

Design and Optimization of Actuation Mechanisms
for Rapid Skin Closure Device

by

Andrew T. Erickson

Submitted to the
Department of Mechanical Engineering
in Partial Fulfillment of the Requirements for the Degree of

Bachelor of Science in Mechanical Engineering

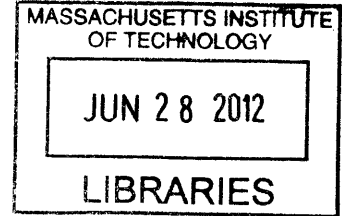
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June 2012

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ABSTRACT

Innovative mechanism designs were explored for the actuation of critical components in a novel rapid skin closure device used to close long surgical incisions. The rapid skin closure device is designed to speed up the wound closure process and achieve the aesthetic results of a plastic surgeon by automatically placing bio-absorbable adjustable clips in the dermal layer of skin along a surgical incision. Precise alignment of the wound edges, deployment of needles pre-loaded with clips, and the successful connection of the two clip ends inside the wound are critical for the proper function of the device. The iterative design of the actuating mechanisms for the skin alignment, needle deployment, and successful clip connection were accomplished in four prototypes. The first two prototypes demonstrated the proof of concept that needles could follow a pre-determined path and two ends of a clip could be reliably connected. The second pneumatically actuated prototype connected over a hundred clips in a row and measured a repeatability of 98%. The third and fourth prototypes focused on refining the design into a production product by reducing the size, complexity, and cost. Many types of actuators and power transmission components were used, combined, and compared. It was found that the skin alignment could be reduced to a passive rail system that did not require an actuator. Furthermore, the needle and ejector pin motions critical for the success of placing a clip were combined into a single actuating motion. The combination was made possible by a series of nested cylinders separated by a stiff compression spring, and actuated by a slotted angled bar that optimized efficiency. All electronics were eliminated from the device with the inclusion of a manually actuated handle to drive the main slotted bar. The results from testing in human skin revealed that the needle deployment and clipping were successful, but the passive rail alignment failed due to the elastic nature of the tissue. Further refinement will be required to make the device production ready. However, the innovative designs from this research will have a significant impact on the success of the device as a product.

Thesis Supervisor: Alexander H. Slocum
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INTRODUCTION

1.1 Opportunity

In the modern operating room, manual wound closure stands out as an archaic throwback amidst the technological wonders of robotic arms, 3D imaging, and life support systems used in today's surgical procedures. The process of closing surgical incisions involves hand stitching individual sutures through multiple layers of the skin, which is both tedious and time consuming.

Particularly in the field of plastic surgery, where the quality of wound closure is valued the most, the closure process may encompass up to 70% of operative time. Such inefficiency not only drains hospital resources and patients' wallets, it also increases the risk to patients due to their prolonged exposure to anesthesia and infection prone environment. Thus, the labor intensive and time-consuming process of manual wound closure is ripe for a modern upgrade that leverages the speed of an automated device with the aesthetic results of a seasoned plastic surgeon.

1.2 Wound Closure Mechanics

Skin consists of three main layers: the epidermis, dermis, and fascia. The thickness of the uppermost layer of skin, the epidermal layer, is on the order of 100 μm and acts as a protective barrier between the outside world and the body. The layer of skin directly below the epidermal is called the dermis. The dermal layer is approximately 1 to 3 mm thick, depending on the person and the area of the body, and is considered the strength layer of skin due to one of its main components, collagen [1]. Finally, a layer of connective tissue called the fascia is separated from the dermis by a layer of fat and interfaces with the interior parts of the body.

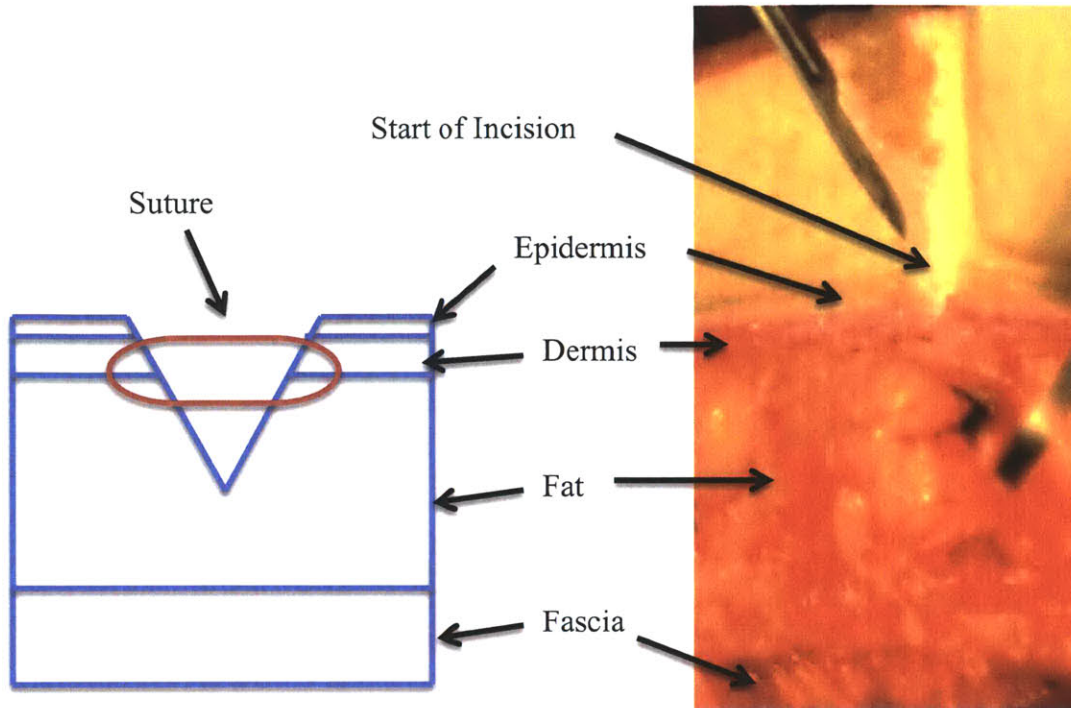


Figure 1.1: Cross-section of wound showing the layers of skin. Left: Model of skin layers and placement of surgical suture. Right: Cross-section of human skin excised from a patient and used for testing.

In order to close a long incision a surgeon begins by grossly aligning skin edges with reference marks and staples, as seen in Figure 1.2. Interrupted sutures are then placed between the staples in the fascia layer for extra closing strength and alignment if needed. The fascia closure is a relatively quick part of the operation because the sutures can be placed every couple inches unlike the dermal closure, which requires sutures approximately every centimeter. Next, the alignment staples are taken out as interrupted sutures are placed in the dermis. The dermal closure represents about 70-80% of the total wound closure time and is the focus of this project. In some cases it would be sufficient to only close the dermal layer to reduce tension on the wound edges and encourage adequate wound healing. However, for aesthetic appearances, speed of healing, and to reduce the risk of infection, a running suture is often placed in the epidermis to form an everted closely matched skin closure. Finally, a layer of Dermabond™, topical skin adhesive, may be applied on the surface of the closed wound to provide a watertight seal against possible infections.

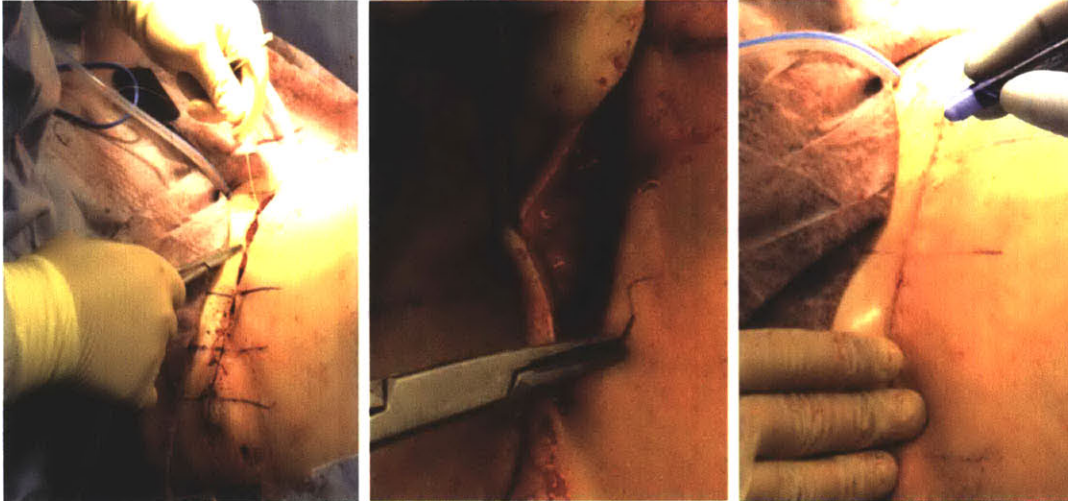


Figure 1.2: Current wound closing procedure. Left: Gross alignment stitches are placed in the fascia layer. Middle: Interrupted stitch in the dermal layer of skin. Right: Running suture in the epidermal layer of skin followed by a layer of Dermabond™ to form a watertight seal.

1.3 Risks of Conventional Practice

In 2010, over 9 million cosmetic surgical procedures were performed in the United States. Out of those 9 million, breast reductions (135,000) and circumferential body lifts (145,000) are some of the most common that necessitate closing long surgical incisions as described above [2].

Through talks with clinicians in the field of plastic surgery from Massachusetts General Hospital (MGH) in Boston, the approximate procedural times for breast reductions and circumferential body lifts were determined. For breast reductions, the initial incisions and tissue resection takes about 30-60 minutes to complete, while the wound closure can vary between 1.5 and 3 hours. Similarly for abdominoplasty, body lift procedures typically performed on patients with excess skin due to significant weight loss, it takes approximately 1-2 hours to complete skin and soft tissue resection, while more than 3 hours could be spent on wound closure. The significant percentage of total operation time spent on the repetitive rote procedure of closing wounds presents a great opportunity for improvement.

How great is this opportunity? \$6.2 billion is spent each year on surgical procedures [3]. With an operating room cost as high as \$66 per minute, wound closure could amount to approximately \$6000 per operation or more [4]. Therefore, any time saved during the procedure would reduce the overall cost of that procedure and allow for an increase in the number of patients treated per

day. Both results could lead to a decrease in costs for the patient and an increase in profits for the hospital. Reducing the wound closure time by 20min in breast reductions and abdominoplasty alone could result in a savings of \$370M per year. In addition, less time in the operating room means less time the patient is under anesthesia, which would reduce their risk of stroke, blood clots, and heart attack during and after the procedure [5].

1.4 Alternative Approaches

Prior inventions have endeavored to capitalize on this great opportunity and create a superior alternative to manual wound closure, but all have fallen short. The fact that a majority of plastic surgeons continue to hand stitch wounds together is a testament to the failure of previous attempts. Reasons for failure vary among devices, but some of the main issues were ugly scarring, foreign material spitting out of the wound, compromised wound integrity, tedious manual alignment of skin, and a complicated user interface. Surgical staples, for example, may shorten the closure time by 70-80% [6]. They are easily disposable and modestly priced at \$10 per device. However for delicate tissues, wounds in finely contoured areas, around bony prominences, and cosmetically sensitive areas, surgeons still suture wounds together by hand. The main reason staples are not used is because they lead to bad scarring caused by less precise skin alignment and the staple legs, as shown in Figure 1.3. This has rendered surgical staples useless for many operations within plastic and reconstructive surgery. Staples are also non-absorbable and require a secondary visit to remove them, which increases the costs associated with the procedure.

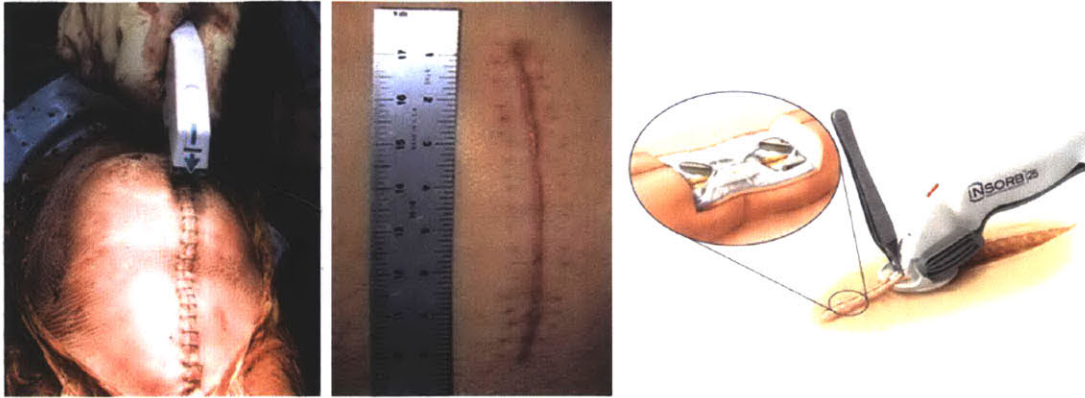


Figure 1.3: Past devices that tried to solve the skin closure problem. Left: Disposable surgical staplers are fast but can only be used on certain parts of the body. Middle: Closing the wound with staples would leave ugly track marked scars due to less precise wound edge alignment. Right: INSORB™ stapler [7] can place absorbable staples inside of skin but requires special training to correctly grasp skin with forceps and sometimes the staples lose their strength due to absorption [8].

To address the problem of scarring with surgical staples, Incisive Surgical Inc. (Plymouth, MN) developed the INSORB™, a stapler with absorbable clips, for closing the dermal layer. This particular stapler deploys a U-shaped staple composed of a polylactic and polyglycolic copolymer directly into the dermal layer to achieve wound closure. Fick et. al. [9] reported a reduced inflammatory response when using this dermal stapler device in an animal study. Cross et. al. [8] further investigated the utility of INSORB™ in a clinical trial involving eleven patients and reported a closure speed 4 times faster than that of standard suture closure. Despite its fast speed, the stapler is not very easy to use, and requires training in how to grasp and align the skin with specialized forceps to ensure proper staple positioning. Even though Herridge's study [10] measured hold strength to be 40% around the closure site at 14 days, surgeons have experienced staples spitting out of the wound or absorbing too fast, resulting in the wound reopening in many cases. The INSORB™ device is also designed to be disposable and costs \$45 per unit. However it is important to remember that the cost of materials to close a wound is small when compared to the cost of the time for wound closure. The material cost can be made up in less than 1 minute of operating time. The real decision that needs to be made is between the cost of operating time and aesthetic outcome. The INSORB™ struggled to succeed because it did not achieve an aesthetic durable wound closure comparable to hand stitching in its quest for the speed of a surgical stapler.

1.5 Overall Project Goal

In order to succeed, the goal is to address the problems associated with available wound closing technologies, and seize the clear opportunity to combine the speed of surgical staplers with the functionality of common absorbable sutures in a rapid skin closure device. The device will attack the most time consuming part of the wound closure process, the dermal closure, in order to close the wound faster than hand stitching, while achieving the same results. If it succeeds, the rapid skin closure device will be adopted, first by plastic surgeons and then general surgeons, as the new standard operating procedure for wound closure.

1.6 Thesis Focus

This thesis focuses on the design, development, and optimization of the actuation mechanisms for the needles, clipping, and alignment parts of the rapid skin closure device. The design and optimization of the actuation mechanisms for this device are critical to its success as a viable mass-produced product capable of revolutionizing the field of wound closure.

The rapid skin closure (RSC) project was developed during the fall semester of 2011 and spring semester 2012 at MIT by a team of five mechanical engineers including myself, and the expertise of two doctors from MGH in Boston. The RSC team designed and manufactured two prototypes each semester for the class 2.75. The prototypes from the fall semester were created to prove the team's design strategy was feasible. The prototypes created in the spring semester improved on the designs from the fall and focused on bringing the device closer to a production ready product. This thesis does not cover the design process for the clip, needle, or loading mechanism unless it directly affects the design or requirements for actuating the desired motions of the device. My main role in the project was the design and development of the actuation mechanisms.

The chapters on prototype development will follow the chronological order the prototypes were designed in, and the beginning of each chapter will contain a preview of the final prototype design discussed in that chapter. After the preview of the prototype, the chapter will examine the development process of the actuation mechanism for the alignment, needles, and clip motions. Possible design solutions will be identified and initial analysis performed to highlight the

strengths and weaknesses before down selecting to a particular design to prototype. The results of the prototype's actuation mechanisms will then be discussed and improvements suggested for the next iteration. Insights regarding possible future developments that are beyond the scope of the project's deadlines and resources will be discussed briefly throughout the thesis and in the concluding chapter.

BACKGROUND

2.1 Wound Closure Strategy

The overall functional requirements and strategy for the rapid skin closure device were developed after two months of research into the mechanics of wound closure, talks with clinicians from MGH, and extensive concept generation. The results of this research produced the following functional requirements summarized in Table 2.1, and the concept strategy depicted in Figure 2.1.

Table 2.1: Rapid Skin Closure Device Functional Requirements	
Associated Operating Costs	<< Hand stitching
Aesthetic Results	≥ Hand stitching
Wound Closure Strength	≥ 28N
Discrete Closure of Dermis	Interrupted dermal connections
Operation Speed	≥ 3cm/min (50% faster than hand stitching)
Simplicity	No training or postoperative procedures
Revisable	Simple to fix errors
Flexibility	Compatible with: straight and curved wounds; range of dermis thicknesses and wound tensions; wound lengths 15-60cm
Safety	≤ Risk of hand stitching

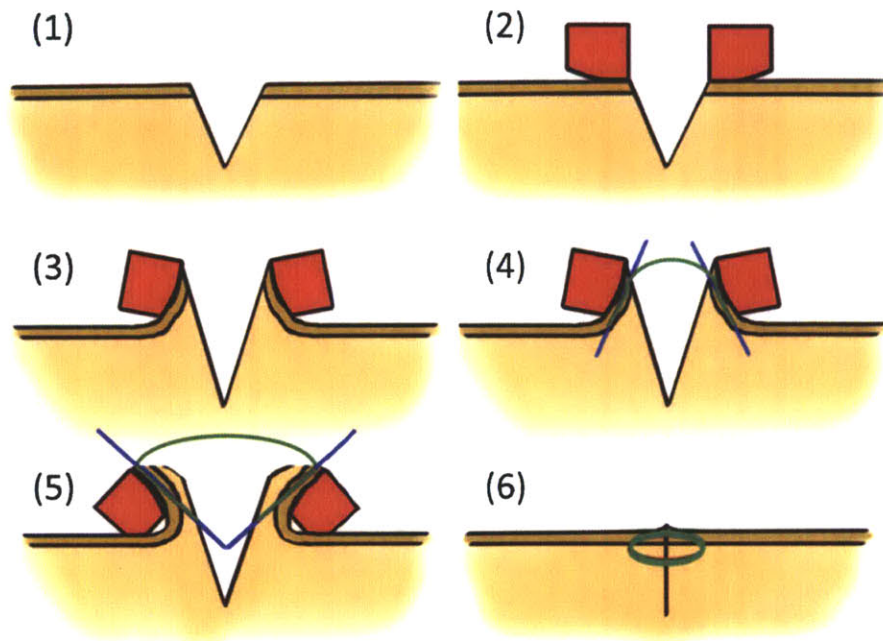


Figure 2.2: Project strategy for wound closure in 6 steps.

Strategy steps:

1. The incision viewed as a cross-section. Dermal layer represented by the top layer and the Fat layer directly below it.
2. Skin alignment component lines up with skin edge and surface.
3. Alignment component actuated to lift skin into pre-determined position.
4. Needles load clip ends and are inserted into the dermal layer of skin following a pre-determined path.
5. Needles come together at 90-degree angle and an ejector pin pushes the clip ends together to form a closed loop.
6. The closed loop clip is left behind in the dermal layer. The clip is absorbable and can be tensioned similar to a zip-tie by a doctor to create the proper wound tension for minimal scarring.

Due to the compressed time schedule and limited resources for the project a fully adjustable and bio-absorbable clip was not possible to prototype at the desired scale. However, a simple non-adjustable clip was made to function in a similar way to future clip designs, where a male end of a clip would be pushed through a female end of the clip to form a closed loop. A model of the clip can be seen in Figure 2.3.

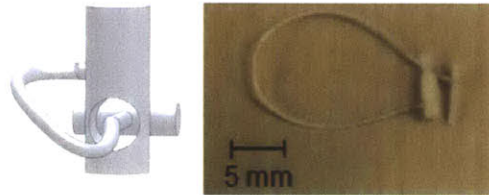


Figure 2.3 Clip design. Left: Cad model of clip. Right: 5x scale prototype of clip.

The closed loop clip design was created to solve the problem INSORB™ had with the absorbable staples losing their strength too quickly. The “U” shape of the INSORB™ staple is an open loop structure that will begin to pull apart as the wound puts tension on the ends during the healing process. This problem becomes magnified as the staple becomes absorbed and loses material thickness. A closed structural loop solves this problem because the strength of the material comes from the tensile strength not the bending stiffness.

The ability to adjust the clip in a zip-tie like fashion is another key future design feature for the clip because wound tension can have a significant effect on scarring. Wound tension also varies greatly depending on the type of incision, location on the body, and each patient’s personal body type. This makes it difficult to have a single non-adjustable clip that will work in the majority of cases. The adjustable design allows for the flexibility to adapt to different wound tensions, and harness the experience and knowledge of the doctors, who can judge the proper tension needed to ensure healing with minimal scarring.

2.2 Actuating Mechanisms: Requirements and Goals

In order for the device to be successful, the actuation mechanisms need to enable the device to meet its functional requirements from Table 2.1. In addition, there are several goals regarding the

size and complexity of the device that are directly impacted by the design of the actuating mechanisms. Table 2.2 summarizes some of the most important requirements for the actuating mechanisms that will affect the success of the device.

Table 2.2: Summary of Actuator Requirements	
Force Delivered for Needle Actuation	$\geq 10\text{N}$
Simple User Interface	≤ 2 required user motions to deploy clip
Repeatability	≥ 60 clips deployed without error
Total Device Cost	$< \$100$
Speed	≤ 15 sec. from one clip to the next

2.2.1 Cost

The cost of the device must be relatively inexpensive compared to the cost saving benefits it delivers by saving operating time. The cost of the device includes material costs, manufacturing costs, and the cost of disposable needle modules for each procedure. The actuating mechanisms for the device will most likely be the main cost-driving factor.

2.2.2 Form Factor

A small form factor that can be mass-produced through methods such as injection molding is desired because it will reduce costs. If the form is of comparable size to current devices used in the operating room, the device will have a higher chance of being adopted by doctors.

2.2.3 User Interface

Doctors using the device must find it easy to use in comparison to other methods of wound closure. Limiting the number of user inputs required for actuation will make the device simpler to use. A Balanced weight distribution of the actuators within the device will also increase the ease of use and ergonomics.

2.2.4 Force

The actuator must be able to generate the appropriate amount of force to insert needles through the dermal layer of skin. The needle insertion is the greatest force requirement for device at approximately 10N per needle. [11]

2.2.5 Speed

Fast actuation mechanisms are desired to increase the speed of the device. This is important because the speed of the device will determine the amount of money that can be saved per operation. In addition, the repeatability of the device is important for speed because errors will cause delays. A device that is less sensitive to tolerance errors and performs with high repeatability will be more reliable, cost effective, and speedy.

2.2.6 Complexity

Simple Actuation Mechanisms that reduce the total part count will make assembly and manufacturing cheaper and faster. A lower part count also reduces the probability of errors, which would affect the speed and accuracy. Reducing the total number of actuators in the device is crucial for lowering the complexity, size, and cost of the device.

Prototype 1

3.1 Development Goals

The design process of the first prototype focused on creating the desired motion for needle insertion in the dermal layer of skin and bringing the ends of a clip together with an ejector pin.

3.2 Prototype 1 Final Design

Figure 3.1 displays the final design of the first prototype, which used multiple cams for the actuation of the needles and ejector pins. Special thanks to Steven Lam for having the initial idea to use slotted paths and rotating cams, and the RSC team for helping build the prototype

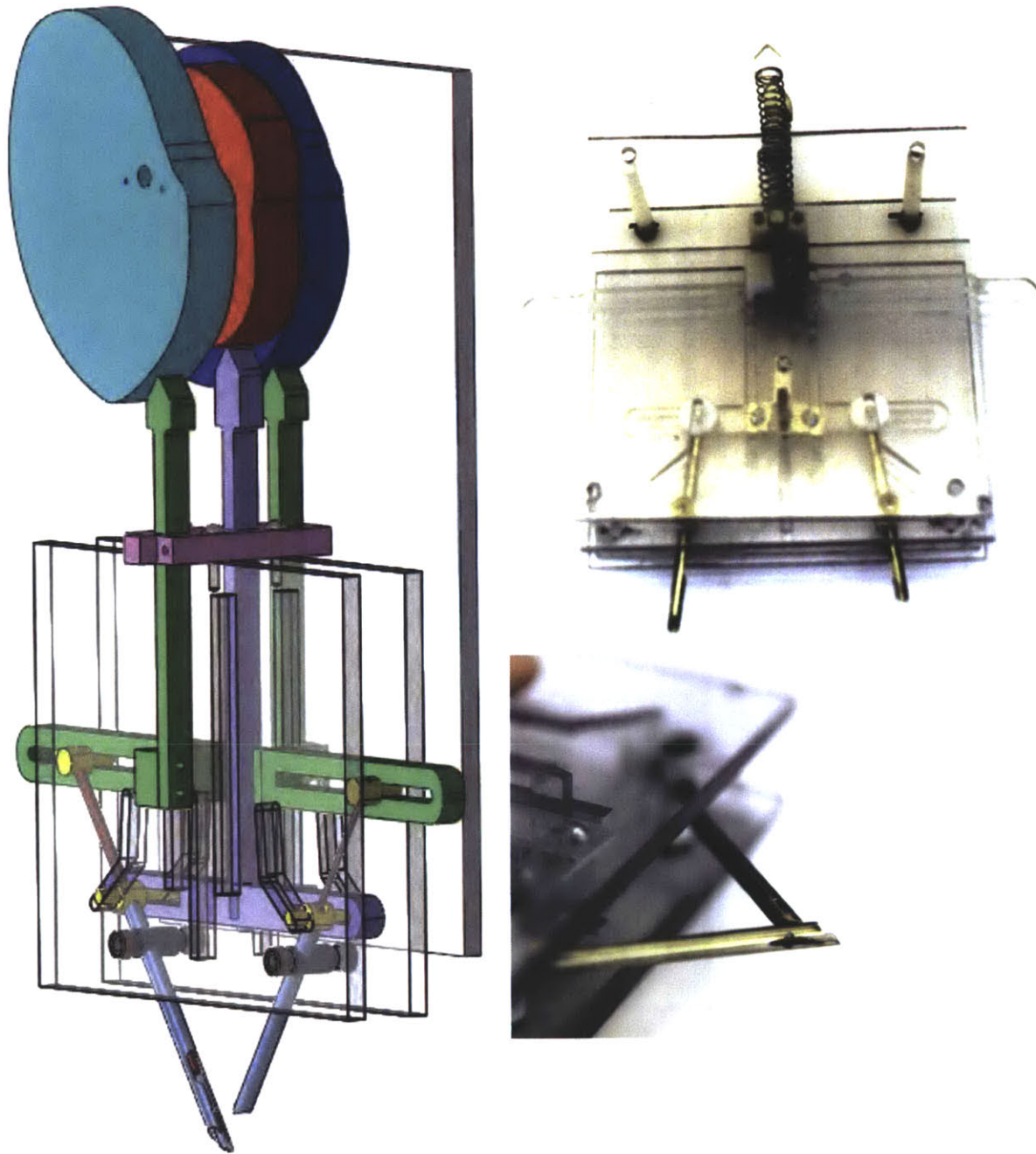


Figure 3.1: Final design of Prototype 1. Left: Solid model of Prototype 1. Top Right: Photograph of Prototype 1 without the cams. Bottom Right: Close up of needles coming together.

3.2.1 Actuation Steps

The description of the actuation motion for Prototype 1 is followed by corresponding figures representing each step.

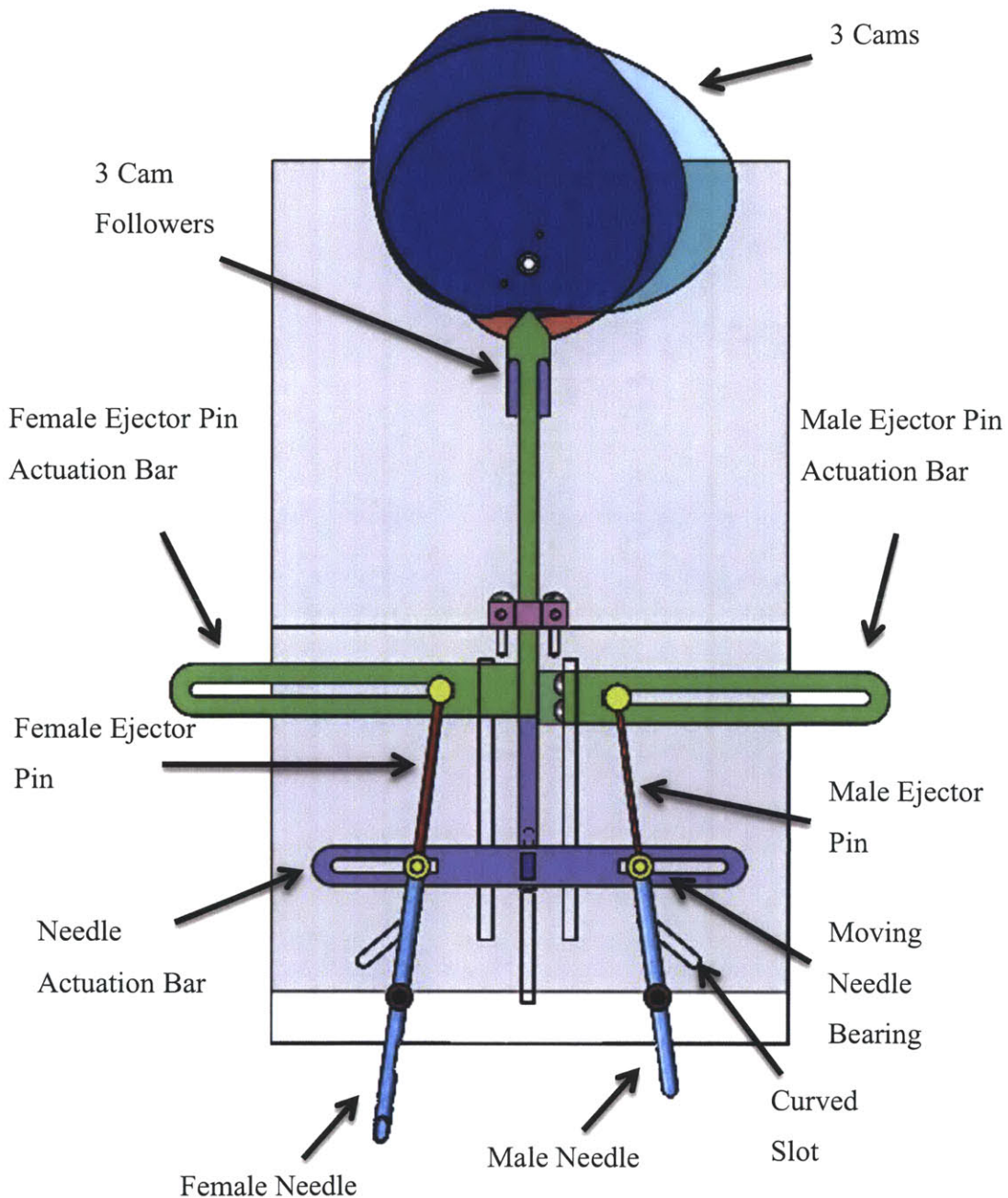


Figure 3.2: Annotated model of Prototype 1.

Actuation steps:

1. Starting position for needles and ejector pins. Cams start to rotate counter clockwise.
2. Clips are loaded into the side of the needles during pause in motion created by the rotating cam geometry.
3. The actuation bars for the ejector pins begin to descend vertically driven by separate cams.
4. The actuation bar for both needles begins to descend in time with the ejector pins. The needle bearings follow a curved slot in the wall to create a straight dermal insertion followed by a rotation to bring the needle tips together.
5. A cam actuates the right ejector pin in the male needle, while the other components stay in place during the rotation of the cams. This ejector pin pushes the male end of the clip through the female end of the clip.
6. The male ejector pin retracts.
7. The needles and male ejector pin begin to ascend. The ejector pin in the female needle stays in place as the needle moves, which causes the clip to be pushed out.
8. Both ejector pins and needles move back to the starting position in step 1.

