University of Wisconsin - Madison

Improved Method of Securing Surgical Drains

BME 400

12/14/2022

Client: Dr. Katie Kalscheur

Advisor: Dr. Tracy Puccinelli

Team Members:

Dana Stumpfoll (Team Leader)

Lauren Heller (BSAC)

Rebekah Makonnen (BPAG)

Oscar Zarneke (Communicator)

Abdoulahi Bah (BWIG)

ABSTRACT

Development of a new and improved method for securing surgical drains can improve the lives of patients who need them after surgery to prevent accumulation of bodily fluids. The current method of securing surgical drains is to attach them to the body using a single suture. This method can be very uncomfortable for patients as the drain tends to get tugged on and can pull on the single suture site. Additionally, the tugging can lead to drain displacement, slowing down the overall healing process. After extensive research on current methods, a design has been created that aims to distribute the pressure at the suture site and secure the surgical drain in place. The final design must be comfortable for the patient and also effective at decreasing tension at the suture site for the duration that the drains need to be used. After evaluating the preliminary designs, plans for fabrication and testing were created to evaluate the design's effectiveness. These plans included obtaining all materials, creating a surgical drain site model, and testing the effectiveness of the design in securing the drain in place. Following testing, the team decided to move forward with the hydrocolloid clip design. This design is the most reliable for holding the drain in place and utilizes the most reliable adhesive material. Future work needs to be done to ensure this design will be comfortable and to determine if further modifications are necessary.

TABLE OF CONTENTS

ABSTRACT 2

TABLE OF CONTENTS 3

1 INTRODUCTION 4
- 1.1 Motivation / Global Impact 4
- 1.2 Existing Devices & Current Methods 4
- 1.3 Problem Statement 5

2 BACKGROUND 6
- 2.1 Anatomy and Physiology 6
- 2.2 Client Information 6
- 2.3 Product Design Specification 6

3 PRELIMINARY DESIGNS 7
- 3.1 Design 1 - Adhesive Bandage with Clip 7
- 3.2 Design 2 - Interior Pressure Distributing Flaps 8
- 3.3 Design 3 - Exterior Pressure Distributing Flaps 10

4 PRELIMINARY DESIGN EVALUATION 11
- 4.1 Design Matrix 11
- 4.2 Evaluation of Preliminary Designs 11
- 4.3 Proposed Final Design 12

5 DEVELOPMENT PROCESS 12
- 5.1 Materials 12
- 5.2 Fabrication Methods 13
- 5.3 Testing 13
- 5.4 Results 16
- 5.5 Discussion 17
- 5.6 Final Prototype 18

6 CONCLUSIONS 19

7 REFERENCES 21

8 APPENDIX 24
- 8.1 Product Design Specifications 24
- 8.2 Material Expenses 32
- 8.3 Testing Protocols 35
- 8.4 MATLAB Code 37
- 8.5 FEBio Results 63

1 INTRODUCTION

1.1 Motivation / Global Impact

Surgical drains are commonly used for a variety of purposes: therapeutically, palliatively, diagnostically, prophylactically, and for monitoring fluid output [1]. There were an estimated 75.5 million drains sold in 2020 with projections reaching 95.5 million by 2030 [2]. However, because of their current methods of fixation, surgical drains are reported to be uncomfortable, with tugging on the sutures that hold them in place. This is particularly relevant when the drain must be in place for extended periods of time, as drainage must consistently be less than 25-30 cc of fluid a day before removal, which can take up to 1-5 weeks [3], [4].

1.2 Existing Devices & Current Methods

Surgical drains are secured using many different methods based on the attending's preference and the equipment available. However, by and large, the most common method involves using sutures. Sutures are tied with various techniques (Figure 1) [5]–[9], but they will all encounter the same patient comfort issue of tugging on the sutures. Tape (Figure 2) [9] or disposable adhesive devices (Figure 3) [10]–[12] may be used instead to increase patient comfort. They function by attaching a locking mechanism (e.g., clip, locking tie, etc.) to an adhesive. The locking mechanism attaches to the drain tube, holding it in place while the adhesive fixes the device to the skin around the drain insertion site. These techniques, though, only last for approximately a week before requiring removal as the adhesive wears down.

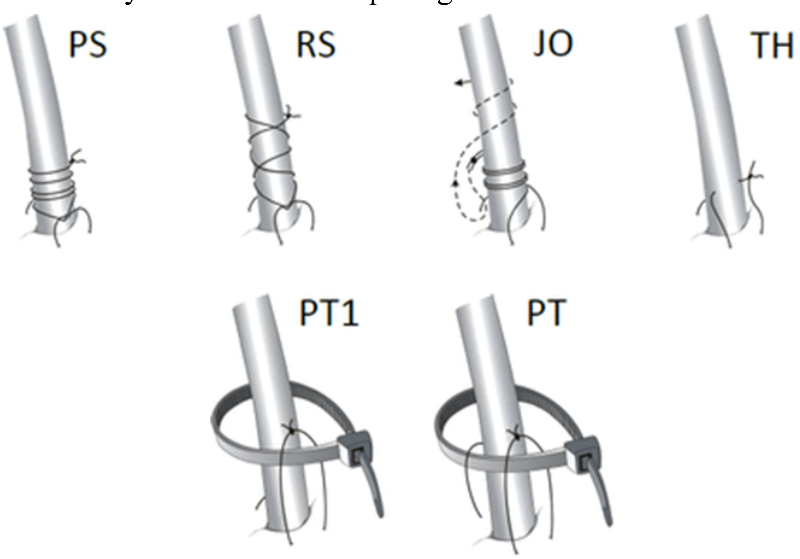


Figure 1: A non-exhaustive diagram of suturing used to secure surgical drains including Purse String (PS), Roman Sandal (RS), Jo'burg (JO), through the tube (TH), one-pass locking tie (PT1), and two-pass locking tie (PT2) [9].

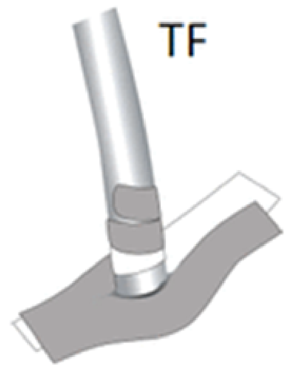


Figure 2: A tape fixation method for securing surgical drains using Leukoplast tape [9].

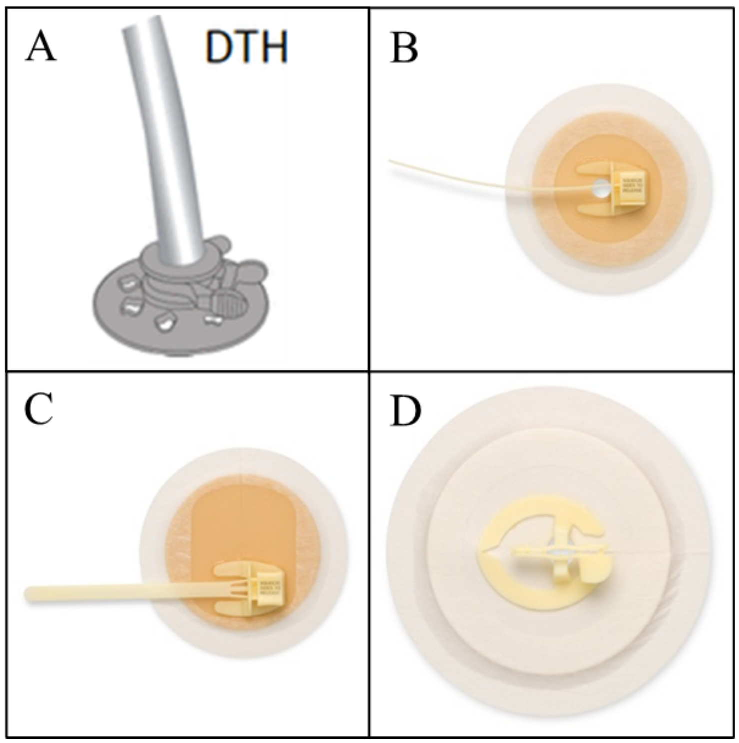


Figure 3: Disposable tube attachment devices from (A) Changzhou Haiers Medical Devices Co. Ltd. [9] and (B-D) Hollister Incorporated [12].

1.3 Problem Statement

Suturing is the most prevalent method of securing surgical drains after they are placed to prevent the accumulation of fluids and gasses [13]. These sutures, though, cause pain and discomfort due to the tension at the suturing site [3], [14]. However, alternative methods of attaching drains [9]–[12] are for aiding in comfort for short-term drain usage. Therefore, a new method of fixing surgical drains to the body will be developed to increase patient comfort when a long-term drain is placed.

2 BACKGROUND

2.1 Anatomy and Physiology

Surgical drains are generally needed after surgery in order to try and prevent a build-up of fluid, or a seroma, from forming in the body. Seromas occur when there is a collection or build-up of fluid in an open space or pocket below the skin [15]. They usually develop in areas where tissue has just been removed through surgery. An empty space between tissues can form if the wound does not heal correctly. This along with damage to the lymphatic system around the empty space can cause leakage of fluid, which results in a seroma forming in the skin [16]. Seromas can have a negative impact on the healing of the surgical wound. In the case of a mastectomy, the buildup of fluid causes the flaps of the chest wall to elevate and interferes with their adherence to the tissue bed. This can cause dangerous complications such as delayed wound healing, wound infection, hematoma, flap necrosis, wound reopening, longer hospitalization time, delayed recovery time, and are at risk of becoming infected which causes an abscess [17]. The most effective postoperative way that seromas can be prevented is by the use of surgical drains [18].

2.2 Client Information

Dr. Katie Kalscheur is a professor at the University of Wisconsin-Madison. She has her Ph.D. in Civil and Environmental Engineering and currently teaches the interdisciplinary freshman design course at the College of Engineering. She has tasked the team with developing an improved method for a more comfortable securement of surgical drains.

2.3 Product Design Specification

Since the drain is placed in an open wound, the device should be replaceable and removable until the drain collects less than 23-30 cc of fluid, this can take between 1-5 weeks [3] [4]. This device should also prevent any tube displacement that is caused by any tugging on the tubing and relieve the tension that is caused by sutures at the drain site. It should not cause any additional irritation or inflammation to the area nor should it inhibit the flow of the fluid that is passing through the tube. This device should hold the tube in place while preventing displacement greater than 3.6 ± 1.0 mm [7]. This device should be able to last for up to 1 week after it is installed on the patient and withstand typical, everyday activities such as walking, sleeping, stretching, and exercise. Since this device is placed near an open wound, it will need to maintain its function while exposed to body temperatures, this means that the device should remain secure at a body temperature of 98.3 ± 4.0°F [19]. The device should accommodate surgical drains with diameters ranging from 0.6-2.5 cm and should not weigh more than 28.35 g in order to remain competitive with other devices and not to increase discomfort on the patient's skin [4][20]. In order for this device to be successful, it must not interfere with the natural wound-healing process or evoke an immune response [21]. This device should cost no more than $35 in order to remain market competitive [22]. A complete set of product design specifications can be found in Appendix 8.1.

3 PRELIMINARY DESIGNS

3.1 Design 1 - Adhesive Bandage with Clip

One method for improving the fixation of surgical drains is to use a clip that will be attached to an adhesive bandage. This adhesive bandage with a clip design would be used alongside the suture placed by the surgeon to hold the drain in place. The adhesive would be made from a hydrocolloid bandage, as they are designed to be worn for up to a week [23]. The hydrocolloid bandage consists of an outer layer that acts as a barrier to protect the wound from bacterial contamination and foreign particles [23]. The hydrocolloid adhesive layer is used to absorb moisture from the wound and create a hydrogel that promotes healing [23]. This bandage would be placed right over the wound site and would encourage proper wound healing while the patient has to wear it. Since surgical drains are typically in place for 1-5 weeks, this bandage would need to be replaced weekly to ensure proper cleanliness at the drainage site [4]. To prevent irritation at the suture site, a gauze pad would be attached at the bottom of the bandage where the adhesive touches the skin. This would lead to less tugging directly at the suture site, and would also prevent any adhesive from pulling on the suture or drain during bandage replacement.

The clip would be made from high-density polyethylene since this material absorbs little water and is typically used as the plastic material for most medical devices [24]. The clip would be attached to a platform made from high-density polyethylene to allow for easy attachment to the adhesive portion of the design. The clip mechanism also allows for adaptability between different drain sizes, ranging from 6.35-25.4 mm in diameter [4]. This can be seen at the bottom of Figure 4.

Since this design would be made from a waterproof material, the patient will be able to shower and conduct their daily activities without having to replace the bandage as often. Replacing the design would be needed and would increase the price of this product. The use of adhesive material with multiple replacements may irritate the patient's skin over time.

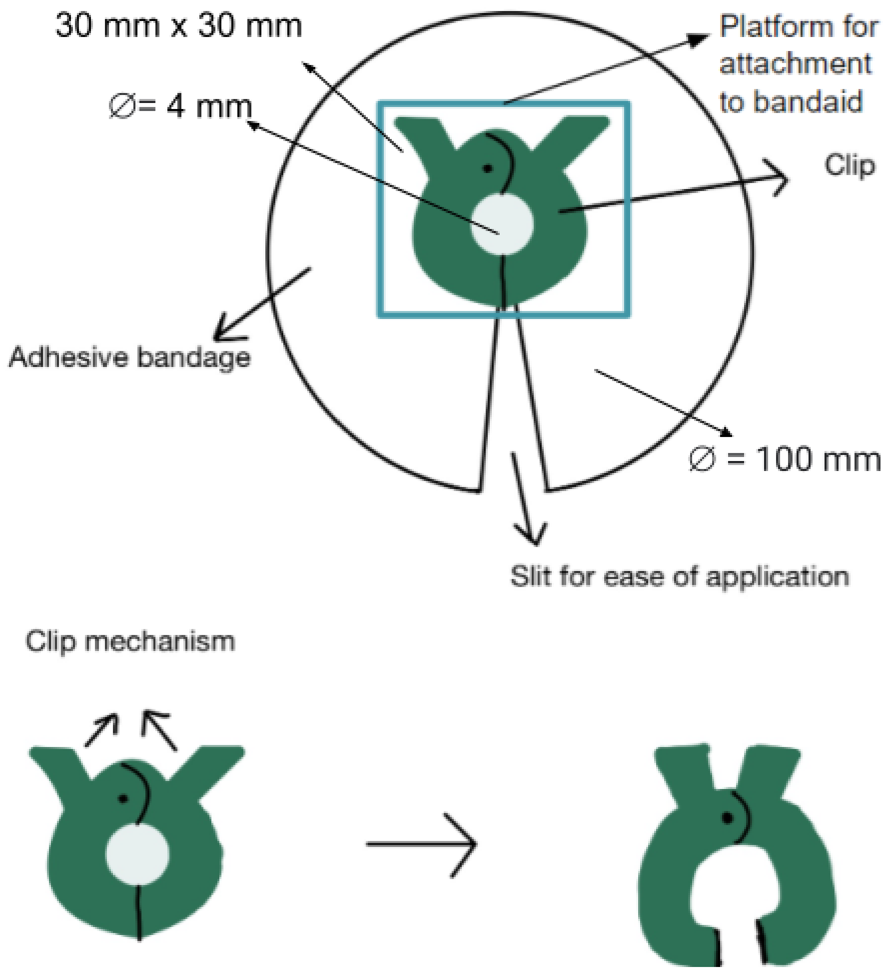


Figure 4: Drawing of the adhesive bandage with clip design placed at the drainage site. The clip would wrap around the surgical drain tubing exiting the patient's skin.

3.2 Design 2 - Interior Pressure Distributing Flaps

Another method for securing the surgical drain would be to replace the use of sutures with another device. This device consists of a rigid tube that would be made from high-density polyethylene to fit the diameter of the surgical drain tubing. The high-density polyethylene was the chosen material since it is a rigid plastic that is biocompatible [24]. The flaps would be made from silicone since silicone is a flexible material that is also biocompatible [25].

The device would be placed around the tubing of the surgical drain and implanted when the surgeon places the surgical drains. The flaps would be pulled up and flattened to allow them to be placed into the wound site as seen in Figure 5. Once under the skin, the rigid tube would be pulled up to allow the silicone flaps to flatten out underneath the skin as seen in Figure 6. Each flap would be used to distribute the pressure under the skin in different spots. A locking tie or clip would be wrapped along the edge of the tube outside the body to prevent the tube from getting pushed back further into the patient's body, and to prevent the displacement of the device.

This device would remain in place for the entire duration the surgical drains would need to be in place. One drawback of this design would be that it could increase the chances of infection since the surgical drain tubing could not be stripped where the rigid tube is. It would also be difficult to remove this device and an extra incision would be needed to remove it. This device is also not adjustable as it would be slid on once the drain is in place and multiple sizes would need to be created to accommodate different drain sizes.

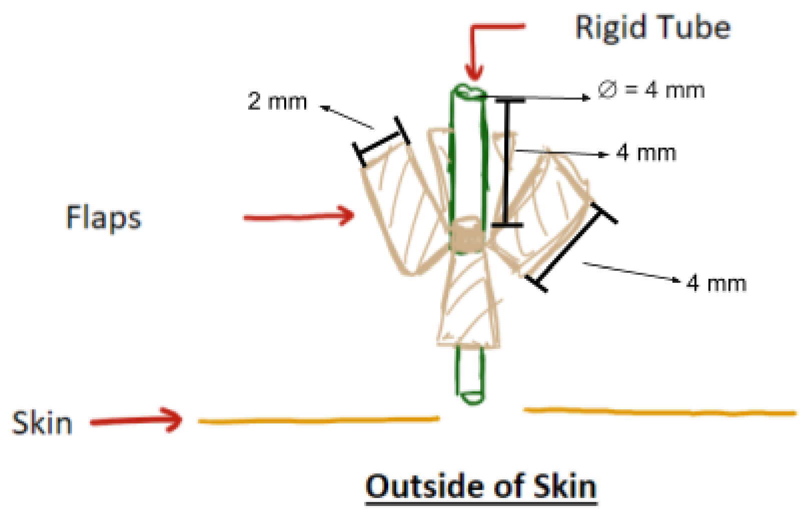


Figure 5: The silicone flaps in their upright position against the rigid tube for insertion at the wound site.

