

Joint Arthroscopy Manikin for Viable Cartilage Midyear Review Report



Manikin Skywalker

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Executive Summary

Knee arthroscopies permit the visualization, diagnosis, and treatment of tissue in the joint space. They are the most common minimally-invasive orthopedic procedure performed within the United States each year. Unfortunately, practice with an anatomically correct model of the knee that simultaneously allows for the optical measurement of tissue health is limited. Tissue health is governed by redox levels, which regulate inflammation, angiogenesis, and the wound healing process during and after surgeries, and easily become imbalanced due to oxidative stress. Therefore, the creation of a knee manikin that will permit the optical measurement of redox levels will allow for surgeons to diagnose and treat tissue health in real time, ultimately improving procedural efficacy as well as the quality of life for the patient receiving the procedure.

The implementation of this manikin was divided into three subsections: the knee joint system, the manikin enclosure assembly, and the media pump system. The knee joint system focused on the creation of a knee joint system, the fabrication of the ends of femur and tibia, and a cartilage-attachment mechanism to the bones. This team plans to implement a wire staple attachment mechanism that will function to hold the variable cartilage samples in place during testing. Success of the knee joint system will be evaluated based on its ability to provide a sufficient mechanism of cartilage attachment to the bone models. The manikin enclosure assembly implements a 3D printed frame, silicone sleeve, and bone-frame attachment mechanism. The primary function of this system is to provide a mobile, but structurally supportive environment for the inner bone models, while also preventing media leakage out of the manikin. Success of the enclosure system will be based on its ability to house the bone, cartilage and media without applying mechanical stresses to the cartilage samples or permitting any leakages. The media pump system, via a nitrogen bubbler, functions to pump deoxygenated PBS throughout the enclosure in order to keep the cartilage samples alive during testing. Success of the media pump system will be based on its ability to keep the dissolved oxygen (DO_2) content of the media between 2-10% and the pump pressure between 0.5-1.5 psig.

Testing has been focused on the media pump team, as it is necessary to determine a method of nitrogen dispersal as well as a media pumping mechanism. Future testing will involve the creation of the complete enclosure assembly, containing the bones, frame and silicone sheet, and once the media reservoir is constructed, user testing will be conducted and a statistical analysis will be performed.

This manikin is designed with intention to be an economical, unprecedented advancement in the diagnosis and treatment of tissue health during arthroscopic procedures.

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Introduction

Background

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].

arthroscopy also refers to cutting, debridement etc. - just the visualization is with camera

Problem Statement

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].

Client Need

Dr. Corinne Henak is the principal investigator at Henak Lab, a lab studying orthopedic biomechanics looking for a model to measure cartilage health. Their specific goal is to eventually be able to provide orthopedic surgeons real-time knee tissue information during arthroscopic procedures. To advance this technology, the Henak lab requires the design and fabrication of an economically viable, anatomically-correct knee manikin. 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].

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Report Mapping

There are three components to the creation of an anatomically correct manikin of the knee that will be used for arthroscopic knee procedures. The report is therefore sub divided into three sections. The knee joint system refers to the design and fabrication of the joint system and the mechanism of attachment of the cartilage to the manikin. The manikin enclosure assembly refers to the design and fabrication of the enclosure mechanism that holds in the media and joint system. Lastly, the media pump system deals with how the media will flow through the manikin.

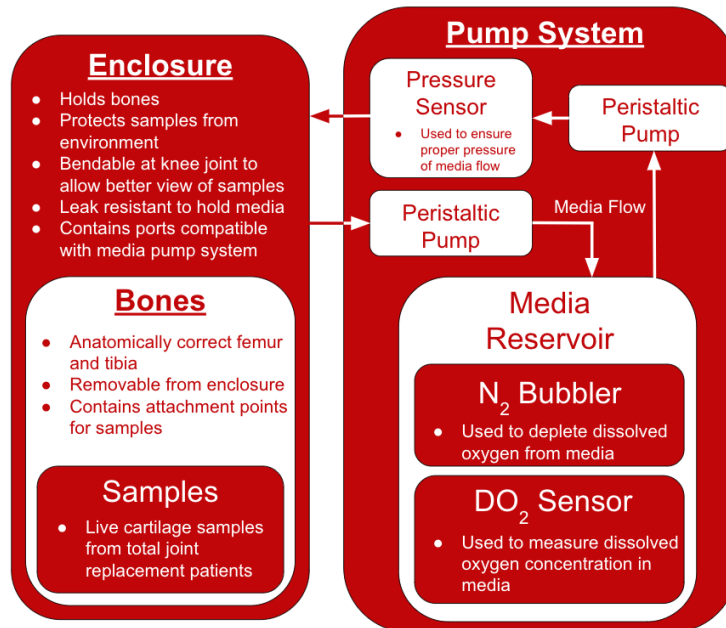


Figure 1: System concept block diagram

Knee Joint System

The first sub-team of the Joint Arthroscopy Manikin consists of the design and implementation of the knee joint system. This includes the modeled bones and cartilage sample 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 design specifications (Appendix A).

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 and proximal midshaft tibia. These bones must correctly model human anatomy but it is not necessary to include any ligaments if the enclosure mechanism provides sufficient knee joint stability. The bone models must be based on the tibia and femur of an average-weighted middle-aged individual. However, the samples will be coming from a variety of patients and thus the models must be able to account for variability in sample and bone dimensions present.

