APPROXIMATING SURFACE MATRIX BAND FOR DENTIST TO USE FOR PATIENTS

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Abstract

Background

Our objective is to create a dual matrix-band which can provide a tooth contour for the filling composite applied to adjacent teeth undergoing restoration. The following is an account of our design, manufacturing, and testing plans formed to successfully produce a dual matrix band which may alleviate the tedium of installing individual matrix bands on adjacent teeth undergoing restoration.

Methods

The team intended to fabricate each band by taking a sheet of 316L type stainless steel (of 0.002 in thickness and about 3 inches in length) and thinning a 1x1in square at the center of the band to 0.001 inches in thickness. To achieve dimensional precision, outsourcing fabrication was considered. Detailed mechanical and functional testing plans were arranged to assess the viability of the product post manufacturing.

Results

Simulated mechanical testing proved that the thinnest part of the band (0.0019 cm) could withstand a max stress of 249 MPa before failure, so a band of 0.00254 cm will be used instead

for fabrication. Functionality testing was unable to be conducted as the prototype could not be fabricated in a timely fashion.

Conclusions

Mechanical testing suggests that the design and material of choice are optimal for durability during clinical use. Functionality testing must be executed to determine the design's ease of use and practicality before the tool is deemed appropriate for clinical use.

Practical Implications

The viability of our design will provide dentists with another matrix band alternative which gives support to adjacent teeth undergoing repair, maintains a tight and flossable tooth contact, and reduces the procedure time

Key Words

Matrix Band • Class II Restoration • Cavity

Tooth decay is a very common and painful experience approximately 91% of adults 20 - 64 years of age suffered from in 2011-2012 [1]. In addition, dental caries, also known as cavities, are the most prevalent disease that affects both children and adults [2]. 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 [3]. 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) [4]. 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 [5]-- prove to be very challenging to restore because of the need to maintain a tight contact and maintain the tooth

contour[6]. Matrix bands are meant to assist dentists by providing a contrours 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.

Our client is well versed with the Tofflemire matrix band, which is a popular matrix band used by dentists. The Toffelmier matrix band comes in a variety of thicknesses (ranging from 0.0015 - 0.002 in [7] 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 [8]). 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.

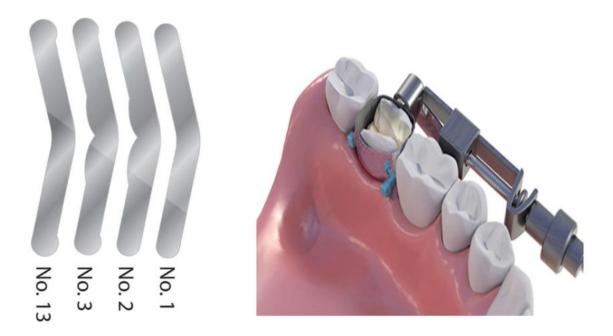


Figure 1: Image of a universal Tofflemire matrix bands unformed (left) and formed around the tooth in the standard set up. The tooth wedge (used to increase the contact gap) and retainer (used to maintain the band shape) are also depicted in the right image. [10][11]

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[12]).

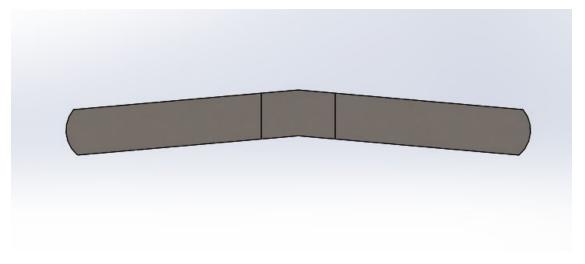
Matrix bands are a commonly used dental tool which assist dentists by providing a wall to maintain a tooth's structure and shape during restorative procedures, such as cavity fillings[13].During typical filling procedures--particularly filling cavities on interproximal surfaces--dentists must fill one 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. Our matrix band design alleviates 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. Upon testing, the finalized product should also maintain the tensile strength, malleability, and space efficiency of current matrix bands. 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.

Methods

The "Doug" is essentially a modified version of the current device that our client uses, therefore, the traditional material of choice (most likely the 316L type stainless steel based on its biocompatibility and corrosion resistance [14]) will be used in the fabrication of our prototype. We suspect the palodent tooth wedge (or any tooth wedge) would be compatible to use with our dual matrix band system. For testing purposes, two retainers will be used to tighten the matrix bands and hold their position, however, future work will warrant an updated retainer which can accommodate two bands.

