



Approximating Surface Matrix Band for Dentist to Use for Patients

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Abstract

Dental caries is an infectious, transmissible disease characterized by the breakdown of tooth structure due to bacterial activity [1]. A common area of infection is the proximal contact between two posterior teeth, and often, both teeth are affected [2]. The current treatment option is a Class II restoration, which removes decay and restores tooth structure while maintaining proximal contact. Current products used in this procedure include circumferential and sectional matrices [2]. However, when both adjacent teeth are affected, these tools are inefficient due to the use of only one matrix at a time to preserve the contact area. This is problematic, as it requires repetition of pre-operative processes which dentists and patients find to be inconvenient. To address this, a device capable of treating two adjacent interproximal cavities with one round of pre-operative steps and without compromising the contact area was proposed. Out of three preliminary designs, the “Hole” design was selected due to its efficacy, simpler use and fabrication, and lower cost (Table 1). To evaluate functionality, MTS tensile, SolidWorks FEA, and compatibility tests were performed in Fall 2025. The SolidWorks results proved the model to be mechanically effective, but MTS testing showed the stiffness of the chosen material to be higher than that of matrices currently used. Compatibility testing showed that the dimensions are sufficient, but that the shape requires refinement for improved adaptation to tooth contours and gingival tissue, increasing filling efficacy and comfort. Future iterations will incorporate a less stiff material and improved shaping to meet these requirements. In addition, the contours will have greater resolution through the use of precision laser cutting.

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Introduction

Motivation and Global Impact

Dental caries (commonly known as cavities or tooth decay) is an infectious, transmissible disease which is characterized by the gradual breakdown of tooth structures due to microbial activity [1]. It is a widespread disease affecting both children and adults [3]. One study found that approximately 90% of adults between the ages of 20-64 years have experienced tooth decay [4].

Untreated dental caries are problematic, as they can lead to pain, infection, swelling, potentially requiring emergency hospitalizations and dental extractions under general anesthesia [5]. One study looked at the correlation between untreated caries and mortality and found that they can lead to various lethal complications, including meningitis, cavernous sinus thrombosis, and chronic maxillary sinusitis [1]. Another study looked at children in particular and found that untreated caries have been linked to delayed growth, chronic medical conditions, and cardiovascular disease [1]. It has also been found that untreated caries are associated with a 26% increased risk of all-cause mortality, and a 48% increased risk of heart disease mortality [6]. Improving the efficacy of the treatment of caries is of paramount importance when it comes to increasing the number of restorations being done.

Existing Devices and Current Methods

Class II restorations focus on getting rid of decay and rebuilding the interproximal (in-between the teeth) tooth surface of a posterior tooth (which is found in the back of the mouth) [7]. With regard to the treatment of posterior teeth, in order to avoid overhanging proximal margins and insufficient proximal contact areas, matrix band systems must be used [8]. Matrix bands function to support the composite resin material used to fill the tooth, as well as to provide shape and contour to the restored tooth [8].

Currently, there are two main types of matrix bands which can be used for Class II restorations, including sectional matrix bands and circumferential matrix bands, which are produced by a variety of companies. Circumferential matrix bands have a circular shape, wrap around the entire tooth being restored, and are typically secured with integrated tighteners or retainers (Figure 1); they are favored in scenarios where there are missing adjacent teeth or malocclusions (misalignment of teeth) [2]. On the other hand, the sectional matrix band covers only a segment of the tooth and relies on wedges and rings to hold it in place (Figure 2) [9]. Multiple studies have shown that sectional matrix bands are more effective than circumferential matrix bands in Class II restorations based on their ability to provide more anatomically accurate contours and stronger proximal contact areas [8].

Most circumferential and sectional matrices on the market are made of either stainless steel or polytetrafluoroethylene (PTFE); some are coated with Teflon to prevent adhesion of the filling material to the matrix system [10]. The typical thickness of sectional matrix bands currently on the market is 0.0381 mm, with lengths varying between 12.57 - 14.33 mm, heights between 3.2 - 6.4 mm, and widths between 1.24 - 1.64 mm [11]. The variation in lengths is to account for patient-to-patient variability in tooth size and topology.

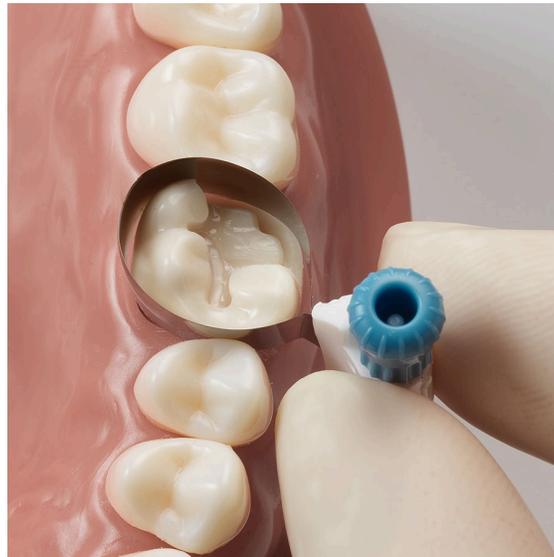


Figure 1: Circumferential matrix [12].



Figure 2: Sectional matrix system [13].

Problem Statement

Surface matrix bands are devices used by dentists to separate adjacent teeth during restorations of inter-proximal cavities (cavities found in between two teeth). The matrix band serves to support the

restoration material, to provide shape and contour to the tooth being restored, and to protect the adjacent tooth. Ideally, the width of the space between the two adjacent teeth is just large enough to fit one matrix band in order to ensure close proximal contact area, which prevents food impaction and decay. In the case of two cavities on two adjacent teeth, this process is tedious, as the dentist must complete the process from start to finish for each adjacent tooth individually. The goal of this project is to create a dental matrix band that effectively partitions adjacent teeth for more efficient tooth restoration procedures on interproximal cavities by making it possible to complete two adjacent restorations simultaneously.

