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DEPARTMENT OF SURGERY**

**Assessment of the Impact and Efficacy of The First Simulator-
Based Bilateral Cleft Lip Repair Training Conducted in Ethiopia**

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Abstract

Background: Bilateral cleft lip is a common problem that mandates intervention. However, the surgery has a high learning curve and is technically demanding, which requires a delicate skill with an understanding of the complex three-dimensional anatomy of the lip and the nose. More recently, cleft surgery simulators have been developed and proposed as potential solutions for challenges facing cleft surgery education. Trainings using a simulator were shown to significantly improve the competence and proficiency of trainees. The first simulator-based bilateral cleft lip repair training was conducted at ALERT Hospital in Addis Ababa, Ethiopia. We evaluated the impact and effectiveness of the training in this study.

Objective: The main purpose of this study was to evaluate and assess the efficacy and impact of the first simulator-based bilateral cleft lip repair training in Ethiopia, which was conducted at ALERT Hospital in Addis Ababa, Ethiopia.

Methods: A simulator-based bilateral cleft lip repair workshop was delivered to plastic and reconstructive surgery attendings and trainees in Addis Ababa, Ethiopia. Before the workshop, all participants received a supplementary video on the subject matter. A didactic lecture followed by a simulation session was delivered during the workshop. Both pre- and post-workshop, participants completed an online survey, which was entered into the Smile Train database. The data was retrieved from the Smile Train database, entered into the latest version of SPSS, and analyzed. Paired t-test was conducted to assess a statistical effect on impact and efficacy of the training. Outputs were summarized into different charts, figures and table formats.

Results: A total of 18 participants (18/20) had finished the training. A significant improvement in their level of confidence after the workshop was declared. Before the training, only 38.9% had had excellent confidence. However, this figure rose to 67% after the training. Two-thirds (66.67%) of the participants strongly agreed on the training's relevance, content, usefulness, and educational value. About 55.56% strongly believed in the training content and would

recommend the workshop to their colleague. More than three-fifths (61.11%) strongly believed the workshop covered relevant surgical contents, and two-thirds (66.67%) agreed on the realistic simulation of the workshop. The paired t-tests indicated an efficacy was changed with an adjusted mean difference ($-4.39 \pm \text{SD } 3.24$ ($-2.78, -5.99$), $p < 0.000$).

Conclusion and recommendations: Simulator-based bilateral cleft lip repair training is very vital for a trainee's efficacy improvement, so we recommend such training on a larger scale. Therefore, curriculum developers and stakeholders, including non-government organizations, should consider engaging in providing simulator-based training to surgical trainees to be skilled at bilateral cleft lip repair.

Keywords: Assessement, Impact, Efficacy, Simulator, Bilateral Cleft Lip Repair, Ethiopia

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LIST OF TABLES

Table 1: Response of participants for the question before the workshop was conducted-----	13
Table 2: Response of participants for the question after the workshop was conducted-----	17
Table 3: Pre-Post comparison -----	22

List of Figures

Figure 1: Participants' level of confidence to perform bilateral cleft lip surgery before training-----	18
Figure 2: Participants' level of confidence to perform bilateral cleft lip surgery after training-----	19

LIST OF ACRONYMS

ALERT-All African Leprosy and Rehabilitation Center

AAU-Addis Ababa University

SoM-School of Medicine

SPSS-Statistical Package for the Social Sciences

PRS-Plastic and reconstructive surgery

ETB-Ethiopian Birr

G.C-Gregorian Calendar

WHO-World Health Organization

COSECSA-The College of Surgeons of Eastern, Central, and Southern Africa

Contents

Abstract	
Abstract	i
Acknowledgments	iii
LIST OF TABLES	iv
LIST OF ACRONYMS	v
Chapter 1: Introduction	1
1.1.1. Background	1
1.1.2 Statement of the problem	3
1.1.3 Rationale of the study	4
Chapter 2: Literature review	4
Chapter 3: objectives	7
3.1 General objective	7
3.2 Specific Objective	7
Chapter 4. Methods	8
4.1. Study area	8
4.2. Study Design and Period	8
4.3. Source and Study Population	8
Source Population	8
Study Population	8
4.4. Sample survey Size and Sampling Technique	9
4.5. Data Collection Procedure and Tools	9
4.6. Variables	9

4.7. Operational Definitions	10
4.8. Data Analysis	10
4.9. Data Quality Management	10
4.10. Ethical Consideration	11
4.11. Strength and Limitation of the Study	11
4.12. Dissemination Plan	11
CHAPTER 5. Results	12
5.1. Attendant's response before the workshop	12
5.2. Attendants' response after workshop	14
5.3. Participant's level of confidence to perform bilateral cleft lip surgery before the workshop	17
5.4. Participant's level of confidence to perform bilateral cleft lip surgery after workshop	17
5.5. Skill Development, confidence building, procedural understanding ,challenges and suggestions from participants	18
5.6. Confidence and preparedness	19
5.7. Overall positive experience and enjoyment and reflection	19
5.8. Relevance and impact on professional growth	20
5.9. Data analysis and results	20
Chapter 6: Discussion	21
Strengths and limitations of the study	23
Chapter 7: Conclusion and recommendation	23
DECLARATION OF THE PRINCIPAL INVESTIGATOR	24
References	25
Annexes	28

Chapter 1: Introduction

1.1.1. Background

Cleft lip and palate anomalies are among the most frequent craniofacial abnormalities, affecting approximately 10 million people worldwide, equating to 1 in 500 to 2500 live births (Hammond and Dixon, 2022). These birth defects might result in psychosocial and functional impairments; therefore, the need for intervention is paramount. However, cleft lip surgery has a high learning curve, is difficult to perform, and necessitates a mastery of intricate anatomy, delicate techniques, and dimensions. It is technically demanding to do cleft lip surgery because it requires knowledge of three-dimensional (3D) morphology, the dissection of several tissue planes, the interaction of various tissue types, and skill with techniques that must be performed precisely to produce optimal outcomes (Hsieh, Timbang and Tollefson, 2020). According to (Baek *et al.*, 2018), bilateral cleft lip repair is specifically challenging and necessitates knowledge of the morphological traits that set it apart from unilateral cleft lip repair (Xue, Buchanan and Hollier, 2022). This entails a variable prolabium and premaxilla protrusion, which puts more strain on the repair (particularly in cases lacking naso-alveolar shaping). The prolabium lacks muscle, and the midline's upper labial sulcus is deficient. There is no cupid's bow, which needs to be created, and the prolabium's cutaneous roll and vermillion are of poor quality and size. Furthermore, compared to unilateral surgeries, bilateral cleft lip case volumes are smaller (Mossey *et al.*, 2009), which decreases operating experience and prolongs the learning curve for becoming competent and well-versed in bilateral cleft lip repair techniques.