Fabrication planning began with determining the required thickness of the double-sided band through our preliminary research, and the matrix band thickness was determined to be somewhere in the range of .0015 - .002 inches. We presumed that making each matrix band--the portion of the band that is placed between the teeth-- half this thickness (0.00075 - 0.001 in) will ensure that the thickness when the two bands are adjacent to one another does not exceed the natural tooth contact gap. To achieve this idea, we intended to fabricate each band by taking a sheet of 316L type stainless steel (of 0.002 in thickness and about 3 in in length) and thinning a 1x1in square at the center of the band to 0.001 inches in thickness. To ensure that the precision we desire for the center thickness of the matrix band is achieved, we initially pursued outsourcing fabrication, as we lack the machining skills and the 3D printer quality to do it ourselves; however, it has proven to be a challenge this year to find a manufacturing company with the technology to create a part with the dimensions we need. In response to this, we are currently deciding upon an alternative design, and or alternative fabrication method: these tentative plans will be expanded further in the future work section.

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 2 shows the SolidWorks model of the matrix band used today, which was the control for the experiment. Figure 2 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 [14]. 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.



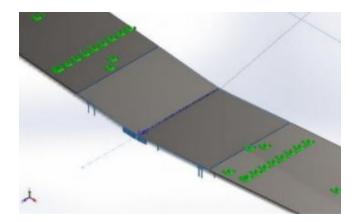


Figure 2: (Top) Side view of the matrix band. This represents the side view of both the prototype and the control as the cutout cannot be seen from this view. (Bottom) Top-side view of the final prototype. This view shows how the 62% incline was added. The thickness of the middle is 0.0038 cm, while the two lines that are 0.5cm away are 0.0061 cm.

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 toefelmeier 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 (included in the appendix) by ranking the device on a scale of 1-5 by the metrics outlined in the survey (detailed in the appendix). 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.

Discussion

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 3 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 3 shows the distribution of stresses in the proposed design after rupture. Appendix III and IV describes the testing parameters and results in more detail.

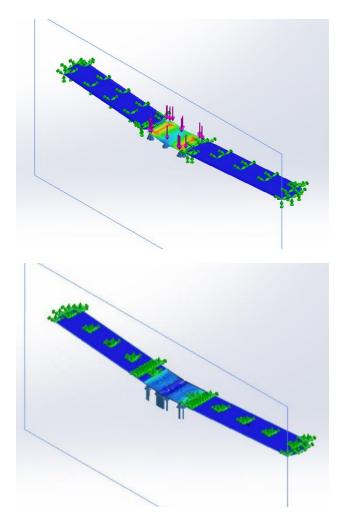


Figure 3: (Top) Stress distribution for the control band. The highest stresses are concentrated in the orange areas. (Bottom) Stress distribution for the final design. The dark blue section in the middle shows where the tear occurred. This area had max stresses greater than the yield stress.

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 testing has not been completed, due to a delay in the manufacturing process. The team intends to make an upscaled prototype from 316L type stainless steel sheets of the new thickness to simulate functionality testing in the time being. Since the design failed with a 0.00381 cm thickness, a 0.00508 cm thickness will be used instead. This decreases the stress on the band enough to become below the yield stress. One manufacturer has responded back saying they are able to make the design. The team just needs to now get confirmation from the client to get that process started. The manufacturer is Big Blue Saw. Since there is a minimum of 200 dollars on a special order, a couple bands would need to be made. It would take around 10-12 days to complete the fabrication, so testing could still be completed this semester.

Conclusions

The viability of the matrix band design proposed is contingent on its functionality testing and mechanical testing success. Upon functionality testing of the upscaled prototype, the team will decide whether the design satisfies the requirements of ease of use and application/ removal efficiency as compared to the existing tofflemire matrix band. The team will first try to complete testing with a scaled up version of the band until the final prototype from the manufacturer is finished.

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Appendix

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.

<u>Client Requirements</u>

- 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.

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 [9].



Figure 2: Using the Wave-Wedge from Triodent to separate the adjacent teeth during filling [9].