Background

Anatomy & Physiology

Caries are formed by the interaction of the cariogenic oral flora (commonly referred to as biofilm) with fermentable carbohydrates [1]. Bacteria within the biofilm (often the *Streptococcus mutans* bacterial strain) is able to metabolize the carbohydrates found on the surface of the tooth, producing lactic acid as a byproduct [1]. Gradually, the lactic acid on the tooth surface will lower the pH of the tooth plaque, which initiates the formation of a cavity through the process of demineralization [1]. Contributing factors toward decay include sugar consumption and plaque buildup on the teeth, as well as other factors such as smoking [3].

One common area of tooth decay is on the interproximal surface of the posterior teeth, which is the tooth surface in between two of the teeth in the back of the mouth; this is due to the increased bacterial colonization found within the tight, difficult-to-clean space [2]. Poor proximal contact between two teeth can lead to food impaction, increasing the risk of an interproximal cavity [9]. These types of cavities are treated via Class II restoration, and it is important to maintain a large proximal contact area following the restoration to prevent food impaction and recurrent tooth decay.

Client Information

Dr. Donald Tipple, DDS, is the owner of Nakoma Dental LLC. Dr. Tipple has owned and operated this dental practice since 1989.

Product Design Specification

The client requires the fabrication of a dental matrix for use in filling interproximal cavities. This dental matrix would replace the need for two separate sectional matrices being used throughout the course

of the procedure. The device must maintain its mechanical properties throughout the course of one procedure, which is approximately one hour. The materials used in the construction of the dental matrix must not be harmful to the patient and must not corrode in exposure to the environment of the human mouth. To keep in line with current dental matrices, the product must maintain a thickness between 0.0381mm to 0.05 mm (0.0015 in - 0.002 in) [14]. The unit cost must remain under \$5 to compete with current dental matrix prices [15]. The device must follow ISO standards 18556-2016 *Dentistry — Intraoral spatulas* and 10993-1 *Biological Evaluation of Medical Devices* [16, 17].

Preliminary Design Evaluation

Preliminary Designs

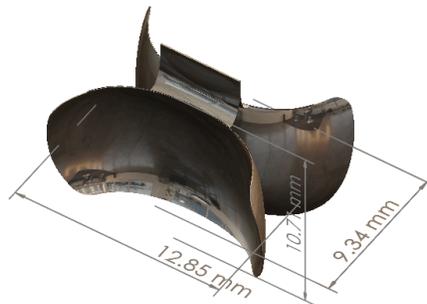


Figure 3: Adjusted Butterfly Design.

The first design idea builds on the design that the previous semesters' groups came up with, and is shown above in Figure 3. The difference between this design and those used in previous semesters is that there is a gap into which a wedge can be inserted, and to minimize interaction with the patients' gums. Additionally, this design features a tab at the top, which allows for easy placement and removal of the matrix before and after the filling process. This design would be fabricated using three separate pieces of metal and assembled via adhesive or a micro weld.



Figure 4: Hole Design.

The second design idea is similar to the Adjusted Butterfly Design, as it has a similar contour and features a tab, but with a few key differences. To ensure that there remains proximal contact between the

two teeth being filled, there is a void at the proximal contact location, ensuring a smaller gap between the teeth being restored. To overcome the inconsistencies that would be found in the teeth afterwards (due to overhangs by excess filling material), the dentist must properly burnish the tooth that is associated with the void.



Figure 5: Slot Design with model teeth

The final design preserves the “butterfly” shape, but instead of having a void in the middle of the matrix, there is a void at the top of the matrix to ensure optimal proximal contact. This makes it easier to fill, but the burnishing process is more difficult at the top of the teeth as compared to what it would be in the hole design. Additionally, the lack of a tab feature would make it less user-friendly.

Design Matrix

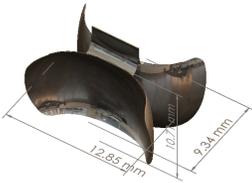
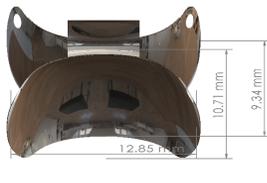
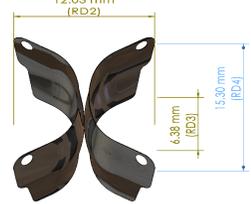
Criteria	Weight	Design 1: Altered Butterfly		Design 2: Hole Design		Design 3: Slot Design	
							
Efficacy	40	5/5	40	5/5	40	4/5	50
Ease of use	20	5/5	20	5/5	20	4/5	20
Efficiency	15	5/5	15	4/5	12	3/5	9
Ease Of Fabrication	15	2/5	6	5/5	15	3/5	1
Cost	5	2/5	2	5/5	5	3/5	4
Safety	5	5/5	5	4/5	4	4/5	3
Total:	100	88		96		73	

Table 1. Design Matrix of the three design ideas.

Summary of Design Matrix Criteria and Ranking

Efficacy: Pertains to how effective the design is as a traditional surface matrix. The new design must be as effective as current surface matrices to be a viable option for dentists. To be an effective surface matrix, the design must protect surrounding tissue from filling, allow for sufficient molding to fit natural tooth curvature, and allow for an acceptable surface finish of the filling. Higher scores indicate better projected performance as a surface matrix, while lower scores project worse performance as a traditional matrix. The efficacy of the altered butterfly design and the hole design was greater than that of the slot design because the burnishing required on the top of the tooth to use that matrix could lead to a lower quality final fill shape. Although it is less effective, burnishing will likely already have to take place with the hole design as well, even though it is more likely to be a simpler process based on the matrix geometry. This is why the slot design still scored high in comparison to the other two matrices.

