

Approximating Surface Matrix Band For Interproximal Cavity Tooth Restoration

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Abstract

Matrix bands are a commonly used dental tool which assist dentists by creating an outside contour of a decayed tooth. During typical filling procedures for cavities on interproximal surfaces, or two adjacent teeth, dentists must fill each tooth separately because two matrix bands cannot fit in the interproximal space as they are too wide. Our butterfly matrix band design allows dentists to operate on adjacent teeth during an interproximal cavity procedure without removing and reapplying the matrix band. The model has two sets of wings that wrap around adjacent teeth and meet in a center tab that can be easily placed into the interproximal space. The bands are cut out of 316 stainless steel shim stock with a laser cutter, folded together, and adhered with epoxy. The bands were tested via simulated loads on Solidworks and mechanical tensile testing using an MTS machine to confirm that the 316 stainless steel exhibits similar mechanical properties to the stainless steel used in market grade matrix bands. Qualitative testing was done with a survey given to dentists to assess the functionality and effectiveness of the bands. The qualitative testing suggests that while the epoxy was unnecessary for the prototype, the design and functionality improve the efficacy of interproximal cavity procedures. Slight modifications to the dimensions and better data from mechanical testing would be able to improve the quality of the product.

Introduction

The average American has about three dental fillings, while one in four Americans have eleven or more fillings. Cavities are one of the most common dental procedures, yet, the CDC still estimates that about one-third of adults have untreated dental caries that require fillings [1]. Matrix bands are a commonly used dental tool which assist dentists in restoring the shape and integrity of a decayed tooth. They provide support, shape, and contour for replacement filling material all while protecting the gingival tissue.

During filling procedures for cavities in interproximal spaces, or the space between two adjacent teeth, dentists must fill the cavities of each tooth separately [2]. This process includes shaping the matrix band to the proper size, shape, and contour, placing the matrix band around a singular tooth, securing the band with other dental devices, inserting and packing the dental filling material, curing that material, and then removing the matrix band and repeating the entire process for the second tooth. Adjacent teeth must be filled separately as the thickness of current matrix bands prevent two matrix bands from fitting into interproximal spaces and doing so would lead to poor tooth contact after the filling material has been cured. Proper tooth contact is necessary for keeping food and bacteria from entering the space and causing further decay.

Existing matrix bands can be placed into two broad categories, sectional and circumferential [3]. As their names suggest, sectional matrix bands wrap around a section of the tooth and circumferential matrix bands wrap around the entire circumference of the tooth. Sectional matrix bands are typically secured around a tooth using two other dental devices: wedges and rings. Wedges are inserted along the gums and placed in between the matrix band and adjacent tooth. Wedges can be inserted from the buccal or lingual side, or can be inserted on both sides depending on the shape and size of both the tooth and wedge. Their purpose is to help contour the matrix band to the shape of the tooth and to prevent any filling material from

leaking into the gingival cavity. A ring is used to apply pressure to the part of the sectional matrix band that wraps around the tooth and keeps the band in place while the filling procedure occurs. In a circumferential matrix band, the ring is often replaced with a device called a Tofflemire. A matrix band is inserted into a Tofflemire and secured to the device using a knob. After placing the band and Tofflemire around the tooth, a second knob is used to tighten the matrix band around the tooth, creating a tight contact with the tooth and holding it in place [4].

A new dental matrix band device should be created which allows adjacent restorations to be done consecutively, without the need for replacement. The band should have a total thickness equivalent to current matrix bands, such that the fit is secure and the band molds to the convex contour of each tooth. It should also maintain the tensile strength, malleability, and accessibility of current matrix bands [5]. Having an application process similar to existing matrix bands and being able to integrate with existing dental devices is desirable. A new matrix band device could help advance the public dental health industry by helping to reduce procedure times by up to 30%, making treatment more efficient, convenient, and less costly.



Figure 1: On the left is an unfolded, circumferential matrix band. In the middle is a Tofflemire attached to a circumferential matrix band. The upper right image shows how the entire device would be used to wrap around the tooth.

Methods

Design Process. Dental matrix band alternatives were developed through an iterative

process, beginning by establishing product design specifications based on functional requirements and characteristics of popular existing matrix bands, among other miscellaneous criteria. These specifications were then used in the formulation and evaluation of three main designs which were compared through a design matrix. One design was selected from this evaluation in the creation of an initial prototype. Throughout the process of determining potential methods of fabrication, concurrent research was conducted, and advice from experts was sought out. This resulted in modifications to our initial prototype's design before its fabrication as illustrated in Figure 2.

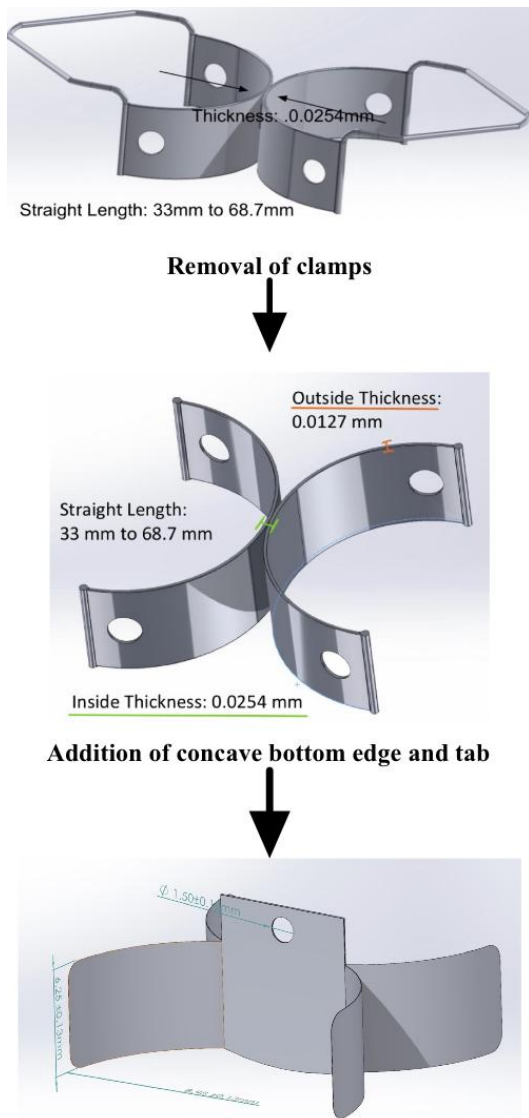


Figure 2: Evolution of Solidworks designs for the Butterfly design from the first model (top) to the third iteration (bottom)

The initial design incorporated built-in clamp-like structures which were removed after concerns of fabrication difficulty and obstruction during the procedure. A concave bottom edge and its dimensions were included and adjusted to create a more effective protective barrier between the tooth and gingiva. A tab with a centered hole was also incorporated to allow for improved handling of the matrix band, and compatibility with existing tools, namely tweezers.