Opportunities to perform the technical parts of a cleft lip repair are typically limited due to the complexity of the procedure, the significance of patient safety, and the necessity for excellent long-term results. Strict work schedule constraints, an increase in nonclinical responsibilities, a rise in resident supervision, and patient demands to reduce resident involvement in their care convey challenges to resident surgical education in the contemporary academic environment (Jamal, Wong and Whalen, 2014). Additionally, the traditional approach to cleft lip surgery training has been centered on a gradual apprenticeship model with considerable amounts of operative exposure. As a result, the "see one, do one, teach one" model of the apprenticeship has changed to include more objective competency-based metrics (Stefanidis *et al.*, 2015).

Due to the previously mentioned challenges, cleft surgery education is facing several obstacles. In line with the requirement for surgical education, digital and haptic cleft surgery simulators have been developed and put out as possible solutions (Diaz-Siso *et al.*, 2016). Evidence showing that utilizing surgical simulation results in enhanced outcomes in the operating room has been added to this.

Over the past two decades, there has been a fast increase in the use of simulation in surgery due to decreased trainee operational caseloads, duty-hour constraints, and an increased emphasis on patient safety (Stefanidis *et al.*, 2015). It has been demonstrated that simulation training helps substantially enhance the transfer of skills. Research supports the use of simulations to promote continuing skill development in a variety of surgical specialties (Elayah *et al.*, 2023). Through simulations, participants can integrate information, intricate cognitive processes, and technical skills in a risk-free setting, which may boost their proficiency and confidence. There is a growing recognition among the plastic surgery community that simulations deserve to be viewed as a crucial instrument for promoting continued education and surgical quality, rather than just an extra layer of training (Rogers-Vizena *et al.*, 2018).

Surgical simulators could be an invaluable tool for assisting in the development of skills in a risk-free setting. This is especially important when performing an operation that calls for a high degree of technical proficiency and geometric accuracy because technical mistakes could cause the child to have troubles for the rest of their life.

A novel and high-fidelity bilateral cleft lip simulator was introduced after it was evaluated by a group of experienced surgeons to determine its ability to emulate bilateral cleft lip repair, its anatomical accuracy and realism, as well as its value as a training tool (Zaga-Galante *et al.*, 2024). Among the various simulators developed, the high-fidelity cleft lip simulator can provide a realistic representation of cleft anatomy. The construction of the simulators is based on computer tomography, modeling, and 3D printing. The replication of mechanical properties akin to their real-life anatomical sub-units results in a level of haptic feedback that lends itself to a realistic simulation. Consequentially, users can simulate the cleft lip repair from start to finish rather than carrying out technical markings alone. Multiple studies have shown evidence of positive feedback expressed by specialist cleft lip surgeons regarding the realism and

applicability of high-fidelity simulators in surgical training. High-fidelity simulations have the potential to facilitate both the progression and refinement of technical skills through repetition, experimentation, and a learned understanding of the nuances associated with cleft lip and palate surgery. The aim of this study was to assess and evaluate the impact as well as the effectiveness of this simulator-based bilateral cleft lip training on PRS trainees and attendings, which was conducted for the first time in Ethiopia at Addis Ababa, Ethiopia. The study is going to be the first of its kind in Ethiopia.

1.1.2 Statement of the problem

Clefts of the lip and/or palate (CLP) are the most common craniofacial birth defects, with a worldwide birth prevalence of approximately 1/700 (Mossey *et al.*, 2003). The prevalence of cleft lip and palate in Addis Ababa, Ethiopia, is 1.49 per 1000 live births (Eshete *et al.*, 2011). Cleft lip surgery, specifically that of the bilateral cleft lip, is technically demanding. It also requires a detailed, refined approach with optimal geometric relationships to ensure good functional and aesthetic outcomes. Complication rates in surgery have been shown to be associated with less skilled and less experienced surgeons. Furthermore, it is a challenging procedure to teach and assess in the operating room because of the delicate tissue handling that is required and the potential complications that can arise from subtle technical errors. Supervising surgeons are reluctant to allow trainees to perform this procedure, making it impractical for trainees to learn or be evaluated on live patients. As a result, training in cleft lip surgery takes time, requiring gradual increases in hands-on experience. On the other side, 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 (Jamal, Wong and Whalen, 2014). To obviate the challenges, simulator-based cleft lip training is coming into play. However, a comprehensive evaluation of available cleft surgery simulators has yet to be performed. This study determined and evaluated the impact and effectiveness of one of the recent high-fidelity simulator-based trainings conducted in Ethiopia for the first time.

1.1.3 Rationale of the study

This study is exceptional in that it specifically examines the impact and effectiveness of the most recent bilateral cleft lip simulator-based training. In addition, the training to be studied as well as the study itself are the first of their kind in Ethiopia. In our opinion, this research will contribute to the understanding of the impact of this recently introduced simulator, and it is going to be used as a base-line study for future studies in the field. It will also encourage the use of this simulator on a larger scale.

Chapter 2: Literature review

In English articles, several studies exist about simulation in cleft surgery as a whole with inclusion of cleft palate and unilateral cleft lip, unlike bilateral cleft lip.

The most recent study done on bilateral cleft lip simulation (Zaga-Galante *et al.*, 2024) evaluated the features, anatomic accuracy, and educational value of a high-fidelity bilateral cleft lip simulator by expert cleft surgeons. Eleven experienced surgeons participated in the evaluation during a meeting of the Latin American Craniofacial Association. They performed a simulated bilateral cleft lip repair and were assessed on the simulator's features, realism, and value as a training tool. The surgeons agreed with the simulator's realism and anatomic accuracy, with an average score of 3.7 out of 5. They also strongly agreed with the simulator's value as a training tool, with an average score of 4.6 out of 5. The study concluded that a high-fidelity bilateral cleft lip simulator is a valuable and realistic training tool for surgeons.

A study of innovation (Rogers-Vizena *et al.*, 2018) concluded that a high-fidelity cleft lip simulator provides an "on-demand" opportunity to realistically practice all steps of a cleft lip repair, potentially overcoming volume-outcome relationship challenges for resident surgeons after a digitally simulated patient with a typical unilateral complete cleft lip and alveolus using existing three-dimensional imaging studies was analyzed. A prototype high-fidelity simulator was built with silicone and synthetic polymers, piloted by three surgeons using multiple techniques, and digitally compared to real patients. All surgeons completed key steps of a cleft lip repair on the simulator, finding it approximated the haptics and anatomy of a cleft lip. Surface change and anthropometric movements were similar for all three surgeons.

