# A Device for Quantitative Assessment of Thumb Ulnar Collateral Ligament Injury

by

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B.S. Mechanical Engineering
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Submitted to the Department of Mechanical Engineering
in partial fulfillment of the requirements for the degree of

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## Abstract

Injury to the Ulnar Collateral Ligament (UCL) of the thumb, known as "Skier's Thumb," is treated by surgical repair for complete tears, or by splinting for partial tears. Because of this radical difference in treatment options, diagnostic accuracy is critical. The primary mechanism of diagnosis is through a clinical assessment of joint integrity. This method requires a high degree of examiner skill and experience, and is inherently qualitative. Secondary diagnosis through magnetic resonance imaging (MRI) is often required to ensure accurate diagnosis. This additional testing delays the treatment and adds to the cost of care. A method to quantitatively assess the thumb UCL in a clinical setting is desired.

This thesis presents the deterministic design of a device to quantitatively measure the stiffness of the thumb UCL. A stepper motor is used to rotate the thumb, while a cantilever load cell is used to measure torque. The device is designed to be operated by the physician, and has alignment features to properly orient the motor axis of rotation. Several safety features were incorporated into the device, including a magnetic breakaway that prevents applied thumb force from exceeding 10 N. The prototype was constructed, and preliminary testing was performed on healthy human subjects. Peak thumb torque was measured at $213.5 \pm 19.2$ N-mm, and peak stiffness was calculated to be $4.70 \pm 0.39$ N-mm/degree. Potential pathways for further device testing and improvement are outlined. The Thumb UCL Device has the potential to improve the speed of injury diagnosis and reduce the need for imaging studies.

Thesis Supervisor: Alexander Slocum
Title: Walter M. May and A. Hazel May Professor of Mechanical Engineering

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# Chapter 1

# Background

## 1.1 Anatomy of the Thumb

The bones of the thumb include the first metacarpal, proximal phalanx, and distal phalanx. The thumb articulates with the carpal bones of the wrist via the carpo-metacarpal (CMC) joint. The metacarpo-phalangeal (MCP) joint is located between the first metacarpal and the proximal phalanx. Movements of the thumb include flexion, extension, abduction (moving away from the fingers), adduction (moving towards the fingers), and opposition (moving across the palm).

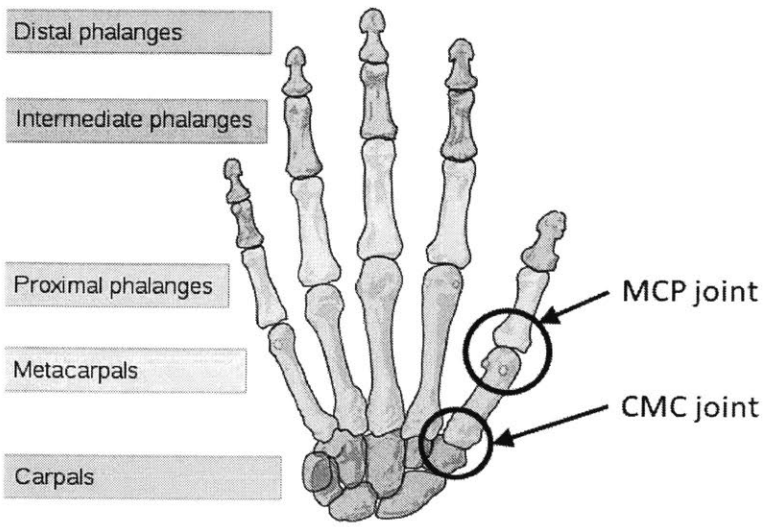


Figure 1-1: Bony anatomy of the hand [25]

The thumb ulnar collateral ligament (UCL) is located at the MCP joint. As shown in Fig. 1-2, it attaches to the first metacarpal and proximal phalanx, oriented roughly longitudinally. The UCL is located on the ulnar side of the thumb (towards the fingers); a corresponding radial collateral ligament is located on the opposite side. Of note, there are ulnar collateral ligaments located elsewhere in the body (i.e. fingers, elbow). Any mention of the UCL without a qualifier is intended to refer to the thumb UCL.

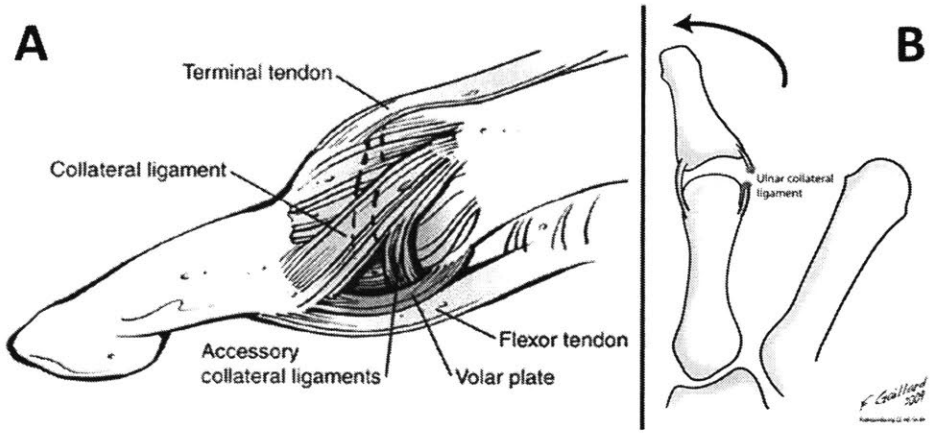


Figure 1-2: A) Detailed view of the UCL [8]; B) Drawing of a torn UCL [7]

## 1.2 Injury of the Thumb UCL

Injury to the thumb UCL is commonly known as "Skier's Thumb" due to a high incidence among skiers. This injury represents 5-10% of all skiing injuries [12], and is the second most common ski injury overall (behind knee injuries) [10]. Overall, roughly 200,000 cases per year of thumb UCL injury are estimated to occur in the US [16].

The most common mechanism of UCL injury is sudden, forceful abduction of the thumb, such as falling on an outstretched hand while grasping a ski pole. Many other sports also have high risk for UCL injury, such as football, basketball, and hockey [14]. Chronic repetitive strain of the ligament can also result in injury; historically, the injury was referred to as "Gamekeeper's Thumb" because the motion used to

snap the necks of game birds would frequently cause this injury over time [22]. The severity of injury can vary from a partial tear to complete rupture of the ligament.

### 1.2.1 Diagnosis

#### Physical Exam Technique

The diagnosis of Skier's thumb begins with a direct physical exam by a hand surgeon. The physician stabilizes the metacarpal while applying a radial stress to the thumb. The variables assessed during this test are 1) maximum joint angle, and 2) end-point stability. The joint angle is measured between the metacarpal and proximal phalanx of the thumb; an absolute angle of $30^o$, or 15-$20^o$ greater than the non-injured thumb, is indicative of a tear [24]. The end-point stability is determined through tactile feedback; a "hard" endpoint at maximum displacement indicates an intact ligament, while a "soft" endpoint indicates a tear [18]. This determination is inherently qualitative; no quantitative measure for assessing end-point stiffness currently exists.

#### Imaging

X-ray images of the thumb are obtained for all patients with suspected UCL injury. They are often taken before physical examination to rule-out any avulsions[1], which could be exacerbated by the physical exam technique described above.

If the physical exam cannot definitively distinguish a full vs partial tear, MRI is used as the gold standard for diagnosis. MRI has been shown to have >90% sensitivity and specificity for identifying tears of the UCL [21]. However, MRI is expensive and exposes the patient to radiation, and generally not indicated unless the physical exam cannot definitively distinguish between a full and partial tear.

Ultrasound imaging can be used as a faster, less expensive alternative to MRI. However, the sensitivity and specificity are 76% and 81%, respectively, for diagnosing UCL tears [6].

[1]An avulsion is a piece of bone at the base of a ligamentous attachment that fractures due to ligament injury

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# Chapter 2

# Design Process

## 2.1 Motivation

The topic of this thesis was motivated by a project form the Fall 2016 course "Medical Device Design (2.75)". In this course, physicians present a clinical problem from their practice to a group of engineers, who form teams and spend a semester designing a solution. Dr. Jay Connor, a hand surgeon, initially proposed the problem of diagnosing injury to the thumb UCL. A team of four students [1] were assigned to this project; the author served as a engineering and clinical mentor, as well as the Teaching Assistant for the course. The class culminated with a $\alpha$-prototype, which performed successfully in preliminary testing.

The project is continued in this thesis, with the goal of producing a $\beta$-prototype consisting of iterative design improvements, and performing initial human subjects testing to assess the clinical feasibility. The project also affords an opportunity for the author to combine engineering fundamentals with clinical perspective, to produce a working mechanical prototype ready for in-depth clinical assessment.

[1] Team members were Woojeong Elena Byun, Ava Chen, Kristina Kim, and Kaitlyn Nealon. The mentorship team consisted of Thomas Cervantes, Daniel Teo, Tyler Wortman, Alexander Slocum, and Dr. Jay Connor.

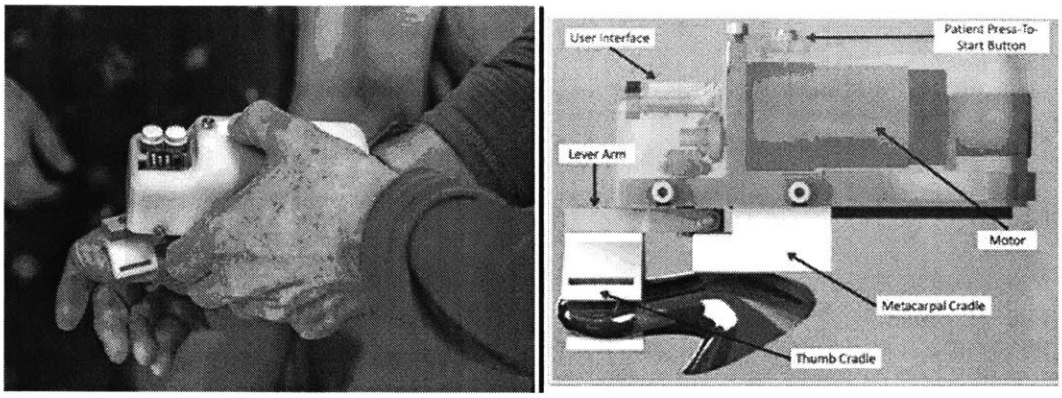


Figure 2-1: $\alpha$-prototype of the Thumb UCL Device

## 2.2 $\alpha$-Prototype

The $\alpha$-prototype designed as part of the 2016 2.75 course is shown in Fig. 2-1. The device uses a gearmotor with a $90^o$ bevel gear train to apply a torque to the thumb. Thumb angle is measured with an encoder, and torque is calculated from the motor current. Preliminary testing on a simulated thumb MCP joint showed reliable detection of differences in stiffness. For further details, see Appendix A for a conference paper that describes the device (accepted by the 2018 Design of Medical Devices Conference). Testing of the $\alpha$-prototype highlighted a number of opportunities for improvement:

- The size and weight was cumbersome for many to use
- The orientation of the hand used to operate the device was uncomfortable
- The data recorded during testing could not be easily exported
- Securing the thumb in the cradle was difficult
- Switching the thumb cradle from left to right was time consuming
- The motor control algorithm was jerky and unpredictable

These observations provided a helpful starting point for the design of the $\beta$-prototype. Although many design features were kept, a re-evaluation of the higher-level strategies was conducted for thoroughness.

## 2.3 Functional Requirements

A deterministic design process was used throughout the project to evaluate design decisions. The first step was to define the functional requirements of the device, which are the minimum set of conditions that must be satisfied for the solution to be successful. At the beginning of the $\beta$-prototype design process, these functional requirements were reevaluated and adjusted based on the preliminary testing from the 2.75 project. Table 2.1 shows the updated list.

Table 2.1: Functional Requirements for the Thumb UCL Device

| Functional Requirement | Description |
|---|---|
| **1. Accurately & reliably quantify UCL injury** | |
| • Measure thumb angle | |
| • Measure thumb torque | Torque & angle used to calculate stiffness |
| • Stable interface to hand | Avoid misalignments that may skew data |
| • Examiner independent | Should be an improvement over the current examiner-dependent process |
| **2. Easy to use** | |
| • Ergonomic operation | Comfortable for a wide range of users & patients |
| • Easily switch between left/right | |
| • Minimal size & weight | $\alpha$-prototype testing indicated that the bulky size and heaviness impeded proper use |
| **3. Safe** | |
| • DOES NOT increase damage to UCL | |
| • Simple to turn off | "Dead-man's switch" to turn off if not actively controlled |
| • Biocompatible materials | |
| **4. Feasible for clinical use** | |
| • Fits into clinical workflow | Does not require significant time, resources, or training to implement |
| • Cost appropriate | Components do not prohibit appropriate pricing |

## 2.4 Prior Art

Another important aspect of a deterministic design process is a thorough investigation into the prior art. In addition to researching the clinical background & context, devices that aim to solve the same problem (or similar) should be sought and evaluated. This section highlights some devices found during review of the academic and patent literature that proved relevant for this project.

In one study, a soft actuator was used in a device for thumb rehabilitation after stroke [15]. The actuator, which was controlled by varying pressure, aimed to mimic a natural movement of the thumb by combining flexion, rotation, and skin stretching. The device was attached to the hand via malleable aluminum straps, secured by Velcro. The soft actuator is a useful design parameter for achieving natural, multi-axis motion; however, it is less applicable for the Thumb UCL device because highly constrained motion in one plane is desired. The malleable aluminum attachment mechanism allows a high degree of customization per patient, and could perhaps achieve better orientation & stabilization than the cradle method used in the $\alpha$-prototype.

Another study used a custom wrist orthosis to measure the torque required for passive abduction of the thumb CMC joint (proximal to the MCP joint) [27]. The orthosis was comprised of an aluminum base frame, with linkages used to position an external torque measurement device (CDI Multitorq) over the joint. The thumb was manually actuated by the investigators. The external torque measurement was an interesting design parameter for obtaining reliable, accurate torque measurements. Similarly to [15], the aluminum frame/linkages provides a high degree of customization per patient. However, adjusting the device for each patient might prove tedious and cumbersome. The external measurement device is also expensive, and could prove difficult to integrate into a streamlined solution.

In another soft robotic device, strain gauges were used to measure the flexion angle of the ankle [20]. The application required measurement of large strains over a flexible surface, so a custom solution was designed using micro-channels of a liquid

metal alloy embedded within a silicone elastomer. This design parameter could prove useful for this application at the Thumb MCP joint; however, the cost and resources of building the custom sensor could prohibit production scaling.

## 2.5 Ligament Biomechanics

A primary functional requirement for the Thumb UCL Device is to avoid further damage to the ligament during testing. An analysis of the forces acting on the joint was conducted to approach the problem in a deterministic manner. Figure 2-2 shows a force diagram of the thumb MCP joint. The MCP is modeled as a pinned joint with a fixed base. The UCL inserts along the proximal phalanx of the thumb at a distance, $L$, from the center of rotation, and at an insertion angle of $\alpha$. From this representation a force balance can be constructed to determine the maximum allowable motor torque, $\tau_{motor}^{max}$, as shown in Eq. 2.2-2.4:

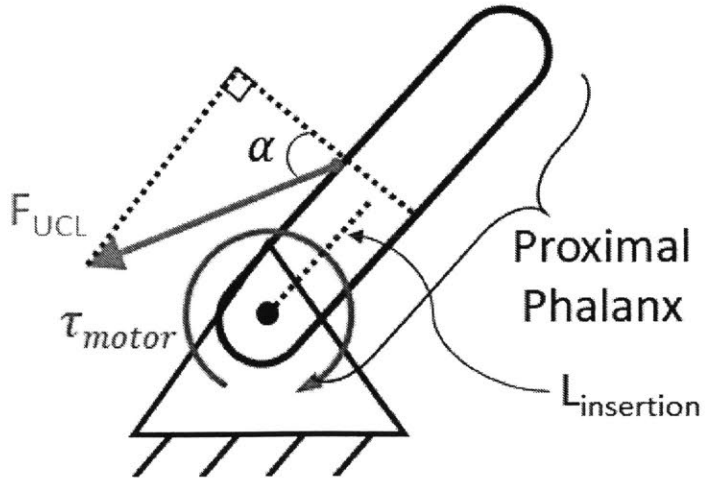


Figure 2-2: Diagram of the forces acting on the thumb UCL

$$\tau_{motor}^{max} = F_{max} * \cos(\alpha) * L \tag{2.1}$$

$$\sigma_{max} = \frac{F_{max}}{A} \tag{2.2}$$

$$F_{max} = \sigma_{max} * A \tag{2.3}$$

$$\boldsymbol{\tau_{motor}^{max} = \sigma_{max} * A * L * \cos(\alpha)} \tag{2.4}$$

$F_{max}$ is the maximum force on the UCL; $\sigma_{max}$ is the failure stress of the UCL.

Equation 2-2 was used to create a design spreadsheet for calculating a target motor torque. A stiffness of 81 N/mm was calculated for an average intact UCL using values published in the literature. If a ligament is 50% torn, an maximum of 288 N-mm can be applied before risking further injury. The true value is likely larger due to conservative estimates for ligament insertion length and angle, which were not found in literature.

Table 2.2: UCL Biomechanics Calculations

| **UCL Stiffness Estimations** | | | |
|---|---|---|---|
| Parameter | Value | Units | Notes |
| Young's modulus | 37.3 | $N/mm^2$ | [11] |
| Diameter | 6 | $mm$ | [26] |
| Area | 28.3 | $mm^2$ | |
| Length | 13 | $mm$ | [26] |
| **Stiffness** | **81.1** | $N/mm$ | $K = \frac{AE}{L}$ |
| **Maximum Torque Estimation** | | | |
| Failure load | 266 | $N$ | [26] |
| Failure Stress | 9.4 | $N/mm2$ | |
| UCL insertion length | 4 | $mm$ | estimate 1/3 of length |
| UCL insertion angle | 60 | $^o$ | conservative estimate |
| **Torque Limits** | | | |
| Area (% max) | Max Torque (N-mm) | | |
| 100 | 576 | | |
| 75 | 432 | | |
| 50 | 288 | | |
| 25 | 144 | | |
| 10 | 58 | | |

Another primary functional requirement for the device is to accurately quantify UCL injury. Thumb torque and angle are used to calculate the stiffness of the MCP joint as a surrogate for stiffness of the UCL. However, a possible source of error is "parasitic" stiffness due to swelling from an acute injury. The effect of a parasitic stiffness is analyzed below.

The total stiffness of a healthy and torn MCP joint are defined as:

$$K_{healthy} = K_{skin} + K_{muscle} + K_{UCL} \tag{2.5}$$

$$K_{tear} = K_{skin} + K_{muscle} + (1 - \gamma) * K_{UCL} + K_{swell} \tag{2.6}$$

$K_{healthy}$ is the total stiffness of a healthy MCP joint; $K_{skin}$ is the stiffness of the skin surrounding the joint; $K_{UCL}$ is the stiffness of a healthy UCL; $K_{swell}$ is the stiffness from joint swelling; $\gamma$ is the percent tear of the UCL.

Patients with a thumb UCL injury can be expected to have a healthy thumb for comparison on the opposite hand. Thus, a calculation of the percent difference between healthy and injured thumbs, $\%\Delta$, can be performed and used to solve for the percent tear of the UCL:

$$\%\Delta = \frac{K_{healthy} - K_{tear}}{K_{healthy}} = \frac{\gamma K_{UCL} - K_{swell}}{K_{healthy}} \tag{2.7}$$

$$\gamma = \frac{\%\Delta * K_{healthy}}{K_{UCL}} + \frac{K_{swell}}{K_{UCL}} \tag{2.8}$$

Equation 2.8 demonstrates that parasitic stiffness from joint swelling is a potential risk to accurate measurement of UCL tears. Additionally, the stiffness of a healthy UCL ligament is needed; although the stiffness was calculated in Table 2.2, the standard variation in the population is unknown. As a countermeasure to this problem, cadaver studies are needed to determine the full range and population statistics of UCL stiffness values, and the parasitic stiffness associated with joint swelling.

## 2.6 Market Assessment

Perhaps one of the most challenging aspects of medical device design is the need to understand the regulatory and reimbursement pathways unique to the field. Often, the person who uses the device (the physician) is different from the person purchasing the device (the hospital/clinic); the person benefiting from the device (the patient) is different from the person paying for it (the insurance company). The incentives of each stakeholder are not necessarily aligned, and the true cost is frequently obscured from multiple parties.

The proposed Thumb UCL device has an interesting value proposition; it aims to provide benefit by improving speed of diagnosis, and reducing need for MRI imaging. As a patient and physician, both of these are desirable. As organizational entity (i.e. hospital), the benefits are less clear; improving the speed of diagnosis could increase the quantity and frequency of surgical procedures, which are often profitable. However, reducing the need for MRI means that this cannot be billed to the insurance (some healthcare organizations use imaging centers as a means for building revenue [13]).

From the perspective of insurance and reimbursement, the device could save money by decreasing payouts for imaging. The device introduces a new procedure to the clinical encounter; a new CPT[2] code would need to be created in order to bill for it. Many new medical devices seek this route, but the process takes time and resources.

These considerations were further researched and incorporated into a spreadsheet, shown in Table 2.3. The total cost burden of hand MRIs ordered for indeterminate physical exam testing is on the order of $30 million. This could represent a savings opportunity for payers. If the device was sold to all hand surgeon practices in the US, at a price of $500, the total market opportunity is in the range of $310,000. This number represents a lower bound, as other healthcare organizations besides hand surgery clinics may find utility in the device (emergency departments near ski areas, family practice/sports medicine clinics). Although the scope for market expansion

[2]CPT = Current Procedural Terminology. CPT codes are used to define different medical services for billing purposes.

