

# Journal of Contemporary Medical Education

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## Original Research

### High, low and mixed fidelity simulation for continuous curvilinear capsulorhexis in cataract surgery

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**Received:** November 03, 2012

**Accepted:** December 17, 2012

**Published Online:** December 31, 2012

**DOI:** 10.5455/jcme.20121217025539

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**Keywords:** *Computer simulation, cataract extraction education, medical "internship and residency" fidelity*

**ABSTRACT**

Simulation models for the continuous curvilinear capsulorhexis (CCC) can be thought of to differ in their fidelity, or the degree to which they accurately reflect *in vivo* surgery. Low and high fidelity simulations can differ in terms of efficacy and cost. The present investigation aims to determine if these two modalities can be combined to enhance overall learning. In this randomized controlled interventional trial, first year ophthalmology residents with no previous CCC experience (n=25) were randomized into one of three simulation groups: low, high, or mixed fidelity. Low fidelity simulation involved capsulorhexis practice on the skin of a grape in a self-directed manner. High fidelity simulation was on a 3D virtual reality (VR) unit in a scheduled manner. Mixed fidelity utilized both. Participants were tested on a cadaver model that was graded by a masked evaluator. Overall CCC performance was poor, as was self reported confidence. There was some improvement in process indices of performance by the high fidelity group. There was no difference between mixed and high fidelity groups on any outcome measure. Low fidelity simulation appeared less efficacious in the acquisition of skill, and did not enhance overall performance when done in conjunction with high fidelity simulation.

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## INTRODUCTION

The continuous curvilinear capsulorhexis (CCC) maneuver in cataract surgery is a good target for simulation learning in that it is a challenging task [1,2], that is difficult to master and has a significant effect on surgical outcome. In response, multiple models have been developed to simulate this surgical step. These models can be thought of to vary in terms of their fidelity, which is defined as the extent to which the simulation environment matches the real system that is being simulated [3]. Low fidelity simulations include the use of a grape [4] or tinfoil. They have the principle advantages of being inexpensive and easily accessible. However, their use as a training tool has not been formally evaluated.

High fidelity simulations utilizing biologic tissue such

as porcine [5] and human cadaver eyes [6,7] have also been described. These approaches simulate the physical aspects of the CCC more closely, however they have also not been formally evaluated and are considerably limited by the availability of tissue and equipment.

Virtual reality (VR) simulation is another high fidelity strategy. VR systems have the advantages of being suitable for multiple uses, not relying on a supply of tissue and requiring less human resources to manage. Empirical study has shown VR simulation to reasonably simulate the surgical environment [8] and to be effective in the learning the CCC [9]. However, these machines have substantial associated capital and maintenance costs, and are typically purchased a single

shared unit for a residency program, thus making access challenging across multiple trainees with busy clinical schedules.

In terms of relative efficacy, studies comparing low and high fidelity simulation have been conflicting. Some authors have found no difference between the two [10-12], while others have found that certain aspects of a manual task can be better learned on higher fidelity simulation [13]. However, none of these studies have investigated the interaction of these two modalities. With the principle advantage of low fidelity simulation being access and the main disadvantage of high fidelity being limits on access, it seems reasonable to consider combining these in to a single program.

The purpose of this study was to investigate the relative value of low and high fidelity simulation, and their interaction, for learning the CCC within the constraints of access and resources in a busy ophthalmology training program.

Our hypothesis is twofold. In the first we contend that high fidelity simulation will translate to greater performance on the CCC maneuver than low fidelity simulation. The second is that the practice of both high and low fidelity simulation will lead to greater improvement on the performance of the CCC than either alone.

## METHODS

### Protocol overview

Institutional approval for this study was obtained from the University of Toronto Research Ethics Board and all procedures were performed in accordance with the 1964 Declaration of Helsinki.

In this randomized single blinded interventional trial, ophthalmology residents (N=25) from multiple training programs with no previous CCC experience were randomized (1:1:1) in to one of three groups, low fidelity (N=9), high fidelity (N=8) or mixed fidelity (N=8).

