Joint Arthroscopy Manikin for Viable Cartilage

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Executive Summary

Knee arthroscopies are the most common orthopedic surgical procedure with approximately two million procedures performed every year. There currently exist no systems which allow for surgeons to optically measure redox imbalance, a tissue health indicator, in real-time during procedures. Providing this information real-time during procedures would allow for delivery of treatment such as steroid injections to unhealthy tissue, improving patient outcomes. To develop this technology, the Henak lab requires the design and fabrication of a low-cost, anatomically correct manikin of the knee to test live cartilage tissue imaging capabilities in a controlled preclinical environment. Similar products exist, but do not allow for the culture of live cartilage tissue. The development of this technology offers a creative and novel method for improving outcomes for millions of patients every year as well as advancing research in the field.

The development of the project will be split into three collaborative teams focused on the design and fabrication of the joint system to hold the cartilage, the enclosure of the media and joint system, and the pump system to promote the flow of media through the manikin. Evaluation of the efficacy of the device will quantitatively measure potential damage to the cartilage tissue, security of cartilage attachment, media leakage, media flow pressure, and media oxygen concentration. The development of the device will be conducted in close collaboration with Dr. Henak and Dr. Johnson for regular feedback and guidance regarding design choices. Despite not being conducive to commercialization, this device has the potential to aid in research which could impact the millions of patients who receive knee arthroscopies every year.

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Introduction

Arthroscopy is a minimally-invasive surgical procedure utilizing an arthroscope, or small camera instrument, to access and visualize a joint space [1] . Usage of such instrumentation avoids the creation of large incisions when opening up the joint, allowing for a faster recovery for the patient. The arthroscope also allows the surgeon to distinguish between partial and complete ligament tears that are otherwise indistinguishable. Arthroscopy is the most common orthopedic procedure in the United States as it allows for direct visualization of all intra articular structures. It is a low-risk procedure with a complication risk of less than 1% and an infection rate of approximately 0.1%[1].

Orthopedic surgery in the United States requires a minimum of thirteen years of higher level education, including four years of residency training in arthroscopic surgical procedures [2]. In 2013, the average orthopedic surgeon completed over 300 arthroscopic procedures in residency prior to graduation [1]. Despite the commitment required, surgeons still have to make decisions regarding the biological health of certain joint tissue purely visually with incomplete information with respect to the condition of said tissue on a cellular level. An indicator of tissue health with clinical applications is redox balance. It is crucial to maintain redox homeostasis during arthroscopic procedures in order to minimize tissue damage, inflammation, and promote postoperative recovery [3]. Redox imbalance arises as a consequence of the accumulation of reactive oxygen species (ROS), which are natural byproducts of the mitochondrial electron transport chain [3]. During surgical procedures, a significant inflammatory response is triggered, resulting in an elevated production of ROS by immune cells [4]. This surge in ROS production can disrupt the redox balance within the body. Currently, no system exists to allow surgeons to optically measure redox imbalance. The existing devices mainly focus on training procedures and do not allow for the housing of live cartilage [5]. Equipping surgeons with this information enables them to apply techniques aimed at reducing ROS levels and preventing imbalances. It is well-established that antioxidants can effectively mitigate ROS, given their nucleophilic properties that can react with oxidants [4]. To advance this technology, the Henak lab requires the design and fabrication of an economically viable, anatomically-correct knee manikin. This manikin will serve as a platform to assess real-time cartilage tissue imaging capabilities within a carefully controlled preclinical setting. While similar products are available, they do not facilitate the cultivation of live cartilage tissue [5]. The development of this simulator represents an innovative and distinctive approach to enhancing the well-being of the approximately two million patients who undergo arthroscopic knee procedures annually [6].

Knee Joint System

The first team of the Joint Arthroscopy Manikin consists of the design and implementation of the knee joint system. This includes the modeled bones, ligaments, and cartilage attachment mechanism that will be included in the final design. The joint will be designed with consideration towards existing designs and will meet the requirements as outlined by Dr. Henak in the problem statement (Appendix A).

Existing Designs

Current models used for arthroscopic surgery simulations include anatomically correct patient models used for surgical training purposes. Within these models, internal structures such as bones, ligaments, and cartilage are designed to replicate the anatomy of the human knee as accurately as possible. As seen in Figure 1, it is common for models to include the femur, tibia, fibula and patella as well as the cruciate ligaments and menisci. These models ensure proper training and are able to simulate the tactile feedback of real-life arthroscopies (Figure 2). Additionally, existing models are designed in a way that allows for manipulation and positioning of the leg and knee during training to adequately simulate arthroscopic surgery techniques [5].

