Cast Saw Cooling Device

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Abstract

The application of hard plaster or fiberglass casts is common in clinical settings to immobilize appendages or larger sections of the torso and aid in the healing process. Casts are most often used in long bone fractures which occur with the greatest frequency in adolescent and elderly patients. Friction between casts and cast saws used in cast removal is known to heat the vibrating saw blade. While burns can occur at temperatures as low as 44 °*C*, cast saw blades can reach 101 °*C* during the removal process[3]. While studies have attempted to use extra padding, different cutting techniques, heat sinks, pressurized air/water, blade material, and vacuums to cool saw blades, no solution has been practical and effective enough to change hospital practices. Our goal was to design a system that cools saw blade temperatures below 44 °*C* and is adaptable enough to function for the various cast saw models used in hospitals. The final prototype used mist to consistently cool the saw blade below 25 °*C*. The mobile product with simple components could be implemented in clinical practice with no necessary operator training.

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I.Introduction

1. Motivation

In Orthopedics, casts are commonly applied to patients to immobilize healing structures, mostly bone. Splints may be applied temporarily before a cast when swelling is present. Casts provide protection and support for a bone to repair itself. After the patient has healed, the casts are then removed with cast saws. A brace may be required after cast removal[19]. While cutting, the saw generates heat and the blade can reach temperatures of up to 101°C[3]. In a study conducted by Ansari *et al*, 28 of 3,875 (0.72%) patients who had a cast removed suffered burning and blistering of skin[1]. While cast saw burns may seem rare, it is not only bad practice to ever inflict unnecessary harm to a patient, but the costs associated with cast saw related injuries have been reported to be as high as 15,898 USD per patient for one year[1].

Orthopedic pediatrics and geriatrics use casts with the greatest frequency. The most frequent major injury among children are extremity fractures[2]. Some children experience a significant amount of fear during the cast removal process. The fear may be a result of many factors: the loud, vibratory nature of the cast saw, proximity of a saw near their recently injured body, unfamiliarity in hospitals, or other factors.

2. Problem Statement

During the removal of the cast, oscillating cast saws are used to cut through the plaster or fiberglass material. As the saw is cutting through the material, friction between the blade and cast material generates heat and the blade can reach temperatures of up to 101°C[3]. As temperatures as low as 44°C and 60°C can result in second and third degree burns respectively, there exists a need to design a system that prevents heat damage to patients' skin[4].

II. Background

1. Skin and Conditions for Burning

The skin consists of three layer subtypes. The epidermis is the first layer and is composed mostly of keratinocytes and dendritic cells. The second layer, the dermis layer, makes up the bulk of the skin, giving it its flexibility and tensile strength. The hypodermis, or subcutaneous layer is comprised of connective tissues, larger blood vessels, nerves, and stores lipocytes[21]. Burns are generally classified into three severity levels. First degree burns are superficial only and don't penetrate through the epidermis. Second degree burns penetrate at least partially into the dermis layer. Third degree burns damage tissue through the dermis layer and into the hypodermis.

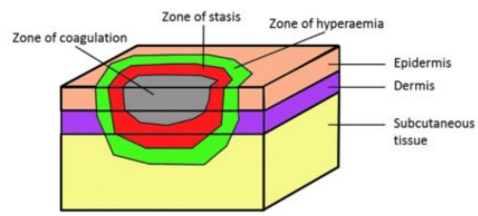


Figure 1: Dermal layers and burn injury zones [20].

Burnt tissue heals at a slower rate than most other flesh injuries. At the center of a third degree burn, low oxygen penetration in the zone of coagulation limits cell survival and regeneration[20]. The zone of stasis surrounds this necrotic tissue and is associated with vessel damage. While this injured zone usually recovers fully, local inflammatory reactions can lead to persistent vasodilation and edema. The inflammatory response phase resolves with the apoptosis of neutrophils and macrophages' expression TGF-β1, fibroblast growth factor, and epidermal growth factor to facilitate tissue remodeling. Fibroblasts continue to remodel the extracellular matrix for two weeks.

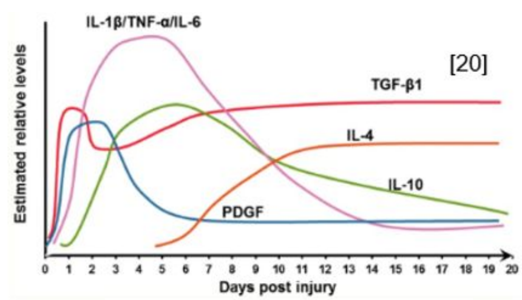


Figure 2: Cytokines and growth factor levels fluctuate as the wound site is remodeled [20].

Skin burns are the most commonly occurring problem when using a cast saw. Because of the vibration of the cast saw blade, high temperatures can result from the friction of the blade against the cast material. Contact of the hot blade with skin will certainly cause a burn, but heat inducted even through cotton padding has been known to injure patients. However, some safety procedures that could prevent burn include applying lighter pressure when cutting the cast or waiting several minutes before the next cut to allow blade to cool[5]. Also, replacing old blades more frequently would reduce friction. Moreover, previous research has examined methods to reduce blade temperature. According to Puddy et al., cooling the cast saw blade with 70% isopropyl alcohol or with water spray resulted with the fastest cooling times for the blade as opposed to air cooling[6]. Additionally, Shuler and F. N. Grisafi suggested that applying more layers of the cast padding could decrease temperature change[7].

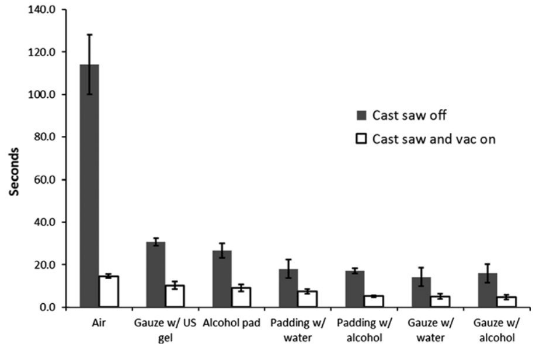


Figure 3. Cooling time (in seconds) of various blade-reducing temperatures. Taken from [6] A. C. Puddy, J. A. Sunkin, J. K. Aden, K. S. Walick, and J. R. Hsu, "Cast Saw Burns," *Journal of Pediatric Orthopaedics*, vol. 34, no. 8, 2014.

2. Casts and Cast Saws

The cast saw is a vibratory tool that is used to remove orthopedic casts. Unlike circular saws with rotating blades, cast saws have sharp, small-toothed blade oscillating back and forth over a very small arc to cut the material. The general design enables the saw to cut through rigid cast materials but not through soft tissues such as skin. An orthopedic cast is frequently made from plaster or fiberglass along with a cotton bandage as a padding to skin. Plaster cast consists of a fine white powder (calcium sulfate hemihydrate), which can be hardened after contacting water[18]. Fiberglass, on the other hand, is often impregnated with polyurethane, therefore it can change shapes by altering temperature. It is lighter and more durable than plaster and it is water resistant. Both materials offer high heat resistance and low thermal conductivity[18]. For both however, the cast saw generates friction with the cast during cutting process, which is the major cause of burns.

