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Evaluation of ophthalmic surgical simulators for continuous curvilinear capsulorhexis training

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Purpose: To evaluate performance and assessments by expert surgeons tasked to create a continuous curvilinear capsulorhexis (CCC) on 3 commercially available surgical simulators.

Setting: Montefiore Medical Center Department of Ophthalmology and Visual Sciences, Bronx, New York.

Design: Randomized, cross-sectional, comparative study.

Methods: Expert cataract surgeons (N = 7) were tasked to create a 5.5-mm CCC on 3 surgical simulators (Bioniko, Kitaro, and SimulEYE). Surgeons rated how well each simulator approximated human tissue on a modified Likert scale (1 to 7). Duration, size, and number of forceps grabs were evaluated.

Results: 7 surgeons performed a total of 63 trials. Bioniko required a greater number (6.53 ± 3.14) of forceps grabs for CCC creation than Kitaro (4.90 ± 2.47, P = .01) and SimulEYE (3.90 ± 1.34, P < .0001). Surgeons created the 5.5-mm CCC most accurately on Bioniko and SimulEYE, with the largest mean CCC performed on Kitaro (8.00 ± 0.84) compared with that on Bioniko (5.24 ± 0.60, P < .0001) and SimulEYE (5.11 ± 0.41, P < .0001). Surgeons spent more time (seconds) performing the CCC on Bioniko (41.95 ± 26.70) than that on Kitaro (32.05 ± 14.99, P = .02) and SimulEYE (28.90 ± 15.18, P = .002). Kitaro (4.56 ± 0.84, P < .0001) and SimulEYE (4.19 ± 0.92, P < .0001) were rated as more realistic than Bioniko (1.38 ± 0.80).

Conclusions: SimulEYE and Kitaro were believed to most closely approximate human capsular tissue, and surgeons performed the CCC fastest on these models. However, surgeons created a 5.5-mm CCC most accurately on SimulEYE and Bioniko. SimulEYE had the best overall performance and fidelity across all studied metrics; however, each simulator demonstrated its own unique advantages and disadvantages. Larger validation studies will help residency programs best use training tools for novice surgeons.

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Integration of surgical simulation in residency training allows novice surgeons the opportunity to safely practice critical procedures prior to performing surgery on live patients. The importance of this type of training cannot be overstated, and the incorporation of surgical skills development resources and a hands-on laboratory is indeed mandated by the Accreditation Council for Graduate Medical Education for all ophthalmology residency training programs (Accreditation Council for Graduate Medical Education Ref: Program Requirement: I.D.1.d). This mandate, however, does not provide specific recommendations, and significant variability exists across training programs regarding resident simulation experience.

A variety of simulation resources have been commercially developed, including virtual reality systems such as the EyeSi (Haag-Streit Simulation), along with more traditional tissue simulators such as those created by Kitaro, SimulEYE, Bioniko, Phillips Studio, and others. Tissue simulators have notable logistical and quality advantages over ex vivo animal eyes regarding ease of use, cost, reusability, and consistency in tissue quality.[1] Previous studies have found a common trend toward improved surgical skills among trainees who have access to surgical simulators.[2–4] In addition to helping trainees prepare for actual clinical procedures, ophthalmic surgical simulators also allow for programs to develop a formal wet-lab curriculum and evaluate residents' progress throughout their training.

Given the clinical needs of our aging population, a significant amount of time and resources are dedicated to training residents on how to safely and effectively perform cataract surgery. As such, a commensurate amount of

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simulation time and resources are directed toward mastering the individual steps of cataract surgery throughout residency training.[5] Among the most technically challenging maneuvers to master during this procedure is the continuous curvilinear capsulorhexis (CCC), where even small errors can lead to severe vision-threatening complications. Despite this well-recognized fact, there remains a paucity of validation studies that evaluate the most commonly used commercial training simulators. We aimed in this analysis to systematically compare 3 capsulorhexis simulation models, Kitaro DryLab, SimulEYE SimuloRhexis, and Bioniko Rhexis, from the perspective of expert cataract surgeons.

