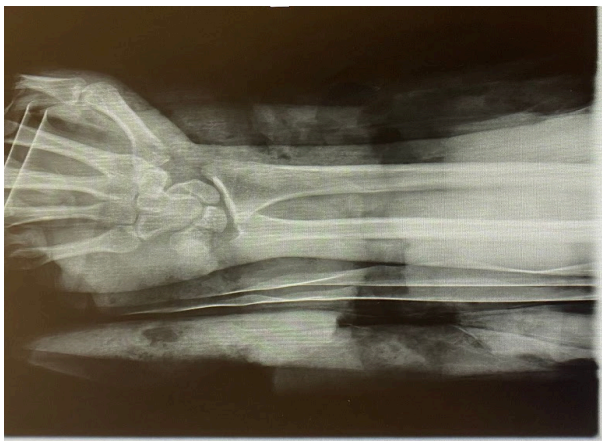
CoolSplint: Inflammation Reduction Accessory Final Report

Sponsors: Elizabeth Mentel & Michael Clausson



California Polytechnic State University, San Luis Obispo

BMED 456-03

Dr. iian Black

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Laura Denney ladenney@calpoly.edu

Winston Giang whgiang@calpoly.edu

Aanchal Singh asing130@calpoly.edu

1. Executive Summary

This document outlines a project sponsored by Elizabeth Mentel and Michael Clausson that addresses the shortcomings in current splinting options, particularly for wrist fractures in elderly patients. Stakeholders include clinicians, patients, and emergency medical technicians. Multiple improvements can be made to current splinting options to help alleviate inflammation along with splint versatility, affordability, accessibility, and ease of use. After determining the critical customer requirements, the primary objective of this project was to find a way to manage inflammation. The project explores existing splinting solutions and proposes a new design that utilizes cooling rods to reduce inflammation. The document reviews various patented splint designs, highlighting their advantages and drawbacks. Existing splints often face issues with inflammation, long-term effectiveness, and improper usage. The goal of this project is to redesign a splint add-on targeting wrist fractures, prioritizing reducing inflammation with the help of cooling rods to improve patient outcomes in the long run.

2. Introduction

After participating in a clinical rotation in the emergency medicine department, project sponsors Elizabeth Mentel and Michael Clausson observed a need for improved splinting options for patients. They determined that the most common fracture type was the wrist in elderly patients, many of whom came to the hospital with an ineffective, homemade splint. The major areas for improvement for splints are increasing the versatility of the types of fractures a splint could stabilize and making splints more affordable, available, and easy to use for consumers. The splints could be used by medical professionals like nurses, first responders, or patients prior to being transported to the hospital. By accessing this large population of patients with fractures, this project will explore previous splinting solutions and aim to improve them to make them more affordable, versatile, accessible, and manageable. Project management strategies, like a Gantt chart, will be used throughout the project to ensure efficiency, attention to detail, and success in all deliverables throughout the design process.

3. Background

Worldwide, the elderly population makes up a significant portion of the entire human population. As humans age, they develop sarcopenia and osteoporosis, leading to an increasing number of falls. Injuries from these falls can include bone fractures, which are most commonly wrist injuries. As they fall, they extend their arms to prevent their fall, leading to extreme stress on the wrist and sprains and fractures requiring splints, which is seen in 2.4 to 10 out of every 1000 elderly patients [1]. Long bone fractures are also commonly seen among many young and working-age adults as they are more likely to be physically active and more likely to perform risky activities, leading to a lifetime risk of any fracture of 53.2% at age 50 years among women and 20.7% at the same age among men [2]. The scope of the issue is worldwide and can be universally applied to most of the working-age and older populations. The total available market would apply to almost sixty percent of the world's population and all first responders and medical professionals using splinting techniques.

The most common treatments for these fractures and injuries involve using splints to immobilize the injured bones to either stabilize the injury until the patient arrives at the hospital for surgery or to immobilize the limbs to allow the bones to connect and heal in the proper position. Emergency first responders typically apply splints, nurses, and sometimes even the patients themselves, where the bone is manually set in the proper position [3]. The motor and

sensory functions are checked on the injured limb to determine any additional nerve damage, and medical professionals must stop bleeding if there is bleeding [3]. Once everything is seen as stable, the splint is chosen, and then applied, and they do one more final check for sensory and motor function.

Current Splints, while effective in the short term to protect and set injuries in the proper position to begin healing; however, in the long term, they have inconsistent and faulty results. A commonly seen issue with these splints is prompting healing and inflammation of the injury, leading to irritation and reduced or slowed healing at the injury site [4]. Another study states, "They are also used for injury prevention and chronic pain reduction, and to alter the function of a joint. It is important for the family physician to choose the appropriate brace or splint for the patient's condition and to determine the correct size, fit, and duration of use. Selection of an inappropriate brace or splint may lead to delayed healing or further injury. Unnecessarily prolonged use can lead to joint stiffness and muscle weakness, which may increase the risk of injury." [5]. This means that splints do not have any noticeable adverse effects in the short term however in the long term, however do not address inflammation in the short term. Acute inflammation is a problem since it can cause chronic inflammation due to the injury and if the acute inflammation is not addressed properly it will devolve into chronic inflammation [6]. This chronic inflammation turns into a chronic problem from further agitation, "...bone injury elicits an inflammatory response that is beneficial to healing when acute and highly regulated; however, if this response becomes chronic, inflammation can be detrimental to healing." [6]. There are a multitude of complications that can be caused by the chronic inflammation but most applicable to splinting issues are arthritis/joint diseases and the ability for the bone injury to be able to heal itself. Chronic inflammation of the wrist joint has been linked to rheumatoid arthritis along with significant joint damage[7], and with increasing amounts of inflammation tends to exacerbate the arthritis leading to more inflammation and even more damage to the joint creating a feedback loop which actively hurts the patient. Another large issue seen with splinting and chronic inflammation is that if inflammation interferes with bone remodeling and modeling process [7], this negative feedback loop caused by inflammation ultimately stems from the acute inflammation from injuries and splints that can not adequately address and prevent this inflammation. This is the main issue with the current splints on the market today, where they are made to quickly stabilize the injury but fail to address the short term inflammation that can lead to long term complications.

There are a multitude of different types of splints that are available on the market, with different methodologies to solve the issues of immobilizing the injury and promoting the healing process. The table below shows five patents of current splints on the market that treat fractures and injuries, each with its own unique method.

Table 1: Patent Search Results

Patent Name	Patent No.
Splint Kit Set Patent	10143584
Cold Therapy Dynamic Hand Splint System	11364174
Splint Device and Splint System Comprising	18315818

the Same	
Splint for Immobilizing a Limb of a User	18350934
Inflatable Flexion Correcting Knee Brace	11707374

The common splint that first responders currently favor is the Splint Kit Set, Patent No. 10143584, made with an easy-to-open and transport package designed for maximum efficiency for emergency first responders [8]. The Splint Kit Set is a strap designed mainly for wrist and thumb injuries in adults since most emergencies usually involve adults, and it is always helpful for many paramedics and other emergency medical personnel to have a quick splint on hand.

The main advantage of the Splint Kit Set (Ready Splint) is its multi-use effectiveness and adaptiveness. It is easily opened and used with easy-to-use instructions printed within the packaging so even amateurs can learn how to use it. The packaging maintains the cleanliness of the splint before application so that it can be applied anywhere from a doctor's office to the middle of the forest. The wrap-around design of the strap "splint" allows for multiple options of splinting since the size can be adjusted based on the limb, so it can be applied not only to the forearm and wrists but can also be used to treat the femur and lower leg fractures for a quick stabilization. The strap is malleable initially, but after being wrapped around the injury and after a couple of minutes of air exposure, the fiberglass material within will harden and form a cast. The ready splint is excellent in the short term but uncomfortable for patients in the long term. It does not effectively treat inflammation, as it is built to stabilize the limb until further care can be given at a hospital. According to surveys from healthcare professionals, patients, and our sponsors in person, there were many long-term complications for "quick-use" splints, which is the category under which the Ready Splint falls for splints.

However, other splints have more unique and unusual approaches that aim to reduce or improve the range of motion for patients. The Cold Therapy Dynamic Hand Splint System, Patent No. 11364174, uses cold temperatures to reduce swelling and inflammation by using cold compresses with water circulation. The splint consists of an inflatable bladder compress with straps filled with cold water hooked up to pumps and a refrigeration unit to cool the water as it circulates within the cast. The cast would first be applied to the hand by strapping it on, then cold water would be added to the splint, and the pumps and refrigeration would circulate the water to provide a cooling and compression effect on the limb.

The design of this splint requires much additional technology, requiring pumps and a refrigeration device, making it difficult to move and uncomfortable since it takes lots of energy to maintain the cold temperatures to reduce swelling and promote healing. This design aspect makes it hard to deploy quickly in emergencies, especially for emergency medical responders, since they value portability and versatility in their line of work. [9] The other disadvantage of this specific splint using the cold compress is that it can only be used as a rehabilitation and healing-promoting splint, not as an actual splint to immobilize the limb [9]. It is not robust enough to hold bones in place and places a heavier emphasis on the comfort and motion afforded to the patient. This design shows promise to reduce swelling and inflammation, which can be incorporated into the Arm Splint Redesign. Although instead of something so bulky requiring machines, the new design could use soft "ice-packs" instead.

There are also inflatable splints that have been patented and are on the market to tackle inflammation and the flexibility aspects with the added benefit of compression. Expanding

inflatable bladders are seen in Splint for Immobilizing a Limb of a User, Patent No. 18350934, shown in the figure below. The figure depicts the device as two rigid plates around inflatable bladders intended to go around the injured limb. The patient slides their arm and wrist into the holes of the splint, where the bladders are then slowly inflated to the desired pressure to compress and for maximum comfort for the patient [10].

The shell is rigid, meaning it cannot be changed or adjusted for different limbs or sizes, so it can only be used for wrist injuries [10]. However, the inflatable bladders allow for better fitting and comfort for the user since they can be inflated, and the bladders can conform to the geometry of the patient's hand and provide compression to reduce swelling. At the same time, the rigid shell helps with the actual immobilization of the bone. The design of the inflating bladders shows much promise. It can be used in the splint redesign due to the advantages of the inflating bladders, such as the versatility and comfort provided to the patient since it can be adjusted on the go by changing the air within the splint.

The other splint design on the market is the Inflatable Flexion Correcting Knee Brace, Patent No. 11707374. This design updates the traditional knee brace with inflatable bladders for increased range of motion and mobility for the patient. It would stay on and provide support and cushioning for the knee, which is extremely helpful for rehabilitating those who need to walk since it allows a greater range of motion than standard knee braces [11].

The inflatable bladders are not as rigid as regular knee brace supports, allowing the bladders to “squish” and change shape and size to allow for knee movement. This sort of inflatable design is desirable for the splint redesign to provide the maximum range of motion for the splint while maintaining the support needed for immobilization of the bone to ensure comfort and motion for the patient.

The last splint patent design that was unique was the Splint Device and Splint System Comprising the Same, Patent No. 18315818. This design uses a traction splint to hold limbs in place. The device consists of straps and a big flat strap that acts as a splint. It consists of three different layers: one on the surface, a layer of padding, and a second malleable layer.

The malleable layer allows the bending and manipulation of the splint, which is then hardened after a while, similar to the earlier Splint Kit Set design of using a malleable material to do the initial setting and then locking in the position after correct positioning [12]. However, with three layers, this new splint provides more stress due to the construction of the splint layers, which can hopefully be used in the splint redesign, where the multiple layers can each be different materials chosen for different properties to modify and change the attributes of the splint.

Since splints are non-invasive medical devices, they would be classified as Class 1 medical devices requiring codes and standards to be passed for certification by the FDA for commercial use. One of the more relevant codes and regulations the device must follow is ISO-10993, the biocompatibility test, to ensure the materials used to create the splint are nontoxic. They will not cause damage to the patient, especially their skin. The most applicable test required from ISO-10993 is the irritation and inflammation test for the skin to ensure that the splint padding materials will not worsen the inflammation of the injury. The inflammation test is usually done on animal and sometimes human clinical testing; if deemed safe enough, it would involve placing the splint/device directly on the skin of a mouse model or porcine model since their skins most closely resemble that of humans to check for inflammation or reduction of inflammation by observing the surface area of the "rash" or taking a blood sample from the

inflamed area and measuring the concentration of histamines and other inflammation factors. For manufacturing and legal sale in the United States, the device must also pass through the FDA's general controls, not needing PMA since it is not a Class III medical device [12]. The general controls detailed regulations about proper labeling, manufacturing, and product registration for the general public.

