Orthopedic Drill Stop Device

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Abstract

Orthopedic surgery is a field in which the patient's health relies on the precise motor skills of the surgeon. When drilling through bone, the surgeon must be able to quickly cease the advancement of the drill after passing through the far cortex to avoid penetrating and delivering potential damage to the underlying soft-tissue structures. Currently, surgeons rely solely on their experience, the feel of the force applied from the bone, and auditory feedback. This can lead to higher than acceptable plunge depths seen occasionally from surgeons but more relevantly with less experienced residents. Our team of Biomedical Engineers has chosen to design and build an orthopedic drill stop device that removes the high plunge depth variability from the sensory control of the operator. This device contains a stopping mechanism for the drill bit and a trigger which allows a 1.5mm dynamic advancement of the bit per trigger pull. This device decreases the plunge depth of the bit and the corresponding injury to soft tissue surrounding the bone.

Background

Surgical technical skills require sophisticated motor skills. Many fields such as psychology, neuroscience, ergonomics, and biomechanics contribute to the learning and performance of these motor skills, from the error detection mechanisms of the brain, the biomechanical constrains of the movements, and the sources of sensory information that are integrated to guide in surgical motions. When drilling through a bone, an orthopedic surgeon must have precise motor skills to be able to quickly cease the advancement of the drill when the full thickness of the bone has been traversed to avoid penetrating and delivering a potential injury to the underlying soft-tissue structures. The length of the bit protruding past the bone that has been drilled is known as “plunge depth”. Minimizing the plunge depth is the primary goal of mastering this motor skill. [6]

Studies done by Adam Dubrowski and David Backstein found that orthopedic surgeons demonstrated significantly less plunge depth than junior residents did. The results showed that junior residents relied mainly on reactive control during surgery, whereas the surgeons used anticipatory control for the application of the drilling force. This reactive control translates to larger temporal delays between penetration of the bone and the termination of the drilling action. [6]

Aside from personal experience, other factors such as distracting noise can adversely affect a surgeon’s performance during drilling. In a study done by Monate Praamasma *et al*. it was found that in general residents plunged deeper than intermediate trainees and surgeons. With the addition of distracting noise, the plunges of both residents and surgeons were adversely affected [9].

Motivation

As stated previously, many studies have been done showing that over-penetration of the bone during orthopedic surgery is a significant problem. There are a variety of unavoidable factors that cause plunging during surgery. Our client, Dr. Tim O’Connor is concerned about this problem and is looking for a solution that could eliminate this plunging to prevent injury to the soft tissue on the opposing side of the bone. The current method of surgery involves using a drill sleeve to ensure that the drill bit enters the bone straight; however there is no stopping mechanism to prevent over-penetration of the bone. Other devices have adjustable depth setting but are cumbersome because the depth cannot be changed while drilling. This leads to extended drilling time and may compromise the patient’s stability and healing. Plunging depends solely on the motor skills, auditory feedback, and feel of the surgeon. Dr. O’Connor has asked our team to come up with a device that would eliminate plunging during orthopedic surgery by removing the dependence on the surgeon’s motor skills, feel of the bone, and auditory feedback.

Problem Statement

Our client, Dr. Tim O’Connor is a Resident in the Department of Orthopedic Surgery at the University of Wisconsin Hospital and Clinics. He is concerned about over penetration of the drill bit into soft tissue during bicortical drilling in orthopedic surgery. For most surgeries the current methods of preventing over-penetration is based solely on sensory skills of the surgeon. A drill guide is used to ensure straight penetration; however there is nothing to prevent over penetration. The closest current method to solve our problem is used in spinal surgeries. It involves setting a pre-determined drill depth that is too cumbersome to adjust during the procedure. Our team has been asked to create a design that minimizes the plunge depth of the bit after penetrating the far side of the bone to prevent injury to soft-tissue.