Table 2.3: Market Analysis for a Thumb UCL Diagnostic Tool

| Parameter | Value | Notes |
|---|---|---|
| Hand surgeons in the US | 3100 | [1, 23] |
| Estimated #surgeons/practice | 5 | likely to vary widely |
| **Hand Practices (US)** | **620** | |
| UCL injuries/year (US) | 200,000 | [16] |
| Rate of diagnostic difficulty | 27% | [17] |
| Patient candidates for device | 54,000 | (per year) |
| per surgeon | 17.4 | |
| per practice | 87.1 | |
| Hand MRI Cost: | | [3] |
| nominal | $630 | |
| min | $504 | |
| max | $1,575 | |
| **Total Potential cost burden** | | (per year) |
| nominal | **$34.0M** | |
| min | $27.2M | |
| max | $85.1M | |
| Theoretical CPT fee ratio | 10% | compared to MRI fee, conservative estimate |
| CPT Fee per procedure | $63 | |
| Theoretical cost of device | $500 | |
| # patients to recoup cost | 7.9 | |
| Market opportunity | $310K | if sold to practices |

is limited, there is currently no direct competition in the space. However, there is support from current hand surgeons (including Dr. Conner, the project proposer) for development of the device as a useful clinical tool. In contrast, the following section describes a case study where preliminary market research showed promise, but interviews with physicians indicated an unfavorable outlook.

## Case Study: Fetal Laceration Analysis

Initial work for this thesis was focused on an opportunity to reduce fetal laceration injuries during Cesarean-section, motivated by clinical observations. Accidental fetal lacerations can occur when the uterus is incised by a scalpel blade; if the surgeon uses too much force while cutting, the fetus can be inadvertently harmed once the blade has passed through the uterine wall. Risk of this injury is increased if the C-section is

Table 2.4: Market Analysis for a Fetal Laceration Prevention tool

| Parameter | Value | Notes |
|---|---|---|
| # births/year (US) | 3,988,076 | 2014 census data [19] |
| # C-sections/year | 1,284,551 | 2014 CDC data [19] |
| Rate of emergent C-sections | 9.5% | [29] |
| Fetal laceration rate (all) | 1.1% | |
| Fetal laceration rate (emergent) | 3.0% | [9] |
| Lacerations/year (all) | 14,130 | |
| Lacerations/year (emergent) | 3661 | |
| Serious complication rate (%) | 0.062 | moderate to severe [9] |
| **Serious complications/year** | | |
| lower bound | 226 | |
| upper bound | 874 | |
| **average** | **550** | |
| # hospitals performing obstetrics | 3760 | estimate 2/3 of all hospitals [5, 30] |
| Malpractice costs per complication | $500,000 | [2] |
| Total cost for laceration lawsuits | $275M | per year |
| **Risk per hospital** | **$73,170** | |
| Risk per C-section (all) | $214 | |
| Risk per C-section (emergent) | $2,254 | |
| CSAFE cost | $28 | |
| Market opportunity (emergent) | $3.4M | per year |

performed on an emergent basis, where stress is often high and there is time pressure to complete the delivery.

When searching for prior art during the early design phase, a seemingly simple, low-cost, and effective solution was identified. However, the device (CSAFE) had not gained much traction with obstetricians (OB-GYNs). A market analysis, shown in Table 2.4 was performed to determine feasibility; up to 550 serious complications from fetal lacerations may occur per year, and on average each hospital faces a risk of $70,000 per year from lawsuits. This corresponds to a risk of $2,200 per emergency C-section. These numbers are conservative estimates, drawn from available literature sources; however, the true rate of fetal lacerations is likely larger, since hospitals are not incentivized to publish data about their complications.

Initially, the market assessment pointed to a favorable opportunity; hospitals stood to lose a nontrivial amount of money due to fetal lacerations. Furthermore, the

CSAFE device retailed at $28, only 10% of the risk per emergent C-section. However, discussions with several OB-GYN physicians revealed factors which may have hindered its adoption as a preventative measure.

While physicians acknowledged that fetal lacerations are a problem, they did not consider themselves (or their hospitals) to be at risk. One physician pointed out that the highest risk is likely at low-volume centers, where C-sections are performed less frequently, and fewer resources may be available in case of emergencies. Ultimately, a different project (the Thumb UCL device) was pursued instead due to lack of interest from a primary stakeholder.

## 2.7 Strategies & Concepts

Design of the Thumb UCL Device was conducted using a coarse-to-fine methodology. High-level strategies and concepts were evaluated based on the functional requirements, first-principle analysis, literature review, and a comparison of risks & countermeasures before conducting more detailed engineering design. For the $\beta$-prototype design phase, the primary high-level strategy that was reevaluated was active vs passive torque application.

The original decision for an active torque application solution (i.e. motor) was made based on the recommendation of the physician who proposed the project. The primary advantage of this approach is simple, streamlined operation from the user perspective. Engineering challenges include component integration and ensuring smooth, safe motor control. A potential risk is the addition of expensive components (motor & associated driver), which could prohibit appropriate pricing.

A passive actuation strategy (i.e. doctor moves the thumb) has some distinct advantages; there is reduced risk of over-torquing the thumb, since the physician can use tactile feedback to control thumb rotation. The cost is potentially reduced since an actuator component is not needed. However, a passive strategy would require an elaborate fixation device, similar to the design in [27], that would increase the set-up time and training needed for operation. Ultimately, an active actuation strategy was

chosen for the purposes of this thesis. However, a passive alternative could be a viable alternative if the cost of an active device proves unfeasible.

At a concept level[3], the primary design change considered was patient vs physician control of the device. The $\alpha$-prototype was designed for patient control with the aim of providing an additional measure of safety; the patient can immediately stop the device if the rotation becomes too painful. A risk for this approach is that the patient does not properly orient the device on the thumb, which could skew the data. A possible countermeasure would be to design a fixturing jig for the hand to ensure that the patient maintains proper positioning throughout the procedure.

A physician-operated approach would reduce the risk of improper device orientation; a hand surgeon could easily identify the relevant anatomical landmarks and position the device appropriately. However, patients may feel apprehensive if their injured thumb is being moved by a motor without their control. After considering both approaches, a physician-operated device was ultimately chosen. Countermeasures to reduce the risk of patient injury & discomfort were factored into the design of several components, as described in Chapt. 3.

[3]Here, a "concept" is defined as more granular than a strategy. In order from coarse to fine: Strategy > Concept > Module > Component.

# Chapter 3

# Device Description

## 3.1 Overview

The redesigned Thumb UCL device is shown in Fig. 3-1. The device is operated by the physician, and controlled through a button mounted on the top of a vertical handle. A direct-drive stepper motor is used to actuate a load cell, which measures the torque being applied to the thumb. The thumb is held in a magnetically-attached cradle, which is designed to break-away at 10N of force. During testing, real-time data is transmitted wirelessly via Bluetooth to a nearby phone or computer. Part drawings for all custom components are included in Appendix B.

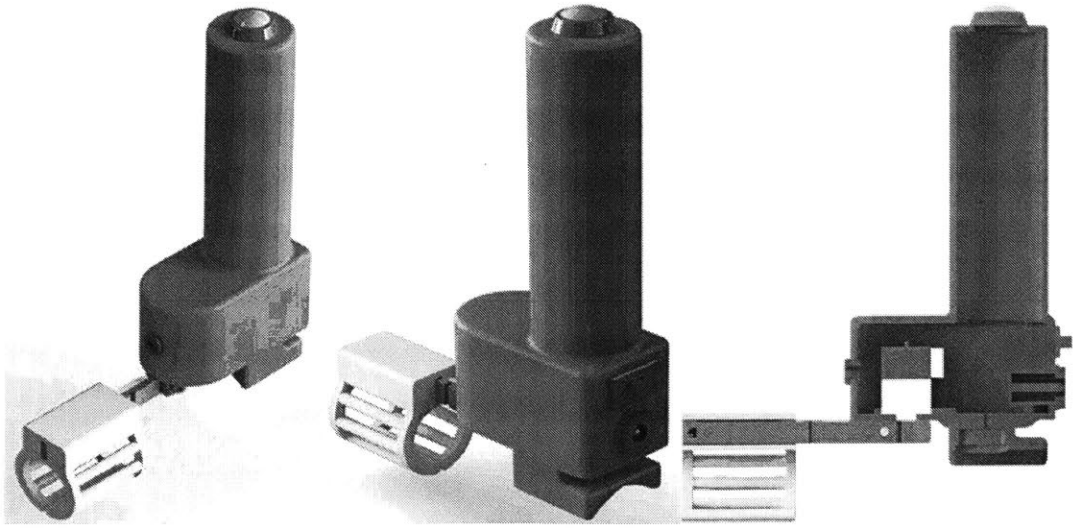

Figure 3-1: CAD Renderings of the full Thumb UCL Device

## 3.2 Torque Application

One of the critical modules focused on for re-design was the motor; in $\alpha$-prototype, the motor was principle driver of the overall dimensions. The Pololu gearmotor used had a stall torque of 1765 N-mm, with dimensions of 37Dx52Lmm. Based on calculations from Section 2.5, the torque specification is much higher that is necessary, or safe. At a minimum, the motor needs to apply enough torque to evaluate the linear stiffness of the joint. At a maximum, the applied load should not exceed the yield stress of the ligament, especially when partially torn. Based on calculations in Table 2.2, a conservative torque maximum of 150 N-mm was chosen; this would avoid risk of further ligament injury for tears up to 75% surface area.

In addition to downsizing the motor torque and dimensions, the motor type was considered. For this application, the motor needs to operate at slow speeds on the order of 1rpm or less, with high resolution. Full, continuous rotation is not required. A servomotor or Stepper motor are well-suited for these criteria. Motor catalogs were searched with these parameters, while optimizing for the the smallest possible dimensions.

Ultimately, the NMB PG15S Stepper motor, shown in Fig. 3-2, was chosen for its small size and peak hold torque of 150 N-mm. The motor operates at 15V, with a current rating of 100mA. The motor also has high step resolution, with 2048 steps per revolution.

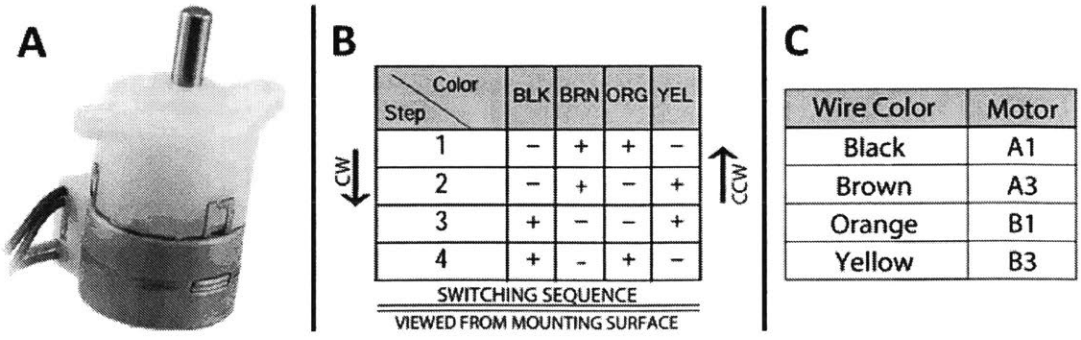


Figure 3-2: A) NMB PG15S stepper motor; b) Switching logic; C) Wire color coding

A concern of using this motor is that the calculated torque limit is too low; a

maximum of 150 N-mm is based on the yield stress of the UCL ligament. However, other structures in the thumb contribute to stiffness about the MCP joint, as described in Section 2.5. To account for this possibility, a larger motor in the same family was evaluated. The Minebea PG25L stepper motor has a holding torque of 450 N-mm and a modest size increase (25mm diameter vs 15mm).

The remainder of this section discusses design of components to interface with the smaller 150 N-mm motor. The corresponding components for the larger motor were also designed in parallel, using the scaling ability of the deterministic design process.

## 3.3 Torque Measurement

The decision to use a stepper motor necessitates a change in torque measurement technique. In the $\alpha$-prototype, torque was derived from motor current measurements. However, a stepper motor draws full current continuously. A direct method of torque or force measurement is needed.

Strain gauges were investigated as a possible design parameter for this functional requirement. Advantages of this approach include a small form factor, and the flexibility to design custom shapes. A primary risk is the low signal amplitude derived from a strain gauge sensor; the required amplification can result in a low signal-to-noise ratio.

An analytical approach was used to determine if a feasible strain gauge configuration could be achieved given the constraints of the system. Equation 3.3 shows the relationship between the output voltage of the strain gauge and the relevant parameters:

$$V_{out} = \frac{1}{2} G * \epsilon * V_{ex} \tag{3.1}$$

$$\epsilon = \frac{6M}{Ebh^2} \tag{3.2}$$

$$V_{out} = \frac{3G}{Ebh^2} M * V_{ex} \tag{3.3}$$

Table 3.1: Strain Gauge Analysis

| Parameter | Value | Units |
|---|---|---|
| Modulus (steel) | 200 | $GPA$ |
| Yield Strength (steel) | 1105 | $MPa$ |
| Beam width | 7 | $mm$ |
| Beam height | 0.8 | $mm$ |
| Gauge factor (constantan) | 2 | N/A |
| Resistance | 1000 | $Ohms$ |
| Excitation voltage | 15 | $V$ |
| Applied moment (max) | 150 | $N-mm$ |
| Desired ADC voltage | 5 | $V$ |
| **Output Voltage (max)** | **14.7** | $mV$ |
| **Resolution** | **10.2** | $N-mm/mV$ |
| **Bending Stress** | **201** | $MPa$ |
| **Required Amplifier Gain** | **340** | $N/A$ |

$V_{out}$ is the output voltage from the strain gauge circuit, $G$ is the Gauge factor (specific to the material used, typically Constantan), *epsilon* is the strain experienced from an applied moment, $M$; $V_{ex}$ is the excitation voltage; $E$ is the Young's modulus of the beam material; $b$ is the beam width, $h$ is the beam height.

A design spreadsheet was created using this equation. The maximum possible $V_{out}$ is desired; a value of $150N-mm$ was used for the applied moment based on the peak holding torque of the NMB stepper motor. Table 3.1 shows a feasible configuration that was determined.

A small beam width of 0.8mm is needed to achieve a feasible amplifier gain. With a beam this thin, plastic yielding of the material is a significant risk - with a bending stress of 201 MPa, a hardened material such as 17-4 PH stainless steel is needed, and an aluminum alloy would not be usable. However, the design table demonstrates that the strain gauge strategy is overall feasible.

A cantilever load cell from Futek (FSH00889), shown in Fig. 3-3, was selected to meet these strain gauge criteria. The load cell has an integrated Wheatstone bridge, and an overall size that integrates well with the rest of the device.

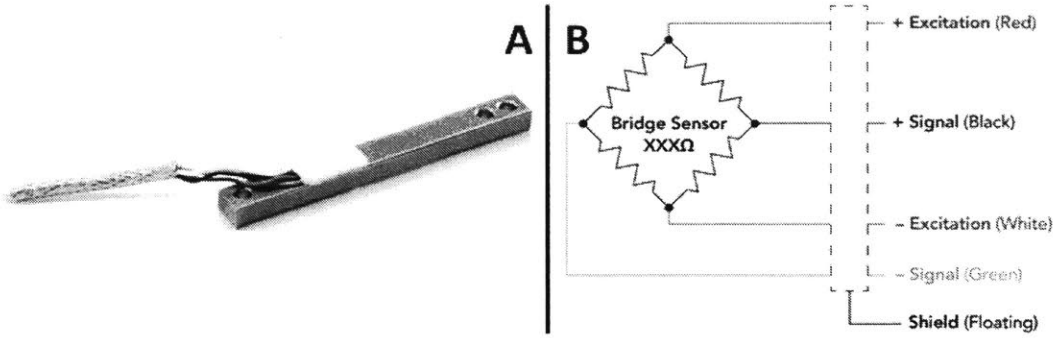


Figure 3-3: A) Futek cantilever load cell; B) Wheatstone bridge wiring diagram

## 3.4 Thumb Interface

### 3.4.1 Thumb Cradle

The thumb cradle interacts with phalanges of the thumb to transfer the motor torque to the MCP joint. The $\alpha$-prototype thumb cradle consisted of a semicircular shape that was attached to the device via screws, and secured to the thumb using Velcro. To switch between right- and left-handed operation, the cradle had to be unscrewed and flipped in a cumbersome, time-consuming process. The thumb cradle was redesigned to improve upon this feature, while maintaining patient safety.

A magnetic breakaway concept for the thumb cradle attachment was explored and implemented. Figure 3-4 shows CAD renderings of the design. Neodymium magnets are used to attach the thumb cradle to the stainless steel load cell. With embedded magnets, the thumb cradle is easy to attach/detach, which facilitates easy swapping of different sizes. Bilateral cradles are used to obviate the need for different left/right configurations. Additionally, the magnets serve as a torque "fuse"; if the applied force exceeds a predetermined threshold, then cradle will detach. In this way, the magnetic breakaway concept satisfies multiple functional requirements; it provides a mechanism for patient safety, and it allows for simple attachment/removal.

The dimensions of the thumb cradle are driven by the load cell size and by ergonomic principles. The "semicircle" is actually an ellipse with the major and minor radii set based on anthropometric tables [28]. Initial prototyping was done using the average of the $50^{th}$ percentile male and female dimensions. The prototypes were able

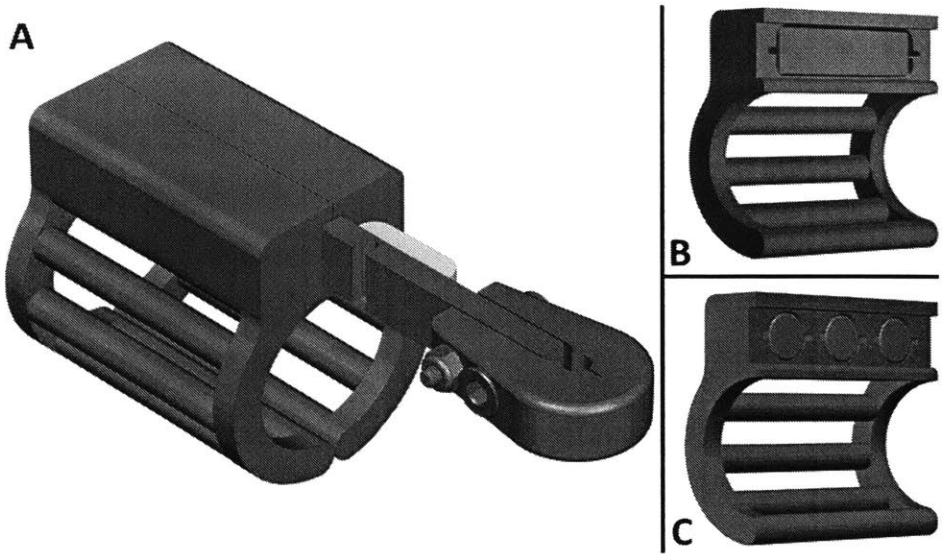


Figure 3-4: Thumb Cradle with a magnetic breakaway design. A) Thumb cradles attached to the Futek load cell; B) Square magnet version; C) Round magnet version

to accommodate the test subject sample used in this study. The CAD model of the thumb is constructed such that the ellipse dimensions can be modified with minimal reconfiguration needed in the rest of the body, as shown in Fig. 3-5.

Several rounds of design iteration were employed before converging on the final thumb cradle configuration. Figure 3-6 shows different stages of the cradle design. Initially, the magnets were designed to attach from the top, and a symmetric design would be used to eliminate the need for left/right switching (Fig. 3-6A). However, the magnets are oriented such that applied force is perpendicular to the magnetic force; the cradle would "slide" off of the device. This poses a difficult analytical scenario, as magnets are typically rated for perpendicular pull force only. Although an acceptable configuration could be determined through brute-force prototyping, a closed-form analytical model is desired.

The next iteration (Fig. 3-6B) used magnets that were oriented parallel to the direction of force application, which would adhere to the model in Fig. 3-7. However, Velcro was still needed to secure the thumb to the cradle, a step that is ideally eliminated. The final semi-circular configuration (Fig. 3-6C) removes the Velcro requirement, but does pose the risk of sizing mismatches for very large or small thumbs. As a countermeasure, multiple sizes (small, medium, large) could be provided

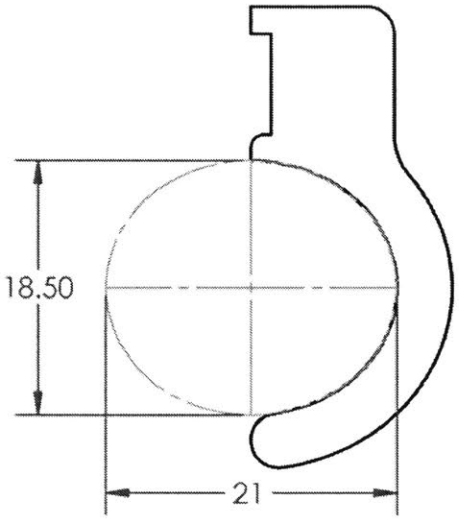


Figure 3-5: Drawing of the thumb cradle showing the ellipse used to drive the overall dimensions based on anthropometric data

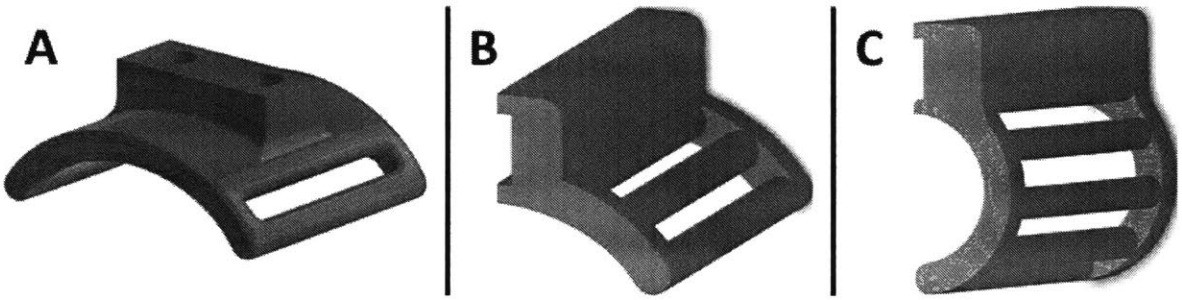


Figure 3-6: Design evolution of the thumb cradle

to the user. The design spreadsheet for selecting the magnets easily accommodates these changes.