This study (Kantar *et al.*, 2019) appraised the available digital and haptic simulators for cleft surgery education, their role in a simulation-based educational strategy, associated costs, and data supporting or refuting their utility. A total of 22 articles were included, with 11 (50%) descriptive of simulator features and 50 (50%) evaluating specific outcomes related to cleft

surgery simulators. Out of these, 43.8% were high-fidelity haptic simulators, 31.2% were low-fidelity haptic simulators, and 25.0% were digital simulators. The cost to the simulator user ranged from freely available up to \$300. The study concluded that cleft surgery simulators vary significantly in features, purpose, cost, availability, and scientific evidence.

A study conducted in Australia (Khoo *et al.*, 2023) assessed the confidence of plastic surgery trainees in performing cleft lip repair before and after a simulation exercise. The researchers used 3D high-fidelity simulation models and a confidence scale questionnaire to assess the trainees' surgical skill, knowledge, and anxiety level when performing the surgery. The survey included questions about the trainees' level of training and prior experience. The results showed an average increase of 53.5% in total scores between pre- and post-simulation surveys. Improvements were found for all attendees, regardless of their training level or prior experience. The study concluded that simulation training is a validated solution for skill acquisition and

knowledge transfer, and its inclusion in the surgical curriculum has the potential to improve operative learning.

(Cheng *et al.*, 2018) evaluated technical performance in cleft palate repair using a new assessment tool and a high-fidelity simulator. The Cleft Palate Objective Structured Assessment of Technical Skill (CLOSATS) and end-product scales were developed to assess performance. Results showed that the average procedure-specific, global rating, and end-product scores increased logarithmically after each simulation session. The simulator and technical assessment scores can be used to determine performance before operating on patients. The study concluded that a high-fidelity cleft palate simulator can improve cleft palate repair.

.A study done in Syria (Borg *et al.*, 2022) involved delivering cleft lip and palate repair workshops to 50 doctors, providing them with additional learning material, didactic teaching, and simulation sessions. The results showed that 96% of the attendees had never independently performed cleft lip repair, and 100% had not previously performed cleft palate repair. The workshop and simulator provided an effective training tool for surgical training globally, particularly in low-income countries.

Chapter 3: objectives

3.1 General objective

The main purpose of this study was to evaluate and assess the efficacy and impact of the first simulator-based bilateral cleft lip repair training in Ethiopia, which was conducted in Addis Ababa, Ethiopia.

3.2 Specific Objective

1. To assess the effectiveness of the simulator-based training conducted in Addis Ababa, Ethiopia.
2. To evaluate the impact of the training on the trainees

Chapter 4. Methods

4.1. Study area

The training to be studied was delivered during the 23rd COSECSA scientific conference at ALERT comprehensive specialized hospital, Addis Ababa, Ethiopia. The study captured data from the training on the impact of the simulator-based training conducted in Addis Ababa, Ethiopia.

4.2. Study Design and Period

A mixed study design was conducted to assess the efficacy and impact of simulator-based training on bilateral cleft lip surgery. The bilateral cleft lip simulator training was conducted on November 27, 2023, with the support of Smile Train.

4.3. Source and Study Population

Source Population

All attendees and senior residents of the department of PRS, AAU, and ALERT Center.

Study Population

All trainees who participated in the workshops.

Inclusion criteria

All participants in the workshops who fully attended the training and completed both the pre- and post-workshop surveys were included

Exclusion criteria

Participants who didn't fully attend the training.

Participants who didn't complete the pre- and post-workshop surveys.

4.4. Sample survey Size and Sampling Technique

For this study, a convenient sampling technique was used. All (20) trainees had a response on pre-training survey. However, about 18 had finished the post-training survey. Therefore all (18) trainees who had attended and responded on post workshop survey were eligible for the study.

4.5. Data Collection Procedure and Tools

Pre- and post-training data were collected during the training. We retrieved both data from the Smile Train database for this study. The simulators were produced and generously provided by Simulare Medical, a division of Smile Train, a not-for-profit entity that disseminates and distributes cleft surgical simulators. These models were 3D-printed, providing highly lifelike, tactile architecture as well as complete and realistic anatomy. The validity of such 3D-printed models in cleft surgery training has been previously reported (Podolsky et al., 2018). They comprised a one-time-use cartridge that could be inserted into a reusable base and stand to adjust the flexion and extension of the model. Attendings and senior residents were randomly selected from the department of PRS, AAU, and ALERT Center for participation in the workshop. The participants were involved voluntarily, and none of them were involved in the development of the simulators used for the training. All participants received a supplementary bilateral cleft lip repair teaching video ahead of the training day. They also filled out a pre-workshop online survey pertaining to their level of experience, degree of confidence, and related factors (Annex). During the workshop, a didactic lecture on bilateral cleft lip was given by a senior plastic and reconstructive surgeon. Following the lecture, simulation sessions were delivered, during which the trainee performed a simulated bilateral cleft lip repair under the supervision and mentorship of senior cleft surgeons. Post-workshop, attendees completed a second questionnaire regarding their post-workshop confidence, surgical skill, performing cleft lip repair, and others (Annex). The completed surveys were entered into the Smile Train database. After obtaining permission from the organization, the data was retrieved from the Smile Train database and statistically analyzed using the latest version of SPSS.

4.6. Variables

Dependent Variable: simulator-based bilateral cleft lip training efficacy and impact

Independent Variables: relevance of the training, understandability of the training, comprehensiveness of the training, usefulness of the training, educational value of the training, realism, durability, user friendliness of the simulators, confidence and proficiency to train

4.7. Operational Definitions

Impact: A significant or major effect

Simulation: A model that mimics the original object

Assessment: the action of judging and evaluating something.

High-Fidelity simulator: A model that reproduces an actual patient to a high level of realism.

Smile Train: a nonprofit organization and charity providing corrective surgery for children with cleft lips and palates, headquartered in New York City, United States.

Simulare Medical: A division of Smile Train, a not-for-profit entity that disseminates and distributes cleft surgical simulators.

4.8. Data Analysis

The collected data was retrieved from the Smile Train database, entered into an XL spreadsheet, checked for completeness and consistency, and then transported to latest version of SPSS for analysis. The descriptive analysis was conducted and presented using text, table and figure formats. Pre-post test score was conducted and finally paired t-test was employed to show statistical significance in improvement of the efficacy of the training studied.

