OPTIMAL DESIGN
10 October 2012

Project 22:
Device to Monitor and Control Intra-Articular Hydraulic Distension Therapy for Adhesive Capsulitis Treatment

Team 11
Kyle Bagshaw
Vesko Zlatev

Faculty Advisor and Client:

Dr. Krystyna Gielo-Perczak
University of Connecticut
School of Engineering
Bronwell Bldg., Office 204
260 Glenbrook Rd., Unit 2247
Storrs, CT 06269-2247, USA
(860) 486-0370

TA:
Sarah Brittain
1) OPTIMAL DESIGN: PROJECT 22

1.1) INTRODUCTION

Presented herein is a proposed device to control and monitor in real time a medical procedure known as Intra-Articular Hydraulic Distension (IHD), a novel treatment for patients suffering from a condition that causes painful stiff shoulders. The condition, known as adhesive capsulitis, is the result of swelling of tissue in the shoulder joint capsule and a decrease in synovial fluid volume within the capsule. This causes chronic pain and stiffness and greatly reduces the shoulder range of motion [1]. IHD is a possible treatment alternative to surgery, which involves the injection of a volume of fluid into the joint capsule. This increases the capsule volume and distends the shoulder, which should increase range of motion and ultimately speed recovery drastically. IHD is still an experimental technique, however, and there are only limited studies on its effectiveness and on the optimal parameters for its use. The proposed device addresses this lack of established data by presenting a way to administer the procedure, to monitor it in real time, to use feedback based on pressure in the shoulder and volume of fluid injected to exert greater control than is currently possible, and to collect data that ultimately could be used to better understand the mechanics of the shoulder and the effectiveness of the therapy.

The proposed design is innovative in its integration of many different components of the procedure into one package, and in its use of feedback to control the injection process. Current techniques use more improvised, experimental setups, and typically involve monitoring an injection at a fixed rate [2]. This design attempts to include different parts necessary for the procedure in a single portable unit that can be quickly attached to a PC and be ready to use. By running the device through a PC, the design not only enables the operator to collect and export a number of measurements with ease, but to control the procedure in a way that is not currently possible. The result will be a device that can be easily used for a number of applications, including research and clinical treatment. The total desired functionality of the device is shown in Fig. 1.1a, which demonstrates the desired inputs, outputs, and feedback loops. A program such as LabVIEW would be very useful in implementing this scheme, as discussed in the subunits.
For reasons of feasibility, the optimal design is based primarily around the second alternative design, and features a purchased syringe pump packaged in a case with a pressure sensor, tubing, and some necessary electronics, with inputs and outputs limited to the fluid tubing, a power cable, and a PC connection cable (such as a USB cable). That design will be modified somewhat to include easily accessible but secure compartments for supplies such as extra needles, sanitary supplies, spare parts or other materials that might be desired. A patient restraint system or protocol (to prevent moving during the procedure that may disrupt the measurements) will be included as a separate piece; it would be infeasible to incorporate both the patient restraint device and the rest of the device components in one piece as the first alternative design called for. The third alternative called for the design of an entirely new pump; this was deemed impractical since there are commercially available syringe pumps and the time necessary to design a custom pump would restrict the ability to meet other design specifications.

1.2) SUBUNITS

Subunit: Spinal Needle
The needles chosen to use are spinal needles originally intended for use in spinal taps. They are manufactured by Excel Corp. and are 3.5 inches in length with a 22 gauge. The length was chosen to be 3.5 inches in order to guarantee that the tip of the needle will reach the shoulder capsule of the patient, all while having some “left over” needle length for the larger sized patients who require the extra length; this means that the longer spinal needles have to be used. The gauge of the needle was chosen to be an intermediate between two extremes so as to allow easy fluid flow during the procedure while minimizing invasiveness and disruption of tissue. The opposite end of the needles has an industry standard Luer-Lock hub that provides a leak-free seal, along with a very easy to remove lock ensuring the user can easily replace the needles. All of the needles come in sterilized packaging and are latex free to ensure no adverse reactions occur to the patient. The needles come 50 in a box with 2 boxes per case, for a grand total of 100 needles for just under $150 [3]. Figure 1.2a shows an image of these spinal needles.