The first prototypes were constructed with 1008/1010 metal, which was selected due to its low carbon content and predicted dead-soft properties [6]. The current industry standard for matrix bands is a dead-soft steel primarily due to its mechanical properties and non-toxicity [7]. “Dead-soft” steel refers to a lower carbon and manganese content at less than 0.1% and 0.2-0.5%, respectively. 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 [8]. However, after handling the prototype, it became apparent that the metal did not plastically deform readily enough to properly contour to the tooth. The following prototypes were fabricated out of 316 steel as it was deemed to have better plasticity. The dimensions of the opposing wings were then shortened, both in length and height, to better fit the mouth models available to use, as well as, the anatomy of many patients.

Preliminary Fabrication. Our design, nicknamed the butterfly design, effectively works as two sectional matrix bands that are combined into one. There are 2 wings that each curve in opposite directions and can be used to surround adjacent teeth. The wings meet at a common center that is used to properly space teeth. The band is .05 mm width at this center portion and .025 mm on the wings. The center portion of the band has a tab that comes off the top, sitting above the crown of the molars. These are used to allow for a contact point if

a dentist is using a ring. The bottom of the center section has a concave edge that is used to dig better into the gums and prevents sliding. A 3D model of the design is included below as Figure 3.

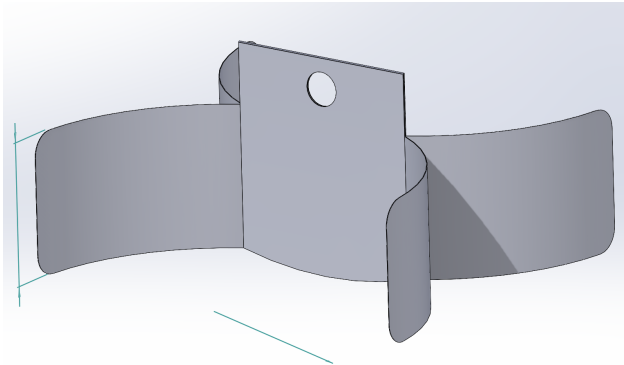


Figure 3: Solidworks model of butterfly design

The band wings are 21.98mm long and 5mm in height. The center tab width is 11.79mm and the height is extended to 8.4mm due to the added length from the tab and concave edge. If brought to market, the lengths of the bands would vary to adapt to multiple tooth sizes.

The matrix band models are created using stainless steel shim stock and cut using laser cutting technology. The grade of stainless steel is 316 and the metal stock is used in sheets that are .001” thick. The tracings of the models were created in Solidworks by outlining one wing of the design on a flat surface. The model is then mirrored about the top edge of the tab on the band to create a 2D model of both wings of our model as seen in figure 4.

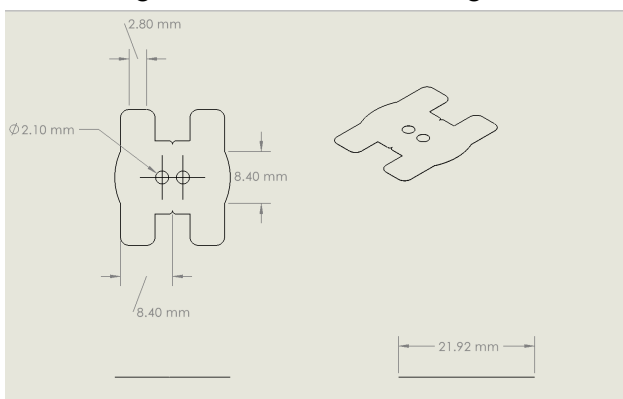


Figure 4: SolidWorks Drawing of flattened butterfly matrix band design with dimensions

The two wings are connected at the top of the tab so a curved edge is added to use as a perforation for easier alignment. The file was saved as a drawing and as a dxf. File and can be traced by AI to be sent to laser cutting software. Models were cut using a 5 watt UV laser cutter by fastening a sheet of the shim stock with magnets. The models were folded and aligned by hand after cutting. Then a thin layer of generic brand epoxy (permatex) was applied between the wings using a micropipette and left to cure overnight. Through laser cutting, hundreds of bands could be made in the short span of an hour. Many bands could be processed to be laser cut at once all on the same sheet of shim stock. An 8” x 12” sheet could contain 96 bands and be cut out in under 10 minutes.

Mechanical Testing. The tensile strength of the metals selected for the butterfly matrix band, as well as the Tofflemire matrix band, were tested under the same conditions in an MTS machine. MTS testing was performed on two separate occasions: once comparing the 1008/1010 stainless steel to the Tofflemire matrix band stainless steel, and once again comparing the 316 stainless steel to the Tofflemire matrix band stainless steel. This was done to compare properties of the unknown metal constituting the Tofflemire matrix band with the metals selected for the butterfly design, and ensure sufficient mechanical stiffness and strength. Due to constraints with the Tofflemire band, the dimensions for each sample were required to be 6mm in width. The first material tested was 1008/1010 steel shim stock with a thickness of 0.0254 mm was cut into 6 mm wide strips, for a cross sectional area of 0.1524 mm. These were placed in 1 kN flat screw grips, with labeling tape placed around the ends of the sample strips within the grips for increased friction and more effective fixation. Figure 5 displays the setup for the first round of mechanical testing.

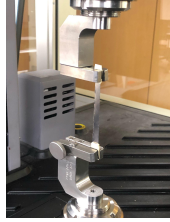


Figure 5: Sample being loaded in the MTS machine for tensile testing.

A tensile force was then applied at a rate of 20mm/min until failure of the material or fixation. This process was repeated with 316 steel shim stock of the same 0.0254 mm thickness. The Tofflemire was also tested under the same conditions, but with samples that were slightly shorter in length. Due to the curvilinear nature of the bands that were provided, a cut at the vertex was made to ensure samples were linear, and evenly distributed load during tensile testing. These samples had a pre-manufactured width of 6mm and thickness of 0.0375 mm. Both testing occasions followed identical testing protocols, with the exception of different fixtures being used. Once raw load and displacement data was obtained from the MTS machine, Matlab was used to create stress-strain curves in order to determine the Young's Modulus of each run for comparison between the two materials. A one-way analysis of variance (ANOVA) test was done between the resultant data for 1008/1010 steel and 316 steel, and the Tofflemire steel to determine if there was a statistically significant difference between the tensile stiffness of each of the materials.

