Optimization for Commercialization of
A Two Degree of Freedom Powered Arm Orthosis

By

Steven Paul Toddes, Jr.

A Masters Thesis Submitted to the Faculty

of the

Worcester Polytechnic Institute

In Partial Fulfillment of the Requirements for the

Degree of Master of Science

in

Mechanical Engineering

Submitted by: _____

Steven Paul Toddes, Jr.
Friday, April 13, 2007

Approved:

_____
Professor Allen H. Hoffman, Ph.D., Advisor

_____
Professor Yiming Rong, Ph.D., Graduate Committee Representative

_____
Professor Brian J. Savilonis, Ph.D., Committee Member

_____
Professor John M. Sullivan, Ph.D., Committee Member

DISCLAIMER:

In the design of marketable products, engineers seldom work in seclusion; teamwork and collaboration have become status quo of modern engineering. In this spirit, the design of a 2nd generation powered orthosis was completed as partnership of two simultaneous theses. This thesis concerns the design methodology of the mechanical and structural components, and their verification using FEA and other numerical analyses. A parallel thesis has been completed by Michael J. Scarsella, which developed an integrated control and monitoring system that not only drove the orthosis, but provided real-time feedback of the position of device. This collaboration has produced a functional device with the potential to benefit millions suffering neuromuscular diseases.

As the designing of the two unique systems was completed in parallel, the background of the document was also completed as a common effort. The sections of 2.0 *Background* and 3.0 *1st Generation Proof-of-concept Prototype* were written in collaboration and are similar in both theses. Additionally, the testing of the orthosis was completed in common, although as the data was extrapolated and compared to unique task specifications, the respective testing sections were not written as a unified effort.

Acknowledgements

I would like to thank several people for their help and encouragement during the completion of my thesis. Without their support, this thesis could have not been possible.

Allen H. Hoffman – As my advisor for more than three years, his guidance and patience during this project has proved inexhaustible. I am proud to be one of his students.

Paul Kalenian – His belief and commitment to the goals of this project created the potential of this project to accomplish much more than anyone initially thought possible.

Gina Betti – Her enthusiastic ambition for this project has inspired me to look outward from the walls of WPI and to redirect the goal of this project from a research to further the state of the art into the development of a marketable product that could directly affect the lives of millions.

Gary Rabideau – By suggesting this project as potential student project, he began a project that would effect numerous students lives. His continued involvement in the project is a testament to his passion for advancing the art of treatment for neuromuscular disease.

Michael J. Scarsella – As my collaborator in both the development of the proof-of-concept prototype and the completed powered arm brace, he brought with him a source of knowledge perpendicular to my own, the product of which has made this development of the orthosis possible.

Erin K. Toddes – Erin has steadily supported during the long sleepless nights, frantic searches for lost documents, and other quirks of graduate student life. She has suspended her dreams and wishes to see mine fulfilled. I am forever indebted and grateful to her.

Abstract

In the United States, more than 18 million people suffer from upper extremity injury. This population is in need of a device both to aid in the completion of activities of daily living (eating and grooming), as well as to provide daily muscular therapy. To assist persons suffering from disabling upper extremity neuromuscular diseases, this thesis concerned the redesign of a powered arm brace from a proof-of-concept design to a more functional, marketable product. The principles of Design for Manufacturability and Assembly (DFMA) were employed as part of the design methodology to create a product that could be scaled into production. Additionally, numerical analyses including Finite Element Analysis (FEA) were completed to prove the both the safety and structural integrity of the orthosis in computer simulations. The design was then successfully tested with marked improvement over the previous design, including a 58% reduction in weight, decreased manufacturing costs, and a significant improvement in functionality and comfort.

Table of Contents

Table of Figures

List of Tables

1.0 Introduction

In the United States, more than 5.7 million people suffer from upper extremity neuromuscular conditions or diseases. The root causes of many for these conditions is either challenging to treat or no treatment exists currently. Essential Tremor, called the most difficult tremor to treat, disrupts the lives of more than 5 million Americans. Musuclar Dystrophy, a genetic disease, afflicts more than 270,000 people in the United States. With an aging population, it can be expected that these numbers will only increase. Additionally, more than 12 million Americans are living with either the debilitating effects of stroke or an upper extremity injury. As the population grows and ages, these numbers, too, will increase placing more strain on an already stressed healthcare system. For example in response to these changes, the Dept. of Labor expects the numbers of employed therapists to rise by more than 27% during the next 10 years just as many therapists are entering retirement.

In the past 15 years, undergraduate and graduate students at WPI have sought a solution to upper extremity injury and neuromuscular disease by designing mechanically driven powered arm braces, which could replace the functionality of lost muscle control or strength in the completion of activities of daily living (ADL), such as eating or washing one's face. Prior to this project, Abramovich, Scarsella and Toddes developed a proof-of-concept 2 degree of freedom (DOF) "Arm Orthosis", which proved the functionality and potential usefulness of such a device (Figure 1). Based on that design, a new iteration of the orthosis has been developed. This project, as the culmination of this effort, seeks to design, fabricate and test a powered arm orthosis for persons suffering from neuromuscular disease and upper extremity injury. The new powered arm brace has
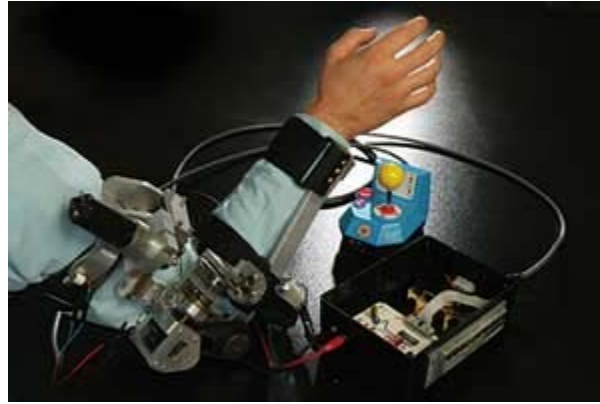
Figure 1: Proof-of-concept Prototype Developed by Abramovich, Scarsella and Toddes

been optimized for functionality, durability, and manufacturability. The previous design was shown to be able to complete ADL in 3 to 4 times longer than the same task would take an able-bodied person. Although functional, the previous orthosis used an unrefined control, and when driven at low speed, did not deliver maximum working torque. Additionally, the early device extended radially from the arm, thereby increasing the perceived bulkiness of the device. The proof-of-concept prototype was designed to fit to an individual, while being built, but after the initial fitting, and such offered no method to easily resize the device. Additionally, the early prototype employed open gearing with no simple method of shielding, which not only presented a safety hazard, but was susceptible to dirt, grit and fluids that could damage the gearing. Also, after causal use, the slider system that allowed humeral rotation began to deform, which restricted functionality and performance. The new powered orthosis has been designed for a much longer working life.

The new powered arm brace uses pulse width modulation (PWM) to deliver full voltage to the motor even when driven at low speeds to increase the sensitivity of the control, as well as full torque when driven below maximum speed. The maximum lifting torque of the device has been improved from a stall torque 9.7 N•m to a working torque

in excess of 12 N•m. The frame of the new orthosis has also been improved: The profile of the device now closely follows the profile of the arm, and the total mass has been reduced from 2.8kg to 1.2kg (57% mass reduction from the previous mass). The new device is also resizable with simple tools, to accommodate both limb growth and muscle deterioration. With these improvements, users wearing the new powered orthosis for testingwere able to complete a sample ADL in only 2-3 times longer than an able-bodied person. With nearly all of the gearing systems completely enclosed, any damage to the gearing from fluids or dirt has been prevented. Each component of the brace was also verified with FEA to ensure the robustness of design.

This thesis presents the mechanical redesign of the powered orthosis into a truly commercializable and manufacturable powered arm brace.

2.0 Background

In an effort to further the state-of-the-art, we have assessed the current and recent advances peripheral to our immerging technology and the conditions of potential users of this technology. Defining the field of research solidifies the framework of engineering task specifications, around which methodology and design can be constructed. As a prelude to this study, the broad scope of background research included applicable diseases and conditions applicable to the device, arm musculoskeletal biomechanics and kinematics, previous research, and similar commercial products, including U.S. and International patents related to the device. This background is a summation of these topics and practical research around which our device has been constructed.

2.1 Early Iterations of the Orthosis

This project is the sixth iteration of a series of both Senior Design Projects and Graduate Thesis Studies. The earliest iterations of the project date to 1996, and were concerned primarily with the construction of a wheelchair mounted, four degree of freedom (DOF) assistive arm.

1995
Project Proposal
Proposed by: Rabideau, Gary Massachusetts Hospital School Rehabilitation Engineer
> *Mr. Rabideau approached Prof. Allen Hoffman regarding the idea of a powered arm orthosis. This was verbalized in a one paragraph summary of his project expectations, which were brief, and did not have technical ideation included, but rather a qualitative description of the goals of the project.*

Fall 1996- Spring 1997
Title: Powered Arm Orthosis I
Origin: Senior Design Project
Disclosure: Report disclosed, on file at WPI
Students: Moynihan, Shawn Timothy; Pousland, Michael R.;Prince, Rebecca Ann
Advisor: Hoffman, A. H. (ME)

The goal of this project was to design and manufacture a device that would effectively increase the mobility of the user to enable daily functioning such as grooming and feeding. The final device furnishes the user with powered flexion/extension about the elbow, powered flexion/extension about the shoulder, and passive rotation about the shoulder allowing for the desired mobility functions. The drive components of this wheelchair mounted orthosis iteration were mainly by AC motors, and chain/sprockets.

Fall 1997 – Spring 1998
Title: Powered Arm Orthosis II
Origin: Senior Design Project
*Disclosure***:** Report disclosed, on file at WPI
Students: Guy, Victor Achilles; Hubbard, Dennis Brian; Murphy, Gregory Raymond
Advisor: Hoffman, A. H. (ME)

The objective of this project was to design and manufacture a powered arm orthosis to improve the quality of life for individuals suffering from Duchenne's Muscular Dystrophy (DMD). The orthosis supports the user's left arm and is controlled by the fingers of the right hand. Two degrees of freedom, shoulder and forearm flexion and extension, are powered with hydraulic cylinders. Two passive degrees of freedom, shoulder and forearm abduction and adduction, are lockable by the user in variable positions. This iteration of the orthosis was also wheelchair mounted.

Fall 1998
Title: Powered Arm Orthosis III
Origin: Senior Design Project
Disclosure: Report disclosed, on file at WPI
Students: Felice, Christopher James; Smith, Sean Allen
Advisor: Hoffman, A. H. (ME)

The goal of this project is to design a body-mounted arm orthosis that will aid individuals with Duchenne Muscular Dystrophy, a degenerative muscular condition. The orthosis is designed to provide powered shoulder flexion/extension, abduction/adduction, humeral rotation and elbow flexion/extension over a significant range of normal motion. A Computer Aided-Design (CAD) model of the orthosis was analyzed using Pro/Engineer. A detailed kinematic analysis was performed, and static and dynamic forces and moments were determined for three typical daily living motions. No prototype was produced or evaluated for this iteration of the orthosis.

Fall 1998
Title: *"Powered Arm Orthosis"*
Origin: *Publication*
Disclosure: *Published, disclosed*
Reference: A.H. Hoffman and H.K. Ault, "Powered Arm Orthosis" , *Rehabilitation R&D Progress Reports*, Vol. 35, pp. 225, 1998. (abstract).

> *This was a short publication consisting of a paragraph regarding the progress made on the Orthosis I iteration, and hinted toward the development of Orthosis II, both wheelchair mounted versions of the device.*

Spring 1999
Title: Design and Mechanical Analysis of an Arm Orthosis Using Pro/Engineer
Origin: Undergraduate Independent Study
Disclosure: NOT disclosed, on file with advisor
Students: Smith, Sean A.
Advisor*:* Hoffman, A. H. (ME)

> *This project also dealt directly with the third iteration of the powered arm orthosis, specifically using Pro/Engineer computer-aided design software to determine the exact stresses that daily use could exert on the orthosis II design, and from those results made suggestions for improving the design. Many of the test runs are inconclusive and incomplete. Also, because of the changes Toriumi subsequently made to the project, much of the data became obsolete.*

Spring 2000
Title: Design Modification, Fabrication, Construction and Performance
Evaluation of a Prototype Body Mounted Upper Extremity Orthosis
Origin: Masters Thesis
Disclosure: Report disclosed, on file at WPI
Student: Toriumi, Hiroshi
Advisor*:* Hoffman, A. H. (ME)

> *This thesis research included the construction of a four degree of freedom orthotic-like device which did not incorporate any methods of electromechanical power. This device was passive, and was utilized in order to quantify the range of motion in each degree of freedom which is required to perform acts of daily living. This Kinematic evaluation led to a publication within the Proceedings of the 2002 RESNA conference.*

January 2002

Title:　　　Design of Power Body Mounted Arm Orthosis Prototype
Origin:　　　Directed Research
Disclosure:　NOT disclosed, on file with advisor
Student:　　Cooke, Michael T.
Advisor:　　Hoffman, A. H. (ME)

Cooke used the kinematic evaluation from Toriumi's work, and upon the advice of Hoffman, used the information from two of the four DOF to conceptualize an orthosis. This design consisted of three major pieces: the upper arm assembly, the mid arm assembly and the lower arm assembly. Both the upper and lower portions consisted only of simple gears without any true technical reasoning behind their selection. Cooke achieved humeral rotation by driving a worm gear and slider with a worm, which was connected directly to a single motor. A second motor drove the forearm extension and flexion by a simple combination of gears, which resulted in an adjustable angle between the lower and middle arm assembly.

This design was conceptualized as a CAD model based on presumptions rather than technical evidence or mathematical confirmation. The design was assembled into a visual demonstration by Michael Galecki in Spring 2002.

Spring 2002

Title:　　　No Report Completed
Origin:　　　Masters Thesis (Abandoned)
Disclosure:　None
Student:　　Galecki, Michael
Advisor:　　Hoffman, A. H. (ME)

There is no report to have been disclosed, as the research was never formally completed. Only rough notes, and progress reports held on file by the advisor can attribute any work to the student. A prototype was partly assembled based on the design by Michael Cooke (January 2002) which included a slider mechanism with a hollowed out brass worm gear for humeral rotation, as well as motors with gearheads used as sources of electromechanical power for both degrees of freedom. Galecki acted as a technician, obtaining parts, and assembling them based on the non-technical assumptions presumed by Cooke. This prototype was reduced to practice in the form of a visual representation, rather than a functional prototype. This device was not usable, or testable, and no documented proof of its capabilities is believed to exist.

2002
Title: "The Design and Kinematic Evaluation of a Passive Wearable Upper Extremity Orthosis."
Origin: Publication
Disclosure: Published, Disclosed
Authors: A.H. Hoffman, H.K. Ault, H. Toriumi, S.A. Smith, C. Felice
Reference: Hoffman AH, Ault HK, Toriumi H, Smith SA, Felice C. *The design and kinematic evaluation of a passive wearable upper extremity orthosis*. In: Proceedings of the 2002 Annual RESNA Conference; 2002 Jun 27-Jul 1; Minneapolis, MN. Washington (DC): RESNA; 2002. p. 160-62.

Fall 2004 – Spring 2005
Title: Two Degree of Freedom Powered Arm Orthosis to Augment Arm Function in Persons with Disabilities
Origin: Senior Design Project
Disclosure: NOT disclosed, on file with advisor
Students: Abramovich, Daniel N.; Scarsella, Michael J.; Toddes, Steven P.;
Advisor: Hoffman, A. H. (ME)

This group reviewed the previous work done at WPI, and a new design of a powered arm orthosis was conceptualized, manufactured and tested. Though minor design similarities exist to previous attempts, Abramovich's, et al. orthosis design is unique in that the design was reduced to practice and was shown to be capable of allowing a person suffering from DMD to perform some ADL independently. In this iteration, far reaching changes were made to all parts of the orthosis including the method of framing, gearing, direct drive methods, and especially control.

This orthosis had a dedicated control unit, which provided analog control to the device via a simple joystick. Using H-bridge switching, the number of wires to the device were limited. The joystick electronics also included a meter to measure power levels to the orthosis, which could serve to indicate battery life. For additional information concerning this iteration of the orthosis, see section

2.2 Prevalence & Physiology of Applicable Conditions

Assistive technology device demographics have been explored in the past without specific consideration to unique devices.[1] Investigating client potential in the United States for a device which serves not only assistive, but also rehabilitative applications requires further exploration to quantify prospective user population.

This investigation includes the methodology of isolating the conditions benefiting from use of the device, understanding the physiological limitations of each condition, and quantifying the prevalence within the United States. The conditions are divided into two distinct categories: those who would use the device primarily as an assistive tool to overcome disabilities and those who would use the device as a means of rehabilitation.

2.2.1 Assistive Device Beneficiaries

Disabled users that would benefit from use of this device as a means of assistance are mainly affected by one of several degenerative neuromuscular or motor neuron disorders. Their disability is derived from a weakening or loss of function in their upper extremities. Assistance in amplifying their arm use would result in an increased sense of independence and an overall betterment of quality of life. The following section outlines, and summarizes the main groups which would be considered an eligible candidate to use the device as an assistive technology.

2.2.1.1 Muscular Dystrophy

Muscular dystrophy (MD) is an "umbrella" term used to describe a group of degenerative muscular diseases. MD causes weakness or wasting of the skeletal muscles due to insufficient production of Dystrophin. The Muscular Dystrophy Association recognizes nine specific types of MD. They are hereditary and expressed in known patterns of inheritance. The diseases are considered to be myopathies due to their degenerative nature within the muscles. MD affects all populations with no variation among regions.[2]

Myopathies are a group of diseases that manifest as inflammation of the muscles and may be associated with diseases of internal organs. Symptoms are muscle weakness in the upper arms, thighs, neck, muscle pain, fatigue, joint pain and swelling, rashes over the face and knuckles, fevers, difficulty swallowing and shortness of breath. The cause of myopathies is unknown, but environmental factors (such as viral infections) and genetic predisposition are felt to be important in some cases.[3]

Muscular dystrophies are a relatively rare condition. The incidence in the US is approximately 1 per 4000 male births. As of 1994, the prevalence of MD clients in the United States was roughly 270,000. Muscular Dystrophies are inherited as an X-linked recessive disease, generally affecting males. Females are responsible for carrying the gene, but only in very rare cases ever experience symptoms of the disability.

Symptoms typically begin before the age of three as difficulty walking. By adolescence, patients become confined in wheelchairs. Dexterity in the fingers and wrist remains high through the natural pathology of the disease, which affects the proximal muscle groups initially, and eventually progresses to smaller distal muscle groups. Eventually MD affects the respiratory muscles causing death.

The following is a description of the predominant muscular dystrophies, including onset, symptoms, progression, and genetic heredity. [4]

Becker – Onset within adolescent years or adulthood. Symptoms are nearly identical to Duchenne but often much less severe. There can be significant heart complications yet the disease progresses slower and is more variable then Duchenne, with survival well into mid to late adulthood. (X-Linked Recessive)

Congenital – Onset at birth, symptoms are generalized muscle weakness with possible joint deformities, but progression is slow. The Fukuyama form is more severe and affects mental functions. (Autosomal recessive, Autosomal dominant)

Distal – Onset between the ages of 40-60, symptoms are weakness and wasting of muscles of the hands, forearms and lower legs. Progression is slow, but not life threatening. (Autosomal Dominant)

Duchenne – Onset within early childhood, about 2-6 years, symptoms include generalized weakness and muscle wasting affecting limb and trunk muscles first. The disease progresses slowly but will affect all voluntary muscles making survival rates rare beyond the late 20s. (X-Linked Recessive)

Emery-Dreifuss – Onset between childhood to early teen years. Symptoms are weakening and wasting of shoulder, upper arm and shin muscles. Joint deformities become common. Disease progresses slowly with frequent cardiac complications. (X-Linked Recessive)

Facioscapulohumeral – Onset within childhood to early adulthood. Symptoms are facial muscle weakness with weakness and wasting of the shoulder and upper arms. The disease progresses slowly with some periods of rapid deterioration. (Autosomal dominant)

Limb-Girdle – Onset within childhood to middle age. Symptoms are weakening and wasting affecting shoulder and pelvic girdles first. Usually progresses slowly with cardiopulmonary complications in the later stages of the disease. (X-Linked autosomal recessive)

Myotonic – Onset during childhood to middle age. Symptoms are generalized weakening and wasting affecting the face, feet, hands and neck first, with delayed relaxation of muscles after contraction. Congenital myotonic MD has severe symptoms, though the progression is slow, sometimes spanning 50 to 60 years. (Autosomal dominant)

Oculopharyngeal – Onset during early adulthood to middle age. Symptoms first affect the muscles of eyelid and throat. Slow progression with swallowing problems common as disease progresses. (Autosomal dominant)

There exists no cure for muscular dystrophy. Physical therapy helps prevent joint locking and muscle wasting and surgical procedures can repair spine curvature. Treatments, however, merely delay the progression and are not a long-term cure.

Rehabilitation assistive technology (AT) remains one of the best tools to mitigate the worsening symptoms of MD. Electric wheelchairs with specialized controls and accessories alongside orthotic and respiratory assistance devices are among the various

tools employed by therapists to manage the symptoms of MD. Still, there has yet to be a substantial therapeutic tool available for increasing independence of people with MD. Such a tool would improve the mental health and quality of life for persons with MD.

2.2.1.2 Arthrogryposis Amyoplasia

Arthrogryposis is a general term used to describe joint contractures at birth[5]. Arthrogryposis Amyoplasia is a more specific term, which describes a lack of growth of muscle tissue after birth. Similar to MD, people with Arthrogryposis Amyoplasia have low muscle tone, which limits their activities of daily living (ADL). An orthotic device could provide upper arm strength, added freedom and allow people with this condition to perform arduous tasks, such as carrying a load or moving objects. There are 400 instances of Arthrogryposis Amyoplasia per year in the United States, or about 1/10000 births.[6]

2.2.1.3 Multiple Sclerosis

Multiple Sclerosis is a gene related degenerative disease. Myelin deficiencies in people with MS lead to scarring of the muscular control nerves. After a nerve is damaged, function can usually be partially restored through rehabilitation. However after repeated "flare-ups," muscle function may be permanently disabled[7]. About 400,000 people living in the US have been diagnosed with MS. The National Multiple Sclerosis Society characterizes MS into four distinct patterns of progression:

Relapsing-Remitting – This is the initial diagnosis of ~85% of those with MS. Relapses of MS are clearly defined by periods of stability and recovery, followed by periods of severe attacks of the symptoms of MS.

Primary-Progressive – This is the initial diagnosis of ~10% of those with MS. The progression of the disease is a slow but continuous decline of the central nervous system, unlike the Relapsing-Remitting pattern of highs and lows.

Secondary-Progressive – This track typically follows about 10 years of Relapsing-Remitting, after which, a progression similar to Primary-Progressive results. About 50% of those diagnosed with Relapse-Remitting MS will eventually develop Progressive MS.

Progressive-Relapsing – A rare form of MS (~5% of those diagnosed with MS), Progressive-Remitting, as the name suggests, is characterized by a slow progression of MS, with intermittent, but severe attacks of the disease.

Persons suffering from MS often use assistive technology to perform routine ADL's. Since they do not generally lose arm function until late in the progression of MS, a powered arm orthosis could help restore arm function and strength, while simultaneously serving mentally and physically therapeutic purposes.

2.2.2 Therapeutic Device Beneficiaries

Much research has been performed which details the performance of rehabilitative robotics when used as an accompaniment to physical therapy. For over a decade, domestic and foreign research has proven efficacy in therapeutic assistance with robots in conditions ranging from hemiparetic arm recovery due to stroke to traditional post-operative recovery.[8,9,10,11]

2.2.2.1 Stroke

The American Stroke Association reports a prevalence of 5.4 million stroke victims as of 2002 with an annual incidence of 700,000[12]. In 2003, 157,804 of the 700,000 annual incidences were fatal. Although stroke is one of the leading causes of

death; being responsible for 1 of every 15 fatalities, the death rate from stroke declined from 1993 – 2003 by 18.5%[13]. The decrease in fatalities equates to an increased number of stroke survivors, each of which require some degree of physical therapy.

Not all stroke survivors regain their original quality of life; 15%-30% of all survivors are permanently disabled. However, 50-70% will regain functional independence. For the survivors of stroke, rehabilitation is a necessary way of life requiring speech, cognitive, and physical therapy. Those stroke patients requiring physical therapy for rehabilitation constitute the population eligible for robotic assisted rehabilitation.

A recent study involving hemiparetic patients[14] compared robotic training therapy to traditional physical therapy. The robotic therapy group was prescribed bicep curl exercises at 20 repetitions for 4-5 hours per week for 7 weeks on their affected arm, while the traditional group was given normal repetitive strengthening exercises. Results indicated that the "robot trained group demonstrated significantly greater gains in elbow and shoulder motor function and elbow and shoulder strength".

Utilizing these statistics, the total clientele eligible for robotic therapy rehabilitation due to stroke would be derived from 700,000 per year, minus fatality rates; the total annual incidence is as high as 543,000 new clients per year.

2.2.2.2 Neuromuscular Syndromes

A variety of neuromuscular syndromes such as muscular dystrophy (MD) in its various forms, and amyotrophic lateral sclerosis (ALS) require therapeutic regimens that would benefit from upper extremity robotic therapy.

Muscular dystrophy patients receive physical therapy from the moment of diagnosis to ensure longevity of muscle life and joint flexibility. Without range of motion and loading therapy, joint locking and muscle atrophy progress rapidly.

Additionally, the potential exists to aid in other upper extremity debilitating disorders such as cerebral palsy, multiple sclerosis, spinal chord injury, and Traumatic Brain Injury[15]. All the aforementioned injuries require varying degrees of rehabilitation and therapy. An estimate of the population, which would be eligible for robotic therapy from these groups, is roughly 1.3 million people in the US.

2.2.2.3 Upper Extremity Injury

Upper extremity injury can be classified in three different anatomical sites: skeletal, muscular, and tendon. Each requires therapy for range of motion and muscle strengthening. Range of motion therapy slowly increases the range of motion at the nearest affected joints. Muscle strengthening is accomplished by therapeutic strength training. Both of these methods are consistent with sports injury rehabilitation techniques[16]. The prevalence of upper extremity injury in the United States due to fracture, muscle strains, elbow strain, tennis and golfer elbow, dislocation, and tendonitis in sports injuries alone indicates 4.5 million injuries eligible for rehabilitation[17].

2.2.3 Applicable Disease and Condition Summary

As discussed in this document, a significant clientele exists within the United States for a functional, body-mounted powered upper extremity orthosis. Those clients that have their daily lives affected by their disability have a need and desire to improve their independence and regain the ability to complete acts of daily living (ADL).

The potential number of users of an upper extremity, powered orthosis could be as high as 5.7 million. Figure 2 graphically displays the percentage of clientele versus US population as compared to the current US Census information as of Nov. 2006. Utilizing a second approach for the device's functionality as a rehabilitative or therapeutic tool, market potential of a device such as this would substantially increase.

Assistive Device Applications in the U.S.

▪ US Population	▪ Essential Tremor	▫ Arthrogryposis Amyoplasia	▪ Muscular Dystrophy	▪ Multiple Sclerosis

20000
270000
400000

5000000

Total = 5.7 Million
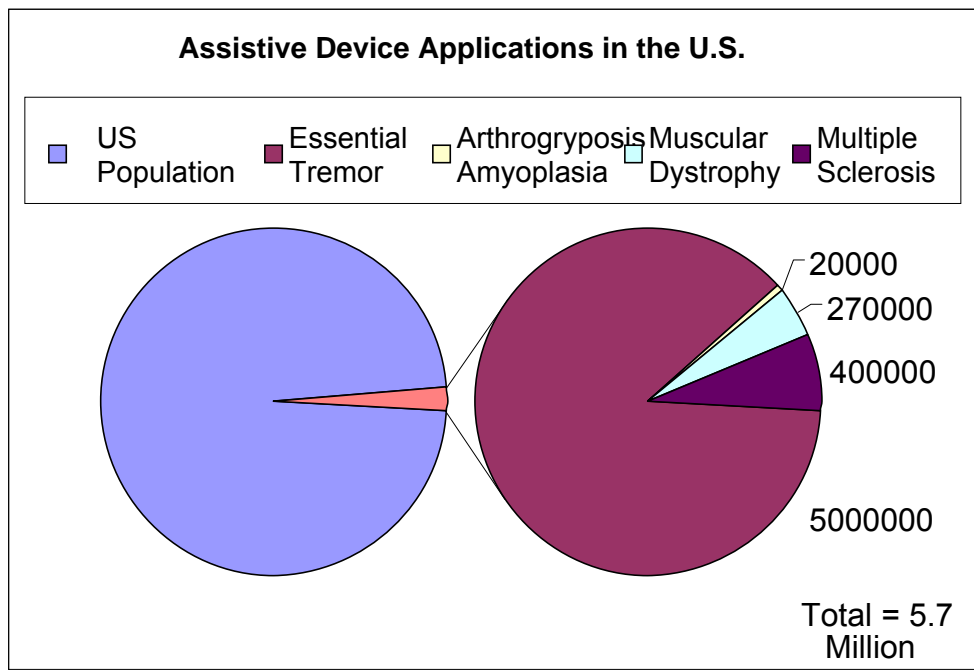
Figure 2: Prevalence of clients benefiting from Assistive Technology Application
The US Population as of 11/1/2006 was 300,119,290.

A good indicator of demand as a tool in physical therapy is portrayed by the demand for Physical Therapists (PT) in the US. The US Department of Labor reports that jobs in the PT field are expected to grow faster than average (21-35%) through 2012 as

demand for therapy increases[18]. The US DOL attributes this to the growing elderly population, and the baby-boom generation entering the prime age for heart attacks and strokes.

Considering the clients affected by stroke, upper extremity injury, stroke, neuromuscular, and other motor-neuron diseases, the estimated potential for clients of this nature would reach nearly 12.9 million persons in the US (Figure 3).
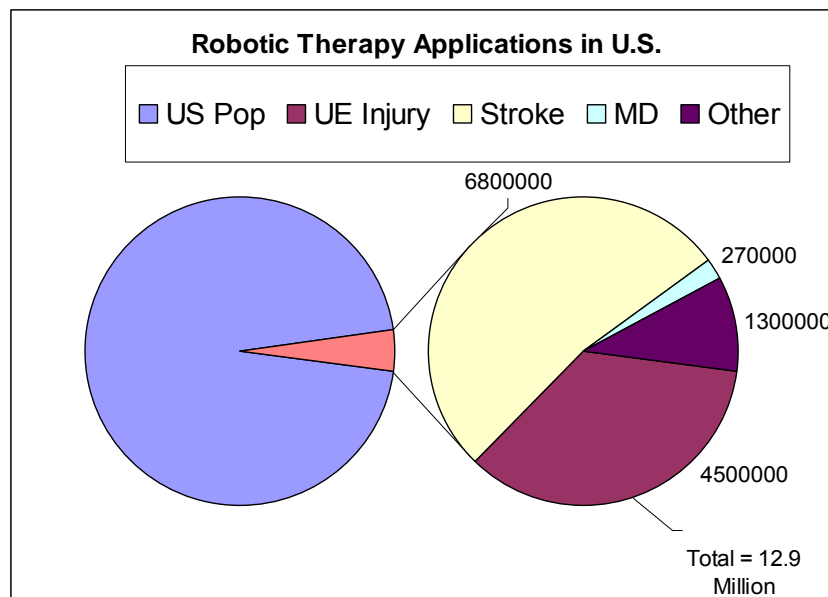
Figure 3: Prevalence of clients benefiting from Robotic Therapy Application

The US Population as of 11/1/2006 was 300,119,290.

In the United States, the current estimated population eligible to benefit from the body mounted upper extremity orthosis whether by assistive or rehabilitative means, totals 18.6 million (Table 1).

Table 1: Total User Prevalence / Incidence Summary		
Client Segment	Prevalence (Actual/Rounded)	Annual Incidence (Estimate)
Assistive	5,700,000	139,930
Rehabilitative/Theraputic	12,900,000	1,187,000
Totals	18,600,000	1,326,930

2.3 Neural Plasticity

Neural Plasticity is the ability of the brain and/or certain parts of the nervous system to adapt to new conditions, such as injury[19]. The resilience of the nervous system has been studied systematically as early as the 1930s while studying ablation of brain tissue in the motor cortex of monkeys[20]. The results showed a sharp decline in motor function, followed by a recovery as the brain tissue reorganized its synaptic pathways.

Emphasis on neural plasticity studies have seen a recent shift from focus on naturally occurring phenomena, to those that are aided by outside sources such as robotic constraint-induced therapy, and robotically assisted repetitive motion therapy.

2.3.1 Robotic Therapy and Neural Plasticity

In the period following a stroke or upper extremity injury, a decrease in the extension of the cortical representation areas is noticed for the affected muscles: since they are not in use (aren't working regularly), its correspondent area in the brain is not stimulated. In an effort to decrease or to recover from the "learned nonuse" effects, one of the practices that have been used is the Constraint-Induced (CI) Movement Therapy[21] or forced use, which increases the plastic changes that are favorable to the patient's recovery.

This technique consists in the forced use of the affected arm by the limited use of the non-affected arm. During a 10 to 15 days period[22], the patient's non-affected arm is immobilized. Consequently, many activities like dressing, eating, writing, cooking, etc. can only be done by the affected arm, stimulating the damaged cortex. In this period, the patient has a six daily hours of physiotherapy training, doing repetitive tasks with the

affected arm. Due to this increased use of the affected arm, the brain area connected to it is stimulated once again and results in an intense cortical reorganization[23]. This reorganization increases the representation area of this limb in the cortex and the motor function ability is improved. Thus CI-therapy can be considered remarkably effective against the "learned nonuse".

One of the applicable conditions that has gained much attention is in the case of hemiparetic stroke. In this condition, where brain tissue has been damaged due to internal hemorrhage, whole limb rehabilitative training induces cortical plasticity that has been linked to improvements in upper-limb motor function[24]. Additionally, the use of robot-aided therapy seems to support these data by improving short and long-term motor control of the hemiparetic shoulder and elbow in subacute and chronic patients[25]. If this consistency resulted in similar outcomes, then robot-aided therapy would be an excellent compliment to existing treatment methods in cases where multiple therapists are typically necessary, thereby reducing healthcare costs[26].

2.3.2 Home Therapy

By creating a situation where the range of motion can be preset, and the speed can be controlled, physical therapists could potentially use robotic therapy as an at-home solution between, or as a replacement for therapy sessions. The potential of at-home therapy has been explored with an emphasis on knee rehabilitation. Upper extremity, rehabilitation may be considered as similar in function.

A vigorous rehabilitation program following discharge from the hospital is necessary for patients having a total knee arthroplasty to maintain and improve range of motion and

function. To compare the effectiveness of the continuous passive motion (CPM) machine as a home therapy program versus professional physical therapy, a prospective, comparative, randomized clinical study of 103 consecutive primary total knee arthroplasties in 80 patients (23 bilateral) was performed. The CPM group consisted of 37 patients (49 knees), and the physical therapy group consisted of 43 patients (54 knees). At 2 weeks, knee flexion was similar in the two groups, but a flexion contracture was noted in the CPM group (4.2°). This difference is felt by the authors to be clinically insignificant. At 6 months, there were no differences in knee scores, knee flexion, presence of flexion contracture, or extensor lag between the two groups. The cost for the CPM machine group was $10,582 ($286 per patient), and the cost for professional therapy was $23,994 ($558 per patient). They concluded that using the CPM machine after the hospital discharge of patients having total knee replacement is an adequate rehabilitation alternative with lower cost and with no difference in results compared with professional therapy[27].

2.4 Modern Orthosis Devices

Orthosis devices are mechanical machines which provide assistance through a variety of different means to an existing appendage. Upper extremity orthotics either serve a rehabilitative purpose, to restore arm function through increased strength and dexterity, or are used by a patient in an assistive role, adding both strength and dexterity to the existing function of an arm. Most devices currently available on the commercial market fall within the spectrum of these two extremes, but can be differentiated by their main function.

2.4.1 Rehabilitative Devices

Rehabilitative devices are orthoses which are primarily intended for therapeutic purposes. Among other applications, physical therapists may use upper extremity rehabilitative devices to prevent joint locking and muscle deterioration, and to assist in the regeneration of neural pathways. Rehabilitative devices can are either powered or passive depending on their configuration and use.

2.4.1.1 Powered Rehabilitative Devices

Powered devices are those rehabilitative devices which use supplemental power to move a device attached to the affected appendage. The source of the additional power maybe from external power sources such as a battery or by a separate, unaffected muscle group of the patient.

Many powered rehabilitative devices seek to replace the motions of the therapist with the repetitive motion of a robot arm. Because of their simplicity, availability and relative low cost when compared to other robot configurations, many multi-DOF therapeutic devices are built from *industrial robots* known as SCARA's (Selective Compliance Assembly Robotic Arm).

The most well-known of these devices is the *MIT-MANUS* rehabilitation robot. The *MIT-MANUS* robot uses an industrial SCARA robot to move a patient's hand, and arm, through three-dimensional space[28]. The *MANUS* is designed to be both back-drivable and to exert a minimum force on the hand, as not to force the body into any unnatural positions. By using 16-bit resolvers mounted to each of the controlling motors,

the instantaneous position and direction of the hand, (and also velocity, acceleration, etc) can be monitored.

The *MANUS* is controlled by a therapist, who has several potential control schemes. The therapist has the option to input a programmed set of movements for the patient, similar to a regimented routine. The therapist can also manipulate a single robot, while other robots mirror the controlling robot, comparable to a dance class following the instructors movements. Both of these options are attractive because they allow a single therapist to conduct physical therapy on multiple patients, reducing physical therapy costs and increasing physical therapy time[29].

Larger 6-DOF robots can generate complex motions in the forearm, helping a patient move their entire arm. This kind of motion would use all joints/DOF in the arm and shoulder[30]. The additional DOF of the robot and the more advanced programming of these robots, make them both more expensive and cumbersome.

Alternatively, some robots incorporate only minimal DOF to aid in rehabilitation therapy. *GENTLE/S*, a design of a rehabilitative robot for stroke patients[31], used a 3-joint robot to help lift a patients arm. Since the device could not position the entire arm correctly with so few active DOF, several passive joints were employed for kinematic compliance. *GENTLE/S* has only achieved minimal success thus far due partly to its incomplete motion control and its awkward size and configuration.

Recently, researchers at the University of Zurich designed a rehabilitative device coined *ARMin*[32]. *ARMin* is a wall mounted robot-like device, which uses three DOF mounted external to the body to control shoulder movements, and three DOF mounted around the upper arm and forearm to allow for fluid motion through-out the arm. Though

some of the DOF are passively controlled, *ARMin* actively controls the shoulder, humeral rotation and elbow flexion.

Shoulder abduction is driven by a linear actuator, which lifts the elbow, thereby changing the angle between the upper arm and the body. A rotational DC motor mounted vertically over the arm controls shoulder pronation.

Humeral rotation is driven by a cable system. A series of cables are placed in a track (connected distally) around the upper arm, each with one loop around an external axle (connected proximally). The arm is actuated by rotating the axle, thereby translating its position along the cables and driving proximal rotation.

Recently, researchers at Arizona State Univ. and Kinetic Muscles, Inc. have developed a wearable orthotic device for stroke survivors. *RUPERT* (Robotic Upper Extremity Repetitive Therapy) is powered by four pneumatic cylinders, which allow for shoulder movement, full arm extension, and grasping[33]. *RUPERT* mounts to a patient's torso at strategic locations to disperse the reactionary forces created during operation. As *RUPERT* is powered by compressed air, it requires a bulky air compressor. This limits a patient use of *RUPERT* for assistance during ADL.

2.4.1.2 Passive Rehabilitative Devices

Passive devices use the patient's own affected muscles to manipulate a device through a regiment of exercises. Patients using passive rehabilitation devices must be able to create some muscle force in their affected arm because the movement of the device is generated in the affected muscle groups. To minimize the required force, passive devices often incorporate springs or planer systems to negate the forces of

gravity. A planer system allows users with limited muscle tone to move in a plane normal to gravity. A spring systems are often used in planer systems because they do not require complex drive systems, or alignment. A patient using a spring system can move out of a normal plane by either lifting their arm, or applying pressure downward. As they relax their muscles, their arm will gently return to the neutral plane. In planer systems, movements within a plane are completely passive because movements along a place are not effected by gravity.

TheraJoy [34] is a passive device for retraining coordinated muscle movements in the affected upper extremity muscle of people suffering from stroke related neuromuscular conditions. Patients using *TheraJoy* hold a handle and move their arm through space, as the device helps negate the force of gravity with a system of springs and levers. Like many of the powered rehabilitative devices, rotational and sliding joints are displaced from the natural joints of the body. The TheraJoy uses a sliding joint to allow for vertical movements and a bearing to accommodate movement in a horizontal plane. Though the patient can move through 3 dimensional space, the patient must continually adjust body posture to reach distant and confined spaces. Initial work has shown the potential for rehabilitative use, however, no clinical studies of the device have been completed to date.

2.4.2 Assistive Orthoses

Assistive orthosis devices provide support, additional strength, stability or dexterity to patients with disabilities. Assistive orthoses, like therapeutic orthoses, can be either powered or passive, though passive devices are more prevalent. Persons with

disabilities use assistive devices to perform ADLs, including eating, grooming, playing or work typical of an office environment.

2.4.2.1 Powered Assistive Orthoses

The spectrum of powered assistive orthotics is very similar to their counterparts, powered therapeutic orthotics. Many therapeutic devices can be used independently as assistive devices, though this usually requires new control strategies and device power storage. Another obstacle to the implementation of a powered therapeutic device as an assistive device is the continual relocation of a fixed/mounted device, as the disabled person travels from place to place.

One design strategy has been to create orthotics as fixed assistive orthotics, for single purposes or as workstations. The *GENTLE/S* (see *2.4.1.1 Powered Rehabilitative Devices)* is one example of a basic workstation orthotic device. Researchers at Ritsumeikan University have also taken this approach with their design of an assistive robot orthosis for working over a large flat table. Their orthosis[35] can move in 8 DOF, though in actuality, many of the DOF are dependant upon each other for body kinematic compliance. Using the Ritsumeikan Orthosis, disabled persons with limited muscle tone and dexterity can hold their arm above a table to draw, play board games, or engage in craft like activities.

Currently, there are no known and marketed truly mobile assistive upper extremity orthotics. This may be due, in part, to the limitations inherent in battery storage capacity, or motor weight restrictions, which made the device too bulky or heavy to be wearable.

2.4.2.2. Passive Assistive Orthoses

Several passive assistive orthoses exist for daily use. Most of these devices are rigid braces for supporting the upper limbs. A wide variety of products are available for bracing each or multiple joints of the arm. Many of the devices additionally have the ability to allow only partial rotation of joints.

An *Orthosis Device* (Patent # 6,821, 259) designed by Rahman, et al. is unique orthotic, which uses springs to increase the functionality of people confined to a wheelchair. The device is mounted to the wheelchair near the patient's shoulder, and supports the patient's forearm and hand. Between the hand and the wheelchair mount, the *Orthosis Device* employs two four-bar linkages and two springs. The major disadvantages of the device are that it is wheelchair mounted, and therefore not available to the wider population of non-wheelchair bound clientele and that the four-bar linkages prevent the user's arm from reaching a table or other horizontal surface. For more information, see the following Section 2.5 Patents.

2.5 Patents

Numerous patents focusing on orthotic devices have been filed with the US Patent and Trademark Office (USPTO) although few devices pertain specifically to wearable, upper arm orthotics. Fewer patents concern the mechanics of the orthotic devices as opposed to novel control methodologies. Of the few patents, which concern the mechanics of upper extremity orthotics, most have since expired. Only two patents are currently active that concern the mechanics of at least one DOF body/wheel chair mounted orthosis.

2.5.1 Orthosis Device (#6,821,259)

Developed by Rahman, et al., this *Orthosis Device* is a passive wheelchair mounted orthosis to aid in the completion of ADL. The device uses a set of springs to offset the weight of the arm, while still allowing 3 DOF motion. Abduction and adduction of the shoulder are accommodated by a pin joint at the junction between the device and the wheelchair. Shoulder flexion/extension and elbow flexion/extension are achieved through a set of equal length four-bar linkages. These linkages are supported with a spring system that allows for movement up and down, while providing enough force to counter the weight of gravity.

2.5.1.1 Summarized Claims

1.   The patent claims a system of four-bar linkages that attached by pivots and held by springs.
2-3.   The elbow segment is adjustable in length
4.   The elbow spring could be pre-stressed.
5.   The elbow can be mounted to an additional linkage.
6 – 7. The elbow can use different springs.
8-10. Additional connectivity claims
11-19. Similar claims to 2-10, concerning upper arm movements.
20.   The device can be mounted to a wheelchair.

2.5.1.2 Summery

The *Orthosis Device* has been a successful device. Though definite numbers of patients using the device are not known, the device's simple operation and use of the patients own arm make the potential users numerous. As this device has only recently been introduced to the market, the acceptance of this device remains unknown. Two factors potentially limit the functionality of this device. Primarily the device is

wheelchair mounted, which limits the potential client for the orthosis to user's who are wheelchair bound, and can align themselves to the device. Secondly, the device does not allow a user's arm to make contact with a horizontal surface, such as a table. The full text patent of this device is included in Appendix 1.

2.5.2 Combination Pro/Supination and Flextion Therapeutic Mobilization Device (#7,101,347)

Developed by Culane, et al. this device is a body mounted, two DOF orthotic, which allows for elbow flexion/extension and wrist pronation and Supination. The first DOF of the device is located at the elbow. Elbow flexion is achieved by applying a moment at the natural pivot of the elbow. Along this rotational axis, the moment, generated by a motor, causes the device to move from a 90 degree base position to an extension of 180 degrees. Wrist rotation is achieved using a slider type system. From the orthosis frame, which extends along the base of the forearm, a mechanical slider allows rotation around the natural axis of the wrist. The slider system moves along a circumferential path, creating motion in the wrist.

2.5.2.1 Summarized Claims

1. The device is attached to the forearm and is meant to actuate the elbow and wrist.
2 -3 The device moves the elbow and wrist by moving itself.
4. The orthosis is adjustable.
5-7. The device moves the 2 DOF independently.
8. The device is strapped to the arm.
9-12 The device uses a slider mechanism to rotate the wrist.
13-17 The device is powered.
18. The device can be controlled by several user interfaces.
19-20 The orthosis can use anything that comprises a slider type mechanism.

2.5.2.2 Summery

Since this device was recently patented (Sept. 2006), it has not yet been commercialized. Though this device can be used for both rehabilitation and assistance with ADL, wearing the device limits the use of the patients' hand. Another potential problem with this device is that it does not create a workspace for the user. The full text patent of this device is included in Appendix 1.

2.6 Kinematics of the Human Arm

The human body is composed of some of the most intricate and ingenious mechanical systems known. The arm, specifically, involves a precisely arranged set of muscles and joints, which allows a person to target any anterior object within his/her arm's radius. Since the goal of this orthotic device is to facilitate human motion as closely as possible, it is important to define the human arm kinematics and anatomy.

In total, the arm incorporates seven degrees of freedom (DOF) to complete its specified motions. These DOF occur at joints of the shoulder, elbow, and wrist regions by multiple movements at each joint. The shoulder joint allows the arm to swing forward and backward (forward flexion and backward extension), swing laterally (horizontal flexion and horizontal extension), and swing about an axis through the front of the body (abduction and adduction). The wrist joint allows the hand to swing up and down (flexion and extension) and swing sideways (radial deviation and ulnar deviation). The elbow joint accounts for the remainder of the arm's DOF with forearm pronation and supination (rotation of the forearm and wrist about an axis through the forearm) and its elbow flexion and extension (angular deviation between the forearm and humerus) (Cook,

1995). Table 2 illustrates the different motions at each joint along with the angular range of each movement.