4.9. Data Quality Management

The principal investigator first assured that that all the pre- and post-training surveys were fully answered and collected after which the principal investigator retrieved all the available information from the completed surveys from the Smile Train data base using guidelines. The

principal investigator also double checked for the completeness of the collected data before transporting it to SPSS for analysis.

4.10. Ethical Consideration

Ethical clearance for the study was obtained from the surgical department, School of Medicine, Research Ethics Committee

4.11. Strength and Limitation of the Study

This is the first study conducted in Ethiopia considering simulator-based bilateral cleft lip repair. Pre and post training assessment was done to evaluate the efficacy improvement among participants. Paired t-test was conducted to test statistically significant improvement. However, the study had its own limitation like sample size, simulator itself does not bleed, and this likely represents additional challenges to using both systems on a live patient. Another weakness of the study was lack of comparison group of trainees who received standard bilateral cleft lip surgery training despite the fact that there is no standardized training protocol for bilateral cleft lip surgery, and the amount of hands-on experience that trainees pursue varies widely depending on the institution. The short time frame of the training was also another weakness.

4.12. Dissemination Plan

The findings of the study will be primarily presented to the department of surgery, school of medicine, college of health sciences, and AAU as part of the requirements for postgraduate surgical training in plastic and reconstructive surgery. It is also going to be submitted for publication in peer-reviewed journals and reach the scientific community at both local and international levels. The findings will also

reach other stakeholders working in line through document sharing and scientific presentations at conferences, workshops, and seminars. In addition, it will also be disseminated through society's annual conferences. The Ethiopian Society of Plastic and Reconstructive Surgery annual conference will be a good forum.

CHAPTER 5. Results

5.1. Attendant's response before the workshop

From a total of 20 participants selected for the workshop only 18 finished the training and completed the post workshop survey, which yields 90% response rate. The majority of the participants were PRS residents, 14(77.8%) and the rest 4(22.2%) were junior attendings with less than 10 years of experience. Furthermore, each response is presented in details (**Table 1**)

Table 1: Response of participant for the question before workshop is conducted

College of Surgeons of East, Central and Southern Africa (COSECSA) Pre-conference event N= 18/20				
S.no	Questions assessed before workshop	Category	Frequency	Percent (%)
1	How confident are you overall in performing the surgical repair in this workshop?	Very confident	1	5.55
		Confident	5	27.77
		Somewhat confident	9	50
		Not at all confident	3	16.66
2	What is your surgical skill level in performing this type of repair?	Above average skill	2	11.11
		Average skill	11	61.11
		Below average skill	5	27.77

3	Do you worry that something will go wrong when performing this type of repair?	Constantly worry	1	5.55
		Occasionally worry	9	50
		Often worry	3	16.66
		Sometimes worry	5	27.77
4	Do you feel anxiety about performing this type of repair?	Frequent anxiety	1	5.55
		Some anxiety	8	44.44
		Occasional anxiety	6	33.33
		Never anxiety	3	16.66
5	Based on your current performance, would you prefer to avoid doing this type of repair altogether?	Never avoid	9	50
		Occasionally avoid	6	44.44
		Often avoid	2	10
		Sometimes avoid	1	5
6	How comfortable are you with independently planning and marking a cleft lip and palate repair?	Very Comfortable	1	5
		Comfortable	12	60
		Neutral	4	20
		Uncomfortable	3	15
7	How comfortable are you with independently executing a cleft lip and palate repair?	Very Comfortable	1	5
		Comfortable	11	55
		Neutral	5	25
		Uncomfortable	3	15
8	Based on your training to date, how comfortable are you with independently performing a cleft lip and palate repair?	Very Comfortable	1	5
		Comfortable	10	50
		Neutral	7	35
		Uncomfortable	2	10
9	How comfortable are you when you think about performing the surgical repair in this workshop?	Very Comfortable	3	15
		Comfortable	10	50
		Neutral	6	30
		Uncomfortable	1	5

5.2. Attendants' response after workshop

Two-thirds (66.67) of the participants strongly agreed with the training relevance, workshop content, usefulness, and educational value of the workshop. More than half (55.56%) of the participants strongly believed that the workshop content was easily understandable on the practical engagement of the training, revealed that they would recommend the workshop for their colleague and believed that the proctors were well-prepared. More than three-fifths (61.11%) of the participants strongly believed that the workshop covered relevant surgical contents and proctors were knowledgeable. About two-thirds (66.67%) of the participants agreed on the realistic simulation of the workshop (Table 2).

Table 1: Questionnaire Responses Amongst the participants

S. no		5-Strongly Agree	4- agree	3- neutral	2- disagree	1-Strongly disagree
1	The workshop content was relevant	12 (66.67)	4 (22.22)	0 (0.00)	0 (0.00)	2(11.11)
2	The workshop content was comprehensive	8 (44.44)	8 (44.44)	0 (0.00)	0 (0.00)	2 (11.11)
3	The workshop content was easy to understand	10 (55.56)	6 (33.33)	0 (0.00)	0 (0.00)	2 (11.11)
4	The workshop content was useful	12 (66.67)	4 (22.22)	0 (0.00)	0 (0.00)	2 (11.11)
5	The workshop session covered relevant surgical content	11 (61.11)	5 (27.78)	0 (0.00)	1 (5.56)	1 (5.56)
6	The workshop session provided engaging practical learning experiences	10 (55.56)	6 (33.33)	0 (0.00)	0 (0.00)	2 (11.11)
7	The model provided a realistic simulation of the procedure	6 (33.33)	12(66.67)	0 (0.00)	0 (0.00)	0 (0.00)
8	The model durability was of high quality	1 (5.56)	8 (44.44)	0 (0.00)	9(50.0)	0 (0.00)
9	The workshop's level of difficulty was sufficient	2 (11.11)	12(66.67)	0 (0.00)	4 (22.22)	0 (0.00)
10	The workshop was educationally valuable	12 (66.67)	6 (33.33)	0 (0.00)	0 (0.00)	0 (0.00)
11	The workshop session achieved the intended learning objectives	8 (44.44)	7 (38.89)	0 (0.00)	0 (0.00)	3 (16.67)
12	As an assessment and evaluation tool for surgical skills (CLOSATS) framework is relevant	9 (50.00)	8 (44.44)	0 (0.00)	1 (5.56)	0 (0.00)

