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Orthopedic Anti-Plunging with External Cooling Drill System

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BME 496 Project Proposal Report

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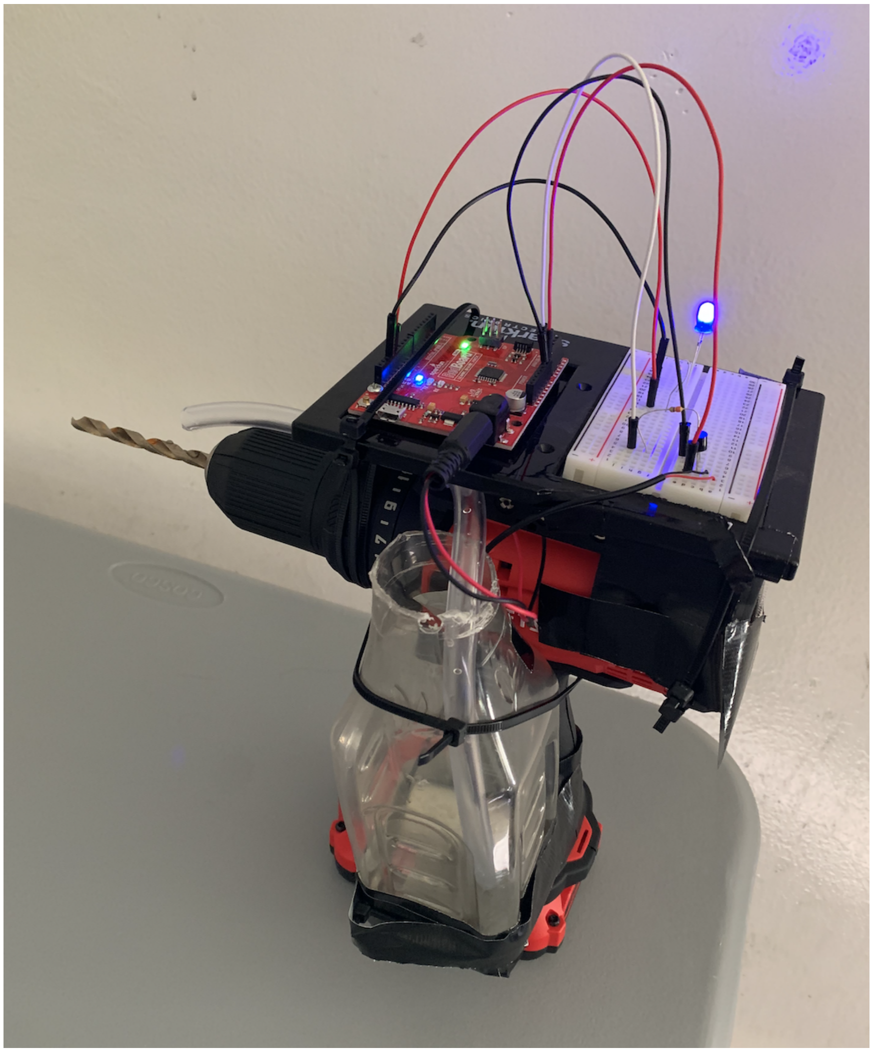
June 8, 2021



Background

Orthopedic surgery is the source of reparation to numerous neuromuscular injuries. There are over twenty million orthopedic surgeries performed each year, making it one of the most rapidly increasing surgical procedures. On average, orthopedic surgeries span slightly over two and a half hours, not including additional time in the operating room and the duration under anesthesia. In a surgical setting, the greater time a procedure takes, the higher the risk for infection. Within operations, orthopedic drills are one of the most important tools used by surgeons as they allow for the creation of holes within the patient's bone which are needed for implanting screws. While medical grade drills do exist, many surgeons prefer to use common household drills to insert screws into bone. The insertion of screws may be necessary depending on the degree, or location, of fractured bone or damaged ligaments. The drill bit used in this process is essential to the successful regeneration of bone and/or adjacent tissues. Helix angle, shape and other factors can lead to dangerously high bone temperatures or the possibility of drilling too deep into the bone encouraging us to focus on thermal necrosis and plunging, which are frequently occuring complications as a result of bone drilling.

Thermal necrosis occurs when heat produced by the drill bit on the impacted bone kills cells in the bone and surrounding tissue [Appendix A]. This excessive heat is typically caused by drills rotating at high speeds but can also occur when surgeons apply too much force to the bone while operating the drill [1]. The drill bit rotation speed and applied thrust force at which necrosis occurs are well understood, but surgeons currently operate on patients without knowing the exact drill speed and force they are applying [2] [Appendix B]. In order to minimize the risk of injuring the patients, surgeons reduce the drill speed and have to constantly monitor the temperature of the drill bit. Reducing the drill speed and force applied can increase the time it takes to complete the procedure and does not eliminate the risk of necrosis due to the increased time it would take to drill the hole. The increased drilling time would also cause an overall increase in temperature at the drilling site.

When osteonecrosis occurs at the site of implants, it weakens the contact between the implant and the bone, due to cell death or reduced regeneration, leading to implant failure. Implant failure is noted to be seen in 2.1%-7.4% of lower leg osteosynthesis, with failure due to osteonecrosis making up a majority of that percentage [3]. It was determined through various studies that drilling at 47°C for one minute can lead to reduced bone regeneration, drilling at 50°C can lead to complete impairment of bone regeneration, and when the temperature reaches 70°C cell death is seen. Therefore in order to avoid serious issues of complications during and post surgery, the temperature of drilling should never exceed 50°C [4].

One way currently used to help maintain lower temperatures was through internal or external cooling systems [Appendix C]. In order to understand temperatures reached during drilling, a number of different parameters have to be considered, with force, feed rate, and drill speed being the most important [5]. Thermal osteonecrosis can be the result of a drilling speed that is too high, drilling for too long of a time duration, or the surgeon applying too much force, all of which have the potential to result in numerous complications within an operation.