METHODS

The study was approved by the Institutional Review Board of the Albert Einstein College of Medicine and was conducted in association with the Office of Clinical Trials and the Henkind Eye Institute at the Montefiore Medical Center in the Bronx, New York. Funding for the project was provided by a restricted educational grant from the Manhattan Eye and Ear Foundation.

Three commonly used capsulorhexis simulators were chosen and sourced based on experience and availability, namely the Kitaro DryLab model (Frontier Vision Co., Ltd.), SimulEYE SimuloRhexis model (InsEYEt, LLC), and the Bioniko Rhexis (Bioniko Consulting LLC).

The Kitaro DryLab model (Figure 1, a) has a central pupil diameter of 14.0 mm with an open-sky configuration and prefabricated openings that simulate clear corneal incisions. The simulated capsule is composed of a 5-micron-thick, polyester bilayer that comes on a roll allowing multiple attempts. The capsule is placed slightly taut on a reusable artificial resin clay nucleus that simulates a cataract.[1] In this study, the simulated eye was mounted within a rubber face to simulate human facial contours. As recommended by the manufacturer, ophthalmic viscosurgical device was placed on the surface of the capsular film to simulate an anterior chamber.

The SimuloRhexis model (Figure 1, b), with a physiological central pupil diameter of 8.0 mm, features an anterior chamber that can be filled with ophthalmic viscosurgical device and an artificial cornea that requires a standard keratome incision prior to the CCC, as is performed in actual cataract extraction. This model suctions directly onto a flat surface and allows the user to simulate variable posterior pressure by mechanically adjusting the base of the simulator.[6]

The Bioniko Rhexis model (Figure 1, c), with a central pupil diameter of 9.0 mm, was stabilized with the recommended Mini Holder prior to use in this study. Similar to Kitaro DryLab, this model has an open-sky configuration but, by contrast, features a limbal corneal ridge that can be incised with a standard keratome blade. To maintain proper consistency of the material, the entire surface was moistened with water prior to use as per recommendations.[7]

Expert cataract surgeons (N = 7), defined as having performed greater than 1000 primary cases, were identified, and informed consent was obtained. Each surgeon was tasked to create a 5.5-mm CCC on all three simulators, which were presented in a randomized sequence for a total of three trials on each model. The study was performed under standard operating room conditions at the Hutchinson Metro Center Operating Suite in Bronx, New York. With a sample size of 7 surgeons performing a total of 63 total trials, the study had 80% power with a 2-sided type I error rate of 5% to detect a minimum effect size of 1.3 in the measured outcomes among simulators.

The surgeons were instructed to position themselves as they would for an actual procedure, and foot-pedal controlled Zeiss Lumera microscopes with recording capabilities were used for each trial. The unmarked and previously prepared simulators were each placed directly in front of the surgeons on a raised metal tray table in randomized fashion. The standardized materials used included the following: a dual-bevel, 2.75-mm microkeratome blade to make the clear corneal incisions for SimulEYE and Bioniko, dispersive ophthalmic viscosurgical device (VISCOAT) for Kitaro and SimulEYE, a standard bent cystotome needle on a 1-mL syringe to make the initial anterior capsular rent, and a pair of standard titanium Utrata forceps to create the CCC.

The primary measured outcomes included the size of the completed CCC (millimeters), the number of capsular forceps manipulations (number of grabs) required, and the task duration (seconds). Immediately after each CCC attempt, surgeons were asked to subjectively rate on a modified Likert scale (1 to 7) how closely the model simulated human tissue using the following question: "On a scale from 1 to 7, with 1 signifying the least realistic simulation experience and 7 signifying the most realistic simulation experience, how well does this kit simulate performing a CCC on real tissue?" The names of the simulators were not revealed to the surgeons until after all trials were completed. Outcome measures were summarized for each kit and trial by computing means and standard deviations. In addition, multiple linear regression models that included kit, trial, and surgeon as predictor variables were fit to the data to assess the independent effects of each factor on each of the outcomes. A 2-sided P value less than 0.05 was considered statistically significant. All analyses were performed using SAS v. 9.4 (SAS Institute Inc.).

