Construct validity testing of af low cost vitreoretinal surgical simulator

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Declaration Page

I, Dr Dean van der Westhuizen, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree at this or any other university.

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Literature Review

Introduction

Vitreoretinal surgery is well known for its technical challenges and steep learning curve, as the margin for error is minute and the complications of poor dexterity can have dire consequences for patients.[1] The movement of small gauge instruments under high magnification requires extreme precision with low tolerances for error. Classically – like most surgical specialties – surgical skill and dexterity comes with practice, and traditionally this practice is carried out on live patients using traditional 'Apprenticeship' training techniques. Having an inexperienced surgeon practise his skill in this manner, means that one can expect higher complication rates. Surgery as a field is reliant on the fine motor skill of the surgeon to complete a task to treat a disease. Motor tasks improve through repetition and practice, and, as the saying goes, "practice makes perfect". [2, 3]

Throughout the surgical specialties there has been a shift away from the apprenticeship model toward a more competency-based approach that has objective measures of a trainee's skill, instead of the subjective opinion of an experienced surgeon.[4] This is evident in the multitude of surgical simulators that are available for a wide variety of surgical specialties. Ophthalmology is no exception, and simulators such as the EYE-SI (VRmagic, GmbH, Mannheim, Germany) and PhacoVision (Melerit Medical) have been implemented extensively in ophthalmic training programmes that can afford them.[5-7]

These simulators have been very effective in improving dexterity and surgical skill without putting patients at risk. This allows trainees to do hours of training until reaching a high level of competency – before moving onto real patients. It also offers scoring tools, which allows supervisors to assess the progress and competency of a trainee.[8-12] A possible limitation to the adoption of these simulators is cost, and many ophthalmic training programmes may not have the budgets to accommodate this technology.

The purpose of this review is to assess the need for simulation in vitreoretinal surgery, and assess what is currently available in order to determine the benefit of providing construct validity of a low cost vitreoretinal surgical simulator developed by Dr James Rice at Groote Schuur Hospital in Cape Town.

Burden of disease

The burden of vitreoretinal diseases on ophthalmic services worldwide and in Africa is increasing, and, therefore, so is the need for competent and skilled retinal surgeons.[13-15] Diabetes causes severe morbidity, whether it be from diabetic retinopathy itself or from epiretinal membrane formation, diabetic macular oedema, neovascular glaucoma or its relation to vein and artery occlusion[16]. Many of these conditions may require surgical treatment and sub-Saharan Africa is poorly equipped to deal with this epidemic. The estimated number of people with diabetes in Africa was estimated to be 12 million in 2010, but is expected to rapidly over the next 10 years.It is expected that the numbers of diabetics in developing countries will increae by 69% compared to the 20% increase expected in developed countries[17]. Unfortunately, the vitreoretinal training and services in the developing world are still lagging behind those of developing countries.

Much research funding goes into the detection and screening of diabetic retinopathy, including artificial intelligence software grading of fundus photos to identify and allow referral of patients in need.[18-20] With more diabetic patients and more efficient screening, the healthcare systems are inevitably going to be burdened with an increasing workload that needs to be prepared for. Included in this preparation should be the training of vitreoretinal surgeons.

Surgical training

Teaching surgical technique has, from the beginning, been an apprenticeship approach, where a training surgeon would work alongside an experienced surgeon, where they would observe initially, then start to perform some steps of the procedure – before moving onto more challenging steps. Eventually, over many years of practice, the training surgeon would one day become competent. The definition of training may be described as "The process of bringing a person to an agreed upon standard by practice and instruction".[21] In many residency programmes, the agreed upon standard is the opinion of the consultant overseeing the resident.[22] This is no longer acceptable and the old mantra of "see one, do one, teach one" is outdated and should not be encouraged.[23]

The shift away from an apprenticeship model toward a competency-based model has meant a more structured approach to surgical training, where competency is central to training, and not purely how much time or how many procedures a trainee has performed.[22] Some have even advocated that a residency should not have a prescribed time period, but that once certain competencies have been met, the resident is qualified. This also accommodates the different learning curves that different residents are on. Competency-based training provides a blueprint outlining the necessary skills required, how these skills are assessed, and are judged by a standard set of requirements.[22, 24] Defining competency and formulating ways of measuring it, is what many surgical training programmes are wrestling with, and one of the pillars of this new thinking includes scoring/assessment rubrics, as well as surgical simulation, whether it be in the form of wet labs, dry labs or virtual reality simulators.[4, 9, 11, 25-27]

Scoring rubrics are tools that allow the grading of a specific tasks by breaking it up into components and assigning a score using behavioural descriptors for each level. It is an important component of a competency based system as it allows a way of assessing competency .[28] Rubrics set clear expectations through explicit criteria which allows trainees and trainers to set goals and provide feedback and advice on what components are lacking or proficient. [29]

Rubrics have been incorporated into many different surgical skills training programmes, of note is the field of laparoscopic surgery which was a new surgical skill that needed to be introduced quickly into training programmes at the technology gained popularity.[30] Ophthalmology has been somewhat of a pioneer in the field of surgical assessment and there are many different scoring rubrics for a variety of surgical skills including, strabismus, phacoemulsification and even oculoplastic procedures [9, 11, 31, 32] Many of the rubrics are based on the modified Dreyfus model of skill acquisition which goes from novice, beginner, advanced beginner, competent and finally to expert. [31] This provides trainees with a scale of where their ability currently is, and what needs to be done to attain competence. Many rubrics do not include the expert category, as residents may not be required to become experts in a procedure, but rather to become competent.[31]

There are many validated rubrics used in the training of ophthalmology-based surgical skill. Some of the more well-known and used rubrics include the Objective Assessment of Skills in Intraocular surgery (OASIS), the Global Rating Assessment of Skills in Intraocular Surgery (GRASIS), the Objective Structured Assessment of Cataract Surgical Skill (OSACSS), and the Eye Surgical Skills Assessment Test(ESSAT)[12, 33] These rubrics use mostly subjective measures plotted on a scale from 1-5, in keeping with a modified Dreyfus scale for each task performed. There is often a "Global Rating scale of operative performance", which is a subjective grading assessed over all the tasks performed (see Figure 1).[12]

Simulation

Surgical simulation has been around for many years. Probably the earliest simulation in medicine was that of Dr Gregoire of Paris, who, in the 1700s, used a pelvis with skin stretched across it, along with a deceased foetus, to simulate complicated deliveries to healthcare professionals involved in child birth.[34] Simulation in the aviation and aerospace industry is well documented, and all modern pilots learn firstly on simulators prior to flying a real aeroplane or spacecraft.[35, 36]

Simulation has come a long way since the 1700s. Of particular interest was the introduction of laparoscopic surgery, because it had a steep learning curve, but, due to its popularity, it became a required skill that both new and experienced surgeons were quickly expected to attain. Many laparoscopic surgical simulators were developed, both high-fidelity and low-fidelity – enabling novice surgeons the opportunity to practise their skill prior to moving onto " live" patients.[35, 37] Many of the challenges present in laparoscopic surgery are present in retinal surgery. It requires a training surgeon to get familiar with a new way of viewing a familiar field in an unfamiliar way – as well as getting used to new instruments and their different ergonomics.[35] The most elementary of laparoscopic simulators became known as the "black box" simulator. These simulators were low fidelity simulators that were made from cardboard boxes through which laparoscopic instruments were placed – allowing simple tasks simulating those needed in surgery to be performed. The tasks used simple low cost material to simulate surgical tasks, and some of these included knot tying, suturing foam, placing pegs into boards, and transferring elastic bands.[38-41] These simulators offered a cheap, do-it-yourself, option for effective surgical simulation for the training laparoscopic surgeon. The cheaper, low-fidelity models were non-inferior to the more expensive high-fidelity commercial alternative simulators.[35, 41]

Another motivation for the use of a competency based training curriculum is that different individuals have different learning curves. Some training surgeons have a higher innate ability for performing tasks than others, and those that start with a high innate surgical ability may benefit less from simulation – although one study looking at laparoscopic cholecystectomy simulation showed that about 63% of participants benefited significantly from simulation, where they attained proficiency after approximately 25 procedures.[42]

