Digitization of Nonsurgical Intervention for Neonates with Cleft Lip/Palate and Robin Sequence

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Background

- Cleft Lip and/or Palate (CLP) affects approximately 1 in 700 newborns[1], and Robin Sequence (RS) affects approximately 1 in 8500 newborns. RS results in a partially obstructed airway that poses significant risk to the infant[2].
- Nasoalveolar molding (NAM) and Orthodontic Airway Plate (OAP) are accepted nonsurgical devices used to delay or eliminate surgery in infants with CLP and RS, respectively.
- Mandibular Distraction Osteotomy is used in around 75% of Robin cases and is traumatic for the patient. OAP is used in ~1% of cases (estimates by Dr. Choo).
- Current production of orthodontic devices requires significant specialist time (14+ hours), which limits availability of non-surgical treatment.

Objectives

- Primary: Evaluate the feasibility of replicating handmade NAM and OAP orthodontic devices with 3D printed devices.
- Secondary: Explore existing tools and develop methods to translate clinical knowledge into an all-digital workflow

Methods

- ASTM D790 flexural tests were performed on Lucitone Digital Print (LDP) and hand cured dental Acrylic (PMMA) standard test specimens (.125 x .5 x 5 inch).
- PMMA specimens were molded using a milled .125 inch thickness aluminum mold. PMMA was added by clinician and cured to their specifications while clamped pressed between two borosilicate glass sheets, as demonstrated in Fig. 1. Any warping away from the mold was refilled and recured until dimensions were flat and square. Specimens sanded lengthwise by hand with 120 and 800 grit sandpaper to size.
- Carbon M2 CLIP printers prepared multiple orientations of LDP specimens, shown in Fig. 2. Standard layer thickness was used in all cases. All post processing and curing was done to the exact specifications of Dentsply Sirona, the manufacturer of the resin. Horizontal prints used Carbon release film due to large surface area.
- 5 PMMA and 15 LDP tests (5 of each print orientation, fig. 2) were performed at .01 mm/min and .1 mm/min strain rates. Specimens were bent to failure or until 12mm displacement using a standard 3-point bend on an MTS Criterion 42 with a 5kN load cell, as shown in figure 3. Results of testing are shown in figure 5.
- 4 MicroCT scans of identical orthodontic devices (handmade vs. 3D printed from scan 3Shape E4 desktop) and D790 specimens were performed to compare the porosity of both materials as shown in figure 4.

Results and Figures

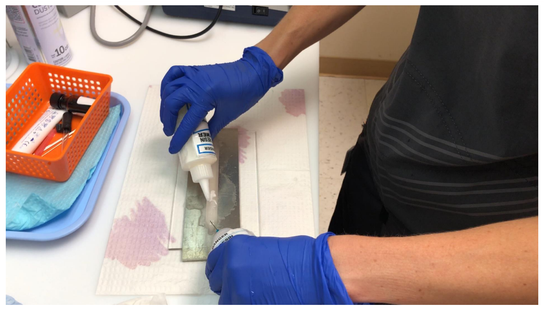

Figure 1: Mold used to cure (and recure) PMMA used for traditional devices

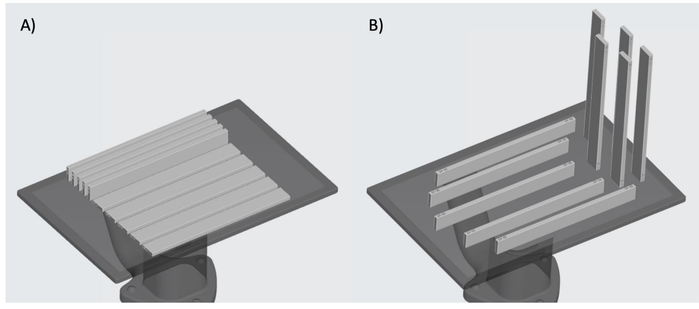

Figure 2: Each print orientation of LDP. A) Edge and Horizontal B) Edge and Vertical