Table 2: Motion and Range of Human Arm (Cook, 1995)

#	Origin	Motion	Range (degrees)
1	Shoulder	Abduction and Adduction	255
2		Horizontal Flexion and Horizontal Extension	180
3		Forward Flexion and Backward Extension	240
4	Elbow	Flexion and Extension	160
5		Pronation and Supination	160
6	Wrist	Radial Deviation and Ulnar Deviation	50
7		Flexion and Extension	150

2.6.1 Human Arm Anatomy

The musculoskeletal structure powers and guides each of the motions of the arm. The musculoskeletal structure is composed of two subsystems: the skeletal system and the muscular system. The skeletal system is the framework of bones, which the ligaments, skeletal muscles, and tendons of the muscular system manipulate. Together, these two systems complement each other to provide structured movement of the human body.

The skeletal structure of the arm is a necessary consideration for the design of an upper extremity orthosis.
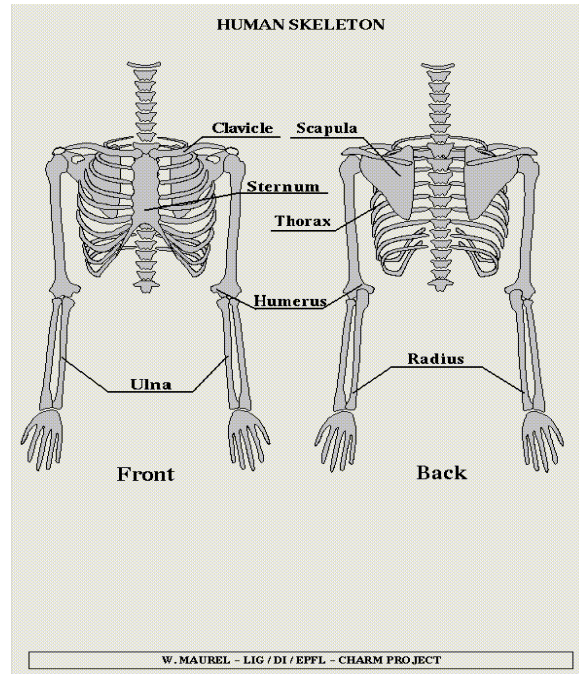
Figure 4: Human Skeletal Structure (Maurel/LIG/EPFL, 1996)

The humerus is the solitary bone in the upper arm's skeletal structure (Figure 4 *humerus*). This bone pivots in three rotational DOF from its proximal end at the shoulder joint, the way a rod pivots with its end connected to a socket as in a ball joint. The connection of the humerus to the joint occurs at the scapula and the clavicle at the shoulder. The scapula's glenoid cavity serves as the socket joint in this connection. The motions that this joint allows include the abduction, flexion, extension and humeral rotation as described in the previous kinematics section. Humeral rotation may appear to yield an eighth degree of freedom not mentioned in, but it is in fact associated with the motion of forward flexion and backward extension. As one extends his/her arm forward, the arm rotates orthogonally about an axis through the side of the shoulder. When the arm abducts

to 90 degrees so the side axis runs through the length of the arm, the person can still make a rotation about that axis by rotating the humerus. This shows that the DOF of rotation about that axis can be achieved at different positions, which works greatly to the advantage of orthosis designers by allowing them to take advantage of humeral rotation to complete ADL's. The distal end of the humerus connects to the elbow joint, where it is the base for the flexion and extension of the forearm. The ulna and radius are the two bones that comprise the skeletal structure of the forearm. The ulna serves as an axis about which the radius can revolve, in order to produce the pronation and supination of the wrist. The proximal end of the forearm attaches to the elbow joint, where it acts as a lever with respect to the humerus. The distal end of the forearm connects to the hand with an intricate array of muscles, bones, and ligaments[36].

The elements in the arm's muscular structure connect to the various bones and work in groups to carry out different movements. These groups overlap at certain joints, such as the elbow joint where there are fifteen overlapping muscle groups, and at the shoulder, where there are eleven overlapping muscle groups. The intricate configuration of the muscle group attachments allows them to act concurrently to produce complex motions. These intricate arrays along with the varying masses of the muscle groups contribute to a restriction in the range of motion for each of the arm's movements

2.6.1.1 Shoulder Anatomy

Multiple muscle groups create the different movements from the shoulder joint. The arrangement of the various muscle groups limits the range of motion of the arm.

For example, a flexing combination from the clavicular pectoralis (Figure 2) and anterior deltoid muscles (Figure 4), both of which connect the humerus to the clavicle, results in shoulder flexion. As the shoulder flexes, the tension in the clavicular pectoralis becomes greater (maximum tension occurs at 115 degrees) and the flexion is limited as if there was a rope tying down the arm. The anterior deltoid also limits this flexion. Shoulder abduction presents another example of this limitation. The middle deltoid and the supraspinatus provide the movement for shoulder abduction and act as a connection between the humerus and the scapula (Figure 4). Once the abduction is over 90 degrees, the tension in the deltoid increases, and the supraspinatus assists the deltoid up to 110 degrees of abduction.
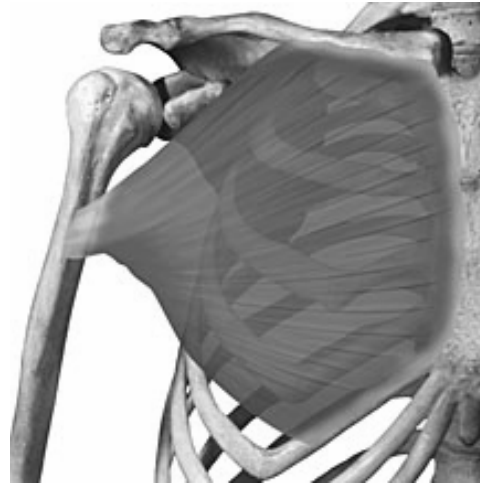
Figure 5: Human Shoulder with Pectoralis Major, Image: Michael Richardson M.D.

In order to counteract the interference and tension based movement restrictions in the shoulder (like the ones described above), the scapulothoracic (shoulder girdle) adjustment shifts the entire muscle arrangement in the desired direction of rotation to overcome these restrictions and achieve a full range of motion (Figure 6). The scapula stays in place for the initial 30 degrees of abduction and 60 degrees of forward flexion (where the shoulder
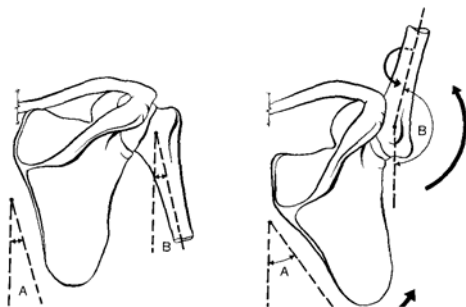
Figure 6: Scapula Movement During Abduction (Hay and Reid, 1982)

muscles do not experience restriction) and then begins to rotate one degree for every two degrees of humeral motion to allow full motion. Along with the scapula, the infraspinatus (Figure 7, #2), teres minor (#3), teres major(#4), and the subscapularis (#5) assist in augmenting the range of motion for abduction by facilitating medial and lateral rotations of the shoulder.

This rotation (with a 90 degree range of motion) causes the points of connection of the muscles on the humerus to rotate as well, therefore, reducing potential blockages and tensions on the pectoralis major and deltoid muscles to allow full 180 degree abduction. Without this rotation, the orientation of these muscles will limit the abduction to approximately 90 degrees. The limit in abduction range when the palm of the hand is facing the thigh illustrates this phenomenon.

2.6.1.2 Elbow Anatomy

Various muscles contribute to movement of the elbow region. The triceps brachii (Figure 7, #6), biceps brachii (#7), the brachialis (#8) and the brachioradialis, primarily execute the movements created at this joint. During supination of the forearm, the biceps brachii is highly dynamic in the process of resisted elbow flexion, as opposed to the
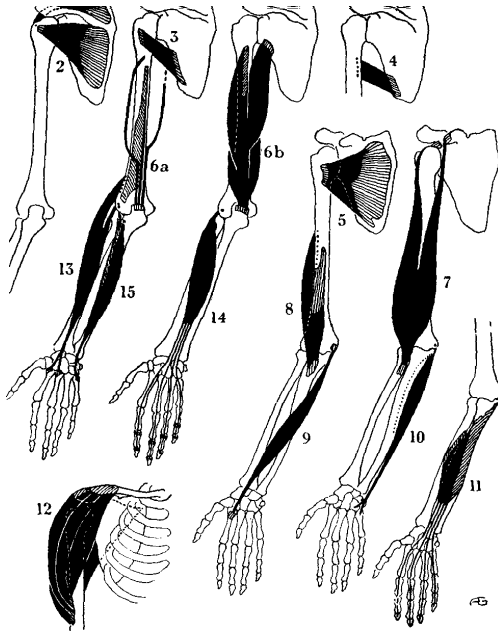
1. **Supraspinatus**
2. **lnfraspinatus**
3. **Teres minor**
4. **Teres major**
5. **Subscapularis**
6. **Triceps brachii**
7. **Biceps brachii**
8. **Brachialis**
9. **Flexor carpi radialis**
10. **Flexor carpi ulnaris and profundus**
11. **Flexor digitorum sublimis**
12. **Deltoid**
13. **Extensor carpi radialis longus and brevis**
14. **Extensor digitorumcommunis**
15. **Extensor carpi ulnaris**

Figure 7: Human Arm Muscles (Hay and Reid, 1982)

decrease in activity during resisted elbow flexion when the forearm is pronated. The main restriction on elbow flexion is a result of the relative size of the biceps brachii and brachioradialis muscles. The larger these muscles are the less one will be able to flex the arm due to interference of the muscle mass (as in large bodybuilders who have limited range of motion for elbow flexion). Normal flexion reaches a maximum somewhere between 120 and 150 degrees. The human anatomy does not allow for a great deal of hyperextension of the elbow, and normal ranges are from 0 to 20 degrees. The main factors in ability to hyperextend the forearm lie in the way the bones in the elbow joint are arranged and in the elasticity of the

35

biceps brachii. The elbow joint is also associated with the pronation and supination of the forearm and wrist. The movement is caused by the rotation of the radioulnar joints and is powered by the pronator quadratus, pronator teres, anconeus, supinator, and biceps brachii muscles. Typical range of motion for this supination and pronation is about 160 degrees and can vary along with the ability and elasticity of these muscle groups.

Table 3 illustrates the muscle groups that work together to create specific ranges of motion within the human arm.

Table 3: Arm Movements and their Corresponding Muscle Groups (Hay and Reid, 1982)

Movement	Muscle Groups Involved
Shoulder Flexion	Clavicular Pectoralis, Anterior Deltoid
Shoulder Extension	Sternocostal Pectoralis, Latissimus Dorsi, Teres Major
Shoulder Abduction	Middle Deltoid, Supraspinatus
Shoulder Adduction	Sternocostal Pectoralis, Latissimus Dorsi, Teres Major
Humerus Rotation (Inward)	Teres Major, Subscapularis
Humerus Rotation (Outward)	Teres Minor, Infraspinatus
Elbow Flexion	Biceps Brachii, Brachialis, Brachioradialis
Elbow Extension	Triceps Brachii
Radioulnar Pronation	Pronator Quadratus, Pronator Teres, Anconeus
Radioulnar Supination	Supinator, Biceps Brachii

2.6.2 Ranges of Motion for Activities of Daily Living

Table 4 represents information obtained by Felice and Smith in 1999 for activities of daily living and the ranges of motion required to complete them. Felice and Smith used visual inspection of the performed tasks to obtain the angular values. The motion category of arm rotation is equivalent to the combined motions of humeral rotation, radioulnar pronation, and radioulnar supination. The tasks presented in this table are

examples of tasks that disabled patients could perform with the assistance of the arm orthosis and seem consistent with clinical biomechanical research[37].

Table 4: Activities of Daily Living and Ranges of Motion

Activity of Daily Living (ADL)	Adduction & Abduction at Shoulder	Arm Rotation	Extension & Flexion at Elbow
Shake Hands	0 to 90°	0 to 90°	0 to 90°
Operate Stereo	0 to 45°	-90 to 90°	0 to 90°
Fork-Feed	0 to 20°	-90 to 90°	45 to 135°
Drink from Cup	0 to 50°	-30 to 90°	45 to 135°
Read Book	0 to 100°	0 to 90°	0 to 100°
Use Phone	0 to 30°	0 to 90°	0 to 150°
Play Chess	0 to 100°	-90 to 90°	0 to 120°
Brush Teeth	0 to 30°	0 to 90°	0 to 150°
Comb Hair	0 to 90°	0 to 90°	0 to 150°
Shave	0 to 80°	0 to 90°	0 to 150°
Blow Nose	0 to 40°	0 to 90°	0 to 135°

(Felice and Smith, 1999)

2.7 Human Factors in Design

Human factor design considerations are those that incorporate human capabilities. These can include physical stature, comfort, and decision making abilities. By gathering information about the mean attributes of a population, design points can be quantitatively specified, and evidential reasoning can be given for each decision. The first book on human factors considerations in engineering design was published in the early 1950s (Sanders, 1993).

Emphasis on human factors design considerations has been spurred in the past 20 years by an increase in lawsuits, especially in the workplace. In the 1980s, courts came to recognize the need for experts in explaining human behavior, responses, defective design, and effectiveness of workplace warnings and instructions.

The following sections outline the necessary design considerations as they relate to the Powered Arm Orthosis with regard to Anthropometrics and Ergonomics.
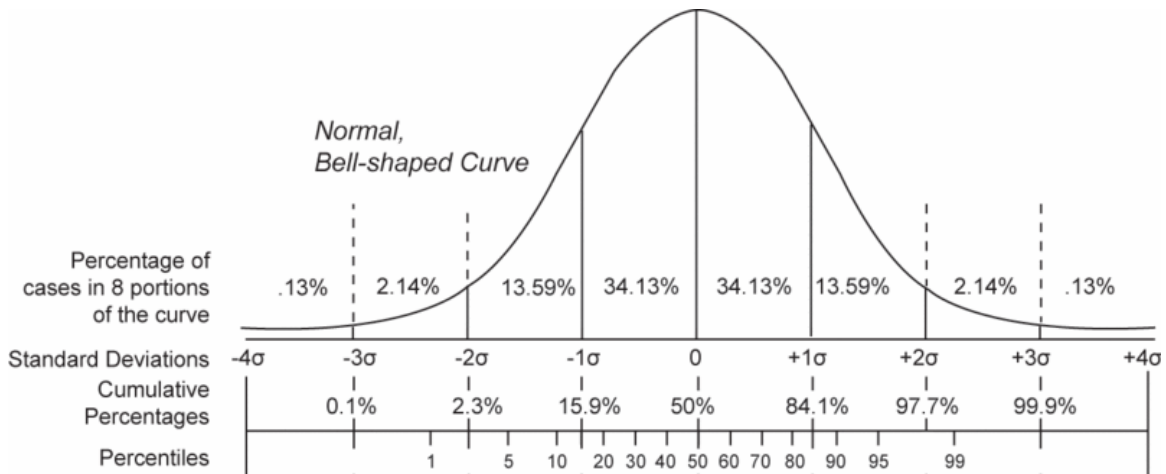
Figure 8: Percentile within a normal distribution (Image Source: Wikipedia)

2.7.1 Anthropometrics

Anthropometrics is the application of scientific physical measurement techniques on human subjects in order to design standards, specifications, or procedures. Typically, measurements are given statistically and can be given as a size (length, height, width, thickness), distance between body segment joints, weight (or volume or density), circumference, contour, and center of gravity. These dimensions are related to, and vary with other factors such as age, gender, ethnicity, occupation, and percentile within specific population group. A percentile dictates the location among a population distribution by a numeric percentage indicator. Figure 8 shows the percentile within a normal Gaussian distribution. Typically, designs should allow for flexibility between the 5th and 95th percentile of the population being considered[38].
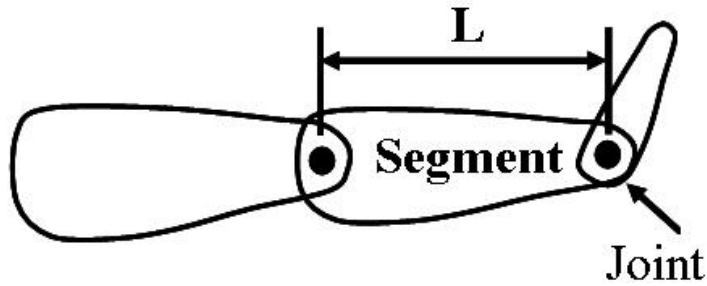
Figure 9: Forearm Segment Length

Segment length is one of the measurements being considered for this design, as it may apply in terms of adjustability in order to fit different size clients. Figure 9 shows the method to find the distance, L, of a forearm as measured from the two bounding joints, the elbow on the proximal side, and wrist distally. The other major segment we will focus on in this study is the upper arm, where the humerus resides. The length of this segment is bound by the elbow distally, as shared by the forearm, and proximally by the shoulder.

Center of gravity (COG), also known as center of mass, is important to determine when calculating forces on a segment, as this is the mathematical location at which to consider the influence of gravity. Since the segments of the body are not typically symmetrical in all axial directions, this indicates that the location will not reside at the geometric center.
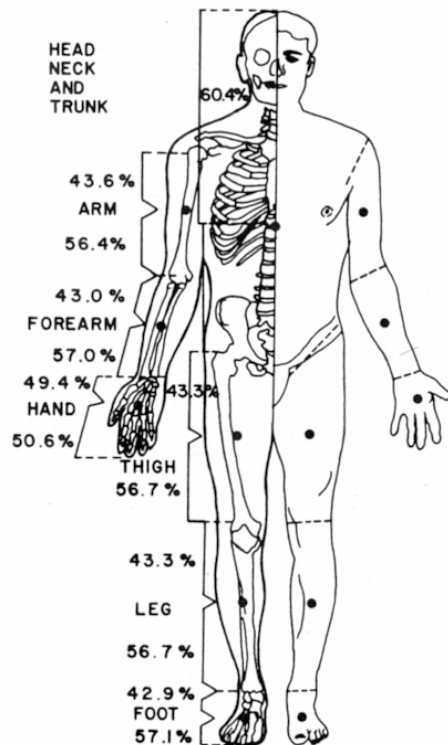
Figure 10: Segment COG shown as percent of segment length (Dempster, 1955)

39

Typical location indicators for COG of a body segment are given as a percentage of the overall segment length[39] from the proximal and distal bounding joints, as shown in Figure 10. As an example, the COG of the forearm is located 43% of the segment length (L_s) from the elbow, and thus 57% of segment length (L_w) from the wrist ($L_s=1-L_w$).

2.7.2 Ergonomics

Ergonomics is the study and optimization of the interaction between people and their physical environment by considering their physical, physiological and psychological characteristics. It applies to this study in that comfort of the orthotic device must be paramount in order for effective usage, as well as patient acceptance. Additionally, controls must conform to ergonomic standards in order to make the actuating of the user interface as seamless and simplified as possible.

`In ergonomic design, there are several factors that must be considered[40].

Minimize:

1. Soft tissue, artery and nerve compression,
2. Grip/Finger/Torque/Push/Pull strength required to perform task successfully
3. Vibration levels
4. Temperature changes (+/- 2 deg)
5. Repetitive motion
6. Prolonged performance of task
7. Prolonged maintenance of "fixed position"
8. Angle deviation away from "neutral" hand position
9. Pinching, sharp corners, edges
10. cost

Maximize:

1. General feeling of "comfort"
2. Adjustability of design
3. Ease of use

2.8 Control of Powered Orthotics / Prosthetics

State-of-the-art prosthetic technology has used several methods by which to control the motion of the powered device. The control methods for powered orthotics have not yet been established within the field, and therefore will be assumed to parallel those of prosthetics. The following section outlines an examination of the current technology used to control upper extremity prosthetics.

2.8.1 Input Switching Devices

An input device is a mechanical or electrical device which is intermediary between the user and the controls. It serves as a means of transforming a human command into an electrical or mechanical stimulus to be interpreted by the control system that then initiates the desired response.

With respect to powered prosthetics and orthoses, input devices are mainly found in two styles: passive or active. Passive devices are those that require an intentional stimulus in order to execute a response, such as in the case of a switch, or button. Active input devices are those that are constantly searching for a stimulus, usually from neural pathways or skin electrodes, in order to elicit a response.

2.8.1.1 Passive Switching

There are 2 basic types of passive switches, touch pads, and switches. Touch Pads are strain gauges in a flattened position that respond to surface pressure upon deformation. As their name implies, Touch Pads are operated by touch. The user simply moves the residual limb to push lightly on the Touch Pad to operate the device. These input devices are a cost-effective alternative while still providing proportional speed

control, since the amount of pressure applied determines the speed of the device. Touch Pads are normally supplied in a 0.75 inch diameter, but are also available in smaller and larger sizes.

Switches, a more basic option, are available in various styles. Switches command the device motors to operate in one direction or the other at a fixed speed. Switches do not provide proportional control; they simply turn the motors on or off. Dual action switches control motion in two direction or may be used to operate multiple devices.

2.8.1.2 Active Switching

Myoelectrodes are receptors that reside on the surface of the skin, which are capable of receiving the electric signals generated by muscles as a result of nerve activation. Myoelectrodes can regulate both the speed and the direction of the device. The speed is directly proportional to the strength of the input muscle signal. Proportional speed gives the most precise control of a device.

Manufactureres of powered prosthetics are utilizing this technology rather than using mechanically operated switches in order to create a seamless integration from user control to device response.

In 2005, Jesse Sullivan (Figure 11) was given the title of "bionic man" when the 58 year old man was given the power to operate several power prosthetics simultaneously without traditional passive pressure switches. Dr. Todd Kuiken, MD, PhD of the Rehabilitation Institute of Chicago (RIC) grafted the nerves from Mr. Sullivan's shoulders to the healthy muscles on his chest [41]

Jesse learned to utilize the electrical signals picked up by tiny myoelectrodes on the surface of his chest as a means of operating his powered prosthetics. This seamless transition from control of various muscles to an electrical signal is the basis of what makes myoelectric control so favorable and simplified for clients.

Figure 11: Jesse Sullivan, the "Bionic Man"

2.8.1.3 Proportional Control

Passive and active switching can control both on and off functions, but it also can determine the strength of the switched signal through proportional control. Passive switches, like strain gauges, use internal resistance to alter voltage throughput, singaling a device to operate a different speeds depending on strain. Active switches, such as myoelectrodes, relay the strength of a signal to an internal microprocessor, which drives motors to run at a correlated speed. Both methods of control allow the user interface to not only switch on the device, but to control the overall speed of the device.

2.8.2 Motor Control

Most powered prosthetics use some form of a motor to create power electromechanically. Whether a linear motor, or a standard rotational motor, the interface between the input device and the motor requires a method of interpreting the motor control. There are classic methods of motor control, which incorporate a few electrical

technologies. The following section outlines the electrical methods used in the original 1st generation prototype, as well as methods incorporated into the next generation prototype.

2.8.2.1 H-bridge

The h-bridge is a classic method of controlling DC motors. It allows control with minimum components, is simple to build and use and offers 3 basic functions: Rotate forward, rotate in reverse, stop.

The h-bridge is the core design for the electronics in the 1st generation prototype. Designing it properly allowed voltage switching across the motor to change direction and to even stop completely. Each input is connected to a pair of transistor switches that determine if the voltage should be placed across the

Figure 12: Typical h-bridge Schematic

positive or negative motor terminal. A typical h-bridge is shown in Figure 12.

The basic H bridge consists of 4 'switches', a motor and a power supply. Depending on which combination of switches are switched on or off, the motor can be made to spin forward, in reverse, or force it to stop. In normal use the switches are electronic, using some form of transistor.	
Switching S1 on and S4 on, (ensuring S2 and S3 are off) will result in the motor rotating forward. It is possible to follow the current flow, from the +V (Blue) to the motor, and then through to 0V (red).	

Switching S2 on and S3 on, and (S1 and S4 off), will result in the motor rotating in reverse. It is possible to follow the current flow, from the +V (Blue) to the motor, and then through to 0V (red).	
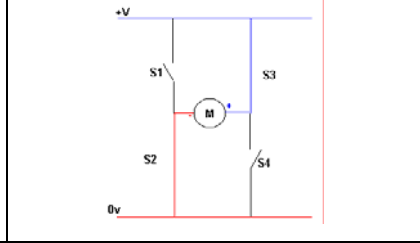
Figure 13: h-bridge Function (micromouse.co.uk/micropic/hbridge)

The h-bridge is available as a complete device, on one integrated circuit (IC). However, limitations to this technology include heat buildup in high current situations, such as simultaneously running high-torque motors. Most h-bridge chips such as the seen in Figure 14, offered by Texas Instruments, have limitations to current at values such as $0.5 - 1.0A$. In our 1st generation design, the motors drew a minimum of .80 amps individually. This meant that the chip would be appropriate for our use, however the goal of this thesis

Figure 14: T.I. 1.0Amp Dual h-bridge

is to create a situation where we can simultaneously run motors, where the sum of the amperage to run both exceeds a chip of this type.

2.8.2.2 Speed Control by Voltage Regulation

The simplest method of proportionally controlling the power output of a D.C. motor, is by limiting the voltage supply. This can be done from the power source itself, or through the circuit by way of potentiometer (variable resistor). By limiting the power supplied to a motor, the output speed, and thus its resulting torque is altered. Most DC motors are supplied with a Torque-Speed Curve (Figure 15) and datasheet table, which dictates its operating ranges (Table 5).
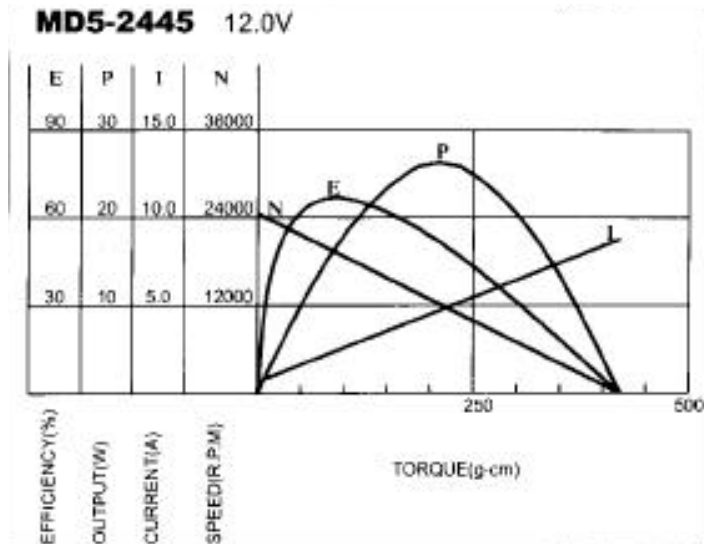
Figure 15: Typical Torque-Speed Curve

Table 5: Typical DC Motor Datasheet

MODEL	VOLTAGE		NO LOAD		AT MAXIMUM EFFICIENCY					STALL	
	OPERATING RANGE	NOMNAL	SPEED	CURRENT	SPEED	CURRENT	TORQUE	OUTPUT	EFF	CURRENT	TORQUE
			rpm	A	rpm	A	g-cm	W	%	A	g-cm
MD5-2445	6.0 — 12.0	12.0V CONSTANT	24500	0.65	19850	2.05	79.70	16.23	65.98	8.75	420
MD5-2070	6.0 — 12.0	12.0V CONSTANT	15700	0.30	12150	1.20	62.24	7.76	54.06	4.09	275
MD5-1885	6.0 — 18.0	12.0V CONSTANT	12500	0.20	9820	0.74	53.50	5.39	60.73	2.70	250
MD5-12160	12.0 — 24.0	12.0V CONSTANT	5600	0.12	4000	0.30	34.29	1.41	39.10	0.75	120

The motor specification chart typically includes the operating voltage, and a corresponding speed, current draw, stall torque, and power output under both load and no-load conditions.

Controlling the motor with a potentiometer, is actually a form of analog circuitry. Analog voltages and currents can be used to control things directly, much as the volume

of a car radio. In a simple analog radio, a knob is connected to a variable resistor. As the knob is turned, the resistance goes down. As that happens, the current flowing through the resistor increases. This is the same current driving the speakers, thus the volume is increased. An analog circuit is one whose output is linearly proportional to its input.

As intuitive and simple as analog control may seem, it is not always economically attractive or otherwise practical. Analog circuits tend to drift over time and can, therefore, be very difficult to tune. Precision analog circuits, which help alleviate this problem, can be very large, heavy, and expensive. Analog circuits can also get very hot. The power dissipated is proportional to the voltage across the active elements multiplied by the current through them. Analog circuitry can also be sensitive to noise; because of its infinite range of resolution, even minor perturbations of an analog signal interfere and change its value[42].

2.8.2.3 Speed Control by Pulse-Width Modulation

Pulse-Width Modulation (PWM) is a powerful technique for controlling analog circuits with a processor or microcontroller's digital outputs. The concept behind PWM is to digitally encode (modulate) analog signal levels through the use of high-resolution counters which calculate the duty cycle of a square wave that corresponds to a specific analog signal level.

The PWM signal remains a digital signal because, at any given instant of time, the full DC supply is either fully on or fully off. The voltage or current source is supplied to the analog load by means of a repeating series of on and off pulses. The *on-time* is the time during which the DC supply is applied to the load, and the *off-time* is the period

during which that supply is switched off. Given a sufficient bandwidth, any analog value can be encoded with PWM. One of the advantages of PWM is that the signal remains digital from the processor to the controlled system; no digital-to-analog conversion is necessary. By keeping the signal digital, noise effects are minimized.
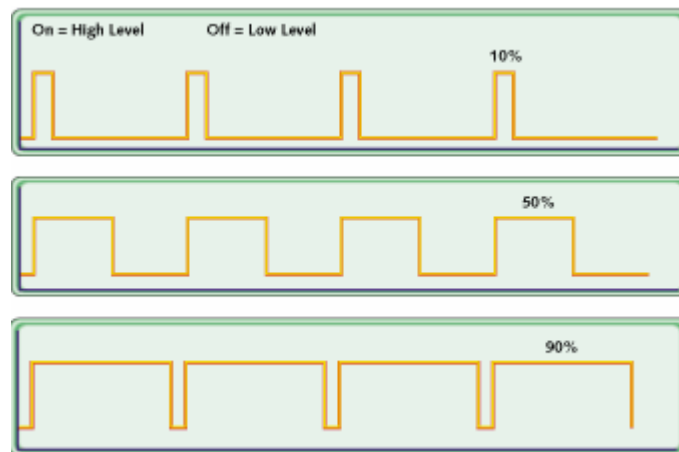
Figure 16: PWM duty-cycles

Figure 16 shows three different PWM signals. The top square wave shows a PWM output at a 10% duty cycle. That is, the signal is on for 10% of the period and off the other 90%. The middle and bottom waves show PWM outputs at 50% and 90% duty cycles, respectively. These three PWM outputs encode three different analog signal values, at 10%, 50%, and 90% of the full strength. If, for example, the supply is 9 V and the duty cycle is 10%, a 0.9 V analog signal results.

3.0 1st Generation Proof of Concept Prototype

A 1st generation proof of concept prototype was constructed and tested by Abramovich, Scarsella and Toddes. The prototype was manufactured in several sub-assemblies, assembled and tested. After testing, conclusions were made by Abramovich, Scarsella and Toddes for future optimization of function, assembly and user comfort.

3.1 Prototype Components

The prototype of the 1st generation wearable, upper extremity orthosis was designed and built in three sub-assemblies: Frame, Elbow Drive and Humeral Drive sub-assemblies.

3.1.1 Frame

The frame of the 1st generation orthosis (Figure 17) consisted of two parts: The forearm support (distal to the elbow) and the humeral bars (proximal to the elbow). The upper arm support and strapping also serve to function as parts of the frame, but these parts are included in the Humeral Drive System, and are not strictly part of the frame sub-assembly.

The frame was constructed from 6061 aluminum for ease of machining, bending, and welding. The forearm portion of the frame had two sidebars, which narrowed from the elbow to the wrist, and two semi-circular braces, one forward of the elbow, and one aft the wrist. Proximal to
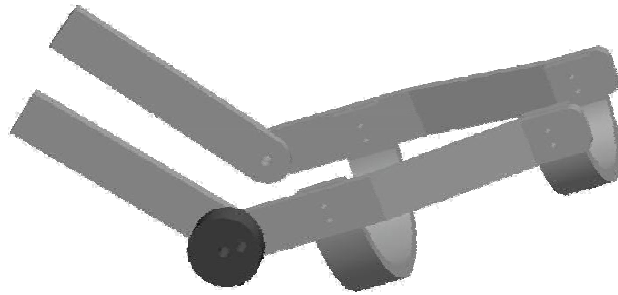
Figure 17: 3D Representation of Frame Assembly

the elbow, the humeral bars were 1" by ¼" stock, and pinned to the forearm portion, allowing for rotation about the elbow. Additionally, the humeral bars terminated in junction blocks to mate the worm gear and slider track.

3.1.2 Mechanical Drive

The prototype was intended to drive 2 DOF; two distinct mechanical systems were designed to control each degree of freedom. These mechanical drives consisted of the Elbow Drive System and the Humeral Drive System.

3.1.2.1 Elbow Drive System

The Elbow Drive System created the necessary moment acting between the forearm and upper arm to flex or extend the orthosis (and the user's arm). The system (Figure 18) included the motor, gearing, and a coupling to the frame. The motor provided the initial torque and angular velocity to drive the system. The gearing increased the torque and reduced the speed of the motor, controlled the maximum torque of the system, and to created a non back-drivable system.

Torque was limited using an inline slip-clutch. At a set torque, the clutch would exceed the static friction of the clutch and the axle would spin free. It was necessary to limit the maximum torque of elbow flexion because of the potential for the user to place his hand under an unmovable object, and strain his wrist.

Task specifications required the device to be non back-drivable, so that when the motors were not powered, the device would not sag. To prevent back-drivablity, a worm and worm gear were used.

Since the Elbow Drive System was mounted as a sub-system to the frame, it was important to allow for slight misalignment; a chain drive was used to further reduce the angular velocity and to allow for mating compliance with minimal inefficiencies.

A coupling system connected the motor and the gearing directly to the frame. The final sprocket gear of the gearing system was fastened to the forearm frame by two pins, as shown in Figure 17. The motor and other gearing of the
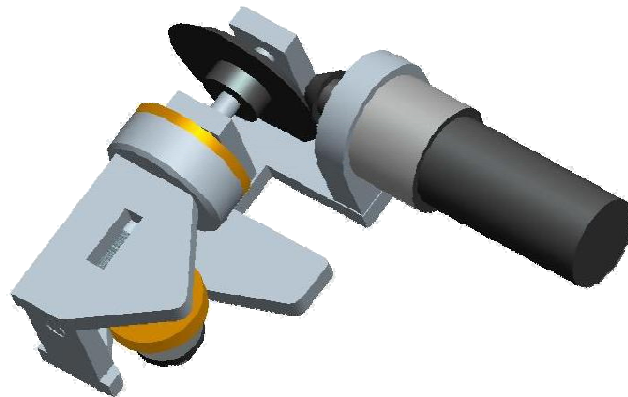
Figure 18: 3D Representation of Elbow Drive System

Elbow Drive System was mounted directly to the humeral bars of the upper arm portion of the orthosis.

3.1.2.2 Humeral Drive System

The Humeral Drive System created a moment between the distal portion of the orthosis, and the proximal portion, with the center of rotation about the axis of the upper arm. The drive system consisted of a motor, simple gearing and a coupling system. Simple gearing was used to arrange the motor in a convenient position. The gearing then drove a worm and worm gear.
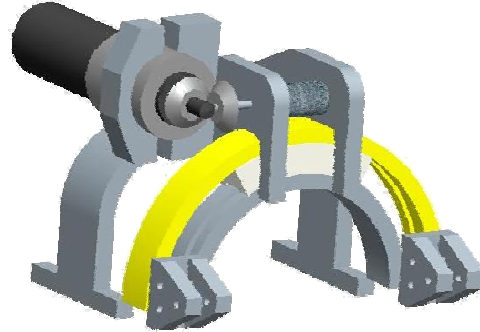
Figure 19: 3D Representation of Humeral Drive System

The worm gear served three purposes in the Humeral Drive System. Primarily, it drove rotation between the distal and proximal portions of the orthosis. Secondly, the worm gear made the rotation non back-drivable, while increasing torque. Lastly, the worm gear, along with an aluminum ring, captivated the slider. This junction maintained the rigidity of the orthosis, while allowing for rotational translation about the center of the upper arm.

3.1.3 Prototype Control System and Electronics

The original electrical system controlling the 2 DOF orthosis was constructed of individual components in a dual H-Bridge system (Figure 20). The electronic components were selected to handle to withstand the heavy flow of current created by running two motors simultaneously.

Figure 20: Prototype with power source, and control system

3.1.3.1 Prototype Control System

Original task specifications for the orthosis controls called for an intuitive format, allowing the user to control both degrees of freedom with little difficulty. To meet these goals, the design needed to be unobtrusive and easy to understand/control. The final design evolved from methodology used in the design of a wheelchair control.

During a visit to the Massachusetts Hospital School rehabilitation engineering office several different models of powered wheelchairs were viewed each with different functions and abilities. The common trait among all chairs was that they all utilized joystick control. The reasoning behind this is that joysticks, as opposed to individual switches, are the most intuitive and most user-friendly way of condensing several operations into one compact controlling device. An additional benefit of joystick control is that the controlling hand may stay in one position, and control requires on only minor finger tactility, and wrist motion in order to achieve the full range of necessary functions.

Joysticks can be divided into two basic groupings: momentary and proportional. Momentary joysticks are simply an arrangement of push-button momentary switches arranged in a plane perpendicular to the vertical axis, so that the user may tilt the axis in the desired direction, actuating the corresponding switch. Proportional control joysticks consist of dual potentiometers, each controlling one axis, which measure the proportional deflection in each direction.

The desired joystick required fore-aft direction, as well as left-right direction. The original intent of the joystick control was to control elbow flexion and extension with the fore-aft motion, and the humeral rotation by the left-right motion.

Figure 21: Prototype Joystick and controls box

This would require a joystick which had four momentary switches. For the purpose of prototyping, ultimately the decision was made to adapt an existing commercially available device (Figure 21).

3.1.3.2 Prototype Electronics

The electronic circuit for the powered arm orthosis served as the logic unit between the user interface (in this case, the joystick controls) and the two DC motors, which drove each degree of freedom. The circuits modified the four directional input signals from the

joystick control, and sent the proper voltage to the appropriate motor. The intended

scenarios are shown in Table 6 .

Table 6: Circuit Distributing Proper Voltages Based on Control Input

Joystick Directional Impulse	Circuit	Voltage Output to Motors
Up		+ 12 V
	Circuit # 1	
Down		- 12 V
Left		+ 12 V
	Circuit #2	
Right		- 12 V

During design of the motor circuitry, it was important to ensure the motors could

be run simultaneously. This concept allowed the possibility for coupled motion of both

degrees of freedom on the orthosis. The design realized this possibility by utilizing

independent circuits for each motor, which provided enough current to run both motors

simultaneously (Figure 22).
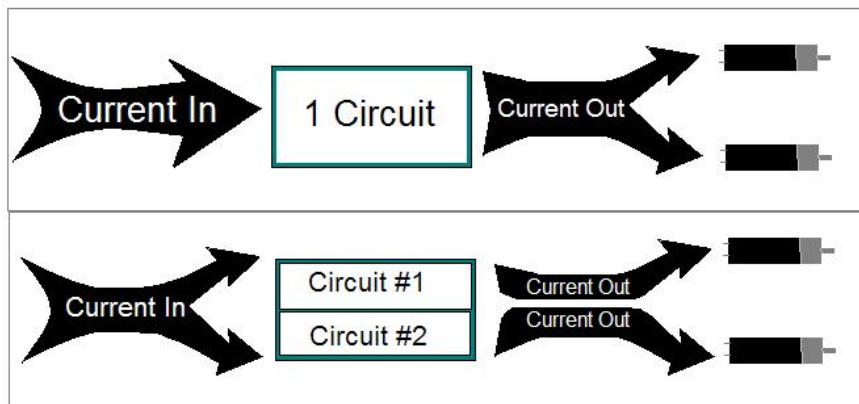
Figure 22: Current Divided after Circuit (above) and within Circuit (below)

The end result of the design proved successful. The circuitry, however, was

comprised of a large control box since both H-bridge circuits were built from individual

components placed on breadboard rather than one chip on PCB. As mentioned

previously, this shortcoming resulted from the assumption that the current to drive two

motors would generate excessive heat, and necessitate larger components. Proper chips

for this type of operation were not available during initial prototyping. A vie of the final

breadboard configuration is shown in Figure 23.
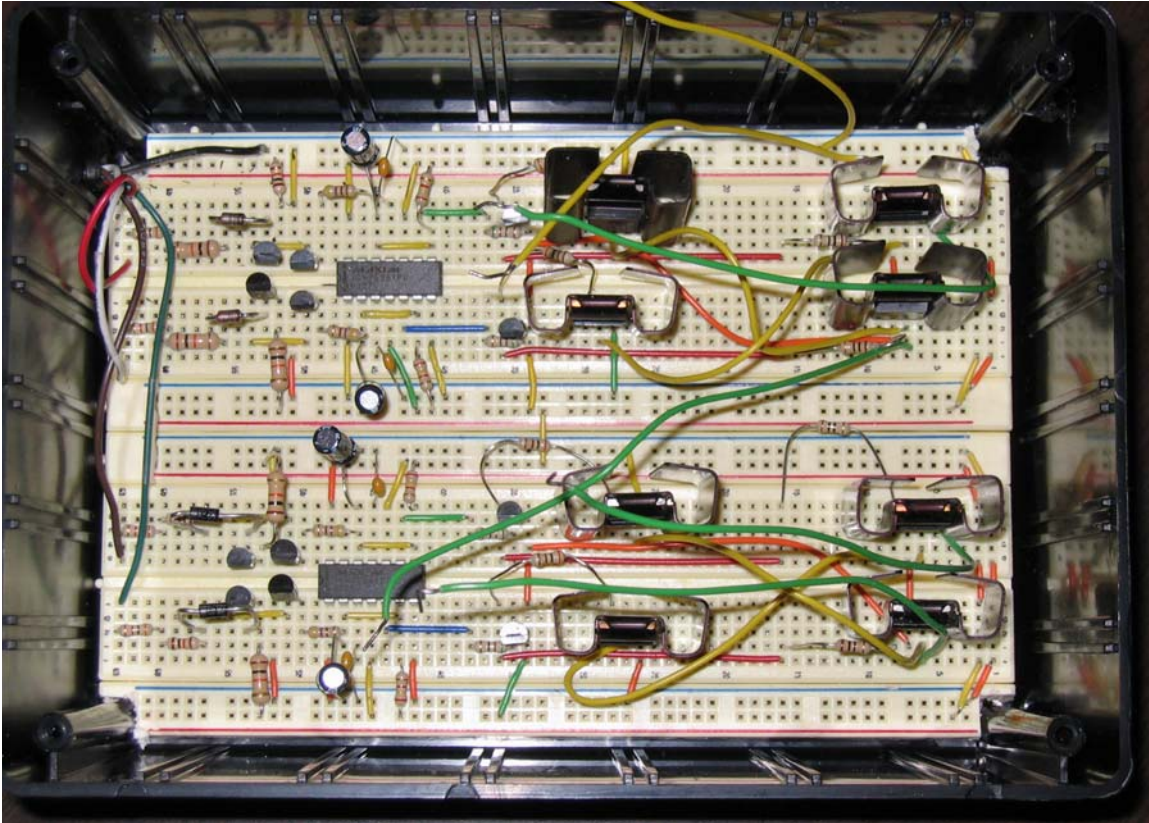
Figure 23: Photo of Final Assembled Circuit

3.2 Evaluation of Existing Design

Following prototype development, recommendations were made by the design

team for future improvements to the device. In addition an evaluation was informally

conducted by potential Duchenne Muscular Dystrophy (DMD) clientele and

rehabilitation specialists at the Massachusetts Hospital School in Canton, MA on

November 8, 2005 (Appendix B). The culmination of observations, recommendations,

and comments from both parties has led to a full evaluation of the current state of the orthosis design, as well as potential ideas to further the functionality of the device.

3.2.1 Current Design Limitations

The current design iteration includes features requiring improvement or an increase in functionality, that would have to be made for the device to have commercial interest and application. Areas of interest include: weight and size reduction, elimination of controls box, adjustability of the device to fit any sized client; pinch or chafing points; range of motion characteristics; and increasing the strength of the weakest component: the large brass worm gear. Each limitation is discussed in this report, and improvement strategies within the next iteration of design can be seen in the following sections.

3.2.1.1 Adjustability

Customization of an assistive device for a particular user is inherently simple, as only one set of anthropometric data needs to be accomodated. However, if a device is to be widely commercially accepted or mass produced, a method for adjustability must be employed in order for compatibility with any given body size or type.

Within the current orthosis design, there exists little potential for deviation from the original designed parameters. In order for multiple persons to use the device, excessive padding and other adaptive measures must be taken to ensure a proper fit. This method, although acceptable for evaluation of the device, would not be logical for a commercial device.

All portions of the device distal to the elbow joint, which is used as the key fitting location, are considered as non-critically dimensioned on the current design, and can fit a variety of people, although the distal portion may be too large for small users. However, there is critical distance between the elbow and the position of the alignment of the humeral rotation mechanism. Since this distance is not adjustable in the current orthosis, significant area exists for improvement. Improving this situation would require adjustability translating down the length of the humerus in order to accommodate a variety of users, thereby aligning both the axis of the elbow joint and the midline of the humerus, accommodating clients with differing humeral lengths.

3.2.1.2 Pinch/Chafing Points

Pinch points and chafing points are a result of the hardware on the device rubbing against the user's skin or clothing. The importance of minimizing these points is emphasized as it may compromise the safety of the device. In addition, discomfort while wearing the device would dissuade the client from usage, resulting in an obsolete product.
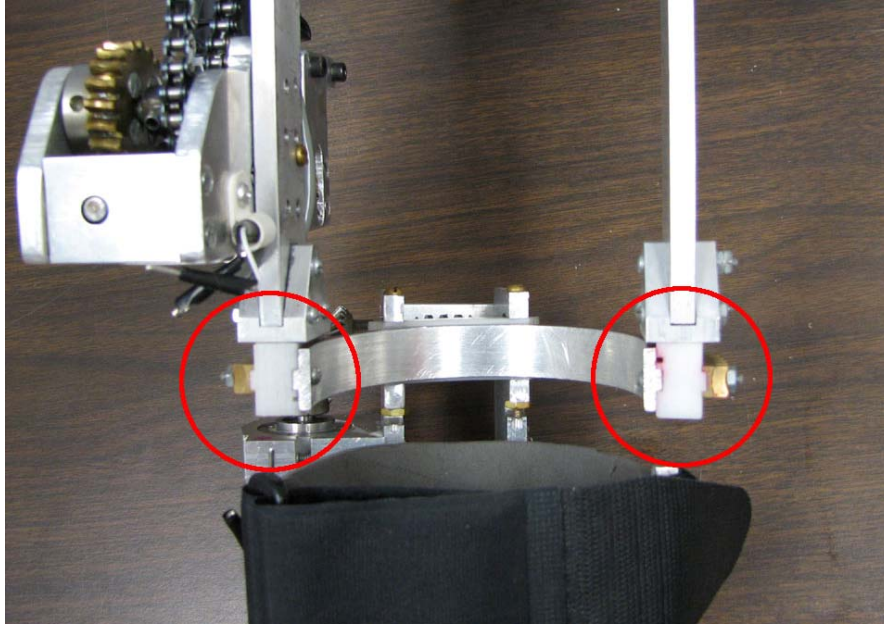
Figure 24: Pinch Points on Slider Bearing

Within the current design, there are three locations that produce reduced comfort and possible safety issues. Two of these areas reside on the humeral rotation mechanism. On the slider bearing, there are sharp corners on both the lateral and medial side that are unprotected from contact with the user's skin. Figure 24 shows the underside of the device, indicating the points of chafing located on the inside of the bearing arc, just above the black Velcro strap. This usually occurs when humeral rotation occurs and the system is torqued. Ideally, these points would be shrouded, and torque motion would be minimized.

