APPROXIMATING SURFACE MATRIX BAND FOR DENTIST TO USE FOR PATIENTS

PRELIMINARY REPORT

BME 400

October 7, 2020

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Abstract

Dental Cavities have been labeled as a silent “epidemic” as they are among the most prevalent and chronic diseases in children and adults in the US [1]. Approximately 175 million people receive at least one dental filling every year [2] and about 27% of adults (20 - 64 years of age) fail to receive any proper treatment for their tooth decay [3]. The implications of untreated decay could lead to severe pain, tooth abscess, or even tooth loss [4]. As dental fillings are the most commonly performed procedure to restore moderate cavities, it is critical that the procedure is optimized to save dentists and patients time and simultaneously preserve accuracy. Current matrix bands, such as the Sectional and Toffelmeier bands, are effective in maintaining a tight and flossable tooth contact and providing a sturdy tooth contour, however, they fail to accommodate the concurrent restoration of two adjacent interproximal cavities. Our goal is to create a dual-matrix band system which can provide a sturdy contour for two adjacent teeth undergoing restoration and maintain a tight and flossable contact between them. Our solution will incorporate the general appearance and material basis of the Tofflemire matrix band, however, we will redesign it to accommodate two teeth at a time and account for proper contact between the teeth. The viability of the device will be determined proceeding a series of functionality tests conducted on model teeth. The results of the functionality assessments will either determine any further adjustments to be made to the matrix band or confirm the device’s ability to give support to adjacent teeth undergoing repair, maintain a tight and flossable tooth contact, and reduce the procedure time.

Table of Contents

Abstract **1**

Table of Contents: **2**

Introduction **3**

Existing Devices 4

Problem Statement 5

Background **6**

Design Specifications 6

Relevant Oral Physiology and Biology 6

Preliminary Designs **8**

Design 1: The Butterfly 8

Design 2: The DoubleHug (Doug) 9

Design 3: The Potato Wedge 10

Preliminary Design Evaluation **11**

Design Matrix 11

Safety 11

Effectiveness 11

Cost 12

Adjustability 12

Patient Comfort 12

Ergonomics 12

Proposed Final Design: Doug **13**

Fabrication/Development Process **13**

Materials 13

Methods 13

Testing 14

References **14**

Appendix **16**

I. Introduction

Through the course of the next two semesters, we intend to create a dual-band matrix tool which may alleviate the tedium of installing individual matrix bands on adjacent teeth undergoing restoration. This device will be used by our client, Dr. Donald Tipple, to optimize the amount of time it takes to complete a restorative procedure and reduce patient discomfort.

Tooth decay is a very common and painful experience approximately 91% of adults 20 - 64 years of age suffered from in 2011-2012[5]. In addition, dental caries, also known as cavities, are the most prevalent disease that affects both children and adults[6]. The rise in dental caries has been labeled as a “pandemic” of sorts to highlight the prevalence, severity, and sometimes life-threatening, impact of tooth decay [7].

There are a plethora of methods to repair dental carries--which also depend on the severity of the cavity--however, the most common method is dental restoration (or dental fillings) [8]. As dental fillings serve as one of the primary means to repairing tooth decay, it is a procedure dentists dedicate several hours a year to perform. Therefore, it is critical that dentists can efficiently and effectively perform restorative procedures in order to tend to as many patients possible. The process of filling a cavity varies in duration and complexity depending on the severity and classification of the cavity, and class II cavities--cavities on the interproximal surfaces of the premolars and molars [9]-- prove to be very challenging to restore because of the need to maintain a tight contact and maintain the tooth contour[10]. Matrix bands are meant to assist dentists by providing a contrours to follow when filling the decayed tooth, and when used with tooth wedges (designed to increase the tooth contact gap), they are fairly accurate in recreating a tight contact, however, matrix bands fail when dentists must perform dental filling procedures on two adjacent class II cavities. Because matrix bands have a thickness which exceeds the contact gap between the teeth and the tooth wedge is not capable of increasing the tooth contact gap beyond the thickness of a single matrix band, dentists have no option but to extend the total procedural time and perform restoration on one tooth at a time.

Existing Devices

Our client is well versed with the Tofflemire matrix band, which is a popular matrix band used by dentists. The Toffelmier matrix band comes in a variety of thicknesses (ranging from 0.0015 - 0.002 in [11] which allows space for adjustment from patient to patient, it is very simple for dentists to use in junction with a retainer (used to tighten and maintain the desired band shape) and tooth wedges or rings(used to increase the contact gap between teeth), and it is very inexpensive (approximately $10.00 for 100 bands [12]). The Toeffelmier band is also very effective in maintaining tight tooth contact and providing adequate structural support when forming the filling materials, however, it is not possible to place two bands adjacent to each other when restoring two interproximal cavities. Our client has found this caveat to make some filling procedures unnecessarily tedious and repetitive.

