



Department of Biomedical Engineering

UNIVERSITY OF WISCONSIN-MADISON

Approximating Surface Matrix Band for Dentist to Use for Patients

BME 200/300

2026/10/07

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Abstract

Dental matrices are used in cavity restorations to provide shape and support for composite filling material. There are both sectional and circumferential matrices which can only be used to treat caries on one premolar or molar tooth at a time. The use of two matrices requires dentists to complete adjacent interproximal restorations on molars and premolars individually, which is time consuming. To increase efficiency, the proposed device will slot in between adjacent caries and provide a guide for both teeth at once. This will allow for simultaneous restorations. The device will be timed in use and compared to the time of completion for two individual restorations which will test the device's time saving capabilities.

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Introduction

Motivation and Global Impact:

Dental cavities affect approximately 2.3 billion people worldwide and 620 million children [1]. Dental cavities develop when a thin biofilm coats the teeth, breaking down the enamel and then dentin. As the condition progresses, soreness, pain, and tooth sensitivity increase. Advanced cavities require tooth canals or removal of the tooth. Restorations prevent caries from progressing by drilling the affected area and sealing it [2]. Class II lesions are the most frequent, as the interproximal space allows for easy food packing and therefore bacterial colonization [3].

The median time to complete a Class II filling is 39 minutes. The extended time requirement for two adjacent Class II restorations costs patients in loss of productivity, increased billable time, and a potential escalation of dental anxiety [4]. A dental device that promotes procedure efficiency will reduce patient cost and amplify doctor productivity, as more patients can be seen during the same time period.

Existing Devices:

Dental matrix bands can be separated into two categories: sectional matrices and circumferential matrices. Circumferential matrices wrap around the entire tooth and are secured with a gingival wedge. The Tofflemire circumferential matrix system exemplifies this device and is frequently used in dentistry [5]. Sectional matrix bands are a crescent shape, covering just the filling and margins. They are used in tandem with gingival wedges and separation rings.

Sectional matrices produce tighter contacts because of their use of separation rings and crescent shape. Tighter contacts decrease the possibility of new cavity formation. Sectional matrices are also easier to use. However, sectional matrices can be more time consuming to place than circumferential matrix systems as there are more components. The time cost of sectional matrices has resulted in their proliferation being less than that of circumferential matrices [6].

Problem Statement:

Matrix bands are devices used by dentists to restore interproximal cavities during Class II restorations. The band itself is used as a support to retain the composite material and conform it to the natural tooth shape. The issue with the current system is that dentists have to fill each cavity sequentially rather than at once. This is because the interproximal spacing must be fine tuned in order to prevent food impaction resulting in further breakdown of the enamel and possibly more cavities. Ultimately, this is a time consuming procedure which results in greater costs for the patient. To solve this, the goal of the project is to design a device capable of filling interproximal cavities simultaneously and effectively to reduce the overall procedure time.

Background

Anatomy and Physiology:

Cavities are characterized by the progressive destruction of the crown and roots of the tooth due to metabolic processes carried out by microorganisms. This is when the biofilm interacts with fermenting carbohydrates from food. This interaction over time creates lactic acid which decreases the overall pH of plaque below 5.5 and leads to stripping minerals from the tooth known as demineralization [7].

One of the most common areas for cavities to form is the interproximal space because of the increased bacteria accumulation in hard to clean areas. Cavities that occur between teeth are also known as interproximal cavities or Class II cavities. These cavities are treated in a process called a Class II restoration in which the tooth decay is drilled out, then the gaps are filled using a matrix band to contour to the tooth shape, and then the hole is filled with a filling material [8].

Client Information:

The client, Dr. Donald Tipple is a retired dentist, and business owner of Nakoma Dental LLC. He has a wealth of knowledge thanks to over three decades of experience after taking ownership of Nakoma Dental in 1989 [9].

Design Specifications:

The client requested a dental matrix capable of filling two interproximal cavities simultaneously. The device must be compatible with all existing dental equipment including gingival wedges and tensioning rings. Additionally, the device must successfully perform by providing a high quality filling comparable to other devices on the market while maintaining structural integrity throughout the procedure. The device must also be safe to use and biocompatible as it is used within the mouth. Lastly, the production and design of the prototype must not exceed \$100 due to the budget provided by the client.

Preliminary Designs

S-Design:

The S-Design, as shown in Figure 1 below, approaches the problem of too much width between the teeth in a different way than previous semesters. Instead of using a folding sheet of metal, this design uses two separate pieces of metal fit together via a slit. Each sheet will be folded into an S shape, then fit together to make the desired matrix shape. The benefit of this design is that the center of the matrix will be at most one sheet thick. This removes the need to cut a hole in one of the folds to reduce overall thickness. Additionally, this design can be catered to any type of tooth; the dentist can manually change the S shapes of each sheet to perfectly contour each tooth. One sheet is taller than the other to make it easy to remove from the mouth

once the cavities are filled. Some disadvantages of the S-design are that the filling quality may not be as good. This is because when the two sheets come together, they may have a less optimal angle at their intersection, and therefore less ideal tooth contact. The S-design may also be harder to remove because it is two pieces. This design is likely harder to use compared to the other designs because it has to be put together and folded for optimal tooth contact by the operator, and this may be more difficult since it is two pieces. Additionally, it may be less safe to use in the mouth because the pieces can come apart and cause complications.

