APPROVAL SHEET

Title of Thesis: Development of a Universal Hand Assist Tool for Patients with Reduced Upper Extremity Mobility Resulting From Cervical Spinal Cord Injury.

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ABSTRACT

Title of Document: DEVELOPMENT OF A UNIVERSAL HAND ASSIST TOOL FOR PATIENTS WITH REDUCED UPPER EXTREMITY MOBILITY RESULTING FROM CERVICAL SPINAL CORD INJURY.

Jarod Chrystopher Horn, Master of Science of Mechanical Engineering, 2018

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Tetraplegia caused by cervical spinal cord injury is a devastating condition resulting in limited or complete loss of sensation and motor function beyond the location of the injury. The lack of mobility drastically affects the independence and quality of life of the injured individual. In order to improve the quality of life of these individuals who retain some upper extremity mobility, it is imperative that adaptive devices are developed to assist with day to day activities. Such devices must be inexpensive, lightweight, and robust. The Universal Hand Assist Tool was developed to address these needs. This adaptive hand tool was designed using lean development principles to ensure robust and reliable performance, and fabricated with all 3D printed custom components. Five activities were developed for the hand tool, including using a touchscreen, writing pen, silverware, focused force stylus and quarter-inch hex tools. The Universal Hand Assist Tool is to be distributed through open-source channels to provide a low-cost adaptive hand tool platform.

DEVELOPMENT OF A UNIVERSAL HAND ASSIST TOOL FOR PATIENTS WITH REDUCED UPPER EXTREMITY MOBILITY RESULTING FROM CERVICAL SPINAL CORD INJURY.

By

Jarod Chrystopher Horn

Thesis submitted to the Faculty of the Graduate School of the
University of Maryland, Baltimore County, in partial fulfillment
of the requirements for the degree of
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Mechanical Engineering
2018

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Dedication

I dedicate this work to my amazing wife and son. Without Lauren's encouragement and Ryder's inspiration, my graduate work simply would not have been possible.

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First, I would like to thank my graduate advisor, Dr. S. Andrew Gadsden, for your guidance and support through this process. Without your encouragement, this thesis would not have been possible. I also extend my thanks to my project advisor Dr. Neil Rothman for your support and encouragement, for not only this project, but for the last four years of engineering school. Also, thanks for teaching me that MDF may not be an acceptable engineering material *for every project*! I would also like to thank Dr. Tim Topoleski for reviewing my thesis and serving on my defense committee. Thanks also to the VLINC organization for providing funding for this project, and for everything you do for the mobility needs community. Thanks also to Kurtis Boulter, Andy Wallace, Nick Lorenzo, Chris Gunther, and Joe Skura for making graduate school awesome. Finally, my best goes out to the Geezers, Rob Son, Jesse Hellman, and Geoff Hiscox, for being the other old guys, and making my time at UMBC and in Maryland tremendous.

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Chapter 1: Introduction

1.1 Overview

Tetraplegia (also known as quadriplegia) is a condition generally resulting from a traumatic event which damages the cervical spine, leaving the patient with limited or the complete loss of upper extremity (UE) mobility and sensation, and complete loss of mobility and sensation lower than the cervical spine [1]. This lack of mobility dramatically reduces the independence of a person that was likely previously productive and completely independent, drastically reducing the patient's quality of life [2]. To improve the quality of life for a tetraplegic individual that retains some UE mobility, it is imperative that inexpensive, robust, and reliable hand tools are developed to assist in day to day activities that are limited by the patient's limited mobility.

The development of tools to aid patients with tetraplegia is nothing new. Even a cursory Google search turns up dozens of devices to aid patients with reduced upper extremity mobility, as is further examined in Chapter 2. While having access to a different tool for every possible function is preferable to having none at all, being confined to a wheelchair with limited space makes it convenient to have *one tool that will serve multiple purposes*. This cuts down on the number of implements a patient needs to have to carry around or have to purchase in the first place. Furthermore, purchasing a host of tools to address specific needs becomes a costly affair for the dramatically disabled, who are generally buried in medical debt [3]. Many hand assist tools also are designed

to be one-size-fits-all, regardless of the ergonomic needs of individual tetraplegics. This economic and ergonomic need, as well as space limitation of tetraplegic patients, inspired the design of the Universal Hand Assist Tool (UHAT).

While this tool is being developed with the purpose of aiding those with cervical spinal cord injury (c-SCI), any patient with limited UE mobility can potentially benefit from the UHAT. For instance, patients with advanced multiple sclerosis tend to lose fine motor control in the hand and digits, sometimes even severe UE mobility and sensory loss [4].

1.1.1 What is Tetraplegia?

Spinal cord injuries are most often caused by trauma to the spine due to traffic accidents (36.5%), falls (25%), with sports injuries, gunshot/knife injuries, and other less common causes making up the rest, totaling to about 40 incidences per million per year of SCI worldwide [1], [5]. In 2014, more than 250,000 Americans are living with SCI, according to the National Institute of Neurological Disorders and Stroke [5]. Of these incidents, most occur in men aged 20 to 35 [1] , with 80% of all SCI being men of any age [5]. According to a meta-study of the epidemiology of SCI, the United States has the highest prevalence of SCI worldwide at 906 per million [6]. While there has been little change in prevalence over the last 30 years, there has been an increase in incidence in North America and Europe, with an increasingly higher percentage of tetraplegia and “complete” injuries [7]. Any SCI is considered “complete” when all sensory and motor function is lost below the location of the injury. If the patient retains some

sensory or motor function, the injury is considered “incomplete” [8]. Worldwide, the most common anatomical region of injury is the cervical spine [6]. The cost of managing the care of these patients totals more than $3 billion each year [5], having a significant financial impact on the patients’ families and communities.

Tetraplegia is a condition that generally results from lesions resulting from trauma to the cervical spinal cord [9]. A lesion is considered any abnormal change in a region of tissue caused by an injury or disease. The location and severity of these lesions dictate the sensory and motor functions affected. To fully appreciate this, a brief overview of cervical spinal anatomy is required. Figure 1, shows the cervical spine, including 7 vertebrae and 8 nerve roots, all located in the neck [10]. The term “root” simply denotes the location where a particular nerve connects to the spinal cord. On the right-hand side of Figure 1, the location of each nerve root, relative to each cervical vertebrae is labeled. It is convention that each nerve root is labeled for the vertebrae below. For example, the C2 nerve root lies between the C1 and C2 vertebra. Each of these 8 nerves carry motor and sensory information between the brain and certain parts of the body [10]. It is intuitive (if a bit oversimplified) at this point to see that if a spinal lesion occurs between the C5 and C6 vertebra, part or all motor and sensory function will be lost for the C6 nerve and below. A diagram of the nerve associations is included in Figure 2 part a).

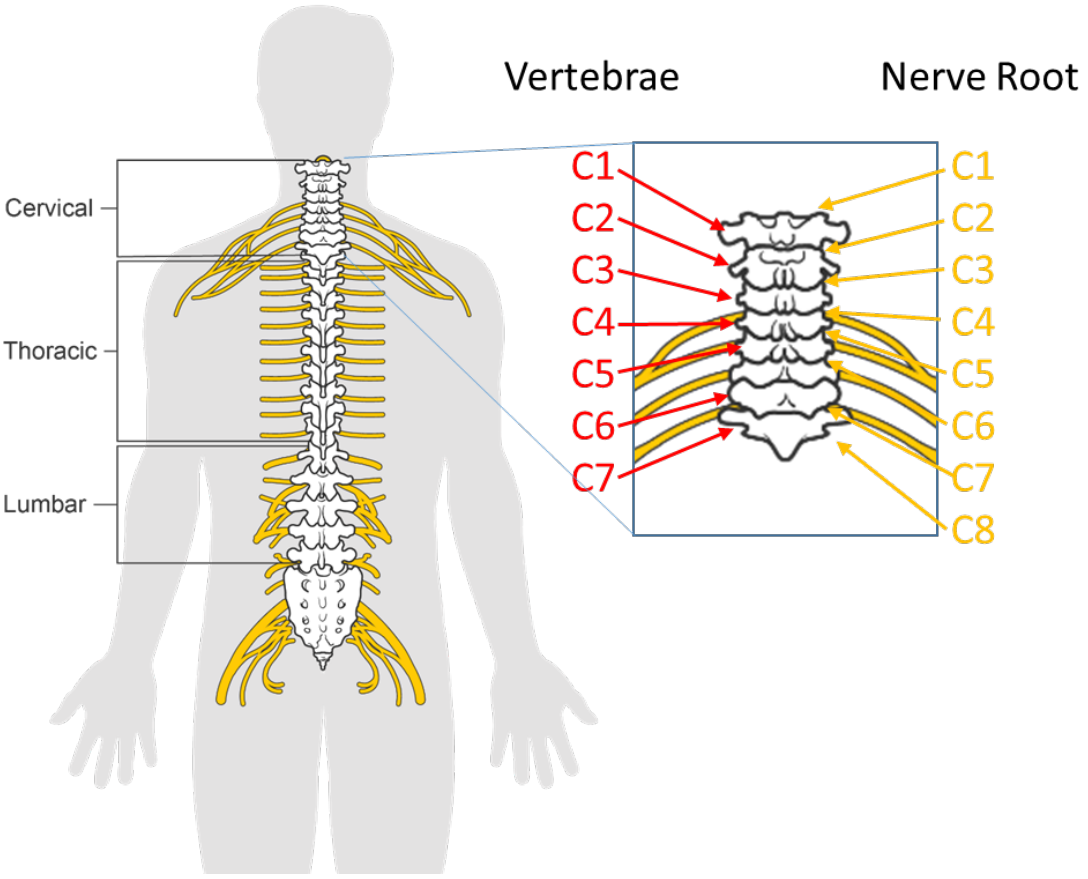

Figure 1: Diagram of the anatomy of the nerves and vertebrae of the cervical spine. The vertebral bones are labeled on the left in red, and the nerve root locations are labeled on the right in yellow.

A particular SCI case is considered “complete” if the individual has no motor or sensory ability below the location of the lesion. “Incomplete” SCI implies limited, but partial motor and/or sensory function below the injury location [5]. The American Spinal Injury Association Impairment Scale, shown below in Figure 2 part b), is used to classify the severity of SCI in the patient. For example, if a patient retains no sensory or motor function below their C5-C7 injury, they would be classified as AIS-A with a

Neurological Level of Injury (NLI) of 5-7. This thesis will focus on patients with cervical SCI (c-SCI) that allows some UE motor and sensory function, making it necessary for assistive devices to aid their day to day activities. These injuries typically occur between the C5 and C7 vertebrae, as seen in Figure 2 [11].

Sustaining a cervical spinal injury resulting in tetraplegia is an acutely life changing event, resulting in the need for significant health care resources for the patient. Even until the time of World War II, the prognosis for SCI, especially c-SCI, was very grim. Survivors of such an injury had to live in a world without accommodation for wheelchairs, or even access to sufficient healthcare methods to circumvent potentially lethal secondary conditions such as blood clots, infection due to pressure sores or respiratory problems, and kidney failure, which are all common pathologies for patients living with severe SCI [5]. Presumably due mainly to improvements in healthcare, the life expectancy of patients living with SCI is increasing. Today, there are spine centers, such as the International Center for Spinal Cord Injury at the Kennedy Krieger Institute, that focus completely on improving outcomes for patients with SCI. For patients sustaining a spinal cord related injury between years 25 and 34, it is predicted that the life expectancy is to be about 38 years post injury, with 43% surviving up to 40 years [7].

According to an SCI quality of life (QOL) focused literature meta-analysis, high level spinal cord injury with complete paralysis is one of the most devastating conditions that a person can endure [12]. Some even postulate that death would be preferable to living with this level of paralysis [12]. Quality of life, however, is relative, and that

when even living at the edge of what is tolerable, humans express a strong desire to survive [12]. What makes living with SCI so difficult is the inability to contribute to the family and community through having a job, playing with kids, etc., especially with high level paralysis. Further analysis of the QOL of patients with all levels of SCI demonstrates that social disadvantage is the main driver of dissatisfaction with life [12]. Being socially disadvantaged is a difficult problem to address on a large scale, however it is something that can be more readily pursued at an individual level. When asked to examine which functions they would have restored, *arm and hand function* is the area that most tetraplegics specifically prioritize over all other functions, including sexual, bowel and bladder, etc. [2].

This being stated, it becomes increasingly important for the scope of this thesis to examine how the availability of a comfortable hand tool can have a profound effect on the quality of life of someone living with tetraplegia.

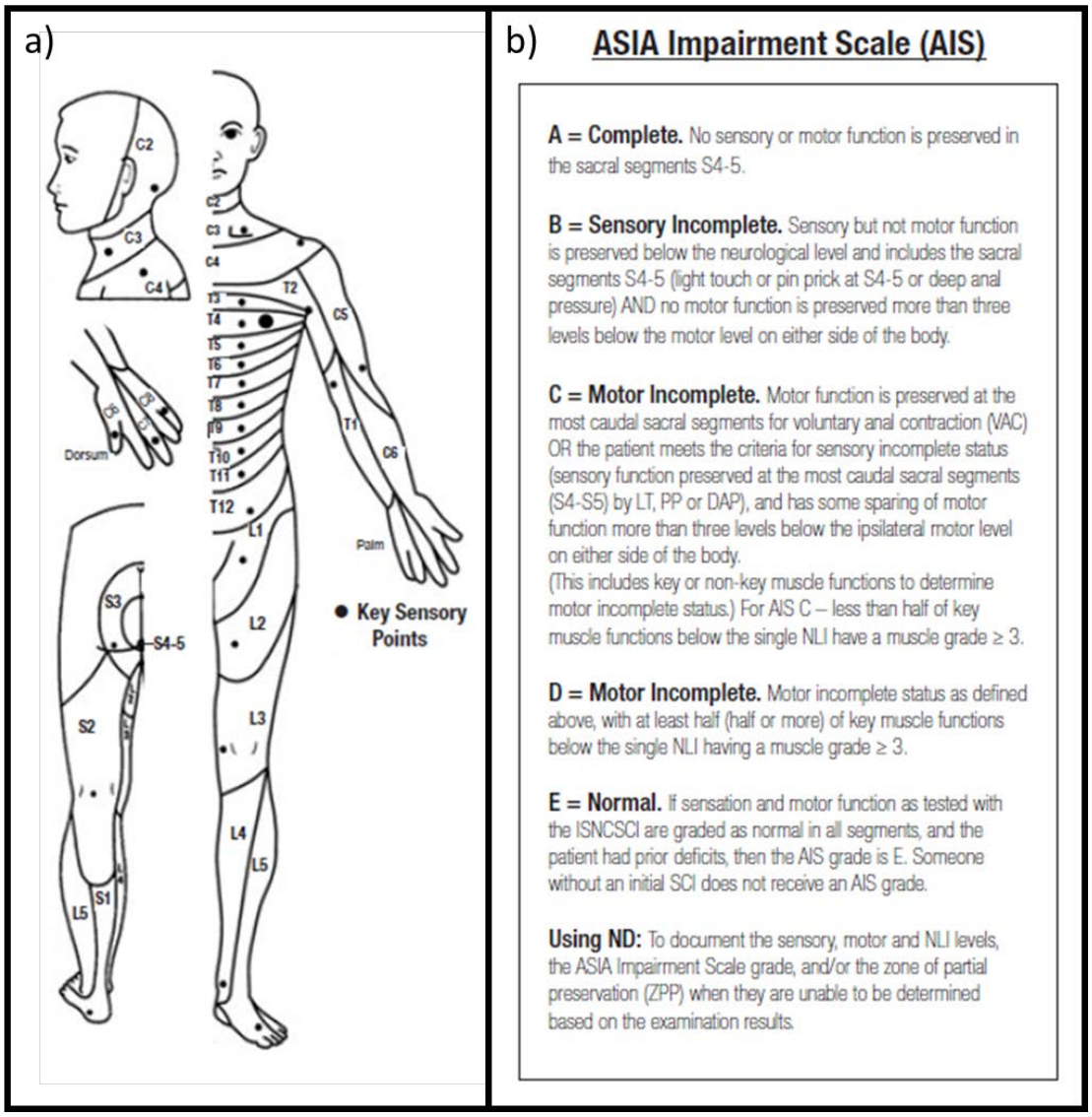

Figure 2: The American Spinal Injury Association Impairment Scale is used to identify and classify the location and severity of injury and impairment of motor/sensory function in patients with SCI [4]. In part a), the region that each nerve is responsible for is labeled. It is easy to see that C5 to C8 nerves control the lateral arm and hand, with T1 and T2 nerves controlling the medial arm and below. In part b), each impairment classification is defined.

1.1.2 Motivation for Developing the Universal Hand Assist Tool

While there is not a staggering prevalence of c-SCI in the United States, there are about 250,000 Americans that live with a devastating chronic paralysis. This number can only increase, as it correlates with population growth and increased life expectancy within the disabled population. It has also been posited that a hand assist device can help improve the social function of tetraplegics by allowing them greater independence. It is therefore reasonable that designing this device will impact society by assisting a growing population of its citizens living with devastating paralysis with day to day activities that were lost due to their disability. As arm and hand function is the area that tetraplegics most prioritize having restored, from a QOL standpoint it is reasonable that an effective way to assist the tetraplegic community as a mechanical engineer would be to *design a device to assist with arm and hand function*. This being stated, individuals with tetraplegia will benefit from the availability of an affordable hand tool that will assist with day to day activities lost due to their injury.

1.2 **Design Objectives and Goals**

The key objective of this thesis is to develop a hand assist tool for patients with tetraplegia to aid in becoming more independent. To produce an appropriate and effective design, the intended end-users and functions must be defined. The UHAT design process will be broken into several parts defined below.

1.2.1 Defining User Needs

The most critical part of any design process is developing rational system constraints in order to generate a robust design that is most helpful to the greatest number of end-users. In the case of the UHAT, user needs must be defined such that the final production model of the UHAT is helpful to the greatest number of people. User needs were determined through meeting with a medical doctor and occupational therapists at the Kennedy Krieger Institute, who specialize in SCI, to determine the needs of a tetraplegic end-user. A focus group for patients with tetraplegia or other forms of UE disability was used to inform individual needs. A past collaborator with UMBC with chronic c-SCI induced tetraplegia also advised the design process. These meetings were used to determine ergonomic considerations and 5 activities that the UHAT was designed to perform.

Once user needs were determined, the documentation required to inform a design process was generated. These include a System Requirements Specification (SRS), and a Prototype Test Protocol. These documents are necessary to constrain the scope of the design and prototyping process, and perform a detailed functional analysis of the product system architecture.

1.2.2 End Users

The Universal Hand Assist Tool (UHAT) was designed specifically for adults 18 and older who have suffered cervical spinal cord injury. The need for a hand assist tool

implies that the end-users must retain some UE mobility, and the intended extent of injury was informed by input from OTs and medical experts.

1.2.3 Functions

The tool was designed to be adjustable enough to comfortably fit the hand of any adult end-user. It also is an appropriate weight to not fatigue the end-user, and not require more force to use than can be applied by an end-user, as defined in Section **Error! Reference source not found.**. The UHAT addresses five different activities, and is expandable to accommodate more. These activities were defined with input from a focus group, occupational therapists (OTs) and medical experts. The UHAT also was designed to be inexpensive for individuals with tetraplegia on a meager fixed income.

1.2.4 Prototype Construction and Revision

Once the product functions and user needs were determined, prototyping cycles commenced. First, an initial prototype was constructed solely based on the SRS. Short cycles then were defined and implemented in order to get an early prototype into the hands of a single user, so that shortfalls of the design could be identified and fixed quickly and early in the design process. This achieved the most robust design in the shortest amount of time [13].

1.2.5 Design a Clinical Trial

Once a prototype has gone through several single user design cycles, a clinical trial will be designed so that a robust prototype can be tested by a group of users.

1.2.6 Final Product Evaluation and Documentation

Once the prototype successfully progressed through the designated prototyping cycles and the design objectives had been met, a final product was deployed. Final documentation was generated, including assembly instructions and a bill of materials.

1.3 **Organization of Thesis**

This thesis is organized as follows. Chapter 2 contains a survey of currently available hand assist tools, relevant anthropometric analysis, ergonomic considerations, and the results of focus group meetings and consultations with expert collaborators. Chapter 3 details the design process of the UHAT project, including evaluation methodology, SRS documentation, the design testing protocol, and the clinical trial protocol. Chapter 4 outlines the prototyping process. Chapter 5 contains the evaluation results, and a discussion about the design process challenges and results, as well as the limitations of the UHAT. Chapter 6 summarizes the project, and discusses possibilities for future development.

Chapter 2: Market and User Population Survey

2.1 **Adaptive Equipment for Tetraplegia**

Devices to aid specifically with tetraplegia related disability are relatively new. As medical technology and the level of care has increased, tetraplegics are living longer post injury than ever before, and require devices and tools to retain maximal independence.

One category of hand assist devices includes braces and orthoses. These are generally made custom for the patient by an occupational therapist and are used to support weak muscles and/or limit joint movement [14]. One example of this is the wrist/hand orthosis, which stabilizes the hand and wrist. Furthermore, there are assistive grasp orthoses, such as the Powergrip, as seen in Figure 3, which uses the flexion of the wrist to close the fingers in order to grasp an object. This device must be fit and mounted by a licensed orthotist. Note that the device both stabilizes the hand and fingers, while mimicking the contractile force of the forearm to close the stabilized fingers around and object. It is also obvious from Figure 3 that this is not an out of the box one-size-fits-all solution, nor is it user adaptable to any size hand. These must be custom “fit and mounted” for each patient, as stated in their product description [15].

Figure 3: PowerGrip Assisted Grasp Orthosis.

It is important to understand that the UHAT is not designed to be an orthosis or prosthesis, but a tool that tetraplegics can use *with their existing strength and range of motion* to perform tasks that were made difficult due to injury. Orthoses are designed to be worn for long periods of time and are subject to FDA regulation [16], as they can affect the musculature that they are mimicking or assisting. As an ergonomic hand tool, the UHAT may be subject to FDA guidelines, considered a non-significant risk device, if considered a device at all.

2.2 **Survey of Currently Available Adaptive Equipment for Tetraplegia**

This section presents different currently available “adaptive tools”, such as the UHAT, that address various needs for patients with tetraplegia. While all of these tools may not be directed toward tetraplegic needs directly, they are included to provide a framework for the necessity for developing a tool like the UHAT.

