BME 400
Approximated Surface Matrix Band For Dentistry
Preliminary Design Specifications (version 1.0)

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Date: September 18th, 2020

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.

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].

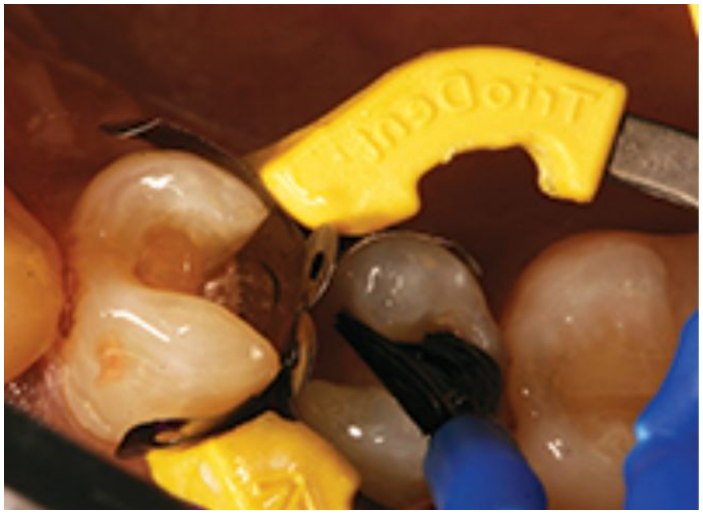

Figure 1: Using the Triodent to spread the adjacent teeth to place two separate matrix strips. This allows for the filling of two adjacent teeth simultaneously [x].

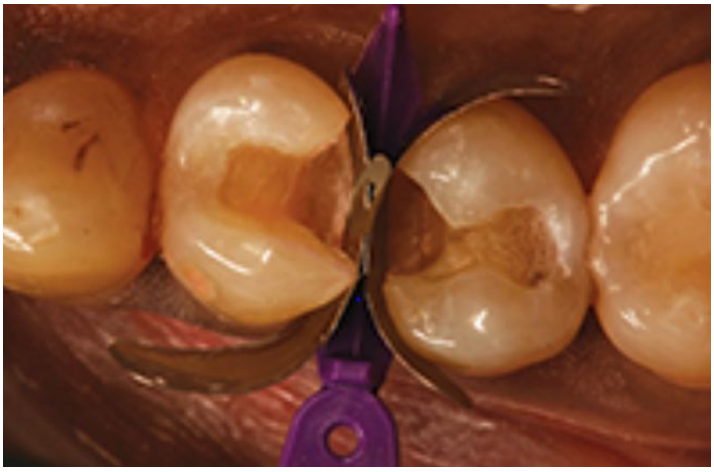

Figure 2: Using the Wave-Wedge from Triodent to separate the adjacent teeth during filling [x].

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4. References

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