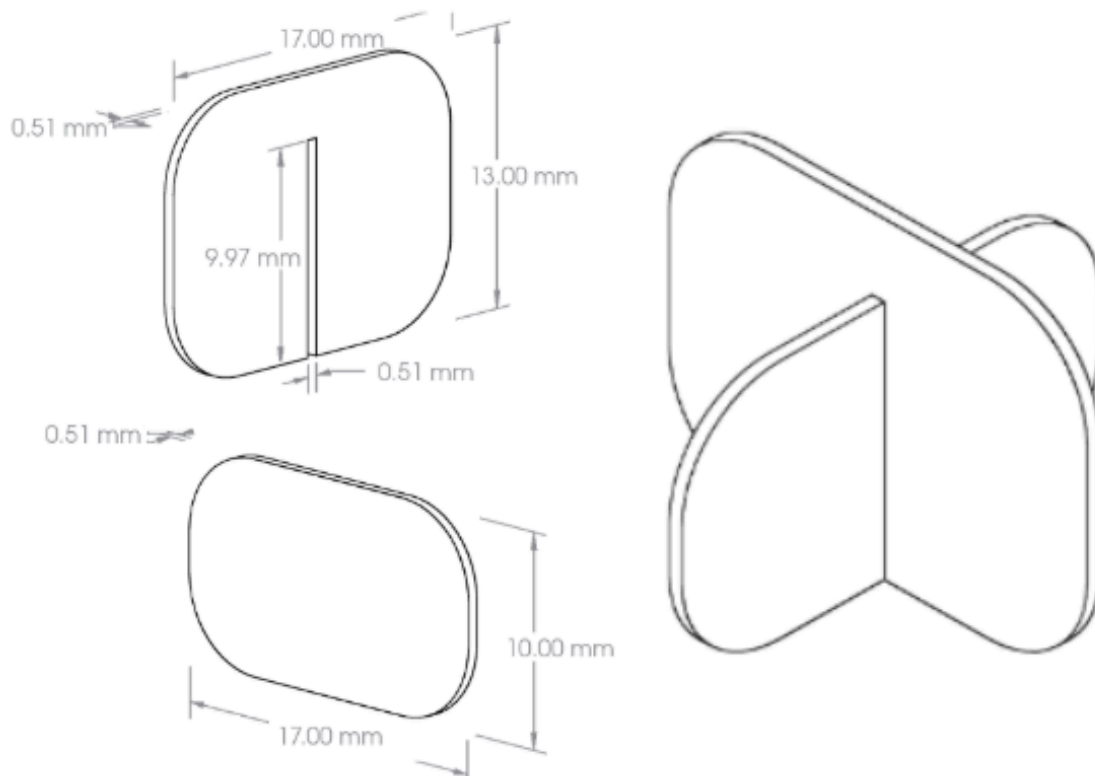


Figure 1: S-design modeled in SolidWorks by Samuel Zakaib.

Half-Oval Design:

The half-oval design, as shown in Figure 2 below, folds into a butterfly shape across the horizontal midline. It has a cutout to ensure that the device is not too thick once folded, so as to be able to fit between the teeth properly and allow for ideal contact. Additionally, the shape of the cutout could help make removal of the device easier, which was a problem with previous designs. The cutout goes to the bottom of the wing to prevent it from catching the tooth and causing damage to the tooth or to the device. The tapered wings allow the device to fit well within the gumline, and the chamfered edges will minimize any gum irritation that may occur. This device will allow for fillings that mimic the natural tooth shape. Some disadvantages of the half-oval design are that the filling quality may not be as good compared to the other prototypes

due to the size of the cut-out, it is not as easy to use compared to the perforation design because of the cutout which may cause complications (unintended folding, irritation in the gumline, etc.), and it is more difficult to fabricate than the S-design because it is a slightly more complex design.