Figure 1. Existing knee model design highlighting included bones, ligaments, and cartilage [7].

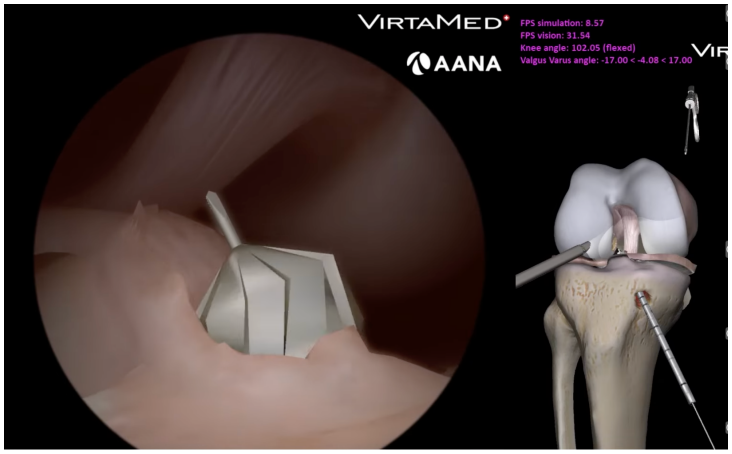

Figure 2. Existing knee arthroscopy surgery training model for active tactile feedback and physical manipulation of the leg [5].

Design Requirements

Design requirements for the knee joint model have been outlined by Dr. Henak. First, the knee joint bones must be anatomically correct and include the distal midshaft femur, proximal midshaft tibia, and proximal midshaft fibula. These bones must correctly model the human anatomy while conforming together and moving as actual knee joint bones would. Furthermore, the cartilage samples obtained come from a variety of patients. As a result, the bone models must be able to account for the variability that arises due to a number of factors including but not limited to patient age, sex, and weight.

It is required that the ligaments included provide sufficient support for the knee joint and allow for different positions to be maintained. It is not necessary that the ligaments be anatomically correct, nor do they need to actually be modeled ligaments.

Finally, the cartilage samples received from surgeries must be able to be adequately attached to the knee joint models without being placed under any mechanical stress. These samples are often fragmented and contain bone remnants, so it is crucial that the model is able to effectively join the samples with the modeled bones throughout the entirety of the testing process.

Design and Evaluation Plan

In order to meet the requirements outlined by the client and ensure the model's functionality, the team intends to 3D print the femur, tibia, and fibula. Through research, various computer aided design (CAD) and finite element (FE) models of the bones of the knee were analyzed. However, these models included shortcomings such as inability to bend, holes in the geometry from CT reconstruction, and inclusion of extra anatomy including muscles and ligaments [8][9]. Based on these limitations of other models and additional factors including cost, quality of the model, and ease of replication, the knee models to be used are those acquired through Open Knee(s), a public-sourced and freely available database from Cleveland Clinic [10]. This database contains a variety of different FE models of the bones of the knee, allowing for adaptation of the model due to any patient-to-patient variability that arises. As shown in Figure 3, the individual

geometries of the femur, tibia, and fibula will be exported, modified, and 3D printed. Formlabs Clear resin will be used for initial prototypes as it is lower in cost compared to Formlabs Biomed Clear, which will be used for final prototypes due to its biocompatibility. The ligaments of the knee will not be 3D printed but instead will be made of a non-toxic wire or other type of string to ensure joint stability. The performance of the knee joint model will be determined by its ability to bend to 80° of flexion, straighten to full extension, hold the positions in which it is placed, and provide a suitable surface for cartilage attachment [11].

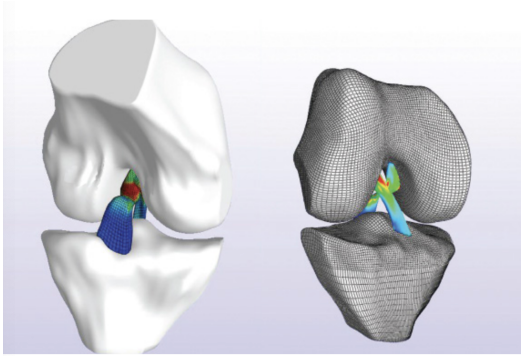

Figure 3. Finite element computer model including the distal femur, proximal tibia, and proximal fibula (not visible) as well as various cruciate ligaments [10].

