Thumb CMC Joint Biomechanics: A Novel Device for Dynamic Splinting

A Major Qualifying Project (MQP)
Submitted to the Faculty of
WORCESTER POLYTECHNIC INSTITUTE
In partial fufillment of the requirements for the
Degree of Bachelor of Science

BY:
Victoria G. Fleek (BE)
Lauren N. Frank (BE)
Samara R. Garcia (BE)
Rachel E. Hesse (BE & ME)
Domenick R. Mastascusa (BE)

DATE:
April 30, 2015

ADVISORS:
Dr. Samandar Dowlatshahi (UMass Medical School)
Professor Karen Troy (WPI)

Abstract

Thumb Carpometacarpal (CMC) joint arthritis is a major detriment to predominately post-menopausal women. The project team, working in collaboration with the University of Massachusetts Medical School, was asked to create a dynamic splint that combats the CMC joint arthritis, as most splints on the market do not treat the specific arthritis of the thumb. Along with the splint, the team developed a preliminary Finite Element Analysis (FEA) model of the CMC joint that was designed to analyze the stresses and strains that act on the joint during specific movements. The team performed material testing and tested the novel splint on non-arthritic patients to observe the efficacy of the splint on all parts of the hand, not just the CMC joint. Based on the results, the team was able to revise their design as well as make future recommendations if the project were to be continued.

Acknowledgements

The project team would first like to thank Dr. Samandar Dowlatshahi (UMass Medical School) and Professor Karen Troy (WPI) for advising this project. Their dedication to this project was obvious through countless meetings, emails, and phone calls over the entire academic year. The combined efforts and expertise of the advisors allowed the team to complete and understand various elements of the project. Dr. Dowlatshahi's experience advising past projects, medical expertise, and experience with patients was crucial for research and collection of data. Professor Troy's knowledge of biomechanics and resources for conducting biomechanical research and data acquisition was extremely useful to complete calculations and data collection.

The team would also like to thank Professor Troy's graduate students, Tiffiny Butler and Joshua Johnson for devoting their time and assistance. The team would also like to extend thanks to Professor Sakthikumar Ambady (WPI) and Lisa Wall (WPI) for their efforts in coordinating MQP projects and research and also designating usable laboratory space for the team. Additionally, the team would like to thank Professor Amanda (Zoe) Reidinger for her help using the Instron® testing system.

Thank you to all of the survey participants. The team appreciates your availability and cooperation in answering surveys and completing activities to provide feedback and data concerning the team's design. Lastly, the team would like to extend a special thanks to Sandra Fleek for her expertise in sewing and fabric construction.

Authorship

1. Introduction	All
2. Literature Review	
2.1 Anatomy	Victoria Fleek & Rachel Hesse
2.2 Thumb CMC Osteoarthritis (OA)	Victoria Fleek, Lauren Frank, & Rachel Hesse
2.3 Surgical Solutions	Lauren Frank & Samara Garcia
2.4 Nonsurgical Solutions	Samara Garcia
2.5 Patents	Domenick Mastascusa
2.6 FEA Modeling	Lauren Frank & Rachel Hesse
2.7 Prototype Testing and Evaluation	Lauren Frank
2.8 Conclusion	Victoria Fleek
3. Project Strategy	
3.1 Initial Client Statement	Victoria Fleek
3.2 Objectives and Constraints	Rachel Hesse
3.3 Revised Client Statement	Victoria Fleek & Rachel Hesse
3.4 Project Approach	Samara Garcia & Domenick Mastascusa
4. Alternative Designs	
4.1 Needs Analysis and Design Specifications	Victoria Fleek & Rachel Hesse
4.2 Feasibility	Lauren Frank
4.3 Manual Calculations	Rachel Hesse
4.4 FEA Model	Rachel Hesse
4.5 Conceptual Designs	Victoria Fleek & Rachel Hesse
4.6 Alternative Designs	Victoria Fleek
4.7 Decision Making Process	Samara Garcia
4.8 Initial Splint Prototype	Victoria Fleek
4.9 Experimental Methods	Victoria Fleek, Lauren Frank & Rachel Hesse
5. Design Verification	
5.1 Compression Testing of Bulk Materials	Lauren Frank
5.2 Planned Patient Surveying	Victoria Fleek
5.3 Unaffected Individual Surveying	Victoria Fleek & Samara Garcia
5.4 Team Testing	Victoria Fleek & Samara Garcia
6. Discussion of Results	
6.1 Planned Patient Surveying	Rachel Hesse
6.2 Unaffected Individual Surveying	Rachel Hesse
6.3 Team Testing	Rachel Hesse
6.4 Compression Testing	Victoria Fleek
6.5 FEA Model	Rachel Hesse
6.6 Device Comparison with Current Solutions	Rachel Hesse
6.7 Limitations of Results	Rachel Hesse
6.8 Prospective Impacts of Design	All
7. Final Design and Validation	
7.1 Changes Based on Survey Results	Lauren Frank
7.2 Changes Based on Advisor Feedback	Lauren Frank
7.3 Changes Based on Mechanical Testing	Lauren Frank
7.4 Team Testing with Final Design	Victoria Fleek

8. Conclusions and Final Recommendations	
8.1 Design Benefits and Cost	Lauren Frank
8.2 Business Model	Domenick Mastascusa
8.3 Future Recommendations	Lauren Frank
8.4 Future Projects for Thumb CMC OA	Lauren Frank

Table of Contents

List of Figures and Tables

List of Equations

1. Introduction

Injury and arthritis in the thumb carpometacarpal (CMC) joint presents a serious issue to both doctors and patients. The carpometacarpal joint is the junction between the first metacarpal and the trapezium, and arthritis of the joint occurs most often between these two bones. However, the first metacarpal and the trapezium do not provide complete stability to the joint; rather the surrounding joints and ligaments provide the overall structure. This structure allows for a wide range of motion of the thumb, which aids in the completion of a variety of daily tasks. Unfortunately, since this joint is used so often to accomplish these tasks, it is more susceptible to injury than other joints in the body. The most common issue with the CMC joint is osteoarthritis, which typically occurs due to high loads, natural joint configuration, and loose ligaments (Xu, Strauch, Ateshian, Pawluk, Mow, and Rosenwasser, 1998). Osteoarthritis of the CMC is characterized into four stages. Different classification systems have been derived to distinguish these stages. Generally as the disease progresses, the CMC joint continuously narrows and causes degeneration of the neighboring metacarpophalangeal (MCP) joint (Matullo, Ilys, and Thoder, 2007).

Although arthritis is typically seen in adults over the age of 65, people of all ages can be afflicted with the disease. According to the Morbidity and Mortality Weekly Report published by the Center for Disease Control and Prevention (CDC), between 2010 and 2012 one in five adults in the United States had reported doctor-diagnosed arthritis. In this same time period, 49.7% of adults over 65 had also reported an arthritis diagnosis (Barbour, Helmick, Theis, Murphy, Hootman, Brady, and Cheng, 2013). Additionally, this report stated that about 1 in 250 children in the United States were diagnosed with some form of arthritis (Sacks, Helmick, Luo, Ilowite, and Bowyer, 2007). Other reports showed an increasing trend in the occurrence of arthritis, such

as a recent study published by the CDC that stated by the year 2030 an estimated 67 million Americans over the age 18 will have arthritis (Hootman and Helmick, 2006). In addition, many individuals that reported having arthritis often experience activity or work limitations as a result. If these trends continue to increase, more and more individuals with arthritis will find themselves struggling with huge medical costs and unable to afford the treatment they require. These statistics show a need for a solution that can be used to treat patients of all age demographics who are affected by arthritis.

There are currently a variety of treatment options for CMC osteoarthritis, including both surgical and nonsurgical options. However, none of these alternatives adequately address the needs of the doctor or the patient. Treatment is selected based on what stage of osteoarthritis the patient is determined to be in at the time of the diagnosis. Nonsurgical options are considered "conservative treatment" for treating patient pain (Egan and Brousseau, 2007). Current nonsurgical options such as splints, joint protection, and joint strengthening are not always adequate at treating osteoarthritis for all patients. Recent designs constructed of polyurethane, neoprene, or plasters are either too rigid or too flexible to cover all patient needs. In addition, many of these splints are necessary during post-operative recovery to facilitate proper healing even if the surgical procedure was successful at relieving pain or restoring joint function.

Doctors often consider surgical options when patient pain becomes "intractable" (Egan and Brousseau, 2007). Surgical procedures often involve cutting some part of the joint or reconstructing the ligament. These procedures are very expensive, and the outcome is often unexpected. In 2003, costs in the United States that were attributed to either arthritis or arthritis-like conditions reached nearly $128 billion, an increase of nearly $42 billion from 1997 (Yelin, Cisternas, Foreman, Pasta, and Helmick, 2007). The present gold standards for treatment are still

inadequate options for treatment because little progress has been made in the field in the last 40 to 50 years. Hand surgeons are still performing surgeries developed many years ago, and prescribe the same treatments they have always prescribed because there are no better options (Dowlatshahi, 2014). Therefore, the need for a low cost, nonsurgical treatment method is very high.

The goal of this project was to design a dynamic splinting device to stabilize and support the thumb CMC joint to promote pain-free and effective joint use in daily activity. The team acquired a thorough and well-rounded knowledge of the anatomy and physiology of the joint in order to develop a Finite Element Analysis (FEA) model. FEA programs solve complex mathematical problems by creating much smaller elements from the original problem domain and consequently interpolating the field variables through the use of shape functions. It is a useful tool for predicting the effects of stress on implants and bones (Geng, Tan, and Liu, 2001).

The team utilized computed tomography (CT) scan images obtained from the National Institute of Health (NIH) to create the FEA model. The planned purpose of this model was to not only extensively detail the bones of the joint, but also highlight the tendons, ligaments, and surrounding soft tissue. In addition, the team planned to use the model as a tool to analyze the kinematic stresses and strains the joint experiences during daily tasks and movements. A preliminary FEA model was produced while a functional and user-friendly splint prototype was developed as a nonsurgical treatment option to be both aesthetically pleasing and marketable to possible clientele.

Once preliminary design concepts were developed, design testing and validation were performed to determine the optimal design to solve the problem. The validation included completing biomechanical calculations, mechanical testing, team testing, and patient and

unaffected individual surveying. In the end, the testing resulted in a final design that would not only reduce pain and stabilize the joint, but also serve as a unique and marketable product.

The following chapters of this report detail the entire process of developing a nonsurgical treatment method. The literature review provides information on the anatomy of the joint, a more in depth explanation of FEA functions, and current nonsurgical treatment options on the market. The project strategy chapter outlines the steps the team took to complete the process, and shows the objectives and constraints that helped guide the project as well as the client statement and its subsequent revision. The alternative designs chapter describes the functions the device must perform, the preliminary designs the team developed, and the feasibility study. The design verification section presents the raw data for the design and summarizes how the design was tested and validated. Finally, the conclusions and recommendations chapter summarizes what the team accomplished and what that means in a global sense. The conclusions chapter also discusses areas of the project that require further research and suggests what steps should be taken in the future to produce a functional product that will help treat osteoarthritis in the thumb CMC joint.

2. Literature Review

2.1 Anatomy

The thumb carpometacarpal (CMC) joint is the interaction between the carpal, or trapezium, and the first metacarpal bones. The surrounding bones of the joint are composed of both cortical and cancellous bone. The cortical bone, the denser and stiffer type of bone, forms the outer layer. The cancellous bone forms the interior of the bone, and is generally weaker than cortical bone due to its decreased stiffness and density. The CMC joint itself is constructed of collagen, which provides the tension and resistance to the surrounding bone. Specifically, hyaline cartilage is found in joints to reduce friction (Polito, Rucco, and Wood, 2013).

The major ligaments (Figure 1) include the deep anterior oblique, superficial anterior oblique, dorso-radial, ulnar collateral, intermetacarpal, and dorsal intermetacarpal (Batra and Kanvinde, 2007). The major roles or responsibilities of these ligaments can be found below in Table 1.

Table 1: Major ligaments of the thumb CMC joint (Batra and Kanvinde, 2007)

Ligament	**Description**
Deep anterior oblique	• Often referred to as the "beak ligament" • Primary stabilizer of the trapeziometacarpal (TMC) joint • Pivot point • Dorsal translation is limited due to this ligament
Superficial anterior oblique	• Aids in stabilization of subluxation of the volar metacarpal
Dorso-radial	• TMC joint's thickest and shortest ligament
Ulnar collateral	• Aids in limitation of volar subluxation
Intermetacarpal	• Contributes to the stabilization of the metacarpal during radiovolar translation
Dorsal intermetacarpal	• Aids in preventing the metacarpal from collapsing after trapezial excision

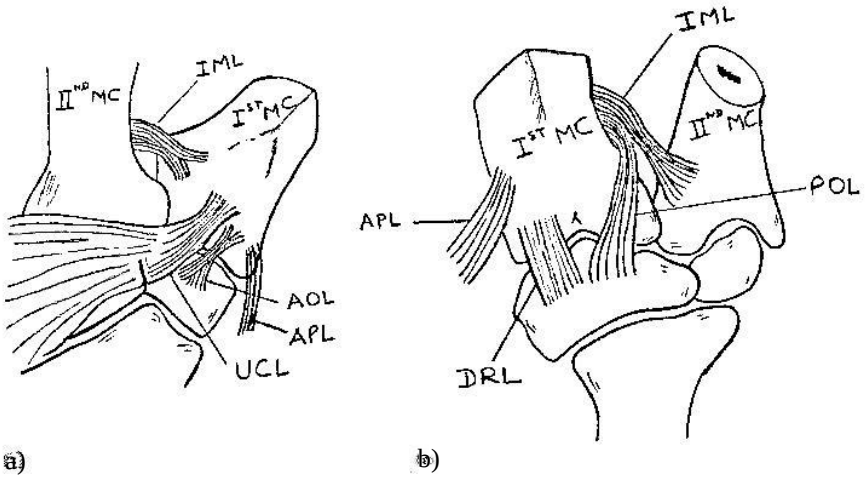


Figure 1: Volar view (a) and dorsal view (b) of the major ligaments of the thumb CMC joint (Batra and Kanvinde, 2007)

Four main muscles dictate thumb motion (Figure 2 and Figure 3): flexor pollicis brevis, abductor pollicis brevis, opponens pollicis, and adductor pollicis. The flexor pollicis brevis (FPB) controls thumb flexion across the palm. The abductor pollicis brevis (APB) allows for abduction of the thumb across the palm. The opponens pollicis (OP) and adductor pollicis (AP) are the two larger muscles controlling the thumb; the OP rotates the thumb while the AP allows the thumb to contract towards the second metacarpal (Colditz, 2000).

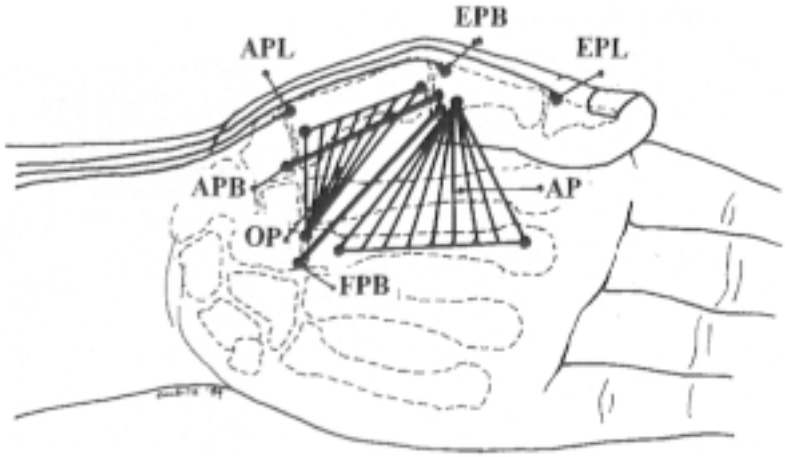


Figure 2: Location of muscles in hand and lines of motion (Colditz, 2000)

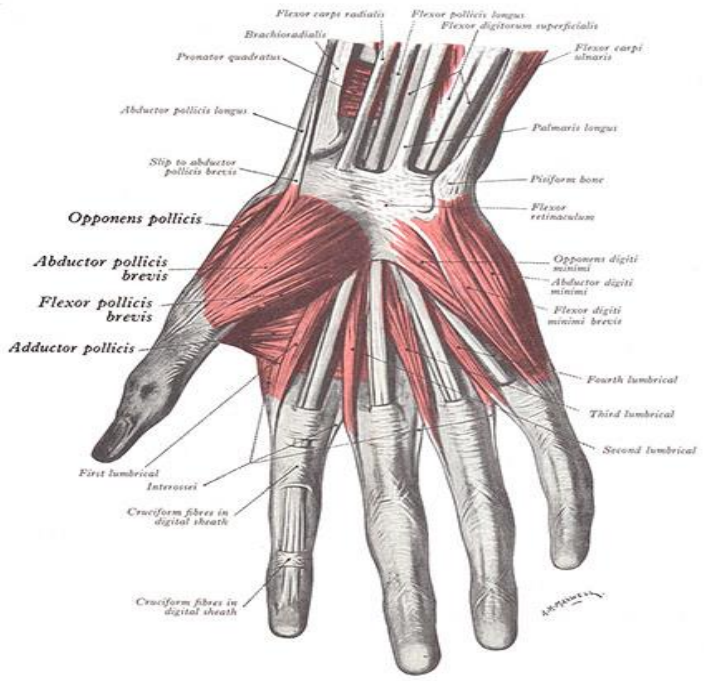


Figure 3: Muscles of the hand and thumb <http://www.paulmanley.co.uk/thumb_joint_pain.html>

2.2 Thumb CMC Osteoarthritis (OA)

The human thumb is responsible for over 60% of common prehensile function, making it a common subject for over exertion in daily stress and strain scenarios (Young and Mikola, 2004). The base of the thumb has subsequently become the site that most often requires surgical intervention for osteoarthritis (OA) symptoms. This disease is associated with increased thumb laxity of the CMC joint capsule. As the carpometacarpal joint diminishes, basal joint instability increases, resulting in pain when the individual engages in restricted thumb movement such as forceful pinching (Damen, van der Lei, and Robinson, 1996).

OA of the thumb CMC joint is divided into four different stages. Arthritic degradation and patient treatment are based on the disease progression. Two different classification systems, the Burton system and the Eaton system are utilized to determine the stage of the osteoarthritis. The Burton classification system takes a wider range of information and evidence into account to determine what stage the patient is in while the Eaton classification system is based solely on

radiographic evidence (Matullo et. al., 2007). A table summarizing the description of Stages I-IV based on both the Burton and Eaton classification systems is shown below in Table 2.

Table 2: Stages of thumb CMC osteoarthritis (Koff, Ugwonali, Strauch, Rossenwasser, Ateshian, and Mow 2003, Young, 2004, and Matullo et. al., 2007)

Stage	Description
Stage I	Pain, ligamentous laxity, normal or slightly widened TMC joint, mild joint narrowing, no osteophytes present, no subluxation
Stage II	Instability, joint narrowing (less than 2 mm) at the TMC joint, osteophytes being to appear, movement towards the metacarpophalangeal joint, mild subluxation
Stage III	Continued joint narrowing (more than 2 mm), large osteophytes, cysts and sclerosis beginning moderate subluxation, involvement of the scaphortrapezial joint or other surrounding joints
Stage IV	Stage II or III with degenerative changes at the metacarpophalangeal joint, cystic and sclerotic subchondral bone changes from osteophyte formation, CMC joint becomes fixed

A key indicator of the disease is the degradation of cartilage layers in the CMC joint. Significant soft tissue and skeletal pathology has found to be present in up to 75% of diagnosed patients (Tytherleigh-Strong, Hampton, and McCullough, 1999). Injury in the thumb CMC joint is normally attributed to repetitive daily tasks that create stress on the joint. High local stresses that result from repetitive, forceful gripping and pinching motions can slowly degrade cartilage layers. These stresses typically occur in three planes of movements (Figure 4): opposition, flexion-extension, and abduction-adduction (Matullo et. al., 2007).

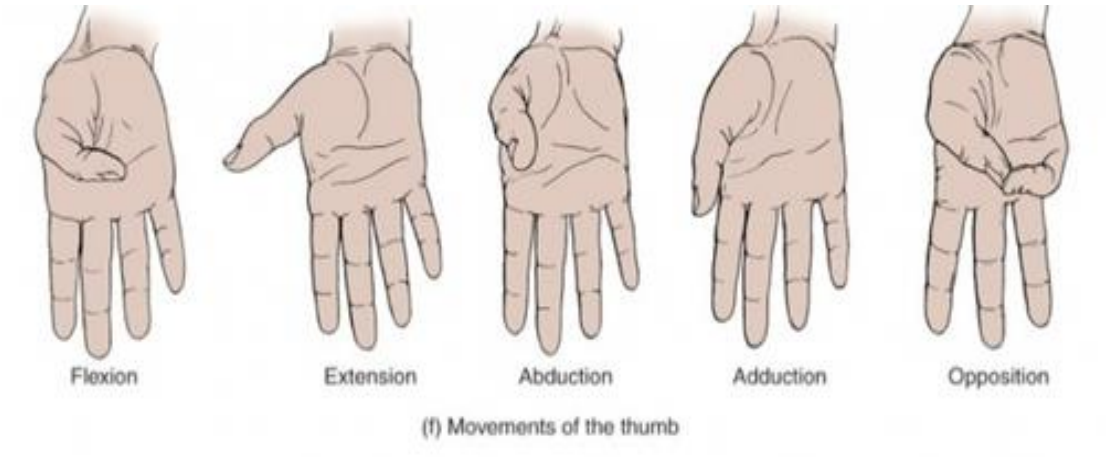


Figure 4: Planes of movements in the hand <http://morphopedics.wikidot.com/scaphoid-fractures>

Joints also experience a higher, incongruent force to a normal load applied on the thumb surface. A 1 kg load applied at the tip of the thumb is equivalent to a 12 kg force at the CMC joint (Young, 2004). Rotational motions increase this force dramatically. Simple activities such as ringing out a towel can produce a force up to 120 kg. Joint incongruity and ligamentous laxity are also secondary causes of the disease. When bony constraint lacks, strong ligament support is needed to optimize the joints stability (Tytherleigh-Strong et. al., 1999). When the ligament itself becomes incompetent, dorsal translation of the metacarpal base may occur thus increasing the rate of cartilage degradation. Issues with the CMC joint are uncommon in traumatic injuries. Some problems with the thumb CMC joint are reported when there are fractures to the hand that involve joint surfaces (Klenner, Towfigh, and Klenner, 2014).

Disease prominence has been correlated to an increase in age. OA is particularly present in elderly patients, with an estimated 70-90% of both men and women over 75 experiencing some form of the disease. However, there is also a younger group of patients between the ages of 20-30 (Matullo et. al., 2007). One study found that although 49.7% of patients were 65 years of age or older, 7.3% were between the ages of 18 and 44. In addition, 1 out of every 250 children in the United States has reported suffering from arthritis (Barbour et. al., 2013). While OA

affects both men and women, investigative studies and other statistics show that women, postmenopausal women in particular, are more likely to be affected by the disease. Recent studies show that arthritis has a 6% prevalence in men ages 55 to 64, but a 25% prevalence in postmenopausal women (Young, 2004). Between 28% and 55% of these patients complain of debilitating thumb pain. Similar statistics state that approximately 25% of women and 8% of men have "radiographic evidence" of joint degradation (Matullo et. al., 2007).

A study conducted with patients 40-94 years analyzed the prevalence of osteoarthritis in the hand in multiple locations including the thumb CMC. Participants in study broken into five age groups (40-49, 50-59, 60-69, 70-79, 80+). The results of this study showed that 20.5% of both men and women had confirmed radiographic OA. Of those with confirmed OA, 19.7% were men and 20.9% were women (Wilder, Barrett, and Farina, 2006). This affirms that women are more likely to be affected by OA, particularly in the thumb CMC joint. Prevalence consistently increased with age for both genders. Surprisingly, men were almost twice as likely as women in the 40-49 age category to have prevalence of thumb CMC osteoarthritis. This disputes some other reported statistics. However, women were more likely to have thumb CMC OA in every other age grouping in the study (Wilder et. al., 2006).

The reasons for this discrepancy are not completely understood by researchers, although several theories exist. Women are known to have a smaller trapezium in relation to their metacarpal base as well as a flatter trapezial articular surface. The less congruent CMC joints create smaller contact areas that lead to higher stress for similar daily activities. Women have also been found to have a 20% thinner cartilage layer (Young, 2004). Recent studies have further indicated that hormonal differences between men and women could play a factor. Another study explores the effects of using hormone replacement therapy (HRT) to combat onset of OA in

menopausal and postmenopausal women. While this may not have direct implications for use on the thumb CMC joint, the use of HRT was somewhat effective for use on for OA in the knee. The results of the study indicated "important implications" for further research on the onset of OA (Spector, Nandra, Hart, and Doyle, 1997).

Arthritis follows a pattern of degradation that can be translated to distinct stages of clinical diagnosis. A physician will complete an examination for arthritis following a patient's complaint of thumb pain. In a majority of cases, a prominence along the dorsal section of the CMC joint, also known as a shoulder sign, is physically present on the patient's hand (Koff, Ugwonali, Strauch, Rosenwasser, Ateshian, and Mow, 2003). This is due to the joints subluxation, as well as observable osteophyte formation and measurable hypertension in motion. Upon compression, an inflicted individual will feel discomfort directly over the volar radial aspect of the CMC joint. Several other tests are observed in clinical practice including the torque test, TMC stress test, and compression grind test. These can be completed in addition to radiographic evaluation for further assurance of the disease staging. Typically taken in the Robert's hyperpronated anteroposterior, or more commonly known Robert's view, the observed degree of ligamentous laxity is used as a proportional determination to the amount of radial subluxation at the joint (Young, 2004).

2.3 Surgical Solutions

Currently those afflicted with thumb CMC arthritis can either undergo surgical or nonsurgical procedures to treat the pain and discomfort accompanied by the arthritis. When patients with severe cases of the arthritis have difficulty physically moving their thumb or have severe pain, surgery is the most viable treatment. Three most common surgeries to treat thumb carpometacarpal arthritis include: Trapeziectomy with hematoma distraction arthroplasty,

ligament reconstruction tendon interposition (LRTI), and hemitrapeziectomy with osteochondral allograft (Park, Lichtman, Christian, Weintrau, Chang, Hentz, Ladd, and Yao, 2008).

All three surgical procedures listed involve the removal of the trapezium bone. The extraction of the bone leaves a large absence in the hand that can cause dislocation of the thumb CMC joint altogether. All three surgeries prevent this dislocation from occurring, all the while attempting to restore function of the joint and alleviate pain. In a trapeziectomy with hematoma distraction arthroplasty procedure, a K-Wire is inserted into the first metacarpal. The subsequent fibrosis and hematoma formation fills the trapezial absence, stabilizing the joint. Those that undergo this surgical procedure have to keep the thumb completely immobile for weeks following the surgery. In a LRTI procedure, the void of the trapezium is filled by repositioning the abductor pollicis longus, the flexor carpi radialis, or the palmaris longus. While this surgical technique restores minor functions of the joint, pinch strength of the joint can decrease significantly. The hemitrapeziectomy with osteochondral allograft inserts either a "costochondral interposition graft" or a graft made out of synthetic material to fill the trapezial void. This can potentially restore function of the joint, but grafts made of synthetic materials can be hazardous to the patient because they can break and fragments can cause inflammation of the synovial membrane. The inflammation can therefore cause destruction of the joint (Park et. al., 2008).

2.3.1 Anthrex – TightRope®

Although originally applied as an alternative surgical technique following failed implant arthroplasty, suspension arthroplasty is presently employed as the primary treatment for CMC osteoarthritis (Melville, Taljanovic, Scalcione, Eble, Gimber, DeSilva, and Shepard, 2015). Following trapeziectomy, an artificial tightrope suspension device is secured with fasteners at the thumb metacarpal base and second metacarpal shaft. This procedure is considered advantageous

by many in the medical community because of its relative ease, removal of the APL deforming forces, and preservation of the FCR (Yao and Lashgari, 2014). The technique further allows the physician to decrease operative time as well as reduce the risk of surgical complications related to autologous tendon harvesting.

Surgical utilization of the Mini TightRope®, in conjugation with biological repair, has asserted itself as a unique means to stabilize the thumb metacarpal after a trapezial resection for OA treatment (Melville et. al., 2015). Successful application as an adjunct and stabilizer in CMC instability for the device has also been documented in cases of revision with proximal migration after tendon reconstruction. The success of the repair kit lies in its use of a pulley principle as its primary basis. Device suspension reduces the thumb and index metacarpals into proper relationship and is maintained through healing (Yao and Lashgari, 2014). Successful Tightrope surgery has allowed patients to reverse years of osteoarthritic damage; a feat unheard of in the CMC surgical realm (Dowlatshahi, 2014). The splint designed by the team will utilize a similar concept to that of the Tightrope surgical procedure. Localized pressure rather than suspension between the metacarpals will be used to prevent joint subluxation and promote joint healing replicative of this employed medical procedure.

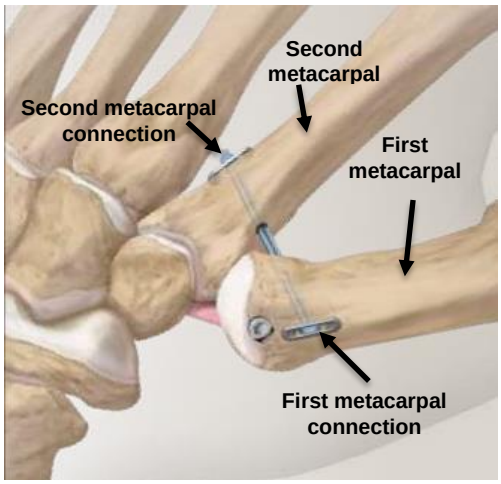


Figure 5: Anthrex TightRope® schematic (Melville et. al., 2015)

2.4 Nonsurgical Solutions

2.4.1 Current Splint Designs

There are a wide variety of nonsurgical methods for treating early thumb CMC joint arthritis that include taking Nonsteroidal Anti-Inflammatory Drugs (NSAIDS), undergoing occupational therapy treatments, corticosteroid injections, and splint use, as the most popular treatments. NSAIDS are typically over the counter medications (aspirin, ibuprofen, and naproxen) that work to relieve both the inflammation and the pain in the joint (Kit and White, 2013). The effects of these medications are usually short-term, and the patient will have to take the medication every few hours. Those afflicted with arthritis can also work with an occupational therapist to strengthen the joint. Corticosteroid injections are more of a long-term treatment for inflammation, where a steroidal anti-inflammatory is injected into the point of inflammation. The patient can undergo shots every few months instead of every few hours. To further treat arthritis pain, splints can be used to keep the joint immobile, preventing pain and alleviating inflammation to help the patient complete daily tasks.

On the market today, multiple splint designs are manufactured to treat thumb CMC joint arthritis. The *Comfort Cool® Thumb CMC splint* is made of neoprene supports that wrap around the thumb and provide compression (North Coast Medical, 2014). While the splint prevents mobility, it also restricts the thumb's functionality and restricts motion of other parts of the hand due to its bulky wrist-wrap design. Restricting motion of other parts of the hand can deteriorate the strength of the patient's hand. The *MedSpec CMC Thumb Support* is a splint that uses an elastic strap to secure around the base of the thumb to stabilize the CMC joint and provide compression. The elastic material aids in flexibility to retain some functional use of the thumb,

but does not offer the all-around comfort and flexibility the patient needs (The Brace Shop, 2014). The main advantages and disadvantages of these splints can be seen below in Table 3.

Table 3: Summary of current splints on the market

Splint	Materials	Function	Main Advantage	Main Disadvantage	Stabilization Technique
The Comfort Cool® Thumb CMC Splint	Neoprene with terrycloth lining	Support wraps around thumb and provides compression	Compression to prevent arthritic swelling and lining to keep patient's hand cool	Restricts entire thumb functionality	Neoprene support/ glove design
The MedSpec CMC Thumb Support	Elastic Material with internal padding	Elastic strap with padding provides compression	Compression to prevent arthritic swelling and padding for comfort	Restricts thumb functionality	Elastic strap wrapped around thumb and wrist

2.4.2 Splint Material Analysis

In order to provide a splinting device that fits the parameters defined by the objectives, constraints, and functions, the properties of potential materials must be considered. The team's advisor highly recommended silicone as a splinting material. Silicone is a water resistant material that retains its resistance at all temperatures, allowing the patient to keep their splint on while doing tasks like washing dishes. Silicone is also flame retardant, flexible, and offers enough stability without too much stiffness (Kulik, Boiko, Bardakhavanoc, Park, Chun, and Lee, 2010). These properties allow safety of the splint in different temperatures as well as offering enough stability of the joint while still allowing for proper range of motion of the thumb. Silicone is a soft, comfortable material as well, which is desirable for the patient's own comfort, as splints on the market today are too stiff and uncomfortable.

Thermoplastics are also considered as splinting materials for their versatile properties. Thermoplastics are materials that melt when heated, but as they are cooled they set form. Thermoplastics retain their form, remain firm, and are also flexible after molded, making the

material hard to break, but able to bend. They are a durable material, giving splints made of thermoplastics the ability to survive long-term wear and not fall apart easily (Colditz and Koekebakker, 2010).

Plaster is a bandaging material used by doctors to set broken bones or used in common splinting procedures. Plaster typically comes in the form of a tape made of interwoven fiberglass with a polyurethane resin for wrapping purposes as well as layering to reinforce splints or casts, giving the material moldable properties. When exposed to water or humidity, the plaster tapes produce a chemical reaction that solidifies the material. After exposure to water, the tape dries quickly, resulting in a rigid structure. Plastics or silicone can easily attach to plaster because of its strong binding properties, allowing plaster to be a versatile material: can be used for either a splint lining or the primary splinting material. In a particular study, patients using the plaster tape in their splinting device said that their splints were lightweight and comfortable. Limitations in plaster designs include the removal of the plaster splint if the patient will be in contact with water because the plaster cannot be re-wet (Mazon, Ulson, Davitt, Laurito, Jacob, and von Glehn, 1996).

Neoprene is a soft, elastic material that is used in many splints on the market today. Neoprene is widely used because it is a comfortable material, allowing for soft compression, flexibility, and stability in its applications and it is less expensive than many materials (Mochel and Nichols, 1951). In the case by Becker et al, when used for TMC arthritis splints, using neoprene improved the pinch strength, grip strength, and pain of 37 of the 40 patients assessed (Becker, Bot, Curley, Jupiter, and Ring, 2013). Upon property assessment of neoprene, it was concluded (based on testing) that neoprene has a close to uniform molecular weight distribution

that decreases elastic deformation which means that upon stretching or deformation, neoprene can return back to its original form (Mochel and Nichols, 1951).

Although splinting is a common nonsurgical treatment option, little research has been completed on stabilizing the CMC joint. Today, splint therapy is accomplished in coordination with anti-inflammatory drugs in addition to steroid and thumb strengthening injections (Colditz, 2000). A number of issues, however, remain with the current design models and subsequent patient treatment. Immobilizing the first metacarpal can prove difficult without decreasing proximal joint range of motion. Molding the splint circumferentially around the CMC joint can also create difficulty. Although smaller implants are preferred to allow daily usage in patients, they are difficult to accurately produce. This often results in poor patient compliance when the individual is forced to wear a larger, more restricting device. Immobilization robs the hand of valuable flexion, extension, and radial and ulnar joint deviation (Sillem, 2009). The restricted movement can also place greater demands on the patient's wrist by requiring a greater motion range for the individual's proximal joints making subsequent tasks more demanding. Long-standing issues regarding the stabilization of the CMC joint have lead researchers to question what factors determine the success of splint immobilization. Successful splint stabilization has since been separated into a number of design requirements. These include but are not limited to: accurate pattern printing, precise positioning of the CMC joint during the molding process, accurate molding such that the distal end of the first metacarpal is supported, and a high attention to detail so that pressure is well distributed in the splint-joint system (Colditz, 2000).

2.4.3 Splint Manufacturing Processes

2.4.3.1 Accurate pattern production

In order to successfully immobilize the first metacarpal in a palmar abduction position, the splint pattern must accommodate the desired metacarpal positioning. During palmar abduction, the metacarpal rests on a 90-degree angle to plane of the palm. The large angle allows accurate molding across the fist metacarpal when the thumb is correctly positioned. Therapists, however, are frequently given designs that display the flanges, or flaps of the splint, at inadequate angles. Incorrectly patterned splints can result in poor placement of the first metacarpal, allowing the splint to supply insufficient support (Colditz, 2000).

