Approximating Surface Matrix Band for Dentist to Use for Patients

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BME 400 Lab 305

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Function:

Surface matrix bands are devices used by dentists to separate adjacent teeth during restorations of interproximal cavities (cavities found in-between two teeth). The matrix band serves to support the restoration material, to provide shape and contour to the tooth being restored, and to protect the adjacent tooth. Ideally, the width of the space between the two adjacent teeth is just large enough to fit one matrix band in order to ensure close proximal contact area, which prevents food impaction and decay. In the case of two cavities on two adjacent teeth, this process is tedious, as the dentist must complete the process from start to finish for each adjacent tooth individually. The goal of this project is to create a dental matrix band that effectively separates adjacent teeth for more efficient tooth restoration procedures on interproximal cavities by making it possible to complete two adjacent restorations simultaneously.

Client requirements

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

Design requirements

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

        Surface matrices are used in dental restoration to recreate the natural tooth shape and protect surrounding tissue. This product must fulfill all the existing requirements of surface matrices in addition to creating a more efficient reconstruction procedure. Surface matrix systems are most commonly used for treatment of smooth surface class II posterior caries [1]. Because proximal contact must be maintained in the restoration, the surface matrix must be very thin. Common surface matrix thicknesses in industry range from 0.038 mm to 0.05 mm [2]. If the matrix band's thickness is too great the interproximal contact between teeth will be lost post procedure causing food packing, which can lead to gingivitis and periodontitis, and loss of arch stability. A large part of maintaining this critical proximal contact is reconstructing the natural shape of the tooth. To ensure this dentists often use wedges and tension rings to help form the matrix to the tooth. To allow full functionality and easier adoption by dentists, this product must be compatible with these existing products. To help match the shape of the biting surface of the tooth, surface matrices have an occlusal curve which allows for better reconstruction. Additionally, sectional matrices often have a curve or

extended section that sets into the sulcus between the tooth and gum. This protects the gums and allows for better filling. The product should include these features to be an effective solution. The surface matrix must be malleable enough to easily wrap around the tooth. Most current matrices are near dead soft meaning they are nearly fully annealed, however, over annealing and creating a grain structure too large can cause the matrix to be too ductile and crimp upon insertion into the interproximal space or during wedge insertion. Therefore, the mechanical properties of the matrix must balance ductility, malleability, and durability. This balance must be determined through testing to find a correctly annealed alloy. Surface matrices are usually considered single use products so repeated loading is not a major concern. This is because the matrix is often warped as it is conformed to the patient's tooth and would compromise future filling success. Filling overhangs are another point of concern for dentists. To address this problem, the product must be malleable enough to properly conform to the tooth and work seamlessly with tension rings and wedges. The material, again, must be properly annealed, near dead soft but not too soft, to achieve this task. Some sectional matrix systems have a tab or extended piece at the top of the tool for easier handling. This is not a required feature, but easy handling for dentists in a constrained environment must be considered in design.

b. **Safety:**

The device should avoid any materials that patients are commonly sensitive to, for example, nickel. Additionally, the final product should have rounded, not sharp, edges to minimize irritation and damage to the patient's gums. If sold, the product must be within sterilized packaging with warnings to discourage tampering.

c. **Accuracy and Reliability:**

Accuracy is an important consideration for dental matrices because they must be able to form to the tooth, interact with other components, and maintain the interproximal gap between teeth. The accuracy of thickness, the most important dimension for matrix systems, will depend on the supplier because post processing of metal alloys can be expensive and challenging, so modifying the thickness of the material after purchasing will be difficult. McMaster-Carr sets their thickness tolerance for 0.0508 mm thick (0.002") austenitic grade stainless steel at ±0.00508 mm, which is a reasonable standard for the thickness of the product [2]. The height of sectional matrices vary depending on tooth type from 3.5 mm to 7.5 mm. This variety in size gives more leniency in tolerance, especially because the height dimension of the matrix has fewer interactions with other components. Additionally, with the variety of tooth sizes from both genetic and gender differences, height dimensions are not as critical as the thickness. Because the variance in length from the occlusal surface to the gingival surface has variance from patient to patient a larger tolerance of ±0.2 mm is permissible.