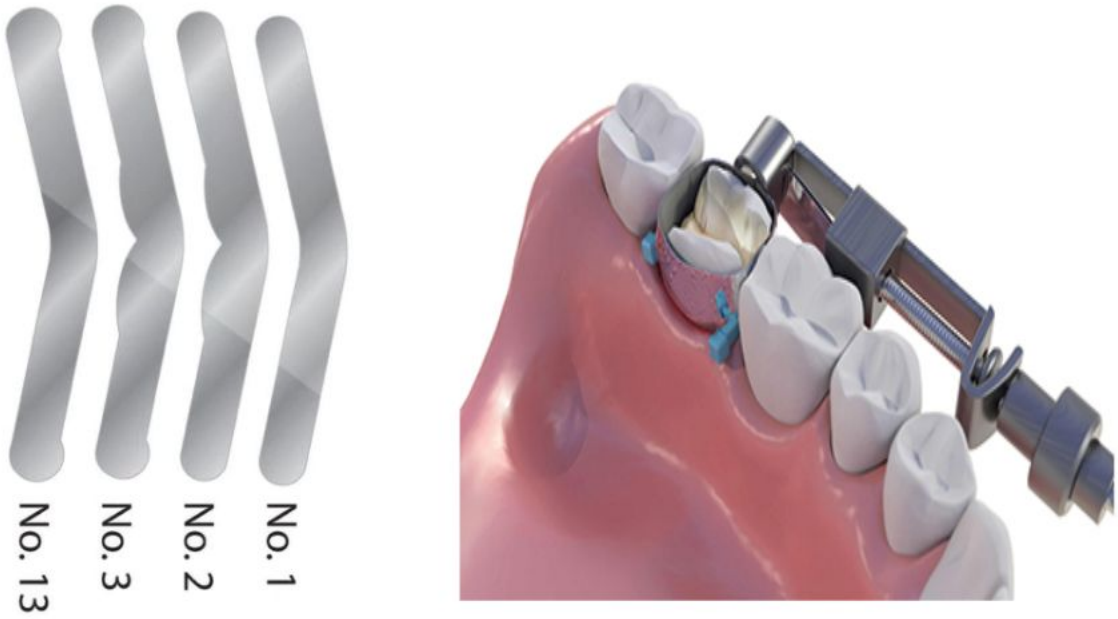


Image 1: Image of a universal Tofflemire matrix bands unformed (left) and formed around the tooth in the standard set up. The tooth wedge (used to increase the contact gap) and retainer (used to maintain the band shape) are also depicted in the right image. [13][14]

The Sectional matrix band is another widely used alternative. The Sectional matrix functions to give form to the restoration material and provide a tight contact, as the Toffelmier, however instead of encircling the entire

tooth, the Sectional matrix only supports the section of the tooth that is undergoing repair. It is more space efficient than the toffelmier as it does not require a retainer to maintain its form around the tooth (the Sectional matrix requires a more compact tooth ring to keep it sturdy instead). Similar to the Toffelmeier matrix band, the Sectional matrix band varies in sizes to better accommodate the patients tooth morphology, it is also exceptional in maintaining tight tooth contact, although it is more expensive in contrast to the Toffelmeier band (approximately upwards of $60.00 for 100 pieces[15]).

Image 2: Image of Sectional Matrix Band unformed (left) and in the typical procedural set up (right). The tooth ring (used to keep the band formed around the affected area and increase the tooth contact gap) is also depicted in the right image. [15][16]

Problem Statement

Matrix bands are a commonly used dental tool which assist dentists by providing a wall to maintain a tooth's structure and shape during restorative procedures, such as cavity fillings[17].During typical filling procedures--particularly filling cavities on interproximal surfaces--dentists must fill one tooth at a time since matrix bands cannot be placed adjacent to one another, as the thickness of two bands exceeds the aperture diameter between the teeth. The resulting process of placing matrix bands for both teeth is cumbersome and time inefficient. The proposed design should alleviate the need to repeatedly place bands by employing a dual band system which is thin enough to securely and comfortably fit in between the affected teeth and able to simultaneously fit the appropriate convex/concave contour of each tooth. The finalized product should also maintain the tensile strength, malleability, and space efficiency of current matrix bands.

II. Background

Design Specifications

Our Client, Dr. Donald Tipple, is a dentist at Nakoma Dental. He has requested that we create a dual matrix-band which can provide a contour and support for the filling materials for adjacent teeth undergoing restoration. The client's primary request was that the device be constructed from non-toxic materials, and the device mechanism should encourage a tight but flossable contact between the affected teeth. In addition, the device should be equally or less costly to manufacture than current matrix bands, and the device should not be obstructive or clash with other tools to be used (rotary instruments, mirrors, forceps, suction etc.). Lastly, the band material should be thin and have high tensile strength.

Relevant Oral Physiology and Biology

In order to re-create a matrix band which allows dentists to work on two teeth at a time, it was necessary to gain a better understanding of tooth anatomy, nature of tooth decay and the process of restoring a compromised tooth. Teeth are composed of four dental tissues--enamel, dentin, cementum (hard tissues), and pulp (soft tissue)[18]. The development of a cavity occurs when the bacteria residing on the surface of the tooth (plaque) produces an acidic byproduct which weakens and softens the enamel layer (the hard exterior of the tooth) over time [18]. Once the bacteria penetrates the enamel layer, the softer layers underneath are susceptible to rapid degeneration as decay advances. At the stage of enamel penetration, dental fillings are typically the appropriate treatment method [19], however, more severe cavities may warrant root canals, crowns, or even removal [8].