2.4.3.2 Precise Positioning of the CMC Joint

Before the manufacturing process occurs, the hand must be measured and documented through a detailed sketch. By first outlining the dorsum of the inflicted hand onto paper, lines can be used to mark out the proximal joints of the carpometacarpal. At this point the drawing is cut and traced on a thermoplastic slab. Shears or other cutting tools are used to remove the slab design before being placed in hot water to heat. After the slab appears transparent, it is cooled to room temperature before molding to avoid damaging the patient's skin during the molding process. At this time, the patient is instructed to stabilize their elbow on a hard surface while simultaneously touching the tip of their thumb to the tip of their index finger. Positioning the hand in this manner maintains that the patient will comfortably be able to reach their thumb to their fingertips while wearing the splint. However, this must be performed in a relaxed position rather than a pinching motion to ensure that the thenar muscles are not contracted while the splint is being molded. This would result in excessive internal space within the splint, decreasing

stabilization of the muscles required to compensate for the carpometacarpal joint while the splint is worn (Colditz, 2000).

2.4.3.3 Molding the Support of the First Metacarpal

As the thermoplastic material begins to cool and set into proper positioning, a gentle pressure is applied palmarly over the thenar muscles and distally to the proximal end of the first metacarpal. In order to prevent the first metacarpal from moving forward, the therapist should compress the thenar muscles with the splint material. This must be done with enough care to not push the metacarpal into over extension. This would restrict the motion of their patient by making a finger to tip pinch increasingly difficult. The palmar edge of the splint must also be cared for in such a way that placement is well below the CMC joint to allow for full metacarpophalangeal flexion. Observation of splint length is crucial during this period. The splint should be long enough to stabilize the distal end of the metacarpal without impeding necessary metacarpophalangeal flexion (Colditz, 2000).

Adequate pressure during the molding process is detrimental to splint success. The goal of the therapist is to ensure that the splint fits conformably around the base of the thumb, not to fix the subluxation at the metacarpal base. The prevention of motion by the splint at this location, not joint subluxation, reduces the arthritic pain during movement. Attempts made to reduce subluxation through pressure have been shown to increase pain in the inflicted individual. This trend can be witnessed in those patients with severely dislocated CMC joints. Individuals such as these who show minimal joint alignment can still find alleviation of pain if motion is restricted (Colditz, 2000).

Following completion of the molding process, the straps are attached by the use of a rivet on the dorsoradial splint area. Bonding the two straps together without the use of a rivet is a

secondary option left to the therapist's discursion. After the final splint is completed, the patient is instructed to compress the splint fully on the thumb so that it experiences full contact area over the thenar. This further ensures that the splint will retain its fitted shape without becoming loose and decreasing its stabilization ability (Colditz, 2000).

2.4.3.4 Distribution of Pressure

Three areas must be taken into consideration during the molding process to ensure that the splint remains comfortable to the patient. These include: the dorsoradial area of the first metacarpal, the first web space, and the dorsum of the second metacarpal (Colditz, 2000). The dorsoradial aspect of the first metacarpal is frequently swollen from joint subluxation and osteophyte formation. This can lead to discomfort if pressure is exerted from the splint's edge. Therefore, splint length must be completed in a way that allows the metacarpal to be covered without limiting wrist motion. If the patient's joint shows significant subluxation or dislocation, any induced pressure will be poorly handled and additional gel padding may be required.

The splint must be carefully handled in the molding process so it is not pulled overly tight across the first web space. Radial deviation of the metacarpophalangeal joint and index finger extension will allow the web skin to rub uncomfortably against the splint. As a preventative measure, the splint material should be rolled in a circular shape prior to heating. Rolling allows the splint to maintain strength while decreasing the bulkiness of the material in the web space. As the patient holds their instructed position the material is placed through the web space. The curled material is then allowed to lift as it hardens so the skin and material are not forced to rub against one another.

The section of the splint bordering the ulnar ends as the material starts to dorsally wrap. If the border over extends dorsally, applying and removing the splint can become difficult for the

patient (Colditz, 2000). The radial border should end just before the dorsal area of the second metacarpal. If the strap is pulled too firmly across this area, the radial edge can be pushed to place pressure on the second metacarpal resulting in pain for the patient. Attention to possible discomfort issues such as this assist in improving patient compliance throughout splint therapy.

Splint construction through the described manufacturing methods can also be completed with alternative materials. Materials such as epoxies, metals, or resins can replace the thermoplastic. In a majority of cases, there are various methods of construction for a single splint design. Alterations and modifications to the splint can also be performed. Many of the methods can be modified or emitted depending on the desired output.

2.5 Patents

A number of patents from literature will aid in future design by leading to the development of a new, unique design. Current patented CMC splint designs on the market for the joint, hand, and wrist provide additional insight into current solutions. Some patents of particular interest are explored in this section. With aspects and inspiration from these designs, the team will design a new splint that will comfortably stabilize the thumb CMC joint and remove pain effectively.

2.5.1 U.S. Patent Number: 6496984 - Fingertip flexor glove (Chow, 2001)

This CMC joint splint has an open sleeve at one end that fits over the user's hand and extends over the wrist/arm (Figure 6). The distal end of the sleeve has spaced openings for the fingers of the user. A drawback of this design is that the distal openings do not account for different sized fingers or hands.

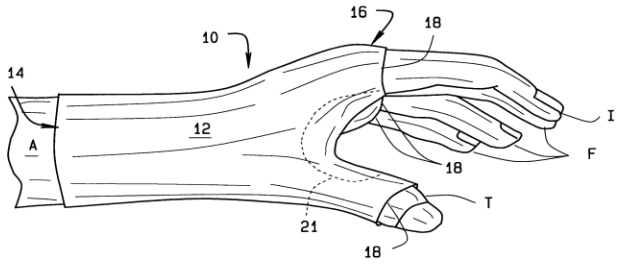


FIG. 1

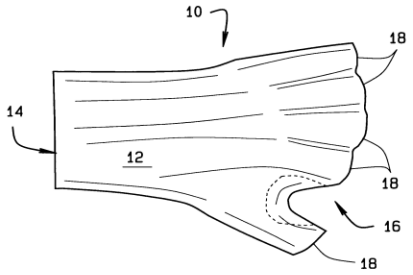


FIG. 2

Figure 6: CMC Joint Splint (Chow, 2001)

Although it does not account for different sized fingers, the design is easy to put on the hand because it slides right on. This gives the splint design an advantage over designs with straps because patients commonly get straps caught on pieces of clothing or in bed sheets when trying to sleep. The design features curved pads between the patient's thumb and index finger. A pro of this design is that the material still allows for use of the hand; it can be worn during rehabilitation and daily activity. A few more pros of the design are that it is lightweight, skin colored, and washable.

2.5.2 U.S. Patent Number: 7887497 - Non-immobilizing thumb brace (Weber, 2008)

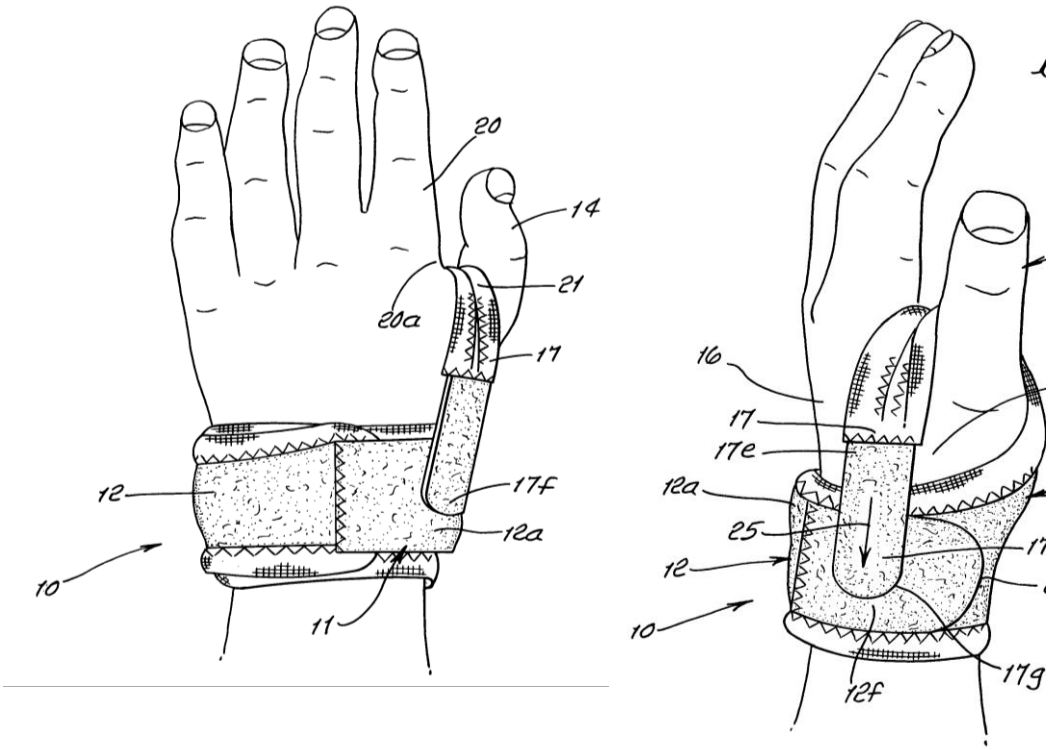


Figure 7: Non-Immobilizing Thumb Brace (Weber, 2008)

This splint design is flexible and has an anchor portion wrapping around the wrist to support it (Figure 7). The thumb, palm, and dorsum are freely offset. The web space and forefinger are separated by a support extension. The securement is for the positioning of the thumb and thumb CMC joint. The splint can be used for arthritis or sprain treatment. The design maximizes bracing comfort, does not cover the thumb, and pressurizes the CMC joint. A drawback of this design is it is bulky and limits motion of the wrist and hand. It also is very noticeable and not very aesthetically pleasing.

2.5.3 U.S. Patent Number: 6702772 - Thumb CMC restriction splint (Colditz, 2004)

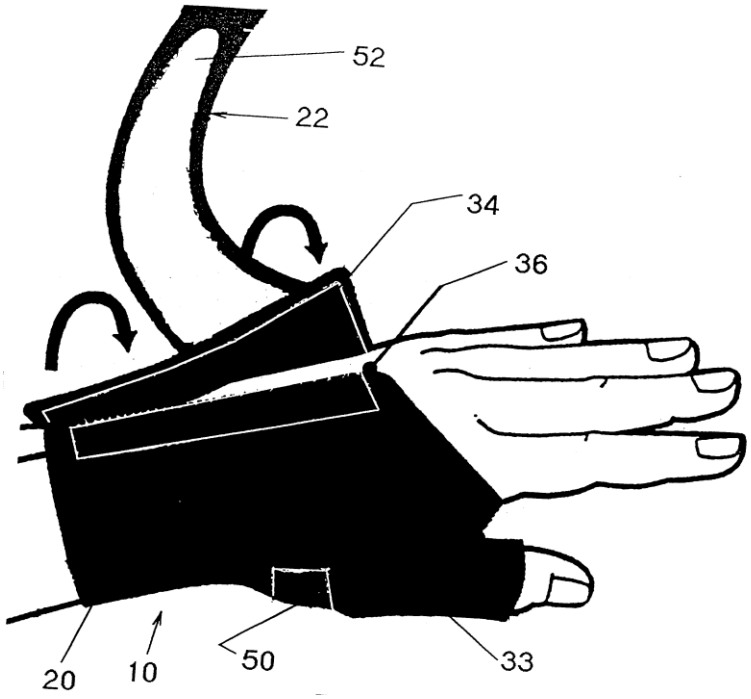


Figure 8: Thumb CMC Restriction Splint (Colditz, 2004)

This dynamic splint reduces joint pain without loss of hand functionality. The splint comprises of an adjustable wristband that wraps around and puts pressure on the wrist securing it in place (Figure 8). The design is made of a soft material called neoprene laminated with cloth knit. The dorsal flap overlies the bottom and side of the hand splint. The tensioning strap attaches at one end of the splint to the top of the surface of the wristband and tensions over the dorsal flap to keep the wrist secure. The strap extends around the capsule and extends over the thumb and first finger web tensioning the distal end. The tensioning strap also provides peripheral support. There is no loss of thumb or joint functionality. A drawback of this design is it is not very aesthetically pleasing and the strap can get caught on the user's clothing.

2.5.4 U.S. Patent Number: 8784348 - Splint assembly for positioning of the hand (Farrell, 2014)

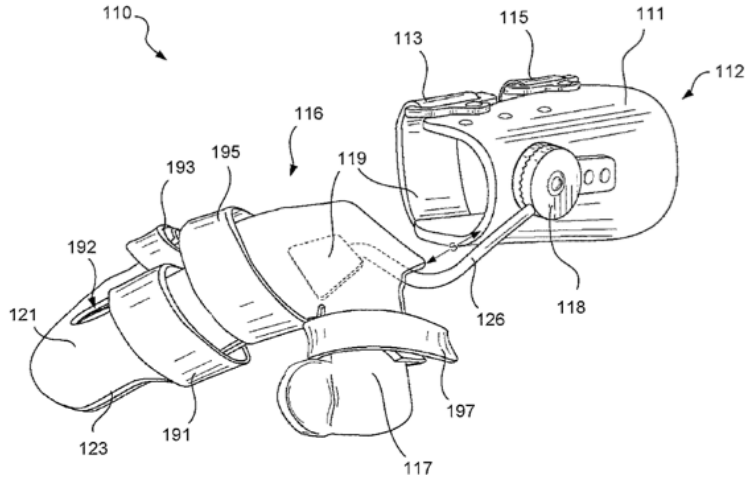


Figure 9: Splint assembly for positioning of the hand (Farrell, 2014)

This design consists of a forearm and hand piece. It is used for specific positioning of the hand and is intended to keep the hand stabilized (Figure 9). A drawback of this design is that it is not used for thumb CMC joint stability. It is used for a condition caused hemiparesis, which is a neurological injury in which the arm or hand no longer functions correctly and the patient has less control over the extremities. The design forces the hand to stay in the outstretched position, is very rigid, and offers good palm support. The design is also very bulky.

2.5.5 U.S. Patent Number: 8328743 - Dynamic Hand Splint (Farrell, 2009)

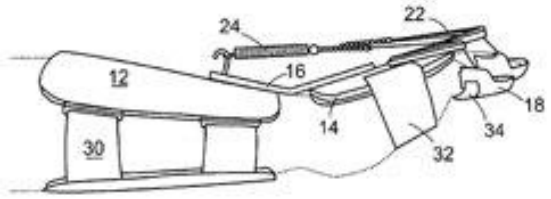


Figure 10: Dynamic Hand Splint (Farrell, 2009)

This wrist and hand splint is another bulky, rigid design. The splint exercises the hand by providing resistance to the hand's fingers and thumb (Figure 10). The hand is held in an

extended position to provide resistance for the hand muscles to work against. The thumb also has its own tensioner for exercise. The design prevents the fingers from moving into a gripping position. This design is unique because it aims to strengthen the hand, fingers, and wrist while at the same time stabilizing it. Again, it is not aesthetically pleasing and is very bulky.

2.6 FEA Modeling

Predicting the mechanical response of the carpometacarpal joint can serve as a major clinical importance as a planning and analysis tool to assist orthopedists in treatment planning. Improved characterization of the CMC joint as it relates to anatomy, function, and genetic influences will expand and clarify future treatments for osteoarthritis. Greater biomechanical understanding can also help surgeons determine whether a surgical or non-surgical treatment is preferable, and when surgery is required, to choose the optimal procedure (Ladd, Weiss, Crisco, Hagert, Wolf, Glickel, and Zao, 2013).

Predicting the joint's mechanical response is presently limited since it is dependent on the geometric complexity of the compromising bones, their distinct cortical and trabecular internal regions, the anisotropic and inhomogeneous material properties that vary among individuals, and the inaccessibility to the living bone for validation (Yosibash, Padan, Joskowicz, and Milgrom, 2007). Thus, as an initial step it is desirable to develop an analysis tool capable of simulating the mechanical response of the joint for individuals.

Finite element analysis (FEA) for orthopedic application has been utilized for over three decades. Although bone is a complex biological tissue, the use of FEA is attractive because at the micro level it exhibits elastic linear behavior for loads in the normal range for daily activities (Ladd et. al., 2013). Further advantages of the three-dimensional FEA model include the ability to perform reliable simulation of patient-specific bones when combined with quantitative

computer tomography (QCT) and estimate deflections or internal material stresses and strains (Yosibash et. al., 2007).

2.6.1 Currently Available FEA Software

There are several different software options available to accomplish the development of the FEA model of the CMC joint. First is Mimics®, which is a medical image processing software that can be used to convert CT scans into 3D models in the form of stereolithography files (.stl files). It can also be used for MRI, micro-CT, CBCT, and 3D ultrasound images, and can perform 2D or 3D measurements. The files it produces can either be exported for use in other software or used in a different Mimics® software called 3-matic. This software can prepare the model for FEA analysis or can be used to design medical devices such as patient-specific implants or surgical guides and prepare them for FEA analysis as well.

Once the medical image has been converted into a 3D model, a mesh must be created in order to prepare it for analysis using FEA software. However, many FEA software options incorporate this step into the overall FEA process. There are three major FEA programs that are the most viable options for the development of a CMC joint FEA model: Abaqus™, ANSYS, and FEBio. Abaqus™ has a wide variety of software options that are tailored to certain situations or types of analyses. It is best used when accurate results are needed for static or low-speed dynamic problems. In a single simulation it can analyze stresses in both time and frequency domains. CAD models can be imported for meshing and analysis, and the software provides many visualization options such as graphs or color-coded models to enhance interpretation or communication of the results from any type of analysis (Dassault Systemes, 2014).

ANSYS is a very good tool for understanding how simulated loads and environments will affect a model in the real world. Like Abaqus™, ANSYS also has a wide variety of software

options ranging from mechanical and structural analyses to fluid analyses, electrical analyses and academic resources. Each product contains both CAD import tools and meshing tools that can be used to import CAD models and subsequently develop a mesh of the model. The meshing tools allow for a variety of different meshes that can be applied to a variety of situations. This software can also represent many different material behaviors and can model many mechanical behaviors. The analysis results can be modeled as vector plots or contours, and slicing tools can be used to see detailed results of the inside of the model. These results can also be exported to be used in further calculations or analyses (ANSYS, INC., 2014).

Finally, FEBio is a software that was designed specifically for biomechanical applications. It solves 3D problems through a variety of analysis types including rigid body mechanics, interstitial growth mechanics, nonlinear elasticity and viscoelasticity, multiphasic mechanics, and heat conduction. The downside to this software is that it by itself cannot generate meshes for any models – the input files must first be preprocessed by meshing software before they can be imported into FEBio. However, there are several other software options associated with FEBio that can be used to prepare files for importation and to analyze the results from the FE analysis. The first, called PreView, essentially prepares models for use in FEBio. It can specify both material properties and boundary conditions, and can be used with models of varying complexity. The second, called PostView, can develop several different types of plots to provide a graphical interface for the visualization of the FE analysis results. These plots can be used to visualize not only typical stresses and strains, but also displacements and velocities (FEBio, 2014).

2.6.2 Previous MQP FEA Research

In 2013 a group of students from WPI completed a Major Qualifying Project entitled "Digitone: A Novel Soccer Goalkeeping Device" advised by Dr. Dowlatshahi, a surgeon at UMass Medical School. This project focused on the thumb metacarpophalangeal (MPJ) joint and the prevention of injuries that occur as a result of goalkeeping in soccer. The main goal of this project was to develop an FEA model of the MPJ joint and design a device that could protect this joint from injury. The process that this project team used to develop the FEA model of the MPJ joint is the same process that will be used to develop the FEA model of the CMC joint. First, the team obtained CT scans from the National Institute of Health (NIH) database after the team determined that MRI scans were not of an appropriate quality for the development of a 3D model. They then used 3D Slicer™ 4.2.1 and DeVIDE™ 12.2.7 to create stereolithography (.stl) files of the CT scans of the joint. These files were then imported into a meshing program (IA-FEMesh™) that created a solid mesh model of the scans to be used in the finite element analysis. The team then imported this mesh into FEA software called Abaqus™ (Polito et. al., 2013).

Once the file was imported, the team needed to assign material properties to the bone model. These material properties were determined from extensive research into the properties of both cancellous and cortical bone. Since material properties are not uniform across the bone, the team had to take that into consideration when assigning material properties. The distribution of cancellous bone versus cortical bone was determined from the CT scan used to develop the 3D model. The team then had to manually add the necessary soft tissue (i.e. ligaments, tendons, or muscles) by designating the insertion points and specifying their respective material properties, which were again determined through extensive research. After all necessary soft tissues were incorporated into the model the team had to specify the boundary conditions and constraints of

the model to ensure the joint behaved as it does in normal physiological conditions. Finally, the team needed to create the necessary steps for force simulation before the analysis could be run. The team decided to use two steps: one for preloading to ensure the bones in the joint were in contact before the real load was applied, and one for the real applied load (Polito et. al., 2013).

2.7 Prototype Testing and Evaluation

Previous studies and experiments have used a variety of means to validate and test their designs. Biomechanics-related manual calculations, mechanical testing methods, and patient surveying techniques were researched to understand different experimental methods and procedures associated with splint prototyping and testing.

2.7.1 Supporting Manual Calculations

It was important to development manual calculations and to analyze mechanical forces and moments to understand the function and anatomy of the thumb CMC joint. Several previous studies were completed that outlined the general process for biomechanically analyzing the joints in the hand. The first resulted in a workable, three-dimensional model of the hand that can be used to perform motion and force analyses for either a normal or a pathological hand. The authors first took 10 fresh cadaver specimens and inserted markers into the tendons and muscles at both the proximal and distal ends of each joint. They then performed several x-rays in order to accurately analyze the tendon locations for each joint.

Once all anatomical locations were determined, the authors developed six Cartesian coordinate systems – two at each joint. The primary coordinate systems were placed at the approximate center of rotation of the metacarpal and phalangeal heads, while the secondary systems were translations of the primary systems to the centers of the articular surfaces. The x-axes are projected along either the metacarpal or phalangeal shafts (depending on the location of

the system), the y-axes are projected dorsally, and the z-axes are projected radially and dorsally for the right and left hands respectively. The creation of these coordinate systems allowed for the accurate placement and measurement of the tendons in three-dimensional space.

The tendons were described in terms of force potential (the contribution of the tendon in generating joint constraint forces expressed in terms of the directional cosine in respect to the distal system) and moment potential (the functional moment provided by the tendon to rotate the joint in three mutually perpendicular directions, expressed as the moment arm in regards to the joint center and in the direction of each of the coordinate axes in the distal system). The authors then combined these principles using static force analysis during certain isometric hand positions. The authors summed both the forces and the moments and set them each equal to zero to provide a system of equations to solve for the unknown tendon forces and joint constraint forces and moments (Figure 11).

Force equations

$$\begin{aligned} \Sigma \alpha_i F_i + C_x + R_x &= 0 \\ \Sigma \beta_i F_i + C_y + R_y &= 0 \\ \Sigma \gamma_i F_i + C_z + R_z &= 0 \end{aligned} \qquad (1)$$

Moment equations

$$\begin{aligned} \Sigma a_i F_i + M_x + T_x &= 0 \\ \Sigma b_i F_i + M_y + T_y &= 0 \\ \Sigma c_i F_i + M_z + T_z &= 0, \end{aligned} \qquad (2)$$

where

$\alpha_i, \beta_i, \gamma_i$ = force potential parameters,
a_i, b_i, c_i = moment potential parameters,
C_x, C_y, C_z = unknown joint constraint forces,
M_x, M_y, M_z = unknown joint constraint moments,
F_i = unknown tendon or muscle forces,
R_x, R_y, R_z = externally applied forces, and
T_x, T_y, T_z = externally applied moments.

Figure 11: The force and moment equations used to find unknown tendon forces (An, Chao, Cooney, Linscheid, 1979)

For these calculations, each tendon was represented as a line, and simplifications were performed such that the force parameters were represented as a unit force vector and the moment arm was subsequently altered so the moment arm and the unit force vector were orthogonal. These simplifications were then used to calculate the coordinate points for each tendon. Ultimately, the work of these authors provided a three-dimensional mathematical model of the human hand that could be used for both motion and force analysis of the hand (An, Chao, Cooney, and Linscheid, 1979).

The second study was performed by Chao, Opgrande and Axmear in 1976 and resulted in an increased understanding of the functional anatomy of the hand, the pathological deformities involving the hand, and the basic requirements that need to be considered when designing prosthetic finger joints. The functional anatomy was determined by studying the tendon and joint forces during isometric hand activities, and the increased understanding thereof provided a basis for the development of proper concepts and techniques for both therapeutic rehabilitation and surgical treatment.

The overall objective of the study was to present a three-dimensional analytical method for determining the forces in various finger joints during several hand functions. To do this, the authors first needed to find the accurate locations of each joint and its surrounding tendons. As in the previous study, the authors in this study placed markers into each tendon and muscle and then exposed each cadaver hand to biplanar X-rays. They also developed six Cartesian coordinate systems to more easily specify the location and orientation of each tendon. Each joint had a primary and secondary coordinate system to provide an accurate description of the tendon location without having to take into account the angulation of the joint. Rotational and

translational transformations then defined the relationship between the proximal coordinate system and the distal coordinate system (Figure 12).

$$\begin{bmatrix} X' \\ Y' \\ Z' \end{bmatrix} = \begin{bmatrix} l_{x'x} & l_{x'y} & l_{x'z} \\ l_{y'x} & l_{y'y} & l_{y'z} \\ l_{z'x} & l_{z'y} & l_{z'z} \end{bmatrix} \begin{bmatrix} X \\ Y \\ Z \end{bmatrix} + \begin{bmatrix} X'_0 \\ Y'_0 \\ Z'_0 \end{bmatrix} \quad (1)$$

in which,

X', Y', Z' = coordinates of a tendon point measured with respect to the distal system,

X, Y, Z = coordinates of the same point measured with respect to the proximal system,

X'_0, Y'_0, Z'_0 = coordinates of the center of the proximal system as expressed in the distal system, and

$l_{x'x}$ = directional cosine of the angle between the X' and X axes of the distal and proximal systems, respectively.

Figure 12: The general transformation equation relating the proximal system to the distal system (Chao, Opgrande, & Axmear, 1976)

The authors then used directional cosines measured from the biplanar X-rays to express the direction of a tendon as a unit vector as follows:

$$\bar{e}_T = l_T\bar{i}' + m_T\bar{j}' + n_T\bar{k}'$$

where

$$\begin{aligned} l_T &= (X'_{DT} - X'_{PT})/L \\ m_T &= (Y'_{DT} - Y'_{PT})/L \\ n_T &= (Z'_{DT} - Z'_{PT})/L \end{aligned} \quad (2)$$

and

$$L = \sqrt{(X'_{DT} - X'_{PT})^2 + (Y'_{DT} - Y'_{PT})^2 + (Z'_{DT} - Z'_{PT})^2}$$

Figure 13: The direction of a tendon T expressed as the unit vector $\bar{e}_T$ (Chao, Opgrande, & Axmear, 1976)

The authors then applied a free-body analysis at each joint, including tendon forces, joint constraint forces, and externally applied forces. The equilibrium equations were expressed in the following form:

$$\bar{F} + \sum_{i=1}^{n} |\bar{T}_i|\bar{e}_i + \sum_{j=1}^{m} |\bar{A}_j|\bar{e}_j = 0 \qquad (5)$$

$$\sum_{i=1}^{n} |\bar{T}_i|(\bar{r}_i \times \bar{e}_i) + \bar{M} + \sum_{j=1}^{m} |\bar{A}_j|(\bar{s}_j \times \bar{e}_j) = 0. \qquad (6)$$

in which,

$\bar{T}_i$ = tendon force vector,
n = number of unknown tendon forces at the joint,
$\bar{e}_i$ = unit vector in the direction $\bar{T}_i$ expressed in the base coordinates of the joint,
$\bar{F}$ = joint constraint force vector,
$\bar{A}_j$ = applied forces in pinch or grasp function,
$\bar{e}_j$ = unit vector in the direction $\bar{A}_j$ expressed in the base coordinates of the joint,
$\bar{r}_i$ = position vector of $\bar{T}_i$ with respect to the base coordinate center,
$\bar{M}$ = constraint moment vector at the joint, and
$\bar{s}_j$ = position vector of $\bar{A}_j$ with respect to the base coordinate center.

Figure 14: Equilibrium equations for the forces and moments at each joint (Chao, Opgrande, & Axmear, 1976)

When combined, the system of equations for all joints was found to be statically indeterminate. To try and simplify the system, the authors eliminated excessive variables through physiological or EMG assessment. However, a system solved in this manner may provide illogical solutions in which the joint-contact force is negative and the tendon force is compressive. Another technique used to solve a similar indeterminate system of equations was linear programming, however the justification for the minimization criterion used in the process is debatable according to the authors. The authors chose to use a much simpler system that used a systematic combination to assume that several of the tendons carried no force. This made the system statically determinate and able to be solved.

The results of this study included several conclusions concerning, for example, the functions of certain tendons as compared to others and the role of certain muscles. These

conclusions are important in understanding not only the functional anatomy of the hand, but also the pathomechanics of finger joint deformity and the minimal load requirements for prosthetic finger design (Chao, Opgrande, and Axmear, 1976).

2.7.2 Mechanical Testing Methods

An Instron® 5544 testing system, which is part of Instron's® 5500 series, was available to complete mechanical testing on device components. The Instron® 5544 is a single column table top model, designed to perform routine mechanical tests including compression, three point bending, four point bending, and torsion. This testing system interfaced with Bluehill® 3 software to supply data from the mechanical testing performed. Compression testing was of particular interest for the purposes of this project. The Instron® 5544 has a maximum load capacity of 200 kgf (2N). The system also has a maximum speed of 1000 mm/min, and a minimum speed of 0.05 mm/min (Instron, 2007). To program the system, a user inputs the designated parameters into the Bluehill® 3 software program. Parameters must be carefully selected to make sure that the desired test will not cause the machine to malfunction or work beyond its designated range.

2.7.3 Patient Surveying Methods

The major objective of evaluative research is to detect a significant differential change in two or more treatment groups exposed to separate interventions. In order to ensure successful detection of such changes, the employed instruments must be considered reliable, valid, and responsive. Recently, the current definitions, criteria, and proposed tools for clinical assessment involved in hand OA have been reviewed allowing physicians to employ a standardized clinical approach to assessing patient cases (Bagis, Sahin, Yapici, Cimen, and Erdogan, 2003). Following the consensus agreement methodology used by the Osteoarthritis Research Society International

(OARSI), several patient survey guidelines have been recognized for their consistent and accurate performance in the clinical setting of OA (Luc, 2008).

Since 1966, patient completed questionnaires designed to evaluate the hand and upper limbs along with related domains have been published. Now utilized on a worldwide scale, a distinction can be made between the more general questionnaires that grossly measure general health and the modern, domain-specific questionnaires that measure specific disease-induced function of a specified body part. Disability over impairment, in such cases, is designed to be focus of the evaluation.

Both the AUSCAN Index and DASH score have been used increasingly as an outcome measure for upper limb pathology. Each has been extensively investigated with respect to its reliability, repeatability, internal consistency, and validity as well as its degree of acceptance in clinical practice (Bellamy, Campbell, Haraoui, Gerecz-Simon, Buchhinder, Hobby, and MacDermid, 2002). For the purpose of the team's clinical testing, a combination of the two surveys was created and distributed to patients. Use of clinically accepted questions ensured that the device provided the desired improvements in the function of the patient's CMC joint.

2.8 Conclusion

Extensive background research was conducted to understand the anatomy of the first metacarpal and the thumb CMC joint. This research provides critical knowledge for understanding the components, actions, and interactions within the thumb CMC joint. Once a foundational understanding of the thumb CMC joint was established, research on thumb CMC OA was conducted. At this point in research, the team was beginning to understand how the anatomy of the thumb CMC joint allowed for different levels of OA. While researching thumb

CMC OA, the team also uncovered a variety of papers, experiments, and studies that conducted similar testing and research on the disease.

Since thumb CMC OA is a prevelant and concerning issue, a variety of surgical and non-surigical solutions have been created and built upon to correct the issue. Surgical solutions are normally seen as a last resort, since they require extensive and costly procedures, long recovery times, and patient inconvenience. Because of this, there is an increased focus on conservative, non-surgical solutions for thumb CMC OA such as splinting.

Many different splints have been created, tested, and patented for thumb CMC OA. Despite all of these so-called solutions, there does not seem to be a clear, obvious splinting solution. The team conducted research on various patented devices to understand what past research focused on, and possibly determine where these devices had failed. Additionally, the team researched different splints and assistive devices sold in drugstores and other retailers. Research on these devices included a manufacturing study and material analysis.

After establishing an understanding of the thumb CMC joint, thumb CMC OA, and current solutions to the disease, the team began investigating tactics to design an improved thumb CMC OA splinting device. The team focused on FEA modeling of the thumb CMC joint. Since there are a variety of FEA programs and software tools available, the team looked into which would be best suited for the purposes of this project. The team also spent time reviewing the past work done by an MQP team working on the metacarpophalageal (MCP) joint. This project also focused on the first metacarpal and used FEA to model specific areas of the thumb.

The team planned to use FEA software to create a model of the thumb CMC joint to better understand the components and functions of the joint. Since the team planned to conceptualize and create a splint prototype, it was important to research different ways of testing

and evaluating the prototype. For these purposes, research was conducted regarding biomechanical manual calculations and mechanical testing methods. Additionally, the team reviewed similar studies that surveyed patients to solicit feedback for the device. This background research prepared the team to move forward and put the project into action.

3. Project Strategy

3.1 Initial Client Statement

The following initial client statement was provided by the client and primary project advisor, Dr. Samandar Dowlatshahi, from the University of Massachusetts (UMass) Medical School:

> "This MQP will study thumb CMC joint biomechanics using Finite Element Analysis and will design a dynamic splinting device that will help stabilize the joint without surgery, hereby relieving pain as well as improving the overall function and longevity of the joint."

The initial client statement equipped the team with a general overview of the tasks associated with the project. However, it also left the team with many questions concerning the direction of the project. To revise the client statement, the team focused on questions that needed to be answered for clarification including:

- What information is needed to understand the thumb CMC joint for this project?
- What kind of Finite Element Analysis (FEA) program will be used?
- What does the team hope to find by creating an FEA model?
- What makes the splinting device "dynamic"?
- How and why will the device stabilize the joint?
- How will the device relieve pain and improve functionality?

3.2 Objectives and Constraints

From preliminary background research and discussions with the client, the team developed a list of objectives, functions, and constraints that the design is intended to comply with. The team selected the following primary and secondary objectives for the splinting device:

Primary Objectives:

- Durable
- Flexible
- Marketable
- Aesthetic
- User friendly
- Comfortable

Secondary Objectives:

- Water resistant
- Left/right hand compatible
- Manufacturable
- Ergonomic
- Cleanable
- Adjustable
- Lightweight
- Breathable

The primary objectives were ranked using a Pairwise Comparison Chart (PCC). The PCC is a tool that helped the team rank the objectives in order of importance by comparing each objective to every other objective and scoring them. These scores are then totaled, and the objective with the highest score is seen as the most important. However, if an objective has a score of zero it does not mean that the objective is of no importance and should no longer be considered. The results of the team-created PCC was presented to and discussed with Dr. Dowlatshahi and the secondary project advisor, Professor Karen Troy (Table 4).

Table 4: Pairwise Comparison Chart

	Durable	Flexible	Marketable	Aesthetic	Comfortable	User Friendly	*Total*
Durable	X	1	1	1	0.5	1	**4.5**
Flexible	0	X	1	0.5	0.5	1	**3**
Marketable	0	0	X	0	0	0	**0**
Aesthetic	0	0.5	1	X	0	0	**1.5**
Comfortable	0.5	0.5	1	1	X	1	**4**
User Friendly	0	0	1	1	0	X	**2**

The results of the PCC showed that durability was the most important objective for the design, followed by comfortable, flexible, user friendly, aesthetic, and marketable. Based on the evaluation of the primary objectives, the secondary objectives can be ranked accordingly in the following order:

1. Durable
    1A. Water resistant
2. Comfortable
    2A. Lightweight
    2B. Breathable
3. Flexible
4. User Friendly
    4A. Cleanable
    4B. Adjustable
5. Aesthetic
    5A. Ergonomic
6. Marketable
    6A. Manufacturable
    6B. Left/right hand compatible

Durability and flexibility were both selected as primary objectives because they are essential to the splint design. The device must be able to withstand wear-and-tear experienced from continuous use. The device must also be marketable, meaning that it must appeal to

customers based on price, design, and features. The device must be aesthetically pleasing so customers are willing to wear it on a day-to-day basis and it does not hinder the performance of any daily tasks. The device should be user friendly so there are not complicated procedures to properly put on and take off the device. Ease of use will allow customers to maintain their independence. Lastly, the device should be comfortable so it does not cause any pain in addition to that experienced from osteoarthritis.