Ease of Use: Refers to how easy it is for the dentist to use the device; it considers comfort during the restoration process, as well as during the removal process. Also takes into account the amount of refining to be done after removal of the device. A higher score indicates that the device is intuitive to use and easy to handle, whereas a lower score indicates that the device is counter-intuitive and difficult to work with. The altered butterfly design and the hole design are tied for being easier to use because they both include a tab that the dentist can use to pull the matrix out of the teeth after the cavity filling. The slot design does not have this feature, and the slot could potentially make the matrix harder to handle with a pair of tweezers.

Efficiency: Considers how the device will impact the adjacent cavity filling process timing. A higher score means that the device makes the process go faster without sacrificing quality; a lower score means the device makes the process go slower and can sacrifice quality. The efficiency of the altered butterfly scored the highest because it does not induce any extra burnishing and would therefore be the quickest. The slot design is the least efficient because it would take the longest amount of time to burnish.

Ease of Fabrication: Considers how easy it is to manufacture, specifically with the tools available to the team at UW Madison. A higher score indicates that the device is easier to make, while a lower score shows that the device is harder to make with the equipment available. A lower score could be due to a more difficult manufacturing process or the use of materials that are harder to work with. The hole design scored the highest for this category by a significant margin because it does not involve any other materials beyond the matrix material, and there is one part that has to be folded, rather than trying to use epoxy or another form of welding to join the parts. The altered butterfly design is the least easy to fabricate because it requires joining three parts, whereas the slot design only requires joining two.

Cost: Considers the amount of money needed to fabricate and maintain each design. Low scores indicate a higher cost, and higher scores indicate a lower cost. The cost of the hole design scored the highest because there aren't any other materials besides the stainless steel and nothing else is being used to join the parts together. The other two designs have much lower scores because they involve the materials required to join the parts together, and the altered butterfly design has the most parts to conjoin.

Safety: Consider how safe each design is to use. Low scores indicate a less safe design and higher scores indicate a safer design. The altered butterfly scored the highest because it does not have a hole for the resin to escape from, which could cause complications during the filling process.

Fabrication and Development Process

Materials

Last semester, three materials were used in prototyping: 316 fully annealed stainless steel, 302/304 full hardness stainless steel, and 301 half hardness stainless steel. The biggest material consideration is based on stiffness; balancing the stiffness and ductility of the material is vital because the matrix must be stiff enough to survive placement between the teeth without crimping or crumpling upon contact with the teeth, but still allow for formability during the procedure. Initially 316 steel was used, however, it proved too ductile and was torn apart during waterjet fabrication. Stiffer materials, 301 and 302/304, were opted for in a second round of fabrication. Although 301 and 304 inherently have stiffnesses similar to 316, 301 and 304 had half and full hardness rating respectively compared to the fully-annealed 316, so they were substantially stiffer in comparison. Testing was performed to determine the stiffness of the 301 and 304 samples compared to existing matrices using a C43 MTS Criterion machine, but data could not reliably be obtained from the existing matrices because their thinness and short length would not allow for proper fixation in the machine. The 301 and 304 were continued into prototyping and testing this semester. However, with new laser cutting fabrication methods, more ductile material can now be used to allow for better formability during the procedure.

Methods

Initially for prototyping, the parts were cut using water jet cutting. The water jet that was used was an Omax Protomax located in the UW Makerspace. For file preparation, the SolidWorks model in Figure 4 was rolled back to show only one body, which was flattened using the surface flattening tool. This flattened surface was mirrored, and the connecting tab was sketched and filled between the two bodies shown in Figure 6. This was exported into a SolidWorks drawing along with other design iterations and material test coupons, which was exported into a .dxf file. The .dxf file was run through the Protomax Layout software to refine the cut path and produce a .omx file (Figure 7). The .omx file was run on the Omax Protomax to cut the material. The 0.001" (0.025 mm) 316 stainless steel was sandwiched between two pieces of HDF to support the stock in the water jet. The water jet cutting was unsuccessful as it destroyed too many pieces with the high pressure water jet. The parts that were salvaged were left with significant burs unsuitable for further use in prototyping and testing.

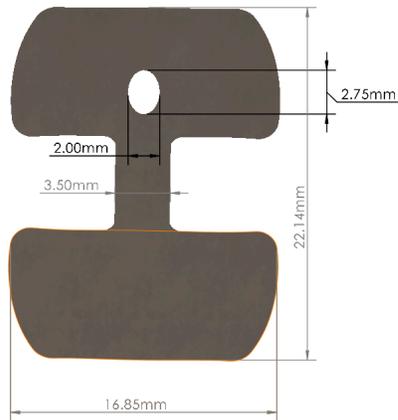


Figure 6: Flattened SolidWorks model to be used for waterjet cutting.



Figure 7: Cut path for Omax Protomax water jet cutter.

After the failed water jet attempt, new material was purchased, and a new fabrication plan was developed. The new fabrication plan used laser cut templates that were developed similarly to the water jet cutting (see Appendix B). The templates were cut from $\frac{1}{8}$ in HDF. The templates included holes at the top and bottom of the part for alignment (Figure 8). The stainless steel stock was covered in blue painter's tape for protection, support, and removal. The top template was then glued to the blue tape. The locating holes were drilled, and the bottom template was bolted to the part, sandwiching the steel between the templates (figure 9). This was a rough cut using scissors. The parts were then ground down to the final dimension using a dremel tool with a 2 mm diamond wheel point bit and a $\frac{1}{2}$ in drum sander bit. The tabs were cut off with a dremel cut off wheel and ground to the final dimension. The holes in the "Hole"

design were drilled using a Milwaukee 1/16 in cobalt drill bit and ground to the final dimension with the dremel tools. The parts were removed from the template and the tape was peeled off (Appendix C).