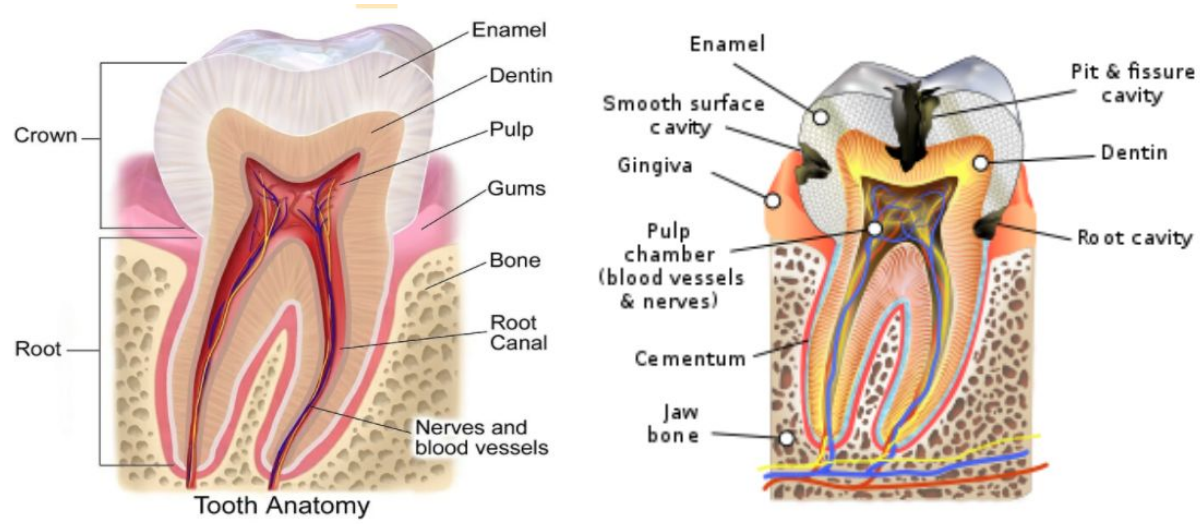


Figure 3: Labeled anatomical structure of a standard normal (left) and decayed tooth (right) [20][21]

Furthermore, cavities are classified by their location on the tooth. For instance, a class II cavity is one that is located on the interproximal surface of the premolar and molar interface [22]. This is a very common location for cavities to develop, due to the difficulty to properly clean in between the teeth, and it is also difficult to restore, as maintaining the appropriate tooth contact tightness may be challenging. The location and severity of a cavity dictate the method of treatment, however, moderate class II cavities typically require a dental filling to repair. Dental restorations are comprised of several steps: first, the decayed portion of the tooth is drilled away; second, the matrix band is fitted to form the tooth contour; third, either amalgam (metal alloy filling) or composite resin (tooth colored filling) is placed in the newly drilled hole and either formed and packed into place or formed and harded via photo-polymerization (respectively); lastly, the filling is polished and assessed to fit securely and properly[23].

Figure 4: Process of restoring a decayed tooth with composite resin material

III. Preliminary Designs

Design 1: The Butterfly

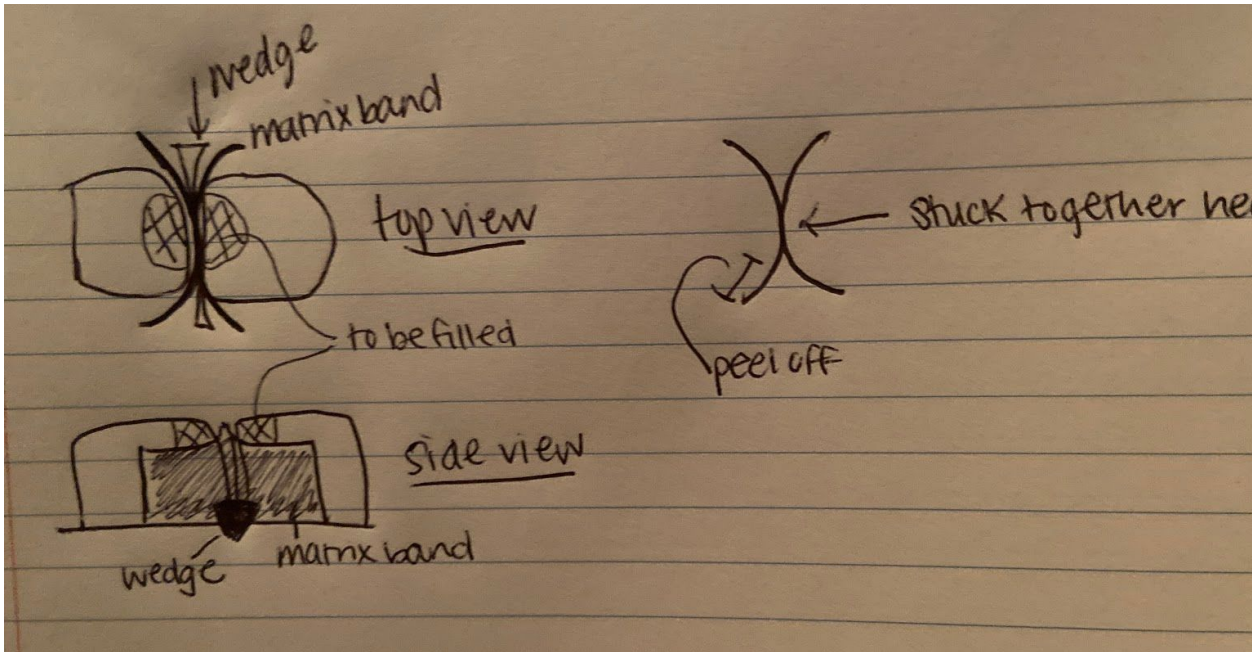


Figure 5: Sketch of the "butterfly" design. The crosshatched area is where the filling would need to be placed.