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10. Preliminary Designs

Design 1: The Butterfly

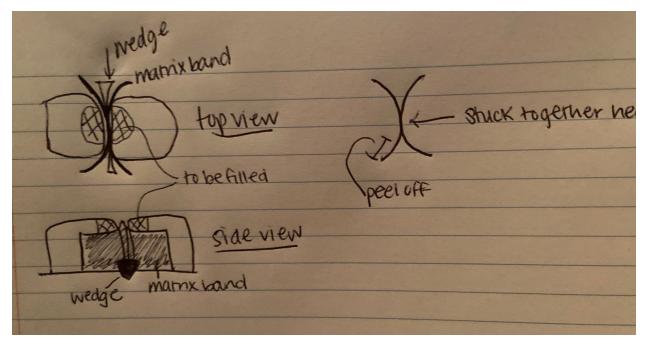


Figure 5: Sketch of the "butterfly" design. The crosshatched area is where the filling would need to be placed.

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)

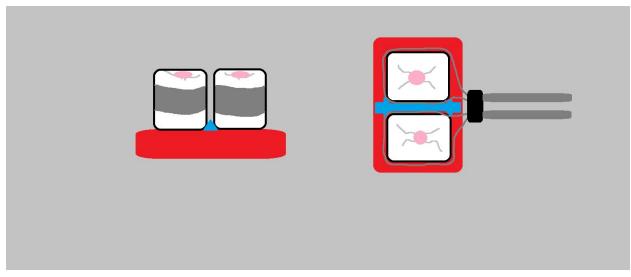


Figure 6: Model of the Doug design showing a top and side view. The blue portion is the wedge, the bands are in silver, and the teeth are white.

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

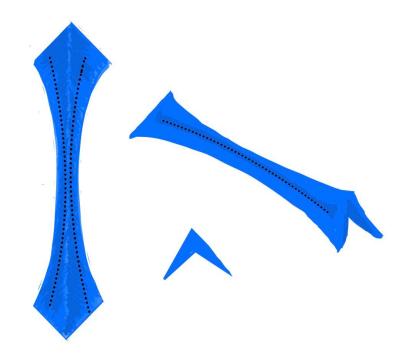


Figure 7: Sketch of the potato wedge design showing all views. The dotted lines are where the bands would be placed.

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]

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 eat through more cost.

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 a terrible 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.

11. Proposed Final Design: Doug

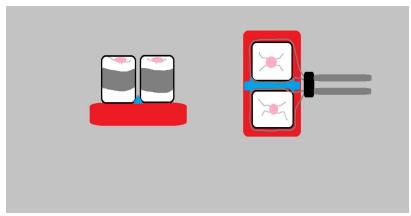


Figure 8: Repeated image of the Doug design.

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.

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

- 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
- 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

- 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.

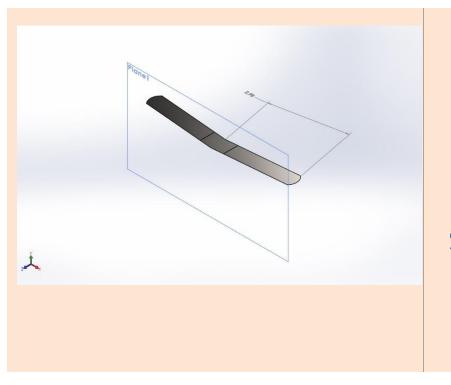
	1	2	3	4	5
--	---	---	---	---	---

*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

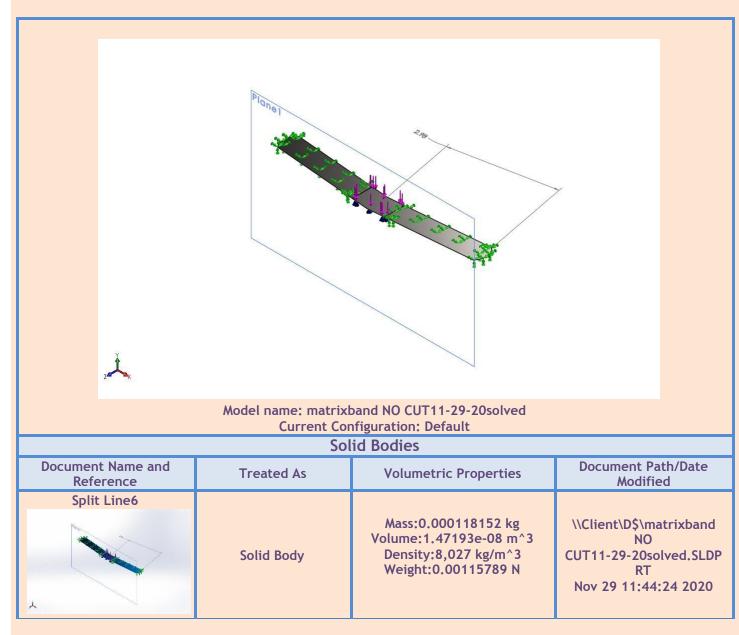
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Description Matrix band