13	As an assessment and evaluation tool for surgical skills (CLOSATS) framework is useful to measure surgical skills	9 (50.00)	6 (33.33)	0 (0.00)	3 (16.67)	0 (0.00)
14	As an assessment and evaluation tool for surgical skills (CLOSATS) framework is comprehensive	5 (27.78)	12(66.67)	0 (0.00)	1 (5.56)	0 (0.00)
15	As an assessment and evaluation tool for surgical skills (CLOSATS) framework is easy to understand	9 (50.00)	8 (44.44)	0 (0.00)	1 (5.56)	0 (0.00)
16	I would recommend this workshop to a colleague who needs training or practice?	10 (55.56)	6 (33.33)	0 (0.00)	1 (5.56)	1 (5.56)
17	The workshop Trainer during this session was knowledgeable	12 (66.67)	6 (33.33)	0 (0.00)	0 (0.00)	0 (0.00)
18	The workshop Trainer during this session was well-prepared	9 (50.00)	9 (50.00)	0 (0.00)	0 (0.00)	0 (0.00)
19	The workshop Trainer during this session was responsive to questions and comments	12 (66.67)	6 (33.33)	0 (0.00)	0 (0.00)	0 (0.00)
20	The workshop Proctors during this session were knowledgeable	11 (61.11)	7 (38.89)	0 (0.00)	0 (0.00)	0 (0.00)
21	The workshop Proctors during this session were well-prepared	10 (55.56)	8 (44.44)	0 (0.00)	0 (0.00)	0 (0.00)
22	The workshop Proctors during this session were responsive to questions and comments	12 (66.67)	6 (33.33)	0 (0.00)	0 (0.00)	0 (0.00)

5.3. Participant's level of confidence to perform bilateral cleft lip surgery before the workshop

The participant level of confidence was measured initially. As a result, 11.1% of the attendants had excellent confidence, 38.9 % had fair confidence level and 11.1% had poor confidence level. This result indicated that most of the participant were not confident enough to perform bilateral cleft lip repair (**Figure 1**)

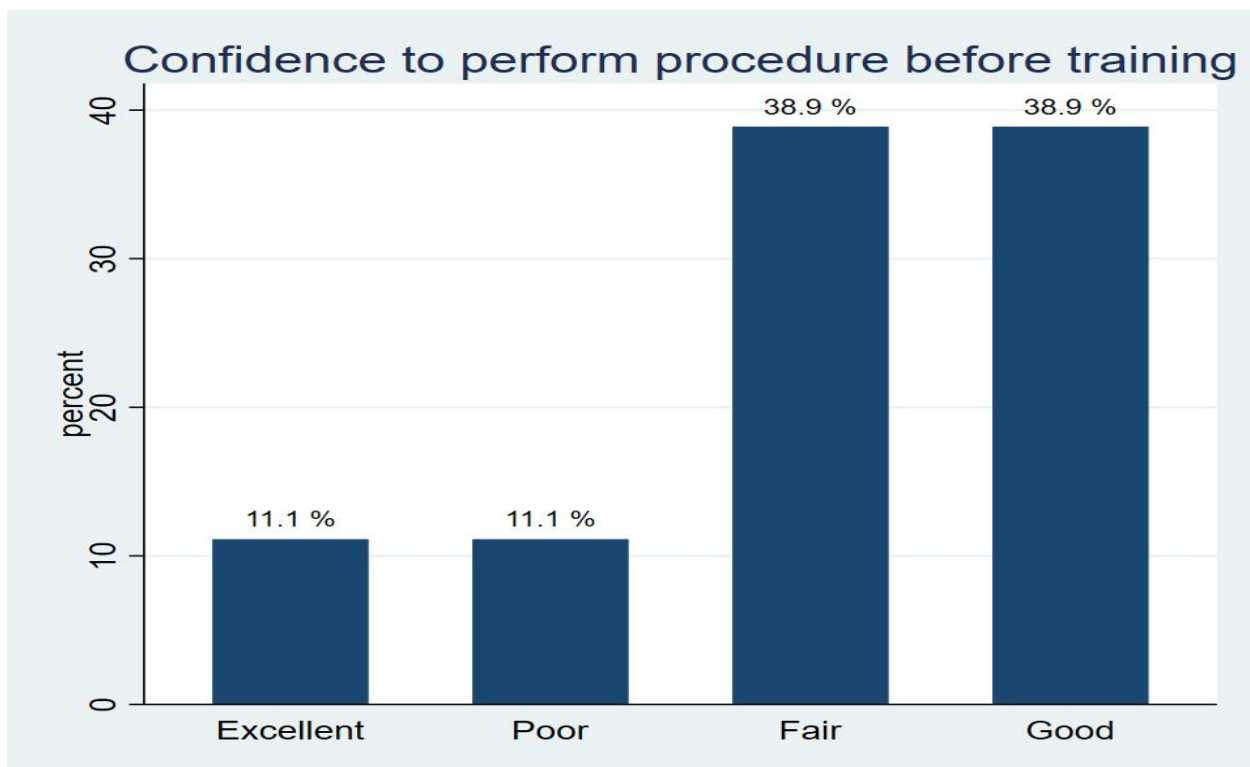


Figure 1: Participants' level of confidence to perform bilateral cleft lip surgery before training

5.4. Participants' level of confidence to perform bilateral cleft lip surgery after workshop

To evaluate the improvement of efficacy among participants, post test was conducted and level of confidence was measured after training was given. The result showed that there was a

significant improvement in their level of confidence, which was evidenced by near to 67%, and 5.6% of attendants have Excellent, and fair level of confidence respectively, to perform the procedure. Even after they took training no participants responded poor level of confidence (Figure 2)