Qualitative Performance Survey. The efficacy and overall quality of the butterfly matrix band was assessed through a nine question survey that was distributed to dentists for evaluation. The design was evaluated according to the following criteria: protective coverage (protection of the gingival tissue from filling material), ease of placement, compatibility with current filling tools (such as wedges and the ring system), the chosen 316 stainless steel material, proper placement (the band sits correctly in the interproximal space), proper contact of the adjacent teeth, comparison to the 1008/1010 material prototypes, comparison to

the Tofflemire system and decreased procedure time. A rating of 1-5 was assigned to each of the above criteria with a score of 1 being the least favorable score in a category and 5 being the most favorable score in a category.

Testing & Results

Simulated Tensile Strength and Displacement.

Solidworks Simulink testing was used to determine if the 316L alloy had more favorable characteristics than the Tofflemire matrix band stainless steel. 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 excessively 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.

The Solidworks Simulink testing suggested that the 316 steel alloy is very similar to the Tofflemire matrix band steel it was compared to. In all of the tests, the yield strengths were 180.0 MPa and 172.2 MPa for the 316 and generic stainless steel bands respectively, showing little disparity between the materials. The maximum displacement was slightly higher in the 316 alloy band at 2.141m with 1.873m for the stainless steel band. The Von Mises stresses matched up very similarly (5969 GPa and 5990 GPa for the stainless steel and 316 alloy), and the observed forces were distributed very similarly. For the tensile load test, the displacements were within .1 mm with the 316 alloy at 4.352 mm and the stainless steel at 4.201 mm. Likewise, the Von Mises max stresses were also similar for the

tensile stress test. The 316 alloy recorded a maximum Von Mises stress of 652.2 GPa and the stainless steel recorded a Von Mises max stress of 651.5 GPa.

Comparative MTS Tensile Strength and Elongation. The first round of tensile MTS testing yielded an average Young’s Modulus for the Tofflemire matrix band stainless steel and 1008/1010 stainless steel to be 162.8GPa and 672.7GPa, respectively. At a .05 significance level, there was not a significant difference between the Young’s Modulus values of the 1008/1010 stainless steel and the Tofflemire matrix band stainless steel (p-value of 0.0796). Stress-strain curves and Young Modulus values for these runs are shown in Figure 6 and 7.

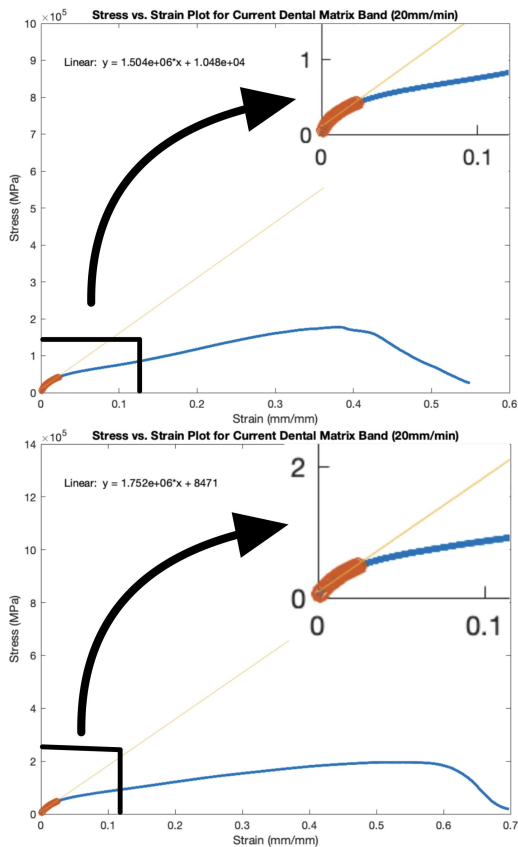


Figure 6a-b: Plotted Stress-Strain curves from tensile testing on an MTS machine to determine Young’s Modulus. Both runs above are with the Tofflemire matrix band stainless steel. The linear region used for the line of best fit is represented by the

orange marking. Runs averaged a Young’s Modulus of 162.8 GPa.

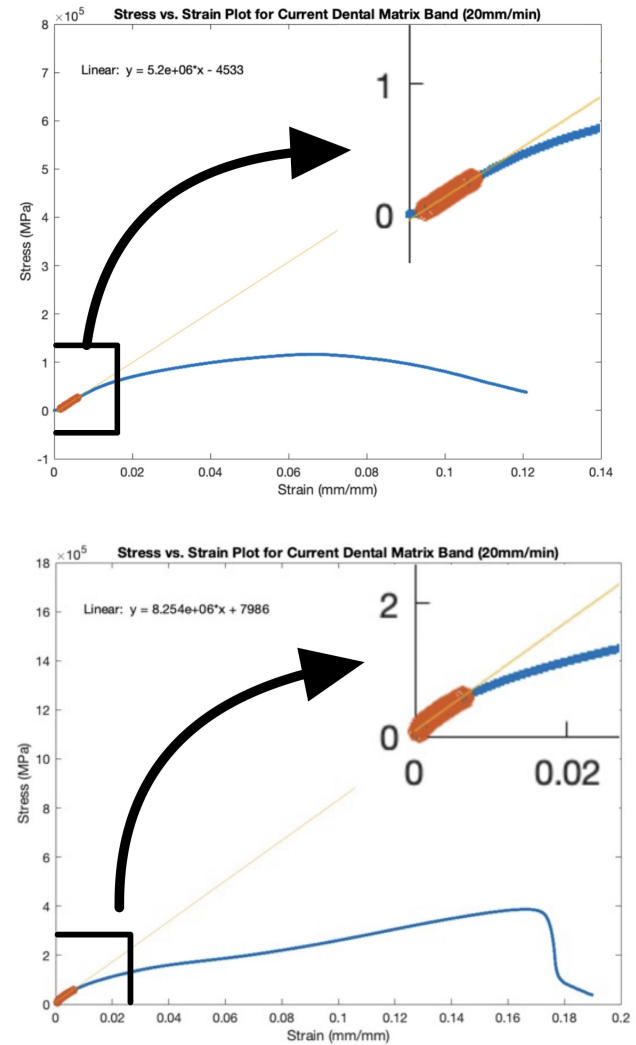


Figure 7a-b: Plotted Stress-Strain curves from tensile testing on an MTS machine to determine Young’s Modulus. Both runs above are with the 1008/1010 stainless steel. The linear region used for the line of best fit is represented by the orange marking. Runs averaged a Young’s Modulus of 672.7GPa.

Further MTS testing that evaluated the new 316 stainless steel material found the average Young’s Modulus of the 316 stainless steel and Tofflemire matrix band stainless steel was 9.8 GPa and 1.9 GPa, respectively. There was a significant difference between the Young’s Modulus values of the 316 stainless steel and the Tofflemire matrix band stainless steel yielding a p-value of 0.0011.