Finally, the cartilage samples must be able to be adequately attached to the knee joint models without being placed under any mechanical stress or experiencing any cell death. 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 Considerations

In order to meet the requirements outlined by the client and ensure the functionality of the model, modifications were made to finite element (FE) models of the tibia and femur. The FE models of human knees as shown in Figure 2 were accessed through Open Knee(s), a public-sourced and freely available database from Cleveland Clinic [7]. This database contains a variety of different FE models of the bones of the knee based on the magnetic resonance imaging (MRI) scans of various patients. In order to account for patient-to-patient variability, models oks001 and oks003 were chosen which correspond to a middle-aged man of average weight and a more petite woman ~~of age 23~~. The chosen patients and their respective characteristics are outlined in Table 1.

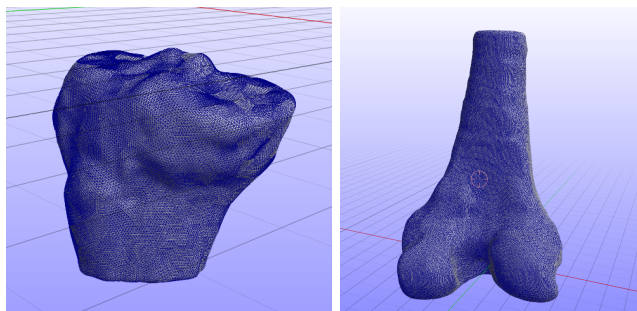


Figure 2. Finite element models of tibia (L) and femur (R) imported into FEBio software from Open Knee(s) database [7].

Patient	Leg	Sex	Age	Race	Height (m)	Weight (kg)	BMI (kg/m ²)
001	R	Male	71	White	1.83	77.1	23.1
003	L	Female	23	White	1.73	68.0	22.8

Table 1. Open Knee(s) patient characteristics for chosen knee models [7].

Three different sample attachment mechanisms were considered and evaluated: biocompatible glue, wire staples, and a rubber band. These designs were compared against each other in a variety of categories including damage to cells, strength of attachment, assembly time, removability, and cost (Appendix B). The attachment mechanism that received the highest overall score in the design matrix based on the above criteria was the wire staple mechanism. This design scored particularly high in the categories of strength of attachment, assembly time, and removability. The wire will be tapped through the bone aspect of the samples and inserted through the pre-cut holes in the 3D printed bones, thus resulting in minimal damage to the cartilage. Additionally, especially in comparison to the biocompatible glue, this mechanism results in a relatively short and easy assembly and removal. It is also a low-cost solution and will be made out of stainless steel, a biocompatible material that will not be toxic to the samples. With this said, it is important to note that the design may not be able to handle all the variability present within the samples received. Through testing, it will be determined if the wire staple attachment mechanism will be able to effectively secure all sizes and bone to cartilage ratios of samples.

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. Based on the results of testing, modifications may be made to the attachment mechanism and/or its characteristics.

Autofluorescence won't measure stress - we measure FAD and NADH,NADPH in the two channels. We expect that checking those will allow us to determine if the cells have been damaged through insertion. Could alternatively look at cell viability (maybe just green channel, live cells) with dye to check this condition.

Prototyping and Materials

The knee models from Open Knee(s) were imported into FEBio (Figure 2), where unnecessary components of the knee anatomy were removed in order to isolate the tibia and femur. The FE models of the isolated bones were then imported into SOLIDWORKS, where modifications were made to ensure the bones were compatible with the enclosure design and met the requirements as outlined by Dr. Henak. These modifications include hollowing out of the bones, flattening the ends and cutting wire holes for sample attachment, decreasing femur shaft length to minimize excess material, and adding magnet attachment points for easy insertion into the enclosure. The updated computer-aided design models (CAD) of the femur and tibia with modifications made are shown below in Figure 3.

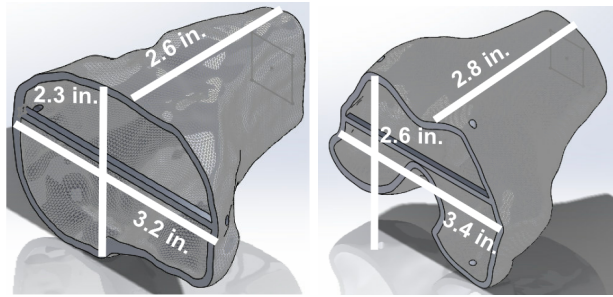


Figure 3. Modified CAD models of tibia (L) and femur (R)

When 3D printing the initial prototypes of the bone models, Formlabs Clear resin was used due to its lower cost. For the final prototype, Formlabs Biomed Clear will be used due to its increased biocompatibility. For the wire staple attachment mechanism, the wire to be implemented is 0.045” diameter 304 stainless steel wire. This wire was chosen due to its biocompatibility, surgical grade, and resistance to corrosion. The wire will be tapped through the live bone of the samples, inserted through the pre-cut holes in the 3D printed bone, and secured in place via bending and twisting.

