Department of Mechanical and Mechatronics Engineering

ME 482 Final Report:

MR Compatible Wrist Loading Device

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Team 43

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3 EXECUTIVE SUMMARY

This final report documents Joint Effort's process behind designing an MR-compatible wrist loading device for a fourth-year capstone design project. The initial motivation was due to a wrist injury that impacted the team member, Kelly. This led the project down the path of designing a biomechanical research tool. The team successfully built a functional prototype that was verified to meet the critical requirements identified to solve this problem. Over the course of eight months, the team collaborated in person in the Fall 2019 term and remotely in Winter 2021. This report summarizes key changes from ME481 to ME482; technical design work performed in ME482; manufacturing and verification of the prototype; project management driving the project's success; and concludes with recommendations and a future outlook for the device.

The project did not come without significant challenges. The first term presented the daunting challenge of learning about medical device research and how to design a device with biomedical requirements. Neither of the two founding project members had experience in this field so the learning curve was steep but rewarding. The major challenge of the second term was adapting plans to work with the stay-at-home restrictions of the COVID-19 pandemic. Luckily, manpower increased by 50% with the addition of a new member and allowed the team to improve the design, restructure the verification plan, and learn a great deal about overcoming unprecedented obstacles collaboratively.

In the end, the milestones for the capstone project were all met on time and the team is proud of their work. Joint Effort could not have accomplished this without the inspiration from Wendy Medeiros, the constructive feedback from Professor Teertstra, Professor Lambert, and Dr. Lalone, and especially the unending support and guidance from Professor McLachlin.

Going forward, Joint Effort is releasing the design, bill of materials, and other relevant files as an open-source project for researchers to utilize and advance knowledge of wrist disease pathology.

4 INDIVIDUAL CONTRIBUTIONS

Team Member	Contributions
Beals, Michael	• Physical prototype manufacturing and assembly • Analytical/simulation work (force analysis) • Verifications • Deliverables (presentation, reports)
Hao, Kelly	• Design work (modelling) • Analytical verification • Deliverables (presentation, reports)
Tsang, Catherine	• Project management • Initial physical prototype manufacturing • Deliverables (presentation, reports)

We the undersigned take responsibility for this design.

Michael Beals

Kelly Hao

Catherine Tsang

5 SUMMARY OF ME481

5.1 MOTIVATION

The primary motivation for this project was born from a personal wrist injury sustained by one of the capstone team members that left her debilitated in most activities in daily life: brushing teeth, turning a doorknob, using a pen, among many others. This stemmed an interest in developing a rehabilitative wrist device, but the team quickly found a device on the market that appeared to satisfy their objective, the WristWidget [1].

Figure 5-1 WristWidget

The WristWidget inventor, Wendy Medeiros, was contacted to learn more and after some conversation, the team was encouraged to pursue a different path with a greater need. Medeiros suggested weight-bearing imaging, a new diagnostic technique that could help detect wrist degenerative diseases sooner. After conducting further research and realizing its valuable societal benefit, the team decided to pursue this path with great interest.

5.2 BACKGROUND

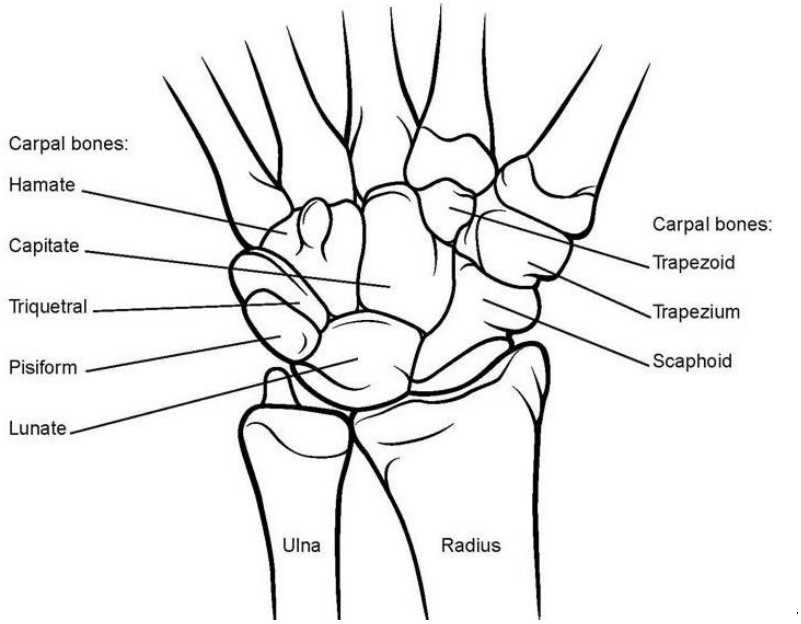

Figure 5-2. Bone anatomy of the wrist [2]

The wrist joint is composed of eight carpal bones (all labelled in Figure 5-2) located between the two forearm bones – the radius and ulna – and the bones that form the base of the fingers – the metacarpals. To allow for motion within the wrist, the contacting surfaces between bones are sheathed in smooth, white tissue known as articular cartilage that provides a low-friction contact surface [3]. Articular cartilage is also responsible for transmitting compressive loads between bones. With no direct blood supply, articular cartilage has poor healing properties and is difficult to regenerate after deterioration. Cartilaginous deterioration is the musculoskeletal indicator of osteoarthritis (OA) [4]. OA is the most common form of arthritis, a disease that affects 1 in 5 North Americans [5]. Left untreated, OA can lead to severe joint pain limiting daily activities [5].

To diagnose damage to soft tissues like articular cartilage, magnetic resonance imaging (MRI) is the gold standard in imaging. It is a common clinical procedure used for painless and non-invasive diagnoses. X-ray scans are unable to image soft tissues because X-rays are well absorbed by dense materials with a relatively high atomic number such as calcium (i.e., bone); soft tissues are neither dense nor have many particles with high atomic numbers [6]. MRI, on the other hand, uses the magnetic properties of protons that are present in all biological materials, so they are capable of imaging all internal body structures [7]. MRI equipment includes a powerful magnet housed within the main structure, a bed for the patient to rest on, and radiofrequency coils that

collect the signals from the body during imaging. The main structure and table can be seen in Figure 5-3.

Figure 5-3: Typical MRI equipment [8]

While the main MRI structure has a built-in radiofrequency coil, it is common to connect a small accessory coil when the image is meant for a specific structure located on an extremity. Accessory coils also have the benefit of being in closer proximity to the biological structure which improves image resolution [9]. An example of an extremity MRI coil is seen in Figure 5-4 [10].

Figure 5-4: An example of an extremity MRI coil [10]

For the excellent imaging that MRI brings, it also carries specific restraints. These include:

- **Material restriction.** Ferromagnetic materials react strongly to the magnet so only certain materials are considered MR compatible.
- **Size constraints.** Typical MRI bores are within the range of 600-700 mm [11]. If an accessory coil is used, these have even smaller diameters.
- **Patient position.** For forearm and wrist scans, patients are positioned in one of two ways: face up with the arm beside the body (see Figure 5-4) or face down with the arm raised

above the body (see Figure 5-5). From research on prevalence of each position, the face down position will be used for the project design.

Figure 5-5. MRI wrist and forearm imaging position [10]

- **Cost.** MRI is an expensive technique requiring trained professionals, supplementary equipment, and dedicated rooms. Consequently, the longer the time required to prepare a patient for imaging, the more expensive the procedure.
- **Long scan times.** While scan times vary based on the body part being imaged, one session can last between 15 to 90 minutes [12]. As the wrist is a smaller limb, the MRI scan will take less time. It will be assumed that an MRI session will take 15-20 minutes based on a conversation with a sports physician and professor.

Typical MRI scans are non-weight bearing. That is, the structure being imaged is not subject to any external load. In recent years, researchers have been exploring the potential benefits of weight bearing scans where the structure being imaged is subject to compressive loading. This research is especially popular in knee MRIs because the knee is typically weight bearing (i.e. carrying the load of the individual) and has indicated the potential to detect OA earlier than non-weight bearing imaging [13] [14] [15].

Compared to the knee, weight bearing research on the wrist is relatively scarce; the literature review conducted for this project found only one 2017 paper where weight bearing images were used to determine the increased risk of OA in patients with scapholunate ligament (SLL) injuries (the SLL is a ligament between two carpal bones) [16]. However, other studies have used weight bearing wrist images for easier detection of scapholunate instability (SLI), and to detect biomechanical differences between healthy wrists and wrists suffering from carpal tunnel syndrome [17] [18]. For more weight bearing research to be conducted on the wrist, it would be valuable to have a device that could compressively load the wrist like devices that compressively

load the knee. Figure 5-6 below shows one example of how the knee has been loaded in studies [15].

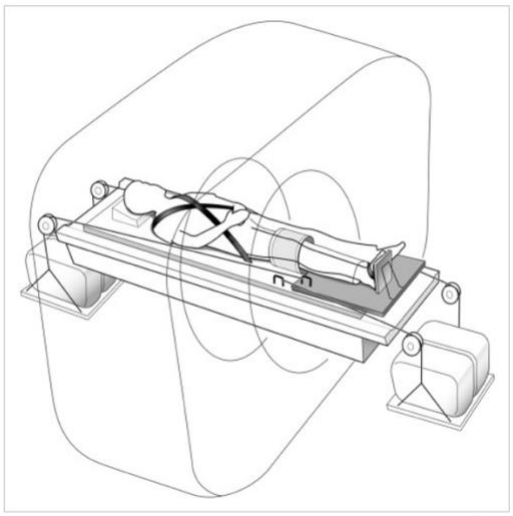

Figure 5-6 Weight-bearing knee MRI

5.3 PROBLEM SCOPE

Weight bearing MRI scans have provided valuable research into earlier detection of OA in the knee. To test for similar insights into the wrist joint, it is necessary to develop an MR compatible device that can compressively load the wrist. The device would have to restrict the wrist's range of motion to ensure consistency in imaging. Working within the constraints of MRI, the device must also consider material restrictions, size constraints, patient positioning, and the time MRI scans typically take.

5.4 OBJECTIVE

The objective of this project is to design an MR-compatible wrist loading device that can fit within a typical accessory coil. The device will be designed for the face down patient position and use a loading mechanism that is comfortable enough to withstand for 15 minutes. The device will have adjustable sizing mechanisms and be bilateral (i.e. usable on both wrists).

5.5 CHANGES SINCE ME481

Since ME481, the motivation, problem scope, and objective have not changed. The following requirements, constraints, and verifications, however, have. ME481 was completed in the fall of 2019. The ensuing global pandemic and stay at home orders required the team to make some

significant changes to the project in ME482. To indicate changes from ME481 to ME482, footnotes are used.

5.6 REQUIREMENTS

This section outlines the key criteria of the device. The functional requirements, non-functional requirements, and constraints are considered.

5.6.1 Functional Requirements

This section outlines the key functional requirements.

5.6.1.1 Limit Wrist Range of Motion

To develop consistency in wrist positioning between different patients, the three wrist movement couples (pronation/supination, extension/flexion, abduction/adduction) should have limited ranges of motion[1].

5.6.1.2 Bilateral Design

The device must be able to fit on left and right upper limbs. This will be a significant consideration during the CAD design.

5.6.1.3 Compressive Loading

Most weight bearing studies have not put importance into the exact weight being loaded. After discussion with a clinical researcher, it was understood that only a small load was required to cause biomechanical change [19]. Consequently, the goal is to load any wrist within a weight range of 2-5 lbs[2].

[1] The initial goal was to limit the range of motion for each motion couple to 10º, but this was considered too difficult to verify with only one volunteer (COVID19 stay-at-home orders limited number of volunteers). A sample size of one cannot give a meaningful result about a population. This requirement was reduced from quantitative to qualitative to get at least a rough understanding of wrist motion restriction.

[2] This value used to be 10-20 lbs based on estimates inferred from reading papers. From discussions with Dr. Emily Lalone, a clinical researcher at the Roth McFarlane Hand & Upper Limb Centre with expertise in upper limb medical imaging, it was clear that 10-20 lbs was unnecessary [19]. A small amount of compression (< 5 lbs) is enough to change the biomechanical structure of the wrist, so consequently the required loading was reduced.

5.6.2 Non-Functional Requirements

This section outlines the key non-functional requirements.

5.6.2.1 Variable Sizing

Being a medical device, it must fit most patients. The desired range is the 95-percentile male to the 5-percentile female[3]. This will be a significant consideration in the CAD design and will likely involve adjustable sizing mechanisms such as straps.

5.6.2.2 Comfort Level with Load

The patient should not feel serious discomfort when loaded in the device. This is important to consider over the length of the scan time which can vary around 15 minutes[4].

5.6.2.3 Aesthetic (Removed)

This specification was removed due to low importance and difficulty in verifying with stay-at-home orders[5].

5.6.2.4 Ease of Use

The device should take minimal time to set up to minimize the cost required with using an MR room. The device should take less than 120 seconds to set up and less than 120 seconds to take down.

5.6.2.5 Safe for Patients

Safety is a huge concern in any field, but especially within the medical field. The device should be free of allergenic materials and should not cause any unexpected skin reactions/abrasions. The device will also be designed for the avoidance of pinch points and sharp ends.

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[3] This value was 1st – 99th percentile in our ME481 report. Further research in ME482 revealed that 5-95 percentile sizing is more common in medical devices than 1-99 percentile, so the range was adjusted to match standard practices [31].

[4] The team originally planned to verify comfort with a statistically significant volunteer sample size, asking individuals to rate their comfort on a scale of 1-10. Different people will rate discomfort differently, so a large sample size would give the best representation of a population. With stay-at-home orders, however, a quantitative result from one tester is not very meaningful, so this was changed to a qualitative result. See 5.7 VERIFICATIONS for more details.

[5] Initially, an aesthetic design was important to make the product more attractive and make the experience for the patient more comfortable.

5.6.2.6 *Ease of Assembly (Removed)*

With the design more thoroughly developed, this requirement became irrelevant and was better absorbed into Ease of Use[6].

5.6.2.7 *Ease of Cleaning (Removed)*

Ease of Cleaning of the device is very important for the final design. However, stay at home orders forced difficulty in manufacturing options. The design is intended to be made of a polypropylene base with medical grade Velcro cuffs, but these were difficult to source so the prototype was made from a common construction wood and non-medical cuffs. While this requirement could be verified with the prototype, it would not be very valuable because the prototype materials are markedly different from the design materials[7].

5.6.3 Constraints

This section outlines the key constraints.

5.6.3.1 *Cost*

With an ME481/482 reimbursable budget of $375 for an additional member this term, the project should aim to be within this budget.

The additional member in 482 brought an additional budget of $75.

5.6.3.2 *Accessory Coil Size Constraint*

Past the upper forearm strap, the device should fit within the inner diameter of an accessory coil. The inner diameter used for design is 7 inches based on a ScanMed knee coil[8] [20].

[6] The initial requirement was to have an assembly time of 5 minutes or less to be technician friendly.

[7] Original requirement was to have a sanitation time of less than 60 seconds.

[8] The device was originally designed with a semi-flex elbow/wrist coil in mind [20]. However, the design in ME482 was found to be too big for a wrist coil, so a larger coil was selected.

5.6.3.3 Weight

The device is not meant to be fixed within the MRI and would need to be portable. This means that nurses and technicians should be able to lift the device in and out of the MRI with ease. Based on this, the max device weight is set to 15 kg.

5.6.3.4 Eco-Friendliness

The device will be made of at least 50% recyclable materials to reduce its carbon footprint.

5.6.3.5 MR Compatible

All materials used in the device must be non-ferromagnetic and considered MR compatible.

5.6.3.6 Medical Grade Materials

To be accepted in a clinical setting, the materials must be medical grade; that is, they comply with a medical grade standard such as ISO 10993-1 or USP Class VI [21].

5.7 VERIFICATIONS

In ME481 a full verification plan was developed for all requirements and constraints. Many of the verifications required testing on a statistically significant size of volunteers. As a compromise between confidence level and practicality, the sample size chosen was 41 volunteers.

Due to the stay-at-home orders of COVID-19 in ME482, testing on multiple volunteers was abandoned. Instead, the testing was done on only one team member. However, this was going to leave one team member with the major jobs of manufacturing the prototype and performing all the verifications. To lighten their workload, the team chose to focus on verifying the most critical specifications to create a smaller test suite. Non-critical specifications that could not be confidently verified by one test on one member were removed.

The full verification set can be found in the Engineering Design Specification (EDS) located in 14. The following subsections will highlight the critical verifications.

5.7.1 Limit Wrist Range of Motion

Ensure that wrist range of motion is limited for consistent positioning between scans[9]. Qualitatively assess limitations and report any extreme movements. This is a qualitative assessment due to the inability of testing more than one volunteer (COVID19 restrictions).

5.7.2 Bilateral Design

Ensure that the bilateral feature (removable puzzle piece) functions properly and allows both arms to use the device equally.

5.7.3 Compressive Loading

Ensure that the device can apply 2-5[10] lbs of compressive loading to the range of arm sizes specified. Create dummy limbs sized to the largest (95th percentile male) and smallest (5th percentile female) arms. Place each arm in the device and use a force gauge to measure the force applied to the arm with the band applied. Repeat the measurement 10 times for each arm to account for measurement variability and take the averages.

5.7.4 Variable Sizing

Ensure the device can fit wrist and arm sizes ranging from the 5th percentile female to the 95th percentile male[11]. Use the dummy limbs previously mentioned and check for proper fitment.

