Approximating Surface Matrix Band for Dentists to Use in Patients

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Abstract

Fifty-three million people live with untreated tooth decay, labelling cavities as a silent epidemic. This issue disproportionately affects disadvantaged communities, and unfortunately, cavities become more difficult to repair the longer they are left untreated [1]. Untreated tooth decay can lead to severe tooth pain and discomfort, and in some cases, tooth loss. Dental fillings remain the most common method of combating tooth decay, thus, it is essential that filling procedures are optimized. Current matrix bands used in these procedures, such as sectional and circumferential bands, fail to allow concurrent restoration of adjacent interproximal cavities. The team was tasked with designing a matrix band that can support this simultaneous filling of two adjacent teeth while maintaining proper tooth contact. The final design mimics two adjacent sectional matrix bands, but is designed with half the thickness of a regular matrix band to support the proper, flossable tooth contact within the interproximal space. The device incorporates a holed tab for easy placement and removal as well as a space between each band side to allow the use of a wedge. Preliminary mechanical testing indicates that the 1008-1010 steel used to fabricate early prototypes provides similar structural support when compared to the stainless steel widely used in existing matrix bands. Improved fabrication methods, such as using a water jet, are necessary in order to develop a more precise model. Following this, qualitative testing can be conducted to determine whether the design is both effective and favorable for dentists to use in filling procedures.

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I. Introduction

A. Motivation - Inefficient Tooth Restoration

It is estimated the average American has three dental fillings, while one in four Americans have eleven or more fillings. Although cavities are one of the most common dental procedures, the CDC still estimates that about one-third of adults have untreated dental caries that require fillings [2]. Dental caries are also known as tooth decay, and they result from enamel breakdown. The goal of a filling is to remove the decayed part of the tooth, which is referred to as the cavity, and fill the area with an enamel mimicking material to prevent any further damage [3]. Pathologies resulting from untreated cavities have disproportionately affected black and hispanic adults, younger adults, and those from lower income communities. Approximately 9% of the world's population is affected by untreated dental caries. There has been a significant amount of evidence that tooth disease has gone down in many countries. However, dental caries continue to affect many people, especially children, which can lead to premature dental loss [4]. A new matrix band device could help advance the public dental health industry by helping simplify procedures for practicing dentists, making treatment more efficient, convenient, and less costly.

B. Problem Statement

Matrix bands are a commonly used dental tool which assist dentists by creating an outside contour of a decayed tooth. They provide support, shape and contour for replacement filling material while protecting surrounding tissues. During typical filling procedures for cavities on interproximal surfaces, or two adjacent teeth, dentists must fill each tooth separately. This is a tedious procedure as each matrix band must be prepared for each tooth, which includes shaping, placement and securing with dental wedges and rings. These must be done one after another because two matrix bands cannot fit in the interproximal space as together they are too wide and would create gaps in the restoration. A new dental matrix band design is desired to alleviate the need to repeatedly place bands. The device should employ a dual-band system with a thickness less than or equivalent to current matrix bands throughout such that the fit is secure and the band molds to the appropriate convex/concave contour of each tooth. The finalized product should also maintain the tensile strength, malleability, and space efficiency of current matrix bands. The material used to fabricate the matrix band must not cause any irritation, must be biocompatible, and must be non-reactive to filling materials.

C. Current Devices - Existing Sectional and Circumferential Dental Matrix Bands

The earliest implementation of matrix bands generally required minor custom fabrication techniques such as soldering, scoring and cutting, or using fusing compounds. However, preformed, adjustable bands became the standard in the last 50 years [5]. Preformed bands reduce the time to placement as structural modifications are not necessary, only forced bending. There are two main types of preformed dental matrix bands, sectional and circumferential [6]. Sectional matrix bands are more suited for proximal cavities and only fit around half of the tooth. They are required to be supported by a ring fit as well as levered by a wedge between two teeth. Circumferential matrix bands are generally used with a Tofflemire™ retainer, seen in Figure 1, and are wrapped around the whole tooth. The Tofflemire is able to tighten the band around the tooth but still requires the use of a wedge for a tight contact, contour, and separation of the teeth. Dental matrix ring clamps are often used as well as dental wedges for the same purposes. Both sectional and circumferential matrix bands are used commonly in practice although 74% of dentists prefer the sectional band method [7]. Most bands that are created for interproximal cavities use a circumferential model which was not desired by the client. There are a couple examples of sectional matrix band models but none are mainstays in the market and some have issues that make the models undesirable for the client.

The Tofflemire™ matrix band and retainer is a circumferential design meant to wrap around a single tooth during an interproximal procedure. This system is used in conjunction with dental wedges to create a better fit with the gingival surface and create space in the interproximal area of the teeth. The band is first burnished to create a contour along the bottom edge to fit between the gum line and tooth. Then the band is folded into a teardrop shape, placed into the head of the retainer and clamped into place, ready for tightening around the tooth [8]. Our client currently uses this system, as seen in Figure 1, but is limited by the tedious setup and ability to only work on one tooth at a time.

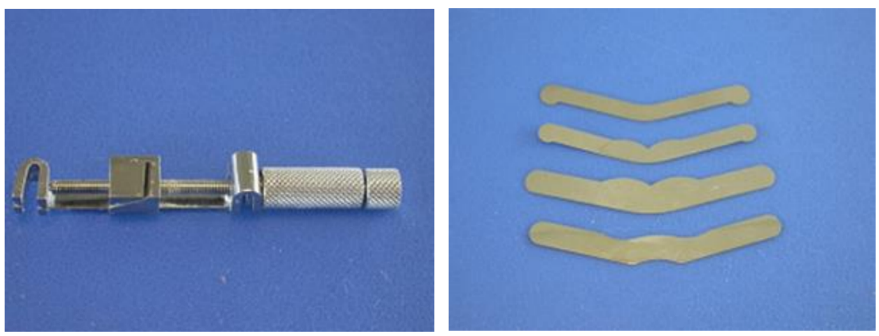


Figure 1: Tofflemire™ Matrix Band system. Circumferential matrix band system consisting of the proprietary retainer (left), bands (right), and any dental wedges (not pictured) [5]. Primary 4 matrix band sizes are shown on the right.

The Pro-Matrix Single Use Matrix Band from Astek Innovation, as seen in Figure 2, is a circumferential design that combines the tofflemire and matrix band into one easy to use device. The device has two key components, switch and dial, that allow the device to be used on many different tooth sizes. The switch is used to change the angle of the matrix band relative to the device, to allow the device to be used on either side of the mouth with maximum band-tooth contact. Once the device is placed around the tooth, the dial on the bottom can be spun to tighten or loosen the matrix band around the tooth. The dentist will then have to install a wedge underneath the band to ensure no movement and to protect the gums.

Figure 2: Pro-Matrix Bands. The left image shows the colored switch at the top and colored dial at the bottom. The right image shows how the device would install around a tooth [9][10].

The Triodent V3 Ring used alongside the Triodent Wave-Wedge, as shown in Figure 3, is advertised as a sectional matrix system that allows for superior functionality compared to the circumferential band (Tofflemire) [11][12][13]. However, if this Triodent ring is used to separate adjacent teeth with the placement of two matrix bands, the contact between the teeth would not offer optimal contact leading to a larger gap than desired.

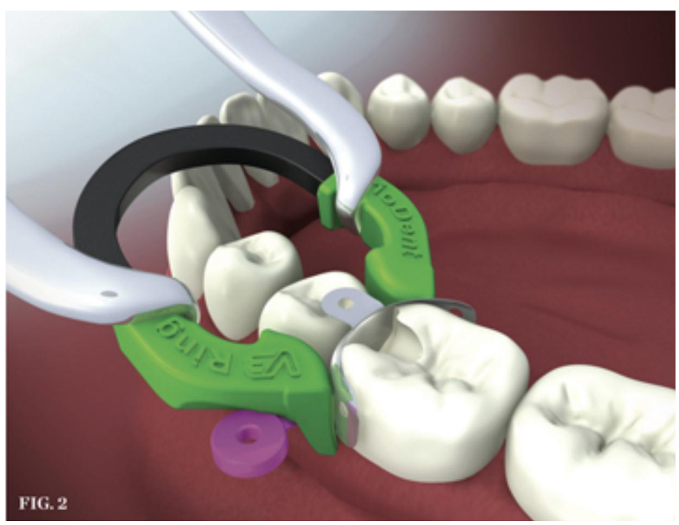


Figure 3: Triodent V3 Ring and Triodent Wave-Wedge. Sectional matrix band system consisting of Triodent V3 ring (green), Triodent Wave-Wedge (purple), and sectional matrix band (silver) [13].

II. Background

A. Design Research - Relevant Anatomy, Procedures and Existing Dental Tools

Dental matrix bands are designed to be placed in the interproximal space between a tooth undergoing restoration and its adjacent tooth. The band functions in creating the outside contour for the restorative material so that the decayed tooth may be repaired back to its original shape and structure. Most matrix bands are made from a dead soft metal, the softest form of metal, such as a very low carbon steel, which allows them to be malleable and easily shaped to fit a variety of tooth sizes [14].

The average crown height of maxillary (upper) and mandibular (lower) teeth together is 8.69 mm, with a range of measurements from 7.2 mm to 11.2 mm. The mesiodistal crown width, which measures the diameter of the tooth in the direction from its more anterior adjacent tooth to its more posterior adjacent tooth, averages 8.20 mm, with values ranging from 5.3 mm to 11.4 mm. The faciolingual crown width, which measures the diameter of the tooth in the direction from cheek side to tongue side, averages 8.71 mm, with values ranging from 5.7 mm to 11.5 mm [15]. Based on these values, approximations for tooth perimeter average 33.82 mm, ranging from 22.0 mm to 45.8 mm.

The thickness of dental matrix bands typically ranges from 0.001 to 0.002 inches, or 0.0254 to 0.0508 millimeters [16]. The band width must fall into these precise ranges in order for the device to securely fit between adjacent teeth without exceeding the width of the interproximal space. Correctly placed and effective matrix bands are rigid against the existing tooth structure and maximize matrix-tooth contact, properly contouring to the shape of the tooth [17]. They must restore appropriate contact with the adjacent tooth and be easily removable once the restorative material is set [8]. Upon insertion, dental matrices often require the use of retainers, rings, clips, or wedges to hold the band in place and widen the interproximal space. These tools, however, make the patient's mouth crowded and therefore make the restorative procedure more difficult for the dentist.

The previous BME design team from last semester was able to develop a dual-matrix band device, but mechanical and functionality testing led to failure and incomplete results [18]. The team did, however, come up with a promising design idea that could be further developed by the current team. This design, the "Butterfly" design, is outlined in *III. Preliminary Designs*.

B. Client Information - Dr. Donald Tipple

Dr. Donald Tipple is a dentist and the sole owner of Nakoma Dental in Madison, WI. He has over 30 years of experience as a dental practitioner, specializing in preventative care and restorative solutions.

C. Design Specifications

In addition to satisfying thickness requirements and accommodating a wide variety of tooth sizes as previously mentioned, the matrix band device must meet a variety of functional criteria. It must be fabricated with a material that is malleable, non-toxic, and non-reactive with materials used in the filling procedure. The material must exhibit mechanical properties similar to those of existing matrix band materials, which most often incorporate a dead soft stainless steel. This steel has a tensile strength of around 260 - 340 MPa and an elastic modulus of 200 - 215 GPa [19]. In terms of performance, the device must be single-use and provide a rigid contour for the filling material for up to one hour [20]. It must be convex at its bottom edge to prevent any filling material from entering the gingiva and causing infection. Overall, the design must allow for a shorter procedural time, which currently can take up to 30 minutes per tooth, by enabling the dentist to simultaneously fill two teeth. For further detailed criteria, refer to *Appendix A - Product Design Specifications*.

