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Design and fabrication of a generic 3D-printed silicone unilateral cleft lip and palate model

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Summary The complexity of plastic surgery procedures often requires visualization of the anatomy in three dimensions and therefore demands the development of new and innovative teaching methods. This work describes the development and manufacture of a 3D silicone cleft lip and palate (CLP) model evaluated by surgical residents on its similarity to the biological model.

Thirty unilateral CLP models were created and distributed to residents at two different institutions. The model was based on an adult CT scan that was manipulated to resemble an infant with a complete unilateral CLP. This digital model was directly printed in silicone elastomer pieces and later assembled. The residents rated the model based on its realistic value as well as whether or not they felt it improved their surgical technique.

Twenty residents used the model to simulate a CLP repair. The structure of the model was rated as fairly realistic while both the material and assembly of the model require improvement in subsequent manufacturing. Post simulation, residents rated the model highly for how accurately it simulated the surgical procedure.

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An accurate 3D silicone unilateral cleft lip and palate replica was successfully created for educational purposes. This new approach combines a flexible generic design with automated manufacture.

Introduction

In recent years, the use of three-dimensional (3D) printed anatomical models has increased. 3D-printed models have previously been used to visualize pathology based on patients' radiological imaging data, but they lacked the ability to adequately recreate various tissue properties, which limited the use of these traditional composite 3D models. Accurate models are essential to surgical planning in a wide variety of fields and serve an increasingly important role in improving the technique of surgical trainees. This is particularly true for difficult procedures, rare pathologies, and when other training methods are limited. The advent of 3D printing of soft and elastic materials, such as silicone, provided an opportunity to manipulate hardness, elasticity, and other surface structures to create adequate replications of anatomic structures and tissue characteristics. This advancement also created the opportunity for these models to be used for surgical simulations.[1-10]

One procedure that has limited teaching methods is the repair of cleft lip and palate (CLP). CLP is one of the most common craniofacial anomalies affecting 1 in 700 infants.[1] However, traditional training for CLP currently relies solely on intraoperative teaching owing to the lack of cadaveric sources available. This has prompted a number of investigators to develop various models such as nonhaptic visual simulations, virtual-reality simulations, hard 3D models, and soft handmade or conventionally manufactured CLP models to increase technical skill preoperatively.[2-10] Although these options have useful applications, they have several limitations. One major limitation in the nonhaptic visual simulators is the inability for trainees to gain experience for the mechanical handling of tissues. Furthermore, the rigid 3D-printed models prove useful for only the visualization of the anatomy and have no use for practical applications. Handmade or conventionally manufactured silicone cleft models are more malleable than the rigid 3D models and can replicate multiple tissue types. However, they often require a substantial amount of time to produce. Therefore, the development of a realistic model that can be easily manufactured and utilized in educational settings is still necessary. The current study examines the practical applications of the first unilateral cleft lip and palate model completely 3D printed directly in 100% silicone elastomers with an accurate and flexible anatomic design that includes all tissue types encountered in the pathology.

Material and methods

Model generation

Initial segmentation and post-processing

Segmentation of a normal skull computed tomographic (CT) image data MW skull 1.0.0 from the medical image platform

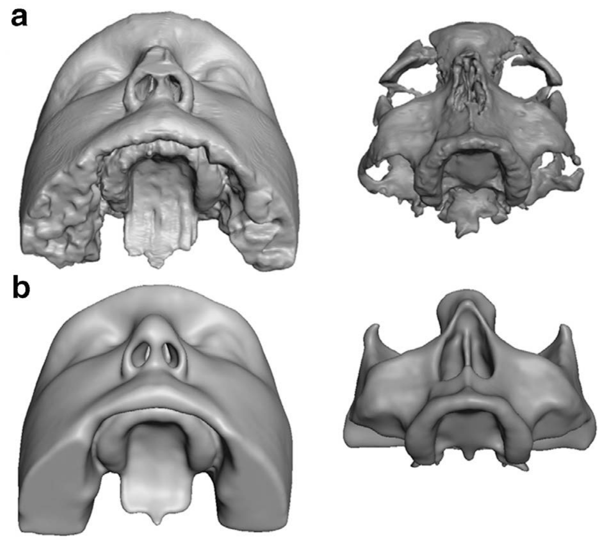

Figure 1 (a) Segmented model of soft (left) and hard (right) tissue, (b) Postprocessed models.