After consent and randomization, subjects received introductory training sessions. All participants attended a didactic instructional session introducing the CCC maneuver. Additionally, brief explanatory sessions concerning the specific performance of his or her assigned simulation were provided for each subject. Details concerning these sessions can be found below.

Participants were surveyed at this study entry for previous ophthalmology training and surgical experience. Additionally, they were asked to describe their perceived confidence in being able to perform the CCC by marking a line on a ten centimeter a visual

analog scale.

For two weeks following these sessions, subjects performed their assigned simulations. This constituted the practice period. Low fidelity simulations were performed in a self-directed manner, while high fidelity simulation was organized into a structured schedule of practice opportunities. These are described in further detail below.

One week after the practice period, the participants were tested. Each performed a single trial of the capsulorhexis maneuver on a human cadaver model. This trial was graded by a blinded observer. Details of the assessment protocol are found below.

All participants were again surveyed prior to testing for perceived confidence utilizing the same visual analog scale as at study entry. Subjects also self-reported their total overall time spent on simulation during the practice period.

### Introductory Training Sessions

All groups attended a 20 minute introductory session in which the principles and instrumentation of performing the CCC maneuver were described. They also watched two short instructional videos. The videos demonstrated the performance of the capsulorhexis in a live surgical context and with the VR simulation machine respectively. Questions were answered and the opportunity to review the videos was provided via the internet for one week.

Each subject then attended a short supplemental training session based on group assignment. Those in the low fidelity group were provided a group instructional session on performing the grape simulation and had the opportunity to attempt the maneuver with supervision. They were also provided with a personal capsulorhexis forceps and a bunch of grapes for self directed practice.

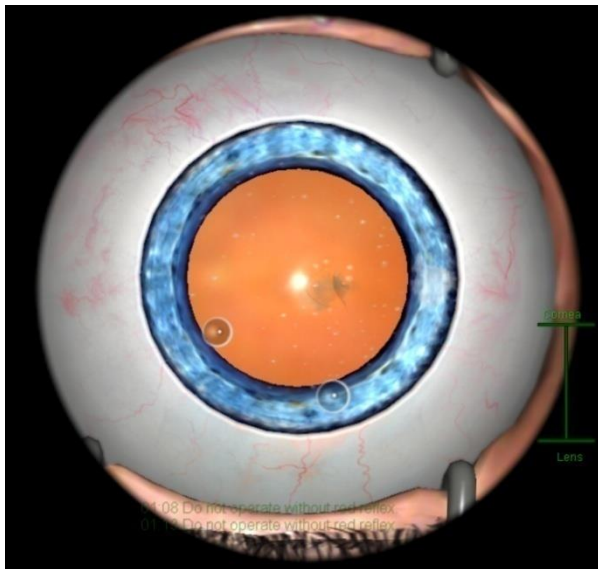
The high fidelity group each individually received a short instructional briefing on the use of the VR machine and the various controllers prior to their first VR simulation session. The mixed fidelity group received both of these supplementary sessions.

### Low fidelity simulation

Participants in the low fidelity group practiced the CCC utilizing the skin of a grape. The use of a *Vitus vinifera* grape to simulate the capsulorhexis maneuver has been described previously [4]. The utility of this model is based on the physical similarities between the tensile strength of this grape and the human anterior lens capsule [4]. There have been no formal evaluations of this simulation method for learning the CCC.

### High Fidelity simulation

Subjects in the high fidelity groups trained on the EYESi VR machine (VRmagic: Mannheim, Ger). This platform is intended to physically simulate many key aspects of intraocular surgery. The student sits at the head of the bed and works on a life like head and eye model. Instruments are inserted in to the eye and real movements are translated in to virtual space dynamically. The microscope functions allow for changes in zoom and focus as the student works and the modeled properties of the capsulorhexis allow for complications such as running out, as well as salvage maneuvers to save the capsulorhexis in progress. A student's view of the capsulorhexis module can be found in Figure 1.



**Figure 1.** Student's view of the capsulorhexis module with the EYESi VR machine (VRmagic: Mannheim, Ger).

Performance metrics, part of the simulator, have been previously validated by differentiating between novice and experienced surgeons [14], demonstrating improvement in performance with practice [15] and showing skill transfer from the VR environment to the a porcine wet lab model [9]. The participants utilized the capsulorhexis module.

