PROSTHETIC ADAPTER FOR AGRICULTURAL MACHINERY

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Technical Design Report

Prosthetic Adapter for Agricultural Machinery

Final Report

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Abstract

The goal of this project was to create a robust, task-specific prosthetic limb for agricultural workers to operate the primary controls in the cockpit of agricultural machinery. General use prosthetics are often insufficiently functional and durable for amputees who perform manual labor. Advanced bionics are expensive, delicate, and heavy. This project aimed to design a solution that enabled an agricultural worker to complete a specific task while increasing worker safety and extending device lifetime over commercially available prosthetics. While the concept was applicable to controls for any heavy machinery, this specific design was intended for agricultural applications. The Capstone Design scope focused narrowly on enabling a right-side unilateral, transradial amputee to operate a tractor.

Assisted tractor control was accomplished with a terminal device attached to the user's prosthetic socket and a set of adapters installed on the most frequently used controls. The terminal device and adapters consisted of non-locking mating surfaces that enabled an amputee user to independently and reversibly engage each control. This design eliminated the need for a grasping mechanism and minimized device complexity. The terminal device was universal for users, and the adapters were custom-installed for specific machine controls. The solution was designed for safety, ergonomics, manufacturability, functionality in harsh environments, and long term wear resistance. Field tests and a design validation test were performed. The project is currently at the design for manufacturability phase. Plans for commercialization will be executed in the coming months.

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2 Copyright

3 Introduction

Over 1.8 million amputees currently live in the United States, and thousands of amputations occur each year.[1] Farming and agriculture have the highest prevalence of limb loss over any other industry in the US. Despite the high rate of amputation, prosthetics used in such occupations often fall short of the patients' demands of utility and durability. Farmers often resort to modifying their procedures and/or equipment rather than relying on available prosthetic limbs to complete occupational activities.[2] This report begins by outlining the extensive background research into the demographics and epidemiology of amputations as well as the unique needs of different amputee populations. It then proceeds to summarize the project definition and design progress to date.

3.1 Problem Statement

The goal of this project is to design a device that enables operation of heavy machinery by an agricultural worker whose upper extremity is missing or functionally compromised.

3.2 Project Inspiration

The team aligned on a desire to develop a prosthetic, orthotic, or assistive device that significantly improves the lives of a limb deficient population. Developments in the field of prosthetics over the past few decades have transformed from simple walking prosthetics into enabling technologies that allow amputees to regain control of their lives. The products available on the market today vary from shock absorbent, sports-specific, high-energy return prosthetics to myoelectric devices that actuate powered limbs. New research and development has responded to the hundreds of American troops that have come home with amputations due to improvised explosive devices (IEDs) over the past ten years in the Iraq and Afghanistan war.[3] Despite the impressive technological advances in the field of prosthetics, there is still space for innovation to improve the lives of amputees worldwide. The prosthesis user community has identified many areas for improvement in available solutions. The firsthand stories of amputee communities provide inspiration to deliver a product with the power to improve lives.

3.3 Team Goals

The prosthetics design team proposed the project with a very broad scope. Extensive research was required upon approval. The team aligned on common values and goals for the Capstone Design project. The first desired outcome for this project was to leave a lasting impact on a community of amputees by restoring a work related functional capacity. The second goal driving the project definition process was the potential for the group to deliver a complete solution within the given scope of the Capstone Design course and team member's individual skills and expertise. The team defined a complete solution as having a prototype that could be tested, evaluated, and demonstrated by an amputee by the final Capstone presentation. The team strives to identify a need, and then deliver a solution that is successful in the eyes of advisors, faculty, and peers.

4 Background

This project requires extensive background research into the different aspects of amputees. This section aims to completely yet concisely cover the main areas of research: medical background of prosthetics, amputee populations, and existing prosthetics.

4.1 Medical

4.1.1 Types of Amputation

Different mechanisms of amputation result in several classifications of amputations. A need for amputation arises from poor vascular condition, trauma, tumor removal, congenital disorder, or infection. Vascular related amputations occur primarily in diabetics, who constitute up to 90% of the amputee population in the United States. The second greatest cause for amputations is trauma such as high velocity crashes, burns, frostbite and injury by labor-related machinery.[4]

Healthcare professionals (HCPs) classify amputations as either a lower limb amputation (LLA) or upper extremity amputation (UEA). Disarticulation amputations occur at a joint, whereas other amputations occur across the bone of the limb. As depicted in Figure 1, LLAs range from a partial foot amputation such as the loss of a toe to a hemipelvectomy, which removes all of the leg and part of the pelvis. Other LLAs include hip disarticulation (removing the entirety of the limb including the femur), transfemoral (TF) amputation (leaving a residual member above the knee), knee disarticulation, transtibial (TT) (below the knee), and ankle disarticulation (removing foot at the ankle). Comparatively, UEAs demonstrate an analogous range of classifications from finger loss to removal of the entirety of the arm through part of the shoulder. Specific amputations, also shown in Figure 1 below, include metacarpal amputation, disarticulation of the elbow, wrist, and shoulder, transradial (TR) amputation (below elbow), and transhumeral (TH) amputation (leaving a residual limb above the elbow).[4]

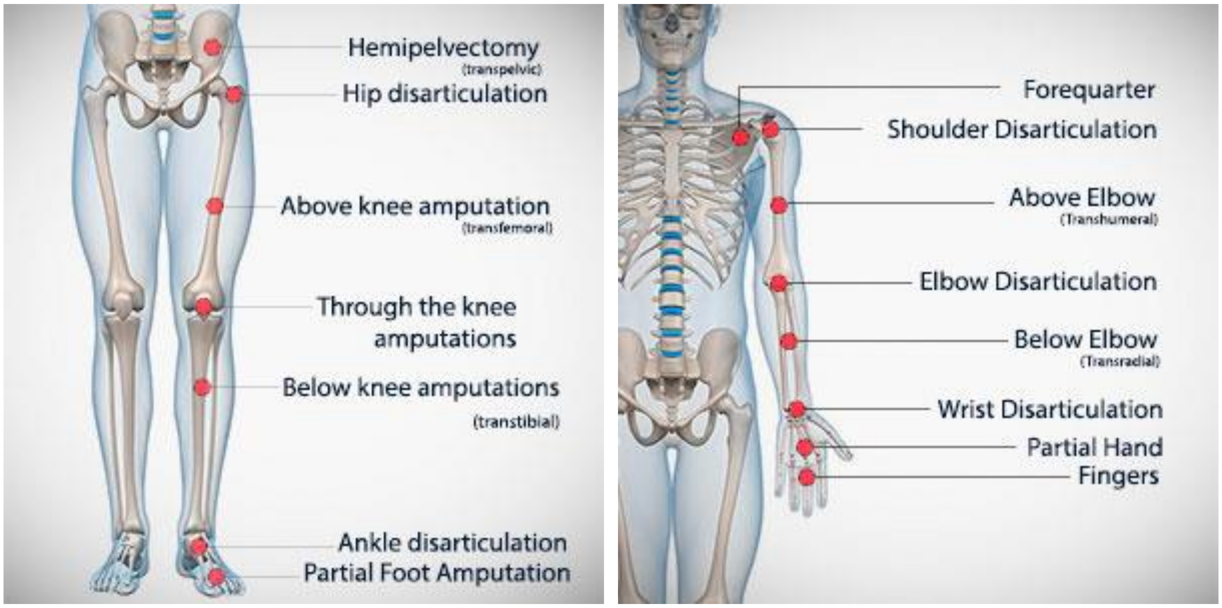

Figure 1: Diagram of lower limb amputations and upper extremity amputations[5]

4.1.2 Rehabilitation

After diagnosis of the amputation, proper rehabilitation is vital to recovery. This process includes post-amputation medical care, prosthesis fitting, physical therapy, and re-integration into daily life. The rehabilitation phase restores functional independence and prevents post-amputation complications. The first step entails wound care of the affected extremity. After the wound has sufficiently healed, a prosthetist provides support necessary to fit, fabricate, and train the amputee to use the prosthetic. The fitting process varies depending on availability and affordability of products and services. For example, a prosthetic limb might be designed with a universal or custom interface depending on the level of supportive technology available. While traditional practices entail casting a "check socket" mold out of plaster, more modern prosthetic approaches use three-dimensional body scanning and computer-aided design/computer-aided manufacturing (CAD/CAM) technology to improve the comfort and thus functionality of the patient's unique fit. Once a patient receives a prosthesis that fits their lifestyle and amputation, training with his or her prosthetic limb begins. In training, the patient practices using his or her prosthetic limb until they feel confident and comfortable in their ability to resume independent daily activities.[6-8]

Unfortunately, such rehabilitative resources as prosthetists and therapy are not prevalent in low-income countries (LICs). If an amputee living in an LIC is able to get a prosthesis, they are usually forced to learn how to use it unaided. This results in a higher rate of post-amputation complications and more difficulty living independently.[9, 10]

4.1.3 Post-Amputation Complications

Amputation surgery requires a long physical and psychological healing process. The length of the residual limb determines the resulting muscle mass, degree of balance, proprioception, and complexity of fitting a prosthesis. After surgery, soft or hard dressing is applied to the residual limb based on surgical technique and the patient's level of amputation. Dressing rigidity protects the residual limb. Ideally, an HCP fits an early state prosthetic to enable the patient to ambulate as soon after surgery as possible. HCPs classify prostheses on a scale of 1-4 based on level of ambulation capability.[4]

For LLAs in the western world, basic prosthetic components include a soft liner that interfaces with the residual limb, a rigid socket, and a rigid pylon. A gel or silicone liner interfaces for comfort between the limb and the socket. A quality design of the socket fit by a prosthetist is critical to alleviate pain and sores during healing and especially to optimize pressure distribution, stability, and motion control for weight bearing limbs. A modern suction sleeve uses "elevated vacuum technology" to prevent swelling in the healing limb by creating a constant internal pressure environment within the socket. The pylon typically contains torque absorbers to compensate for motion lost from lower limbs. Contemporary prosthetic limbs utilize microprocessors to control angles (e.g. Ottobock), hydraulics to alleviate impact (e.g. Ossur), and myoelectric sensors to optimize gait and reduce risk of post-amputation complications. However, higher complexity results in heavier and more expensive devices. Also, asymmetry of the resulting biomechanical motion between a natural and a prosthetic limb increases propensity for injury.[11]

4.1.4 Regulatory Compliance & Medical Coverage

4.1.4.1 Coverage & Reimbursement

Medicare Part B ensures patients are covered for hospital outpatient settings. The Center for Medicare and Medicaid Services (CMS) uses the Healthcare Common Procedure Coding System (HCPCS) to classify reimbursements for prosthetic components. Immediately after an amputation is a patient is given a diagnosis code (i.e. 886.1 in the case of a below-the-elbow amputation). Prosthetic components are billed through "L-codes" as a sum of fees called allowables.[12] For example, in the case of the "workers hook" (below-the-elbow with a molded exoskeleton, foam-lined socket, flex-hinge "economy-wrist", and tricep-pad collectively, have a prosthetic device base code of L6100. A heavy duty cable (L6660) with harness (L6675) secures the socket, and enables voluntary open of the terminal device hook (L6704 or L6706). The entire system amounts to no more than $3,000.00, with Medicare reimbursing 80% and the remaining 20% the patient is responsible for out of pocket unless a secondary insurance carrier is available to reimburse the remainder.[13] The workers hook allowable (L6706 or L7621) approximates $2000.00, which enables one to infer a similar amount for the prosthetic adapter, however, the product would have to go through Medicare approval (see Appendix C). The arm would be classified as durable medical equipment (DME) and reimbursement would occur with the remainder as a lump sum purchase, which was the case for the test subject in design validation visit.[14]

4.1.4.2 Coverage & Reimbursement

In the US, most prosthetic components, including upper extremity, are Class 1 (exempt) medical devices with minimal regulation. The requirements are the following: manufacture under a quality assurance program, be suitable for intended use, adequately packaged and properly labeled, and have established registration and device listing forms on file with FDA". Devices are exempt from premarket approval or 510(k) requirements as long as the device operates on the same fundamental scientific technology as existing products.

In the case of the prosthetic adapter, custom, investigational, or experimental devices have no regulations regarding custom parts made by prosthetic technicians or to customization of parts after distribution by a registered establishment (or mechanical engineers). The registration requirement for an establishment manufacturing prosthetics mandates nondisclosure of the registration code to avoid any suggestion that the FDA has approved of the establishment or device. Prosthetic service providers routinely customize, modify and fabricate items for prosthetic use, and we are unaware of any that are registered as manufacturing establishments.

Because we are dealing with a Class I (exempt) medical device that doesn't require a 510(k) submission, it could reasonably be argued that one need not do anything, The Investigational Device Exemptions (IDEs) require that an Institutional Review Board (IRB) approve a study, receive patient consent, properly label devices for investigational use, monitor the study, and require records and reports are maintained. If these steps are complied with, the manufacturer need not even be a registered manufacturer. It might reasonably be argued that for a device for which there are no requirements other than those outlined above, that a subset of these requirements might reasonably be complied with, e.g.: consent the patients, label the devices, and maintain records and reports on the use of the devices.[15]

4.2 Needs of Populations

4.2.1 Sport-Specific Prosthetics for Athletes

Amputee participation in sports increases annually. Thus, optimization of a sport-specific prosthesis offers a promising lead for markets in more developed countries. With the emergence of successful amputee athletes such as Olympian Oscar Pistorius (a.k.a. "The Blade Runner"), amputees are encouraged and inspired to realize their athletic potential. Patients who were active prior to amputation often seek prosthetic solutions that will return them to active living.[16] Amputees less active prior to amputation (such as those suffering from vascular diseases) often recognize the importance of exercise to combat their health conditions. Regardless of patient background, studies prove that sports are crucial to both psychological and physiological well-being.[17]

The pain that results on the socket interface limits amputees' participation in a variety of sports. Groomed skiing and road cycling are popular for their exchange of high-speed motion that minimizes physical impact. Swimming offers a promising option as a low-impact activity, though prostheses are forbidden for competitive water sports. For LLAs, especially below the knee, running remains a preferred athletic activity, and current prosthetic technology has advanced to a level of preserving the natural cadence of a runner.[17]

While some amputees avoid sports because of residual limb pain, one article reveals that exercise can reduce phantom pain from nerve endings in the residual limb for Paralympic athletes.[18] Inadequate athletic equipment in recreational facilities is another obstacle to sport participation. Affordability of sports prosthetics often presents an economic obstacle for amputee athletes, as Medicare limits the reimbursement on prostheses based on the relevant functionality for basic daily activities. A sport-specific prosthesis can price up to $10,000, which for some patients is affordable only by donation from foundations (such as the Wounded Warrior Project for soldiers) or fundraising. But self-consciousness and social anxiety remain by far the most threatening barrier to participation in sports by amputees.

A phone conversation occurred between a team member and Rob Hickey, a Sales Consultant at Ossur America, an industry leader for prosthetic solutions worldwide. Mr. Hickey identified an opportunity to serve an athletic population through the design of a high-impact, sports-capable prosthesis that not only falls within Medicare coverage, but also remains aesthetic for everyday wear. Such a solution would eliminate fear of social judgment, remain affordable, and reduce transition time to between different prosthetics to improve the standard of living for a full-time worker who wants to maintain an athletic lifestyle.

4.2.2 Agriculture Amputations

The farming and agriculture industry has a high rate of amputation. According to a report by the National Safety Council, 10% of all agricultural workers in the United States will suffer some sort of amputation in their lifetime.[19] This high instance results in a large population of workers who need treatment and fitting of prostheses. The causes of these amputations vary from entanglement in heavy machinery (e.g. corn pickers, power takeoffs, bailers) to vehicular accidents and vascular disease complications.[20] Amputations in the farming and agriculture industry create a unique subset of problems.

One major problem with treating and fitting farmer amputees is the geographical remoteness of agricultural workers. By nature of the industry, many patients live very far from urban hospitals and treatment centers. The majority of farmers and ranchers are, "geographically isolated, working in remote settings far away from prosthetic clinics." This geographic isolation makes fitting prostheses, training patients, and making repairs costly and time-consuming, which, "may drive some farmers to repair their own prostheses or go without a replacement prosthesis."[2]

Durability of available products is a second concern regarding prostheses in the farming industry. Agricultural jobs are physically demanding, and most prosthetic manufacturers do not design for the wear and tear a prosthesis must endure in such an environment. Problems reported by farmers include breaking bolts in lower limb prostheses, snapping cables in upper extremity prostheses, and ripping suspension and gel sleeves. These durability problems lead to lack of productivity on the job as well as new safety concerns. These situations demonstrate a need to design for higher stresses and longer fatigue life. The working environment also shortens the life of prostheses in the agricultural industry. Farmers with a prosthetic limb face environmental factors such as, "dust and dirt, which can interfere with the motion of any moveable prosthetic part…[and] biological and chemical contaminants [which] can corrode components and necessitate disinfecting or decontaminating prostheses."[2]

Another shortcoming of modern prostheses is inability to adapt to agricultural tasks. Most farming tasks are labor intensive and require strength and dexterity in both limbs. Farmers must, "adapt by making changes to their farm equipment and, sometimes, to their prosthesis, which can affect durability and safety."[2] These modifications might include extra handholds, assistive steering devices, electronic hydraulic controls and other jigs that facilitate machinery operation. The National AgrAbility Project, a foundation established by the United States Department of Agriculture, provides assistance to farmers working with disabilities. One of AgrAbility's main resources is a database of both commercially available and homemade assistive devices and alterations to facilitate work on a farm. The existence of these devices highlights the challenges of working in agriculture with a prosthetic device.[21]

The high incidence of amputations and the shortcomings of available prostheses indicate space for innovation. All of the above challenges can be corrected by product design. New prostheses and assistive technology should be low cost, durable, and adaptable to help restore the livelihood of agricultural populations.