2.2.1 Universal Cuff

Possibly the most commonly referenced hand assist tool is the Universal Cuff. The universal cuff is a strap of elastic with a hook-and-loop closure, which is attached to the hand across the grip. This strap contains a pocket that rests across the palmar surface along its length. Common implements can be placed in this strap, such as styli, eating utensils, pens, etc. The strength of this design is that it is very simple, and easily adaptable to any size hand. The universal cuff is also very inexpensive, which is important for those whose injury prevents them from working. However, it requires the user have a relatively large range of pronation and supination of the forearm, with pronation and supination occurring when the hand is palm down or palm up, respectively, while elbow is held to the side of the body. Complete c-SCI above the C7 nerve will have very limited range of motion in this area [11].

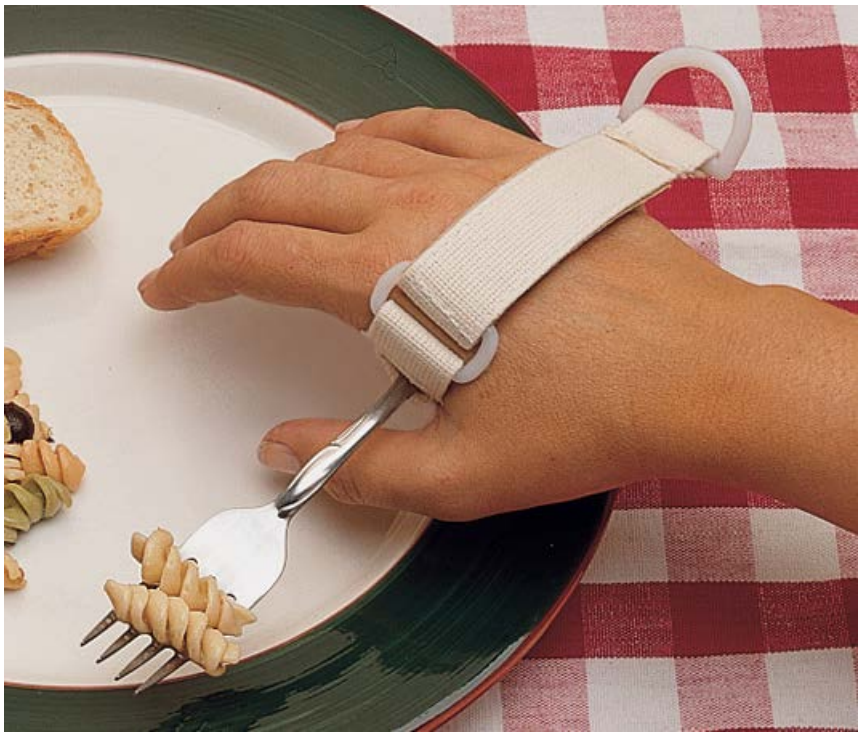

Figure 4: The Norco Universal Cuff [17].

2.2.2 Active Hands

Active Hands is a company that produces several mobility aids for different needs, one of which is the General Purpose Gripping Aid. This is a much more heavy-duty grip strength solution than the Universal Cuff. The General Purpose Gripping Aid has two hook and loop closures, one that closes around the wrist, and another that closes over the outside of the fingers, clamping the fingers around an object. This provides a high level of grip strength that may have been lost due to injury or neurologic damage. As with the Universal Cuff, the General Purpose Gripping Aid is user scalable to any size hand and wrist, however it is more expensive [18]. While it may be useful to C7

tetraplegics, those with higher level injuries may not even have the strength to fasten and remove the hook and loop closures, much less use a tool like a hammer.

Figure 5: The Active Hands General Purpose Gripping Aid [18].

2.2.3 Quadtools

Unlike the Universal Cuff, or Active Hands tools, Quadventure Quadtools products are designed specifically for C5-C7 tetraplegics [19]. Quadtools are assorted stainless steel reaching and gripping tools that are designed for specific tasks. All of the tools consist of cuffs that brace the tool against the forearm, with a handle that is gripped by the hand. Different extensions lengths and grips allow the user to grasp objects directly in front of them, or even on the floor from a wheelchair. The gripper can be actuated by extending and flexing the wrist, or with a “sipper” mouth-actuator. This is an extremely

useful tool for those who are wheelchair-bound with limited UE mobility. It is well-suited for the single purpose that it was designed for: reaching and grasping. An important part of the design aspect of these tools is that the designer himself is C5-C6 tetraplegic. The insight from being within the target population itself has allowed him to design a product that is very useful. For a designer outside this population, this level of insight is best achieved through prototyping in incremental stages with constant input from the target population.

Figure 6: Quadventure Quadtools Original Lightweight Cripper [19].

2.2.4 Stylus

An essential tool for any C5-C7 tetraplegic is a stylus, such as the one seen in Figure 7. This allows the user to apply focused force directly to a point on an object from the shoulder through the wrist, rather than through injury weakened digits. It also aids the user in producing more precise movements than the hand and digits may not be capable of, by giving the user a rigid “finger” for pressing. From Figure 2, it can be seen that the C6-C8 nerves control hand movements and higher nerves control the wrist and shoulder. As stated before, this means that C5-C7 have partial control of the shoulder

and arm movement, making such a tool indispensable for activities like using keyboards, flipping pages, or opening drawers. Many of these tools are made specifically for a particular user, based on their range of motion, or wrist/forearm mobility. They are very inexpensive to make, as this particular one is made from riveted aluminum stock and thermoplastic hose that can be purchased at any hardware store.

Figure 7: Hand Assist Stylus

2.3 **Biometrics**

This section addresses the biometric considerations of designing a hand tool for use by those living with tetraplegia.

2.3.1 Hand Anthropometry

When designing a hand tool that is to be scalable to fit almost any hand, it is important to consider the anthropometric data of the human hand. Due to the nature of c-SCI, the

anthropometrics of the hand do not change appreciably with regard to the injury [20], although the amount of contracture (the chronic shortening and hardening of muscle tissue) may affect the effective hand size [21]. Table 1 contains hand anthropometric data collated by Georgia Tech (Pheasant, et al.) to assess the functional limitations associated with arthritis. These data were collected from non-disabled adults.

Table 1: Hand anthropometry of non-disabled individuals [22][23].

Dimension	Gender	5th percentile (mm)	50th percentile (mm)	95th percentile (mm)
Hand length	Male	173-175	178-189	205-209
	Female	159-160	167-174	189-191
Palm length	Male	98	107	116
	Female	89	97	105
Thumb length	Male	44	51	58
	Female	40	47	53
Thumb breadth	Male	11-12	23	26-27
	Female	10-14	20-21	24
Index finger length	Male	64	72	79
	Female	60	67	74
Hand breadth	Male	78	87	95
	Female	69	76	83-85

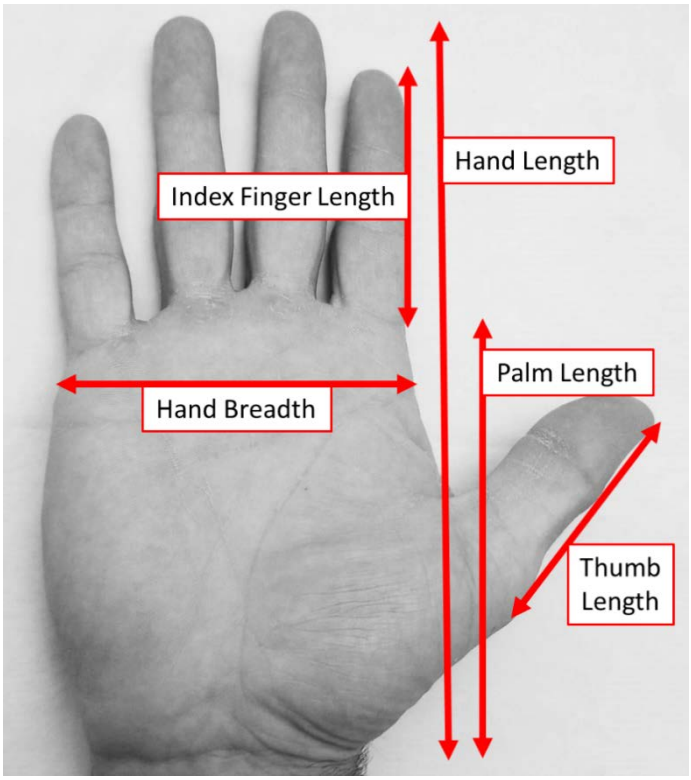

Figure 8: Figure explaining above metrics from Table 1 [23].

The most relevant metrics to the design of the UHAT are hand breadth and palm length. Hand breadth is the length across the knuckles of the little and index fingers, and the palm length is the distance from the base of the wrist to the base of the index finger. These lengths will help determine the windows of length and width dimensions of the UHAT.

2.3.2 Grip Diameter

Table 2 contains maximum grip diameter data collated by Georgia Tech. While C5-C7 tetraplegics retain very little grip strength, designing the UHAT to remain within the

grip diameter will allow the fullest use of the patients' existing strength while using the UHAT.

Table 2: Maximum grip diameters of individuals with and without dexterity disabilities [22].

	Gender	5th percentile (mm)	50th percentile (mm)	95th percentile (mm)
Non-disabled	Male	45	52	59
	Female	43	48	53
Dexterity-disabled	Male	34	40	47
	Female	34	40	48

2.4 **Medical Device versus Ergonomic Hand Tool**

An important distinction to make with the design of the UHAT is the difference between a medical device and an assistive tool. Medical devices are defined by the FDA as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its

primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." [24]

By this definition, the UHAT could be considered a non-significant risk medical device, as it is not designed to affect the structure or function of the hand of the end-user.

2.5 **Focus Group Research**

A previously scheduled support group session for mobility impaired adults was attended on June 28th, 2016 at the Kennedy Krieger Institute to obtain input from potential end users on which activities and ergonomic needs are most important.

2.5.1 Group Makeup

The group consisted of about 12 people with different levels of hand and arm function, ranging from walking with braces to only being able to move the neck. Most of the group consisted of patients with advanced multiple sclerosis, leaving them with debilitating UE paresis on what they considered to be "bad days". There were some SCI patients, but mostly with thoracic spine injury, leaving them with a high level of UE mobility and function.

2.5.2 Activities and Ergonomic Needs

Based on the focus group, the following activities were identified for the UHAT:

- Holding wine glass

- Opening can tab
- ¼” tool attachment
- Pudding/yogurt container opener
- Ability to use any kitchen knife
- Telescoping reach tool
- Ambidextrous design
- Hair/makeup
- Back scratcher
- 15º, 35º, 45º adapter for attachments
- Open shampoo bottle

After the meeting, these activities were discussed with three occupational therapists that attended the meeting and we shaped the list into five reasonable activities. These include, capacitive touchscreen stylus, focused force stylus, eating utensil adapter, pen/pencil holder, and extension hook/grabber.

2.6 **Single-User Design Input**

During the design phase of the UHAT, a tetraplegic collaborator with an appropriate level c-SCI was consulted provide feedback on design ideas. Prior to beginning the prototyping process, design features, anthropometry, force requirements, and end-user range of motion were validated or verified through this feedback. During these consultations, new activities for the UHAT, as well as activities identified from the focus group, were distilled into five activities that were included in the initial prototype.

With the market survey and end-user populations consulted, a set of system requirements and specifications were generated.

Chapter 3: Design of Hand Assist Tool

3.1 **Design Overview**

This section will describe the design process implemented in the UHAT project.

3.1.1 Initial Planning and Design Phase

Input from the market review, focus group, interviews with a collaborator with c-SCI, and interviews with collaborators in the Spine Center at the Kennedy Krueger Institute (KKI) at Johns Hopkins University (JHU) informed the initial design of the UHAT, as seen at the top of Figure 9. These recommendations were collated into the framework of the project, and ultimately used to define the scope of the design. The System Requirements Specification (SRS) in Section 3.4 outlines the scope of the project. The SRS is used to define when each functional requirement is satisfied, providing a framework for concept exploration and a validation mechanism for the UHAT. A lean development approach was used to generate these requirements from conception, as shown in the cycle at the bottom of Figure 9, and discussed in detail in Section 4.2.1. The project is conceptualized from a market needs analysis, resulting in high-level system requirements. User input informs the generation of system requirements resulting in design specifications, and these specifications are then used to generate a prototype to be tested and verified against the system requirements. These high-level requirements were distilled into functional requirements, including performance requirements, hardware requirements, and documentation requirements for the UHAT.

This process of generating functional requirements and validation mechanisms was informed by multiple meetings with primary and secondary experts, such as a focus group, interviews with occupational therapists and a physician at KKI, and a collaborator living with c-SCI.

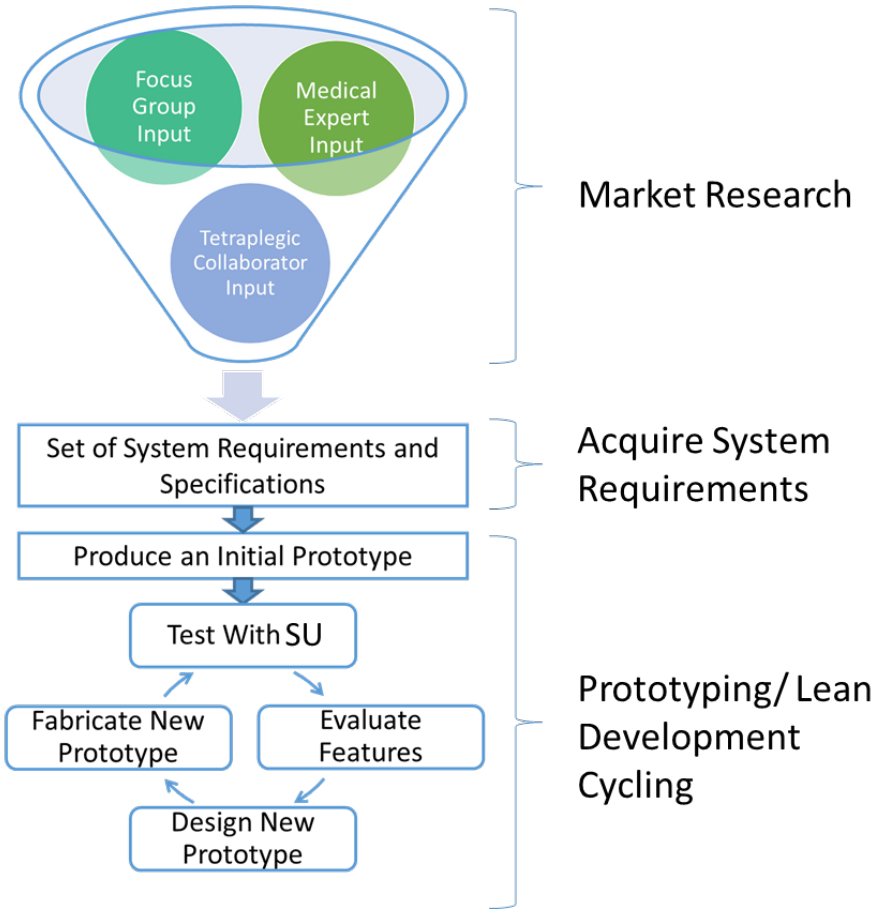

Figure 9: Product design and development methodology.

3.2 **Evaluation Methods**

3.2.1 Single User Evaluation Method

After the SRS was acquired, input from a single collaborator with high level c-SCI was used to inform the design of the initial prototype, as well as to improve the initial prototype before a multiple user study takes place. Figure 9 shows the testing cycle timing in the design process. Input from the SU was collected via frequent, informal meetings with the collaborator in an informal interview setting. Single user evaluation continued throughout the duration of the project. Lean development methodology was used in SU testing. Lean development methods were chosen over traditional methods in order to save time and wasted resources, arriving at a robust prototype as quickly as possible. Traditional methods use resources to generate a detailed design prior to testing, whereas lean methods arrive at a quick design and move quickly into testing, as shown in Figure 10.

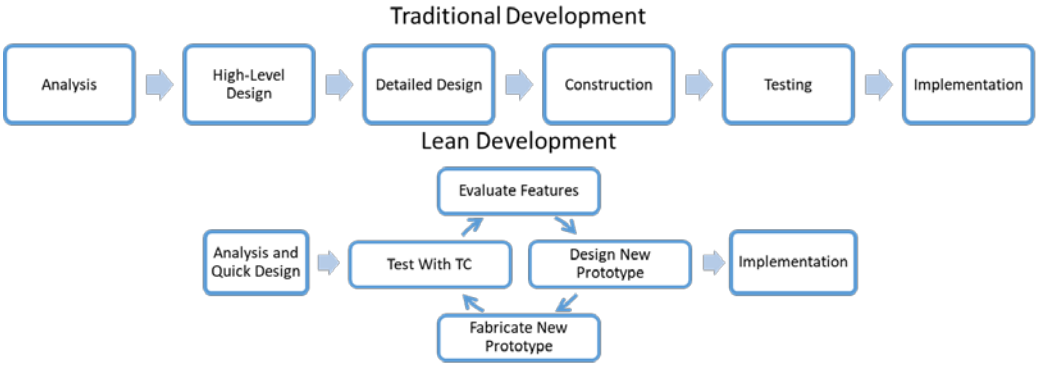

Figure 10: Traditional versus lean development methods [25].

The hallmark of lean prototyping is to use testing to evaluate a prototype feature, then, depending on the outcome, decide to pivot or persevere with the particular feature [13].

3.2.2 Multiple User Evaluation Method

A research protocol was submitted to the John's Hopkins IRB, in order to conduct a multiple user clinical study to validate design features of the UHAT. This is discussed in depth in Section 5.2.5. The evaluation will be carried out in five development cycles, each lasting two weeks. In the first week, a study participant will meet with a research assistant (RA) at KKI for up to two hours to test the prototype in a supervised setting. At the end of the two-hour period, the RA will assist the participant in filling out an evaluation form, found in Appendix E, where the participant will rate features and functions of the prototype on a 1-5 Likert scale. This evaluation form will be used to inform revisions of the current prototype, and the prototype will be revised and constructed during week 2. This will conclude the first prototyping cycle, and week 3 starts the new cycle. This will be repeated for 5 cycles, totaling 9 weeks of testing for each participant.

3.3 **Clinical Study Protocol**

A clinical study research protocol was generated reflecting the Multiple User Evaluation Method, to further test the broad usability of the UHAT. This protocol can be found in Appendix A.

3.4 **Acquiring System Requirements**

In order to generate an initial prototype, a set of system requirements are useful to constrain the functions and performance of the UHAT into a defined space. Using market research performed in the previous section, a system requirements specification was developed to inform the initial prototype. This section includes that system acquisition process.

3.4.1 Identifying Activities for the UHAT

Activities for the UHAT were defined through patient population research with input from occupational therapists and medical experts at the Kennedy Krieger Institute. Desirable activities that were identified include the ability to use a keyboard, touchscreen tablet or phone, painting, playing an instrument, etc. The final UHAT will deploy with 5 popular activities. These activities include (1) a Stylus for Tablet/Smartphone, (2) the ability to use various eating utensils, (3) three different sized rubber coated styli for general focused force application such as pushing piano keys, using a computer keyboard, and flipping book pages, (4) a ¼" hex adapter for tools such as a cross head screwdriver or a nut driver, and finally an (5) extension hook/grabber.

3.4.2 Mission Scenario

Figure 11 demonstrates the full mission scenario for the user of the Universal Hand Assist Tool, from removal from storage to returning to storage.

Figure 11: Mission Scenario Diagram

3.4.3 System Boundaries

The user will insert the intended activity implement into the Universal Hand Assist Tool, then use the tool to interact with their surroundings through the activity implement. The System Boundary Diagram in Figure 12 demonstrates these interfaces.

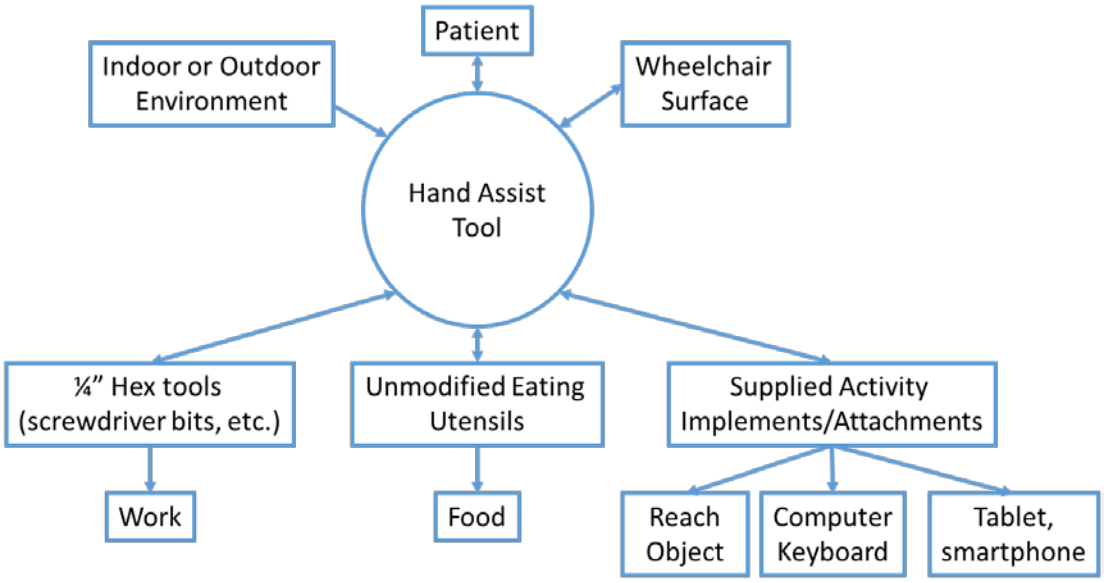

Figure 12: System Boundary Diagram

3.4.4 Functionality

Figure 13 outlines the device functions involved in the use of the Universal Hand Assist Tool.