### Magnetic Breakaway Force Analysis

As with all engineering modules, the FRDPARRC approach was used to guide deterministic selection of the magnets for a desired breakaway force. Figure 3-7 shows the forces acting on the thumb cradle. The applied force of the motor acts through the center of the cradle, where the midline of the thumb is in contact. The magnetic force acts through the midline of the magnets, oriented perpendicular to the face of the load cell. Gravity acts on the center-of-mass of the cradle, which can be determined from the solid model.

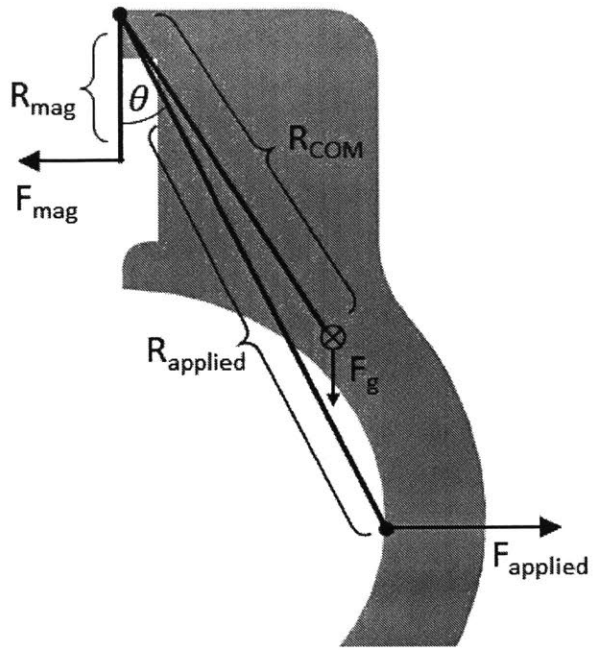


Figure 3-7: Force Diagram of the Magnetic Break-Away Concept

In this diagram, the top-left corner of the thumb cradle is the rotation point. A simple force balance can then be used as shown in Eq. 3.4:

$$F_{mag}R_{mag} = F_{app}R_{app}\cos(\theta_{app}) + F_gR_{COM}\sin(\theta_{COM}) \tag{3.4}$$

$$F_{mag} = (1/R_{mag}) * [F_{app}R_{app}\cos(\theta_{app}) + F_gR_{COM}\sin(\theta_{COM})] \tag{3.5}$$

$$F_{mag} = S_F(1/R_{mag}) * [F_{app}R_{app}\cos(\theta_{app}) + F_gR_{COM}\sin(\theta_{COM})] \tag{3.6}$$

$F_{mag}$ is the holding force of the magnet(s), $R_{mag}$ is the distance between the rotation point and center of magnetic force application, $F_{app}$ is the applied force on the thumb (from the motor); $R_{app}$ is the distance between the rotation point and the center of applied force; $\theta_{app}$ is the angle of applied force (relative to vertical; $F_g$ is the force due to gravity, $R_{COM}$ is the distance between the rotation point and the center of mass; $\theta_{COM}$ is the angle of the center of mass (relative to vertical); $S_F$ is the shape factor.

A design spreadsheet was then constructed to evaluate magnets with a range of sizes and shapes. Table 3.2 shows the results for some of the magnets tested. Preliminary testing with the D42SH magnet revealed a breakaway force of roughly 5

Table 3.2: Thumb Cradle Magnetic Breakaway Analysis

| **Magnet Details** (supplier: K&J Magnetics) | | | |
|---|---|---|---|
| Magnet Name | D42SH | D44-N52 | BX044-N52 |
| Pull force (N) | 10.2 | 18.5 | 72.4 |
| Diameter (mm) | 6.35 | 6.35 | 6.35 |
| Thickness (mm) | 3.2 | 6.4 | 6.4 |
| Weight (gm) | 0.754 | 1.51 | 7.68 |
| **Thumb Cradle Details** | | | |
| Moment arm (mm) | 23.09 | 23.09 | 23.09 |
| Angle (degrees) | 27.0 | 27.0 | 27.0 |
| Mass (gm) | 4.22 | 5.02 | 4.44 |
| # magnet slots | 3 | 3 | 1 |
| Rotation point z-offset (mm) | 5.7 | 5.7 | 5.7 |
| COM x-coord (mm) | 6.49 | 7 | 7.28 |
| COM z-coord (mm) | 9.81 | 7.9 | 8.94 |
| COM moment arm (mm) | 16.8 | 15.3 | 16.4 |
| COM angle (degrees) | 22.7 | 27.2 | 26.4 |
| **Magnetic Force Calculations** (see Eq. 3.4) | | | |
| Desired Max Force (N) | 10 | 10 | 10 |
| Total magnet force needed | 72.3 | 72.4 | 72.5 |
| # Magnets Needed | 7.1 | 3.9 | 1.0 |
| **Expected breakaway force (N)** | **4.2** | **7.6** | **9.99** |

N, which is half of the desired value. This discrepancy may be explained by the testing conditions used by the supplier to determine the magnetic force rating; pull force is calculated using a thick, flat steel plate [4]. However, the load cell is relatively thin, and is less than 1mm wider than the magnet diameter. To account for this difference, a "shape factor," $S_F$ was introduced to Eq.3.6.

Using the design spreadsheet, the BX-044-N52 magnet was determined to most closely fit the desired breakaway force of 10N. As an additional benefit, the rectangular shape of this magnet minimizes the steps needed during assembly. A potential risk of this strategy is that the BX-044 is the strongest magnet available for a reasonable shape/size (1/4" wide, 1" long). If a threshold higher than 10N is needed, larger magnets must be used, which will then increase the size and weight of the thumb cradle.

### Assembly

The thumb cradle is assembled using an adhesive to bond the magnet within the main structure. Two important considerations in this process are 1) ensuring that the adhesive is strong enough to hold the magnet, and 2) ensuring that the magnet surface is flush with the mounting face of the thumb cradle. The bonding shear strength of candidate adhesives was used to determine if sufficient bonding could be achieved. Loctite SuperGlue, a cyanoacrylate, was investigated for it's ease of application. The shear strength of this adhesive is $7.1N/mm^2$ and the bonding surface area is $526mm^2$, resulting in a pull-out force of $3.7kN$. This provides a comfortable margin of safety over the $72.4N$ total force from the magnet, so the adhesive is not expected to be a source of failure. Vent channels are incorporated into the magnet pocket to allow for displacement of the SuperGlue.

Assembly of the magnets and thumb cradle was accomplished using a steel plate as an alignment surface as shown in Fig. 3-8. The assembly procedure is listed in Table 3.3.

Table 3.3: Assembly steps for the magnetic thumb cradle

1. Clean all surfaces using isopropyl alcohol and ensure no particulates remain
2. Apply Mold Release to the alignment plate
3. Place the magnet(s) onto the alignment plate
4. Apply Loctite Superglue to the pocket within the thumb cradle
5. Align the thumb cradle over the magnet and press until flush
6. Leave undisturbed for 24hr
7. Remove the thumb cradle from the plate and scrape off any excess glue

## 3.4.2 Metacarpal Cradle

The metacarpal cradle design did not change appreciably from the $\alpha$-prototype, as its function is straightforward. A gothic arch profile, shown in Fig. 3-9, was determined to fit comfortably on the hand while maintaining alignment with the long axis of the

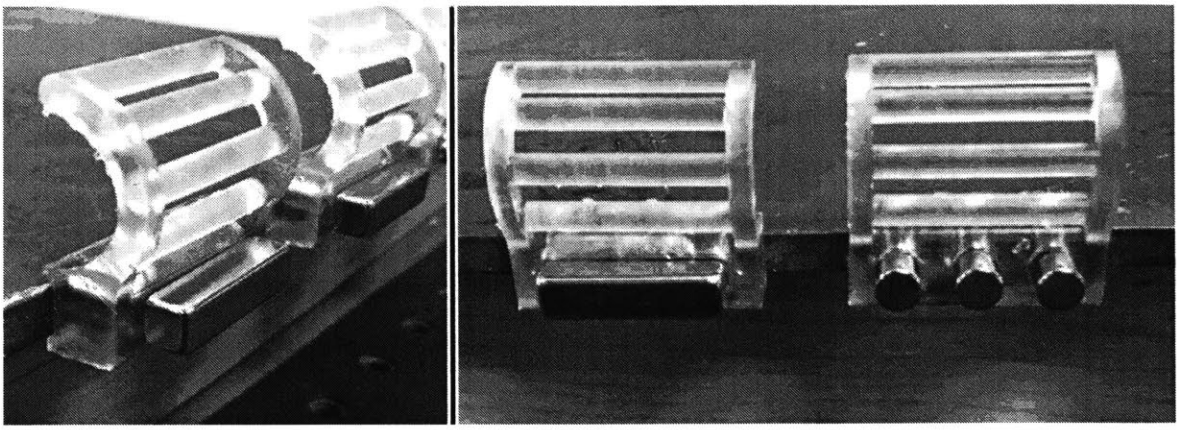

Figure 3-8: Thumb cradle assembly setup. The magnet placed on the outer surface acts as a clamp to keep the cradle aligned to the steel plate.

metacarpal bone. The cradle is mounted to the bottom of the device using an M3 screw; a slot is provided to allow for small distal/proximal adjustments.

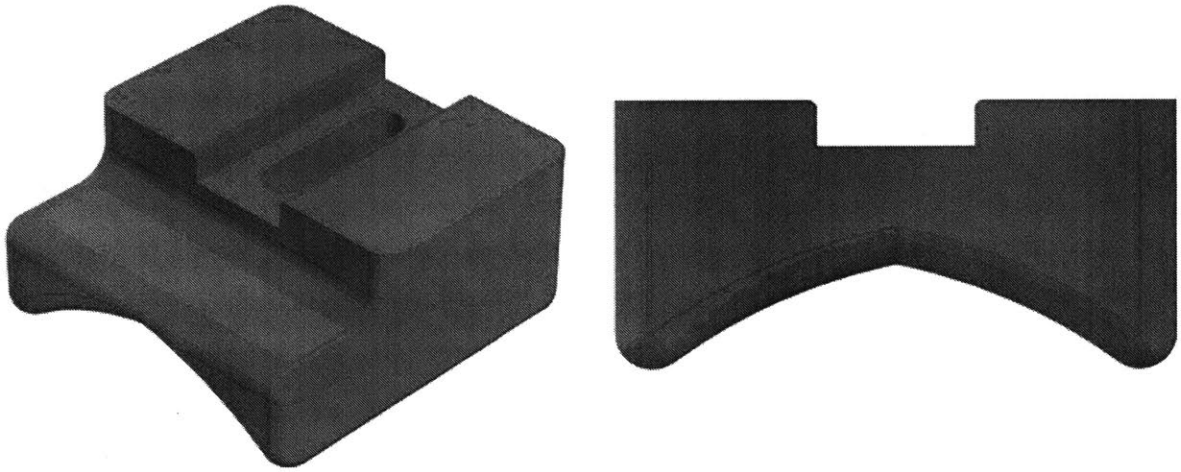

Figure 3-9: Metacarpal cradle showing the gothic arch groove shape that constrains rotation about the UCL axis

## 3.5 System Integration

### 3.5.1 Shaft Coupling

To actuate the thumb, the motor shaft must be coupled to load cell such that it is perpendicular to the direction of rotation. Given the space constraints and unique hardware involved, a custom shaft couple was designed as shown in Fig. 3-10.

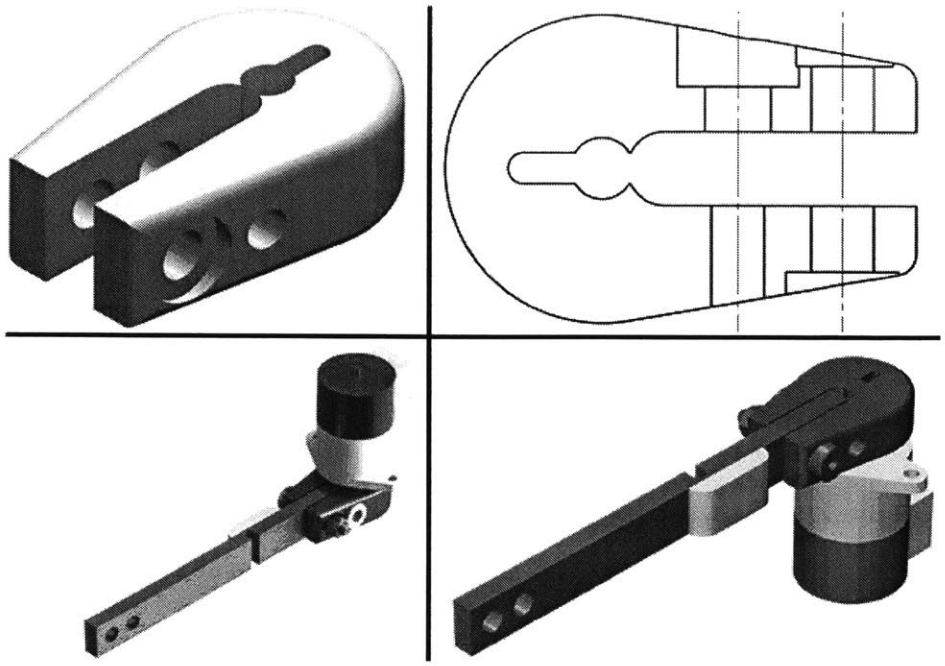

Figure 3-10: Shaft coupling designed to couple the motor and load cell

The design is based on standard shaft clamps, with the addition of a rectangular pocket to accommodate the Futek load cell. A 3mm shoulder bolt and an M3 screw are used to affix the load cell; the screw also provides the force needed to clamp the shaft. A recess in the posterior end of the shaft clamp reduces the stiffness, allowing a greater clamping force to be applied without risking material failure of the coupling.

A risk of this design is failure of the motor shaft due to bending or torsional stress. A bending stress is applied to the shaft from the weight of the load cell & associated components (cradle, magnets). Additionally, the patient may inadvertently flex the thumb downwards, further increasing the bending moment. Torsional stress comes from the motor. Table 3.4 shows the design spreadsheet used to evaluate the integrity of the motor shaft. With a conservative estimate of 5N applied by the patient, the Von Mises stress within the shaft is well below the yield strength of the material, and with a comfortable margin of safety.

The final design of the motor shaft is an improvement on several rounds of iteration. Version 01 (Fig. 3-11A-d) used an off-the-shelf shaft clamp from Pololu, with a separate attachment for the load cell . This design was cumbersome to assemble,

Table 3.4: Motor Shaft Stress Analysis

| **Bending Stress Calculation** | | | |
|---|---|---|---|
| Parameter | Value | Units | Notes |
| Assembly weight | 37.25 | g | coupling + load cell + cradles + magnets |
| COM distance from shaft | 40.5 | mm | |
| Thumb flexion force | 5 | N | |
| Distance from shaft | 50.8 | mm | |
| Shaft diameter | 3 | mm | |
| Shaft moment | 269 | N-mm | |
| Area moment of inertia | 4 | $mm^4$ | $I = \pi D^4/64$ |
| **Bending Stress** | **101** | **MPa** | $\sigma = \frac{Mc}{I}$ |
| **Torsional Stress Calculation** | | | |
| Motor torque | 150 | N-mm | |
| Polar moment of inertia | 8 | $mm^4$ | $J = \pi D^4/32$ |
| **Torsional Stress** | **28.3** | **MPa** | $T = \frac{\tau c}{J}$ |
| **Von Mises Stress Calculation** | | | |
| Motor shaft yield strength | 300 | MPa | steel |
| **Von Mises Stress** | **112.6** | **MPa** | $\sigma_{VM} = \sqrt{\sigma_{bend}^2 + 3\tau_{torsion}^2}$ |
| **Margin of Safety** | **2.7** | | |

and carried significant excess weight which could compromise the motor performance. Version 02 (Fig. 3-11E-H) was based on a two-piece shaft clamp from McMaster; the front half was re-designed to accommodate the load cell . While this is much smaller and lighter than the first design, assembly was tedious due to the 4 fasteners needed. Version 03 (Fig. 3-11I-L) is a monolithic part that uses only 2 fasteners. However, the stiffness of the posterior section was too large, and the 3D-printed prototypes were prone to fracture when tightened. The final design in Fig. 3-10 includes a slot that reduces stiffness to reduce this risk.

For prototyping purposes, the shaft coupling was fabricated using SLA printing (Formlabs Form2). Larger production runs will require a metal coupling (aluminum or steel) for reliability. The metal part can be fabricated using a Waterjet for the outer contours; holes for the M3 screw and shoulder screw can be added in a secondary machining process using a jig to align the part and prevent parasitic deflection.

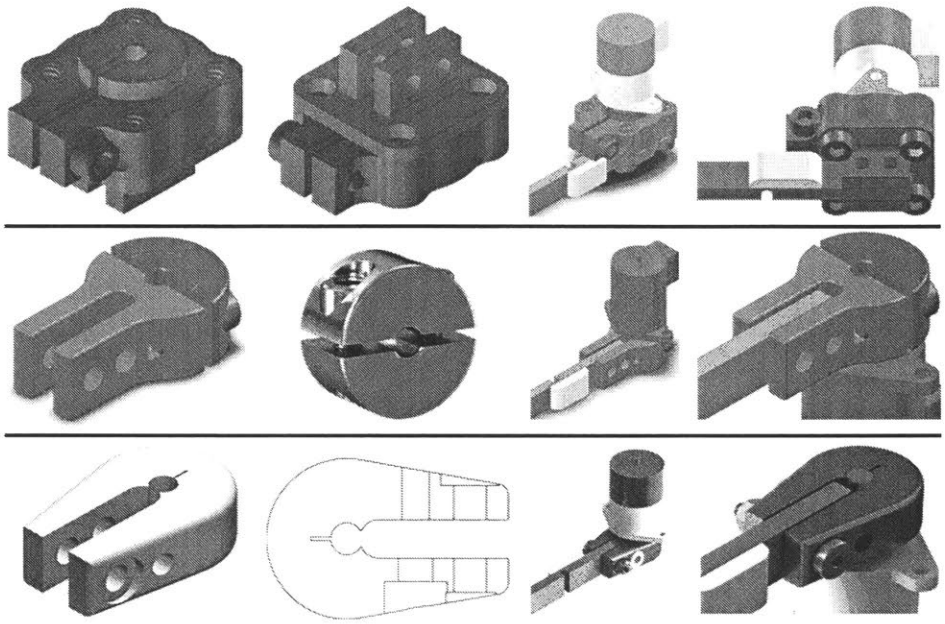

Figure 3-11: Design evolution of the shaft coupling: Version 01 (top), Version 02 (middle), and Version 03 (bottom). Final design is shown in the previous figure.

### 3.5.2 Mounting Plate

The mounting plate, shown in Figs. 3-12 & 3-13, is attached to the bottom of the upper housing, and secures both the motor and the metacarpal cradle. A raised hub for the motor's mounting flange positions the motor in the center of the device; Two countersunk M2 screws are used to secure the motor in place. For a finalized production run, adhesive can be used in place of fasteners to improve ease of assembly.

The metacarpal cradle is positioned using a rib on the bottom surface of the mounting plate, and secured using an M3 screw. The mounting rib also adds stiffness to the structure. A small rib is also placed on the top surface to provide stiffness to the space between the motor mounting hub and the metacarpal rib.