4.2.3 Underdeveloped Countries

In underdeveloped countries, the causes of amputation differ from those in developed countries. There is a much higher rate of traumatic injury from natural disasters, war, and unsafe working and living conditions. Natural disasters such as earthquakes, tsunamis, and even hurricanes and flooding cause many amputations in underdeveloped countries due to the lack of building codes and regulations. For example, most buildings in Haiti are constructed using unregulated concrete and steel rebar. When a 7.0 magnitude earthquake hit Haiti's capital city of Port-au-Prince in 2010, more buildings collapsed then did not collapse. For example, 60% of the city's hospitals and 80% of the city's schools collapsed.[22] These collapsed buildings created tens of thousands of amputees in the region surrounding the nation's capital.[23] Another example is a typhoon that hit the Philippines in late 2013. Similarly, unregulated construction of homes and infrastructure allowed the typhoon to cause devastating destruction.

Approximately 1.2 million homes were destroyed by severe winds and flooding, and many survivors were left injured.[23] These amputees are no longer able to perform activities of daily living or fulfill their livelihoods. Access to prostheses in these areas is limited and usually based on donations from developed nations.

Warfare and genocide cause many amputations in underdeveloped countries as well. For example, Cambodia suffered a civil war in the late 1970s during which millions of landmines were placed. There are an estimated 1 million landmines that remain undetonated and pose a daily risk to civilians. So far, these landmines have created a population of over 40,000 Cambodian amputees.[23] Another example is the Bosnian War that occurred in the early 1990s. All factions involved in the conflict used landmines, causing over 5,000 fatalities or injuries.[23]

Mining and related occupations comprise a major industry in Bosnia and Herzegovina. Coal and iron ore mines operate throughout the country. Mining requires strength and coordination for multiple job functions and is recognized as one of the most dangerous occupations in the world. Workers risk injury by cave-ins, gas explosions, fires, heavy mine machinery accidents. Besides injury on the job, limb loss due to landmines also negatively affects this region's workforce, with 70.9% of landmine amputees becoming and remaining unemployed after injury.[24] Government resources fund distribution only of lower limb prostheses; so many UEAs go without any prosthetic assistance.

This situation inspired the potential project of a prosthesis or orthotic that assisted in the everyday tasks involved with mining, particularly within Bosnia and Herzegovina. A list of motions and tasks that would be inhibited by an amputation was compiled by reviewing video documentation of several mine sites. These motions include heavy lifting, lifting wide and unusually shaped objects requiring firm grips with both hands, shoveling, pushing heavy objects, and tightly grasping several tools.[18] However, the main task observed in the research on mining was the operating heavy machinery. A prosthetic limb that could help an amputee operate this machine, regardless of location or machine type, would help keep mines well-staffed and amputees employed.

4.3 Existing Prosthetics

4.3.1 Brief History on Prosthetics

There is evidence of prosthetics use since the times of ancient Egypt. One mummy from the 5th Egyptian dynasty from about 1800 BC was found to have a splint, and another from the 18th Egyptian dynasty (1500 BC) was found with a prosthetic toe attached to its foot made of leather and wood.[25] The first known functional prosthesis was made for a Roman general who lost an arm in combat. He was given a steel hand that held a shield in battle. In the middle ages, wealthy knights on attached metal legs to their riding saddles solely to improve their appearance on horseback.[25] Amputees were often socially outcast, so most prosthetics during this period were designed to mask an amputation rather than assist the user.

Ambroise Pare, a military surgeon who is now known as the father of prosthetics, was born in France in 1510. He developed a hand prosthesis actuated by catches and springs and a position-locking knee with a suspension harness still used in prosthetics today.[25] Technological progress in prosthetics was slow until the World Wars created a massive increase in amputations. The United States government established the

Artificial Limb Program and began to fund more research. In the time since, prosthetics have become more lifelike and have improved functionality.

4.3.2 Common Prosthetic Materials

For any limb, comfort is the key factor in prosthesis use or disuse. An amputee uses a prosthetic limb only as long as it is comfortable, and the prosthetic limb benefits the amputee only as long as they use it. Comfort is most affected by interface and by prosthetic limb weight. Thus, socket fit and component materials determine the effectiveness of a prosthetic limb in rehabilitating an amputee.

A rigid socket for a prosthetic limb is typically formed by creating a positive model of the patient's residual limb and applying socket materials to the model. A laminated socket is built by arranging structural materials such as fiberglass or carbon fiber around the positive model and binding them with thermosetting plastic.[26] A thermoformed socket is created by vacuum-forming a sheet of thermoplastic, typically polypropylene (PP), over the model. The model itself can be fabricated using CAM processes from a digital scan of the patient's limb, or it can fill a physical cast of the limb made of plaster casting tape or reusable particles (sand or micro beads).[27, 28]

The pylon of a prosthetic limb must be stiff, strong, and lightweight. Typical high-performance pylon materials include wood, aluminum, titanium and carbon fiber.[26, 27] In LICs, pylons and other limb components are commonly made of polypropylene because it is inexpensive and recyclable.[29]

4.3.3 Myoelectric Prosthetics

Myoelectric prostheses are prosthetic limbs controlled by electrical impulses from the amputee's muscles. The joints are powered externally to the body by battery-operated motors. Electrodes attached to muscles near the prosthetic socket activate the motors. Some patients may have nerves rerouted after amputation to allow for more complex muscle use and control over the prosthesis.[30] Myoelectric prosthetics are considered the most advanced, multi-functional, and naturally controlled, but they are extremely complex and expensive to produce.

4.3.4 Prosthetics in Underdeveloped Countries

Prosthetics services are scarce in LICs and often inaccessible or unaffordable for rural populations. Many prostheses used in these regions are improvised with found parts and materials. Others are limbs donated from high income countries (HICs).[31] Prosthetic limbs designed in HICs and intended for production in LICs must meet criteria for "appropriate technology" as established by the International Society for Prosthetics and Orthotics (ISPO): "appropriate technology is a system providing proper fit and alignment based on sound biomechanical principles which suit the needs of the individual and can be sustained by the country at the most economical and affordable price."[32]

Inexpensive, locally manufacturable designs usually incorporate wood and thermoplastics such as PP and high-density polyethylene (HDPE) for structural components and vulcanized rubber for wearing surfaces. Solid-ankle cushion heel (SACH) feet are the most popular model of feet used in LICs. The simple design comprising a wooden core and rubber exterior makes a lightweight prosthesis that is easily produced in most countries. The rubber exterior is resilient and withstands water damage better than most competitors.[33] The most widely tested foot for LICs is the Jaipur foot, designed in India. Its rubber exterior decreases the impact of walking on uneven terrain.[32] The foot's flexibility also allows its wearer to squat as is customary in Indian culture. It can be manufactured for less than $5.00.[31]

Lower limb pylons are typically made of plastic piping. Length can be adjusted for alignment by adding spacer discs at the connection between the pylon and ankle. The additive manufactured monolimb is a socket and pylon formed with one continuous piece of plastic. This design minimizes components and connections.[31]

There is no widely used prosthetic knee joint, but many of the commonly used products are variations of one design. The knee typically includes a locking mechanism to mimic normal walking and crouching as much as possible. Two recently designed prosthetics are the Jaipur Knee, created in India, and the LIMBS knee, intended primarily for Africa/Haiti. The Jaipur knee is a joint attachment between a thigh and shin piece with a 165º range of motion. It uses bar linkages to mimic a natural knee's motion during walking. The LIMBS knee is a single axis knee that functions similarly to the Jaipur knee, but it can be manufactured for just $15.00 compared with $20.00 for the Jaipur knee.[33]

Upper extremity prostheses are rarely used in LICs because unilateral UEAs receive the lowest priority from aid organizations. When prostheses are worn in LICs, they are typically either passive cosmetic hands or under-actuated prosthetic hands (UAPH). A UAPH is a limb with a voluntary-closing terminal device that is actuated by the wearer's shoulder muscles. These devices have minimal dexterity and limited strength, and they are difficult to service.[31]

In LICs, prosthetic limb rehabilitation of an amputee is most affected by the availability, quality, and access to patient services. High cost is cited by prosthetists throughout the world as the greatest barrier to prosthetic provision.[34] As rehabilitation in LICs is largely dependent upon aid organizations and governmental support, adequate care for amputees is often simply unfeasible.[29] Then, a patient treated in an LIC may suffer from poor quality of care. Amputation surgeries are frequently performed without consideration of limb condition for prosthetic rehabilitation.[35] An undertrained prosthetist may not have sufficient skills to create a comfortable custom limb.[29] Finally, even where prosthetist and rehabilitation services are available, a patient might still not access them. Without sufficient communication between hospitals, rehabilitation centers, and patients, amputees do not know that they can or should receive follow-up care. Further, amputees in rural areas are often unable to travel to medical care locations for necessary evaluations, fittings, and training.[35]

4.3.5 Existing Prosthetics Specific to Agriculture & Machines

The most widely used prosthesis in the agricultural industry is the Hosmer-Dorrance prosthesis, commonly known as the "farmer's hook". It is depicted in Figure 2. It sits on the vestige of an amputated forearm and has a split metal hook in place of a hand. The hook can be made from any of several different metals to change its weight and comes in various shapes to suit different tasks. It is actuated by a series of cables attached to a figure eight harness wrapped around the user's shoulders. The hook is closed in its passive state and is opened by shoulder excursion, or spreading apart of the harnessed shoulders. There are several similar prosthetics worldwide, but none have achieved the widespread use comparable to the farmer's hook.[36]

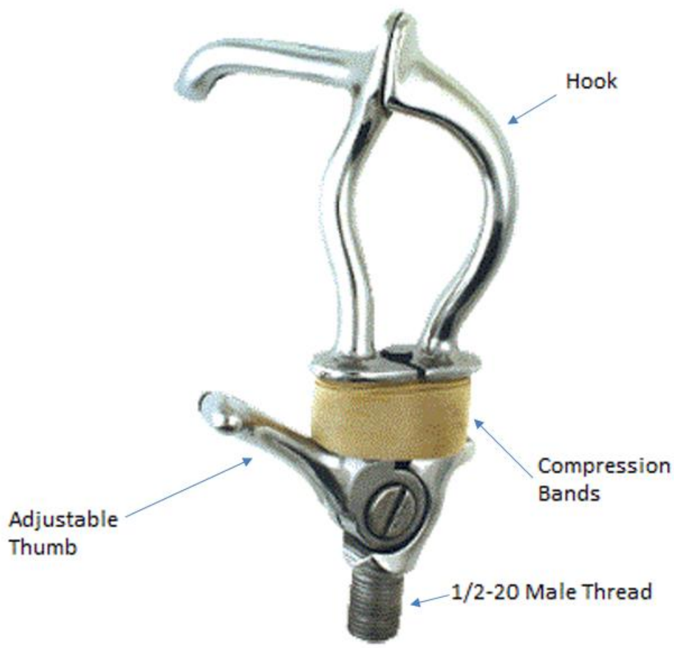

Figure 2: Hosmer-Dorrance "Farmer's Hook"[36]

The naturally closed position can present difficulties for the user. In a conversation with Bill Hanson, President of Liberating Technologies Inc., Mr. Hanson detailed several problems often reported on the farmer's hook. Users often add extra bands to the hook to increase grip strength, which in turn increases the force they must exert with their shoulders as well as the pressure of the harness on their bodies. With long-term use, this harness pressure can cause serious nerve damage on the auxiliary nerve of the intact contralateral limb. In addition, if the amputee wants to grip an object softly without removing bands from the hook, they must exert a constant force to work against the bands. The farmer's hook also has a limitation in grasping objects to the side of the user. When the arm supporting the hook is extended laterally and away from the body, the magnitude of shoulder excursion is reduced and the user is less capable of fully opening the hook. This makes the prosthesis significantly less capable of grasping an object not directly in front of the user.

While the Hosmer-Dorrance hook is "voluntary-open", meaning that it is passively closed and requires user input to open, the Army Prosthetic Research Lab (APRL) hook is "voluntary-close." This means that applying a force through the harness cables by shoulder excursion closes the split hook. The APRL hook enables variable gripping force and greater maximum grip strength over the farmer's hook. In addition there is a locking opposable thumb that allows the user to maintain a grip without force input, making it superior for holding smaller or heavier objects.[36] However the APRL hook has not been commercially competitive with any Hosmer-Dorrance products on the market.

Very few existing products address the needs identified in the team's problem statement. The N-abler, a tool produced by Texas Assistive Devices, allows different attachments to connect at the wrist of a prosthesis. Its attachments include brushes, spoons, screwdrivers and other common tools.[37] There are not many attachments that could assist a user in driving or operating heavy machinery because the N-abler targets simpler tasks. Further, many of commercial assistive devices involve electrical components that can drive up the price to over $4000 for premier products.[38] In addition, many of the homemade solutions, such as ones found on the AgrAbility Toolbox database (a resource for disabled farmers) are not easily replicated without sufficient mechanical expertise.[39] The farmer's hook is often used with such homemade tools and modifications when driving automatic cars, however the inability to turn a key or manipulate other car controls remains a chief complaint.[40]

Sometimes farmers will alter the controls within the tractor as well to better enable operation of the controls. One example of this tinkering on the control side as opposed to the prosthetic side is the Brodie knob, or "suicide knob." Depicted in Figure 3 the Brodie knob allows for more confident operation of a steering wheel when only one hand is available for its operation.

Figure 3: Brodie Knob, or Suicide Knob outfitted for tractor steering wheel[39]

Brodie knobs durable enough to last years of use on a farm are often too expensive for a farmer to purchase, nearing $800.[21, 39] This causes farmers to alter the controls of their machinery themselves; making unique, one-off solutions limited by the fabrication processes they are able to perform on their own. Many of these homemade solutions are shared online by a community of disabled agriculture workers called AgrAbility. AgrAbility's "Toolbox" is an online, "resource that contains assistive technology solutions for farmers, ranchers, and other agricultural workers with disabilities…to find: products, designs and ideas, [and] techniques and suggestions."[39] Using a homemade solution on powerful machinery can endanger the amputee farmer for possible traumatic injury.

Another example of manipulating the control as well as the terminal device for operation of a machine is the Mert's Hand. This two-part solution was originally invented for the operation of motorcycles. It is now used mostly to allow amputees to operate bicycles and dirt bikes. The terminal device is a ball shape, and the handlebar adapter is a socket with six threaded ball-plunger detents, which allow for customization of the force required to safely disengage the terminal device from the adapter. This means that there is an almost fixed connection once engaged. This would inhibit the quick engagement and disengagement of the controls within a tractor, which is necessary while working on the farm. Figure 4 shows a picture of the components of the Mert's hand and it in use on a dirt bike.

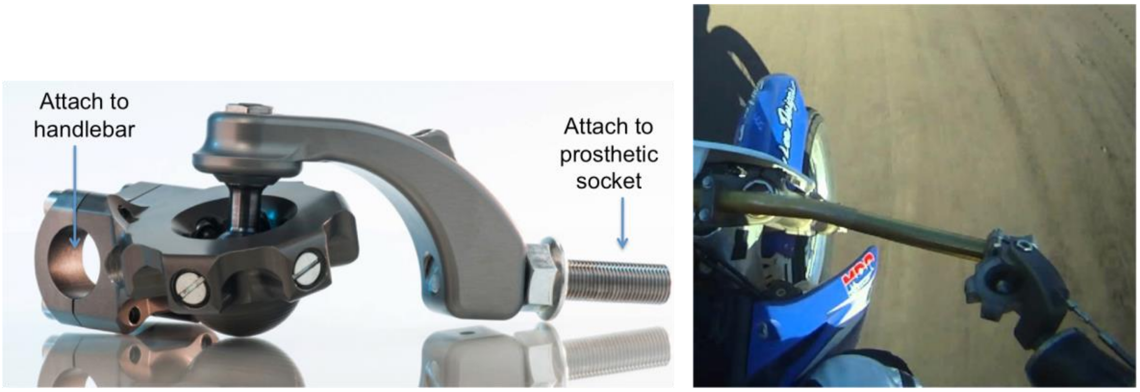

Figure 4: Mert's Hand components and in use on dirt bike[41, 42]

5 Project Characterization

The topics covered in the Section 4 demonstrate specific needs of three different amputee populations. Each population posed its own unique set of challenges and rewards for community impact. The team evaluated potential projects in these researched amputee populations based on the goals of Capstone discussed in the Section 3 and in terms of: societal accessibility, technological constraints, and design space.

5.1 Societal Accessibility

Cultural, political, geographical, and economic obstacles threaten the ability to positively impact amputee communities in LICs. Physical disability has a greater stigma in underdeveloped nations. Some cultures interpret disability as a form of divine punishment and refuse to allow the disabled a place in society. Even in the absence of overt hostility, an amputee might self-isolate to avoid real or perceived judgment by members of his or her community. This isolation makes it difficult to reach amputees in LICs for evaluation and aid. Also, many target populations identified by the research are located in countries whose governments limit foreign medical aid. To underserved amputees in these regions, access to a prosthetic limb and rehabilitation are greater barriers than shortcomings in existing prosthetics technology. In either situation, delivery of a useful prosthetic solution to an amputee in a LIC is improbable.

Inadequate resources in LICs also present an obstacle. Provision of quality prosthetic devices requires trained personnel, high-performance materials, and sophisticated manufacturing equipment. The most impactful solutions would require education, materials science, or process engineering rather than a mechanical design.

