A Prospective, Randomized, Blinded Trial Comparing Digital Simulation to Textbook for Cleft Surgery Education

Natalie M. Plana, B.A.
William J. Rifkin, B.A.
Rami S. Kantar, M.D.
Joshua A. David, B.S.
Samantha G. Maliha, B.A.
Scott J. Farber, M.D.
David A. Staffenberg, M.D.
Barry H. Grayson, D.D.S.
J. Rodrigo Diaz-Siso, M.D.
Roberto L. Flores, M.D.

New York, N.Y.

Background: Simulation is progressively being integrated into surgical training; however, its utility in plastic surgery has not been well described. The authors present a prospective, randomized, blinded trial comparing digital simulation to a surgical textbook for conceptualization of cleft lip repair.

Methods: Thirty-five medical students were randomized to learning cleft repair using a simulator or a textbook. Participants outlined markings for a standard cleft lip repair before (preintervention) and after (postintervention) 20 minutes of studying their respective resource. Two expert reviewers blindly graded markings according to a 10-point scale, on two separate occasions. Intrarater and interrater reliability were calculated using intraclass correlation coefficients. Paired and independent t tests were performed to compare scoring between study groups. A validated student satisfaction survey was administered to assess the two resources separately.

Results: Intrarater grading reliability was excellent for both raters for preintervention and postintervention grading (rater 1, intraclass correlation coefficient = 0.94 and 0.95, respectively; rater 2, intraclass correlation coefficient = 0.60 and 0.92, respectively; $p < 0.001$). Mean preintervention performances for both groups were comparable (0.82 ± 1.17 versus 0.64 ± 0.95; $p = 0.31$). Significant improvement from preintervention to postintervention performance was observed in the textbook (0.82 ± 1.17 versus 3.50 ± 1.62; $p < 0.001$) and simulator (0.64 ± 0.95 versus 6.44 ± 2.03; $p < 0.001$) groups. However, the simulator group demonstrated a significantly greater improvement (5.81 ± 2.01 versus 2.68 ± 1.49; $p < 0.001$). Participants reported the simulator to be more effective ($p < 0.001$) and a clearer tool ($p < 0.001$), that allowed better learning ($p < 0.001$) than textbooks. All participants would recommend the simulator to others.

Conclusion: The authors present evidence from a prospective, randomized, blinded trial supporting online digital simulation as a superior educational resource for novice learners, compared with traditional textbooks. (*Plast. Reconstr. Surg.* 143: 202, 2019.)

The traditional Halstedian surgery training model is increasingly challenged by restrictive hospital and educational policies that limit patient interaction, decrease independent decision-making, and increase time spent performing documentation.[1] As a result, contemporary trainees must assimilate increasingly complex surgical procedures more efficiently and independently to maximize the limited operative time afforded to them. Surgical training programs are thus increasingly relying on simulated surgical patients and environments to better prepare residents for the operating room experience.

From the Hansjörg Wyss Department of Plastic Surgery, New York University Langone Health.
Received for publication January 26, 2018; accepted May 30, 2018.

DOI: 10.1097/PRS.0000000000005093

Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*

Supplemental digital content is available for this article. Direct URL citations appear in the text; simply type the URL address into any Web browser to access this content. Clickable links to the material are provided in the HTML text of this article on the *Journal*'s website (www.PRSJournal.com).

The successful application of simulators to aviation training served as a model to the incorporation of simulation across medical schools and residency programs.[2] Early application of medical simulators used mannequins for team and basic procedural training,[3] but it was simulation of laparoscopic surgery that put this teaching modality on the map for surgical education.[4] Today, technological advancements permit incorporation of a digital component to further enhance the simulation experience, more closely mimicking surgical reality. Digital educational tools, including simulations, have been increasingly used by surgical trainees, and their reliance on textbooks continues to decrease.[5] In addition to easy access, computerized illustrations and online videos provide the three-dimensional anatomical detail that is difficult to capture in print.

