PROPOSAL
19 September 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
EXECUTIVE SUMMARY

In order to study and treat the condition known as “stiff” or “frozen” shoulder (known technically as adhesive capsulitis), proposed herein is a device to administer and monitor in real time the procedure known as “hydraulic distension,” a novel treatment that involves the injection of a fluid into the shoulder joint capsule to relieve the symptoms. Stiff shoulder is a chronic debilitating condition that results from inflammation of tissue in the glenohumeral joint capsule and results in chronic pain and greatly reduced range of motion.

Typical treatment ranges from physical therapy and time to cortisone injections and surgical options; one alternative option that has received some attention is known as hydraulic distension. This treatment is limited at this time due to a lack of optimization of conditions and lack of a controlled standard. The proposed device would enable a consistent standard protocol for the treatment, and would provide measurements and feedback that could be used to study the treatment and eventually optimize the parameters. This would be accomplished by integrating sensors, analysis, feedback and control in a single user-friendly, safe package, which at this time does not exist for this treatment.

1. INTRODUCTION

1.1. Background

The client, Dr. Krystyna Gielo-Perczak, has focused her research on human biomechanics with the hopes of further expanding the fields of preventative and rehabilitative health care for musculoskeletal injuries. Her main area of interest is centered on the human shoulder complex and the associated mechanics and dynamics.

Adhesive Capsulitis, or more commonly referred to as “Frozen Shoulder Syndrome”, is an extremely debilitating condition in which the tissue of a person’s shoulder capsule thickens and becomes inflamed. This forms a mass of scar tissue and reduces the volume of fluid in the joint, which in turn severely limits the patient’s range of motion as well as causing chronic pain. It has been observed that a patient’s symptoms will have a gradual onset (2-9 months), a long duration phase (4-12 months), and a very slow recovery period (5-12 months), all coupled with the possibility of future return. Aside from traumatic injuries to the shoulder, no other significant causes for Adhesive Capsulitis have been discovered with many of the suffering patients not even being aware that they have this condition.
Treatment options include physical therapy for the more mild cases and invasive surgery if the condition continues to worsen over time or is already at a critical stage. Unfortunately, these treatments do not guarantee a full recovery, as seen with physical therapy, and could prolong the recovery period or even worsen the symptoms experienced if invasive surgery is performed along with introducing the risk of complications.

To counteract these downsides, the medical community has devised a novel procedure that is both minimally invasive, and shows virtually immediate pain relief and increased range of motion in the patient’s shoulder. This technique, Intra-articular Hydraulic Distension, involves a needle being placed into the shoulder of the patient with a variable mixture of saline, corticosteroids, and pain killers slowly injected into the shoulder capsule. The purpose of this technique is to both expand the capsule’s volume and to refill the missing lubricating fluid found within. The biggest issue currently encountered with this method of treatment is the lack of an optimization protocol so as to introduce an ideal amount of fluid while preventing the shoulder capsule of the patient from rupturing during the procedure, an event that may set the recovery process backwards.

1.2. Purpose

The purpose of this project is to design and construct a device that is optimized to perform Intra-articular Hydraulic Distension on a patient with Adhesive Capsulitis. The device should be able to control and monitor the exact volume of fluid being injected into the shoulder with an imaging modality included for the insertion of the needle into the proper location of the shoulder. Since the safety of the patient is the most crucial aspect of Intra-articular Hydraulic Distention, the device must have built-in feedback to serve as an early detection system in order to prevent and minimize any potential shoulder capsule ruptures, as well as monitor the progress of the procedure.

In addition, the device needs to be able to gather and compile all relevant data on that patient’s unique biomechanical properties of the shoulder, as well as perform some real-time analysis. This will serve both as a tool for diagnosis of adhesive capsulitis, its severity, or any other potential shoulder injuries, and as a source of information for the biomechanical properties of all of the patients examined and treated. The device should be highly functional both on a case-by-case basis (able to monitor and control the procedure for individual patients) as well as in the long term by
collecting relevant data that can be exported and analyzed statistically given a group of patients.

1.3. Previous work

While the technique for hydraulic distension has been performed in the past, there is no current standard in either procedure methods or tools used. Therefore, the only devices similar to this have been seen only as experimental setups with their components custom built for that specific experiment (Lee et al, 2008). One experiment in particular utilized an experimental rig featuring a syringe pump and pressure sensor to study the change in pressure in the shoulder joint as the procedure progressed; however, this device is experimental in nature and lacks much of the desired functionality.

While an internet search reveals a number of patents for different treatments of adhesive capsulitis, a fairly thorough search did not reveal any patents on a device for hydraulic distension of the shoulder capsule. It seems reasonable to say that there is no device currently available that meets the needs of the client in this case, that no one has ever produced a device with the depth of consideration proposed herein, and that there are no intellectual property barriers to designing such a device.

2. PROJECT DESCRIPTION

2.1. Objective

When completed, the device that will ultimately be produced should be a self-contained, user-friendly, multifunctional tool for applications in hydraulic shoulder distension research and treatment. While there have been numerous studies of hydraulic distension, there is a notable lack of consistency across them with regard to procedures and techniques, which this device will ultimately address as its major innovation.