5.2 Technological Constraints

While a project idea was to merge functionality of current running and walking prosthetics, research revealed that the associated biomechanical complexity was outside the scope of the Capstone Design project. Load bearing applications such as running require a high level of expertise in gait biomechanics. After assessing the project requirements, the idea of creating a multipurpose run-walk prosthetic within the timeframe was reasoned unattainable.

The field of myoelectric prostheses was not considered because of its high costs and the systems and controls, electrical, and other technical challenges that were determined outside the scope of this project.

Technological challenges were also considered when determining whether the project would focus on upper or lower extremity amputations. A recurring complaint of prosthetics users was of the socket design. The socket is weight bearing and faces challenges in pressure distribution and maintaining the health of the residual limb. Sockets must fit the unique shape and size of its user's residual limb. Lower extremity prosthetic limbs must support the amputee's entire body weight safely and must align with the first leg for healthy gait. These factors led the team away from developing a product that involved the design of the socket interface.

5.3 Design Space

There is a current push in both academia and industry to advance myoelectric devices. These devices provide the user with a prosthetic limb that mimics the biomechanics of natural anatomy. Companies such as Ossur, BiOM, and Ottobock lead the field in design and manufacture of these devices. The Defense Advanced Research Projects Agency (DARPA) provides millions in funding each year towards such neural controlled prosthetics.[43] Companies and researchers also currently focus on passive devices usable for both walking and running. Biomedical conferences are filled with professionals trying to address this amputee community's complaints. The crowded field of general-use prosthetics directed the team toward a niche, task-specific focus.

5.4 Problem Statement Selection

After much consideration, the team decided to develop an assistive device for the agricultural amputee community. There is a high incidence of amputation in agriculture and therefore a large population of farmer amputees in the United States. This community is more accessible than communities of amputees in developing nations, making design and product implementation more feasible. The target population spans the country allowing more opportunity for advice and feedback. Also, the National AgrAbility Foundation could serve as a great contact to assist in the evaluation of the needs of disabled farmers and providing user feedback on prototypes.

Intellectual property searches for prosthetics reveal sufficient design space to develop a task-specific prosthesis for an agricultural application. Farmers express a need for a prosthesis that is more durable, cost-effective, and adaptable to life in an agricultural environment.

A specific focus on needs of the American agricultural industry allowed the team to target a specific demographic of amputees for the design. The team aligned on an upper extremity design focus. Working with UEA populations requires creating a device that restores the amputee's ability to complete a task safely and independently. Farmers with upper extremity amputations often modify their farm equipment to be able to complete tasks associated with their livelihood. After reviewing literature on farming with a disability, the team resolved to focus on the challenges associated with operating motor vehicles and heavy machinery.

The narrow focus of the task-specific prosthesis fit well within the constraints of both the Capstone Design scope and the team's abilities. The team also aligned on a further specific scope of designing a terminal device solution for farmer amputees in order to stay away from the complexities and challenges associated with socket design. Finally, after identifying that most of the implements' controls within a tractor's cockpit were located on the right-side of the user, the problem statement was narrowed one last time to design a prosthetic adapter that enables a right-side unilateral, TR, UEA to operate agricultural machinery.

6 Design

6.1 Problem Statement Reiteration

The extensive background research and the analytical focusing of scope allowed for a narrowed project goal of enabling a unilateral, TR UEA to operate agricultural machinery. The team began by identifying further research areas and anticipated challenges. The operation of tractors, pickers, and other heavy machinery was investigated to define the functional requirements of the solution. In addition to these operations, the biomechanics of how the controls in agricultural machinery are used was studied. The ranges of motion, required movements, and necessary forces for these controls were determined as well. This portion of the report outlines the design process.

6.2 Design Goals

6.2.1 Functional Requirements

The project goal of enabling a unilateral, TR UEA to operate heavy machinery was broad and needed further classification in order to develop achievable functional requirements. The following five design aspects were identified as functional requirements.

6.2.1.1 Force Transmission

This device shall be able to transmit force from the user to the controls on the machinery. This force transmission shall allow precise, minute displacements of the different levers, sticks, and wheels, maximizing control of the machinery.

6.2.1.2 Speed of Operation

This device shall allow for the operation of heavy machinery controls at speeds comparable to that of an unaffected user. The device must be able to enable quick alternating between operating different controls within the cockpit of the machine without hindering operation.

6.2.1.3 Adaptability

This device shall be sufficiently adaptable to be used with various makes, models, and manufacturers of heavy machinery. The device shall be able to manipulate controls including but not limited to throttle levers, hydraulic levers, joysticks, and steering wheels.

6.2.1.4 Durability

This device shall be durable enough to withstand multiple years of operation in an agricultural environment. This includes being able to withstand harsh environments, weathering, and being resistant to chemicals and oils found in farming applications. The device shall be durable enough to withstand the fatigue of daily use, including many mating cycles per day, without exhibiting excessive signs of wear.

6.2.1.5 Safety

This device shall not pose any safety risk to the user. The device shall meet all standards set for prosthetic devices and shall be manufactured from compliant materials. Also, the device shall exhibit additional safety features due to the unique operating environment in the agricultural industry. The device shall be snag resistant to avoid entanglement or catching in machines and electrically insulated to avoid electrocution.

These five functional requirements will be used to evaluate potential design concepts. Failure to meet any of these specifications will result in the rejection of a design. In addition to these functional requirements, this project has the goals of minimizing cost and weight. Agricultural workers do not usually have a large budget or sufficient insurance coverage for multiple prosthetic devices, such as the solution proposed by this project. Based on conversations with industry contacts (Bill Hansen of LTI, Arthur Graham of NextStep B & P, and Byron Backus of Ottobock), this solution should not exceed a customer cost of $500.00, and the part of the solution attached to the user's prosthetic socket should not exceed a weight of 400 grams.

6.2.2 Biomechanical Considerations

6.2.2.1 Anthropometric Variation

User body size will vary in both stature and anthropometrics. To create a universal tool for all users, the terminal device will be sized to match Hosmer work hooks. This design assumes that the user already has a custom-fitted forearm socket and an appropriate length pylon for use with commercial terminal devices. Matching the size of the terminal device to the size of popular commercial products should ensure that the subsequent length of the full prosthetic arm is sufficiently similar to the comfortable working length prescribed by the user's prosthetist.

6.2.2.2 Ergonomic Design

A positive mate between the terminal device and the machine controls should be accomplished with a natural, comfortable reaching motion. This comfortable reach is made possible by a precise custom installation of the control adapters. Adapters will be semi-permanently fixed to the machine contact points at angles chosen by the individual user's reaching and actuating motions.

The machine control mating system intends to accommodate multiple reaching and actuation motions. For example, a driver with an uncompromised arm would likely grasp a joystick palm-down and move it medially and laterally using elbow flexion and extension. However, this action creates a moment on the forearm that a transradial amputee might not be comfortable with. A user with a prosthetic arm might choose instead to exert forces parallel to the control's line of action when possible. To change force direction, the user must then rotate the arm about the point of contact with the control. Therefore, to allow comfortable joystick manipulation, the mating interface should not restrict planar rotation about the axis of the control.

6.2.2.3 Body Motion

Transradial amputees have no capacity for forearm pronation and supination (rotation about the axis of the forearm), and a solid prosthetic arm does not have dynamic wrist mobility. Without these means of distal limb positioning, amputees may compensate with shoulder and torso movements. These movements change the user's body posture, and a user whose body is not neutrally aligned while working is more susceptible to injury. Poor core posture creates a risk for spinal injury, and shoulder instability under working forces can result in tendonitis. Therefore, for greatest comfort and least bodily risk the user should be able to position the mating terminal device without misaligning the body. Neutral alignment in the upper body means that the spine is straight, the shoulders are retracted and depressed, and limbs are close to the sides with palms medially facing.

Unilateral UEAs, even prosthetics users, often utilize the intact limb for all one-handed tasks. The compromised limb is used only for support in two-handed tasks. The amputated limb is rarely active and lacks the intrinsic strength of a functional limb and thus is more prone to fatigue and injury. The design of the control mating system should minimize potential for discomfort by promoting conservative working motions. It should enable and encourage the user to both maintain neutral body alignment and utilize non-stressing movements. While exerting forces through the arms, a worker can minimize joint stress first by maintaining postural stability in the shoulder girdle (retraction and depression) but also by avoiding shoulder abduction as much as possible. Abducting the upper arm more than 20 degrees from the vertical increases force on the glenohumeral joint of the shoulder and decreases time to muscle fatigue[44, 45]. The control mating system therefore will be positioned such that the user can establish mates without significant shoulder abduction. The user can also avoid fatigue by utilizing large muscle groups rather than small individual muscles for actuation forces. For example, when pulling a heavy lever such as the tractor throttle, the driver should pull using shoulder extension (latissius dorsi) rather than elbow flexion (biceps brachii). The angle of the terminal device will primarily determine the possible muscle actions, and the angle of the adapters will determine whether the user can mate with the controls in a neutral body alignment. Anticipated muscle actions for control actuation are given in Table 1 below.

Table 1: Anticipated muscle actions for control actuation[46]

Relevant Action	**Required Biomechanical Action of Unaffected Upper Limb**	**Key Control Actuators**	**Meas. Force (lbs)**	**TR UEA Restrictions**
Actuate hydraulic lever horizontally	Shoulder flexion (110̊ degrees above the neutral axis), abduction (10 degrees), Elbow flexion/extension, (+/- 20), forearm pronation, thumb opposition & phalanges flexion (grasp), Wrist flexion	Elbow flexion and extension	*6.5*	Pronation & Grasp/Opposition, Wrist Deviation & Flexion/Extension

Actuate hydraulic lever vertically	Shoulder flexion (110 degrees above NA), abduction (10 degrees), external/internal should rotation, protraction and retraction, forearm pronation, thumb opposition & phalangeal flexion (grasp), wrist ulnar/radial deviation (45 degrees)	Protraction and retraction of trapezius and middle rhomboids	*7.1*	Pronation & Grasp/Opposition, Wrist Deviation & Flexion/Extension
Actuate hydraulic lever diagonally	Shoulder flexion (110 degrees above the NA), abduction (10 degrees), Outward external/internal rotation, (+/- 20) as well as elbow flexion/extension, 90 degree forearm pronation, thumb opposition & phalangeal flexion (grasp), wrist ulnar/radial deviation (45 degrees)	Elbow flexion and extension, protraction and retraction of trapezius and middle rhomboids	*10.1*	Pronation & Grasp/Opposition, Wrist Deviation & Flexion/Extension
Quick Dump	Shoulder flexion (110° degrees above the neutral axis), abduction (15 degrees), Elbow flexion/extension, (+/- 20), forearm pronation, thumb opposition & phalanges flexion (grasp), Wrist flexion	Elbow flexion and extension	*14.1*	Pronation & Grasp/Opposition, Wrist Deviation & Flexion/Extension
Actuate Throttle Lever	Shoulder flexion, (70 degrees above NA), Elbow extension and flexion, (+/- 20), 80 degree forearm supination, phalangeal flexion (grasp), slight thumb opposition	Elbow flexion, shoulder extension	*34.6*	Supination & Grasp, Wrist Deviation & Flexion/Extension
Turn Steering Wheel (Powered)	Shoulder flexion (60 degrees above NA),Forearm pronation with shoulder adduction turns wheel (>90degrees), phalangeal flexion (grasp), slight thumb opposition	Shoulder adduction, radial pronation	*9.4*	Pronation & Grasp/Opposition, Wrist Deviation & Flexion/Extension
Actuate Hitch Adjustment Lever	Shoulder extension/flexion (+/-20 degrees), elbow extension/flexion actuates hitch, wrist radial and ulnar deviation	Tricep extension	*7.7*	Wrist Deviation/Extension
Ignition Torque (in-lbs)	Supination of forearm (biceps and supinator), thumb opposition on keys	Supination	*7.0*	Supination, Opposition, Phalangeal Flexion

6.2.3 Material Considerations

When looking into the materials that the product may be made of, several different material properties were taken into consideration. These properties include density, chemical resistance, fatigue strength, yield strength, wear factor, maximum temperature, manufacturability, and cost. The physical properties are important for determining how external elements may affect the device. Density is important in determining the materials effect on the total weight of the design. Maximum temperature is important for plastics, which may soften if used in hot climates under prolonged exposure sunlight. Chemical resistance, particularly to organic solvents such as oils and fuels, is important to consider as the device may degrade is exposed to the wrong solvents.

The mechanical properties of fatigue strength, yield strength, and wear factor are necessary to ensure that the materials can withstand the worst case scenarios of consumer use. Yield strength is valuable, but high force impacts are not expected for the device. Fatigue strength is much more of a priority, as it will allow prediction of how the materials can withstand numerous cycles of mating between the two pieces. Wear factor is a numerical representation of how much volume of a material is worn off at a material interface under frictional stress. This is important for determining how the mating process will wear down the different materials.

Since the tractor is used outdoors, the design must also consider possible environmental effects including precipitation, temperature changes, and environmental contaminants such as dirt. Water and contaminants could decrease the coefficients of friction between the two mating surfaces and increase the risk of slip. Slippage hinders the device's operational effectiveness, possibly creating a dangerous situation for the user. The mating prosthesis design should be effective despite challenging farming conditions.

6.3 Initial Designs

6.3.1 Force Transmission Mechanisms

To start the design process, the team focused on the first functional requirement, force transmission. The UEA must be able to transmit force to the different controls to complete each action. The team considered three mechanisms of transmitting force: locking, gripping, and mating.

6.3.1.1 Locking

The UEA's prosthetic would connect to adapters on the machine controls. Once engaged, the terminal device would lock into place and allow the user to manipulate the control with motion in any direction. Once the action is complete, the user would disengage from the adapter and retrieves the terminal device.

Locking a user to a control is beneficial because it would simulate the grasp of an intact hand. The user could transmit sufficient force to the control with precision and without fear disconnecting accidentally. This design posed some risks including speed and safety. An intact biological hand can release its grasp of a control almost instantaneously. Connecting the terminal device to the machine requires a method of quick disengagement for safety and usability. This disengagement would require extra time and user attention. In the event of an emergency, the user may need to change controls rapidly or quickly exit the machinery. Locking the user to the control, using a mechanism similar to the Mert hand, would hinder his or her ability to react quickly to an emergency situation or escape from the machinery.

6.3.1.2 Gripping

The end of the terminal device would have a high-friction surface. This surface would temporarily adhere to the different machine controls to allow the user to manipulate the levers and steering wheel with a force normal to the surface interface. This design relies on the coefficient of friction between the terminal device and the surface of the controls on the machinery.

The gripping surface mechanism offers the advantage of adhering directly and universally to different machine controls, eliminating the need for an adapter. Drawbacks to this design include angle-dependent force transmission, environmental effects on friction, and frictional resistance to terminal device rotation. The maximum force transmittable by the terminal device would be completely dependent on the amount of normal force the user could apply to the control. The normal force required to achieve an actuating force could fatigue the user. Moisture and other contamination from an agricultural environment could decrease the coefficient of friction between the terminal device and the control. When the friction is as high as desired, the device would oppose the terminal device rotation created by the natural biomechanical motion of actuating a control.

6.3.1.3 Mating

The terminal device would not connect, but instead have surfaces that would mate with control adapter surfaces when engaged. The mating surfaces of the terminal device and adapters would allow force transmission in the direction of a control's actuation and easy disengagement.

The mating surface mechanism would provide the advantages of allowing force transmission without connecting to the control. The normal contact surfaces of the mating adapters would allow for force transmission in all directions within the plane perpendicular to a control lever. The engagement and disengagement of the two devices would be instantaneous and would fulfill the engage and release time requirements. The possible risks of this design include slip between the mating surfaces and difficulty of properly angling the terminal device. If the normal contact surface is insufficient, there is risk that the two devices may disengage and the control of that specific lever, knob, or wheel would be lost.

The mating surface design was chosen as the force transmission mechanism. The connection method and gripping method were each ruled out for their safety and environmental risks. The mating design transmits force using normal contact surfaces while allowing speed of operation similar to that of an unaffected individual.

6.3.2 Preliminary Designs

Five viable designs emerged from the mating surface brainstorm. The conical design, presented in the next section, was chosen for further development. The discarded four are briefly described below.

First, a simple eyelet and pin solution was drawn. This used the first mechanism of force transmission discussed previous section, using the concept of engagement. The terminal device would end in either a pin or hook and interface with an eyelet attached to the different tractor controls, as depicted in Figure 5. The eyelet would have a slightly larger inner diameter than the pin or hook's cross-sectional diameter to allow for quick engagement and disengagement. A single point on the inside of the eyelet would act as the mating point and translate the forces from the operator's residual limb to the control. The biggest drawback with this design is that the angles of the controls connected to the eyelet with respect to the operator would cause multiple incident angles with the operator's terminal device. A high level of fine motor control and coordination would be necessary to link the couple. Also, the pin or hook does not self-correct as some of the other design ideas would, reducing its quick engagement. Both the pin and eyelet would most likely be made of metal.

