Approximating Surface Matrix Band for Dentist to Use for Patients

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Abstract

Fifty-three million people live with untreated tooth decay, labelling cavities as a silent epidemic. This issue disproportionately affects disadvantaged communities, and unfortunately, cavities become more difficult to repair the longer they are left untreated [1]. Untreated tooth decay can lead to severe tooth pain and discomfort, and in some cases, tooth loss. Dental fillings remain the most common method of combating tooth decay, thus, it is essential that filling procedures are optimized. Current matrix bands, such as sectional and circumferential bands, fail to allow concurrent restoration of adjacent interproximal cavities. The team is tasked with designing a matrix band that can support the simultaneous filling of two adjacent teeth with interproximal cavities while maintaining proper tooth contact. A design has been proposed that utilizes two matrix bands attached at the interproximal region, each having half the thickness of a regular matrix band, to support the proper and flossable tooth contact. This design incorporates a metal piece coming out from the band that would aid in the placement and removal of the device while exerting inward force to maintain a tight contact with the tooth surface. The viability of the device will be determined by functionality tests that determine whether the design allows for the proper tooth contact that current matrix bands create. This functionality testing will reveal further accommodations the team will need to make to confirm the device is able to support two adjacent interproximal cavities undergoing repair, while maintaining a flossable tooth contact and reducing procedure time.

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I. Introduction

A. Motivation

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

B. Current Devices

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

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

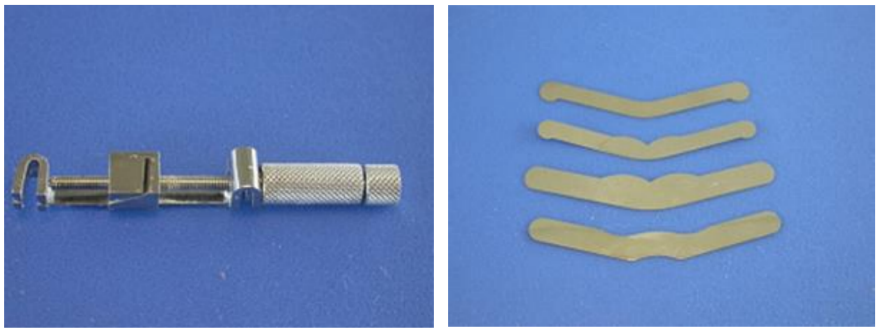

Figure 1: Tofflemire™ Matrix Band system. Circumferential matrix band system consisting of the proprietary retainer (left), bands (right), and any dental wedges (not pictured) [5]. Primary 4 matrix band sizes are shown on the right.

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

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

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

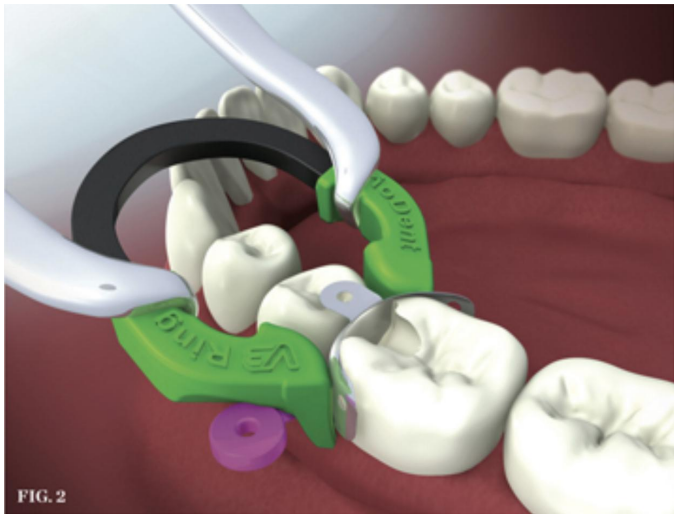

Figure 3: Triodent V3 Ring and Triodent Wave-Wedge. Sectional matrix band system consisting of Triodent V3 ring (green), Triodent Wave-Wedge (purple), and sectional matrix band (silver) [13].