Figure 8: Laser cut templates.



Figure 9: Assembly used for fabrication.

The flat parts were molded using a 3D printed mold made from PLA. The flats were placed in between mold halves to create the final curvature (Figure 10). The length of the part was measured and the half point was found. Using a razor blade to keep the fold square the part was folded in half to create the final part geometry. In total, three matrices were made from the ½ hard 301 and three from the full hard 302. Additionally, six control matrices were made without a hole and six material test coupons for future testing, three from each material. This fabrication produced semi-viable prototypes, however, the surface finish and accuracy were not sufficient. Going forward, a laser cutter will be used to generate

future prototypes. The laser cutter accepts .svg files which were generated from .dxf files exported from SolidWorks [11].

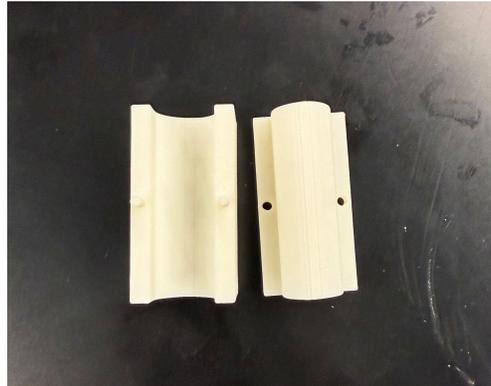


Figure 10: Mold used to form matrices.



Figure 11: .svg file for laser cutter with design iterations (not to scale).

Final Prototype

The final design was based on the “Hole” preliminary design idea. This design uses a hole cutout in the middle of one of the bands to allow for a smaller overall thickness of the device, subsequently leading to tighter interproximal gaps. It is a two sided matrix made of one piece of metal that was folded at the tab. In total, six sectional matrices were fabricated. The average height measured from top of the tab to bottom of the matrix was 9.475 ± 0.2738 mm. The average functional height measured from top of the wing to bottom of the wing was 6.445 ± 0.3432 mm. The average width of the matrices was 12.9625 ± 0.989 . The average hole height and hole width was 0.251 ± 0.444 mm and 1.9475 ± 0.0343 mm respectively. There was significant part to part dimensional variation. This needs to be improved in future fabrication efforts.

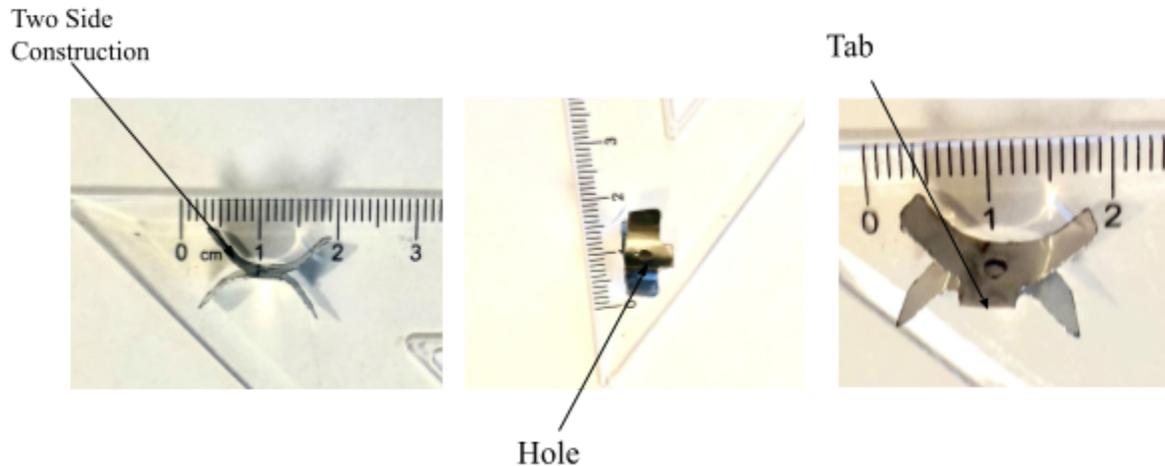


Figure 11: Final Design of sectional matrix.

Testing

In order to evaluate the functionality of the device, mechanical strength testing will be conducted. Due to the absence of numerical data on the mechanical properties of dental matrices, baseline data will be collected at the client's dental office. Dr. Tipple will simulate an interproximal filling on model teeth using a sectional matrix band currently on the market. After performing the restoration and curing the composite resin filling material, a force gauge will be attached to the tab of the matrix, and the force that it takes to remove the matrix band will be obtained and recorded. This process will be repeated for a total of ten samples, and the values obtained will be averaged and used as a clinically-relevant threshold value; it will represent the minimum force that the prototype will have to withstand during the matrix removal process.

Following the baseline data collection, a tensile test will be performed via MTS machine. A prototype sample will be secured within the machine, with connections at the top tab and bottom of the matrix. The sample will be loaded in tension until ultimate failure, and a stress-strain curve will be generated from the data; this will be done in Microsoft Excel. The mechanical properties of the sample will be obtained from the stress-strain curve, including the elastic modulus, yield strength, and ultimate tensile strength. This process will be repeated for a total of ten samples, and the values of the mechanical properties will be averaged. The ultimate strength factor of safety will be calculated for each sample, with a safety factor of 1 indicating no failure.

