Spring 2023

Enhancing Dental Aligners with Direct 3D Printing Manufacturing

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Directly 3D Printing Dental Aligners for Cleft Lip and Palate

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I. *Abstract*- Infants born with cleft lip and palate typically have a hole in the roof of the mouth and an incomplete gum line. This condition can cause issues with tooth formation, eating, speaking, hearing, and frequent ear infections. The current treatment options include multiple surgeries between birth and turning 18 to fully correct the defect. Additionally, a nasoalveolar molding, NAM, device can be used to move the gum lines together similar to a dental retainer. The current process of creating a NAM aligner with thermoformed plastic is expensive and time consuming. By directly 3D printing an aligner the cost and post processing time is dramatically reduced.

Index Terms:

Nasoalveolar molding device also known as a NAM aligner is a nonsurgical device that through a series of sequences moves the gum line to close the gap in patients with cleft lip and palate.

T***hermoformed aligner*** describes the traditional way NAM aligners are created. This device is currently made using a piece of plastic that is stretched and heated on a mold under pressure to the desired shape of the mouth.

MeshMixer is a free software that was used to edit the models of the aligners before they were sent to be printed out. It is available online.

FMEA stands for Failure Mode and Effects analysis and takes the form of a table. It is used during the design process of medical devices to analyze potential failures and their underlying causes as well as corresponding solutions.

II. Introduction

Around 1,600 infants are diagnosed with cleft lip and palate every year in the United States. This defect is essentially a hole in the roof of the mouth and an incomplete gum line which can cause issues with tooth formation, eating, speaking, hearing, and frequent ear infections. Current options for treatment include multiple surgeries between birth and turning 18 to fully correct the defect. Nasoalveolar molding aligners are patient specific and are being researched to decrease the impact of cleft lip and palate and to reduce the number of surgeries needed to improve the childrens' lives. The goal of this project is to improve upon existing aligners via bypassing post 3D printing and finishing techniques to deliver a product without compromising current aligner properties. Currently these aligners are thermoformed in a process similar to Invisalign products. There are no current patents on the market for direct 3D printed dental aligners which is the product of this project.

III. User Needs

Developing a clear understanding of the medical problem is the first step in establishing the user's needs. Our project deals with week old babies who have a severe face and mouth deformities, known as cleft lip and palate. Often this is the parents first child who will have to endure extensive surgeries and treatments. Knowing these factors aids in the design and application of the device. After talking with our clinicians Dr. Nick Kochenour and Dr. Niyant Patel, the goal of the project became clear. Directly 3D print plastic aligners, also known as nasoalveolar devices (NAM), so that parents and patients will visit treatment centers less often. On average the treatment centers are 60 miles away and

families must travel to them once a week. By providing multiple NAM devices to the patient the family should be able to visit less frequently while receiving the same standard of care. Additionally, these 3D printed aligners should be approximately 1 mm in thickness. Combining all these factors should significantly reduce the financial burden on the clinician side and therefore the patient side. These requirements provide the basis for user needs.

IV. Design Inputs

This project had several goals split into three broad categories; Material, Process, and General requirements as outlined in phase 1 of the QFD and Engineering Requirements table; see Tables 1 and 2 of the appendix. The material requirements were standard for this type of device in that the material must be 3D printable, stress and crack resistant, and biocompatible. The process requirements are the chief objectives of this project and follow as: quick printing, bypassing thermoformed print moldings, and accurate printing with a target of 1mm thickness. The combination of the requirements from the material and process categories are the engineering requirements that are based on the more general objectives of the project; those being reducing visitations, lowering costs, and reducing processing/finishing time. A concept FMEA was developed with these project requirements in mind as outlined in Table 3; see appendix. Potential failure modes were analyzed with respect to potential causes, engineering requirements, and potential solutions to derive a comprehensive list of research and manufacturing steps to ensure the project was successful. Material testing procedures were based on ASTM standard D638 for tensile testing and D790 for 3-point bend testing as outlined in Table 4; see appendix. Material property analysis was based on ISO standards for toxicity (ISO-10993-11), sensitizer/irritancy (ISO-10993-10), and medical device standards (EN-ISO-13485:2016 and EN-ISO-14971:2012) as outlined in Table 5; see appendix.

V. Design Process

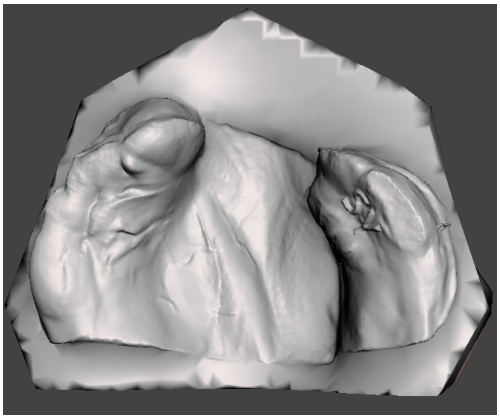

Figure 1: 3D mold of an infant with cleft palate's gums used for the creation of NAM aligners.

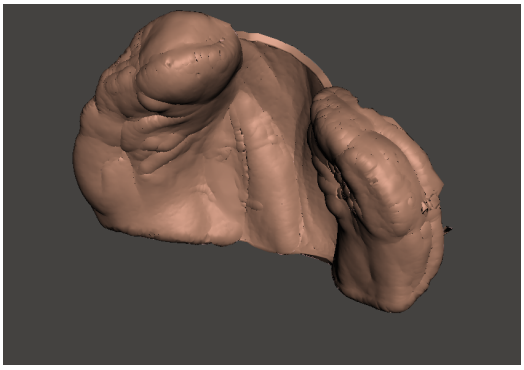

Figure 2: 3D model of the NAM aligner used for direct 3D printing.

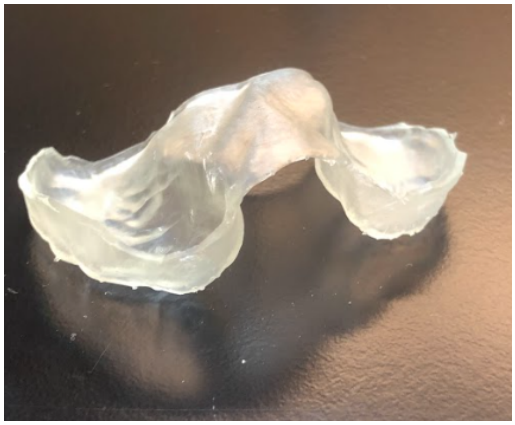

Figure 3: First 3D printed NAM aligner that was printed for validation testing.