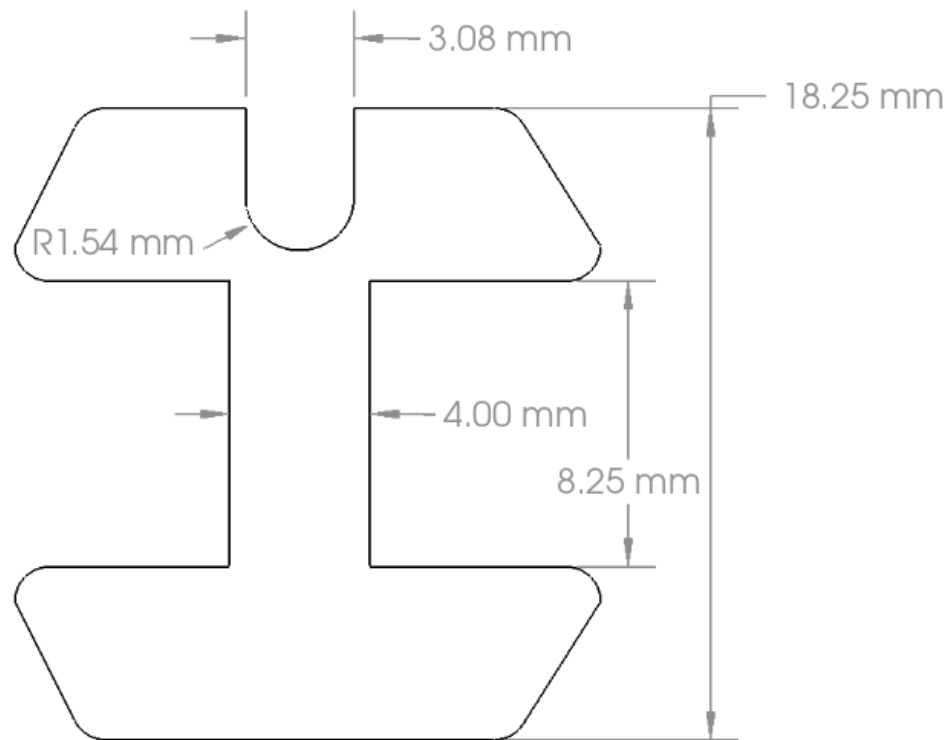


Figure 2: Half-Oval design modeled in SolidWorks by May Kennelly.

Perforation Design:

The perforation design, as shown in Figure 3 below, is similar to the half-oval design in that it folds into a butterfly shape, has tapered wings, and chamfered edges. The butterfly shape allows for ideal contact between the teeth; the tapered wings allow the device to fit well within the gumline, and the chamfered edges will help minimize gum irritation. However this design has a perforation near the center, and the hole is shifted closer to the center of the device for better tooth contact and ideal device thickness. The perforation is meant to address the issue of device removal at the end of the procedure, allowing the device to be removed in two pieces, which should be easier for the operator to do. Some disadvantages to the perforation design is that it may be harder to remove compared to the half-oval design due to the perforation/removal of two pieces, and it may be harder to fabricate compared to the other prototypes because it is slightly more complex than each with the perforation.

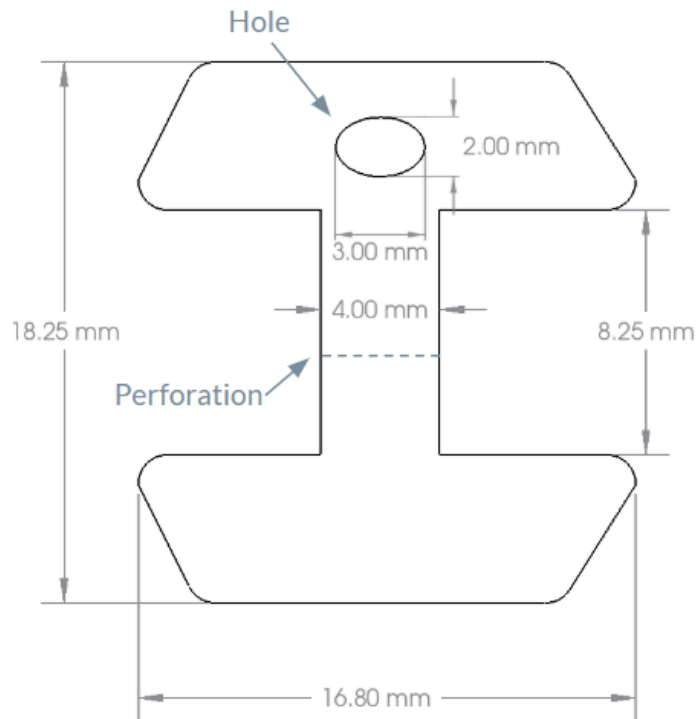


Figure 3: Perforation design modeled in SolidWorks by May Kennelly.