The secondary objectives provided more insight into the meaning of primary objectives. The material the device is constructed of should be water-resistant to increase the product's durability. If the device is marketable, it should be compatible with either the left and/or right hand and be manufacturable. The splint should be interchangeable between the left and right hand to appeal to all patients using CMC splints. The device should be easily manufacturable to reduce selling costs. Between the two, manufacturability is more crucial to marketing the device because this will ultimately dictate costs. If the splint is constructed to be aesthetically attractive, it should be ergonomic so that it is fits into the customer's lifestyle. To increase user-friendliness, the device should be cleanable and adjustable so the customer can use the product with ease. In this category, it is equally important for the device to be cleanable and adjustable. Lastly, the device should be constructed of material that is lightweight and breathable for customer comfort. To address comfort, it is more important that the design is constructed of lightweight material so it does not add any additional stress or strain on the injured joint or surrounding muscles and tissues.

Once the primary and secondary objectives were finalized, the team created an Objective Tree to further organize and analyze the objectives. The Objective Tree (Figure 15) was used to organize the primary objectives and develop secondary objectives.

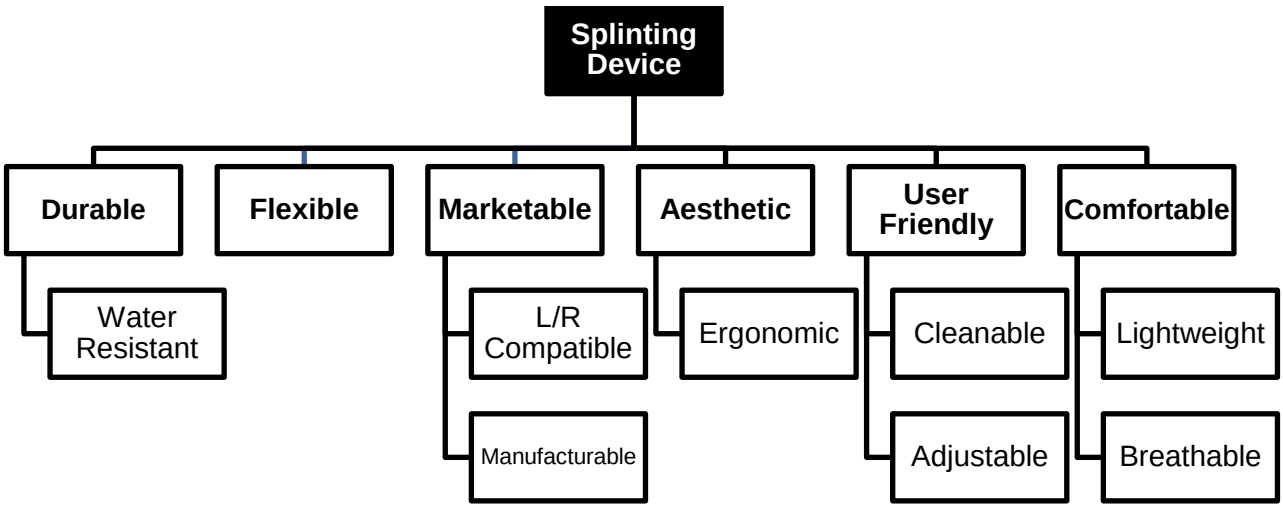


Figure 15: Objective tree to organize the objectives

After the objectives were finalized, the team moved on to determining the specific functions that the device must perform. These functions included:

- Provides support to the joint,
- Allows mobility
- Relieves pain
- Promotes healing
- Can be used for a variety of daily tasks such as pinching movements

The device must provide support to the joint in order to help stabilize the CMC and reduce pain. In addition, the device should promote healing of the joint without taking away from or causing harm to any other anatomical structures in the area. The device should also allow mobility of the joint by allowing as much movement as possible while still providing the support necessary for joint stability. Finally, the device should be able to be used for a variety of daily tasks such as pinching or gripping movements.

Once the functions were determined, the team then focused on defining the project's constraints. The first constraint was cost - both of the project and the device. The team was allotted a budget of $780.00 for any prototyping and testing, and this was considered during project planning and device design. In addition, Dr. Dowlatshahi informed the team that many insurance companies are only willing to pay for devices that are priced similar to other devices currently on the market. This means the final design must not cost more than other current designs that are generally sold for $30-$40. Safety was another constraint because the device must not be detrimental to the customer's health. Therefore the final device must be carefully designed so it does not harm other parts of the hand or wrist during use. Along these same lines, the device also must be biocompatible. It cannot have any harmful effects on the customer, including any irritation or sensitivity to the device's material. Such negative reactions could be caused by an allergy or cytotoxicity. It will be important to consider standards set by the American Society for Testing and Materials (ASTM) when selecting a material for this device. The device must also comply with any applicable FDA regulations, or it will not be approved for human use. Finally, the last constraint was time to complete the project, as it must be completed by May 2015.

3.3 Revised Client Statement

After dissecting the initial client statement provided by Dr. Dowlatshahi, the team worked to revise and finalize the client statement as follows:

Thoroughly ***understand the anatomy*** of the thumb carpometacarpal joint to ***create a detailed model*** of the joint using ***Finite Element Analysis***. This model should take into consideration not only the bones of the joint, but also the tendons, ligaments, and soft tissues surrounding the

bones. Additionally, use this model to ***analyze and understand*** the stresses and strains experienced during normal movement and ***design a dynamic splinting device*** to stabilize the joint ***for post-operative use or use in place of surgery***. This device should be aesthetically pleasing, durable, comfortable, flexible, marketable, and user-friendly. The device design is constrained by the by the provided ***budget of $780.00*** and the ***28-week timeline***. Additional constraints include ***product safety*** and adherence with the American Society for Testing and Materials (ASTM) and Food and Drug Administration (FDA) standards and regulations.

The team arrived at this finalized client statement after thorough discussion with Dr. Dowlatshahi and preliminary background research. The first sentence was revised because Dr. Dowlatshahi stressed the need for the team to thoroughly understand the anatomy of the CMC joint before any other work could be done. This understanding would help simplify the process of developing the FEA model. The second sentence was added to specify that the FEA model should not only include the bones, but also the surrounding soft tissues. The surrounding tendons, ligaments, and muscles play a large role in the stability of the joint, so the client was interested in how they would affect the stresses experienced in the joint during normal movement.

The third sentence describes the client's desire to understand exactly what types of stress the joint experiences during daily movement so this information could be used to develop a design that would counteract these stresses and support the joint. In addition, the client specified that the dynamic splinting device should be able to be used post-operatively or in place of surgery, not one or the other. The next statement mentions the primary objectives of the potential

splint design. Final points were added to the client statement regarding budget, time, and regulatory constraints.

3.4 Project Approach

The project strategy from the Thumb Joint Model and Splint project is presented below in Table 5.

Table 5: Overall Project Timeline

A Term	• Completed chapters 1-3 of report • Finalized client statement • Determined objectives, functions, and constraints • Established client-team relationship • Brainstormed preliminary design ideas
B Term	• Develop design alternatives • Began work on Finite Element Analysis (FEA) joint model • Analyzed joint forces and moments through manual calculations • Conceptual design phase • Prototyping • Preliminary testing
C Term	• Develop prototype • Perform team testing and validation • Complete patient and unaffected individual surveying • Make any necessary design changes
D Term	• Final model • Complete final report • Final presentation

At the end of the first term, the team had completed extensive background research in order to acquire a general understanding of all the parameters to develop the objectives, functions, and constraints of the project. The group also built a strong dynamic amongst the team members and both advisors. The first three chapters of the report were completed. However, some revisions were necessary as the project progressed.

The remaining three terms of the project focused on creating multiple design alternatives, analyzing joint stresses and strains, and selecting a design concept. FEA modeling of the CMC

joint including the surrounding soft tissue was partially completed. Eventually, a design prototype was selected and tested, making necessary design changes as needed. Planned testing included patient and unaffected individual surveying, as well as team data collection. After reviewing the results from surveying and team testing, the team discussed design changes. Some of these changes were iterative in the design process and were used to create the final designs. Planned changes that were not feasible within the project limits team were discussed in the 8. Conclusions and Final Recommendations chapter of this report. Finally, the team delivered a final report and presentation. A schematic of the project flow is shown in Figure 16.

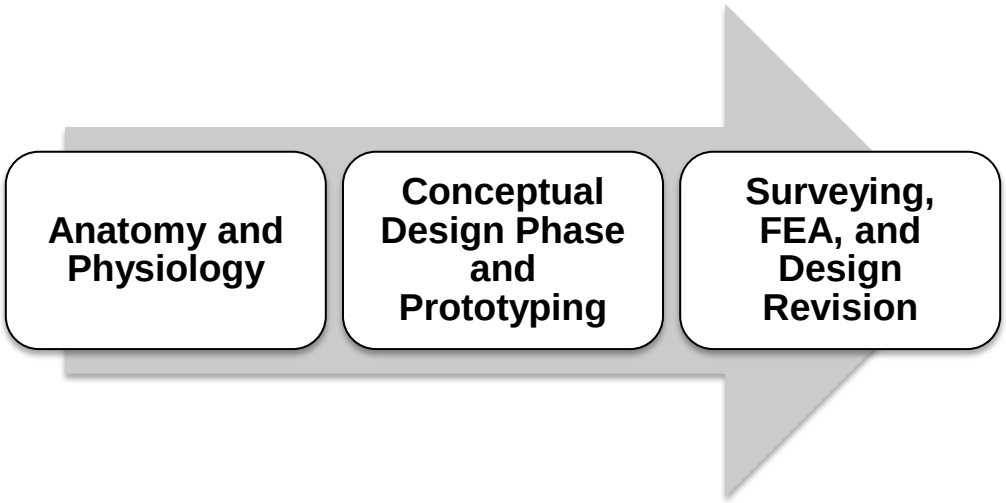


Figure 16: Flow chart depicting project strategy

Before modeling the thumb carpometacarpal (CMC) joint, the team extensively researched the anatomy and physiology of the joint and surrounding tissue. This provided an understanding and a baseline of knowledge for the development of a model of the CMC joint in a FEA program, as well as for a splint to address osteoarthritis at the joint. The team worked concurrently on the FEA model and the splint design. For the FEA model, the team used Computer Tomography (CT) scans obtained from the NIH database and knowledge from the literature to model the geometry and mechanical properties into a FEA model. Medical image processing software was used to convert the CT scan into a model of the geometry of the CMC

joint in FEA. The FEA model was a novel display of the carpometacarpal bone and the trapezium. The team planned to use this model to analyze how the thumb, joint space, and surrounding cartilage and tendons respond to various forces.

The team completed a conceptual design phase that lead to the alternative design phase. After analyzing each of the proposed alternative designs with various decision matrices, the team selected a design to prototype. The team developed surveys for both patients and unaffected individuals to gather data and feedback about the first prototype. Next, the team analyzed results and discussed iterative and future changes for the design. As with the first prototype, the team conducted team testing to determine how effective the changes were for the device. An overall flow chart depicting the design process for the project can be seen below in Figure 17.

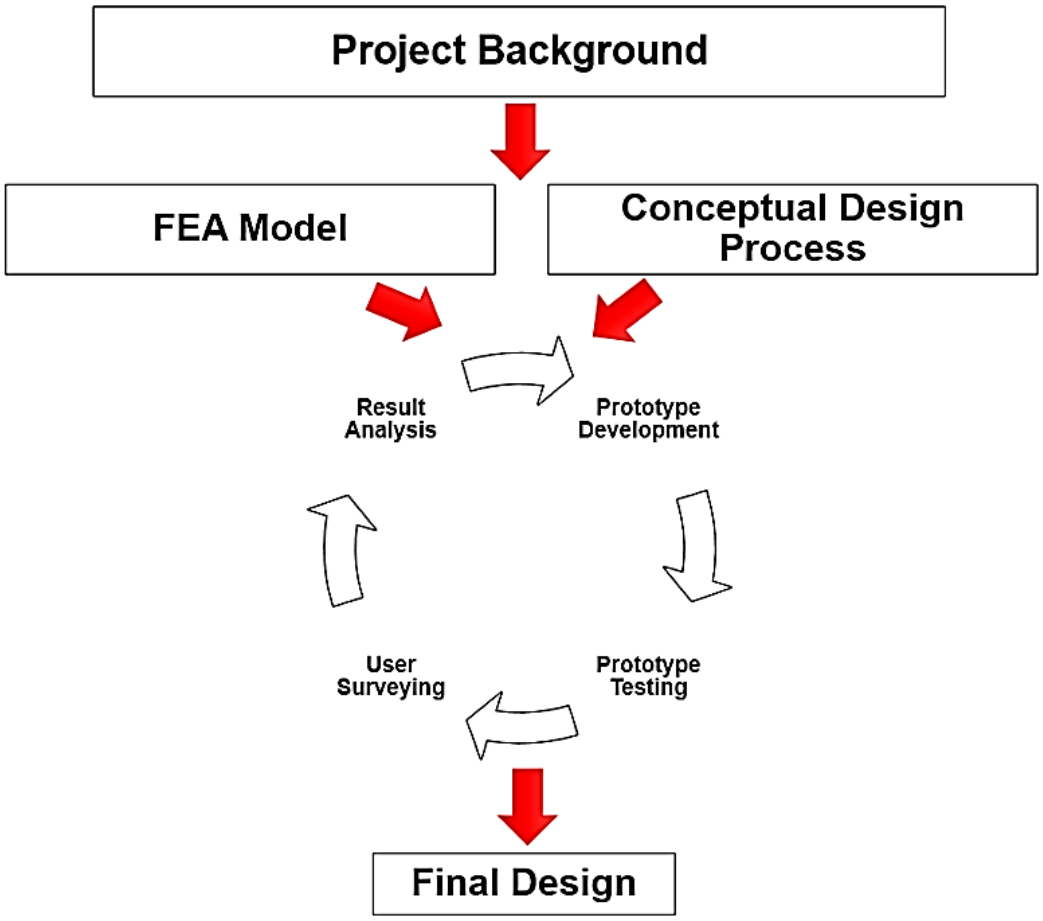


Figure 17: Flow chart depicting the technical process of the project

4. Alternative Designs

4.1 Needs Analysis and Design Specifications

As stated previously in Chapter 3, the required functions of the splint design are as follows: it should provide support to the joint, it should promote healing, it should not cause harm to any other anatomical structures in the area, it should allow mobility of the joint, it should foster joint stability, and it should be able to be used for a variety of daily tasks. From this list of functions, the team developed a list of measurable and specific design specifications that the splint design must meet in order to be considered a successful device. These design specifications are as follows:

1. The device should be able to withstand 120 kg of force
2. The compression provided by the device should not exceed 16 kPa
3. The device should be no longer than 16 cm
4. The device should allow the following ranges of motion: 30-60 degrees of palmar abduction, 25-60 degrees of radial abduction, and 100% of adduction
5. The device should increase the joint space from 0.5 mm to 1 mm
6. The device should be able to be used for a variety of daily tasks including turning a key in a lock, holding a glass, opening a jar, zipping a zipper, opening a door, tying a shoelace, and writing a sentence
7. The device should be biocompatible and not cause any negative reactions

These specifications were developed based off of additional background research and encompass all of the previously defined functions. The first specification was based off of the

maximum amount of force experienced in the CMC joint during a jar opening motion, which is the motion that produces the largest force in the joint. Therefore the device must be able to withstand this force so it does not fail during use. The second specification was defined to ensure that the device does not harm any of the other anatomical structures. It must provide enough compression to be effective and provide the necessary support without restricting blood flow or causing harm to the surrounding muscles, tendons, or ligaments.

Based on the principles of blood pressure readings, the team determined that the splint must not provide compression larger than 16 kPa (120 mmHg). When a sphygmomanometer is used to take blood pressure, the cuff is compressed to completely cut off blood flow to the limb. The pressure is then slowly released until blood begins to flow again. This value is normally recorded as the systolic blood pressure, but for the purposes of this study, it is being equated to the amount of pressure needed to cut off blood flow. Therefore, the team is restricting compression to below 120 mmHg or 16 kPa to avoid damaging surrounding biological structures (Mayo Clinic, 2015). Along these same lines, the third specification describes the length requirements for the device. In order to be an effective device, the splint does not need to cover the entire forearm. Therefore the team restricted the length of the splint to 16 cm to ensure that the splint only covers the necessary anatomy so no harm can come to surrounding structures that are not involved in the CMC joint.

The fourth specification details the range of motion that the device needs to allow. Lateral pinch has the smallest joint range of motion in flexion/extension (13 degrees), while tip pinch has the smallest range of motion in abduction/adduction. In normalized range of motion analysis, the spherical grip (52%) and cylindrical grip (44%) exhibited the largest percentage of IP joint flexion/extension motion capacity, while the smallest percentages occurred in power grip

(22%) and lateral pinch (22%). Since the metacarpal arch degree of freedom allows the hand to conform to the shape of an object and provide grip during a prehensile task, the splint must be able to accommodate the healthy range of motion of the CMC. In relation to mean palmar abduction, radial abduction, and adduction the device should function to provide as similar range of motion as possible for the affected and unaffected hand. Therefore, palmar abduction should range from 30-60 degrees, radial abduction from 25-60 degrees, and be able to obtain 100% adduction (Butz, Merrell, and Nauman, 2012).

The fifth design specification requires that the device promote healing of the joint by increasing the joint space (the space between the metacarpal and the trapezium). A study was performed to gain a better understanding of the effects of osteoarthritis on the CMC joint by comparing geometrical measurements between healthy patients and osteoarthritis patients. The results of this study showed that in a healthy joint, the average joint space between articulating surfaces of the metacarpal and the trapezium is 1 mm. However, the results also reported that in an osteoarthritis patient the average joint space is only 0.46 mm, which shows a significant decrease in joint space due to the degeneration of the joint as a result of the osteoarthritis (de Raedt, Stilling, van de Giessen, Streekstra, Vos, and Hansen, 2012). Therefore, to relieve joint pain, the splinting device should increase this space from 0.46 mm to 1 mm to reduce the occurrence of bone-on-bone contact and thus reduce joint pain. The sixth design specification ensures that the device will not prevent the completion of daily living activities such as the ones listed. These activities are considered most common according to background research, and were therefore the activities included on the patient surveys. Finally, the last design specification ensures that the device will not cause any negative reactions in the user due to the materials used

in the design. Each potential material will be thoroughly researched to ensure its biocompatibility and any materials that are not biocompatible will not be included in the final design.

Also as discussed in Chapter 3, the splint prototype was designed to address the following desires:

- Ergonomic design
- Durable fabric and materials
- Patient comfort
- Patient-specific fitting
- Relieve pain with or without surgery
- Promote healing

4.2 Feasibility

There are five main areas of feasibility that were considered for this design project: time, budget, manufacturing, testing, and surveying. Each of these areas impacted the design decisions and choices. The team first addressed the logistical issues – time and budget. The team's design was limited by the timeline of the project. The team was given approximately seven months to complete the entire design process including creating background research, conceptualizing different design alternatives, performing testing on the prototype design, and producing a final design based on the results of prototype testing. Next, the design was limited by the budget set by the Biomedical Engineering (BME) department at Worcester Polytechnic Institute (WPI). The BME department allotted each Major Qualifying Project (MQP) team a certain budget based on the number of team members. The total budget for this project to cover all aspects of the design process was $780.00

Next, the team considered manufacturing, testing, and surveying, all of which pertained directly to the outcome, or the final design. To manufacture and test the prototype, the team was limited to the resources available on WPI's campus and those that were accessible at UMass Medical School. The team relied heavily on the primary and secondary advisor to accomplish manufacturing and testing needs. Team members were responsible for reaching out to other professors, graduate students, and doctoral students for aid. To conduct surveying, the team relied on the primary advisor, Dr. Dowlatshahi, to recruit and arrange time with previously confirmed OA patients.

4.3 Manual Calculations

4.3.1 Joint Force Calculations

In addition to developing the FEA model described in the previous section, manual mathematical calculations were performed to provide additional support to the results gained from the model. These calculations were based on the principles of biomechanics, and focused on analyzing the forces and moments experienced in the joint as a result of three separate movements: pinching, grasping, and opening a jar. However, before joint forces could be manually calculated, several assumptions needed to be defined.

First, since there is currently no research defining anthropometric data of the thumb bones (including center of mass points and bone lengths), the weight of each bone was assumed to be acting at the midpoint of the bone and the lengths of each bone were estimated by averaging the lengths of each group member's thumb (the group members that were measured were all 21 year old females). These lengths and subsequent averages can be seen below in Table 6. The weight of each bone was also assumed by calculating the approximate volume of each bone and using the volume-density-mass relation to find the mass of each bone. To do this, the

distal phalange was assumed to be a rectangular prism, while both the proximal phalange and the metacarpal were assumed to be cylinders. This simplified both density calculations and force and moment calculations. The bone density was determined from previous studies to be approximately 1.75 g/cm^3 (Densities of Different Body Matter). Finally, all angles throughout the calculations were measured from the positive horizontal x-axis.

Table 6: Average anatomical data for thumb bones

	Length (cm)			Width (cm)			
Subject	**Distal Phalange**	**Proximal Phalange**	**Metacarpal**	**Distal Phalange-x**	**Distal Phalange-y**	**Proximal Phalange**	**Metacarpal**
1T	2.7	2.9	4.6	1.7	1.5	1.7	1.4
2S	3.3	2.5	5.1	2.0	1.7	1.8	2.4
3R	2.7	3.0	4.8	1.4	0.8	1.4	1.4
4L	-	-	-	1.9	1.3	1.7	1.6
Average	2.9	2.8	4.8	1.75	1.33	1.65	1.70

There were also several assumptions that needed to be made for each individual motion. For the pinching calculations, the value for the applied force was averaged for subjects aged 20-75+ and was specific to females and to the right hand. In addition, it was assumed that the force acted perpendicular to the shaft of the distal phalange. For the gripping calculations, the value for the applied force was again averaged for subjects between the ages of 20 and 75+, and was specific to the right hands of the female subjects. In this case the force was assumed to act at two points along the thumb: the midpoint of the distal phalange and the midpoint of the proximal phalange. The applied forces at each point were assumed to be half of the total applied force to ensure equilibrium of the system (Mathiowetz, Kashman, Volland, Weber, Dowe, and Rogers, 1985). Finally, for the jar-opening calculations, the study from which the values were taken reported a tangential force and normal force acting on the thumb (assumed to be F_x and F_y respectively) (Chang, Ho, and Su, 2008). The force angle was calculated using these forces and the relationship between the sides and angles of a triangle.

After clearly defining the previous assumptions, the calculations were completed. The calculations for each movement followed the same procedure, starting with the development of a free body diagram for each movement (Figure 18) where K represents the force experienced as a result of the movement.

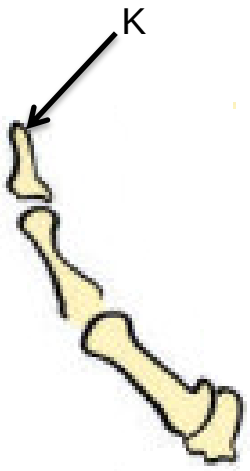


Figure 18: General free body diagram of the thumb

This free body diagram was then split into three segments for the biomechanical analysis. The first segment that was analyzed was the distal phalange, as that was where the force was directly acting. The free body diagram of this segment can be seen in Figure 19:

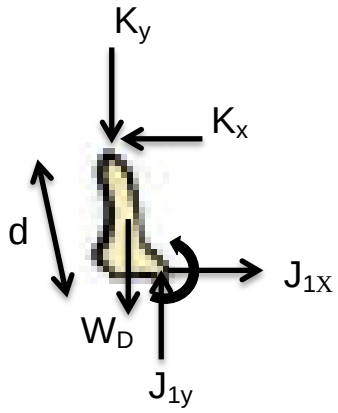


Figure 19: Free body diagram of the distal phalange

Once the free body diagram was completed, the biomechanical analysis was performed. First the forces in both the x and y directions were summed using the following equations where positive x is defined as pointing in the right direction and positive y is defined as pointing down:

$$\sum K_x = 0 \quad \textbf{(1)}$$

$$\sum K_y = 0 \quad \textbf{(2)}$$

Where K_x and K_y are defined in terms of the applied force and the angle at which the force is applied:

$$K_x = K * \cos(\theta) \quad \textbf{(3)}$$

$$K_y = K * \sin(\theta) \quad \textbf{(4)}$$

This resulted in the following equations:

$$K_y - J_{1y} + W_D = 0 \quad \textbf{(5)}$$

$$J_{1x} - K_x = 0 \quad \textbf{(6)}$$

Rearranging these equations gives the joint reaction forces in terms of the applied force:

$$J_{1y} = K_y + W_D \quad \textbf{(7)}$$

$$J_{1x} = K_x \quad \textbf{(8)}$$

These forces were then translated into the second free body diagram (of the proximal phalange):

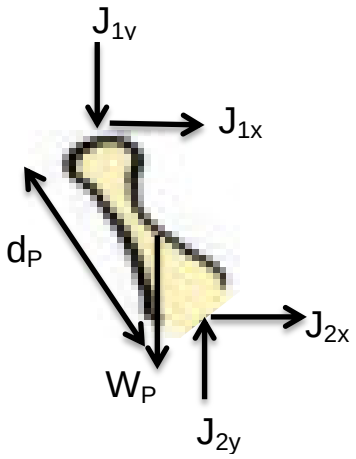


Figure 20: Free body diagram of the proximal phalange

Following the general force summation equations outlined above, the MCP joint forces were calculated to be:

$$J_{1y} - J_{2y} + W_P = 0 \quad \textbf{(9)}$$

$$J_{2y} = J_{1y} + W_P \quad \textbf{(10)}$$

$$J_{1x} + J_{2x} = 0 \quad \textbf{(11)}$$

$$J_{2x} = -J_{1x} \quad \textbf{(12)}$$

These forces were then again transferred to the third free body diagram as shown below:

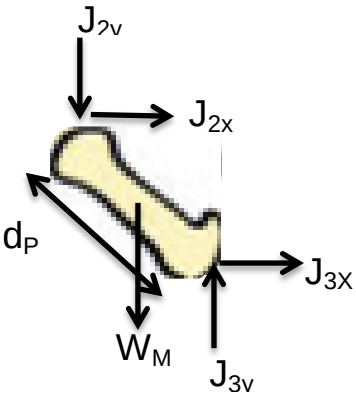


Figure 21: Free body diagram of the metacarpal

This free body diagram depicts the metacarpal bone, which shows the forces that the CMC joint will experience (J_{3x} and J_{3y}). Therefore, the forces experienced in the CMC joint are as follows:

$$-J_{3y} + J_{2y} + W_M = 0 \quad \textbf{(13)}$$

$$J_{3y} = J_{2y} + W_M \quad \textbf{(14)}$$

$$J_{3x} + J_{2x} = 0 \quad \textbf{(15)}$$

$$J_{3x} = -J_{2x} \quad \textbf{(16)}$$

This segmentation process was completed for each movement (pinching, gripping, and jar opening) in order to compare the forces experienced in the CMC joint for each movement. However, for the gripping calculations an additional external force was added on the proximal phalange to accurately represent the force distribution during the motion. The results of these equations can be seen in Table 7 below, where theta is the angle of the applied force. All forces are in terms of Newtons (N).

Table 7: Results from joint force calculations

Movement	K	θ	K_x	K_y	J_{1x}	J_{1y}	J_{2x}	J_{2y}	J_{3x}	J_{3y}
Pinching	50.3	0	50.3	0	50.3	0.17	-50.3	0.22	50.3	0.41
Gripping	279.3	45°	197.5	197.5	197.5	197.6	-394.9	395.2	395.0	395.4
Jar Opening	45.5	165°	44.0	11.8	44.0	11.9	-44.0	12.0	44.0	12.2

4.3.2 Joint Moment Calculations

After calculating the joint reaction forces, the moment around the joint was calculated separately for each particular movement. The five ligaments included in these calculations are: the anterior oblique ligament (AOL), the ulnar collateral ligament (UCL), the intermetacarpal ligament (IML), the posterior oblique ligament (POL), and the dorsoradial ligament (DRL). The positions of each of these ligaments are shown in Figure 22 below.

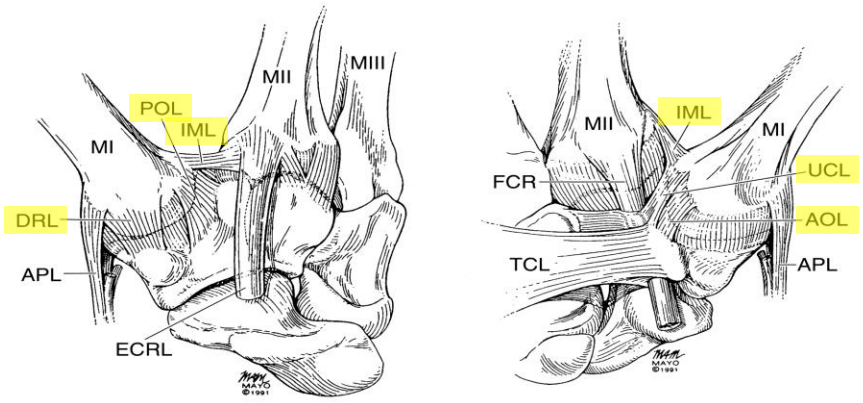


Figure 22: The ligaments of the carpometacarpal joint – the joints relative to this study are highlighted (Bettinger, Linscheid, Berger, Cooney, An, 1999)

Extensive background research was completed in order to determine the lengths, widths, thicknesses, and insertion/origin positions of each of the aforementioned ligaments. These values are summarized in Table 8 below.

Table 8: Anatomical information of relevant CMC ligaments (Bettinger, P.C., Linscheid, R.L., Berger, R.A., Cooney, W.P., An, K., 1999)

Ligament	Insertion Point	Point of Origin	Length (mm)	Width (mm)	Thickness (mm)
AOL	Palmar tubercle of the trapezium	Palmar-ulnar metacarpal	8.91	8.59	1.34
UCL	The distal margin of the transverse carpal ligament (TLC) ulnar to the TLC's insertion on the trapezial ridge	Palmar-ulnar tubercle of the 1st metacarpal	8.05	3.35	0.83
IML	Dorsoradial aspect of the 2nd metacarpal	Palmar-ulnar tubercle on the base of the 1st metacarpal	9.67	3.47	1.03
POL	The dorsoulnar side of the trapezium (adjacent to the DRL)	The dorsoulnar aspect of the 1st metacarpal and palmar-ulnar tubercle	10.08	4.97	1.35
DRL	The dorsoradial tubercle on the trapezium	The dorsal edge of the base of the 1st metacarpal	7.12	11.39	2.25

As with the joint force calculations, before the joint moment calculations could be completed several assumptions needed to be defined. First, each ligament was assumed to be acting equally on the metacarpal during each moment. Therefore each variable could be

represented in terms of only one of the ligaments, thus simplifying the calculations. In this case, each ligament was represented as a fraction of the DRL, as outline below in Table 9.

Table 9: Variables for each ligament used throughout the moment calculations

Ligament	Original Variable	Variable in Terms of the DRL
DRL	T_1	$1T_1$
AOL	T_2	$.454T_1$
UCL	T_3	$.108T_1$
IML	T_4	$.139T_1$
POL	T_5	$.262T_1$

To make these comparisons, the cross-sectional area of each ligament was calculated based off of the widths and thickness described above in Table 8. Since each ligament was assumed to have similar properties and the force exerted by the ligament is proportional to its cross-sectional area, each ligament could be represented as a fraction of the DRL by dividing each ligament's area by that of the DRL. This decreased the number of unknown variables in the problem from five to one, thus making the problem possible to solve.

The other assumptions involved in this calculation covered the points at which the weights of each bone and the applied forces acted on the thumb. The moment was calculated around the midpoint of the end of the metacarpal (hereafter referred to as the origin), so it was necessary to determine the perpendicular distances between the point at which each force acted on the thumb and the line of action through the origin. Figure 23 below provides an example of the type of free body diagram used for the moment calculations, while Table 10 outlines the necessary distances to complete the calculations.

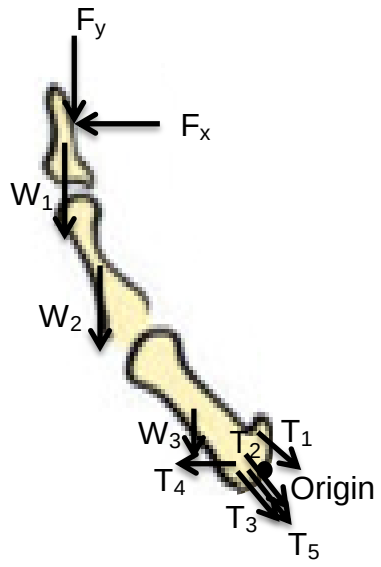


Figure 23: Example of a free body diagram for moment calculations

Table 10: Distances to the origin for all major variables

Motion	Force Variable	Distance to the Origin (cm)
Pinching	F_x	9.05
Gripping	F_{1x}	9.05
	F_{2x}	6.20
	F_{1y}	0.88
	F_{2y}	0.83
Jar Opening	F_x	9.05
	F_y	0.88
Tendons	T_1	0.373
	T_2	0.075
	T_3	0.224
	T_4	0.261
	T_5	0.075

To further simplify calculations, the weights of each bone were assumed to be negligible. In most cases, the weights would be acting close enough to the line of action of the origin that they would contribute very little to the overall moment. Therefore they were not considered in these calculations.

Once all assumptions were thoroughly explored and defined, the calculations to find the moment around the CMC joint for pinching, gripping, and jar opening motions were performed based on the following equations:

$$\sum M = 0 \quad \textbf{(17)}$$

$$M = F * d \quad \textbf{(18)}$$

Where M is the moment, F is the applied force, and d is the perpendicular distance between the applied force and the origin. In order for the joint to be stable, the sum of the moments caused by all forces acting on the joint must be equal to zero. To calculate the force applied by each tendon, the forces were summed and set equal to zero as seen in the previous section for the force calculations. These forces were then plugged into the equation above to solve for the moments. The results of the joint moment calculations are summarized in Table 11 below:

Table 11: Results from joint moment calculations

Movement	T_1 (N)	T_2 (N)	T_3 (N)	T_4 (N)	T_5 (N)	M (N·m)
Pinching	25.4	11.5	2.7	3.5	6.7	-4.5
Gripping	142.1	64.5	15.3	19.8	37.2	-33.0
Jar Opening	23.0	10.4	2.5	3.2	6.0	-4.0

4.4 FEA Model

Despite the prevalence of thumb CMC joint osteoarthritis, there is little definitive understanding of how altered joint biomechanics relate to the natural history of the disease. The precise position of the metacarpal on the trapezium during functional activities in live subjects can be visualized with various imaging techniques, although correlating force in these positions has yet to be quantified (Ladd et. al., 2013). In an attempt to further define the kinematic factors that influence the development of thumb osteoarthritis, an FEA model was created by the team

for three-dimensional in vivo kinematic analysis in normal individuals and individuals diagnosed with early CMC osteoarthritis.

The studies conducted by the team provide a solid framework to further analyze the kinematics of patients with early osteoarthritis and determine whether changes in motion over time can predict osteoarthritis progression in symptomatic patients with little evidence of radiographic disease. Although computer analysis has been used to accurately measure a number of joints in the hand and wrist, similar analysis has not been previously used to analyze the kinematics of the CMC joint (El-shennawy, Nakamura, Patterson, and Viegas, 2001). The model completed by the team will therefore not only serve as a clinically important tool in joint biomechanics but also as a modern anatomical representation of the CMC which has remained a controversial and often outdated medical topic.

4.4.1 The Model System

The structures the team planned to include in the Finite Element Analysis (FEA) model are outlined in Table 12.