In order to meet this goal, the device will be self-contained, with all equipment and materials needed for a variety of functions integrated in a single package. This would involve incorporating a method for controlling the fluid injection based on user inputs, a method of measuring the injection and providing continuous feedback in real
time, incorporated data collection and analysis, visual displays, patient stabilization capabilities, instructions, and storage for disposable pieces such as needles, all in a package that is easily transported, tidy, and safe. The device should be assembled as completely as possible, such that it might be used on a regular basis with the minimal possible assembly demands (ideally, the user would only need to turn on a power switch, attach a new sterile needle, and be ready to use the device).

No such device exists at this time—currently, the injection is done either by hand with a syringe with no measuring or feedback, or else the setup is experimental in nature and has a number of separate parts which is not convenient for clinical or therapeutic purposes. By packaging all of the hardware, software, and other equipment needed to study or perform this procedure into one package, with a user-friendly interface and with a variety of relevant functions, this innovative device will enable study and use of the technique that is not feasible at this time.

The device is also innovative in that it attempts to standardize a procedure for Intra-articular Hydraulic Distension, which, combined with further research, may improve its efficacy as an alternative to invasive surgery for patients with stiff shoulder complaints. Hydraulic distension is minimally invasive, and early research seems to indicate that it is effective; however, it is not a well-established clinical option and many sources of information for patients with stiff shoulder (such as the National Institute of Health website) don’t discuss it as a therapeutic option. By creating a standard tool, better scientific research into the technique could be enabled through use of the device, as well as a means of providing the procedure consistently to patients in a clinical setting if research supports its viability as a treatment option.

2.2. Methods

While the design of the packaging for the device and some other considerations such as the patient restraint system have not yet been established, there are several components that will definitively be required given the desired functionalities, as well as some more that will likely be included.

Since control and feedback of a mechanical system (injection of a fluid into the shoulder) as well as data measurement and analysis are an integral part of the proposed device, a PC or a very powerful microprocessor with data acquisition (DAQ) capabilities will be needed, along with some sort of visual display, such as a computer monitor. A means for interaction with the computer will also be necessary, which would
require either a mouse and keyboard setup or a touch-screen interface. If control of the injection is desired, a device such as a syringe pump will be necessary, preferably one that can be controlled through the main user interface. Further, since the fluid pressure within the shoulder capsule is of key interest, a pressure sensor would be required that communicates data to the computer in real time. If it proves infeasible to incorporate the computer, monitor, and interface into the device itself, but a computer with sufficient power is available in the clinical setting, one solution may be to establish a plug-and-play connection through a simple attachment such as a USB cable to the client’s own PC.

Since the procedure requires insertion of a needle into the shoulder capsule, a supply of needles must be readily available, as should a biological hazard disposal container for the used needles; depending on the clinical environment that the device will be used in, storage for new and used needles may be incorporated into the device, unless it is reasonable to expect that the environment already has such capabilities. Clear instructions on biowaste management relevant to the machine will be provided with the documentation to the customer.

The hydraulic distension technique typically requires some method of imaging the shoulder capsule in vivo so as to guide insertion of the needle and visually monitor the progress of the procedure. One common method that is quite safe is ultrasound imaging; however, ultrasound equipment can be quite expensive. Ideally this will be incorporated in the device as well; however if that is not feasible it might be assumed that the device operator has an independent visualization method.

Some other materials that will be needed include hydraulic tubing, equipment for stabilizing the patient in some ideal position (of which more study is needed), and equipment for packaging and transportation. The device should be encapsulated as much as possible in a lightweight, durable, easily transported container, the specifications of which depend on the specific design of the device. A DAQ device, wiring, A/D converter, and other circuitry would be necessary as well.

The general functionality of the device can be seen in flowchart form in Figure A, which shows major components as well as some of the feedback pathways. As with any medical device, the patient is of paramount importance, so it is important that the procedure be stopped as easily as possible if the patient expresses immense discomfort or pain. Assuming there is no pain and the procedure goes smoothly, the process would roughly follow Figure A. Ultrasound imaging of the shoulder will provide a detailed view to the operator, who can then easily guide the needle into the joint capsule.
The operator would then establish parameters for execution of the procedure, enter them into the PC and begin. Based on operator input, the PC would send a signal to a data acquisition (DAQ) device, which in turn will control a pump. This pump will inject fluid through tubing into the needle and the patient’s shoulder capsule. The pump would return information to the PC via the DAQ device regarding the injection process. Attached to the pump will be a pressure sensor, which will measure the pressure in the tubing (assuming low flow rate, this will be equal to pressure within the joint capsule). The pressure sensor will also return information to the PC via the DAQ device.

