PROJECT STATEMENT and SPECIFICATIONS
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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
STATEMENT OF NEED

Intra-articular Hydraulic Distension (IHD) is a novel technique used to treat Adhesive Capsulitis of the shoulder, more commonly referred to as “Stiff” or “Frozen Shoulder Syndrome,” but there haven’t been any attempts to optimize this potentially dangerous treatment. IHD is based around the idea of injecting fluid into the glenohumeral (shoulder) joint capsule in an attempt to relieve the chronic and debilitating pain suffered by the patient and increase the motion of the shoulder joint. Due to the lack of optimization for this technique the IHD procedure has been shown to rupture the patient’s shoulder joint capsule, which will in turn introduce a new complication and set back the overall recovery process. Furthermore, there is no universally accepted data regarding the effectiveness of the therapy, due to factors like variance among patients and experimental error on the part of the operator.

In order to truly optimize this technique, it is vital to design a device capable of monitoring the pressure and volume within the patient’s shoulder joint capsule in real-time so that maximum distension and stretch can be achieved without rupturing the joint. Due to the biological differences between patients, the real-time data gathered must also be utilized to further understand the biomechanical properties of the glenohumeral joint so that future diagnoses can be facilitated. This tool needs to also account for any potential patient or user made errors and correct them, all while being portable and easy to operate.

INTRODUCTION & OVERVIEW

Stiff or “frozen” shoulder is a painful, chronic medical condition of the glenohumeral joint (where the humerus joins the torso). In individuals suffering this affliction (technically referred to as adhesive capsulitis), the tissue of the glenohumeral joint capsule has thickened, corresponding to a decrease in volume of the synovial fluid that cushions the joint. The result is a range of symptoms, most notably pain (both chronic and stimulated by sudden movement or overexertion) and an greatly decreased ability of bones in the shoulder joint to move freely against each other (which results in stiffness of the shoulder and a greatly decreased range of motion [ROM]). These symptoms are not isolated—pain in the shoulder discourages motion, which results in increased stiffness and decreased ROM, which in turn leads to more pain and so on. Recovery is variable in different individuals and can range from eighteen months to several years in duration, with physical therapy recommended even after the condition has subsided in order to avoid relapse. Treatment for this condition has two main goals: reducing pain, and keeping the joint mobile. Some common treatments include physical therapy, painkillers, corticosteroid injections, and surgery in severe cases to relieve the tissue inflammation.

Another course of treatment that has seen some attention recently is known as “Intra-articular hydraulic distension,” but it is not yet widely accepted. This treatment involves the controlled injection of fluid into the joint capsule, increasing the fluid volume. This pushes the
humerus away from the glenoid fossa (known as distension) and allows the joint to move more freely. This also stretches out the capsule and disrupts some of the tissue interactions that cause stiffness. The fluid injection is a solution that may include painkillers or corticosteroids. While the technique has been known for some time, there is currently not a significant collection of data to understand the best protocol for the procedure. This lack of information is the result of several factors, including: no certain knowledge of the optimal parameters such as pressure, injection volume or rate, shoulder position, or when the procedure should stop; large variations among individual shoulders due to a number of factors such as age, activity, or other medical conditions; lack of standards for controlling the procedure; and experimental error due to the operator or the equipment.

The purpose of this design is to create a device capable of controlling, monitoring, and analyzing a shoulder joint distension process that is functional in diagnostic, therapeutic, and analytical settings.

- The device should be able to continuously monitor the injection of fluid into the joint (including volumetric flow rate and pressure).
- It should be consistent and automated to the greatest possible degree while maintaining minimal risk to the patient, to reduce as much as possible experimental error on the part of the operator.
- It should accept input from the operator regarding things such as age, height, weight, severity of the condition, other medical conditions, or other factors relevant to treatment of the disease, and use such inputs to analyze the optimal conditions for use; it should also track and analyze shoulder ROM before and after the process or incorporate other measurements of effectiveness.
- It should have a method of stabilizing the arm to eliminate movement during the procedure.
- It should also function in a diagnostic setting, using information such as pressure in the joint capsule to analyze the presence or severity of the condition.
- It should function in an analytical setting, both by collecting data on each individual trial and by comparing individual trial results to data sets where appropriate.
- The device should be user friendly, safe, and portable.
- It should have a way of storing and exporting data for purposes of quantitative or qualitative analysis.
- It should be built from off-the-shelf components, with a budget cap of $1000 for a prototype.
- A model of the device should be created in CAD, SolidWorks, or a similar computer program.
- A strict protocol for use should be established, including clear instructions on use of the machine, an overview of safety features, and a procedure for distension therapy based on the best available information (for which a computer-based mechanical shoulder model may be useful).
● It should be compatible with variations in the procedure at the discretion of the operator, and its functionality should be comprehensive based on the most commonly cited factors in performing such a procedure.

REALISTIC CONSTRAINTS

Health and Safety
The Intra-articular Hydraulic Distension procedure itself is inherently somewhat invasive due to the need to insert a needle deep into the glenohumeral joint capsule in order to pump the fluid in. This means that all of the proper sterilization methods and techniques required for such a task will need to be performed each time the device is used so that the risks for any disease transmission or infection are virtually eliminated. The patient’s feedback on their perceived pain and comfort levels must also be taken into account so that the IHD procedure can be easily terminated if they so desire. Another major constraint comes in during the testing such that no human patients will be available to perform the procedure on, but instead porcine models will be the test subjects. Clearly, this will be an obstacle that has to be addressed in some way in the future.

Economic
Manufacture of the device needs to be relatively low-budget and will use off-the-shelf items, which in turn will place restrictions on the components and functions that can be implemented. The need to use a new needle each time the IHD procedure is done will also mean that there is a price attached to just using it, which has to be accounted for in the overall budget. Power consumption by the device needs to be within reasonable limits and comply with all safety and hazard protocols.