There are many wet and dry lab eye models that are implemented in ophthalmology, but probably the most well-known and validated simulator is the Eyesi ophthalmic surgical simulator made by VR magic (VRmagic Holding AG). It has a variety of modules, which include anterior and posterior segment tasks, and has been validated to improve novice surgeons' dexterity to expert surgeon levels. [43] The simulator comprises a model eye on a gimbal with two proprietary instruments placed into the model. The instruments are tracked via video cameras that feed data into a computer. The user is provided with a binocular stereoscopic view through eye pieces, which have two small LCD displays within them – simulating looking through a microscope. Different software modules are loaded depending on the task being learnt. A user can choose to learn how to perform a continuous curvilinear capsularhexis or perform a cataract extraction, phacoemulsification surgery in total, and a variety of other modules.[6, 43, 44] The Eyesi is a relatively mature platform that has shown face, content and construct validity, and decreases complication rates and shortens the learning curves of training surgeons.[7, 45, 46] As a result, many institutions are adopting the Eyesi into their surgical training curricula, but the main limiting factor – especially in an African or third world context – is the price, as it is priced in excess of $150 000 or R2 148 090. While one study's cost analyses of the simulator found that it wasn't a cost-effective model.[47] Another looked at the cost benefit of the Eyesi for phaco-sim training and found that two residents in training using the simulator would save about $5502 over 5 years due to increased efficiency . If there were nine residents using the simulator over 10 years, the expected saving would be about $46 117 – which is only a third of the cost of the simulator itself.[47] This drives the need for other low cost simulation options that can hopefully provide surgeon training in a lower resource setting with some of the benefits that simulation surgery provides.

Low cost, low fidelity simulation is not a new concept in ophthalmology. Many residents have used baked tomatoes/grape skins as a surrogate for the anterior lens capsule or bacon is used as a substitute for extraocular muscles.[48-50] There are also wet lab kits such as the popular Kitaro Dry Lab and Wet Lab system Kit (FCI Ophthalmics, Pembroke, MA, USA), Phak-I (Gulden Ophthalmic), Marty the Surgical Simulator (Iatrotech Inc., Del Mar, CA) and others – although there does not seem to be much literature validating these specific models.[51] Currently, the only low cost vitreoretinal dexterity simulator published, is the simulator published in *Retina* in 2018, and developed under Dr James Rice at Groote Schuur hospital, and here the concept was published providing the simulator with face and content validity.[52]

Validity

Prior to implementing a simulation device, it is critical that it is validated to ensure that its use is scientifically grounded. Five forms of validity are recognised. Face, content, construct, concurrent and predictive validity.[53]

Face validity is an informal assessment of a simulator assessed by non-experts – to determine if a simulator represents what it is supposed to represent.[53, 54] The degree to which the simulator appears effective in terms of it's stated aims.

Content validity involves the evaluation of a simulator by experts in the field in which the simulator is being used. Experts provide their opinion with regard to how useful the simulator would be for training.[53, 55]

Construct validity is often viewed as one of the most valuable and important assessments and is an essential assessment of a simulator. Construct validity ensures that a simulator can tell the difference between the performance of expert and novice surgeons. Assessment of construct validity entails comparing the performance of experts to novice surgeons.[53, 56]

Concurrent validity requires the simulator to be compared to the gold standard for teaching the skill it was designed to teach.[53] In the case of this low cost retinal simulator, one could argue that testing it against the EyeSi would provide concurrent validity.

Predictive validity is determining what the long-term effects of the simulator are on the outcomes of surgery. This requires long-term follow up comparing two groups – one group that has used a simulator and another that hasn't, and then comparisons of their surgical outcomes need to be made to assess the true long-term value of a simulator.[53]

The low cost vitreoretinal simulator developed by Dr Rice has face and content validity and its concept was published in *Retina* in 2018 – but it has not undergone construct validity testing.[52] Therefore, it is an important step to compare the performance of expert and novice surgeons using a scoring rubric, to test its ability to differentiate the novice from the expert surgeon.

Most construct validity studies define their expert as qualified specialists that have performed a procedure a certain number of times, and this expert group along with a novice group of training surgeons performs the same set of tasks on the simulator to be validated. In a dry/wet lab setting the tasks are video recorded and then graded using a scoring rubric. In the case of virtual reality simulators – the computer itself does the grading. The scores between the expert and novice group are then compared using analysis of variance (ANOVA).[53, 56, 57]

Innate ability, past experience, the design of the training programme, mentors, simulation and many other factors play a role in the development of competent surgical skill. An often-assumed important factor for surgical dexterity is stereoacuity. Surgical dexterity involves using eye-hand coordination to locate objects and tissue in space. Stereoacuity is one of many factors that allows a surgeon to assess depth and position objects. There are both monocular and binocular cues for depth perception. Monocular cues include perspective-based cues, shading, familiar size, relative size, texture, shadowing, relative brightness, focus and distance to the horizon. Binocular depth cues include oculomotor cues, which include convergence and accommodation and of course, stereopsis. Stereopsis is the function of binocular vision, where two different but similar images which fall in Panums fusional area, along the horopter, are used to give the perception of depth. Many monocular cues can be used, but are not as reliable in the setting of a surgical field viewed through the microscope. Therefore, stereoacuity is relied on by many surgeons to assist them with completing surgical tasks.

However, it is not accepted that stereoacuity is a prerequisite for performing ophthalmic surgery.[58] Countries like The Netherlands have had stereoacuity requirements for admission as a resident since 2001,[58] but it has been shown that although stereoacuity allows for better initial performance in dexterity tasks, it does not prevent surgeons from developing the appropriate skills over time.[59] So with sufficient practice, one can overcome ones lack of stereoacuity. In the case of laparoscopic surgeons who view a two dimensional image, stereoacuity conferred no benefit to surgeons.[60] With studies using the Eyesi simulator it was found that those that had a stereo acuity of <80 sec and less, performed significantly worse than those with greater than 60 seconds of arc.[61] Therefore, it is important to take stereoacuity into account when doing research into microsurgical dexterity. More studies are needed to show whether there is a long-term benefit in surgical outcomes when stereoacuity is absent or decreased.

Conclusion

Training of surgical skill is undergoing a paradigm shift from an old apprenticeship model to a newer competency-based model. The way surgical techniques are taught needs to be more structured, with objective assessment and criteria for trainees and trainers to benchmark a learning surgeon against. One of many valuable tools in this newer and more effective approach is the implementation of surgical simulation – as well as the development of assessment rubrics. Although virtual reality simulators are effective, their cost is prohibitive – especially in a developing country perspective. In the same geographical setting, there's an expected increase in burden on retinal ophthalmic services, including surgical retinal management. The development of a low cost surgical simulator may be a valuable tool for assisting both residents and specialists in improving their microsurgical dexterity – in conjunction with or prior to transferring these skills to live patients. Hence the value in assessing the construct validity of a low cost vitreoretinal surgical simulator. [62]

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Full Text Journal Article For Submission

Title page

Full Title:

Construct validity testing of a low cost vitreoretinal surgical simulator

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First Author: Dr Dean van der Westhuizen

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- Development of the low cost retinal surgical simulator validated in this study
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- Supervisor to the first Author for his MMed Minor thesis
    - Guidance and contributions with regards to
        - Support and mentorship
        - Study design and research protocol
        - Human research ethics committee submission
        - Proof reading and editing of final write up

Third Author: Tonya Esterhuizen

- Sample size advice and data management
- Statistical analysis of data
- Write up of results

Disclaimer: All views expressed in this article are our own and are not an official position of the institution or funder.

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Title: Construct validity testing of a low cost vitreoretinal surgical simulator

Abstract

Objective:

To test the construct validity of a low cost, low fidelity vitreoretinal surgical simulator

Design:

Construct validity study. Six microsurgical dexterity tasks,performed on a low cost vitreoretinal surgical simulator, were graded using a scoring rubric designed to assess microsurgical dexterity. Tasks one and two were dominant hand exercises, tasks three-five required bimanual dexterity and task six assessed visualization through a retinal viewing system The scores of a novice group (Ophthalmology residents who had never performed a pars plana vitrectomy) were compared to an expert group (Vitreoretinal surgeons who had performed in excess of 20 pars plana vitrectomies). Scores were graded via video recordings of the tasks, by blinded independent graders using a scoring rubric.

