

APPROXIMATING SURFACE MATRIX BAND FOR DENTIST TO USE FOR PATIENTS

FINAL REPORT



BME 400

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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.

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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 day 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 contours 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 Tofflemier 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.

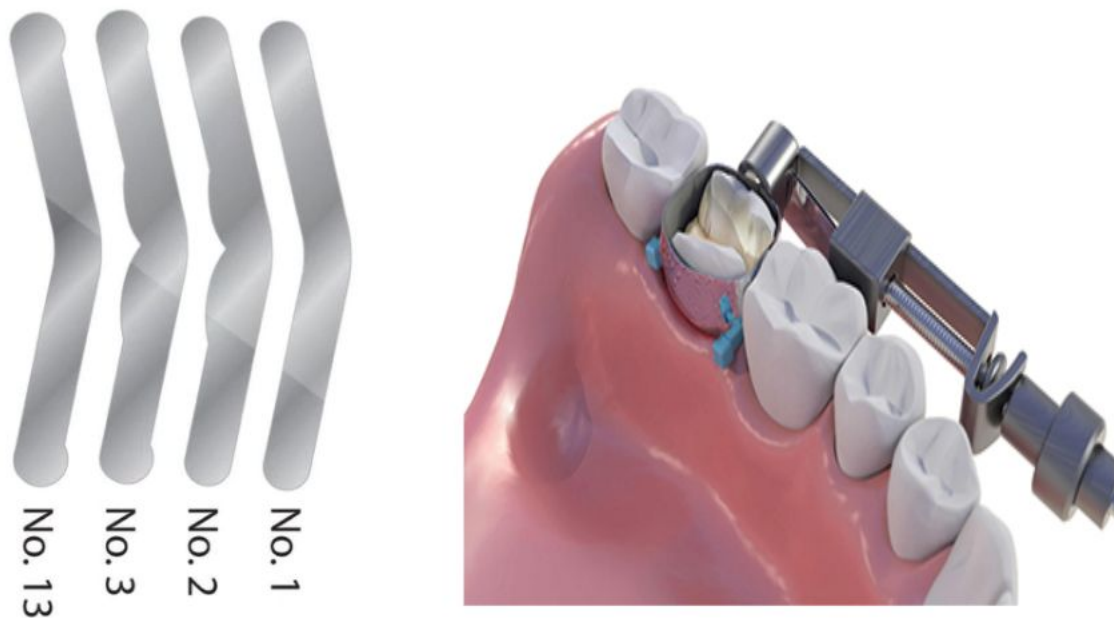


Figure 1: Image of a universal Tofflemire matrix bands unformed (left) and formed around the tooth in the standard set up. The tooth wedge (used to increase the contact gap) and retainer (used to maintain the band shape) are also depicted in the right image. [13][14]

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].

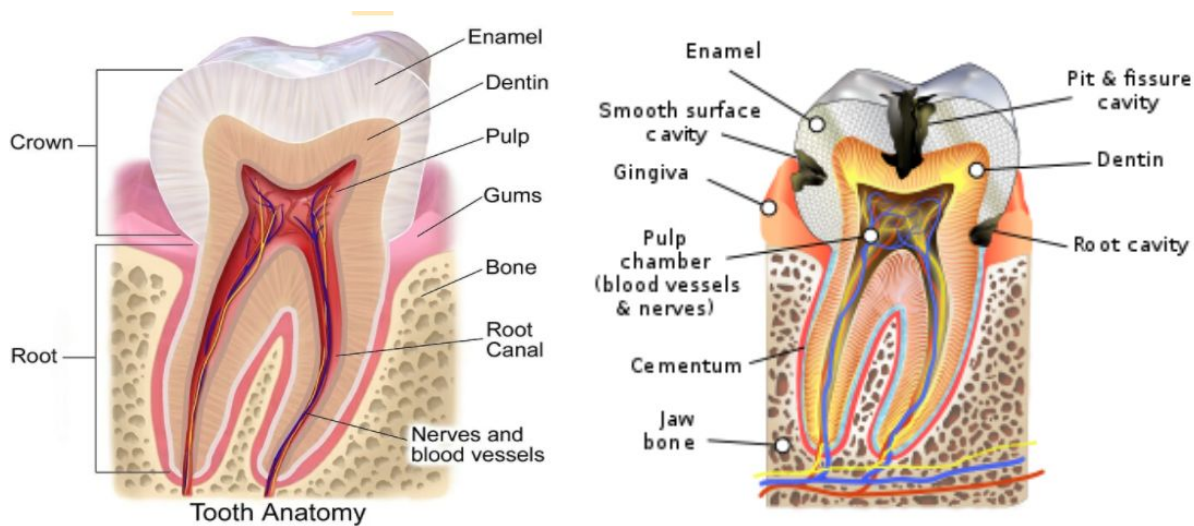


Figure 3: Labeled anatomical structure of a standard normal (left) and decayed tooth (right) [20][21]

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 hardened 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

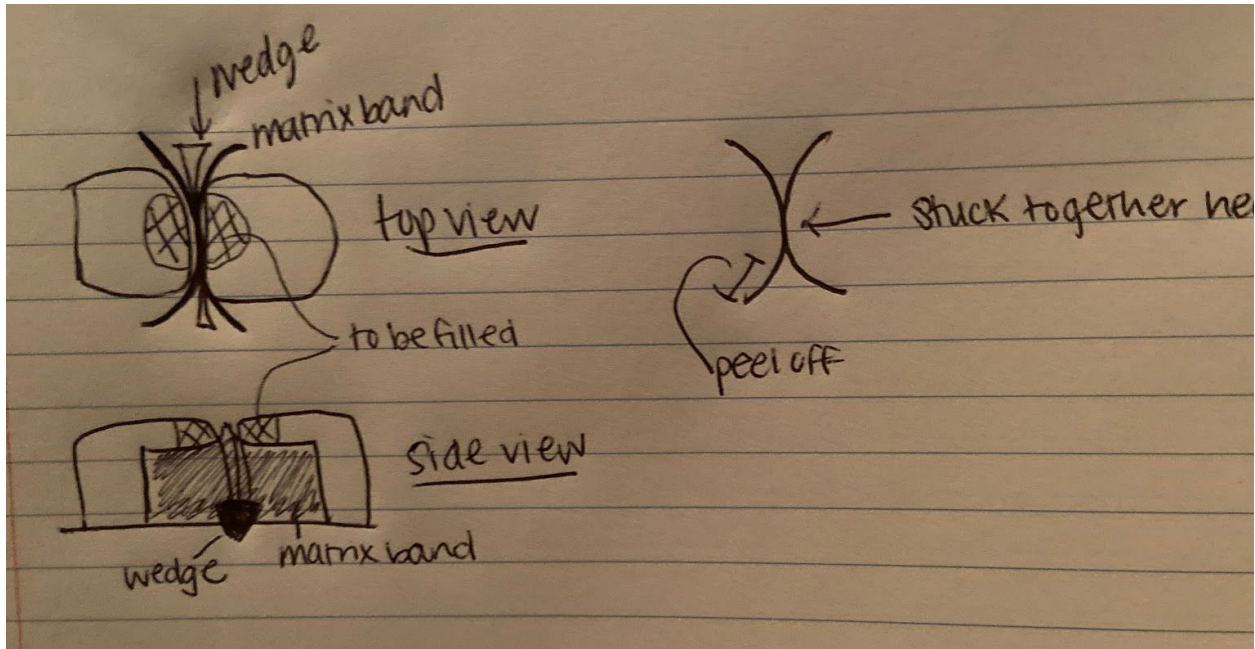


Figure 5: Sketch of the “butterfly” design. The crosshatched area is where the filling would need to be placed.

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)

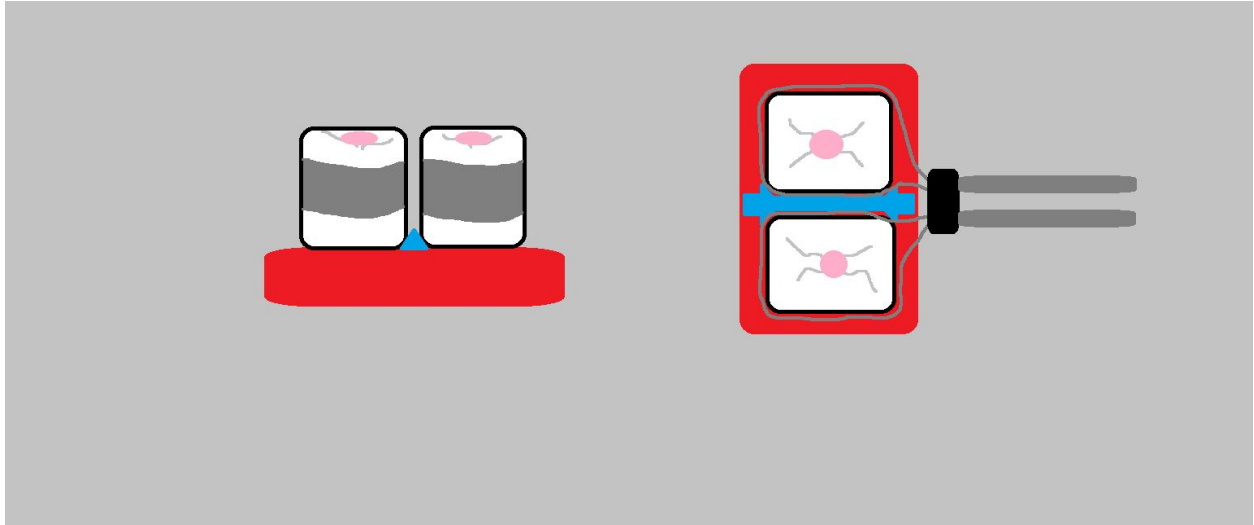


Figure 6: Model of the Doug design showing a top and side view. The blue portion is the wedge, the bands are in silver, and the teeth are white.