3. Competing Designs

Two designs that currently exist are a cooling system for rotary blade used in sawing of concrete and a patent for vacuumized surgical cast saw cutter. For the cooling system, cooled air travels through inlet pipes[12]. Water absorbs and carries away the dust created by the saw blade. This design is useful because only small amounts of water are necessary to cool the blade. For the vacuumized surgical cast saw cutter, testing showed temperature of the saw blade decreased as a result of the vacuum[13].

4. **Design Specifications**

Since the ultimate goal of this project is to cool the temperature of the cast saw, the cast saw temperature must not reach 44 $°C$. The client requested modifications to the cast saw, not the cast itself. In addition, adding more layers to a cast increases costs for hospitals and clinics. Overall, the only part of the blade that needs to be cooled is the bottom third, or the only part making contact with the cast itself. Some specific requirements were discussed below. First, the cast saw should not cause burns or cuts to patient, and the cooling solution should not cause any allergic reactions. Moreover, the device needs to cool the blade temperature below 44 $°C$ to prevent secondary injury. At the same time, the device should be reusable and have the same service life as the blade. Also, the saw with the design should be able to be comfortably held in one hand. So the cooling system should not impede cutting ability. The entire assembly should be no more than 2.94 kg. Furthermore, the device should be mass producible and be compatible to all saw types. The budget for the project is 100 USD .

III. Preliminary Designs -

Design Idea 1- Cold Tubing

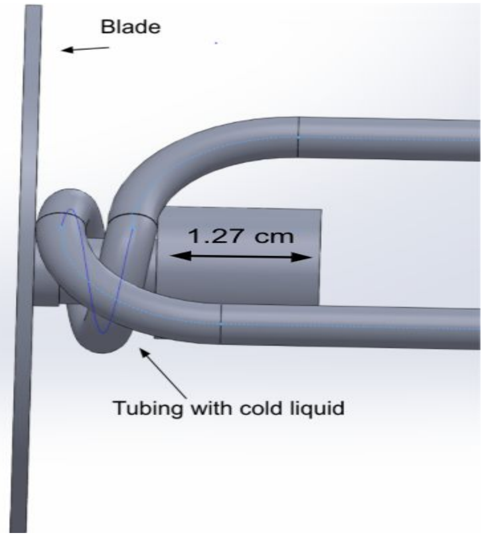
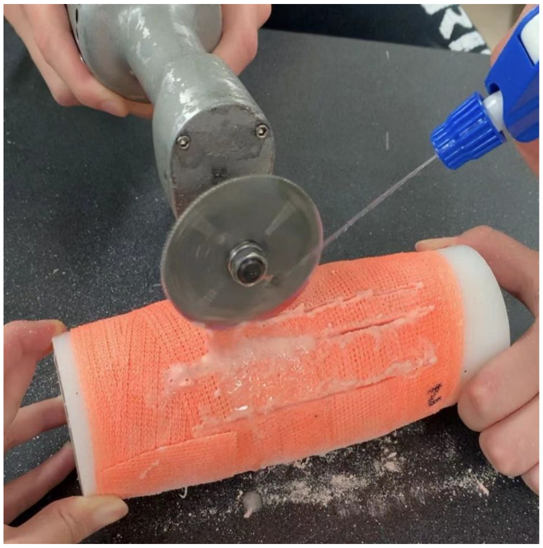


Figure 4. Initial Cold Tubing design with 1 mm diameter PVC tubing wrapped 360° to the blade attachment (left); The preliminary testing procedure following the initial design idea (right).

A cold tubing design uses the high heat capacity of water and the thermal conductivity of the PVC tubes to cool the blade down. PVC tubing was utilized in design instead of metal because it was readily available and also provides the flexibility to wrap 360 degrees around the saw blade. The design includes a running water system that flows water through the tube then down into a reservoir so that water could continuously carry heat away from the blade. The idea comes from the cooling system for PC computers where the coolant is used to cool down a copper metal (high thermal conductivity) then copper cools the computer drive[8]. One of the advantages of the cold tubing design is that water does not directly contact with the blade or the cast so that it prevents further wetting of the device. Also, the replacement of the tubing design is convenient for users.

Design Idea 2: Mist +Vacuum



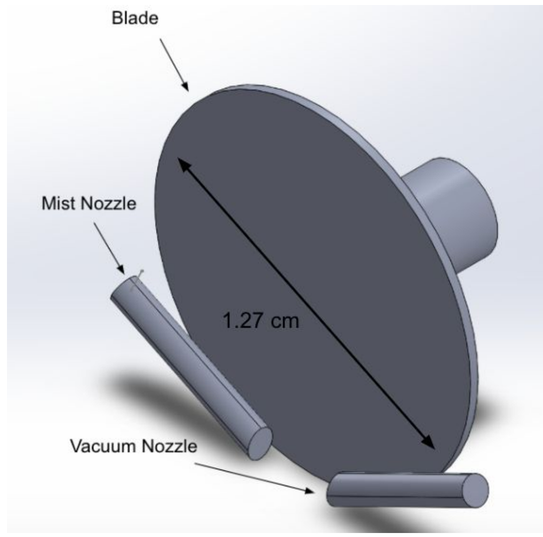


Figure 5. The left image shows the preliminary design where the team used a spray bottle to mimic the misting effect. Sketch of misting + vacuum design with one misting nozzle spraying either water or alcohol and the vacuum nozzle gathering water (right).

Cooling the saw with alcohol along with Stryker Cast Vacuum results in a lower temperature of the oscillating blade[9]. Both a vacuum and misting nozzle are installed in front of the blade where the blade cuts the cast. Two nozzles face each other in order for the vacuum to immediately suck the mist without leaving any alcohol on the blade. The advantage of the design is that it rapidly cools both the blade and the cast without impeding the oscillation. Also, the oscillation of the blade would not cause an early deterioration of the cooling device as there should be no friction from the saw on the misting device. However, the two nozzles may block physicians views when they are performing the cutting process. At the same time, the design creates a saw with a significant mass, making it difficult for the user to carry.