The information gathered from the pressure sensor and pump would provide data that will be analyzed by the PC and used to adjust the fluid injection in real time, forming a feedback control loop. The PC will also display neatly presented data to the operator in real time, who can make adjustments or stop the procedure based on that information. Finally, the device will be capable of exporting data to other computers once the procedure is done, allowing for later tabulation, analysis, and comparison (which will be very important for any future research applications.)

![Figure A: Flow chart for desired device functionality & interfacing.](image-url)
Figure A represents the key points that the device must address, which will make it an effective clinical tool for research and ultimately patient care. In terms of design, it appears that implementation of this scheme could be accomplished. A program such as LabVIEW provides an excellent opportunity to accept inputs, control a mechanical process, collect data, perform analytical calculations, and export data to a visual display as well as produce data files. There are commercially available pressure sensors and pump devices which could be connected to a PC using some knowledge of circuits and data acquisition techniques. Real-time pressure monitoring of the procedure has been accomplished experimentally using a basic syringe pump and pressure sensor setup to collect data (Lee et al 2008). The subsequent major obstacles are in the mechanical construction of the device--how compact, lightweight, safe, and user-friendly it can be while having the greatest functionality--and in implementing the control loop between the computer, pressure sensor, pump, and user.

3. BUDGET

The estimated budget for the construction of the Intra-articular Hydraulic Distension device is currently expected to fluctuate. This is due to the fact that some designs might require components that other designs do not, along with the current supply and demand of those parts. The initial budget has been capped at $1,000 (though some amount of additional funding may be possible if absolutely necessary) with the components being either bought “off-the-shelf” or custom built if there is no commercial option. Regardless of financial limits, there are several fundamental elements that must be included in order for this device to be functional. They include needles, syringes, tubing, a syringe pump, pressure monitor/transducer, and a device for data acquisition and computation, such as a PC or laptop. (As discussed previously, it may be possible to create a device with a plug-and-play connection to the client’s laptop if the hardware costs or feasibility concerns prevent incorporation with the device itself.)

The procedure requires spinal needles, which are designed for deep insertion into the body; common IV needles such as those used for insulin injections are not sufficient. Spinal needles are more expensive than IV needles, and even though IV needles are relatively cheap, the fact that they are not reusable will increase the cost over the device’s lifetime (though since there will be no human testing during the design process due to lack of qualifications, this cost will not be immediately visible; rather it
will accrue to the client over the course of normal device use). The spinal needle’s cost on the market today appears to be ~$95 for a pack of 50 20-gauge/3.5 in long spinal needles.

The tubing needed to deliver the fluid to the shoulder capsule needs to be non-elastic so that the tube won’t deform when the pump is operational. This will guarantee that the pressure sensor readings remain consistent and accurate, and that any volume changes are confined to the joint capsule itself. The tubing will also need to have the appropriate Luer Lock ends so that the needle and syringe are securely connected throughout the procedure. A box of 25 of these specialized tubes costs around $100.

If syringes are used as part of the pump assembly, they must be able to contain at least 30 mL of fluid due to the fact that a healthy shoulder joint capsule’s volume is approximately 30 cc, and must have a Luer Lock tip for the tubing. One major drawback is that the state of Connecticut has passed a law that allows only up to ten syringes to be purchased without a prescription or a physician’s approval--although a box of ten 30 mL syringes costs only $7.50. It is not clear at this time how often syringes must be replaced.

The syringes will need to have their infusion rates precisely controlled by a specialized syringe pump. The majority of syringe pumps for medical uses found online range in price from $1,000-$5,000, but simpler models retail for around $200 to $300; for the prototype it is expected that one of these less expensive models would suffice.

In order to properly insert the needle into the patient’s shoulder capsule without causing damage to other surrounding tissues, it becomes necessary to use an ultrasound machine to image the area. There are many different makes and models of ultrasound machines with a wide range of prices out on the market today, but our client has agreed to speak with Mr. Kaputa and Dr. Sun of the University of Connecticut in the hopes of gaining access to an ultrasound machine that is already available. This will only ease the weight on the budget, especially with the high cost of some of the other parts of the device.

4. CONCLUSION

An estimated 2-3% of the population suffers from Adhesive capsulitis, and yet, there is currently no device out on the market, nor is there a standardized procedure for this potentially useful medical treatment. This device will be a novel instrument that
could both standardize and potentiate the therapeutic capabilities of Intra-articular Hydraulic Distension procedures already being performed. In addition, it will be able to perform crucial analyses and gather information on the biomechanical properties of the human shoulder in an effective manner for use in any future studies. The only realistic constraint encountered thus far has been with Connecticut’s laws on limiting the purchase of some of the parts, such as needles and syringes, but, other than that, it seems more than feasible to construct and test such a tool that will fall under the proposed budget of $1,000.

5. REFERENCES


http://www.sisweb.com/lc/new-era-ne500.htm


http://www.harvardapparatus.com/webapp/wcs/stores/servlet/haisku3_10001_11051_44368_-1_HAI_ProductDetail_N_37951_37956_37957

http://www.amazon.com/Syringe-30cc-Luer-Lock-Sterile/dp/B000FN65ZG/ref=pd_sbs_indust_2