Approximating Surface Matrix Band

Product Design Specifications

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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. 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 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 that is thin enough to securely and comfortably fit between the affected teeth and is able to simultaneously mold to 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. 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.
        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 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 [2].
        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 [3]. 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 [4].
    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 [5].
ii. The perimeter of teeth can be approximated by treating teeth as rectangles and using average mesiodistal and faciolingual measurements. This approximation would result in an average tooth perimeter of 33.82 mm, with a range of 22 mm to 45.8 mm [5].
iii. Current matrix bands commonly come in three different sizes: 0.001 gauge (0.0254 mm), 0.0015 gauge (0.0381 mm), and 0.002 gauge (0.0508 mm) [6]. 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 [7]. 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 [8]. 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 a couple models 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 [9]. 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 [10]. 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 [10]. 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 [11].

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 [12]. 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-Wedgde are advertised as a sectional matrix system that allows for superior functionality compared to the circumferential band (tofflemire) [13][14][15]. 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. .

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