Table 12: Anatomical structures the team planned to include in the FEA model

Hard Tissue	**Bone**	Metacarpal
		Trapezium
Soft Tissue	**Cartilage**	Metacarpal Cartilage
		Trapezial Cartilage
	Ligaments	Anterior Oblique Ligament (AOL)
		Ulnar Collateral Ligament (UCL)
		First Intermetacarpal Ligament (IML)
		Posterior Oblique Ligament (POL)
		Dorsoradial Ligament (DRL)

4.4.2 Creating the Model

The first step in modeling the thumb CMC joint was to obtain CT scans that could be converted into a 3D model for finite element analysis. The CT scans used for the model were obtained from the NIH database, and encompassed both the hand and the arm. These images

were in the form of a .dcm file, which is a file type created by the Digital Imaging and Communications in Medicine standards. The obtained images have a resolution of 512, a pixel size of 0.25 and a slice thickness of 0.5 mm. After obtaining the CT scans, they were imported into Mimics® to develop a 3D model that could be imported into Abaqus™ for use in FEA.

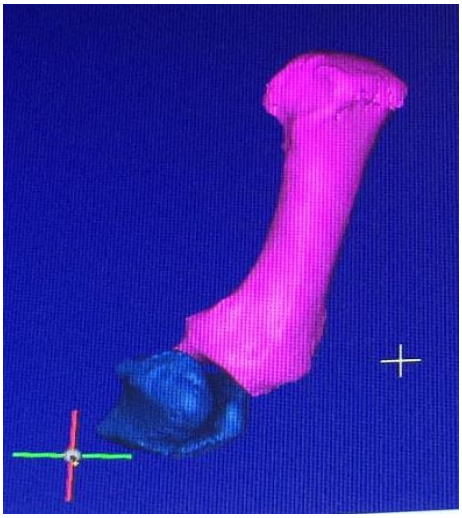


Figure 24: 3D model of the metacarpal and trapezium in Mimics®

Once in Mimics®, the scans were used to create a 3D model of the metacarpal and the trapezium to accurately model the CMC joint (as seen above in Figure 24). This model was then imported into a subsidiary of Mimics® called 3-matic® for meshing. The first step in 3-matic® was to Auto-Remesh the model to optimize the mesh by controlling the size and quality of the surface triangulation (the triangles that make up the mesh on the surface of the model). The quality threshold for the Auto-Remesh was 0.3 and the maximum edge length was 3.0 mm. After the Auto-Remesh was complete, a volume mesh was created with similar parameters as the Auto-Remesh. The maximum edge length was again defined as 3.0 mm; however the quality threshold was much higher at 25. The volume mesh of the metacarpal contained 34,698 volume elements and 8,964 nodes, while the volume mesh of the trapezium contained 23,692 volume elements and 6,103 nodes. After meshing was completed, each bone was exported from 3-matic

as an .inp (input) file to be imported into Abaqus™ for the FEA. The two models were then combined in Abaqus™ to create an accurate model of the CMC joint with each bone in its proper position, as can be seen below in Figure 25.

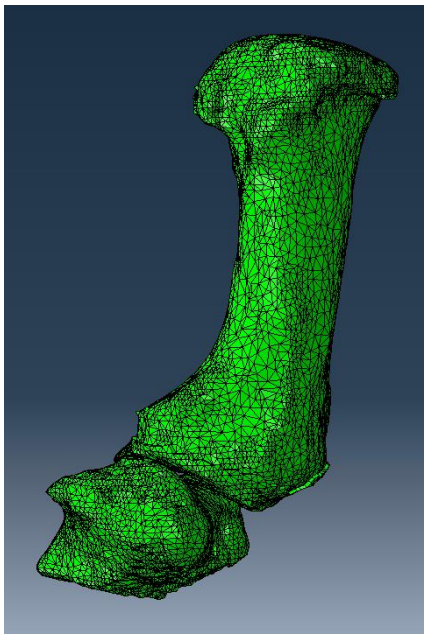


Figure 25: FEA model of the CMC joint in Abaqus™

4.4.3 Modeling the Soft Tissue

Once the model was imported into Abaqus™, the soft tissue also needed to be included in the model. For this model, the only cartilage considered was that found on the contact points of the trapezium and the metacarpal. To model this cartilage, the surfaces of each bone were extruded by 0.3 mm (Polito, Wood, Rucco, 2014) and then assigned the material properties of cartilage. In addition, the team planned to include the following ligaments in the model: the anterior oblique ligament (AOL), the ulnar collateral ligament (UCL), the first intermetacarpal ligament (IML), the posterior oblique ligament (POL), and the dorsoradial ligament (DRL). However, the team was unfortunately unable to complete this portion of the model.

4.4.4 Assigning Material Properties

After the cartilage was included in the model, the material properties for both bone and cartilage needed to be defined and assigned. All material properties are based on the extensive background research completed by Polito, Wood and Rucco in their 2014 study.

4.4.4.1 Cortical Bone

To simplify section definitions and material assignments, the bone was assumed to be entirely cortical bone. This assumption can be made because each bone was modeled as a shell, and therefore did not account for the cancellous bone on the interior. Therefore, the outer shell layer was defined as cortical bone and the cancellous bone was not considered. Each bone was defined as an isotropic, linear elastic material where the Young's Modulus and Poisson's Ratio were defined as 16 GPa and 0.29 respectively.

4.4.4.2 Cartilage

Similar to the ligaments, the cartilage was modeled using the Mooney-Rivlin strain energy density function for an incompressible hyperelastic model (shown in Equation 19 below).

$$W = C_1(I_1 - 3) + C_1(I_2 - 3) \qquad \textbf{(19)}$$

This model is best suited for this application since the impact loading will cause very high strain rates in the cartilage. In addition, linear elastic models can typically only accurately predict deformation behavior up to an elastic strain of 5%. The coefficient values for this equation are taken from previous work and are as follows: C_{01} = 0.41 MPa and C_{10} = 4.1 MPa (Polito et. al., 2014).

4.4.5 Creating the Steps

Each simulation run in Abaqus™ is based off of a series of steps that define the load or action being performed. The load on the CMC joint was split into two separate loads: a pre-load

to ensure proper contact between the metacarpal and the trapezium, and the actual applied force. For the pre-load step, the distal head of the metacarpal was subjected to 1 Newton of force to ensure that the bones were already in contact when the actual load was applied. The second step varied for each movement being studied (pinching, gripping, and jar opening) and mimicked the force that the thumb would experience for each movement. The direction of application and the magnitude of the applied force varied for each movement and were obtained from extensive background research of prior studies (as explained in the previous section concerning manual calculations).

4.4.6 Constraints and Boundary Conditions

In addition to creating the steps for the simulation, constraints and boundary conditions also needed to be defined and applied to the model. Applying these constraints and conditions ensured that when the load was applied the joint would behave as it does in the human body. The base of the trapezium was fixed for the entire simulation to ensure that there would be no extraneous movement of the entire model during the application of the load. During the pre-load step the metacarpal was fixed in the x and y directions, because only motion in the z direction was required to ensure contact between the two bones. In addition, all rotational variables were constrained because rotational motion was not required to gain contact between the bones.

4.4.7 Modeling the Load

The team planned to apply loads to the thumb during the actual load portion of the simulation that would vary depending on the motion being modeled. The location and magnitude of each load was estimated from previous literature detailing biomechanical analyses of the thumb. However, since all of these forces are typically applied at the distal phalange, joint force calculations (seen in the previous section) were completed to translate the applied force into the

joint reaction force at the MCP joint. Therefore each applied force was split into its x and y components and was assumed to act on the distal head of the metacarpal. As seen in Table 7, the x and y forces for pinching, gripping, and jar opening are 50.3 N and 0.22 N, 395.0 N and 395.2 N, and 44.0 N and 12.0 N respectively.

4.5 Conceptual Designs

To complete the conceptual design process, each team member generated a sketch of their ideas on a whiteboard and shared their thoughts with the rest of the team. This was similar to a gallery method style, where sketches are presented to the group and then pros and cons of each design are discussed. While each team member's design looked somewhat similar, members envisaged different components and materials being used in their design. This is why explanation and subsequent discussion was crucial to the conceptual design process. Some of the conceptual modeling involved the team discussing "easy fix" options for osteoarthritis including taping with medical or athletic tape, or creating a firm plaster shell to completely immobilize the joint. A brief explanation of the further developed ideas for each conceptual design and the accompanying sketch are included below.

4.5.1 Conceptual Design #1

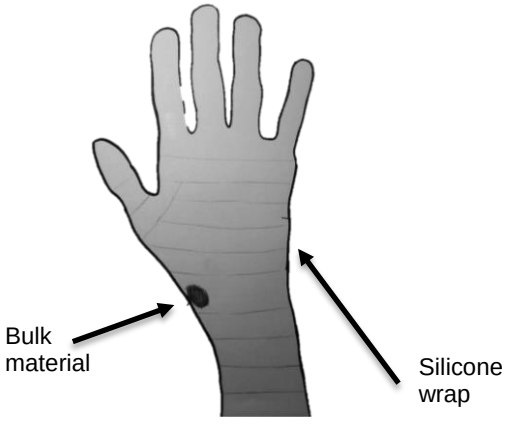


Figure 26: Conceptual Design #1

This design was created in collaboration with the team's client. The design featured a bulk material that would be placed around the thumb to provide joint stability. Precise placement of the bulk material around the thumb would hopefully prevent subluxation of the thumb CMC joint. A silicone wrap would cover the hand and part of the wrist to keep the bulk material in place.

4.5.2 Conceptual Design #2

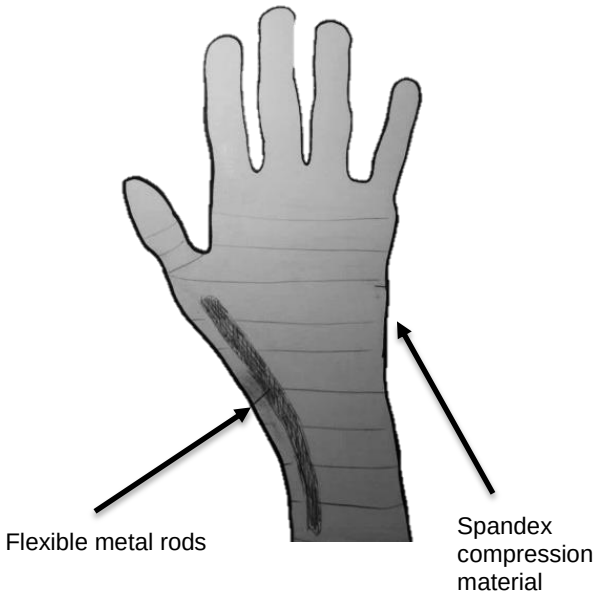


Figure 27: Conceptual Design #2

The second design used thin, flexible metal rods to keep the thumb CMC joint in place. The metal rods would run from the wrist to the base of the joint for stability. The rods would be wrapped in a spandex compression material to keep them in place, while still allowing the patient some mobility of the thumb.

4.5.3 Conceptual Design #3

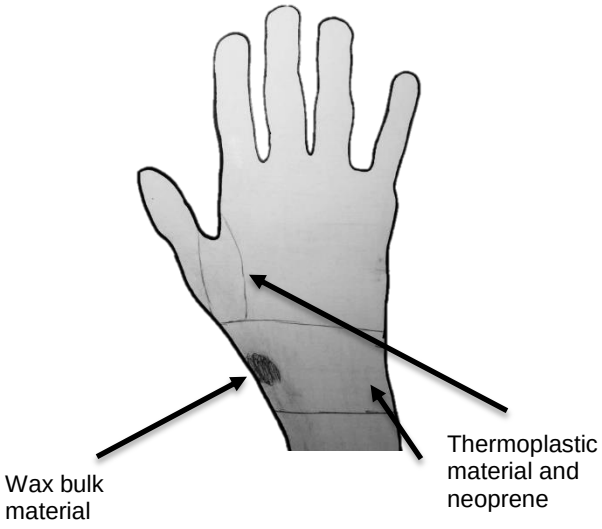


Figure 28: Conceptual Design #3

Similar to the first conceptual design, this design features a bulk material (in this case wax) positioned at the base of the joint to provide additional stability and support to the joint. However in this design, instead of a silicone wrap, there would be a thermoplastic exterior to provide additional support as well as a neoprene wrapping to increase comfort and to make the design waterproof.

4.5.4 Conceptual Design #4

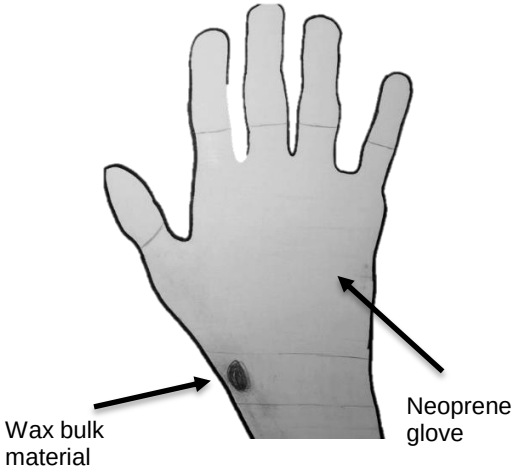


Figure 29: Conceptual Design #4

This design again features a bulk material (made of wax) sewn into the underlying material at the base of the joint. There would be an additional wrapping component over the bulk material to compress the joint and provide additional support. Finally, there would be a neoprene glove-like covering that would provide additional compression and comfort.

4.5.5 Conceptual Design #5

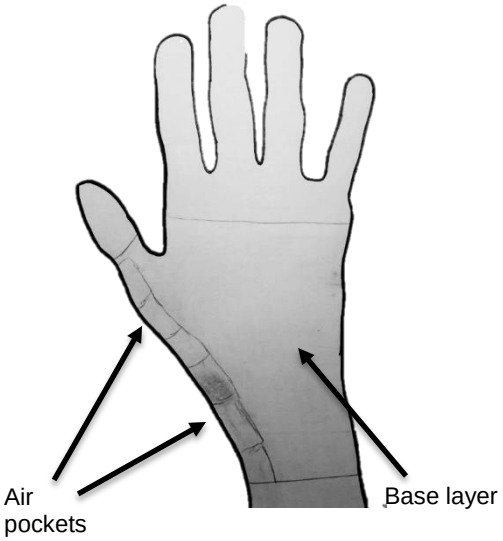


Figure 30: Conceptual Design #5

This design is mainly comprised of a base layer material covered with pockets that could be pumped with air to allow patient specific conformity. These pockets could either be sewn on or attached with Velcro, and would allow the patient to adjust the amount of air to provide the specific amount of compression needed to reduce the pain in their joint.

4.5.6 Conceptual Design #6

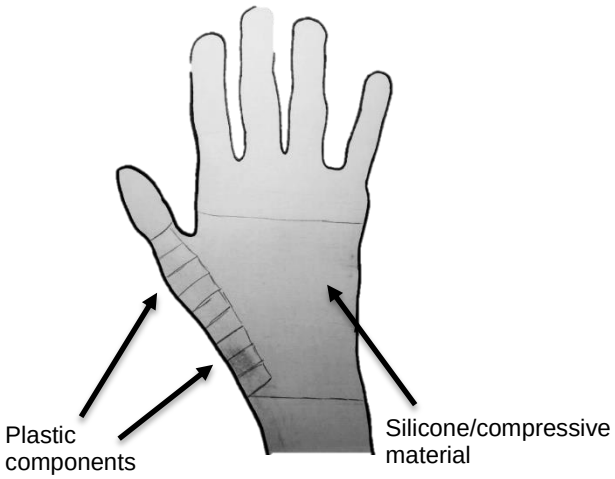


Figure 31: Conceptual Design #6

This design is made of interlocking plastic components to provide support to the joint. These components are wrapped between either layers of silicone or a compressive material to provide both comfort and additional compression.

After completing the gallery method discussion, the team presented their ideas to the client. This again involved each team member openly discussing the desired functionalities of his or her design. It was important to discuss the design's various options such as shape, material, and joint support system. The client provided feedback about each design. Although it was still early in the design phase, the team carefully assessed the client's feedback in comparison to any decisions the team had made separate from the client's input. The conceptual design process allowed the team to share ideas and begin thinking of more innovative solutions to the problem.

4.6 Alternative Designs

4.6.1 Proof-of-Concept

To further process all of the possible design ideas, the team decided that each member should create a physical model of their imagined device. At this point, the team had tentatively

agreed on a joint support system based on the client's recommendations. The joint support system was based off a surgical technique called the Mini Tightrope® CMC pioneered by Arthrex. The surgical procedure is completed by fixing the first and second metacarpal using stainless steel buttons and two strands of FiberWire®, a type of Kirschner wire (Arthrex, 2014). This surgery is advantageous in comparison to other thumb CMC surgical techniques because it does not require lengthy immobility of the patient's joint and has been shown to have drastically shorter recovery times (Yao and Song, 2012).

While the Mini TightRope® CMC surgery is minimally invasive and proves promising for certain thumb CMC patients, the team was focused on nonsurgical methods. After researching the surgery, the team wanted to focus on a joint support system that would externally prevent excessive movement at the thumb CMC joint. This is somewhat similar to the aims of the Mini Tightrope® CMC surgery which "suspends the thumb ray and effectively prevents subsidence into the CMC space" (Yao and Song, 2012). To accomplish this, the team attempted to generate functional models of a device that included small disks of gel materials to provide support at the base of the thumb. The disks were placed to prevent subluxation of the thumb CMC joint because research suggested this was where the most movement is experienced in the thumb.

Similar to the conceptual design process, each individual created a functional splint model and presented their design to the group. The models were created using items that members could easily obtain from retail stores. Such materials included gel shoe inserts, spandex material, and medical tape. Each member of the team tried on the different designs and asked the designer to clarify any questions they had regarding the rudimentary plans. The five alternative designs that were created are pictured and discussed below. A summative list of the base

material, shell material, disk material, adjustment style, and any additional types of support are also provided with the description.

4.6.2 Alternative Design #1

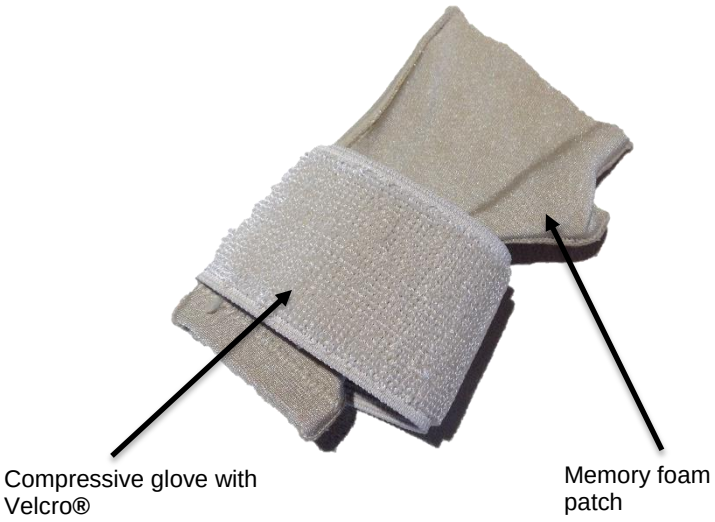


Figure 32: Alternative Design #1

This design consisted of a compressive glove made of polyester/spandex. This material was chosen since it could be easily put on or taken off. A comfortable memory foam patch was sewn into the glove so it could surround the joint and prevent the CMC joint subluxation. With its superior comfort and flexibility, the memory foam would provide patients with thumb mobility, but also keep the joint in proper alignment during daily movements and while at rest. The compressive material of the glove would provide additional joint stability and security to prevent patient pain and joint laxity that occurs with thumb CMC osteoarthritis.

Table 13: Materials for each portion of alternative design #1

Base Material	Polyester-spandex blend, memory foam
Shell Material	Polyester-spandex blend
Bulk Material	Memory foam (consistent to the firmness of a memory foam mattress)
Adjustment	Glove (controlled by compressive material)
Additional Support	N/A

4.6.3 Alternative Design #2

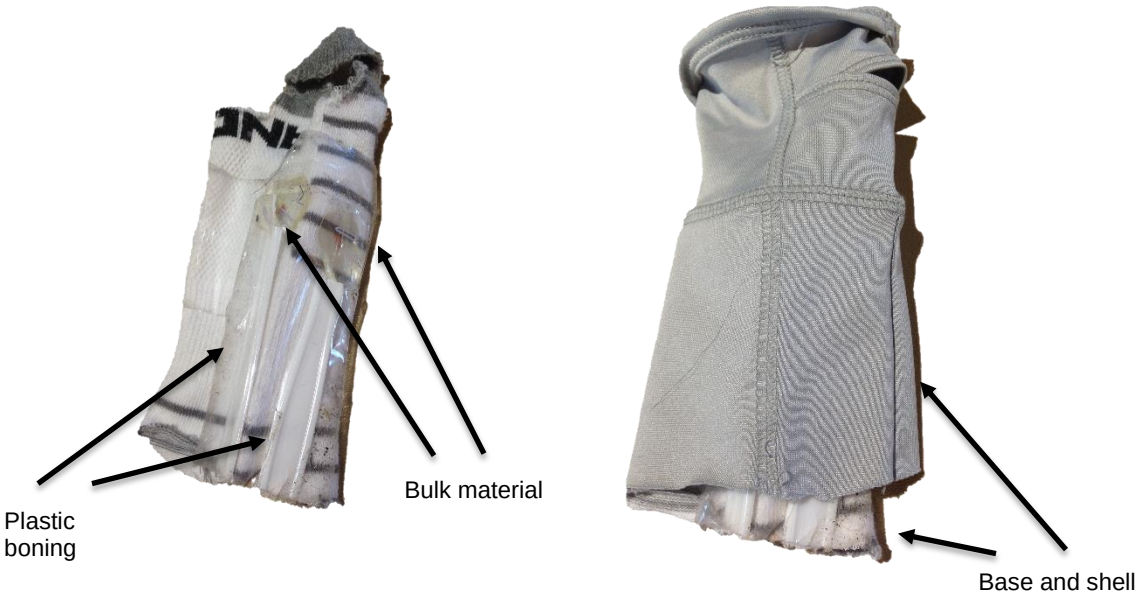


Figure 33: Alternative Design #2

This design included two distinct pieces. The base material was constructed of a cotton-spandex blend. The bulk material disks were sewn into place within the base material, along with two flexible plastic pieces that ensured that the bulk material disks would stay in place. The disks were constructed of a firm gel that was comfortable, but would also stabilize the joint. A polyester material covered the base material. Both the base material and shell material were stretchy so the patient can easily put on the splint and remove it, similar to a glove.

Table 14: Materials for each portion of alternative design #2

Base Material	Cotton-spandex blend
Shell Material	Polyester
Bulk Material	Gel
Adjustment	Glove
Additional Support	Flexible plastic boning

4.6.4 Alternative Design #3

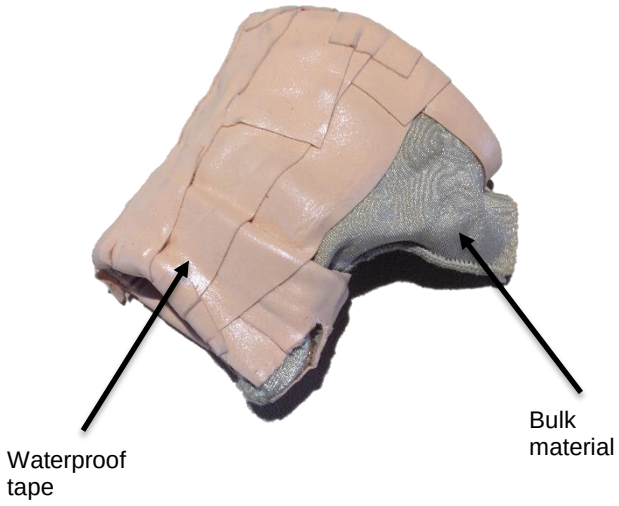


Figure 34: Alternative Design #3

The design utilized a compression glove of a spandex material that was cut to allow full phalangeal and wrist motion. Two splint bulk material disks (made of shape memory gel) sat within the metacarpal space to prevent further joint subluxation caused by CMC joint arthritis. The exterior shell of the splint was made of waterproof tape (similar to Nexcare Absolute Waterproof Tape™) that allows for flexibility and is durable enough to resist everyday patient wear.

Table 15: Materials for each portion of alternative design #3

Base Material	Spandex
Shell Material	Waterproof tape
Bulk Material	Shape memory gel
Adjustment	Glove
Additional Support	N/A

4.6.5 Alternative Design #4

Figure 35: Alternative Design #4

The design consisted of two bulk materials made of a comfortable gel material that provides support and resistance in accordance with patient movement. The wrapping that secures the splint was constructed of neoprene, which made this splint design waterproof and thus more durable. However, the neoprene material did not allow for much breathability and was not very flexible. The Velcro® strip was utilized to secure both the splint and bulk material disks in place to apply appropriate compression where needed without compressing the entire hand/wrist. Compression of areas of non-interest could cause detrimental effects to the outside anatomy of the hand/wrist.

Table 16: Materials for each portion of alternative design #4

Base Material	Neoprene
Shell Material	Neoprene
Bulk Material	Gel
Adjustment	Velcro® strip
Additional Support	N/A

4.6.6 Alternative Design #5

Figure 36: Alternative Design #5

The design consisted of three parts. First, base material was constructed from a cotton wrap, similar to an ace bandage. A bulk material disk was wrapped within the base material to hold it in place. Lastly, a shell material was added to secure the cotton wrap and bulk material firmly. The shell was secured with a Velcro® adjustment strap at the wrist. While this design was somewhat bulky due to multiple layers, the design aimed to secure the bulk material as to prevent laxity of the CMC joint.

Table 17: Materials for each portion of alternative design #5

Base Material	Cotton (Everlast® boxing wrap)
Shell Material	Cotton and leather (Harbinger glove/wrist wrap with the fingers cut off below the knuckles)
Bulk Material	ThermaPak® pearls encased within a balloon or gel material wrapped in tape
Adjustment	Leather Velcro® strip attached to the shell material
Additional Support	N/A

4.7 Decision Making Process

In order to ascertain specific materials, properties, and design specifications, the team organized information in various charts to draw conclusions for final designs.

The morphological chart (Table 18) contains the materials that the group had collaboratively brainstormed and/or used within their design to address various design aspects. The selection of materials was based on splinting devices that were purchased from drugstores, as well as from discussions with Dr. Dowlatshahi, and upon research of materials that closely fit the desired properties of the splint.

Table 18: Conceptual Design Morphological Organizational Chart

Aspect of Design	**Means**					
Base material	Neoprene	Cotton	Silicone	Bandage	Polyester	Spandex
Shell material	Neoprene	Cotton	Silicone	Bandage	Polyester	Spandex
Bulk material	Gel	Fluids	Memory foam	Foam	Squishy fluid beads	
Adjustment	Velcro	Strings	Tape	Sleeve	Wrapping	
Additional support	Plastic boning					

The base and shell materials were selected based on availability and what had been previously utilized in splints, gloves, and First Aid. The bulk material portion of the morphological chart refers to the material of the disks that were utilized to prevent CMC joint subluxation. The group unanimously decided that the materials of these disks should be flexible enough to allow range of motion of the joint, but firm enough to keep the joint in place. Upon analysis of materials that had the potential of the team's material qualifications, five potential

bulk materials were considered. The adjustment portion of the chart indicated how the splint would be secured onto the patient's hand. The additional support section was a miscellaneous section of the chart used to decide what other techniques could be utilized that do not otherwise fit into any other category of the chart.

Next, the team scored the materials using a Best-of-class chart (Table 19). The team determined the scoring through an open discussion that focused on conceptual designs and previous research. This chart differs from the morphological chart (Table 18) because it indicates a ranking of the listed options for each category. A score of 1 indicated the most desirable material/method for the final design. Lower scores suggest the material is less desirable for the final design, but still considered an alternative solution.

Table 19: Best-of-class Category Ranking Chart

Aspect of Design	**Means**					
Base material	Neoprene **(3)**	Cotton **(5)**	Silicone **(4)**	Bandage **(6)**	Polyester **(2)**	Spandex **(1)**
Shell material	Neoprene **(3)**	Cotton **(4)**	Silicone **(6)**	Bandage **(5)**	Polyester **(1)**	Spandex **(2)**
Bulk material	Gel **(1)**	Fluids **(5)**	Memory foam **(3)**	Foam **(2)**	Squishy fluid beads **(4)**	
Adjustment	Velcro® **(1.5)**	Strings **(5)**	Tape **(3)**	Sleeve **(1.5)**	Wrapping **(4)**	
Additional support	Plastic boning **(1)**	Band-Aid® tape **(2)**				

Base and shell materials were selected based on the comfort and durability of the material. The base material needed to be breathable, light, flexible, and comfortable so it would allow for patient specificity. The shell material needed to be durable in order to withstand a

patient's daily tasks: washing dishes, exposure to hot temperatures, provide gripping quality to open doors, etc. The bulk material was ranked primarily on material properties that would prevent laxity of the joint, flexibility, and comfort. Mechanical testing of materials further supported bulk material selection (Section 6.4 Compression Testing) Adjustment methods were scored with two important criteria in mind: prevention of splint/bulk material movement and ease of putting on and taking off the splint. Additional support was selected as the best reinforcement method to ensure both joint placement and adequate thumb range of motion.

Based on the rank of the materials, the group determined the basis of materials that would produce an ideal splint:

Table 20: Materials the team decided would be best for each portion of the device

Base Material	Spandex – compressive, but breathable and stretchy (easy to take on and off)
Shell Material	Polyester – still stretchy, but a little more rugged (like a running jacket), lightweight, breathable, comfortable, almost weatherproof
Bulk Material	Gel (see mechanical testing results in Section 6.4 Compression Testing)
Adjustment	Velcro®/sleeve – sleeve is easy to take on and off, but Velcro® needed to secure splint and provide patient-specific compression level
Additional Support	Plastic boning – made of a flexible polymer to keep materials in their designated/desired placement

After each team member constructed their own alternative design and design analysis, each personal design was presented to the other members of the group. The team collaboratively compared each team member's design to the constraints, primary objectives, and secondary objectives in a chart, ranking how closely each design met the criteria that were established by the group. The evaluation scale and chart can be seen below in Table 22: Evaluation scale for Numerical Evaluation MatrixTable 22 and Table 23 respectively:

Table 21: Key for Numerical Evaluation Matrix

C	Constraint
PO	Primary objective
SO	Secondary objective

Table 22: Evaluation scale for Numerical Evaluation Matrix

0	Does not meet
10	Slightly meets
20	Partially meets
30	Mostly meets
40	Fully meets

Table 23: Numerical Evaluation Matrix of Individual Conceptual Designs

	Design #1	**Design #2**	**Design #3**	**Design #4**	**Design #5**
C: Safety					
C: Biocompatible					
C: Regulations					
PO: Durable	20	30	40	30	40
PO: Flexible	40	20	10	30	20
PO: Marketable	30	30	30	30	30
PO: Aesthetic	30	40	30	20	20
PO: User-friendly	30	40	40	30	20
PO: Comfortable	40	20	40	30	30
SO: Water Resistant	10	30	40	40	30
SO: Left/Right hand compatible	40	40	40	40	0
SO: Manufacturable	30	10	20	20	20
SO: Ergonomic	40	20	30	30	30
SO: Cleanable	10	20	10	30	30
SO: Adjustable	0	0	0	30	30
SO: Lightweight	40	40	20	40	30
SO: Breathable	20	20	0	0	20

Based on the group's decisions, each individual design received a score based on the sum of the ranks given by the group. The totals are as follows:

Alternative Design #1: 380

Alternative Design #2: 360

Alternative Design #3: 350

Alternative Design #4: 400

Alternative Design #5: 350

4.8 Initial Splint Prototype Construction

Based on the conceptual designs, alternative designs, and design making process, the team constructed an initial splint prototype. The prototype was constructed of a separate base component and a shell component. The base component was constructed of an elastane (spandex)-polyester blend material. This component had the two gel bulk material pieces sewn in designated locations at the base on the metacarpal to prevent subluxation. The shell component was constructed from 100% polyester material. A thin ¾ inch-thick Velcro® strip was sewn onto the shell component near the anatomical location of the pisiform bone, on the opposite side of the metacarpal.

The team planned to use the initial splint prototype to conduct the first round of surveying and mechanical testing. To do so, the team needed to construct different sizes of the splint to fit a wide range of patients. To properly size the splint, the team relied on anthropometric data. This data was obtained from Man-Systems Integration Systems (MSIS), National Aeronautics and Space Administration (NASA) (NASA, 2011).

Each of these measurement numbers included a value for the 5^{th} percentile, 50^{th} percentile, and 95^{th} percentile. The team converted these percentiles into sizing categories for both males and females separately. For both sexes, the 5^{th} percentile was considered a female or male size small (FS or MS), the 50^{th} percentile was a female or male size medium (FM or MM), and the 95^{th} percentile was a female or male size large (FL or ML). The following data tables were created for both sexes to display and further analyze the data obtained from this study:

Table 24: Female measurement table (NASA, 2011)

FEMALE	**5th percentile (FS)**	**50th percentile (FM)**	**95th percentile (FL)**	***Range***
Hand breadth	6.9 cm	7.8 cm	8.6 cm	1.7 cm
Hand circumference	16.5 cm	17.9 cm	19.3 cm	2.8 cm
Hand length	15.8 cm	17.2 cm	18.7 cm	2.9 cm
Wrist circumference	13.7 cm	15.0 cm	16.2 cm	2.5 cm

Table 25: Male measurement table (NASA, 2011)

MALE	**5th percentile (MS)**	**50th percentile (MM)**	**95th percentile (ML)**	***Range***
Hand breadth	8.2 cm	8.9 cm	9.6 cm	1.4 cm
Hand circumference	20.3 cm	21.8 cm	23.4 cm	3.1 cm
Hand length	17.9 cm	19.3 cm	20.6 cm	2.7 cm
Wrist circumference	16.2 cm	17.7 cm	19.3 cm	2.7 cm

The range represents the maximum value (95th percentile) minus the minimum value (5th percentile) for each measurement. On average, the measurements for males had a greater range than measurements for females. To determine proper sizing of the splint prototype, the team decided to create three unisex small, medium, and large sizes. The sizes were created by averaging neighboring measurement values. The small unisex splint averaged FS and FM values, the medium unisex splint averaged FL and MS values, and the large unisex splint averaged MM and ML values. These averages are shown below:

Table 26: Averaged values for unisex sizing

	Unisex small (FS/FM)	**Unisex medium (FL/MS)**	**Unisex large (MM/ML)**
Hand breadth	7.4 cm	8.4 cm	9.3 cm
Hand circumference	17.2 cm	19.8 cm	22.6 cm
Hand length	16.5 cm	18.3 cm	20.0 cm
Wrist circumference	14.4 cm	16.2 cm	18.5 cm

These averaged values were then rounded to create different sizing for the base component and shell component. The shell component needed to be slightly larger so that it could properly fit over the base component without creating a poor fit or user discomfort. It was also necessary to consider a cutout portion of both the base and shell component that would

allow for adequate thumb space. The length value was also adjusted. The team wanted the splint to extend from the base of the metacarpals 2-5 slightly passed the wrist bone. This measurement was approximated by measuring the length that would fit the unisex small category and increasing the value based on a simple ratio for each size. This value (length of splint) was used instead of hand length in the final values for splint sizing. This was accomplished by averaging measurements of thumbs that would fit the unisex small category and increasing this value based on a simple ratio for each size. Additionally, the handbreadth measurement was not used for final sizing, as the other measurements proved sufficient for sizing. To properly cut and sew material for the splint, the team created sewing patterns. These sewing patterns can be found in Appendix E. The final sizing for the unisex splint sizes for both the base component and shell component are shown below:

Table 27: Base component values for unisex sizing

	Unisex small (FS/FM)	**Unisex medium (FL/MS)**	**Unisex large (MM/ML)**
Hand circumference	17.5 cm	20.0 cm	23.0 cm
Wrist circumference	14.5 cm	17.0 cm	20.0 cm
Length of splint	14.0 cm	15.0 cm	16.0 cm
Thumb cutout width	4.0 cm	5.0 cm	6.0 cm
Thumb cutout length	1.5 cm	2.5 cm	3.5 cm

Table 28: Shell component values for unisex sizing

	Unisex small (FS/FM)	**Unisex medium (FL/MS)**	**Unisex large (MM/ML)**
Hand circumference	18.0 cm	20.5 cm	23.5 cm
Wrist circumference	15.0 cm	17.5 cm	20.5 cm
Length of splint	15.0 cm	16.0 cm	17.0 cm
Thumb cutout width	4.25 cm	5.25 cm	6.25 cm
Thumb cutout length	1.75 cm	2.75 cm	3.75 cm

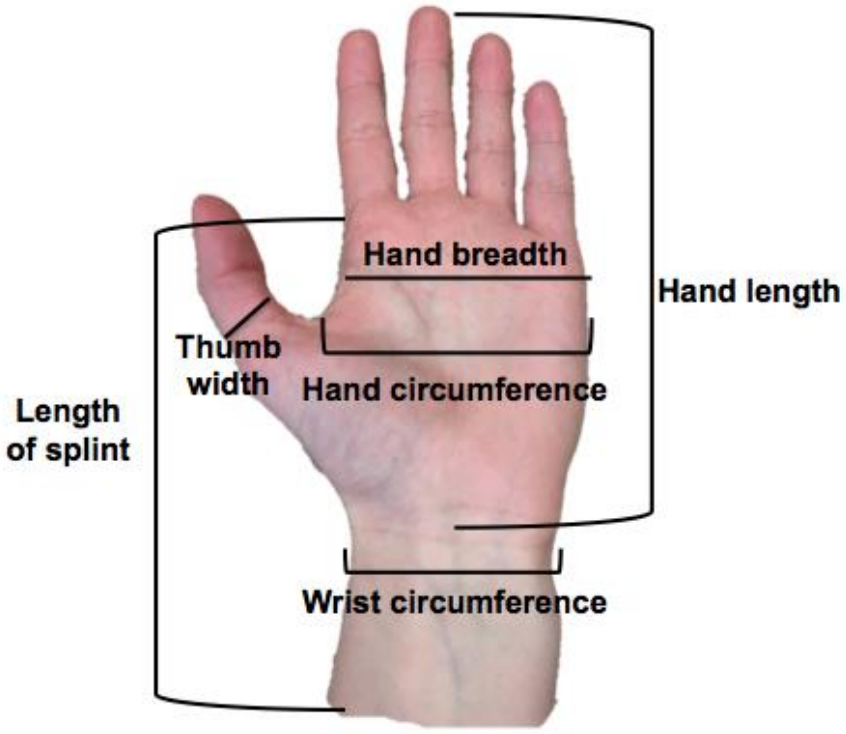


Figure 37: Hand length diagram

Lastly, the team needed to determine the proper size and location for the bulk material. To do this, the team members collected measurements of each team member's hand. For the size of the bulk material, the team measured the length and width of both subluxation points at the base of the thumb (see Figure 38). For the small sized splint, the length and width of subluxation points was collected and averaged for the four female members of the group. Similarly, the length and width of the male team member's subluxation points was used for the large sized splint. The median value between the small and large size was used for the medium sized splint.