Results

At this point, the new testing has not been completed. From the MTS data, the team intends to run a one sample t-test with the actual force of removal obtained from Dr. Tipple, which will result in a p-value. Since we set a 95% confidence interval, with an α value of 0.05. A sub 0.05 value would indicate that the failure point is significantly different from the population of failure values for the material, as determined by MTS. A p-value larger than 0.05 indicates that the stress applied to the dental matrix prototype would be enough to cause failure in the intended material. This calculation and analysis of MTS data will be completed using MATLAB and/or RStudio. Qualitative data collected from the questionnaire will be used to judge the final design and whether or not it would be accepted by the larger dental community.

Discussion

Although full mechanical testing has not yet been completed, the preliminary fabrication and evaluation of the matrix band prototype provides several insights into the feasibility of the design. The SolidWorks finite element analysis suggested that the geometry of the device is mechanically capable of withstanding forces encountered during removal and clinical manipulation. However, mechanical observations from last semester and client preference indicate that the stainless steel materials tested may be stiffer than currently used dental matrices. Excess stiffness could limit the ability of the matrix to conform to natural tooth curvature, which is essential for proper proximal contact and restoration quality.

Dimensional testing also demonstrated that while the overall size of the device falls within ranges commonly used in dental matrix systems, the current fabrication process introduced noticeable variation between parts. This suggests that improvements in fabrication precision will be necessary before clinical usability can be properly evaluated.

Several ethical considerations must be addressed when developing a dental device intended for clinical use. Patient safety must be prioritized through the use of biocompatible materials and adherence to ISO medical device standards such as ISO 10993 for biological evaluation [25]. Stainless steel alloys commonly used in dental devices are generally well studied and considered safe for short-term intraoral contact.

Additionally, any device used clinically must not increase the risk of restoration failure, patient discomfort, or tissue damage. Thorough mechanical and usability testing is therefore necessary before

clinical implementation. In the research phase, ethical considerations also include transparent reporting of results and ensuring that prototype testing does not expose patients to any sort of unnecessary risk.

As a result of fabrication and preliminary evaluation, there is a possibility of changing the material selection as current stainless steel shim stock may be too stiff. A solution for this explores thinner materials or alternative alloys. Manual fabrication introduced dimensional variation, as a solution precision laser cutting should improve reproducibility and manufacturing precision. Finally, adjustments to curvature and contour are needed for better adaptation to tooth anatomy. This can be mediated by hole size and placement which may require optimization to balance strength and contact preservation.

Sources of error that may influence both current observations and future testing include fabrication variability, material inconsistencies, limited testing data, and prototype scale. Manual cutting and grinding likely introduced inconsistencies in dimensions and surface finish, which is what we plan to mediate through laser cutting instead. Differences in cold working and heat treatment between steel samples could influence different mechanical behavior between samples. Testing on model teeth may not perfectly represent conditions in the human mouth or from person to person, including teeth size difference, saliva, temperature, and tissue interaction. At this stage, conclusions about clinical performance cannot confidently be made until mechanical testing and removal force measurements are completed. Addressing these sources of error will improve the reliability of future results.

Conclusions

This project aimed to design a dental matrix band capable of allowing dentists to restore two adjacent interproximal cavities simultaneously while maintaining appropriate proximal contact and procedural efficiency. Three preliminary concepts were evaluated, and the “Hole” design was selected based on its projected efficacy, ease of use, fabrication feasibility, and cost. Initial fabrication and modeling indicate that the design is mechanically viable and capable of fitting within typical dimensional constraints of current matrix systems. However, preliminary observations suggest that the current material may be stiffer than desired and that fabrication methods require improved precision. The design successfully demonstrated that a single-piece folded matrix could support the concept of dual restoration. The fabrication process also confirmed that the geometry can be produced using accessible manufacturing techniques. However, manual fabrication methods introduced variability between samples, and the selected materials may not provide the optimal balance between strength and flexibility required for clinical performance.

Future iterations will prioritize higher precision manufacturing methods such as laser cutting earlier in development. Additionally, testing multiple materials at the prototype stage will help identify

the best mechanical properties before producing multiple samples. Future work will focus on mechanical testing using an MTS machine to determine tensile properties, measuring removal forces from existing dental matrices to establish performance benchmarks, statistical comparison between prototype performance and clinical requirements, refining geometry for improved anatomical adaptation, and evaluating usability through dentist feedback. These steps will determine whether the design can meet the mechanical and clinical requirements necessary for practical dental application.

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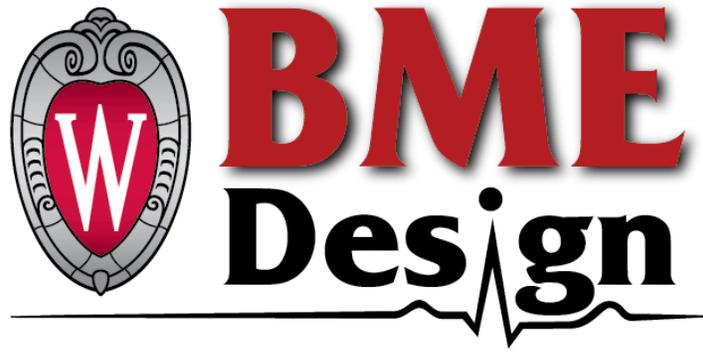
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Appendix

Appendix A



Approximating Surface Matrix Band for Dentist to Use for Patients

Product Design Specifications | September 18th, 2025

BME 400 Lab 305

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Function:

Surface matrix bands are devices used by dentists to separate adjacent teeth during restorations of interproximal cavities (cavities found in-between two teeth). The matrix band serves to support the restoration material, to provide shape and contour to the tooth being restored, and to protect the adjacent tooth. Ideally, the width of the space between the two adjacent teeth is just large enough to fit one matrix band in order to ensure close proximal contact area, which prevents food impaction and decay. In the case of two cavities on two adjacent teeth, this process is tedious, as the dentist must complete the process from start to finish for each adjacent tooth individually. The goal of this project is to create a dental matrix band that effectively separates adjacent teeth for more efficient tooth restoration procedures on interproximal cavities by making it possible to complete two adjacent restorations simultaneously.