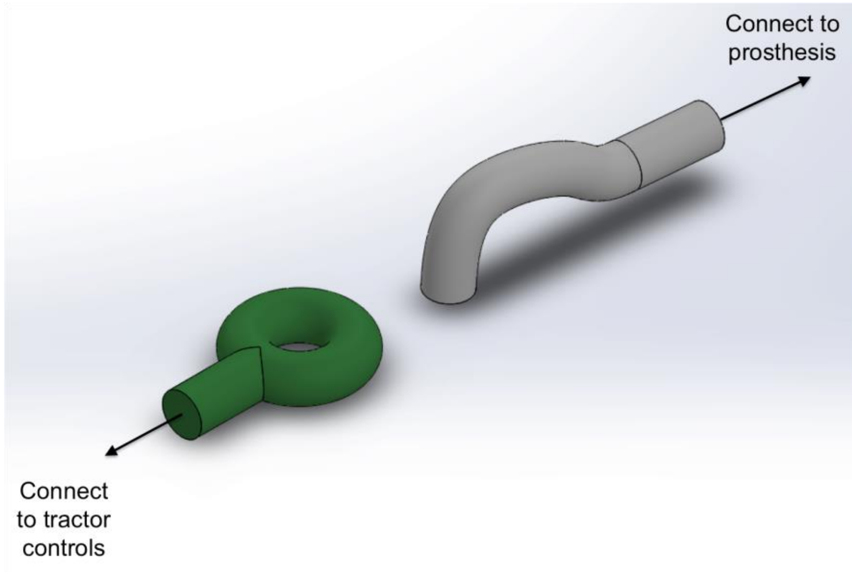

Figure 5: Concept diagram of initial design 1 - Hook & Eyelet

The second design concept used the second mechanism of force transmission discussed in the previous section, which relies on frictional forces between the terminal device and the controls. It was only a single part solution, not requiring adapters on the tractor's controls, excepting the steering wheel. This design consisted of multiple concave surfaces oriented at different angles. It would be made out of a gripping material to increase friction between the controls and the terminal device. The different concave surfaces would be oriented on the terminal device to couple with interfaces of different controls.

The third design idea involved a spherical terminal device and bowl shaped adapter on the controls. As shown in Figure 6, the radius of curvature on the male terminal device was smaller than the radius of curvature on the female control adapter. This design relied more on the friction at the point of contact and therefore the adapter, terminal device, or both may be made of a frictional material. This design would allow for quick engagement and disengagement, however once mated, it is only constrained in one direction, normal to the point of contact between the devices. This allows the user to engage at a wide range of angles but may not be constraining enough to maintain mates.

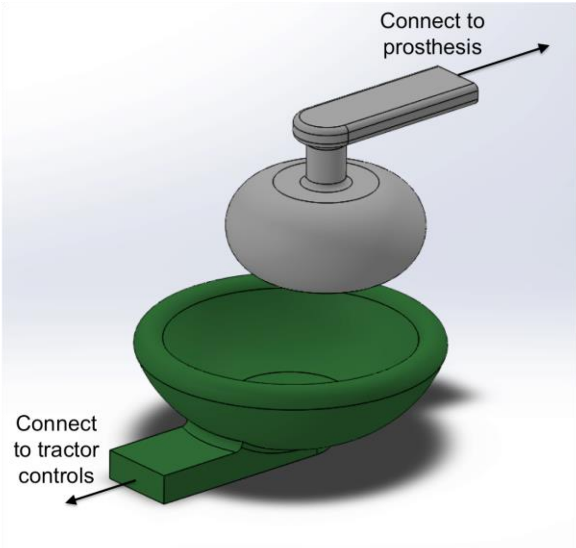

Figure 6: Concept diagram of initial design 2 - Ball & Cave

The fourth design concept has a terminal device with holes on multiple faces to engage with pins attached to the different tractor controls. As seen in Figure 7, this allows for the different angles of engagement between the adapter and terminal device to be accounted for in one device. Engagement with the multiple pins at the different angles would most likely be difficult and would not allow for much user placement error.

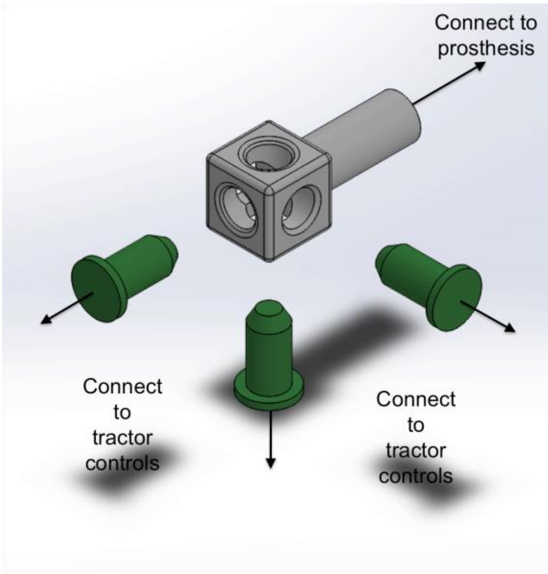

Figure 7: Concept diagram of initial design 4 - Swiss Cheese

The team ultimately chose to move forward with a fifth design concept, which consisted of a male and female conical geometry design. This design comprises a positive revolved conical shape that mates with a negative cone of similar geometry. This design is constrains in all but one degree of freedom while mated, only allowing for rotation about the axis of revolution of the cone. Figure 8 below illustrates this design concept.

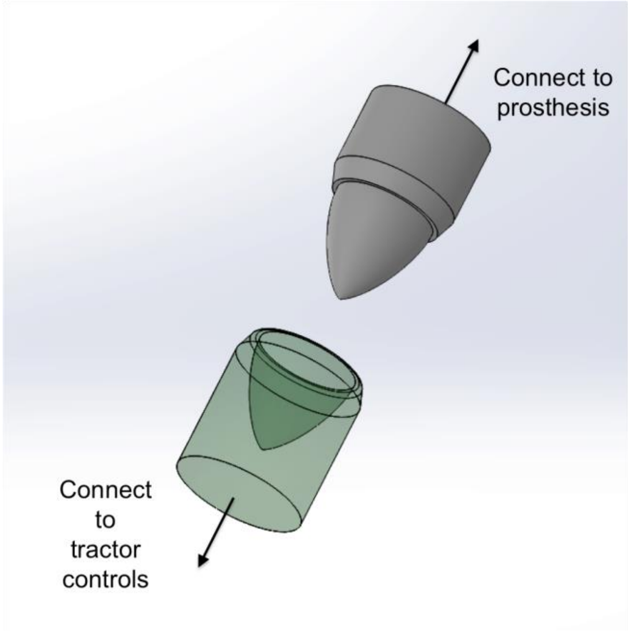

Figure 8: Concept diagram of initial design 5 - Conical Design

The cone has a self-correcting design. The users of this device are UEA who rely mainly on visual feedback when actuating the terminal device. The cone guides itself to its target, which is the inner diameter of the adapter. The cone geometry also allows the user to insert the positive mating surface at up to 1” from the central axis of the negative surface and still achieve successful mating. The drafted surface of the cone also corrects for angular rotation approximately 15˚ off the central axis of the adapter. Figure 9 demonstrates the self-correcting abilities of the conical design.

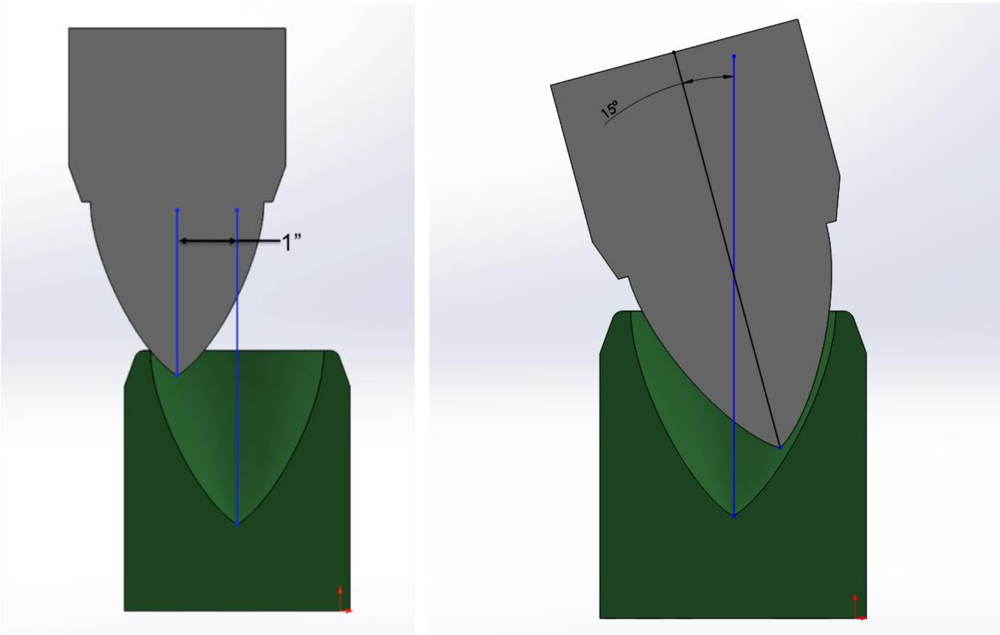

Figure 9: Cross-sections depicting conical design's self-correcting nature

The conical design also has the advantage of force transmission in a full 360˚ of rotation about the central axis. At any point in the 360˚ circle, there is always a normal face on the cone that can transmit force to the adapter. This means that the terminal device can actuate levers back and forth, move joysticks in any planar direction as well as turn a steering wheel. Figure 10 demonstrates the ability of the device to transmit forces in any direction. The smooth surface of the cone also allows the terminal device to rotate about its central axis while mated. With adjustment of angles of approach, this design can manipulate virtually any control of the heavy machinery.

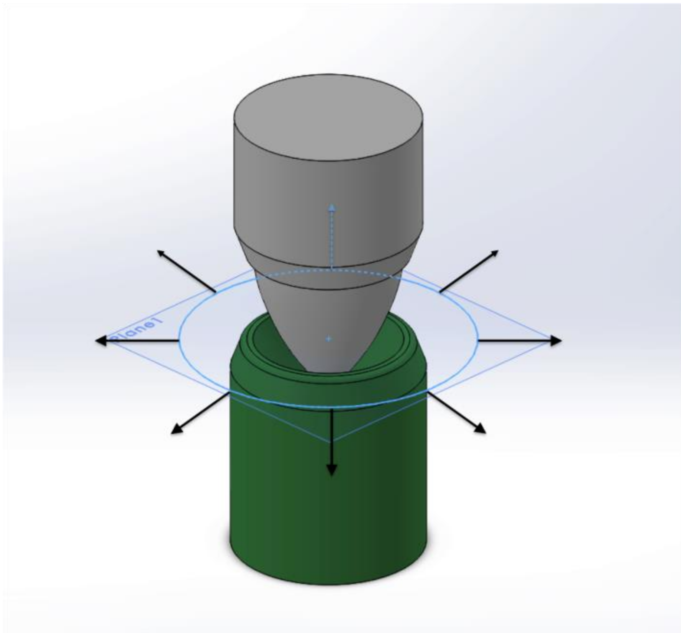

Figure 10: Terminal device half mated with adapter, showing plane of control

Another reason for moving forwards with the conical design concept was that the design could provide feedback to the user when engaged due to a hard-stop limit to engagement. UEA's do not receive tactile feedback from a prosthetic arm, so they cannot sense incremental engagement. A hard stop feature lets the user know that they are completely mated with the adapter and that no additional insertion is necessary. Figure 11 below demonstrates the hard stop design. It comprises a flat ledge along the circumference of the terminal device cone that sits against the top surface of the adapter when the mating pair are fully engaged. The adapter surface perimeter has a draft towards the base of the adapter that allows the terminal device a few degrees of tilt while mated.

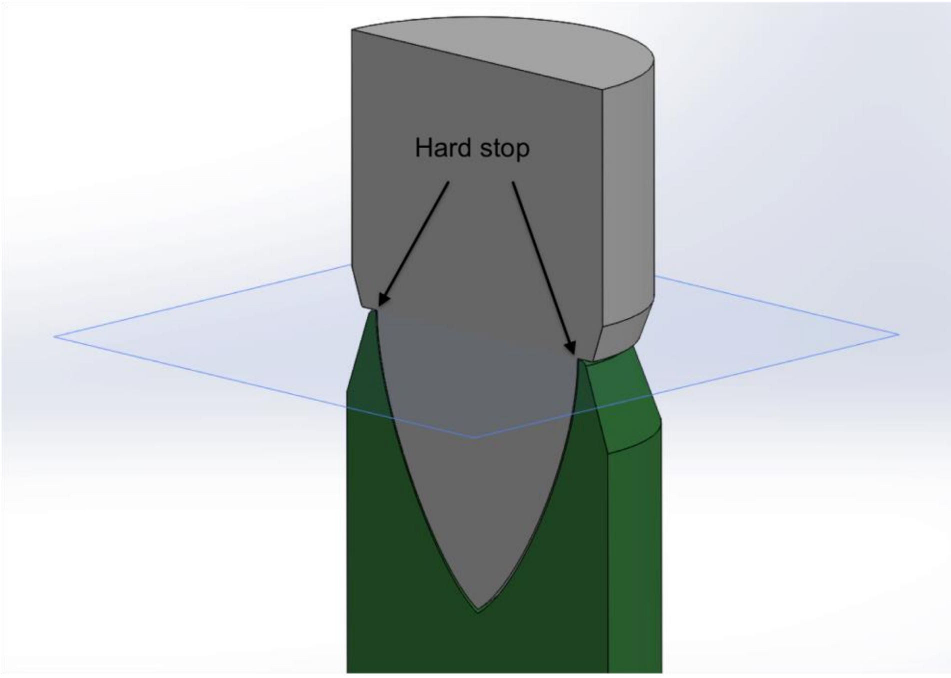

Figure 11: Cross-section showing hard stop feedback for user

6.3.3 Design Refinement

The geometry of this device must be able to accommodate diverse controls and their respective actuations. Controls such as steering wheels revolve about a center axis in a plane with a large range of motion. Other controls such as hydraulic levers and joysticks require mostly translational planar movement with some angular displacement. Figure 12 shows an overhead shot of a hydraulic lever and its approximate range of motion.

Figure 12: Tractor hydraulic lever and its approximate range of motion

This image illustrates the challenge of designing to a variety of different controls. The three inches of travel to either side translates into a maximum change in angle of 11.5˚ from parallel. This is an important consideration when designing the tolerances and geometry of the mating surfaces. The conical design must accommodate the change in angle without binding or disengaging. One possible solution to this problem is designing a larger tolerance between the male and female surfaces. The extra space between the two surfaces will forgive slight rotations from parallel. However, this solution may hinder the device's actuation of other controls when there is no required pivot between the central axes of the terminal device and adapter. Another possible solution is keeping the tolerance band at the top of the adapter surface tight while drafting out the bottom of the negative cone to allow for slight translation and rotation inside of the adapter. Figure 13 below demonstrates the differences between the two designs.

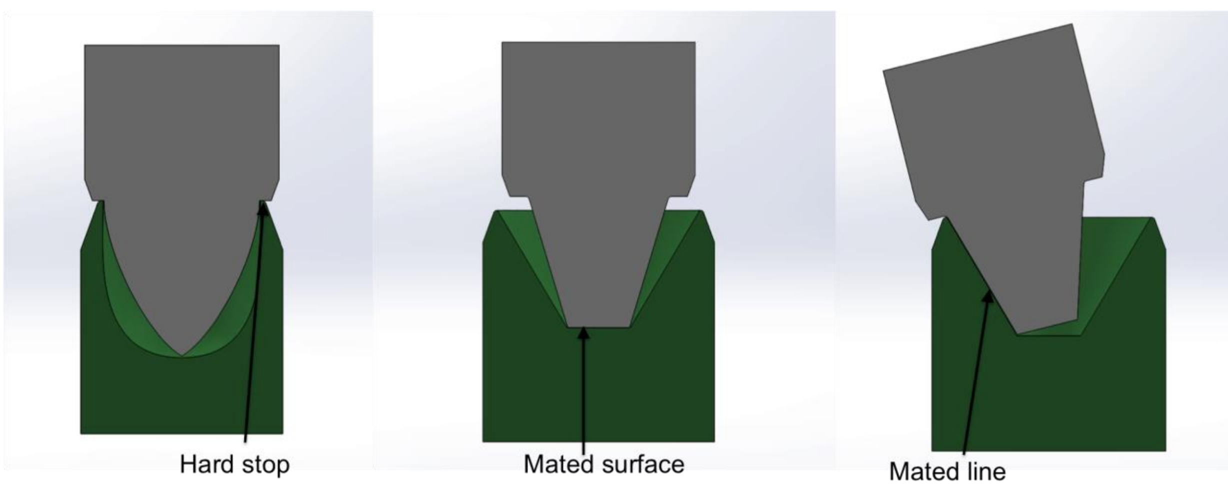

Figure 13: Cross-sections of variations of conical design, allowing for less constraining mates

This concept of angular deviation tolerance was proved necessary in initial testing, which is discussed further in the Section 7.1.

6.3.4 Criteria for Final Design

For the final design, the functional requirements, biomechanical considerations, and material considerations were revisited. During discussions about the final design, the variety of tractor controls between different tractor makes and models were discussed. Testing results and feedback dictated the majority of the final design decisions, included a moving from a cone terminus and a perfect negative adapter to a rod with a hemispherical end terminus and an adapter with drafts allowing for angular deviation tolerance.

6.4 Final Design

6.4.1 Overview

The final design incorporated the benefits of the conical surface mating geometries while incorporating new features to accommodate controls with larger angular motions. The final mating surface geometry includes a spherical tipped cylindrical rod as the terminus on the terminal device. The adapter geometry includes a recessed hemispherical bottom surface with walls incorporating a 30˚ draft. The following sections will describe the final design and its features in depth. Figures 14 and 15 show a model of the design with the parts labeled and an exploded view of the final design, respectively.