### 3.5.3 Housing

The housing of the thumb device, shown in Fig. 3-14 A, features a vertical hand grip atop a motor & electronics compartment. The housing has several panel cutouts to accommodate snap-in electronics components (see Section 3.6), and a grommet for the load cell cable. The housing is attached to the mounting plate via 4 countersunk

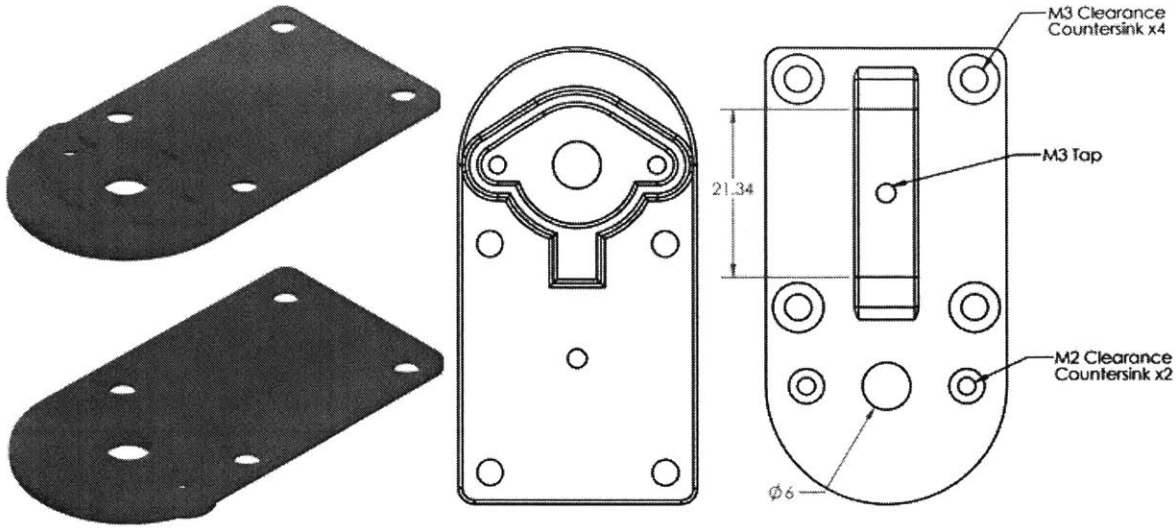


Figure 3-12: Mounting plate for the motor, housing, and metacarpal cradle

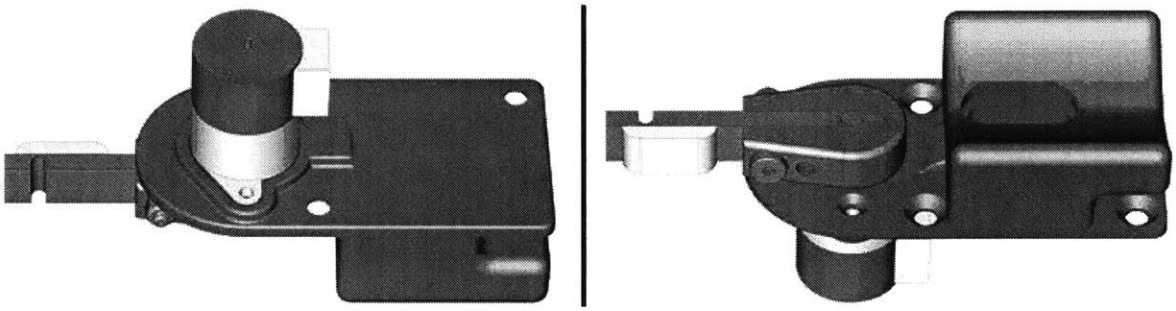

Figure 3-13: Mounting plate assembly showing the positions of the motor and metacarpal cradle

M3 screws on the bottom face. The grip diameter is set at 30mm in accordance with recommended human factors guidelines [28].

The vertical hand grip is the primary modification from the $\alpha$-prototype, which required awkward positioning to operate. Clay modeling was used to explore different shapes; Version 01 (Fig. 3-14 B) retained the horizontal orientation of the original prototype, but used a more ergonomic size and featured finger grips. Version 02 (Fig. 3-14 C) explored the vertically-oriented grip. However, the handle was too short for some users so the height was increased for the final design.

The final iteration of the housing was fabricated using FDM printing of an ABS-derived material (Stratasys uPrint SE plus). The wall thickness was set at 2mm, and the part was printed as a single piece. Larger production runs of the device will

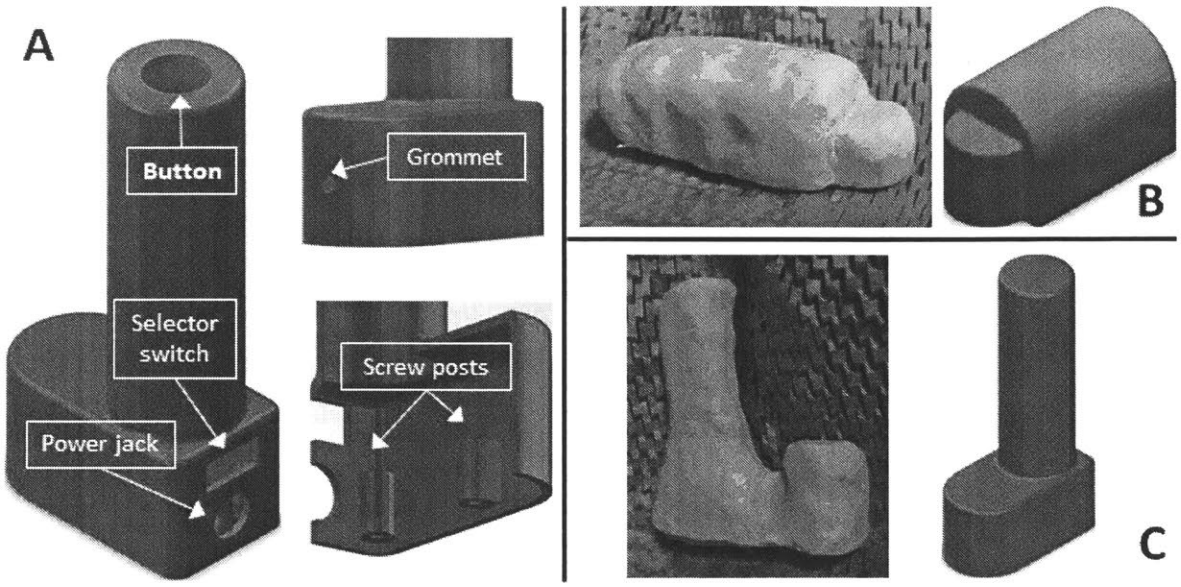


Figure 3-14: Housing Top Details

require alterations to the part design for manufacturability. For example, the screw posts create an undercut, and the panel cutouts would require side actions. One solution could be to split the part into two components that are then assembled via fasteners or snap-fits.

## 3.6 Electronics

The following electronic components, shown in Fig. 3-15, are needed to operate the thumb UCL device: 1) Motor Driver (Pololu A4988), 2) Instrument Amplifier (Sparkfun HX711), 3) Microcontroller (Arduino Nano), and 4) Bluetooth (Sparkfun BlueSmirf Silver). Wireless communication is achieved through the Bluetooth module; the only wire input to the device is a 15V power supply via a power jack on the posterior face of the housing.

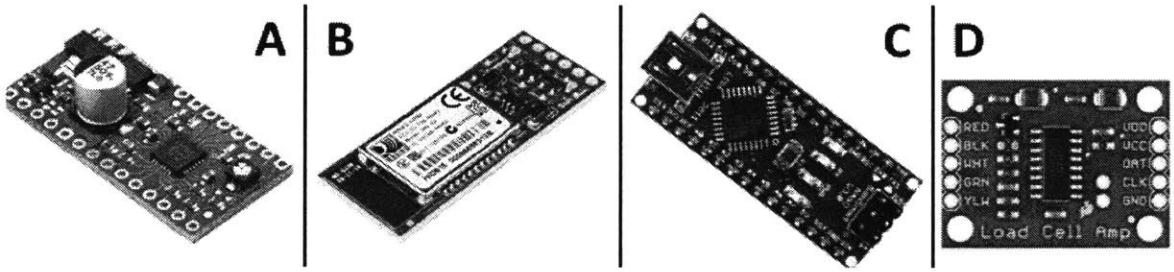


Figure 3-15: Electronic components: A) Pololu A4988, B) SparkFun BlueSMiRF, C) Arduino Nano, D) SparkFun HX711

User control of the device is facilitated through a button at the top of the housing. A snap-fit SPST-NO Off-Mom switch was selected (Fig. 3-16B) for this purpose; a button press closes the circuit, and it remains closed until the button is released.

Electronic components were assembled into a breadboard configuration for validation & testing according to the wiring schematic in Fig. C-1. Figure 3-17 shows the completed breadboard assembly. An adjustable power supply was used for the required 15V to run the motor.

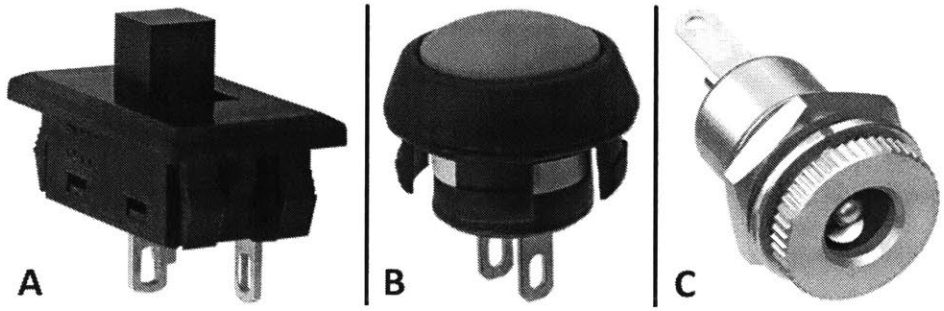


Figure 3-16: Accessory electronic components: A) switch, B) button, C) power jack

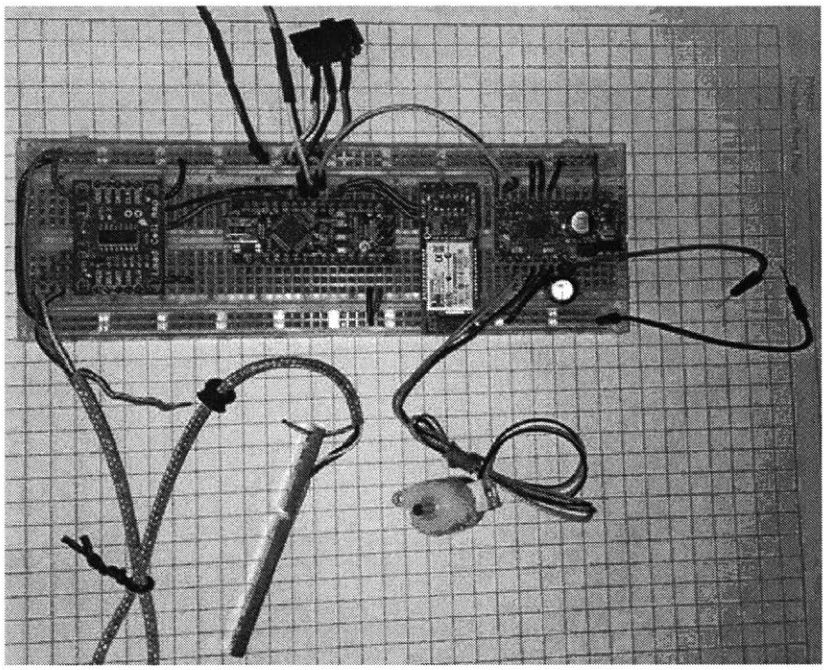

Figure 3-17: Breadboard assembly of the electronic components used for testing & validation

### 3.6.1 Motor Driver

The Pololu A4988 breakout board was selected for controlling the stepper motor. The board incorporates a stepper translator, and thus requires only 2 logic inputs; step on/off, and direction. Microstepping capabilities are supported, with up to $1/16^{th}$ steps possible. Additionally, the board has voltage regulators, which means that a single high-voltage input can also be used for 5V logic power.

The A4988 board also has an adjustable current control, which allows for higher supply voltages to be used while maintaining the desired motor operating current. A current limit of 100 mA was set using Eq. 3.7; the VREF potentiometer was adjusted until 40 mV was obtained.

$$CurrentLimit = VREF * 2.5 \tag{3.7}$$

$$100mA = VREF * 2.5 \tag{3.8}$$

$$VREF = 40mV \tag{3.9}$$

The single input for motor directional control facilitates simple switching of the device for left- and right- handed operation. A snap-fit SPDT switch was selected (Fig. 3-16A) for this purpose.

### 3.6.2 Instrument Amplifier

The SparkFun HX711 breakout board was used as an instrument amplifier and analog-to-digital converter for the Futek load cell output voltage. This board was selected due to it's straightforward operation and interface with a microcontroller. However, the gain is limited to 128, which is much lower than the value calculated in Table 3.1. Additionally, the load cell can only be driven at 5V, which does not allow for the highest possible resolution. A future iteration of this device could incorporate a different amplifier, such as the INA125 which can operate at up to 36V and has a gain up to 10,000 (this would require a filtering circuit to be incorporated as well).

### 3.6.3 Microcontroller

The Arduino Nano microcontroller was selected for this application primarily due to its small size, and the availability of a mini-USB port for programming. Because the HX711 functions as an ADC, only the digital IO pins are needed on the Nano. A list of inputs and outputs is shown in Table 3.5. Pseudocode for the Arduino program is shown below (full code is in Appendix D). Limits for angular displacement and thumb torque are pre-defined at $45^o$ and $150N - mm$, respectively. If either of these values is exceeded, the program stops; otherwise, if the button is pressed, the motor advances and a readout of the angle, torque, and stiffness is sent.

Table 3.5: Inputs and Outputs to the Arduino Nano

| **Inputs** | **Outputs** |
|---|---|
| Button input | Bluetooth Tx |
| Motor Direction Switch Input | Bluetooth Rx |
| HX711- Data Out | Motor Step Signal |
| HX711 - Clock | |

**Arduino Pseudocode**

```
#include software libraries
define pins & constants
initialization;
while Angle < limit do
    if Peak Torque < max then
        Read button;
        if Button=Pressed then
            Turn motor;
            Read load cell;
            Print data;
        end
    else
        terminate program;
    end
end
```

### 3.6.4 Bluetooth Serial Communication

Wireless data communication with the Thumb UCL device is achieved using the SparkFun BlueSMiRF Silver modem.The device supports serial communication up to 115200bps, and has a range of 18m. The Arduino program uses this Bluetooth interface to print the following data during each operating loop: 1) System time, 2) Angle, 3) Torque, and 4) Stiffness. The data is sent as lines of comma-separated values, and can be easily read through serial monitors on a computer (such as Tera Term), or a phone (Serial Bluetooth Terminal on Android). Currently, the data is displayed as raw serial strings; post-processing is needed to parse and graph the results. In the next iteration of the device, a Microsoft Excel macro program, or smartphone app could be created to facilitate more aesthetically pleasing real-time data.

## 3.7 Prototype Assembly

The fully assembled prototype is shown in Fig. 3-18, and the final bill of materials is shown in Table 3.6. The overall assembly process was straightforward; however, some difficult steps are noted as possibilities for improvement. The power jack uses an internal hex nut for attachment. There is very little clearance between it and the screw posts (Fig. 3-19 A), and is thus difficult to grip. A mounting slot to secure the hex nut could remove this difficulty, or snap-fit options could be explored. The M2 hex nuts were difficult to install due to tight clearances between components (Fig. 3-19 B). A press-fit dowel pin could be used in place of the shoulder bolt to eliminate one of the nuts, and adhesive could be used in place of screws to secure the motor. Finally, the cable from the load cell proved difficult to bend into position. The cable must be curved to avoid a parasitic torque on the load cell, and also fit around the motor inside the housing. If a custom load cell is used, the thickness of the cable shielding should be minimized to reduce this effect.

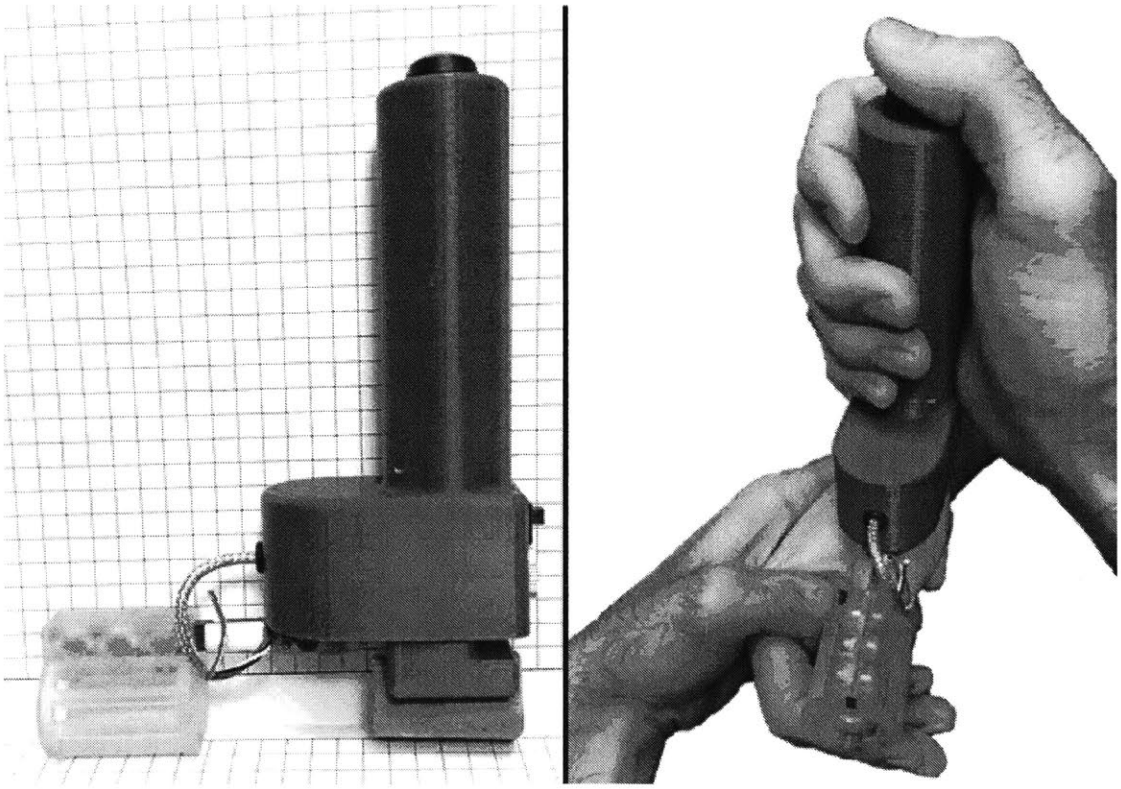

Figure 3-18: Fully assembled $\beta$-prototype of the thumb UCL device.

Table 3.6: Bill of Materials for the Thumb UCL Device

| # | Description | Manufacturer | Part No. | QTY | Cost ($) |
|---|---|---|---|---|---|
| **Custom components** | | | | | **18.72** |
| 01 | Housing | FDM-printed | N/A | 1 | 12.41 |
| 02 | Mounting plate | FDM-printed | N/A | 1 | 1.57 |
| 03 | Shaft coupling | SLA-printed | N/A | 1 | 0.43 |
| 04 | Thumb cradle | SLA-printed | N/A | 2 | 1.19 |
| 05 | Metacarpal cradle | FDM-printed | N/A | 1 | 3.12 |
| **Mechanical components** | | | | | **165.58** |
| 06 | Motor | Minebea | PG15S-D20-HHB9 | 1 | 33.58 |
| 07 | Load cell | Futek Inc. | FSH00889 | 1 | 132.00 |
| **Fasteners** | | | | | **12.54** |
| 08 | Magnet | K&J Magnetics | BX044-N52 | 2 | 2.44 |
| 09 | Grommet | Davies Molding | 5104 | 1 | 0.15 |
| 10 | Shoulder screw | McMaster-Carr | 90263A117 | 1 | 6.96 |
| 11 | M3 shaft couple screw | McMaster-Carr | 91290A113 | 1 | 0.07 |
| 12 | M3 countersunk screw | McMaster-Carr | 92125A132 | 5 | 0.06 |
| 13 | M2 countersunk screw | McMaster-Carr | 92125A054 | 2 | 0.26 |
| 14 | M2 lock nut | McMaster-Carr | 93625A101 | 3 | 0.70 |
| 15 | M2 washer | McMaster-Carr | 93475A195 | 2 | 0.01 |
| **Electronic Components** | | | | | **92.81** |
| 16 | Arduino Nano 3.0 | Gravitech | ARD-NANO30 | 1 | 29.74 |
| 17 | A4988 motor driver | Pololu | 1183 | 1 | 7.95 |
| 18 | HX711 amplifier board | SparkFun | SEN-13879 | 1 | 8.46 |
| 19 | Bluetooth modem | SparkFun | WRL-12577 | 1 | 21.21 |
| 20 | Button | Grayhill | 30-105 | 1 | 4.54 |
| 21 | Switch | CW Industries | G-107-SI-0511 | 1 | 1.62 |
| 22 | Power jack | Tensility Int. | 54-00064 | 1 | 1.58 |
| 23 | Power supply | Inventus Power | IPD5015-760 | 1 | 17.97 |
| **Total Cost of Goods** | | | | | **270.93** |

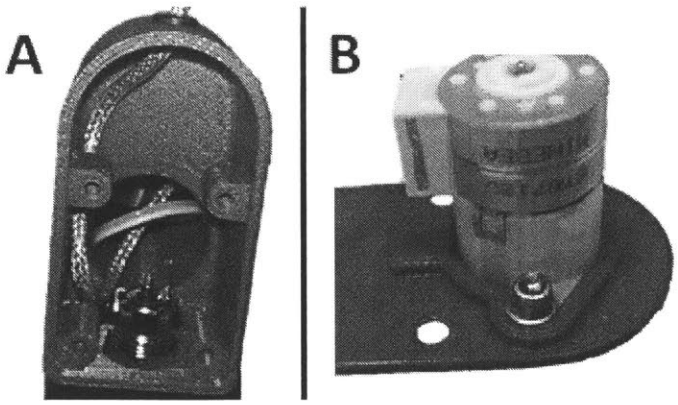


Figure 3-19: Fully assembled $\beta$-prototype of the thumb UCL device.

A version of the Thumb UCL device using the larger NMB motor was also prototyped (Fig. 3-20). Although 2/3 larger, the device is not overly cumbersome to position on the hand & operate, and is a feasible option if higher torque is needed. Figure 3-21 shows details of the components that are unique to this version.