Client Requirements

Our client has given us a number of requirements that our design has to meet. The most important requirement is that our device minimizes the plunge depth after penetrating the far side of the bone. Previous studies have shown plunge depths to be up to 1.5 – 3 cm depending on the experience of the surgeon. This over penetration has the potential to cause injury to nerves, vascular structures, or tendons. The goal of this design will be to decrease this plunge depth to 1 – 3 mm past the far side of the bone. In order to accomplish this, the device should advance in increments of 1 – 2 mm in depth. The device must able to change the drill depth dynamically, or simultaneous while drilling. Since it will be used during surgery, it needs to be able to be cleaned and fully sterilized between uses. Also because of its use in an operating room, electronic components could become an issue interfering with devices such as EKG machines or pacemakers etcetera. Thus, the device should, but is not limited to, operate by mechanical properties. This device should be able to be reused and sold in a kit that comes with the drill bit, and it should have a lifespan of approximately 6 uses. The device will be sold as an accessory to the drill and should not affect the functioning of the drill. An orthopedic drill is very large and durable, so this device must be tested to withstand the force exerted by the drill during surgery and its function should not be altered by this force. We have been given an initial budget of $500 to begin the construction of this device; however each device should be able to be manufactured for under $50 as it is an accessory device. In order for this device to be successful, it must be an intuitive design for ease of use of the surgeon. The use of the device should not in any way hinder the surgeon from his or her operating performance.

Existing Devices

Orthopedic surgery is a wide branch of surgery that deals with conditions of the musculoskeletal system. There are many different devices that are used for different types of orthopedic surgeries. Dr. Tim O’Connor introduced us to some of the devices used in different types of orthopedic surgeries at the University of Wisconsin Hospital. These devices vary from a basic drill sleeve to an adjustable drill stop used in spinal surgeries to a pressure activated drill bit used in neurosurgery. The goal of this project is to replace the basic drill sleeve that is used in most general orthopedic surgeries with the option of incorporating some of the concepts from the other two devices.

The current device that is used for most general orthopedic surgeries is a very basic drill sleeve as shown in Figure 1. Each end is a different size to fit to a different size drill bit. The fit of the drill sleeve to the drill bit is very snug and allows the drill bit to pass through without excess wobble. This drill sleeve ensures that the drill bit will be drilled straight into the bone to allow the screw to be placed easily through the bone. However, this device has no stopping mechanism or gauge for the surgeon to realize how far through the bone the drill bit has penetrated. This device requires experience from the surgeon to stop the drill after penetrating the far side of the bone as it is based solely on the feel of the surgeon. This device used for most orthopedic surgeries is what our device is aiming to replace.

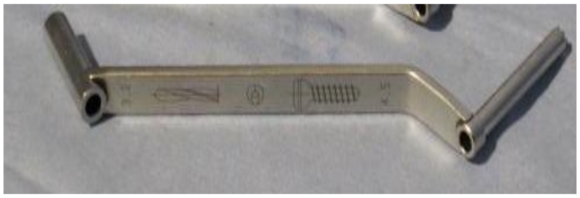

Figure 1: Drill sleeve used for most orthopedic surgeries. It contains no stopping device; it just ensures the drilling of a straight hole [7].

These next two devices are current devices used for specified surgeries, spine and brain, that require much more precision than the drill sleeve. Some of the concepts from these devices are used in our final design. In spinal surgeries, the surgeon uses a spinal drill guide as seen in Figure 2 below. This device consists of an adjustable inner sleeve that can be preset prior to surgery to a specific length. The outer sleeve contains a depth adjustment with ruler increments so the surgeon knows what length to preset the drill guide to before surgery. The surgeon is then able to drill during surgery and the inner sleeve will stop the drill bit at the specified length. This device is useful in preventing over penetration only if the exact depth of the bone is known, which is very rare. The issue with this device is that the stop depth is not able to be adjusted while the drill bit is in the inner tube. This design requires the depth of the inner stop to be adjusted prior to drilling. This can lead to various problems such as; if the depth was chosen by the surgeon prior to surgery is too long, the drill bit over penetrates the bone and damages the underlying tissues, and if the chosen depth is too short, the surgeon must remove the drill bit all the way from the guide, place the drill down, choose a new depth, and start over. This process is too cumbersome and time consuming during surgery, which is why this device is not used in most general orthopedic surgeries.

In emergency neurosurgery procedures when pressure inside the skull needs to be released immediately the most precise device is used. This is an ACRA-CUT Smart Drill

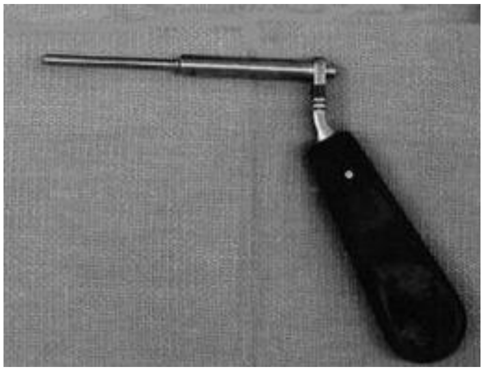

Figure 2: Drill guide used in spinal surgeries. It has a pre-set depth, but it is not able to be adjusted during operation [11].