![Excel Corp. Spinal Needles](image)

**Figure 1.2a) Excel Corp. Spinal Needles**

**Subunit: Luer-Lock Tubing**

The spinal needle’s Luer-Lock will then connect to the first segment of tubing that will have male-female Luer-Locks on the ends. The tubing chosen was the All-Med
Medical Male-Female Luer-Lock IV extension sets, seen below in Fig. 1.2b. They are non-DEHP PVC tubing as well as both Latex-free and Lipid-resistant. With a length of 16 in. they also feature a priming volume of 0.5 mL, or the amount of fluid required to clear the catheter from beginning to end. It will be necessary to use two tubes, one for the spinal needle and another for the syringe, for the IAHD procedure due to the three-way stopcock and pressure sensor attached in between the two ends. Sanitation of the tubes is very important, so they should be easily accessible to be removed from the device for cleaning or replacement.

Figure 1.2b) Luer-Lock Tubing from All-Med Medical [4]

Subunit: Syringes

The second PVC hose stemming from the stopcock/pressure sensor will have its Luer-Lock connected to the male end of a 30 mL syringe. They come in individual sterile packaging in cases of multiple syringes, typically at less than $1 each in bulk quantities. This turns out to be very convenient due to the Connecticut laws placed that allow only up to 10 syringes to be purchased without a doctor’s prescription. The advantage of using syringes in the design is that they can be easily removed or replaced, which makes it easier to keep the device clean (rather than allowing moisture to collect in a sealed container, the syringe can be removed, cleaned, and dried between uses). Syringes are also intended for manual use, which means it would be easy to do some operations by hand, for example drawing fluid into the syringe. The gradations on the syringe are another advantage for a prototype design, presenting a visual method for the operator to verify that the pump is working as it is supposed to by comparing the computed volume pump to the actual volume pumped. Finally, the ready availability of programmable syringe pumps and the low price of syringes make this
setup favorable to a long device life, particularly of the prototype which may require modifications to the design as it is built. Figure 1.2c) shows an image of a 30 mL syringe by Terumo [5].

![30 mL syringe manufactured by Terumo (Philippines)](image)

**Figure 1.2c)** 30 mL syringe manufactured by Terumo (Philippines)

**Subunit: Syringe Pump**

The use of a syringe means that a proper syringe pump will be required to administer the Intra-Articular fluid to into the patient's shoulder capsule. It becomes vital to obtain a pump whose infusion rates are able to be modified in real time based on the integrated pressure sensor. In order to minimize the possibility of encountering a ruptured shoulder capsule, the intra-articular pressures must be utilized in a negative feedback loop. This system is one where the operator sets the maximum allowed pressure within the capsule through a front panel interface, and the LabVIEW control mechanism will be designed to terminate the injection automatically if that pressure is met or exceeded. The program will also be designed to terminate after a certain volume is injected, so that the pump does not break itself trying to pump after the syringe is fully depressed. User input is important as well-the operator must observe the syringe to make sure it doesn't dry out, as well as take feedback from the patient regarding pain or discomfort and stop the procedure if necessary. Figures 1.2d and 1.2e show two images of the NE-500 programmable syringe pump, available for around $500 [6].
Once more data has been established regarding the mechanics of the procedure and trends regarding the conditions, more elaborate control mechanisms may be incorporated—for example, if there is a consistent physiological response such as a discontinuity in the pressure curve that occurs at rupture, the algorithm might be made to identify such an event and automatically terminate injection. An even more advanced step would be attempting to predict rupture—is there a consistent physiological behavior just before the point of joint capsule rupture that can be identified and used to terminate the injection prematurely. Due to the current lack of optimization, such monitoring is the responsibility of the operator, so the program also allows the user to terminate the injection from the PC at any moment. It is important to note that the device will rely on control of the pump through the PC—while some available pumps have integrated
controls, the focus of this device will be automating and controlling the pump through the computer.

