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Fixation System for Post-Trochanteric Osteotomy

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Capstone Senior Design Project

Fixation System for Post-Trochanteric Osteotomy

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Table of Contents

Section 1: Acknowledgements

Section 1.1 Acknowledgements:

The group would like to extend a very special thanks to DePuy Orthopaedics for making this project possible. Without their support and technical experience this project would not have been possible. We are especially grateful to Dan Lashure of DePuy for taking the time to answer our questions and provide us with guidance when needed. We would also like to extend a special thanks to the DePuy prototype facility for their excellent work on creating our prototype.

We would also like to thank Dr. Nashwan Younis who took the time to meet with us and provide his support and direction throughout the entire process. Along with Dr. Younis we would also like to thank the faculty of IPFW Department of Engineering for providing insight and constructive criticism throughout the design process.

Section 2: Abstract

Section 2.1 Abstract:

The purpose of this document is to outline the testing process for the prototype model manufactured to the specification and design laid out in senior design I. Included in this report are the initial problem statement from senior design I, a detailed description of the design, the building process, the testing and analysis performed, evaluation and recommendations. The ultimate goal of this project is to develop an instrument that surgeons can use to cable an opened femur back together following a trochanteric osteotomy. The instrument should be an improvement to the current instrument that is offered by DePuy. It must also meet all the guidelines set by DePuy.

Section 3: Problem Statement

Section 3.1 Problem Statement:

We have included the problem statement in this report as a reminder of the initial criteria set by DePuy and a bench mark to which our design was evaluated. DePuy Orthopaedics has requested the design of a Cable Tensioning Instrument. The instrument may be used as a cerclage fixation device in general orthopedic repair. These include procedures such as: Reinforcement of bone; reattachment of the greater trochanter; fixation of long bone fractures with grafting; fixation of patellar fractures; and closure of the sternum following open heart surgery. To achieve this, the instrument must improve upon the current tensioning instrument that is offered.

The new tensioning instrument must be able to achieve the required cable tension while remaining easy for the surgeon to use. It must also meet all of the other requirements and specifications laid out by DePuy.

Section 3.2 Requirements:

The cable tensioning instrument must have a smaller footprint than the current instrument has which is 7 cm. The instrument must also be able to fit into a given instrumentation case with dimensions of 60 cm x 24 cm x 10 cm. The instrument must be able to place the cable in varying tensions from 0 to 150 lbs. It should also weigh less than the existing instrument of 710 grams.

Section 3.3 Design Parameters:

The final design must meet certain parameters that have been outlined by DePuy. The instrument must be able to be operated by one person. It must provide the operator with some sort of tension meter to read the amount of tension in the cable easily by the operator. It is not required by DePuy, but the instrument should have some kind feature that temporarily holds the cable in tension so that adjustments can be made before the cable is permanently fixed in place. The instrument must also meet the sterilization requirements that are outlined by the microbiology lab at DePuy.

Section 3.4 Design Variables:

Almost all aspects of the current design can be modified to create a new design. The new design must incorporate a method in which the cable can be inserted into the instrument and the tensioning device rather easily, in order to make the tensioning process as easy as possible for the surgeon operating the instrument. It should not be difficult or cumbersome for the surgeon operating the instrument to achieve the desired tension in the cable using the new design. The tension display should also present the amount of tension on the cable in a manner in which it is easily read and interpreted by the operating surgeon.

Section 3.5 Limitations and Constraints:

The design must not exceed the budget limit of $5,000. The instrument design must be safe for the surgeon operating the instrument, the patient, and anyone else in the near vicinity of the instrument while in operation. Appropriate materials must be used in the design in order to comply with the sterilization requirements specified by DePuy.

Section 4: Detailed Design

Section 4.1 Overview of Design:

At the completion of the first senior design semester the design of a Fixation System for Post-Trochanteric Osteotomy was complete. Generally speaking this is a system which wraps a stainless steel braided cable around the patient's bone and through a special sleeve. Once this is accomplished a desired amount of tension is applied to the cable and the specialized sleeve is crimped, permanently maintaining the desired cable tension. This new design is an improvement from an existing system which DePuy currently offers. The new design, shown below in Figure 4.1, consists of 2 separate devices; the temporary locking device and the cable tensioning device.

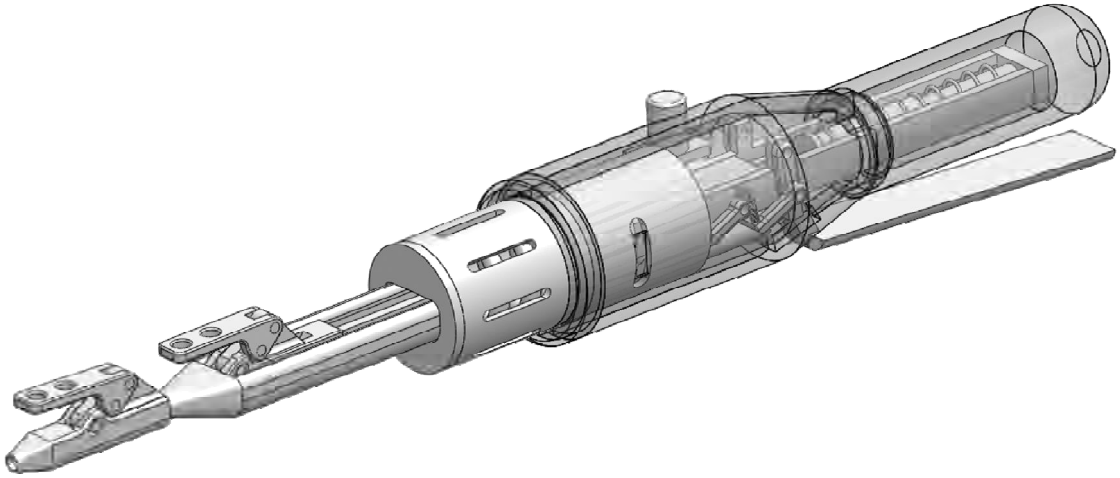


Figure 4.1: Solid model of a Fixation System for Post-Trochanteric Osteotomy.