Due to the nature of this project, the outcome is not based upon a singular product but rather the success and viability of a process. Proof of concept through a successful print demonstrates the viability of the process and the completion of the project's goals. The major components used for this project were a Form 3+ 3D printer, Dental LT Clear

V2 Resin 1 L, and a Resin Tank v2.1. All engineering requirements can be directly correlated to the material that was chosen for the aligners, Dental LT Clear V2 Resin. Additionally, along with the printing of the physical aligner, the addition of a “button” to allow for the easy installation and maintenance of the aligner.

VI. Design Outputs

The main design outputs consisted of the chosen material as well as the 3D models. After researching and selecting the Dental LT Clear V2 Resin, material testing was performed to ensure the material specifications met the customer and engineering requirements. From the design process, the 3D models were created using a test material and the verification plan and procedure were utilized to verify the accuracy of the model and the overall response from the direct 3D printed aligner. Figure 2 and Figure 3 represent the single model given to us by one of our mentors, Dr. Nick Kochenour, and the final product able to be produced via the direct 3D printing process. The bill of materials for this project was limited to two items, a 1 liter tank of Dental LT Clear V2 Resin as well as a new resin tank for the Form 3+ 3D Printer. The total costs of these purchases was $500, our limit for the project.

VII. Design Verification

To verify the design parameters, various tests were performed. For the material specifications, a tensile test and 3 point bending test were performed. For the tensile test, ASTM D638 standard was used. Similarly, the ASTM D790 standard was used for the 3 point bending test. Additionally, to check the printer accuracy, a test was designed and executed. Using a thin coat of paint on the inner wall of the molding and a 3D printed model of the NAM defect as a reference, the printer accuracy was checked to ensure the major points of contact matched. The series of tests performed should result in an accurate comparison between the currently used thermoplastic and the Dental LT Clear V2 Resin. Table 6 of the appendix represents the numerical data collected from verification testing for both thermoplastic and printed material samples. The engineering requirements, Table 1 of appendix; target achieved column was primarily a result of the data collected from the verification testing. A short summary of engineering requirements completed is listed below in Table 1-1.

Category	Targets Achieved
Material	4/4
Process	3/4
General	2/2

Table 1-1: Summary of Engineering Requirements achieved. See Table 1 in appendix for category breakdown.

VIII. Medical Device

The process to create a 3D printed NAM aligner was successful. The first step to building a 3D-model includes taking a putty-like substance and generating a solid model from the infant's mouth. The putty is placed on a tray and put into the child's mouth until it solidifies, modeling the cavity and gum lines. After this, the solid model is scanned with an intra oral scanner. In Meshmixer this scan, modeled in Figure 1, is used to generate aligners by slowly moving the gum lines together. Figure 2 represents one of many NAM aligners used to bring the gums together. After generating the mold of the infant's mouth and the aligner, each piece is 3D printed using a FormLabs 3B+ resin printer. The mold of the mouth should be printed first, the students used FormLabs Clear Resin. The aligner however, was printed using the Dental LT Clear V2 resin. After the mold has been printed and cured according to manufacturer's instructions the aligner will be printed. After printing it will be placed on the mold to cure for 1 hour at 60 °C which will ensure the proper fit. Mold release is also used to easily remove the aligner after curing. Aligners are then washed in isopropyl alcohol for no longer than 20 minutes to ensure quality. This process allows for multiple minimal post processing activities and reduces the burden from clinicians.

IX. Validation

There were 5 validation components to this project. Three of them were based on material and engineering aspects of the project which were able to be completely validated within the allotted time frame of this project. These customer requirements followed as; aligners being 3D printable, reducing processing time and cost, and printing within the thickness range of 0.030-0.040 inches. 3D printability of the aligner was the main goal of the project and that has been completely validated. The aligners were also printed within the specified range the project was

targeting which completes the second validation. Processing time and costs have been thoroughly reduced with this manufacturing process. While a single aligner does take longer to manufacture, this is an increase in hands off production time. Post processing such as cutting excess material and trimming has been dramatically reduced in terms of total production time. Additionally, thermoformed aligners are produced one at a time. Multiple aligners can be printed at once depending on the size of the printer, therefore validating this requirement. The fourth validation requirement was unable to be completed due to the nature of the project. This was the reduction in overall visitation time and total number of visits. To fully validate this customer requirement, the product would have to enter the marketplace to gather the appropriate data. The last validation requirement was given as a tentative requirement. If it was able to be completed during the project time table, it would be great, and if not, the project would still be considered a success. This tentative requirement was the feasibility of the button being printed directly with the aligner. Currently, the physician glues a 3D printed button onto the thermoformed aligners. Due to time constraints, this requirement was unable to be fully tested, verified, and validated. Overall, this project was able to fully validate its three main engineering customer requirements. The tentative customer requirement can be completed relatively easily at a later date and the last requirement needs the product to have sufficient time in the marketplace in order to become fully validated. A summarized validation plan and matrix are shown in the appendix, see Table 7 and Table 8.

X. Risk Mitigation

The risk priority number was calculated by evaluating the occurrence, severity, and detection of a potential failure. High occurrence, catastrophic failure, and absolute uncertainty when detecting a failure are all valued at five. Low occurrence, minimal severity, and easily detectable failures are assigned values of one. The lower the risk priority number the safer the product. There are six main concerns that were identified with the use of this device. These include; toxicity of the aligner, improper fit of the aligner, improper use of the aligner, plaque and stain buildup, button breaking from the device, and cracking of device. To mitigate toxicity and the aligner cracking, proper material selection is required. Extensive biocompatibility and mechanical testing would ensure that the device is strong enough to be handled and can withstand a week of use. Additionally, the correct material selection may aid in reducing staining or the buildup of plaque. To ensure proper fit, use, and cleaning of the device thorough instructions on how to install and care for the device will be the best preventative measure. The use of this device improves surgical outcomes and can lessen the burden of cost to families and medical staff. Ultimately, by accounting for these failures the risk of using the device is limited and categorized as having acceptable risk. The risk summary table is shown in its entirety in Table 3, see appendix.

XI. Summary Feasibility Discussion

The prototypes, thus far, have proven the concept for the feasibility of the project. Figure 3 shows a successful print of the prototype. Additional testing and printing has shown that with the selected material, Dental LT Clear V2 Resin, a direct 3D printed aligner is possible and satisfies the primary engineering requirements of the project. This project was ultimately a development of a manufacturing process with the resulting product being a prototype.