C. Problem Statement

Matrix bands are a commonly used dental tool which assist dentists by creating an outside contour of a decayed tooth. This contour maintains the tooth's structure and shape during restorative procedures, such as cavity fillings. During typical filling procedures for cavities on interproximal surfaces, dentists must fill each tooth separately. This tedious procedure is due to matrix bands not fitting adjacent to one another in the interproximal space, as the thickness of two bands exceeds the tooth contact diameter between the teeth. The resulting process of placing matrix bands for both teeth is cumbersome and time inefficient. A new dental matrix band design is desired to alleviate the need to repeatedly place bands. The device should employ a dual-band system with a thickness less than or equivalent to current matrix bands, 0.05 mm, throughout such that the fit is secure and the band molds to the appropriate convex/concave contour of each tooth. The finalized product should also maintain the tensile strength, about 400 MPa, malleability, and space efficiency of current matrix bands. The material used to fabricate the matrix band must not cause any irritation, must be biocompatible, and must be non-reactive to filling materials.

II. Background

A. Design Research

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

The average crown height of maxillary (upper) and mandibular (lower) teeth together is 8.69 mm, with a range of measurements from 7.2 mm to 11.2 mm. The mesiodistal crown width, which measures the diameter of the tooth in the direction from its more anterior adjacent tooth to its more posterior

adjacent tooth, averages 8.20 mm, with values ranging from 5.3 mm to 11.4 mm. The faciolingual crown width, which measures the diameter of the tooth in the direction from cheek side to tongue side, averages 8.71 mm, with values ranging from 5.7 mm to 11.5 mm [15]. Based on these values, approximations for tooth perimeter average 33.82 mm, ranging from 22.0 mm to 45.8 mm.

The thickness of dental matrix bands typically ranges from 0.0015 to 0.002 inches, or 0.038 to 0.051 millimeters [16]. The band width must fall into these precise ranges in order for the device to securely fit between adjacent teeth without exceeding the width of the interproximal space. Correctly placed and effective matrix bands are rigid against the existing tooth structure and maximize matrix-tooth contact, properly contouring to the shape of the tooth [17]. They must restore appropriate contact with the adjacent tooth and be easily removable once the restorative material is set [8]. Upon insertion, dental matrices often require the use of retainers, rings, clips, or wedges to hold the band in place and widen the interproximal space. These tools, however, make the patient's mouth crowded and therefore make the restorative procedure more difficult for the dentist.

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

B. Client Information

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

C. Design Specifications

The matrix band should be able to maintain its structure and function from the time it is placed in the mouth until the filling procedure is over, up to 1 hour [18]. The device will be single-use, but should still be sterilizable before it is used in procedure. The band should still be malleable and able to shape around any tooth, incorporating wedges and/or ring clamps that effectively separate the approximating teeth being filled. Also, the new device should be easier and much less time consuming to install, adjust, and use than existing products on the market, like the sectional and circumferential matrix bands.

In terms of dimensions, the device thickness should be accurate to a hundredth of a millimeter during manufacture to ensure it remains below 0.05mm, an acceptable interproximal space [16]. Current matrix bands commonly come in three different thicknesses: 0.001 gauge (0.0254 mm), 0.0015 gauge (0.0381 mm), and 0.002 gauge (0.0508 mm), the maximum acceptable interproximal space to maintain tooth contact [19]. The device should be adjustable and/or scalable to accommodate all sizes of teeth while still maintaining the proper thickness.

The matrix band is expected to be made out of a dead soft metal, meaning it is rigid in its resting state while still being malleable [20]. This would include materials such as stainless steel and aluminum. If possible, the material should be able to be sanitized, allowing for a more sustainable product that is also more cost effective. For the purposes of this project, the wedge will likely be made of some sort of plastic due to the ease of fabrication. The band and the wedge should not be colored the same as a tooth to avoid confusion while operating. The aesthetics were not a priority with the client and depend more on functionality. There must be safety considerations when considering designing the prototype. The material

used to fabricate the matrix band should not cause any irritation to patients (i.e. Nickel) and must be biocompatible. The device also must come with the proper safety labels and warnings to inform users how to properly handle the device. The device should match the shelf life of current matrix bands (so indefinitely), while kept in the proper packaging and must be stored at or near room temperature. Along with storage while not in use, the human mouth is a variable environment with both physical, chemical and biological factors to consider. The device must maintain its integrity when forced in between teeth which have a Mohs hardness rating of 5 [21]. It must also be blunt enough to prevent injury of the, potentially compromised, tooth and surrounding gums. Operating temperature ranges from room temperature (~20℃) to body temperature (~37℃). The mouth has a pH with a range of 6.2-7.6. There are also a variety of enzymes in the saliva that the device must withstand [22].