Participants:

The novice group of surgeons included 8 ophthalmology residents training at the Groote Schuur hospital department of Ophthalmology. The expert group of surgeons included 5 vitreoretinal surgeons working at the Groote Schuur hospital department of Ophthalmology, and 2 vitreoretinal surgeons working in the private sector in Cape Town, South Africa.

Results:

Expert surgeons performed significantly better($P= <0.05$) than the novice surgeons across all six microsurgical dexterity tasks. Greater differences were seen in bimanual tasks(tasks three-five) *and in task six that was designed specifically to assess the surgeon's ability to ensure good visualisation through a retinal viewing system.*

Conclusions:

The microsurgical dexterity tasks performed on This low cost, low-fidelity vitreoretinal surgical simulator can distinguish between novice and expert retinal surgeons demonstrating *significant construct validity. Its use can be encouraged in the training of novice vitreoretinal surgeons.*

Key Words:

Education, Ophthalmology, Simulation, Training,Vitreoretinal, Validity

Competencies:

Practice-Based Learning and Improvement

Introduction

The long used "see one, do one, teach one" mantra that has been present in medical training, and more specifically in surgical training, is outdated, and is now considered unacceptable.[1] There is a move toward competency-based curricula that provide a stepwise approach to gaining competency and confidence prior to moving onto "live" patients.[2-5] Surgical simulation training is a key component to improving, assessing and monitoring surgical skill as surgeons move through the different competency levels from Novice to Expert[6].

It is well documented and accepted that “practice makes perfect” and that surgical competency improves the more one repeats the same task.[7] The notion of expert performance being a result of innate talent is a view seldom held, intense, deliberate practice is what results in the skill of elite performers[8]. This is evident in the classical surgical logbook that is required in most surgical training curricula. It is assumed that once one has performed a certain number of procedures that one has become competent. The main concern with this approach, however, is the safety of a patient who is receiving the surgical treatment from someone who has never performed the procedure before. The outcomes have been shown to be poorer and therefore the patients bear the burden of a new surgeon learning.[9] The onus is on training facilities to attempt to decrease the risks involved in novice surgeons performing their first cases. One of the main ways that this can be achieved is by using surgical simulation.[2-4, 10]

Ophthalmic surgical simulators such as the EYE-SI (VRmagic) (see Figure 1) and PhacoVision (Melerit Medical) have been validated and implemented throughout the world in an attempt to improve competency prior to or in conjunction with training on live patients.[11-13] Their use has also been shown to decrease complication rates, improve visual outcomes, and improve wet lab surgery performance. [14-16]

Figure 1 EYE-SI high fidelity ophthalmic surgical simulator[10]

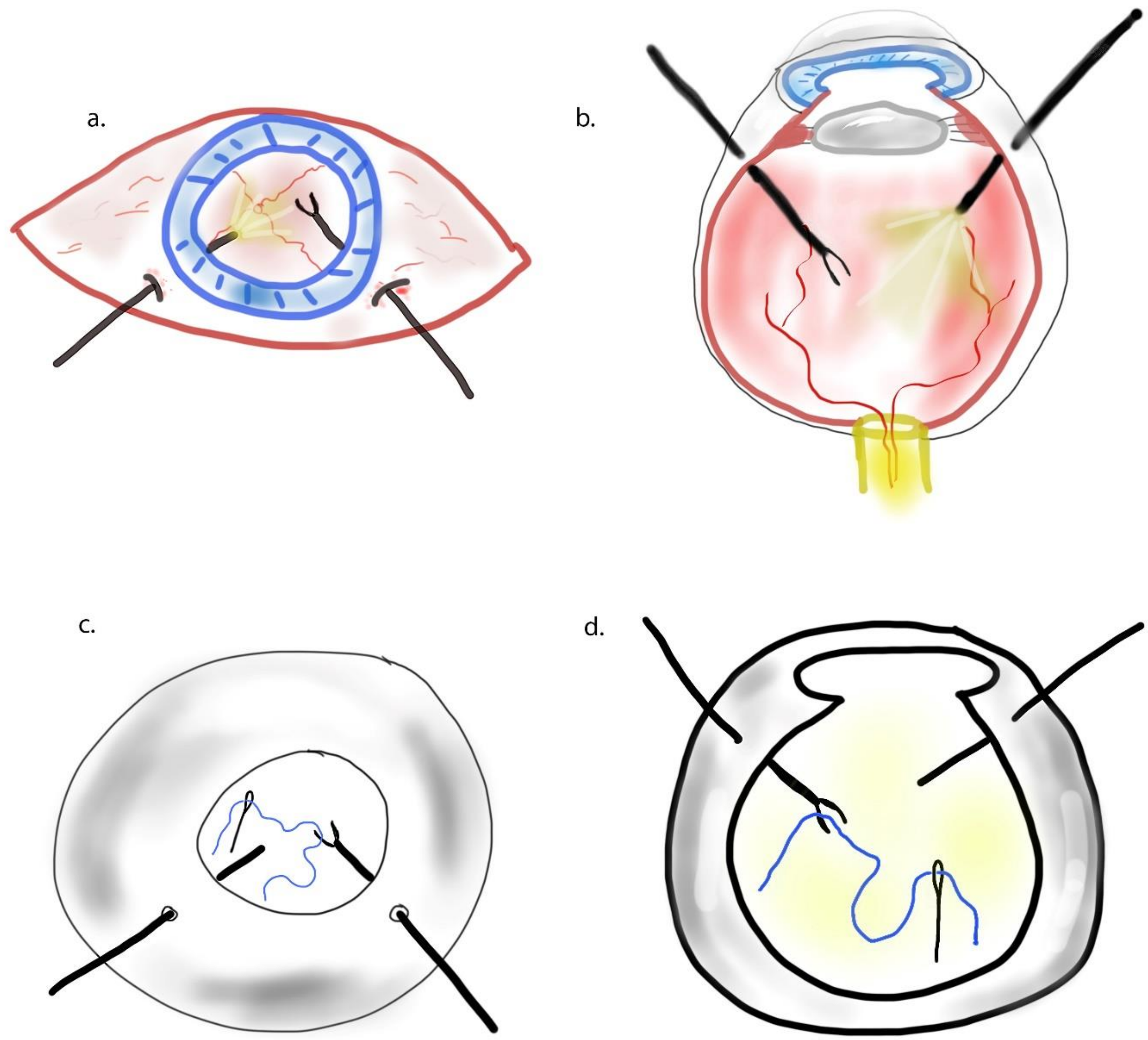
Many of the advancements and adoption of surgical simulation came from the advent of laparoscopic surgery. The laparoscopic simulation technology was stimulated by the fact that laparoscopic surgery had a steep learning curve – coupled with a high demand for competency. Both experienced and novice surgeons were required to learn a new skill quickly.[17, 18] High fidelity expensive laparoscopic simulators (see Figure 2) were developed and validated. But of particular interest was the invent of the low cost, low fidelity "cardboard box" surgical simulator (Figure 3), which was shown to be as effective as the high-fidelity alternatives.[19-23] A stark parallel can be made between laparoscopic surgery and vitreoretinal surgery. Both use imaging systems to get a view of the surgical field, and then instruments are then passed through "ports" to practise dexterity tasks inside a cavity.

Figure 2 LapVR high fidelity laparoscopic surgical simulator[17]

Figure 3 "Black box" cardboard box laparoscopic surgical simulator[22]

Dr James Rice of the Department of Ophthalmology at Groote Schuur Hospital pioneered the development of a low cost, low fidelity vitreoretinal surgical simulator using a table tennis ball, through which ports are placed to allow a training surgeon to practice microsurgical dexterity tasks (see Figure 4). A hole is drilled in the table tennis ball to mimic a pupil. Through this pupil the surgeon using a retinal viewing system and an operating microscope can view the posterior surface of the table tennis ball where a variety of tasks can be performed (see Figure 5). The purpose of this study is to measure the construct validity of this low cost, low fidelity surgical simulator for vitreoretinal surgery.