XII. Discussion, Lessons Learned, and Conclusions

There have been many lessons learned in the development of this project. The entire design process for medical devices was something new to our entire group. From risk analysis and mitigation, to validation and verification of customer requirements. This class has been extremely informative on the development lifecycle of creating new medical devices. Due to the nature of the aligner, there is not much to design differently, as each device is patient specific. The only real change we can make is a material selection and the underlying printer type. We selected resin printing due to its similarities to the thermoforming process that is used currently for aligners. Additionally, our material selection was limited due to biocompatibility and material property requirements for this project. This project took the form of designing a new process rather than creating a completely new medical device and that is represented throughout this document.

XIII. Future Work

There are two main goals to complete in terms of future work. The assisting physician of this project noted if it would be possible to 3D print the

buttons of the aligner directly on during the aligner print process. Currently, the physician 3D prints the buttons and just glues them onto the thermoformed aligners. There is no reason as to why buttons can't be printed directly onto the aligner with the method described in this report. Time restraints regarding this project were the only reason this requirement could not be fully validated. The secondary goal of any future work is to determine if directly printed aligners reduce overall visitation time either through less total visits or less time per visit. The aligners would have to hit the market and only after thorough data analysis between thermoformed and printed aligners visitation time; could this requirement be validated. Due to the time frame of this project it was not able to be completed even though it is a relatively simple analysis.

XIV. Individual Responsibilities

This project requires careful planning, documentation and execution. To stay organized and on time each individual had set requirements in addition to group responsibilities. Erin has acted as the project manager, made the Gantt chart, and spearheaded the editing of the NAM device in mesh mixer and Solidworks. Her extensive 3D modeling made her the key candidate for this portion of the project. Tyler was tasked with testing research and design as well as being a lead on the regulatory plan. He was very familiar with various types of testing due to his co-op experiences. Lauren was in charge of meeting minutes, the work log, and material based research. Lauren has been conducting research on campus and was already familiar with several different types of 3D printing. Her experiences were best utilized for researching and record keeping. The group as a whole was responsible for meeting with mentors, writing reports, presenting and generating gate reviews, as well as doing background research on the current treatments for cleft lip and palate.

XV. Professional and Ethical Responsibilities

Due to the nature of a 3D printed aligner there will be very little material waste. The print will include nearly the exact amount of resin required. If polishing were required it would remove a negligible amount of material. The current thermoforming method wastes over half of the material. Additionally this would reduce the economic burden on families and clinicians significantly. While the resin cannot be recycled, the waste produced is significantly less.

XVI. Acknowledgements

We would like to thank Dr. Niyant Patel and Dr. Nicholas Kochenour for their assistance at every stage of this project. For guiding our research and providing us with samples and materials that helped us to complete our project. We thank Stephen Paterson for assisting us every step of the way. For helping us with 3D printing, material selection, and process development. Thank you to the staff at the University of Akron for preparing us for this project and your aid throughout the past two semesters.

XVII. References

[1] Bous, R. M., Kochenour, N., & Valiathan, M. (2020). A novel method for fabricating nasoalveolar molding appliances for infants with cleft lip and palate using 3-dimensional workflow and clear aligners. American journal of orthodontics and dentofacial orthopedics : official publication of the American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics, 158(3), 452–458. https://doi.org/10.1016/j.ajodo.2020.02.007

[2] Centers for Disease Control and Prevention. (2022, December 16). *Facts about cleft lip and cleft palate*. Centers for Disease Control and Prevention. https://www.cdc.gov/ncbddd/birthdefects/cleftlip.html

[3] *Clear aligners market size & trends analysis report, 2030*. Clear Aligners Market Size & Trends Analysis Report, 2030. (n.d.). https://www.grandviewresearch.com/industry-analysis/clear-aligners-market

[4] Dental LT clear V2 resin 1 L. Formlabs. (n.d.). Retrieved February 22nd, 2023, from https://formlabs.com/store/materials/dental-lt-clear-resin-v2/

[5] Dental LT clear resin. Formlabs. (n.d.). Retrieved February 22nd, 2023, from https://dental.formlabs.com/store/dental-lt-clear-resin/

[6] Kitching, I. (2014, July 16). Direct manufacture of orthodontic aligner appliance.

[7] *Resin Library and 3D printing materials*. Formlabs. (n.d.). Retrieved April 24, 2023, from https://dental.formlabs.com/materials/

[8] Sischo L, Chan JW, Stein M, Smith C, van Aalst J, Broder HL. Nasoalveolar molding: prevalence

of cleft centers offering NAM and who seeks it. Cleft Palate Craniofac J. 2012 May;49(3):270-5. doi: 10.1597/11-053. Epub 2011 Jul 8. PMID: 21740168; PMCID: PMC3358428.

[9] Shetye, P. R., & Wangsrimongkol, B. (2022, April 14). Nasal molding device.

[10] Smile Prep. (2023, March 18). *The true cost of invisalign (five factors that impact your final bill)*. Smile Prep. Retrieved April 24, 2023, from https://smileprep.com/invisalign-cost/

[11] The Pew Charitable Trusts. (2020, October 5). *What Is Medical 3D Printing—and How Is it Regulated?* The Pew Charitable Trusts. https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/10/what-is-medical-3d-printing-and-how-is-it-regulated

[12]The Pew Charitable Trusts. (2022, July 27). *FDA's regulatory framework for 3D printing of medical devices at the point of care needs more clarity*. FDA's Regulatory Framework for 3D Printing of Medical Devices at the Point of Care Needs More Clarity | The Pew Charitable Trusts. https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/07/fdas-regulatory-framework-for-3d-printing-of-medical-devices-needs-more-clarity

[13] Winebrenner, J., & Jackson, A. (2019, November 10). *3D Printing: Product Liability Risk at the Point of Care*. Medical Alley. https://medicalalley.org/2019/11/3d-printing-product-liability-risk-at-the-point-of-care/

XVIII. Appendix

Category	Engineering Requirements	Target Achieved
Material	3D printable	Yes
Material	Stress resistant	Yes
Material	Crack resistant	Yes
Material	Biocompatible	Yes
Process	Thickness	1mm-Yes
Process	Manufacturing speed	Yes
Process	Button on aligner	No
Process	Printing material	Yes
General	Time saving	Yes
General	Cost saving	Yes

