ORIGINAL ARTICLE

Face and Content Validity of a Synthetic Eye Model for Ab-interno Goniotomy and Canaloplasty

Adam Gorner[1], Derek Waldner[1], Andrew Swift[1], Gavin Docherty[2], Matt Schlenker[3], Patrick Gooi[2]

[1]Department of Medicine, Cumming School of Medicine – University of Calgary, 2500 University Drive NW, Calgary, AB T2N 1N4, Canada, [2]Department of Surgery, Section of Ophthalmology, University of Calgary, 7007 14th 7 St. SW, Calgary AB, T2V 1P9, Canada, [3]Department of Ophthalmology and Visual Sciences, University of Toronto, 340 College Street, Suite 400, Toronto, ON M5T 3A9, Canada

ABSTRACT

Purpose: The purpose of the study was to determine the face and content validity of the SimulEYE ab-interno canaloplasty (AbiC) and goniotomy iTrack model (InsEYEt, Westlake Village, CA) by surveying ophthalmologists using the model. **Setting:** 2019 Canadian Ophthalmological Society meeting. **Design:** Face-to-face survey of participants in skills transfers course. **Materials and Methods:** Eighteen ophthalmologists participated in 30 min simulation sessions on goniotomy and ABiC using the artificial eye. ABiC used the iTrack (Ellex iScience, Inc., Freemont, CA, USA). Gonioscopy-assisted transluminal trabeculotomy (GATT) was simulated with the iTrack or 5-0 blue-dyed polypropylene suture. A 17-question survey assessed the face and content validity of the model. Mann–Whitney *U*-test non-parametric analysis determined whether prior experience performing these surgeries (≥30 cases/lifetime) or being a course instructor had a significant influence on responses compared to non-expert participants (<30 cases/lifetime) and non-instructors. **Results:** Most participants had never previously performed GATT or ABiC. Respondents rated all statements regarding the model with a median response of 4 (agree)–5 (strongly agree). Mann–Whitney *U*-test non-parametric analysis revealed no significant difference in responses for any of the survey statements. The SimulEYE model received highest ratings for utility in novice skill acquisition and increased accessibility and ease of preparation compared to human cadaveric models. The lowest rating was for realism compared to human cadaveric models. **Conclusion:** This model realistically simulated gonioscopy and bimanual techniques for ABiC and GATT. Reusability of the model and the absence of biological tissue make training sessions logistically streamlined. Further research is required to compare this model to other training techniques, such as virtual reality or cadaveric/animal eyes.

Key words: Education, glaucoma, gonioscopy, surgery

INTRODUCTION

Glaucoma is a leading cause of blindness worldwide.[1] Recent advances in glaucoma surgery include the minimally invasive glaucoma surgeries (MIGS) which are designed to provide lasting reduction in intraocular pressure (IOP) while eliminating or minimizing the number of drops required.[2,3] Studies have shown that these surgeries tend to achieve a decrease of IOP and a reduction of glaucoma medications with a low complication rate.[3] One of the MIGS available is the ab-interno canaloplasty (ABiC) performed with the iTrack (iTrack 250, Ellex iScience, Inc., Freemont, CA, USA). The iTrack is used to perform a canaloplasty, wherein aqueous outflow is theoretically increased by breaking adhesions in Schlemm's canal, stretching trabecular plates to create microperforations in the inner wall of the trabecular meshwork, and separating herniations from the inner wall in the outer wall collector

Address for correspondence:
Adam Gorner, 11367 Rockyvalley Dr. NW Calgary, AB T3G 5C3, Canada

channels[4]. This technique can be performed ab externo or ab interno, the latter of which is considered a MIGS.[4] Another MIGS technique, known as gonioscopy-assisted transluminal trabeculotomy (GATT), involves cannulating Schlemm's canal with a suture and subsequently applying tension on the suture to unroof Schlemm's canal.[5] This titratable technique can produce an ab-interno goniotomy of up to 360° and is a cost-effective MIGS technique.