The temporary locking clamp is a hollow stainless steel sleeve through which the cable is fished. There is a knurled pin which is forced against the cable by a crank slider mechanism. This friction force maintains the position of the cable and prevents the cable from slipping. This maintains the tension in the cable until the clamp is released.

The cable tensioning devise can be broken in to seven sub-components:

The cable clamp assembly is identical in its function to the temporary locking clamp. It is attached to the front of the slide assembly as shown in Figure 4.1. Its purpose is to attach the cable to the slide assembly so, as it is drawn back the tension in the cable is systematically increased.

The tension meter assembly is used to monitor the tension in the cable and is shown in Figure 4.2. It consists of a slotted barrel which houses a compression spring and a plunger. The clamp assembly nests inside the plunger on rails so it is free to slide independent from the plunger. As the slide assembly is drawn back the whole device is indexed forward. This applies a force on the tip of the plunger and compresses the spring equal in amount to the tension in the cable. The slots in the barrel provide windows so the surgeon can see how far the plunger has retracted. A graduated scale is also provided between the slots for reference.

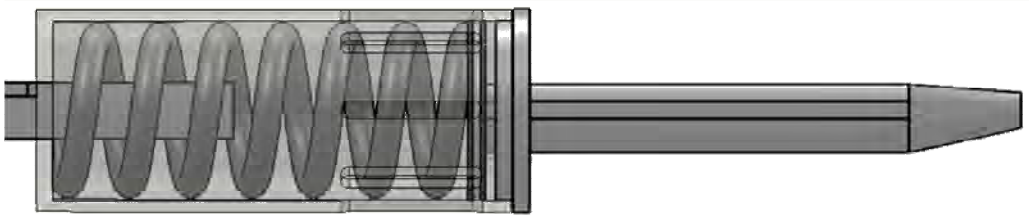


Figure 4.2: The solid model of the assembly of the tension meter.

The frame weldment is a central rigid structure to which all other components are attached. The frame provides a sturdy handle for the surgeon to grip. The tension meter assembly is welded to the front of the frame and it partially surrounds the frame and is shown in Figure 4.3. This was done to reduce the overall length of the device. Between the rails of the frame is the slide assembly, which slides on rails, and the recoil spring, which is part of the reset mechanism. The ratchet mechanism hangs below the frame from its outer walls (circled in red). The reset release is attached to its side. The plastic cover surrounds the back half of the frame.

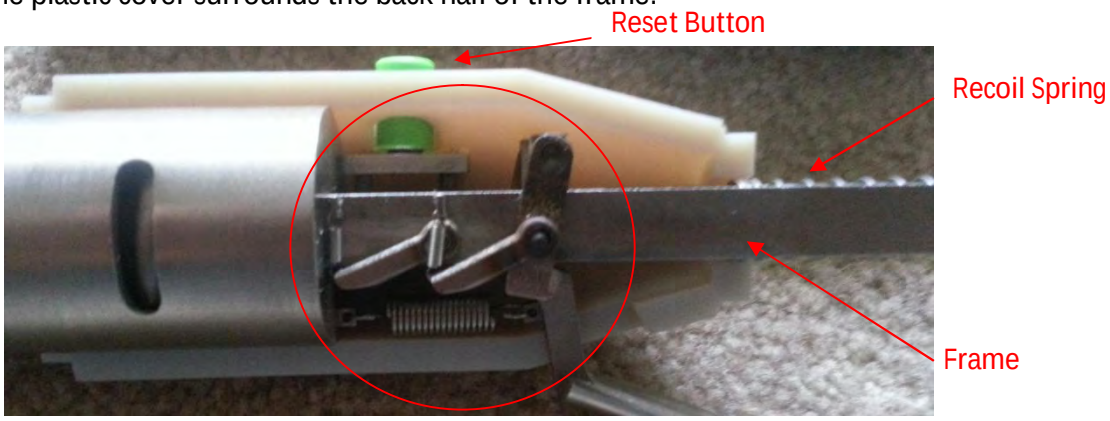


Figure 4.3: The assembly of the tension meter and the frame with the surrounding components.

The cover is made of four plastic components which surround the back half of the device. This creates an appropriate handle for the surgeon to grip and covers the majority of the moving components of the device. This helps to protect the surgeon and the patient during operations. The four parts are shown in Figure 4.4.

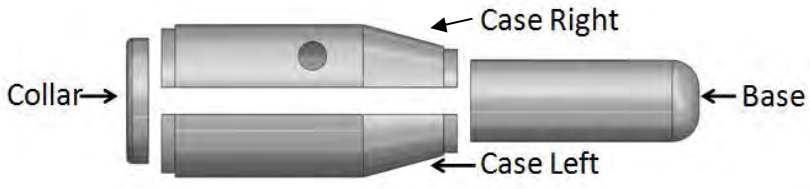


Figure 4.4: The 4 sections of the outer casing shown from the top view.

The slide assembly consists of a stainless steel block with teeth on its lower surface which are engaged by the ratchet mechanism and is shown in Figure 4.5. On the front is attached a slender

rod which travels through the tension meter assembly and attaches to the back of the cable clamp assembly. On the back of the block is a plunger which centers the recoil spring. On the sides of the slide block are grooves. This attaches the slide assembly between the frame rails and limits it motion to one degree of freedom, front to back.

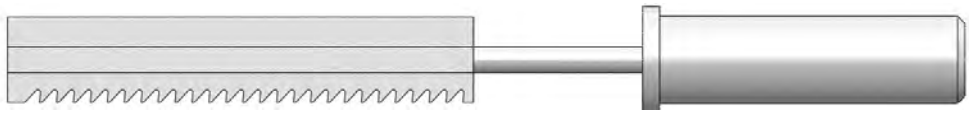


Figure 4.5: The solid model of the slide assembly.

The ratchet mechanism is a four bar crank slider which uses the surgeons grip strength to rotate a lever, and via a latch engaged in the teeth of the slider assembly, draw it back resulting in an increase of cable tension. The configuration of the four bar crank slider mechanism is shown in Figure 4.6. This mechanism also contains a secondary latch in the front which serves as a lock. This prevents the slide assembly from moving as the grip pressure of the surgeon is released and the spring loaded lever rotates the four bar crank slider back to its original position which engages the next tooth of the slide assembly.