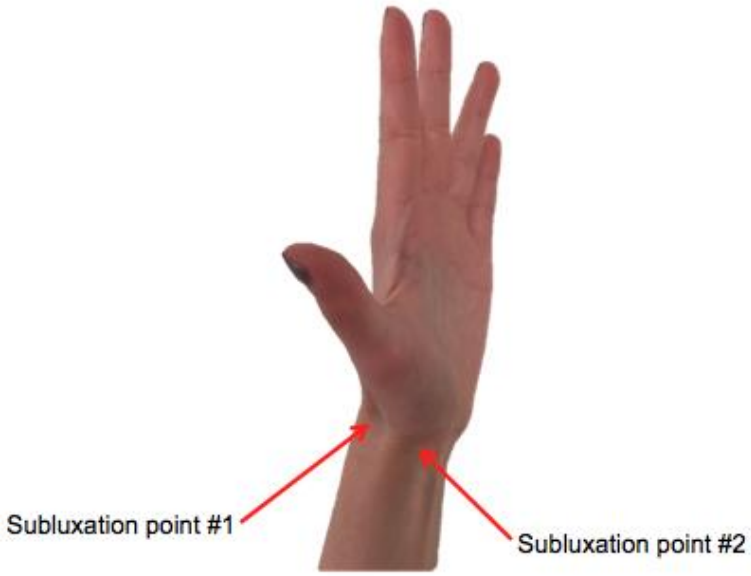


Figure 38: Labeled subluxation points on the hand

The length and width values were used to cut oval shapes from the gel material chosen for the bulk material. For the location of the bulk material, one team member tried on the appropriate sized splint while another team member marked the location of the subluxation point on the splint with a marker. The team then sewed the bulk material disk in place on the base material of the splint. An image of the first prototype is shown in Figure 39 with important components labeled.

Figure 39: Side view (left) and back view (right) of the initial splint prototype

4.9 Experimental Methods

The initial aim of splinting is to stabilize the first CMC thumb joint and prevent its movement during activities such as pushing and catching (Ladd et. al., 2013). Other splints for hand OA such as the one devised by the team are designed to support, protect, and immobilize the joint in order to reduce pain and allow efficient time for healing of inflamed joints and tissue, to prevent deformity, and/or correct existing deformities. The primary goal of stabilization at the base of the first metacarpal during the pinch is to prevent dorsal subluxation (Melville et. al., 2014). Although efficacies of previous splint designs utilized for treatment are scarce, researchers have developed a series of protocol testing for splint comparison and patient preference (Kjeken, Smedslund, Slatkowsky-Christensen, Uhlig, and Hagen, 2011). The team followed a similar protocol for the testing of the splint prototype.

The primary goals of conservative treatment are to reduce patient pain, improve the joint space position and thumb performance, and produce an increase in pinch and grip strength (Bagis et. al., 2003). Improvement in each of these categories can result in an increase in the ability to perform daily activities as well as a general improvement in the quality of life for those inflicted with CMC osteoarthritis. The team's method of patient splinting is considered to be the routine conservative method used.

4.9.1 Planned Patient Surveying

The team was unable to complete the planned patient testing due to various setbacks and conflicts. However if patient surveying was possible, the team planned to test their splint prototype design with twenty patients of Dr. Dowlatshahi. Testing would be completed at the Hand and Upper Extremity Care clinic at the Hahnemann Campus, UMass Memorial Medical Center (also referred to as Hahnemann Hand Clinic) that met the criteria for the American

College of Rheumatology (ACR) diagnosis of hand osteoarthritis. After a team member explained the aims, surveying and testing procedure, and reporting associated with the project, the patients would sign a waiver to confirm their participation.

The team created two surveys for use if patient surveying had been completed: an in-office survey (Appendix A – IRB Consent Form and Letter of Approval) and an additional survey (Appendix B – In-Office Patient Survey). The in-office survey would have been proctored, observed, and recorded by a team member, while the patients were expected to independently complete the additional survey while still in the office.

The in-office survey consisted of four total sections. The first two sections asked for patients to answer questions based on their pain and stiffness experience in the last week. The third section asked patients to report pain at rest, gripping, pinching, and turning both without wearing the splint prototype and while wearing the splint prototype. These movements would have been assessed using a hand dynamometer. Quantitative data would have also been collected from the hand dynamometer independently from the survey to record strength values for each patient. This data would be used to quantify OA patient strength and serve as a comparable for their perceived pain while completing the motions.

For the first three sets of questions, the team utilized a visual analogue scale (VAS). This scale consisted of a straight line between two extremes. The straight line was 5 centimeters (cm) in length. The left end of the line was considered the zero point, indicating no interference, pain, or stiffness based on the question being asked. The right end of the line was considered the maximum, indicating "cannot complete any…", or worst stiffness or pain possible based on the question being asked. Patients were asked to indicate their particular experienced limitations, pain, or stiffness by marking an "X" at a location on the line. The spot where the patient marked

was measured from the left end point of the line to the center of the "X". The location of the marking was then converted into a scale system adapted from Bellamy et. al., 2003 (Table 29).

Table 29: Classification Scale for In-Office Survey VAS

Distance	Classification
0-1 cm	None - little
1-2 cm	Mild
2-3 cm	Moderate
3-4 cm	Severe
4-5 cm	Incapacitating

The final section of the in-office survey asked patients to complete seven functional activities of daily living (ADLs). These activities were selected because they impact patient's completion of daily tasks essential to living a normal life. Patients were asked to complete the tasks without wearing the splint and while wearing the splint. They were instructed to check a box regarding the difficulty experienced while completing the task (no difficulty, mild difficulty, moderate difficulty, severe difficult, or completely unable). The different levels of difficulty were adapted from the Disability of the Arm, Shoulder, and Hand (DASH) questionnaire. Activities of daily living (ADLs) are activities that must be performed during daily life in order to function as a normal human being. They are routine activities that contribute to an individual's self-care abilities and are often used to assess the level of ability or disability an individual has. ADLs typically encompass the following activities: bathing, dressing, grooming, eating, toileting, and functional mobility. Many assistive technologies on the market today focus on restoring the independence of an individual with a disability by improving their ability to perform these simple tasks. There are also other common tasks an individual might need to perform throughout the day that may not necessarily be required for daily living. These activities are called Instrumental ADLs (IADLs) and cover a broad range of activities including going

outside the home, keeping track of money, taking prescription medicines and using the telephone.

Both severe and non-severe disabilities can interfere with ADLs and IADLs, therefore most assistive technology focuses on restoring these abilities in people with disabilities. This project provides an assistive technology to patients whose CMC osteoarthritis causes pain or difficulty performing daily tasks. By providing additional support and compression to the joint to prevent joint subluxation, the splint allows people with CMC osteoarthritis to complete daily tasks such as eating, grooming and dressing without any pain or discomfort. Any pinching, grasping or turning motion that would need to be performed during an ADL is often painful or impossible for patients with CMC osteoarthritis. This splint provides the necessary support to the joint to allow these patients to more easily and painlessly complete these tasks and therefore return to a normal, independent life.

The DASH is a comprehensive assessment tool that has been validated to measure functioning in the upper extremities (Luc, 2003). It includes 30 questions that assess both function and symptoms through the following categories: physical function (21 questions), symptoms of disease (6 questions), and social aspects (3 questions), along with two optional sections composed of 4 questions for work and athletes. A DASH score change of 10-14 following splinting was considered clinically meaningful. The DASH questionnaire was also used to help create the additional patient survey. Some questions were taken directly from the DASH questionnaire, while others were slightly adapted or removed from the survey completely due to over-specificity.

For each of the physical measurements of the in-office survey planned for collection in the study, the team hoped to glean more insight about the patient's hand functional integrity. For

proper assessment of the patient's grip using the hand dynamometer, patients would be seated with the elbow at 90 degrees with wrist flexion in the neutral position between supination and pronation. A hand dynamometer would be used to complete the in-office surveys and data collection. Grip strength would be evaluated in kilograms force (kgf) and the mean quantitative results would be used for analysis. The mean grip strength would also be evaluated from the mean of three tests for in the inflicted hand. A short period of rest would also be allowed between each test to avoid thumb fatigue. In the Framingham Study, participants with symptomatic hand OA experienced 2-3 kg (10%) less grip strength compared to those individuals without symptomatic hand OA (Johanson, Valero-Cuevas, and Hentz, 2001). In a second study, women with OA had only 60% of the expected grip strength norms for their age. Therefore, measuring both grip and pinch strength of each patient was deemed an important measure for testing for an improvement in hand function.

Pinch would also be assessed using a hand dynamometer. For assessment of the patient's pinch strength, patients would be seated with the upper limb in the same position that was adopted for grip strength. Pinch strength would be measured in kilograms force (kgf) and the mean of the results were used for team analysis. The mean pinch strength would also be evaluated from the mean of three tests for in the inflicted hand. It is commonly assumed that if the pinch force of the weakened or paralyzed thumb can be increased, then functional performance will be improved (Bani, Arazpour, Kashani, Mousavi, Maleki, and Hutchins, 2013).

The team also planned to analyze turning, or torque, strength for each patient. Contact forces in the thumb have been demonstrated to produce contact forces ranging from 6.4 to 16.4 times the input force at the carpometacarpal and consequently reflect a significant portion of the stress and strain enacted on the joint (Butz, Merrell, and Nauman, 2012). Torque analysis would

be completed using a hand dynamometer. Dr. Dowlatshahi informed the team that the dynamometer available at the Hahnemann Hand Clinic had a unique attachment capable of measuring torque strength, or turning strength.

The goals of the in-office patient survey and additional patient survey were to answer questions regarding the splint prototype's ability to correct thumb subluxation during repetitive motions and daily activities. The first question of the in-office survey asked patients to quantify how greatly their osteoarthritis interfered with work activities and daily activities. From this question, the team wanted to understand how greatly the disease actually impacted the patient's life. The team hoped responses on this question would indicate if the majority of splint wearers would be wearing the splint for an approximate eight-hour workday, or if patients would be wearing the splint for much longer spans of time. This section also attempted to address the overall need for the splint. The team sought an answer to the question "How could patients' daily lives be improved by this product?"

The next section of the in-office survey focused on stiffness experienced in the thumb, wrist, and hand overall. From these questions, the team wanted to understand the severity of individual patient's condition. If patients were to report high levels of stiffness in each category, they would be expected to report greater pain and difficulty in subsequent sections. The team also inquired about stiffness to determine if other areas of the splint could help address problems beyond thumb CMC osteoarthritis. The next two sections regarded patient pain both without wearing and while wearing the splint prototype. To complete these sections, patients were asked to use the hand dynamometer. The team planned to ask questions regarding pain without wearing the splint first to establish a pain "threshold." The patient would mark on the VAS scale their experienced pain, while the team member would also record a value collected from the hand

dynamometer. The team then planned to analyze the patient's ranking of their pain versus the recorded values from the hand dynamometer and see if there was any correlation across the surveyed population. This section regarding pain experienced without the splint prototype also served as a control to determine how greatly the patient's responses and measured strength values would change while completing the same tasks wearing the splint prototype.

Accordingly, the following section asked patients to repeat the same hand dynamometer procedures while wearing the splint prototype. Similarly to the previous section, the patients would be asked to quantify their pain experienced during the tests using the VAS scale on the survey while a team member recorded the output values from the hand dynamometer. This was the experimental section – the team planned to compare the results from control section to the experimental section to see if there were any remarkable changes.

For the last section of the in-office survey, a team member would instruct the patients to complete a series of daily tasks using props. These tasks simulated gripping, pinching, and turning motions. The patients would be asked to check a box regarding their difficulty experienced while completing the task. This section would have proved difficult for the team to proctor. It would be important not to use the words "pain" and "difficulty" interchangeably. While there is some ambiguity involved, the team wanted the last section of the survey to focus on how the splint either allowed patients to complete the task with more or less ease than they typically experienced. The additional survey, which patients would be expected to quickly complete before leaving the office, focused on similar goals. The team wanted to understand how much difficulty patients experienced in the past week completing daily tasks that were also based on gripping, pinching, and turning motions, and compare these answers to those collected in the in-office survey.

4.9.2 Unaffected Individual Surveying

Since the team was unable to complete patient surveying at the Hahnemann Hand Clinic, they needed to devise another method to evaluate the splint prototype. To do so, the team created an unaffected individual survey. This survey could be used on a more general population since the team did not have access to a contingency of thumb CMC osteoarthritis patients.

The unaffected individual survey used some of the same questions as the in-office patient survey. However, participants in this survey were only asked questions about pain and difficulty experienced completing selected daily tasks while wearing the splint prototype. By answering these questions, the team hoped to learn more about the splint's comfort and adjustability. If the splint prototype limited unaffected participant's ability to complete the described tasks, it would indicate major flaws in the design.

For the first section of the unaffected individual survey, participants were asked to indicate their pain experienced at rest and performing gripping, pinching, and turning motions while wearing the splint prototype. Because the team was unable to borrow a hand dynamometer for an extended period of time necessary to complete surveying, the team improvised with props. To answer questions regarding pain during grip, participants were asked to hold a glass for approximately five seconds. To indicate pain experienced during pinching, participants were asked to pinch the thick end of a key between their thumb and index finger. For pain experienced during turning, participants were asked to open the lid of a jar. Some of these tasks were then repeated during the next section. Again, there was some ambiguity between what qualifies as "pain" and what is "difficulty," but the team members conducting the survey attempted to collect unbiased answers from all participants.

4.9.3 Team Testing

The team was not able to collect hand dynamometer values from unaffected individuals. Instead, gripping and pinching hand dynamometer strength values were collected and recorded for each team member. The team was not able to collect any turning strength values with the hand dynamometer since they were not able to obtain the necessary apparatus to perform turning tests.

Each team member performed gripping and pinching motions using the hand dynamometer both without and while wearing the splint prototype in three trials. Team members were given thirty seconds of rest in between each trial. The values of the trials were averaged to analyze how the splint may have affected the team member's grip or pinch strength value.

Similar to the methods described for planned in-office patient surveying, team members were seated with the elbow at 90 degrees with wrist flexion in the neutral position between supination and pronation for data collection. A Baseline® Evaluation Instruments hydraulic hand dynamometer (Appendix F – Troy Hand Dynamometer Information) was used to complete data collection. Both grip and pinch strength were assessed in kilograms force (kgf).

5. Design Verification

5.1 Compression Testing of Bulk Materials

Biomechanical forces have shown that forces increase exponentially from the tip of the thumb to the CMC joint with grasping and pinching motions. The joint reactive force at the base of the thumb is 12 times greater than that generated at the tip of the thumb during forceful pinching. Compressive forces approaching 120kg may occur at the trapeziometacarpal joint with forceful grasping (Ladd et. al., 2013). In order for our device to successfully prevent joint subluxation, the material chosen as the splint insert must be able to withstand forces equivalent and or greater than those that would occur during daily wear. The team discussed possible bulk materials and subsequently tested the performance for each individual material under compressive forces. This was used as a proof-of-concept that the splint would perform its desired function when incorporated into the final design.

Four separate gel samples were subjected to compression to fracture testing at a crosshead speed of 10 mm/min on an Instron® Universal Testing Machine equipped with a 1 kN load cell. Instron® software was used to operate the instrument and collect data. All samples were clamped to avoid slippage during testing. The load experienced (N), time (s), and extension of the material under compression (mm) was documented for each trial in a designated spreadsheet. The maximum force experienced by each material can be seen in Table 30 below. The Instron® was manually stopped when the crosshead was in contact with the lower grip, ensuring that the material was fully compressed. In addition, the interval testing of each material from compression to time of failure was compared graphically in Figure 40.

Table 30: Maximum force experienced by each material

Material Description	Maximum Compressive Force (N)
Foam insole	28.1
Clear gel insole	334.5
Blue gel insole	1094.4
Pink gel insole	170.6

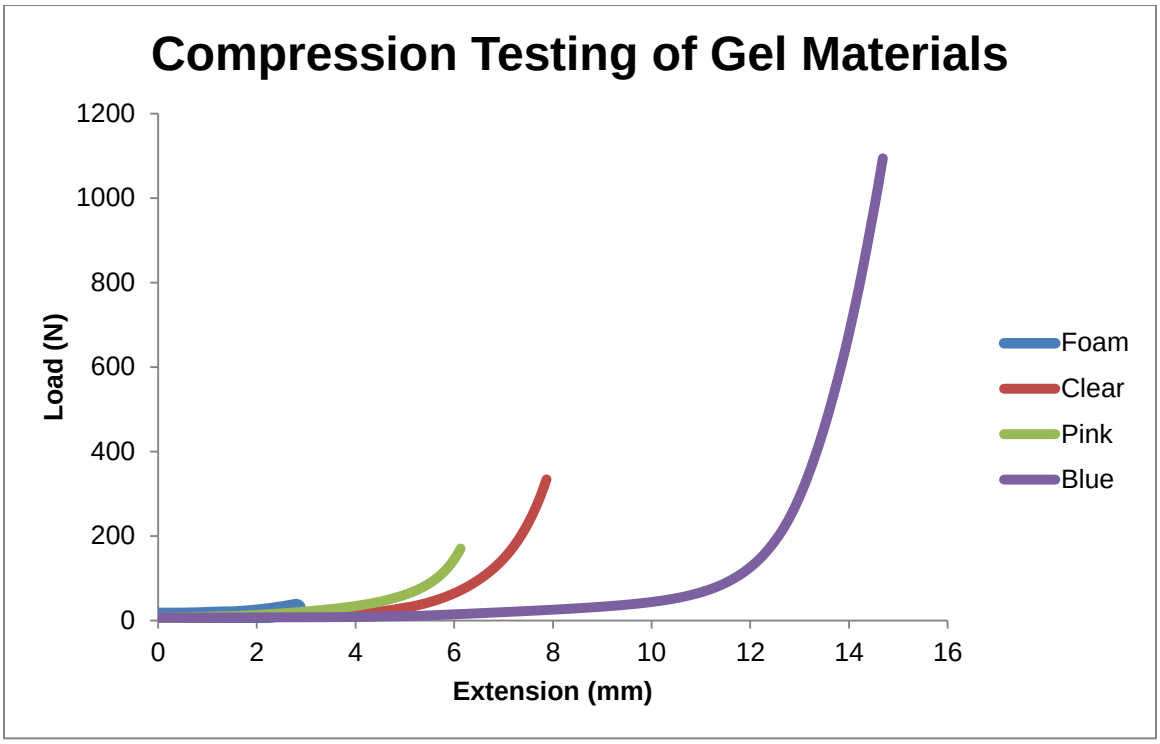


Figure 40: Gel compression testing comparison

Since the rate of compression was based off of the in-vitro mechanical loading experienced on the joint, the tested materials were rated as pass or fail in regards to a minimum value decided by the team. This was determined by comparing the induced stress of each material from the applied force. Since the size of the gel is restrained by the joint space of the carpometacarpal, the team required a material that could withstand maximum force on a minimal area. Subsequently, the gel would be able to experience a force similar to the average daily force that could occur in typical joint function. Based off averages for a healthy individual's grip and pinch strength; a value of 300N was chosen to represent the maximum force endured by the

carpometacarpal during daily activity. An averaged value over that of a maximum was chosen due to the team's knowledge that patients are unlikely to routinely experience forces of an equivalent magnitude to those determined from a patient's maximum grip strength. The repetitive stresses of conducted over a patient's lifetime represents the true cause of the induced joint wear and tear.

Two of the 4 materials tested under compression demonstrated the capacity to withstand this force; these include the blue gel insert and the clear gel insert. The following materials were subsequently allowed to represent a possible alternative for the team's splint insert. However, based on the superior performance of the blue gel shoe insert compared to the other gels, the blue gel was utilized by the team for the initial splint prototype and subsequent testing. Due to limited access of material data sheets provided by the company an exact chemical composition of the gel could not be determined by the team. Despite the team's limited information, a gel of similar chemical composition and mechanical properties was chosen by the team to be used in the final design of the device.

5.2 Planned Patient Surveying

The team planned to survey twenty patients. The first page of the survey utilized a visual analog scale (VAS) (Table 29). Patients would be asked to mark on the 5 cm line their appropriate level of interference, stiffness, or pain experienced based on the question. The second page of the survey was more straightforward, asking patients to check their level of experienced difficulty while completing certainly daily tasks. The patients would be asked to complete the same series of daily tasks both while wearing and without wearing the splint prototype. The team expected to see changes in the patient's responses in the two different

scenarios. Ideally, patients would report less difficulty completing the daily tasks. This would indicate that the splint stabilized the joint and provided comfort during movement for the patient.

The team also planned to ask all surveyed patients if they had an additional hand conditions that could affect their ability to perform certain tasks. The team expected that about half of patients would report other cases of hand or wrist arthritis.

Similar to the second page of the in-office survey, the team planned to ask patients to indicate their level of difficulty experienced while completing certain tasks. This was a reflective survey – patients were asked to report their difficulty level over the past week. The team expected that patients would most frequently report "Moderate Difficulty" for these tasks over the past week.

5.3 Unaffected Individual Surveying

To gather further data regarding the splint prototype, the team conducted surveying with unaffected individuals. Individuals were considered "unaffected" if they did not have any known cases on thumb CMC OA or any other forms of hand arthritis.

Fifty total individuals were surveyed. There was an even distribution of men and women participants (25 men, 25 women). The average age of survey participants was 21.23 +/- 2.61. The first section of questions utilized the VAS. Patients were asked to report their pain experienced at rest and performing gripping and pinching actions while wearing the splint. Participants were asked to hold a drinking glass to report pain experienced during gripping action. To report pain experienced during pinching action, participants were asked to hold the top of a key between their thumb and index finger. The responses using the VAS were converted using the scale presented in Table 29. The team hoped that participants would indicate low levels of pain while wearing the splint.

Table 31: Summary of results from VAS section of unaffected individual surveying

	At rest		*Gripping*		*Pinching*		*Turning*	
VAS SCALE	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**
No Pain	23	23	23	23	23	22	22	22
0-1 cm: None – little pain	2	2	2	2	2	3	3	3
1-2 cm: Mild pain	0	0	0	0	0	0	0	0
2-3 cm: Moderate pain	0	0	0	0	0	0	0	0
3-4 cm: Severe pain	0	0	0	0	0	0	0	0
4-5 cm: Incapacitating pain	0	0	0	0	0	0	0	0
Worst pain possible	0	0	0	0	0	0	0	0

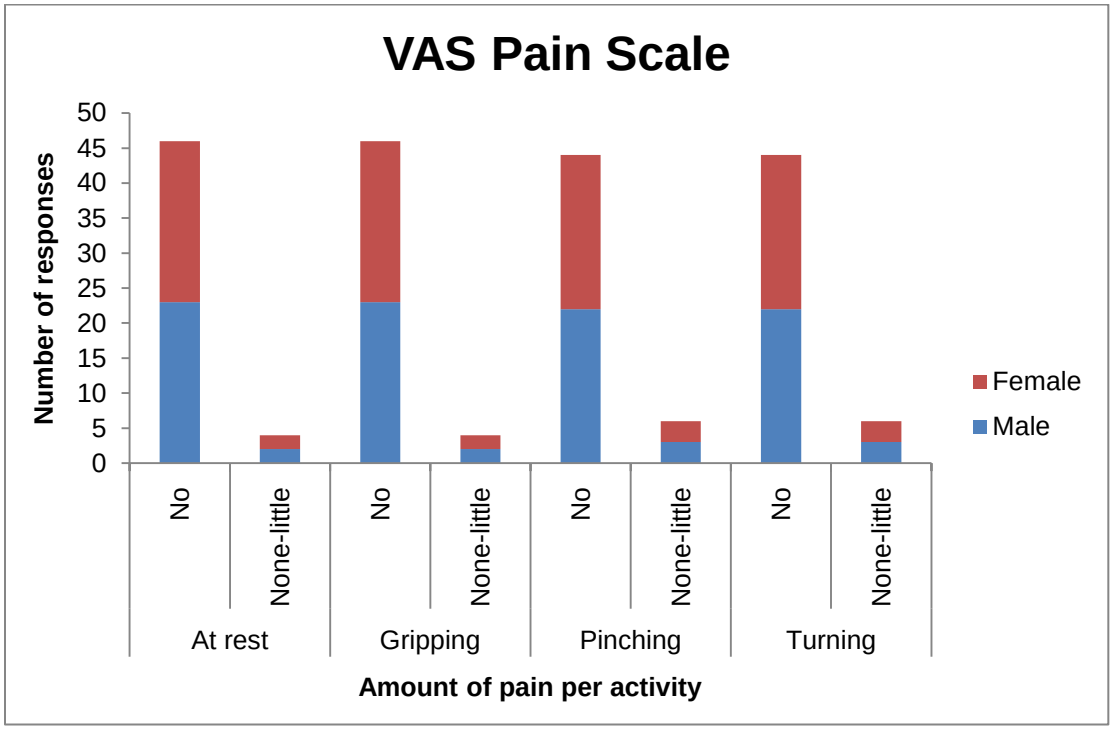


Figure 41: Graphical results of unaffected individual surveying from the VAS

Next, participants were asked to complete a series of daily tasks and report their difficulty in completing the tasks while wearing the splint prototype. The team hoped that participants would indicate low levels of difficulty while wearing the splint during performance of daily tasks.

Table 32: Summary of results from daily tasks section of unaffected individual surveying

	Task 1		*Task 2*		*Task 3*		*Task 4*		*Task 5*		*Task 6**	
DIFFICULTY LEVEL	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**
No difficulty	25	22	25	23	22	22	25	23	25	23	**--**	**1**
Mild difficulty	0	3	0	0	3	2	0	1	0	2	--	--
Moderate difficulty	0	0	0	2	0	0	0	1	0	0	--	1
Severe difficulty	0	0	0	0	0	0	0	0	0	0	--	--
Completely unable	0	0	0	0	0	1	0	0	0	0	--	--

Task 1: Turning a Key
Task 2: Holding a glass
Task 3: Zipping a zipper
Task 4: Opening a door
Task 5: Tying a shoelace
Task 6:* Writing a sentence

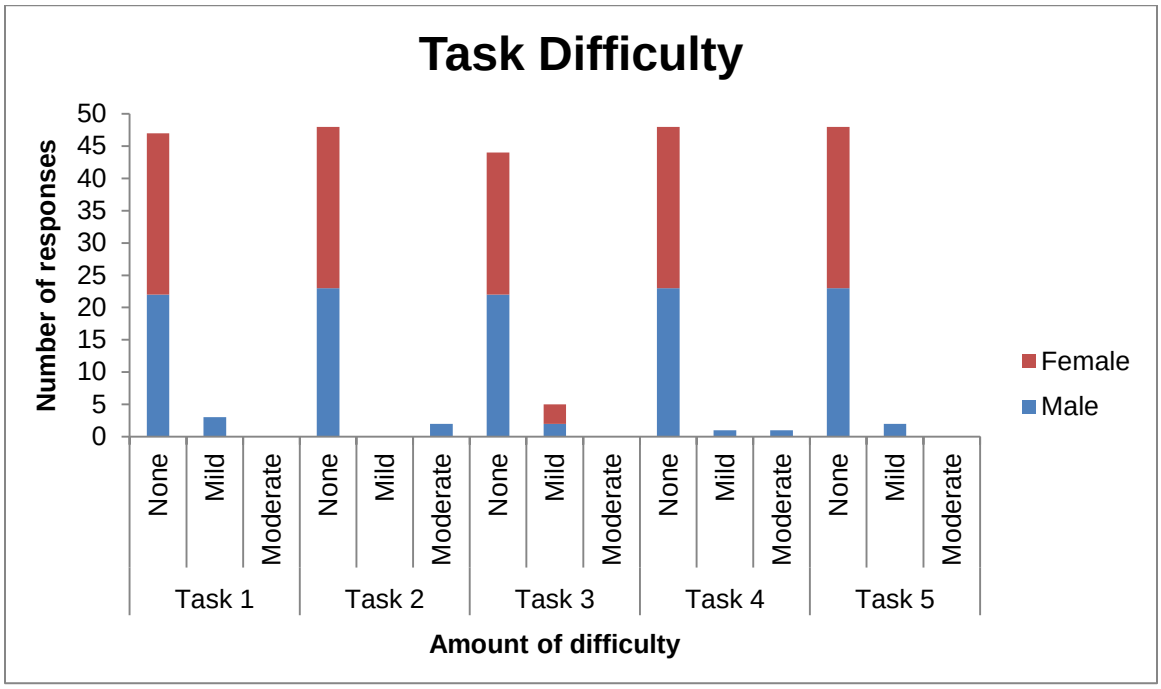


Figure 42: Graphical results of unaffected individual surveying for task difficulty

Task 6 was not performed by the majority of participants because the splints were better fit for the left hand. The results shown in Table 32 above account for the two left-handed people who participated in the survey.

5.4 Team Testing

Due to certain constraints, the team could only perform certain device tests amongst members. The team utilized Professor Troy's hand dynamometer (Appendix F – Troy Hand Dynamometer Information) to quantify actual grip strength and pinch strength values. The team was unable to collect hand dynamometer values for torque because this equipment was not available in Professor Troy's laboratory. Only team members were able to participate in hand dynamometer data collection because the equipment could not be removed from the laboratory space in Gateway Park.

Each member of the team completed gripping and pinching tests both without wearing the splint prototype and while wearing the splint prototype. These tests were completed using the left hand as the splint prototype was better fit to the left hand. This was also the non-dominant hand for each member of the group. Four of the five group members (all female) wore the unisex small sized splint. One member of the group (male) wore the unisex large sized splint. The average age of the team members was 21 years old. The results indicate the average calculated from three trials.

Figure 43: Hand dynamometer team testing front view

Figure 44: Hand dynamometer grip testing without splint

Figure 45: Hand dynamometer grip testing with splint

Figure 46: Hand dynamometer pinch testing with splint

Table 33: Summary of results for team testing with hand dynamometer

				***Gripping* (kgf)**			***Pinching* (kgf)**		
Name	***Gender***	***Splint Size***	***Age***	**W/O**	**W**	**Diff.**	**W/O**	**W**	**Diff.**
Fleek	F	S	21	9.2	9.0	- 0.2	1.9	1.5	- 0.4
Frank	F	S	21	26.7	24.3	- 2.4	3.0	4.0	+ 1.0
Garcia	F	S	21	13.0	15.0	+ 2.0	2.5	3.0	+ 0.5
Hesse	F	S	21	24.7	20.7	- 4.0	3.3	3.3	+ 0.0
Mastascusa	M	L	21	33.0	36.7	+ 3.7	6.0	8.3	+ 2.3

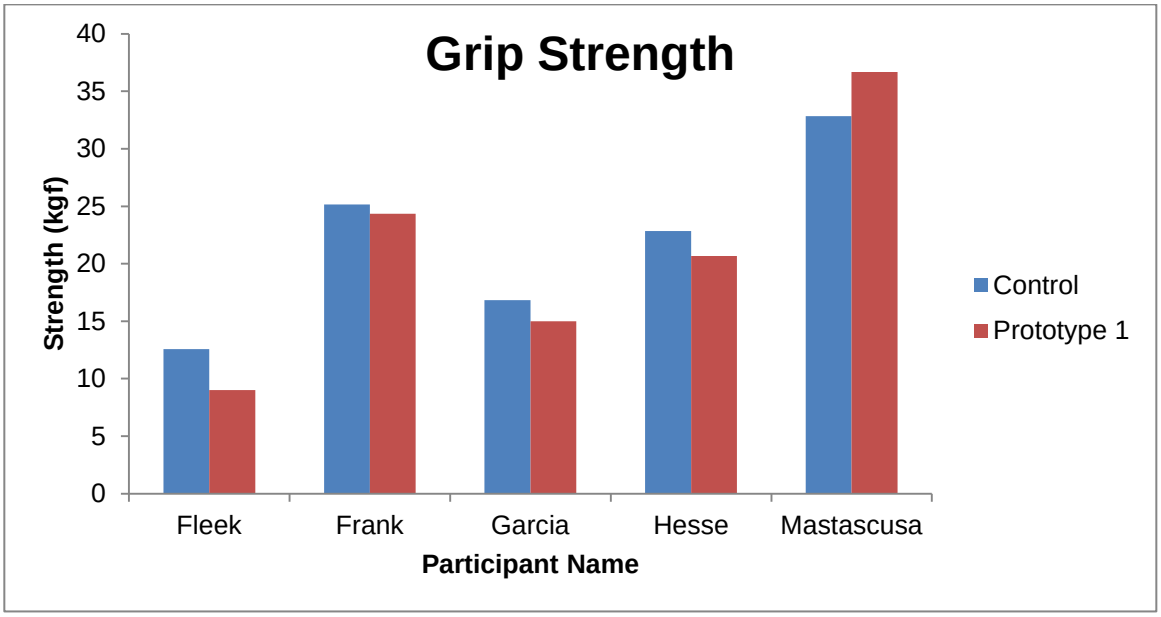


Figure 47: Graphical results of team testing grip strength comparing without splint, with splint, and overall difference

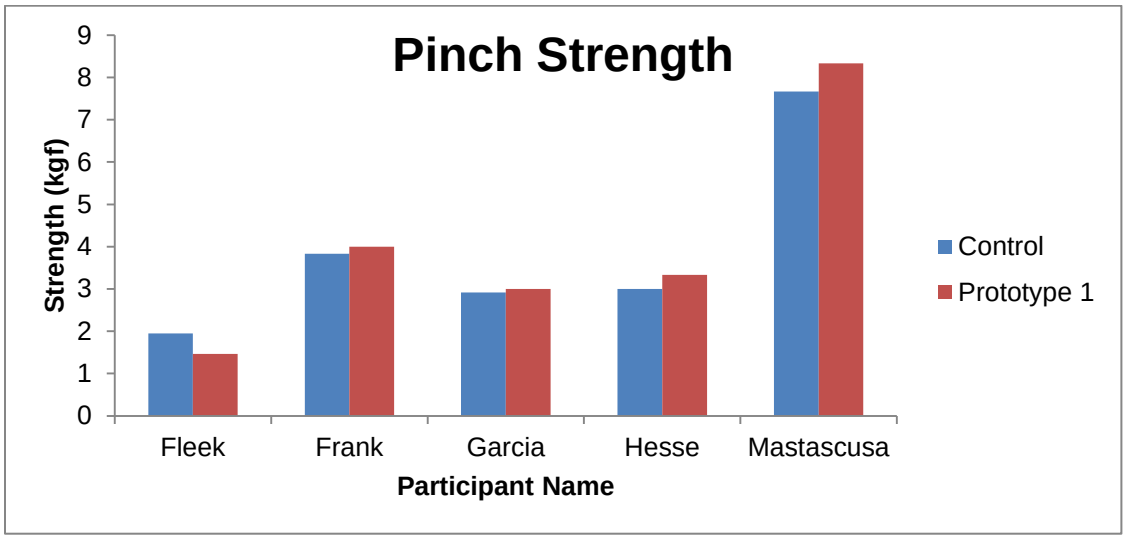


Figure 48: Graphical results of team testing pinch strength comparing without splint, with splint, and overall difference

6. Discussion of Results

6.1 Planned Patient Surveying

6.1.1 In-Office Patient Survey

Due to circumstances out of the team's control, the team was unable to complete any patient testing. Originally, the team was expecting that wearing the splint would both decrease the amount of pain the patient experienced during daily activity and decrease the difficulty of completing said activities. However, since the team was unable to perform any sort of patient testing, these expectations were unable to be confirmed or denied.