Developing a splint add-on to address inflammation alongside immobilization represents a significant advancement in the field of splinting technology. Current splints prioritize immobilization but often fail to effectively manage inflammation, which is critical in promoting optimal healing and reducing long-term complications. Our innovative approach fills a crucial gap in existing splint designs by focusing on mitigating inflammation. Our idea is unique because we are not attempting to reinvent the wheel; instead, we propose an add-on solution that should seamlessly integrate with established splinting technologies. This approach not only streamlines the adoption process for medical professionals but also enhances the versatility and effectiveness of existing splints. By leveraging this strategy, we maximize the impact of our innovation while minimizing disruption to established practices, ultimately offering a pragmatic solution to a longstanding challenge in the field of orthopedic care.

4. Objectives

Current splints face significant challenges in providing adequate long-term support for injuries due to their limited versatility and the potential for inflammation-related complications. These issues hinder the optimal healing and rehabilitation of individuals with injuries, as existing splint designs may fail to adapt to evolving recovery needs and contribute to discomfort and extended recovery periods. Addressing the shortcomings of current splint technology is crucial to enhance patient outcomes and promote more efficient and versatile solutions for sustained injury management. Those in the medical field, paramedics, doctors, nurses, and most importantly, the patients, have had to deal with these complications for a while now. At the same time, newer splints can only solve one issue at a time, with no new splint being able to address all these issues adequately. However, to combine the best of both worlds, the project has decided on designing a splint add-on to apply to most splints as a method to reduce inflammation while at the same time keeping the familiar splints that medical professionals are used to but giving an added benefit of reducing inflammation.

Indications for Use

Updated IFU to remove all language that refers to an "air splint" or "long bone" since we have deviated from focusing on the long bone to solely the wrist.

The splint redesign boundary will involve creating a unique splint add-on that targets the most common splints, a design choice that is both familiar to medical professionals and highly convenient. This innovative splint will also incorporate an anti-inflammatory aspect, a feature not commonly found in other splints, achieved through inflated bladder compression or cold temperatures to cause vasoconstriction. The project scope primarily focuses on creating a user-friendly splint that can reduce inflammation in the long term, leading to improved patient outcomes. The splint add-on is indicated for use to assist in stabilizing wrist fractures to promote healing and prevent further injury to soft tissue following a traumatic injury. Unlike the current splints offered, this unique splint add-on will help reduce inflammation. First responders may use the add-on to respond quickly to an emergency or practicing physicians to set injuries properly. Splints may be adjusted by the patient or attending nurses for more comfort without

compromising the integrity or effectiveness of the splint. Patients receiving the splint add-on should be those who have been injured through physical trauma resulting in wrist fractures, most likely from falls, commonly seen in skiers and skateboarders. The splint is applied on the outside around the wrist by a trained professional who sets the bone in the correct orientation.

Customer Requirements

- Immobilize the limb
- Reducing Inflammation
- Affordable for the Customer
- Comfortable for the Patient

For the customer's requirements, the most important "need" is the ability to immobilize the limb to allow for proper bone growth and healing. The following critical need would be for the splint to reduce the inflammation as this is seen as the second most significant cause of long-term complications from splint use, the first being the improper setting of the splint, causing the healing process to be disrupted. In contrast, inflammation disrupts the healing process less in the short term and more in the long term from persistent inflammation. Some wants for the users, and patients would be for the splint to be affordable or priced consistently with competitors. Another want would be the comfortability and durability of the splint for the patients and users; if the splint is rigid to keep on and not durable, patients would dislike the splint and are more likely to take off the splint and prevent the healing process. However, this is not as necessary as the earlier points since doctors can instruct patients to prevent disturbing and moving the splint more than necessary, which can lead to better results and can be included in the instructions for use with the splint instead of having to design a whole new feature for comfort if the design does not allow for it.

A House Of Quality table was meticulously created to ensure the comprehensive fulfillment of all customer requirements. This table is a crucial tool in calculating the prioritization of design aspects during the design and ideation process (see **Appendix A**). The QFD table shown in the figure below details the wants and needs of each specific customer and the relationships between the design specifications. The necessary quantifiable specifications from the House of Quality have been meticulously organized into an Engineering Specifications Table, shown in **Table 2** below.

Table 2: Engineering Specifications

Spec #	Parameter description	Requirement or Target (Units)	Tolerance	Risk	Compliance
1	Use time	2 hours	± 30 minutes	Medium	Test, Analysis
2	Immobilization of bone fractures	5°	Max	High	Test, Analysis
3	Reduces Inflammation	21°C	Min	High	Test, Analysis, Similarity
4	Cost	$100	± $20	Low	Similarity
5	Weight	0.5lb (8oz)	Max	Low	Analysis, Similarity

- Use life of splint
    - How long the ice pack can provide the cooling capability before having to be refrozen
    - According to Sponsors and those in the medical field, splints are commonly used short-term, and ice packs should be used short-term to reduce inflammation.
- Immobilization of bone fracture
    - Must hold the joint and injury in place without further agitating the injury and making the injury worse
    - According to the Journal of Occupational Therapy, doctors would rather have the movement of wrist injuries limited to 0° of range of motion, but 5° of flexion is the maximum safety limit.
- Reduce Inflammation
    - Reduce inflammation by inducing vasoconstriction to prevent long-term complications.
    - Vasoconstriction occurs when subcutaneous tissues reach 21°C [17]
- Cost
    - The average cost of a splint in America is $150-240 [20], and the add-on should be slightly lower to make it affordable.
- Weight
    - The weight of the splint should be kept low for patient comfort.
    - The average weight of a splint varies between 3 oz and 12 oz depending on the model, so the target would be the middle, around 8 oz.

There are several critical quantifiable specifications on the table with many varying levels of risk and different measurement methods and targets. For the durability of the splint, it is seen as low risk as there is little effect for the patients and users aside from replacing and re-applying the splint after a couple of weeks; it will be tested through simulated use testing having someone wear the splint and go through life generally for a month and at the end the damage will be assessed. Instron compression testing will be used to test the strength of the splint required to hold bones in place, test the tensile and compressive strength for failure points, and determine the maximum strength and rigidity the splint can provide. To determine the effectiveness of the splint in reducing inflammation, simulated irritation was measured, and the temperature was 21 degrees Celsius, the temperature where vasoconstriction of blood vessels occurs. The splint cost would be better if it were lower to lower costs for the patients and medical professionals. However, this is seen as a low-risk item since the costs of splints are still relatively low compared to surgery and can even be covered by health insurance. The weight of the splint will be measured after it has been made on a scale and is seen as a low-risk item since it is for the comfort and mobility of the patient. If it is too heavy, it would restrict movement and reduce circulation to the limb. Lastly, the range of motion of the splint is a medium risk since it is unavoidable that the patient will move the splint when going through the motions of their daily lives, so having the splint be able to stay on and provide some range of motion and provide the rigid support at the same time would be best for the patients since they can maintain some of their quality of life without compromising the healing process.

5. Morphology

Various concepts were generated and tested for the splint, focusing on four core functions paramount to the device's design and function: immobilization, reducing inflammation, comfort for the patient, and ease of use and deployment for emergency first responders and patients. A morphology chart has been developed with six concepts for each of the four functions required by the design (shown in **Appendix B)**.

The immobilization of the injury is a vital function of any splint; for bone knitting and repair to occur, the bones must first be realigned and combined for the healing process to begin and to ensure full recovery of all motor functions. Some designs that had been considered were using magnets to hold the limb in place using electromagnetic force and to provide for easy deployment of the splint. Another two designs involved using air, one through an inflatable splint to use the air pressure within bladders to try and hold the limb in place. The other design involving air was the use of a vacuum sealing cast that would use suction force pressure to instead conform the limb to a preset shape by wrapping the limb in the cast and sucking all the air out, similar to how a sou-vide works. The fourth idea generated was a simple splint using tape or adhesives with solid supports, which most closely resembles splints currently used on the market, using a form of adhesive to adhere to the body and strong, rigid supports to mold the bones correctly. The fifth concept was a spray-on plaster splint for quick application, which would harden like a plaster. However, removing and accurately controlling how the limb would be positioned before application would be challenging, especially since foam is rigid enough to accurately control when it is liquid and hardens, reducing the limb's breathability. The sixth and final concept considered for splint immobilization was using a series of adjustable clamps that would attach to the injury. However, clamps could damage the bones and joints further if applied with too much pressure, and this concept was ruled out.

The second function considered in the splint is also to reduce swelling and inflammation since the swelling and inflammation interfere with the healing process and misalign the bones. Several methods are used to reduce swelling and induce vasoconstriction of the blood vessels to reduce fluid permeability. The most promising concept was the use of ice packs and cooling as a method to induce vasoconstriction; since the body naturally vasoconstricts blood vessels to maintain homeostasis and preserve blood flow in the core, it would be most affordable and much more accessible to induce vasoconstriction. The second concept generated was to add a patch with anti-inflammatory salve/balm to the underside of the splint that would directly contact the skin, where the drug can diffuse through and induce vasoconstriction through chemical means and signaling mechanisms. However, this would be a one-time use for each patch and must be replaced every time. The third concept is using heat packs to induce vasodilation, which might seem contrary initially. However, lowered blood pressure would also reduce the blood flow, reducing the amount of actual fluid pumped to the injury. Compression was the fourth concept involved in reducing inflammation, using a tight-fitting sleeve that would compress the arm, "forcing" the inflammation to go down and preventing the fluid from building up at the injury. This method, however, is complex to test and could cause injury if misused. The fifth and sixth concepts were immobilizing "floating splints" to isolate the injury within a cage and reduce possible movement, which could agitate the injury or bones to cause further inflammation.

The third attribute/function we wanted for the splint and concept was to be comfortable for the patients. These concepts mainly focused on the padding and the skin-to-splint interface for the patients, like using a skin-tight form-fitting material with maximum breathability, like the materials found in athletic wear. The other option was a down or fleece to provide maximum

softness and feel for the patient's skin. Some other ideas considered were to make the splint fully adjustable so it can fit properly on anyone's arm or adjust it to make the fit more comfortable as the patient is recovering. Moreover, some general improvement concepts the last two used were smooth edges and breathability. These are more seen as a quality of life improvement since they prevent digging or scratching and allow the sweat to evaporate more quickly.

The last attribute evaluated was the ease of use since it must be easy for first responders to deploy in emergency conditions. The primary concept was to include a packet of easy-to-read instructions with simple pictures and directions on deploying the splint. Another method was a "stick-and-go" application method where the number of steps to apply was reduced to as few as possible to reduce the possibility of making mistakes and simplify the whole process. The last few concepts mainly focused on the user interface with the splint, such as color coding the splint for specific injuries and helping with positioning, i.e., using colored bands to indicate where to place and position the splint around an injury and to protect the joint. Another concept considered was to make cleaning easy for re-usability, prevent infection, and make it convenient so customers do not need to order multiple splints for replacements.

6. Concept Evaluation

After completing the Morphology analysis, our team concluded that the top three design concepts are the Ice Pack Splint, Inflatable Splint, and Compression/Magnetic Splint. To evaluate our three different concept options, we created Pugh Matrices. We identified ten criteria for our product: Immobilizing, Anti-Inflammatory, Affordability, Ease of Use (Attachment), Comfortability, Durability, Ventilation, Ease of Cleaning, Insulation, and Aesthetics. The most crucial criterion decided by the whole team was that the product is anti-inflammatory, which was achieved by the three concepts we were testing. We then assigned a weight to each quality based on how important we felt that quality was. We set the SAM Splint as the baseline, and each team member filled out a Pugh Chart evaluating our three concepts against the baseline (see Appendix C). After each team member had filled out a Pugh Chart, a final chart, shown in Table 3, was made with the average scores.