Table 1: Engineering Requirements

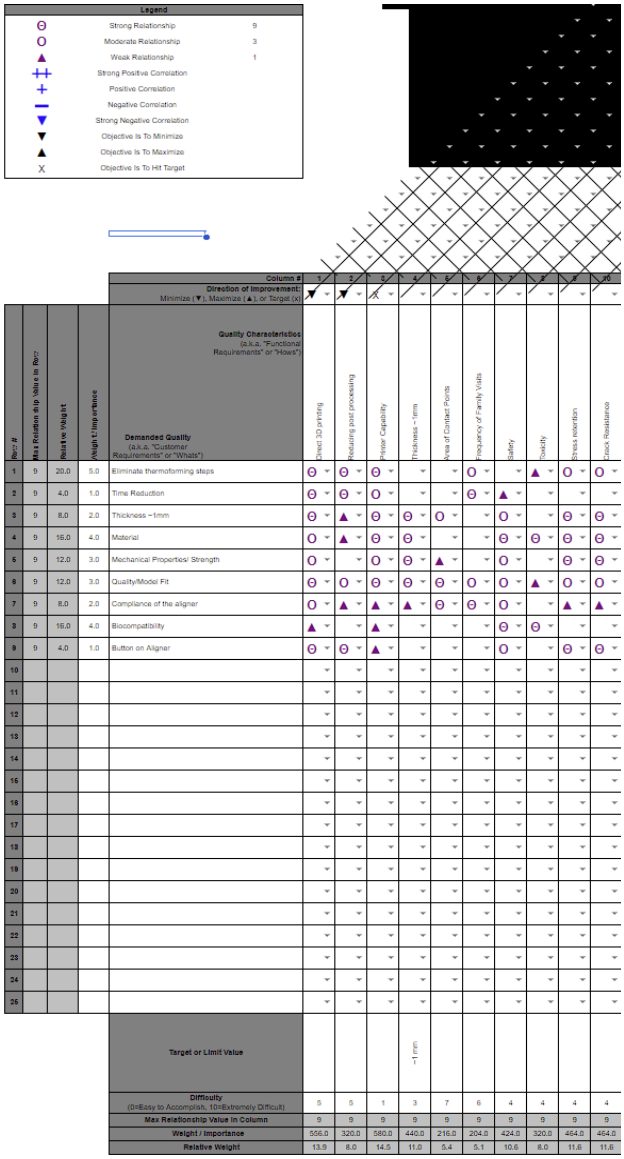

Table 2: QFD Diagram. For better viewing of QFD, see supplemental Table S-3 and S-4

Process Step/ Input	Potential Failure Mode	Potential Failure Effects	Severity	Potential Causes	Occurrence	Current Controls	Detection	RPN	Actions Recommended	Severity
What is the process step and input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (customer requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure mode?			What are the actions for reducing the occurrence of the cause or improving detection?	
Material Selection	Toxicity	Dangerous to health and development, infection	5	Improper material selection, gross negligence	1	Enhanced Material testing	4	20	Detailed material testing and research	5
During Use	Staining/ plaque buildup	infection, decreased contact area	5	Improper care of aligner, material selection has slight impact, diet	3	Daily cleaning, maintainance of aligner	1	15	Material selection, dietary changes, as well as regular and thorough cleaning	5
Installation	Improper fit within mouth	Poor compliance, reduced function	2	Incorrect modeling/printing	2	Tolerences	3	12	Fit checks on 3D printed models	2
Installation	Button breaks off	Aligner would fall off, choking hazard, lack of fit	5	Weak structural point from printing process, not enough support, user interference	2	Added support during printing process, reinforcing with resin material	1	10	Refined printing process standard, proper instruction of care	5
During Use	Aligner cracks	Breaks and renders aligner useless or reduced function	4	Incorrect material selection, curing error, printing error	1	Tensile testing, Mechanical testing, complete understanding of the forces invovled in the mouth	2	8	Enhanced material testing, ensuring a complete understanding of the forces at work	4
Installation	Improper user use	Choking hazard, reduced efficiency, reduced function	3	Lack of instructions, stress, impatience, anxiety	2	Clear instructions, weekly doctors appointments	2	12	Clear instructions simplifying the process (video instructions)	3

Table 3: Risk Management and Risk Priority Number (FMEA)

Standard Type	Standard Number	Description
ASTM	D-638-10	Elongation
ASTM	D-790-15	Flexural Strength

Table 4: Material Testing Standards

Standard Type	Standard Number	Description
ISO	10993-10	Not a Irritant
ISO	10993-10	Not a Sensitizer
ISO	10993-11	Nontoxic
EN-ISO	13485:2016	Medical Devices
EN-ISO	14971:2012	Medical Devices

Table 5: Material Property Standards

Test Format	Dental LT Clear Resin	Zendura A
Tensile Test		
Tensile Modulus (MPa)	1346	1100
Mean Max Tensile Strength (MPa)	49.75	58.44
Elongation at Break	19%	195%
Tensile Strength at Yield	44.62	53.76
Flexural Test		
Flexural Modulus Mean (MPa)	421.7	3.2633
Flexural Modulus Standard Deviation	21.46	0.8050
Strain to Failure Mean	31.14	64.37
Strain to Failure Standard Deviation	0.8280	3.778
Flexural Strength Mean (MPa)	3103	79.96
Flexural Strength Standard Deviation	99.25	9.312

Table 6: Verification Report

Customer Requirement Number	Customer Requirements	Validation Method Planned	Validation Description	Validation Procedure Number
1	Reduce/eliminate 3D printing of correct oral models via printing the aligners directly. (Print aligners Directly)	Direct 3D printing aligners (Demonstration)	By being able to 3D direct print the aligners, we can validate this customer requirement. The customer statement requires we 3D print.	CRWN-1
2	Drastically reduces processing time and cost.	Measuring total manufacturing and processing time. (Analysis)	Time measurements must be taken for the total current manufacturing process and then compared to the new process in order to validate this requirement. A cost analysis from the different materials and time spent will also be created and analyzed.	CRWN-2
3	Produce aligners with thicknesses between 0.030 and 0.040 inches.	Measure thickness of aligner in 3 different spots. (Inspection)	We can use a caliper to measure the thickness of the aligner.	CRWN-3
4	Reduce visitation time and overall number of visitations.	Measure the stay of parents and how frequently they visit (Analysis)	Quantifying the amount of visits as well as the length of visits to compare against previous records will validate this requirement.	CRWN-4
5	Directly print buttons on the aligners to reduce processing time and allow for insertion into patient's mouth	Verify the button is printed securely on the aligner (Inspection, Testing)	We can validate this objective visually. Essentially, we just need the button to protrude out of the aligner after printing. We can also subject the button to mechanical testing to ensure the breaking point far exceeds any point that would occur in the patient's mouth.	CRWN-5

Table 7: Validation Plan

Validation Number	Description	Validation method	Results
CRWN-1	Direct 3D printing capabilities	Demonstration	Yes
CRWN-2	Reduce processing time and cost	Analysis	Yes
CRWN-3	Aligners between 0.030- 0.040 inches	Inspection	Yes
CRWN-4	Reduce overall visitation time and number of visits	Analysis	Further Testing Required
CRWN-5	Button printed onto aligner	Inspection, Testing	Further Testing Required