Embodi3D was used as the basis for the silicone CLP model (Figure 1(a)).[11] Using *Brainlab Elements (Brainlab AG, Munich, Germany)*, individual voxels on the CT scans were labeled based on the focus area, the jaw, and the grayscale value. For the CLP, two objects, namely, soft tissue and bone, were created. Digital post-processing was achieved with *Autodesk Meshmixer (Autodesk, Inc., San Rafael, CA, USA)* (Figure 1(b)). Subsequently, the soft tissue and bone were combined and cropped to display the anatomic region of interest. The boundaries of the combined model included the superior nasofrontal suture, inferior oral commissures, bilateral zygomas, and posterior uvula.

Model manipulation

Using the normal model, the size of the skull was scaled to the dimensions of a two-month-old infant by decreasing the length and width of the alveolar process by 45% and 70%, respectively. A mean value of 57% was used for the palatal depth.[12] The growing tooth system located in the tissue of the alveolar process was simulated using a manual inflation tool.

Photographs of clinical cleft defects were used as a guide to construct the cleft in the model. As the operative closure of the cleft lip and palate includes the connection of muscle and skin layers, the orbicularis oris, levator veli palatine, and tensor veli palatini muscles were modeled. The muscles extended approximately 1.2 mm from the outer contour and accurately depicted the muscle shape.

Preparation for manufacture

Unique anatomical elements were designed to be differentiated by different colors and Shore A hardness, a measure

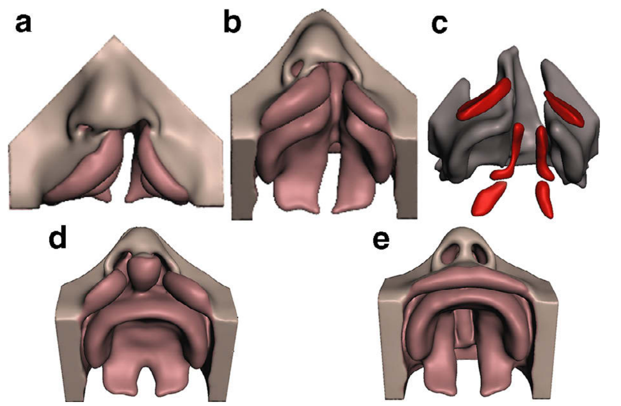

Figure 2 Digital model of a left-sided complete cleft through lip, palate, mucosa, and uvula; (a) frontal view, (b) view inside the mouth, (c) inside view picturing only the hard/bone model part (gray) and the muscles (red), (d) cleft lip, bilateral according to ICD-10-CM Q36.0 [12], (e) cleft hard palate with cleft soft palate according to ICD-10-CM Q35.5 [12].

of the malleability of soft elastomers. To prepare these anatomical elements for assembly, the interface between the bone and the surrounding tissue model was adapted and pockets for the muscles were created to be inserted within the soft tissue model postprinting. A minimum wall thickness of 1 mm was ensured to avoid holes in the printed model. After checking the surface network for errors and coarsing areas with low accuracy to reduce the computing intensity, all exported objects were transferred to the 3D printer. Figure 2 presents the assembled digital model of the continuous left CLP (Figure 2(a) and (b)) along with the eight-piece deconstructed model (Figure 2(c)) generated for this study. Using this technique, 19 different digital cleft models were constructed, including bilateral defects as well as isolated palate defects (Figure 2(d) and (e)).

Manufacture of the model

The models were 3D printed using the ACEO® Technology (Wacker Chemie AG, Munich, Germany), which uses a drop on-demand process for various 100% silicone elastomers with a layer-wise UV-curing of the silicone. All structures were manufactured separately. Bone was printed in white silicone (Shore A 60), muscles were printed in red (Shore A 10), and the soft tissue was printed in skin color (Shore A 10).