Table 3: Pugh Matrix with Average Scores for Each Design Concept

Pugh Matrix					
			Alternative Concepts		
Concept Selection Legend Better + Same S Worse -	***Importance Rating***	Benchmark Option	Ice Pack Splint	Inflatable Splint	Compression/Magnetic Splint
Immobilizing	9	Datum	S	+	+
Anti-Inflammatory	10		+	S	S
Affordability	7		S	S	S
Ease of Use (Attachment)	3		+	S	S
Comfortability	2		+	S	+
Durability	5		-	-	-
Ventilation	1		+	-	-
Ease of cleaning	1		+	+	S
Insulation	8		S	S	S
Aesthetics	1		+	+	+
Sum of Positives			6	3	3
Sum of Negatives			1	2	2
Sum of Sames			3	5	5
Weighted Sum of Positives			18	11	12
Weighted Sum of Negatives			5	6	6
TOTALS			13	5	6

After thoroughly evaluating each design concept using the Pugh charts, our team decided that the Ice Pack Splint was the most optimal solution for redesigning the splint. One of the main factors leading to this decision was the effectiveness of the Ice Pack Splint in being anti-inflammatory, which scored the best among the other design concepts. It also scored positively in critical areas such as ease of use (attachment), comfortability, ventilation, ease of cleaning, and aesthetics. While insulation was initially a concern, we realized that refinement and material selection could adequately address this issue. Overall, the Ice Pack Splint had the highest weighted sum of positives, which indicated that it is the best option for our redesigned splint.

7. Conceptual Model

Model Description and Images

The model was created using SOLIDWORKS 3D CAD Design Software. The ice rods depicted in Figure 1 are held in place with a rigid plastic shell with straps to be placed around the whole splint to allow for fastening upon the limb or wrist. This would allow the "cooling rods" on the concave side of the splint to wrap around the arm and wrist for maximum surface area contact to help heat transfer and cooling. The hard, rigid shell will prevent the range of motion and movement of the rods and the wrist for comfort and to prevent the injury from moving and

causing problems in the recovery process. It will also protect from daily bumps and protect the wrist from further damage and inflammation.

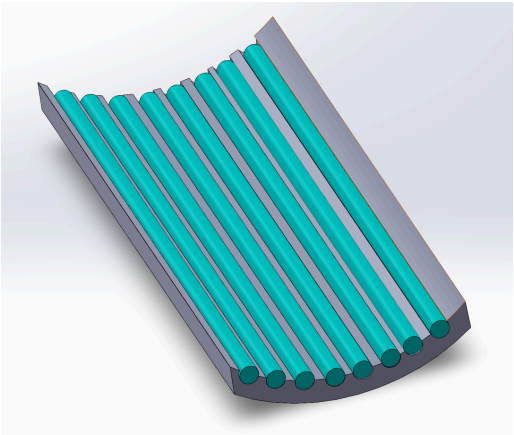

Figure 1. Ice Splint Concept. Depicts a conceptual model for a splint with incorporated ice rods to combine immobilization and ice therapy for treatment of wrist fractures.

Mathematical Analysis

Removed the word "hypothermic" when describing the functionality of the device.

Instead of conducting FEA analysis, the core functionality of our product was to prevent inflammation through cold temperatures to induce vasoconstriction. Our team conducted a temperature and heat transfer analysis of the actual splint to determine whether the splint can cool the skin effectively and cause vasoconstriction. A mathematical model, using the heat conductivity equation $dq/dt=k \cdot A \cdot dx/dT$, was constructed using several sources to gather all relevant data and equations by measuring heat loss and temperature of subcutaneous tissue. According to Cohen, the heat transfer through coefficient through the bioheat equation with a resulting k value of 0.81 W^-l *°C^-l l m [13]. The values were calculated by using the skin, fat, and muscle heat transfer values in the forearm according to Ducharme from their study involving the study of thermal conductivity of the inner forearms, which would be most applicable to our splint since that is where the vast majority of splints are applied [13]. The splint would cover the whole forearm when in use. The surface area of the forearm was also calculated to be 0.13m^2 using average anthropometric data of adults from Nomoto's study [14]. Vasoconstriction typically occurs at 21°C [15], which would require about 7-17 kcal/hr of heat loss rate, varying linearly over 3 hours in cold air (21°C) to achieve vasoconstriction in arms and legs[16]. Using the heat conduction equation of dQ=kA(dT/dx)*dt, with dQ being the change of heat, using the average value from 7-17 kcal to 12 kcal/hr and extrapolating to 3 hours, which would be 36 kcal of heat energy was lost from the arm to achieve vasoconstriction and k being the specific heat constant and A is the surface area of the forearm which is where the splint will be placed. dT is the temperature change calculated from the average extremity temperature being around 31°C and hypothermia being achieved at 21°C, dT is 10°C. dx is the thickness of the skin, which is estimated to be about 5 mm [17]. The calculations, are shown in **Figure 2** below, where the time it would take for the splint to achieve vasoconstrictive temperatures assuming direct contact and the temperature of the splint being close to freezing would be about 12 minutes, which supports our purpose of rapid response and an adequate answer to acute inflammation that occurs right after injury and prevent long term healing problems due to inflammation.

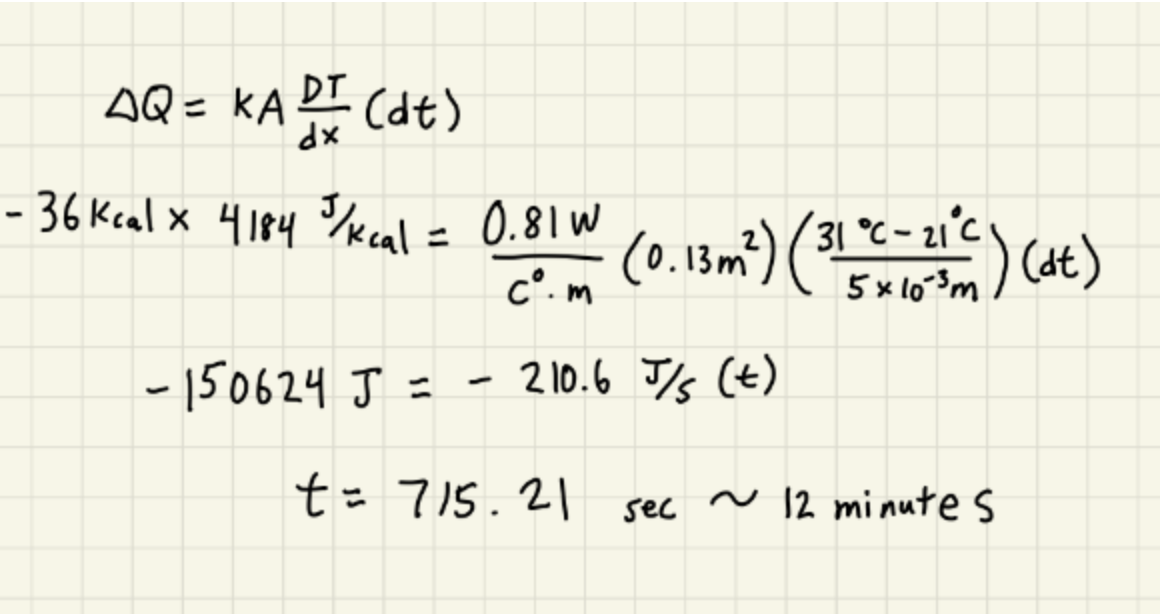

Figure 2: Hand Calculations for Heat Transfer Analysis of direct contact

It is proven for direct contact that the splint would be able to effectively induce vasoconstriction. For a more accurate calculation further analysis was done to account for the presence of a splint. The new design now uses aluminum to conduct the heat for the skin. The heat transfer of aluminum is 237 W m-1k-1. The calculation required is to calculate the heat transfer through two materials, the skin and the splint with the equation dQ/dt= UAdT, where U is the overall heat transfer coefficient. The equation for U is $1 / U = 1 / h_{ci} + \Sigma (s_n / k_n) + 1 / h_{co}$, where h is the convective current of the fluid on either side of the heat transfer, and assuming that there is no direct contact and there is minimal airflow between the splint and skin since splints would be applied on tightly the convective terms *hci and hco* drop out of the equation.. Sn is the thickness of the material and k is the heat coefficient. The calculations are shown in the figure below, where it was determined that effective cooling would take 435.47 seconds to cool the skin down to 21 C which is much more effective due to the use of aluminum as a more effective material to conduct heat away from the body.

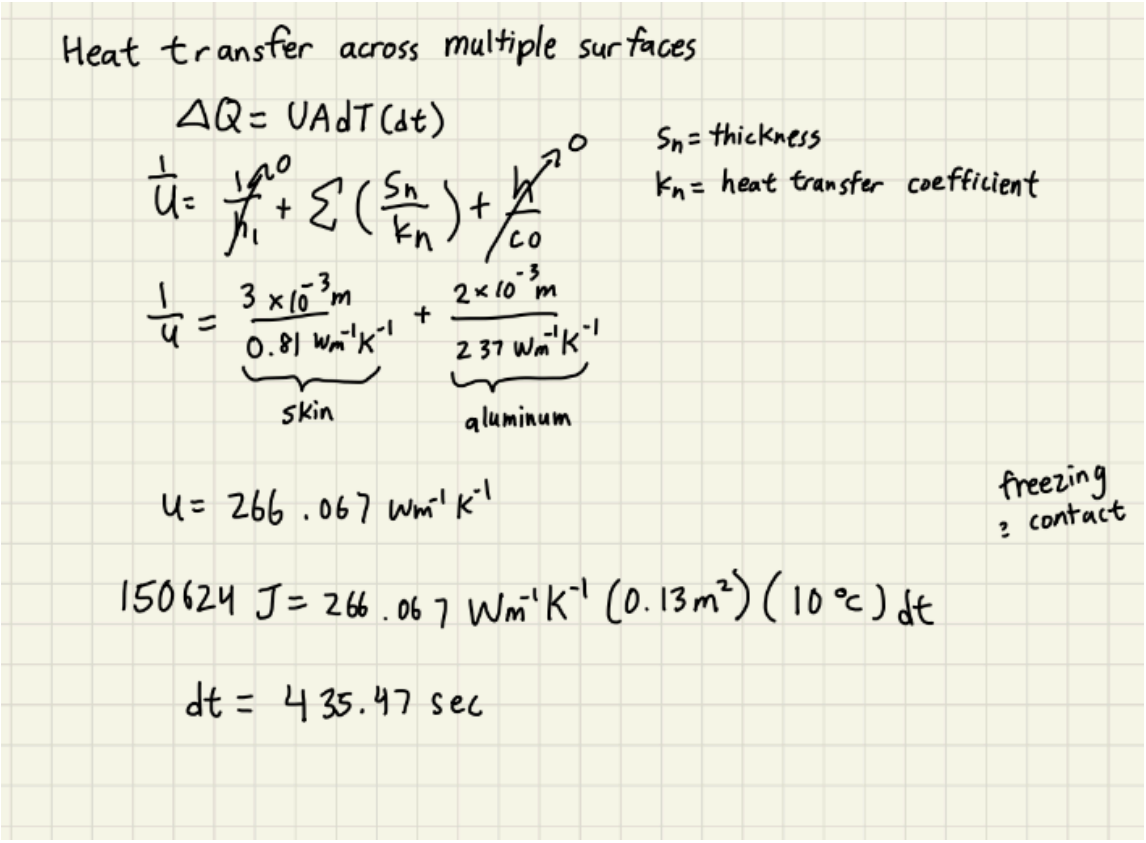

Figure 3: Calculations for combined heat transfer including the Splint

Key Takeaways

Through our model development and analysis, we gained valuable insights into the effectiveness and feasibility of our design concepts for redesigning the wrist splint add-on. We learned that adding cooling rods provides a promising approach to preventing inflammation through cold temperatures to induce vasoconstriction, which proved to be a viable strategy. We determined its ability to effectively cool the skin and induce vasoconstriction by conducting temperature and heat transfer analyses of the actual splint. Our mathematical model indicated that the splint could achieve hypothermic temperatures in about twelve minutes, supporting our objective of rapid response to acute inflammation and prevention of long-term healing problems. This shows the potential of our approach in addressing immediate post-injury inflammation and improving overall patient results. Overall, our model development and analysis have validated the viability of our design approach and highlighted areas for further refinement and optimization, such as including more metal parts to help conduct the heat away from the body faster through the splint and to the ice.