Digital simulation is becoming more commonplace in plastic surgery clinical practice,[6] allowing the specialty to integrate and study computerized techniques as part of residency education. Although digital simulation is a potentially positive educational adjunct, rigorous studies validating its utility are lacking. McGaghie et al. discovered that less than 1 percent of reports on medical education and simulation directly compare simulation-based and traditional teaching approaches for medical learners.[7] Furthermore, compared with other surgical subspecialties, plastic surgery lags in reporting high-level evidence in support of simulation for training.[8] This lack of evidence-based support may explain the continued skepticism by faculty members regarding the utility of these educational resources.[9] However, the field of surgical simulation has developed impressive models across a wide breadth of procedures, and these training modalities have been progressively embraced, particularly among microsurgery fellowship directors.[10] For digital simulation to earn a valued space in plastic surgery education, more scientific assessment of the efficacy of simulation in knowledge and skills acquisition will be required. We present a prospective, randomized, blinded trial comparing digital simulation and a textbook using novice learners at their first exposure to surgical markings of cleft lip repair.

METHODS

Development of the Virtual Surgical Simulator

A three-armed collaboration among plastic surgeons, a philanthropic organization (Smile Train), and a biotechnology company (BioDigital, Inc., New York, N.Y.) resulted in development of an online, virtual simulator for cleft surgery.[11–13] Three-dimensional digital simulations were designed to illustrate the complex anatomy (both normal and abnormal) and the detailed surgical markings and techniques involved in cleft lip and palate repair (Fig. 1). The simulations are built on an interactive interface whereby the user can manipulate structures for better understanding of anatomical relationships, accompanied by

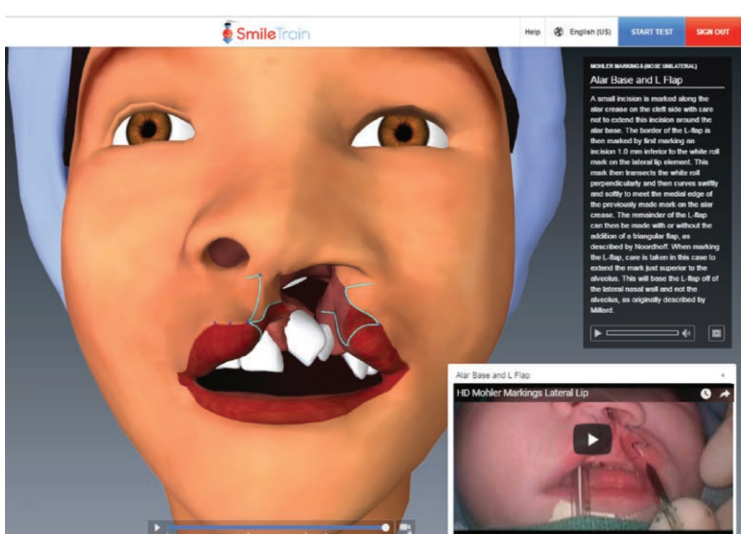

Fig. 1. Snapshot of the Smile Train Virtual Surgical Simulator. A digital animation of the unilateral cleft lip module with surgical markings outlined is shown. The intraoperative video appears minimized (*inset*). On the *right* are text descriptions that reflect voiceover content.

descriptive voiceover. Modules of surgical techniques are also supplemented by intraoperative videos displaying critical steps of the procedure described. All content was created by craniofacial surgeons with active practices in cleft lip and palate care. The simulator is entirely Web-based and freely accessible on Google Chrome or Mozilla Firefox at www.cleftsim.com.

Clinical Study

After obtaining institutional review board approval, first-year medical student volunteers ($n = 35$) were recruited for participation through mass e-mail. This study population was selected to represent "novice learners," as they had a working knowledge of anatomy and physiology but had not been previously exposed to the operating room environment, cleft care, or the content being studied.[14] Each participant gave consent and was assigned a unique study number. The study design is outlined in Figure 2.