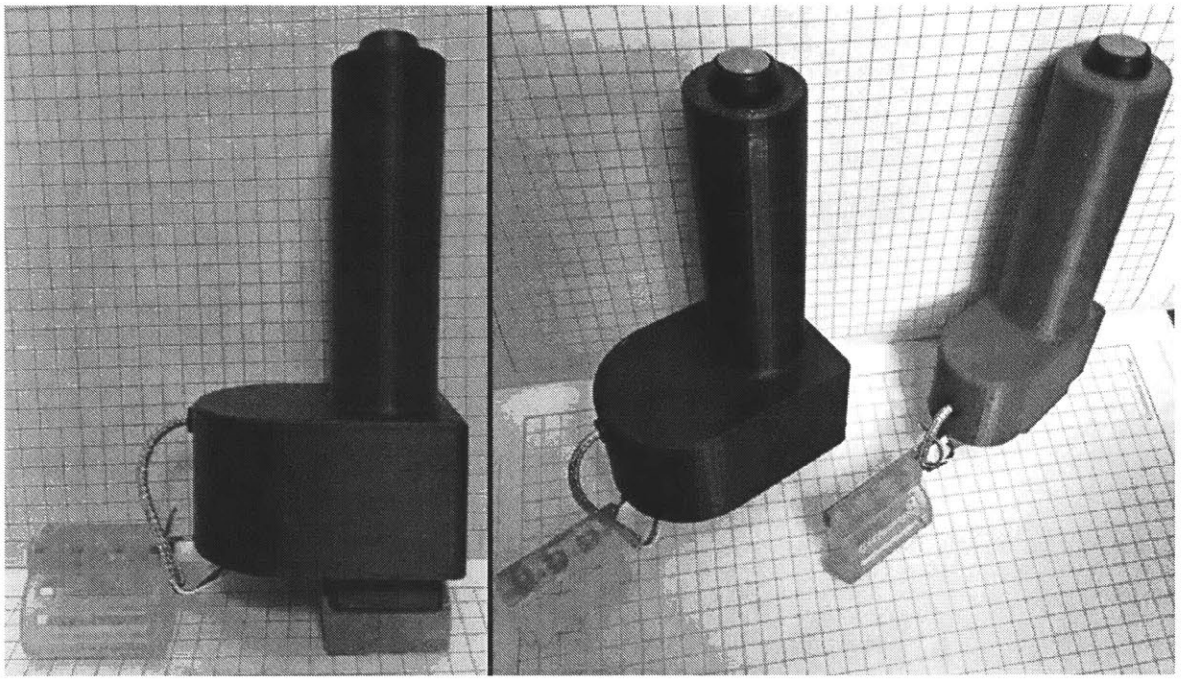

Figure 3-20: Prototype using the larger stepper motor version

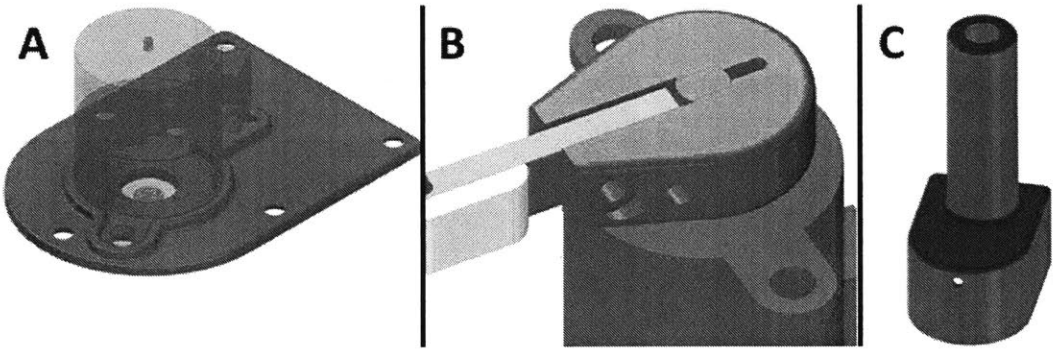


Figure 3-21: Detailed view of the components specific to the large prototype version: A) mounting plate; B) shaft coupling; C) housing.

# Chapter 4

# Device Evaluation

## 4.1 Component Validation

### 4.1.1 Load Cell Calibration

The Futek load cell must be calibrated with the HX711 amplifier to obtain accurate measurements. The HX711 has an accompanying Arduino library that provides a calibration code. A *zero factor* is used in the program to specify the no-load scenario. A *calibration factor* is defined to calculate the desired result from the raw digital output. The following protocol was used to find the appropriate *calibration factor* for an applied torque (in N-mm):

1. The Futek load cell was attached to the shaft coupling
2. The load cell-coupling assembly was oriented and fixed in a horizontal position
3. The *zero-factor* was set using the HX711 calibration code
4. A weight of 299g was affixed using the distal mounting holes of the load cell, a distance of 50.8 mm (corresponding torque of 148.85 about the motor axis)
5. The *Calibration factor* was adjusted until the digital readout of the HX711 was equal to 148.85

6. The load cell-coupling assembly was flipped $180^o$ and re-evaluated to ensure that the calibration factor was orientation-independent

7. The *Calibration factor* was determined to be: **-6200**

A continuing challenge for obtaining accurate load cell measurements is setting the *zero factor* during active use. Currently, the Arduino code sets the *zero factor* after power-on, and before motor rotation begins. If the device is rotated, an erroneous value will be used, thus skewing the data. Future implementations can have improved algorithm for zeroing by potentially incorporating an inertial measurement unit (IMU) to correct for any off-axis alignments.

### 4.1.2 Magnetic Breakaway Testing

The thumb cradles with embedded magnets were tested to validate the analytical model for breakaway force. The testing setup is shown in Fig. 4-1. The Futek load cell is fixed in a horizontal orientation, and the thumb cradle is placed on the bottom surface of the beam. A weight was attached to the center portion of the rib, where the thumb force vector is expected to be. The weight was increased until breakaway was achieved.

Initial testing was performed with the D42SH magnet; expected breakaway force was 8.49N. However, the actual breakaway force was 4.13N. As detailed in Section 3.4.1, this discrepancy was attributed to a "shape factor" that influences the magnetic pull on the relatively small surface of the load cell. With the shape factor accounted for, the expected breakaway force is 4.23N; the tested value then matches the model with 97.6% accuracy.

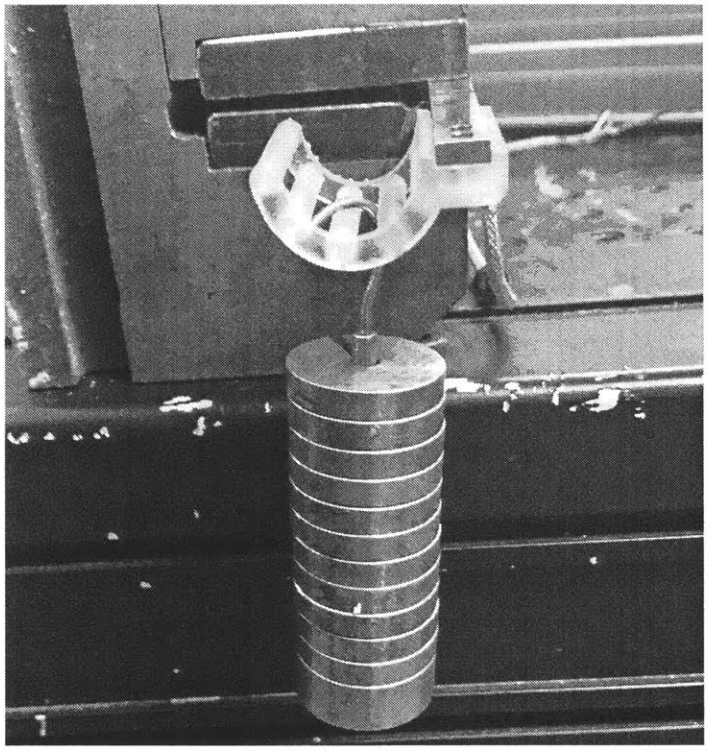

Figure 4-1: Testing setup to determine the thumb cradle magnetic breakaway force

## 4.2 Human Subjects Testing

### 4.2.1 Protocol

Human subject testing was performed to evaluate device performance and gather user feedback. Initial testing was done using healthy subjects, who are not expected to experience any pain or injury during testing. Additionally, testing of healthy subjects will provide data to calculate a range of normal values for UCL stiffness. An application for human subjects testing was submitted to and approved by the MIT COUHES[1] office (see Appendix E for application and subject consent form). The testing protocol is shown in Table 4.1.

[1]Committee On the Use of Humans as Experimental Subjects

Table 4.1: Protocol for human subject testing

**Preliminary Logistics**

01 Provide subject with Consent Form and obtain signature

02 Determine the following demographic data:

- Age
- Gender
- Handedness
- Injury history of either thumb

03 Determine if patient meets inclusion criteria

- Ensure full range of motion & no current pain
- Perform stress test maneuver and ensure no laxity

04 Demonstrate device to subject and answer any questions about the procedure

**Anthropometric Data**

Measure the following parameters on both hands:

01 Length of first metacarpal and proximal & distal phalanges

02 Hand thickness at the thenar eminence

03 Ellipse diameters of the MCP and PIP joints

04 Distance between the MCP joints of the thumb and index finger at maximal thumb abduction

**UCL Testing**

01 Open TeraTerm or other Bluetooth serial interface

02 Plug power supply into the power jack

- Ensure device is oriented parallel to ground for proper zeroing of load cell

03 Connect to Bluetooth COM port in serial interface and confirm data transmission

04 Move switch to correspond with hand being tested

05 Position & orient device onto subject's hand

- Metacarpal cradle aligned with long axis
- Motor axis centered on MCP joint
- Thumb fully extended in thumb cradle

06 Press button to begin testing

- Ensure device is kept parallel while testing
- Stop if subject feels any discomfort
- Device will automatically stop if angle or torque thresholds are exceeded ($45^o$ & $150N - mm$, respectively)

07 Export serial data as CSV file

**User Feedback**

01 Obtain general feedback on the testing experience

02 Allow subject to handle & inspect device

03 Obtain feedback on device operation, comfort of use, overall design aesthetic, etc.

### 4.2.2 Results

The Thumb UCL device was tested on a small number of subjects to validate the design and testing protocol for a larger human subjects study. Both small and large versions of the device were evaluated.

The small version of the Thumb UCL Device was not able to deliver enough torque to complete testing. The failure of the 150 N-mm motor suggests that the stiffness of other thumb tissues (skin, muscle) is on the same order of magnitude as the UCL stiffness. Additionally, the plastic gearbox of this motor was prone to stripping when moving the load cell with the device unpowered.

The large version of the device (450 N-mm) was able to successfully perform testing on healthy thumbs. A representative graph of data output is shown in Fig. 4-2.

Thumb angle is plotted against the measured torque and calculated stiffness. The data shows a noticeable jump in stiffness at $\sim 35^o$, which likely represents "engagement" of the UCL ligament (prior stiffness due to skin/muscle stiffness). This trend matches observations from preliminary testing of the $\alpha$-prototype (see Appendix A).

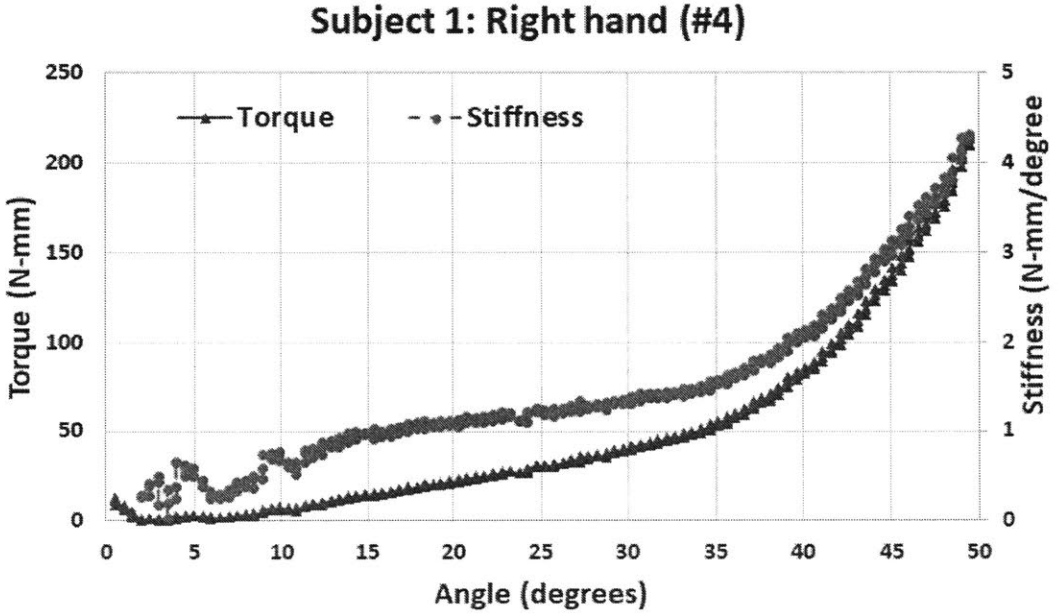


Figure 4-2: Representative plot of torque and stiffness vs angle for a test subject

Several tests were performed on each hand to assess the reliability of device measurements. Table 4.2 shows the average torque and stiffness values measured for one subject across 4 trials. The standard deviation was $< 10\%$ of the average for all values except for measured torque on the Left hand. Two possible sources of error to explain this discrepancy are noted: first, leveling of the device must be done by estimation, and the device likely tilted off-center during testing. A small bubble level affixed to the device could improve this challenge. The other possible source of error is reactionary torque on the metacarpal. As the torque on the thumb increases, the user must apply a compensatory force to keep the device aligned with the long axis of the metacarpal. The current metacarpal cradle is relatively short; a longer length could improve the ability to keep alignment throughout testing.

Table 4.2: Average peak values of torque and stiffness for a test subject. Standard deviation shown in parentheses (N=4 measurements per hand)

| | Torque (N-mm) | Stiffness (N-mm/degree) |
|---|---|---|
| Left hand | 213.9 (26.3) | 4.88 (0.40) |
| Right hand | 213.1 (6.7) | 4.51 (0.29) |

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# Chapter 5

# Conclusion

Tears of the thumb ulnar collateral ligament require accurate diagnosis to determine the appropriate treatment option. Some injuries can be diagnosed through physical exam, but many cases require secondary diagnosis through imaging. MRI is the gold standard for definitive diagnosis of thumb UCL injury. However, this testing is expensive and can delay treatment. A solution for rapid in-clinic evaluation of the thumb UCL integrity was developed.

The proposed device uses a stepper motor to rotate the thumb while measuring the applied torque using a strain gauge-based load cell. The device is held and operated by the physician, and is aligned to metacarpal using a v-groove cradle. A magnetic breakaway mechanism was incorporated into a thumb cradle to reduce the risk of injury from excessive torque application. Preliminary testing was performed on healthy human subjects. Peak thumb torque was measured at $213.5 \pm 19.2$ N-mm, and peak stiffness was calculated to be $4.70 \pm 0.39$ N-mm/degree.

Overall, most of the the functional requirements listed in Section 2.1 have satisfied or demonstrated to be feasible. The device is able to accurately measure the thumb angle, applied torque, and can be stabilized to the hand by a knowledgeable operator. Further testing is needed to determine if the device is examiner-independent. The device has an improved ergonomic design, and the size & weight are significantly reduced compared to the $\alpha$-prototype. The motor torque limit, magnetic breakaway mechanism, and on-button provide multiple levels of safety in different components.

The primary unanswered functional requirement is the Feasibility for Clinical Use. Further testing and demonstrations to physicians are needed to determine if the device can be accepted into a clinical workflow at an appropriate cost.

Additionally, the solution for quantitative joint stiffness measurement presented in this device could be potentially applied to other scenarios. For example, tears of the anterior cruciate ligament (ACL) in the knee are diagnosed using a fundamentally similar physical exam maneuver. The device could also be used to improve diagnosis in low-resource settings such as developing nations or during long-duration exploration missions where MRI imaging is not readily available.

# Future Work

## Testing

Further testing on healthy human subjects is needed to characterize the device performance, and establish a baseline range for normal thumb UCL stiffness values. Additionally, cadaver testing is needed to test the ability to distinguish UCL tears of differing severity; this can be accomplished by creating cuts of known depth into the ligament, and then performing testing with the device. Finally, when the device is fully characterized, testing on injured thumbs can occur (preferably in areas with lots of skiers).

## Mechanical

Assembly and testing of the device highlighted some small improvement opportunities for the mechanical design of the device. A mounting slot could be added to ease assembly of the power jack. The shoulder screw could be replaced by a press-fit pin to obviate assembly with an M2 nut. A bubble level could be incorporated on the top surface of the device to aid in orientation during testing. Finally, the length of the metacarpal cradle should be increased to improve stabilization while resisting reaction torque from the motor.

## Design for Manufacturing

Two components in particular would benefit from a DMF-oriented redesign: the thumb cradle and device housing. In their current configuration, neither can be manufactured using injection molding. The housing will likely need to be split into two parts to eliminate the screw mount undercut, and reduce the need for side actions. The thumb cradle will need a re-design of the ribbed "semicircular" section.

## Electronics

As detailed in Section 3.6.2, a more robust solution for strain gauge amplification and analog-to-digital conversion would improve the resolution and signal-to-noise ratio of the load cell data acquisition. An improved algorithm for load cell calibration and stepper motor control could improve the accuracy of of torque and angle measurement. A custom PCB board to integrate the components would reduce noise and greatly simplify assembly of the electronic components. Finally, a smartphone app or Excel macro is needed for real-time processing and aesthetic display of the data for the surgeon. Eventually, this program could be streamlined for uploading data to an electronic medical record.

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# Appendix A

# Design of Medical Devices 2018

The following paper was accepted for the 2018 Design of Medial Devices conference in Minneapolis, MN.

# A device for quantitative analysis of the thumb ulnar collateral ligament.

**Thomas Cervantes[1,2], Woojeong Elena Byun[1], Ava Chen[1], Kristina Kim[1], Kaitlyn Nealon[1], Jay Connor[3], Alexander Slocum[1]**

Department of Mechanical Engineering, Massachusetts Institute of Technology, Cambridge, MA[1]
Stanford University School of Medicine, Stanford, CA[2]
Mount Auburn Hospital, Cambridge MA[3]

## 1 Background

A device to quantitatively assess the ulnar collateral ligament of the thumb was developed to facilitate rapid and accurate diagnosis of the ligamentous injury known as Skier's thumb.

Skier's thumb is a partial or complete tear of the ulnar collateral ligament (UCL), which connects the first metacarpal to the proximal phalanx of the thumb. This injury commonly occurs when falling while grasping an object (such as a ski pole), and has a yearly incidence of ~200,000 [1]. The UCL plays a key role in the ability to grip objects; patients suffering from Skier's thumb are often forced to take a leave of absence from work until the injury is healed. Timely, accurate diagnosis is essential for patients to receive proper treatment and regain functionality of their hand.

The treatment of skier's thumb is a function of UCL tear severity and falls within two categories of treatments. Partial UCL tears can be left to heal on their own with cast stabilization, while full tears require surgical intervention to ensure full recovery [1]. The optimal window for surgical repair is within two weeks of the initial injury [2].

Initial diagnosis occurs through physical exam of the thumb metacarpo-phalangeal (MCP) joint. The physician performs a stress test to analyze the integrity of the UCL ligament. The metacarpal is held fixed in space while the thumb is moved laterally by the examiner. The metrics of the stress test are 1) maximum angular deflection of the thumb, and 2) assessment of endpoint stability at maximum deflection. A "soft" endpoint, with maximum deflection greater than 30-35 degrees, is indicative of a full UCL tear. A "firm" endpoint, with smaller angular deflection, is considered to be partially torn [3]. The injured thumb is typically compared against the healthy thumb to account for normal variations in joint flexibility [4].

The initial stress-test is a primarily qualitative assessment, and relies heavily on the experience of the examiner to accurately diagnose the degree of injury. Because the difference in treatment options for full vs partial tear is so drastic (surgery vs cast), patients are often referred for further imaging studies to confirm the diagnosis. MRI is the gold standard for UCL secondary diagnosis [3]. However, MRI can add significant cost to the patient's treatment, and can also push surgery outside of the optimal treatment window of two weeks.

Diagnosis and treatment of Skier's thumb injuries could be improved through precise, quantitative assessment of the UCL at the time of initial examination. A reliable method for performing this assessment has the potential to reduce the costs of care and improve surgical outcomes by precluding the need for MRI as a secondary diagnostic tool.