The butterfly consists of one matrix band that has two sections on either side of it that peel apart. These two sections can be contoured around the adjacent teeth on both sides making it possible to do two fillings at once. The peel feature also allows you to adjust the band size in order to accurately fit the patient's teeth. The part of the band that stays between the teeth would be permanently stuck together to give more stability. This part would also only be the thickness of one band to give a better contact between the teeth after filling. There would also be a wedge inserted between the teeth to give more separation during the procedure, which allows for the spring back to happen once the wedge is removed, which also promotes close contact between the teeth. The two ends would be two bands thick, but once peeled apart they would be the thickness of bands used today, which would allow for increased stability around the adjacent teeth. With this design you could either use a retainer or a Palodent ring to hold the band in place.

Design 2: The DoubleHug (Doug)

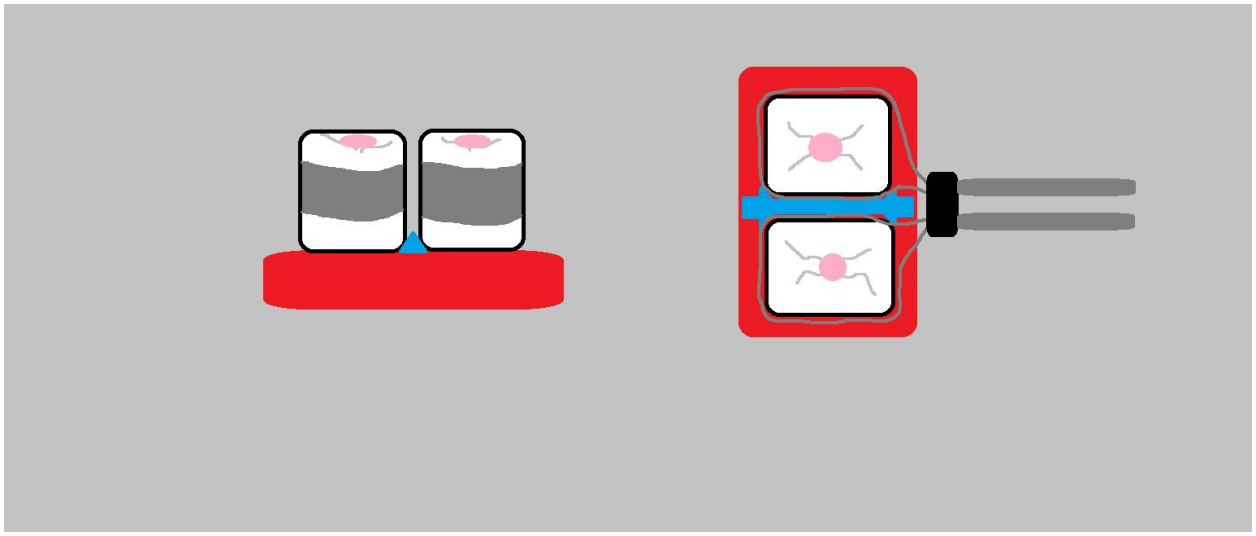


Figure 6: Model of the Doug design showing a top and side view. The blue portion is the wedge, the bands are in silver, and the teeth are white.

The Doug consists of a similar mechanism to the current model, but rather than one tightening system on one band, its two separate tightening mechanisms on two independent bands within the same device. This device is promising as it is simply making the current model function as two, without the ergonomic complications of two separate devices. The sole issue at hand with this model is that the width of two matrix bands during the filling process makes the junction between the teeth too weak once the fillings are complete, so we are researching methods, including material adjustments, to thin out the bands and allow for a tighter fit post-filling.

Design 3: The Potato Wedge

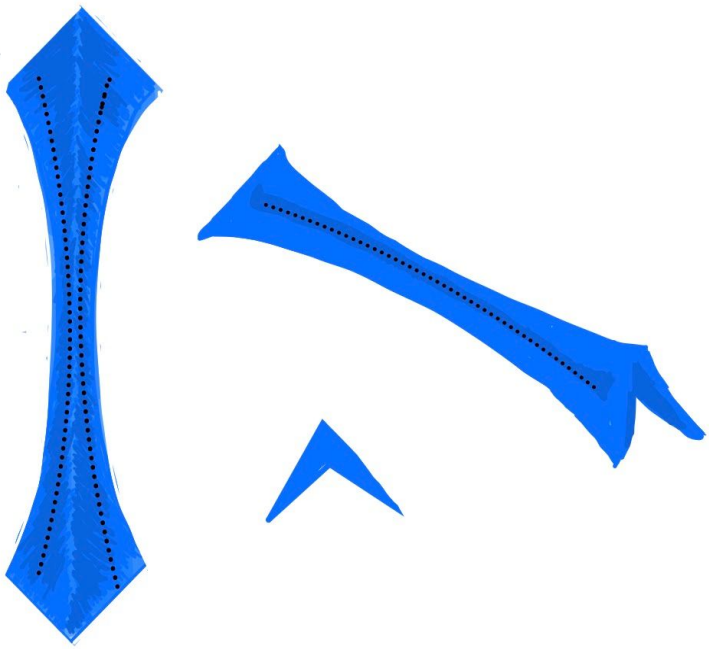


Figure 7: Sketch of the potato wedge design showing all views. The dotted lines are where the bands would be placed.

