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3D-Printed Ophthalmic-Retrobulbar-Anesthesia Simulator: Mimicking Anatomical Structures and Providing Tactile Sensations

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Institutional Review Board of Seoul National University Hospital under Approval No. H-1902-027-1009.

ABSTRACT Objective: A simulator for retrobulbar anesthesia administration mimicking the orbital anatomy and providing tactile sensation is proposed. **Methods:** The production process involves 3D modeling of anatomical structures on the basis of computerized tomography (CT) images, printing the models using a 3D printer, and casting the silicone. Twenty ophthalmologists administered retrobulbar anesthesia using the simulator with four different ocular axial lengths (including extreme myopes); the position of the needle tip was evaluated. The effectiveness of this simulator for training was also surveyed. **Results:** The proportions of the final location of the needle tip were 59.25%, 36.25%, and 4.5% for the retrobulbar space, peribulbar space, and intraocular space, respectively. Experienced ophthalmologists showed lower complication rates than residents (0.5% vs 8.5%, P < 0.001) and agreed that this simulator will help young ophthalmologists advance their anesthesia-administering skills. **Discussion/Conclusion:** The 3D-printered simulator for retrobulbar anesthesia was produced and performance was verified. The technology could be used to simulate critical orbital anatomic features and could be used as a training tool for resident ophthalmologists.

INDEX TERMS Anatomical 3D model, education, ophthalmic retrobulbar anesthesia, simulator, 3D printing.

Clinical and Translational Impact Statement: Improve understanding of orbital anatomy and ophthalmic retrobulbar anesthesia to successfully deliver anesthetics to the retrobulbar space.

I. INTRODUCTION AND HEALTHCARE NEED

Retrobulbar anesthesia blocks the ciliary nerves and the optic (II), oculomotor (III), and abducens (VI) cranial nerves, thus effecting ocular anesthesia and akinesia. To obtain optimal results, the anesthetic drug needs to be deposited into the retrobulbar space, the posterior intraconal space where II, III, and VI cranial nerves pass through before they enter the four rectus muscles [1].

In many cases, conventional procedures are performed as blind techniques solely relying on the physicians' knowledge of anatomy and their haptic sensitivity. This makes it difficult to safely and successfully administer anesthetics into the intraconal space without proper comprehension of anatomy and relevant ophthalmic procedures. Indexterity and imprecision when handling the needle can lead to injury to anatomical structures. The major risk factor for such surgical complications is a long ocular axial length. Although these complications are rare, they can be vision-threatening when the ocular globe and optic nerve are injured; they can be fatal in a case of brainstem anesthesia.

To prevent surgical complications, the need for a training simulator for retrobulbar anesthesia has continually arisen.



Prior researches have demonstrated that medical device simulation training is effective and useful for non-skilled people [2]–[5]. Merril et al. [6] developed a training simulator comprising ultrasonic detectors—which locate the needle tip and that utilized real-time digital footage. To simulate the orbital environment, the digital footage of orbital anatomy and the needle was observed on a monitor. Nonetheless, the simulator was unable to provide feedback on the proximity of the needle to other ocular structures, which is essential when practicing anesthesia-administering skills to avoid damage to the adjacent structures. Mukherjee et al. [7]-[9] developed a series of intermediate simulators, finally developing one that could provide a quantitative feedback of the proximity of the needle to other ocular structures through the use of electrical sensors. Although their simulator was cheaper and smaller than the former (ultrasound-based) simulator, the circuitry was too complex to properly mimic anatomical structures. More importantly, it did not provide any haptic feedback, which is crucial in real situations with real patients.

In this paper, we present a novel simulator comprising a three-dimensionally (3D) printed orbit model based on patients' computerized tomography (CT) images. Eyeball models with various axial length were produced using CT images of patients with different ocular axial length. Thus, cases prone to complications can be simulated for effective instruction of residents. The soft tissues in the orbit were achieved using an elastic material that can endure repetitive procedures. The trajectory and final location of the needle were easily visualized. The haptics of the procedures was similarly achieved by creating each part using materials with similar physical properties.