Manikin Enclosure Assembly

The second sub-team of the Joint Arthroscopy Manikin consists of the design and implementation of the manikin enclosure assembly. This includes the frame, silicone sleeve, and bone attachment system which will be included in the final design. The enclosure will be designed with consideration towards existing designs and will meet the requirements as outlined by Dr. Henak in the design specifications (Appendix A).

Design Requirements

Design requirements for the knee joint model have been outlined by 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 tissue. The structure of the enclosure should allow for the joint system to bend up to 130° 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 Considerations

In order to meet the requirements outlined by the client and ensure the functionality of the model, multiple CAD models were designed in SolidWorks and fabricated for evaluation. The preliminary design shown in Figure 4 was generated with arbitrary dimensions as a proof of concept to convey key design elements of the enclosure and receive feedback from the client. It consists of two identical circular frame components which form a joint, bending around a single point. Both frame pieces also contain a port for connection to the pump system. Despite these design elements, this design is still rudimentary, lacking proper dimensions and many of the client requirements for the enclosure.

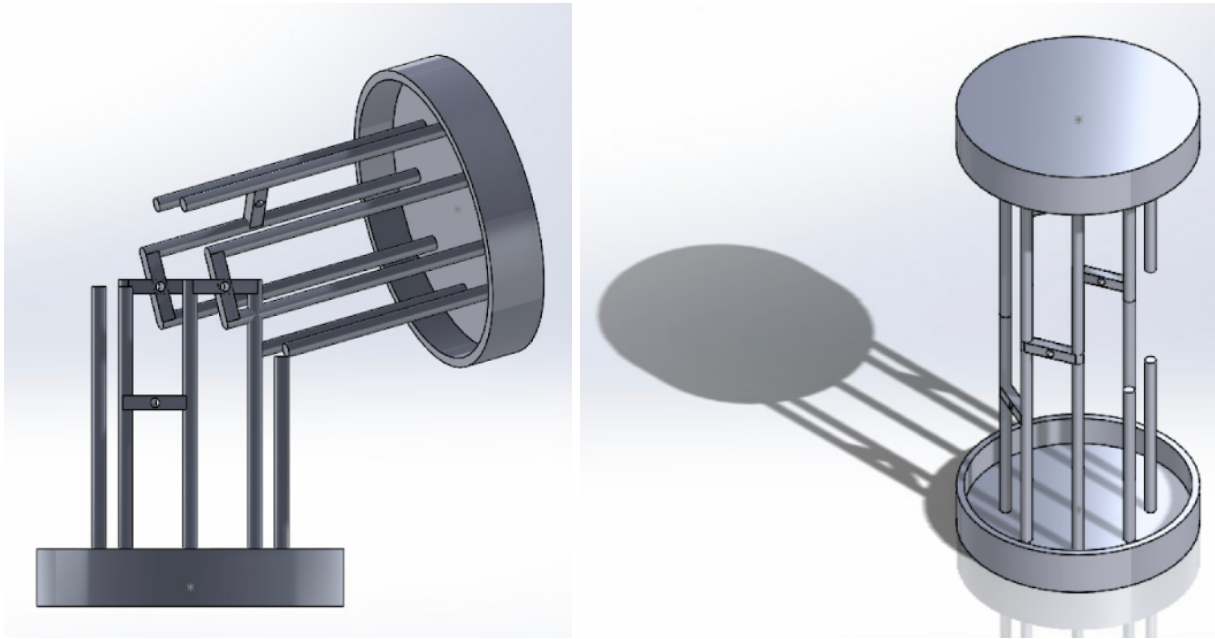


Figure 4. Preliminary proof of concept enclosure CAD

Following the approval of this design by Dr. Henak, a more detailed model for fabrication was created as shown in Figure 5. This iteration mimics the design principles of the preliminary prototype while incorporating key missing features required to achieve full functionality. The femur frame (top piece) is $\frac{3}{4}$ " longer than the tibia frame (bottom piece) to accommodate the length of the 3D printed femur bone model. Semicircular attachment points for the bone models were included at the base of each enclosure. A semicircle was chosen as the shape for this design to prevent the bones from being inserted in an improper orientation. Following testing, it was determined that this semicircular slot design made it too difficult to accurately insert the bones in an efficient manner. To facilitate integration with the pump system, $\frac{1}{2}$ " threaded holes were included on both halves of the enclosure for connection to barbed tube fittings compatible with $\frac{1}{4}$ " inner diameter tubes. The two anterior and posterior rods act as physical limiters to prevent hyperextension or hyperflexion of the enclosure assembly.

The prototype was fabricated by 3D printing the model in Tough PLA at 20% infill. Physical testing of the model revealed difficulty inserting bone models as mentioned earlier, frame rods snapping under minimal stress, collision of bones during knee flexion, and an inability to efficiently place bones within the model due to the lack of a dedicated entrypoint.