Figure 4.6: The ratcheting mechanism made up of a four bar crank slider configuration.

The reset mechanism is a simple spring loaded slide mechanism, mounted on the side of the frame and shown in Figure 4.7. When the surgeon depresses the green button, two rods travel down and disengage both the ratchet latch and the locking latch from the teeth on the lower side of the slide block and are shown circled in Figure 4.7. At this point the recoil spring, housed in the handle portion of the device pushes the slide assembly back to the front of its travel. This resets the device and when the reset button is released the device is ready to tension another cable.

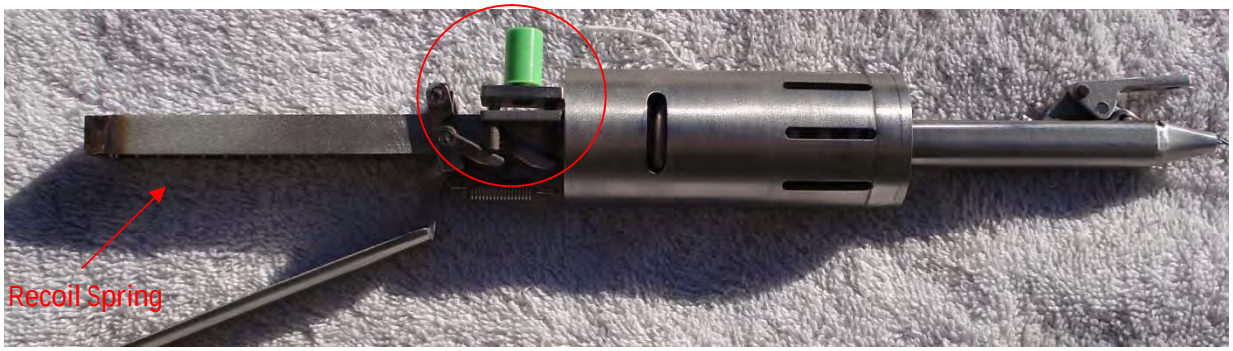


Figure 4.7: The reset mechanism to restore the instrument to the initial setting.

Section 4.2 Redesign:

After a few cycles of testing the device, the cable clamp assembly lost its ability to hold the cable beyond just a few pounds of tension in the cable. It was initially speculated there was not enough force being applied by the crank slider mechanism which forces the knurled tip of the slider into the cable creating the friction force which holds it in place. The length of the knurled slider was increased to create greater friction force on the cable. The red arrow in Figure 4.8 points to the location where the cable was slipping.

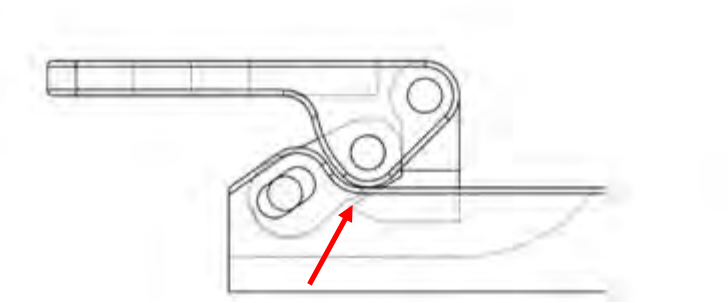


Figure 4.8: Image displaying the location of the part where the redesign occurred.

The device was returned to DePuy's model shop for the modification. When the clamp was disassembled it was discovered that the knurled portion on the tip of the slider was worn. Because of this, the new longer slider was heat treated to increase its hardness. The revised clamp assembly provides increased clamping force at the point indicated by the red arrow in Figure 4.8 and a harder surface which will not wear with repeated use.

Section 5: Building Process

Section 5.1 Building Overview:

The build was completed by the prototype facility at DePuy Orthopaedics. All of the components that make up the instrument were made using rapid prototype machines. The stainless steel components of the instrument were made using a rapid prototype machine that is capable of producing parts made of stainless steel. An example of the machine that DePuy uses is shown in Figure 5.1 below. The process works by laying down a fine layer of powdered metal. A laser is then used to sinter the metal powder together. This layering process continues until the part is complete.

Figure 5.1: Example of laser sinter machine like the one used to produce our parts

The plastic case of our instrument was also made entirely out of rapid prototype material. This machine also uses fine layers stacked on top of one another to build up the part. It should be stated that while each individual component of the instrument was created using rapid prototype techniques, conventional methods were still used to assemble the components into the final instrument. Since conventional methods were only needed to assemble the parts and help them fit together properly, the number of man hours needed to complete the prototype was relatively small. This helped us stay under budget because the only cost that our group was responsible for were the number of man hours that were needed for DePuy to complete the project. The use of the rapid prototype machines also saved our group time because we were not required to make detailed drawing for each part. The employees of the prototype shop were able to load the solid models that had been created directly into the machine.

As stated in the section above, the only modification that was needed for the instrument was to remake the link that is used to hold the cable in place. It was discovered through experimentation that the metal in the cable was harder than the metal used to make the link. This caused the link to wear with repeated use. In order to fix the problem, the geometry of the link was slightly redesigned and heat treated to increase its hardness so that it is now harder than the cable.

Section 6: Testing

Section 6.1 Testing Overview:

A testing unit was designed by the group to verify that the instrument would meet the specifications outlined by DePuy Orthopaedics. The testing unit was designed, implemented, and analyzed by the group members to confirm that the results of the test would accurately determine if the instrument meets the appropriate specifications required for the project.

A test station was designed and built to determine if the instrument would be able to achieve up to 150 pounds of tension in the cable. In order to determine if the new instrument design is easier to use than the previous instrument, a poll of 5 experienced design engineers was performed and each participant rated the new and old instruments. Sterilization analysis was also performed by a sterilization scientist at DePuy to verify that the instrument would be able to be cleaned of any soil or tissue that may be on the instrument after an operation.

