Concurrent and Face Validity of a Capsulorhexis Simulation with Respect to Human Patients

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Abstract. A prototype version of the ImmersiveTouch® virtual reality simulator were applied to capsulorhexis, the creation of circular tear or “rhexis” in the lens capsule of the eye during cataract surgery. Virtual and live surgery scores by residents were compared. The same three metrics are used in each mode: circularity of the rhexis, duration of surgery (sec), and number of forceps grabs of the capsule per completed rhexis (fewer is better). The average simulator circularity score correlated closely with the average live score (P = 0.0002; N = 4), establishing “concurrent validity” for this metric. Individuals performed similarly to each other in both modes, as shown by the low standard deviations for average circularity (virtual 0.92 ± 0.04; live 0.88 ± 0.04). By contrast, the standard deviations are high for the other two metrics, capsulorhexis duration (virtual 96.91 ± 44.23 sec; live 94.42 ± 65.74 sec, N = 8) and number of forceps grabs (virtual 10.66 ± 4.81; live 10.31 ± 5.23, N = 8). Nevertheless, the simulator was able to demonstrate that the surgeons with wide variations in total duration and number of capsular grabs in 2 to 4 trials of simulated surgery also had similar variations in live surgery, so that the simulator retains some realism or “face validity.”

Introduction: Cataract Surgery and Virtual Reality

Modern cataract surgery by phacoemulsification has five main steps: 1) corneal incision; 2) capsulorhexis, create a circular tear or “rhexis” in the anterior lens capsule through the corneal incision; this makes the next three steps possible: 3) phacoemulsification.; 4) irrigation and aspiration; and 5) intraocular lens insertion. Of these five steps, residents find capsulorhexis and with capsulorhexis sometimes rated most difficult followed by phacoemulsification.12 This paper presents results of a new, completely virtual simulation of capsulorhexis by ImmersiveTouch®-Sensimmer®.

The Accreditation Council for Graduate Medical Education (ACGME) states that all ophthalmology programs: “Residents must have access to a surgical skills development facility (e.g., a wet lab, materials or simulators) and instruction within the program.”3 For capsulorhexis, wet labs using enucleated animal eyes, often from pigs, are a subject of research because of the need to stiffen the highly elastic porcine lens capsule to make it more fragile and tearable like the capsule of the typical elderly patient. Such stiffening agents can include mixtures of trypan blue with formaldehyde and an Ophthalmic Viscosurgical Device (OVD).4 The advantages that surgical simulators provide is the fact that they do not use real tissues, but beyond that they can be based on either virtual reality or physical reality. Three capsulorhexis simulators may be compared on this basis.

The EYESI eye surgery simulator (VRmagic, Mannheim, Germany) is based on the physical reality of a cardanically suspended mechanical eye set within a plastic model patient head with a posterior segment model (vitreoretinal surgery) and an anterior segment model (cataract surgery). To represent the anterior chamber, the eye model includes a clear glass to allow a view into the eye, with the glass held by a circumferential metal ring which in turn is anchored on the front of the eye globe. The ring has regularly spaced small entry holes to represent possible locations of corneal incisions. After specially designed instruments are inserted into the mechanical eye through preset openings, movements of the instruments and the eye are detected by optical tracking (CCD cameras) and transmitted to a computer that creates a virtual image—including a virtual lens capsule for cataract surgery—which is then presented via a stereo microscope in a three-dimensional mode to the user. The EYESI can therefore be called a mechanical system with a virtual overlay, a kind of hybrid.

Another commercially available cataract surgery simulator, PhacoVision (Melerit Medical AB, Linköping, Sweden), also relies on both virtual and physical reality. The only article archived in the PubMed database deals with PhacoVision phacoemulsification,2 and no haptic feedback is provided for this procedure. Although a PhacoVision capsulorhexis simulation is now represented in online videos, published details are hard to find.

The simulator tested here, the ImmersiveTouch-Sensimmer Virtual Phaco Trainer, differs from most others in relying entirely on virtual representations not only of the eye, but also of the surgical instruments. These are designed in virtual reality and appear as such in the surgeon’s view through a stereoscopic 3D microscope. The position of the virtual instruments is collocated with the position and angle of the stylus of the SensAble Technologies Phantom Omni haptic robot. Hence in Fig.
1, the realistic looking capsulorhexis forceps exists only in virtual reality, correlated with the physical reality of the stylus.