5.7.5 Comfort Level with Load

Ensure that users experience sufficient comfort when the device is worn, with and without compressive loading. Place device on volunteer unloaded for 15 minutes and loaded for 15 minutes and record any discomfort/pain. Verification satisfied if no pain is reported. This is only tested on one volunteer with a qualitative measurement due to the stay-at-home restrictions[12].

[9] Original ME481 plan: limit range of motion to within 10 degrees for each motion couple.

[10] Original ME481 plan: 10-20 lbs.

[11] Original ME481 plan: 1st to 99th percentiles.

[12] Original ME481 plan: 41 volunteers for statistical significance.

5.7.6 Ease of Use

Ensure that the device is easy to set up and take down. Verify this requirement by performing 10 trials each of set up and take down. Take the average time of each and check they are both less than is less than 2 minutes.

5.7.7 Safe for Patients

Ensure the device is safe for surface contact with patients. All materials must be hypoallergenic. Verify material selection with material analysis. Record and fix any pain/pinch points found in the prototype.

5.7.8 Accessory Coil Size Constraint

Device must fit within a 7-inch coil[13] with the largest arm size (95th percentile arm). Verify by making a dummy coil with accurate internal dimensions and check fitment with largest dummy arm.

5.7.9 MR Compatible

Ensure that the final device design is compatible with MRI machines. Verify with a material analysis.

5.7.10 Medical Grade Materials

Ensure all materials are medical grade and able to operate in a clinical environment. Verify with a material analysis.

5.8 ENGINEERING DESIGN SPECIFICATION

As mentioned before, the summarized specifications and verifications from ME481 and the updated EDS with changes added in ME482 can be found in 14.

5.9 ME481 DESIGN WORK

This section summarizes the critical design work performed in ME481.

[13] Original ME481 plan: 4" elbow/wrist coil.

5.9.1 Fundamental Mechanisms

The first aspect of design was selecting the best mechanisms for applying a load, securing the arm, and applying reactionary forces. To counteract the load pushing on the wrist and create compression, there would have to be an opposing force somewhere along the arm, shoulder, or body, so this was called the reactionary force. Multiple options were considered for each mechanism and eventually a morphology chart was used to select the final design combination of a resistance band for applying the force, Velcro cuffs for securing the arm, and reactionary force applied at the elbow.

5.9.2 CAD

Next, the design was iterated using CAD as potential issues were considered and addressed. The design environment can be seen in Figure 5-7 which was used to design how the component should fit. The MR bore, bed, and human CAD model were files taken from GrabCAD and used for reference to design the MR compatible loading device [22] [23]. The wrist coil was created as a simple model using key specifications from the Semi-Flex Elbow/Wrist Coil by ScanMed [20].

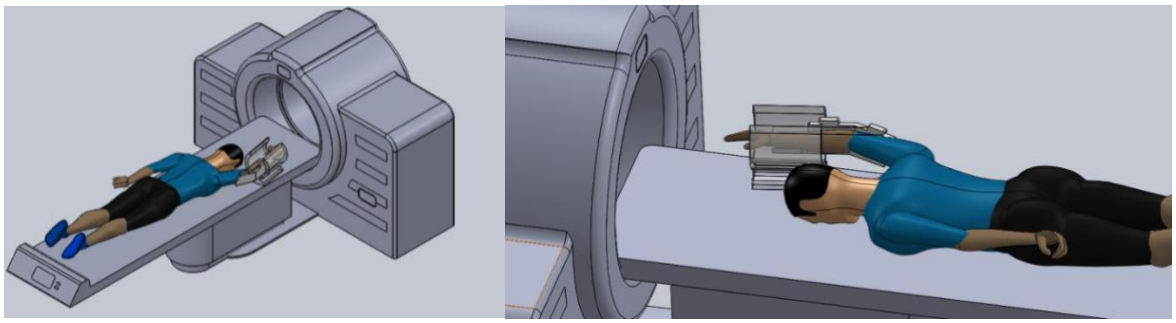


Figure 5-7 CAD model of design in MRI setting (left: top view, right: side view)

Figure 5-8 shows the CAD design, with labels. The configuration shown in the figure is for the right upper extremity.

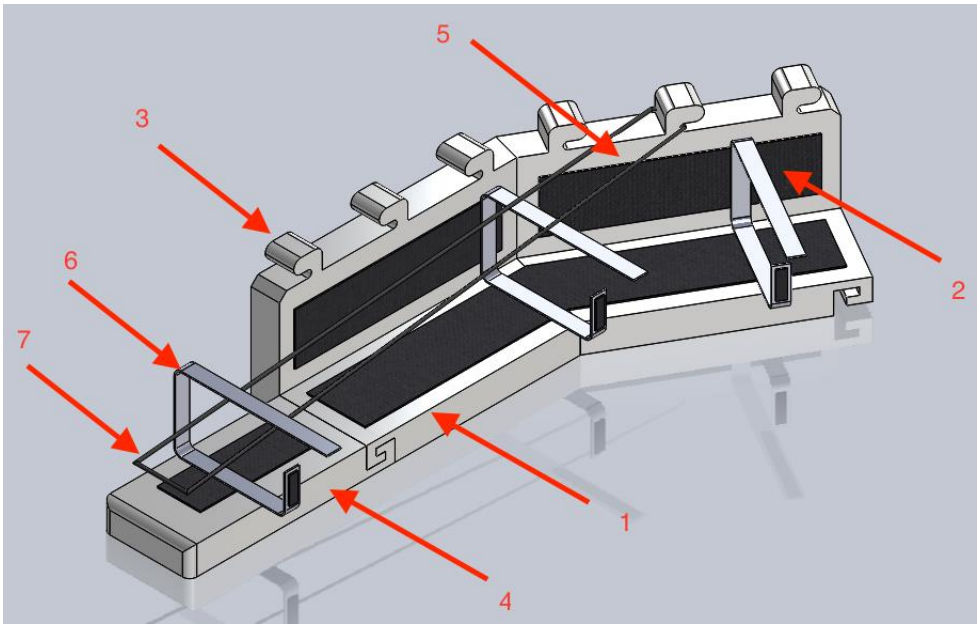


Figure 5-8 Final CAD design from ME 481

The purpose of each piece is as follows:

1. **Base Platform:** enables the patient to rest their forearm and bicep on the device.
2. **Support Walls:** provides a location for hooks that does not interfere with the arm and provides a bend where the elbow rests. The bend will prevent the elbow from translating in response to the band force, thereby providing the reactionary force.
3. **J-Hooks (6):** attachment points for the band. Multiple hooks to allow for variation in force applied.
4. **Removable Puzzle Piece:** accommodates different arm sizes while allowing bilaterality. Between the 1st percentile female and 99th percentile male, there is significant variation in forearm and upper arm length. If the base platform was sized to fit the 99th percentile male, the platform would dig into the underarm of the 1st percentile female and cause discomfort. By using a removable piece that can add length only to the forearm side, the device can fit both the largest and smallest arm without causing discomfort. The piece is designed with a slide-puzzle fit for easy attachment/removal. To accommodate both left and right arms, the puzzle fit is added to both sides of the base platform so the piece can be flipped around and used in the same manner.
5. **Velcro:** provide attachment points for straps. Shown as black rectangles all along device. Adhesively attached.
6. **Straps**: secure the arm to the device. The straps have a Velcro exterior and are adjustable in size.

7. **Resistance Band:** The resistance band will attach to the device by hooking through the J-hook. The other end will loop around the palm of the patient's hand, resting above the thumb.

5.9.3 Component Sizing

As stated previously, the device is intended to fit the range of arm sizes from 1st percentile female to 99th percentile male. Anatomical data for component sizing was collected and used to size the design. Figure 5-9. An example of anatomical sizing data is shown below in Figure 5-9.

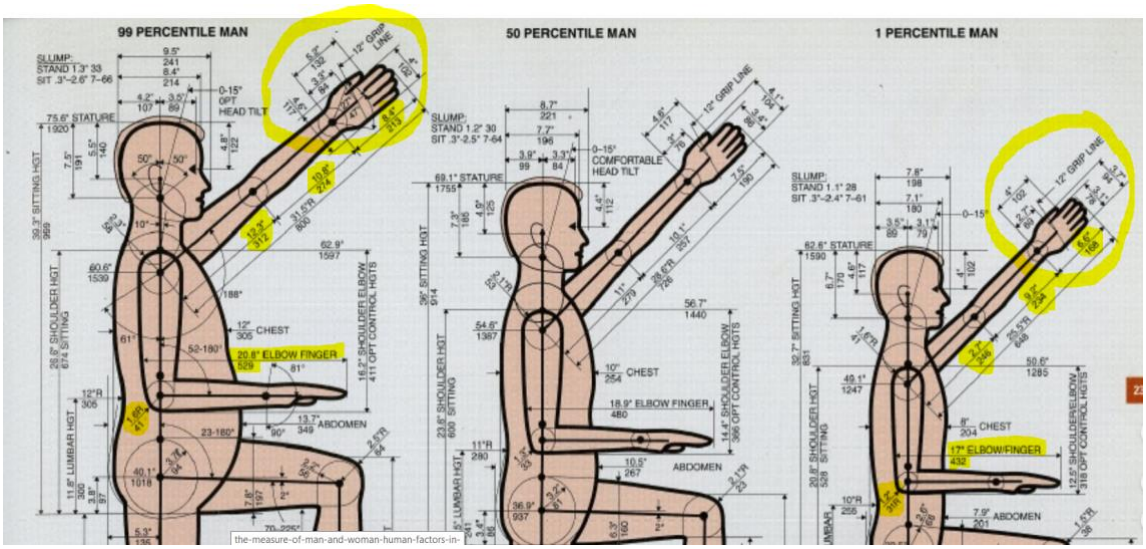


Figure 5-9 Anatomical sizing diagram for 99, 50, and 1st percentile from left to right

5.9.4 Additional Work

Additional design performed in ME481 included:

- A rudimentary force analysis to illustrate the forces applied on the wrist
- Selected suitable materials for all components of the design. All materials are hypoallergenic, MR compatible, and medical grade. Most notably, the base member and puzzle piece were to be made of polypropylene, a common plastic used in MR environments [24].
- A plan for manufacturing in ME482 centered around 3D printing

5.10 ME481 PROJECT MANAGEMENT

Project management in ME481 included creating a project timeline, cost estimate, work breakdown structure, and a risk register. While these will be discussed more thoroughly at the end of the report, it is useful to mention the set of goals that were laid out for ME482:

1) **Order the materials.** With the BoM complete, this should be a simple task.
2) **Manufacture the initial prototype.** The initial prototype will be manufactured from low-cost polyethylene (PE) 3D print plastic. Iterating this prototype to meet all verifications will be the most time-consuming task of ME482.
3) **Produce final prototype**. Once the PE prototype passes all verifications, the final prototype will be made from the intended design material of polypropylene (PP). The final prototype will undergo all the engineering design specifications again. Should it pass all the specifications, it will mark the completion of the project. If not, the team will return to iteratively improving the prototype until a final revision can pass all the verification tests.

While this set of goals was mostly followed, there was additional work done in ME482 including some redesign of the device. The next sections will discuss the work carried out in ME482.

6 DESIGN WORK

ME482 started off with the addition of a new team member: Catherine Tsang. Catherine brought valuable project management skills to the group and prototyping assistance. While the original plan was to only manufacture, prototype and project manage, bringing on an additional member allowed the team to first revisit the design. Seeing the design with fresh eyes after a year-long gap gave revealed areas of improvement that required attention before starting manufacturing.

6.1 COMPONENT SIZING

In ME481, the team intended the design to fit into an elbow/wrist coil. This was achieved from preliminary research for approximate coil dimensions. In ME482, following a scope change prompting further development of the design (due to COVID19, addition of new group member), the team reached out to a coil manufacturer, ScanMed to build an accurate CAD model of the coil and assess fitment prior to physical build. The creation of an applicable CAD model of the elbow/wrist coil showed clear indication that the existing design from ME481 would not fit within an elbow/wrist coil (4” ID) from ScanMed [25].

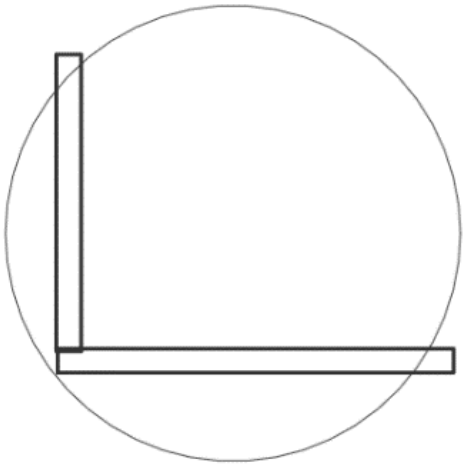


Figure 6-1 Rough depiction of fitment issue

The team reached out to ScanMed, asking for larger coil models, to which ScanMed provided drawings of a knee coil (7” ID) with dimensions that are ideal for the device [**Error! Reference source not found.**].

The change of accessory coil type is justified because all accessory coils improve image resolution, regardless of the limb for which they are sized for. The 7” ID knee coil is capable of providing superior scan quality, just as the elbow/wrist coil is, and therefore does not affect the use of the device within the knee coil for scanning.

The fitment of the 7” ID knee coil had no interference within the CAD assembly, and the fit was further verified with the physical prototype and a physical accessory coil mock-up.

6.2 PUZZLE JOINT

The puzzle joint connects the removable piece to the base structure.

6.2.1 ME481 Initial Design

In ME481, joining the base and the puzzle piece together was achieved with a pin joint (Figure 6-2).

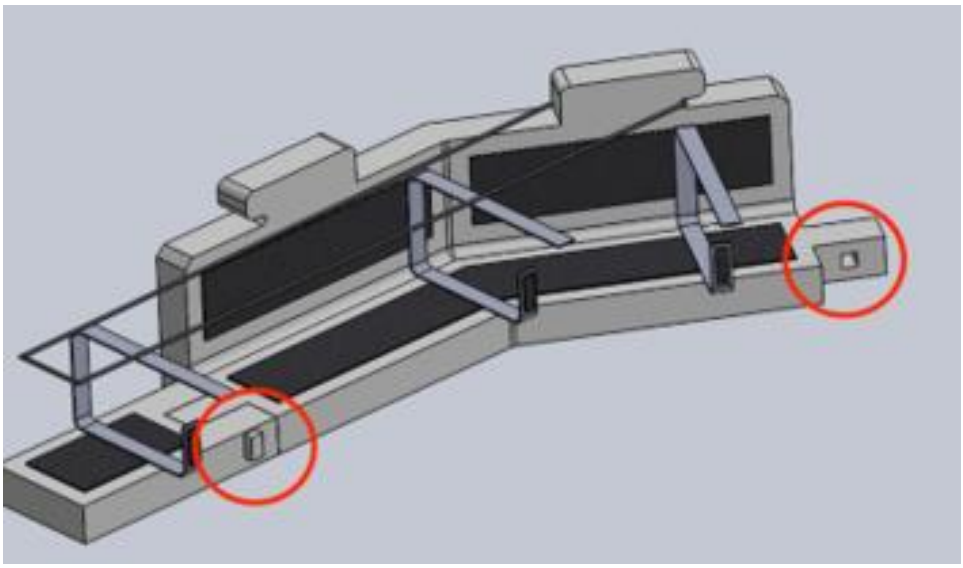


Figure 6-2 Emphasis on pin joints connecting puzzle and base components

The team received feedback from the Final Design Presentation in ME481 with suggestions to eliminate the pin, as it has the potential to cause catastrophic damage to the MRI machine and economic loss if lost in an irretrievable place.

6.2.2 Design Iteration 1

The joint was redesigned to be a slight interference fit, where the puzzle piece would slide into the base member and stop at contact with the guard wall.

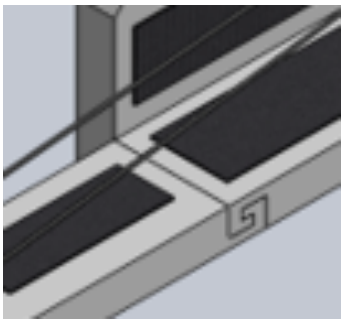


Figure 6-3 Puzzle Joint: Design Iteration 1

After reviewing this design, the team noted significant flaws:

- Thin material would fracture easily under stress
- Precise tolerancing requirements would be too expensive and difficult
- Difficult to produce perfect level of friction to:
    - a) prevent piece slipping out
    - b) avoid too much surface area friction to overcome

- Difficult to manufacture (tough to incorporate appropriate draft angle)

6.2.3 Final Design

The final design of the joint is pictured in Figure 6-4.

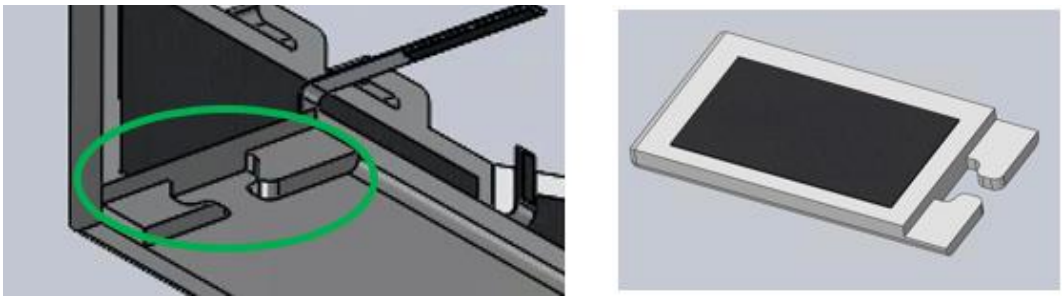


Figure 6-4 Final Puzzle Joint Design

The joint was redesigned to address the following issues:

- Less thin sections where stress concentrations would develop
- Can accompany a wider range of tolerances
- Easier to manufacture

Connecting the two pieces together would be done in the direction of gravity. Slippage is prevented by gravity and the weight of the user's wrist laying on top. This is verified with the physical prototype.