Preliminary Design Evaluation

Table 1: Design Matrix

Design Criteria (Weight)	Design 1: S-Design		Design 2: Half-Oval		Design 3: Perforation	
Filling Quality (25)	4/5	20	2/5	10	5/5	25

Ease of Removal (25)	3/5	15	5/5	25	4/5	20
Ease of Use (20)	3/5	12	4/5	16	5/5	20
Ease of Fabrication (10)	5/5	10	4/5	8	3/5	6
Safety (5)	4/5	4	5/5	5	5/5	5
Cost (5)	4/5	4	5/5	5	5/5	5
Total (100)	65		69		81	

Matrix Category Definitions:

Filling Quality: Expected filling quality describes the ability of the device to replicate the natural tooth shape. To successfully replicate the natural tooth shape and protect the gums, there must be proper interproximal contact and wedging. Proper interproximal contact prevents food packing, which can lead to gingivitis, tartar, and tooth decay. Adequate wedging prevents gingival margin leakage, protecting the gums.

Ease of removal: Ease of removal is integral to the success of the project because the device aims to be as efficient as possible. Less time removing the device results in the overall restoration time decreasing. The objective of the device is to reduce procedure time. If the dentist must take extra time to remove the matrix, there will be no time saving effect and dentists will continue using two matrices back to back.

Ease of Use: It is crucial that the design is easy for the dentist to use. The design aims to replace the standard of interproximal cavity restorations, and to do this, the design must be user-friendly. A design that is only one piece will be easiest to use because the oral cavity is small and accounting for several pieces would require the dentist to take more steps.

Furthermore, the device will arrive flat, and the dentist will fold it into the butterfly shape. It will be more difficult to contour the matrix band if it is made of more than one piece.

Ease of Fabrication: A design that is easy to fabricate will consistently produce accurate dimensions, which is crucial to device functionality. Easier fabrication also reduces the time and cost needed to produce the device. A quick, easy manufacturing process allows the team to spend more time on quality checking, smoothing edges, and testing performance. Together, these benefits make the matrix more practical for dentists to use.

Safety: Safety is of the utmost importance to ensure patient comfort during and following the restoration. Thin metal bands can easily slice gingival tissue, so it is important to choose a design that fits snug to the contour of the tooth without needing to force it into the gumline. Additionally, the metal needs to be burnished carefully to avoid sharp edges or burrs which can also cut the soft tissue during placement or removal. Removing the device in the least amount of pieces possible will also ensure no metal components are left in the oral cavity.

Cost: The cost is imperative as the design requires functionality but also must remain at a competitive price relative to competitors in order to sell. Despite this importance, it does not take precedence over other categories as the primary function of the device is to save time and not money.

Ranking Explanations:

Filling Quality: Expected filling quality is weighted 25 because filling quality is integral to the device. This is because the purpose of the device is to reduce restoration times by performing two restorations at once. The device must produce a quality filling otherwise it will not replace current devices. The Perforation design is ranked 5/5 for quality because it provides good tooth contact with a tooth-like shape while allowing for proper wedging. The S-design is ranked 4/5 because it allows for mostly good contact and wedging; however, its use would not result in a tooth-like shape. The Half-Oval design is ranked 2/5 because although its contact on the upper part of the tooth is good, the opening on the bottom will result in the composite resin leaking into the gum area and onto the wedge.

Ease of Removal: Ease of removal is weighted 25 because the client indicated removal difficulties as the largest issue with previous design iterations. The Half-Oval design earned a score of 5/5 because there is no bottom to the circle, allowing the matrix to slide straight up and out of between the teeth. It also has a tab. The Perforation design is ranked 4/5 because breaking the matrix into two pieces should allow the dentist to remove one side after the other. However, the side with the circle cutout could still get stuck on filling. The S-Design is ranked 3/5 because there could be a gap between the two metal sheets either causing a lip or one filling to connect to

another which would make it difficult to remove. It also has no tab to grab.

Ease of Use: Ease of use is weighted 20 because the device must be easy to shape, otherwise dentists will likely not adopt its use. The Perforation design is the easiest to use because the dentist can simply fold the piece in half to create the butterfly shape, which is why it has a score of 5/5. The wings are also easy to mold because they are connected throughout the bottom. The Half-Oval design is similar to the Perforation design in that the user can simply fold it to create the butterfly shape. However, the Half-Oval design will be more difficult to contour than the Perforation design because the bottom is not connected on one side. So, it earned a score of 4/5. The S-Design is more difficult to use compared to the others because it is made of two pieces, rather than one. This requires more assembly. Additionally, it will be more difficult to contour because it does not taper in towards the gums, resulting in an ease of use score of 3/5.

Ease of Fabrication: Ease of fabrication is weighted 10 because easier fabrication reduces production time and cost, which in turn reduces device cost. A cheaper device is more desirable to dental offices. The Perforation design is rated a 3/5 for ease of fabrication because there are several small pieces that must be cut out and be smoothed. Similarly, the Half-Oval design has several small cut-outs; however, there is no perforation which means fabrication will be easier. So, it is rated a 4/5. The S-Design only requires one slit to be extruded and a chamfering of edges, which is why it is rated a 5/5 for ease of fabrication.