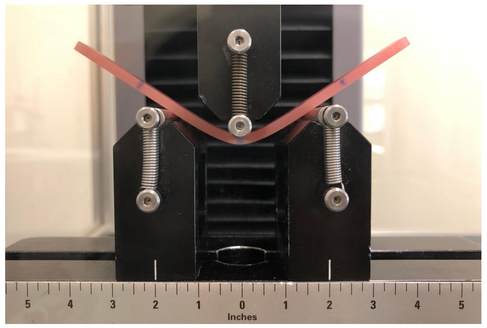

Figure 3: MTS 3-point bend shown after reaching maximum test displacement for LDP (12mm)

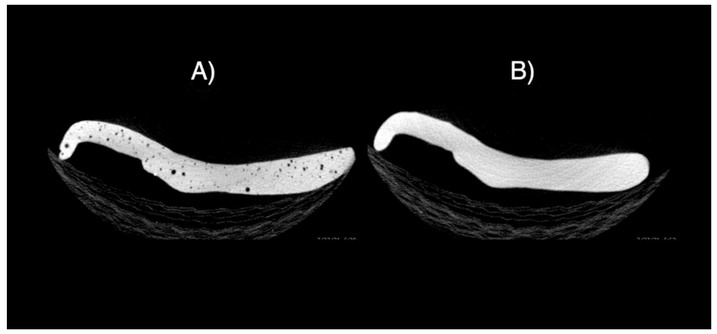

Figure 4: Cross sectional view of identical NAM device models scanned with MicroCT to compare porosity. A) PMMA handcrafted device. B) LDP 3D printed copy from surface scan of A.

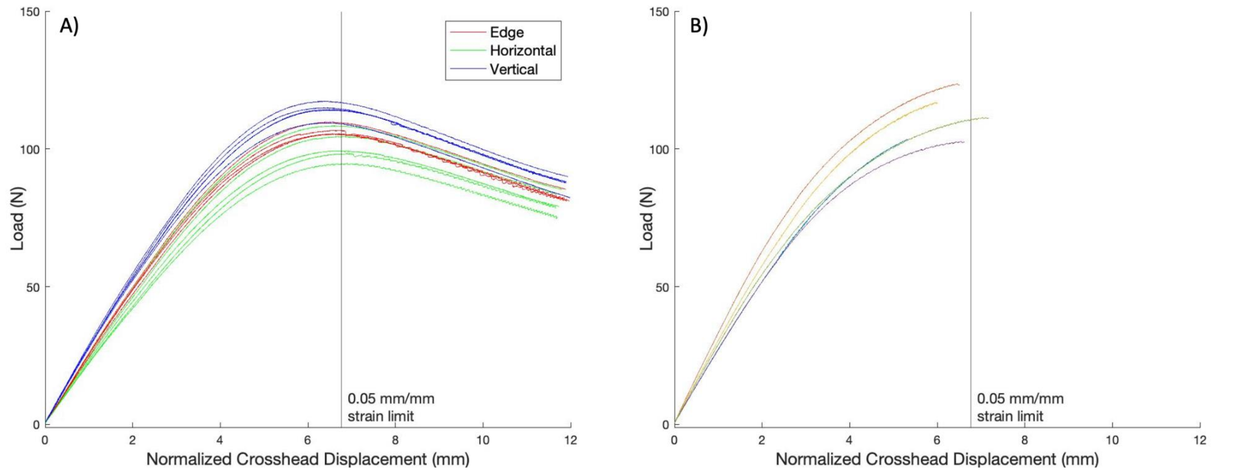

Figure 5: ASTM D790 flexural testing performed at .01 mm/mm/min. The .05 mm/mm strain limit is where D790 is valid. A) 15 LDP 3D printed standard tests, 5 per print orientation noted in legend. B) 5 PMMA hand-molded tests, sanded to standard thickness.