In order to make these MIGSs more widely available, surgeons will need to be trained in these techniques. One of the challenges inherent in passing on surgical skills is finding a training model that replicates real-world experience with high fidelity, is affordable and accessible, and is simple to operate. The SimulEYE iTrack model (InsEYEt, Westlake Village, CA) is one of a range of ophthalmic surgical training models that have been designed to provide a high-fidelity alternative to cadaveric eyes for hands-on surgical experience. Although an effective training tool, the use of cadaveric eyes comes with drawbacks in terms of cost, ethical implications, accessibility, and safety.[6-8] This artificial model is designed specifically for use with the Ellex iTrack device to practice ABiC. There is a pre-placed goniotomy in the trabecular meshwork to insert the iTrack catheter, as well as pre-placed side port and main incisions where instruments can be introduced. The main incision and side ports allow for correct angle of approach and proper movement of MST forceps. Right and left side ports accommodate both right- and left-handed surgeons. A gonioprism can be used to visualize the simulated anterior chamber and the blinking light on the iTrack can be seen through the simulated sclera from the outside of the model [Figure 1]. Viscoelastic can be injected into the anterior chamber as would be done during the procedure on a real eye.[9] Each SimulEYE iTrack eye costs $200 USD and can be used multiple times. This training model can be a very valuable tool for teaching and practicing without some of the drawbacks of using cadaveric eyes. Despite the evident benefits of this model, no validation study has been reported.

In this study, we sought to determine the face and content validity of the SimulEYE iTrack model by surveying individuals with varying levels of ophthalmic surgical experience following a 30 min skills transfer course utilizing the model at the 2019 Canadian Ophthalmology Society annual meeting. Procedures simulated were ABiC and GATT.

MATERIALS AND METHODS

Eighteen respondents were given a 17-response survey [Appendix A] assessing the face and content validity of the SimulEYE iTrack model immediately after a 30 min hands-on training session at the 2019 Canadian Ophthalmology Society annual meeting. ABiC used the iTrack. GATT was simulated with the iTrack or 5–0 blue-dyed polypropylene suture. Participants were introduced to the technique and model with a short presentation followed by hands-on practice with appropriate surgical instrumentation and instruction (with one instructor per two participants). Course instructors and participants were both surveyed. Responses to statements addressing the model were recorded on a 5-point Likert-type scale ranging from (1) strongly disagree to (5) strongly agree. Respondents also self-reported their lifetime and past year experience

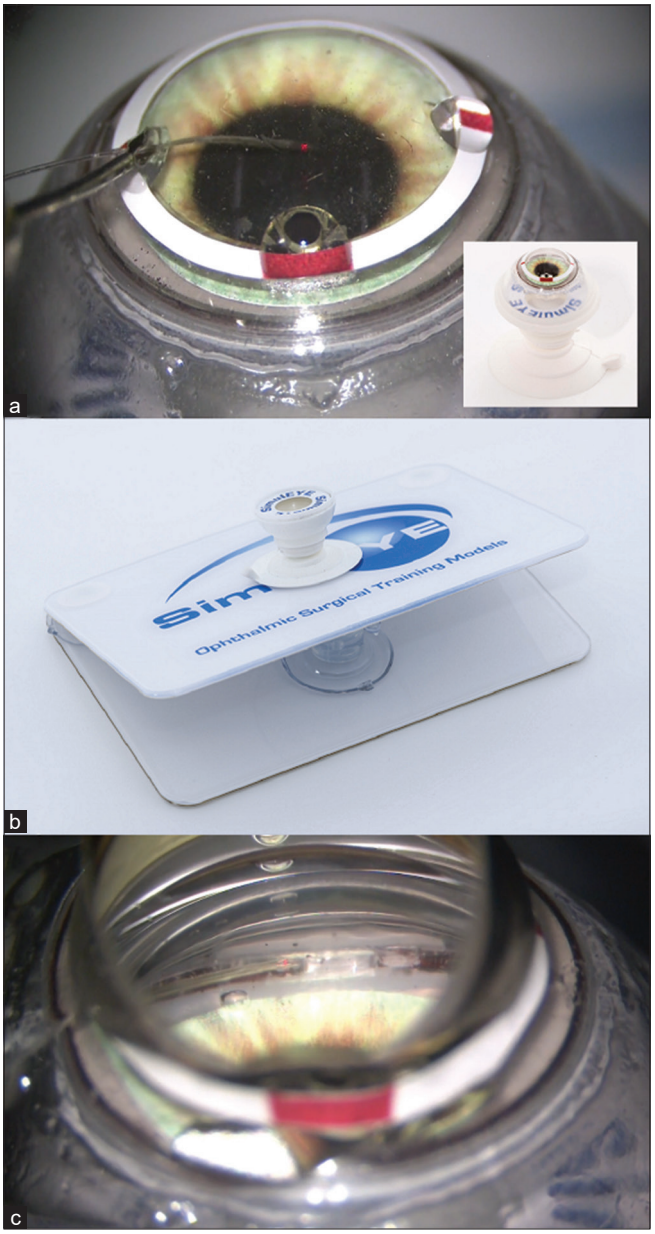

Figure 1: (a) The SimulEYE iTrack model for ab-interno canaloplasty. (b) The angled stand simulated the angle at which live surgery would be performed. (c) Gonioscopic view of iTrack in simulated Schlemm's canal

performing iTrack ABiC surgeries and were given opportunity to provide general comments. Mann–Whitney *U*-test non-parametric analysis was performed to determine whether expertise in performing ABiC surgeries (>10 cases/lifetime; $n = 3$) or being a course instructor ($n = 5$) had a significant influence on responses compared to non-expert participants (≤10 cases/lifetime; $n = 12$) and non-instructors ($n = 13$). Statistical analysis and graph generation were performed with GraphPad Prism 8.2.0.