Table 8: Validation Matrix

Supplemental Images

Risk Severity		
Rating	**Term**	**Value Assigned**
Acceptable	Negligible	1
Acceptable	Minor	2
Concerning	Serious	3
Unacceptable	Critical	4
Unacceptable	Catastrophic	5

Probability of Occurrence		
Rating	**Term**	**Value Assigned**
Acceptable	Improbable	1
Acceptable	Remote	2
Concerning	Occasional	3
Unacceptable	Probable	4
Unacceptable	Frequent	5

Risk Detection		
Rating	**Term**	**Value Assigned**
Acceptable	Almost Certain	1
Acceptable	High	2
Concerning	Moderate	3
Unacceptable	Low	4
Unacceptable	Absolute Uncertainty	5

Table S-1: Summary of RPN Numbers and Classifications

Test Format	Standards Followed	Values Obtained	Testing Method	Completed
Tensile Testing	ASTM D638	Tensile Modulus Tensile Strength (Max) Elongation at Break Tensile Strength at Yield	Test	Yes
3 Point Bend Test	ASTM D790	Flexural Modulus Flexural Modulus (St. Dev) Strain to Failure Mean Strain to Failure (St. Dev) Flexural Strength Flexural Strength (St. Dev)	Test	Yes
Paint Test	Self-Created	Printer Accuracy of Aligners	Test, Inspection	Yes

Table S-2: Verification Plan Summarized

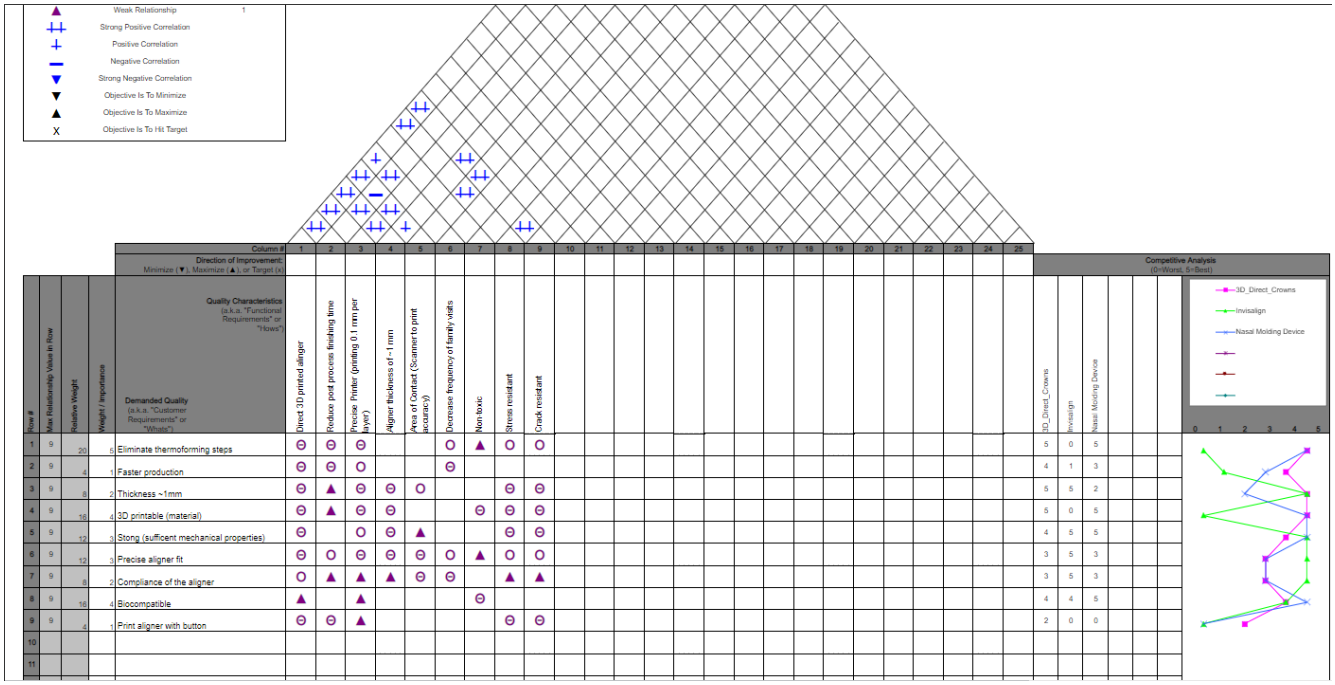

Table S-3: QFD Complete Top View

Target or Limit Value	To 3D print NAM aligners	Less than 30 minutes spent finishing	Printer can print layers 0.1mm in thickness	Aligner is approximately 1 mm in thickness	Aligner correctly fits model (positive fits negative)	Less than 1 visit a week on average	Aligner should not contain BPA	Material should not break or deform while in use or while being stored before use	Material should not crack while in use or while being stored before use	
Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	5	5	1	3	7	6	4	4	4	
Max Relationship Value in Column	9	9	9	9	9	9	9	9	9	
Weight / Importance	724.0	320.0	580.0	440.0	216.0	204.0	320.0	464.0	464.0	
Relative Weight	19.4	8.6	15.5	11.8	5.8	5.5	8.6	12.4	12.4	

Table S-4: Complete Bottom View of QFD

RS-F2-DLCL-02	"Our library of Dental Resins enables dental practices and labs to rapidly manufacture a range of dental products in-house, from biocompatible surgical guides and splints to fixed prosthetic and clear aligner models. Dental LT Clear Resin (V2) is our second-generation, long-term biocompatible material for directly printing affordable, high-quality splints and occlusal guards in-house. Highly durable and resistant to fracture, this color-corrected material prints clear, polishes to high optical transparency, and resists discoloration over time for a finished appliance you'll be proud to deliver."	$349.00	1
RT-F3-02-01	"Low Force Stereolithography (LFS)™ 3D printing uses linear illumination and a flexible film tank to turn liquid resin into flawless parts. A key component of the LFS process, the strong dual-layer film at the bottom of the Form 3 Resin Tank, allows for a dynamic and precise print process. For use with Form 3 and Form 3B. Notice: Form 3 Resin Tank V2.1 is compatible with all Formlabs resins, but is required for use with some specific materials. There are two previous versions of the Form 3 Resin Tank, Tank V1 and Tank V2, each with their own compatibility requirements."	$149.00	1