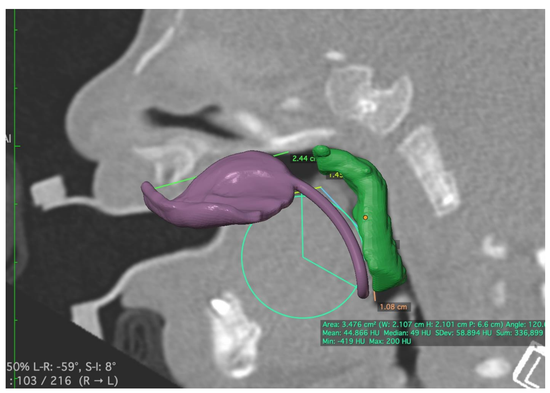

Figure 6: Device designed completely digitally in Blender. Purple is digitally designed device, green is model of constricted airway extracted from CT scan .

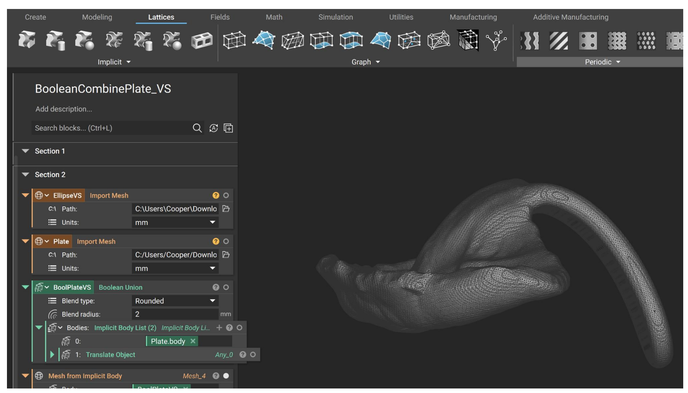

Figure 7: Complex boolean merge of two separately designed models in nTopology. Replicating this process in Blender will allow in-house, open-source opportunities to scale software to handle many custom designs.

Methods cont.

- Blender, an open-source modeling software, was used to digitally design orthodontic devices using only a scan of a mouth model. The resulting design is shown in purple in figure 6.
- nTopology was used to perform complex modeling operations in a repeatable and easily manipulated manner. The final Boolean merge of two models is shown in figure 7.

Limitations

- 3D printed specimens are repeatable. Traditional material cannot be repeatably molded in a matter consistent with clinical use. Confidence in data reported for PMMA is low.
- Digital design must be automated to save clinician time.

Discussion

- Materials testing indicates comparable material properties for 3D printed devices. Ultimate strength is comparable, although the PMMA is difficult to mold, so the data has a larger spread. Additionally, LDP does not shatter after yielding, and thus will be safer than PMMA. More PMMA testing is needed with a more even and repeatable molding and/or sanding process. However, inconsistent molding and testing may mirror inconsistent properties in handmade devices.
- Porosity in LDP devices is essentially nonexistent. Porosity in PMMA is irregular. More CTs are needed to quantify this, and we must locate a DICOM reading tool for volume analysis.
- *Digital design of NAM and OAP devices is feasible. However, automating/simplifying the process while maintaining quality remains to be realized.* Our current digital workflow is on track to reduce provider time by 7x.

Future Directions

- Retest PMMA once a better molding technique is developed.
- Rerun the ASTM tests at body temperature to see changes in strength and rigidity.
- Quantify porosity with medical software.
- Automate design software for printing alongside clinical treatment to allow accurate and precise printed devices.

References

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2. Bush PG, Williams AJ. Incidence of the Robin Anomalad (Pierre Robin syndrome). Br J Plast Surg. 1983 Oct;36(4):434-7. doi: 10.1016/0007-1226(83)90123-6. PMID: 6626822.

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