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Simulation in Cleft Surgery

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Background: A number of digital and haptic simulators have been developed to address challenges facing cleft surgery education. However, to date, a comprehensive review of available simulators has yet to be performed. Our goal is to appraise cleft surgery simulators that have been described to date, their role within a simulation-based educational strategy, the costs associated with their use, and data supporting or refuting their utility.

Methods: The following PubMed literature search strategies were used: "Cleft AND Simulation," "Cleft Surgery AND Simulation," "Cleft Lip AND Simulation," "Cleft Palate AND Simulation." Only English language articles up to May 1, 2019, were included. Simulation phases of learning were classified based on our previously proposed model for simulation training.

Results: A total of 22 articles were included in this study. Within identified articles, 11 (50%) were strictly descriptive of simulator features, whereas the remaining 11 (50%) evaluated specific outcomes pertinent to the use of cleft surgery simulators. The 22 included articles described 16 cleft surgery simulators. Out of these 16 cleft surgery simulators, 7 (43.8%) were high fidelity haptic simulators, 5 (31.2%) were low fidelity haptic simulators, and 4 (25.0%) were digital simulators. The cost to simulator user ranged from freely available up to $300.

Conclusions: Cleft surgery simulators vary considerably in their features, purpose, cost, availability, and scientific evidence in support of their use. Future multi-institutional collaborative initiatives should focus on demonstrating the efficacy of current cleft simulators and developing standardized assessment scales. *(Plast Reconstr Surg Glob Open 2019;7:e2438; doi: 10.1097/GOX.0000000000002438; Published online 26 September 2019.)*

INTRODUCTION

Traditional models of surgical training have relied on extensive operative exposure and an apprenticeship model of gradual responsibility.[1] In the current academic landscape, resident surgical education is challenged by strict work-hour limitations, growing nonclinical duties, increasing resident supervision, and patient requests to limit resident participation in their care.[2] In light of the impact of these factors on resident operative exposure and progression to surgical autonomy, training programs and leaders in surgical education have extensively evaluated resources to supplement surgical residency training, and ensure that trainees graduate as competent, safe, independent surgeons.[2,3] As a result, simulation-based educational tools and platforms have materialized as potential solutions to address current challenges facing resident surgical education. Moreover, simulation-based training has become an essential component of the residency curriculum in general surgery through fundamentals of laparoscopic surgery and fundamentals of endoscopic surgery training, with similar initiatives in other surgical specialties.[3–5]

Although animal and cadaveric models allow surgical trainees to practice surgical procedures in a high fidelity environment, they are often associated with significant costs and may not be readily accessible.[6] These limitations are further compounded by the restricted educational time that is available to surgical residents, making readily available educational tools such as hands-on mannequins and digital simulators more attractive for procedural learning. These trends in surgical education have not spared plastic and reconstructive surgery training, which has resulted in growing emphasis placed on simulation for resident education.[6] Simulation-based educational opportunities in plastic and reconstructive surgery have ranged from hands-on experiences to computer-aided 3-dimen-

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sional simulators, and have generally been well received by trainees and practicing surgeons.[6–10]

Clefts of the lip and/or palate affect 1 in every 500–700 live births with a variable global incidence and lead to an increased risk of morbidity and mortality if untreated.[11,12] Cleft surgery is technically complex and requires detailed attention to restore form and function to achieve optimal patient outcomes. Achieving proficiency in cleft surgery relies on extensive surgical training and expertise. Traditional cleft surgery training has relied on primary literature, textbooks, lectures, and surgical knowledge and skills acquired in the operating room. More recently, digital and haptic cleft surgery simulators have been developed and proposed as potential solutions for challenges facing cleft surgery education, consistent with the shift in focus of surgical education needs.[6] However, a comprehensive review of available cleft surgery simulators has yet to be performed. Through this article, our goal is to appraise cleft surgery simulators that have been described to date, evaluate their role within a simulation-based educational strategy, report the costs associated with their use, and present data supporting or refuting their utility.

METHODS

For this review, the following PubMed literature search strategies were used: "Cleft AND Simulation," "Cleft Surgery AND Simulation," "Cleft Lip AND Simulation," "Cleft Palate AND Simulation." Only English language articles up to May 1, 2019, were included. The references in articles identified through this search strategy were also reviewed. Inclusion and exclusion of articles relied on the definition of healthcare simulation by Gaba, which defines simulation as a "technique to replace or amplify real experiences with guided experiences, often immersive in nature that evokes or replicates substantial aspects of the real world in a fully interactive manner."[13] Digital and haptic simulators were included in our study.