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

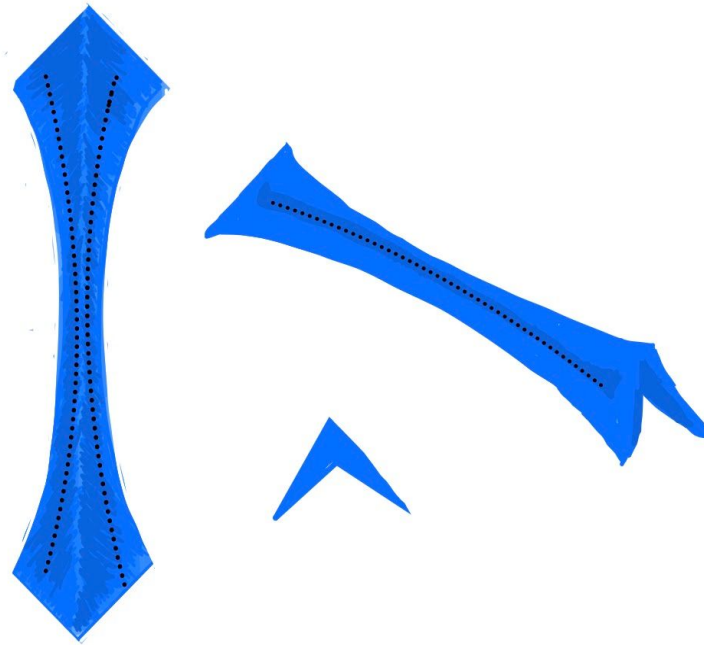


Figure 7: Sketch of the potato wedge design showing all views. The dotted lines are where the bands would be placed.

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


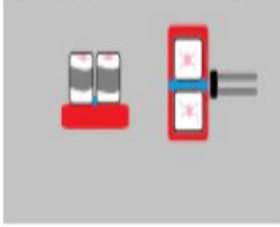

| | The Butterfly!  | (Doug) DoubleHug  | The Potato Wedge  |
|----------------------|--|---|--|
| Safety (30) | 24 (4) | 30 (5) | 18 (3) |
| Effectiveness (20) | 16 (4) | 20 (5) | 16 (4) |
| Cost (20) | 16 (4) | 20 (5) | 12 (3) |
| Adjustability (15) | 12 (4) | 15 (5) | 6 (2) |
| Patient Comfort (10) | 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 increase costs.

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 an unpleasant 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(double hug)

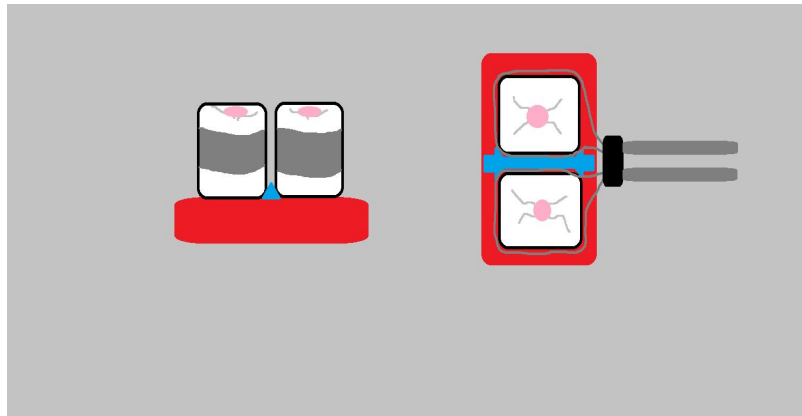


Figure 8: Repeated image of the Doug (double hug) design.

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 is essentially a modification to the current device that our client uses, which means that the materials needed would likely be very similar, if not the same. 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. The matrix band is currently made of stainless steel [25], which is most likely the 316L type based on its biocompatibility and corrosion resistance [26].

Methods:

Fabrication started with determining the required thickness of the double-sided band through material testing, determined to be somewhere in the range of .0015 - .002 inches. For the retainer, we must reverse engineer the current design to determine how it functions, and then design a mirrored version in order to weld two independent bands. Finally, we will have to outsource our design for production in the spring semester, as we lack the machining skills and the 3D printer quality to do it ourselves.

Testing:*Mechanical:*

To assess the viability of the final design before fabrication, mechanical testing on SolidWorks was completed. This quantitative test gave preliminary data on how the prototype would compare to bands used in the clinic now in terms of the stress and strains put on them. Figure 9 shows the SolidWorks model of the matrix band used today, which was the control for the experiment. Figure 10 shows the SolidWorks model of our final design. This design consisted of the same material and same overall shape as the control, but with slightly different dimensions. AISI Type 316L stainless steel was used as it is often a material used for medical and chemical devices, but not as expensive as the medical grade type 316L stainless steel. Since any 316L stainless steel is biocompatible, it might not be necessary to get the stainless steel used for implants, or the medical grade [26]. For this experiment, a 62% incline was added to the middle 1 cm of the band. This allowed for a decrease in thickness towards the middle while keeping the integrity of the rest of the band. The exact middle was half the thickness of the band, while everything farther than 0.5 cm from the middle remained the full thickness. In this experiment, a band of 0.0038 cm thickness was used, which is the smaller of the two bands used in practice.

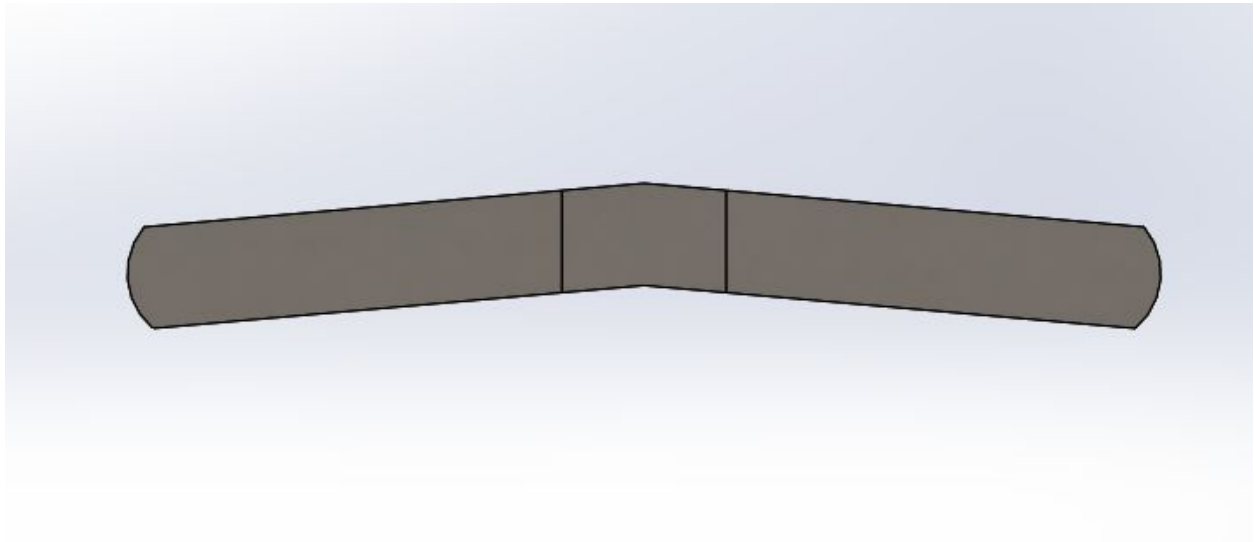


Figure 9: Side view of the matrix band. This represents the side view of both the prototype and the control as the cutout cannot be seen from this view.