While drilling, it is also possible to penetrate too deep. When the feed rate and force are not properly applied to the bone, there is potential to plunge into the bone, crack the bone, or even lead to drill breakage [Appendix D]. Plunging occurs when the drill bit travels through the entire thickness of the bone. Wire depth-gauges have been used to prevent this, however 30% of surgical screws initially placed are the wrong length because of the inaccuracies associated with the use of wire depth-gauges [6], demonstrating their inaccuracies which can still lead to plunging. Minimizing the potential risk for operational complications surrounding plunging, hole depth control has the potential to eliminate the possibility for plunging.

Even with the critical limits of temperature, for thermal osteonecrosis, and depth, for plunging, being known, the drill relies on human control and therefore is susceptible to human error. In order to minimize the risk of osteonecrosis, plunging, or drill breakage, the parameters of drilling must be closely monitored or even controlled by the drill. Therefore, creating a drill system that accounts for depth control gauge and a cooling mechanism that successfully drills holes at minimal speeds with minimal force while still occurring efficiently could pose immense benefits to both medical professionals and patients.

As the physical design process began, looking into various patents that closely resemble design aspects that we were trying to accomplish. The first relevant patent we found was titled “Drill Bit Systems With Temperature Sensors and Applications Using Temperature Sensor Measurements” by Martin E. Poitzsch. This patent claimed to incorporate a drill bit with numerous blades and temperature sensors adjacent to these blades/teeth. The temperature sensors would then provide data regarding the drill bit and the environment in which it is operating [7]. After some review, this patent appeared to be very applicable to our project since our team aimed to incorporate temperature sensors on the drill bit to obtain identical data. This patent was not specific to orthopedic purposes but with additional research, we should be able to utilize similar methods to those of Poitzsch. An additional patent we found was titled “Drill With Cooling Channel” by Knut Gühring. Gühring’s design incorporated a helical cooling channel that travels along the entirety of the drill bit. With this cooling channel, the design maintains a large degree of mechanical and thermal stability which is vital when designing a medical tool. This patent appeared to be particularly relevant to our design since we initially had some difficulties incorporating a functional cooling channel [8]. As a result, our group should be able to gain a better understanding of how this cooling channel functions and how it may help us with our system design. While both of these design aspects did not make it into our final design, we quickly realized that due to our time constraints and readily available resources, we would not be able to pursue either of these avenues. However, while moving away from both of these design ideas, we learned and discovered more feasible design approaches, including our mechanical depth sensor and external cooling system that made it into our final design.

Problem statement

Orthopedic drilling during surgery requires a high level of experience and expertise to minimize complications involving thermal osteonecrosis and plunging through the bone. Thus, an improved orthopedic drill system that allows for the close monitoring of temperature and drilling depth as well as an external cooling system would mitigate the risks of operations and increase the probability of properly functioning implants.

Device Customer Requirements

To serve the needs of our target audience we aim to design and manufacture a drill encompassing the necessary safety features to prevent thermal osteonecrosis and plunging. We have determined a number of different requirements to be included in our design that would be beneficial to the customer. With regards to the prevention of thermal osteonecrosis we have decided it would be very important for the drill to have a continuous cooling system. In addition, it would be of great importance that the coolant does not affect the sterility of the drill. In order to prevent plunging it would be significant for the drill to incorporate a depth measurement system. Along with the measurement it would be helpful if this system was adjustable for varying incision site sizes, as well as if the measurement could be sent to an LCD screen on the drill to be easily read by the surgeon. For more general requirements of the drill, it would be ideal if this system could work for all types of drills and bits, as well as not interfere with the need to change bits during surgery [Appendix E].

Device Functions

Our new drill will successfully drill holes into bone while preventing thermal osteonecrosis and plunging. In order to accomplish this, our drill consists of two main functionality groups: the cooling system, shown in blue, and a depth system, shown in orange (Figure 1).

First, to successfully prevent thermal osteonecrosis, the drill must contain a cooling mechanism to stop the drill bit from generating a bone temperature that poses the threat of inducing thermal osteonecrosis. This will be done by loading a coolant into a reservoir. This reservoir will be connected to a tube in which will be angled towards the drill bit and will expel coolant at set intervals during drilling. This will ultimately reduce the temperature of the bit, not allowing the bone temperature to exceed a dangerous threshold during surgery.

In order to help prevent plunging, the drill must contain a mechanism in which can read the depth that the surgeon has drilled into the bone. This will be accomplished by a mechanical system that attaches to the drill and pushes a bar that measures the displacement of the drill into the bone. This mechanical system should be adjustable to account for differences in incision site size, as well as send the reading to a screen that can be easily read by the surgeon when drilling. In addition, when the drill reaches a certain depth it should alert the surgeon and/or stop the drill.