Dentist Evaluation of Prototype. The design received an average score of 3.92 across all dentists and criteria. The design was scored highest in protective coverage, compatibility, material and procedure time with scores of 5, 4, 4 and 4.25, respectively. The design received the lowest score in proper placement, proper contact, and comparison to the current Tofflemire system with scores of 3.5, 3.5 and 3.25, respectively. Table 1 details all results from the survey with individual scores for further reference.

Category	Average Score (\pm SD)
Protective Coverage	5 (\pm 0)
Ease of Placement	4 (\pm 1.41)
Compatibility	4 (\pm 1.41)
Material	4 (\pm 2)
Proper Placement	3.5 (\pm 1.29)
Proper Contact	3.5 (\pm 1.29)
Comparison-1008/1010	3.75 (\pm 1.89)
Comparison-Tofflemire	3.25 (\pm 0.96)
Procedure Time	4.25 (\pm 0.96)
Total	3.92 (\pm0.74)

Table 1: Results from survey taken by dentists with a 1 being the least favorable and 5 being the most favorable score in each category.

Discussion

Solidworks Simulink testing was used as a tool to prove that the slight differences in tensile strength, displacement, and related mechanical properties between generic stainless steel and 316 stainless steel are negligible. The values of displacement and Von Mises stresses were similar enough to comfortably substitute the material used in most dental matrix bands for the 316 stainless steel. This agrees with our qualitative testing and

observations as we felt the 316 alloy acted very similar to other sectional and circumferential matrix bands that were researched. The material is relatively dead-soft and easy to bend making it effective for use in our model.

In both rounds of tensile MTS testing, only the linear region of the stress-strain curves were analyzed due to slippage that occurred during testing between the MTS machine fixtures and the material. 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. This slippage would occur prior to the ultimate stress and strain points and thus, these mechanical properties were not analyzed. Since slippage did not appear to occur through the linear region of the stress-strain curve in the first round of MTS testing, the Young's Modulus was analyzed. A similar approach was taken for the second round of MTS testing, however, in an attempt to prevent slippage from occurring so mechanical properties could be analyzed beyond the linear region, different MTS clamps were used.

The second round of MTS tensile testing with the 316 stainless steel and Tofflemire matrix band steel had significantly different values from both each other and literature sources. This result was not anticipated considering the results of the first round of testing. The first round of MTS tensile testing with the 1008/1010 stainless steel and Tofflemire matrix band stainless steel yielded favorable results, both showing Young's Modulus values similar to reported literature values and similarity amongst the materials. It was anticipated that further MTS testing would yield a similar Young's Modulus to prior testing for the Tofflemire matrix band stainless steel (of around 160 GPa) and that the 316 stainless steel would have a Young's Modulus between the Tofflemire matrix band (160 GPa) and the 1008/1010 stainless steel (670 GPa). The most probable reason for the significantly lower Young's Modulus value is the different fixtures that

were utilized during the second round of testing. It is likely that the material was slowly and consistently slipping out of the fixtures throughout the linear region. Slow and consistent slippage would have not been as visible when compared to the sudden slippage that had been occurring in the first round of testing after the linear region of the stress-strain curve. This would have directly impacted the Young's Modulus values obtained, yielding lower values than expected which is what was observed. Thus, due to the slippage limitation, these values cannot be compared to those of literature. However, since both materials followed identical testing protocols, including their cut out/shape, the insertion of the material in the machine, the fixtures used and the rate of deformation, the Young Modulus values were compared to one another.

There are limitations to this comparison since it cannot be certain that the slippage was occurring at the exact rate and amount between the two materials. However, numerous trials were conducted on each material and with all other conditions maintained, the Young's Modulus values were still analyzed. Although statistical analysis on the second round of MTS testing revealed a significant difference in the Young's Modulus between the Tofflemire matrix band stainless steel and the 316 stainless steel, it was more relevant that the 316 stainless steel was able to withstand forces in a similar range (GPa range) compared to the Tofflemire matrix band steel. The Young's Modulus of the 316 stainless steel was much greater, and thus, would require a significantly greater force to be contoured in the mouth when compared to the Tofflemire matrix band stainless steel, but also less likely to break.

In regard to the clinical relevance of these results, stresses in the GPa range never occur in the mouth during filling procedures. It is essential to know the selected material could theoretically tolerate stresses this high, to ensure it is capable of withstanding even the greatest stresses that a typical Tofflemire matrix band would experience during a filling. Both the old material (1008/1010 stainless

steel) and the new material (316 stainless steel) would be suitable substitutes for dental matrix band material in regard to their mechanical properties since overall, they both behaved very similarly to the Tofflemire dental matrix bands and were able to withstand greater stresses.

The qualitative feedback received from dentists was promising in displaying the functionality and clinical relevance of the butterfly matrix band. After distributing samples to four dentists for evaluation, all dentists agreed they preferred the prototypes without epoxy in the interproximal space. This is due to the dentist's ability to pack down filling material with their ball burnisher tool in order to ensure proper restorative contact distance between the two sides of the matrix band. Thus, no epoxy would be needed in this application and prototypes with epoxy were not evaluated. In protective coverage, an average score of 5 was received which was the most favorable score, as discussed in the methods section. This meant the device was sufficient in protecting the gingival tissue from filling material, largely due to the convexity along the bottom of the matrix band. Ease of placement, compatibility and the favorability of the 316 stainless steel material averaged a score of 4 in each of their respective categories. The compatibility criteria was concerned with whether the design worked alongside current filling tools such as wedges and the ring system. The design's shortcoming here was that the dimensions of the middle section were slightly too large and thus, simultaneous usage of the matrix band with the ring system was difficult. Decreasing the width of the middle section would allow for easier placement of the ring. Proper placement and proper contact each averaged a score of 3.5. This was again mainly due to the dimensions of the middle section of the band. Since this section was too wide, the correct tooth contact would not be achieved because the actual tooth contact covers less of a surface area than the contact allowed by the butterfly matrix band. By decreasing the contact point in the interproximal space that the current butterfly matrix band is

creating, the proper placement and contact should be achieved. When the 316 stainless steel was compared to the previous material, the 1008/1010 stainless steel, it received an average score of 3.75. Although it was an improvement upon the previous material, it was not dead-soft enough. This could be addressed by replacing the 316 stainless steel with 316L stainless steel which has a lower carbon content and is thus, more dead-soft [9]. Additionally, 316L stainless steel is already largely used in dentistry, specifically in orthodontics and implants, so it would be an appropriate substitute [10]. When compared to the Tofflemire matrix band system, the butterfly matrix band received an average score of 3.25. This was greatly due to limitations of the butterfly matrix band discussed above, most notably the inaccurate dimensions of the middle section that is placed in the interproximal space. Lastly, the butterfly matrix band received a very favorable score of 4.25 for procedure time. All dentists found that this matrix band would decrease procedure time, with answers ranging from an estimated 25% to 50% decrease in standard procedure time which was overall the main motivation behind the design.

