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Face and Content Validity of an Artificial Eye Model for Secondary IOL Fixation

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Abstract

Purpose: *To evaluate the face and content validity of the use of artificial eye models (SimulEYE Iris Suturing & IOL model, InsEYEt, Westlake Village, CA) in training physicians the techniques required for secondary intraocular lens (IOL) fixation. Secondary IOL fixation, or secondary IOL implantation, is a common yet technically challenging skill useful in the treatment of primary IOL implantation failure, zonular instability, or aphakia related to trauma or surgery.*

Materials and Methods: *Twenty-eight ophthalmologists at the 2019 Canadian Ophthalmology Society annual meeting underwent a secondary IOL fixation wet-lab using artificial eye models. The technique was scleral suturing of a single piece IOL with via 4 closed-loop haptics. All of the ophthalmologists were given an 18-response survey immediately following the training session which were composed of statements which addressed the face and content validity of the artificial eyes. Responses were recorded on a 5-point Likert-type scale ranging from (5) strongly agree to (1) strongly disagree. Mann-Whitney U analysis compared instructor versus non-instructor and expert versus non-expert respondent responses.*

Results: *Respondents rated all statements regarding the model with a median response of 3 (Neither Agree or Disagree) to 5 (Strongly Agree). Mann-Whitney U analysis did not show a significant difference in responses for expert versus non-expert and instructor vs non-instructor respondents for any of the survey statements. The artificial eye received highest ratings for its usefulness for training residents, ease of set-up and clean-up compared to cadaveric models and how using the model is a better way to learn the procedure than discussion or observation and will likely result in future surgical success. The lowest survey ratings were for the model's realism when compared to human cadaveric models.*

Conclusions: *The artificial eye model was generally regarded highly by ophthalmologists with all levels of experience performing secondary IOL fixation. These results suggest that this artificial eye may be a valuable tool for teaching secondary IOL fixation in competency-based ophthalmology education programs.*

Keywords: *Secondary IOL Fixation; SimulEYE; Simulation eye; artificial eye; competency based learning.*

Introduction

Vision loss due to cataracts is the second leading cause of preventable blindness in the world, affecting over 65 million people globally. Most people over the age of 70 will develop some form of cataracts and often these cataracts progress to negatively impact visual function and thus decrease quality of life (1). The only definitive treatment for cataracts is removal through a surgical procedure. Modern cataract surgery involves extraction of the opacified natural lens and implantation of a prosthetic lens into the capsular bag left behind. When the capsular bag fails however, due to a complicated surgery, trauma, or anatomic instability of the supporting zonules, secondary intraocular lens (IOL) fixation is required (2).

In these complex surgeries, the IOL can be fixated in a variety of ways. Secondary IOL positions include anterior chamber placement, ciliary sulcus placement, or posterior chamber placement, either sutured to the sclera or iris for stability (3)scleral-sutured posterior chamber, and iris-sutured posterior chamber intraocular lenses (IOLs. Not only are these procedures more technically challenging and carry higher intraoperative and postoperative risks, the relative infrequency of their use also creates difficulty for learners and experienced surgeons alike(4). Complications of commonly used secondary IOL fixation methods include escalation of glaucoma, cystoid macular edema, lens tilt or dislocation, retinal detachment, and corneal edema or decompensation(5) visual acuity, and refractive outcomes of secondary intraocular lens (IOLs.