Figure 3: ACRA-CUT Smart Drill bit used in emergency neurosurgery to release pressure inside the skull. It has two offset bits and the drill only operates when pressure is applied to the inner bit. Thus, when the skull is penetrated, pressure is released from the inner bit and the bit stops operating, preventing over penetration [1].

Bit as seen in Figure 3 above. It has two offset bits, an inner and an outer bit. The drill bit is only allowed to operate when the bits are engaged and 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 when drilling through the skull there is absolutely no plunge depth into the brain. Although it is perfect for its function, this device is not able to be used for general orthopedic surgeries. This drill bit is way too thick to be used to drill holes for bone screws. This design would not be feasible to scale down for a smaller drill bit because by requiring the separation of the cutting surfaces, the inner bit must be strong enough to withstand the torque and force applied from the drill.

Aside from the devices currently used, many similar concepts have been found in patents. Devices such as the penetration limiting stop elements for a drill bit used in bone tissue [4], the adjustable drill stop sleeve [3], the sleeved stop for a drill bit [11], and the drill stop [8] are relevant to the client's needs. Although many of these ideas have similar concepts to what our client is looking for, none of these devices are suitable for the desired application.

Ethics

This device has been designed with the intent to be used in surgical environments. Currently in most orthopedic surgeries a drill guide is only used as an aid for the surgeon. By adding a more complex device to aid the surgery, it adds another variable to the surgical environment. Thus its design and ultimately the construction must be error proof. It must be guaranteed that this device will not adversely affect either the surgical environment or the patient. There must be adequate testing done on this device, and regulation guidelines must be met before it can be used.

Ergonomics

This device should be easy to use with one hand while a surgeon controls a drill with the other hand. It should be comfortable to use for long periods of time. The handle of the device should provide good grip for the user. The mechanism should be easy to operate with one hand and minimal shifting and setting during the procedure would be ideal.

Design Proposal 1: Electronic Feedback Mechanism

The electronic feedback mechanism was created by Benedetto Alotta *et al.* in order to better control penetration of the bone [2]. The surgeon exerts a force on the back end of the device, and this force is measured right at the tip of the drill bit. This measurement is relayed to another component of the device to control the speed and feed rate of the drill. The mechanism prevents excess penetration past the bone without requiring the user's judgment or reflexes. Although the precision of this would be great, its complexity and ease of use make this design somewhat undesirable.

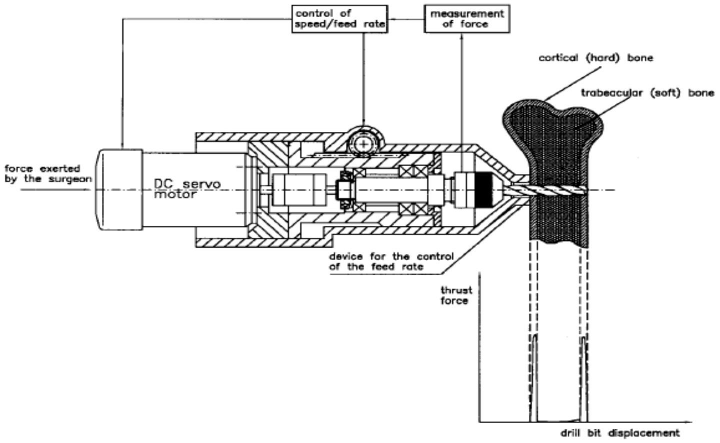

Figure 4: Electronic feedback mechanism [2]

Design Proposal 2: Pressure-Clutch Mechanism

With a pressure-clutch mechanism design, the pressure exerted from the drill bit would activate the clutch and spin the bit. Once the bit had penetrated the posterior cortex of the bone that was being drilled, the bit would stop spinning. This would mean that the device would lock when the clutch was disengaged, as shown in Figure 6. An example of a pressure-clutch mechanism in an automobile wheel is shown in Figure 5.