This design closely resembles the Insert Palodent® plus wedge guard, however, the Potato Wedge incorporates slit inserts on the sides where matrix bands may be inserted and shaped to the respective curvature of the adjacent teeth. The premise of this design is to incorporate a mechanism which ensures the secure placement of two bands for each tooth while maintaining the natural spacing. Ideally, the wedge may be easily slid into place between the two teeth undergoing restoration (as a typical wedge currently on the market would), and the bands can easily slide into place between the teeth. This design is also promising as sectional bands have shown to have better contact post filling over circumferential bands. [24]

IV. Preliminary Design Evaluation

Design Matrix

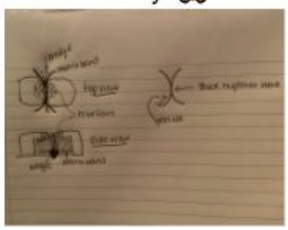
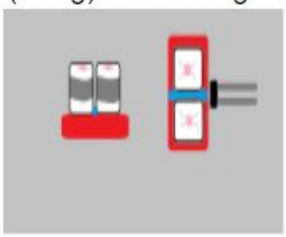
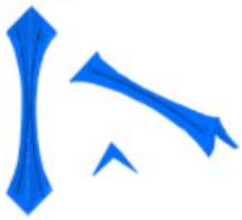
	The Butterfly!	(Doug) DoubleHug	The Potato Wedge
			
Safety (30)	24 (4)	30 (5)	18 (3)
Effectiveness (20)	16 (4)	20 (5)	16 (4)
Cost (20)	16 (4)	20 (5)	12 (3)
Adjustability (15)	12 (4)	15 (5)	6 (2)
Patient Comfort (10)	8 (4)	6 (3)	10 (5)
Ergonomics (5)	5 (5)	4 (4)	5 (5)
Total	81	95	67

Table 1: The six design criteria on the far-most left column were evaluated for each preliminary design. Each design was given a number score out of 5 for each category. Finally, each design's ratings were totaled to determine which design was best. Dark green shaded blocks indicate the highest ranking in each category.

Safety

Safety was ranked as our highest category, as ensuring the wellbeing of the patient is of utmost priority and importance. This involves having bioinert, nontoxic materials in our design, as well as ensuring there are no cutting edges that could possibly harm the patient. The Doug design was ranked highest in this category due to the assurances given since this is a modification of the current design in use today.

Effectiveness

Effectiveness is ranked next on our list, as the function of the device is crucially important. If the device

doesn't function at least as well as the current design in terms of both quality and time, then the device is useless. This describes how well the teeth can be filled, as well as how close the teeth are to each other post-filling. The Doug design also ranked highest in this category, as it can function exactly the same as the current design in use, just twice as fast.

Cost

Cost is ranked equally with effectiveness, as if the design we are making isn't at least the same price as the model in use today, then there is no point in using it. The potato wedge was the lowest of the three, as it would require purchasing or modeling of a separate rubber material, something in which the other two designs do not require, and the butterfly requires some manipulation of matrix bands which would possibly eat through more cost.

Adjustability

Adjustability was ranked next, and this describes the ability for the device to be manipulated to function on different sized and shaped teeth, all while maintaining function. The Doug won this category as it allowed for both bands to be adjusted during use, whereas the potato wedge and butterfly would be much harder to adjust during, or slightly prior to insertion.

Patient comfort

This describes how unpleasant the operation would be for the patient, and the Potato Wedge won this category as it is the smallest design, keeping the patient from possibly gagging and having a terrible experience.

Ergonomics

This describes the ease-of-use for the dentist themselves, and all scored fairly well, but the Doug lost a point as the double articulation might be slightly cumbersome during the operation, while the other two have no arms reaching from the filling site.

V. Proposed Final Design: Doug

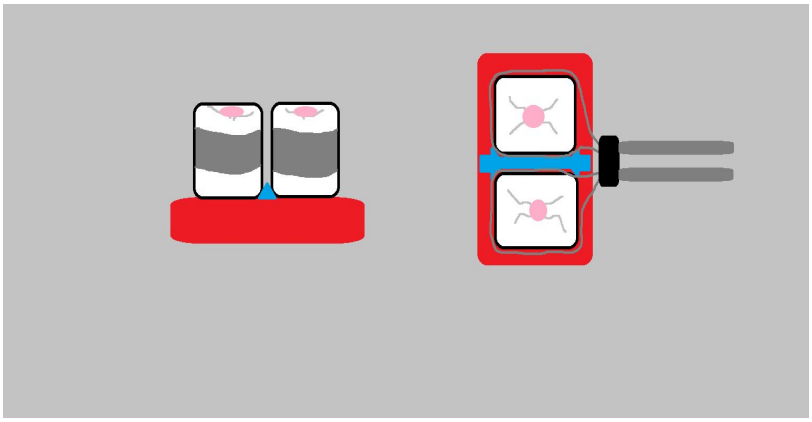


Figure 8: Repeated image of the Doug design.

The Team has decided to continue with the Doug design, as the assurance of functionality is a comfort, and the modifications that must be made to increase efficiency seem achievable. This design is the simplest design created, as it incorporates a lot of the current design aspects and only includes a thinner band and bigger retainer.