Conclusion

The development of a novel matrix band meant for interproximal cavity tooth restorations is an advancement in dentistry that could save dentists significant amounts of tedious procedure time. It would prevent the placement and replacement of current matrix bands, as is required for millions of people and procedures every year. While the butterfly design may not be as effective as some other matrix bands in its current state, there has been promising feedback given by multiple experienced professionals about its potential.

Throughout this design process thus far, the butterfly design has been proven to be a concept that can provide the protective coverage of existing matrix bands and reduce procedure times significantly. Given a few improvements, it could also prove to provide other functional characteristics just as effectively as other matrix bands as well.

Substitution of the 316 steel for 316L steel would likely offer more plastic and dead-soft properties that allow for a better fit and contour. Modification of dimensions and the offering of multiple sizing options could improve the fit, protective coverage, and the ease and efficacy of placement. As an iterative process, new designs would still have to be tested to characterize and address any other future deficiencies. Additionally, more effective and thorough testing methods would have to be carefully created to ensure the reliability of these potential improvements or deficiencies.

Acknowledgement

The authors would like to thank Dr. Tracy Puccinelli of the biomedical engineering department at UW-Madison for her guidance in this design process. We would also like to thank Dr. Donald Tipple of Nakoma Dental for sponsoring and assisting in this project. Finally, we give thanks to Chris Meyer and Sector67 for allowing us to use their facilities and aiding us in fabrication.

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Appendix

Appendix A - Product Design Specification

Product Design Specifications

December 15th, 2021

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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].
- ii. The device should be single-use.
 1. The device should maintain similar mechanical characteristics of existing

matrix bands, withstanding loads placed on it during filling.

- a. It should still be malleable and able to shape around any tooth. 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°C) to body temperature (~37°C).
 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.

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Appendix B - Preliminary Designs

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.

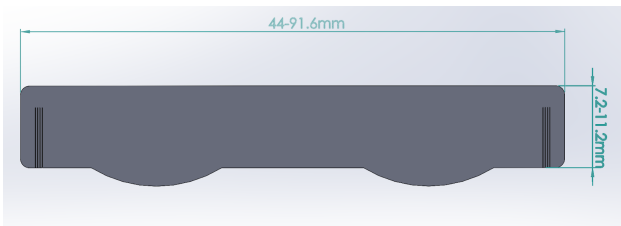


Figure 8: Handcuff Design SideView. Slot fittings are gaps in the matrix band used to secure the device during

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.

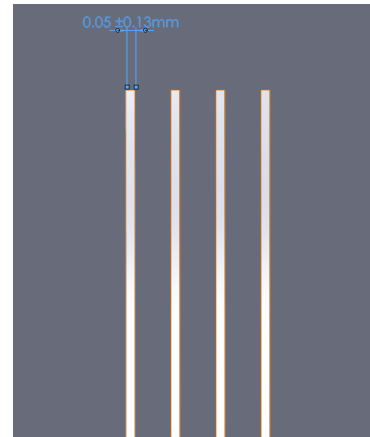


Figure 9: Handcuff Design Securing Mechanism. Close-up of the slot fittings used to secure the handcuff design once it is wrapped around the teeth.

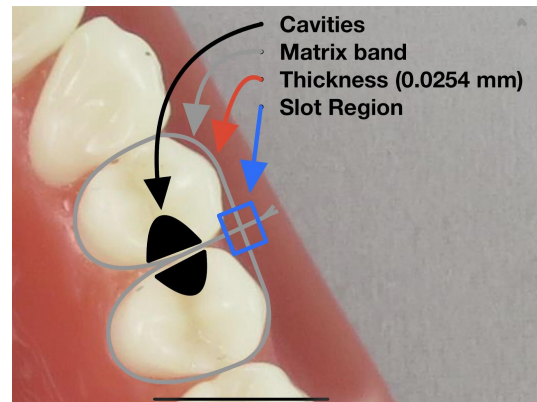


Figure 10: Handcuff Design Top View. The handcuff band is wrapped around two teeth with an interproximal cavity. The band is held in place by placing the center of the band through any of the slots located in the region with the blue box.

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.

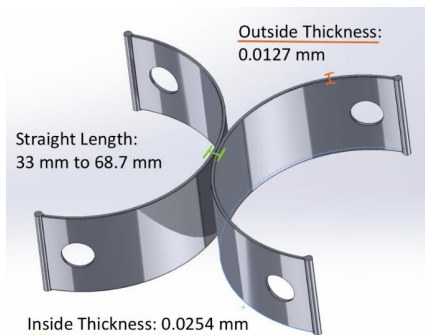


Figure 11: Butterfly Design Solidworks 3D Model. This design consists of two sectional matrix bands conjoined together in the middle to produce a band that slightly resembles a butterfly. Holes in the band will help to aid the removal of the device.

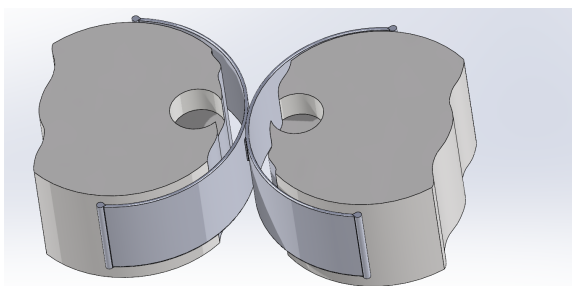


Figure 12: Butterfly Design installed. This CAD image shows how the butterfly band (silver) would sit between two teeth infected with a cavity (gray/tan).

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.

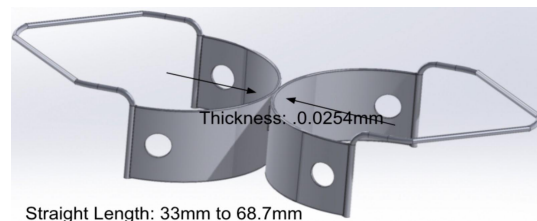


Figure 13: Butterfly + U Pinchers Design Solidworks 3D Model. Similar to the butterfly design, the device consists of two sectional matrix bands with the addition of U Pinchers. Holes added to aid in the removal of the device.

Not shown in figure: spring clamp.