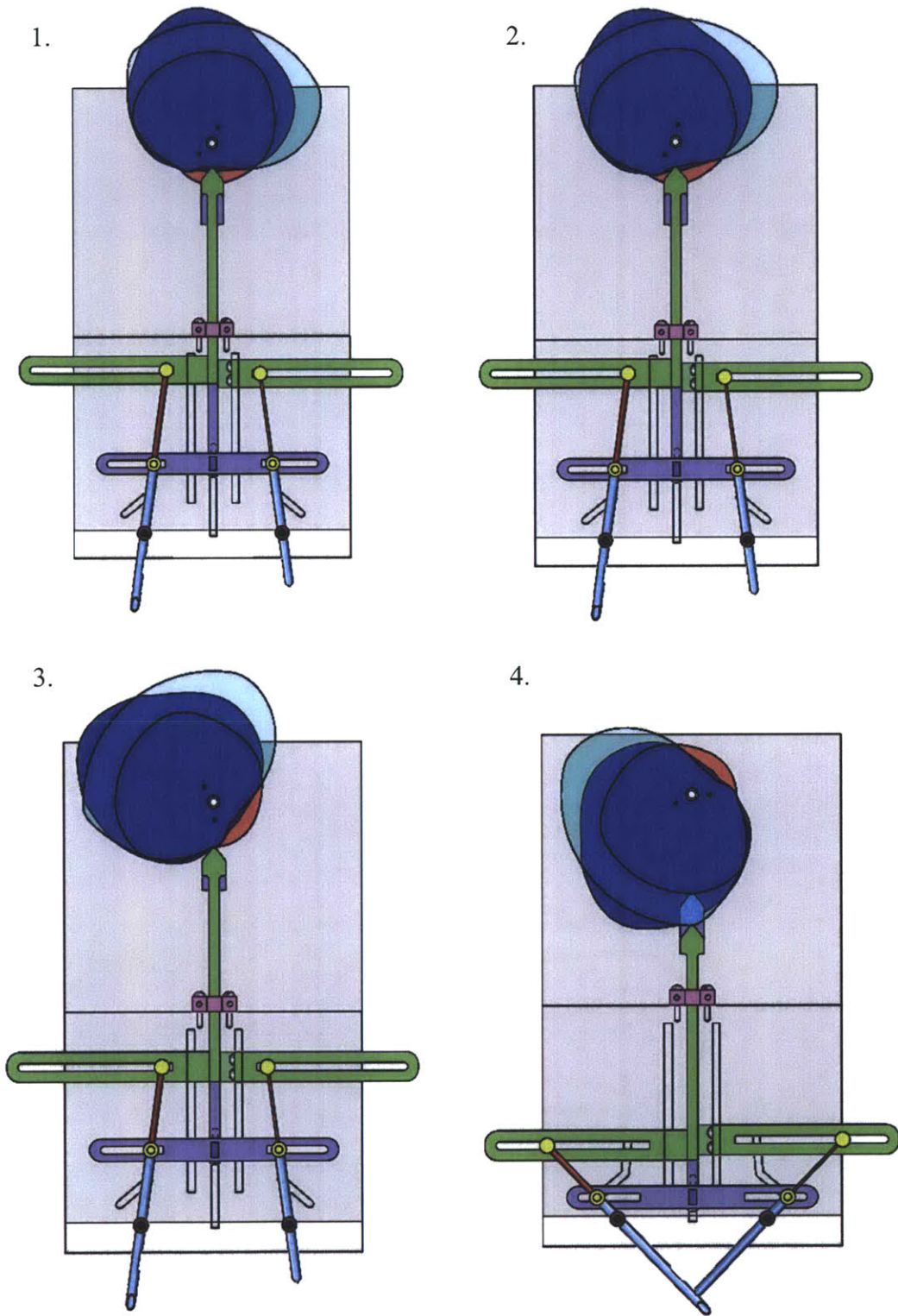


Figure 3.3: Prototype 1 actuation steps 1-4.

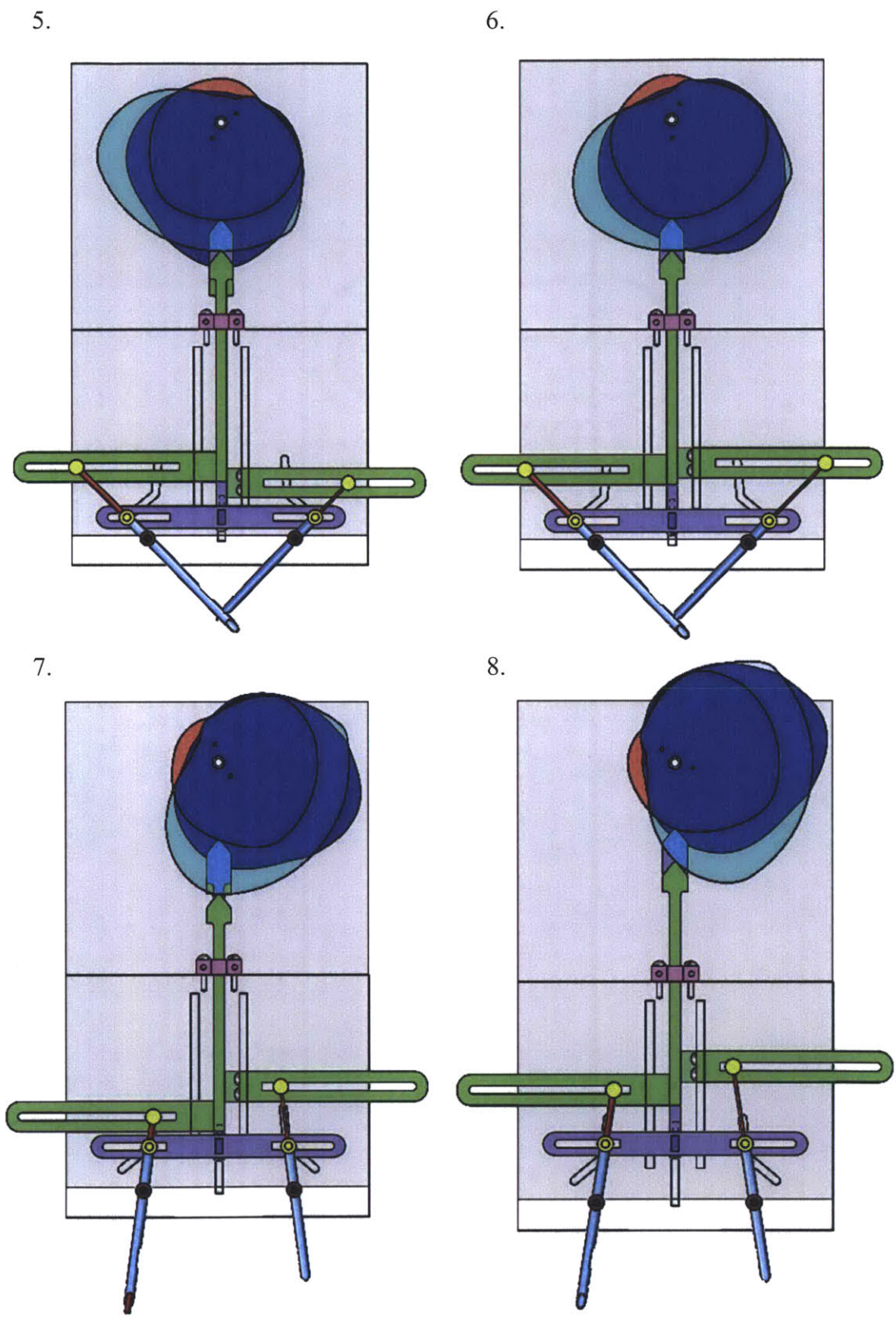


Figure 3.4: Prototype 1 actuation steps 5-8.

3.3 Actuator Design

The initial design for the actuation of the needles and ejector pins involved the identification of possible actuators and power transmission elements. These are the building blocks for the mechanism designs. Table 3.1 contains actuators that were selected because their size, weight, cost, and force specifications were within the desired range for the device.

Table 3.1: Actuator Comparison		
	<u>Strength</u>	<u>Weakness</u>
Servo Motor	<ul style="list-style-type: none"> • Compact size • Low cost, • Electrically powered • Precise position control 	<ul style="list-style-type: none"> • Medium weight • Linear motion difficult to obtain
Pneumatic Cylinder	<ul style="list-style-type: none"> • Light weight • Broad range of forces 	<ul style="list-style-type: none"> • Requires air supply • Imprecise position control • Rotary motion difficult to obtain
Linear actuator	<ul style="list-style-type: none"> • Light weight • Precise position control • Electrically powered 	<ul style="list-style-type: none"> • High cost • Rotary motion difficult to obtain
Solenoid	<ul style="list-style-type: none"> • Electrically powered 	<ul style="list-style-type: none"> • Heavy for larger throw lengths • Imprecise position control • Rotary motion difficult to obtain

Table 3.2 identifies possible mechanisms to translate the power from the actuator into the desired motion of the device.

Table 3.2: Power Transmission Elements		
	<u>Strength</u>	<u>Weakness</u>
Gears	<ul style="list-style-type: none"> • Rotary motion • Variable timing possible • Drive multiple motions • Allows tradeoffs between torque and speed 	<ul style="list-style-type: none"> • Requires precise alignment for efficiency
Linkages	<ul style="list-style-type: none"> • Rotary and linear motion 	<ul style="list-style-type: none"> • Fixed length
Bearings	<ul style="list-style-type: none"> • Rotary or sliding motion • Cam follower 	<ul style="list-style-type: none"> • Higher cost
Cams	<ul style="list-style-type: none"> • Complex motions and timing • Rotary and Linear motion 	<ul style="list-style-type: none"> • Poor efficiency if forces not inline • Requires precise machining
Cables	<ul style="list-style-type: none"> • Flexible attachment • Rotary and Linear motion 	<ul style="list-style-type: none"> • Elongation from creep leads to imprecision • Can only pull to actuate
Rotating lead screw with nut follower	<ul style="list-style-type: none"> • Rotary to linear motion • Allows trade offs between torque and speed 	<ul style="list-style-type: none"> • Requires additional space to constrain properly with bearings • Higher cost

3.3.1 Design Selection

Initial designs of the actuation elements for prototype 1 centered on using a servo powered rotating shaft to drive 3 separate cams. Rotary motion combined with a round cam surface allowed for complex motion and timing through the course of a single rotation. The main cam

follower geometry was pressed against the rotating cam surface using springs and was constrained to travel in the vertical direction. The main cam followers were attached to slotted bars, which acted as cam surfaces for the needle and ejector pin bearings.

The main cam surface allowed for the slotted bars of the followers to be actuated in the vertical direction at different times in order to control movement. The bars for the ejector pin bearings allowed them to slide horizontally as the angle of the needles changed and then actuate the ejector pin in and out of the needle at the appropriate time. Timing is critical between the ejector pin and the needle actuation so that the ejector pin does not push out too soon or not at all. The position of the ejector pin controls the placement of the clip inside the needle.

The actuation bar for the needle bearings also allowed the needle bearings to slide horizontally, during actuation in the vertical direction. The actuation bar's vertical motion was important because it pushed the bearings along a curved path in the case of the device. This path acted as another cam surface that allowed the needles to move linearly during the needle insertion phase and then rotate together for clipping. The curved path designs minimized the amount of required space for the motion and brought the needles together at a 90-degree angle, which was optimal for reliable alignment of the tip of the needles.

The cam follower method was the simplest way using one actuator to achieve the complex curving motion of the needles with the proper timing of the ejector.

3.4 Results

There were significant jamming problems with the prototype after construction. Ejector pins bent due to bending moments on the small shaft diameter. It was also difficult to rotate cams because forces were not inline with the main cam followers. Finally, the resolution needed for the rotating cam geometry was not met due to the limitations of the water jet used to manufacture them.

3.5 Discussion

The jamming problems were mainly caused by the high friction losses on the multiple cam surfaces due to out of line forces and sliding friction instead of rolling friction. The main rotating cams were large and bulky due to the size required to obtain the necessary motion in a single rotation. The geometry of the cams was optimized for the motion and is unlikely to have a significant size reduction with future development. The millimeter accuracy required for manufacturing the cams could also lead to higher manufacturing costs. These issues with the cam design led to the decision to search for alternate methods of actuation in the next prototype.

The curved needle paths that direct the needle motion and the vertically actuated slotted bars were worthwhile concepts to keep in the next iteration. However, the ejector pin will need more support to counteract the bending moments.

PROTOTYPE 2

4.1 Development Goals

The goal for Prototype 2 was to improve upon the design in Prototype 1, evaluate alternate methods for needle and ejector pin motions, and begin development of a skin alignment mechanism and actuation.

4.2 Prototype 2 Final Design

Figure 4.1 displays the final design of Prototype 2, which used three pneumatic cylinders to actuate the alignment, needles, and ejector pin. The alignment mechanism involved vacuum suction to adhere to the skin before rotating into position. Special Thanks to the RSC team for helping build Prototype 2.

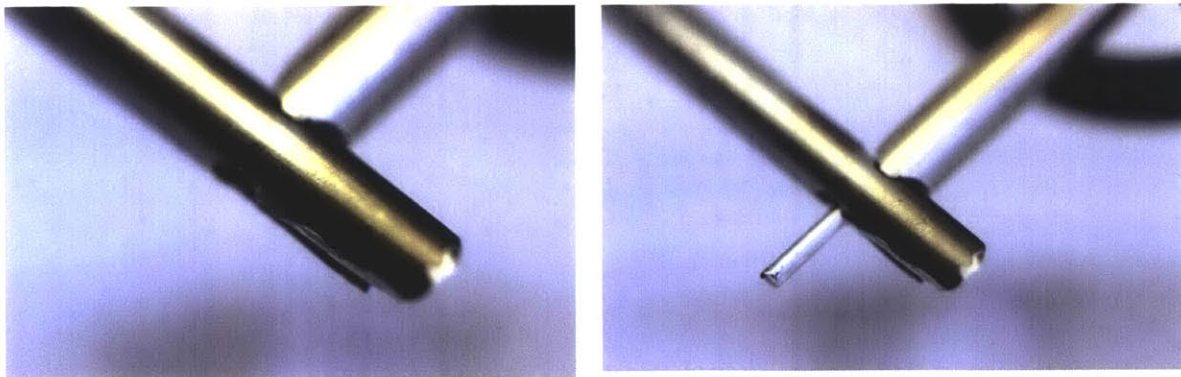
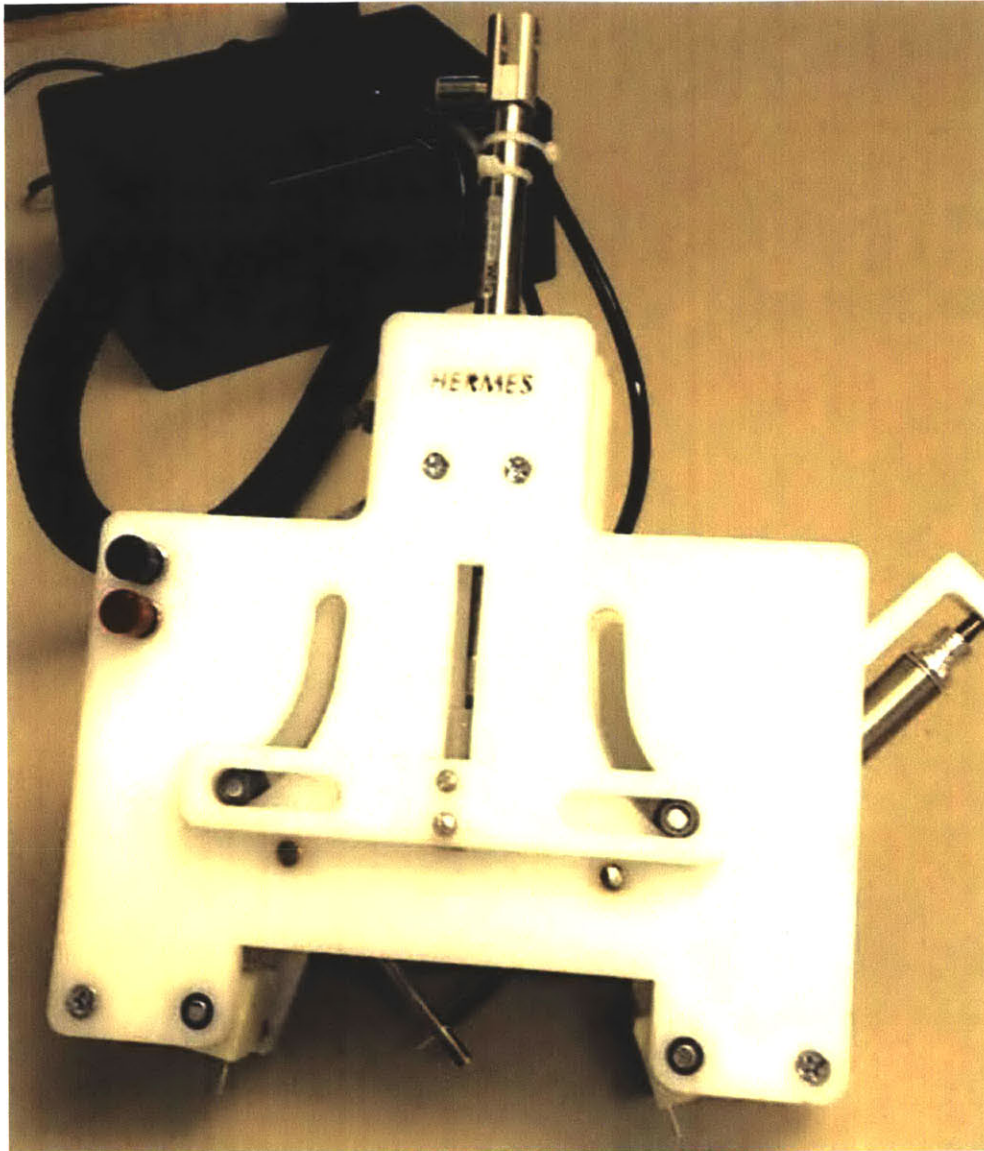


Figure 4.1: Pictures of the final Prototype 2 Design. Top: Front of Prototype 2. Bottom: Needle alignment and ejector pin actuation.

4.2.1 Actuation Steps

The description of the actuation motion for Prototype 2 is followed by corresponding figures representing each step.

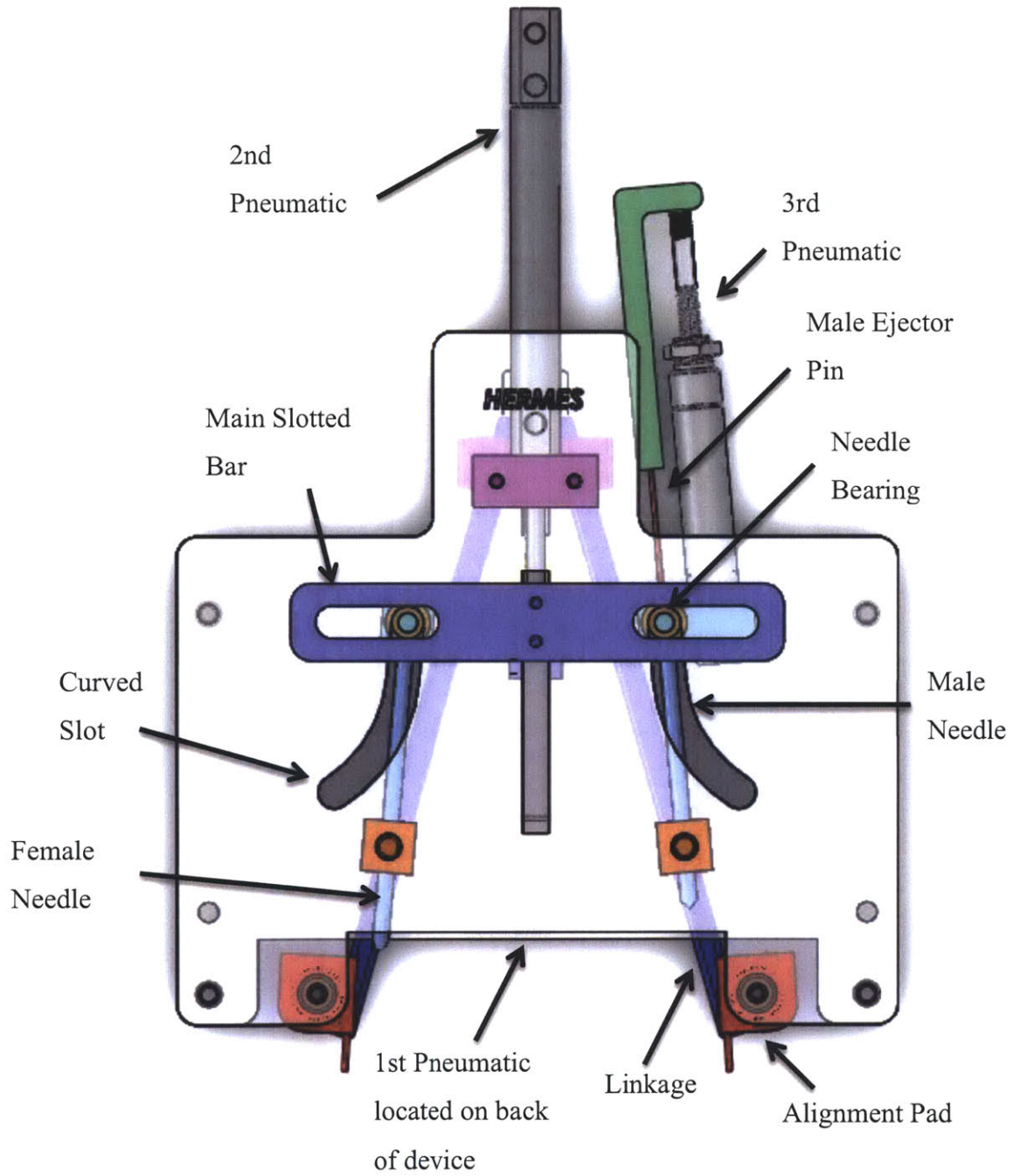


Figure 4.2: Annotated model of Prototype 2.

Actuation steps:

1. Starting position. Alignment pads are pressed against the wound edge with the aid of a torsion spring and adhere to the skin with vacuum suction.
2. A pneumatic cylinder in the rear of the device actuates and pulls two linkages connected to the alignment pads causing them to rotate the skin into position for needle insertion.
3. A second pneumatic cylinder actuates the main slotted bar downward directing the needle bearing along the curved paths on the front of the device. At this point a clip is loaded through the front of the needles before the needles insert through the dermal layer of skin.
4. The slotted bar continues to drive the needle bearings to the end of the curved paths, which causes the needles to rotate towards each other and meet at 90-degrees.
5. Throughout the previous movement a third pneumatic cylinder has traveled with the needle bearing and is connected to an ejector pin located in the needle where the male end of the clip is located. This pneumatic cylinder actuates and drives the ejector pin through the other needle and successfully pushes the male end of the clip through the female end located in the other needle.
6. The third pneumatic connected to the ejector pin retracts to its initial start position.
7. Next, the slotted bar is actuated upward by the second pneumatic cylinder which returns the needles to their starting position. The clip pulls out of the female needle during this process because it is rigidly attached to the skin.
8. Finally, the alignment pads lose suction and the pneumatic cylinder releases them so they rotate, due to a torsion spring, into the wound edge to align the device for the next clip.

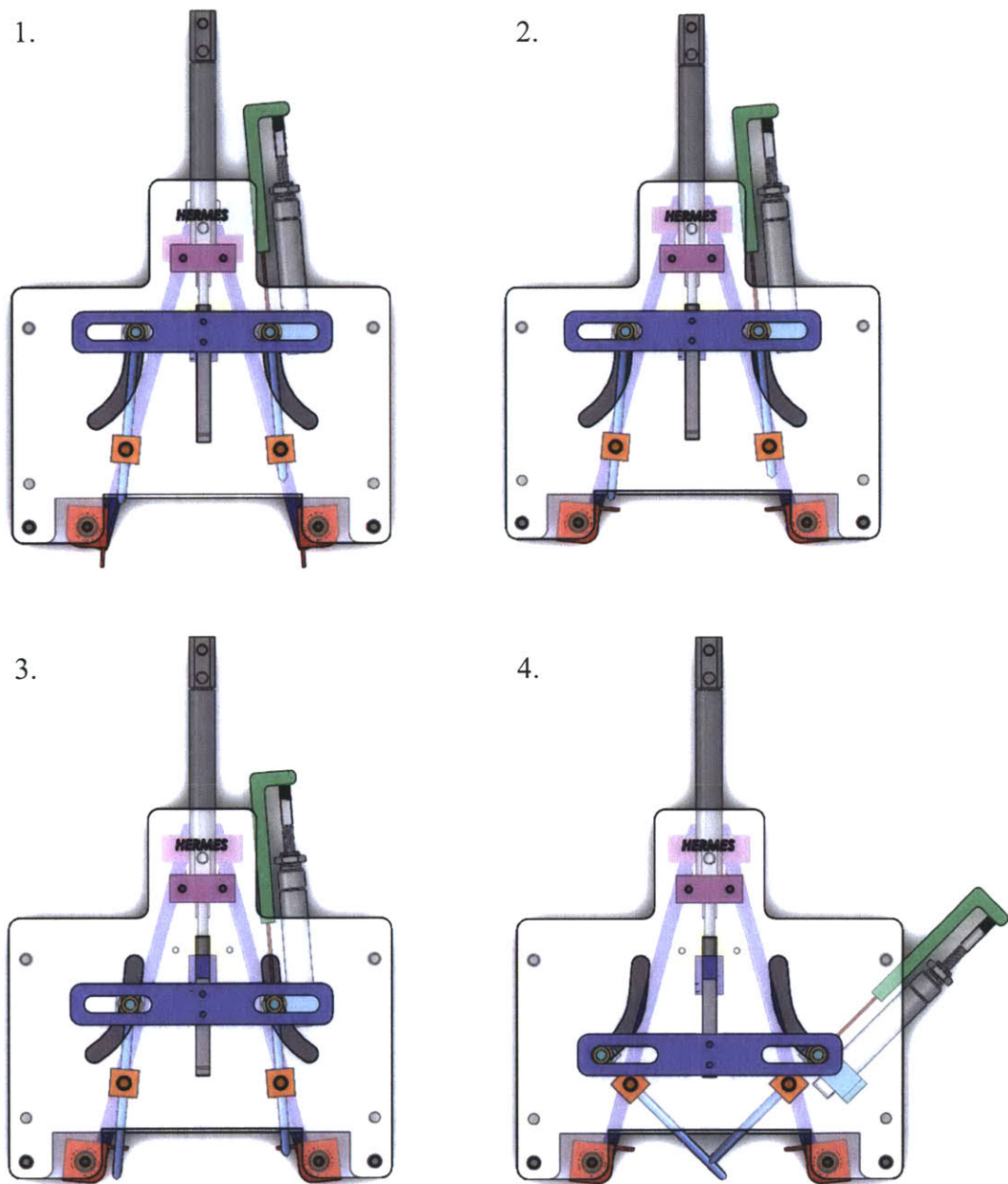


Figure 4.3: Prototype 1 actuation steps 1-4.

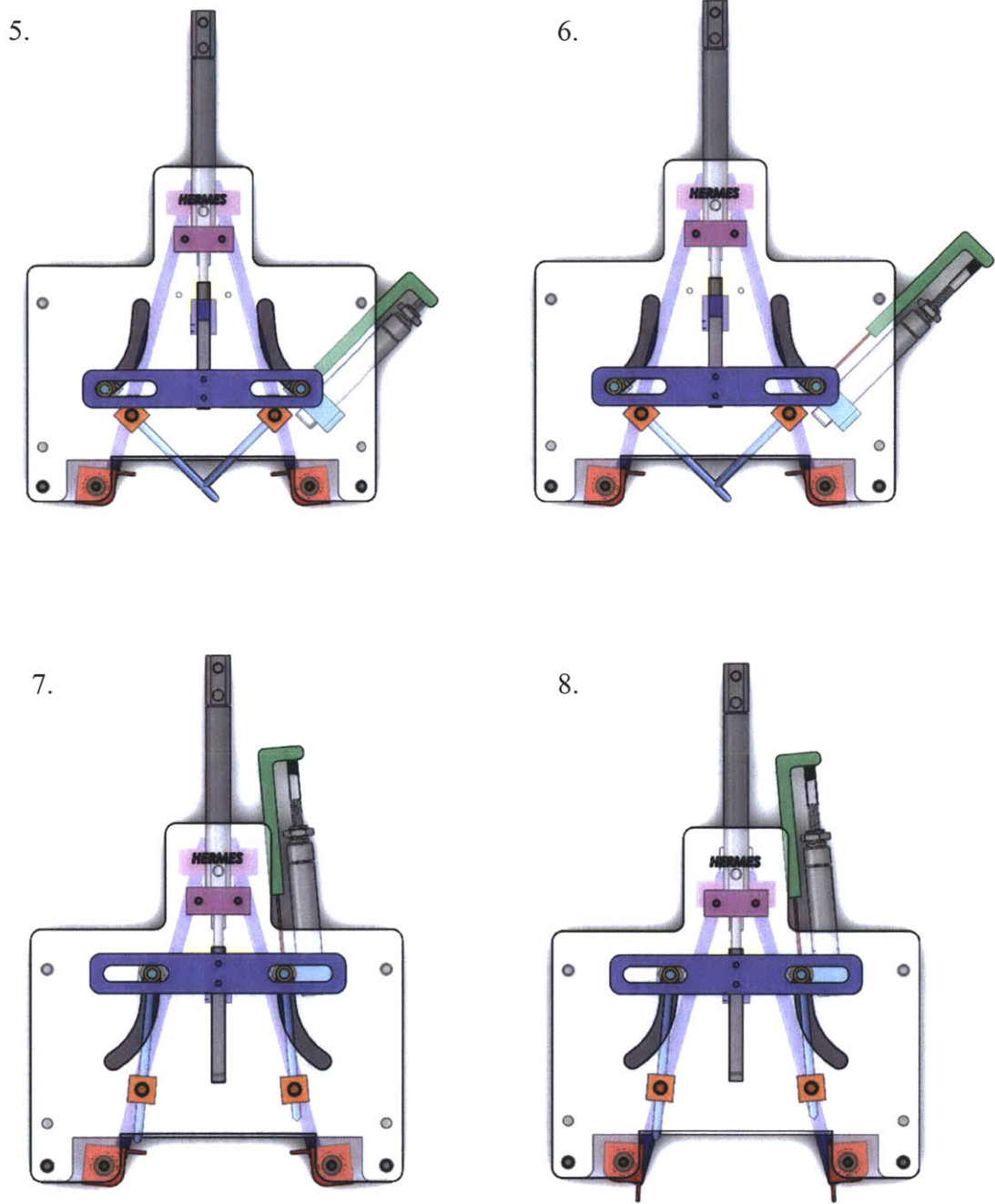


Figure 4.4: Prototype 1 actuation steps 5-8.

4.3 Skin Alignment Design

A main focus of Prototype 2 is to develop a strategy that aligns the wound edges consistently and reliably for proper needle insertion. The strategy for aligning skin requires an actuation of some kind to move the skin into position. The basic method that all the designs must accomplish is (i) adhere to a section of skin on each side of the wound and (ii) rotate it into position so that the needles insert the same depth into the dermal layer of skin directly across from each other.

Table 4.1 summarizes the strengths and weaknesses of the main alignment concepts that were considered.

Table 4.1: Skin Alignment Concepts		
Method	<u>Strength</u>	<u>Weakness</u>
Vacuum Pad	<ul style="list-style-type: none"> • Minimal skin trauma • Air supply readily available in O.R. • Simple actuation for turning suction on • Simple rotating actuation 	<ul style="list-style-type: none"> • Proper suction can take seconds • Strength of suction variable
Forceps	<ul style="list-style-type: none"> • Strong holding force • Same as current manual methods 	<ul style="list-style-type: none"> • Some tissue trauma • Complicated actuation to grab and rotate
Adhesive	<ul style="list-style-type: none"> • Sticks to skin with minimal trauma • Simple rotating actuation 	<ul style="list-style-type: none"> • Not revisable for advancing forward • Adhesion compromised by blood and liquids at wound edge
Velcro	<ul style="list-style-type: none"> • Low cost • Simple rotating actuation 	<ul style="list-style-type: none"> • Requires Velcro with adhesive back to be applied along wound • Difficult to detach and advance • Small particles detach and contaminate wound

4.3.1 Design Selection

Concepts involving Velcro and adhesives were problematic because of wound contamination with Velcro particles and the inability to advance forward with adhesives. These were not issues that would go away with further refinement. This narrowed down the options to the vacuum pad and forceps concepts. For this prototype, the vacuum pads were chosen because they could be actuated with a simpler mechanism. The forceps required a mechanical mechanism for grabbing and rotating, while the vacuum only required a mechanism for rotation. Figure 4.5 shows the final design of the alignment mechanism. Special thanks to Steven Lam for developing the suction pad design.