Ideally the results of the in-office surveys would show a decrease in joint pain as well as an increase in ability to perform daily activities. However upon further consideration and analysis of the final design, the team's hopes of seeing these results began to fade. Had the team been able to complete patient testing, the results would most likely not have been what the team was hoping to see. The splint would probably have had a very limited effect on the patients both in respect to the joint pain and the ease of completing daily tasks. For the first page of the survey, the team was expecting to see a decent amount of pain experience in the joint at rest and while completing gripping, pinching, and turning motions. In addition, the team expected these values to decrease once the splint was on. If this was the case, the decrease in pain could be attributed to the additional support provided by the splint or the potential increase of joint space as a result of wearing the splint. However, it needs to be kept in mind that pain is subjective and thus means different things to different patients. It is also worth mentioning that many OA patients would consider almost anything as relatively helpful, so the team would have had to analyze the results with this in mind.

On the other hand, there is also a decent chance that wearing the splint could also increase the joint pain experienced by the patients. If the gel does not provide enough resistance to have very much effect on the subluxation of the joint, patients could experience more pain while performing daily activities than they experienced without wearing the splint. In addition, the compression of the device as a whole could potentially hinder some patients' ability to perform daily tasks. For the second page of the survey, the team expected that the difficulty performing daily tasks would decrease for some tasks and increase for others depending on the degree of mobility needed to complete the task. When analyzing these results and the results from the first page of the survey, the team would have also needed to take into account whether or not the patient had an additional hand condition. If so, the results could be skewed on account of this condition, and it would be impossible to tell if the reported pain or difficulty was a result of the splint or of the additional hand condition.

Another important aspect of the design that the team expected to see a slight issue with is the placement of the gels. The team expected it to occasionally be very difficult to get accurate placement of the gels on the patient due to varying hand sizes and a lack of education on the patient side. Patients would not be trained medical professionals and therefore would not know much, if anything, about the anatomy of the hand. In order to get correct gel placement, the doctor would have to teach the patient about the anatomy of the joint to enough of an extent that they know where the joint spaces are and can adjust the splint on their own. This would cause a very steep learning curve that might turn some patients off of purchasing the device.

The team was also unable to determine the long-term effects of wearing the splint. The compression from both the gels and the spandex base layer could potentially be enough to reduce the swelling in the joint and thus reduce the stiffness experienced during daily activities, but the

team was unable to complete a long term study due to time and resource constraints. In addition, the team would not have had access to the equipment necessary to make these kinds of measurements on the patients before and after wearing the splint for an extended period of time.

6.1.2 Additional Patient Survey

The purpose of the additional survey was to see how the patient's osteoarthritis affects their ability to perform daily tasks. It asked the patients to reflect over the past week and determine how much difficulty they had performing a variety of tasks. Their responses on this additional survey acted as a control group or a baseline for comparison with their responses on the in-office survey. The team expected the patients to report having moderate difficulty performing most, if not all, of the provided actions. In addition, the team expected there to be several outliers who reported much less or much more difficulty performing these tasks depending on the severity of their osteoarthritis.

The team also expected certain tasks to be more difficult to complete than other tasks. For example, tasks that require more fine motor skills such as preparing a meal or using a knife to cut food would hypothetically be more difficult for a patient with CMC osteoarthritis than activities such as commuting or physical exercise. Activities that require fine motor skills would be more difficult and painful for these patients because of the accuracy and delicacy the task may require.

Even if the team were able to obtain results that were mostly what the team expected to see, they would not necessarily be reliable results. Many of the tasks on the survey would require interpretation by the patient, and would therefore mean different things to different people. For example, completing household chores encompasses a wide variety of tasks and could garner many different answers depending on which task a patient is thinking about when they answer the question. There would be no way to be entirely sure that the results from each survey are

comparable, because there would be no way to be certain that each patient is answering exactly the same question unless the questions are very specific. Therefore, the results could be compared but no reliable or statistically meaningful conclusions could be drawn based on data gathered from the additional survey.

6.2 Unaffected Individual Surveying

The results from the able body surveys showed almost exactly what the team was expecting. Only 4 subjects of the 50 that were surveyed consistently reported none-little pain while wearing the device while the rest reported no pain. The motion that was reported to be the most painful while wearing the device was the turning motion, which is to be expected. This is the motion that generates the most force within the joint, and because of the positioning of the hand during the motion; it is most prone to causing pain in the CMC joint. In addition, there did not seem to be any difference in pain experienced between subjects wearing the small splint and subjects wearing the large splint.

As for the difficulty portion of the survey, several subjects reported mild difficulty performing daily tasks while the majority of subjects tested reported no difficulty performing any of the daily tasks. For subjects wearing the small splint, the most difficult task was tying a shoelace. This was most likely due to the increased dexterity required for this task, as the splint limited motion in the joint and hand enough to interfere slightly with performing this task. For subjects wearing the large splint, the most difficult task seemed to be turning a key in a lock. This is most likely due to the wrist motion needed to complete the task. The compression of the splint on the wrist coupled with the placement and compression of the Velcro strip tended to make moving the wrist a little more difficult while wearing the splint than while not wearing the splint.

Another important consideration when analyzing the results of this testing was the possibility of subjects having previous hand conditions. One subject reported having a metal plate and five screws in his thumb, while another reported arthritis in her right hand (even though testing was being completed on the left hand). In addition, one subject mentioned that her wrist usually cracks due to a prior wrist sprain but that it did not crack at all while wearing the splint. It is important to consider prior hand conditions because they could potentially skew the reported data. If these prior conditions influence a subject's pain or ability to perform a task it would be impossible to determine whether their reported pain or difficulty levels are a result of wearing the splint or just of their prior hand condition.

The last major issue with the able body testing was that the device was tested on each subject's left hand due to a minor prototyping error. Most subjects tested were right hand dominant, so putting the splint on the subject's left hand meant that the data gathered would be less clinically relevant and significant conclusions would be harder to draw. For the second half of the survey, each subject had to be instructed to only consider the difficulty from wearing the splint, not from attempting to perform the task with their non-dominant hand. However it is impossible to tell whether or not the difficulty reported by the subjects was entirely due to wearing the splint or if it was from performing tasks with their non-dominant hand. In addition, the task in which subjects were supposed to write a sentence was no longer considered relevant since most subjects could not write with their left hands. Along these same lines, many subjects reported pain in the top of the thumb due to the constriction of the base material around the shaft of the metacarpal. The opening for the thumb was not as large as it should have been, so subjects had to be instructed to report only pain caused by the bulk material within the splint, not from the constriction around the thumb opening. This again made it impossible to tell whether the pain

reported was actually from the bulk material or if it was from the thumb opening portion of the splint. The bulk material also needed to be manually adjusted by the tester to ensure they resided in the proper location before the Velcro was applied. This shows that there is a need for a future design iteration that reevaluates bulk material location and determines a better way to ensure accurate bulk material location on each patient without extensive involvement by the doctor or medical professional.

The results of all the surveys are in line with what the team expected, because all the subjects tested were healthy young adults with an average age of 21 years. No subjects had osteoarthritis in their thumb, and therefore should not have had much difficulty or pain performing these tasks. However it was then possible to conclude that any difficulty or pain experienced was a direct result of wearing the splint. From these results, the team was able to conclude that the device is relatively comfortable to wear and does not cause significant additional pain in the joint both at rest and while performing daily activities. In addition, the device does not interfere with or hinder the performance of these daily activities, and can therefore be worn in a variety of settings.

6.3 Team Testing

The team completed dynamometer testing to determine the effect of the splint on the ability to perform certain activities such as pinching and gripping. The results were averaged for each splint sized used during testing to determine the average effect of wearing the splint. The results from the gripping tests showed a 1.1 ± 2.6 kgf decrease in force for the small splint and a 3.7 kgf increase in force for the large splint. This showed that even though the device added additional support to the joint, it did not have a significant impact on the ability of patients to perform a gripping motion. The change in force for this motion was relatively small as compared

to the applied force (i.e. a 1.1 kgf decrease from 18.4 kgf to 17.3 kgf) which shows that although the splint may have had a slight effect on the force produced, it was not a very significant change. In addition it did not have a similar effect on all subjects. Three team members experienced a decrease in grip force while wearing the splint while the other two team members experienced an increase in grip force while wearing the splint. Therefore statistically significant conclusions cannot be drawn about the effect of the splint on the ability to perform a gripping motion. However, all team members noted that it felt somewhat easier to perform this motion while wearing the splint than while not wearing the splint. The team noticed the intended effect of the bulk material even though all team members admitted that they were not in quite the right place nor made out of the right material.

The team also performed pinching tests to see if the splint affected the ability to perform the motion or the force applied while performing the motion. The results from this test showed an average increase in force of 0.3 ± 0.6 kgf for the small splint and 2.3 kgf for the large splint. The change in force for each subject was almost consistently a positive change in force except for one team member who experienced no change and one team member that experienced a decrease of 0.4 kgf. Again the change in force for this test was relatively small (only a 10% increase for the small splint and an approximately 30% increase for the large splint) and the team members noted that it was relatively easier to perform this task while wearing the splint as compared to not wearing the splint.

Overall the results between the large and small splints were mostly proportionally similar. For the gripping motion the average force for the large splint was roughly twice that of the small splint, and similarly the average difference for the large splint was between 2-3 times that of the small splint. For the pinching motion, the average forces for the large splint were

almost 3 times those of the small splint. However the difference for the large splint was almost 8 times that of the small splint. This is most likely due to the difference in subjects for each category, which skews the results gathered during the testing and makes comparison of the values difficult. There was only one subject that used the large splint while four subjects used the small splint. Therefore it was easy to gather an average value for all tests for the small splint while the values for the large splint were based on only one subject. This means that the data for the small splint could be used to represent a larger population for statistical analysis, while the data for the large splint could not.

As mentioned previously in the able body testing section, it is also important to note that all subjects were healthy 21 year olds and thus should not have experienced as large of a difference in pinch or grip strength that a patient with osteoarthritis might. In addition, each three trials were performed for each test to ensure accuracy of the data. Unfortunately, this may have caused slight fatigue in the hand and the CMC joint and thus could be the cause of the difference between the force values for wearing the splint and not wearing the splint. Therefore the team was unable to conclude that the change in grip or pinch force was due entirely to the effects of the splint.

Another important factor for this testing was the anatomical differences between the CMC joints of males and females. In this test there were four female subjects and only one male subject, so the difference in pinch and grip strength could be due to these anatomical differences. This unfortunately renders the comparison between the large and small splints are relatively inaccurate because the lack of subjects made it impossible to determine what caused the differences in reported forces between the small and large splints. Had there been an equal mix of males and females for both splint sizes, the team could draw accurate conclusions about the

grip and pinch strengths for each splint and the effect of each splint on the user. In addition, hand size varies greatly between individuals, so the effect on the splint is not the same in each subject. Some subjects may experience more compression or more force from the bulk material than other patients, and would therefore get different results during this test. This makes it nearly impossible to accurately average the change in force due to the effect of the splint because it is impossible to quantify the effect the splint has on each individual patient.

6.4 Compression Testing

The results of the compression testing completed using the Instron® machine were used to select the material that was most suitable for use as the bulk material. The bulk material needed to withstand particular compressive forces experienced at the trapeziometacarpal joint in order to prevent subluxation associated with OA. The team decided to use compression testing because it would provide the most valuable data regarding the materials. The results of compression testing were limited by the parameters of the Instron® system. The team needed to select a crosshead speed and load cell force that were within the machine's capabilities.

Additionally, the team was required to manually stop the compression crosshead attachment when the gel appeared to be fully compressed. This was determined visually as to when the gel was compressed so much so that the crosshead was nearly touching the platform on the lower grip. This could have caused some error within the results since the team had to discern when to halt data collection. Thus, the total time of testing varied slightly for each material.

6.5 FEA Model and Manual Calculations

The team planned to develop an FEA model that incorporated not only the bones in the CMC joint but all of the surrounding soft tissues. However, the team was unable to entirely complete this goal. The final model included the metacarpal, the trapezium and the

corresponding cartilage for each bone, but not the tendons or ligaments due to a lack of necessary feedback and insufficient anatomical knowledge. In addition, the team was able to model the preload (the small load to ensure proper bone contact) but was unable to perform loads to mimic typical hand motions such as pinching, gripping, or turning. The intended purpose of these loads was to study the stresses and strains experienced in the joint during each of these movements. The team had hoped that this in turn would help drive the design of the splint by showing the team where the largest stresses were in the joint and how the joint reacted to certain applied stresses. This information could then have been used to better place the bulk material and better choose a material that could withstand a large amount of force while still being comfortable for the user to wear.

The team additionally performed various manual calculations to verify the results from the FEA model. Using biomechanical principles, the team manually calculated the joint forces and moments as a result of the applied loads that mimicked pinching, gripping, and turning. Unfortunately, the accuracy of these calculations is relatively uncertain because of the many assumptions that needed to be made in order to complete the calculations. The team hoped to use these calculations to ensure that the FEA model acted in a manner that was similar to how the joint would react in the body by comparing the maximum stresses in the model to the manually calculated stresses.

6.6 Progress towards Defined Goals

6.6.1 Meeting Design Goals

The device was able to entirely meet four of the previously defined design specifications, and was unable to meet the additional three due to time and resource constraints. The first design specification outlined that the device must be able to withstand 100 kg of force. The team

performed mechanical testing using an Instron® to test the gel material to ensure that it could withstand this force. As discussed in the Mechanical Testing section above, the gel used in the final prototype was able to withstand 1094.4 N (111.6 kgf). Therefore, the device met this design specification.

The second design specification detailed the maximum amount of compression the device could supply to the joint. Unfortunately, the team lacked the necessary technology required to test the device for this design specification, so the team was unable to definitively say whether or not the device met the specification. However, each team member was able to wear the device for extended periods of time without experiencing any symptoms of reduced blood flow.

The third design specification related to the length of the device and how much of the arm the device covered. Based on background research of anthropometric data, the team developed a sewing pattern for the device. The length on this pattern (which was subsequently used to develop the prototype) was 14-16 cm, which was under the specified value of 16 cm. In addition, the team measured each prototype's length, and all measurements were below the specified value. Therefore the team concluded that the device met this design specification.

Similar to the second design specification, the team was unable to evaluate the fourth or fifth design specification. The fourth specification described the range of motion the device must allow in terms of palmar abduction, radial abduction, and adduction. The team was unable to make these measurements due to time and resource constraints, so the team was unable to conclude whether or not the device met this specification. The fifth design specification detailed the ideal increase in joint space as a result of wearing the splint. To reduce joint pain, the device should aim to increase the joint space from roughly 0.5 mm to 1 mm. However, the advanced technology and in-depth measurement process to obtain these values is very complex and out of

the scope of this project. Therefore the team was again unable to determine if the device met this design specification.

The sixth design specification specifies the daily tasks that a subject should still be able to perform while wearing the device. These tasks were the daily activities included in both the additional patient survey and the able body survey. Since able body surveying was completed and most subjects had little to no difficulty performing these tasks, the team was able to conclude that the device met this design specification.

Finally, the seventh and last design specification required that all materials used in the device be biocompatible and not cause any harm to the patient. Background research showed that all materials used in the device were already approved for their biocompatibility since they all had to go through thorough testing in order to be put on the market. Therefore, the team was able to conclude that the device met this design specification since all materials used in the device are considered biocompatible.

6.6.2 Meeting Overall Project Goals

The following bulleted list indicates the major tasks associated with each term of the project:

A TERM:

- Familiarizing with the project
- Meeting with advisors to understand team expectations and proposed project outcomes
- BME 4300: Capstone Design class presentations
    - Literature review
    - Objectives, constraints function
    - Initial client statement → final revised client statement

    - Research on current products
    - Draft project approach
- Writing/sequential editing of Chapters 1, 2, and 3 based on professor and teaching assistant feedback

B TERM:

- Advisor meetings
- Defining experimental methods and planning
- Conceptual design phase
- Conceptual design prototyping
- Conceptual design prototype testing
    - Surveying
- FEA model
- Chapter 4 writing

C TERM:

- Advisor meetings
- IRB submittals
- FEA model
- Finalizing prototype
- Surveying
- Team testing of prototype
- Mechanical testing

- Resign
- Drafting report

D TERM:

- Remaining surveys
- Editing draft report
- Preparing presentation
- Finalizing conclusions and recommendations

6.7 Device Comparison with Current Solutions

6.7.1 Device Comparison with Current Splinting Devices

There are currently a variety of nonsurgical treatment options for CMC osteoarthritis. However, none of these alternatives adequately address the needs of the doctor or the patient. Nonsurgical options are considered "conservative treatments" for treating patient pain (Egan and Brousseau, 2007). Current nonsurgical options such as splints, joint protection, and joint strengthening are not always adequate in treating osteoarthritis for all patients. Recent designs constructed of polyurethane, neoprene, and plasters are either too rigid or too flexible to cover all patient needs. On the other hand, the team's final design fulfills the medical need for a functional and user-friendly, nonsurgical treatment option that is both aesthetically pleasing and marketable to possible clientele. The designed splint also promotes patient compliance for wear by promoting great functionality and comfort. An appealing exterior that maintains both comfort and stability will receive fewer objections from patients who commonly complain that the splinting devices of today are too uncomfortable, unattractive, and restricting to be worn on a daily basis.

The primary goal of the team's device was to restore thumb range of motion and alleviate the associated pain of CMC osteoarthritis. While a majority of splints on today's market restrict both thumb and wrist motion as a means of preventing carpometacarpal hypertension, the team's design incorporates the idea of localized pressure to increase joint space. This allows the patient to maintain full range of motion while preventing joint laxity during hand functioning. The combination of compressive materials and joint stabilizing inserts which rest in the metacarpal joint space allows the splint to provide a similar ideological result that is applied in surgical procedures for arthritic treatment. By focusing solely on the inflicted arthritic joint adjacent joints can also avoid the subsequent weakness that results from repetitive motion restriction, a common occurrence in the orthopedic products of today.

Two common splints currently on the market include the *Comfort Cool® Thumb CMC Restriction Splint* and the *Medspec CMC Thumb Support* (North Coast Medical, 2014; The Brace Shop, 2014). Both designs oppose osteoarthritis in a similar manner: restricting thumb and hand motion to prevent joint pain and laxity. The team chose to capitalize on the faults in their design. Upon proper analysis of their design and patient feedback, the team found that the splints restrict the functionality and range of motion of the thumb and wrist, thus creating an extrinsic joint weakness. The splints do not accommodate the patient needs of functionality and practicality for daily wear. Daily tasks increase in difficulty and frequently leave the patient frustrated. In order to capitalize on the discrepancies found on today's splint market the team devised a flexible, user-friendly design that solely treats the laxity and associated pain of the CMC joint through a simple yet effective combination of joint stabilizers and compression.

6.7.2 Device Comparison with Surgical Methods

Doctors often consider surgical options when patient pain becomes “intractable” (Egan and Brousseau, 2007). Surgical procedures typically involve cutting some part of the joint or reconstructing the ligament. These procedures are highly expensive, and the outcome is often unexpected. The present gold standards for treatment are still inadequate due to the lack of progress in the field in the last 40 to 50 years. Hand surgeons are still performing outdated surgeries and prescribing similar treatment protocols from a lack of better options (Dowlatshahi, 2014). The search for a low cost, nonsurgical treatment method has since become particularly prominent in the medical industry.

Primary competition for the team’s device comes from the hospitals and surgeons who pursue these surgical routes for the treatment of CMC. These surgeries often involve the most severe cases of patient osteoarthritis and joint degradation, and entail ligament and tendon reconstruction and/or removal of the trapezium bone degraded by arthritis that is then substituted with a graft in the void. While these surgeries effectively prevent joint subluxation, adverse side effects such as decreased strength and range of motion of the thumb are prevalent through documentation of the patient’s torsion, pinch, adduction, and abduction strength pre and post-surgery (Park et al, 2008). The exorbitant cost of the surgery -- ranging anywhere from $1,000-8,000 – further defines it as an unwanted treatment option (Holly House Private Hospital, 2014). The team’s splint negates the heavy cost of the surgeries while maintaining and/or improving functionality and strength of the thumb. It provides similar joint support and stabilization but drastically decreases the cost and entirely eliminates the invasiveness experienced during these surgeries.

A newly developed surgical technique for treating CMC osteoarthritis was created based off of suspension arthroplasty, a procedure used as an alternative surgical technique following failed implant arthroplasty. This technique employs an artificial tightrope strung between the thumb metacarpal base and the second metacarpal shaft. Surgical utilization of the Mini Tightrope, in conjugation with biological repair, has asserted itself as a unique means to stabilize the thumb metacarpal after a trapezial resection for OA treatment (Melville et. al., 2015). Device suspension reduces the thumb and index metacarpals into proper relationship and is maintained through healing (Yao and Lashgari, 2014). The splint designed by the team will utilize a similar concept to that of Tightrope surgical procedure. Localized pressure rather than suspension between the metacarpals will be used to prevent joint subluxation and promote joint healing replicative of this employed medical procedure. However the splinting device will have several advantages over the surgical procedure. As stated above, the cost of the splint is significantly lower than that of the surgery, and the splint achieves a very similar effect without the invasiveness of surgery. The bulk material in the splint served the same function as the tightrope by filling the joint space and ensuring that the first metacarpal stays in its proper position. This reduces joint pain by increasing joint space and increase joint stability by reducing the ability of the metacarpal to undergo subluxation.

6.8 Limitations of Results

The results for this project are quite limited due to time, resource and technology constraints. The team was unable to complete patient surveying, so there is no significant data detailing the effect of the splint on patients with osteoarthritis. The team was unable to see if the device decreased joint pain or difficulty performing daily tasks, which were the two main goals of the project. In addition, the team was unable to get any feedback from patients that could have

been used to develop future design iterations. In addition, the team was unable to administer the additional survey to the osteoarthritis to see how much their OA interferes with their daily life. The only testing the team was able to complete was on able body subjects and on the team members. As discussed above, the data from both the able body surveys and from the team testing is only relatively reliable due to a variety of factors. Prototyping errors also required slight alterations to the testing methods, which could have resulted in unreliable data.

A major limitation to the mechanical testing results is that the team did not have an accurate method for stopping the testing. There has been no reliable previous work in the area, so the team had to manually stop the testing when it looked like the gel could no longer be compressed. This means that the maximum compression the team reported for each gel relies largely on the team's ability to judge when the cross head was in contact with the surface the gel was sitting on. Therefore the data is relatively unreliable and revised testing methods would have to be developed in order to ensure proper data collection and analysis.

Finally, there has been very little previous work in manual calculations of joint forces and moments in the CMC or in the development of anatomically correct FEA models. This means that many assumptions had to be made in order to accurately complete these tasks. For the manual calculations, several assumptions had to be made about bone geometry and density as well as force magnitude and placement in order to calculate the internal joint forces at the CMC joint. In addition, even more assumptions had to be made to complete the moment calculations. Assumptions concerning insertion and origin points, geometric data and applied force had to be made in order to accurately model the ligaments acting on the joint. Since there was very little prior research to work off however, the team completed these calculations as accurately as possible. As for the FEA, there has been almost no prior work completed on modeling the CMC

joint. It is a novel concept, so conclusions had to be drawn from work on other joints and applied to the CMC joint. Since none of the team members has an in depth medical background, the CMC joint was modeled as well as can be expected but may be lacking in the eyes of a medical professional.

6.9 Prospective Impacts of Design

6.9.1 Economics

Design stakeholders include competitive manufacturers and those involved in the medical industry, although primary competition comes from the hospitals and surgeons who pursue the alternative treatment route of CMC arthritis through surgical procedures. These surgeries often involve the most severe cases of patient osteoarthritis and joint degradation, and entail ligament and tendon reconstruction and/or removal of the trapezium bone degraded by arthritis that is then substituted with a graft in the void. While these surgeries effectively prevent joint subluxation, adverse side effects such as decreased strength and range of motion of the thumb are prevalent through documentation of the patient's torsion, pinch, adduction, and abduction strength pre and post-surgery (Park et. al., 2008). The exorbitant cost of the surgery – ranging anywhere from $1,000-8,000 – further defines it as an unwanted treatment option (Holly House Private Hospital, 2014). The splint designed in this project negates the heavy cost of the surgeries while maintaining and/or improving functionality and strength of the thumb.

The manageable cost will allow the splint to be marketable. The novel device is composed of easily manufactured materials comparable in price to others on today's market. Research into the base materials of the device have allowed the team to draft a cost comparison table which can be seen in Table 34 below:

Table 34: Estimated marketing costs for device

Design	Market Cost
Our Splint	$35-$42
Comfort Cool® Thumb CMC Splint	$25-35
Medspec CMC Thumb Support	$22-30
Surgery	$1,000-$8,000

Due to the fact that the team's design is slightly more costly than those on today's market, investors may be hesitant in purchasing and transitioning to our device. However, the superior efficacy of the device allows it to easily surpass the market competitors. This idea can also be applied to patient hesitation in using the new splint. Since it offers an alternative to surgery and is relatively affordable, patients and manufacturers alike can benefit from the device and explore the newfound possibilities of a future for those affected with CMC arthritis.

6.9.2 Environmental Impact

The use of the base polyester material of the splint, Poly(ethylene terephthalate) (PET) significantly impacts the environmental portion of our project. PET is best known for its recyclability. PET is not seen as a detriment to the environment directly, but there exists high volume of PET used in plastics such as bottles, jars, and some clothing materials. This causes an environmental standard for recycling for the PET plastics. PET is commonly recycled by a method called materials recycling where PET materials are collected, disintegrated, and refined to a PET waste polymer. This waste product can then be recirculated into production again. In addition to material recycling, PET can undergo chemical recycling which uses a certain degrading agent, which can also breakdown the PET to be recirculated and reused (Paszun and Spychai, 1997).

6.9.3 Societal Influence

Men and women with osteoarthritis would experience less pain in the thumb CMC joint and would be more comfortable performing daily activities. People who wear the device when performing specific activities will protect the joint from becoming lax in the future. People with OA will feel comfortable wearing the splint in public and over longer periods of time.

6.9.4 Political Ramifications

Surgeons who constantly use instruments that put stress on the thumb CMC joint will experience less pain and more comfort when using the splint device. This will allow surgeons to perform surgery for longer periods of time. Hopefully, it will save the CMC joint from stress and increased laxity over a long period of time. Injury or pain in the thumb CMC joint for surgeons can lead to less precise movements and inability to procedures repeatedly.

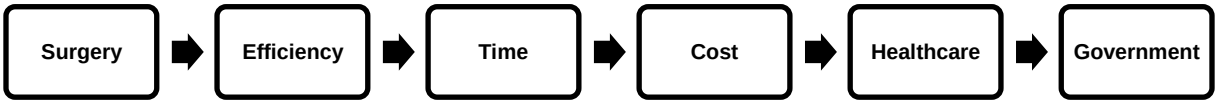


Figure 49: Process of potential political ramifications

6.9.5 Ethical Concerns

This device will greatly increase the quality of life for patients with CMC OA. By providing additional support and compression to the joint the inflammation due to the OA will decrease, thus decreasing the pain experienced by the patient. In addition, the additional support will allow patients to complete daily tasks with less difficulty, therefore increasing their independence and quality of life. The materials used in our design are synthetic materials whose development does not cause harm to any living beings. In addition, all materials were determined to be biocompatible and will subsequently not cause any negative reactions to the wearer's skin. The device is only meant to be used on the hand and only for patients with CMC OA. It is not

recommended that this device be used on any other part of the body or by people not afflicted by OA.

The manufacturing of this device will also not cause any ethical concerns, as all the manufacturing requires is correctly following a sewing pattern. The manufacturing process does not include any steps such as sterilization that, if not completed, would compromise the integrity of the device. Finally, failure of the device will not cause sufficient harm to the user. For example, if the Velcro® fails (becomes unattached) the device will not perform the desired amount of compression, but no negative effects would occur. In addition, if either of the base materials were to fail by coming apart, the device would merely fall off but again no negative effects would occur.

6.9.6 Health and Safety Issues

There are two major organizations to consider when examining health and safety issues. Both the U.S. Food and Drug Administration (FDA) and the International Organization for Standardization (ISO) have imposed various protocols on the medical device industry. These protocols are meant to not only standardize any developmental procedures associated with medical devices, but also to fully protect the general public or consumers who may purchase the device.

The splinting device constructed for this project is classified within splint, hand, and limb orthosis. The device is identified as Regulation section 890.3475, which defines the following protocols:

"Limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities to align body structures for functional improvement" (FDA, 2014).

Devices in this category are also classified as Class I, meaning the device poses minimal risk to users and can be regulated by the FDA's General Controls, which state that, the device and associated tasks must have:

1. Registration of establishments for any associated manufacturers, distributors, etc.
2. A proper device listing with the FDA
3. Good manufacturing practices (GMP) that are in accordance with the Quality Systems Regulation (QSR)
4. Proper labeling on any product containers and
5. Premarket notification – 510(K) (Johnson, 2012).

This device would be 510(K) exempt, meaning that the FDA only requires a premarket submission that demonstrates the device is as "safe and effective" as a current legally marketed device (FDA, 2015). The exemption qualifies the Class I device to enter the market without extensive FDA involvement. Despite this exemption, the device manufacturer would still need to comply with FDA general requirements for records and complaint files.

Concerning the ISO, the device manufacturing site of the device would require ISO 13485:2003 certification. This certification ensures that the manufacturing site has "quality management systems" in place to ensure their processes follow regulatory procedures. Additionally, this ISO certification ensures that device manufacturing satisfies customer needs for safety (ISO, 2003).

6.9.7 Manufacturability

The manufacturing of this device is relatively simple but is not something that could be accomplished solely by a machine. The manufacturer would rely on a sewing pattern to construct

the base material and for placement of the bulk material on the base material. To ease manufacturing, the device should be assembled using an assembly line type process. Unfortunately, the most difficult and time-consuming part of the process would be the sewing of the base material, the bulk material, and the Velcro®.

If the device is to be mass manufactured, future design teams should seriously consider altering the construction of the device to simplify manufacturing. The need for sewing should potentially be eliminated to reduce both the time and effort required for the process. In addition, the method of securing the bulk material needs to be reevaluated. The method used in prototype production (sewing the bulk material to the base material and sewing a covering over the bulk material onto the base material) is very time consuming and inefficient. It also increases the amount of material needed for the device. Therefore, changing this process would reduce time, effort and material, which would in turn reduce manufacturing costs and increase overall profit.

6.9.8 Sustainability

The environmental impact of landscape changes on health is now gaining attention in both public and private health and conservation arenas where it is recognized that environmental disturbance impacts the ecological balance. In combination with a surge in the global demand for medical devices, awareness of insufficient production in medical plants has sparked the need to promote sustainable manufacturing. Due to this interest in conservation, modern companies have increasingly supported the use of good-practice regimes within industry that support long-term sustainability rather than simply short term production.

Promoting long-term sustainability over simply short-term production through the use of sustainably sourced medicinal plant products and eco-labeling has also allowed companies to bring costumers in as a market force of those in support of conservation. To ensure the most

successful device marketability, the splint manufacture will entail the most modern and applicable measures of sustainable practices applied in the biomedical industry. Splint materials will be produced and assembled in a single location to avoid excessive transportation to alternative urban centers. Device production will consist of recyclable materials with an emphasis on manufacture efficiency and sustainable material use. Practice and practitioners will further be monitored to ensure device sustainability. Adequate funding will also be supplied to prevent poor practice and material substitutions made in the name of reducing costs.

7. Final Design and Validation

After completing testing and analyzing the results, the team began redesigning the initial prototype. The team considered the results from surveys, advisor suggestions, and mechanical testing to make iterative changes that were feasible within the scope of the project.

7.1 Changes Based on Survey Results

Due to the team's inability to perform patient testing at UMass Medical School, able-bodied testing was used as a replacement for prototype evaluation. Although the tests would not be able to indicate whether subjects experienced a relief from the painful symptoms of CMC osteoarthritis, they provided an unbiased critique of the splint's level of comfort, mobility, and material choice. Based on the 50 individuals tested, a number of common complaints and comments were received and documented by the team from future splint adjustments. The thumb opening of the splint was described as uncomfortable and irritating by a number of test subjects. Others experienced difficulty adjusting the gel inserts into the correct joint space location and required team member assistance to accurately adjust the splint positioning. Such difficulty would be likely to increase with OA inflicted patients who are already of limited hand and thumb functionality and mobility. Adjustment of splint sizing may be needed by the team to assure correct compression placement.

7.2 Changes Based on Advisor Feedback

Upon meeting with the team's advisors from UMass, alternative device adaptations were also advised based on their clinical experience with orthopedic devices. An elastic Velcro band was suggested for the wristband over a pure Velcro strap to provide greater comfort to the patient and allow for greater adjustability. The two-piece sleeve design was merged into a single

material that possesses superior elastic qualities. This allowed the splint to be universally sized rather than separated into three sizing components of small, medium, and large. The splint was further scaled in size to allow greater mobility and aesthetic appeal to the device. Due to the timing of the input received from the doctors at UMass, not all critiques could be incorporated into the final design. Adaptations that provided the greatest device improvement under the given time restraint were applied while further suggestions were recommended as future recommendations.

7.3 Changes Based on Mechanical Testing Results

A variety of mechanical tests were conducted by the term to determine appropriate materials selection. Fatigue strength of possible compressive gels for the splint insert was accessed using the Instron®. Due to the limited availability of gel materials, shoe insoles provided the majority of material alternatives, each of which held minimally informative material data sheet for determining gel composition. The team advises alternative compressive gels to be subject for testing to ensure superior functional quality of the splint insert. This would allow performance to be based on the most functional material rather than solely the material that performed superior in a small testing selection.

Further testing was also performed to simulate splint functionality. Pinch and grip strength were quantified through the use of a hand dynamometer. Although the team received similar readings to previous research for both tests, force readings for forceful pinch were estimated due to the higher range of the dynamometer. In order to receive a more accurate force reading, the team will perform a similar pinch measure using a more precise pinch gauge for further prototype analysis.

7.4 Team Testing with Final Design

Based on the recommendations of clients and users, the team adjusted the splint design to produce the final design. The changes are highlighted in Figure 50 below.