In terms of production, the product is expected to be non-reusable. That means if it is made market available, the product would need to be mass produced to meet the demand of dentists for every adjacent tooth filling procedure. If the final design were able to be sterilized, then the demand for the product would go down to one per dentist. For the purposes of the product, there will likely be a couple models produced. The goal when planning out the designs is to keep the products as cost effective as possible without sacrificing quality. Current matrix bands go for about 50 cents to a dollar [23]. Given the possible complexity of our design, it might be more expensive to fabricate but keeping the price under $3-5 should be prioritized. The budget for the project is expected to be around $200-300 given the testing needed to be done.

FDA approval is necessary for medical devices. Current matrix bands are Class 1 devices as specified in the Codes of Regulations Title 21, Chapter 1, Subchapter H, Part 872 Subpart E. They are identified as low risk devices that present minimal potential for harm. If the new design utilizes the same materials used before 1976 , it would be exempt from premarket notification procedures specified in Subpart E. Otherwise, a premarket notification submission would need to be completed to the Food and Drug Administration at least 90 days prior to the proposed introduction of the product [24]. An Investigational Device Exemption (IDE) would need to be obtained to pursue clinical studies with the device to collect data on safety and effectiveness in support of the Premarket Approval (PMA) application or Premarket Notification 510(k) submission. These studies must be approved by the Institutional Review Board (IRB) before the studies begin [24]. For the full Product Design Specifications, refer to Appendix A.

III. Preliminary Designs

A. Design 1 - Handcuff Design

Figure 4: Handcuff Design Side View. Length, measured left to right, should be in the range of 44 mm to 91.6 mm. Height, measured top to bottom excluding “spikes”, should be in the range of 7.2 mm to 11.2 mm. Slot fittings, in

blue, are gaps in the matrix band, used to secure the device after installation. Spikes, small points medial to the slots, are used to help keep the device in place and prevent cavity material from seeping into the gums.

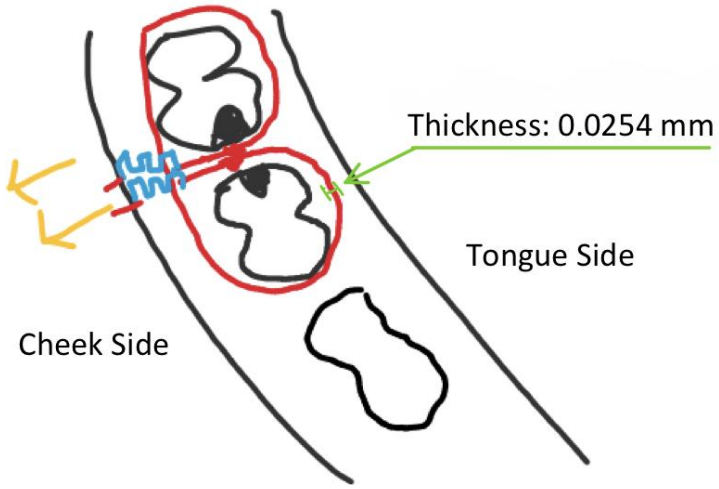

Figure 5: Handcuff Design Top View. The handcuff band is wrapped around two teeth with cavities (dark holes in the teeth). The band is held in place by placing the center of the band through any of the blue slots. Thickness of the band would be 0.0254 mm.

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

B. Design 2 - Butterfly Design

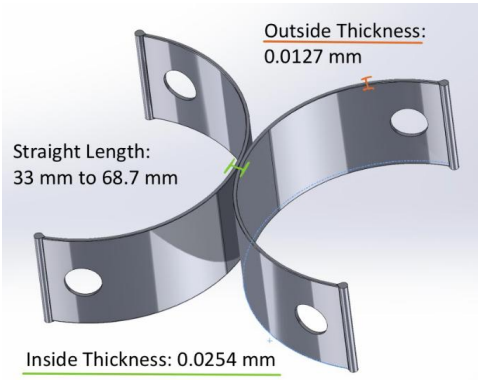

Figure 6: Butterfly Design Solidworks 3D Model. This design consists of two sectional matrix bands conjoined together in the middle to produce a band that slightly resembles a butterfly. Holes in the band will help to aid the removal of the device. Outside thickness of 0.0127 mm, inside thickness of 0.0254 mm, and straight length (when the curve of the band is bent straight) of 33 mm to 68.7 mm.

Figure 7: Butterfly Design installed. This hand drawn image shows how the butterfly band (dark blue) would sit between teeth (light blue) and be held in place by two wedges (orange).