**Subunit: Pressure Sensor**

The specifications of this device require a pressure transducer to accurately measure the fluid pressure within the shoulder capsule via the tubing. There are a number of pressure transducers available on the market, with much variation based on cost, quality, and other functions. Based on the given requirements for the product (biocompatibility, ease of replacement, Luer Lock fittings, reasonable costs) one possible part is the PendoTECH disposable pressure sensor [7]. Intended for medical applications, the sensor is approved for human use and would not present any health hazards. They are available in several sizes and configurations, so one could be found that meets all technical specifications. The product is also designed to fit Luer Lock tubing, which is required for this design as it is the necessary fitting for syringes.

The PendoTECH sensors, according to product details available on the company’s website, are validated for a range of pressures in excess of the expected pressures for the system (approved for an operational range of -7 to 75 psi, the literature on IHD indicates a range of pressures from 0 to 900 mmHg, which is equivalent to just 18psi). The sensors are listed as single-use on the website; however, since precautions are being taken to avoid any biological contamination of the pressure transducer in this device, it should be reasonable to expect a number of uses out of each sensor. The fact that they are considered “disposable” should serve to increase the ease of replacement should it prove necessary—a more expensive component that malfunctions is much more difficult to replace, especially if one wishes to replace the sensor periodically to further reduce the risk of contamination. The website even lists directions for cleaning and sterilizing the sensors, which could serve to prolong the life of each. Figure 1.2f shows an image of one such sensor from the company’s website.
Once the precise configuration of the pump, tubing, and pressure sensor system is known, equations of fluid mechanics can be used to correct the measured pressure to the pressure in the joint capsule. Since the pressure sensor measures the pressure of a moving fluid at potentially a different elevation to the shoulder, in which the fluid is static, the measured pressure will not be exactly the intra-articular pressure (though error might be minimized by keeping the sensor at the same height as the needle tip and using a low flow rate). Further considerations include viscous effects (probably negligible given the low flow rate) and the flow field within the tube. The fact that the system changes with time presents further complications (preventing use of Bernoulli’s equation, for example, which assumes steady state), and the solution will likely involve a numerical method executed within the computer program itself. Testing of the system is needed to analyze exactly how the pressure is different between the tip of the needle and the pressure sensor, however; this can only be done once the pump, tubing, and sensors have arrived.

There is a device available from the company that the sensors hook up to read measurements, however purchasing this device will not be necessary. The technical details available from the website indicate the signal terminals (as the sensor is converting a pressure difference to an electrical voltage) which means the sensor should be easily hooked up to a microcontroller or DAQ device. This would be useful because it allows the signal from the pressure transducer to interface directly with the rest of the system, meaning the system can operate faster. To enable this direct connection, a filter will be necessary to remove noise from the signal and amplify it to the necessary strength before the signal reaches the DAQ or microcontroller. Such a filter could be designed using the FilterLab software, which designs an analog circuit that produces the desired gain and filter properties. Figure 1.2g shows a sample filter for this application (a 4th-order Butterworth filter with a cutoff frequency of 1000 Hz and a gain of 2).

The FilterLab program can also export the designed filter to the Multisim circuit analysis and design package, where it can be analyzed to ensure it works properly and also used to design an actual circuit (complete with list of components). The exact specifications of this filter will most likely change as more information becomes known about the performance of the sensor in the given conditions (for example, the signal output voltage depends on the power voltage supplied to the sensor, which is unknown at this time).
Subunit: PC Interface

At the current time, LabVIEW presents a potent platform as the primary program for this device, as it has many features that overlap the desired functions of the device. Some of these functions are listed below, and a sample front panel is shown in Fig. 1.2h.

Figure 1.2g) Example filter for pressure sensor, created in FilterLab

Figure 1.2h) Example LabVIEW Front Panel for IHD control
Most importantly, LabVIEW provides a tool to create user-friendly Graphical User Interfaces (GUIs) which is desired for this device because it makes it as intuitive and understandable as possible. The sample front panel in Fig. 1.2h demonstrates the clean appearance and organization that is either very difficult or impossible to create in other programs. It presents clear input spaces for all parameters, allows the user maximum freedom to set parameters of interest without being overwhelming, and can be organized attractively and professionally.

LabVIEW is also a good program because it can easily be configured for data acquisition purposes, and can further function in a control setting. This is important because the specifications require that the device accepts data input from the pressure sensor and uses this information, as well as user inputs, to control the injection of fluid via a pump. LabVIEW has extensive toolboxes to acquire and process signals. Furthermore, a search of the Internet has shown there is a number of LabVIEW-based drivers for syringe pumps similar to that being considered for use here, suggesting that control is possible.

