



Modernizing Geppetto's Workshop: Predicting Aesthetic Outcomes Of 3D-printed, Patient-specific Dorsal Nasal Implants Utilizing A Novel Imaging Protocol

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PURPOSE

To develop a low-cost, rapid protocol for the design and production of custom-fabricated dorsal nasal implants

BACKGROUND

- Craniofacial augmentation is a common surgical procedure.**² Indications vary widely, from correction of dramatic congenital, oncologic, or traumatic anatomical insults to elective aesthetic enhancement (Figure 1)
- Autologous or allogeneic augmentation is suboptimal.** While surgeons can utilize autologous tissue or cadaveric grafts to restore and reshape facial contours, the technical expertise, obligatory donor site morbidity, and careful shaping required of allografts have resulted in strong preference for synthetic implants^{3,4} (Figures 2-3)
- Off-the-shelf implants do not account for patient-specific anatomy.** Individual anatomical variations routinely require crude implant reshaping on the day of surgery, considerably limiting predictability of cosmetic outcomes⁵ (Figure 3)
- Rapid, inexpensive method of custom implant fabrication would attenuate such concerns.** We have developed a novel, low-cost protocol for precise, 3D preoperative imaging to allow for fabrication of customized, biodegradable dorsal nasal implants that addresses the issues associated with industry-standard implants

METHOD

- Generation of facial mannequin.** De-identified computed tomography (CT) data from a facial bones scan was used to provide “ground truth” patient anatomy and reveal all relevant bony landmarks (Figure 4)
- Fabrication of facial mannequin.** Using these data, 3D models of the subject's skull and soft tissue were 3D-printed with polylactic acid (PLA) on a Prusa i3 3D printer (Prusa Research a.s., Prague, Czech Republic) (Figure 5) and cast in silicone, respectively. In union, these components created a “face phantom,” which was then imaged to generate a 3D point cloud and mesh model utilizing commercially available photogrammetry software (Agisoft Metashape v1.7)
- Design and fabrication of custom-designed dorsal nasal implant.** Desired augmentation was determined via virtual deformation of this model. A corresponding, custom-designed dorsal nasal implant was 3D-printed in PLA, implanted on the phantom, and reimaged as above
- Appraisal of fidelity to expected parameters.** To demonstrate fidelity, the photogrammetrically-derived model with and without augmentation was co-registered and compared to CT-derived “ground truth.” A deviation < 1 mm was regarded as cosmetically insignificant

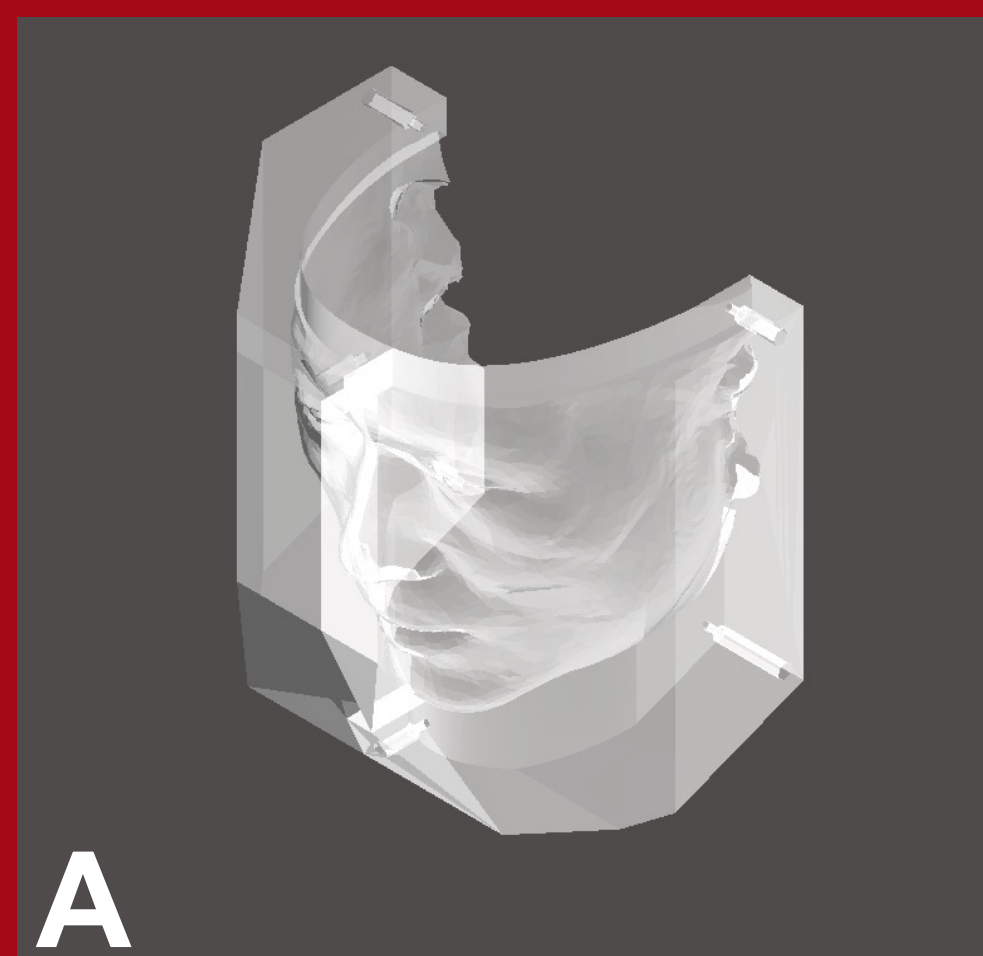


Figure 4A | Virtual schematic of the negative soft tissue facial mold generated from patient CT data as captured by 3D printing software (Autodesk Meshmixer v3.5)