The following data were extracted from articles that were included in our review: simulator purpose, simulator manufacturing, simulator cost, phase of learning addressed by the simulator, and if applicable, study design, outcomes evaluated, and study findings. Simulation phases of learning were classified based on a previously proposed model for simulation training by Diaz-Siso et al.[6] that integrates phases of simulation training and stages of motor skills acquisition (Table 1)[43]. The model organizes the simulation training process along 3 phases: (1) skills, (2) procedure, and (3) team training. Each of these phases is further classified into 3 stages of motor learning: (A) cognition, (B) association, and (C) automaticity. We classified haptic simulators as "high fidelity" if they included multiple tissue layers emulating anatomical properties of different structures of the lip and palate (skin, mucosa, muscle, etc…), whereas any other haptic simulators identified were classified as "low fidelity."

RESULTS

Our search methodology yielded 22 articles describing 16 cleft surgery simulators that were included in this study. Out of these 16 cleft surgery simulators, 7 (43.8%) were high fidelity haptic simulators (Table 2), 5 (31.2%) were low fidelity haptic simulators (Table 3), and 4 (25.0%) were digital simulators (Table 4). There were 6 (37.5%) simulators designed for cleft lip repair and markings, 2 (12.5%) simulators designed for cleft lip repair, 4 (25.0%) simulators designed for cleft palate repair and markings, 3 (18.8%) simulators designed for Furlow cleft palate repair and markings, and 1 (6.2%) simulator designed for learning cleft lip and palate anatomy, as well as cleft lip and palate repair, and markings.

The cost of simulators ranged from freely available up to $300 (Tables 2–4). Out of the 16 identified simulators, 11 (68.8%) targeted phases 2B (procedure association) and 2C (procedure automaticity) of simulation training, 2 (12.5%) targeted phase 2B (procedure association), 1 (6.2%) targeted phase 2A (procedure cognition), 1 (6.2%) targeted phases 1A (skills cognition) and 2A (procedure cognition), and 1 (6.2%) targeted phases 1B (skills association) and 2B (skills automaticity).

Within identified articles, 11 (50%) were strictly descriptive of simulator features, whereas the remaining 11 (50%) evaluated specific outcomes pertinent to the use of cleft surgery simulators.[14–24] Within these 11 studies, 4 (36.4%) described only proof of concept findings or participant-reported outcomes including satisfaction with the simulator, or perceived improvement in surgical confidence and surgical knowledge.[14,15,19,20] Only 2 studies relied on raters and cleft-specific scales to evaluate participant surgical performance or markings performance.[16,23] Within studies reporting outcomes, the largest included 35 participants and was the only prospective randomized, blinded study.[23] The study designs, outcomes evaluated, and main findings of the studies that were included in our review are highlighted in Table 2–4. Examples of digital cleft surgery and high fidelity cleft lip surgery simulators are shown in Figures 1, 2, respectively.

Table 1. Integrative Model of Phases of Simulation Training and Stages of Motor Learning

	Phase of Simulation Training		
Stage of Motor Learning	**1.Skills**	**2.Procedure**	**3.Team Training**
A.Cognition	1A: Skills cognition	2A: Procedure cognition	3A: Team training cognition
B.Association	1B: Skills association	2B: Procedure association	3B: Team training association
C.Automaticity	1C: Skills automaticity	2C: Procedure automaticity	3C: Team training automaticity

Adapted with permission from *Stud Health Technol Inform* 2013;184:205–209 and *J Gastrointest Surg* 2008;12:213–221. Published in *Plast Reconstr Surg* 2016;138:730e–738e.

