucoma simulated surgery*

Aims

To investigate whether enhanced simulation-based surgical education improves competence, knowledge, surgical outcomes, and confidence.

Intervention

All participants will (by the end of the study) receive the educational intervention of 'six-days intense simulation-based training' at the Surgical Training Unit, University of Cape Town. The intervention groups will receive this training at week one; and the matched controls after a period of one year. The 'intervention training' specifically is a six-day intense course of lectures, small-group teaching, practical surgical simulation training, videos, and assessments. ***This training is in addition to, and an enhancement of the trainees' normal current standard conventional training, and not designed to replace it.***

Control Training

Control, or standard/conventional, training will be variable between countries, training institutions, and individuals. Typically, training involved a weekly timetable of clinics (general or specialist), theatre sessions (cataract, or specialist), research, and teaching. This 'control' training will be monitored for the first three months of all participants in terms of numbers of clinical and surgical sessions.

Outcome measures

Assessments and follow-up time points are at baseline (month 0, and week 1), 3 months, 12 months and 15 months.

Primary outcome measure*:* mean global competency assessment score at twelve-months post-training intervention:

OLIMPICS Trial

The primary outcome will be the procedure-specific repeated measures analysis of OSCAR score of three live SICS surgical procedures performed at 12-months.

Secondary outcome measures:

- OSSCAR(Simulation) assessments at 3-months for the OLIMPICS Trial; mean value of three replicates, performed in the same manner as per the primary outcome measure.
- OSSCAR(Simulation) assessment at 12-months for the OLIMPICS Trial; mean

value of three replicates, performed in the same manner as per the primary outcome measure.

- The number of live surgical procedures (SICS) will be recorded for twelve months between 0-months and 12-months.
- OLIMPICS Trial (SICS): Three further 'live' cataract (supervised) surgery procedures on patients at 12-months. These will be filmed (using a Zeiss OPMI operating microscope) and scored in the same masked manner using the SICS OSCAR.
- OLIMPICS Trial (SICS) – for a period of twelve months (for all SICS surgical procedures performed):
    - Day 1 Visual Acuity (un-corrected & best corrected) – LogMAR (equivalent)
    - Peri-operative Complications (posterior capsule rupture)

Further Exploratory Analysis:

- Surgeon confidence rating scores (Assessed at baseline, three and twelve months)

Population

The simulation surgical training will be conducted in Cape Town, South Africa. Trainees will have follow-up assessments in their home training institutions in the University of Nairobi, Kenya; Makerere University, Kampala, Uganda; MURHEC, Mbarara, Uganda; KCMC, Moshi, Tanzania; and University of Zimbabwe, Harare.

Patient cataract and trabeculectomy surgical outcome data will be collected by participants as per normal good clinical practice. This data will be summarised over 15 months, and a summary report sent to the PI with no personal patient identifiable information.

Eligibility

OLIMPICS Trial Inclusion criteria for trainee:

1. Trainee ophthalmologist in year one or two of MMed course of collaborating Institution
2. Agree to be randomly allocated to training 'Intervention' or 'Control' groups
3. Agree to, and sign agreement to not discuss, or share in any way, any of the details of the educational intervention for the first three months
4. Have performed zero complete SICS procedures
5. Have performed part of <10 SICS procedures
6. Agree to baseline assessment, assessment at three, twelve and fifteen months.
7. Agree to monitor, anonymise, and report all surgical outcomes of all patients operated during the one year period

OLIMPICS Trial Exclusion criteria:

1. Performed one or more complete SICS procedures, or parts of ten or more separate procedures

Duration

The anticipated overall project duration is about three years. The fieldwork will take about one and a half years.

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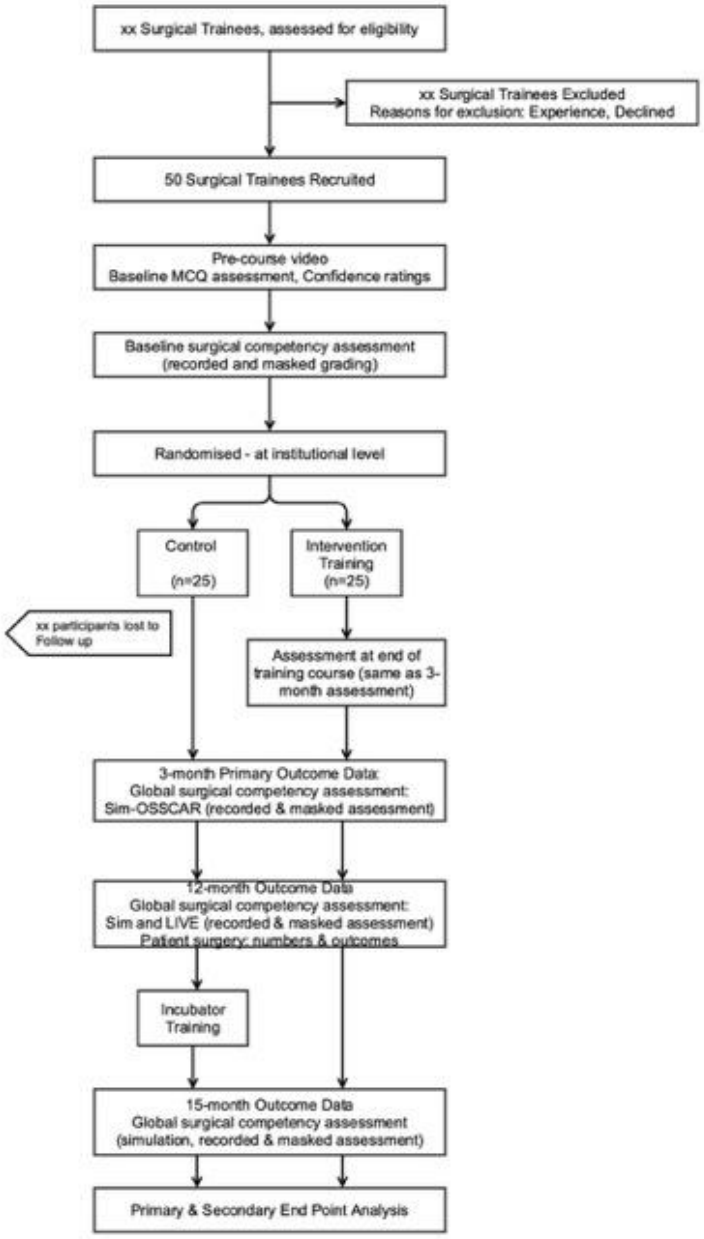
Study Outline Reference Diagram



Executive Summary

There is a huge need to perform high volumes of surgery in sub-Saharan Africa, to tackle the backlog of avoidable blindness. There is a great need to train many eye surgeons safely, efficiently, effectively, and to an acceptable level of competence. There is also a need to maintain and improve the quality and outcomes of surgery.

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.

We will test the hypothesis that intense modular simulation-based ophthalmic surgical education is superior to conventional training for the initial acquisition of competence.

Pilot studies have been conducted in Malawi, Uganda, and South Africa to develop, test and refine aspects of modular simulation-based ophthalmic surgical training in cataract and glaucoma surgery. Assessment tools have been developed and validated for use in this simulation-based training (see Appendices 3a and 3b). Subsequent to these pilot and validation studies, we are now able to test the efficacy of focussed modular simulation-based ophthalmic surgical training in two separate parallel-group randomised controlled trials.

We will conduct an RCT of intense simulation-based ophthalmic surgical education for training ophthalmologists in the procedures for cataract: the two leading cause of blindness in sub-Saharan Africa. Trainee eye surgeons will be randomised to the 'intervention' of focussed simulation-based surgical training (in addition to, and as an enhancement to conventional training), or to the 'control' group of current conventional training alone. The 'control' group participants will receive the same simulation training, only after a period of one year. Follow-up assessments will measure whether the trainees have gained in surgical competence (objectively assessed using a specific and validated grading score), knowledge, their perceived confidence as a surgeon, and in terms of the benefit to their patients (the quality and quantity of surgery performed).

All the training within the 'educational intervention' of this study will be performed using simulation. There is no testing or surgical training on patients within the study educational-intervention of both training trials. The only times when patients are indirectly involved is entirely as part of standard, regulated, and supervised clinical training within a Nationally accredited and registered ophthalmology training programme. When three anonymised and non-identifiable recordings of cataract surgical procedures are video-recorded (at twelve months), patients will be informed of the planned recording, and invited to sign a standardised informed consent as for any clinical image recording within standard clinical practice.

Background

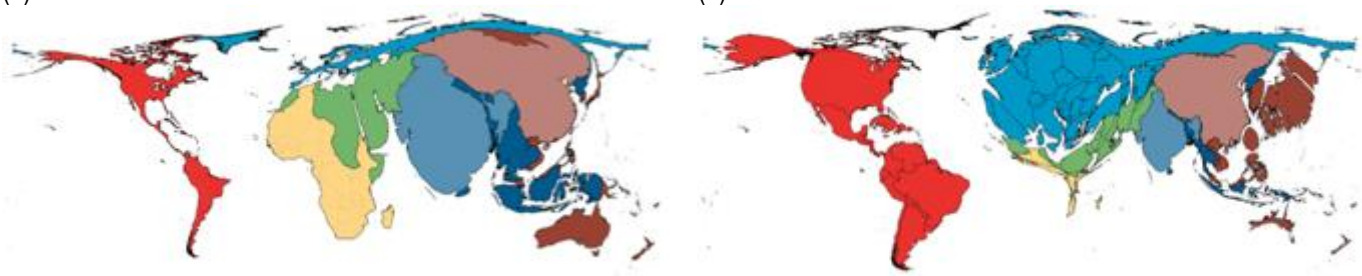
The burden of cataract and glaucoma in sub-Saharan Africa

Globally there are an estimated 36 million people who are blind and a further 217 million with moderate or severe visual impairment.[1] Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in Low and Middle Income Countries (LMIC). Sub-Saharan Africa (SSA) has the highest prevalence of blindness of any region at 9% in >50 year olds. Age-related cataract accounts for about half this blindness. Small incision cataract surgery (SICS) is a widely accepted, appropriate and affordable procedure with high quality visual outcomes.[2-5]

Together, cataract and glaucoma account for two-thirds of blindness in SSA, and both require surgical management. However, SSA is the region with the lowest number of ophthalmologists per capita, with about 2.6 per million, compared to 16.7 per million in Europe and the North America.[6] There is a striking mismatch between the burden of blinding disease and the availability of skilled staff to address it within SSA (Figure 1). The region urgently needs an increased number of proficient eye surgeons to counter avoidable blindness from cataract and glaucoma.[7]

Figure 1: Density equalised cartograms showing: (a) prevalence of blindness by WHO region, and (b) number of practicing ophthalmologists by country.[8]

(a) (b)



For example, the cataract backlog in SSA is approximately 15,000 operations per surgeon. Relatively few ophthalmologists perform trabeculectomy. There are around 500 people per ophthalmologist already blind from glaucoma, and the number with advanced glaucomatous disease who potentially warrant surgery is considerably more.

Surgical training in Sub-Saharan Africa

Of the more than two hundred thousand ophthalmologists in the world, only a very low proportion are trained and work in sub-Saharan Africa (SSA).[9] The shortage of ophthalmologists in SSA is well documented in the literature.[10] This leads to several challenges, including the amount of time that is available for training. There is a need to develop innovative, efficient, evidenced-based, and cost-effective strategies for ophthalmic training in the region, and globally.