Table S-5: Bill of Materials

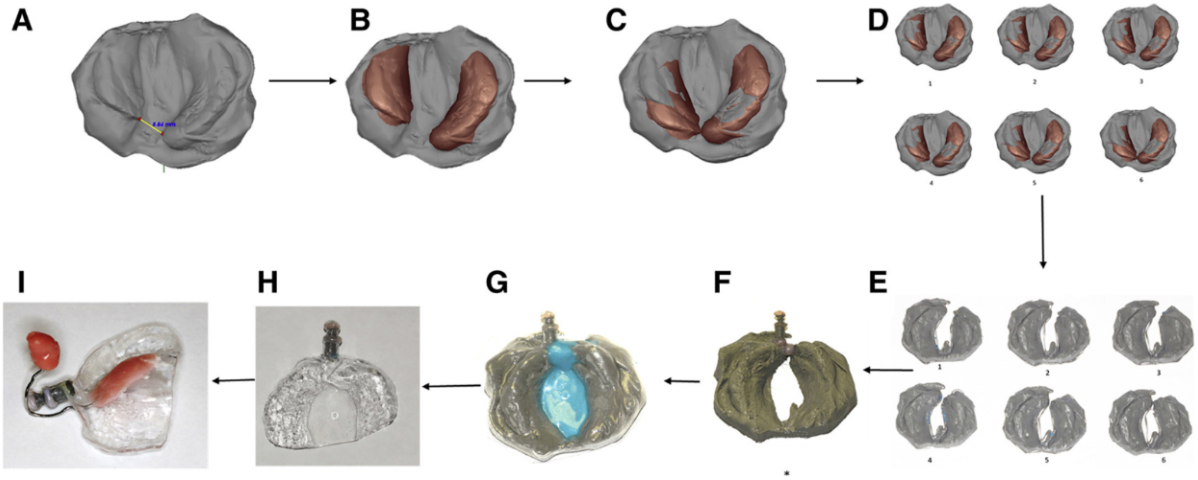

Figure S-1: Aligner Manufacturing Process

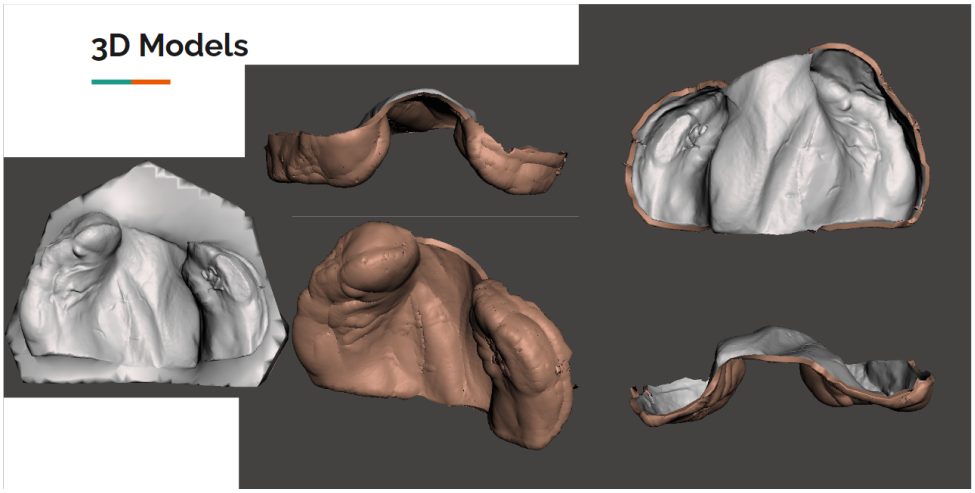

Figure S-2: 3D Models

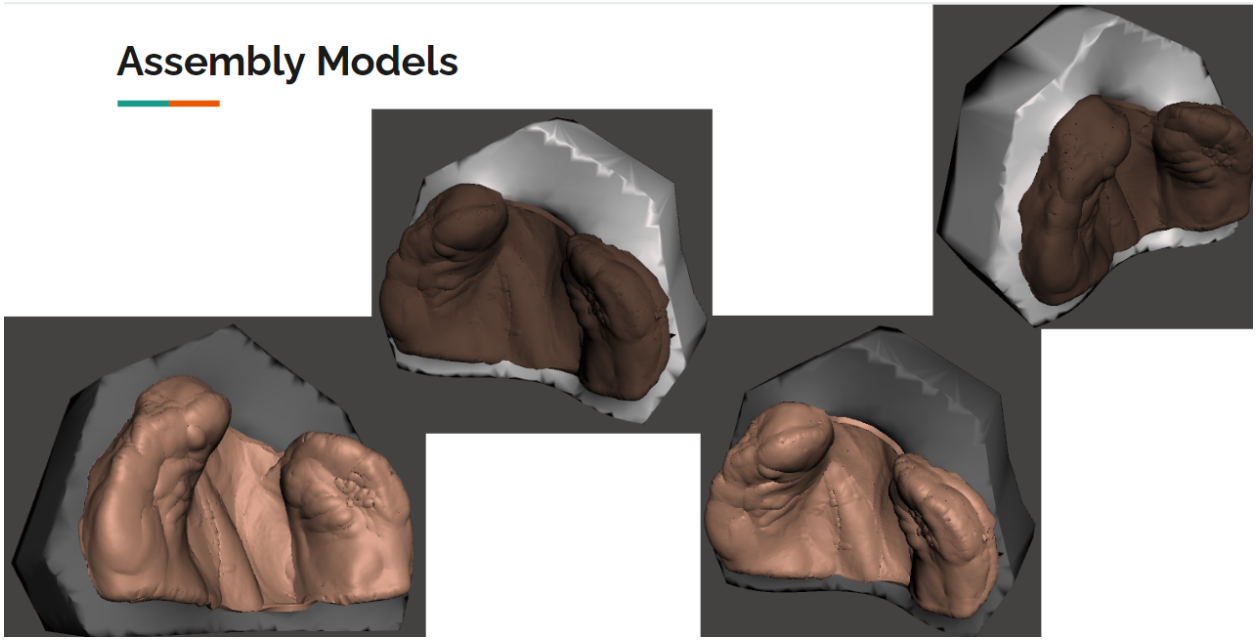

Figure S-3: Assembly Models

Failure Modes	Mitigation
Toxicity	• Enhanced research prior to clinical trials
Improper fit	• Compliance checks on 3D print models
Improper user use	• Clear instructions • Videos of use • Simplifying process

Failure Modes	Mitigation
Button breaks	• Refine printing process standards • Instruction of proper care
Aligner cracks	• Enhanced material testing • Force modeling
Staining and plaque buildup	• Improved cleaning • Dietary choices • Material selection