Table 2. High Fidelity Haptic Simulators

First Author	Year	Simulator Purpose	Simulator Manufacturing	Simulator Cost	Simulation Phase of Learning	Study Design	Outcomes Evaluated	Study Findings
Zheng	2015	Cleft lip repair and markings	CAD/CAM and silicone material	<$50	2B and 2C	N/A	N/A	N/A
Podolsky	2017	Cleft palate repair and markings	CAD/CAM, 3D-printed material, and silicone material	$250–300	2B and 2C	Evaluation of plastic surgery residents (n = 2), fellows (n = 11), and attending (n = 6) performing cleft palate repair using the simulator	Satisfaction with the anatomical accuracy of the simulator and its effectiveness as a teaching tool, participant perceived surgical confidence, and knowledge gained from the simulator	Participants agreed that the simulator is anatomically accurate, effective as a teaching tool, and had increased perceived surgical confidence and knowledge after using it
Podolsky	2017					Evaluate feasibility of performing robotic cleft palate repair using the simulator	Feasibility of performing robotic cleft palate repair using the simulator	Robotic cleft palate repair using the simulator is possible
Podolsky	2018					Evaluation of plastic surgery residents (n = 4), fellows (n = 2), and attendings (n = 2) performing cleft palate repair using the simulator	Surgical performance using the CLOSATS scale, end-product scale, and global rating scale	High inter-rater reliability for the CLOSATS and global rating scales. CLOSATS successfully stratified performance based on experience level. Logarithmic modeling suggested that 6.3 sessions are required to reach the minimum performance standard
Cheng	2018					Evaluation of plastic surgery residents (n = 9) and fellows (n = 1) performing cleft palate repair using the simulator	Procedural confidence and knowledge	Improved procedural confidence and knowledge among participants
Ghanem	2019					Hand motion tracking of plastic surgery residents (n = 2), fellows (n = 2), and attendings (n = 2) performing cleft palate repair using the simulator	Surgical time, number of hand movements, and path length to complete the procedure	Residents required the most time, number of hand movements, and path length to complete the procedure. Number of hand movements was closely matched between fellows and attendings, but overall total path length was shorter for the attendings. Estimated number of simulation sessions to reach within 5% and 1% of attending level were 25 and 113, respectively
Ueda	2017	Cleft lip repair and markings	CAD–CAM, 3D-printing, and polyurethane	N/A	2B and 2C	N/A	N/A	N/A
Cote	2018	Cleft palate repair and markings	CAD/CAM, 3D-printing using PLA for hard palate and silicone for soft palate and tissues	$7.31	2B and 2C	Comparison of residents and physicians in an academic medical center (n = 6) and international (n = 6) settings	Participant-reported likeness to human tissue, ability to manipulate and suture tissue, and surgical skills improvement	Both groups reported high likeness to human tissue, ability to manipulate and suture tissue, and surgical skills improvement. More improvement in surgical skills in residents

(*Continued*)

Table 2. *Continued*

First Author	Year	Simulator Purpose	Simulator Manufacturing	Simulator Cost	Simulation Phase of Learning	Study Design	Outcomes Evaluated	Study Findings
Reighard	2018	Cleft lip repair and markings	CAD/CAM, 3D printing using polylactic acid for skeletal components, and silicone for soft tissues	$11.43 for reusable mold and $4.59 for consumables	2B and 2C	Evaluation of attendings performing cleft lip repair using the simulator (n = 5)	Participant-reported satisfaction with physical attributes of simulator, realism of experience, value of simulator, relevance to practice, ability to perform tasks, and global rating of simulator	High satisfaction with the simulator for all outcomes evaluated
Rogers-Vizena	2018	Cleft lip repair and markings	Silicone and synthetic polymer cartridge in a rigid nylon base	$220	2B and 2C	Evaluation of attendings performing cleft lip repair using the simulator (n = 3)	Simulator surface anatomy changes between surgeons and compared with surface anatomy changes in patients	Similar surface anatomy changes between surgeons and compared with real patients
Podolsky	2018	Cleft lip repair and markings	CAD/CAM, 3D-printed material, and silicone material	$250–300	2B and 2C	N/A	N/A	N/A

3D, three dimensional; CAD, computer-assisted design; CAM, computer-assisted manufacturing; CLOSATS, Cleft Palate Objective Structured Assessment of Technical Skills; N/A, not applicable; PLA, polylactic acid.

DISCUSSION

Simulation-based training was popularized by its role in civilian and military pilot and astronaut training.[25] Since then, this teaching modality has been widely adopted for medical and surgical training through mannequin-based, haptic, and digital-simulated clinical scenarios.[3] Within surgical specialties, general surgery demonstrated early adoption of simulation-based training, with its formalized integration into surgical curricula, most notably through laparoscopic training programs such as fundamentals of laparoscopic surgery in the late 1990s.[26] In plastic and reconstructive surgery, there is growing interest in simulation-based resident education, with the emergence of a number of simulation-based haptic and digital educational tools.[6–9] A similar trend has been observed in cleft surgery, where a number of digital and haptic cleft lip and/or palate educational simulators have been described.[14–24,27–38] Our group has previously proposed a simulation-based training strategy that integrates the 3 stages of motor skills acquisition (cognition, association, and automaticity) described by Fitts and Posner, with the 3 phases of simulation training (skills, procedures, and team training) described by Rosen et al. through the American College of Surgeons/Association of Program Directors in Surgery Skills Curriculum.[6,39–41] This simulation-based educational strategy includes 9 stages through which trainees can progress from the novice level to operative autonomy.[6] The goal of this study is to perform a comprehensive review of described cleft surgery simulators, evaluate which phase of simulation-based learning they target, appraise their characteristics including cost and manufacturing, and assess data associated with their use.