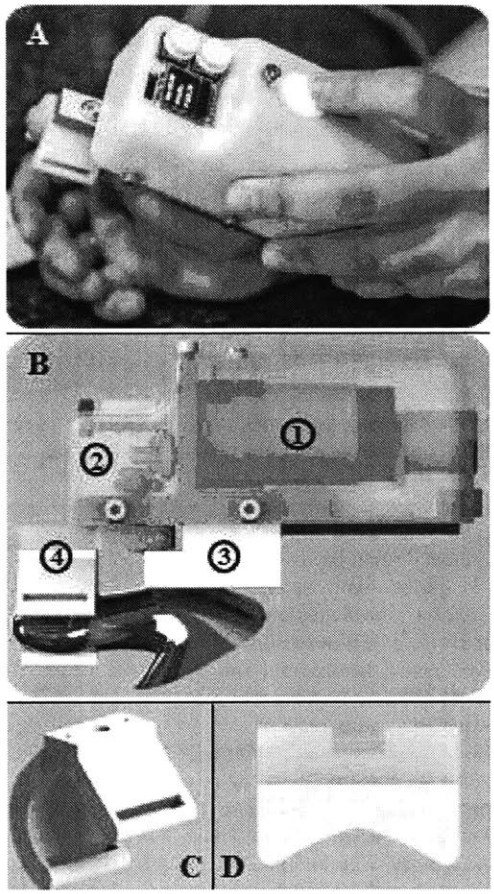


**Figure 1: (A)** Final prototype of the device being used to test a thumb. **(B)** Transparent schematic of the device showing 1) motor, 2) gear train, 3) metacarpal cradle, and 4) thumb cradle. **(C)** Isometric view of the thumb cradle. **(D)** Side view of the metacarpal cradle showing a gothic arch profile

## 2 Methods

A device to quantitatively assess the thumb UCL was developed using a deterministic design process. The following functional requirements were identified:

1) Measure parameters that directly correspond to UCL integrity
2) Examiner-independent performance
3) Stabilize metacarpal to isolate MCP abduction in the coronal plane
4) Accommodates a wide range of bilateral thumb sizes
5) User-friendly operation
6) Safe operation through emergency stop functionality

The final device design (Fig. 1A, 1B) is a motorized, hand-held device that abducts the thumb while recording torque and angular displacement. Torque is calculated through motor input current measurements, while angular displacement is measured directly from the motor encoder. The device attaches to the patient's thumb through a cradle (Fig. 1C) that is designed to

accommodate up to the 99th percentile male thumb dimensions [5]. The device interfaces with the patient's hand via a metacarpal cradle (Fig. 1D) that uses the rigid surface of the first metacarpal bone to constrain the position of the device.

The device is designed to be operated by the patient so that testing can be paused if necessary due to discomfort. Before testing, the physician will help position the device such that the axis of rotation is aligned with the MCP joint. The patient initiates testing by pressing and holding the button on the top of the device. The device then slowly rotates the thumb until a threshold torque is released. If the button is released, the device immediately stops. A graph of angular displacement vs torque, as well as the maximum torque and angle values, are displayed on an OLED screen. Right hand vs left hand operation can be selected via a switch.

## 3 Results

Quantitative testing of the device was performed using a series of thumb models designed to mimic the articulation of the MCP joint. Extension springs with different spring constants were incorporated in the joint to simulate UCL tears of differing severity. Each thumb model was affixed to the device using the metacarpal and thumb cradles. Testing was performed for simulated full and partial UCL tears, as well as a simulated intact ligament. Results are shown below in Fig. 2. There is a clear distinction between the torque-angle curves of the fully torn UCL model, compared to the curves of the intact and partially torn UCL models.

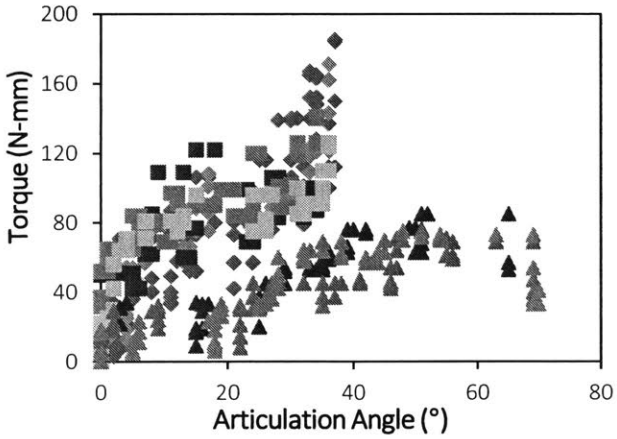


**Figure 2:** Torque vs articulation angle plot of thumb model tests. Squares = intact UCL, Diamonds = partially torn UCL, Triangles = full tear of UCL

## 4 Interpretation

A device was created to quantitatively assess the integrity of the thumb UCL through measurement of applied torque and angular displacement. These measurements correspond to the parameters currently used in the clinical stress-test, namely the "soft vs hard" endpoint. Preliminary testing on thumb models showed that full tears of the UCL can be readily distinguished from partially torn and intact ligaments.

Future iterations of the device are focused on improving the mechanism of torque measurement, as well as the ergonomics of the operator. Further human subject testing is needed to assess the clinical utility of the device for diagnosis of Skier's thumb injuries.

## Acknowledgements

The authors would like to acknowledge the students, faculty, and staff from the Medical Device Design class at MIT (2.75)

## References

[1] Mahajan, M. and Rhemrev SJ, 2013, "Rupture of the ulnar collateral ligament of the thumb – a review," Int. Journal of Emergency Medicine, 6 (31). doi:10.1186/1865-1380-6-31.

[2] Ritting, A.W., Baldwin, P.C., and Rodner, C.M., 2010, "Ulnar collateral ligament injury of the thumb metacarpophalangeal joint," Clin J Sport Med, 20(2), pp. 106-12. doi: 10.1097/JSM.0b013e3181d23710

[3] Arende, C.F. and da Silva, T.R., 2014, "The role of US in the evaluation of clinically suspected ulnar collateral ligament injuries of the thumb: spectrum of findings and differential diagnosis," Acta Radiologica. 55(7), pp. 814-23. doi: 10.1177/0284185113506139

[4] Chuter, G.S., Muwanga, C.L., and Irwin, L.R., 2009, "Ulnar collateral ligament injuries of the thumb: 10 years of surgical experience," Injury, 40(6), pp. 652-6. doi: 10.1016/j.injury.2009.01.107

[5] Tilley, Alvin, 2002, *The Measure of Man & Woman.* Wiley, New York. Print.

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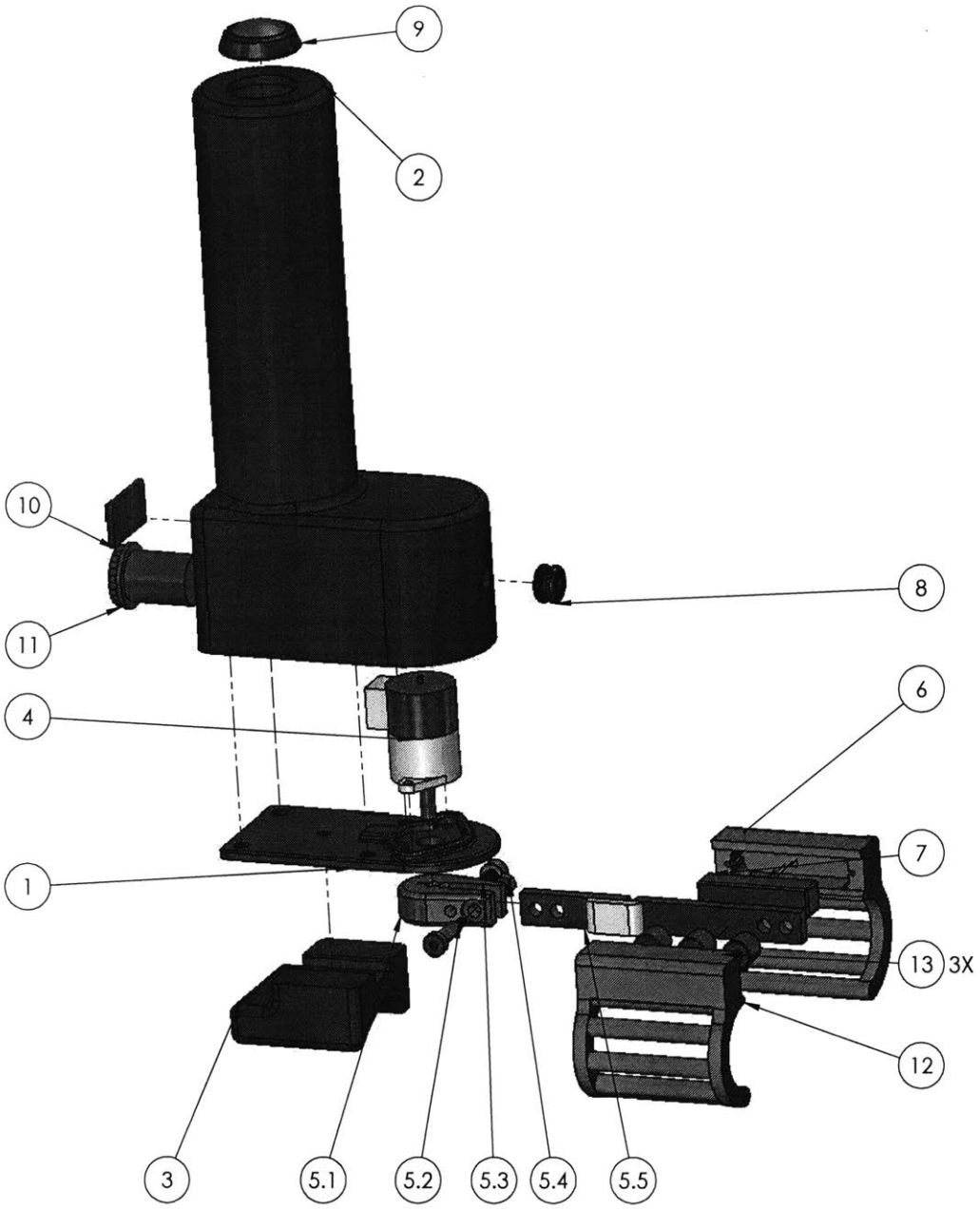
# Appendix B

# Part Drawings




| REVISIONS | | | | |
|---|---|---|---|---|
| ZONE | REV. | DESCRIPTION | DATE | APPROVED |

| ITEM NO. | PartNo | DESCRIPTION | D170 Engine/QTY. |
|---|---|---|---|
| 1 | THUMB DEVICE | Housing Floor | 1 |
| 2 | Housing Top v3 | Housing Top , | 1 |
| 3 | Metacarpal cradle v2 | Metacarpal Cradle , | 1 |
| 4 | NMB_PG15S-D20-HHB9 | NNB Stepper Motor , | 1 |
| 5 | Motor-Load Cell Coupling Assembly | Futex Load Cell , Subassembly | 1 |
| 5.1 | Motor-Load Cell Coupling v3 | Motor Load Cell Coupling , | 1 |
| 5.2 | 90263A117_TYPE 316 SS TIGHT-TOLERANCE SHOULDER SCREW | 3 mm Shoulder Dia. Soulder Screw , 10mm length, 2M thread, 316 SS Shoulder Screw | 1 |
| 5.3 | 91290A113_BLACK-OXIDE CLASS 12.9 SOCKET HEAD CAP SCREW | M3x8mm Bolt , Black Oxide Steel | 1 |
| 5.4 | 93625A101_TYPE 18-8 STAINLESS STL NYLON-INSERT LOCKNUT | M2 Locknut , 316 SS | 1 |
| 5.5 | Futek Cantilever Load Cell LBB200 | Futek Cantilever Load Cell , LBB200 | 1 |
| 6 | Thumb Cradle v5B - AVG | Thumb Cradle , | 1 |
| 7 | BX044-N52 | Bar Magnet , BX044-N52 | 1 |
| 8 | Grommet | Gromet , | 1 |
| 9 | button | Button , | 1 |
| 10 | switch | Switch , | 1 |
| 11 | Power Connector | Power Connector , | 1 |
| 12 | Thumb Cradle v5 - AVG | Thumb Cradle , | 1 |
| 13 | Magnet D42SH | Round Magnet , D42SH | 3 |

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MM
TOLERANCES:
ANGLES: MACH ±0.5° BEND ±1.5°
X.XX ±0.05 X.X ±0.12
X ±0.5
BREAK ALL EDGES 0.03 min
3rd ANGLE PROJECTION
MATERIAL ABS
FINISH 125 UNLESS NOTED
DO NOT SCALE DRAWING

| | NAME | DATE |
|---|---|---|
| DRAWN | TMC | 1/17/2018 |
| CHECKED | | |
| ENG APPR. | | |
| MFG APPR. | | |

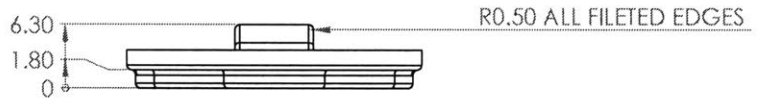
THOMAS CERVANTES
TMCNEB@MIT.EDU

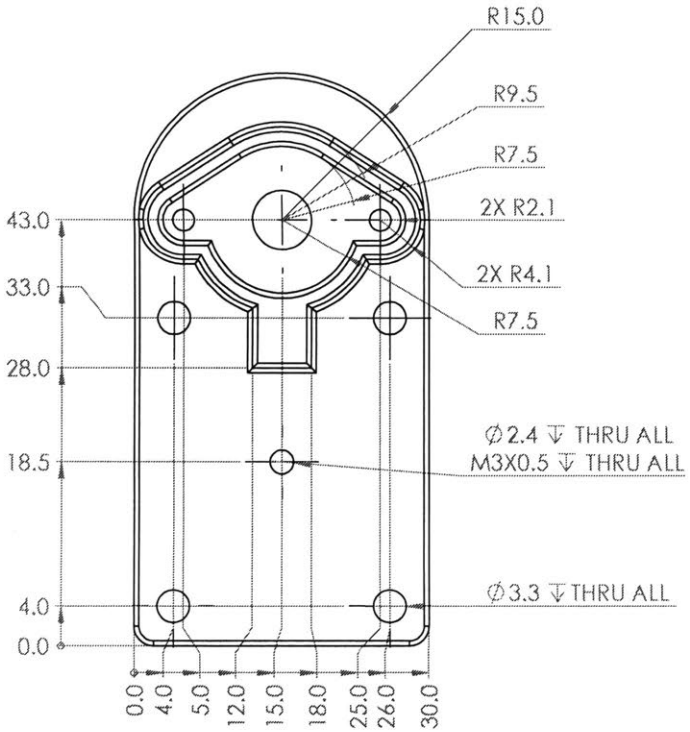
TITLE:
# Assembly Thumb ULC Device

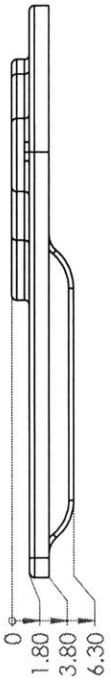
| SIZE | DWG. NO. | REV |
|---|---|---|
| B | DRAWINGS | A |

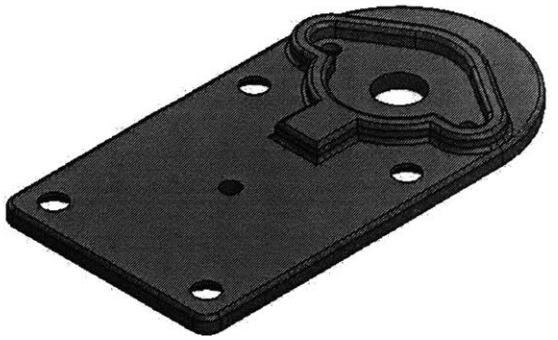
SCALE: 2:1 MASS: 3.97 SHEET 1 OF 6

| REVISIONS | | | | |
|---|---|---|---|---|
| ZONE | REV. | DESCRIPTION | DATE | APPROVED |



NOTES:

1. 3D Printed
2. Deburr and remove all sharp edges
3. See CAD for dimension details.

| UNLESS OTHERWISE SPECIFIED: | | NAME | DATE |
|---|---|---|---|
| DIMENSIONS ARE IN MM | DRAWN | TMC | 1/17/2018 |
| TOLERANCES: ANGLES: MACH±0.5° BEND ±1.5° X.XX ±0.01 X.X ±0.12 X ±0.5 | CHECKED | | |
| | ENG APPR. | | |
| BREAK ALL EDGES 0.03 min | MFG APPR. | | |
| 3rd ANGLE PROJECTION | | | |
| MATERIAL ABS | | | |
| FINISH 1.6 UNLESS NOTED | | | |
| DO NOT SCALE DRAWING | | | |

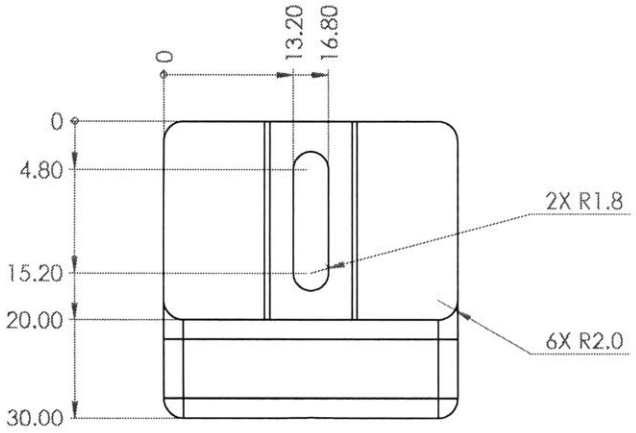
THOMAS CERVANTES
TMCNEB@MIT.EDU

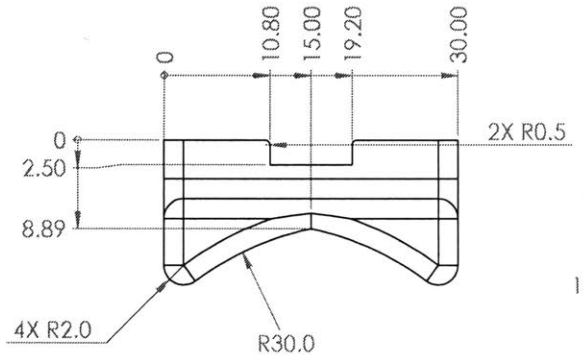
TITLE:
Housing Floor
Thumb ULC Device

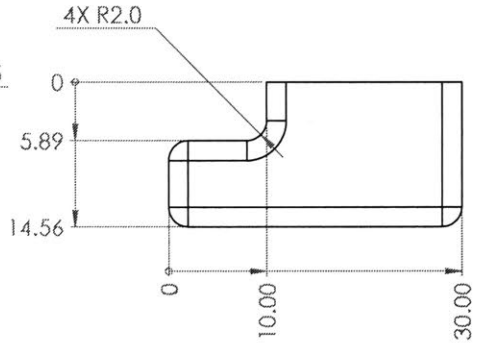
| SIZE | DWG. NO. | REV |
|---|---|---|
| B | DRAWINGS | A |
| SCALE: 2:1 | MASS: 3.97 | SHEET 2 OF 6 |

REV A
DRAWINGS
B

| REVISIONS | | | | |
|---|---|---|---|---|
| ZONE | REV. | DESCRIPTION | DATE | APPROVED |




NOTES:

1. 3D Printed
2. Deburr and remove all sharp edges
3. See CAD for dimension details.

| UNLESS OTHERWISE SPECIFIED: | | NAME | DATE |
|---|---|---|---|
| DIMENSIONS ARE IN MM<br>TOLERANCES:<br>ANGLES: MACH ±0.5° BEND ±1.5°<br>X.XX ±0 .05 X.X ±0.12<br>X ±0.5 | DRAWN | TCM | 1/17/2018 |
| | CHECKED | | |
| | ENG APPR. | | |
| BREAK ALL EDGES 0.03 min | MFG APPR. | | |
| 3rd ANGLE PROJECTION | | | |
| MATERIAL Material <not specified> | | | |
| FINISH 1.6 UNLESS NOTED | | | |
| DO NOT SCALE DRAWING | | | |

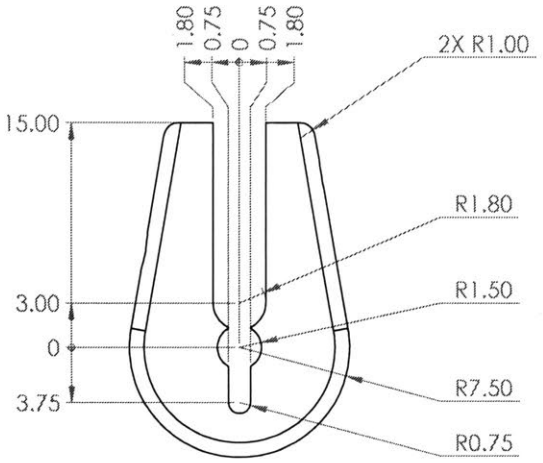
THOMAS CERVANTES
TMCNEB@MIT.EDU

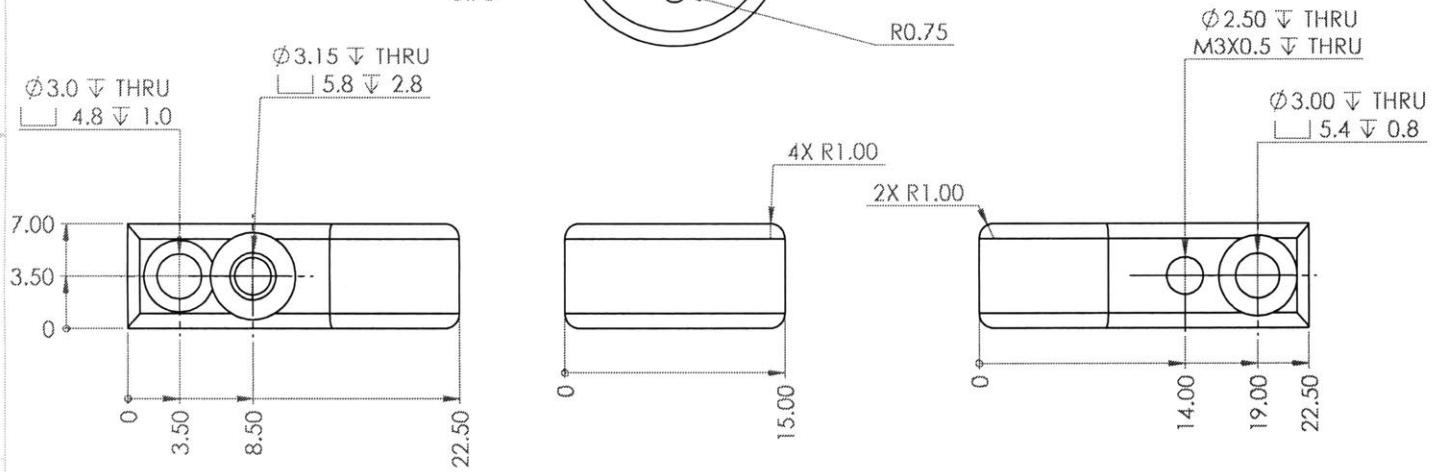
TITLE:
# Metacarpal Cradle
## Thumb UCL Device

| SIZE | DWG. NO. | REV |
|---|---|---|
| B | DRAWINGS | A |

SCALE: 2:1 MASS: 7.76 SHEET 3 OF 6

| REVISIONS | | | | |
|---|---|---|---|---|
| ZONE | REV. | DESCRIPTION | DATE | APPROVED |




NOTES:

1. Deburr and remove all sharp edges
2. See CAD for dimension details.

| | | NAME | DATE |
|---|---|---|---|
| UNLESS OTHERWISE SPECIFIED: | | | |
| DIMENSIONS ARE IN MM | DRAWN | TCM | 1/17/2018 |
| TOLERANCES: ANGLES: MACH±0.5° BEND ±1.5° X.XX ±0 .05 X.X ±0.12 X ±0.5 | CHECKED | | |
| | ENG APPR. | | |
| BREAK ALL EDGES 0.03 min | MFG APPR. | | |
| 3rd ANGLE PROJECTION | | | |
| MATERIAL: Aluminum 6061 | | | |
| FINISH 1.6 UNLESS NOTED | | | |
| DO NOT SCALE DRAWING | | | |

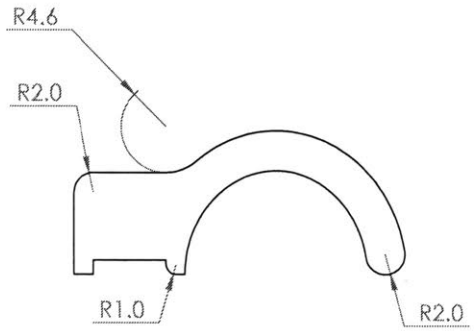
THOMAS CERVANTES
TMCNEB@MIT.EDU

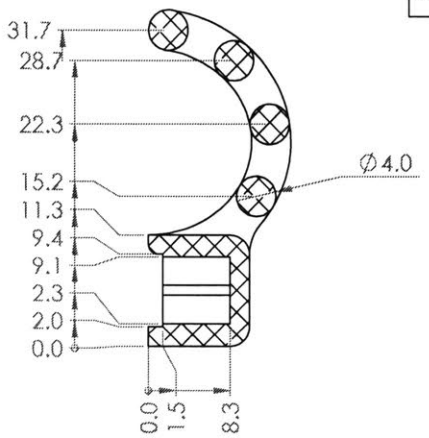
TITLE: Motor Load Cell Coupling Thumb UCL Device

| SIZE | DWG. NO. | REV |
|---|---|---|
| B | DRAWINGS | A |

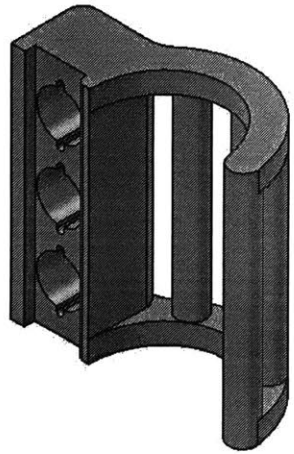
SCALE: 3:1 MASS: SHEET 4 OF 6

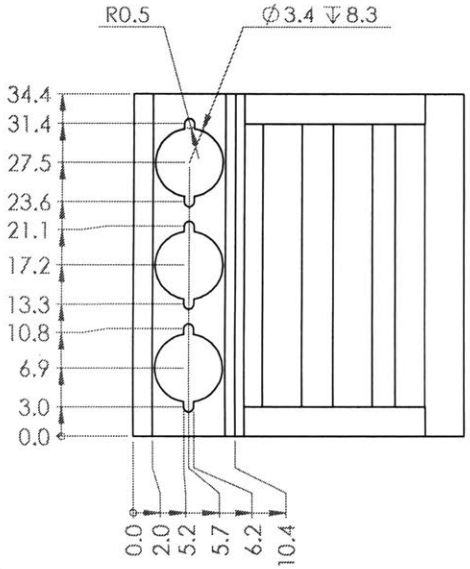
| REVISIONS | | | | |
|---|---|---|---|---|
| ZONE | REV. | DESCRIPTION | DATE | APPROVED |

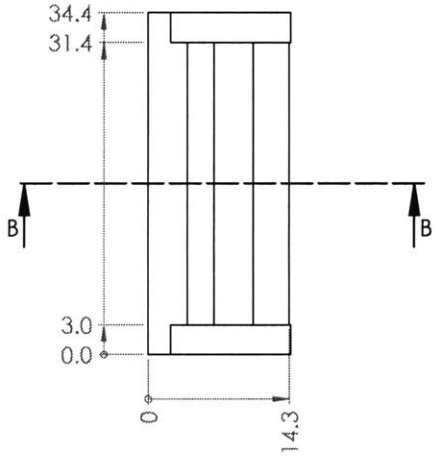



SECTION B-B






NOTES:

1. 3D Printed
2. Deburr and remove all sharp edges
3. See CAD for dimension details.

| | | NAME | DATE |
|---|---|---|---|
| UNLESS OTHERWISE SPECIFIED: | | | |
| DIMENSIONS ARE IN MM | DRAWN | TMC | 1/17/2018 |
| TOLERANCES: ANGLES: MACH ±0.5° BEND ±1.5° X.XX ±0 .05 X.X ±0.12 X ±0.5 | CHECKED | | |
| | ENG APPR. | | |
| BREAK ALL EDGES 0.03 min | MFG APPR. | | |
| 3rd ANGLE PROJECTION | | | |
| MATERIAL ABS | | | |
| FINISH 1.6 UNLESS NOTED | | | |
| DO NOT SCALE DRAWING | | | |

THOMAS CERVANTES
TMCNEB@MIT.EDU

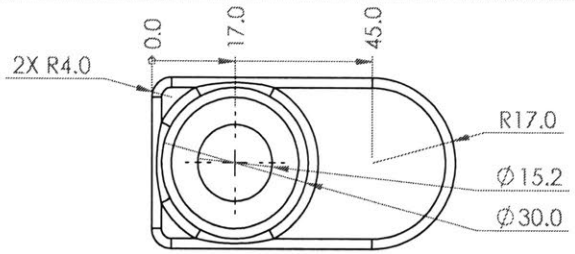
TITLE:

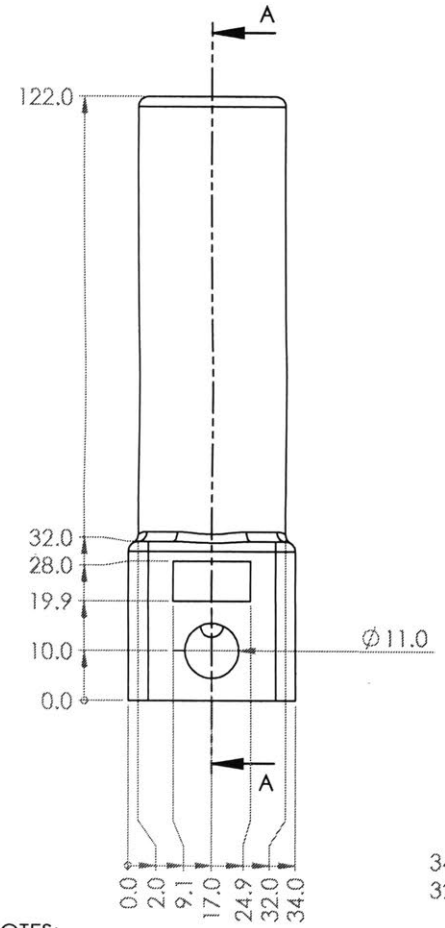
Thumb Cradle

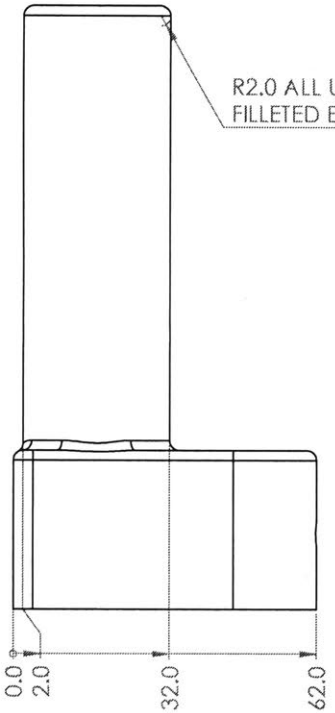
~~Thumb UCL Device~~

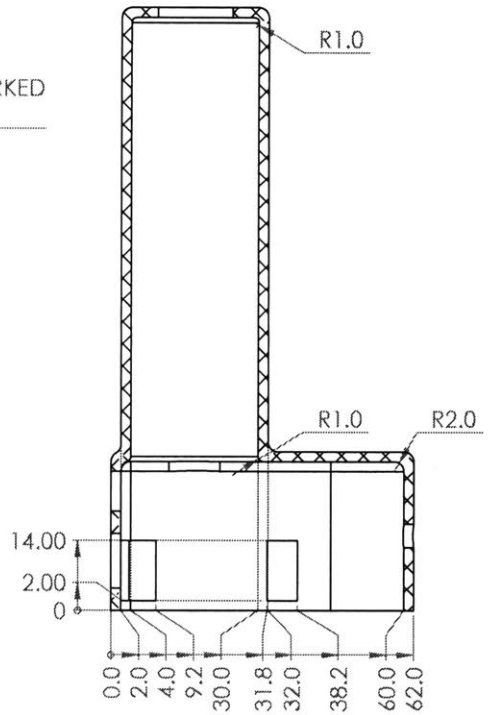
| SIZE | DWG. NO. | REV |
|---|---|---|
| B | DRAWINGS | A |
| SCALE: 2:1 | MASS: 3.97 | SHEET 5 OF 6 |

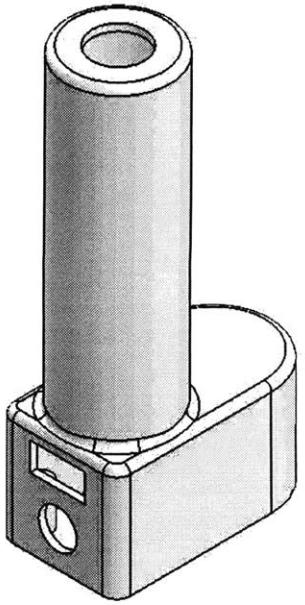
| REVISIONS | | | | |
|---|---|---|---|---|
| ZONE | REV. | DESCRIPTION | DATE | APPROVED |



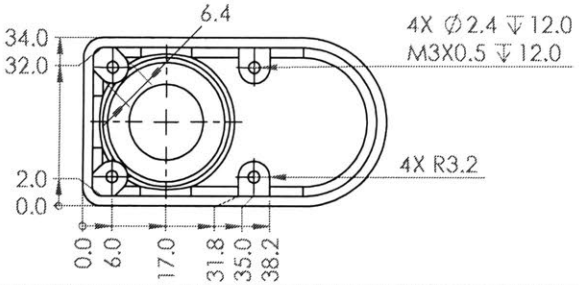



SECTION A-A




NOTES:

1. 3D Printed
2. Deburr and remove all sharp edges
3. See CAD for dimension details.

| UNLESS OTHERWISE SPECIFIED: | | NAME | DATE |
|---|---|---|---|
| DIMENSIONS ARE IN MM<br>TOLERANCES:<br>ANGLES: MACH ±0.5° BEND ±1.5°<br>X.XX ±0.05 X.X ±0.12<br>X ±0.5 | DRAWN | TCM | 1/17/2018 |
| | CHECKED | | |
| | ENG APPR. | | |
| BREAK ALL EDGES 0.03 min | MFG APPR. | | |
| 3rd ANGLE PROJECTION | | | |
| MATERIAL ABS | | | |
| FINISH 1.6 UNLESS NOTED | | | |
| DO NOT SCALE DRAWING | | | |

THOMAS CERVANTES
TMCNEB@MIT.EDU

TITLE:

# Housing Top
## Thumb UCL Device

| SIZE | DWG. NO. | REV |
|---|---|---|
| B | DRAWINGS | A |

SCALE: 1:1 MASS: 31.37 SHEET 6 OF 6

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# Appendix C

# Circuit Wiring Schematic

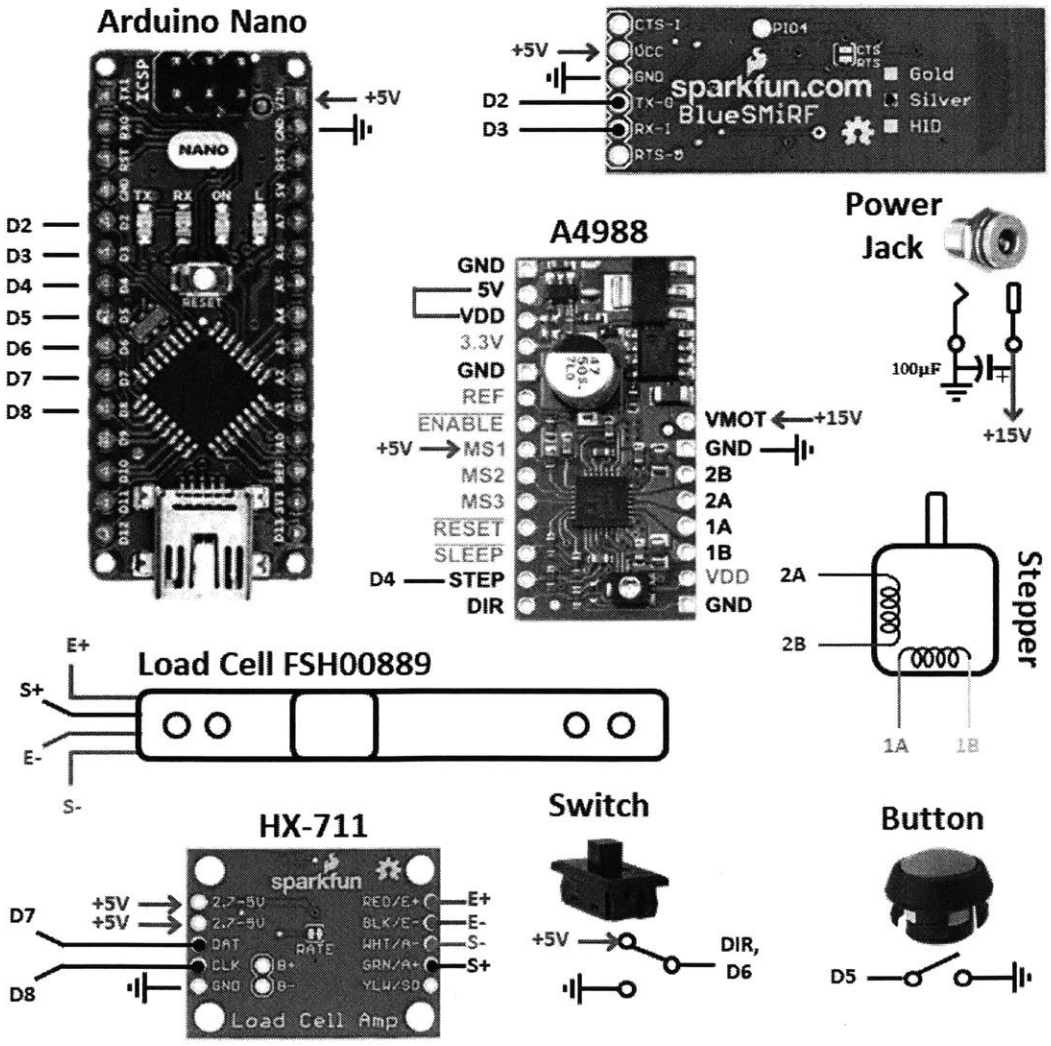


Figure C-1: Wiring Schematic

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# Appendix D

# Arduino Code

```
#include <BasicStepperDriver.h>
#include <SoftwareSerial.h>
#include <HX711.h>

////////////////////////////////////////////////////////////////
// PIN/CONSTANT DEFINITIONS

const int bluetoothTx = 2;
const int bluetoothRx = 3;
const int stp = 4;  // A4988
const int buttonInput = 5;
const int motorDirInput = 6;
const int DOUT = 7; // HX711
const int CLK = 8; // HX711

const int motorSteps = 727; //# steps per revolution
const float motorSpeed = 0.375;
//RPM to rotate 45 degrees in 20 seconds
const int stepPeriod = 220;
```

```
// ms per step for 45 degrees in 20 sec

const float angleLimit = 60;
const float torqueLimit = 450; // torque limit of large motor

const float calibration_factor = -6200;
const long zero_factor = 84784;

////////////////////////////////////////////////////////////
// VARIABLE DECLARATIONS

int stepCount = 0;
int buttonState = 0;
bool beginTest = false;
long motorTimeStamp = 0; // time of last motor step
int motorTimeCount = 0; // time since last step

float Angle = 0.00;
float LoadCellTorque = 0.00;
float Stiffness = 0.00;

BasicStepperDriver stepper(motorSteps, 12, stp);
// use 12 as empty pin for direction output
SoftwareSerial bluetooth(bluetoothTx, bluetoothRx);
HX711 scale(DOUT, CLK);

void setup()
{
  pinMode(stp, OUTPUT);
  pinMode(buttonInput, INPUT);
```

```
  digitalWrite(buttonInput, HIGH);
  pinMode(motorDirInput, INPUT);
  bluetoothInit();
  LoadCellInit();
  stepper.begin(motorSpeed, 1);
  delay(1000);
  dataInit();
}

void loop()
{
  if (Angle < angleLimit && abs(LoadCellTorque) < torqueLimit) {
    buttonRead();
    if (beginTest == true) {
      if (buttonState == LOW) {
        motorStep();
      }
      bluetoothPrintData();
    }
  }
}

////////////////////////////////////////////////////////////
// STEPPER CONTROL FUNCTIONS

void motorStep() {
  if (checkTime() == true) {
    stepper.move(1); // move 1 step
    motorTimeStamp = millis();
    // reset time stamp since last motor step
```

```
    stepCount++;
  }
}

bool checkTime() {
  motorTimeCount = millis()-motorTimeStamp;
  // update motorTimeCount based on current time
  if (motorTimeCount >= stepPeriod) {
    return true;
  }
  else
  {
    return false;
  }
}



////////////////////////////////////////////////////////////////
// BLUETOOTH & PRINT FUNCTIONS

void bluetoothInit() {
  bluetooth.begin(115200);
  bluetooth.print("$");
  bluetooth.print("$");
  bluetooth.print("$");
  delay(100);
  bluetooth.println("U,9600,N");
  bluetooth.begin(9600);
  bluetooth.println("POWER ON");
```

```
}

void dataInit() {
  bluetooth.println("Subject Identifier:,,,Peak_Torque(N-mm),
  Peak_Stiffness(N-mm/deg)");
  bluetooth.print("Hand:,");
  if (digitalRead(motorDirInput) == HIGH) {
    bluetooth.print("LEFT");
  }
  else if (digitalRead(motorDirInput) == LOW) {
    bluetooth.print("RIGHT");
  }
  bluetooth.println();
  bluetooth.println("Time,Button_On/Off,Angle_(deg),Torque_(N-mm),
  Stiffness_(N-mm/deg)");
}

void bluetoothPrintData() {
  bluetooth.print(millis());
  bluetooth.print(",");
  if (buttonState == HIGH) {
    bluetooth.print("OFF");
  }
  else if (buttonState == LOW) {
    bluetooth.print("ON");
  }
  bluetooth.print(",");
  bluetooth.print(getAngle());
  bluetooth.print(",");
  bluetooth.print(LoadCell_read());
```

```
  bluetooth.print(",");
  bluetooth.print(getStiffness());
  bluetooth.println();
}

////////////////////////////////////////////////////////////////
// BUTTON FUNCTIONS

void buttonRead() {
  buttonState = digitalRead(buttonInput);
  if (buttonState == LOW && beginTest == false) {
    beginTest = true;
  }
}

////////////////////////////////////////////////////////////////
// DATA ANALYSIS FUNCTIONS

float getAngle() {
  Angle = stepCount*360.00/727*1;
  return Angle;
}

float getStiffness() {
  Stiffness = LoadCellTorque/Angle;
  if (Stiffness < 0) {
    Stiffness = Stiffness*-1;
  }
  return Stiffness;
}
```

```
////////////////////////////////////////////////////////////
// LOAD CELL FUNCTIONS

void LoadCellInit() {
  scale.tare();
  scale.set_scale(calibration_factor);
}

float LoadCell_read() {
  LoadCellTorque = scale.get_units();
  if (LoadCellTorque < 0) {
    LoadCellTorque = LoadCellTorque*-1;
  }
  return LoadCellTorque;
}
```

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# Appendix E

# COUHES Forms

| | | | |
|---|---|---|---|
| | **Massachusetts Institute of Technology**<br>Committee on the Use of<br>Humans as Experimental Subjects | **Protocol #**<br>(assigned<br>by<br>COUHES) | |

## APPLICATION FOR USE OF HUMANS AS EXPERIMENTAL SUBJECTS (STANDARD FORM)

*Please answer every question. Positive answers should include details. N/A must be marked where the question does not pertain to your application. Any incomplete application will be rejected and returned for completion. This application **must** include the secondary personnel list form otherwise this application will be returned to you.*

### I. BASIC INFORMATION

**1. Title of Study**

Evaluation of a Thumb Ligament Diagnostic Device

**2. Principal Investigator**

| | |
|---|---|
| Name: Alexander Slocum | Building and Room #:3-442 |
| Title: Professor of Mechanical Engineering | Email: slocum@mit.edu |
| Department: Mechanical Engineering | Phone: 6035917505 |

**3. Funding.** *If the research is funded by an outside sponsor, please enclose one copy of the research proposal with your application. A draft of the research proposal is acceptable.* ***Do not leave this section blank. Check all that apply. If your project is not funded, check No Funding.***

A. Sponsored Project Funding:

☐ Current Proposal Grant/Proposal #_____
Sponsor _____
Title _____

☐ Current Award Grant/Account #_____
Sponsor _____
Title _____

B. Institutional Funding:

☐ Gift ☐ Departmental Resources
☐ Other (explain) _____

C. No Funding
☒ This protocol will not be funded

**4. STATEMENT OF FINANCIAL INTEREST**

Does the investigator, study personnel involved in the study or their family have a financial interest in a company or other organization participating in or providing drugs, devices, biological agents, investigational medical devices, or any other tangible material or financial sponsorship for the research?