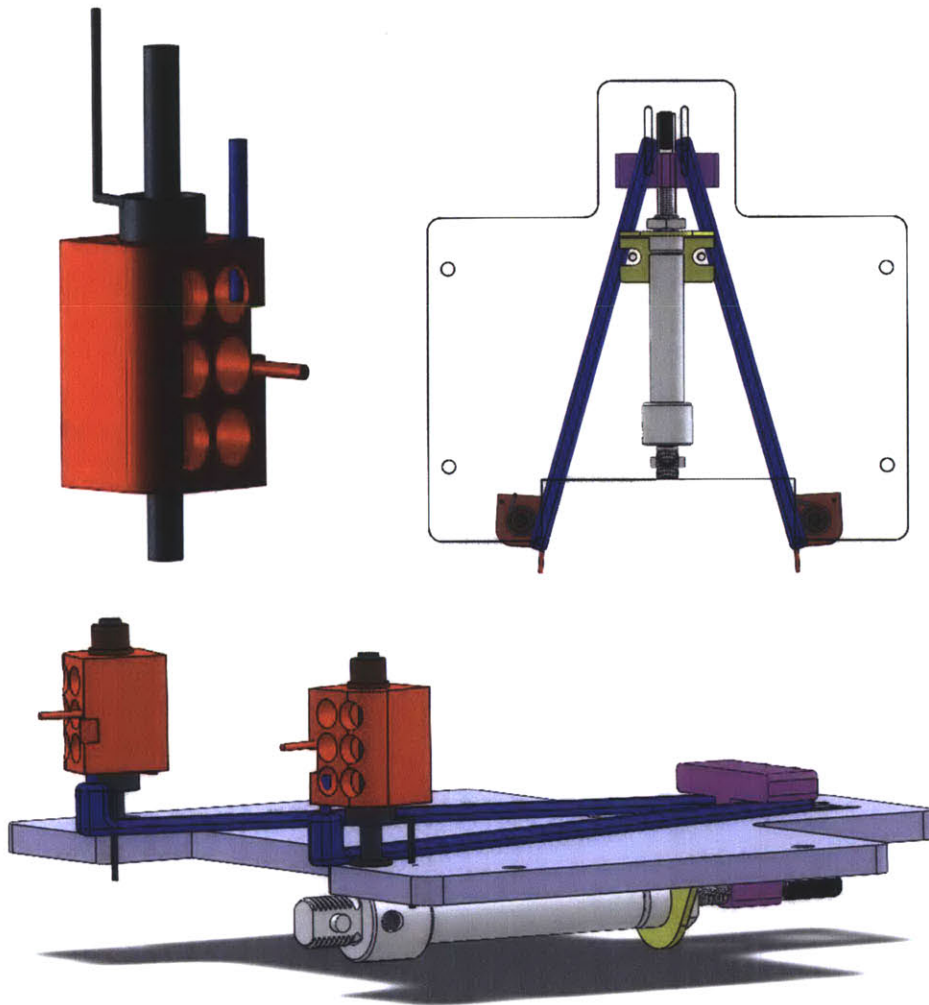


Figure 4.5: Solid models of suction skin alignment mechanism. Top Left: Suction pad design. Top Right: Rear view of device showing complete actuation design. Bottom: Side view of suction pads in context.

4.3.2 Actuation Steps

Steps:

1. Starting position. Suction pads are rotated outward due to a torsion spring. Vacuum suction is turned on.
2. The pneumatic actuates a driving bar that pulls the linkages constrained by slots in a vertical direction. The linkages rotate the suction pads in order to hold the skin in the proper position for needle insertion.
3. Vacuum suction is turned off, and the pneumatic lowers the driving bar. The torsion spring rotates the suction pads back to their start position from step 1.

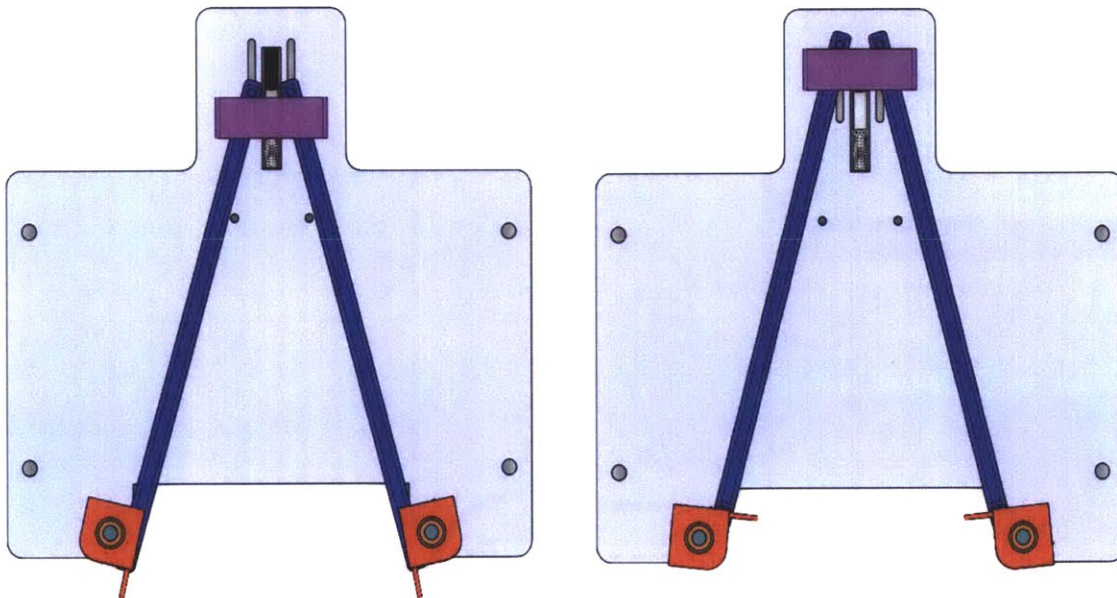


Figure 4.6: Suction skin alignment actuation steps.

Initial force calculations for the vacuum pressure showed that 185mmHg of pressure was required, and further testing showed that 195mmHg was adequate to grab and move the skin.

4.4 Ejector Pin Actuation For Clips

The goal for the ejector pin actuation was to reduce the complexity of the device and find alternative methods to the rotating cams for actuation. To reduce complexity the female ejector pin was eliminated because it was no longer required to eject the connected clip. The clip would slide out of the needle during needle retraction because of its rigid attachment to the wound. The search for alternative actuation methods revealed several key design challenges because the ejector pin motion was no longer precisely controlled with respect to the needles. This was not an issue in prototype 1 because the rotating cams allowed for control over the actuation timing, position of the ejector pins, and the position of the needles. However, these challenges needed to be addressed in order to develop a viable concept. The two main challenges were asynchronous movement and achieving precise ejector pin positions within the needles.

Curved needle paths cause asynchronous movement between the ejector pin bearing and needle bearing. As the needle bearing travels through an arc the ejector bearing must travel a farther vertical and horizontal distance in order to maintain the same position of the ejector pin within the needle. In order for this to happen, the ejector pin bearing needs to travel at a different horizontal and vertical speed than the needle bearing. This is because it needs to travel through a longer arc in the same amount of time. Figure 4.7 illustrates this concept.

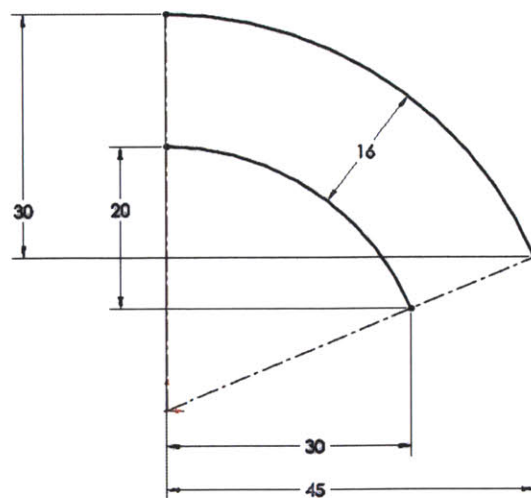


Figure 4.7: Depiction of asynchronous ejector pin and needle movement.

In Figure 4.7, the smaller arc represents the path of the needle bearing, and the longer arc represents the path of the ejector pin bearing. In order for them to maintain a constant distance apart through the entire motion, the ejector pin will need to be traveling faster than the needle bearing with the correct timing.

The difference in ejector pin and needle motion presents a problem if there is little control over the timing and speeds of the two bearings, and ejector pins require precise positioning within the needle. If the speeds and timing are off, the ejector pin will move in and out of the needle and potentially push a clip out before it is ready. This creates the challenge of achieving multiple states of the ejector pin position within the needle through the actuation movement.

The ejector pin position within the needle is critical because it controls the location of the loaded clip. The three required positions are presented in Figure 4.8.

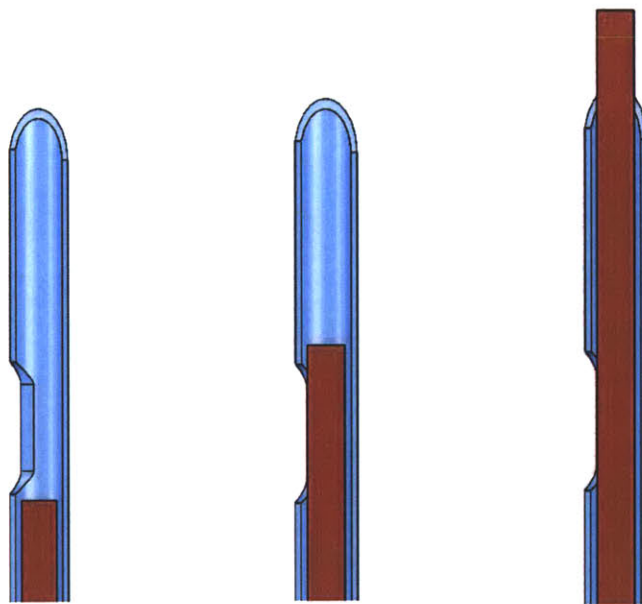


Figure 4.8: Critical ejector pin positions. Left: Initial position of ejector pin when clip is loaded through the side of the needle. Center: After clip is loaded into the needle the ejector pin advances forward a small distance to prevent the clip from falling out the side, but far enough to push the clip out of the needle. Right: Ejector pin pushes the male end of the clip all the way through the female end of the clip in the other needle.

The spacing is minimized within the needle to reduce the packaging size of the device. This means if the ejector pin is a couple millimeters out of place it is possible for the clip to fall out or fail to connect the male end with the female end of the clip.

These two design challenges become problematic when reviewing the available actuators for the device described in Table 3.1. The challenge of asynchronous movement makes it difficult to have an actuator separated from the needle movement. If the ejector pin actuator is traveling with the needle bearing, then the ejector pin will act as an extension of the needle. The actuator mounting will provide the appropriate constraints and stiffness for the ejector pin. The need for the actuator to travel with the needle bearing eliminates the solenoid as an actuating mechanism because it will be too heavy. The servomotor is also a poor choice because it delivers rotary motion. It would require additional space and components to convert to the required linear motion of the ejector pin. That leaves pneumatic cylinders and position controlled linear actuators. In this case, a pneumatic will not work because it can only deliver two end states and 3 controlled states are necessary for the ejector pin. Based off the requirements the only actuator that can meet the design challenges is the position controlled linear actuator. Unfortunately these actuators cost on the order of \$100 or more and put the cost of the device above the suggested design requirement.

4.4.1 Reverse “Pen Click” Design

The challenge of achieving 3 precise end states with a cheap and imprecise actuator needed careful thought. In the end, the mechanical click of a pen brought on a spark of creativity. Pen clicks use an imprecise actuation method, a button, to achieve two consistent end states. The motion involves pushing the pen tip to its farthest position so it retracts back to a writing position or inside the case. As the pen is continuously clicked using the same button the end states of the pen tip alternate. Applying the same concept in reverse to the ejector pin, the ejector pin could be pulled back to its farthest position by an imprecise actuator then released to fall into one of its predetermined end states. In this case the ejector pin would have three possible states that it would rotate between instead of the two used by pens. The following figures represent the solid model of the reverse pen click concept and the steps involved in its actuation.

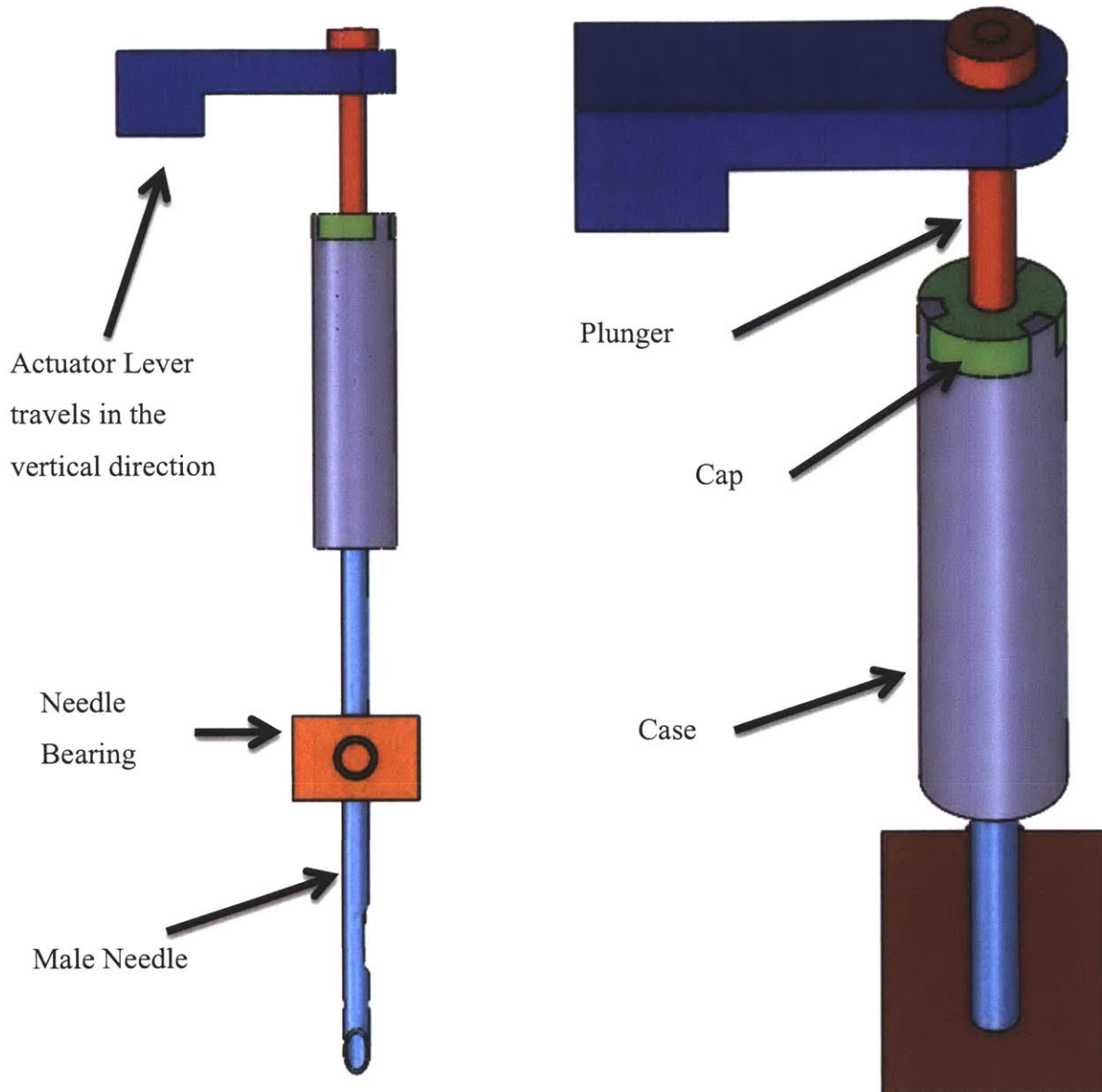


Figure 4.9: Annotated model of reverse pen click design. Left: Solid model representation of pen click concept. Right: Concept is comprised of a case, cap, and plunger. The plunger is pushed up and then released to reach the next state. The cap snaps onto the case and includes geometry to house a spring and facilitate the movement of the plunger.

Actuation steps:

1. The plunger is directly connected to the ejector pin and represents the position of the ejector pin in the needle. In this position the plunger is resting on a groove in the case, and the ejector pin is in its initial state for the loading of the clip.
2. The plunger is pulled upward by the actuator and hits the angled geometry on the cap.
3. The plunger slides up the angled geometry on the cap
4. The actuator releases the plunger, and the compression spring located within the cap pushes the plunger down on to the angled groove of the case.
5. The plunger slides down the groove.
6. The plunger falls into the groove channel of the case.
7. The plunger slides down the channel.
8. The plunger reaches the bottom of the channel representing state 2 for the ejector pin position.
9. The plunger is then pulled up again and the motion continues as the ejector moves to state 3, then state 1, and so on.

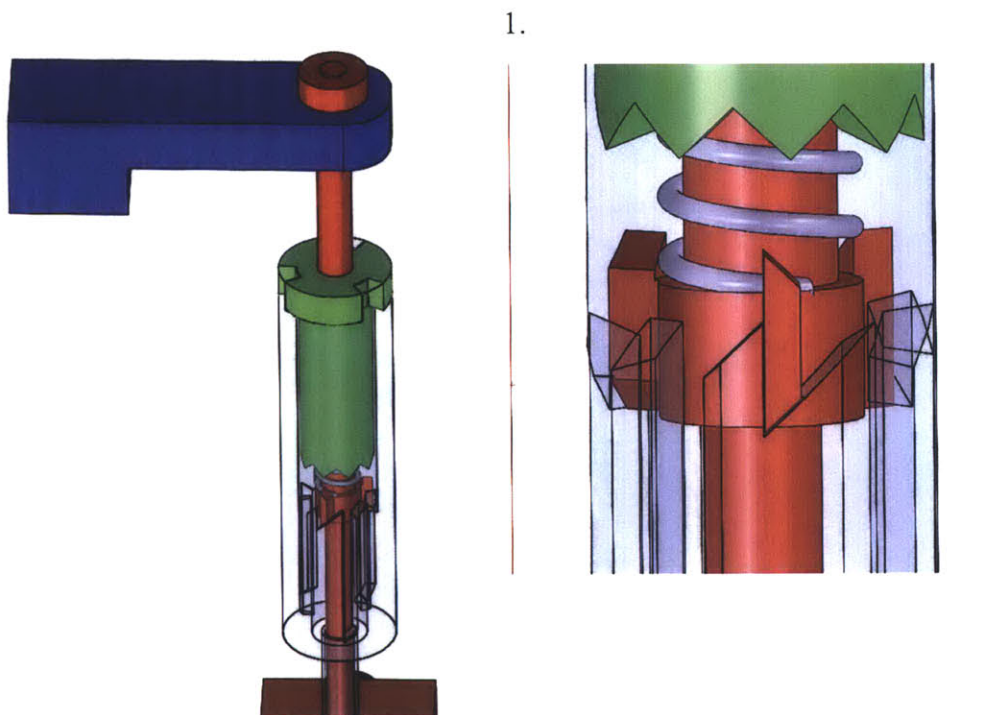
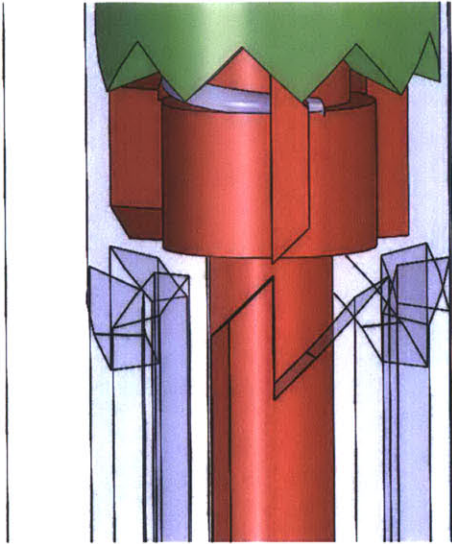
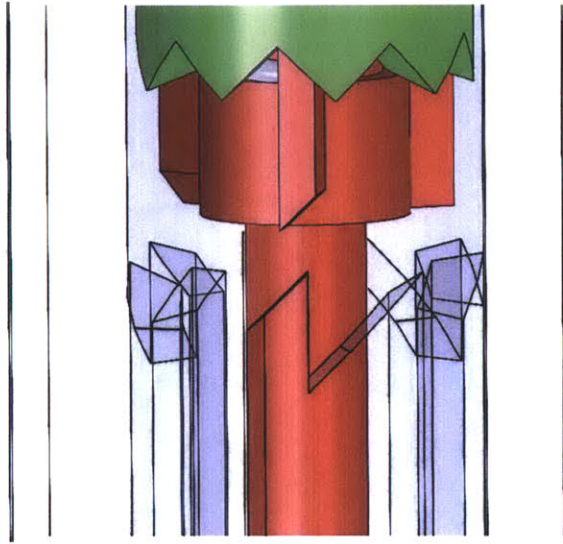


Figure 4.10: Reverse pen click concept actuation step 1. Left: Inside view of the Case. Right: Step 1.

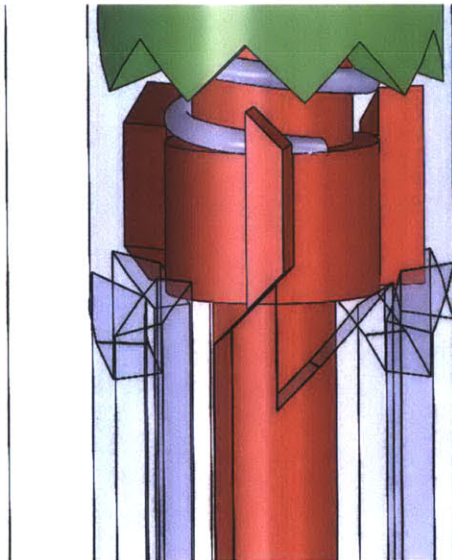
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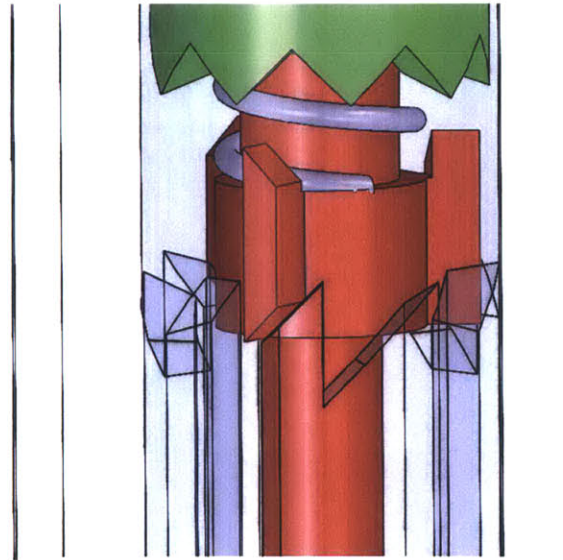
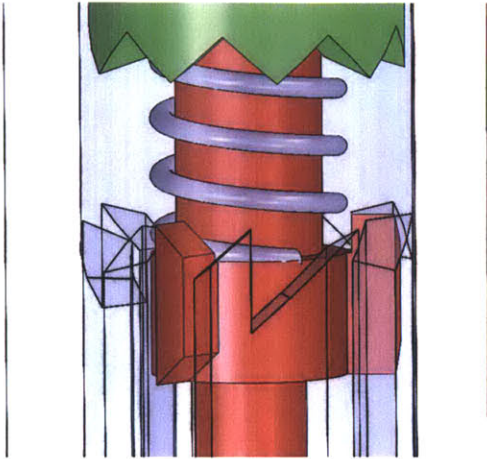
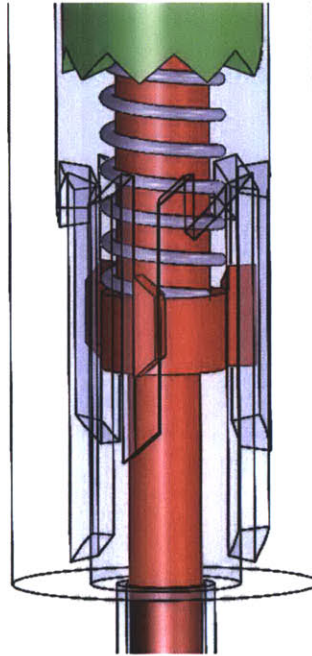


Figure 4.11: Reverse pen click concept actuation steps 2-5.

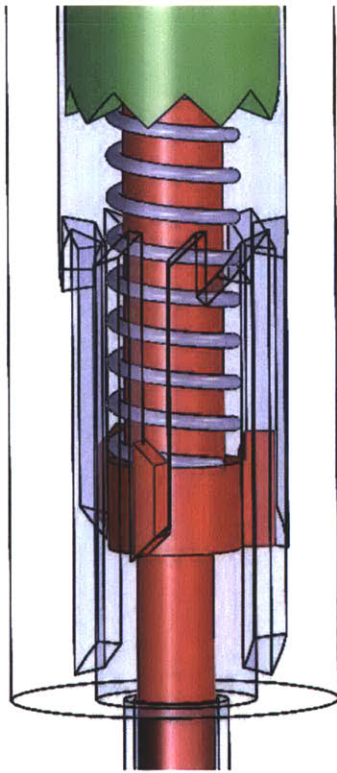
6.



7.



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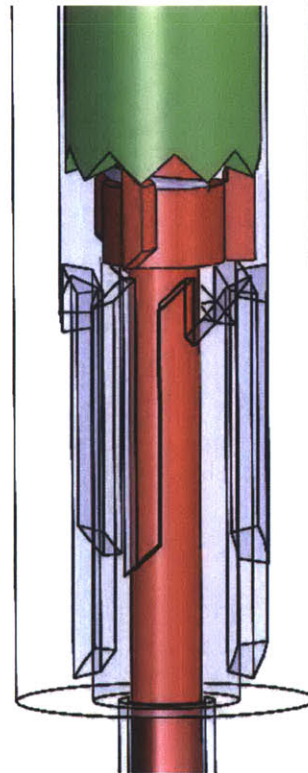


Figure 4.12: Reverse pen click concept actuation steps 6-9.

The reverse pen click concept was 3D printed due to the complex geometry. The prototype worked as expected, but during the printing phase a design change was made that allowed for a simpler solution.

4.4.2 Ejector Pin Design Change

The assumption for the ejector pin motion was that the clips would be loaded into the side of the needle. In order to reduce the complexity and have more flexibility in the design, it was decided that the clips could be loaded through the front of the needles. This would expand the length of the needle paths and size of the device but would cut the number of required ejector pin states from three to two.

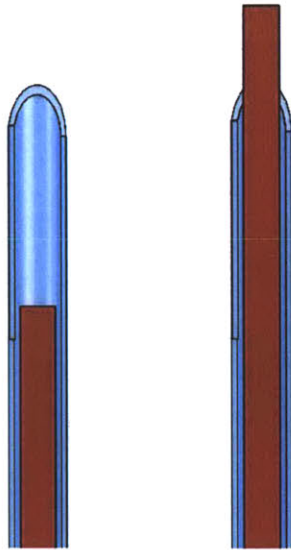


Figure 4.13: New critical ejector pin positions. Left: State 1 of the ejector pin to allow for clip loading. Position can vary a little but it is desirable to keep the clip towards the front of the needle so tissue does not clog the needle during skin insertion. Right: State 2 of the ejector pin to push the clip out.

4.4.3 Actuator Design Concepts

The reduction in the number of states for the ejector pin allowed for more flexibility in the design of the ejector pin actuator. Table 4.2 represents the main concept strategies that were thought of.

Table 4.2: Ejector Pin Actuation Concepts		
Method	<u>Strength</u>	<u>Weakness</u>
Pneumatic actuator travels with needle bearing	<ul style="list-style-type: none"> • Low complexity • Forces inline 	<ul style="list-style-type: none"> • Medium space requirements • Actuator travels with needle assembly
Ejector pin aimed at needle after motion stopped	<ul style="list-style-type: none"> • Actuator not required to travel with needles • Forces inline 	<ul style="list-style-type: none"> • Medium complexity • Large space requirements
Lever that pushes a simple button attached to the ejector pin	<ul style="list-style-type: none"> • Actuator not required to travel with needles • Small space requirements • Multiple designs to actuate lever 	<ul style="list-style-type: none"> • Medium complexity • Possible friction losses

4.4.4 Design Selection

Based off the strengths and weaknesses from the Table 4.2, the design selection for the ejector pin actuation narrowed down to a pneumatic that traveled with the needles and an ejector pin button hit by a lever. The trade off between the designs is complexity versus space requirement. The button would need to be 3D printed, while the pneumatic was already on hand. The pneumatic concept was also attractive since pneumatics were already being used for the alignment actuation. All the forces would be inline, which would reduce friction losses in the system and bending moments on the ejector pin. The button concept would be worth pursuing in

a future design that tries to optimize the form factor of the device, but for the purpose of the deliverable for this prototype the function was a bigger concern. Since the presentation for the project was in 7 days, the risk of prototyping the button idea was too great, and the decision was made to go with the pneumatic design.

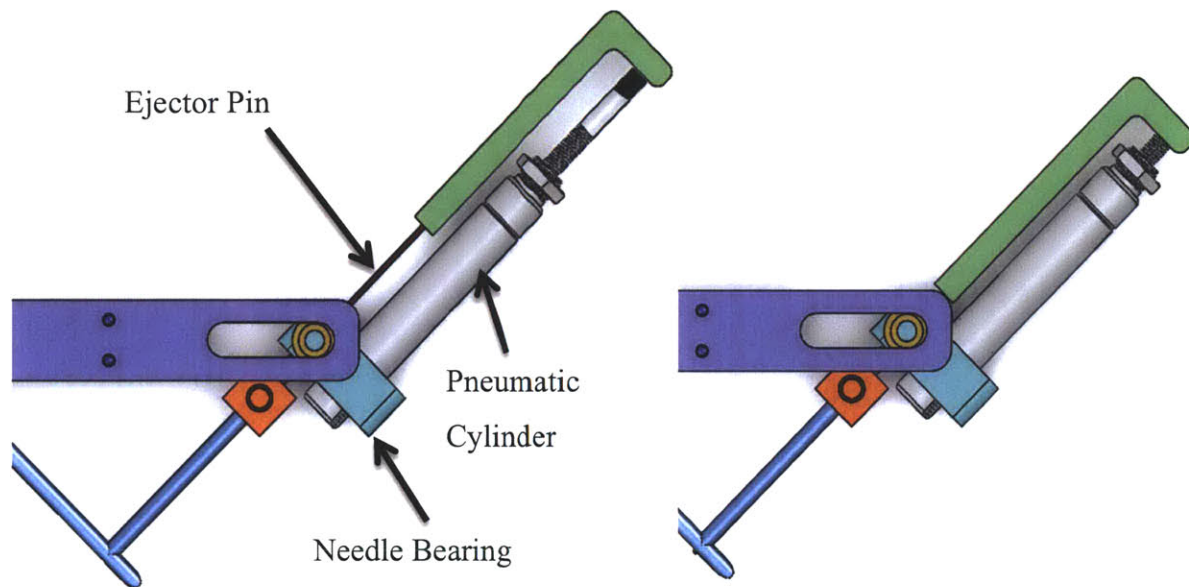


Figure 4.14: Pneumatically actuated ejector pin design. Left: Solid model of ejector pin assembly in its first state. Right: The pneumatic cylinder has actuated and pushed the ejector pin to its second state.

4.5 Needle Actuation

Actuation of the needles in this design will be similar to the actuation in Prototype 1. The needle bearings will follow a curved path in the device case and will be driven by a slotted bar that travels in the vertical direction. The curved paths were optimized from Prototype 1 to reduce friction, create a smaller form factor, and achieve smoother motion.