Our review identified a significant number of described cleft surgery educational digital and haptic simulators. These simulators displayed significant variability in the level of fidelity and characteristics. Moreover, the majority of identified simulators targeted procedure association and automaticity phases of simulation-based cleft surgery training. Although these findings highlight encouraging growing enthusiasm and efforts in the field of cleft surgery education, they also underscore a critical need for collaboration between different cleft surgery simulation teams. Current patterns of simulator development are suggestive of divergent and silo-based, rather than coordinated and synchronized educational efforts. Collaborations between different teams can allow a thorough assessment of the educational needs of current surgical trainees, and the development of complementary simulation-based educational tools targeting all phases of cleft surgery education. This would also allow researchers to build on existing models to develop higher fidelity and cheaper simulators as opposed to going through all phases of simulator development. Such collaborative efforts would allow leaders in surgical education to develop comprehensive, standardized, needs-based, simulation-driven educational curricula in cleft surgery. Moreover, these collaborative efforts could also serve to unify research initiatives driven by different simulation teams, and overcome a significant limitation of simulation-based research, limited sample size, and study power. Within studies including research participants, the largest study was a

Table 3. Low Fidelity Haptic Simulators

First Author	Year	Simulator Purpose	Simulator Manufacturing	Simulator Cost	Simulation Phase of Learning	Study Design	Outcomes Evaluated	Study Findings
Matthews	1997	Furlow cleft palate repair and markings	Cardboard or Styrofoam for hard palate and latex for soft palate	Negligible	2C	N/A	N/A	N/A
Vadodaria	2007	Cleft palate repair and markings	Plastic, latex, and foam	Negligible	2C	N/A	N/A	N/A
Nagy	2008	Furlow cleft palate repair and markings	Plaster, rubber, ink pad, alginate, disposable water cup, rubber dam, and rubber band	Negligible	2C	N/A	N/A	N/A
Senturk	2013	Cleft palate repair and markings	Sponge and foam	Negligible	2C	N/A	N/A	N/A
Liu	2014	Furlow cleft palate repair and markings	Sticky note	Negligible	2B	N/A	N/A	N/A

N/A, not applicable.

Table 4. Digital Simulators

First Author	Year	Simulator Purpose	Simulator Manufacturing	Simulator Cost	Simulation Phase of Learning	Study Design	Outcomes Evaluated	Study Findings
Tanaka	2001	Cleft lip repair	Software based	N/A	2B	N/A	N/A	N/A
Cutting	2002	Cleft lip and palate anatomy, markings and repair	Software based	Free	1A and 2A	N/A	N/A	N/A
Kantar	2018					Evaluation of simulator analytics	Global reach, simulator use, users reached, and user satisfaction with the simulator	Within 5 years of launch, simulator had been accessed in 136 countries, for a simulator screen time of 1,676 hours. Most users were surgeons or surgical trainees, and found the simulator to be useful as an educational tool
Plana	2019					Evaluation of medical students randomized to digital simulator (n = 18) or textbook (n = 17)	Cleft lip markings performance using 10-point scale, and participant-reported satisfaction with each educational tool	Students in the digital group performed better
Montgomery	2003	Cleft lip markings and repair	Software based	N/A	1B and 2B	Comparison of nonmedical individuals (n = 6) to plastic surgery residents (n = 6)	Cleft lip markings performance using software-generated score	Both groups improved with repeated attempts and plastic surgery residents improved quicker
Kobayashi	2006	Cleft lip repair	Software based	N/A	2A	N/A	N/A	N/A

N/A, not applicable.

prospective randomized, blinded trial in which 35 participants were recruited to test the effectiveness of digital simulation in teaching cleft lip surgical markings compared with textbook.[23] Collaborative multi-institutional studies would increase sample size and study power by providing a larger pool of participants and validate results obtained at the institutional level, through testing at multiple sites and across more heterogeneous cohorts.

Strict work-hour limitations, increasing resident supervision, patient requests to limit resident participation in their care, and growing nonclinical duties are challenging resident surgical education in developed countries.[2] In developing countries, surgical expertise is often lacking which can jeopardize patient access to safe surgical care.[42] Simulation-based training can potentially address some of these challenges in various surgical specialties, including cleft surgery, by allowing surgical trainees in developed countries to compensate for limited operative exposure, and providing training to surgical trainees in developing countries. For educational tools, including cleft surgery simulators, to be successful at achieving their intended goal, they need to be readily available and easily accessible to surgical trainees. Moreover, these simulators also need to be affordable to ensure that they are reaching their intended

Fig. 1. Example of digital cleft surgery simulator.