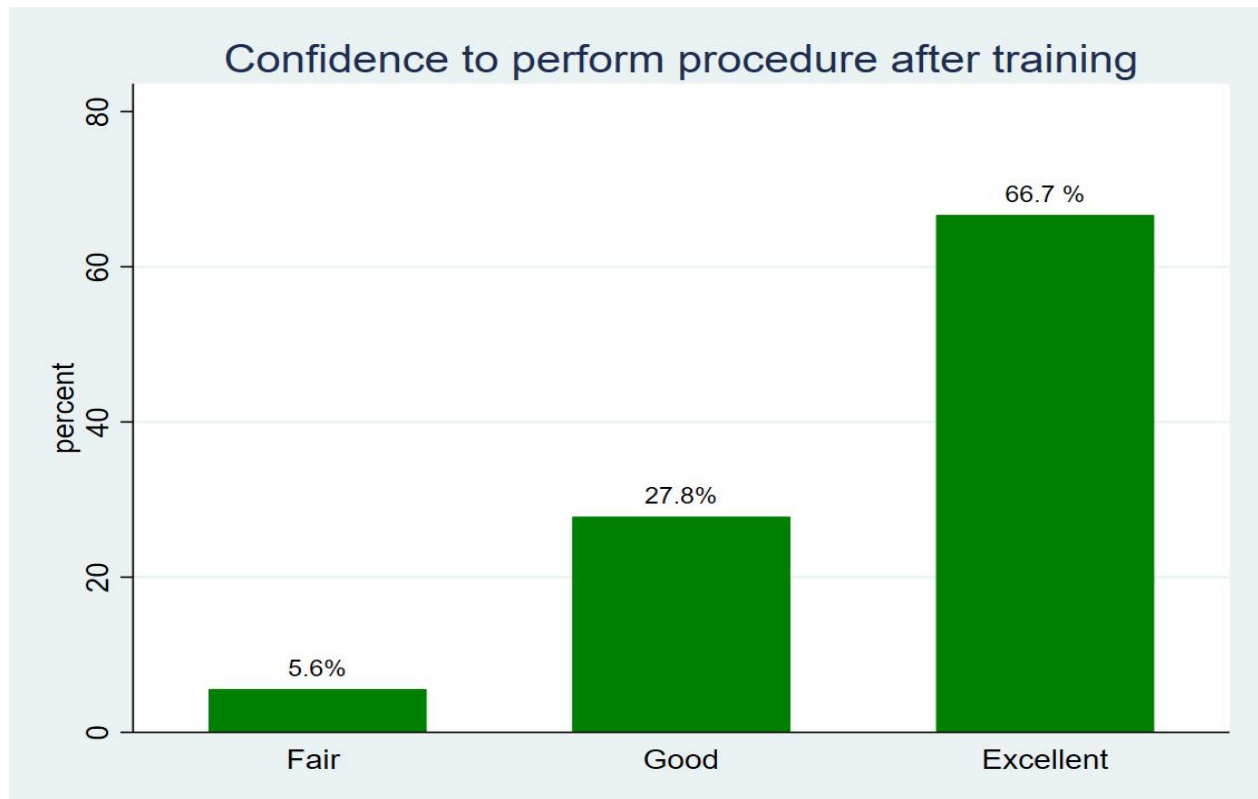


Figure2: Participants' level of confidence to perform bilateral cleft lip surgery after training

5.5. Skill Development, confidence building, procedural understanding, challenges and suggestions from participants

Regarding skill development and confidence building, two participants (p2 and 3) clearly indicated that the training was a good experience and helped them boost their skill and confidence. Four participants (p4, p5, p6, and p13) reported that marking was the most challenging step in the course of action. Additionally, the following issues were pointed out as challenges: dissecting the nasal septum to create the nasal floor (p9), identifying the

mucoperiosteal flap pedicle (p11), suturing (p1-3, p14-16, and p18), nasal wall/floor repair or reconstruction (p7, p8, p10, and p17), and the lack of a palate repair workshop (p12). Cartridge (p9 and p10), base (p2), headlamp (p5), and others (p1, p3, p6, p8, p11, and p15) were explained as components that caused confusion or failed during the workshop. It was challenging to carry out simulator-based surgery on the simulators because the silicone material was brittle or tore too easily, according to the majority of the participants (p1-3 and p6-17). The most challenging aspect of performing virtual surgery on the simulators, according to another participant, was prolabium detachment. However, two people (p4 and p5) had not encountered any challenges.

One participant (p3) stated, "It is good to involve more residents and fresh graduate plastic surgeons to transfer knowledge with hands-on training," in response to a question about suggestions for improving the simulator or training. Three participants (p5, p8, and p12) also stated that the doll tissue was fragile and that it would be better to make it softer. Additionally, a different participant (p14) expressed a desire for more frequent simulator-based workshops.

5.6. Confidence and preparedness

About 14/18 participants (77.8%) were proficient enough and ready to train or serve as a workshop proctor in their region after the training

5.7. Overall positive experience and enjoyment and reflection

About 72.2% of the participants (13/18) didn't know about the Smile Train Simulare Medical Cleft Models before this workshop. Participants (p2, p8, and 12) clearly indicated that the training provided an excellent experience, was fruitful, and helped them to boost their confidence. And one participant (P8) also explained as he/she enjoyed it. Many of the participants who gave their suggestions (p2, p3, p4, p7, p8, p9, p10, p12, p17, p18) declared that the training was practical. Moreover, two participants also gave their recognition for being realistic and less complicated.

However, trainees had raised their overall reflection. Three participants (P8, P9, and P17) stated that the training was excellent when asked why they gave it this rating. Four participants (P2, P4,

P5, and P10), however, expressed dissatisfaction with the training's limited time and stated that they would like to continue. According to two participants (P12 and P18), it is preferable to incorporate instruction on unilateral cleft and cleft palate, and the special prolabium of the model is readily detachable. Six (p2, p5, p7, p10, p13, and p14) of the 12 participants who stated their opinions when questioned about the training's shortcomings said that the training was too short. Four participants, however, thought the training was excellent and had no complaints. One participant stated that it would have been preferable if it had been available to all senior trainees, whereas two participants disclosed that it was limited to bilateral cleft lip surgery.

When asked about what they would want to have before the training, three out of ten participants (p3, p4, p8) said that watching videos and reading before the conference were beneficial. Two (P5 and P12) stated that written modules were preferable. Additionally, the other pair of participants (p2 and p9) stated that it is preferable to assess trainees' competency and use greater adaptability as a real-life patient, which could reveal some dissection. In line with this, when participants were asked for additional comments or feedback, one participant (P9) insisted that it would be better to add more than one technique than cleft lip closure so that trainees could practice various techniques.