Participants were presented with a standardized patient photograph of a complete unilateral cleft lip deformity and given 10 minutes to draw the markings for surgical repair (preintervention markings). (**See Figure, Supplemental Digital Content 1**, which shows a standardized patient photograph capturing a complete unilateral cleft lip deformity, ***http://links.lww.com/PRS/D193***.) They were then assigned randomly to one of two study arms (textbook group and digital simulation group), indicating the educational resource assigned for intervention. The digital simulation group participants ($n = 18$) were provided individual computers with access to the virtual surgical simulator, demonstrating the markings for the extended Mohler unilateral cleft lip repair. The textbook group participants ($n = 17$) were provided a textbook chapter[15] describing the detailed markings for the same cleft lip repair technique. All participants were given 20 minutes to review their respective educational resources. No assistance or further instruction was provided to any participants. On completion of the review period, each participant was given a blank patient photograph identical to that provided at the start of the study, and allotted 10 minutes to once again draw the surgical markings for a complete unilateral cleft lip repair (postintervention markings).

After completion of the postintervention markings, participants were exposed to the educational resource provided to the other group (i.e., participants in the textbook group explored the digital simulation, and those in the digital simulation group read through the textbook chapter).

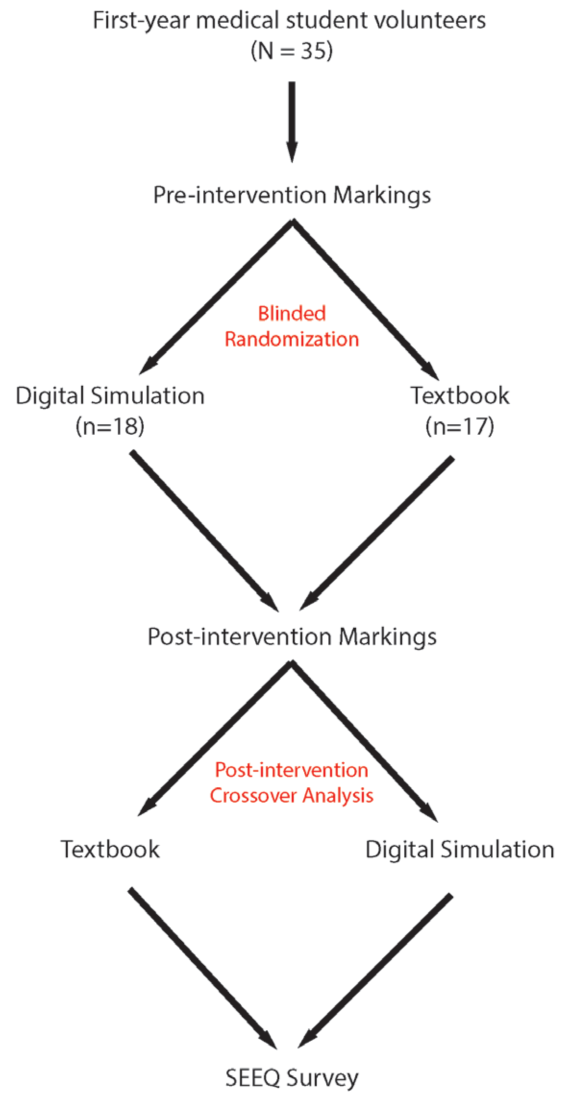

Fig. 2. Study design. Thirty-five medical students were recruited and asked to perform markings for a complete unilateral cleft lip deformity before any educational intervention; this are referred to as preintervention markings. Participants were randomized to two study arms (digital simulation and textbook), indicating the educational resource they would study. After reviewing either the simulation or textbook material, participants were again asked to draw the markings for a cleft lip repair on a blank photograph identical to that presented to them at the start of the study; these are referred to as postintervention markings. Participants were subsequently shown the learning material given to the group to which they were not assigned. Finally, volunteers were given modified versions of the Student Evaluation of Educational Quality (*SEEQ*) survey.

