Metacarpophalangeal Joint Replacement

Semester One Final Report

12/10/2009

BME 400

Team Members:

Nate Cira-BWIG

Amanda Feest-Communicator

Hallie Kreitlow-Leader

Kenny Roggow-BSAC

Advisor: Naomi Chesler Ph.D.

Client: Ramzi Shehadi M.D.

Abstract

Patients with congenital hand defects or severe trauma have few options for recovering normal function. Current metacarpophalangeal joint replacements rely on ligaments to stabilize the implant. Several design alternatives for the joint that do not depend on ligamentous support have been designed and the most promising has been pursued. The design is comprised of two main components: one embedded in the distal portion of the metacarpal, and the other in the proximal portion of the phalange. The phalangeal component is allowed to translate along the length of the curved groove located on the metacarpal component. The design has been theoretically tested for range of motion and ability to bear loads as seen in pinch and power grip. The range of motion is 45° of extension, 90° of flexion, 10° adduction/abduction at 0° of flexion, and 1° adduction/abduction at 90° of flexion. The metacarpal component is capable of withstanding reaction forces from pinch and power grip. The phalangeal component, however, is not capable of withstanding either load. Improvements to the design will be pursued next semester.

Table of Contents

Anatomical Terminology

Designing a functional joint replacement requires knowledge from the fields of anatomy and physiology to explain the terminology related to the normal MCP joint. Proximal means closer to the point of attachment to the body whereas distal means further from the point of attachment. Proximal to the MCP joint is the metacarpal. Distal to the MCP joint is the phalange, known more commonly as the proximal phalange since it is the closest to the body (Figure 1). Both the metacarpal and the proximal phalange are long bones, which have a hard outer shell composed of cortical bone. Inside that shell is the medullary canal, which is filled with spongy trabecular bone and bone marrow.

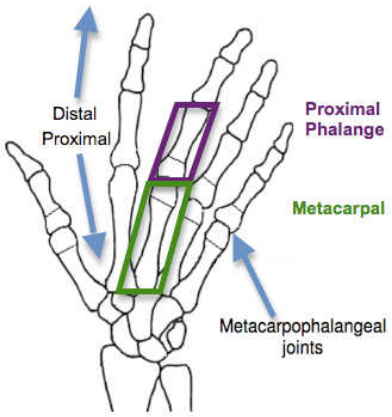


Figure 1. MCP skeletal structure. Modified from [1].

The act of extension occurs when the joint angle increases. Flexion opposes extension and occurs when the finger curls toward the palm. Other motions of the finger include adduction and abduction. When a person is standing in the anatomical position, adduction occurs when the finger is brought closer to the body. The motion of abduction opposes adduction. Tendons attach muscle to bone in order to actuate these motions [2]. The tendons of interest to actuate the MCP joint are the flexor digitorum profundus (FDP), flexor digitorum superficialis (FDS), and extensor digitorum, which connect with muscles of the same name.

The metacarpal and proximal phalange are connected by collateral ligaments (Figure 2), which limit joint range of motion and prevent tensile dislocation. When the MCP joint is flexed, the collateral ligaments are pulled tight and limit the adduction and abduction. When

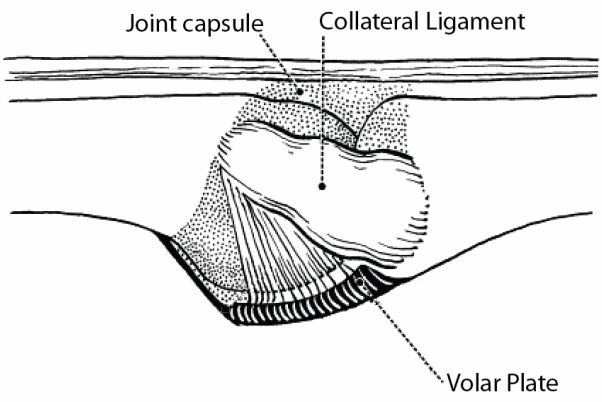


Figure 2. Ligaments of the MCP joint [3].

the joint is not flexed, they are not in tension and allow adduction and abduction [4]. Another broad, flat MCP ligament, called the volar plate, limits hyperextension (Figure 2).