This should be achievable for larger scale stamping or laser cutting procedures while not compromising the effectiveness of the product [3]. Dimensions like length of the band are also not as critical as the thickness of the band because of the variation between teeth and patients. However, because the width of the matrix has interactions with other components like tension rings and must be able to accommodate a variety of filling sizes its accuracy is still important. Considering this the tolerance should be kept to ±0.1 mm. In terms of GD&T specifications that must be considered are symmetry, surface profile, and line profile when the product is in its final configuration before use and surface roughness before product is formed to its final shape. Symmetry is important because of its interaction with other components like the tension ring as well as forming to the tooth and recreating a natural looking filling. Surface and line profile tolerances are important for the curvature of the matrix and recreating the natural form of the tooth. Surface roughness should be measured before the matrix is curved to ensure that the product is smooth and will not create any defects in the filling or adhere to the filling. These tolerances are harder to measure and specify, additionally, line and surface profile tolerances may not be as critical because the dentist can use rings and wedges to modify the shape of the matrix to match the tooth. Specifying these dimensions is difficult and outside of the scope of this project, however, they should not be entirely neglected and should be kept in consideration during design and manufacturing. Repeatability will vary depending on the manufacturing process. The most likely processes will be metal stamping, laser cutting, or water jet cutting. Each of these should be able to produce parts with high fidelity. During initial prototyping, a standard of 9/10 units should be within specification. If the product scales 1/100,000 should be defective.

d. **Life in Service:**

The device is designed to be single-use. It must maintain its structure for the duration of the procedure and be able to withstand removal from the patient in one piece.

e. **Shelf Life:**

The product should be kept in a dry and sterile environment. The humidity of the storage area should be low to prevent corrosion of the metal. It should be away from potential contaminants and oxidizing agents that could potentially damage the mechanical integrity of the matrix or mar the finish of the unit. If more than one size is produced this should be clearly organized and distinguished to avoid confusion. The product should be kept near room temperature to avoid compromising material properties and shape of the product. The matrix should be stored with care to avoid bending and deforming the preformed shape.

f. **Operating Environmen**t:

The product will be used within the human mouth, which will expose the device to multiple physical, chemical, and biological factors.

I. The human mouth exposes the device to high levels of moisture. While stimulated, like during a dental procedure, the human mouth can produce 4-5mL/min of saliva [4]. This can cause corrosion or rusting in certain untreated metals. Another factor that increases the risk of corrosion is the slight acidity of saliva with a pH of 6.7 [5]. Though slight, this decreased pH can cause increased corrosion in metals like steel.

II. Heat is another important factor when operating within the mouth. The standard temperature of the mouth is 37℃ (98.6℉). So, the device must be able to maintain its mechanical properties within a range of 20℃ (room temperature) to 37℃ at a minimum to reach design requirements.

III. The device must be able to withstand being pushed between teeth while not damaging them. The enamel of the tooth has a Vickers hardness of 274.8 [6]. Any material under consideration must have a hardness score below that to minimize damage.

g. **Ergonomics:**

The device must be at least as easy to install and use as current solutions, such as sectional and circumferential matrix bands. The device must also be faster to use than the two prior solutions it aims to replace. After use, the device must come out of the teeth easily and without excessive damage to the patient's gums.

h. **Size:**

As specified by the client, the thickness of the improved dual sectional matrix design should be the same as that of sectional matrices currently on the market. This is to ensure that there is sufficient proximal contact between the two restored teeth to prevent food impaction and further decay [7]. The typical thickness of sectional matrix bands currently on the market is 0.0381 mm, and in previous semesters, a thickness of 0.0254 - 0.0508 mm was used for the matrix band design [8]. Typically, current sectional matrices on the market have lengths between 12.57 - 14.33 mm, heights between 3.2 - 6.4 mm, and widths varying between 1.24 - 1.64 mm [8]. The overall size of the sectional matrix band will vary depending on the tooth (a wide range should be made), but the thickness of the device should remain between 0.0254 and 0.0508 mm.

