UNIVERSITY OF WISCONSIN-MADISON

Orthopedic Drill Stop

Biomedical Design

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Dr. Timothy O'Connor is a surgery resident at the UW Hospital. He is concerned with nerve and tissue damage associated with over-penetration of a drill bit when drilling through bone. Tissue damage can occur when the drill bit penetrates as little as four millimeters through the back side of the bone. The current practice for surgeons is to rely on experience, pressure, and auditory feedback in order to stop the drill bit before tissue damage occurs. A device needs to be created that can advance the drill through the bone in one millimeter increments and withstand a force of 20 N without allowing the drill bit to plunge through the bone. In order to limit damage to the bone caused by heat transfer the device must allow the surgeon to complete the drilling in 15 seconds. The team has created a rack and worm gear device that advances the drill bit with one hand using a thumb wheel. The device was tested by novice and experienced subjects to determine effectiveness and possible improvements that can be made.

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Background

Client Description

The client Dr. Tim O’Connor is a Resident in Orthopedic surgery at the UW Hospital. He is conducting research involving eliminating nerve and tissue damage that occurs during orthopedic drilling, primarily on the extremities of the body. He has proposed a project to create a device that stops the drill bit within two millimeters of the posterior of the bone. This device would limit tissue damage as well as simplify the process for determining the length of the screw to be inserted.

Orthopedic Drilling

The focus of this device is to increase the precision with which a bone can be drilled without damaging tissue behind the bone. Damage can be caused by over penetrating as little as 4 mm past the bone. During the process of drilling, an orthopedic surgeon typically relies on experience and the feel of the drill as it penetrates. With practice surgeons can expect accuracy of approximately 4 mm, but this varies depending on orientation of the bone and type of drill and bit being used. In a study performed by Praamsma, it was found that general residents plunged deeper into the tissue beneath the bone than more experienced surgeons. With the addition of distracting noise the residents and more experienced surgeons were both negatively affected. The study showed that plunge depth for novice operators was 30 mm and for experienced operators 5 mm without masking noise and up to 15 mm when the sound of the drill was masked [1]. After the bit penetrates the bone the surgeon must determine the proper length of the screw to be inserted. A separate device is used to gauge the length of the screw to be inserted (Figure 1). This process takes time and requires the use of an additional device. After the hole is drilled and the gauge of screw is determined the surgeon inserts the screw. Bone can be damaged by overheating due to the drill bit which requires surgeons to not only be precise with the procedure but work as quickly as possible [2].

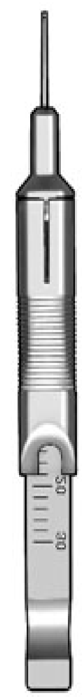

Figure 1: Device used to gauge length of screw, which is operated by inserting into screw hole hooking the tip of the gauge on the posterior side of the bone. It can be difficult to determine if tip is hooked on bone.

Penetration through the far cortex requires sensory feedback by the opportunity to stop advancement of the drill rapidly to limit injury to vascular, nerve, and tendon tissue on the far side of the bone. Different types of bone can alter the drilling time required in order to insert a screw, and can change the rate at which bone is heated. Soft bone located in the epiphysis region is easier for the drill bit to penetrate through and requires less drilling time. Heat transfer is decreased with drilling time and over penetration is less on average [3]. Hard bone located in the diaphysis region requires a surgeon to apply more pressure to the drill in order to keep heat transfer and time limited. By applying more pressure the surgeon runs the risk of increasing distance the bit penetrates through the bone. Certainly there are anatomic structures within the average plunge distance that are at risk during drilling. For instance, the mean distance from the inferior aspect of the clavicle to the subclavian artery is 11.1 mm (range 7.4-14.5) [4]. The distance between the superficial femoral artery and the femur was less than 10 mm in 30/48 (62.5%) and less than 5 mm in 4/48 (8%) of limbs studied [5].

Existing Devices

Dill Guide

The device shown in Figure 2 is an example of an orthopedic drill guide. It is made to have two size options for each separate device, but a surgeon would have access to multiple sized devices. The sizes of the device depend on the size of the drill bit being used. The device holds the drill bit securely to ensure it is driven straight through the bone allowing easier penetration for a screw. This device has no method of stopping the bit once it has penetrated the bone. It is used by a surgeon in one hand while the drill is being held in the other hand.

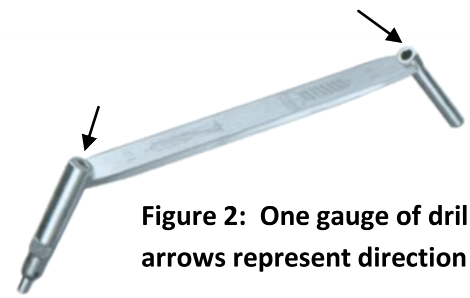

Figure 2: One gauge of drill guide, arrows represent direction of drill bit

http://www.alibaba.com/product-free/108852771

Spinal Drill Guide

A spinal drill guide (Figure 3) is a precise way to stop the drill bit once it has drilled through the bone. In order to use the device the surgeon must first know the diameter of the bone, and set the device in advance to stop the bit at this pre determined depth. Spinal guides are adjustable for any length of screw that would be required and are easily adjusted by loosening a set screw, repositioning a slide, and retightening the screw. This device has been tested and has been found to be simple, ergonomic and accurate. The problem with this device is the need to know the diameter of the bone prior to drilling. In most orthopedic surgery procedures the diameter is unknown prior to drilling [3].