A major review in 2015 by the International Agency for the Prevention of Blindness (IAPB) resulted in the publication of the IAPB Training Institutions Database. Within this there are listed ten ophthalmology training institutions in nine Francophone SSA countries, two in two Lusophone countries, and thirty-nine ophthalmology training programmes in ten different Anglophone African countries.[11] The total capacity of trainees within the ophthalmology training programmes in the College of Ophthalmology East Central and Southern Africa (COECSA) region was 64 (in total, for all years). However, this capacity does not necessarily equate to or reflect the numbers currently being trained, and the IAPB concludes that "more needs to be done to assess and address the strength of individual training institutions as well as understand why some institutions are regularly over-subscribed..".[11]

Within the COECSA region, the duration of training programmes varies from three years (in Kenya, and Uganda), to four years (in Ethiopia, Malawi, Tanzania, and Zambia). Ophthalmology training programmes in COECSA follow a competency-based curriculum. Trainees' timetables are often divided into 'semesters' of three to six months, where a particular domain of ophthalmology is focused upon. Training in cataract surgery generally starts towards the end of the first year, and training in glaucoma surgery (which is more complex), begins towards the end of the third year. Aside from the overall need in Africa to train greater numbers of proficient ophthalmologists, there are a limited number of consultant ophthalmologists / surgeon trainers within training institutions, with only limited time available for provision of training. With ever increasing demands on ophthalmology training programmes, most have reached capacity. There is a current pressing need to develop and validate new innovative approaches to deliver more effective, efficient and safer surgical ophthalmology training.

As a consequence of this shortage of trained ophthalmologists in SSA, a specific paramedical cadre has developed. 'Cataract surgeons' were originally described in 1987 [12], and over the past three decades training institutions and programmes have been established for ophthalmic clinical officers (OCO), or non-physician cataract surgeons (NPCS), in Malawi, Kenya and Tanzania. Currently seventeen countries in SSA employ NPCS, including Malawi and Uganda. However, two thirds of all the NPCS in SSA work in only three countries: Ethiopia, Kenya and Tanzania.[13] This current study will not include the cadre of OCO/NPCS, simply for the reason of standardisation; however this model of surgical training and the data from this study may provide great benefit to NPCSs in the future.

This study will include a systematic review of ophthalmology training in SSA. Data will also be collected for a focussed situational analysis and trainee survey of ophthalmic surgical training.

Cataract Surgery

The procedure of sutureless scleral-tunnel small-incision cataract surgery (SICS) is the most commonly performed cataract surgery procedure in SSA, and is the 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 small-incision cataract surgery (SICS) are comparable. [3 4 14 15] SICS is an appropriate, safe, and affordable technique.

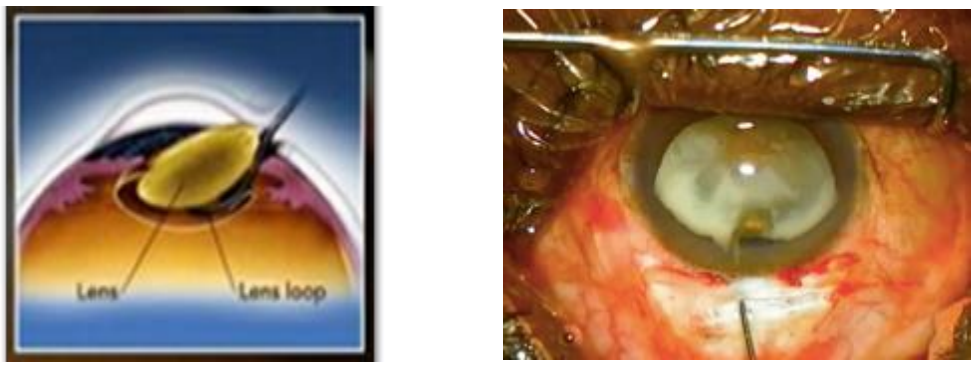


Figure 2. The cataract is removed in SICS.

The live surgical procedure can be viewed for small-incision cataract surgery on YouTube: https://www.youtube.com/watch?v=LszyZqqR5v4

The Iowa ophthalmology wet laboratory curriculum for teaching and assessing cataract surgical competency was described after a systematic review of literature and selection of best practices.[16] An interesting finding of this study was that several residency programmes had relied on the

outsourcing of cataract surgical training to "out-of-state or out-of-country institutions". This suggestion may or may not be appropriate for ophthalmology training institutions SSA; however, as part of this study, we will be testing the utility of setting up simulation surgical training facilities. These may be within institutions, or perhaps available regionally for several training institutions. In the USA, as well as the UK, the use of surgical wet-labs / dry-labs is now standard. A few centres in SSA do use simulation wet/dry-labs for surgical training, although perhaps not in a structured way with trainees often being self-directed.

Outcomes of Cataract Surgery

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.[17] 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.[18] Tools for monitoring the outcomes of cataract surgery have been developed, and measurements included are: VA and complications.[19]

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%.[14 15 20] The WHO recommends to aim for a complication rate (PCR rate) of less than 5%.

Surgical Education and Simulation

It is of course of benefit to patients, trainees and trainers that 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 the trainee 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.

A systematic review of sixteen randomized controlled trials of simulation of techniques used in laparoscopic procedures concluded that there was a 'positive impact of simulation on operative time and predefined performance scores, however these alone are insufficient to demonstrate transferability of skills from the laboratory to the operating room'.[21]

A critical review of simulation-based medical education suggested twelve areas of best practices and features,[22] many of which have also been identified by other educational theorists as presented earlier. These twelve features and best practices included feedback, deliberate practice, curriculum integration, outcome measurement, simulation fidelity, skill acquisition and maintenance, mastery learning, transfer to practice, team training, high-stakes testing, instructor training, and educational and professional context. These twelve educational features are built into this current study.

Much of the initial literature of the utility of simulation in surgical training is in the medical domain of laparoscopic surgery.[23 24] This is important to emphasise, as the methodology used in these studies provides an excellent foundation for current and future ophthalmology simulation-based surgical education research.

There are several challenges in surgical training. As Prof Roger Kneebone explains, "demands for patient throughput are increasing, while reductions in work hours mean that trainees' opportunities for hands-on experience have been curtailed".[25] These challenges are global, and in Sub-Saharan Africa the demand for patient throughput is enormous for all healthcare professionals: trainees and trainers alike. Kneebone continues to argue that if "adequate experience can no longer be gained wholly through operating, effective adjuncts must be found. Simulation offers an environment in which learners can train until they reach specified levels of competency".

In a review paper on the features of medical simulators, it was illustrated that high-fidelity medical simulators facilitate learning in the right conditions. These include repetitive practice, providing feedback, curriculum integration, having a range of difficulty level, and having multiple learning strategies. The importance of individualized learning; where trainees have reproducible, standardized educational experiences and are active participants and not merely passive bystanders, was also highlighted.[26]

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,[26] however this has not yet been comprehensively proven for ophthalmic surgical training.[27]

Simulation in Ophthalmic Surgical Training

The College of Ophthalmology of Eastern Central and Southern Africa (COECSA) has adopted a competency-based curriculum for ophthalmic trainees in the region. There are several learning domains, one of which is surgical skills. Of the seventeen separate surgical skills to be learnt, the very first is for 'Simulation and Wetlab'.[28] This illustrates the importance placed within COECSA on the use of simulation in surgical training. It has been acknowledged however that this curriculum-integration is only in its infancy, as with many ophthalmology training programmes around the world. There is no coherent, sustainable, standardised and educationally-underpinned regional training programme employing simulation. Furthermore, there is no robust evidence or significant data testing the efficacy of simulation-based surgical education in cataract and glaucoma surgery.

As for most other surgical specialities, the use of simulation is a relatively recent addition to surgical education. In ophthalmology, as with other medical specialities, there has been a focus and fascination on attractive and highly sophisticated technology models of simulation training.[29] There is an argument to be made that high-tech does not always imply high-fidelity simulation. Certain aspects of a procedure are almost impossible to simulate using computer simulation models. Low-tech models of ophthalmic simulated surgical training have been used for decades, and recent developments include the use of artificial eyes.

A difficult and yet crucial aspect of simulation in surgical education has been identified is the predictive validity: the transfer of simulated skill to clinical practice in the operating theatre. However, it has been consistently demonstrated that skills acquired on simulators do transfer to the operating room, and proficiency-based training maximises this benefit.[30] Although there is some evidence, and it is implicitly accepted, more and robust educational research is needed to explicitly prove the predictive validity of simulation in ophthalmic surgical education.

Artificial Eyes

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.[31]

Figure 4: The artificial eyes that were used in the surgical training programmes in Malawi and Uganda, as part of the pilot studies ahead of this current project.

www.phillipsstudio.co.uk

'Kitaro DryLab' is a tool to teach and learn some steps of cataract surgery, including the capsulorrhexis and sclero-corneal tunnel construction of SICS. It is mobile, and can be used on a desktop, and without the use of an operating microscope (Frontier Vision Co. Ltd., Hyogo, Japan).

Computerised simulators or virtual-reality models.

The use of computerized simulation models have been validated for cataract[32-34] and retinal surgery.[35] Three computerised 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).[36]

A simulation-based performance test and certification for 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.[37] Other assessment tools used in ophthalmic surgical education will be discussed in the next section.

HelpMeSee (New York, USA) are in the final stages of developing a full-immersion surgical training simulator for the use within high capacity surgical education programmes for small-incision cataract surgery.[38]

The OLIMPICS Trial focuses on the utility of low-cost, high-fidelity simulation within a bespoke educational package of curriculum, assessment, practice, and feedback.

Assessment tools in ophthalmic surgical training.

Equally, if not more important than the selection of substitutes in the development of a simulation training curriculum for ophthalmic surgical training, is the choice of the right assessment tool to evaluate the fidelity, reliability and validity of the training approach.

As post-graduate surgical education has changed over the past decade to a competency-based model, surgical training programmes have been directed by the Royal Colleges and General Medical Council (GMC) in the UK, Surgical Colleges in Africa, and the Accreditation Council for Graduate Medical Education (ACGME) in the US, to provide evidence of the attainment of competence by trainees.

For this, training institutions and programmes need valid competency assessment tools. Several such tools have been developed for surgical training in the field of ophthalmology. Validation of the use of artificial eyes and associated training assessment tools are important, to determine their use as an objective and reliable training and assessment of surgical competence in ophthalmic surgical training. Much of the work on validation of simulation competency assessment tools related to this study, have been completed in pilot studies conducted by Will Dean and several of the co-applicants in Uganda, Malawi and South Africa over the past two years.

Ophthalmic surgery competency assessment tools include the OSACSS (objective structured assessment of cataract surgical skill), developed as an objective performance-rating tool for phacoemulsification cataract surgery.[39] The ESSAT (eye surgical skills assessment test) is a three-station wet laboratory surgical skills assessment course was developed for ophthalmic trainees in the USA.[40] [41]. The OASIS (objective assessment of skills in intra-ocular surgery) was developed in Harvard, Boston in 2005.[42] The aim was to develop an objective ophthalmic surgical evaluation protocol to assess surgical competency and improve outcomes – developed specifically for phacoemulsification cataract. The main purpose of OASIS is the direct observation of live surgery, and surgical assessment.