☐ Yes ☒ No

Does this study contemplate receiving/using any materials/data (data sets, confidential information) or making any purchases from or subawards to a company or other organizations in which you or a family member hold a Financial Interest?

☐ Yes ☒ No

If yes was checked for any of the questions above, then attach a **Supplement for Disclosure of Financial Interest** for each individual with an interest. *This supplement, together with detailed guidance on this subject and definitions of the highlighted terms, is available in the COUHES site under Policies & Procedures in the Financial Conflicts of Interest section.*

| **5. Anticipated Dates of Research** | |
|---|---|
| Start Date: 11/20/2017 | Completion Date: 11/19/2018 |

**6. Collaborating Institutions.** *If you are collaborating with another institution(s) then you must obtain approval from that institution's institutional review board, and forward copies of the approval to COUHES.*

N/A

**7. Location of Research.** *If at MIT please indicate where on campus. If you plan to use the facilities of the Clinical Research Center you will need to obtain separate approval from the MIT Catalyst Clinical Research Center.*

Room 3-443, 3-438 (Precision Engineering Research Group), MIT, Cambridge, MA

## II. STUDY INFORMATION

**1. Purpose of Study.** *Please provide a concise statement of the background, nature and reasons for the proposed study. Use non-technical language that can be understood by non-scientist members of COUHES.*

The study is for the evaluation of a device to test the mechanical properties of the ulnar collateral ligament (UCL) of the thumb. The device was developed as part of a Master's thesis project.

The goals of the study are to 1) gather user feedback on the ergonomics and overall design features of the device, and 2) gather biomechanical data of the thumb UCL. The biomechanical data will aid in the understanding of device performance. The subject feedback will guide future iterations of the design.

**2. Study Protocol.** *For* **biomedical, engineering and related research,** *please provide an outline of the actual experiments to be performed. Where applicable, provide a detailed description of the experimental devices or procedures to be used, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of special diets. For applications in the* **social sciences, management and other non-biomedical disciplines** *please provide a detailed description of your proposed study. Where applicable, include copies of any*

*questionnaires or standardized tests you plan to incorporate into your study. If your study involves interviews please submit an outline indicating the types of questions you will include.*
*You should provide sufficient information for effective review by non-scientist members of COUHES. Define all abbreviations and use simple words. Unless justification is provided for additional length, this part of the application must not exceed 5 pages.*
*Attaching sections of a grant application is not an acceptable substitute for a description of your study as requested here.*

Subjects will be asked to undergo testing of the thumb UCL ligament using a device developed by the Precision Engineering Research Group at MIT (see Appendix, Fig. 1). The device rests on the dorsal surface of the user's thumb metacarpal, and on the distal phalanx of the thumb. A motor within the device applies a torque to the thumb joint, which causes palmar abduction. The torque is measured through a Futek cantilever load cell. An Arduino microcontroller is used for motor control and data collection. The Arduino is connected to the device via wires.

When using the device, the operator will place the device on the user's thumb and orient it to the proper alignment. When the operator and subject are ready to begin testing, the operator will press a button on the device, causing the motor to engage. The motor will stop once the Arduino calculates the ligament stiffness (through analysis of the torque-displacement relationship). Additionally, the motor will stop if the motor exceeds a torque threshold (150 N-mm), or if the operator releases the button. Testing will be conducted on each thumb (if applicable), and may be repeated if necessary to ensure data quality. The maximum force applied to the thumb will be 10 Newtons (2.2 lbs). This force limit is below the threshold of damage for both healthy and injured thumbs.

Before the testing is performed on the subject, the investigator will provide a description of the device, and perform a self-demonstration of the device. The subject will also have the opportunity to handle the device and provide general feedback. The investigator will ask specific questions about the device design, operation, and comfort.

The investigator will also gather anthropometric measures of the thumb using calipers (length of metacarpal, proximal and distal phalanges; hand thickness at thenar eminence; thumb diameter at inter-phalangeal joint; diameter at thumb metacarpo-phalangeal joint; distance between thumb and index metacarpo-phalangeal joints at maximal thumb abduction).

**3. Drugs and Devices.** *If the study involves the administration of an investigational drug that is not approved by the Food and Drug Administration (FDA) for the use outlined in the protocol, then the principal investigator (or sponsor) must obtain an Investigational New Drug (IND) number from the FDA. If the study involves the use of an approved drug in an unapproved way the investigator (or sponsor) must submit an application for an IND number. Please attach a copy of the IND approval (new drug), or application (new use.).*

*If the study involves the use of an investigational medical device and COUHES determines the device poses significant risk to human subjects, the investigator (or sponsor) must obtain an Investigational Device Exemption (IDE) number from the FDA.*

**Will drugs or biological agents requiring an IND be used? YES ☐ NO ☒**
*If yes, please provide details:*
**Will an investigational medical device be used? YES ☒ NO ☐**

*If yes, please provide details:* The device for measuring thumb ligament mechanics has been developed by the Precision Engineering Research Group at MIT. Preliminary studies on design feasibility and efficacy have been completed, and multiple prototypes made. The device will have minimal contact with the skin, and is made of materials that are non-toxic and non-irritating. Multiple safety features have been engineered into the device.

**4. Radiation** *If the study uses radiation or radioactive materials it may also have to be approved by the Committee on Radiation Exposure to Human Subjects (COREHS). COUHES will determine if you need COREHS approval.*

**Will radiation or radioactive materials be used? YES** ☐ **NO** ☒
*If yes, please provide details:*
**Will any type of lasers be used YES** ☐ **NO** ☒
*If yes, please provide details:*

**5. Diets**

**Will special diets be used? YES** ☐ **NO** ☒
*If yes, please provide details*

## III. PERSONNEL

**Fill out the personnel list attached to this form.** *If the personnel list is not included, the application will be returned to you.*

## IV. HUMAN SUBJECTS

**1. Subjects** (*that will be consented for this study*)

**A. Maximum number of subjects:** 20

**Adults:**20 **Minors:** 0

**B. Age(s):** 18+

**C. Inclusion/exclusion criteria**

**i. What are the criteria for inclusion or exclusion?** Acceptable subjects for this study will have unrestricted range of motion of one or both thumbs, and no recent history of injury to the thumb.

Subjects with thumb pathology or a current thumb injury will be identified with the following series of questions:

1. Do you have any pain in your thumb currently?
2. Do you have full range of motion of your thumb? If so, please demonstrate.
3. Have you ever experienced an injury to your thumb(s) that limited your ability to perform everyday tasks?

Subjects answering "yes" to questions 1 or 3, or "no" to question 2 will be excluded from the study. Additionally, the examiner will visually inspect the subjects' thumbs for any signs of deformity or injury. The examiner will also perform a stress test of the thumb, a physical exam maneuver used to

evaluate the thumb joint. To perform the stress test, the examiner will grasp the palm and thumb of the subject, and gently move the thumb through it's full range of motion. If subjects experience pain during any part of this maneuver, they will be excluded from this study.

**ii. Are any inclusion or exclusion criteria based on age, gender, or race/ethnic origin?** *If so, please explain and justify.* Only adults 18+ will be considered.

**iii. Please explain the inclusion of any vulnerable population (e.g. children, cognitively impaired persons, non-English speakers, MIT students), and why that population is being studied.** MIT students might be used as subjects, given they are colleagues of the investigators.

**2. Subject recruitment** *Identification and recruitment of subjects must be ethically and legally acceptable and free of coercion. Describe below what methods will be used to identify and recruit subjects. Attach any and all recruitment documents associated with the protocol (i.e. flyers, e-mails, advertisements, etc.)*

Subjects will be recruited through personal contacts and colleagues of the investigators. Subjects will be asked if they would like to participate in a study of a device to improve thumb injury diagnosis. If subjects show interest, they will be given a full description of the study, and shown a demonstration of the device on the investigators.

**3. Informed consent.** *Documented informed consent must be obtained from all participants in studies that involve human subjects. You must use the templates available on the COUHES website to prepare these forms. Draft informed consent forms must be returned with this application. Under certain* ***very limited*** *circumstances, COUHES may waive the requirement for informed consent. If you are requesting a* ***waiver or alteration of consent****, please attach the Waiver or Alteration of Informed Consent Request form.*

**[Attach informed consent form(s) with this application.]**

**4. Subject compensation.** *Payment must be reasonable in relation to the time and trouble associated with participating in the study. It cannot constitute an undue inducement to participate.*

**Describe all plans to pay subjects in cash or other form of payment (i.e. gift certificate):**
No compensations.

**Will subjects be reimbursed for travel and expenses?**
No travel or expenses required.

**5. Potential risks.** *A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g., appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.*

**What are the risks / discomforts associated with each intervention or procedure in the study?**
The device could cause pain to the thumb being tested

**What procedures will be in place to prevent / minimize potential risks or discomfort?**

There are 3 countermeasures built into the device that address the risk of user pain:

1) The motor torque output is smaller than the threshold of ligament injury.
2) The operator must continually press a button for the device to be operated. If the operator releases the button, the test will end.
3) The thumb is not rigidly attached to the device, allowing the user to completely remove the handheld device from the thumb being tested.

**6. Potential benefits**

**What potential benefits may subjects receive from participating in the study?**
N/A

**What potential benefits can society expect from the study?**
A device to accurately and reliably diagnose thumb UCL injuries could expedite patient care and reduce the need for expensive and time-consuming imaging studies such as MRI.

**7. Data collection, storage, and confidentiality**

**How will data be collected?**
Qualitative data will be collected via a written survey and through informal conversation recorded in a lab notebook. Biomechanical data (torque, angle) will be recorded onto computer storage by the device. No protected health information will ever be associated with the biomechanical or quantitative data collection

**Is there audio or videotaping? YES ☒ NO ☐** ***Explain the procedures you plan to follow.***
Video of the device in operation may be recorded. Recording will take place using a cell phone camera or other camera device. Subjects will be informed if recording is to take place. Subjects may refuse to participate in video recording. No protected health information will be recorded in the video.

**Will data be associated with personal identifiers or will it be coded?**

**Personal identifiers ☐ Coded ☒** ***Explain the procedures you plan to follow.***
The data will be labeled with a code by which it can be identified later. The user age, handedness, and gender will be associated with each label. Names or other personal identifiers are not required.

**Where will the data be stored and how will it be secured?**
Qualitative data will be recorded in a lab notebook or kept in a secure office. Biomechanical data will be kept on a secure server (MIT dropbox account).

**What will happen to the data when the study is completed?**
Qualitative data will be destroyed or archived in a secure office following the study. Biomechanical data will be archived on a secure server (MIT drobox account).

**Can data acquired in the study affect a subject's relationship with other individuals (e.g. employee-supervisor, patient — physician, student-teacher, family relationships)?**
No

**8. Deception** *Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.*

**Will information about the research purpose and design be withheld from subjects?**
**YES** ☐ **NO** ☒

***If YES, explain and justify.***

**9. Adverse effects.** *Serious or unexpected adverse reactions or injuries, and/or unanticipated problems involving risks to subjects or others must be reported to COUHES within 48 hours. Other adverse events should be reported within 10 working days.*

**What follow-up efforts will be made to detect any harm to subjects, and how will COUHES be kept informed?**
The study is not expected to cause any physical or mental harm to the researchers or participants. Any extraordinary conditions will be referred to MIT Medical and CHOUHES will be promptly informed.

**10. Health Insurance Portability and Accountability Act ("HIPAA").** *If your study (i) involves individually identifiable health information and (ii) is sponsored by MIT Medical, an MIT Health Plan or another healthcare provider, then you must complete the questions below because HIPAA likely applies to your study. For more information regarding the applicability of HIPAA to human subjects research, please click here.*

**Do you plan to obtain, use or disclose identifiable health information in connection with your research study?**
**YES** ☐ **NO** ☒
*If YES, then all participants must complete an Authorization for Release of Protected Health Information Form. Please attach a copy of this draft form. You must use the template available on the COUHES website.*

*Alternatively, COUHES may grant a Waiver of Authorization in certain **very limited** circumstances when use of individually identifiable health information would pose only minimal risk to study participants (among other requirements). For additional information regarding whether your study might qualify for a waiver, please click here.*

**Are you requesting a Waiver of Authorization?**
**YES** ☐ **NO** ☒
*If YES, explain your rationale for concluding that: (i) use of participant health information poses no more than minimal risk; (ii) the research could not be conducted without the waiver and (iii) the research could not be conducted without the information. In addition, please explain your plan for (i) ensuring the participant health information is not improperly used or disclosed either within MIT or to any outside third parties and (ii) destroying identifiers at the earliest possible opportunity.*

**Will the health information you will receive for use in this study be de-identified?**
**YES** ☒ **NO** ☐

*If YES, you do not need to obtain a signed Authorization for Release of Protected Health Information Form from study participants. Note, however, that if you receive identifiable participant health information that you plan to convert into de-identified information for use by other researchers, then you must obtain a signed Authorization for Release of Protected Health Information Form from each*

*participant before receiving their identifiable health information for use in your study.*

**Will you be using or disclosing a limited data set?**
**YES ☐ NO ☒**

*If YES, and you will only receive participant health information in limited data set form, then you do not need to obtain a signed Authorization for Release of Protected Health Information Form from study participants. You must complete a formal data use agreement with the party from whom you will receive the limited data set information in order for your application to be approved.*

*If YES, and you will receive identifiable participant health information that you plan to convert into limited data set form for use by other researchers, then you must obtain a signed Authorization for Release of Protected Health Information Form from each participant before receiving their identifiable health information for use in your study. You must complete a formal data use agreement in order for your application to be approved.*

## V. INVESTIGATOR'S ASSURANCE

**I certify the information provided in this application is complete and correct.**

**I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by COUHES**

**I agree to comply with all MIT policies, as well all federal, state and local laws on the protection of human subjects in research, including:**

- **ensuring all study personnel satisfactorily complete human subjects training;**
- **performing the study according to the approved protocol;**
- **implementing no changes in the approved study without COUHES approval;**
- **obtaining informed consent from subjects using only the currently approved consent form;**
- **protecting identifiable health information, to the extent required by law, in accordance with HIPAA requirements; and**
- **promptly reporting significant or untoward adverse effects.**

**Signature of Principal Investigator** _____ **Date** _____

**Print Full Name and Title** _____

**Signature of Department Head** _____ **Date** _____

**Print Full Name and Title** _____

**By signing this form you confirm a scientific review of the proposed research has been conducted, and that the proposed research is of scientific and scholarly validity.**

***The electronic file should be sent as an attachment to an e-mail: couhes@mit.edu. In addition, two single sided hard copies (one with original signatures) should be sent to the COUHES office: Building E25-Room 143B.***

| | | | |
|---|---|---|---|
| | **Massachusetts Institute of Technology**<br>Committee on the Use of<br>Humans as Experimental Subjects | **Protocol #**<br>(assigned by COUHES) | |

## PERSONNEL LIST

*This form must be attached to both standard and exempt form applications.* ***Any application submitted without a completed personnel list will be returned to you.***

*Personnel is defined as anyone who plays a role in research involving human subjects, including direct contact, indirect involvement, analysis of data, blood or tissue samples. This extends to principal investigators, associate investigators, student investigators, study coordinators, visiting scientists, consultants, laboratory technicians and assistants.*

*All study personnel must be listed below. This listing must include contact information, a brief statement of qualifications and their study role.*

*Important note: all study personnel are required to complete Human Subject Training before work begins on the project. Proof of training must be attached for non-affiliates. (Documentation from collaborating institutions may be submitted in lieu of training certificates.)*

### A. MIT AFFILIATES

| *Personnel name, and e-mail address* | *Qualifications: Describe briefly* | *Study role(s):* | *Check if obtaining consent* |
|---|---|---|---|
| **Contact***<br>Name: Alexander Slocum<br>Email: slocum@mit.edu | Professor of Mechanical Engineering, project advisor | Project Advisor | ☐ |
| Name: Tom Cervantes<br>Email: tmcneb@mit.edu | Graduate student, device designer | Design, implementation, and analysis of research | ☒ |
| Name:<br>Email: | | | ☐ |
| Name:<br>Email: | | | ☐ |
| Name:<br>Email: | | | ☐ |
| Name:<br>Email: | | | ☐ |

**CONSENT TO PARTICIPATE IN NON-BIOMEDICAL RESEARCH**

Evaluation of a Thumb Ligament Diagnostic Device

You are asked to participate in a research study conducted Thomas Cervantes, BS and Prof. Alexander Slocum, PhD, from the department of Mechanical Engineering at the Massachusetts Institute of Technology (M.I.T.) The results of this study will contribute to the SM thesis of Thomas Cervantes. You were selected as a possible participant in this study you are over 18 years of age, have unrestricted range of motion of one or both thumbs, and have no recent history of injury to the thumb. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this study is completely voluntary and you are free to choose whether to be in it or not. If you choose to be in this study, you may subsequently withdraw from it at any time without penalty or consequences of any kind. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

- **PURPOSE OF THE STUDY**

The study is for the evaluation of a device to test the mechanical properties of the ulnar collateral ligament (UCL) of the thumb. The device was developed as part of a Master's thesis project.

The goals of the study are to 1) gather user feedback on the ergonomics and overall design features of the device, and 2) gather biomechanical data of the thumb UCL. The biomechanical data will aid in the understanding of device performance. The subject feedback will guide future iterations of the design.

- **PROCEDURES**

If you volunteer to participate in this study, we would ask you to do the following things:

1) Thumb Ligament Measurement
   - An investigational device developed by the researchers will be used to measure the mechanical properties of a ligament in your thumb
   - The researchers will demonstrate the device before testing begins.
   - The device will rest on the top of your hand. Your thumb will be strapped into a cradle on the forward end of the device.

- The device will slowly apply pressure to push the thumb away from the hand. Measurements will be taken by the device during this process. The maximum force applied to the thumb will be 10 Newtons (2.2 lbs). This force limit is below the threshold of damage for both healthy and injured thumbs.
- The process will be done for both thumbs (if applicable), and may be repeated to ensure the quality of data collection.

2) Feedback on Device Design
- You will be given an opportunity to inspect and handle the device. If interested, you may also perform the thumb testing protocol on the researcher.
- Your feedback on the overall device design, performance, ergonomics, etc. will be solicited through conversation and a questionnaire.

3) Anthropometric Measurement
- The researcher will take measurements of different aspects of your hand (thumb length, hand width, etc.)

The complete experiment should take around 30-45 minutes.

- **POTENTIAL RISKS AND DISCOMFORTS**

1) Thumb pain or injury
- There is a small chance that the testing procedure could cause pain or injury to the thumb
- Many safety features have been built into the device to reduce injury risk, including:
    - The strength of the motor was selected to be smaller than the threshold of ligament injury (10 Newtons, or 2.2 lbs)
    - The device will only operate if a button is continually pressed – if this button is released, the motor will immediately stop
    - The thumb is not rigidly attached to the device, allowing you to rapidly remove your hand at any point during testing.

- **POTENTIAL BENEFITS**

There is no direct benefit to you for participating on this experiment.

The data collected from this study will provide a practical quantification of thumb ligament stiffness, which will be useful for researchers in the field. The design of the thumb ligament testing device will be improved; such a device could be used by hand surgeons to improve the diagnosis and treatment of thumb ligament injuries.

- **PAYMENT FOR PARTICIPATION**

No payment will be offered for participation in this study.

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. In addition, your information may be reviewed by authorized MIT representatives to ensure compliance with MIT policies and procedures.

All data will be recorded using an acquisition system and a password protected personal computer. Only the research team will have access to this data. No personal information is required. Data will be stored indefinitely.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact:
Thomas Cervantes tmcneb@mit.edu 402-679-0013
Alexander Slocum slocum@mit.edu 603-591-7505

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

## SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____
Name of Subject

_____
Name of Legal Representative (if applicable)

_____ _____
Signature of Subject or Legal Representative Date

## SIGNATURE OF PERSON OBTAINING INFORMED CONSENT

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____
Name of Person Obtaining Informed Consent

_____ _____
Signature of Person Obtaining Informed Consent Date

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