6.3 J HOOKS

The J-Hooks allow attachment of the resistance band to the device and connects to the palm of the wearer's hand.

6.3.1 ME481 Design

The original design was for a fixed location of the J-Hook, to have one hook per side wall for a total of two on the device (Figure 6-2). The team received feedback from ME481 suggesting increased control in force variation.

6.3.2 Design Iteration 1

The side walls were modified to have 3 J-Hooks per wall (Figure 6-5).

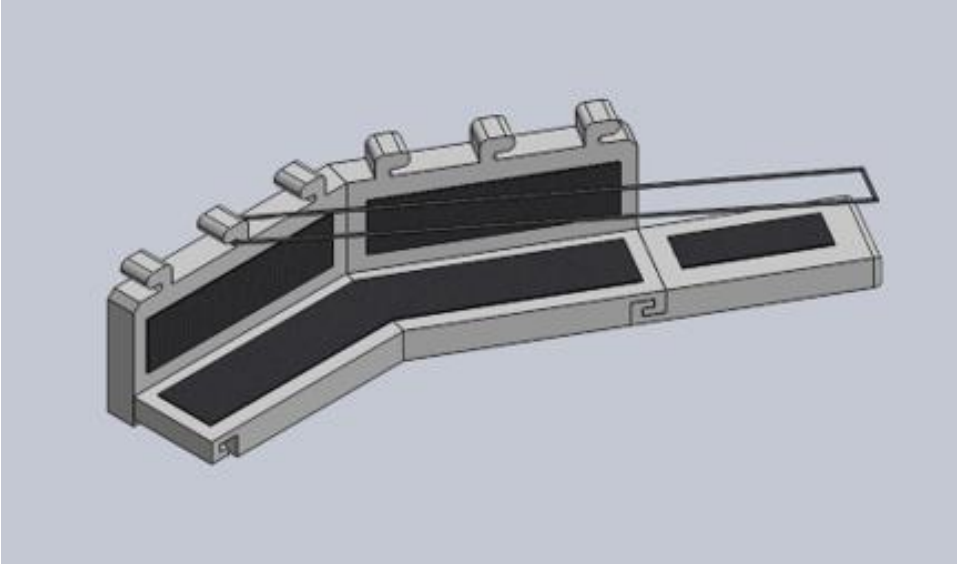


Figure 6-5 J-Hooks: Design Iteration 1

This proved to be an issue during the verification stage with the physical prototype because the outermost hook would interfere with the accessory coil, preventing small arms from being within the coil (5th percentile female arm in the device has the wrist located approximately underneath the outermost hook).

6.3.3 Final Design

The device was only required to fit slightly into the coil, enough for the center of the coil to align with the intended imaged wrist portion. The removal of an end hook at each side wall resolved the interference issue. The final design is shown in Figure 6-6.

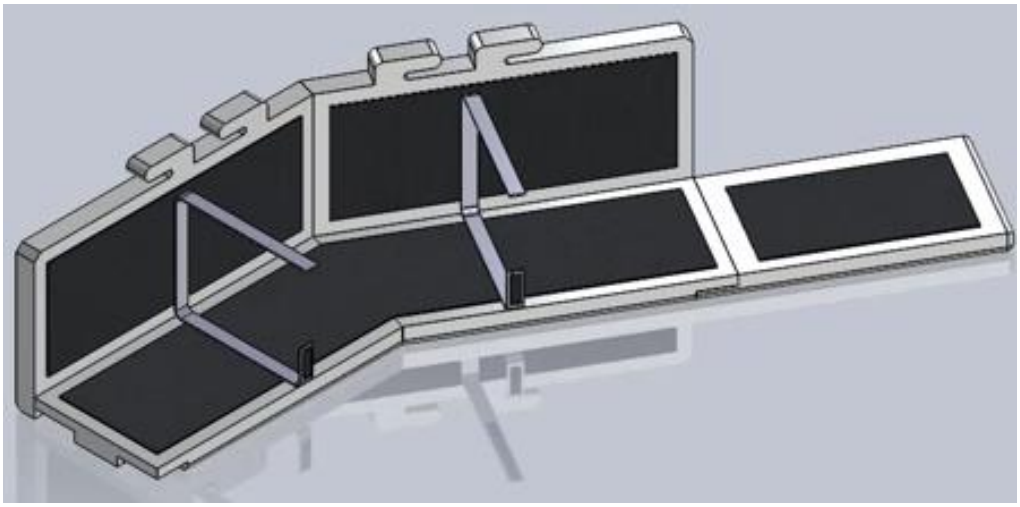


Figure 6-6 J-Hook: Final Design

6.4 FORCE ANALYSIS

The original force analysis done in ME481 was rudimentary. It was less of an analysis and more an illustration, shown below in figure Figure 6-7.

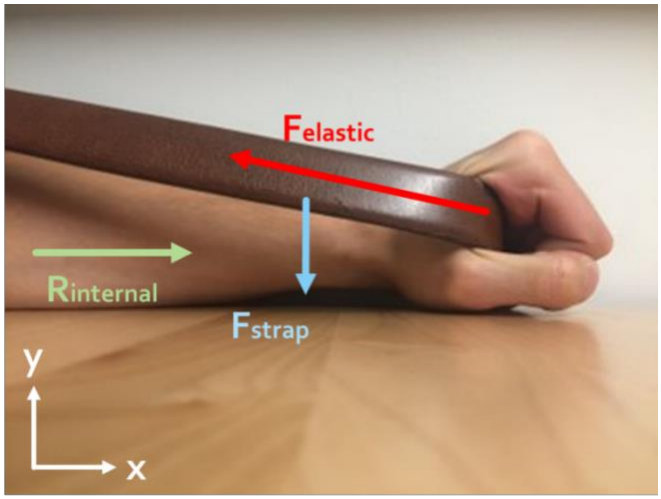


Figure 6-7 Free-body diagram of resistance band on wrist

While the illustration gave a rough idea of force vectors, it could not determine if the design could solve with the given constraints. It was important to do a thorough analysis to validate that the design geometry could satisfy the requirements of:

- No coil interference
- Apply 2-5 lbs of compressive load to the full range of arm sizes (5^{th} percentile female – 95^{th} percentile male)
- Not apply excessive torque to the wrist to cause discomfort (this had not been considered in ME481)

To set up the design space, consider Figure 6-8 below of an arm in the device.

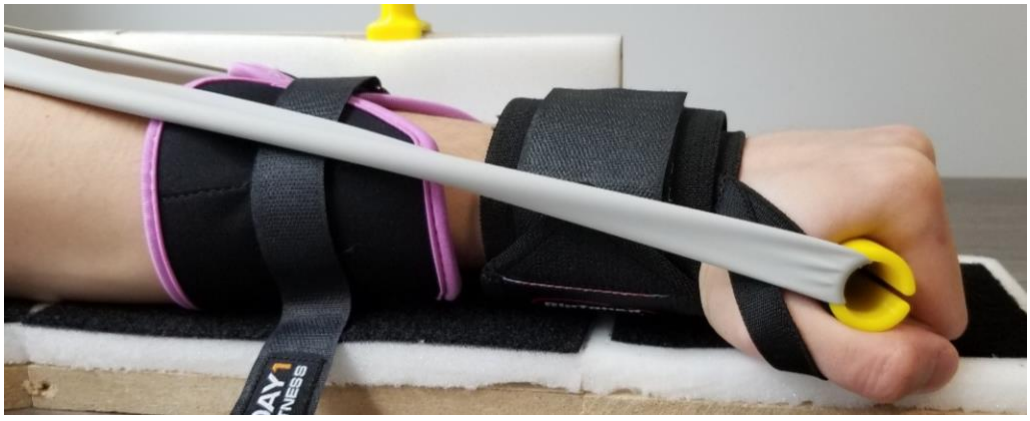


Figure 6-8 Free-body diagram of device loaded on arm

The arm is attached to the device by two straps: one on the forearm and one on the wrist. The resistance band is connected to the rear of the device on a J-hook and loops around the patient's palm through a handle. Now, important geometry and lines of actions are overlaid onto the above figure in Figure 6-9.

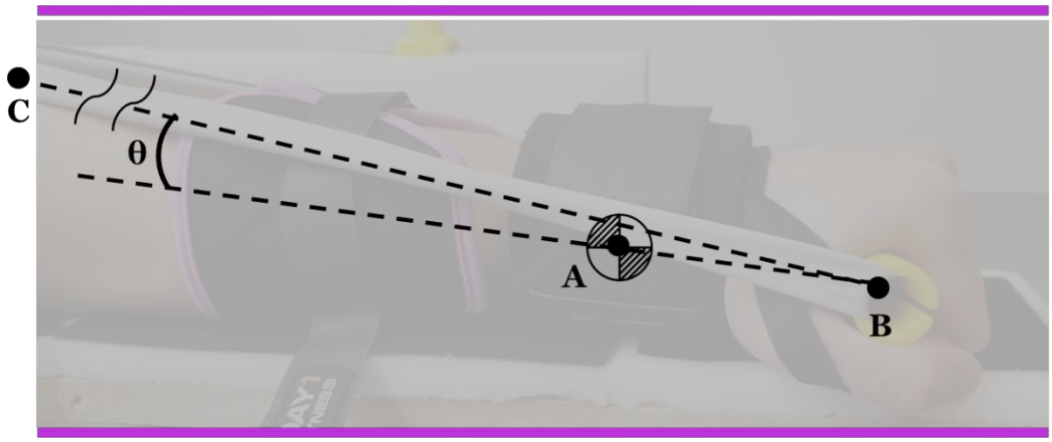


Figure 6-9 Free-body diagram with geometry and lines of actions

Point A is the center of the wrist, B is the center of grip, and C is the J-hook where the band attaches to. There is one line of action for the band, and one line of action for the arm. The angle between these two is labeled θ. Additionally, the purple lines indicate the cross section of the accessory coil. To avoid interference, no objects can cross these lines. Now, Figure 6-10 overlays external forces on the arm.

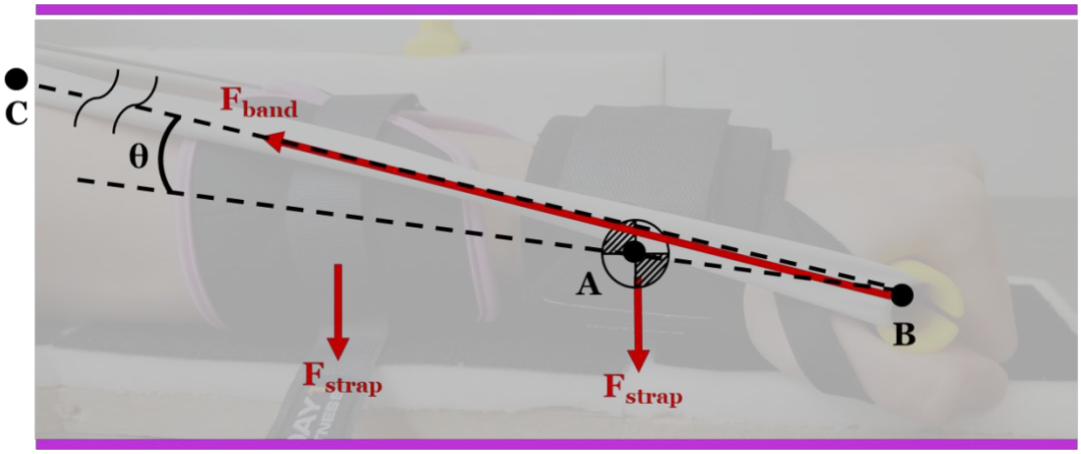


Figure 6-10 Free-body diagram with geometry, lines of actions, and external forces

The arm is subjected to downward strap forces that resist the upward component of the band force, F_{band}. It should be noted that the weight of the arm and the normal force of the device base

are not displayed because they are not significant to the analysis. Next, internal reactionary forces are added in Figure 6-11.

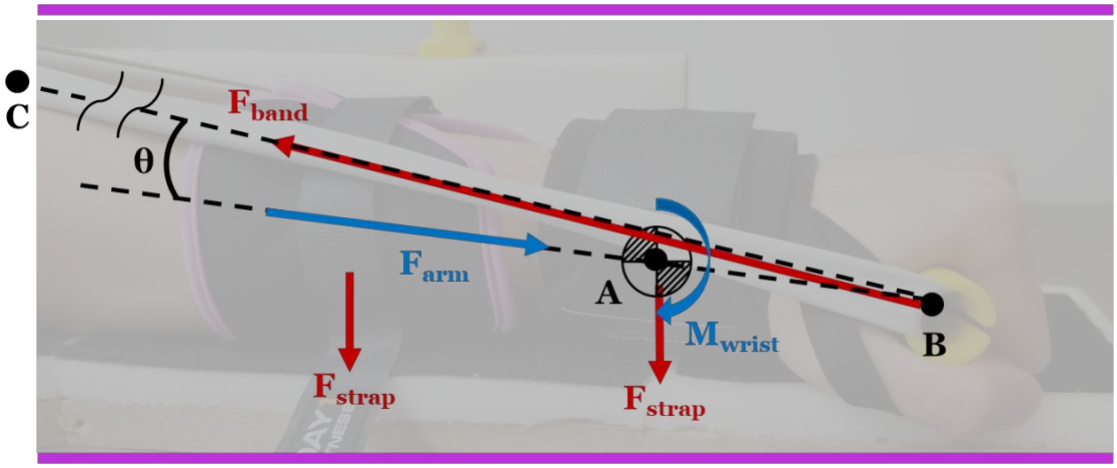


Figure 6-11 Free-body diagram with geometry, lines of actions, external forces, and internal reactionary forces

To resist the horizontal component of F_{band}, the arm will react with an opposing F_{arm} force originating at the point where the elbow contacts the device. There will also be a reactionary moment induced at the patient's wrist to resist the torque induced by the vertical component of F_{band} about the wrist (center of rotation). With forces laid out, constraint values are now determined.

6.4.1.1 Constraint on θ

θ must be large enough to avoid interference with the arm and small enough to avoid interference with the coil. By taking measurements of the 95th percentile male arm and the dimensions of the ScanMed coil, the range of permissible values was found to be $10° < \theta < 30°$.

6.4.1.2 Constraint on F_{arm}

As stated in the requirements, the objective is to have a compressive wrist loading between 2-5 lbs. This translates directly to the constraint 2 lbs < F_{arm} < 5 lbs.

6.4.1.3 Constraint on M_{wrist}

The patient-induced torque must remain low to avoid discomfort. Research found that on average a healthy adult (age 15 – 59) could resist 8 Nm of wrist torque before feeling discomfort [26]. The device-induced torque should remain far below this so a factor of safety of 4 is applied to develop the constraint that M_{wrist} < 2 Nm.

6.4.1.4 Constraint on Arm Size

Not only must the device satisfy all the previous constraints, but it must do so for the full range of arm sizes from 5th percentile female to 95th percentile male. Geometrically, this will change the green values in Figure 6-12: the angle θ and the distance between the center of wrist and center of forearm.

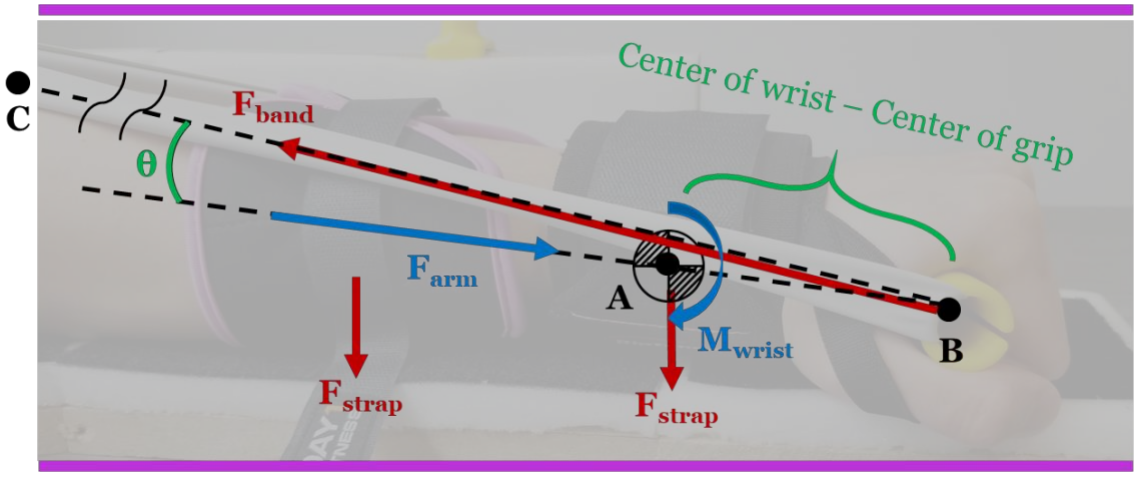


Figure 6-12 Description of FBD

Having laid out the forces and constraints, the next step was to develop systems of equations to relate variables together. Taking the line of action of the arm to be the X axis, equilibrium equations were written for X, Y, and moments about the center of wrist. The two important equations developed are shown below.

$$2F_{band}cos\theta = F_{arm} \quad (1)$$

$$2F_{band}sin\theta\overline{AB} = M_{wrist} \quad (2)$$

Where $\overline{AB}$ is the distance between A and B. In the two equations above, F_{band} is the only variable that is not fixed or constrained in range. With more unknowns (free and range-constrained values) than equations, there exist many solutions that can be visualized using a contour plot. A plot was created for both the 5th percentile female and 95th percentile male, shown in Figure 6-13.