RESULTS

A total of 63 trials (7 surgeons completing three trials on each of the 3 simulators) were performed in a randomized fashion. The results for each primary outcome are presented. There were statistically significant differences among the simulators and across the 3 trials for all outcome measures.

Regarding size (maximum diameter in millimeters), surgeons created the 5.5-mm CCC most accurately on the Bioniko and SimulEye models. Surgeons performed the largest average CCC on the Kitaro model (8.00 ± 0.84) compared with both Bioniko (5.24 ± 0.60, $P < .0001$) and SimulEYE

A B C

Figure 1. The surgical simulation models used in the study: (*a*) Kitaro DryLab, (*b*) SimulEYE SimuloRhexis, and (*c*) Bioniko Rhexis.

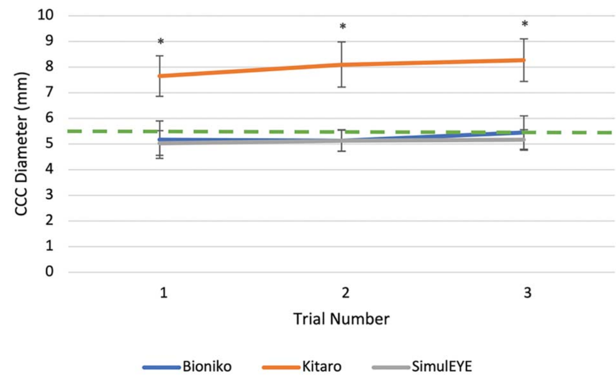

Figure 2. CCC size (longest dimension in mm). Surgeons created the 5.5-mm-sized CCC most accurately on the Bioniko and SimulEYE models. The *dashed green line* indicates the tasked CCC size of 5.5 mm. *The Kitaro CCC was statistically significantly larger than both the Bioniko and SimulEye models ($P < .0001$) for all trials. CCC = continuous curvilinear capsulorhexis

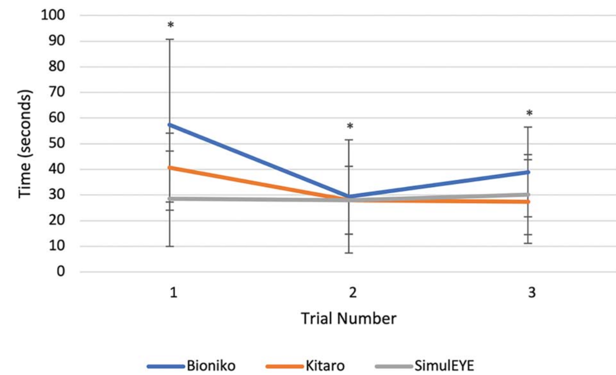

Figure 3. Duration of CCC (seconds). Surgeons overall took the longest amount of time to perform the CCC on the Bioniko model compared with Kitaro ($P = .02$) and SimulEYE ($P = .002$). CCC = continuous curvilinear capsulorhexis

(5.11 ± 0.41, $P < .0001$). Across all simulators, CCC size was overall larger in the third trials (6.29 ± 1.56) compared with the first trials (5.94 ± 1.39, $P = .003$, Figure 2).

Surgeons spent more time (seconds) performing the CCC on Bioniko (41.95 ± 26.70) than on both Kitaro (32.05 ± 14.99, $P = .02$) and SimulEYE (28.90 ± 15.18, $P = .002$) and more time on average on trial 1 (42.24 ± 25.23) than that on trials 2 (28.48 ± 15.87, $P = .001$) and 3 (32.19 ± 16.44, $P = .01$, Figure 3).

Bioniko required a greater number of grabs (6.53 ± 3.14) than both Kitaro (4.90 ± 2.47, $P = .01$) and SimulEYE (3.90 ± 1.34, $P < .0001$). Trial 1 (6.19 ± 3.57) had a greater number of grabs than both trials 2 (4.33 ± 2.01, $P = .002$) and 3 (4.81 ± 1.63, $P = .02$, Figure 4).

The Kitaro (4.56 ± 0.84, $P < .0001$) and SimulEYE models (4.19 ± 0.92, $P < .0001$) were rated as more realistic by the surgeons than the Bioniko model (1.38 ± 0.80) on a 7-point modified Likert scale (Figure 5). The highest numbers on the modified Likert scale represent the most realistic simulation experience.