A modified survey was then administered to all participants based on the Student Evaluation of Educational Quality survey, a validated tool for measuring higher education student satisfaction. [**See Figure, Supplemental Digital Content 2**, which shows the volunteer educational assessment form, the Student Evaluation of Educational Quality survey administered to all participants in the postintervention crossover analysis. Surveys explored the (*left*) digital simulation and (*right*) surgical text resources independently from one another, ***http://links.lww.com/PRS/D194***.] Each participant completed the survey for both digital simulation and the textbook such that each resource could be evaluated independently.

Preintervention and postintervention markings were graded in a blinded fashion by two craniofacial surgeons (R.L.F. and S.J.F) on two separate occasions. Neither the assigned group nor the preintervention or postintervention status of the markings was revealed to the graders. Preintervention and postintervention markings were graded according to a 10-point scale developed by the senior authors (D.A.S. and R.L.F.) based on the following criteria:

1. Cupid's bow points marked.
2. Cupid's bow points marked correctly.
3. Back-cut marked on medial lip element, which would result in downward rotation of Cupid's bow.
4. Height of back-cut on the columella and in an appropriate position.
5. Base of back-cut on the superior border of the philtral line on the noncleft side.
6. M-flap/C-flap border drawn correctly along the mucosa/skin border.
7. Medial border of M-flap drawn correctly.
8. Horizontal line from medial border of the lateral lip to the alar base along the border of the upper lip with the nostril floor.
9. Lateral border of L-flap correctly drawn on the lateral lip.
10. Inferior border of L-flap correctly drawn on the vermillion.

Statistical Analysis

Intrarater and interrater reliability of the graders was evaluated using intraclass correlation coefficients. Paired and independent t tests were used to compare differences in preintervention and postintervention marking scores and survey responses for each group. A power analysis was performed to certify that the sample size was adequately powered for statistical comparison. Statistical significance was defined as $p < 0.05$.

RESULTS

Preintervention and postintervention markings for all participants in both study groups are superimposed as four separate images in Figure 3, and individual student markings for both groups are illustrated. [**See Figure, Supplemental Digital Content 3**, which shows samples of student markings from (*above*) the textbook group and (*below*) the digital simulation group before studying their respective educational resources, ***http://links.lww.com/PRS/D195***.] Mean preintervention scores between the two study groups were comparable (0.57 ± 0.69 versus 0.44 ± 0.61; $p = 0.56$). Mean postintervention scores for all participants in the study significantly improved relative to their pretest performance (4.19 ± 2.24 versus 0.51 ± 0.65; $p < 0.001$). However, the digital simulation group demonstrated a significantly greater improvement (5.17 ± 1.86) compared with the textbook group (2.11 ± 1.27; $p < 0.001$).

Rater 1's intrarater reliability was determined to be excellent for both the preintervention (intraclass correlation coefficient = 0.94; $p < 0.001$) and postintervention (intraclass correlation coefficient = 0.95; $p < 0.001$) grading. Rater 2's intrarater reliability for the preintervention grading (intraclass correlation coefficient = 0.60; $p < 0.01$) was good, and the postintervention grading (intraclass correlation coefficient = 0.92; $p < 0.001$) was stronger. Interrater reliability was excellent for both preintervention (intraclass correlation coefficient = 0.78; $p < 0.001$) and postintervention (intraclass correlation coefficient = 0.96; $p < 0.001$) grading.

Student survey results significantly favored the simulator compared with the textbook (Fig. 4). Participants reported that when compared to the textbook, digital simulation was more stimulating (3.74 ± 0.98 versus 1.69 ± 0.87; $p < 0.001$), increased their interest in the subject (3.91 ± 1.01 versus 2.31 ± 1.21; $p < 0.001$), allowed better learning of the subject matter (3.83 ± 0.95 versus 2.17 ± 1.2; $p < 0.001$), had greater clarity (3.66 ± 1.08 versus 2.17 ± 1.22; $p < 0.001$), and was a more effective means of teaching surgical skills (4.14 ± 0.94 versus 2.31 ± 1.21; $p < 0.001$). Participants were more likely to recommend the digital simulation resource (4 ± 1.11) over the textbook (2.14 ± 1.19) ($p < 0.001$).