Assumptions

Model Information

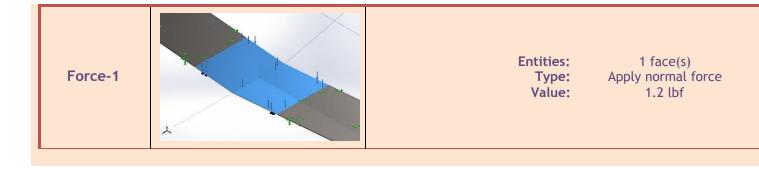


Study Properties				
Study name	Static 2			
Analysis type	Static			
Mesh type	Solid Mesh			
Thermal Effect:	On			
Thermal option	Include temperature loads			
Zero strain temperature	77 Fahrenheit			
Include fluid pressure effects from SOLIDWORKS Flow Simulation	Off			
Solver type	FFEPlus			
Inplane Effect:	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\$)			

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

Material Properties					
Model Reference	Proper	Properties			
t to the second se	Name: Model type: Default failure criterion: Yield strength: Tensile strength: Elastic modulus: Poisson's ratio: Mass density: Shear modulus: Thermal expansion coefficient:	AISI Type 316L stainless steel Linear Elastic Isotropic Unknown 1.7e+08 N/m^2 4.85e+08 N/m^2 2e+11 N/m^2 0.265 8,027 kg/m^3 8.2e+10 N/m^2 1.7e-05 /Kelvin	SolidBody 1(Split Line6)(matrixband NO CUT11-29-20solved)		
	Curve Data	a:N/A			

Loads and Fixtures						
Fixture name	Fi	xture Image		Fixture Details		
Fixed-1	*			2 face(s) Fixed Geometry		
		Res	sultant Forces			
Compone	ents	Х	Y	Z	Resultant	
Reaction for	n force(N) -0.0139348		0.905536	0.00270818	0.905648	
Reaction Mome	Reaction Moment(N.m) 0		0	0	0	
Load name	Load name Load Image Load Details					



Connector Definitions

Connector Name	Connector Details		Connector Image
Elastic Support-1	Entities: Type: Normal stiffness value: Shear stiffness value: Units:	1 face(s) Elastic Support 5,000 5,000 (lbf/in)/in^2	Lastic Support-1

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 informa	tion - 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	
Study name: Satic 2(-Default-) Mesh type: Solid Mesh	.ter Instructional Use Only.	



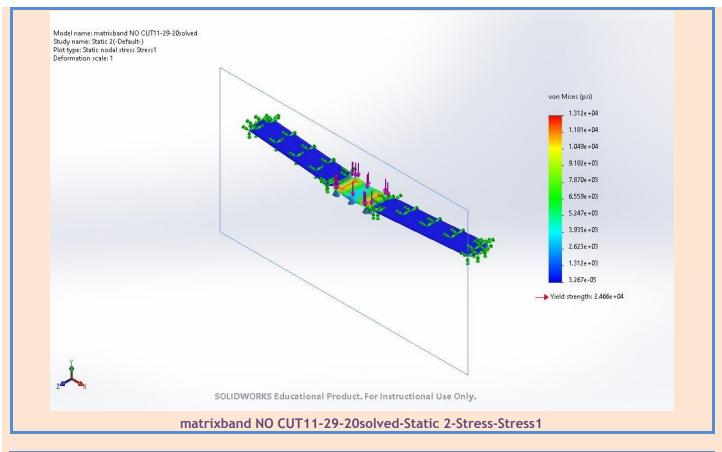
Reaction forces						
Selection set	Units	Sum X	Sum Y	Sum Z	Resultant	
Entire Model	Ν	-0.00225955	5.3529	-0.00305129	5.3529	
	Reaction Moments					
Selection set	Units	Sum X	Sum Y	Sum Z	Resultant	
Entire Model	N.m	0	0	0	0	
Free body forces						
Selection set	Units	Sum X	Sum Y	Sum Z	Resultant	
Entire Model	Ν	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	