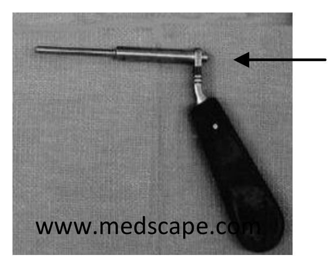

Figure 3: Spinal Drill Guide

ACRA-Cut Smart Drill

The ACRA-Cut Smart bit is shown in Figure 4. It has two offset bits, an inner and an outer bit. The drill bit is only allowed to operate when both bits are engaged; this occurs when pressure is applied to the inner bit. Once pressure is released from the inner bit and the bits become disengaged, the drill bit immediately stops operating. This is a very important device for neurosurgery because it is imperative that when drilling through the skull there is absolutely no

Figure 4: ACRA-Cut Smart bit

www.acracut.com/perforators.html

plunge depth into the brain. Although it is perfect for this function, this device is not able to be used for general orthopedic surgeries. The bit is too thick and in order to scale a similar bit down to a usable size the diameter of the inner bit would be too small to handle the torque created while drilling [6].

Prior semester prototype

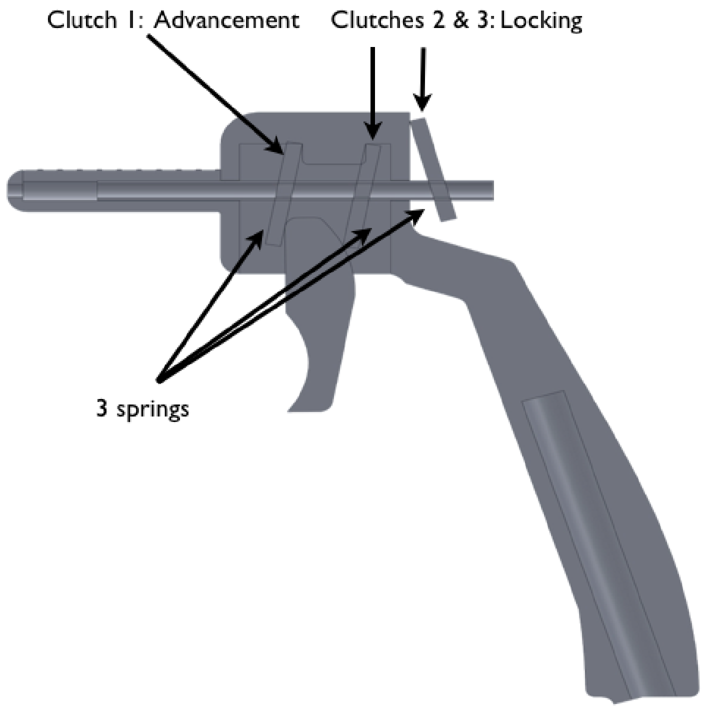

Figure 5: The first alternative design, modification of the current device. Pins will be added to the top of the trigger. They will interface with the metal tube, locking it in place and preventing forward slipping.

The previous team that worked on this project designed and prototyped a trigger controlled mechanism. This device works in a similar manner to a caulk gun. Through a system of metal plates and springs, pulling the trigger causes an incremental advance of a metal tube (bit sleeve) of approximately one to two millimeters. This metal tube passes through the main housing of the device, holding the drill bit and preventing over penetration during surgery.

The function of this design is made possible by the location of the three metal plates, all of which the bit sleeve passes through. These plates act as clutches that control the advancement and locking of the tube. The first clutch is located inside the housing and acts as the advancing mechanism. When the trigger is pulled, this plate pushes the tube forward approximately one to two millimeters. The other two clutches act as locking mechanisms.

The first of two locking clutches is located in the interior housing directly behind the trigger and is designed to prevent forward motion of the tube while the trigger is at equilibrium. Pulling the trigger rotates the plate to a vertical position, allowing the tube to advance without the resistive force of friction. When the trigger is released this clutch returns to its original position, creating friction between the tube and preventing motion. The third clutch is located on the exterior of the device and acts as a second locking mechanism. By the use of friction, this plate prevents the tube from returning to its original position when the trigger is released.

This design is not, however, without its flaws. One of the biggest concerns the client still has is slippage of the bit sleeve. Because the design relies solely on friction to prevent unwanted motion of the drill bit, it is possible to exert enough force to cause the tube to "slip" through the clutches and advance in a large increment to an unwanted depth. This level of force can be reached by the pressure the user applies to the drill while drilling.

Problem Motivation

The client's request for the construction of an orthopedic drill stop device arises from the need to be more precise and more efficient in drilling through and installing a screw in a bone. Over penetration of the drill bit and screw can lead to severe nerve and tissue damage depending on the location of the screw being implanted. In addition, temperature elevation during drilling can cause irreversible damage and bone necrosis. There are several factors that affect the onset of osteonecrosis, including drill speed and diameter [2]. The longer it takes to drill the bone, the higher the risk for bone necrosis [3]. As a result, the client would like use to develop a prototype which accounts for these issues.

Design Requirements

It is important that the device can be used efficiently and not slow the process of drilling, while advancing the drill bit in 1-2 mm increments. By reducing the time of drilling, reduction of heat and damage to the bone will occur. Damage occurs when the temperature remains elevated for an extended time, so by reducing the drilling time, the temperature will be able to return to a safe level more quickly. By moving in 1-2 mm increments, it will be possible to prevent over penetrations and limit damage to nearby tissues [7].