<u>Design Idea 3:</u> Compressed Air + Vacuum

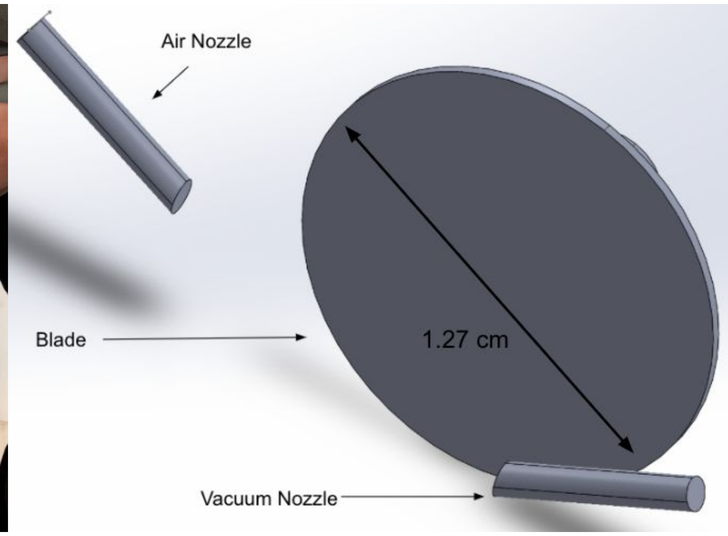
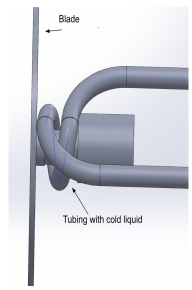
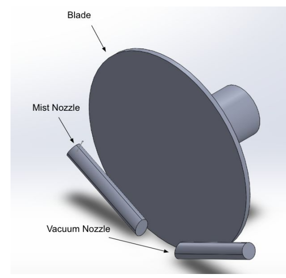
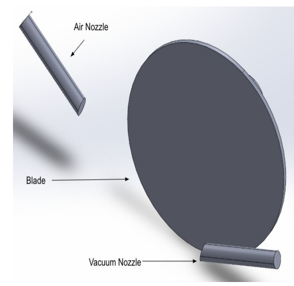


Figure 6. Compressed air design with an air compression nozzle blowing directly into the cast following along with the saw, while vacuum sits facing the air nozzle (left/right).

The design aims at taking away the heat by blowing cold air directly towards the cutting site. Compressed air would need to be accessible in the procedure room when the cast is removed[9]. Due to the high pressure from the air, the device can be cooled within a few seconds. However, the major concern for this design is that the air may blow dust in many directions, making the vacuum less efficient. Moreover, the compressed air needs to be carried with a compressed air tank, which is very hard for storage. In addition, the client shared that compressed air is not present in casting rooms. Implementing this design would increase hospital costs as they would need to place a compressed air system in the casting room.

IV. Preliminary Design Evaluation

1. Design Matrix

	Design #1 	Design #2 	Design #3 
Design Criteria	Cold Tubing	Misting System	Compressed Air + Vacuum
Cooling Reliability (35)	4/5 28	5/5 35	4/5 28
Ease of Fabrication/Assembly (15)	5/5 15	5/5 15	3/5 9
Ergonomics/Ease of Use (10)	3/5 6	2/5 4	2/5 4
Durability (10)	2/5 4	3/5 6	4/5 8
Aesthetics (10)	3/5 6	4/5 8	3/5 8
Cost (10)	4/5 8	4/5 8	3/5 6
Safety (5)	5/5 5	4/5 4	3/5 3
Fear Factor (5)	4/5 4	3/5 3	1/5 1
Total (100)	76	83	67

2. Justification of Criteria and Weight

Cooling Reliability

Cooling reliability (weight: 0.35) is the most important criteria because it is the main problem that the client mentioned. Cooling the blade will reduce the number of burns. Compared to other factors, cooling reliability is the most important factor. If the blade is not reliably cooled, the problem has not been solved.

Ease of Fabrication/Assembly

The time frame for creating one prototype was one semester, or three months. Special consideration of the time frame is essential in determining if the final design is mass producible and able to manufacture. The client only asked for one unit, but the design should not be too complex that it can not be easily manufactured.

Ergonomics/Ease of Use

Removal technician should be able to remove cast using the new design with relative ease. The added features of the cooling system should not hinder cast saw operation and translocation hindrances should be minimized. This constraint has a higher weight (0.15) than other factors because if the operator cannot properly operate the saw, the likelihood of injuries arises. The main goal is to avoid injuries.

Durability

The cast saw cooling mechanism should have the ability to withstand wear and tear due to normal use.

Aesthetics

Final design should look professional. Working with pediatric patients, careful consideration is noted when choosing parts for the design.

Cost

Although budget is important to any design, the parts required for the cooling system are relatively inexpensive. The estimated expense is less than $60, whereas the client has communicated a budget of roughly $100. Therefore, cost is not as important is cooling reliability or ease of use, per se.

Safety

While safety is perhaps the most important consideration in any health related design, we gave it a low weight because the main danger to the patient is caused by the saw itself. The design should not add a significant amount of safety concern so the weight is low (0.05).

Fear Factor

Fear factor has the lowest weight of the design criteria. However, the fear factor is a design criteria because some of the designs include the vacuum system and mist, which may scare children. As the client mentioned, the device will often be used in pediatrics so it should not cause any discomfort for children.

3. Proposed Final Design

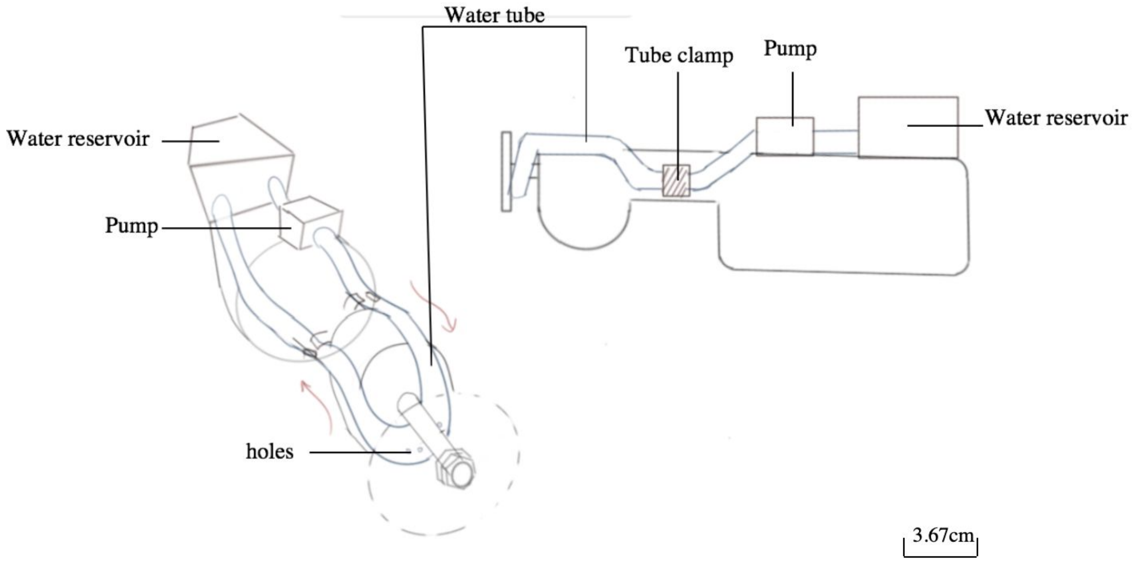


Figure 7. Preliminary design that incorporates mist and cold tubing idea. The tube was attached to the blade attachment point, wrapping approximately 360°. The tube was connected to a pump and reservoir used to provide constant flow and recycle water.