### Practice Schedule

The trainees in the low fidelity group utilized a *Vitis vinifera* grape simulation [4]. In order to enhance access to the simulation, each participant was given the grapes and a personal capsulorhexis forceps in order to practice in a self-directed manner. As noted, these subjects attended the introductory session and were subsequently instructed on the use of the grape simulation. Subjects were instructed to train in preparation for testing session to be held three weeks subsequently.

The trainees in the high fidelity group trained on the EYESi VR machine (VRmagic: Mannheim, Ger). After the instruction sessions outlined above, participants were provided opportunity to practice the capsulorhexis maneuver in the virtual environment during two unsupervised 20-minute sessions. Internal EYESi performance metrics were provided to at the end of each VR capsulorhexis trial. In order to approximate limits on access, only two sessions were offered per subject and each was scheduled based on a timetable working around clinical/educational duties.

Trainees in the mixed fidelity group utilized both simulations. These subjects received pre-simulation instruction in the same manner as the other groups. They utilized the high fidelity model as the high fidelity group, and the low fidelity model as the low fidelity group.

### Assessments

A single, masked expert observer assessed the performances on the cadaver model. The assessment instrument was an amalgamation and modification of multiple evaluation tools found in the published literature [16-18]. Modifications were made to focus on three aspects of the CCC: process (opening, starting, grasping and moving), product (size, shape, centration and complications) and global performance (treatment of structures, flow, microscope use, instruments and use of non-dominant hand).

The two task scales were utilized to emphasize procedure focused learning and improve observer objectivity [19]. Process and product were evaluated separately, as these measures have been shown to differentiate learners trained on systems of varying fidelity [13]. The global scale was based on a validated and published measure for ophthalmic microsurgery [20], and represents a generalized assessment of basic intraocular skills.

Subjects were given the opportunity to self-determine if they have completed the cadaver trial, whether they have accomplished the goal of a complete capsulorhexis or not. There was also a time limit of 30 minutes, after which the trial was considered to be complete.

### Analysis

Analysis was performed utilizing SPSS version 18.0 for mac. Repeated measures analyses of variance (ANOVA) was performed on confidence scores for a main effect of time and between subjects effect of group assignment. A series of independent one-way ANOVAs with a single factor (3 groups) were performed for cadaver scores respectively (process,

product and global). All significant ANOVA effects were compared with Tukey’s post hoc test.

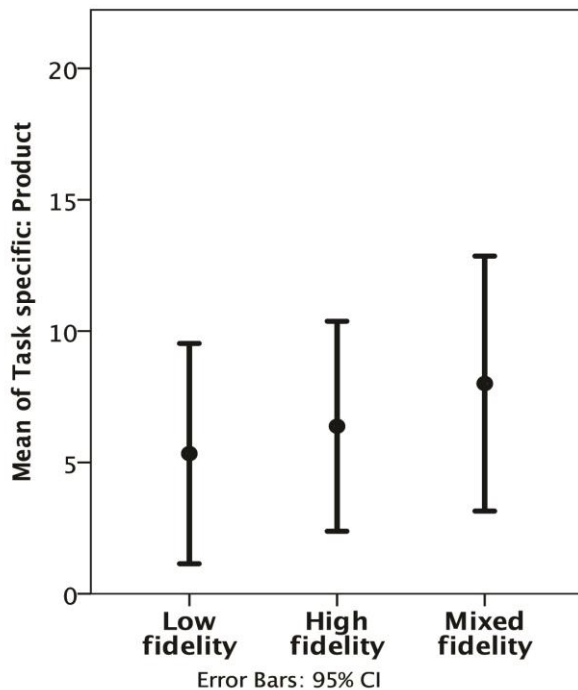
**RESULTS**

Mean age was 28 years with 13 females and 12 males. None had any previous experience performing a capsulorhexis on a live person. There were no differences between the groups in age, sex or previous surgical experience. Baseline characteristics can be found in Table 1.