Implant Terminology

There are three types of MCP joint replacements: unconstrained, semi-constrained, and constrained. Unconstrained designs have no resistance to tensile or ulnar dislocation. Semi-constrained designs have geometrical features that provide limited resistance to ulnar dislocation, but no resistance to tensile dislocation. Finally, constrained devices will only experience tensile or ulnar dislocation if the device fractures.

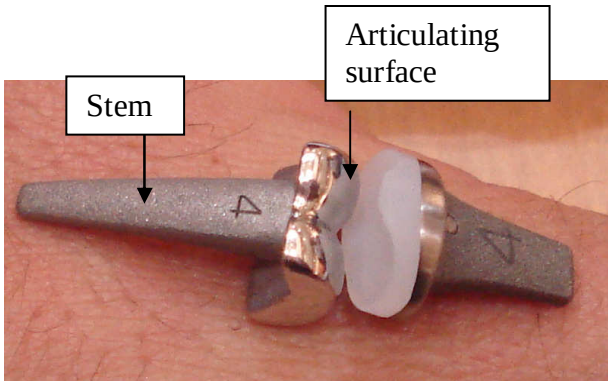


Figure 3. Key Features of a MCP joint replacement.

MCP implants have two important features: the stem and the articulating surface (Figure 3). The stem has a long and narrow geometry that has dimensions to the medullary canal. The stem is inserted into the medullary canal, and the surface of the stem contacts the inner surface of the cortical bone to form the bone/implant interface. Motion of the joint occurs at the articulating surface, where the two implants slide past each other as the joint moves through its range of motion. This area is also known as the implant/implant interface.

Problem Statement

Available MCP joint replacements require collateral ligaments and a volar plate to prevent tensile and ulnar dislocation. Patients with congenital defects, severe trauma, and severe rheumatoid arthritis do not have adequate ligamentous support to benefit from current implants [5]. The designed joint replacement must provide joint stability to patients without collateral ligaments or a volar plate.

Client Requirements

The client, Ramzi Shehadi, M.D. of Dean Health System, has specified the requirements for this project. His impetus for the project stems from his son's symbrachydactyly, a congenital defect characterized by hand deformities. It occurs in every 1 out of 32,000 births and the degree of severity varies in each case [6], but typically patients with symbrachydactyly lack collateral ligaments and a volar plate and have smaller than average bones [5]. The implant will only be implanted after bone growth is complete. The MCP joint replacement must provide the patient with a functional range of motion without ligamentous support. The device must withstand physiological loading and last at least 10 years. The design must be capable of osteointegration to prevent micromotion between the bone and the stem of the implant. Additionally, the materials used in the implant must be biocompatible. And finally if the implant is exposed to extreme loads, it should fail at the connection between the two halves of the implant (implant-implant interface) rather than at the bone-implant interface. This will help ensure the small, difficult-to-repair bones of the finger are not broken, mitigating the severity of failure.

Design Specifications

The client requirements were translated into measureable quantities that can be used during testing. The replacement should be capable of 20° of extension to 90° of flexion, 40° total in abduction and adduction at 0° of flexion, and 0° in abduction and adduction at 90° of flexion [7]. The implant must withstand reaction forces from a 70 N static pinch [7] and a 464 N static power grip [8]. It must endure ~310 million cycles at varying movement angles as defined in a study, which measured the motion of the MCP joint [9]. To allow osteointegration, the surfaces of the stems of the implant should be surface treated as detailed in the materials section. The device must use materials that are FDA-approved. Lastly, the lowest factor of safety must occur at the implant-implant interface.

Competition

Several MCP joint replacements exist, but do not fulfill the design specifications. The most frequently-used replacement is made of silicone. According to one study, after 11 years, over half of the silicone implants fractured [10]. Furthermore, silicone implants can cause

erosion at the bone/implant interface, weakening the patient's already fragile bones [11]. Another type of implant used is the semi-constrained finger prosthesis, which relies on ligamentous support to connect the two separate halves of the implant. Without supporting ligaments, there is nothing to prevent dislocation. Current implants are most commonly used in patients having rheumatoid arthritis to alleviate pain and increase function [12]. Most patients are elderly and do not require implants to last long or withstand high loads. An implant that does not require ligamentous support could also be used in certain cases of rheumatoid arthritis where collateral ligaments are intact but are stretched beyond usefulness. During current implant procedure, surgeons must be cautious not to damage surround ligaments as described in the surgical implantation section of the appendix. With a device that does not rely on these ligaments, this would be less of a concern. Effectively, the device could benefit patients with or without ligaments. Furthermore, the joint replacement could be used for MCP joints on any of the phalanges excluding the thumbs.