The printed model consisted of eight pieces: six muscles, one soft tissue, and one bone (Figure 3). To create the musculature of the lips, muscle pieces were inserted into the pockets created during the digital manipulation. The openings were then sealed with adhesive. As it is not yet possible to 3D print the mucosal layer with the appropriate softness, a manual approach was utilized, in which a red transparent mixture was applied to the model by adding a small dose of red dye to a 2-component silicone (Elastosil® P7670, Shore A 7). Next the model underwent a curing process, which was accelerated by an infrared lamp and lasted for 24 h. The final step consisted of a 4 h post-curing process at 200 °C, which fixated the coating layer to the model, removed volatiles, and finalized the mechanical properties of the silicone. Thirty of the finalized silicone haptic models (Figure 4) were produced and distributed for evaluation.

Figure 3 Eight separately printed parts of the model; left: soft tissue model, middle: hard tissue model, right: models of orbicularis oris, tensor veli palatini, and levator veli palatine.

Figure 4 Haptic silicone model of a left-sided complete cleft through lip, palate, mucosa, and uvula (soft tissue model: skin colored, hard/bone model: white).

Evaluation of the model

CLP models were manufactured and provided to surgical residents at the University of California, Los Angeles, and the University of Chicago to simulate a teaching scenario. These residents were instructed by their respective craniofacial surgery faculty members (JCL and RRR) on how to perform the CLP repair with the 3D silicone model. The residents completed a two-part questionnaire. Before the teaching session, information regarding the residents' surgical experience, experience with CLP repairs, and experience with artificial models was collected along with their first impressions of how realistic the dimensions, hardness, and elasticity of the model were. The second part of the questionnaire was distributed at the end of the teaching session and asked residents to evaluate the success at which they could cut, stitch, how realistic simulation was, and if their technique improved with the artificial model. Evaluations were scored on a Likert scale, with a higher score indicating a more realistic impression and better success

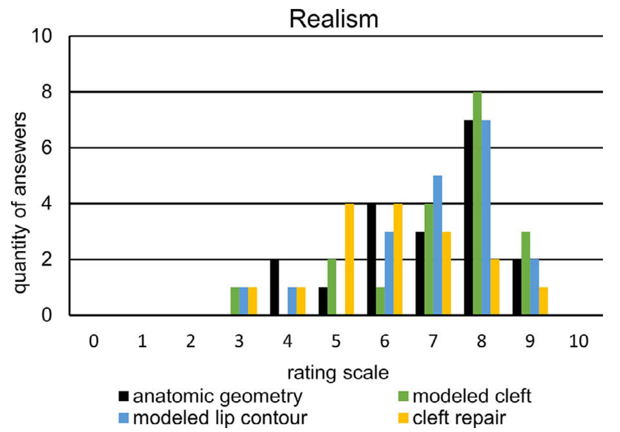

Figure 5 Realism of the anatomic geometry of the model, the modeled cleft, the modeled lip contour and the overall simulated cleft repair from 0 (not at all) to 10 (absolutely).

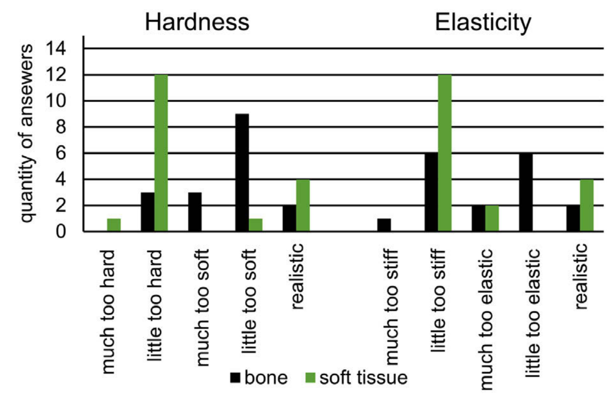

Figure 6 Rating of the hardness and elasticity of the bone and soft tissue model part.