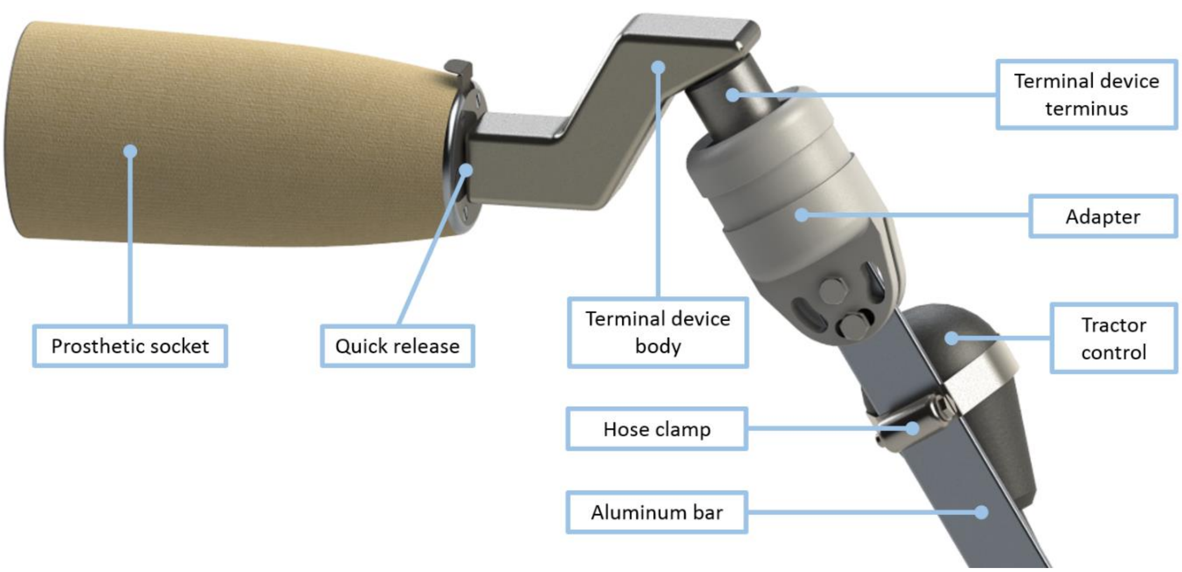

Figure 14: Final design with labels

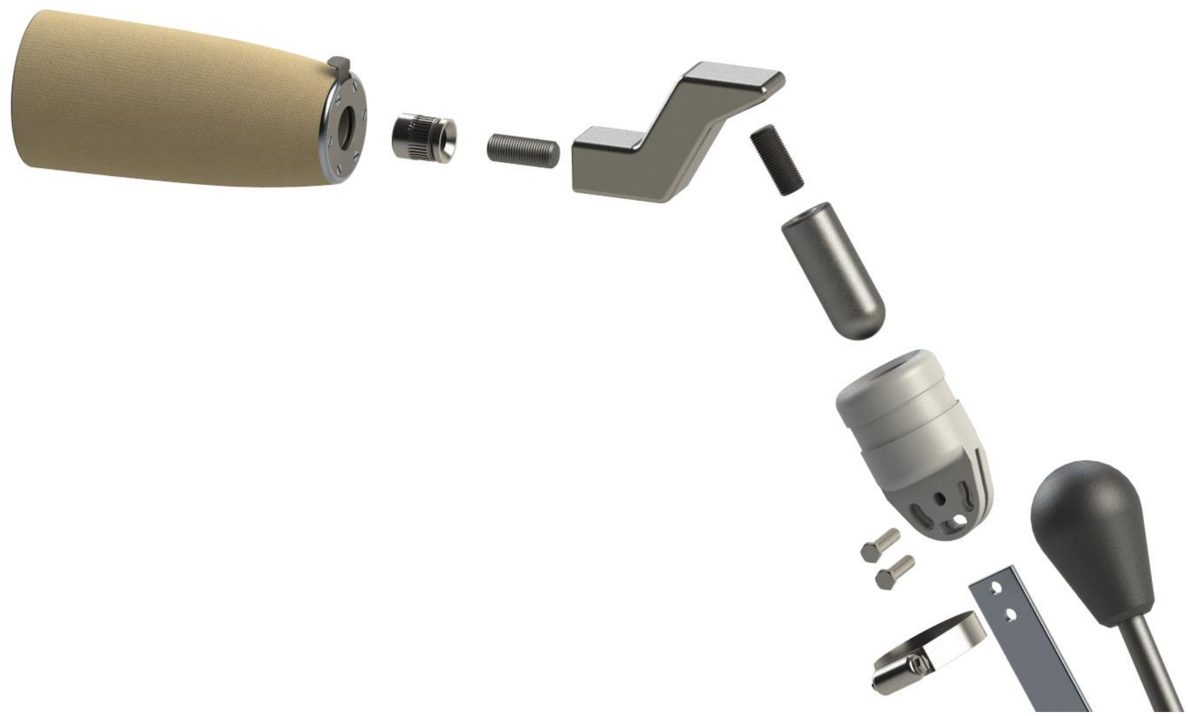

Figure 15: Exploded view of the final design, showing a prosthetic socket and a tractor control

6.4.2 Terminal Device

The body of the terminal device serves three functions; connecting the mating surface geometry to the pylon of the UEA's socket, supporting the weight of the terminus and the relevant force transmission loads, and extending the terminus too the correct anatomical position. The body of the design was designed to be of minimal cost and weight, to have a snag resistant geometry, and to meet the material consideration requirements concerning the harsh agricultural environment. Figure 16 shows the overall geometry of the terminal device body.

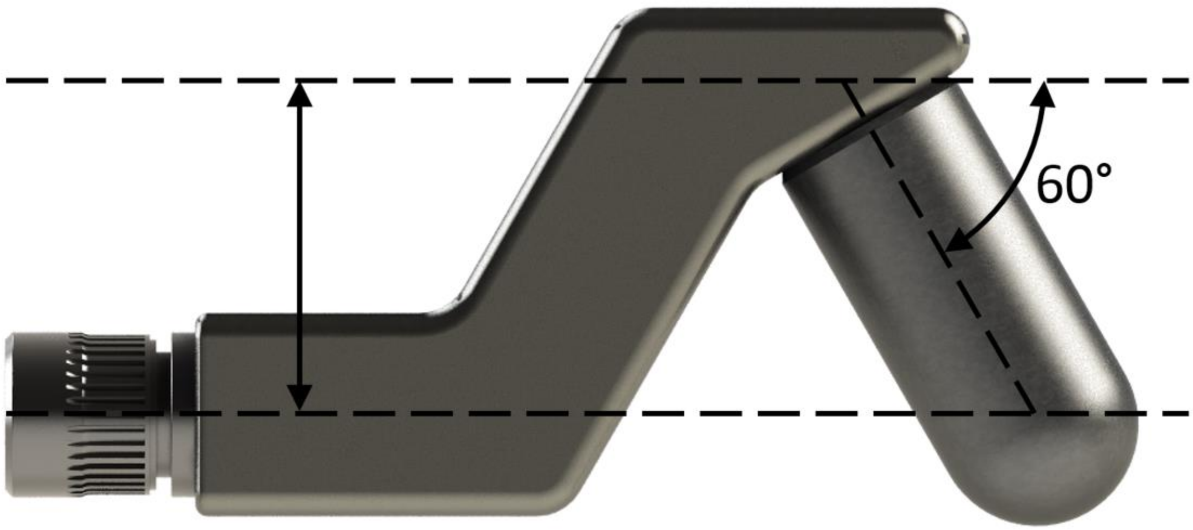

Figure 16: Geometry of terminal device components: body and terminus

The proximal end of body contains a ½ -20 threaded hole for a threaded rod attachment. The majority of prosthetic socket designs used use a ½ -20 threaded insert for connection to terminal devices. The distal end of the body has a ½-20 threaded hole for terminus connection. A threaded rod was used as connection between the terminal mating surface and the body to ease manufacturing of the body and to allow for dissimilar materials to be used for each component. The distal end of the body has the ½-20 threaded hole angled at 30˚ from the horizontal. This feature was derived from testing explained in depth in Section 7.1.3 to optimize ease of insertion of the mating surface and visual feedback. A vertical offset of 1.5 inches elevates the terminal device such that the spherical mating surface was positioned on the same plane of the wrist socket. This feature was incorporated from feedback from Sections 7.1.3 and 7.2.2. The mating surface contact point was intended to be positioned in the plane of the wrist socket so that the contact point would occur at the position of the amputated limbs phantom fingertips. Figure 17 shows the positioning of the mating surface contact point in relation to phantom fingertips of an UEA.

Figure 17: Terminal device with translucent overlaid average hand size showing positioning of mating surfaces with respect to the wrist

This feature proved to be valuable for the UEA in control of the terminal device due to inherent muscle memory. Aluminum was chosen as the body material for its strength, stiffness, and chemical resistance which will be discussed further in Section 6.4.5.

One last feature considered when designing the terminal device body was a vibrational damping element. Segmental vibrations are low amplitude high frequency vibrations that can cause physiological damage to nerves and vascular tissue over long periods of exposure. The tractor environment creates these segmental vibrations that could propagate through the controls and cause discomfort in the user. The team considered both material damping characteristics as well as other damping mechanisms when researching this topic. However, after thorough conversation with industry experts as well as testing detailed in Sections 7.1 and 7.2, the team discovered that segmental vibration propagation through the device body was not a concern and the user did not experience any discomfort. After addressing this concern, the team decided to move forward with the static aluminum body design.

6.4.3 Mating Surfaces Interface

The mating surface of the final design incorporated a hemispherical surface at the distal end of a cylindrical rod that mated with a recessed hemispherical contact surface within the adapter. Initial test results detailed in Section 7.1.3 showed the possibility of binding between the two conical mating surface geometries at the far ROM of the hydraulic control lever. The large angular deviation of this control caused disengagement of the two surfaces and therefore a loss of control. The new mating surface geometry addresses this concern with the spherical contact surfaces and the drafted walls of the adapter. The spherical surfaces allow for constant contact between the terminal device and adapter while the drafted walls allow for angular deviation about the center axis of the adapter through the ROM of the control. Figure 18 demonstrates the angular deviation tolerance of the new mating surface design.

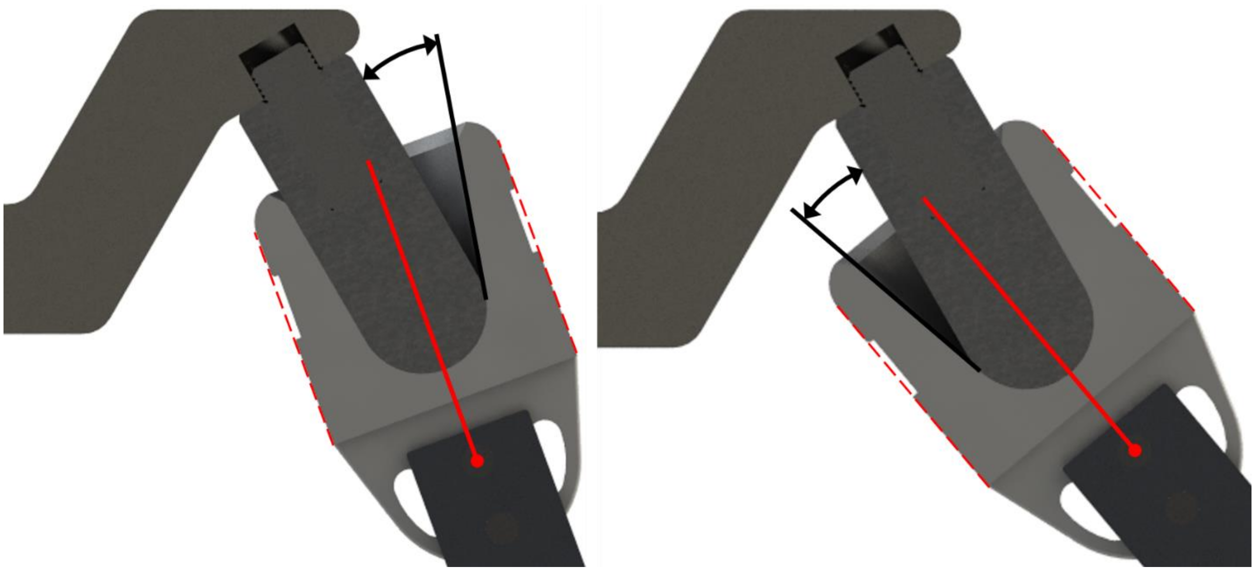

Figure 18: Cross-section showing concept behind angular deviation tolerance

The final mating surface design incorporated the design features of the conical geometry design detailed in Section 6.3.2 while incorporating a greater angular deviation tolerance. Lastly, the terminus was designed to be easily manufactured from 1" diameter stock material. The cylindrical rod geometry facilitates component ordering and machining.

6.4.4 Adapter

The adapter was designed with the functions of supporting the female mating surface geometry as well supporting the connection to the tractor controls. One main design goal was to design the external geometry of the adapter to mimic that of existing knobs on tractor controls. This external geometry would ensure that an unaffected user could still operate that piece of machinery without being hindered by the prosthetic adapter. Figure 19 shows the external geometry of the adapter.

Figure 19: Model of adapter connected to tractor control using off-the-shelf hardware

The connection between the adapter and the control must be rigid enough to transmit force from the user to the machine and universal enough to connect the adapter to a variety of controls including steering wheels, throttle levers, joysticks, and hydraulic levers. It must also have an adjustable orientation such that a universal design mounted on any control can be custom installed for its individual user's unique reaching angle.

At the prototyping phase, the connection is achieved with aluminum bar stock, hose clamps, pipe insulation, and other conformal foams. The base of the adapter has a flat aluminum bar that is fixed parallel to a control lever using the hose clamps. The lever and extension together are enclosed in pipe insulation and other conformal foam to create a uniform compression surface. The final design will incorporate similar features to the prototype version. Aluminum bar stock serves as rigid structural support for the connection. Conformable poron urethane adhesive backed foam of 0.5" thickness is attached the aluminum stock to create a surface adaptable to the various control interfaces of agricultural machinery.

The adapter is pinned by a nut and bolt to its connector extension at a central pivot, and its orientation is determined by a second nut and bolt through one of three holes. This configuration creates three discrete angle options. The adapter connector prototype is large because it is 3D printed in ABS which does not reflect the actual strengths of a solid injection molded thermoset polymer. The final design will incorporate a more permanent antivibrational fastener system where the user can adjust the angle of the adapter during the installation phase and then set the angle with the antivibrational hardware.

6.4.5 Materials Selection

Researching existing market products served as a useful starting point for material selection. CES Edupack material database software was the main source for all of the material properties and information in this section. Density was a major constraint on material because a heavy prosthetic, especially on the distal end of the limb, could cause discomfort or operational difficulties for the user. The acceptable market standard for weight of a hand/wrist attachment does not exceed 500g according to Bill Hanson of LTI. Plastic is typically used for components of prosthetics that are not load-bearing or at particular risk of wear/damage. Low-temperature thermoplastics, or shapeable plastics that soften when heated, are used in some low stress components. For such materials, a heat gun or hot water denatures the three-dimensional structure thus making exposure to heat from machinery and extended sunlight a serious risk. These materials were eliminated from the potential materials due to the high impacts associated with heavy machinery in agricultural environments. High-temperature thermoplastics, which soften at much higher temperatures (above 150° C), are used for high stress activity components. Thermosets or materials that can be heated and molded once into a permanent shape are also used in high stress activity components. Assuming the worst-case scenario that a machine might heat up higher than 150° C, a thermoset or high temperature thermo-plastic was more appropriate for the device.

After reviewing some of the common rubbers and plastics available, the team ordered several rubbers including polyurethane (60A, 70A, 90A durometer) and neoprene (60A, 70A durometer). Both sets of materials were weather and vibration resistant, suiting them to variable-weather and high-vibration environments. Although these materials performed well under most mechanical stresses, research showed that the specific chemical solvents found on farms would be a potential risk. During a visit with farming educator Ben Holmes of The Farm School, the team learned that diesel fuel, motor oil, hydraulic fluid, grease (lubricant) were the major chemicals to be concerned with. Using CES Edupack Level 3, neoprene and polyurethane were compared to other materials and initially appeared satisfactory in terms of strength and flexibility.

However, as the design changed to allow more rotation in the adapter and build a fixed wrist, the needs of the midsection material changed. With a fixed wrist, metals became much more suitable for the task, particularly light metals such as aluminum. This gave the body of the terminal device much greater chemical resistance and strength. The base however, which consisted of a male ½-20 thread was made of steel. It was a small piece that did not add significant weight, and it needs to withstand the fatigue of repeated attachments and removals. The farmer’s hook base is made of stainless steel and the team originally planned to use the same material. This ½-20 threaded rod with mate with a quick removal attachment of the user’s choice. This would allow the device to attach to nearly all modern prosthetic arms and do so in a quick and easy manner that the consumer is already familiar with.

With the materials for the majority of terminal device likely being aluminum, more research was done using both CES software and online resources to determine an ideal material for the adapter and the mating surface of the terminal device. Metal mating surfaces were deemed appropriate to undergo many fatigue cycles and high environmental impact. Materials used in door keys were researched due to the high number of cycles and low impact collisions they experience. Most keys are made of brass or nickel-plated brass. This research led to looking into the mechanical properties of fatigue and wear factors.

While researching wear factors, prosthetic knee socket data detailing the wear factor of common socket materials was found. Due to the similar motions and geometry to the terminal device and adapter design, emphasis was placed on this information. Ultra High Molecular Weight Polyethylene (UHMW-PE) was found to be a very common material due to its lubricious surface properties, appropriate strength, chemical durability, and wear characteristics. This information was confirmed using bubble charts in CES, comparing the yield strength of UHMW-PE against both fatigue strength (as seen in Figure 20) and chemical resistance to organic solvents such as oils and fuels (as seen in Figure 21).