OSCAR (ophthalmology surgical competency assessment rubric) origins

An assessment matrix (Ophthalmology surgical competency assessment rubric – OSCAR) for "live" ocular surgery (i.e. on patients) has been developed and validated by the International Council of Ophthalmology (ICO).[43] These OSCARs (Appendices 3c and 3d) were originally based on the OSACSS, however expanded by creating a set of behaviourally-anchored scoring matrices that precisely and explicitly define what is expected for each step. The rubric was based on a modified Dreyfus scale (novice, beginner, competent),[44] as trainees were not expected to become experts during training.

For the purpose of this research project, this template was selected and re-designed an ophthalmic simulated surgical competency assessment rubric (OSSCAR(simulation)) for two of surgical techniques on artificial eyes (Appendices 3a and 3 b).

Existing Simulation-Based Surgical Training and Assessment in Ophthalmology: Validity and Research

In a major systematic review, a team from Denmark screened over a thousand papers, and studied one hundred and eighteen trials involving simulation-based training or assessment of ophthalmic surgical skills among health professionals.[27] They correctly state 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 patient-related outcomes. A lot more, and more rigorous, educational research investigating the validity, reliability and efficacy of simulation-based ophthalmic surgical training is needed.

Ophthalmology Simulation-Based Surgical Training Pilots in SICS and Glaucoma Surgery: Development of the OLIMPICS Study and GLASS Trial Interventions

Over the past three years, we have conducted six separate pilot training courses in Uganda, Malawi, and South Africa. As part of these, two-day to one week modular simulation-based training courses and curricula were designed and conducted. Participants were trained using different modalities, and various simulation techniques, including artificial eyes. The courses in Malawi and South Africa were for cataract surgery, and the courses in Uganda for trabeculectomy.

Development of the Training Curriculum

Pilot training course timetables and curriculum aimed to be a comprehensive intense training in either SICS (Malawi and South Africa pilots), or trabeculectomy (Uganda pilots). Specific elements of the courses included: basic sciences, epidemiology, surgical procedure and complications, numerous practical simulation surgical training tasks, public health screening, and clinical governance of monitoring outcomes of surgery. Feedback was obtained and recorded during group discussions, semi-structured interviews (which were recorded, transcribed and thematised), and formal feedback.

There were 29 participants in the six pilot courses. All aspects of the training courses scored either 4 or 5 out of five in feedback evaluation, except for one trainee scoring 3/5 for 'experience of using model eyes' in Uganda and one trainee scoring 3/5 for 'basic sciences' in South Africa.

Qualitative analysis of the semi-structured interviews revealed five themes that trainees valued with respect to simulation-based surgical education. These were patient safety, practical skills, ease & efficiency, transference to theatre, and the building of confidence.

This work has led up to this current protocol, and the current detailed and robust randomised controlled trials. The curriculum piloted in Malawi, South Africa, and Uganda has been refined into the detailed timetable/curriculum as follows (see also the training programme timetables on pages 30 and 31):

Table 1: Training Course Curriculum & Objectives

Pre-Course	• Formal baseline multiple-choice test of knowledge of basic and clinical sciences • Video of procedure (SICS or Trabeculectomy) • On-line basic and clinical sciences lectures (anatomy, physiology, epidemiology, surgery)
Course Curriculum	• Video of procedure (SICS or Trabeculectomy) • Epidemiology & Burden of Disease • Basic microsurgical skills (suturing) • Learning theory • Learning & Assessment tools • Screening and pre-operative assessment • Surgical procedure specifics & practice

	• Complications and how to manage them • Post-operative care and monitoring (audit) of outcomes
Post-Course	• Individualised plan for sustained-deliberate-practice, including: • Weekly practice of simple simulation techniques. • Once monthly practice of SOS on artificial eyes with recording of procedure, compression of video file, and encrypted CyberSight upload for evaluation and feedback (email monthly, and a phone/Skype call at one and two months) • Provision of a basic set of surgical instruments, 4 artificial eyes & 1 mount, consumables (blades, needles, syringes)

Economics of Surgical Education

A review of surgical training in the COSECSA (College of Surgeons of Eastern Central & Southern Africa) region in 2011 showed a range of costs for tuition per trainee per annum from US$1,800 to $11,500.[45] There are direct costs of tuition fees, as well as indirect costs of extra time taken in theatre or clinics. These extra direct and indirect costs make it challenging to make an accurate determination of total costs. Furthermore, tuition fees and living expenses change over time. In 2015 the International Agency for the Prevention of Blindness (IAPB) estimated the total mean cost (fees and living costs) for training an Ophthalmologist in Africa is US$43,484; with an extra $28,000 needed for basic equipment to make the new graduate productive.[11]

There are several different indicators for the health economics of training and education. These will be explored in the context of cataract and glaucoma surgery in SSA.

Cost is an issue with simulation training in ophthalmology. An analysis in the USA showed cost-reductions and savings of tens of thousands of US Dollars' for residency training programmes using ophthalmic surgical simulators[46]. However, the initial capital expenditure of these high-tech computerised simulators may be prohibitive, especially for smaller training programmes.

In this current study, we will be focusing on the use of bespoke high-fidelity, low-tech yet affordable and sustainable models of ophthalmic simulation-based surgical education (see Figure 5).

Figure 5. Pilot ophthalmic simulation-based surgical training courses in Malawi & Uganda

Costs of the study intervention (intense simulation-based surgical training) will be assessed in terms of capital costs, instruments, consumables, educational materials, time (faculty time, and trainees' time away from work), and incidental costs (local transport, accommodation etc.). This will be added to a more detailed incremental cost effectiveness analysis.

Rationale

There is a huge need for eye surgery. In Sub-Saharan Africa alone, there are an estimated 4,8 million people who are bilaterally blind, and an estimated 21.4 million who are visually impaired. About 80%of this blindness and visual impairment is avoidable. The ratio of eye surgeons to population in SSA is 2.6 per million.[6] If there was a goal to treat all the cataract eyes in people who are blind or vision impaired, then each ophthalmologist would have a personal backlog of an average of 15,000 cataract surgeries to perform. Glaucoma may be treated by surgery as a first line of management, rather than topical medications (eye drops). If this were the case, then each ophthalmologist would have a backlog of well over 500 surgical trabeculectomies to perform.

There is a huge need to train eye surgeons. Training opportunities and the number of trainers are limited. Trainers' time is limited. Surgical training needs to be accelerated, be more efficient, and be made safer.

In parts of the world, eye surgeons may be emerging from programmes not necessarily fully trained. A recent survey of ophthalmology training programmes in the USA illustrated that in final year residents, that 71.4% had performed <100 cataract surgeries, and 88.6% had performed <10 trabeulectomies.[47] A survey of ophthalmology residents in China showed that the median number of cataract surgeries performed was zero.[48]

Simulation-based surgical education 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.[26] however this has not yet been robustly tested or proven for ophthalmology surgical training.[27]

As previously described, pilot training courses using intense simulation training for trabeculectomy and SICS have recently been conducted in Mbarara (Uganda), Blantyre (Malawi), and Cape Town (South Africa) by the Principal Investigator and local Heads of Departments (see Figure 5). This involved specially designed modular curricula with repeated simulated practice of the components of procedures on artificial eyes and other "models". Performance was assessed using 'ophthalmic simulated surgical competency assessment rubrics' (OSSCARs). Feedback from trainees was very positive in terms of competence, perceived benefits of focused simulation-based training and the enabling of deliberate practice.

The scope of this PhD study lies within a much broader context. The ultimate goal is to reduce the prevalence of avoidable blindness. One important aspect of this goal is human resource development, within which lies the education and training of eye surgeons. This PhD is aimed specifically at testing the efficacy of the intervention of simulation-based surgical education as an enhancement to conventional training.

Objectives

Overall Objective

The hypothesis this study will test is that enhanced modular simulation-based ophthalmic surgical education together with conventional training, is superior to standard conventional training alone, for the acquisition of competence.

The overall purpose of this research is to develop the evidence base to guide enhanced, high-quality skills development in ophthalmic surgical training in SSA which could then be scaled-up to include other regions. The evidence-base could subsequently be used to inform the planning and implementations of ophthalmology surgical training programmes globally. The main question for both trials is whether adding simulation-based surgical training to conventional training results in improved acquisition of high-quality skills. The outcomes will include measures of surgical competence, surgical quality, confidence and knowledge.

Specific Objectives

1. To conduct the OLIMPICS Trial: a randomised controlled trial for SICS; whether simulation-based surgical incubator training leads to improved acquisition of high-quality surgical skills, with objectively assessed competence, confidence, knowledge, and surgery-specific outcomes and surgical numbers.

Methodology

Design Summary

This research programme will involve a randomised controlled single-masked, parallel-group, 'educational-intervention' trials:

- OLIMPICS Trial; Small Incision Cataract Surgery (SICS)

The trial will have two arms: (a) 'simulation-based educational intervention' and (B) 'standard' control training. They will be randomised to one of the two arms. Surgical competency will be assessed at baseline, 3-months, 12-months and 15-months. The primary outcome will be the 12-month simulation score.

Study Setting

This is a multi-centre and multi-country study. We will enrol trainee ophthalmologists (doctors who have graduated from medical school, and are currently undergoing specialist training) from six ophthalmology training programme institutions in East and Southern Africa: Nairobi, Kenya; Moshi, Tanzania; and Kampala and Mbarara, Uganda; and Harare, Zimbabwe. The simulation-based 'incubator' training will be conducted at the Surgery Training Unit, Community Eye Health Institute (CEHI), University of Cape Town, South Africa.

Study Duration

The training will be conducted during late 2017, 2018, and 2019. Follow-up of the participants' surgical outcomes and output is expected to be completed by the end of 2019.

Study Participants

Current trainees (between October of 2017 and December 2018) in all five training institutions will be selected according to the inclusion and exclusion criteria, and randomised. Participants will be recruited from ophthalmology training programmes in Nairobi (Kenya), Moshi (Tanzania), Makerere (Uganda), Mbarara (Uganda), and Harare (Zimbabwe) during visits by the PI.

Inclusion / Exclusion Criteria

OLIMPICS Trial (SICS):

Inclusion Criteria

- Zero complete SICS procedure performed
- Parts of less than ten separate SICS procedures performed
- Trainee ophthalmologist in year one or two of MMed course of collaborating Institution.
- Agree to be randomly allocated to 'Intervention' or 'Control' training groups
- Agree to, and sign agreement not discuss, or share in any way, any of the details of the educational intervention for the first three months
- Agree to baseline assessment, assessment at three, twelve and fifteen months; Agree to monitor, anonymise, and report all surgical outcomes of all patients operated during the fifteen-month period (month 0 to 12)
- Good English language skills

Exclusion Criteria

- One or more complete SICS procedures performed

- Performed parts of ten or more separate SICS procedures

Informed Consent

Potential participant trainees will be informed of the training opportunity and the study. Heads of Department will be involved in the process and are co-applicants to this study submission.

Trainee participants will be informed in detail about the nature of the education-intervention study; that the training offered in the 'intervention' arm offers no official qualification and will not be recorded in their national training evaluation; that trainees in the 'control' arm will be offered exactly the same simulation-based education opportunity in Cape Town after an initial study period of one year. All surgeons participating will be free to leave the study at any time. See Appendices 1a to 1d for detailed Information and Consent Forms.