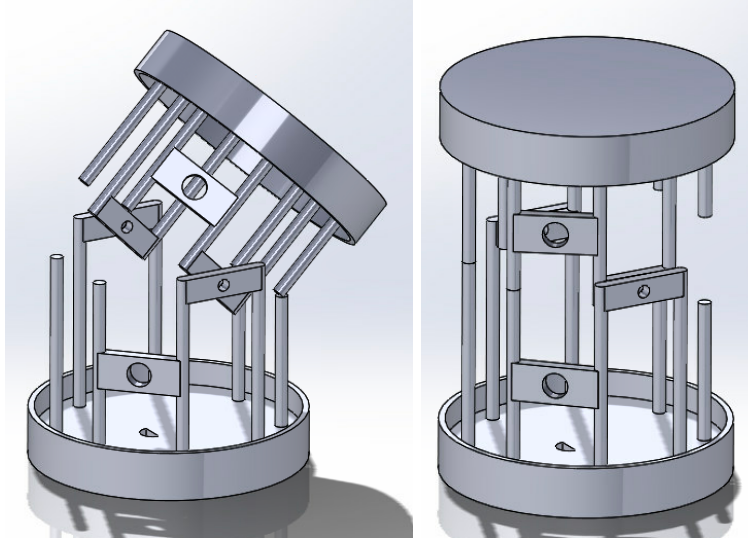


Figure 5. CAD of first fabricated enclosure prototype

Following testing of the first physical prototype and feedback from Dr. Henak, a second design as shown in Figure 6 was created to address the previously listed shortcomings. This design elongated all frame rods by $\frac{1}{4}$ " to prevent collisions between bones and samples. The semicircular bone attachment slots were replaced with 14 mm square slots for the insertion of magnets. Magnets are glued into these slots as well as identical slots present on the inferior and superior faces of the tibia and femur models, respectively. This allows for easier attachment and orientation of the bones due to the attraction and polarity of the magnets. To facilitate the insertion of the bones and samples into the model, the femur enclosure was redesigned to include a removable plate located at the top of the model as shown in Figure 6. Removal of this plate allows for the user to insert the tibia at the bottom of the model and magnetically attach the femur model to the plate. To seal the model, the user will insert the removable plate with the femur attached until flush with the rest of the enclosure. Preliminary testing of this insertion method has returned positive feedback from users relating to ease of insertion and insertion time. This prototype was 3D printed using Tough PLA at 60% infill, dramatically increasing the strength of the frame rods compared to the previous prototype.

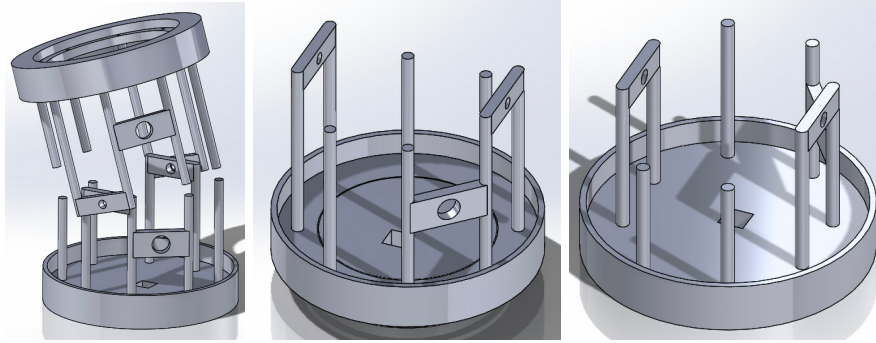


Figure 6. CAD of latest fabricated enclosure prototype

Prototyping and Materials

The completed prototype assembly including the enclosure and bone models is shown below in Figure 7. The final design of the enclosure will be printed from polycarbonate filament and the bones will be printed from Formlabs Biomed Clear resin. Due to economic considerations, enclosure prototypes are printed from Tough PLA and the bones are printed from Formlabs Clear resin. If further evaluation reveals that Tough PLA is satisfactory for the structural integrity of the enclosure, it will be used in the final model due to its lower cost. Formlabs Biomed Clear must be used in the final model due to the requirement of all materials to be biocompatible.

The enclosure will be wrapped in a United States Pharmacopeia (USP) Class VI silicone sheet and sealed with a silicone caulk to prevent leakage of media. USP Class VI materials are certified to be biocompatible while in long-term contact with the body. The silicone sheet will be attached between the “lip” of the enclosure base plates and the rods. The purpose of the silicone is to both act as a container for the media within the enclosure and act as a skin analog for the manikin, enhancing realism. The caulk will act as both an adhesive and a sealant to prevent unnecessary loss of media.

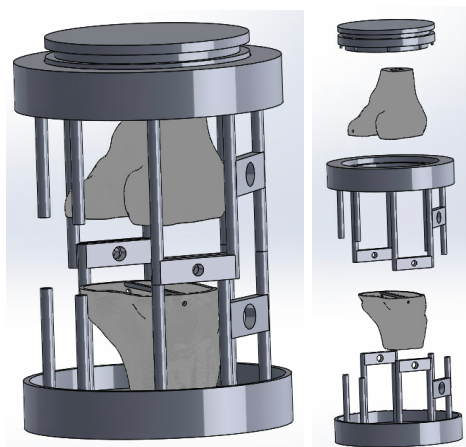


Figure 7. Completed assembly of prototype and exploded view

Pump System

The third subgroup of the Joint Arthroscopy Manikin is the pump and reservoir team. The pump system exists outside the enclosure and is used to pump media through the joint space. The fluid to be used in preliminary testing is phosphate-buffered saline (PBS), a commonly used solution in research settings. During final product use, a chondrocyte growth medium will be used to maintain tissue viability during testing. The purpose of the reservoir is to hold the media and facilitate the depletion of dissolved oxygen before the media is pumped through a pressure gauge and into the enclosure. The media passes through the enclosure and is passed through a filter to remove particulates before flowing back into the reservoir to complete the loop.