i. **Weight:**

Depending on the material used for the sectional matrix band design (usually stainless steel or polytetraflouroethylene (PTFE)) and its size, the typical weight of a sectional matrix band is between 0.01 and 0.02 grams (although not clinically relevant).

j. **Materials:**

The materials that make up the device must be biocompatible while temporarily pushed between the teeth of the patient; it is not required to meet the stringent standards of permanent implants. The device must be made of materials that can withstand the forces and environment of the tooth (described in section f) while still being malleable by the dentist, so that it can be moved to fit any specific patient's tooth. Materials like stainless steel are commonly used to accomplish these requirements. The material must be able to withstand autoclaving at 121°C (250°F) for 30 minutes in accordance with CDC guidance [9].

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

The final design should feature a slightly curved appearance to easily fit the anatomy of the tooth which it lines, subsequently reducing the time spent shaping the restoration. The product should be made of either polished stainless steel or PTFE, which can further be coated with a teflon finish to provide a non-stick surface. The design should also feature a tab, which makes for easy manipulation by the dentist during insertion and removal.

2. **Production Characteristics**
   a. **Quantity:**

The client has requested a single prototype to test the functionality of the device.

b. **Target Product Cost:**

To be competitive, the device would need to be in parity with similar dental matrices costing ~$0.50 - $1.00 [10]. However, because of the relative complexity of our device and the time savings that it should provide, the cost of the device must remain under $5 per unit to manufacture. The total budget for development and testing of the device must stay under $200 as provided by the client.

1. **Miscellaneous**
   a. **Standards and Specifications:**

Dental matrix bands are regulated by the FDA. The FDA classifies sectional matrices under “Dental Hand Instruments” which are class I devices that are 510(K) exempt. However, the FDA does not exempt the device from GMP, so this must be considered in the design for manufacturing. In addition to FDA

regulations, ISO sets standards for sectional matrices under ISO standard 18556-2016. The standard classifies “intraoral spatulas” into two categories based on design and material properties. As designated by the standard, type 1 intraoral spatulas are oval shaped and are more rigid, while type 2 are more rectangular, flat, and flexible [11]. ISO also regulates the materials used in surface matrix bands under ISO standard 10993-1 *Biological Evaluation of Medical Devices,* which regulates biocompatibility of medical devices. The standard regulates testing for cytotoxicity, interactions with blood, irritation, and skin sensitivity, as well as identification and quantification of degradation products from medical devices [12]. Of these testing standards, irritation and skin sensitivity are the most relevant because of the minimal contact of the device. If further processing is required of the materials to increase ductility and malleability, the testing would likely fall under ASTM standard A666/A666M-24, which sets specifications for annealed or cold worked austenitic stainless steel sheet, strip, and flat bar [13]. This could be relevant because the thinness of the stock may limit the processing of the steel, especially for prototyping. It may be difficult to find medical grade (316L or 304) stainless steel at the required thickness with the correct annealing to allow for the ductility and malleability required for sectional matrices. Considering this, the ASTM standard for annealing austenitic stainless steel could be valuable in testing modified purchased materials.

b. **Customer:**

The intended customer of this product is any dental office or dentist who performs Class 2 dental restorations on their patients. This device can also be used by dental schools to train students on interproximal restorations.

c. **Patient-related concerns:**

Comfort is a large concern, which is related to the size of the matrix. On a patient-to-patient basis, patients with larger teeth may require a different sized matrix than patients with smaller teeth. This means that if there were to be a universal design, it must account for the different sizes of teeth, or it could be both uncomfortable and incapable of filling the teeth properly.

d. **Competition:**.

One of the leading competitors in the market is the Halo Sectional Matrix Kit, which contains bands that are held in place by nitinol rings and glass-filled nylon tines [14]. A downside to this product is that the kit used to install this sectional matrix on the teeth is about $700, which is far higher than the client’s budget. A current device on the market that is used to fill cavities is the Triodent V3 Ring [15]. This device is capable of filling cavities, but when used, it isn’t capable of filling adjacent cavities without leaving too large of a gap.

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