In addition, the device needs to be able to resist peak forces of 20 Newtons exerted on the drill bit without allowing the bit to slip. This is the estimated maximum force exerted by an average person driving a drill forward. If the drill bit sleeve is not stopped, over penetration can still occur, resulting is tissue damage. To improve on the current device, some sort of opposing force mechanism must be introduced, as opposed to relying only on friction to resist the drill force.

After penetrating the posterior of the bone the surgeon should be able to easily determine the length of the screw needed and reset the device without difficulty. To do this, the bit sleeve tube of the prototype will have calibration markings on it, eliminating the need for an additional length-determining tool. If the device is to be used multiple times, it should have an easy reset mechanism [8].

Alternative Designs

Current Device Modifications

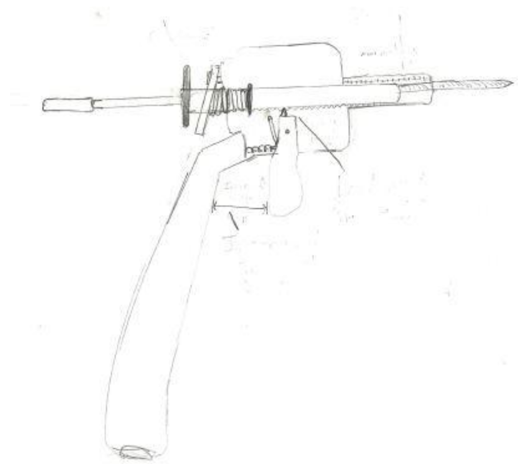

Figure 6 shows the first alternative design: current design modifications. The pins are located on the trigger and move along notches on the drill bit sleeve.

The first proposed design is strictly an improvement on the previous team's final product (Figure 6). The current design uses the friction of metal to stop the hollow cylinder from slipping. It is proposed that this will be improved by cutting notches from the outside of the hollow cylinder and allowing pins to move in and out of the notches allowing the cylinder to advance incrementally. Our group progressed to a design that used a spring loaded trigger of the drill stop as a controller of the movement of two pins on the top and bottom of the hollow cylinder. Pulling the trigger engages the top pin and disengages the bottom pin, and releasing the trigger disengages the top pin and engages the bottom pin. The notches on the top and on the bottom of the hollow cylinder are offset by 1 mm so as to allow 1 mm increment advancements made for each pull or release of the trigger. A more ergonomic trigger and handle assembly is also implemented. There is a drill reset washer attached to the rear of the hollow cylinder which enables easy reset of the device.

Mechanical Pencil Mechanism Design

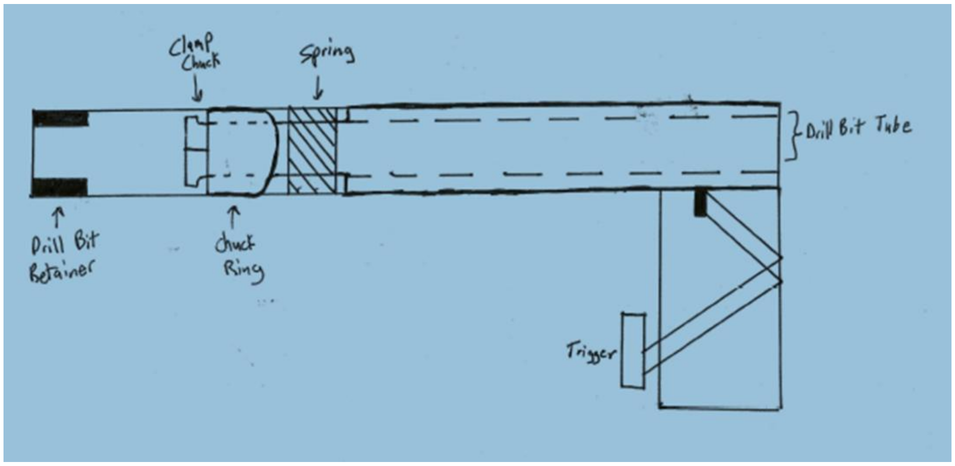

Figure 7: A preliminary sketch of the mechanical pencil design shows how the trigger activates the clamp chuck.

The design resembles a gun and makes use of a mechanism mimicking that used in a mechanical pencil (Figure 7). The drill bit will slide into a metal tube and protrude out the far end. This metal tube will be gripped by a clamp chuck and chuck ring. A trigger pull will push the entire apparatus forward until the chuck ring hits a resistance point and releases from the clamp chuck. The clamp chuck will separate, allowing the metal tube and drill bit to slide forward in the desired 1-2 mm increment. A spring mechanism will return the device to its original position, with the clamp chuck gripping the metal tube at a lower location. The tip of the “gun” will have a material with a high coefficient of friction so that the metal tube and drill bit cannot move freely unless moved by a trigger pull, so that slipping does not occur. The device can be reset after use by pulling and holding the trigger and pulling the metal tube back to its starting position.

Worm Gear Design

The third design involves the use of a worm gear system to advance the hollow cylinder (Figure 8). With a worm gear system, movement of the system is only possible by turning of the worm gear directly and not by turning the attached spur gear. This eliminates the possibility of slip. A crankshaft, which will be spun via a thumb wheel, protrudes out of the housing of the drill stop. When a thumb spins the crankshaft, the worm gear spins and turns a spur gear. This secondary gear pushes a track which is on the exterior of the bit sleeve, and therefore advances the drill bit.