LabVIEW can also enable feedback control of the pump based on the signal from the pressure transducer, which is one of the novel aspects of the device to be built. While available syringe pumps are capable of pumping at a constant volumetric flow rate (where volume is a linear function of time), one option that this design seeks to provide is the ability to pump at a constant pressure flux (to control the process such that pressure is a linear function of time). Due to the nature of the proposed tests, pressure may not be linearly related to volume, so a computational method of adjusting the volumetric flow rate to keep the rate change of pressure constant is needed. Such a method can be derived based on knowledge of the change in pressure and volume (from the pressure sensor and the pump) for very small intervals of time, which should allow the pump to increase pressure linearly with time (see Appendix). This derivation might also be extended to other functions based on future analysis of what the optimal procedure is; for example, it might be adopted to make the pump increase pressure proportionally to some power of $t$, or to adjust the volumetric flow rate as some function of pressure. Such control is not possible with currently available pumps.

Finally, LabVIEW has the ability to display data to the operator in real-time in a graphical format, and to export data as well. This is important because one purpose for the device is to collect data from many patients to help optimize the parameters for the procedure and better understand the mechanics of the shoulder. LabVIEW can export raw data in tabular form, as well as perform some data operations to get a summary of data. Future work may include using established parameter optimizations to recommend a course of treatment to the operator based on inputs about the patient, but
such work may not be done at this time because of the lack of optimization and understanding of the mechanics that this device is primarily intended to address.

The most likely method for input and output between the PC with LabVIEW and the device is a DAQ device from National Instruments, such as the USB 6008 shown in Figure 1.2i [8]. Such a device has the advantage of being readily integrated with LabVIEW and straightforward to build around, though some additional circuitry such as a microcontroller may be necessary to control the pump itself.

![National Instruments DAQ device (USB-6008)](image)

**Figure 1.2i) National Instruments DAQ device (USB-6008)**

**Subunit: Other Electronics**

While the components listed above comprise the major parts of the design, there are a few additional considerations that must be made regarding the electronics within the device. As discussed, the pressure sensor will require analog filter circuitry, which will consist of certain electrical components soldered to a small circuit board. Since the pump requires a power source and it is undesirable to rely on battery power, some sort of power source must be incorporated into the device. A surge protector would be desirable, with as many outlets as needed to accommodate any other components that require a power source. Including such a device will allow us to run a single sturdy power line from the device to a standard wall outlet, while minimizing risks of disrupting connections within the device. In addition, an AC/DC converter will be needed to connect the power source to the pump; a compatible device is available from the pump manufacturers. Such a design would present a failsafe method of stopping the injection in an emergency, if for some reason it is not terminated by the computer program. By making a power switch easily accessible, perhaps even light up, in an emergency one need only push the switch to kill power to the pump.

Furthermore, a number of cables will be needed to connect the pump, pressure sensor, other analog components, and the DAQ device or microcontroller to each other.
and the PC. This depends on the connections available from each device. The ideal situation would be to unite the pump and pressure sensor with filter within the device itself (preferably through the DAQ device) and run a single connection cable from that device to the PC. This will maximize the ease of use of the device, as well as minimize the risk of error by maintaining almost every single connection when the device is not in use (compared to having separate cables running from each component to the PC). This is also the most attractive way to package the device.

Once the cables, connections, and outputs are known, it becomes necessary to modify the casing of the device in such a way that all input and output cables are secure but easily accessible, while all other connections are secure, insulated, and protected from accidental disconnections. Securing the interior components so that they do not move or come apart if the device is moved is critical to prolonging the lifetime of the device.

**Subunit: Carrying Case**

In order to ensure that the equipment and setup constructed remains protected and easy to transport around to different patients, a special case must be built that is both light and yet durable. Perhaps the best material selection option for this purpose would have to be some sort of thick plastic, much like the ones shown in Fig. 1.2j below. Those were constructed from polyethylene by Ameripack, and have the features of being water proof, having shock resistant thick round corners, and a hinged or separated cover [9].