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

C. Design 3 - Butterfly + U Pinchers Design

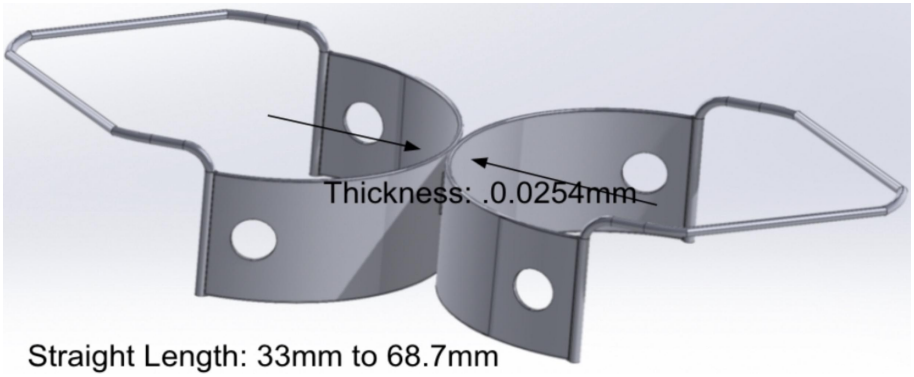

Figure 8: Butterfly + U Pinchers Design Solidworks 3D Model. Similar to the butterfly design, the device consists of two sectional matrix bands with the addition of U Pinchers. Holes added to aid in the removal of the device. Not shown in figure: spring clamp.

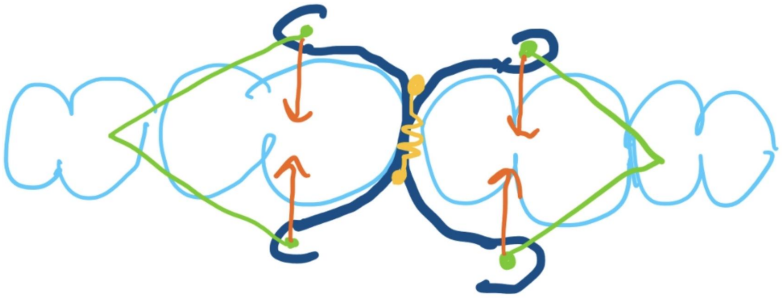

Figure 9: Butterfly + U Pinchers Design installed. This hand drawn image shows how the butterfly band (dark blue) will sit between the teeth (light blue). A spring clamp (yellow) is added to the center of the band to help keep the band in place. U pinchers (green) will produce an inward force (orange arrows) on the butterfly band to help the band sit flush against the teeth.

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

IV. Preliminary Design Evaluation

A. Design Matrix

Table 1: Preliminary Design Matrix

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

**The six design criteria on the far-most left column were evaluated for each preliminary design. The designs were given a number score out of 5 for each category and ratings were totalled to determine which design was best (described under justification of criteria section below). Shaded sections indicate the highest ranking design for each criteria. The lighter shading indicates ties between designs.

*The functionality criteria was based on the design's ability to allow the dentist to complete the procedure with both quality and time efficiency.

B. Justification of Criteria

Functionality: The functionality criteria was based on the design's ability to allow the dentist to complete the procedure with both quality and time efficiency. The Butterfly Design received the lowest score in this category (2/5) due to its lack of adjustability and tightness. The band needs to securely fit around the tooth in order for a quality tooth contact, however, with the Butterfly Design, some variation in tooth sizes amongst different patients would result in different results. For example, the greater thickness in the middle of the band may need to be longer for some patients than others. The Butterfly + U Pinchers Design received the highest score in this category (5/5). This design has pinchers which maintain a close fit between the teeth and matrix across the entire section. This inward force allows the design to be used

across varying shapes and sizes of teeth. The spring clamp also improves the design by widening the gap between the teeth if needed. The Handcuff Design received a score of 3/5 because it may have factors that contribute to increased procedural time. It is a circumferential design, rather than a sectional one, that would require steady placement of the band in its slot fillings. This may be both a frustrating and time consuming task.