Client requirements

1. The new design of the surface matrix band should not be thicker than existing matrix bands on the market.
2. The new device should make it possible to perform two Class 2 restorations simultaneously instead of sequentially.
3. The device should come into contact with both surfaces of the two adjacent teeth.
4. The device should avoid harming the gums in-between the two affected teeth.

Design requirements

1. Physical and Operational Characteristics

a. Performance requirements:

Surface matrices are used in dental restoration to recreate the natural tooth shape and protect the surrounding tissue. This product must fulfill all the existing requirements of surface matrices in addition to creating a more efficient reconstruction procedure. Surface matrix systems are most commonly used for treatment of smooth surface class II posterior caries [1]. Because proximal contact must be maintained in the restoration, the surface matrix must be very thin. Common surface matrix thicknesses in industry range from 0.038 mm to 0.05 mm [2]. If the matrix band's thickness is too great the interproximal contact between teeth will be lost post procedure causing food packing, which can lead to

gingivitis and periodontitis, and loss of arch stability. A large part of maintaining this critical proximal contact is reconstructing the natural shape of the tooth. To ensure this dentists often use wedges and tension rings to help form the matrix to the tooth. To allow full functionality and easier adoption by dentists, this product must be compatible with these existing products. To help match the shape of the biting surface of the tooth, surface matrices have an occlusal curve which allows for better reconstruction. Additionally, sectional matrices often have a curve or extended section that sets into the sulcus between the tooth and gum. This protects the gums and allows for better filling. The product should include these features to be an effective solution. The surface matrix must be malleable enough to easily wrap around the tooth. Most current matrices are near dead soft meaning they are nearly fully annealed, however, over annealing and creating a grain structure too large can cause the matrix to be too ductile and crimp upon insertion into the interproximal space or during wedge insertion. Therefore, the mechanical properties of the matrix must balance ductility, malleability, and durability. This balance must be determined through testing to find a correctly annealed alloy. Surface matrices are usually considered single use products so repeated loading is not a major concern. This is because the matrix is often warped as it is conformed to the patient's tooth and would compromise future filling success. Filling overhangs are another point of concern for dentists. To address this problem, the product must be malleable enough to properly conform to the tooth and work seamlessly with tension rings and wedges. The material, again, must be properly annealed, near dead soft but not too soft, to achieve this task. Some sectional matrix systems have a tab or extended piece at the top of the tool for easier handling. This is not a required feature, but easy handling for dentists in a constrained environment must be considered in design.

b. Safety:

The device should avoid any materials that patients are commonly sensitive to, for example, nickel. Additionally, the final product should have rounded, not sharp, edges to minimize irritation and damage to the patient's gums. If sold, the product must be within sterilized packaging with warnings to discourage tampering.

c. Accuracy and Reliability:

Accuracy is an important consideration for dental matrices because they must be able to form to the tooth, interact with other components, and maintain the interproximal gap between teeth. The accuracy of thickness, the most important dimension for matrix systems, will depend on the supplier because post processing of metal alloys can be expensive and challenging, so modifying the thickness of the material after purchasing will be difficult. McMaster-Carr sets

their thickness tolerance for 0.0508 mm thick (0.002”) austenitic grade stainless steel at ± 0.00508 mm, which is a reasonable standard for the thickness of the product [2]. The height of sectional matrices vary depending on tooth type from 3.5 mm to 7.5 mm. This variety in size gives more leniency in tolerance, especially because the height dimension of the matrix has fewer interactions with other components. Additionally, with the variety of tooth sizes from both genetic and gender differences, height dimensions are not as critical as the thickness. Because the variance in length from the occlusal surface to the gingival surface has variance from patient to patient a larger tolerance of ± 0.2 mm is permissible. This should be achievable for larger scale stamping or laser cutting procedures while not compromising the effectiveness of the product [3]. Dimensions like length of the band are also not as critical as the thickness of the band because of the variation between teeth and patients. However, because the width of the matrix has interactions with other components like tension rings and must be able to accommodate a variety of filling sizes its accuracy is still important. Considering this the tolerance should be kept to ± 0.1 mm. In terms of GD&T specifications that must be considered are symmetry, surface profile, and line profile when the product is in its final configuration before use and surface roughness before product is formed to its final shape. Symmetry is important because of its interaction with other components like the tension ring as well as forming to the tooth and recreating a natural looking filling. Surface and line profile tolerances are important for the curvature of the matrix and recreating the natural form of the tooth. Surface roughness should be measured before the matrix is curved to ensure that the product is smooth and will not create any defects in the filling or adhere to the filling. These tolerances are harder to measure and specify, additionally, line and surface profile tolerances may not be as critical because the dentist can use rings and wedges to modify the shape of the matrix to match the tooth. Specifying these dimensions is difficult and outside of the scope of this project, however, they should not be entirely neglected and should be kept in consideration during design and manufacturing. Repeatability will vary depending on the manufacturing process. The most likely processes will be metal stamping, laser cutting, or water jet cutting. Each of these should be able to produce parts with high fidelity. During initial prototyping, a standard of 9/10 units should be within specification. If the product scales 1/100,000 should be defective.