In order to adequately attach the cartilage samples to the bone models, the samples received will be glued or stapled to the 3D printed bone. This will allow the samples to be attached regardless of the variability they present with and undergo less stress than other attachment mechanisms such as screws or staples. The method to be used will be determined through testing and experimentation results. The success of the attachment will be determined based on a variety of factors. First, if the samples stay firmly in place on the bone models throughout the entirety of the testing period. There must be no loosening or movement of the samples, as this would interfere with the simulated arthroscopy. Second, there must be no sign of degradation of the samples or death of the cells/tissue due to mechanical loads or stresses caused by the attachment mechanism. Autofluorescence will be used to measure stress outside of the manikin compared to inside the manikin to determine if the sample is experiencing any significant levels of mechanical stress.

Manikin Enclosure Assembly

The second team of the Joint Arthroscopy Manikin consists of the design and implementation of an enclosure assembly to house the knee joint system. It will serve as a support structure for the joint system as well as serving as a reservoir for the media required to keep the cartilage tissue viable. The enclosure should be compatible with the ports of the pump system while holding the interior joint and cartilage structures in place while fulfilling the design requirements outlined by Dr. Henak in the problem statement (Appendix A). There are currently no manikin enclosures which allow for the culture of live tissue.

Existing Designs

Commercially available knee manikins are most frequently designed for the purpose of being used as anatomically correct models to train surgeons. They contain all relevant anatomy on the interior of the knee and are unable to hold live tissue. Due to the support provided by the muscles of the knee, a silicone layer can be pulled over the manikin to act as an enclosure and simulate skin as seen in Figure 4 [12]. This layer is typically replaced after incisions are made during training exercises. Since the desired application of our device is to house cartilage being cultured in media, no such support will be provided by the interior of the manikin and the enclosure must provide structure and support while allowing access to the interior of the model.

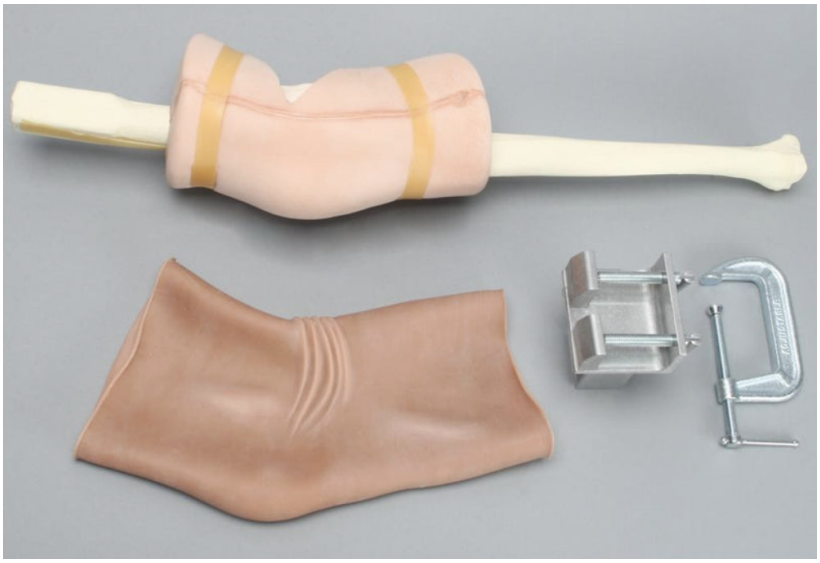

Figure 4. Existing knee arthroscopy manikin for surgical training. Enclosure "skin" is shown separate from interior components [12].

Design Requirements

The design requirements of the enclosure were created with the direct input and feedback of Dr. Henak. First, the enclosure should provide sufficient support to maintain its structure and positioning while being manipulated during testing procedures. Since the testing will involve simulation of arthroscopic procedures, the enclosure should allow for incisions and access to the joint space. The enclosure should minimize leakage of media at any sites of incision and prevent leakage entirely at all other sites. The enclosure should be made of biocompatible materials at any sites with either direct or indirect contact with the live cartilage tissues. The structure of the enclosure should allow for the joint system to bend but should prevent any other movement of the assembly which could potentially damage the cartilage tissue. Finally, the enclosure should provide ports for the pump system to provide a steady flow of media through the manikin.