Design Requirements

Design requirements for the pump system have been outlined by Dr. Henak (Appendix A). First, the pressure of the liquid flowing through the enclosure must be between 0.5 - 1.5 psig. This range is consistent with irrigation pressure used during clinical arthroscopic procedures. Secondly, the media flowing through the system must have a dissolved oxygen concentration of 2-10%. This is the required oxygen concentration to maintain cartilage viability during testing. Finally, the pump system must be able to run consistently for at least one hour to facilitate testing without failure.

Design Considerations

Two different designs were considered and evaluated: a gravity-infused system and a dual pump system. These designs were evaluated based on pressure adaptability, ease of use, safety for human use, ease of fabrication, and cost (Appendix C). The system that received the highest overall score in the design matrix based on the above criteria was the dual pump system. This design scored particularly high in the categories of pressure adaptability and ease of use.

First, both pumps must maintain equal pressure. This is to ensure that there is a consistent volume of media within the enclosure. If the inlet pump has a higher pressure than the outlet pump, this could lead to more liquid than desired in the knee joint, which could impact the quality of the image obtained from the experimental imaging. Next, a pressure gauge is required to measure fluid pressure entering the enclosure. The chloride ions present in chondrocyte growth medium and PBS are corrosive to brass. All lower-cost and finer-resolution gauges investigated possessed wetted brass components, making them unsuitable for the device. Therefore, a gauge with stainless steel wetted parts is required. However, the majority of stainless steel gauges are used for high-pressure applications. Due to this, acceptable measurement resolutions are only found on specialized gauges, but these were typically priced at over 50% of the teams' budget. Balancing material considerations, measurement resolution, and cost, an analog stainless steel gauge with a range of 0-15 psig and a resolution of 0.2 psig was

purchased. The range is larger than required, but an acceptable level of measurement resolution is still achieved.

Do acronyms need to be redefined after executive summary?

Next, the media reservoir must measure and remove excess DO₂ while allowing for a constant flow of media throughout the system. The DO₂ content will be measured with a digital DO₂ meter. The team has access to one of these instruments that reads DO₂ content on a digital display from a probe that will be placed in the media through the top of the reservoir. The reservoir will be at atmospheric pressure where the typical DO₂ levels are approximately 20%, which is much higher than the acceptable 2-10% range set by the client. To control the DO₂ concentration, nitrogen gas will be dispersed into the media using a small bubbler that is inserted through the top of the reservoir. This bubbler will either be a small cylindrical bubbler consisting of two bottle caps glued together or a ¼" tube with a plug in one end. Figure 8 shows the prototypes for each of these designs.

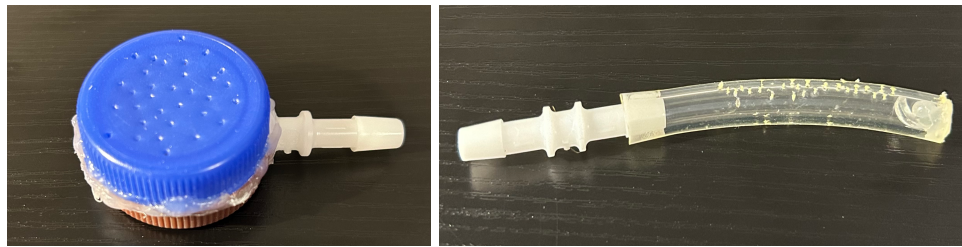


Figure 8. Initial prototypes of cylindrical bubbler (L) and bubbler tube (R).

Prototyping and Testing

A full prototype of the pump system incorporating all necessary components has not been completed yet. However, multiple tests have been completed on individual components of the project. The bubbler prototypes in Figure 8 were fabricated and used in rudimentary testing with air, but testing has not been conducted with N₂. Once the reservoir is constructed, experimental testing will determine which design is more effective by supplying each bubbler the same amount of N₂ gas over a selected time and measuring how much the DO₂ content decreases. The design that removes excess DO₂ most efficiently will be chosen and implemented into the reservoir prototype. Next, multiple basic flow loops were constructed to evaluate the pump, plastic fittings, and pressure gauge. After confirming the peristaltic pump acquired was functional, the first test was designed to measure the static pressure of water leaving the pump. However, the initial setup was not able to produce any pressure readings. To determine if the testing setup was poorly designed, the pressure gauge was faulty, or if the pump was not producing enough pressure, the test was replicated using an aquarium pump that supplies a much higher pressure output. This test produced pressure values of 3-5 psig, which are significantly outside the design constraints, but the values confirmed the pressure gauge was functioning correctly. The next iteration of the testing setup attempted to read pressures from the peristaltic pump using a modified enclosure. The water was pulled from a reservoir, pushed through the pressure gauge, and then into a semi-closed volume metal can in an attempt to simulate the conditions of the actual enclosure. The can had an inlet directly after the pressure gauge and an outlet tube that was mostly plugged. Small pressure values were observed, confirming the peristaltic pump could produce enough pressure to obtain readings, but the tests were very

inconsistent due to leaks in the inlet and outlet of the can. The most recent tests used a similar configuration, however, the can was replaced with a semi-closed volume bottle. The new bottle did not leak unless a small pressure was applied, in which case water could exit the bottle through the top of the cap and a small slit in the side of the bottle. Figure 9 provides an image of each of the three testing setups described.