DISCUSSION

Ophthalmic surgical simulators are in popular use by residency training programs and offer novice surgeons the opportunity to practice complex maneuvers in preparation for actual surgery in a safe and controlled environment. Studies demonstrated improved performance by students and residents after practicing either on simulator devices or in the wet lab.[2–4] Specifically, Belyea et al. showed that surgeons who trained on EYESi had shorter phacoemulsification times, lower phacoemulsification power, fewer intraoperative complications, and a shorter learning curve on average than those who were not trained on EYESi.[2] Pokroy et al. also found that ophthalmic surgical simulators shortened the learning curve for the first 50 cataract cases, with less adept residents benefiting the most from the training.[4] It is imperative to note that both of these studies involved virtual reality surgical simulation through the EYESi module; neither used any of the 3 models that were used in this study.

The Kitaro model has been studied for steps including the CCC; however, this was performed using the Da Vinci Robotic Surgical System on the Kitaro WetLab model.[8] In our analysis, we chose the Kitaro DryLab model with manual CCC creation as this is the more commonly used training tool for this task. To the authors' knowledge, no studies have been reported on the Bioniko Rhexis or SimulEYE SimuloRhexis models. The advertised cost of

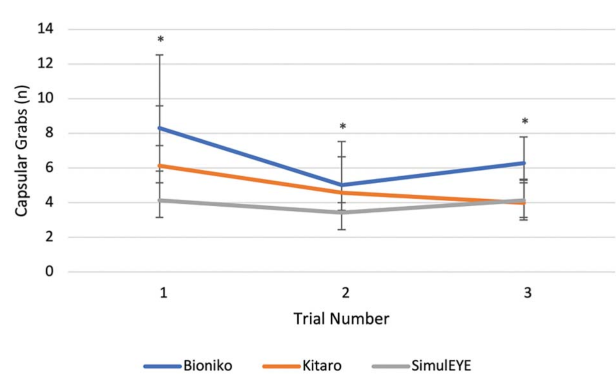

Figure 4. Number of capsular grabs: The Bioniko model overall required a greater mean number of grabs compared with Kitaro $P = .01$ and SimulEYE ($P < .0001$).

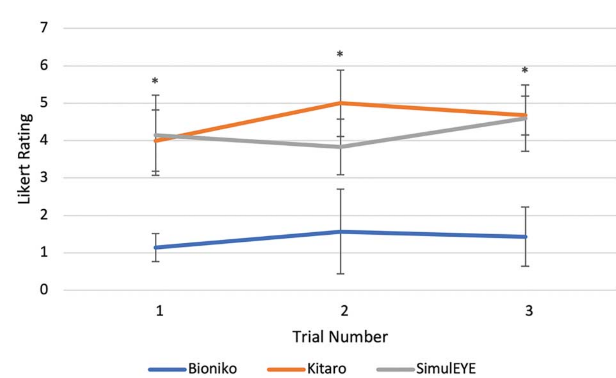

Figure 5. Realism of simulated tissue based on modified Likert rating (1 to 7): Surgeons rated the overall experience of performing the CCC on the Kitaro and SimulEYE models as more realistic than that on the Bioniko, with a score of 7 being the most realistic ($P < .0001$). CCC = continuous curvilinear capsulorhexis

Table 1. For Each Metric, the Best Performing Models Are Listed.

Summary of metrics

Metric	Simulator[a]
Task accuracy (closest to a 5.5-mm CCC)[b]	Bioniko SimulEYE
Fewest no. of forceps grabs[b]	SimulEYE Kitaro
Task duration (fastest CCC)[b]	SimulEYE Kitaro
Most realistic feel (Likert scale)[b]	SimulEYE Kitaro
Simulated cornea and iris tissue included	Bioniko SimulEYE
Ability to increase posterior pressure	SimulEYE

CCC = continuous curvilinear capsulorhexis
No statistically significant differences were noted between the models for the listed metric. Simulated cornea and iris tissues are included in the SimulEYE and Bioniko models, and the SimulEYE model allows for additional functionality (not tested) to increase posterior pressure.
[a]No statistically significant differences found between the listed simulators
[b]Metrics analyzed within this study

materials to perform 100 CCCs, not accounting for institutional discounts, was $970 for Bioniko, $995 for Kitaro, and $715 for SimulEYE. Of note, the Kitaro kit uses a roll of replaceable capsular film that allows for multiple additional practice opportunities.