The second problematic location is a pinch point which occurs where the slider meets the slider stoppers. This mechanical stop is exposed, and could pose harm if an object were to become sandwiched between the stopper and slider.

The last point which may lead to problems over time is a pinch point on the forearm strap. When the elbow flexion occurs, the skin distal to the elbow, but proximal to the forearm strap begins to relax, and fold, creating a build-up of excess skin, which is

being held down by the tightened forearm strap. This pinching of relaxed skin could become a discomfort to the user when flexion occurs beyond 80°. Possible solutions to this pinch point include padding between the strap and skin, and also attaching the strap distal to the current location.

Although the final design was able to achieve 110° of elbow flexion and 90° of humeral rotation, the ranges could be extended in order to conform to true anatomical dynamics. By allowing for additional motion on both degrees of freedom, additional flexibility would be allotted to the orthosis. This would not only benefit in terms of assistive technology, but also as a rehabilitative and therapeutic function.

Figure 25 shows the elbow DOF fully flexed at 110° from the fully extended position. As a result of the motor positioning, a mechanical stop halts the progress of the forearm cage, engaging the slip clutch, and stopping at the current position of maximum flexion. Ideally, flexion would be maximized at around 135°, closer to the true anatomical range of an able-bodied person.

Figure 25: Elbow DOF fully flexed

3.2.1.3 Range of Motion

In the humeral rotation mechanism, the track upon which the slider translates currently allows for 95° of motion for the 60° slider along the 155° arc (Figure 26). With the current setup, there are mechanical "mini slider" stops constructed of delrin plastic at both ends of the arc, not allowing for an easy way to increase the range. The only alternative to altering the range is to alter the materials used, and create a new arc for the slider mechanism to follow, with a larger range of motion.

A number of rehabilitation and assistive technology professionals have suggested that incorporating a method by which to control the range of motion may be of use. In the case of DMD patients for example, full range of motion would be undesirable with their limited joint motion, and could be potentially harmful. In the case of a rehabilitative standpoint, having a therapist prescribed range would be invaluable not only to track progress of therapy but also to limit motion for safety.
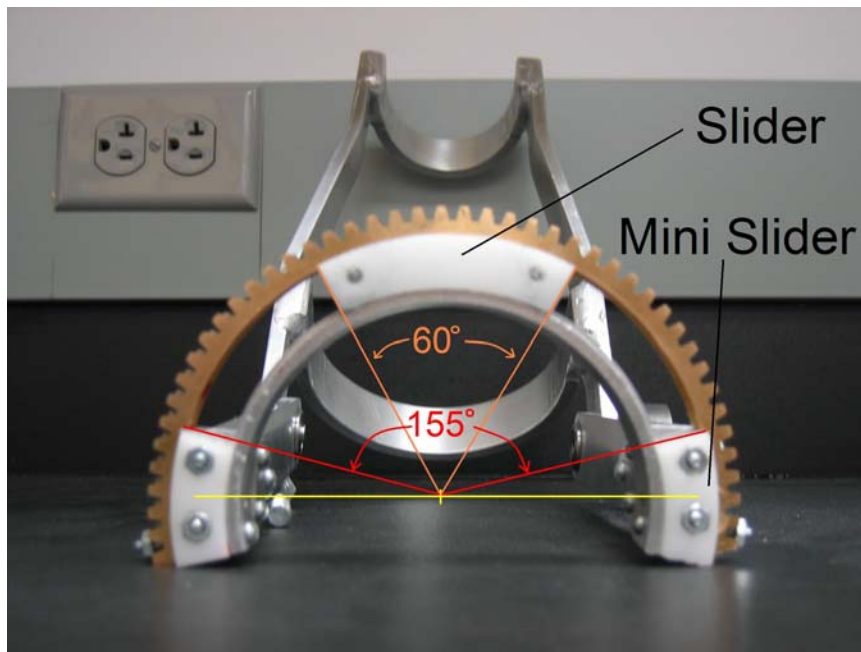
Figure 26: Humeral Rotation Range of Motion

3.2.1.4 Brass Worm Gear Strength

During testing, the brass worm gear driven by the worm on the humeral rotation mechanism experienced some bending along the plane normal to the humeral axis due to torque in the system. Brass is typically a good choice for worm gears because any imperfections in the worm / worm gear alignment are typically melded away by the shaping of the relatively soft metal. However, in a system where rigidity and structural integrity are important, as is the case in this device, a more appropriate material should be selected.

The brass gear has been altered so that it allows 95° of motion of the slider. If this gear were to be replaced, a more thorough search of materials should be carried out to examine any potential for stronger, more rigid gearing metals. If the metal remains as brass, the loading must be relieved from the intersection of the slider and bearing in order to avoid damaging the delicate gear and gearing alignments. Any change in alignment may compromise the humeral rotation mechanism, attached motors, and possibly the electrical circuits.

3.2.2 Potential Areas for Optimization

After constructing a working prototype, several areas for potential design optimization have been identified. The purpose of design optimization will be to create a lighter, less bulky device, while increasing the overall durability.

3.2.2.1 Weight

Though the original task requirements called for a working design under 6 pounds a significantly lighter device is desirable. The potential identified users include persons

with significant muscular deterioration or abnormalities, persons with abnormal neuromuscular function, and those seeking rehabilitation.

Persons with significant muscular deterioration or abnormalities would generally use the device when confined to a wheelchair. While sitting in a wheelchair, the user can partially support the device with their elbow with their elbow acting as a pivot for the device. This scenario significantly reduces the weight of the device supported by the shoulder, though the weight of the device will still apply weight to the shoulder and elbow.

In many persons with significant muscular deterioration, for example, those with DMD, muscles waste globally, increasing the chances for shoulder dislocations. As such, even small loads on the shoulder are a concern for these patients. To reduce the risk of shoulder dislocations due to the weight of the orthosis, the weight of the orthosis should be reduced for this clientele.

For a population of more able bodied people, who would use the device as both a non-essential assistive technology, for example, to minimize the effects of Essential Tremor and those who would use the device for rehabilitation purposes, the device would be worn both while standing and sitting. While standing the users would sustain the entire weight of the device with their shoulder muscles. While this population generally does not suffer global muscle weakness or widespread neuromuscular disabilities, extended use of the device could fatigue the shoulder. To extend the time users of the device could wear the orthosis, it is, again, desirable to lighten the device.

3.2.2.2 Slip

In preliminary tests several users wore the device and attempted to complete ADL, some users found that during humeral rotation, the device began to slip around their upper arm. As the user rotated the humeral portion of his/her arm from a vertical position to a horizontal position, the slip of the device became more pronounced. The slip occurred at the junction between the user's arm and the humeral strap. Since slip occurs in gradual increments, successive periods of slip could result in a misaligned orthosis, which could potentially injure the user. Any slip in the device is also detrimental to the user's precision and maximum strength as they complete ADL.

3.2.2.3 Bulk of the Orthosis

Although attempts were made to minimize the overall size of the arm orthosis, the current prototype, with gear shields installed, can be made less obtrusive to the user. Both drive assemblies each cover an area greater than 25 square inches and extend more than 2 inches from the arm.

The articulating frame has also been found to be over-designed. Since the entire device (for financial reasons) was scheduled to be constructed from a single piece of stock aluminum, little consideration was given to the bulk of the frame. The current solid bars extend from the elbow to the wrist on either side of the forearm. The cage is also held rigid by two bent bars, which curl under the forearm. Finite Element Analysis (FEA) has shown that almost no deformation occurs during normal use. Optimizing the frame will reduce the profile of the design and the weight of the design; improving both the unobtrusiveness and the functionality of the device.

3.3 Design Alterations and New Concepts

Several new ideas have been conceptualized due to a combination of necessity, and optimization. Some design ideas act as improvements to the current prototype in order to increase functionality or improve performance, while others counteract any deficiencies that were present in the original design. Concepts and alterations have been categorized by structural, mechanical and electrical components.

3.3.1 Structural

The following subcategory represents a group of concepts that aid in maintaining the structural integrity of the orthosis design, as well as stability during operation.

3.3.1.1 Humeral Sleeve

The humeral sleeve was designed as a method to rectify two deficiencies in the current design. First, there are pinch points on the bottom side of the medial, and lateral side of the slider bearing, which create an uncomfortable condition and poses a safety risk. Second, the weight of the orthosis, and torque about the humeral rotator causes a rotation with respect to the arm during operation. As noted above, this unintended rotation reduces the precision of the device, and can potentially create a dangerous misalignment.

The humeral sleeve is appropriately named, as it is a sleeve, made of flexible, yet sturdy material such as foam, or neoprene. This sleeve sits is affixed to the proximal section of the device and would cover the upper arm from the most proximal portion of

the orthosis to the elbow. As it extends the entire length of the humeral portion of the orthosis, it acts as a barrier between the exposed metal, and the user's arm, while simultaneously providing a rigid connection along the length of the user's bicep.

The sleeve would not impede with donning and doffing of the orthosis, as it would encompass the top half of the bicep, while straps would tighten the sleeve to the humerus around the tricep area, thereby providing a secure connection. The material for the sleeve would ideally be similar to the hot plate grips from KitchenGrips® (www.kitchengrips.com) where there is a tacky surface suitable for providing friction on the surface of the skin or clothing, and a decorative cloth surface for the viewable side. The method of connecting this flexible member to the proximal section of the humeral rotation mechanism is yet to be determined.

3.3.1.2 Forearm Cup

The current forearm cage is both too large for small users and over-designed for even the largest users. A more practical design should incorporate adjustability for users of different sizes, while not being too large or bulky. Such a design would increase the users' comfort, improve functionality, and reduce the overall weight and bulk of the device. The change, however, should not be so drastic as to require additional testing of the already functioning prototype.

A forearm cup (Figure 27) could accommodate users of different sizes and reduce the bulk of the device. The forearm cup would replace the distal portion of the existing forearm cage. The portion of the frame closest to the elbow would remain intact, while the aluminum members adjacent to the forearm and toward the wrist would be completely removed. In its place, a thermoplastic cup (such as ABS) would support the

weight of the arm. Since the cup would be made of a thermoplastic, it could be easily molded to the patient's arm, reducing the need for excess padding. The cylindrical shape of the forearm cup would also increase the rigidity of the member.
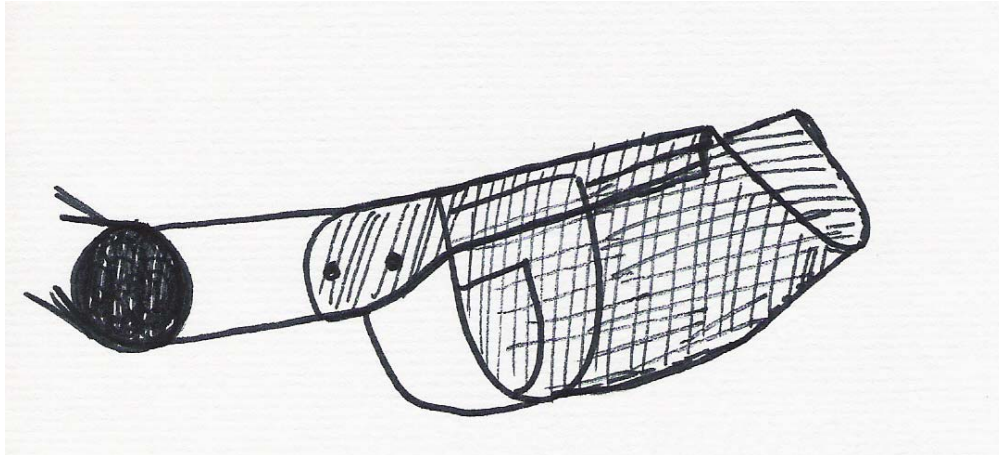
Figure 27: Forearm Cup Concept Sketch

The forearm cup would also be less obtrusive than the current design. The forearm up could be molded to maintain a uniform offset from arm. More like a shirt, rather than a support, the forearm cup could match the contours of the individuals arm. The close contouring around the forearm, also has additional benefits, it would also help alleviate the pressure points, which are present in the current design.

The forearm cup would be attached to the remaining portion of the aluminum cage by a set of screws, which would screw through the plastic cup, into threaded holes in the aluminum. By setting the screws into the aluminum, the slim profile of the forearm cup can be maintained.

3.3.2 Mechanical

In order to address limitations found within the orthosis design that required mechanical redesign, several changes will be made to increase the durability, functionality, and adjustability of the device. The three issues addressed include improvement of the mechanics within the slider design, overcoming the effect of gravity and excess weight on motor performance in the elbow flexion mechanism, and finally mechanical stops to increase adjustability in the elbow, and humeral degrees of freedom.

3.3.2.1 Slider Type Mechanism Redesign

While the design principles applied to the slider mechanism have been tested, and appear functional, there still remains significant potential for improvement of the design. As mentioned in the previous section, the slider is both a point of instability between the proximal and distal portions of the humeral rotator, and the slider track does not add additional rigidity to the humeral bars.

Keeping with the design of interlocking profiles, the slider has been redesigned with additional material located further from the centerline of the part (to increase structural rigidity), and with deeper pockets (to increase part to part rigidity). The former and new slider brass ring, slider and humeral slide profiles can be seen in Figure 28. From this side by side comparison, the two designs can be compared. The material further from the centerline will increase the torsional and bending rigidity of the components. The deeper pockets of the new slider will also increase the rigidity of the interface between the humeral and forearm portions of the orthosis.
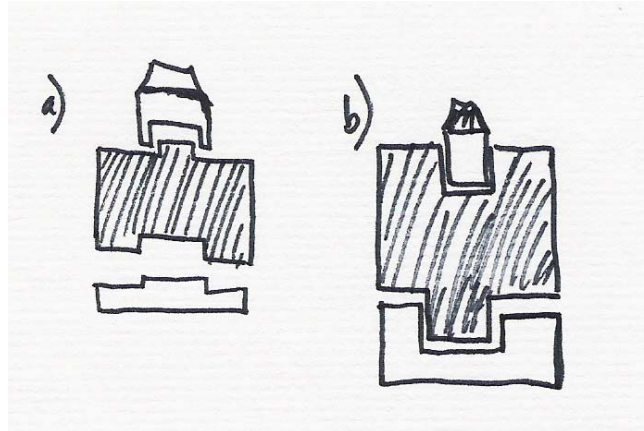
Figure 28: Slider Cross-Section Redesign
(a) Current slider design showing (top to bottom): Brass Gear, Slider, Aluminum Bearing. (b) Proposed redesign of slider.

3.3.2.2 Springs to Power Elbow Flexion

In any system driven by a motor, it is adventitious to balance the required force from one step to another. During elbow extension in the vertical plane, reduced motor torque is required because gravity works to pull the weight of the arm down. During flexion, however, gravity works against the motor; the motor must lift the weight of forearm, the forearm cage, and any object in the hand.

Examining other motor systems, where intermittent forces are applied, rotational energy is stored in flywheel to balance rotational torque in the motor. Since the elbow flexion/extension mechanism only function for brief pulses, a kinetic method to store energy is not feasible.

Springs are often used as another method to store energy. Torsion springs are an excellent choice to balance the unequal motor torque between elbow flexion and extension. The current design also accommodates the use of springs. Because the friction

within the worm gear will hold the wound springs, the springs natural tendency to unwind will be controlled by the orthosis, even when the motors are not being driven.

In the horizontal plane, though, springs will work against the motor, without providing any additional benefits. Since the, however, horizontal elbow flexion is nearly passive, the motors will not be required to lift any weight, and will only work to wind the springs.

Springs also offer a secondary benefit to the device; springs can help balance the lifting force on the forearm cage/cup. In the current design, all of the lifting torque is applied to one side of the cage. By having a stiffer spring on the undriven side of the forearm cage/cup, the weight distribution during lifting will be equalized.

3.3.2.3 Range of Motion Stops

Safety should always be a primary concern in the development of a powered orthosis or prosthesis. While the motion of the arm orthosis can be precisely controlled, the maximum positions of the arm orthosis should be limited to prevent users from moving the arm orthosis past the physical limitations of their muscles and joints. Since many of the intended users have malformed or dysfunctional muscles, there is no standard range of motion for the device. The device, therefore, may require adjustable stops to control the range of motion.

To control the motion of the humeral rotation mechanism, additional stops, with a profile shape similar to the slider, will be included with the orthosis. By installing additional stops, the range of motion can be limited. The stops will allow the user to control the range of motion in 10 degree increments.

The range of motion in the elbow flexion/extension mechanism can also be limited by stops. In the current design, a large sprocket gear is pinned to the forearm cage. This sprocket is the last gear from the motor, and links the forearm cage/cup to the gearing. By limiting the motion of this gear, the motion of the forearm cage can also be limited. The rotation of this gear will be limited by a set of settable dials (one to limit extension and the other flexion). The dials will have a single protruding tooth, which will collide with a welded stop. The position of the tooth is adjustable by removing the stop, and repositioning it on sprocket. The sprocket and stop will have a similar star pattern, which will allow the stops to be placed in any position, in 18 degree increments.
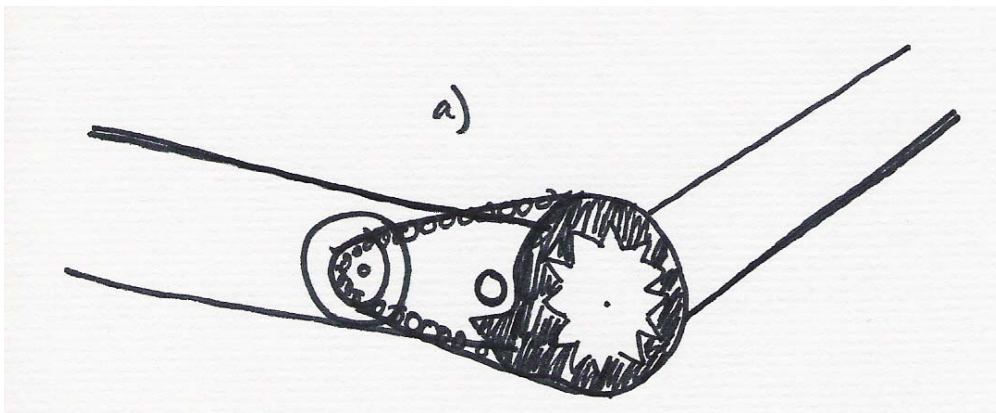
Figure 29: Elbow DOF Range of Motion

3.3.3 Electrical

Optimization of any system generally requires that it become more powerful, smaller, or more efficient. Electronics are no exception, and more specifically, are normally a leader in all three respects.

The original electrical system controlling the 2 DOF orthosis was bulky, and comprised of individual components in order to complete the dual H-Bridge. This system was built with individual components with the maximum current and voltage

characteristics in order to be able to handle a large flow of current, which was expected while running two motors simultaneously. After prototype development, a better understanding of the necessary electrical conditions was observed, and more ideal and compact methods of controlling and powering the orthosis have been discussed.

3.3.3.1 Onboard Power and Circuitry

The current power situation for the device requires a power supply to send roughly 14 volts of DC power through the circuit box, which then outputs 12V DC to the motors on both channels. Additionally, the joystick has an internal battery supply allowing 6V to act as the switching voltage.

The next iteration of this device design will incorporate onboard power, thereby eliminating the need for a bulky external power supply. Similar to the methods by which prosthetics are powered, a high-capacity, low-profile, lightweight Lithium-ion battery will be supplying power to the motors. Typical amp-hour ratings for batteries of this type will allow for operation of the orthosis for 1-2 hours of normal use.

Eliminating the external controls box by placing circuitry onboard the orthosis would require creating printed circuit boards (PCB) for each motor. By having two lightweight PCB's, one on the humeral rotation apparatus, and one on the elbow flexion apparatus, the bulky exterior control box could be eliminated. The main benefit to this transition would be the improved portability of the device, and the aesthetic improvement without a bulky peripheral control box.

Fortunately, technology has improved within the past two years with regard to h-bridge technology. As robotics becomes more mainstream as both a hobby, and a method of automating manual labor, the drive systems and components have been rapidly

improving. H-bridge chips are being manufactured by companies such as National Semiconductor, which can accommodate over 3 amps of current at 55 volts (LMD18200), which is more than enough to accommodate our dual motor setup.

By reducing the current set of two H-bridge circuits which individually spanned the full length of standard breadboard, down to a single chip, all circuitry can be placed onboard, with one H-bridge on the humeral rotation apparatus, and one on the elbow flexion. Since electronic circuitry is so small, and lightweight, design size and weight would not be compromised by placing circuitry onboard.

In addition, plans for the driving circuits include using the H-bridge in conjunction with a Pulse-Width Modulator (PWM) for switching, which will use less current, less voltage, less power, and therefore increase the battery life, and improve motor control. PWM technology allows the motors to overcome static forces to begin rotation utilizing the full current flow, rather than a ramped current. This is analogous to moving a car by rolling it down a hill with the old controller, versus the PWM technology which would give it an instantaneous push.

3.3.3.2 Velocity Control

Focus on velocity control has become a recent issue thanks to input from rehabilitation professionals. The concept of controlling the orthosis at differing speeds has been approached from two possible points of view. Both scenarios incorporate a method by which to change the speed of each degree of freedom, however the application would be a bit different for each.

The first application scenario incorporates user-controlled velocity with a wired proportional control joystick. The user would then control a joystick comprised of dual potentiometers, so each direction has inherent "sensitivity" controlled by the amount of throw distance the joystick is moved in each axis. This interface would be ideal in assistive technology situations as the smaller throw distance would increase accuracy and targeting for the user, and better control. One disadvantage to this setup includes the wire that still exists from the joystick to the control board.

The second scenario includes a user-defined velocity which allows the user to operate the orthosis in the current single velocity manner, however the onboard potentiometers would determine the speed as dialed-in by the user and the joystick would be operated wirelessly. This would be the preferred method for rehabilitative and therapeutic scenarios as it includes wireless use, which increases the functionality of the orthosis. One major disadvantage is the less versatile, less accurate targeting obtained from the single velocity control.

4.0 Task Specifications

At its roots, engineering is the purposeful implementation of math and science to solve known problems[43]. Fundamental to engineering is definition of a problem and purposeful design of a solution. Task Specifications, which clearly define the attributes of a final solution, are an important keystone between a defined problem and solution.

Task Specifications for a functional and marketable powered arm brace have been formulated. The task requirements for the orthotic device were divided into two categories: those that could be defined quantitatively, and those that were qualitative measures. The qualitative category was subdivided into design specifications that were based from the perspective of the user or were inherent qualities of the design.

4.1 Qualitative

4.1.1 User

1. **The user should be able to complete ADL within 2-3 times longer than the time it takes a normally functioning person to complete them.** The device is not intended to return normal functional ability to the user, but users should be able to complete activities of daily living (ADL) in a reasonable amount to time.

2. **An assistant must be able to remove the device, even without power to the motors.** It is important that the user not be "trapped" within the device if power is interrupted for long periods.

3. **Operation of the device should not cause pressure sores or bruising.** The intent of the device is to improve the quality of the user's life, and not cause further harm.

4. **The device should be aesthetically pleasing**. The user must be comfortable with the appearance of the device if it is to get adequate usage.

5. **The device should have the potential to serve therapeutic functions.**

6. **The device should be easily donned and doffed.** People will be more likely to wear and use the device if it is not a nuisance to put on and remove. More able-bodied people should be able to don the device will minimal assistance.

7. **An assistant should be able to easily dress the device onto a patient.** Placement of the device should be intuitive to assure proper alignment. The assistant should also be able to dress the device to a less able patient in a reasonable amount of time.

4.1.2 Design

1. **The device should be maintainable and cleanable if fluids are spilled into the device.** In patients with poor muscle strength, accidents are bound to occur. Unintentional fluid spill should not lead to damage to the mechanisms or electronics within the device.

2. **The device should have a working life of 5 years.** The orthosis must have a suitable lifespan, withstanding wear and tear to mechanical, electrical, and stability components.

3. **The device should contain no exposed gears or possible pinch areas.** As the device will be designed as an aid to patients, it should itself pose an increased risk of injury. Areas that may cause pinching, or could catch loose clothing should be avoided to reduce the potential for injury.

4. **The device should weigh less than 3 lbs not including user interface, and power supply.**

5. **The device should easily fit a variety of users and accommodate for growth.** The device must be designed with resize potential, to fit a variety of users.

6. **The device should include 2 DOF including elbow flexion and humeral rotation.**

7. **The device should minimally restrict current abilities of the user.** Since the intent of this device is to improve quality of life, it should not interfere with activities the user currently engages in.

8. **The device should dampen the unintentional movements of the wearer.** The orthosis is intended to provide power to the intended movements, and additionally should minimize movements not intended by the user.

9. **The device must have a mechanical resistance to remain stable in case of power failure.** As a safety feature, power interruption will cause the device to maintain rigidity due to mechanical resistance within the mechanisms.

10. **The design of the device should follow best practices of Design for Manufacturability and Assembly.** By designing for manufacturing and assembly, not only will the overall quality of the device improve, but the device will be scalable to production runs as a commercialized product.

4.2 Quantitative

1. **The range of motion of the device must be controllable for users with both normal and less than normal range of motion.** Each user, fully able bodied or disabled,

has a maximum range of motion. The powered brace should not exceed the range

of motion for any user and as every user has a unique range of motion, the device

should be able to be customized to each user.

2. The device should make the user capable of lifting up to 2.3 kg. A lifting power of

2.25kg (5 lb$_m$.) will allows a patient to lift most food and drink items. Based on

this lifting strength at the center of the hand, and anthopometric data, the device

will need to exert a moment of no less than 11.5N•m to lift the forearm, hand,

brace and an additional 2.25kg of payload[44]. (Equation 1)

3. The device should not exert a moment greater than 11.5 N•m about the elbow. If a

protrusion blocks the user's elbow flexion, or a mass in excess of 2.25 Kg was

place in the hand, the user's wrist may not be capable of supporting the additional

strain. As such the device will not induce a moment in excess of 11.5 N•m around

the elbow.
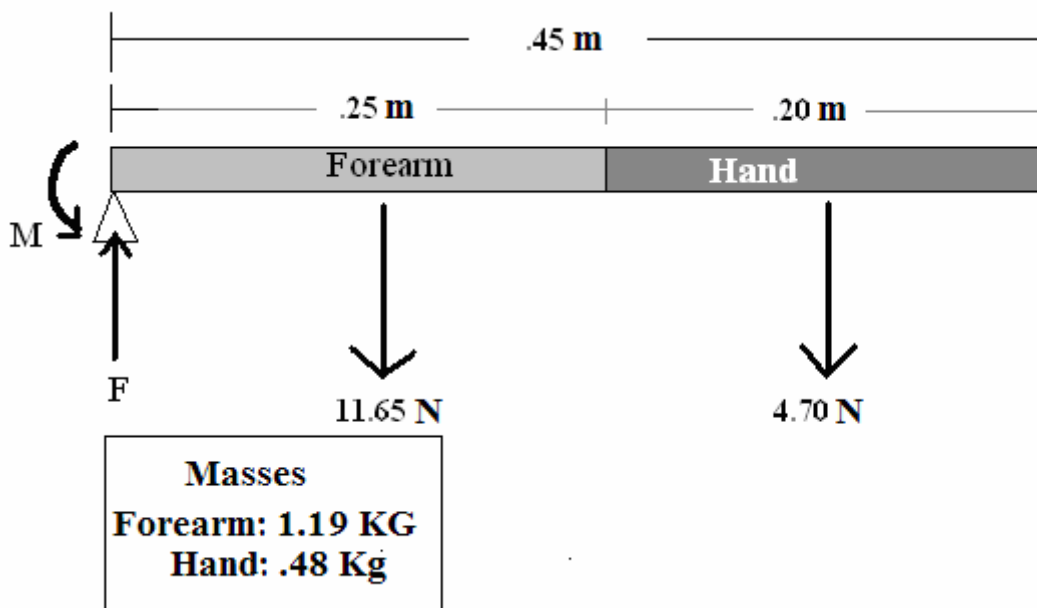
Figure 30: Free Body Diagram of Unweighted Forearm and Hand

Equation 1: Expected Torque Loads on both Humeral and Elbow Rotation

$$\Sigma_{moments} = (11.65N \times .13m) + (4.70N \times .35m) + (13.33N \times .45m) + (4.45 \times .13m) = 11.5N \cdot m$$

Calculation of torque at the elbow to allow a typical user to lift 2.3 kg in their hand. By appearance left to right: Forearm, Hand, Additional Weight, Expected Weight of Previous Device.

4. The device should have a manufacturing cost under $2500. To be commercially

successful, the retail costs should be within an affordable price range on the

consumer market, if subsidized by federal Medicaid and private insurance. For

this to be achievable, the base manufacturing costs must be held to a maximum

threshold.

5. The loaded device should be able to move through the full range of motion in less

than 8 seconds. Users should be able to complete ADL in a reasonable amount of

time. Only a device that can allow patients to move though a full range of motion

in a set time can be considered truly functional.

5.0 Mechanical Design

The redesign of the arm orthosis involved the integration of several new designs, which when assembled needed to function as a single working device. To aid in the design of the powered arm brace, the design was divided into a series of several distinguishable stages. Within each design stage, the individual systems of motion control were considered separately (Humeral and Elbow), as well as the junction between these two systems (Humeral and Elbow "Mate"). In the preliminary design stage, ideas were measured against design specifications and general functionality. A basic design was then selected and a more rigorous review of the design highlighting the principles of DFMA was used to decrease the complexity of the design, while heightening functionality and manufacturability. After standardized parts were selected, custom parts were designed and designs finalized, in preparation for testing using FEA. Based on the CAD FEA analysis, custom parts were redesigned to meet a minimum safety factor of 2.0. Finally, in preparation for fabrication, numerical models of expected functionality were derived to ensure that the final design met all task specifications (Figure 31).
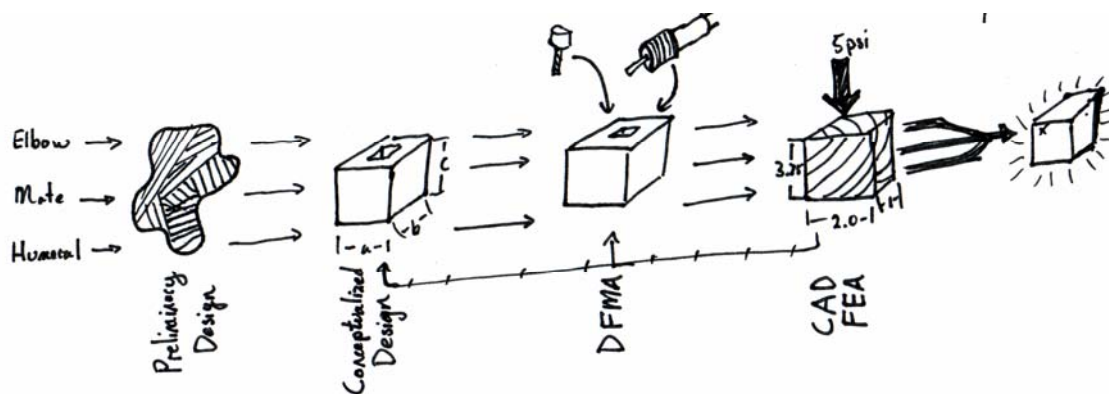
Figure 31: Chart of Design Methodology

Each step of the planned design process was conducted in series. Within each step, the individual systems of the Humeral Drive, Elbow Drive and Humeral Mates were designed in parallel. This design methodology both decoupled the Degrees of Freedom, making for a more manageable task, and also ensured that the design's final form was uniform and "seamless."

5.1 Preliminary Design

Based on the conclusions reached after the proof-of-concept prototype, several new component designs and configurations were examined for use in the commercialized powered arm brace, although both the previous and new arm brace share a common layout of components. This layout of *functional areas* is referred to heavily in the remainder of the document and serves as the basis of the design. This division of the orthosis into separate sections was an intentional decoupling of unique areas with dissimilar functions. As shown in Figure 32, the brace can be subdivided into six regions. These six regions are:
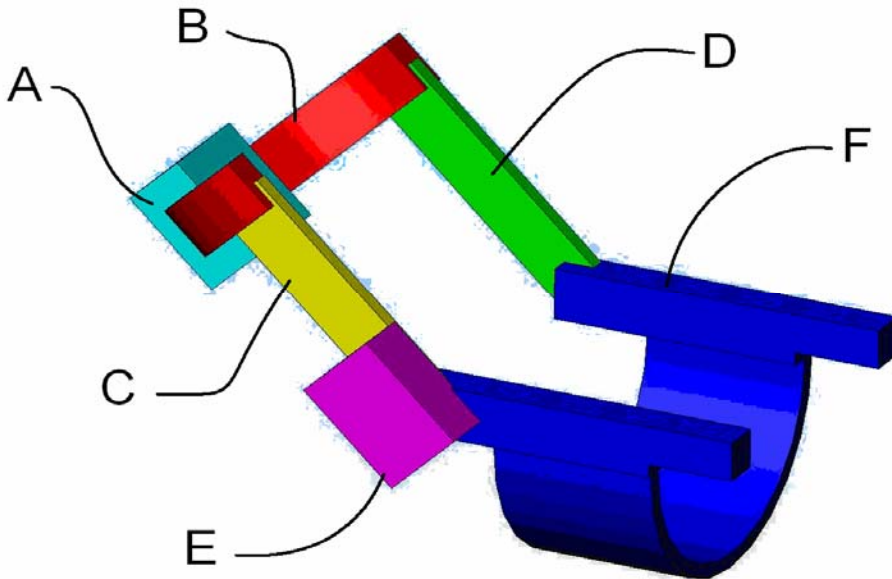
Figure 32: Basic Layout of the Powered Arm Brace

Solid models showing the basic configuration of the Powered Arm Brace as decoupled into distinct functional areas. As shown: Left to Right: Humeral Drive (A), Humeral Rail (B), Lateral Humeral Bar (C), Medial Humeral Bar (D), Elbow Drive (E), Forearm Cage (F).

Humeral Drive- The stationary Humeral Drive converts the torque from the humeral motor to torque at the Humeral Rail, which drives the Humeral Rail around the center of the arm. The position of the Humeral Rail is held constant to the shoulder during normal operation of the device. In the previous proof-of-concept design, the Humeral Drive consisted of the motor, the upper arm gearing and housing, and an upper arm strap as shown in Figure 33.
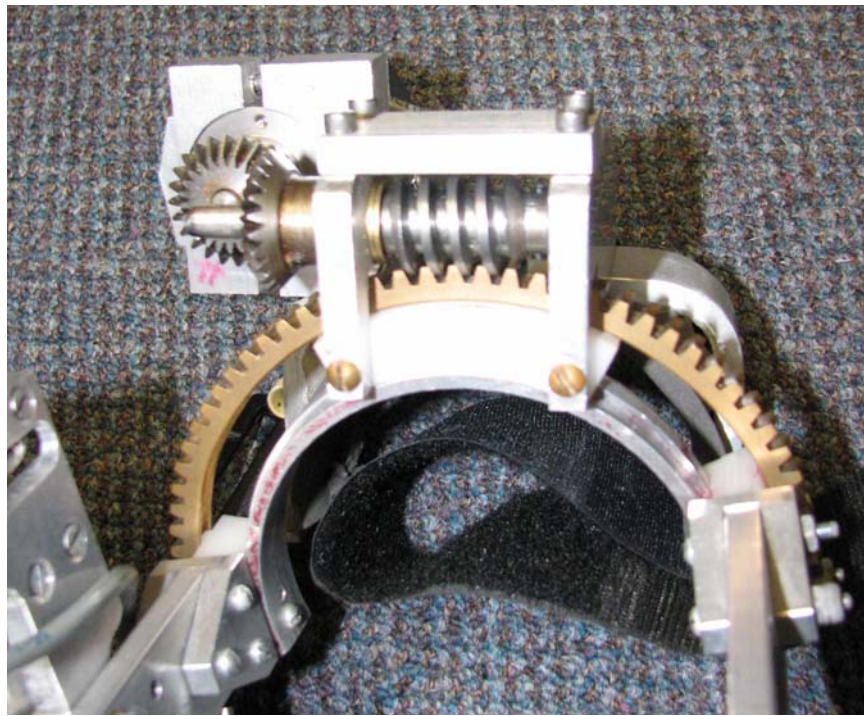
Figure 33: Proof-of-Concept Prototype Humeral Drive

Humeral Rail- As previously noted, the Humeral Rail converts the torque from the Humeral Drive into humeral rotation. The Humeral Rail not only transfers the torque from the Humeral Drive, but also serves as a structural support, holding constant the inner diameter of the device (Figure 34). The Humeral Rail and the Humeral Drive are often referred to as the *Humeral Drive System.*

Figure 34: Humeral Rail Positioned Around the Upper Arm

The Humeral Rail (A) is positioned on the upper arm (Forearm "C" shown for reference) and holds the inner diameter or radius (R) constant about the center of humeral rotation (C).

Elbow Drive- The Elbow Drive converts the power supplied by the elbow motor to the necessary torque to drive the Forearm Cage (elbow rotation). It is placement necessitates that it be fixed or integrated into one of the Humeral Bars. In the previous proof-of-concept prototype, the Elbow Drive was an entire sub-assembly, consisting of all of the elbow gearing, towers to hold the gearing, a mounting plate, and shielding (Figure 35).

Figure 35: Proof-of-Concept Prototype Elbow Drive

Forearm Cage- The Forearm Cage is the most distal part of the powered arm brace. The Forearm Cage converts torque from the Elbow Drive to drive elbow rotation.

The Forearm Cage ultimately drives humeral rotation as humeral rotation is manifested as rotation about the elbow along the axis of the upper arm (Figure 35). The Forearm Cage
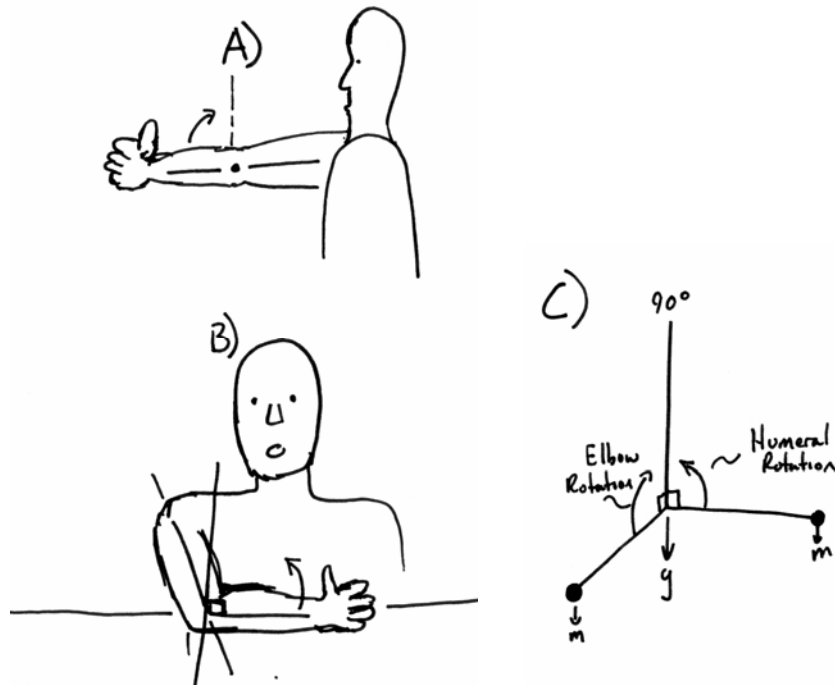
Figure 36: 0 Degrees of Elbow and Humeral Rotation
Elbow rotation at 0° (A) and humeral rotation at 0° (B). A basic sketch of rotation about a common elbow, showing elbow rotation and humeral rotation is also shown (C). Arrows indicate positive direction of rotation.

is the distal portion of the device that holds constant the inner radius of the orthosis at the forearm (Figure 37). In the previous iteration, the Forearm Cage was considered part of the basic frame of the device (3.1.1 Frame), rather than an extension of the elbow drive. The Forearm Cage and the Elbow drive are often referred to as the *Elbow Drive System* because these two systems work together to drive elbow rotation.

Lateral Humeral Bar- The Lateral Humeral Bar runs parallel to the upper arm on the inner side of the upper arm. The Lateral Bar serves as a mate between the Elbow Drive and the Humeral Rail.

84

Figure 37: Forearm Cage Positioned around the Forearm
The Forearm Cage (A) holds constant the radius (R) of the orthosis around the center of the forearm (B).

Medial Humeral Rail- The Medial Humeral Bar runs parallel to the upper arm on the outer side of the upper arm. The Medial Humeral Rail provides a base of support for the Elbow Drive. In the previous design, the pair of Humeral Bars, and the Forearm Cage were considered part of the basic frame of the device (Figure 38). Although they bear they same name, the new components were not designed to resemble the previous design and are similar only in functional purpose. In the new design of the powered arm brace, the Lateral and Medial Humeral Bars work as a unit to mate the *Humeral Drive System* and the *Elbow Drive System*.
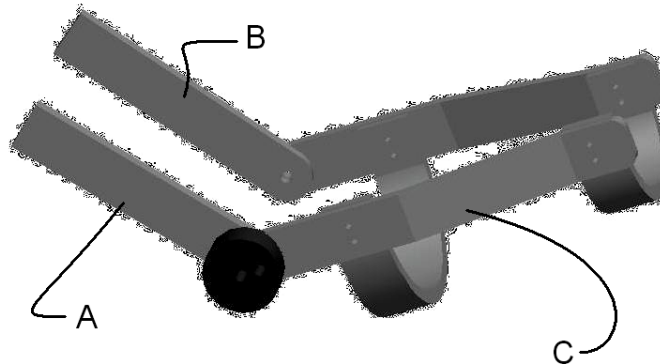
Figure 38: Proof-of-concept Prototype Relabeled for the New Design Methodology
The Proof-of-concept solid model labeled as the new powered arm brace showing the Medial Humeral Bar (A), Lateral Forearm Bar (B), and Forearm Cage (C).

After scrutinizing several redesigns for the Humeral Drive System, Elbow Drive System, and Humeral Mates, the basic design concepts were finalized. These conclusions were reached after testing with simple mocked-up parts and fixtures and based on previous design experiences. The potential designs, selection processes and final conclusions are presented in the following sections based on the three previously noted paired sub-systems.

5.1.1 Humeral Drive System

The Humeral Drive System functions primarily to create humeral rotation about the upper arm. Normally, rotation is achieved using a driven gear mounted to a centrally located axis. This common solution was not applicable to drive humeral rotation. As humeral rotation is about the upper arm, with the axis through the length of the arm, the arm must be rotated using a system that allows for direct rotation, without access to the center of rotation of the arm (center of the humerus) to hold the driven components. A design was needed to drive the humeral rotation from the shoulder region to the forearm, while maintaining a constant axis of rotation about the arm and the overall rigidity of the powered brace.

The proof-of-concept prototype employed an axial follower, which was keyed radially along both the inner and outer diameters to slide between an inner aluminum ring and an outer brass gear (Figure 39). Though this design was functional, the brass ring was shown to be too malleable to withstand even short-term use. Three new methods were investigated to drive humeral rotation: An Improved Humeral Slider, a Belt Drive system and a Captive Track system.
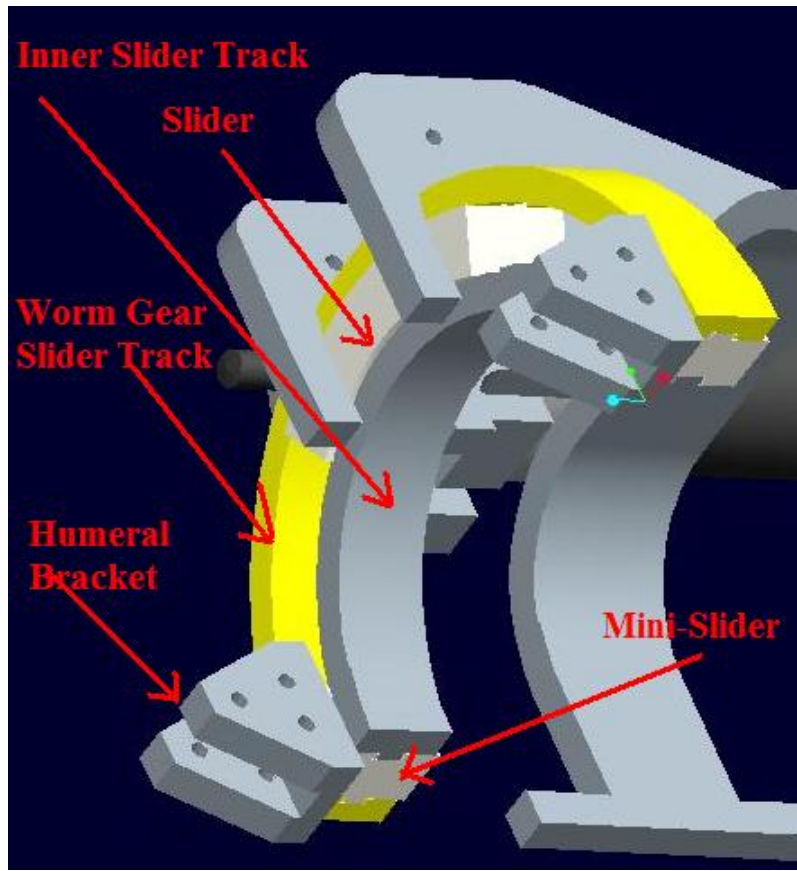
Figure 39: Proof-of-concept Humeral Slider
The *Slider* of the proof-of-concept design was held stationary while the *Worm Gear Slider Track* and *Inner Slider Track* rotated around the upper arm. In the new division of parts into functional groups, the *Worm Gear Slider Track* and *Inner Slider Track* are considered the Humeral Rail, while the *Slider* and other more proximal parts are part of the Humeral Drive.

5.1.1.1 Improved Humeral Slider

An Improved Humeral Slider was considered based on conclusions reached during the testing of the proof-of-concept prototype. As previously described, the slider was shown to be functional, but during testing, the "worm gear slider track" and "inner slider track" began to deform. The disfigured worm gear led to decreased performance of the proof-of-concept orthosis, and inconsistent angular rotation. To eliminate deformation during operation a potential slider redesign was considered.

Similar to the previous design, the new slider would be held captive by a "worm gear slider track" and "inner slider track" (Figure 40). The new design would be designed with more consideration to the various properties of the components, including how the cross sectional profile would affect the moment of inertia and subsequently the stiffness of the design. The proof-of-concept worm gear had thin side rails to help hold the slider in place. These thin rails were prone to deformation and did not improve the rigidity of the worm gear. Instead, the new humeral gear's profile would be rectangular without the two protruding side rails, although its outer dimensions would remain the same. The lack of any concavity would be design that is more robust and improve functionality.

Additionally, the Humeral Rail at the inner diameter of the slider could be modified. To increase the rigidity of the Humeral Rail, the Delrin slider would be nested in an aluminum humeral rail, rather than having the rail nested within the slider. This change would allow more of the Humeral Rail profile to be further from the centerline, increasing the stiffness of the rail.
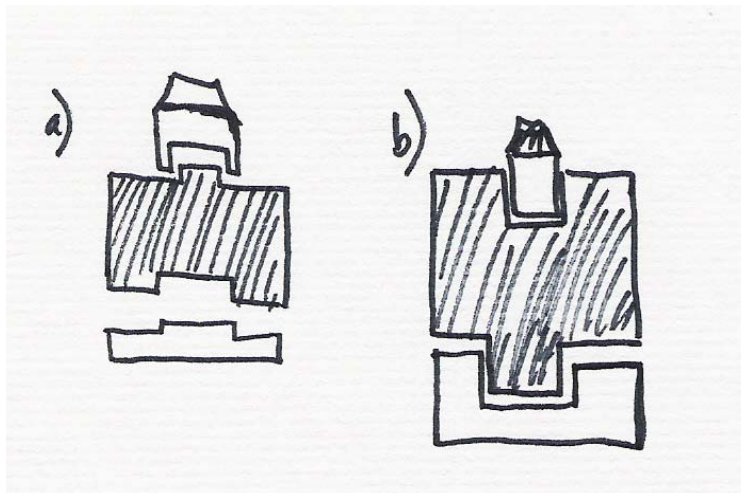
Figure 40: Improved Slider Design
(a) Current slider design showing (top to bottom), (b) Proposed redesign of slider. As shown in each assembly, top to bottom: Brass Gear, Slider, Aluminum Bearing.

