JOURNAL OF CME
2025, VOL. 14, 2467566
https://doi.org/10.1080/28338073.2025.2467566

RESEARCH ARTICLE

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Face and Content Validity of Farra Eye Model as a Surgical Simulator for Capsulorhexis Training

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ABSTRACT
Several simulation models are available for cataract surgery training, but they have limitations in terms of quality and availability. The Farra Eye Model, a new cataract surgery simulator, was developed using 3D-printing technology to provide residents with more options. This study aims to determine its face and content validity as a surgical simulator for training capsulorhexis, a crucial step in cataract surgery. Ophthalmology residents and consultants at the Faculty of Medicine, Universitas Indonesia, were asked to complete three capsulorhexis tasks in the eye model. Then, subjects were surveyed using a validated questionnaire to assess the face and content validity of the model. Responses were recorded using a 5-point Likert scale ranging from (1) disagree to (5) strongly agree. Twenty-two subjects completed the tasks. The overall face validity score was favourable (3.67 ± 0.67). However, the resident group considered capsule elasticity poor (2.73 ± 1.1), while the consultant group still felt it realistic (3.64 ± 0.9). The content validity had a favourable score in the overall assessment (4.15 ± 0.58) and for each assessment component. Despite the challenge of replicating human lens capsule elasticity, the Farra Eye Model demonstrates initial evidence supporting its use for capsulorhexis training. It can be helpful for training programs with limited access to commercially available simulation models.

ARTICLE HISTORY
Received 28 October 2024
Revised 6 January 2025
Accepted 31 January 2025

KEYWORDS
Farra Eye Model; surgical simulator; cataract surgery; capsulorhexis; validity

Introduction

According to Rapid Assessment of Avoidable Blindness (RAAB) surveys in 15 provinces in Indonesia during 2013–2017, up to 71.7% to 95.5% of blindness is caused by cataracts [1]. Competence in cataract extraction, whether through extracapsular cataract extraction (ECCE), manual small incision cataract surgery (MSICS), or phacoemulsification is highly valuable for ophthalmologists, especially given the global demand for cataract surgery [2].

Shifting from the traditional Halstedian model: "see one, do one, teach one", which has put patients at risk, simulation training offers to practice surgical skills outside the operating room without direct patient involvement [3]. Capsulorhexis is one of the most challenging skills to master in cataract surgery [4,5]. Repetitive training with the simulation models is effective for learning cataract skills [6].

Very few simulation models have been formally validated in ophthalmology [7]. Current high-fidelity simulation training in cataract surgery uses animal eyes, artificial eye models such as Kitaro™, and virtual reality. However, animal eyes and Kitaro™ have several drawbacks, while virtual reality is not yet available in Indonesia.

In animal eyes, microwave heating or formalin injection induces cataract formation. Still, it also induces cloudiness of the cornea, which interferes with the visualisation of the lens capsule [8–10]. Moreover, the quality and availability of the animal eyes are difficult to predict. On the other hand, Kitaro™ uses an artificial lens capsule that is more realistic but has a larger pupil diameter, so it tends to produce a larger capsulorhexis size [11]. Due to its high price [12], the use of Kitaro™ is limited in the laboratory room. Performing 100 capsulorhexis training sessions with the Kitaro™ DryLab incurs a material cost of approximately 12 USD for replaceable capsular films. This does not include the model's initial purchase price, which is approximately 1,035 USD per unit.

In a descriptive study conducted at the Department of Ophthalmology, Faculty of Medicine Universitas Indonesia, Pradessatama and Widyawati reported a decreased number of resident cataract surgeries by 36.3% in 2020, with the most significant decline

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occurring in the second quarter when COVID-19 cases peaked [13]. In this current situation, cataract surgery training relies on simulation use outside the operating theatre. Therefore, the Department of Ophthalmology, Faculty of Medicine Universitas Indonesia, developed the Farra Eye Model, a domestically produced simulation model for cataract surgery training. The eye model uses a capsule membrane made of cellulose, which can resemble the characteristics of the human lens capsule [14]. Residents can train repetitively using this tool at home at a more affordable price.

