Approximating Surface Matrix Band for Dentist to Use for Patients

Biomedical Engineering 400 - Preliminary Report, October 8th, 2025

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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 in-between the proximal contact of two posterior teeth, and often, both teeth are affected [2]. The current treatment option for this condition is a Class II restoration, which focuses on the removal of decay and restoration of tooth structure while maintaining proximal contact between the teeth. Current products on the market to assist in this procedure include circumferential and sectional matrices [2]. However, when there are two adjacent interproximal cavities, these tools are inefficient due to the need for preservation of the proximal contact area. Using one matrix at a time requires repetition of pre-operative processes such as pre-wedging and wedging, which dentists find to be inconvenient. In order to address this discrepancy, a device which is able to be used for two adjacent interproximal fillings without compromising the proximal contact area was proposed. Out of three preliminary design ideas, the "Hole Design" was chosen due to its superior efficacy, ease of use and fabrication, and cost (Table 1). To test the functionality of the device, the following design aspects will be analyzed: thickness, biocompatibility, and mechanical properties. Additionally, efficacy testing will be performed by filling in cavities, and a survey will be conducted on local dentists' opinions on the product.

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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 re-building 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

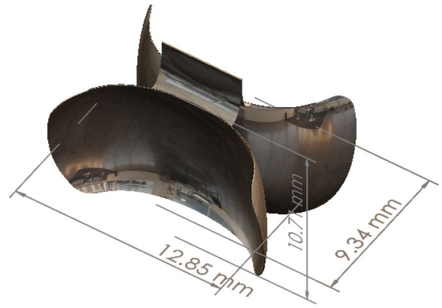


Figure 3: Adjusted Butterfly Design.

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.

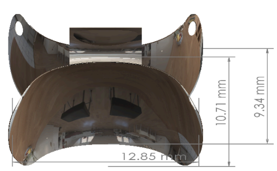


Figure 4: Hole Design.

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.

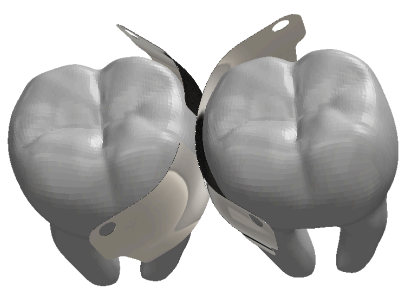


Figure 5: Slot Design with model teeth

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

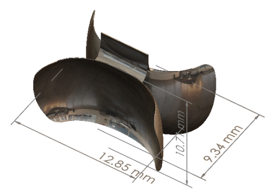
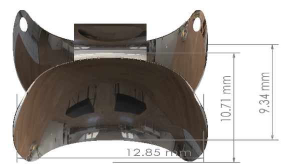
Criteria	Weight	Design 1: Altered Butterfly		Design 2: Hole Design		Design 3: Slot Design	
							
Efficacy	40	**5/5**	40	**5/5**	40	**4/5**	50
Ease of use	20	5/5	20	5/5	20	4/5	20
Efficiency	15	5/5	15	4/5	12	3/5	9
Ease Of Fabrication	15	2/5	6	5/5	15	3/5	1
Cost	5	2/5	2	5/5	5	3/5	4
Safety	5	5/5	5	4/5	4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

Table 1. Design Matrix

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

Stainless steel is the most commonly used material in dental matrix bands because of its corrosion resistance and good formability. Titanium alloys like Ti6Al4V have increased corrosion resistance and are less stiff than common stainless steel alloys, which can allow for easier formability, but the cost to benefit ratio inhibits their popularity for dental sectional matrices. Nitinol (NiTi) is another material to be considered for fabrication. Its phase change induced "shape memory" allows for intriguing design alternatives and innovative products, but difficulty in fabrication and cost prevent it from mainstream use in dental matrix systems. This leaves 316 and 304 stainless steel as the most popular options for dental matrices. First, 316, especially 316L stainless steels, is commonly used in medical devices, especially for surgical implants and surgical equipment. The high molybdenum content permits increased corrosion resistance in aqueous environments with high ionic quantities, especially chloride. Comparably, 304 has negligible molybdenum content, but because of its high chromium content, it still possesses sufficient corrosion resistance to be considered. In addition to providing increased chloride corrosion resistance, the molybdenum substitution distorts the 316 steel lattice, preventing dislocations from propagating, increasing the strength of the metal[18]. This higher yield strength will give the sectional matrix more durability during the procedure. However, because of these lattice distortions, 316 has less ductility than