5.1.1.2 Belt Drive System

A novel approach to driving humeral rotation was the use of a drive belt to control humeral rotation. As an evolution from a basic pulley system, the Belt Drive System would use a toothed belt to drive a centerless driven pulley. The driven pulley is centerless, because its movement is not confined to a single center of rotation, as are traditional gears. Instead of the central axle fixing the center of the driven pulley (as in most toothed gears), the belt tension and a pair of guide bearings (Figure 41) could maintain the position of the Humeral Rail, while controlling its angular orientation. In this way an elliptical shape, which could result from deformation, could be driven with a continually varying center of rotation.
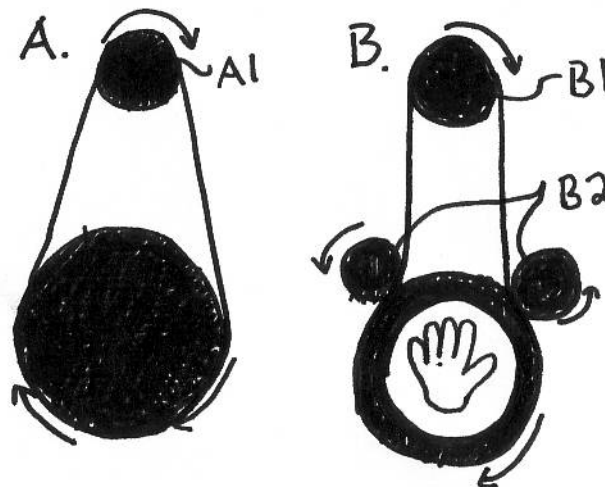
Figure 41: Belt Drive System
Evolution of Humeral Drive System comparing basic pulley drive (A1) and driven gears, with the modified design (B). The large driven gear and the arm are driven by the drive gear (B1), and two guide wheels (B2). Belt tension is maintained by either tensioning the belt manually or lengthening the distance between B1 and B2.

This type of system would be advantageous because unlike other humeral drive systems, which require precise alignment between the humeral drive gearing and the Humeral Rail component, the Belt Drive System could allow the Humeral Rail to slightly

deform, without major consequence to the Humeral Drive System's function. The belt drive also offers the benefit of having no exposed teeth, as the teeth of a positive belt drive would face into the center of a rail when not inside a drive housing.

The immediately apparent drawback to this system is the necessary tension in the belt. In this system, the tension of the belt would provide the only force holding the Humeral Housing to the Humeral Rail. Because of the high pre-stress that would need to be applied to the belt, a belt with low elasticity would be required (Figure 42).
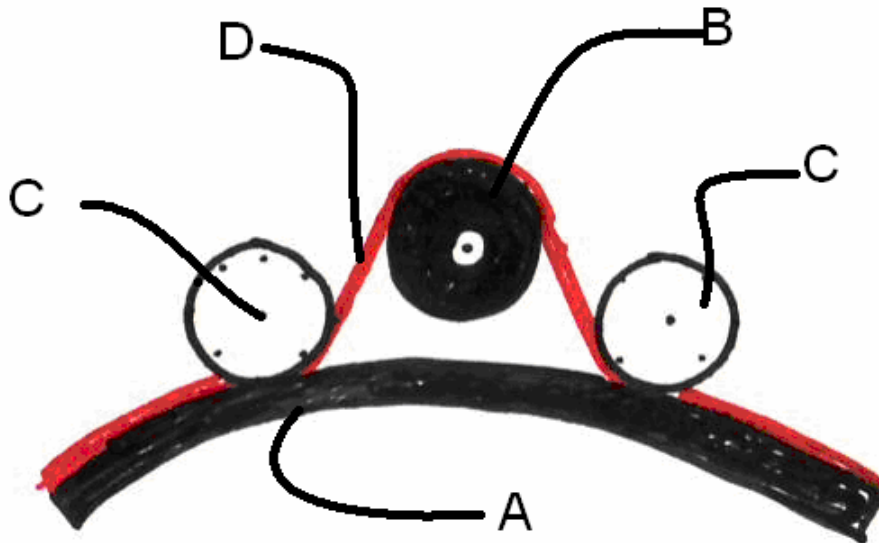
Figure 42: Depiction of Low Belt Angle
Belt Drive System shown with the Humeral Rail (A), drive pulley (B) and two bearings (C). The less than 90° tension angle of the belt drive would place heavy stress on the belt (D) and require a belt with very low elasticity, as the tension of the belt supplies the only force holding the assembly together. As the system became more vertically compact, and the angle of the belt decreased, the tension on the belt would drastically increase as the vector of the tension perpendicular to the rails arc became nearer to zero.

5.1.1.3 Captive Track System

Another potential design was a Captive Track System. This system is similar to the tracks system of a monorail rollercoaster. On a single rail rollercoaster, the coaster contacts the rail with paired sets of wheels that each holds the coaster vertically or

horizontally (Figure 43). In this way, the rollercoaster's motion is always either forward or backward because the multiple paired sets of wheels along its length create numerous couples, which prevent all movement, except linearly along the track.

The wheels of a rollercoaster also provide a load-bearing surface with minimal friction. Under the proper conditions, it is conceivable for the wheels to be replaced with a low coefficient of friction surface. Using this same principle, the Humeral Rail, like the single rail of the rollercoaster, could be encapsulated by low friction, load-bearing frame. Instead of wheels, the Captive Track System would rely on selected materials and smooth surfaces that could be designed to minimize the friction of a Humeral Drive Housing sliding on the Humeral Rail. An additional benefit of the system, would be the potential for a gear to be cut in such a way to mate with the Humeral Housing, negating the need for a drive gear distinct from the Humeral Rail.
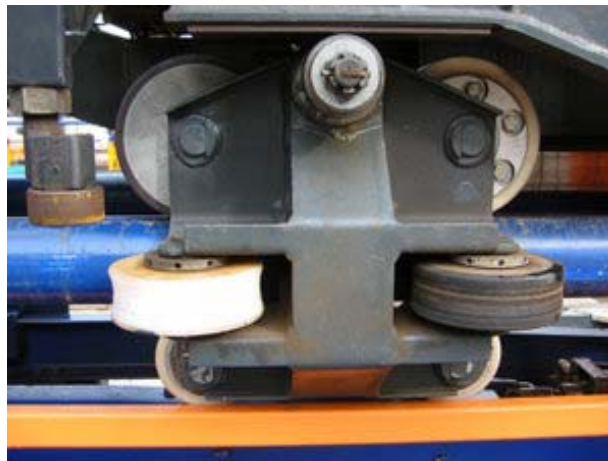
Figure 43: Rollercoaster Wheels
Half of a pair of rollercoaster wheels. The top wheels maintain the coaster's distance from the track and side and bottom wheels ensure the coaster does not move sideways or off from the track.

5.1.1.4 Final Humeral Drive System

As the improved Humeral Mate was only a slight modification of the original design and used the same materials, it was not tested. From previous experience, its

performance was expected to be only slightly better than the proof-of-concept prototype. Instead, consideration was given to replacing the malleable brass worm gear with a hardened steel spur gear. The feasibility of a steel spur gear was examined by coring a steel gear, and cutting it to 180º arc similar to the worm gear used in the proof-of-concept prototype. The center of a hardened steel spur gear was turned on a lathe and resulting gear was tested for compressive rigidity and overall weight (Figure 44). Although the resulting gear was found to be both stiff and resilient, the total mass of the gear was over 270g. It was decided that this mass was unsuitable for the device as it alone constituted approximately 30% of the target mass of the entire device.

Figure 44: Machined Steel Spur Gear

A belt drive system was constructed and tested to mimic the function of the potential belt drive. An aluminum ring was turned and two plates were fabricated to hold bearings and drive pulley. A neoprene, fiberglass HTD belt from Boston gear was selected as the drive belt. The belt has very little elasticity and is rated to over 390 Newtons of tension (Figure 45). This type of belt is know as a positive drive belt because the belt has "teeth", which lock into a drive gear to prevent slippage during operation.

With proper tension in the belt, the belt held the Humeral Rail in place and prevented deflection of the Humeral Rail from the common center axis of rotation.
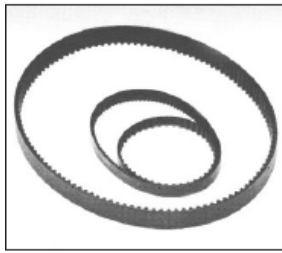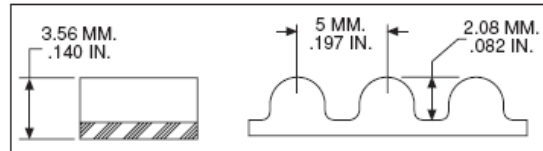
Figure 45: Boston Gear 5M HTD Belt

However, as a result of the testing this belt and additional testing of other belts, this Belt Drive System's efficiency was found have to be inadequate for use as the Humeral Drive

System. Although the belt drive prototype functioned properly and did not seriously deflect under normal bending forces, the belt drive had an especially high rolling friction as the belts radius of curvature was flexed through the drive pulley and rollers (Figure 46). Upon examination of additional low elasticity belts, it was found that belts with low stretch also have high rolling drag, when loaded near maximum working tension.
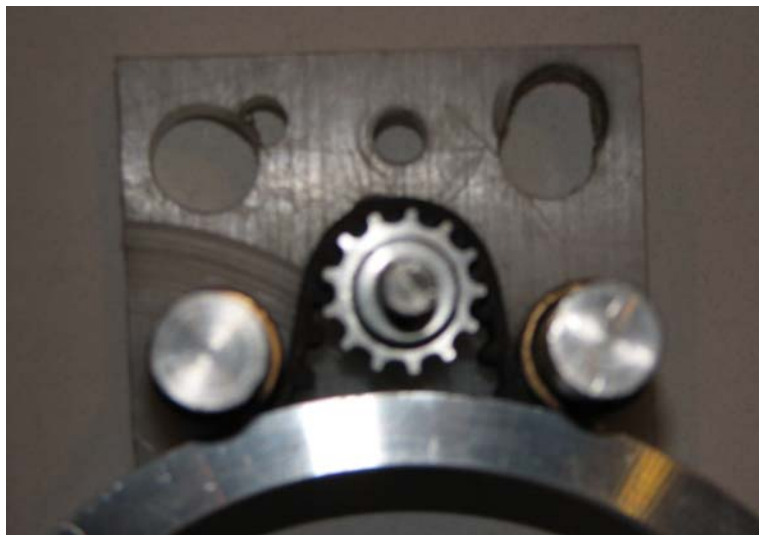
Figure 46: View Inside the Tested Humeral Belt Drive
Belt Drive System showing the Humeral Rail (bottom), drive pulley (center), and bearings (right and left). The bearings rotated on axles that were also used to attach a cover to the body (not shown).

Finally, a basic captive rail system was built to test the Captive Rail Drive. This testing prototype was constructed from two similar blocks of Delrin (with arc shaped slots) and a turned aluminum ring. The Delrin blocks were fit over the aluminum ring, and the ring was rotated through the blocks under various torsional loads. This system was found to be especially light and functional. Because of the dissimilar surfaces and Delrin's low coefficient of friction, the rolling friction of the system was extremely low, even under compressive forces perpendicular to the center axis. This was surprising because it was thought that the compressive stresses on the Humeral Rail would deform the rail enough to bind the Delrin block to the rail. The Delrin block, however, continued to slide on three points of contact (Figure 47).
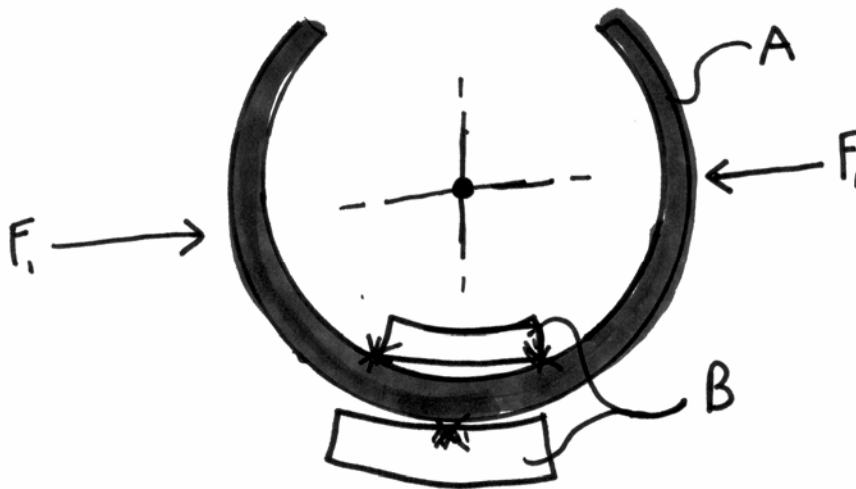
Figure 47: Exaggerated Captive Rail Diagram
Exaggerated visual model of the uneven surface loading of the Delrin Slider (B) resulting from compressive forces (F_1) on the Humeral Rail (A) perpendicular to the center axis.

As the result of successful testing, a captive ring was chosen as the Humeral Drive System. Although this method of fixing the Humeral Drive to the Humeral Rail would be used in the final design, the final shape of the Humeral Rail and the captivating

shape of the Humeral Housing were defined later in "5.2 Design for Manufacturability and Assembly (DFMA)", as their shape would affect the manufacturability of the final design.

5.1.2 Elbow Drive System

Two potential designs were considered for the Elbow Drive System to control elbow flexion and extension. Like the Humeral Drive System, these designs focused on the basic configuration and placement of components, and not the actual power transmission methods. The two designs that were considered were whether to affix the Forearm Cage to either the inside or the outside of the Humeral Bars. Although this difference may appear trivial, the selection of one method over the other would affect the Elbow Housing design, as well as the comfort of the device, the dimensions of other components, and basic assembly procedures of the entire device.

5.1.2.1 Outer Affixed Forearm Cage

The previous proof-of-concept prototype affixed the Forearm Cage outside the Humeral Bars. Abramovich, Scarsella and Toddes chose this method because it most easily allowed for the fixation of the final elbow drive gear to the Forearm Cage assembly. In the proof-of-concept prototype, the Forearm Cage was placed against the final elbow drive gear, and the pair was pinned together, without the need for an additional axle though an axle pin was used (Figure 48).

Figure 48: Elbow Gear and Forearm Cage of Proof-of Concept Prototype
Picture of the original final drive sprocket gear (center), the Forearm Cage (right) and the Humeral Bar (upper left). The final drive gear was pinned to the Forearm Cage by two steel pins, one through the axle and a second pin off center of the axle. This pinning prevented any potential slippage, but also necessitated that the forearm cage be wider than the Humeral bars.

Although this method is the most secure method of fixing the elbow drive gear to the Forearm Cage, additional problems were created by this design. The most notable problem was the team's difficulty shielding the gearing. A single shield could not be used because as the Forearm Cage moved though the normal range of motion, it would come into contact with the shielding. Instead, a two-part cover would be needed, with one part stationary on the Elbow Drive, and the other moving with the Forearm Cage (Figure 49).
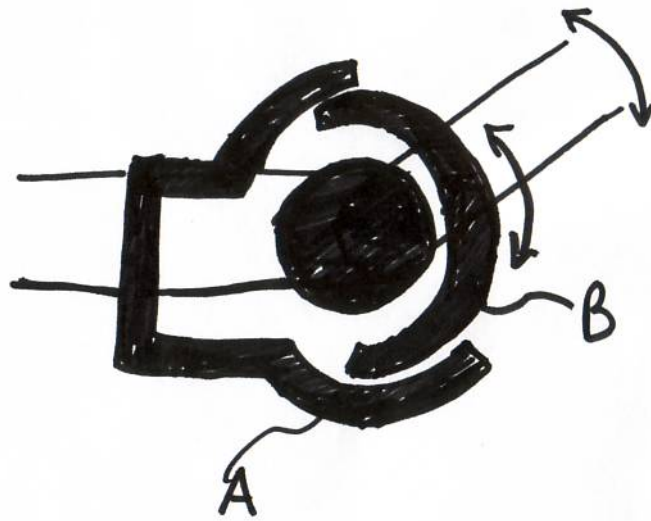
Figure 49: Two Part Shielding System
Likely sliding elbow gear shielding system: Proximal humeral part (A), distal forearm articulating part (B). For spatial reference: The upper arm is located to the left of the diagram, the elbow at the center of the diagram, and the hand is to the right.

5.1.2.2 Inner Affixed Forearm Cage

The Forearm Cage could also be designed to assemble to the inside of the Humeral Bars. This mounting system would eliminate the need for problematic shielding because a single protruding axle would drive the Forearm Cage instead.

An additional benefit to the inner Forearm Cage was that as viewed from above the arm, the spatial transition from the Humeral Bars to the Forearm Cage would more closely follow the contour of the arm at the elbow as it narrows from the upper arm through the elbow and to the wrist. This change would allow the device to be ultimately less obtrusive, aiding in the acceptance of the device by disabled users (Figure 50).
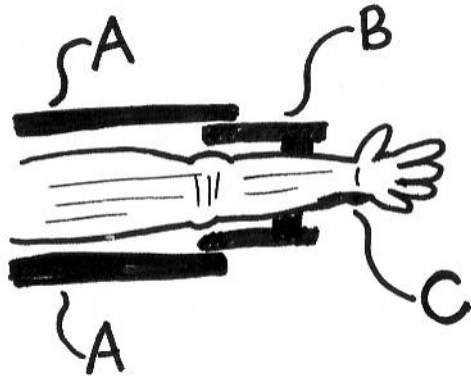
Figure 50: Narrowing Effect of Inner Affixed Forearm Cage
Sketch of Humeral Rail and Forearm Cage mating showing Humeral Rails (A),
Forearm Cage (B), and representative profile of the arm (C).

5.1.2.3 Final Elbow Drive Configuration

While placing the Forearm Cage outside of the Humeral Bar allowed for the strongest junction between the final drive gear and the Forearm Cage, it drastically complicated shielding and widened the brace in a portion of the arm where (if it were to follow the profile of the arm) it should become slimmer. Conversely, if the Forearm Cage was inside of the Humeral Bars, the Forearm Cage would need to be driven by an axle that could be a potential point of failure.

Based on these two scenarios, it was decided that the Forearm Cage should be inside of the Humeral Bars. To ensure proper function of the device, Stress Analysis would need to conducted on the axle and whatever mechanical method was used to affix the axle to the Drive Gear and Forearm Cage.

5.1.3 Humeral Bars

The Humeral Bars were another potential area for redesign from the original proof-of-concept prototype. The Humeral Bars, as previously described, are responsible for mating the Humeral Drive System with the Elbow Drive System. The joint between

these two parts must allow the planer Humeral Bars to join with the circular Humeral Rail. Three potential designs for the Humeral Bars were considered: Capped Bars, Rectangular Parallel Bars and Cylindrical Parallel Rods. These designs only focused on the end responsible for mating the Humeral Bars with the Humeral Rail, as the Humeral Bars would mate to the Forearm Cage using a pin joint for rotation about the elbow.

5.1.3.1 End Cap System

The earlier prototype design used stock rectangular bars as Humeral Bars. Because the flat bars were required to mate with the arced humeral rail, a system was devised to allow the ends of the Humeral Bars to take the profile of the circular rail. In this way, the Humeral Bars were essentially "capped" with a yoke and slider. The yoke section was bolted to the squared Humeral Bars, and the arced slider was bolted to the inner and outer components of the Humeral Rail (Figure 51). While this design was functional, it was only semi-adjustable because it required the Humeral Bars to be cut and redrilled for adjustment, and because they could only be cut to a shorter length, no allowance was made for growth after the initial fitting. Although this design lacked real adjustability, it did provide for an easy fitting method, and was successful in securely fixing the Humeral Bars to the Humeral Rail.
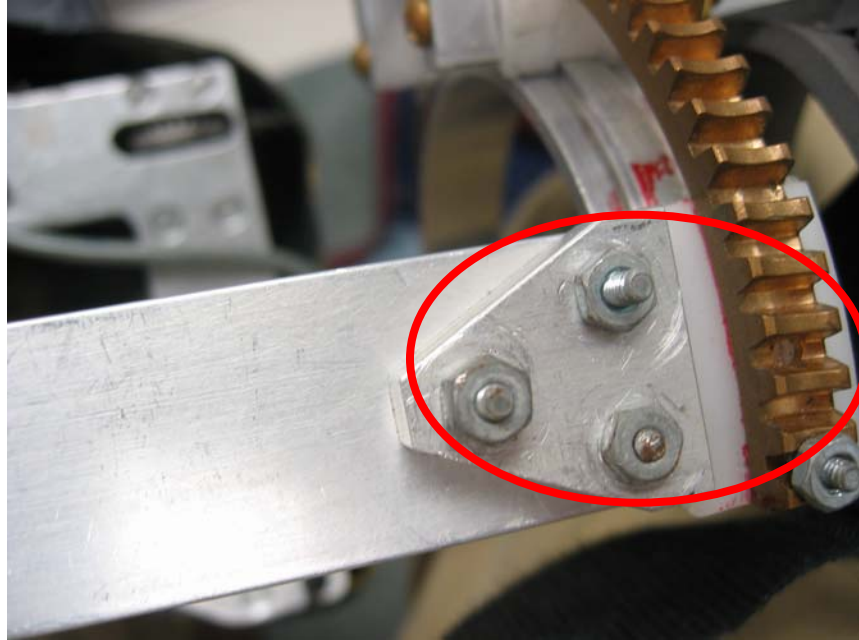
Figure 51: Proof-of-concept Prototype Humeral Mate
The proof-of-concept prototype used two Humeral Mates (one side is shown circled in red), which were constructed from an aluminum saddle yoke and a Delrin block to mate to the curved surface of the Humeral Rail and the bar stock of the Humeral Bar. This design was non-adjustable, but could potentially be customized for a specific user

5.1.3.2 Rectangular Parallel Bars

The Humeral Bars could also potentially be mated to the Humeral Rail by a set of Parallel Rectangular Bars. The bars would extend from the main body of the Humeral Bar (Figure 52), similar to the prongs of a tuning fork. To mate to the Humeral Rail, the prongs would nest inside machined slots in the Humeral Rail, secured by a screw or

Figure 52: Rectangular Bars
Rectangular bars as machined from a stock piece of aluminum. The bars can be machined in a single pass by choosing the appropriate mill diameter size.

clamping mechanism (Figure 53). Since the bars would be of a uniform profile, they could potentially slide in the rail and be adjusted (either shorter or longer) at a later refitting. This feature would meet the customizable and adjustable design criteria, while also providing a clean look to the device.
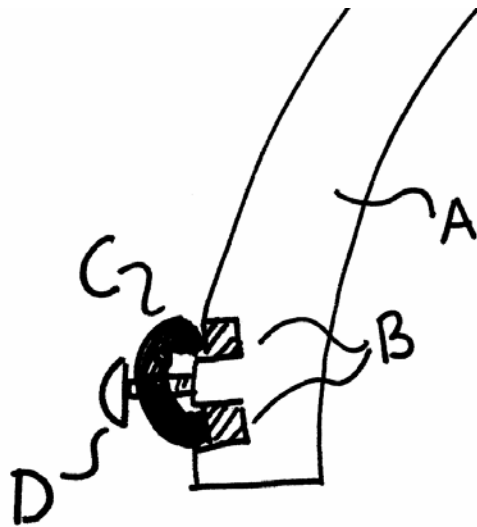
Figure 53: Sketch of Humeral Rail and Parallel Bar Mounting Method
The Rectangular Humeral Bars could be mounted to the Humeral Rail (A) into machined slots (B) and secured with a clamp(C) and bolt (D).

5.1.3.3 Cylindrical Parallel Bars

A potential improvement of the Rectangular Parallel Bars was Cylindrical Parallel Bars. The Humeral Bars would be attached to the Humeral Rail in the same maner as the Rectangular Parallel Bars, but would be circular to match the profile of the bars (Figure 54). This system was considered a potential improvement because the bars could be made

Figure 54: Sketch of Humeral Rail and Parallel Rod Mounting Method
The Cylindrical Humeral Rods could be mounted to the Humeral Rail (A) into
machined slots (B) and secured with a clamp(C) and bolt (D).

from a stock shape and pressed into a smaller Lateral or Medial Humeral Bar (Figure 55).

This method decreased machining time and reduced the material and wasted resources to

purchase aluminum to be machined away.

Figure 55: Cylindrical Humeral Bars
Stock rod cylindrical bars pressed into the Elbow Drive or Humeral Rail (scrap metal
used as testing fixture).

5.1.3.4 Mating the Humeral Rail to Humeral Bars

Each of the Humeral Rail Mating methods was tested for both rigidity and

adjustability before selection of the final mating method. Prototypes of both rectangular

bar and cylindrical rod mating systems were fabricated. Because the end caps were non-adjustable, they did not meet the basic design criteria and as such, they were not considered a viable solution.

During testing of the rectangular bars and circular rods, each mating system withstood deflection along each plane. During torsional testing, however, the circular rods tended deflect torsionally, while the rectangular bars did not. It was determined that this effect was due to each circular rods rotating within the clamping system, which more easily allow for twisting (Figure 56). The non-uniform radial profile of the rectangular

Figure 56: Twisting of Circular Rod Mate Prototype
End view of permanently deformed circular rods after testing as mock Humeral Bars. Cylindrical Bars into mock Humeral Mate. The humeral bars were affixed at both ends and tested in torsion, compression, and bending for stiffness and rigidity. The circular profile of the rods allowed them to roll relative to the clamping end, which resulted in an easily twisted bar.

bars better resisted this type of twisting because the bars would be forced to deflect entirely around the mid plane, where the circular rods could partially deflect around the mid-plane, while also rotating around their individual centerlines (Figure 57). Due to

their superior performance of the rectangular bars, the rectangular bars were selected as the mating method between the Humeral Rail and the Humeral Bars.
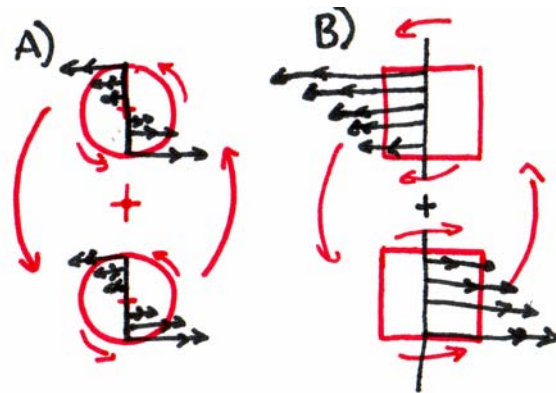
Figure 57: Sketch of Humeral Bar Deflection and Stress
Sketch of circular rod rotation (A) and rectangular bar rotation (B). Rotational stresses within the rails are shown as straight lines (with double arrows) and rotation/deflection is shown as single arrow lines.

5.2 Design for Manufacturability and Assembly (DFMA)

Design for manufacturability and assembly (DFMA) is the purposeful design of components for ease of manufacturing and assembly. DFMA design techniques include the use of standardized parts, generally simple components, minimal numbers of parts and top-down manufacturing techniques, as well as many other principles.[45] DFMA was employed during the design of this project to aid in the development of an easily manufacturable powered arm brace, with potential for scalable production into a commercial product. Although many parts of the working prototype were fabricated from various materials using a wide variety of techniques, preference in part selection was first given to standardized purchasable parts, over custom or modified components. Additionally, the selection of standardized parts aided in the design of custom parts by fixing otherwise intended variables such as clearance holes, gear axle alignment and

104

surface finish requirements. Both purchased parts and custom parts were selected and designed with the intention of fabricating custom parts using basic casting methods.

5.2.1 Identification of Purchased Parts

Purchased parts were identified early in the design process not only to reduce the number of custom parts, but also to simplify the manufacturing of custom parts. Standard parts, for the purposes of this thesis, include only standard track parts and specifically do not include manufacturer modified or special order/custom parts, even when purchased directly from the manufacturer. This distinction is important because although many manufacturers will pull parts from their assembly line to be modified at the factory, this service is provided at a premium and restricts future changes from vendors or suppliers.

5.2.1.1 Motor Selection

Since the motors of the proof-of-concept prototype constituted over 50% of the total weight, the motors were identified as an area for drastic weight reduction and potentially increased electrical power efficiency. Additionally, the original motors were the two most expensive parts of the proof-of-concept prototype.

Electric motors are generally rated in Watts (W) or Horsepower (HP). Watts are usually used in reference to electrical power as the product of amperage (I) and voltage drop (V).[46] Watts and HP, however, as measures of power, can also be applied to mechanical work. Watts are defined as N•m x Radians/second. Because of frictional losses and motor inefficiencies, manufactures also label their motors with

electromechanical efficiencies. Although the efficiency is not constant over the entire torque curve, it can be considered constant during the motor selection. Due to cost and controller limitations, only brushed motors were considered for this project. Brushed motors also have nearly uniform efficiencies over the continuous drive portion torque curve (part of the curve not including areas of thermal overload).

The design specifications of the powered arm brace called for the brace to be able to apply 12 N•m of torque while moving 90 degrees in approximately 5 seconds (3.0 rpm, .314 Radians per second). Based on these requirements, the base Wattage of an electric brushed motor needed to exceed 3.77 W. Most brushed motors have efficiencies between 80% and 90%. A motor gearhead, supplied by the manufactures also have associated losses typically about 15%. Additionally, any gearing would introduce additional frictional losses. Based on the proof-of-concept prototype gear efficiencies were expected to be near 60% (40% of power lost to friction) (Equation 2). With these multiplicative inefficiencies, the total required electrical Wattage of a motor was 9.2 Watts. Motors ranging from 9.0 to 12.0 Watts were considered acceptable for use.

Equation 2: Power Output Required after Estimated Losses
$$\frac{3.77 \text{ W}}{.80 \times .60 \times .85} = 9.2 \text{ Total Watts}$$

While several motor manufactures offered motors at this Wattage, Maxon Motors was selected as the motor manufacturer. Maxon Motor USA was chosen for several reasons (Table 7). Maxon motors were among the lightest and most compact of 10 Watt motors. Additionally, Maxon motors have numerous standardized gear-heads for their motors, and offer bulk discounts at low order quantities. Low order quantities, as well as

the short lead time, deriving from the standardization of parts, would aid in the future commercialization of the orthosis because parts could be ordered on a needed basis and inventories of a comparatively expensive part could be minimized.

			118740	118741	118742	118743	118744	118745	118746	118747	118748
Motor Data											
	Values at nominal voltage										
1	Nominal voltage	V	4.5	8.0	9.0	12.0	15.0	18.0	24.0	32.0	48.0
2	No load speed	rpm	5350	5310	5230	4850	4980	4780	5190	5510	5070
3	No load current	mA	79.6	44.3	38.6	26.2	21.7	17.2	14.3	11.6	6.95
4	Nominal speed	rpm	4910	4510	4230	3820	3940	3740	4150	4470	4030
5	Nominal torque (max. continuous torque)	mNm	11.4	20.9	24.0	29.1	28.8	28.9	28.8	28.6	28.7
6	Nominal current (max. continuous current)	A	1.50	1.50	1.50	1.26	1.03	0.823	0.668	0.529	0.325
7	Stall torque	mNm	138	139	126	137	138	133	144	152	140
8	Starting current	A	17.2	9.73	7.72	5.82	4.83	3.72	3.28	2.76	1.56
9	Max. efficiency	%	87	87	86	87	87	87	87	88	87
	Characteristics										
10	Terminal resistance	Ω	0.261	0.822	1.17	2.06	3.10	4.84	7.31	11.6	30.9
11	Terminal inductance	mH	0.0275	0.0882	0.115	0.238	0.353	0.551	0.832	1.31	3.48
12	Torque constant	mNm / A	8.00	14.3	16.4	23.5	28.6	35.8	44.0	55.2	90.0
13	Speed constant	rpm / V	1190	667	584	406	333	267	217	173	106
14	Speed / torque gradient	rpm / mNm	39.0	38.3	41.6	35.6	36.1	36.0	36.1	36.3	36.4
15	Mechanical time constant	ms	4.74	4.15	4.12	4.00	3.98	3.97	3.97	3.97	3.97
16	Rotor inertia	gcm²	11.6	10.3	9.45	10.7	10.5	10.5	10.5	10.4	10.4

Table 7: Maxon Motor 10 Watt Motor Chart
Shown are various 10 Watt motors offered by Maxon Motor. Since the system was to run at nominal 12 volts, Motor #118744 was selected from among the other 10 Watt motors because its nominal voltage was 15V, providing safety against overload.

Maxon Motor RE-25mm motors were selected. Although the maximum voltage of the orthosis is 12V, care was taken in selecting motors that would not be overloaded during repeated use. When the motors are initially powered, the initial amperage surge can far exceed the nominal amperage of the battery. Additionally, as the motor is at rest, the inertia of the motor prevents immediate rotation. During the brief milliseconds of initial loading, serious damage can be done to a motor from the combination of these two effects. With this in mind, the 15V motor line was used to eliminate the risk of overloading the motors.

5.2.1.2 Drive Gearing Selection

The components of the drive system were the most tightly constrained parts of the powered arm brace. The drive system would need support torques in excess of 20 N•m, reliably drive torques as high as 12 N•m, be compact and lightweight, and be non-backdriveable.

The constraint of non-backdriveability can be achieved by two methods, either by the use of components with inherent self-locking or electromechanical systems, which prevent backdriving when the motor is not powered. In DFMA, it is always preferable to use simple systems, and it is therefore preferable to use systems with the needed inherent properties rather than engineering those properties into a design. For this reason, effort was directed to find a method to drive the humeral and elbow systems which was non-self-locking by nature.

Worm gears are the most common self-locking systems. The steep pressure angle of the worm prevents backdriving under most conditions. The pressure angle also allows for even force distribution along each tooth, increasing a worm gear's working torque. Worm gears, however, suffer from relatively high frictional power losses, although these power losses can be mitigated by increasing the number of leads (also called starts) to either two or four and by pairing hardened worms with soft brass worm gears.

Driving humeral rotation required a large gear due to the space constraints of the upper arm: As previously mentioned, the humeral rotational axis is along the center of the upper arm, and a track system to hold the gearing must be larger than the diameter of the arm. As a large gear was to be the driving gear of humeral abduction and adduction, a logical choice of gears was a large worm gear, driven by a worm within the humeral housing. To minimize the profile of the device, a 64 diametric pitch (DP), 5.375" pitch

diameter worm was chosen. This worm gear is rated to drive 122 N•m under intermittent loads (5.3.1.1 *Gearing Stress Analysis*).

Driving elbow flexion required a compact worm gear, capable of driving similar torque loads as the humeral drive. Since radius and force are inversely related when their product (torque) is held constant, a significantly stronger worm gear was required. The maximum force on a gear is limited by the tooth size, and the face width of a tooth. While the large humeral worm gear used a 64 diametric pitch tooth, with a .250" face width, considerably larger tooth size and face width were selected for the elbow worm gear: 24 diametric pitch, 0.313 face width. Even at the smaller diameter of 2.063", the elbow worm gear was is capable of driving intermittent loads of 45.6 N•m (5.3.1.1 *Gearing Stress Analysis*).

5.2.1.3 Gearhead Selection

After selecting gearing, and the specific motor specifications, it was possible to determine the proper gearing reduction of the gearheads to proper match the speed and torque of the motor to the speed and torque of necessary at the arm to meet design criteria. To begin the initial torque at the motor was considered. For simplicity, the torque curve of the motor was reduced to a single point at the maximum continuous torque point. At this point, based on a 15V motor, the torque was .0288N•m with a calculated angular velocity of ~3800 rpm.

As previously stated, the target RPM of the brace was approximately 3.0 rpm in the both the humeral rotation and elbow flexion/extension. Based on this speed the target gear reduction for humeral rotation was less than 7.0:1. A single stage, 4.4:1 (#144027)

gearhead was selected to achieve the proper gear reduction (Table 8). Similarly, the gear reduction for the elbow was less than 138.2:1. A standard gearhead at 53:1 (#144035) was selected. This gearhead employed a two-stage reduction, which would slightly decrease efficiency. Although the necessity of another stage increased the weight of the gearhead, the weight savings, when compared to open gearing, offset the extra weight at the motor. Also, since the power of the motors was calculated early in the design of the drive system, by correctly selecting a gearhead for the appropriate angular velocity at the arm, the proper torque was also achieved.

Table 8: Maxon Motor Gearhead Selection Chart

		Stock program / Standard program / Special program (on request)	**Order Number**			
			144026	**144029**	**144035**	144041
Gearhead Data						
1	Reduction		3.8 : 1	14 : 1	53 : 1	104 : 1
2	Reduction absolute		$15/4$	$225/16$	$3375/64$	$87723/845$
3	Max. motor shaft diameter	mm	4	4	4	3.2
	Order Number		**144027**	144030	144036	144042
1	Reduction		4.4 :1	16 : 1	62 : 1	109 : 1
2	Reduction absolute		$57/13$	$855/52$	$12825/208$	$2187/20$
3	Max. motor shaft diameter	mm	3.2	3.2	3.2	4
	Order Number		144028	**144031**	144037	**144043**
1	Reduction		5.4 : 1	19 : 1	72 : 1	128 : 1
2	Reduction absolute		$27/5$	$3249/169$	$48735/676$	$41553/325$
3	Max. motor shaft diameter	mm	2.5	3.2	3.2	3.2
	Order Number			144032	144038	144044
1	Reduction			20 : 1	76 : 1	157 : 1
2	Reduction absolute			$81/4$	$1215/16$	$19683/125$
3	Max. motor shaft diameter	mm		4	4	2.5
	Order Number			144033	**144039**	
1	Reduction			24 : 1	84 : 1	
2	Reduction absolute			$1539/65$	$185193/2197$	
3	Max. motor shaft diameter	mm		3.2	3.2	
	Order Number			144034	144040	
1	Reduction			29 : 1	89 : 1	
2	Reduction absolute			$729/25$	$4617/52$	
3	Max. motor shaft diameter	mm		2.5	3.2	
4	Number of stages		1	2	3	3
5	Max. continuous torque	Nm	0.5	0.6	1.3	1.3
6	Intermittently permissible torque at gear output	Nm	0.8	0.9	1.9	1.9
7	Max. efficiency	%	84	70	59	59
8	Weight	g	65	86	108	108
9	Average backlash no load	°	1.0	1.2	1.6	1.6
10	Mass inertia	gcm²	0.6	0.5	0.4	0.4
11	Gearhead length L1*	mm	29.2	36.0	42.8	42.8

Selection chart for various gearheads that are compatible with RE-25 motors. Gearheads are shown in columns of similar gear stages. Descending down the columns, gear reduction increases, through the use of different gear sets.

To reduce the additional parts, gearheads with cylindrical bearings were selected, rather than designing bearings into the motor mount locations. The bearings in the gearhead would help to reduce wear generated by radial loads, as well as slightly increase the actual working efficiency of the motors. The cylindrical bearings minimally increased the mass of the motors (less than .5g), and were offered at the same price as non-bearing gearheads.

5.2.1.4 Bearing Selection

Although bearings are a very basic component of the overall design of the powered arm brace, their inclusion in the design has a significant impact on the functionality and manufacturability of the powered arm brace.

Functionally, the bearings reduce frictional losses between the spinning shafts and the housing surfaces. Flange bearings can be used as thrust bearings between the worms and housing walls to also decrease the losses from friction along the worms' axis of rotation. By reducing frictional losses, not only is the torque and angular velocity maximized, but wear to the motor and gears is minimized, which also reduces strain on the battery, increasing the per charge working time the brace.

Though the principles of DFMA generally lean toward the reduction of total parts, DFMA also stresses the design of parts to tolerances well within the ability of fabrication methods. Plastic cast parts generally have tolerances of ±.002" per 1.000" in addition to a base tolerance of ±.005". Although these tolerances could create significant misalignment, they can be mediated through the "casting-in" axle and pin holes in the mold to ensure proper shaft to shaft alignment. However, this process creates additional

complications. At the parting line between the pins and the base mold, sharp non-uniform edges can form, which would seriously degrade the performance of worm gears. Working gears also generate heat and cause wear at the contact between moving parts and the housing. Although many castable materials are rugged, localized wear from continual friction and heating can cause serious degradation. As encountered during most material selection processes, the heightening of one specific property, inevitably causes the reduction of another desirable property: Castable materials, which are meant to withstand the wear caused by axial friction are often more expensive, heavier, or more difficult to cast than more common castable plastics.

These concerns were alleviated by eliminating any contact between the cast parts and the moving gears and axles by using purchased standard flange bearings at any surfaces, which contacted moving axles. Five different bearing materials were considered: Delrin, Nylon, Rulon 641, Vespel and PTFE. Table 9 shows a comparison of the five bearings made from different materials showing relative wear tolerance, maximum rpm, and cost per bearing (.25" ID).

Table 9: Flange Bearings shown by Material, Wear Characteristics, RPM and Cost

Bearing Material	Wear	Max RPM	Bearing Cost
Delrin	5	1,000	$3.13
Nylon	6	360	$0.36
Rulon 641	8	400	$10.50
PTFE	8	100	$3.60
Vespel	9	10,000	$40.00

Table showing different bearings by material and their relative wear at maximum rpm and cost per bearing.

Based on cost, both Rulon and Vespel are prohibitively expensive, and their use would negate any savings gained from the use of bearings. Although both Nylon and Delrin are relatively inexpensive, their poor wear performance could lead to premature failure, also negating any beneficial working properties gained by the use of bearings. By

process of elimination, PTFE bearings were selected. It is important to note that although PTFE bearings are rated to the lowest RPM, proper gearing and motor gear-head selection discussed earlier, will hold the worm axles' RPM to less than 100 rpm

5.2.2 Design of Custom Parts

After the selection of purchased parts, the finalized design concepts discussed in Section *5.1 Preliminary Design* were detailed using DFMA principles. Based on the functional requirements of the parts, the individual components were either designated to be cut from stock aluminum 6061, or two-part cast with an FDA-*skin contact* compliant material.

5.2.2.1 Aluminum Parts

To minimize the weight of the powered arm brace, as few parts as possible were designed to be machined from aluminum. Only two parts, the Humeral Rail and the Medial Humeral Bar, were designed to be machined parts.

Functionally, the Humeral Rail is the main structural component in the proximal half of the device. The Humeral Rail not only maintains the inner distance between the medial and lateral sides of the device, the humeral rail must also maintain its shape to allow the Captive Track system to move easily around the axis of the upper arm. When designing the Humeral Rail it was important to design a system that could be easily fabricated without unnecessary fixturing steps and exotic tooling. To accommodate these requirements, the Humeral Rail was designed to be easily turned on either a manual or

CNC lathe. Additionally, because the Humeral Rail's shape was a semi-circle, the lathed profile of two humeral rails could be made from a single turned ring.

As earlier defined, the Humeral Rail would be captive to the Humeral Drive (*Section 5.1.1 Humeral Drive System*), while also stabilizing a worm gear ring. To meet these functional requirements, the Humeral Rail was required to be relatively rigid, have features that allowed the Humeral Drive to clamp around it, and have a pocket to hold the humeral worm gear in place. Additionally, the rail could not interfere with the worm, which would mated to the worm gear inside the housing. While several designs were reviewed, a single design was selected for the profile of the Humeral Rail (Figure 58).
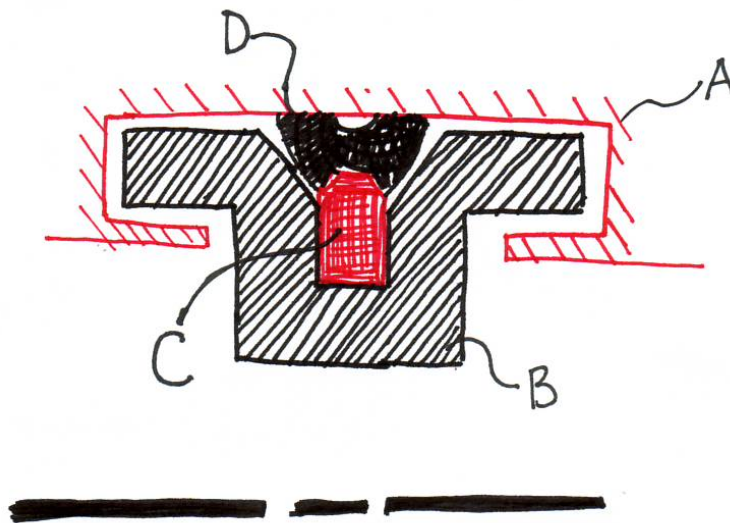
Figure 58: Cut Profile of Humeral Rail Design
Section view of the Humeral Rail design showing the relative positions of other important components: Humeral Housing (A), Humeral Rail (B), Humeral Worm Gear (C), and Humeral Worm (D), as well as the relative center of rotation, below the Humeral Rail profile.

If during FEA testing it were found the current design was not rigid enough, the design could be made more rigid by widening the Humeral Rails "arms" and increasing the distance between the inner and outer diameters (radial thickness) to mimic the shape of a "T-Beam" (5.3.2.1 Humeral Rail). This shape also provided a nest for housing the

soft brass worm gear, while minimizing exposure of the teeth to damage as they were well within the outer diameter of the Humeral Rail. Finally, the design clearly could be dimensioned in such a way as to allow the worm to smoothly contact the worm gear, through a full 90 degrees of humeral rotation without interference from the rail.

Most important to the design of an easily manufacturable product, this Humeral Rail shape could be turned with minimum fixturing steps and tooling: Two fixturing positions, five steps, and only basic tooling (Figure 58):

A. Beginning with "E" to the chuck, basic outer diameter surface cut.
B. 45° plunging cuts (-y direction) with a cutting tool remove region B
C. Plunge (-y direction) with a cut-off tool to cut region C
D. Surface cut in the –x direction
E. After refixturing, surface cut in the x direction.
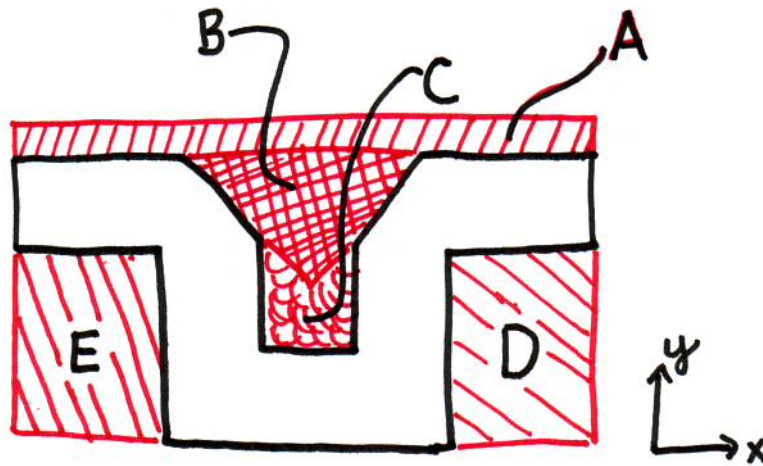
Figure 59: Manufacturing Cuts of the Humeral Rail
Final Humeral Rail profile shown against possible cuts: Surface cut (A), 45° plunging cut (B), plunge cut (C), face cuts (D & E).

The entire profile of the Humeral Rail could be cut with a single tool, mounted in different orientations, demonstrated the ease of cutting this profile. In addition to cutting the profile, this design calls for two machined slots (to mate to the Humeral Bars) and two tapped holes (to secure the Humeral Bars).