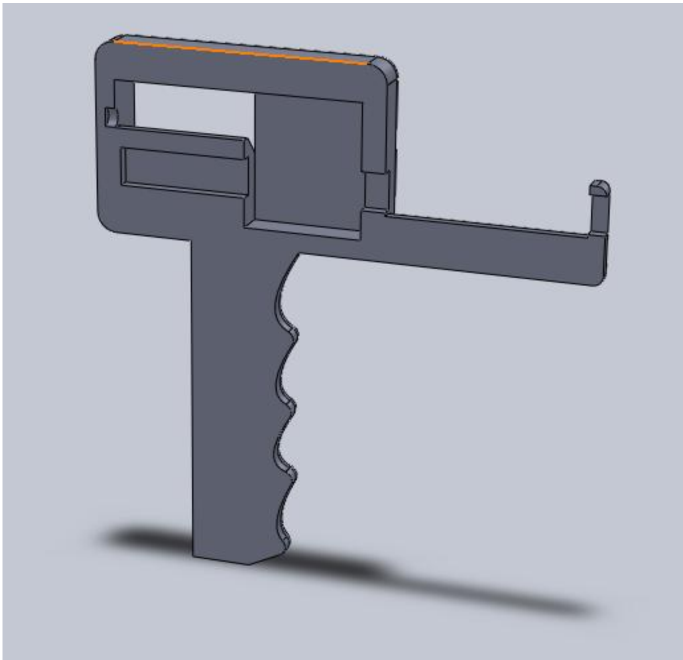

Figure 8: The housing for the worm gear design is shown. The worm and spur gear would rest on top of the drill bit sleeve. The opening shows where the thumbwheel would protrude from the housing.

<u>Design Matrix</u>

In order to assess the value of each of the three designs for an orthopedic drill stop device, a comparison of the proposals was conducted with a design matrix, shown in Table 1 below. The matrix provided a quantitative analysis of which design would prove most beneficial. The categories used for analysis were ability to advance in 1-2 mm increments, prevention of slipping, ease of reset after use, ability to calibrate, and cost. Each category was evaluated on a scale of 1-10, then weighted based on importance to final design. Based on the point breakdown seen in the design matrix, the worm gear design received the most points, so our team has chosen to proceed with this design.

Table 1: The design matrix used for comparative analysis of the design alternatives. Each category was evaluated on a scale of 1-10, and then multiplied by a weighted factor, indicated in the parentheses seen in row headings. The worm gear design will be used at the primary design going forward.

	Current Device	**Mechanical Pencil**	**Worm Gear**
Advance in 1-2 mm Increment (3)	5	7	9
Prevention of Slipping(3)	3	5	10

Ease of Reset (2)	3	6	8
Ability to Calibrate (1)	8	9	10
Cost (1)	9	9	5
Total (out of 100)	47	66	88

Ability to advance in 1-2 mm Increments

The ability to advance in 1-2 mm increments was given the largest weight because of its importance to the application of this device. Since the goal of this device is to prevent over drilling, the ability to limit motion to such an increment is crucial, so that the drill does not penetrate too far beyond the posterior side of the bone and damage other structures, such as blood vessels. The modifications to the current device received the fewest points because it uses friction and a trigger pull to move the drill bit forward, which allows for variance based on the trigger pull force and friction on tube force. Depending on how the clutches move with each pull, there is considerable room for variation. The mechanical pencil design was next because although it uses similar trigger and friction mechanisms, the design allows for more uniform motion from these same forces. Some of the variability found in the current device will be eliminated by ensuring that even though a trigger pull could result in a different movement length, the method of movement will be consistent. Since the clamp chuck will not release until the tube is pushed forward a certain distance, it will not be as possible for the range of distances to be as big as it can be with the current device. The worm gear received the most points because it is moved by a wheel instead of a trigger. The movement mechanism involves gears, which are much more precise than moving by friction. The combination of these two changes made this design the best option.

Prevention of Slipping

The ability to prevent slipping was also given the largest weight. When the drill is being used, it pushes against the device with a 20 N. If this is not prevented, it will cause for movement in larger than the desired increments, resulting in the device being ineffective. The current device has demonstrated many problems with slipping. Although the design enhancements seek to address this issue, there is still some concern that slipping may occur. Because of the need for such a small incremental advancement, the teeth have to be within 1 mm of each other. Because of this, the teeth will be quite shallow. There is some concern that the teeth will not be deep enough to provide the desired hard stop, so the current device received a low score. The mechanical pencil design will use a material with a high coefficient of friction, which will solve the slipping issue but still leave potential for it under a high enough force. The worm gear design received a perfect score because one quality of a worm gear is that it does not allow for movement except for from the external force, which in this case is from the wheel.

Ease of Reset

The ability to reset the device after use is also important to our client, so it was weighed by a factor of two. The current device has problems with this, as the release mechanism is not easy to use and pulling on the tube is inconvenient, so it received the fewest points. The proposed enhancements to the current device do not seek to directly address this issue, except for adding a more ergonomic hold for the user. This will not substantially improve the ease of reset, so the score was low. The mechanical pencil design received the second highest point value because it will be an easier release mechanism by using the trigger and will have a part to hold onto while pulling back. The worm gear design was given the highest value because it can be reset by turning the wheel in the opposite direction.

Ability to Calibrate

With orthopedic drilling comes the need to read the depth of the hole so that a properly sized screw can be used. To make this easier, the client desires this device to have calibration markings from which the depth of the hole can be measured. All three devices scored high in this category, because calibration should not be difficult. The drill but will fit into a metal tube, and as the tube will slide, calibration markings can be easily placed on the outside. The current device and mechanical pencil designs did not receive full points only because of their issue with slipping, which can result in a lack of accurate calibration if slipping occurs once the bone has been drilled through. The degree of point loss deals with the relative potential to slip. This issue is only with the initial attempt to calibrate the device, and how easy it will be to perform such a task. Once the devices have been calibrated, they will read correctly whether the device slips or not.