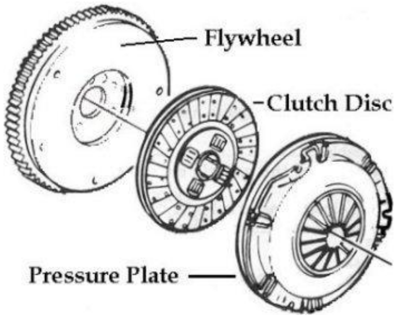

Figure 5: Pressure-clutch mechanism in a car wheel [5]

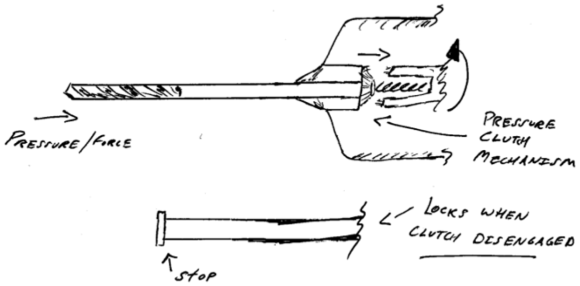

Figure 6: Pressure-clutch design

Design Proposal 3A: Mechanical Design- Thumbwheel

With the mechanical designs, a main focus was to allow for dynamic control of the depth of the drill bit while drilling. The result of dynamic control is a quicker procedure and more accurate drilling. We also plan to measure millimeter increments using detents.

The thumb wheel design consisted of three types of gears: a worm gear, a spur gear (which was the thumbwheel), and a bevel gear. The user would turn the spur gear, which turn the bevel gears. A worm gear would then be used to produce linear translation from the turning of the bevel gears. Detents and indents along the spur gear would provide an audible "click" sound so that the user would know just how far he was increasing the plunge depth. The gear ratios would allow for a very precise depth adjustment. This is a very simple design, but it is somewhat less intuitive and easy to use for the user than the next design, the trigger mechanism.

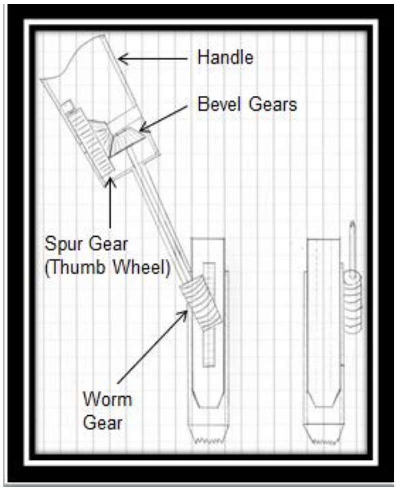

Figure 7: Thumbwheel design

Figure 8: Worm gear example

Design Proposal 3B: Mechanical Design- Trigger

The trigger mechanism is similar to the caulk gun design, where a trigger progresses the drill sleeve forward, which would increase the drill depth. This design is very intuitive and easy to operate for the user. With an ergonomic handle and trigger, the design could be used for long periods of time. The client had originally wanted something similar to a trigger-type mechanism in the early meetings. An example of a current device that uses a trigger is a caulk gun as seen in Figure 9. The trigger and mechanism of the caulk gun inspired some of our ideas for our final design.

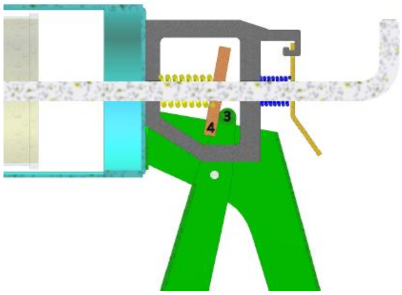

Figure 9: Caulk gun example

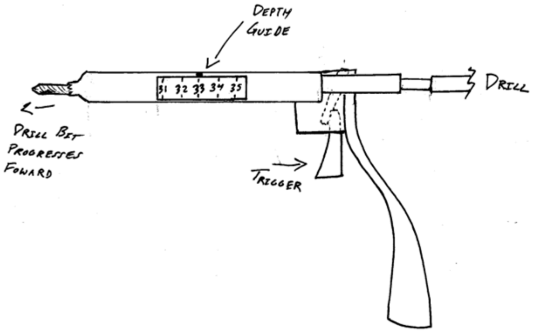

Figure 10: Trigger design

Design Evaluation

Ease of use and precision were weighted the highest in our design selection process because our client emphasized these functions the most when describing what he wanted out of the device. Ease of sterilization, durability, and cost were also factors in our design. Although the electronic feedback mechanism was potentially the most precise design, it would have been more difficult to operate than the other three designs. The pressure clutch mechanism did not stand out in any specific category, although the design would have been fairly precise. The mechanical thumbwheel design was the second most precise design, but it would have been hard to make it easy to use and as ergonomic as the mechanical trigger mechanism. Although the mechanical trigger mechanism was potentially slightly less precise, it scored the highest due to its ease of use as well as high marks in the other areas.