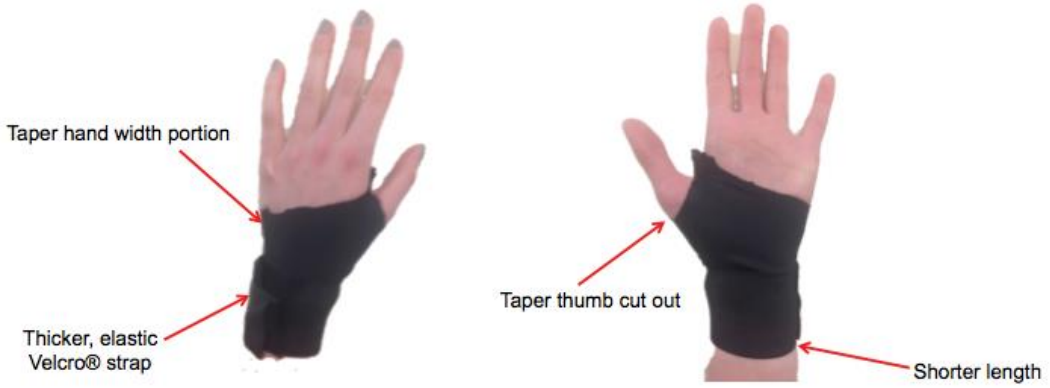


Figure 50: Front view (left) and back view (right) of final design

The team conducted testing using the hand dynamometer to understand how changes to the device design affected grip and pinch strength. Similar to the procedures discussed in section 5.4 Team Testing, all five team members participated in testing. Graphs were created to understand how the iterative changes to the design affected the grip and pinch strength values for each member (Figure 51 and Figure 52). One size splint was used for all team members. The average was calculated from three trials per team member to act as the representative value for both strengths. For the control, or no splint condition, an average value was derived from the average value from the previous testing with the first prototype and the average value from the second testing with the final design.

Table 35: Summary of results from team testing with final design

			***Gripping* (kgf)**			***Pinching* (kgf)**		
Name	***Gender***	***Age***	**W/O**	**W**	**Diff.**	**W/O**	**W**	**Diff.**
Fleek	F	21	2.0	2.7	+ 0.7	16	16.7	+ 0.7
Frank	F	21	4.3	6.0	+ 1.7	23.7	26.7	+ 3.0
Garcia	F	21	3.3	3.3	+ 0.0	20.7	21.3	+ 0.6
Hesse	F	21	2.7	3.0	+ 0.3	21.0	22.0	+ 1.0
Mastascusa	M	21	9.3	9.3	+ 0.0	32.7	42.0	+ 9.3

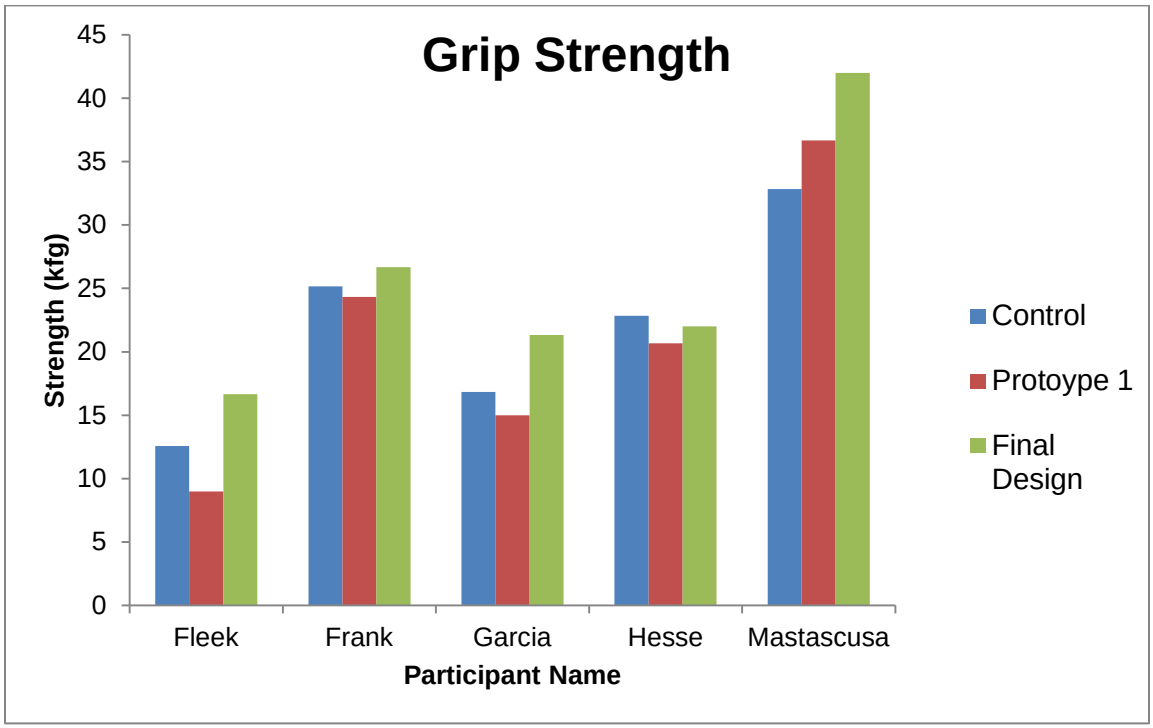


Figure 51: Graphical results of all team grip strength testing

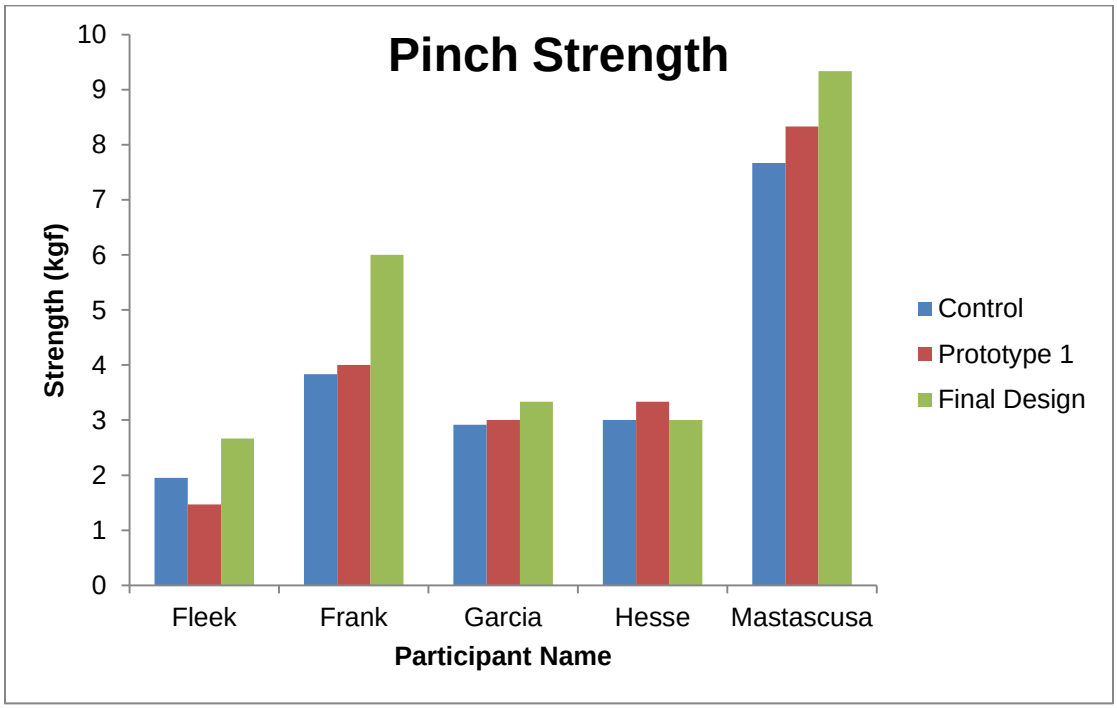


Figure 52: Graphical results of all team pinch strength testing

The team hoped that strength values would increase from the first prototype to the final design. This was generally true, thus the iterative changes made to the final prototype were successful. While some further changes or modifications could be made, these feasible changes had a positive impact on the design overall.

8. Conclusions and Final Recommendations

Osteoarthritis is a crippling disease for those inflicted across the nation, resulting in chronic pain and decreased functionality. Although a variety of treatment options for CMC osteoarthritis exist, including both surgical and nonsurgical, none of these alternatives adequately fit the needs of the physician or the patient. The primary goal of our device was to restore thumb range of motion and alleviate the associated pain of CMC osteoarthritis. While a majority of splints on today's market restrict both thumb and wrist motion as a means of preventing carpometacarpal hypertension, our design incorporated the idea of localized pressure to increase joint space. This allows the patient to maintain full range of motion while preventing joint laxity during hand functioning. The combination of compressive materials and joint stabilizing inserts that rest in the metacarpal joint space allowed the splint to provide a similar ideological result that is applied in surgical procedures for arthritic treatment. By focusing solely on the inflicted arthritic joint, adjacent joints can also avoid the subsequent weakness that results from repetitive motion restriction, a common occurrence in the orthopedic products of today.

Our splint can be utilized to treat and manage all stages of CMC arthritis, which is diagnosed in initial physician consultation as I to IV. For those wanting to pursue a non-surgical option or those diagnosed with initial onset of osteoarthritis, the splint can be used for pain relief on days that produce greater symptom severity. The splint can also be used as a means of daily stabilization as the joint heals post operation. The design of the splint will be able to accommodate multifunction use depending on the needs of the patient.

8.1 Design Benefits and Cost

True success of the design lies in the ability to meet the needs of the patient; this includes alleviating pain, providing stabilization, and reintroducing thumb functionality into the patient's daily life. The device also benefits the biomedical field as a whole, creating an orthopedic treatment option that properly restores functionality of the thumb – a task that has not been successfully completed in splint manufacturing industry. We are providing a novel method to splinting that can be adapted to other splinting procedures.

The manageable cost will allow our splint to be marketable. The device is composed of easily manufactured materials comparable in price to others on today's market. This idea can also be applied to patient hesitation in using our splint. Since our splint offers an alternative to surgery and is relatively affordable, patients and manufacturers alike can benefit from our device and explore the newfound possibilities of a future for those affected with CMC arthritis.

Finite Element Analysis was also developed by the team to detail an extensive and functional model of the joint. A model of the CMC was constructed in Abaqus^{TM} using image data from Computed Tomography images of the hand obtained from the NIH. The soft tissue was modeled using information from medical texts and cadaveric study, with material properties assigned according to previous finite element analysis studies due to limited available information on the mechanical properties of the tissues. After subjecting the computer model to various loading conditions, the computed stress and strain were validated by the available information on experimental stress and strain data.

The constructed model provides a solid framework to further analyze the kinematics of patients with early osteoarthritis and determine whether changes in motion over time can predict osteoarthritis progression in symptomatic patients with little evidence of radiographic disease.

Although computer analysis has been used to accurately measure a number of joints in the hand and wrist, similar analysis has not been previously used to analyze the kinematics of the CMC joint. The model completed by the team will not only serve as a clinically important tool in joint biomechanics but also as a modern anatomical representation of the CMC which has remained a controversial and often outdated medical topic.

The design process for the device was limited due to time constraints. The device was calculated to theoretically reduce forces on the CMC under standard loading conditions, but revisions could be made to the final design in order to maximize stability without compromising joint mobility.

8.2 Business Model and Plan

8.2.1 4 Ps of Business Marketing

8.2.1.1 People

This splinting product is targeted to older women who experience thumb CMC OA. This distinct audience was selected because research indicates that this is the largest demographic of patients who suffer with the condition. This splint could also be targeted to surgeons who want to wear the device as a precautionary measure, since surgeons have been found to develop thumb CMC OA as a result of continuous pinching motions made during surgery.

8.2.1.2 Promote

The device would be promoted through various outlets. The first outlet would focus on be daytime television promotion to target the older women demographic. Advertisements in magazines could be used as another outlet of promotion. This outlet could be used to reach both demographics describes about. The device could also be promoted by forming partnerships with

doctors and hand clinic locations. If clinicians were to recommend and advocate for this product, it would likely receive more attention.

8.2.1.3 Place

The splint would be available for purchase at doctor and clinician offices that endorsed the device. This way, patients and potential users could easily obtain the device after their visit. The device would also be available at common retail stores where similar devices are currently sold. While these locations sell a variety of similar devices, the team is hoping the new novel device would attract customers looking for a new alternative.

8.2.1.4 Price

After performing a cost analysis and discussing price with the project advisors, the team selected a target price for this splint of approximately $30.00 to $40.00. This cost would make the device affordable for patients and also in an acceptable range for healthcare insurance coverage. In comparison, high-end splints such as the Push Ortho Thumb Brace CMC cost approximately $100.00 from online retailers such as Amazon.com and VivoMed. An example of an inexpensive device is the Corflex Basal Thumb Joint CMC Restriction Splint, listed for $24.99 on Amazon.com and Braceability.com. The team would like the device to rival lower cost options, while providing an innovative solution for patients.

8.2.2 SWOT Analysis

The SWOT Analysis considers the possible strength, weaknesses, opportunities, and threats of manufacturing the device to bring it to market.

Table 36: SWOT analysis for business model and plan

Strengths	*Weaknesses*
• Help people with OA • New splint in the market with novel design • Extensive research and testing conducted on new design	• Many other competitors in the market • Hand splinting is a mature industry • No patent on our design
Opportunities	*Threats*
• Sell directly to doctors who are interested in the new design • Can consider filing for a patent if consumers respond well to the product • Consumers can spread word of our product through use • Doctors can be an advocate for our device	• Patients are quick to switch hand splints if they do not like it or find issues with it • Consumers may not respond to the new design • If consumers respond well, competitors can steal our idea

Most importantly, the device would be able to help people with OA. This is the overall goal or motivation for producing the device, so this is an essential strength. Another strength is that the splint is new in the market and has a novel, innovative design to excite customers to purchase the device. Also, the research and testing completed for the design helps provide evidence of its use for stakeholders including doctors, clinicians, and patients. In regards to the possible weaknesses of this device, the hand splint market is mature and there are numerous competitors in the market. This presents difficulty because patients have many products to consider, and there are many other major manufacturers and brands that produce hand splints. Another weakness is that the design currently has no patent, which could enable competitors to copy the design.

The team's new product presents many opportunities and threats as well. If the splint is sold sell directly to doctors and clinicians, patients may be more responsive to buying the product. The patients are more likely to trust the opinion of medical and healthcare professionals. If the product were well received in its designated market, the team would need to consider filing for a patent to protect the design from competitors. This is a significant opportunity because it can be very profitable to have a patent. Another opportunity comes from people who start wearing the device; the popularity will then increase through word of mouth recommendations. A threat to the hand splint market in general is that consumers will usually stop using the product and try another device if not immediately satisfied. Additionally, the large market for hand splints, which may cause consumers to completely ignore the new design, threatens the device. To counteract this threat, the team must devise a strong marketing plan to bolster the device when it is new to market.

8.3 Future Recommendations

Given the extensive nature of the project and time restraint, the team was unable to conduct all previously intended tasks and possible revisions to the device design. Primarily, the team was unable to conduct clinical patient testing with the original prototype. Scheduling difficulties with UMass under a short period of possible testing left the team unable to access the UMass patient database. Given the intentions of our project to establish a fully functional orthopedic device that alleviates OA pain and improve hand functionality, the team was never able to fully assess whether the designed device generated a statistical difference in patient hand performance. Able-bodied testing did generate sufficient data for prototype assessment. However, given an extension in the project life further testing of the final device should be performed in a clinical setting in order to ensure optimal performance before manufacture.

Feedback from physicians at UMass was also unfortunately received late in the project's time period and all revisions were no longer feasible to incorporate in the final prototype. An initial request was to transform the design of the device from a sleeve to a wrist cuff. The cuff would be composed of elastic Velcro of varying thicknesses. Velcro of greater thickness would be placed in coordination with the compressive gel inserts to ensure that the gel capsules rest in their appropriate joint place. Thinner pieces of the material would be utilized for the remainder of the design, resting slightly below the wrist and progressing to the UCL joint of the thumb. This would allow for optimal joint mobility with minimal material. Highly localized gel compression in coordination with a more extensive compressive strap would also provide needed stabilization and thumb functionality.

8.4 Future Projects for Thumb CMC OA

Once damaged, articular cartilage has little capacity for spontaneous healing due to the avascular nature of the tissue. Although many repair techniques have been proposed over the last four decades, especially in the knee, none have successfully regenerated long-lasting cartilage tissue. Tissue engineering approaches such as transplantation of isolated chondrocytes have recently demonstrated tremendous clinical potential for the regeneration of cartilage tissue. It is the team's hope that tissue-engineering approaches such as these can be further applied to cartilage regeneration in the hand. The team suggests that future groups pursue these methods to determine the potential of biomaterial cartilage implants in CMC osteoarthritic patients. Successful application and cell growth in these patients could lead to a significant improvement in quality of life and function for those affected with OA and promote further research in re-stabilizing the CMC joint.

9. References

An, K.A., Chao, E.Y., Cooney, W.P., Linscheid, R.L. (1979). Normative model of human hand for biomechanical analysis. *Journal of Biomechanics, 12*(10). 775-788

ANSYS, INC. (2014). ANSYS Mechanical. *ANSYS.* Accessed on September 28, 2014 from<http://www.ansys.com/Products/Simulation+Technology/Structural+Analysis/ANSYS+Mechanical>

Arthrex (2014). Mini Tightmore® CMC Surgical Technique. *Arthrex*. Accessed on December 15, 2014 from <http://www.arthrex.com/hand-wrist/mini-tightrope>

Bagis, S., Sahin, G., Yapici, Y., Cimen, O. B., & Erdogan, C. (2003). The effect of hand osteoarthritis on grip and pinch strength and hand function in postmenopausal women. Clinical rheumatology, 22(6), 420-424

Bani, M. A., Arazpour, M., Kashani, R. V., Mousavi, M. E., Maleki, M., & Hutchins, S. W. (2013). The effect of custom-made splints in patients with the first carpometacarpal joint osteoarthritis. Prosthetics and orthotics international, 37(2), 139-144

Barbour, K.E., Helmick, C.G., Theis, K.A., Murphy L.B., Hootman, J.M., Brady, T.J., and Cheng Y.J. (2013). Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation – United States, 2010-2012. *CDC Morbidity and Mortality Weekly Report, 62*(44):869-873

Batra, S., and Kanvinde, R.. (2007). Osteoarthritis of the thumb trapeziometacarpal joint. *Current Orthopaedics*, 21(2):135-144

Becker, S.J.E., Bot, A.G.J., Curley, S.E., Jupiter, J.B., and Ring, D.(2013) A prospective randomized comparison of neoprene vs thermoplast hand-based thumb spica splinting for trapeziometacarpal arthrosis. *Osteoarthritis and Cartilage*. 21(5):668-675

Bellamy, N., Campbell, J., Haraoui, B., Gerecz-Simon, E., Buchbinder, R., Hobby, K., & MacDermid, J. C. (2002). Clinimetric properties of the AUSCAN Osteoarthritis Hand Index: an evaluation of reliability, validity and responsiveness. Osteoarthritis and Cartilage, 10(11), 863-869

Bettinger, P.C., Linscheid, R.L., Berger, R.A., Cooney, W.P., An, K. (1999). An Anatomic Study of the Stabilizing Ligaments of the Trapezium and Trapeziometacarpal Joint. *The Journal of Hand Surgery, 24A*(4). 786-798

The Brace Shop (2014). MedSpec CMC Thumb Support. *The Brace Shop.* Retrieved from October 7, 2014 from <http://www.braceshop.com/medspec-cmc-thumb-support.htm>

Butz K.D., Merrell, G., Nauman, E.A. (2012). A biomechanical analysis of finger joint forces and stresses developed during common daily activities. *Computer Methods in Biomechanics and Biomedical Engineering*, 15(2): 131-140.

Carlson, M.G., Warner, K.K., Meyers, K.N., Hearns, K.A., Kok, P.L. (2012). Anatomy of the Thumb Metacarpophalangeal Ulnar and Radial Collateral Ligaments. *The Journal of Hand Surgery, 37*(10). 2021-2026

Centers for Disease Control and Presention (CDC). (2014). "Arthritis-Related Statistics." *Centers for Disease Control and Prevention*, Accessed on September 19, 2014 from <http://www.cdc.gov/arthritis/data_statistics/arthritis_related_stats.htm>

Chao, E.Y., Opgrande, J.D., Axmear, F.E. (1976). Three-dimensional force analysis of finger joints in selected isometric hand functions. *Journal of Biomechanics, 9*(6). 387-396

Chang, J., Ho, K., Su, F. (2008). Kinetic analysis of the thumb in jar-opening activity among female adults. *Ergonomics*, 51(6): 843-857.

Chow, J. C. (2001). *U.S. Patent Number: 6496984*. Washington, D.C: U.S. Patent and Trademark Office

Colditz, J.C. (2000). The biomechanics of a thumb carpometacarpal immobilization splint: Design and fitting.”*Journal of Hand Therapy.* 13(3):228-235

Colditz, J. C. (2004) *U.S. Patent Number: 6702772.* Washington D. C.: U.S. Patent and Trademark Office

Colditz. J., and Koekebakker, N. (2010). A New Splint Design for the Thumb CMC Joint. *White Paper*. 1-11. Accessed on October 1, 2014 from <http://www.handlab.com/ckfinder/userfiles/files/MetaGrip-White-Paper.pdf>

Damen, A., van der Lei, B., Robinson, P.H. (1996). Carpometacarpal arthritis of the thumb. *The Journal of Hand Surgery*, 21(5): 807-812.

Dassault Systemes. (2014). Abaqus Unified FEA. *Dassault Systemes.* Accessed on September 28, 2014 from <http://www.3ds.com/products-services/simulia/portfolio/abaqus/overview/>

de Raedt, S., Stilling, M., van de Giessen, M., Streekstra, G.J., Vos, F.M., and Hansen, T.B. (2012). A three-dimensional analysis of osteoarthritic changes in the thumb carpometacarpal joint. *The Journal of Hand Surgery, 38E*(8). 851-859

Densities of Different Body Matter. Accessed on February 5, 2015 from <http://www.scrollseek.com/training/densitiesofdifferentbodymatter.html>

Dowlatshahi, S. UMASS advisor. Personal Conversation. August 29, 2014

Egan, M.Y. and Brousseau, L. (2007). Splinting for osteoarthritis of the carpometacarpal joint: A review of the evidence. *American Journal of Occupational Therapy,* 61, 70-78

El-shennawy, M., Nakamura, K., Patterson, R. M., & Viegas, S. F. (2001). Three-dimensional kinematic analysis of the second through fifth carpometacarpal joints. The Journal of hand surgery, 26(6), 1030-1035

Farrell, J. F. (2009). *US Patent Number: 8328743.* Washington D.C.: U.S Patent and Trademark Office

Farrell, J.F. (2014). *US Patent Number: 8784348.* Washington D.C.: U.S. Patent and Trademark Office

FDA (2014). Part 890 – Physical Medical Devices. *CFR – Code of Federal Regulations Title 21*. Accessed on February 20, 2015 from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=890.3475>

FDA(2015). Premarket Notification 510(K). *Medical Devices – Device Advise: Comprehensive Regulatory Assistance.* Accessed on February 20, 2015 from <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm>

FEBio Software Suite. (2014). FEBio: Finite Elements for Biomechanics. *FEBio Software Suite*. Accessed on September 28, 2014 from <http://febio.org/febio/>

Geng, J. P., Tan, K. B., and Liu, G. R. (2001). Application of finite element analysis in implant dentistry: a review of the literature. *The Journal of prosthetic dentistry*, *85*(6), 585-598

Gislason, Magnus K.; Stansfield, Benedict; Nash, David H. "Finite Element Model Creation and Stability Considerations of Complex Biological Articulation: The Human Wrist Joint." *Medical Engineering & Physics* 32.5 (2010): 523-31. Print

Holly House Private Hospital (2014). Self-Pay Patients Prices Guide. Accessed on November 12, 2014 from <http://www.hollyhouse-hospital.co.uk/self-pay/prices/>

Hootman, J.M. and Helmick, C.G. (2006). Projections of US Prevalence of Arthritis and Associated Activity Limitations. *Arthritis and Rheumatism, 54(1),* 226-229

Instron® (2007). 5500 Series: Advanced materials testing systems. *Instron®.* Accessed on March 23, 2015 from < http://www.inteszt.hu/PDF/01/5500Brochure.pdf>

ISO (2003). ISO 13485:2003 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. *Standards Catalogue – Quality management and corresponding general aspects for medical devices.* Accessed on February 20, 2015 from <http://www.iso.org/iso/catalogue_detail?csnumber=36786>

Johanson, M. E., Valero-Cuevas, F. J., & Hentz, V. R. (2001). Activation patterns of the thumb muscles during stable and unstable pinch tasks. *The Journal of hand surgery*, *26*(4), 698-705

Johnson, J. (2012). FDA Regulation of Medical Devices. *Congressional Research Service*. Accessed on February 20, 2015 from <http://fas.org/sgp/crs/misc/R42130.pdf>

Kit, Y., and White, C. (2013). Five Things to Know About... Carpometacarpal osteoarthritis of the thumb. *Canadian Medical Association*. Retrieved September 14, 2014

Kjeken, I., Smedslund, G., Moe, R. H., Slatkowsky-Christensen, B., Uhlig, T., & Hagen, K. B. (2011). Systematic review of design and effects of splints and exercise programs in hand osteoarthritis. Arthritis care & research, 63(6), 834-848

Klenner, A.F., Towfigh, A.H., and Klenner, K. (2014). Verletzungen des Sattelgelenks und posttraumatische Rhizarthrose. *Abteilung für Handchirurgie.* 117(4):291-298

Koff, M. F., Ugwonali, O. F., Strauch, R. J., Rosenwasser, M. P., Ateshian, G. A., and Mow, V. C. (2003). Sequential wear patterns of the articular cartilage of the thumb carpometacarpal joint in osteoarthritis. *The Journal of Hand Surgery*. 28(4):597-604

Kulik, V.M., Boiko, A.V., Bardakhavanoc, S.P., Park, H., Chun, H.H., and Lee, I. (2010). Viscoelastic properties of silicone rubber with admixture of SiO_2 nanoparticles. *Materials Science and Engineering A.* 528(2011):5729-5732

Ladd, A. L., Weiss, A. P. C., Crisco, J. J., Hagert, E., Wolf, J. M., Glickel, S. Z., & Yao, J. (2013). The thumb carpometacarpal joint: anatomy, hormones, and biomechanics. Instructional course lectures, 62, 165

Luc, D. E. (2008). The DASH questionnaire and score in the evaluation of hand and wrist disorders. Acta orthopaedica Belgica, 74, 575-581

Mathiowetz, V., Kashman, N., Volland, G., Weber, K., Dowe, M., Rogers, S. (1985). Grip and Pinch Strength: Normative Data for Adults. *Arch Phys Med Rehabil, 66*. 69-72

Matullo, K.S., Ilyas, A., and Thoder, J.J. (2007). "CMC Anthroplasty of the Thumb: A Review." *Hand*, 2:232-239

Mayo Clinic (2015). High blood pressure – Hypertension. *Diseases and Conditions*. Accessed on February 27, 2015 from <http://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/blood-pressure/art-20050982>

Mazon, C., Ulson, H., Davitt, M., Laurito, F., Jacob, L., and von Glehn, V. (1996). The Use of Synthetic Plaster Casting Tape for Hand and Wrist Splints. *Journal of Hand Therapy*. 9(4):391-393

Melville, D. M., Taljanovic, M. S., Scalcione, L. R., Eble, J. M., Gimber, L. H., DeSilva, G. L., & Sheppard, J. E. (2015). Imaging and management of thumb carpometacarpal joint osteoarthritis. Skeletal radiology, 1-13

Mochel, W.E. and Nichols, J.B. (1951) Structure-Property Relationships for Neoprene Type W. *Industrial and Engineering Chemistry*. 43(1): 154-157

National Aeronautics and Space Administration (NASA) (2011). Man-Systems Integration Standards (MSIS). *NASA*, 3. Accessed on February 26, 2014 from <http://msis.jsc.nasa.gov/sections/section03.htm>

North Coast Medical (2014). Comfort Cool® Thumb CMC Restriction Splints. *North Coast Medical.* Accessed on October 7, 2014 from <https://www.ncmedical.com/item_77.htmlhttps://www.ncmedical.com/item_77.html>

Park, M., Lichtman, G., Christian, J., Weintraub, J., Chang, J., Hentz, V., Ladd, A.L., and Yao, J. (2008). Surgical Treatment of Thumb Carpometacarpal Joint Arthritis: A Single Institiution Experience from 1995-2005. *American Association for Hand Surgery*, 3(4):304-310

Paszun, D. and Spychaj, T. (1997). Chemical Recycling of Poly(ethylene Terephtalate). *Industrial & Engineering Chemistry Research*. 36(4): 1373-1383

Polito, D.A., Rucco, J.B., and Wood, T.W. (2013). Digitone: A Novel Soccer Goalkeeping Device (Undergraduate Major Qualifying Project No. E-project-042513-044509). Retrieved on September 15, 2014 from Worcester Polytechnic Institute Electronic Projects Collection: <http://www.wpi.edu/Pubs/E-project/Available/E-project-042513-044509/>

Sacks, J., Helmick, C., Luo, Y., Ilowite, N., and Bowyer, S. (2007). Prevalence of and Annual Ambulatory Health Care Visits for Pediatric Arthritis and Other Rheumatologic Conditions in the United States in 2001-2004. *Arthritis and Rheumatism, 57(8)*, 1439-1445

Sillem, H.S. (2009). Comparison of two carpometacarpal stabilizing splints for individuals with thumb osteoarthritis. *Rehabilitation Sciences – UBC.* Accessed on September 23, 2014 from <http://elk.library.ubc.ca/handle/2429/11099>

Spector, T.D., Nandra, D., Hart, D.J., and Doyle, D.V. (1997). Is hormone replacement therapy protective for hand and knee osteoarthritis in women?: The Chingford Study. *Annals of the Rheumatic Diseases – The Eular Journal*. 56(7):432-434

Tytherleigh-Strong, G., Hampton, R., and McCullough, C.J. (1999). Carpo-metacarpal arthritis of the thumb. *Current Orthopaedics*, 13(4): 302-308

Weber, J. J. (2008). *US Patent Number: 7887497*. Washington D.C.: U.S. Patent and Trademark Office

Wilder, F.V., Barrett, J.P., and Farina, E.J. (2006). Joint-specific prevalence of osteoarthritis of the hand. *Osteoarthritis and Carilage* 14(9):953-957

Xu, L., Strauch R.J., Ateshian, G.A., Pawluk, R.J., Mow, V.C., Rosenwasser, M.P. (1998). Topography of the osteoarthritic thumb carpometacarpal joint and its variations with regard to gender, age, site, and osteoarthritis stage. *The Journal of Hand Surgery*, 23(3), 454-464

Yao, J. and Song, Y. (2012). Suture-button suspensionplasty of the treatment of thumb carpometacarpal joint arthritis. *Operative Techniques in Orthopaedics*, 2,3:136-141

Yao, J. and Lashgari, D. (2014). Thumb basal joint: Utilizing new technology for the treatment of a common problem. *Journal of Hand Therapy*, 27(2): 127-132

Yelin, E., Cisternas, M., Foreman, A., Pasta, D., and Helmick, C.G. (2007). National and State Medical Expenditures and Lost Earnings Attributable to Arthritis and Other Rheumatic Conditions --- United States, 2003. *CDC's Morbidity and Mortality Weekly Report,* 56(01), 4-7

Yoganandan, N.; Kumaresan, S.C.; Voo, Liming; Pintar, F.A.; Larson, S.J. "Finite Element Modeling of the C4-C6 Cervical Spine Unit." *Medical Engineering & Physics* 18.7 (1995): 569-74. Print

Yosibash, Z., Padan, R., Joskowicz, L., & Milgrom, C. (2007). A CT-based high-order finite element analysis of the human proximal femur compared to in-vitro experiments. Journal of biomechanical engineering, 129(3), 297-309

Young, S. D., and Mikola, E. A. (2004). Thumb carpometacarpal arthritis. *Journal of the American Society for Surgery of the Hand*, 4(2), 73-93

Appendix A – IRB Consent Form and Letter of Approval

Informed Consent Agreement for Participation in a Research Study

Investigator:
Victoria G. Fleek
Rachel E. Hesse
Lauren N. Frank
Samara R. Garcia
Domenick R. Mastascusa

Contact Information: Professor Karen Troy
BME Department
WPI
100 Institute Road
Worcester, MA 01609
Tel. 508-831-6093, Email: ktroy@wpi.edu

Title of Research Study: Thumb arthritis splint prototype survey

Sponsor: UMass Medical School (Worcester, MA) and Worcester Polytechnic Institute (WPI) (Worcester, MA)

Introduction:
You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study:
In this experiment, we will ask questions regarding your experienced hand arthritis pain in the past week, as well as asking you to complete certain daily tasks and hand strength measurements both wearing and without wearing a splint prototype designed by the team. This information will be used to further understand how the arthritis affects hand strength. It will also determine how the splint prototype affects completion of daily tasks.

Procedures to be followed:
You will be asked to complete two surveys regarding hand arthritis pain. It will take approximately 15 to 20 minutes total to complete both of these surveys. You will be asked to answer some questions regarding the following:

- Arthritis pain experienced while completing certain tasks over the past week
- Stiffness of thumb, wrist, and other fingers during simple motion
- Pain experienced while performing strength test using a special scale that measures hand strengths
- Difficulty experienced while performing daily activities using props provided to you

Next, you will be asked to put on a splint prototype provided by the team and re-answer some questions regarding the following:

- Pain experienced while performing strength tests (as mentioned above)
- Difficulty experienced while performing daily activities using props provided to you

Risks to study participants:
There is some possibility of minor discomfort experienced while completing certain tasks or while wearing the splint prototype. This may result in soreness after the office visit. You may experience some skin irritation from wearing the splint prototype.

Benefits to research participants and others:
Your responses may aid in designing a functional splint that will provide a non-surgical conservative treatment method for hand arthritis.

Record keeping and confidentiality:
Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury:
In the unlikely event of physical injury resulting from participation in the research, you understand that medical treatment may be available from WPI, including first aid emergency care, and that your insurance carrier may be billed for the cost of such treatment. No compensation for medical care can be provided by WPI. You further understand that making such medical care available, or providing it, does not imply that such injury is the fault of the investigators. You do not give up any of your legal rights by signing this statement.

Cost/Payment:
There is no cost or payment associated with this study.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:
Prof. Karen Troy, Biomedical Engineering Department, WPI, 100 Institute Road, Worcester, MA (Tel. 508-831-6093) and/or Dr. Samander Dowlatshahi, Plastic Surgery, UMass Medical School, Worcester, MA. You may also contact the chair of the WPI Institutional Review Board (Prof. Kent Rissmiller, Tel. 508-831-5019, Email: kjr@wpi.edu) or WPI's University Compliance Officer (Michael J. Curley, Tel. 508-831-6919).

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit. Data obtained in this experiment will become the property of the investigators and WPI. If you withdraw from the study, data already collected from you will remain in the study.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____

Study Participant Signature

APPROVED
WPI IRB 1
2/26/15 to 1/27/16

_____

Study Participant Name (Please print)

_____ Date: _____

Signature of Person who explained this study

Worcester Polytechnic Institute IRB# 1
HHS IRB # 00007374

26 February 2015
File: 14-310

Re: IRB Expedited Review Approval: File 14-310 "Thumb arthritis splint prototype survey"

Dear Prof. Troy,

The WPI Institutional Review Committee (IRB) approves the above-referenced research activity, having conducted an expedited review according to the Code of Federal Regulations 45 (CFR46).

Consistent with 45 CFR 46.116 regarding the general requirements for informed consent, we remind you to only use the **attached stamped approved consent form** and to give a copy of the signed consent form to your subjects. You are also required to store the signed consent forms in a secure location and retain them for a period of at least three years following the conclusion of your study. You may also convert the completed consent forms into electronic documents (.pdf format) and forward them to the IRB Secretary for electronic storage.

The period covered by this approval is 26 February 2015 until 27 January 2016, unless terminated sooner (in writing) by yourself or the WPI IRB. Amendments or changes to the research that might alter this specific approval must be submitted to the WPI IRB for review and may require a full IRB application in order for the research to continue.

Please contact the undersigned if you have any questions about the terms of this approval.