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

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

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

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

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

C. Proposed Final Design

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

V. Fabrication Plan

A. Materials

The current industry standard for matrix bands is a dead-soft steel primarily due to its mechanical properties and non-toxicity [5]. "Dead-soft" steel refers to a lower carbon and manganese content at less than 0.1% and 0.2-0.5%, respectively [25]. Additionally, it is processed by heating to a critical temperature and cooled more slowly, creating larger grains, making the material less hard, but more ductile. The tensile strength is 260-340 MPa, which must be relatively high to withstand tightening around the tooth [26]. The Rockwell B hardness is about 55, which is important for preventing deformations from forming when pressed up against the teeth but is limited due to the method of processing which allows for a lower elastic modulus. The elastic modulus is 200-215 GPa , sufficient for both allowing the thin material to bend around the tooth while maintaining tight contact with the tooth even when withstanding high outward stresses from packing the filling material [26].

In the past, materials such as copper, silver and titanium have been used to fabricate matrix bands but the mechanical characteristics, biocompatibility, and cost of dead-soft steel have made them obsolete [5].

B. Methods

Once the CAD model of the proposed final design is fully refined with proper dimensions and materials, it can be sent to a professional 3rd party manufacturer of precision metal parts. More research will be done to find a manufacturer capable of fabricating parts on the scale of hundredths of a millimeter, which is the precision required for the desired thickness of our design. From early brainstorming sessions, it is postulated that this could be done via laser cutting the desired shape from a block of dead-soft steel. With this first prototype, a mold can be cast and further manufacturing can be done with this mold.

C. Testing

Both qualitative and quantitative testing will be done on the first prototype to ensure compliance with product design specifications and FDA regulations. Primary qualitative testing will be done with the team to confirm that the matrix band fits in the interproximal space of the mouth model, found in the expenses table of Appendix B. The matrix band will also be tested to ensure it properly conforms with the teeth and is compatible with the spring clamp. Secondary qualitative testing will be done with the client, Dr. Donald Tipple, along with his colleagues to determine if the new design is more easily and quickly installed and removed, without impeding on the efficacy or speed of the tooth restoration. Quantitative

testing will be done both virtually in SolidWorks on our CAD model with proper dimensions and materials, and physically with the first prototype in an MTS machine. These tests must show equivalent or superior tensile and ductile properties to the Tofflemire bands that our client currently uses.

VI. Conclusion

Dental care is very important for overall well being. One-third of adults have untreated dental caries; if left untreated, these can lead to infection and permanent tooth loss. 175 million people receive at least one dental filling every year [27]. Providing dentists with the proper tools and resources to perform these fillings with both quality and time efficiency is essential in helping the millions of people with untreated cavities. The current process to fill cavities varies depending on the classification and severity of the cavity. Matrix bands are a tool used by dentists to assist in providing the proper contour of the tooth during filling. They are often used along with tooth wedges which serve to tighten the seal and prevent gingival overhang. Class II cavities are those on the interproximal surface of premolars and molars. They are known to be difficult to restore due to the necessity of maintaining a proper and tight tooth contact [28]. Current matrix bands, such as sectional and Tofflemire matrix bands have shortcomings when it comes to restoring Class II cavities because they cannot be used concurrently to fill two adjacent teeth. The dentist must perform one filling, then reposition the matrix band and wedge in order to perform the second filling. This is not only very tedious, but also very time consuming and minimizes the amount of time dentists have to care for other patients.

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

There are various considerations that must be made prior to fabrication of this design. The team must perform some sort of assessment to determine whether the pinchers would block the view of the dentist. This can be done by quantitative assessments of the shape of the device with a prototype that can be used on a tooth model. Additionally, the team has discussed including a tab with a hole for further ease of placement and removal via tweezers. Current sectional matrix bands have a tab with a hole on the occlusal edge and wing ends for this exact purpose. Incorporating a tab may further increase the ease of use of this design.

The team plans on proceeding with this design using dead-soft steel. Once the team has finalized the CAD model of our proposed final design with necessary modifications, the team will send it out to a third party manufacturer. Qualitative and quantitative testing would then be done to ensure it meets the product design specifications. Qualitative testing would include the team utilizing the matrix band in a model mouth followed by Dr. Donald Tipple's evaluation. Quantitative testing will be done in SolidWorks and then physically done in an MTS machine. Successful testing results will reveal equivalent mechanical properties and ease of use compared to current matrix bands, while allowing for decreased procedural time due to the concurrent fillings it will allow.

VII. References

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[28] Admin, “Survey results show what is key: Class II fillings - routine but still challenging,” Press & Media, 07-Aug-2017. [Online]. Available: https://news.dentsplysirona.com/en/business-units/restorative/2017/class-ii-fillings--routine-but-still-challenging.html. [Accessed: 19-Oct-2021].