Further Design Development

The insights gained from our model development and analysis will guide our design in multiple ways. We will focus on refining the integration of cooling rods and insulating material to ensure optimal performance and comfort for the user. We will experiment with different types of materials and rods to achieve the desired cooling temperature to facilitate swelling reduction. We will also explore ways to enhance the splint's cooling properties by incorporating an instant ice pack or other cooling technologies. By testing different materials and cooling methods, we

will determine the optimal method to reduce inflammation and swelling effectively. By incorporating these findings into our further development efforts, we aim to create a cooling compression splint add-on that effectively addresses the needs of patients with wrist injuries while offering a user-friendly and clinically effective solution.

8. Failure Modes and Effects Analysis

The Failure Modes and Effects Analysis (FMEA), seen in **Appendix D**, summarizes valuable insights into potential failure modes and their respective effects, along with recommended actions to mitigate risks throughout the splint redesign project. The analysis covers various critical aspects of the splint's functionality, including affordability, anatomical fit, anti-inflammatory properties, comfort, durability, ease of cleaning and use, immobilization effectiveness, and ventilation. Each potential failure mode is assessed based on its severity, occurrence, and detectability, resulting in a Risk Priority Number (RPN) that helps prioritize mitigation efforts. The FMEA highlights critical issues such as excessive manufacturing costs impacting affordability, improper fit leading to loss of immobilization, and ineffective cooling mechanisms causing discomfort. Mitigation strategies range from design simplification and material selection to user instruction improvements and structural reinforcement.

Despite its thoroughness, the FMEA may have some blind spots that could impact its effectiveness in risk mitigation. One potential blind spot is the reliance on user error as a cause of failure for several failure modes, such as improper application or compression being too tight. While user error is undoubtedly a significant factor, it might only partially account for some potential failure scenarios, such as unforeseen environmental conditions or unexpected stresses during use, which is challenging to evaluate with the current conceptual model. Lastly, the analysis could benefit from more explicit consideration of interdependencies between failure modes and their cumulative effects, as inevitable failures may exacerbate others or create new risks that are not immediately apparent.

To enhance the effectiveness and accuracy of the FMEA, it may be beneficial to incorporate feedback from a broader range of stakeholders, including end-users, manufacturing experts, and regulatory specialists, to ensure comprehensive risk identification and mitigation. Additionally, conducting periodic reviews and updates to the FMEA throughout the project can help address emerging risks and evolving priorities as they arise. By addressing additional potential blind spots and continuously refining the analysis, our team can better anticipate and mitigate risks, ultimately enhancing the likelihood of success for the splint design project.

9. Detailed Design

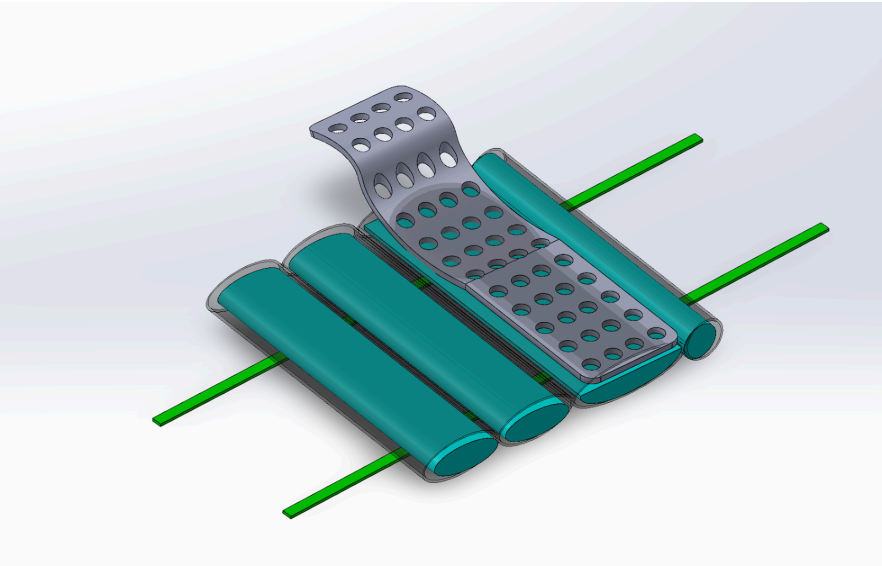

Figure 4. Detailed Design

The biggest issue surrounding the original conceptual model in Figure 1 is that it needs a way to attach to an arm. The detailed design in Figure 4 depicts a method to fasten ice packs using fabric and velcro to a splint board. For more functionality, the splint board can be removed, and the ice pack can be fastened to other injured areas of the body. Additionally, it can be used in conjunction with other wrist splints to meet the user's needs and improve their anatomical fit. The splint board depicted in Figure 4 is just for modeling purposes. The DJO wrist/forearm splint will be used to improve anatomical fit. It is made of aluminum and foam, which conducts the ideal amount of cold through the splint. No data is available for the specific dimensions or heat transfer rate, so further testing and analysis will need to be conducted.

10. Prototype Manufacturing Plans

a) Ice Packs
The manufacturing plan for the ice packs involves acquiring Uline 3 oz ice packs from a designated supplier or distributor. The Uline 3 oz ice packs are ideal for this cool splint because they stay frozen for longer and are the right size and shape to provide cooling to the contours of the wrist. The cool splint prototype uses 10 ice packs to allow for flexibility to accommodate the DJO splint and the wrist anatomy. Additionally, these ice packs were very low cost compared to other ice packs on the market. These ice packs will then be frozen for a minimum of 72 hours prior to assembly and testing to ensure they are fully frozen and ready for use. The freezer can be used in one of the group member's personal freezers.

b) Ice Pack Holder

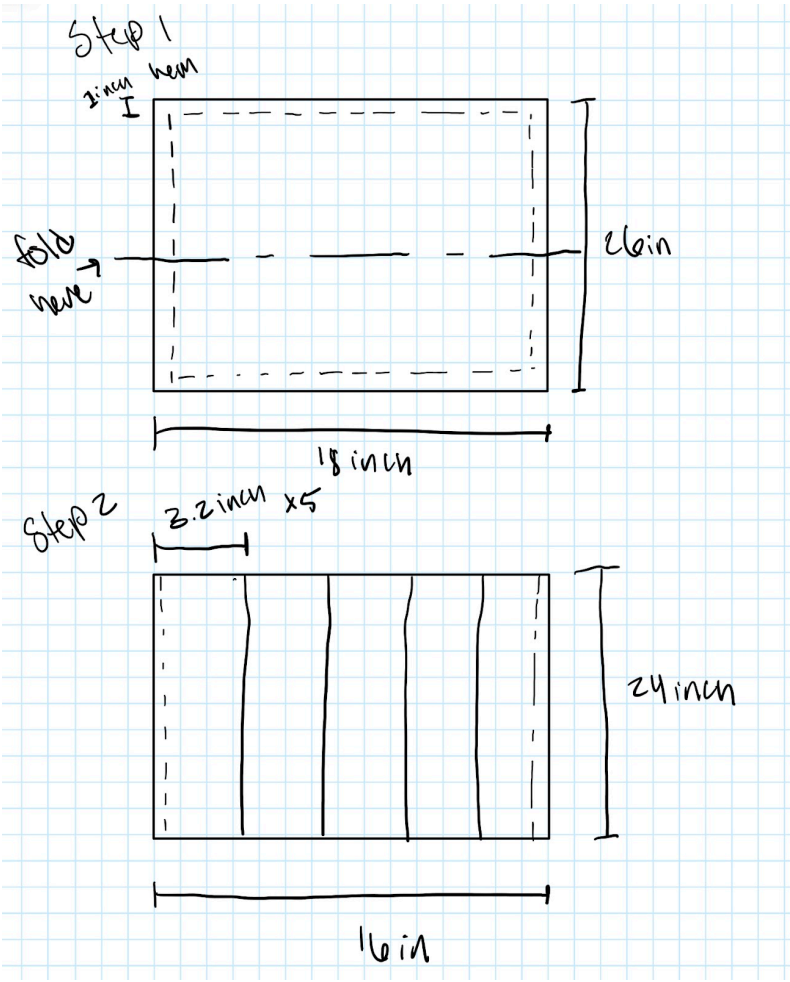

Figure 5. Ice Pack Dimensions

1. For the ice pack holder, the process begins with cutting the fabric into a rectangular shape with the dimensions of 18 inches by 26 inches. .
2. Once cut, the edges are folded in and pinned to create a 1 inch hem.
3. Then, the edges are sewn and pins are removed to create a hem to prevent the spandex from fraying and make the edges look cleaner.
4. Next, the spandex is folded in half, and the edges are lined up and pinned together. The outer edges are sewn, leaving the long edge opposite the fold open.
5. Then, compartments for holding ice packs are measured in 3.2 inch segments, marked, pinned, and sewn to create slots for the ice packs to fit into.
6. Finally, Velcro strips are attached onto the edges to facilitate easy closure and adjustability.

c) Assembly

1. In the prototype assembly stage, the ice packs are slid into the designated pockets of the holder, and the DJO Wrist Splint is inserted.

Overall assembly involves following these steps to assemble the ice pack holder, ensuring proper alignment and placement of the components. Thorough testing is conducted to verify functionality, comfort, and usability, with adjustments made based on testing feedback before

final production. Using the DJO splint allows for the prototype to provide adequate splinting. The use of spandex material and many smaller ice packs allows for the cool splint to conform around the DJO splint and wrist anatomy.

Table 4. Proposed Prototype Budget

Item Description	Product Number	Purpose	Associated Task (on Gantt Chart)	Planned			
				Unit	Quantity	Cost/Unit	Total Cost
Superflex Heavy Compression Spandex Fabric	ACTV005-005	Holder for ice pack and immobilization pad	Complete prototype	yards	1	18	18
Velcro	SKU 90320	Fastening and application	Complete prototype	yards	2	3.33	6.66
Uline 3 oz Ice packs	S-13376	Cooling	Complete prototype	case	1	24	24
DJO Wrist Splint	79-72117	Immobilization and support	Complete Prototype	Unit	1	15.85	15.85
Sam Medical Splint 36 INCH	SP1121F-36	Splint Testing	Testing	Unit	1	16.99	16.99

Based on the budget presented in Table 4, the proposed total cost for the prototype is $81.50. Additional splints may be purchased for the testing phase.

Table 5. Actual Prototype Budget

Item Description	Actual		
	Quantity	Cost/Unit	Total Cost
Superflex Heavy Compression Spandex Fabric	3	$7.99	$33.96
Uline 3 oz Ice packs	1	$26.00	$42.49
Velcro	1	$16.99	$16.99
DJO Wrist Splint	1	$15.01	$15.01
Sam Medical Splint 36 INCH	1	$10.90	$10.90
TXJ Sports Carpal Tunnel Wrist Splint	1	$9.90	$9.90
Supportive Elastic Wrap - 3"x1.6 yd - up & up	1	$1.39	$2.51
Thermometer	-	-	-
Sewing machine	-	-	-
Duct Tape	-	-	-
		Total	$133.77

Table 5 reflects the actual amount the team has spent on items for the prototyping and testing. Due to the addition of a new type of splint, sales tax, and shipping costs, the actual total is about $50 more than the proposed budget, but still below our max budget of $200.

11. Test Plans

The test plan of the device mainly revolves around the ability of the splint to stop acute inflammation of the injury. This would mainly involve testing the effectiveness of the cooling of the splint to stop the inflammation, and it would consist of two different tests. The first test is to simulate the splint's use by attaching it to a currently used product and wrapping it around a fake arm with a thermocouple. The thermocouple will measure the temperature at the skin's surface to see if it can reach 21°C to cause vasoconstriction. An additional test will test the range of motion with the add-on to see if it can maintain the stability of the wrist splint and minimize the range of motion that the wrist can bend to prevent further injury. The comfort of simulated use in everyday life will also be tested by having volunteers wear the device, and we will give them a survey to get a satisfaction score.