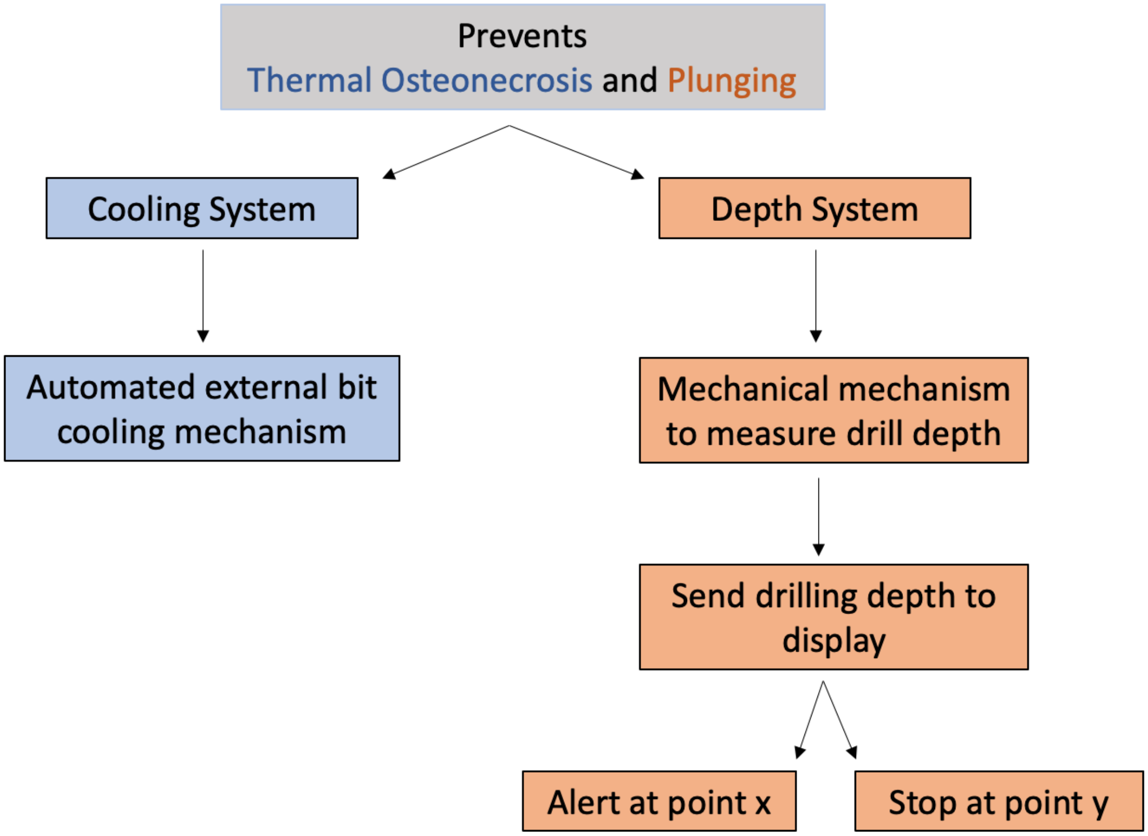


Figure 1. Functional Decomposition

Design Specifications

The design specifications for our orthopedic drill were determined by considering the generated customer requirements, with two more general requirements in mind, which were developing a system that helps prevent thermal osteonecrosis and while also preventing bone plunging. The main functional requirements for our current device are the measuring depth to 1mm accuracy and the external cooling system which cools a drill bit more during surgery than other external cooling techniques. Over the last term we have made adjustments to the requirements as we spoke to medical professionals and heard their critiques and priorities.

Our original requirements surrounding the cooling system aspect of the drill included measuring the temperature and being able to stop when a certain threshold is reached, in addition to a constant internal cooling system. After speaking with our AMC mentor, Dr.Mulligan, we realized how difficult it would be to measure temperature, as well as fit cooling channels in some of the very small drill bit sizes. With his advice that external cooling is effective, we decided to switch to that path. Therefore our new specifications with relevance to the cooling system would be to expel coolant in set intervals onto the bit during drilling, and for the coolant to last the duration of an average surgery. This would eliminate the need for a surgical technician to spray coolant during the surgery and the need to frequently stop in order to refill the coolant reservoir.

As for the depth system, our requirements have also been modified after our conversation with Dr. Mulligan. Our new specifications include a mechanical system that measures the displacement of the drill into the bone. With advice, we also prioritize this system to be adjustable, by roughly 10 cm, due to the variability of incision sites. Another important specification, with relevance to the depth system, would be for the displacement to be displayed for the surgeon to read during drilling.

Documentation of the final design

For the final design of our improved orthopedic drill system we proposed two attachable systems that would help surgeons prevent thermal osteonecrosis and bone plunging in patients. The first, designed to lower the temperature of the bit during drilling, is an external cooling mechanism that automatically sprays a coolant onto the bit at a specified interval. This would mitigate the need for an assistant to spray saline and would allow for more frequent cooling of the bit. The second system is a mechanical depth measurement sensor that includes a biocompatible rod which is in contact with the patient adjacent to the incision site. As the drill proceeds further into the bone the rod is pushed upwards and the depth can be recorded by temperature markings. Both systems are designed to be attachable so that they can be used on any orthopedic drill. They were also designed to meet our original functional requirements of accurately measuring depth to within 1mm of error and reducing the maximum temperature of the bit by 50%.

The final design for our depth measurement sensor is a mechanical system with measurement markings that act like a ruler. The system includes a clear plastic tube attached to the side of the drill with a biocompatible rod inside. The tube is designed to extend a minimum of 5 cm from the drill so that the rod is a safe distance from the incision site. When the bit is first in contact with the bone the rod is placed on the skin of the patient adjacent to the site. As the drill proceeds further into the bone the rod is pushed upwards through the clear plastic tube. Ruler markings on the biocompatible rod can be seen through the clear tube allowing the surgeon to observe the depth measurement. Figure 2 below shows the final design for our depth measurement system.

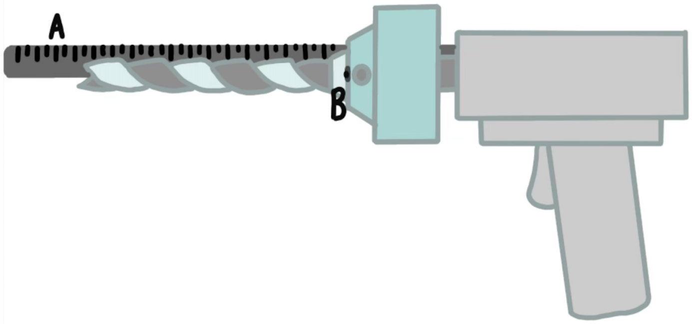


Figure 2. Part A shows the final design for the depth measurement system. The biocompatible rod has measurement markings that can be read through the clear plastic tube which holds it.

The final design for our external cooling system includes a coolant reservoir with a tube that sprays the coolant onto the bit. The reservoir is attached to the handle of the drill and contains a submersible pump with an outlet tube that carries the coolant out of the reservoir to a point directly above the bit as seen in Figure 3 below.

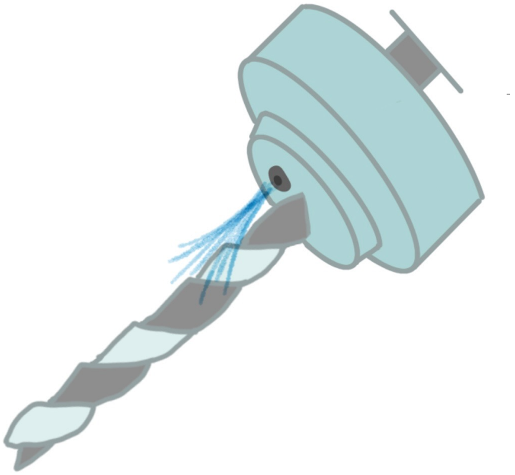


Figure 3. Image showing the outlet of the tube from the cooling reservoir which sprays the entirety of the bit.