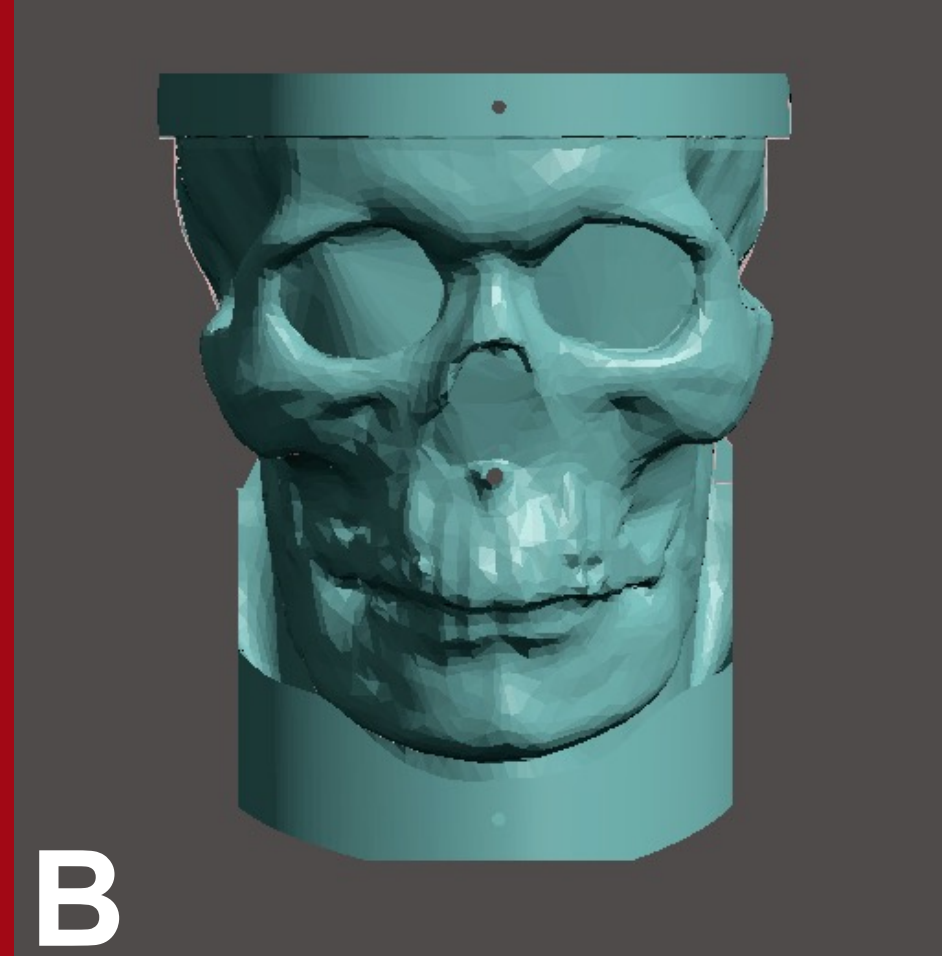


Figure 4B | Virtual schematic of the bony skull generated from patient CT data as captured by 3D printing software (Autodesk Meshmixer v3.5)



Figure 4C | Virtual schematic of anatomic union between soft tissue and bony facial components generated from patient CT data as captured by 3D printing software (Autodesk Meshmixer v3.5)



Figure 4D | Resulting “face phantom” consisting of a cast silicone soft tissue model (Ecoflex Super Soft Platinum Silicone, Macungie, PA) placed upon a PLA-printed bony skull base