Design and Evaluation Plan

In order to meet these requirements, an internal frame will be fabricated from a biocompatible material to provide the required support. The frame will have two ports for the media inlet and outlet. The size and shape of the ports will be determined in conjunction with the pump team to ensure optimal flow, high ease of use, and minimize potential leakage. A cutout window will also be created to allow access for the arthroscopic tools to the interior of the manikin. After initial prototypes of the frame are created using CAD software, it will be 3D printed using Formlabs Clear resin at the cost of $.24 per milliliter at the Makerspace as a cost minimization effort. Once the device is ready for testing using live cartilage, the frame will be printed using Formlabs Biomed Clear resin at the cost of $.42 per milliliter. Biomed Clear has similar mechanical properties to standard Clear but is biocompatible and will not cause any chemical damage to the cartilage tissue. The internal frame will be covered using a thin silicone layer which is biocompatible and simulates skin similar to existing devices [12]. The silicone layer will have cutouts at the locations of each pump port but will cover the cutout window. When a cartilage sample is ready for testing, the user will make an incision in the silicone at the site of the window and insert any tools required for the procedure. The frame will possess two mounting points, one at the top and bottom of the assembly, for the joint system to minimize unwanted movement which could potentially damage the cartilage. The frame itself will also contain a joint included in the model to allow it to bend with the joint during procedures. The previously mentioned prototyping and fabrication techniques are all readily available for use on campus and have been utilized frequently on projects in the past.

To quantitatively evaluate the efficacy of the device, a series of tests will be conducted to ensure that media does not leak from the enclosure and cartilage viability is not compromised. To ensure the enclosure is leakproof, it will be configured in its experimental setup with the joint system placed in the interior and allowed to run with the pump system for three hours, the maximum procedure time as confirmed by Dr. Henak. The device will be placed over a beaker to collect any liquid which has leaked. At the end of the procedure, the liquid in the beaker will be measured and compared to the total liquid flow throughout the entire procedure. Three replicates of this protocol will be conducted and an average percentage of leakage will be calculated. Any value under five percent of leakage will be deemed acceptable. The same protocol described to evaluate unwanted tissue stress in the knee joint section will be used.

Media Pump System

The third team of the Joint Arthroscopy Manikin consists of the design and implementation of a media pump system to circulate media through the knee manikin. The system will include the tubing, fluid reservoir, fluid pumps, and dissolved oxygen content monitors. It will be compatible with the ports of the enclosure while fulfilling the design requirements outlined by Dr. Henak in the problem statement (Appendix A).

Existing Designs

There are many anatomically correct knee manikin models currently available, however, no existing solutions include a media pump system. These models are commonly used for surgical training which does require the presence of live cartilage. This difference in design eliminates the need for a pump system as they do not hold live cartilage samples which require media circulation to maintain cell health. However, there are many pump system solutions that are used in arthroscopic procedures. The three most common designs include gravity infusion, single roller pump, and double roller pump systems as seen in Figure 5.