304 stainless steel, with 304 being around 20% more ductile [19][20]. 316 also has a higher Rockwell hardness in comparison to 304, which increases the durability of the surface finish. Because of its higher strength, 316 is less formable than 304, which is a vital consideration in material selection for this project. Additionally, 304 is more economical than 316, especially considering most of 316 steel's benefits surround its corrosion resistance, which has decreased importance because of the short time in use. Perhaps the most important consideration is the availability of stock. This is critical because reducing the thickness of the material will be an interesting challenge, and the stock will ideally be purchased at the necessary thickness. McMaster-Carr has shim stock in 18-8 (304) stainless steel with a thickness of 0.0254 mm that would be suitable for the design[21]. Unfortunately, the material's temper rating is "full hard" which would be unsuitable for the forming required. Changing material temper at this thickness will be hard without easy access to a heat treat furnace. McMaster-Carr has ½ hard tempered 18-8 steel available at 0.127 mm thickness, which would exceed the allowable thickness dimension. Annealing or changing temper could be attempted to increase the formability of the full hard steel but the thickness may make temperature control challenging without a readily available heat treat oven. For 316 steels, McMaster-Carr has 0.0508 mm thick fully annealed steel [22]. Although this is on the high end of the thickness range, it should be satisfactory for preliminary fabrication and testing purposes. So, because of its corrosion resistance, durability, and availability, 316 stainless steel shim stock will be the material used for the main structure of the design.

Methods

There are two main fabrication techniques that can be used to prototype this design: cutting or punching. Cutting includes waterjet cutting or laser cutting. Punching involves creating dies and using a hydraulic press to punch out the form of the part. For prototyping, waterjet or laser cutting is favorable because it allows for easy changes to CAD files to change the form of the design. Changing the design with a punch would be more involved. Because of this, waterjet or laser cutting will be used. The laser cutter at the Wendt Commons' makerspace is unable to cut metals, so it will not be suitable for iterative prototyping. This leaves the waterjet as the best fabrication technique. For file preparation, the SolidWorks model in Figure 6 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 7. This was exported into a SolidWorks drawing, which was exported into a .dxf file. This template can then be used to cut out the flat form of the surface matrix from the 12x6 in 0.0508 mm 0.002 mm 316 stainless steel shim stock from McMaster-Carr. After cutting, the edges will be rounded using sandpaper or, if necessary, a dremel. If coatings like PTFE are used, they will be added at this time. The flat will then be formed to a curvature mold shown in Figure 6. The mold will be 3D printed using tough resin. The 3D printed part may need to be sanded to create a more satisfactory surface finish. After both sides are formed with the mold, the part will be folded in half at the connecting tab, giving the final confirmation shown in Figure 6. Multiple prototypes should be cut and formed to allow for testing and ensure quality. Additionally, different sizes and shapes should be cut to allow for comparison and optimization, because waterjet availability is limited; these should be cut at the same time from the same sheet.

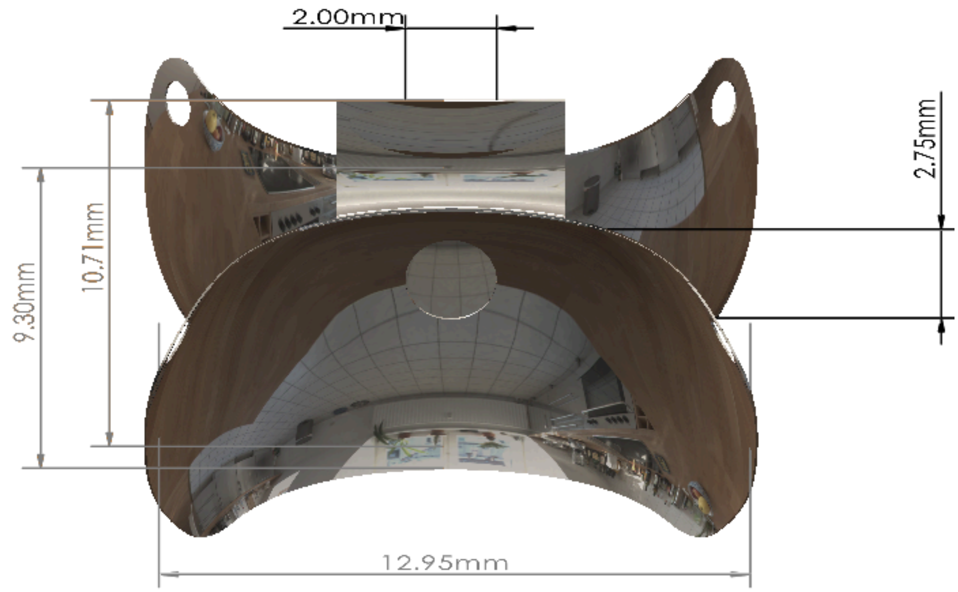


Figure 6: Hole Design SolidWorks model.