From the perspective of the expert surgeons who participated in this study, the experience of creating the CCC on the SimulEYE SimuloRhexis and Kitaro DryLab simulator kits were believed to most closely approximate the experience of creating the CCC in a real-life cataract surgery. Surgeons also tended to perform the CCC faster on average with both of these simulators compared with the Bioniko model. This result is reasonable given the Bioniko model is designed to tear in a manner that allows more capsular grabs attempts. Regarding size, surgeons created a 5.5-mm diameter CCC most precisely on the Bioniko and SimulEYE models compared with the Kitaro model. We surmise that this is due to the naturally larger pupil diameter on the Kitaro model, which may have led to a tendency for surgeons to create a larger CCC. In general, surgeons performed faster CCCs over the three trials on the Kitaro and Bioniko models, suggesting a learning curve on these simulators with practice. Of interest, there was no significant learning curve with the SimulEYE model across the three trials, and surgeons' overall performance was the most consistent among the three trials on this model.

Beyond the formal survey, extemporaneous comments from the surgeons regarding each of the models were also recorded in real-time during each CCC trial (Table 1). Regarding task difficulty, it was noted that the Kitaro DryLab model was oversimplified relative to the SimulEye and Bioniko simulators, which incorporate the creation of a triplanar clear corneal incision. Furthermore, a distinct advantage of the SimulEYE SimuloRhexis model noted by the surgeons was the ability of the capsular tissue to remain everted between grabs. Some surgeons did find the SimulEye capsule to be overly brittle and tear more easily than a true capsule, however. Regarding the clear corneal incision, it was noted by some that the Bioniko Rhexis felt the most realistic as the consistency and memory of the wound felt similar to that of a true cornea. However, surgeons overwhelmingly found that the capsular tissue of the Bioniko model was overly friable and did not tear naturally. Of note, the Bioniko Rhexis model is purposefully designed to promote frequent capsular regrasping and allow for the assessment of the amount of corneal wound manipulation.[7]

This pilot study was designed to formally analyze both subjective and objective differences among the three simulators. The underlying assumption was that highly experienced surgeons can provide the most nuanced feedback comparing the simulators to human tissue. These results, however, do not necessarily validate the efficacy of these simulators in training novice surgeons. Larger case–control studies designed to formally evaluate learning curves, surgical complication rates, and possibly ergonomics are necessary to make broader conclusions and recommendations.

To the authors' knowledge, this is the first study to systematically evaluate CCC training simulators from the perspective of expert cataract surgeons. Although the SimulEYE SimuloRhexis was found in our study to have an advantage when looking at the overall performance and fidelity across the studied metrics, each of 3 capsulorhexis simulators tested have their own unique advantages and disadvantages. Each residency training program should make decisions on which simulator best suits their training needs based on an individual assessment and resources available. Further validation studies are needed to determine the effect the simulation training has on actual surgical outcomes for novice surgeons.

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The Manhattan Eye Foundation for providing funding to purchase the simulators used in this study and the Montefiore Hutchinson Operating Suite for allowing use of essential operating room equipment.

WHAT WAS KNOWN

- Ophthalmic surgical simulators allow surgeons of all skill levels to practice specific steps of ophthalmic surgery in preparation for the operating room.
- The continuous curvilinear capsulorhexis (CCC) is a fundamental step of cataract surgery and one of the most challenging maneuvers for surgeons to master.

WHAT THIS PAPER ADDS

- To the authors' knowledge, this is the first study to formally compare the experience of creating the CCC on a variety of ophthalmic surgical simulators from the perspective of expert cataract surgeons.
- This study presented objective and subjective feedback of CCC creation on surgical simulators, allowing residency programs to determine which simulators best suit their training needs.

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