The controlling electronics and power source for the pump are designed to be attached to the top of the drill. Both of these parts extend the height of the drill by only 3 cm which ensures that it will not interfere with the surgeon's line of sight while drilling. The pump can be programmed to dispense coolant at any desired interval. For our initial attempt we wrote a code to have the pump spray coolant for a duration of 2 seconds every 10 seconds. This achieves our goal of constant cooling and should prevent the bit from reaching temperatures that can cause thermal osteonecrosis. We also decided to include an LED that turns on while the pump is running to inform the surgeon when the cooling system is on. For the low fidelity prototype of the cooling system we designed a circuit using a Sparkfun RedBoard that can be seen in Figure 4 below. The proposed circuit includes a transistor to ensure enough power is being applied to the pump. By attaching the base of the transistor to an analog input the pump can be programmed using a simple Arduino code which is provided below in the Final Prototype section.

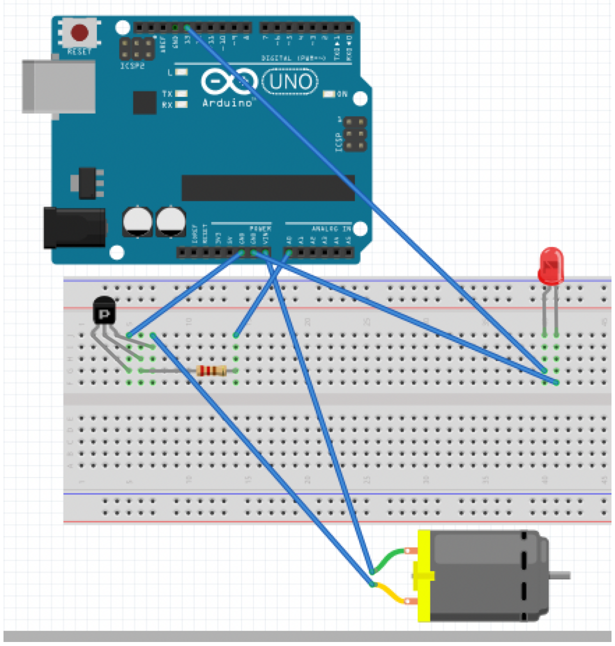


Figure 4. Fritzing diagram of the proposed circuit for the external cooling system.

Final Prototype

Although our final prototype was a fairly low fidelity model of what we were hoping to develop, it serves as a good proof of concept. We were able to attach both the depth measurement system and external cooling system to a hand held drill we bought at Lowes. We decided not to use an orthopedic drill to test our systems because they are very expensive and similar in shape to the drill we found. Both systems are similar to what we had planned for in our final design and function as expected.

The final prototype for our depth measurement system is almost identical to our final sketch seen in Figure 2 above. We fit a clear plastic tube to a wooden dowel and attached it to our drill. We then used a tape measure to put centimeter markings on the clear tube and marked a line on the wooden dowel to be able to record the depth as the dowel moved. Figure 5 below shows an image of our final prototype for the depth sensor. It is very similar to our final design with the exception of the measurement markings being on the plastic tube component instead of the rod. We also have yet to extend the rod further from the bit and incision site as well as find an appropriate biocompatible material.

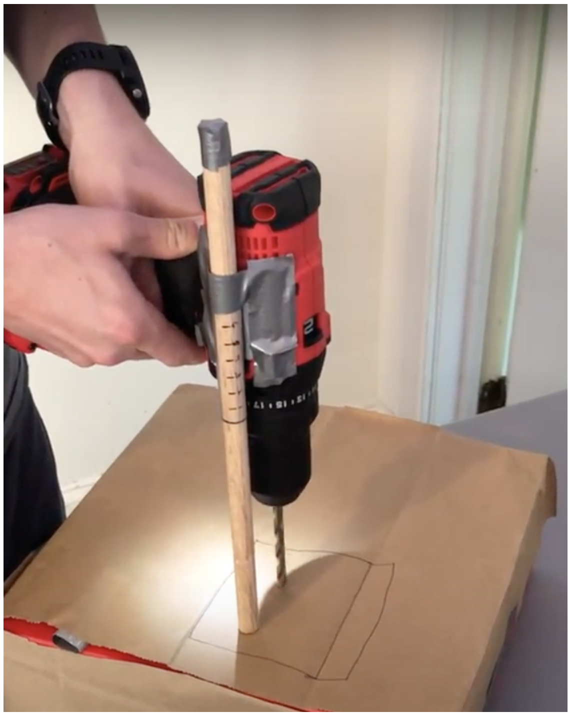


Figure 5. Final prototype for the depth measurement system. Measurements are in centimeters.

The prototype for the external cooling system functioned exactly as expected with the sole exception of the coolant flowing onto the bit instead of spraying. We thought the spray might not apply enough coolant to effectively cool down the bit so we decided to let the coolant flow out of the tube itself. We used a plastic container to act as the reservoir and secured it to the handle of the drill using zip ties. Vinyl tubing was then fitted to the micro submersible pump before the pump was placed inside the reservoir. The other end of the tube was secured to the top of the drill directly above the bit also using zip ties. Lastly, the circuit shown in Figure 4 was built and a code was written using Arduino. Figure 6 below shows the system as a whole.