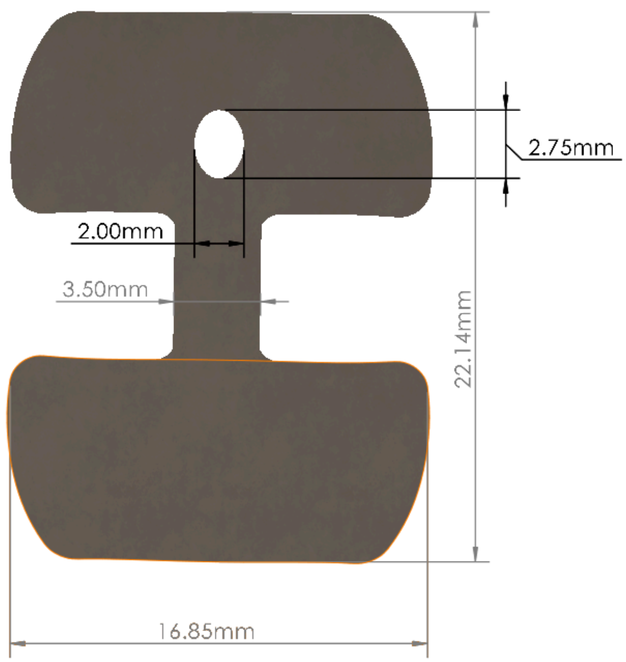


Figure 7: Flattened SolidWorks model to be used for waterjet cutting.

Final Prototype

The final prototype has not been fabricated yet, but it will center around the hole design described in the preliminary design evaluation and shown in Figure 8. Also included below in figure 9 is the designed positioned between two teeth as it would be in a filling procedure.