Design Matrix

Design Characteristics	**Mechanical (Trigger)**	Mechanical (Thumbwheel)	Electronic Feedback	Pressure Clutch
Cost (5)	**5**	5	2	4
Durability (15)	**13**	12	10	10
Ease of Use (30)	**30**	25	20	22
Ease of Sterilization (10)	**6**	5	4	6
Precision (40)	**35**	38	40	35
Total	**89**	85	76	77

Table 1: The design matrix.

Final Design

Figure 11: Picture of our final constructed prototype

The completed product is a fully working initial prototype of the mechanical design, and it is shown in Figure 11. This initial prototype was constructed as a proof of concept for our design. Our final design will be a prototype designed for future testing. It will be similar in concept to the initial prototype but with the following improvements: the device is scaled down to the appropriate dimensions for a smaller drill bit, the housing is more compact, the handle is connected to the housing and made out of the same material, a view window is present in the tube of the housing to measure how far the drill bit has advanced, and the trigger is smaller and more ergonomic.

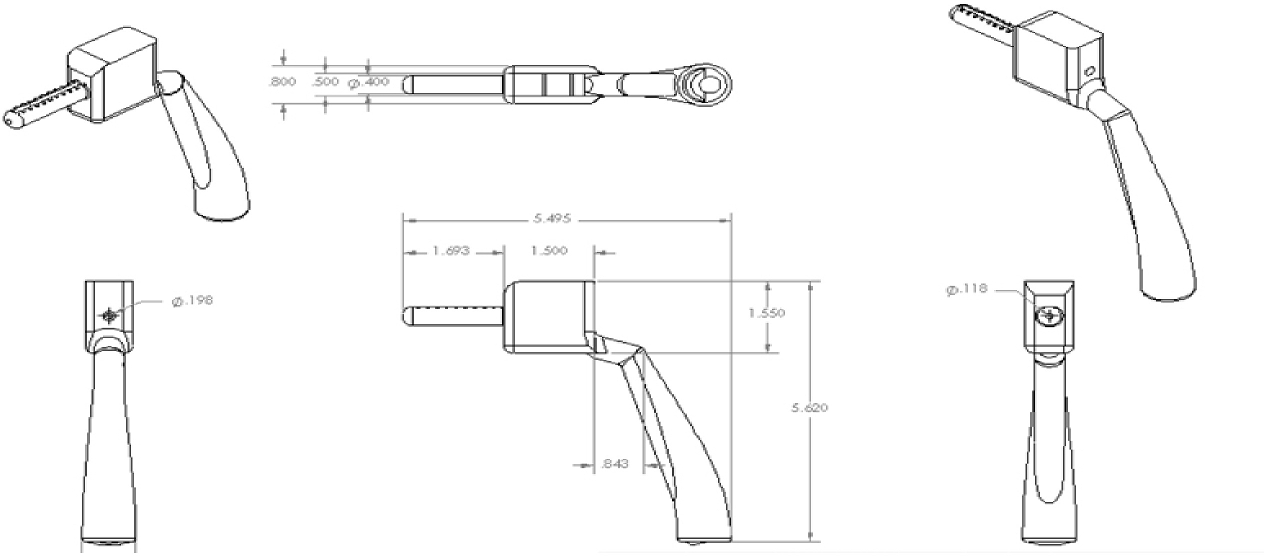

Figure 12: SolidWorks design with dimensions of the final device. Housing will be received on 12/9 and construction will be completed by 12/13 for testing.