Safety: Safety is weighted 5 because the patient's health and safety is our first priority and as such all designs that are on the matrix are already highly safe. The perforation design was ranked 5/5 for safety because the perforated section allows for a lower risk of tearing into 3 or more pieces, which reduces the likelihood of metal being swallowed by the patient. The half oval design is also 5/5 because there is no lower lip for the matrix to get caught on, so there is minimal tearing likely. The S-design is ranked slightly lower than the others because the 2 pieces sliding together in the middle could pose a higher risk of accidentally cutting the gums.

Cost: The Perforation and the Half Oval designs were rated 5/5 as their material and fabrication costs are relatively low as they are composed of a single piece of metal. For the S-Design however, it is rated a 4/5 because it is composed of two separate pieces and would require more cutting and material costs compared to the other two designs.

Proposed Final Design:

The Perforation design meets the most criteria of the three designs. This is because it will produce high quality fillings while being relatively efficient to remove. It will also be compatible with current devices and methods and result in an increase in speed of the procedure. Furthermore, the Perforation design will be safe to use as it has chamfered edges, allows for

wedging to protect the gums, and minimizes swallowing risk. The design will also be under budget.

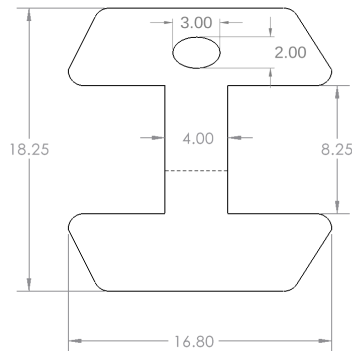


Figure 4: SolidWorks drawing of perforation design



Figure 5: Tinfoil model of the perforation design

The final design for prototyping was the “Perforation” preliminary design idea. The main features of this design are the hole in the middle to ensure that the device is only one layer thick in the middle, and the perforation line to make the device easier to remove. The height measured from top of the tab to bottom of the matrix was 18.25 mm. The average functional height measured from top of the wing to bottom of the wing was 8.25 mm. The average width of the matrices was 16.80. The average hole height and hole width was 2.00 mm and 3.00 mm respectively.

Fabrication

Materials:

Material choices for prototyping included 316 fully annealed stainless steel, 304 full hardness stainless steel, and 301 half hardness stainless steel. The biggest criterion when choosing a metal is that it needs to be stiff to place between teeth without deforming, but also very ductile and malleable to form to the teeth during the filling procedure. Based on last semester's testing, 316 steel proved to be too ductile and was torn apart during waterjet fabrication. 301 steel and 304 have a similar stiffness to 316, however 301 and 304 have half and full hardness ratings compared to the fully-annealed 316, making them substantially stiffer [10]. Also, 304 steel is biocompatible and resistant to corrosion. It contains 18% chromium, which reacts with oxygen to form thin chromium oxide (Cr_2O_3) passivation layer on its surface [11]. The layer limits contact between the underlying metal and oral environment. Due to this, 304 will be continued into prototyping and fabrication this semester.

Methods:

Fabrication for the device has not yet started since materials still need to be purchased, and it is uncertain whether a metal laser cutter or a waterjet would be best suited for this design. In addition, an FEA analysis on SolidWorks should be performed on the “Perforation” design before fabrication.

Testing and Results

Future testing will include timed restorations, MTS failure analysis, and an FEA analysis in SolidWorks. The team will time Dr. Tipple in running trials with and without the device. He will perform five adjacent interproximal restorations with the device and five using individual sectional matrices. Team members will track the time of each step in the process to determine weak points of the device and analyze the device’s time saving effects. The MTS Universal Testing Machine will be used to determine the elastic modulus, ultimate tensile strength and fracture stress of the device. The team will run one trial on a duplicate of the prototype. The MTS testing will allow for investigation into material selection. To further analyze the device, Solidworks FEA analysis will be used. It will model how the device performs under the loads it experiences in the mouth and will allow for repeated trials.

Discussion

From the preliminary analysis of the initial three designs, the perforation design has been chosen as the final design to move forward with. This is because it has the most advantages compared to the other designs. Although the S-design is unique and would be easy to fabricate, it may cause issues with filling, removal, and overall make the procedure more difficult for the operator, which are all not ideal. For the half-oval design, despite its similarity to the perforation design, it is less optimal for filling quality and ease of use, mostly due to the size of the cut-out and the possible complications that may cause. The perforation design is predicted to have the best filling quality and ease of use, while also being safe to use in the mouth. However, it may be more difficult to manufacture the perforation design compared to the oval design, and to remove the device at the end of the procedure.