Validity tests need to be carried out to ensure the effectiveness of surgical training using a simulation model [15]. This study aimed to assess the face and content validity of the Farra Eye Model as a novel surgical simulator for capsulorhexis training.

Materials and Methods

Study Design and Participants

A cross-sectional pilot study was carried out in November 2022, at the surgical skills lab of the Department of Ophthalmology, Faculty of Medicine Universitas Indonesia, Cipto Mangunkusumo Hospital, Jakarta, Indonesia. Participants were ophthalmology residents and consultants. The residents included in this study should have experienced at least 10 cataract surgeries independently, whilst the consultants had performed at least 500 cataract surgeries and were certified as cataract surgeons. They were excluded from this study if they had capsulorhexis training more than 10 times using the Farra Eye Model during the last three months and had not performed cataract surgery in a year. The samples were taken consecutively.

Ethics Approval and Consent to Participate

The study received ethical approval from the Ethics and Research Committee of Universitas Indonesia (No. KET-1056/UN2.F1/ETIK/PPM.00.02/2022; protocol no: 22-09-1022; approval date: 3 October 2022). Written informed consent to participate was obtained from each subject.

Development of the Farra Eye Model

The Farra Eye Model was developed by the Department of Ophthalmology, Faculty of Medicine, Universitas Indonesia, to address the challenges of cataract surgery training, particularly capsulorhexis, in settings with limited access to high-fidelity commercial simulators. Its purpose is to provide a practical and cost-effective solution for repetitive surgical practice outside the operating theatre, ensuring accessibility for institutions in resource-limited settings. Introduced in 2021, it was designed to be an affordable and reusable option for ophthalmology residents, with each set priced at approximately 394 USD, making them a cost-effective alternative to other commercial simulator models, such as Kitaro™. Additionally, performing 100 capsulorhexis training sessions with the Farra Eye Model incurs a material cost of approximately 11 USD for replaceable capsular films [16,17].

The Farra Eye Model is developed using 3D-printing technology, following the human eye dimension [18]. The base, lower, and upper parts are photopolymer resin. Meanwhile, the pivot hump is made of silicon with a certain flexibility, connecting the lower part to the base. It functions as a pivot that allows this artificial eye to roll like an actual eyeball. The top of the lower part becomes the artificial lens holder. A thread system locks the upper and lower parts, which makes it easy to install and can be reused. The cornea is made of silicon and gives a similar incision sensation to the actual cornea. There is a dividing line to mark the limbus with a diameter of 11 mm (Figure 1). In early development, the Farra Eye Model focuses on capsulorhexis training.

Some steps are needed to use this model. First, place the base part onto a flat surface or styrofoam board with pins. Then, install the pivot hump and lower part on top of the base consecutively. The plasticine clay or artificial nucleus is placed on the bowl at the top of the lower part forming the desired lens convexity. Afterwards, a 2.5×2.5 cm blue cellulose membrane was placed on the top of the nucleus as a lens capsule. The artificial cornea is then placed on top of the capsule membrane. Lastly, the upper part locks onto the lower part, and the model is ready to use.

Validating Questionnaire

Before data collection, the questionnaire assessing the face and content validity of the Farra Eye Model was validated by a panel of experts consisting of four ophthalmology consultants and one methodologist. The set of questions was formed based on previous research, which also assessed the face and content validation of the eye surgery simulation training model [19–21]. Questions were then modified and selected for their comprehensiveness and relevance to the capsulorhexis trial.