VI. Fabrication/Development Process

Materials:

The Doug uses a lot of concepts from current devices, which means that the materials needed would likely be very similar. The wedge and retainer used would just need to be updated to fit between the matrix bands and allow for double the space in the tightening mechanism, respectively. The matrix band is currently made of stainless steel [25], but the Doug would require a metal or material that is thinner but still as strong as stainless steel in order to fit between the teeth without compromising proximal contact.

Methods:

Fabrication should start with determining the desired thickness of the double-sided band. Once this thickness is decided, the retainer can be made. Either a current retainer will be used if possible or one will be fabricated to fit the desired thickness. Different materials will be tested to see if they would be viable. This would be determined by its biocompatibility, thickness, and strength. Once a material was selected, the whole band would be tested on model teeth by the team members along with the client.

Testing

A lot of critique and analysis of the design will be qualitative, since prior to clinical testing, the design will be rated based on if it will be feasible. This means that before most quantitative tests are done, the design must be able to properly fit around and between two teeth with a wedge, hold up to light pressure on the sides, and fit in the retainer. Once these criteria are met, other testing will need to be done. In order to quantitatively measure this, bending tests, compressive tests, and biocompatibility tests would need to be completed. More tests might be required as the design progresses. Bending tests would give a value for the ductility of the material, which is important as it must be able to get contoured around the tooth without losing its shape. Compressive testing should be done to see if the band will withstand the compressive forces put on it during the procedure. Finally, biocompatibility testing is of high importance as the material cannot be used if it is not biocompatible.

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: 07-Oct-2020].
2. 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: 07-Oct-2020].
3. A. M. O. M. Otto, View all posts by Mary Otto →, M. Otto, and M. Otto, “Percentage of adult Americans with cavities remains high, study notes,” Association of Health Care Journalists, 23-Jun-2015. [Online]. Available: https://healthjournalism.org/blog/2015/06/percentage-of-adult-americans-with-cavities-remains-high-study-notes/. [Accessed: 07-Oct-2020].
4. “Cavities/tooth decay,” Mayo Clinic, 19-Jul-2017. [Online]. Available: https://www.mayoclinic.org/diseases-conditions/cavities/symptoms-causes/syc-20352892. [Accessed: 07-Oct-2020].
5. “Products - Data Briefs - Number 197 - May 2015,” Centers for Disease Control and Prevention, 06-Nov-2015. [Online]. Available: https://www.cdc.gov/nchs/products/databriefs/db197.htm. [Accessed: 07-Oct-2020].
6. “Dental Caries Overview,” National Institute of Dental and Craniofacial Research. [Online]. Available: https://www.nidcr.nih.gov/research/data-statistics/dental-caries. [Accessed: 07-Oct-2020].

7. B. L. Edelstein, “The dental caries pandemic and disparities problem,” BMC oral health, 15-Jun-2006. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2147591/. [Accessed: 07-Oct-2020].
8. “Cavities/tooth decay,” Mayo Clinic, 19-Jul-2017. [Online]. Available: https://www.mayoclinic.org/diseases-conditions/cavities/diagnosis-treatment/drc-20352898. [Accessed: 07-Oct-2020].
9. StackPath. [Online]. Available: https://www.dentistryiq.com/dental-hygiene/student-hygiene/article/16352162/mustknow-classifications-of-dental-caries-for-the-national-dental-hygiene-boards. [Accessed: 07-Oct-2020].
10. 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: 07-Oct-2020].
11. Original Tofflemire® Matrix Bands. [Online]. Available: https://www.waterpik.com/oral-health/pro/dental-supplies/matrix/band-tofflemire/. [Accessed: 07-Oct-2020].
12. Dental City - Tofflemire Matrix Bands 144/Pack. [Online]. Available: https://www.dentalcity.com/product/16927/dental-city-tofflemire-matrix-bands-144pack?91-052. [Accessed: 07-Oct-2020].
13. “Matrix Bands No. 2 (0.0015),” The Dental Market U.S. [Online]. Available: https://thedentalmarket.net/1989-matrix-bands-no-2-00015?gclid=EAIaIQobChMIua6x0P2T7AIVhL7ICh2jbA0IEAQYAiABEgJNJfD_BwE. [Accessed: 07-Oct-2020].
14. D. Today, “PinkBand Dental Solutions - Tofflemire-Type Matrix Band,” PinkBand Dental Solutions - Tofflemire-Type Matrix Band | Dentistry Today. [Online]. Available: https://www.dentistrytoday.com/products/item/pinkband-dental-solutions-tofflemire-type-matrix-band. [Accessed: 07-Oct-2020]
15. Palodent Matrix System Refill - Standard Matrices 100/Bx. Contoured sectional | Dental Supplies. [Online]. Available: https://www.net32.com/ec/palodent-matrix-system-refill-standard-matrices-100-d-77427?utm_source=google. [Accessed: 07-Oct-2020].
16. “Tinman Dental Supplies,” Dental Supplies. [Online]. Available: https://www.tinmandental.com/show_Products.aspx?ID=1606. [Accessed: 07-Oct-2020].
17. Ryzvee, M., 2015. Matrix Bands. [online] Slideshare.net. Available at: <https://www.slideshare.net/masurizvi/matrix-bands> [Accessed 18 September 2020].
18. “Tooth,” Mouth Healthy TM. [Online]. Available: https://www.mouthhealthy.org/en/az-topics/t/tooth. [Accessed: 07-Oct-2020].