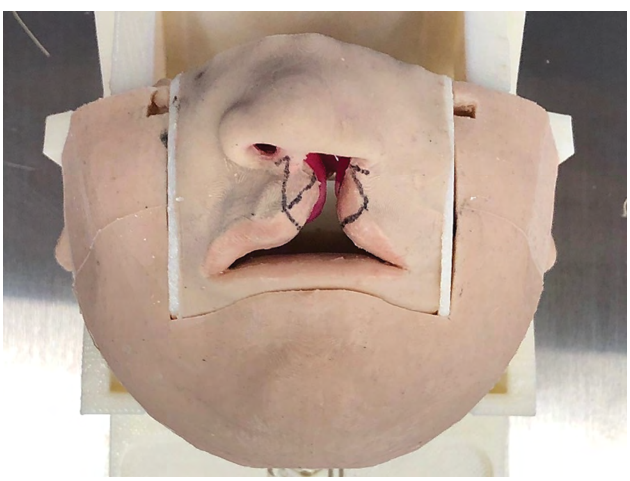

Fig. 2. Example of high fidelity haptic cleft lip simulator. The highlighted markings are not a standard component of this haptic simulator and have been drawn to demonstrate cleft lip repair markings for the extended Mohler technique.

surgical audience irrespective of demographic, social, or economic factors. Our review of the literature shows that the reported cost of cleft surgery simulators for users has ranged from freely available with digital simulators, up to $300 with high fidelity haptic simulators.[14,22] Ongoing efforts are underway to reduce the cost of high fidelity haptic cleft surgery simulators to ensure their wide-scale distribution, particularly in low resource settings.[21] These include creating disposable cartridges of cleft lip and/or palate defects for surgical training that fit into a reusable base and adopting rapid prototype manufacturing techniques for simulator production.[14,21,32] It is also important to highlight that cleft surgery simulators that are free and widely available to users can only be sustainable through strong collaborations and partnerships between invested stakeholders in cleft surgery education from the academic, philanthropic, and industry sectors.[6,22] These partnerships and success stories in cleft surgery education should serve as roadmaps for educational simulator development.

Our review of the literature demonstrated that only half of the studies which were included evaluated specific outcomes pertinent to the use of cleft surgery simulators (Tables 2–4). Moreover, the level of evidence of these studies was variable, with only 1 reported prospective randomized, blinded trial.[23] Nevertheless, all studies reported encouraging and positive outcomes associated with simulator use, including reaching a significant global surgical audience, high participant-reported satisfaction with simulator use, improved surgical confidence and surgical knowledge, improved cleft lip markings performance, and better surgical performance and efficiency.[14–24,27–38] Assessment of these outcomes was mostly performed using modified versions of existing scales, with only 2 reported cleft surgery-specific scales including the Cleft Palate Objective Structured Assessment of Technical Skills scale for cleft palate repair performance, and a 10-point scale developed for evaluation of extended Mohler unilateral cleft lip repair markings performance.[16,23] Future efforts in cleft surgery simulation should focus on developing, testing, and validating cleft lip and cleft palate repair specific scales through multi-institutional collaborative efforts, to support the efficacy of current simulation-based cleft surgery educational tools and guide future development. Standardized and validated cleft-specific scales can also allow better assessment of trainee performance, identify opportunities for improvement, and guide remedial efforts if necessary.

CONCLUSIONS

Surgical simulation can potentially address significant challenges facing surgical trainees around the world. In cleft lip and palate surgery, significant emphasis has been placed on developing digital and high fidelity and low fidelity haptic surgical simulators. Cleft surgery simulators vary considerably in their features, purpose, cost, and availability. The level of evidence supporting the use of these simulators has also varied widely, but results are favorable. These promising efforts in cleft surgery simulation should be coupled with future multi-institutional collaborative initiatives that are focused on demonstrating the efficacy of current cleft simulators and refining them. This will also require the development, testing, and validation of cleft lip and palate-specific assessment scales that can be used to report standardized trainee performance results, identify opportunities for improvement, and guide remedial efforts. Standardized data in support of the educational utility of cleft surgery simulators can provide key stakeholders in surgical education with the necessary evidence for investing in these simulators and spearheading their development.

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