Materials

Since the focus of this project is on design and not research, only materials currently approved by the FDA are considered. Two categories of materials are reviewed: bulk materials and surface treatments.

Bulk Material

When choosing a bulk material, there are two important properties: elastic modulus and wear characteristics. The proper choice of elastic modulus will minimize stress shielding, which occurs when there is a mechanical mismatch between the bone and implant [13]. Bone dynamically remodels according to the stresses applied [14], and stiffer materials, such as metal, bear more of the load causing bone resorption [13]. Since bone has an elastic modulus of 15-23 MPa, it is desirable to have a material with an elastic modulus close to this range. [15] Additionally, good wear characteristics are required to avoid particulate buildup which can illicit foreign body reaction, decreasing functionality of the joint and reducing its lifetime [16].

One bulk material is called “trabecular metal” for its resemblance to spongy bone, and would only be used for the stems of the implant. It is comprised of elemental tantalum with a porosity of 80 percent. High porosity reduces density, making this material very light. This porosity allows ample in-growth of osteocytes which creates a physically interlocked connection between implant and bone. It is also desirable because it has an elastic modulus of 25-30 MPa, similar to bone. [17] The metal has added benefits of strength and corrosion resistance. A major drawback of trabecular metal is its complicated fabrication process, which uses high temperature and high-pressure for the combustion of metal powder. Furthermore, “Machining this material to complex shapes with close tolerances is difficult because of its open structure and the ductile nature of metallic tantalum” [18]. The difficult manufacturing process precludes trabecular metal from further consideration.

A second material that mimics the elastic modulus of bone is pyrolytic carbon, or pyrocarbon, with an elastic modulus of 20-25 MPa. Again, this match helps minimize stress shielding to prevent bone resorption. Pyrocarbon exhibits a very low coefficient of friction, desirable for easy movement. [19] Currently, unconstrained MCP joint replacements use this material. Fabrication is completed by chemical vapor deposition (CVD) usually on graphite. The nature of CVD and the thickness of the coating required confines implant geometries to generally smooth shapes without small features. The manufacturing process applies a uniform coating of ½ mm to all surfaces [19], which makes it impossible to achieve a thickness less than 1 mm. Due to the complex geometry of the designs, pyrolytic carbon implants would not be feasible to manufacture and will not be further considered.

The only remaining materials include metals and a polymer. There is approximately six times more wear with a polymer-on-polymer combination than a metal-on-polymer combination [7]. Metal-on-metal produces undesirable wear as well [20]. For this reason, only metal-on-polymer combinations will be considered. Metals considered include titanium alloy coupled with ceramic and cobalt chromium (CoCr) alloy. These metals will be coupled with ultra high molecular weight polyethylene (UHMWPE). Advantages and disadvantages of each material are reviewed here.

UHMWPE is a polymer with long parallel hydrocarbon chains. It is known for chemical resistance, low coefficient of friction, and impact resistance, abrasion resistance, and

biocompatibility [21]. These properties make it a natural choice for implant surfaces and indeed it is used industry wide [21].

Titanium alloy coupled with ceramic (Ti_6Al_4) is the first metal that was considered. It is very biocompatible and has good corrosion resistance [22]. However, it is a soft metal with an elastic modulus of 75-100 GPa [23]. It also shows poor wear characteristics over time when used as an articulating surface [22]. These poor wear characteristics would decrease the lifespan of the implant.

Cobalt chromium alloys are preferable to titanium alloy for two reasons. First, CoCr on UHMWPE has better wear characteristics than titanium on UHMWPE [24]. Also, the elastic modulus of CoCr is 18.6 GPA [25], which is closer than titanium to the elastic modulus of bone, which will minimize stress shielding. It also is widely used and tested in the orthopedic industry. For these reasons, CoCr and UHMWPE will be used as the bulk materials for the implant.

However, one design uses silicone with CoCr stems because it requires the elastic properties of silicone. Medical grade silicone is the bulk material most frequently used in MCP joint replacements [26]. It has high flexibility, but poor wear characteristics and is prone to fracture [26]. It also leaves particulates in the joint space, which leads to particulate synovitis [26]. Silicone implants can cause erosion at the bone/implant interface [11] so it will not be used on the stems of the implant. Use of silicone is only relevant to one of the five proposed designs.