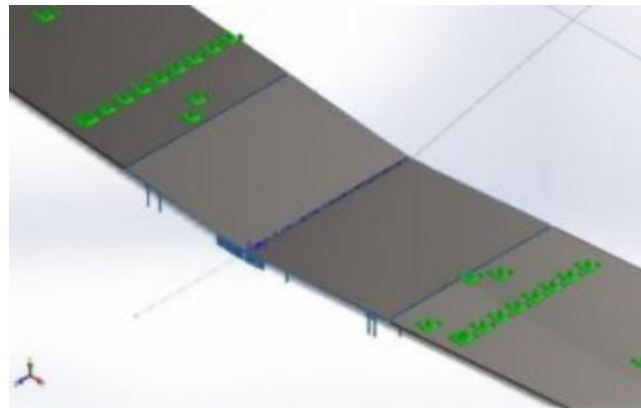


Figure 10: Top-side view of the final prototype. This view shows how the 62% incline was added. The thickness of the middle is 0.0038 cm, while the two lines that are 0.5cm away are 0.0061 cm.

A static test was performed on both bands with the same fixtures and loads. A solid mesh was placed on the material and the portion of the band outside of the area changed to eliminate any movement from the sides of the band. This was important as the only area we were concerned about was the area receiving the forces. An elastic support was added to the sloped part of the prototype and one side of the control band in the 1 cm area near the middle. In the clinic, the sloped side of the prototype would be in contact with the adjacent tooth, while the flat

side would be in contact with the filling composite. This was used to reduce the allowed deformation to match the small amount that could occur between the teeth when separated. This distance was set at 0.00508 cm, which is the thickness of the larger of the two bands used in practice. To get this value, multiple tests were run to get to this deformation on the control band. This was found to be a 351.5 kg/in² stiffness value in SolidWorks. Finally, a force was placed on the opposite side of the elastic support in the 1 cm area around the middle. This force was set at 0.544 N to mimic the force a dentist would be putting on the matrix band when contouring the new filling. This was experimentally determined by pushing on a scale with similar force a dentist would use. This force was found to be 0.272 N, but a factor of safety of two was added to account for error.

The control band resulted in a 90.46 MPa max stress, which was focused on the sides of the elastic support area. Figure 11 shows the distribution of the stress around where the force was applied. The orange area shows where the stress was highest. Since the yield stress of the AISI Type 316L stainless steel is 170 MPa, this design, unsurprisingly, does not fail. However, the proposed design had a 249 MPa max stress concentrated in the middle of the band. The section of the band with half thickness tore as the max stress in that area was greater than the yield stress. Figure 12 shows the distribution of stresses in the proposed design after rupture. Appendix III and IV describes the testing parameters and results in more detail.

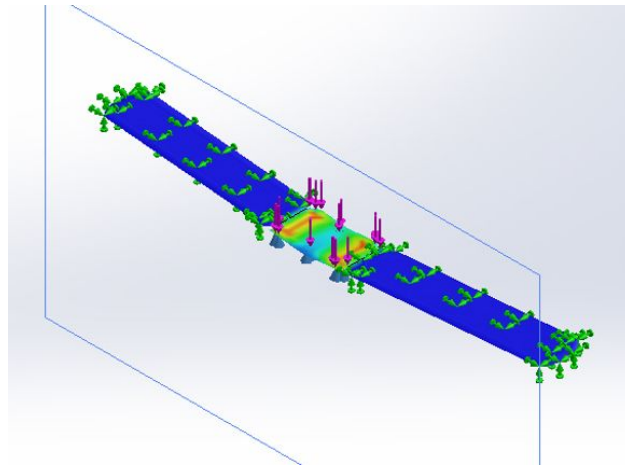


Figure 11: *Stress distribution for the control band. The highest stresses are concentrated in the orange areas.*

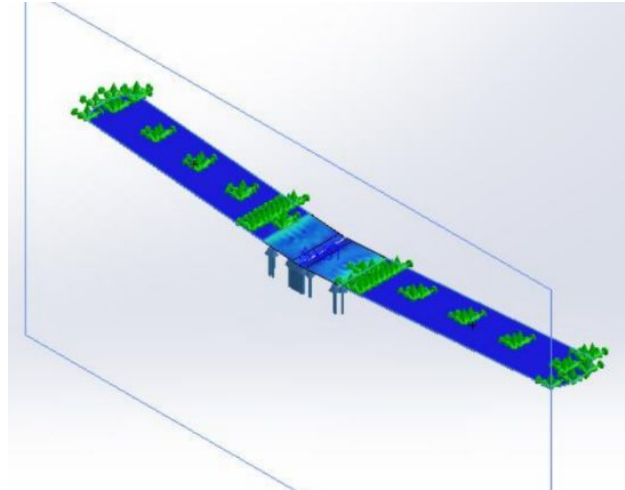


Figure 12: *Stress distribution for the final design. The dark blue section in the middle shows where the tear occurred. This area had max stresses greater than the yield stress.*

Although this test showed that the design failed, there are multiple explanations for this. The factor of safety was set at two, but since the repercussions of breakage are not very detrimental to the patient's health, a factor of safety of 1.5 might be sufficient. The force used was also not entirely accurate as the team decided on the force without having expertise in the field. In order to get a more accurate force value, a dentist should be the one using the scale. One other big factor that could be changed is the thickness of the middle of the band where the tear took place. Matrix bands used in dentistry today are either 0.00381 or 0.00508 cm thick. Since this experiment used a thickness of 0.00381 cm, there would still be 0.00127 cm of extra space that could be used. This could be incorporated by either decreasing the slope used to cut the band and ending at a larger thickness or by increasing the full thickness of the band, which would increase the thickness of the middle to 0.00254 cm instead of 0.002 cm. Both scenarios would increase the thickness of the 1 cm area, which would lead to a decrease in stress. If this decrease in stress is less than the yield stress, then this design could still be viable.

Functionality:

To assess the overall functionality of the band, we chose to create a battery of performance tests by which the client will engage with the device and compare the double hug band's effectiveness and ease of use to the device currently in use: the toeffelmeier band. The tests are intended to compare and contrast the toffelmier band with the double hug band, as our device is intended to be an improved iteration of the toeffelmeier. If the double hug band fails to outperform the toeffelmeier band, we will have to make design adjustments. These tests will be used as an assessment to qualitatively determine the overall functionality, structural integrity, and ease of use of the "doublehug" matrix band. The client will assess several criteria detailed in the testing protocol (Appendix VIII.II) by ranking the device on a scale of 1-5 by the metrics outlined in the survey (detailed in Appendix VIII. II). The client will also be prompted to make comments on any observations made that the survey did not entail. Furthermore, each question will be assigned a point value (1-5), and the scores will be tallied to quantitatively determine whether the double hug design is eligible to move forward in the prototyping process or undergo further refinement (according to the inadequacies noted in the assessment). The score will be out of 65 points. We will proceed in finalizing our prototype if the scored outcome of the assessment is in the top 5% of scores (to ensure that all the device's practical needs are satisfied). On the contrary, a score of 61/65 or below will warrant us to make any necessary design adjustments before creating a final prototype. This assessment will be repeated after redesigning, until the double hug is deemed satisfactory to move on to prototype finalization.

Future Work / Conclusion

The team is looking forward to getting more work done on this project next semester. In order to make sure that the bands that are thin enough while not fracturing in the final chosen design, the mechanical testing for the band would have to be done with a thickness of .002 inches instead of .0015 inches. This needs to be done with a factor of safety of 1.5, as this is a regular factor of safety used that will allow for a strong final prototype.

Additionally, the team would like to meet with our client to discuss the final prototype, and get some measurements of the actual force applied by the dentist while the procedure is

happening and the retainer is being used. Discussion will need to continue with our client to make sure that the final design fits with the design criteria as changes continue to be made.

Of course, the next logical steps on top of that would be a collection of materials in order to craft a prototype of the band, as well as possibly the retainer to hold both of the bands in the design. After the materials are gathered, the team will begin fabrication, followed by testing with the criteria listed above. After this testing is done, the team will present the information to the client and continue to update the prototype until it successfully accomplishes the task the project wishes to solve.

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VIII. Appendix

I. 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.

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 Triodont 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 Triodont to separate the adjacent teeth during filling [9].

4. References

1. Ryzvee, M., 2015. Matrix Bands. [online] Slideshare.net. Available at: <<https://www.slideshare.net/masurizvi/matrix-bands>> [Accessed 18 September 2020].
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 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>>

II. Testing Protocol

Functionality Testing Protocol

** insert images of procedure once we have prototype

**clarify the demarcation of the thinner portion of the band

Premise: These tests will be used as an assessment to qualitatively determine the overall functionality, structural integrity, and ease of use of the “doublehug” matrix band.