III. Preliminary Designs

After gathering a thorough understanding of the client's expectations and determining design specifications, the team brainstormed and selected three designs to meet these. Descriptions and images of each design are outlined below.

A. Design 1 - Handcuff Design

The Handcuff Design is a modification of a circumferential matrix band so that it can be used to surround two adjacent teeth. The design consists of a single band of fairly thin width, 0.0254 mm, with slot fittings on either end that are slightly wider, as seen in Figures 4 and 5. The idea is that the band would wrap around the two targeted teeth laterally (cheek side) and come together medially (tongue side) in the interproximal space, visually shown in Figure 6. The band should be thin enough to fit through this space, but if the teeth are too close together for the band to fit, the dentist can use a ring to create a temporary gap in the teeth. However, to save time, the thickness of the device could be changed to better fit a majority of interproximal spaces. Once the band is in place, each end of the band is pulled tight. One pair of the slot fittings (one from each side of the band) would then slide over the middle of the band, completing the loops around the teeth and locking the band securely in place. To account for multiple different tooth sizes, different length bands could be produced with just a few slots at a specified distance from the end, or one larger size band could be produced with a large number of slots across the majority of the band. The band would need to be made of a dead soft metal in order to ensure its form-fitting properties. The band would also likely be one time use before needing to dispose of it. The band would have to be used in tandem with a wedge in order to provide more support in driving matrix bands against the wall of the tooth. Fabrication of the device could be carried out relatively easily by using a laser cutter on a very thin sheet of dead soft metal. A few major drawbacks to this device is that it may run into some issues when trying to create a very tight fit around the teeth and sliding the tiny slots around the thin matrix band may turn out to be very time consuming.

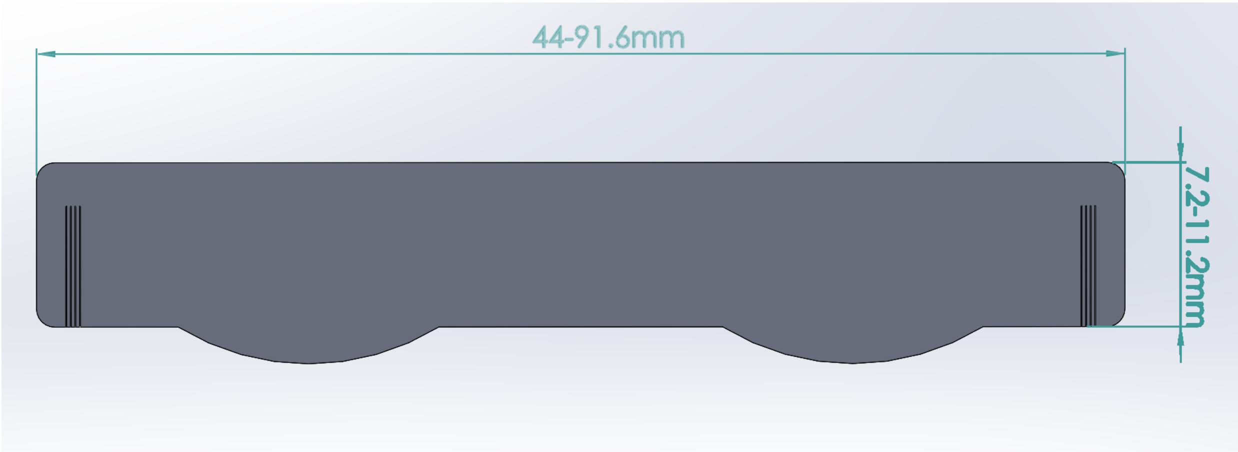


Figure 4: Handcuff Design Side View. Slot fittings are gaps in the matrix band used to secure the device during installation. The fins (rounded protrusions along the bottom edge) are used to help keep the device in place and prevent cavity material from seeping into the gums. The height of the fins is variable depending on the procedure and patient.

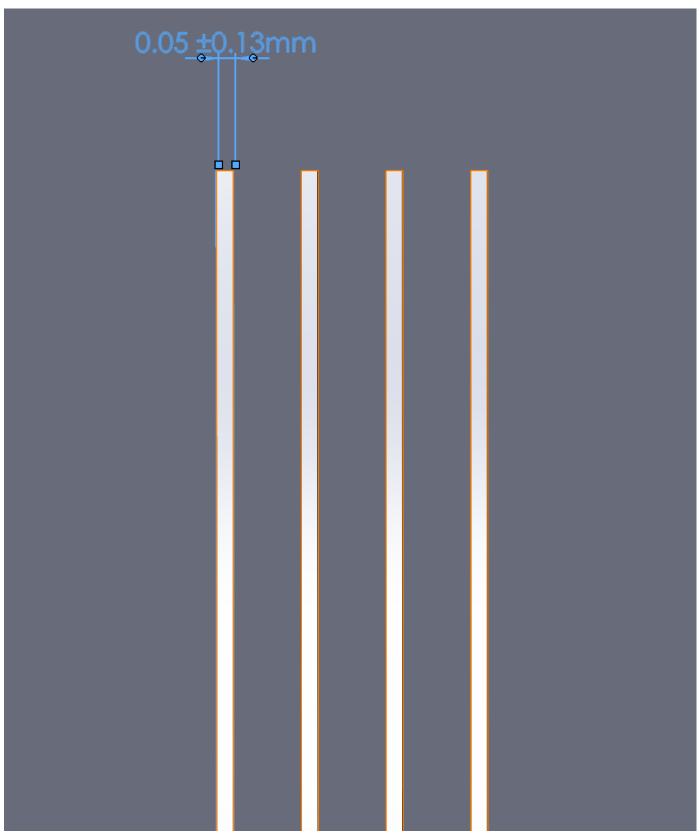


Figure 5: Handcuff Design Securing Mechanism. Close-up of the slot fittings used to secure the handcuff design once it is wrapped around the teeth.

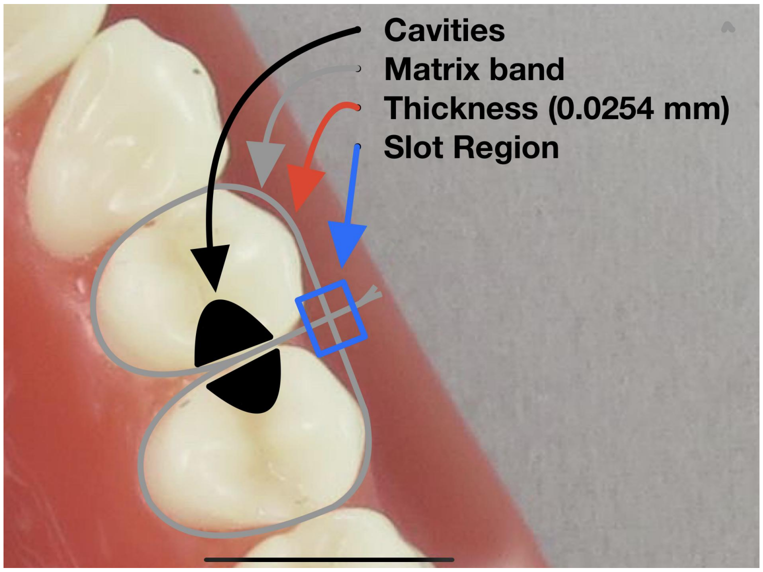


Figure 6: Handcuff Design Top View. The handcuff band is wrapped around two teeth with an interproximal cavity. The band is held in place by placing the center of the band through any of the slots located in the region with the blue box.

B. Design 2 - Butterfly Design

The Butterfly Design is a single matrix band that can be thought of as two sectional matrix bands conjoined where tooth contact will occur. The curvature of each side of the band would allow this design to wrap around each tooth. The center of the butterfly band would have a thickness of 0.0254 mm to ensure a fit between the teeth. To ensure the center thickness, each half of the butterfly band would have a thickness of 0.0127 mm, shown in Figure 7. As in the Handcuff Design, this device would also be fabricated from a dead soft metal. Installation of this device should be much faster and easier than installation of the Handcuff Design, as this design would only require the dentist to separate the teeth if needed and then the band could be slid into place, Figure 8. Once the device is installed between the target teeth, two wedges must be placed between the gums and the band to help secure it in place. This device may also need to be used in combination with two rings, to secure the edges of the matrix band to the teeth and ensure proper contact to prevent any cavity filling material from seeping out of the device and into the gums of the patient. These rings can be quite large and may end up inhibiting the cavity filling process.

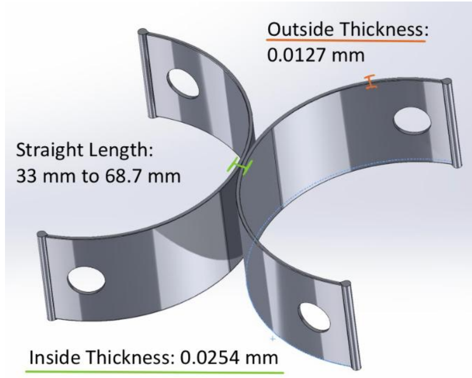


Figure 7: Butterfly Design Solidworks 3D Model. This design consists of two sectional matrix bands conjoined together in the middle to produce a band that slightly resembles a butterfly. Holes in the band will help to aid the removal of the device.

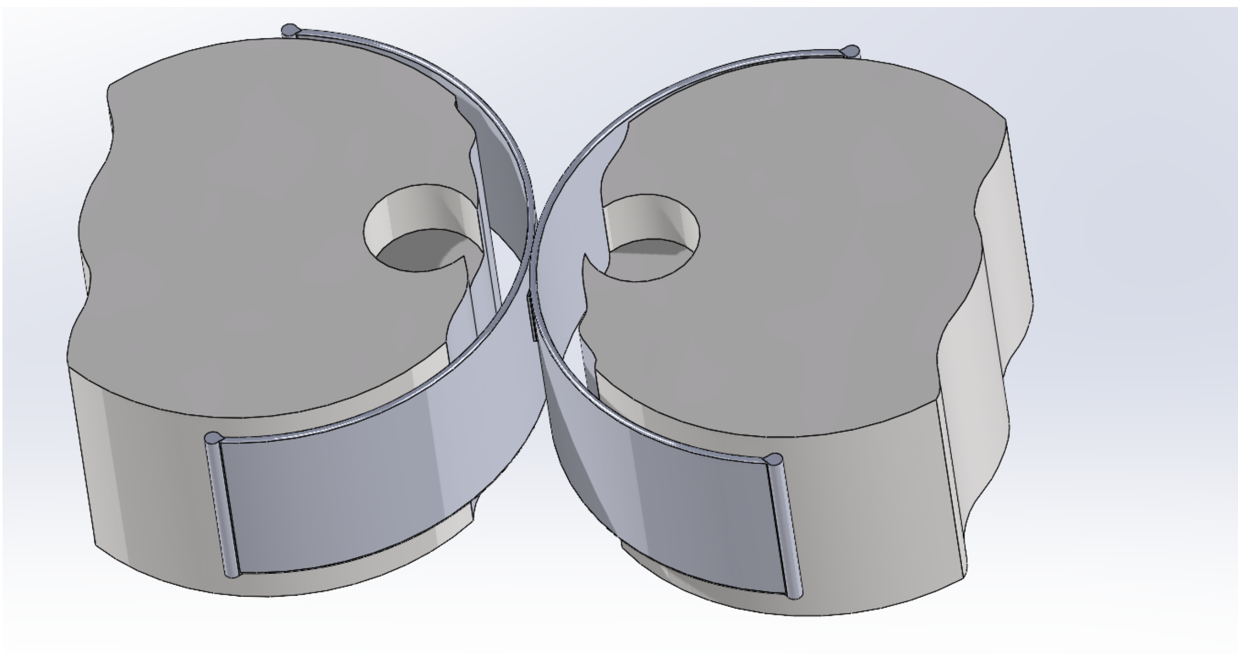


Figure 8: Butterfly Design installed. This CAD image shows how the butterfly band (silver) would sit between two teeth infected with a cavity (gray/tan).