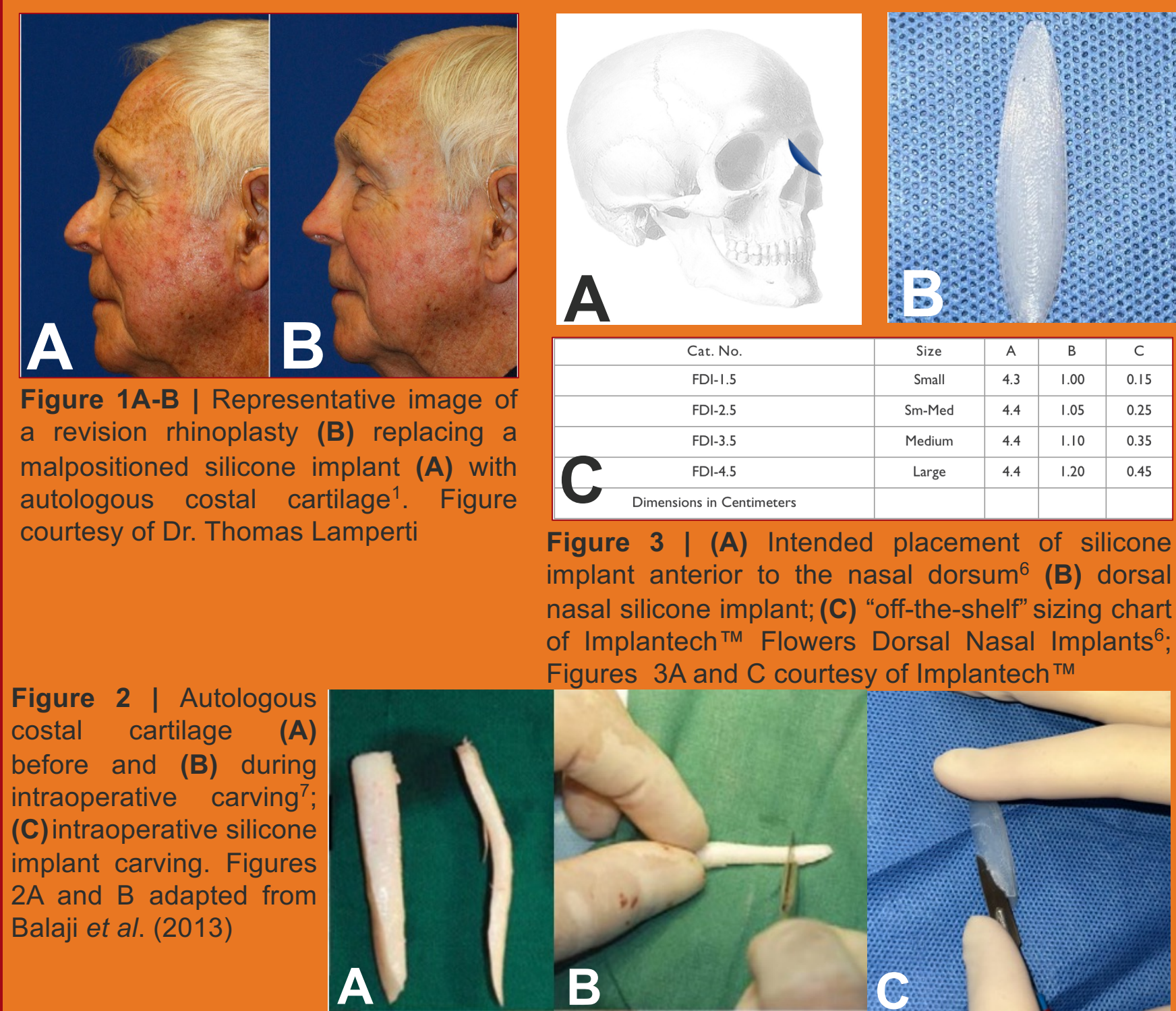


Figure 1A-B | Representative image of a revision rhinoplasty (B) replacing a malpositioned silicone implant (A) with autologous costal cartilage¹. Figure courtesy of Dr. Thomas Lampert

Figure 2 | Autologous costal cartilage (A) before and (B) during intraoperative carving¹; (C) intraoperative silicone implant carving. Figures 2A and B adapted from Balaji *et al.* (2013)

Cat. No.	Size	A	B	C
FDI-1.5	Small	4.3	1.00	0.15
FDI-2.5	Sm-Med	4.4	1.05	0.25
FDI-3.5	Medium	4.4	1.10	0.35
FDI-4.5	Large	4.4	1.20	0.45

Figure 3 | (A) Intended placement of silicone implant anterior to the nasal dorsum⁶; (B) dorsal nasal silicone implant; (C) “off-the-shelf” sizing chart of Implantech™ “Flowers Dorsal Nasal Implants⁶”; Figures 3A and C courtesy of Implantech™