Materials:

1. Doublehug matrix band prototype

2. Universal tofflemire matrix band (0.0015 thickness)
3. 2, standard universal matrix band retainers
4. Palodent wedge guard--tooth wedge
5. Standard adult teeth model

Procedure:

1. Place the palodent wedge guard in between the molars undergoing mock restoration
2. Take one of the double hug bands and bend it to the appropriate shape of one molar making sure the area of the band marked with a rectangle (the portion with the thinner cross section area) is placed in between the tooth contact gap
 - a. Make note on the provided questionnaire how strenuous is it to bend the band to shape (1-much effort and force is required, 5- very little effort and force is required)
 - b. Make note on the provided questionnaire how much force is required to fit the band between the contact gap (1- much force is required to fit the band between the teeth--very tight fit, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit)
3. Tighten the 1st band using the retainer (as typically performed in a clinical setting)
4. Take the second double hug band and, again, bend it to the appropriate shape of the adjacent molar making sure the area of the band marked with a rectangle is placed in between the teeth
 - a. Make note on the provided questionnaire how strenuous is it to bend the band to shape (1-much effort and force is required, 5- very little effort and force is required)
 - b. Make note on the provided questionnaire how much force is required to fit the band in between the contact gap (1- much force is required to fit the band between the teeth--very tight fit, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit)
 - c. Make note on the provided questionnaire if there is a distortion of the band shape once both bands are placed next to each other (1- there is severe bending/distortion of the curvature of one/both bands upon inserting the second band, 5- there is no bending/distortion of the curvature of one/both bands upon inserting the second band)
5. Tighten the 2nd band using another retainer (as typically performed in a clinical setting)
6. On the questionnaire, provide any other comments pertaining to the rigidity of the interproximal part of the band (1- the band is relatively flimsy and the contour is easily disrupted by placing light force against it, 5- the band is appropriately rigid and the contour is not disrupted by placing light force against it)
7. Under each question on the questionnaire, elaborate on any observations that are not adequately communicated by ranking from 1-5.
8. On the molars on the opposite side of the mouth, perform a standard set up for a mock restoration

****Steps 9-15 are simply steps 1-7 performed again but using a tofflemire band. The point of the following is to gauge the performance similarities/ discrepancies between the two**

bands. All the ranks assigned should be the toffelmier performance AS COMPARED TO the double hug band (1 indicates underperformance of the toffelmier compared to double hug, 3 indicates no significant difference between the two, 5 indicated overperformance of toeffelmeier compared to double hug)

9. Place the palodent wedge guard in between the molars undergoing mock restoration
10. Take one of the tofflemire bands and bend it to the appropriate shape of one molar.
Make note on the provided questionnaire how strenuous is it to bend the band to shape (1-much effort and force is required, 5- very little effort and force is required)
 - a. Make note on the provided questionnaire, **as compared to the double hug band**, how strenuous is it to bend the band to shape (1-much effort and force is required compared to the double hug band, 5- very little effort and force is required compared to the double hug band)
 - b. Make note on the provided questionnaire, **as compared to the double hug band**, how much force is required to fit the band between the contact gap (1- much force is required to fit the band between the teeth--very tight fit compared to the double hug band, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit compared to the double hug band)
11. Tighten the 1st band using the retainer (as typically performed in a clinical setting)
 - a. Make a written note of any differences experienced in tightening the toffelmier band vs double hug band (i.e. differences in resistance, security etc.)
12. Take the second toffelmier band and, again, bend it to the appropriate shape of the adjacent molar
 - a. Make note on the provided questionnaire, **as compared to the double hug band**, how strenuous is it to bend the band to shape (1-much effort and force is required compared to the double hug band, 5- very little effort and force is required compared to the double hug band)
 - b. Make note on the provided questionnaire, **as compared to the double hug band**, how much force is required to fit the band between the contact gap (1- much force is required to fit the band between the teeth--very tight fit compared to the double hug, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit compared to the double hug)
 - c. Make note on the provided questionnaire, **as compared to the double hug band**, if there is a distortion of the band shape once both bands are placed next to each other (1- there is severe bending/distortion of the curvature of one/both bands upon inserting the second band compared to the double hug, 5- there is no bending/distortion of the curvature of one/both bands upon inserting the second band compared to the double hug)
13. Tighten the 2nd band using another retainer (as typically performed in a clinical setting)
14. On the questionnaire, provide any other comments pertaining to the rigidity of the interproximal part of the band, **as compared to the double hug band**, (1- the band is relatively flimsy and the contour is easily disrupted by placing light force against it compared to the double hug, 5- the band is appropriately rigid and the contour is not disrupted by placing light force against it compared to the double hug)

15. Again, under each question on the questionnaire, elaborate on any observations that are not adequately communicated by ranking from 1-5.

Qualitative Doug (Double Hug) Functionality Performance Assessment

Doug Double Hug Band One

1. How strenuous is it to bend the band to shape?(1-much effort and force is required, 5-very little effort and force is required). Circle one.

1 2 3 4 5

2. How much force is required to fit the band in between the contact gap (1- much force is required to fit the band between the teeth--very tight fit, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit). Circle one.

1 2 3 4 5

3. Assess the rigidity of the interproximal part of the band (1- the band is relatively flimsy and the contour is easily disrupted by placing light force against it, 5- the band is appropriately rigid and the contour is not disrupted by placing light force against it)

1 2 3 4 5

*Additional Comments:

Doug Double Hug Band Two

1. How strenuous is it to bend the band to shape?(1-much effort and force is required, 5-very little effort and force is required). Circle one.

1 2 3 4 5

2. How much force is required to fit the band in between the contact gap ? (1- much force is required to fit the band between the teeth--very tight fit, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit). Circle one.

1 2 3 4 5

3. Is there a distortion of the band shape once both bands are placed next to each other ? (1- there is severe bending/distortion of the curvature of one/both bands upon inserting the second band, 5- there is no bending/distortion of the curvature of one/both bands upon inserting the second band). Circle one.

1 2 3 4 5

4. Assess the rigidity of the interproximal part of the band (1- the band is relatively flimsy and the contour is easily disrupted by placing light force against it, 5- the band is appropriately rigid and the contour is not disrupted by placing light force against it). Circle one.

1 2 3 4 5

*Additional Comments:

Tofflemire Band One

1. **As compared to the double hug band**,how strenuous is it to bend the band to shape? (1-much effort and force is required compared to the double hug band, 5- very little effort and force is required compared to the double hug ban). Circle one.

1 2 3 4 5

2. **As compared to the double hug band**, how comfortably the band sits in between the contact gap (1- much force is required to fit the band between the teeth--very tight fit compared to the double hug band, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit compared to the double hug band). Circle one.

1 2 3 4 5

3. Comment. Are there any differences experienced in tightening the toffelmier band vs double hug band (i.e. differences in resistance, security etc.)

*Additional Comments:

Tofflemire Band Two

1. **As compared to the double hug band**, how strenuous is it to bend the band to shape (1-much effort and force is required compared to the double hug band, 5- very little effort and force is required compared to the double hug band).Circle one.

1 2 3 4 5

2. **As compared to the double hug band**, how much force is required to fit the band in between the contact gap (1- much force is required to fit the band between the teeth--very tight fit compared to the double hug, 5- very little force is required to fit the band between the teeth--seemingly appropriate fit compared to the double hug). Circle one.

1 2 3 4 5

3. **As compared to the double hug band**, if there is a distortion of the band shape once both bands are placed next to each other? (1- there is severe bending/distortion of the curvature of one/both bands upon inserting the second band compared to the double hug, 5- there is no bending/distortion of the curvature of one/both bands upon inserting the second band compared to the double hug). Circle one.

1 2 3 4 5

4. Assess the rigidity of the interproximal part of the band, **as compared to the double hug band**, (1- the band is relatively flimsy and the contour is easily disrupted by placing light force against it compared to the double hug, 5- the band is appropriately rigid and the contour is not disrupted by placing light force against it compared to the double hug). Circle one.

1

2

3

4

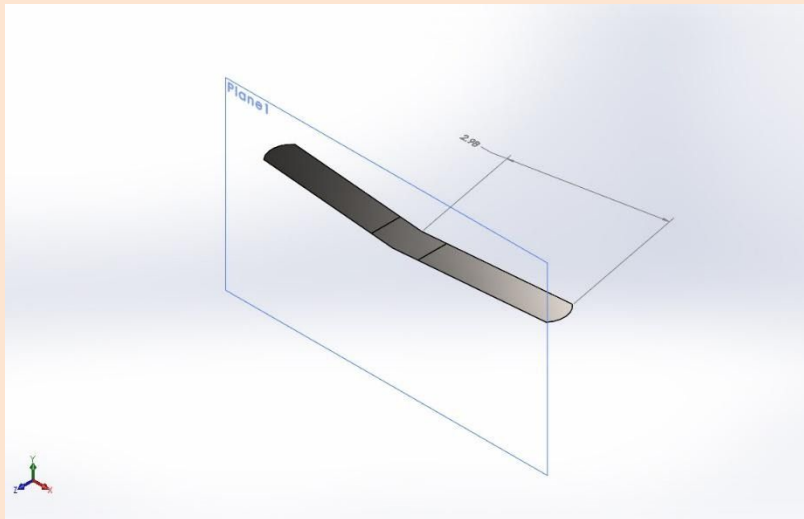
5

*Additional Comments:

Total Score: / 65

III. Results

Control Mechanical Testing Results



Simulation of Control Matrix Band

Date: Wednesday, December 2, 2020
Designer: Solidworks
Study name: Static 2
Analysis type: Static