The dimensions for the housing and handle of our final design are shown in Figure 12 above. The final design is composed of this outer housing created from a 3D printer using acrylonitrile butadiene styrene (ABS), an inner tube of stainless steel seamless tubing, three metal clutch pieces, three precision compression springs, and a trigger composed of polycarbonate. The set of up the clutches and trigger restricts the advancement of the inner tube to advance only when the trigger is pulled. Two of the clutches are set up inside the housing. There are slots in the upper wall of the housing to hold these clutches in place along with an opposing spring between the clutch and the wall. Looking at Figure 13, from left to right, the geometry of the first clutch allows it to be a locking mechanism such that when the trigger pulls the inner tubing forward, the tubing is not able to return to its original position with the return of the trigger to equilibrium. The second clutch is a locking mechanism that is designed such that at equilibrium, the inner tubing is not allowed to advance forward. This prevents the tubing from sliding forward from force of the drill. When the trigger is pulled towards the handle, the trigger rotates clockwise and the backside of the trigger straightens this clutch allowing forward motion only when the trigger is pulled. The third clutch is what determines the forward advancement of the inner tubing. When pulled, the rotation of the trigger causes forward translational motion of this clutch and increments the tubing by 1.5mm.

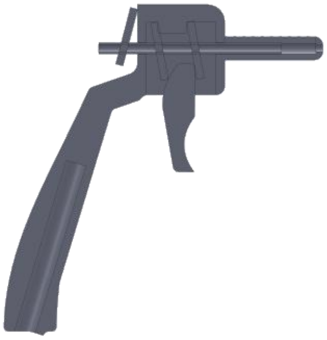

Figure 13: SolidWorks design of a slice through our prototype showing the clutch orientation.

This design is the most appropriate design that fulfilled all of the client requirements. The intent of this device is to minimize plunging and future testing will be done to show the decrease in plunge depth compared to using the current drill sleeve. The current prototype increments the drill bit 1.5mm each time the trigger is pulled. This increment amount can be decreased in the future by adjusting the geometry of the trigger. The current device is a prototype but future work will be done to make the device out of materials appropriate for surgical settings.

Budget

Our client gave us an initial budget of $500 in the beginning of the semester. Thanks to the UW biomedical engineering department, Wisconsin Institute of Medical Research and Wisconsin Institute for Discovery (WID), which printed our plastic housings for free with a 3D printer, it allowed us to stay way under our initial budget. Pending future grants, our budget will be increased for future work in the following semester. Table 2 on the following page breaks down our spending for the entire semester.

Date Ordered	**From**	**Item**	**Product**	**Price**
11/9/2010	McMaster	89955K22	4130 Alloy Steel Aircraft-Grade Round Tube, .250" OD, .049" Wall Thickness, 6' Length	$21.24
	McMaster	9002T24	302 SS Ultra Precision Compression Spring, 3/4" Length, .18" OD, .016" Wire Diameter	$7.47
	McMaster	8574K32	Polycarbonate Sheet, 1/2" Thick, 12" X 12", Clear	$26.31
			Shipping	$16.00
11/11/2010	McMaster	9434K7	Music Wire Precision Compression Spring Zinc-Plated, 3/4" Length, .36" OD, .026" Wire, Packs of 5	$4.98
12/1/2010	McMaster	9435K6	302 SS Precision Compression Spring 11/16" Length, .3"OD, .032" Wire, Packs of 5	$6.11
			Shipping	$4.24
	Online Metals	404822	Stainless T-316/316L Seamless Tube 0.1875"x0.028"x0.1315"	$16.86
			TOTAL	**$103.21**

Table 2: Budget used for the semester so far

Future Work

This semester, our group has worked to design a proof of concept prototype for our client that provides a stop mechanism and drill increment for bicortical drilling surgeries to prevent plunging. A variety of steps now need to be taken in order for this device to be useable by our client and eventually marketable. Now that a prototype is constructed that is dimensioned to fit the desired drill bit used for surgery, testing must be done with Dr. O'Connor. Testing will be done using the prototype to drill into bones to test its compatibility with the drill, its ergonomic feasibility from the user's perspective, and its results on minimizing plunging. The results can be compared to similar testing environments using the current drill sleeve to record improvements using this device. After successful initial testing with the prototype, an actual device can be constructed out of materials appropriate for a surgical environment. Research will have to go into regulations that must be followed with medical device testing. Applications to get approval for animal or human testing can be completed to advance the validity of the testing of our device. Throughout this process more work can go into the improvement of the design, such as making the device smaller and more compact, creating this device for different sized drill bits, and making the initial depth adjustable. Following more testing, an application for a patent can be created and sent to WARF for consideration. Once these have been accomplished, a marketable item can be produced and used by orthopedic residents and surgeons worldwide. This device will reduce human and environmental errors that cause injury to soft tissue past the bone in orthopedic surgeries.

Works Cited

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http://www.acracut.com/perforators.html.