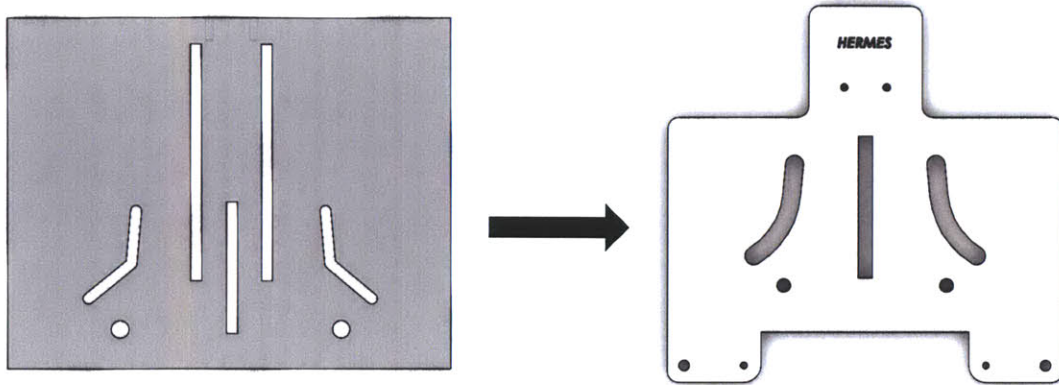


Figure 4.15: Optimized needle path geometry. Left: Prototype 1 design. Right optimized Prototype 2 design.

Since the timing of the needles is different from the alignment mechanism and ejector pin in this prototype, the needles will require a separate actuator to push the slotted bar up and down. Pneumatics were selected for the actuator to drive the slotted bar because the needles only required an initial state and end state for deployment. Pneumatic cylinders were also being used for the alignment and ejector pin mechanisms, and it would be simpler to control if all the actuators were the same. In addition, pneumatics are cheap, easy to control, and simple to mount.

There was another small modification with the slotted bar actuating the needles. In prototype 1 the bar supported the bearings on just one side, which caused frictional losses due to forces out of line with the direction of motion. For Prototype 2 it was decided to support the needle bearing on both sides to fix the problem of misaligned forces.

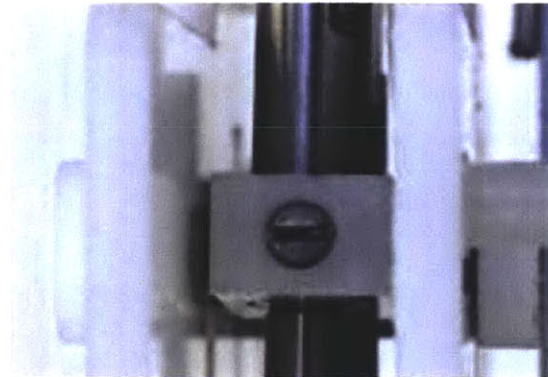
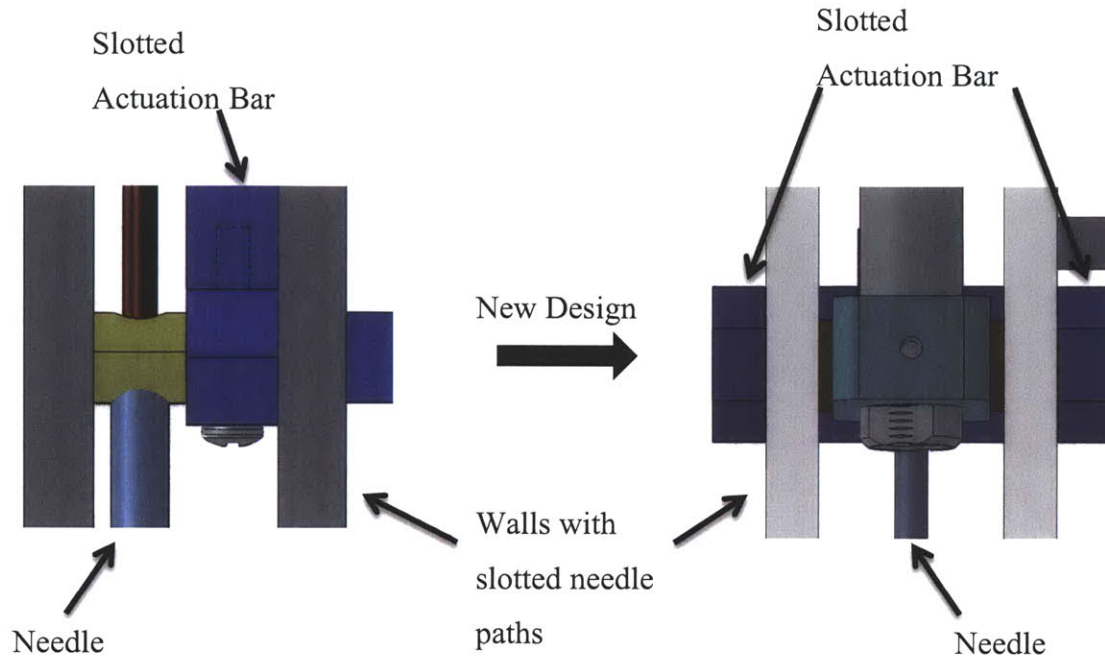


Figure 4.16: Needle bearing supports. Top Left: Solid model of Prototype 1 design with the needle bearing support on just one side. Top right: Solid model of Prototype 2 with the slotted bar supporting the needle bearing on both sides. Bottom: A close up picture of Prototype 2 that shows the needle bearing supported by the slotted bar.

4.6 Results

Initial alignment testing proved promising. The vacuum pressure from a compressor was strong enough to grab skin and move it around at 195 mmHg. However, it was discovered that vacuum pressure in hospitals only have a high, medium, and low setting that can vary with the weather and from room to room. The unreliability of the proper vacuum pressure would require a compressor or compressed air container to use device. Also, the rotation of the alignment pads

was difficult because the air hoses tended to pinch and close off due to the small space requirements.

Results for the needle and clip actuation were positive. The pneumatically actuated mechanism connected clips reliably over a hundred times in a row and had a 98% success rate over 300 trials. The pneumatic cylinders were controlled through a 2-button user interface, which satisfied the functional requirement of a simple to use device. Unfortunately tests could not be conducted in human skin because needles were prototyped at 5x scale in order to make prototyping easier for the clips and needles.

4.7 Discussion

The problem of unreliable vacuum pressure in the operating room makes the use of pneumatics less desirable. Pneumatic cylinders are also tall because of the required draw length and would be difficult to package into a smaller design. Future designs should attempt to reduce the number of actuators by combining motions and avoid using pneumatics. This will aid in reducing complexity, size, and cost. It is important to reduce the packaging and size of the device because it is much bigger than most devices found in the O.R. Smaller needles should be made to enable testing in human skin, and the ramifications of smaller needles on the actuating mechanisms should be considered. Finally, alternate alignment mechanisms that do not rely on vacuum pressure should be developed.

PROTOTYPE 3

5.1 Development Goals

The goal for the semester in which prototype 3 was built, was to refine the rapid skin closure device and bring it close to a production ready product. The specific goals for Prototype 3 were to address the problems with Prototype 2 by reducing the number of actuators, developing a new alignment method, and reducing the overall size of the device.

5.2 Prototype 3 Final Design

The final design of Prototype 3 used passive rail alignment and combined the actuation of the needles with the ejector pin, which allowed for the device to be manually actuated by a handle. Special thanks to the RSC team for helping build Prototype 3.

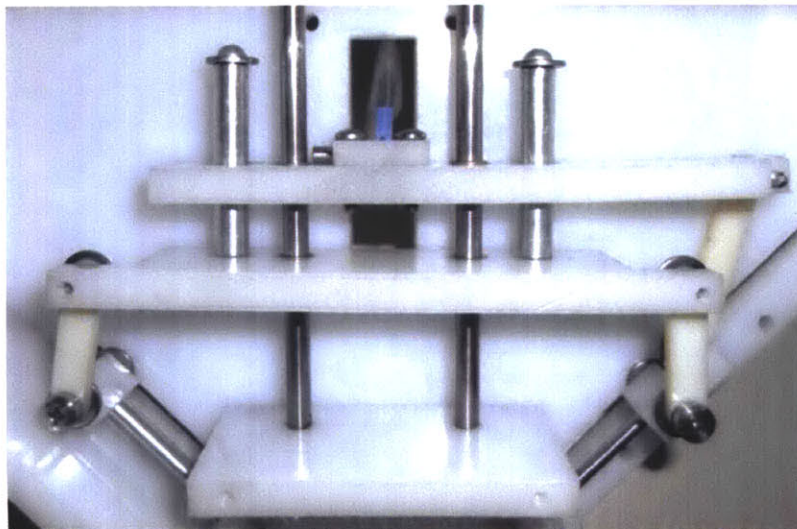


Figure 5.1: Picture of inner components of Prototype 3.

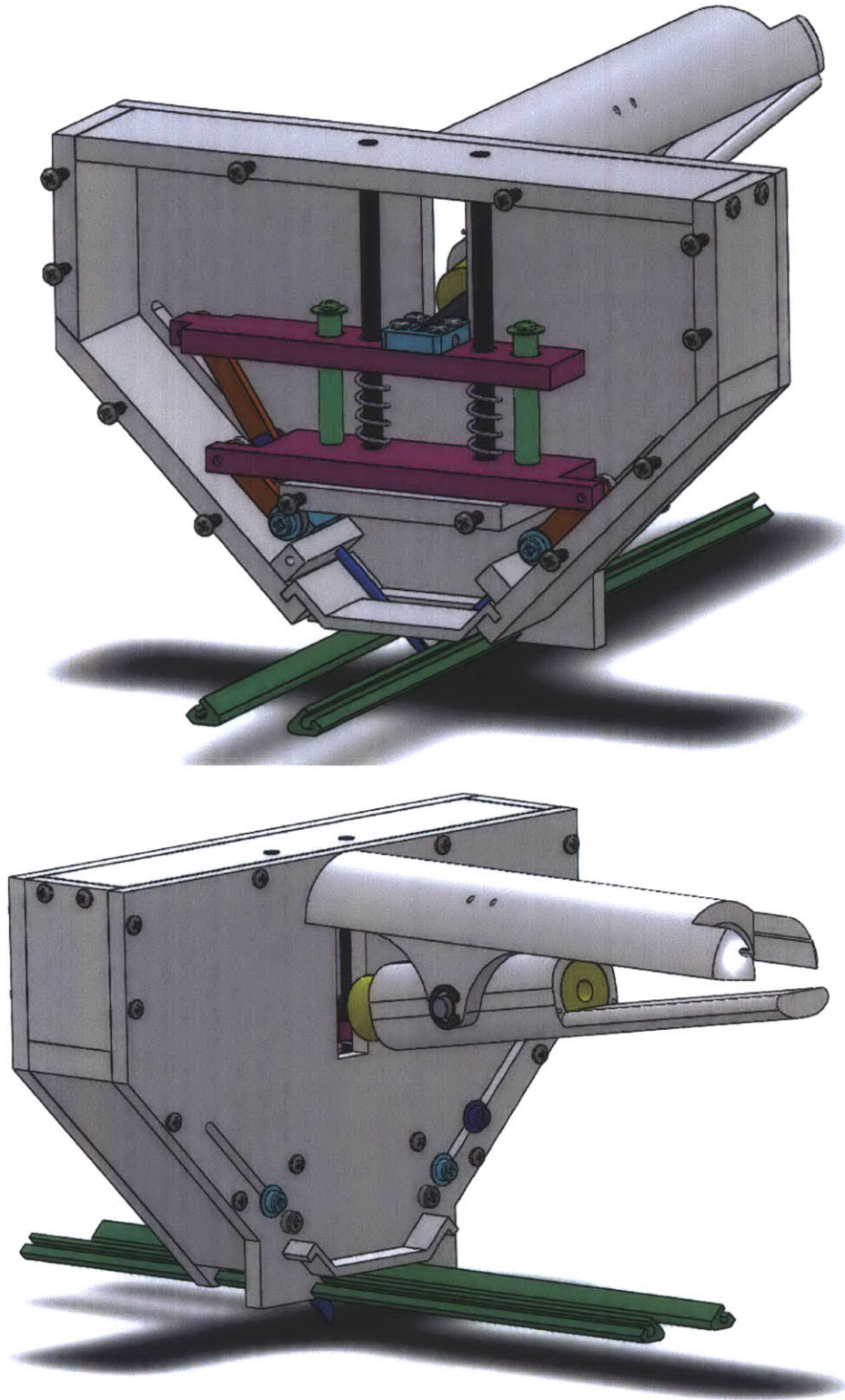


Figure 5.2: Solid model of Prototype 3. Top: Front view with the Front wall removed. Bottom: Rear view. Special Thanks to Omar Carrasquillo for helping with the solid modeling of Prototype 3.

5.2.1 Actuation Steps

The description of the actuation motion for Prototype 3 is followed by corresponding figures representing each step.

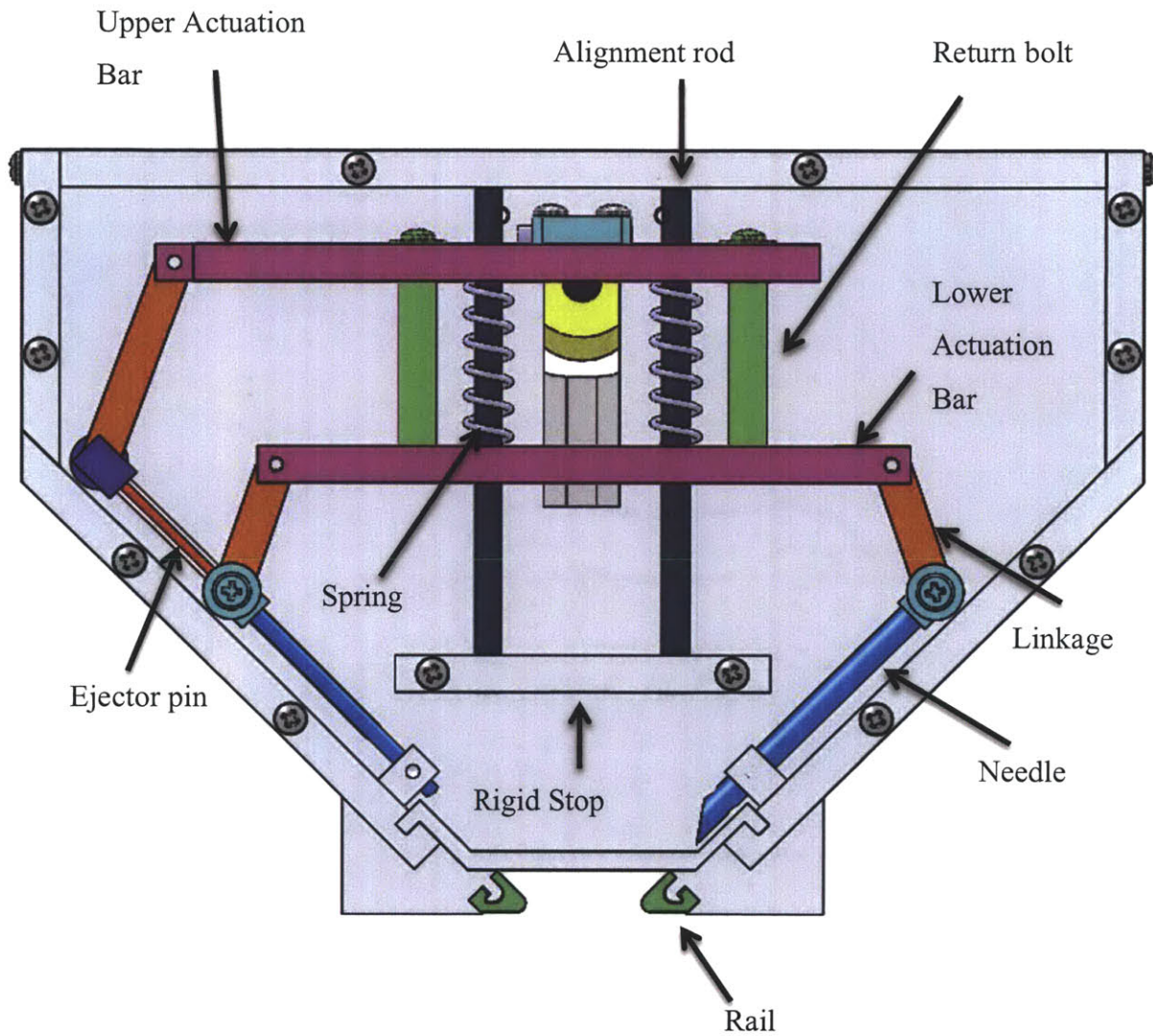


Figure 5.3: Annotated model of Prototype 3.

Actuation steps:

1. Starting position of device. Device has already slid along the rail geometry, which has rotated the wound edge into the correct position for needle insertion.
2. The upper actuator bar begins to move downward. The clips load into the front of the needles, then the springs between the upper and lower bar compress slightly as the needles insert into the skin along straight paths.
3. The needles come together at 90 degrees. The lower bar hits a ridged stop.
4. The upper continues to move downward compressing the springs and actuating the ejector pin.
5. The upper bar moves upward and the springs relax as the ejector pin is retracted. The upper bar catches on the return bolts and then the upper and lower bar move together back to the initial position in step 1.

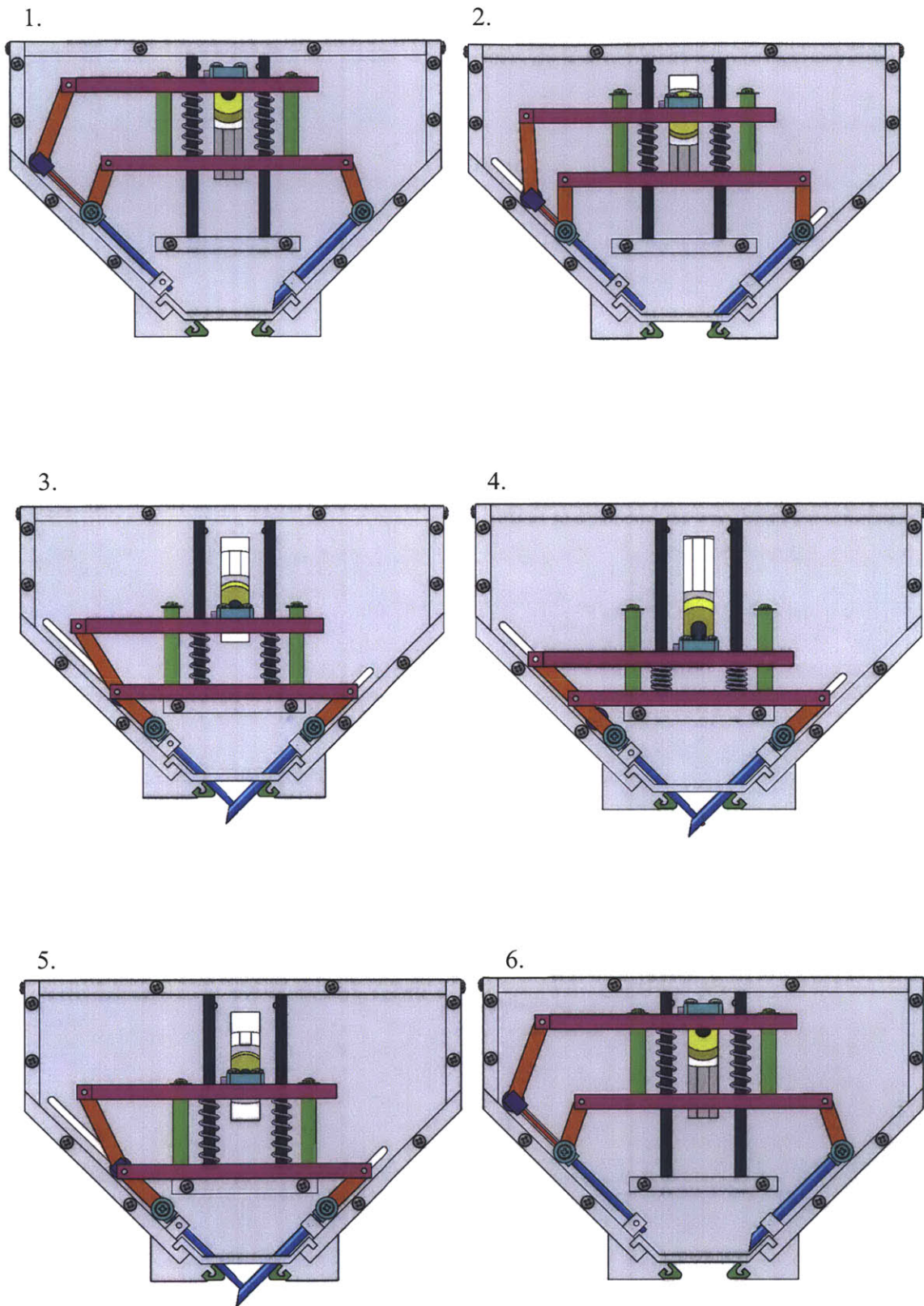


Figure 5.4: Prototype 3 actuation steps 1-6.

5.3 Combined Actuator Design

The goal for minimizing the number of actuators on the device is to reduce the complexity, cost, and space requirements. Based on the results from prototype 2, designs will focus on more compact actuators like servomotors that do not rely on vacuum pressure. Servos are great because they are cheap, compact, and easy to control.

The most profitable strategy to reduce the number of actuators in the device is to combine the motions of the needles and ejector pin since their motions are the most similar.

Challenges in combining the motions of the needles and ejector pin are similar to those brought up in section 4.4. Asynchronous movement still exists because of the curved paths, and it causes the design to focus around the ejector pin traveling with the needle assembly to avoid pushing the clip out at the wrong time. In order to eliminate pneumatics from the design without using a different lightweight actuator to travel with the needle assembly, a button like actuation of the ejector pin was developed. The button has 2 position states that would meet the requirements of the ejector pin positions.

In order to combine the motions of the needle and ejector pin there needs to be some kind of timing element in the actuation where one part is moving while the other is paused. The two main strategies that the concepts revolved around for timing were rotary motion or a spring connection that can be stiff through part of the motion then compress when a component hits a rigid stop. A list of possible power transmission elements was generated as building blocks for the design of a combined actuator mechanism in Table 5.1.

Table 5.1: Building Blocks For Combined Actuator Movement		
Power Translators	<u>Strength</u>	<u>Weakness</u>
Barrel Cams	<ul style="list-style-type: none"> • Allows for variable timing based on the pitch of the groove 	<ul style="list-style-type: none"> • Friction losses from cam • Complex to constrain • Difficult to prototype
Variable Gear timing	<ul style="list-style-type: none"> • Allows for timed actuation • Simple to prototype 	<ul style="list-style-type: none"> • Difficult to align properly
Electro-permanent Magnet clutches	<ul style="list-style-type: none"> • Electrical actuation to engage clutches that is easy to control 	<ul style="list-style-type: none"> • Technology is new • Size could be an issue • Possible safety concerns
Rotating gear with pin following cam surface	<ul style="list-style-type: none"> • Compact design • Timing easy to achieve 	<ul style="list-style-type: none"> • Friction losses from Cam • Medium complexity
Springs	<ul style="list-style-type: none"> • Stiff springs allow for timed actuation 	<ul style="list-style-type: none"> • Stiffness might require too much user input force.
Lead screw and nut	<ul style="list-style-type: none"> • Vertical actuation that can deliver high forces • Compatible with servos 	<ul style="list-style-type: none"> • Requires bearings and extra space to properly constrain
Lever for button	<ul style="list-style-type: none"> • Less precision required • Low cost 	<ul style="list-style-type: none"> • Out of line forces
Slotted bar	<ul style="list-style-type: none"> • Easier to constrain • Inline forces 	<ul style="list-style-type: none"> • Requires a bearing for rolling friction
Linkage	<ul style="list-style-type: none"> • Delivers rolling friction without bearing • Translates between rotary and linear motion 	<ul style="list-style-type: none"> • Fixed length can be used in a limited number of designs • Forces not inline

Table 5.2 compares possible designs that could accomplish the combined actuation motion.

Table 5.2: Combined Actuator Designs

Concepts	<u>Strength</u>	<u>Weakness</u>
<p>Barrel Cam Design: One cam used for timing of needles, and the other connected to the same rotating motion to drive timing for ejector pin.</p>	<ul style="list-style-type: none"> • Accomplishes motion 	<ul style="list-style-type: none"> • Several shafts that need to be supported, constrained, and aligned properly • Pause in motion can only last for one rotation of shaft
<p>Clutch Design: Servo rotates a lead screw, then a magnetic clutch can activate to drive a lever that pushes an ejector pin button</p>	<ul style="list-style-type: none"> • Accomplishes motion • Compact design 	<ul style="list-style-type: none"> • Electro permanent magnet clutches are not readily available • Difficult to prototype
<p>Cam Design: Rotating gear with pin drives cam surface attached to needle actuating bar. Variable gear timing used with main gear to actuate slotted bar on ejector pin.</p>	<ul style="list-style-type: none"> • Accomplishes motion • Compact design 	<ul style="list-style-type: none"> • Possible frictional losses • Limited to one rotation for timing • Medium difficulty for prototyping
<p>Lead screw Design: A lead screw drives actuating bars with springs in between them. The lower bar actuates the needles, then the spring compresses and the upper bar actuates the ejector pin button.</p>	<ul style="list-style-type: none"> • Accomplishes motion • Simple to prototype 	<ul style="list-style-type: none"> • Complexity and space requirements in constraining and supporting lead screw shaft

5.3.1 Design Selection

The Lead screw and Cam designs looked to be the most promising, but it was difficult to tell which one was better without further exploration. Solid models of both designs were created and then evaluated.

5.3.1.1 Cam Concept

The following figures represent the solid model of the Cam concept and its actuation steps.

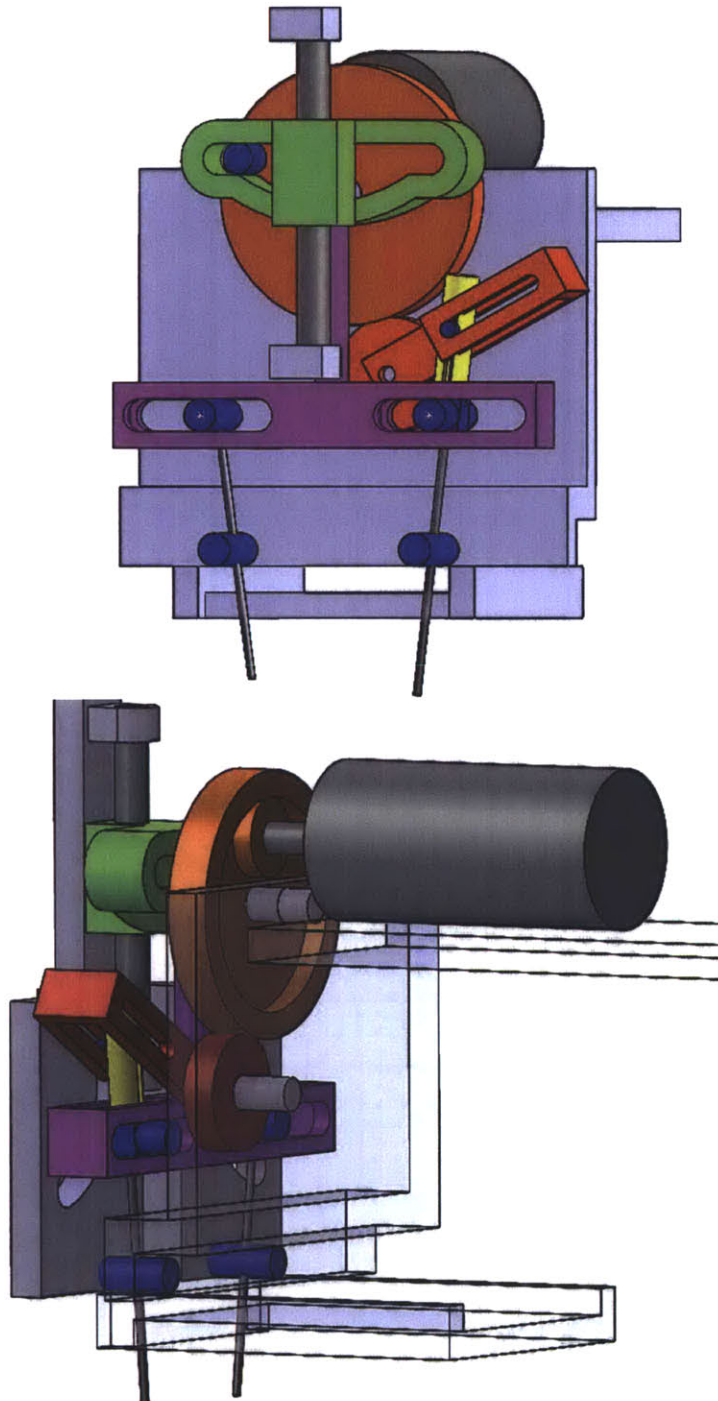


Figure 5.5: Solid model of Cam concept. Top: Front view. Bottom: Back view.

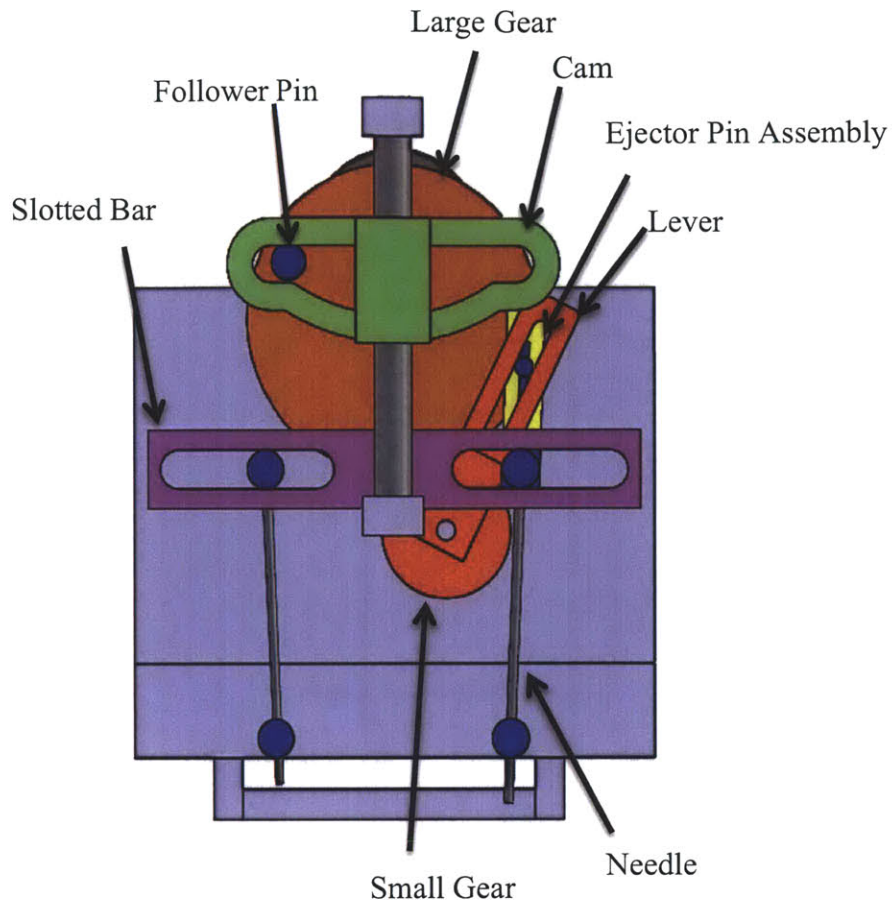


Figure 5.6: Annotated model of Cam concept.