The Medial Humeral Bar was designed be the only other aluminum part in the final commercial product. The Medial Humeral Bar can be cut from of stock bar, with a single .25" end mill and no fixturing changes. Figure 60 shows the one possible machining and fixturing method that could be used to cut the Medial Humeral Bar.
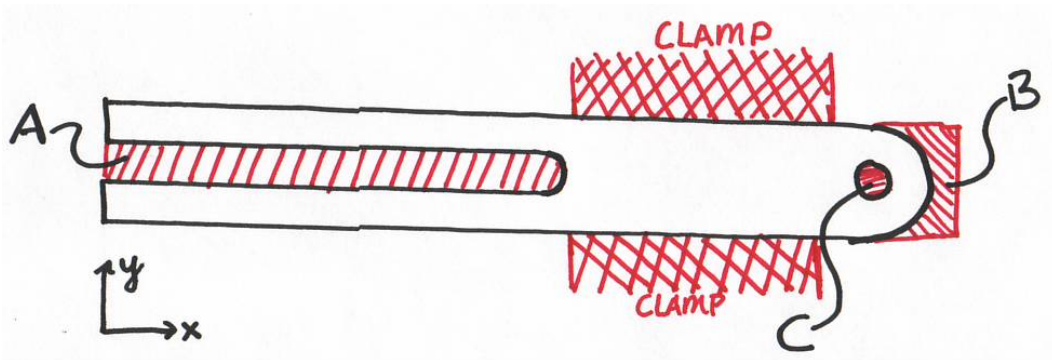
Figure 60: Cutting Method for Medial Humeral Bar
One potential manufacturing method of the Medial Humeral Bar is to use a 0.750" stock bar, and using a 0.250" diameter end mill, machine a slot in a single pass (A), and used an OD and ID hole pattern to machine a smooth round over (B) and a 0.438" diameter axle hole (C).

5.2.2.2 Cast Parts

Many of the powered arm brace components were designed as cast parts for several reasons. The primary reason for designing parts for casting is the ease of manufacturability and relatively low commitment to design. Every cast part is made from a negative of the part, called the mold. In thermo-set casting, the molds are often made of soft silicon. Most soft castings, used for casting two part thermo-set plastics, begin to break down after a set number of castings, requiring that additional models be fabricated. During the making of new models, the design can be easily altered at no additional cost.

Soft molds are constructed using the same methods foundries us to fabricate cast iron molds. First, the part is molded using stereo lithography (SLA) or selective laser sintering (SLS) material. The model is then placed in a tub of silicon. Depending on the

geometry of the part, the tub can sometimes have machined aluminum features to provide structural rigidity the silicon mold. After the silicon hardens, the entire part is removed from the silicon and aluminum mold. The resulting negative of the part can then be used to cast new parts in a thermo-set plastic.[47]

Two part plastics are ideal for this type of application because most thermo-set plastics designed for casting have very low shrinkage (1%, compared to injection molded plastics +3%)[48], which allows for the design of parts with varying wall thicknesses and non-uniform webs and ribs. Composites can also be cast into the parts to increase rigidity and strength. Additionally, the FDA has approved the use many thermo-set plastics for skin contact and medical use. The parts designed to be cast include the Forearm Cage, Elbow Housing, Elbow Housing Cover, and the Front and Rear Humeral Housings of the Humeral Drive. These five parts are all designed to be cast from RoyalCast 3101, and reinforced with G-10 Composite 0.125" sheet stock.

The Forearm Cage is both the simplest and the largest of the cast parts. In the final commercial product, the Forearm Cage will be cast as two halves: a top half and bottom half, with axle holes drilled into the sides. Axle pin holes would also be drilled along mid-plane of the Forearm Cage. As the Forearm Cage maintains the radius around the arm, the center portion of the Forearm Cage will be reinforced with .125" thick, G-10 cut to be cast into the Forearm Cage (Figure 61).
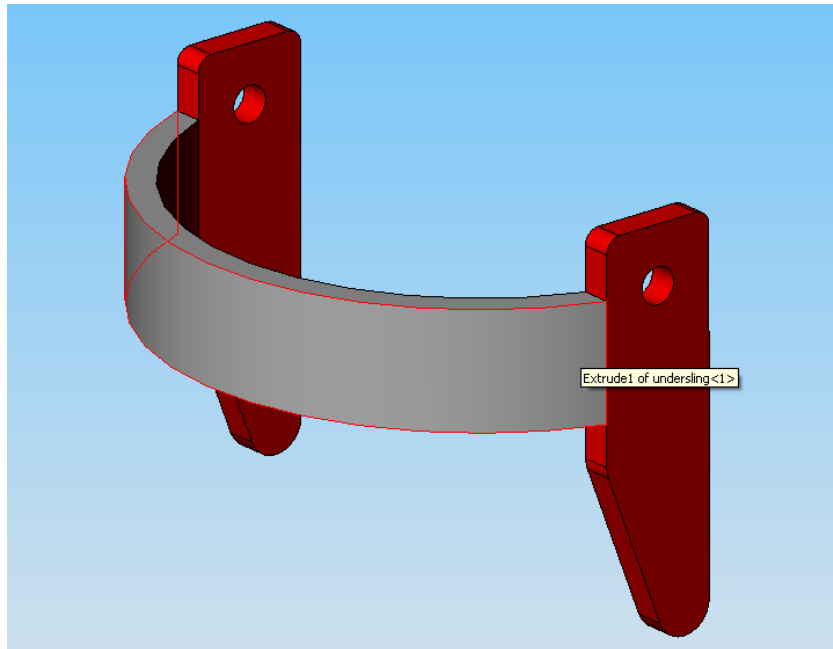
Figure 61: Forearm Cage in Casting Position

The Forearm Cage in casting position showing surfaces contacting mold half "A" (shown in red) and mold side B (shown in gray). Pre cast pins will be used to hold the G-10 composite as it is molded into the gray area. The pins will support the G-10 from mold side "A", so that any surface imperfections are hidden under the user's arm.

Although the Forearm Cage is designed to be cast as previously described, due to cost constraints, the Forearm Cage was constructed from chemically welded Lexan, reinforced with G-10, to mimic the properties of the cast part.

The Elbow Housing is the most geometrically complex of the cast parts, but it is also the most easily cast part, aside from the Elbow Housing Cover. The Elbow Housing can be molded with an single "A" side mold, capped with a stock sheet of silicon covered aluminum. As shown in Figure 62, the Elbow Housing could be postitioned sideways with the long flat inside of the housing facing up and the open part of the housing facing down into a mold. Along the top (inside when assembled) of the Elbow Housing, G-10 sheet stock will be cast in to increase the rigidity of the housing.
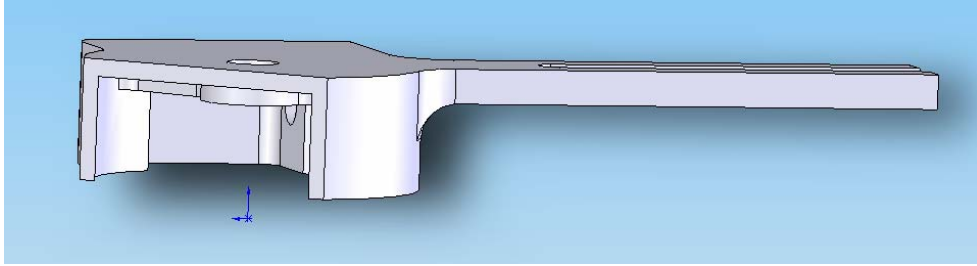
Figure 62: Elbow Housing in Cast Position
The Elbow Housing in its casting position, shown with as a sectioned view. While the axle hole for Elbow Axle connecting the worm gear and Forearm Cage can will be cast in, the axle hole and the motor mount will be drilled in a secondary operation to ensure proper fit.

Again, due to cost considerations, the Elbow Housing was machined from aluminum. While most all of the dimensions between the two parts remain the same, the machined Elbow Housing lacks the draft angle characteristic of cast parts.

The Elbow Housing of the Elbow Drive was not only designed to be easily cast, but also for ease of assembly. As shown in Figure 63, the Elbow Drive can be assembled in what is generally a top down assembly, beginning with the Elbow Housing being pressed down, on top of the elbow pin flange bearing. The two worm flange bearings, as well as the worm would then be inserted, followed by the elbow worm gear.
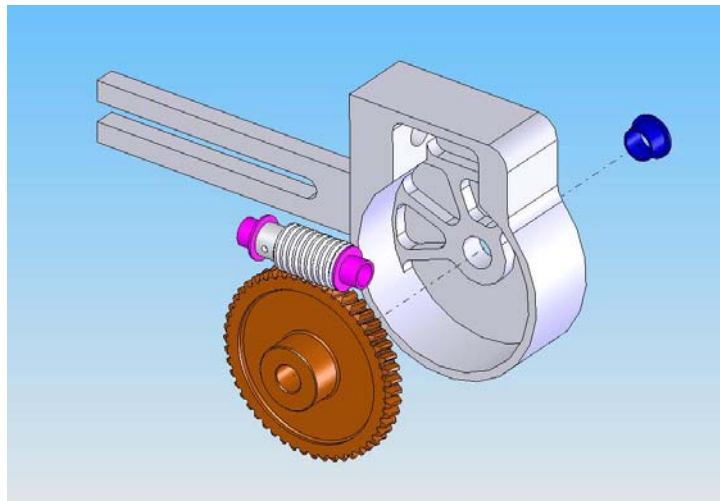
Figure 63: Elbow Rotation Assembly
Elbow Drive Assembly showing the worm and worm gear, as well as the flange bearings to hold both the worm axle from the motor (not shown) and the worm gear.

While the Elbow Housing was designed to have gears built inside of the housing, the two halves of the Humeral Housing (Humeral Housing Front and Humeral Housing Rear) were designed for preassembled shafts, gears and bearings to be sandwiched
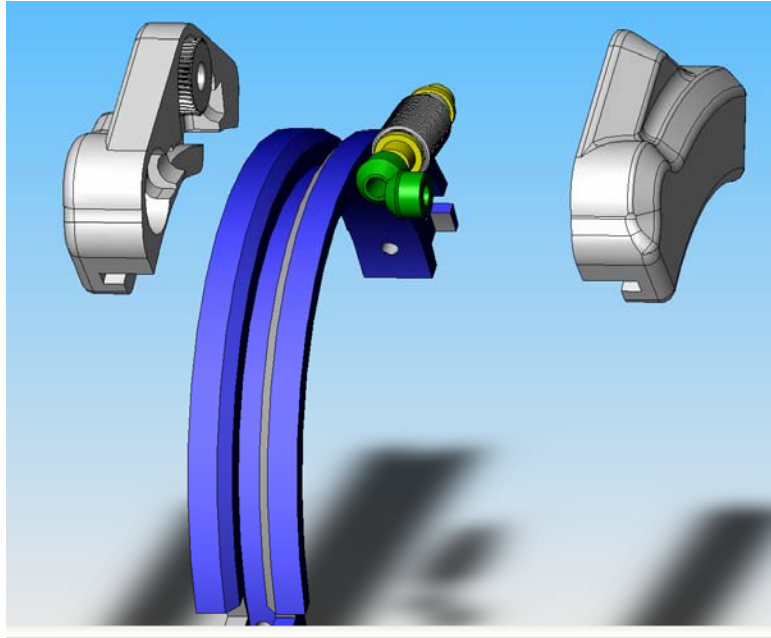
Figure 64: Humeral Rotation Assembly
Exploded view of the humeral rotation assembly. Left to Right: Humeral Housing Rear, Counting Worm Gear, Humeral Rail, Humeral Worm and bearings, Humeral Housing Front.

between the two halves (Figure 64). This design was advantageous for DFM for several reasons. Since each half of the Humeral Housing shared the central axle, the arc of the axle "trough" was fully exposed, and could be cast with a simple two-part mold (Figure 65). Additionally, because the flange bearings had already been specified for the axle, the surface finish of slot for the central shaft was not critical. By differing attention from the central shaft, more care could be given to holding the tolerance between the mating plane of the Front and Rear Housings. During assembly, the design of the Humeral Housings also allowed for a top down assembly approach, significantly simplifying the assembly of the humeral drive system when compared to the proof-of-concept prototype.
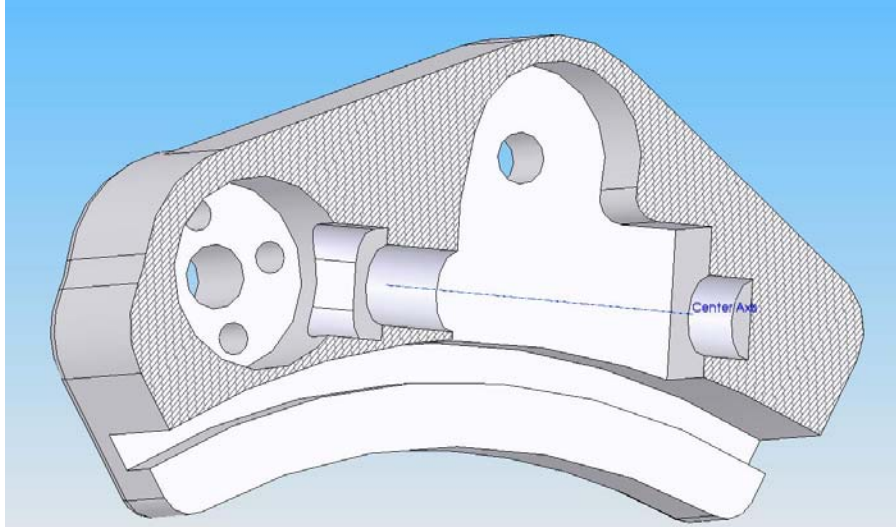
Figure 65: Rear Humeral Housing Showing Mating Surface and Center Axle Axis
Rear Housing, showing the Mating surface (hatched) and the Center Axis as labeled.

Again, however, due to cost constraints the Humeral Housings were not cast from RoyalCast 3101, but were instead printed from Duraform PA, a functional prototyping SLA material. Duraform PA is a structural SLA material and has properties similar to those of RoyalCast 3101.

5.2.3 Fully Assembled Model

Just as the individual components were designed to be assembled into the various sub-assemblies (Humeral Drive, Elbow Drive and Humeral Mate), the entire orthosis was also designed to be assembled in a straightforward assembly of these sub-assemblies. Beginning at the most distal portion, the Elbow Drive is first fitted to the Forearm Cage by locking the drive axle (from the Forearm Cage) to the Elbow Worm Gear. The Lateral Humeral Bar is then placed onto the lateral side of the Forearm Cage. Both Humeral Bars are the fit into the Humeral Rail and secured in place (Figure 66).
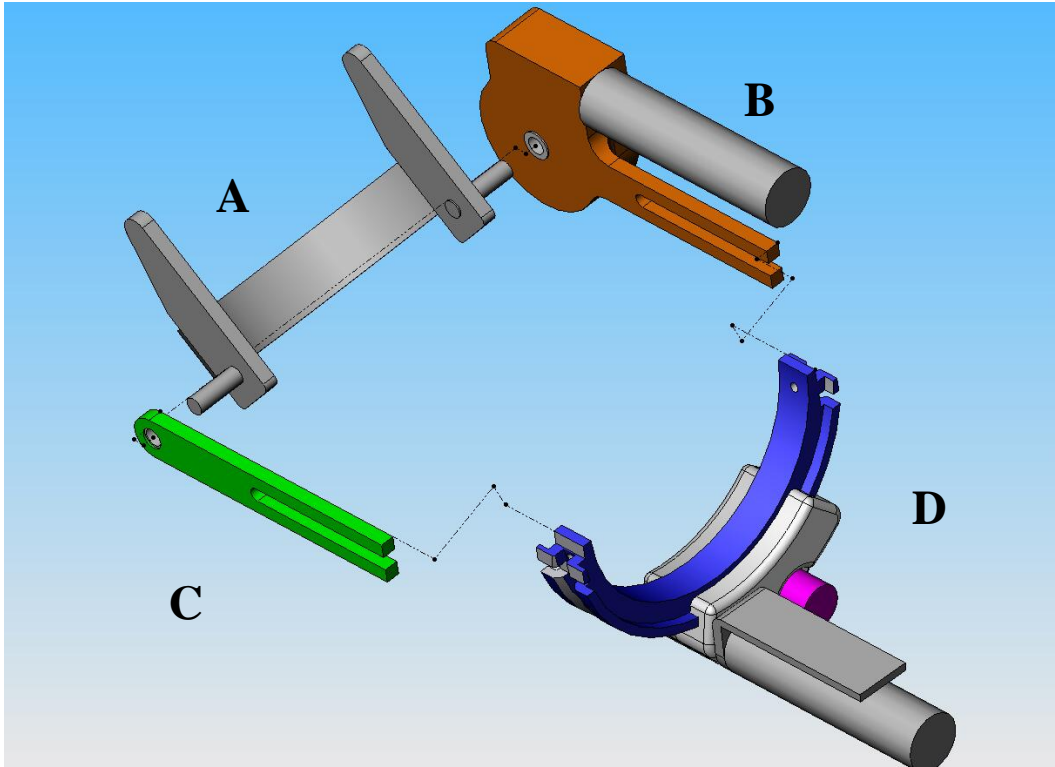
Figure 66: Exploded Assembly of the Powered Arm Brace
Exploded assembly of the powered arm brace with assembly lines. The Forearm Cage
(A) is first assembled to the Elbow Drive (B), then to the Lateral Humeral Bar (C).
The ends of the Humeral Bars are then fitted to the machine slots in the Humeral Rail
(D), completing the assembly.

5.3 Model Stress Analysis

All loaded structures deform under stress. These deformations can lead to
catastrophic failure as cracking and permanent deformation. In the design of driven
systems, which require tight alignments, even minor elastic deformation can initiate
misalignments that lead to premature wear and reduction in function. Furthermore, in the
design of orthotic devices, which are designed to work harmoniously within existing
body kinematics, both catastrophic failure and unpredicted deformation can cause global
misalignments between the device and patient, heightening rather than mitigating injury.

As the powered arm brace is to be used with patients prone to injury, who already
weakened joints, it is important to conduct thorough stress analysis to predict and correct

unacceptable stress and resulting deformation. Additionally, it is important to define the effects of unintended wear from falling on the device or attempting to lift heavy loads with the device. Both manual, static stress analysis and CAD FEA were conducted to adequately model the reactions to predictable stresses. Additionally, when possible, stress analysis tests were completed with partially fabricated models.

5.3.1 Static Stress Analysis

Several of the components of the design were standard parts, which are used throughout industry. These parts include gears, screws and axles. Because these parts are so common, basic tables are available for specific components (material and dimensions), which can be used to predict failure modes and normal working life. In addition to basic static stress analysis techniques, these published figures were used to adequately predict the working characteristics of the gears, screws and axles used in the design of the powered arm brace.

5.3.1.1 Gearing Stress Analysis

As only two worm gears were employed as open gearing to drive the powered arm brace, relatively few equations were used to calculate the working torque limits of the gearing. Based on recommendations from the American Gear Manufactures Association (AGMA)[49], the following equations were used to predict the holding and working torques of the worm and worm gear sets in both the humeral and elbow drives.

Equation 3: Maximum Holding Torque of a Worm Gear

M_b (N•m)= 0.0018 (m/mm$^{.5}$) • X_{b2} •σ_{bm} •m •l_{f2} •d_2

Where: X_{b2} = speed factor of bending

σ_{bm} = bending stress factors of the worm wheel (N/mm^2)

m = axial module (mm)

l_{f2} = length of root of the worm gear tooth (mm$^{.5}$)

d_2 = pitch diameter (mm)

Based on these equations the maximum holding torque of the worm gears were calculated.

Equation 4: Maximum Static Torque of Humeral and Elbow Worm Gears

$M_{max\ humeral}$(N•m)= 0.0018 •.32 •63 •20.37 •1.56 •142 = 163.8 N•m of holding torque

$M_{max\ elbow}$(N•m)= 0.0018 •.56 •63 •7.64 •1.87 •053 = 48.1 N•m of holding torque

Additionally, the maximum permissible working torques of the worm gears were also calculated.

Equation 5: Maximum Worm Gear Working (Dynamic) Torque

M_c= 0.00191(m/mm$^{.8}$) • X_{c2} •σ_{cm} •Z •m •$d_2^{1.8}$

Where: X_{c2} = speed factor of wear (unitless)

σ_{bm} = surface stress factors of the worm wheel (N/mm^2)

m = axial module (mm)

Z = Zone factor (unitless)

d_2 = pitch diameter (mm)

Based on these equations the maximum operating torque of the worm gears to maximize their life was determined.

Equation 6: Maximum Dynamic Torque of Humeral and Elbow Worm Gears

$M_{wear\ humeral}$(N•m)= 0.00191 •.18 •6.3 •.37 •20.37 •142$^{1.8}$ = 122 N•m of operating torque

$M_{wear\ elbow}$(N•m)= 0.00191 •.34 •6.3 •1.15 •7.64 •053$^{1.8}$ = 45.6 N•m of operating torque

Upon inspection, the close proximity of the driving torques and holding torques demonstrated the slim margin between sustainable loads and working loads. However, since the working torques are to be limited to 12 N•m and holding torque to 20 N•m, both gears have a calculated safety factor of well above 2.0.

5.3.1.2 Screw Stress Analysis

As screws are the most prevalent mechanical fastener, published data of maximum allowable shear stress is highly reliable and available. Both of the motor housings are shipped pre-threaded for four M3 screws in a 20mm diameter around the motor shaft. By basic torque calculations, the maximum shear stress a screw must be capable of withstanding is:

Equation 7: Shear Force on Pin/Screw
Shear Force $= \tau /(R \bullet n)$
Where:
  n = number of screws
  τ = maximum torque (N•m)
  R = Radius from the center of rotation (m)

Although misuse by the user may cause the maximum torque on the device to exceed the working torque of 12 N•m, the non-backdriveable worm gears will prevent any undue torque from working back the system to the motors. Additionally, by monitoring the amperage draw of the motors, the motor torque can be limited to within the motors working range: 0.6 N•m

Due to space constraints, the elbow motor was only secured with two M3 screws, while the humeral motor was fully secured with four M3 screws. And as the radius of the both circle for the screws was defined to be 10mm (0.01 m), the necessary single-shear rating of the screws was required to be higher than torque 0.3N and 0.15N, respectively. As shown in Figure 67, single-shear strength is a the rated force a single pin of a given diameter can withstand before it shears (breaks), as tested between two polished steel plates.
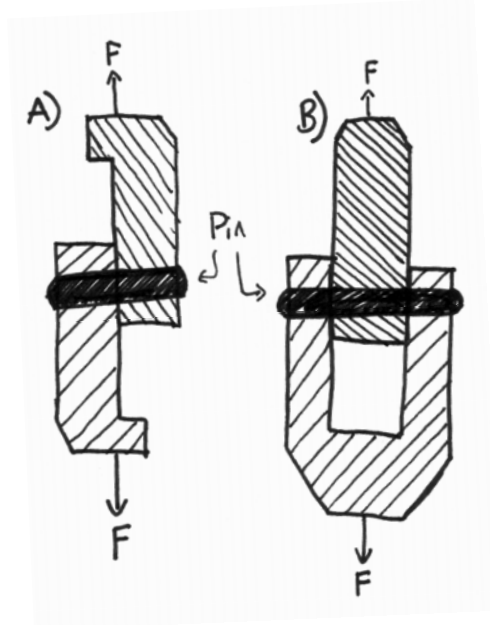
Figure 67: Diagram of Single and Double Shear Force
Single shear (A) test, shown as two steel plates sliding past one another held by a single pin. Double shear (B) is nearly the same test, except that the force is applied in two locations. Depending on the material, double shear can be more or less than twice single shear, and it is therefore important to use the proper table.

All standardized thread pitches have distinct major, pitch and minor diameter (Figure 68). The major diameter is the outer diameter of a thread measured at the peak of the threads, and is also used as the callout of the thread: A 3M screw has a major diameter of 3mm. The minor diameter of a screw thread is the outer diameter of a screw measured at the bottom to thread. The minor diameter of a 3M thread is 2.43mm.[50]
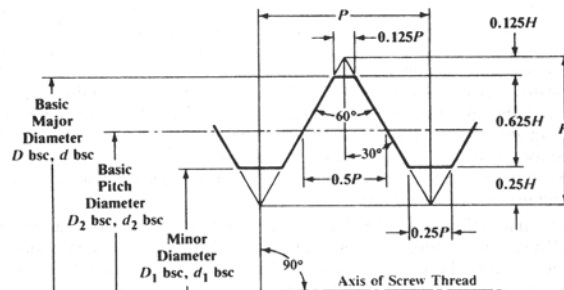
Figure 68: Thread Pitch Diagram
Thread pitch diagram showing major, minor and pitch diameters.
Machinery's Handbook, 27th ed. (p. 1726)

As the minor diameter of the thread, 2.43mm, is also an American National Standard pin size (3/32"), published single shear stress data is available. Based on tables included in *Machinery's Handbook*, considered an industry standard reference manual, a 3/32" diameter pin can withstand a single shear load in excess of 3500N, well above 0.3N. Additionally, threaded fasteners are generally rated much higher than their single shear load as calculated unloaded. When a fastener is properly tightened, the screw holds the surfaces in compression and the compressive forces build a high static friction between the two surfaces, which itself, prevents a screw from being subjected to any shear load. Based on these calculations, the deformation of breaking of the screws was of little concern.

5.3.1.3 Axle Stress Analysis

Although each of the axles along the gear train undergo a measurable and calculable stress, the final axle in the Elbow Drive System, which holds the Forearm Cage, experiences the highest level of stress because it is after and, therefore, unprotected by the non-backdrivable gears. This axle also experiences higher working torques simply because it is furthest along the gear train. This would also be true of the final axle in the Humeral Drive System, but as the worm gear rotates around the arm, there is no "final" axle in the system.

The design of the final elbow drive axle calls for the axle to be pinned through both the worm gear hub, and at the Forearm Cage. From *Machinery's Handbook*, the maximum working stress of the axle is calculated by referencing the axles "normal" max stress load with the stress concentration factor (Figure 69).
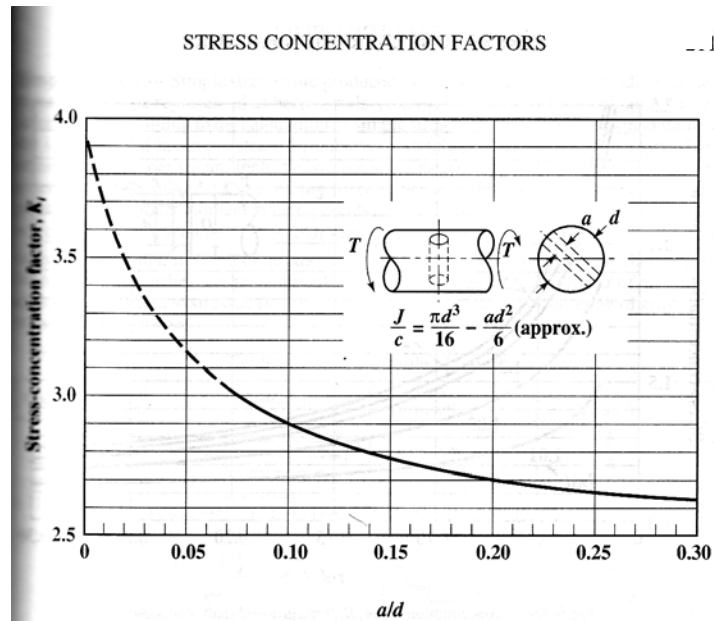
Figure 69: Stress Concentration Factor of Pinned Axle in Torsion
The maximum working stress of a shaft can be calculated by finding the stress concentration factor in the pinned region.

Machinery's Handbook, 27th ed. (p. 211)

To determine the maximum stress on the elbow axle, the pin diameter through the axle was first determined. Again, the basic torque equation (Equation 7) was used to calculated the shear force on the pin at the point just between the axle shaft and the gear hole. As the diameter of the shaft was 6.33mm (.25"), the minimum double shear of the pin was determined to be 3200N (~700 lbs). This criteria was met by a 2.38mm (3/32") diameter unhardened steel pin[51].

Based on a 2.38mm pin diameter and a 6.33mm shaft diameter, the basic calculated stress concentration factor (K_t) was found to be ~2.60. The final calculated stress concentration (K) was calculated to be 1.24 times the calculated torque. At a predicted maximum torque of 20N•m, a new torque of 24.8N•m was used to calculate the factor of safety factor of the axle shaft.

Equation 8: Stress Concentration Factor
$K = 1 + q \cdot (K_t - 1)$
Where: K_t = Stress concentration factor
    q = 0 (ductile materials), 0.15 (hardened steels)
    $1.24 = 1 + 0.15(2.6-1)$

A hardened steel shaft with a diameter of 6.33mm has a polar shear modulus (Z_p) of 48.4 mm³. As hardened steel has a yield strength of 750N/mm², the maximum permissible torque on the shaft is 36300N•mm (36.3N•m), above the corrected torque of 24.8N•m (1.46 SF). The relatively low safety factor of the pin compared to the other components of the device is actually an advantageous to the safety of the device. During a serious fall or during misuse, the pin will be first component to break, allowing the arm to hang free, preventing further injury to the user.

5.3.2 Finite Element Analysis

Many of the components in the powered arm brace were designed as custom parts. Because of the complicated geometry of these parts, Computer Aided Finite Element Analysis was conducted to accurately predict any deformations, which would occur under normal conditions.

5.3.2.1 Humeral Rail

As previously noted, the Humeral Rail is a major component of the Humeral Drive. A structural failure of the Humeral Rail could not only bind the Humeral Drive System, it could also lock the Elbow Drive System. Because of the Humeral Rail's importance in the proper function of the powered arm brace, extensive FEA was conducted to predict any possible failure. Failure of the Humeral Rail could result from

two loading conditions: Compression perpendicular to the axis of rotation, and a coupled force in a plane parallel to the access.

FEA of the Humeral Rail was first conducted in compression. A 50N compressive force was applied to the cut flats at both ends of the hemispherical Humeral Rail. Based on FEA, the Humeral Bar would deflect by only 0.5mm and a total safety factor of 3.1.

FEA of the Humeral Rail was then conducted to mimic the normal operating conditions (arm outstretched with 2.25 kg in the hand). A bending stress was placed on the Humeral Rail to mimic the stresses that would result if the brace were loaded without the benefit of human skeletal structure. The resulting stress analysis showed that the Humeral Rail was robust enough to withstand normal working conditions.

Based on FEA the Humeral Rail was found to have a factor of safety of 2.0 (Figure 70) and normal operating deflection of less than 0.21mm. Both of these values were well within acceptable limits.
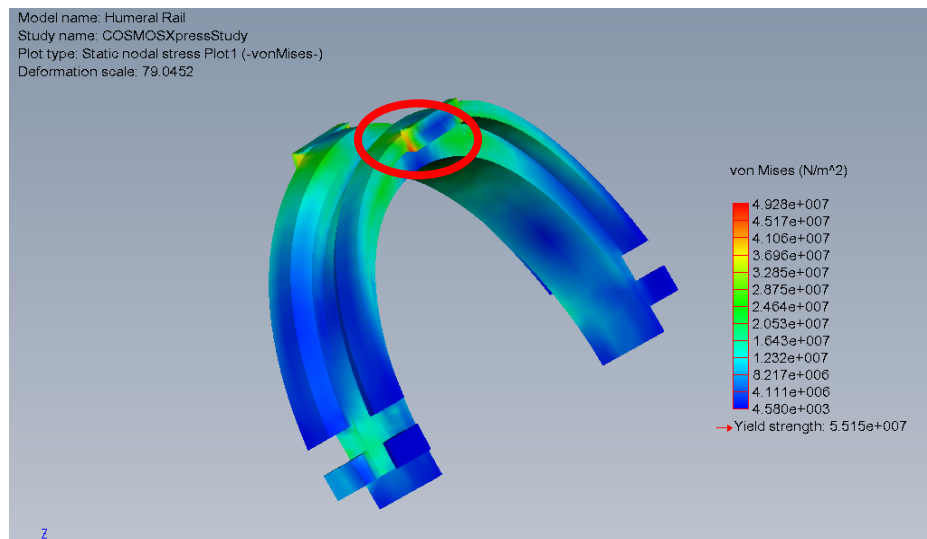
Figure 70: FEA of Humeral Rail Stress
Stress on Humeral Rail. Maximum stress is shown at the point of contact between where the sliding surface of the Humeral Housing and Humeral Rail would meet.

5.4.2.2 Humeral Housing

Stress analysis of the Humeral Housing was conducted to ensure that the portion of the housing that was responsible for holding the Humeral Rail captive was robust and rigid to allow for smooth action of the Humeral Rail. As before stress analysis was conducted under the worst cast scenario, with the arm brace outstretched and the 2.25 kg placed at the point of the hand, and the results of the tests were recorded.

In the FEA model, acrylic plastic was used because its physical properties are very similar to RoyalCast 3101 cast resin. Based on the FEA testing, the Humeral Housing was predicted to deflect a maximum of .15mm (.009") (Figure 71) and maximum von Mises stresses at 5.4 N/m^2 x 10^6 (Figure 72).
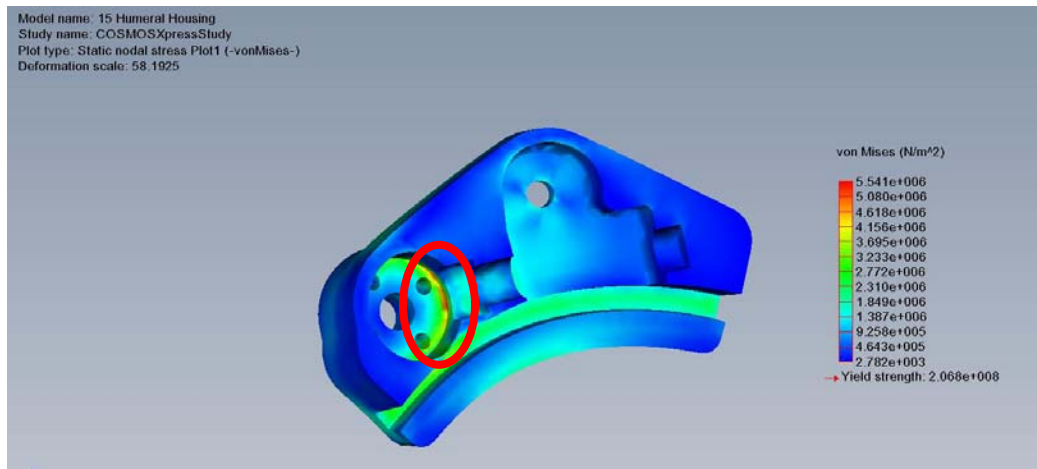
Figure 71: Humeral Housing Stress
The maximum stress area (circled in red) was on the inside of the cutout for the miter gears. Around the Humeral Rail area, the stresses were much less, about 2.5x106 N/m2.

The calculated deflection factor was within an acceptable range as the stated tolerance of the casting process over the length of the Humeral Housing was ~±.25mm. Additionally, the safety factor of the Humeral Housing was 33.1.

131
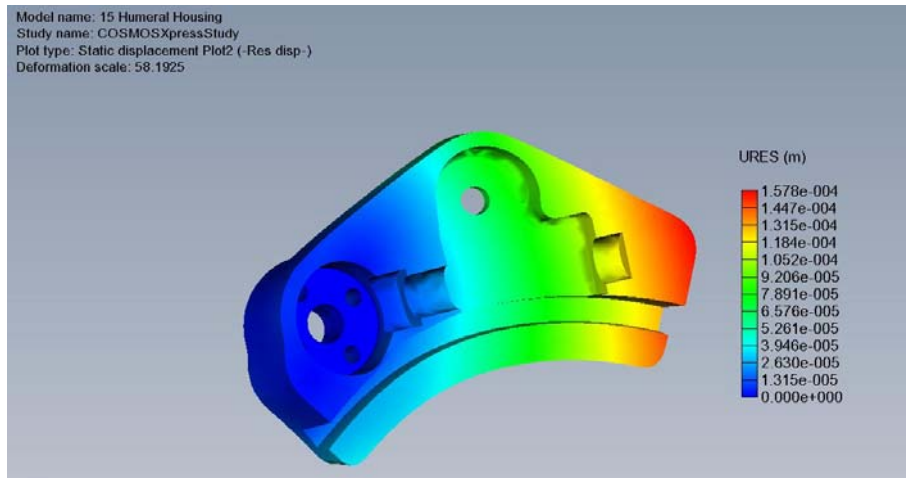
Figure 72: Humeral Housing Deflection

Deflection across the Humeral Housing shows that the rate of defection was constant, without any drastic bends or deformations, which could lead to binding.

5.4.2.3 Elbow Drive Stress Analysis

The Elbow Drive was the most complicated part of the powered arm brace with over 50 features. As it was also potentially the heaviest, the wall thickness of the part was minimized wherever possible. Although this created a relatively light part (110g), minimizing the wall thicknesses also led to a structurally weak design. To accurately predict the behavior of the Elbow Drive System under working conditions, several different loading schemes were designed and tested using FEA on various redesigns to improve the structural integrity of the Elbow Drive.

Of most concern in the Elbow Drive System were deflections at the worm drive axle and at the boss of the worm gear axle, which could result in axle binding and premature wear of the gearing. Initial testing showed significant deflection under normal working conditions (Figure 73). Deflection occurred between the mounting surfaces of the worm axle, and when tested at the center hole for the worm gear. While under normal working stress the side wall could deform as much as 0.25mm, but if the full holding torque of 20N•m was placed on the device that deflection could be as high as 0.50mm.
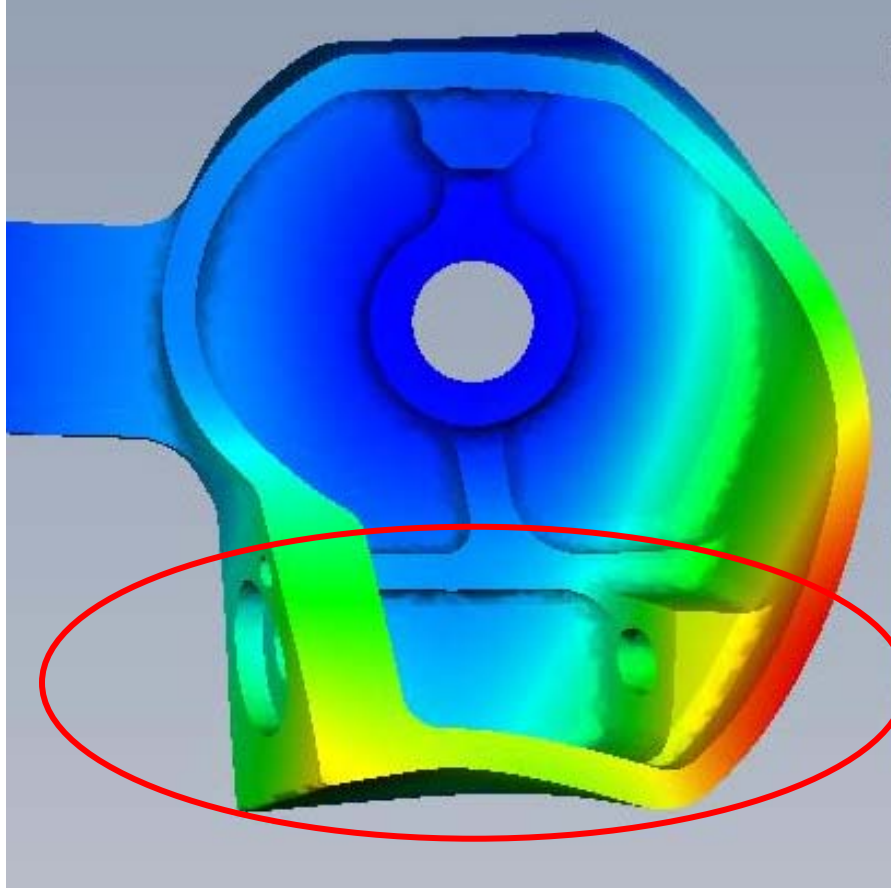
Figure 73: Deflection of Elbow Housing
Elbow Drive (Elbow Housing) shown in exaggerated deformation. The least deformation occurs around the worm gear boss (top center), and the highest deformation occurs in the worm axle region (bottom left and right). What is important in this drawing is that the relative deformation between the two worm axle mounts are similar (right and left sides of the circled area), that is they deform together, and would not bind an axle.

To remedy the significant deflection, the sidewall nearest the worm gear was thickened by 50%, additional webs were added to the worm gear boss and the base of the Elbow Housing was thickened by 25%. These changes added only 10% to the weight of the housing, but significantly increased the stiffness of the housing (Figure 74). The new housing only deflected by 0.03mm under normal load, and deflected by .07mm under the maximum recommended holding load.
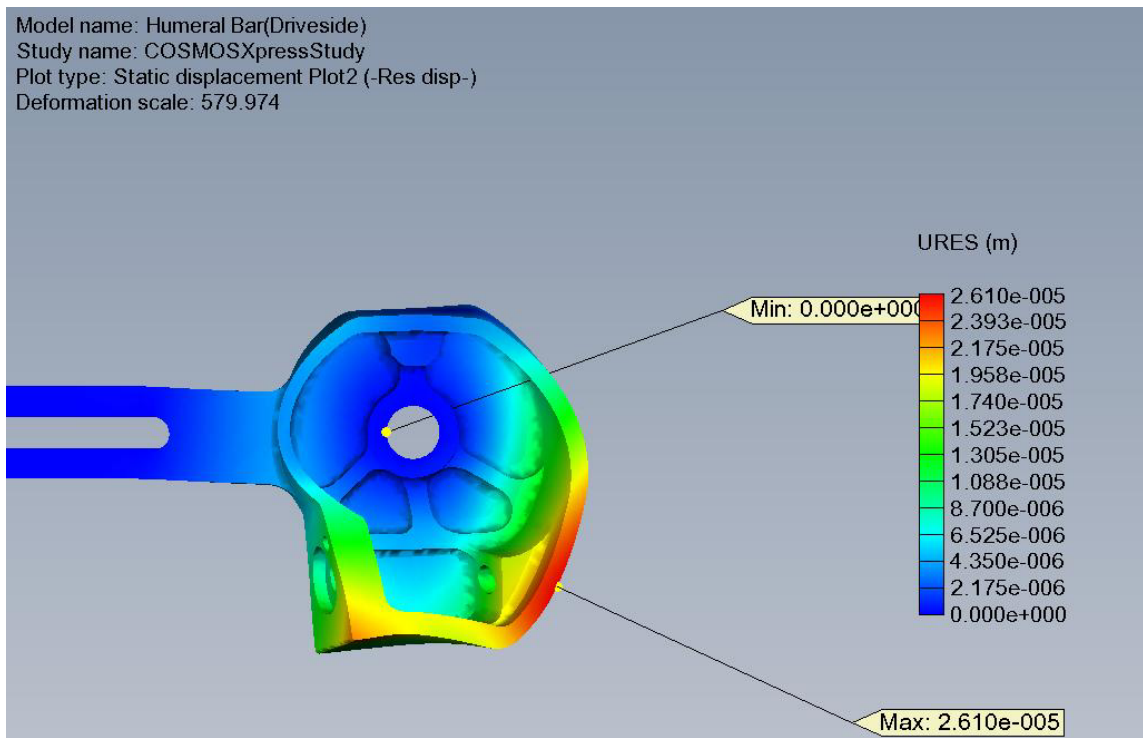
Figure 74: Deflection in Modified Housing

The additional webbing in the base of the housing improved the deflection of the housing.

5.4.2.4 Humeral Bar Stress Analysis

The previous testing of the Humeral Bars was checked using FEA both to validate the earlier testing and to validate the previously discussed FEA. Both of the Humeral Bars were tested (Medial Humeral Bar and humeral bars extending from Elbow Housing) by fixing the free end (left side) of the humeral bars and applying a force to the rotational pivot of the elbow (hole right side). This loading condition mimics the normal loading of the humeral bars as they are pinned and loaded at the elbow, and each of the bar beams is fixed to the Humeral Rail.

The FEA of the humeral bars confirmed that the bars would withstand not only normal use, but would no experience any noticeable deflection. Based on the position of the far end of the bars, the Elbow Housing deflected about .24mm (Figure 75). The
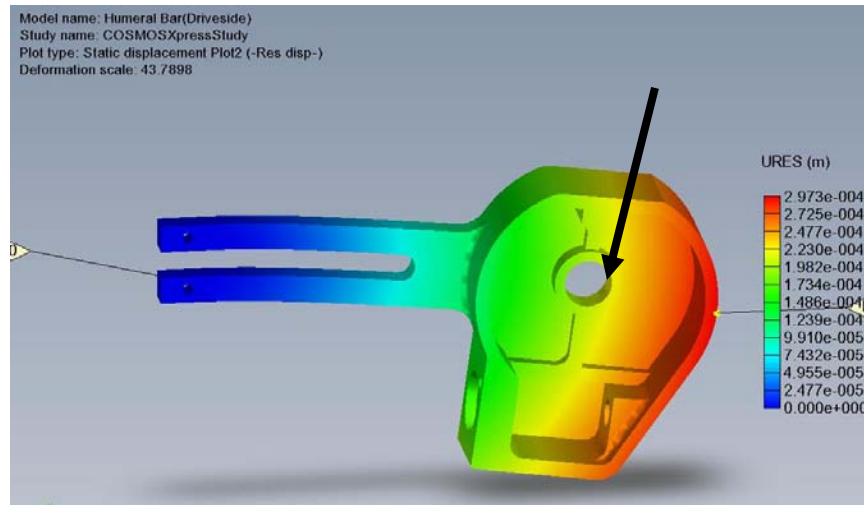
Figure 75: Elbow Housing Bar Deflection
Deflection at the elbow rotation axle (arrow) was only 0.223mm.

Medial Humeral Bar deflected only .05mm at the rotational axis of the elbow. Both of these tests helped to validate the physical testing (*5.1.3.2 Rectangular Parallel Bars*) conducted earlier in the design process, as well as validate the FEA models of other parts, as the FEA models were shown to perform as predicted.
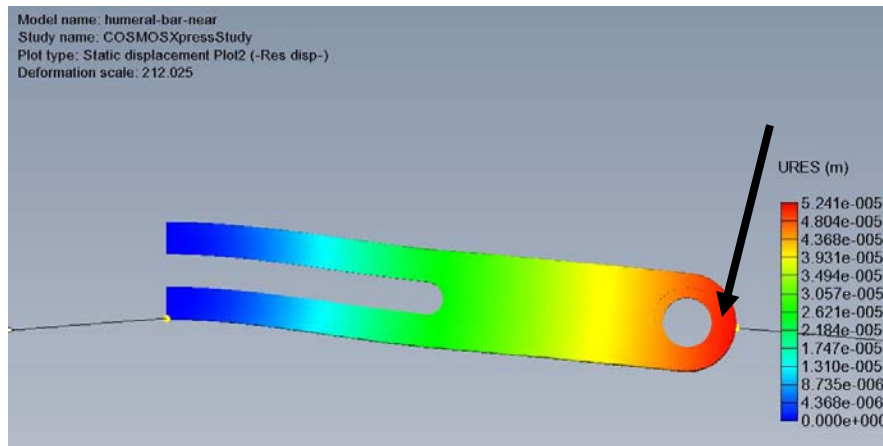
Figure 76: Medial Humeral Bar Deflection
Deflection at the elbow rotation axle (arrow) was only 0.048mm, an almost unnoticeable deflection.

5.4 Final Design

After completing extensive FEA and redesigning components for acceptable safety factors, a final design was constructed and detailed. In addition, basic numeric modeling was used to predict performance.

5.4.1 Final Model

The final model of the humeral brace consisted of twenty-one mechanical parts including each of the major parts as well as bearings and axles (not including screws). Figure 77 shows a completed Solidworks model of the major components. Additionally,
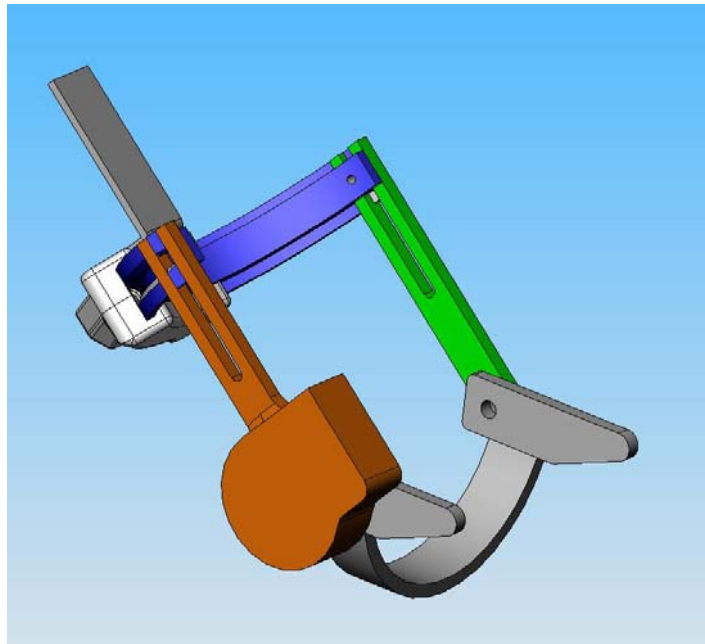
Figure 77: Final Solid Model of the Powered Arm Brace
Final solid model of the powered arm brace. Parts are as labeled in previous sections.