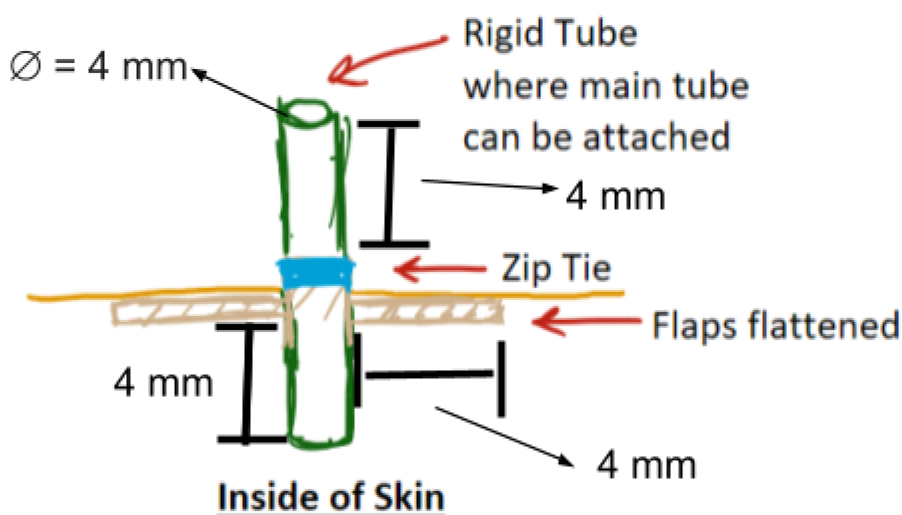


Figure 6: The silicone flaps are flattened underneath the skin with a tie around the rigid tube to hold the device in place outside the patient's skin.

3.3 Design 3 - Exterior Pressure Distributing Flaps

The third design would be used alongside the sutures that the surgeon typically uses to hold the drain in place. This design consists of pressure-distributing flaps made from a material similar to elastic therapeutic tape. Elastic therapeutic tape is made from a cotton-woven base that allows for a more breathable bandage [26]. Elastic therapeutic tape is very porous allowing for moisture to seep through the bandage, preventing the degradation of the adhesive material [26]. This allows for elastic therapeutic tape to remain in place for up to a week at a time. This is ideal for this project as this will reduce the cost of the device and allow for the patient to continue to do daily activities such as showering and physical therapy exercises that may be assigned by their doctor without having to constantly replace the tape. Each flap would distribute the pressure evenly on the patient's skin away from the suture site.

The silicone ring of the design is used to hold the drain securely in place. Silicone was chosen for this as it is very flexible and will not compress the surgical tube enough to stop the flow of fluid out of the drain [27]. The gauze padding would be placed on the underside of the adhesive where the wound site and suture site are as can be seen in Figure 7. This ensures that the wound site and suture are not being tugged on by the adhesive material.

This design would be beneficial in distributing the pressure evenly on the patient's skin. The elastic therapeutic tape material is not waterproof and this means the patient would have to replace it when showering or when it begins to fall off. This would increase the cost of this design.

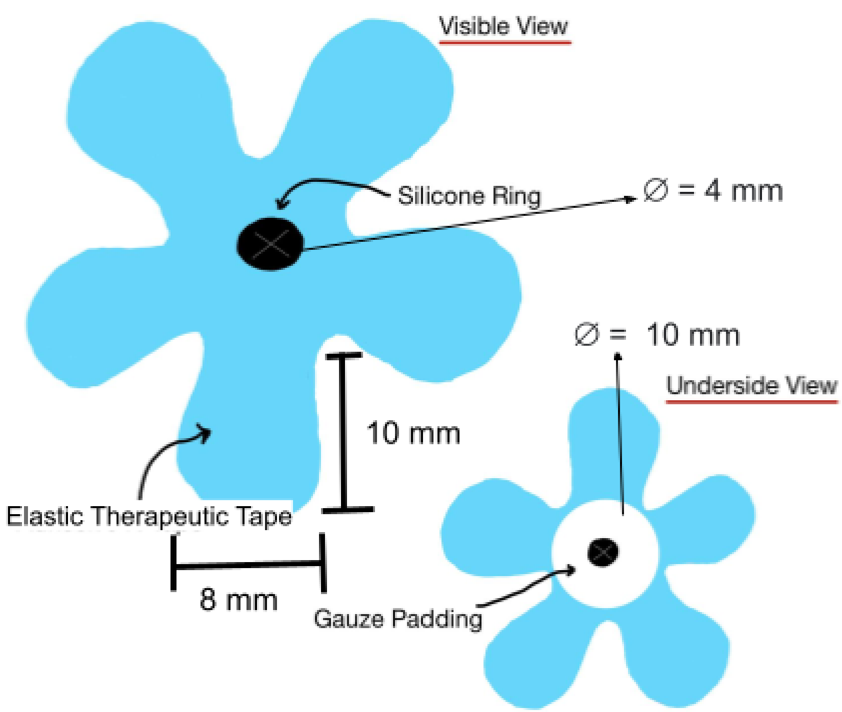


Figure 7: The pressure-distributing adhesive flaps with a top and bottom view.

4 PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

The criteria for the designs are ranked in importance based on the client's needs. Effectiveness is ranked the highest because the design needs to be able to hold the surgical drain tubes in place and prevent any displacement from occurring. In addition, if effectiveness is low, it could bring up other problems relating to safety and comfort. Patient comfort is ranked next, as this is emphasized by the client as a problem with the current method of attaching surgical drains to a patient. This criterion is scored on how comfortable the design will be once it is installed on the patient. Additionally, it is rated on how well the design will ideally be able to alleviate the pain that occurs at the wound site. The next criterion used to score the designs is the ease of use. Ease of use is described as how easily the design is able to be installed and the amount of maintenance required once it is installed. The cost is then used to assess the necessary expenses to fabricate and maintain the design. Lastly, adaptability analyzes how well the design is able to be used in various locations on the patient's body.

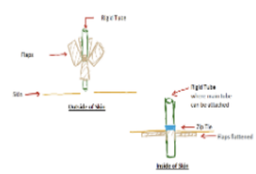
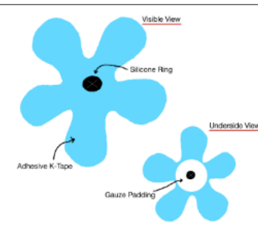
		 Adhesive Bandage with Clip		 Interior Pressure Distributing Flap		 Exterior Pressure Distributing Flap	
Criteria	**Weight**	**Score (10 max)**	**Weighted Score**	**Score (10 max)**	**Weighted Score**	**Score (10 max)**	**Weighted Score**
Effectiveness	30	8	24	6	18	8	24
Patient Comfort	25	8	20	3	8	9	23
Ease of Use	20	7	14	9	18	6	12
Cost	15	8	12	9	14	6	9
Adaptability	10	10	10	7	7	8	8
Sum	100	**Sum**	80	**Sum**	66	**Sum**	76

Figure 8: The preliminary design matrix.

4.2 Evaluation of Preliminary Designs

The adhesive bandage with clip design and pressure-distributing flaps outside scored highest for effectiveness. This is because the two designs would still implement sutures to attach surgical drains [5]. Both designs would increase the stability and support of the surgical drains at the wound site. For patient comfort, the pressure-distributing flaps scored the highest due to its use of elastic therapeutic tape which would help with comfortability and disperse the pressure when surgical tubes were tugged on. The second design scored low because some components would be under the skin, which could cause pain if the tubes were tugged on. In addition, inflammation could occur due to foreign body reactions of the silicone flaps going under the skin [28]. As for ease of use, the second design scored the highest since it does not require sutures to attach the tubes and requires little maintenance once it is installed. This is different from the first and second designs because these designs require the need for sutures and adhesives which would need to be changed on a daily basis. This reasoning is also applied to the cost criterion resulting in the second design scoring the highest. Lastly, for the adaptability criterion, the first design scored the highest. This is because this design uses a clip mechanism that is adjustable for the use of different-diameter drains.

4.3 Proposed Final Design

After analyzing each design using the criteria generated above the adhesive bandage with clip design was chosen as the final design. This design was chosen because of its ability to provide added support for the surgical drain tubes at the wound site and prevent their displacement. In addition to the added support, this design is able to relocate the tension that occurs at the suture site to lessen the discomfort that the patient experiences. A gauze ring will also be implemented in this design to collect any fluid that is released from the wound. Lastly, the device is adaptable for different diameter drains and can be attached to different areas of the body.

5 DEVELOPMENT PROCESS

5.1 Materials

The materials used in the design process included four initial prototypes made from different bandage materials that were tested using an MTS machine. The materials used were a hydrocolloid dressing, elastic therapeutic tape, a waterproof adhesive, and a silicone bandage. These materials were all tested to determine whether they were isotropic or not, an important mechanical property of the skin. The hydrocolloid bandage was chosen due to its ability to stay adhered to the skin for long periods of time and its capability to help promote wound healing. The elastic therapeutic tape was chosen for its ability to stretch without rupture and its compatibility with skin in both wet and dry environments. The waterproof adhesive was to be used in conjunction with the elastic therapeutic tape, as a two-layer bandage. The silicone bandage was chosen because of its antimicrobial properties, promotion of wound healing, and decreased pain with removal. Once all of the materials had arrived, the team obtained the mechanical properties of each material to determine the ideal dressing.

Once initial testing was completed, the team decided to use a hydrocolloid dressing, an elastic resin material, and a cyanoacrylate adhesive for the final design. The hydrocolloid, as mentioned above, was chosen as the final bandage material due to its isotropic properties, its ability to promote wound healing, and its ability to remain on the skin for extended periods of time. The elastic resin was chosen as the material for the 3D-printed clip as it is rigid enough to secure the drain tube in place with minimal displacement while also being soft and flexible enough to minimize patient discomfort while in use. A general cyanoacrylate adhesive was used for an initial prototype to adhere the clip to the bandage. However, in the future, the team plans to look into a double-layered adhesive that would secure the clip to the bandage. A comprehensive list of all materials and their costs can be found in Appendix 8.2.

5.2 Fabrication Methods

To begin the fabrication process, the team obtained a set of large hydrocolloid bandage sheets. After testing various geometries in FEBio, it was determined that the geometry of the bandage does not have a significant effect on force distribution. The team decided to proceed with an oval shape to allow for a greater distance between the clip and drain site. Detailed testing procedures and results for both material choice and bandage geometries can be found in the following two sections.

Methods to fabricate the correct shape of the hydrocolloid bandage involved the use of a Cricut Maker 3. The use of the Cricut machine allowed precise and uniform cuts of the bandage. The bandage shape, drain tube opening, and slit for easy application were all created using this fabrication method. The proposed clip design was rendered in Solidworks and printed in the UW Makerspace using a Formlabs Form 2 SLA printer. The clip was printed with an elastic resin, allowing for a structured clip with moderate flexibility to accommodate different tubing diameters.

The complete bandage assembly process involved the attachment of the clip to the bandage. For the purpose of prototyping and testing, the clip was adhered to the bandage using a generic cyanoacrylate adhesive. The use of a non-medical grade adhesive was used to create a prototype for proof of concept rather than for medical-grade patient use. The team plans to explore the fabrication of a double-layer adhesive that would allow for the base of the clip to be secured between the layers. This would decrease the rigidity of the bandage at the site where the adhesive is attached.

5.3 Testing

The team began testing by constructing a testing apparatus to closely mimic the drain site when the drain is sutured into the patient. To fabricate the testing apparatus, the team used a practice suture kit designed for medical students and first responders. The suture kit was used to mimic the layering of skin, fat, and tissue without the need to involve a real patient [32]. The team has also obtained several Jackson-Pratt drains with 100cc drain bulbs [33]. This is the same drain type that is used in mastectomy procedures and is the starting point for designing a prototype.

To create the physical apparatus, the team met with Dr. Lee Wilke to have the drain professionally sutured into the suture kit. Her suturing expertise helped remove a potential source of error in creating the model. This model served as a basis for determining how well our device would secure around the surgical drain tubing. It also allowed for visualization of the surgical drain site for a conceptual understanding of prototype performance.

The next priority for testing was to determine what adhesive material would be best for the design. MTS testing was conducted to determine the mechanical properties of each material. 16 different samples were created using a dog bone cutout. The materials that tested were the hydrocolloid bandage, the elastic therapeutic tape parallel to and perpendicular to the direction of its fibers, the elastic therapeutic tape parallel to and perpendicular to the direction of its fibers with a waterproof adhesive layer, and generic silicone bandages. Three samples were tested for each material and the elastic modulus of each material was determined using MATLAB.

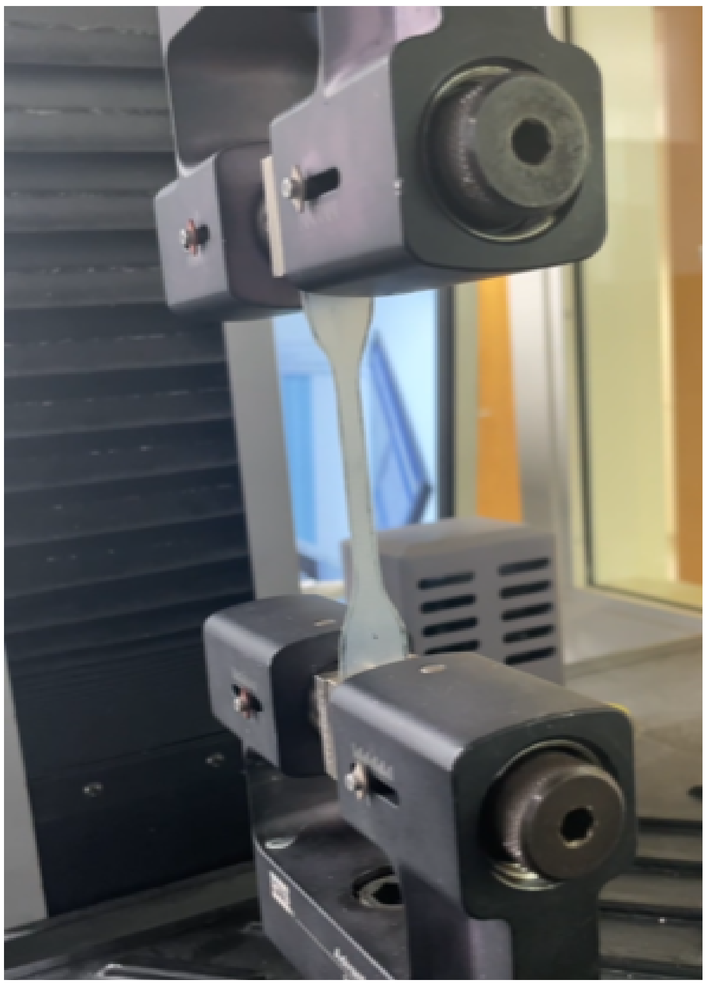


Figure 9: MTS testing setup for hydrocolloid bandage.

Testing for Poisson's ratio and shear modulus was also conducted for the required inputs in FEBio. This was done by drawing squares on the materials and measuring the displacement of the lines when the bandages were stretched. For full testing protocols, see Appendix 8.3. These properties were then used to test different geometries of the materials in FEBio to determine what shape would distribute the pressure the best. This testing did not show a significant difference in distribution between the geometries, but it did show that the hydrocolloid bandage was the best for the purposes of our design (See 5.4 Results).

Lastly, once prototyping was completed, two mechanisms for securing the drains needed to be tested, the Grip-Lok® design and the clip design. Both designs were expected to hold the drain tubing in place relatively well, but force testing was conducted to determine which mechanism would secure the drain better. This force testing was conducted by adhering the hydrocolloid to a clean vertical surface, in this case, a whiteboard was used. Then water was slowly added to the bulb of the drain and allowed to hang freely from the securement mechanism. Water was pipetted into the bulb using a serological pipette, adding 10 g (10 ml) at a time until the drainage bulb was full. If this amount of weight did not displace the bulb, 50 ml centrifuge tubes were taped onto the bulb and 10 g of water was added to incorporate additional weight. More water was pipetted into the tubes, 10 g at a time until the surgical drain was completely displaced from the mechanism of securement. This testing provided the max weight that each mechanism could hold until the drain tubing would be displaced. The clip mechanism secured more weight and the statistical results can be seen in 5.4 Results. All analyses were performed in MATLAB. The complete script can be found in Appendix 8.4.

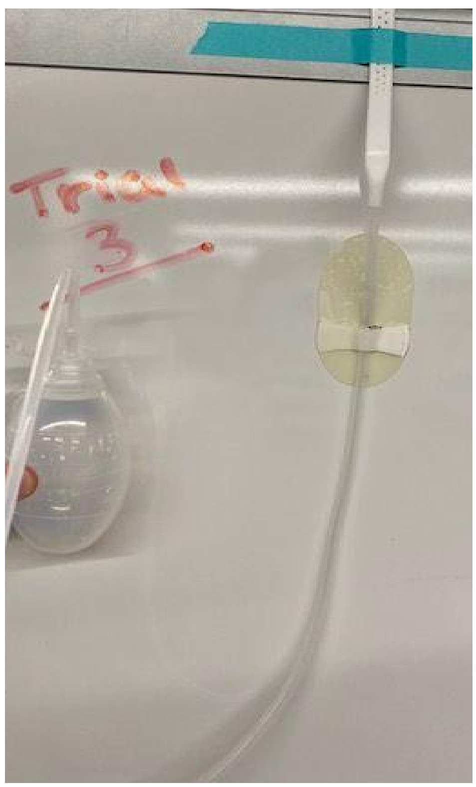


Figure 10: Force testing setup for Grip-Lok® design.

Figure 11: Force testing setup for clip design.

Future testing of the design includes an adhesive wear test that will need to be developed to ensure that the design is easily removable and replaceable as needed for daily drain site cleaning [21]. The design will also be tested on pig skin or untanned sheepskin to mimic the adhesion properties on human skin and for testing how long the device will be able to adhere to the skin [31]. When using an adhesive, it will also be important to confirm there are no adverse effects in material choice, and that removal and reapplication of the design do not create unnecessary irritation to the patient's skin. For user purposes, a protocol for the removal of the design would need to be created, and a potential topical removal solution may need to be considered, based on testing results.