Permission will be sought from the Head of Department for trainees to be enrolled, and take time away from work duties to be involved in the training. Further ethical considerations are discussed in detail on page 40.

Withdrawal Criteria

Trainee participants, in either the 'intervention' or 'control' groups 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. If participant withdrawal rates impact the sample size needed in either study, then a reserve training institution will be recruited.

Pre-randomisation baseline assessment

Following consent, participant trainees will be evaluated in-country. This will include evaluation of previous surgical experience, and introduction to the ICO OSCAR.[49] 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 OSSCAR). This provides the baseline score for all participants: intervention and control. A standardised quiz/test will also be administered: 30 multiple choice questions on basic sciences, and the basic diagnosis and surgical management of either glaucoma or cataract.

Randomisation

Sequence generation

The randomisation sequences will be computer generated and administered centrally by a statistician based at the LSHTM who is independent of all other aspects of the trial. We will use block randomisation (block size 2 or 4), with a separate sequence for each recruitment site, 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.

Randomisation Implementation

Trainees within the same training institution, who have met the appropriate inclusion and exclusion criteria for the OLIMPICS Trial (as detailed above), will be eligible for randomisation to the 'intervention' or 'control' arm. Each group of four trainee participants will be agreed by the Training Programme Director / Head of Department.

For example:

A block of four potential participants are identified in Uganda for the OLIMPICS trial. These are the 7th, 8th, 9th, and 10th participants in the trial overall. The statistician will be asked to randomly allocate participants using a randomly generated code for a block of four. Physically, in Uganda, the numbers 7, 8, 9, and 10 will be printed on cards and placed in a bag. Participants will be invited to pick one number from the bag. The randomisation sequence from the statistician will then be electronically unveiled: for example:

OLIMPICS 7	Control
OLIMPICS 8	Intervention
OLIMPICS 9	Intervention
OLIMPICS 10	Control

Trial Arms

A) Simulation-based training "intervention" arm:

The participants randomised to 'intervention' arms of the two trials will be invited to Cape Town for the six-day intense simulation-based educational intervention course.

Phase 1:

We will provide a safe, focused, appropriate, educationally-validated and already piloted intense six-day residential training programme based at the Surgical Training Unit at the University of Cape Town (UCT) in South Africa. The detail of the course timetable is shown on pages 30 and 31. The course will be a blended curriculum: incorporating online and in-person elements; small group teaching, varied individual practical sessions, videos and lectures. There will be focus on epidemiology and the burden of disease, the challenges of screening, and the indications for surgery. Each component of this course has been educationally validated by a panel of cataract and glaucoma experts, which rated and scored the course content, coverage, adequacy and quality.

The procedures of trabeculectomy, and in the separate course SICS, will be "deconstructed" and each step explained in detail with the aid of video and simulation demonstration. The separate steps will be repeatedly practiced under simulated conditions. We will use both low cost / moderate fidelity materials (e.g. foam for suturing, fruit for scleral tunnel/flap construction etc.) and higher cost / high fidelity model eyes which are mounted under a head manikin. [www.simulatedocularsurgery.com]. Further presentations, small group discussions, and practical presentations will be conducted on potential surgical complications and their management. Individual guided exercises and discussions on audit/monitoring of outcomes will be held and evaluated.

Phase 2:

A three-month period of sustained deliberate practice of surgical skills using the simulated surgery system and ongoing monthly remote feedback/mentorship, in addition to the standard conventional training practice available in the institution. Specifically, 'intervention arm' trainees will be provided with surgical instruments, artificial eyes, Sim-OSSCARs (simulation) and individual plans of simulation practice, as well as an iPad mini recording device (Apple, CA, USA) installed with video compressor App (Fbm Developments, Hong Kong). Monthly remote evaluations (via compressed video file over the internet) will be conducted, and appropriate feedback given. In summary, the 'educational intervention' / training will involve pre-course teaching, a five-day intense course in Cape Town, and a period of 12 weeks of sustained-deliberate practice.

The final visit in the local hospital at three months will be for the Sim-OSSCAR assessment (secondary outcome measure). Specifically this is a video recording of three separate simulation surgical procedures which are then anonymised, and marked using the Sim-OSSCAR in a masked assessment by two independent surgeon experts. The repeated measures analysis of the three Sim-OSSCAR scores will be a secondary end-point measure.

Table 2**: OLIMPICS Trial (SICS) Training Programme**

Pre-course online modules:

- SICS video
- Anatomy & physiology
- OSCAR & Sim-OSCAR

Pre-course administration:

- Informed consent for participation
- Study of outcome measurements

Day	Morning 8:00 – 10:30	Midday 11:00 – 1:00	Afternoon 2:00 – 5:00	Evening ***(Homework)***
Sunday	*Candidates arrive in Cape Town*			Free
Monday	Burden of disease. Suturing.	SICS Video. Learning theory & expertise. OSSCAR.	Suturing. Review.	*SICS Video.* *Suturing.*
Tuesday	Review. Scleral Tunnel. OSSCAR. Demonstration of SICS SOS.	Pre-operative assessment. Capsulotomy.	Review. Complications. Management of complications SOS.	*Tunnel.* *Capsulotomy.*
Wednesday	Review. Post-operative care/Audit (outcome monitoring). Endophthalmitis: protocol & SOS.	OSSCAR. Demonstration of SOS. SICS SOS practical: nucleus extraction & IOL placement.	SICS SOS. Teamwork & flow in theatre. Anterior vitrectomy SOS. Review.	*SICS Video.* *What to cover again.*
Thursday	Review. SICS SOS. What to cover again.	In-depth interviews. SICS SOS.	Suturing. Scleral Tunnel. Capsulotomy.	*SICS SOS.*
Friday	Review. OSSCAR/OSCAR.	SICS SOS.	Planning forward: SDP and Individual Training Plans.	
Saturday	*Candidates depart Cape Town*			

B) Standard conventional training "control" arm:
Controls will be offered the same training in Cape Town after a period of one year. Both the 'intervention' and 'control' arms will continue to undergo conventional post-graduate ophthalmology training. This typically includes a mixed timetable of out-patient clinics, surgical operating lists (observing or assisting a senior surgeon), and teaching or research sessions. The frequency and nature of these timetables will be collected for all participants.

Outcomes

In the OLIMPICS Trial, participants will be assessed on three occasions after recruitment (in addition to baseline): 3-months, 12-months, and 15-months (3 months after the control group receive the intense simulator training). On the baseline assessment, simulation SICS procedures will be recorded (with masked assessment using the OSSCAR(simulation)). At 3-months, 12-months and 15-months, supervised live surgical SICS procedures will be recorded and marked (remote and masked assessment using the OSCAR).

Primary Outcome – OLIMPICS Trial
The primary outcome measure of the OLIMPICS Trial will be the procedure specific repeated measures analysis of Sim-OSSCAR score performed three times at 12-months. The analysis of the primary outcome measure will be based on the differences in the Sim-OSSCAR scores by arm. This score is derived from an assessment matrix or rubric of procedure specific and general microsurgical skill indices (see Appendix 3a). Each item in the matrix is graded on a modified Dreyfus score (novice, advanced beginner, and competent). The total possible score is 40 points.

This live surgery assessment will be recorded using a standard microscope and recording device (Zeiss OPMI operating microscope; Zeiss, Oberkochen, Germany), with all participants wearing similar blue 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:

1. Sim-OSSCAR(Simulation) assessments on the final day of the intervention training course, for the OLIMPICS Trial; mean value of three replicates, performed in the same manner as per the primary outcome measure.
2. Sim-OSSCAR(Simulation) assessments at 12-months; mean value of three replicates, performed in the same manner as per the primary outcome measure.
3. Live SICS surgery ICO-OSCAR assessment at 12-months; mean value of three replicates, performed in the same manner as per the primary outcome measure.
4. The number of surgical procedures (SICS) will be recorded for twelve months between 0-months and 12-months.
5. OLIMPICS Trial (SICS) – for a period of fifteen months (for all SICS surgical procedures performed):
    - Day 1 Visual Acuity (un-corrected & best corrected) – LogMAR (equivalent)
    - Peri-operative Complications (Posterior capsule rupture)

Gathering and recording of surgical outcome data is part of normal good clinical practice. No patient identifiable information will be made available through this study. Anonymised surgical audit outcome data on all patients operated on by trainee ophthalmologists (as part of their normal supervised and regulated ophthalmology training) in both the 'intervention' and 'control/standard training' groups of both trials will be collected from their log-books for the period of fifteen months, between 0 months and 15 months (post-educational intervention). Send a summary audit report to the PI.

Qualitative Outcomes / Additional Exploratory Analysis:

6. Surgeon confidence scores: recorded at baseline, three and twelve months (Appendix 5b)
7. Semi-structured individual interviews conducted in the second week of the training course to primarily learn about surgical training experience and perspectives (see Appendix 5a). These interviews will be recorded, transcribed, thematised and analysed. All information will be kept confidential and anonymous.

Analysis

It is hoped that the majority of participants (25 in each arm, total 50) will complete the educational-intervention OLIMPICS study. However, it is recognised that RCTs often suffer from two major complications: non-compliance and missing outcomes. Intention-to-treat (ITT) analysis is one potential solution to this problem. ITT analysis includes every subject who is randomized according to randomized intervention/control assignment. It ignores non-compliance, protocol deviations, withdrawal, and anything that happens after randomization. ITT analysis maintains prognostic balance generated from the original random treatment allocation. A better application of the ITT approach is possible if complete outcome data are available for all randomized subjects. Per-protocol population is defined as a subset of the ITT population who completed the study without any major protocol violations.[50]

Statistical analysis

The primary outcome measure (mean Sim-OSSCAR score at three months) will be analysed using a t-test.

It is expected that the important baseline characteristics will be balanced between the two arms by stratified (for training centre) randomisation. This will be reported using a t test, Rank Sum or Chi squared test. If this is the case, the outcome in the two arms will be compared by linear regression model for Sim-OSSCAR at three months, adjusted for surgical training centre as a fixed effect. Adjustment will be made for baseline mean Sim-OSSCAR score in the model. An alpha level of $p<0.05$ will be considered statistically significant, and a γ coefficient of ≥ 0.75 for inter-rater agreement.

Qualitative analysis

Semi-structured interviews (conducted as per Appendix 5a) will be recorded, transcribed, thematised and analysied. Confidence ratings (Appendix 5b) do contain elements of open-ended questions which will be analysed per participant, and per stage of assessment.

Sample size

Based on pilot data from Malawi and Uganda in collected 2015 we anticipate the mean OSSCAR (Simulation) score to be 15/40 (S.D.10) at baseline. We anticipate an Effect Size of 0.9SD in the mean OSSCAR(Simulation) between the two arms of each trial at one year. We expect such a large effect (0.9SD increase) based on piloting of the Sim-OSSCAR(Simulation), and that this increase applies to the difference between a 'novice' or 'competent' surgeon in a specific technique, not generally as a surgeon.

We also anticipate a fairly strong correlation between the baseline and follow-up scores within individual surgeons (in other words, the people who are best at the start would probably still be better at the end). We might expect a narrowing of this gap (with the less competent gaining the most out of training). Therefore, we assume a correlation between these observations of 0.8. Variation between clusters (training institutions) was accounted for with a co-efficient of variation of 0.5.