Figure 78 displays an exploded view of the Humeral Drive, and Figure 79 is an exploded view of the Elbow Drive. Detailed prints of the individual components are available in *Appendix B: Dimensioned Drawings*.
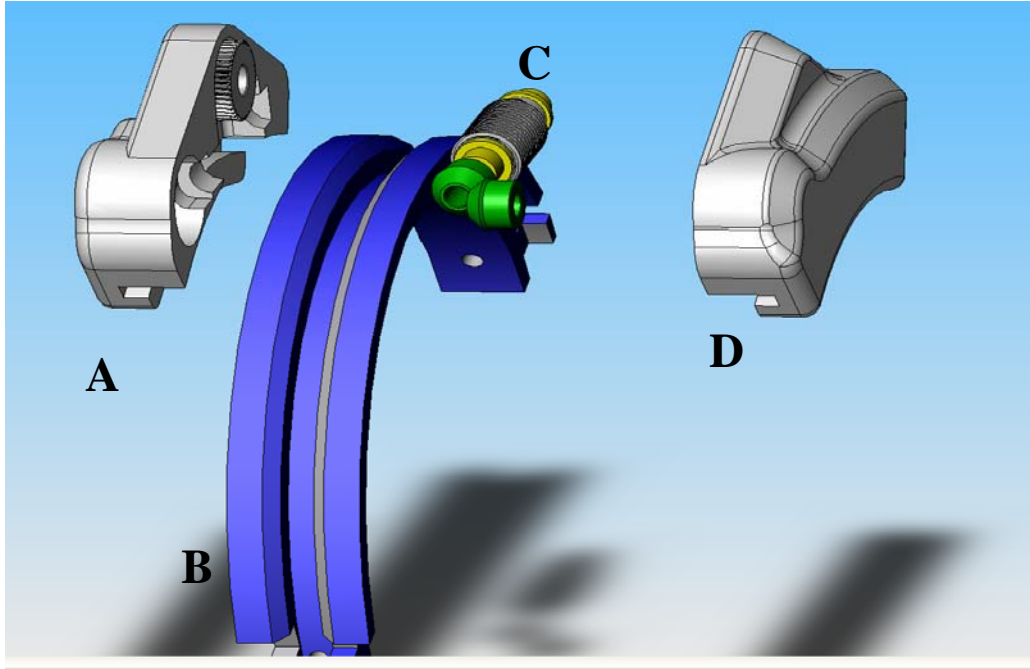
Figure 78: Exploded View of Humeral Drive Assembly
Humeral Drive Assembly showing the Rear Housing and Counting Worm Gear (A), the Humeral Rail (B), the Worm, flange bearings and Miter Gear Set (C), and the Front Humeral Housing.
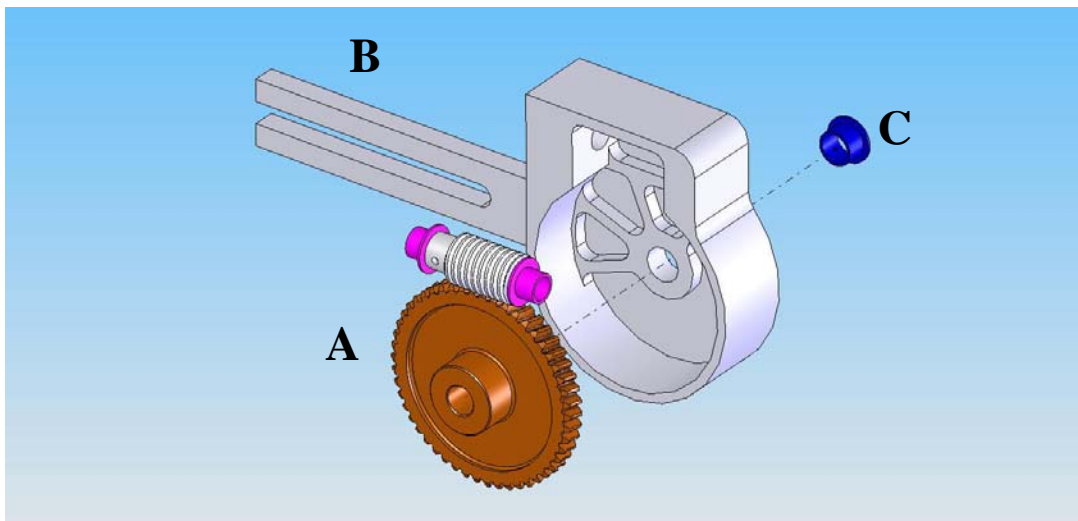
Figure 79: Exploded View of Elbow Drive Assembly
Elbow Drive Assembly showing the Elbow Worm Gear, Worm and flange bearings (A), the Elbow Housing (B) and the elbow pin flange bearing (C).

5.4.2 Bill of Materials

A Bill of Materials of the final design was constructed to aid in manufacturing and review of the design. The total maximum price for a single brace was defined under the task specifications to be less than $2500. Based on the final Bill of Materials, the total

#	Name	Qnty	MFG'er	MFG #	Price	Total
Table 10: Bill of Materials						
1	Forearm Brace	1	Polymer Corp	Based on Quote	$60.00	$60.00
2	Forearm Cup	1	Client		$50.00	$50.00
3	Medial Forearm Bar	1	Polymer Corp	Based on Quote	$39.00	$39.00
4	Lateral Forearm Bar	1	Polymer Corp	Based on Quote	$175.00	$175.00
5	Elbow Bearings	2	McMaster	6627K15	$4.05	$8.10
6	Medial Elbow Pin	1	WPI	Aluminum	$10.00	$10.00
7	3.4 Motor	1	Maxon		$250.00	$250.00
8	Lateral Elbow Pin	1	McMaster	98380A585	$7.65	$7.65
9	Elbow Drive Gear	1	SDP/SI	A 1B 6-Y24050	$40.95	$40.95
10	Elbow Drive Worm	1	SDP/SI	A 1Q55-Y24	$46.44	$46.44
11	Elbow Drive Axle	1	WPI	Additional Machining	$15.00	$15.00
12	Elbow Thrust Bearings	2	McMaster	6627K13	$3.82	$7.64
13	1:53 Motor	1	Maxon		$250.00	$250.00
14	Humeral Rail	1	Local MFG		$250.00	$250.00
15	Front Humeral Housing	1	Polymer Corp	Based on Quote	$90.00	$90.00
16	Back Humeral Housing	1	Polymer Corp	Based on Quote	$90.00	$90.00
17	Worm Gear	1	SDP/SI	S1C86Z-P064B360D	$82.10	$82.10
	-Post Machining	1	Local MFG		$100.00	$100.00
18	Miter Gear	2	SDP/SI	A 1B 4-Y32016	$9.54	$19.08
19	Humeral Extension	1	Polymer Corp	Based on Quote	$30.00	$30.00
20	Humeral Worm	1	SDP/SI	S1D94Z-P064SD	$14.79	$14.79
21	Counting Worm Gear	1	SDP/SI	S1C86Z-P064B040D	$19.98	$19.98
22	Humeral Thrust Bearings	2	McMaster	6638K13	$0.40	$0.80
				Total price	$1,638.72	$1,656.53

cost for a single unit was $1656.53. In higher quantities (runs of 20), it is expected that this cost could decrease as much as 33% for several reasons. The most basic reason is the significant discounts available in larger order quantities. For example the cost per part of the Humeral Brass Worm Gear (Part #17) is $182.10. In larger orders the base part cost is discounted by 15%. Additionally, since only 120° of the gear is used, the potential exists to minimize waste, and machine three working Worm Gear arcs from a single worm gear.

The per part cost of higher run quantities is, therefore, expected to be near $1200, half of the expected cost after the proof-of-concept prototype.

5.4.3 Expected Functionality

Using the RPM/Torque curve, the time to 90º rotation from a horizontal position could be approximated based on the initial lifting torque and the force vector of gravity iterated over a specific time. A model of the approximate lifting times was iterated using Excel. These times were then compared to the heating and thermal overload of the motor to ensure motor longevity. Because the angular acceleration and final rotational speed were low compared to the force of gravity, the angular acceleration and velocity was approximated based on the force of gravity alone. Additionally, although motor inefficiency is dependent upon time, an average required rotation of 3 RPM was used.

5.4.3.1 Humeral Rotation

Using published and calculated efficiencies, the calculated efficiency of the Humeral Drive was 55% at a gear reduction of 792:1 (Table 11). Using this gearing

Table 11: Humeral Gearing Specifications

Time Step	0.05	Sec	50	milli-sec
Start Torque	12	N·m	12000	mN·m
Max RPM	4980	Rpm	0.000201	Minute/ rot
RPM/Torque	36.1	N·m·min/rot	36100	mN·m·min/rot
Gear Red	1:180		0.65	Gear Eff
M. Gearr Red.	1:4.4		0.84	M Gr Eff

To calculate the expected torque/time and angle/time curves, the starting torque (initial torque), motor rpm and torque curves, the and the gear reduction and efficiencies were used to generate a model of motor performance. Iterating over a time step allowed the rpm and torque to vary with varying position. For ease of calculation some of the inputs were modified (Right hand column).

efficiency, the force placed on the motor, as well as the motor rpm, was calculated based

angle of the arm relative to the direction of gravity. The maximum torque was calculated

to be 27.75 milli-Newton meter (mN•m), falling below 25 mN•m after 0.90 seconds

(Figure 80). The initial rotational speed of the motor was calculated to be 3980 RPM

(Figure 81).
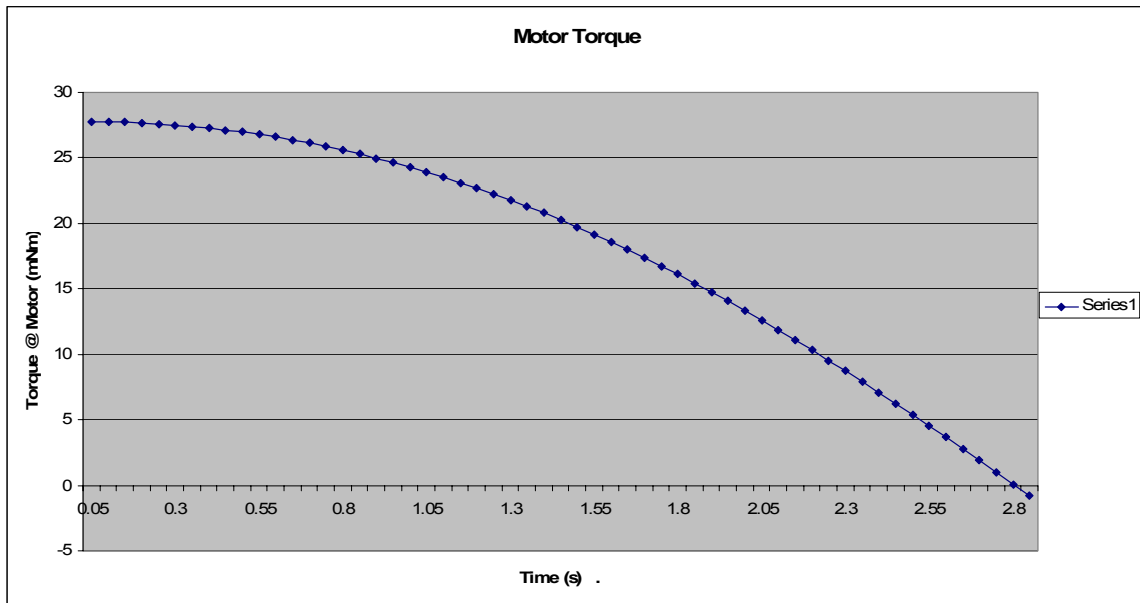
Figure 80: Humeral Motor Torque Curve
Graph showing torque at the humeral motor over the expected time to lift 2.3kg in the
hand. The maximum torque on the motor is 27.75 mN•m. As shown in *Table 7:
Maxon Motor 10 Watt Motor Chart*, the maximum continuous torque of the motor is
28.80 mN•m, or ~104% of maximum expected load.
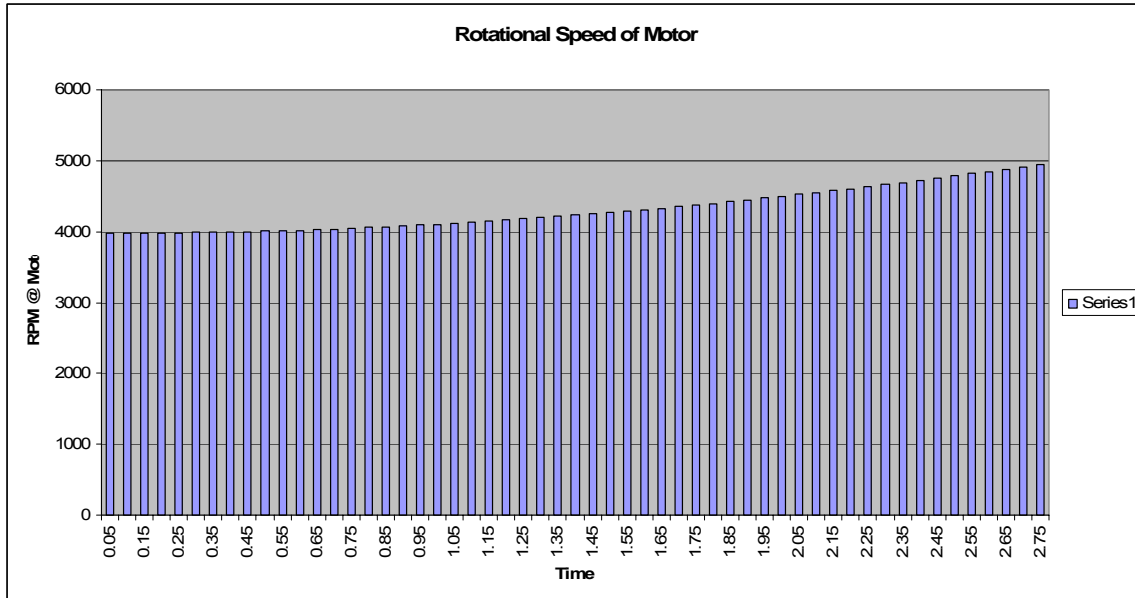
Figure 81: Humeral Motor Maximum RPM Curve
Graph showing the Maximum RPM of the motor while lifting 2.3kgs in the hand. With PWM control, all RPM are possible below the maximum speed. Iteration step size is .05 seconds

Since the continuous maximum operating torque of the motor was 29.2 mN•m, the Humeral Motor was shown be underloaded by 5.0%, the motor under normal operating conditions would not experience thermal overload. An amperage overload switch would protect the motor; this condition will ensure long motor life.

5.5.3.2 Elbow Rotation

Using published and calculated efficiencies, the calculated efficiency of the Elbow Drive was 57% at a gear reduction of 1457.5:1 (Table 12). Using this gearing

Table 12: Elbow Gearing Specifications

Time Step	0.05	sec	50	millisec
Start Torque	12	N•m	12000	mN•m
Max RPM	4980	rpm	0.000201	Minute/ rot
RPM/Torque	36.1	N•m•min/rot	36100	mN•m•min/rot
Gear Red	1:27.5		0.8	Gear Eff
M. Gr Red.	1:53		0.71	M Gr Eff

As before, to calculate the expected torque/time and angle/time curves of elbow rotation, the starting torque (initial torque), motor rpm and torque curves, the and the gear reduction and efficiencies were used to generate a model of motor performance. Iterating over a time step allowed the rpm and torque to vary with varying position. For ease of calculation some of the inputs were modified (Right hand column).

efficiency, the force on the elbow motor, as well as the motor rpm, was calculated based

angle of the arm relative to the direction of gravity. The maximum torque was calculated

to be 14.5 mN•m, falling below 12 mN•m after 1.90 sec. (Figure 82). The initial

rotational speed of the motor the motor was calculated to be 4460 RPM (Figure 83).
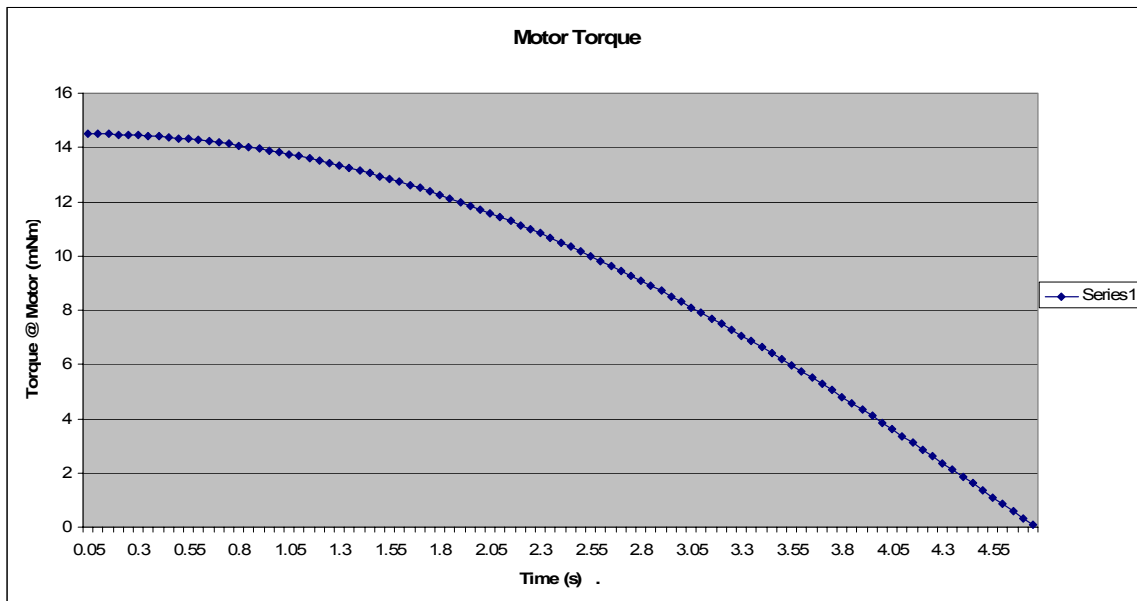
Figure 82: Elbow Motor Torque Curve
Graph showing torque at the elbow motor over the expected time to lift 2.3kg in the hand. The maximum torque on the motor is 14.50 mN•m. As shown in *Table 7: Maxon Motor 10 Watt Motor Chart*, the maximum continuous torque of the motor is 28.80 mN•m, or ~199% of maximum expected load.
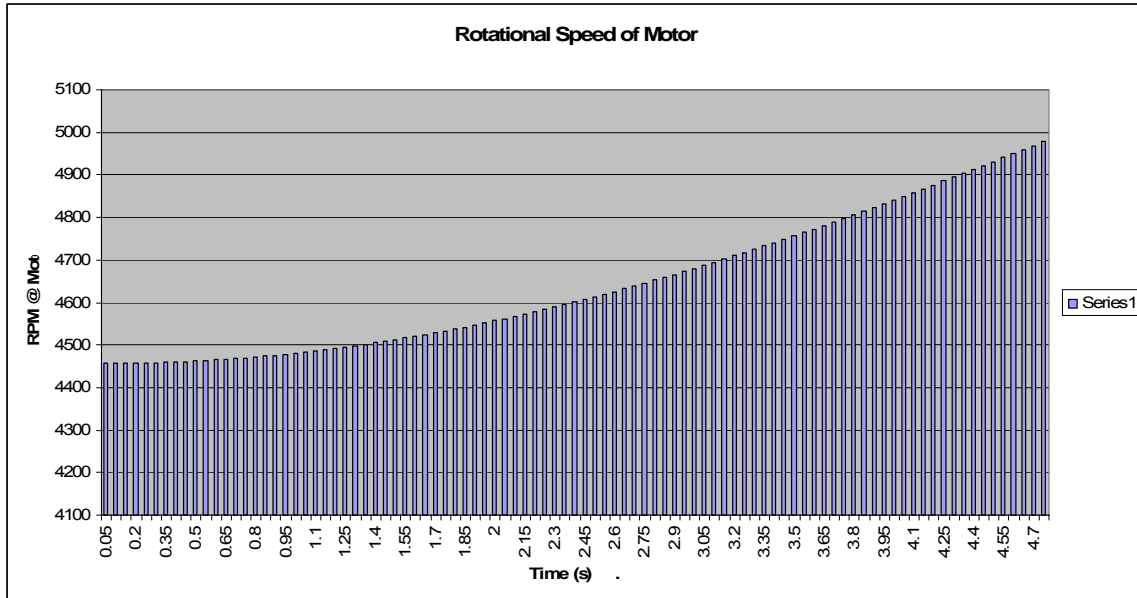
Figure 83: Elbow Motor Maximum RPM Curve
Graph showing the Maximum RPM of the motor while lifting 2.3kgs in the hand. With PWM control, all RPM are possible below the maximum speed. Iteration size is .05 seconds.

As the continuous maximum operating torque of the motor was 29.2 mN•m, the Humeral Motor was shown be under loaded by 51.5%, the motor under normal operating conditions would not experience thermal overload. At the motor would be protected by an amperage overload switch. This condition will ensure a full motor life.

6.0 Fabrication and Testing

The final design was fabricated to model specifications. The individual components were then mated with purchased parts and a working model was assembled. The final prototype was then rigorously tested to ensure that all design criteria were successfully achieved.

6.1 Manufactured Parts

Although many of the parts were designed to be cast from RoyalCast 3101 and reinforced with G-10 Garolite, the prohibitive price of casting a single model prevented their manufacture in this manor. Instead parts were built using SLA, machined from aluminum and built from extruded Lexan.

6.1.1 Humeral Housing

The Humeral Housing was printed using stereolithography (SLA). As shown, the Humeral Housing of the Humeral Drive is made of similar front and rear components. The parts were designed to allow the worm axle to rest between the two parts, so that during assembly the preassembled worm, axle, bearings and miter gear could be placed onto the Rear Housing and clamped into place (Figure 84).
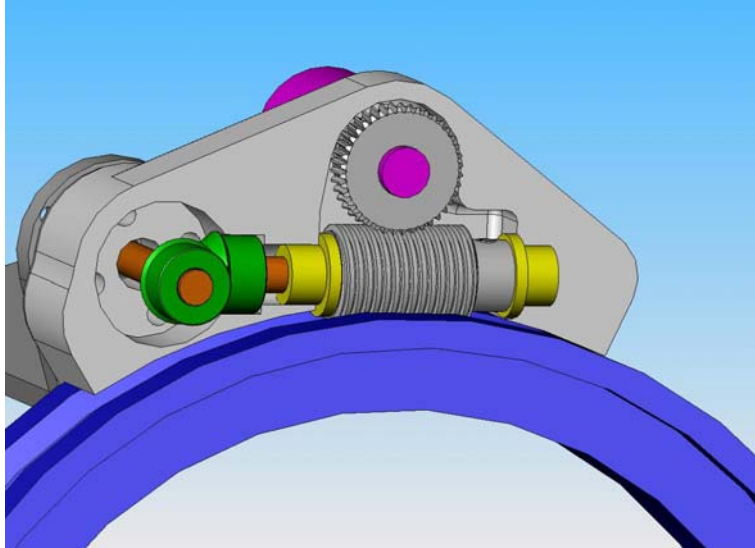
Figure 84: Humeral Assembly Shown without Front Humeral Housing
View of the Humeral Housing during assembly. After inserting the worm axle sub-assembly, and aligning the miter gears, the Front Humeral Housing is mated to the Rear Humeral Housing, completing the Humeral Drive Assembly.

The fabricated Humeral Rail Housing was constructed from Duraform-PA, a commonly used SLA material (Figure 85). Although the Duraform was slightly more brittle than the designed for RoyalCast 3101 material, the difference was not so drastic as to cause concern of cracking.

Figure 85: SLA Humeral Housing
Printed and painted SLA Humeral Housings showing inside(left)and outside (right) views of Front Housing.

6.1.2 Humeral Rail

The final Humeral Rail was turned from a block of 6061-0 Aluminum. The part is nearly identical to the solid model, with only the addition of 4 screw holes, which were used to lock the Humeral Worm Gear in place.
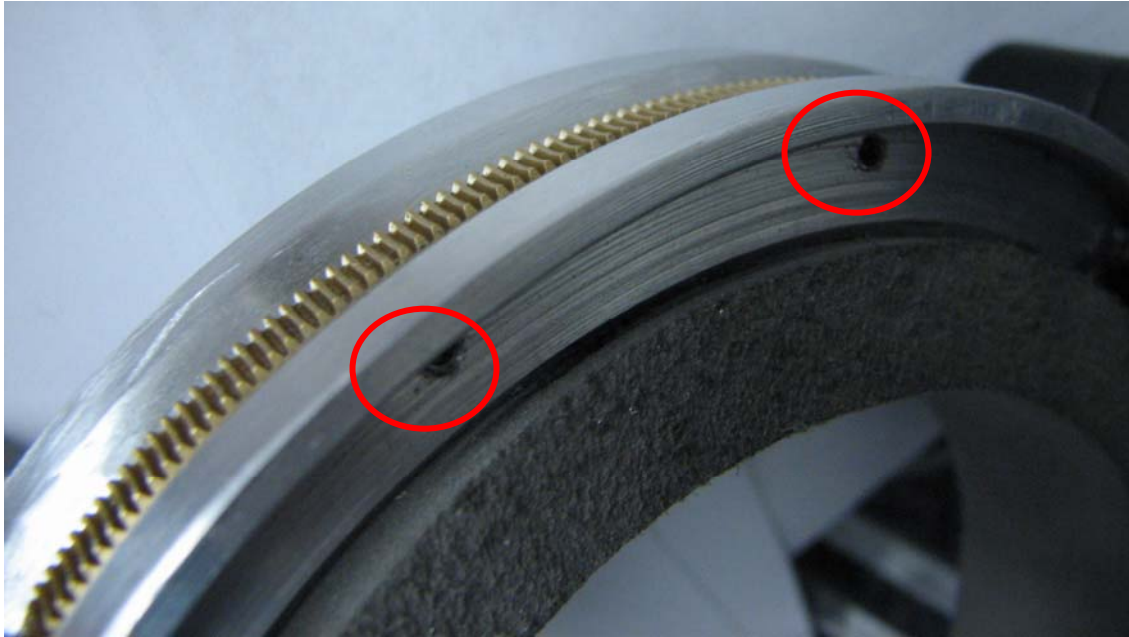
Figure 86: Humeral Rail

Humeral Rail showing 2 of 4 drilled and tapped holes (circled in red) used for set screws, which in turn, lock the Humeral Worm Gear in place.

6.1.3 Elbow Housing

Rather than cast the Elbow Housing from RoyalCast 304, the component was cut from machined aluminum. While this would clearly increase the overall strength of the Elbow Housing, it would not effect the rigidty of the design along the intergrated Humeral Bar portion, or within the housing itself. The similar rigidity would be due the to inclusion of G-10 composite material. Although a cast housing would have been preferred, in the interest of cost savings, a machined part was substituted. In addition to the aluminum housing, a housing cover was also fabricated from stock Lexan sheet (Figure 87).

Figure 87: Fabricated Aluminum Housing
The Elbow Housing was fabricated from aluminum to save in both cost and manufacturing time. Although aluminum has a much higher tensile strength than RoyalCast 3101, the rigidity of the two parts would be similar because the cast part would also contain a composite strengthening bar.

6.1.4 Forearm Cage

The Forearm Cage was also to be cast from RoyalCast 304. Again, the cost of casting a single part made this prohibitively expensive. Instead, the Forearm Cage was built from stock Lexan sheets, which were temperature formed. In this way, the component was constructed from three parts, the center arc and the two similar side rails.

Figure 88: Solid Model of the Forearm Cage
Solid model of the Forearm Cage, showing the Center arc and the two similar side rails. In the final step of fabricating the Forearm Cage, the three parts were solvent welded together.

After the individual parts were constructed and dry fitted, they were sand blasted and cleaned with solvent cleaner. Using a specially constructed jig, the parts were then held in their relative position to one another and a solvent weld was used to temporarily dissolve the Lexan at the joint between the parts. As the solvent weld evaporated, the Lexan hardened to bind the parts as a continuous piece of Lexan. The resulting part one single piece, just as the design of the commercialized arm brace calls specified.

6.2 Mechanical Testing

After fabricating both the mechanical and electrical components of the powered arm brace, the orthosis was rigorously tested to ensure that it met each of the design criteria. Each of the Task Specifications were reviewed and used as benchmarks for the performance of the device. For comparison, the performance and function of the proof-of-concept prototype were also used.

6.2.1 User Qualitative Tests

As many of the User Qualitative Task Specifications were integrated into the design of the orthosis, they were either fully met, or significant progress was shown over the proof-of-concept design.

Of the Qualitative Task Specification the most important specification was that, "The user should be able to complete ADL within 2-3 times longer" than it takes an able bodied person (4.1.1 *User Task Specifications*) because this specification embodies the minimum basic functionality of the device. In testing the proof-of-concept design, the unassisted "washing of one's face" was used as a benchmark of performance. This test was again used to test the design's functionality of completing basic ADL. A wash tub, and wash cloth were laid out as shown in Figure 89. The steps to washing one's face were defined as:

1. Pick up the wash cloth
2. Dip it in the water
3. Wash their face with three complete circular motions
4. Replace the wash cloth to its original location

An able-bodied test subject was twice asked to wash his/her face using the outlined steps and the times were recorded. The subject was then allowed to acclimate to the powered arm brace for 60 seconds before being asked to complete the activity.
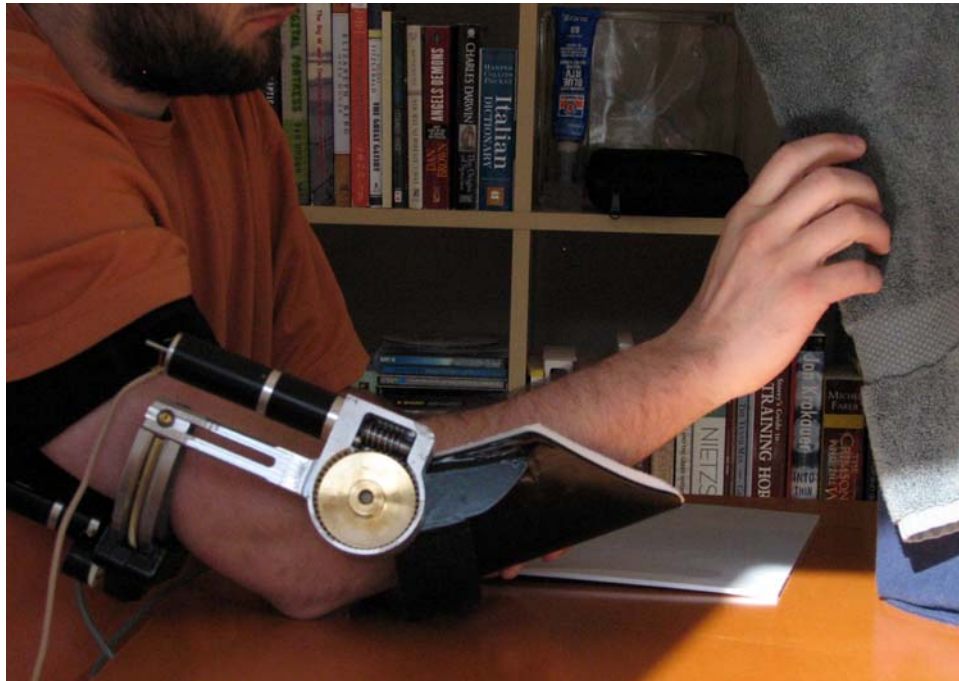
Figure 89: Testing of the Powered Arm Brace
Subject beginning the ADL by removing the washcloth from its stand and placing it in the mock wash basin (white square in background).

To test the device, the two investigators of this project, as well as the spouse of one of the team members used the device to complete the ADL.[1] Based on the results of the three subjects (Table 13 & Table 14), ADL were found to take approximately 2.7 times longer when using the device as when without the powered brace (14.5 seconds wearing the brace, 5.5 seconds without the brace). Additionally, the control of the device was shown to be intuitive, as time to complete ADL decreased by more than 10% on average for the second attempt.

---

[1] Because an IRB or other regulatory board had not reviewed the project, it was decided to only use subjects who could provide willing consent, and who, therefore, understood the risks of wearing an untested powered arm brace.

Table 13: Time for Able-bodied Subject to Complete Sample ADL without Orthosis

	Attempt 1	Attempt 2
Subject 1	5.2	6.3
Subject 2	4.7	4.1
Subject 3	6.2	6.3

Time in seconds to complete ADL of washing the face. Average time is 5.5 seconds.

Table 14: Time for Able-bodied Subject to Complete Sample ADL while Wearing Orthosis

	Attempt 1	Attempt 2
Subject 1	15.1	12.8
Subject 2	12.0	12.3
Subject 3	19.0	16.0

Time in seconds to complete ADL of washing the face while wearing the powered arm brace. The average time of the first attempt is 15.4 seconds, while the average time of the second attempt is 13.7 seconds.

When compared to the results of the proof-of-concept prototype, the latest generation far outperforms the previous design. At the conclusion of their testing, Abramovich, Scarsella and Toddes found that the proof-of-concept prototype could complete a similar task in an average of 18 seconds after acclimation to the device. As previously noted, after acclimation, users were able to complete the ADL in 13.7 seconds, a 24% improvement in performance. This increase was attributed mainly to the simple gearing system and proportional control.

Other User Qualitative Task specifications dealt with the function of the look and feel of the device, as well as wearing the device. While the padding of the powered arm brace prevents pressure sores, the drastic weight reduction will also prevent pressure sores. When compared to the proof-of-concept design, this design is also much easier to both don and doff with the help of an assistant. Additionally, as the orthosis is meant to be donned and doffed while undriven, the Task Specification that it be can be donned and doffed while unpowered is inherently fulfilled. This is because the new design has most of the drive components and frame below the arm, rather than half above and half below

as in the original design. This new design allows the patient's arm to simply be placed into the device rather than threaded through frame. Additionally, because the drive systems are predominantly below the horizontal plane of the arm, and because the elbow drive is more compact, the device is much more aesthetically pleasing.

6.2.2 Design Qualitative Tests

Several Task Specifications also concerned the overall design of the orthosis, but did not directly affect the user. By reviewing these design criteria against the completed powered arm brace, it was possible to judge the fitness of the design. As required, the brace drove two degrees of freedom (DOF) and dampened unintentional movements.

The design was initially reviewed for life expectancy. If the average user used the brace for 4 hours a day, 5 days a week, the patients total use would be 1000 hours a year, or 5000 hours every 5 years. Since the motors were designed to be operated within normal working limits, their life expectancy, based on interviews with Maxon Motor applications engineers, would be in excess of 8000 hours, 60% longer than the required life of the brace. Additionally, because the worm gears were to be used below 50% of their maximum capacity, the worm gears were expected to last more than 5000 working hours. Although manufactured to withstand more than 10,000 hours of use, an exact life expectancy of the bearings was difficult to determine since specified the bearings would be exposed to a wide variety of conditions and contaminants. The bearings, however, could be easily field serviced or replaced during regular check-ups at an OT or PT. Based on the motor selection and gearing selection, it was expected that the device would have a working life in excess of 5 years.

As both a concern for the well-being of a user and the functional robustness of the device, no gears were to be exposed in the final design. In the final design, however, the humeral worm gear is exposed. It was determined, though, that the gear was sufficiently within the Humeral Rail as to prevent damage to the gear, and teeth were sufficiently small to prevent injury to the user. Because worm gears were used for both humeral and elbow rotation, injury to the user was also prevented in the event of a power failure, since the worm gears could only be driven from the worm/motor, and would not backdrive the system.
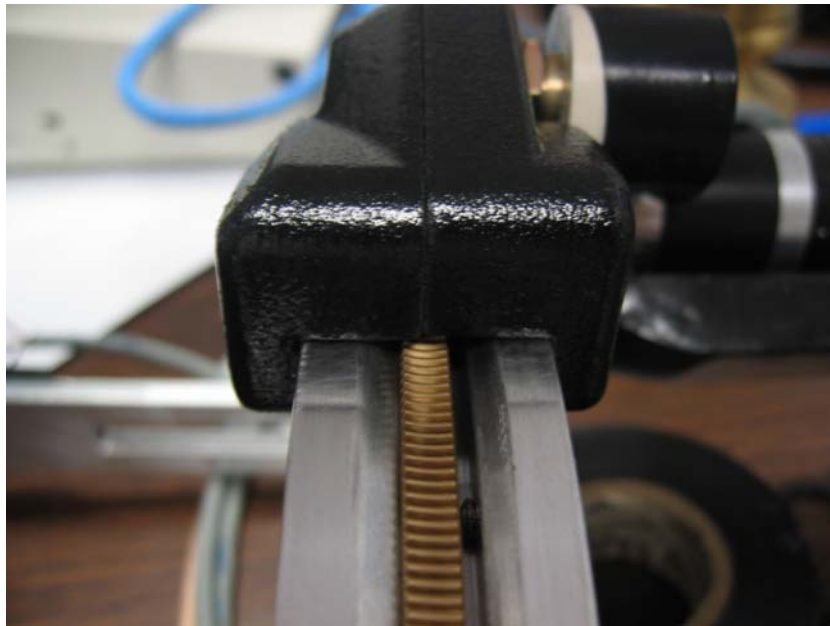
Figure 90: Humeral Worm Gear Inside of the Humeral Rail
Picture of the Humeral Worm Gear secured within the Humeral Rail. The worm gear is partially protected from accidental damage from foreign objects by the sides of the Humeral Rail, and injury to the user is minimized due to the minute size of the worm gear teeth.

As required by the Task Specifications, the eventual growth of the user could be accommodated for by simply unscrewing two tightening screws at either end of the Humeral Rail and extending the Humeral Bars (Figure 91). The bars allowed for 55mm of extension over the life of the device. Although this may not suffice for all users, it will satisfy the growth of most users over a 5-year period. Additionally, the ease of extension

easily allows therapists to use the device with multiple patients. The inclusion of the new humeral bar system is a significant improvement over the previous design, which has no easy method to short the bars, and no method to extend them over time.

The humeral bars are one area where the weight of powered arm brace has been significantly reduced when compared to the proof-of-concept prototype. Each component of the device is significantly lighter than the previous design from the motors to the Forearm Cage. The final, fitted powered arm brace weighs only 2.6lbs, it is nearly 60% lighter than its predecessor.
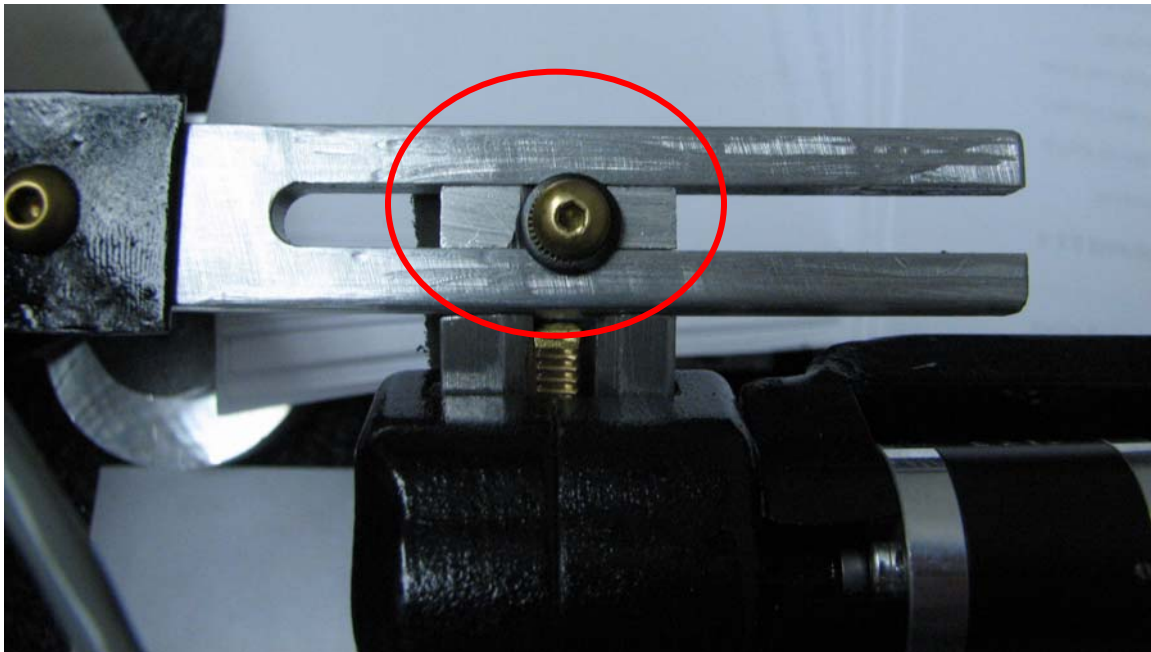
Figure 91: Humeral Bar Length Adjustment
Humeral Bars are shown set to a medium length. To adjust the length, the Humeral Bar screws on both sides (near side shown) are loosened, which allows the Humeral Bars to slide freely along the slots of the Humeral Rail. When the proper length is achieve, the screws are simply retightened.

Finally, as the design was to be moving toward a commercialized and manufacturable product, the principles of Design for Manufacturability and Assembly were followed. The design is constructed of only twenty-two unique parts, and most assembly processes on the device are from a single direction. Additionally, the device can

be built in four sub-assemblies parts: Humeral Drive Assembly, Medial Elbow and Lateral Humeral Bars, and the Forearm Cage. These sub-assemblies were all assembled in a short amount of time during the fabrication of the device. The total cost of the powered arm brace was also much less than the $2500 specification, and could be substantially less by ordering parts in batches rather than as individual items

6.2.3 Quantitative Task Specifications

The Quantitative Task Specifications dealt mostly with the performance of the device outside to performing ADL. To test the device during operation, the device was placed on a testing fixture and several tests of the device were completed under various loading conditions.

Before testing was completed, the device was calibrated to ensure proper feedback of the angle of the device. Using a simple fixture, both Humeral Rotation and Elbow Flexion were set to work within a range of 0-90º (Figure 92). 0º of elbow rotation was defined as the arm extended fully, and 0º of humeral rotation was defined as the rotation of the bent forearm toward the body, lengthwise, shoulder to shoulder (Figure 93). For both elbow and humeral rotation, the forearm was moving from a plane perpendicular to gravity to an axis inline with gravity. In this way, rotation from 0-90º resulted in the same load on the brace, whether as humeral or elbow rotation (rotating the hand to the cranial caudal axis); the torque on the brace of 60º of elbow rotation is the same as 60º of humeral rotation.

Figure 92: Model Fixed to for Calibration

Before testing could begin, the orthosis was calibrated to ensure accurate monitoring of the arm's angular position. To calibrate the orthosis, data points were taken at 15º intervals along both elbow and humeral rotation. A simple inclinometer was used to measure the angle of the Forearm Cage, relative to the horizontal plane.
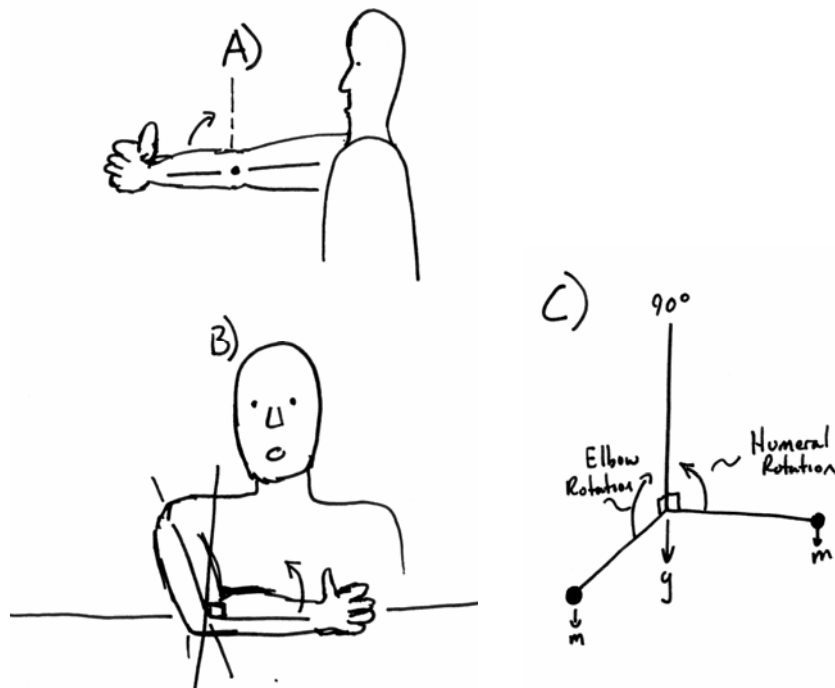
Figure 93: 0 Degrees of Elbow and Humeral Rotation (previously shown as Figure 36)

Elbow rotation at 0º (A) and humeral rotation at 0º (B). A basic sketch of rotation about a common elbow, showing elbow rotation and humeral rotation is also shown (C). Arrows indicate positive direction of rotation.