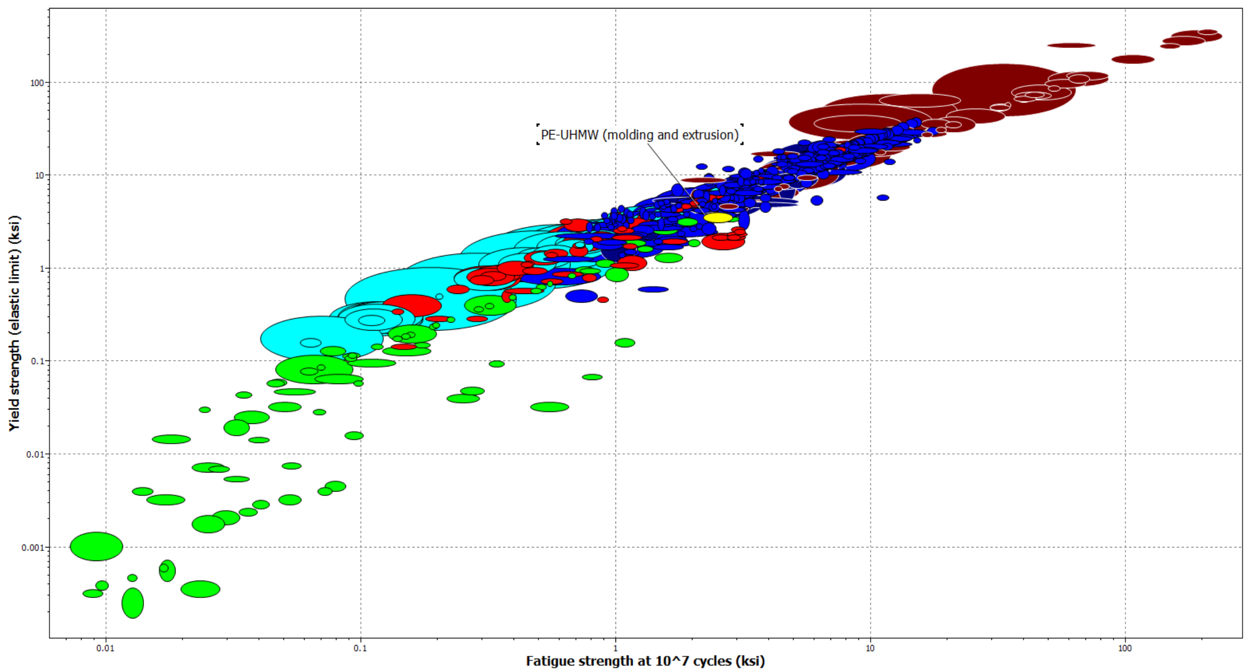

Figure 20: Yield Strength vs. Fatigue Strength

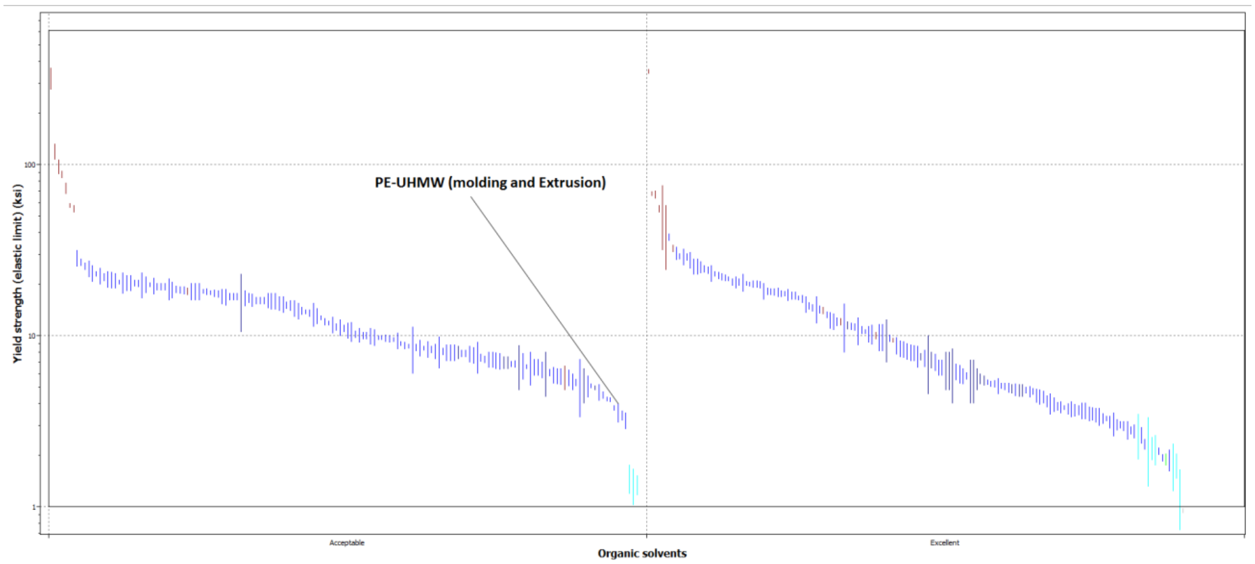

Figure 21: Yield Strength vs. Resistance to Organic Solvents

When selecting the materials, one of the most important properties considered was the wear factor of the materials, would show how well the materials would withstand repeated use and slippage. Research on knee sockets and related geometries has developed the wear factors for several different materials on UHMW-PE in the Journal of Engineering in Medicine as seen below in Table 2.

Table 2: Wear Factors of Common Materials[47]

Average wear factors, standard errors and surface roughness results for eight wear tests. Group A: 0.005–0.008 μm; Group B: 0.01–0.019 μm; Group C: 0.033–0.040 μm

Material	Surface roughness R_a (μm)	Average wear factor (1×10^{-9} mm^3/N m)	Standard error (1×10^{-9} mm^3/N m)
Alumina	0.016	10.8	1.1
Zirconia	0.005	7.4	1.6
CoCr (lapped)	0.010	11.3	1.0
Stainless steel (lapped)	0.017	11.5	1.1
Stainless steel (fine lapped)	0.008	6.1	0.75
CoCr (hand polished)	0.019	12.6	1.2
CoCr (cast)	0.033	16.5	2.4
CoCr (cast, sintered)	0.040	13.8	2.1

With more information, possible alternatives to aluminum for the mating surface material were considered. Aluminum is a rather soft metal and if a consumer were to bump the device against steel surfaces inside a tractor, scratches and small indentations could form on the mating surface. Although not a structural risk, this would increase the surface roughness which would result in a greatly increased wear factor. UHMW-PE is typically used with a cobalt-chrome (CoCr) piece in hip sockets,[47] however, further research showed the materials high cost proved to be a limiting factor in keeping the design costs down. Steel was then considered for its higher resistance to scratching and low wear properties. A concern with steel however was its high density, which was particularly important as the mating surface is located at the distal end of the device. A high weight at the end of the device would further extend the center of gravity of the device, making it potentially uncomfortable and cumbersome after extended use. After further research, titanium was determined to be the ideal material due to its lower density than steel and higher surface strength that aluminum. Further research into the wear factor of titanium lead to research reported by Rensselaer Polytechnic Institute, seen below in Figure 22.[48] Titanium was found to have a higher wear factor against UHMW than the previous metals, but it was still low enough not to be a concern.

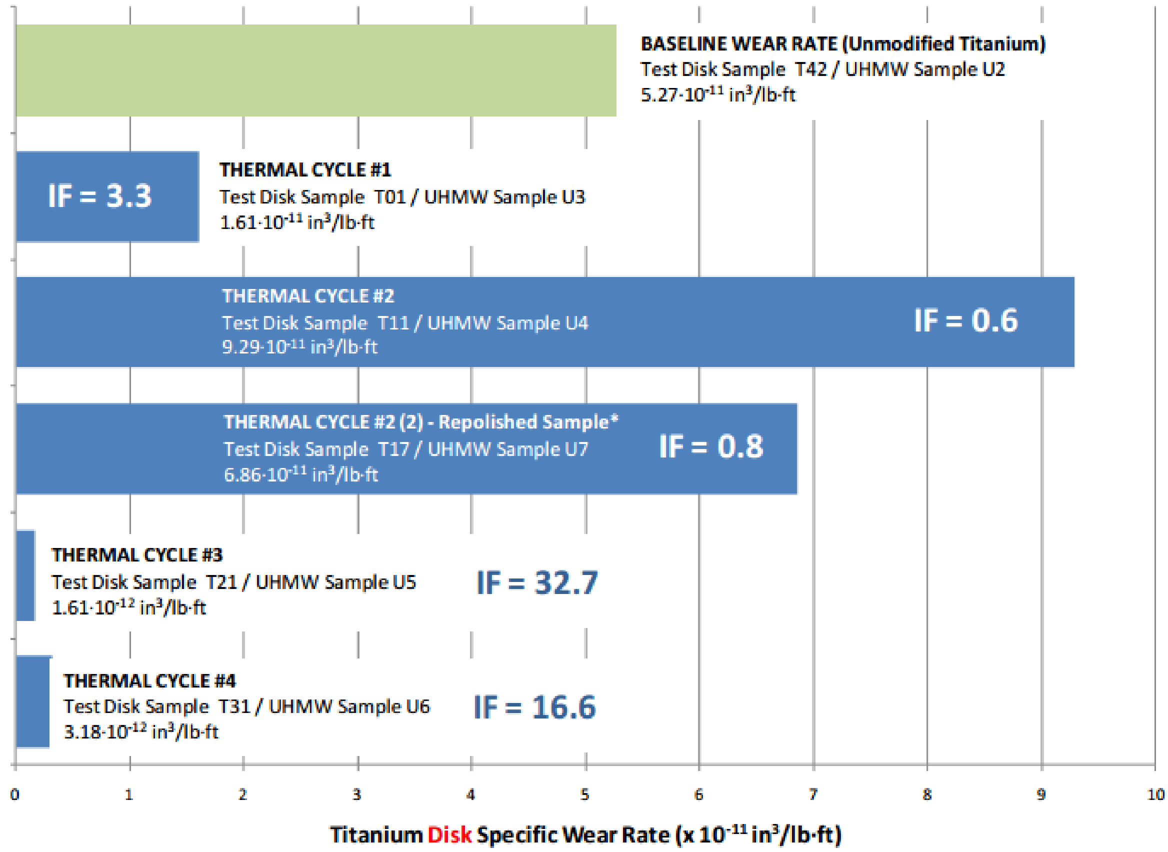

Figure 22: Titanium wear data

In the final prototype, 6061 aluminum was used for the midsection due to its wide availability and manufacturability. High-Strength Grade 5 Titanium was used, again for its availability and high strength compared to other titanium alloys.

7 Testing & Analysis

7.1 Field Testing

The first phase of evaluating the prosthesis design was testing prototypes on an actual tractor. Tests were designed to evaluate device ergonomics, verify effectiveness, determine optimal terminal device angle relative to the forearm, and acquire qualitative user feedback to improve device geometry. Ergonomic considerations were fatigue and strain of the arm and shoulder, the amount of shoulder flexion and the amount of lateral spinal flexion. User feedback evaluated effectiveness of using the terminal device at actuating the different controls, user confidence level of manipulating controls, and speed of transition between controls. This test was performed three times, each time with new iterations of terminal device and adapters.

7.1.1 Test Fixtures & Prototypes

Testing the prosthetic system for usability required a device that allowed a test user with a full biological arm to simulate being a transradial amputee. To review, the factors in which a transradial prosthetic arm differs from a biological arm are:

- No dynamic wrist joint
- Limited (<50% typical range of motion) or no forearm rotation
- No distal tactile sensation

A fixture for user testing must artificially, temporarily, and repeatedly limit the user's biological arm without significantly affecting the biomechanical motions of actuating the controls. This change was accomplished by enclosing the test user's forearm and hand in a rigid PVC tube as seen in Figure 16. This full enclosure bypasses the wrist joint and inhibits user tactile perception except at the forearm attachment point. The test arm attaches to the user's forearm by an optimal diameter that enables a pressure fit with the tube's interior. The tube attaches at the proximal forearm (rather than the upper arm or distal forearm) so as to decrease rotational range of motion without interfering with the elbow joint. In order to simulate the worst case scenario transradial amputee, rotation is further limited by two metal extensions from the proximal end of the tube. These two stops, one lateral (marked "a" in Figure 23) and one medial to the elbow joint, contact the biological arm and inform the user of accidental pronation or supination. The distal end of the test arm (marked "b" in Figure 23) is a mechanical attachment point for the terminal device mating surface.

Figure 23: First iteration of test fixture in use on Kubota tractor

The tractor used for testing was a Kubota B2150 model with a front-end loader. The terminal device and adapter prototypes were 3D printed. Prototype adapters were secured to the different controls using pipe clamps, pipe insulation, and aluminum bar stock (1/8" thickness). Adapters were added to the throttle control lever, the hydraulic lever, and the hitch adjustment lever.

7.1.2 Test Design & Purpose

The test required the test user to manipulate the tractor controls both with and without the test fixture to create a basis of comparison for evaluating the device. The control sequences utilized the hydraulic, throttle, and hitch adjustment levers. The user manipulated the hydraulic lever to pick up piles of debris, scrape the ground in a leveling pattern, and do a plowing motion. The user changed the engine speed with throttle lever and the hitch height with the hitch adjustment. The order of actions was randomized in each test run to best mimic typical work in an agricultural environment.

Baseline testing was completed without modification to the tractor or user. Upon completion of the baseline, adapters were installed on the tractor and the user was fit with the test fixture. The user then completed the same tasks in another random order. The user rated the device qualitatively on ease of use, confidence in control, successful mating, and speed of transition between controls. Testing was also recorded on video for evaluation of biomechanical motion. In addition to dynamic use, installation angle was important in the first test. The two critical angles are the angle of the terminal device with respect to the line of the forearm and the angle of the adapter with respect to the lever arm.

The team used a goniometer (a biomechanical angle measurement tool shown in Figure 24 below) to monitor the range of motion at the elbow and shoulder during control actuation.

Figure 24: Goniometer used for measuring angles in biomechanical applications[49]

Biomechanical motions were evaluated with video footage taken lateral and posterior to the test user. Red tape on the user's body marked lines of the spine and right humerus to observe lateral flexion and abduction of the shoulder, respectively, as shown in Figure 25 below.

Figure 25: Red tape on operator to show biomechanical motions, with and without test fixture

The team considered using electromyography (EMG) to observe muscle stimulation in the test user to determine the test arm's effectiveness at mimicking an amputated arm, but the equipment could not be transported to the test site.

7.1.3 Results

The user conveyed positive feedback after the test was completed. First, the user was able to manipulate the throttle lever, hydraulic lever, and hitch adjustment lever. The user indicated that there was minimal distraction when mating the terminal device with the adapter. There were minimal amounts of eye deviation from the specific tasks when switching from control to control. The specific tasks were all completed with similar precision to the baseline tests. The speed of actuation was not hindered with the prosthetic and the tasks were completed in a similar timeframe. The only concern of the user was that the weight of the test fixture caused slight strain in the shoulder muscles after prolonged testing. The test fixture is much heavier than the actual device due to the large section of PVC piping used to limit the range of motion of the wrist, and the shoulder must also support the weight of the full biological arm.

The new mating surface geometry allowed successful actuation of the hydraulic lever throughout the full range of motion without binding. The spherical mating surface and angular deviation tolerance allowed for smooth actuation over the entire range of motion.

First, the proof of concept was determined with successful force transmission from the terminal device to the different controls. The hydraulic lever was successfully actuated to complete tasks including scooping and dumping. Also, the throttle lever, an area of significant concern due to the much higher force required (5 times) was actuated successfully setting the engine at a variety of different speeds. One of the design takeaways from this preliminary test was to set the terminal device at an angle of 30 degrees from the center plane of the socket. This angle provided the user with sufficient visual feedback as well as successful mating and decoupling. The adapter angle was also found to be successful at an angle of 180 degrees for the hydraulic lever and an angle of 90 degrees for the throttle lever. One last takeaway from the preliminary test was that the male and female mating surface geometry could not be exact negatives of each other. The range of motion in actuating the hydraulic lever proved to be problematic during testing. Dumping the front-end loader requires the user to actuate the lever away from the median plane at the far reach of their range of motion. This reach causes the hydraulic lever angle to change such that binding occurs between the male and female mating surfaces. Figure 26 below demonstrates this failure mode.

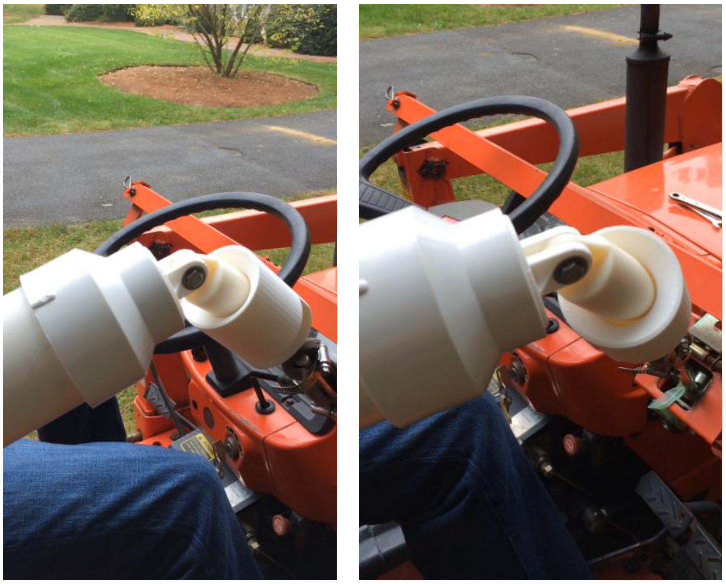

Figure 26: Full engagement at hydraulic neutral position vs. semi-engagement at hydraulic bucket dump position

After recognizing this shortcoming in the design, the team implemented a slightly modified mating surface geometry. The new geometry involved a greater radius of curvature at the point of the terminal device. The adapter incorporated the same surface geometry in negative and an angled revolved cut around the wall of the cavity. The revolved cut allows for an angular tolerance from the center mating axis. This new geometry is shown in Figure 27 below.