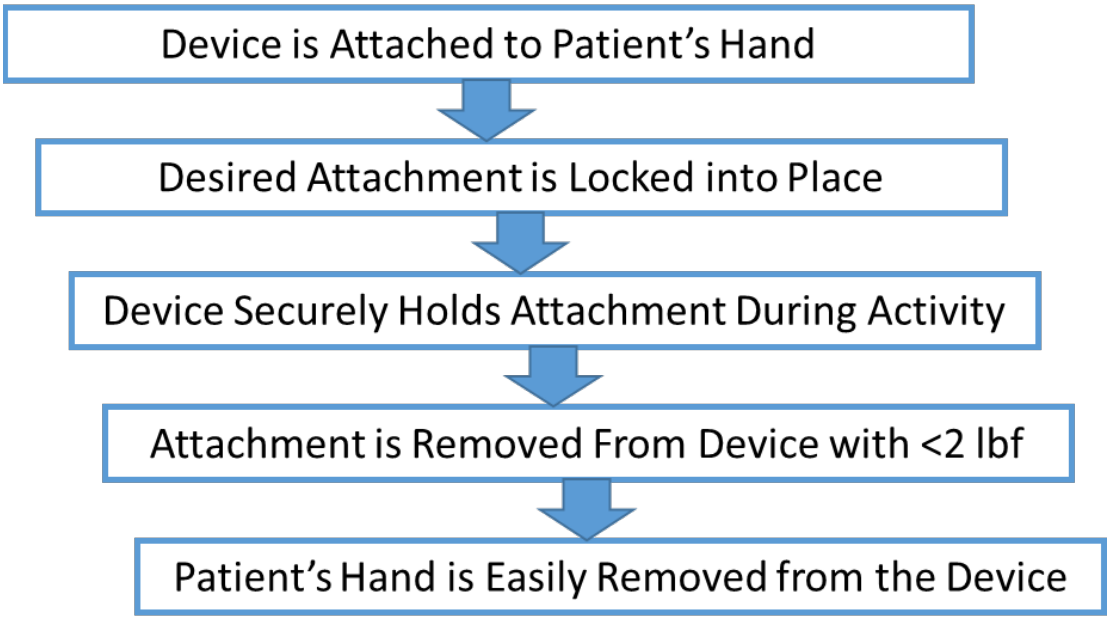

Figure 13: Functional Block Diagram

3.4.5 System Requirements Specification

Three categories of system requirements were defined for the UHAT, including functional requirements, performance requirements, and documentation requirements. Functional requirements include any hardware features of the system. In the case of the UHAT, five activities were defined in Section 3.2.1 are included in the functional requirements. Other hardware requirements include that any custom components of the UHAT are 3D printed, and any fasteners or other hardware components be readily available off-the-shelf at reliable retailers.

Performance requirements are the quantifiable, verifiable constraints that the UHAT is designed within. These requirements were separated into five categories, including Physical Constraints, Force Required for Operation, Safety, Product Life, and Maintenance Requirements. Examining these individually, the physical constraints of the UHAT are that the system is designed to be used by an adult, thus limiting the hand anthropometry to be considered for the design. The grip length of the UHAT is to be between 70 to 95 mm, and the grip diameter scale from 45 to 60 mm. The device should weigh less than 4 ounces, based on the weight of other assistive devices that the SU is currently able to use.

The force required for operation was determined to need to be less than 2 lbf, as tested with the SU collaborator. First, the SU demonstrated the capability of pushing with a force between 3 to 3.6 lbf against a pressure scale 8 times before becoming exhausted. A test was then designed to test gripping and pulling strength involving an apparatus where two disc magnets are separated in two different orientations. After the SU was

successfully able to separate the magnets it was measured that the grip force needed was less than 2 lbf. As the grip and pull force is smaller than the push force, the force requirement is set to be less than 2 lbf.

A life cycle of 5 years was determined, based on the requirement that the UHAT is constructed of 3D printed plastic, and designed for hand only use. The maintenance schedule of the UHAT includes inspection and removal of debris prior to each use, and to be cleaned with soap and water every 30 days to ensure optimal performance in the device life cycle. Furthermore, the device is not intended for physical therapy, or critical life-saving operations.

Documentation requirements for the UHAT include the open source distribution of all CAD files, assembly instructions, bill of materials, and directions for use.

A summary of the system requirements are detailed in Figure 14

System	Requirement Type	Requirement
Universal Hand Assist Tool	Functional Requirements	Activities: Touchscreen, Silverware, Stylus, ¼" Hex tool, Reacher
		All Custom Components 3D Printed. Other hardware readily sourced from reliable vendors
	Performance Requirements	Weighs less than 4 ounces Requires less than 2 lbf to use
		Life Cycle is 5 years.
		Not used for physical therapy or as a life saving device
		Length: 70 to 95 mm Grip Diameter: 45 to 60 mm
		Inspect for debris before each use Wash and clean every 30 days
	Documentation Requirements	Open Source Distribution
		Required Documents: CAD Files, Assembly Instructions, Bill of Materials, Directions for Use

Figure 14: System Requirements Specification for the UHAT.

3.5 **Materials**

3.5.1 3D Printed Parts

Any custom fabricated parts will be designed to produce on a 3D printer using ABS (acrylonitrile butadiene styrene) filament. ABS is preferable to PLA (polylactic acid) as the filament in the UHAT, as PLA will break down over time when exposed to water, even humid air. ABS is not suitable for oral use, therefore the design does not include any 3D printed parts that will be used orally [26].

3.5.2 Hardware

Any hardware used in the design are common and readily available from common hardware retailers.

Chapter 4: Initial Prototype

4.1 **Generating the Initial Prototype**

Taking into consideration the design specifications in Chapter 3, an initial design was generated to have a starting point from which to begin the prototyping cycle process.

4.1.1 Design Considerations

Knowing that the design had to be constructed from parts that could be assembled to *fit any potential user*, the design needed to be constrained to a space that called for no post-design customization. This left several avenues of design reasoning. Either the design itself could be customizable, or there could be a variety of components that the end user could select from to end up with a model that fit any user. For example, Figure 15 below shows the difference between these options. The benefit of the "customizable" method would be that every hand tool would be printed from the exact same set of files, then customized for each user. This presented a difficult design challenge, as there were more moving parts to be accounted for and potential for assembly complexity that would need to be addressed in the design itself. Also, more moving parts increases the potential for components to eventually fail, leading to a potentially less robust design. The benefit of the "variety of components" method would be that there would be no moving or changing parts that would need to be adjusted for the hand tool to fit the end user. This lack of complexity also leads to a naturally more robust design. However, there would need to be enough variety in

design such that it would indeed fit any hand. Furthermore, a potentially complex "fitment flow diagram" would need to be implemented so that the end user could easily identify which parts would need to be printed and assembled.

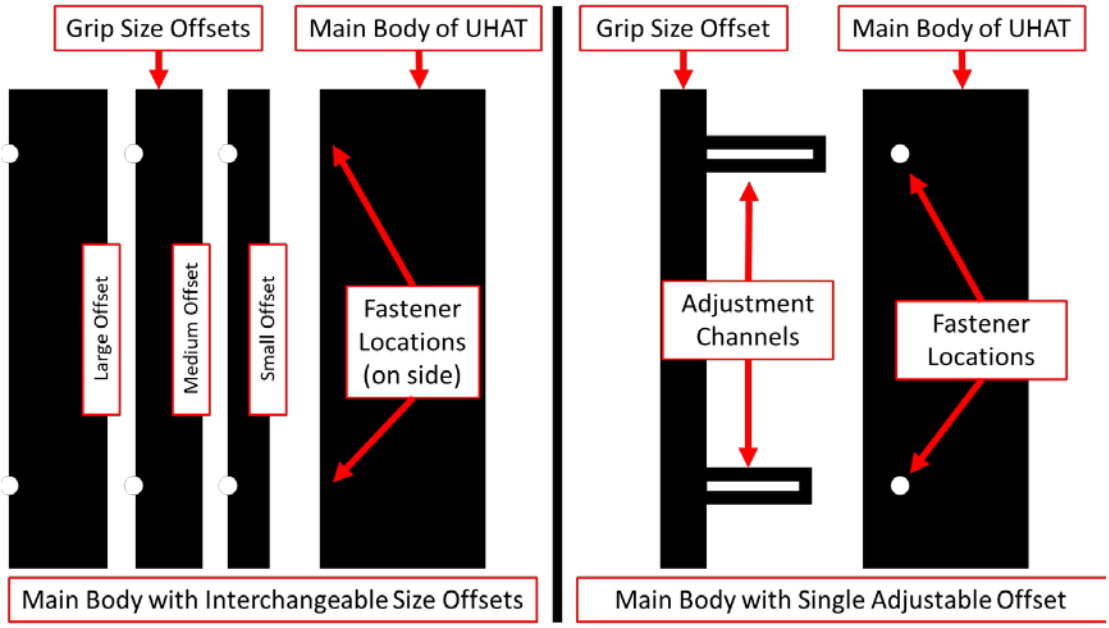

Figure 15: Method of changing grip diameter in UHAT. Pictured on the left is a method with interchangeable, different sized offset sides that can be attached directly to the UHAT. Pictured on the right is a single offset with an adjustment channel, allowing for a single offset to be used to adjust the grip size. On both diagrams, the offsets are attached to the sides of the UHAT main body.

In the end, it was determined that the "variety of components" method would be the most sensible. Being bound to a wheelchair with little UE strength makes it difficult to readjust a product that keeps coming out of adjustment. This was determined to be the

best method of satisfying the life cycle requirement of the SRS, in Section **Error! Reference source not found.**.

4.1.2 General Form of the Design

Most hand tools for tetraplegics consist of a bar to grasp with a strap to hold the user's hand in place, as seen in Figure 4 and Figure 7. It is reasonable that the UHAT also consist of a "Main Body" that is grasped by the user, and a "Flap" that holds the device in place by producing pressure between the user's palm and back of the hand. In the examples in Figures 4 and 7, the straps are hook and loop fasteners or some type of metal strap that is bent to fit the user's hand, respectively. Neither of these solutions are optimal, as a bendable metal strap will change shape over time, and hook and loop is a fabric that must be cleaned often. Furthermore, removing hook and loop fasteners requires a constant force of 1.2 lb to peel [27], which becomes difficult to remove with several inches of strap, as this force would need to be demonstrated by the end-user *over time*. If the user can only muster 2 lbf for an instant, pinching and pulling 1.2 lb for several seconds would be impossible. After consideration, a 3D printed plastic flap would be used on the back of the hand, with a closing force to pull the flap toward the main body, effectively holding the UHAT in place in the user's palm.

Initially, an elastic strap was considered to provide the closing force for the flap, which is the component of the UHAT that holds the hand in place. There were several problems with this design. First, the elastic strap needed to be very taut to provide a reasonable closing force. This was problematic, as any fasteners used to secure the strap

would need to be constantly tightened to ensure that the elastic band was tight enough for the hand to remain secured. Second, the strap would begin to creep after several hours of simply being attached to the UHAT, making the closing force reproducibility inconsistent. Also, having an elastic strap would mean having a part that would need to be cleaned often, otherwise the fabric would become unsanitary and discolored.

Taking this into consideration, the flap portion of the UHAT will be a 3D printed component that uses a hinge mechanism to clasp the hand in place, as seen in Figure 18 The hinge would rest closed with torsion springs providing the holding force. This would allow the amount of holding force to be titrated to a comfortable level by selecting springs with appropriate spring constants. Steel torsion springs would also allow for consistent closing strength, as long as the opening is restrained as to not deform the spring itself.

The shape, diameter, and length of the UHAT must also meet the criteria defined in the SRS.

After these considerations, the general form of the UHAT was determined to be a “Main Body” that the user grasps in the palm, with a 3D printed “Flap” that closes against the back of the hand. The closing force would be provided by steel wire torsion springs.

4.1.3 How Activities Work

With the general form of the main body and the way that it fits the user’s hand addressed, how the UHAT will address each activity needs to be addressed. Since the

UHAT is being designed to become a platform that can accommodate a growing list of activities, it makes sense to have a *common receptacle that an implement that is specifically designed for a single activity* can be plugged into. This being stated, the method in which implements must interface with the main body must now be determined. When an activity is selected, the corresponding implement will be placed into at receptacle on the main body to facilitate that activity. The question at this point became where and by what mechanism do the implements attach to the main body. Figure 16 outlines possible locations for activity insert receptacles on the main body of the UHAT.

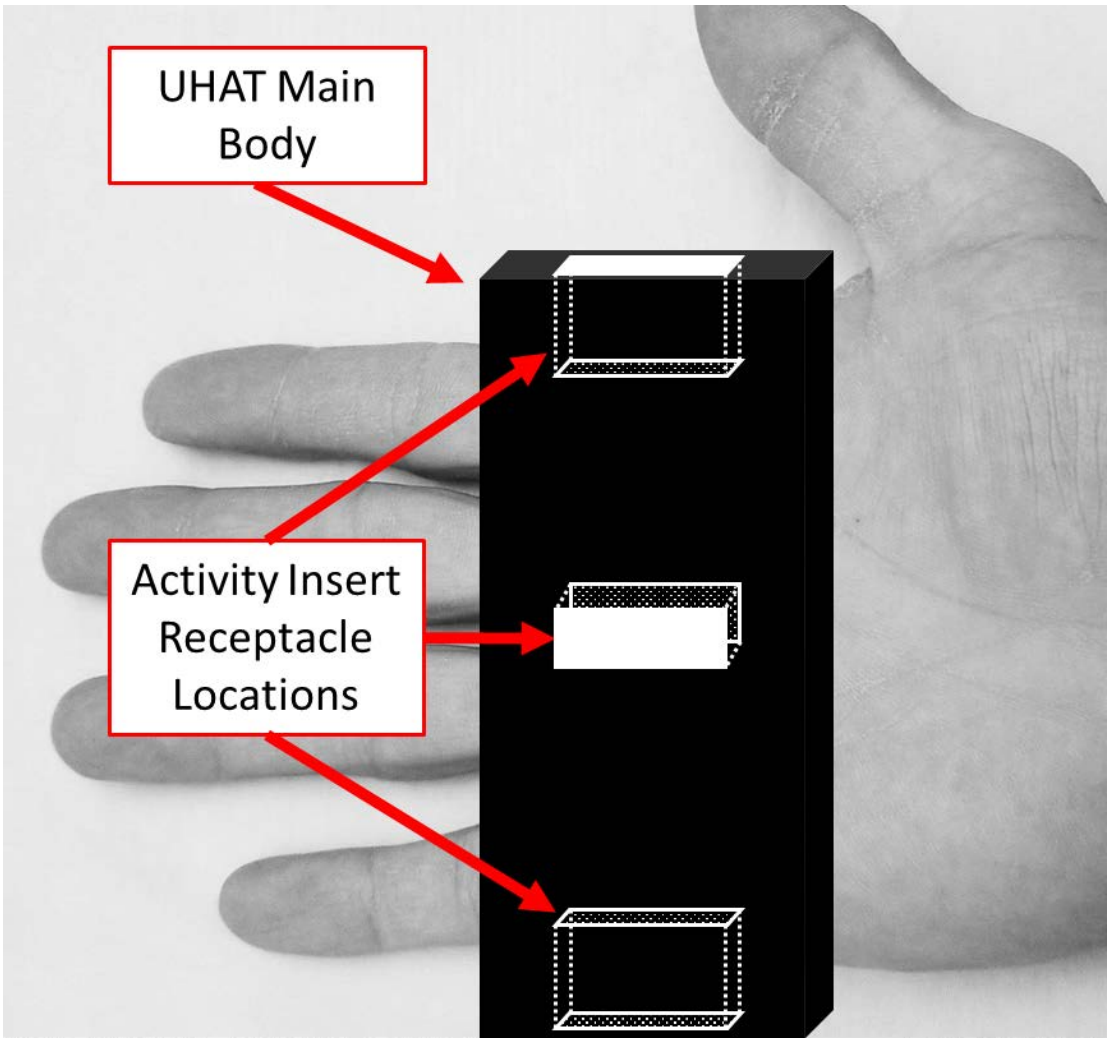

Figure 16: Possible locations for activity insert receptacles. The black box represents the UHAT body, while the white boxes represent the cutouts for the insert receptacles.

Next, the mechanism to hold the implement in place would need to be decided. The most obvious mechanisms would be to simply pressure fit the implements, have magnets hold them in place, or have some sort of click in/button release. Again, having a mechanism like click and release introduces moving parts that have a finite number of uses before breaking down, detracting from the robustness of the design. It was

specified that no more than 2 lbf be required to use the UHAT. Anything pressure fit will require much more than 2 lbf to remove to be useful as a mounting mechanism. Using magnets to hold the implements in place seemed like a feasible solution, however it needed to be demonstrated that it required less than 2 lbf to separate the magnets. A test was designed to determine the type of magnet and how they should be oriented. This test coupled two 3/8 inch, neodymium rare-earth disc magnets together in a 3D printed apparatus that allowed a force gauge to test the axial and radial forces required to separate the disc magnets.

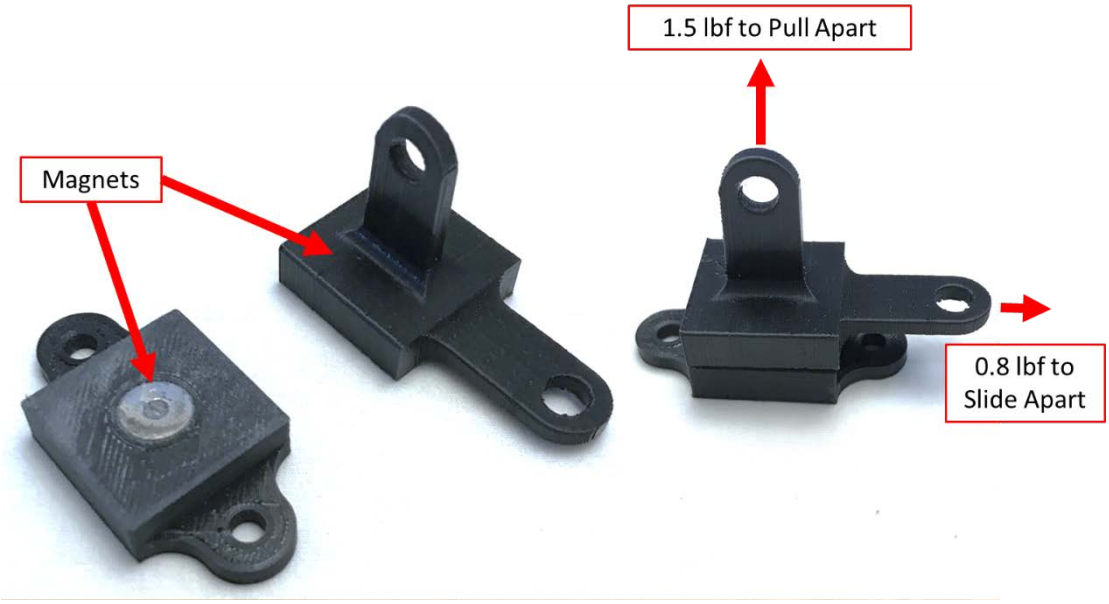

Figure 17: Magnet test setup used to test the amount of force required to separate two disc magnets. It was found that 1.5 lbf is required to pull the magnet faces directly apart, and 0.8 lbf to slide them apart. This was determined by using a force gauge to pull the two pieces of the test apparatus apart.

From Figure 17, it is seen that it requires 1.5 lbf to separate the magnet faces while pulling axially along the disc magnet faces. Only 0.8 lbf was measured to separate the magnets by sliding the faces apart in the radial direction. Another helpful aspect was that the magnets would “snap together” radially as well as axially, which meant that they would assist the user in pulling the implements into place in the receptacle.

4.1.4 The First Design

Taking the design considerations from Section 4.1.1 into account, the following design was generated. Four different views are shown to detail each side of the UHAT in the top panels of Figure 18, and the bottom and top of the UHAT in the bottom left and right panels, respectively.

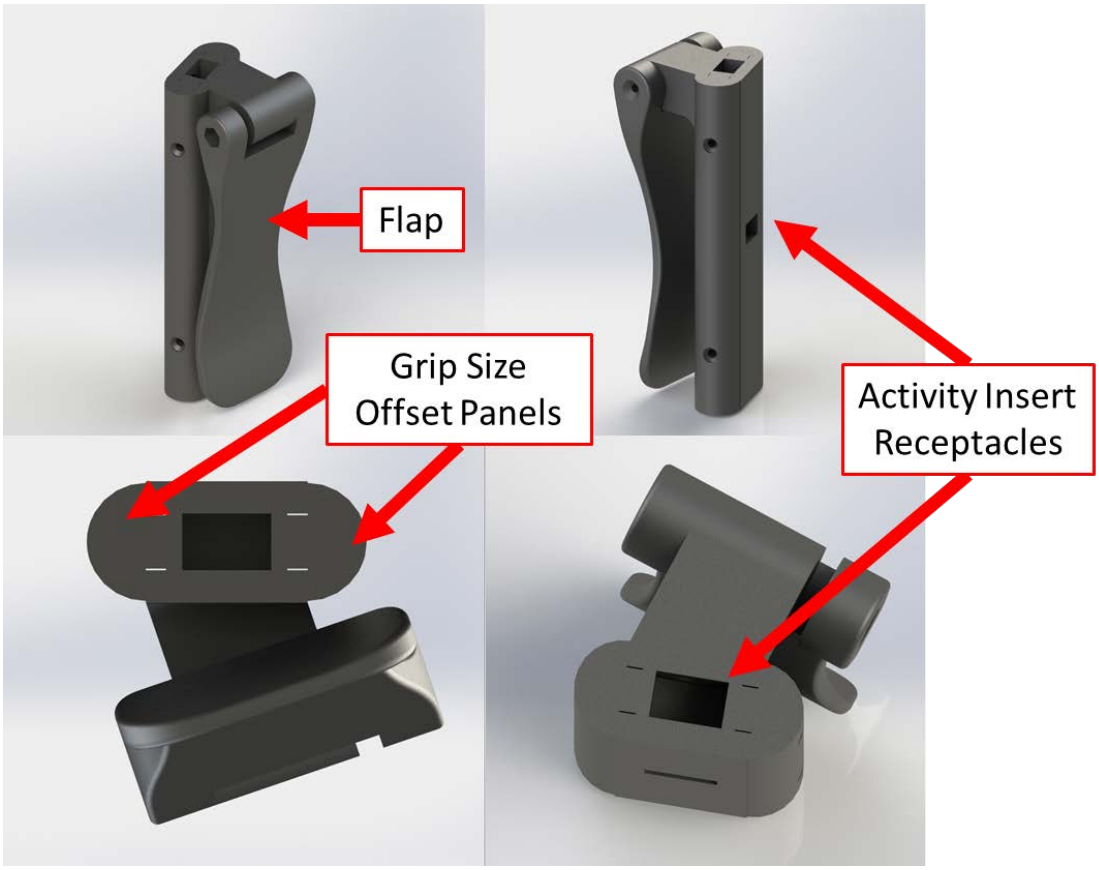

Figure 18: Diagram of the first design of the UHAT main body, side offset panels, and flap to brace the user's hand into the device.