RESULTS

The respondents included five instructors, eight participants, and five unspecified individuals with diverse experience. Most participants had never previously performed the iTrack ABiC before the course and survey (Table 1).

Respondents rated all statements regarding the SimulEYE iTrack ABiC model with a median response of 4 (agree)–5 (strongly agree). Mann–Whitney *U*-test revealed no significant difference in responses for any of the survey statements (Appendix B for a full table of values and comparative statistics).The SimulEYE model received highest ratings for utility in novice skill acquisition before performance on patient and increased accessibility and ease of preparation compared to human cadaveric models. Lowest ratings were received for the statements to whether the model was easier to set up/clean up compared to human cadaveric and realism compared to human cadaveric models [Figure 2].

DISCUSSION

As MIGS becomes more established in treatment algorithms for glaucoma, there will be a need for modalities to train residents and physicians in angle-based surgery.[2] The SimulEYE iTrack model of ABiC represents a viable model for such training. Advantages include accurate anatomical and clinical simulation providing a platform for surgical training before operating on a patient. This has potential applications for not only practicing one's surgical skills but also to evaluate trainees in a safe environment that allows for feedback and discussion.

Table 1: Respondent's self-reported experience performing ab-interno canaloplasty before the SimulEYE iTrack training course and survey

Procedure range	# Procedures past year	# Procedures lifetime
0	10	9
1–10	2	3
11–40	2	0
71 ≥ 80	2	3
Count (*n*)	16	15

On evaluating feedback regarding the use of the SimulEYE iTrack model, it scored highly in most areas. Users felt that it was easy to prepare, useful for training purposes, and was more accessible than human cadaveric eyes. Criticisms of the iTrack model included the opinion that it was more difficult to clean up or dispose of, and less anatomically realistic when compared to cadaveric eyes. While both of these points are valid, obtaining human tissues for purposes of surgical training can be difficult and rigorous programs for dealing with biohazardous materials must be in place.

The mastery of surgical technique is a challenging venture and involves repeated practice.[10] The ideal model for the ophthalmic surgeons is a living human eye. This, however, is not an ideal situation for a surgeon to begin learning a new technique given the potential risk for complications to the patient. Furthermore, the expectations for increased safety in MIGS create an even greater need for simulation training before a surgeon's first *in vivo* case. Having a realistic model that simulates the anatomy, procedural steps, and the angle required for gonioscopic-assisted surgery is invaluable as acquiring an optimal view of the angle structures is often the most challenging aspects of MIGS. The SimulEYE iTrack model would allow residents and surgeons the opportunity to learn the approach to safely perform GATT and iTrack canaloplasty. To the authors knowledge, no previous model has been described or validated for these procedures.

Recently, the Accreditation Council for Graduate Medical Education has advocated that residents must have access to surgical simulators or a wet lab[11]. Maintenance, setup, and adhering to biohazard protocols can be barriers to facilitating a true wet lab. Surgical models such as the one described in this paper as well as virtual reality simulators can help prepare residents for surgery while bypassing some of the more rigorous cleaning and disposal requirements for biohazardous materials.[12-16]

The essential steps for ABiC and GATT are bimanual gonioscopy and atraumatic cannulation of Schlemm's canal with the catheter or suture. In these aspects, the evaluated model performed well. In addition, this model is a cost-effective, realistic training platform for GATT, which may greatly benefit global health initiatives. Limitations of this study include a relatively small sample size. In addition, participants self-selected to attend the review course representing a potential source of bias. Furthermore, there was no control group or alternative model for comparison. Future studies should attempt to compare various training models for different surgical procedures and assess cost as well as access when considering their value to a potential training program or surgeon interested in advancing their skills in a simulated environment.