This version of the Phaco Trainer used for the present study is an advancement on the one described previously. The new lens tearing algorithm uses NVIDIA PhysX platform with position-based dynamics (PBD). Based on properties of PBD, a wrapper class is developed to implement an interactive, customizable and fully controllable tearing algorithm. Even this version of the Phaco Trainer, which was used for the experiments in 2010 and early 2011 reported below, is still a prototype. Recent developments have significantly improved the computational efficiency of the PhysX implementation, resulting in even greater realism of capsulorhexis.

Our experimental description begins with concurrent validity, which exists when the results of two different tests (e.g., virtual and live surgery) “concur” or “agree with” each other. Our test is a test of concurrent validity because the simulated and live surgery events are recorded at the same time or stage in the residents’ training; we are not proposing a training intervention of extensive simulator practice to show it will lead to better surgery performance in the future. “Concurrent validity” is therefore the “validity of a test or a measurement tool [i.e., the ImmersiveTouch simulator] that is established by simultaneously applying a previously validated tool or test [i.e., real surgery performance] to the same phenomenon [e.g., capsulorhexis] … and comparing the results.”

Experimental Study of Virtual and Live Capsulorhexis Performance Metrics

Purpose. To compare capsulorhexis performance metrics between the ImmersiveTouch phaco simulator and live surgery performed by PGY 4 ophthalmology residents.

Methods. The following three performance metrics were developed for both the virtual and the live capsulorhexis: 1) duration of the capsulorhexis procedure (in seconds); 2) number of capsular grabs per completed capsulorhexis; and 3) circularity of the capsulorhexis. Circularity index was defined as the average radius divided by the maximal radius in the capsulorhexis trajectory measured at 45 degree intervals. Twelve senior residents from 4 training programs, who had similar surgical experience between months 7 and 9 of their PGY 4 year, were recruited as participants. However, the effective number of residents was reduced to 8 since this group had sufficient simulator data and scorable surgery videos for duration and capsular grabs. Because rhexis circularity was most difficult to determine from the videos, only four residents with clear videos received scores for this metric. Capsulorhexis performance metrics were extracted from three video recordings of non-complicated cataract surgery cases from each resident; and during the same time frame on the simulator from these simulator-naive residents who were given brief simulator training prior to testing in 2 to 4 trials. The results were compared for the three performance metrics: 1) duration, 2) number of forceps grabs per completed rhexis; and 3) circularity of the capsulorhexis. Averages, standard deviations, and correlations using a two-sample t-test were calculated.

Results. The average time for all residents to complete the capsulorhexis was 96.91 ± 44.23 sec on the simulator and 94.42 ± 65.74 sec during surgery (N = 8). The mean number of forceps grabs on the simulator was 10.66 ± 4.81 and during surgery it was 10.31 ± 5.23 (N = 8). (See Figs. 2 and 3.) Standard deviations here are large, roughly half the mean value for forceps grabs and 70 percent of the mean for duration. Finally, the circularity index of the capsulorhexis on the simulator was 0.92 ± 0.04 and in surgery it was 0.88 ± 0.04 (N = 4; Fig. 4). Although the average values for duration of the capsulorhexis and the number of grabs were comparable between the groups in surgery and on the simulator, there were considerable performance differences between individual residents under the two test scenarios. Surgeons who showed the greatest variability in duration and capsular grabs in their 2 to 4 simulator trials appeared to show increased variability in these metrics in their 3 live surgery procedures. By the same token, residents that demonstrated less variability on the simulator showed reduced variability during the actual surgical procedures. For all residents with scorable surgery videos, there was a high correlation between the circularity index on the simulator and in surgery (P = 0.0002, N = 4) using a two-sample t-test, indicating that this metric possesses “concurrent validity.”

Conclusions. PGY4 residents who completed comparable numbers of surgical cases showed considerable variability during surgery in two metrics: duration of capsulorhexis and number of forceps grabs per completed rhexis. The capsulorhexis simulator was able to identify this variability. This indicated that the average performance measures of a group may be misleading and may not reflect surgical performance of an individual resident. The metric measuring the capsulorhexis circularity with the simulator correlated best with surgical performance suggesting that this metric possesses concurrent validity and may be useful in assessment of surgical performance in residents. Additional training tools and techniques are needed to try to reduce performance variability of residents-in-training.