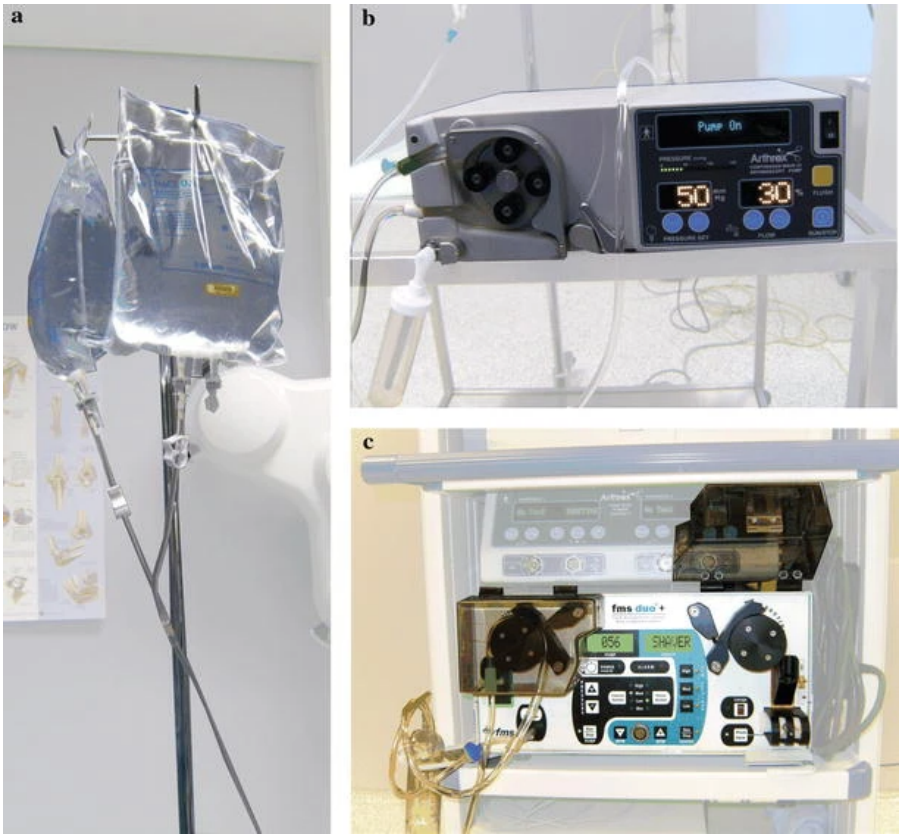

Figure 5. Images of common arthroscopic irrigation systems including gravity infusion (a), single roller pump (b), and a double roller pump (c) [13].

Gravity infusion irrigation consists of the fluid reservoir being hung at a standard height of approximately five to six feet above the operation site. This system utilizes only gravity to deliver pressures that have the potential to be more consistent with the pressures experienced by a knee naturally [14]. Single roller and double roller pump systems both utilize pumps to push fluid in and out of the knee during a procedure. These provide the ability to turn the pressure up or down depending on how the knee is reacting during the procedure. Some systems will only pump fluid in while others will pump fluid out as well.

Design Requirements

Basic design requirements for the media pump system have been outlined by Dr. Henak. The first requirement is that the pump system delivers the media at pressures that are consistent with what is seen during arthroscopic procedures. This means the system must maintain pressures between approximately 40-80 mmHg throughout a test [15]. Ideally, the pressure the pump system provides would be adjustable during a test, but this is not a requirement. The next requirement is that the system can maintain a dissolved oxygen concentration of two to ten percent within the media. This is required to maintain the health of the cartilage within the manikin for an extended period of time. There must also be a system in place to measure this oxygen content within the media before it flows out of the reservoir and into the manikin. Once the fluid has left the reservoir and is flowing through the manikin the oxygen content no longer needs to be monitored. The final design requirement set by Dr. Henak is that the media needs to be flowing continuously throughout

the duration of a test. The system cannot simply fill the model with media, but it must pump in and pump out the media at all times while research is being conducted.

Design and Evaluation Plan

To meet these requirements, either a gravity infusion feed and single pump system or a dual pump system will be implemented. In the first system, the reservoir of media would be suspended in the air at a height of five to six feet which would obtain a theoretical pressure of approximately 20 mmHg. Due to losses from the tubing, friction, and other forces, the flowing fluid would only reach pressures of around 50 mmHg, which is within the range of acceptable pressures [15]. A pump would then be used to provide the suction on the other port of the knee to pull fluid out of the manikin. This solution would eliminate the need to purchase two pumps and would allow for easier setup of the model. However, it would be more difficult to match the inflow and outflow rate of media coming in and out of the model as the exact pressure of media entering the model will not be known without including a pressure sensor. Additionally, this system may make it more difficult to filter the media coming out of the model and pump it back into the system. Although, for the scope of the project the results produced by using a correctly setup gravity system should be just as effective as a pump system. The second option is to replace the gravity feed system with a second pump. This may allow for more precise adjustment of pressure the liquid is being pumped, more consistent pressures across tests, as well as an increased overall pressure. Two pumps would also make creating a closed system that filters and pumps used media back into the reservoir significantly easier as the fluid reservoir could be kept at the height of the manikin and not five to six feet above it. However, adding a second pump will increase the cost as well as the complexity of creating and using the system. To measure the dissolved oxygen content of the media in the reservoir either a probe or a small sensor will be used. Most likely a larger probe will be used as it will be easier to obtain and significantly less expensive to obtain. The lab is already in possession of a probe that may be suitable for our application. The downside of a probe measuring device will be slightly more difficult to integrate into the physical probes and readers are often quite large. The alternative is a dissolved oxygen sensor which would be significantly smaller, could be placed within the reservoir rather easily, and could potentially provide more accurate readings. However, the majority of these small sensors are significantly too expensive for the scope of this project and for this reason, are most likely not a viable option.