Test Protocols

Anti-Inflammatory Cold Test

- Purpose: To determine how effective the cooling mechanism is through the splint to achieve low enough temperatures for vasoconstriction to occur.
- Scope: The test will determine at which temperature the splint can cool the surface of the splint down.
- Equipment:
    - Splint (top three most popular wrist splints)
    - Hand and forearm model
    - Thermocouple or thermometer
- Facilities: This can occur on campus or at home, with a clean benchtop surface and comfortable room temperature.
- Procedure
    1. Set up the arm and hand model on a level surface and in a horizontal position, like an outstretched hand, to model how someone would hold their arm with a splint.
    2. Attach the thermocouple/thermometer to the surface of the model and then put on a splint to secure it.
    3. Apply the splint add-on with the cooling ice packs and then measure the temperature.
    4. Repeat the test as needed for each different type of splint.
- Results:
    - Pass Criteria: If it can attain temperatures of 21C or lower on the skin
    - Number of Samples: 3, one for each type of popular splint
    - Contingencies: Increase the surface area of the cooling pad to improve heat transfer
    - Performed by all Team members
- Data Analysis
    - The final temps will be recorded in Excel and plotted
    - T-test and ANOVA will be conducted to see if there is noticeable differences
- Expected Outcomes
    - Under 21 C temperature reading

Time to Cool Test

- Purpose: This is a continuation of the previous test to determine how fast the splint can effectively induce vasoconstriction since it must first be able to reach the vasoconstriction temperature.
- Scope: The test will determine how quickly the splint add-on can reach cool enough temperatures for vasoconstriction to prevent initial acute inflammation.
- Equipment
    - Splint (top three most popular wrist splints)
    - Hand and forearm model
    - Thermocouple or thermometer
    - Stopwatch/Timer
- Facilities: It can take place anywhere at room temperature to replicate normal conditions
- Procedure
    1. First, ensure the testing environment is at a stable room temperature of around 70F.
    2. Set up the arm and hand model on a level surface and in a horizontal position, like an outstretched hand, to model how someone would hold their arm with a splint.
    3. Attach the thermocouple/thermometer to the surface of the model and then put on a splint to secure it.
    4. Apply the splint add-on with the cooling ice packs and then measure the temperature.
    5. Set up a timer and stop the timer when a temperature of 21C is reached.
    6. Repeat for the other two splints.
- Results
    - Pass Criteria: able to reach 21C within ten minutes
    - Number of Samples: 3 (one for each type of splint)
    - Performed by all team member**s**
- Data Analysis
    - Record the data in Excel
    - Plot the temperature as a function of time
    - Find the R^2 value
    - Determine the cooling trend
- Contingencies
    - If unable to go below 21 C then the splints will have to be modified to provide better cooling
- Risk and Hazard Mitigation
    - No known risks except the hypothermia, but very low risk and the test can be stopped before any harm is done

Comfort Test

- Purpose: To evaluate the comfort level of wearing the splint add-on and identify areas for improvement.
- Scope: The test will assess the comfort of the splint add-on when worn over various types of wrist splints.
- Equipment:
    - Splint (top three most popular wrist splints)

    - Several volunteers.
    - Survey form with a rating scale from 1 to 10
- Facilities: The test will be conducted in a controlled environment at room temperature to replicate typical conditions.
- Procedure
    1. Volunteers will be provided with one of the wrist splints to wear.
    2. The splint-add prototype is then attached to the splint.
    3. The volunteer will be instructed to move their hand around to become accustomed to movement.
    4. After wearing the splint add-on for a specified duration (e.g., 10 minutes), participants will fill out a survey form.
    5. The survey will contain the following:
        - Overall Comfort: On a scale of 1-10, how comfortable is the splint add-on to wear?
        - Fit: How well does the splint add-on fit over the splint? (1 being poor fit, 10 being perfect fit)
        - Tightness: Rate the tightness of the splint add-on. (1 being too loose, 10 being too tight)
        - Itchiness: Did the splint add-on cause any itchiness or irritation? (1 being severe itchiness, 10 being no itchiness)
        - Breathability: How breathable is the material of the splint add-on? (1 being not breathable, 10 being very breathable)
        - Weight: Rate the weight of the splint add-on. (1 being very heavy, 10 being lightweight)
        - Durability: How durable does the splint add-on feel? (1 being very fragile, 10 being highly durable)
        - Overall Satisfaction: On a scale of 1-10, how satisfied are you with the comfort provided by the splint add-on?
- Results
    - Pass Criteria: A high average score of at least 7 for each aspect of comfort evaluated.
    - Number of Samples: 3 (one for each type of splint)
    - The test will be performed by all team members to ensure consistency and reliability of results.

Ease of Use Test

- Purpose: This test aims to evaluate the efficiency and user-friendliness of attaching the splint add-on to both oneself and another person.
- Scope: The test will assess the time taken for participants to apply the splint add-on independently and when assisting another person.
- Equipment:
    - Splint (top three most popular wrist splints)
    - Splint add on prototype
    - Timer or stopwatch
    - Volunteers

- Facilities: The test will be conducted in a controlled environment at room temperature to replicate typical conditions.
- Procedure
    1. Set up the testing area with clear instructions for participants.
    2. Part 1 (Individual Application):
        a. Participants will be provided with a splint add-on prototype and instructed to apply it to themselves.
        b. They will be given clear verbal or written instructions on how to attach the splint add-on.
        c. Participants will start the timer when they begin applying the splint add-on and stop it when they have successfully attached it.
    3. Part 2 (Assisted Application):
        a. Another participant (the helper) will be provided with a splint add-on prototype and instructed to assist the first participant (the recipient) in applying it.
        b. The recipient will give verbal instructions to the helper on how to attach the splint add-on.
        c. Both the recipient and the helper will start the timer simultaneously when they begin the application process and stop it when the splint add-on is successfully attached.
    4. Record the time taken for both the individual and assisted application processes in minutes and seconds.
    5. Conduct multiple trials with different participants to ensure consistency and reliability of results.
    6. After completing the trials, gather feedback on the ease of use and any challenges encountered.
        - How did you find the process of applying the splint add-on to yourself/assisting someone else?
        - Can you describe any challenges you encountered during the application process?
        - How easy was it to attach the splint add-on to the splint? (1 being very difficult, 10 being very easy)
        - Were the instructions provided clear and easy to follow?
        - Were there any steps in the process that you found confusing or difficult to understand?
        - Did you feel confident in your ability to attach the splint add-on?
        - Were there any specific features of the splint add-on that made it easier or more difficult to apply?
        - Do you think the time taken to apply the splint add-on was reasonable?
        - Were there any factors that contributed to the application process taking longer than expected?
        - How comfortable did you find the splint add-on once it was applied?
        - Did you encounter any issues with the fit or positioning of the splint add-on?
        - Based on your experience, are there any changes or improvements you would recommend to make the application process smoother?

        - Is there anything else you think we should consider when designing the splint add-on for ease of use?
        - Is there anything else you would like to share about your experience with the splint add-on?
- Results
    - **Pass Criteria:** The average time taken for both individual and assisted application should be within a reasonable range.
    - **Number of Samples:** Multiple trials will be conducted with different participants to ensure comprehensive data collection.
    - The test will be performed by all team members to ensure consistency and reliability of results.

Table 6. Summary of Test Plan

Test Name	Test Description	Facilities	Equipment	Test target (units)	Number of samples for Testing
Anti Inflammatory Cold	Measure how cold the splint can get to stop inflammation	Cal Poly Campus	Splints Prototype Hand Thermocouple	21°C	3
Time to Cool	Measure how long it would take for the cooling to reach vasoconstriction temperature	Cal Poly Campus	Splints Prototype Hand Thermocouple Timer	Max 10 minutes	3
Comfort	Survey people using the splint	Cal Poly campus	Splints Prototype Volunteer	10 (survey of satisfaction)	10
Ease of Use	See how long it takes to put on the splint	Cal Poly campus	Splints Prototype Volunteer Timer	2 Minutes	3

12. Testing Data and Analyses

Cooling Test Data and Results

The cooling test data was recorded and analyzed in Excel and JMP for statistical analysis. The first test conducted was a steady state temperature comparison test for a normal use of a splint compared to the performance of the CoolSplint. Temperature readings were taken after applying the splint for about 20 minutes or when equilibrium temperature was reached. The table with the data can be Appendix G, and the data was then exported to JMP and a t-test was conducted to determine whether or not the CoolSplint made a significant difference in cooling temperature. The results of the test are that the normal use of the splint results in an average equilibrium temperature of 30.99°C close to body temperature and the CoolSplint was able to reduce the equilibrium to 21.08°C with statistically significance difference with a p-value less than 0.05. This is evidence that the CoolSplint is able to cool the arm effectively.

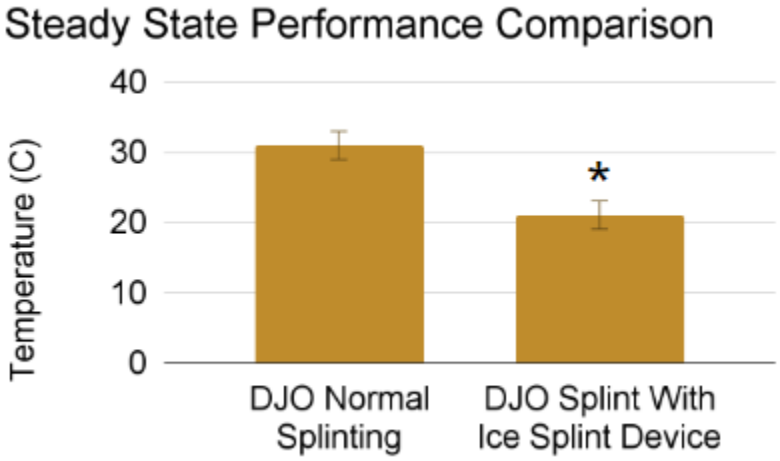

Figure 6. Steady State Performance comparison between DJO Splint and CoolSplint, (*, indicates $p<0.05$)

The cooling profile of the CoolSplint was then tested to see how fast and how well the cooling performance of the CoolSplint can cool within ten minutes. There were multiple different combinations and permutations of splint applications tested to determine which would produce the best results along with control groups of just applying the splints normally and taking the temperature. The temperatures of each test were taken at thirty second intervals and were recorded in a table found in Appendix H. The cooling profile tests were performed independently for two different splints, for the DJO and the SAM Splint. Figure 7 is the cooling profile of the DJO splint and does show significant temperature drops for the combinations that use the CoolSplint. The best result from the cooling profile tests was the modified splint, the foam had been removed from the DJO splint leaving only the aluminum shell which conducted heat away the fastest and was able to drop below the target temperature of 21°C.

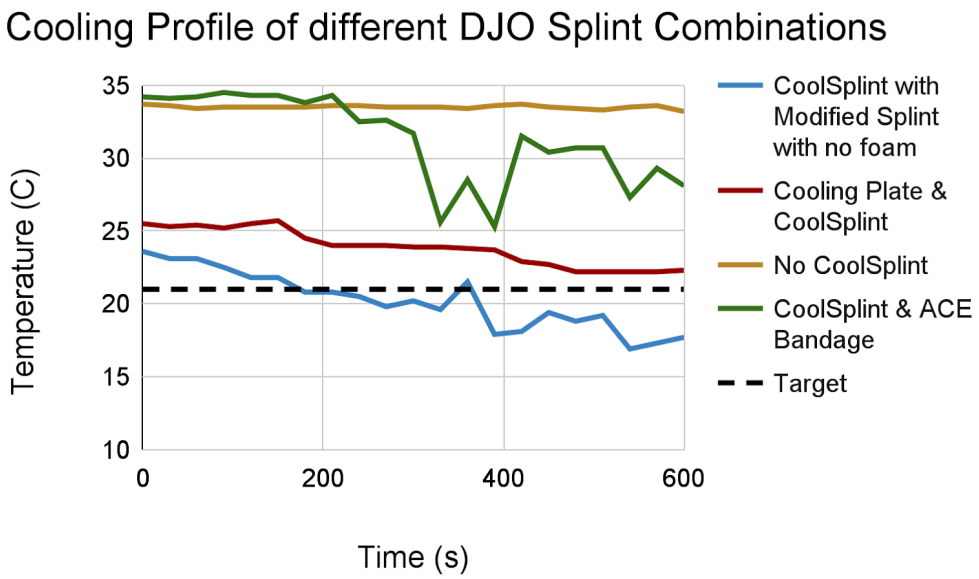

Figure 7. Cooling Profile for the DJO Splint

The same cooling profile test was conducted once more on the SAM Splint for different combinations, with the same testing method. The SAM Splint had slightly higher temperatures than the DJO splint on average however there were still noticeable temperature drops for the CoolSplint as shown in Figure 8. None of the combinations for the SAM Splint, even including the metal plate for better heat conduction could reach the desired temperature, which would require more testing and a modification of the existing design for and to create a better or bigger plate to increase surface area to conduct more heat away from the wrist.