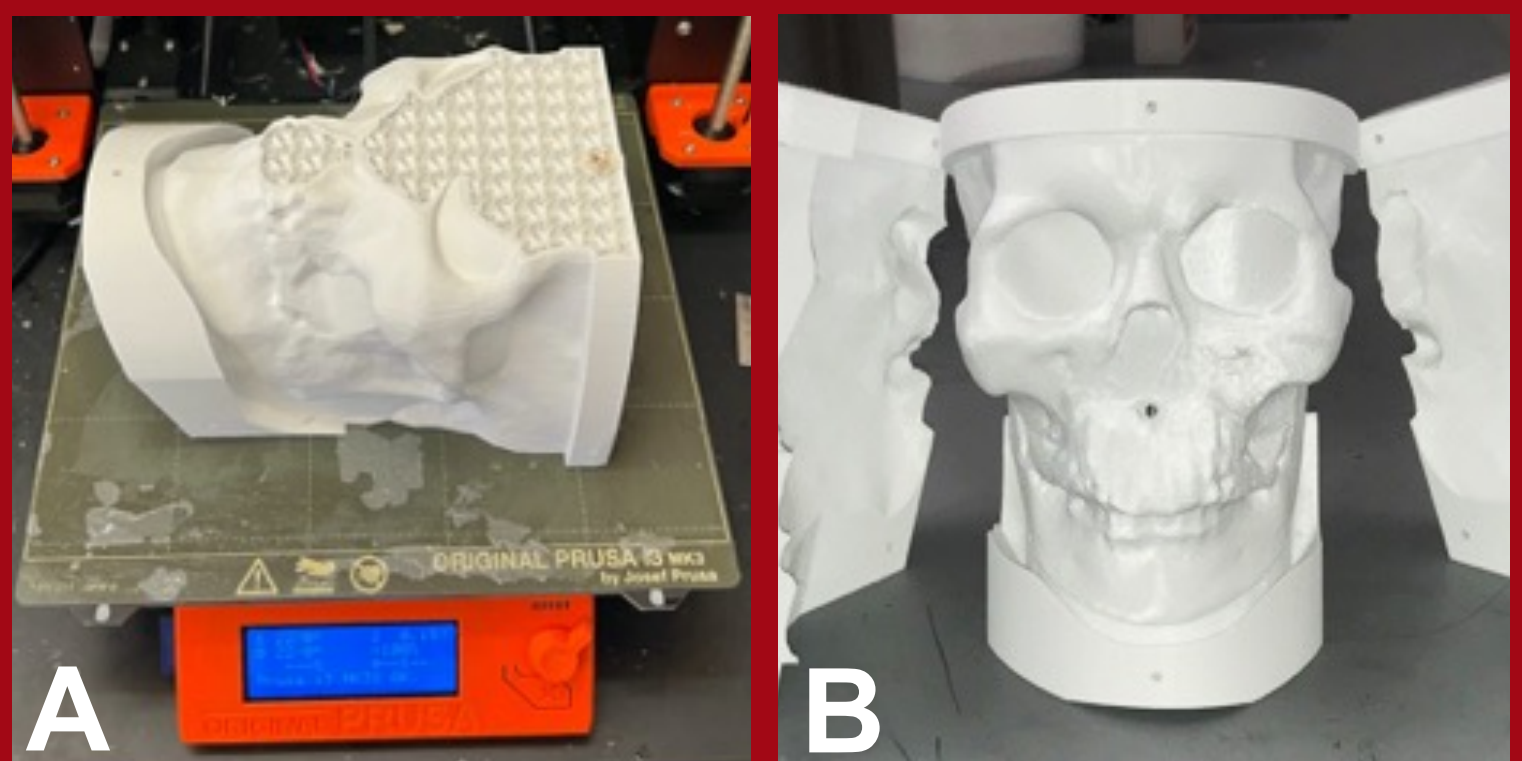


Figure 5 | (A) In progress 3D-print of bony skeleton and (B) complete 3D-printed bony skeleton (soft tissue PLA molds seen on extreme sides)

RESULTS

- High quantitative fidelity between expected and actual facial anatomy.** Photogrammetric assessment of fidelity between baseline “ground truth” CT data (Figure 6A) and the 3D photograph (Figure 6B) revealed an average Hausdorff distance of 0.198 mm (95% 0.640 mm) with a Dice coefficient=0.989
- Heatmap analysis demonstrates congruence of anatomic contours in all key facial areas.** Subsequent heatmap analysis demonstrated high congruence in all relevant anatomical areas of interest (Figure 6C)
- High fidelity between expected and actual augmentation after sub-silicone implant placement.** Dorsal nasal augmentation revealed an average Hausdorff distance of 0.381 mm (95% 1.56 mm; Dice coefficient=0.978) compared to “ground truth” CT data. Comparison between expected and actual augmentation revealed an average Hausdorff distance of 0.276 mm (95% 1.24 mm; Dice coefficient=0.985), with variation noted exclusively along the nasal dorsum as expected (Figure 6D)

Figure 6A | Virtual schematic of expected “ground truth” patient anatomy generated from patient CT data