Sincerely,

Kent Rissmiller
WPI IRB Chair

Appendix B – In-Office Patient Survey

Thumb CMC OA Patient Survey - In-Office Survey **Patient # _____**

Please circle one: **Left hand dominant** **Right hand dominant** **Ambidextrous**

Answer the following questions based on the past week:

- *Response ranges from "No interference" to "Cannot complete any...", "Worst stiffness possible", or "Worst pain possible"*
- *If you experience one of the extremes, mark an "X" in the box next to the extreme*
- *Otherwise, place an "X" on the line to indicate the level of pain.*

HOW MUCH DOES YOUR OA PAIN INTERFERE WITH:

Work activities	**No interference [ ]**	**[ ] Cannot complete any work activities**
Daily activities	**No interference [ ]**	**[ ] Cannot complete any work activities**

STIFFNESS EXPERIENCED DURING:

Thumb movement	**No stiffness [ ]**	**[ ] Worst stiffness possible**
Wrist movement	**No stiffness [ ]**	**[ ] Worst stiffness possible**
All- finger movement	**No stiffness [ ]**	**[ ] Worst stiffness possible**

PAIN EXPERIENCED WITHOUT WEARING SPLINT PROTOTYPE:

At rest	**No pain [ ]**	**[ ] Worst pain possible**
Gripping	**No pain [ ]**	**[ ] Worst pain possible**
Pinching	**No pain [ ]**	**[ ] Worst pain possible**
Turning	**No pain [ ]**	**[ ] Worst pain possible**

PAIN EXPERIENCED WHILE WEARING SPLINT PROTOTYPE:

At rest	**No pain [ ]**	**[ ] Worst pain possible**
Gripping	**No pain [ ]**	**[ ] Worst pain possible**
Pinching	**No pain [ ]**	**[ ] Worst pain possible**
Turning	**No pain [ ]**	**[ ] Worst pain possible**

Check the appropriate level of difficulty to complete the following daily tasks after completing them with and without wearing the splint:

DIFFICULTY EXPERIENCED WITHOUT WEARING SPLINT PROTOTYPE:

Action Item	No difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Completely Unable
Turning key in lock					
Holding a glass					
Opening a jar					
Zipping a zipper					
Opening a door					
Tying a shoelace					
Writing a sentence (if dominant hand)					

DIFFICULTY EXPERIENCED WHILE WEARING SPLINT PROTOTYPE:

Action Item	No difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Completely Unable
Turning key in lock					
Holding a glass					
Opening a jar					
Zipping a zipper					
Opening a door					
Tying a shoelace					
Writing a sentence (if dominant hand)					

DO YOU HAVE ANY OTHER DIAGNOSED/KNOWN HAND CONDITIONS THAT WOULD AFFECT YOUR ABILITITY TO COMPLETE THESE TASKS? (Circle one)

Yes **No** **Not sure**

Appendix C – Additional Patient Survey

Thumb CMC OA Patient Survey – Additional Survey **Patient # _____**

Check the appropriate normal level of difficulty experienced to complete the following daily tasks in the past week.

Action Item	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
Prepare a meal					
Open a door					
Retrieve an object from a shelf or cupboard					
Complete household chores					
Garden or do yard work					
Make a bed					
Carry a bag or briefcase					
Carry a heavy object (over 10lbs)					
Wash or blow dry your hair					
Put on a pullover sweater					
Use a knife to cut food					
Commuting (driving, biking, public transport.)					
Sustained physical exercise/activity (30 min or more)					

Appendix D – Unaffected Individual Survey

Unaffected Individual Survey **Identifier # _____**

Answer the following questions:

- *Response ranges from "No pain" to "Worst pain possible"*
- *If you experience one of the extremes, mark an "X" in the box next to the extreme*
- *Otherwise, place an "X" on the line to indicate the level of pain.*

PAIN EXPERIENCED WHILE WEARING SPLINT PROTOTYPE:

At rest **No pain [ ] ——————————— [ ] Worst pain possible**

Gripping **No pain [ ] ——————————— [ ] Worst pain possible**

Pinching **No pain [ ] ——————————— [ ] Worst pain possible**

Turning **No pain [ ] ——————————— [ ] Worst pain possible**

Check the appropriate level of difficulty to complete the following daily tasks after completing them with and without wearing the splint:

DIFFICULTY EXPERIENCED WHILE WEARING SPLINT PROTOTYPE:

Action Item	No difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Completely Unable
Turning key in lock					
Holding a glass					
Opening a jar					
Zipping a zipper					
Opening a door					
Tying a shoelace					
Writing a sentence					

DO YOU HAVE ANY OTHER DIAGNOSED/KNOWN HAND CONDITIONS THAT WOULD AFFECT YOUR ABILITITY TO COMPLETE THESE TASKS? (Circle one)

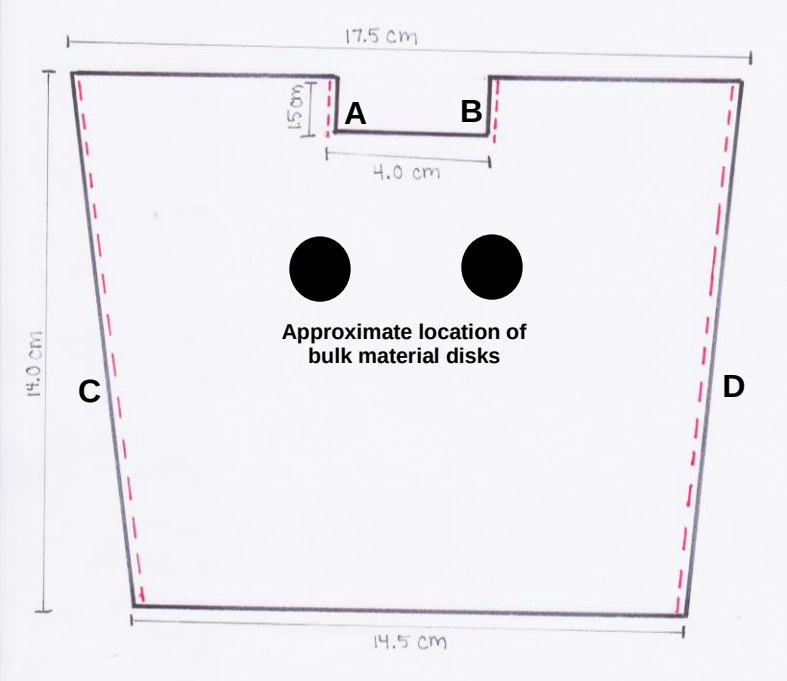
Yes **No** **Not sure**

Appendix E – Sewing Patterns (Splint Prototype Iteration No.1)

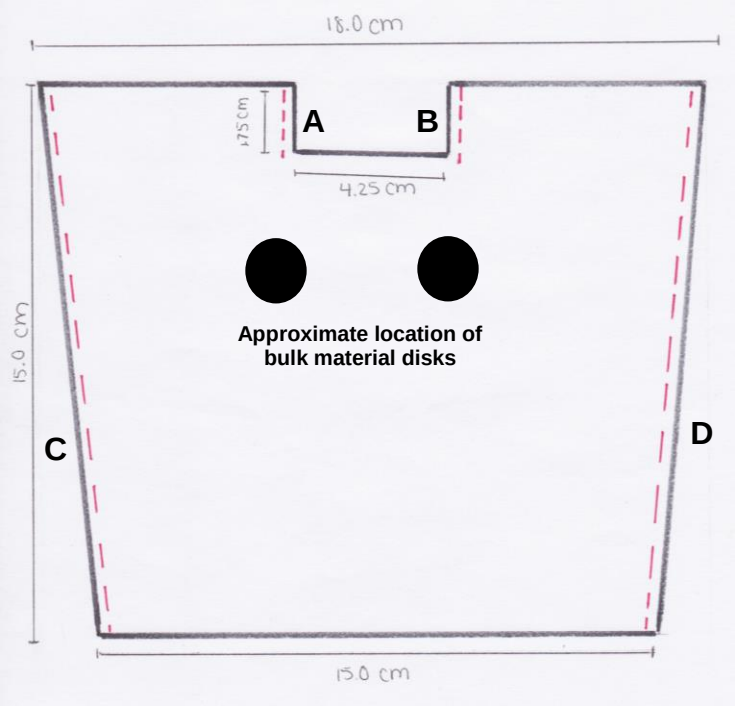
To sew each individual pattern together, sew side labeled A to side labeled B (thumb cut out), and side labeled C to side labeled D (outer edge of device). The base component and shell component are independent pieces for each size. To place the bulk material disks, the team members collected measurements of each team member's hand. For the size of the bulk material, the team measured the length and width of both subluxation points at the base of the thumb. For the small sized splint, the length and width of subluxation points was collected and averaged for the four female members of the group. Similarly, the length and width of the male team member's subluxation points was used for the large sized splint. The median value between the small and large size was used for the medium sized splint.

Solid black line – Outer edge
Dashed red line – Location of seam (sewn to parallel side)

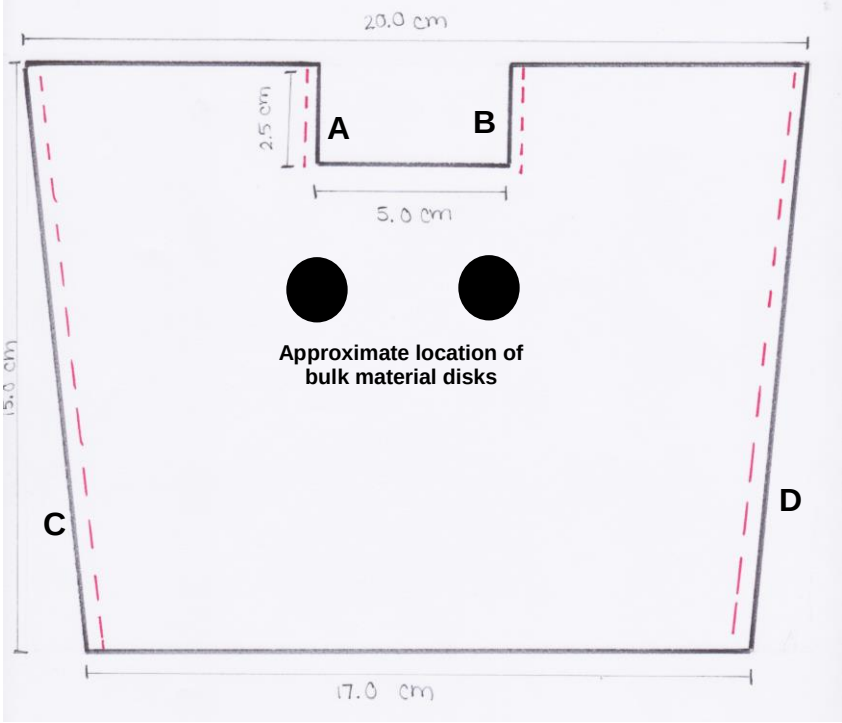
Unisex Small - Base Component



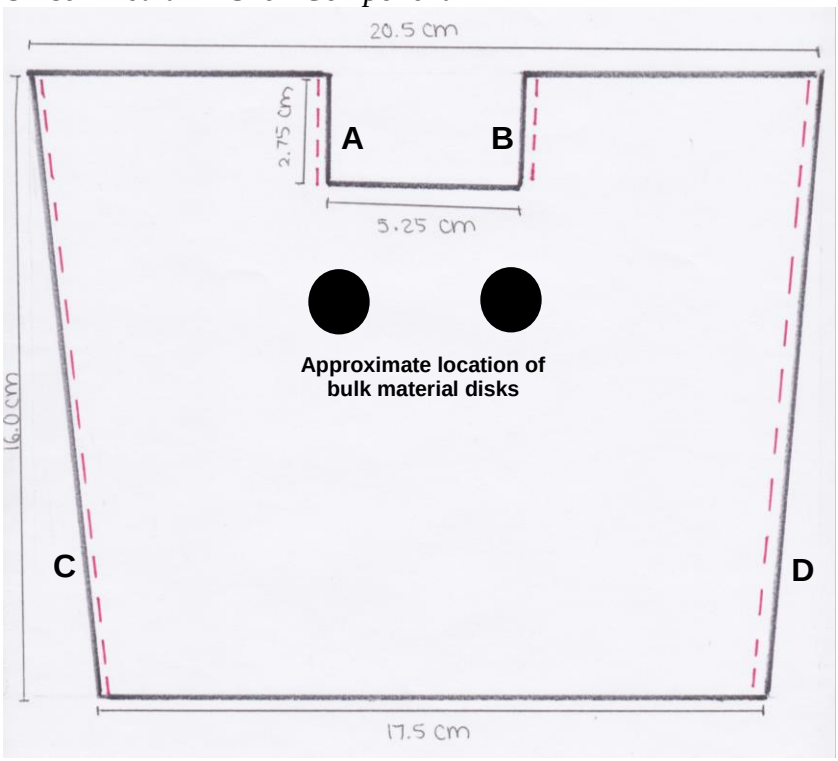
Unisex Small - Shell Component



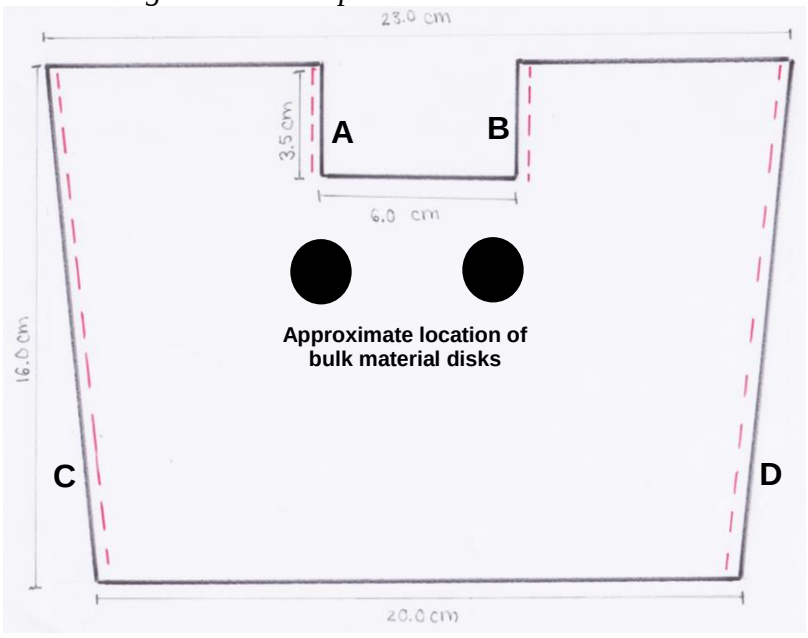
Unisex Medium - Base Component



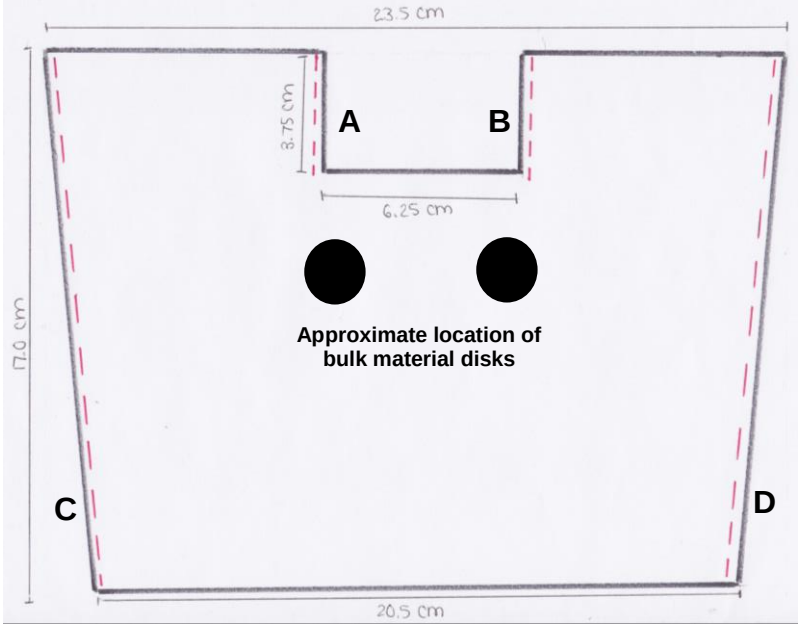
Unisex Medium - Shell Component



Unisex Large – Base Component

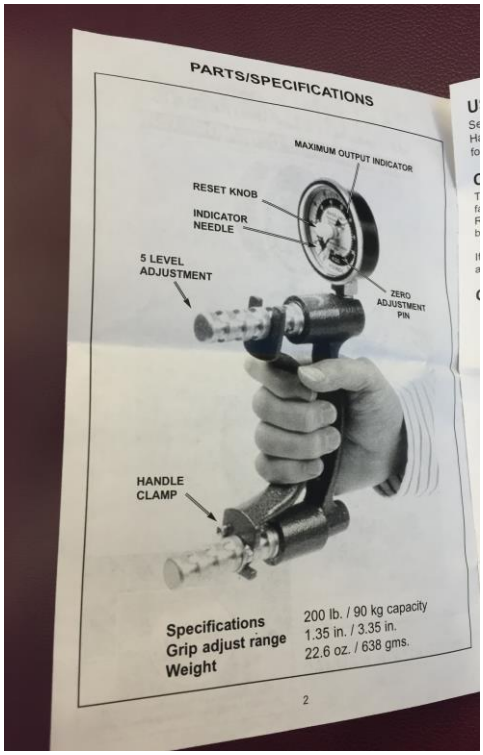


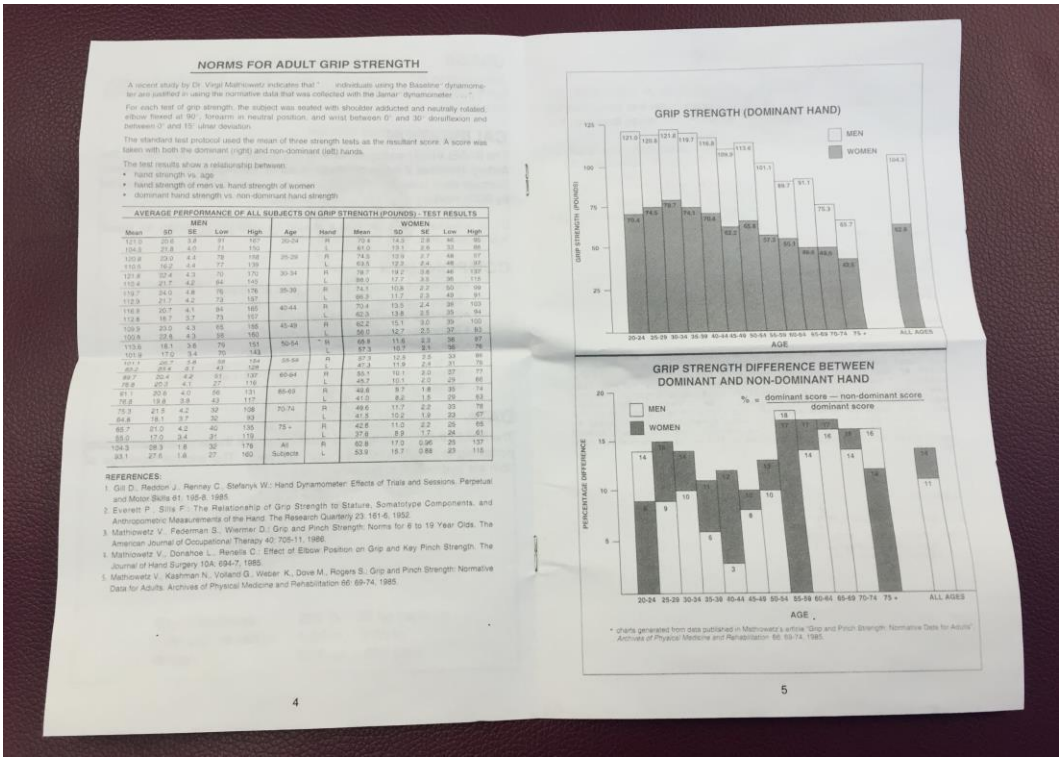
Unisex Large – Shell Component

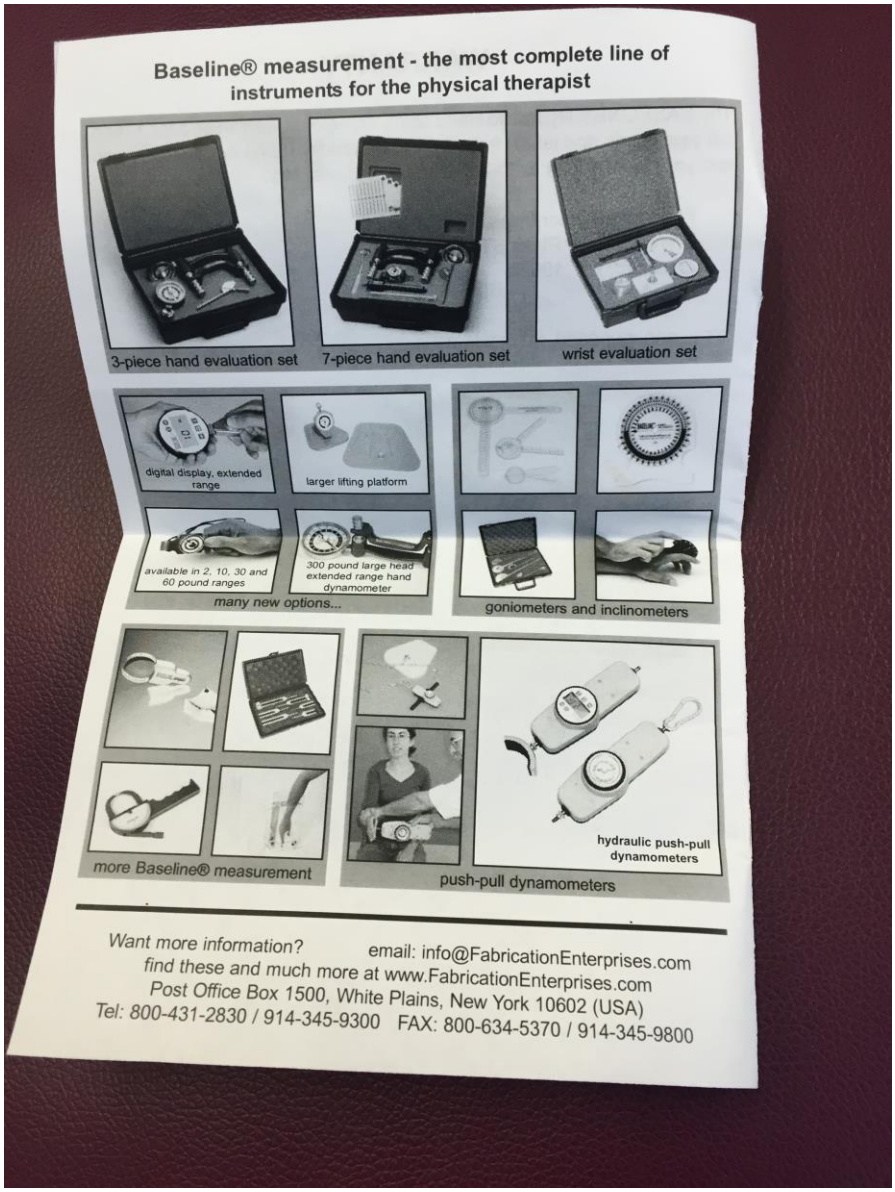


Appendix F – Troy Hand Dynamometer Information

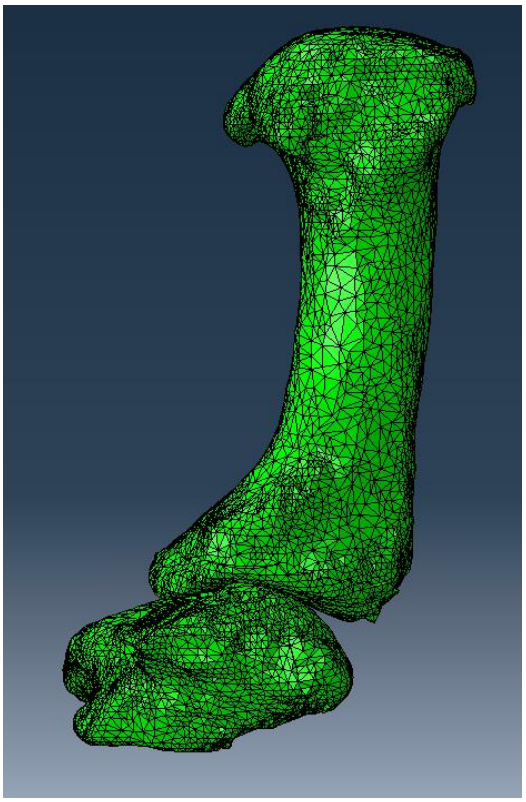
Baseline® Evaluation Instruments – Hydraulic Hand Dynamometer (User's Manual)



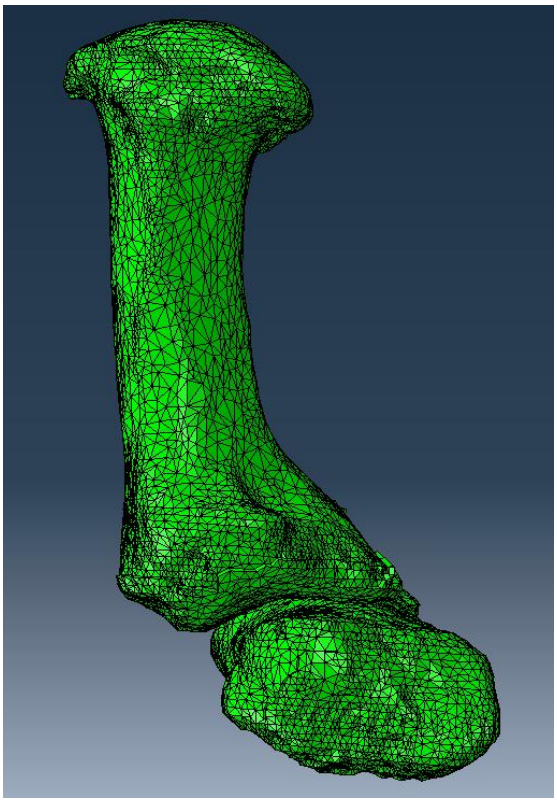



Baseline® measurement - the most complete line of instruments for the physical therapist
3-piece hand evaluation set
7-piece hand evaluation set
wrist evaluation set
digital display, extended range
larger lifting platform
available in 2, 10, 30 and 60 pound ranges
300 pound large head extended range hand dynamometer
many new options...
goniometers and inclinometers
more Baseline® measurement
hydraulic push-pull dynamometers
push-pull dynamometers
Want more information?
email: info@FabricationEnterprises.com
find these and much more at www.FabricationEnterprises.com
Post Office Box 1500, White Plains, New York 10602 (USA)
Tel: 800-431-2830 / 914-345-9300 FAX: 800-634-5370 / 914-345-9800

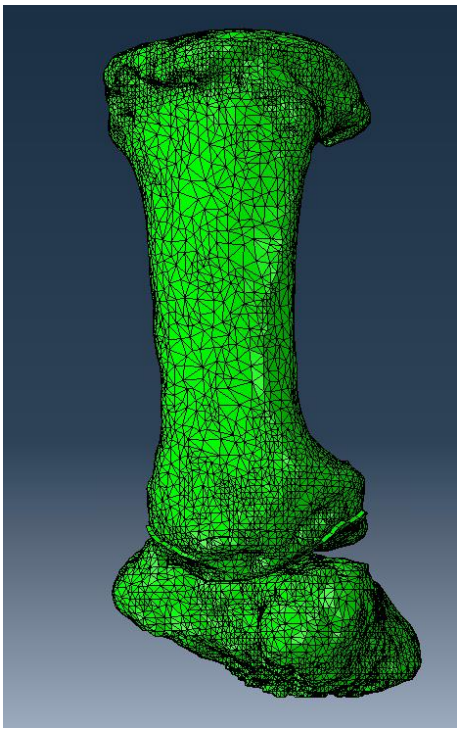
Appendix G – FEA Screenshots



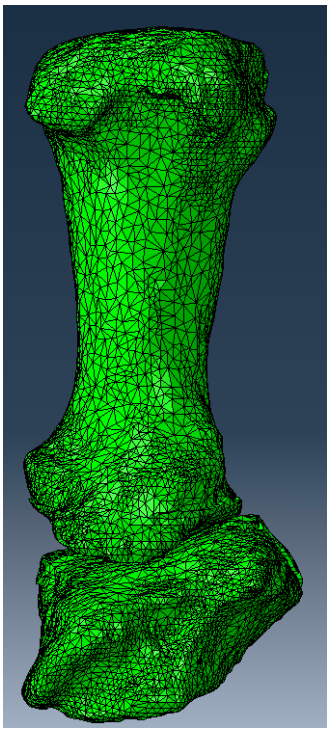
Volar view



Dorsal view



Posterior view



Anterior view

Appendix H – Full Unaffected Individual Survey Results

VAS Pain Scale Results:

Identifier	Gender	Age	Splint Size	At Rest #	At Rest Descriptor	Grip Pain #	Grip Pain Descriptor	Pinch Pain #	Pinch Pain Descriptor	Turning Pain #	Turning Pain Descriptor	Hand
D1	M	20	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D2	M	21	L	0	No pain	0	No pain	0-1	None - little pain	0	No pain	R
D3	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D4	M	21	L	0-1	None - little pain	0-1	None - little pain	0-1	None - little pain	0-1	None - little	R
D5	M	31	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D6	M	20	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D7	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D8	M	20	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D9	M	19	L	0	No pain	0	No pain	0	No pain	0	No pain	R
D10	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L1	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L2	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L3	M	20	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L4	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L5	M	20	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L6	M	19	L	0	No pain	0	No pain	0	No pain	0	No pain	R
L7	F	22	S	0	No pain	0	No pain	0	No pain	0	No pain	R
L8	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
L9	F	22	S	0	No pain	0	No pain	0	No pain	0	No pain	R
L10	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
R1	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
R2	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
R3	F	21	S	0	No pain	0	No pain	0	No pain	0-1	None - little	R
R4	F	20	S	0	No pain	0	No pain	0	No pain	0	No pain	R
R5	F	18	S	0	No pain	0	No pain	0	No pain	0	No pain	R
R6	F	19	S	0	No pain	0	No pain	0	No pain	0	No pain	R
R7	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
R8	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
R9	M	22	L	0	No pain	0	No pain	0	No pain	0-1	None - little	R
R10	M	22	L	0	No pain	0	No pain	0	No pain	0	No pain	R
S1	F	21	S	0-1	None - little	0-1	None - little	0-1	None - little	0-1	None - little	R
S2	M	26	L	0	No pain	0	No pain	0	No pain	0	No pain	L

S3	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	L
S4	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
S5	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R
S6	F	31	S	0	No pain	0	No pain	0	No pain	0	No pain	R
S7	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
S8	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
S9	F	22	S	0	No pain	0	No pain	0	No pain	0	No pain	R
S10	F	22	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T1	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T2	F	21	S	0-1	None - little	0-1	None - little	0-1	None - little	0-1	None - little	R
T3	F	20	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T4	F	19	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T5	F	20	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T6	F	20	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T7	M	20	L	0-1	None - little	0-1	None - little	0-1	None - little	0-1	None - little	R
T8	F	21	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T9	F	18	S	0	No pain	0	No pain	0	No pain	0	No pain	R
T10	M	21	L	0	No pain	0	No pain	0	No pain	0	No pain	R

Task Difficulty Results:

Identifier	Turning Key	Holding Glass	Opening a Jar	Zipping a Zipper	Opening a Door	Typing a Shoelace	Writing a Sentence	Hand Condition?
D1	No	No	No	No	Mild	No	N/A	No
D2	No	No	Mild	No	No	Mild	N/A	No
D3	No	No	No	No	Mild	No	N/A	No
D4	Mild	Moderate	No	Moderate	Mild	No	N/A	No
D5	No	No	No	No	No	No	N/A	No
D6	Mild	Moderate	Unable	Mild	No	Moderate	N/A	No
D7	No	No	No	No	No	No	N/A	No
D8	No	No	No	No	No	No	N/A	No
D9	Mild	No	No	No	No	No	N/A	No
D10	No	No	No	No	No	No	N/A	No
L1	No	No	No	No	No	No	N/A	No
L2	No	No	No	No	No	No	N/A	No
L3	No	No	No	No	No	No	N/A	No
L4	No	No	No	No	No	No	N/A	No
L5	No	No	No	No	No	No	N/A	No
L6	No	No	No	No	No	No	N/A	No
L7	No	No	No	No	No	No	N/A	No

L8	No	No	No	No	No	No	N/A	No
L9	No	No	No	No	No	No	N/A	No
L10	No	No	No	No	No	No	N/A	No
R1	No	No	No	No	No	No	N/A	No
R2	No	No	No	No	No	No	N/A	No
R3	No	No	Mild	No	No	No	N/A	No
R4	No	No	No	No	No	No	N/A	No
R5	No	No	No	No	No	Mild	N/A	No
R6	No	No	No	No	No	No	N/A	Not sure
R7	No	No	No	No	No	No	N/A	No
R8	No	No	No	No	No	No	N/A	No
R9	No	No	No	No	No	No	N/A	No
R10	No	No	No	No	No	No	N/A	No
S1	No	No	No	No	No	No	N/A	No
S2	No	No	No	No	No	No	Moderate	No
S3	Mild	No	Mild	No	No	No	No	No
S4	No	No	No	No	No	No	N/A	No
S5	No	No	No	No	No	No	N/A	No
S6	No	No	No	No	No	No	N/A	Yes
S7	No	No	No	No	No	No	N/A	No
S8	No	No	Mild	No	No	No	N/A	No
S9	No	No	No	No	No	No	N/A	No
S10	No	No	No	No	No	No	N/A	No
T1	No	No	Mild	No	No	Mild	N/A	No
T2	No	No	No	No	No	No	N/A	No
T3	No	No	No	No	No	Mild	N/A	No
T4	No	No	No	No	No	Mild	N/A	No
T5	No	No	No	No	No	No	N/A	No
T6	No	No	No	No	No	No	N/A	No
T7	No	No	No	No	No	No	N/A	No
T8	No	No	No	No	No	No	N/A	No
T9	No	No	No	No	No	Mild	N/A	No
T10	No	No	No	No	No	No	N/A	No

Appendix I – Full Team Testing Results

First Prototype Results:

	Pinch (-Splint) (kgf)	Grip (-Splint) (kgf)	Pinch (+Splint) (kgf)	Grip (+Splint) (kgf)	Splint size	Hand
Tori	2.0	9.0	1.9	9.0	Small	Left
	1.9	9.0	1.5	10.0		
	1.8	9.5	1.0	8.0		
Average:	**1.9**	**9.2**	**1.5**	**9.0**	-	-
Samara	2.0	14.0	4.0	14.0	Small	Left
	2.5	13.0	3.0	16.0		
	3.0	12.0	2.0	15.0		
Average:	**2.5**	**13.0**	**3.0**	**15.0**	-	-
Dom	6.0	36.0	9.0	35.0	Large	Left
	7.0	30.0	8.0	38.0		
	5.0	33.0	8.0	37.0		
Average:	**6.0**	**33.0**	**8.3**	**36.7**	-	-
Rachel	3.0	28.0	4.0	20.0	Small	Left
	4.0	22.0	2.0	20.0		
	3.0	24.0	4.0	22.0		
Average:	**3.3**	**24. 7**	**3.3**	**20.7**	-	-
Lauren	3.0	28.0	4.0	26.0	Small	Left
	3.0	26.0	4.0	24.0		
	3.0	26.0	4.0	23.0		
Average:	**3.0**	**26.7**	**4.0**	**24.3**	-	-

Second Prototype (Final Design) Results:

	Pinch (-Splint) (kgf)	Grip (-Splint) (kgf)	Pinch (+Splint) (kgf)	Grip (+Splint) (kgf)	Splint size	Hand
Tori	2.0	14.0	3.0	18.0	Universal	Left
	2.0	18.0	3.0	16.0		
	2.0	16.0	2.0	16.0		
Average:	**2.0**	**16.0**	**2.7**	**16.7**	-	-
Samara	3.0	20.0	3.0	24.0	Universal	Left
	4.0	22.0	4.0	22.0		
	3.0	20.0	3.0	18.0		
Average:	**3.3**	**20.7**	**3.3**	**21.3**	-	-
Dom	10.0	30.0	10.0	46.0	Universal	Left
	8.0	32.0	10.0	38.0		
	10.0	36.0	8.0	42.0		
Average:	**9.3**	**32.7**	**9.3**	**42.0**	-	-
Rachel	3.0	21.0	3.0	22.0	Universal	Left
	2.0	22.0	3.0	22.0		
	3.0	20.0	3.0	22.0		
Average:	**2.7**	**21.0**	**3.0**	**22.0**	-	-
Lauren	4.0	24.0	6.0	29.0	Universal	Left
	5.0	23.0	6.0	24.0		
	4.0	24.0	6.0	27.0		
Average:	**4.3**	**23.7**	**6.0**	**26.7**	-	-