![Ameripack cases](image)

**Figure 1.2j) Ameripack cases**

The crucial component to the case will end up being the protective foam that encapsulates each part of the device. There are several different types of foams by Ameripack to choose from based on different polymers, such as polyurethane foam, poly-ester/polyurethane, poly-ether/polyurethane, and polyethylene foams. Due to the
electrical components present in this device, the foam chosen for protecting the delicate hardware would need to be able to keep away moisture and humidity, which would require the polymer having "closed cell" composition as opposed to an "open cell" one. Along with the environmental factors, the foam will need to exhibit anti-static material properties with the intention of preventing interference of the electrical circuits present in the mechanical feedback control system.

The benefit of using these types of cushions is that they are easily manipulated such that one must just trace an outline of their object, cut out the foam piece by piece, and finally custom trim the excess pieces, all seen depicted in Fig. 1.2k below. The foam inserts chosen for this job, along with the carrying care itself, cannot be accurately determined at this moment due to a lack of knowledge on the device’s component dimensions. A harder material (such as some sort of stiff plastic) might be used if more rigid compartments are necessary, but it is crucial that all components are either well padded or secured immovably, ideally both, to ensure security if the device is moved or disturbed suddenly. Once parts have been acquired and the overall setup determined, only then shall the case and foam be focused on, as the exact dimensions and shapes will be designed around the exact components used.

**Figure 1.2k**) Foam inserts from Ameripack and the steps of form fitting them to an object
Subunit: Patient Restraint System

Because one purpose of this device is to establish relationships between injection volume and pressure in the shoulder, it is very important that the patient’s shoulder be stabilized in a stationary position, as any movements (particularly sudden ones) could negatively affect the data gathered. Discussion with the client about the best patient restraint system is needed, and such a system might be considered a secondary requirement to the pump device itself; however, it is a very important consideration. Some possible methods include a shoulder brace similar to those used by patients recovering from shoulder surgery, a chair with adjustable arms and straps to prevent shoulder movement during the injection, or a protocol to be followed to ensure consistency between patients (such as asking the patient to assume a seated position with their palm resting on their leg). A brief search of the internet reveals several devices that might be adapted to suit this experiment’s purposes, but the best design for this part of the device is not clear at this time and depends much on how the client plans to perform the experiment. (One option is to use the pump device and its analytical tools to study different restraint systems or arm positions to make a statistically significant estimate of the best procedure.)

2) REALISTIC CONSTRAINTS

2.1) Engineering Standards

One constraint for this product is that of units--while the dimensions of many parts are specified in English units and anything done in the machine shop must use English units, some other parts are specified in SI. While manufacturing can most likely be done fairly easily in English units (converting from SI when necessary), there is more of a problem that arises during regular use of the product. Ordering replacement parts in the proper units would have to be made as simple and straightforward as possible, so extensive documentation about sizes of all components must be included (with diagrams or images if possible).

The major concern lies in establishing parameters and analyzing results in consistent units, making it clear to the operator what units are being used, and if possible allow the user maximum flexibility in choosing units suitable to their purposes. (For example, pressure may be measured in pounds per square inch [psi], pascals [Pa], millimeters mercury [mmHg], bars, or atmospheres [atm]; height may be measured in centimeters [cm] or inches [in]; weight may be measured in pounds [lbs] or kilograms [kg]; or flow rate may be measured in milliliters per hour [mL/h], milliliters per second [mL/s], etc.) Ensuring consistent units throughout any analysis or control program is crucial, and which unit is being used must be absolutely clear at all times. This is to
make the device more user-friendly—for example, there might be some established dataset in one unit system that the operator wishes to compare to but is different from the system they normally use, or perhaps the operator normally uses metric units but the patient only knows their height in inches. Ensuring consistency and easy conversion of units will minimize concern of the constraint caused by having different measuring system; incorporating conversion options from the very beginning of the design process will make this process easier.

2.2) Economic

There are a number of economic constraints affecting the production of this device. As far as design and future of this prototype is concerned, economic constraints arise primarily from the cost of buying parts for the first time, and then from the costs of buying replacement parts, new needles and other supplies, cleaning and other maintenance, and purchasing chemicals needed to make the injection solution. Ultimately some estimation of the costs of these items may be produced based on first-time purchase cost and expected frequency of use, replacement, or maintenance, providing a clear picture of the costs of this device over time.