DISCUSSION

Technological advancements in simulation have revolutionized the trainee's approach to surgical scenarios and have simultaneously mitigated challenges of modern medical education.[2] Our group has previously underscored the potential of simulation in plastic surgery education and

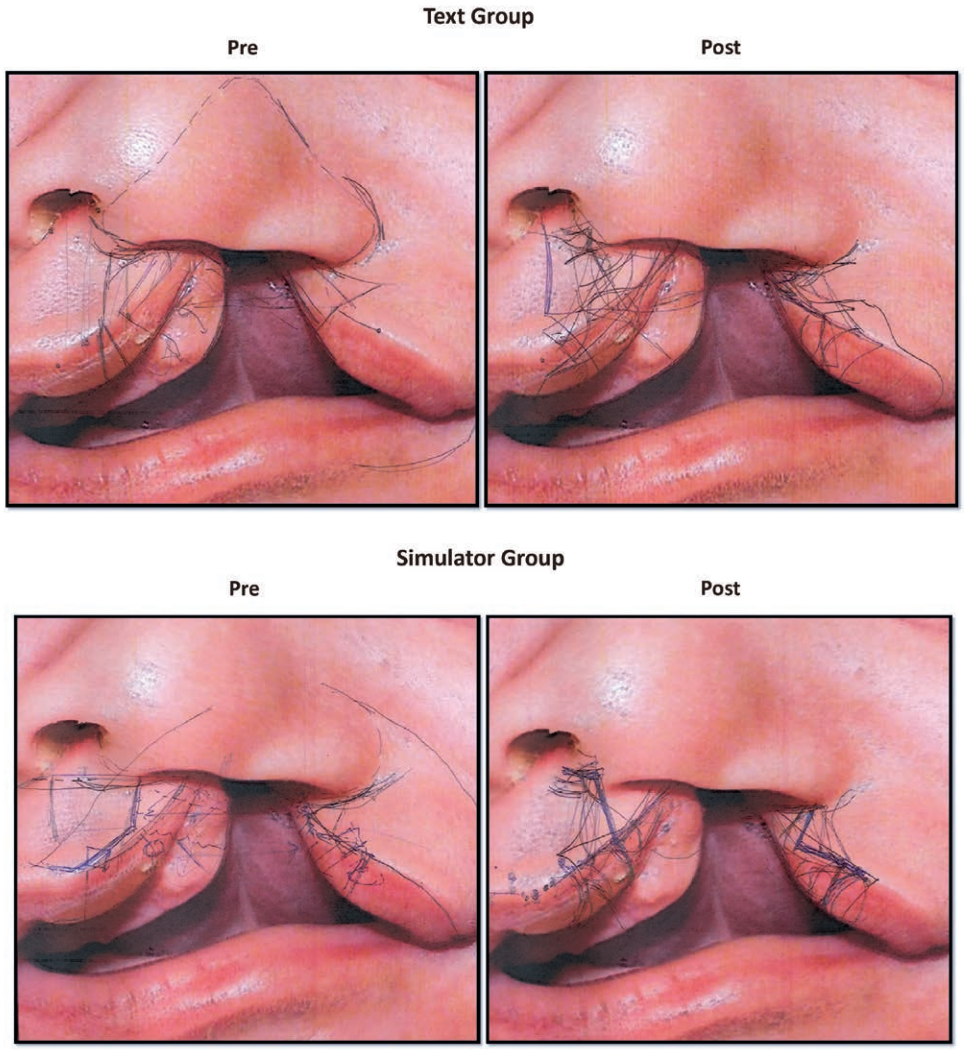

Fig. 3. Overlay of participant markings. All preintervention and postintervention markings for (*above*) the textbook group and (*below*) the digital simulation group were superimposed to generate a single image for the purpose of illustration during publication. Adobe Photoshop (Adobe Systems, Inc., San Jose, Calif.) was used to create the overlays, but each marking was performed and rated separately. Preintervention markings are largely inconsistent between participants and veer far from the correct markings for cleft lip repair. Postintervention markings in the textbook group appear less consistent and more chaotic, whereas those for the digital simulation group appear both more accurate and more precise.

proposed an integrative training scheme with graded stages of learning, to which simulation can be applied.[11] We now present the results of a prospective, randomized, blinded study demonstrating the superiority of computerized simulation as a resource for teaching novice learners the tenets of surgical markings for cleft lip repair.