The main body of the design consists of four 3D printed components. The part that is gripped by the hand takes the shape of a rounded rectangle that is extruded to a length

5.5 inches. On the “top” end, the flap is mated to the main body assembly on an angled panel that places the hinge 1 inch away from the body. The flap was angled at 13° in order for the back of the hand to comfortably fit inside the device. This can be seen in the bottom left of Figure 18. Two main body versions were generated, with the angle mirroring to -13°, in order to accommodate left and right hands. The grip size offset panels fasten to the sides of the main body, allowing for different sized offsets to be attached to accommodate different sized hands. These offsets increase in width by 0.25 inch increments up to 1 inch, for a total of four offset widths. A total of three activity insert receptacles are placed on the top, bottom and middle of the device. These receptacles each contain 3/8 inch disc magnets oriented such that the inserts slide in past the magnets, rather than directly contacting them at the bottom of the receptacle.

4.2 **Single User Prototyping**

With the first design printed and assembled, the single-user (SU) evaluation process was conducted.

4.2.1 Implementing Lean Development Principles with the SU

Over several months, numerous informal development meetings with the SU facilitated the generation of a very robust prototype. The lean development methodology discussed in Chapter 2 was modeled after the “Lean Startup” method of product development [13]. First, a “minimum viable prototype” was quickly generated and assembled, as shown in Figure 9 as the “Initial Prototype”. Next, SU feedback was quickly solicited to find which features worked and which did not. Each design feature

was examined based on SU input, and I decided to either “pivot or persist” with that particular feature. If a feature worked well, then it was kept and improved. If it failed it would either be changed, dropped, or further refined until it was met with satisfaction from the SU. This process would be iterated until a satisfactory prototype was achieved. In the case of the SU prototyping, this process was to be iterated until a multiple tester clinical study was scheduled.

4.2.2 Refining the Initial Prototype

The SU had a valuable perspective on how the UHAT should function, due to the SU high level tetraplegia. The first major insight was how the SU put their hand into the main body of the UHAT. It was backwards from how it was envisioned. The SU essentially set the hinge end (top) of the UHAT down on their wheelchair desk and chopped their hand into the bottom end, as shown in Figure 19. It was expected that the user would push their hand straight in through the side, however the SU did not have sufficient mobility or hand strength to straighten their fingers.

Figure 19: The flap of the UHAT was made longer, so that there was a 0.25” “lip” at the end so that the SU could “chop” their hand down into the UHAT.

This resulted in lengthening the flap of the UHAT so that it was longer than the body itself, making it easier to push the hand in through the bottom. Furthermore, the lack of control in the SU hand resulted in them fully turning the flap around, deforming the springs that close the flap. This happened within a few minutes of testing the first prototype. This resulted in a stopping mechanism placed on the main body, so that it could not be opened much more than what was needed to accommodate the hand being pushed in, seen in Figure 20.

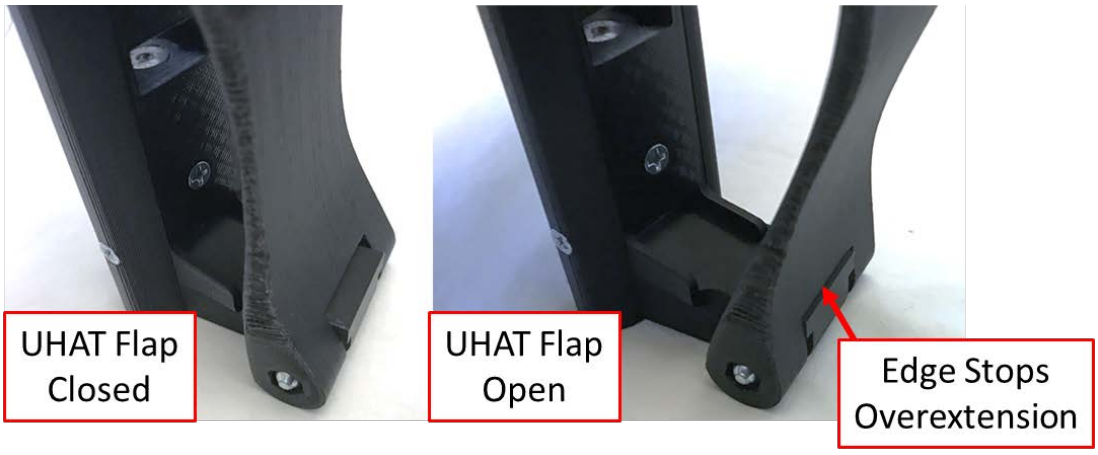

Figure 20: The edge annotated above was added to the UHAT to prevent overextension of the flap.

Another key insight was that the UHAT would not need to be made thicker or longer to accommodate different sized hands. Without grasping strength, it was more important that the palm itself be sandwiched between the flap and main body than make

it comfortable to clasp fingers around the entire main body. Most end users will not be able to close their hands into a tight fist, so expecting them to close their fingers all the way around the UHAT is unreasonable. *What was important to the SU was to have sides that were wide enough to comfortably and fully span the palm of the hand.* In keeping with the design decisions in Section 4.1.1, different sized side extensions were made so that the UHAT maximum dimension could be adjusted to fit the specifications in Section **Error! Reference source not found.**.

Another issue with the initial prototype was that, at 8 ounces, it was simply too heavy for the SU, with any more than a few minutes of use causing muscular fatigue. The SU provided me with a stylus that had been used for many years, to compare the weight against. At 2 ounces, the stylus was much lighter than the initial prototype. At this point, it was easiest to adjust the weight by testing the amount of internal support, or "infill", to see if weight could be saved in unnecessary plastic. With "fused deposition modeling" (FDM) 3D printers, a slicing software is used to render a solid model into a shell with a grid of infill for support. Too much infill makes parts brittle and heavy, with too little infill, flat surfaces and interior corners have difficulty filling in between the infill structure, as seen in Figure 21. With higher quality printers, this difficulty may be lessened, however it requires a frame to build a roof, and the same applies for FDM 3D printers.

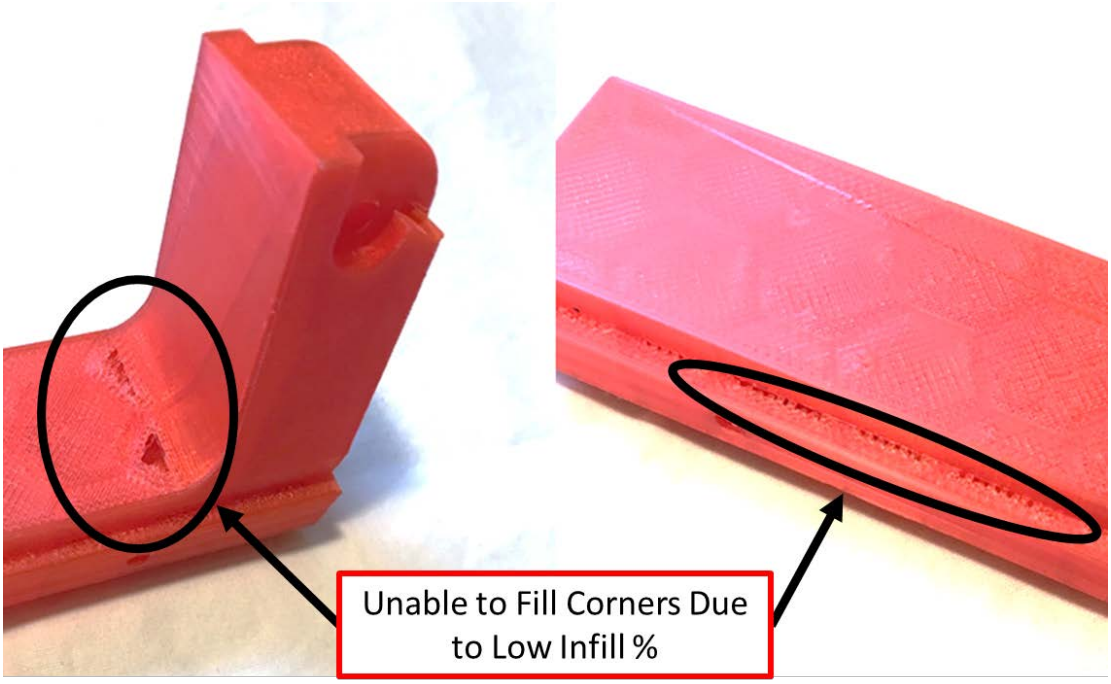

Figure 21: Inside corners are unable to fill when the infill is too low for the design. No amount of adjusting the print speed could keep these corners from pillowing in.

After several test prints where infill %, print speed, and the extrusion amount parameters were adjusted, it was found that 10% was the least amount of infill that could be used with this particular model to get full closure between the infill structures. By reducing the infill percentage of the 3D printed parts to 10%, the weight was reduced to about 4.2 ounces with a stylus insert attached, and 3.95 ounces empty. The empty weight is within the SRS value, and was found to be acceptable through SU evaluation.

Another, request by the SU was to print the UHAT in skin colored plastic. Prototypes were made in a basic black plastic, however having it blend in with the user's skin would make it less obvious that they are using an adaptive device. This lessens the

attention that would be drawn to the user, who is already subject to much unwanted attention. While not all end users may want a skin colored UHAT, it is an important consideration that each user be asked what color is important to them, and to let them know their options.

4.2.3 Activity Insert Design and Refinement

The SU provided many insights for the activity inserts as well. First, it was difficult for the SU to remove the inserts, as they were unable to pull the inserts directly out of the receptacle. The edges were square, and required that force be concentrated directly in away from the receptacle. Chamfering the edges of the activity implements made this much easier. In addition, the insert and receptacle surfaces were sanded to smooth any stray 3D printed layers. Once the edges were chamfered, the force required to remove the inserts was measured to be 1.2 lbf. In addition, the receptacles were very small due to the fitment of the grip size offset panels. This mate was changed such that the male side was on the main body of the UHAT, allowing for a larger receptacle size, as seen below in Figure 22.

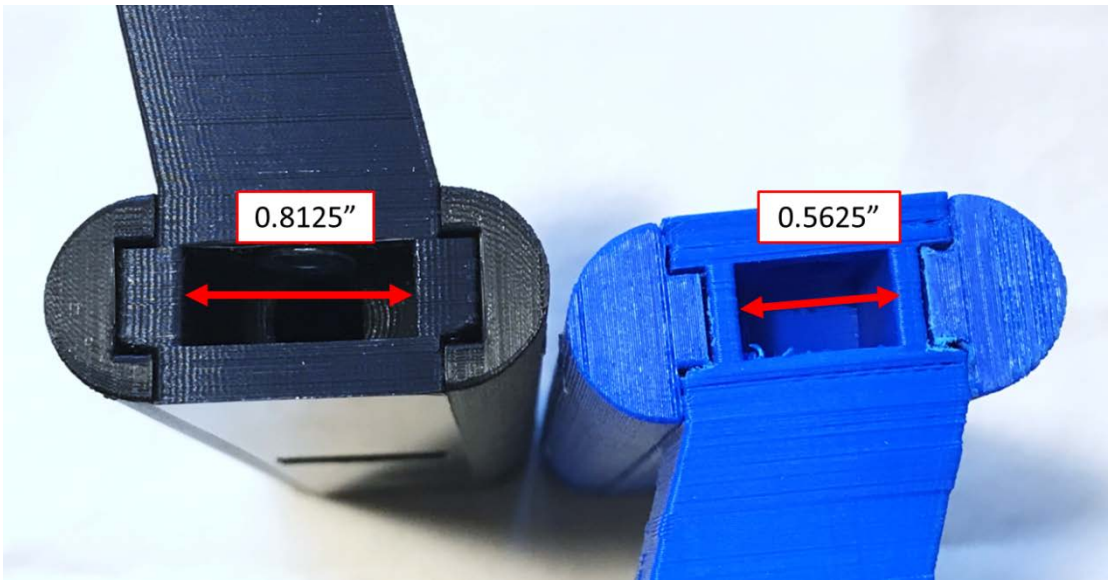

Figure 22: The revised main body prototype is on the left, and the older iteration is on the right. Changing the mate between the side panel offsets and the main body allowed for 0.25” wider inserts, making the mate between the activity insert and receptacle much more stable.

It was determined through SU testing that having a dedicated writing attachment would be beneficial, and more appropriate for hand-grasped form of the UHAT. Most reacher tools require forearm support to be effective for users with little grip strength. Adding forearm support added significant weight to the device, and thus was determined to be too large of a tradeoff for a single activity. This also would be a difficult part to design to be 3D printed and easily portable like the other activities. Furthermore, none of the other attachments could be used as a writing attachment and holding a pen is a fine motor ability that is compromised with tetraplegia. For these reasons it was decided,

with input from the SU, that *a writing insert would be a suitable replacement for the reacher/grabber insert*.

Chapter 5: Design Project Results

5.1 **Resulting Universal Hand Assist Tool Design**

The following section describes the final result of SU prototyping of the UHAT. All CAD design and modeling in the UHAT project was performed using Solidworks.

5.1.1 Models and Diagrams

The design of the main body of the UHAT did not dramatically change from the initial prototype to the end result, however many details changed as a result of SU testing. The final version of the main body is shown below in Figure 23. Three activity inserts remain on the top, bottom and middle of the main body. Most notably different from the initial design are the thumb restrain seen in the upper right hand side of the figure, the larger activity receptacles, and the silverware cutout passing through the middle of the main body. The middle activity insert passes directly through the main body, as well. The activity insert openings are rectangles measuring 0.8 by 0.35 inches.

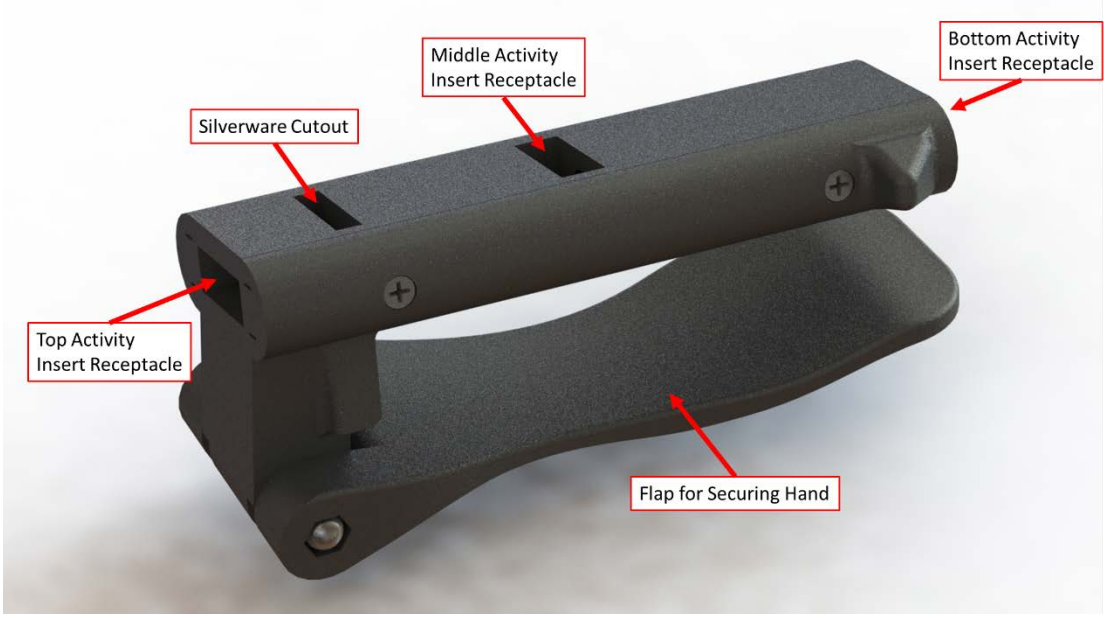

Figure 23: Rendered model of the UHAT, with all hardware included. All insert receptacles are labeled.

Figure 24 shows the top and bottom views of the UHAT. In the bottom view in the right hand panel, the silverware guides can be seen on the arm connecting the flap to the main body.

Figure 24: Top and side views of the UHAT.

The UHAT main body consists of four 3D printed components, held together with #6 fasteners. This design is elegant and easy to assemble, as seen in the exploded view of the main body shown in Figure 25.

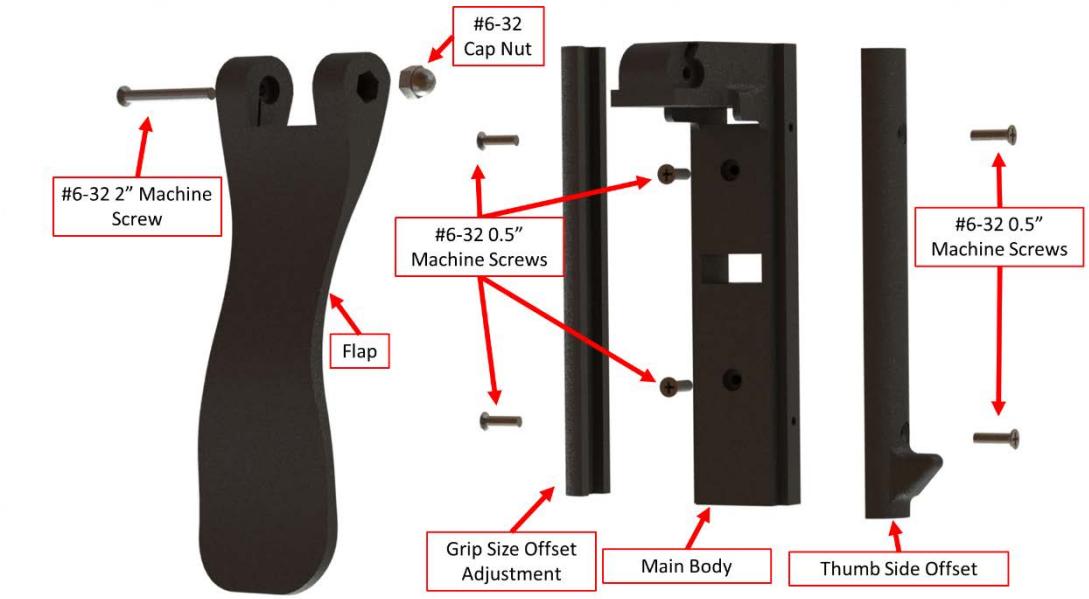

Figure 25: Exploded view of the UHAT main body, with labeled components.

Grip size adjustment in the final UHAT version is made by mating different size adjustment offset panels, displayed in Figure 26. The female channels on the grip adjustment offset panels mate to male guides on the UHAT body itself. These mated channels allow force on the sides of the UHAT to be distributed along the entire length of the UHAT side, rather than only on the fasteners. Only one side of the main body requires grip size offsets to meet SRS grip size requirements.

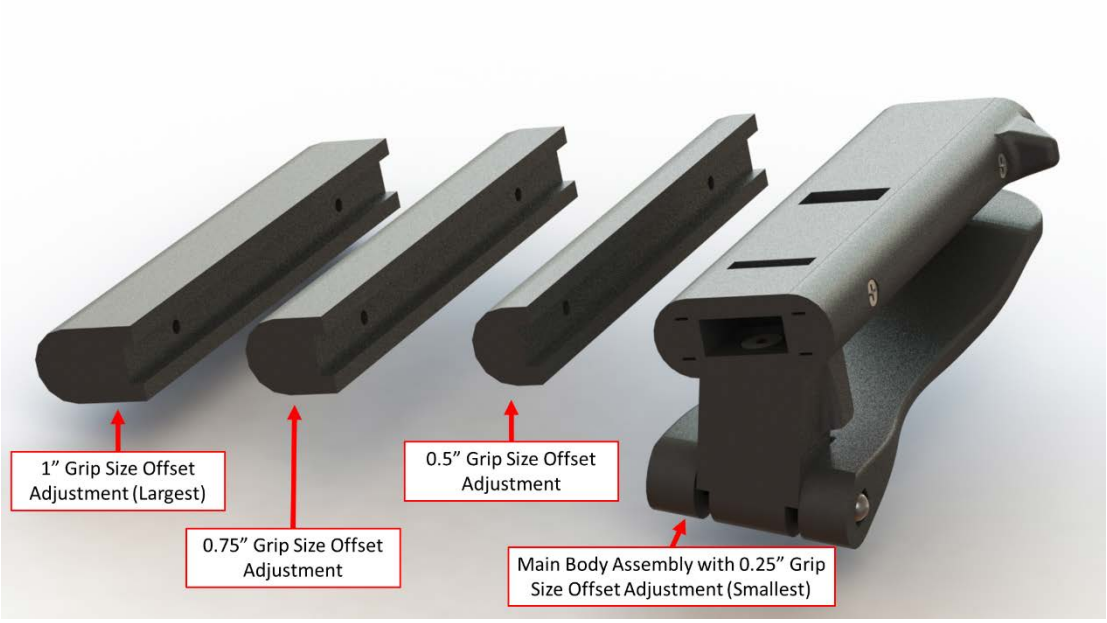

Figure 26: Rendering of the UHAT with the four grip size adjustment panels. These can be changed to fit the user of the UHAT, making it more adaptable to different hand sizes.

Figure 27 shows each of the activity inserts that resulted from SU testing. Small 3/8 inch disk magnets on each activity insert side mate with identical magnets inside each of the activity insert receptacles on the main body. The blank insert on the right hand side is included in the UHAT deployment package as a base for new activity inserts to be made. Each activity insert base is chamfered on the edges to provide ease of insertion and removal for the end-user.