C. Design 3 - Butterfly + U Pinchers Design

The Butterfly + U Pinchers Design is similar to the Butterfly Design in its shape, size, and thickness but has incorporated a spring clamp and U Pinchers to fix some flaws of the design, as shown in Figures 9 and 10. The U Pinchers serve a main purpose of creating an inward force that pulls the matrix bands close to the teeth to maximize surface contact. In addition, they could also be used as something to hold onto while the dentist is placing the matrix bands in the patient’s mouth. The design also incorporates an innovative spring clamp to hold the matrix bands in place and widen the gap between the targeted teeth during a filling. Like the other two designs, this design would be created out of a dead soft metal, would most likely be single use, and would have a center thickness of 0.0254 mm. All dimensions of the butterfly band in this design would be the same as in the Butterfly Design. With the inclusion of all of these components, the device will be the most expensive and hardest fabricate.

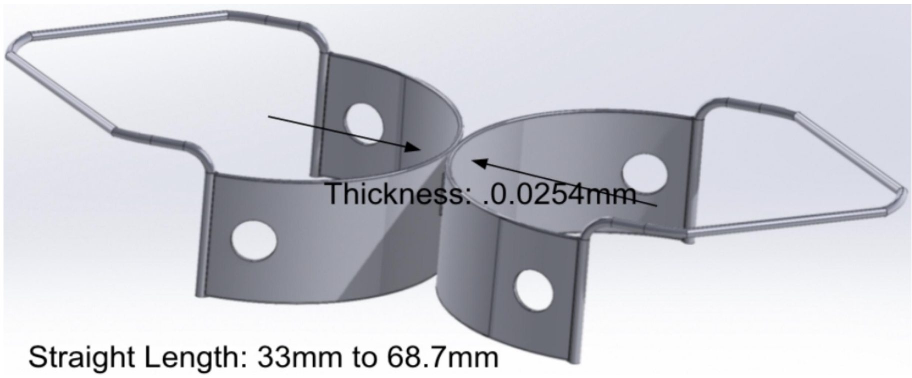


Figure 9: Butterfly + U Pinchers Design Solidworks 3D Model. Similar to the butterfly design, the device consists of two sectional matrix bands with the addition of U Pinchers. Holes added to aid in the removal of the device. Not shown in figure: spring clamp.

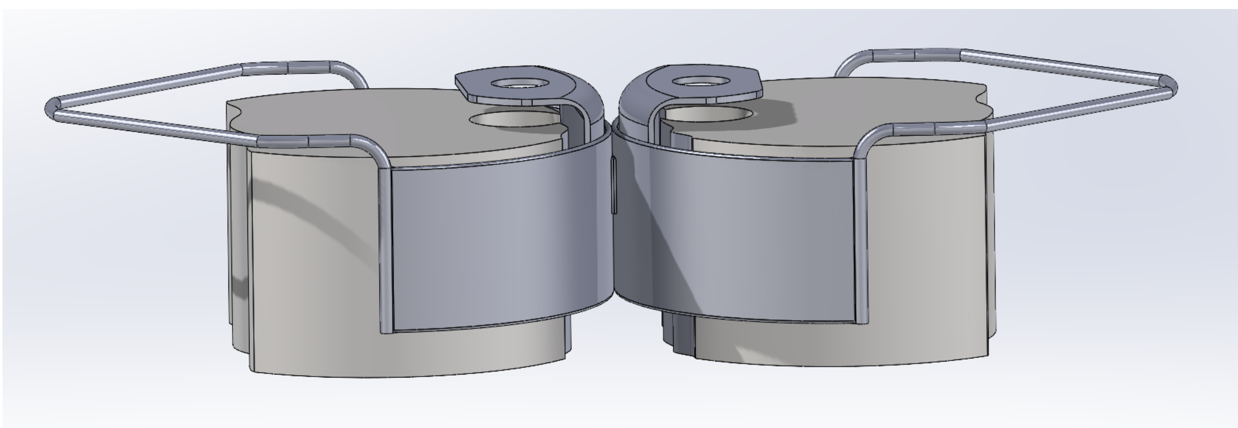


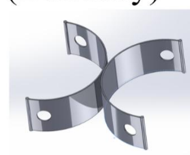
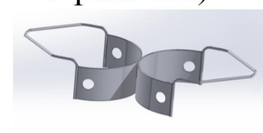
Figure 10: Butterfly + U Pinchers Design installed. This CAD image shows how the butterfly band (silver) will sit between the teeth (gray/tan). U pinchers (silver) will produce an inward force on the butterfly band to help the band sit flush against the teeth. Not shown in figure: spring clamp

IV. Preliminary Design Evaluation

The designs from the previous section were evaluated based on weighted criteria. These criteria and the evaluations can be seen below in Table 1.

A. Design Matrix

Table 1: Preliminary Design Matrix

Dental Matrix Band Design Matrix						
Design Criteria (Weight)	Design 1 (Handcuff) 		Design 2 (Butterfly) 		Design 3 (Butterfly + U pinchers) 	
Functionality (30)*	3/5	18	2/5	12	5/5	30
Ease of Use (20)	2/5	8	4/5	16	4/5	16
Fabrication (15)	4/5	12	3/5	9	3/5	9
Ease of Sterilization (15)	3/5	9	3/5	9	3/5	9
Safety (10)	4/5	8	5/5	10	5/5	10
Cost (10)	4/5	8	3/5	6	2/5	4
Total (100)	63		62		**78**	

**The six design criteria on the far-most left column were evaluated for each preliminary design. The designs were given a number score out of 5 for each category and ratings were totalled to determine which design was best (described under justification of criteria section below). Shaded sections indicate the highest ranking design for each criteria. The lighter shading indicates ties between designs.
*The functionality criteria was based on the design's ability to allow the dentist to complete the procedure with both quality and time efficiency.

B. Justification of Criteria

Functionality: The functionality criteria was based on the design's ability to allow the dentist to complete the procedure with both quality and time efficiency. The Butterfly Design received the lowest score in this category (2/5) due to its lack of adjustability and tightness. The band needs to securely fit around the tooth in order for a quality tooth contact, however, with the Butterfly Design, some variation in tooth sizes amongst different patients would result in different results. For example, the greater thickness in the middle of the band may need to be longer for some patients than others. The Butterfly + U Pinchers Design received the highest score in this category (5/5). This design has pinchers which maintain a close fit between the teeth and matrix across the entire section. This inward force allows the design to be used across varying shapes and sizes of teeth. The spring clamp also improves the design by widening the gap between the teeth if needed. The Handcuff Design received a score of 3/5 because it may have factors that contribute to increased procedural time. It is a circumferential design, rather than a sectional one, that would require steady placement of the band in its slot fillings. This may be both a frustrating and time consuming task.

Ease of Use: This design criteria outlined how easy the dental matrix band design would be for dentists to place in between teeth and remove from the mouth. It also took into consideration any view obstruction the dentist would encounter from the shape of the design. The Handcuff Design scored the lowest (2/5) in this area due to it requiring a tedious placement procedure and therefore tedious removal. Both the Butterfly and Butterfly + U Pinchers designs tied for the higher scores of (4/5). Neither design received a perfect rating due to the Butterfly Design's slightly more time consuming placement and the Butterfly + U Pinchers Design's possible view obstruction.

Fabrication: This criteria was graded on how easily the design could be fabricated based on the intricacy of parts as well as characteristics and availability of materials. While it is important to ensure that the design is viable to actually manufacture, and do so on a scale that would allow for the device to be single-use, the function does not require intricacy and there is significant literature available on viable materials. Therefore, this section was given a relatively low weight of 15/100. The Handcuff Design scored the highest on this criteria (4/5) as it only requires simple modifications to the matrix bands currently used, and the same, single material. Both the Butterfly and Butterfly + U Pinchers designs scored lower at (3/5) because of the thin, split, and curved metal structures that must be custom manufactured and accurate on a very small scale.

Ease of Sterilization: All of the designs have the same score for sterilization. This is due to the fact that all are made from the same material and all would react the same to sterilization processes. While all designs are meant to be one time use, they could be sterilized based on the material used and durability of the material.

Safety: Each design ranked very similarly in safety as all designs have little chance of harming the patient during a filling procedure. Also any materials that could be toxic to a patient could be subbed out easily in all designs. However, the handcuff design ranked slightly worse in safety due to a higher chance of the band slipping off or coming undone.

Cost: The cost criteria was scored based on type, and amount of material required, and associated fabrication costs. This section was given a weight of 10/100 as there likely won't be much variability and early cost estimates are not a primary concern. The Handcuff Design ranked highest in this section (4/5) as it is a modification of the most common current matrix bands which are inexpensive. The Butterfly Design was given a 3/5 as the fabrication process is more involved. The Butterfly + U Pinchers Design was given a 2/5 as both the fabrication process is more difficult and more material is required.

C. Proposed Final Design

The team weighted and scored each criteria of the design matrix while taking the client's preference for sectional matrix bands over circumferential matrix bands into consideration. This determined the highest scoring design idea to be the Butterfly + U Pinchers Design. The design will be harder to fabricate and will cost more in terms of materials and fabrication, but the team believes that these hurdles will be worth the final result.

V. Fabrication & Development Process

A. Materials

The current industry standard for matrix bands is a dead-soft steel primarily due to its mechanical properties and non-toxicity [5]. "Dead-soft" steel refers to a lower carbon and manganese content at less than 0.1% and 0.2-0.5%, respectively [21]. Additionally, it is processed by heating to a critical temperature and cooled more slowly, creating larger grains, making the material less hard, but more ductile. The tensile yield strength is 260-340 MPa, which must be relatively high to withstand tightening around the tooth [21]. The Rockwell B hardness is about 55, which is important for preventing deformations from forming when pressed up against the teeth but is limited due to the method of processing which allows for a lower elastic modulus. The elastic modulus is 200-215 GPa , sufficient for both allowing the thin material to bend around the tooth while maintaining tight contact with the tooth even when withstanding high outward stresses from packing the filling material [19].

In the past, materials such as copper, silver and titanium have been used to fabricate matrix bands but the mechanical characteristics, biocompatibility, and cost of dead-soft steel eliminated them from our considerations [5]. The team decided upon using a shim stock roll of 1008-1010 Grade Stainless Steel, steel containing 0.08 to 0.1% carbon by weight, for fabrication of the matrix band device [22]. The material has a thickness of 0.0254 mm, consistent with the thickness of current matrix bands [16]. The finalized expense table including this steel product as well as the dental tooth model used in brainstorming can be found in *Appendix B - Expense Table*.

B. Final Design & Fabrication Methods

After concluding that the proposed final design, the Butterfly + U Pinchers Design, would require a tedious and difficult fabrication, the team decided to move forward in a different direction. The Butterfly Design was reconsidered, and adjustments were made to the design so that it better satisfied the client's needs and the specified design criteria. The updated Butterfly Design, as seen in Figure 11, can be made from a single sheet of material, decidedly the 1008-1010 stainless steel, to make the fabrication process more feasible for the team and for possible mass production. The design has a band thickness throughout of 0.0254 mm, except at the center portion where the thickness is twice that, 0.0508 mm, due to folding of the steel sheet. Its height is 6.25 mm, consistent with the height of the circumferential matrix bands given to the team by the client. The updated design incorporates rounded edges for safety in the patient's mouth, a holed tab to aid in placement and removal of the device, and a convex bottom edge to prevent filling material from entering the gingiva during a procedure. Due to the folded nature of the design, there is space between each band to allow the use of a wedge during a procedure as well.