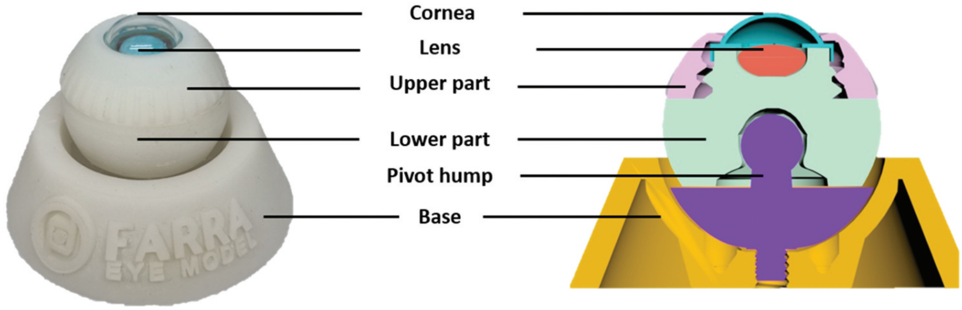

Figure 1. Farra Eye Model.

Study Protocol

Research participants who met the inclusion and exclusion criteria and agreed to participate in the study signed informed consent. To ensure all the subjects obtained similar information, a video aid explaining the capsulorhexis procedure and demonstrating how to use the Farra Eye Model were distributed to each subject.

Subjects were asked to perform capsulorhexis three times after familiarising themselves with the simulation tools and microscopes. The capsulorhexis step includes making an initial flap using a cystotome, then forming and completing the circular rhexis using Utrata forceps. Immediately after completing the capsulorhexis tasks, subjects were asked to rate the face and content validity assessment in the questionnaire using a 5-point Likert scale.

Face validity measures the resemblance of the simulation to the actual surgery procedure. It was performed by assessing the feedback from the subject on the realism of the tissue simulated by the model, mainly focusing on the lens capsule and capsulorhexis practice experience. Content validity assesses whether the eye model helps train specific skills. It surveyed how the subject believed the model was helpful in teaching capsulorhexis [15,22].

Statistical Analysis

Research data were analysed using the Statistical Package for Social Sciences (SPSS) computer program version 26. Characteristics of the subject were presented in descriptive analysis. Categorical data were presented in numbers and percentages. While, numerical data were presented in the mean and standard deviation if the data distribution is normal, or the median and range if the distribution is abnormal according to the Shapiro-Wilk test. In addition, according to data distribution, the Student's T-test or Mann-Whitney test was used to analyse two numerical variables. The analysis results were considered significant if the p-value was < 0.05.

Face and content validity assessment was rated on a scale of 1 (disagree) to 5 (strongly agree). Based on previous studies on face and content validation, scores > 3.5 were considered favourable, and scores < 3.0 were deemed inadequate [15,19]. The questionnaire was considered reliable if Cronbach's alpha $> 0,7$ and valid if corrected item-total correlation > 0.273.

Results

We had a total of 22 subjects (Table 1): ophthalmology residents ($n = 11$) who had performed cataract surgery at least 22 to 52 times; and consultants ($n = 11$) with cataract surgery performed over 500 cases, four of them (36%) performing cataract surgery on more than 2000 cases.

All residents have had experience using animal eyes and Kitaro^{TM} artificial eyes, while only 36% of consultants ($n = 4$) had used Kitaro^{TM} artificial eyes. Two residents and a consultant had experience using the Farra Eye Model six months before data collection.

Regarding the reliability of each subscale on the questionnaire, using Cronbach's alpha analysis, we found that the value for question items assessing face validity, content validity, and utility was 0.841, 0.763, and 0.769 respectively. Those scores indicate good reliability of the questionnaire. In addition, the validity of individual items was confirmed based on a corrected item-total correlation ($r > 0.273$).

Face Validity

Subjects reported that the model simulated the capsulorhexis procedure and replicated the eye accurately for training (Table 2). However, the elasticity of the lens capsule was only considered adequate (3.18 ± 1.1) by both groups, even though lens capsule tearing still felt realistic (median 4, range 1–5). Subjects also agreed that practising the commencement of the flap; and then formation and completion of circular rhexis were similar to actual surgery (median 4, range 1–5; and median 4, range 2–5, respectively).