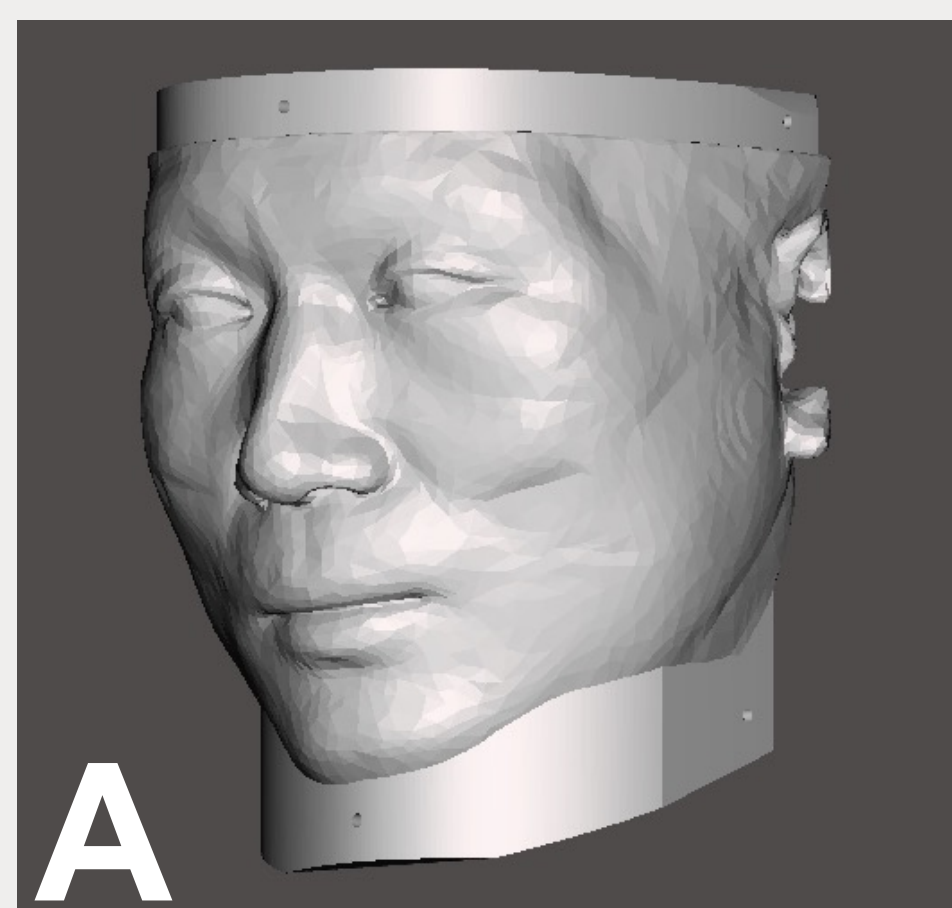


Figure 6B | Resulting captured 3D photograph of the completed facial mannequin consisting of the silicone cast soft tissue component overlaid upon the PLA-printed bony face