Actuation steps:

1. A servomotor begins to turn the large gear with a pin. As the gear spins the pin follows a cam surface. The cam surface is rigidly attached to the slotted bar that drives the needles. The lever attached to the small gear freely spins to follow the ejector pin assembly.
2. When the pin on the gear starts to reach its lowest point, the cam surface becomes curved and effectively pauses the needle motion.
3. As the main gear continues to rotate it has gear teeth on the outside face of the gear that suddenly mesh with the smaller gear. This is called variable gear timing and it actuates the lever of the small gear. The lever drives the ejector pin down for clipping.
4. Next, the gear teeth on the large gear pass by the small gear. Now the lever can freely rotate again allowing a spring in the ejector pin assembly to retract the ejector pin.
5. Finally, the cam surface changes and the needles are brought back to their starting position

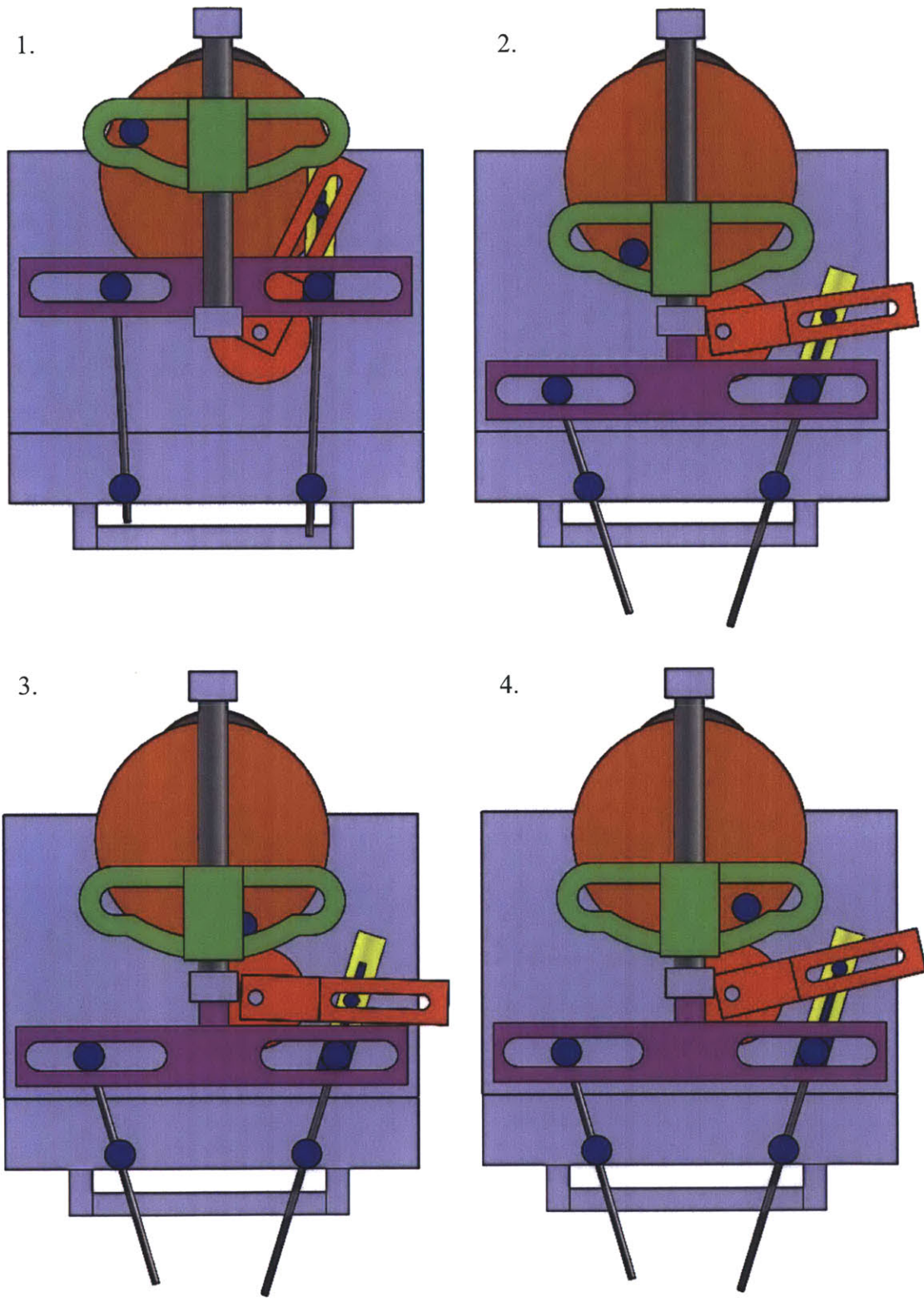


Figure 5.7: Cam concept actuation steps 1-4.

5.

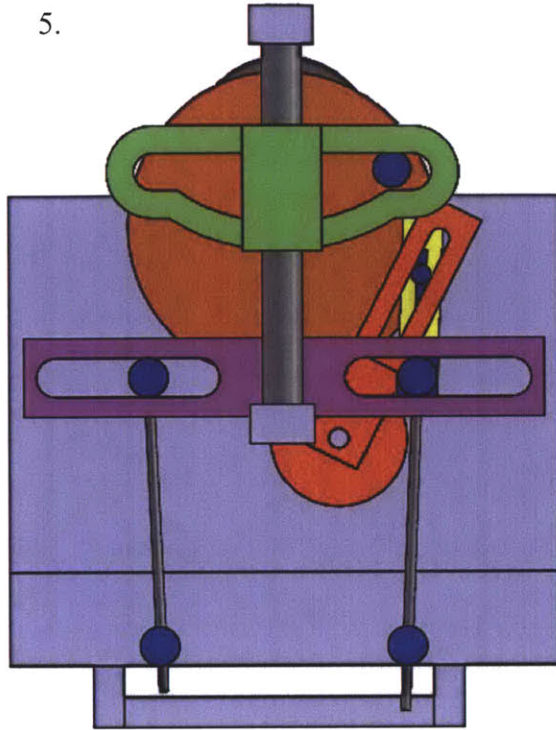


Figure 5.8: Cam concept actuation step 5.

5.3.1.2 Lead Screw Concept

The following figures represent the solid model of the Lead Screw concept and its actuation steps.

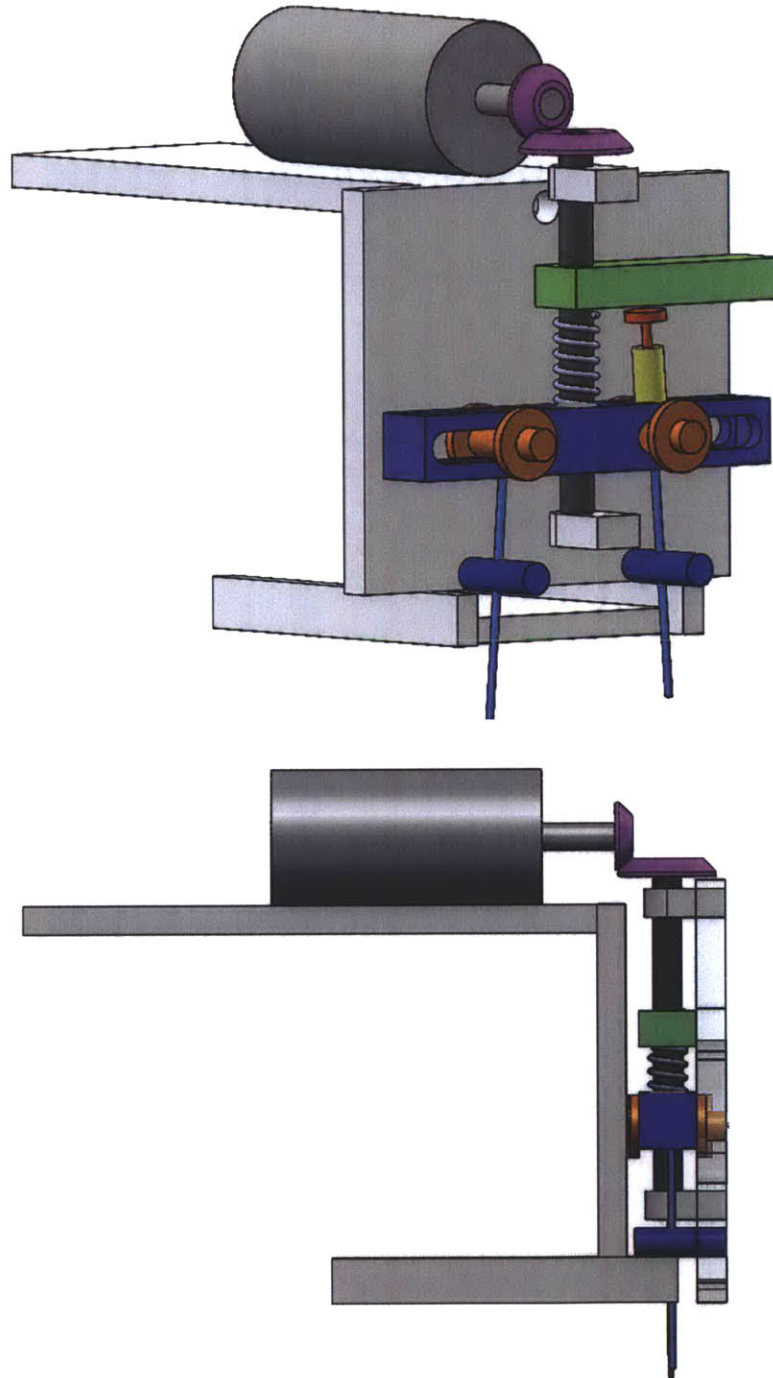


Figure 5.9: Solid Model of Lead Screw concept. Top: Front view. Bottom: Side view.

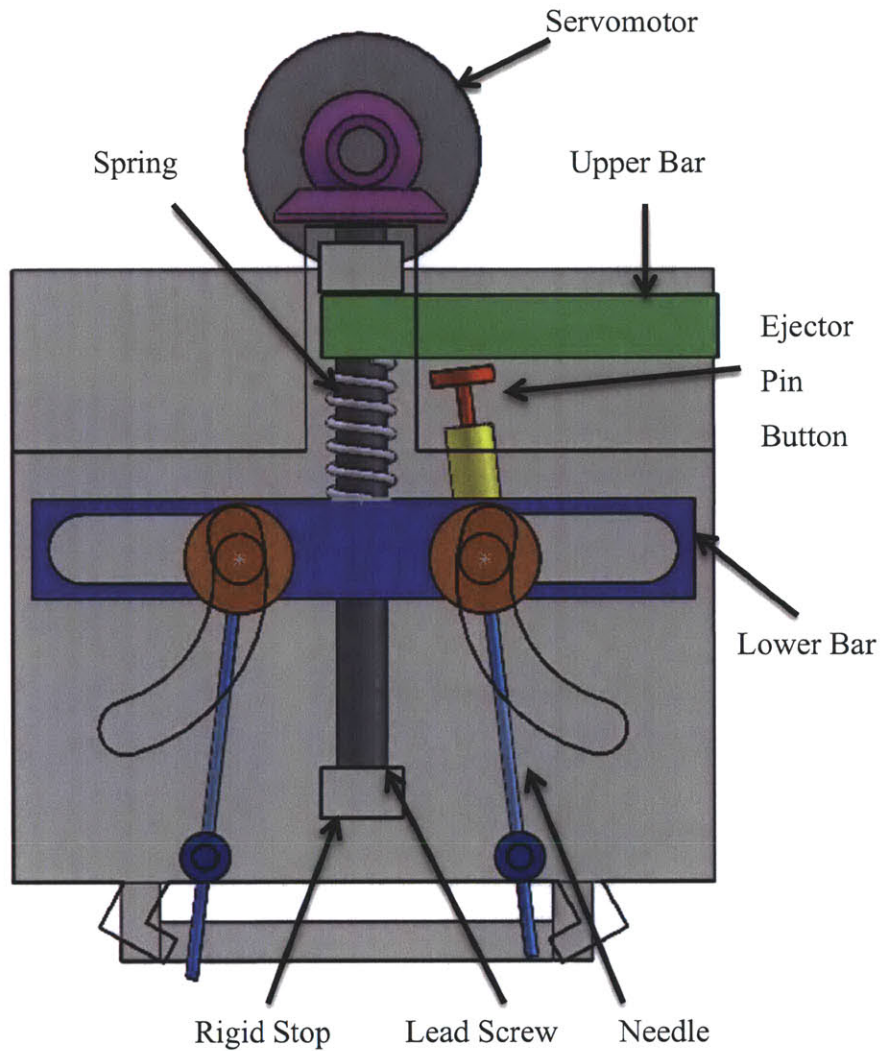


Figure 5.10: Annotated model of Lead Screw concept.

Actuation steps:

1. The upper actuator bar begins to move downward as a servomotor turns the lead screw. The clips load into the front of the needles, and then the springs between the upper and lower bar compress slightly as the needles insert into the skin.
2. The needles come together at 90 degrees. The lower bar hits a ridged stop.
3. The upper continues to move downward compressing the springs and pushing the ejector pin button down.
4. The lead screw reverses direction, and the upper bar moves upward. The springs relax as the ejector pin is retracted. The upper and lower bars then move together back to the initial position in step 1.

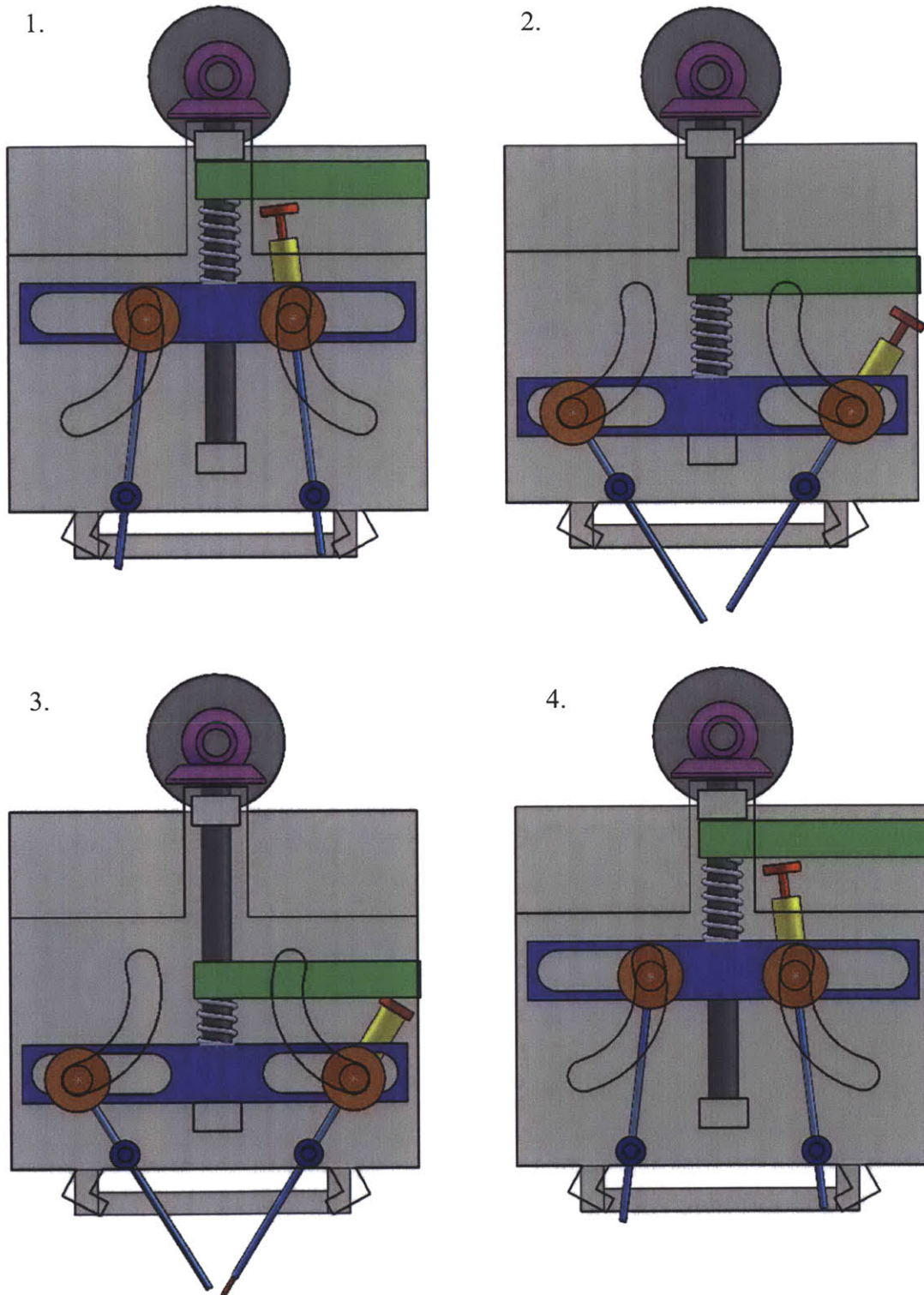


Figure 5.11: Lead Screw concept actuation steps 1-4.

A slight modification to the design of the Lead Screw concept would allow for a second actuator to be placed if the concept did not work as planned. This provided a countermeasure to minimize the risk of going with the Lead Screw concept.

After modeling both designs, a chart was used to evaluate the risks of the concepts and how well they met the functional requirements. The following table was set up so that “Low” is the desirable ranking and “High” is undesirable.

Table 5.3: Combined Actuator Concept Comparison			
	Cam Concept	Lead Screw Concept	Double Lead Screw Concept
Space	Low	Medium	High
Cost	Medium	Low	Medium
Complexity	High	Medium	Medium
Risk	Medium	Low	Low

The decision was made to go with the Lead Screw concept because it had the best ranking with no highs, and a low risk factor because it could be converted to a double lead Screw design in a worst-case scenario.

5.4 New Alignment Design

A new alignment mechanism design was required after the results of the vacuum alignment on the previous prototype. The unreliability of the appropriate amount of vacuum suction in the operating room made the suction pads a risky design. In addition, the necessity of a hose attachment would make the device more cumbersome and difficult to use.

The development of the alignment mechanism is important to this design because it will directly affect how complicated the actuation motion will be.

The challenge for the alignment mechanism was to align with the wound edge, adhere to the skin in some fashion, and then actuate to bring the skin into the correct position for needle insertion.

Table 5.4 shows some comparisons of the alignment concepts that were generated.

Table 5.4: Alignment Concepts

Concepts	<u>Strength</u>	<u>Weakness</u>
Forceps	<ul style="list-style-type: none"> • Similar to current methods 	<ul style="list-style-type: none"> • Medium actuator complexity
Current vacuum design	<ul style="list-style-type: none"> • Minimal tissue trauma 	<ul style="list-style-type: none"> • Vacuum pressure unreliable
Vacuum wheels	<ul style="list-style-type: none"> • Avoids having to reapply pressure for every clip advancement 	<ul style="list-style-type: none"> • Unproven technology • Same weakness as current design
Velcro rails	<ul style="list-style-type: none"> • Simple mechanism for grabbing skin • Low cost 	<ul style="list-style-type: none"> • Particles contaminate wound • Difficult to advance • Finding adhesive for the rail
Magnetic rails	<ul style="list-style-type: none"> • Simple interface between rails on skin and device 	<ul style="list-style-type: none"> • Potentially dangerous for patients with pacemakers
Sliding hook rails	<ul style="list-style-type: none"> • Easy to advance • Simple actuating mechanism 	<ul style="list-style-type: none"> • Possible jamming • Needs to slide to access center of the wound • Finding adhesive for the rail
Attach/Detach rails	<ul style="list-style-type: none"> • Same as sliding hook • Can easily jump to any section of the wound 	<ul style="list-style-type: none"> • Could miss rail geometry on attachment and cause frustration for user • Finding adhesive for the rail
Passive rails	<ul style="list-style-type: none"> • No actuating mechanism required • Simple to use • Easy to prototype • Low cost 	<ul style="list-style-type: none"> • Possible jamming • Finding adhesive for the rail • Needs to slide to access center of the wound

5.4.1 Design Selection

The consensus choice that emerged from the possible concepts was the passive rail system. This concept eliminates the need for an actuating mechanism by using the geometry of a cut groove and slider to achieve skin rotation as the device slides along. It is also easy to prototype at low cost. The simplicity of the design lends itself well for manufacturing, assembly, and reliability.

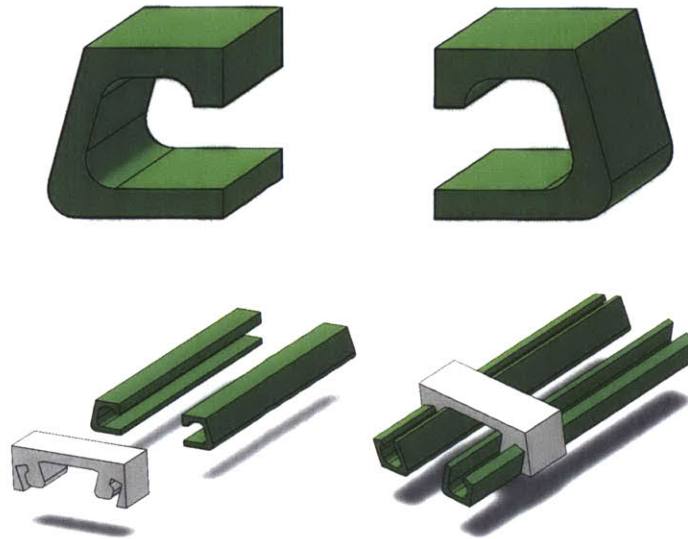


Figure 5.12: Solid model of passive rail alignment. Top: Model of rails. Bottom: Depicts a slider mating with rails and sliding along them.

5.4.2 Actuation Steps

1. Start with an open incision.
2. Apply adhesive to the bottom of the rail.
3. Adhere rails to the wound edge. Future designs will have locating features for easy alignment to wound edge.
4. Slide the device along the rails and the rails will rotate into the proper position to expose the dermal layer of skin for needle insertion.

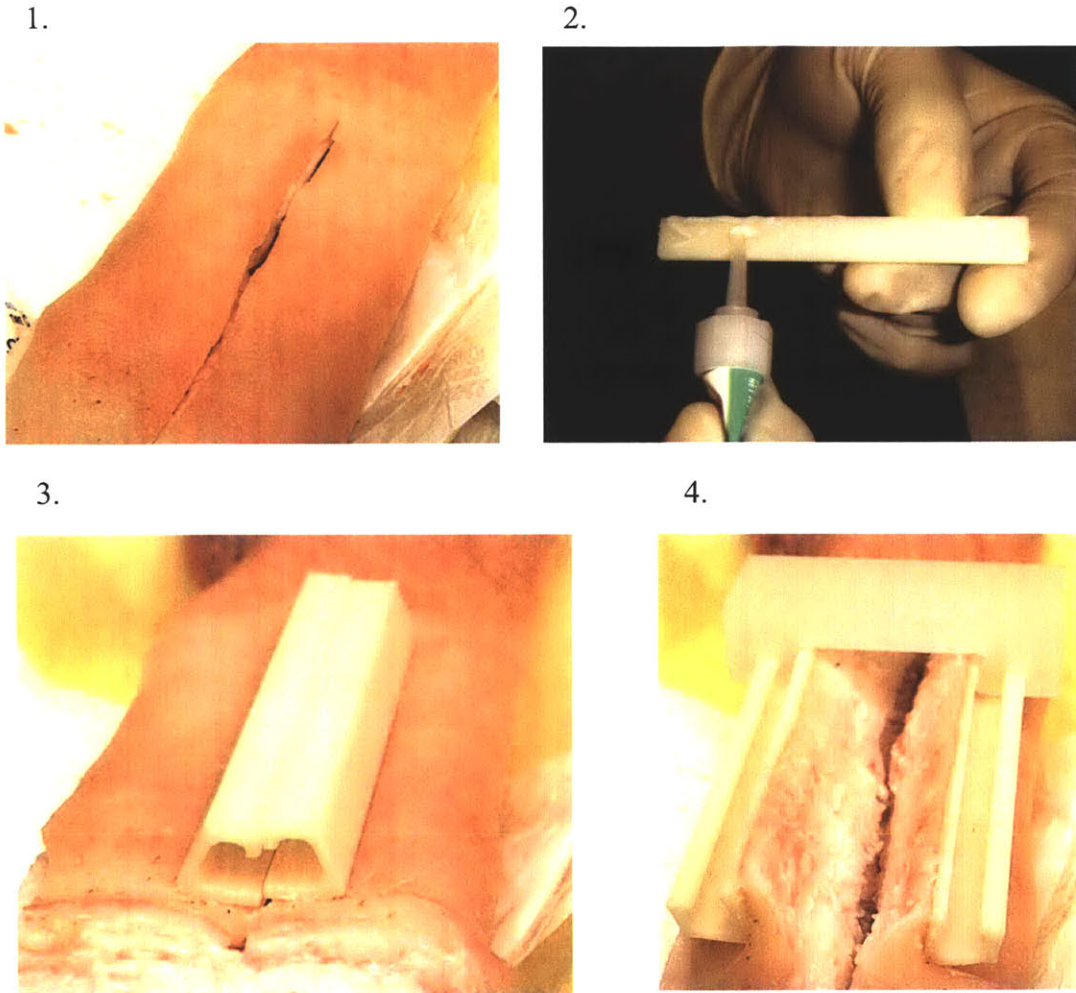


Figure 5.13: Passive rail alignment implementation steps 1-4.

The specific design of the rail geometry took into account St. Venant's principle to avoid jamming. It was also modeled to estimate the approximate alignment error in the needle it would cause, in order to achieve a sliding fit. Overall, the passive alignment rails worked well with the actuator strategy of combining motions and simplifying the design. The new device only requires one actuator now because of the combined ejector pin and needle motions and the passive alignment rails. This opened up an exciting possibility for manual actuation instead of a servo. Special thanks to Steven L. for 3D printing the alignment rails and conducting the tests with Omar C.

5.5 Manual vs. Electric Actuation

With the reduction in the required number of actuators for the device, it allows for the design of a simple manual actuator. Table 5.5 compares the advantages and disadvantages of manual and electrical actuation for the device.

Table 5.5: Manual vs. Electric Actuation		
Method	<u>Strength</u>	<u>Weakness</u>
Manual	<ul style="list-style-type: none"> • Simple • Low cost • Easy to sterilize • Viewed by doctors as more accessible and easy to use than electrical devices • Smaller space requirement 	<ul style="list-style-type: none"> • Input force limited by user • User could tire from actuating throughout a procedure
Electric	<ul style="list-style-type: none"> • High force • User will not tire while using 	<ul style="list-style-type: none"> • Possibly slower than manual • No tactile feel • High cost • Complex

Manual actuation was selected for this prototype because of the lower cost, complexity, and space requirements. Also in consulting with clinicians from MGH, we found that a manually actuated device was viewed as more reliable, accessible, and easy to use than an electric device. This means a manual actuation could help with adoption of the product in the future.

5.5.1 Manual Actuation Design

There were two main design requirements for the manual actuator. One, it needed to accommodate the grip and reach of a female adult to be comfortable to use. Two, the required force for the device needed to be less than the maximum capacity of an adult female operator.

Both of these requirements were satisfied with the final design of the handle seen in Figure 5.14. Based on the torque balance around the pivot, the required force from the user is 29.7 N, which is well below the maximum capability of a female operator 470.7N [12].

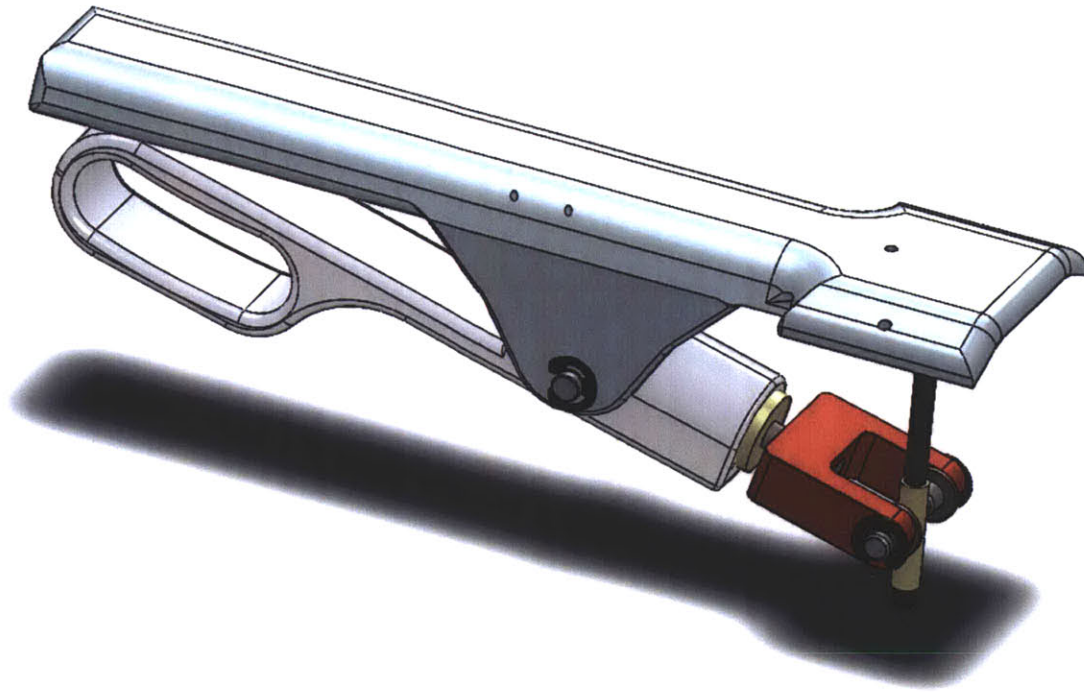


Figure 5.14: Solid model of manual actuator. Special thanks to Faye W. and Omar C. for helping with handle and clevis design and prototyping.

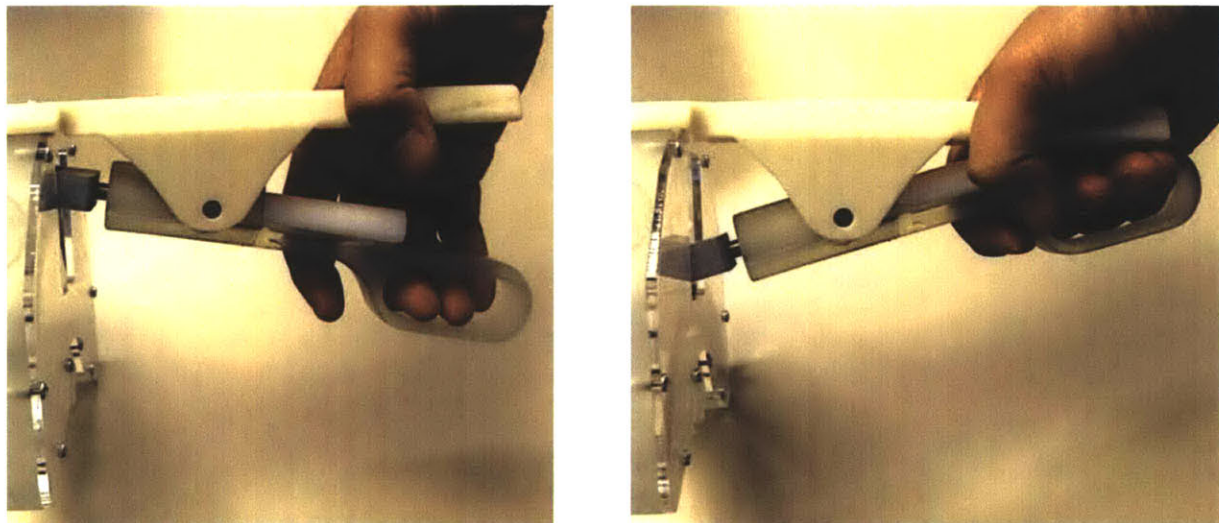


Figure 5.15: Pictures of manual actuator in action.

5.5.2 Actuation Steps

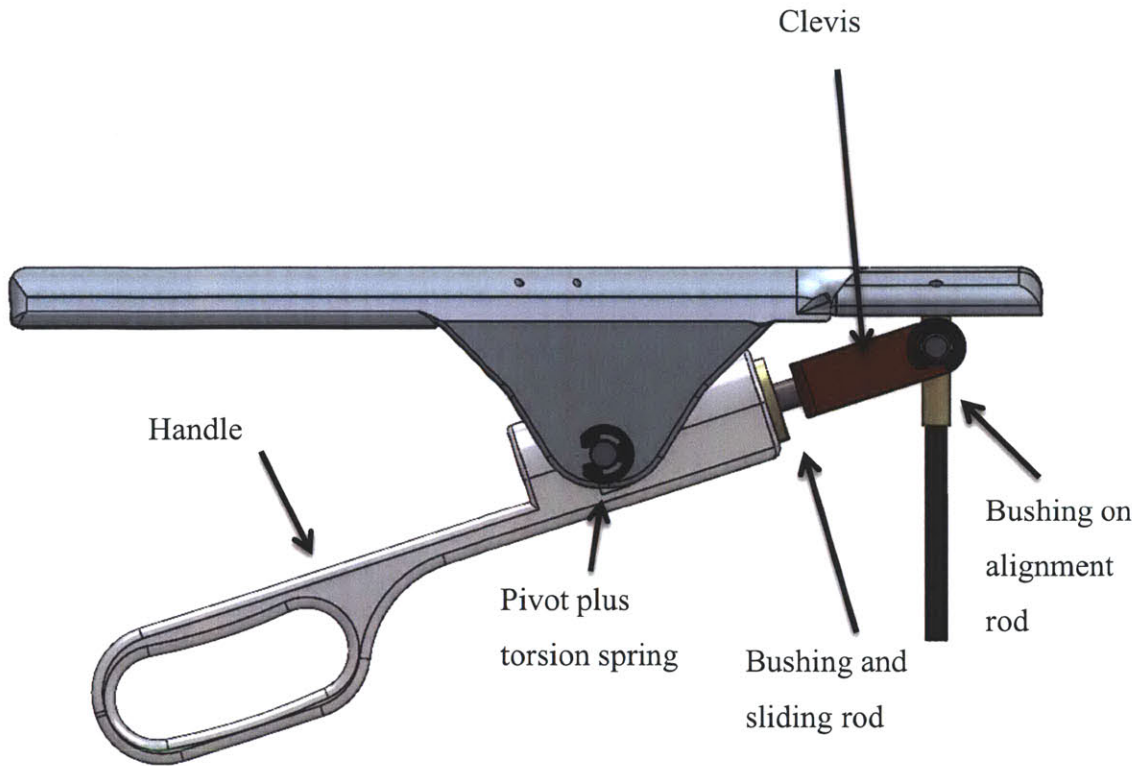


Figure 5.16: Annotated model of the manual actuator.