d. Life in Service:

The device is designed to be single-use. It must maintain its structure for the duration of the procedure and be able to withstand removal from the patient in one piece.

e. **Shelf Life:**

The product should be kept in a dry and sterile environment. The humidity of the storage area should be low to prevent corrosion of the metal. It should be away from potential contaminants and oxidizing agents that could potentially damage the mechanical integrity of the matrix or mar the finish of the unit. If more than one size is produced this should be clearly organized and distinguished to avoid confusion. The product should be kept near room temperature to avoid compromising material properties and shape of the product. The matrix should be stored with care to avoid bending and deforming the preformed shape.

f. **Operating Environment:**

The product will be used within the human mouth, which will expose the device to multiple physical, chemical, and biological factors.

- I. The human mouth exposes the device to high levels of moisture. While stimulated, like during a dental procedure, the human mouth can produce 4-5mL/min of saliva [4]. This can cause corrosion or rusting in certain untreated metals. Another factor that increases the risk of corrosion is the slight acidity of saliva with a pH of 6.7 [5]. Though slight, this decreased pH can cause increased corrosion in metals like steel.
- II. Heat is another important factor when operating within the mouth. The standard temperature of the mouth is 37°C (98.6°F); the device must be able to maintain its mechanical properties within a range of 20°C (room temperature) to 37°C at a minimum to reach design requirements.
- III. The device must be able to withstand being pushed between teeth while not damaging them. The enamel of the tooth has a Vickers hardness of 274.8 [6]. Any material under consideration must have a hardness score below that to minimize damage.

g. **Ergonomics:**

The device must be at least as easy to install and use as current solutions, such as sectional and circumferential matrix bands. The device must also be faster to use than the two prior solutions it aims to replace. After use, the device must come out of the teeth easily and without excessive damage to the patient's gums.

h. **Size:**

As specified by the client, the thickness of the improved dual sectional matrix design should be the same as that of sectional matrices currently on the market. This is to ensure that there is sufficient proximal contact between the two restored teeth to prevent food impaction and further decay [7]. The typical thickness of sectional matrix bands currently on the market is 0.0381 mm, and in previous semesters, a thickness of 0.0254 - 0.0508 mm was used for the matrix band design [8]. Typically, current sectional matrices on the market have lengths between 12.57 - 14.33 mm, heights between 3.2 - 6.4 mm, and widths varying between 1.24 - 1.64 mm [8]. The overall size of the sectional matrix band will vary depending on the tooth (a wide range should be made), but the thickness of the device should remain between 0.0254 and 0.0508 mm.

i. **Weight:**

Depending on the material used for the sectional matrix band design (usually stainless steel or polytetrafluoroethylene (PTFE)) and its size, the typical weight of a sectional matrix band is between 0.01 and 0.02 grams (although not clinically relevant).

j. **Materials:**

The materials that make up the device must be biocompatible while temporarily pushed between the teeth of the patient; it is not required to meet the stringent standards of permanent implants. The device must be made of materials that can withstand the forces and environment of the tooth (described in section f) while still being malleable by the dentist, so that it can be moved to fit any specific patient's tooth. Materials like stainless steel are commonly used to accomplish these requirements. The material must be able to withstand autoclaving at 121°C (250°F) for 30 minutes in accordance with CDC guidance [9].

k. **Aesthetics, Appearance, and Finish:**

The final design should feature a slightly curved appearance to easily fit the anatomy of the tooth which it lines, subsequently reducing the time spent shaping the restoration. The product should be made of either polished stainless steel or PTFE, which can further be coated with a teflon finish to provide a non-stick surface. The design should also feature a tab, which makes for easy manipulation by the dentist during insertion and removal.

2. **Production Characteristics**

a. **Quantity:**

The client has requested a single prototype to test the functionality of the device.

b. **Target Product Cost:**

To be competitive, the device would need to be in parity with similar dental matrices costing ~\$0.50 - \$1.00 [10]. However, because of the relative complexity of the device and the time savings that it should provide, the cost of the device must remain under \$5 per unit to manufacture. The total budget for development and testing of the device must stay under \$200 as provided by the client.

3. **Miscellaneous**

a. **Standards and Specifications:**

Dental matrix bands are regulated by the FDA. The FDA classifies sectional matrices under “Dental Hand Instruments” which are class I devices that are 510(K) exempt. However, the FDA does not exempt the device from GMP, so this must be considered in the design for manufacturing. In addition to FDA regulations, ISO sets standards for sectional matrices under ISO standard 18556-2016. The standard classifies “intraoral spatulas” into two categories based on design and material properties. As designated by the standard, type 1 intraoral spatulas are oval shaped and are more rigid, while type 2 are more rectangular, flat, and flexible [11]. ISO also regulates the materials used in surface matrix bands under ISO standard 10993-1 *Biological Evaluation of Medical Devices*, which regulates biocompatibility of medical devices. The standard regulates testing for cytotoxicity, interactions with blood, irritation, and skin sensitivity, as well as identification and quantification of degradation products from medical devices [12]. Of these testing standards, irritation and skin sensitivity are the most relevant because of the minimal contact of the device. If further processing is required of the materials to increase ductility and malleability, the testing would likely fall under ASTM standard A666/A666M-24, which sets specifications for annealed or cold worked austenitic stainless steel sheet, strip, and flat bar [13]. This could be relevant because the thinness of the stock may limit the processing of the steel, especially for prototyping. It may be difficult to find medical grade (316L or 304) stainless steel at the required thickness with the correct annealing to allow for the ductility and malleability required for sectional matrices. Considering this, the ASTM standard for annealing austenitic stainless steel could be valuable in testing modified purchased materials.