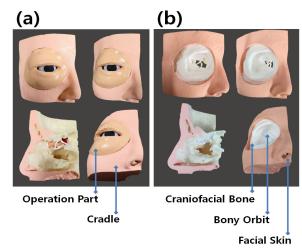
II. METHOD

This study was approved by the institutional review board of Seoul National University Hospital (H-1902-027-1009) and which adhered to the tenets of the Declaration of Helsinki. Written informed consent to participate was provided by all subjects.

A. FABRICATION OF THE SIMULATOR

The simulator consists of an operation part and a cradle (Fig. 1). The operation part mimics periorbital skin, the eyeball, extraocular rectus muscles with inferotemporal intermuscular septum, and orbital fat. It is made of silicone and has physical properties similar to those of a living tissue. Because the procedure is performed using the simulator model, it is damaged and needs to be replaced for routine training. The cradle mimics the bony orbit, the part of craniofacial bone and facial skin which was not included in the operation part. This immobilizes the operation part during training. It is made of a single material (solid); thus, it is not easily damaged and can be used for a longer time.

The simulator production process entails the following steps (Fig. 2):



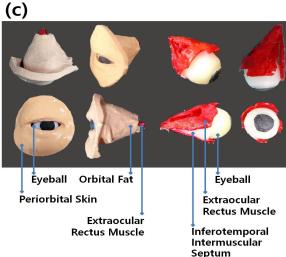


FIGURE 1. (a) Structure of the simulator consisting of an operation part and a cradle; (b) Cradle: It mimics the bony orbit, the part of craniofacial bone and facial skin which was not included in the operation part. This immobilizes the operation part during training. It is composed of one solid material; thus, it is not readily damaged and can be used for a long time; (c) Operation part: It mimics periorbital skin, the eyeball, extraocular rectus muscles, inferotemporal intermuscular septum, and orbital fat. It is made of silicone and has physical properties similar to those of a living tissue. Because the procedure is performed using this part, it is damaged and needs to be replaced after repetitions.

- a) 3D modeling of anatomical structures using CT images: To fabricate a realistic anatomical structure, CT images were input into the SEG3D program v2.4.4 (The Center for Integrative Biomedical Computing, University of Utah, Utah, USA). Each part was segmented separately, and 3D modeling was performed. Eye models with four different axial lengths (AXLs) (22, 26, 30, and 34 mm) were printed using CT images of patients with different ocular axial lengths (Fig. 3). The intermuscular septum was artificially designed because it was difficult to identify with CT images.
- b) Modifying anatomical 3D models to simulator 3D models: Anatomical 3D models were grouped under the operation part and the cradle. Among the operation part, the eyeball, orbital fat, and intermuscular septum models

VOLUME 9, 2021 3800206



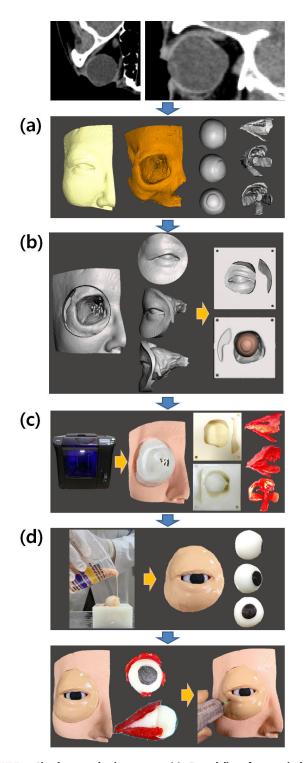
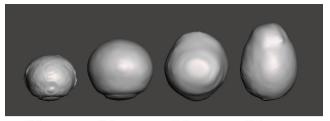


FIGURE 2. Simulator production process: (a) 3D modeling of anatomical structures using CT images; (b) Modifying anatomical 3D models to simulator 3D models; (c) Printing the models using an material-extrusion-type desktop 3D-printer 3D Printer; and (d) Casting the silicone using the printed molds.

were converted into molds for casting silicone using Mesh-Mixer v3.5 (Autodesk, Inc., CA, USA) and Inventor 2019 (Autodesk, Inc., CA, USA). For the cradle, the components were merged.