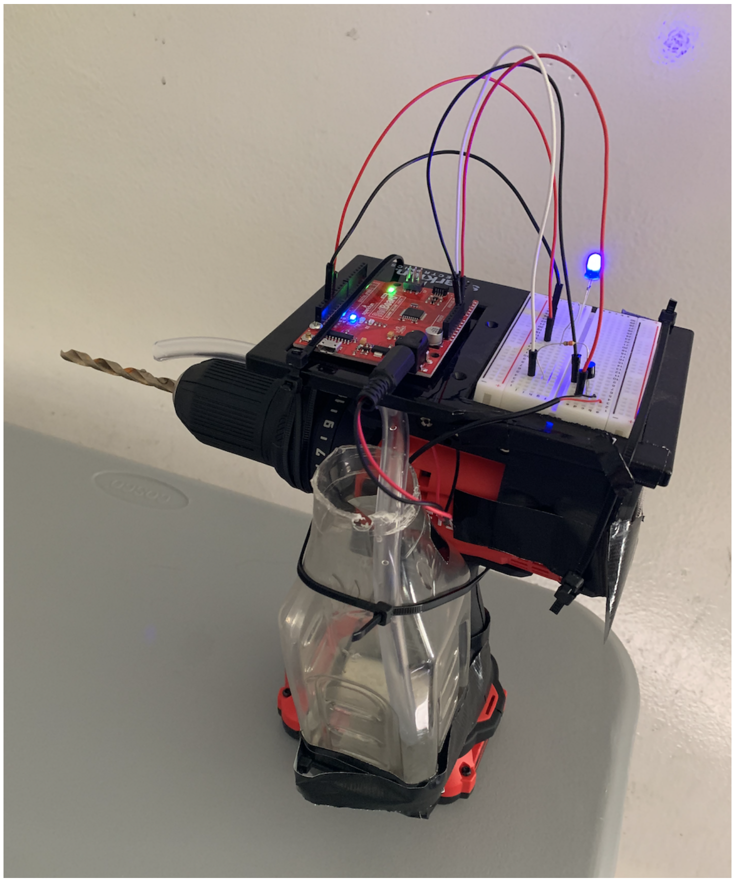


Figure 6. External cooling system including the coolant reservoir in the middle, the outlet of the tube above the bit, and circuit that controls the pump on top.

As specified in the final design, the pump was programmed to run for a duration of 2 seconds every 10 seconds. When the pump is running the blue LED turns on to signal to the surgeon that coolant is being dispensed. Images of both the actual circuit and final code can be seen in Figures 7 and 8 respectively.

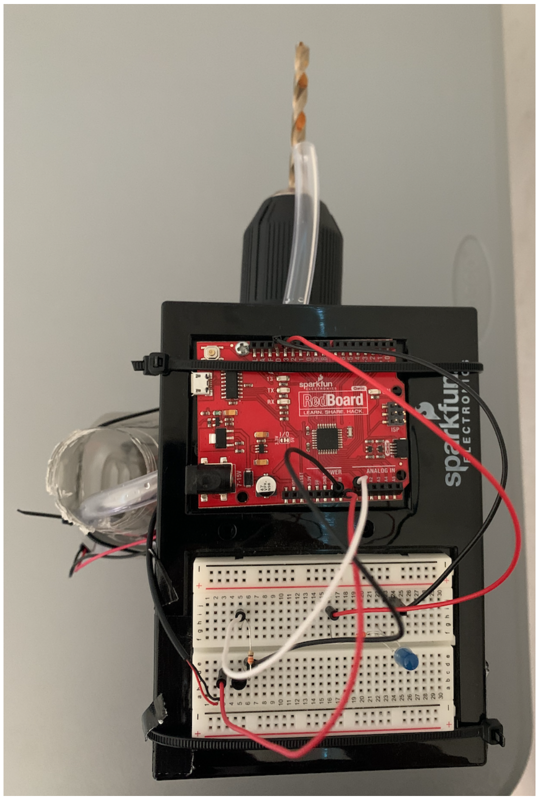
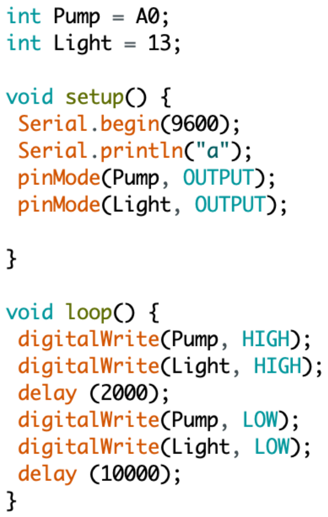


Figure 7. Circuit used to control the pump for the external cooling system.



```
int Pump = A0;
int Light = 13;

void setup() {
 Serial.begin(9600);
 Serial.println("a");
 pinMode(Pump, OUTPUT);
 pinMode(Light, OUTPUT);

}

void loop() {
 digitalWrite(Pump, HIGH);
 digitalWrite(Light, HIGH);
 delay (2000);
 digitalWrite(Pump, LOW);
 digitalWrite(Light, LOW);
 delay (10000);
}
```

Figure 8. Code used to program the pump. The delays can easily be altered to allow for an ideal spray interval for the surgeon.

Design Validation

For our final design, there were two major elements that we tested. The first element was the angle of our tubing that dispenses the coolant. We sought to have the coolant dispensed over the drill bit and onto it so that the drill bit and the surgical site are being cooled simultaneously. To achieve this, we bent the tubing at a few different angles in order to determine the position in which the majority of the coolant is dispensed onto the bit. In doing this, it was determined that a slight downward angle of the end of the tube would allow the coolant to be evenly dispensed over the drill bit while also reaching the surgical site. The angled tubing can be seen below in Figure 9.

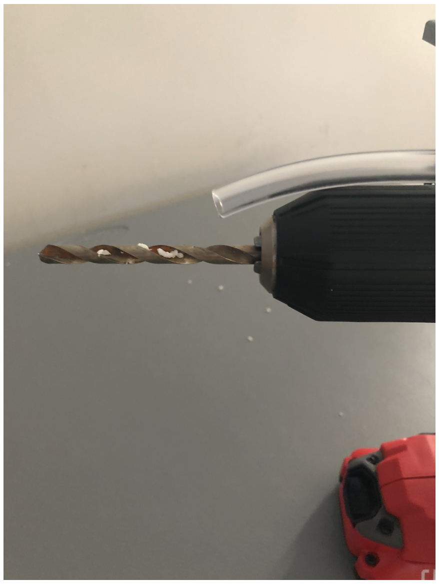


Figure 9. Image depicting the angled tubing that evenly dispenses the coolant over the drill bit.