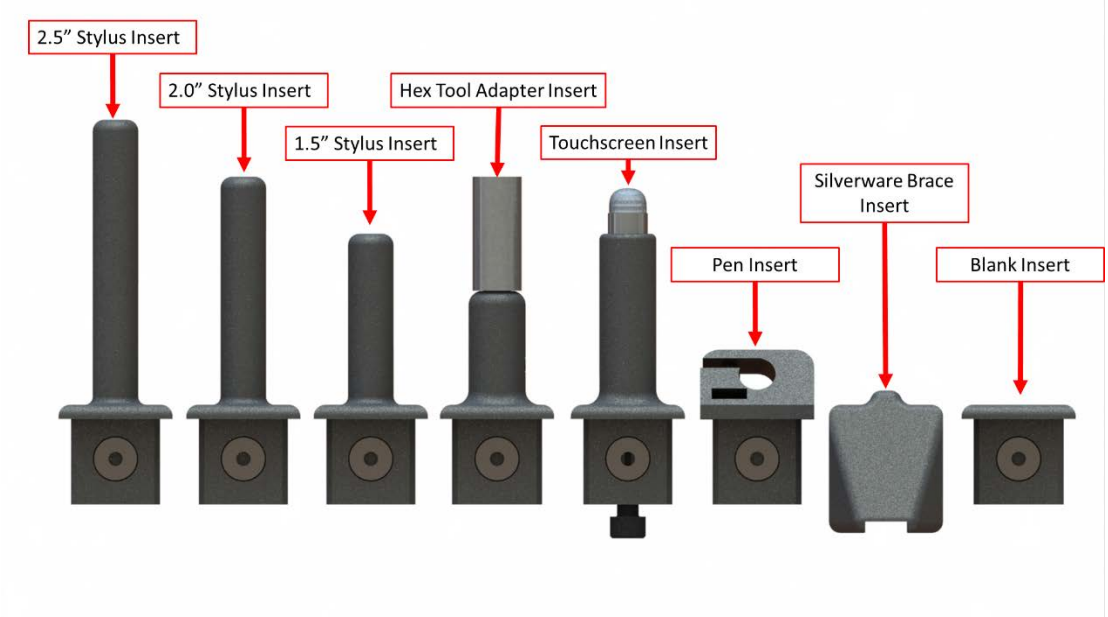

Figure 27: Annotated rendering of all activity inserts for the UHAT.

5.1.2 Finished and Assembled UHAT

Shown below in Figure 28 is a picture of the fully printed and assembled UHAT main body.

Figure 28: Pictures of the actual assembled UHAT device.

Figures 29 and 30 mirror the models presented in Figures 26 and 27.

Figure 29: The UHAT with the four grip size offset panels. This figure follows the same orientation as Figure 26.

Figure 30: Activity inserts for the UHAT. These follow the same order as Figure 27.

The silverware activity insert is shown in Figure 31. Channels on each side of the arm connecting the flap to the main body are seen in the top panels, and the hardware stop for the flap can be seen in the upper left hand panel. Once silverware is placed in the channel through the main body, the activity insert is clipped into place, restraining the lateral movement of the silverware.

Figure 31: Silverware activity insert for the UHAT.

The touchscreen stylus activity insert is shown in Figure 32. Detailed diagrams for this activity are presented and discussed further in Section 5.2.4.1.

Figure 32: Touchscreen activity insert for the UHAT.

The writing activity insert is shown in Figure 33, with a BIC Round Stic pen installed. A single #6 machine screw closes a C channel around the pen, holding it in place.

Figure 33: Writing activity insert for the UHAT.

5.1.3 Engineering Drawings

Figures 34 through 38 are detailed engineering drawings of the UHAT device. These are presented to show the dimensioning of the device.

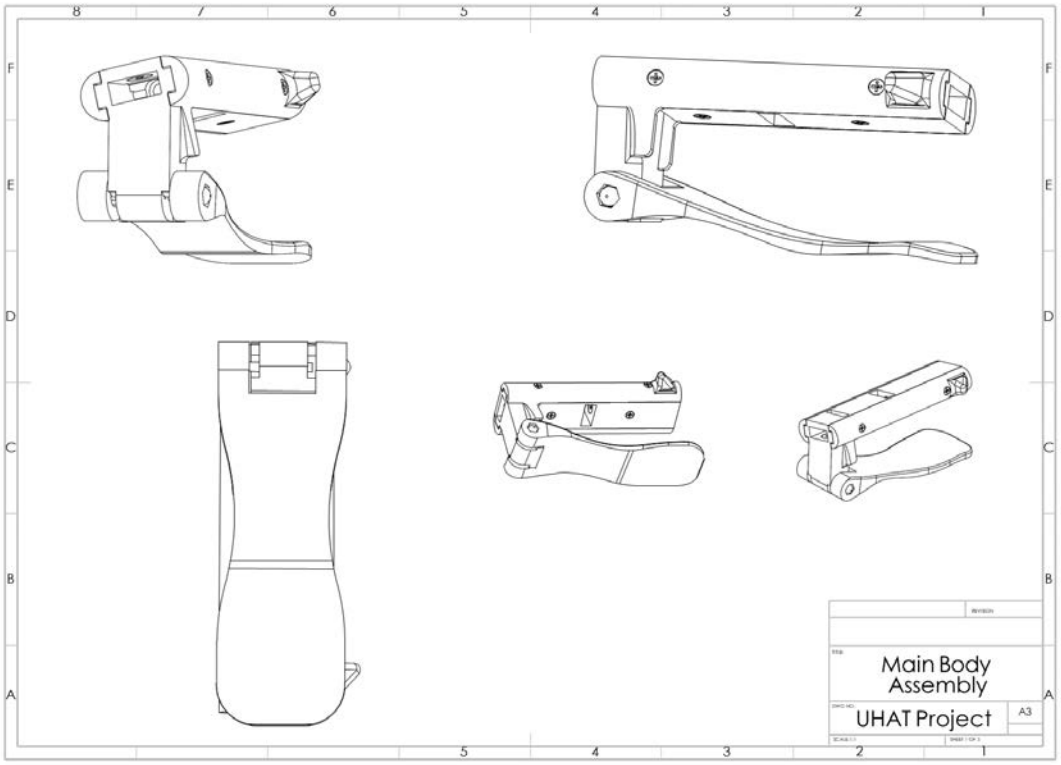

Figure 34: Engineering drawing of the main body assembly of the UHAT.

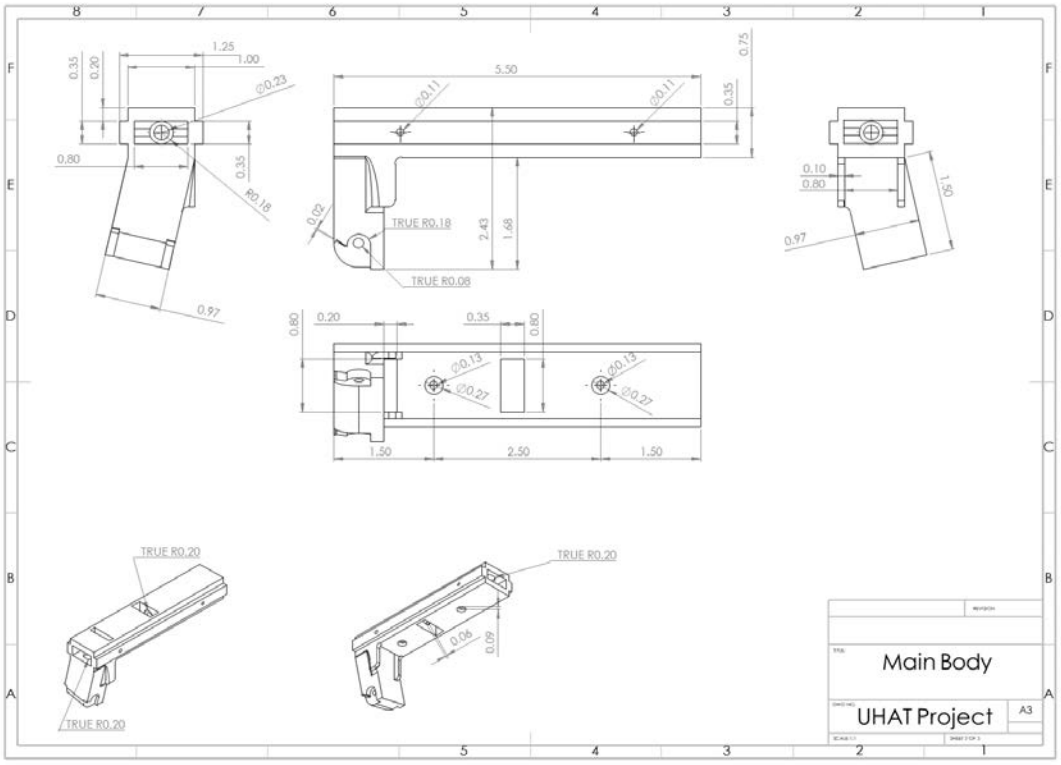

Figure 35: Annotated drawing of the main body, with measurements.

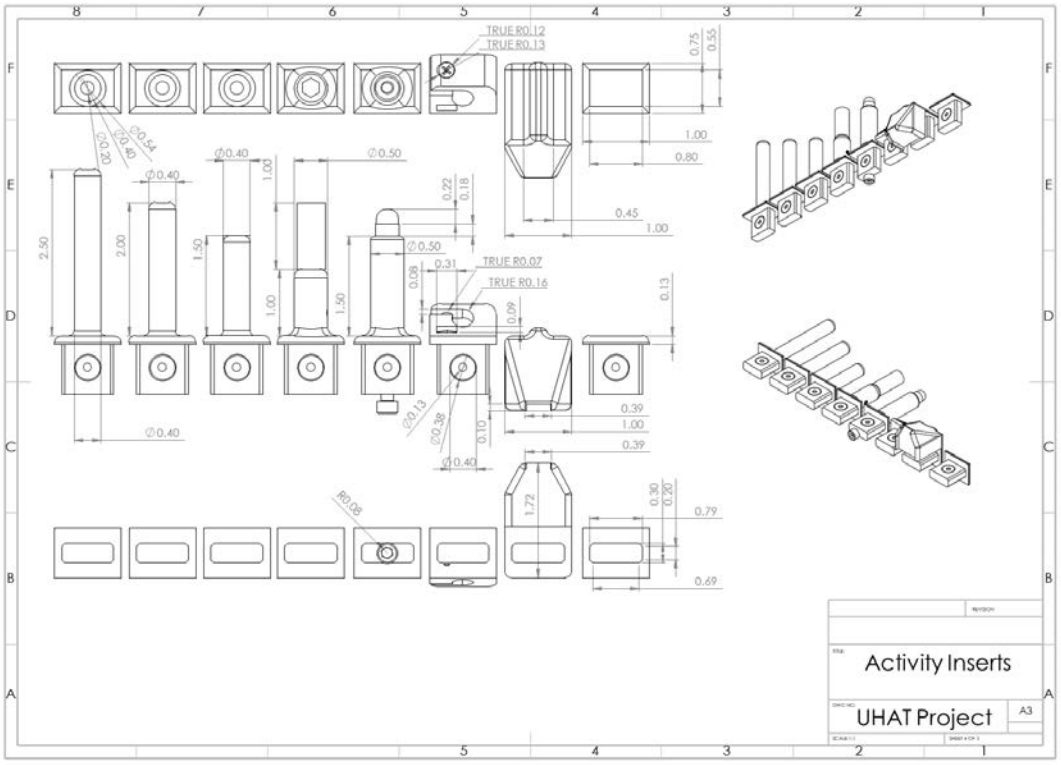

Figure 36: Annotated drawing of the activity inserts, with measurements.

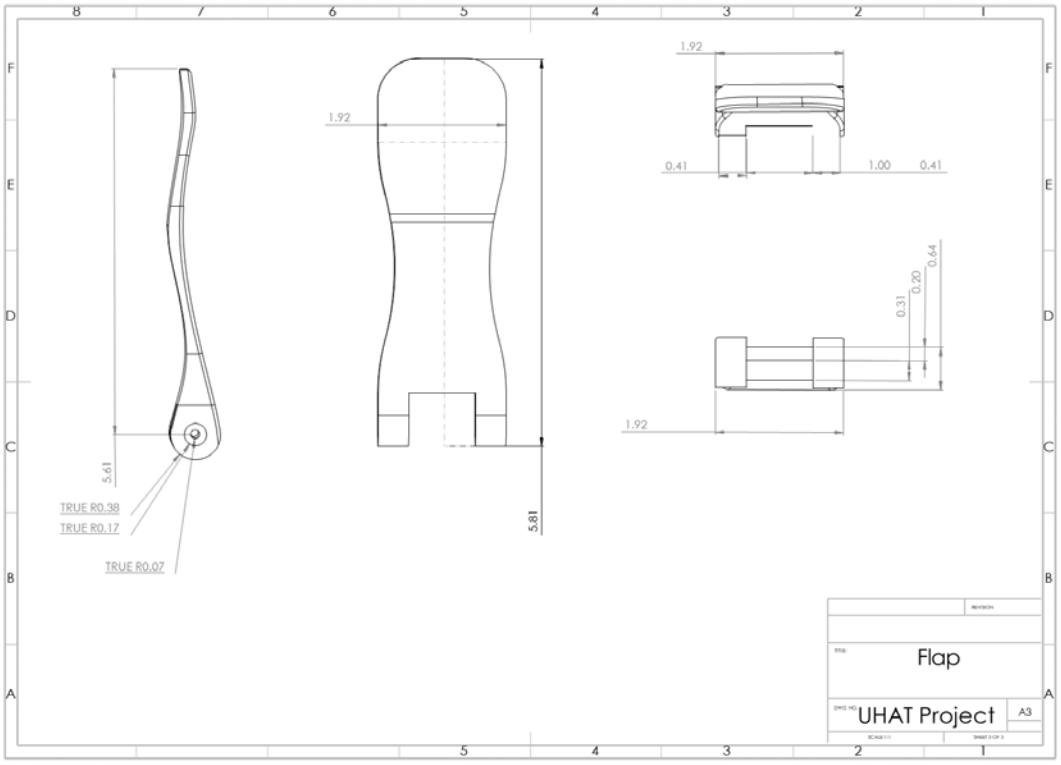

Figure 37: Annotated drawing of the flap, with measurements.

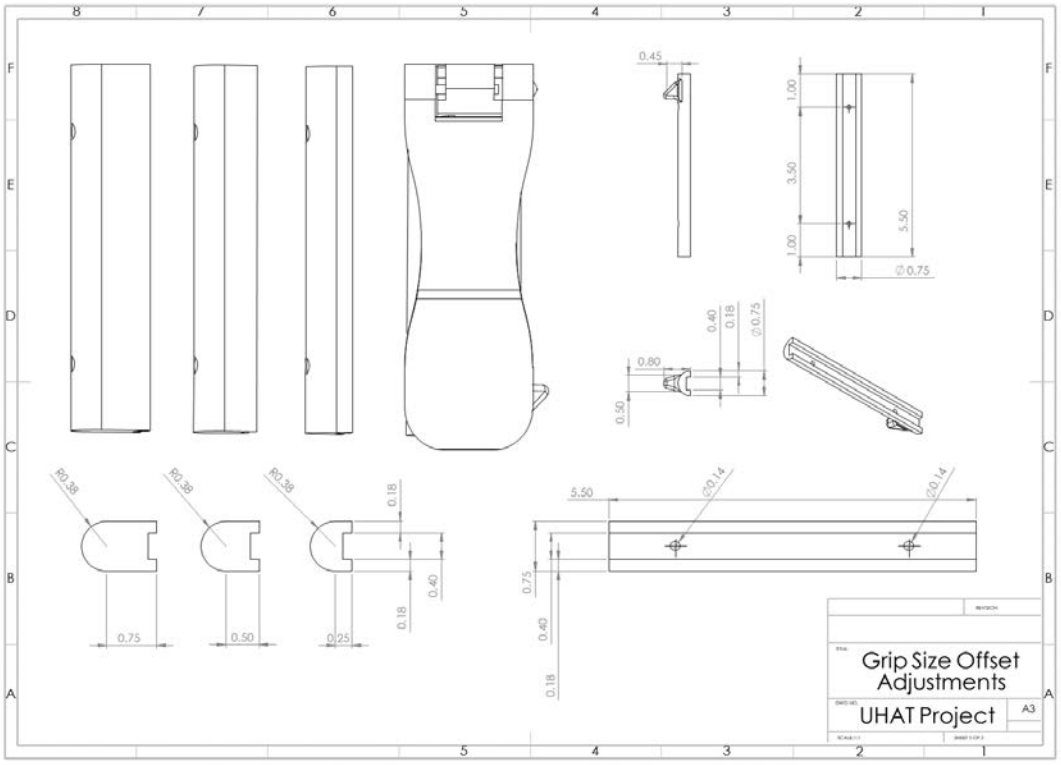

Figure 38: Annotated drawing of the grip size offset panels, with measurements.

5.1.4 Bill of Materials

The following section contains bills of materials for the UHAT. Table 3 contains a bill of materials if the fabricator has access to a 3D printer, and Table 4 contains a bill of materials for outsourcing the 3D printing to 3DHubs.com. The two prices on the UHAT include the total for purchasing all of the materials to build the first UHAT on the left, and the actual unit price to build each UHAT is shown on the right. It is shown that a UHAT can be printed for $41 dollars if self-printing, and $72 if outsourcing printing.

Table 3: Bill of Materials if printing on an available 3D printer.

Bill of Materials for Universal Hand Assist Tool (Self Print)					
Qty	Item Description	Number in Package	Number per UHAT	Package Total	Price Per UHAT
1	Music-Wire Steel Torsion Spring	6	1	$6.89	$1.15
	90 Degree Left-Hand Wound, 0.309" OD				
	9271K35 McMaster Carr				
1	Music-Wire Steel Torsion Spring	6	1	$6.89	$1.15
	90 Degree Right-Hand Wound, 0.309" OD				
	9271K34 McMaster Carr				
1	Bob Smith Industries BSI-157H Maxi Cure/Insta-Set	20	1	$11.44	$0.57
	Combo Pack, 1,500 cps, 3 oz.				
	Amazon.com				
2	MASTER MAGNETICS 3/8 in. Neodymium	12	20	$3.98	$6.63
	Rare-Earth Magnet Discs (12 per Pack)				
	Home Depot				
1	Pack of 10 Replacement Fiber Tips for The Friendly	10	1	$10.99	$1.10
	Swede Replaceable Fiber Tip Capacitive Stylus Pens Only				
	Amazon.com				
1	#6-32 tpi x 1/2 in. Zinc-Plated Flat-Head Phillips Drive	8	7	$1.18	$1.03
	Machine Screw (8-Piece)				
	Home Depot				
1	#6-32 tpi x 2 in. Zinc-Plated Oval Head Phillips Machine	4	1	$1.18	$0.30
	Screw (4-Piece per Bag)				
	Home Depot				
1	#6-32 Coarse Zinc Plated Steel Cap Nuts (6-Pack)	6	1	$1.18	$0.20
	Home Depot				
1	7/32" diameter 1.5" long Compression Spring	10	2	$4.99	$1.00
	200 Piece Assorted Spring Set				
	item#67562 Harbor Freight				
1	2 in. Magnetic Bit Tip Holder	1	1	$1.97	$1.97
	Home Depot				
1	5/32"-32 - 150 Piece Set Screw Assortment	10	1	$8.99	$0.90
	Item#67671 Harbor Freight				
1	HATCHBOX ABS 3D Printer Filament, Dimensional Accuracy	1000	182.51	$27.30	$4.98
	+/- 0.03 mm, 1 kg Spool, 1.75 mm, Black	(1000 grams per box)	(182.51 grams per UHAT)		
	Amazon.com				
1	1 Hour Labor to Assemble	1	1	$20.00	$20.00
			Total to Self Print	$106.98	$40.97

Table 4: Bill of Materials if outsourcing 3D printing to www.3dhubs.com.

Bill of Materials for Universal Hand Assist Tool (Outsource Printing)					
Qty	Item Description	Number in Package	Number per UHAT	Package Total	Price Per UHAT
1	Music-Wire Steel Torsion Spring	6	1	$6.89	$1.15
	90 Degree Left-Hand Wound, 0.309" OD				
	9271K35 McMaster Carr				
1	Music-Wire Steel Torsion Spring	6	1	$6.89	$1.15
	90 Degree Right-Hand Wound, 0.309" OD				
	9271K34 McMaster Carr				
1	Bob Smith Industries BSI-157H Maxi Cure/Insta-Set	20	1	$11.44	$0.57
	Combo Pack, 1,500 cps, 3 oz.				
	Amazon.com				
2	MASTER MAGNETICS 3/8 in. Neodymium	12	20	$3.98	$6.63
	Rare-Earth Magnet Discs (12 per Pack)				
	Home Depot				
1	Pack of 10 Replacement Fiber Tips for The Friendly	10	1	$10.99	$1.10
	Swede Replaceable Fiber Tip Capacitive Stylus Pens Only				
	Amazon.com				
1	#6-32 tpi x 1/2 in. Zinc-Plated Flat-Head Phillips Drive	8	7	$1.18	$1.03
	Machine Screw (8-Piece)				
	Home Depot				
1	#6-32 tpi x 2 in. Zinc-Plated Oval Head Phillips Machine	4	1	$1.18	$0.30
	Screw (4-Piece per Bag)				
	Home Depot				
1	#6-32 Coarse Zinc Plated Steel Cap Nuts (6-Pack)	6	1	$1.18	$0.20
	Home Depot				
1	7/32" diameter 1.5" long Compression Spring	10	2	$4.99	$1.00
	200 Piece Assorted Spring Set				
	item#67562 Harbor Freight				
1	2 in. Magnetic Bit Tip Holder	1	1	$1.97	$1.97
	Home Depot				
1	5/32"-32 - 150 Piece Set Screw Assortment	10	1	$8.99	$0.90
	Item#67671 Harbor Freight				
1	Printing all parts in Standard ABS	1	1	$36.31	$36.31
	https://www.3dhubs.com/				
1	1 Hour Labor to Assemble	1	1	$20.00	$20.00
			Total to Outsource Print	$115.99	$72.30

5.2 **Discussion**

5.2.1 Verification of UHAT Specifications

The following section will compare the results of the UHAT prototype against the design specifications presented in Section 3.4.

5.2.1.1 Functional Requirements

The five activity inserts presented in the SRS were successfully completed, with the exception of the extension hook/grabber. A writing activity insert was substituted for the reacher. Furthermore, the styli inserts were changed to 1.5”, 2” and 2.5” lengths, as 1”, 3”, and 5” were found to be awkward in practice. 1.5”, 2” and 2.5” were found to be much more useful during SU validation.

Through SU validation, each functional requirement is met for the UHAT using these activity inserts as directed. Individual activity inserts will be further discussed in Section 0.