Surface Treatments

Surface treatments are applied for the sole purpose of improving osteointegration. Since there are no ligaments to aid in supporting loads on the implant, osteointegration is essential to long-term stability of the replacement. Good osteointegration is characterized by a strong connection between the bone and implant. A strong connection often involves bone in-growth, which creates mechanical interlocking on the microscale, or chemical bonds between bone and implant.

Underlying materials can be modified with surface treatments and coatings. Metals can be modified with treatments such as plasma spraying, powder sintering, and grit blasting. Plasma spraying is an additive process that creates a shell of porous metal over the area sprayed. This technique creates an open-cell porous surface with high interconnectivity between the

pores, which allows for good cell in-growth and therefore better osteointegration [27]. Since this is a surface coating, it largely preserves the material properties of the bulk, but it does not allow as deep of in-growth as an entirely porous material. In addition to plasma spraying, metal sintering can accomplish an additive porous surface coating. In this process, the substrate is coated in fine metal grains or powder and the combination heated just above the melting point so the particles fuse to themselves and the implant [27]. The construct is cooled to retain the initial granular porosity [27]. Metal sintering can also accomplish an open-cell porous surface, but does not provide as much cellular penetration as plasma spraying [Ryan]. Grit blasting is a subtractive process to roughen the surface of an implant. The substrate to be roughened is exposed to a stream of glass or ceramic particles moving at high velocities that erode the surface. Small surface irregularities help increase friction through greater surface area, which has been shown to increase pullout strength. [28] However, grit blasting is a closed-cell technique, which does not allow deep cellular infiltration [27].

Hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) is the crystal component of bone. It can be applied using plasma spraying. The benefits are twofold. First, the body recognizes the material and it does not provoke immune response. Second, the surface coating is recognized by osteocytes and chemical bonds are formed between the coating and the body [29]. The coating is compatible with other surface treatments and bulk materials, making it a default addition to most implant stem coatings.

After analyzing all osteointegration methods, a dual surface treatment of plasma spray and hydroxyapatite was chosen. The two bulk materials (trabecular metal and pyrocarbon) were precluded from further consideration due to biocompatibility and manufacturability concerns. The plasma spray was chosen over grit blasting and metal sintering because it achieves a higher degree of cellular penetration. Hydroxyapatite will then be used as a second surface coating over the plasma spray to further increase the osteointegration capabilities of the implant.

Design Alternatives

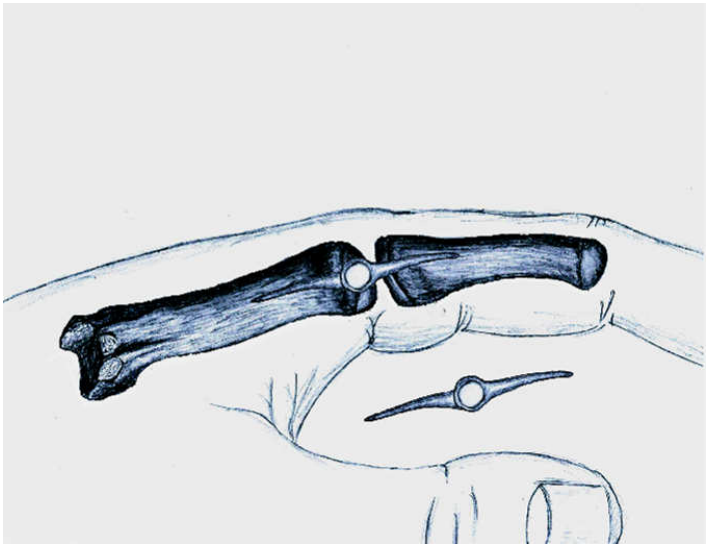
The following five designs address the challenge of creating a stable osteointegrated MCP joint replacement. These designs remain as they were presented in the mid-semester presentation. Further improvements of the selected design will be discussed in a later section.