Figure 4 Low cost retinal simulator made from a 4o mm table tennis ball as described in text above



a. **Schematic of actual retinal surgery, anterior posterior view(Illuminating light pipe and retinal microforceps in an eye)**
b. **Schematic of actual retinal surgery, coronal view(Illuminating light pipe and retinal microforceps in an eye)**

c. **Schematic of simulator, anterior posterior view(Light pipe and retinal microforceps in a table tennis ball)**
d. **Schematic of simulator, anterior coronal view(Light pipe and retinal microforceps in a table tennies ball)**

Figure 5

Methods

Study design

Construct validity is an essential assessment of a simulator as it proves that it can distinguish between an expert and novice surgeon. Construct validity is often viewed as one of the most valuable and important assessments and is an essential assessment of a simulator. Construct validity ensures that a simulator can tell the difference between the performance of expert and novice surgeons. Assessment of construct validity entails comparing the performance of experts to novice surgeons.[24, 25]

We designed a construct validity study comparing microsurgical tasks performed within the simulator of a novice group (group 1) comprising ophthalmology residents, who had never before performed a pars plana vitrectomy, but who all had at least 2 years microsurgical experience ,and an expert group comprising consultant ophthalmologists that had performed in excess of 20 pars plana vitrectomies.

Each group performed 6 tasks on the simulator. The performance of each participant was recorded via a beam splitter and camera mounted to the operating microscope. The recorded video offered the graders the same view as the participants, who, using a scoring rubric, graded the performance of the participants (Appendix 1). Each of the six tasks were scored out of 20. In addition, a global overall indices value was assessed using the scoring rubric. The scoring rubric is based on similar surgical skill grading rubrics: Objective Assessment of Skills in Intraocular surgery (OASIS), the Global Rating Assessment of Skills in Intraocular Surgery (GRASIS), and the Objective Structured Assessment of Cataract Surgical Skill (OSACSS).[26, 27] These rubrics use mostly subjective measures plotted on a scale from 1-5, in keeping with a modified Dreyfus scale for each task performed. There is often a “Global Rating scale of operative performance” which is a subjective grading assessed over all the tasks performed. [27]

Like the above-mentioned rubrics, the assessment was mostly based on subjective measures, but some tasks that allowed for it also had some objective parameters measured. The above mentioned rubrics were adapted to suite the tasks being assessed.

The simulator

The simulator comprises a standard 40 mm table tennis ball. A hole is made in the centre of the ball which acts as the pupil and 2 smaller holes placed 10 mm form the centre of the “pupil” at 10 and 2 o’clock positions to allow the insertion of retinal instruments. The 40 mm table tennis ball is then placed in a 40 mm piece of PVC piping connector. This allows the ball to be freely rotated in any direction, similar to a ball and socket joint. Simple white led lights were placed beneath the table tennis ball powered by a small battery pack, and the external lighting was diffused by the table tennis ball itself – allowing a diffusely lit environment in which to work. Details on the construction of the simulator were published in “ Eye Health” [28] A variety of tasks were then developed to test microsurgical dexterity. The basic concept and face validity of the simulator was published in *Retina* in 2017.[29] For the first 5 tasks a pupil size of 7 mm was used, which meant the tasks could be performed with minimal to no need to move the microscope during the task. For the 6th task, the pupil was made intentionally small(1.5mm) to force the participant to continually need to adjust the position of the microscope to maintain visualisation of the task.

Microsurgical dexterity tasks

Task 1: Cups and glitter

Coloured glitter was placed at the back of the simulator and participants were required to pick up individual pieces of glitter and place them in the appropriately coloured “bucket”(see Figure 6)

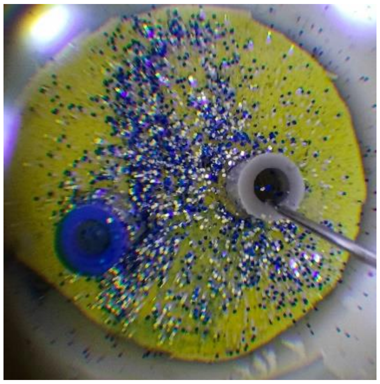


Figure 6 Cups and glitter task viewed through ophthalmic microscope

Task 2: Washing line

V-shaped wire clips were placed in the “eye” and 2 black “washing lines” were place anteriorly in the simulator. Participants were required to pick up a single wire V and place it on the “washing line” (see Figure 7)

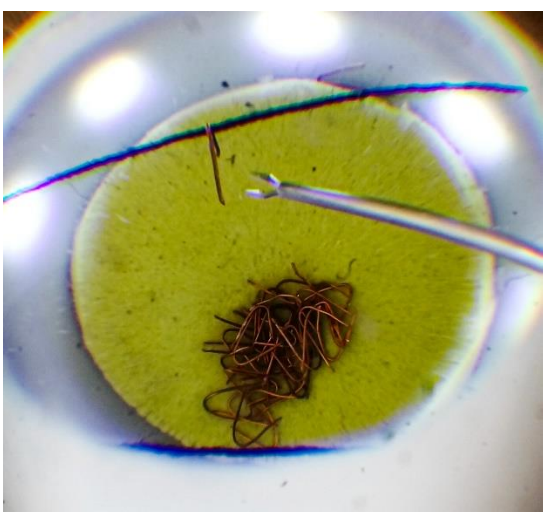


Figure 7 Washing line task viewed through ophthalmic microscope

Task 3: Eye of the needle

Three needles were placed in the simulator with the eye of the needle facing upward and at different heights within the globe. The Participants were required to thread 10/O nylon sutures through each of the three needles before starting over again if time allowed (see Figure 8).

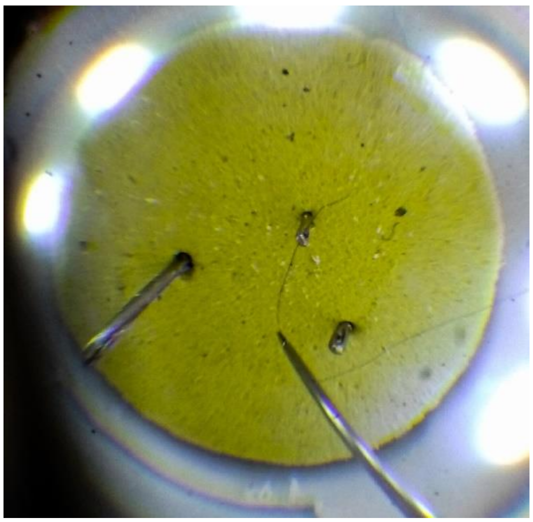


Figure 8 Eye of the needle task viewed through ophthalmic microscope

Task 4: Shape cutting

A paper disc with an arrow printed onto it was placed in the simulator and participants were required to cut the shape out using a retinal forceps in their non-dominant hand, while cutting the shape with their dominant hand (see Figure 9).

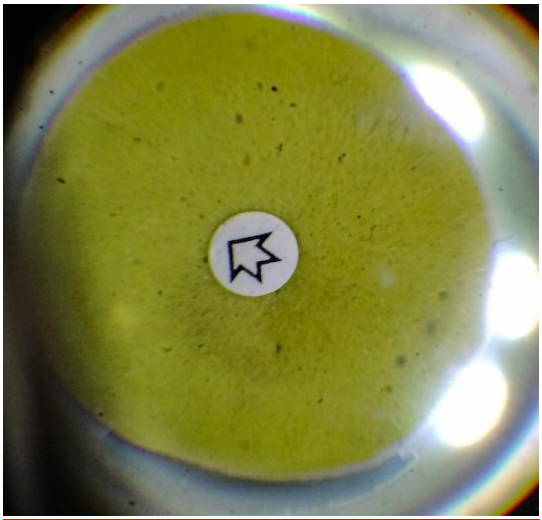


Figure 9 Shape cutting task viewed through ophthalmic microscope

Task 5: Membrane dissection

"Opsite® spray" was used to create a membranous film on the surface of a pieces of silicone. The membrane was coloured with a red marker, creating discs which participants were required to peel/cut/dissect using a grasping forceps in their dominant hand and retinal scissors in their non-dominant hand (see Figure 10).