Each DOF of the arm orthosis was then tested independently. The orthosis was initially tested without any weight in the hand as a benchmark of performance. For this test the device was driven from a resting position of 0º at maximum speed through 90º in both humeral and elbow rotation

The device was then retested while being worn on the arm. Using the same testing procedures, three functionality tests were completed with the users arm: Lifting only the arm, lifting the arm with .75 kg in the hand, and lifting the arm with 1.5kg in the hand. The results of these tests are shown in Figure 94 and Figure 95.
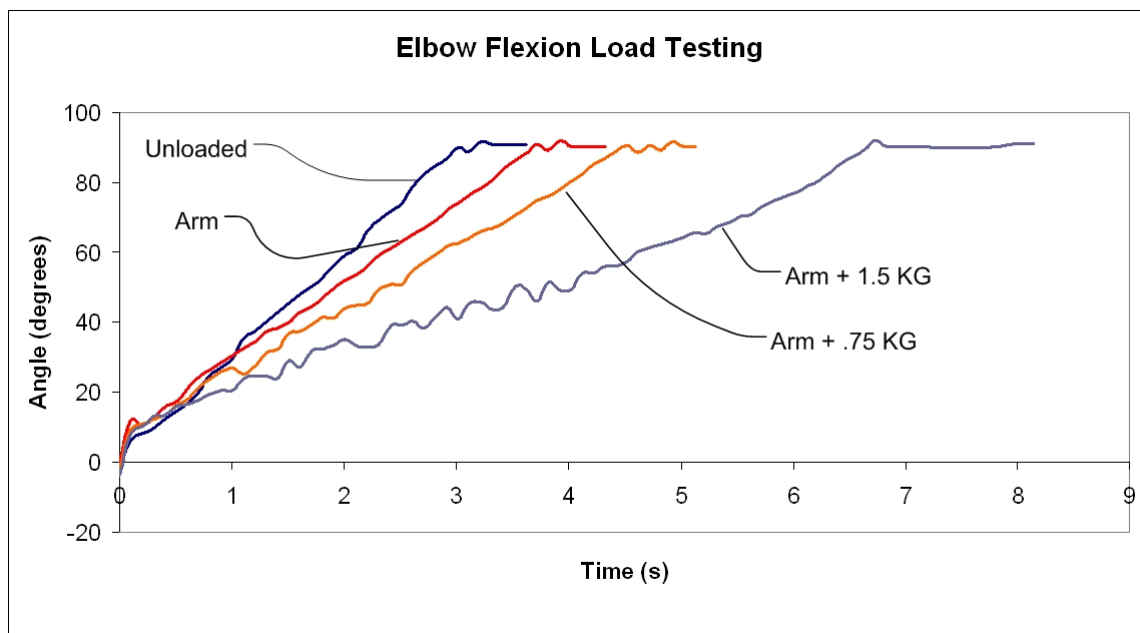
Figure 94: Elbow Rotation as shown by Absolute Position vs Time
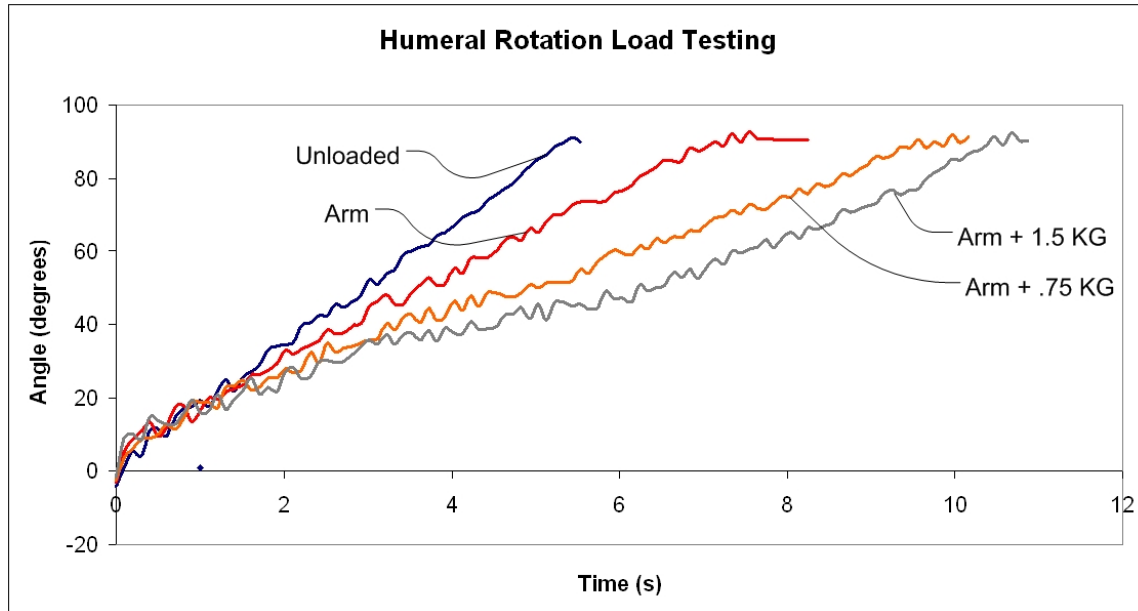
Figure 95: Humeral Rotation as shown by Absolute Position vs Time

From the figures, it is clear that additional weight drastically decreases the angular velocity of the orthosis. From these charts, it is also clear that the elbow rotation consistently operates at a higher angular velocity than the humeral rotation although the estimated velocity of the elbow DOF (as shown in Figure 81 and Figure 83) was expected to be slower than the humeral rotation.

Upon further review of the orthosis, it was found that the Humeral Housings were slightly warped, which led to misalignment of the worm and worm gear mating. This misalignment would greatly increase gear loss, which would have multiplicative effect on the torque at the humeral motor. Unfortunately, this effect would not only decrease the angular velocity of the humeral rotation, but it could also lead to premature motor wear. Although the humeral drive did not function to its full potential, it was still found to be suitable for completing ADL (*6.2.1 User Qualitative* Tests).

158

The Elbow Drive was also slower than expected, although not nearly as drastic as the Humeral Drive. It was determined that this was due to both the internal resistance to movement in the arm, as well as possibly higher than expected losses in the gearing. Even with these losses, however, the Elbow Drive was considered acceptable for completing ADL.

6.3 Project Success

This project successfully constructed a functional powered arm brace (Figure 96). Although slight problems were found during testing, the design was shown to be sound, functional, and within design specifications. Additionally, the design was easy to manufacture and produce, and it was shown that the design could be scaled to a commercialized product. Additionally, contacts with part suppliers and manufactures, as well as custom design facilities were formed, which would aid in the manufacturing of the orthosis.
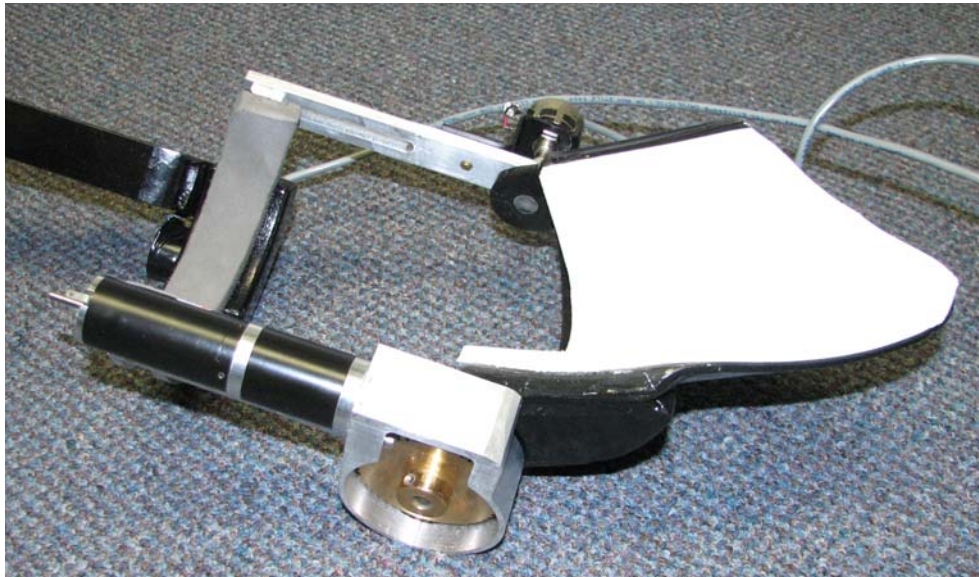
Figure 96: Manufactured and Assembled Powered Arm Brace

One major barrier to market entry of the original proof-of-concept prototype was size and weight of the orthosis. The new orthosis was shown to have increased functionality and lifting power, while reducing the weight of the device by nearly 60%, moving the power and controls to a portable platform, and reducing the size of the device when worn on the arm. The new device, unlike the previous design, can now be worn under loose clothing (Figure 97).

Figure 97: The Orthosis Concealed under Loose Clothing

6.4 Future Work

Although successful, additional tasks remain before the powered arm brace can become a commercialized product. Primarily a shoulder mount for the device needs to be designed and integrated into the orthosis. A shoulder mount would allow non-seated

patients to comfortably use the device and would also further reduce any pressure sores from the weight of the orthosis on the user's arm.

Additionally, a prototype with the appropriate plastic cast parts (Humeral Housings, Elbow Housing, and Forearm Cage) should be fabricated and additional testing completed to ensure the design meets expectations. Because a cast part will hold tighter tolerances than either a SLA part or refixtured machined part, it is expected that the functionality of the orthosis will improve. Rather that casting a single device, several powered braces should be built and tested beyond the laboratory environment, in clinical settings under the supervision of IRB. This *real world* testing with patients suffering from neuromuscular diseases would provide invaluable feedback about the device concerning all facets of the orthosis from functionality to comfort and aesthetics. Based on the conclusions reached by the users, therapists and designers, the device should be redesigned and beta tested for FDA approval.

Although specific parts and dimensions of the orthosis will undoubtedly change during a future iteration, the current design's methodology has provided a working prototype of an optimized powered arm brace, which has successfully met all task specifications and design requirements.

7.0 Conclusions

The goal of this project was to move beyond the previously designed proof-of-concept prototype to a more functional design, with the potential to be commercialized. Although the early device proved basic functionality of the design, the primary issues of concern of the original prototype were the weight of the device, cost and time to fabricate, durability, exposed gearing, and poor aesthetic appearance.

The heavy weight of the original prototype not only affected the performance of the device, but it also placed undue pressure on the elbow and shoulder. For a clientele with already degraded muscle mass, this extra stress posed serious health risk. To reduce the mass of the device, special attention was given to the materials selected for the components. Additionally, with the help of CAD FEA, the volume of the components were reduced will maintaining or exceeding a minimum safety factor (SF) of 2.0. To further reduce the mass of the device, new motors of minimal size and mass were selected based on tight, predefined requirements of power, torque and speed. The conjoining of these distinct design methodologies helped to reduce the weight of the new generation orthosis by over 57%, while maintaining the rigidity and functionality of the previous design.

Just as FEA was useful in determining the proper shape and size of components, Design for Manufacturability and Assembly (DFMA) was used to specify what components were most appropriate for use in the powered arm brace, and how those parts should be configured. Though the original proof-of-concept design was constructed for less than $400 in additional materials, most of the most costly components (pair of motors: $500, aluminum: $150, gearing: $200), were donated or salvaged from earlier

designs. This cost, too, did not include the weeks of time spent fabricating the numerous custom parts. The cost to manufacture and distribute the previous orthosis would, clearly, be prohibitive to the success of the product. By using DFMA in the part selection, and component layout of the device, a new orthosis was designed that had only 22 unique parts (not including fasteners), 10 of which were custom parts. Furthermore, the custom parts were designed to maximize castability or machinability in accordance with the process dictated to minimize the cost of these parts. After formally discussing the parts with vendors, a final manufacturing cost of $1640 was estimated, although based on quantity discounts, this price could decrease as much as 20% or ~$1310 per orthosis. Not factoring the drastic savings in assembly time from the early orthosis to the current version, the final manufactured, ready to assembly parts of the orthosis are only marginally more expensive than the sum of raw purchased materials for the previous design: $1310 (new) vs. +$1250 (old).

While both of cost and weight of the device would have prevented the commercial success of the proof-of-concept design, the exposed gearing and low durability of the device would have prevented the acceptance of the orthosis by the FDA as a cleared medical device. Much of the gearing in the previous prototype was unshielded and created several pinch points, which could grab both clothing and skin. The open design of the gearing also created numerous entry points for dirt or fluids to disrupt the function of the device, or deformation to occur, which would ultimately reduce the performance of the device. In the new generation orthosis, all of the gearing, except the humeral worm gear, has now been encased in protective housings. The

humeral worm gear, the only exposed part, has been shielded within a more robust sliding rail, and intentionally designed to minimize the risk of pinching or snagging.

As the nature of any first prototype, the appearance of the original proof-of-concept design was rough. The inherent appearance of the device, however, was often described as "robotic" or "heavy-duty." While these terms might be flattering in regards to machinery or construction equipment, these comments highlighted the prototypes inherent rigid, highly mechanical look, and not the active assisting nature of the product. With the goal to make the orthosis as unobtrusive and unnoticeable as possible, the device was designed with minimal hard lines, and structure that mimicked the outer contours of the arm. Additionally, by amending the previously discussed shortcomings of the previous design, many of the causes of the mechanical "look" were eliminated. The final aesthetic of the device is far from the original design; the new design (in private viewings), has been called both sleek and slick, alluding to the minimalist look of the design.

Based on the conclusions reached after functional testing and critiquing of the device compared to defined task specifications, the new orthosis has either met or exceeded design expectations. The current device is functional, easily manufacturable, durable and aesthetically pleasing. What has been designed is a commercially viable product, with potential to serve the over 18 million Americans suffering from debilitating neuromuscular disease, increasing their quality of life through functional independence.

8.0 Bibliography

[1] Stanger, et.al. *Demographics of rehabilitation robotics users*, Technology and Disability, Vol. 5, No. 2, September 1996, pp 125-137.

[2] Muscular Dystrophy Association. August 6, 2006.<www.MDA.org>

[3] Rheumatology.org, 2004.

[4] Muscular Dystrophy Association. *Diseases.* August 7, 2006.<www.MDA.org/disease/>

[5] Wheaton Resource Corp, "*Arthrogryposis*". orthoseek.com/articles/arthrogryposis.html Visit: September 19, 2005.

[6] Hall, Judith G. "*Arthrogryposis.*" American Family Physician. January, 1989.

[7] National Multiple Sclerosis Society, "*Who Gets MS?*" nationalmssociety.org Visit: Sept. 26, 2005

[8] Harwin WS, Rahman T, Foulds RA *A. Review of Design Issues in Rehabilitation Robotics with Reference to North American Research.* IEEE Transactions on Rehabilitation Engineering, Vol. 3, No. 1, March 1995.

[9] Dallaway JL, Jackson RD, Timmers PHA. *Rehabilitation Robotics in Europe*. IEEE Transactions on Rehabilitation Engineering. 3. pp. 35-45.

[10] Prange GB, et.al. *Systematic Review of the Effect of Robot-Aided therapy on Recovery of the Hemiparetic Arm After Stroke*. Journal of Rehabilitation Research & Development, Vol 43, No.2, pp. 171-184.

[11] Nerf T, Riener R, (2005) *ARMin – Design of a Novel Arm Rehabilitation Robot*. Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics June 28-July 1, 2005, Chicago, IL, USA.

[12] Broderick J, et.al. *The Greater Cincinnati/Northern Kentucky Stroke Study: Preliminary First-Ever and Total Incidence Rates of Stroke Among Blacks*, Stroke, Vol 29, pp 415-421.

[13] American Stroke Association *Heart Disease and Stroke Statistics – 2005 Update* AHA, 2005. April 16, 2006. <www.americanheart.org>

[14] Fasoli et.al. *Robotic therapy for chronic motor impairments after stroke: follow-up results*. Archives of Physical and Medical Rehabilitation, Vol 85 No.7 pp 1106-1111.

[15] Stanger, et.al. *Demographics of rehabilitation robotics users*, Technology and Disability, Vol. 5, No. 2, September 1996, pp 125-137.

[16] Kibler WB, et al. *Functional Rehabilitation of Sports and Musculoskeletal Injuries*. Gaithersburg: Aspen Publishers; 1998. pp.181.

[17] Roy S, Irvin R. *Sports Medicine: Prevention, Evaluation, Management, and Rehabilitation*. Englewood Cliffs: Prentice-Hall; 1983. pp. 224.

[18] U.S. Department of Labor. Occupational Therapists. March 27, 2007. <www.bls.gov/oco/ocos078.htm>

[19] Kolb, Bryan, Brain Plasticity and Behavior. Lawrence Erlbaum Associates, Inc. Hillsdale, NJ, 1995.

[20] Kennard, M.A. *Reorganization of Motor Function in the Cerebral Cortex of Monkeys Deprived of Motor and Premotor Areas in Infancy,* Journal of Neurophysiology, Vol. 1, pp. 477-496.

[21] Taub ,E., Uswatte, G., Pidikiti, R.D. *Constraint-Induced Movement Therapy. A New Family of Techniques with Broad Application to Physical Rehabilitation - A Clinical Review,* Journal of Rehabilitation Research & Development Vol.36 No.3, 1999. pp.237–251.

[22] Cramer, S. C., Moore, C. I., Finklestein, S. P., Rosen, B. R. *A Pilot Study of Somatotopic Mapping After Cortical Infarct*. Stroke Vol. 31, 2000. pp. 668-671

[23] Liepert, J. Bauder, H., Miltner, W. H. R., Taub, E., Weiller, C. *Treatment-Induced Cortical Reorganization After Stroke in Humans*, 2000. Stroke Vol. 31 pp. 1210-1216

[24] Liepert J, et.al. *Motor Cortex Plasticity During Constraint-Induced Movement Theraphy in Stroke Patients*, Neuroscience Letters, Vol. 250, pp. 5-8

[25] Prange GB, et.al. *Systematic Review of the Effect of Robot-Aided therapy on Recovery of the Hemiparetic Arm After Stroke*. Journal of Rehabilitation Research & Development, Vol 43, No.2, pp. 171-184.

[26] Hidler J, Nichols D, Pelliccio M, Brady K. *Advances in the Understanding and Treatment of Stroke Impairment Using Robotic Devices*, Topics in Stroke Rehabilitation, pp.22-35. 2005.

[27] Worland R, et.al. *Home continuous passive motion machine versus professional physical therapy following total knee replacement*. The Journal of Arthroplasty Vol. 13, No. 7, 2004. pp. 784-787.

[28] Hogan, N. and H.I. Krebs. *Interactive Robots for Neuro-Rehabilitation*. Restorative Neurology and Neuroscience Vol 20 pp1-10 RNN277, IOS Press, 2004.

[29] Hermano Igo Krebs, et al. *Robot-Aided Neurorehabilitation*. IEEE Transactions on Rehabilitation Engineering, Vol. 6, No. 1, March 1998.

[30] Lum P, et al. *Quantification of Force Abnormalities During Passive and Active-Assisted Upper-Limb Reaching Movements Post-Stroke Hemiparesis.* IEEE Transactions on Biomedical Engineering, Vol. 46, No. 6, June 1999.

[31] Hawkins P, et al. *GENTLE/S Project: Design and Ergonomics of a Stroke Rehabilitation System.* Proceedings of 1st Cambridge Workshop on Universal Access and Assistive Technology (CWUAAT), University of Cambridge, Cambridge, UK, March 25 - 27. (2002).

[32] Nerf T, Riener R. *ARMin – Design of a Novel Arm Rehabilitation Robot*. Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics June 28-July 1, 2005, Chicago, IL, USA. 2005.

[33] He J, et al. *RUPERT: A Device for Robotic Upper Extremity Repetitive Therapy*. Proceedings of the 2005 IEEE Engineering in Medicine and Biology. Sept. 2005.

[34] Johnson L, Winters J. *Evaluation of Tracking Performance Using Manipulators that Engage Different Arm Workspaces*. Proceedings of the 2005 IEEE Conference on Rehabilitation Robotics. 2005.

[35] Nagai K, et al. (1998) *Development of an 8 DOF Robotic Orthosis for Assisting Human Upper Limb Motion*. Proceedings of the 2005 IEEE Conference on Robotics and Automation. May 1998.

[36] Hay JG, Reid JG. *The Anatomical and Mechanical Bases of Human Motion*. Prentice-Hall, Inc., Englewood Cliffs, New Jersey, 1982.

[37] Magermans DJ et.al,. *Requirements for Upper Extremity Motions During Activities of Daily Living*, Clinical Biomechanics, Vol 20. pp. 591-599. 2005.

[38] Kroemer, K. H. E., Kroemer, H. J., and Kroemer-Elbert, K. E. *Engineering Physiology: Bases of Human Factors/Ergonomics* (3rd ed.). New York, NY: Van Nostrand Reinhold - Wiley. 1997.

[39] Dempster, WT. *Space Requirements of the Seated Operator, Geometrical, Kinematic and Mechanical Aspects of the Body with Special Reference to the Limbs*. Michigan State Univ. Publishing, East Lansing, MI July, 1955

[40] Chaffin DB, Gunnar BJ, Martin BJ, Occupational Biomechanics. John Wiley & Sons, Inc. New York, NY 1999.

[41] Rehabilitation Institute of Chicago, May 2006.<http://www.ric.org/>

[42] O'Reilly Network, Introduction to Pulse-Width Modulation. July 2003

<www.oreillynet.com/pub/a/network/synd/2003/07/02/pwm.html>

[43] Merriam-Webster Dictionary. "Engineering." March 2, 2007. <http://www.m-w.com>

[44] Human forearm and hand properties from
http://www.motco.dir.bg/Data/MassInertial.html

[45] Bralla, James G. *Design for Manufacturability*. 2nd ed. McGraw-Hill, New York. 1998.

[46]Beer, Ferdinand P., Johnston, E. Russell Jr. <u>Mechanics of Materials</u>. New York: McGraw-Hill, Inc., 1981.

[47] Interview with Sam Hart of Polymer Corporation. Jan 25,2006. Polymer Corporation, Rockland, MA.

[48] Hapco. March 05, 2207. www.hapcoweb.com

[49] American Gear Manufactures Association. "Worm Gear Selection and Design." Jan. 18, 2007. <http://www.agma.org//AM/Template.cfm?Section=Home>

[50] *Machinery's Handbook.* "Screw Thread Systems." 27ed. Industrial Press, New York. 2004.

[51] *Machinery's Handbook.* "Pinning Systems." 27ed. Industrial Press, New York. 2004. pp. 1686-1688.

Appendix A: Patents

Orthosis Device

United States Patent   6,821,259

Rahman , et al.   November 23, 2004

Orthosis device

Abstract

An orthosis device generally includes two limb sections pivotably attached to each other in at least one degree of freedom and adapted for insertion of or attachment to adjacent portions of a limb of a user. Each limb section further includes a four-bar linkage and a spring member adapted to provide an equilibrium-inducing force corresponding to a combined weight of the limb section and the limb inserted therein or attached thereto. The equilibrium-inducing force allows every point in three-dimensional space to be a balanced position, such that a user with muscular abnormalities can move his or her limbs and hold them in place. A pivotable shoulder bracket for attaching the orthosis device to a wheelchair may also be provided. Furthermore, the orthosis device can be adapted to accommodate individuals of varying weight or with varying levels of disability by adjusting the spring member or providing powered actuators and force sensors.

Inventors: Rahman; Tariq (Wilmington, DE), Sample; Whitney (Wilmington, DE)

Assignee: The Nemours Foundation (Wilmington, DE)

Appl. No.: 10/024,133

Filed: December 21, 2001

Current U.S. Class: 601/24 ; 601/33; 602/20

Current International Class: A61F 5/01 (20060101); A61G 5/00 (20060101);
                                       A61G 5/12 (20060101); A61H 001/00 ()

Field of Search: 602/20,19,16,6 601/33,24,23,26
                                       482/67,100,124,131,139

References Cited [Referenced By]

U.S. Patent Documents

4651719	March 1987	Funk et al.
4975016	December 1990	Pellenc et al.
5020790	June 1991	Beard et al.
5417643	May 1995	Taylor
5466213	November 1995	Hogan et al.
6565493	May 2003	Geh

Other References

Transaction of the ASME, Journal of Mechanical Design, vol. 117, Dec. 1995, pp. 655-658, "A Simple Technique to Passively Gravity-Balance Articulated Mechanisms". Tariq Rahman et al.* .
Journal of Rehabilitation Research and Development vol. 37 No. 6, Nov./Dec. 2000 pp. 675-680, "A body-powered functional upper limb orthosis" Tariq Rahman et al. .
Transactions of the ASME, Journal of Mechanical Design, "A Simple Technique to Passively Gravity-Balance Articulated Mechanisms" Tariq Rahman et al, pp. 655-658, vol. 117, Dec. 1995..

Primary Examiner: Lucchesi; Nicholas D.
Assistant Examiner: Pham; Huong Q.
Attorney, Agent or Firm: McGuire Woods LLP

Parent Case Text

This application claims priority under 35 U.S.C. .sctn..sctn. 119(e) and 120 of U.S. Provisional Patent Application Ser. No. 60/308,109, filed Jul. 30, 2001, the content of which is hereby incorporated by reference.

Claims

What is claimed is:

1. An orthosis device for providing a gravity-balanced equilibrium for a limb of a user, said orthosis device comprising: a first limb section and a second limb section, said first and second limb sections being pivotably connected in at least one degree of freedom; said first and second limb sections each further comprising: a first link and a second link, said first and second links being substantially parallel to each other; a third link and a fourth link, said third and fourth links being substantially parallel to each other and pivotably connecting corresponding opposing ends of said first and second links to thereby define a four-bar linkage; a first mounting mechanism attached to said first link and a second mounting mechanism attached to said second link, said first and second mounting mechanisms being offset from each other along a length of respective said first and second limb sections; and a spring member attaching between said first and second mounting mechanisms and being adapted to provide an equilibrium-inducing force corresponding to a combined weight of said limb section and the limb of the user.

2. The orthosis device according to claim 1, wherein said first mounting mechanism is provided on a carriage attached to said first link, a position of said carriage on said first link being adjustable along a length of said first link.

3. The orthosis device according to claim 2, wherein the position of said carriage on said first link is adjusted via a lead screw provided on said first link.

4. The orthosis device according to claim 2, wherein the position of said carriage on said first link is adjusted to pre-stress said spring member by an amount corresponding to the weight of the limb of the user.

5. The orthosis device according to claim 1, wherein said first and second mounting mechanisms each further comprise a pair of mounting posts, said mounting posts being disposed along a length of said first or second link and separated by a predetermined distance.

6. The orthosis device according to claim 5, wherein said distance is predetermined based on a spring stiffness of said spring member.

7. The orthosis device according to claim 5, wherein said spring member is comprised of an elastic cord stretched between said mounting posts of said first and second offset mounting mechanisms.

8. The orthosis device according to claim 1, wherein said first and second limb sections are pivotably connected in two degrees of freedom via an elbow joint.

9. The orthosis device according to claim 1, further comprising a shoulder bracket attached at an attached end to a proximal end of said first limb section and adapted at a

free end for attachment to a chair.

10. The orthosis device according to claim 9, wherein said shoulder bracket is comprised of at least two links pivotably connected to each other.

11. The orthosis device according to claim 10, wherein said shoulder bracket is comprised of four links pivotably connected to each other.

12. The orthosis device according to claim 1, further comprising powered actuators and force sensors.

13. An assistive medical system, comprising: a wheelchair; and an orthosis device for providing a gravity-balanced equilibrium for the limb of the user, said orthosis device comprising: a first limb section and a second limb section pivotably connected to said first limb section; said first and second limb sections each further comprising: a first link and a second link, said first and second links being substantially parallel to each other; a third link and a fourth link, said third and fourth links being substantially parallel to each other and pivotably connecting corresponding opposing ends of said first and second links to thereby define a four-bar linkage; a first mounting mechanism and a second mounting mechanism attached to respective said first and second limb sections, a position of at least one of said first and second mounting mechanisms being adjustable to pre-stress said spring member; a spring member attached between said first and second mounting mechanisms and adapted to provide an equilibrium-inducing force corresponding to a combined weight of said limb section and the limb of the user; and a shoulder bracket attached to a proximal end of said orthosis device at a first end and attached to said wheelchair at a second end.

14. The assistive medical system according to claim 13, wherein said shoulder bracket is comprised of at least two links pivotably connected to each other.

15. The assistive medical system according to claim 14, wherein said shoulder bracket is comprised of four links pivotably connected to each other.

16. The assistive medical system according to claim 13, further comprising a mounting bracket attached to said wheelchair.

17. The assistive medical system according to claim 16, wherein said shoulder bracket attaches to said wheelchair via said mounting bracket.

18. The assistive medical system according to claim 13, wherein said first and second mounting mechanisms are attached to said first and second links, respectively, and are offset from each other along a length of said limb section.

19. The assistive medical system according to claim 13, wherein said orthosis device further comprises powered actuators and force sensors.

20. An orthosis device for use in an assistive medical system, said orthosis device comprising: a first limb section and a second limb section, said first and second limb sections being pivotably connected in two degrees of freedom via an elbow joint; said first and second limb sections each further comprising: a first link and a second link, said first and second links being substantially parallel to each other; a third link and a fourth link, said third and fourth links being substantially parallel to each other and pivotably connecting corresponding opposing ends of said first and second links to thereby define a four-bar linkage; a first mounting mechanism attached to said first link and a second mounting mechanism attached to said second link, said first and second mounting mechanisms being offset from each other along a length of respective said first and second limb sections; a spring member attached between said first and second mounting mechanisms and adapted to provide an equilibrium-inducing force corresponding to a combined weight of said limb section and a limb of a user; and a shoulder bracket attached at an attached end to a proximal end of said first limb section and adapted at a free end for attachment to a chair.

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to assistive medical devices. More particularly, the present invention relates to a device for assisting and augmenting the movements of a person with neuromuscular abnormalities or weakness.

2. Background Description

Individuals with neuromuscular abnormalities, such as anterior horn cell disease or muscular disorders (e.g., Muscular Dystrophy), often lose the ability to place their limbs in space due to the weakening of their proximal muscles. Typically, the muscles of these individuals become so weak that they cannot support their arms against gravity, thereby making it difficult to perform routine tasks such as eating.

An orthosis is an exoskeletal device that is attached to flail or weakened limbs to augment strength deficiency. Articulated upper limb orthoses, ranging from the mobile arm support to electrically powered wrist-hand orthoses, have been investigated for a number of years.

Among the earliest and most accepted devices is the Balanced Forearm Orthosis ("BFO"), also called the mobile arm support. The BFO, a passive (e.g., body-powered) device was developed in 1965, and provides people with weak musculature the ability to move their arms in a horizontal plane. Two linkages having joints along the vertical axes

accomplish this task. One end of the BFO is attached to a wheelchair, while the other end is connected to a trough into which a person places his or her forearm. The trough uses a fulcrum at mid-forearm that permits the hand to elevate if the shoulder is depressed. The BFO allows a person to move horizontally, for example, over a lap tray, and to use compensatory movements to attain limited movement in the vertical direction.

An enhanced version of the BFO allows vertical movement by providing a horizontal joint at the base. Attaching rubber bands to the joint compensates for the weight of the arm. Due to the inexact gravity compensation that results, this device is rarely prescribed. The majority of BFO users settle for planar movement and rely on compensatory body movements to achieve vertical motions.

Various forms of overhead slings that allow for movement in three dimensions have also been used to assist arms with proximal weakness. These devices, in addition to being aesthetically unappealing, are prone to oscillations when the arm is moved. One such overhead device is the Musgrave orthosis, which uses a weight at the back of a wheelchair to counterbalance the arm.

The first computerized orthosis was developed at the Case Institute of Technology in the early 1960s. The manipulator was configured as a floor mounted, four degree-of-freedom, externally powered exoskeleton. Control of this manipulator was achieved using a head-mounted light source to trigger light sensors in the environment.

Rancho Los Amigos Hospital continued the Case orthosis and developed a six degree-of-freedom, electrically driven "Golden Arm." The Rancho "Golden Arm" had a configuration similar to the Case arm, but was without computer control. It was significant, however, in that it was mounted on a wheelchair and was found to be useful by people who had disabilities with intact sensation resulting from polio or multiple sclerosis. The Rancho "Golden Arm" was controlled at the joint level by seven tongue-operated switches, which made operation very tedious. The "Golden Arm" was subsequently modified to add computer control and input from eye trackers.

In 1975, the Burke Rehabilitation Center modified the BFO by adding actuators. Direct current motors powered the Burke orthosis, with five degrees-of-freedom, including pronation/supination and elbow flexion/extension. However, control was maintained through use of a joystick, control pad, or various microswitch assemblies, making it a less-than-ideal interface.

Examples of other orthoses that have not gone beyond the prototype stage include the hybrid arm orthosis, which was externally powered and controlled by a combination of contralateral shoulder movement and air switches operated by the head, and the powered orthotic device for the enhancement of upper limb movement. This latter project was conducted at The Hugh Macmillan Rehabilitation Center and targeted people with amyotrophic lateral sclerosis. This mechanism allowed three degrees-of-freedom, used external power, and was controlled by signals from the eyebrows.

While the existing orthosis devices have advanced the state of the knowledge in design of orthoses that interact with humans with disabilities, the technology has yet to make a significant impact on the lives of people with disabilities. This is in large part due to the complex control requirements of the devices and the prohibitive cost of powered devices.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an orthosis device with a natural human-machine interface.

Another object of the present invention is to provide a fully functional yet cost-efficient orthosis device.

Yet another object of the present invention is to provide a gravity-balanced sense of "floatation" that will allow a person with neuromuscular weakness to move his or her limbs with minimal effort.

Still another object of the present invention is to provide an orthosis device adaptable to a range of user weights and disabilities.

The present invention is an orthosis device for providing a gravity-balanced equilibrium for a limb of a user. The orthosis device generally includes two limb sections that are pivotally connected in at least one, and preferably two, degrees of freedom. Each of the two limb sections comprises a four-bar linkage and a spring member adapted to provide an equilibrium-inducing force corresponding to a combined weight of the limb section and the user's limb attached thereto. The equilibrium-inducing force allows every position in three-dimensional space to be a balanced position, such that minimal effort is required to move the limb or hold it in place.

Two mounting mechanisms attached to each limb section are used to attach the spring member. At least one of the mounting mechanisms may be adjustable to pre-stress the spring member, allowing a single embodiment of the orthosis device to be used for individuals of a range of weights. Furthermore, individuals with varying degrees of muscular degeneration can be accommodated by including force sensors and power actuators.

The orthosis device, in embodiments, includes a shoulder bracket for mounting the orthosis device on a wheelchair. The shoulder bracket includes several pivotally connected links, which adds additional degrees of freedom to the orthosis device. Thus, the orthosis device according to the present invention allows for anatomical movement in essentially four degrees of freedom: two at the elbow and two at the shoulder.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a is a schematic diagram illustrating the gravity-balancing principle utilized by the present invention;

FIG. 1b is a diagram of the geometry of the structure shown in FIG. 1a;

FIG. 2 is perspective view of the orthosis device with limb section covers;

FIG. 3 is a perspective view of the orthosis device with the limb section covers removed;

FIG. 4 is a perspective view of the orthosis device with shoulder bracket;

FIG. 5 is a perspective view of the attached end link of the shoulder bracket;

FIG. 6 is a perspective view of the free end link of the shoulder bracket;

FIG. 7 is a perspective view of an interior shoulder bracket link;

FIG. 8 illustrates the assistive medical system of the present invention;

FIG. 9 is a schematic diagram of a limb section illustrating the selection of the dimensions for constructing and adjusting the orthosis device; and

FIG. 10 is a graph illustrating the selection of the spring stiffness k of the spring member.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

Referring now to the Figures and more particularly to FIGS. 1a and 1b, there is shown a schematic diagram illustrating the gravity-balancing principle utilized by the present invention. FIG. 1a illustrates a rigid link 2 pinned at axis "O" and held by a linear spring 4 at position "V," which is attached to a vertical wall 6 at position "W." Link 2 has a length 2l and mass m, while spring 4 has a spring constant k. For the system to be in equilibrium, M.sub.O, the moment about "O," must be 0. From FIG. 1b, it can be seen that

For .theta..noteq.0, this reduces to ##EQU1##

If x.sub.0 =0, the equation further reduces to

Equation (1) shows that the stiffness k becomes a constant independent of the angle .theta. of link 2. This is achievable only if the unstretched length x.sub.0 of spring 4 is chosen to be 0. This condition may be physically realized if spring 4 is placed outside the line V-W. Therefore, by choosing a spring 4 of stiffness k according to Equation (1), and placing spring 4 outside of the line V-W connecting link 2 and wall 6, link 2 can be perfectly balanced for all angles .theta. from 0.degree. to 180.degree..

Though FIGS. 1a and 1b illustrate gravity-balancing of a single link only, one skilled in the art will understand how to extend the one-link solution above to arrive at the

generalized solution ##EQU2##

for n links connected in series, where 1.ltoreq.t.ltoreq.n. One skilled in the art will also recognize that each link comprises a four-bar mechanism to ensure that vertical members exist at the end of each link.

Turning now to FIG. 2, there is shown an orthosis device 10 according to the present invention. Orthosis device 10 generally includes a first limb section 12 and a second limb section 14 adapted to fit adjacent portions of a limb of a user. For example, in a preferred embodiment of the invention herein described, first limb section 12 is adapted to fit a user's upper arm, while second limb section 14 is adapted to fit the user's forearm. However, first and second limb sections 12 and 14 may be adapted to fit other limbs (e.g., upper and lower legs) within the spirit of the invention. First and second limb sections 12 and 14 are pivotally connected in at least one degree of freedom, and are preferably pivotally connected in two degrees of freedom via elbow joint 16, which is generally aligned with the anatomical elbow. Elbow joint 16 can be any well known hinge mechanism, and provides orthosis device 10 with rotation about a vertical axis at a point generally corresponding to the anatomical elbow. Second limb section 14 is also fitted with a trough (not shown) that the user places his or her forearm into, though other methods of attaching orthosis device 10 to the user are contemplated (e.g., strapping it directly to the limb via a belt-buckle type arrangement).

FIG. 3 shows orthosis device 10 with covers removed in order to better illustrate the similar inner structures of first and second limb sections 12 and 14. Each section includes a first link 18, a second link 20, a third link 22, and a fourth link 24. First and second links 18 and 20 are substantially parallel to each other, as are third and fourth links 22 and 24. Third and fourth links 22 and 24 pivotally connect corresponding opposing ends of first and second links 18 and 20 by any well known hinge mechanism, thereby defining a four-bar linkage in each of first and second limb sections 12 and 14. One skilled in the art will be familiar with a four-bar linkage and the kinematics thereof.

First and second limb sections 12 and 14 further include a first mounting mechanism 26, a second mounting mechanism 28, and a spring member 30 having a spring constant k. First and second mounting mechanisms 26 and 28 are adapted for attachment of spring member 30 thereto, preferably via a pair of mounting posts 32 separated from each other by a distance determined based upon the spring stiffness k of spring member 30. Spring member 30 may be an elastic cord (e.g., a bungee cord) stretched between mounting posts 32 of the mounting mechanisms 26 and 28, or another type of spring (e.g., a coil spring). The elastic cord embodiment is preferred, however, because of the ability of an elastic cord to stretch over a post (e.g., mounting posts 32) and the superior elastic properties thereof (e.g., an elastic cord will stretch more than a coil spring with lower initial force requirements). Spring member 30 is selected to provide an equilibrium-inducing force corresponding to a combined weight of limb section 12 or 14 and the limb therein, as will be described below.

In one preferred embodiment of the invention, first and second mounting mechanisms 26

and 28 are mounted on first and second links 18 and 20, respectively, such that they are offset from each other along a length of the limb section 12 or 14. Additionally, the position of first mounting mechanism 26 is adjustable along the length of link 18. This is preferably accomplished by providing first mounting mechanism 26 on a carriage 34 attached to first link 18, the position of which is controlled via a lead screw 35 or other mechanism provided on first link 18. By adjusting the position of carriage 34 along link 18, spring member 30 can be pre-stressed by an amount corresponding to the weight of the limb of the user, thereby allowing a single orthosis device 10 to be used by users having a range of weights.

Orthosis device 10 also may include shoulder bracket 36, as shown in FIGS. 4-7. Shoulder bracket 36 attaches at an attached end link 38, shown in FIG. 5, to the proximal end of first limb section 12, and is adapted at a free end link 40, shown in FIG. 6, for attachment to a chair (e.g., a wheelchair). Shoulder bracket 36 may also include any desired number of interior links 42, shown in FIG. 7. The links are pivotably connected to each other via any known hinge mechanism, which allows for shifting of the user's torso with respect to orthosis device 10 and misalignment between the user and orthosis device 10. As best shown in FIG. 4, links 38, 40, and 42 are hinged about a vertical axis, allowing for rotation of orthosis device about a vertical axis at a position generally corresponding to the anatomical shoulder.

Furthermore, by introducing additional degrees of freedom into the system, more natural movement of the limb within orthosis device 10 is facilitated. One skilled in the art will recognize that at least two pivotably connected links will be required, and that four pivotably connected links will provide enough additional degrees of freedom to achieve the desired level of mobility at the anatomical shoulder. Thus, as will be readily apparent to one skilled in the art, the orthosis device according to the present invention assists and augments anatomical motion in generally four degrees of freedom: rotation about horizontal and vertical axes at both the elbow and the shoulder. Free end 40 of shoulder bracket 36 may be directly attached to a wheelchair 44, or may be attached to a mounting bracket 46 in turn connected to wheelchair 44, as shown in FIG. 8.

FIGS. 9 and 10 illustrate the selection of the dimensions and parameters used to construct and adjust orthosis device 10 for a particular individual. One skilled in the art will recognize that FIG. 9 is a schematic illustration of second limb section 14 according to the present invention, and that a similar schematic could be drawn for first limb section 12. Dimension 21 is the length of first and second links 18 and 20, dimension b is the length of third and fourth links 22 and 24, dimension c is the fixed distance between mounting posts 32, and dimension a is determined by the position of carriage 34 along first link 18. Angle .theta. varies as orthosis device 10 rotates about a horizontal axis in one degree of freedom. It should be noted that carriage 34 is fixed with respect to first link 18 as the angle .theta. changes; that is, dimension a is fixed as .theta. varies. Dimension a can, however, be varied to accommodate varying user weights (e.g., via the lead screw mechanism described above).

The choice of spring member 30 and dimensions a, b, and c are governed by the equation

where k is the stiffness of spring member 30, m is the combined mass of second limb section 14 and the limb inserted therein, and g is the gravitational constant. One skilled in the art will recognize that Equation 3 is derived from Equations 1 and 2, above, and that a similar equation can be derived for first limb section 12. Dimension c is chosen from a graph of the stiffness k of spring member 30, such as that shown in FIG. 10, where reference numeral 48 indicates the actual force-displacement curve for spring member 30, and reference numeral 50 denotes the unstretched length of spring member 30.

Once the appropriate dimensions and spring stiffness k have been selected and set, orthosis device 10 is configured to provide a gravity-balanced equilibrium to the user. That is, spring members 30 will offset the combined weight of orthosis device 10 and the limb of the user, thereby generally balancing the limb for all positions in three-dimensional space. This is analogous to movement in a zero-gravity environment, and will allow individuals with muscular degeneration to move their limbs to perform routine tasks (e.g., eating, shaving) with minimal effort.

As muscular disabilities are often progressive, however, the gravity-balancing provided by spring member 30 alone may not be sufficient to allow movement of the user's limb. Thus, orthosis device 10 may optionally be provided with powered actuators and force sensors (not shown). Force sensors detect the intention of the user to move in a particular direction in a fashion analogous to power steering in a vehicle. The force sensors then send a signal to activate the powered actuators. In this manner, the user is in control of the movement, but the necessary power to complete the movement is supplied by the powered actuators. Since orthosis device 10 inherently compensates for gravity, the powered actuators will require less power than existing powered orthoses, and may be powered, for example, by electric wheelchair batteries already present.

While the invention has been described in terms of its preferred embodiment, those skilled in the art will recognize that the invention can be practiced with modifications within the spirit and scope of the appended claims. Thus, it is intended that all matter contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative rather than limiting, and the invention should be defined only in accordance with the following claims and their equivalents.

Combination Pro/Supination and Flexion Therapeutic Mobilization Device

United States Patent	7,101,347
Culhane , et al.	September 5, 2006

Combination pro/supination and flexion therapeutic mobilization device

Abstract

A therapeutic mobilization device is disclosed. The device includes a flexion assembly, a pro/supination assembly and a valgus carrying angle compensation device. The flexion assembly has an arm attachment assembly and an elbow actuator and the elbow actuator defines and axes of rotation. The pro/supination assembly is attached to flexion assembly and has a distal forearm attachment assembly and a pro/supination actuator operably connected thereto. The valgus carrying angle compensation device is operably attached to the flexion assembly and the pro/supination assembly. Preferably the pro/supination assembly is slidably mounted on a housing shaft whereby during flexion the pro/supination assembly is free to move along the housing shaft. Further, preferably the arm attachment assembly includes an attachment ring and an adjustable clamp pivotally attached thereto whereby the attachment ring defines a pro/supination axis and the adjustable clamp pivots orthogonally to the pro/supination axis.

Inventors: **Culhane; Jeff** (Phoenix, AZ)**, Solomon; Alex** (Mississauga, **CA**)**, Kruger; Paul** (Toronto, **CA**)**, Milosavljevic; Dragan** (Toronto, **CA**)**, Cotterell; Dan** (Ajax, **CA**)**, MacPhail; Andrew** (Toronto, **CA**)

Assignee: **OrthoRehab., Inc.** (Lowell, MA)

Appl. No.: **10/436,465**

Filed: **May 13, 2003**

References Cited [Referenced By]

U.S. Patent Documents

4538595	September 1985	Hajianpour
5102411	April 1992	Hotchkiss et al.
5117814	June 1992	Luttrell et al.
5219323	June 1993	Singer et al.
5637076	June 1997	Hazard et al.

5683353	November 1997	Hamersly
5848979	December 1998	Bonutti et al.
5951499	September 1999	Saringer et al.

Primary Examiner: Bennett; Henry
Attorney, Agent or Firm: Hill; Nancy E. Hill & Schumacher

Parent Case Text

CROSS REFERENCE TO RELATED PATENT APPLICATION

This patent application is a continuation application of U.S. patent application, Ser. No. 09/689,812 filed on Oct. 13, 2000 now abandoned entitled COMBINATION PRO/SUPINATION AND FLEXION THERAPEUTIC DEVICES with the same inventors, which is related to U.S. Provisional Patent Application, Ser. No. 60/189,051 filed on Mar. 14, 2000 entitled A COMBINATION PRO/SUPINATION AND FLEXION THERAPEUTIC MOBILIZATION DEVICE.

Claims

What is claimed as the invention is:

1. A therapeutic mobilization device for use with a patient comprising: a flexion assembly having an arm attachment means and an elbow actuator having an elbow axes of rotation; a pronation/supination assembly operably attached to the flexion assembly, the pronation/supination assembly having a distal forearm attachment means and a pronation/supination actuator operably connected thereto; and a valgus carrying angle compensation device operably attached between the flexion assembly and the pronation/supination assembly whereby the valgus carrying compensation device compensates for misalignment of the patient in the device, thereby reducing stresses during use.

2. A therapeutic mobilization device as claimed in claim 1 wherein the valgus carrying angle compensation device includes a pivot operably attached between the distal forearm attachment means and the arm attachment means.

3. A therapeutic mobilization device as claimed in claim 2 wherein the pivot is a flexible member.

4. A therapeutic mobilization device as claimed in claim 2 wherein the pivot is an adjustable linkage.

5. A therapeutic mobilization device as claimed in claim 1 wherein the elbow actuator includes a first and second spaced apart elbow actuator and the flexion assembly further includes at least one orthosis rod and an adjustable assembly moveably attached between the first and second spaced apart elbow actuators whereby selectively adjusting adjustable assembly causes the first and second actuators to move towards and away from each other along a path defined by the orthosis rod.

6. A therapeutic mobilization device as claimed in claim 5 wherein the orthosis rod is shaped such that as the first and second elbow actuators move away from each other, each moves forwardly relative to the arm attachment means.

7. A therapeutic mobilization device as claimed in claim 6 further including a second orthosis rod slideably attached between the first and second elbow actuators.

8. A therapeutic mobilization device as claimed in claim 1 wherein the elbow actuator is attached to the arm attachment means and an orthosis stay is rotatably attached to the elbow actuator and to the valgus carrying angle compensation device whereby rotation of the orthosis stay moves the user's elbow through flexion.

9. A therapeutic mobilization device as claimed in claim 8 wherein the valgus carrying angle compensation means is a pivot.

10. A therapeutic mobilization device as claimed in claim 9 wherein the pronation/supination assembly includes a housing shaft and the distal forearm attachment means is slideably mounted on the housing shaft whereby during flexion distal forearm attachment means is free to move along the housing shaft.

11. A therapeutic mobilization device as claimed in claim 10 wherein the housing shaft defines a pronation/supination axis and wherein the distal forearm attachment means includes a distal forearm clamp pivotally attached to a pronation/supination housing whereby the distal forearm clamp pivots orthogonally to the pronation/supination axis.

12. A therapeutic mobilization device as claimed in claim 11 wherein the elbow actuator is pivotally attached to the arm attachment and has a first elbow position and a second elbow position and the pivot has a first pivot position and second pivot position and whereby the first elbow position and first pivot position define a right hand orientation and the second elbow position and the second pivot position define a left hand orientation.

13. A therapeutic mobilization device as claimed in claim 1 wherein the pronation/supination assembly is slideably attached to a housing shaft which is attached to the valgus carrying angle compensation device.

14. A therapeutic mobilization device as claimed in claim 2 wherein the pronation/supination assembly is slideably attached to a housing shaft.

15. A therapeutic mobilization device as claimed in claim 14 wherein the pronation/supination assembly further includes a pronation/supination housing, an attachment ring rotatably attached to the housing and distal forearm attachment assembly attached thereto, a belt attached to the attachment ring and to the pronation/supination actuator whereby actuation of the pronation/supination actuator causes the belt to move the attachment ring in pronation and supination.

16. A therapeutic mobilization device as claimed in claim 15 wherein the distal forearm attachment assembly includes an adjustable clamping mechanism having at least one adjustable clamp whereby selectively adjusting the adjustable clamping mechanism a patient's limb can be anatomically aligned and secured in the device.