5.4 Results

Following the collection of the mechanical properties of hydrocolloid bandages, waterproofed, and non-waterproofed elastic therapeutic tape, the team modeled the bandages to perform finite element stress analyses. To know whether to model elastic therapeutic tape as an isotropic or orthotropic material, a two-tailed T-test was performed on the elastic moduli of the directions parallel to and perpendicular to the fibers. This was conducted for both the waterproofed and non-waterproofed elastic therapeutic tape with a significance level of 0.05. Both materials showed a significant difference in elastic modulus between the two directions (waterproofed: tstat=-10.933, df=4, p=0.000398; non-waterproofed: tstat=-3.141, df=4, p=0.0348), proving that both should be modeled as orthotropic for finite element analysis.

FEBio was used to conduct simulations of a 20 N load applied to bandages of various materials (hydrocolloid, elastic therapeutic tape, and waterproofed elastic therapeutic tape) and geometries (circle, 1:0.75 oval, 3:1 oval, 2:1 oval, and four-petal flower). The complete table of results can be found in Appendix 8.5. Using visual analysis, the distribution of stress did not change between trials. Therefore, the team analyzed how effective stress (the stress calculated using the maximum distortion energy theory) changed due to bandage geometry and material. An ANOVA was performed using the maximum effective stress between both bandage geometry and bandage material. A significance level of 0.05 was used. The team found no significant difference between bandage geometries (F=0.754, df=4, p=0.583), but a significant difference was found between bandage materials (F=6.098, df=2, p=0.0246). Use of the MATLAB multcompare() function showed a difference between the waterproofed and non-waterproofed elastic therapeutic tape, but no significant difference between either elastic therapeutic tape and the hydrocolloid.

To determine whether the clip or the Grip-Lok® could support more weight, a two-tailed T-test was performed using the maximum supported weight of the two attachment methods. A significance level of 0.05 was used, and a significant difference was found between the two (tstat=3.450, df=4, p=0.0261), with the clip supporting more weight (mean=577.38g, std=50.51g) than the Grip-Lok® (mean=474.40g, std=11.07g).

5.5 Discussion

The statistical analysis done through material comparison indicated that there is a significant difference between the mechanical properties of materials. The results indicate that both the waterproof and non-waterproof elastic therapeutic tape have orthotropic properties, while the hydrocolloid bandage has isotropic properties, making it the ideal choice for this design. While the statistical analysis to determine if there is a difference in the bandage geometry did not reveal any statistically significant differences, the team decided on an oval shape for the bandage since it allows for space for the drain to be secured within the clip, slightly away from where the tube exits the body. This distance aims to move the site of possible tugging away from the suture site. Testing to compare the weight that the Grip-Lok® and clip can support showed that the clip is able to hold more weight than the Grip-Lok®. This supports the team's decision to use the clip in the final design. Further testing should be completed once a new clip with a larger diameter hole for the drain can be reprinted in order to reaffirm the results that the clip is able to hold more weight than the Grip-Lok®. Due to technical difficulties while printing the clip, the dimensions of the hole that was used in testing slightly compressed the drain tubing, which could cause a source of error in the results.

For ethical considerations for this project, the team did not want to conduct any clinical testing until confirming through pre-clinical testing that this design is able to be assembled while maintaining the sterility of the bandage. All initial testing plans should be completed before this step. This includes performing an adhesive test, longevity test, waterproof/sweat test, and a test of fluid flow through the drain tube. Once these tests are completed and the sterility of the bandage is confirmed, the team would transition to clinical testing.

5.6 Final Prototype

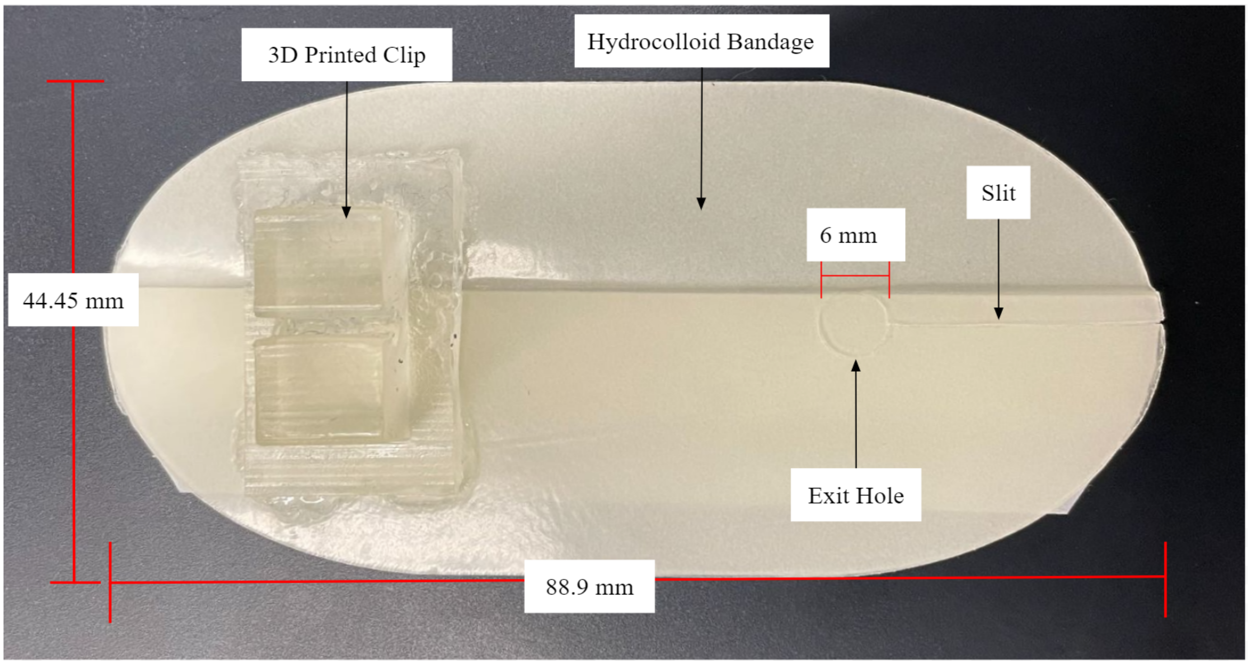


Figure 12: Top View of final prototype highlighting the important features.

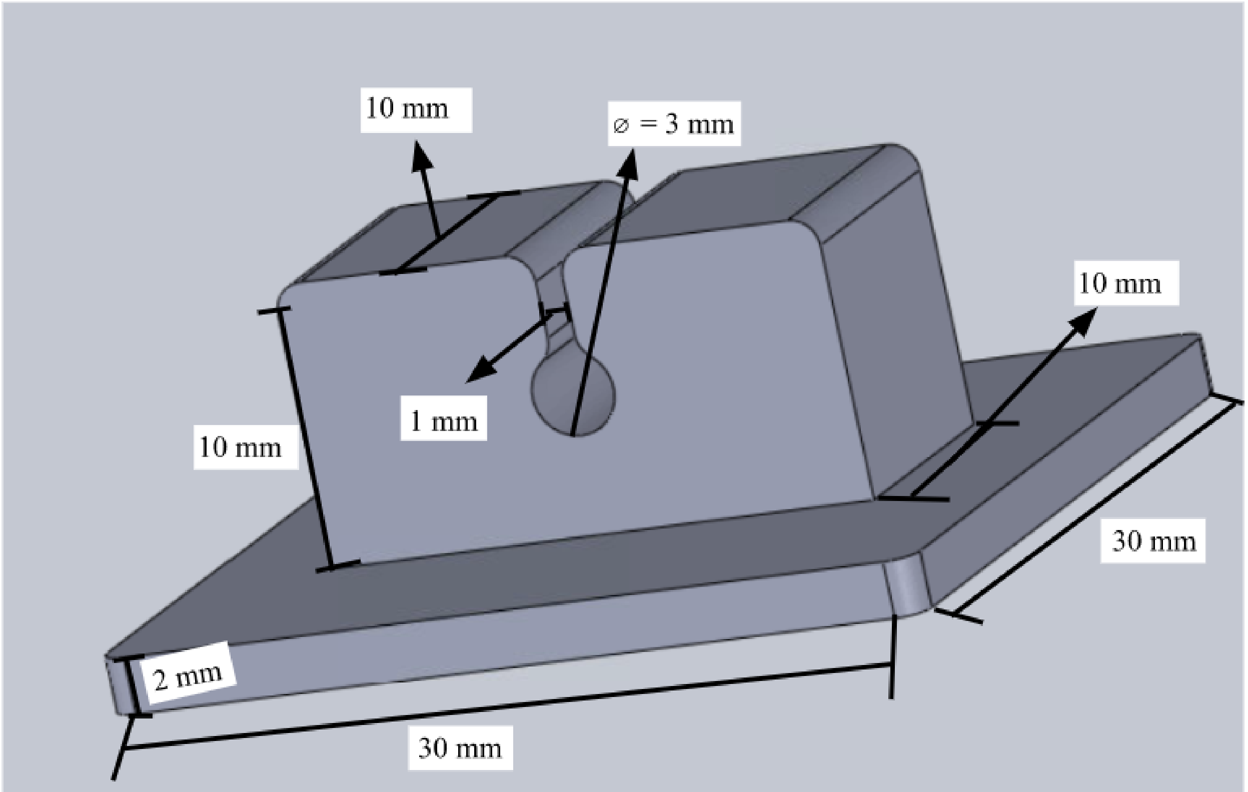


Figure 13: Final clip design with dimensions.

After analyzing the results from the various tests, the team decided on the hydrocolloid bandage with a clip as the final design. The design implements a slit to easily place the hydrocolloid bandage around the surgical drainage tube at the insertion site. The surgical drain will then come from the sutured site through the exit hole to be secured into the 3D-printed clip. The clip is designed to hold the surgical drain in place and resist any movement that will occur if the surgical drain tube were to be pulled on. As a result, this would minimize the tension experienced at the suturing site, overall reducing pain caused by surgical drains.

6 CONCLUSIONS

Suturing is the most common method for securing surgical drains for the prevention of the accumulation of fluid in the body. These sutures are the single point of contact on the patient's skin to hold the drain in place and may cause pain and discomfort. Alternative methods have been designed for attaching drains but only last for up to a week before the surgical drain has to be removed. A new and improved method of securing surgical drains to the body allows for increased patient comfort when a surgical drain is placed. The final design that has been detailed works alongside the suture to secure the surgical drain in place using a clip mechanism attached to an adhesive hydrocolloid bandage. This clip mechanism utilizes an adaptable open-top design that can accommodate the diameter of different drain sizes. By using a bandage design around the suture site, the pressure at the suture site should be reduced. Fabrication and testing methods for this device are described in detail in Section 5, and detailed testing plans are provided in Appendix 8.3. The final goal of this design is to provide a more comfortable experience for the patient for the duration of time they need a surgical drain.

The aforementioned design has various components that plan to be modified in the future, as well as various additional testing protocols that will be explored as the project continues. An adhesive test will be performed to test the strength of the adhesive under ideal conditions. A longevity test will be performed on pig or chicken skin to mimic daily activities that may be conducted while the bandage is in use. This includes, but is not limited to, artificial sweat exposure, water exposure, and movements such as twisting or bending. These tests will confirm that the design does not limit the patient from showering or practicing physical therapy activities.

The current clip design was shown through testing to support a mean weight of 577.38 g and outperformed the Grip-Lok® when tested with the 4 mm diameter tubing. A redesign of the clip will be done to decrease the thickness and rigidity for added comfort and accessibility for a larger range of tubing diameters. Once the clip has been remodeled, a test on various diameters will be conducted in the form of a fluid flow test. The fluid will mimic drainage with small clots and will be compared to drainage through an unsecured tube to ensure the clip does not impose on drainage ability.

Following additional testing and modifications to the design, the team must explore manufacturing protocols. A double-layer adhesive will be explored to allow for the securement of the clip between the layers, replacing the current cyanoacrylate adhesion of the clip. Prior to the fabrication of the hydrocolloid bandages into ovular shapes, the bandage is sterile in packaging. The bandage must be removed from the packaging to cut proper shapes and secure the clip, eliminating the sterility aspect. In order to market this device, plans to sterilize and package the fabricated product need to be explored in the future.

7 REFERENCES

[1] J. G. Makama and E. A. Ameh, “Surgical Drains: What the Resident Needs To Know,” *Nigerian Journal of Medicine*, vol. 17, no. 3, pp. 244–250, Aug. 2008.

[2] S. C. Sajeev and O. Sumant, “Surgical Drains Market Statistics, Growth Drivers| Forecast-2030,” *Allied Market Research*, May 2022. https://www.alliedmarketresearch.com/wound-drainage-surgical-drains-market-A07517 (accessed Oct. 10, 2022).

[3] W.-Y. Li, “Dr. Li’s Guide to Getting Drains After Surgery,” *Surgical Seecrets*, 2022. https://surgicalseecrets.com/blogs/articles/guide-to-getting-drains-after-surgery (accessed Oct. 10, 2022).

[4] J. Campbell, “How To Take Care of Your Drains After Breast Surgery,” *Verywell Health*, Sep. 10, 2021. https://www.verywellhealth.com/managing-your-surgical-drains-following-breast-surgery-4021630 (accessed Oct. 10, 2022).

[5] A. Tiwari, J. P. McFarlane, and J. L. Peters, “A simple technique for securing surgical drains,” *Injury Extra*, vol. 35, no. 11, pp. 91–93, Nov. 2022, doi: 10.1016/j.injury.2004.07.025.

[6] P. O’flynn and S. Akhtar, “Effective securing of a drain,” *Ann R Coll Surg Engl*, vol. 81, no. 6, pp. 418–419, Nov. 1999, doi: PMID: 10655897; PMCID: PMC2503306.

[7] L. Heskin, V. Cahill, G. Filobbos, P. Regan, S. O’Sullivan, and K. Bryan, “A new adaptation for a secure surgical drain placement and a comparison with four common drain fixation methods,” *The Annals of The Royal College of Surgeons of England*, vol. 101, no. 1, pp. 60–68, Jan. 2019, doi: 10.1308/rcsann.2018.0177.

[8] Epomedicine, “Techniques of Securing Surgical Drain to Skin (Drain Fixation),” *Epomedicine*, Jun. 10, 2021. https://epomedicine.com/surgical-skills/techniques-securing-surgical-drain-fixation/ (accessed Oct. 10, 2022).

[9] Y. Ringel, O. Haberfeld, R. Kremer, E. Kroll, R. Steinberg, and A. Lehavi, “Intercostal chest drain fixation strength: comparison of techniques and sutures,” *BMJ Military Health*, vol. 167, no. 4, Oct. 2020, doi: 10.1136/bmjmilitary-2020-001555.

[10] A. Yousefpour, A. J. Gibbons, and N. M. Whear, “A simple way of securing suction drains: Technical note,” *British Journal of Oral and Maxillofacial Surgery*, vol. 44, no. 2, pp. 161–162, Apr. 2006, doi: 10.1016/j.bjoms.2004.10.019.

[11] “Disposable Drainage Tube Holder - Changzhou Haiers Medical Devices Co., Ltd.,” *Hasmedicalstapler.com*, 2018. https://www.hasmedicalstapler.com/Disposable_Drainage_Tube_Holder (accessed Oct. 10, 2022).

[12] “Tube Attachment Devices | Critical Care Products | Hollister US,” *www.hollister.com*, 2022. https://www.hollister.com/en/products/Critical-Care-Products/Tube-Securement/Tube-Attachment-Devices# (accessed Oct. 10, 2022).

[13] R. Durai and P. C. H. Ng, “Surgical vacuum drains: types, uses, and complications,” *AORN*, vol. 91, no. 2, pp. 266–71, 2010, doi: 10.1016/j.aorn.2009.09.024.

[14] L. U. M. Corion, M. J. C. Smeulders, P. P. M. van Zuijlen, and C. M. A. M. van der Horst, “Draining after breast reduction: a randomised controlled inter-patient study,” *J. Plast.*

Reconstr. Aesthet. Surg., vol. 62, no. 7, pp. 865–868, 2009, doi: 10.1016/j.bjps.2008.01.009.

[15] L. Marion, "Everything You Need to Know About Surgical Drains - Chicago Plastic Surgery," *Plastic Surgery of Chicago*, Jun. 09, 2020. https://www.plasticsurgeryofchicago.com/surgical-drains/ (accessed Oct. 10, 2022).

[16] "Seroma: What Is It, Causes, Treatment, and More | Osmosis." https://www.osmosis.org/answers/seroma (accessed Oct. 10, 2022).

[17] A. Agrawal, A. A. Ayantunde, and K. L. Cheung, "Concepts of Seroma Formation and Prevention in Breast Cancer Surgery," *ANZ Journal of Surgery*, vol. 76, no. 12, pp. 1088–1095, 2006, doi: 10.1111/j.1445-2197.2006.03949.x.

[18] J. E. Janis, L. Khansa, and I. Khansa, "Strategies for Postoperative Seroma Prevention: A Systematic Review," *Plastic and Reconstructive Surgery*, vol. 138, no. 1, pp. 240–252, Jul. 2016, doi: 10.1097/PRS.0000000000002245.

[19] "Fever: First aid - Mayo Clinic," *Mayo Clinic*, Jun. 11, 2022. https://www.mayoclinic.org/first-aid/first-aid-fever/basics/art-20056685 (accessed Oct. 10, 2022).

[20] "Vertical Tube Attachment Device (VTAD) | Critical Care Products | Hollister US," *Hollister*. https://www.hollister.com/en/products/critical-care-products/tube-securement/tube-attachment-devices/vertical-tube-attachment-device-_vtad_# (accessed Oct. 10, 2022).

[21] "Patients & Families | UW Health." https://patient.uwhealth.org/healthfacts/4603 (accessed Oct. 10, 2022).

[22] "Seecret Apron™ - post-surgical drain holder & pouch – Surgical Seecrets," *Surgical Seecrets*. https://surgicalseecrets.com/products/seecret-apron (accessed Oct. 10, 2022).

[23] H. R. Barnes, "Wound care: fact and fiction about hydrocolloid dressings," *J Gerontol Nurs*, vol. 19, no. 6, pp. 23–26, Jun. 1993, doi: 10.3928/0098-9134-19930601-08.

[24] J. Dewing, "Medical Devices Equipment: What Plastic Materials Are Used in Them?," *Proto Plastics*, Feb. 18, 2022. https://protoplastics.com/plastic-materials-medical-devices-equipment/ (accessed Oct. 10, 2022).

[25] D. C. C. França, A. L. de Castro, A. M. P. Soubhia, S. M. H. C. Á. de Aguiar, and M. C. Goiato, "Evaluation of the Biocompatibility of Silicone Gel Implants – Histomorphometric Study," *Acta Inform Med*, vol. 21, no. 2, pp. 93–97, 2013, doi: 10.5455/aim.2013.21.93-97.