Environmental
Precautions must be taken to ensure that all of the used needles are properly disposed of so as to not have a negative impact on the environment. Any biohazardous waste must be properly disposed of, and the device must be kept sanitary.

Sustainability
Certain components could be very sensitive to being handled/used. Some parts might not be replaceable by just the operator and could require outside expertise.

Manufacturability
Getting all of the different components to synchronize properly and give proper readings will be a constraint due to the inability to actively test the device on real patients. Construction should be solid, but also easily adjusted.

Social and Political
No obvious political constraints are currently seen. A potential social constraint could be that the patient doesn’t understand the device/procedure and unintended actions could alter or ruin the results. Making the device look professional and function properly will make patient interactions easier.

**Ethical**

Since the technique involves injecting a fluid into a human patient, there is a host of ethical concerns and standards. The device must only be used by qualified individuals with approval to work with human subjects, in accordance with all laws and standards therein. Sanitation is a major concern for patient and operator health and the device will have to address all such issues.

**OTHER INFORMATION**

The client, Dr. Krystyna Gielo-Perczak, wishes to further pursue her interests of studying, modelling, and simulating of the musculoskeletal system with a focus on the shoulder complex. Her goal has been to better understand human biomechanics in order to prevent musculoskeletal injuries, to facilitate their treatments, and to spread the knowledge of preventative care.

**QUESTIONS**

- What information are people who would use this device looking for?
- How should the patient be situated? How will this device accommodate that?
- Is there a specific program that would be preferred for the device interface?
- How can the device be modelled? What program is preferred?
- What sort of container/carrying case should there be?
- What is the desired hardware for the interface (ie laptop or standalone program with a monitor)?
- What else besides a pressure sensor should be included? (ie. Goniometer)
- What analyses should the device be capable of? What data should it be capable of exporting?
- Should there be a way to ensure patient stability? If so, what would be the optimal position?
- What are relevant standards for devices with human subjects? How would our device address these standards?
- What is the target market for this device/who would be the primary users? How can the device be best fitted to their needs? Is this device limited to a specific set of experiments, or should there be a more universal approach?
- How should fluid injection be controlled? What are concerns specifically with the injection, ie how fast, how much, and how will the device address these?
- How should the real-time pressure monitoring be displayed?
- Should there be some sort of needle stabilizer/holder to ensure no capsule volume change?
- Should the patient’s age/height/sex/medical history be implemented in the procedure/data analysis?
- Are there any related products or devices that share any common features with the desired product? Does this project have to start from scratch or is there an existing design that could be modified to get the desired functionality?
## TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Physical</th>
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<tbody>
<tr>
<td>Casing</td>
<td>Lightweight, durable plastic when possible</td>
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<td>Patient accommodations</td>
<td>Comfortable restraints</td>
</tr>
<tr>
<td></td>
<td>Adjustable based on patient height, weight etc.</td>
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<tr>
<td>Storage</td>
<td>Place to store any equipment needed for testing (needles, extra tubing, gloves, sanitizers, bandages, swabs etc.)</td>
</tr>
<tr>
<td>Injection protocol compliance</td>
<td>Sterile hypodermic needles for any live tests</td>
</tr>
<tr>
<td>Sensors</td>
<td>Pressure sensor (fluid)</td>
</tr>
<tr>
<td>Portability</td>
<td>Device should be easily transported and functional.</td>
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<tr>
<th>Electrical</th>
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<tr>
<td>Power Source</td>
<td>120V AC via adaptor/battery</td>
</tr>
<tr>
<td>External Communication Protocols</td>
<td>USB, Ethernet</td>
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<th>Software</th>
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<tr>
<td>User Interfaces</td>
<td>Keyboard, mouse</td>
</tr>
<tr>
<td>Hardware</td>
<td>Small monitor, DAQ device, measurement devices, injection controller</td>
</tr>
<tr>
<td>Imaging</td>
<td>Ultrasonic imaging capabilities to guide needle insertion and for live monitoring</td>
</tr>
<tr>
<td>Features</td>
<td>Stand-alone program; user interface; organized access to all functions; user-friendly; real-time monitoring, control, and analysis as described above; data input/output capabilities; includes digital copy of protocol</td>
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<tr>
<th>Environmental</th>
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<tr>
<td>Temperature range</td>
<td>40 degrees F - 100 degrees F</td>
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### Environmental conditions
- Variable humidity; indoor use

### Safety
- Emergency kill switch to stop a procedure
- Precautions to eliminate risk of electric shock
- Minimize free wires/tubing
- Eliminate rough surfaces, sharp corners
- Use by qualified professionals only
- Observes all ethical/design standards for human subject research
- Extensive testing of device before any human use

### Maintenance

<table>
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<tr>
<th>Biohazard Waste Management</th>
<th>Anything that touches exposed flesh (needle etc) must be disposed of in a safe manner</th>
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<tbody>
<tr>
<td>Cleaning</td>
<td>The device should be easily cleaned &amp; sanitized between uses</td>
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<tr>
<td>Tubing replacement</td>
<td>Any tubing should be readily accessible for cleaning or changing, but must attach securely</td>
</tr>
<tr>
<td>Upgrade compatibility</td>
<td>Information on hardware/software should be included with the product to improve ease of future modifications</td>
</tr>
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### REFERENCES
- [www.nhs.uk/conditions/frozen-shoulder/Pages/Introduction.aspx](http://www.nhs.uk/conditions/frozen-shoulder/Pages/Introduction.aspx)
- [www.ncbi.nlm.nih.gov/pmc/articles/PMC2051310/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2051310/)
- [www.bmj.com/content/283/6298/1005](http://www.bmj.com/content/283/6298/1005)