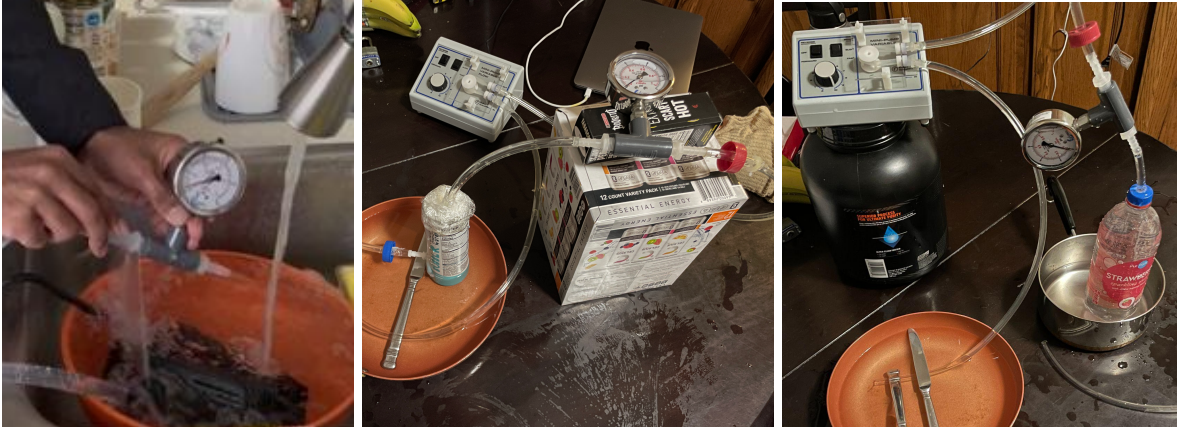


Figure 9. Aquarium pump test (L), Semi-closed volume test one (M), Latest configuration (R)

Using the latest configuration, pressure values were measured consistently across multiple tests. Three replicates of data were taken on the “fast” pump setting, recording the pressure values at speed settings one through nine on the tuning knob. Averaging these replicates gave a relatively linear pressure range of 0.73 - 1.73 psig which is displayed in Figure 10. Therefore the peristaltic pump provided a range of values consistent with the irrigation pressure used in clinical arthroscopic procedures.