[26] V. Tunakova, M. Tunak, J. Mullerova, M. Kolinova, and V. Bittner, "Material, structure, chosen mechanical and comfort properties of kinesiology tape," *The Journal of The Textile Institute*, vol. 108, no. 12, pp. 2132–2146, Dec. 2017, doi: 10.1080/00405000.2017.1315797.

[27] M. Zare, E. R. Ghomi, P. D. Venkatraman, and S. Ramakrishna, "Silicone-based biomaterials for biomedical applications: Antimicrobial strategies and 3D printing technologies," *Journal of Applied Polymer Science*, vol. 138, no. 38, p. 50969, 2021, doi: 10.1002/app.50969.

[28] A. Carnicer-Lombarte, S.-T. Chen, G. G. Malliaras, and D. G. Barone, "Foreign Body Reaction to Implanted Biomaterials and Its Impact in Nerve Neuroprosthetics," *Frontiers in Bioengineering and Biotechnology*, vol. 9, 2021, Accessed: Oct. 10, 2022. [Online]. Available: https://www.frontiersin.org/articles/10.3389/fbioe.2021.622524

[29] "What is High Density Polyethylene (HDPE)? | Acme Plastics." https://www.acmeplastics.com/what-is-hdpe (accessed Oct. 10, 2022).

[30] D. E. Heath, S. A. Guelcher, and S. L. Cooper, "1.3.2A - Polyurethanes," in *Biomaterials Science (Fourth Edition)*, W. R. Wagner, S. E. Sakiyama-Elbert, G. Zhang, and M. J. Yaszemski, Eds. Academic Press, 2020, pp. 103–107. doi: 10.1016/B978-0-12-816137-1.00010-6.

[31] F. Selva, A. Pardo, X. Aguado, I. Montava, L. Gil-Santos, and C. Barrios, "A study of reproducibility of kinesiology tape applications: review, reliability and validity," *BMC Musculoskelet Disord*, vol. 20, p. 153, Apr. 2019, doi: 10.1186/s12891-019-2533-0.

[32] "Amazon.com: Complete Sterile Suture Practice Kit for First Aid Field Emergency and Medical Students Training - Including Large Silicone Suture Pad and Sterilized Suture Tools Threads and Needles : Industrial & Scientific." https://www.amazon.com/Complete-Suture-Practice-Medical-Students/dp/B07TNRHKGW (accessed Oct. 10, 2022).

[33] "Jackson-Pratt® Perforated Flat Drains," *Cardinal Health*, 2022. https://www.cardinalhealth.com/en/product-solutions/medical/infection-control/wound-drains/jackson-pratt-perforated-drains/perforated-flat-drains.html (accessed Oct. 10, 2022).

8 APPENDIX

8.1 Product Design Specifications

Function:

Surgical drains are used to keep certain fluids and air from accumulating in a dead space that is created during surgery [1]. These are attached to patients using sutures which are stitches that attach and hold the tube in the patient's skin [1]. However, these sutures cause pain and discomfort due to tension at the suturing site [2][3]. The created device will address this problem by reducing the amount of tension produced at the suturing site. This problem will be addressed with two approaches. One approach will be to develop a device that improves the attachment of the surgical drains to the skin. The other approach will be to create a housing for the drain tubing and bulb. As a result, the patient will have a much more comfortable and painless experience with the surgical drains.

Client requirements:

- The device will need to work effectively in various environments including hot and cold temperatures as well as exposure to water.
- The device should be able to work for any type of surgical drain and be placed in any location.
- The device should maintain function and provide comfort when the patient is performing various movements and daily activities including walking, sleeping, stretching, and exercising.
- The drainage wound site should be accessible for sanitizing using alcohol or various soaps.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

The device should be replaceable and removable for sanitary reasons until the surgical drain collects less than 25 - 30 cc of fluid, which can take 1 to 5 weeks [2][4]. Once the drainage amount is consistently below 25 - 30 cc of fluid, the drain can be removed. The device should also prevent displacement of the surgical drain tube, especially during patient movement or when pulled on. In addition, the device should relieve the tension created at the attachment site of the surgical drain tube. It will also be necessary that the device is biocompatible with the skin to avoid irritation when in use. Lastly, the device will need to follow certain FDA protocols highlighted in section 3a.

b. *Safety*:

This attachment device should not cause any additional irritation or inflammation to the patient. It should not inhibit drainage flow or cause the tube to be displaced. The site should also be able to be cleaned to ensure that it is sanitary and will not cause any infections.

c. *Accuracy and Reliability*:

The attachment device should be able to hold the surgical drain in place without irritating the patient's skin. This device should not allow for displacement greater than 3.16 +/- 1.0 mm [5]. It should also be adjustable to ensure it is adequately secured and for patient comfort.

d. *Life in Service*:

This product should be able to last for the duration that the surgical drain is attached to the patient, up to one week. This device should be able to withstand all of the activities that accompany a normal life without any impact on its function or how secure it is.

e. *Shelf Life*:

While not in use, this device will be stored in a standard healthcare storage closet at room temperature. If properly stored, the attachment device should be able to be kept for 36 to 40 months [6].

f. *Operating Environment*:

The attachment device will be placed near the exit site of a surgical drain and will have to maintain its function while exposed to body temperatures, cleansing and showering, and stripping of the drain to ensure the drain does not become clogged. The design will likely be attached to the patient's skin and should be able to maintain its function at body temperatures ranging from 98.3 +/- 4.0 °F [7]. This range accounts for the temperatures the patient's body might get to if they are instructed to do light exercises while the drains are still in place. Patients are instructed to shower while their surgical drains are in place so the design should not lose its integrity when exposed to water [8]. Drains also need to be regularly stripped to ensure they remain functional, so the design should not detach or displace during this process [2].

g. *Ergonomics*:

The design should not detach from the patient's skin after accidental tugging or movement [2]. The housing design should allow the patient to move around and attend to their daily activities without interruption. The housing design will incorporate a way to easily hide or wrap this extra tubing. The patient should also be able to access their drain site for the duration they need the drain which can range from 1 to 5 weeks [9].

h. *Size*:

Most surgical drain diameters range from 6.35 mm to 25.4 mm and are 355.6-457.2 mm long [4][10]. The attachment device will be able to accommodate this range of diameters.

i. *Weight*:

The design should weigh less than 28.35 g this competes with current devices on the market and will not cause increased discomfort on the patient's skin [11].

j. *Materials*:

The design must use sterile materials that do not interfere with natural wound healing. The materials should not evoke an immune response at the drainage site. Water-soluble materials cannot be used, as the site must be washed frequently [12]. The material should not notably expand or contract. The design must also use durable materials to withstand use for up to several weeks, but must be easy to remove in as little as a few days [13]. Drains are used for varying durations of time, and the design must be versatile to represent this.

k. *Aesthetics, Appearance, and Finish*:

The final design must have a smooth finish to avoid any unnecessary catching on clothing [2]. In addition to this, it should conceal the appearance of the drains. Ideally, the design will have patterned options as well as various skin tone options for a more discreet appearance [14]. The design should also incorporate a method of securing tubing and drainage bulbs so that the design accounts for all portions of the drainage process, not just at the drain-skin contact point [15].

2. Production Characteristics

a. *Quantity*:

Only one or two units will be needed to show proof of concept. The design should be easily scalable to large quantities to match the rapidly growing need for surgical drains [16].

b. *Target Product Cost*:

Various other products on the market typically fall in the range of $25 to $35 [14]. Our design should fall within this range, however, it will ideally be lower in cost than similar products on the market. If scaled up to match market demand, the price will ultimately be lower than the initial cost of production.

3. Miscellaneous

a. *Standards and Specifications*:

The FDA classifies surgical sutures [17], topical adhesives [18], and surgical drains [19] as class II medical devices. Therefore, new attachment methods must follow the FDA's general and special controls. All equipment must be sterilized following FDA sterilization guidelines [20].

b. *Customer*:

The housing device should prevent tugging on the drain, a source of pain and discomfort for the patient. Additionally, it should be concealed under normal clothing or be designed to appeal to all customers.

c. *Patient-related concerns*:

New attachment methods must be sterilizable prior to use and must allow visual access to the insertion site. The housing device should be machine washable and avoid kinking the drain tube.

d. *Competition*:

Many variations of surgical drain bulb holders have been patented including:

- Medical drainage pouch [21]
- Post-surgical drainage bulb support sling [22]
- Post-surgical drainage container carrier [23]
- Drain tube belt and shower pack kit [24]
- Surgical recovery brassiere [25]
- Drainage reservoir support assembly [26]
- Surgical drainage device [27]
- Abdominal binder with improved drainage bulb holding system [28]
- Apparatus and method for carrying and storing medical drains [29]
- Drain pouch caddy [30]
- Post-operative compression bra and drain apron [31]
- Surgical drain management apparatus [32]
- Drain tube holder system [33]

- Ostomy pouch holding system [34]
- Surgical drainage reservoir support [35]
- Medical drain carrier [36]
- ** This is a non-exhaustive list **

Methods for surgical drain attachment include:

- Sutures with Tie-Lok [37]
- Adhesive device [38]
- Prolene suture with beads [39]
- Centurion sandal [5]
- Centurion sandal with two locking plastic ties [5]
- Centurion sandal with Steristrips [5]
- Double loop sutures [5]
- Multiple loop sutures [5]
- Classical suture loop and knot [40]
- Roman Gaiter suture technique [40]
- Locking-Turns suture technique [40]
- ** This is a non-exhaustive list **

References:

[1] R. Durai and P. C. H. Ng, “Surgical vacuum drains: types, uses, and complications,” AORN J., vol. 91, no. 2, pp. 266–71; quiz 272–4, 2010.

[2] D. W.-Y. Li, “Dr. Li's guide to getting drains after surgery,” Surgical Seecrets, 07-Oct-2020. Available: https://surgicalseecrets.com/blogs/articles/guide-to-getting-drains-after-surgery.

[3] L. U. M. Corion, M. J. C. Smeulders, P. P. M. van Zuijlen, and C. M. A. M. van der Horst, “Draining after breast reduction: a randomised controlled inter-patient study,” J. Plast. Reconstr. Aesthet. Surg., vol. 62, no. 7, pp. 865–868, 2009.

[4] M. S. Jean Campbell, “How to take care of your drains after breast surgery,” Verywell Health, 05-Apr-2016. Available: https://www.verywellhealth.com/managing-your-surgical-drains-following-breast-surgery-4021630.

[5] L. Heskin, V. Cahill, G. Filobbos, P. Regan, S. O’Sullivan, and K. Bryan, “A new adaptation for a secure surgical drain placement and a comparison with four common drain fixation methods,” The Annals of The Royal College of Surgeons of England, vol. 101, no. 1, pp. 60–68, Jan. 2019, doi: 10.1308/rcsann.2018.0177.

[6] J. James, “Do Bandages Expire?”, Survivalfreedom.com, 17-Oct-2019.

[7] “Fever: First aid,” Mayo Clinic, 11-Jun-2022. [Online]. Available: https://www.mayoclinic.org/first-aid/first-aid-fever/basics/art-20056685.

[8] “Care of your surgical drain at home,” Uwhealth.org. Available: https://patient.uwhealth.org/healthfacts/4603.

[9] “After surgical procedure instructions for JP drain and surgical incision,” Ucdavis.edu. Available: https://health.ucdavis.edu/surgery/specialties/oncologic/jp_instructions.pdf.

[10] J. Easley and J. Schumacher, “Basic equine orthodontics and maxillofacial surgery,” in Equine Dentistry, Elsevier, 2011, pp. 289–317.

[11] “Vertical tube attachment device (VTAD),” Hollister.com. [Online]. Available: https://www.hollister.com/en/products/critical-care-products/tube-securement/tube-attachment-devices/vertical-tube-attachment-device-_vtad_.

[12] “Patients & families: UW health,” Health and Nutrition Facts for You | Patients & Families | UW Health. Available: https://patient.uwhealth.org/healthfacts/4603.

[13] B. J. C. L. W. R. M. T. C; “How long should suction drains stay in after breast surgery with axillary dissection?,” Annals of the Royal College of Surgeons of England. Available: https://pubmed.ncbi.nlm.nih.gov/9422871/.

[14] “Seecret Apron™ - post-surgical Drain Holder & Pouch,” Surgical Seecrets. [Online]. Available: https://surgicalseecrets.com/products/seecret-apron.

[15] “PATFT.” [Online]. Available: https://patft.uspto.gov/.

[16] “Surgical drains market statistics, Growth Drivers: Forecast- 2030,” Allied Market Research.[Online].Available: https://www.alliedmarketresearch.com/wound-drainage-surgical-drains-market-A07517.

[17] Center for Devices and Radiological Health, Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff. Food and Drug Administration, 2003.

[18] Center for Devices and Radiological Health, Tissue Adhesive for the Topical Approximation of Skin - Class II Special Controls Guidance for Industry and FDA Staff. Food and Drug Administration, 2008.

[19] Center for Devices and Radiological Health, "Wound Drain Catheter System FDA Classification, Life Cycle Events [5825]," Food and Drug Administration. https://fda.report/Product-Code/deviceId/5825 (accessed Oct. 10, 2022).

[20] Center for Devices and Radiological Health, "Sterilization for Medical Devices," Food and Drug Administration, Jun. 06, 2022. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

[21] G. C. Persichetti and F. W. Piraino, "Medical drainage pouch," Oct. 23, 2012

[22] D. Bachelder, "Post-surgical drainage bulb support sling," Apr. 19, 2011

[23] N. F. Turner, "Post-surgical drainage container carrier," Jul. 01, 1997

[24] P. L. Watson and V. M. Watson, "Drain tube belt and shower pack kit," Nov. 28, 2000

[25] D. A. Brooks, "Surgical recovery brassiere," May 21, 2002

[26] M. Hadley-Fruit, "Drainage reservoir support assembly," Feb. 25, 2003

[27] M. R. Prody and Dale Medical Inc, "Surgical drainage device," Aug. 26, 2003

[28] A. Frazer and Dale Medical Products Inc, "Abdominal binder with improved drainage bulb holding system," Nov. 29, 2011

[29] M. Barnes and Hudson Holder Inc, "Apparatus and Method for Carrying and Storing Medical Drains," Apr. 19, 2012

[30] S. S. Wellborn and J. E. Hildreth, "Drain pouch caddy," Jun. 11, 2015

[31] L. M. Blackwell, "Post-operative compression bra and drain apron," Dec. 23, 2015

[32] J. Baker and M. Baker, "Surgical drain management apparatus," Jan. 04, 2018

[33] L. R. Fee, P. Fee, and Red Oak Innovations LLC, "Drain tube holder system," Feb. 19, 2019

[34] S. Blatt, "Ostomy pouch holding system," Jun. 15, 2021

[35] M. A. R. Prody, "Surgical drainage reservoir support," Aug. 17, 2021

[36] C. J. Dolphin, "Medical drain carrier," Dec. 14, 2021

[37] A. Tiwari, J. P. McFarlane, and J. L. Peters, "A simple technique for securing surgical drains," Injury Extra, vol. 35, no. 11, pp. 91–93, Nov. 2004, doi: 10.1016/j.injury.2004.07.025.

[38] A. Yousefpour, A. J. Gibbons, and N. M. Whear, "A simple way of securing suction drains: Technical note," British Journal of Oral and Maxillofacial Surgery, vol. 44, no. 2, pp. 161–162, Apr. 2006, doi: 10.1016/j.bjoms.2004.10.019.

[39] P. O'flynn and S. Akhtar, "Effective securing of a drain," Ann R Coll Surg Engl, vol. 81, no. 6, pp. 418–419, Nov. 1999, doi: PMID: 10655897; PMCID: PMC2503306.

[40] Epomedicine, “Techniques of Securing Surgical Drain to Skin (Drain Fixation),”Epomedicine, Jun. 10, 2021. https://epomedicine.com/surgical-skills/techniques-securing-surgical-drain-fixation/

8.2 Material Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Practice Suture Kit	Complete Sterile Suture Practice Kit for First Aid Field Emergency and Medical Students Training - Including Large Silicone Suture Pad and Sterilized Suture Tools Threads and Needles	NeoProMedical	MN-062719	9/29/2022	1	$27.99	$27.99	Practice Suture Kit
Hydrocolloid dressing	Bandage Hydrocolloid Blister White BX10 -19926	DUKAL CORPORATION	76407-780 (BX)	10/17/2022	1	$5.20	$5.20	Hydrocolloid Dressing
K-Tape	SB SOX Original Cotton Kinesiology Tape (16ft Uncut Roll) – Best Latex Free, Water Resistant Tape for Muscles/Joints – Perfect for Any Activity – Easy to Apply/Use, Works Great for Several Days!	SB SOX	B07L7NQN3V	10/17/2022	1	$12.30	$12.30	K Tape
Adhesive Tape	100 Pieces Transparent Stretch Adhesive Bandages	Nuanchu	B099WJ4ZXJ	10/17/2022	1	$15.99	$15.99	Adhesive Tape

	Waterproof Film Dressing Breathable Tape Clear Adhesive Skin Covers Shower Protective Patch for Bath Supplies Swimming (4 x 5 Inch)							
Silicone Adhesive Bandages	Curad Truly Ouchless Extra Large Silicone Bandages, Flexible Fabric, 8 Count Packaging May Vary	Medline	CUR5003V1H	10/17	$1.00	$11.98	$11.98	[Curad Silicone Adhesive Bandages]
Velcro Tape	VELCRO Brand Extreme Outdoor Mounting Tape | 20Ft x 1 In, Holds 15 lbs | Strong Heavy Duty Stick on Adhesive | Mount on Brick, Concrete for Hanging, 30702	VELCRO Brand	VEL-30702-AMS	10/21/2022	1	$19.99	$19.99	[Velcro Tape]
Grip-Lok Device	TIDI Grip-Lok Small Securement Device — Pack of 10 — White — Flexible Material — Low-Profile Design for	TIDI	3200S-10PK	10/21/2022	1	$30.25	$30.25	[GripLok]

	Comfort — Home Healthcare — Medical Supplies (3200S-10PK)							
Kinesiology Tape	SpiderTech Therapeutic XXL Kinesiology Tape Roll (6 inch - 152 mm x 5 m) Reduce Inflammation, Preferred by Athletes, High-Grade Water-Resistant Material, Help Re-Train Muscles (Beige)	SpiderTech Inc.	B08JHCPQMK	11/11/2022	1	$29.99	$29.99	Kinesiology Tape
Hydrocolloid Bandage	Dimora Hydrocolloid Dressing 4" x 4" for Wound Care, 10 Pack Large Patch Bandages with Self-Adhesive for Bedsore, Burn, Blister, Acne Care, Super Absorbent for Fast Healing	Winner	B08F9Y9GBV	1/11/2022	1	$15.00	$15.00	Hydrocolloid Bandage
						TOTAL:	$168.69	

8.3 Testing Protocols

1. MTS Testing for Tensile Properties and Elastic Modulus

Detailed Steps of testing:

1. Set up the MTS machine for tensile testing.
    a. Use 100N rubber tensile grips unless otherwise specified by the instructor.
2. Obtain the bandages for testing (elastic therapeutic tape, hydrocolloid bandage, silicone bandage, elastic therapeutic tape with waterproofing).
3. Cut each sample of each bandage type into a bone shape.
    a. Bone shape size should be consistent between each material sample.
4. Load a bandage, testing in the direction of the fibers.
5. Perform a tensile test to failure.
6. Record the elastic modulus.
7. Repeat steps 3-5, loading the bandage with fibers in the perpendicular direction.
8. Repeat steps 3-6 using the next bandage.