The second element we tested was the positioning of the tubing. In building the cooling system, we realized that a poor position of the tubing could potentially interfere with the functioning of the drill as well as an effective flow of the coolant. Therefore, we tested a few different lengths of tubing that went to the middle of the drill bit, the insertion point of the drill bit, and a length that does not reach the drill bit. From this we determined that having the tubing remain right over the beginning of the bit would allow for an effective flow rate and it paired nicely with the downward angle of the tubing. The position of the tube with respect to the drill can be seen below in Figure 10.

Figure 10. Image depicting the positioning of the tubing with respect to the drill and the bit.

Ethical Considerations

As with any medical device, ensuring that ethical considerations and requirements are met is of the utmost importance. Not taking into account the ethics behind a device can largely increase the risk of harm coming to a patient that could then potentially lead to further complications. Therefore, when developing our design for the orthopedic drilling system, we did extensive research on an equivalent medical product, in this case a normal orthopedic drill, and based our design off of the equivalent product's classification.

We first determined that our drill would be comparable with other class II devices. The term "class II" essentially incorporates products that have moderate to high risks for patients. The interesting part about our design is that it does not have too many extra parts that would pose further risks when compared to a common orthopedic drill. If this device were to reach the market, the only new potential risk would come from our cooling system. Whether there was too much or too little coolant dispensed, or if the coolant was dispensed in the incorrect location this would be the primary risk coming from our design. It is important to mention however, that it would still have the same risks as the orthopedic drill that is currently used. Overall, our redesigned drill is equatable to the modern orthopedic drill in its ethical considerations.

Anticipated Regulatory Pathway

When introducing a new medical device to the market, there is an extensive regulatory pathway that it must follow if it is to be approved by the FDA. This process begins with the classification of one's product as a medical device. In our case, the orthopedic drill was determined to be a medical device and as it was mentioned in the ethical considerations section, a class II device. As it is consistent with most class II devices, our orthopedic drill will most likely undergo a 510(k) submission. As a result, we looked at other 510(k) submissions on the FDA database that were similar to our proposed drilling system. In doing this, we found a device called "Consensus (™) Orthopedic Drill Bit". The 510(k) number was K950013 and its applicant was "U.S. Medical Products, Inc., 912 South Capital of Texas HWY, Suite 100, Austin, TX 78746". The product code was "HWE" and this refers to surgical instruments motors and accessories/attachments as the regulation description, an orthopedic review panel, and a regulation number of 878.4820. Unfortunately, this product did not provide any summary but our assumptions for its intent of use was for the drill bits to be compatible with orthopedic drills.

As for any differences that this FDA approved device has with our proposed drilling system, the only real differences would lie in the additional functions of our drill. Since the FDA approved device is simply drill bits, there would be no difference here since our system made no changes to commonly used drill bits. It is simply the cooling system and depth measurement system that are different and even then, these systems do not affect the drill bit in any way.

Conclusions and Future Work

After having worked on this project for the past twenty weeks, we have learned a lot about the time and effort it takes to design a functioning medical device. We were very optimistic with our plans from the very beginning, but we quickly learned how many obstacles there are on the way to success. To begin, our initial plans were to redesign orthopedic drill bits so that they can be changed much more quickly in the operating room while maintaining sterility. Within three weeks after formulating this plan, our design underwent a huge pivot as we realized that the changing of drill bits is not a huge issue within the operating room. From there, we did a lot of brainstorming in order to come up with our new problem to solve. This new issue of thermal osteonecrosis and bone plunging was the driving force of our final product. At this point, we formulated many goals for the design that included an internal cooling system, a laser-based depth sensor, alert systems and other ideal subsystems. However, as time passed and more research was conducted, we soon learned that not all of this could be achieved in such a short period of time. Our first and second prototypes saw a degree of success but nowhere near where we had hoped to be. This is not to say that we are not proud of how everything came out. In our final design, we had an external cooling system that dispenses coolant intermittently and if this design were to be pursued, then it could potentially be brought to the market in the future.

If we were to evolve this design going forward, we would first pursue a higher fidelity prototype for the cooling system. As it stands, the cooling system has not been tested for temperature change in the material being drilled. Therefore, we would need to acquire some temperature sensors and OpSite spray in order to ensure that the cooling system works for its intended purpose. We would also need to get higher quality materials for the cooling system and make sure that they work seamlessly within the system while not inhibiting the surgeon's work in any form. As for the depth system, we would need to figure out a way to ensure that it is useful for the surgeons since the way it stands now, the surgeons would need to know the exact dimensions of each patient's bones and tissue which is not plausible.

The past two terms of working on our orthopedic drill has been both informative and exciting as we had the opportunity to learn the ins and outs of creating a medical device and bringing it to the market. We underwent numerous challenges and issues but those obstacles were all a vital part of the learning process. With more time and commitment, our orthopedic drill has the potential to become a formidable medical device that can help prevent thermal osteonecrosis and aid both doctors and patients.