Actuation steps:

1. User grips handle and begins to squeeze towards the top piece.
2. As the handle rotates about the pivot, the clevis rotates, the sliding rod retracts into the main bushing, and the smaller bushing travels down the alignment rod.
3. The handle continues to rotate to the highest position, the sliding rod extends from the main bushing, the clevis rotates, and the smaller bushing travels to the bottom of the alignment rod. A torsion spring at the pivot helps reverse the motions back to the starting position.

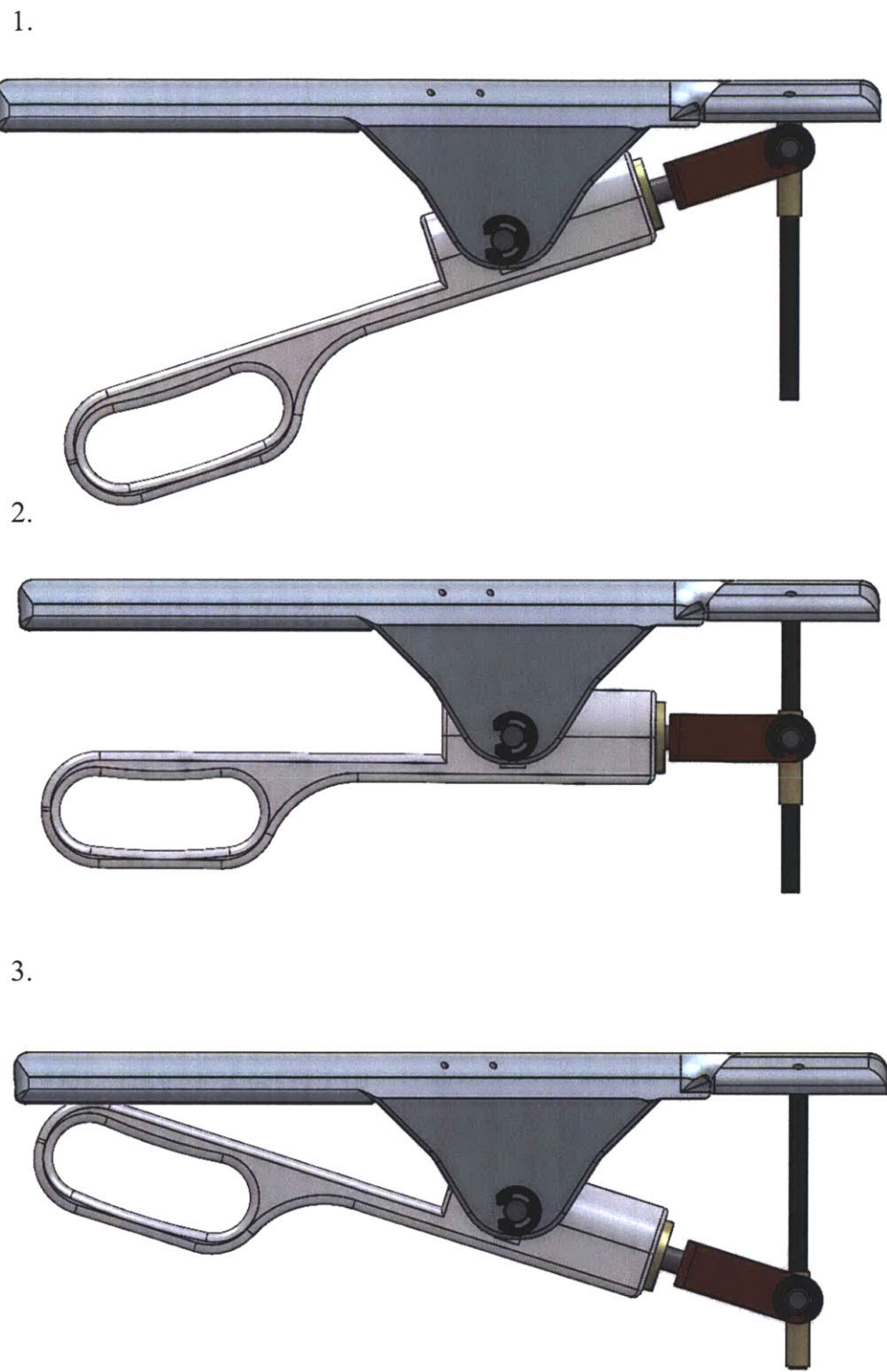


Figure 5.17: Manual actuator steps 1-3.

The handle of the device was designed for a female doctor in order to ensure that the majority of users would be able to actuate the device. However, there is a large range in hand sizes between an adult female and an adult male. The handle might not be comfortable for an adult male with bigger hands so future designs will need to incorporate a more adjustable handle than the one prototyped for this model.

A torsion spring was used at the pivot of the handle to assist with the return of the handle to the starting position. The reason a full spring return was not used is because it would add more force to actuate the device and it could fail to bring the handle completely back if there are larger frictional forces than initially anticipated.

5.6 Design Change Due To Needle Concerns

Towards the end of the design phase for Prototype 3, there were several problems that arose regarding the needles that caused a change in the actuating motion. Originally, the needles followed a curved path and rotated after dermal insertion for the tips to meet. This rotation becomes a concern when used in conjunction with the new passive rail alignment mechanism. The rails are fixed in place throughout the needle insertion, which causes more stress on the needles and tissue than the previous design. The additional stress could cause misalignment with the needle tips or undesired trauma to the tissue. Also, the needles might not cut through the skin because they will be rotating sideways through the skin.

There were several possible design solutions to address these problems that appear in Table 5.6.

Table 5.6: Concepts To Fix Needle Deflection		
Concepts	<u>Strength</u>	<u>Weakness</u>
Curved needles	<ul style="list-style-type: none"> • Reduce stress on needles and tissue • Can cut through a rotational movement 	<ul style="list-style-type: none"> • Requires a rotational actuation • Geometry is complex to package • Ejector pin will need to actuate along a curved path.
Straight needle paths	<ul style="list-style-type: none"> • No bending moments on needles • Minimal tissue trauma • No rotational movement 	<ul style="list-style-type: none"> • Difficult to reduce size of the device once the needle paths are optimized. • Slightly bigger packaging
Rotation in rails	<ul style="list-style-type: none"> • Reduces some stress on needles and tissue 	<ul style="list-style-type: none"> • Needles have problem cutting through rotation • Needles still feel some stress • Possible jamming or misalignment

5.6.1 Design Selection

It was determined that changing the design to straight needle paths would offer the best solution to all the concerns with the stress on the needles. Curved needles are an interesting thought but would require a longer development time, which made it too risky with a project presentation deadline looming 6 weeks away.

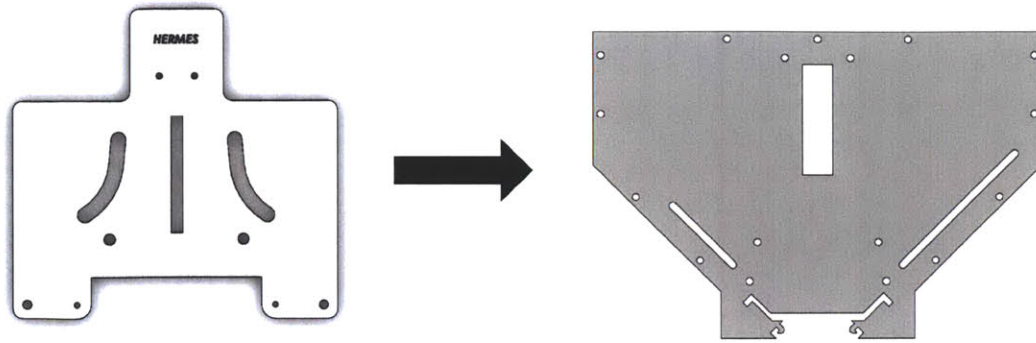


Figure 5.18: Change from curved to straight needle paths.

Rotating rails could lead to possible jamming or rotation during needle insertion when alignment is critical, and they only minimize the problems instead of eliminating them. Straight needle paths eliminate the bending stresses and also allow for a simpler ejector pin design, which reduces complexity. With straight paths, the ejector pin bearing can follow the same path as the needle bearing instead of requiring a button assembly. The asynchronous movement from the curved paths is replaced with synchronous movement in straight paths. In addition, linkages replaced the slotted actuation bar in order to reduce losses by achieving rolling friction instead of sliding friction.

The new straight needle paths did present a challenging packaging problem. In order to reduce the length of the needle paths, the ejector pin bearing and needle bearing needed to be as close as possible. This forced the linkages to be placed on opposite sides of bearing as seen in Figure 5.19. Now the forces on the bearing are off axis by as much as half an inch. The off axis forces were concerning, but if St. Venant's principle was applied correctly there should be no jamming and minimal friction losses.

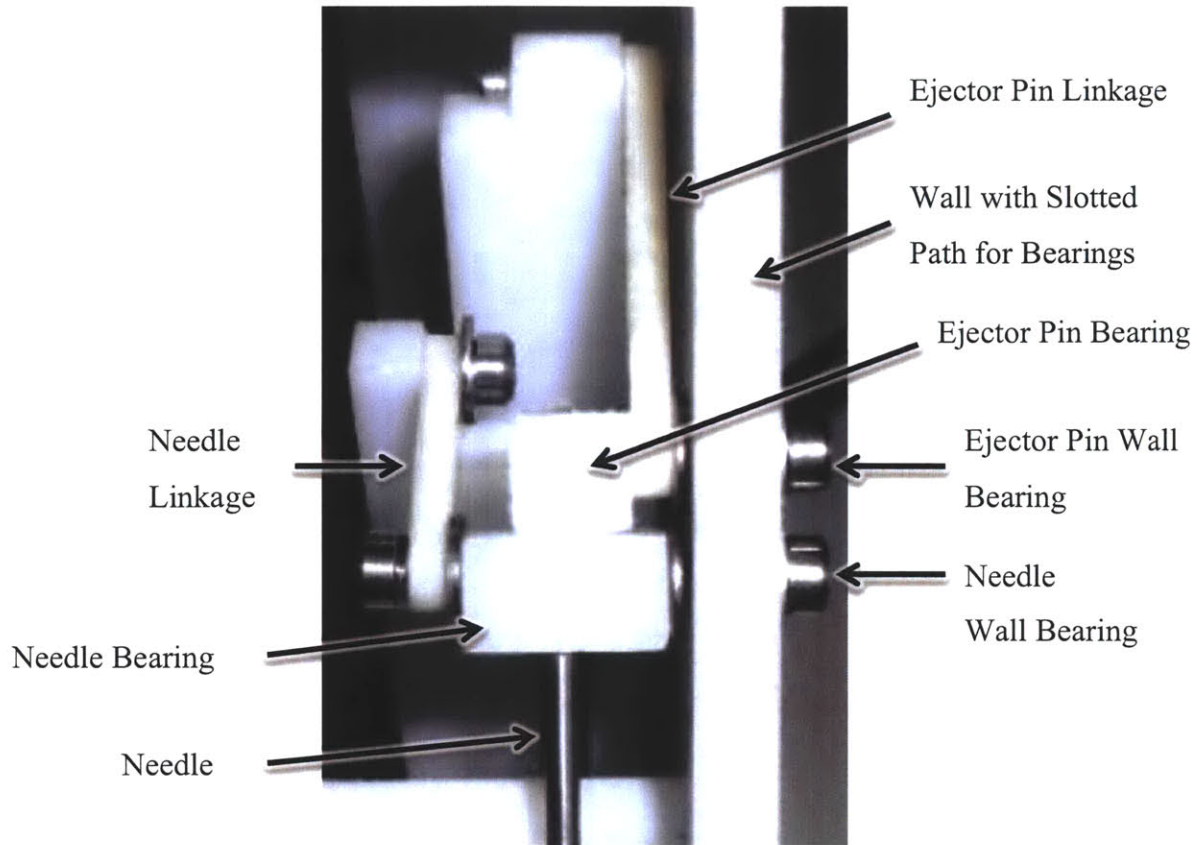


Figure 5.19: Packaging challenges create off axis forces on bearings.

St Venant's principal was applied so that the flange on the wall bearing was 3-5 times the height of the slot it was sliding in. when the bearings are receiving the max force during needle insertion, the needle forces will cancel out part of the moment arm coming from the linkage.

5.7 Results

The passive alignment rails were tested on pork belly with positive results. The rails adhered to both sides of the incision and rotated to the proper angle as a slider was pushed through them. The dermal layer of skin was exposed, and looked like it would be in the correct position for the needles on the device.

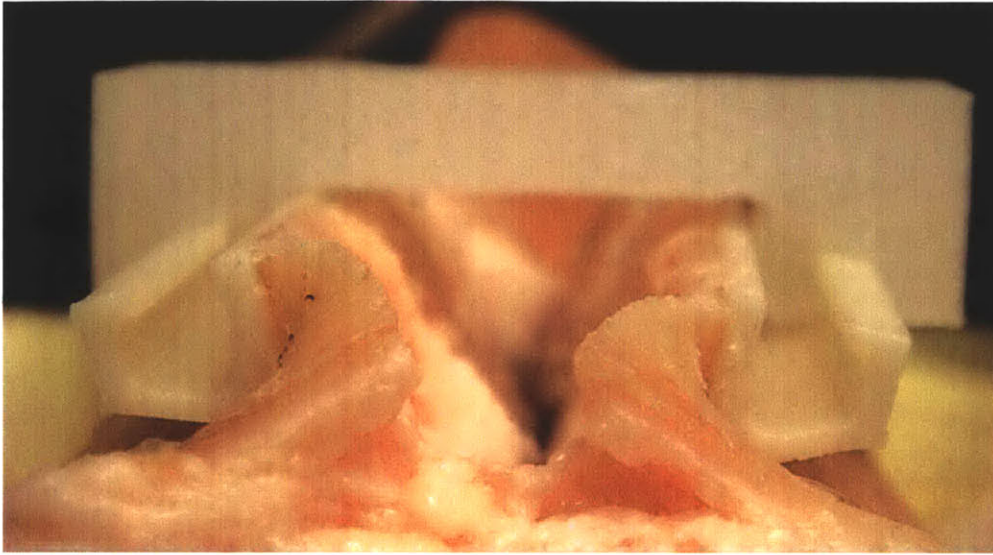


Figure 5.20: Picture of passive rail alignment testing in pork belly.

Unfortunately, the passive rails were not tested with the full device because there were two major jamming errors in Prototype 3. The jamming errors occurred because St. Venant's principle was not satisfied properly in two key locations.

The first location where jamming occurred was with the bushings on the two alignment rods. In the case of two parallel alignment rods, there are two characteristic lengths that must be satisfied by St. Venant's principle. The first one is the diameter of the alignment rod. The length of the bushing should be 3-5 times the diameter of the shaft to apply St. Venant's correctly. The second characteristic length that had been missed is the distance between the center axes of the parallel alignment rods. The bushing also needs to be 3-5 times the length of this distance. The two characteristic lengths can be seen in Figure 5.21 in comparison to the bushing length. The design followed St. Venant's correctly for the diameter of the shaft, but was too short for the other case. To fix the problem, the bushing length could either be extended to meet the requirement of the second characteristic length or the device could use a single alignment rod with a shorter bushing to satisfy St. Venant's principle. Since the actuator bar does not require the precision of 2 alignment rods, it was decided to use one alignment rod for the design.

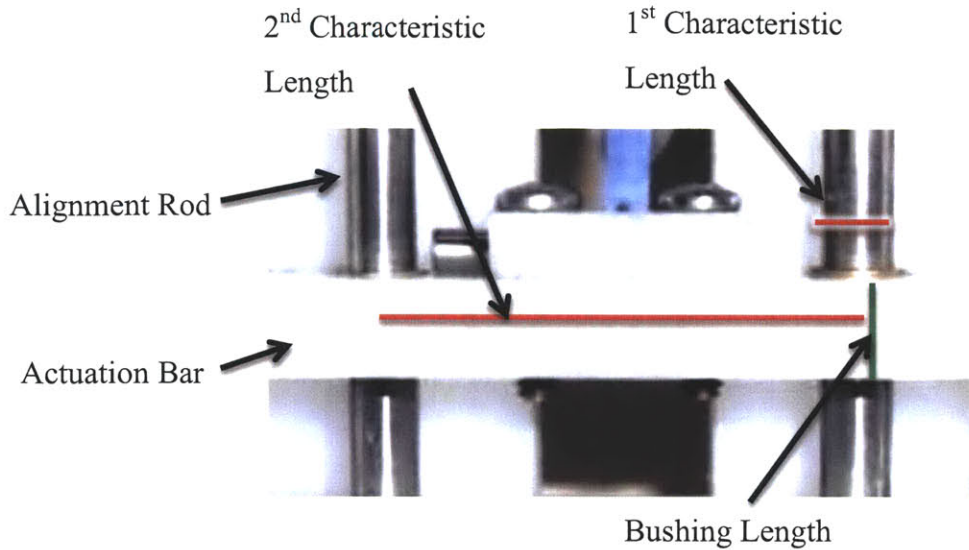


Figure 5.21: Alignment rod jamming condition.

Jamming also occurred between the wall bearings and the needle path slots. In this case, St. Venant's principle was applied to the wrong characteristic length. Originally the flange of the wall bearing (C) was designed to be 3 times the height of the slot (B) it was sliding in. However, the appropriate application of St. Venant's principle would be to design the wall flange (C) to be 3 times the depth of the slot (A), which in this case is the thickness of the wall. See Figure 5.22 for a representation of the geometry involved.

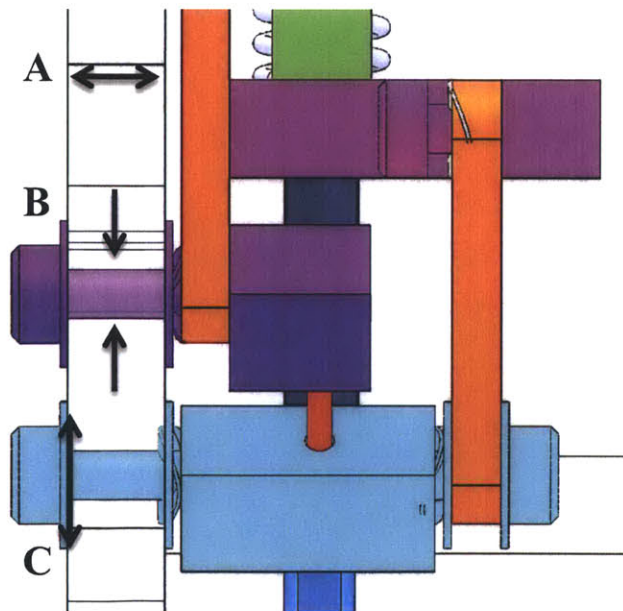


Figure 5.22: Jamming condition between wall bearings and needle path slots.

A Free body diagram was developed for the forces involved in this geometry in order to verify St. Venant's principle and ensure it would be applied correctly in the future. See Appendix A for pictures of the free body diagram of the wall bearings sliding in the needle path slots.

From the free body diagram, I solved for the forces involved and calculated the efficiency in an excel spreadsheet. I varied the inputs to see how it would change with different geometry and forces. The results showed that efficiency dropped off significantly when the wall bearing flange was less than 2 times wall thickness, thus proving St. Venant's principle. The height of the slot compared to the length of the flange had little effect. However, the analysis also revealed that frictional losses were larger than originally expected and that they became significantly reduced when the forces on the needle bearing were closer to inline for the wall bearing. This makes intuitive sense. Originally the design focused on preventing jamming, but the analysis showed that there can be inefficient power transmission even if jamming does not occur.

The findings made it necessary to re-examine the forces in the device and identify the areas of inefficiency for redesign. The first place that was looked at was the rotating linkage. Due to the changing angle of the linkage throughout the actuation of the device, most of the forces were not inline. In order to change this, the linkage would need to be much longer so that less change in angle would occur, but this would be unacceptable given the space constraints set for the device. This pointed to a slotted bar design where the angle could be optimized to have the most inline forces. A free body diagram was created in figure 5.23 for the case of a single angle pushing down on a needle or ejector pin bearing throughout the entire motion.

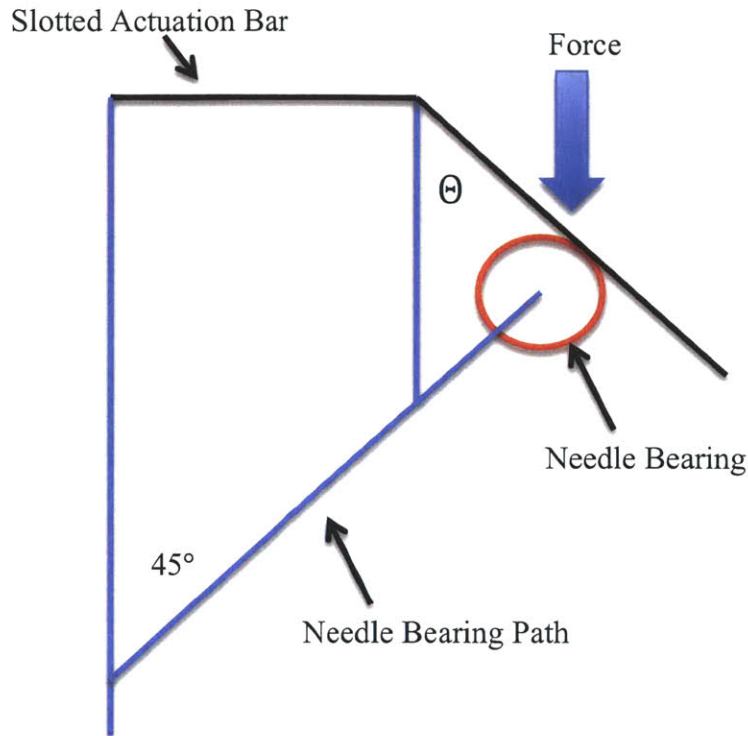


Figure 5.23: Free body diagram of forces angled actuation bar forces.

Next, a graph was created comparing the inline force for every angle theta between 0 and 90 degrees.

Magnitude of Inline Force With Respect to Change in Angle of Actuation Bar

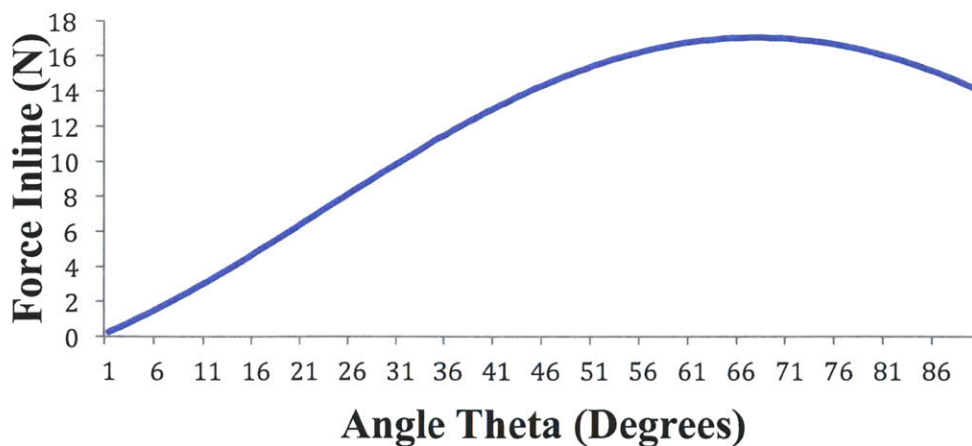


Figure 5.24: Graph of inline forces versus change in actuation bar or linkage angle. Special thanks to Faye W. for her help with the analysis of inline forces.

The results of Figure 5.24 show that a linkage arm that varied between 45 and 90 degrees would have inline forces that varied between 13.5N and 17N, whereas a slotted actuation bar could have a set angle at about 68 degrees and generate inline forces that are always 17N. This was compelling evidence to switch to a angled actuation bar. However, the initial reason for using the linkage was to achieve rolling friction and reduce frictional losses. In order to make an informed decision about the trade offs of rolling and sliding friction to justify the cost of a small ball bearing, another graph was generated that modeled the frictional losses at different actuator bar angles. This comparison can be seen in Figure 5.25, which shows that rolling friction will be approximately an order of magnitude smaller than sliding friction with a total difference of 5N at the optimal actuation bar angle.

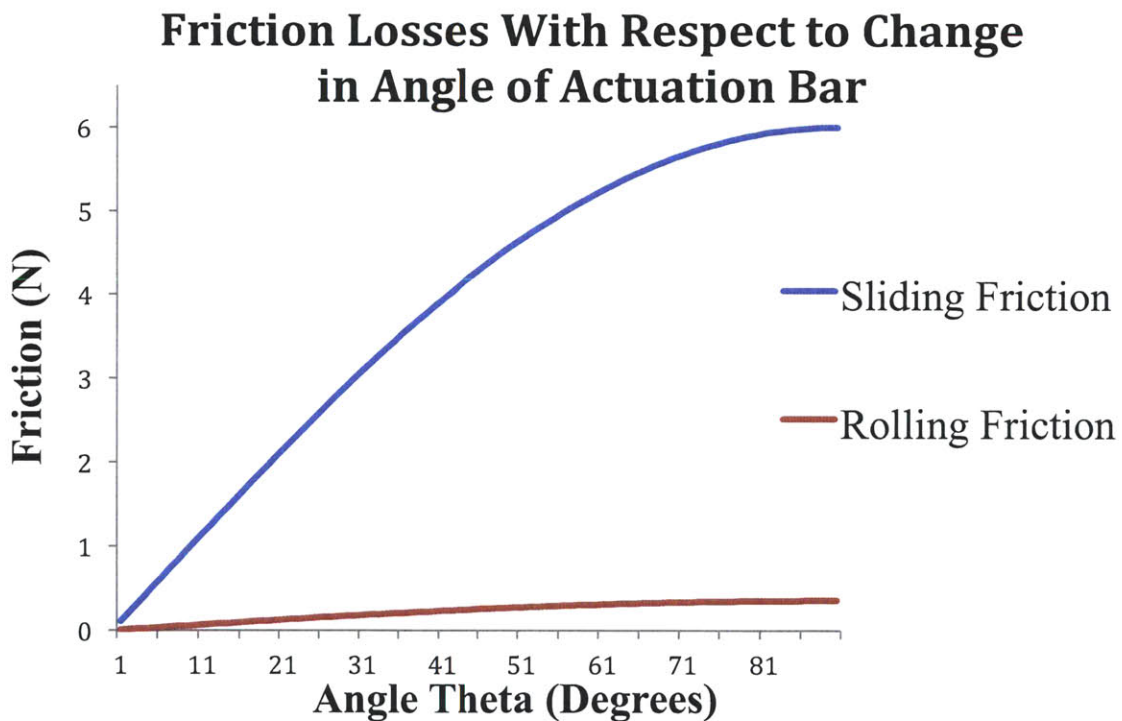


Figure 5.25: Friction Losses with respect to change in angle of actuation bar. Special thanks to Faye W. for her help with the analysis of friction losses.

Saving 5N through rolling friction could have a noticeable affect on the feel of the device and ease of use. It was decided that it would be worth the extra \$2 cost for small ball bearings to achieve rolling friction because the user experience will be key to the success of the product.

Plus, the material cost of the device does not have a significant impact compared to the cost savings that could be realized by cutting down the wound closure time.

5.8 Discussion

The Jamming problems in Prototype 3 prevented the device from working and required a re-design. The specific problems relating to the principal of St. Venant could be solved relatively easily, but the analysis of the forces showed that the design is inefficient and would be susceptible to tolerance errors. In addition, from a manufacturing standpoint the device had too many parts and a redesign of the case for injection molding was required. In the process of reducing the number of parts and designing for mass production, the packaging of the needles and ejector pin could be improved to increase efficiency by moving the forces to be inline with the required movement using a slotted bar similar to the one in Prototype 2. The new prototype needs to be rapidly developed within a 3-week time period to meet the final presentation deadline for the project.

PROTOTYPE 4

6.1 Development Goals

The goal for Prototype 4 was to address the problems of jamming and inefficiency from Prototype 3, while at the same time improving the packaging, lowering the part count, and designing for mass production and assembly. The manual actuating handle and passive skin alignment rails both worked well in initial testing and the goal will be to streamline the designs in Prototype 4.

6.2 Prototype 4 Final Design

The final design of Prototype 4 combined the needle and ejector pin into a single easily removable module, reduced the part count, and streamlined the design of the alignment rails and the handle for manual actuation. The custom parts were also designed for injection molding processes. Special thanks to the RSC team for helping to build Prototype 4 in time to meet the project deadline.

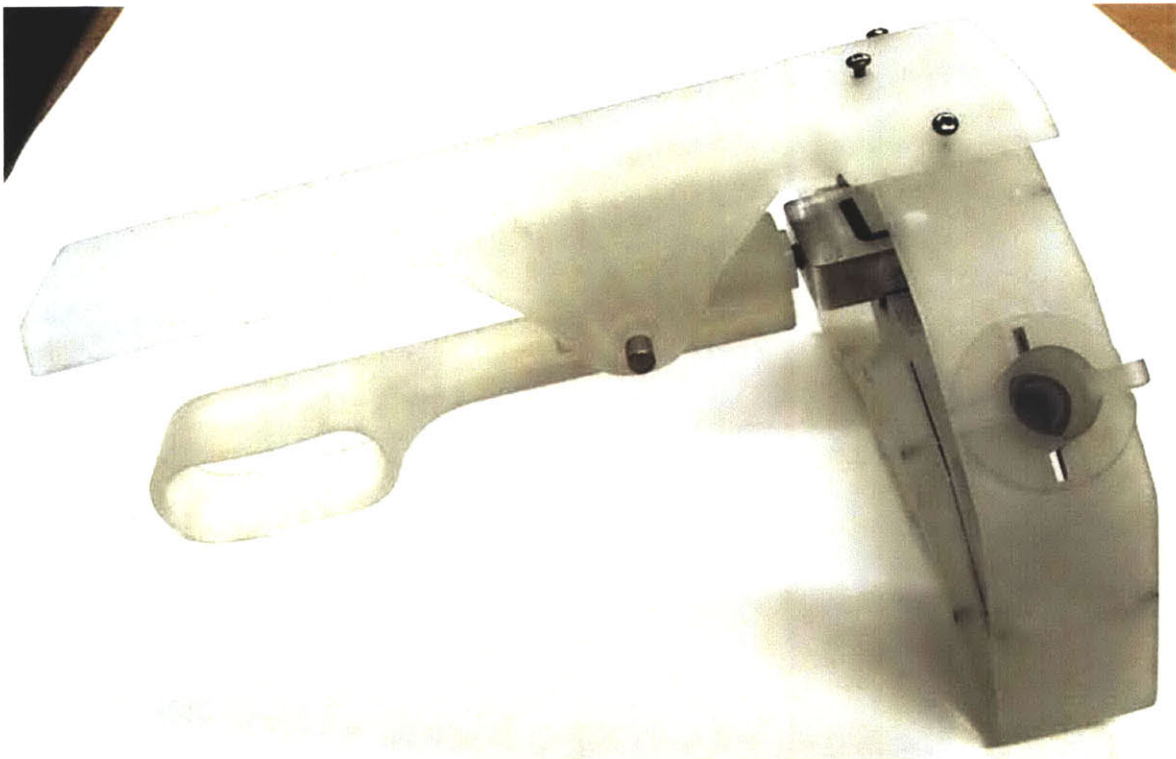
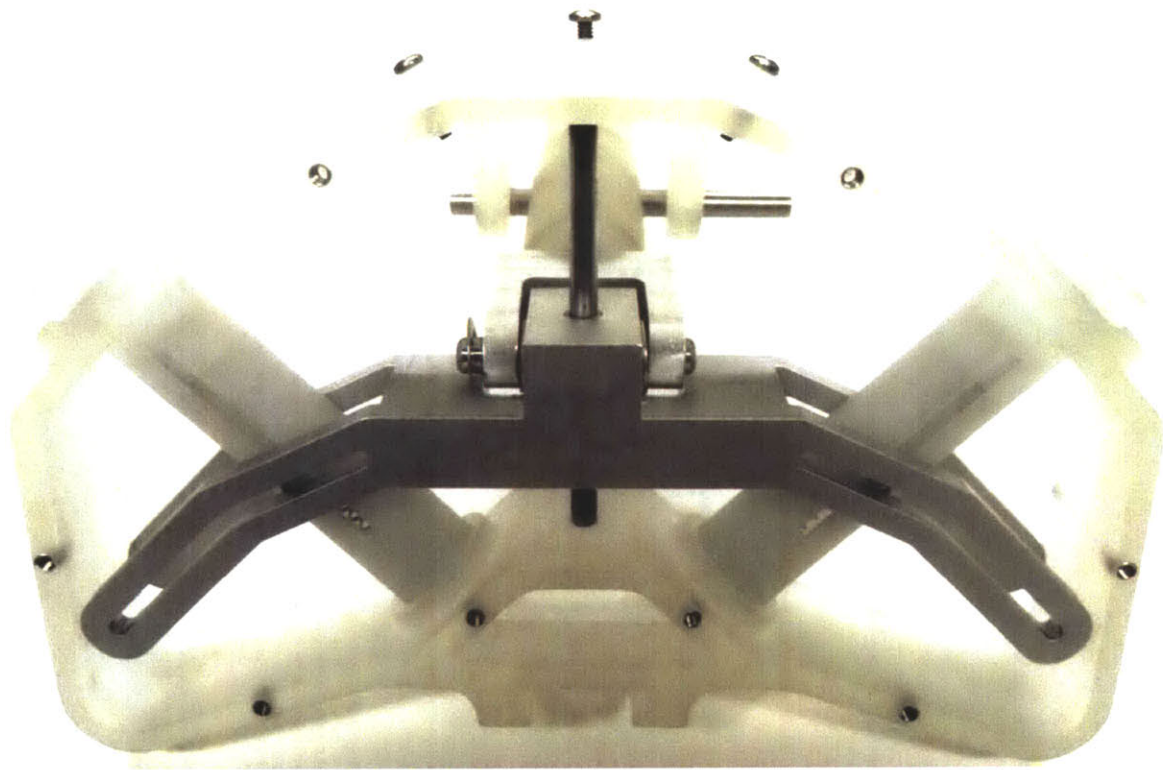


Figure 6.1: Pictures of completed Prototype 4.