The major ethical considerations for this project are the safety, procedure time, ergonomics, user acceptability, and environmental impact. As dental matrix bands are a medical device, they must be safe to use with humans. The device must be biocompatible so as to prevent any harmful interactions from occurring between the matrix band and the patient. Biocompatibility can be achieved through choice of material. Additionally, the design must be acceptable to the patient and operator. For the patient, the device must sit comfortably on the gumline without causing irritation or other negative effects, and for the operator, the device must be easy to assemble and utilize. Studies have shown that circumferential matrix bands are more comfortable for patients [12]. However, the final design has features that should allow the device to be comfortable for patients as well, despite being a sectional matrix band. The procedure time should be as short as possible without making trade-offs that may cause additional problems so as to make the procedure accessible for a broader group of the population. The final design

should help reduce procedure time by allowing the operator to simultaneously fill cavities, rather than filling them sequentially. Lastly, the chosen material should be safe for the environment. The material should be highly durable and have a long service life, as well as easy end-of-life management, like recyclability.

The cost of each prototype will likely be higher than that of two traditional sectional matrix bands, or more similar to that of one traditional circumferential matrix band. Any increase in fabrication costs will likely affect the cost of the procedure for the patient, however, the price will be kept as low as possible to ensure the procedure remains as accessible and affordable as possible for all groups of the population [13]. The cost of the final design will remain unknown until each of the prototypes can be fabricated. The potential time savings of using the prototyped matrix band could offset the material costs in order to keep the design affordable. The cost will be evaluated throughout experimentation and at the termination of the project to ensure that the device remains affordable and accessible.

The next step in the design process is to begin prototyping the device. The final design will first be prototyped in SolidWorks. FEA testing will be conducted on the modeled prototype before fabrication to predict stress, deformation, and other factors assuming the material is 304 stainless steel. Data from the FEA testing can be compared to the previous design data to allow for changes to be considered and made prior to fabrication. The device will be fabricated using 304 stainless steel sheets, however, a machining plan must still be developed. Fabrication of the device will likely be done using laser cutting, however, this will have to be outsourced as there are no available metal laser cutters on the University of Wisconsin-Madison campus. Other future testing will be conducted as described in the Testing and Results section.

Conclusions

The Approximating Surface Matrix Band for Dentists to Use for Patients project aims to design a sectional matrix system that increases procedure efficiency. Dentists will be able to easily and quickly repair two adjacent premolar and molar interproximal cavities simultaneously while ensuring adequate contact when employing the device. Three preliminary designs were presented, with the Perforation design meeting the most criteria. It was selected based on its filling quality, ease of use and removal, manufacturability, safety, and cost. A machining plan will be developed to prototype the device and perform time, MTS, and FEA testing. These steps will determine if the product can meet the mechanical and clinical requirements necessary for practical dental application.

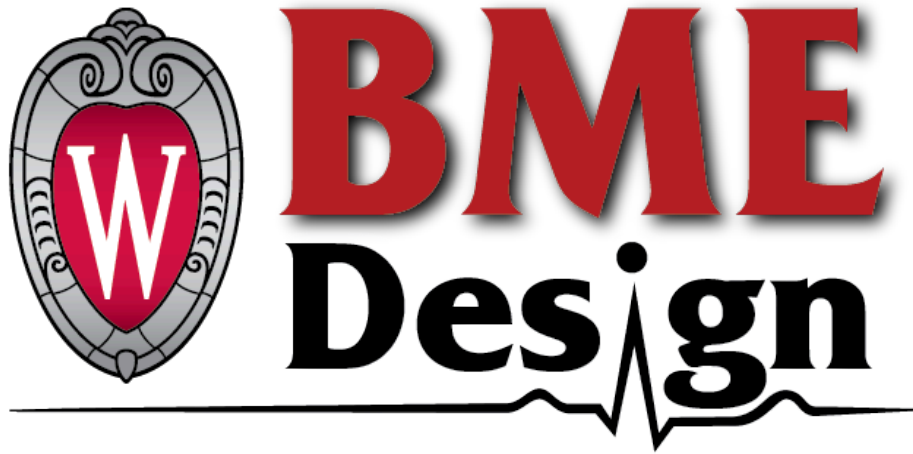
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Appendices

Appendix A: Product Design Specifications



Dual Matrix Product Design Specifications

BME 200/300

Team Name: Dual Matrix

Fall 2026

09/17/2026

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Advisor: John Puccinelli

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Function

Matrix bands are used to restore interproximal cavities. They are used in tandem with gingival wedges and separation rings and must be thin to allow proper contact between teeth. Improper contact may result in food impaction which can cause gingivitis and decay. The standard of care for two adjacent interproximal caries on premolars and molars is completing each filling separately. The Dual Matrix aims to allow the dentist to more efficiently complete two adjacent restorations because they can occur 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 II 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 restorations to aid dentists in creating natural tooth shape with optimal contact while shielding gum tissue. The Dual Matrix is a sectional surface matrix which is most commonly used for treatment of Class II caries. Sectional surface matrices are used with gingival wedges and separation rings [1]. The device must work with these existing products. The Dual Matrix device must have a tab so that the dentist can easily place the device. It must be removed in one to two pieces to ensure that metal does not travel into the patient's airway, which is a risk if the matrix rips repeatedly while it is removed. The matrix should have a factor of safety around 1.5 as the device is a Class 1 medical device under *FDA Product Classification 21 CFR 872.4565* and has minimal potential for harm if it fails [2]. Common matrix band thickness is 0.038mm to 0.05mm [3]. If the matrix band is too thin, it will be too weak and fail to work as a barrier. If the matrix band is too thick, the interproximal contact between the teeth will be minimal leaving a gap that is prone to food packing. Food packing can lead to gingivitis and decay [4]. The band must also be malleable enough to form around the tooth. Most current matrices are fully annealed; however, testing must be done amongst several levels of annealment to determine an appropriate balance between ductility, malleability, and durability. The Dual Matrix will be in the oral