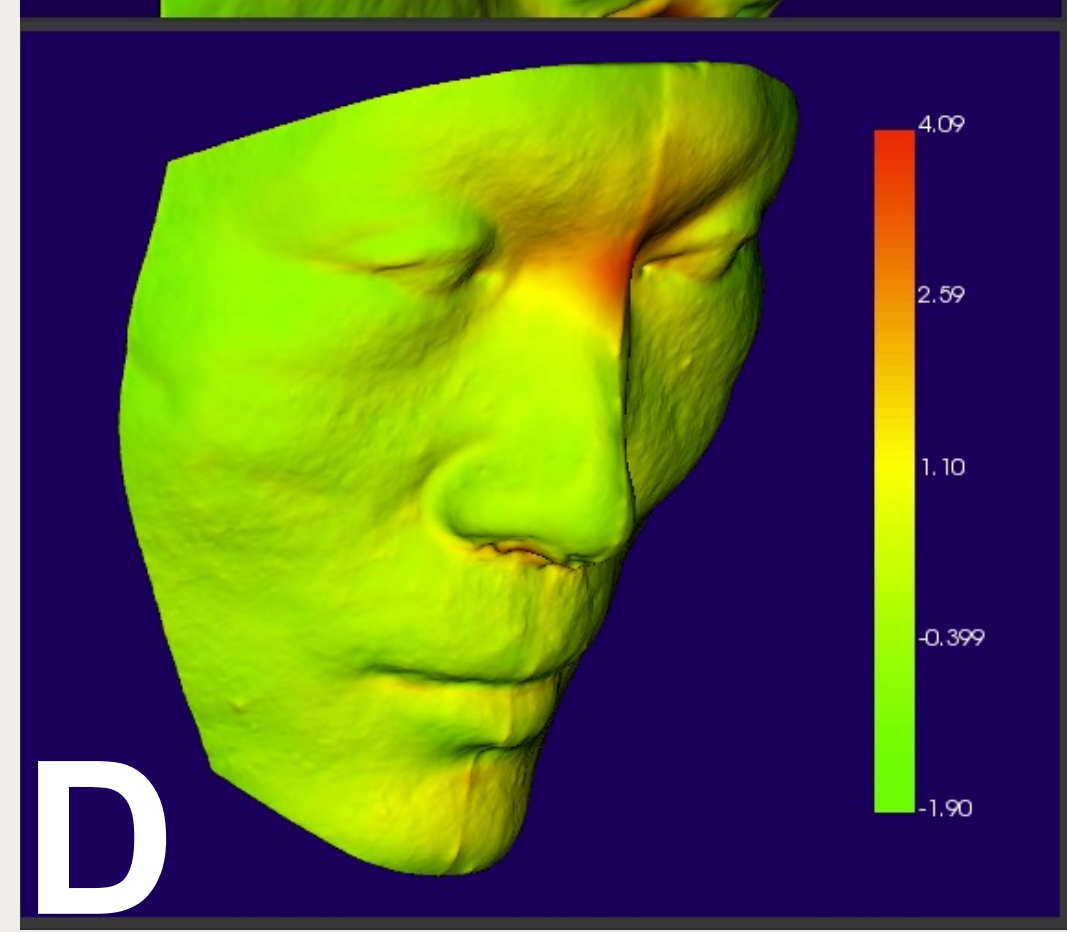
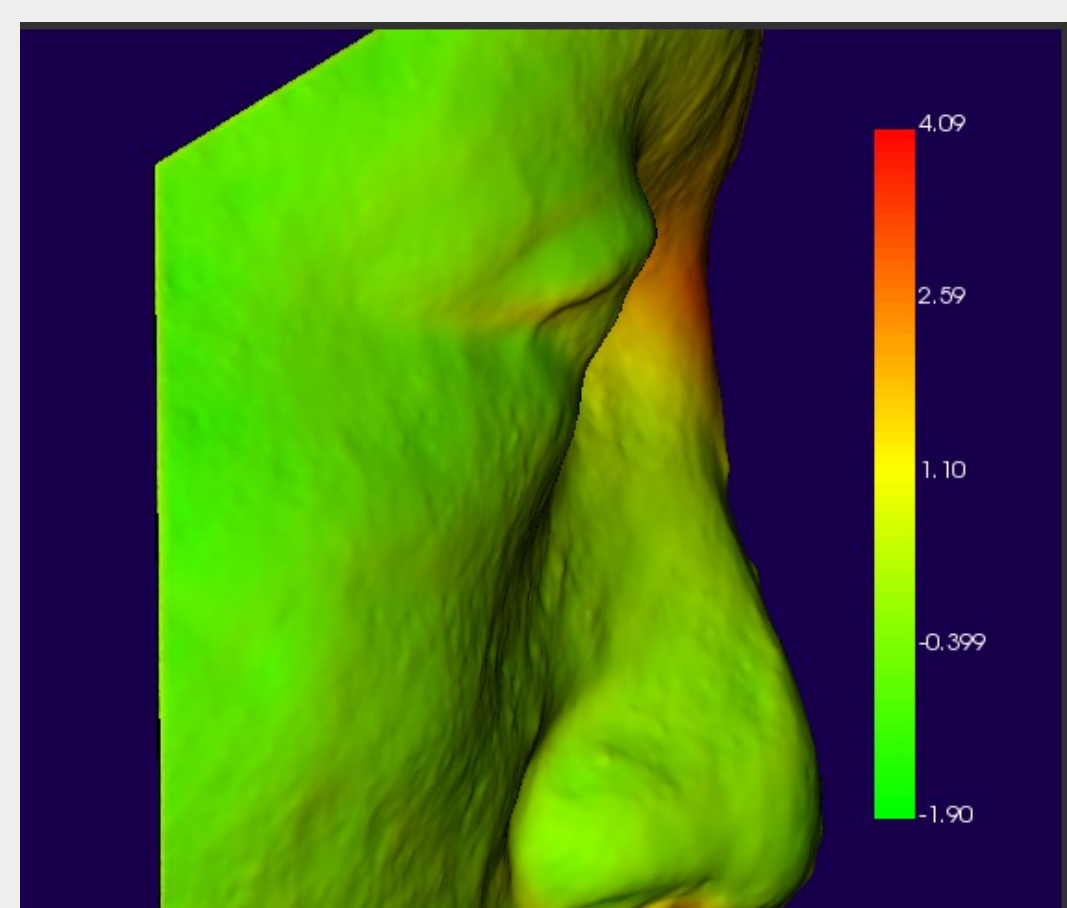
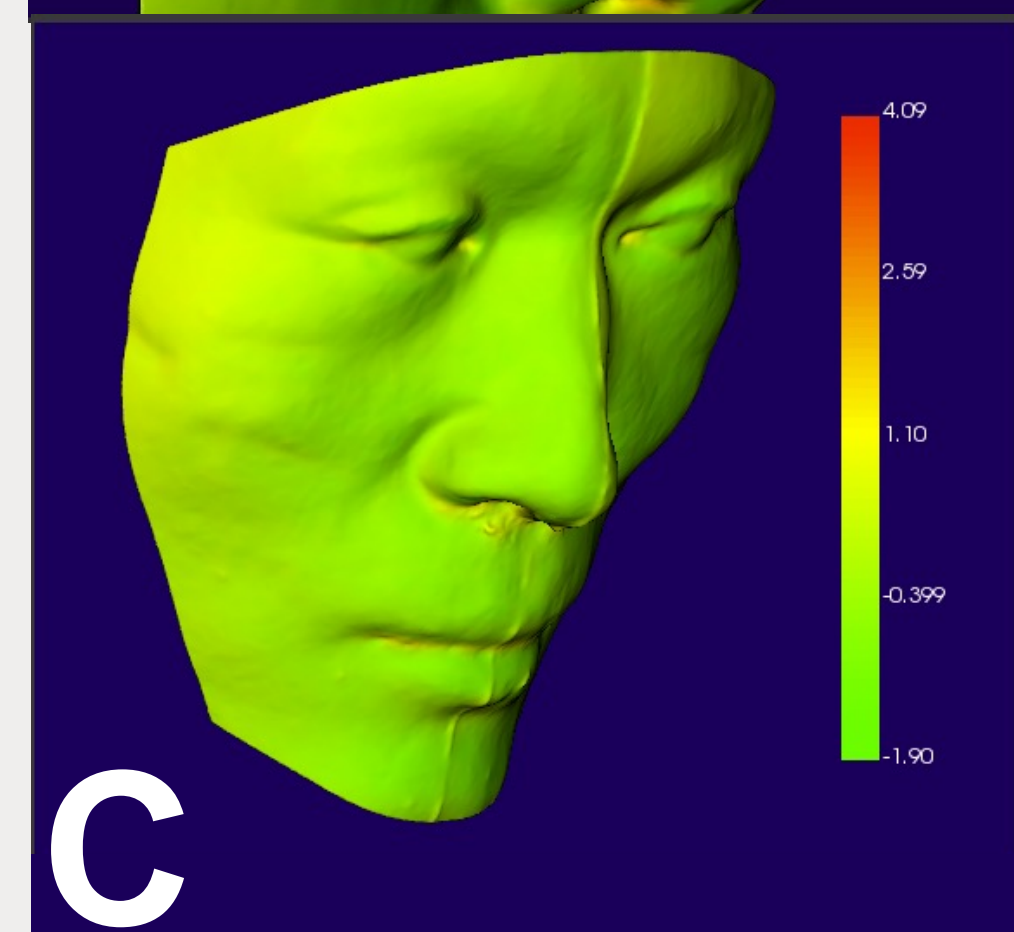