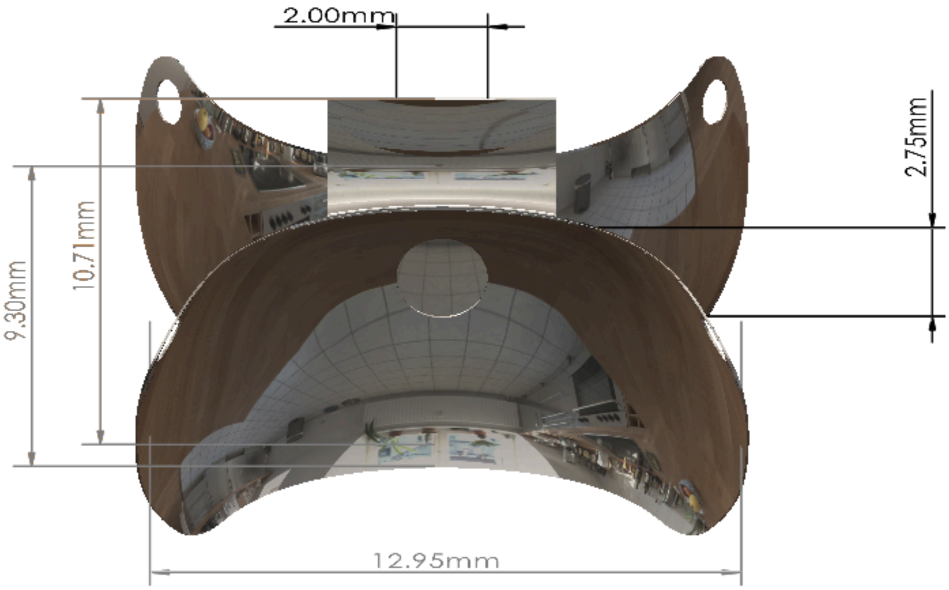


Figure 8: SolidWorks model of hole design

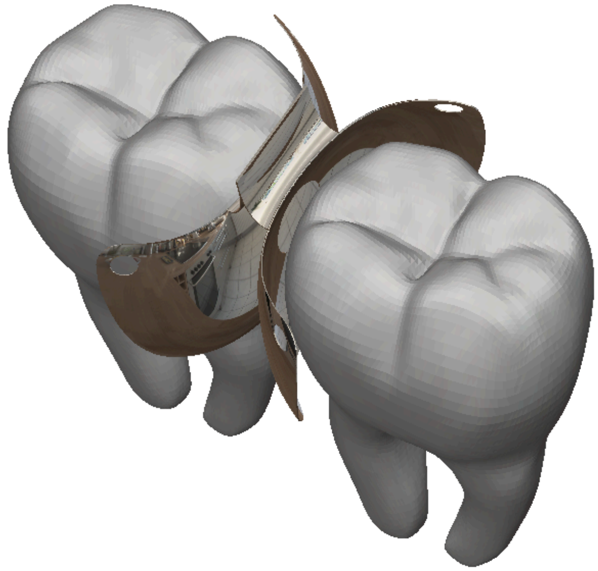


Figure 9: Hole design in the position between teeth

Testing

The testing of the product will involve thickness testing, compatibility testing, mechanical testing, surveying dentists, and filling testing. Thickness testing will be run initially on the stock material purchased to determine its accuracy to reported value from the supplier. It will then be run again on the formed sectional matrix to determine how the forming has changed its thickness. Additionally, the thickness should be tested if a coating is added to the matrix to determine the thickness of the coating. This measurement should be taken from several different points across the matrix surface to ensure uniformity of the coating. The results will provide insights into the success of the application of the coating and if the coating makes the matrix too thick. This will center around areas with double thickness and the hole section. Compatibility testing will then be run using the tension rings, wedges, tweezers, burnishing tools, and mouth model supplied by the client. The matrix will be inserted between teeth, and tension rings and wedges will be placed similarly to current filling procedures. This will determine how compatible the new model is with current wedges and tension rings, and the test will provide insights into modifications that need to be made. Mechanical testing will be done using the MTS Criterion - Model C43 machine. Initially, tension tests should be run on existing surface matrix material to determine what the ideal elastic modulus is for the product. This can be used to better narrow down material purchasing. Tension tests will then be run on a test strip of the purchased material, likely 316 stainless steel shim stock, and current sectional matrices that have been flattened. A stress strain curve will be generate,d and the elastic modulus of both materials will be derived from the data. This will determine the similarities of the material stiffness and how the material will perform as a sectional matrix. Compression testing will be run comparing current sectional matrices with the formed matrix, with compression being applied to the top and bottom of the matrix. Both matrices will have to be altered, removing the tab to allow for uniform compression. From this tes,t the yield strength of the matrix in its formed configuration will be determined. This will determine if the matrix can withstand compressive forces experienced during insertion between teeth compared with existing products. Hardness testing should be run on purchased material and material currently used on sectional matrices. The test will be run using scratch testing. It will not give an exact hardness, but should allow for sufficient comparison. This will provide insight on the durability of the surface of the matrix compared to current matrices. After the previous tests are run and necessary modifications are made, the design can be sent to the client and local dentists to receive more feedback on the design. A survey will be made to focus the results on points of concern. After receiving feedback and further improvements are made to the prototype, filling tests will be conducted. This will involve using 3D printed tooth models with cavities and using the prototype to fill the cavities. This test will ideally be conducted by the client, but due to time constraints and availability, may have to be conducted by the design team. This test will provide insight into the surface finish and removal of the matrix after filling is complete. This test should be timed, and a control using two separate matrices that are currently on the market should be run to allow for comparison.

Results

At this point, testing has not been conducted, so results have not been generated. Thickness testing will generate quantitative results that will be compared to the thicknesses of commercially available sectional matrices. Compatibility testing will generate qualitative results, which should be narrowed down using a matrix to determine how compatible different tools used in filling are with different features of the design. Mechanical testing will provide quantitative data that will need to be processed with MATLAB or RStudio to generate stress strain curves. Hardness testing will provide a comparison of the hardness of the material and will generate quantitative data from the hardness of the materials used to scratch the matrices. The dentists' surveys will provide qualitative feedback on overall design, compatibility, and viability for the market. Currently, most of the data from the filling test will be qualitative from visual observations of the surface finish, but this could be further analyzed using 3D scanning to get quantitative data. The force required to remove the matrix can be measured using a force gauge, however, this might not be an accurate representation of the difficulty of removing the matrix, because, generally, in removal, there are additional forces used to wiggle the matrix out of position, which would not be read accurately by the force gauge. The test will provide quantitative data on the time ofthe procedure compared to current matrices.

Discussion

Although testing has not yet been conducted, the cost of the device is expected to be higher than that of two traditional sectional matrices. The increase in fabrication costs would likely affect the price of the procedure for the patient. Until a prototype is constructed, it remains unknown how much more the design will cost compared to the traditional method. However, the potential time savings of using the sectional matrix could offset the material costs. This will need to be evaluated at the termination of the project to ensure that the device remains affordable and accessible to the average person.

Conclusions

The need for a simpler and quicker alternative for sectional matrices used for interproximal fillings has led to the design of a new dental matrix specific for this use case. This final design leverages design and manufacturing processes that ensure minimal interproximal thickness, which has been an issue in past semesters. Once constructed, testing will be performed to ensure similar mechanical properties to current dental matrices and that the thickness falls within the set tolerance. Testing will also reveal ease of use and dentists' opinions on the devices. These few factors will be the major deciding components on the success of the device.

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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 Environmen**t:

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℃ (98.6℉); the device must be able to maintain its mechanical properties within a range of 20℃ (room temperature) to 37℃ 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 polytetraflouroethylene (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 our 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 Triodent 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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