2. Testing for Poisson's Ratio and Shear Modulus

Detailed Steps of testing:

1. Draw or stamp on a perfect square onto the bandage. Record its dimensions.
2. Stretch the bandage using a uniaxial load. Record the square's dimensions.
3. Repeat step 2 with the load applied in the perpendicular direction.
4. Calculate Poisson's ratio ($^{\text{lateral deformation}}/_{\text{longitudinal deformation}}$) in both directions.
5. Assume elastic modulus and Poisson's ratio is the same in either perpendicular direction.
6. Calculate the shear modulus in three directions ($E=2G(1+\nu)$).

3. FEBio Simulation

Detailed Steps of testing:

1. Create different geometries of the bandage in SolidWorks. Export as .STEP files.
2. Open the model in FEBio.
3. Set the material (orthotropic elastic) and its properties (density, elastic modulus in three directions, shear modulus in three directions, and Poisson's ratio in three directions).
4. Set the boundary condition to be on the adhesive surface, constrained in all directions.
5. Set the load at the clip location as a pressure surface load. Set the scale (as a stress).

6. Optimize the mesh to find the one that has the best performance with the fewest elements.
7. Analyze the stress distribution using the optimized mesh.
8. Repeat steps 2-7 using each geometry.
9. Compare the distributions and the maximum stresses in each geometry. Choose the geometry that minimizes the maximum stress.

4. Force Testing Protocol

Detailed Steps of testing:

1. Gather eight hydrocolloid bandages, four with Grip-Lok® and four with the clip attached to them.
2. Gather uniform weights.
3. Adhere the bandage to a clean vertical surface with the hole with the slit facing up.
4. Secure the surgical drain tube to the bandage using either the Grip-Lok® or the clip.
5. Draw a line on the surgical drain tube relative to the top edge of the mechanism holding it in place.
6. Attach the weight to the surgical drain tubing using tape.
    a. If no weights are available, fill the surgical bulb with 10 ml of water at a time by pipetting it into the opening of the bulb.
    b. If additional weights are needed 50 ml centrifuge tubes can be taped onto the bulb and 10 ml can be added at a time.
7. Release the weight and allow it to hang freely.
8. Record the weight and displacement of the surgical drain.
    a. Measure the displacement from the line on the tubing to the top edge of the mechanism holding the drain in place.
9. Repeat steps 3-8 using an increased amount of weight until failure (bandage falls, tube falls out of attachment device, or something tears/breaks) and record the weight of failure.
    a. Determine the weight added by using the density conversion of water.
        i. 1 g/ ml x 10 ml = 10 g for every 10 ml added.
10. Repeat steps 3-9 using another bandage.

8.4 MATLAB Code

Table of Contents

 1
Hydrocolloid 1
Elastic Therapeutic Tape - Parallel 5
Elastic Therapeutic Tape - Perpendicular 9
Waterproof Elastic Therapeutic Tape - Parallel 12
Waterproof Elastic Therapeutic Tape - Perpendicular 16
Statistics on mechanical properties 19
Statistics on effectiveness of clip vs GripLok 25


```
%==========================================================================
% Purpose:
%   Analyze MTS data to get elastic modulus and yield strength of
%   various bandages. Compute statistics on FEBio analysis, difference
%   between parallel and perpendicular directions in the elastic
%   therapeutic tape, and difference between GripLok and clip.
%
% Inputs:
%  Raw MTS data in .txt files. Five bandage types, three samples for each
%   bandage.
%
% Outputs:
%  None
%
% Written By: Oscar Zarneke (12-7-2022)
%
%==========================================================================
clear
clc
close all

L0 = 0.033; % Initial length (m) - constant for all trials
A_hydro = 0.000035; % Cross-sectional area (m^2) - hydrocolloid
A = 0.000007; % Cross-sectional area (m^2) - all except hydrocolloid
```

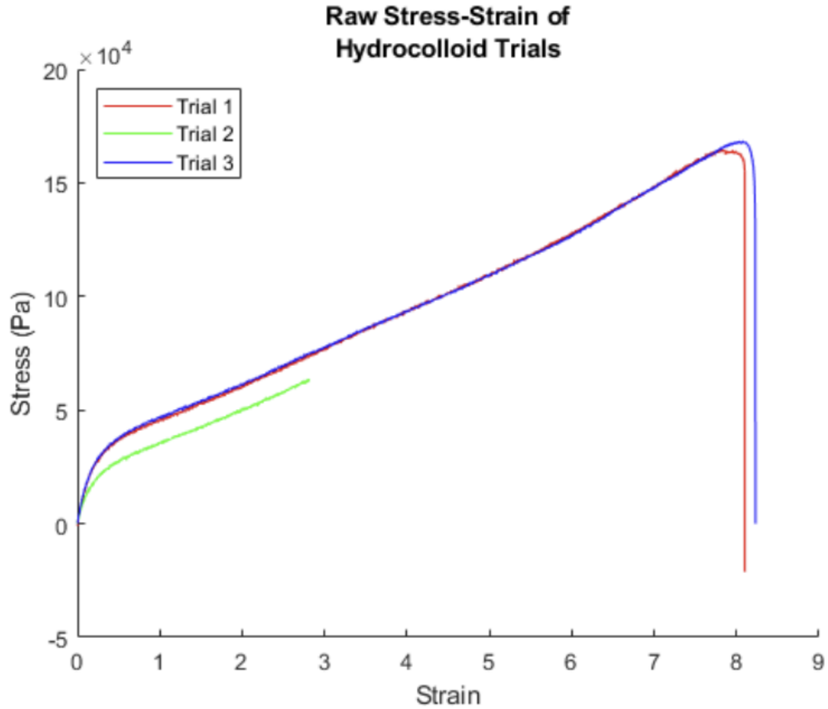
Hydrocolloid

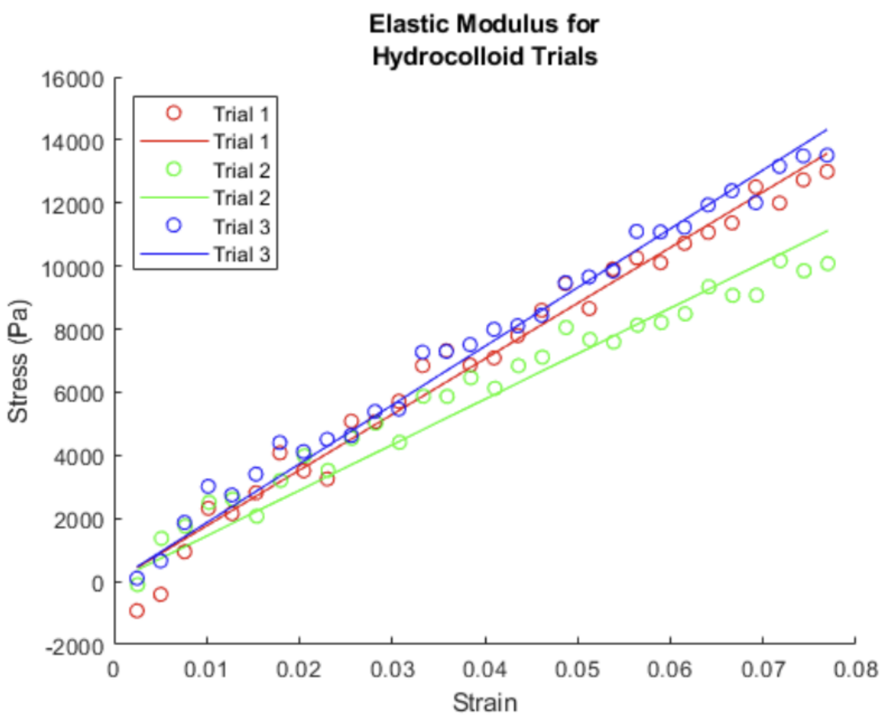
```
data1 = readtable("Hydrocolloid_1.txt"); % Read to data to a table
data1.Stress = data1.Load / A_hydro; % Calculate the stress (Pa)
data1.Strain = data1.Crosshead / (L0*1000); % Calculate the strain

data2 = readtable("Hydrocolloid_2.txt"); % Read to data to a table
data2.Stress = data2.Load / A_hydro; % Calculate the stress (Pa)
data2.Strain = data2.Crosshead / (L0*1000); % Calculate the strain

data3 = readtable("Hydrocolloid_3.txt"); % Read to data to a table
data3.Stress = data3.Load / A_hydro; % Calculate the stress (Pa)
data3.Strain = data3.Crosshead / (L0*1000); % Calculate the strain
```

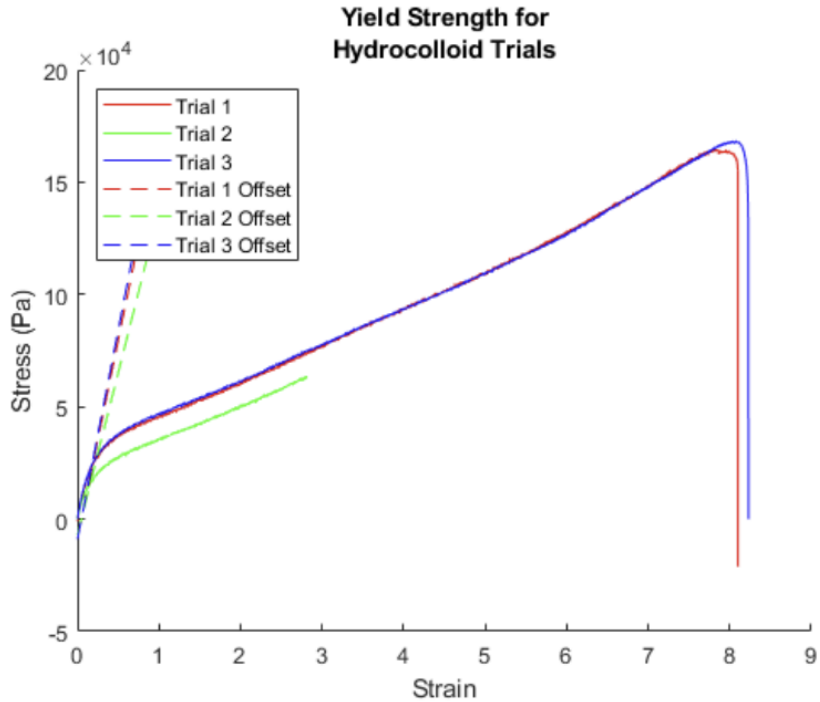
```
% Figure to check raw data
figure;
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
legend('Trial 1','Trial 2','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Raw Stress-Strain of', ...
    'Hydrocolloid Trials'})

% Index of data cutoff for elastic modulus
i_1 = 30;
i_2 = 30;
i_3 = 30;

% Calculation for elastic modulus of each trial
E_Hydro_1 = data1.Strain(1:i_1)\data1.Stress(1:i_1);
E_Hydro_2 = data2.Strain(1:i_2)\data2.Stress(1:i_2);
E_Hydro_3 = data3.Strain(1:i_3)\data3.Stress(1:i_3);

% Offset calculation for yield strength
offset1 = E_Hydro_1*(data1.Strain - 0.05);
offset2 = E_Hydro_2*(data2.Strain - 0.05);
offset3 = E_Hydro_3*(data3.Strain - 0.05);

% Calculation for yield strength
[yieldStrain_Hydro_1,yieldStress_Hydro_1] = polyxpoly(data1.Strain, ...
    data1.Stress,data1.Strain,offset1);
[yieldStrain_Hydro_2,yieldStress_Hydro_2] = polyxpoly(data2.Strain, ...
    data2.Stress,data2.Strain,offset2);
[yieldStrain_Hydro_3,yieldStress_Hydro_3] = polyxpoly(data3.Strain, ...
    data3.Stress,data3.Strain,offset3);

% Figure to check elastic modulus calculation
figure;
hold on
scatter(data1.Strain(1:i_1), data1.Stress(1:i_1),'r')
plot(data1.Strain(1:i_1),E_Hydro_1 * data1.Strain(1:i_1),'r')
scatter(data2.Strain(1:i_2), data2.Stress(1:i_2),'g')
plot(data2.Strain(1:i_2),E_Hydro_2 * data2.Strain(1:i_2),'g')
scatter(data3.Strain(1:i_3), data3.Stress(1:i_3),'b')
plot(data3.Strain(1:i_3),E_Hydro_3 * data3.Strain(1:i_3),'b')
legend('Trial 1','Trial 1', ...
    'Trial 2','Trial 2', ...
    'Trial 3','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Elastic Modulus for', ...
    'Hydrocolloid Trials'})

% Figure to check yield strength calculation
```

```
figure
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
plot(data1.Strain(1:400), offset1(1:400), 'r', "LineStyle","--")
plot(data2.Strain(1:400), offset2(1:400), 'g', "LineStyle","--")
plot(data3.Strain(1:400), offset3(1:400), 'b', "LineStyle","--")
legend('Trial 1','Trial 2','Trial 3', ...
    'Trial 1 Offset','Trial 2 Offset','Trial 3 Offset', ...
    'Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Yield Strength for', ...
    'Hydrocolloid Trials'})

% Outputs
E_Hydro = (E_Hydro_1 + E_Hydro_2 + E_Hydro_3) / 3
yield_Hydro = (yieldStress_Hydro_1(1) + yieldStress_Hydro_2(1) + ...
    yieldStress_Hydro_3(1)) / 3
```

```
E_Hydro =

     1.691328098672856e+05


yield_Hydro =

     2.129024510483322e+04
```


Raw Stress-Strain of
Hydrocolloid Trials
$\times 10^4$
Trial 1
Trial 2
Trial 3
Stress (Pa)
Strain
20
15
10
5
0
-5
0
1
2
3
4
5
6
7
8
9


Elastic Modulus for
Hydrocolloid Trials
Trial 1
Trial 1
Trial 2
Trial 2
Trial 3
Trial 3
Stress (Pa)
Strain
16000
14000
12000
10000
8000
6000
4000
2000
0
-2000
0
0.01
0.02
0.03
0.04
0.05
0.06
0.07
0.08



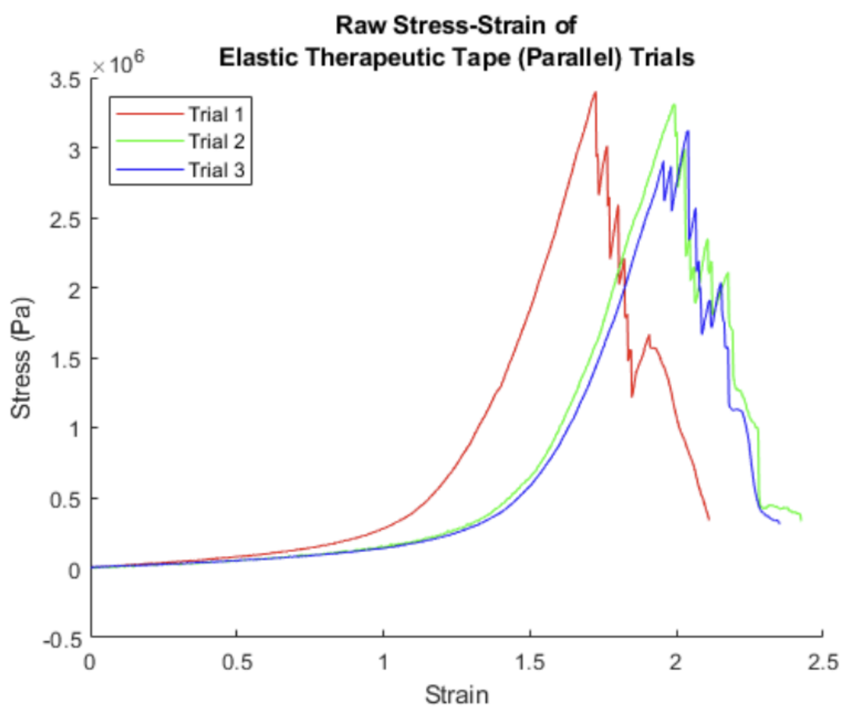
Elastic Therapeutic Tape - Parallel

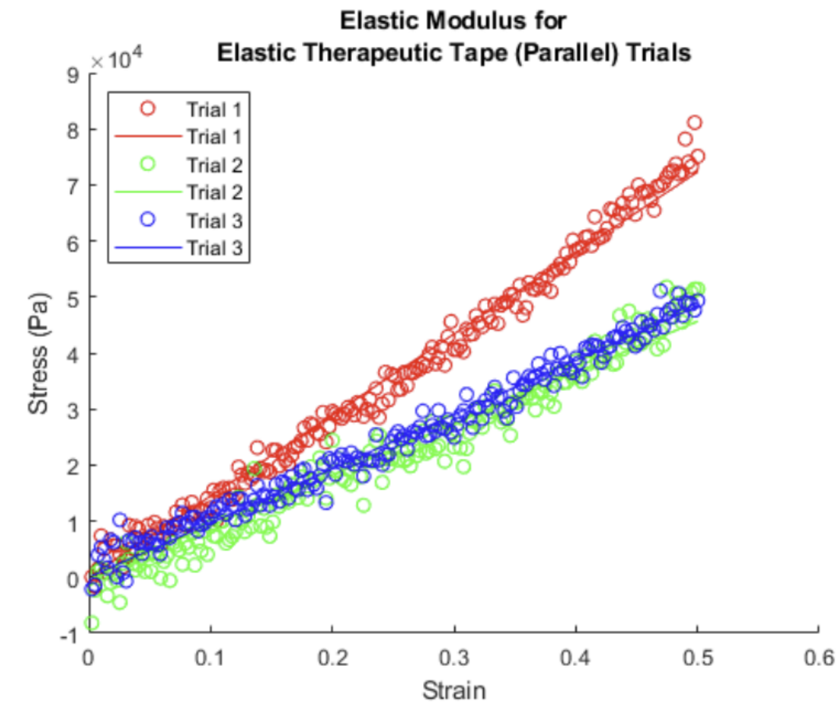
```
data1 = readtable("KT_Parallel_1.txt"); % Read to data to a table
data1.Stress = data1.Load / A; % Calculate the stress (Pa)
data1.Strain = data1.Crosshead / (L0*1000); % Calculate the strain

data2 = readtable("KT_Parallel_2.txt"); % Read to data to a table
data2.Stress = data2.Load / A; % Calculate the stress (Pa)
data2.Strain = data2.Crosshead / (L0*1000); % Calculate the strain

data3 = readtable("KT_Parallel_3.txt"); % Read to data to a table
data3.Stress = data3.Load / A; % Calculate the stress (Pa)
data3.Strain = data3.Crosshead / (L0*1000); % Calculate the strain

% Figure to check raw data
figure;
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
legend('Trial 1','Trial 2','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Raw Stress-Strain of', ...
    'Elastic Therapeutic Tape (Parallel) Trials'})
```