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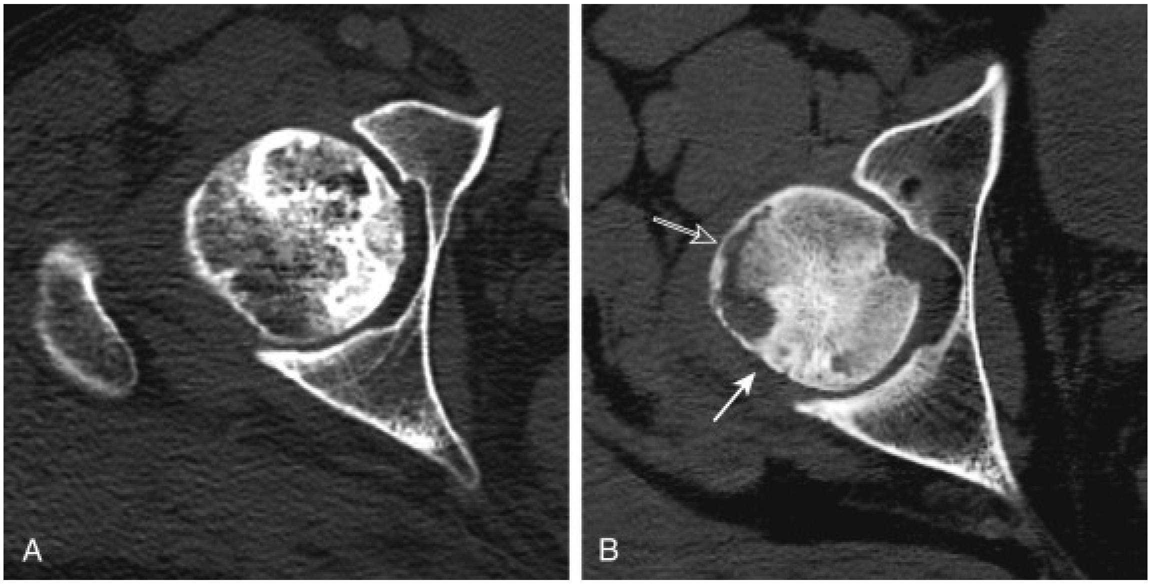
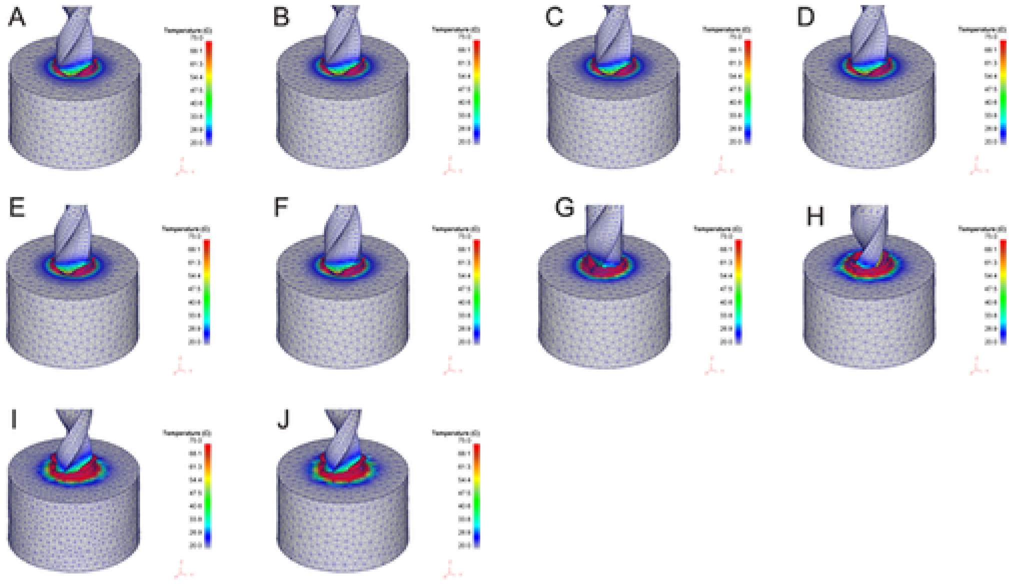
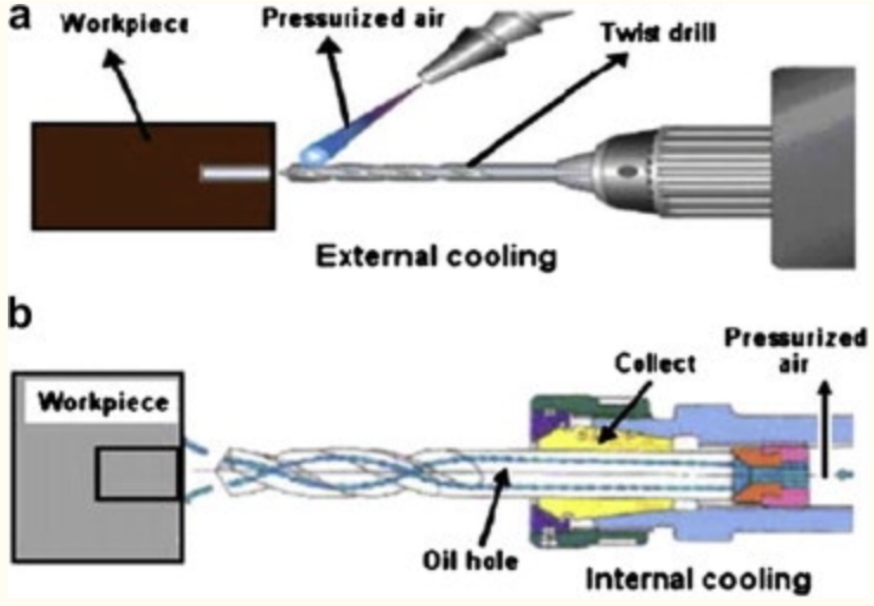
Supporting documents



Appendix A. Tomography scan showing osteonecrosis of the femoral head. This is relevant in joint replacements or any procedure involving an implant because osteonecrosis causes bone resorption which loosens the bone's grip on the implant.