Subsets of general surgery have fully embraced the benefits of simulation and have scientifically established that exposure to, repeated use of, and standardized evaluation using simulated procedures are effective means of training residents.[16–19] Similar evidence specific to plastic surgery training is scarce,[12] a likely limit to the more formalized incorporation of simulated training seen in other surgical specialties. A variety of simulators have been described for developing or enhancing surgical skill,[20–22] with few primarily aiming to improve skills and procedural understanding.[23–27] Moreover, actual validation in trainees appears to be a common goal for future studies.[28] Existing data are primarily limited to participant feedback regarding realism and confidence levels, surveys testing theoretical knowledge, and subjective

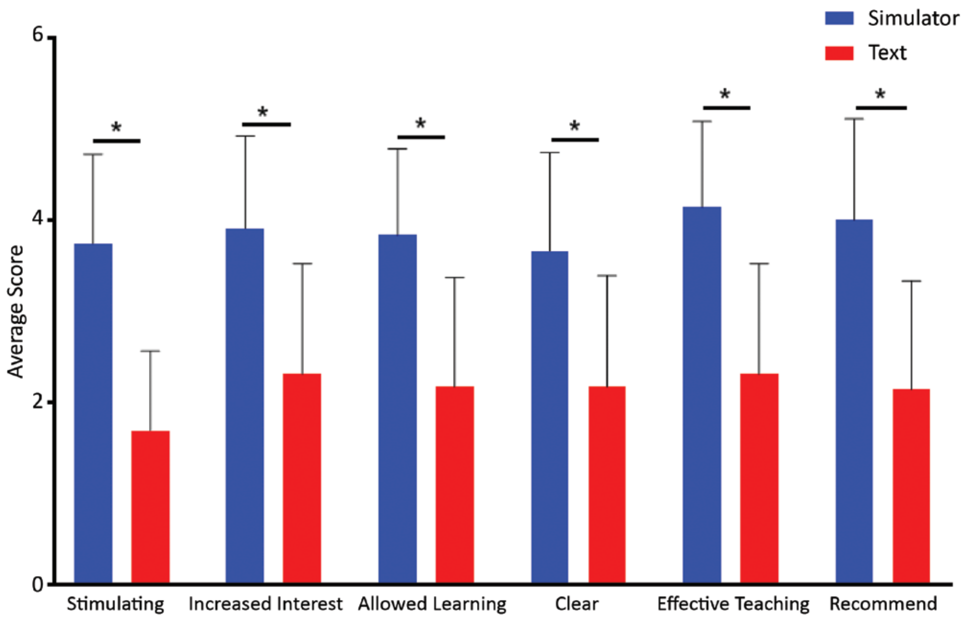

Fig. 4. Survey results. Participant feedback toward the digital simulator and textbook material as educational resources.

evaluation by study members,[8,29–31] all of which are legitimate but not rigorous tools for concluding on the effectiveness of a simulator as an educational resource.[32] Thus, the present study represents one of the first in the specialty to affirm that simulation-based education significantly improves conceptualization of surgical principles compared with conventional resources.