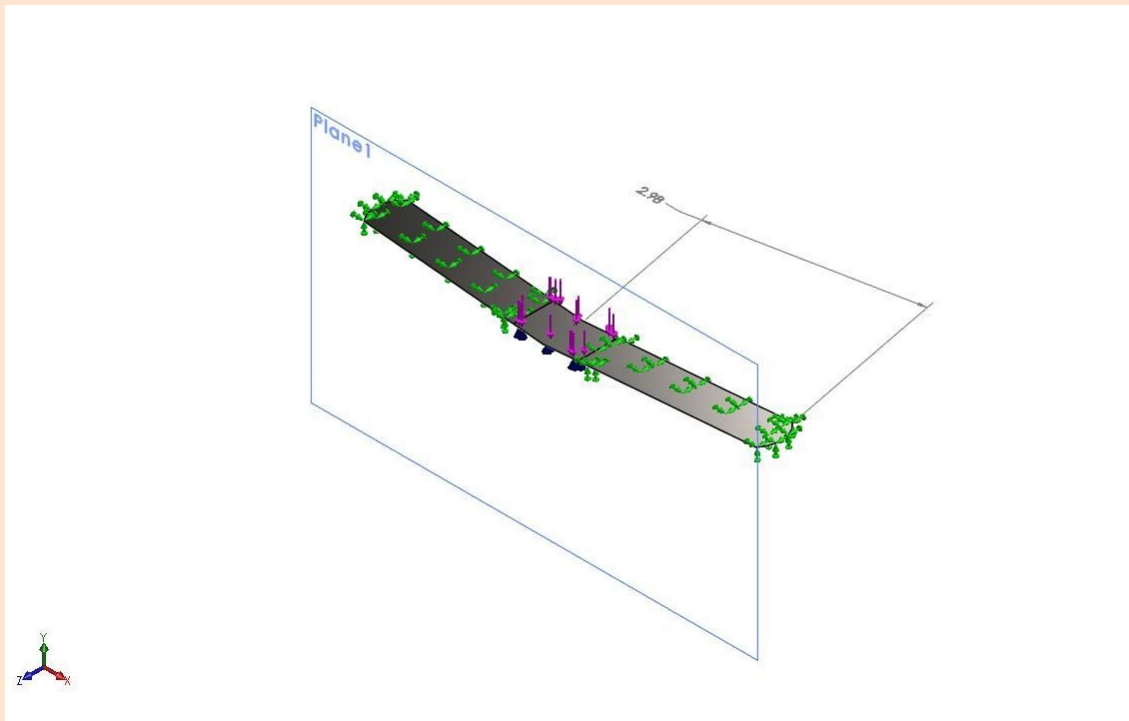
Description
Matrix band

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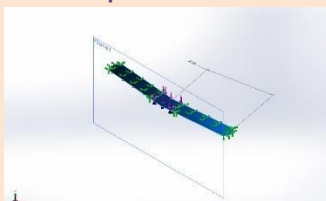
Assumptions

Model Information



Model name: matrixband NO CUT11-29-20solved
 Current Configuration: Default

Solid Bodies

| Document Name and Reference | Treated As | Volumetric Properties | Document Path/Date Modified |
|--|------------|--|---|
| Split Line6  | Solid Body | Mass:0.000118152 kg Volume:1.47193e-08 m ³ Density:8,027 kg/m ³ Weight:0.00115789 N | \\Client\D\$\matrixband NO CUT11-29-20solved.SLDP RT Nov 29 11:44:24 2020 |

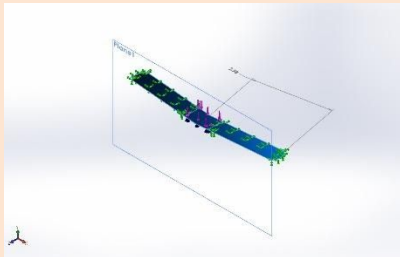
Study Properties

| | |
|--|------------------------------------|
| Study name | Static 2 |
| Analysis type | Static |
| Mesh type | Solid Mesh |
| Thermal Effect: | On |
| Thermal option | Include temperature loads |
| Zero strain temperature | 77 Fahrenheit |
| Include fluid pressure effects from SOLIDWORKS Flow Simulation | Off |
| Solver type | FFEPlus |
| Inplane Effect: | Off |
| Soft Spring: | Off |
| Inertial Relief: | Off |
| Incompatible bonding options | Automatic |
| Large displacement | Off |
| Compute free body forces | On |
| Friction | Off |
| Use Adaptive Method: | Off |
| Result folder | SOLIDWORKS document (\\Client\D\$) |

Units

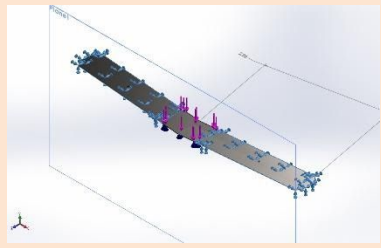
| | |
|---------------------|------------------|
| Unit system: | SI (MKS) |
| Length/Displacement | mm |
| Temperature | Kelvin |
| Angular velocity | Rad/sec |
| Pressure/Stress | N/m ² |

Material Properties

| Model Reference | Properties | Components |
|---|--|--|
|  | <p>Name: AISI Type 316L stainless steel</p> <p>Model type: Linear Elastic Isotropic</p> <p>Default failure criterion: Unknown</p> <p>Yield strength: 1.7e+08 N/m²</p> <p>Tensile strength: 4.85e+08 N/m²</p> <p>Elastic modulus: 2e+11 N/m²</p> <p>Poisson's ratio: 0.265</p> <p>Mass density: 8,027 kg/m³</p> <p>Shear modulus: 8.2e+10 N/m²</p> <p>Thermal expansion coefficient: 1.7e-05 /Kelvin</p> | <p>SolidBody 1(Split Line6)(matrixband NO CUT11-29-20solved)</p> |

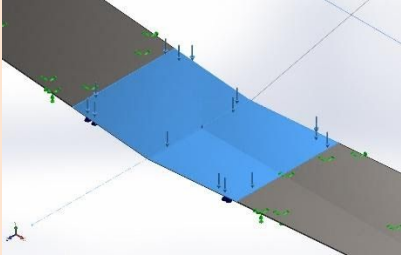
Curve Data:N/A

Loads and Fixtures

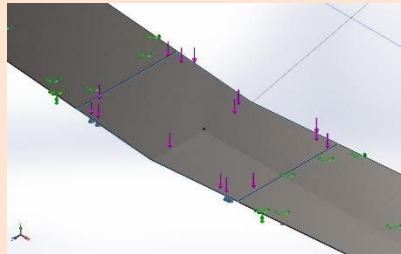
| Fixture name | Fixture Image | Fixture Details |
|--------------|---|--|
| Fixed-1 |  | <p>Entities: 2 face(s)</p> <p>Type: Fixed Geometry</p> |

| Resultant Forces | | | | |
|----------------------|------------|----------|------------|-----------|
| Components | X | Y | Z | Resultant |
| Reaction force(N) | -0.0139348 | 0.905536 | 0.00270818 | 0.905648 |
| Reaction Moment(N.m) | 0 | 0 | 0 | 0 |

| Load name | Load Image | Load Details |
|-----------|------------|--------------|
|-----------|------------|--------------|

| | | |
|----------------|---|--|
| <p>Force-1</p> |  | <p>Entities: 1 face(s) Type: Apply normal force Value: 1.2 lbf</p> |
|----------------|---|--|

Connector Definitions

| Connector Name | Connector Details | Connector Image |
|--------------------------|--|---|
| <p>Elastic Support-1</p> | <p>Entities: 1 face(s) Type: Elastic Support Normal stiffness value: 5,000 Shear stiffness value: 5,000 Units: (lbf/in)/in²</p> |  <p>Elastic Support-1</p> |

Mesh information

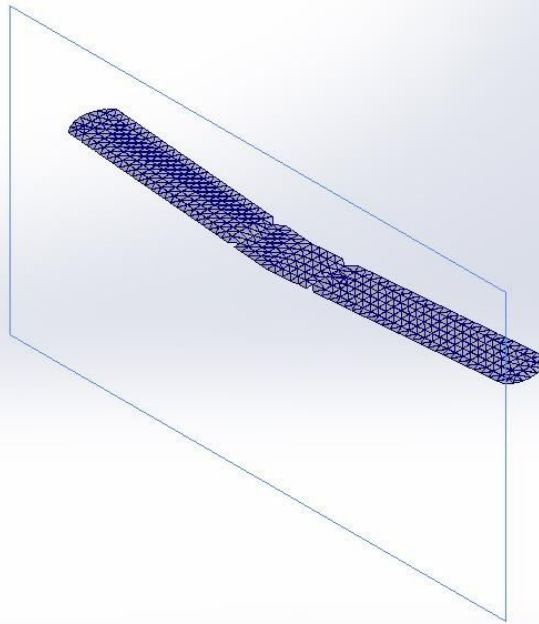
| | |
|---------------------------------------|---------------|
| Mesh type | Solid Mesh |
| Mesher Used: | Standard mesh |
| Automatic Transition: | Off |
| Include Mesh Auto Loops: | Off |
| Jacobian points for High quality mesh | 16 Points |
| Element Size | 0.101795 cm |
| Tolerance | 0.00508977 cm |

| | |
|--------------|------|
| Mesh Quality | High |
|--------------|------|

Mesh information - Details

| | |
|---|----------|
| Total Nodes | 4133 |
| Total Elements | 1874 |
| Maximum Aspect Ratio | 188 |
| % of elements with Aspect Ratio < 3 | 0 |
| Percentage of elements with Aspect Ratio > 10 | 100 |
| Percentage of distorted elements | 0 |
| Time to complete mesh(hh:mm:ss): | 00:00:03 |
| Computer name: | WIN-3021 |

Model name: matrixband NO CUT11-29-20solved
 Study name: Static 2(-Default-)
 Mesh type: Solid Mesh



SOLIDWORKS Educational Product. For Instructional Use Only.