6.2.1 Actuation Steps

The description of the actuation motion for Prototype 4 is followed by corresponding figures representing each step.

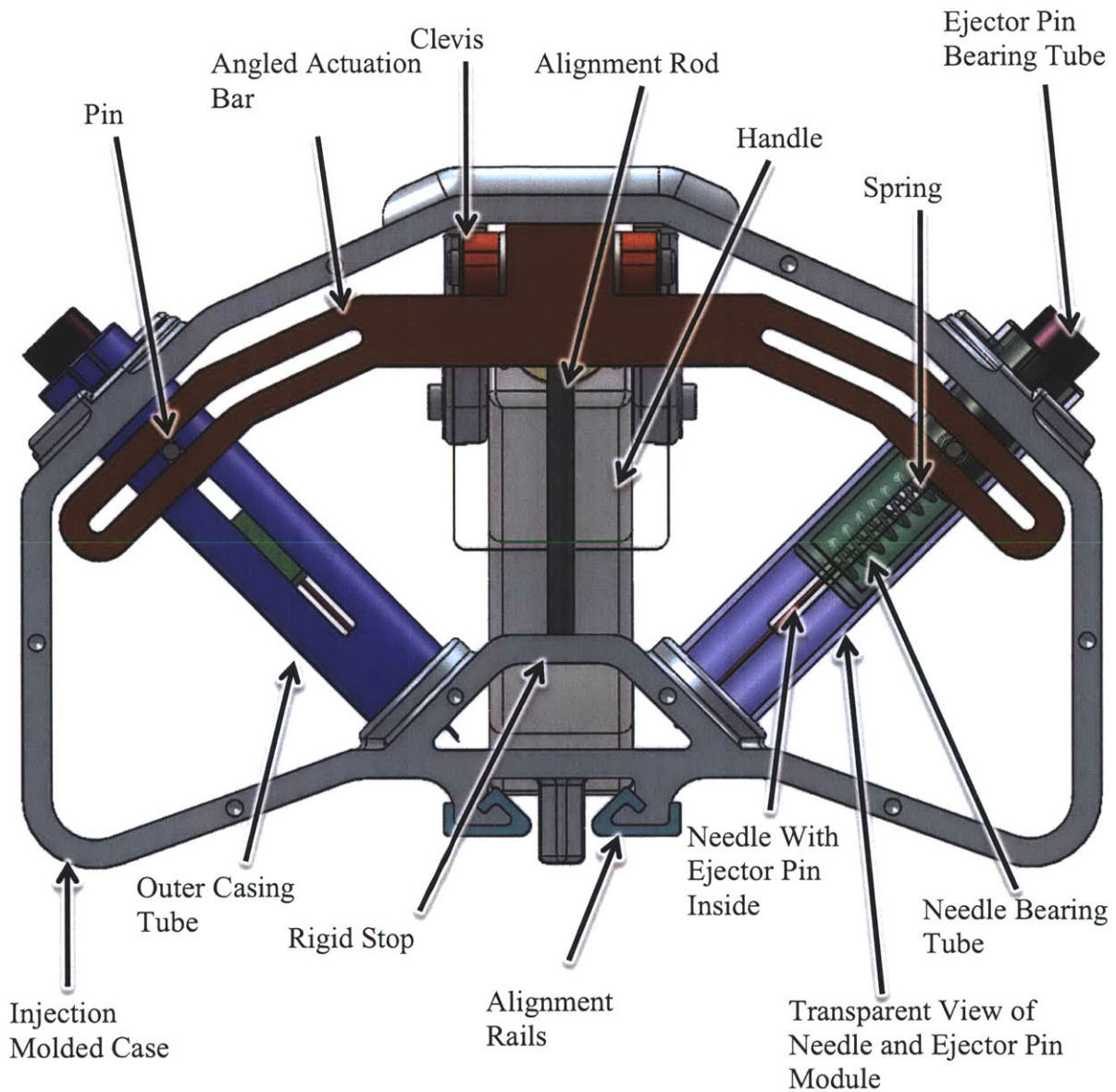
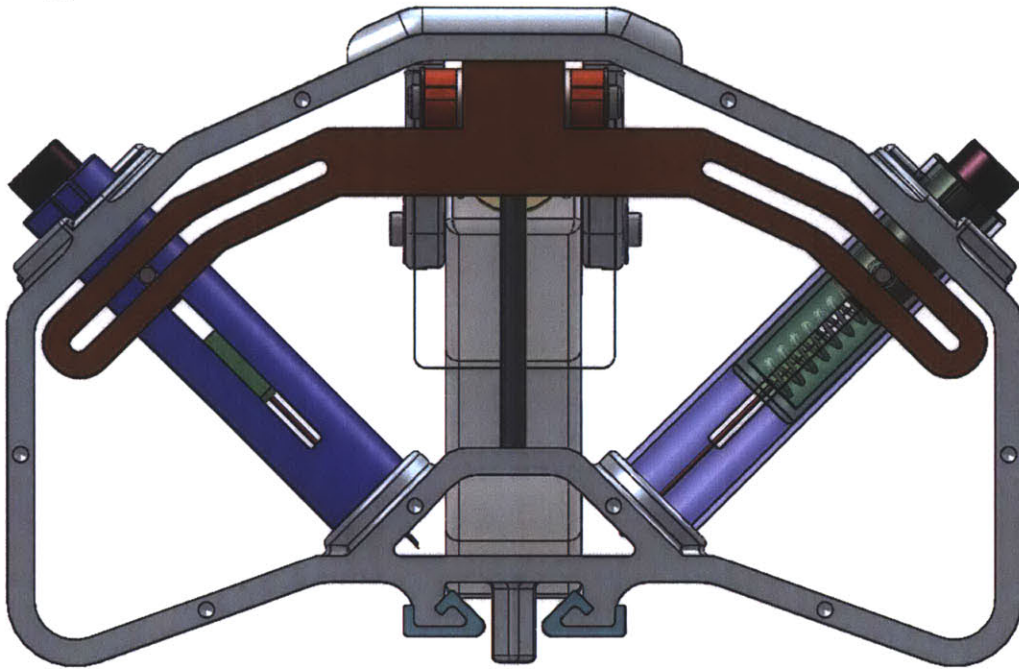


Figure 6.2: Annotated solid model of Prototype 4.

Actuation steps:

1. Starting position of device. Device has passed along the rail geometry, which has rotated the wound edge into the correct position for needle insertion.
2. The user squeezes the handle and the angled actuation bar begins to travel downward along the alignment rod. A pin is constrained between the angled bar and tube slots, and it rotates within a ball bearing constrained to the ejector pin bearing tube. The spring between the ejector pin bearing tube and the needle bearing tube compresses slightly as the needles load the clips and begin to insert through the dermal layer of skin. The ejector pin bearing tube is sliding inside the needle bearing tube, which is sliding inside the outer casing tube connected to the device.
3. Needles meet and stop moving when the needle bearing tube hits the bottom of the outer case tube.
4. The actuation bar continues to move the ejector pin bearing tube downward by forcing the spring between the ejector pin bearing tube and needle bearing tube to compress. The ejector pin attached to the ejector pin bearing tube pushes the male end of a clip through the female end.
5. Step 4 is reversed as the handle is pushed apart, which causes the actuation bar to travel upward and causes the spring between the ejector pin bearing tube and the needle bearing tube to relax.
6. The pin constrained to the tube slots, ejector pin bearing tube, and actuation bar hits the top of the needle bearing tube slot which causes the needle bearing tube and the ejector pin bearing tube to travel upward together to the starting position in step 1.

1.



2.

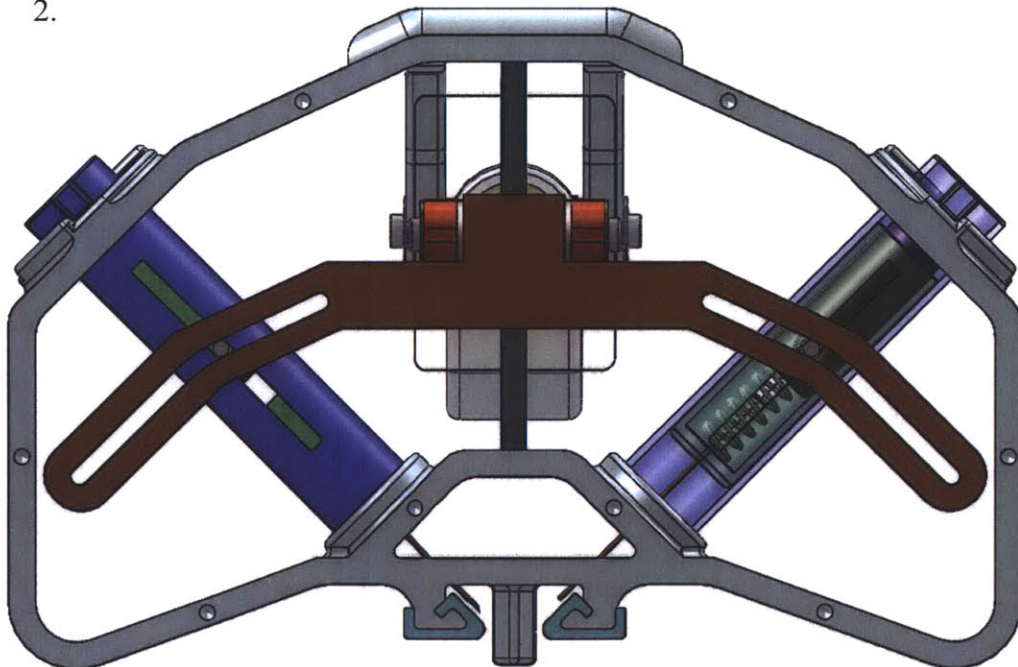
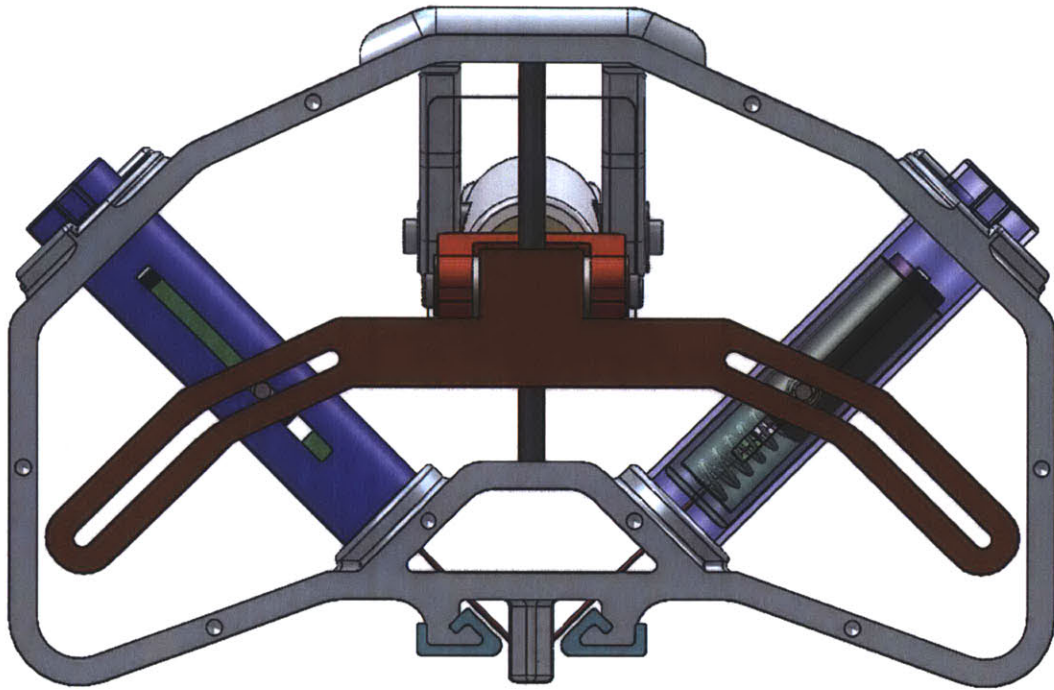


Figure 6.3: Prototype 4 actuation steps 1-2.

3.



4.

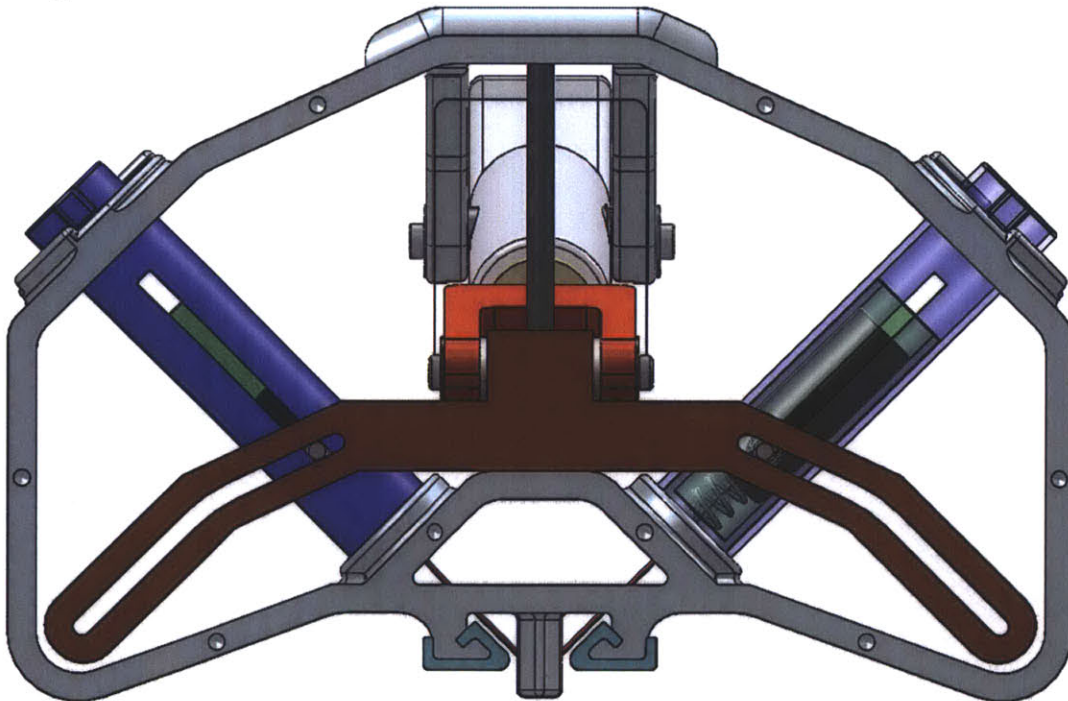
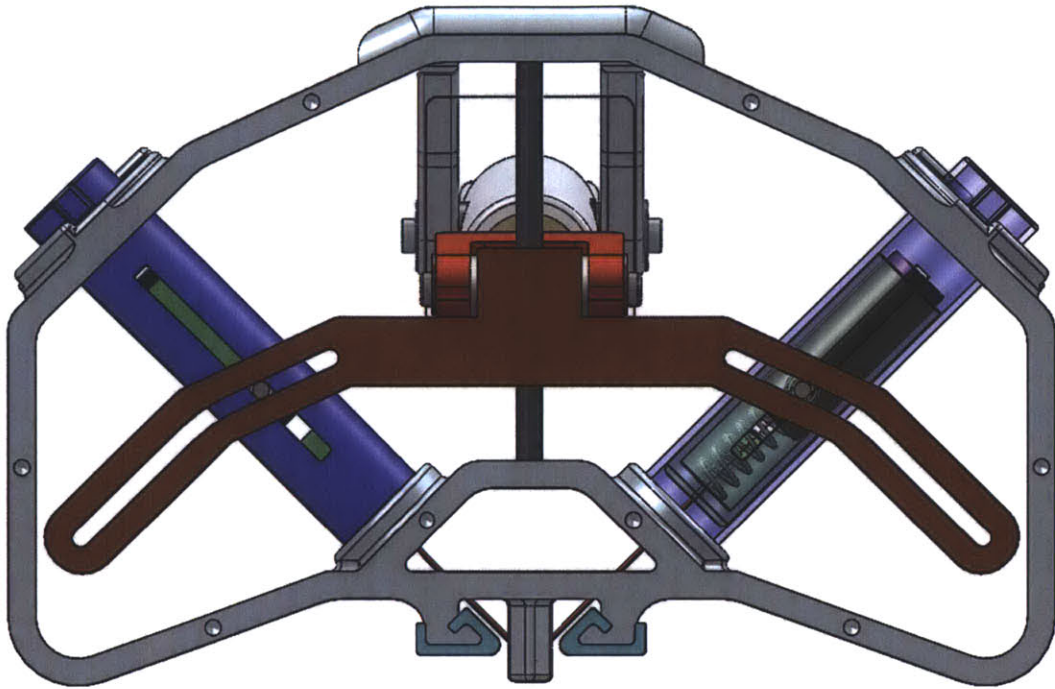


Figure 6.4: Prototype 4 actuation steps 3-4.

5.



6.

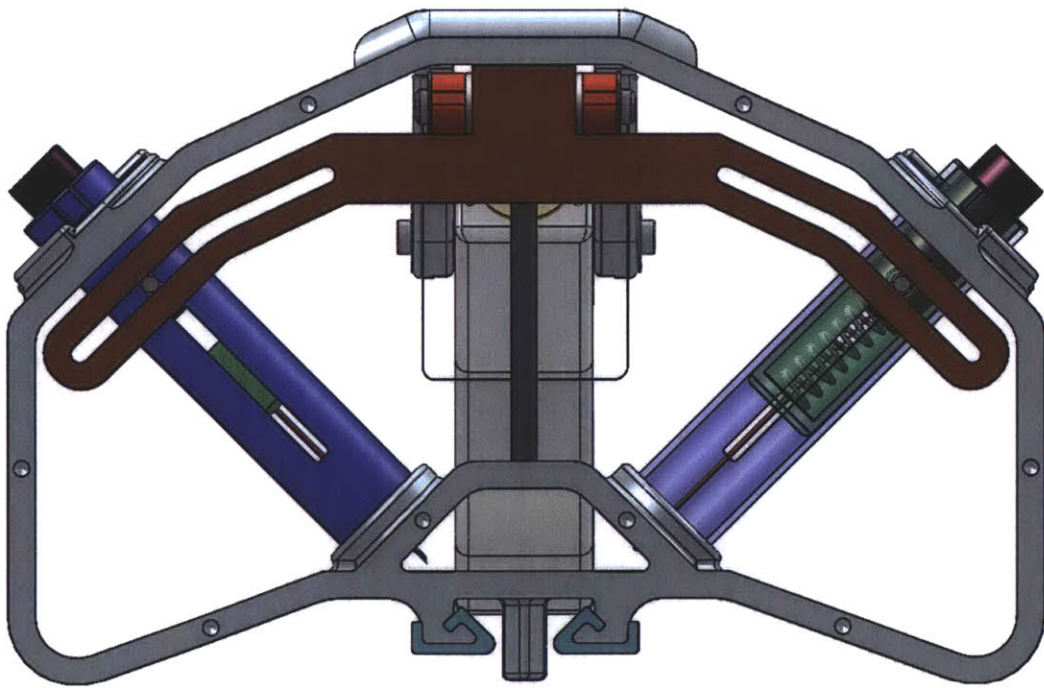


Figure 6.5: Prototype 4 actuation steps 5-6.

6.3 Reduction In Part Count

Relating back to the actuation mechanism requirements and goals in section 2.2, reducing the part count and improving the packaging will cut down the cost, complexity, assembly time, and space. There were several ideas to accomplish this that were evaluated in Table 6.1.

Table 6.1: Part Reduction Concepts		
Method	<u>Strength</u>	<u>Weakness</u>
3D print casing and snap on front/back covers	<ul style="list-style-type: none"> • Eliminates hardware • Simple assembly • Lowers cost 	<ul style="list-style-type: none"> • Snap feature wears out
Eliminate return bolts with extra compression spring	<ul style="list-style-type: none"> • Allows for spring return of device 	<ul style="list-style-type: none"> • Not strong enough if jamming occurs • Not strong enough to return full length • Increases force user inputs for actuation
Move bolt and spring to needle bearing assembly	<ul style="list-style-type: none"> • Compact packaging • Eliminates actuation bar • Allows for removable module 	<ul style="list-style-type: none"> • None

6.3.1 Design Selection

The two design improvements selected were the 3D printed snaps and re-locating the bolt and spring to the needle bearing assembly. Both designs had clear strengths inline with the goals for the actuating mechanisms as well as few or no weaknesses. The snaps were implemented for assembling the alignment rod and Lego™ features on the needle bearing assembly. The extra

compression spring concept was not ideal because the negatives far out weighed the benefits to the user interface.

6.4 Jamming Reduction In Combined Actuation Motion

In order to improve the main actuation of the device, St Venant's principal needed to be applied properly to avoid jamming and the forces needed to be inline with the direction of motion to improve efficiency. The results from Prototype 4 showed that an actuation bar with an optimized unchanging angle would be more efficient than a linkage that changes angle throughout the motion. Therefore, the improved designs all used an angled actuation bar. If St. Venant's is applied to the current wall bearing slot design from Prototype 3, the bearings will need to be at least 3.8cm apart with the current wall thickness. Reducing the wall thickness would allow a closer bearing placement, but the structure of the device would be unstable. The new bearing placement would cause the device to expand in size, which is unacceptable since size reduction is the goal. This conclusion points out the need for new design solutions that can reduce the size of the device while following St. Venant's principal and keeping the forces in line with the direction of motion. Table 6.2 evaluates several new designs that try to satisfy those needs.

Table 6.2: Efficient Needle And Ejector Pin Path Concepts

Concepts	<u>Strength</u>	<u>Weakness</u>
2 wall supports for bearings	<ul style="list-style-type: none"> • Keeps forces inline 	<ul style="list-style-type: none"> • Requires extra space to meet St. Venant requirements
2 alignment rods instead of slots	<ul style="list-style-type: none"> • Simple constraints to follow St. Venant's principle 	<ul style="list-style-type: none"> • Alignment of rods difficult • Tradeoff between packaging and part count • Forces slightly out of line
Ejector pin sliding in needle bearing like a sled	<ul style="list-style-type: none"> • Smaller packaging • Forces inline 	<ul style="list-style-type: none"> • Difficult to prototype
Nested Tubes	<ul style="list-style-type: none"> • Small packaging • Forces inline • Easy to prototype • Simple alignment 	<ul style="list-style-type: none"> • Sliding friction between tubes

6.4.1 Nested Tube Design Selected

From Table 6.2, it is clear that the nested tube concept meets all the requirements, has fewer negatives, and is less risky to proceed forward with than the other concepts which are either difficult to build or only solve some of the problems from the previous prototype. The following sections will show and explain the design of the nested tubes in more detail.

6.4.1.1 Nested Tube Concept

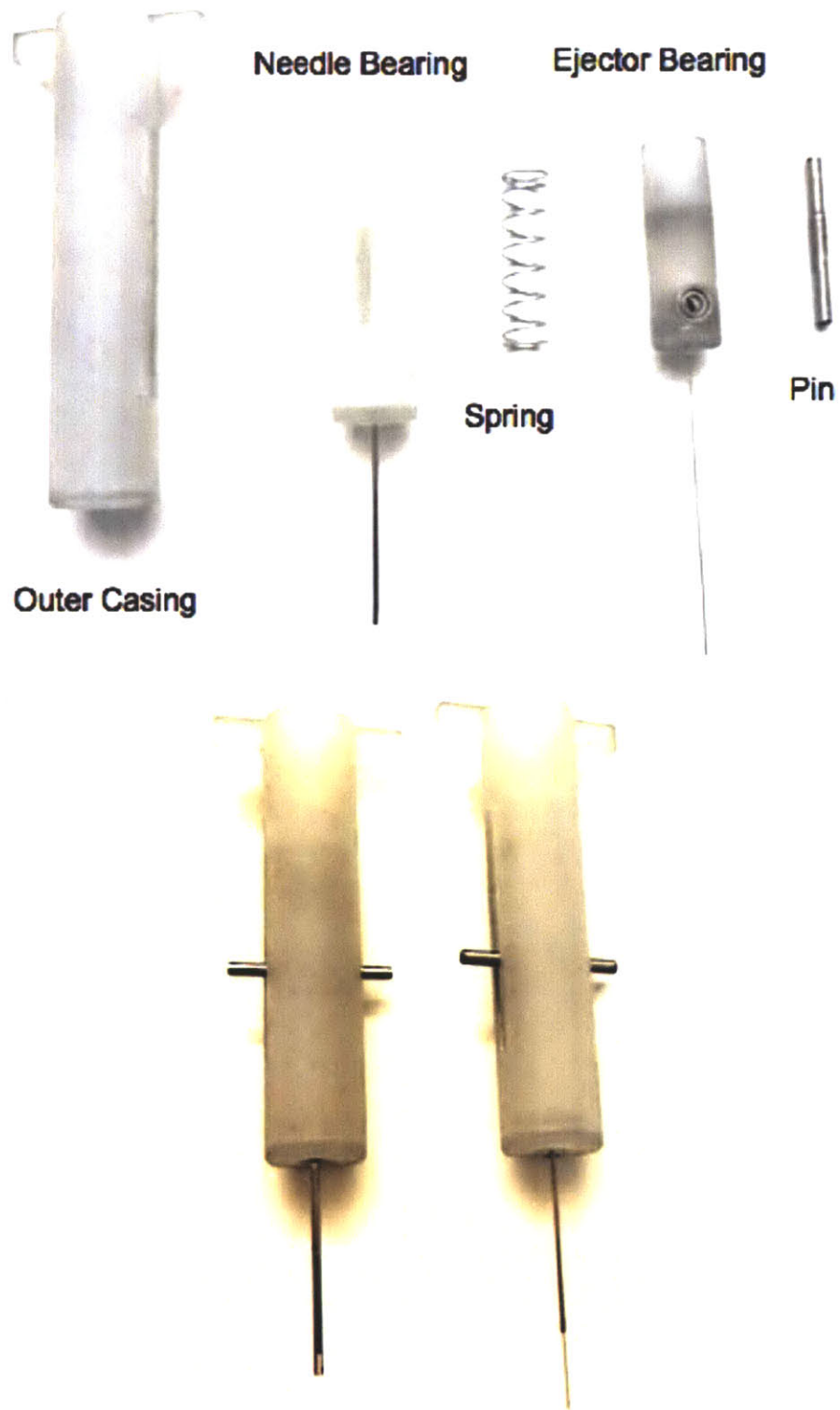


Figure 6.6: Picture of 3D printed nested tube components and assembly.

6.4.1.2 Actuation Steps

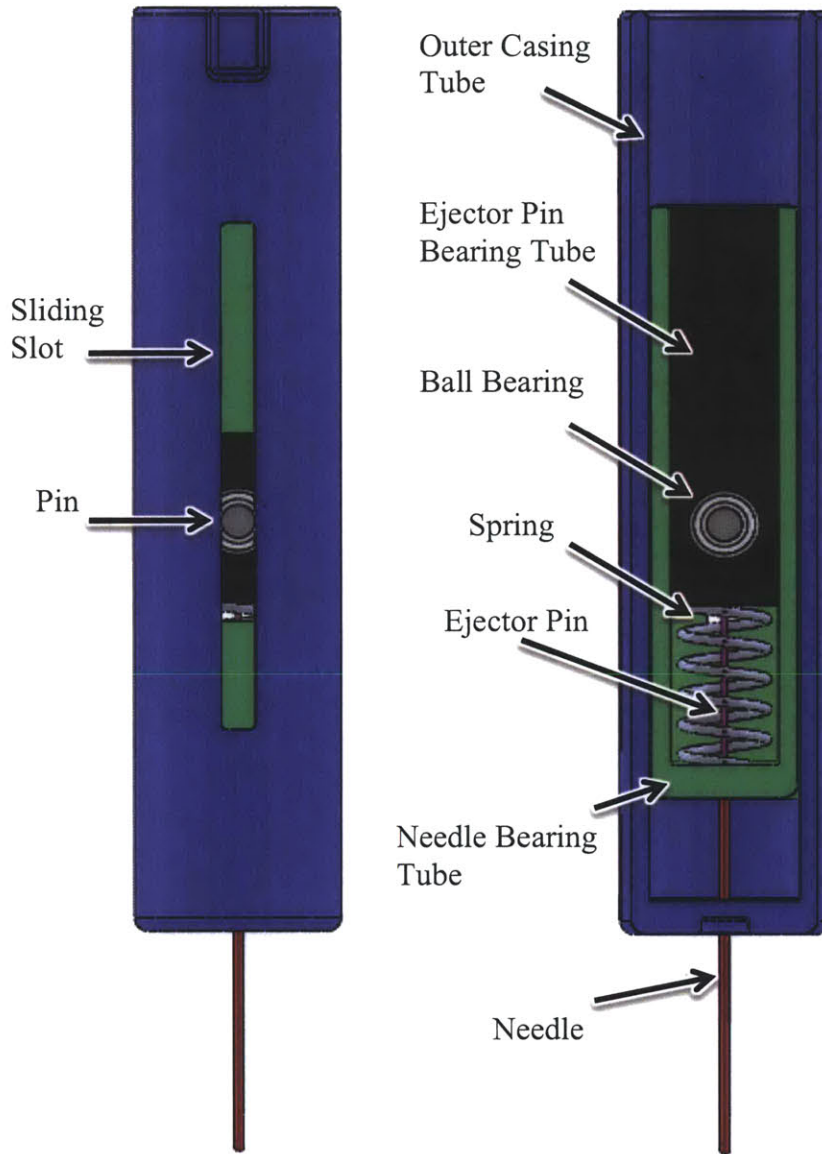


Figure 6.7: Annotated solid model section view of nested tube concept.

Actuation steps:

1. The pin can rotate in the bearing connected to the ejector pin bearing tube, slide in the tube slots, and is actuated by the main angled actuation bar. When the pin is first actuated downward, the spring is compressed slightly because the needles meet a resistance force from the dermal skin insertion.

2. After the skin insertion, the needle bearing tube slides all the way to the bottom of the outer casing tube as the pin slides down the slot with the ejector pin bearing tube.
3. Next, the pin is pushed down farther which compresses the spring more and allows the ejector pin to slide through the needle to connect the clip ends.
4. Then the pin is pushed upward and the ejector pin retracts as the spring relaxes.
5. The pin continues upward until it hits the top of the needle bearing tube slot. After that, the needle bearing and ejector pin bearing tubes move together back to the starting position.

6.4.1.3 Benefits

The initial idea for the nested tube concept came from the button idea where a tube slides inside another tube. Nested tubes have the benefits of being perfectly constrained, structurally sound, and easy to slide with the right materials. Other benefits of the nested tube design included simpler mass production techniques and prototyping. The nesting of the tubes allowed the principal of St. Venant to be followed while minimizing the space, reducing hardware, and simplifying the assembly process. In addition, the nested tubes created a needle and ejector pin module that can be disposed of and easily replaced. This simplifies the sterilization of the device and ease of use, since the needles will need to be changed for every procedure. The slotted tubes allow for the actuator to interact with the pin on both sides and keep the forces inline to improve efficiency. The ball bearings ensure that rolling friction will take place and further reduce the power losses in the device. Overall, this design solves the majority of problems from the previous prototype in a simplistic way that is inline with goals for the actuating mechanism.

