A High Fidelity Cleft Lip Simulator

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Background: Cleft lip surgery is technically difficult requiring precise planning and understanding of 3-dimensional structures to obtain an optimal outcome. A physical cleft lip simulator was developed that allows trainees to gain experience in cleft lip repair and primary rhinoplasty before operating on real patients.

Methods: A cleft lip simulator that comprises multilayered soft tissues, bone, and realistic dissection planes was developed using 3D printing, adhesive and polymer techniques. Four experienced cleft surgeons performed a total of 7 simulated repairs on the simulator. Feedback on the realism and value of the simulator was obtained from the surgeons.

Results: Six of the repairs were a Fisher anatomic subunit approximation technique, and 1 was a rotation advancement repair. All repairs were completed with successful performance of markings, incisions, dissections, and multilayered closure. All surgeons agreed that the simulator is realistic and that the simulator is a valuable tool for training in cleft lip surgery.

Conclusions: A cleft lip simulator that allows performance of a cleft lip repair and primary rhinoplasty from start to finish was developed and pilot tested. The simulator provides a training platform to gain experience in cleft lip repair before operating on real patients.

INTRODUCTION

Cleft lip surgery is technically demanding, has a steep learning curve, requires understanding of subtle techniques and dimensions and complex 3-dimensional anatomy. As a result, cleft lip surgery is a suitable procedure for the use of a surgical simulator for training.1,2 Several cleft lip simulators have previously been developed as both virtual and physical models with various levels of fidelity and ability to perform the steps of cleft lip surgery.3,4 However, none allow performance of a cleft lip repair procedure in a realistic physical environment from start to finish. A high-fidelity bench top cleft lip simulator was developed and tested that allows performance of a unilateral cleft lip repair and primary cleft rhinoplasty procedure.

METHODS

The cleft lip simulator (Figs. 1–3) was developed from segmentation of a computed tomography scan of a left unilateral cleft lip and palate patient. The computed tomography scan served as a template for extensive computer modeling to develop multilayered, anatomically accurate bony and soft-tissue structures. Skin, subcutaneous tissue, muscle, cartilage, and bone were developed with different material properties (durometer, tear strength) to match tissue feel during dissections, incisions, and tissue manipulation. Table 1 describes the components and features of the simulator.

Four expert cleft lip surgeons (> 100 previously performed repairs) performed a total of 7 simulated cleft lip repairs using real surgical instruments. Six of the repairs were a Fisher anatomic subunit approximation technique,5 and 1 was a rotation advancement repair. A primary cleft rhinoplasty was performed at the same time of the lip repair for all simulation sessions.

Disclosure: The cleft lip simulator is available commercially and sold by Simulare Medical Corp. (Toronto, Ontario, Canada). Drs. Podolsky, Fisher, Wong, Drake, and Forrest are each shareholders of Simulare Medical Corp. The Article Processing Charge was paid for by Simulare Medical.

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RESULTS

All steps of the respective cleft lip repair techniques were successfully performed by all participants for all simulation sessions.

The overall steps of the repairs included:

1. Marking and taking measurements of the medial and lateral lip elements skin, vermillion, and mucosa (see video, Supplemental Digital Content 1, which demonstrates highlights of performing the lateral lip markings. This video is available in the Related Videos section of the Full-Text article at PRSGlobalOpen.com or at http://links.lww.com/PRSGO/A823).

2. Incising through skin, subcutaneous tissue, orbicularis oris and mucosa on both lip elements removing lip marginal tissue (see video, Supplemental Digital Content 2, which demonstrates highlights of incising and removing marginal lip tissue. This video is available in the Related Videos section of the Full-Text article at PRSGlobalOpen.com or at http://links.lww.com/PRSGO/A824).

3. Releasing the orbicularis oris muscle from the surrounding soft tissue.

4. Repositioning of the nasal septum over the anterior nasal spine.

5. Upper buccal sulcus incision to release the accessory cartilage/lower lateral cartilage and investing fascia from the piriform rim allowing the cleft side nose to move anteriorly (see video, Supplemental Digital Content 3, which demonstrates highlights of repositioning the nasal septum and nose. This video is available in the Related Videos section of the Full-Text article at PRSGlobalOpen.com or at http://links.lww.com/PRSGO/A825).

6. Internal nasal valve plication and alar transfixion sutures.

7. Making a vermillion triangle to address the vermillion height deficiency.

8. Closure of the mucosa.

9. Closure of the muscle.

10. Closure of the skin (see video, Supplemental Digital Content 4, which demonstrates highlights of skin closure. This video is available in the Related Videos section of the Full-Text article at PRSGlobalOpen.com or at http://links.lww.com/PRSGO/A826).

Qualitative feedback from the surgeons was positive with respect to the simulators realism and anatomic accuracy. All participants agreed that the simulator is a valuable training tool, that use of the model will increase resident and fellow competency of performing a cleft lip repair and that they would be interested in using the model to train residents and fellows.

DISCUSSION

Surgical simulators allow less experienced trainees and surgeons to progress along the learning curve without compromising patient outcomes. Cleft lip repair 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. Therefore, practicing cleft lip repair techniques on a model may minimize surgical errors on real patients.
The cleft lip simulator comprises detailed, accurate anatomy and multi-layered tissue planes that allow a complete end-to-end unilateral cleft lip repair using real surgical instruments. Feedback from its use were overall positive with respect to its realism, anatomic accuracy, and value as a training tool. The simulator is a platform to allow surgeons and trainees to practice cleft lip surgery and for experts to assess competence and eventually proficiency before operating on real patients.

The cleft lip simulator cartridges are disposable and cost around $250 per use. The simulator is complex due to the fidelity of the components. However, the training experience is extensive, given the inclusion of its many features that are necessary to provide a truly valuable

Table 1. Features and Components of the Cleft Lip Simulator

| Bone          | Soft Tissue                | Cartilage                  | Surface Features                  | Dissection Planes              |
|---------------|----------------------------|----------------------------|-----------------------------------|-------------------------------|
| Palate        | Nasal mucosa               | Upper laterals             | Philtral columns                  | Skin-subcutaneous tissue      |
| Alveolus      | Oral mucosa                | Lower laterals             | Cutaneous roll                    | Subcutaneous tissue-muscle    |
| Piriform apert | Vermillion                | -Middle                    | Nostril sil                       |                                |
| Anterior nasal spine | Orbicularis oris (within subcutaneous tissue/skin/mucosal envelope) | -Medial crura                  | Soft triangle                    | Nasal mucosa-septal cartilage |
| Concha        | Subcutaneous tissue        | -Lateral crura             | Accessory cartilage               | Noordhoff’s point             |
|               | Skin                       | Septum                     | Vermillion-mucosal junction       | Vermillion-cutaneous junction |
|               |                            |                            | Cupids bow                        |                                |
learning opportunity. In contrast, virtual simulators allow repeat repairs at no cost with lower fidelity and the absence of operating within a tactile environment. A future study is required to compare the efficacy of these 2 modalities and to determine how they may complement each other in providing a rich training experience.

Although not performed, more extensive primary rhinoplasty procedures including nostril rim incisions, medial and lateral nasal approaches should be possible, given the accuracy of the simulators anatomy.

A future study will perform a more comprehensive assessment of the simulators ability to improve technical performance in cleft lip repair techniques. As we move to more competency-based surgical training models, simulators provide a platform for real time feedback and intervention to ensure skill level reaches minimum requirements before operating on real patients.

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