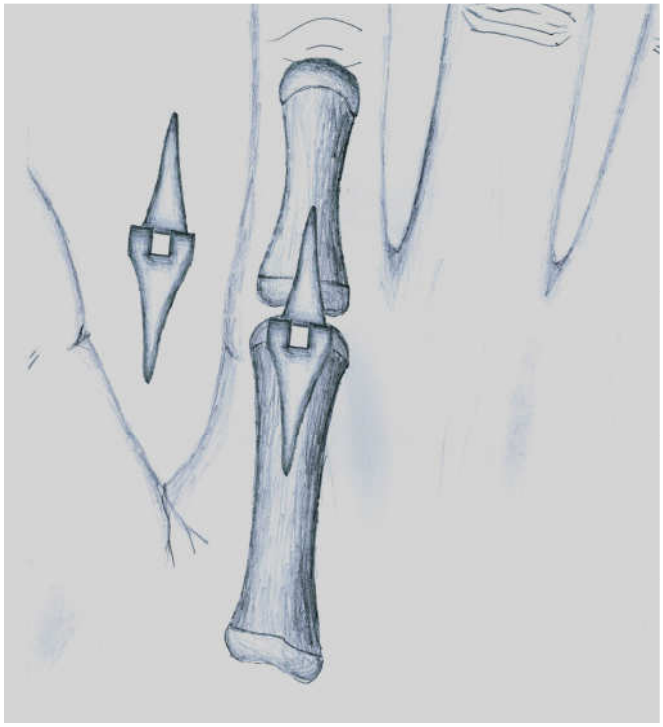
Each design contains a description including its geometry and how it limits the range of motion in the flexion/extension, adduction/abduction and longitudinal axial rotation directions. Next the materials used are described. An important facet of each design is its mode of failure. The surgical implantation of each device is considered, and finally a critical analysis of each design's strong and weak points is provided.

Rigid Hinge

The rigid hinge is comprised of three components. One component attaches to the metacarpal and one to the phalange. They interlock and possess a cylindrical cavity into which the third component is inserted and about which they rotate. These pieces articulate in the same way a standard hinge does. Flexion and extension are limited to physiological ranges by the geometry of the metacarpal and phalangeal pieces since this dictates their rotation about the primary axis. Minimal adduction and abduction may be possible by making the design a loose fitting "wobbly" hinge. There is no rotation possible about the long axis of the bone. The pin holding the components together in this design is made of UHMWPE, which displays good wear when in contact with the cobalt-chromium from which the other two components are made. The pin is designed to fail before the other components and before the bone/implant interface. The metacarpal and phalangeal components of the device are inserted into the medullary canals first, and then the pin is secured connecting them. The pin securing mechanism may involve a screw.

The simplicity of this design is attractive, and it limits the flexion and extension well. However, there are constraints that this design fails to adequately address. It does not allow for the proper range of motion in the adduction/abduction direction. Also, it is unlikely that the pin would fail first in a variety of loading configurations particularly if a load were applied in the adduction/abduction direction, as there may be catastrophic bone failure from the strength of the metal-to-metal interaction supporting loads in that direction. This metal-to-metal connection may wear causing device weakness and a potential foreign body reaction (Figures 4 and 5).





Figures 4 and 5: Rigid Hinge design in sagittal and frontal views

Sloppy Hinge

The sloppy hinge design takes its inspiration from a larger scale joint replacement used in the elbow (See Figure 6). As the name suggests, it is a hinge with a third component that allows a small range of motion in the direction of a secondary axis. This design has four main components. The most proximal starts with a stem that becomes one of the two hinge pieces. A pin, as seen in the rigid hinge, attaches the other hinge piece, but instead of connecting to the phalange, it has a dorsal protrusion into which the final piece connects. The distal end of the final piece is the stem in the phalange. The proximal end inserts through the protrusion on the second hinge piece. This design includes a head on the end of the inserting portion of the distal piece that allows tensile load accommodation.

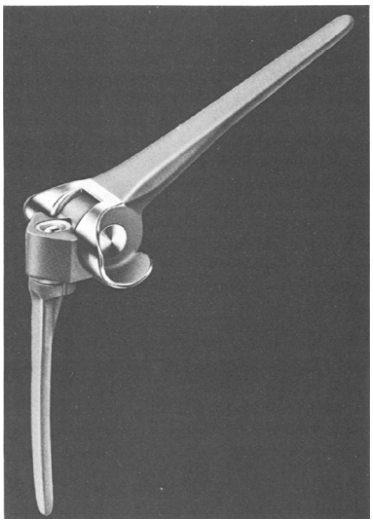


Figure 6: Elbow sloppy hinge joint [30]