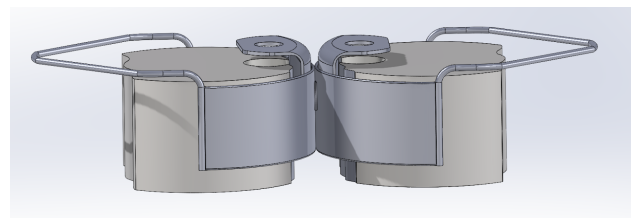


Figure 14: Butterfly + U Pinchers Design installed. This CAD image shows how the butterfly band (silver) will sit between the teeth (gray/tan). U pinchers (silver) will produce an inward force on the butterfly band to help the

band sit flush against the teeth. Not shown in figure:
spring clamp

Appendix C - Design Matrix & Evaluation

Appendix I - Design Matrix

Table 2: 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.

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.

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.

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.

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.

Cost: The cost criteria was scored based on type, and amount of material required, and associated fabrication costs.

Appendix D - Design Evolution



Figure 15: U Band Pincher design. The “pinchers” or clamp-like structures were scrapped early in the design process after concerns of difficult fabrication and obstruction of the procedure.

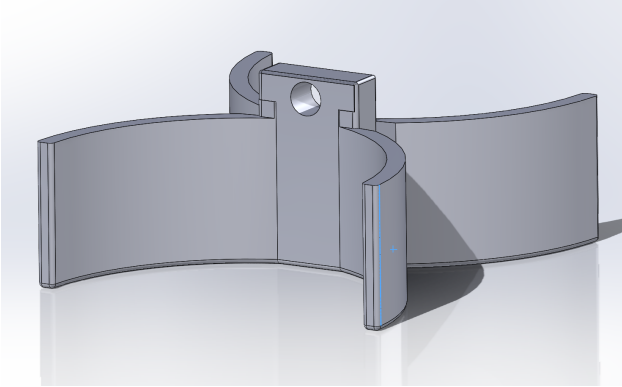


Figure 16: Original CAD model of 3D folded butterfly design idea

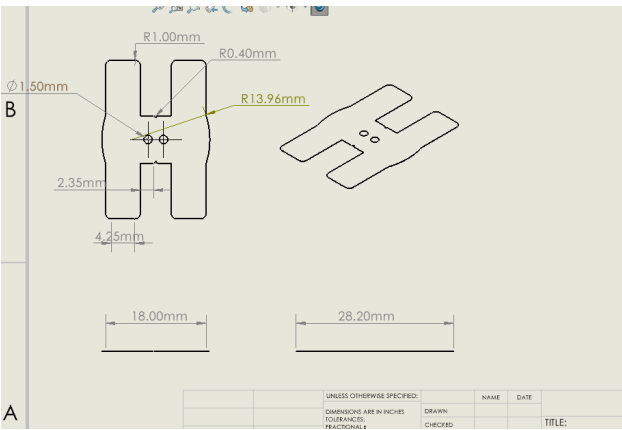


Figure 17: Original design for printing folded. Added concave edge at bottom and slight perforation at the tab