5.2.1.2 Performance Requirements

The grip diameter specification is for the maximum diameter of the UHAT to scale between 1.77” to 2.36”. The UHAT includes four side offset panels, ranging from 0.25” to 1”. As shown in

Table 5, The UHAT scales from 1.775” to 2.542” at approximately 0.25” increments. It is important to note that this is not a circular diameter, but a rounded rectangle. This meets the design specifications for grip diameter.

Table 5: The maximum grip diameter with each grip offset panel attached to the UHAT.

Grip Offset	Grip Diameter
0.25"	1.775"
0.5"	2.021"
0.75"	2.270"
1"	2.542"

As stated previously in Section 4.2.246, the grip length is not a helpful parameter to change according to the SU. This was not varied, but set to exceed the maximum grip length of 3.74” at a length of 4.525”. This meets the specification of maximum length, and the minimum length was neglected due to SU input. As seen in

Table 6, the weight of the empty UHAT with the 0.25” offset is 3.77 ounces, which is within the weight specification of 4 ounces. Larger offsets and adding activity inserts increase the weight to over 4 ounces, with the heaviest configuration being 6.14 ounces.

Table 6: Weight of the UHAT configured with each grip offset in the left-hand column, compared with each activity insert to the right. Units of length are in inches, and units of weight are in ounces.

Grip Offsets	Activity Inserts (weight in ounces)						
	Empty	Touchscreen	0.25" Tool	Pen	Stylus	Silverware	Plasticware
0.25"	3.77	4.23	5.11	4.20	3.99	5.57	4.34
0.5"	3.95	4.41	5.29	4.37	4.16	5.75	4.51
0.75"	4.16	4.62	5.50	4.62	4.37	5.96	4.73
1"	4.37	4.80	5.71	4.80	4.59	6.14	4.90

The amount of force required to remove implements was measured to be 1.2 lbf, with a high degree of precision. Ten removal tests shown in Table 7 were performed with the UHAT using a force gauge, and the force was measured reliably to be 1.2 lbf. Two removal speeds were tested, and the force to remove the insert remained consistent. This is well within the maximum specified 2 lbf requirement.

Table 7: Force to remove the activity insert from the UHAT activity insert receptacle. Units are in lbf.

	Test Number									
Removal Speed	1	2	3	4	5	6	7	8	9	10
Fast	1.2	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.1	1.2
Slow	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2

Drop testing was performed with each activity insert, and with the main body of the UHAT to ensure a robust design. Each component was pushed from a 5 foot tall

platform a total of 20 times. After no damage to the UHAT was observed at 20 drops, testing was considered complete.

5.2.2 Finite Element Analysis

A Finite Element Analysis was performed on the UHAT main body activity insert receptacle and 2.5” stylus, to verify that the design is able to withstand forces that occur during use. These were chosen, since the activity insert receptacle is the thinnest part of the UHAT main body, and the 2.5 inch stylus activity insert is a long, thin extrusion of ABS plastic. This was performed within the Solidworks CAD program. First, the main body was examined, applying 6 lb of force to the inside face of the top activity insert receptacle. This force was chosen since it is double what the SU was able to produce. The material was assumed to be linear elastic isotropic ABS plastic. The length of the sides were fixed for the analysis, and a force of 6 lb was applied to the inner face of the top activity insert.

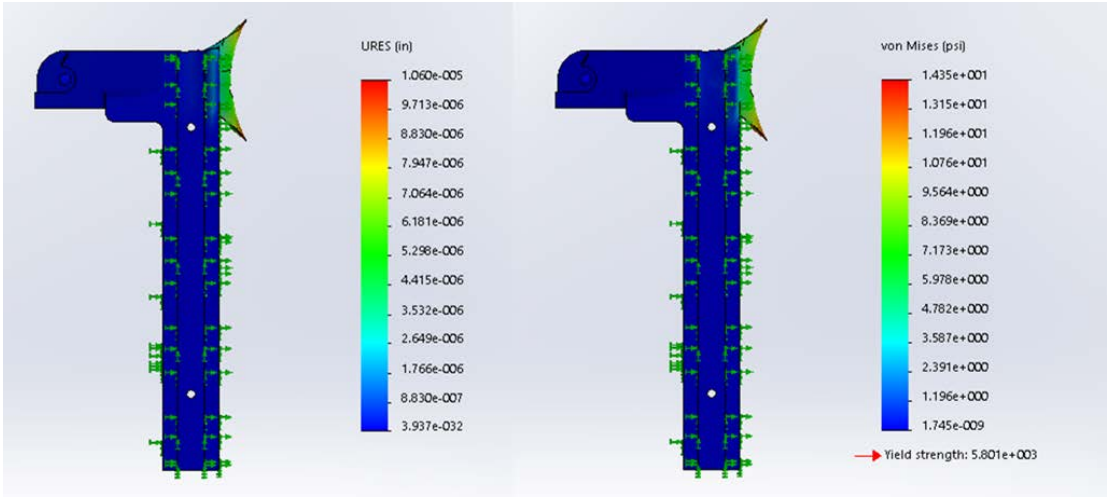

Figure 39: FEA Analysis of the UHAT main body, with 6 lb of force placed on the inside face of the top activity insert receptacle.

As seen in Figure 39, the maximum displacement was on the order of hundred thousandths of an inch. The factor of safety for this stress is calculated to be over 400, based on Solidworks estimation. The simulated von Mises stress is 1.4375 psi, which is negligible compared to the yield strength of ABS, which is 5801 psi.

For the 2.5 inch stylus, the four sides of the insert base, except for the chamfered corners, were fixed. A force of 6 lb was exerted along the length of the 2.5 inch extrusion, normal to plane of the largest faces of the insert base.

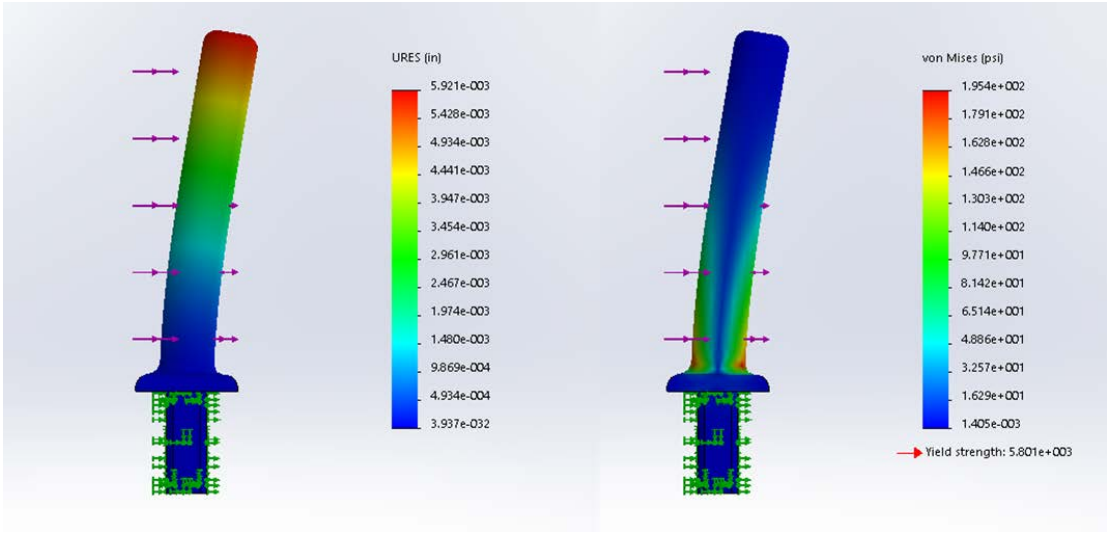

Figure 40: FEA of the 2.5 inch stylus activity insert of the UHAT.

In Figure 40, it can be seen that the maximum displacement is 5.921 thousandths of an inch, and the maximum von Mises stress of 195.4 psi occurs at the base of the stylus, as is expected, and well below the yield strength of ABS plastic. The lowest factor of safety in this simulation was calculated to be 29.6.

These simulations indicate that even the structurally weakest design elements of the UHAT are well within the capabilities of the materials that were chosen. The major limitation of these simulations were that it is difficult to simulate the behavior of 3D printed plastic, with internal structure. Since the factor of safety is so large for both cases, it is still a useful prediction of the robustness of the UHAT design.

5.2.3 Single User Validation Analysis

Single user validation has been an invaluable part of the success of the UHAT device development. Working with the SU allowed for rapid development and refinement of

concepts and features through frequent testing with immediate feedback that could be implemented and iterated quickly. This enabled faults to quickly be identified with the model or prototype, especially since it is extraordinarily difficult for someone with full mobility to discern what would be helpful to someone with tetraplegia. For example, a tester with no injury might never identify the need to lengthen the flap to allow for the hand to "chop" into the back of the UHAT, as seen in Figure 19. This perspective can only be obtained by an actual end-user. Furthermore, logistically obtaining feedback for quick iterations of the design is much easier with a single individual tester, especially to identify early refinements for the prototype. It is important to note that UE mobility is varied between each user's injury, so the SU evaluation is a useful tool to validate design features, a multiple user clinical study will show if the UHAT will truly work with a broad range of injuries, hand sizes, and user needs.

This rapid iteration is the hallmark method of lean development. Utilizing this design method, allowed for the rapid identification of design and reasoning flaws, as well as the instant feedback from potential end-users *during the design process*. This is much more efficient than spending time generating a finished product based only on system requirements, only to find certain design features are flawed at best, and useless at worst.

5.2.4 Activity Implement Discussion

The following section will discuss each activity insert, and demonstrate their use.

5.2.4.1 Touchscreen Activity Insert

Development of the touchscreen insert required several iterations to reach a robust solution. Capacitive touchscreens, such as the screens used on modern mobile devices, have a grid of dots built in to the screen that can be seen in bright light. By detecting a change in capacitance between several of these points, the device will register a “touch” on a particular location of the screen [28]. This was challenging when designing the touchscreen activity insert, as the touchscreen relies on skin contact to provide this change in capacitance. To address this, a replaceable touchscreen stylus tip were purchased and integrated into the design. This stylus has a metal mesh tip that, given skin contact, will provide the screen with the necessary capacitive perturbation for the screen to register a “touch”. This stylus tip was integrated into the activity as seen in Figure 41. This activity can be used in any activity receptacle of the UHAT, depending on what is comfortable for the user. Figure 42 shows an example of using the touchscreen insert with a mobile device.

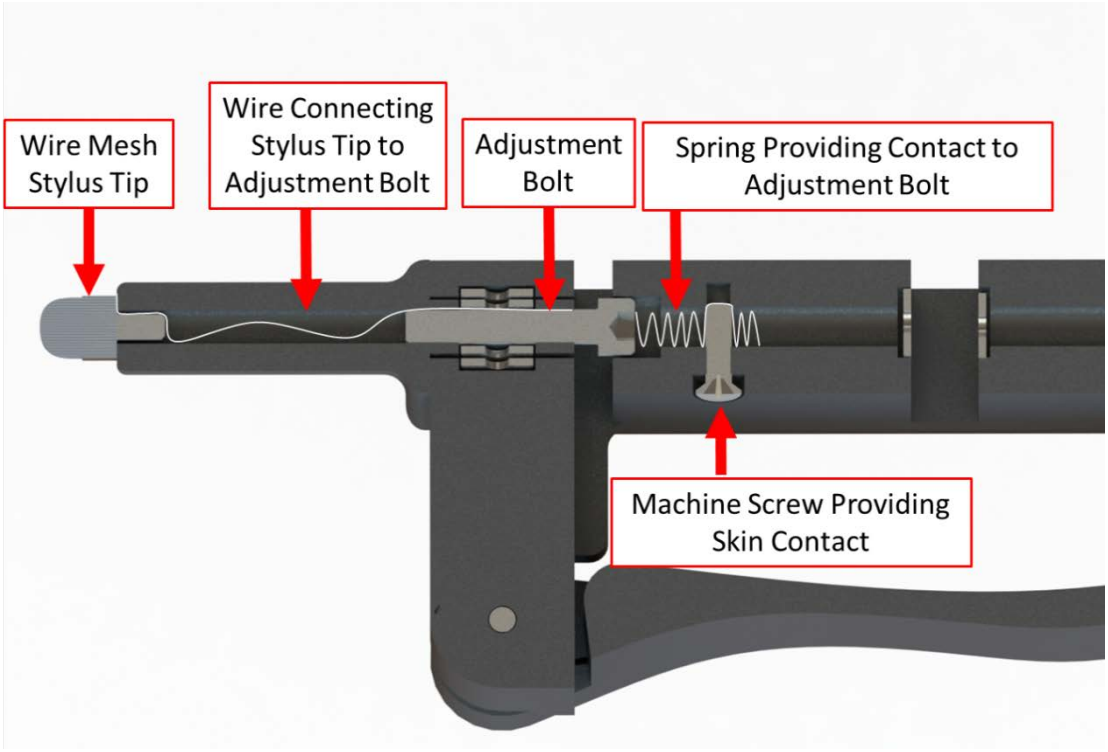

Figure 41: Side cutaway of UHAT with Touchscreen Activity Insert explaining hand to wire mesh stylus tip contact.

Figure 42: Touchscreen activity insert in use.

5.2.4.2 Silverware Activity Insert

An important feature was to be able to use the UHAT to assist with using virtually any silverware. This is a particularly interesting challenge. Silverware comes in varied shapes and sizes, and this attachment is being designed for the user to able to walk into any restaurant and use their silverware. This variability in size and shape is the design challenge. Again, silverware is held like a pen, and not gripped in a fist, and must be nearly orthogonal to the palm. This was achieved by placing a rectangular hole through the UHAT next to the hinge. Guides were put on either side to keep the silverware in place, and an insert for the top side receptacle was designed to push the silverware up and lock it in place. This activity is performed by first inserting silverware, as shown in Figure 43, then inserting the activity insert to clamp the silverware in place. The activity insert pulls into place with the magnets, with the user only needing to line up the insert into the receptacle and guide it in.

Figure 43: Silverware activity insert in use.

Perhaps the biggest design challenge of this project was designing the silverware activity insert for the UHAT. The requirement that the UHAT fit *any piece of silverware* was the main challenge. Several iterations of silverware attachments were generated, all tested with the SU and found to be unsuitable, mainly due to the SU silverware itself being very large, and not fitting in the insert. The breakthrough in this activity is when the leverage was provided with a separate cut-through of the UHAT main body, rather than relying solely on the insert receptacle to hold the silverware. This design, as seen in Figure 43, only uses the silverware insert to clamp the silverware in place, and provide lateral movement stabilization.

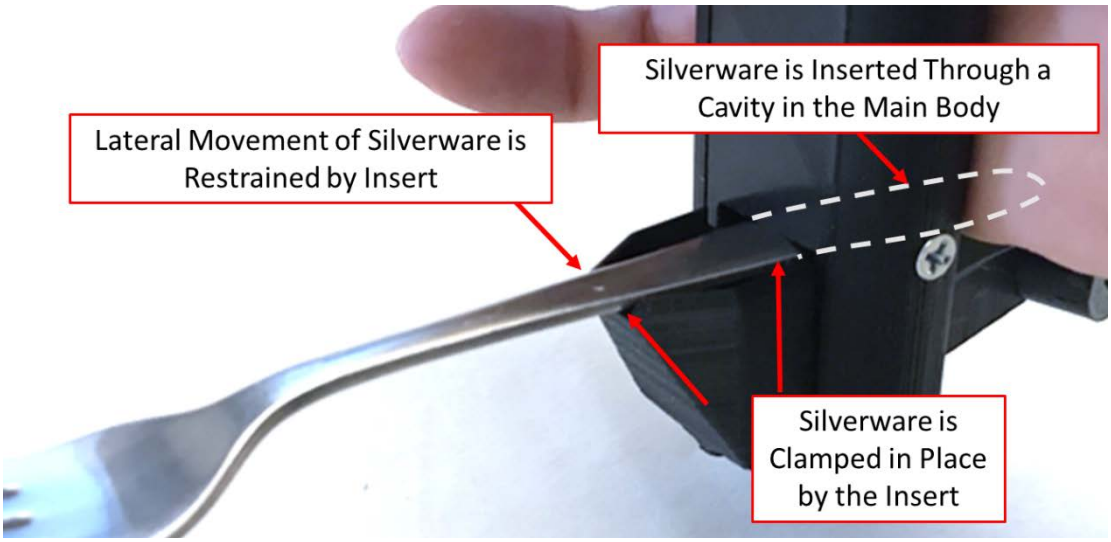

Figure 44: Silverware is inserted into the main body of the UHAT itself, all the way through to the flap, then the insert is pushed in to clamp the silverware in place.

5.2.4.3 Writing Activity Insert

Several iterations of pen insert designs occurred before an acceptable design was reached. At first, the pen attachment was only usable in the ends, with the pen itself parallel to the main body. This is not a natural writing position, essentially requiring the user to grip a pen in their fist to write. The best direction for the pen to face is orthogonal to the palm. This was achieved by aligning the pen to point toward the writing surface with a relaxed elbow and grip. To use this activity, guide the implement into either the top or bottom activity receptacle as shown in Figure 45, and allow the magnets to snap the implement into position.

Figure 45: Writing activity insert in use.

5.2.4.4 Focused Force Stylus Activity Insert

With decreased UE control and mobility, simple tasks such as using a keyboard becomes difficult for a person with tetraplegia. The focused force stylus is a 0.5 inch diameter cylinder extruded up to 2.5 inches from the base insert, and can be used to act as a rigid “finger” that can be used to perform delicate activities that the user might not have the dexterity to perform otherwise. The stylus can be used for multiple activities. End-users more than likely already has a similar tool, so this stylus will be intuitive to begin using. As shown in Figure 46, the focused force stylus can be used for typing on a keyboard.

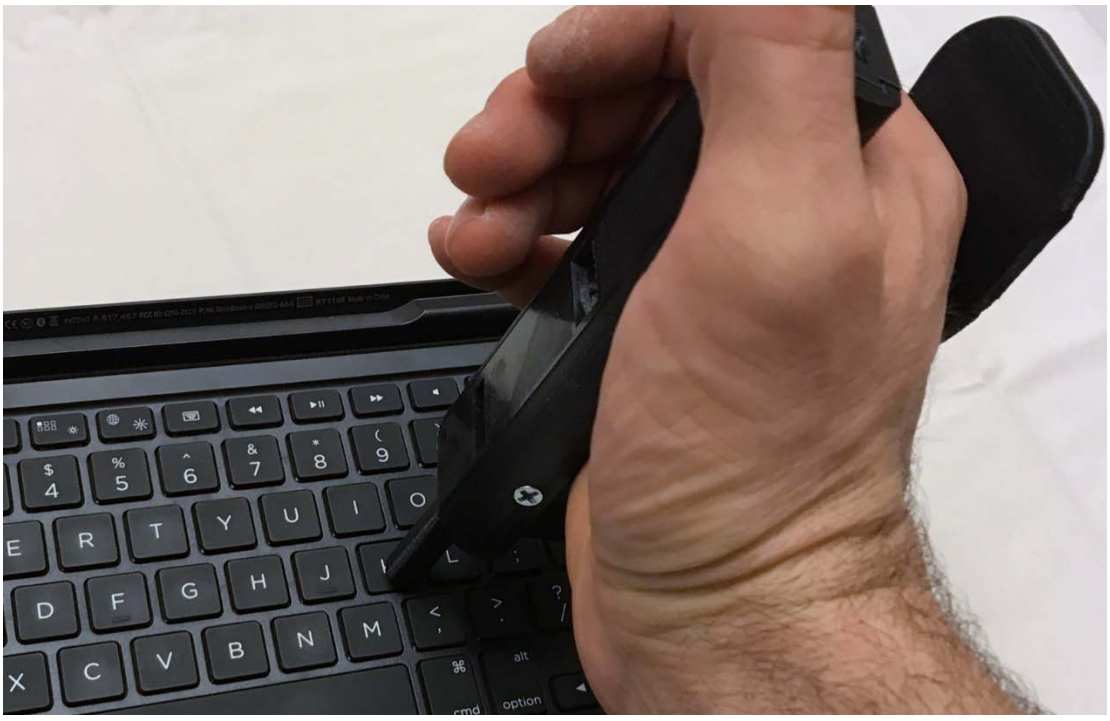

Figure 46: Focused force stylus insert in use.

5.2.4.5 Quarter Inch Hex Tool Adapter

The quarter inch hex tool adapter insert allows the use of multiple tools. This design includes a 0.5 inch diameter cylinder extruded 1 inch, with a 0.27 inch hexagon cut down the center. A 0.14 inch hole placed 0.25 inches from the bottom of the extrusion allow a set screw to hold a hex bit adapter for a power drill in place. The hex bit adapter allows the end-user to swap in multiple tools to be able to perform multiple activities, such as changing batteries in a remote control, which would be extremely difficult without this adaptive tool. Pictured in Figure 47, the quarter inch hex adapter is being used to remove a crosshead screw to change a battery.

Figure 47: Quarter inch hex tool adapter insert in use.

5.2.5 Design of a Clinical Study

A clinical study was designed to further evaluate and refine the UHAT. 6-10 participants will be recruited to test the UHAT prototype. Each participant will test the UHAT for up to 2 hours in a session with a research assistant at Kennedy Krieger, including time to fill out the evaluation form included in Appendix E. A testing session will occur on weeks 1, 3, 5, 7 and 9 of the clinical study, while weeks 2, 4, 6, and 8 will be used to make changes to the prototype based on the results of the evaluation. Each two week block is considered one “test cycle”. If a participant misses a testing session, the prototype will not be changed the following week.

While not necessary to generate a viable, working product, the clinical study can be conducted to further validate the design features of the UHAT and ensure that the UHAT will benefit the greatest number of potential users, and further identify flaws in the design. In order to fully protect participants from potential injury and unintended personal information distribution, an IRB approved clinical study research protocol was deemed necessary. The full clinical study research protocol generated for this project can be found in Appendix A.

5.2.6 Final Project Thoughts

Before the UHAT project, there was no product that could easily include multiple activities into a single device for people living with tetraplegia. This is an important development, as there are 250,000 Americans living with this devastating paralysis that stand to improve their quality of life from having a simple, multi-use tool to assist them

to independently resume some pre-injury activities. This work will be published in an open-access forum, where any occupational therapist, or any interested party, will be able to download the necessary CAD files and bill of materials, and easily assemble a UHAT for a person who would stand to benefit. Furthermore, the UHAT is very cheap to build, especially compared to some of the other single use tools available on the market. This is very important for people that are difficult to employ, and have very little means to purchase expensive adaptive devices. These benefits for mobility impaired individuals are central to what makes the UHAT a beneficial contribution to society.