Cost

The cost of both manufacturing the prototype and potential mass production of this device was also considered as criteria, with the client setting a budget of $200 for production of a prototype and any mass production cost needing to be comparable to current devices on the market. Difference in costs between the three designs arises from the movement mechanism. Since the mechanical pencil and current device designs make use of commercially available materials such as springs and metal tubing, cost of production will remain relatively low with them. The cost of manufacturing of the worm gear will be considerably higher in the final design, due to its need for precision in pitch and number of threads, which will drive up costs. As a result, the worm gear received the lowest score in this category.

Final Design

The final prototype design was constructed out of the thermoplastic acrylonitrile butadiene styrene because the fused deposition printer was used. The fused deposition printer was used because it provided a cheap, quickly constructed, sufficiently strong prototype. SolidWorks was used to model the prototype. The final worm gear design, shown in Figure 9 with dimensions in millimeters, consists of four parts. The housing, blue and labeled 'C' in the figure, consists of two symmetric parts, and the housing contains two moving parts, the worm (green, A) and thumbwheel (yellow, D) couple and the rack (red, B). It was decided to forego the secondary spur gear and have the worm gear directly meshed with the rack as this reduces the amount of moving parts which increases longevity [11].The worm lies directly above the grip and the thumbwheel extends to the rear, outside of the housing. The rack, which contains the hollow metal tube, lies above the worm.

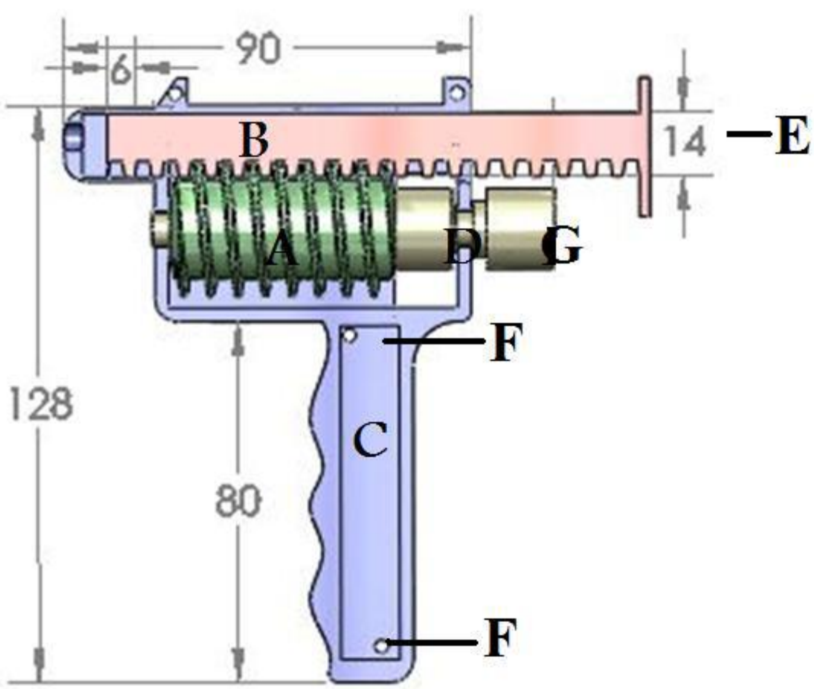

Figure 9: Final prototype dimensions and parts. Seen in the figure are:

A)Work Gear
B) Rack
C) Housing
D) Thumbwheel
E) Metal Tubing
F) Screws
G) Tape on Thumbwheel

Due to the parallel alignment of the worm and the rack and the fact that the rack comes from behind as it enters the housing (slides directly above the thumbwheel), the diameter of the thumbwheel is limited to less than that of the worm. Because of this, it was decided that the worm should be a relatively large diameter, 30 millimeters, in order to accommodate for an ergonomic thumbwheel diameter, 18 millimeters. Due to the clients request that the device allows advancements of increments as small as 1 or 2 millimeters, the worm was designed to have a pitch of 6 millimeters so that advancements of 1 or 2 millimeters could be achieved with turning the thumbwheel 1/6 and 1/3 of a turn, respectively.

The rack, designed to mesh and move along with the movement of the worm, has notches which are 6 millimeters apart in order to accommodate the worm's pitch. The notches are 3.5 millimeters deep and are angled inward at 8 degrees in order to maximize smoothness of advancement. The rack is 90 millimeters long, 10 millimeters wide and contains the metal hollow tube. The metal hollow tube has an internal diameter of 3.5 millimeters and contains the drill bit securely.

It was decided to construct the housing out of two symmetric parts so that it could be assembled and disassembled, cleaned, and analyzed easily. The housing parts contain holes that allow it to be assembled with #6-32 screws. It has an ergonomic handle that is 80 millimeters long and 20 millimeters wide. There is a 15 millimeter tip on the end of the housing in order to provide a protruding point to rest on the bone.

Testing

Testing setup

Testing of the prototype was performed on pig tibias. To prepare the tibias, they first needed to be thawed. This was accomplished by placing them in a warm water bath for 30 minutes. Once this was complete, the meat was removed from the bones. The ends of the tibia were then cut away so that a uniformly flat surface could be used for testing. If the ends were left on, the bones would not sit flat.