Resultant Forces

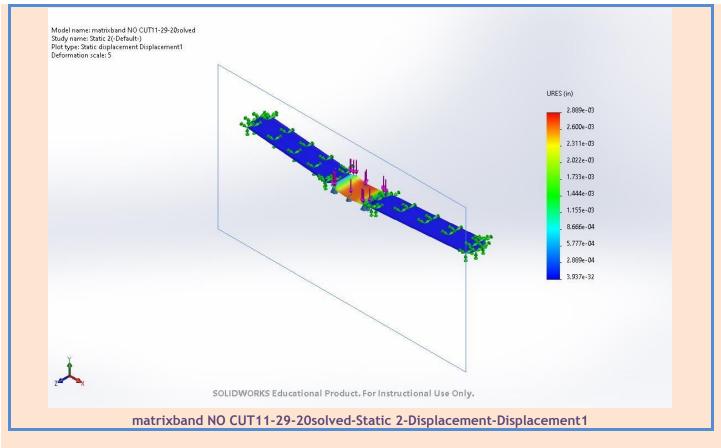
Beams No Data

Study Results

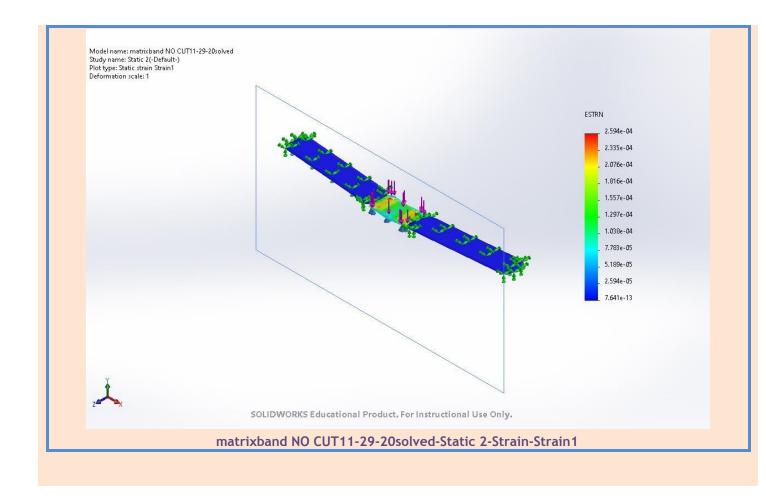
Name	Туре	Min	Max	
Stress1	VON: von Mises Stress	0.225 N/mm^2 Node: 3914	9.046e+07 N/mm^2 Node: 404	

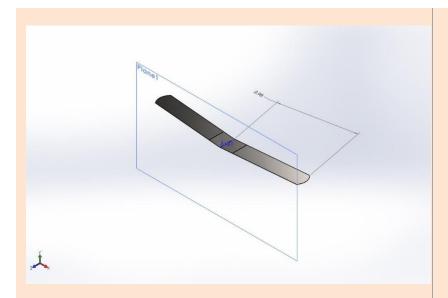


Name	Туре	Min	Max
Displacement1	URES: Resultant Displacement	0.000e+00in Node: 1	2.889e-03in Node: 199



Name	Туре	Min	Max
Strain1	rain1 ESTRN: Equivalent Strain	7.641e-13	2.594e-04
Straini		Element: 214	Element: 1726





Simulation of Final Design

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

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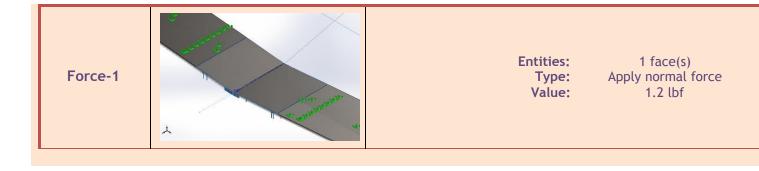
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Study Properties					
Study name	Static refined mesh-force				
Analysis type	Static				
Mesh type	Solid Mesh				
Thermal Effect:	On				
Thermal option	Include temperature loads				
Zero strain temperature	298 Kelvin				
Include fluid pressure effects from SOLIDWORKS Flow Simulation	Off				
Solver type	FFEPlus				
Inplane Effect:	Off				
Soft Spring:	Off Off Automatic				
Inertial Relief:					
Incompatible bonding options					
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)				