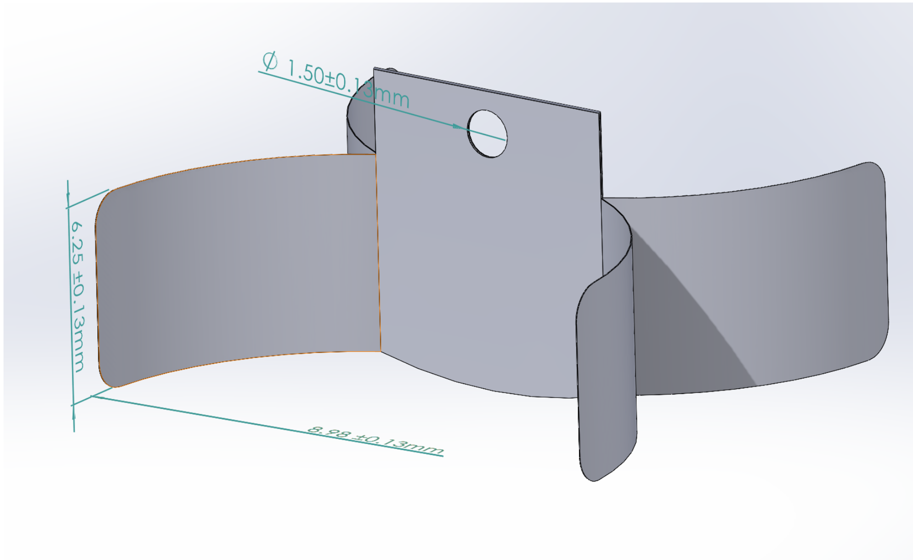


Figure 11: Updated Butterfly Design. Dimensions of the device include a height of 6.25 mm, a band radius of 8.98 mm, a hole diameter of 1.5 mm, and a material thickness of 0.0254 mm. Key features include rounded edges for safety, a holed tab for placement/removal, and a convex, rounded bottom edge for preventing the escapement of filling material.

The team initially fabricated an enlarged, unscaled prototype to emphasize the details of the design and ensure the 1008 steel could be modified for the design's purposes. A 152 mm x 127 mm rectangular sheet was measured from the 1008 steel shim stock using calipers and was cut with scissors. This sheet was then folded to create two equal 76 mm x 127 mm halves. Cuts were made 25 mm long on both ends of the fold, and 51 mm in from the short edges, to create a rectangular tab. Every sharp corner was then cut to be round in accordance with our final design. The four leaflets of the rectangular base created from these cuts were then shaped outwardly to a curvature of about 90 degrees, with a rounded cylinder, to contour. A hole punch was used through both sides of the folded tab to create the hole.

After finishing the enlarged prototype, smaller scaled prototypes were made following the same methods. The team, however, was unable to create smaller details of the design including the hole in the tab and the rounded edges using these methods.

C. Final Prototype

The final prototype was fabricated out of the 2540 mm long by 152.4 mm wide by 0.0254 mm thick shim stock made from 1008-1010 Grade Stainless Steel. This naming convention means that the stainless steel used in the prototype contained 0.08 to 0.1% carbon by weight [22]. As mentioned above, two prototypes were fabricated by hand. The scaled prototype can be seen in Figure 12. The enlarged, unscaled prototype was fabricated to include the key features that the small scale could not incorporate. The larger prototype can be seen in Figure 13.

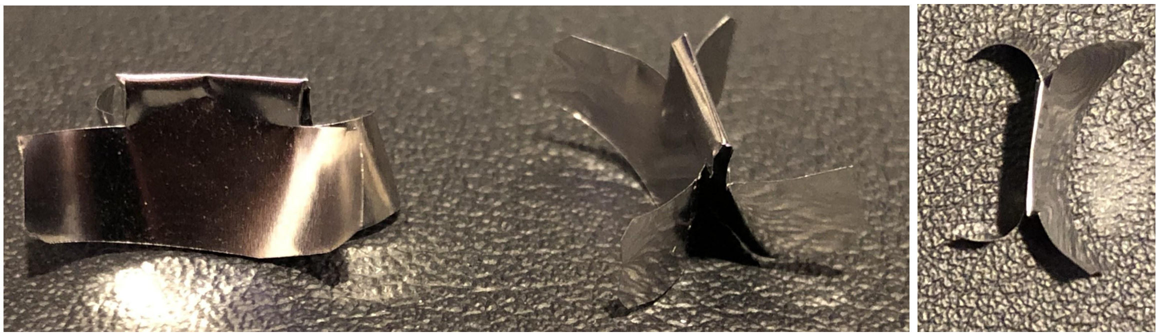


Figure 12a and 12b: Scaled Prototype. From left to right a view of the front, side, and top are shown. Take note of the pointed corners and lack of a hole on the top tab.

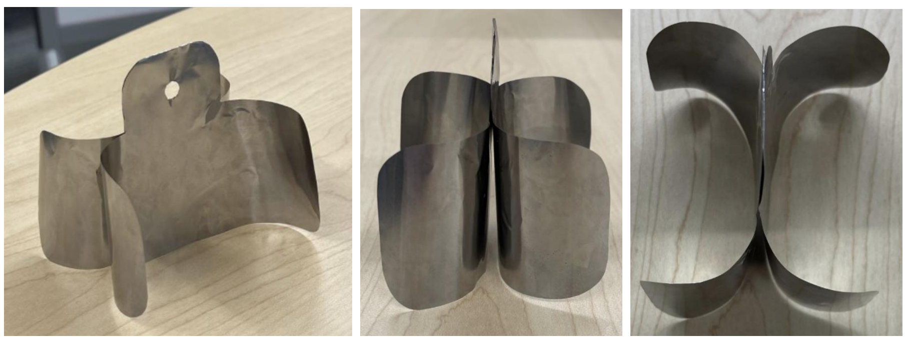


Figure 13a, 13b, and 13c: Enlarged Prototype. From left to right a view of the front, side, and top are shown. Take note of the curved corners and included hole on the top tab.

In the future, a different fabrication plan must be developed to ensure that all features of the design, including the convex bottom curve, are included in the prototype. After communicating with the TEAM lab on campus, it was conveyed that the team may be able to use a laser cutter to accurately cut out a to scale prototype with all the key features. However, laser cutters are not able to cut through highly reflective material but are able to cut through some stainless steel. If it turns out that the stainless steel is too reflective, a water jet may be used to fabricate the prototype. Laser cutting has a minimum cutting slit of 0.15 mm and a processing tolerance of 0.05 mm while the water jet has a minimum cutting slit of 0.5 mm and a processing tolerance of 0.2 mm [23]. While laser cutting may provide a more accurate cut, it may also end up melting the steel and leaving deformed edges. It may also be beneficial to outsource the fabrication to a prototyping company. All options will be considered in the upcoming semester.

D. Testing

There were two separate tests that were run to determine the mechanical properties of the 1008-1010 steel alloy that the final design was created with. The purpose of the testing was to determine if the 1008-1010 alloy had more favorable characteristics than the material that matrix bands are usually made out of, dead soft stainless steel. In the first test, a Solidworks Simulink simulation was run on a test matrix band while one of the lateral ends of the band was fixated. Loads were then applied normal to the band and laterally to the band as separate tests, in order to get resultant stress and strain calculations for multiple directions of force. In the normal test, at 200 N load was applied as the force required to move the band wouldn't need to be super high. Conversely, the load applied laterally was 20 kN as the force required to pull the band apart is much higher than the force required to bend the band. Lastly, each test was run twice to account for the two different materials being compared, totalling in four tests. The output of the simulation provides the Von Mises stress distribution which highlights where the highest stresses are seen on the band via a color gradient key. The simulation also provides the maximum displacement as well as the tensile yield strength and ultimate stress. An example of this output can be found in *Appendix C - SolidWorks Simulink Simulation Output (Normal Force/1008-1010).*

For the second test, a physical tensile test was done on some band prototypes made with the 1008-1010 alloy as well as market-available stainless steel matrix bands. In the protocol, bands were measured for length and cross sectional area, and loaded into an MTS static material test systems device via clamp fixtures. The specific model name is *MTS Insight - 5kN*, as seen in Figure 14, with 100 N rubber fixtures and 100 N (ss) tensile grips [24]. The gauge length and width was measured per sample and the forces were zeroed out on the device. Then, the device was set to a strain rate of 5 mm/min and the bands were pulled until they snapped or until the test failed. From this, the stresses and displacements were recorded and saved into a .txt file which allows the user to download the data and calculate a stress strain curve from the run. The full MATLAB code used to perform this analysis is found in *Appendix D - MATLAB Code to Evaluate MTS Testing Data.*

Figure 14: MTS Insight 5kN by MTS Systems Corporation. MTS machine used to run tensile strength tests on 1008-1010 alloy and market-available dead soft stainless steel.

The plan was to also take qualitative observations such as where the band yielded and how clean the break was. However, during the actual testing, there were many issues that involved the bands slipping out of the fixtures due to the tiny width. Many edits to the protocol were made in order to try and eliminate the slipping including changing the shape of the bands to have wider ends, quickening the strain rate, changing the fixtures, and adding tape to the ends to try improving the friction between the fixtures and the band. All efforts proved to be futile and not much data could be taken from the runs until the slipping affected the results. However, the best results were achieved when the ends of the bands were wrapped with masking tape and the strain rate was increased to 20mm/min.

VI. Results

The Solidworks Simulink testing suggested that the 1008-1010 steel alloy is very similar to the dead soft stainless steel it was compared to. In all of the tests, the yield strengths were 180.0 MPa and 172.2 MPa for the 1008-1010 and stainless steel bands respectively, showing little disparity between the materials. The maximum displacements were also nearly identical at 1.876 m for the 1008-1010 alloy band and 1.873 m for the stainless steel band. The Von Mises stresses matched up very similarly (5969 GPa and 5990 GPa for the stainless steel and 1008-1010 alloy), and the observed forces were distributed very similarly, as outlined in Figure 15. For the tensile load test, the displacements were within .001 mm with the 1008-1010 alloy at 4.202 mm and the stainless steel at 4.201 mm. Likewise, the Von Mises max stresses were also similar for the tensile stress test. The 1008-1010 alloy recorded a maximum Von Mises stress of 650.8 GPa and the stainless steel recorded a Von Mises max stress of 651.5 GPa, as outlined in Figure 16.