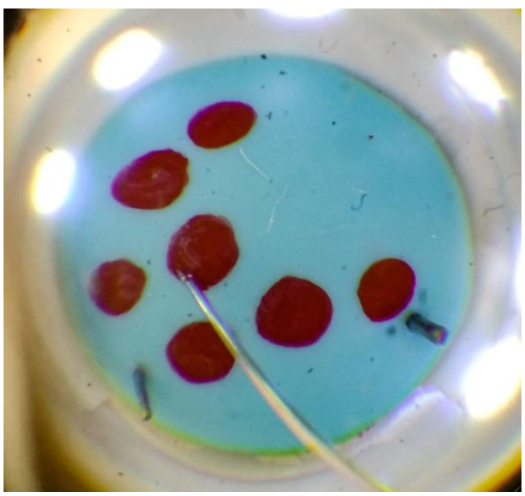


Figure 10 Membrane dissection task viewed through ophthalmic microscope

Task 6: Follow the numbers

Numbers from 1 – 10 were placed on the back surface of the simulator. Participants were required to visualise the numbers in sequence and touch the number with their forceps. The numbers were placed in strategic positions, forcing participants to move the globe and the microscope to ensure good visualisation. The simulator "pupil" was made intentionally small (1.5 mm) to make visualisation more challenging and to encourage the use of movements of the globe and x/y movements using the foot pedal to bring each number into view (see Figure 11).

Figure 11 Follow the number task viewed through ophthalmic microscope

A short video example of a simulator being used can be viewed at the following link:

https://tinyurl.com/retinalsim2

Data collection

The data were collected in the Groote Schuur Hospital theatres using a Möller-Wedel ophthalmic microscope with Eibos® retinal viewing system attached. Participants' visual acuity and stereo acuity was tested prior to enrolment with a visual acuity <6/6 or a stereo acuity <60 seconds of arc acting as exclusion criteria to prevent bias.[12] Each task was timed – with participants having 3 minutes to perform each of the 6 tasks. The tasks were recorded and labelled with a participant number but no identifiable information, ensuring that graders were blinded to the identity of the participant. The video was then graded by two independent graders using the scoring rubric. One grader was an ophthalmology resident and the other a qualified general ophthalmologist. The rubric was designed like many other surgical simulation rubrics – to allow anyone to grade the tasks and not limiting the scoring to retinal specialists.

A side-by-side video example of novice and expert can be viewed here:
https://tinyurl.com/retinalsim

Ethical considerations

Ethical approval was granted by the Human Research Ethics Committee of the University of Cape Town: HREC Ref 519/2019 (see Appendix 2). The main ethical consideration was that participants may feel self-conscious with regard to their microsurgical dexterity being assessed, which could reflect badly on them as surgeons. Informed consent was taken and participants' identity was blinded and kept anonymous (see Appendix 3). Permission was obtained from the

Chief operational officer to conduct the data collection in the Theatres of Groote Schuur (see Appendix 4).

Statistical analyses

IBM SPSS version 25 was used to analyse the data. A p value <0.05 was considered as being statistically significant. The results of the separate tasks and overall scores were compared between the two groups (novice and expert) separately for the two graders using independent t-tests. The results of each test were then compared between graders 1 and 2 separately for the novice and experienced groups. To further assess inter-rater reliability, intra-class correlation coefficients were calculated between each pair of scores. A two-way mixed model was used, which means that 2 fixed raters are defined and each subject is measured by the two raters. The single measures statistic was used, which means that even though more than one measure is taken in the experiment, reliability is applied to a context where a single measure of a single rater will be performed.

Results

To compare the results of the novice and experienced groups.

This was done separately for each grader. The results showed that for each grader and for each task, there was a highly significant difference in all scores between the novice and expert groups. (see Table 1)

To compare the scoring of the two graders

This was done for the two groups, novice and expert, separately. The only difference between grader 1 and 2 was found in the novice group for task 4 (p=0.033). In this case grader 1 scored higher than grader 2. For the expert group there were no differences between the grader scorings. (see Table 2)

Inter-rater reliability measured by the intra-class correlation coefficient.

Table 3 below shows the correlation coefficient (p value) for a 2way-mixed model for consistency with single measures. There were strong correlations between the ratings of the two raters for most measures except for tasks 1 and 5 in the novices. Task 5 had a negative correlation between the raters but on closer inspection this was due to two outlying data points where rater 1 scored lower than rater 2, which in the small sample were influential points. The global indices and total scores showed very high correlations between the raters. (see table 3)

Discussion

This low cost low fidelity vitreoretinal simulator has construct validly for microsurgical dexterity. The performance of the vitreoretinal surgeons in the expert group was significantly better than for the novice group of residents. The statistical significance held true across all 6 tasks, using the global indices score only, and when considering the total scores (see Figure 12, Figure 13)).

The bimanual tasks which included tasks 3, 4 and 5 showed a higher discrepancy between the novice and expert group. The task that showed the largest difference was task 6. The closest scores were noted in non bi-manual tasks – those being tasks 1 and 2 (see Figure 12)

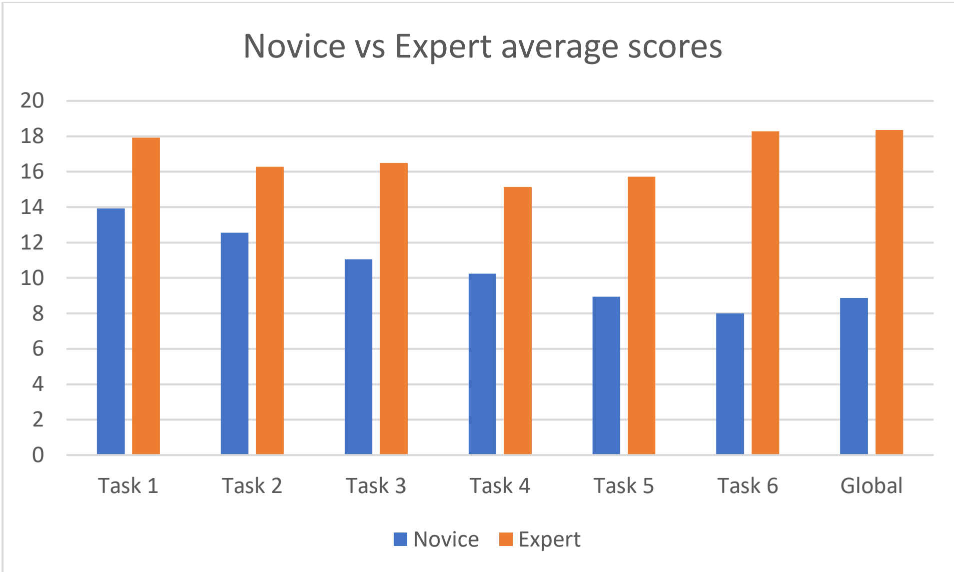


Figure 12 - Novice and expert scores per task

Figure 13 - Total scores out of 140 for Novice(n-8) and Expert(n-7) group

Retinal surgery is required for a number of retinal diseases, but is increasingly for the consequences of diabetic retinopathy. The global prevalence of diabetes is expected to increase from approximately 382 million to approximately 592 million by the year 2035.[30] The prevalence of diabetic retinopathy and vision threatening diabetic retinopathy is 34% and 7% respectively.[31] Retinal surgery has advanced significantly over the last 30 years. Visual outcomes have improved significantly over the decades, with improved techniques and advances in equipment and machines.[32, 33] As a result, there will be an increased demand for surgery and therefore for vitreoretinal surgeons.