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

Material Properties					
Model Reference	Prope	erties	Components		
t to the second se	Name: Model type: Default failure criterion: Yield strength: Tensile strength: Elastic modulus: Poisson's ratio: Mass density: Shear modulus: Thermal expansion coefficient:	AISI Type 316L stainless steel Linear Elastic Isotropic Max von Mises Stress 1.7e+08 N/m^2 4.85e+08 N/m^2 2e+11 N/m^2 0.265 8,027 kg/m^3 8.2e+10 N/m^2 1.65e-05 /Kelvin	SolidBody 1(Split Line1)(matrixband new11-28-20solvedfail)		
	Curve Dat	a:N/A			

			and Fixtures		
Fixture name	Fixture name Fixture Image			Fixture Details	
Fixed-1			Entities: Type:	2 face(s) Fixed Geometry	
		Re	sultant Forces		
Compone	ents	Х	Y	Z	Resultant
Reaction for	rce(N)	-0.0124315	-0.858296	-0.000198672	0.858386
Reaction Moment(N.m)		0	0	0	0
Load name	L	.oad Image		Load Details	



Contact Information No Data

Resultant Forces

Reaction forces						
Selection set	Units	Sum X	Sum Y	Sum Z	Resultant	
Entire Model	Ν	-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	Ν	0	0	0	0	
Free body moments						
Selection set	Units	Sum X	Sum Y	Sum 7	Resultant	

0

0

0

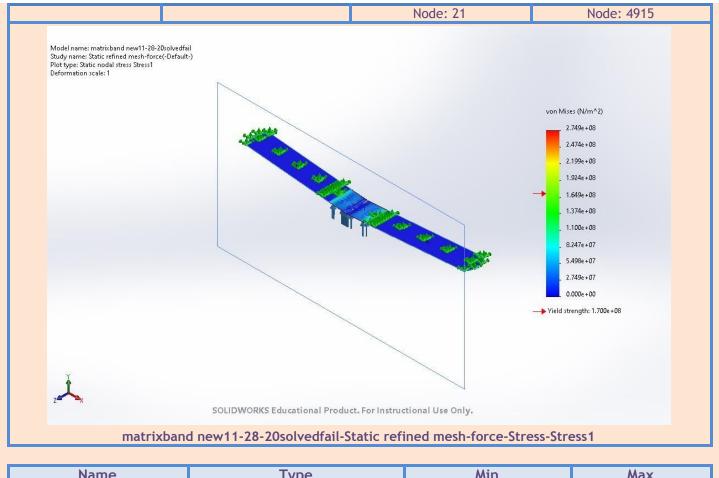
0

Entire Model

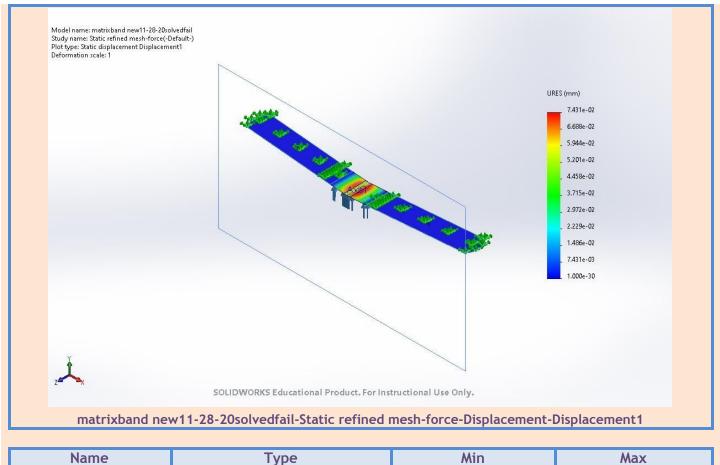
N.m

Study Results

Name	Туре	Min	Max
Stress1	VON: von Mises Stress	0.000e+00N/m^2	2.749e+08N/m^2



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



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