Chapter 6: Concluding Remarks

6.1 Summary of Design Project

In the Universal Hand Assist Tool project, a novel, assistive hand device for those with cervical spinal cord injury resulting in tetraplegia to use to aid in day to day activities was conceptualized, designed and fabricated successfully. During the preparation phase of this project, system requirements were distilled from advice from medical experts, occupational therapists, and a collaborator with high level tetraplegia. Once the system requirements were identified, a set of specifications were generated to guide the design process, and validate the resulting prototype. Lean development principles were used to quickly reach a viable prototype through repeated consultation and testing with the tetraplegic collaborator. The resulting hand tool is a robust platform, with all custom components 3D printed from ABS. The UHAT was tested for robustness through successful drop testing, reliability was verified through hours of SU testing, and, at a unit price of less than $21 dollars to self-print and build the UHAT, it is very inexpensive. Five activities can be performed, including using a capacitive touchscreen device, using any silverware, using quarter inch hex bit tools, using a keyboard or other focused force activity, and writing. These activities and the specifications of the main unit all met the specifications outlined in the system requirements specifications. Documentation was generated to accompany the Universal Hand Assist Tool, including a bill of materials, directions for use, and assembly instructions. In addition, a clinical study research protocol to further validate user-needs of the Universal Hand Assist Tool

was developed and submitted to the John's Hopkins Institutional Review Board, as the Kennedy Krieger Institute that I am collaborating with is a part of John's Hopkins.

6.2 **Challenges**

One of the challenges in this project was learning to optimize 3D printers to print a strong, lightweight UHAT. In the effort of trying to produce the UHAT as inexpensively as possible, the UHAT was mostly printed using a very basic 3D printer [29]. This allowed for an easily printable design to be generated on any 3D printer. The unit cost in parts for a self-printed UHAT was only $21, without labor to assemble. This means, if a family member or friend has access to a 3D printer, a tetraplegic individual can have a comprehensive assistive device for very low cost. Optimized 3D printer settings for PLA filament can be found in Appendix D.

6.2.1 Limitations

Some limitations with the UHAT include, first, while within specifications for the main body by itself, it becomes heavier than 4 ounces when adding implements to the UHAT. Further weight reduction is possible; however, it was found to be acceptable through SU testing as designed. This could be accomplished with new, stronger and lighter 3D printed materials, as the hardware components are very light already. Second, while the hand is sufficiently secured in place with a thumb hook and flap, it would immensely benefit the design to improve the way that the hand is secured to the device. Third, the silverware attachment as designed works very well with slow, deliberate movements.

It is still possible for the insert to come loose, and the silverware to come out of the UHAT, leaving room for further improvement.

6.3 **Recommendations for Future Work**

6.3.1 Conduct Clinical Study

With the research protocol submitted, it is recommended that a clinical study be carried out to further validate the UHAT for broad usability. The research protocol submitted to the John's Hopkins IRB can be found in Appendix A. At the time of this writing, it was submitted and is awaiting final review and approval. This study is designed to continue to validate features of the UHAT design. On a more human note, this clinical study will lead to more individuals living with tetraplegia to have a robust means to achieve better independence through a device that is cheap and fits virtually any hand.

6.3.2 Open Source Publication

With the free availability of the CAD files and supplemental documentation (assembly, directions for use, etc.) on an open-source platform, essentially anyone is able to download and modify the UHAT implements to further fit the needs of particular end users. By publishing the UHAT design files on GitHub [30], or a similar open source platform with version control, any user can modify the CAD files, improve the design, and upload their results while the original version remains freely available. This will

ensure that the UHAT will reach the maximum number of users, as it will be Google searchable via its title once published.

Appendices

Appendix A: Clinical Trial Protocol

The following is the clinical study protocol that was submitted to the John's Hopkins IRB to conduct a UHAT prototype feature validation and revision process.

1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Currently, it is expensive for patients with tetraplegia to purchase effective tools to aid them in daily tasks. The tools that are currently available are generally made to perform a single task, and are designed to be one-size-fits-all, which ends up not fitting anyone well. The high cost excludes many from acquiring the tool in the first place, and since they are designed to perform one task, multiple tools will need to be purchased. The concept of the Hand Assist Tool (HAT) project is to develop a hand tool platform that is scalable to fit the hand of the patient, and is universal in nature. This means that the user will be able to swap in different attachments to perform different activities, all with the same base hand tool. For the HAT to be cost effective, any fabricated parts will be designed to be produced in a 3D printer, and any other required hardware will be readily available from major vendors. The printing files, assembly documentation, and hardware list will be open source, and freely available to produce and distribute. This free availability means that any

occupational therapist with access to a 3D printer will be able to produce a hand tool for very low cost to the patient.

2. Objectives (include all primary and secondary objectives)

The purpose of this study is to design a hand tool to aid patients with cervical spine injury (c-SCI) resulting in tetraplegia with some upper extremity movement to become more independent. The tool will be universal in nature, allowing different attachments for the end user to enjoy different activities. To address this purpose, two primary objectives have been identified.

1) Ensure the HAT will *fit* the largest number of potential users.
2) Ensure the HAT will be *useful* to the largest number of potential users.

These objectives need to be addressed through an iterative design process, where potential users with c-SCI participate in prototyping design cycles. During each design cycle, participant feedback will be evaluated using a questionnaire [1] where each participant will be asked to rank each feature of the prototype on a 1-5 Likert scale. The participants will also be asked to provide free-form feedback. The evaluation will be taken into consideration to design a new prototype, which will be redistributed to the participants for evaluation. This design cycle will allow any improvements of the HAT design to be quantified, and help realize each of the primary objectives of the study.

It was determined that it would be best to perform this study at KKI at JHU due to the number of patients with c-SCI who already frequent the Occupational Therapy (OT)

clinic, with the assistance of Dr. Cristina Sadowsky, who is the clinical director of the International Center for Spinal Cord Injury at KKI.

3. **Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Currently available tools are either prohibitively expensive, as they are not typically covered by insurance, only address a single task, and are typically a "one size fits all" design, which, by design, fits no one well. The Hand Assist Tool is being developed to address these ergonomic and economic concerns of patients with c-SCI.

Based on previous focus group feedback, the most popular attachments for the HAT will include five functions with a guide to be able to design more in the future. The five functions are as follows: (1) Stylus for a capacitive touch Tablet/Smartphone screen, (2) adapter for using various eating utensils, (3) three different sized rubber coated styli for general focused force application (piano keys, computer keyboard, flipping book pages, etc.), (4) ¼" hex adapter for tools (Philips/flat head screwdriver, sockets, etc.), and (5) a writing pen/pencil adapter.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (Distinguish research procedures from those that are part of routine care).

Participants will be recruited from the International Center for Spinal Cord Injury at Kennedy Krieger Institute when individuals are seen for routine medical or rehabilitative care. Participants will be ask to evaluate the HAT for up to but no more than 2 hours. The prototype evaluation protocol will include a total of five development cycles over a period of nine weeks. The evaluation form itself consists of a series of questions evaluated on a Likert scale to measure if prototype changes are improving, as well as a free-form feedback section [1]. This evaluation will be administered by a KKI research assistant after the participant is finished evaluating the prototype.

Development Cycle 1:

Week 1: Participants will schedule a time to evaluate the hand tool prototype. Participants will spend up to 2 hours with a KKI research assistant, who will guide them through the consent process and evaluating the first prototype.

Week 2: The prototype will be updated with revisions from the results of Week 1 evaluations. A new prototype will be prepared for Week 3 evaluations.

Development Cycle 2:

Week 3: Participants will schedule time to evaluate the updated prototype with a KKI research assistant.

Week 4: The prototype will be updated with revisions from the results of Week 3 evaluations. A new prototype will be prepared for Week 5 evaluations.

Development Cycle 3:

Week 5: Participants will schedule time to evaluate the updated prototype with a KKI research assistant.

Week 6: The prototype will be updated with revisions from the results of Week 5 evaluations. A new prototype will be prepared for Week 8 evaluations.

Development Cycle 4:

Week 7: Participants will schedule time to evaluate the updated prototype with a KKI research assistant.

Week 8: The prototype will be updated with revisions from the results of Week 7 evaluations. A final prototype will be prepared for Week 9 evaluations.

Development Cycle 5:

Week 9: Participants will schedule time to evaluate the final updated prototype with a KKI research assistant.

b. Study duration and number of study visits required of research participants.

The study will be conducted over nine consecutive weeks, requiring no more than five study visits from the research participants. The visits will occur once every two weeks for no more than two hours.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

Blinding will not be implemented in this study.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

Participants will not be required to cease or alter any routine care or current therapy.

e. Justification for inclusion of a placebo or non-treatment group.

A placebo or non-treatment group is not applicable in this study.

f. Definition of treatment failure or participant removal criteria.

This study does not involve any type of treatment, so there will be no failure criteria. Participants will be free to discontinue the study at any time.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

There will be no change to a participant's therapy during this study; therefore terminating participation will not affect the participant's therapy in any way.

5. Inclusion/Exclusion Criteria

Inclusion:

- Adults, age 18 to 80
- Cervical SCI (C5-C7), complete and incomplete, with reduced function of arms, hands, and digits

- Condition must be chronic, static SCI related paralysis, with no neurologic changes in at least 12 months prior to enrollment in the study
- Must be able to lift 200 grams, grasped or in an open hand
- Must be able to maintain about 90 degrees of flexion in the elbow

Exclusion:

- Participants not proficient in spoken English
- Open skin ulcers, fresh non-healed upper limb fractures, and joint and soft tissue contractures preventing upper limb mobility

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.

According to the FDA guidelines, a "medical device" is "any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical laser, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy" [2]. The Universal Hand Assist Tool is not a "health care product," but an ergonomic tool that assists patients with c-SCI to more easily perform tasks that are otherwise difficult or impossible due to the nature of their injury. The tool is non-invasive in

nature, as it is grasped by the patient's hand and held in place with a hand strap or clip. As such, the Hand Assist Tool should not be regarded as a "medical device." Therefore, there is no drug or device employed in this study.

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.

Not applicable for this study.

c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

Not applicable for this study.

7. Study Statistics

a. Primary outcome variable.

The primary outcome variable of this study is to increase the participant satisfaction percentage *as much as possible* over 5 prototyping cycles.

b. Secondary outcome variables.

Not applicable for this study.

c. *Statistical plan including sample size justification and interim data analysis.*

The enrollment target is 10 participants. There is no statistical significance to this number of participants, as there are no statistical analyses necessary for this study. This is an arbitrary number of participants to account for attrition during the study to ensure that at least five full prototyping cycles can be finished.

d. *Early stopping rules.*

The study will not be stopped early, however participants are free to discontinue their involvement at any time. Five prototype cycles will be followed, regardless of participant attendance or satisfaction with the prototype.

8. Risks

a. *Medical risks, listing all procedures, their major and minor risks and expected frequency.*

There is a minimal risk of abrasion, pinching, or discomfort from evaluating the prototypes during the evaluation sessions.

b. *Steps taken to minimize the risks.*

A KKI research assistant will be present during all prototype evaluation sessions to facilitate safe and appropriate use of the HAT.

c. Plan for reporting unanticipated problems or study deviations.

In the unlikely event that a participant experiences discomfort or injury during evaluation, that participant's use of the tool will be discontinued, and an adverse event will be reported. Any unanticipated problems or study deviations will be reported in writing by the Principal Investigator to the JHM-IRB and KKI Office of Research Compliance.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There are minimal legal risks associated with breach of confidentiality for this study. To minimize the risk of breach of confidentiality, access to participant/study data will be limited to study team members only. All study data will be stored in a departmental locked cabinet and secure database program where no patient identifiers will be used (e.g. name, full date of birth, actual date of injury, etc.).

e. Financial risks to the participants.

There are no financial risk to the participants and their insurances will not be billed for any time and services related to this study. However, if a study related injury were to occur, the participant's insurance will be billed. If the participant has health insurance, the costs for any treatment or hospital care received as the result of a study related injury will be billed to their health insurer. Any costs that are not paid for by the health insurer will be billed to the patient. If the study participant does not have

health insurance, he or she will be billed for the costs of any treatment or hospital care received as the result of a study related injury. The participants will be responsible for the cost of travel to and from the Institute, as well as any food/meals purchased throughout the day while engaged in study procedures. Valet parking is available at no cost.

9. Benefits

a. *Description of the probable benefits for the participant and for society.*

Participants will be provided a final prototype model of the Hand Assist Tool at no charge, whether they finish the study early or not. Society will benefit from this study by having access to a single Hand Assist Tool that will allow patients with c-SCI greater independence in numerous daily activities.

10. Payment and Remuneration

a. *Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.*

There will be no monetary compensation for participants in this study. There will be no penalty for failure to complete the study.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There is no cost associated with participating in this study.

Appendix B: Assembly Instructions

Main Body Assembly

The following section will detail how to assemble the main body of the UHAT. An exploded diagram and picture of the main body assembly can be seen in Figure 25 and Figure 28, respectively.

Required Components and Fasteners:

- 3D Printed Main Body, Flap, Thumb Side Offset Panel, and desired Grip Size Offset Panel (0.25”, 0.5”, 0.75”, or 1”)
- Bob Smith Industries Cyanoacrylate (CA glue) with Accelerant [31]
- 6 - 0.375” OD by 0.125” ID Neodymium Magnets [32]
- Left and Right side 90° Steel Torsion Springs (McMaster Carr PN: 9271K34 and 9271K35) [33], [34]
- 6 - #6-32 ½ inch machine screws [35]
- 1 - #6-32 2 inch machine screw [36]
- 1 - #6-32 coarse threaded cap nut [37]
- 2 – 7/32” diameter 1 ½” length compression springs [38]

Required Tools:

- Flat head screwdriver – small head (to remove 3D printed scaffolding)
- Phillips head screwdriver (cordless drill preferred)
- Wire cutter – Knipex mini bolt-cutters

Assembly Instructions:

1) Glue 6 magnets into the activity insert receptacles in the main body using CA glue. Two magnets are to be placed in each receptacle. Be sure that the magnets are *in opposition to each other*. Be consistent in magnet pole placement. This is the most tedious part of the assembly process. I recommend to test each magnet (as the poles are unmarked), and mark the side that is being glued to the main body. I placed a 0.25” circle CA glue in each magnet recess, then used a small flat-head screwdriver to hold each magnet in place before spraying the accelerant. Wait 1 minute for curing, then slowly slide the screwdriver out.

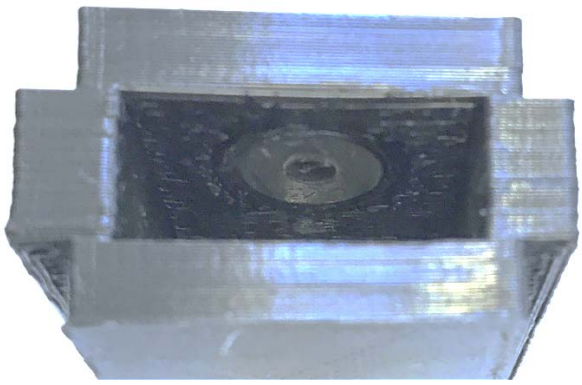

Figure 48: Activity insert receptacle with magnet glued in place.

2) Drop compression springs into the activity insert receptacles in the ends of the UHAT.

Figure 49: Compression spring placement.

3) Adjust springs to be at the top of the countersunk holes in the bottom of the activity insert receptacles. Screw in the two #6-32 ½" machine screws to hold springs in place.

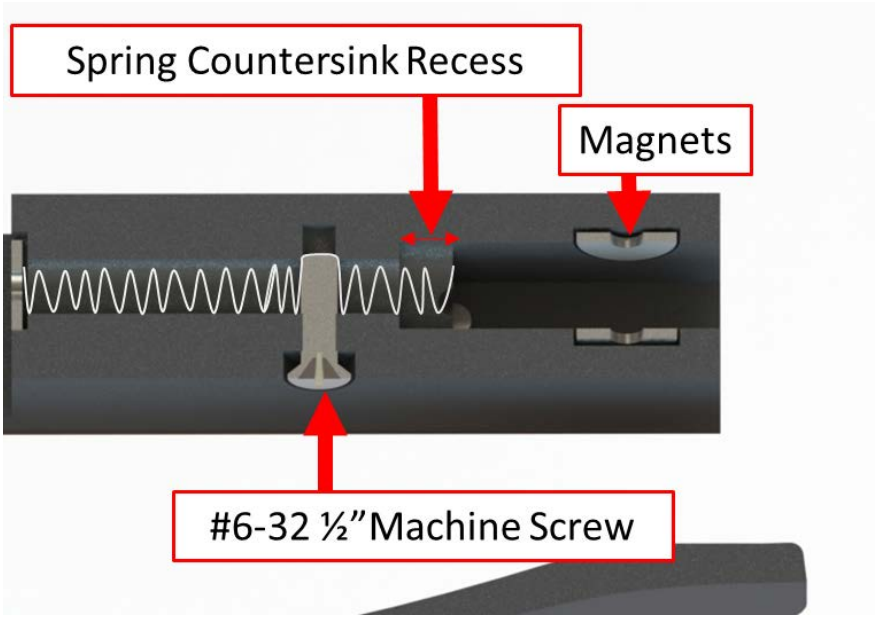

Figure 50: Spring, magnet, and machine screw placement in UHAT main body activity insert receptacles.

4) Trim down torsion springs and place into the UHAT flap.

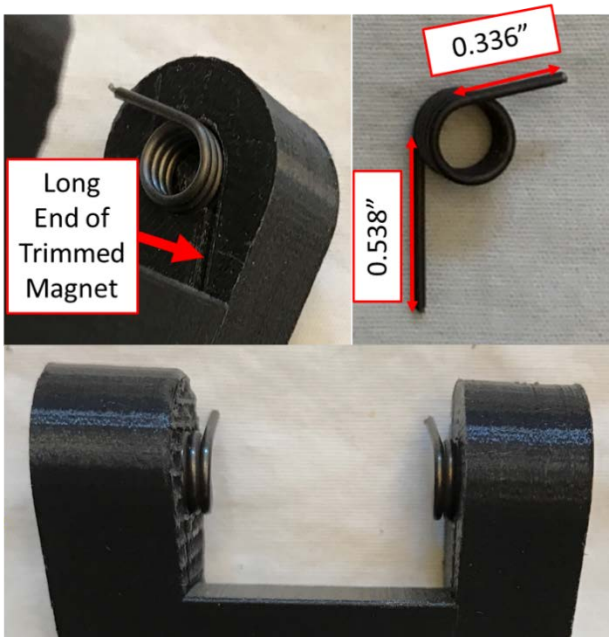

Figure 51: Spring trim and placement guide.

5) Mate flap to main body using #6-32 2” machine screw, and #6-32 coarse thread cap nut.

Figure 52: Mate flap to UHAT main body.

6) Select offsets and use #6-32 ½” machine screws to attach.

Touchscreen Activity Insert Assembly:

Required Components and Fasteners:

- 3D Printed Touchscreen activity insert
- Touchscreen Replacement Mesh Tip [39]
- 3” of 22-24 AWG solid strand copper wire (stripped wire from CAT5 cable works perfect.)
- 2 - 0.375” OD by 0.125” ID Neodymium Magnets [32]
- 1 - #10-32 1” Hex cap screw [40]
- Bob Smith Industries Cyanoacrylate with Accelerator [31]

Required Tools:

- Pliers
- Flat head screwdriver
- Digital Multimeter
- 5/32” hex key
- Cloth

Assembly Instructions:

See the diagram in Figure 41 for a rendered cutaway of the touchscreen activity assembly.

1) Glue in magnets so that the polarity mates with the magnets in the main body.

2) Run 3” wire through from top to bottom.

3) Screw in the touchscreen mesh tip using a pair of pliers. Wrap the tip in cloth to not mar the finish.

4) Screw in the #10-32 1” hex cap screw using the 5/32” hex key.

Figure 53: Components and assembled touchscreen activity insert.

5) Place the assembled touchscreen insert into each receptacle of the UHAT, then use the digital multimeter to test for continuity between the mesh tip and hand-contact screw.

Figure 54: Testing the continuity to ensure proper touchscreen insert operation.

Quarter Inch Hex Tool Adapter Activity Insert Assembly

Required Components and Fasteners:

- 3D printed quarter inch hex tool adapter activity insert
- 5/32”-32 hex set screw [40]
- ¼” hex adapter [41]
- 2 - 0.375” OD by 0.125” ID Neodymium Magnets [32]
- Bob Smith Industries Cyanoacrylate with Accelerator [31]

Required Tools:

- 5/64” hex key

Assembly Instructions:

1) Glue in magnets, as with touchscreen activity insert.
2) Place hex adapter in activity insert.
3) Screw in 5/32”-32 set screw into the indentation in the side of the hex adapter.

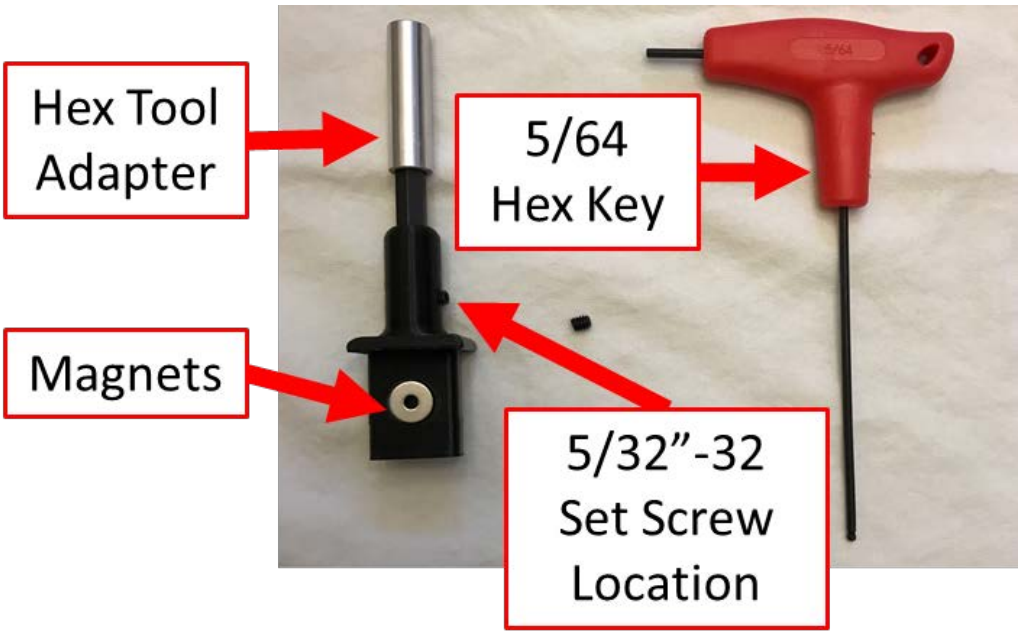

Figure 55: Parts and assembled quarter inch hex tool adapter activity insert.