Overall, the residents gave a lower mean score than the consultants, 3.32 ± 0.66 vs 4.02 ± 0.49, $p = 0.01$. They differed significantly in scoring elasticity of the lens capsule (2.73 ± 1.1 vs 3.64 ± 0.9, $p = 0.049$) and realism of formation and completion of circular rhexis practice (3(2–4) vs 4(3–5), $p = 0.040$).

Content Validity

Farra Eye Model also had a favourable content validity value (Table 3). The Farra Eye Model was considered helpful in training the commencement of the flap, and formation and completion of circular rhexis; both scored 4 (2–5). In addition, the Farra Eye Model was also excellent for developing hand-eye coordination and maintaining capsulorhexis skill (median 4, range 4–5; and median 4, range 3–5, respectively). The residents gave a lower mean score than the consultant group, 3.91 ± 0.41 vs. 4.39 ± 0.64 ($p = 0.049$).

Utility

Table 4 shows that subjects recommended the model for capsulorhexis training (median 4, range 3–5). The Farra Eye Model was reported to be comparable with other simulation models (median 4, range 2–5). Fourteen (64%) subjects compared the model with the Kitaro™ eye model, while the rest compared it with animal eyes (Table 4).

Discussion

Our subjects rated the Farra Eye Model as favourable in both face and content validity assessments. Even though the resident group considered the lens capsule elasticity inadequate, they still felt realistic tearing of the capsule and agreed that the eye model might simulate the capsulorhexis procedure. The lower rating for

Table 1. Characteristics of the participant.

Characteristics	Resident ($n = 11$)	Consultant ($n = 11$)
Age (year, median(range))	31 (29–34)	45 (33–57)
Gender		
Male, n(%)	7 (64)	5(45)
Female, n(%)	4 (36)	6 (55)
Frequently used capsulorhexis instrument		
Cystotome only, n(%)	6 (55)	5 (45)
Utrata forceps only, n(%)	0	2 (18)
Cystotome and Utrata forceps, n(%)	5 (45)	2 (18)
Cystotome, Utrata, and microforceps, n(%)	0	2 (18)
Dominant hand		
Right, n(%)	10 (91)	11 (100)
Left, n(%)	1 (9)	0
Simulation model experience		
Animal eyes only, n(%)	0	6 (55)
Animal eyes and artificial eyes, n(%)	11 (100)	3 (27)
Animal eyes and VR, n(%)	0	1 (9)
Animal eyes, artificial eyes, and VR, n(%)	0	1 (9)

VR = Virtual Reality.

Table 2. Face validity.

Questions	Total ($n = 22$)	Resident ($n = 11$)	Consultant ($n = 11$)	P
(1) Elasticity of the lens capsule felt realistic	3.18 ± 1.1	2.73 ± 1.1	3.64 ± 0.9	0.049*
(2) Tearing of the lens capsule felt realistic	4 (1–5)	4 (1–4)	4 (3–5)	0.056§
(3) Practising the commencement of the flap felt realistic	4 (1–5)	3 (1–5)	4 (2–5)	0.271§
(4) Practising the formation and completion of circular rhexis felt realistic	4 (2–5)	4 (2–4)	4 (3–5)	0.040§
(5) Farra Eye Model simulated capsulorhexis procedure	4 (2–5)	4 (2–4)	4 (4–5)	0.003§
(6) The Farra Eye Model replicated the eye accurately for capsulorhexis training	4 (2–5)	4 (2–5)	4 (3–5)	0.192§
Face validity value	3.67 ± 0.67	3.32 ± 0.66	4.02 ± 0.49	0.010*

*Student t-test between resident vs. consultant group.
§Mann-Whitney test between resident vs. consultant group.

Table 3. Content validity.