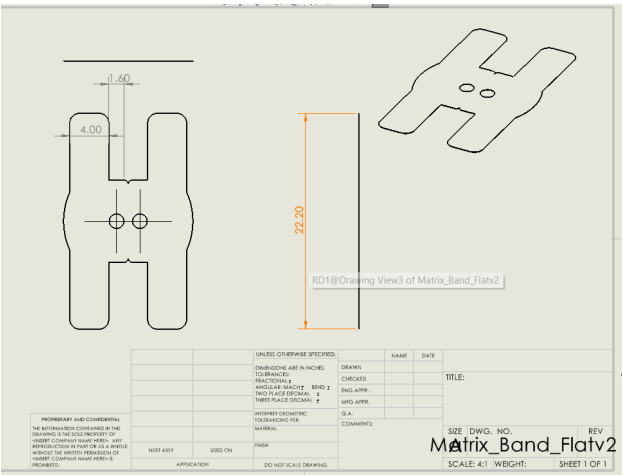


Figure 18: Scaled down model of Figure 17 as requested by client

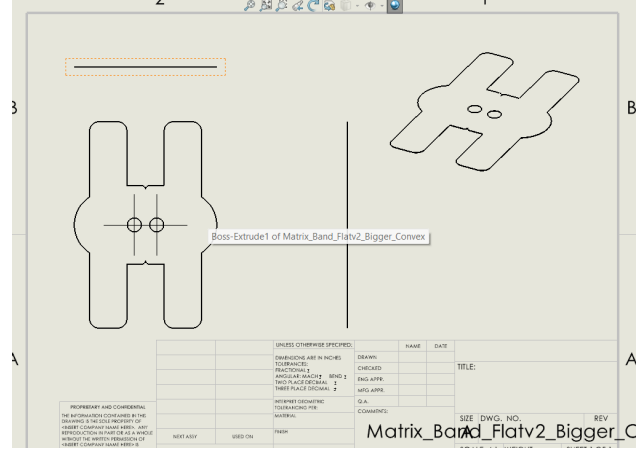


Figure 19: Iteration for larger concave edge testing

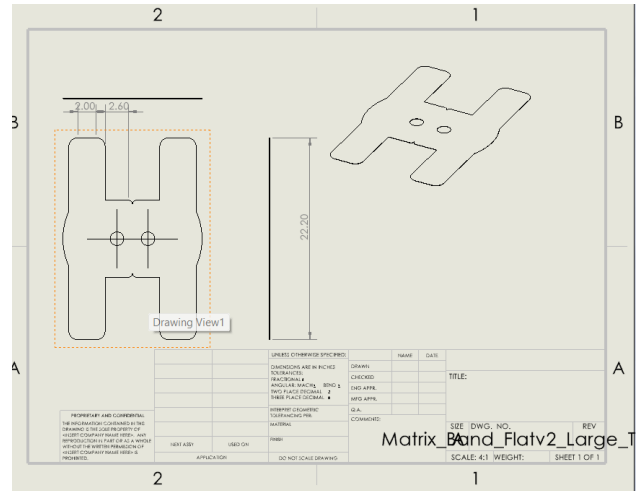


Figure 20: Iteration for larger tab height testing

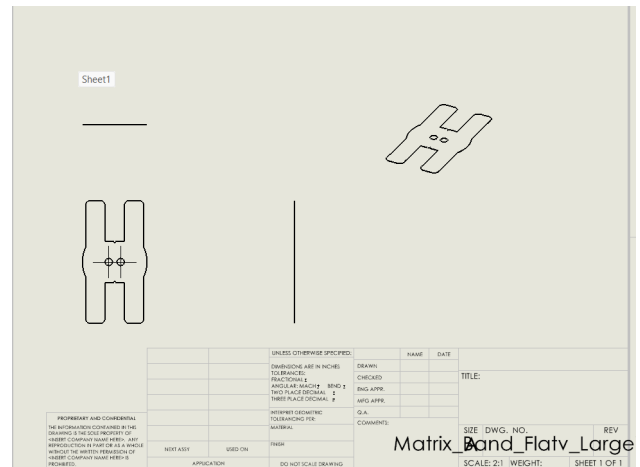


Figure 21: Iteration for longer wing length testing

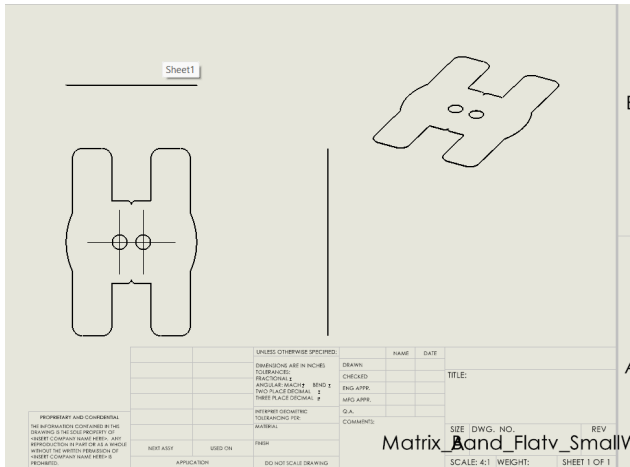


Figure 22: Iteration for shorter wing length

Appendix E - Matlab Code for Stress-Strain Curves and Analysis

```
close all;
clear all;
data=load("TestRun6.txt"); %import the
correct data (different for each run)
disp=data(:,1);
force=data(:,2);
time=data(:,3);
dispMain= disp-disp(1,1); %subtract
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 (N)')
title('Force Measured Using an MTS
Machine over Many Frames');
x1= input("Enter the first frame of
testing");
x2= input("Enter the last frame of
observable data");
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)/A;
strain = dispMain/Lo;
figure(2)
plot(strain(x1:x2),
stress(x1:x2), 'b', strain(j1:j2), stress(
j1:j2), 'g')
xlabel('Strain (mm/mm)')
ylabel('Stress (MPa)')
title('Stress vs. Strain Plot for 316
Stainless Steel Matrix Band
(20mm/min)')
%Change title as appropriate for trials
```

Appendix F - Qualitative Butterfly Matrix Band Performance Assessment Survey

Rate each of the following questions on a scale from 1 to 5, with:
1= strongly disagree
2= disagree
3= neutral
4= agree
5= strongly agree

316 Stainless Steel Band

1. Fabrication Integrity - The adhesive held together and stayed in the proper area of the band

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

2. Protective Coverage - The matrix band protects the gingival tissue and other parts of the oral cavity from filling material

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

3. Ease of Placement The band is easy to place and remove from the interproximal space?

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

4. Compatibility -The design fits with existing tools and procedures.

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

5. Material- The material is easy to bend and placement of the band in the proper shape is achievable.

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

6. The band sits properly in the mouth when placed. In other words, if a filling was performed the correct tooth contour would be created.

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

7. The band aids in restoring the proper tooth contact. If a filling was performed the correct tooth contact would be achieved?

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

In comparison to 1008/1010 Steel Band

1. The new 316 stainless steel band is more favorable than the 1008/101 steel band in regard to achieving proper tooth contour and contact.

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

In comparison to the Tofflemire Bands

1. The team's design offers similar results to the currently used bands in regard to achieving the proper tooth contour and contact.

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

2. The team's design decreases the filling procedure time. (In additional comments please provide how many minutes are saved from filling cavities using this prototype (for adjacent cavities).

<u>Score (1-5)</u>	Additional Comments:
--------------------	----------------------

Appendix G - Qualitative Butterfly Matrix Band Performance Assessment Feedback

Dentist 1	
<u>Category</u>	<u>Score - Additional Comments</u>
Protective Coverage	5
Ease of Placement	5
Compatibility	5
Material	5
Proper Placement	3 - The top bar of the matrix is slightly too wide, which would make the occlusal contour more difficult to create. Additionally,

	because it pinches together at the top, creating a rounded marginal ridge that easily accepts floss may be more challenging
Proper Contact	4 - I believe contact would be achieved but I wonder how easy it would be to floss
Comparison-1008/1010	5
Comparison-Tofflemire	4 - I believe this would perform similarly to Tofflemire but may not create as anatomical of a contact as other sectional matrices (kidney beans, etc.)
Procedure Time	5 - Biggest benefit is this, do not need to place one matrix at a time, which can be tedious and time consuming

Dentist 2	
<u>Category</u>	<u>Score - Additional Comments</u>
Protective Coverage	5 - With use of auxiliary wedge- yes
Ease of Placement	5 - Very easy
Compatibility	5 - Yes
Material	1 - Not dead soft enough
Proper Placement	2 - Ideally needs to be more convex with respect to the filling
Proper Contact	2 - Similar question to

	#6 (No?)
Comparison-1008/1010	4 - Yes, more favorable because it's a little more dead soft, but still could be a little more
Comparison-Tofflemire	2 - Doubtful although I haven't yet tried it for a patient
Procedure Time	4 - Won't need the removing a single band and placing an opposing surface. 8 minutes of time saved perhaps

Dentist 3	
<u>Category</u>	<u>Score - Additional Comments</u>
Protective Coverage	5
Ease of Placement	2 - Band is too wide and tall for placement of palodent ring system.
Compatibility	2 - Not with current height and width. Wedge is good
Material	5
Proper Placement	5
Proper Contact	3 - Too wide of contact. Possible open contact
Comparison-1008/1010	1 - Better without epoxy. Use cheaper material, unable to tell difference
Comparison-Tofflemire	3 - Without filling won't for sure know, but current design won't allow for ring

	placement
Procedure Time	3 - Would guess that it does, but again without testing and current design. Won't for sure know.