The increased demand for vitreoretinal surgeons will require a response from training facilities to meet this need. Like all surgical training, one needs 'hands on time' to improve one's skills, and to attain competency. Traditional apprenticeship models of teaching require one on one teaching with a live patient, which is a very inefficient approach. [34]

Ironically "teaching and testing of technical skills in surgery is the least systematic or standardized component of [the] classical surgical curriculum".[24] One would think that the teaching and testing of technical skills would be the most standardised and systematic in a profession in which the essential basis is technical skill.

Thus, there is a push toward improving and standardising the teaching of surgical skill in all surgical specialties.[34, 35] Many different tools and technologies have been implemented to improve surgical training in an era where cost, increasing demands on doctors' time, litigation risk and increased ethical considerations in the operating room need to be considered.

Two core tools that have been used to address the shortcomings of the traditional model are assessment rubrics and surgical simulators. An assessment rubric is a tool used to score or assess a surgeon's skill in performing a task. A variety of assessment tools have been developed in ophthalmology, which include Objective Assessment of Skills in Intraocular Surgery (OASIS), Objective Structured Assessment of Cataract Surgical Skill (OSACSS), Global Rating Assessment of Skills in Intraocular Surgery (GRASIS), and the Eye Surgical Skills Assessment Test (ESSAT).[27, 36-38] These tools enable training surgeons to have an objective score on which to improve, and provide supervisors a measure of trainee competence. The same way that standardised tests are used to measure medical knowledge, these help provide a standardised measure of surgical skill – which in the past has not been measured.

The other tool that has come to the fore with regard to surgical training is the surgical simulator. The airline and aerospace industry have used simulation for decades and have found it to be a cost effective and efficient way of training pilots and preparing pilots and astronauts for the technical tasks required of them.[39, 40] Interestingly, high fidelity models did not necessarily outperform lower fidelity simulators.[39]

The first surgical simulation recorded was by Dr Gregoire in Paris in the 17th century, who stretched skin across a pelvis and used a deceased foetus to demonstrate complicated deliveries,[41] but simulation has come a long way since then. Two particular procedures have benefited greatly from surgical simulation: laparoscopic surgery and bronchoscopy. When laparoscopic cholecystectomies were first performed, complication rates where high, with a steep learning curve for learning surgeons.[42] The introduction of laparoscopic surgical simulators improved the learning curve and decreased complication rates in the learning surgeon.[42] As with flight simulators, a low fidelity "black box" laparoscopic simulator was developed to decrease the cost of simulating laparoscopic surgery. These "black boxes" were literally cardboard or plastic boxes through which cameras and instruments were placed to simulate surgical tasks[43] (see Figure 3).

These low fidelity cardboard box simulators have been shown to be as effective as more expensive high fidelity virtual reality simulators – especially with very novice surgeons with no previous experience in laparoscopic surgery.[17]

The low fidelity, low cost retinal simulator developed at Groote Schuur Hospital builds on similar principles (see Figure 5). There are expensive high fidelity surgical simulators that assist beginner surgeons who are starting out with vitreoretinal surgery, but these systems are not available in most third world contexts – including South Africa (see Figure 1). In the same way the "black box" simulator has been used in laparoscopic surgery we hope this simulator may have a similar impact in the training of vitreoretinal surgeons.

Our data showed that there was construct validity across all 6 tasks tested. There was a greater difference between novice and experts when performing bimanual tasks over tasks where only the dominant hand was used to complete a task. This is in line with the subjective feeling of retinal surgeons that bimanual work is more challenging. The tasks where the difference between novice and experts was closest, was task number 1. This was to be expected as it was considered to be the easiest task, although there was still a statistically significant difference between the novice and expert groups. The task that showed the greatest difference between novice and expert groups was task 6. This task required moving the retinal viewing system and manipulating the globe appropriately to ensure a clear view of the surgical field. One of the biggest challenges in vitreoretinal surgery is ensuring one has a clear view of the surgical field, which relies on both eye hand and foot coordination. Moving the "eye", focusing the retinal viewing system which needs to be placed at the appropriate distance from the eye, as well as using the surgeon's feet to move the microscope along its x and y axis to keep the retinal instruments, area of interest in view, is a complex interplay of hand and foot movements. This may explain the large difference seen in the scores in task 6. Although the novice surgeons were familiar with using their foot to x-y the microscope for anterior segment surgery, the optics and manoeuvring required to ensure good visualization for posterior segment work was found to be a particular challenge to novices.

Although this is a low cost, low fidelity simulator it does have a significant number of strengths over its more expensive high-fidelity brothers. The main advantage is that one is using actual retinal instruments, including forceps and scissors, that one would use in surgery itself, and the feel in the hand and the way the instruments respond will be the same as in live surgery. With this comes the tactile feedback that one gets from interacting with different substances placed within the simulator. The virtual reality simulators attempt to provide haptic feedback through computer generated movements that are never as intuitive as the actual feedback one gets from using real instruments.

The other major advantage is using an actual retinal viewing system such as an Eibos® or Biom® attached to an operating microscope. This provides a visual environment extremely similar to the live environment, meaning that there are elements of the simulator which may have more fidelity than more expensive simulators. While using the simulator in this way one also is required to use the microscope foot pedal to drive the microscope in different directions to ensure optimal viewing of the “surgical field”, and much of the challenge of vitreoretinal surgery is ensuring one has an optimal view while operating. Using the same microscope footswitch and viewing switch, which one will eventually use to perform live surgeries, is also a major advantage.

The main disadvantage of this low cost simulator over other virtual reality simulators is the ability of virtual reality simulators to grade the trainee automatically – as the tasks are being performed. Software built into the devices is used to grade the trainee and can save and monitor the progress of the user accurately over time. Having immediate progress scores available means the simulator environment is more like a modern video game that encourages the user to improve and progress through different stages and difficulties. With the low cost simulator one requires a secondary observer, along with the scoring rubric to grade ones performance, which means that instant feedback of ability is not available. The high-fidelity simulators are also able to simulate real ocular pathology fairly realistically, allowing trainees to learn the steps in the order they would perform them on real patients. Draining of subretinal fluid, applying laser, peeling membranes and other pathologies can be simulated very realistically. The Eyesi is also a stand alone unit that would be placed as a stand alone unit outside of theatre allowing trainees to make use of the simulator outside of theatre.

There were a number of possible confounding variables in this study. The data collection was done at either 7am or 5pm depending on the schedule of the participant enrolled, performance due to time differences may be considered a confounding factor. The amount of caffeine consumed, use of beta blockers or other substances known to affect microsurgical performance were also not controlled for. The expert group of surgeons that did not operate regularly at the hospital where the data collection was done. Being in an unfamiliar environment, which included different chairs ergonomics, microscope footswitch and optics may have affected scores but didn't affect the overall outcome. One of the main limitation of study is that although it provided construct validity it did not determine how much time it would take for novice surgeons to attain the microsurgical dexterity of the expert surgeons. Allowing novice surgeons to spend time practicing on the simulator before retesting would provide valuable information of the learning curve a novice surgeon can expect.

Conclusion

A low cost, low fidelity vitreoretinal surgical simulator has construct validity for microsurgical dexterity. The low cost simulator measures microsurgical dexterity ability and can accurately determine the differences between novice and expert vitreoretinal surgeons. The scoring rubric across all six tasks showed statistical significance between training residents who had never performed a pars plana vitrectomy and expert vitreoretinal surgeons who had performed in excess of 20 pars plana vitrectomies. Vitreoretinal tasks that require bimanual microsurgical dexterity were shown to be more challenging and the difference between novice and expert scores where greater for these tasks. The largest discrepancy in scores was for the task assessing visualisation skills.

We recommend the use of this validated simulator in the training of novice vitreoretinal surgeons, although further studies looking at concurrent and predictive validity of the device would provide further evidence for its use. Of particular interest would be the direct comparison of this low cost simulator to more expensive simulators such as the Eyesi simulator to determine non-inferiority.

Acknowledgements

Will Dean, who runs the ophthalmic surgical simulation unit at Groote Schuur Hospital, is thanked for his input and guidance around the study design and use of the simulation unit for piloting the simulator and use of the simulation unit for data collection. Dr Jason Thomas and Dr Schabort de Jager are thanked for their contribution as graders. Dr Tonya Estherhuizen helped with statistical analyses and planning with regard to study design and numbers.