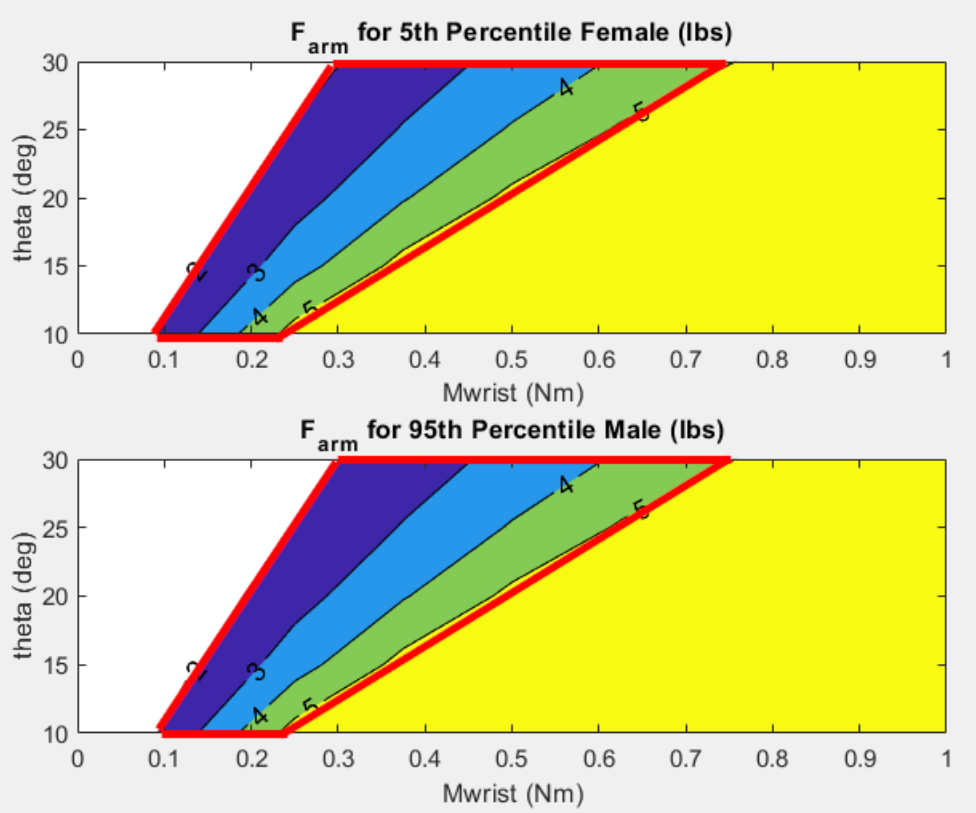


Figure 6-13 Contour plot for F_{arm}, M_{wrist}, and θ constraints for 5th percentile female and 95th percentile male

The isolines show different values for F_{arm}, ranging from 2-5 lbs. The solution space is therefore the coloured region highlighted in red (note that the solution space does not noticeably change between the male and female plots because the difference in $\overline{AB}$ has little impact). Every point within the red highlight satisfies the F_{arm}, M_{wrist}, and θ constraints. The one variable not shown is F_{band} which is free. Each point within the solution space has an associated F_{band} value, so if a resistance band can be found to provide that force, the point is possible to design. This is easy to do because F_{band} is directly proportional to the band stiffness which is widely variable in commercial bands.

Therefore, it can be concluded that yes, there exist solutions for both the 5th percentile female and 95th percentile male. So long as the point C (J-hook position) is selected such that 10° < θ < 30° for both the largest and smallest arm sizes, a resistance band can be found to satisfy the F_{arm} and M_{wrist} constraints.

With force analysis complete, design work is done. Now the device could be manufactured.

7 MANUFACTURING

The original ME481 plan focused on 3D printing the stiff components of the design: the base platform, supporting walls, and puzzle piece. While the manufacturing team member did have a personal 3D printer, it was not big enough to print the flat components as one piece. Another team member mentioned they had a free source of medium density fiberboard (MDF) at home and the means to cut it to the basic component shapes. After weighing the pros and cons of using 3D print plastics vs MDF, MDF was selected because of the free sourcing and easier workability for iterative prototyping.

Another change from the ME481 plan was to only make one prototype instead of an initial one and final one. Working with MDF, it would be easy to make one prototype and improve it until it satisfied all requirements, eliminating the need to make a second one.

7.1 CONSTRUCTION

First, the MDF was sourced and cut to basic shape. Figure 7-1 below shows the stiff member boards glued together and the puzzle piece.

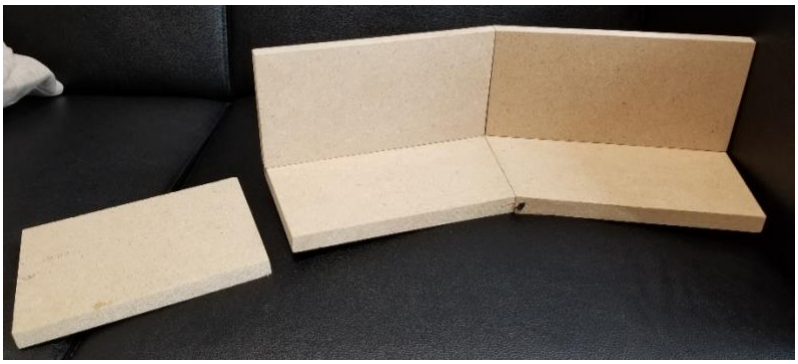


Figure 7-1 MDF cut into basic shape for stuff member construction

Next, the puzzle piece joints were machined on the CNC router on campus with the help of Brian Shuh. This required making technical drawings for the parts that can be found in 14.

With the stiff member complete, cushioning foam was added to the surfaces of the device in contact with the patient to improve comfort. Velcro pads and straps were subsequently added to fix the arm onto the device. Lastly, J hooks and a handle for the resistance band were 3D printed

and added on to complete the prototype. The positioning and quantity of these materials were adjusted over iterations.

7.2 FINAL PROTOTYPE

Figure 7-2 below shows all the components of the final prototype labeled.

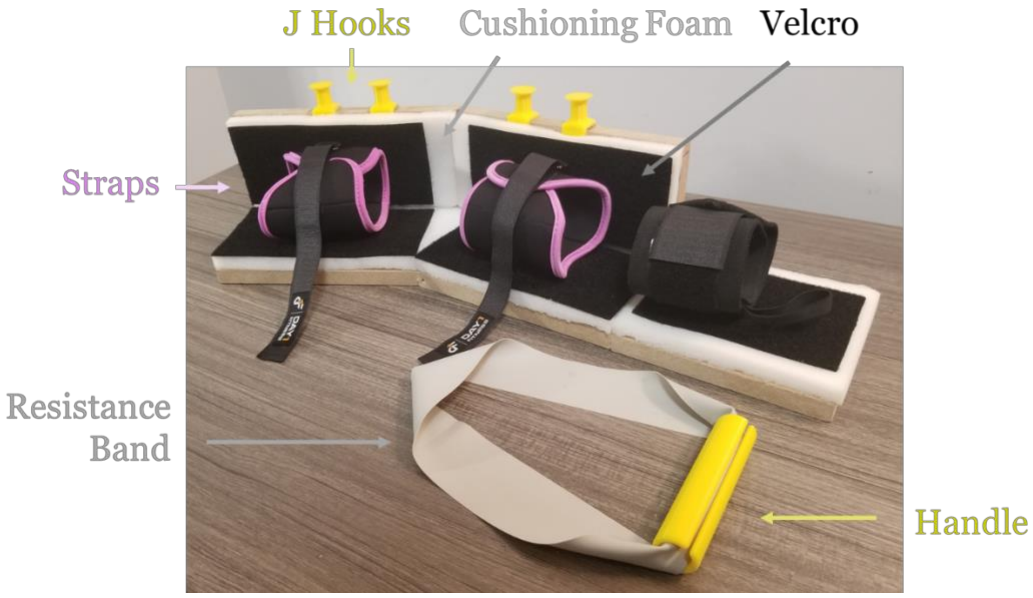


Figure 7-2 Final prototype with components labelled

With the prototype complete, the next important step was to verify the design satisfies the requirements.

8 VERIFICATIONS

The next section will describe the verification approach and result for each requirement. Recall that various tests were modified to work for testing only one volunteer instead of a group.

8.1 LIMIT WRIST RANGE OF MOTION

Requirement: Limit wrist range of motion.

Approach: Qualitative assessment. Load arm in device and record how arm movement feels.

Result: See Figure 8-1 for an image of the arm loaded in the device. With the straps tightened appropriately, there was heavy resistance to pronation, supination, flexion, and extension. Abduction and adduction had the least resistance, likely because the commercial fitness strap used for the wrist strap was not designed to prevent that motion. This qualitative result was useful

for a general confirmation of function, but certainly requires more rigorous quantitative testing in the future.

Figure 8-1 Arm loaded into device

8.2 BILATERAL DESIGN

Requirement: Both arms can use device.

Approach: Check that device fits both arms well.

Result: As the device was designed with symmetry in mind, it functioned equally for both arms. See Figure 8-2 for a visual.

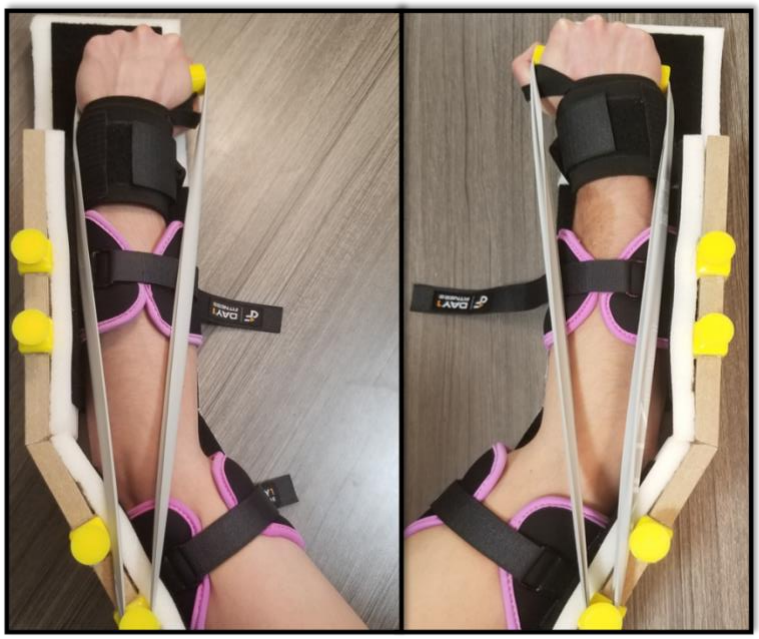


Figure 8-2 Left (top) and right (bottom) arms loaded into device

8.3 COMPRESSIVE LOADING

Requirement: Device applies 2-5 lbs of loading to range of arm sizes.

Approach: Create dummy limbs sized to the largest (95th percentile male) and smallest (5th percentile female) arms. Place each arm in the device and use a force gauge to measure the force applied to the arm with the band applied. Repeat the measurement 10 times for each arm to account for measurement variability and take the averages.

Result: On average, 3.3 lbs were applied to the smallest arm and 4.5 lbs to the largest. These both fall within the desired range. See Figure 8-3 for a demonstration of how the force was measured.

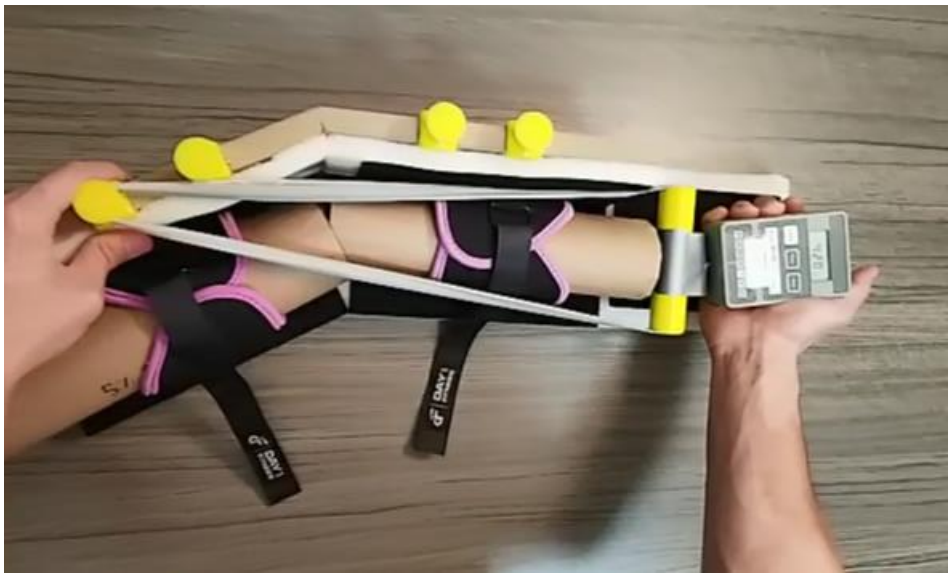


Figure 8-3 Resistance band tested with force gauge for the 5% female dummy limb

8.4 VARIABILITY IN SIZING

Requirement: Device can fit range of arm sizes from 5th percentile female (smallest) to 95th percentile male (largest).

Approach: Use the dummy limbs previously mentioned and check for proper fitment.

Result: Both dummy limbs fit well within the device, satisfying the requirement. See Figure 8-4 for a visual confirmation.

Figure 8-4 Dummy limbs for 95% male (top) and 5% female strapped onto device

8.5 COMFORT LEVEL WITH LOAD

Requirement: Device is comfortable for at least 15 minutes for both loaded and unloaded cases.
Approach: Place device on volunteer unloaded (no resistance band) for 15 minutes and loaded for 15 minutes and record any discomfort/pain. Verification satisfied if no pain is reported.
Result: In both cases, no pain was recorded. The only discomfort noted was the arm falling asleep in both tests. Because it happened in the unloaded case, this can be attributed to the position, not the compressive load. However, this was not enough discomfort to warrant concern. See Figure 8-5 for a visual of the loaded test.

Figure 8-5 Tester lying in prone position with arm loaded into device

8.6 EASE OF USE

Requirement: Device set up and take down both take less than 2 minutes.

Approach: Perform 10 set ups and 10 take downs. Take the averages and check if they are below 2 minutes.

Result: The set up and takedown was done by an external volunteer trained by the prototyping team member (who was the mock patient). The average results in mm:ss format were 1:45 for set up and 00:45 for take down. This successfully satisfies the criteria.

8.7 SAFE FOR PATIENTS

Requirement: Device is safe for surface contact with patients.

Approach: Select all materials to be hypoallergenic. Record and fix any pain/pinch points found in the prototype.

Result: Materials were selected in Granta EduPack 2019 with the hypoallergenic attribute required [21]. In the prototype testing, no pain or pinch points were found.

8.8 ACCESSORY COIL SIZE CONSTRAINT

Requirement: Device must fit within a 7-inch coil with the largest arm size (95th percentile arm).

Approach: Make a dummy coil with accurate internal dimensions and check fitment with largest dummy arm.

Result: With the largest arm, the device fit within the accessory coil as intended. See Figure 8-6 below for a visual validation.

Figure 8-6 Dummy limb for 95% male placed into mock accessory coil

8.9 MR COMPATIBLE

Requirement: Device is MR compatible.

Approach: Select all materials to be MR compatible.

Result: Materials were selected in Granta EduPack 2019 with the MR compatible attribute required [21].

8.10 MEDICAL GRADE MATERIALS

Requirement: Device is made of medical grade materials.

Approach: Select all materials to be medical grade.

Result: Materials were selected in Granta EduPack 2019 with the medical grade USP Class VI attribute required [21].

9 SAFETY, SUSTAINABILITY, AND REGULATION

9.1 SAFETY

Safety has been a critical consideration since the very beginning of this project. First, all the materials in direct contact with the patient: wrist straps, resistance bands, handle, foam padding, and stiff members are hypoallergenic. In addition, the pieces in contact with the patient were designed to avoid pinch points and sharp edges that would harm the person or the technician. Lastly, the patient's comfort was a criterion considered since ME481 with a corresponding verification.

9.2 SUSTAINABILITY

Beyond safety, the team considered sustainability throughout the early design and prototyping stages of the project. A majority of the final materials selected were 100% recyclable: the stiff members and handle were made from recyclable polypropylene summarized per component in the Bill of Materials found in the 1.1.1.1A-1. The remaining materials used were 65% recyclable by weight for the Velcro adhesives and 0% for the resistance bands [27]. In ME482, the prototyping material was changed from recyclable polypropene to biodegradable MDF made from recycled sawdust. Furthermore, the prototype J-hooks and handles were made from PLA which is a recyclable thermoplastic. Lastly, the prototype was assembled using simple adhesives to allow proper separation of all the materials to either be reused or recycled.