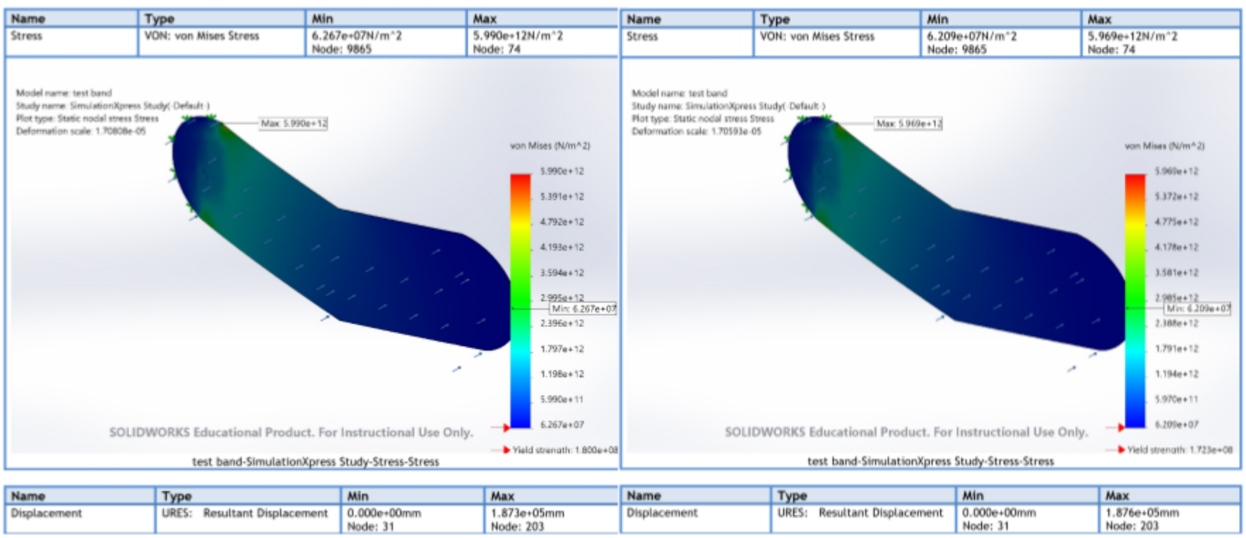


Figure 15a, 15b: Solidworks Simulink stress simulations with load applied normal to the band. Output yields the distribution of Von Mises stresses. 1008-1010 alloy on the left and dead soft stainless steel on the right.

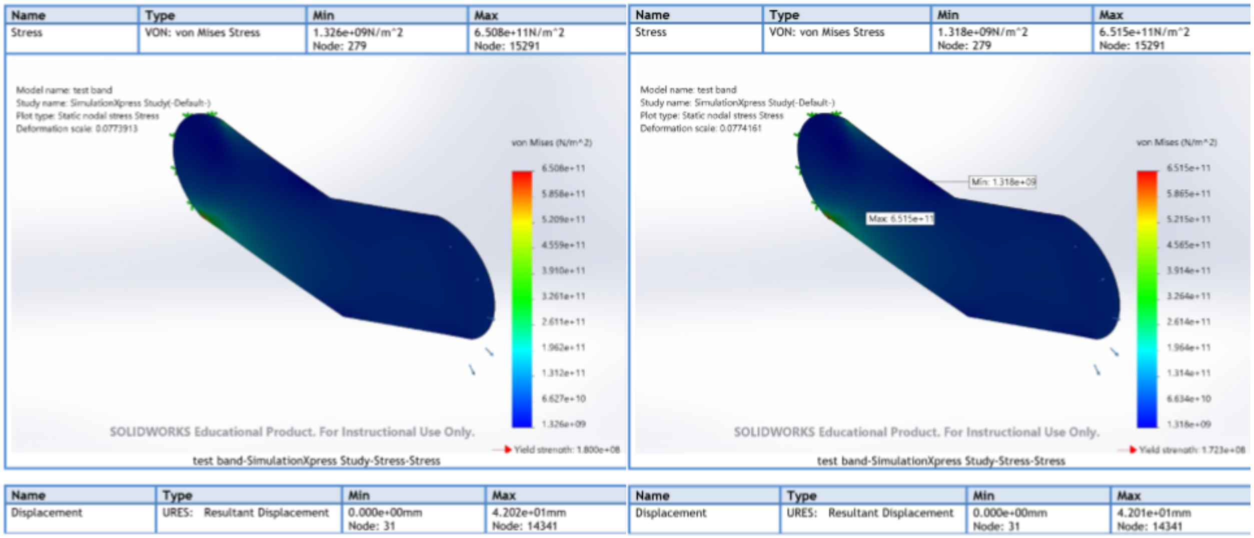


Figure 16a, 16b: Solidworks Simulink stress simulations with load applied laterally to the band. Output yields the distribution of Von Mises stresses. 1008-1010 alloy on the left and dead soft stainless steel on the right.

Although the Solidworks testing revealed fairly similar results for the stress at 200N and the tensile yield strength between the two materials, MTS testing data revealed a difference in Young's Modulus values between the two materials. Figure 17 shows the stress-strain curve for the two best trials (defined as the trials with the least slippage) performed on the 1008 steel alloy. The linear region of the curve was approximated, and a line of best fit was created for only the linear region. The slope of this linear region is the Young's Modulus, which had an average of 627.7 GPa for the 1008 steel alloy. This value was higher than the Young's Modulus obtained for the currently used stainless steel material. Figure 18 shows the stress-strain curves of the two best trials (again defined as the trials with the least slippage) performed on the provided circumferential dental matrix band material (stainless steel). The slope of the linear region for these graphs was 162.8 GPa.

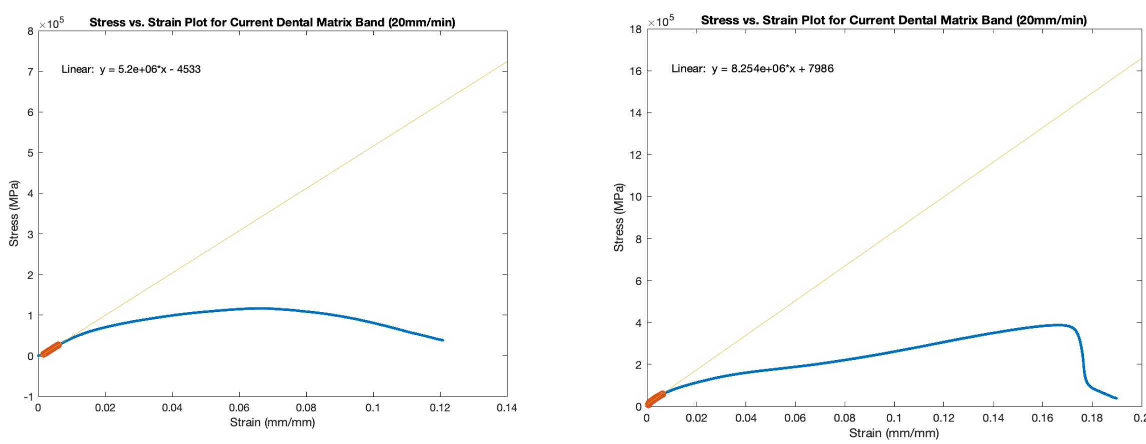


Figure 17: Plotted Stress-Strain curves from tensile testing on an MTS machine to determine Young's Modulus. Both runs above are with the 1008 steel alloy.

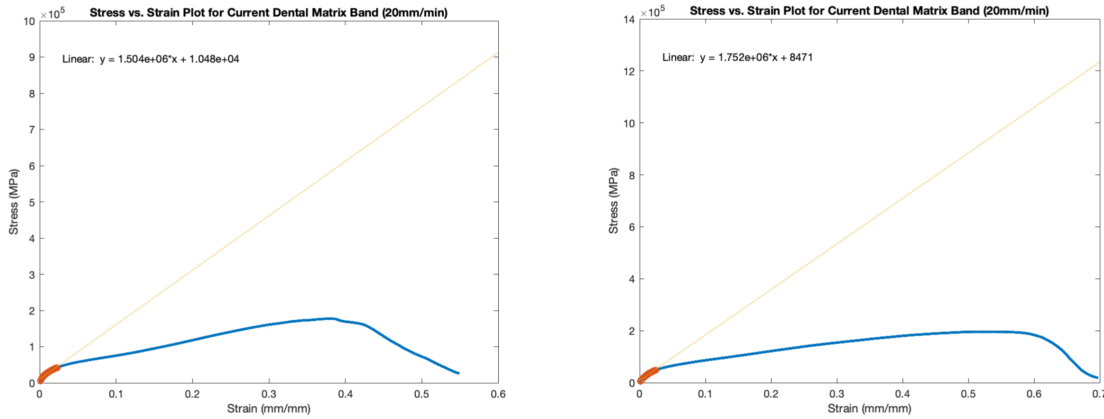


Figure 18: Plotted Stress-Strain curves from tensile testing on an MTS machine to determine Young's Modulus. Both runs above are stainless steel.

Since the difference in Young's Modulus values between the two materials appeared drastically different at first, the team conducted a One-Way ANOVA test on the results with the null hypothesis that there is no difference in the Young's Modulus means. Table 2 and 3 summarize the results of the ANOVA test.

Table 2: Data Summary of the One-Way ANOVA test on the Young's Modulus values of the 1008 steel alloy and the currently used material of the dead-soft stainless steel.

Groups	N	Mean	Standard Deviation	Standard Error
1008 Steel Alloy	2	672700000000	215950410974.3716	152700000000
Dead-Soft Stainless Steel	2	162800000000	17536248173.4264	12400000000

Table 3: ANOVA Test Summary. The F-statistic value was found to be 11.07739 and the P-value was found to be 0.07964.

Source	Degrees of Freedom (DF)	Sum of Squares (SS)	Mean Square (MS)	F-Statistic	P-Value
Between Groups	1	$2.5999800999999998 \times 10^{23}$	$2.5999800999999998 \times 10^{23}$	11.07739	0.0796
Within Groups	2	$4.6942099999999996 \times 10^{22}$	$2.3471049999999998 \times 10^{22}$		
Total	3	3.0694011e+23			

This ANOVA test was tested with an alpha level of .05 (a standard value). Due to a high P-value of 0.07964, the team failed to reject the null hypothesis and thus, did not have sufficient evidence to conclude a significance difference between the Young's Modulus values of the 1008 alloy and currently used dead-soft stainless steel.

VII. Discussion

The results found in the mechanical testing of the materials were similar to those in the literature. The Young's Modulus of the dead soft steel used in dental matrix bands was reported at 200-215GPa, as discussed previously in the materials section, while the team's MTS testing found an average Young's Modulus of 162.8 GPa [19]. Although slightly low, the team felt confident that the MTS machine could be used on the team's ordered material to compare its mechanical properties with those of the current dental matrix bands.

The results of the Solidworks Simulink testing does not show any major mechanical differences between the bands made with the 1008-1010 steel alloy and the bands made with stainless steel, suggesting that the 1008 alloy either is dead soft, or can mimic dead soft metal. More Solidworks Simulink testing could be done by applying loading in different directions and fixing the model in varying locations. However, it was hypothesized that the materials would behave similarly under these conditions as both are dead soft steels that are malleable, yet tough. Therefore it would likely be unhelpful to continue testing as the odds that the materials would display very similar properties once again would be very high. This set of testing suggests that the 1008 steel alloy would be a good substitute for dead soft stainless steel in the final design as the materials behave extremely similarly.

Favorable testing results would mean there was no difference found between the mechanical properties of the team's material, the 1008 steel alloy, and the currently used dental matrix band stainless steel material. Although the statistical analysis from the ANOVA test yielded these favorable results with a high P-value concluding that no significant difference in the Young's Modulus can be concluded, there are a few considerations to be made here [25]. There are many limitations with a sample size this low and thus, this statistical analysis should moreso be used as preliminary evidence that the team's material exhibits appropriate mechanical properties and further testing should be performed.

Slippage was a great issue during testing. Although various factors were tested in attempts of avoiding slippage, such as cutting the material into a dog bone shape, using tape for increased grip, changing the deformation rate of the MTS machine and trying different fixtures, ultimately slippage occurred on every trial. Figure 19 displays some of the samples that were used in the MTS machine and the variety of methods that were put in place to avoid slippage. Figures 20a and 20b display testing that was done with two different MTS fixtures, displaying one of the variables the team tried changing to avoid slippage. Sometimes, damage such as fractures and tears occurred on the samples as well due to the stress applied from the MTS machine clamps onto the samples. This damage is displayed on the second sample from the left in Figure 19.