17. A therapeutic mobilization device as claimed in claim 16 wherein the housing shaft defines a pronation/supination axis and wherein the adjustable clamping mechanism is pivotally attached to attachment ring whereby the adjustable clamping mechanism pivots orthogonally to the pronation/supination axis.

18. A therapeutic mobilization device for use with a patient comprising: an arm attachment means; a distal forearm attachment means; a valgus carrying angle compensation device connected between the arm attachment means and the distal forearm attachment means whereby the valgus carrying compensation device compensates for misalignment of the patient in the device, thereby reducing distraction and compression forces during use; and an elbow actuator operably connected to the arm attachment means and the distal forearm attachment means whereby movement of the actuator causes the user to move through elbow flexion.

19. A therapeutic mobilization device as claimed in claim 18 wherein the valgus carrying angle compensation device is a pivot.

20. A therapeutic mobilization device as claimed in claim 19 wherein a housing shaft is attached to the pivot and the distal forearm attachment means is slidably attached to the pivot.

21. A therapeutic mobilization device as claimed in claim 20 wherein the distal forearm attachment means includes an attachment ring and an adjustable clamping mechanism pivotally attached to the ring whereby the housing shaft defines a pronation/supination axis and the adjustable clamping mechanism pivots orthogonally to the pronation/supination axis.

Description

FIELD OF THE INVENTION

This invention relates to therapeutic mobilization and splinting devices and in particular a combination pro/supination and flexion device.

BACKGROUND OF THE INVENTION

In recent years it has become evident that the rehabilitation and treatment of injured joints and surrounding soft tissue can be expedited by use of continuous passive motion (CPM) static and dynamic serial splinting of the involved joint and surrounding soft tissue. CPM and splinting entails moving the joint via its related limbs through a passive controlled range of motion without requiring any muscle coordination. Active motion is also beneficial to the injured joint, however muscle fatigue limits the length of time the patient can maintain motion or positioning, therefore a device that provides continues passive motion to the joint is essential to maximize rehabilitation results. Numerous studies have proven the clinical efficacy of CPM or splinting to accelerate healing and maintain a range of motion. Static Progressive Splinting (SPS) and Dynamic Splinting (DS) are accepted and effective treatment modalities for the management and modelling of soft tissue surrounding articulations. Both SPS and DS have been proven efficacious and are supported by clinical studies. CPM, SPS and DS are integral components of a successful therapy protocol.

The successful rehabilitation of elbow and forearm injuries is complex, time consuming and often challenging due to the mobility, complex geometry and high stresses in and around the joint.

SUMMARY OF THE INVENTION

The therapeutic mobilization device of the present invention includes a flexion assembly, a pro/supination assembly and a valgus carrying angle compensation device. The flexion assembly has an arm attachment assembly and an elbow actuator and the elbow actuator defines and axes of rotation. The pro/supination assembly is attached to flexion assembly and has a distal forearm attachment assembly and a pro/supination actuator operably connected thereto. The valgus carrying angle compensation device is operably attached to the flexion assembly and the pro/supination assembly.

In another aspect of the present invention the therapeutic mobilization device includes an arm attachment assembly, a distal forearm attachment assembly, and elbow actuator and a valgus carrying angle compensation device. The compensation device is connected between the arm attachment assembly and the distal forearm attachment assembly. The elbow actuator is operably connected to the arm attachment assembly and the distal forearm attachment assembly whereby movement of the actuator causes the user's elbow to move through flexion.

In a further aspect of the invention the therapeutic mobilization device includes an arm attachment assembly, a distal forearm attachment assembly and an elbow actuator. The distal forearm attachment assembly includes a housing shaft and an adjustable clamping mechanism slidably mounted on the housing shaft. The elbow actuator is operably

connected to the arm attachment assembly and the housing ring whereby movement of the actuator causes the user's elbow to move through flexion and the adjustable clamping mechanism is free to move along the housing shaft.

In a still further aspect of the invention a therapeutic mobilization device includes a pro/supination actuator and a pro/supination assembly. The pro/supination assembly includes a pro/supination housing, an attachment ring rotatably attached to the housing and a distal forearm attachment assembly attached thereto. A belt is attached to the attachment ring and to the pro/supination actuator whereby actuation of the pro/supination actuator causes the belt to move the attachment ring in pronation and supination.

It is an object of the present invention to provide continuous passive motion and/or electronically controlled progressive splinting device. The device will have two operating modes. The first and default-operating mode may be CPM. CPM typically involves defining a range of motion (ROM) within which a device operates. A pause can be added at the end of the direction of travel prior to the device returning to the other programmed extreme of motion. This operational mode promotes the maintenance of a joint's ROM. CPM devices are typically configured with a Reverse On Load (ROL) safety feature. The ROL is the level of force or resistance required to reverse the direction of travel or rotation of a CPM device.

The device may be suitable for bed, chair and ambulatory use configurations. The device may be symmetrical and ambidextrous. The device provides a full range of variable elbow flexion. The device also provides a full range of variable pronation and supination motion for the forearm. These motions are available in a synchronized motion, independently or in a serial motion. If pro/supination serial motion is chosen, preferably pro/supination will occur at 90 degrees of elbow flexion or as close thereto as possible. This is to limit stress on the joints. Preferably the device is controlled by a hand-held user interface which allows the operator to adjust the speed of travel (CPM mode only), range of motion, pause time at end of cycle and reverse on load. Preferably the device includes a means to electronically lock the patient settings while still allowing the patient to adjust the speed.

The orthosis of the device is configured to provide anatomical elbow flexion and forearm pro/supination. The orthosis also compensates for the valgus carrying angle. The valgus carrying angle is the result of the lateral migration of the distal radius and ulna relative to the distal humerus as the forearm pro/supinates. The orthosis may also compensates for the anthropometric variances between patients. This is achieved by accommodating differences in arm circumference, length and anatomical axis relative to the exterior surfaces of the arm. The device integrates a novel arrangement of strain gauges to monitor the amount of force in flexion and torque in pro/supination the device is delivering to the involved limb.

The invention relates to continuous passive motion (CPM) and progressive splinting devices for the synovial joints and surrounding soft tissue of the human body. The device

forming the present invention comprises proximal and distal humerus supports. The humerus supports are allowed to move telescopically relative to each other, where the distal humerus support is suitably fixed to the chassis of the device. The device also comprises a distal radius and ulna support. The radius and ulna supports move in rotation relative to the humerus supports to provide pro/supination. The distal radius and ulna support also moves in a planer motion relative to the humerus supports to provide elbow flexion. The device includes two microprocessor controlled electric actuators. The actuators are located at the elbow and distal forearm. The actuators are suitably fixed to the orthosis and provide rotational motion concentric with the elbow and forearm's anatomic axis. The elbow actuator is a simple pivot actuator whereby a mechanical pivot is concentric with the device's elbow anatomical axis.

In typical CPM mode the ROM is defined and the device operates through a consistent defined range. An alternate configuration of elbow anatomical axis compensation includes two semicircular shapes slidably mounted to each other. This configuration can achieve similar results in providing one adjustment to compensate for circumference and position of the elbow's anatomic axis relative to the upper arm.

Further features of the invention will be described or will become apparent in the course of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example only, with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view the combination pro/supination and flexion therapeutic mobilization device constructed in accordance with the present invention;

FIG. 2 is an exploded perspective view of the flexion assembly and the pivot of the combination pro/supination and flexion therapeutic mobilization device;

FIG. 3 is a side view of the combination pro-supination and flexion therapeutic mobilization device;

FIG. 4 is a side view of the combination pro-supination and flexion therapeutic mobilization device showing the device in two positions for the device;

FIG. 5 is an enlarged front view of the combination pro-supination and flexion therapeutic mobilization device with a portion broken away;

FIG. 6 is an enlarged front view of the combination pro-supination and flexion therapeutic mobilization device with a portion broken away showing the device in a different position from the position shown in FIG. 5;

FIG. 7 is a perspective view of the combination pro-supination and flexion therapeutic

mobilization device showing the device attached to a stand;

FIG. 8 is a perspective lateral view of an alternate embodiment of the combination pro/supination and flexion therapeutic mobilization device constructed in accordance with the present invention;

FIG. 9 is a perspective medial view of the combination pro/supination and flexion therapeutic mobilization device shown in FIG. 8; and

FIG. 10 is an enlarged perspective view of the valgus pivot of the combination pro/supination flexion therapeutic mobilization device shown in FIGS. 8 and 9.

FIG. 11 is an enlarged perspective view of the humerus support and flexion actuator assembly of the therapeutic mobilization device shown in FIGS. 8 10;

FIG. 12 is an enlarged perspective view of the humerus support of the therapeutic mobilization device shown in FIGS. 8 11;

FIG. 13 is a perspective view of the mounting stand for use in association with the therapeutic mobilization device of the present invention;

FIG. 14 is a perspective view of a flexion therapeutic mobilization device constructed in accordance with the present invention; and

FIG. 15 is a perspective view of a pro/supination mobilization device constructed in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 and 3 an elbow and wrist therapeutic mobilization device or pro/supination flexion mobilization device is shown generally at 10. The device includes an upper arm or humerus support 22, an elbow or flexion assembly 24 and a wrist or pro/supination assembly 26.

The upper arm or humerus support 22 includes a lower or distal humerus cuff 28 and an upper or proximal humerus cuff 30. Cuff 30 is slidably mounted along cuff support 32. A lower cuff strap 34 (shown in FIG. 3) is attached to the lower humerus cuff 28 and an upper cuff humerus strap 36 is attached to the proximal humerus cuff 30. Straps 34 and 36 use hook and loop type fastener to allow for easy attachment and adjustment. The distance between the lower humerus cuff 28 and the proximal humerus cuff 30 can be adjusted to ensure that device 10 is securely attached to the patient, shown in phantom at 38.

The elbow assembly 24, as shown in FIGS. 1 and 2, includes first and second elbow actuators 40 and 42 respectively, spaced apart top and bottom orthosis rods 44 and 46 respectively and barrel nut assembly 48. Top and bottom orthosis rods 44 and 46 each

have a back portion 50 and forwardly and outwardly extending first and second side portions 52 and 54 respectively. The first 40 and second 42 elbow actuators are slidably mounted on the side portions 52, 54 of the top 44 and 46 bottom orthosis rods. One of the first 40 and second 42 elbow actuators is a drive flexion elbow actuator and the other may be an idler elbow actuator. Elbow actuators 40, 42 each have an elbow axis of rotation 56 that is co-linear. Barrel nut assembly 48 is attached with threaded type connections at one end to the first elbow actuator 40 and at the other end to the second elbow actuator 42. Rotation of the nut 58 in one direction causes the elbow actuators 40 and 42 to move toward each other and rotation in the other direction causes them to move away from each other. As the elbow actuators 40, 42 move relative to each other the elbow axis of rotation 56 remains co-linear.

The elbow assembly 24 is arranged such that it can easily be adjusted to accommodate patients with different sized elbows and different position of the elbow axis or rotation relative to the humerus support 22. As the first and second elbow actuators 40 and 42 slidably move along top 44 and bottom 46 orthosis rods away from each back portion 50 thereof the distance of the elbow axis 56 relative to humerus support 22 proportionately increases and the distance between the first 40 and second 42 elbow actuators increases. Accordingly by adjusting the barrel nut assembly 48 the patient or health care assistant uses one motion and adjustment to accommodate differences in upper arm circumferences and differences in position of the arm elbow anatomic axis relative to the posterior surface of the arm.

The first 40 and second 42 actuators have corresponding first 60 and second 62 rotating shafts respectively. Rotating shafts 60 and 62 rotate in a concentric fashion with the elbow axis 56. First 64 and second 66 drive stays are connected at one end to first 60 and second 62 rotating shafts respectively. At the other end first 64 and second 66 drive stays are connected to valgus pivot 68. Pro-supination assembly 26 is attached to valgus pivot 68.

Pro-supination assembly 26 includes a pro/supination housing 70, housing shaft 72, a ring assembly 74 and a ulna clamping device 76. Housing shaft 72 includes a pair of parallel rods 73. Pro/supination housing 70 is slidably mounted to parallel rods 73 so that it can easily move along the rods during use. Rods 73 include a bent portion 75 at the distal end thereof which limits movement of the pro/supination housing 70. At the other end rods 73 are attached to valgus pivot 68.

Ring assembly 74 has a variable ulna clamp 76 on the inside thereof, as best seen in FIG. 1. Padding and soft goods 80 are attached to screw clamps for comfort. Screw clamps 76 are adjustable to compensate for variations in the size of a patient's distal radius and ulna as well as centering the patient's limb along the pro/supination axis 82. The center of ring assembly 74 is concentric with pro/supination axis 82. The softgoods 80 of the pro/supination assembly 26 are secured to the ulna clamping mechanism 76. The softgoods 80 provide a comfortable patient interface and drive point for the distal radius and ulna. The softgoods 80 can accommodate a range of wrist flexion and deviation positions when secured to the pro/supination drive.

Ring assembly 74 is slidably mounted in pro/supination housing 70. An external belt 84 moves the ring in a rotational fashion relative to pro/supination housing 70. Referring to FIGS. 5 and 6, pro/supination housing 70 includes a pro/supination actuator 86 which drives the belt 84 which in turn drives the ring assembly 74. Idlers 78 help to keep belt 84 taut and in position. A ring channel 88 is formed in the pro/supination housing 70 so that the ring assembly rotates around its center which is concentric with the pro/supination axis 82. The ring assembly 74 is sized to allow the distal portion of the forearm of the patient to be positioned and secured in the center of the ring assembly 74. The pro/supination axis 82 is arranged such that it is concentric with the anatomic axis of the patient's forearm. The pro/supination housing 70 is slidably mounted in a radial fashion relative to the elbow axis 56. The ulna clamp device 76 secures the patient's distal radius and ulna too effectively transfer flexion and pro/supination from the humerus to the forearm. Preferably the ulna clamp device 76 is secured against the patient's distal radius and ulna wrist bone however it will be appreciated by those skilled in the art that ulna clamps could be secured to the patient anywhere along the ulna.

As shown in FIG. 2 valgus pivot 68 includes a top disc 90, a middle disc 92, a bottom disc 94 and a center pin 96 which holds them in pivotal arrangement. Top disc 90 is attached to first drive stay 64. Middle disc 92 is attached to second drive stay 66. Bottom disc 94 is attached to housing rods 73. Each of the discs can move independently of the others thus stays 64 and 66 and housing rods 73 can rotate relative to each other. Pivot 68 compensates for the variations in valgus carrying angle and the adjustable distance between the elbow actuators. Thus the valgus carrying angle is compensated for in a pivot 68 located between the elbow actuator's 40, 42 drive stays 64, 66 and the rods 73 that allow the pro/supination drive to slidably move.

A mounting feature on the orthosis allows the device to be secured to a bed, chair or ambulatory feature. As shown in FIGS. 7, 8, 9 and 13, devices 10 and 120 (described below) may be mounted on a stand 100. Referring to FIG. 13 a mounting receptacle 111 is attached to a mounting post 113. Mounting post 113 is telescopic and its height is adjusted by adjusting knob 102.

The anatomical features are to compensate and align the orthosis' actuators with the anatomic axis of the elbow and forearm. These features serve to minimize stress on the joint and surrounding soft tissue as the device moves through its range of motion.

Device 10 includes a patient controller 104. Device 10 is electrically connected to the patient controller 104 by cord set 106. Switch 108 on patient controller 104 turns the device 10 off and on. Patient controller 104 is connected to power supply 112 via cable 110. Patient controller 104 contains rechargeable batteries and can supply power to device 10 with or without being connected to a wall outlet.

With all of the therapeutic motion and splint devices it is important to align the device appropriately.

Referring to FIGS. 9 through 12 an alternate embodiment of an elbow and forearm therapeutic mobilization device or pro/supination flexion mobilization device is shown generally at 120. Only those elements different from those described above will be described herein in detail. Those elements which are the same will be referred to by the same number.

The mobilization device 120 includes an upper arm or humerus support 22, an elbow or flexion actuator assembly 122 and a wrist or pro/supination assembly 26.

The upper arm or humerus support 22 includes a lower or distal humerus cuff 28 and an upper or proximal humerus cuff 30. Proximal humerus cuff 30 is slidably mounted with respect to humerus support 22 via two parallel rods 32 and secured in position by lock knobs 124. A distal cuff strap 36 is attached to the distal humerus cuff 28 and a proximal cuff humerus strap 34 is attached to the proximal humerus cuff 30. Straps 34 and 36 use hook and loop type fastener in conjunction with buckles 126 and 128 to allow for easy attachment and adjustment. The distance between the distal humerus cuff 28 and the proximal humerus cuff 30 can be adjusted to ensure that mobilization device 120 is securely attached to the patient.

An L-shaped member 146 attaches humerus support 22 to elbow actuator assembly 122. The orientation of the humerus support 22 can be changed by depressing a button 148 that engages one of a pair of aperture 150 and then rotating humerus support 22 until it engages the other of aperture 150. A mounting post 152 is adapted to engage mounting receptacle 111. Mounting post 152 includes a quick release button 154 for disengaging device 120 from stand 100. Elbow actuator assembly 122 is mounted on L-shaped member 146 with a mount 156. Mount 156 includes electronic switches 158.

The elbow actuator assembly 122 includes an orthosis stay 130 and is pivotally connected to actuator 122 at 132 and pivots around the elbow flexion rotational axis 134 as best seen in FIG. 10. Pivot point 132 of orthosis stay 130 is concentric with the elbow pivot axis 134. Orthosis stay 130 is pivotally connected at one end to flexion/elbow actuator assembly 122. The distal end of orthosis stay 130 is connected to valgus pivot 68 as best seen in FIG. 10. Pro/supination assembly 26 is attached to valgus pivot 68 via rods 73. Orthosis stay 130 is attached to valgus pivot 68 by a plurality of fasteners 140. A retractable button 142 engages one of the two opposing positioning aperture 144 in orthosis stay 130. The aperture 144 that is engaged determines the orientation of the rods 73 relative to the orthosis stay 130.

Pro/supination assembly 26 includes a pro/supination housing 70, a ring assembly 74, a variable distal forearm clamping device 76 and pair of parallel rods 73. Pro/supination actuator housing 70 is slidably mounted to parallel rods 73 and is limited in distal sliding range by end stop 136. An elastomeric tether 138 is attached between end stop 136 and pro/supination assembly 26. Elastomeric tether 138 compensates for the weight of the pro/supination assembly 26 and reduces the stress on the users elbow that would be exerted on the patient from the pro/supination assembly.

Ring assembly 74 has a variable distal forearm clamp 76 on the inside thereof, as best seen in FIG. 9. Padding and soft goods 80 are pivotally attached to screw clamps for comfort. Padding and soft goods 80 are attached such that they can pivot around an axis that is orthogonal to pro/supination axis 82. Screw clamps 76 are adjustable to compensate for variations in the size of a patient's distal radius and ulna as well as centering the patient's limb along the pro/supination axis 82. The center of ring assembly 74 is concentric with pro/supination axis 82. The softgoods 80 provide a comfortable patient interface and drive point for the distal radius and ulna. The softgoods 80 can accommodate a range of wrist flexion and deviation positions when secured to the pro/supination assembly 26.

Ring assembly 74 is slidably mounted in pro/supination actuator housing 70. An external belt 84 moves the ring in a rotational fashion relative to pro/supination actuator housing 70. The pro/supination axis 82 is arranged such that it is concentric with the anatomic axis of the patient's forearm when positioned in the device 120. The pro/supination housing 70 is slidably mounted in a radial fashion relative to the valgus pivot axis 83, 134. The forearm clamp assembly 76 and softgoods 80 secure the patient's distal radius and ulna to effectively transfer flexion and pro/supination from the humerus to the forearm. Preferably the forearm clamp assembly 76 and softgoods 80 are secured against the patient's distal ulna and radius. However it will be appreciated by those skilled in the art that ulna clamps 76 could be secured to the patient anywhere along the ulna.

Mobilization device 120 may be mounted on a stand 100 and the height is adjustable with adjusting knob 102. Mobilization device 120 includes a patient controller 104. Device 120 is electrically connected to the patient controller 104 by cord set 106. Switch 108 on patient controller 104 turns the device 120 off and on. Patient controller 104 is connected to power supply 112 via cable 110. Patient controller 104 contains rechargeable batteries and can supply power to device 120 with or without being connected to a wall outlet.

Valgus pivot 68 compensates for the variations in carrying angle. The carrying angle is compensated for in a valgus pivot 68 located between the elbow actuator's 122, orthosis stay 130, and the pro/supination assembly slidably mounted on rods 73. The valgus pivot 68 compensates for misalignment of the patient in the device when it is first attached and during treatment. It minimizes the stresses that are caused by misalignment of the device. The sliding of the pro/supination assembly helps to compensate for the distraction and compression forces during use.

The mobilization device 120 is arranged such that only one adjustment is required to accommodate a range of patients with different sized arms and forearms. Only the proximal humerus cuff 30 is adjusted between patient sizes to accommodate differences in upper arm circumferences and differences in position of the arm's elbow anatomic axis relative to the posterior surface of the arm. This is accomplished by the pro/supination assembly 26 being slidably mounted along rods 73 and having a pivot at the ulna clamping device 76. The anatomical features are to compensate for and align the orthosis' actuators with the anatomic axis of the elbow and forearm and these features serve to minimise stress on the joint and surrounding soft tissue as the device moves through its

range of motion.

Mobilization device 120 is designed to easily be adjusted. The device 120 is asymmetrical with the flexion actuator assembly 122 being positioned on the lateral side of the treated arm to minimise abduction while being treated and improve patient comfort. The device 120 can be converted to treat the left and right arm by unlocking and pivoting three components once it is removed from stand 100. To convert the device from left to right the user unlocks and pivots the humerus support 22, the flexion/elbow actuator assembly 122 and valgus pivot 68.

In use mobilization devices 10 and 120 are suitable for bed, chair and ambulatory use configurations. The devices 10 and 120 are symmetrical and ambidextrous. Each device 10, 120 offers a full range of variable elbow flexion. Each device 10, 120 also offer a full range of variable pronation and supination motion for the forearm. These motions are available in a synchronized motion, independently or in a serial motion. If pro/supination is programmed in a serial motion, preferably pro/supination will occur at 90 degrees of elbow flexion or as close thereto as possible. This is to limit stress on the joints. The device may be controlled by a hand held user interface allowing the operator to adjust the speed of travel (CPM mode only), range of motion, pause time at end of cycle and reverse on load. The device may have a means to electronically lock the patient settings while still allowing the patient to adjust the speed. The orthosis of the device is configured to provide anatomical elbow flexion and forearm pro/supination. The orthosis also compensates for the valgus carrying angle. The valgus carrying angle is the result of the lateral migration of the distal radius and ulna relative to the distal humerus as the forearm supinates. The orthosis also compensates for the anthropometric variances between patients. This is achieved by accommodating differences in arm circumference, length and anatomical axis relative to the exterior surfaces of the arm. The device integrates a novel arrangement of strain gauges to monitor the amount of force in flexion and torque in pro/supination the device is delivering to the involved limb. The anatomical features are to compensate for and align the orthosis' actuators with the anatomic axis of the elbow and forearm. These features serve to minimize stress on the joint and surrounding soft tissue as the device is moved or is positioned through its range of motion.

Referring to FIG. 14 another alternative embodiment of the present invention is shown generally at 160. Device 160 is solely a flexion device that is similar to device 120 but it does not include a pro/supination assembly. Rather than a pro/supination assembly, device 160 includes an arm support 162. Arm support is slideably mounted on rods 73. Arm support has a support ring 168 attached to a housing 166. Soft goods 80 are pivotally attached to support ring 168 and can rotate around axis 82. The remainder of device 160 is similar to that described above with regard to device 120.

Similarly it will be appreciated by those skilled in the art that elements of the present invention could be used for a pro/supination only device wherein the flexion actuator was not used or not included in the device at all. As shown in FIG. 15, a pro/supination mobilization device 170 may also be constructed in accordance with the present

invention. Device 170 includes an upper arm support 22 and a pro/supination assembly 26. As discussed above the pro/supination assembly 26 includes a pro/supination housing 70 slidably mounted on parallel rods 73, a ring assembly 74 and a ulna clamping device 76. Housing shaft 72 includes a pair of parallel rods 73. Rods 73 have and end stop 136 at one end thereof and at the other end thereof are attached to valgus pivot 68 having a valgus pivot axis 83.

Ring assembly 74 has a variable ulna clamp 76 on the inside thereof. Padding and soft goods 80 are attached to screw clamps for comfort. The center of ring assembly 74 is concentric with pro/supination axis 82. Ring assembly 74 is slidably mounted in pro/supination housing 70. An external belt 84 moves the ring in a rotational fashion relative to pro/supination housing 70.

The upper arm support 22 includes a lower or distal humerus cuff 28 and an upper or proximal humerus cuff 30. Cuff 30 is slidably mounted along cuff support 32. A lower cuff strap 34 is attached to the lower humerus cuff 28 and an upper cuff humerus strap 36 is attached to the proximal humerus cuff 30. An L-shaped orthosis stay 130 is pivotally connected at one end thereof to an elongate connector 172 and at the other end thereof it is connected to the vulgas pivot 68. The elongate connector 172 is also attached to the upper arm support 22.

It will be appreciated that the above description related to the invention by way of example only. Many variations on the invention will be obvious to those skilled in the art and such obvious variations are within the scope of the invention as described herein whether or not expressly described.

Appendix B: Dimensioned Drawings

Included are the prints for the manufactured parts: Humeral Housing (Front and Rear), Humeral Rail, Elbow Housing and Lateral Humeral Bar. All dimensions are in mm, unless otherwise noted, and parts are toleranced for casting. These dimensioned prints are considered confidential.

Drawing 1 — Title Block (Humeral Housing)

Dimensions shown: (8.00), R63.50, R69.85, R73.82, 80.36, (53.98), R9.65, Ø7.94, (77.79), 13.76, 21.43, 49.18

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm
TOLERANCES:
FRACTIONAL±
ANGULAR: MACH± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
HAPCO 304

FINISH
LSB(Preferred)

	NAME	DATE
DRAWN	spt	04/10/07
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

Toddes Thesis

TITLE:
Humeral Housing

SIZE **A**   DWG. NO. TBD   REV 01

SCALE: 1:1   SHEET 1 OF 2

NEXT ASSY   USED ON
APPLICATION   DO NOT SCALE DRAWING

Drawing 2 — Title Block (Humeral Rail)

Dimensions shown: (25.40), (9.53), (9.53), (5.40), B, B, R73.82, R60.96, 6.35, 12.70, 19.05, (6.35), (143.35)

SECTION B-B

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm
TOLERANCES:
FRACTIONAL±
ANGULAR: MACH± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
HAPCO 304

FINISH
LSB(Preferred)

	NAME	DATE
DRAWN	spt	04/10/07
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

Toddes Thesis

TITLE:
Humeral Rail

SIZE **A**   DWG. NO. TBD   REV 01

SCALE: 1:2   SHEET 1 OF 1

NEXT ASSY   USED ON
APPLICATION   DO NOT SCALE DRAWING

Dimensions shown: (19.05), (12.70), (6.35), (36.04), (51.34), (30.325), (46.184), (28.58), (127), R30.325

	UNLESS OTHERWISE SPECIFIED:		NAME	DATE	Toddes Thesis		
	DIMENSIONS ARE IN mm	DRAWN	spt	04/10/07	TITLE:		
	TOLERANCES: FRACTIONAL±	CHECKED			Elbow Housing		
	ANGULAR: MACH± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	ENG APPR.					
		MFG APPR.					
	INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.					
PROPRIETARY AND CONFIDENTIAL	MATERIAL	COMMENTS:			SIZE	DWG. NO.	REV
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.	HAPCO 304				A	TBD	01
	NEXT ASSY	USED ON	FINISH	LSB(Preferred)			
	APPLICATION		DO NOT SCALE DRAWING		SCALE: 1:2		SHEET 1 OF 2

Dimensions shown: (19.05), (12.70), (6.35), (36.04), (51.34), (30.325), (46.184), (28.58), (127), R30.325

(19.05)
(12.70)
(6.35)
(127)
R9.53
(6.35)
(69.85)
(9.53)

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	Toddes Thesis
		DIMENSIONS ARE IN mm	DRAWN	spt	04/10/07	
		TOLERANCES: FRACTIONAL±	CHECKED			TITLE:
		ANGULAR: MACH± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	ENG APPR.			Lateral Humeral Bar
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
PROPRIETARY AND CONFIDENTIAL		MATERIAL	COMMENTS:			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.		HAPCO 304				SIZE DWG. NO. REV
		FINISH				A TBD 01
NEXT ASSY	USED ON	LSB(Preferred)				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 SHEET 1 OF 1

197

Appendix C: Elbow Flexion Model

Elbow Flexion was predicted by using an initial angle to calculate the torque on the arm and resulting torque on the motor. The motor torque is then converted to an RPM and the angular displacement over a time step is determined. The displacement is then used to calculate the approximate final angular position. This angle is then used as the initial angle and the process is repeated again. Table 15 shows the gear inputs.

Table 15: Elbow Gear Inputs

Time Step	0.05	sec	50	1000 x sec
Start Torque	12	N·m	12000	mN·m
Max RPM	4980	rpm	0.000201	Mnute/ rot
RPM/Torque	36.1	N·m·min/rot	36100	mN·m·min/rot
Gear Red 1:	27.5	Gear Eff	0.8	
M. Gr Red.1:	53	M Gr Eff	0.71	

Step	1	2	3	4	5	6	7	8	9	10
Time (sec)	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.5
Start Deg.	180.0	179.1	178.2	177.2	176.3	175.4	174.5	173.6	172.7	171.7
Torque	14.5	14.5	14.5	14.5	14.5	14.4	14.4	14.4	14.4	14.3
Spin Speed	4456.7	4456.8	4457.0	4457.3	4457.8	4458.4	4459.1	4460.0	4461.0	4462.1
Finish Deg.	179.1	178.2	177.2	176.3	175.4	174.5	173.6	172.7	171.7	170.8

| Step	11	12	13	14	15	16	17	18	19	20
Time (sec)	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9	1.0	1.0
Start Deg.	170.8	169.9	169.0	168.1	167.1	166.2	165.3	164.4	163.5	162.5
Torque	14.3	14.3	14.2	14.2	14.1	14.1	14.0	14.0	13.9	13.8
Spin Speed	4463.4	4464.8	4466.4	4468.0	4469.8	4471.8	4473.8	4476.0	4478.4	4480.8
Finish Deg.	169.9	169.0	168.1	167.1	166.2	165.3	164.4	163.5	162.5	161.6

Step	21	22	23	24	25	26	27	28	29	30
Time (sec)	1.1	1.1	1.2	1.2	1.3	1.3	1.4	1.4	1.5	1.5
Start Deg.	161.6	160.7	159.8	158.8	157.9	157.0	156.1	155.1	154.2	153.3
Torque	13.8	13.7	13.6	13.5	13.4	13.3	13.2	13.2	13.1	12.9
Spin Speed	4483.4	4486.1	4489.0	4492.0	4495.1	4498.3	4501.7	4505.2	4508.8	4512.6
Finish Deg.	160.7	159.8	158.8	157.9	157.0	156.1	155.1	154.2	153.3	152.4

Step	31	32	33	34	35	36	37	38	39	40
Time (sec)	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0
Start Deg.	152.4	151.4	150.5	149.6	148.6	147.7	146.8	145.8	144.9	144.0
Torque	12.8	12.7	12.6	12.5	12.4	12.3	12.1	12.0	11.9	11.7
Spin Speed	4516.4	4520.4	4524.6	4528.8	4533.2	4537.7	4542.3	4547.0	4551.9	4556.9
Finish Deg.	151.4	150.5	149.6	148.6	147.7	146.8	145.8	144.9	144.0	143.0

Step	41	42	43	44	45	46	47	48	49	50
Time (sec)	2.1	2.1	2.2	2.2	2.3	2.3	2.4	2.4	2.5	2.5
Start Deg.	143.0	142.1	141.1	140.2	139.3	138.3	137.4	136.4	135.5	134.5
Torque	11.6	11.4	11.3	11.1	11.0	10.8	10.7	10.5	10.3	10.2

Spin Speed	4561.9	4567.2	4572.5	4577.9	4583.5	4589.2	4595.0	4600.9	4606.9	4613.0
Finish Deg.	142.1	141.1	140.2	139.3	138.3	137.4	136.4	135.5	134.5	133.6

Step	51	52	53	54	55	56	57	58	59	60
Time (sec)	2.6	2.6	2.7	2.7	2.8	2.8	2.9	2.9	3.0	3.0
Start Deg.	133.6	132.6	131.7	130.7	129.8	128.8	127.9	126.9	125.9	125.0
Torque	10.0	9.8	9.6	9.5	9.3	9.1	8.9	8.7	8.5	8.3
Spin Speed	4619.2	4625.6	4632.0	4638.6	4645.2	4652.0	4658.8	4665.8	4672.9	4680.0
Finish Deg.	132.6	131.7	130.7	129.8	128.8	127.9	126.9	125.9	125.0	124.0

Step	61	62	63	64	65	66	67	68	69	70
Time (sec)	3.1	3.1	3.2	3.2	3.3	3.3	3.4	3.4	3.5	3.5
Start Deg.	124.0	123.1	122.1	121.1	120.1	119.2	118.2	117.2	116.3	115.3
Torque	8.1	7.9	7.7	7.5	7.3	7.1	6.9	6.6	6.4	6.2
Spin Speed	4687.3	4694.6	4702.0	4709.6	4717.2	4724.9	4732.7	4740.6	4748.5	4756.6
Finish Deg.	123.1	122.1	121.1	120.1	119.2	118.2	117.2	116.3	115.3	114.3

Step	71	72	73	74	75	76	77	78	79	80
Time (sec)	3.6	3.6	3.7	3.7	3.8	3.8	3.9	3.9	4.0	4.0
Start Deg.	114.3	113.3	112.3	111.4	110.4	109.4	108.4	107.4	106.4	105.4
Torque	6.0	5.7	5.5	5.3	5.0	4.8	4.6	4.3	4.1	3.9
Spin Speed	4764.7	4772.9	4781.1	4789.5	4797.9	4806.4	4814.9	4823.5	4832.2	4841.0
Finish Deg.	113.3	112.3	111.4	110.4	109.4	108.4	107.4	106.4	105.4	104.4

Step	81	82	83	84	85	86	87	88	89	90
Time (sec)	4.1	4.1	4.2	4.2	4.3	4.3	4.4	4.4	4.5	4.5
Start Deg.	104.4	103.4	102.4	101.4	100.4	99.4	98.4	97.4	96.4	95.4
Torque	3.6	3.4	3.1	2.9	2.6	2.4	2.1	1.9	1.6	1.4
Spin Speed	4849.8	4858.6	4867.5	4876.5	4885.5	4894.5	4903.6	4912.7	4921.9	4931.1
Finish Deg.	103.4	102.4	101.4	100.4	99.4	98.4	97.4	96.4	95.4	94.3

Step	91	92	93	94	95
Time (sec)	4.6	4.6	4.7	4.7	4.8
Start Deg.	94.3	93.3	92.3	91.3	90.3
Torque	1.1	0.8	0.6	0.3	0.1
Spin Speed	4940.3	4949.6	4958.9	4968.2	4977.5
Finish Deg.	93.3	92.3	91.3	90.3	89.2

Appendix D: Humeral Rotation Model

Humeral Rotation was predicted by using an initial angle to calculate the torque on the arm and resulting torque on the motor. The motor torque is then converted to an RPM and the angular displacement over a time step is determined. The displacement is then used to calculate the approximate final angular position. This angle is then used as the initial angle and the process is repeated again. Table 15 shows the gear inputs.

Table 16: Elbow Gear Inputs

	Time Step	0.05	sec	50	1000 x sec
	Start Torque	12	N·m	12000	mN·m
	Max RPM	4980	rpm	0.0002	Minute/ rot
	RPM/Torque	36.1	N·m·min/rot	36100	mN·m·min/rot
	Gear Red 1:	180	Gear Eff	0.65	
	M. Gr Red.1:	4.4	M Gr Eff	0.8	

Step	1	2	3	4	5	6	7	8	9	10
Time (sec)	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.5
Start Deg.	180.0	178.5	177.0	175.5	174.0	172.6	171.1	169.6	168.1	166.6
Torque	29.1	29.1	29.1	29.0	29.0	28.9	28.8	28.7	28.5	28.3
Spin Speed	3928.1	3928.5	3929.6	3931.3	3933.8	3937.0	3940.9	3945.5	3950.8	3956.9
Finish Deg.	178.5	177.0	175.5	174.0	172.6	171.1	169.6	168.1	166.6	165.1

Step	11	12	13	14	15	16	17	18	19	20
Time (sec)	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.9	1.0	1.0
Start Deg.	165.1	163.6	162.1	160.6	159.1	157.5	156.0	154.5	153.0	151.4
Torque	28.2	27.9	27.7	27.5	27.2	26.9	26.6	26.3	26.0	25.6
Spin Speed	3963.6	3971.0	3979.2	3988.0	3997.6	4007.9	4018.9	4030.6	4043.0	4056.1
Finish Deg.	163.6	162.1	160.6	159.1	157.5	156.0	154.5	153.0	151.4	149.9

Step	21	22	23	24	25	26	27	28	29	30
Time (sec)	1.1	1.1	1.2	1.2	1.3	1.3	1.4	1.4	1.5	1.5
Start Deg.	149.9	148.4	146.8	145.3	143.7	142.1	140.6	139.0	137.4	135.8
Torque	25.2	24.8	24.4	23.9	23.5	23.0	22.5	22.0	21.5	20.9
Spin Speed	4069.9	4084.4	4099.6	4115.5	4132.2	4149.5	4167.5	4186.2	4205.6	4225.7
Finish Deg.	148.4	146.8	145.3	143.7	142.1	140.6	139.0	137.4	135.8	134.2

Step	31	32	33	34	35	36	37	38	39	40
Time (sec)	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0
Start Deg.	134.2	132.6	131.0	129.4	127.7	126.1	124.4	122.8	121.1	119.4
Torque	20.3	19.7	19.1	18.5	17.8	17.2	16.5	15.8	15.1	14.3
Spin Speed	4246.5	4267.9	4290.1	4312.9	4336.3	4360.4	4385.2	4410.6	4436.6	4463.3
Finish Deg.	132.6	131.0	129.4	127.7	126.1	124.4	122.8	121.1	119.4	117.7

Step	41	42	43	44	45	46	47	48	49	50
Time (sec)	2.1	2.1	2.2	2.2	2.3	2.3	2.4	2.4	2.5	2.5
Start Deg.	117.7	116.0	114.3	112.6	110.9	109.1	107.4	105.6	103.8	102.0
Torque	13.6	12.8	12.0	11.2	10.4	9.5	8.7	7.8	7.0	6.1
Spin Speed	4490.5	4518.4	4546.8	4575.8	4605.4	4635.4	4666.1	4697.2	4728.8	4760.8
Finish Deg.	116.0	114.3	112.6	110.9	109.1	107.4	105.6	103.8	102.0	100.2

Step	51	52	53	54	55	56
Time (sec)	2.6	2.6	2.7	2.7	2.8	2.8
Start Deg.	100.2	98.4	96.6	94.7	92.9	91.0
Torque	5.2	4.3	3.3	2.4	1.5	0.5
Spin Speed	4793.3	4826.2	4859.5	4893.1	4927.0	4961.3
Finish Deg.	98.4	96.6	94.7	92.9	91.0	89.1

[1] Stanger, et.al. *Demographics of rehabilitation robotics users*, Technology and Disability, Vol. 5, No. 2, September 1996, pp 125-137.

[2] Muscular Dystrophy Association. August 6, 2006.<www.MDA.org>

[3] Rheumatology.org, 2004.

[4] Muscular Dystrophy Association. *Diseases.* August 7, 2006.<www.MDA.org/disease/>

[5] Wheaton Resource Corp, "*Arthrogryposis*". orthoseek.com/articles/arthrogryposis.html Visit: September 19, 2005.

[6] Hall, Judith G. "*Arthrogryposis*." American Family Physician. January, 1989.

[7] National Multiple Sclerosis Society, "*Who Gets MS?*" nationalmssociety.org Visit: Sept. 26, 2005

[8] Harwin WS, Rahman T, Foulds RA *A. Review of Design Issues in Rehabilitation Robotics with Reference to North American Research*. IEEE Transactions on Rehabilitation Engineering, Vol. 3, No. 1, March 1995.

[9] Dallaway JL, Jackson RD, Timmers PHA. *Rehabilitation Robotics in Europe*. IEEE Transactions on Rehabilitation Engineering. 3. pp. 35-45.

[10] Prange GB, et.al. *Systematic Review of the Effect of Robot-Aided therapy on Recovery of the Hemiparetic Arm After Stroke*. Journal of Rehabilitation Research & Development, Vol 43, No.2, pp. 171-184.

[11] Nerf T, Riener R, (2005) *ARMin – Design of a Novel Arm Rehabilitation Robot*. Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics June 28-July 1, 2005, Chicago, IL, USA.

[12] Broderick J, et.al. *The Greater Cincinnati/Northern Kentucky Stroke Study: Preliminary First-Ever and Total Incidence Rates of Stroke Among Blacks*, Stroke, Vol 29, pp 415-421.

[13] American Stroke Association *Heart Disease and Stroke Statistics – 2005 Update* AHA, 2005. April 16, 2006. <www.americanheart.org>

[14] Fasoli et.al. *Robotic therapy for chronic motor impairments after stroke: follow-up results*. Archives of Physical and Medical Rehabilitation, Vol 85 No.7 pp 1106-1111.

[15] Stanger, et.al. *Demographics of rehabilitation robotics users*, Technology and Disability, Vol. 5, No. 2, September 1996, pp 125-137.

[16] Kibler WB, et al. *Functional Rehabilitation of Sports and Musculoskeletal Injuries*. Gaithersburg: Aspen Publishers; 1998. pp.181.

[17] Roy S, Irvin R. *Sports Medicine: Prevention, Evaluation, Management, and Rehabilitation*. Englewood Cliffs: Prentice-Hall; 1983. pp. 224.

[18] U.S. Department of Labor. Occupational Therapists. March 27, 2007. <www.bls.gov/oco/ocos078.htm>

[19] Kolb, Bryan, Brain Plasticity and Behavior. Lawrence Erlbaum Associates, Inc. Hillsdale, NJ, 1995.

[20] Kennard, M.A. *Reorganization of Motor Function in the Cerebral Cortex of Monkeys Deprived of Motor and Premotor Areas in Infancy,* Journal of Neurophysiology, Vol. 1, pp. 477-496.

[21] Taub ,E., Uswatte, G., Pidikiti, R.D. *Constraint-Induced Movement Therapy. A New Family of Techniques with Broad Application to Physical Rehabilitation - A Clinical Review,* Journal of Rehabilitation Research & Development Vol.36 No.3, 1999. pp.237–251.

[22] Cramer, S. C., Moore, C. I., Finklestein, S. P., Rosen, B. R. *A Pilot Study of Somatotopic Mapping After Cortical Infarct*. Stroke Vol. 31, 2000. pp. 668-671

[23] Liepert, J. Bauder, H., Miltner, W. H. R., Taub, E., Weiller, C. *Treatment-Induced Cortical Reorganization After Stroke in Humans*, 2000. Stroke Vol. 31 pp. 1210-1216

[24] Liepert J, et.al. *Motor Cortex Plasticity During Constraint-Induced Movement Therapy in Stroke Patients*, Neuroscience Letters, Vol. 250, pp. 5-8

[25] Prange GB, et.al. *Systematic Review of the Effect of Robot-Aided therapy on Recovery of the Hemiparetic Arm After Stroke*. Journal of Rehabilitation Research & Development, Vol 43, No.2, pp. 171-184.

[26] Hidler J, Nichols D, Pelliccio M, Brady K. *Advances in the Understanding and Treatment of Stroke Impairment Using Robotic Devices*, Topics in Stroke Rehabilitation, pp.22-35. 2005.

[27] Worland R, et.al. *Home continuous passive motion machine versus professional physical therapy following total knee replacement*. The Journal of Arthroplasty Vol. 13, No. 7, 2004. pp. 784-787.

[28] Hogan, N. and H.I. Krebs. *Interactive Robots for Neuro-Rehabilitation*. Restorative Neurology and Neuroscience Vol 20 pp1-10 RNN277, IOS Press, 2004.

[29] Hermano Igo Krebs, et al. *Robot-Aided Neurorehabilitation*. IEEE Transactions on Rehabilitation Engineering, Vol. 6, No. 1, March 1998.

[30] Lum P, et al. *Quantification of Force Abnormalities During Passive and Active-Assisted Upper-Limb Reaching Movements Post-Stroke Hemiparesis.* IEEE Transactions on Biomedical Engineering, Vol. 46, No. 6, June 1999.

[31] Hawkins P, et al. *GENTLE/S Project: Design and Ergonomics of a Stroke Rehabilitation System.* Proceedings of 1st Cambridge Workshop on Universal Access and Assistive Technology (CWUAAT), University of Cambridge, Cambridge, UK, March 25 - 27. (2002).

[32] Nerf T, Riener R. *ARMin – Design of a Novel Arm Rehabilitation Robot.* Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics June 28-July 1, 2005, Chicago, IL, USA. 2005.

[33] He J, et al. *RUPERT: A Device for Robotic Upper Extremity Repetitive Therapy.* Proceedings of the 2005 IEEE Engineering in Medicine and Biology. Sept. 2005.

[34] Johnson L, Winters J. *Evaluation of Tracking Performance Using Manipulators that Engage Different Arm Workspaces.* Proceedings of the 2005 IEEE Conference on Rehabilitation Robotics. 2005.

[35] Nagai K, et al. (1998) *Development of an 8 DOF Robotic Orthosis for Assisting Human Upper Limb Motion.* Proceedings of the 2005 IEEE Conference on Robotics and Automation. May 1998.

[36] Hay JG, Reid JG. *The Anatomical and Mechanical Bases of Human Motion.* Prentice-Hall, Inc., Englewood Cliffs, New Jersey, 1982.

[37] Magermans DJ et.al,. *Requirements for Upper Extremity Motions During Activities of Daily Living*, Clinical Biomechanics, Vol 20. pp. 591-599. 2005.

[38] Kroemer, K. H. E., Kroemer, H. J., and Kroemer-Elbert, K. E. *Engineering Physiology: Bases of Human Factors/Ergonomics* (3rd ed.). New York, NY: Van Nostrand Reinhold - Wiley. 1997.

[39] Dempster, WT. *Space Requirements of the Seated Operator, Geometrical, Kinematic and Mechanical Aspects of the Body with Special Reference to the Limbs.* Michigan State Univ. Publishing, East Lansing, MI July, 1955

[40] Chaffin DB, Gunnar BJ, Martin BJ, Occupational Biomechanics. John Wiley & Sons, Inc. New York, NY 1999.

[41] Rehabilitation Institute of Chicago, May 2006.<http://www.ric.org/>

[42] O'Reilly Network, Introduction to Pulse-Width Modulation. July 2003 <www.oreillynet.com/pub/a/network/synd/2003/07/02/pwm.html>

[43] Merriam-Webster Dictionary. "Engineering." March 2, 2007. <http://www.m-w.com>

[44] Human forearm and hand properties from
http://www.motco.dir.bg/Data/MassInertial.html

[45] Bralla, James G. *Design for Manufacturability*. 2nd ed. McGraw-Hill, New York. 1998.

[46] Beer, Ferdinand P., Johnston, E. Russell Jr. Mechanics of Materials. New York: McGraw-Hill, Inc., 1981.

[47] Interview with Sam Hart of Polymer Corporation. Jan 25,2006. Polymer Corporation, Rockland, MA.

[48] Hapco. March 05, 2207. www.hapcoweb.com

[49] American Gear Manufactures Association. "Worm Gear Selection and Design." Jan. 18, 2007. <http://www.agma.org//AM/Template.cfm?Section=Home>

[50] *Machinery's Handbook*. "Screw Thread Systems." 27ed. Industrial Press, New York. 2004.

[51] *Machinery's Handbook*. "Pinning Systems." 27ed. Industrial Press, New York. 2004. pp. 1686-1688.