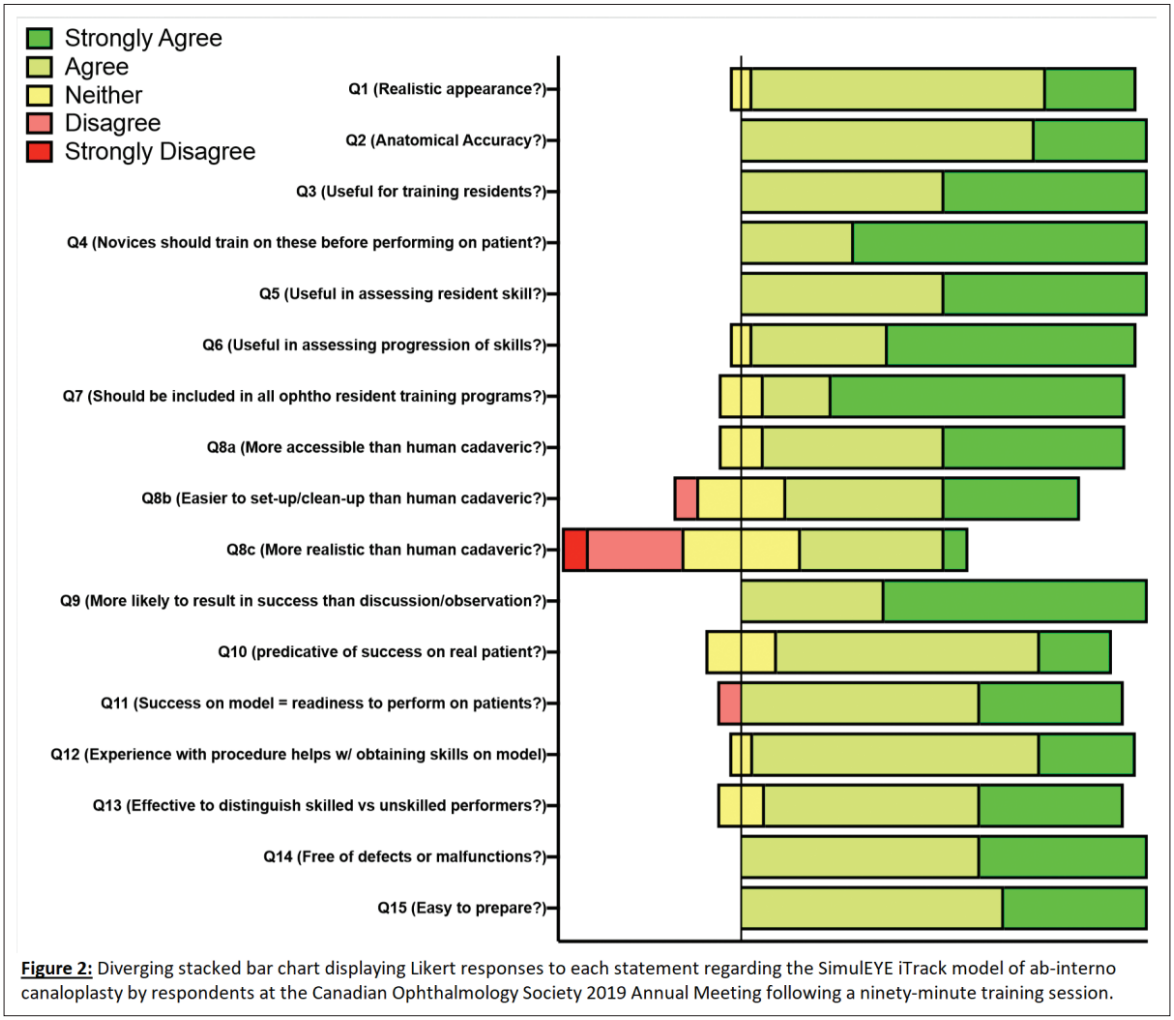

Figure 2: Diverging stacked bar chart displaying Likert responses to each statement regarding the SimulEYE iTrack model of ab-interno canaloplasty by respondents at the Canadian Ophthalmology Society 2019 annual meeting following a 90 min training session

CONCLUSION

The SimulEYE iTrack model offers a realistic surgical experience for those beginning or attempting to master the techniques applicable to performing GATT or iTrack canaloplasty. Survey results indicated that the SimulEYE iTrack model performed favorably across most items assessed. It fell short in comparison to other items in that participants felt cadaveric models were more realistic. However, the SimulEYE iTrack model may be more attainable and does not require access to cadaveric or animal eyes which may be more feasible for some centers. The authors conclude that the SimulEYE iTrack model was met favorably by survey participants as a tool to improve surgical skills, but that further research is required to establish the efficacy and cost-effectiveness of this model for surgical training in comparison to other training techniques, such as virtual reality or cadaveric/animal eyes.