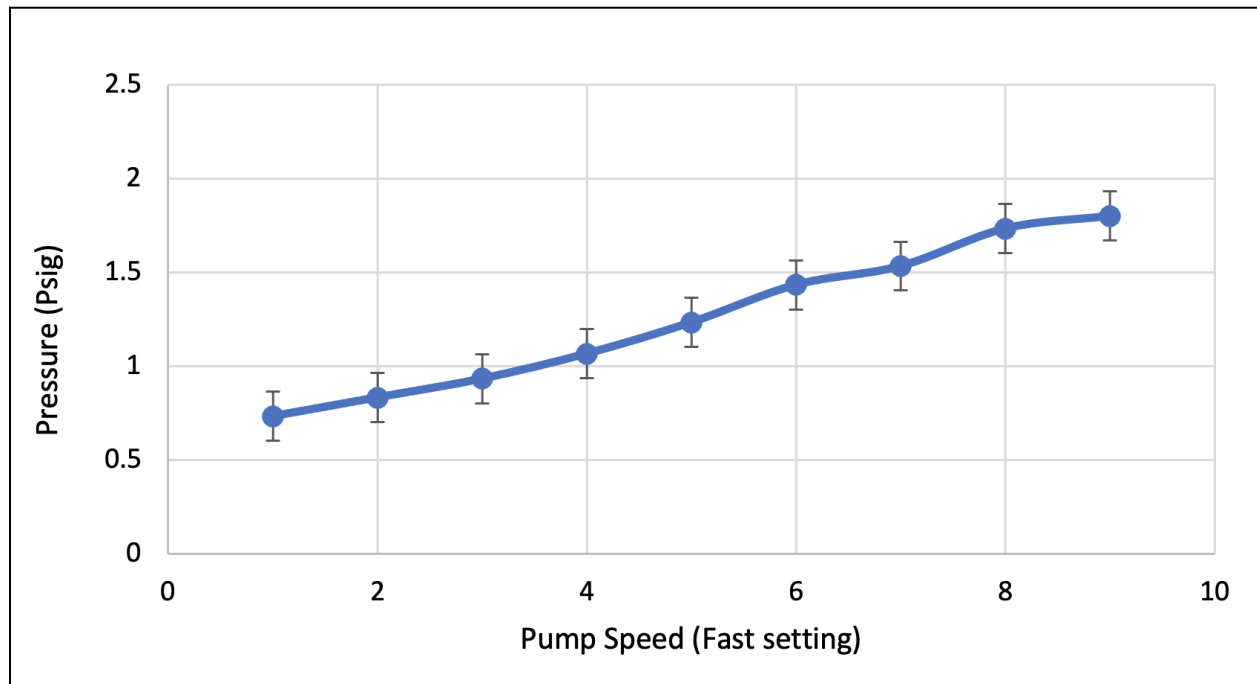


Figure 10. Average pressure vs pump speed data

Conclusions

Arthroscopy is a minimally-invasive procedure involving a camera probe, termed an arthroscope, that functions to examine a joint space. In the case of the knee, arthroscopies are the most common orthopedic procedure performed each year in the United States, and although common, the surgeons performing such a process are limited in their practice with an anatomically correct knee model that simultaneously allows for the optical measurement of redox levels in live cartilage cells. As an important indicator of tissue health, redox levels must be monitored during a procedure as oxidative stress negatively impacts the joint space as well as the overall surgical efficacy. Therefore, the creation of an arthroscopic knee manikin that can house live cartilage tissue would significantly improve the ability of surgeons to detect and diagnose tissue health during a surgical procedure. The implementation of such a model was split into three divisions: the knee joint system, the manikin enclosure assembly, and the media pump system.

The knee joint system involves the creation of a joint system and mechanism of attachment of the live cartilage samples to the manikin. Through the online source Open Knee(s), FE bone models of the tibia and femur were modified using FEBio and SOLIDWORKS and 3D printed using Formlabs Biomed Clear resin. To account for patient-to-patient variability, the chosen bone models were based on a middle aged man of average weight and a petite woman. Moreover, to ensure compatibility with the enclosure assembly, modifications including hollowing out and flattening the ends of the bones, while also decreasing the femur shaft length and adding a magnet-attachment mechanism were done. The mechanism of cartilage attachment is a wire staple. This mechanism will function by tapping the wire through the bone aspect of the cartilage samples and then will be inserted into the respective pre-cut holes within the bones. This method will involve a quick and easy assembly while minimizing damage to the cartilage samples. Future testing will ultimately determine if the wire staple attachment mechanism provides the strength and security required to hold the variable cartilage samples throughout the duration of the testing period. Factors including sample degradation and sample loosening will be indicative of an unsuccessful method of attachment, and will be monitored and measured using autofluorescence. Ultimately, performance of the knee model itself will be determined by its ability to provide a sufficient surface for cartilage attachment.

The manikin enclosure assembly involves the design and implementation of a 3D printed frame, silicone sleeve, and bone-attachment mechanism to the inner frame. The frame, created using SOLIDWORKS, was 3D printed out of Tough PLA material for testing, but for the final model will be printed out of polycarbonate. This frame, containing tolerances and a magnet-attachment mechanism, is designed to house and structurally support the internal bone models. The silicone sleeve functions to fit over the frame, not only acting as outer “skin,” but as a way to contain the media, as it is impermeable to internal media. The silicone and frame are both biocompatible materials that further aid in the maintenance of cartilage cell integrity.

Magnets were implemented on the internal ends of the frame to allow for a convenient and secure mechanism of bone attachment. The enclosure will also include ports for a media pump system that will provide a steady flow of media throughout the model. Future testing will ultimately determine if the enclosure can bend and extend to procedure demands, while preventing any mechanical stress to the internal cartilage samples and media leakage out of the manikin.

The media pump system involves an external reservoir housing media that functions to remove excess DO_2 from the media before it is pumped through a pressure gauge and then steadily throughout the enclosure. This system will contain a stainless steel pressure gauge with a pressure range of 0-15 psig, an oxygen sensor, and a nitrogen bubbler. The primary function of this system is to keep both the pressure of the flowing liquid throughout the enclosure in the range of 0.5-1.5 psig, and the DO_2 concentration of the media between 2-10%. Values outside of these ranges will negatively impact cartilage viability during testing. Two methods of media deoxygenation via nitrogen dispersal were created. The first method involves two bottle caps glued together with a tube fitting. This model permits nitrogen dispersal into the media through small holes within the caps. The second method involves a tube with a stopper containing small holes, permitting nitrogen dispersal into the media. Future testing will determine the most effective method of nitrogen dispersal, which will be based on the rate at which the required media dissolved oxygen content is achieved.

Testing has primarily been conducted with the media pump team in order to determine the functionality of both the pump and pressure gauge. Initial testing was conducted in order to determine if the pump worked, and then the pressure gauge, T-fitting, and threaded barb fittings were acquired. When testing with these elements, the peristaltic pump did yield pressure readings on the gauge. To eliminate the possibility of a faulty pressure gauge, testing with a much more powerful aquarium pump was conducted, and the pressure gauge was able to produce pressure readings. Using the peristaltic pump, semi-closed volume testing with an inlet and outlet was carried out, however, only leakages and inconsistent pressure readings were produced. The most current setup is similar to the semi-closed volume technique, however, a semi-closed bottle was used and managed to yield reasonable readings. Replicates of this experiment yielded values around 0.7-1.75 psig, which are mostly consistent within the required range of 0.5-1.5 psig. Due to the results being few in number and mostly consistent, a statistical analysis could not yet be performed. **What statistical analysis do you expect to perform?**