Figure 19: Samples that were used in the MTS Machine. A variety of methods above are shown that were used in attempts to avoid slippage such as the tape and dog bone cutouts.

Figure 20a and 20b: Two different fixtures being used during MTS testing. The fixture on the left seemed to lead to much later slippage and was the fixture primarily used.

Originally, the team performed a One-Way ANOVA test with many more trials for both materials. However, the team quickly questioned the accuracy of the results due to the early slippage that occurred in the majority of the trials. In most trials, slippage was occurring during the linear region of the stress-strain curve which would drastically impact the Young's Modulus value. Although it would mean a much smaller sample size, the team decided to analyze all the data and only include the samples in the ANOVA test where slippage did not occur until well after the linear region. Fortunately, there were two trials of each material that had slippage occur after the linear region of the stress-strain curve. This is what allowed the team to analyze the Young's Modulus of the stress-strain curve with confidence in the data.

It would be beneficial to repeat quantitative testing moving forward for a few reasons. First, it would be beneficial to analyze other mechanical properties beyond the Young's Modulus. For example, since the team has data on the ultimate tensile strength of the currently used dental matrix band material, testing for the ultimate stress and strain values of the 1008 steel used in our prototypes could be done and analyzed in the future. It would be beneficial to compare other mechanical properties such as bending with 3-edge boundary conditions to mimic use conditions as well as ultimate tensile strength and strain that could not be compared in the above testing due to testing limitations such as clamp slipping, machine availability, and time limitations. The team found some methods for preventing slippage were more effective than others, and by combining methods and creating a new testing protocol, the team may be able to prevent slippage in the future to yield both more property values and a greater sample size.

VIII. Conclusion

Dental care is very important for overall well being. One-third of adults have untreated dental caries; if left untreated, these can lead to infection and permanent tooth loss. 175 million people receive at least one dental filling every year [26]. Providing dentists with the proper tools and resources to perform these fillings with both quality and time efficiency is essential in helping the millions of people with untreated cavities. The current process to fill cavities varies depending on the classification and severity of the cavity. Matrix bands are a tool used by dentists to assist in providing support, patient protection and the proper contour of the filling material during the restoration. They are often used along with tooth wedges which serve to tighten the seal and prevent gingival overhang. Class II cavities are those on the interproximal surface of premolars and molars. They are known to be difficult to restore due to the necessity of maintaining a proper and tight tooth contact [27]. Current matrix bands, such as sectional and Tofflemire matrix bands have shortcomings when it comes to restoring Class II cavities because they cannot be used concurrently to fill two adjacent teeth. The dentist must perform one filling, then prepare another matrix band and wedge in order to perform the second filling. This is not only very tedious, but also time consuming, minimizing the amount of time dentists have to care for other patients.

The team was tasked with designing a device that would allow concurrent restoration of two adjacent interproximal cavities. When initially reviewing this problem, the team discussed the designs of the previous team. One of the designs, The Butterfly, stood out and seemed to offer an easy solution to the current issue at hand. The Butterfly allowed the proper tooth contact to be restored due to its two matrix bands consisting of half the thickness of a regular sectional band. However, the team anticipated some issues with this design upon further consideration. The placement and removal would be difficult without an additional tool to aid the dentists. The team was also unsure whether the contact of the band would be tight along the surface of the tooth without an additional force to keep it in place. Based on these considerations, the team came up with two additional designs to evaluate in the design matrix. The Handcuff Design took a fully different approach by being a circumferential matrix band that relies on its own openings to anchor and tighten the band around the tooth. The Butterfly + U Pinchers Design includes pinchers that improve some of the shortcomings of the Butterfly Design, but comes with its own shortcomings (such as potentially obstructing the view of the dentist). These three designs were evaluated in a design matrix, and ultimately, The Butterfly + U Pinchers Design was the preliminary winner. This is due to the inward force the pinchers exert on the matrix band, ensuring a tight and proper tooth contact, while allowing for easy removal and placement with the pinchers.

After moving forth with the Butterfly + U Pinchers Design, the team quickly noticed some practical aspects of this design were too difficult to overcome. Specifically, fabrication would pose a great issue due the extremely small components, the U pinchers and the main matrix band, of the design needing to be bound together. Due to limitations in the allowable thickness of the device, and manufacturing capabilities and cost, the team had difficulty coming up with a fabrication protocol for the Butterfly + U Pinchers design. After additional issues were found with our design once speaking with our client, such as obstructing the dentist's view, it was determined to be an ineffective and overcomplicated solution.

After many considerations, the team revisited the original Butterfly design, but made many modifications to it while creating a much easier fabrication protocol. The new design utilized a convex bottom edge, a tab with a hole at the top for removal and placement aid, and rounded edges/corners for safe use in the mouth. The team ordered a 1008-1010 steel alloy material to fabricate this design, which the team was able to do conceptually, on larger and roughly accurate scales. This was done by measuring dimensions with calipers and using scissors to make cuts. The sharp corners were then rounded and the matrix band lengths curved to match the form of our early designs. Preliminary testing on the team's ordered material displayed similar mechanical properties to the current standard of material, however, further testing needs to be done due to slippage during use of the MTS machine.

The team is very satisfied with the evolution of the design through the semester, however, much remains to be done. In addition to redoing quantitative testing in hopes of analyzing other mechanical properties such as bending properties, ultimate stress and strain, and increasing sample size, the team must also pursue creating a better prototype and performing qualitative testing. Low fidelity fabrication was successfully completed by the team this semester, however, a better model should be made that can be used in qualitative testing. After meeting with the TEAM lab, the suggestion was made to use a higher power laser cutter, not openly available on campus, on the 1008-1010 steel alloy to create a more precise model. Additionally, the recommendation to use the water jet to cut our planar designs that can be folded was recommended by a previous advisor for the project. Both these fabrication methods will be looked into. If the team is unsuccessful in using both these methods for a higher grade prototype, third party manufacturers will need to be researched into.

The team's most important goal for next semester is completing qualitative testing. This would consist of creating a survey for Dr. Tipple and his colleagues to fill out in order to determine the functionality of our design in its application. This qualitative testing will determine if the new design is more easily and quickly installed and removed, without impeding on the efficacy or speed of the tooth restoration. Likely, the survey should be a questionnaire that allows the dentist to evaluate our design based on its effectiveness in aiding concurrent fillings at once, its ease of use in both its placement and removal, and its time effectiveness. Although quantitative testing was important to ensure the team's material behaves similarly to the standard for matrix band material, qualitative testing is ultimately much more important as the success of the design is dependent on a dentist's desire to use it over the current model that has been used for years.

IX. References

[1] R. M. Benjamin, "Oral Health: The silent epidemic," Public health reports (Washington, D.C. : 1974), 2010. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2821841/. [Accessed: 20-Oct-2021].

[2] "What to Expect with Dental Fillings." Dentist Office in Cincinnati, OH, https://www.blueashdental.com/what-to-expect-with-dental-fillings.

[3] "Is a Dental Filling Always Required for Cavities?" David L. Baker DDS PA Plano Texas, 4 June 2019, https://www.davidbakerdds.com/blog/is-a-dental-filling-always-required-for-cavities/.

[4] Lucas-Rincón, S. E., Robles-Bermeo, N. L., Lara-Carrillo, E., Scougall-Vilchis, R. J., Pontigo-Loyola, A. P., Rueda-Ibarra, V., Loyola-Rodríguez, J. P., Escoffié-Ramirez, M., & Medina-Solís, C. E. (2019). Interproximal caries and premature tooth loss in primary dentition as risk factors for loss of space in the posterior sector: A cross-sectional study. Medicine, 98(11), e14875. https://doi.org/10.1097/MD.0000000000014875

[5] "A historical review of dental matrices from MDJ," *Scribd*. [Online]. Available: https://www.scribd.com/document/112847146/A-Historical-Review-of-Dental-Matrices-From-MDJ. [Accessed: 20-Oct-2021].

[6] Durr-E-Sadaf, Ahmad MZ, Gaikwad RN, Arjumand B. Comparison of two different matrix band systems in restoring two surface cavities in posterior teeth done by senior undergraduate students at Qassim University, Saudi Arabia: A randomized controlled clinical trial. Indian J Dent Res. 2018 Jul-Aug;29(4):459-464. doi: 10.4103/ijdr.IJDR_26_17. PMID: 30127197.

[7] Shaalan O. O. (2020). Evaluation of Matrix Band Systems for Posterior Proximal Restorations among Egyptian Dentists: A Cross-Sectional Survey. Acta stomatologica Croatica, 54(4), 392–400. https://doi.org/10.15644/asc54/4/6

[8] *Matrix placement for Class II Amalgam Restoration*. [Online]. Available: http://www.columbia.edu/itc/hs/dental/operative/matrixband.html. [Accessed: 20-Oct-2021].

[9] "Pro-matrix | disposable matrix system," Pro-Matrix band disposable matrix system. [Online]. Available: https://www.astekinnovations.co.uk/promatrix.php. [Accessed: 20-Oct-2021].

[10] "Medicos Pro-Matrix Single-Use Matrix Band," YouTube. Dental Product Shopper, 21-Jun-2017.

[11] Triodent V3 Better outcomes start here," Triodent V3 | Dentsply Sirona. [Online]. Available: https://www.dentsplysirona.com/en-au/categories/restorative/triodent-v3.html. [Accessed: 23-Sep-2021].

[12] "Dentsply Sirona Launches Ds Primetaper, Announces COMPREHENSIVE Restage of ITS Implant Business," Dental Products Report, 23-Sep-2021. [Online]. Available: https://www.dentalproductsreport.com/view/dentsply-sirona-launches-ds-primetaper-announces-comprehensive-restage-of-its-implant-business. [Accessed: 23-Sep-2021].

[13] A. E. G. I. S. Communications, "V3 sectional matrix system - triodent: Inside dentistry," Triodent | Volume 5, Issue 10 | Inside Dentistry. [Online]. Available:

https://www.aegisdentalnetwork.com/id/2009/12/v3-sectional-matrix-system-triodent. [Accessed: 23-Sep-2021].

[14] “Dental Matrix Systems,” Dentalcompare. [Online]. Available: https://www.dentalcompare.com/Restorative-Dentistry/4630-Dental-Matrices/

[15] R. SCHEID and G. WEISS, Woelfel's dental anatomy. BURLINGTON, MA: JONES & BARTLETT LEARNING, 2020.

[16] U. F. O. Themes, “Principles of tooth preparation,” Pocket Dentistry, 12-Feb-2015. [Online]. Available: https://pocketdentistry.com/principles-of-tooth-preparation-2/.

[17] M. Ahmad, “A Historical Review of Dental Matrices,” Malaysian Dental Journal, vol. 33, no. 2, pp. 1–7, 2011.

[18] S. Stowell, L. Gause, L. Granlund, and M. Sona, “Approximating Surface Matrix Band for Denstist to for Patients,” *University of Wisconsin-Madison Department of Biomedical Engineering*, Dec. 2020.

[19] “ASTM A109 Grade no. 5 dead-soft,” *Matmatch*. [Online]. Available: https://matmatch.com/materials/minfm65939-astm-a109-grade-no-5-dead-soft. [Accessed: 20-Oct-2021].

[20] “Dental fillings: Gold, Amalgam, Composite, ceramic and more,” WebMD. [Online]. Available: https://www.webmd.com/oral-health/guide/dental-health-fillings. [Accessed: 23-Sep-2021].