9.3 REGULATION

To be accepted in a clinical setting, the materials were made to be medical grade; that is, they must comply with a medical grade standard such as ISO 10993-1 or the USP class system. The materials chosen for the final design were verified to be compliant with regulations. Polypropylene sourced from Professional Plastics is both FDA approved and USP Class VI certified [28]. Furthermore, the plastics chosen were sterilizable using steam autoclaving and can be sourced from manufacturers that work with ISO 9001 suppliers to ensure high purity and traceable materials. Furthermore, the latex-free elastomers are sourced from Kent Elastomers who manufacture in compliance with all standard sanitary and safety standards also meeting the biocompatibility standards [29].

If the device was brought to commercialization, it was determined to be accepted as a class II. This was determined by reviewing the 501K and classification of a similar spinal compression device used in CT and MR diagnostic imaging for research and clinical purposes [30].

10 PROJECT MANAGEMENT

10.1 PROJECT SCHEDULE

This section details the project schedule, time budgeted, changes to the schedule, financial budget, risks encountered, and finally what went well and what did not.

10.1.1 Project Objective and Deliverables

The objective of this project was to design and create a prototype of an MR compatible wrist loading device. The prototype was used for verifying the requirements determined for the solution. In the process, the ME481/482 course had term-long deliverables shown in the Gantt chart D-2 below. Also, meetings with the faculty advisor were done on a weekly basis to provide guidance on the project. Each deliverable in the course was completed on time and the feedback from the instructors were applied to the following deliverable. until the last presentation of the course, the capstone symposium.

10.1.2 Changes to Project Schedule

ME481 took place in the last quarter of 2019. For ME482, the original 2-person team took a one-year break and returned in January 2021 with the addition of a new member, Catherine. Consequently, changes were made to the project scope to increase the design and prototyping stages by an extra week into mid-February 2021 for design and early mid-March for prototyping. With an additional member, the team was able to budget more time for the two stages above as the time budgeted for the deliverables were now divided up into three parts instead of two.

In addition, COVID-19 resulted in many changes to the initial plans made in 2019. All the members were in different cities; Kelly living in a city 3 hours behind the other two. This time difference caused some confusion at first when it came to working around each other's schedules but setting up meetings became much easier with the entire team adding their personal calendars to Outlook Calendar, such that all members are aware of free slots of times to schedule meetings.

The COVID-19 provincial guidelines made in-person meet-ups challenging, so the team communicated entirely online using Microsoft Teams for video calls between the three members and with our advisor. Thursday nights 8 P.M. EST for 30 minutes was chosen as the weekly meeting time slot with our advisor. The team met at least 30 minutes before hand and after to prepare and debrief from these meetings. In addition to those, the team scheduled meetings by working backwards from deadlines and finding free time in each other's calendars to meet as needed.

COVID-19 created a huge risk for the volunteer-dependent verification tests that were previously planned at the end of 2019. Due to the provincial laws, the team opted to scale down the number of tests and volunteers and focused only on the most important ones.

10.1.3 Work Breakdown Structure

With the addition of Catherine in ME482, changes were made to the work breakdown structure as the scope was increased. The updated work breakdown structures can be found in Appendix D, but key details of the table are shown in this section.

More time was budgeted for designing and prototyping. Based on the resources available to each member, Catherine was able to take on the initial manufacturing work and run through both iterations as design issues were revealed in prototyping before shipping off the pieces to Michael. Since he had access to the machine shop and a 3D printer, his role was to assemble the pieces. These changes were made to accommodate Kelly's distance from prototyping equipment and the rest of the two members.

Table 10-1 Work breakdown structure

LEVEL 3	Description	Estimated Hours	Actual Hours
3.3	Test prototype	10	18
3.4	Iterative manufacturing prototyping stage	15	25

Comparing the initial time budgeted for the entire capstone project: 350 hours, the team exceeded this time by spending 403 hours in total. The prototyping stages were underestimated by 8-10 hours due to the manufacturing and verification plan changing significantly. The reason for the

increased time expended on item 3.3 is due to increasing the scope of the prototyping by mocking up the MRI setup and creating dummy limbs for verification which was suggested by the instructors during the IDR.

In addition, the original manufacturing plan budgeted for a single prototyping stage, but upon cutting out the MDF and assembling it, the CAD was found to have a sizing error. This led to an additional iteration, thus increasing the time expended in prototyping. Also, without all the members in the same city, the second unexpected iteration required more time to complete due to coordination issues. One member would manufacture, test, take videos to show the rest of the members virtually, and if any issues were found, the coordination of revising the design and preparing the next iteration was handled by a single member.

However, the biggest delta from estimated hour and actual was the meeting time allocated increasing by 20 hours. This was greatly increased due to the increased distractions virtual meetings: socialization, interruptions, technical difficulties. On average, 30 minutes was spent on these distractions compared to in-person meetings.

10.2 PROJECT COST

A comprehensive project cost can be found in the Appendix D. The total budget increased by $75 with the addition of another member increasing the total budget to $375. The total expenses incurred throughout the project was $223.79, leaving $151.21 remaining. Compared to the initial estimate of $268, the cost decreased by $45 due to the material change for the iterative prototyping stage from polypropylene to MDF. This significantly brought down the material and manufacturing services cost of using a 3D printer. Furthermore, the MDF was supplied and cut as a kind-in part of the budget, free of monetary costs to our budget.

10.3 RISK MANAGEMENT

This section provides the key risks encountered in both ME481/482. The entire risk register can be found in Appendix D.

10.3.1 Effectiveness of Risk Management Strategy

The risk management strategy was useful in mitigating the effects of obstacles encountered. A few risks were encountered through the fall 2019 term, all of which were appropriately managed

through following the steps set out in the risk register. This helped us to continue as planned in a reasonably timely manner.

10.3.2 Risks Encountered in 481

Risk Description: Find new information that forces a change in scope (i.e. original scope too difficult)
Risk Mitigation Plan: Keep faculty advisor in loop on a regular basis to ensure that project does not stray too far from what is expected in a 481/482 course.
Category: Technical Risk, Medium Probability, High Impact

Actions were undertaken to immediately contact the faculty advisor on necessary next steps to ensure that the team stays on course for what is expected in ME481. Both team members had to put in extra time to catch up to the project schedule with the change in scope. No time was wasted as an adequate mitigation plan had been put in place in the event of the risk occurrence.

Risk Description: Conflict in team member schedules.
Risk Mitigation Plan: Coordinate a plan for tasks to be completed individually, and tasks to be completed as a team. Set aside weekly slots where all members are free to meet.
Category: Schedule Risk**,** Medium Probability, Medium Impact

In 481, the team members had a full course load in the term with different class schedules. This caused difficulties in finding times to meet up in person. A weekly time slot was reserved for FYDP meetings, such that if meetings were necessary, there would be no time conflicts. Comparing weekly schedules, Wednesdays before 11:30 A.M. was saved for FYDP related work (as well as the course scheduled Friday morning class times). Being a team of two, the coordination and assignment of tasks were quick and convenient to do, so certain tasks could be delegated to individuals to complete in their own time. When meetings were required for both members that could not be completed within the set weekly slot, time was taken outside of school hours (weekends, nights) to complete together.

10.3.3 Risks Encountered in 482

Risk Description: Finding volunteers to perform validation tests
Risk Mitigation Plan: Adjust verification plan to focus on key requirements that can be performed by 1 member

Category: Other, High Probability, High Impact

Given the social distancing regulations due to COVID-19, the risk of finding volunteers to test out the device became high risk this term. Thankfully, there was a mitigation plan to reduce the number of volunteers and focus on only the key requirements. This adjustment to the verification plan was decided on before the IDR, so we were able to adjust the term plan early on.

Risk Description: Remote resources insufficient
Risk Mitigation Plan: Test out online platforms early to ensure all members are synced up and working on the latest revisions of files
Category: Technical, High Probability, Medium Impact

This risk was identified at the start of this term and of course it was highly probable to occur. At first, the team setup all the tools that were used in ME481. However, MS teams was new this term, so we all learned to sync our personal calendars in Outlook and practiced setting up meetings. Furthermore, a list of to-dos with priorities and a color-coded task delegation was used by all members to jot down meeting notes and feedback during Q&A on the OneNote app.

11 REFLECTIONS

More information on lessons learned for each individual can be found in Appendix B. This section is intended to capture group reflections.

Throughout the capstone project, our team encountered major changes and obstacles, summarized chronologically:

- Major scope change (Fall 2019) after discovering new information
- Year long gap by both original capstone members (Jan. 2020 – Dec. 2020)
- COVID19 impacts force another scope change (Winter 2021)
- Wonderful addition of new group member (Winter 2021)

One of the most impactful lessons learned regarding the design is to conduct all appropriate research and fulfill a concrete list of requirements and constraints. As mentioned, Team 43 underwent a major scope change close to the beginning of the 4A term. With this being a

biomedically-focused project, there is a steep learning curve for 3 engineering students with a mechanical background to become familiar with a different industry. Conducting sufficient research to support design decisions paves an easier way for a robust design. Our team collaborated with an expert MRI researcher much later into the 4B term (when the design was too far in for major changes) and realized that there were other significant considerations with the intended design.

Team 43 recognizes the importance of a healthy work environment. We would collectively like to attribute the bulk success of our project to each individual member, all of whom were incredibly helpful and patient throughout a stressful term. The support provided by each member of our team throughout a pandemic and these uncertain times were incredibly significant towards improving mental health. Positive team relations are integral to cultivating a healthy workspace that individuals feel safe in sharing ideas, suggestions, criticism, and to build on each others' ideas. We recognize that every individual has a different set of skills and talents that are useful for achieving a common goal.

Moving forward past graduation, our team will integrate the lessons learned throughout our Capstone process into our professional lives. Extra diligence in starting a project will lead to a more well-defined plan. Great emphasis will be placed on cultivating a healthy team environment and striving to be a teammate others can look toward for support.

12 CONCLUSION

To conclude, Joint Effort designed an MR compatible wrist loading device intended to advance research on osteoarthritis pathology and earlier detection. The device successfully meets the requirements: bilaterality, limits range of motion, applies 2-5 pounds of axial force, adjustable to the 5^{th} to 95^{th} percentile of both sexes, comfortable to use for at least 15 minutes, easy to setup, and safe for patients. Furthermore, it was verified to be within the constraints of a knee accessory coil, eco-friendly, and MR compatible. The final design was selected to be a polypropylene stiff member with multiple J-hooks for the resistance band to hook onto and stretch around a handle that the user will hold with their wrist strapped down onto a detachable puzzle piece.

12.1 RECOMMENDATIONS

This 8-month project provides a starting point for weight-bearing MRI research on the wrist. As the project developed into a prototype, areas for improvement were noted for future reference.

12.1.1 Consistent Wrist Positioning

After speaking with Dr. Lalone at the Hand and Upper Limb Centre, it was learnt that consistent wrist positioning between scans is critical to repeatability, so this should become a requirement and high priority.

12.1.2 Alignment of accessory coil and MR bore axes

Dr. Lalone also mentioned the forearm axis (i.e. the accessory coil position) relative to the centerline of the MR bore should be aligned for better resolution. The two axes are shown in Figure 12-1. Although the qualitative improvement is unknown, future designs should aim to keep this alignment.

Figure 12-1 Axis misalignment

12.1.3 Force Lookup Table

For easier technician use and better setup control, a lookup table of force value for a given resistance band, hook position, and center of wrist position would be very useful. The center of wrist position could be approximated by a discretization using coloured marks on the device, shown in Figure 12-2.

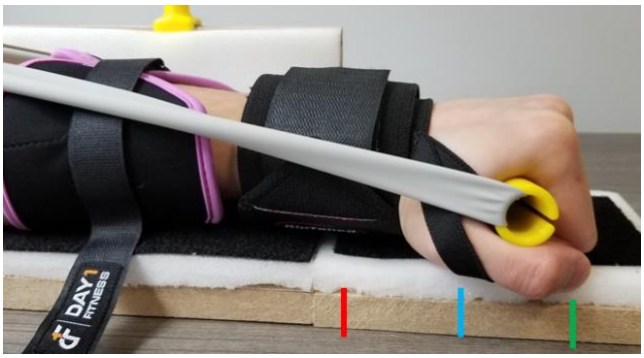


Figure 12-2 Center Wrist Position

12.1.4 Redesign Wrist Strap

During prototyping, it was noticed that not all the reactionary force was being provided by the elbow; some of it was being provided by the wrist strap. This is difficult to control for consistency, so the wrist strap could be replaced by a mechanism that holds the handle and compresses the wrist but cannot provide a reactionary X force. An example would be a horizontal slot that allows the handle to move in X but not in Y.

12.1.5 Variable Elbow Angle

The current design has a fixed elbow angle. To allow researchers the option to try different elbow angles, the stiff member could be redesigned to be two components with a rotational hinge and locking mechanism.

12.2 FUTURE

The future for the device is to release all research, design, and relevant files for open-source community use. The CAD files will be publicly available via GrabCAD and the preliminary research, presentations, and reports will be publicly shared on GitHub. The team hopes the work is valuable for future researchers exploring wrist diseases and novel MR diagnostic tools and is open to be contacted for inquiries. Furthermore, after speaking with Dr. Lalone about the device, it was validated that weight-bearing MRI is a highly pursued topic in medical field. The team plans to provide the prototype free of charge to any researchers interested in using it in their study.

13 REFERENCES

[1] W. Medeiros, "Wrist Widget," Wrist Widget, 2019. [Online]. Available: www.wristwidget.com. [Accessed 20 11 2019].

[2] "W4 Sonosim: Wrist," Quizlet, [Online]. Available: https://quizlet.com/221003797/w4-sonosim-wrist-flash-cards/. [Accessed 22 September 2019].

[3] Orthoinfo, "Articular Cartilage Restoration," February 2009. [Online]. Available: https://orthoinfo.aaos.org/en/treatment/articular-cartilage-restoration/. [Accessed 22 September 2019].

[4] OrthoInfo, "Arthritis of the Wrist," April 2016. [Online]. Available: https://orthoinfo.aaos.org/en/diseases--conditions/arthritis-of-the-wrist/. [Accessed 23 November 2019].

[5] Arthritis Foundation, "Arthritis Facts," Arthritis Foundation, [Online]. Available: https://www.arthritis.org/about-arthritis/understanding-arthritis/arthritis-statistics-facts.php. [Accessed 22 November 2019].

[6] National Institute of Biomedical Imaging and Bioengineering, "X-rays," [Online]. Available: https://www.nibib.nih.gov/science-education/science-topics/x-rays. [Accessed 23 November 2019].

[7] A. Berger, "Magnetic resonance imaging," NCBI, 2002.

[8] Stanford Health Care, "PET/MRI Scan," https://stanfordhealthcare.org/medical-tests/p/pet-mri-scan.html, 2019. [Online]. Available: https://stanfordhealthcare.org/medical-tests/p/pet-mri-scan.html. [Accessed 20 11 2019].

[9] MR TIP, "MRI Coils," MRI Technology, 2019. [Online]. Available: https://www.mr-tip.com/serv1.php?type=co&sub=11. [Accessed 20 11 2019].

[10] Hitachi Medical Systems America, Inc, "MRI Anatomy and Positioning," 2019. [Online]. Available: https://www.hitachimed.com/self-learning-activity/docs/UpperExtremityModule/?WT.ac=med_mg_cussite_selflear_ueoi. [Accessed 25 Nov 2019].

[11] GE Healthcare, "MRI Bore sizes and Beneftis," 16 Jan 2019. [Online]. Available: gehealthcare.com/feature-article/mri-bore-sizes-and-benefits. [Accessed 25 Nov 2019].

[12] National Health Service England, "MRI scans: How it's performed," 9 August 2018. [Online]. Available: https://www.nhs.uk/conditions/mri-scan/what-happens/. [Accessed 23 November 2019].

[13] S. Apprich, T. Mamisch, G. Welsch, D. Stelzeneder, C. Albers, U. Totzke and S. Trattnig, "Quantitative T2 mapping of the patella at 3.0T is sensitive to early cartilage degeneration, but also to loading of the knee.," European Journal of Radiology, Vienna, 2012.

[14] T. Lange, J. Maclaren, M. Herbst, C. Lovell-Smith, K. Izadpanah and M. Zaitsev, "Knee cartilage MRI with in situ mechanical loading using prospective motion correction," Magnetic Resonance in Medicine, 2014.

[15] T. Nishii, K. Kuroda, Y. Matsuoka, T. Sahara and H. Yoshikawa, "Change in knee cartilage T2 in response to mechanical loading," Journal of Magnetic Resonance Imaging, 2008.

[16] S. Modaresi, M. S. Kallem, P. Lee, T. E. McIff, E. B. Toby and K. J. Fischer, "Evaluation of Midcarpal Capitate Contact Mechanics in Normal, Injured and Post-operative Wrists," Clinical Biomechanics, 2017.

[17] S. K. Sikora, S. K. Tham and J. N. Harvey, "The Twist X-Ray: A Novel Test for Dynamic Scapholunate Instability," Thiem Medical Publishers, New York, 2018.

[18] J. E. Goetz, N. M. Kunze, K. E. Main, D. R. Thedens, T. E. Baer, E. A. Lawler and T. D. Brown, "MRI-Apparent Localized Deformation of the Median Nerve Within the Carpal Tunnel During Functional Hand Loading," *Annals of Biomedical Engineering,* vol. 41, no. 10, pp. 2088-2108, Oct 2013.

[19] E. Lalone, Interviewee, *Discussion.* [Interview]. 10 March 2021.