Section 6.2 Cable Tensioning Test:

Test Procedure and Set Up

A test station and testing procedure were established in order to determine if the instrument would be able to apply up to 150 pounds of tension in the cable and can be seen in Figure 6.1. Two sawhorses were set up as the main structural support for the test. A 2”x4” board was placed on top of the sawhorses with a hole drilled though the center of the board and was placed on top of the sawhorses.

Figure 6.1: The test fixture used to test the tensioning capacity of the instrument.

A hole was drilled in the outer ring of a washer and the washer was placed on the testing cable by the beaded end and is shown below in Figure 6.2. A 10”x1”x1” board with a hole drilled through the

center was placed against with washer with the cable running through the board and washer. A series of weights were used in order to provide varying amounts of resistance to the device during operation.

Figure 6.2: A close up picture of the parts used to support the weights used during the tests.

Testing was performed on the device by varying the amount of resistance in the wire by changing the weights on the test fixture. Initially, testing started at 20 lb. of resistance and the weight was increased in 10 lb. increments until 150 lb. was tested. Testing was concluded at 150 lb. because 150 lb. was the maximum amount of tension the instrument was designed to operate under. Once the cable was tensioned, the deflection in the spring was recorded in order to calibrate the spring. In production, markings would be placed on the instrument so the surgeons using the instrument would know how much tension they have applied to the cable as they are tensioning the cable with the instrument. Figure 6.3 shows two different weights being tested. Figure 6.3.a. is a picture of 20 lbs. being tested, and Figure 6.3.b. is a picture of 150 lbs. being tested.

a.

b.

Figure 6.3: a) Testing 20 lbs. using the test fixture; b) Testing 150 lbs. using the test fixture.

Using the test fixture, a test procedure was developed to standardize the testing to guarantee that comparable results could be achieved by repeating the testing procedure. Once the test fixture is set up:

1. Run the cable through the opening at the nose of the instrument and through the clamp; secure the cable by locking the clamp.
2. Starting at 20 lbs., place one end of the 10”x1”x1” board through the center of the weights so the board is supporting the weight.
3. Squeeze the handle of the instrument 8 times.
4. Measure the displacement of the spring from a reference point and record the displacement.
5. Remove the weight from the equipment.
6. Reset the instrument to the original position.
7. Increase the amount of weight by 10 lbs.
8. Repeat steps 3-7 until 150 lbs. has been tested.

Results

The instrument was able to place up to 150 lbs. of tension in the cable without slipping which meets the requirements specified by DePuy. Zero failures occurred throughout the tensioning tests. The instrument was not tested until failure, rather only to determine if the instrument fulfills the all requirements. The instrument was not tested until failure, because only one working prototype was provided by DePuy due to budget and time constraints.

Table 6.1 shows the deflection of the spring for each of the testing increments measured. The measurements were performed from a reference point at the base of the spring chamber to the end of the spring. The distance between the reference point at the base of the spring chamber and the spring was measured as 6 mm in the solid model. Therefore, the deflection of the spring is 6 mm less than the measured distance. The test measurements can be used to mark the spring chamber so a surgeon can know how much tension is in the cable while they are operating the instrument. From the table, the displacement varied 3-20 mm while varying the weight from 20 to 150 lbs. Therefore, all tensioning and tension calibration testing was passed.

Table 6.1: The measurements of the deflection of the spring for each weight increment.

Weight (lbs.)	Deflection (mm)
20	3
30	4.5
40	5.5
50	6.5
60	7.5
70	9
80	10.5
90	12
100	13
110	14
120	15.5
130	17
140	18.5
150	20

The measurements of the deflection of the tension meter spring have also been plotted and are shown in Figure 6.4. A linear trend is observed in the plot. A linear trend was expected because a linear spring was used in the design. The spring is deflected roughly 1.5 mm every 10 lbs. The slope of the trend line in Figure 6.4 is 0.1291, meaning the spring is deflected 0.129 mm per pound. During testing, the spring deflected 1.29 mm every time 10 lbs. was added to the test station.

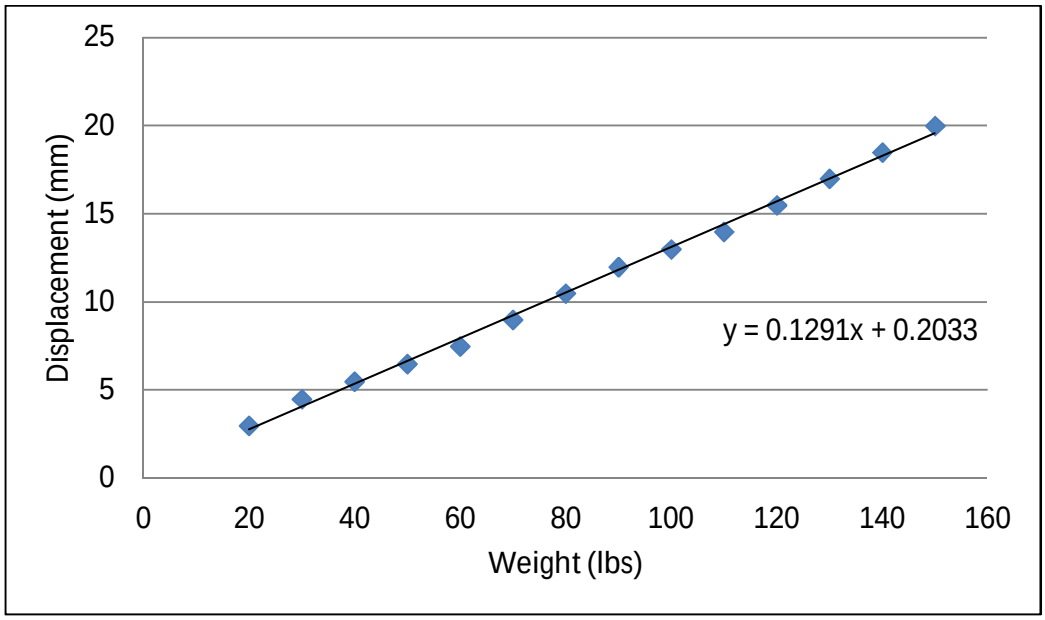


Figure 6.4: The results of the deflection in the tension meter spring tabulated in Table 6.1.