Writing Activity Insert Assembly

Required Components and Fasteners:

- 3D printed writing activity insert
- #6-32 1/2” machine screw [35]
- #6-32 hex nut [35]
- Writing pen
- 2 - 0.375” OD by 0.125” ID Neodymium Magnets [32]
- Bob Smith Industries Cyanoacrylate with Accelerator [31]

Required Tools:

- Straight pick tool
- Phillips head screwdriver

Assembly Instructions:

1) Use the straight pick to completely clean left over scaffolding plastic out the nut recess.
2) Place pen through pen hole as shown, place nut into the nut recess, and screw in the #6-32 ½” machine screw to finish.

Figure 56: Writing activity insert components and assembled part.

Focused Force Stylus and Silverware Insert Assemblies

For these, the only assembly required is to 3D print the respective components, and glue in 2 magnets into each, as with the other activity inserts. No other assembly is required.

Appendix C: Directions for Use

Refer to the Mission Scenario Diagram in Figure 11 for high-level directions for use. This section will outline specific instructions for each activity insert. Depending on each individual's mobility, the UHAT may be placed on the hand using different methods. As discussed previously, the SU would place the UHAT *hinge side down*, then chop her hand into the opposite end until the little finger was touching the hinge itself. This can vary between users, and experimentation is encouraged to find the best method for each user.

Touchscreen Activity Insert:

- Can be used in any activity insert receptacle.
- Simply insert into the desired receptacle, and firmly place it on the touchscreen to use.

Quarter Inch Hex Tool Adapter Activity Insert:

- Can be used in any activity insert receptacle.
- Simply insert into the desired receptacle, and insert the desired hex tool to use.

Writing Activity Insert:

- Can be used in either of the end insert receptacle, not in the middle receptacle.
- Simply insert into the desired receptacle, and begin writing to use.

Focused Force Stylus Activity Insert:

- Can be used in any activity insert receptacle.
- Simply insert into the desired receptacle to use.

Silverware Activity Insert:

- Can only be used in the hinge side activity insert receptacle, next to the silverware pass-through.
- Place hand in UHAT.
- Place silverware into pass-through.
- Place silverware activity insert into receptacle to lock the silverware in place.
- Using firm and deliberate movements as possible, use the silverware to eat.

Appendix D: 3D Printing Considerations

This section contains settings used to 3D print the UHAT in PLA for testing purposes. This may be useful to those interested in 3D printing the UHAT themselves, as many days and weeks of printing was involved with optimizing these settings. All printing was performed using Simplify3D [www.simplify3D.com] slicer software, mostly on a Monoprice Maker Select 3D printer with Hatchbox black PLA filament.

Again, *it is recommended to print the UHAT with ABS*, however, for testing purposes only, PLA has desirable qualities. Over long term use, ABS will be much stronger and slow to break down.

Print Bed Layout:

This is the most important consideration to achieve a successful print of the UHAT. By placing each of the components on the print bed as shown in Figure 57, the parts will print with strong layering with respect to how the UHAT will be used. If the orientation is changed, parts may split along layers during use or assembly. All prints were made using a brim, however it is up to the user whether or not to use a raft. A raft was found to be helpful to prevent the bottom layers from warping. This especially helps the activity inserts prints.

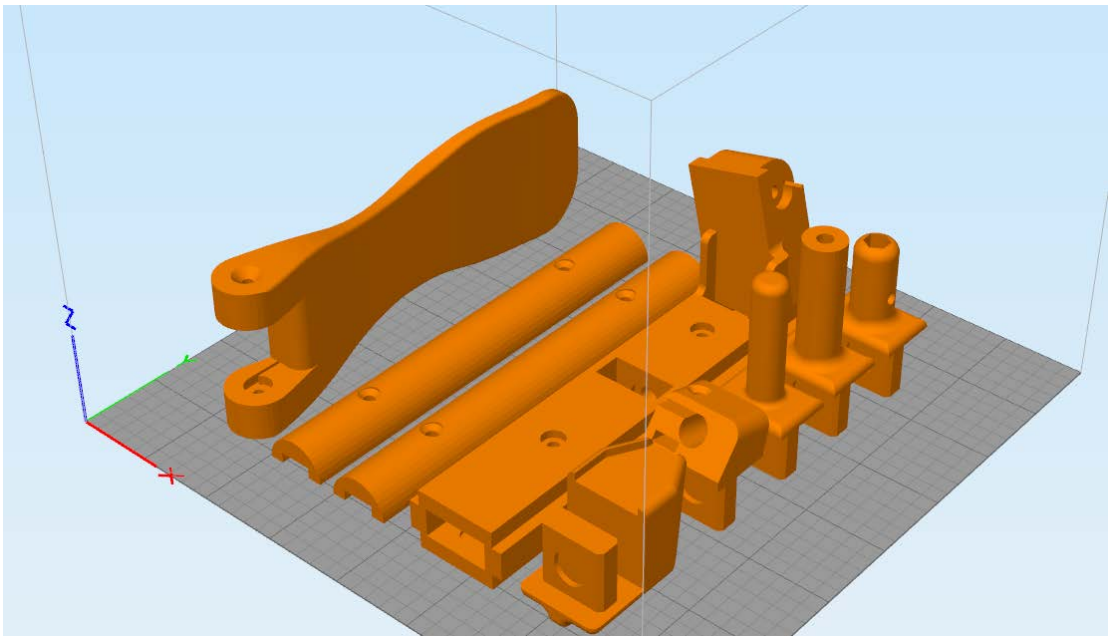

Figure 57: Print bed layout. An entire UHAT can be printed on a 7 inch square print bed.

Simplify 3D Settings:

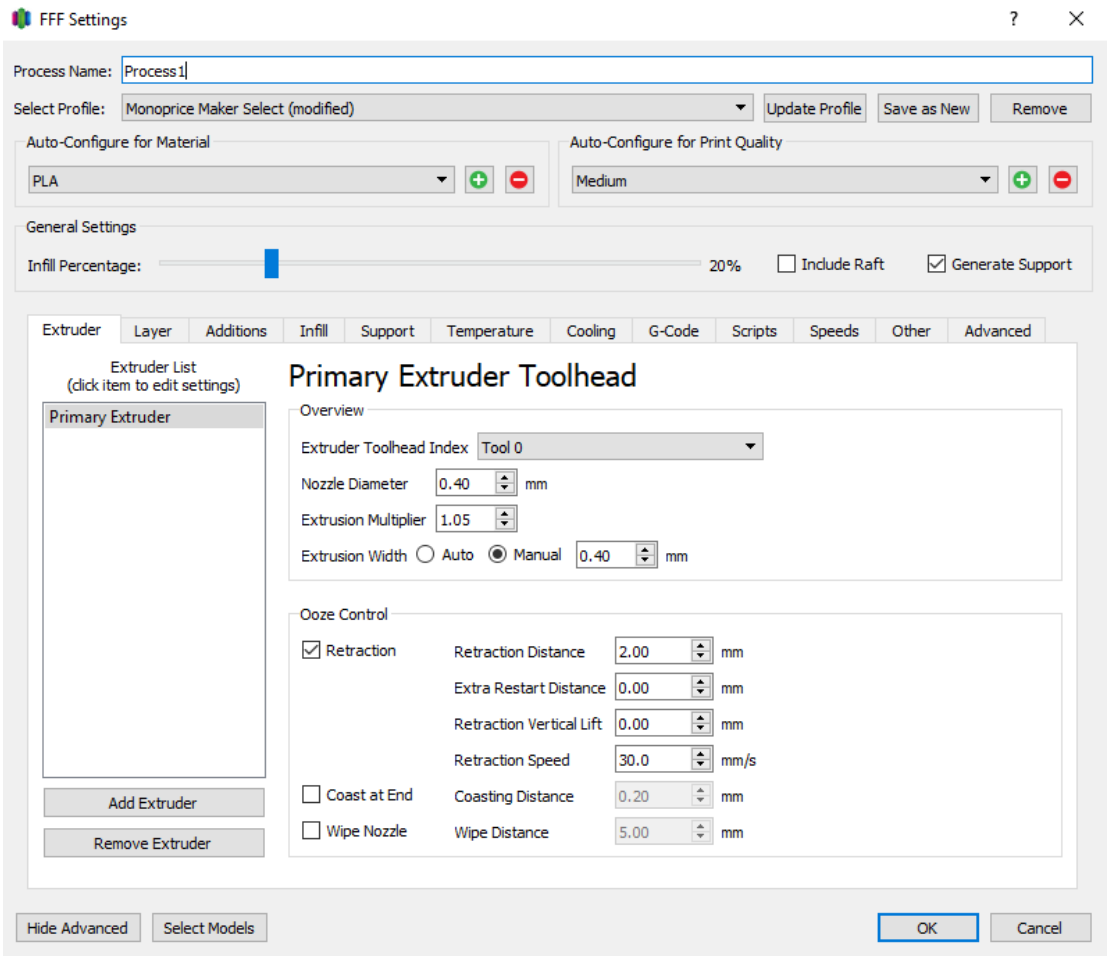

Figure 58: Retraction settings, nozzle diameter and extrusion multiplier.

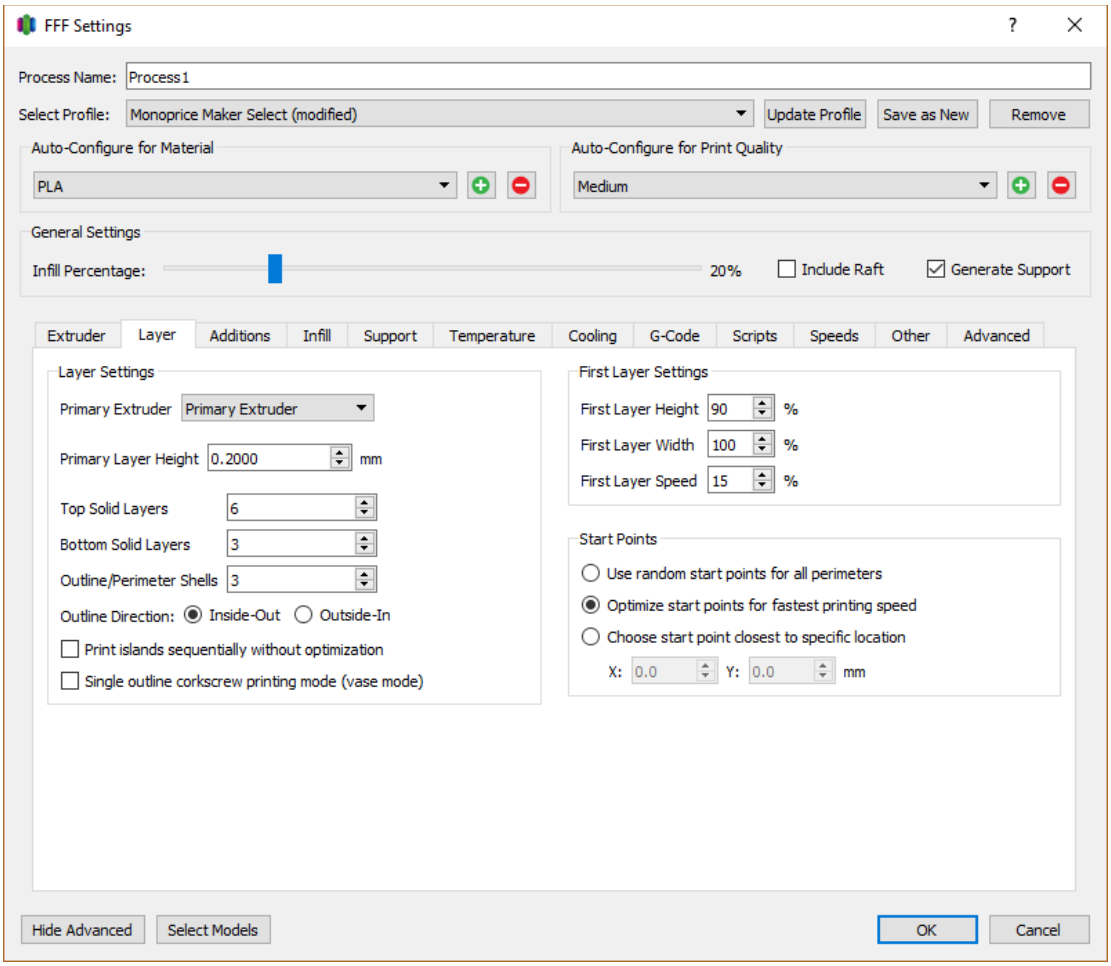

Figure 59: Layer height, top, bottom and perimeter shell layers.

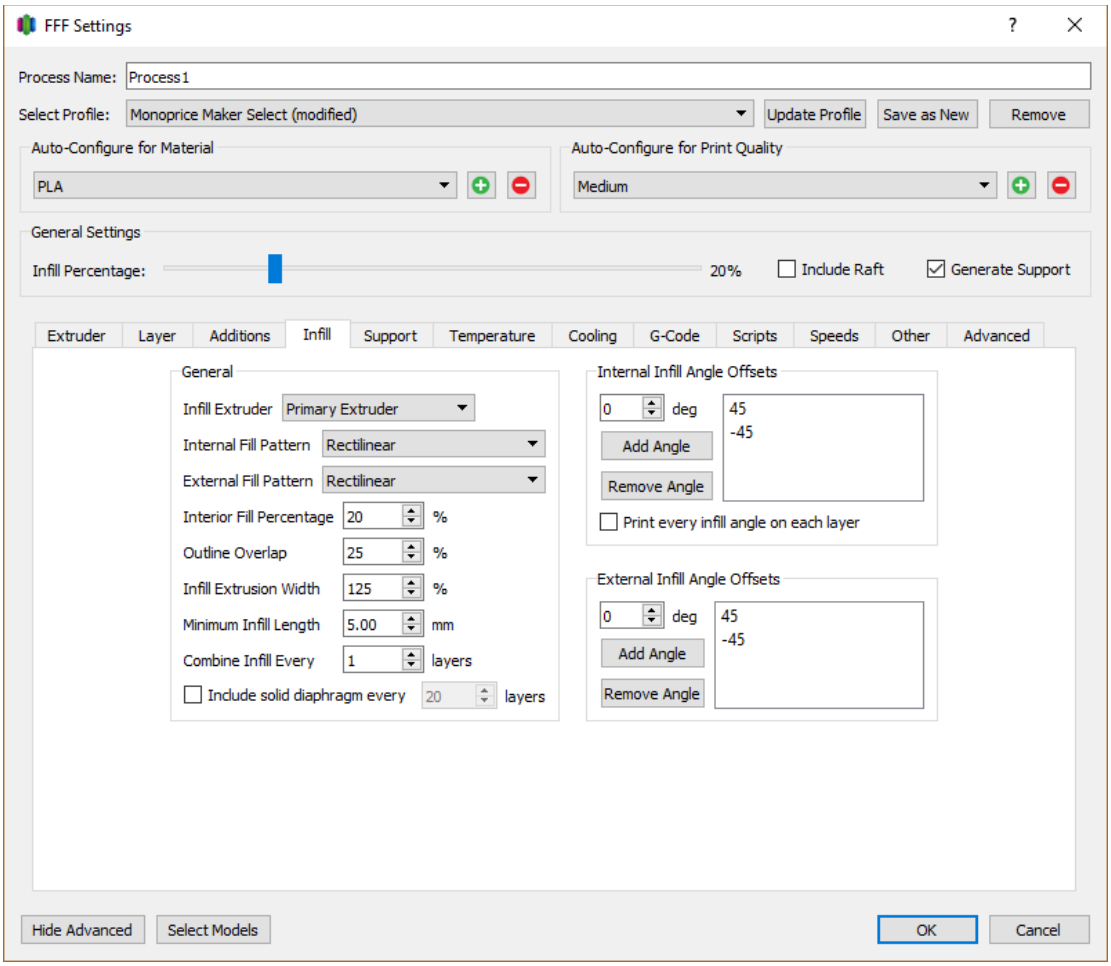

Figure 60: Note that the main body and grip size offset panels of the UHAT were printed at 10% infill, while the flap and inserts were printed with 20% infill.

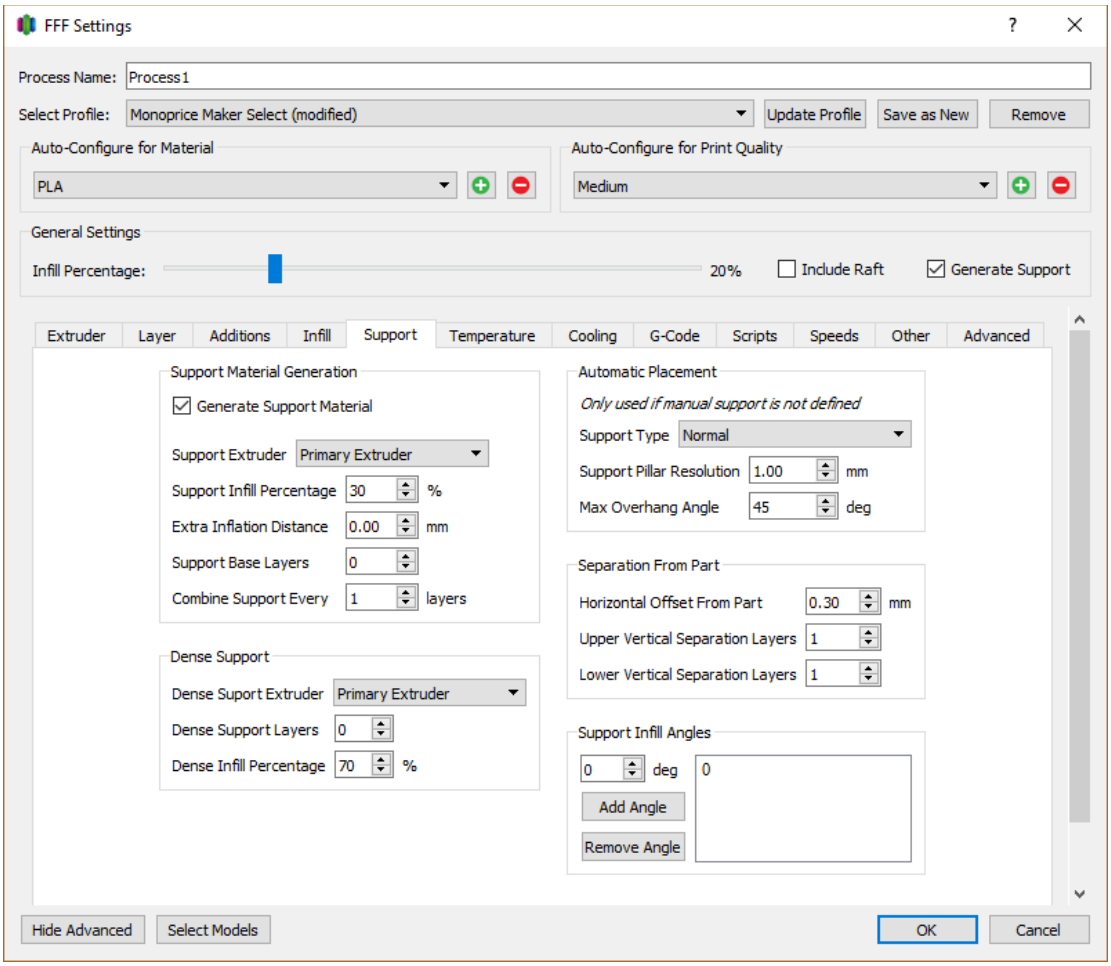

Figure 61: Scaffolding support is necessary for this print bed. The supports do not need to be dense, but they do need to touch the model as well as the print bed.

Appendix E: Clinical Study Evaluation Form

The following is the clinical study evaluation form submitted to IRB to obtain feedback from the study participants, and will be used to inform further development and refinement of the UHAT.

Universal Hand Assist Tool Design Trial Evaluation Form IRB00138874						
Date:	Participant ID Number:					Evaluator:
On a 1-5 scale, rate the current hand tool prototype…	**1**	**2**	**3**	**4**	**5**	
is not comfortable at all	☐	☐	☐	☐	☐	is very comfortable
is not useful at all	☐	☐	☐	☐	☐	is very useful
does not fit my hand at all	☐	☐	☐	☐	☐	fits my hand very well
is very difficult to replace implements	☐	☐	☐	☐	☐	is very easy to replace implements
is not helpful for eating at all	☐	☐	☐	☐	☐	is very helpful for eating
is not helpful for writing at all	☐	☐	☐	☐	☐	is very helpful for writing
is not helpful for using a touchscreen at all	☐	☐	☐	☐	☐	is very helpful for using a touchscreen
does not hold my hand in place at all	☐	☐	☐	☐	☐	holds my hand in place perfectly
makes activities it was designed for more difficult	☐	☐	☐	☐	☐	makes activities it was designed for easier
it is not easy to replace eating utensils at all	☐	☐	☐	☐	☐	it is very easy to replace eating utensils
gets very heavy after 30 minutes of use	☐	☐	☐	☐	☐	is not heavy at all after 30 minutes of use

The current hand tool prototype…	**Yes**	**No**	Notes
is too short	☐	☐	
is too long	☐	☐	
is too wide	☐	☐	
is not wide enough	☐	☐	
is too heavy	☐	☐	
grip surface too slippery	☐	☐	
grip surface has sharp edges	☐	☐	
main body broke during implement use	☐	☐	
main body broke as a result of dropping	☐	☐	
implement broke	☐	☐	

Figure 62: Clinical study evaluation form used to inform the prototype revision process.

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