Our proposed final design is the mist + vacuum design. This design faired best among the criteria listed. Overall, the mist + vacuum design has the highest potential for cooling reliability, the largest factor in the design matrix. Although there are cons to this design, such as a greater fear factor and usage difficulty, the main priority is solving the client's issue. It is likely that the final design will include aspects of all three designs to eliminate other issues. Figure 7 shows a preliminary design that combines mist and cold tubing together. The mist can be generated from the holes of the tube. The whole device can be easily detached from the saw for carry.

V. Fabrication/Development Process

1. Materials (appendix 2)

The materials used for the design were circuit components, a tube with perfume nozzle attachment, and a water reservoir. The circuit was comprised of a 1 *kΩ* potentiometer, 12 *V* DC battery sources, 2-snap switch, and a peristaltic pump. These parts were responsible for moving water throughout the tubing A velcro strip was purchased to attach the tubing and nozzle securely to the cast saw on top of an HDPE block. A 60 ml syringe was used as the water reservoir because it was readily available in the lab, easy to use, and the perfect size for the chosen design. In addition, a hole could easily be drilled into the syringe. Then, the tubing could be attached the syringe for water to flow through the tubing.

2. Methods

The circuit component was designed in series (**Figure 8**). Battery was used as the power source, as the peristaltic pump can only withstand maximum 12 *V* power. A potentiometer controls the voltage supplied to alter flow rate as needed. The smallest, most-budget friendly potentiometer available was a 1 *kΩ* one. A two-snap switch was used to control the voltage. The switch can be used on 10 *A* 125 *V* or 6 *A* 250 *V*, therefore it was safe enough to be implanted on the design. A peristaltic pump is used so that the pump does not come in contact with the water. All the components were soldered to keep components sterile. The components were then placed into an ABS circuit box (**Figure 8**).

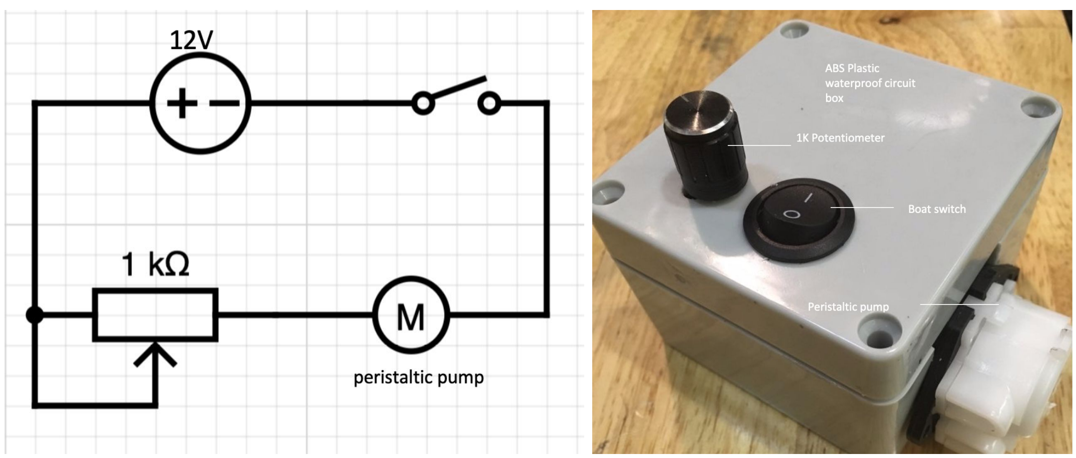


Figure 8: The schematic circuit in series(left). The circuit includes a peristaltic pump, *kΩ* potentiometer, 12 DC voltage and a 2-snap switch. A final composed circuit box (right) with pump, switch and potentiometer stick out. The ABS plastic circuit box measured 8.4 cm x 8.1 cm x 5.6 cm.

The chosen silicone tube (l = 3 m, d = 2 mm) was compatible with the pump because the tube needs to be stretchable in order for the pump to work. Also, Figure 10 suggested that increasing the tube length didn't decrease the flow rate of the pump, so a longer tube could increase the mobility of the design. HDPE block was used for tube holder because HDPE material can withstand temperatures of 130°C without melting, and it is easy to manufacture. The HDPE holder contains a notch to secure the tube and also a hole for the velcro strip. The block was manufactured using mills in the TeamLab at the University of Wisconsin-Madison. The velcro strip secured the tube to the saw. Changing the length of the tube is possible, making the design compatible to every saw type (**Figure 13**). A metal gardening nozzle was originally going to be used for the design; however, it turned out that the peristaltic pump couldn't generate enough pressure for the nozzle. This caused water to leak at the side. Luckily, a perfume nozzle could be attached onto the tube, even with the supplied pressure. Although the perfume nozzle is not ideal for sterility purposes, it worked well with the design. The perfume nozzle was removed from free cologne sample (**Figure 9**).

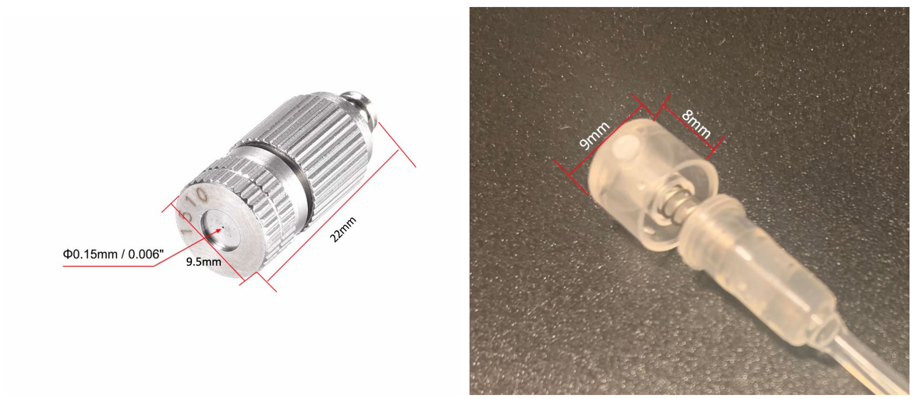


Figure 9: The metal nozzle initially used for testing (left). This nozzle required higher water pressure otherwise it leaks from the side. The perfume nozzle (right) was the one that is currently in use.