Once the pig tibias were ready, testing was performed using the setup seen in Figure 10. A foam block was wrapped in tin foil and held in place with four wood pieces. Two metal bars of 4 mm thickness were then placed on top of the block. A pig tibia was strapped down on top of the two bars so as to create a 4 mm space between the posterior side of the tibia and the tin foil barrier. The final preparation step was to drill a 5 mm deep hole for the thermocouple and mark a drill location 0.5 mm away. The thermocouple was secured in the hole using conductive putty.

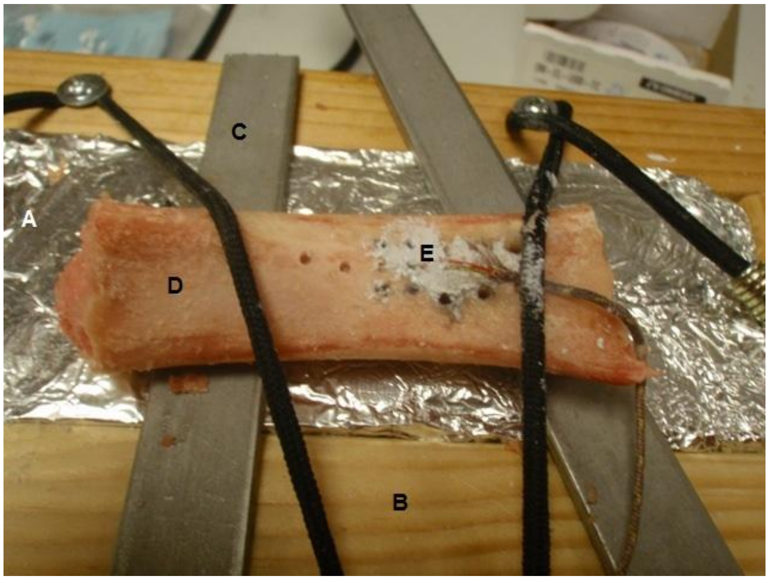

Figure 10: Testing setup used for comparison of prototype to freehand drilling. Labeled parts are:

A) Foam block wrapped in tin foil
B) Wood blocks used to hold foam block in place
C) Two 4 mm thick bars used to establish gap between bone and foil
D) Pig tibia used for testing
E) Thermocouple used to gather temperature data

Testing procedure

Testing consisted of having participants drill through the bone both freehand and using the prototype. In total, four novices and one surgical expert performed testing trials. Each novice performed three trials freehand and three using the prototype. The expert performed eight freehand trials and seven trials with the prototype. For each trial, three factors were considered and evaluated: drill time, heat generated, and ability to prevent over penetration. Results of testing can be seen in Appendix A.

Drill Time

Drill time was evaluated by timing each trial from start to penetration through the posterior side of the bone. Results of this testing were analyzed to determine whether or not the prototype produced a statistically significant improvement on drill time. Testing with the prototype yielded an average of 18.6±8.5 s, while freehand resulted in an average of *44.2*±44.2 s. To compare a t-test between the times while using the prototype and the time while drilling freehand was performed. A T value of 2.53 was calculated. As this exceeded the 95% confidence interval critical value of 2.10, testing showed that the prototype performed statistically better than freehand testing.

The other aspect of time considered was the effect of using the prototype on individual performance. Average trial times for each subject are plotted in Figure 11. From this it is clear that each subject performed better while using the prototype. The standard error for each subject is included, showing that three of the five subjects performed statistically better (this is defined by the error bars of time with and without the device not overlapping). Of particular importance is the significant improvement seen in the expert test subject, T.O. This subject's freehand time was approximately three times as long as that using the device. Our team considers this particularily important, as the expert has been trained in appropriate surgical practices, while the novices were going without any guidance. To see such an improvement with the expert shows that the prototype has potential to improve surgical procedures.

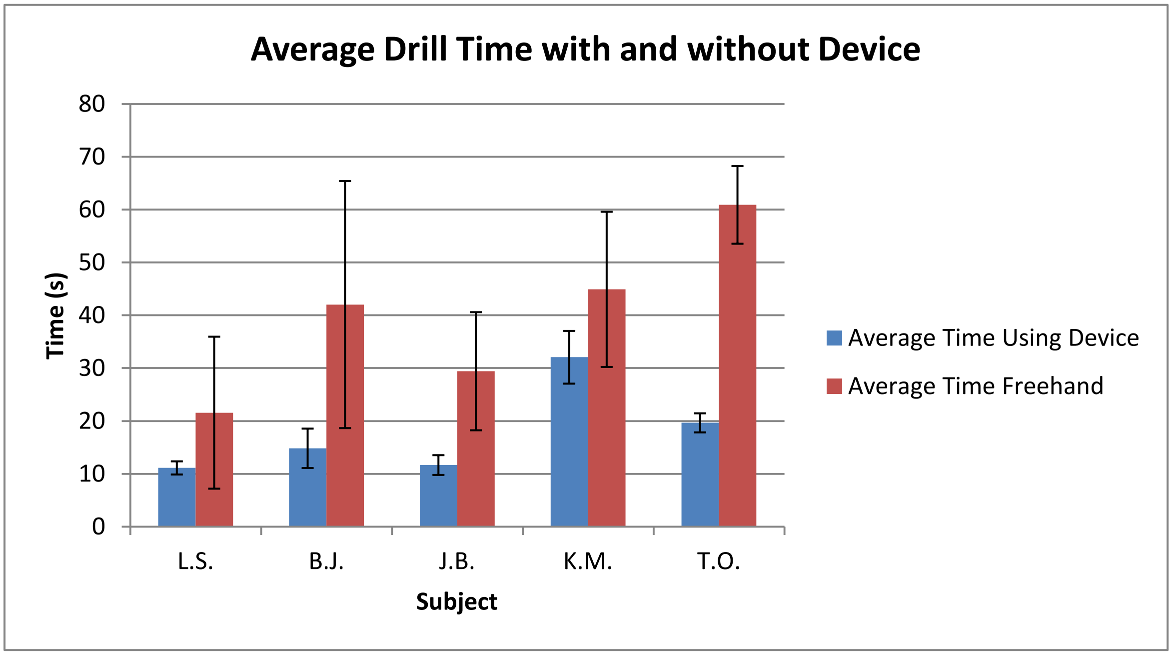

Figure 11: Plot of average drill times with and without device for each subject. Positive and negative standard error of the mean is shown.