Dentist 4	
Category	Score - Additional Comments
Protective Coverage	5
Ease of Placement	4
Compatibility	4 - See [Proper Placement]
Material	5
Proper Placement	4 - Making the top of the band shorter may allow the band to better adapt to the proximal box on each side
Proper Contact	5 - Better if adjusted as in [Proper Placement] question
Comparison-1008/1010	5
Comparison-Tofflemire	4
Procedure Time	5 - 10-15 min easy depending on provider

Appendix H - Solidworks Simulink Reports 316 Stainless Steel Normal Load

Study Results

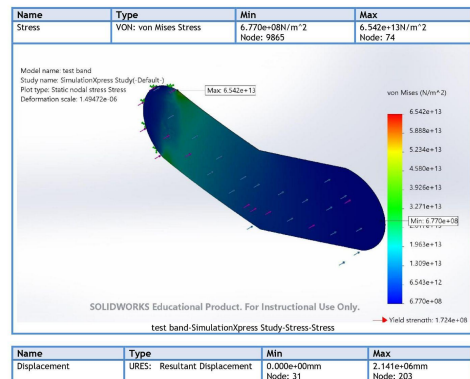


Figure 23: Von mises stress distribution of forces during Solidworks Simulink for 316 Stainless Steel normal load

Model Information

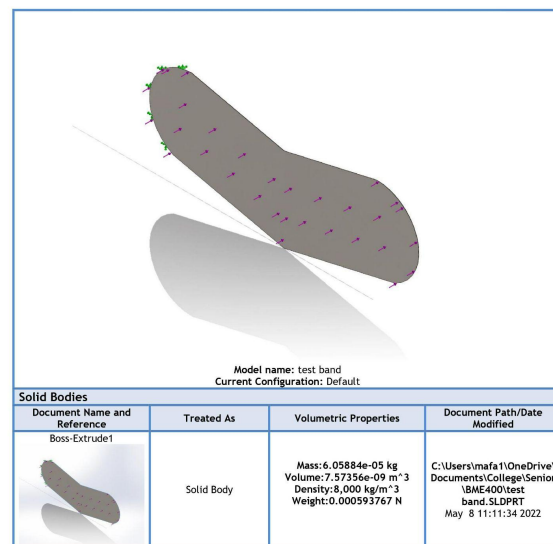



Figure 24: Volumetric Properties and applied forces during Solidworks Simulink for 316 Stainless Steel normal load

Material Properties

Model Reference	Properties	Components
	<p>Name: AISI 316 Stainless Steel Sheet (SS)</p> <p>Model type: Linear Elastic Isotropic</p> <p>Default failure criterion: Max von Mises Stress</p> <p>Yield strength: $1.72369 \times 10^8 \text{ N/m}^2$</p> <p>Tensile strength: $5.8 \times 10^8 \text{ N/m}^2$</p>	SolidBody 1(Boss-Extrude1)(test band)

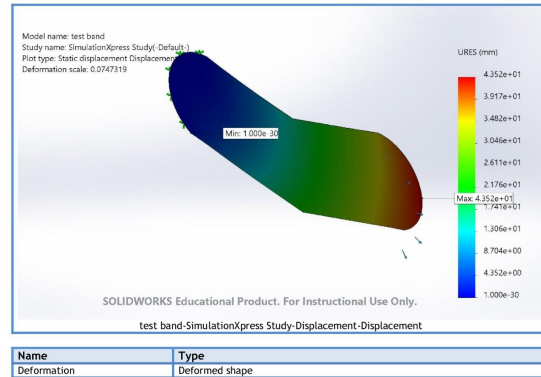


Figure 26: Von mises stress distribution of forces during Solidworks Simulink for 316 Stainless Steel tensile load

Figure 25: Mechanical properties for Solidworks Simulink for 316 Stainless Steel normal load

316 Stainless Steel Tensile Load

Model Information

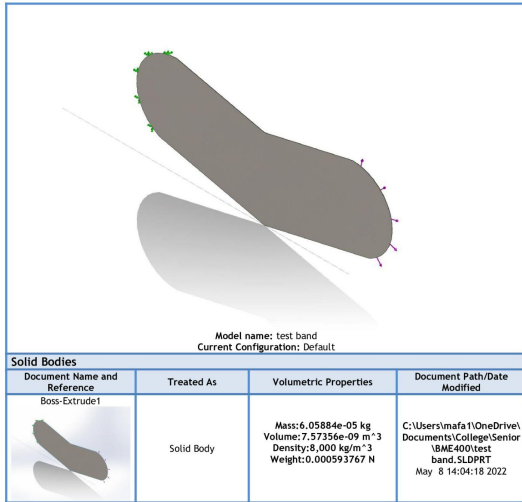


Figure 27: Volumetric Properties and applied forces during Solidworks Simulink for 316 Stainless Steel tensile load

Material Properties

Model Reference	Properties	Components
	Name: AISI 316 Stainless Steel Sheet (SS) Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 1.72369e+08 N/m ² Tensile strength: 5.8e+08 N/m ²	SolidBody 1(Boss-Extrude1)(test band)

Loads and Fixtures

Fixture name	Fixture Image	Fixture Details
Fixed-4		Entities: 1 face(s) Type: Fixed Geometry
Load name	Load Image	Load Details
Force-4		Entities: 1 face(s) Type: Apply normal force Value: -20,000 N



Figure 28: Mechanical properties for Solidworks Simulink for 316 Stainless Steel tensile load

Appendix I - One-Way Anova Test Results

Table 3: One-Way ANOVA Test between 1008/1010 stainless steel and Tofflemire matrix band stainless steel Young's Modulus yielding p-value of 0.0796. Values below are given in MPa.

Groups	N	Mean	Standard Deviation	Standard Error	F-Statistic	P-Value
Tofflemire Band Steel	2	162800	17536	12400	11.08	0.0796
316 Steel	2	672700	215950	152700		

Table 3: One-Way ANOVA Test between 316 stainless steel and Tofflemire band stainless steel Young's Modulus yielding p-value of .0011. Values below are given in MPa

Groups	N	Mean	Standard Deviation	Standard Error	F-Statistic	P-Value
Tofflemire Band Steel	3	1884	206	119	69.25	0.0011
316 Steel	3	9817	1638	946		

Appendix J - Expense Report

Table 4: Expense table overviewing total costs

Item	Supplier / Brand	UPC / Item Number	Link	Quantity	Date	Price
Dental Implant Teeth Model Study Teach Standard Model with Removable Teeth	Amazon / Smile1000	UPC: 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=dsrItems_5EY10	1	11/21/21	\$35.96
Permatex 84109 PermaPoxy 4 Minute Multi-Metal Epoxy, 0.84 oz	Amazon	UPC: 8622684109	https://www.amazon.com/dp/B000ALDXV2/ref=cm_sw_r_sms_api_glt_i_GVTR56HW6JCMF75DXPMF?_encoding=UTF8&psc=1	1	2/24/2022	\$8.11
316 Stainless Steel Shim Stock, 8" x 12" Sheet, 0.001" Thick	McMaster - Carr	Item Number: 2317K51	https://www.mcmaster.com/2317K51/	1	4/9/22	\$19.99
				Semester 1	Total	\$64.38
				Semester 2	Total	\$28.10