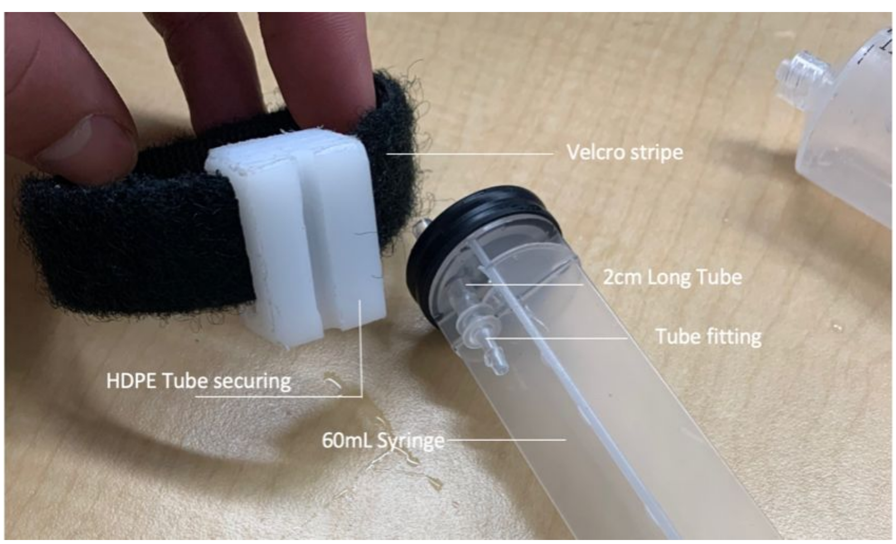


Figure 10: the prototype for the HDPE tube holder and the 60mL syringe water reservoir.

A syringe pump was used as the water reservoir because it is convenient for the saw operator to pull water from the syringe, then turning the syringe upside down as a water reservoir (**Figure 11**). The water reservoir was manufactured using an electric drills with *d* = 2 mm drill bits. A small hole was drilled through the rubber and plastic area of the syringe. Thus, the 2 cm silicone tube could be secured through the hole with a fitting that connected the tube and pump. Glue sealed the hole to create a vacuum for the ease of pulling water into the syringe.

Finally, in order to decrease the fear factor, the circuit was placed into a stuffed animal and with the tube running from the toy's hand. The toy can be placed next to the operator, distracting the child from the oscillating saw blade. The circuit comes as a separate part from the saw and is housed within the stuffed animal.

3. Final Prototype

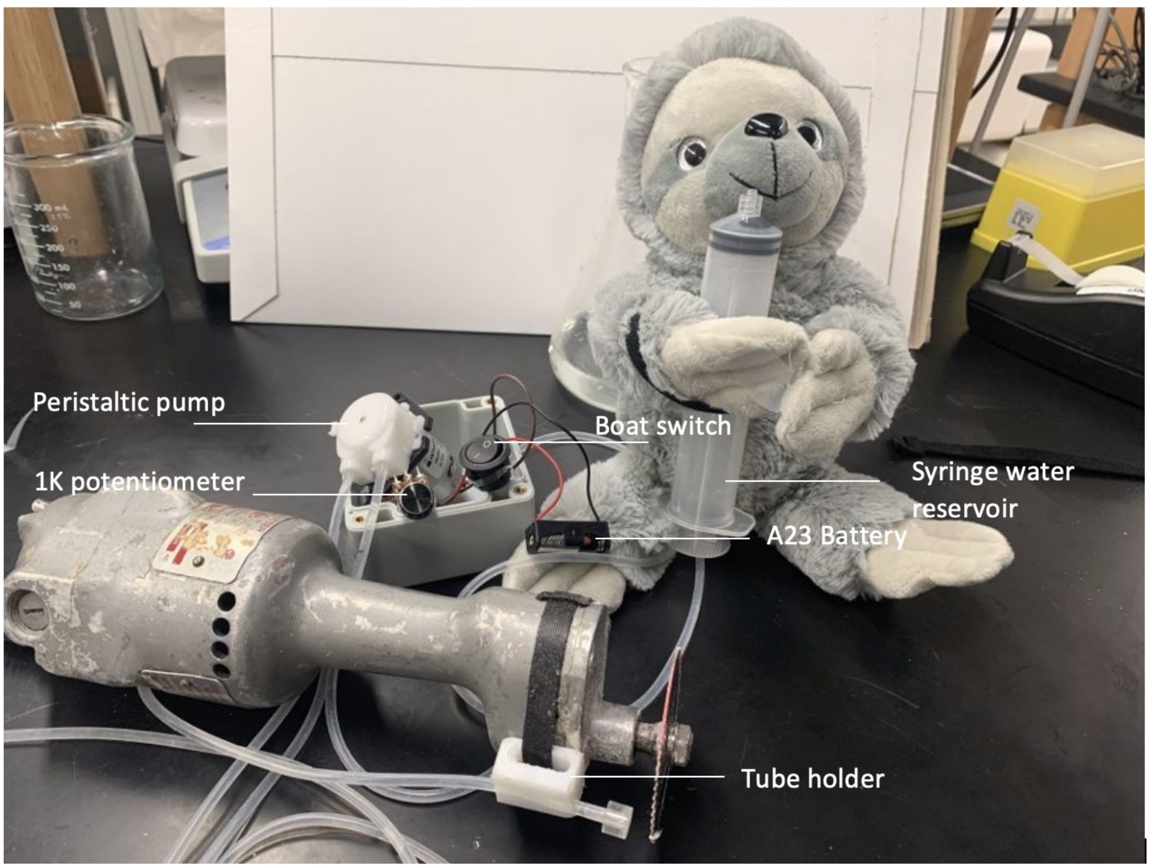


Figure 11: Final design setup with cast saw, open circuit box, and other labeled components.

The final prototype is made up of the components described above. It is equipped with the plastic perfume nozzle (**Figure 9**) as it created the finest spray. In practice, the device is small enough to be carried by one clinician from patient to patient, and it is recommended that the tube holder (**Figure 10**) remain secured to the saw even for storage to decrease set up time. To draw up water, the saw and cooling unit should first be set on the counter next to the sink provided in most regulation patient rooms. Assuming the desired spraying liquid is water, the clinician can either draw water up with the syringe's vacuum design, or place a finger over the syringe spout and fill the body with the plunger-handle removed. Once full, the syringe is placed snugly inverted under the stuffed animal's arm as shown in Figure 11. This orientation is important for water to be drawn into the tubing. At this point, the misting tube end can be secured to the tube holder if it is not already, and the switch in the stuffed animal's back should be flipped just before the commencement of sawing. The syringe volume is sufficient to last for 2.5 minutes of spray before needing to be refilled. If the potentiometer is used to reduce the current, flow rate decreases and time between refills increases.

4. Testing

Before proposing a final design, a preliminary test mimicking each design was carried out. An HDPE rod was used to represent the patient's arm, and the temperature was recorded after two cutting processes in a row. The cast and the saw sat directly on the table, so they were nearly room temperature. The control trial was performed without any cooling system installed. Each of the designs was able to cool the blade temperature to half of the control, but only mist and compressed air met the requirement that having below 44 °C (Burning temperature of skin). For the cast temperature, all of the three designs had very close results with the control, meaning that the cast temperature was hardly cooled. The reason may be due to the thermal conductivity of the plaster is really low, while the blade (made by stainless steel) had very high thermal conductivity. 30 seconds after cutting, the cast saw temperature with the compressed air was only 25 °C. This provides an insight that, if physicians change their procedure by waiting a few seconds before doing another cut, the patient would decrease the possibility of getting burnt. Based on the preliminary test result the mist design was chosen.