19. “The Physiology of Cavities,” What You Need to Know, 07-May-2019. [Online]. Available: https://premierdentalohio.com/preventative/the-physiology-of-cavities/. [Accessed: 07-Oct-2020].
20. B. D. Editors, “Teeth,” Biology Dictionary, 07-Sep-2017. [Online]. Available: https://biologydictionary.net/teeth/. [Accessed: 07-Oct-2020].
21. “Tooth decay,” Wikipedia, 05-Oct-2020. [Online]. Available: https://en.wikipedia.org/wiki/Tooth_decay. [Accessed: 07-Oct-2020].
22. S. Watson, “What are the different cavity classifications?,” HowStuffWorks, 07-Sep-2011. [Online]. Available: https://health.howstuffworks.com/wellness/oral-care/problems/cavity-classifications.htm. [Accessed: 07-Oct-2020].
23. “How Do Professional Cavity Fillings Work?,” ImmediaDent, 19-Nov-2019. [Online]. Available: https://immediadent.com/blog/cavity-filling-questions-answered/. [Accessed: 07-Oct-2020].
24. M. Z. Ahad, D. E. Sadaf, R. N. Gaikwad, and B. Arjumand, “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 journal of dental research : official publication of Indian Society for Dental Research, 2018. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/30127197/. [Accessed: 06-Oct-2020].
25. R. H. White and M. J. Geissberger, “Additional Uses for the Classic Matrix Band,” *Operative Dentistry*, 01-Jul-2007. [Online]. Available: https://meridian.allenpress.com/operative-dentistry/article/32/4/412/107238/Additional-Uses-for-the-Classic-Matrix-Band. [Accessed: 07-Oct-2020].

VIII. Appendix

Product Design Specifications (PDS)

Function:

Matrix bands are a commonly used dental tool which assist dentists by providing a wall to maintain a tooth’s structure and shape during restorative procedures, such as cavity fillings[1].During typical filling procedures--particularly filling cavities on interproximal surfaces--dentists must fill one tooth at a time since matrix bands cannot be placed adjacent to one another, as the thickness of two bands

exceeds the aperture diameter between the teeth. The resulting process of placing matrix bands for both teeth is cumbersome and time inefficient. The proposed design should alleviate the need to repeatedly place bands by employing a dual band system which is thin enough to securely and comfortably fit in between the affected teeth and able to simultaneously fit the appropriate convex/concave contour of each tooth. The finalized product should also maintain the tensile strength, malleability, and space efficiency of current matrix bands.

Client Requirements

1. Function Importance (as ranked by the client)
    a. Device must be able to securely fit to the convex/concave contour of 2 adjacent teeth undergoing restoration
    b. Device should be equivalent or less costly to manufacture as compared to existing matrix bands
    c. Device must remain inert in the presence of filling materials (amalgam, ceramic, composite etc.)
    d. Device should not be obstructive or clash with other tools to be used (rotary instruments, mirrors, forceps, suction etc.)
    e. Device material must be non-toxic
    f. Device should be thin and have high tensile strength

Design Requirements

1. Physical and Operational Characteristics

a. *Performance requirement*
    i. Must include some mechanism to maintain adequate separation between teeth being filled (the appropriate spacing is to be determined)
    ii. The device must include some fence-like feature which is capable of fitting both concave and convex curvature of the adjacent teeth undergoing repair
    iii. Device material must be malleable and able to easily bend to shape according to the tooth's contour
    iv. Device material must be thin enough (dimensions to be determined) to be secured between the adjacent teeth, and it must have a high tensile/compressive strength(force to be determined) to withstand manipulation

b. *Safety*
    i. This device must adhere to safety standards/ regulations (if any) specified by the

FDA as a class I device[2]

ii. Labelling should include instruction for proper installation and handling to avoid harm to the patient and ensure sterility

iii. Warnings should discourage use of the device if sterilized packaging has been tampered or if the device appears damaged

iv. Device should be handled with the appropriate tools (i.e. forceps, cotton pliers etc.[3])

c. *Accuracy and Reliability*:

i. The band matrix should range in thicknesses of 0.0254 mm to 0.0508 mm (approximately the thicknesses of the commonly used universal Tofflemire Matrix Bands[4])

d. *Life in Service:*

i. The device must maintain its structural integrity and form throughout the duration of a standard filling procedure (approximately 1 hour [5])

ii. This device is intended for single use

e. *Shelf Life*:

i. The device must should stable and sterilized, if left in its original sterilized packaging, for an indefinite amount of time

ii. If device packaging is compromised, it is no longer fit for use and should be disposed in the appropriate sharps collection container

iii. Must be stored in dry, temperate conditions.

f. Operating Conditions:

i. The device should maintain structural integrity within the span of ambient and body temperature, from 20°C to 37°C.

ii. The device should be able to withstand high humidity and moisture levels for the span of time in which it is in use, in the patient's mouth.

g. Ergonomics

i. The device should not be more difficult to use than the current retainer and band method, preferably a similar system.

h. Size

i. The device must be thin enough to fit between two separate teeth in a patient's oral cavity

ii. The device must have variable matrix height to account for different teeth within the mouth, as well as different patients

iii. The device must be small enough to maintain maneuverability within the oral cavity, as to make the application of the band, and subsequently the filling, easier.

j. *Materials*: The current device is being made with stainless steel or aluminum. This material

the bands would be made of would most likely be some form of strong metal to be a rigid wall and resist deformation.

k. *Aesthetics*, *Appearance, and Finish*: Aesthetics are not the biggest concern. It cannot be covered in any material that would be considered toxic due to insertion of this device in the mouth. The bands are typically made out of metal, and the device as a whole will be made of mostly metal and plastic of no particular aesthetic and appearance.