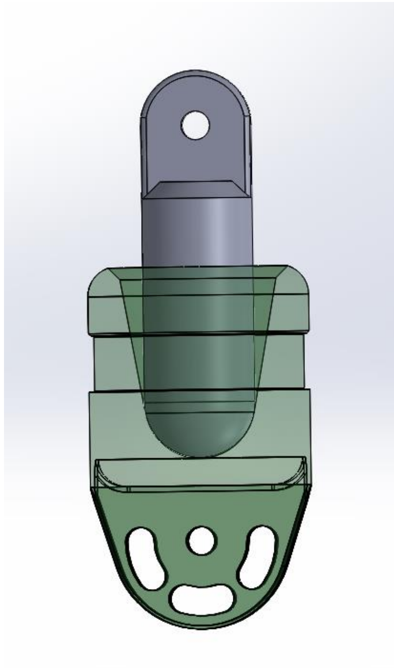

Figure 27: Cross-section of refined prototype model

The second round of prototype testing with the terminal device and adapter pair confirmed functionality. A 60 degree angle in the terminal device from the axis of the pylon sufficed to actuate all of the controls with adapters. The adapter on the throttle required an orientation of 105 degrees from the lever shaft. The hydraulic required an angle of 10 degrees from the axis of the control shaft, and rotation of 55 degrees clockwise about the shaft away from the back plane of the tractor. This setup is shown below in Figure 28. The hitch adapter was positioned in front of the hitch lever, parallel to the lever's axis, with zip ties securing the adapter to the lever.

Figure 28: Setup of adapters on hydraulic lever and throttle

7.2 Design Validation Testing

7.2.1 Test Design & Purpose

The second phase of testing involved a field visit to a transradial amputee's farm to validate the prosthetic adapter design in an agricultural environment. The test was secured through outreach to the National AgrAbility Project who identified a transradial amputee who owned and operated his own farm. The test took place on a Zetor 8441 tractor, a much more advanced machine then the tractor used in phase one testing. The test subject used a stainless steel work hook as a terminal device to perform his everyday farming tasks including machine operation.

The goals of this test were to gain user feedback with a final prototype in a relevant farming environment. The final prototype was fabricated to match the dimensions of the users worker hook and incorporated all of the design changes from the first iteration of testing. One major area of exploration was the biomechanical concerns of the device. The team wanted to validate the ergonomics of the device and ensure there were no unnatural motions, excessive reaches or body contortions, and no excessive strain or fatigue. Also, the team aimed to address early concerns of segmental vibration propagating through the terminal device. The second major area of focus for this test was the validating the mechanical design. The first goal was to ensure that the design worked with the test subject and the anatomical considerations were correct. The team wanted to verify that the device could be securely attached to a prosthetic socket and oriented at the correct angle without excessive effort. Also, the team wanted to validate that the body design oriented the mating surface in the correct anatomical position in both the distal distance and wrist plane. The team wanted to gain qualitative feedback on the user's confidence level while performing everyday farming operations. Specific areas of concern were speed of transition between controls, confidence of manipulating each control, ease of use and successful mating with each control. Lastly the team wanted to gain feedback on the design features and any other functional improvements that could be incorporated to improve the design.

The test procedure began with an introduction of the project and an initial interview of the test subject. The interview served to provide a baseline for the farmer's prosthetic use on the farm. The team paid certain to attention to the pros and cons of using the work hook while operating a tractor or other heavy machinery. After the introduction, the team presented the testing prototype to be used by the farm. The prototype comprised of a machined aluminum body, a titanium terminus, and 3D printed ABS adapters. The terminal device threaded directly to the socket of the farmer. The correct orientation was ensured through compression of a neoprene rubber gasket within the socket. Next, seven adapters were attached to various hydraulic and hitch levers, gearshift levers, and the steering wheel. The subject was instructed to complete various operation tasks used in daily farming. Feedback was recorded continuously throughout the test and video cameras mounted within the tractor captured the operations for future analysis of biomechanical considerations.

7.2.2 Results

The second phase of testing yielded VOC validation of the mating surfaces concept. After installation and a few slight adapter angle adjustments, the user was able to demonstrate various operations used on a farm. The user had previously communicated trouble with operating the hydraulic joystick with the workers hook device due to the hook involuntarily opening at the far left motion of the control. The user conveyed confidence in control during the test when using the hydraulic lever throughout the entire range of motion. The user was able to actuate the joystick at the far left range of motion without the fear of disengaging with the control. The user also conveyed that the device was beneficial when operating the gearshift lever. This lever requires the contralateral limb to remain on the steering wheel while the prosthetic device engages the lever to change the tractors gears. The user did not have to voluntarily connect to the lever due to the mating surface design. The user also displayed positive feedback when using the steering wheel adapter. Previously, the test subject had used a modified Brody Knob with an eyelet attachment to be used with the workers hook terminal device. The user expressed that the eyelet design of the Brody knob required conscious disengagement when switching between controls. The user found that the steering wheel attachment was successful in multiple ways. First, the user expressed that they felt confident in the control over the wheel to the extent that, "if you [rotate] this too quickly, the tractor is going to roll over." The user conveyed that they were extremely pleased with the operation of the steering wheel adapter and also commented on the ease of transition between controls. The user said the transfer between the wheel and the gearshift lever did not require any conscious effort.

The user also expressed comfort throughout the entire test. The user indicated that there were no unnatural motions required to actuate the controls and nothing required excessive force. The user's torso did not deviate greatly from its standard posture in order to accommodate the lack of motion. The user did indicate that there was trouble when manipulating the rear PTO's hydraulic controls. The user expressed that this was due to the stiff nature of the controls and required additional force. The user then indicated that if the adapter were secured to the control in a more permanent and rigid fashion, they would not foresee any problems in using that control. The team addressed the concerns of segmental vibrations propagating through the terminal device and the user assured that there was no discomfort due to the machines vibrations. Lastly, the expressed that the weight of the device was not a concern and there was no discernable difference between the prototype and his everyday work hook.

The user did have suggestions to improve the design. First, the user suggested that a feature should be incorporated in the terminal device body that would secure the cable of the harness. This cable would not be used to operate the device however it would help maintain retention of the prosthetic socket through tension in the cable. A second suggestion for improving the device was to steepen the angle of the terminus with respect to the body. The user indicated that if the angle of attack was slightly steeper, insertion of the mating device would be much more intuitive. The user recognized that the adapter installation to the machine was temporary and therefore not at their optimum rigidity. They did however mention that if the adapters were designed to replace the manufacturer knobs and be located directly on top of the shaft, the actuation of the controls would be easier. The user found that in some of the motions of the controls with large angular deviations, there could be possible binding in the far ranges of motion. This was slightly due to testing different 3D printed adapter draft angles, however the user expressed that a compliant wrist feature could help alleviate this issue. The user indicated that if a conforming material were incorporated in between the terminus and terminal device body, there could be a small tolerance for slight angular deviation at the wrist joint in instances of extreme ranges of motion.

In conclusion, the user indicated that they were happy with the performance of prosthetic adapter. The user validated the functional requirements and verified the biomechanical considerations of the device. The user also verified that a device like this has merit and possible marketability to the agricultural amputee community. Lastly, the user expressed interest in purchasing the prosthetic adapter for their tractor and other machinery.

7.3 Design for Manufacturability Analysis

The team analyzed the main three components for Design for Manufacturability (DFM) after successfully validating the prototypes performance in a relevant testing environment. The team considered cost and weight reduction as well as various manufacturing processes in order to plan for production of the of realistic production quantities. A decision on actual production quantities requires further market analysis and is dependent on the chosen exit strategy from Capstone Design project. The team plans to execute an exit strategy during the spring of 2015.

7.3.1 Body

The terminal device body was modified greatly from the original prototype to minimize material and process requirements. The original prototype incorporated unnecessary amounts of material at the distal end of the device that increased the overall footprint of aluminum stock required. The final design minimized the size of the overall footprint of the body and allowed for multiple bodies to be made from a single block of 1” thick aluminum stock. The ½-20 tapped hole was relocated on the body to minimize the amount of material required and eliminate possible snag points in the design. The body is estimated to require 1 machining process on the mill to cut the stock down to the desired body geometry. The body then required one drill and tap for the ½-20 threaded inserts at the wrist and terminus attachment points. Attention was paid to minimize the amount of intermediate component relocations within the machining jig. The final design requires only 5 machining processes. Figures 29 and 30 below shows the initial prototype design of the body and the refined design of the body, and the technical drawing sent to three different machine shops to be quoted at varying quantities.

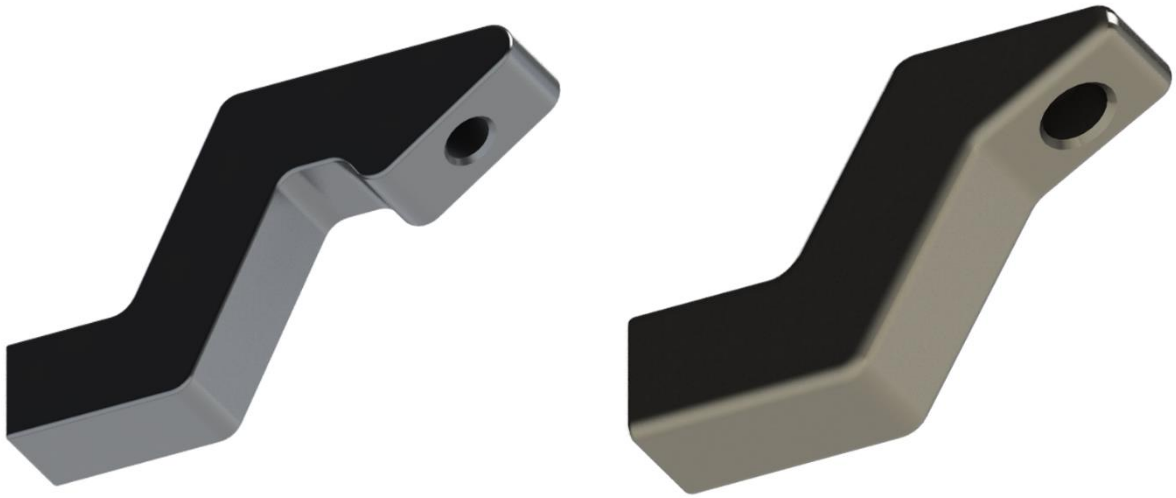

Figure 29: Initial prototype design and the refined design of the body

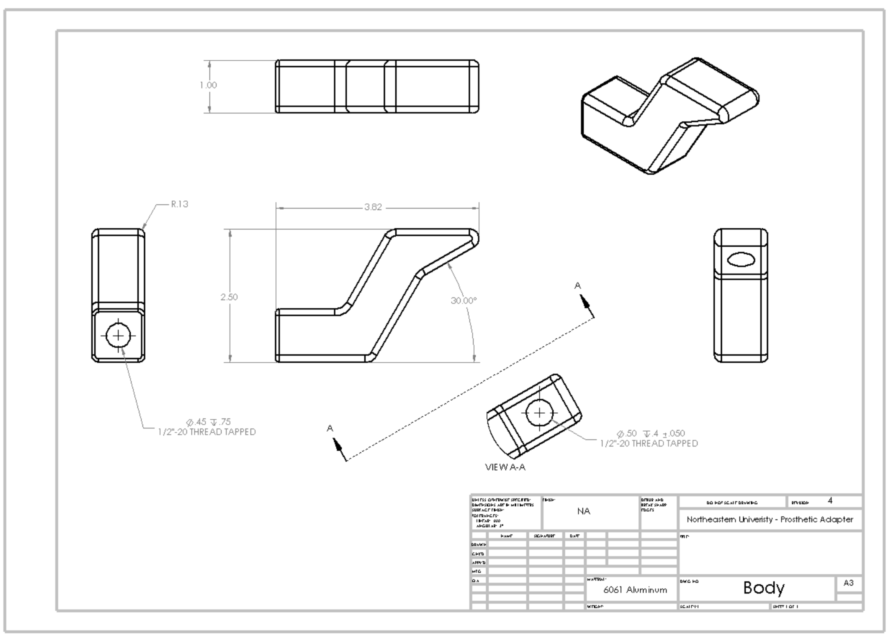

Figure 30: Technical drawing of body sent to manufacturers to quote

7.3.2 Terminus

The terminus design was kept as simple as possible in order to minimize machining requirements during production. The terminus can be manufactured from readily available 1" cylindrical titanium stock. The final design requires only three machining processes including one lathe operation to create the hemispherical mating geometry, one hole drill-out and finally tapping the hole for a ½-20 threaded rod insert. Figure 31 below shows the technical drawing sent to three different machine shops to be quoted at varying quantities.

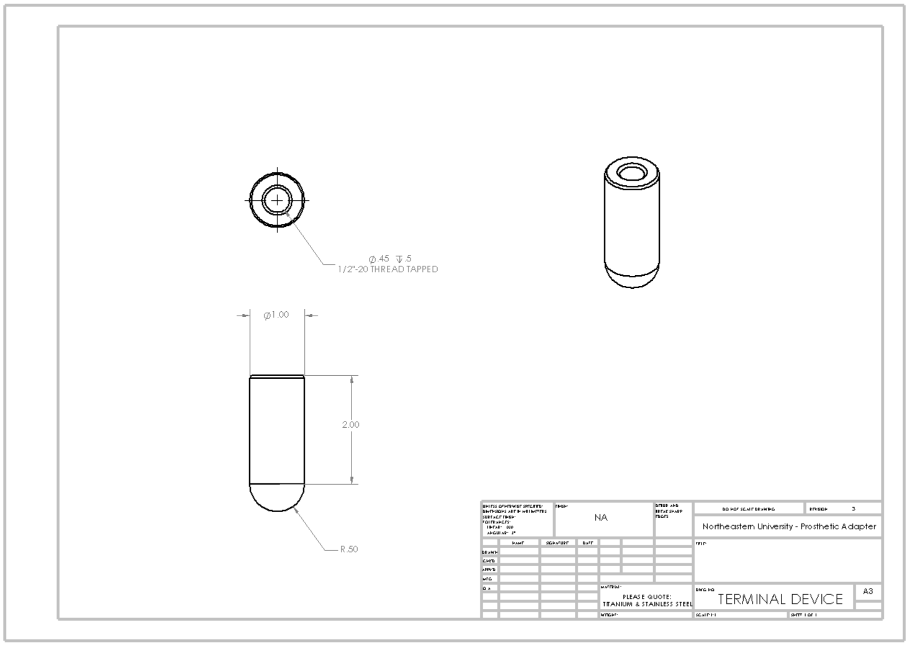

Figure 31: Technical drawing of terminus sent to manufacturers to quote

7.3.3 Adapter

The adapter required the most change from prototyping to final design. The original prototypes were fabricated using 3D printed using ABS model material with non-dissolving support material. The initial design incorporated several features to accommodate adapter angle adjustment during testing. The different through holes and adjustment support flanges would require complex mold and slide designs in a production environment. Also, the complex contours of the external sidewalls of the adapter used to facilitate hose clamp placement would add increased complexity to the mold design. In order to create a production ready design, the team incorporated an extruded boss at the base of the adapter in which a threaded PEM insert could be placed. This insert would allow for the complex angular adjustment to be accomplished through a separate piece of hardware incorporated in the control connection component of the system. The elimination of these complex features in the adapter design allows for a much simpler two piece, one action mold design which greatly reduces tooling cost and complexity. Last, the adapter design was revisited to ensure universal wall thickness was uniform throughout the piece and that the maximum deviation of the wall thickness did not deviate more than 125% of the minimum wall thickness. Also, a 3˚ draft was incorporated into the wall geometry of the adapter to facilitate part removal from the mold. Lastly, injector pin locations were placed at noncritical portions of the design to reduce risk of damaging important mating surface geometries. A STEP file of the final adapter design was sent to three different injection molding manufacturers to be quoted at various quantities in UHMW-PE or a recommended similar material. Figure 32 below shows a cross-section and isometric view of the STEP file sent to be quoted.