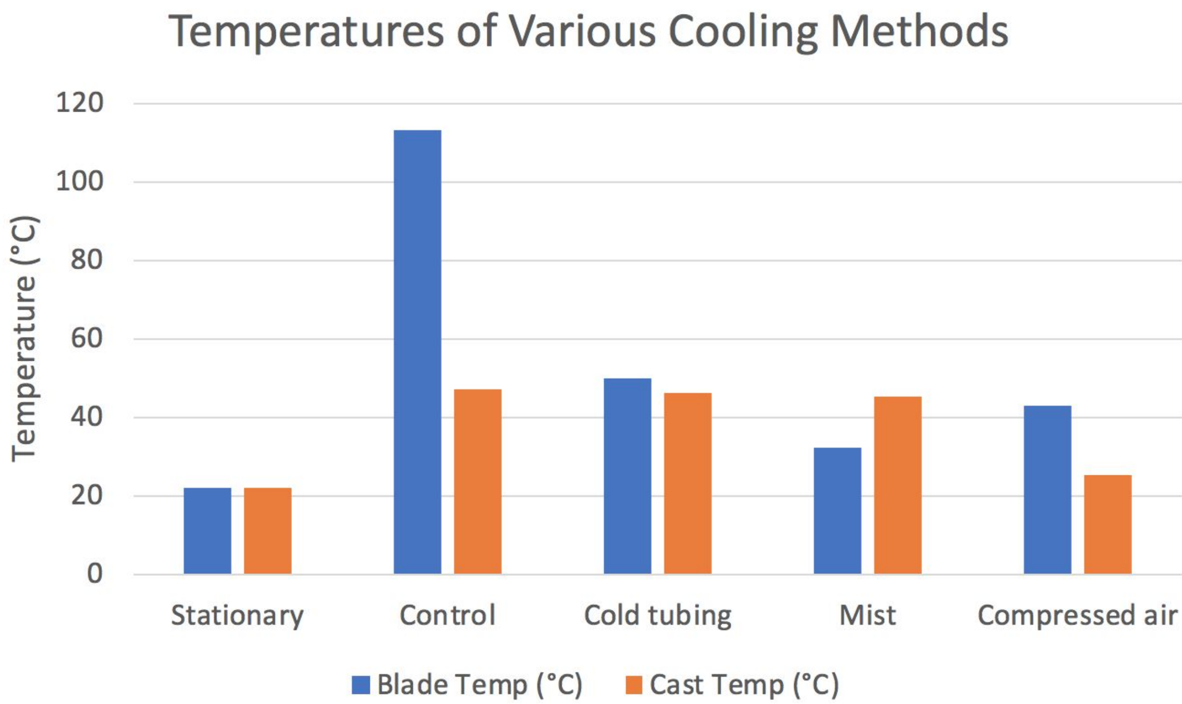


Figure 12. Preliminary testing results for all three proposed designs. The testing was performed following the client's procedure and the temperature was recorded using an infrared camera.

The next test was aimed at testing flow rate at different lengths of the tubing in order to justify the proper length for introducing misting (**Figure 13**). From the graph, there was not a large difference in the flow rate of different tube lengths, and all the trial results stayed consistent. As a result, the tube length wouldn't decrease the pressure generated by the pump.

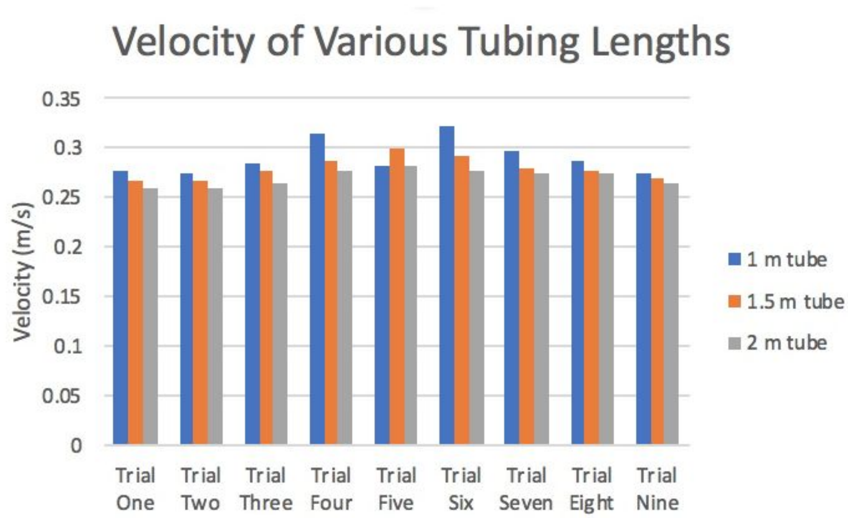


Figure 13. Flow velocity testing for each length of the silicone tubing. Nine trials were completed. The velocity was measured by marking the tube with at lengths of 1 m, 1.5 m, 2 m, then recording the time for flow to reach the markers.

The final testing was performed by comparing the temperature change through different species including control (no cooling), tap water and 70% ethanol. The test was performed by one person cut the cast for one minute with different treatments, and the initial temperature prior to the cutting and the final temperature just finished cutting were recorded using IR camera at the blade. Each trial had five repeats. Figure 14 showed the average temperature for each species. The figure showed that without our design implanted, the final temperature of the blade could reach about 71°C, which could result in second or third degree burns. While using ethanol or water to cool down the blade will result in a final temperature that was very close to the initial room temperature, which suggested that our design could help to prevent injury.

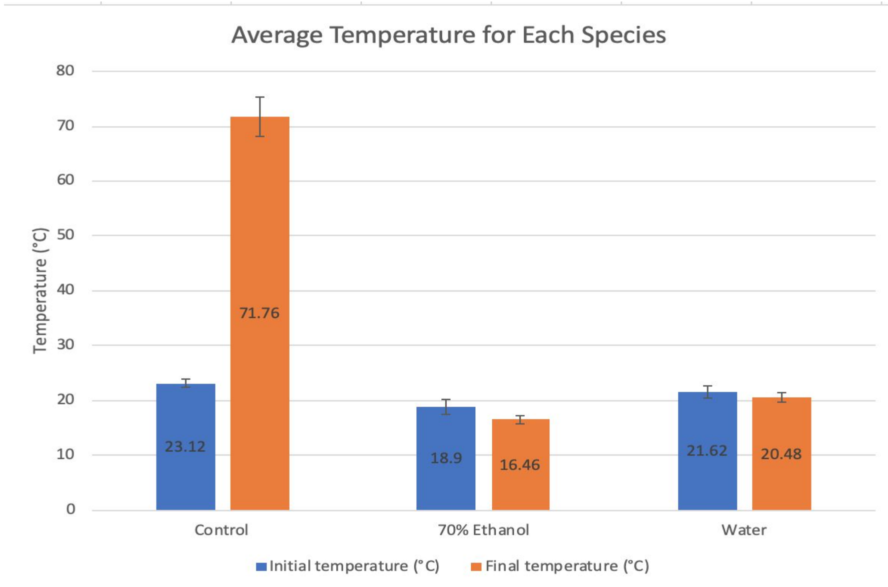


Figure 14. Average initial and final temperature for water, 70% ethanol, and control trials.