Analysis

The results were also compared to the predicted results in Senior Design 1. Table 6.2 shows the predicted and measured results due to a 10% tolerance in the spring. The results obtained are all within the predicted range. This verifies that the spring was appropriately chosen based on the application.

Table 6.2: The predicted displacement of the compression spring used to measure the tension in the cable varying from 50 lbs. of tension to 150 lbs. of tension compared to the measured deflection after testing.

Cable Tension (lbs.)	Cable Tension (kg)	Rated Spring Rate (kg/mm)	Predicted Deflection (mm)	Measured Deflection (mm)	Calculated Spring Rate (kg/mm)
150	68.04	2.95	23.07	20	3.40
		3.28	20.76		
		3.60	18.88		
100	45.36	2.95	15.38	13	3.49
		3.28	13.84		
		3.60	12.58		
50	22.68	2.95	7.69	6.5	3.49
		3.28	6.92		
		3.60	6.29		

The cable tensioning test was set up to determine how much tension the instrument could provide within the cable. Once the cable was secured in the clamp of the instrument, the cable would have slipped if the instrument was not able to lock the cable in place. However, once the cable was secured to the clamp, the weight was added, and the instrument was ratcheted. The cable never slipped when operating 20-150 lbs. Therefore, by analyzing the results, the instrument will be able to apply up to 150 lbs. of tension within the cable.

The results also prove that there will be no issues with the cable during the operation, because a single cable was used for all the test trials and the cable never failed. The cable did not fray throughout the testing and the bead at the end of the cable was able to withstand all the force being applied to it from the weights. Based on the testing, the group has concluded that there are no other issues that need to be addressed in order to assure that the equipment can be used according to the specifications.

Section 6.3 Performance Test:

Survey

One of the main goals of the project was to develop an instrument that is easier to use than DePuy's current instrument. In order to determine if the new instrument is easier to use than the previous design, a survey of 5 experienced design engineers from DePuy was conducted and their responses were recorded. The new instrument design should be voted as easier to use by at least 80% of the survey participants. The participants should rate the various aspects of the instrument to compare the old and new designs by category and all together.

Results

The performance of the new instrument has been increased tremendously when the instrument is compared to DePuy's current instrument. Table 6.3 shows the results of the people who were surveyed. The people surveyed were all experienced design professionals who all have experience designing medical equipment. Each person surveyed attempted to tension a cable around an artificial bone with each instrument. Every person surveyed believed that the new design was easier to use than the old design. The new design is much less cumbersome and operates much more efficiently than the previous design.

Each survey participant rated each design category on a scale of 1-5, where 1 was unsatisfactory and a 5 is excellent. After averaging the results, the new instrument design outscored the old instrument in every category. The new instrument scored less than a 4 in three categories: durability, size, and weight. The new instrument greatly outperformed the old instrument in all functionality categories. The results are shown below in Table 6.3.

Table 6.3: A summary of the survey results comparing the old and new instruments.

Category	Original Design	Improved Design
Loading the Cable	1.8	4.4
Fixing the Cable	1.6	4.6
Tensioning the Cable	2.6	4.6
Tension Interpretation	1.8	4.4
Releasing the Cable	2.8	4.4
Resetting the Tensioner	2.2	4.4
Size	2.4	3.6
Weight	2.8	3.8
Durability	3.6	3.8
Safety	3.6	4.6
Total	25.2	42.6

Analysis

The results from the survey demonstrate that the new instrument design is overwhelmingly easier to use than the previous instrument. It was clear from Table 6.3 that the new instrument performed better than the original instrument in every category. The participants noted that the operating procedure was much easier and more efficient with the new instrument. The results show it was easier to load the cable, secure the cable, tension the cable, interpret the amount of tension in the cable, release the cable, and reset the instrument. Therefore, the old instrument is much more difficult to operate effectively and efficiently.

Section 6.4 Sterilization Test:

Study

It is very important for the instrument to be able to conform to all of DePuy's sterilization standards set by the DePuy Microbiology and Sterilization Department. This type of testing is performed to verify that the instrument can be cleaned thoroughly after being used in an operation by a surgeon. Therefore, proper materials and design characteristics must be used in order to satisfy the requirement of the sterilization testing.

Results

The final design was taken to the DePuy Microbiology and Sterilization Department to evaluate whether or not the instrument would comply with DePuy's sterilization standards. This means that the device must be able to be adequately cleaned after the surgeons use it. The sterilization department examines the instrument for lumens, internal springs, mated surfaces, rotating and sliding mechanism, O-rings, button, and any small or hidden crevices that could make it difficult to clean the instrument properly. The instrument was analyzed by one of DePuy's sterilization scientists and it was concluded that the device passed all sterilization standards. The memo that was presented to the group can be found in Appendix 11.1. The instrument did not go though the standard sterilization procedure because the instrument was made using the rapid metal prototype machine. Instead, the instrument was compared to previous DePuy instruments.

Analysis

The analysis by DePuy's sterilization department concluded that the instrument would comply with all of DePuy's sterilization standards. This analysis was done by Ashley Armstrong, a Sterilization Scientist at DePuy. A few internal springs and sliding mechanisms were an area of concern when analyzing the instrument from a sterilization perspective. The four areas of concern are highlighted below in Figure 6.5. These areas were identified because they involve moving parts or small crevices. It was determined that DePuy has cleaning and sterilization validations for instrumentation that is more challenging to clean and sterilize than the new design. The ability to

remove the outer casing allows for flushing of the internal mechanisms of the instrument. For these reasons, the instrument passed all sterilization and cleaning standards.