[21] Flyingchimp, “Dead soft steel,” *Falcon Aerospace*, 01-Aug-2013. [Online]. Available: https://www.falconaerospace.com/dead-soft-steel/. [Accessed: 20-Oct-2021].

[22] F. T. C. Ltd, “SAE/Aisi Carbon Steel Naming Conventions,” AZoM.com, 08-Aug-2014. [Online]. Available: https://www.azom.com/article.aspx?ArticleID=6151. [Accessed: 08-Dec-2021].

[23] Sculpteo, “Laser Cutter vs Waterjet Cutting: 5 points to set them apart,” Laser Cutting or Water Jet Cutting: Which is Best for Your Application? [Online]. Available: https://www.sculpteo.com/en/3d-learning-hub/laser-cutting/laser-cutting-vs-water-jet-cutting/. [Accessed: 15-Dec-2021].

[24] MTS SYSTEMS CORPORATION, 2006 MTS Insight™ ElectromechanicalTesting Systems: User Manual, Eden Prairie, MN

[25] “One-way ANOVA in SPSS statistics,” One-way ANOVA in SPSS Statistics - Step-by-step procedure including testing of assumptions. [Online]. Available: https://statistics.laerd.com/spss-tutorials/one-way-anova-using-spss-statistics.php. [Accessed: 15-Dec-2021].

[26] R. S. King, “A Closer Look at Teeth May Mean More Fillings,” The New York Times, 28-Nov-2011. [Online]. Available: https://www.nytimes.com/2011/11/29/health/a-closer-look-at-teeth-may-mean-more-fillings-by-dentists.html. [Accessed: 19-Oct-2021].

[27] Admin, “Survey results show what is key: Class II fillings - routine but still challenging,” Press & Media, 07-Aug-2017. [Online]. Available:

https://news.dentsplysirona.com/en/business-units/restorative/2017/class-ii-fillings--routine-but-still-chall
enging.html. [Accessed: 19-Oct-2021].

X. Appendix

A. Appendix A - Product Design Specifications

Approximating Surface Matrix Band

Product Design Specifications

December 15th, 2021

Client: Dr. Donald Tipple

Advisor: Dr. Tracy Puccinelli (Section 309)

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Function:

Matrix bands are a commonly used dental tool which assist dentists by creating an outside contour of a decayed tooth. This contour maintains the tooth's structure and shape during restorative procedures, such as cavity fillings. During typical filling procedures for cavities on interproximal surfaces, or two adjacent teeth, dentists must fill each tooth separately. This is a tedious procedure as each matrix band must be prepared for each tooth, which includes shaping, placement and securing with dental wedges and rings. This results because two matrix bands cannot fit in the interproximal space as together they are too wide and would create gaps in the restoration. A new dental matrix band design is desired to alleviate the need to repeatedly place bands. The device should employ a dual-band system with a thickness less than or equivalent to current matrix bands throughout such that the fit is secure and the band molds to the appropriate convex/concave contour of each tooth. The finalized product should also maintain the tensile strength, malleability, and space efficiency of current matrix bands. The material used to fabricate the matrix band must not cause any irritation, must be biocompatible, and must be non-reactive to filling materials.

Client Requirements:

- The matrix band should be sectional, or non-circumferential, so that only the approximating surfaces of the teeth being filled are in contact with it.

- Nickel and other irritating materials must not be used to make the matrix band.
- The material used to fabricate the matrix band should not interact with or adhere to materials used in filling cavities and must be biocompatible.
- The device must either be single-use or sterilizable if used more than once.
- The matrix band should include a small hole for floss to fit through so that dentists may easily retrieve the piece if it falls into a patient's mouth.
- The inferior edge, or the gum edge, of the matrix band should be made slightly concave to encapsulate the entire cavity being filled and to help with orientation of the device.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:*
        i. The matrix band should be able to maintain its structure and function from the time it is placed in the mouth until the filling procedure is over, up to 1 hour [1].
            1. The device should be single-use.
        ii. The device should maintain similar mechanical characteristics of existing matrix bands, withstanding loads placed on it during filling.
            1. It should still be malleable and able to shape around any tooth.
                a. Tensile strength of dead-soft stainless steel is 260-340 MPa and the elastic modulus is 200-215 GPa [2].
        iii. The device should incorporate wedges or another component that effectively separates the approximating teeth being filled.

    b. *Safety:*
        i. The material used to fabricate the matrix band should not cause any irritation to patients (i.e. Nickel) and must be biocompatible.
        ii. The device must not have any sharp edges or points.
        iii. The device must come with a safety label to inform users how to properly handle it to ensure safety.
            1. It must also come with a safety warning that encourages users to dispose of the device if sterile packaging is tampered or the device is broken.

    c. *Accuracy and Reliability:*
        i. The device thickness should be accurate to a hundredth of a millimeter during manufacture to ensure it remains below 0.0508 mm, an acceptable interproximal space [3].

ii. The matrix must maintain this thickness and its conformation to the tooth such that there are no abnormalities when the filling is packed and solidified.

d. *Life in Service:*
   i. The device must maintain the target properties for the duration of the procedure in which it is used. For a cavity filling, this is generally within an hour [1]. After this, it will be disposed of.

e. *Shelf Life:*
   i. Most current matrix bands are made of stainless steel or natural plastics which have an indefinite shelf life for practical purposes. Our device should match this shelf life while kept in the proper packaging.
   ii. This device should be kept at or near room temperature.

f. *Operating Environment:*
   i. The human mouth is a variable environment with both physical, chemical and biological factors to consider.
      1. This device must maintain its integrity when forced in between teeth which have a Mohs hardness rating of 5 [4]. It must also be blunt enough to prevent injury of the, potentially compromised, tooth and surrounding gums. Operating temperature ranges from room temperature (~20℃) to body temperature (~37℃).
      2. The mouth has a pH with a range of 6.2-7.6. There are also a variety of enzymes in the saliva that the device must withstand [5].
      3. The device must be non-toxic to the cells of the body as well as essential bacteria of the mouth and free of common allergens like nickel.

g. *Ergonomics:*
   i. The new device should be easier and much less time consuming to install, adjust, and use than existing products on the market, such as the sectional and circumferential matrix bands.

h. *Size:*
   i. The device should be adjustable and/or scalable to accommodate all sizes of teeth. The dimensions of human teeth can vary greatly with type of tooth, sex, age, race, and many other factors. On average, maxillary teeth have a crown height of 8.77 mm, ranging from 7.2 mm to 11.2 mm, and

mandibular teeth have a crown height of 8.62 mm, ranging from 7.5 mm to 11.0 mm [6].

ii. The perimeter of teeth can be approximated by treating teeth as rectangles and using average mesiodistal diameter and faciolingual diameter measurements of 8.20 mm and 8.71 mm, respectively. This approximation would result in an average tooth perimeter of 33.82 mm, with a range of 22 mm to 45.8 mm [6].

iii. Current matrix bands commonly come in three different thicknesses: 0.001 gauge (0.0254 mm), 0.0015 gauge (0.0381 mm), and 0.002 gauge (0.0508 mm) [7]. The device should have a similar or smaller thickness than current matrix bands.

i. Weight:

i. Current matrix bands are made of stainless steel. Using the gauge size (0.0015), approximate tooth size (height = 8.695 mm, perimeter = 33.83 mm), and the density of stainless steel (7.99 g/cm^3) we can calculate the weight of one matrix band [8]. This comes out to a weight of 0.0895 grams. The device should weigh similar to current matrix bands.

j. Materials:

i. The matrix band is expected to be made out of a dead soft metal, meaning it is rigid in its resting state while still being malleable [9]. This would include materials such as stainless steel and aluminum. The material must also be non-toxic to humans to prevent harm to a patient. The material also must not react with both silver fillings and white fillings.

ii. If possible, the material should be able to be sanitized. This would allow for a more sustainable product that is also more cost effective.

iii. The wedge is traditionally made out of wood. For the purposes of this project, the wedge will likely be made of some sort of plastic due to the ease of fabrication.

k. Aesthetics, Appearance, and Finish:

i. The band and the wedge should not be colored the same as a tooth to avoid confusion while operating. The aesthetics were not a priority with the client and depend more on functionality.

2. Production Characteristics

a. Quantity:

i. The product is expected to be non-reusable. That means if it is made market available, the product would need to be mass produced to meet the demand of dentists for every adjacent tooth filling procedure. For the purposes of the product, there will likely be 1-3 prototypes produced.

b. *Target Product Cost:*
    i. The goal when planning out the designs is to keep the products as cost effective as possible without sacrificing quality. Current matrix bands go for about 50 cents to a dollar [10]. Given the possible complexity of our design, it might be more expensive to fabricate but keeping the price under $3-5 should be prioritized.
    ii. The budget for the project is expected to be around $200-300 given the testing needed to be done.

3. Miscellaneous

a. *Standards and Specifications:*
    i. FDA approval is necessary for medical devices. Current matrix bands are Class 1 devices as specified in the Codes of Regulations Title 21, Chapter 1, Subchapter H, Part 872 Subpart E. They are identified as low risk devices that present minimal potential for harm. If the new design utilizes the same materials used before 1976 , it would be exempt from premarket notification procedures specified in Subpart E [11]. Otherwise, a premarket notification submission would need to be completed to the Food and Drug Administration at least 90 days prior to the proposed introduction of the product [11]. An Investigational Device Exemption (IDE) would need to be obtained to pursue clinical studies with the device to collect data on safety and effectiveness in support of the Premarket Approval (PMA) application or Premarket Notification 510(k) submission. These studies must be approved by the Institutional Review Board (IRB) before the studies begin [12].

b. *Customer:*
    i. This design should mainly appeal to dentists. Thus, the design needs to be optimized to fit the user's comfort and ease of use while decreasing procedural time. Dental suppliers would also be target customers, so the design must outcompete others on the market. The client specifications should be closely followed, as the client has the perspective of a dentist and, thus, potential customer.

c. *Patient Related Concerns:*
    i. The device will be in direct contact with the patient's oral cavity, so the materials must be non-toxic and non-allergenic. Common metal allergies

include: nickel, cobalt, copper and chromium [13]. This design should also be one-time use, similar to the current matrix band used. Thus, sterilization would not be a concern. Ideally, the device would not add any additional discomfort during the filling process.

d. *Competition:*

   i. There are numerous devices and techniques that can be considered competing designs, however, those that relate most to this project are sectional matrix systems. The Triodent V3 Ring used alongside the Triodent Wave-Wedge is advertised as a sectional matrix system that allows for superior functionality compared to the circumferential band (tofflemire) [14][15][16]. Specifically in Class II cavities, if this Triodent ring is used to separate adjacent teeth with the placement of two matrix bands, the contact between the teeth would not offer optimal contact leading to a larger gap than desired.

References

[1] “Dental fillings: Gold, Amalgam, Composite, ceramic and more,” WebMD. [Online]. Available: https://www.webmd.com/oral-health/guide/dental-health-fillings. [Accessed: 23-Sep-2021].

[2] “ASTM A109 Grade no. 5 dead-soft,” *Matmatch*. [Online]. Available: https://matmatch.com/materials/minfm65939-astm-a109-grade-no-5-dead-soft. [Accessed: 20-Oct-2021].

[3] U. F. O. Themes, “Principles of tooth preparation,” Pocket Dentistry, 12-Feb-2015. [Online]. Available: https://pocketdentistry.com/principles-of-tooth-preparation-2/. [Accessed: 23-Sep-2021].

[4] K. Watson, “Hardest substance in the human body: All about tooth enamel,” Healthline, 22-Sep-2020. [Online]. Available: https://www.healthline.com/health/hardest-substance-in-the-human-body#:~:text=According%20to%20the%20Mohs%20Hardness,10%20on%20the%20Mohs%20scale. [Accessed: 23-Sep-2021].