Questions	Total ($n = 22$)	Resident ($n = 11$)	Consultant ($n = 11$)	P
Farra Eye Model would be useful for:				
(1) Training the commencement of the flap	4 (2–5)	4 (3–4)	4 (2–5)	0.342[§]
(2) Training formation and completion of the circular rhexis	4 (2–5)	3 (2–5)	4 (4–5)	0.001[§]
(3) Developing hand-eye coordination for capsulorhexis	4 (4–5)	4 (4–4)	4 (4–5)	0.034[§]
(4) Maintaining skills in capsulorhexis procedure	4 (3–5)	4 (3–4)	4 (4–5)	0.046[§]
Content validity value	4.15 ± 0.58	3.91 ± 0.41	4.39 ± 0.64	0.049*

*Student t-test between resident vs. consultant group.
[§]Mann-Whitney test between resident vs. consultant group.

Table 4. Simulation model recommendation.

Questions	Total ($n = 22$)	Resident ($n = 11$)	Consultant ($n = 11$)	P*
(1) Farra Eye Model was recommended for capsulorhexis training	4.5 (3–5)	4 (3–5)	5 (4–5)	0.021
(2) Realism of the model is an important factor in the recommendation	4 (3–5)	4 (3–5)	4 (3–5)	0.259
(3) Farra Eye Model is comparable to other simulation models I have used	4 (2–5)	4 (2–4)	4 (3–5)	0.055

[§]Mann-Whitney test between resident vs. consultant group.

lens capsule elasticity might be related to its thickness. The Farra Eye Model uses a cellulose membrane with 30 µm thickness, while the actual anterior lens capsule in humans is only 14 µm thick [23]. Further investigation is needed to determine and create the most identical membrane that resembles the human lens capsule.

In most aspects, consultants gave a higher rating than residents. Higher face validity assessments by more experienced groups were found in other surgery simulator validation studies [19,24]. More experienced subjects had better tissue handling, thus giving different evaluations than less experienced subjects [24]. Moreover, they were more suitable in assessing whether the training model had met the standard required for surgery training as they had encountered more varied cases compared to less experienced participants [19]. Nevertheless, the ratings given by the residents can not be ignored because they represent the targeted population for this simulation use.

In this study, the Farra Eye Model received a higher content validity score than the face validity. Despite lacking lens capsule elasticity, the model was still rated useful for capsulorhexis training, developing hand-eye coordination, and maintaining skills. In simulated training, the ability of the simulation model to train the skill is more important than the similarity of the model with the actual eye [7]. Norman et al. reported no significant advantage of high-fidelity simulator learning over low-fidelity simulation learning [25].

The majority of respondents recommended the Farra Eye Model for capsulorhexis training. Nevertheless, the realism of the model still plays an essential factor. Also, the Farra Eye Model was comparable to other simulation models, such as the animal eye (64%) and the Kitaro™ artificial eye (36%).

Limitation

This pilot study only represents the face and content validity of the Farra Eye Model for capsulorhexis training. The result of this study should not be generalised for the other procedures on the Farra Eye Model and does not represent the other validity tests.

There is the possibility of recall bias with the subject, as they did not directly compare the live surgery with the simulation model during the assessment, even though we excluded subjects with no surgery within the past year [22]. Subjects might have misinterpreted the questions, yet it has been minimised by experts validating the questionnaire. All subjects also came from institutions that developed simulation models, which could lead to response bias. To avoid this bias, all subjects were ensured to receive the exact instructions using video and were accompanied by one instructor during data collection. Subjects also filled out questionnaires immediately after the third capsulorhexis trial.

Conclusion

The Farra Eye Model has good face and content validity values for capsulorhexis training. This newly developed cataract surgery simulation model may be an option for residency training programs with limited access to commercially available eye models.

However, it remains a challenge to replicate the elasticity of the human lens capsule; thus, further study is needed.

Acknowledgments

We would like to thank all the staff of Cipto Mangunkusumo General Hospital and the Faculty of Medicine Universitas Indonesia for their continuous and unending support for this study.

Disclosure Statement

No potential conflict of interest was reported by the author(s).

Funding

The author(s) reported that there is no funding associated with the work featured in this article.

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