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2. Production Characteristics

a. *Quantity*: This project requires only one unit of the device to be developed. In the end, many of these devices will need to be created at a low cost in order to be used commonly or commercially

b. *Target Product Cost*: The goal of this project is to keep the bands low cost similarly to the cost of other bands. Currently bands can be purchased at a fairly low cost, anywhere from .50 cents to one dollar per band. [6] The project's band would most likely have to be around this cost. Additionally, in this projects past the handle piece parts totaled around $300, so this cost can be the target for the reusable handle piece.

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3. Miscellaneous

a. *Standards and Specifications*: This device will have direct contact with the patient, so FDA approval is required. In the Code of Regulations Title 21, Chapter 1, Subchapter H, and Part 872, the dental matrix band is mentioned as a Class I device. If the device designed is made with the same materials as previously FDA approved matrix bands before 1976, then the device would be exempt from premarket notification processes 510(k). However, if it was made with materials used in later devices, it would need to go through that process, which requires a 90 day notice to the FDA before marketing the product [7]. Other FDA documents and steps would be required including the establishment registration, listing the medical device to the FDA, obtaining an investigational device exemption if doing clinical studies, a quality system regulation, following labeling

requirements, and reporting the medical device if necessary [8]

b. *Customer*: The two primary targets for this device would be dentists and dental supply companies. Therefore, maintaining standards and outcompeting competition is especially important. As the client is a dentist himself, the customer specifications are very similar to the client specifications in that the device should decrease procedure time, improve proximal contact, and correctly contour the tooth.

c. *Patient-related concerns*: As this device will come in contact with a patient's oral cavity, it is extremely important that the materials it is made of are non-toxic and provide no harm to the patient. The device should also not provide discomfort, as getting the filling in itself will already be uncomfortable. Since this will be a one-time use device, no sterilization of the band will be needed. The retainer, however, will need to be sterilized if it is used on another patient. The device should also not increase procedure time.

d. *Competition*: Although there are many similar devices on the market, they all don't allow for the filling of more than one tooth at a time. There are two devices that allow for this, which is called the Triodent V3 Ring and the Triodent Wave-Wedge, which are both used to separate adjacent teeth. While the device is in, matrix bands can be placed around both teeth. Although this method does work in theory, the contact is not optimal. By using two matrix bands between the teeth, the gap can be bigger than anticipated in both methods [9].

Figure 1: Using the Triodent to spread the adjacent teeth to place two separate matrix strips. This allows for the filling of two adjacent teeth simultaneously [9].

Figure 2: Using the Wave-Wedge from Triodent to separate the adjacent teeth during filling [9].

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4. References

1. **Ryzvee, M., 2015. Matrix Bands. [online] Slideshare.net. Available at: <https://www.slideshare.net/masurizvi/matrix-bands> [Accessed 18 September 2020].**
2. **2009. Slicks Matrix Bands And Sectional Matrix Bands. [ebook] FDA. Available at: <https://www.accessdata.fda.gov/> [Accessed 18 September 2020].**
3. **re-invent Dental Products. 2020. Re-Invent Dental Products. [online] Available at: <https://re-inventdental.de/en/sterilization-guideline> [Accessed 18 September 2020].**
4. **Henry Schein, I., 2020. Tofflemire Matrix Band 1 Adult Universal 0.002 In 144/Pk - Henry Schein Dental. [online] Henryschein.com. Available at: <https://www.henryschein.com/us-en/dental/p/restorative-cosmetic/matrix-materials/tofflemire-bands-1-002/9532378> [Accessed 18 September 2020].**
5. **Mitchell, J., 2020. How Long Does It Take To Fill A Cavity? | Colgate®. [online] Colgate.com. Available at: <https://www.colgate.com/en-us/oral-health/procedures/fillings/how-long-does-it-take-to-fill-a-cavity--> [Accessed 18 September 2020].**
6. **Net32.com. 2020. *Palodent Matrix System Refill - Standard Matrices 100/Bx. Contoured Sectional | Dental Supplies*. [online] Available at: <https://www.net32.com/ec/palodent-matrix-system-refill-standard-matrices-100-d-77427?utm_source=google&utm_medium=cpc&adpos=&scid=scplp77427&sc_intid=77427&gclid=Cj0KCQjwtZH7BRDzARIsAGjbK2bnuqW_k7VFN1nRmUme2oW0O9T5wxNIyAT5yByZzzOrArFVFeDcz0saAnM4EALw_wcB> [Accessed 18 September 2020]**
7. **Accessdata.fda.gov. 2020. *CFR - Code Of Federal Regulations Title 21*. [online] Available at:**

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=872.4565>

8. **U.S. Food and Drug Administration. 2020. *Overview Of Device Regulation*. [online] Available at: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation#ide>**
9. **Jeffrey M. Rosenberg, D., 2020. *Making Contact: A Method For Restoring Adjacent Posterior Direct Resin | Dentistry Today*. [online] Dentistrytoday.com. Available at: <https://www.dentistrytoday.com/restorative/8821-making-contact-a-method-for-restoring-adjacent-posterior-direct-resin>**