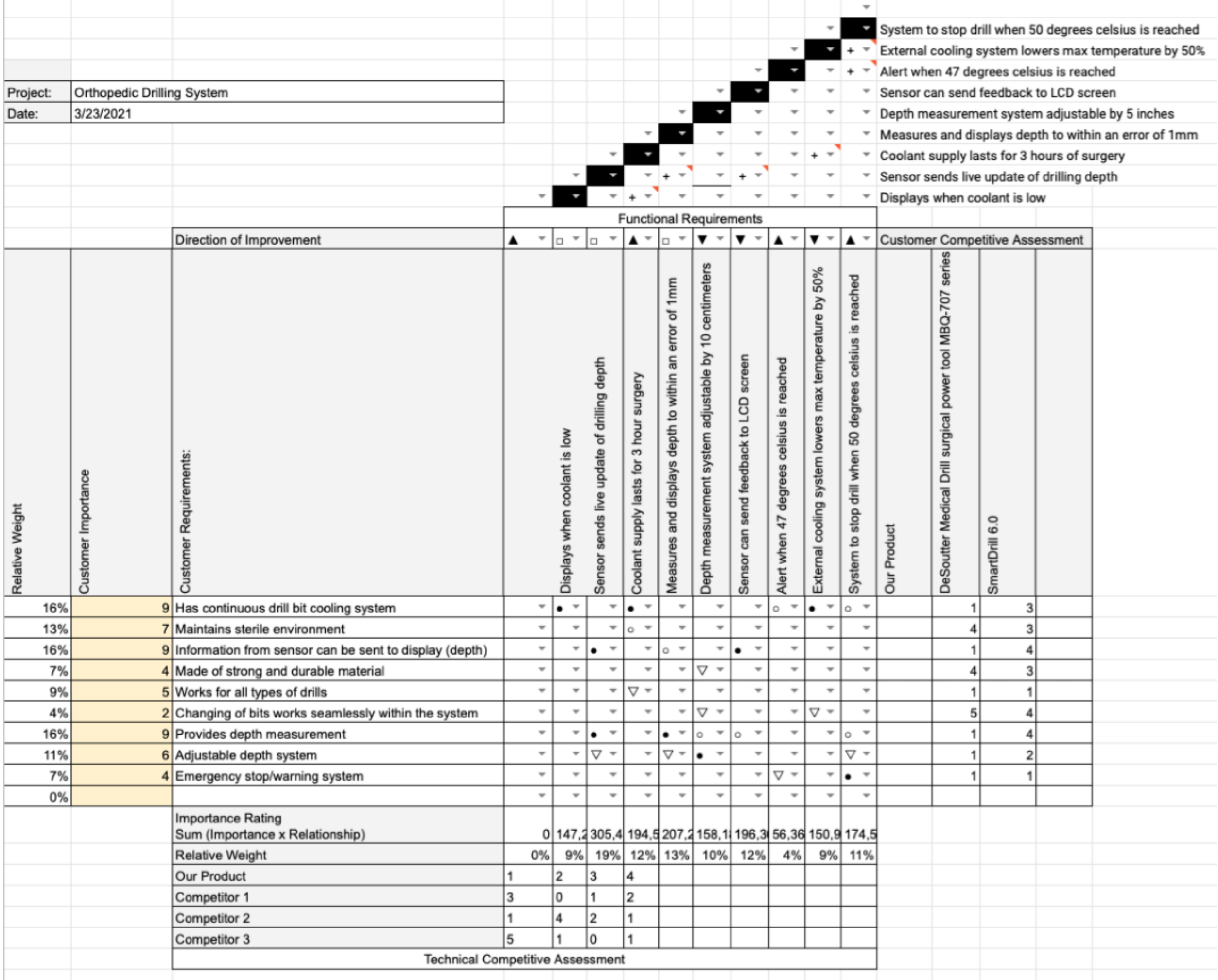


Appendix B. Temperature distribution of a drill while drilling into bone in a simulation using FEA. Drill speeds that create temperatures leading to necrosis can be determined. This would make a drill that provided speed feedback useful for surgeons.



Appendix C. This shows internal and external cooling techniques used in orthopedic drills. These techniques of cooling are found to be very helpful at keeping the temperature below the critical value of 50°C. The internal technique could be something to consider during concept development and as an emergency response implemented in the drill for cooling.

Appendix D. This figure is showing an X-ray of a broken portion of the drill bit left behind. This is often caused when there is excessive force. Drill breakage is not good for the patient and could be avoided with better monitoring of force and feed rate.



Project:	Orthopedic Drilling System
Date:	3/23/2021

								■	System to stop drill when 50 degrees celsius is reached
							■	+	External cooling system lowers max temperature by 50%
						■		+	Alert when 47 degrees celsius is reached
					■				Sensor can send feedback to LCD screen
				■					Depth measurement system adjustable by 5 inches
			■						Measures and displays depth to within an error of 1mm
		■					+		Coolant supply lasts for 3 hours of surgery
	■		+		+				Sensor sends live update of drilling depth
■		+							Displays when coolant is low

Functional Requirements

Relative Weight	Customer Importance	Customer Requirements:		Displays when coolant is low	Sensor sends live update of drilling depth	Coolant supply lasts for 3 hour surgery	Measures and displays depth to within an error of 1mm	Depth measurement system adjustable by 10 centimeters	Sensor can send feedback to LCD screen	Alert when 47 degrees celsius is reached	External cooling system lowers max temperature by 50%	System to stop drill when 50 degrees celsius is reached	Our Product	DeSoutter Medical Drill surgical power tool MBQ-707 series	SmartDrill 6.0	
		Direction of Improvement	▲	□	□	▲	□	▼	▼	▲	▼	▲	Customer Competitive Assessment			
16%	9	Has continuous drill bit cooling system		●		●				○	●	○		1	3	
13%	7	Maintains sterile environment				○								4	3	
16%	9	Information from sensor can be sent to display (depth)			●		○		●					1	4	
7%	4	Made of strong and durable material						▽						4	3	
9%	5	Works for all types of drills				▽								1	1	
4%	2	Changing of bits works seamlessly within the system						▽			▽			5	4	
16%	9	Provides depth measurement			●		●	○	○			○		1	4	
11%	6	Adjustable depth system			▽		▽	●				▽		1	2	
7%	4	Emergency stop/warning system								▽		●		1	1	
0%																
		Importance Rating Sum (Importance x Relationship)	0	147,2	305,4	194,5	207,2	158,1	196,3	56,36	150,9	174,5				
		Relative Weight	0%	9%	19%	12%	13%	10%	12%	4%	9%	11%				
		Our Product	1	2	3	4										
		Competitor 1	3	0	1	2										
		Competitor 2	1	4	2	1										
		Competitor 3	5	1	0	1										

Technical Competitive Assessment

Appendix E. QFD of the orthopedic drilling system. The chart displays both the customer and functional requirements of the drill system as well as their correlations. In addition, there are two competitors within the QFD that are compared with our drill system. It can be found at the following link: https://docs.google.com/spreadsheets/d/1pcm55vSC7XierEDTwE0-p4GFI5sN3zW6xwgMilx4UCY/edit#gid=0