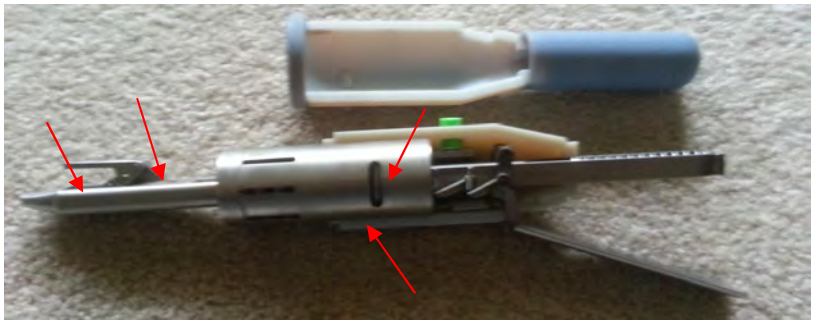


Figure 6.5: The areas of the instrument most likely to cause sterilization problems

Section 7: Cost Analysis

Section 7.1 Bill of Materials:

Listed in Table 7.1 is the bill of materials for the instrument. Using standard parts wasn't an option for most of the components that were chosen because of the strict material constraints required by the orthopedics industry.

Table 7.1: Bill of materials for the final design.

Item Number	Part Description	Supplier	Quantity
1	Handle Section of Case	DePuy	1
2	Left Half of Case	DePuy	1
3	Right Half of Case	DePuy	1
4	Narrow Ratchet Latch	DePuy	1
5	Wide Latch	DePuy	1
6	Release Button	DePuy	1
7	Spring Body	DePuy	1
8	Spring Body Cap	DePuy	1
9	Cable Clamp Body	DePuy	1
10	Cable Clamp Lever	DePuy	1
11	Cable Clamp Link	DePuy	1
12	Cable Clamp Pin	DePuy	3
13	Compressor	DePuy	1
14	Frame	DePuy	1
15	Rear Frame Cap	DePuy	1
16	Handle	DePuy	1
17	Rail	DePuy	1
18	Compressor Tip	DePuy	1
19	Short Latch Pin	DePuy	2
20	Long Latch Pin	DePuy	2
21	Tension Meter Spring	Lee Spring	1
22	Latch Reset Spring	Lee Spring	2
23	Handle Reset Spring	Lee Spring	1
24	Rail Reset Spring	Lee Spring	1

Section 7.2 Cost Analysis:

Custom Parts

DePuy creates all of the prototypes for surgical instruments in house. This made the cost analysis very difficult for our instrument. It was difficult because the materials used in the production of a prototype are not tracked. The way that DePuy has decided to measure that amount of resources given to this project is by recording the number of prototype services hours spent working on the project. We were told to assume that prototype services cost $65 per hour. It was stated in the limitations and constraints section of the report that our budget was $5,000. This means that our design had to use less than 75 hours or about 2 weeks of prototype time to create. We were able to meet this goal with our final design. Since all of the parts were created using automatic rapid prototype technique there was actually very few man hours required to complete our project.

Standard Parts

The springs that we had chosen to use for our instruments were standard parts. We received each of our 4 springs free of charge from Lee Spring. They told us that they would be willing to donate the springs that we needed for prototyping because of their existing relationship with DePuy. Cables were also donated to the group from Fort Wayne Metals. Fort Wayne Metals also supplies other cables to DePuy. Therefore, they were willing to donate a package of 10 cables.

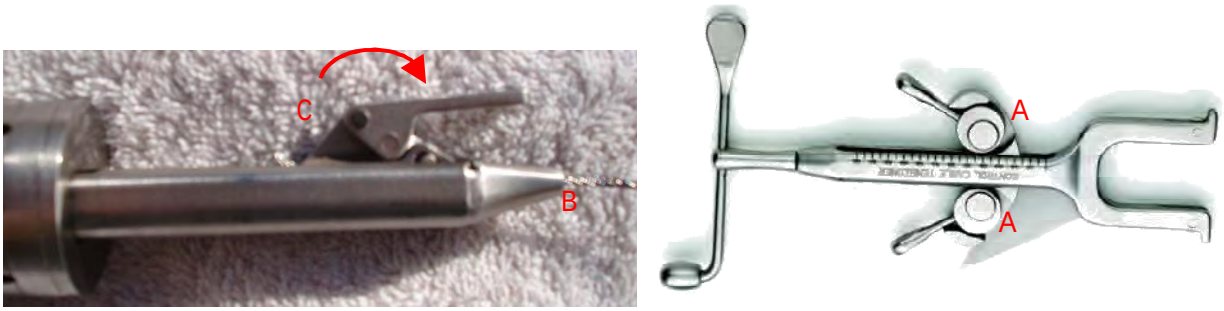
Section 8: Evaluations and Recommendations

Section 8.1 Evaluations:

When evaluating the Cable Tensioning Instrument, the group gave a lot of consideration to all specifications that were established in the problem statement for the project. It was absolutely critical that the critical parts of the instrument perform adequately. A design problem with any of the core parts of the instrument could lead to a failure. Surgeons will not try to use the instrument if there is any chance the instrument could cause harm to the patient or the surgeon during operation. Also, surgeons will not use the new instrument if it is not easier to use and more efficient that DePuy's current instrument. For these reasons, functionality and safety during operations are very important.

Securing the Cable

The first step in the operation would be to pass the cable through the temporary locking mechanism and through the locking device on the instrument to secure the cable to the instrument. On the previous instrument, the cable had to be secured to the instrument in two locations. Figure 8.1.b shows the point where the cable is secured to the instrument (Point A). In Figure 8.1.a, the wire is passed through the clamp (Point B) and the operator locks the cable by rotating the clamp (Point C). In Figure 8.1.b, the cable is secured to the old instrument by rotating the spring-locked levers and passing the cable through both sides. The feedback from the surveys indicated that the new design was much easier and more efficient. Therefore, when securing the cable to the instrument, the new design will provide for greater efficiency during operation and can reduce the time of the operation. A noticeable time reduction will occur because it is much easier to pass the cable through the new design and less awkward trying to make sure the cable is tightly secured. During the operation, multiple cables are wrapped around the patient's bone, this will save time during each iteration.



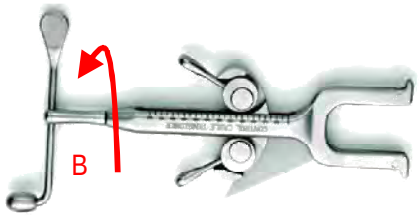
a. b.