b. **Customer:**

The intended customer of this product is any dental office or dentist who performs Class 2 dental restorations on their patients. This device can also be used by dental schools to train students on interproximal restorations.

c. **Patient-related concerns:**

Comfort is a large concern, which is related to the size of the matrix. On a patient-to-patient basis, patients with larger teeth may require a different sized matrix than patients with smaller teeth. This means that if there were to be a universal design, it must account for the different sizes of teeth, or it could be both uncomfortable and incapable of filling the teeth properly.

d. **Competition:**

One of the leading competitors in the market is the Halo Sectional Matrix Kit, which contains bands that are held in place by nitinol rings and glass-filled nylon tines [14]. A downside to this product is that the kit used to install this sectional matrix on the teeth is about \$700, which is far higher than the client's budget. A current device on the market that is used to fill cavities is the Trident V3 Ring [15]. This device is capable of filling cavities, but when used, it isn't capable of filling adjacent cavities without leaving too large of a gap.

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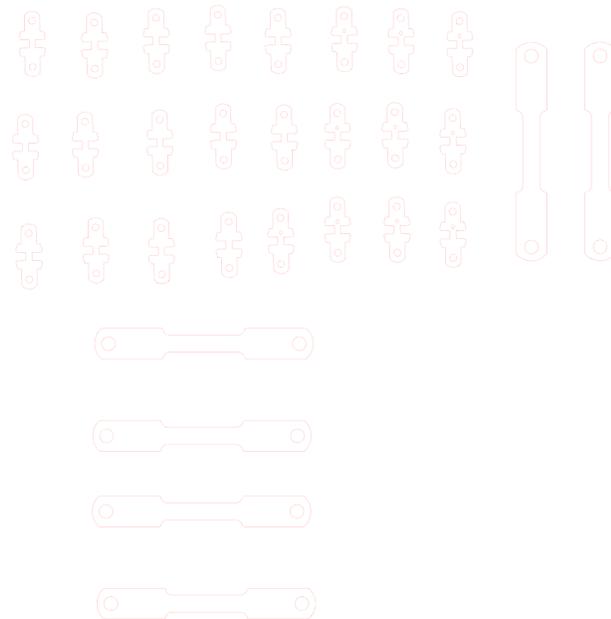
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Appendix B: Files for Laser Cutter



Note: The template is difficult to see because the line weight is so small, zooming in helps

Appendix C: Full Final Fabrication Procedure

1. Convert 3D SolidWorks model into 2D flattened surface
 - a. Rolled back model to one sided 3D model
 - b. Flattened surface using surface flatten tool
 - c. Mirrored to create two surfaces
 - d. Connected two surfaces with boundary surface
2. Prepare files for laser cutting templates
 - a. Added tabs with holes for locating
 - b. Created SolidWorks drawing file and layout all pieces to be cut
 - i. A
 - c. Exported as .pdf to Adobe illustrator
 - d. Converted line color to RGD #FF0000 and line weight to 0.0001 mm
 - e. Exported as .ai file
3. Print .ai file to Universal Laser System ILS9.150D-150 machine
 - a. Placed $\frac{1}{8}$ in HDF on cutting bed
 - b. Calibrated laser
 - c. Cut material
4. Prototype flat fabrication
 - a. Covered both sides of metal shim stock with blue painters tape
 - b. Glued one template onto tape
 - c. Rough cut with scissors
 - d. Drilled out alignment holes and part hole
 - e. Used bolts and nuts attach second template to opposite side of shim stock and tighten
 - f. Cut away extra tape using razor blade to improve visibility during grinding
 - g. Used dremel $\frac{1}{2}$ " drum sander bit to remove as much material as possible
 - h. Finished with $\frac{5}{64}$ " tip diamond wheel grinder to remove material up to template
 - i. Took off one template
 - j. Used dremel cut off wheel to rough cut off tab
 - k. Finished bottom surface off part with $\frac{1}{2}$ " drum sander and diamond wheel grinder
 - l. Repeated for all parts
5. 3D model fabrication
 - a. Printed mold
 - b. Placed flat matrix between mold halves and compressed
 - c. Measured matrix to find halfway point which was marked
 - d. Used a razor blade to maintain square folding and folded matrix to create final geometry

Appendix D: AISI 304 stainless steel from SolidWorks material library

Material properties
 Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.

Model Type: Save model type in library

Units:

Category:

Name:

Default failure criterion:

Description:

Source:

Sustainability:

Property	Value	Units
Elastic Modulus	190000	N/mm ²
Poisson's Ratio	0.29	N/A
Shear Modulus	75000	N/mm ²
Mass Density	8000	kg/m ³
Tensile Strength	517.017	N/mm ²
Compressive Strength		N/mm ²
Yield Strength	206.807	N/mm ²
Thermal Expansion Coefficient	1.8e-05	/K
Thermal Conductivity	16	W/(m·K)

Appendix E: Expense Table

Item	Description	Manufacturer	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total
Fabrication Materials								
316 Stainless Steel	316 Stainless Steel Shim Stock	Trinity	Mcmaster Carr	2317K51	9/29/2020 5	1	\$22.55	\$22.55
301 Half Hard Steel	301 Half Hard Steel Shim Stock	Trinity	Mcmaster Carr	2316K327	11/19/20 25	2	\$8.94	\$17.88
304 Full Hard Steel	304 Full Hard Steel Shim Stock	Trinity	Mcmaster Carr	9784K623	11/19/20 25	2	\$10.04	\$20.08
Total Spent								\$60.51