VIII. Appendix

A. Appendix A - Product Design Specifications

Approximating Surface Matrix Band

Product Design Specifications

October 20th, 2021

Client: Dr. Donald Tipple

Advisor: Dr. Tracy Puccinelli (Section 309)

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Function:

Matrix bands are a commonly used dental tool which assist dentists by creating an outside contour of a decayed tooth. This contour maintains the tooth's structure and shape during restorative procedures, such as cavity fillings. During typical filling procedures for cavities on interproximal surfaces, dentists must fill each tooth separately. This tedious procedure is due to matrix bands not fitting adjacent to one another in the interproximal space, as the thickness of two bands exceeds the tooth contact diameter between the teeth. The resulting process of placing matrix bands for both teeth is cumbersome and time inefficient. A new dental matrix band design is desired to alleviate the need to repeatedly place bands. The device should employ a dual-band system with a thickness less than or equivalent to current matrix bands, 0.05 mm, throughout such that the fit is secure and the band molds to the appropriate convex/concave contour of each tooth. The finalized product should also maintain the tensile strength, about 400 MPa, malleability, and space efficiency of current matrix bands. The material used to fabricate the matrix band must not cause any irritation, must be biocompatible, and must be non-reactive to filling materials.

Client Requirements:

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

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

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:*
        i. The matrix band should be able to maintain its structure and function from the time it is placed in the mouth until the filling procedure is over, up to 1 hour [1].
            1. The device will most likely be single-use, but if sterilizable, it should be capable of performing up to 50 procedures.
        ii. The device should maintain similar mechanical characteristics of existing matrix bands, withstanding loads placed on it during filling.
            1. It should still be malleable and able to shape around any tooth.
                a. Tensile strength of dead-soft steel is 260-340 MPa and the elastic modulus is 200-215 GPa [2].
        iii. The device should incorporate wedges or another component that effectively separates the approximating teeth being filled.

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

    c. *Accuracy and Reliability:*
        i. The device thickness should be accurate to a hundredth of a millimeter during manufacture to ensure it remains below 0.05mm, an acceptable interproximal space [3].

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

d. Life in Service:

i. The device must maintain the target properties for the duration of the procedure in which it is used. For a cavity filling, this is generally within an hour [1]. Currently, most matrix bands are single-use to ensure sterile conditions.

e. Shelf Life:

i. Most current matrix bands are made of stainless steel or natural plastics which have an indefinite shelf life for practical purposes. Our device should match this shelf life while kept in the proper packaging.

ii. This device should be kept at or near room temperature.

f. Operating Environment:

i. The human mouth is a variable environment with both physical, chemical and biological factors to consider.

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

g. Ergonomics:

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

h. Size:

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

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

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

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

i. Weight:

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

j. Materials:

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

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

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

k. Aesthetics, Appearance, and Finish:

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

2. Production Characteristics

a. Quantity:

i. The product is expected to be non-reusable. That means if it is made market available, the product would need to be mass produced to meet the

demand of dentists for every adjacent tooth filling procedure. If the final design were able to be sterilized, then the demand for the product would go down to one per dentist. For the purposes of the product, there will likely be 1-3 prototypes produced.

b. Target Product Cost:

i. The goal when planning out the designs is to keep the products as cost effective as possible without sacrificing quality. Current matrix bands go for about 50 cents to a dollar [10]. Given the possible complexity of our design, it might be more expensive to fabricate but keeping the price under $3-5 should be prioritized.

ii. The budget for the project is expected to be around $200-300 given the testing needed to be done.

3. Miscellaneous

a. Standards and Specifications:

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

b. Customer:

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

c. Patient Related Concerns:

i. The device will be in direct contact with the patient's oral cavity, so the materials must be non-toxic and non-allergenic. Common metal allergies include: nickel, cobalt, copper and chromium [13]. This design should also be one-time use, similar to the current matrix band used. Thus, sterilization would not be a concern. Ideally, the device would not add any additional discomfort during the filling process.

d. Competition:

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

References

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Appendix B - Expenses Table

Item	Supplier / Brand	UPC	Link	Quantity	Date	Price
Dental Implant Teeth Model Study Teach Standard Model with Removable Teeth	Amazon / Smile1000	601263927587	https://www.amazon.com/dp/B071JVJ1LG/ref=cm_sw_r_sms_api_glt_fabc_BZN7G1DC333NTE4CCJVE	1	10/20/21	$28.42
					Total	$28.42