Also, using the same set of data, the team did a box plot and bar chart analysis comparing statistical difference within each group of treatment using R (**Appendix 3**). Fig 15 compared temperature difference (final-initial) in each species. From the figure, the control group has the highest temperature difference, while water and ethanol were kind of similar. Those two groups had temperature difference slightly below zero, indicating that the blade can be cooled below room temperature. From the independent t-test, the p-value between water and ethanol is 0.0545, which indicated no significant difference within those two groups of treatments. However, the control group with ethanol/water gave p-values of about 3.57e-5/1.21e-4 respectively, which were far less than 0.05, suggesting that there were significant difference between the control group and the treatment groups. As a result, our design successfully lowering the temperature for the saw blade, and both ethanol and water would provide similar cooling effect. Therefore, the clinician would choose either of the coolant depending on the availability in the examination room.

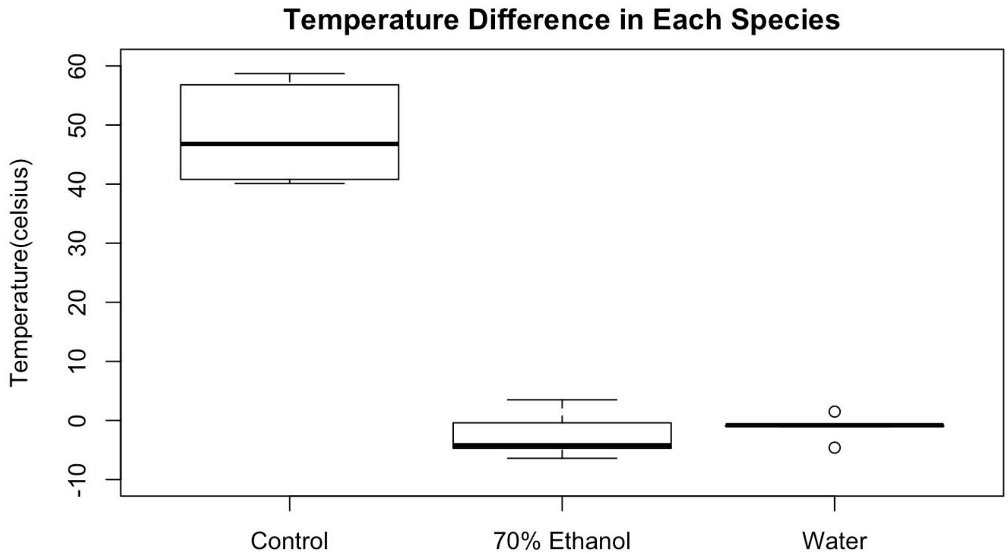


Figure 15. Boxplot for temperature difference in each species. Temperature difference was measured by final temperature - initial temperature. A negative value means the final temperature is lower than the initial temperature. From the t-test result, no statistical difference resulted in the cooling between water and 70% ethanol trials.

VI. Discussion

The cast saw cooling device is an important instrument in ensuring patient safety and comfort as they undergo cast removal. There has been minimal research to find methods to cool the saw blade while it is operating. In a research paper outlining “simple techniques” for minimizing patient burns and blisters, it was shown that 70% isopropyl alcohol or water were the two most effective solutions to be applied to the cast removing procedure.

Because our addition to the marketable original cast saw added no additional safety concerns, the ethical concerns would be similar to that of the cast saw itself. Even though our version of the cast saw significantly reduces the probability of burning the patent, it may not be 100% effective. There is still a chance that the patient could be harmed by an increase in heat when the saw makes contact with the cast. Additionally, and specific to only our version of the cast saw, there is a dignity aspect that must be taken into account for pediatric patients. When run, our cast saw mists the water onto the blade, which then drips from the saw onto the cast and surrounding area. If a pediatric patient is coming into the clinic to remove a cast from their leg, the cooling liquid could potentially spray on the patient’s clothing to appear as if the child had a bladder control mishap. This could cause emotional distress to the patient especially upon exiting the clinic.

Changes that would be made following the presentation include testing the new stainless steel nozzle that arrived the day prior to the presentations along with making the device battery operated. The stainless steel nozzle could prove to be a more effective nozzle for the long term as opposed to the plastic nozzle we used initially, not eroding or breaking as easily with increased use. By making the device battery operated, as opposed to its current state with an outlet plug, the device would be more integrated and fluid in use at the hospital or clinic. The saw already needs a plug, and outlets can be hard to come by, thus a battery pack for the pump would prove to be more flexible for the operator.

Throughout the testing process, we aimed to be consistent in the temperature of the cutting environment, the temperature of the water used for misting and in the pressure applied during the cutting process. Testing errors could have arised from duration of cutting. The time for which the saw was running and cutting through cast plaster was not always consistent until the final round of testing. The saw blade was rotated between the first and second rounds of testing, leading to differences in the control temperature by nearly 30°C. The first round of testing was done on the already-used side of the blade, which visibly had buildup from previous cast removals. The second round of testing was done on the new, clean side of the blade. This difference in control temperature between the side with buildup and the side that was clean lead the team to question if this was a procedural issue about not cleaning the saw blade frequently enough. There is also some variability between different nozzles on their ability and quality of misting. This could provide some source of error in the cooling of the saw blade as it is operating.

VII. Conclusion

The client communicated that the main problem with cast saws is that they have the potential to burn patients when their cast is removed. After thorough research, it was determined that there are various cast saw cooling methods. Many methods involved using different mediums to reduce the temperature of the blade. Through testing, misting with water or ethanol proved to be the most effective at reducing the temperature. Therefore, the final design is a misting system, which uses a nozzle to spray water from a reservoir onto the bottom third of the cast saw blade.

Currently, the final design nozzle is a perfume bottle nozzle. In the future, a steel nozzle should be used for sterility and durability purposes. The mist reliably cools the blade and removes cast plater particulates from the air; however, the water creates a mess in the surrounding area of use. One next step is adding the vacuum component from the preliminary designs. For the future, more research is needed to find materials that could mimic skin's thermal properties for testing. This would ensure that the temperature of the skin itself is not becoming overly hot.