Therefore, a sample of 23 individuals in each arm would have 80% power and 95% confidence to detect a difference of 9 points (0.9SD) We will recruit 25 per arm in each trial, to provide 2 extra participants per arm as we anticipate a modest loss to follow-up.

We and our collaborators consider this sample size of 50 participants per trial 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.

Table 4 shows different scenarios: sample size calculations for different standard deviations, and various baseline correlations.

Table 4: Range of Effect Sizes

		Correlation with baseline measurements										
		0	*0.1*	*0.2*	*0.3*	*0.4*	*0.5*	*0.6*	*0.7*	*0.8*	*0.9*	*1*
Effect Size (i.e. how many SDs difference between control and intervention groups)	*0.1*	*1469*	*1463*	*1448*	*1421*	*1385*	*1338*	*1280*	*1212*	*1134*	*1045*	*945*
	0.2	*384*	*383*	*379*	*373*	*364*	*352*	*337*	*320*	*301*	*279*	*254*
	0.3	*179*	*179*	*177*	*174*	*170*	*165*	*158*	*151*	*142*	*132*	*121*
	0.4	*106*	*106*	*105*	*103*	*101*	*98*	*94*	*90*	*85*	*80*	*73*
	0.5	*71*	*71*	*71*	*70*	*68*	*66*	*64*	*61*	*58*	*55*	*51*
	0.6	*52*	*52*	*52*	*51*	*50*	*49*	*47*	*45*	*43*	*41*	*38*
	0.7	*41*	*40*	*40*	*40*	*39*	*38*	*37*	*35*	*34*	*32*	*30*
	0.8	*33*	*33*	*32*	*32*	*31*	*31*	*30*	*29*	*28*	*26*	*25*
	0.9	*27*	*27*	*27*	*27*	*26*	*26*	*25*	*24*	***23***	*22*	*21*
	1	*23*	*23*	*23*	*23*	*23*	*22*	*22*	*21*	*20*	*19*	*18*

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 standardise the training offered to the 'Intervention' participants. The intense simulation course will be held in the same standardised surgical training unit at the University of Cape Town. The training will be conducted by the PI. All recordings of simulation procedures will be performed using the same microscope (Zeiss Stemi 305), and all intervention and control participants will wear the same colour blue surgical gloves. All recordings of live surgical procedures will be performed using the same operating microscopes (Zeiss OPMI and camera, using the Elgato video capture software), with all participants using the same blue surgical gloves, and note being taken of if/when the supervising Consultant Ophthalmologist takes over.

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.

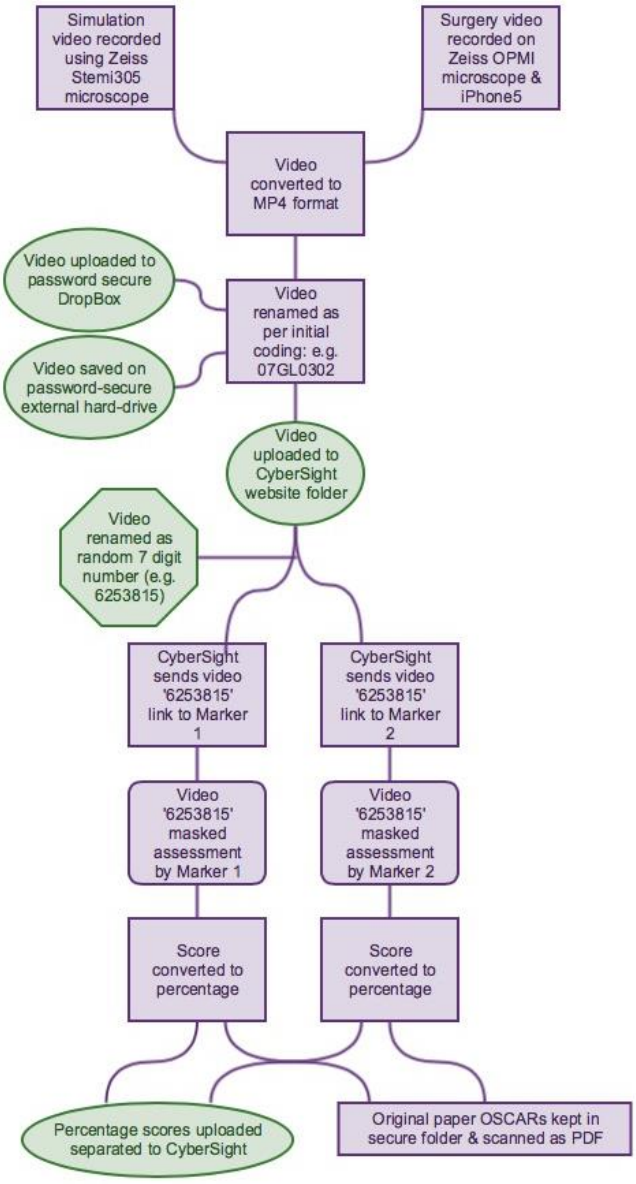
It is recognised that surgical education is complex and multi-faceted. However, every effort will be made to reduce 'contamination' bias. It will be agreed with Heads of Departments that there will be no local comparable or equivalent simulation-based training courses for SICS or trabeculectomy for the duration of the study. Participants will furthermore sign an informed consent form detailing that they will in no way share any of the details of the course or educational intervention between either 'intervention' and/or 'control' groups; for a minimum of three months following the primary intervention in Cape Town.

Observer Bias

Recordings will be converted to an MP4 format, and coded. The coding will identify the pre-randomisation number of the participant and which trial (e.g. participant 07 in the OLIMPICS trial [07OL]; with subsequent numeration of the month of assessment (e.g. month 3 [03]); and finally the order of recording of that group of assessment (e.g. second recoding of three [02]). This with the above example, the second recording of the three-month assessment for the seventh participant in the OLIMPICS trial would be enumerated: 07OL0302. This recording will then be saved on a password-protected external hard drive, and uploaded to a password-protected DropBox folder by an independent administrator (Deon Minnies in UCT). The recording will also then be uploaded to the CyberSight website, into a login and password-protected account.

At CyberSight/Orbis, the recording will be renamed as a randomly generated seven-digit number (e.g. 6253815). The code sheet will be generated by a LSHTM statistician (Min Kim) and only be known to him and the CyberSight administrator (Jonathan Scollard). 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. Figure 6 details the flow of video recording, masked marking, and recording of scores.

Figure 6. Video recording and marking flow diagram



A number of standard risk-of-bias criteria are suggested for RCTs (or studies with a separate control group). The following are either evaluated within this study protocol, or will be addressed during the SOS Trails as appropriate.

Table 5: Risk of bias criteria assessment

Criteria	Risk	Comments
Allocation sequence randomly generated (selection bias)	Low	Process described on page 28
Allocation sequence concealed (selection bias)	Low	Centralised randomisation scheme (LSHTM)
Similarity of baseline outcome measurements	Low	Performance measured prior to intervention (Baseline MCQ and OSSCAR)
Baseline characteristics similar	Low	Intervention & Control participants block randomised within same training institution
Blinding of participants & personnel (performance bias)	Unknown / Low	Participants & PI will know which arm they are in. Objective assessments will be masked.
Incomplete outcome data addressed (attrition bias)	Unknown	Missing outcome measures may bias the results. ITT (intention-to-treat) analysis possible
Study adequately protected against contamination	Unclear	Contamination between 'Intervention' and 'Control' groups is possible, but all effort has been made to reduce this.
Study free from selective outcome reporting (reporting bias)	Low	All outcomes will be included in analysis and reported
Intervention independent of other changes	Low	Other events/variables within surgical training will be identified and noted, for both arms
Intervention likely to affect data collection	Unclear / Low	Collection of patient-specific surgical outcome data is part of GCP, however, the intervention itself may increase reporting.

The PIs and co-investigators declare that they have no financial or other conflicts of interest.

Benefits of the Study

Benefits to the study participants

The trainee participants in both arms (intervention and control) of both RCTs (cataract and glaucoma surgical training) will receive intense simulation-based surgical education. This is not designed to replace any standard training, but to augment it. Trainees will not only benefit from focussed modular training in Cape Town, but will be enabled to engage in the process of sustained deliberate practice for the months following the course. This sustained deliberate practice, and other education and learning theories employed in this study should form a sound basis for participants in their future journey to becoming proficient and expert surgeons.

An element of training-the-trainers is included in the study. After the first year of training, Trainers and Heads of Departments (from collaborating institutions) will be invited to a Training-the-Trainers course, which would benefit them as Surgeon Educators. Five head trainers will be invited to Cape Town to participate in and run the simulation-based eight-day training courses. Further International expert faculty will also be established for running the courses for the 'control' arms (after year 1).

General benefits

The results of these two trials would have major implications in augmenting and streamlining ophthalmic surgical education, and potentially changing the way ophthalmologists approach initial surgical training entirely. More importantly this study could have major impact on the safety of the initial surgical training: reducing patient complications while the training eye surgeon moves from 'novice' to 'competent'.

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

Risks

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. Patients are involved only as part of fully-supervised, standardised, regulated and accredited post-graduate clinical and surgical training within the collaborating training institutions.

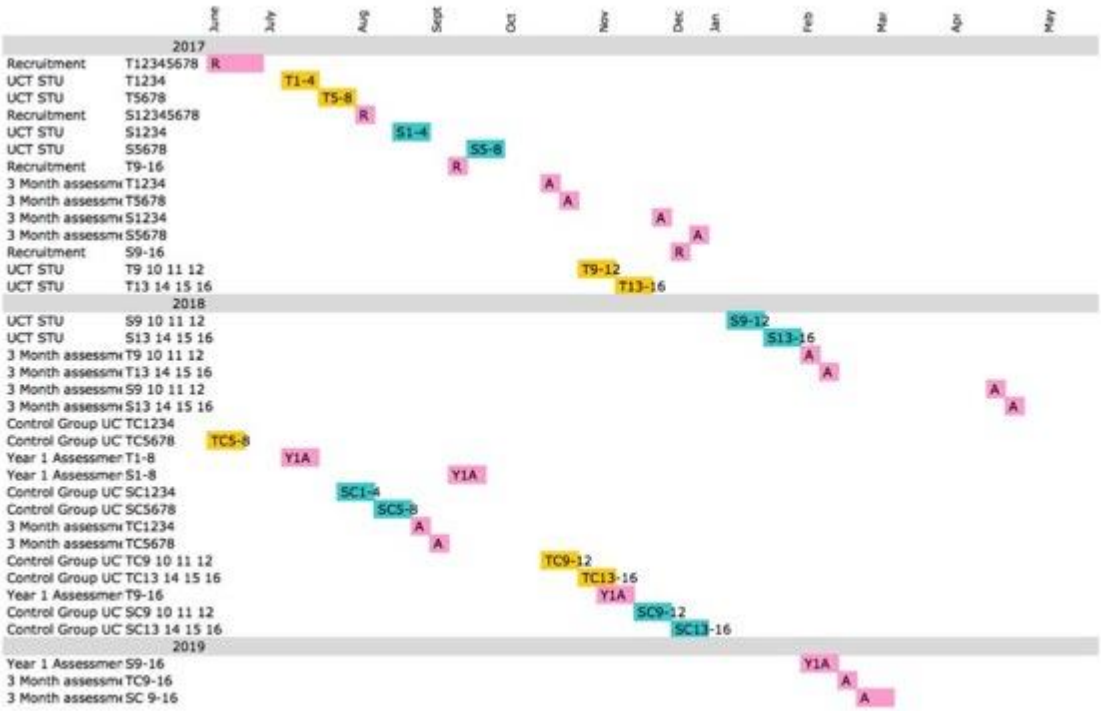
There are a number of broad risks in conducting this study.