In terms of further production of similar devices, other economic concerns arise depending on projected use, clientele, and desired product quality. This device is limited by the budget allotted. For example, high-quality medical syringe pumps can cost upwards of $2000, well above the budget of this design. Future device models may require a higher-quality pump which would drive future production costs upwards and may also require modifications of the control mechanism or casing design. However, larger-scale production costs may be overestimated in some ways by the cost of this product due to the possible savings from buying parts in bulk loads, especially once the working prototype is established and the design work is complete. Such work future work depends, however, upon the success of the prototype.

Another economic constraint is the potential for the device to recoup its costs through money made by treating patients or provided for research by grants. The prototype will be important for establishing the viability of the design as a treatment option and subsequent research will be needed to justify its use in a clinical or therapeutic setting; only then will a similar design be ready for large-scale use. Such work is the client’s responsibility once the prototype is built by the conclusion of the design project; the project team will make every effort to fully document the device and process in order to make future improvements easier for the client. Ultimately it may be an economically favorable procedure if many people opt for IHD over a surgical option, since the total cost of the product for its lifetime over the number of people treated with it should be significantly less than the per person cost of surgery. This could make it
possible to profit from using the device while still costing much less to the patients than surgery.

2.3) Environmental

Environmentally, this device is constrained by the requirement of safe disposal of any biologically hazardous materials and chemicals, particularly of used needles. This may incur some additional cost to the user; however such constraints must be observed for the safety of the patient or subject, of the operator, and of the general public.

2.4) Sustainability

Since this is a fairly small device that is designed to be long-lasting, sustainability is not really a major concern. Insofar as it is an issue, it should be considered in regards to minimizing the need to replace or throw parts away. This could be accomplished by minimizing risks of contamination of tubing in the design, using durable parts as much as possible, and ensuring that the protocol for use of the device produces as little waste as possible.

2.5) Manufacturability

Since this is a prototype that may undergo significant modifications throughout the design process, it must be constructed in such a way that it can be assembled and disassembled fairly easily without compromising structural integrity or any other specifications. This could be accomplished, as discussed above, by using layers of plastic machined such that the assembled form meets all requirements. Care must also be taken to make sure that all connections are secure, even those meant to be easily adjusted for the purposes of the prototype.

2.6) Safety and Health

Safety and health constraints are discussed in greater detail in Section 3, but focus on the risks of biological contamination, patient safety and comfort, electrical and mechanical safety, and safe disposal of parts.

2.7) Ethical

Since this device is intended ultimately for human research, care must be taken to observe ethics of human testing. This means incorporating failsafes and guaranteeing patient safety as outlined in section 3, as well as ensuring any human testing done during our involvement meets all standards for human research. Due to
our personal lack of qualifications for human research, the design team itself will not do any live animal testing, including human testing; such tests are the client’s prerogative. Some testing on animal tissue may be incorporated in the later stages of this device, or to analyze a more realistic injection for purposes of device validation. Otherwise, testing will be done in the safest manner possible, for example by injecting fluid into balloons for ordinary testing purposes.

2.8) Social and Political

There are no realistic social or political constraints to this project provided all ethical standards listed above are observed. In fact, social and political factors may support this device since it presents a possibly much more affordable alternative to surgery (as discussed above). The only constraint worth speaking of in this area is perhaps surprising—there is a limit placed on the number of syringes a non-physician in Connecticut can buy at any one time. This limits our ability to purchase syringes to ten per pack. Since contamination will not be an issue during testing, this should be sufficient for our own purposes; however, it may be an issue in future use of the device.

3) SAFETY ISSUES

There are a number of safety issues that accompany the use of this product, particularly regarding the safety of the patient him or herself. The major safety concern for this device is based on biological hazard management, since it involves insertion of a needle into a patient. Therefore, good sterile and sanitary practice must be observed to minimize risk to the subject. Nitrile gloves must be worn whenever the device is used on a patient or tissue sample, for the safety of the patient as well as the operator. Sterile needles must be used each time and discarded after use, so proper disposal in a biohazardous sharps container must be available. There must also be a biohazardous waste disposal available for non-sharp waste (bandages, gloves etc). The site of injection must also be cleaned and sterilized prior to use, while antiseptic bandaging must be applied afterwards. Further precautions must be taken to ensure that tubing is not contaminated between uses. A one-way valve just before the needle might be utilized to prevent backwash of biological fluids; this would minimize the amount of tubing that would have to be replaced or sterilized between uses. Clearly, there are a number of precautions to be taken during the procedure itself that must be observed, regardless of the device.