Table S-6: Failure Modes and Risk Mitigation Summarized

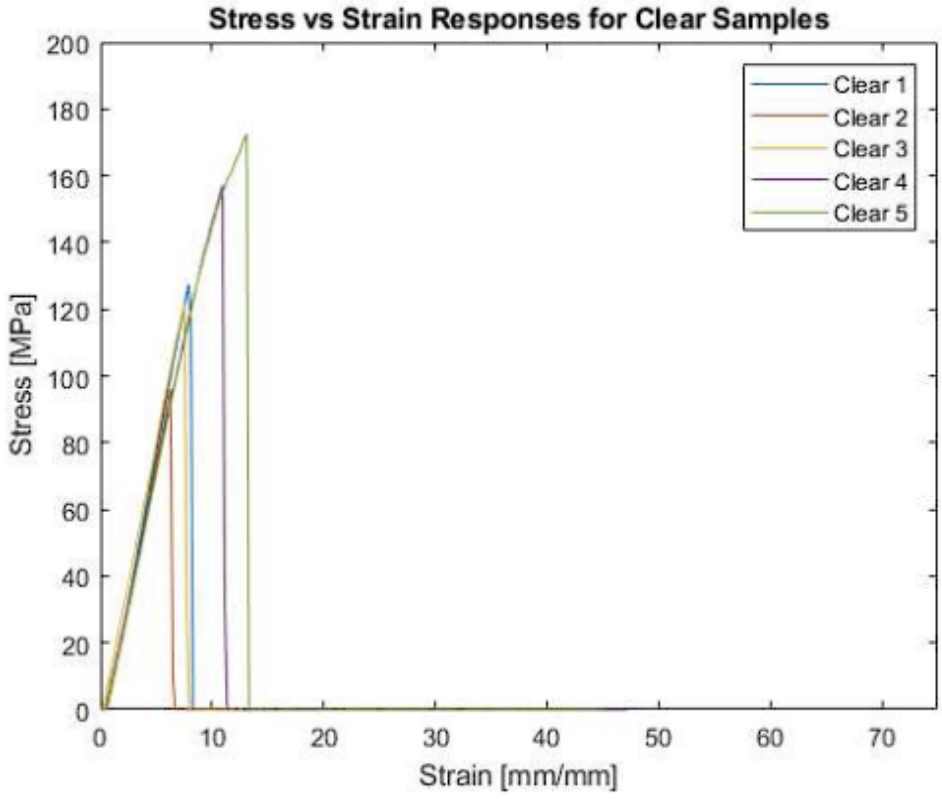

Figure S-4: Bending Data-Dental LT Clear V2 Resin

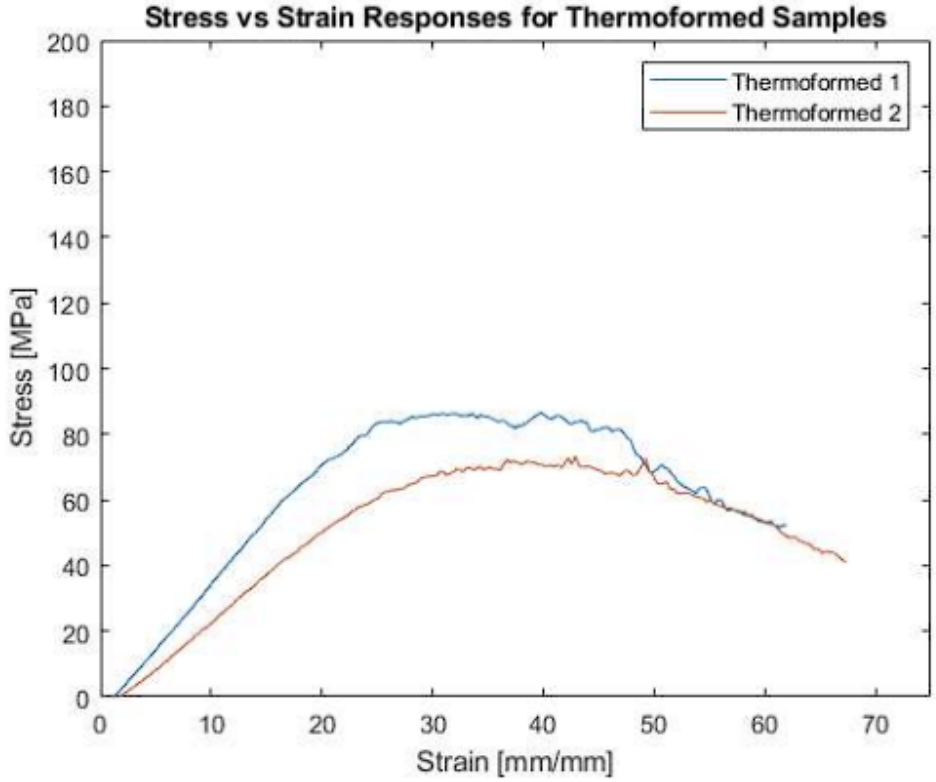

Figure S-5: Bending Data-Zendura A (Thermoformed)