Sensor Details

No Data

Resultant Forces

Reaction forces

| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|-------------|--------|-------------|-----------|
| Entire Model | N | -0.00225955 | 5.3529 | -0.00305129 | 5.3529 |

Reaction Moments

| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|-------|-------|-------|-----------|
| Entire Model | N.m | 0 | 0 | 0 | 0 |

Free body forces

| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|------------|------------|------------|-----------|
| Entire Model | N | 0.00964612 | 0.00910821 | 0.00145974 | 0.0133468 |

Free body moments

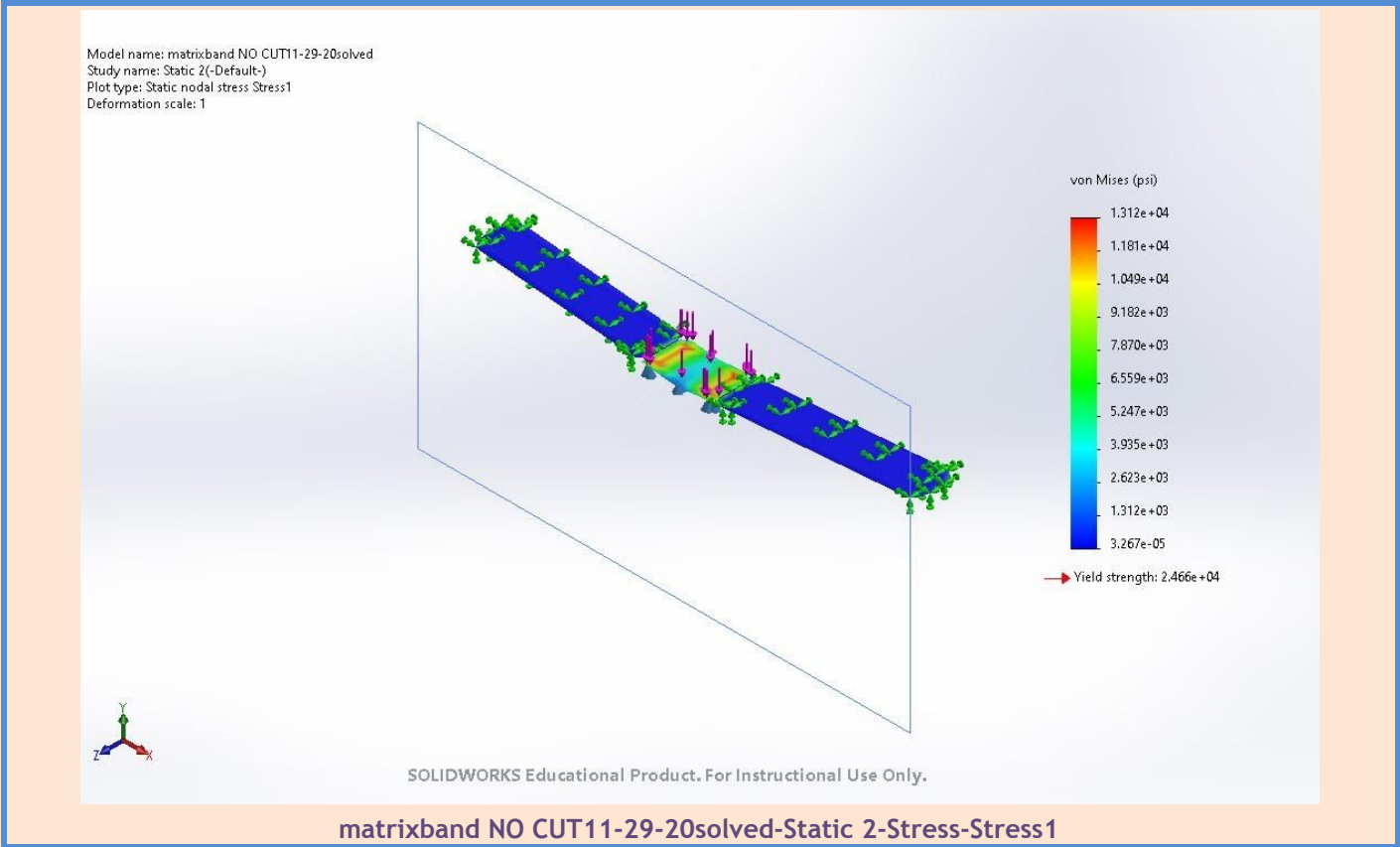
| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|-------|-------|-------|-----------|
| Entire Model | N.m | 0 | 0 | 0 | 1e-33 |

Beams

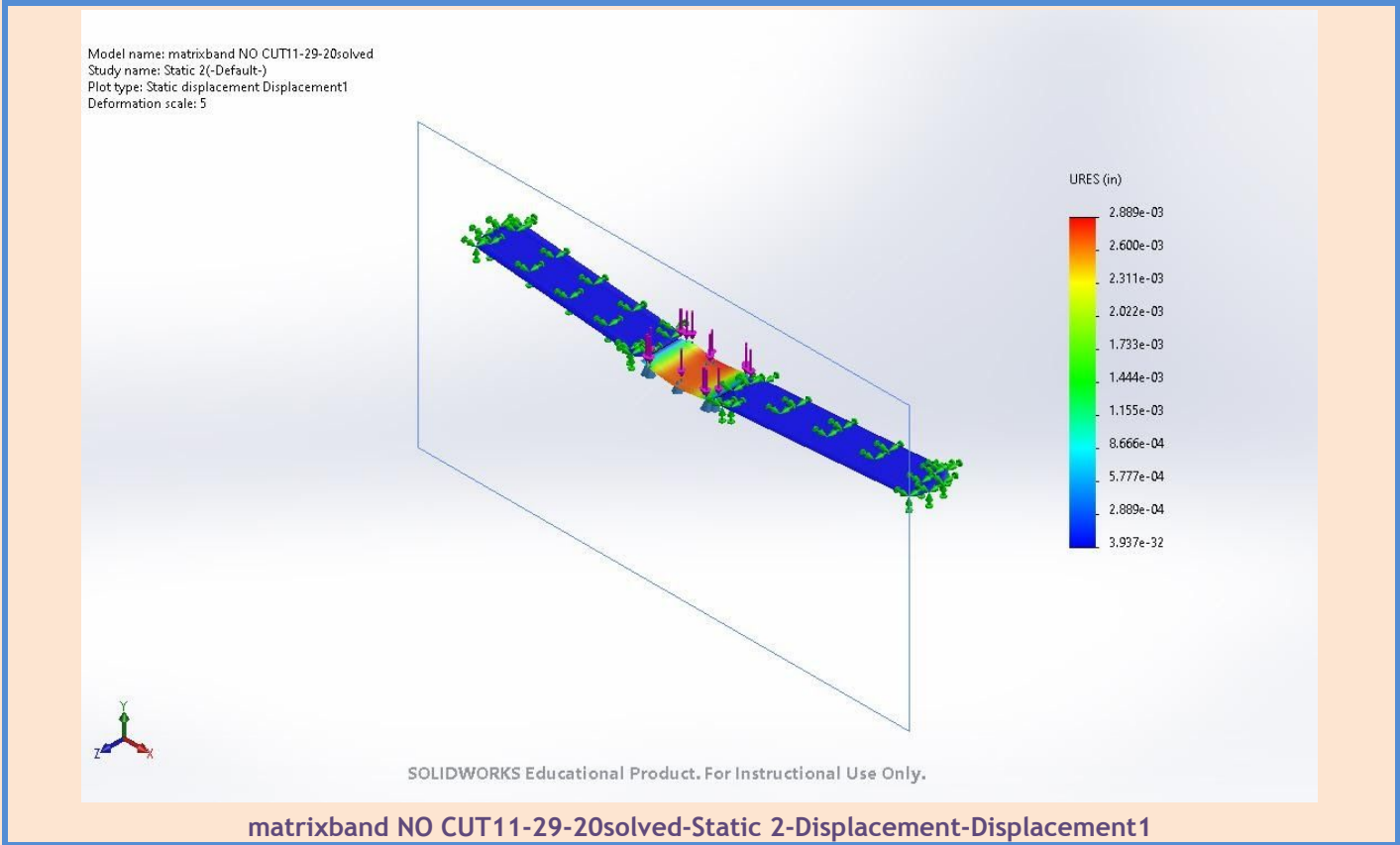
No Data

Study Results

| Name | Type | Min | Max |
|---------|-----------------------|---------------------------------------|--|
| Stress1 | VON: von Mises Stress | 0.225 N/mm ² Node: 3914 | 9.046e+07 N/mm ² Node: 404 |