There are some additional safety features that must be added to the device itself regarding patient comfort and safety. The patient must be continuously monitored for signs of injury or bleeding, and an emergency stop feature must be added to end any injection if there is evidence of injury or error (ideally, several ways to immediately stop
the injection would be available). Furthermore, the restraint system used must not cause excessive discomfort (though some minimal discomfort may be unavoidable due to the nature of the condition). Continuous or regular verbal feedback from the patient to the operator during the procedure is necessary since the device cannot measure things like patient discomfort. Some other concerns include mechanical stability of the device (the case housing the pump must be stable and resist tipping over or slipping across a surface) and of the patient restraint system (it must be stable and resist collapsing or sudden shifts in position). The patient restraint device must also be designed such that it does not cause discomfort by itself—for example, straps that dig into a patient’s arm must be avoided.

Another major safety hazard is electrical—since the device uses both a line of fluid connected straight to the patient and electrical components hooked up to the fluid tubing via the pump and pressure sensor, care must be taken to minimize risk of electrical shock. Proper grounding must be established to make sure there is no unsafe charge buildup, and that the device does not become grounded through the patient herself. All electrical components must be well insulated from each other and the surroundings, preferably in an isolated container within the device. Special care must be taken to eliminate any contact whatsoever between tubing and electrical wires. Moisture must be considered as well—electronics will be housed in as moisture-free an environment as possible, which can be accomplished through the addition of some sort of moisture-absorbing material such as silica gel. The electronics must also be protected against fluid spills, such that if some fluid does spill by accident it will not leak into the compartment housing electronics.

Chemical hazards of this device depend largely on the operator, who is responsible for injecting solutions that will not harm the patient. As in vivo testing lies beyond the scope of this product, such concerns will not be discussed herein, and are solely the responsibility of the operator. The only other chemical or material concern that is not biological nature lies in ensuring that the patient will not suffer an adverse reaction to the material in the needle, which is unlikely. (Allergic reactions must always be considered by the operator—for example, one cannot use latex gloves if the patient has a latex allergy, though latex may be an acceptable substitute for nitrile gloves for other patients.) Radioactive, thermal, and biocompatibility issues are not relevant to the product and will not be discussed.

4) IMPACT OF ENGINEERING SOLUTIONS

The optimal design’s overall impact on the field of engineering extends on several interconnected levels. Looking on a global scale first, the use of this device will
be able to generate biomechanical data that can be then shared with the rest of the medical community. This will be an advantage for the global community because it has the potential to reveal newer and more critical information regarding the diagnosis, characterization, and treatment of adhesive capsulitis for future cases. The information gathered can then also be compared with other data regarding different types of shoulder injuries in order to make a potential diagnosis more accurate.

From an economic perspective, this tool has the potential to make intra-articular hydraulic distention a very cost efficient alternative to treating adhesive capsulitis. The device’s syringe pump, pressure sensor, and National Instrument’s DAQ system have been chosen so that they can easily be integrated together in a seamless fashion all while keeping the overall project under the $1,000 budget. The spinal needles are meant for a single use only with the intention to discard them afterwards, which introduces a nominal fee to properly use this device. Other parts that could potentially need regular replacement or cleaning are the syringes used for the fluid, the tubing connecting the syringe to the stopcock/pressure sensor/needle, and the stopcock itself. The proper disposal of this biohazard waste could potentially incur an unforeseen fee itself.

The economics of this device also plays a role in its environmental impact on several issues. Power consumption by the overall device must be kept to a low all while achieving the desired functionalities so as to minimize both the environmental and economic impacts. The pump and DAQ system seem to be the two major sources of power usage, but they both can be ran using simple power outlets due to their lower power requirements. The computer or laptop that the DAQ systems will feed into require their own separate power sources, but that is left up to the user to provide.