6.4.1.4 Assembly Considerations

The nested tubes created a modular design for a disposable unit that has the potential to greatly enhance the assembly process. Small Lego™ like features were designed for the module to connect with the device in a simple, repeatable, removable motion. In addition, small handles were placed on the outer casing tube to turn it into the correct position, and slots were made in the device case to allow the pin to enter in the correct orientation. The assembly steps are described next followed by pictures of the process.

Assembly steps:

1. The module is inserted through a hole in the device casing and the pin slides through a particular slot.
2. The module is pushed further into the device and the needle tip is directed into a shaft.
3. The module begins to turn into position.
4. As the module turns into position, the pin turns into the angled actuator bar slots on the inside of the device.
5. The module turns into its final orientation and hits a stop. Then it is pushed into connecting snap features on the device case. Removal of the module happens in the reverse order of steps 1-5.

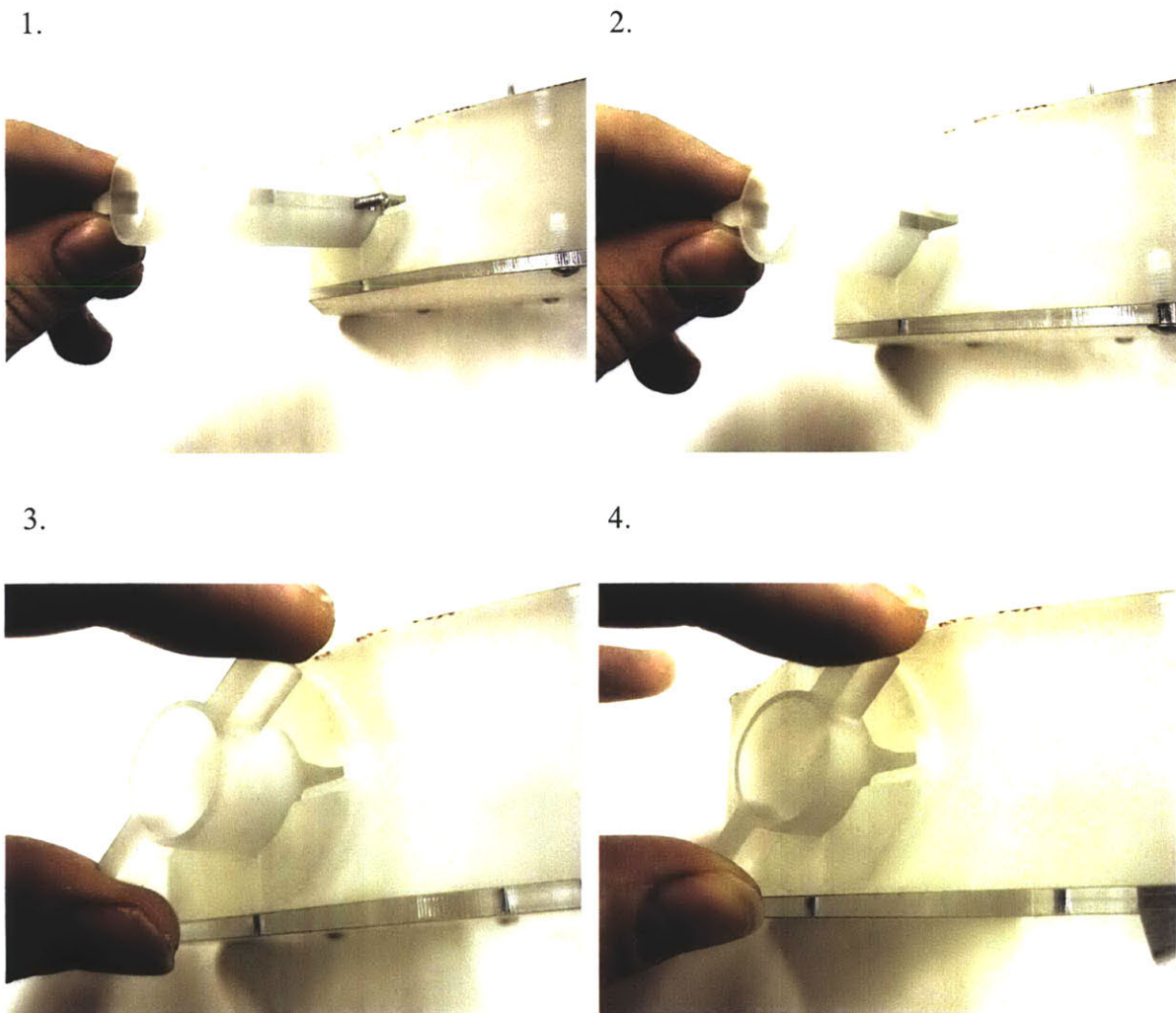


Figure 6.8: Pictures of nested tube assembly to Prototype 4 steps 1-4.

5.

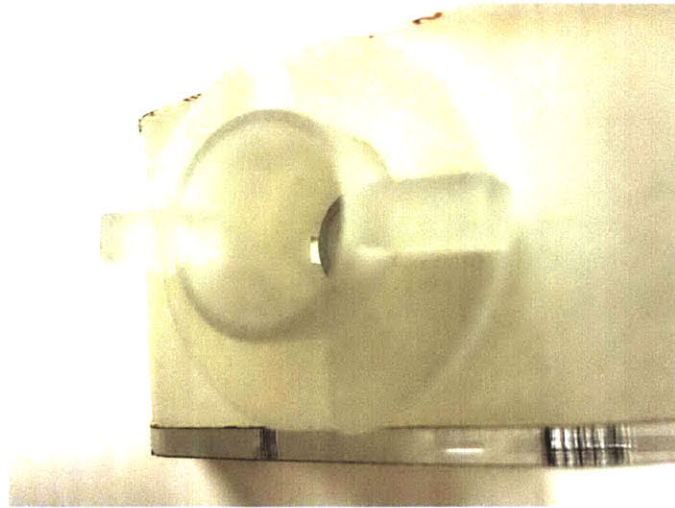


Figure 6.9: Picture of nested tube assembly to Prototype 4 step 5.

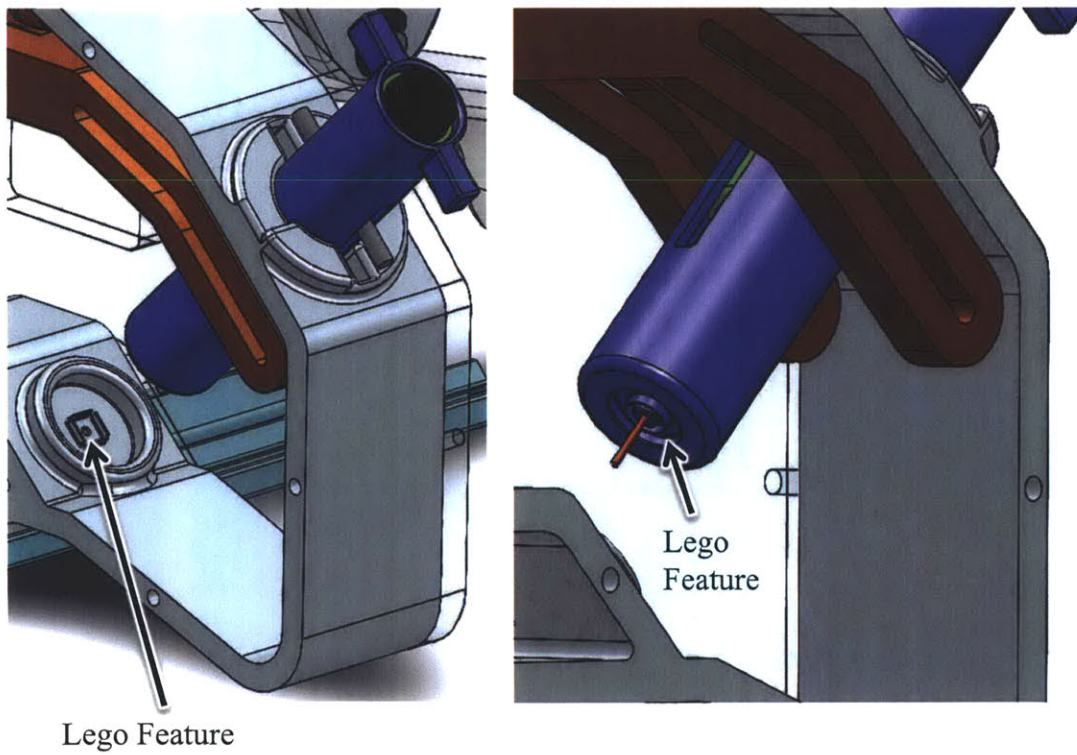


Figure 6.10: Solid model of Lego™ features on case and needle module for easy assembly. Special thanks to Carmen G. For designing and modeling the Lego™ features.

6.4.1.5 Actuation Bar Design

The design of the angled actuator bar was based off the initial design from Prototype 2 and the analysis of the optimal angle from the results section of Prototype 3. The angle was modified from the optimal angle to accommodate the assembly of the removable needle module. A 45-degree angle was required for the end section of the bar to avoid interference with the pin as it spins into place. The final design is represented in Figure 6.11.

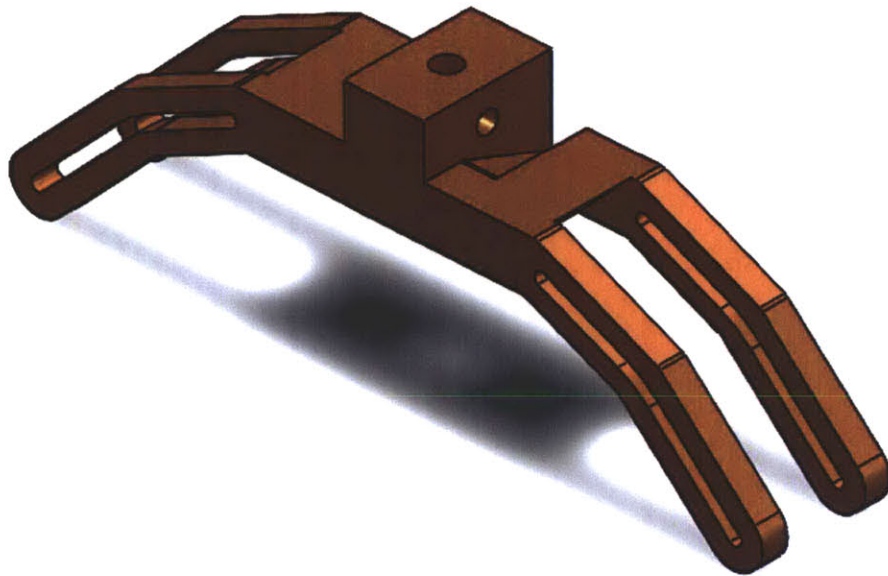


Figure 6.11: Solid model of angled actuation bar. Special thanks to Omar C. For helping with the FEA and beam bending analysis of the actuating bar.

One challenge with the design of the actuation bar was the material selection. The geometry was difficult to model with beam bending analysis so an FEA analysis was performed. The results showed that if the actuation bar were made of plastic, the arms would deform too much for this application. Aluminum was selected as an alternative because it is cheap, easy to machine, and lightweight. The FEA results for aluminum showed it was well within the acceptable stress and displacement range for this application with a max von mises stress of about 13 MPa and a max strain of 0.014%.

6.5 Manufacturing Considerations

One of the main design challenges of Prototype 4 was designing the custom components for mass production. Specifically, the main case of the device needed to be designed as one injection molded part. The following figure shows the results of the final design of the case as one injection molded piece.

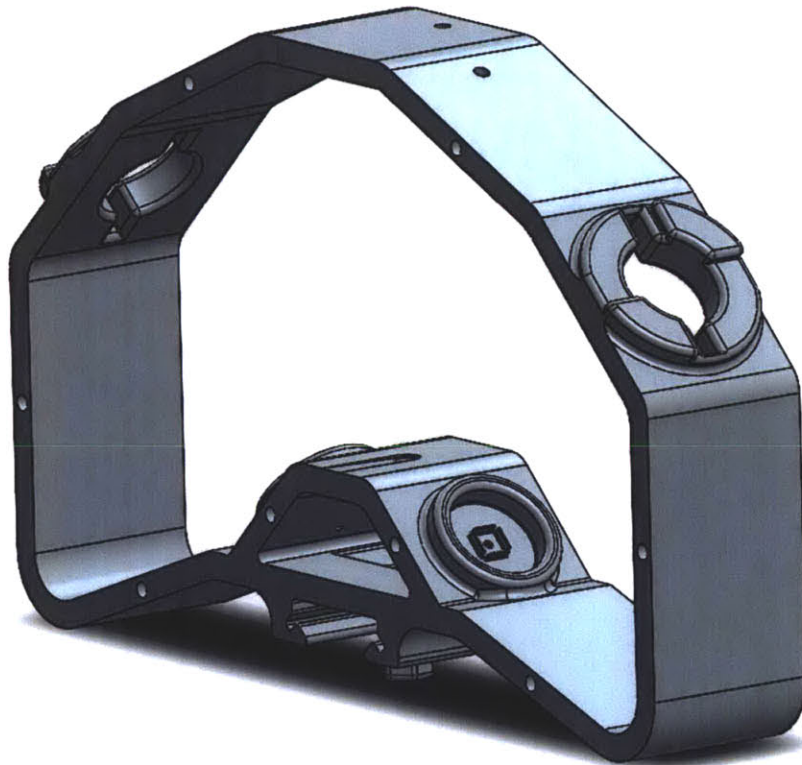


Figure 6.12: Solid model of injection molded case design for Prototype 4.

Overall, the design of Prototype 4 focused on reducing the number of custom parts, which cut down on the cost and complexity of the device. A basic cost analysis was conducted to determine the approximate cost of the device if produced in quantities of 5,000. The tooling, material, and production costs were estimated for each component and divided by the number of components to get the cost per component. An example of the cost estimate for the main device case can be seen in Table 6.3.

Table 6.3: Device Case Pricing	
Material	\$7,501 (\$1.50 per part)
Production	\$4,408 (\$0.88 per part)
Tooling	\$18,950 (\$3.79 per part)
Total	\$30,859 (\$6.172 per part)

The other components were estimated in a similar fashion, and the overall estimates can be seen in Table 6.4.

Table 6.4: Cost to Produce Body Components	
<u>Part</u>	<u>Price (\$/part)</u>
Case	6.17
Handle	3.17
Outer Needle Case	1.60
Inner Needle Case	1.53
Actuation Bar	1.769

The total cost of the body would be around \$15, the disposable needles \$10, the absorbable clips \$10, and the whole device total would be approximately \$35. The device could be sold for \$40 because the main revenue stream would be the on going sale of the disposable needles and clips for every procedure. This makes the device cheaper than the INSORB™, which costs \$45. The cost over other devices like the surgical stapler and sutures would be recouped by hospitals in the amount of time and money saved in the operation. Since operating time is approximately \$66 per minute, the device would pay for itself in less than 30 seconds of saved time [4]. Special thanks to the RSC team for helping with the cost estimates of different components.

6.6 Results

The results of the assembly actuation mechanism for the needles and ejector pin were mostly positive. Assembly was quick and simple using the snap geometry for the alignment rod and the rotating insertion feature of the needle module. The required force for manual actuation of the needles and ejector pin was reasonable and comfortable for multiple actuations in a row. No jamming occurred in the device. The needle tips were able to align and connect a clip. Clips were put together multiple times, but were difficult to load. More testing will be necessary in the future with an automatic loading mechanism to enable enough tests to be conducted to determine repeatability of the needle alignment. The only problem with the actuation mechanism for the needles and ejector pin was that the Lego™ features did not 3d print properly because the resolution of the printer was not good enough.

During tests in human skin, see figure 13, the passive rail alignment encountered two main problems that will need to be addressed in future iterations.

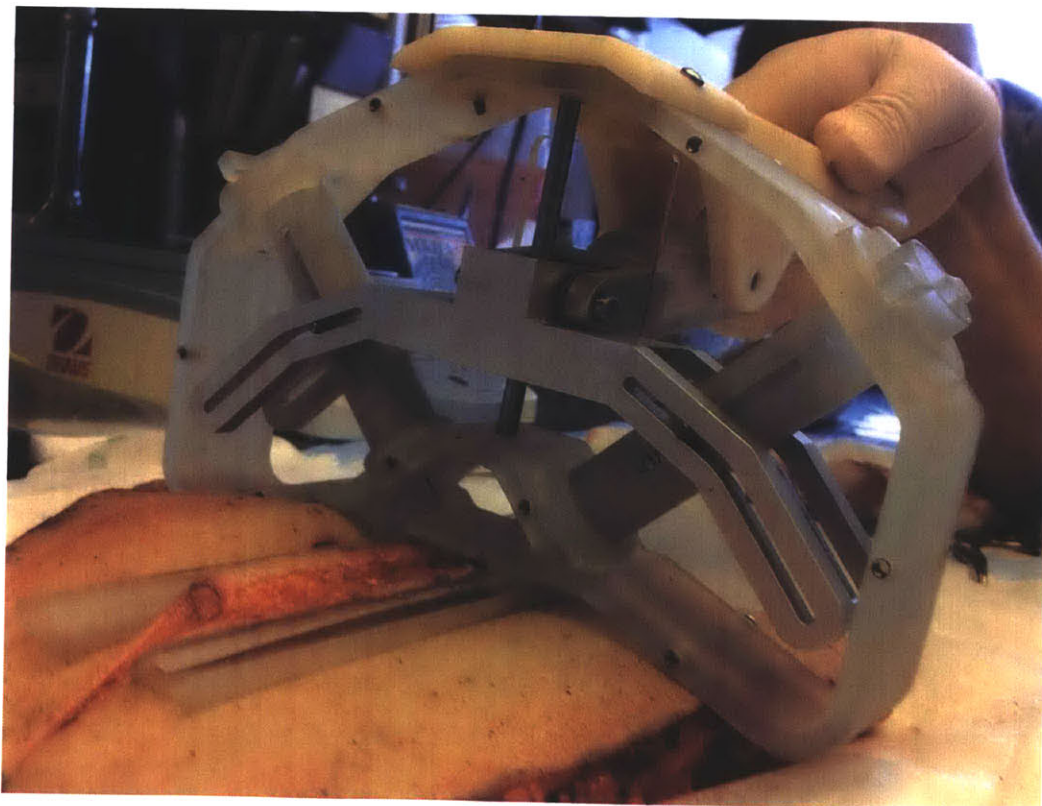


Figure 6.13: Picture of Prototype 4 testing in human skin.

The rails had a difficult time adhering to the skin surface with enough force to rotate the skin without it peeling off. Using Dermabond™ as the adhesive solved this problem for testing purposes, but it would never be an acceptable long-term solution according to the clinicians we worked with because it would be difficult to remove the rails after the procedure. The second problem for the alignment rails was the elasticity of human skin. The rails were able to expose the dermal layer, but instead of presenting a perpendicular face for the needles to pierce, the dermal layer drooped down at an angle and caused the needles to push it aside instead of piercing it. This problem prevented the prototype from successfully deploying a clip in human skin.

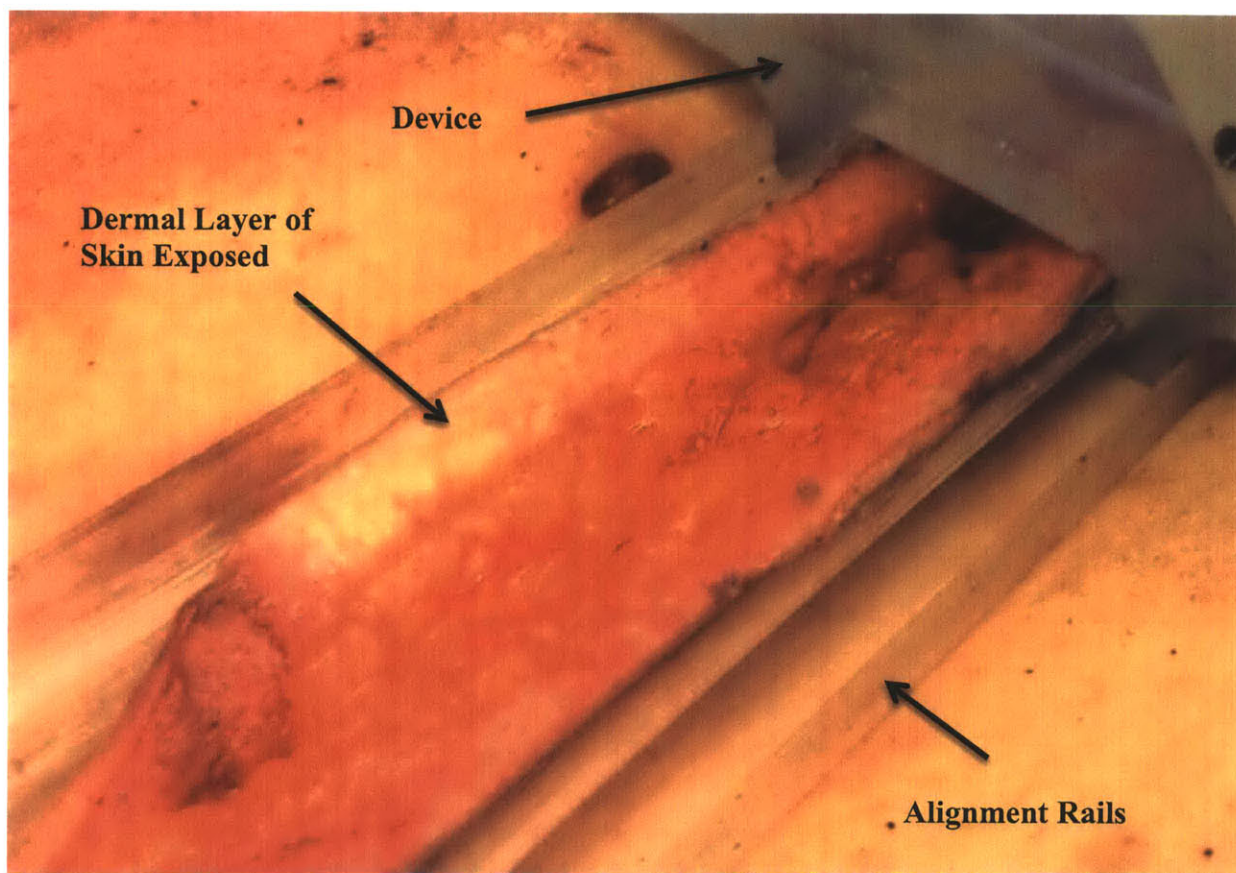


Figure 6.14: Close up picture of Prototype 4 rail alignment testing in human skin. The rails adhere to the skin and rotate as the device slides along, but the dermal layer droops down and is not in the correct position.

6.7 Discussion

Selecting a better material and using a precise injection molding process could fix the problems with the 3D printed Lego™ features on the needle module. However, alternate designs for latching and securing should be evaluated in order to cut down costs associated with manufacturing Lego™ features that require greater precision.

To address the problems that the alignment mechanism encountered, a better method for grabbing the skin and holding the dermal layer in place needs to be developed. A combination of rails and forceps might be an innovative approach. The rails could provide the passive actuation geometry and the forceps would provide the attachment to the skin in a similar way to manual wound closure methods. In addition, the size of the device needs to be reduced to make it easier to use. The current actuation method using straight needle paths will be difficult to make smaller because the lengths are already close to optimal. Several new design options to reduce space, like curved needles, could be explored in the future when more time is available for development.

CONCLUSION

7.1 Summary of Actuator Mechanism Development

Several innovative actuation mechanisms were designed and developed to accomplish the required motions of a novel wound closure device. The mechanisms related to the alignment of skin, insertion of needles, and connecting of clip ends with an ejector pin. For each of these three areas, multiple concepts were brainstormed, evaluated, and compared. The prototyped designs represented the combination of concepts that were most likely to succeed in delivering the basic functional requirements of the device. In addition, the designs focused on reducing the size, complexity, and cost of the actuating mechanisms to make the device more desirable and cost effective to use in the operating room. After each Prototype was created and tested, the results revealed which concepts worked well and which ones needed to be improved. Each prototype improved upon the previous one using an iterative design process. The final prototype represented the culmination of ideas from the previous three. The actuation mechanisms for Prototype 4 combined the motions of the ejector pin with the needles and utilized rail geometry for passive alignment. It was also designed for mass production processes, minimal friction losses, ease of assembly, and a low part count. The results of testing Prototype 4 in human skin revealed the need for further development of the skin alignment mechanism to find a better way to attach the rails onto the skin surface and deal with lack of control over the dermal layer of skin drooping. Future development should also focus on reducing the size of the device, the bio-absorbable clip design, and loading mechanism.

7.2 Future Development Strategy

The future development of the RSC device will focus primarily on addressing the skin alignment issues, reducing the size, and minimizing the complexity. The clip design and loading mechanism are of secondary importance because they could be outsourced to another company if the device can demonstrate a reliable clip delivery system in production ready packaging.

However, the current prototype does leave space for a future loading mechanism that uses a magazine of clips. The most promising design direction for fixing the skin alignment issues is to replicate the forceps method of manual wound closure more closely. The rail geometry could have multiple spring-loaded forceps along its length that could clamp down in a simple motion to attach the rail to the skin and avoid the problems with adhesives. Adhesives have questionable holding strength, are cumbersome to apply, and difficult to remove. The other significant advantage of the forceps strategy is that it holds the dermal layer from both sides and keeps it rigidly in place for needle insertion to avoid the drooping effect. The next challenge future designs need to address is the overall size of the device. There are several strategies for reducing the size that involve changing the actuation method of the nested tubes or switching to a curved path or needle design. If the nested tubes were actuated by pneumatics or a cheap linear actuator instead of an angled bar, then the forces would remain inline and the space under the tubes could be eliminated. This would create a “V” shape for the device, which would make it easier to use and reduce the space closest to the wound area. The second strategy for reducing space would be to use curved needles or curved tubes that allow for tighter packaging. These space saving strategies offer the best direction for reducing the size of the device because they can accomplish the required space reduction, and the challenges they create are solvable. Finally, an innovative design strategy that could significantly reduce the complexity of the device focuses on eliminating the need for an ejector pin. The ejector pin is needed in current designs to connect the ends of an adjustable clip, but if the ends of the clip could be connected through the needle motion it would eliminate the need for an ejector pin. In order to accomplish this, the male end of the clip could be made out of metal and function as the tip of the needle that pierces the dermal layer of skin. After the dermal insertion, the male clip end could pierce through the female clip end and be prevented from retracting through geometrical interference. The needles would then retract and leave the clip in place. The reason the male end does not need to be absorbable is

because it will be cut off after the clip is adjusted to the appropriate size. This design strategy could be one of the keys to the success of the device because it would significantly reduce the complexity, which could also reduce the space requirements, reliability, and cost.

7.3 Final Recommendation

The goal of the RSC project was to create an automated device that rapidly closes wounds with aesthetic results comparable to plastic surgery. One of the main keys to its successful implementation is the design of the actuation mechanisms. The results of this thesis have shown the potential of the actuation mechanisms and the work left to be accomplished. Significant progress has been made toward solving the challenges associated with this device, and a clear development strategy to tackle the remaining hurdles has been set forth. Therefore, it is recommended that the RSC project should continue forward and build off the work presented in this thesis to create the next generation of wound closure technology.

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A.1 Free Body Diagram of Forces on Needle Bearings

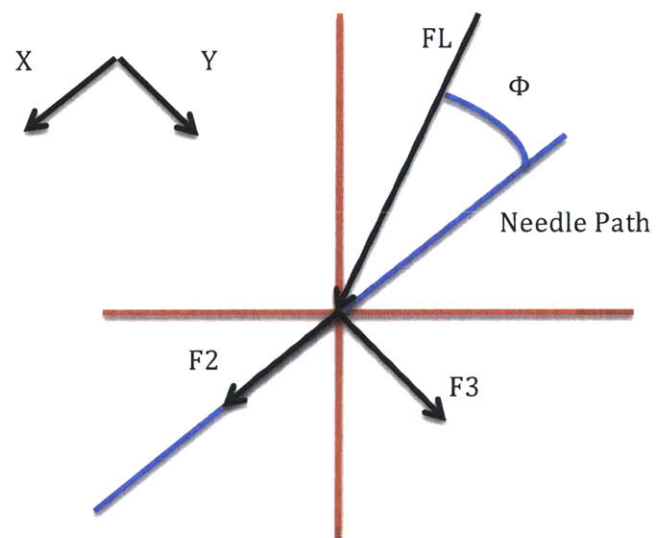


Figure A.1: Input and reaction forces for actuation linkage.

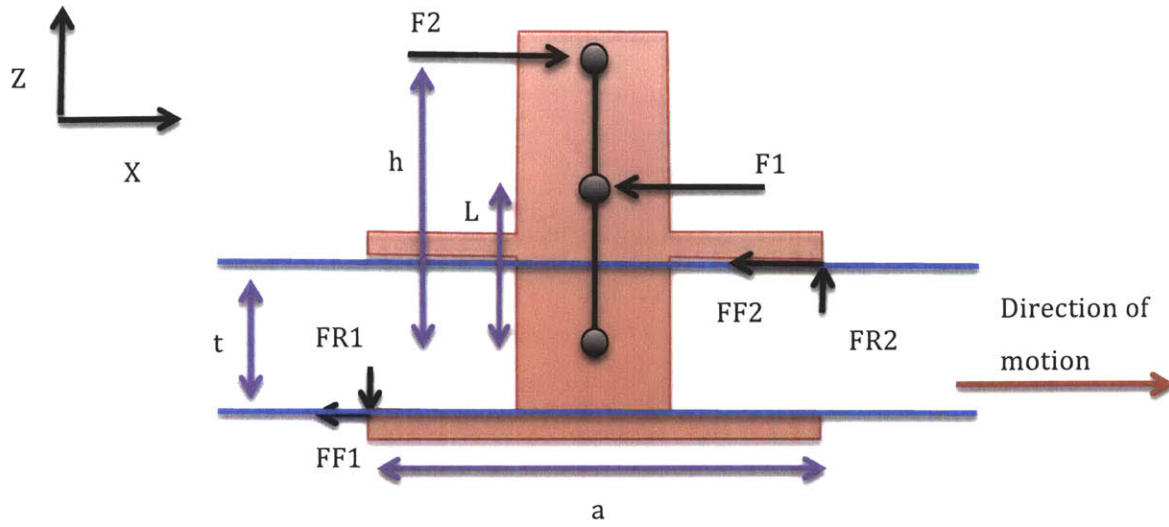


Figure A.2: XZ plane of needle bearing FBD

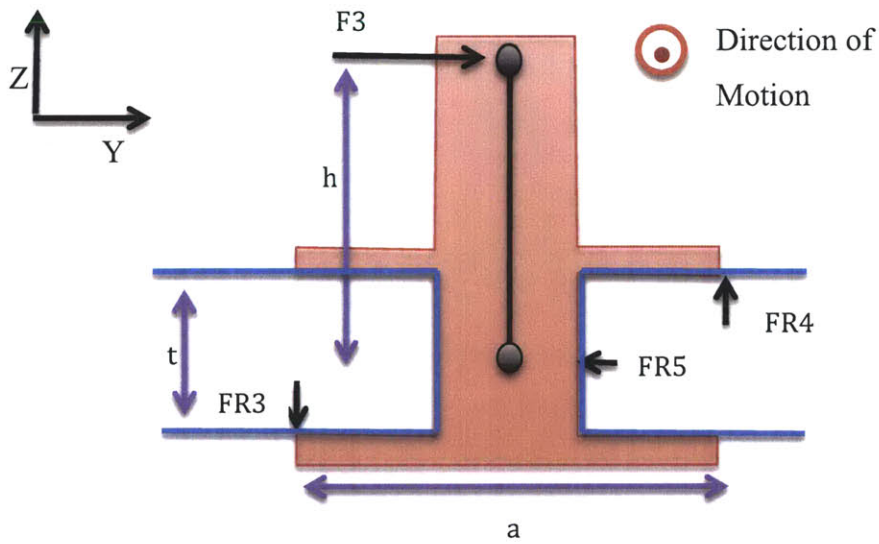


Figure A.3: YZ plane of needle bearing FBD

* To request access to spreadsheets, cad models, and FEA analysis associated with the RSC project or if you have any questions please email aerickson@alum.mit.edu