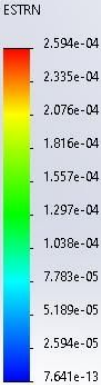
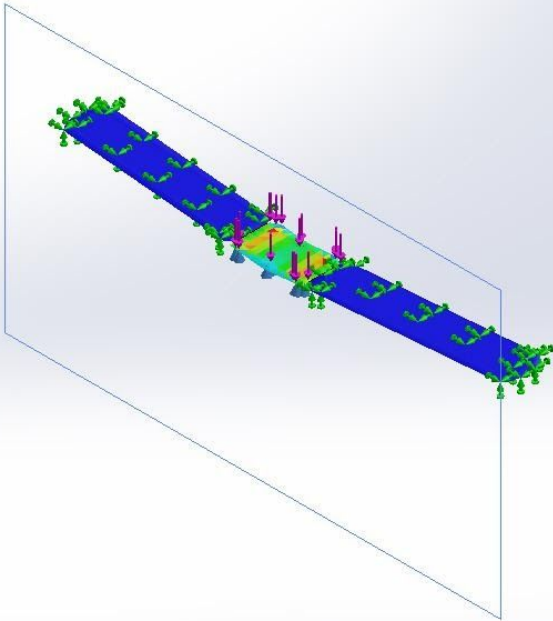


| Name | Type | Min | Max |
|---------------|------------------------------|------------------------|--------------------------|
| Displacement1 | URES: Resultant Displacement | 0.000e+00in Node: 1 | 2.889e-03in Node: 199 |



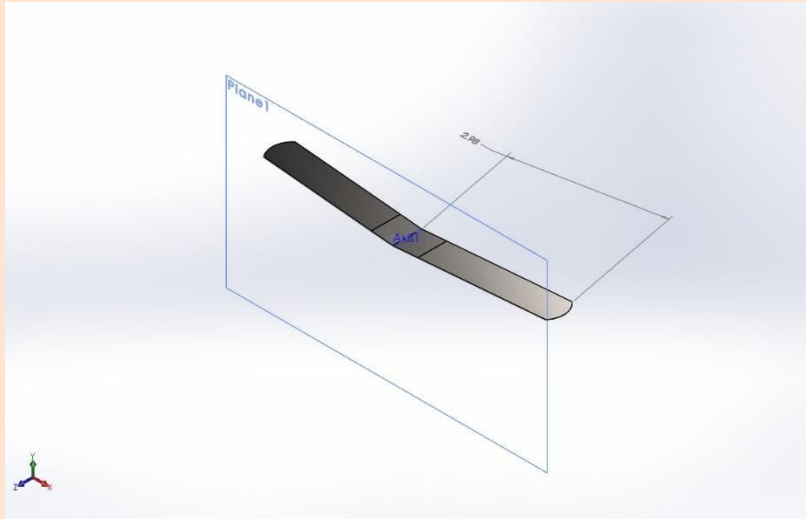
| Name | Type | Min | Max |
|---------|--------------------------|---------------------------|----------------------------|
| Strain1 | ESTRN: Equivalent Strain | 7.641e-13 Element: 214 | 2.594e-04 Element: 1726 |

Model name: matrixband NO CUT11-29-20solved
Study name: Static 2(-Default-)
Plot type: Static strain Strain1
Deformation scale: 1



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matrixband NO CUT11-29-20solved-Static 2-Strain-Strain1



Simulation of Final Design

Date: Sunday, November 29, 2020
Designer: Solidworks
Study name: Static refined mesh-force
Analysis type: Static

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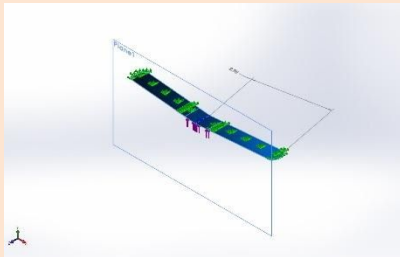
Study Properties

| | |
|--|--|
| Study name | Static refined mesh-force |
| Analysis type | Static |
| Mesh type | Solid Mesh |
| Thermal Effect: | On |
| Thermal option | Include temperature loads |
| Zero strain temperature | 298 Kelvin |
| Include fluid pressure effects from SOLIDWORKS Flow Simulation | Off |
| Solver type | FFEPlus |
| Inplane Effect: | Off |
| Soft Spring: | Off |
| Inertial Relief: | Off |
| Incompatible bonding options | Automatic |
| Large displacement | On |
| Compute free body forces | On |
| Friction | Off |
| Use Adaptive Method: | Off |
| Result folder | SOLIDWORKS document (I:\matrixband new11-28-20-Static 2) |

Units

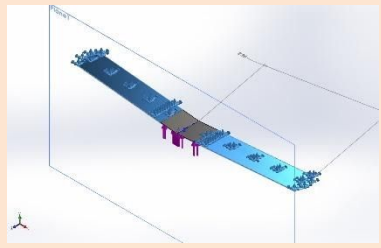
| | |
|---------------------|------------------|
| Unit system: | SI (MKS) |
| Length/Displacement | mm |
| Temperature | Kelvin |
| Angular velocity | Rad/sec |
| Pressure/Stress | N/m ² |

Material Properties

| Model Reference | Properties | Components |
|---|--|---|
|  | <p>Name: AISI Type 316L stainless steel Model type: Linear Elastic Isotropic Default failure criterion: Max von Mises Stress Yield strength: 1.7e+08 N/m² Tensile strength: 4.85e+08 N/m² Elastic modulus: 2e+11 N/m² Poisson's ratio: 0.265 Mass density: 8,027 kg/m³ Shear modulus: 8.2e+10 N/m² Thermal expansion coefficient: 1.65e-05 /Kelvin</p> | <p>SolidBody 1(Split Line1)(matrixband new11-28-20solvedfail)</p> |

Curve Data:N/A

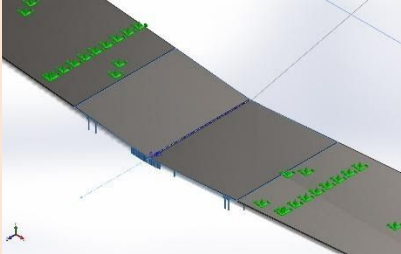
Loads and Fixtures

| Fixture name | Fixture Image | Fixture Details |
|--------------|---|--|
| Fixed-1 |  | <p>Entities: 2 face(s) Type: Fixed Geometry</p> |

Resultant Forces

| Components | X | Y | Z | Resultant |
|----------------------|------------|-----------|--------------|-----------|
| Reaction force(N) | -0.0124315 | -0.858296 | -0.000198672 | 0.858386 |
| Reaction Moment(N.m) | 0 | 0 | 0 | 0 |

| Load name | Load Image | Load Details |
|-----------|------------|--------------|
|-----------|------------|--------------|

| | | |
|-----------------------|---|---|
| <p>Force-1</p> |  | <p>Entities: 1 face(s) Type: Apply normal force Value: 1.2 lbf</p> |
|-----------------------|---|---|

Contact Information

No Data

Resultant Forces

Reaction forces

| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|------------|----------|------------|-----------|
| Entire Model | N | -0.0223731 | -5.21491 | -0.0014857 | 5.21496 |

Reaction Moments

| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|-------|-------|-------|-----------|
| Entire Model | N.m | 0 | 0 | 0 | 0 |