- Trainees not being available for enrolment (due to examinations, closure of training institutions, personal reasons, visa or passport issues).
- Civil unrest (including national elections in Kenya, election and succession planning in Uganda).
- No patients being available in hospital for standard and ongoing surgical training (especially true for glaucoma patients).
- No or very few patients being enrolled for video assessments (applicable to both Trials, but especially true for glaucoma patients). This risk is inherent in glaucoma surgical training throughout the world. Glaucoma Specialist Consultants are often very hesitant to allow more junior trainees to perform trabeculectomy.
- Surgery on patients is regulated by local and national training institution protocol, and by the national Medical Councils. As part of normal standardised training, supervision of surgery conducted by trainees is also regulated.

Training Timetable:

Four trainee participants will be invited for each six-day course. Trainees from different countries, or the same country will be allowed. The PI will conduct all the training for the 'intervention' arm for standardisation. In year two, the controls will be trained in Cape Town, with the same course; however a faculty of senior surgical trainers from SSA, including the five participating centres and further afield will deliver the training.

Figure 6. Detailed timeline of recruitment, assessment, and training.



Key: T = Trabeculectomy training 'intervention' arm participant
S = SICS training 'intervention' arm participant
TC = Trabeculectomy training 'control' arm participant
SC = SICS training 'control' arm participant
UCT STU = University of Cape Town Surgical Training Unit

Data Management

All recordings of surgeries (either simulated or real) will be anonymised. 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 randomised. 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. Recordings will be transported on an encrypted hard-drive where possible. 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 simulation-based surgical education' versus 'standard surgical training' in Sub-Saharan Africa (for glaucoma and separately for cataract surgical competency).

If the analysed data from this study does indeed statistically prove the alternate hypothesis, then there is the potential that the results will be a true 'game-changer' for ophthalmic surgical training, not only in sub-Saharan Africa, but globally. This study has the potential of proving, and providing the robust data, that simulation-based surgical education in the two major causes of global blindness improves competence and outcomes.

Quality Assurance

Good Clinical Practice

Institutional, National, and Regional Good Clinical Practice (GCP) guidelines will be followed and monitored in terms of training, performance of supervised surgery as part of training, patient care, patient confidentiality, and monitoring of outcomes of surgery.

Data management

All data collected will be anonymised: no participant or patient identifiable information will be available. The anonymization and randomisation 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 the three major funders. Weekly Project Reports will be sent to the Principal Investigator (LSHTM).

Advisory Panel

The advisory panel are:

- Dr Simon Arunga, MURHEC, Mbarara, Uganda
- Miss Morgon Banks, ICEH, LSHTM (Qualitative research)
- Dr John Buchan, ICEH, LSHTM
- Professor Colin Cook, Department of Ophthalmology, University of Cape Town, South Africa
- Dr Stephen Gichuhi, University of Nairobi, Kenya
- Min Kim, LSHTM (Statistics & quantitative research)
- Dr William U Makupa, KCMC, Moshi, Tanzania
- Dr Agrippa Mukome, University of Zimbabwe, Harare
- Dr Juliet Otiti, Makerere, Uganda
- Dr Francisco Pozo-Martin, LSHTM, UK (Healthcare Economics)

Funding

The British Council for the Prevention of Blindness (London, UK)

Ulverscroft Foundation (Leicester, UK)

CBM USA (Greenville, SC, USA)

The Queen Elisabeth Diamond Jubilee Trust (London, UK)

L'Occitane Foundation (Paris, France)

Medical Registration

No medical registration is necessary for participants in South Africa, as no patients will be involved in the simulation-based surgical training. The principal investigator will neither be registered with the Medical Councils of Kenya, Tanzania, Uganda or Zimbabwe; again, as no patients will be operated on by him.

Trial Registration

The study will be registered at the London School of Hygiene and Tropical Medicine and the Pan-African Clinical Trial Registry.

Data and safety management

All participant information will be randomised, anonymised and encrypted. All patient-related surgical outcomes data will be anonymised 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

Ethics approval would be obtained from National Ethics Committees of Kenya, Tanzania, Uganda, and Zimbabwe. Ethics approval has already been attained from the London School of Hygiene and Tropical Medicine (reference: 11795) and University of Cape Town (references: UCT HREC 259/2017, and DRC 2016/191).

The initial Pilot studies in 2015 were approved by the Medicine Education Ethics Committee (MEEC) Coordinator, Faculty Education Office (Medicine), Imperial College, London (MEEC1415-12). Furthermore approval from the University of Malawi and the Mbarara University of Science and Technology was sought, and ethics waivers were obtained.

Educational ethics are important to consider separately for this study.

Patient Informed Consent

Patient participants will be informed that the outcomes of their surgery will be recorded as per normal good clinical practice and standard training. At the three month, year one, and fifteen-month assessment, three patients per 'intervention' participant and three patients per 'control' participant will be asked for informed consent to video record their surgery. 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. A standard consent form (Appendix 6), similar to local consent forms for clinical photography for research purposes only, will be read to patients in their local language; and they will be invited to sign.

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 emphasise 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 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.

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. A 'certificate of attendance' will be provided to all participants who complete the training (in both the 'intervention' and 'control' groups) in Cape Town and subsequent three-month assessment. However, it will be made clear that this certificate and all/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.

It is important to clarify that trainee participants in the 'control' arm will be offered exactly the same training as the 'intervention' arm, only one year later.

Patients with cataract and glaucoma are indirectly involved in this study. However, it is important to emphasise that supervised surgery conducted in this study, by trainee participants (in both the intervention and control arms), is part of standard and regulated training; and supervised by qualified and registered senior eye surgeons as per normal practice.

Patient outcome data will be anonymised, and 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 the country. Patients operated in both the 'intervention' and 'control' arms will be during normal standard training, and thus regulated by the Medical Councils and Educational Training Committees of Kenya, Malawi, Tanzania and Uganda.

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 analyse 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 Informed Consent Forms & Participant Information Sheets

Appendix 2 Budget

Appendix 3 OSSCARs and OSCAR

Appendix 4 Questionnaire

Appendix 5 Semi-structured Interview & Confidence Scoring

Appendix 6 Patient Consent to Clinical Photography Form

Appendix 1a Participant Consent Form (SOS)

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East Africa. OLIMPICS Trial (Ophthalmic Learning & Improvement Initiative in Cataract Surgery)

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK
University of Cape Town, South Africa
Mbarara University of Science and Technology, Uganda
University of Nairobi, Kenya
Kilimanjaro Christian Medical Centre, Tanzania
Makerere University, Uganda
University of Zimbabwe, Harare

I _____ (name) have been invited to participate in a trial of surgical training, involving an eight day intense training and education course for cataract surgery in Cape Town, South Africa and ongoing assessment for the following 15 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.	☐
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 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.	☐
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 anonymised video recording and assessment at baseline, three / twelve / fifteen months of my surgery	☐
9. I commit to ensuring that **all** surgical outcome data for patients operated by myself (supervised or other) for SICS, that this data (day 1 VA and complications of PCR) is captured onto a recording sheet (with no patient identifiable data), and reported for a fifteen-month period (from initial intervention to fifteen months).	☐
10. I finally understand, agree, and wholly commit to NOT discussing or sharing any of the details in any way with the 'control' group of peers in this study for at least the first three months after the Cape Town training.	☐

Signed _____ Date: _____

_____

Countersigned by Principal Investigator (Dr Will Dean)

Principle Investigator (Africa) / PhD Student: Dr William H Dean FRCOphth MEd MBChB BSc
Principle Investigator (LSHTM): Prof. Matthew Burton PhD FRCOphth

Co-Investigators:
Dr Simon Arunga FCOECSA MMed(Oph) MBChB
Dr John Buchan MBBS FRCOphth MD
Prof Colin Cook MBChB DO MPH FRCOphth FCS(Ophth)SA
Dr Stephen Gichuhi PhD MMed
Dr Agrippa Mnukome MBChB MMed
Dr William U Makupa MD, MMed Ophth, FCOphth ECSA, VRS
Dr Juliet Otiti MBChB MMed(Ophth)

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 RSA +27(0)710 701 272

Please refer to Participant Information Sheet (OLIMPICS Version 1.0)

Appendix 1c Participant Information Sheet – SICS Training

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East Africa. The OLIMPICS Trial (Ophthalmic Learning & Improvement Initiative in Cataract Surgery).

Participant Information Sheet (OLIMPICS Version 1.0)

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK
Mbarara University of Science and Technology, Uganda
University of Nairobi, Kenya
Kilimanjaro Christian Medical Centre, Tanzania
Makerere University, Uganda
University of Zimbabwe, Harare
University of Cape Town, South Africa

LSHTM Principal Investigator: Dr William Dean FRCOphth MEd MBChB BSc
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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 programme 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 MMed 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 39 million people who are blind and a further 124 million with significant visual impairment (excluding uncorrected refractive error). Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in Low and Middle Income Countries (LMIC). Sub-Saharan Africa (SSA) has the highest prevalence of blindness of any region at 9% in >50 year olds. Age-related cataract accounts for about half this blindness. Small incision cataract surgery (SICS) is a widely accepted, appropriate and affordable procedure with high quality visual outcomes. Glaucoma is the second leading cause of blindness in SSA (15%), and surgical trabeculectomy is often the primary treatment, partly due to the challenges of sustaining medical therapy. Together, cataract and glaucoma account for two-thirds of blindness in SSA, and both require surgical management. However, SSA is the region with the lowest number of ophthalmologists per capita, with about 2.6 per million.

The College of Ophthalmology of Eastern Central and Southern Africa (COECSA) has adopted a competency-based curriculum for ophthalmic trainees in the region. There are a number of learning domains, one of which is surgical skills (SS). Of the seventeen separate surgical skills to be learnt, the very first, 'SS1', is 'Simulation and Wetlab'. This illustrates the importance placed within COECSA on the use of simulation in surgical training. It has been acknowledged however that the curriculum-integration of simulation is only in its infancy, as with many ophthalmology training programmes around the world. There is no coherent, sustainable, standardised and educationally-underpinned regional training programme 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 two hundred thousand ophthalmologists in the world, a disproportionately low number are trained and work in sub-Saharan Africa. The shortage of expert eye surgeons in SSA 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 SSA Region, and Globally.

This is a prospective, single-masked randomised controlled education-intervention trials of intense simulation-based surgical education versus current standard training of ophthalmologists-in-training in four East African countries. The aim is to investigate whether simulation-based surgical education improves competence, knowledge, surgical outcomes, and confidence. All participants will (by the end of the study) receive the educational intervention of 'eight-days intense simulation-based training' at the Surgical Training Unit, University of Cape Town. The intervention groups will receive this training at week one; and the matched controls after a period of one year. The 'intervention training' specifically is an five-day intense course of lectures, small-group teaching, practical surgical simulation training, videos, and assessments. 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 in East Africa, and you may meet all the eligibility criteria.

How many people are taking part in this trial?