Tables

Table 1 Group statistics and comparison by grader

Group Statistics and Comparisons by Grader						
grader		group	N	Mean	Std. Deviation	P value
1	Task 1	novice	8	14.13	.991	<0.001
		expert	7	17.86	1.464	
	Task 2	novice	8	12.88	2.295	0.005
		expert	7	16.43	1.718	
	Task 3	novice	8	10.88	2.031	<0.001
		expert	7	16.29	1.799	
	Task 4	novice	8	10.50	1.195	<0.001
		expert	7	15.57	1.272	
	Task 5	novice	8	8.75	.707	<0.001
		expert	7	15.57	1.618	
	Task 6	novice	8	8.00	2.330	<0.001
		expert	7	18.14	.900	
	global indices	novice	8	8.63	2.264	<0.001

		expert	7	18.43	2.070	
	Total /140	novice	8	73.75	9.083	<0.001
		expert	7	118.29	7.825	
	Total percentage	novice	8	52.6786	6.48782	<0.001
		expert	7	84.4898	5.58963	
2	Task 1	novice	8	13.75	1.669	<0.001
		expert	7	18.00	1.155	
	Task 2	novice	8	12.50	2.138	0.003
		expert	7	16.14	1.773	
	Task 3	novice	8	11.13	1.642	<0.001
		expert	7	16.71	1.976	
	Task 4	novice	8	9.50	1.604	<0.001
		expert	7	14.71	1.799	
	Task 5	novice	8	9.25	1.035	<0.001
		expert	7	15.86	1.864	
	Task 6	novice	8	7.63	1.847	<0.001
		expert	7	18.43	1.272	
	global indices	novice	8	9.00	2.828	<0.001
		expert	7	18.29	2.430	
	Total /140	novice	8	72.75	9.020	<0.001
		expert	7	118.14	8.071	
	Total percentage	novice	8	51.9643	6.44273	<0.001
		expert	7	84.3878	5.76508	

Table 2 Paired samples statistics by group

Paired Samples Statistics by Group						
group			Mean	N	Std. Deviation	P value
novice	Pair 1	Task1.1: Task 1	14.13	8	.991	0.528
		Task1.2: Task 1	13.75	8	1.669	
	Pair 2	Task2.1: Task 2	12.88	8	2.295	0.504
		Task2.2: Task 2	12.50	8	2.138	
	Pair 3	Task3.1: Task 3	10.88	8	2.031	0.711
		Task3.2: Task 3	11.13	8	1.642	
	Pair 4	Task4.1: Task 4	10.50	8	1.195	0.033
		Task4.2: Task 4	9.50	8	1.604	
	Pair 5	Task5.1: Task 5	8.75	8	.707	0.351

		Task5.2: Task 5	9.25	8	1.035	
	Pair 6	Task6.1: Task 6	8.00	8	2.330	0.197
		Task6.2: Task 6	7.63	8	1.847	
	Pair 7	globalindices.1: global indices	8.63	8	2.264	0.197
		globalindices.2: global indices	9.00	8	2.828	
	Pair 8	Total140.1: Total /140	73.75	8	9.083	0.264
		Total140.2: Total /140	72.75	8	9.020	
	Pair 9	Totalpercentage.1: Total percentage	52.6786	8	6.48782	0.264
		Totalpercentage.2: Total percentage	51.9643	8	6.44273	
expert	Pair 1	Task1.1: Task 1	17.86	7	1.464	0.689
		Task1.2: Task 1	18.00	7	1.155	
	Pair 2	Task2.1: Task 2	16.43	7	1.718	0.457
		Task2.2: Task 2	16.14	7	1.773	
	Pair 3	Task3.1: Task 3	16.29	7	1.799	0.356
		Task3.2: Task 3	16.71	7	1.976	
	Pair 4	Task4.1: Task 4	15.57	7	1.272	0.111
		Task4.2: Task 4	14.71	7	1.799	
	Pair 5	Task5.1: Task 5	15.57	7	1.618	0.457
		Task5.2: Task 5	15.86	7	1.864	
	Pair 6	Task6.1: Task 6	18.14	7	.900	0.457
		Task6.2: Task 6	18.43	7	1.272	
	Pair 7	globalindices.1: global indices	18.43	7	2.070	0.356
		globalindices.2: global indices	18.29	7	2.430	
	Pair 8	Total140.1: Total /140	118.29	7	7.825	0.864
		Total140.2: Total /140	118.14	7	8.071	
	Pair 9	Totalpercentage.1: Total percentage	84.4898	7	5.58963	0.864
		Totalpercentage.2: Total percentage	84.3878	7	5.76508	

Table 3 Correlation coefficient(p value) for 2 way-mixed model for consistency with single measures

Task	Novice	Expert
1	0.322 (0.199)	0.767 (0.013)
2	0.770 (0.008)	0.852 (0.004)
3	0.508 (0.081)	0.820 (0.006)

4	0.714 (0.015)	0.696 (0.028)
5	-0.273 (0.761)	0.852 (0.004)
6	0.937 (<0.001)	0.627 (0.048)
Global indices	0.958 (<0.001)	0.986 (<0.001)
Total/140	0.967 (<0.001)	0.965 (<0.001)
Total percentage	0.967 (<0.001)	0.965 (<0.001)

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Appendices

Appendix 1 – Scoring rubric

Participant number: ___________________			Group number: _________________			
	1	2	3	4	5	SCORE
1.Cups and Glitter(3min)						
Number of pieces correctly placed 1a	<5 pieces	10 pieces	15 pieces	20 pieces	>20 pieces	
	1	2	3	4	5	/5
Grasping glitter 1b	Multiple attempts required to secure glitter in forceps. Increased tremor with poor control		Glitter secured with little hesitation and minimal repeat attempts		Glitter grasped on 1st attempt without hesitation. Excellent control and minimal tremor	
	1	2	3	4	5	/5
Travel/Transfer 1c	Awkward, inefficient, tremulous movements when transferring				Efficient, direct and controlled movement when transferring	
	1	2	3	4	5	/5
Placing glitter 1d	Glitter placed in cups with much hesitation, marked tremor and poor control.				Glitter placed in correct cup on first attempt without	

					hesitation, tremor and excellent control.	
	1	2	3	4	5	/5
Total task 1						/20
2.Washing line (3min)						
Number of clips placed on line 2a	<5 clips	5-8 clips	8-10 clips	10-13 clips	>13 clips	
	1	2	3	4	5	/5
Travel/Transfer 2b	Poorly planned, awkward, inefficient, tremulous movements when transferring				Well planned, efficient, direct and controlled movement when transferring	
	1	2	3	4	5	/5
Grasping clips 2c	Multiple attempts needed to place clip in forceps		Clip secured in forceps with little hesitation and minimal repeat attempts		Clip secured in forceps on first attempt without hesitation	
	1	2	3	4	5	/5
Placing clip on line 2d	Clips often dropped when attempted to place on line				Clips placed on line on first attempt with no hesitation	
	1	2	3	4	5	/5
Total task 2						/20

3.Eye of the needle(3min)						
Number of successful threads 3a	0 threads	1 threads	2 threads	3 threads	>3 threads	
	1	2	3	4	5	/5
Grasping thread 3b	Multiple attempts needed to grasp thread		Thread secured in forceps with little hesitation or repeat attempts		Thread secured in forceps with no hesitation on first attempt	
	1	2	3	4	5	/5
Thread dropped/regrasped 3c	Thread dropped or regrasped multiple times to improve thread position in forceps				Thread never dropped or regrasped. Thread held in correct position in forceps on first attempt	
	1	2	3	4	5	/5
Feeding thread through needle 3d	Cumbersome movements and difficulty in getting thread to eye of needle				Thread placed easily through eye of needed with minimal corrected movements	
	1	2	3	4	5	/5
Total task 3						/20