cavity for about seven minutes and under load for about five minutes [5], so future testing should reflect this interval of loading. Surface matrices are considered single use because they matrix is molded to the patient's tooth while in use, so continued loading is not a concern.

b. Safety

The Dual Matrix device must have smooth, rounded edges to minimize risk of irritation and damage to the patient's gums. The device must not contain more than 0.02% mass fraction of beryllium, cadmium, or lead. Nickel is also hazardous and the device must not have more than 0.1% mass fraction of nickel [6]. The matrix bands must be sold in sterile packaging under infectious control procedures as they must not be contaminated before being placed [7][8]. The device must also be easily removable in at maximum three pieces to minimize risk of ingestion. If the shards of the matrix are ingested there is a possibility of choking, trauma to the esophagus or stomach lining, infection, and mediastinitis or peritonitis [9].

c. Accuracy and Reliability

Consistent dimensions are important to ensure fit and compatibility with gingival wedges and separation rings. The Dual Matrix's thickness requires especially tight control because an inaccurate band could create poor contact which results in low quality fillings. The selected McMaster-Carr 304 stainless-steel strip has a thickness of 0.002 inches with a tolerance of only ± 0.0001 inches [10]. This narrow tolerance should produce consistent matrix thickness across prototypes. The material is also hardened to Rockwell C40 and has a listed yield strength of 140,000 psi, allowing it to resist unwanted deformation during placement. Matrix height and length are not as critical as thickness. Gender and tooth height play a role in differences in tooth height and size; however, ideal tooth spacing is consistent no matter the patient. Matrix smoothness is also important to consider. Since the matrix has to slide in and out during the procedure, it is important that the edges of the matrix do not irritate the gums because they are too sharp or rough. Determining the exact specifications for smoothness of the matrix is out of the scope of this project; however, it is important the team is still mindful of these concerns during the manufacturing process. It is likely that the manufacturing process of the matrix includes but is not limited to, water jet cutting, metal stamping, or metal molding. Each of these methods must be able to create samples reliably and accurately. For the manufacturing done in our project, the method chosen must produce 9/10 samples to our specifications. If the matrix were to be manufactured at scale, 49,999/50,000 must match specifications.

d. **Life in Service**

The product is designed to be a single use device which needs to maintain its structural integrity throughout the entire procedure without any structural deformation. The device also needs to be easily removable in a maximum of three pieces.

e. **Shelf Life**

The product should be kept around room temperature to ensure the material retains its mechanical properties and does not warp. It must be packaged in a sterile container, so it can be stored in a non-sterile environment. If there are multiple sizes or types of matrices, they should be neatly organized and handled with care to prevent bending or breaking.

f. **Operating Environment**

The sectional matrix system will operate inside the human mouth, where it will be continuously exposed to saliva. Saliva is more than 99% water, and approximately 750 mL is produced each day, making the mouth consistently moist. Salivary pH normally ranges from approximately 6.2 to 7.6, with an average near 6.7, although it can vary between individuals and with oral health conditions [11]. The matrix must be able to withstand constant exposure to acidic moisture during the duration of the procedure. The matrix must not corrode. The matrix must have enough mechanical strength and stiffness to withstand insertion between adjacent teeth and resist bending, tearing, or permanent deformation. Dentin is reported to have a Vickers hardness of 52 ± 9 HV, while demineralized dentin ranged from 20 to 45 HV [12]. The matrix should withstand the forces of use without applying enough concentrated pressure to damage the tooth. The design should prioritize adequate strength and dimensional stability while minimizing scratching or indentation of dental tissue.

g. **Ergonomics**

The device must fit between the premolars and molars with appropriate length to span half of the interproximal tooth. It must be easy for the dentist to place the Dual Matrix as the oral cavity is a confined space. To ensure ease of placement and removal, the device should have a tab for insertion and perforations for removal in two pieces. The device could also employ a pre-contoured design which would allow the matrix band to be seated without having to carve the marginal ridge extensively. Additionally, the device's hole for ideal contact cannot get caught on the tooth during removal. This is because fragmented removal poses danger to the patient and reduces efficiency.