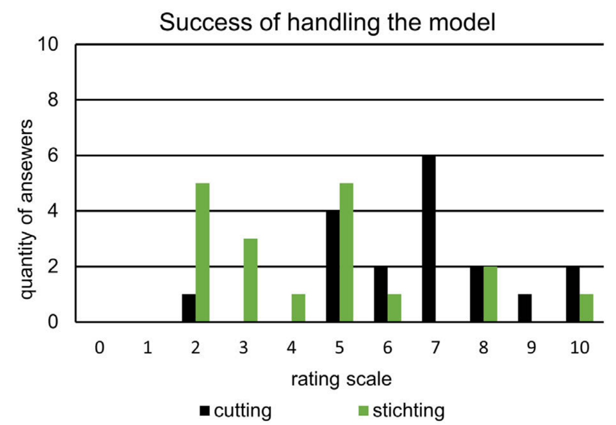

Figure 7 Success of handling the model concerning cutting and stitching on a scale from 0 (not at all) to 10 (absolutely).

with the model. All responses were kept anonymous and the mean values were derived.

Results

Resident background

Data were collected from 20 residents with an average postgraduate year level of 2.5 ± 1.6 years, during which these residents assisted on a mean of 5.8 ± 8.0 repair surgeries (range 0–30). Nine out of 20 residents trained on an artificial model before, from which three trained on an artificial cleft model. In general, 50% said there are no current training options for cleft repairs, 40% mentioned artificial models, and 15% human cadavers.

Evaluation of the model

Seventy-four percent of the participants rated the size of the model as realistic, 5% as slightly larger than expected, 21% as slightly smaller than expected than the anatomy of a 2- to 3-month-old cleft baby. Sixteen percent assessed the relative dimensions between the anatomical features of the model as perfectly right, 84% as almost right, and none as wrong. With regard to the geometry of the model overall, the cleft, and the lip contour, residents rated the overall dimensions of the model as 6.9 ± 1.5, the cleft as 7.3 ± 1.5, and the contour of the lip 7.0 ± 1.5 on a 10-point Likert scale, with 10 being identical to the expected anatomy of a 2- to 3-month-old cleft infant (Figure 5).

In terms of mechanical properties of the model, residents were asked to rate the hardness, elasticity, and handling of the model. Most residents (52%) rated the hard tissue as slightly softer than expected for bone and 67% rated soft tissue as slightly too hard (Figure 6). Concerning the elasticity of the bone the opinions split, 35% agreed that the model was slightly too stiff, while 35% thought it was slightly too elastic. For the soft tissue, 67% of residents rated the elasticity to be slightly too stiff (Figure 6). Because of the layering effects of the 3D printing process, the surface of the model is rougher than that of the conventional silicone parts. Forty-two percent of the residents rated the 3D-printed soft tissue surfaces as slightly too rough, 32% as sufficient, 16% as too sticky, 11% as realistic, and none as too smooth or considerably too rough. The results show that for 47% the roughness of the coated part was sufficient, for 26% too sticky, for 11% realistic, for 11% too rough, and for 5% considerably too smooth.

During the CLP repair simulation, 12 models sustained partial tears and avulsion of portions of the models occurred in 6. Two of the most common problems were that the orbicularis oris was pulled out of the soft tissue during suturing and that the material snapped back to strongly (Table 1). Overall, 83% of the participating residents stated that they could successfully repair the cleft. The feedback when cutting the model was assessed at 6.7 ± 1.9 and for stitching at 4.4 ± 2.3 (Figure 7). Concluding, the residents rated the surgical simulation on the model a score of 6.1 ± 1.5 in accuracy to their personal experience in unilateral cleft lip repair (Figure 5). Furthermore, all of the residents indicated that use of the model improved their surgical technique. Figure 8 shows a successful repair of the cleft lip on the silicone model.

Table 1 Problems that occurred during the trial surgery.