4.Shape cutting(arrow)(3 min)						
Number of sides successfully cut 4a	1-2	3-4	5-6	6-7	>8	
	1	2	3	4	5	/5
Paper dropped 4b	>4 drops	3 drops	2 drops	1 drop	0 drops	
	1	2	3	4	5	/5
Non-dominant hand grasping 4c	Struggles to pick up shape and difficulty holding it in position				Picks up shape and maneuvers into stable position for cutting	
	1	2	3	4	5	/5
Dominant hand cutting 4d	Hesitation in initiating cut with ragged cuts that don't follow the lines of the shapes 1	2	3	4	Fluid initiation of cut, smooth and accurate cutting along lines of shapes 5	
	1	2	3	4	5	/5
Total task 4						/20
5.Membrane dissection) (3 min)						
	1 disc	2 discs	3 discs	4 discs	>5 discs	

Number of discs peeled 5a	1	2	3	4	5	/5
Accuracy or dissection 5b	< 40% of disc removed OR tearing/cutting outside of disc area				>90% disc removed with small lip remaining	
	1	2	3	4	5	/5
Non-dominant hand cutting 5c	Struggles to place scissors in correct position for cutting, many redundant scissor closures without cuts being made				Intentional and efficient cuts made with scissors, scissors placed in correct position on first attempt and cut made	
	1	2	3	4	5	/5
Dominant hand grasping 5d	Hesitation in lifting a flap to initiate tear. No respect for underlying tissue				Careful and efficient lifting of flap, with respect for underlying tissue	
	1	2	3	4	5	/5
Total task 5						/20
6. Path finding(3 min)						
Numbers found 6a	1-5 1	5-10	10-20	20-30	>30 5	

		2	3	4		
	1	2	3	4	5	/5
Fluidity 6b	Staccato movements, losing track of path often, multiple maneuvers required to bring path back into view 1	2	3	4	Path kept in central view and very fluid maneuvers used to keep path in central view 5	
	1	2	3	4	5	/5
Centration 6c	Numbers brought briefly into view on edge of field of view 1	2	3	4	Numbers placed clearly in center of view and held in position for clear visibility 5	
	1	2	3	4	5	/5
x/y movements of microscope 6d	Difficulty following view with microscope/limited movement of microscope/movements in opposite direction to that required 1	2	3	4	Microscope moved accurately in conjunction with required view/only when necessary/always in correct directions	
	1	2	3	4	5	/5
Total task 6						/20

Global indices						
Rotation and visualization 7a	Struggles to maintain position of globe to allow optimal viewing		Fair manipulation of eye with acceptable visualization of the task being performed		Manipulates position of eye exceptionally to ensure a clear view of task at hand	
	1	2	3	4	5	/5
Time motion and energy 7b	Many unnecessary or repetitive movements		Efficient time/motion but some unnecessary and repetitive movements		Clear economy of movement and maximum efficiency	
	1	2	3	4	5	/5
Instrument handling 7c	Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments but appeared occasionally stiff or awkward		Fluid moves with instruments and no awkwardness	
	1	2	3	4	5	/5
Flow of procedure 7d	Frequently stopped and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of task		Obvious planned course with effortless flow from one move to the next	
	1	2	3	4	5	/5
Total task 6						/20

					Total	/140

Appendix 2 – Ethics Approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

14 August 2019

HREC REF: 519/2019

Dr J Rice
Division of Ophthalmology
Ward D 4
NGSH

Dear Dr Rice

PROJECT TITLE: CONSTRUCT VALIDITY TESTING OF A LOW COST VITREORETINAL SURGICAL SIMULATOR IN IMPROVING MICROSURGICAL DEXTERITY (MMED CANDIDATE - DR D VAN DER WESTHUIZEN)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study, subject to adding the FHS HREC contact details to the informed consent document.

Approval is granted for one year until the 30 August 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Dean van der Westhuizen will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Appendix 3- Informed consent

Informed Consent form for participants the study into the construct validity of a low cost vitreoretinal surgical simulator in improving microsurgical dexterity

Principal Investigator: Dr Dean van der Westhuizen

Supervisor: Dr James Rice

Department of Ophthalmology Groote Schuur Hospital

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

This study aims to provide construct validity for a low fidelity surgical simulator made from a table tennis ball.

Type of Research Intervention

Each participant will be asked to complete 6 timed tasks where microsurgical dexterity is assessed via a video recording of the view that the participant has down the operating microscope. The test will take approximately 20 minutes and your ident ity in the study will remain anonymous.

Participant selection

There are 2 Groups in this study

Group 1: Ophthalmic registrars who have done more than 100 cataract procedures but less than 20 retinal procedures: Novice group.

Group 2: Retinal surgeons who have completed more than 20 retinal surgical procedures. Expert group

Voluntary Participation

Participation is completely voluntary and at any point you can choose to exclude yourself from participating.

Procedures and Protocol

You will be shown a short video describing the tasks that need to be performed prior to assessment. You will then be timed while the maneuvers and tasks are video recorded. There will be 4 consecutive tasks. Once the tasks are completed the recorded video will be labelled by number and be sent to assessors who will review the video and use an assessment rubric to grade the tasks. Your identity will remain anonymous and the assessors will be blinded to who is performing which task. The tasks will be held at the Ophthalmic surgical simulation unit at Groote Schuur.

In order to prevent bias in the study we will asses your stereoacuity using the Titmus fly test and your visual acuity using a standard Snellen chart. Only participants with 6/6 Snellen visual acuity and those with a stereoacuity greater than 60 seconds of arc will be included.

Duration

The assessment will take approximately 20minutes

Benefits

The main benefit is to provide construct validity for a low fidelity microsurgical surgical simulator. The future use of the simulator may improve the quality of training of Ophthalmic surgeons learning to perform retinal surgery.

Reimbursements

There is no financial or other reimbursement provided for participating in the study.

Confidentiality

The video files collected on the day will be labelled by participant number. The identity and which group(of the 2 mentioned above) the participant is in will not be provided to the assessor.

Sharing the Results

The videos may be used at future date during presentations or as supplemental media for journal publications. Stills from the videos may also be used for presentation and journal publication purposes.

Right to Refuse or Withdraw

Participation is voluntary and includes the right to withdraw at anytime. You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected

Who to Contact

If you have any questions before, during or after the study please contact Dr Dean van der Westhuizen at :

Email: deanandrevdw@gmail.com

Phone: 0823232660

This proposal has been reviewed and approved by the surgical department research committee.. It has also been approved by the University of Cape Town's Human research and Ethics committee.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant__________________
Signature of Participant ___________________
Date ___________________________

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.They will perform 6 microsurgical tasks on a low fidelity retinal surgery simulator.

2. The tasks will be recorded and reviewed to be scored using a standardized rubric.

3. The identity of the participants will remain anonymous.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Print Name of Researcher/person taking the consent________________________

Signature of Researcher /person taking the consent__________________________
Date ___________________________

Day/month/year

Appendix 4 – Permission letter from Groote Schuur hospital to perform data collection at Groote Schuur hospital

Western Cape Government
Health

GROOTE SCHUUR HOSPITAL
Enquiries: Dr Bernadette Eick
E-mail : Bernadette.Eick@westerncape.gov.za

Dr J. Rice
SURGERY: OPHTHALMOLOGY

E-mail: james.rice@uct.ac.za / deanandrevdw@gmail.com

Dear Dr Rice,

RESEARCH PROJECT: Construct Validity Testing Of A Low cost Vitreoretinal Surgical Simulator In Improving Microsurgical Dexterity (MMed Dr Dean van der Westehuizen)

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 August 2020.**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) No additional costs to the hospital should be incurred i.e. Lab, consumables or stationary. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form.**
d) **No patient folders may be removed from the premises or be inaccessible.**
e) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
f) Confidentiality must always be maintained .
g) Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).
h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
i) Please discuss the study with the HOD before commencing.
j) Please introduce yourself to the person in charge of an area before commencing.
k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
l) Kindly submit a copy of the publication or report to this office on completion of the research.
m) At no time should any posters encouraging patients to partake in research, be displayed within a clinical area.

I would like to wish you every success with the project.

Yours sincerely

Signature Removed

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 9 September 2019

C.C. Mr. L. Naidoo; Dr B. Jacobs, Professor N. du Toit, Professor G. Fieggen

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