5.8. Relevance and impact on professional growth

Regarding the impact of the training on professional growth, three participants (p2, p12, and p13) revealed that it was very important, valuable, and fruitful as well. And P2 also added that it was helpful to understand how to do a bilateral cleft lip repair practically. All the participants found the simulator models to be user-friendly. As stated by participants (p3, p5, p8, p9, 10, p12, and p14), the reason behind this was that the simulator models were similar to the actual anatomy. Moreover, the procedure was easy to practice on simulator models (p2)

5.9. Data analysis and results

To assess the efficacy of training pre- and posttest scoring was conducted using skill categories and paired t-tests were used to assess significant differences. Finally, for measuring increment in skills usage from pre- to post-training, frequency of individual skills was used as the unit of measurement, and paired t-tests were used to assess changes in outcomes from pre- to post-training. Given that we conducted paired t-tests on 18 individual skills. The efficacy was

changed with adjusted mean difference (-4.39±SD 3.24 (-2.78, -5.99), $p<000$). This training provided significant change in all main domains of skills. Overall self-efficacy significantly improved [t (-5.75), df 17, $p < .001$] from pre (mean = 16.9, standard deviation = 3.76) to post-training (mean = 21.3, Standard Deviation = 1.97) (Table 3)

Table 3: Pre-Post comparison

Variable	Obs	Mean	Std.err.	Std.dev.	CI	DF	T value	P value
Pre	18	16.945	0.887	3.765	(15.07, 18.82)	17		
Post	18	21.334	0.464	1.970	(20.35, 22.31)	17		
Diff	18	-4.389	0.763	3.24	(-5.99, -2.78)	17	-5.75	0.00

Obs: Observation, Std.err: standard error, Std.dev: standard deviation, DF: Degrees of freedom, CI: Confidence interval

Chapter 6: Discussion

This study was done to assess the impact and effectiveness of the first simulator-based bilateral cleft lip training conducted in Ethiopia. As a result, the training resulted in a significant improvement in the confidence, Skill, knowledge, and ability of the participants involved in the study. Finding of this study is in line with the result of similar studies (Taché et al., 2009; Cheng et al., 2018; Borg et al., 2022; Elayah et al., 2023; Khoo et al., 2023; Zaga-Galante et al., 2024) done across the world particularly low-resource setting countries (Borg et al., 2022) where simulator-based cleft lip and palate training resulted in a significant confidence, skill and knowledge improvement among surgical trainees filling the gap of trained cleft surgeons.

In similar studies (Mulliken, Wu and Padwa, 2003; Podolsky *et al.*, 2018; Xue, Buchanan and Hollier, 2022; Khoo *et al.*, 2023; Zaga-Galante *et al.*, 2024), vital requirements for bilateral cleft lip repair such as confidence to perform the procedure, and surgical skill level, saw the biggest improvement overall which supports the hypothesis that targeted simulator-based training can refine surgical skills. This was reported from our study participants that the simulator-based cleft

lip training significantly helped them improve their surgical skills, confidence, and professional development when doing bilateral cleft surgery.

The training workshop not only improved the participants' skills, knowledge, and attitude but also contributed to their overall professional development as different participants expressed their desire for more frequent simulations. This indicates the training impact on creating future leaders in their respective fields particularly cleft surgery. In relation to this, about 72.2% of the participants were unaware of even a smile train simulating medical cleft models before. Thereby the training gave chance for those participants to get to know the importance and implications of these newly innovative devices.

Many participants indicated that the training helped them to have experience and confidence, and they also enjoyed it a lot. This might be due to the practical and realistic nature of the training, as it had been witnessed by many participants. This explanation reflects findings from a previous study, where surgeons valued the simulator's realism and anatomic accuracy as a training tool.(Mulliken, Wu and Padwa, 2003; Khosla *et al.*, 2012; Stefanidis *et al.*, 2015; Diaz-Siso *et al.*, 2016; Cheng *et al.*, 2018; Rogers-Vizena *et al.*, 2018; Khoo *et al.*, 2023)

Different procedural techniques such as marking, dissecting the nasal septum to create the nasal floor, identifying the mucoperiosteal flap pedicle, suturing, nasal wall or floor reconstruction, and difficulty and confusion in cartridge, base, and headlamp components were explained during the training. In addition, fragility and prolabium detachment of the simulator were also raised as challenges to carrying out simulator-based surgery on the simulators. Previous studies(Khosla *et al.*, 2012; Palter and Grantcharov, 2014; Stefanidis *et al.*, 2015; Podolsky *et al.*, 2018; Zaga-Galante *et al.*, 2024) also declared the drawback and challenges of simulators when it comes to lip repair particularly bilateral cleft lip.

Bilateral cleft lip repair is challenging to perform. Therefore, the realistic and comprehensive nature of the simulator, which incorporates prolabium and lateral lip elements, complete nasal anatomy, including the nasal cartilages, and integration within a bony soft tissue construct, provides a valuable training experience specific to bilateral cleft lip repair techniques. This includes marking, handling, and dissection of the prolabium, creation of a labial sulcus over the premaxilla, as well as the user's ability to perform closure of the mucosa and muscle over the

premaxilla and suturing the skin of the lateral lip elements to the prolabium. This problem may also be raised by the participant's increased tension when bringing the mucosal and skin edges of the lateral lip elements over the premaxilla, resulting in synthetic tissue tearing.

The training was received well by the participants. However, there were some shortcomings raised by the trainees that needed to be addressed. Video demonstrations, reading materials, and access to written modules for the participants may further enhance the training effectiveness. Moreover, participants expressed dissatisfaction with the training's limited time and least involvement of residents implying that, multiple training sessions should be organized to maintain an optimal outcome. More residents and recent graduates of plastic surgery should be included in such workshops in order to transfer knowledge through hands-on training.

Strengths and limitations of the study

This is the first study conducted in Ethiopia considering simulation-based bilateral cleft lip repair. Pre-post training assessment was done to evaluate the efficacy improvement among participants. A paired t-test was conducted to test statistically significant improvement. However, the study had its own limitations, like small sample size; the simulator itself does not bleed, and this likely represents additional challenges to using both systems on a live patient, and there is a lack of a comparison group of trainees who received standard bilateral cleft lip surgery training. Furthermore, there is no standardized training protocol for bilateral cleft lip surgery, and the amount of hands-on experience that trainees pursue varies widely depending on the institution.

Chapter 7: Conclusion and recommendation

This study is the first of its kind in Ethiopia and it showed a positive, immediate and sustained impact of simulator-based training on key and core surgical skills improvement in bilateral cleft lip repair. Evaluating the efficacy of the training is essential for providing targeted, constructive feedback to residents. Simulator-based bilateral cleft lip repair training play a crucial role for the PRS trainee's efficacy improvement. The paired t-test result indicated statistically significant

difference observed for efficacy improvement after the workshop was conducted. The implication behind this study is that curriculum developers and relevant stakeholders including non-government organizations should strongly consider such kinds of training and help the concerned health workers by providing training to improve their readiness to manage bilateral cleft lip repair.