To prepare surgeons for these challenging cases, hands on training and structured teaching is essential. For this reason, cadaveric specimens have long been used to simulate ocular techniques and procedures. A systematic review published in 2017 suggested cadaveric simulation was an effective medium for surgical teaching, although raising concerns for ethical issues, high cost and availability (6)largely based on the Halstedian model \u201csee one, do one, teach one\u201d is not as effective in the era of working time restrictions and elaborate shift-patterns. As a result, contemporary surgeons turned to educational methods outside the operating theatre such as simulation. Cadavers are high fidelity models but their use has ethical and cost implications and their availability may be limited. In this review, we explore the role of cadaveric simulation in modern surgical education. Methods: All the Evidence-Based Medicine databases were searched for relevant reviews. The resulting studies were assessed for inclusion to this review, according to pre-determined criteria. Data extraction was performed using a custom-made spreadsheet, and the quality of included reviews was assessed using a validated scoring system (AMSTAR. Our study examines use of the SimulEYE Iris Suturing & IOL model (InsEYEt, Westlake Village, CA) as an alternative to cadaveric specimens for secondary IOL fixation training. The artificial eye model (**Figure 1**) replicates typical ocular anatomy with a flexible iris, clear cornea, and dense but penetrable sclera for practice of various IOL fixation techniques including iris suture fixation, and scleral fixation. This artificial eye also allows for multiple procedures to be performed on each model, thus reducing overall costs (7). Currently the SimulEYE Iris Suturing & IOL model retails for 50$ USD, thus making it a potentially attractive training tool for resident physicians and experts alike.

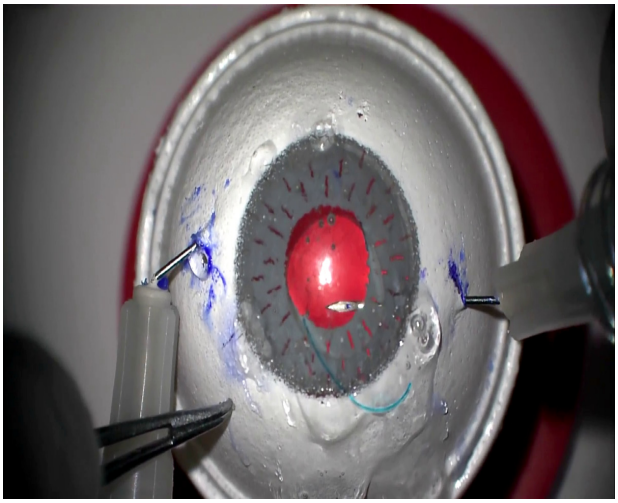

Figure 1. *SimulEYE Iris Suturing & IOL model*

Since no formal validation of the model has yet been completed for secondary IOL fixation training, we sought to determine its face and content validity by surveying ophthalmologists with varying experience following a ninety-minute wet-lab course which included hands on simulation with the model.

Materials and Methods

The face validity, content validity and other aspects of the artificial eye were assessed by an 18-response survey (Appendix A) filled out by twenty-eight respondents immediately after completing a 90-minute hands-on training session at the 2019 Canadian Ophthalmology Society annual meeting. The survey respondents comprised of 9 instructors, 17 participants and 2 unspecified individuals with a diversity of experience. To derive our definitions of face and content validity, we used McDougall, 2007 (8), as a reference. Our survey statements were adapted from Alzahrani et al., 2013 (9). The training session started with a short presentation of the secondary IOL fixation procedure followed by a hands-on practice with the artificial eye using the appropriate surgical instrumentation. The secondary IOL fixation procedure was scleral suturing of a single piece IOL via 4 closed-loop haptics (Akreos Adapt AO60, Bausch and Lomb, Bridgewater, NJ). The haptics were sutured

to sclera using 8-0 polytetrafluoroethylene sutures (Gore-Tex, Flagstaff, AZ). This procedure has previously been described by Ayres (10). Every participant had their own complete simulation set-up. Instructors were paired with two participants and provided guidance on how to complete the procedure by demonstrating on their own simulation set-ups. Immediately following the training session, both instructors and participants filled out the 18-response survey with minimal time for discussion amongst respondents to avoid any potential bias. The survey consisted of statements about the artificial eye model which the respondents graded based on a 5-point Likert-type scale which ranged from (5) strongly agree to (1) strongly disagree. Along with the survey, respondents also self-reported their past year and lifetime experience performing secondary IOL fixation and were encouraged to leave general comments about the artificial eye. Six of the participants did not fill out their previous experience with the secondary IOL procedure. Mann-Whitney U nonparametric analysis was completed to determine if being one of the nine course instructors (n=9) or having expertise in performing secondary IOL fixation, which we defined as having completed 30 or more secondary IOL fixation cases in their lifetime (n=10), had a significant impact on the survey responses compared to the seventeen non-instructors (n=17) and twelve non-expert participants who had completed less than 30 secondary IOL fixations in their

lifetime (n=12), respectively. All statistical analysis and graph generation was performed on Microsoft Excel 2011.