Figure 8.1: a) Securing the cable to the new instrument; b) Securing the cable to the old instrument.

Tensioning the Instrument

The cable is wrapped around the patient's bone and tension is applied to the cable using each instrument. In the new design, the operator squeezes the ratchet, as shown in Figure 8.2.a. On DePuy's old instrument, the end of the instrument is rotated by the operator causing the location where the cable is secured to move away from the bone, as shown in Figure 8.2.b. One person can operate the new design with one hand. One person can operate the old design, but two hands are required. Once the appropriate amount of tension is achieved, one person can crimp the sleeve using the new design, but two people are needed to crimp the sleeve with the old design because the old design does not have a temporary tensioner retaining device.

a.



b.

Figure 8.2: a) Tensioning the cable with the new instrument; b) Tensioning the cable with the old instrument.

The results of the survey indicate that the participants found it much easier to use the new instrument design to tension the cable and crimp the sleeve. A 7-year-old child was also able to use the instrument to verify that people of all grip strengths would be able to use the instrument even under extreme conditions. The child was able to operate the instrument on our testing station with 150 lbs. of weight. Due to the convenience and ease of use, the new instrument design operates better than the original instrument.

Resetting the Instrument

Once the cable is secured around the bone, the cable is cut and the instrument is reset. Cutting the cable is the exact same regardless of the instrument. However, resetting the device varies depending on which instrument is being used. For the new design, the instrument is reset by depressing the green button shown below in Figure 8.3.a. (Point A). Similar to how the old instrument was tensioned; the old instrument is reset by rotating the end of the instrument the opposite direction as shown below in Figure 8.3.b. (Point B). Resetting the old instrument can be very tedious depending on how much the cable was tensioned. Therefore, it is much quicker to reset the new instrument to the original starting position. This was also the consensus of the survey participants.

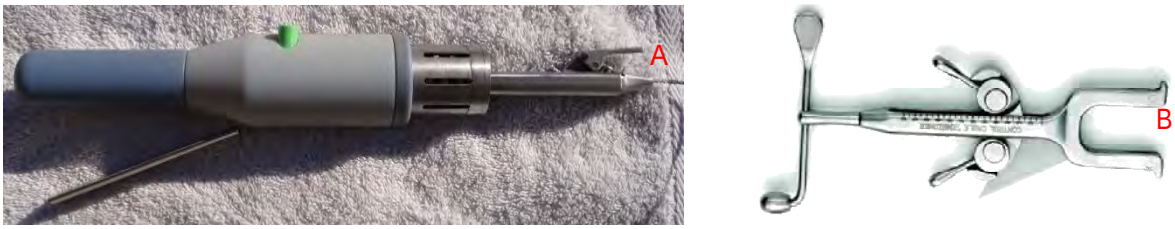
a. b.

Figure 8.3: a) Resetting the new instrument; b) Resetting the old instrument.

Size and Weight

It is also important that the size and the weight of the new instrument be similar or smaller than the original instrument. One of the specifications for the project was to reduce the size of the footprint of the instrument in the patient's wound. The footprint on the new instrument is 2.2 cm at Point A in Figure 8.4.a. The footprint for the old instrument was 7 cm at Point B in Figure 8.4.b. The result was a 350% reduction in the size of the footprint needed during the operation.

The handle of the new instrument is also much more ergonomic than the old instrument. The new instrument's handle in easier to grip and tension compared to trying to operate the old device. The two instruments are very close in length with the both instruments being about 32 cm in length. The mass of the new instrument is about 756 grams. One of the goals of the project was to keep the mass of the new instrument below 710 grams, which is the mass of the old instrument. This goal was not achieved, but the new device offers a much more efficient process and added features to the instrument. Therefore, a 6% increase in the mass of the instrument is acceptable. The distribution of the weight also occurs towards the handle of the instrument, this makes it easier to control compared to an instrument with a majority of the weight at the tip of the instrument.



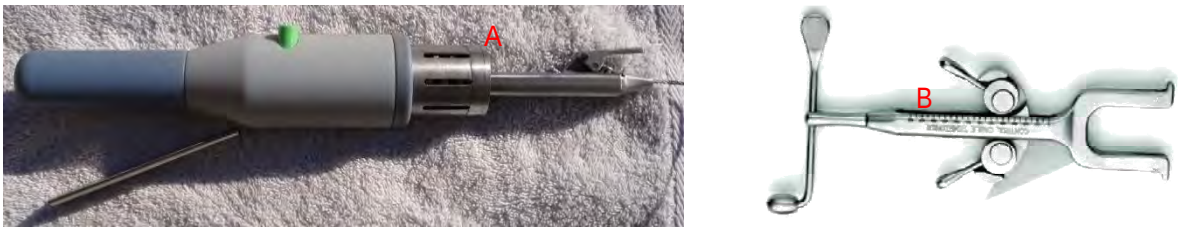
a. b.

Figure 8.4: a) The new instrument's footprint is 2.2 cm; b) The old instrument's footprint was 7 cm.

Tension Meter

The new instrument also has a much improved tension meter that the previous instrument did not have. The tension meter is shown at Point A in Figure 8.5.a. The tension meter displays the amount of tension in the cable so the surgeon is aware of the amount of tension applied to the bone during

operation and can be etched on the outside of the cylinder near Point A. A spring is compressed as the cable is tensioned at Point A. Knowing the spring constant of the spring, the group was able to design a chamber larger enough to tension a cable from 0 – 150 lbs. The scale of the old instrument shown in Figure 8.5.b at Point B displays the displacement from the original position but does not have any representation of the amount of tension the displacement correlates to.



a. b.

Figure 8.5: a) The new instrument's tension meter; b) The old instrument's tension meter.

Sterilization

The sterilization standards of the medical industry require that each instrument used during a surgical operation meet the appropriate standards and regulations. The new and old instruments both pass DePuy's sterilization tests. The old instrument would be easier to clean and sterilize because it contains very few tight crevices and small parts. The new instrument would be tougher to sterilize but more detailed attention must be provided in order to ensure the instrument is safe to use. In summary, both instruments pass the sterilization requirements but the old instrument would be easier to sterilize because it has less complicated parts.