AUTHORS' CONTRIBUTIONS

Concept and design, AG, DW, AS, PG; date acquisition, AG, DW, AS, PG; data analysis/interpretation, AG, DW, MS, PG; drafting manuscript, AG, DW, AS, GD, MS, PG; critical revision of manuscript, AG, DW, AS, GD, MS, PG; statistical analysis, DW; supervision, MS, PG; final approval, AG, DW, AS, MS, PG. All authors have read and agreed to the published version of the manuscript.

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Author name	Concept and design	Data acquisition	Data analysis/ interpretation	Drafting manuscript	Critical revision of manuscript	Statistical analysis	Supervision	Final approval
Adam Gorner	X	X	X	X	X			X
Derek Waldner	X	X	X		X	X		X
Andrew Swift	X	X			X			X
Gavin Docherty				X	X			
Matt Schlenker			X		X		X	X
Patrick Gooi	X	X	X	X	X		X	X

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How to cite this article: Gorner A, Waldner D, Swift A, Docherty G, Schlenker M, Gooi P. Face and Content Validity of a Synthetic Eye Model for Ab-Interno Goniotomy and Canaloplasty. Clin Res Ophthalmol 2020;3(1):1-7.

APPENDIX A

1. The SimulEYE tissue had a realistic appearance.
2. The size and spatial relationship of the structures was anatomically accurate.
3. The model is useful for training residents in ABiC.
4. All novices to ABiC should have training on the SimulEYE model before performing these procedures on patients.
5. The SimulEYE model is useful in assessing the resident's skill to perform ABiC.
6. The SimulEYE model is useful in assessing the progression of the trainee's skills at performing ABiC.
7. The SimulEYE model should be included in all Canadian residency programs.
8. Compared to traditional human cadaveric eyes, the SimulEye model is:
   a. More accessible
   b. Easier to set up and clean up
   c. More realistic
9. Performing ABiC on the SimulEYE models before real patients is more likely to result in success than discussion of theory and observation alone.
10. Successful performance of ABiC on the SimulEYE models is predictive of success on a real patient.
11. Successful performance of ABiC on the SimulEYE models indicates readiness to perform these procedures on real patients.
12. Previous experience performing ABiC helps in obtaining skills on the SimulEYE model.
13. The SimulEYE model is an effective tool to distinguish those with experience performing ABiC from novices.
14. The SimulEYE model was free of defects or malfunctions for the duration of its use.
15. The SimulEYE model was easy to prepare and set up (if performed).

APPENDIX B

Attribute in Question	Number of values	Min	25% percentile	Median	75% percentile	Max	IQR	Instructor versus participant	Experience versus none
Q1 (realistic appearance?)	18	1	4	4	4.25	5	0.25	0.93	0.72
Q2 (anatomical accuracy?)	18	1	4	4	5	5	1	0.65	0.27
Q3 (useful for training residents?)	18	1	4	4.5	5	5	1	0.80	0.72
Q4 (novices should train on these before performing on patient?)	18	1	4	5	5	5	1	0.65	0.90
Q5 (useful in assessing resident skill?)	18	1	4	4.5	5	5	1	0.80	0.72
Q6 (useful in assessing progression of skills?)	18	1	4	5	5	5	2	0.16	0.11
Q7 (should be included in all ophtho resident training programs?)	18	1	4	5	5	5	2	0.72	0.30
Q8a (more accessible than human cadaveric?)	18	1	4	4	5	5	1	1.00	0.65
Q8b (easier to set up/ clean up than human cadaveric?)	18	1	3	4	5	5	2	0.94	0.57
Q8c (more realistic than human cadaveric?)	17	1	2	3	4	5	2	0.61	1.00

Q9 (more likely to result in success than discussion/observation?)	17	1	4	5	5	5	1	0.77	0.41
Q10 (predicative of success on real patient?)	17	1	4	4	4	5	0	0.93	0.80
Q11 (success on model = readiness to perform on patients?)	17	1	4	4	5	5	1	0.92	0.90
Q12 (experience with procedure helps / obtaining skills on model)	17	1	4	4	4.5	5	0.5	0.93	0.72
Q13 (effective to distinguish skilled vs. unskilled performers?)	17	1	4	4	5	5	1	0.87	0.25
Q14 (free of defects or malfunctions?)	17	1	4	4	5	5	1	0.50	0.10
Q15 (easy to prepare?)	17	1	4	4	5	5	1	1.00	0.48

Minimum, maximum, 25% and 75% percentile, median, interquartile range, and Mann–Whitney *U*-test non-parametric analysis of groups for the SimulEYE iTrack model survey responses