Range of Procedures Completed	No. of Participants for procedures completed in Past Year	No. Participants for procedures Completed in Lifetime
0	6	4
1-10	8	5
11-20	3	2
21-30	0	1
31-40	3	1
41-50	1	3
51-60	0	0
61-70	0	0
71-80	0	0
81-90	0	1
91-100	0	1
>100	1	4
Count (n)	22	22

Table 1. *Respondent's self-reported experience with the secondary IOL fixation procedure before the training course and survey*

Results and Discussion

After compiling the survey results, most of the respondents (n=15) had performed between 1 and 50 secondary IOL fixations in the last year and only 4 respondents had never completed the procedure before the course and survey. Table 1 explores the self-reported prior experience of the respondents.

Participants rated all statements regarding the artificial eye model with a median response ranging from 3 (Neither Agree or Disagree) to 5 (Strongly Agree) (fig. 2). Mann-Whitney U statistical analysis indicated no significant difference among expert, non-expert and instructor, and non-instructor survey responders (Appendix B). The artificial eye received highest ratings for its usefulness for training residents,

ease of set-up and clean-up compared to cadaveric models and how using the model will be more likely to result in a successful secondary IOL fixation than by learning through discussion or observation. The lowest survey ratings were for the model's realism when compared to human cadaveric models (Figure 2).