h. **Size**

The height should be around 8 mm to provide the best mold for premolars and molars. A height of 8 mm ensures that the matrix band extends sufficiently apically. If the matrix band does not extend far enough apically, it can cause a gingival overhang that cannot be corrected. The thickness should be between 0.05 mm and 0.038mm [13]. The width should be between 4.5 and 8.4 mm so that the device extends far enough around the decayed teeth [14].

i. **Weight**

The product should be lightweight. Due to the material choices of stainless steel foil with different annealments, all potential prototypes will be an appropriate weight to be placed in the mouth [10].

j. **Materials**

The device will be made from 304 stainless steel because it is strong, malleable, biocompatible for temporary use, and resistant to corrosion. These properties allow the dentist to shape the matrix around a patient's tooth without permanently deforming or breaking it. The oral cavity contains saliva, chloride ions, microorganisms, and changing pH conditions. Three hundred and four stainless steel contains approximately 18% chromium, which reacts with oxygen to form a thin chromium oxide (Cr_2O_3) passivation layer on its surface. This protective layer limits contact between the underlying metal and the oral environment, making 304 stainless steel more corrosion-resistant than ordinary carbon steel [10][15].

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

The Dual Matrix device will be made of 304 stainless steel which appears polished and shiny. It will have two concave pieces with a connecting tab to allow for easy insertion and removal. The device will also have smooth edges to minimize the patient's gum irritation.

2. **Production Characteristics**

a. **Quantity**

The client has requested a single sample in order to focus on design and functionality improvement instead of large-scale manufacturing methods.

b. **Target Product Cost**

In order to maintain competitive pricing with other matrix bands on the market, each unit should be priced between \$1.00 and \$2.00, around \$0.50 more than the average Tofflemire bands, due to the time saving potential of the Dual Matrix device [17]. The client's budget for the development and testing of the individual prototype is 100 dollars.

3. Miscellaneous

a. Standards and Specifications

Dental matrices are regulated by the U.S Food and Drug Administration (FDA) as a Class 1 medical device under *FDA Product Classification 21 CFR 872.4565* [2]. Class 1 medical devices have minimal potential for harm and are subject to the lowest amount of regulatory control. They are also 501(k) exempt, meaning manufacturers don't have to submit a premarket notification application to the FDA. ISO also has standards for dental matrices including ISO 18556:2016 on "intraoral spatulas". This standard divides the devices into type 1 and type 2 categories based on material properties of metallic and non metallic. Type 1 intraoral spatulas are oval shaped and rigid whereas Type 2 are rectangular, flat, and flexible [18]. Another relevant standard is ISO 10993-1:2025 on the biological evaluation of medical devices. It defines principles and requirements for assessing a device's biological safety and biocompatibility. 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 [19]. This is essential for ensuring the patient is safe from any unintended biological harm from the matrix band. In efforts to make the matrix band thinner using a ductile metal alloy material, ASTM standard A666/A666M-24 which sets specifications for annealed or cold worked austenitic stainless steel sheet, strip, and flat bar would be necessary [20]. If the material is changed from previous prototypes, mechanical properties such as yield strength, tensile strength, elongation, and bending tests will be required.

b. Customer

Matrix bands are used to perform Class II dental restorations. There are several different types of matrix bands and each can be applied differently throughout the oral cavity. Dental restorations on two interproximal cavities in the incisors or canines can be done simultaneously with two Tofflemire devices. However, this same process cannot be done on the molars and premolars due to the Tofflemire device shape. Dentists who are interested in increasing filling efficiency in the molars and premolars will benefit from the Dual Matrix device. It can also be implemented to train dental students to promote a new standard of care.

c. **Patient-related concerns**

The main patient concern is gingival discomfort during the restorations. This is especially pertinent as many patients report anxiety about dental procedures. The matrix band must also sufficiently create tooth contact to limit food packing. Food packing can lead to biofilm which irritates the gums and contributes to caries formation [4].

d. **Competition**

The *Quad Sectional Matrix System Intro Kit (QR-KHF-10)* is a sectional matrix which is the standard of care for interproximal cavities [21]. Sectional matrices of several sizes that are available as part of a kit are a common choice for dental offices. The disadvantage of using two sectional matrices in sequence is that each step of the filling has to be repeated for each tooth. In a dual matrix, both restorations can be done at the same time. The *Reel Matrix* is an additional competing product [22]. A similar and highly common tool is the Tofflemire System. Both designs wrap around the circumference of the tooth with functional pins to tighten the band to tooth size.

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Appendix B: Expense Table

Item	Description	Manufacturer	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total
Materials to Buy								
304 Stainless Steel	304 Stainless Steel Sheets	Wieland	McMaster Carr	3254K211	10/6/26	1	\$27.14	\$27.14
Materials from Previous Semesters								
								\$0.00
							TOTAL:	\$27.14