We plan to recruit 50 trainees in total: 25 for the SICS intervention training arm, and 25 in the standard (control) SICS training arm.

Procedures

What will we ask you to do?

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

Randomisation:
Immediately after baseline assessment, we will randomise you to either the first SICS "intervention" training group, or the second SICS "control" training group.

Further Baseline assessment:
Whether you have been randomised to the first ("Intervention") or second ("Control") group, we will show you some of the basics of the procedure of SICS, and the performing of a procedure using simulation (artificial eyes). We will then invite you to perform three simulation SICS procedures, which we will record (these recordings will be anonymised).

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 first "Intervention" group, then you will be invited to the Surgical Training Unit in Cape Town for an intense eight-day simulation-based training course (over a period of ten days). Your flights, accommodation, meals, training (together with all consumables, instruments, and educational materials) will be provided free of charge. If you are allocated to the second "Control" group, then you will be invited to the Surgical Training Unit in Cape Town for the same intense eight day simulation-based training course (over a period of ten days); only this will take place after a period of one year.

Follow-up assessments:
We will revisit you at your Training Institution at 3 and 12, and 15 months after your enrolment to the study. We will invite you to perform three further simulation SICS procedures (which again we will record and anonymise) at 3, 12 and 15 months. We will also, invite you to perform three live SICS surgeries (which again we will record and anonymise). During the period between three to fifteen months (total one year), we will ask you to monitor, record and report all of the outcomes of SICS surgery that you perform in your hospital (in terms of day 1 visual acuity, and incidences of peri-operative complications of posterior capsule rupture).

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 "Intervention" or "Control" group*** for at least the first three months (after the first 'Intervention' group's training in Cape Town). 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. It is also important to emphasise that if sharing of the education between the first "Intervention" or second "Control" is found, then both individuals will be excluded from the study, and the second "control" individual would forfeit their simulation training course in Cape Town at year one. This is really important for the integrity of the trial.

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 a comprehensive eight-day course, and subsequent three months of practice back home. No patients are involved in this training. This training is not meant to replace standard training, but to augment it.

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Benefits

What benefits are there to taking part in the study?

You will be offered free simulation-based surgical training in Cape Town. This will be followed up with three months of practice and feedback (remotely via internet) at your normal place of work. All of this training, and the expenses involved will be offered 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 answer this question.

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 ten days in Cape Town, South Africa. You will have a colleague who is in the same stage of training, with whom you will not be able to share (initially for at least three months) the learning from this educational intervention. There is a danger that if you are in the "Intervention" group, and you do share some or any of the learning from this course with your matched "Control" colleague, that they will forfeit their training in Cape Town (at year one).

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 programme 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 anonymised so that none of your personal information will be identifiable. These recordings will be stored on an encrypted hard drive in Cape Town and London. 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 during the one year period will need to be documented in such a way so they do not include any patient-identifying information. Once this data is reported, none of your personal related information will be made available. Summarised, anonymised 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. 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 sponsored this study?

The study is sponsored through the London School of Hygiene and Tropical Medicine.

Who has reviewed the study?

This study was reviewed by the British Council for the Prevention of Blindness, the Ulverscroft Foundation (Leicester, UK), CBM-USA, the LSHTM Ethics Review Committee, the University of Cape Town ethics committee, the Nairobi University Ethics Committee, KCMC and NIMR ethics boards in Tanzania, the MURHEC and Makerere Universities Ethics Committees in Uganda, and the ethics board of the University of Zimbabwe.

Who is doing this study?

The study will be coordinated by Dr Will Dean who is an ophthalmology consultant who has a MEd (Masters in Education) in Surgical Education at Imperial College, London; a Fellowship of the Royal College of Ophthalmology (UK); over 15 years of experience in ophthalmology and training ophthalmologists in Malawi, Southern Africa and the UK. The recruitment, assessments, and training will be conducted by him, and a small team of specialist ophthalmology consultants.

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 +27 710 701 272 or will.dean@lshtm.ac.uk
Prof. Matthew Burton at +44 20 7636 8636 or matthew.burton@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 3a. SICS 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)

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Appendix 3c. 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	**Draping**	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	**Scleral access & Cauterization**	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	**Sclerocorneal Tunnel**	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	**Corneal entry**	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 maneuvering.	
5	**Paracentesis & Viscoelastic insertion**	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	**Capsulorrhexis: Commencement of Flap & follow-through.**	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	**Capsulorrhexis: Formation and Circular Completion**	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 capsulorrhexis.	
8	**Hydrodissection: 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.	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	**Prolapse of nucleus completely into AC**	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, churns 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	**Nucleus extraction**	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	**Irrigation and Aspiration Technique With Adequate Removal of Cortex**	Great difficulty introducing the aspiration tip under the capsulorrhexis 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 capsulorrhexis 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 capsulorrhexis, aspiration hole usually up, cortex will engaged 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 capsulorrhexis 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	**Lens Insertion, Rotation, and Final Position of Intraocular Lens**	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 capsulorrhexis or the zonule fibers.	
13	**Wound Closure (Including Suturing, Hydration, and Checking Security as Required)**	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	**Global Indices Wound Neutrality and Minimizing Eye Rolling and Corneal Distortion**	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	**Eye Positioned Centrally Within Microscope View**	Constantly requires repositioning.	Occasional repositioning required.	Mild fluctuation in pupil position.	The pupil is kept centered during the surgery.	
16	**Conjunctival and Corneal Tissue Handling**	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	**Intraocular Spatial Awareness**	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	**Iris Protection**	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	**Overall Speed and Fluidity of Procedure**	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.	
					TOTAL=	

Comments: _____

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Appendix 5a Interview Outline

In-Depth Interviews Date:_____

ID. :_____

1> ***Baseline Interview (at selection, pre-randomisation)***

- What are the main challenges (in your area) in surgical training?
- What areas could you use most help with in surgical training?
    - Why?
- Does anything motivate you as a surgeon?

…….

Date:_____

2> ***During Intervention Training in Cape Town***

- What do training surgeons say are the most important ways to learn surgery?
- How do you, or how have you, learnt surgery?
- What are the main challenges (in your area) in surgical training?
- How do you think surgeons can continually improve their surgical skills?
- Think about the best surgical trainer you have worked with. What made them so good?
- Think about the worst surgical trainer you have worked with. What made them bad?
- What, if any, are the main benefits of simulated ocular surgery training?
- Does anything motivate you as a surgeon?

……

Date:_____

3> ***At Year one assessment***

- How, if at all, has the simulation surgical training affected your overall practice as a surgeon over the past year?
    - What aspects of the training?

- Does anything motivate you as a surgeon?

Interviews will be recorded and transcribed, anonymised, and thematised.
No personal identifiable information will be kept.

Appendix 5b Confidence Ratings

Ophthalmology Surgical Training I.D…… Date……

We invite you to answer a few simple questions relating to your own views about your surgery and training. Please be as honest as possible. Your answers will be kept completely anonymous, and will not be made available to anyone in any identifiable way. Please refer to the Participant Information Sheet, and do feel free to ask any questions.

On a scale from one to ten, with 1 being "not confident at all" and 10 being "very confident", please circle the level you most feel at this time:

How do you feel about yourself as an eye surgeon?

1	2	3	4	5	6	7	8	9	10
Not confident at all									Very confident

How do you feel about your own surgical skills?

1	2	3	4	5	6	7	8	9	10
Not confident at all									Very confident

What has impacted your level of confidence?

How do you feel about your cataract surgical skills?

1	2	3	4	5	6	7	8	9	10
Not confident at all									Very confident

What are you most confident about regarding your surgical ability?

What specifically has led to this level of confidence?

Appendix 6a. Consent to Clinical Photography Form

Consent to Clinical Photography Form

PATIENT INFORMATION

Consenting to Clinical Photography or Video recording

The Eye Hospital has a policy to give you the right to control the use of photographs or video recordings, which may be taken during the course of your treatment.

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 what 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.....

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/ 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 the same 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** ...../...../.....

Appendix 6b. Consent to Clinical Photography Form - Swahili

Hati ya Fomu ya Kupiga picha ya Kliniki

INFORMATION PATIENT

Kukubaliana na Upigaji picha wa Kliniki au Kurekodi Video

Hospitali ya Jicho ina sera kukupa haki ya kudhibiti matumizi ya picha au rekodi za video, ambazo zinaweza kuchukuliwa wakati wa matibabu yako.

Unaweza kukataa kuwa na picha au video zilizochukuliwa kwa sababu yoyote isipokuwa kwa kumbukumbu zako za afya. Hii haiathiri matibabu yako kwa njia yoyote.

Umeulizwa kuwa na rekodi za video za matibabu zilizochukuliwa. Hizi zitakuwa kwa:

Tathmini isiyojulikana ya upasuaji wako, kama sehemu ya tathmini inayoendelea ya upasuaji wa macho na mafunzo ya upasuaji.

Video za upasuaji wako hazitasambazwa au zinapatikana kwa njia yoyote kwa umma.

Utapewa taarifa kuhusu kile ambacho rekodi zitatumika, na utaombwa kusaini fomu ya idhini.

Maelezo zaidi: Kama una maswali zaidi tafadhali sungumza na daktari wako.

Kipeperushi hiki kinapatikana katika lugha kubwa na magazeti mengine kwa ombi.

Ruhusa kwa Upigaji picha / Video na Fomu ya Ruhusa

Maelezo ya Mgonjwa

Jina ……..

Tarehe ya kuzaliwa .....

Nambari ya hospitali .....

Nimeelezea madhumuni ya kupiga picha / rekodi za kliniki kwa mgonjwa na jinsi picha zitatumika.	
Taarifa ya subira ya wagonjwa imetolewa.	
Mimi ni mtaalamu wa afya anaomba kuandika picha za kliniki / video.	
Nitahakikisha kuwa picha za video zinazofaa zinachukuliwa kwa namna ya kuhakikisha kwamba **mgonjwa hawezi kutambuliwa**.	

Saini ya mtaalamu wa afya .....

Chapa jina .....

Jina la kazi .....

Maelezo ya mawasiliano ..... **Tarehe** ..... / ..... / .....

Taarifa ya subira (tafadhali duru jibu lako) Nakubali kuwa na rekodi za video za kliniki zilizofanywa. Ombi la sawa limeelezwa kwangu na ninaelewa kikamilifu kile kinachohusu.

Ndiyo **Hapana**

Saini ya mgonjwa ..... **Tarehe** ...../...../.....

Taarifa ya Shahidi wa Uhuru / Mtafsiri

Nimetafsiri maelezo ya juu kwa mgonjwa kwa uwezo wangu wote na kwa njia ambayo ninaamini yeye au anaweza kuelewa.

Saini ya mkalimani ..... **Jina**..... **Tarehe** ...../...../.....