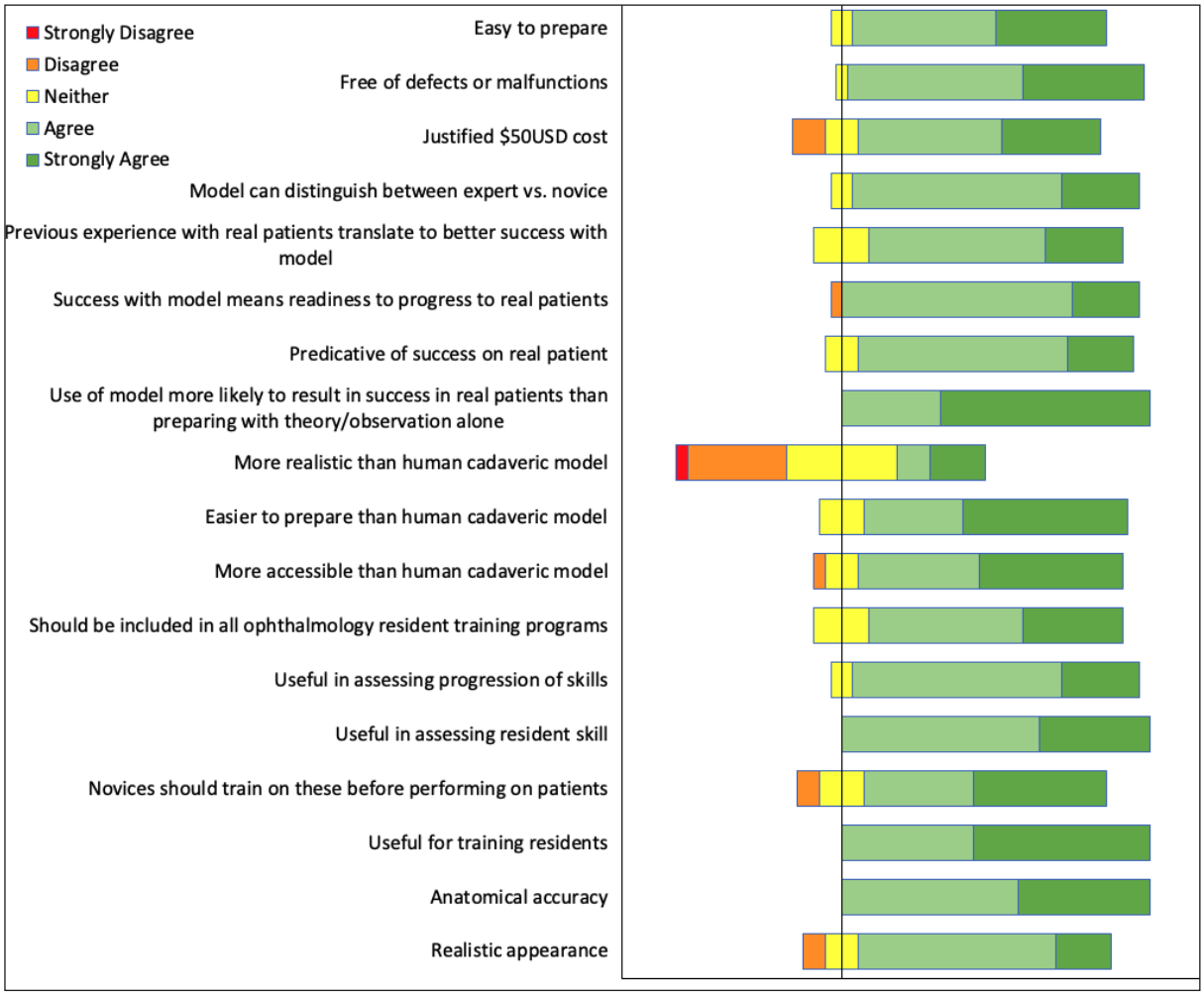

Figure 2. *Diverging stacked bar chart displaying Likert responses to each statement regarding the SimulEYE Iris Suturing and IOL model by respondents at the Canadian Ophthalmology Society 2019 Annual Meeting after a 90-minute training session.*

All in all, Face validity statements were viewed favorably; statements (2 and 15; Appendix A) were rated with a median response of 4 (Agree) and statement (16; Appendix A) 5 (Strongly Agree) by the respondents. There were only two "Disagree" responses for the face validity statements. Similarly, the statements regarding content validity (6-8, 11-13, 15; Appendix A) also scored highly with all statements having a median response of "Agree" or higher; however, there was more disagreement amongst the respondents.

Comments about the model-specific artificial eye by the respondents were quite positive. Some respondents felt they would rather practice on human cadaveric eyes while others thought practicing on the artificial eyes was too expensive and the models should only be used for final surgical assessments of trainees. This statement should be taken in context of the fact that SimulEYE Iris Suturing & IOL model cost ~ US $50 while a human cadaveric eye is estimated at US $500 per research globe (11,12). In fact, one might argue that utilizing these eye models may be much more cost effective, especially for government funded ophthalmology residency programs.

In response to the recent rise of competency based medical education in ophthalmology, the Accreditation Council for Graduate Medical Education has recommended that residents have regular access

to surgical simulators or cadaveric eyes (13,14). Moreover, these artificial eye models become even more attractive when considering their longevity, safety, reproducibility, ease of storage and limited ethical concerns (11,15–17). Additionally, when compared to cadaveric eyes, these models do not require keratoprosthesis to visualize the anterior chamber and they are much simpler to setup (17–19). While animal and cadaveric human eyes have high content and face validity, they are limited in availability, cost and risk of transmissible diseases (18,20).

The results of this study, while encouraging, are limited by the small sample size (N=18 responders). Additionally, the study design lacked a comparison group that utilized a cadaveric eye or an alternative eye model. Due to the small sample size, authors were unable to further delineate meaningful differences in responses as a function of prior experience in secondary IOL fixation. Future work might focus on increasing the number of participants to increase the statistical power and allow for meaningful subgroup analysis. Finally, a longitudinal study that compares surgical skills of learners who primarily use this eye model to those who use cadaveric eyes or alternative models would further delineate the efficacy of this model.