DECLARATION OF THE PRINCIPAL INVESTIGATOR

This is to certify that the research thesis entitled “Assessment of the Impact and Efficacy of The First Simulator-Based Bilateral Cleft Lip Repair Training Conducted in Ethiopia”, submitted as partial fulfillment of specialty in Plastic and Reconstructive Surgery at Addis Ababa University, is a record of my original work. I also agree to accept responsibility for the scientific, ethical, and technical conduct of the research project. The references used for this thesis proposal are properly cited, and the assistance I received has been duly acknowledged.

Name of the Student -----

Date -----

Signature-----

APPROVAL OF THE ADVISOR

I hereby certify that I have supervised, read, and evaluated this research thesis titled “Assessment of the Impact and Efficacy of The First Simulator-Based Bilateral Cleft Lip Repair Training Conducted in Ethiopia” by Dr. Dagmawi Geremew under my guidance, and I have recommended the thesis for oral defense.

Name of the Advisor 1----- Name of the Advisor 2-----

Date-----

Date-----

Signature-----

Signature-----

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Annexes

Pre-workshop Survey

Email-----

*** Indicates required question**

1. I am about to participate in the Simulare Medical _____ workshop. *

- ☐ Bilateral Cleft Lip
- ☐ Alveolar Bone Graft

[Please select the best category]

My level of experience, by title, is: *

- ☐ Medical student
- ☐ Resident or up to 5 years as a resident
- ☐ Junior fellow or less than 10 years of experience
- ☐ Mid-career surgeon or 10-20 years of experience
- ☐ Experienced surgeon or 20+ years of experience
- ☐ Experienced surgeon who trains residents, surgeons, or both with 20+ years of experience

Other:

2. How confident are you overall in performing the surgical repair in this workshop? *

- ☐ Not at all confident
- ☐ Somewhat confident
- ☐ Confident
- ☐ Very confident

3. What is your surgical skill level in performing this type of repair? *

- ☐ No skill whatsoever
- ☐ Below average skill
- ☐ Average skill

- ☐ Above average skill
- ☐ Expert-level skill

4. Do you worry that something will go wrong when performing this type of repair? *

- ☐ Constantly worry
- ☐ Sometimes worry
- ☐ Occasionally worry
- ☐ Often worry
- ☐ I do not worry at all

5. Do you feel anxiety about performing this type of repair? *

- ☐ Constant anxiety
- ☐ Some anxiety
- ☐ Occasional anxiety
- ☐ Frequent anxiety
- ☐ Never anxiety

6. Based on your current performance, would you prefer to avoid doing this type of repair altogether? *

- ☐ Definitely avoid
- ☐ Sometimes avoid
- ☐ Occasionally avoid

- ☐ Often avoid
- ☐ Never avoid

7. How comfortable are you with independently planning and marking a cleft lip and palate repair? *

Very uncomfortable

Uncomfortable

Neither comfortable nor uncomfortable

Comfortable

Very comfortable

8. How comfortable are you with independently executing a cleft lip and palate repair? *

- ☐ Very uncomfortable
- ☐ Uncomfortable
- ☐ Neither comfortable nor uncomfortable
- ☐ Comfortable
- ☐ Very comfortable

9. Based on your training to date, how comfortable are you with independently performing a cleft lip and palate repair? *

- ☐ Very uncomfortable
- ☐ Uncomfortable
- ☐ Neither comfortable nor uncomfortable

- Comfortable
- Very comfortable

10. How comfortable are you when you think about performing the surgical repair in this workshop? *

- Very uncomfortable
- Uncomfortable
- Neither comfortable nor uncomfortable
- Comfortable
- Very comfortable

Post-Workshop Survey

Trainees - Simulare Medical

Thank you for providing feedback about your workshop experience. This survey will take about 6 minutes to complete. Your responses are anonymous and are used to improve the training delivery.

* Indicates required question

The Simulare Medical Workshop that I just completed was the _____ session*

Cleft Palate

Unilateral Cleft Lip

Bilateral Cleft Lip

Alveolar Bone Graft Morning Session

Alveolar Bone Graft Afternoon Session

Other:

Workshop Evaluation

Please select the most appropriate response for each question.

The workshop content was: *

	Strongly Disagree	Disagree	Agree	Strongly Agree
Relevant				
Comprehensive				
Easy to understand				
Useful				

Please add comments about the workshop experience as a trainee:

The workshop session covered relevant surgical content. *

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly Agree

The workshop session provided engaging practical learning experiences. *

- ☐ Strongly Disagree
- ☐ Disagree

- ☐ Agree
- ☐ Strongly Agree

The length of the workshop session was: *

- ☐ Adequate
- ☐ Too short
- ☐ Too long

Rate each of the following based on your observations during the workshop: *

	Strongly Disagree	Disagree	Agree	Strongly Agree
The model provided a realistic simulation of the procedure.				
The model durability was of high quality.				
The workshop level of difficulty was sufficient.				
The workshop was educationally				

valuable.				
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The workshop session achieved the intended learning objectives. *

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly Agree

What is your rationale for the ranking above? Please share any suggested improvements for the next workshop -----

I would recommend this workshop to a colleague who needs training or practice. *

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Agree
- ☐ Strongly Agree

Briefly, what did you like most about the session, and why?

Briefly, what did you like least about the session, and why?

Reflect on something you wish you would have known prior to the workshop. How could Trainees be better prepared to participate in this session?

Do you have any additional comments or feedback?

Trainer, Proctor, and Self-Assessment

Your confidence performing this procedure...*

	Poor	Fair	Good	Excellent
before the workshop was:				
after the workshop is:				

Are you proficient enough to train or serve as a workshop proctor in your region? *

- ☐ Yes
- ☐ No

The workshop Trainer during this session was: *

	Strongly Disagree	Disagree	Agree	Strongly Agree
Knowledgeable				
Well-prepared				
Responsive to questions and comments				

What component, if any, caused confusion or failed during the workshop?

	Base	Headlamp	Cartridge	Surgical device	Other
Caused confusion					
Failed					

Did you know about the Smile Train Simulare Medical cleft models before this workshop? *

- ☐ Yes
- ☐ No

If yes, how did you hear about them?

Do you find the simulator models to be user-friendly? *

Yes

No

Why do you find /not find the simulator models to be user-friendly?

Which option(s), if any, made it difficult to perform simulated surgery on the simulators? Select all that apply: *

- ☐ The silicone material was fragile or tore too easily
- ☐ It was difficult to differentiate between the muscles
- ☐ The surgical area was too narrow
- ☐ N/A: I had no difficulties
- ☐ Other:

Please provide any other suggestions about how the simulator or training experience could be improved

Please leave your name and email address if you'd like us to follow up or would like to become involved in the training, research & innovation, or curriculum development realms.