Focusing on the social impacts of this engineering solution, it is clear that the doctor/patient interaction can have the potential to be improved in several ways. This machine could be able to, for the first time, standardize the already-performed intra-articular hydraulic distension procedure for any future treatment options. That would mean better doctor-doctor communication regarding both the procedure and adhesive capsulitis which could ultimately result in better patient care. The biomechanical information gathered from the usage of the device could potentially provide a much better understanding of shoulder dynamics and injury on a social scale such that preventative measures against adhesive capsulitis becomes commonly distributed information.
5) LIFE-LONG LEARNING

When it comes to just the amount of information acquired and processed during this design project, the list is quite extensive. This is all due to the necessity of looking at and incorporating as many different viewpoints as possible, based on the subject matter at hand. Any Biomedical Engineer’s best starting point when first given a task would have to be investigating the problem at hand by just jumping in the ocean of information about the topic and sorting out the facts in order. Investigation about the current diagnosis, treatment, and characterization of Adhesive Capsulitis provided us with a very solid beginning foundation for the designing of a machine to perform the Intra-Articular Hydraulic Distension (IAHD) procedure. This included learning how to properly perform patent and journal article searches regarding previously performed IAHD procedures and the devices used. It was concluded that there was no set standard procedure or tools used, and the overall method is dependent on the operator and the machines constructed for that particular experiment. There was a certain degree of consistency in the necessary components required for the actual procedure, such as a needle and syringe, but the rest of the setup had variations between journal articles and there were no clear standards for the device or procedure.

It then became necessary to use what was known about the results from the literature to identify weak points in the experimental setups from the previous procedures, and to incorporate the strong points of what was achieved at the same time. In order to get our design ideas out in the clear we began to learn how to sculpt 3D models of the alternative designs that were presented in SolidWorks, and graphically represent the overall system flow with blocks using MS Visio. Following this process, time was devoted to pure searching of potential parts, a learning experience within itself, such as discovering industry standards for syringe pumps and their different functionalities, the legal restrictions placed by Connecticut limiting the number of syringes that can be bought at once to just 10, and how the DAQ systems would integrate with the pressure sensor and pump.

It is necessary to better understand how to control a mechanical system using a computer-based feedback approach so as to change the infusion rate of the fluid to maintain stable intra-articular pressures and prevent joint rupture. This approach could be all controlled and monitored from the LabVIEW software, including data processing and manipulation, meaning that it is vital to uncover how to integrate the National Instruments’ DAQ with both the pump and computer, and to set up a negative feedback loop. Throughout this entire process, it has become more and more evident how important it will be to learn how to distribute and manage time in a more effective manner with the challenges presented.
6) REFERENCES


http://www.pendotech.com/products/disposable_pressure_sensors/disposable_pressure_sensors.htm


Appendix

An equation to be used in an algorithm to control the volume flow rate of a pump such that the pressure flux is constant is presented herein. Assuming that $\Delta P_{ij} = P_j - P_i$ is known from the pressure sensor for a time interval $\Delta t = t_j - t_i$, and that $\Delta V_{ij} = V_j - V_i$ is known for the same interval from the pump, we can say that

$$\frac{\Delta P}{\Delta t} = \frac{\Delta P}{\Delta V} \times \frac{\Delta V}{\Delta t}$$

If we want to establish a constant volume flux such that $\frac{dV}{dt} \approx \frac{\Delta V}{\Delta t} = K$, then we can rearrange the previous equation to get

$$\frac{\Delta V}{\Delta t} = \left(\frac{\Delta P}{\Delta V}\right) \times \frac{\Delta V}{\Delta P} = K \frac{\Delta V}{\Delta P}$$

Since we can set the volumetric flow rate of the pump $V = \frac{dV}{dt} \approx \frac{\Delta V}{\Delta t}$, we can use the previous equation evaluated over a given interval $\Delta t$ (which is a constant increment and so is displayed with no subscripts) from $t = i$ to $t = j$ to set the volumetric flow rate for the subsequent time interval ($t = j$ to $t = k$), as follows.

$$V_{jk} = K \frac{\Delta V_{ij}}{\Delta P_{ij}}$$