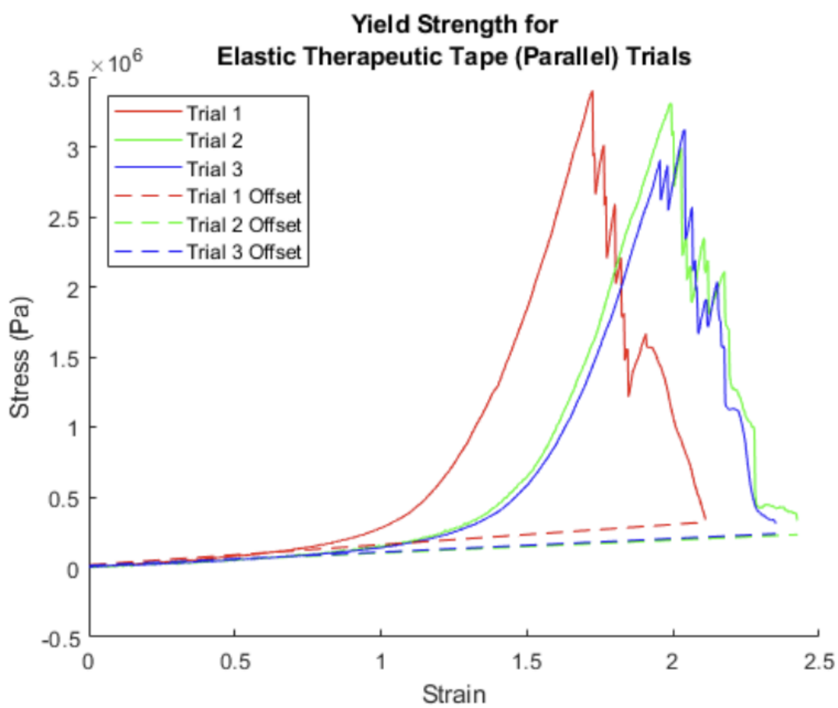
```
% Index of data cutoff for elastic modulus
i_1 = 195;
i_2 = 195;
i_3 = 195;

% Calculation for elastic modulus of each trial
E_KT_Para_1 = data1.Strain(1:i_1)\data1.Stress(1:i_1);
E_KT_Para_2 = data2.Strain(1:i_2)\data2.Stress(1:i_2);
E_KT_Para_3 = data3.Strain(1:i_3)\data3.Stress(1:i_3);

% Offset calculation for yield strength
offset1 = E_KT_Para_1*(data1.Strain + 0.1);
offset2 = E_KT_Para_2*(data2.Strain + 0.1);
offset3 = E_KT_Para_3*(data3.Strain + 0.1);

% Calculation for yield strength
[yieldStrain_KT_Para_1,yieldStress_KT_Para_1] = polyxpoly(data1.Strain, ...
    data1.Stress,data1.Strain,offset1);
[yieldStrain_KT_Para_2,yieldStress_KT_Para_2] = polyxpoly(data2.Strain, ...
    data2.Stress,data2.Strain,offset2);
[yieldStrain_KT_Para_3,yieldStress_KT_Para_3] = polyxpoly(data3.Strain, ...
    data3.Stress,data3.Strain,offset3);

% Figure to check elastic modulus calculation
figure;
hold on
scatter(data1.Strain(1:i_1), data1.Stress(1:i_1),'r')
plot(data1.Strain(1:i_1),E_KT_Para_1 * data1.Strain(1:i_1),'r')
scatter(data2.Strain(1:i_2), data2.Stress(1:i_2),'g')
plot(data2.Strain(1:i_2),E_KT_Para_2 * data2.Strain(1:i_2),'g')
scatter(data3.Strain(1:i_3), data3.Stress(1:i_3),'b')
plot(data3.Strain(1:i_3),E_KT_Para_3 * data3.Strain(1:i_3),'b')
legend('Trial 1','Trial 1', ...
    'Trial 2','Trial 2', ...
    'Trial 3','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Elastic Modulus for', ...
    'Elastic Therapeutic Tape (Parallel) Trials'})

% Figure to check yield strength calculation
figure
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
plot(data1.Strain, offset1, 'r', "LineStyle","--")
plot(data2.Strain, offset2, 'g', "LineStyle","--")
plot(data3.Strain, offset3, 'b', "LineStyle","--")
legend('Trial 1','Trial 2','Trial 3', ...
    'Trial 1 Offset','Trial 2 Offset','Trial 3 Offset', ...
    'Location','northwest')
xlabel('Strain')
```

```
ylabel('Stress (Pa)')
title({'Yield Strength for', ...
    'Elastic Therapeutic Tape (Parallel) Trials'})

% Outputs
E_KT_Para = (E_KT_Para_1 + E_KT_Para_2 + E_KT_Para_3) / 3
yield_KT_Para = (yieldStress_KT_Para_1(1) + yieldStress_KT_Para_2(1) + ...
    yieldStress_KT_Para_3(1)) / 3
```

```
E_KT_Para =

     1.108948599643673e+05


yield_KT_Para =

     7.833945667380402e+04
```




Elastic Modulus for
Elastic Therapeutic Tape (Parallel) Trials
× 10^4
Trial 1
Trial 1
Trial 2
Trial 2
Trial 3
Trial 3
Stress (Pa)
Strain
-1
0
1
2
3
4
5
6
7
8
9
0
0.1
0.2
0.3
0.4
0.5
0.6

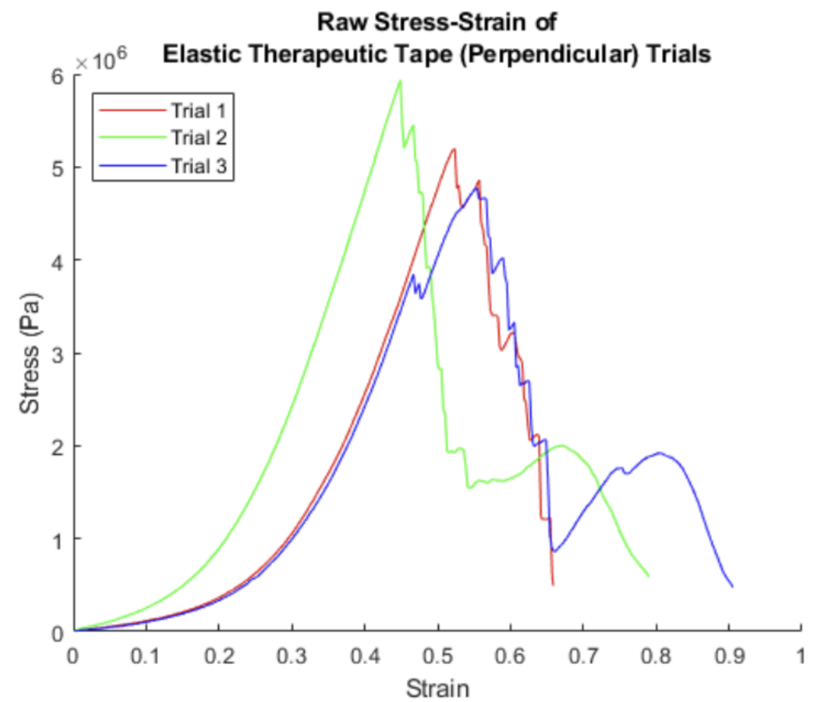

Yield Strength for
Elastic Therapeutic Tape (Parallel) Trials
× 10^6
Trial 1
Trial 2
Trial 3
Trial 1 Offset
Trial 2 Offset
Trial 3 Offset
Stress (Pa)
Strain
-0.5
0
0.5
1
1.5
2
2.5
3
3.5
0
0.5
1
1.5
2
2.5

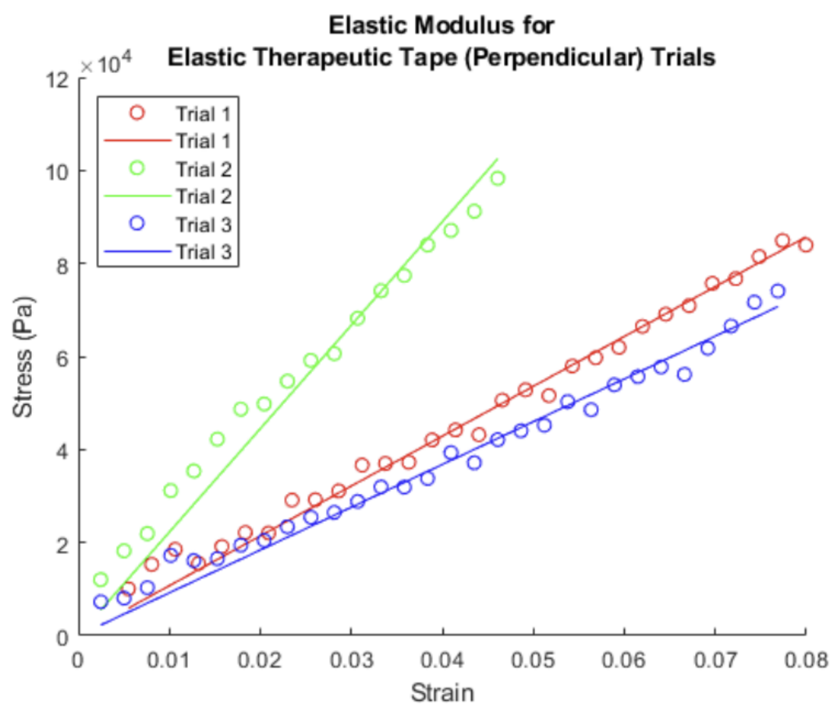
Elastic Therapeutic Tape - Perpendicular

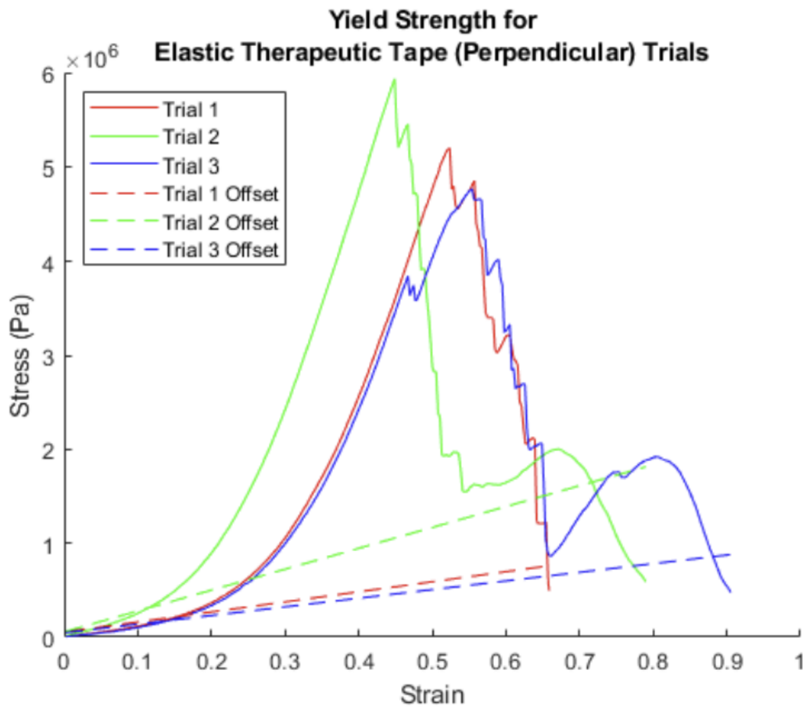
```
data1 = readtable("KT_Perp_1.txt"); % Read to data to a table
data1.Stress = data1.Load / A; % Calculate the stress (Pa)
data1.Strain = data1.Crosshead / (L0*1000); % Calculate the strain

data2 = readtable("KT_Perp_2.txt"); % Read to data to a table
data2.Stress = data2.Load / A; % Calculate the stress (Pa)
data2.Strain = data2.Crosshead / (L0*1000); % Calculate the strain

data3 = readtable("KT_Perp_3.txt"); % Read to data to a table
data3.Stress = data3.Load / A; % Calculate the stress (Pa)
data3.Strain = data3.Crosshead / (L0*1000); % Calculate the strain

% Figure to check raw data
figure;
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
legend('Trial 1','Trial 2','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Raw Stress-Strain of', ...
    'Elastic Therapeutic Tape (Perpendicular) Trials'})

% Index of data cutoff for elastic modulus
i_1 = 30;
i_2 = 18;
i_3 = 30;

% Calculation for elastic modulus of each trial
E_KT_Perp_1 = data1.Strain(1:i_1)\data1.Stress(1:i_1);
E_KT_Perp_2 = data2.Strain(1:i_2)\data2.Stress(1:i_2);
E_KT_Perp_3 = data3.Strain(1:i_3)\data3.Stress(1:i_3);

% Offset calculation for yield strength
offset1 = E_KT_Perp_1*(data1.Strain + 0.05);
offset2 = E_KT_Perp_2*(data2.Strain + 0.025);
offset3 = E_KT_Perp_3*(data3.Strain + 0.05);

% Calculation for yield strength
[yieldStrain_KT_Perp_1,yieldStress_KT_Perp_1] = polyxpoly(data1.Strain, ...
    data1.Stress,data1.Strain,offset1);
[yieldStrain_KT_Perp_2,yieldStress_KT_Perp_2] = polyxpoly(data2.Strain, ...
    data2.Stress,data2.Strain,offset2);
[yieldStrain_KT_Perp_3,yieldStress_KT_Perp_3] = polyxpoly(data3.Strain, ...
    data3.Stress,data3.Strain,offset3);

% Figure to check elastic modulus calculation
figure;
hold on
scatter(data1.Strain(1:i_1), data1.Stress(1:i_1),'r')
```

```
plot(data1.Strain(1:i_1),E_KT_Perp_1 * data1.Strain(1:i_1),'r')
scatter(data2.Strain(1:i_2), data2.Stress(1:i_2),'g')
plot(data2.Strain(1:i_2),E_KT_Perp_2 * data2.Strain(1:i_2),'g')
scatter(data3.Strain(1:i_3), data3.Stress(1:i_3),'b')
plot(data3.Strain(1:i_3),E_KT_Perp_3 * data3.Strain(1:i_3),'b')
legend('Trial 1','Trial 1', ...
    'Trial 2','Trial 2', ...
    'Trial 3','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Elastic Modulus for', ...
    'Elastic Therapeutic Tape (Perpendicular) Trials'})

% Figure to check yield strength calculation
figure
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
plot(data1.Strain, offset1, 'r', "LineStyle","--")
plot(data2.Strain, offset2, 'g', "LineStyle","--")
plot(data3.Strain, offset3, 'b', "LineStyle","--")
legend('Trial 1','Trial 2','Trial 3', ...
    'Trial 1 Offset','Trial 2 Offset','Trial 3 Offset', ...
    'Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Yield Strength for', ...
    'Elastic Therapeutic Tape (Perpendicular) Trials'})

% Outputs
E_KT_Perp = (E_KT_Perp_1 + E_KT_Perp_2 + E_KT_Perp_3) / 3
yield_KT_Perp = (yieldStress_KT_Perp_1(1) + yieldStress_KT_Perp_2(1) + ...
    yieldStress_KT_Perp_3(1)) / 3
```

```
E_KT_Perp =

     1.405213947830393e+06


yield_KT_Perp =

     2.341434736637702e+05
```


Raw Stress-Strain of
Elastic Therapeutic Tape (Perpendicular) Trials
×10^6
Trial 1
Trial 2
Trial 3
Stress (Pa)
Strain
0
1
2
3
4
5
6
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1


Elastic Modulus for
Elastic Therapeutic Tape (Perpendicular) Trials
×10^4
Trial 1
Trial 1
Trial 2
Trial 2
Trial 3
Trial 3
Stress (Pa)
Strain
0
2
4
6
8
10
12
0.01
0.02
0.03
0.04
0.05
0.06
0.07
0.08



