Dual Matrix
Product Design Specifications

BME 200/300
Team Name: Dual Matrix
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Client: Dr. Donald Tipple
Advisor: John Puccinelli

Team Members:
Leader: May Kennelly
Communicator: Olivia Kallas
BSAC: Nicholas Miles
BPAG: Luca Benedetto
BWIG: Samuel Zakaib
BWIG: Justin Schwartz

Function

Matrix bands are used to restore interproximal cavities. They are used in tandem with gingival wedges and separation rings and must be thin to allow proper contact between teeth. Improper contact may result in food impaction which can cause gingivitis and decay. The standard of care for two adjacent interproximal caries on premolars and molars is completing each filling separately. The Dual Matrix aims to allow the dentist to more efficiently complete two adjacent restorations because they can occur simultaneously.

Client requirements

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

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**

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

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

b. **Safety**

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

c. **Accuracy and Reliability**

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

d. **Life in Service**

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

e. **Shelf Life**

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

Operating Environment

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

f. **Ergonomics**

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

g. **Size**

The height should be around 8 mm to provide the best mold for premolars and molars. A height of 8 mm ensures that the matrix band extends sufficiently apically. If the matrix band does not extend far enough apically, it can cause a gingival overhang that cannot be

corrected. The thickness should be between 0.05 mm and 0.038mm [13]. The width should be between 4.5 and 8.4 mm so that the device extends far enough around the decayed teeth [14].

h. **Weight**

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

i. **Materials**

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

j. **Aesthetics, Appearance, and Finish**

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

2. **Production Characteristics**

a. **Quantity**

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

b. **Target Product Cost**

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

3. **Miscellaneous**
    a. **Standards and Specifications**

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

    b. **Customer**

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

    c. **Patient-related concerns**

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

    d. **Competition**

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

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