Education of cleft and craniofacial procedures is particularly challenging because of the sensitive nature of the patient population being served and the complexity of the anatomy and techniques involved. Unsurprisingly, educators and trainees consistently assign high educational value to the sophisticated models simulating these operations.[14,33] The present study goes one step further, and objectively compares digital simulation to the traditional teaching resource for the procedure tested, through a prospective, randomized, blinded trial. An equivalent baseline of knowledge and understanding of markings for cleft lip repair was achieved between participants of both study arms, indicated by comparable preintervention scores between them. Moreover, both teaching modalities proved to be effective teaching methods, as all participants' scores improved after exposure to each study material. The chosen text is considered by many to be the gold standard modern resource from which to learn the studied exercise. The assigned book chapter describes cleft markings in great detail and provides illustrations of the proper marking to the reader. However, digital simulation proved to be a superior resource, as participants learning from this platform significantly outperformed those learning from textbook material by 43 percent during postintervention testing. This improvement is greater than the increase in knowledge transfer observed in other studies that did not compare findings to a negative control.[33] It is important to note that this study evaluated teaching of novice learners who had little to no exposure to cleft anatomy before participation in the study. Nevertheless, the degree of improvement reached by learners at this level with only 20 minutes of study time further supports the educational potential of this digital simulator in teaching surgical residents and fellows the complexities of cleft repair.

Although textbook chapters and journal publications have been the longstanding references for surgical learning outside the operating room, our results support the belief that digital simulation is not only a viable alternative but also an improvement to existing surgical curricula. This notion is further supported by participants' reported preference for digital simulation over textbook learning. However, digital simulation should be intended not to *replace* but to *complement* traditional teaching modalities, enhancing the learning experience so that it may be tailored to the modern trainee.

Integral to the study design was development of an objective and reproducible evaluation tool to grade participant performance. Across the specialty, the need for a systematic, standardized assessment of competency in procedures persists[19] and can be one of the barriers that might explain the lack of high-level evidence reported for simulation training. This allowed an opportunity to generate an assessment specific to comprehension of the cleft lip markings presented in the simulator. A task-based checklist format was adopted from validated instruments that are currently used by other surgical specialties; these primarily function on a binary scoring system accumulating points as specific tasks are completed.[34] Those tasks were determined by experienced cleft surgeons and guided by steps reviewed during plastic surgery oral board examinations. It should be noted that this grading scale has not been validated and as of the time of this writing, there is not a validated grading scale from cleft lip markings. In the future, operative checklists such as the one used in this study can certainly be validated and serve as the first step toward standardized evaluation for widespread training in cleft surgery. The strong interrater and intrarater reliability testing of the instrument developed supports its accuracy and potential for broader use.

This is the first prospective, randomized, blinded trial in simulation training in cleft care. We demonstrate statistically significant improvement in cleft lip repair markings as performed by novice learners who underwent training using digital simulation compared to a textbook. As a student-based trial, a limitation of this study is the recruitment of novice learners to evaluate conceptualization of surgical content that is typically reserved for midlevel to senior residents. Although it is certainly encouraging that participant performance increased significantly on exposure to their respective resources, it may not directly correlate to the level of improvement observed from more experienced trainees. In particular, participants learning from the textbook may have demonstrated greater improvement with multiple resources or additional study time allotted. Furthermore, the quantified improvement in surgical markings cannot be correlated into clinical performance at this time. Evaluation of the role that digital simulation may have in education of higher level trainees is an aim of future studies. Another important consideration is the learning stage that this multimedia simulator intends to enhance. Focus is directed on procedural cognition and even association, as we have described,[11] not the technical skills necessary to carry out the steps. Impressive virtual simulators using haptic feedback to quantitatively assess performance during cleft lip markings have been described[35] but lack the reproducibility required to disseminate such evaluation on a larger scale. Future areas of study include testing trainee performance on more realistic and dynamic cleft models to assess both skills and procedural phases of learning.

CONCLUSIONS

A prospective, randomized, blinded trial comparing digital simulation and a textbook using novice learners at their first exposure to surgical markings of cleft lip repair demonstrates superior knowledge acquisition through digital simulation training. Participants subjectively report that training through digital simulation is more clear, more effective, and allowed for better learning.

Roberto L. Flores, M.D.
Hansjörg Wyss Department of Plastic Surgery
New York University Langone Health
307 East 33rd Street
New York, N.Y. 10016
roberto.flores2@nyumc.org

ACKNOWLEDGMENT

The simulator used in this study was created and is maintained through the generous support of Smile Train.

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