<22 mm> <26 mm> <30 mm> <34 mm>

FIGURE 3. Eye models of various lengths. Eye models of 22, 26, 30, and 34 mm length were produced using CT images of patients with different ocular axial lengths.

- c) Printing the models using material-extrusion-type desktop 3D-printer Cubicon Single Plus (HyVISION, Gyeonggido, Republic of Korea): The mold and cradle were printed using solid polylactic acid (PLA). The rectus muscle model was printed using thermoplastic polyurethane (TPU) with shore 95A—which is harder than the actual rectus muscle—to support the fat model, which otherwise could not support itself due to its softness.
- d) Casting the silicone using the printed molds: The fat part was produced by casting EcoFlexTM GEL (Smooth-On Inc, PA, USA) with shore 000-35 into molds, and Dragon Skin Fx-Pro (Smooth-On Inc, PA, USA) with shore 2A was applied onto the surface to embody skin touch [10], [11]. The eye and intermuscular septum were also cast using Dragon Skin Fx-Pro. For the septum part, the hardness could not be verified using a reference. Therefore, the models were made with various silicones within a hardness range of 00-10A to 29A; the medical staff participating in this study directly injected the needle, and the material with the most familiar haptic sense was selected.

B. DEMONSTRATION AND EVALUATION OF THE SIMULATOR

The goal of the study was to develop a training simulator that improves the trainees' retrobulbar-anesthesia-administering skills by simulating best practices for proper positioning of the tip of the needle. At the end of each trial, the trainees were given feedback with regard to where they had placed the tip of the needle. The final position of the tip was categorized into three groups, namely, retrobulbar space (i.e., intraconal space; the space between intermuscular septum and eyeball globe), peribulbar space (i.e., the space out of intermuscular septum), and intraocular space (i.e., globe perforation) (Fig. 4).

Before training, the participants filled questionnaires to assess their knowledge of ophthalmic procedures and their awareness of the complications associated with retrobulbar anesthesia. Next, the retrobulbar anesthesia administration and the model operation were explained to the trainees. When the overall training processes were complete, the trainees themselves conducted additional surveys to evaluate their levels of upskilling and haptic feedback. The survey

3800206 VOLUME 9, 2021



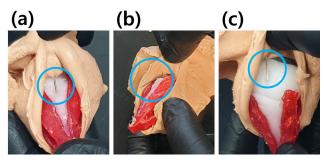


FIGURE 4. Position of the tip was categorized into three groups:
(a) Retrobulbar space (i.e., intraconal space; the space between intermuscular septum and eyeball globe); (b) Peribulbar space (i.e., the space out of intermuscular septum); and (c) Intraocular space (i.e., globe perforation).

consisted of three questionnaires interrogating the effectiveness of the simulator in terms of puncture prevention (questionnaire 1, Q1) and proper positioning of the needle tip in intraconal space (questionnaire 2, Q2) for all ophthalmologists and the effectiveness of the simulator in terms of training of young ophthalmologists (questionnaire 3, Q3) for veteran ophthalmologists.

A study was performed at Seoul National University Hospital with ten resident ophthalmologists (Group A and B), ten subspecialty trainees and attending physicians (Group C). The ten residents were categorized into two groups according to their cumulative learning period at the university. Four orbit models with different AXLs were used. For each model, five trials were conducted with feedback given for each trial. The trials were conducted in the ascending order of AXLs.

For each eyeball model, we tested the inequality of the frequency of the needle's placement in three groups using Fisher's exact tests with Bonferroni correction (retrobulbar space vs. others, peribulbar space vs. others, and intraocular space vs. others).