[2] Allotta, Benedetto. (1997) A Hand-Held Drilling Tool for Orthopedic Surgery. *IEEE/ASME Transactions on Mechatronics*. 2 (4), 218-229.

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http://autorepair.about.com/library/a/1i/bl201i.htm

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[8] Nazarenus, inventor, 1979 Feb 6. Drill stop. United States patent US 4,138,200.

[9] Praamsma, M. , Carnahan, H. , Backstein, D. , Veillette, C. , Gonzalez, D. , et al. (2008). Drilling sounds are used by surgeons and intermediate residents, but not novice orthopedic trainees, to guide drilling motions. *Canadian Journal of Surgery*, *51*(6), 442.

[10] Pichler, W. , Grechenig, W. , Clement, H. , Windisch, G. , & Tesch, N. (2009). Perforation of the third extensor compartment by the drill bit during palmar plating of the distal radius. *Journal of Hand Surgery-european Volume*, *34E*(3), 333-335.

[11] Ryan C, inventor, 2004 Mar. 30. Adjustable depth drill bit. United States patent US 7,163,542.

APPENDIX A

Use of drill stop device for more accurate and efficient drilling in orthopedic surgery

Product Design Specification Report

Team Members
Kara Murphy – *Team Leader*
Jonathan Mantes – *BWIG*
Alex Bloomquist – *Communicator*
Graham Bousley – *BSAC*

Problem Statement

Our client, Dr. Tim O'Connor is a Resident in the Department of Orthopedic Surgery at the University of Wisconsin Hospital and Clinics. He is concerned about over penetration of the drill bit into soft tissue during bicortical drilling in orthopedic surgery. The current method involves setting a pre-determined drill depth that is too cumbersome to adjust during the procedure. Our team has been asked to create a design that minimizes the plunge depth of the bit after penetrating the far side of the bone to prevent injury to soft-tissue.

Client Requirements

- Decrease plunge depth from 1.5-3.0cm to 1.0-3.0mm
- Operable by one person
- Reusable
- Able to adjust for varying bone depths during the procedure

Design Requirements

Physical and Operational Requirements

a) *Performance Requirements* – This design must be able to dynamically change the depth of the drill bit during the operation and decrease the amount that the drill bit passes into the soft tissue
b) *Safety* – The device must increase safety by decreasing the amount that the bit plunges into soft tissue. It must be strong enough to stop the advancement of the drill before it plunges into the soft tissue.
c) *Accuracy and Reliability* – +/-1mm
d) *Life in Service* – ??
e) *Shelf Life* – Indefinite
f) *Operating Environment* – This device will be used in a sterile operating room. Each device needs to be able to be sterilized so it can be used for multiple operations. It needs to be biocompatible such that it can come into contact with human tissue.

g) *Ergonomics* – This device needs to be operated by the user individually during a surgical procedure. It must not put any undue stress or strain on either the user or his environment during the operation.
h) *Size* – The model should be handheld and able to be operated by the surgeon during an operation without putting any undue pressure on the surgeon or the patient.
i) *Weight* – The design must be light enough to not disturb drilling accuracy. The weight must be below 1kg.
j) *Materials* – All of the materials used in this device must be sterile, non-flammable non-radioactive, and non-corrosive
k) *Aesthetics* – The aesthetics of this design and not important. It just needs to be clean and sterile.

Product Characteristics

a) *Quantity* – One product that would be able to be mass produced in the future
b) *Target Product Cost* – The target production cost for one product is under $100.

Miscellaneous

a) *Standards and Specifications* – This product would be a class I medical device and thus only subject to general controls, which requires good manufacturing techniques, proper branding and labeling, notification of the FDA before marketing the device, and general reporting procedures.
b) *Customer* – Our customer is an orthopedic surgeon who is looking for a way to increase patient safety and take the variability out of the hands of the surgeons. He is looking for a very simple device, similar to the drill sleeve that’s currently used except with additional features such as dynamic adjustment during surgery.
c) *Patient-related concerns* – Since the product will be used during surgery, it must have an appropriate biomaterial interface to prevent injury or infection to the patient.
d) *Competition* – There has been research done in 1997 which has a drill that is connected to a computerized interface that is able to sense the force on the drill bit. However, this design is too complex for what our client is looking for, it requires additional equipment and an additional attendant to operate. Currently the surgeons are using drill guides, which the surgeons pre-set an estimated depth. However, these drill guides are not able to be adjusted during the procedure which makes them cumbersome to use.