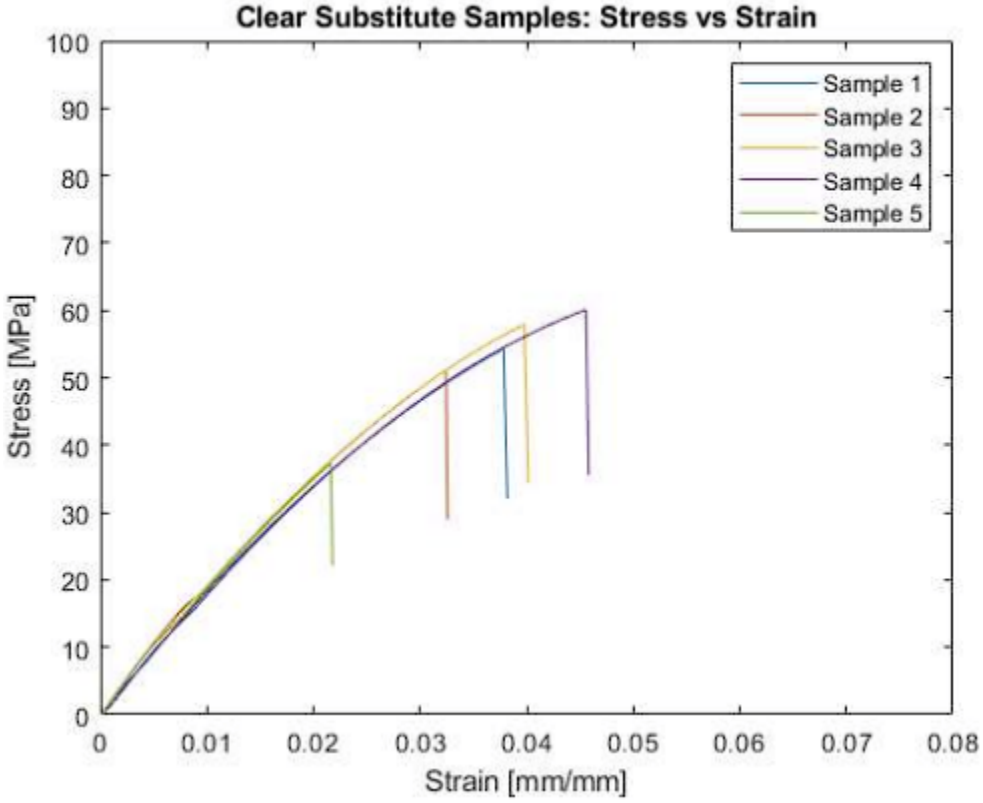

Figure S-6: Tensile Data-Dental LT Clear V2 Resin

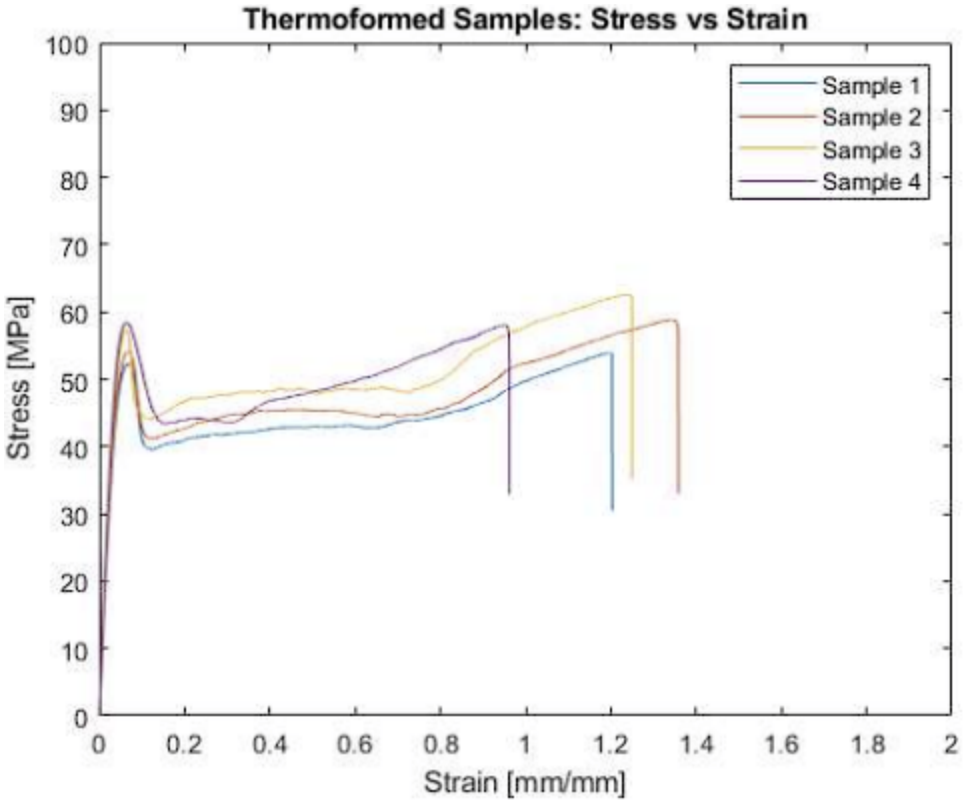

Figure S-7: Tensile Data-Zendura A (Thermoformed)

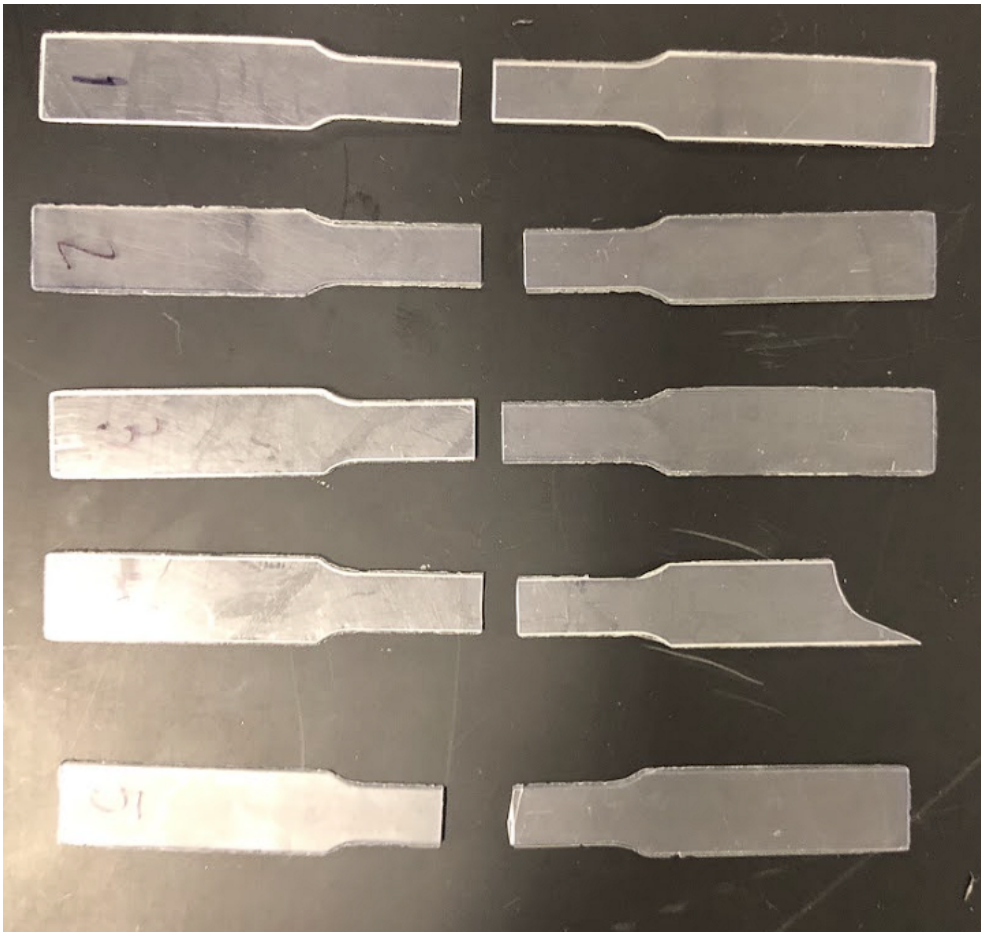

Figure S-8: Dental LT Clear V2 Test Samples (Tensile)

Figure S-9: Thermoformed Test Samples (Tensile)