Temperature Generated

Temperature data was collected using the thermocouple, which provided temperature data in one second intervals. This data was placed into a word document and analyzed using MATLAB computer software. Our team chose to look at change in temperature when comparing freehand trails with those using the prototype. This was done in an attempt to eliminate variability caused by such factors as the bone not being in a human body, and the baseline temperature changing the longer it was exposed to room temperature. The temperature change was measured between the maximum temperature generated and a baseline reading taken before drilling started. This was compared to a critical temperature change of 10 °C, which is the change between body temperature (~37 °C) and the temperature at which tissue damage begins to occur.

Testing with the prototype led to an average temperature of 13.5±9.8 °C, while testing without the device has an average of 18.6±13.7 °C. Again, a T-test comparison was performed. This time, a T value of 1.34 was calculated, which was less than the critical value of 2.10. As a result, the change in temperature was not statistically significant.

Results on an individual basis were also considered and are plotted in Figure 12, with standard error bars included. The results were between individuals were much more variable, with all of the novices either showing no statistical difference, or performing better while drilling freehand. However, the expert did perform statistically better. One possible explanation for this result, and one that would explain the lack of difference amongst the novices, is the manner by which the expert performed his drilling. While some of the novices were inclined to only push while drilling, the expert used an alertation of forward and backward drilling while going freehand.

For most of the trials, temperature data collection was stopped once the drill had penetrated the far side of the bone. Near the end of testing, it was noticed that the temperature remained elevated even once drilling was stopped. In the future, our team would like to continue to collect data until the temperature drops below the critical level. This is due to the fact that damage to the tissue not only occurs with high temperatures, but also when temperature remains elevated for an extended period of time. It has been hypothesized that a reduction of drill time should correlate with a reduction of damage due to temperature. As there was no difference in temperature generated, it is possible that a lower drill time will result in less time to return to a safe level.

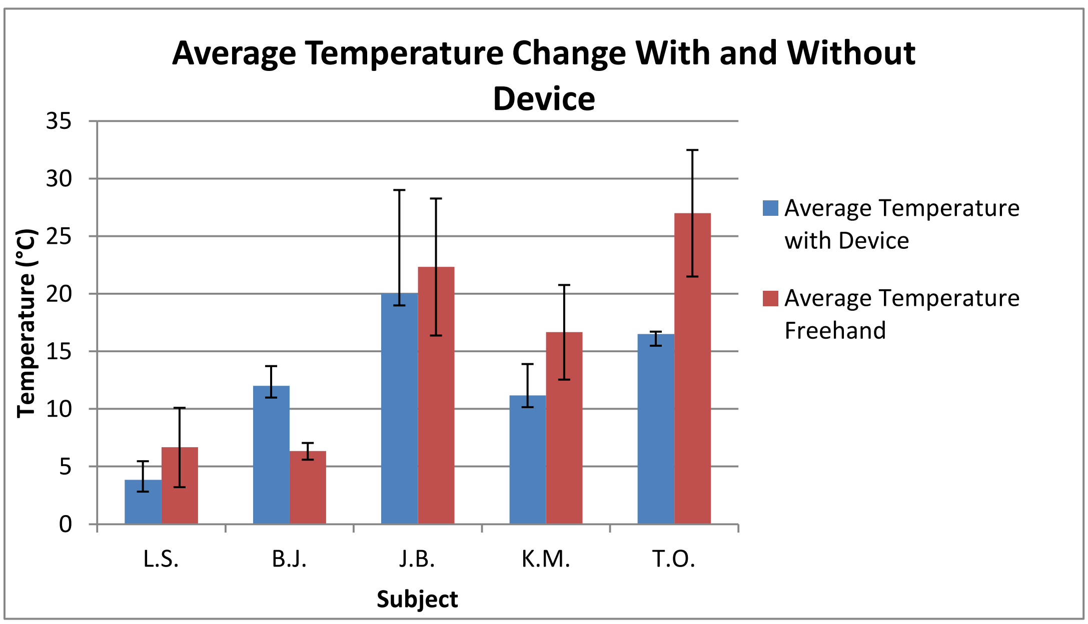

Figure 12: Plot of average temperature changes with and without device for each subject. Positive and negative standard error of the mean are shown.

Over Penetration

The final area considered while testing was the prevention of over penetration. This was evaluated by counting the number of successful and failed trials both freehand and using the prototype. A failure was defined as breaking the foil barrier while a success was drilling through the posterior side of the bone but stopping before breaking the foil. The results of testing can be seen in Table 2.

A success/failure approach was chosen instead of measuring the penetration. Dr. O'Connor was asked about the merit of measuring depth of penetration. According to him, current methods to measure plunge depth involve placing motion sensors on the tip of the drill bit and collecting data during drilling. This was determined to not be worth the effort during initial testing. Thus, evaluating trials as failures or successes served the purpose of evaluating over penetration during testing.