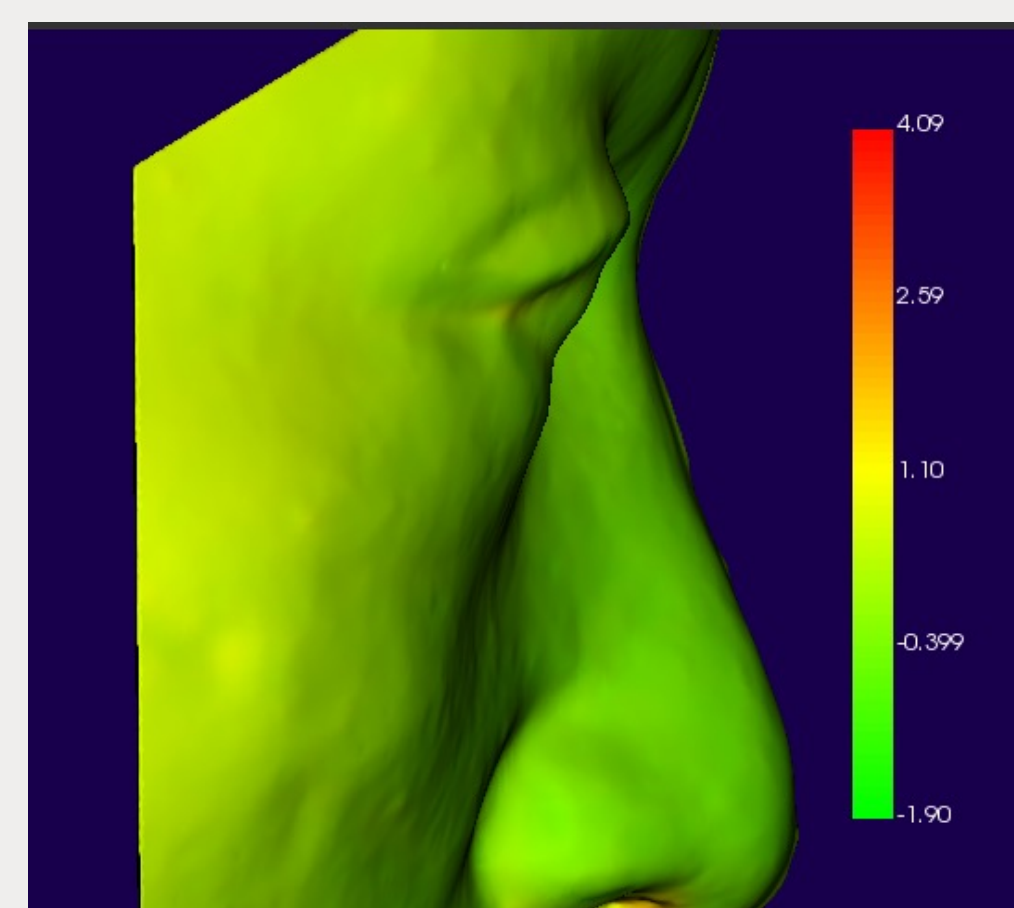
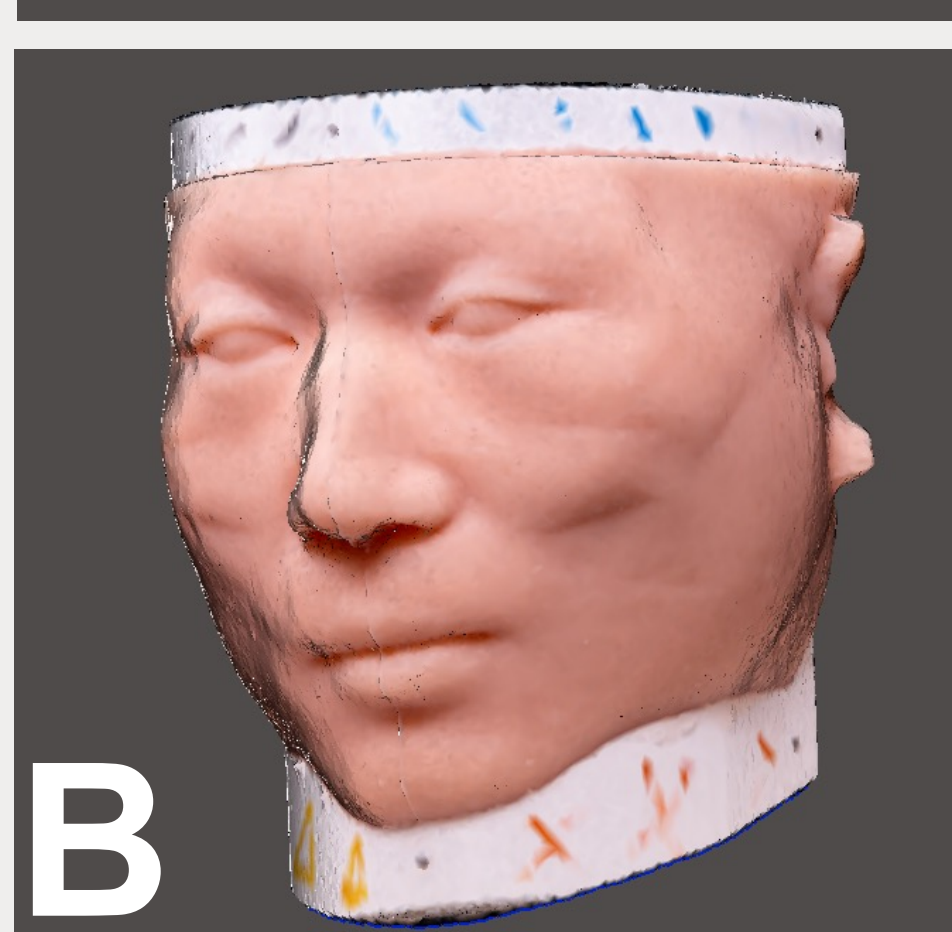