If any test was significant, post-hoc analyses with Fisher's exact tests with Bonferroni correction were conducted again to compare the results between two groups out of the three groups. The level of statistical significance was set at P < 0.05.

III. RESULTS

The mean training period of ophthalmology for the least experienced group (Group A) was 5.2 months. The next group (Group B) had a mean training period of ophthalmology of 24.2 months. The mean training periods of ophthalmology for the three groups significantly varied (P < 0.001, Table 1).

The mean proportions of the final locations of the needle tip were calculated for each group and for each model with different axial lengths. The result is summarized in Table 2.

The proportion of the final location of the needle tip were 59.25%, 36.25%, and 4.5% for the retrobulbar space, the peribulbar space, and the intraocular space, respectively. Ophthalmologists in Group C experienced less eyeball

TABLE 1. Characteristics of trainees.

Group	A	В	С	P-value
Status	Young residents (<12 months of training)	Older residents (>12 months of training)	Subspecialty trainees and attending physicians	
Training period, month	5.2 ± 6.2	24.2 ± 14.2	65.6 ± 8.3	$< 0.001^{a}$

^a Kruskal-Wallis analysis of variance

rupture (i.e., globe perforation) compared to those in Group A or Group B (P < 0.001).

For the eye simulator with axial length of 34 mm, the proportion of the puncture was 0 in Group C, which was statistically different from those of the other two groups (P=0.003). In contrast, the proportion of peribulbar placement was higher in Group C, while the statistical significance was not observed. The result is summarized in Table 2.

The results of the survey (questionnaire) for the appraisal of the ophthalmic-retrobulbar-anesthesia simulator are shown in Table 3. Compared with Group C, Group A (young residents) had a higher proportion of assent to the effectiveness of the simulator in Q2. Every doctor in Group C admitted the high effectiveness of the simulator in terms of training resident ophthalmologists (Q3).

IV. DISCUSSION

A training simulator made up of a 3D-printed-eye-simulator model was developed. The model is based on patients' CT images. In the eye model, the peribulbar soft tissue was replicated and could be easily separated from the socket mimicking the orbit. The retrobulbar fat tissue was modeled using EcoFlexTM Gel. The intermuscular septum between the medial and inferior rectus muscles was modeled using Dragon Skin FX-ProTM.

The ability of the novel simulator to mimic the realistic anatomical structures and tactile sensation made it advantageous over the traditional training simulators.

As a result of training using the simulator, the proportions of the final location of the needle tip were 59.25%, 36.25%, and 4.5% for the retrobulbar space, peribulbar space, and intraocular space, respectively. In some clinical situations, the delivery of anesthetics in a peribulbar space is acceptable and considered safe in terms of avoiding eyeball puncture. Thus, in a broader sense, the success rate of the final positioning of the needle tip was 95.5%—the proportion of the position of the tip in the retrobulbar and peribulbar space.

Physicians were capable of learning how to use their haptic sense, which is also important in real situations. In the procedure, the practitioner cannot see the intraorbital anatomy. Instead of observation, the popping sensation when the needle tip penetrates the intermuscular septum assures the practitioner that the tip is in the muscle cone. This popping

VOLUME 9, 2021 3800206



TABLE 2. Needle-tip positions in the simulator for four different axial lengths.

Axial length of eye model (mm)	Needle-tip position	Group A	Group B	Group C	P-value ^c	Post-hoc ^d
All models						
	Retrobulbar space ^a	60%	47%	65%	0.003	B < C
	Peribulbar space	33%	43%	35%	0.013	
	Intraocular space ^b	7%	10%	1%	< 0.001	A > C, B > C
22 mm						
	Retrobulbar space ^a	56%	32%	66%	0.020	
	Peribulbar space	44%	52%	34%	0.311	
	Intraocular space ^b	0%	16%	0%	0.006	
26 mm						
	Retrobulbar space ^a	56%	40%	68%	0.071	
	Peribulbar space	36%	56%	30%	0.090	
	Intraocular space ^b	8%	4%	2%	0.555	
30 mm						
	Retrobulbar space ^a	80%	72%	78%	0.810	
	Peribulbar space	20%	28%	22%	0.821	
	Intraocular space ^b	0%	0%	0%	>0.999	
34 mm						
	Retrobulbar space ^a	48%	44%	48%	0.966	
	Peribulbar space	32%	36%	52%	0.190	
	Intraocular space ^b	20%	20%	0%	0.001	A > C, B > C