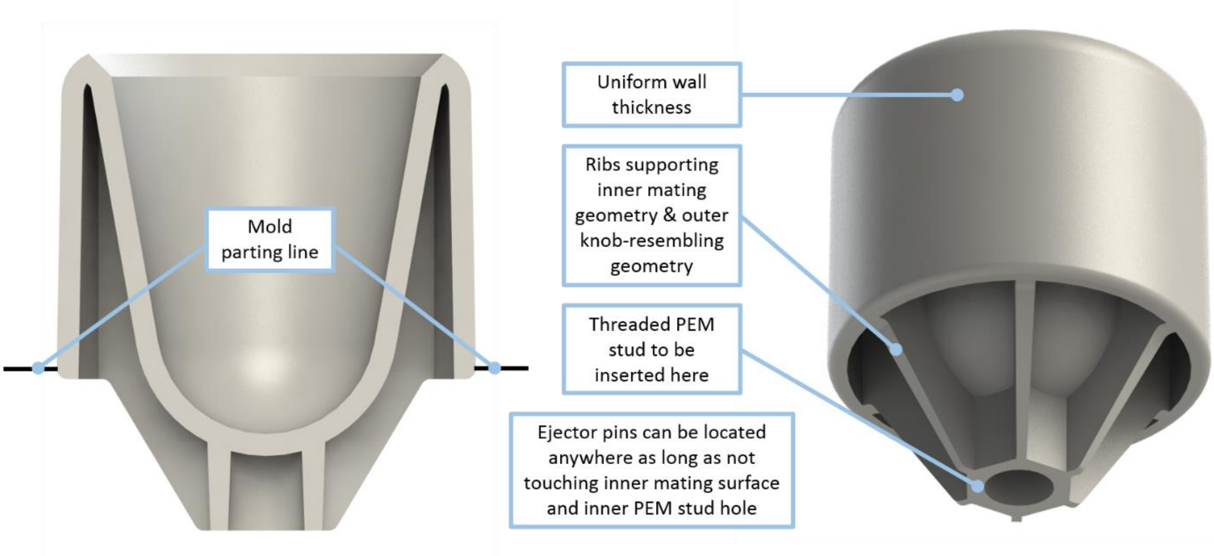

Figure 32: Adapter design after DFM considerations: cross-section & isometric view

8 Intellectual Property

8.1 Description of Problem

The problem addressed by this capstone project is to provide a solution that enables unilateral, transradial (TR) upper extremity amputees (UEAs) to independently operate heavy machinery in the agriculture industry.

8.2 Proof of Concept

Farming has the highest prevalence of amputation due to occupation in the United States. There are not many prostheses on the market specifically designed to aid farmers who have lost a limb and need to continue working in agriculture to carry out their livelihood. Of the farming and general use prostheses, none enable a farmer to operate a tractor or other piece of agricultural machinery with ease. The purpose of this prosthetic adapter is to enable a right-side unilateral, TR amputee to operate agricultural machinery. It consists of a two-part solution. First, there is a terminal device that connects with a ½”-20 threaded hole of a standard prosthetic socket. Next, there is an adapter the mounts on the controls within a tractor’s cockpit, such as the steering wheel, hydraulic lever, throttle lever, and hitch lever. The adapter points off the controls at angles pointing towards the operator and uses off-the-shelf hardware to connect to the controls. The end of the terminal device is a hemisphere, which is inserted into a female hemisphere with drafted wall to allow for angular deviation tolerance as discussed in Section 6. Once fully mated, the terminal device comes to a hard stop, providing feedback to the operator. The operator can then move his or her residual limb, which through the socket and terminal device transmits force to the controls, moving them as desired. The open adapter shape self corrects the operator’s aim if the terminal device enters the adapter off centered by approximately ±1” or misaligned by ±25°. The shape allows for quick engagement and disengagement, which eases the use for the amputee operator in manipulating the tractor’s controls.

8.3 Progress to Date

Through the Summer II semester, thorough research was performed in three main fields of prosthetics: athletics, agriculture, and underdeveloped countries. It was chosen to focus on the needs of agriculture worker amputees. The niche need of enabling such an amputee to operate heavy machinery while working was selected as the group's problem statement. Research into existing products in this focus was completed. Initial designs were brainstormed through September, and a final design was chosen in November. An invention disclosure form was filed through Northeastern University's Center for Research Innovation before Friday, October 3, 2014, and it was given invention number INV-15024. A provisional patent was filed on October 20, 2014. Field testing was performed multiple times through October and November as the final design was iterated. A design validation and feedback test was performed in Rumford, ME on Robert Cameron's farm. Mr. Cameron has owned and run his own farm since 1968. He suffered a traumatic right-side unilateral, transradial amputation in 1969, and has continued to run his own farm since then. After receiving design validation and constructive feedback from Mr. Cameron, the team performed a Design for Manufacturability (DFM) analysis on the three main components: body, terminus, and adapter. Initial STEP files were sent to manufactures to provide DFM analysis on November 10th. Final STEP files and technical drawings were sent out to manufactures to quote various quantities (three machine shops and three injection molding manufactures) on November 25th. The team started brainstorming exit strategies to push this solution to the market.

8.4 Individual Contributions

Jacob's work focused primarily on researching materials to be used for the project as well as purchasing the materials. Jacob facilitated purchasing a used "Farmer's hook", necessary hardware, and bulk materials for all iterations and the final prototype. Jacob also performed the majority of the machining on the final prototype.

Carly's work was on the biomechanical aspect of the design process. She researched biomechanical factors such as the anthropometric variation between potential users, ergonomics associated using the controls, and body motions of the operator within the tractor's cockpit. Carly also led the design and editing of the final poster as well as proofread and edited the paper.

Jon's work focused on designing the mating mechanism, performing field tests within the cab of a tractor, providing a tractor to perform field tests on, and putting the design brainstorms and thought processes into words. Jon wrote a lot of the content in paper, especially the Sections 6 and 7. Jon also led the design and editing of the final presentation.

Andrew's work focused primarily on designing the mating mechanism and adapter, modeling the designs, rendering the models, prototyping and fabrication, leading the DFM analysis, and reaching out to manufacturers for DFM feedback and quotes. Andrew also led the editing of the final paper and intellectual property effort including filling an invention disclosure and securing a provisional patent application.

Danny's work focused on the biomechanical aspects of the design as well as reaching out to all external contacts. Some contacts that he reached out to includes: Limited Technologies Inc., NextStep B. & P., and AgrAbility. Danny facilitated the design validation test in Maine, and led the project branding effort including website (thefarmarm.org), email address (thefarmarm@gmail.com), video editing, business cards, and pursuing intellectual property.

8.5 Future Work

The team is waiting on quotes from manufacturers for the two machined components and one injection molded part for tooling and price per part costs. A more extensive market analysis will be performed to determine actual production quantities to seek. An in depth look into possible exit strategies will be performed in the spring. A full patent will be pursued whether through Northeastern University or independently, depending on the Northeastern University Center for Research Innovation's final decision on pursuing this project's solution further or not. A few initial exit strategies considered are starting a small hardware company and seeking funding for production through angel investors and hardware incubators and/or accelerators such as Bolt, a Boston-based hardware startup accelerator that helps early-stage hardware companies get their products to market by offering funds, mentorship, resources and contacts. Another possible exit strategy would be to go to companies in the prosthetic and orthotic industry with established manufacturing connections and distribution networks and sell or donate the intellectual property from our project to the companies to commercialize.

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10 Appendix A: Glossary

APRL - The Army Prosthetic Research Lab

CAD/CAM - Computer-aided drawing/computer-aided manufacturing

CP - Certified Prosthetist

CPO - Certified Prosthetist and Orthotist

DARPA - Defense Advanced Research Projects Agency

DFM - Design for Manufacturability

DPT - Doctor of Physical Therapy

HCP - Health Care Professionals

HDPE - High-density polyethylene

Hemipelvectomy - LLA which removes all of the lower limb and part of the pelvis

HIC- High-Income country

Hip Disarticulation - removing the entirety of the limb including the femur

IED - Improvised Explosive Device

ISPO - International Society for Prosthetics and Orthotics

LIC - Low-Income Country

LLA - Lower Limb Amputation/Amputee

MS - Master of Science

PP - Polypropylene

Residual Limb - the remaining portion of a limb after amputation, where the prosthesis's socket interfaces with the amputee

SACH - Solid Ankle Cushion Heel

Terminal Device - device attached to the wrist unit of an upper limb prosthesis that provides some functionality

TT - Transtibial: below knee amputation

TF - Transfemoral: above knee amputation

TH - Transhumeral: above elbow amputation

TR - Transradial: below elbow amputation

UAPH - Under Actuated Prosthetic Hand

UEA - Upper Extremity Amputation/Amputee

11 Appendix B: External Contacts

In approximate chronological order of contact:

Contact	Title	Organization
Brian Calandra	Licensed Physical Therapist	United States Army (Ipswich, MA)
Joseph De Mertine	M.D., Primary Care Physician	ServiMed Haiti (Boston, MA)
A.J. Warco	Director of Programs	A Leg to Stand On (New York, NY)
Rann Vannara	Prosthesis and Orthotist	Cambodian School of P & O (Phnom Penh, Cambodia)
Robert Hickey	Rocky Mountain Regional Sales Consultant	Ossur Americas
Pablo Rodriguez	D.P.T., Northeastern University	Performance Physical Therapy (Chelsea, MA)
Jeffery Ruberti	Ph.D., Associate Professor	Northeastern University (Boston, MA)
Arthur Graham	C.P.	NextStep B & P Inc. (Newton, MA)
Kristen Westfall	D.P.T.	Jump Start Physical Therapy & Sports Training (Newton, MA)
Richard Bruuns	Senior Associate and Physical Leader for Clinical Operations, transradial amputee patient at Jump Start Physical Therapy & Sports Training	Boston Children's Hospital (Boston, MA)
Bill Hansen	President	Liberating Technologies Inc. (Holliston, MA)
Byron Backus	C.P., Senior Fabrication Services Manager & Clinical Specialist	Ottobock (Minneapolis, MN)
Cale Konetchy	C.P., Clinical Specialist	Ottobock (Minneapolis, MN)
Paul Jones	Project Manager	National AgrAbility Project (West Lafayette, IN)
Craig Heckathorne	M.S., Research Engineer, Upper-Limb Prosthetics	Northwestern University Rehabilitation Engineering Research Program & Prosthetics (Chicago, IL)
Ben Holmes	Founder	Farm School (Athol, MA)
Nora Weaver	Student, transradial amputee	Farm School (Athol, MA)
Patrick Connors	Director	Farm School (Athol, MA)
Gail Lapierre	Outreach Specialist	Vermont AgrAbility (Burlington, MA)
Therese Willkomm	Ph.D., Program Director	Assistive Technology in New Hampshire, Department of Occupational Therapy at UNH (Durham, NH)
Leilani Carlson	Project Coordinator	Maine AgrAbility, University of Maine (Falmouth, ME)
Ellen Gibson	AgrAbility Specialists	Maine AgrAbility, Goodwill Industries of Northern New England (Lewiston, ME)
Robert Cameron	Farm Owner, right-side unilateral, transradial amputee	Private farm owner (Rumford, ME)

12 Appendix C: Medicare Pricing Data

Cost Summary from Durable Medical Equipment Medicare Pricing Data Analysis, and Coding:

Financing a Worker's Hook (Assuming Coverage)						
Item	**Long Description:**	**L-Code**	**Allowable Fee**	**State**	**Quoted Validity**	
Socket	*BELOW ELBOW, MOLDED SOCKET, FLEXIBLE ELBOW HINGE, TRICEPS PAD*	L6100	$ 1,989.35	ME	1/1/2014	12/31/2014
Cable	*UPPER EXTREMITY ADDITION, HEAVY DUTY CONTROL CABLE*	L6660	$ 109.38	ME	1/1/2014	12/31/2014
Harness	*UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), SINGLE CABLE DESIGN*	L6675	$ 150.42	ME	1/1/2014	12/31/2014
Workers Hook	*TERMINAL DEVICE, HOOK, MECHANICAL, VOLUNTARY OPENING, ANY MATERIAL, ANY SIZE, LINED OR UNLINED*	L6706	$ 375.71	ME	1/1/2014	12/31/2014
Estimated allowable for "Prosthetic Adaptor"	*TERMINAL DEVICE, SPORT/RECREATIONAL/WORK ATTACHMENT, ANY MATERIAL, ANY SIZE*	L6704	$ 550.15	ME	1/1/2014	12/31/2014
Starting Medicare code for new upper prosthetic devices	*UPPER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED*	L7499				
Estimated Cost Breakdown	Total Recommended Allowable (Medicare fee)		$ 2,624.86	ME	1/1/2014	12/31/2014
	Less Discounted Rate for Clinic (rough estimate)		$ (262.49)	ME	1/1/2014	12/31/2014
	Total Amount Billed		$ 2,362.37	ME	1/1/2014	12/31/2014
	Less Medicare Reimbursement (80%)		$ (1,889.90)	ME	1/1/2014	12/31/2014
	Patient Responsible (Limp sum payment)		$ 472.47	ME	1/1/2014	12/31/2014
	Less Secondary Carrier (if applicable)		$ (472.47)	ME	1/1/2014	12/31/2014
	Patient Pays (less medicare & secondary carrier)		$ -	ME	1/1/2014	12/31/2014

13 Appendix D: Project Management

Gantt chart followed and updated throughout the project:

Task Name	Duration	Start	Finish
Preliminary Research:	**10 days**	**Mon 6/30/14**	**Fri 7/11/14**
Athlete Amputee	10 days	Mon 6/30/14	Fri 7/11/14
Agricultural & Demographics	10 days	Mon 6/30/14	Fri 7/11/14
Developing Coutries	10 days	Mon 6/30/14	Fri 7/11/14
Existing Patents and Prior Art	10 days	Mon 6/30/14	Fri 7/11/14
Financial Information	10 days	Mon 6/30/14	Fri 7/11/14
Project Goal Setting/Alignment	1 day	Thu 7/10/14	Thu 7/10/14
Establish Market Space Criteria	1 day	Thu 7/10/14	Thu 7/10/14
Preliminary Round External Contacts	**7 days**	**Mon 7/14/14**	**Tue 7/22/14**
Brian Calandra, DPT	1 day	Sun 7/20/14	Sun 7/20/14
Rann Vannara, CSPO	1 day	Mon 7/21/14	Mon 7/21/14
Northwestern (Craig Heckathorne)	1 day	Tue 7/22/14	Tue 7/22/14
Dr. Joseph DeMertine	9 days	Wed 7/23/14	Mon 8/4/14
Robert Hickey of Ossur Prosthetics	9 days	Tue 8/5/14	Fri 8/15/14
Problem Definition Decision	**1 day**	**Thu 8/7/14**	**Thu 8/7/14**
Vote on Project Scope	1 day	Fri 8/8/14	Fri 8/8/14
Draft Problem Statement	1 day	Mon 8/11/14	Mon 8/11/14
Prepare Report	**3 days**	**Fri 8/8/14**	**Tue 8/12/14**
Assign Technical Roles	3 days	Fri 8/8/14	Tue 8/12/14
Prepare Presentation	2 days	Mon 8/11/14	Tue 8/12/14
Second Round External Contacts	**16 days**	**Tue 9/2/14**	**Tue 9/23/14**
Prosthetic Manufacturers (LTI)	16 days	Tue 9/2/14	Tue 9/23/14
Agricultural Researchers (FarmSchool)	16 days	Tue 9/2/14	Tue 9/23/14
Interview Target Population (IRB)	16 days	Tue 9/2/14	Tue 9/23/14
Second Round of Research	**16 days**	**Tue 9/2/14**	**Tue 9/23/14**
Biomechanics of cockpit research	10 days	Sun 9/7/14	Thu 9/18/14
Study different levers actuators and steering wheels	7 days	Sun 9/7/14	Sun 9/14/14
Take data on required forces	1 day	Mon 9/15/14	Mon 9/15/14
Prosthetist Visit (NextStep Bionics)	1 day	Tue 9/16/14	Tue 9/16/14
Begin solid designs	4 days	Fri 9/19/14	Wed 9/24/14
Place PO's on materials	1 day	Sun 9/21/14	Sun 9/21/14
Finish solid models	2 days	Mon 9/22/14	Tue 9/23/14
Start prototyping	6 days	Tue 9/23/14	Tue 9/30/14
Liberating Technologies Field Visit	1 day	Wed 9/24/14	Wed 9/24/14
Phone Conversation with AgrAbility	1 day	Mon 9/29/14	Mon 9/29/14
Prepare First Cap II Presentation	3 days	Sun 9/28/14	Tue 9/30/14
Prepare Second Cap II Presentation	**1 day**	**Fri 10/3/14**	**Fri 10/3/14**
Establish Connection for User Feedback	1 day	Wed 10/1/14	Wed 10/1/14
Final Design Decision Matrix	1 day	Mon 10/6/14	Mon 10/6/14
Iteratively evaluate alpha prototype(s) with SOP	17 days	Wed 10/1/14	Thu 10/23/14
Weekly design review	1 day	Fri 10/3/14	Fri 10/3/14
Final PO purchase	1 day	Wed 11/12/14	Wed 11/12/14
Prepare Executive Summary Draft	8 days	Sat 11/15/14	Tue 11/25/14
Finish prototyping	**9 days**	**Sun 11/16/14**	**Thu 11/27/14**
Finalize Executive Summary	3 days	Sun 11/16/14	Tue 11/18/14
Final Executive Summary Due	1 day	Tue 11/18/14	Tue 11/18/14
Prepare Poster Display	5 days	Fri 11/21/14	Thu 11/27/14
DFMEA & Life Cycle Testing	3 days	Wed 11/19/14	Fri 11/21/14
Additional Coverage and Regulatory Research	1 day	Wed 11/19/14	Wed 11/19/14
Final PO purchase	1 day	Thu 11/20/14	Thu 11/20/14
Prototype Evaluation/VOC with Farmer	**1 day**	**Sat 11/22/14**	**Sat 11/22/14**
Presentation structuring session	1 day	Mon 11/24/14	Mon 11/24/14
Prepare Final Presentation	**5 days**	**Tue 11/25/14**	**Sat 11/29/14**
Final rough draft of paper	1 day	Wed 11/26/14	Wed 11/26/14
Final Presentation, Paper Due, Poster Session	**1 day**	**Tue 12/2/14**	**Tue 12/2/14**
Follow Up Conference with AgrAbility	1 day	Thu 12/4/14	Thu 12/4/14