Further Discussion of Figures and Study Designs

For circularity index the close correlation between simulator and surgery average scores is seen intuitively in Fig. 4, which also shows low variance of individuals from each other. However, Fig. 3 for number of forceps grabs illustrates another value of ImmersiveTouch scores, which is that they can predict the fact that residents will vary widely in live surgery grab numbers, even though the simulator does not always predict the direction of the variation. Hence three residents performed better on the
simulator, with fewer grabs than in surgery, while the remaining five performed worse, with more grabs (especially residents 5, 7, and 8). Nevertheless, the identification of forceps grabs as highly variable is realistic and gives the simulator “face validity.”

Total duration of the capsulorhexis varies even more than the number of forceps grabs, with much lower simulator performance times compared to live surgery for all residents except for nos. 3 and 7, and also no. 5, who took a little more time on the simulator. But the trend of longer surgery times with human patients is predictable, whereas rapid virtual surgery poses no risk to patients. Nevertheless, such rapidity need not be a bad thing: resident 1 had the lowest simulator time of all, but his or her simulator average grab number was also the lowest (i.e., best). And while this resident’s live procedures took much more time, he or she still used forceps grabs only slightly more often than those with the fewest grabs (residents 5, 7, 8).

Finally, a relevant study with EYESI may be reviewed for its experimental design. Feudner and colleagues describe theirs as “the first study in ophthalmologic surgery to evaluate the skill transfer of a well-defined technical task from VR to wet-lab after a training that required specific target criteria to be met.” Pig eyes were used in the wet lab. Participants at two experience levels, medical students and ophthalmology residents, were randomly assigned to an EYESI trained group or an untrained control group. Compared to their respective controls, VR-trained medical students and residents showed significant improvement in their median pig eye wet-lab capsulorhexis overall performance score (students +3.67 vs +0.33 points, \( P = 0.001 \); residents +3.33 vs ±0.00 points, \( P < 0.0001 \)). The capsulorhexis of VR-trained students and residents was also more consistent with a lower standard deviation compared to controls (students SD 1.3 vs 2.1 points; residents 1.2 vs 1.7 points).

The most important question raised by Feudner’s successful design is whether the randomized, controlled experimental model can be implemented safely when performing capsulorhexis on human patients. In our experiment to correlate scores on the simulator with scores on patients, our PGY 4 residents were not new to cataract surgery. It could be unethical to create a control group of inexperienced residents with little operating time or simulator or wet-lab training, and then compare their operating room scores with those of a simulator trained group. A way out of this dilemma could be to give all inexperienced residents extensive wet lab practice, in keeping with ACGME guidelines, before a baseline human capsulorhexis score is recorded. Subsequently, residents could be randomized to simulator trained and untrained groups, to test whether simulator training improves the capsulorhexis learning curve in live surgery.

As a more fully virtual simulator, ImmersiveTouch may have advantages over the less adjustable EYESI, such as the ability to vary lens capsule tissue properties or zonule strength (a constant based on the EYESI’s cardanic suspension). To the best of our knowledge, ours is the first study to use performance of an ophthalmological surgical procedure with patients as the standard for assessing simulator validity, in this case concurrent validity. Validating a training effect of simulator practice against a control group where both groups operate on patients could also be planned if circumstances warrant.

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**References**

Fig. 1. Experimental version of ImmersiveTouch capsulorhexis simulation showing virtual forceps (collocated with the SensAble haptic robot stylus), 3D stereoscopic eyepiece, and merging of stereoscopic images into one.

Fig. 2. Duration of capsulorhexis (in seconds) on the ImmersiveTouch simulator and in real surgery. (Participant identity shown on x-axis)

Fig. 3. Number of forceps grabs at the rhexis edge for a completed capsulorhexis on the ImmersiveTouch simulator and in real surgery (Participant identity shown on x-axis)

Fig. 4. Circularity or roundness of capsulorhexis (computed value) on the ImmersiveTouch simulator and in real surgery. (Participant identity shown on x-axis)