[20] ScanMed, "Elbow Wrist MRI Coil," ScanMed, Nov 2019. [Online]. Available: https://www.scanmed.com/elbowwristmricoil. [Accessed 29 Nov 2019].

[21] Granta Design, *CES EduPack,* 2019.

[22] T. Lazaridis, "MRI - Magnetic Resonance Imaging," GrabCAD, 2017.

[23] C. Carlos, "Articulated human body," GrabCAD, 2012.

[24] OmNexus, "The Definitive Guide to Polypropylene (PP)," OmNexus, 2021. [Online]. Available: https://omnexus.specialchem.com/selection-guide/polypropylene-pp-plastic. [Accessed 11 April 2021].

[25] ScanMed, *ScanMed Wrist Coil,* Omaha: ScanMed, 2021.

[26] V. Decostre, A. Canal, G. Ollivier, I. Ledoux, A. Moraux, V. Doppler, C. A. M. Payan and J.-Y. Hogrel, "Wrist flexion and extension torques measured by highly sensitive dynamometer in healthy subjects from 5 to 80 years," *BMC Musculoskelet Disord.,* vol. 16, no. 1, p. 4, 2015.

[27] GTAA PARTNERS IN PROJECT GREEN, "Partners in Project Green," 27 03 2014. [Online]. Available: https://partnersinprojectgreen.com/news/velcro-canada-turns-waste-into-recycled-plastic-products/. [Accessed 12 04 2021].

[28] Professional Plastics, "Professional Plastics," 1 2018. [Online]. Available: https://www.professionalplastics.com/professionalplastics/content/downloads/PPL-12018-pageMarketingBrochure_06web.pdf. [Accessed 04 2021].

[29] Kent Elastomer, "FREE-BAND TOURNIQUETS," 2021. [Online]. Available: https://www.kentelastomer.com/free-band-tourniquets/. [Accessed 2021].

[30] Department of Health and Human Services, 13 August 1999. [Online]. Available: https://www.accessdata.fda.gov/cdrh_docs/pdf/k992120.pdf. [Accessed 04 2021].

[31] S. McLachlin, Interviewee, *Discussion.* [Interview]. 10 January 2021.

14 APPENDICES

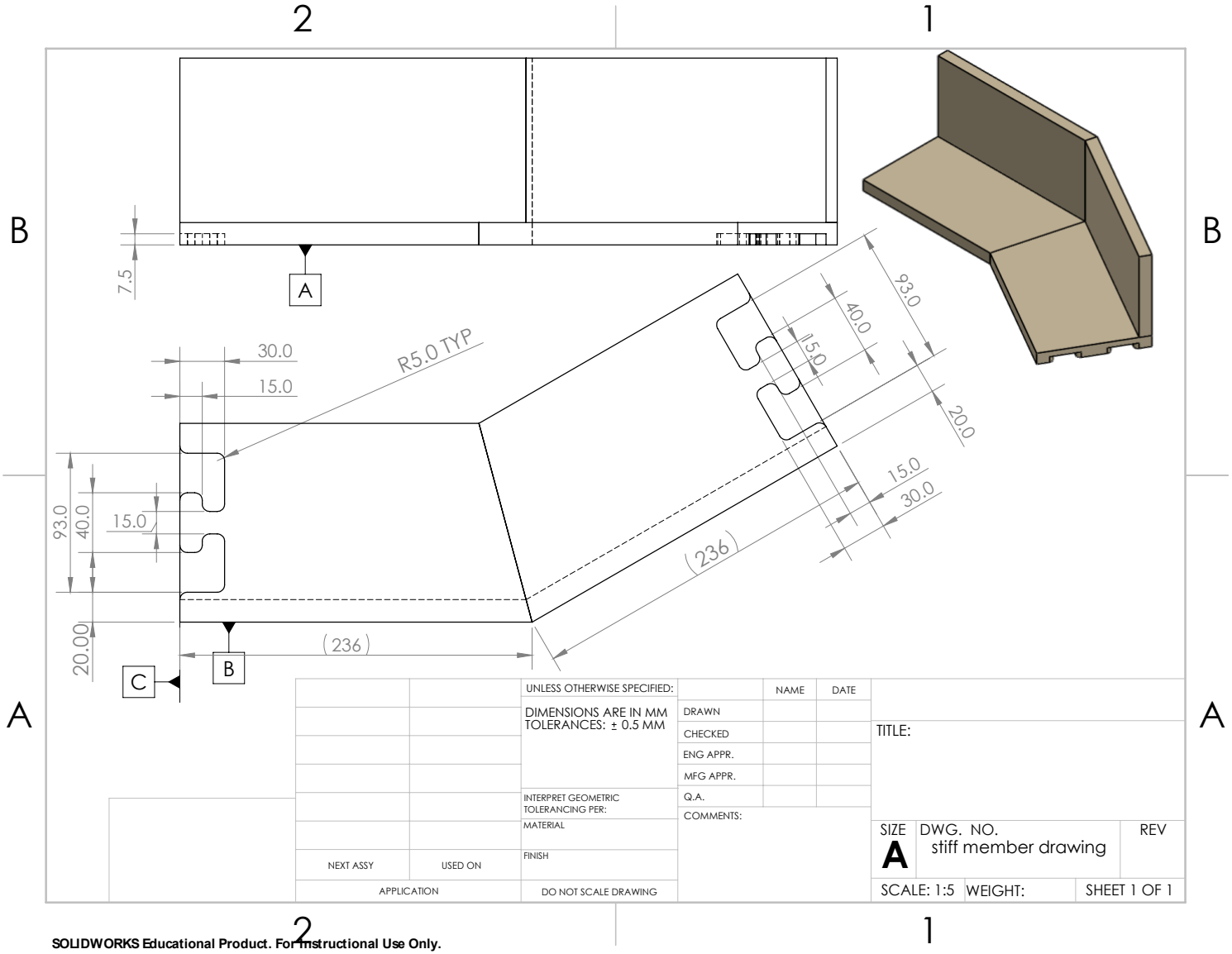
Appendix A Engineering Data

A-1 Bill of Materials

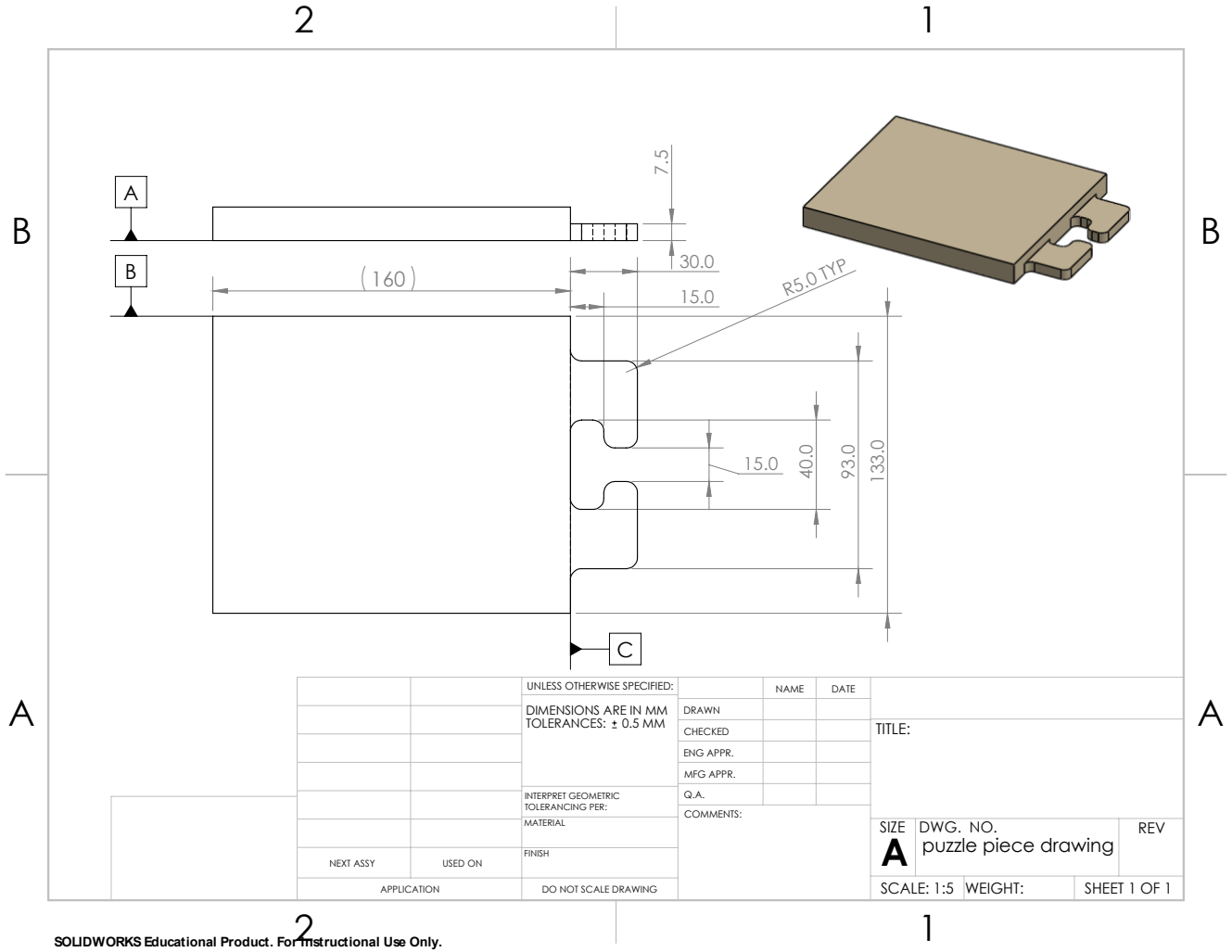
Team Number	43	Rev		Description	Date
Team Members			0	Initial Release	9/26/2019
Kelly Hao			1	Scope modification	10/19/2019
				Updated for MDR -	
Michael Beals			2	Handle	2/23/2021
				Updated for FDR - Stiff	
Catherine Tsang			3	Member Subassembly	2/26/2021

Part	Qty	Item Description	Procurement Type	Material	Recyclablility (% by weight)	Supplier
1-A	2	Stiff Member - Side Guards with J Hooks	Made-to-specification	Polypropylene (PP)	100%	3D Printer
1-B	1	Stiff Member - Base	Made-to-specification	Polypropylene (PP)	100%	3D Printer
1-C	1	Stiff Member - Detachable Puzzle Piece	Made-to-specification	Polypropylene (PP)	100%	3D Printer
2	1	Handle	Made-to-specification	Polypropylene (PP)	100%	3D Printer
3	(30 ft)	Adhesive Velcro	Off-the-shelf	Polyethylene	65%	Universal Medical
4	3	Resistance Bands (different stiffnesses)	Off-the-shelf	Latex-free elastomer	0%	Amazon
5	3	Arm Straps	Off-the-shelf	Vinyl	100%	Amazon
6	(20"x60")	Foam Padding Strips (cut to size)	Off-the-shelf	Polyurethane foam	0%	Amazon

A-2 CAD drawing of stiff member



A-3 CAD Drawing of puzzle piece



A-4 Machine shop submission with links to SolidWorks Files

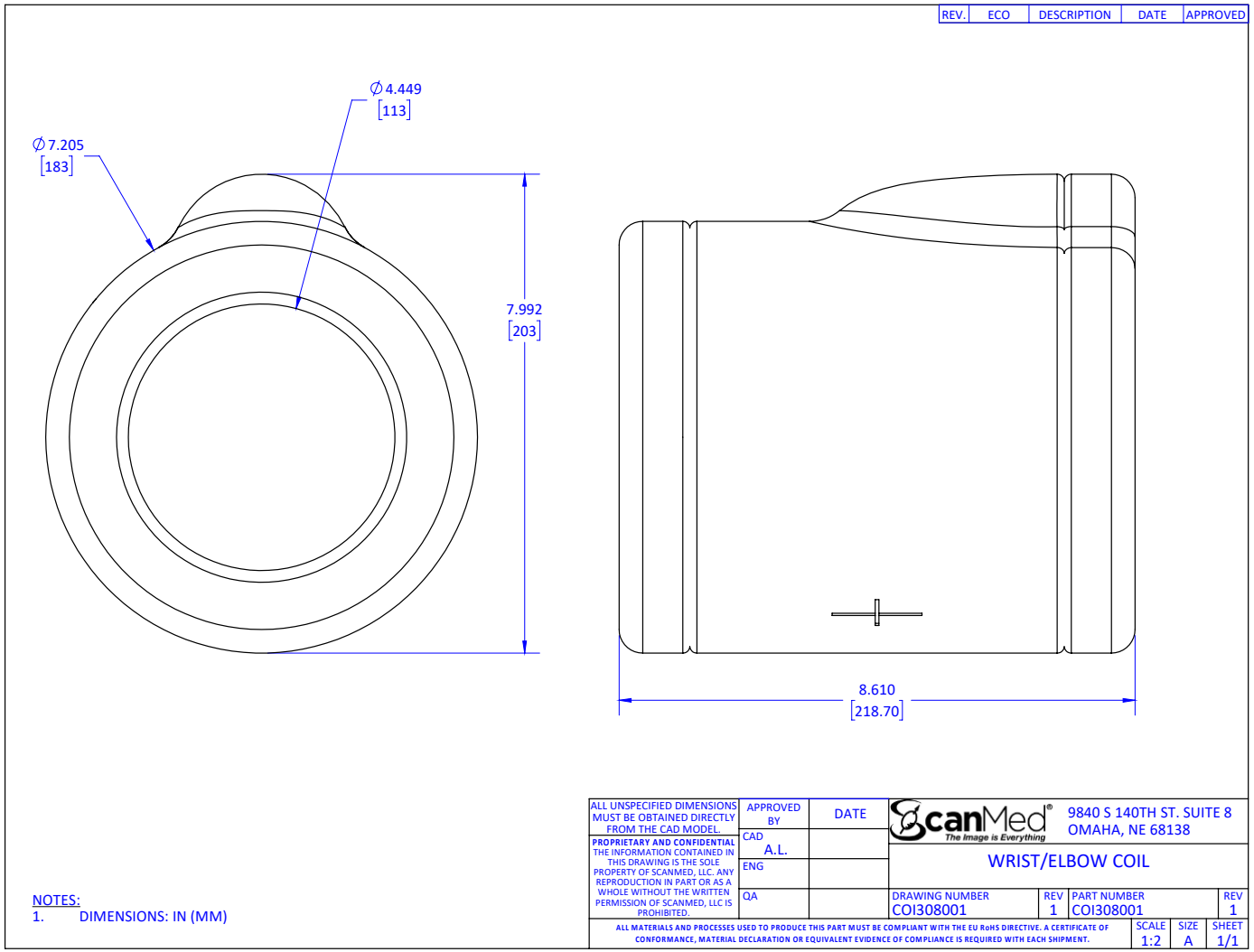
Team number and team name.	G43, Joint Effort
Student Name	Michael Beals
Email	[redacted]
Work Type	Machining (e.g. CNC)
Job Description. Include a detailed description of what you are looking to have made, i.e., a numbered list of each item (drawing).	We're looking for CNC routing of our prototype made from MDF to create a puzzle-type joint. Specifically: 1) Female puzzle joints on each side of the stiff member component 2) Male puzzle joint on the puzzle piece component
Quantity and Material. The quantity required for each numbered item, and a list of material for each item. Note: Only material from the EMS is available (https://ems-stores.uwaterloo.ca/ems-site). You may alternatively say "See attached BOM", and include a Bill of Materials file in your attachments.	We can provide our own material
Briefly explain why this is essential to the success of your project, and why it can't be done using other resources.	Our team has no access to power tools; making a puzzle piece joint would be very difficult without one
Submit Drawings (PDF) , Solidworks Files, Bill of Material (BOM).	File 1 File 2 File 3 File 4 File 5

A-5 Engineering Design Specification

	Team Number	43				**Rev**	**Description**	**Date**
	Team Member					0	Initial Release	2019-09-26
	Kelly Hao					1	Add No 15, 16	2019-10-18
	Michael Beals					2	COVID19 and W21 updates	2021-01-17
	Catherine Tsang							