Success across these requirements will be measured directly using quantitative data. A pressure sensor and oxygen content sensor will be used to measure whether or not the system is performing within the outlined parameters. If the goals set cannot be met or the system cannot reliably provide a flow of media these aspects of the design will not be considered successful.

Conclusions

Knee arthroscopies are the most common orthopedic procedure performed each year within the United States, thus requiring both skilled professionals and real-time diagnostic techniques. Even with the required minimum of 13 years of higher level education for orthopedic surgeons to learn such a procedure, they are limited in their training with an anatomically accurate knee model that also allows for the optical measurement of redox imbalance, as no such imaging technology currently exists. Redox levels are an important indicator of tissue health, and thus it is crucial to minimize ROS levels in order to maintain redox homeostasis throughout the arthroscopic procedure. By mitigating ROS levels, surgeons can further reduce tissue damage and inflammation and optimize postoperative recovery. The development of a knee manikin that allows for surgeons to optically measure redox imbalance will allow for real-time diagnoses and treatments of knee injuries, that would otherwise be nearly unattainable with other methods.

The knee manikin will be composed of three divisions: the enclosure, the bone/joint system, and the pump system. The enclosure will consist of a silicone outer layer that will cover an internal shell, with its primary functions being to contain any irrigating fluid and anatomical elements and provide a barrier to surgical instrumentation. The bone/joint system will involve “bones” that are 3D printed using Formlabs Biomed Clear Resin, allowing for live cartilage attachment by promoting biocompatibility. Given that this is a model of the knee, the system will further function as a hinge-joint that will allow for flexion and extension to the demands of an arthroscopy. The pump system will involve a device that pumps oxygen-depleted phosphate buffered saline into the manikin, while simultaneously maintaining a controlled internal environment between 2-10% oxygen concentration. The first prototype of the knee manikin model will be fabricated and assembled, with the intention of being tested by surgeons. The testing process will involve a procedural arthroscopy on the manikin, with emphasis placed on optically measuring redox levels. Success of this project will determine whether the surgeons can assess real-time cartilage tissue via optical measurement and alteration of redox levels within the manikin.

The development of this an economical, anatomically-correct knee manikin that allows for the optical assessment of living cartilage will ultimately improve procedural efficacy and efficiency while also improving the quality of life for the 2 million people who receive arthroscopic procedures every year worldwide.

Appendix A:
Problem Statement

Orthopedic surgery is an incredibly difficult practice which requires a minimum of thirteen years of higher level education and training [2]. Despite the commitment required, these surgeons still have to make decisions regarding the biological health of certain joint tissue purely visually with incomplete information with respect to the condition of said tissue on a cellular level. Currently, there exist no systems which allow surgeons to optically measure redox imbalance, a tissue health indicator, in real-time during procedures [3]. Providing this information to surgeons during a procedure would allow for the delivery of treatment such as steroid injections to unhealthy tissue, improving patient outcomes. To develop this technology, the Henak Lab requires the design and fabrication of a low-cost, anatomically correct manikin of the knee to test live cartilage tissue imaging capabilities in a controlled preclinical environment. Similar products exist but do not allow for the culture of live cartilage tissue [5]. The development of this simulator offers a creative and novel method for improving the quality of life for the two million patients who receive arthroscopic knee procedures every year [6].

Appendix B:
Empathy Plan

The most important stakeholders in this project are the patients who will be affected by the orthopedic research to be done with the device. In any biomedical research or engineering project, the wellbeing and quality of life of the patients should be the primary driver behind any decisions that are made regarding design and motivation. The ability to work on a project which will positively impact the lives of others in the future is a true privilege. Dr. Henak is also a major stakeholder because she is the Principal Investigator behind the research to be done with this device. PI's spend countless hours writing grants, attending meetings, and making critical decisions which drive research. Our group owes it to Dr. Henak to create the best possible device to support her hard work and drive progress in her lab and the general research community. In order to gain empathy with the patients who will be affected, we will consult with Dr. Henak to determine if it is possible to join a physician and witness an arthroscopic knee procedure and meet the patient and have a conversation regarding the impact of the procedure on their life. To gain empathy for Dr. Henak and other researchers, we will ask to set up time to shadow researchers and students in the lab and potentially attend lab meetings to increase our involvement with those who will be the end users of our product. We hope to continue these conversations with physicians and other researchers throughout the course of the year to gain new perspectives as we progress through the design process.

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