Key takeaways from this past semester focus largely on the functionality of the enclosure, as both the knee joint system, primarily the cartilage attachment mechanism, and the media pump system have yet to undergo assembly and testing. Firstly, a more accurate method of pressure measurement is required. Although the pressure gauge is sensitive enough, its functionality is based on a buildup of pressure on one end of the tubing. On account of a flow-loop system being used for media distribution throughout the enclosure, there is no real

buildup of pressure, thus a different measurement method must be implemented. Secondly, through assembly of the bones within the enclosure, it was determined that it is too difficult to articulate the full knee movement of the knee model without making the prototype too complex. Although attainable, the full anatomical movement of the knee is not key in obtaining viable results from the imaging studies, and thus will be neglected. Thirdly, the silicone sheet may be a sufficient enclosure material, instead of the previously considered combination of polyurethane foam and silicone sheet. The usage of solely silicone will ultimately be determined when testing. The last key takeaway is that the enclosure requires larger tolerances. This is ultimately to aid in the structural support of the bone models within the enclosure, as well as in the overall mobility of the joint system.

Future directions are aimed at implementing the complete enclosure assembly and designing and fabricating the media reservoir. Aside from the silicone sheet, internal frame, and bone models, a silicone caulk will be implemented in the enclosure assembly, functioning as both an adhesive for the silicone sheet to the frame and as another method of preventing media leakage out of the manikin. Looking ahead, the media reservoir will be created, containing both the DO_2 probe and nitrogen bubbler. Once this has been completed, user testing will be conducted. The development of an arthroscopic knee manikin that allows for the optical measurement of redox levels in live cartilage tissue will significantly enhance procedural efficacy and efficiency, ultimately improving the quality of life for the 2 million people receiving this procedure each year worldwide.

Appendix A: Design Specifications

The design requirements as outlined by Dr. Henak are as follows: The manikin must be anatomically correct, spanning from mid-shaft femur to midshaft tibia/fibula, to allow for proper positioning during arthroscopy. Ligaments such as the MCL, PCL, ACL and meniscus should be included/removed as needed. Anatomical correctness will be based on laser scanning the joint and running a comparison with a CT of a knee. This will ensure the bones have the proper cartilage attachment points, as would a typical knee. The ligaments/tendons should function to exist and hold internal elements in place, but do not have to be anatomically or attached to the 3D printed bones. All materials in either direct or indirect contact with samples must be biocompatible. All materials in direct contact with media flow should not corrode over time. The staples must consistently puncture into one hole within the bone models to avoid multiple holes within the model that would warrant frequent reprinting. Inadvertent loading during handling of the cartilage is to be avoided as it can damage the samples.




ligaments
included/removed
as needed for what?

Engineering Specifications					
Specification description	Target	Unit	Test method	Rank	Met
Enclosure					
PBS/irrigating synovial fluid: Media contained within the knee model should remain inside and avoid leakage	-	-	Visual inspection	Must	
Knee model flexion: the enclosure should permit the knee to contract and expand according to the procedure	0-130	degrees	Protractor for accuracy, visual inspection - will serve to determine if the knee model flexes/extends the way a typical healthy knee does	Should	
Reusable				Must	
The enclosure mechanism will involve a silicone-lined polyurethane foam structure that will promote structural support and containment of internal media.			Visual inspection - collapsing of model will be evident of poor structural support and leakage of media will be evident of poor media containment	Must	

angles could be
measured optically

Pump					
The pump system should maintain the oxygen concentration of the media in a healthy range for the chondrocytes	2-10	percent	Oxygen monitoring sensor	Must	
The pump should maintain a flow pressure similar to that which is used in arthroscopic knee procedures	40-80	mmHg	Flow meter/orifice plate	Should	
The pressure gauge should be made out of a stainless steel material in order to prevent biocompatibility. Materials like copper or brass corrode when exposed to media.			Visual inspection	Must	
Joint/Mounting					
No mechanical stress should be applied to cartilage inserted to the model which would cause a difference in the health of the tissue	Same optical redox ratio as control	arbitrary	Comparison between health of mounted and unmounted cartilage by measurement of autofluorescence	Must	
The knee joint should be anatomically correct to the rough dimensions of an average weighted 50 year old	-	-	Visual Inspection	Must	
Each joint model should be reproducible between fabrication attempts	Above 95%	percent	Measurement using laser scanner	Should	
Stainless steel staples should be used for the attachment mechanism to ensure both biocompatibility and structural support	-	-	Visual inspection - cartilage maintains attachment to bone and minimal cell death	Must	

Appendix B: Sample Attachment Mechanism Design Matrix

Sample Attachment Mechanism	Biocompatible Glue 		Wire Staples 		Rubber Band 	
	Damage to Cells (25)	4/5	20	3/5	15	4/5
Strength of Attachment (25)	4/5	20	5/5	25	1/5	5
Assembly Time (20)	3/5	12	4/5	16	4/5	16
Removability (20)	3/5	12	4/5	16	4/5	16
Cost (10)	5/5	10	5/5	10	5/5	10
Total (100)	74/100		82/100		67/100	

**Appendix C:
Pump System Design Matrix**

Pump System	Gravity infusion system		Dual pump system	
Pressure Adaptability (15)	3/5	9	5/5	15
Ease of Use (25)	2/5	10	4/5	20
Safety of Human (20)	4/5	16	4/5	16
Ease of Fabrication (15)	4/5	12	3/5	9
Cost (25)	5/5	25	4/5	20
Total (100)	72/100		80/100	

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