^aSuccess, bona fide

TABLE 3. Questionnaire: Estimation of potential effectiveness for training.

	Group A	Group B	Group C					
` .	Q1: Do you think this simulator will help you avoid complications in your procedure of retrobulbar anesthesia?							
YES	80%	100%	70%					
NO	20%	0%	30%					
	Q2: Do you think this simulator will help you advance your skills of retrobulbar anesthesia?							
YES	100%	80%	60%					
NO	0%	20%	40%					
	Q3: Do you think this simulator helps young ophthalmologists advance their anesthesia-administering skills?							
YES	-	-	100%					
NO	-	-	0%					

sensation was also felt with the eye simulator when the needle penetrated the structure mimicking the intermuscular septum.

Another advantage is the simulator's more direct and intuitive feedback mechanism, which comprises the results of each trial. The gel mimicking retrobulbar fat holds the needle in place after each trial. The user could easily see the location of the needle tip after pulling out the eye model from its socket.

A survey on the effectiveness of the simulator showed that, for both groups of ophthalmology residents (Group A and B), more than 80% of the participants endorsed the training simulator as helpful in improving the surgical skills necessary for proper positioning of the needle and avoiding eyeball puncture. They felt somewhat realistic sensations when compressing the periorbital tissue to identify the position of orbital bone edge by finger. This is because silicones that mimic skin and fat have a similar hardness to that of actual tissue. However, 40% of the subspecialty trainees and attending physicians (Group C) were unsatisfied with the simulator on grounds that the fat model was more viscous than real fat; as the needle went deeper into the soft tissue, the resistance increased, making it difficult to adjust the angle of injection. This hindrance in changing the direction of the needle resulted in it getting placed in the peribulbar space rather than intraconal space (36.25%). To solve this problem, it is necessary to consider both hardness and viscosity when selecting silicone.

In the trial involving the eye model with an axial length of 34 mm, the experienced ophthalmologists (Group C) had a significantly lower globe perforation rate. We interpreted this result as a pointer of the different degrees of risk-awareness among groups; the experienced ophthalmologists knew the high risk of eyeball puncture in retrobulbar anesthesia procedures involving eyes of extreme myopia and

3800206 VOLUME 9, 2021

^bComplication, eyeball puncture

^cFisher exact test with Bonferroni correction

^dPost-hoc analysis with Bonferroni correction



they preferably placed the needle tip in the peribulbar space. Based on this observation, we believe the proposed training simulator could reflect the real characteristics of various patients' eyeballs with different axial lengths and would especially be helpful for training inexperienced administrators of retrobulbar anesthesia.

V. FUTURE DIRECTION AND POTENTIAL HEALTHCARE IMPACT

The training simulator for retrobulbar anesthesia presented herein was made through 3D printing and was based on a patient's CT images. By various axial lengths of the eye simulator, we could specify the effectiveness of the simulator in terms of training residents to improve their anesthesia-administering skills to avoid globe perforation. After each trial in the training, an intuitive and direct feedback of the result was given to the user by pin-pointing the location of the needle's tip. Most of the practitioners positively appraised the simulator, regardless of prior experiences with retrobulbar anesthesia. For future quantitative measurement, the sensor will measure the reaction force applied to the needle during retrobulbar anesthesia and compare this force with the results measured by the simulator.

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VOLUME 9, 2021 3800206