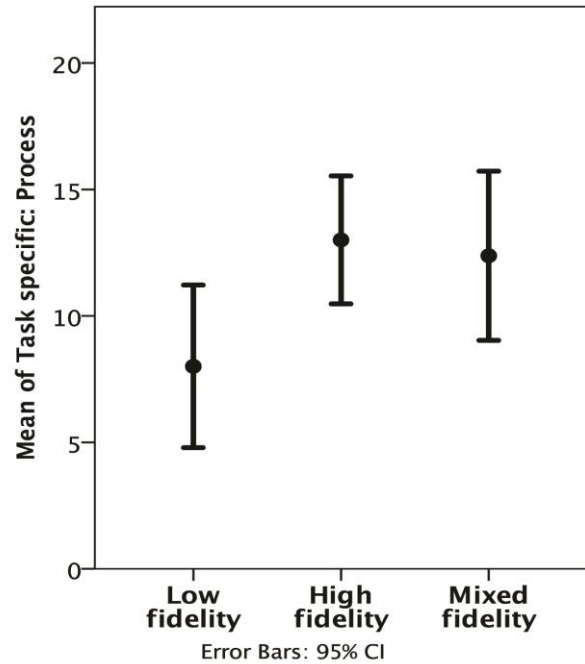
*Total simulation time:* There was a significant between group difference for total time spent on simulation ( $p < 0.05$ ). Post hoc testing revealed that the mixed fidelity group had significantly ( $p < 0.05$ ) greater overall

**Table 1.** Baseline group characteristics.

|  | Low fidelity | High fidelity | Mixed fidelity | p-value    |
|--|--------------|---------------|----------------|------------|
| Age [mean(SD)]                                       | 27.4 (1.7)   | 27.7 (1.8)    | 29 (3.1)       | $p = 0.43$ |
| Male : Female [n]                                    | 5:4          | 4:4           | 3:5            | $p = 0.66$ |
| Years of previous ophthalmology training [n]         | 0            | 2             | 1              | $p = 0.18$ |
| Number of <i>in vivo</i> capsulorhexis performed [n] | 0            | 0             | 0              | $p = 1.00$ |



**Figure 2.** Mean (95% CI) cadaver task product score for each fidelity group.



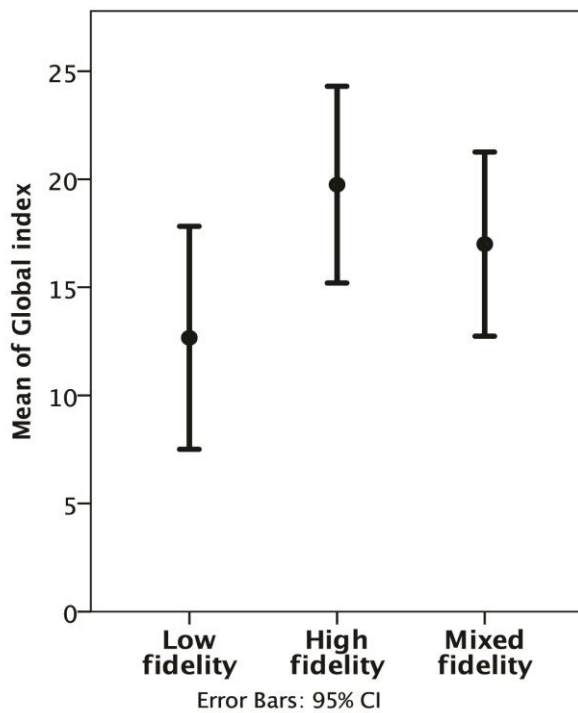
**Figure 3.** Mean (95% CI) cadaver task process score for each fidelity group.

Low and high fidelity groups did not significantly differ in total practice time ( $p = 0.88$ ).

*Confidence:* Overall confidence at entry was low, with a mean (SD) visual analog score of 0.83 (1.98) and 1.94 (2.1) out of a possible 10 for a live and simulated patient respectively. Confidence in a simulated environment did not improve significantly from the pre to post simulation ( $p = 0.122$ ), and there was no difference noted between groups ( $p = 0.938$ ). The same was true for *in vivo* surgery, overall ( $p = 1.61$ ) and between groups ( $p = 0.852$ ).