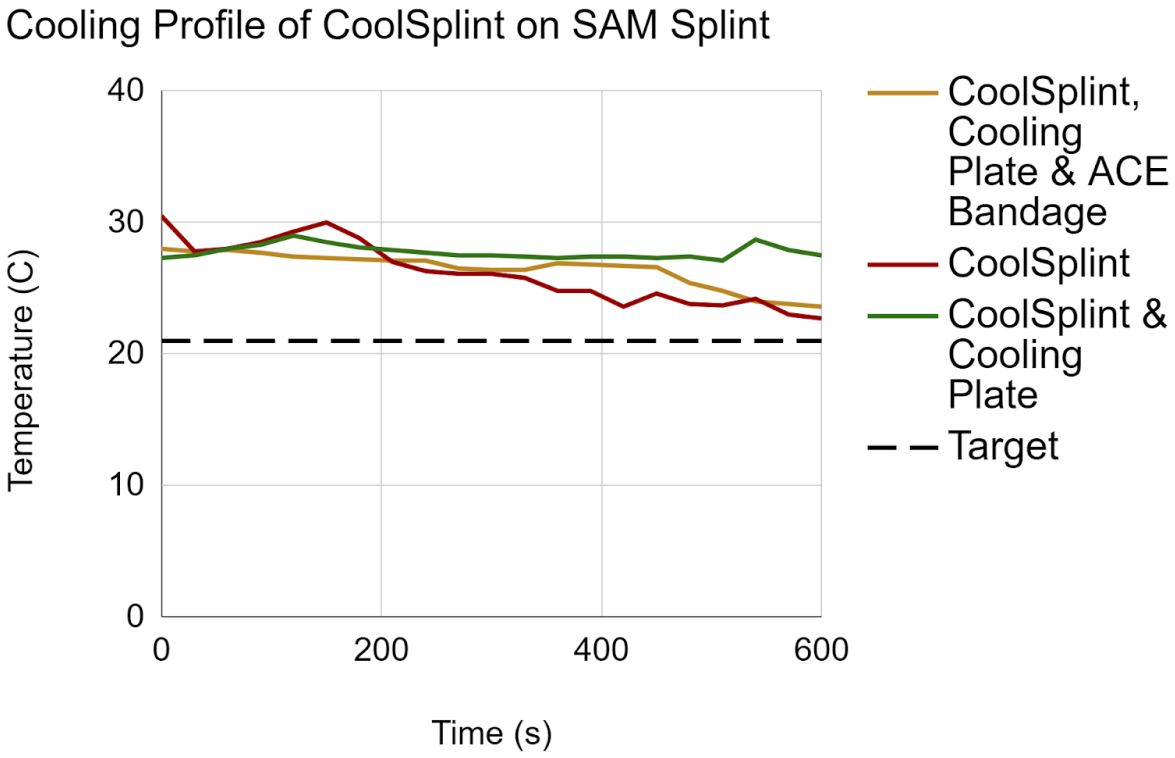

Figure 8. SAM Splint Cooling Profile tests

Comfort Test Data and Results

The comfort test was conducted to evaluate various aspects of comfort for a product by asking several participants to rate different criteria. The criteria included overall comfort, fit, tightness, itchiness, breathability, range of motion, weight, durability, ease of application, and overall satisfaction. Participants rated each criterion on a scale from 1 to 10 through a survey (shown in Appendix H), with 1 being the least favorable and 10 being the most favorable.

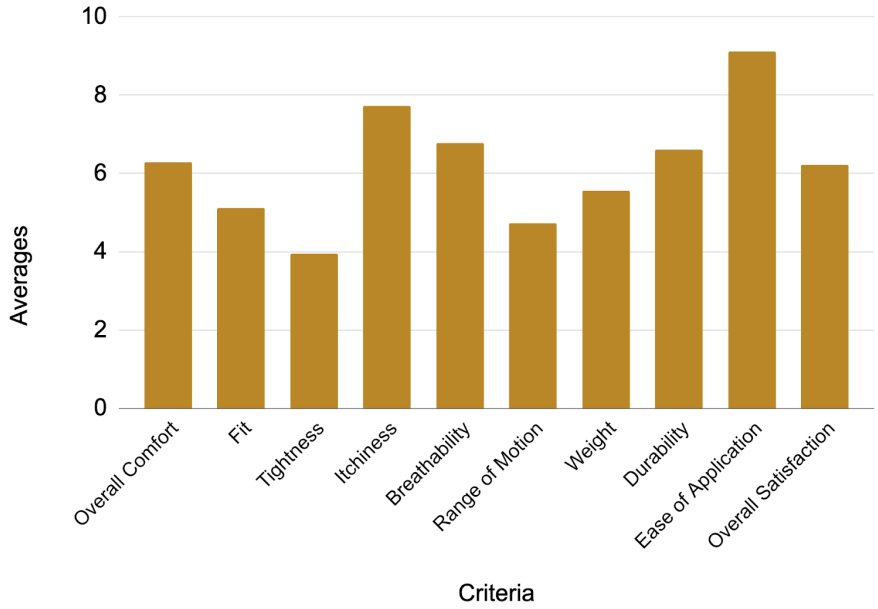

Figure 9. Average Comfort Ratings and Criteria Scores

The comfort test data was collected from six participants. The results for each criterion revealed a range of scores, with overall comfort scores ranging from 4 to 9 and an average of 6.83. The product's fit received scores from 3 to 8, with an average of 5.33, indicating that some participants found the fit to be less than ideal. Tightness was rated between 3 and 7, with an average score of 4.83, suggesting that some participants felt the product was too tight.
On the other hand, itchiness received high scores ranging from 5 to 10, with an average of 8.17, indicating that the product was generally not itchy for most participants. Breathability also received favorable ratings, with scores ranging from 3 to 10 and an average of 7.33, suggesting that participants found the product adequately breathable. Range of motion had scores from 3 to 8, with an average of 5.17, indicating moderate satisfaction with the product's flexibility.
The product's weight received the lowest average score of 4.67, with individual scores ranging from 2 to 8, indicating that participants found the product relatively heavy. Durability received scores between 4 and 9, averaging 6.83, suggesting that participants were generally satisfied with the product's durability. Ease of application was rated between 3 and 10, with an average score of 7.33, indicating that most participants found the product easy to apply. Overall satisfaction scores ranged from 3 to 9, with an average of 6.67, reflecting a generally positive but somewhat mixed response from participants.

The comfort test results provide valuable insights into the product's strengths and weaknesses. While participants appreciated the product's low itchiness, good breathability, and ease of application, there are clear areas for improvement in terms of fit, tightness, and weight. Addressing these issues could enhance the product's overall comfort and satisfaction.

13. Instructions for Use

Instructions for Use with Modified DJO Splint

1. Freeze the CoolSplint for at least 4 hours prior to use.
2. Lay out the CoolSplint on a flat surface with the velcro side down.
3. Ensure that the ice packs are laying flat within the pockets of the CoolSplint.
4. Place the white metal splint board on the center of the CoolSplint, seen in Figure 10.

Figure 10. Metal Splint Board Positioned on CoolSplint

5. Place the affected wrist on the white metal splint board and rest the wrist comfortably on the splint, seen in Figure 11..

Figure 11. Wrist Positioned on Splint Board and CoolSplint

6. Gently wrap the CoolSplint around the wrist and securely fasten with the velcro straps, seen in Figure 12.

Figure 12. CoolSplint Application

7. Once attached, adjust the position and tightness of the CoolSplint to ensure optimal comfort and support.
8. Make sure the ice packs are properly aligned with the affected area of the wrist.
9. Move the wrist gently to ensure that the CoolSplint allows for a limited range of motion while providing comfort and cooling.
10. Make minor adjustments as necessary to improve comfort and effectiveness.

Instructions for Use with SAM Splint

1. Apply SAM Splint as directed per instructions available on splint.
2. Secure the SAM splint using medical tape, ACE bandage, or similar fastener, shown in Figure 13.

Figure 13. SAM Splint Application

3. Freeze the CoolSplint for at least 4 hours prior to use.

4. Lay out the CoolSplint on a flat surface with the velcro side down.
5. Ensure that the ice packs are laying flat within the pockets of the CoolSplint.
6. Place the injured wrist with SAM Splint onto flattened CoolSplint, shown in Figure 14.

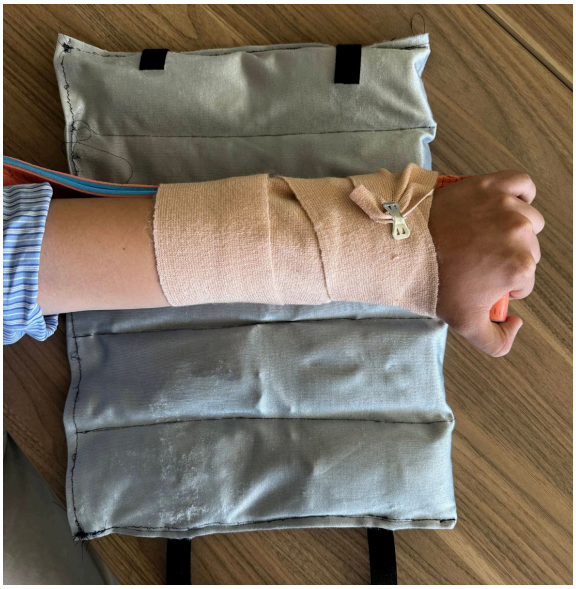

Figure 14. SAM Splint Placement on CoolSplint

7. Gently wrap the CoolSplint around the wrist and securely fasten with the velcro straps, seen in Figure 15.

Figure 15. CoolSplint Placement on SAM Splint

8. Make sure the ice packs are properly aligned with the affected area of the wrist.
9. Move the wrist gently to ensure that the CoolSplint allows for a limited range of motion while providing comfort and cooling.
10. Make minor adjustments as necessary to improve comfort and effectiveness.

13. Project Management

The design process will be utilized to develop this project. The need for a new wrist splint is identified in the discovery phase, considering both clinical requirements and user limitations. The planning stage will involve identifying necessary resources, speculating on device potential, and forming a comprehensive schedule and budget for the development process.

Subsequently, the definition phase will entail generating precise customer requirements and establishing design specifications. Various splint concepts will be modeled and evaluated in the conceptual design stage against the identified requirements. The development stage will entail refining the most viable concept into a wrist splint prototype and employing a thorough test plan. This approach ensures systematic and methodical progression to realize a new and effective wrist splint.

A Gantt chart, shown in **Appendix E**, will be used to track required deliverables, progress, and dependencies to keep the project moving through the design process smoothly. Table 8 lists the major project deliverables, all dependent on the successful completion of the deliverable before it. The critical path follows these dependencies throughout the project. Following the statement of work, the team will begin generating concepts for the conceptual design review. At the same time, an FMEA will be created to assess possible risks associated with the splint. Once the conceptual models have been evaluated, the critical design can be selected and reviewed in the critical design report. Materials can be sourced once the design is selected, and a prototype can be built. The prototype will then be used for extensive testing and compiled into the test plan report. Finally, areas of improvement can be addressed, and the entire project can be summarized with the final report and the expo poster for the engineering fair.

An updated Gantt chart for the final stage of this project is located in Appendix F. The key testing dates are described in Table 7. The final deliverables and their completion deadlines have been updated in Table 8.

Table 7. List of Testing Dates and Locations

Test	Date	Location
Time to Cool	April 29th, 12 PM	BMED 456 Room
Range of Motion	May 1st, 12 PM	BMED 456 Room
Comfort	May 6th, 12 PM	BMED 456 Room
Ease of Use	May 8th, 12 PM	BMED 456 Room

Table 8. List of Key Deliverables and Deadlines

Deliverable	Deadline
Test Plan Report	23 April 2024
Testing Completion	8 May 2024
Expo Poster	28 May 2024
Final Report	4 June 2024

14. Future Directions

Based on the efficacy of the CoolSplint, the dimensions could be adjusted to adapt to treat injuries in other areas of the body, like the ankle, elbow, or knee. The cooling technology could be marketed and monetized to help fight chronic inflammation in other critical joints that may be injured.

To further improve the CoolSplint design, the velcro could be modified with a fastener, like a D ring, for easier tightening. This improvement is based on user feedback from the ease of use data. Integration of this kind of fastener could improve the tightening of the CoolSplint and further user testing would need to be completed.