Table 2: Over penetration testing results. Failure was defined as penetrating through a tin foil layer located 4 mm below the bone

	Freehand		Using Prototype	
	Successes	Failures	Successes	Failures
Experienced	0	8	7	0
Inexperienced	0	12	11	1
Total	0	20	18	1

These tests show a drastic difference between testing while using the prototype and drilling freehand. The fact that only one trial failed while using the prototype, but all 20 trials, including 8 by the expert, failed while drilling freehand shows that there is a definite improvement while using the prototype. This has important implications toward orthopedic surgery. Dr. O'Connor has alluded to the fact that having such a device would be useful for training new surgeons. As 11 of 12 trials by novices, who had never drilled through bone before, were successful, this claim appears to have merit.

Future Work

The first prototype was successful in proving the concept of the design. The gears worked as intended, allowing controlled advancement of the drill bit in small increments (1-2 mm). The design also solved the primary problem of slippage that existed in the trigger-controlled device fabricated last semester. Testing has shown that progress has been made by switching to a gear-controlled mechanism.

Although the design works as intended, there are several modifications that can be made to improve functionality and ease of use. Changes to the thumbwheel should be considered to make it more accessible and easier to spin. The internal thumbwheel should be eliminated completely. Testing showed that the external thumbwheel is more ergonomically practical. The test subjects were not instructed on which thumbwheel to use, and all naturally chose to use the external wheel. Having an open window in the housing also increases the likelihood of bone dust accumulating and clogging up the gears. The current thumbwheel can be improved by adding a textured surface to prevent the user's thumb from slipping.

The handle should be extended 3-5 cm to rest more comfortably in the user's hand. The worm, thumbwheel, and connecting shaft should all be combined into one piece for ease of fabrication. To assemble the current prototype these pieces had to be press fitted together, which proved challenging. The diameter of the worm can potentially be decreased. The current size is unnecessarily large and making it smaller would allow the housing to be more compact. However, the tradeoff to this is the thumbwheel would have to be smaller in diameter to avoid interfering with the rack.

The nose of the device should be modified to more closely resemble the spinal drill guide (Figure 3). The plastic nose of the current prototype should be eliminated and a longer metal tube should be used that extends from the rack. Teeth should be added to the end of the tube to better grip the bone, as the current prototype has a tendency to slide on the surface of the bone during drilling. Finally, a measuring gauge should be implemented into the rack so the drill depth can be read without the use of an additional tool. The measurements will be etched into the rack and calibrated so as to accurately display the depth of the drill bit as the rack is advanced.

Several changes should be made to the testing procedure as well. Additional experienced subjects should test the device; only one surgical resident was available for the first round of testing. The temperature data collection should be extended to include time after drilling has been completed to determine how long it takes to return to the baseline temperature. If the temperature remains elevated for a long enough time, bone necrosis could become a factor.

The drill stop device should be used for the free hand data collection instead of the drill sleeve that was used in the initial testing. If the rack is advanced all the way to start, it will not provide any stopping action and will work only as a guide. Using the same device for all trials will improve consistency between the two sets of data.

If the project is continued in the future, subsequent prototypes should be fabricated that reflect these changes. When the design is finalized, stainless steel parts will be custom ordered and manufactured from an outside vendor. The worm, rack, housing, and thumbwheel will all be stainless steel.

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Appendix

A. Testing Data

Results of prototype testing. Values are collected for the subject initials, whether or not the foil barrier was broken, the time taken to drill, and the change in temperature generated while drilling. The testing results are broken into two tables, results for inexperienced users and experienced users.

Inexperienced Users								
		Free-hand (Using Drill Sleeve)			Using Drill Stop			
Subject	Trial #	Break foil? (Y/N)	Drill Time (seconds)	Temperature Change(Degrees F)		Break foil? (Y/N)	Drill Time (seconds)	Maximum Temperature(Degrees F)
L.S	1	Y	7.72	2.5	2	N	13.6	1.5
L.S	3	Y	6.68	4	4	N	9.63	3
B.J	5	Y	11.25	5	6	N	14.8	9
B.J	7	Y	87.92	6.5	8	---	8.4	15
J.B	13	Y	17.27	32	14	Y	N/A	38
J.B	15	Y	19.27	23.5	16	N	9.38	10
K.M	17	Y	46.63	8.5	18	N	24.22	6.5
K.M	19	Y	18.68	21.5	20	N	30.65	16
B.J	21	Y	26.97	7.5	22	N	21.32	12
J.B	23	Y	51.76	11.5	24	N	13.97	12
L.S	25	Y	50.34	13.5	26	N	10.16	7
K.M	27	Y	69.46	20	28	N	41.33	11

Experienced User							
		Free-hand (Using Drill Sleeve)			Using Drill Stop		
	Trial #	Break foil? (Y/N)	Drill Time (seconds)	Maximum Temperature(Degrees F) *see graphs	Break foil? (Y/N)	Drill Time (seconds)	Maximum Temperature(Degrees F) *see graphs
T.O.	1	Y	23.26	31.5	N	17.52	57.5
T.O.	2	Y	32.14	36	N	17.12	60.5
T.O.	3	Y	N/A	33.5	N	27	32
T.O.	4	Y	19	40	N	24	35
T.O.	5	Y	153	64.5	N	20	30.5
T.O.	6	Y	25	56.5	N	17	32.5
T.O.	7	Y	19	70.5	N	15	37.5
T.O.	8	Y	155	58			