No.	Parameter	Relation	Value/Range	Unit	Functional (F), Non-F (NF), or Constraint (C)	Verification Method	Comments/Notes
1	Limit wrist range of motion	<	10	deg	F	Conduct trials on 1 volunteer. For each volunteer, place the device on their forearm and ask them to move their wrist in each of the 6 basic wrist motions. For each motion, ask them to stop when they encounter resistance. Image each position and use the pairs of complementary motion images to calculate unrestricted ranges of motions for the 3 motion couples using computer-based photo measurements	Purpose: Develop some level of consistency in upper arm positioning for uniformity between trials. The original scope was to use 41 trials for statistical significance. It is the sample size calculated from an infinite population, an unknown p, a confidence level of 80% and a confidence interval of 10%. While these values are relatively low compared to a typical clinical trial (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3148614/), this project is a small-scale exploration so the accuracy is reduced to be reasonable with the timeline.
2	Bilateral design	---	---	---	F	Conduct the upper limb control test on both arms	The device should work for both the right and left arms.
3	Compressive Loading	within	5 - 10	lbs	F	For each band, determine its maximum and minimum elongation based on 5% woman and 95% man. Using its stiffness, calculate the force it applies. Ensure that the range of 5-10 lbs is achievable within the cumulative band ranges. Then use a force gauge to verify the predictions	Purpose: Show that we can load the wrist to within a certain range on every person. This may require multiple resistance bands
4	Variable Sizing	---	---	---	NF	Make a dummy limb with 95% male sizes and another dummy limb with 5% female sizes. Make sure the device fits both dummy arms	ME 482: Increase complexity of manufacturing. Too much risk currently with unstable circumstances, so instead of manufacturing dummy limbs, we will elect to use the smallest female and largest male within our core
5	Comfort level with load	>	5	Scale of 10	NF	Conduct trials on 1 volunteer. Load them into the device for 15 minutes. Every 3 minutes ask them to rate the comfort of the device while loaded on a scale of 10. Take the average of the results. Each 3 minutes should aim to be above an average value of 5	Comfort level in loaded position can be obtained from healthy individuals.
6	Aesthetic	>	5	Scale of 10	NF	Conduct trials on 1 volunteers. For each volunteer, ask them to rate the aesthetic on a scale of 10. Take the average of the results.	A more aesthetic design will increase patient comfortability during testing. COVID19: Only 11 volunteers will be able to assess the aesthetic of the device in person. 30 more volunteers can
7	Ease of use	<	120	s	NF	Conduct trials on 1 volunteers. For each volunteer, use a timer to check how long it takes to get the volunteer into a ready-to-scan position. One of the team members will play the role of the clinician who will be more experienced with the device. Take the average of the results	The device should take minimal time to set up to make the work of the technician and easier and make the patient experience more comfortable.
8	Safe for patients	---	---	---	NF	Provide a Bill of Materials and health effects of each material. Make sure no materials in contact with skin have any allergic or abrasive properties. Then, conduct 41 trials on volunteers to check for any unforeseen discomforts	The device will be designed for the avoidance of pinch points and sharp ends.
9	Ease of assembly	<	5	min	NF	Conduct 41 trials. Use a timer and take the average to test how long it takes for an individual to assemble the device.	Device should be assembly-friendly
10	Ease of transportation	≥	7	Scale of 10	NF	Conduct trials on 1 volunteers. For each volunteer, ask them to rate the ease of transportation on a scale of 10. Take the average of the results	Technicians should be able to comfortably lift the device in and out of a MRI environment.
11	Ease of cleaning	<	120	s	NF	Conduct 41 tests using a timer and take the average to determine how long it takes for an	Since different patients would be using the device in a medical facility, the device should be easy to sanitize by
12	Patient comfort	<	2	---	C	Conduct trials on 1 volunteers. For each volunteer, place the device on them and have them lay down in position for MRI scan. Hold position with compressed wrist and record discomfort on a scale of 10.	MRI scan is assumed to take 15 minutes based on conversations with physiotherapists. Need to ensure force applied to patient is comfortable for 15 minutes
13	Cost	<	375	CAD	C	Create a Bill of Materials with consideration for manufacturing costs	With a reimbursible budget of $375, the full project should aim to be below this. The final prototype should cost
14	Device diameter at wrist	<	4.3	in	C	Measure during CAD and verify during manufacturing	Past the upper forearm strap, it should fit within the inner diameter of a coil considering a 95% male arm size with some clearance. Measurement taken from flex knee/shoulder coil, medium:
15	Weight	<	15	kg	C	Measure during CAD and verify during manufacturing	The device is not meant to be fixed within the MRI and would need to be portable, this means that nurses and
16	Eco-friendliness	>	50	%	C	Literature-backed research during material selection. Provide a Bill of Materials describing recyclability of each material	The brace will be made of at least 50% recyclable materials to reduce its carbon footprint, materials can be separated into their raw components by at least 50% volume.
17	MR Compatible	---	---	---	C	Verify by ensuring all materials used are MR compatible. This will be indicated on a materials sheet.	Materials must be able to run through a MRI scan without interference as it can damage the machine and cause great harm to the patient.
18	Medical grade materials	---	---	---	C	Ensure the materials selected are medical grade; that is, they conform to ISO 10993-1 or USP Class VI. This will be indicated on a materials sheet	

A-6 ScanMed Wrist/elbow Coil Drawing



Appendix B Individual Lessons Learned

B-1 Kelly Hao's Lessons Learned: Design

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments, engineering specification, CAD Model, Analyses etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Identify needs, function, criteria, and constraints for a given design, considering engineering economic, health and safety, environmental and ethical specifications	CAD Model Reports, Presentations Material selection	A lot of research required to be conducted to become familiar with operating environment, user-friendly designs, user safety considerations, and techniques used in the medical industry.	The understanding and appreciation of all the research and effort that goes into fully understanding a problem statement and the effectiveness of a good list of important criteria/requirements.
Identify a solution that satisfies the needs analysis	CAD Model	Diving deep into anthropometric data.	Understanding the tools used for human-interfaced design.
Consider safety, society, and sustainability issues in selecting a solution	Material selection Prototyping methods (Final prototype manufacturing)	COVID19 and distancing ☹	Learning how to work remotely, using patience and co-operation as important tools in efficient task completion.
Generate detailed implementation specifications, including drawings, tolerances, components, etc. as required	CAD model Prototype drawings	Assessing appropriate tolerances with constrained budget and resources available.	GD&T and drafting practice.
Verify the design by implementation, prototype production, bench test validation of key elements, and/or acceptance opinion by recognized expert	Analysis	MATLAB coding.	Place greater importance on creating a detailed design space.

B-2 Kelly Hao's Lessons Learned: Project Management

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Decompose a project into a manageable set of objectives and/or tasks	WBS and schedule	Allocating appropriate work/time breakdowns.	Superior time and project management.
Develop and track a schedule with milestones	Gantt Chart, WBS	Keeping on track.	The importance of buffer times/tasks.
Manage financial, human and/or physical resources	WBS, schedule	Understanding strengths and weaknesses of individual team members.	Building team members' confidence up is important!! Allow less experienced members to try out new things they are not comfortable with, become a supportive guide makes a happy team. ☺
Identify and manage risks	Risk Register	The unexpectedness of major obstacles faced.	The importance of flexibility and adaptability in all aspects (technical, communication).
Apply change management	Risk register, severe changes to EDS and verification plan	Needed to apply a lot of changes!!! (COVID, new member = design scope change, major scope change in beginning of project).	Maintain an open mind.

B-3 Kelly Hao's Lessons Learned: Communication

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Write effective reports and design documentation	Reports Presentations	Condensing 8 months of work into 3000 words and a 10 minute symposium video.	The beauty of keeping things simple and understandable for all audiences.
Make effective presentations	Presentations	Condensing all our work!!	Animations, transitions, and belaboring key takeaways.

B-4 Michael Beal's Lessons Learned: Design

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments, engineering specification, CAD Model, Analyses etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Identify needs, function, criteria, and constraints for a given design, considering engineering economic, health and safety, environmental and ethical specifications	Reports, Presentations Material selection	Completely unfamiliar with designing in the medical field. Had to learn vocabulary and important requirements	Appreciating how important it is to define a problem well and come up with a strong set of requirements that are easy to build forward from
Identify a solution that satisfies the needs analysis	Prototype	Learning how to manufacture a prototype	Understanding how to do rapid prototyping
Consider safety, society, and sustainability issues in selecting a solution	Material selection Prototyping methods (Final prototype manufacturing)	Limited prototyping and material sourcing due to COVID19 restrictions	Learning how to design not only for function, but also how to design safely and sustainably

Generate detailed implementation specifications, including drawings, tolerances, components, etc. as required	CAD model Prototype drawings	Assessing appropriate tolerances with constrained budget and resources available.	GD&T and drafting practice.
Verify the design by implementation, prototype production, bench test validation of key elements, and/or acceptance opinion by recognized expert	Analysis Verifications	MATLAB coding, coming up with modified verification tests due to COVID19	Placing great emphasis on the ability to validate a design

B-5 Michael Beal's Lessons Learned: Project Management

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Decompose a project into a manageable set of objectives and/or tasks	WBS and schedule	Allocating appropriate work/time breakdowns.	Time and project management.
Develop and track a schedule with milestones	Gantt Chart, WBS	Keeping on track and updating it.	The importance of buffer times/tasks.
Manage financial, human and/or physical resources	WBS, schedule, expense tracking	Understanding strengths and weaknesses of individual team members. Estimating costs of materials and manufacturing methods	The more important part of a project is the people that make it work. Focus on understanding your teammates' strengths and weaknesses, use them to your advantage
Identify and manage risks	Risk Register	The unexpectedness of major obstacles faced.	The importance of flexibility and adaptability in all aspects (technical, communication).
Apply change management	Risk register, changing EDS and verification plan	Needed to apply a lot of changes (COVID, new member = design scope change, major scope change in beginning of project).	Maintain an open mind, be adaptable and prepared.

B-6 Michael Beal's Lessons Learned: Communication

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Write effective reports and design documentation	Reports Presentations	Being concise and focusing only on the key points	Keeping explanations simple and clear is the most important to engage audience
Make effective presentations	Presentations	Speaking without a script	Understanding how to convey the most important takeaways

B-7 Catherine Tsang's Lessons Learned: Design

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments, engineering specification, CAD Model, Analyses etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Identify needs, function, criteria, and constraints for a given design, considering engineering economic, health and safety, environmental and ethical specifications	Reports, Presentations Material selection	Research into MR environment, patient experience, medical industry.	Ability to come up with a list of requirements considering those 3 things by thoroughly researching the problem
Identify a solution that satisfies the needs analysis	Sketches, Drawings, Analyses	Finding research on 5^{th} to 95^{th} percentile, searching for results for weight-bearing MRI scans	Using engineering graphics skills to explain ideas

Consider safety, society, and sustainability issues in selecting a solution	Prototyping methods Verification of sustainability for report report	Trade-off between sustainable and functional (medical grade)	Considering 3 factors often forgotten in engineering design. Consideration for each builds trust
Generate detailed implementation specifications, including drawings, tolerances, components, etc. as required	CAD drawings interpreted for manufacturing prototype Labelled manufactured parts to instruct assembly	Unit converting, adjusting thickness of design to prototype thickness	Reading engineering drawings and recognizing mistakes before manufacturing
Verify the design by implementation, prototype production, bench test validation of key elements, and/or acceptance opinion by recognized expert	Analysis	MATLAB coding	Practice validating design choices using mathematical equations

B-8 Catherine Tsang's Lessons Learned: Project Management

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Decompose a project into a manageable set of objectives and/or tasks	WBS, Gantt	Estimating work/time for 4 months	Break down project into smaller tasks
Develop and track a schedule with milestones	Gantt Chart, WBS	Meeting the deadlines	Add buffer time and time for iterating
Manage financial, human and/or physical resources	WBS, schedule, expense	Expense form instructions, Fairly dividing up work	Fairness is important to ensure everyone feels equal in a project
Identify and manage risks	Risk Register	Dealing with extra work because of a risk	Always thinking of what could go wrong and coming up with a plan for that
Apply change management	Risk register, EDS, and verification plan	COVID affecting everything	Be creative and adjust your plans to the new normal

B-9 Catherine Tsang's Lessons Learned: Communication

Performance Indicator	**List the specific deliverables you produced that demonstrated your performance** (i.e. Reports, assignments etc.)	**What challenges were presented to you in achieving this learning outcome?**	**What is the value of this learning outcome for a future design project task?**
Write effective reports and design documentation	Reports Presentations	Being concise and focusing only on the key points	Keeping explanations simple and clear is the most important to engage audience
Make effective presentations	Presentations	Speaking without a script	Using templates to create professional presentations

Appendix C Team Summary Chart

Who a team member mentored, what mentoring they received from other team members

Kelly Hao (Mechanical Lead) • Parametric design (mentor) • GD&T (mentor) • Plastic fabrication processes (mentee)
Catherine Tsang (Project Management Lead) • MDF fabrication processes (mentor) • Effective presentation styles (mentor)
Michael Beals (Prototyping Lead) • Plastic fabrication processes (mentor) • GD&T (mentee) • MDF fabrication processes (mentee)

Appendix D Project Management

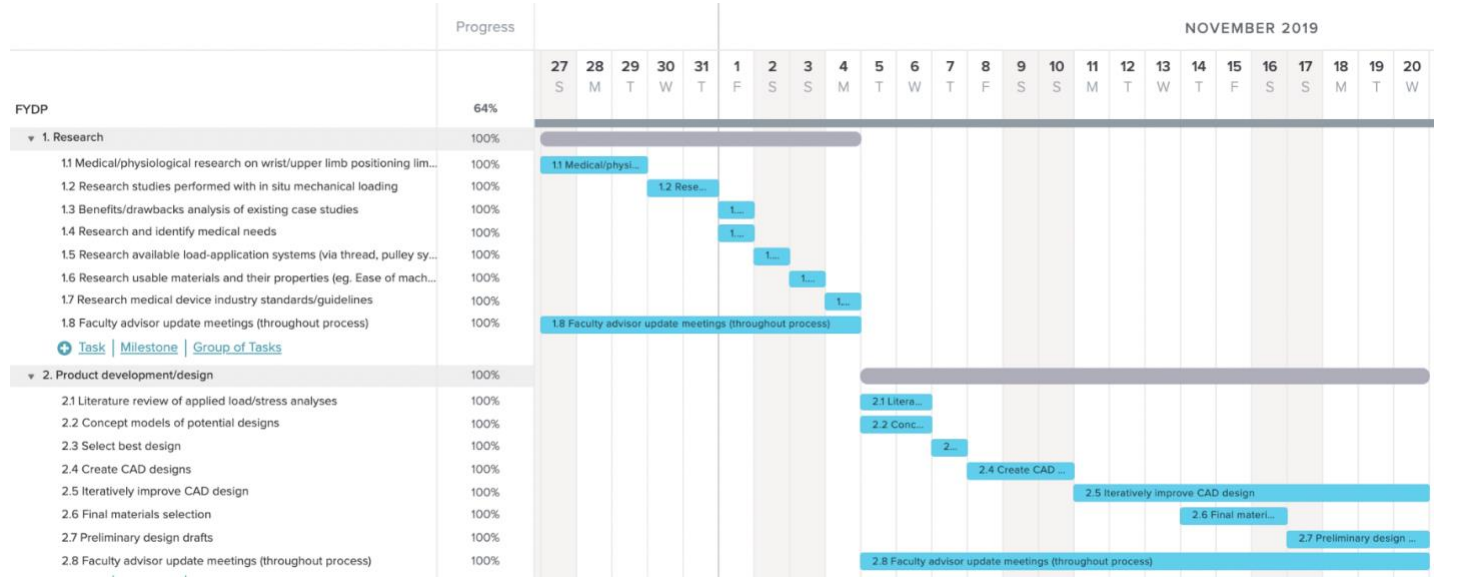
D-1 Work Breakdown Structure

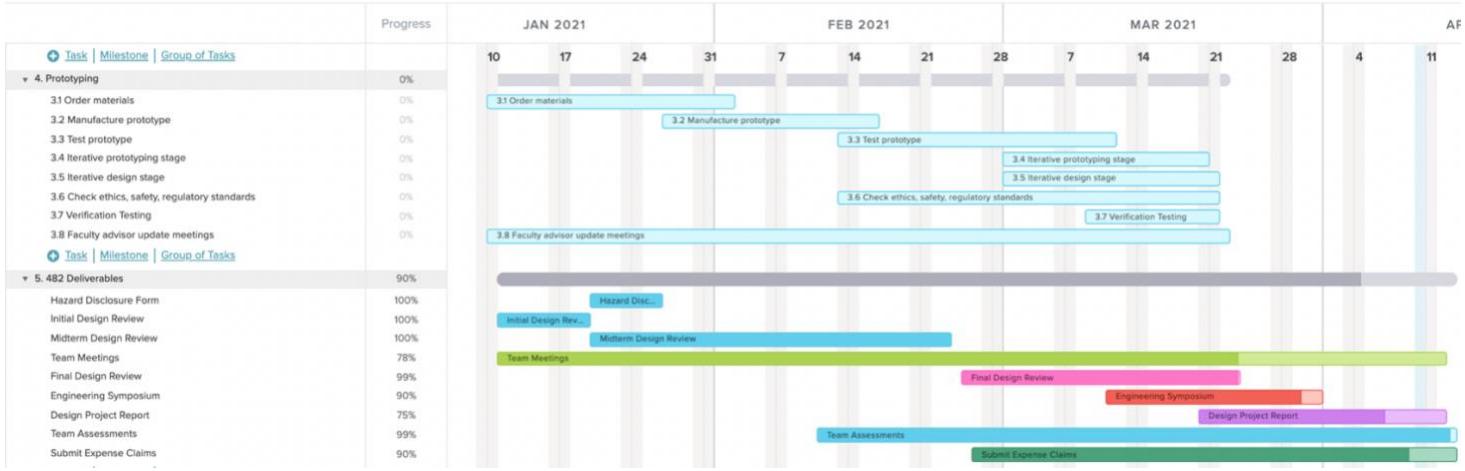
Team Number	43	Rev	Description	Date
Team Members		0	Initial Release	9/26/2019
Kelly Hao		1	Scope modification	10/18/2019
Michael Beals		2	COVID19 and W21 updates	1/17/2021
Catherine Tsang				