Finally, the cooling plate could be improved to expand the versatility and efficacy of the CoolSplint. For the cooling tests, a strip of aluminum foil was used to conduct heat away from the body to be cooled by the CoolSplint. This idea showed some merit during the cooling tests, but could be greatly improved. Changing the material to copper or another material with higher conductivity would increase the effectiveness of the cooling plate. Adjusting the design of the cooling plate would also improve the comfort. This idea of adding a cooling plate has many options that could be explored further to improve the cooling and comfort of the CoolSplint.

15. Conclusion

In conclusion, this document aims to recognize the issues with current splints and focus on creating a splinting add-on to help fight inflammation. We aimed to create a versatile, affordable, and user-friendly solution that immobilizes limbs effectively and addresses inflammation concerns for improved long-term outcomes. After designing, building, and testing the CoolSplint it is clear that these objectives were completed. Temperature testing showed the effectiveness of the CoolSplint by cooling the wrist to below 21 degrees celsius which is the target for vasoconstriction that would fight inflammation. Overall, the CoolSplint was developed and tested to prove it is effective at cooling, easy to use, and comfortable to wear.

16. References

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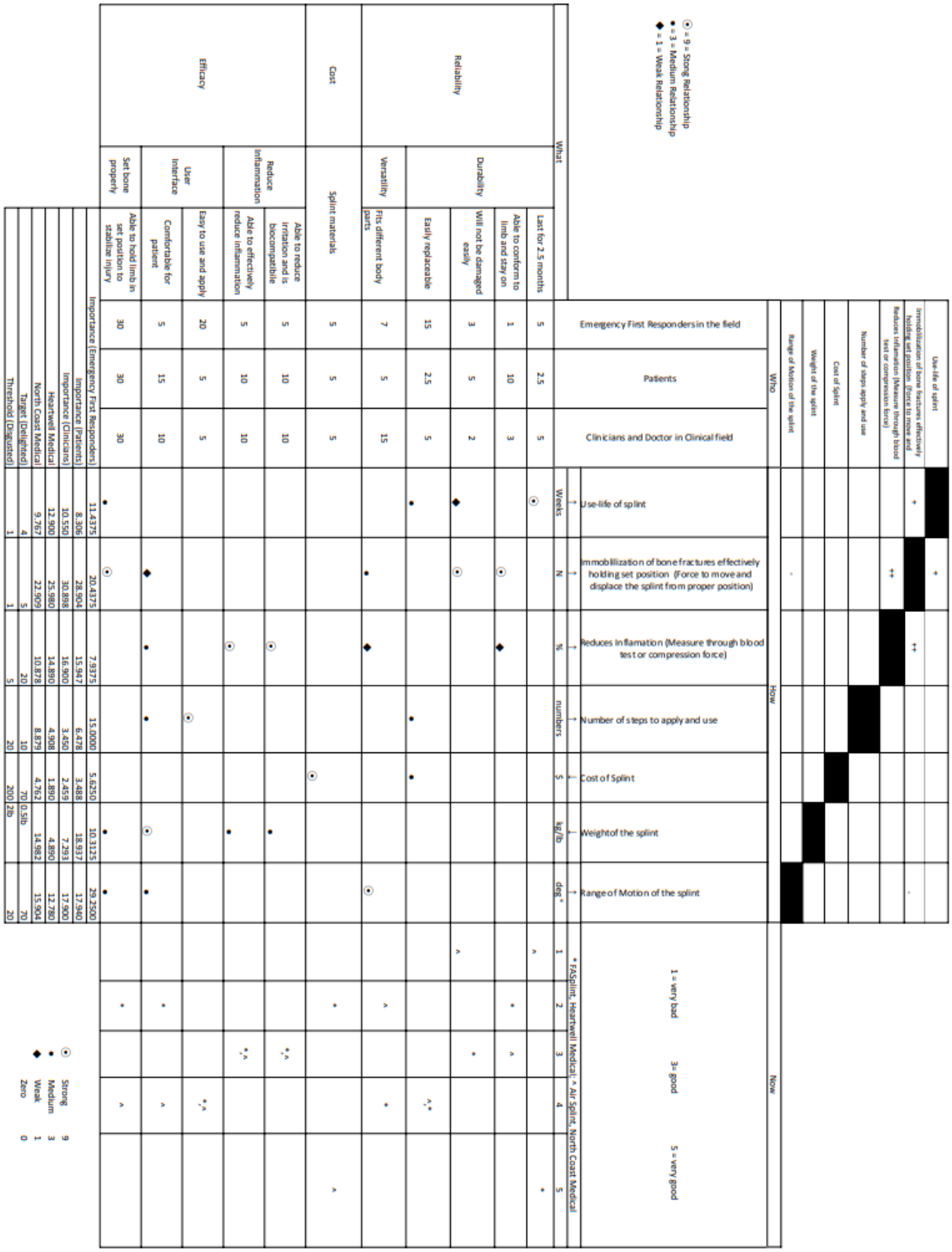
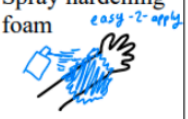
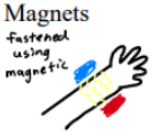
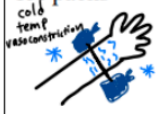
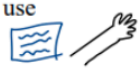
A. Appendices

Appendix A. House Of Quality Table (Customer Wants and Needs)



Appendix B. Morphology Concept Chart

Morphology

Product:Wrist Splint	Organization Name : Air Splint Redesign					
Function	**Concept 1**	**Concept 2**	**Concept 3**	**Concept 4**	**Concept 5**	**Concept 6**
Immobolize limb	Inflatable 	Vacuum seal 	Stick with tape 	Spray hardening foam 	Clamp 	Magnets 
Reduce swelling	Ice packs 	Drug eluding 	Heat packs 	Compression 	Immobilization 	Self-elevating 
Comfortable	Fleece lined 	Soft, Elastic, moisture wicking ‘workout clothes’ material 	Fully adjustable 	Smooth edges only 	Soft Padding 	Breathable materials 
Easy to use	Kit with clear instructions for use 	Minimal steps to apply – stick and go 	Self contained 	Color coding 	Easy to clean 	Form fitting 

Team member: Laura	Team member: Aanchal	Prepared by:Laura	
Team member: Winston	Team member:	Checked by:Aanchal	Approved by:Winston

The Mechanical Design Process
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Designed by Professor David G. Ullman
Form # 15.0

Appendix C. Pugh Matrices

Pugh Matrix

Concept Selection Legend	
Better	+
Same	S
Worse	-

Key Criteria	Importance Rating	Benchmark Option	Alternative Concepts: Ice Pack Splint	Inflatable Splint	Compression/magnetic Splint
Immobilizing	9	Datum	S	+	+
Anti-Inflammatory	10		+	S	-
Affordability	7		S	S	S
Ease of Use	3		+	S	S
Comfortability	2		+	-	+
Durability	5		-	-	S
Ventilation	1		+	-	+
Ease of cleaning	1		+	+	S
Insulation	8		+	-	S
Aesthetics	1		+	+	+
Sum of Positives			7	3	4
Sum of Negatives			1	4	1
Sum of Sames			2	3	5
Weighted Sum of Positives			26	11	13
Weighted Sum of Negatives			5	16	10
TOTALS			**21**	**-5**	**3**

Pugh Matrix

Concept Selection Legend	
Better	+
Same	S
Worse	-

Key Criteria	*Importance Rating*	Benchmark Option	Alternative Concepts: Ice Pack Splint	Inflatable Splint	Compression/magnetic Splint
Immobilizing	9	Datum	S	-	+
Anti-Inflammatory	10		+	+	S
Affordability	7		S	S	-
Ease of Use (Attachment)	3		+	-	-
Comfortability	2		+	+	+
Durability	5		S	-	-
Ventilation	1		-	+	-
Ease of cleaning	1		S	+	S
Insulation	8		S	+	+
Aesthetics	1		+	+	+
Sum of Positives			4	6	4
Sum of Negatives			1	3	4
Sum of Sames			5	1	2
Weighted Sum of Positives			16	23	20
Weighted Sum of Negatives			1	17	16
TOTALS			**15**	**6**	**4**

Pugh Matrix

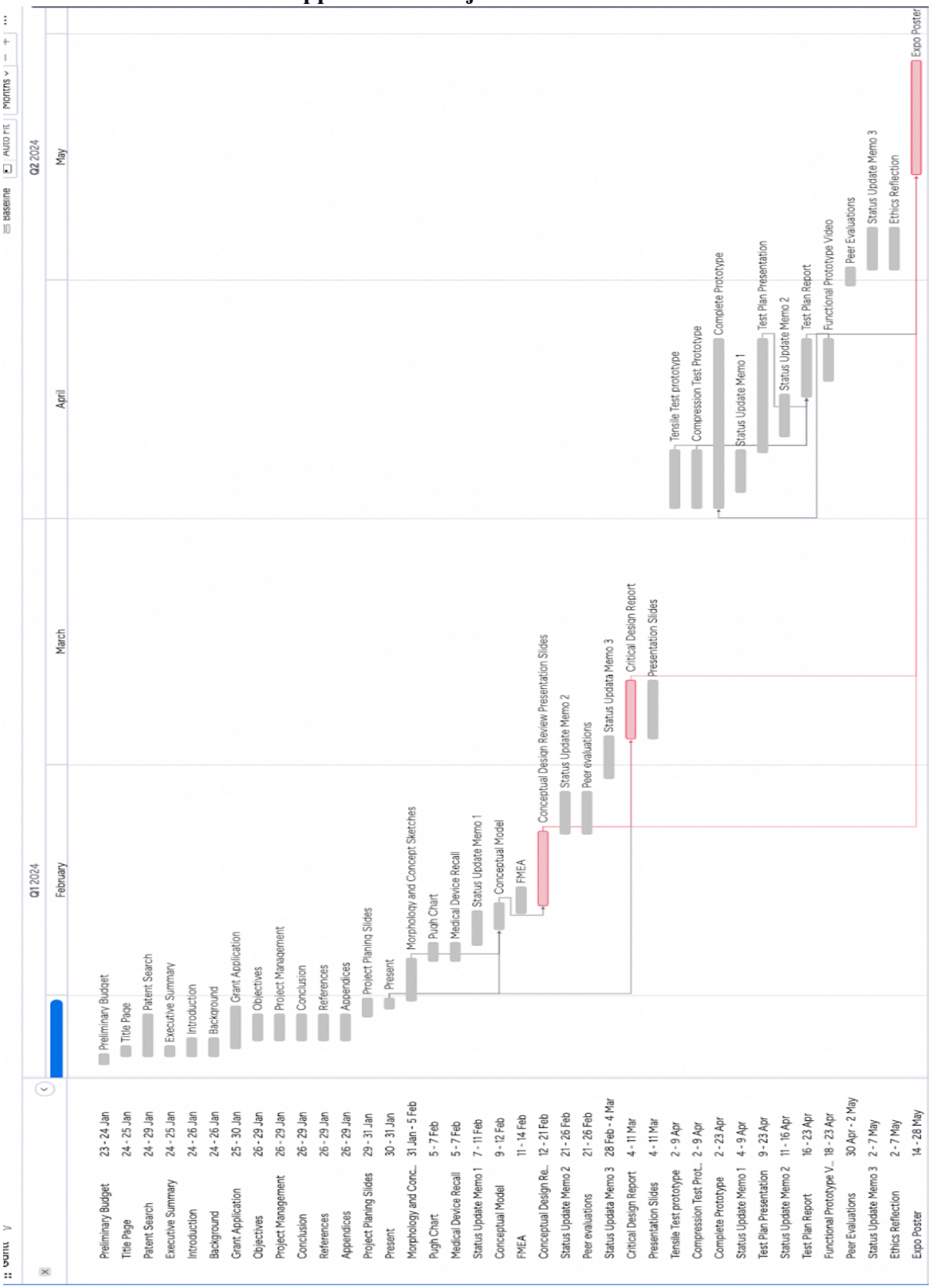
Concept Selection Legend	
Better	+
Same	S
Worse	-