Free body forces

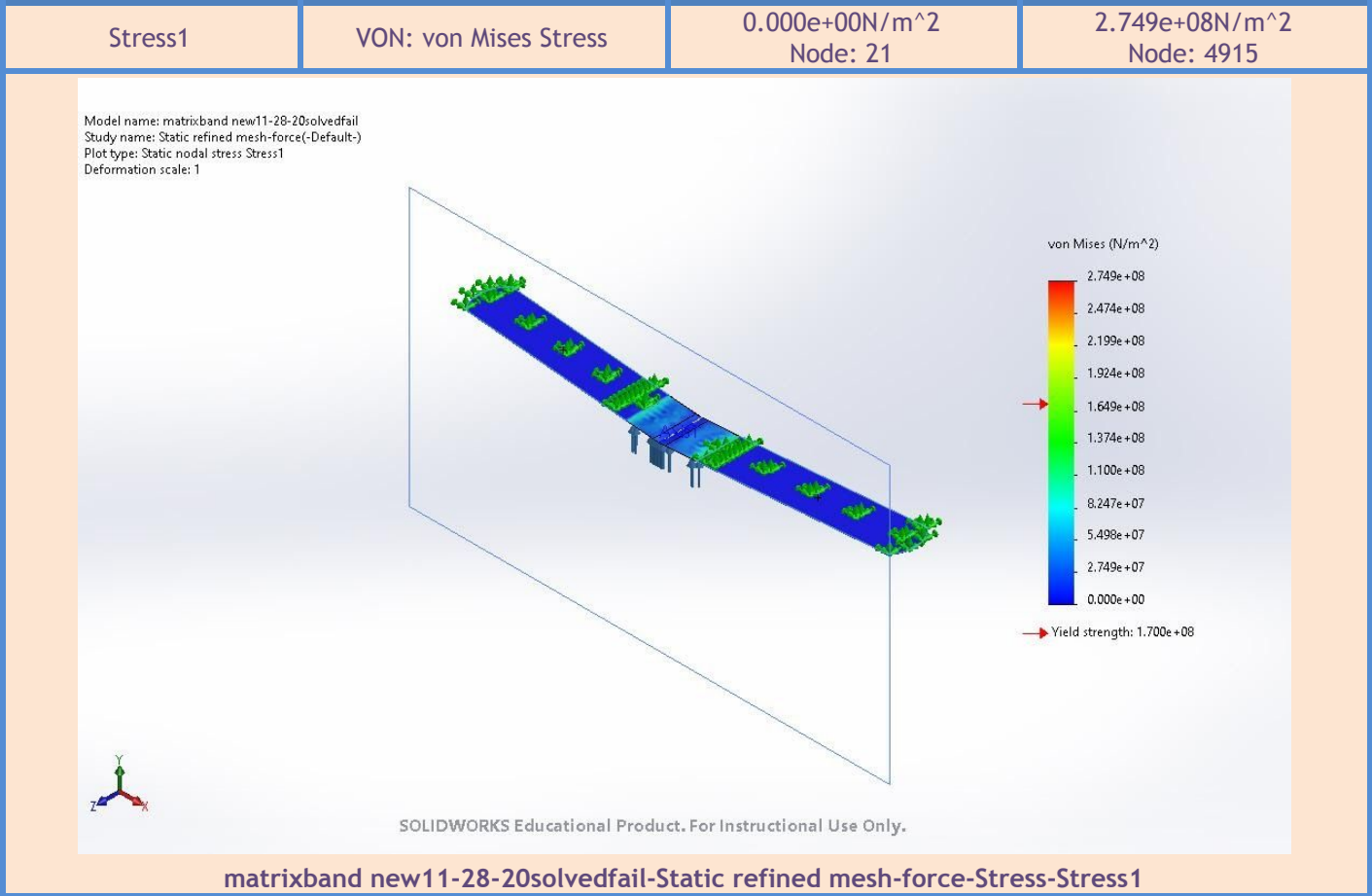
| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|-------|-------|-------|-----------|
| Entire Model | N | 0 | 0 | 0 | 0 |

Free body moments

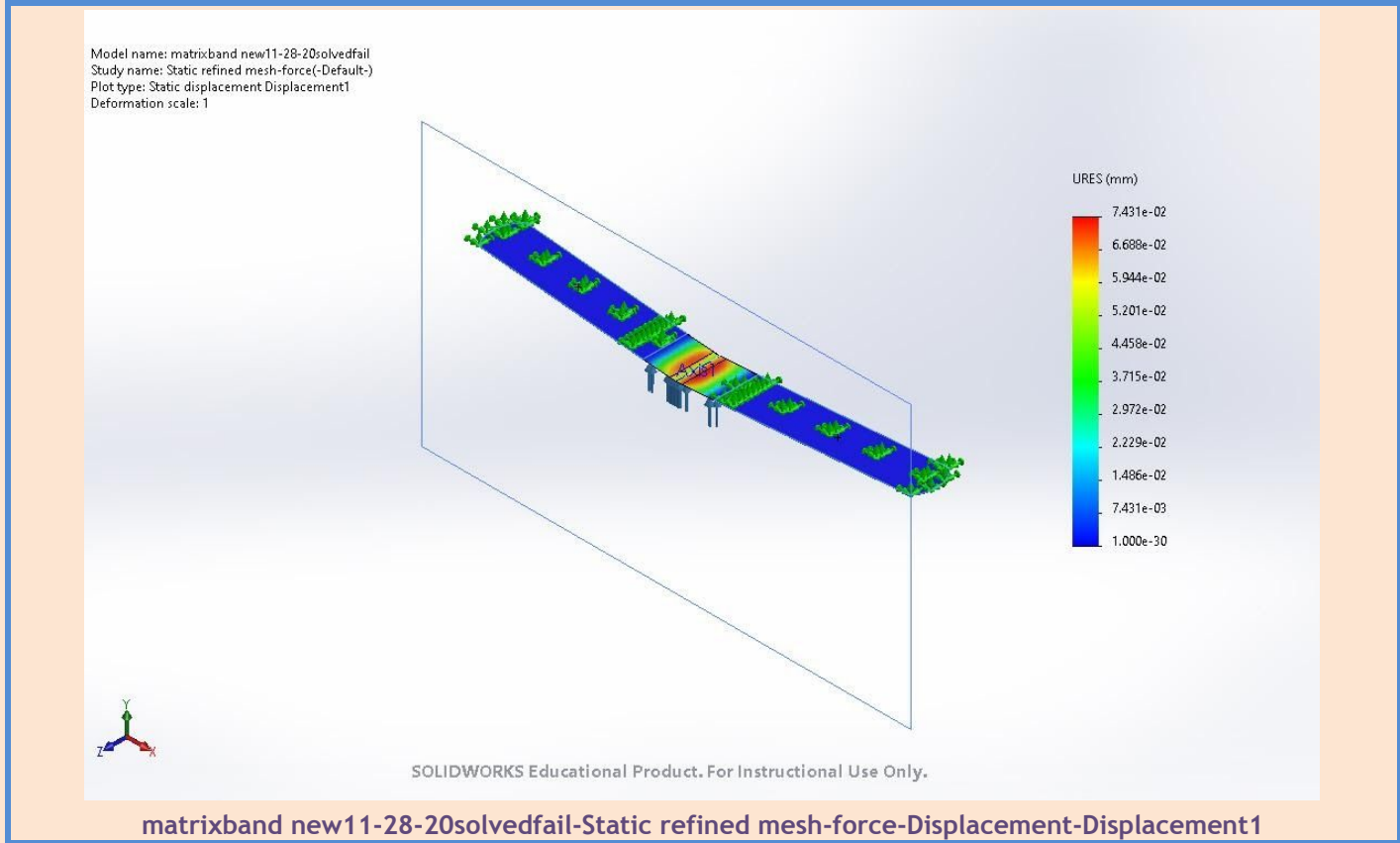
| Selection set | Units | Sum X | Sum Y | Sum Z | Resultant |
|---------------|-------|-------|-------|-------|-----------|
| Entire Model | N.m | 0 | 0 | 0 | 0 |

Study Results

| Name | Type | Min | Max |
|------|------|-----|-----|
|------|------|-----|-----|

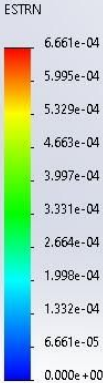
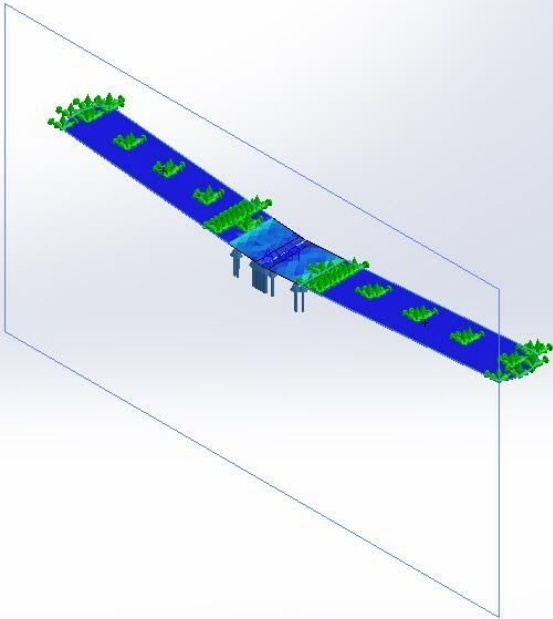


| Name | Type | Min | Max |
|---------------|------------------------------|------------------------|---------------------------|
| Displacement1 | URES: Resultant Displacement | 0.000e+00mm Node: 8 | 7.431e-02mm Node: 4803 |



| Name | Type | Min | Max |
|---------|--------------------------|-------------------------|----------------------------|
| Strain1 | ESTRN: Equivalent Strain | 0.000e+00 Element: 1 | 6.661e-04 Element: 1856 |

Model name: matrixband new11-28-20solvedfail
Study name: Static refined mesh-force(-Default-)
Plot type: Static strain Strain1
Deformation scale: 1



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matrixband new11-28-20solvedfail-Static refined mesh-force-Strain-Strain1