Problem		Quantity
Model separated into parts		6
Material was too elastic to mimic soft tissue behavior/went back to original form too fast		11
Parts were not enough attached to each other		2
Unplanned cracks occurred		12
Other	tears with suture, orbicularis kept tearing, difficult to rotate, a little to stiff, difficult to replicate pliability of normal tissue, upper lip element on non-cleft side was too small	

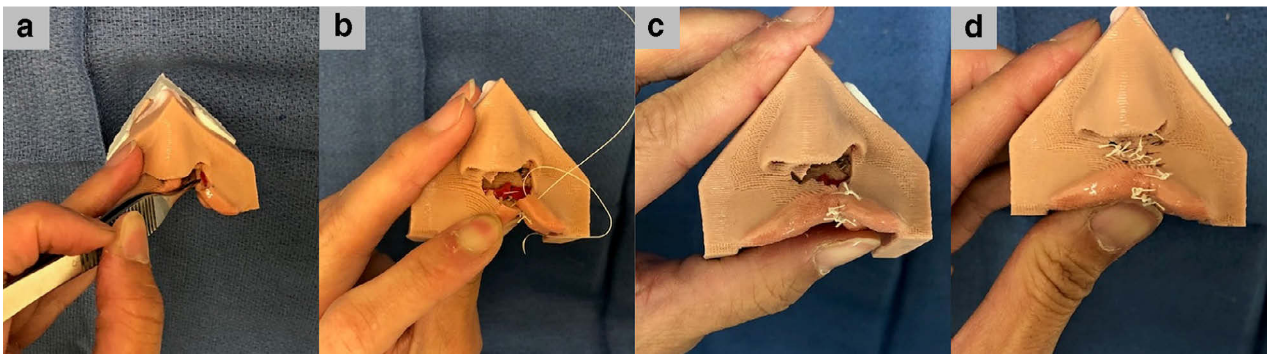

Figure 8 Repair of a cleft lip on the silicone model (a) opening of the skin, (b) stitching of the muscle tissue (red layer) and the lip, (c) reconstruction of the lip contour, (d) successfully repaired cleft lip.

Discussion

The goal of the current study was to create and evaluate a simple 3D-printed, haptic training model for the repair of a complete left-sided cleft lip and palate. The initial digital model was based on the CT scan of a single healthy adult that was then mathematically manipulated to fit the dimensions of an infant with CLP. This study was able to alter that single scan to model all of the defects listed in the ICD-10-M system.[13] However, the use of a single scan could have resulted in certain discrepancies in the measurements between the artificial model and an actual CLP patient.

As compared to other current haptic models, the current study presents a more extensive model that consists of the full geometry and multiple anatomical parts.[3-5,7,8] Despite its complexity, the digital manipulation of this model is faster and more flexible than other models such as the *High-Fidelity Cleft Palate/Lip Simulator*.[6,9,10] This makes it better suited for educational purposes because its generic design can be adapted to fit a multitude of individualized haptic models (Figure 2(d) and (e)). Different colors and Shore A hardness of the silicone elastomers can also be exchanged with minimal effort to generate the various models.

With regard to the manufactured model used in this study, there was an overall positive response and it was rated as having relatively realistic dimensions. However, there is need for improvement. For example, some residents noted that the lip and nasal area were too thin compared to those of a CLP patient. This could be improved with the addition of more material or multi-material printing to create a more accurate representation of the nasal area and flap technique. Furthermore, residents suggested more pliable materials for the skin and muscle and for more differentiation in the coloration of the mucosal layer and the white roll of the lip to gain better orientation. Another issue was the lack of adhesion between the various pieces. For example, the muscles would frequently detach during the dissection, which made the surgical process too simple. However, recent improvements in elastomer printing allow for simultaneous multi-material printing, which would generate a cohesive model and eliminate the need for post-processing assembly. Despite these limitations, all residents in this study felt that they benefited from the silicone model and that their surgical technique improved. This evidence supports the use of artificial models in teaching labs and emphasizes the need to create a more cohesive and efficient 3D-printed model of CLP to improve the education of our surgical residents. The possibility of producing the whole model automated in one 3D print creates benefits toward the other soft complex CLP models, which use multiple manufacturing techniques in a more complex process.[6,9,10]

Conclusion

The current model was based on CT data, generically manipulated and printed with silicone elastomers of different colors and Shore A hardness. It requires various manufacturing improvements, but the efficient process of creating a detailed representation of a cleft lip and palate with multiple anatomical components is promising for educational purposes. This study also demonstrates the model's potential to improve surgical technique and skill.

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