Work Breakdown Structure

LEVEL 1	Hours	LEVEL 2	Description	Hours	LEVEL 3	Description	Estimated Hours	Actual Hours
Estimated	**346.5**	**1**	**Research**	33	1.1	Medical/physiological research on wrist/upper limb positioning limits and MRIs.	4	4
Actual	403				1.2	Research studies performed with in situ mechanical loading	4	4
					1.3	Benefits/drawbacks analysis of existing case studies	3	3
					1.4	Research and identify medical needs	2	2
					1.5	Research available load-application systems (via thread, pulley system, etc.) and with applications specifically in the medical industry	6	4
					1.6	Research usable materials and their properties (eg. Ease of machining, ease of cutting, etc.)	5	4
					1.7	Research medical device industry standards/guidelines	5	
					1.8	Faculty advisor update meetings (throughout process)	4	2
		2	**Development /Design**	72	2.1	Literature review of applied load/stress analyses	4	4
					2.2	Identify on-campus instruments available for use	2	2
					2.3	Concept models of potential designs	6	6
					2.4	Create high-level kinetic-based designs in modelling software	16	16
					2.5	Iteratively improve kinetic-based design	20	20
					2.6	Final materials selection	10	5
					2.7	Preliminary design drafts	5	3
					2.8	Faculty advisor approval	1	1
					2.9	Faculty advisor update meetings (throughout process)	8	8
		3	**Prototyping**	90	3.1	Order materials	5	5
					3.2	Manufacture prototype	10	15
					3.3	Test prototype	10	18
					3.4	Iterative manufacturing prototyping stage	15	25
					3.5	Iterative design stage	30	27
					3.6	Check ethics, safety, regulatory standards	4	2
					3.7	Verification testing	10	12
					3.8	Faculty advisor update meetings (throughout process)	6	6
		4	**Course Deliverables (4A)**	40	4.1	Registration Form (481)	1	1
					4.2	Proposal Document (481)	12	12
					4.3	Team Charter (481)	1	1
					4.4	Progress Report Meetings (481)	4	4
					4.5	Final Design Review (481)	4	4
					4.6	Final Report (481)	18	18
		5	**Course Deliverables (4B)**	111.5	4.7	Initial Design Review (482)	10	8
					4.8	Midterm Design Review (482)	10	11
					4.7	Final Design Review (482)	12	30
					4.8	Team Assessments (482)	1	4.5
					4.9	Team Meetings (482)	28	48
					4.1	Hazard Disclosure Form (482)	0.5	0.5
					4.11	Engineering Symposium	30	27
					4.12	Design Project Report (482)	20	36

D-2 Project Schedule





D-3 Total Expenses

ME 481/482
Project Expense Summary

Course: ME 482 **Term:** Winter 2021

Claimant : Catherine Tsang **E-mail Address:** c9tsang@uwaterloo.ca

Team #: 43 **Claim # :** 4423920610726

Receipt #	Date of Purchase	Vendor	Description of Items Purchased	Amount Claimed	Payment Method	Proof of Payment
1	12/02/2021	Canada Post	Express Ship Parts to Waterloo	$ 21.26	Credit/Debit	Marked "Paid " on receipt
2	05/02/2021	Amazon	Pack of Velcro Strips	$ 17.99	Credit/Debit	Marked "Paid " on receipt
3	05/02/2021	Amazon	Power Drill + Knee Pads	$ 95.58	Credit/Debit	Marked "Paid " on receipt
4	06/02/2021	Amazon	Ankle Weights	$ 19.82	Credit/Debit	Marked "Paid " on receipt
5	15/02/2021	Amazon	Wrist Wraps	$ 18.05	Credit/Debit	Marked "Paid " on receipt
6	17/02/2021	Michael's Craft Store	Polyurethane Foam	$ 14.23	Credit/Debit	Marked "Paid " on receipt
7	26/02/2021	Amazon	Resistance Bands	$ 36.86	Credit/Debit	Marked "Paid " on receipt
			Total	$ 223.79		

Faculty Advisor: Stewart McLachlin
Course Instructor: Stephen Lambert

Date: 08-Apr

D-4 Budget

Team No. 43	Rev	Description	Date
Team Members	0	Initial Release	9/26/2019
Kelly Hao	1	Scope modification	10/19/2019
Michael Beals	4	Expense modification	11/20/2019
Catherine Tsang	5	COVID19 updates	1/17/2020
	6	Updated for MDR	2/23/2021
	7	Updated for FDR	2/26/2021

Budget

No.	Category	$ Budgeted	$ Spent	Kind-in ($0)
1	Materials	$148	$70	MDF (family), Cardboard (home)
2	Shipping	$60	$21	
3	Equipment	$60	$133	Adhesives (family)
4	Manufacturing Services	$0	$0	Cutting MDF (family), Machine Shop (ME 482)
	Budget:	$375	$375	
	Expenses:	$268	$224	
	Remainder	**$107**	**$151**	

D-5 Risk Register

Team Number	43						Rev	Description	Date
Team Members							0	Initial Release	2019-09-26
Kelly Hao							1	Scope modification	2019-10-18
Michael Beals							2	COVID19 and W21 updates	2021-01-17
Catherine Tsang									

Risk Register

No.	Risk Title	Risk Description	Risk Category: Technical	Schedule	Cost	Other	Probability of Occurrence (LMH)	Severity of Impact (LMH)	Mitigation Plan	Comments/ Notes
1	Design Fails Load Spec	Design fails to apply specified load(s)	X				L	H	Ensure load system works by using pre-existing systems (screw system, pulley system, physical weights, etc.)	
2	Design Fails Variable Sizing Spec	Design does not include sizing for 90th percentile forearms	X				L	M	Opt for non-rigid securements during design.	
3	Design causes discomfort	Material produces unexpected allergic effect or features (sharp edges, etc) harm the patient	X				M	L	Thoroughly research material to ensure it has no allergenic side effects, and take care to chamfer/fillet sharp edges/corners, inspect for pinch points	
4	Difficulty finding upper limb data		X				L	M	Verify research with Faculty Advisor and medical professionals, or knowledgeable individuals in the biomedical field.	
5	Unexpected change in scope	Find new information that forces a change in scope (ie. original scope too difficult)	X				M	H	Keep faculty advisor in loop on a regular basis to ensure that project does not stray too far from what is expected in a 481/482 course.	X COVID
6	Poor aesthetics	Design receives a poor rating	X				M	L	Ask for aesthetic feedback throughout design process	
7	Not User (Technician)-Friendly	Design feedback indicates difficult to use	X				H	M	Seek simplicity when designing. Use common attachment mechanisms (e.g. velcro and buttons) instead of highly complex mechanisms that may provide marginal benefits	
8	Poor comfort in loaded position	Design feedback indicates discomfort under load	X				L	M	Indicate clear instructions of use to not load the wrist more than the body is capable of; clearly instruct to start at the lowest load and work up from there, stop at discomfort.	
9	Poor comfort in neutral position	Design feedback indicates discomfort under no load	X				M	L	Identify materials that are comfortable against the skin. If the design includes any abrasive, stiff, or sharp elements such as seams, velcroes, or metal bars, provide adequate cushioning	
10	Design is Too Big	Design exceeds weight specification.	X				M	M	For any CAD designs, include material properties to easily check weight. Cut down on volume/mass where possible during design stages.	X in first iteration (size not weight)
11	Poor Design Methodology	Having to re-do an entire design to make a change	X				H	L	Design parametrically to allow for changes.	
12	Short Lifespan	Design degrades (either materially or by fatigue) over a short time span	X				L	L	For any stiff members, perform basic fatigue calculations to estimate life. For materials, thoroughly research their chemical lifespan, and what environmental factors may cause increased degradation (eg; common sanitation chemicals)	
13	Design fails ease of assembly	Difficult to assemble out of packaging	X				M	L	Keep assembly in mind when designing, opt for simple attachment systems.	
14	Design fails ease of maintenance	Difficult to sanitize/clean regularly.	X				M	M	Opt for spaces without tight corners, and for platforms (that contact human skin) to have enough space for technicians to easy reach.	
15	Design fails ease of use	Set up within MRI fails easiness spec.	X				M	M	Regularly ask for feedback throughout design process to ensure that final product is easy to set up and use.	
16	Course Load	Course loads from other classes begin to affect dedication to project		X			H	H	Set weekly deliverables. Proactively plan course work distribution. Keep an agenda of assignments, labs, projects, and exams.	X MDR & FDR
17	Material(s) Lead Time	Risk of materials arriving later than intended		X			M	M	Order materials as soon as necessity is confirmed, plan for manufacturing with a buffered time to account for late materials	X CNC
18	Poor material selection	Ensure all materials are MRI compatible.		X			L	L	Conduct thorough research during material selection stage.	
19	Resource Risk	Conflict in team member schedules		X			M	M	Coordinate a plan for tasks to be completed individually, and tasks to be completed as a team. Set aside weekly slots where all members are free to meet. Ensure schedules are all up to date and visible to all team members.	X
20	Project Dependencies	Unable to complete a given task until a previous has been complete (eg. unable to test until materials arrive)		X			M	M	Set appropriate buffer times for preceeding tasks.	X
21	Material Cost	Ideal materials too expensive			X		M	M	Source back-up materials. Have multiple options.	
22	Design Fails Cost Spec				X		M	M	Source low-cost materials and low-cost manufacturing processes.	X COVID, Cat's dad
23	Biomedical Regulations	Medical industry regulations introduce too many guidelines to keep track of during design				X	M	H	Take ethical certifications and consult biomedical engineers for standards regularly, go through regular design reviews (progress review meetings and design presentation).	X Prof. Lalone Upper Hand Centre
24	Material Sourcing	Unable to find ideal material				X	L	M	Source back-up materials and have multiple options.	
25	Finding testers	Finding people to test comfort & ease-of-use				X	H	M	Stay within provincial guildelines regarding the COVID19 core bubble restrictions. At the worst case, the team must settle for self-tests and tests on those living within the same household(s).	X 1 tester
26	Communication Faults	Responsibilities and tasks unclear, online communications may add another layer of difficulty				X	M	M	Follow WBS and task delegations, ask questions if steps/tasks are unclear. Keep a clear line of communication between team members and faculty advisor. Regular meetings with the team and faculty advisor to ensure every member is on the same page.	X task delegated
27	Team conflicts	Disagreements between team members				X	M	L	Stay respectful of each other and take space away if necessary.	
28	Unexpected Events	Unexpected illnesses, grievances, etc.		X			M	H	Create a back-up plan of how to proceed in the event that one team member is unable to perform their share of the work.	
29	Online Resources	Remote/online resources are insufficient.				X	H	M	Test out online platforms early, ensure all team members are fully synced up and are all working on the latest versions of files/documents.	X MS suite

Appendix E HAZARD IDENTIFICATION FORM AND OTHER SAFETY DATA

ME482 W21 Hazard Disclosure Form

Team Number[1]:	43
Project name:	Joint Effort
Project Title:	MR Compatible Wrist Loading Device
Brief Project Description: (2-3 sentences)	A device that can compressively load a given wrist (left/right) with positional accuracy and able for use within a MRI and/or MRI accessory coil.

Answer all the following questions. If unsure, answer yes. **If you answer yes to any question you need to attach your own page which provides a concise and quantitative description of the items, use, and safety measures for each item.**

	Hazard exists during:		
Hazard Classification	**Fabrication / Manufacturing**	**Symposium Demonstration**	**Usage - post Symposium**
1. Is electricity used for anything other than stand-alone unmodified computers?	yes ☐	yes ☐	yes ☐
2. Are any lasers used? See UW Laser Program.	yes ☐	yes ☐	yes ☐
3. Are any flashing or strobe lights used?	yes ☐	yes ☐	yes ☐
4. Are any lights brighter than a 60W bulb or 800 lumens?	yes ☐	yes ☐	yes ☐
5. Are there any radiation sources? See UW Radiation Safety.	yes ☐	yes ☐	yes ☐
6. Will there be any X-Rays emitted? See UW X-Ray Program.	yes ☐	yes ☐	yes ☐
7. Is there any combustion occurring?	yes ☐	yes ☐	yes ☐
8. Are any temperatures created above 45°C or below 10°C[2]	yes ☐	yes ☐	yes ☐
9. Are any compressed gasses used? See UW Compressed Gases.	yes ☐	yes ☐	yes ☐
10. Is there any significant stored energy (electrical, chemical, mechanical) in any component?	yes ☐	yes ☐	yes ☐
11. Are any chemicals used other than compressed gases described above? This includes gases, liquids, powders, and solids. See UW WHMIS. Attach MSDS sheets.	yes ☐	yes ☐	yes ☐
12. Are any nano-sized objects used or made? This would include materials that have external dimension less than 100nm.	yes ☐	yes ☐	yes ☐
13. Are there any biological components? This includes (both dead and alive): blood, tissue, fluids, parts, from any organism from bacteria to live humans, or live test subjects. See UW Bio-Safety.	yes ☐	yes ☐	yes ☐
14. Is any food for human or animal consumption used?	yes ☐	yes ☐	yes ☐

[1] Form based on MME Hazard Disclosure v2014-04-28
[2] https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/20100020960.pdf , accessed 190106

ME482 W21 Hazard Disclosure Form

15. Are any gases, particles, or fluids being ejected into the environment?	yes ☐	yes ☐	yes ☐
16. Are there any moving parts?	yes ☒	yes ☐	yes ☐
17. Is any component or the entire project heavier than 10kg ?	yes ☐	yes ☐	yes ☐
18. Can any part fly?	yes ☐	yes ☐	yes ☐
19. Can there be any projectiles?	yes ☒	yes ☐	yes ☐
20. Is any noise generated above normal speaking voice levels?	yes ☒	yes ☐	yes ☐
21. Do you know of or suspect there might be any other hazards?	yes ☐	yes ☐	yes ☐

Please write a concise and quantitative statement to describe each potential hazard and identify your proposed mitigation procedure for each item. Note that you should consider the following hierarchy of Hazard Control:

- Eliminate the hazard
- Substitute a less hazardous component or process
- Implement engineering controls to minimize the hazard
- Implement administrative controls to minimize the hazard
- Use appropriate Personal Protective Equipment (PPE)

"*The most effective way to deal with a hazard is to remove it*"

Item 16[3]:
Fabrication of the product will be done with plywood, so woodworking equipment will be used.
Mitigation of hazards: Wear appropriate PPE (safety glasses, gloves), avoid tampering with machinery/equipment, ensure emergency STOPS are always accessible and know where they are, work in a well ventilated region, inspect equipment prior to use.

Item 19[3]:
Small wooden/plywood parts may fly out.
Mitigation: Wear appropriate PPE and use equipment appropriately. No horsing around.

Item 20[3]:
Woodworking machinery may be loud.
Mitigation: Wear ear plugs.

Faculty Advisor: Prof. Stewart McLachlin

Date disclosure completed: Jan 20, 2021

Completed by: Kelly Hao, Michael Beals, Catherine Tsang

Signature:

[3] Insert the appropriate number corresponding to the hazard identification chart above

ME482 W21 Hazard Disclosure Form

Capstone from Home

Given the ongoing situation of the pandemic many groups will be forced to work on their capstone projects in less-than-ideal locations (homes, apartments, garages, basements, etc.). As a result, it is critical that you take additional safety precautions. These concerns are to ensure the safety of all group members during the manufacturing and presenting of your project. Fabrication concerns include (but are not limited to):

- **Working alone!** If the work being done has any potential for injury, before working alone consider the following questions.
  - Can a second person be safely nearby when working?
  - Does that second person know what you are working on, know your address, and can they call for help?
  - Can your work result in harm (especially if isolated)? Consider if you can be injured or incapacitated.
  - Is there a safer way of doing the specific task?

  Ensure that your evaluation of the hazards and your mitigation strategies are appropriate for your unique situations. Hands-on project work being done should not be in isolation. Ideally, a household member should be aware, and in the vicinity.

- **Ventilation.** If any products are being used that emit fumes (any fumes at all! Even non-toxic fumes displace oxygen) make sure that the work is performed in a well-ventilated area. Ideally, this would be done outside if weather permits, or in a garage with the door open.

- **Tools.** As the work you will be doing at home is unsupervised, please only use tools that you are familiar and comfortable with.

- **Electrical.** Be cautious of anything you are plugging into an electrical outlet. Electronics purchased should be certified for use in Canada (or the country you are working in). Even though your projects will not receive CSA inspection if you are modifying electrical components please follow the CSA certification guidelines.

Ontario has been put into a provincewide shutdown as of the start of the Winter 2021 term and has issued a stay-at-home order. The public health guidelines currently advise that people only interact with those in their household and only leave home for essential services (ex. grocery store, pharmacy, and medical services). If you live with the members of your capstone group, working together is within the guidelines of maintaining contact within your household. If you do not live with your group members, working together is not permitted by public health guidelines. If you are not in Ontario please follow the public health guidelines for your area.

In addition to the questions answered above please also include a page outlining your primary work location, tools to be used, and how you will maintain a safe working environment.

ME482 W21 Hazard Disclosure Form

Team Member	Primary Work Location	Tools Used	Maintaining a safe work environment
Kelly Hao	Home [redacted]	Home	- Practice appropriate COVID protocol, follow PHOs
Catherine Tsang	Home/Garage [redacted]	Woodworking equipment - Routers - Saws - Drills - General tools (screwdrivers)	- Practice appropriate COVID protocol, follow PHOs - Never work alone, make sure another member (that can help) always knows where you are - Only use tools you are familiar with, otherwise ask for help from a member (within core bubble) that has the knowledge
Michael Beals	Home/Garage [redacted]	Woodworking equipment - Routers - Saws - Drills - General tools (screwdrivers)	- Practice appropriate COVID protocol, follow PHOs - Never work alone, make sure another member (that can help) always knows where you are - Only use tools you are familiar with, otherwise ask for help from a member (within core bubble) that has the knowledge