Conclusions

The SimulEYE artificial eye is a realistic surgical model to practice performing secondary IOL fixation. This model was regarded highly by ophthalmologists with various levels of training and experience in performing secondary IOL fixation. These results suggest that this artificial eye may be a valuable tool for teaching surgical procedures, including secondary IOL fixation, in competency-based ophthalmology residency programs. Future research should aim to further delineate the efficacy of this model, especially as it compares to other surgical models, virtual reality, and cadaveric eyes, in enhancing surgical skills.

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Appendix A

1. The artificial eye model was easy to prepare and set up (if performed).
2. The artificial eye model was free of defects or malfunctions for the duration of its use.
3. The training benefits of the artificial eye model justify the cost of $50 USD per eye.
4. The artificial eye model is an effective tool to distinguish those with experience performing secondary IOL fixation from novices.
5. Previous experience performing secondary IOL fixation helps in obtaining skills on the artificial eye model.
6. Successful performance of secondary IOL fixation on the artificial eye models indicates readiness to perform these procedures on real patients.
7. Successful performance of secondary IOL fixation on the artificial eye models is predictive of success on a real patient.
8. Performing secondary IOL fixation on the artificial eye models before real patients is more likely to result in success than discussion of theory and observation alone.
9. Compared to traditional human cadaveric eyes, the artificial eye model is more realistic.
10. The artificial eye model is easier to prepare than human cadaveric model.
11. The artificial eye model is more accessible than human cadaveric models.
12. The artificial eye model should be included in all Canadian residency programs.
13. The artificial eye model is useful in assessing the progression of the trainee's skills at performing secondary IOL fixation.
14. The artificial eye model is useful in assessing the resident's skill to perform secondary IOL fixation.
15. All novices to secondary IOL fixation should have training on the artificial eye model prior to performing these procedures on patients.
16. The artificial eye model is useful for training residents in secondary IOL fixation.
17. The artificial eye was anatomically accurate.
18. The artificial eye had a realistic appearance

Appendix B

	Median	Q1	Q3	IQR	#Responses	Expert vs Non-Expert p-Value	Instructor vs Participant p-Value
Easy to prepare	4.00	4.00	5.00	1.00	25	0.605	0.975
Free of defects or malfunctions	4.00	4.00	5.00	1.00	28	0.582	0.220
Justified 50$ USD Cost	4.00	4.00	5.00	1.00	28	0.821	0.491
Model can distinguish between expert vs. novice	4.00	4.00	4.25	0.25	28	0.628	0.711
Previous experience with real patients translates to better success with model	4.00	4.00	4.25	0.25	28	0.582	0.458
Success with model means readiness to progress to real patients	4.00	4.00	4.00	0.00	28	0.123	0.339
Predictive of success on real patient	4.00	4.00	4.00	0.00	28	0.228	0.634
Use of model more likely to result in success in real patients than preparing with theory/observation alone	5.00	4.00	5.00	1.00	28	0.180	0.560
More realistic than human cadaveric model	3.00	2.00	4.00	2.00	28	0.254	0.958
Easier to prepare than human cadaveric model	5.00	4.00	5.00	1.00	28	0.821	0.410
More accessible than human cadaveric model	4.00	4.00	5.00	1.00	28	0.628	0.874
Should be included in all ophthalmology resident training programs	4.00	4.00	5.00	1.00	28	0.180	0.792
Useful in assessing progression of skills	4.00	4.00	4.25	0.25	28	0.159	0.287
Useful in assessing resident skill	4.00	4.00	5.00	1.00	28	0.418	0.085
Novices should train on these before performing on patients	4.00	4.00	5.00	1.00	28	0.346	0.085
Useful for training residents	5.00	4.00	5.00	1.00	28	0.314	0.426
Anatomical Accuracy	4.00	4.00	5.00	1.00	28	0.456	0.220
Realistic appearance	4.00	4.00	4.00	0.00	28	0.628	0.164

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