[5] S. Baliga, S. Muglikar, and R. Kale, “Salivary ph: A diagnostic biomarker,” Journal of Indian Society of Periodontology, vol. 17, no. 4, p. 461, 2013.

[6] R. I. C. K. N. E. C. SCHEID and G. A. B. R. I. E. L. A. WEISS, Woelfel's dental anatomy. BURLINGTON, MA: JONES & BARTLETT LEARNING, 2020.

[7] “JR Rand Tofflemire,” Net32. [Online]. Available: https://www.net32.com/search?q=JR%2BRand%2BTofflemire%2Btype. [Accessed: 22-Sep-2021].

[8] “305 stainless steel alloy data sheet,” Combined Metals of Chicago, 14-May-2018. [Online]. Available: https://www.combmet.com/305-stainless-steel-alloy/. [Accessed: 22-Sep-2021].

[9] Bell, Eddie. “Understanding Metal Hardness.” Rio Grande, 29 Oct. 2020, www.riogrande.com/article?name=UnderstandingMetalHardness.

[10] Lowe, A., Burke, F., McHugh, S. et al. A survey of the use of matrix bands and their decontamination in general dental practice. Br Dent J 192, 40–42 (2002). https://doi.org/10.1038/sj.bdj.4801286

[11] “CFR - code of federal Regulations Title 21,” accessdata.fda.gov. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=872.4565. [Accessed: 23-Sep-2021].

[12] Center for Devices and Radiological Health, “Overview of device regulation,” U.S. Food and Drug Administration. [Online]. Available: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation. [Accessed: 23-Sep-2021].

[13] Y. Yoshihisa and T. Shimizu, “Metal allergy and systemic contact dermatitis: An overview,” Dermatology research and practice, 2012. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3369403/. [Accessed: 23-Sep-2021].

[14] “Triodent V3 Better outcomes start here,” Triodent V3 | Dentsply Sirona. [Online]. Available: https://www.dentsplysirona.com/en-au/categories/restorative/triodent-v3.html. [Accessed: 23-Sep-2021].

[15] “Dentsply Sirona Launches Ds Primetaper, Announces COMPREHENSIVE Restage of ITS Implant Business,” Dental Products Report, 23-Sep-2021. [Online]. Available: https://www.dentalproductsreport.com/view/dentsply-sirona-launches-ds-primetaper-announces-comprehensive-restage-of-its-implant-business. [Accessed: 23-Sep-2021].

[16] A. E. G. I. S. Communications, “V3 sectional matrix system - triodent: Inside dentistry,” Triodent | Volume 5, Issue 10 | Inside Dentistry. [Online]. Available: https://www.aegisdentalnetwork.com/id/2009/12/v3-sectional-matrix-system-triodent. [Accessed: 23-Sep-2021].

B. Appendix B - Expense Table

Item	Supplier / Brand	UPC	Link	Quantity	Date	Price
Dental Implant Teeth Model Study Teach Standard Model with Removable Teeth	Amazon / Smile1000	601263927587	https://www.amazon.com/dp/B071JVJ1LG/ref=cm_sw_r_sms_api_glt_fabc_BZN7G1DC333NTE4CCJVE	1	10/20/21	$28.42
Steel Shim Stock Roll, 1008-1010 Grade, 0.001 in Thickness, +/-0.0001 in Thickness Tolerance	Grainger	Item Number: 3L432	https://www.grainger.com/product/PRECISION-BRAND-Steel-Shim-Stock-Roll-3L432?opr=PDPRRDSP&analytics=dsrrItems_5EY10	1	11/21/21	$35.96
					Total	$64.38

C. Appendix C - SolidWorks Simulink Simulation Output (Normal Force/1008-1010)

Simulation of test band

Date: Tuesday, December 7, 2021
Designer: Solidworks
Study name: SimulationXpress Study
Analysis type: Static

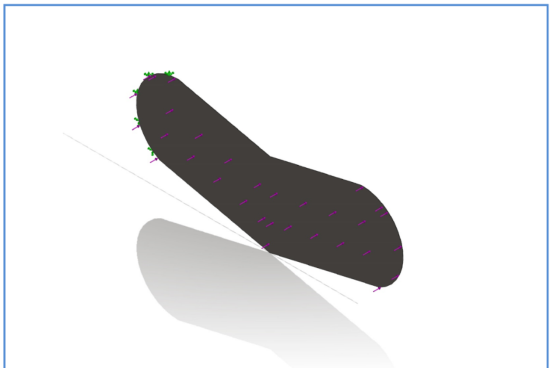
Table of Contents

Description

No Data

Assumptions

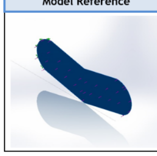
Model Information



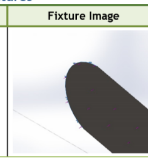
Model name: test band
Current Configuration: Default

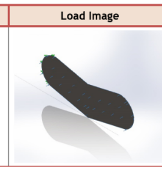
Solid Bodies			
Document Name and Reference	Treated As	Volumetric Properties	Document Path/Date Modified
Boss-Extrude1 	Solid Body	Mass:5.96039e-05 kg Volume:7.57356e-09 m^3 Density:7,870 kg/m^3 Weight:0.000584118 N	C:\Users\mafa1\OneDrive\Documents\College\Senior\BME400\test band.SLDPRT Dec 6 22:22:10 2021

Material Properties

Model Reference	Properties	Components
	Name: AISI 1010 Steel, hot rolled bar Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 1.8e+08 N/m^2 Tensile strength: 3.25e+08 N/m^2	SolidBody 1(Boss-Extrude1)(test band)

Loads and Fixtures

Fixture name	Fixture Image	Fixture Details
Fixed-3		Entities: 1 face(s) Type: Fixed Geometry

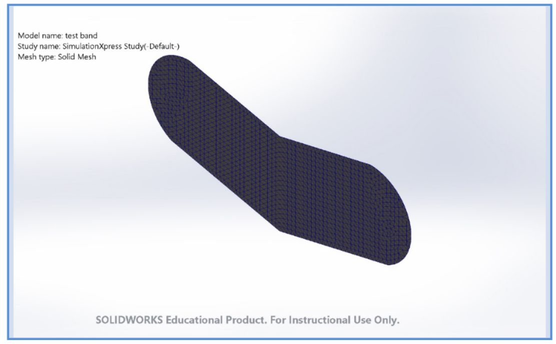
Load name	Load Image	Load Details
Force-3		Entities: 1 face(s) Type: Apply normal force Value: 200 N

Mesh information

Mesh type	Solid Mesh
Mesher Used:	Standard mesh
Automatic Transition:	Off
Include Mesh Auto Loops:	Off
Jacobian points for High quality mesh	16 Points
Element Size	0.489198 mm
Tolerance	0.0244599 mm
Mesh Quality	High

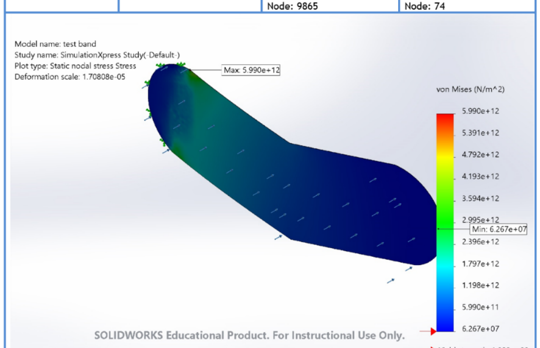
Mesh information - Details

Total Nodes	15445
Total Elements	7488
Maximum Aspect Ratio	52.594
% of elements with Aspect Ratio < 3	0
Percentage of elements with Aspect Ratio > 10	100
Percentage of distorted elements	0
Time to complete mesh(hh;mm;ss):	00:00:02
Computer name:	



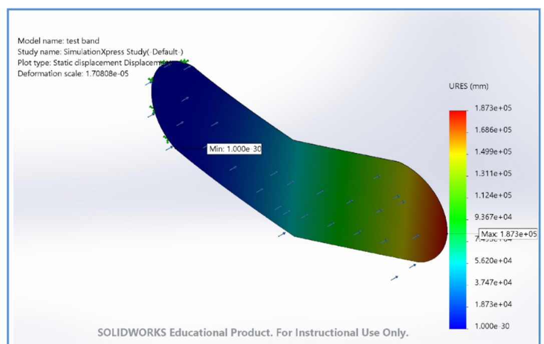
Study Results

Name	Type	Min	Max
Stress	VON: von Mises Stress	6.267e+07N/m^2 Node: 9865	5.990e+12N/m^2 Node: 74



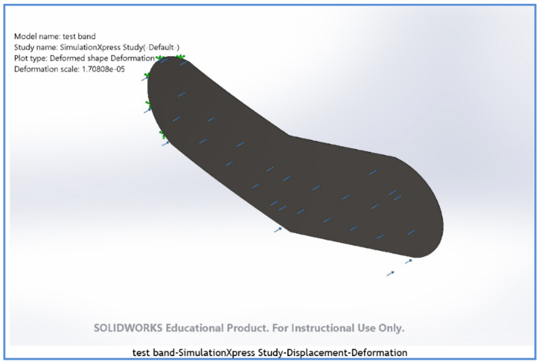
test band-SimulationXpress Study-Stress-Stress

Name	Type	Min	Max
Displacement	URES: Resultant Displacement	0.000e+00mm Node: 31	1.873e+05mm Node: 203



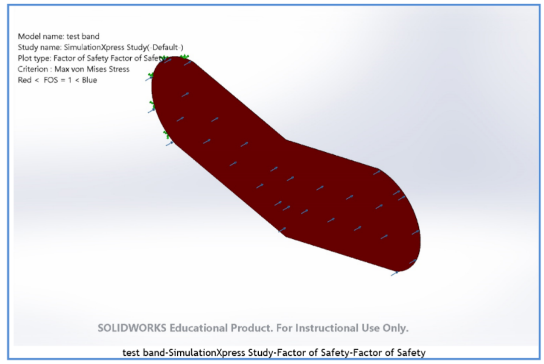
test band-SimulationXpress Study-Displacement-Displacement

Name	Type
Deformation	Deformed shape



test band-SimulationXpress Study-Displacement-Deformation

Name	Type	Min	Max
Factor of Safety	Max von Mises Stress	3.005e-05 Node: 74	2.872e+00 Node: 9865



test band-SimulationXpress Study-Factor of Safety-Factor of Safety

Conclusion

D. Appendix D - MATLAB Code to Evaluate MTS Testing Data

```
close all;
clear all;
data=load("bme400207.txt"); %import the correct data (different for each run)
disp=data(:,1);
force=data(:,2);
time=data(:,3);
dispMain= disp-disp(1,1); %subract initial values (initial values should be 0 regardless)
%Below is a force vs. frame plot to determine where the linear region is.
%This plot is used to select the frame where linear region begins and ends
figure(1);
plot(force);
xlabel('Frame (point)')
ylabel('Force (kN)')
title('Force Measured Using an MTS Machine over Many Frames');
j1=input('Enter first frame of the linear region of loading curve');
j2=input('Enter last frame of the linear region of the loading curve');
Lo=input('Enter the gauge length');
A=input('Enter the cross-sectional area of your specimen');
stress = (force*1000)/A;
strain = dispMain/Lo;
figure(2)
plot(strain,stress,'.',strain(j1:j2),stress(j1:j2),'o')
xlabel('Strain (mm/mm)')
ylabel('Stress (MPa)')
title('Stress vs. Strain Plot for Current Dental Matrix Band (20mm/min)')
%Change title as appropriate for trials
```