SOP 41

Standard Operating Procedure
Data Analysis Plan

SOP Ref:	LSHTM-SOP-SOS Trials-Simulation v Conventional
Version:	1.1
Author: Dr Will Dean	
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Approved by:	Min Kim, David McLeod, John Buchan, Matthew Burton
Signed Will Dean 19 June 2019	

SOP Chronology			
Version	**Date**	**Reason for Change**	**Author**
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1.1	19/6/18	Further refinement & locking prior to analyses	WD

Data Analysis Plan

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1 Introduction

Globally there are an estimated 36 million people who are blind and a further 217 million with moderate or severe visual impairment.[1] Together, cataract and glaucoma account for two-thirds of blindness in SSA, and both require surgical management. There is a huge need for eye surgery. In Sub-Saharan Africa alone, there are an estimated 4,8 million people who are bilaterally blind, and an estimated 21.4 million who are visually impaired. About 80% of this blindness and visual impairment is avoidable. The ratio of eye surgeons to population in SSA is 2.6 per million.[2] If there was a goal to treat all the cataract eyes in people who are blind or vision impaired, then each ophthalmologist would have a personal backlog of an average of 15,000 cataract surgeries to perform. Glaucoma may be treated by surgery as a first line of management, rather than topical medications (eye drops). If this were the case, then each ophthalmologist would have a backlog of well over 500 surgical trabeculectomies to perform.

There is a huge need to train eye surgeons. Training opportunities and the number of trainers are limited. Trainers' time is limited. Surgical training needs to be accelerated, be more efficient, and be made safer.

In parts of the world, eye surgeons may be emerging from programmes not necessarily fully trained. A recent survey of ophthalmology training programmes in the USA illustrated that in final year residents, that 71.4% had performed <100 cataract surgeries, and 88.6% had performed <10 trabeulectomies.[3] A survey of ophthalmology residents in China showed that the median number of cataract surgeries performed was zero.[4]

Simulation-based surgical education 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.[5] however this has not yet been robustly tested or proven for ophthalmology surgical training.[6]

2 General Considerations

2.1 Inclusion and Randomisation

Trainee eye doctors from collaborating training institutions in Eastern and Southern Africa will be assessed for eligibility to either the OLIMPICS trial. Once eligibility criteria are met, trainee eye doctor participants will be randomised within institutions.

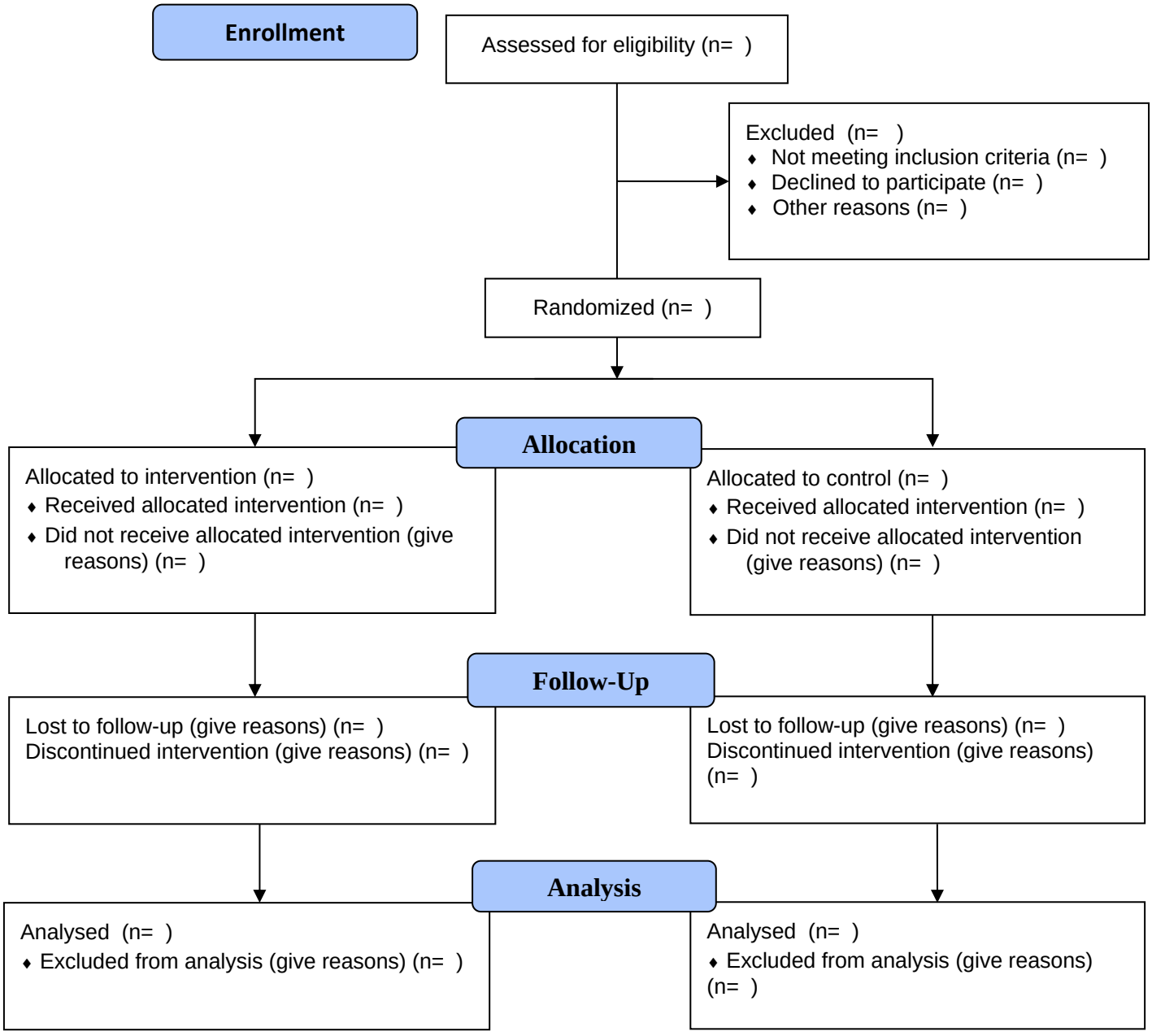
2.2 Intention to Treat

All participants' data will be analysed according to their randomisation allocation irrespective of whether or not they completed all the follow-up assessments.

3 Participant flow

The following will be shown by trial arm in a **flowchart** following 2010 CONSORT statement.[7] Numbers eligible, excluded for different reasons, consenting to take part, randomized, and who received and did not received the intended treatment. The numbers still in follow-up, censored, defaulting, and permanently lost-to-follow-up respectively at each visit and the final number of participants included in the analyses will also be shown by arm. Reasons for declining to take part, not having the allocated surgery, or discontinuing follow-up and exclusion from analysis will be summarized by arm.

3.1 Flow Diagram



4 Data Integrity, Consistency and Range checks

All surgical videos will be graded by two independent masked expert surgeon assessors. A randomly selected 5% of all videos will be independently marked by the primary investigator. The randomly-selected 5% of videos will be re-marked by each grader after a two-month time period. Inter- and intra-observer will be analysed using Krippendorff's Alpha correlation.

A collaborator with no prior access to raw video data will be invited to select more than ten random videos from libraries of the OLIMPICS trial, and correlate these with the anonymised videos (given a randomly allocated seven-digit number) to ensure data integrity. Further random checks will be made on raw data sheets and computerised data.

For numerical variables, such as Sim-OSSCAR scores and confidence ratings, range checks will be performed using maximum checks. Identified outliers will be double-checked by the primary investigator.

5 Description of baseline data

The following characteristics of participants at baseline will be tabulated by arm:

a. Number of participants
b. Age (years)
c. Sex, female (%)
d. Geographic Region / City of collaborating institution: Harare / Kampala / Mbarara / Moshi / Nairobi
e. Knowledge score (30 question standardised MCQ)
f. Pre-intervention surgical experience:

- Total numbers of procedures (performed) (by inclusion criteria should = 0)
- Parts of procedures performed (number)

The distributions of these variables by treatment arm will be compared, to assess whether there is imbalance at baseline in these potential confounding factors.

6 Primary Analysis

6.1 Primary outcome measure

Mean global competency assessment score (as a percentage), using the ophthalmic simulation surgical competency assessment rubric (Sim-OSSCAR) at three-months post-training intervention. The primary outcome measure is the mean score of three masked assessments of simulation surgical performance using the Sim-OSSCAR. If data is missing from one assessment, then the mean of two or one will be used.

6.2 Analysis of primary outcome measure

Intention to treat analysis of the Sim-OSSCAR score by arm.

Primary analysis of primary outcome:

It is expected that the important baseline characteristics will be balanced between the two arms by stratified (for training centre) randomisation. This will be reported using a Rank Sum or Chi squared test. If this is the case, the outcome in the two arms will be compared by linear regression model for Sim-OSSCAR at three months, adjusted for surgical training centre as a fixed effect. Adjustment will be made for baseline mean Sim-OSSCAR score in the model.

Secondary analysis of primary outcome:

a. Effect modification

We will assess effect modification of the intervention on Sim-OSSCAR score at three months with the following factors by including an interaction term with treatment arm in the linear regression model.

a. Surgical training centre
b. Sex
    - Male
    - Female
c. Age of trainee: will be classified based on the distribution

b. Analysis of determinants of Sim-OSSCAR score:

A multivariable linear regression model will be used to identify potential explanatory factors for higher scores by three months, adjusting for arm (intervention/control). Other factors which will be examined in a model of Sim-OSSCAR score will include

a. Age
b. Sex
c. Training centre

c. Sim-OSSCAR score at end of intervention, at one year and 15-months

Intention-to-treat analysis will be used to assess the impact of the intervention on OSSCAR score at one-year and 15-months, using linear regression adjusted for training centre and baseline score, as per the approach used for the primary analysis.

7 *Secondary Analyses*

7.1 Secondary outcome measures

a. Mean live OSCAR score at one year post-training for OLIMPICS trial. These will be analysed by linear regression, adjusting for training centre, as per the approach used for the primary outcome.

b. Number of surgeries performed over one year (from 0 to 12 months). Analysed using a Poisson regression, with trial arm as the exposure of interest, adjusting for training centre.

c. Patient-specific outcomes for all surgeries performed during 0-15 months for OLIMPICS Trial:
    i. Day 1 Visual acuity (LogMAR): uncorrected and pin-hole. Number of patients with good or poor VA per surgeon will be analysed using Rank Sum.
    ii. Operative complications of posterior capsule rupture. Analysed using linear regression.

d. Confidence rating scores (Assessed at baseline, three and twelve months), analysed using Wilcoxon Rank Sum test.

7.2 Training Record

An accurate training record will be maintained and analysed by arm:

a. Data will be collected for the duration of the trials (15 months for each participant) for conventional training: Surgical sessions attended / Numbers of surgeries performed (supervised and un-supervised) / Assisted. Descriptive (no formal analysis)

7.3 Adverse events

The OLIMPICS and GLASS trials are 'educational-intervention' trials. All the educational intervention is using simulation. Data will be collected for all participants in both arms of both trials for all live surgeries performed (under local supervision, as part of conventional regulated and accredited training).

Complications will occur during surgery, these complications will be recorded by all participants (and subsequently summarised and reported to the PI). No patient identifiable data will be available:

For the OLIMPICS trial:

- Posterior capsule tear (with or without vitreous loss)

For the GLASS trial:

- Conjunctival button hole
- Bleb leak
- Hyphaema

Within each trial the proportion of surgeries resulting in an adverse event will be compared using a logistic regression with trial arm as the primary exposure, adjusting for training centre.

8 Qualitative analysis

Semi-structured interviews (conducted as per Appendix 5a) will be recorded, transcribed, thematised and analysed. Thematizaion will be performed manually and electronically using nVivo software (QRS International, Burlington MA, USA). Confidence ratings do contain elements of open-ended questions which will be analysed per participant, and per stage of assessment.

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