Figure 6C | Heatmap analysis demonstrating congruence (green) and deviation (red) between the anterior anatomical face of the “ground truth” idealized model (Figure 6A) and the 3D photograph of the facial mannequin (Figure 6B)

Figure 6D | Heatmap analysis demonstrating congruence (green) and deviation (red) between the anterior anatomical face of the “ground truth” idealized model (Figure 6A) and the 3D photograph of the facial mannequin (Figure 6B) after customized dorsal nasal silicone implant placement

CONCLUSIONS

- Our imaging protocol produces a highly accurate means of capturing critical facial anatomy necessary for design of custom-fabricated dorsal nasal implants**
- Production of a rapidly producible, biocompatible, custom-fabricated implant holds considerable potential to benefit the field of craniofacial surgery**
- Use of implants that are nonimmunogenic, long lasting through integration and fabricated to each patient's anatomical need will dramatically reduce patient operative morbidity and indications for revision, and produce a highly satisfactory aesthetic result**

FUTURE DIRECTIONS

- Demonstrate generalizability to other soft tissue and bony facial structures.** Custom-print chin, submalar, and temporal implants and assess for fidelity, with in-house genial deformation of CT data shown in Figure 7
- Translate protocol to human subjects.** Placement on cadaveric subjects is a necessary next step and will confirm protocol success and provide an efficient and efficacious alternative to the currently limited options for craniofacial augmentation

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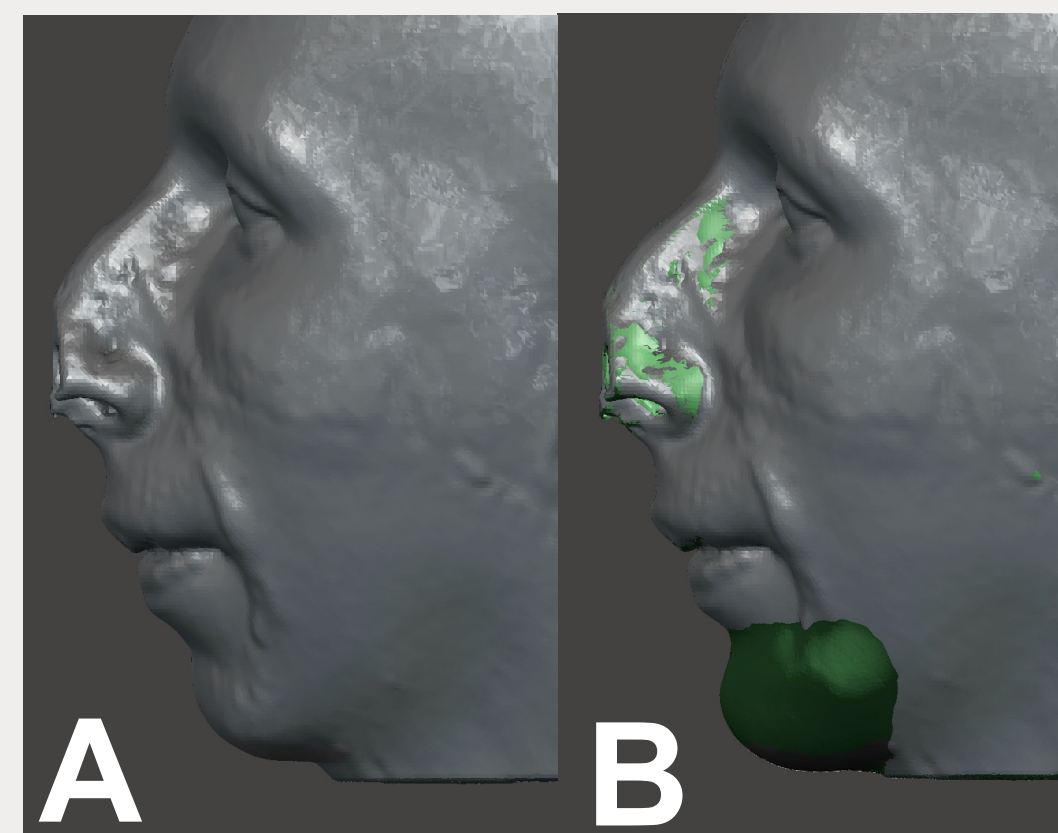


Figure 7 | Cone-beam CT-derived skin surface model of patient with micrognathia (A) before and (B) after in-house deformation by a plastic surgeon