Waterproof Elastic Therapeutic Tape - Parallel

```
data1 = readtable("Water_KT_Parallel_1.txt"); % Read to data to a table
data1.Stress = data1.Load / A; % Calculate the stress (Pa)
data1.Strain = data1.Crosshead / (L0*1000); % Calculate the strain

data2 = readtable("Water_KT_Parallel_2.txt"); % Read to data to a table
data2.Stress = data2.Load / A; % Calculate the stress (Pa)
data2.Strain = data2.Crosshead / (L0*1000); % Calculate the strain

data3 = readtable("Water_KT_Parallel_3.txt"); % Read to data to a table
data3.Stress = data3.Load / A; % Calculate the stress (Pa)
data3.Strain = data3.Crosshead / (L0*1000); % Calculate the strain

% Figure to check raw data
figure;
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
legend('Trial 1','Trial 2','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Raw Stress-Strain of Waterproof', ...
    'Elastic Therapeutic Tape (Parallel) Trials'})
```

```
% Index of data cutoff for elastic modulus
i_1 = 30;
i_2 = 18;
i_3 = 30;

% Calculation for elastic modulus of each trial
E_Water_KT_Para_1 = data1.Strain(1:i_1)\data1.Stress(1:i_1);
E_Water_KT_Para_2 = data2.Strain(1:i_2)\data2.Stress(1:i_2);
E_Water_KT_Para_3 = data3.Strain(1:i_3)\data3.Stress(1:i_3);

% Offset calculation for yield strength
offset1 = E_Water_KT_Para_1*(data1.Strain - 0.05);
offset2 = E_Water_KT_Para_2*(data2.Strain - 0.05);
offset3 = E_Water_KT_Para_3*(data3.Strain - 0.05);

% Calculation for yield strength
[yieldStrain_Water_KT_Para_1,yieldStress_Water_KT_Para_1] =
 polyxpoly(data1.Strain, ...
    data1.Stress,data1.Strain,offset1);
[yieldStrain_Water_KT_Para_2,yieldStress_Water_KT_Para_2] =
 polyxpoly(data2.Strain, ...
    data2.Stress,data2.Strain,offset2);
[yieldStrain_Water_KT_Para_3,yieldStress_Water_KT_Para_3] =
 polyxpoly(data3.Strain, ...
    data3.Stress,data3.Strain,offset3);

% Figure to check elastic modulus calculation
figure;
hold on
scatter(data1.Strain(1:i_1), data1.Stress(1:i_1),'r')
plot(data1.Strain(1:i_1),E_Water_KT_Para_1 * data1.Strain(1:i_1),'r')
scatter(data2.Strain(1:i_2), data2.Stress(1:i_2),'g')
plot(data2.Strain(1:i_2),E_Water_KT_Para_2 * data2.Strain(1:i_2),'g')
scatter(data3.Strain(1:i_3), data3.Stress(1:i_3),'b')
plot(data3.Strain(1:i_3),E_Water_KT_Para_3 * data3.Strain(1:i_3),'b')
legend('Trial 1','Trial 1', ...
    'Trial 2','Trial 2', ...
    'Trial 3','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Elastic Modulus for Waterproof', ...
    'Elastic Therapeutic Tape (Parallel) Trials'})

% Figure to check yield strength calculation
figure
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
plot(data1.Strain, offset1, 'r', "LineStyle","--")
plot(data2.Strain, offset2, 'g', "LineStyle","--")
plot(data3.Strain, offset3, 'b', "LineStyle","--")
legend('Trial 1','Trial 2','Trial 3', ...
```

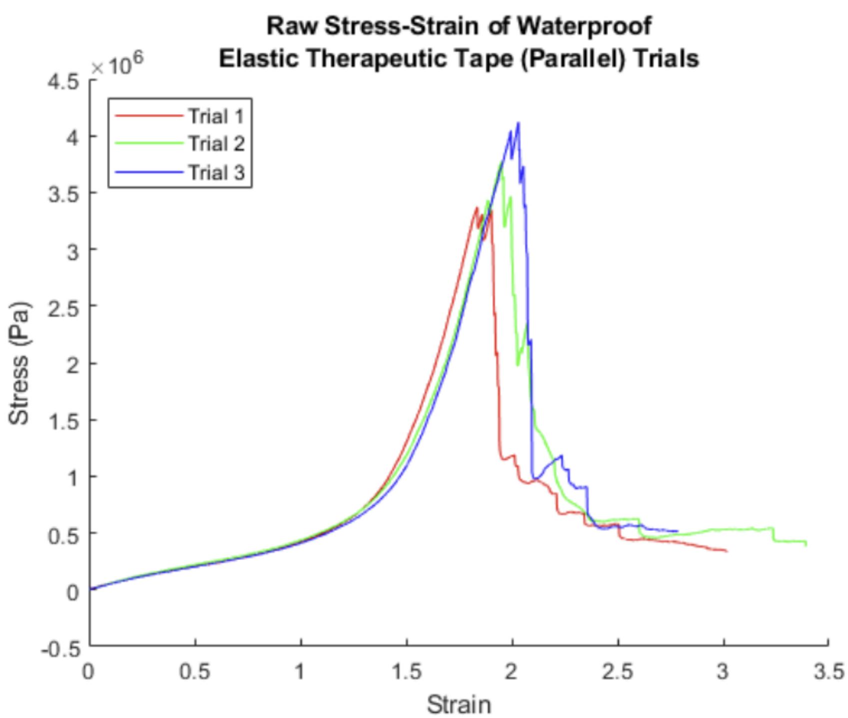
```
    'Trial 1 Offset','Trial 2 Offset','Trial 3 Offset', ...
    'Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Yield Strength for Waterproof', ...
    'Elastic Therapeutic Tape (Parallel) Trials'})

% Outputs
E_Water_KT_Para = (E_Water_KT_Para_1 + E_Water_KT_Para_2 + ...
    E_Water_KT_Para_3) / 3
yield_Water_KT_Para = (yieldStress_Water_KT_Para_1(1) + ...
    yieldStress_Water_KT_Para_2(1) + yieldStress_Water_KT_Para_3(1)) / 3
```

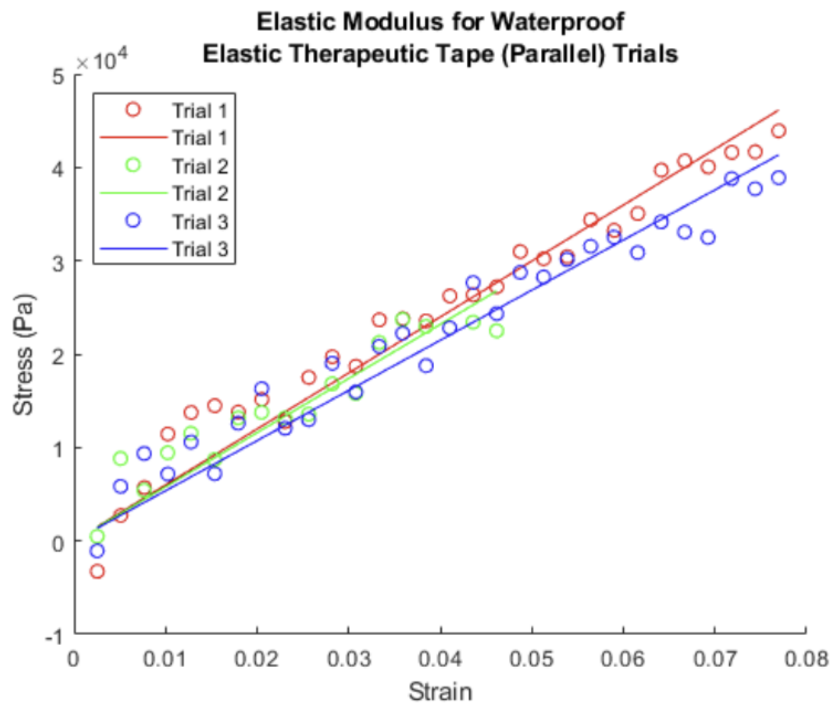
E_Water_KT_Para =

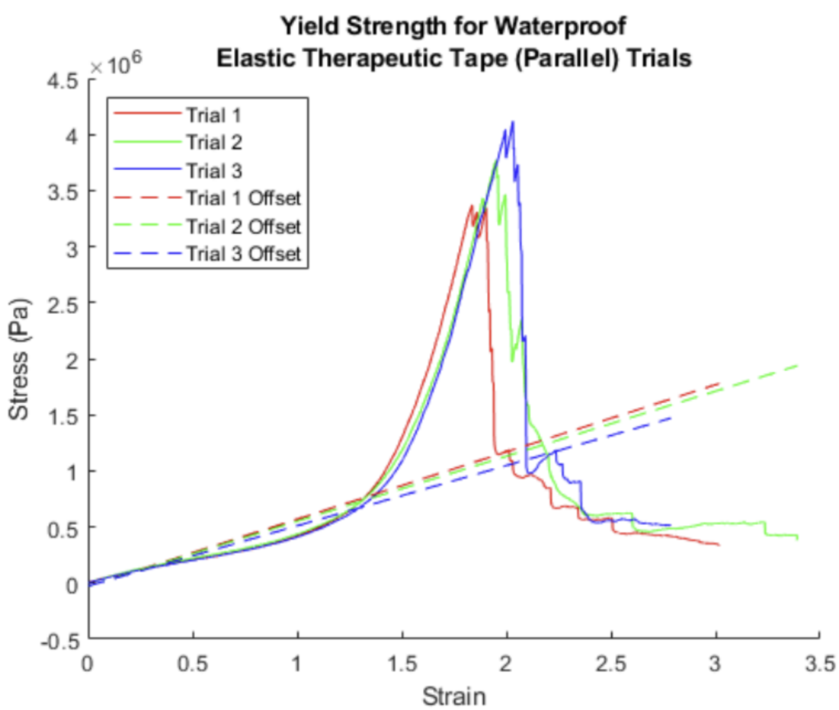
5.720993045630264e+05

yield_Water_KT_Para =

1.321729547441476e+05




Elastic Modulus for Waterproof
Elastic Therapeutic Tape (Parallel) Trials
Trial 1
Trial 1
Trial 2
Trial 2
Trial 3
Trial 3
Stress (Pa)
Strain

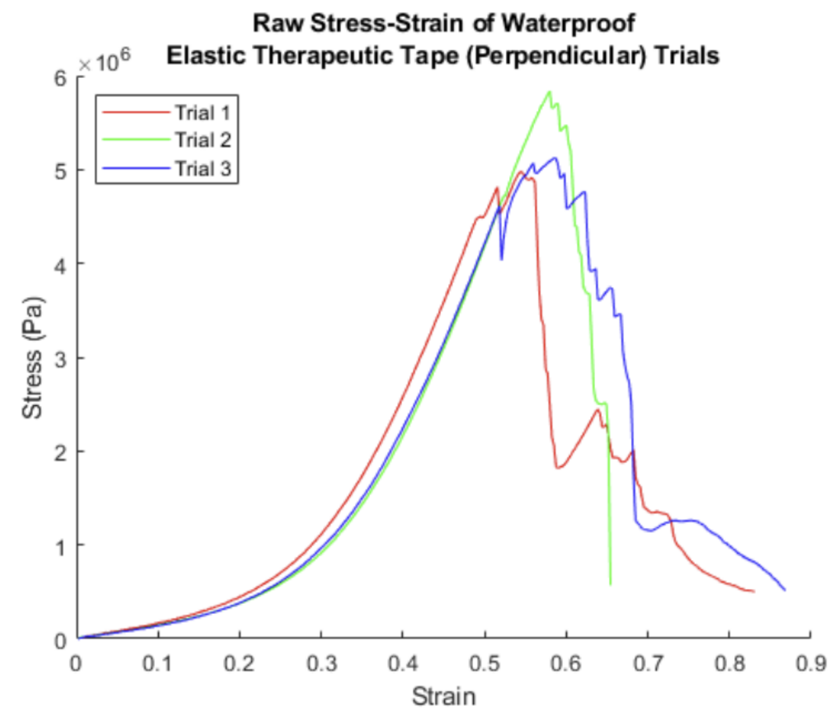

Yield Strength for Waterproof
Elastic Therapeutic Tape (Parallel) Trials
Trial 1
Trial 2
Trial 3
Trial 1 Offset
Trial 2 Offset
Trial 3 Offset
Stress (Pa)
Strain

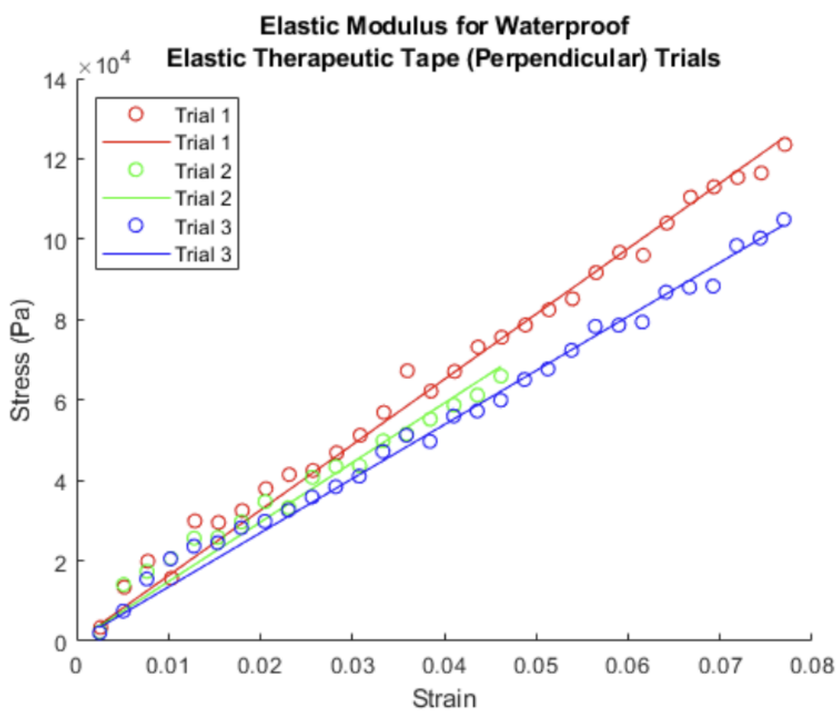
Waterproof Elastic Therapeutic Tape - Perpendicular

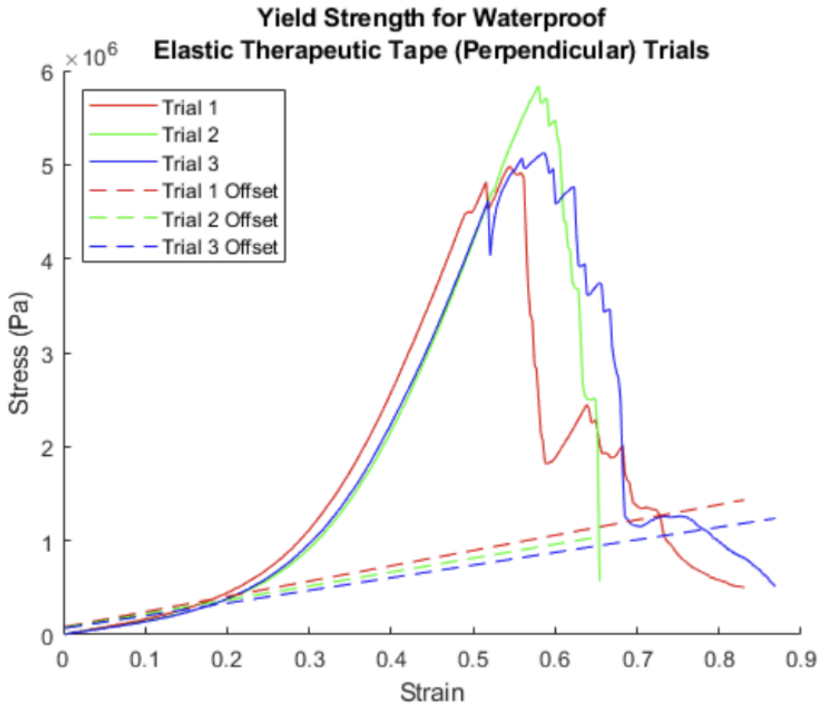
```
data1 = readtable("Water_KT_Perp_1.txt"); % Read to data to a table
data1.Stress = data1.Load / A; % Calculate the stress (Pa)
data1.Strain = data1.Crosshead / (L0*1000); % Calculate the strain

data2 = readtable("Water_KT_Perp_2.txt"); % Read to data to a table
data2.Stress = data2.Load / A; % Calculate the stress (Pa)
data2.Strain = data2.Crosshead / (L0*1000); % Calculate the strain

data3 = readtable("Water_KT_Perp_3.txt"); % Read to data to a table
data3.Stress = data3.Load / A; % Calculate the stress (Pa)
data3.Strain = data3.Crosshead / (L0*1000); % Calculate the strain

% Figure to check raw data
figure;
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
legend('Trial 1','Trial 2','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Raw Stress-Strain of Waterproof', ...
    'Elastic Therapeutic Tape (Perpendicular) Trials'})

% Index of data cutoff for elastic modulus
i_1 = 30;
i_2 = 18;
i_3 = 30;

% Calculation for elastic modulus of each trial
E_Water_KT_Perp_1 = data1.Strain(1:i_1)\data1.Stress(1:i_1);
E_Water_KT_Perp_2 = data2.Strain(1:i_2)\data2.Stress(1:i_2);
E_Water_KT_Perp_3 = data3.Strain(1:i_3)\data3.Stress(1:i_3);

% Offset calculation for yield strength
offset1 = E_Water_KT_Perp_1*(data1.Strain + 0.05);
offset2 = E_Water_KT_Perp_2*(data2.Strain + 0.05);
offset3 = E_Water_KT_Perp_3*(data3.Strain + 0.05);

% Calculation for yield strength
[yieldStrain_Water_KT_Perp_1,yieldStress_Water_KT_Perp_1] =
 polyxpoly(data1.Strain, ...
    data1.Stress,data1.Strain,offset1);
[yieldStrain_Water_KT_Perp_2,yieldStress_Water_KT_Perp_2] =
 polyxpoly(data2.Strain, ...
    data2.Stress,data2.Strain,offset2);
[yieldStrain_Water_KT_Perp_3,yieldStress_Water_KT_Perp_3] =
 polyxpoly(data3.Strain, ...
    data3.Stress,data3.Strain,offset3);
```

```
% Figure to check elastic modulus calculation
figure;
hold on
scatter(data1.Strain(1:i_1), data1.Stress(1:i_1),'r')
plot(data1.Strain(1:i_1),E_Water_KT_Perp_1 * data1.Strain(1:i_1),'r')
scatter(data2.Strain(1:i_2), data2.Stress(1:i_2),'g')
plot(data2.Strain(1:i_2),E_Water_KT_Perp_2 * data2.Strain(1:i_2),'g')
scatter(data3.Strain(1:i_3), data3.Stress(1:i_3),'b')
plot(data3.Strain(1:i_3),E_Water_KT_Perp_3 * data3.Strain(1:i_3),'b')
legend('Trial 1','Trial 1', ...
    'Trial 2','Trial 2', ...
    'Trial 3','Trial 3','Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Elastic Modulus for Waterproof', ...
    'Elastic Therapeutic Tape (Perpendicular) Trials'})

% Figure to check yield strength calculation
figure
hold on
plot(data1.Strain, data1.Stress, 'r')
plot(data2.Strain, data2.Stress, 'g')
plot(data3.Strain, data3.Stress, 'b')
plot(data1.Strain, offset1, 'r', "LineStyle","--")
plot(data2.Strain, offset2, 'g', "LineStyle","--")
plot(data3.Strain, offset3, 'b', "LineStyle","--")
legend('Trial 1','Trial 2','Trial 3', ...
    'Trial 1 Offset','Trial 2 Offset','Trial 3 Offset', ...
    'Location','northwest')
xlabel('Strain')
ylabel('Stress (Pa)')
title({'Yield Strength for Waterproof', ...
    'Elastic Therapeutic Tape (Perpendicular) Trials'})

% Outputs
E_Water_KT_Perp = (E_Water_KT_Perp_1 + E_Water_KT_Perp_2 + ...
    E_Water_KT_Perp_3) / 3
yield_Water_KT_Perp = (yieldStress_Water_KT_Perp_1(1) + ...
    yieldStress_Water_KT_Perp_2(1) + yieldStress_Water_KT_Perp_3(1)) / 3
```

```
E_Water_KT_Perp =

     1.484650595037110e+06


yield_Water_KT_Perp =

     3.490408861830051e+05
```