Safety

The new instrument has many parts that work together, but a plastic casing covers all of the mechanisms associated with the instrument that could cause harm to a surgeon or a patient. There are no reasonably foreseeable serious safety hazards associated with the instrument. When the instrument is reset, a spring drives the cable locking mechanism forward, but the force supplied by the spring is not enough to cause a significant injury to a person. Therefore, the safety awareness was taken into consideration during the design phase to minimize the chance of a serious injury occurring to the surgeon or patient when the instrument is being used as it was intended to be used.

Summary

Many different categories have been taken into consideration when evaluating both instruments. The new instrument design is superior to the previous design based on survey feedback and functionality of the instrument. All design professionals surveyed thought the new design was better overall compared to the previous design. The new design improves on the ease of securing

the cable to the device, tensioning the cable, releasing the cable, resetting the instrument, and reading the amount of tension in the cable. The only specification the new instrument did not meet was the weight of the instrument. After discussions with DePuy personnel, it was determined this was not an issue because most of the weight is distributed throughout the handle of the instrument and because it was not much more than the specification (6%). Therefore, all other specifications were met and the new instrument design functions much better than the previous instrument. This allows the surgeon operating the instrument to tension many cables around the patient's bone in a much more efficient manner.

Section 8.2 Recommendations:

Upon completing the entire project and creating a working prototype, there are a few recommendations that can be made. First, the instrument may be too complicated for mass production. While the instrument worked great for prototype purposes, it would be very expensive to create on a large scale. The instrument contains a lot of small pieces with very precise tolerances. Therefore, it takes a long time to manufacture these pieces which can be time consuming and expensive.

Another recommendation would be to improve upon the body of the instrument. The current body does what it was intended to do, which is protect the users from the internal moving parts. However, there may be opportunities to make it more ergonomic which would make the instrument fit more comfortably in the user's hand. More attention could be applied to the body of the instrument because most of the time the team spent working on the project was spent trying to improve the internal mechanisms of the instrument to improve the functionality of the instrument.

Based on the survey of the experienced design professionals from DePuy, the size and weight of the instrument were the categories where the design scored the lowest. Based on this feedback, another recommendation would be to reduce the size and weight of the instrument without jeopardizing the functional aspects of the instrument. The group recommends that this should be done on a part by part basis. The group has outlined a couple ways the size and weight could be reduced. One option would be to use a lighter material for some parts as it is appropriate. The frame and tension meter chamber are the parts that are the heaviest and largest. If these areas could be reduced, a significant improvement to the size and weight could be seen. If the size and weight can be reduced, the instrument would be even easier for the surgeons to use and it would improve the overall design by addressing the areas of the instrument where the instrument did not score as well when evaluated by biomedical professionals.

Section 9: Conclusions

Section 9.1 Conclusions

We conclude this Design project has been successful. All but one of the design criteria was met. The criterion that was not met was a design requirement that the new device weigh no more than the existing device. This was not accomplished but, the group feels the slight increase in weight is shadowed by the vast improvements in the other criteria. For example, with this design the procedure can now be accomplished by one individual instead of two. In addition the existing device does not directly display the amount of tension in the cable as this device does. The footprint of the instrument was reduced 350% compared to the old instrument and the size of the new design is within the parameters outlined. If DePuy should decide to continue with the required testing for bringing this revised system to market it would offer vast improvements over the existing system.

Section 10: References

Section 10.1 References:

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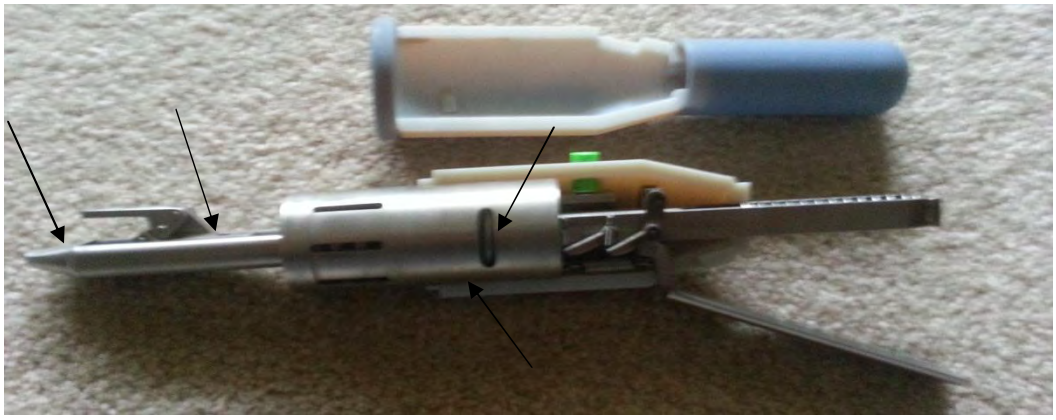
Section 11: Appendix

Appendix 11.1 Sterilization Memo

Cable Fixation Device for Post-Trochanteric Osteotomy
Cleaning & Sterilization Evaluation

For each new instrument that DePuy brings to the market, the DePuy Microbiology and Sterilization Department evaluates whether or not the device can be effectively cleaned and sterilized. In order for an instrument to be terminally sterilized, instrument must first be cleaned effectively. There are certain design characteristics that can impede thorough instrument cleaning. For example, features such as lumens, internal springs, mated surfaces, rotating and sliding mechanisms, O-Rings and buttons can all hinder the cleaning process by trapping soil and tissue from the surgical procedure.

The Cable Fixation Device has internal springs and sliding mechanisms as highlighted in the picture below. Based on these challenging features, the DePuy Microbiology & Sterilization Sciences Department would be able to draw equivalence to existing, worst-case cleaning and sterilization validations. Essentially, it was determined that DePuy has cleaning and sterilization validations for instrumentation that is more challenging to clean and sterilize than the Cable Fixation Device. Additionally, the design of the instrument allows for thorough cleaning. Being able to remove the blue and white sleeve and the various slots along the main body of the instrument allow for flushing of the internal mechanisms. For these reasons stated, the Cable Fixation Device is deemed acceptable for cleaning and sterilization.



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