VII. References

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VIII. Appendix

1. PDS

Function: In Orthopedics, casts are applied to patients all the time. During the removal of the cast, an oscillating cast saw is used to cut through the plaster or fiberglass material. As the saw is cutting through the material it generates heat so the blade can often get quite hot. This may result in the burning and blistering of patients at times. Burning a patient during the removal of a cast should be a "never event" but unfortunately due to the amount of friction generated by the saw against the fiberglass or plaster, burns still occur.

Client requirements:

- A saw blade/cooling device that eliminates the possibility of burning the patient during cast removal process. No further requirements were given.

Design requirements:

1. Physical and Operational Characteristics
    a. Performance requirements: The cooling device should keep the saw blade at a safe temperature, no higher than approximately 44°C when using a prescribed technique [10].
    b. Safety:
        i. General- Cast saw should be unplugged from electrical outlet when not in use. Keep the saw blade away from the power supply cord to avoid damaging the cord. Unplug power cord before blade removal [11].
        ii. Patient- Cast saw should not cause burns or cuts to patient. Cooling mechanism must not cause side effects, such as ethanol contacting skin for long periods of time.
    c. Accuracy and Reliability: The device must reliably cool the saw 5 degrees Celcius under the temperature needed to develop 2nd degree burns (44°C). If a temperature measurement is taken, the temperature measured should be within 5% of the actual temperature on the blade or skin.

d. Life in Service: The life in service will depend on whether the device is reusable. Because the design is implanted into the medical device, it should be replaced after using several times to prevent contamination. Polyethylene may be used in our device. Blades that are well-worn are more likely to cause burns [14]. Replacing the blade is recommended. Lifetime for the Delta-Cast Saw is 111-150 hours [16].
e. Shelf Life: The design will be exposed to ambient clinical conditions. For the majority of locations, the temperature during storage will be near room temperature and within a humidity controlled hospital, however the device should ideally be able to withstand a range of conditions so that its use is not limited to indoor clinical settings. As the design will likely be stored with the cast saw, it should at least last as long as the average cast saw. There is no data on cast saw lifetime apart from the Delta-Cast Saw.
f. Operating Environment: The design will be exposed to ambient clinical conditions. For the majority of locations, the temperature during storage will be near room temperature and within a humidity controlled hospital, however the device should ideally be able to withstand a range of conditions so that its use isn't limited to indoor clinical settings. Cast saw is a vibratory device. The blade will oscillate rapidly to create friction, cutting the cast. Temperature of the cast saw blade, as stated above, must remain below 44°C. Corrosion from fluids may result inside tubing, so tubing must be cleaned out regularly.
g. Ergonomics: The cast saw should be able to be comfortably held in one hand and cooling system should not impede cutting ability.
h. Size: We would want the device to be small enough to attach itself to the head of the cast saw and be light enough that it does not add much weight to the saw already. The device should be portable as the cast saws themselves are portable and we would not want to confine or restrict the location of the saw due to the cooling device.
i. Weight: The entire assembly should be no more than 2.94 kg. The stryker cast saw weighs 1.36 kg. Therefore, the cooling device should be no more than 1.59 kg to keep the additional weight from the device on the saw to a minimum.
j. Materials: We should aim to use solutions that would not cause shorter lifespan of the metal blades i.e. would not rust the saw blade. Materials that may melt or emit toxic fumes below temperatures of 101°C should not be used.
k. Aesthetics, Appearance, and Finish: Most cast saws have blue or white cases so creating a device with a blue or white finish would be ideal to have it match the finish of the manufactured saws. Having a texture similar to the plastic finish of the saw cases would be best as it would be smooth and not pose any harm to potential small cuts to operators.

2. Production Characteristics
   a. Quantity: Currently, looking to provide one model but eventually would want to supply all of the UW Hospital and other hospitals in the United States
   b. Target Product Cost: under $100

3. Miscellaneous
   a. Standards and Specifications: At this time, the device will be used only as a prototype for more advanced modifications. However, if the device is going to put into market, FDA approval is needed. Most class I cast saws are exempted from premarket notification requirements [17]. Based on a survey sent out to orthopedic surgeons in the

surrounding area, blade used in cast saws are not changed, nor are they rotated, after each use. Blade sterility is not an important factor.

b. Customer: hospitals, orthopedic surgeons, clinics
c. Patient-related concerns: The device should not cause any discomfort to the patient and will not cause secondary injury under appropriate use. The device needs to be sterilized as the saw may cut skin. There is no storage of patient data incorporated in this device. Ideally the device will not increase patient anxiety during cast removal. This may entail keeping additional noise, dust, or equipment bulkiness to a minimum.
d. Competition:

1. Cooling system for rotary blade used in sawing of concrete (patent:WO2000023234A1) [12]. The cooling (water) medium is led to into the gap between the blade body and the cover then water is being removed by inlet pipes. Through the design, a large quantity of water is not required and water is able to carry away some of the sawing waste.

2. Patent for vacuumized surgical cast saw cutter (US3103069A) [13]: According to Boardman and Bharathan (2018), the inbuilt vacuum dust extraction system reduced the temperature of cast material being split [14]. Therefore, designing an efficient vacuum system may decrease burning effect. The new vacuum design aims to remove sawing dust during operation, but it can still be used as to decrease saw temperature. This design allows air flow passes directly from the cutting region, along the power motor shaft axis and ultimately to a collection bag or receptacle adjacent the motor end of the tool.

2. Materials List

Material Name	Part Number	Place Purchased	Cost ($)	Quantity
Cast Saw	N/A	Received from client	0	1
Plaster	N/A	Received from client	0	10
Stuffed Animal	N/A	Brought in by Rebecca Swanson	0	1
Misting Nozzle	B07WLMQZ4K	Amazon	7.49	1
Peristaltic Pump	B07PWY4SM6	Amazon	9.80	1
Tube Fittings	HJCP0248	Amazon	6.99	1
Silicone Tubing	43188-345043	Amazon	7.80	1
Potentiometer (5 pack)	a15011600ux0213	Amazon	6.00	1
Rocker Switch (6 pack)	USS-WBS00001	Amazon	5.95	1
A23 Battery	N/A	Amazon	3.60	1
A23 Battery holder (12 pack)	N/A	Amazon	4.98	1
Plastic Junction Box	a2018041509	Amazon	6.99	1
Cable Zip Ties	AMZ-RCT-8IN-50P	Amazon	6.66	1
		Total Cost	66.25	

3. Raw Testing Data

Box plot/ t-test code from R

```
Ethanol <- c(-4.7,-4.2,-6.4,-0.4,3.5)
Control <- c(40.1,56.8,40.8,46.8,58.7)
Water <- c(-1,-4.6,-0.8,-0.8,1.5)
boxplot(Control, Ethanol, Water, main = "Temperature Difference in Each Species",names = c("Control", "70% Ethanol", "Water"), ylim=c(-10, 60), ylab="Temperature(celsius)")
t.test(Ethanol,Control)
t.test(Ethanol,Water)
t.test (Water,Control)
```