Raw Stress-Strain of Waterproof
Elastic Therapeutic Tape (Perpendicular) Trials
×10^6
Trial 1
Trial 2
Trial 3
Stress (Pa)
Strain
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
2
3
4
5
6


Elastic Modulus for Waterproof
Elastic Therapeutic Tape (Perpendicular) Trials
×10^4
Trial 1
Trial 1
Trial 2
Trial 2
Trial 3
Trial 3
Stress (Pa)
Strain
0
0.01
0.02
0.03
0.04
0.05
0.06
0.07
0.08
2
4
6
8
10
12
14



Statistics on mechanical properties

```
% row_labels = ['Circle';'Flower';'Oval 10-5';'Oval 10-7.5';'Oval 15-5'];
% column_labels = ['Hydrocolloid' 'Elastic Therapeutic Tape' 'Waterproof
 Elastic Therapeutic Tape'];

hydro_stress = [9.989420E+05;6.538556E+05;9.417183E+05;7.0515E+05;7.153962E
+05];
KT_stress = [9.509041E+05;9.355949E+05;6.574508E+05;9.400736E+05;9.369509E
+05];
Water_KT_stress = [6.457389E+05;6.355539E+05;4.461168E+05;6.406221E
+05;6.384082E+05];
data_stress = [hydro_stress KT_stress Water_KT_stress];

[p1,tbl1,stats1] = anova2(data_stress)
figure
[c1,m1,h1,gnames1] = multcompare(stats1,'Estimate','column')
% Shows there is a difference due to material
figure
[c2,m2,h2,gnames2] = multcompare(stats1,'Estimate','row')
% Shows no difference due to shape

[h3,p3,ci3,stats3] = ttest2([E_KT_Para_1;E_KT_Para_2;E_KT_Para_3], ...
    [E_KT_Perp_1;E_KT_Perp_2;E_KT_Perp_3])
% Shows difference between parallel and perpendicular directions
```

```
[h4,p4,ci4,stats4] =
 ttest2([E_Water_KT_Para_1;E_Water_KT_Para_2;E_Water_KT_Para_3], ...
    [E_Water_KT_Perp_1;E_Water_KT_Perp_2;E_Water_KT_Perp_3])
% Shows difference between parallel and perpendicular directions


p1 =

   0.024620925975558   0.582555829454056


tbl1 =

  5×6 cell array

  Columns 1 through 3

    {'Source' }    {'SS'                   }    {'df'}
    {'Columns'}    {[2.121994016816692e+11]}    {[ 2]}
    {'Rows'   }    {[5.249937281913734e+10]}    {[ 4]}
    {'Error'  }    {[1.391935661473087e+11]}    {[ 8]}
    {'Total'  }    {[4.038923406481152e+11]}    {[14]}

  Columns 4 through 6

    {'MS'                   }    {'F'                 }    {'Prob>F'
  }
    {[1.060997008408346e+11]}    {[6.097965805606227]}
 {[0.024620925975558]}
    {[1.312484320478433e+10]}    {[0.754336199182902]}
 {[0.582555829454056]}
    {[1.739919576841359e+10]}    {0×0 double         }    {0×0 double
  }
    {0×0 double             }    {0×0 double         }    {0×0 double
  }


stats1 =

  struct with fields:

      source: 'anova2'
     sigmasq: 1.739919576841359e+10
    colmeans: [8.030124200000002e+05 8.841948600000000e+05 … ]
        coln: 5
    rowmeans: [865195 7.416681333333333e+05 6.817619666666667e+05 … ]
        rown: 3
       inter: 0
        pval: NaN
          df: 8


c1 =
```

```
   1.0e+05 *

  Columns 1 through 3

   0.000010000000000   0.000020000000000  -3.195638348677153
   0.000010000000000   0.000030000000000  -0.366569548677154
   0.000020000000000   0.000030000000000   0.445254851322844

  Columns 4 through 6

  -0.811824399999998   1.571989548677156   0.000006128017548
   2.017244400000000   4.401058348677155   0.000000953879319
   2.829068799999999   5.212882748677153   0.000000229987649


m1 =

   1.0e+05 *

   8.030124200000001   0.589901614990391
   8.841948600000000   0.589901614990391
   6.012879800000001   0.589901614990391


h1 =

  Figure (17: Multiple comparison of column means) with properties:

      Number: 17
        Name: 'Multiple comparison of column means'
       Color: [0.940000000000000 0.940000000000000 0.940000000000000]
    Position: [680 558 560 420]
       Units: 'pixels'

  Use GET to show all properties


gnames1 =

  3×1 char array

    '1'
    '2'
    '3'


c2 =

   1.0e+05 *

  Columns 1 through 3

   0.000010000000000   0.000020000000000  -2.485524944126396
   0.000010000000000   0.000030000000000  -1.886463277459730
```

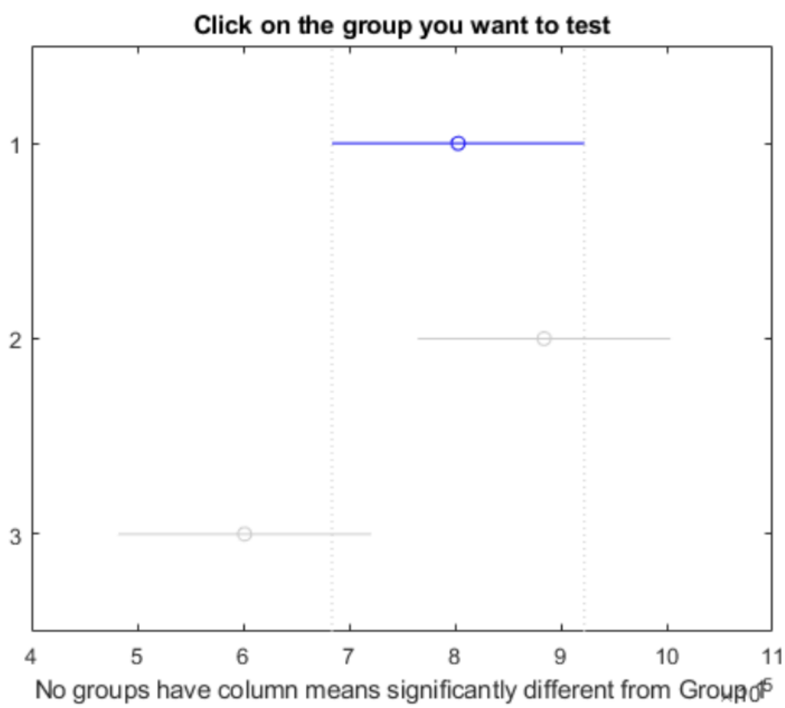
```
   0.000010000000000   0.000040000000000  -2.688329277459731
   0.000010000000000   0.000050000000000  -2.704694610793063
   0.000020000000000   0.000030000000000  -3.121731944126397
   0.000020000000000   0.000040000000000  -3.923597944126398
   0.000020000000000   0.000050000000000  -3.939963277459730
   0.000030000000000   0.000040000000000  -4.522659610793064
   0.000030000000000   0.000050000000000  -4.539024944126396
   0.000040000000000   0.000050000000000  -3.737158944126396

  Columns 4 through 6

   1.235268666666667   4.956062277459730   0.000007791922218
   1.834330333333333   5.555123944126397   0.000004819407630
   1.032464333333332   4.753257944126395   0.000008660667128
   1.016099000000000   4.736892610793063   0.000008722642818
   0.599061666666666   4.319855277459729   0.000009779986238
  -0.202804333333335   3.517989277459729   0.000009996525909
  -0.219169666666667   3.501623944126397   0.000009995281011
  -0.801866000000001   2.918927610793062   0.000009395157522
  -0.818231333333333   2.902562277459730   0.000009353392633
  -0.016365333333332   3.704428277459731   0.000009999999483


m2 =

   1.0e+05 *

   8.651949999999999   0.761559710252881
   7.416681333333333   0.761559710252881
   6.817619666666666   0.761559710252881
   7.619485666666668   0.761559710252881
   7.635851000000000   0.761559710252881


h2 =

  Figure (18: Multiple comparison of row means) with properties:

      Number: 18
        Name: 'Multiple comparison of row means'
       Color: [0.940000000000000 0.940000000000000 0.940000000000000]
    Position: [680 558 560 420]
       Units: 'pixels'

  Use GET to show all properties


gnames2 =

  5×1 char array

    '1'
    '2'
    '3'
```

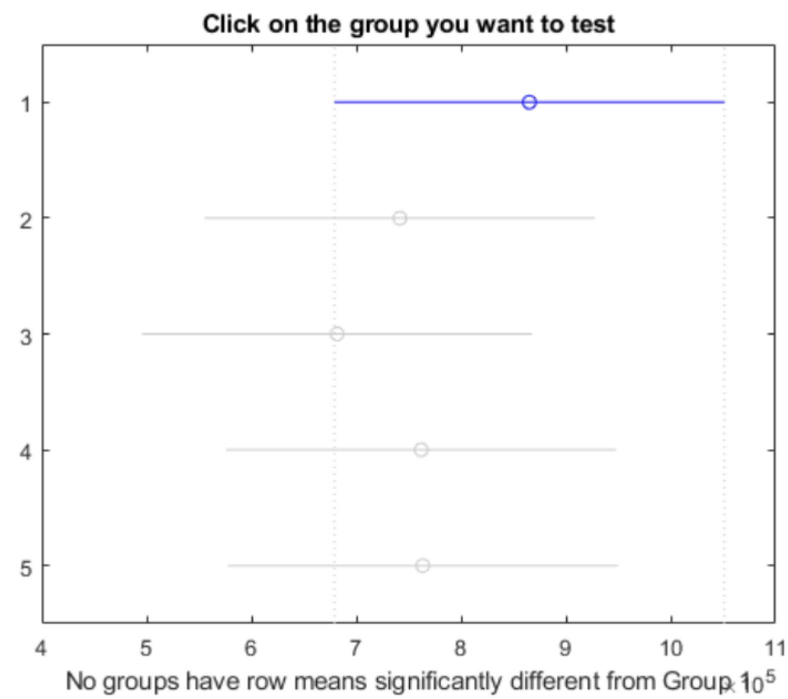
```
    '4'
    '5'


h3 =

     1


p3 =

   0.034824168716290


ci3 =

   1.0e+06 *

  -2.438523561545429
  -0.150114614186623


stats3 =

  struct with fields:

    tstat: -3.140702539392972
       df: 4
       sd: 5.047312328771323e+05


h4 =

     1


p4 =

     3.975097394375142e-04


ci4 =

   1.0e+06 *

  -1.144293963675451
  -0.680808617272716


stats4 =

  struct with fields:

    tstat: -10.933025535081923
```

df: 4
sd: 1.022262784719212e+05

ANOVA Table

Source	SS	df	MS	F	Prob>F
Columns	2.12199e+11	2	1.061e+11	6.1	0.0246
Rows	5.24994e+10	4	1.31248e+10	0.75	0.5826
Error	1.39194e+11	8	1.73992e+10		
Total	4.03892e+11	14			





Statistics on effectiveness of clip vs GripLok

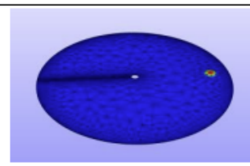
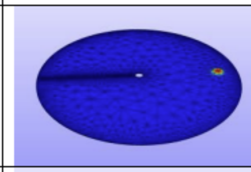
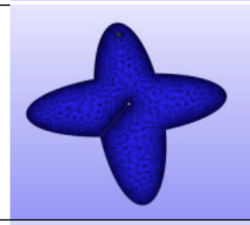
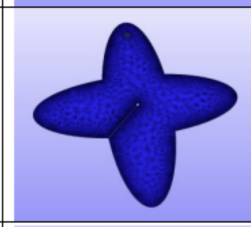
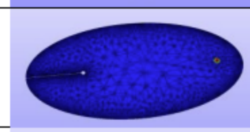
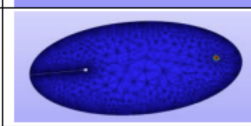
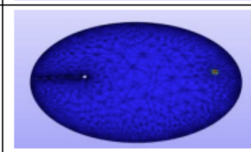
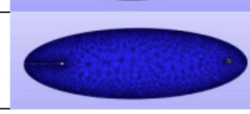
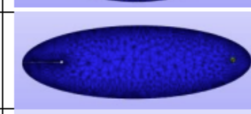
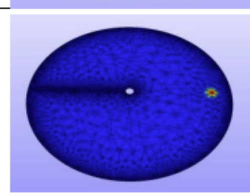
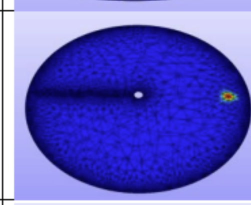
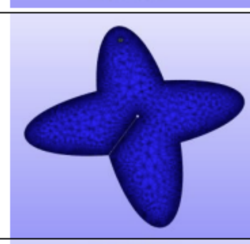
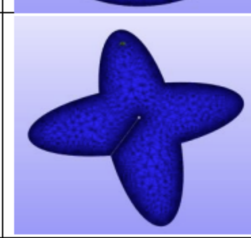
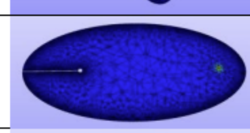
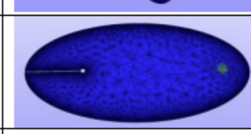
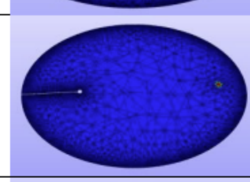
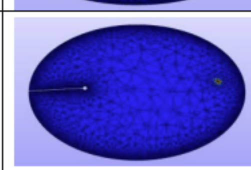
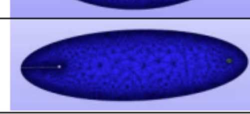
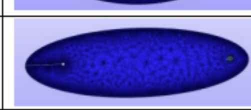
```
clip_fail = [519.35;611.40;601.40];
griplok_fail = [467.14;487.14;468.92];

[h5,p5,ci5,stats5] = ttest2(clip_fail,griplok_fail)
% Shows difference between maximum clip and griplok fail weights
```

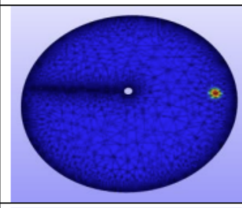
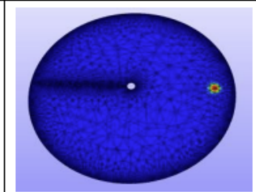
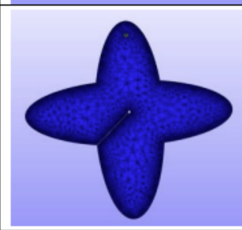
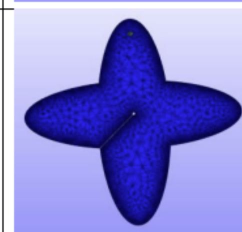
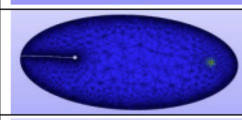
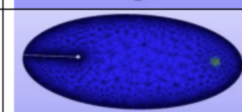
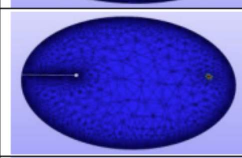
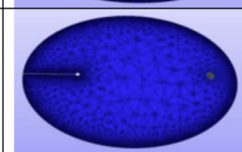
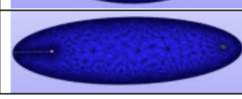
```
h5 =

     1


p5 =

   0.026059269662994


ci5 =

   1.0e+02 *

   0.201009262747351
   1.858657403919314
```

```
stats5 =

  struct with fields:

    tstat: 3.449798116361826
       df: 4
       sd: 36.561069687123016
```

Published with MATLAB® R2021b

8.5 FEBio Results

Material	Geometry			Maximum Effective Stress		Maximum Effective Lagrange Strain	
	Shape	Radius 1 (cm)	Radius 2 (cm)	Value (Pa)	Image	Value	Image
Hydrocolloid	Circle	5	N/A	9.989420E+05		1.98207	
	Flower	15	5	6.538556E+05		1.507506	
	Oval	10	5	9.417183E+05		1.97971	
	Oval	10	7.5	7.0515E+05		1.549128	
	Oval	15	5	7.153962E+05		1.589429	
Elastic Therapeutic Tape	Circle	5	N/A	9.509041E+05		0.5639833	
	Flower	15	5	9.355949E+05		0.5563854	
	Oval	10	5	6.574508E+05		0.410577	
	Oval	10	7.5	9.400736E+05		0.5545577	
	Oval	15	5	9.369509E+05		0.5575991	

Material	Geometry			Maximum Effective Stress		Maximum Effective Lagrange Strain	
	Shape	Radius 1 (cm)	Radius 2 (cm)	Value (Pa)	Image	Value	Image
Waterproof Elastic Therapeutic Tape	Circle	5	N/A	6.457389E+05		0.19634	
	Flower	15	5	6.355539E+05		0.1941284	
	Oval	10	5	4.461168E+05		0.1418563	
	Oval	10	7.5	6.406221E+05		0.1938874	
	Oval	15	5	6.384082E+05		0.1946171