Key Criteria	Importance Rating	Benchmark Option	Alternative Concepts: Ice Pack Splint	Inflatable Splint	Compression/magnetic Splint
Immobilizing	9	Datum	S	+	+
Anti-Inflammatory	10		+	-	-
Affordability	7		S	+	S
Ease of Use (Attachment)	3		+	+	S
Comfortability	2		+	S	+
Durability	5		-	-	-
Ventilation	1		+	-	-
Ease of cleaning	1		+	+	+
Insulation	8		S	S	S
Aesthetics	1		+	-	+
Sum of Positives			6	4	4
Sum of Negatives			1	4	3
Sum of Sames			3	2	3
Weighted Sum of Positives			18	20	13
Weighted Sum of Negatives			5	17	16
TOTALS			**13**	**3**	**-3**

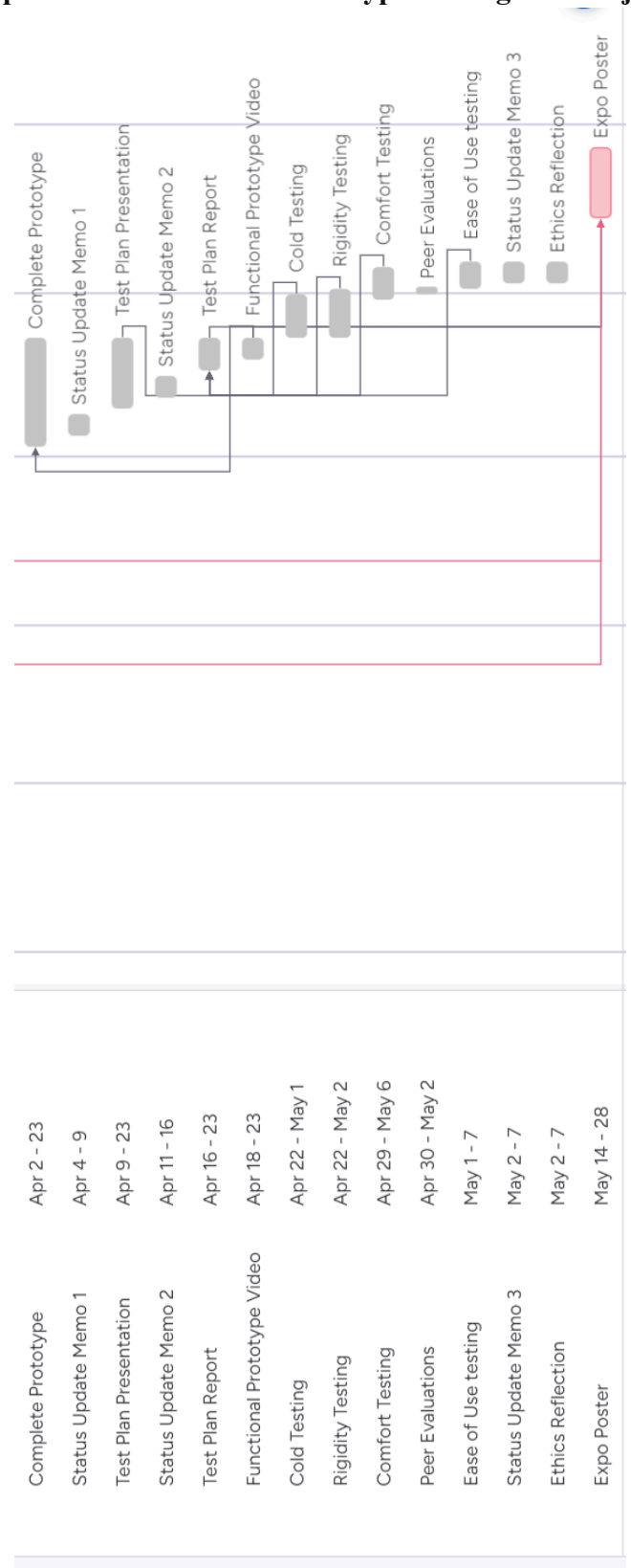
Appendix C. FMEA Table

Function Affected	Potential Failure Mode	Potential Effect(s) of Failure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions	Responsible Person	Taken Actions
Affordability	Excessive manufacturing costs	High production costs make the splint unaffordable	2	1	5	10	Complex design requiring expensive materials	Simplify design; Opt for cost-effective materials	Laura	Revised design for cost optimization
Anatomical Fit	Poor Fit	Loss of Immobilization	4	3	8	96	User Error	Ensure fit supports wide range of anatomies	Aanchal	Introduced customizable sizing options
Anti-inflammatory	Ineffective cooling mechanism	Swelling and discomfort	3	2	4	24	Inadequate ventilation	Add different cooling mechanisms	Winston	Integrated different cooling gel packs
Anti-inflammatory	Compression is too tight	Pressure sores	4	6	9	216	User error, design consideration	Design to consider range of anatomies, provide a check step to ensure proper blood flow after application	Winston	Redesigned splint with pressure-relief features
Anti-inflammatory	too cold, ineffective temperature control	Cold rash	4	6	9	216	Design consideration	Make sure that the cooling rods provide a cooling effect to the user but also properly insulated	Laura	Redesigned splint with proper insulation
Comfort	Uncomfortable material	Skin irritation of discomfort	4	3	4	48	Improper finishing	Smooth edges and use soft materials	Aanchal	Tested materials on users to make sure the material is comfortable
Comfort	Allergy cause reaction	Allergy rash / irritation	2	3	4	24	Material is allergenic	Select hypoallergenic materials	Laura	Tested materials for skin sensitivity
Comfort	Splint gets dirty	Skin irritation or discomfort, bad smell	4	3	2	24	Material is hard to clean	Select material that is easy to clean	Winston	Tested for sterilization
Durability	Material degradation	Breakage or deformation during use	2	3	6	36	Inadequate structural support	Reinforce critical areas; Conduct durability testing	Laura	Reinforced critical areas based on testing feedback
Ease of Cleaning	Difficult to clean	Residue buildup or inability to sterilize	2	3	4	24	Complex surface design	Simplify surface contours; Choose easy-to-clean materials	Aanchal	Simplified surface design for easier cleaning
Ease of Use	Complicated application process	Difficulty in applying the splint correctly	4	3	4	48	Lack of clear instructions	Improve instructional materials; Simplify application process	Aanchal	Updated instruction manual with clear, simple steps
Immobilization	Weak Fasteners	Loss of Immobilization	4	3	8	96	Design consideration	Ensure fasteners are secure with testing	Laura	Tested fasteners
Immobilization	Improper Application	Loss of Immobilization	6	3	8	144	User error	Provide clear instructions for use	Winston	Made sure that the instruction manual is easy to follow
Immobilization	Restriction of Blood Flow	Damage to soft tissue	4	6	9	216	User Error	Provide a check step to ensure proper blood flow after application	Aanchal	Implemented testing after application to ensure that there is blood flow
Immobilization	Broken Splint Board	Loss of Immobilization	4	3	8	96	Weak splint board	Determine desired durability and select material accordingly	Laura	Tested the tensile strength of the splint board
Ventilation	Poor airflow	Heat buildup or moisture retention	2	3	2	12	Insufficient ventilation design	Improve airflow channels; Use breathable materials	Winston	Redesigned splint with enhanced ventilation

Appendix D. Project Gantt Chart



Appendix E. Updated Gantt Chart: Prototype Testing and Project Completion



Appendix F: Steady State Comparison Temperature Test Results

Normal (°C)	CoolSplint (°C)
31.4	21
32.5	22.8
29.8	23.1
30.6	19.2
31.5	18.9
28.9	20.5
32	21.5
31.3	22.3
30.2	21.7
31.7	19.8
30.99	21.08

Appendix G. Cooling Profile Data

Time (s)	Modified Splint with no foam	Splint with Plate and CoolSplint	Splint with foam and Device	Ace Bandage with Ice Splint on DJO Splint	Ace Bandage, Plate & CoolSplint on SAM SPLINT	SAM splint with Ice Splint	SAM Splint, Plate & CoolSplint
0	23.6	25.5	33.7	34.2	28	30.5	27.3
30	23.1	25.3	33.6	34.1	27.8	27.8	27.5
60	23.1	25.4	33.4	34.2	27.9	28	28
90	22.5	25.2	33.5	34.5	27.7	28.5	28.3
120	21.8	25.5	33.5	34.3	27.4	29.3	29
150	21.8	25.7	33.5	34.3	27.3	30	28.5
180	20.8	24.5	33.5	33.8	27.2	28.8	28.1
210	20.8	24	33.6	34.3	27.1	27	27.9
240	20.5	24	33.6	32.5	27.1	26.3	27.7
270	19.8	24	33.5	32.6	26.5	26.1	27.5
300	20.2	23.9	33.5	31.7	26.4	26.1	27.5
330	19.6	23.9	33.5	25.6	26.4	25.8	27.4
360	21.5	23.8	33.4	28.5	26.9	24.8	27.3
390	17.9	23.7	33.6	25.3	26.8	24.8	27.4
420	18.1	22.9	33.7	31.5	26.7	23.6	27.4
450	19.4	22.7	33.5	30.4	26.6	24.6	27.3
480	18.8	22.2	33.4	30.7	25.4	23.8	27.4
510	19.2	22.2	33.3	30.7	24.8	23.7	27.1
540	16.9	22.2	33.5	27.3	24	24.2	28.7
570	17.3	22.2	33.6	29.3	23.8	23	27.9
600	17.7	22.3	33.2	28.1	23.6	22.7	27.5

Appendix H. Comfort Test Data

Comfort Testing Feedback

Disclaimer:
We are students at Cal Poly conducting research on whether or our senior project prototype of creating a wrist splint add-on will be effective. We would greatly appreciate your participation and honesty as it will assist with improving our prototype. The survey will take 5 minutes. Again, thank you so much for participating.

aanchalsingh0804@gmail.com Switch account

Not shared

* Indicates required question

Overall Comfort: On a scale of 1-10, how comfortable is the splint add-on to wear? *

	1	2	3	4	5	6	7	8	9	10	
Poor fit	○	○	○	○	○	○	○	○	○	○	Perfect Fit

Fit: How well does the splint add-on fit over the splint? *

	1	2	3	4	5	6	7	8	9	10	
Too loose	○	○	○	○	○	○	○	○	○	○	Too tight

Tightness: Rate the tightness of the splint add-on. *

	1	2	3	4	5	6	7	8	9	10	
Too loose	○	○	○	○	○	○	○	○	○	○	Too tight

Itchiness: Did the splint add-on cause any itchiness or irritation? *

	1	2	3	4	5	6	7	8	9	10	
Severe itchiness	○	○	○	○	○	○	○	○	○	○	No itchiness

Breathability: How breathable is the material of the splint add-on? *

	1	2	3	4	5	6	7	8	9	10	
Not breathable	○	○	○	○	○	○	○	○	○	○	Very breathable

Range of Motion: To what extent does the splint add-on restrict your hand's range of motion? *

	1	2	3	4	5	6	7	8	9	10	
Highly restrictive	○	○	○	○	○	○	○	○	○	○	No restriction

Weight: Rate the weight of the splint add-on. *

	1	2	3	4	5	6	7	8	9	10	
Very heavy	○	○	○	○	○	○	○	○	○	○	Lightweight

Durability: How durable does the splint add-on feel? *

	1	2	3	4	5	6	7	8	9	10	
Very fragile	○	○	○	○	○	○	○	○	○	○	Highly durable

Ease of Application: How easy was it to attach the splint add-on to the splint? *

	1	2	3	4	5	6	7	8	9	10	
Very difficult	○	○	○	○	○	○	○	○	○	○	Very easy

Overall Satisfaction: On a scale of 1-10, how satisfied are you with the comfort provided by the splint add-on? *

	1	2	3	4	5	6	7	8	9	10	
Not satisfied	○	○	○	○	○	○	○	○	○	○	Very satisfied

Results from the Comfort Test Survey

Timestamp	Overall Comfort	Fit	Tightness	Itchiness	Breathability	Range of Motion	Weight	Durability	Ease of Application	Overall Satisfaction
5/13/2024 13:24:55	9	8	7	10	9	3	5	8	8	9
5/14/2024 20:58:54	4	3	3	9	9	8	4	7	3	3
5/14/2024 21:06:57	8	5	6	10	8	8	2	9	7	8
5/14/2024 21:20:32	8	6	6	5	5	3	5	4	6	8
5/14/2024 21:58:26	8	5	4	10	10	5	8	8	10	7
5/14/2024 22:16:09	4	5	3	5	3	4	4	5	10	5
Averages:	6.83333	5.33333	4.83333	8.16667	7.33333	5.16667	4.66667	6.83333	7.33333	6.66667