*Performance on cadaveric model:* No subject was able to successfully complete the capsulorhexis on the cadaver model. Product scale scores were expectedly low, with an overall average (SD) of 6.5 (5.2), or 21.2%. There was no difference based on group assignment ( $p = 0.598$ ) (Figure 2).

Subjects performed the process of creating a CCC with slightly greater aptitude overall. The overall mean (SD) for this scale was 11.0 (4.3), or 27.5%. There was also a significant effect of group assignment ( $p < 0.05$ ) (Figure 3). Post hoc analyses demonstrated that process scales were significantly higher for participants in the high fidelity group (32.5%) than those in the low fidelity group (20.0%) ( $p < 0.05$ ). There were no significant differences between the high and mixed fidelity groups ( $p = 0.942$ ). Global indices of performance did not significantly differ between the three groups ( $p = 0.60$ ) (Figure 4). These results are summarized in Table 2.



**Figure 4.** Mean (95% CI) cadaver global performance score for each fidelity group.

**DISCUSSION**

The CCC maneuver is often considered the most difficult and complex part of cataract surgery [1,2]. We found this to be true in simulation as well, with participants achieving an overall task product score of only 21% on a cadaver model and with no single successful completion of the task. Low overall confidence further reflected the participants’ accurate self-evaluation. It appears as though the type and duration of simulation practice utilized in this protocol was insufficient to effectively learn the capsulorhexis maneuver. This further points the complexity and difficulty involved in developing intraocular surgical skills. The addition of increased access to low fidelity simulation, despite increased overall simulation time in this group, was not effective in bridging this gap. It is likely that there are other critical elements of a simulation program that are important in skill acquisition, which cannot be filled in with increased access to a lower fidelity model.

These elements may include proficiency based training [21], structured progression [22] and expert feedback [23], all of which can improve performance and enhance the overall efficiency of a simulation curriculum. A program lacking in these elements, such as the one deliberately designed for this protocol, may put learners at significant disadvantage. Further investigation will be required to determine the relative contribution to learning efficacy for each these

**Table 2.** Performance scores for low, high and mixed fidelity groups.

|                          | Low fidelity | High fidelity | Mixed fidelity | p-value        |
|--------------------------|--------------|---------------|----------------|----------------|
| Process index (score/40) | 8.00 (4.18)  | 12.38 (4.00)  | 13.00 (3.02)   | F=4.46, p<0.05 |
| Product index (score/30) | 5.33 (5.45)  | 8.00 (5.81)   | 6.38 (4.78)    | F=0.52, p<0.60 |
| Global index (score/50)  | 12.67 (6.71) | 17.00 (5.10)  | 19.75 (5.44)   | F=3.19, p<0.07 |

elements and/or if simply greater access to VR simulation may have been effective alone. When dissecting the individual components of performance (process, product and global elements), process markers of performance appeared to be most sensitive to learning with the VR device. This tends to agree with the results presented by Sidfhu et al [13], who found that for trainees with minimal or no surgical experience, high fidelity simulation improved scores on procedural checklist markers of performance. They also similarly found that global markers were not sensitive to the fidelity of the training simulation.

A few limitations of our study should be noted. Initially, the sample size is restively small. However, with around 30 trainees starting ophthalmology residents in Canada each year, 25 persons is relatively good participation over all. We also did not include interactive feedback and stepwise progression in the simulation protocols. These elements are important in designing a simulation curriculum, however we were attempting to replicate the practical limitations on simulation programming faced by many residency programs. Additionally, the total simulation time values were based on self-report. Although there was little incentive to misrepresent practice time, possible biases may exist in this data.

We found high fidelity simulation to be superior to low fidelity training in enhancing process markers of performing the CCC maneuver in cadavers. The addition of increased access to a complementary low fidelity model did not significantly affect learning. From this result we conclude that in a complex microsurgical task such as the CCC, inexperienced surgical trainees may require some combination of increased access to high fidelity simulation and/or other simulation program enhancements such as feedback and goal setting in order to effectively learn the CCC maneuver.

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