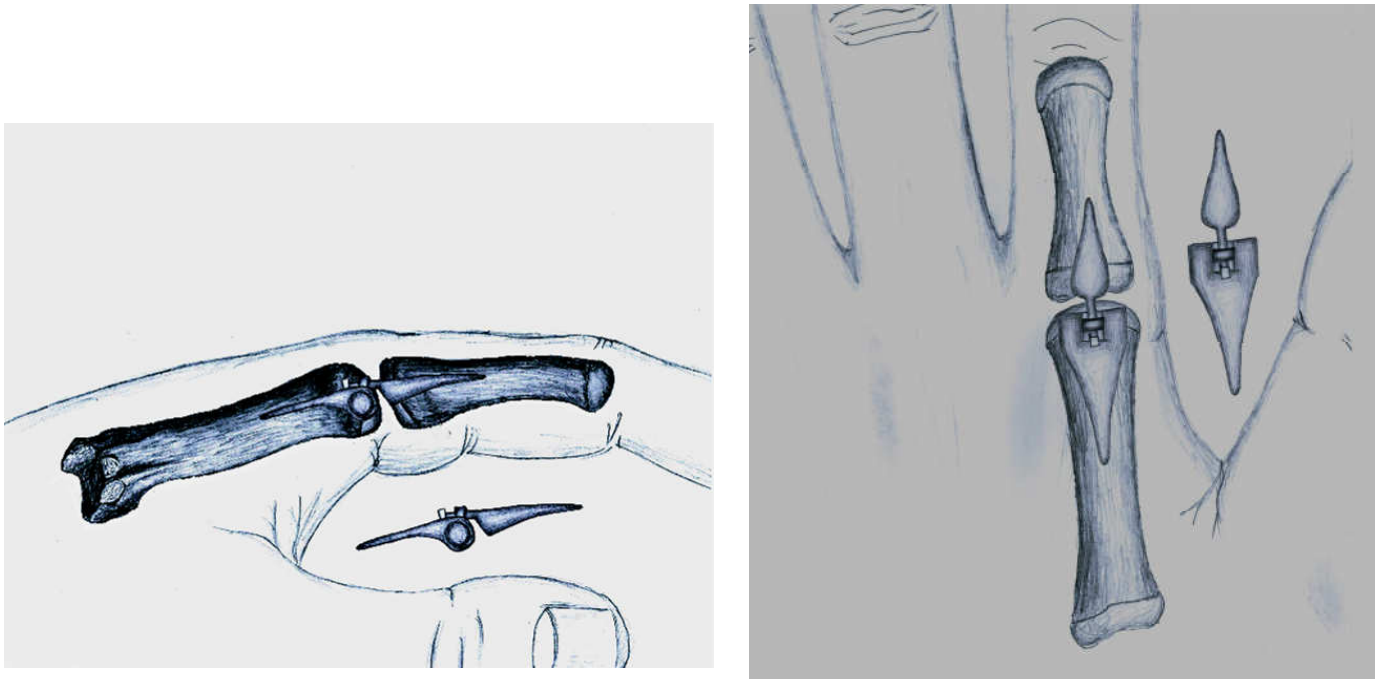
The flexion and extension are limited by the range of motion from the primary axis of the hinge. The adduction and abduction are limited by how much larger the protrusion opening is than the size of the distal insertion. The rectangular shape of these components do not allow for rotation about the axis parallel to the bones.

The pin connecting the proximal component and the second hinge piece is made of UHMWPE to limit the metal-on-metal contact from the two cobalt-chromium hinge components. The most distal component has a CoCr stem to help promote bone integration, and an UHMWPE section that inserts into the distal hinge component. These two components may be attached by a screw or pin. Both stems are grit blasted and coated in hydroxyapatite to promote osteointegration.

Failure occurs first at the UHMWPE extension from the most distal component. By confining failure here, the osteointegrated stems are preserved, as well as the more expensive CoCr components. The surgeon only has to replace the broken UHMWPE piece.

Initial implantation of the device involves insertion of each stem into the bone canal. The proximal stem is pre-attached with the pin to the second hinge component. Next the UHMWPE extending component is inserted through the hinge piece and attached to the distal stem.

This design works well in the elbow, but may not scale down well to the MP joint. In addition, the small dimensions and number of parts would make manufacturing difficult. The metal-to-metal interaction of the hinge is still a concern as with the rigid hinge, but would not likely fail prior to the UHMWPE extension or its metal connection (Figures 7 and 8).



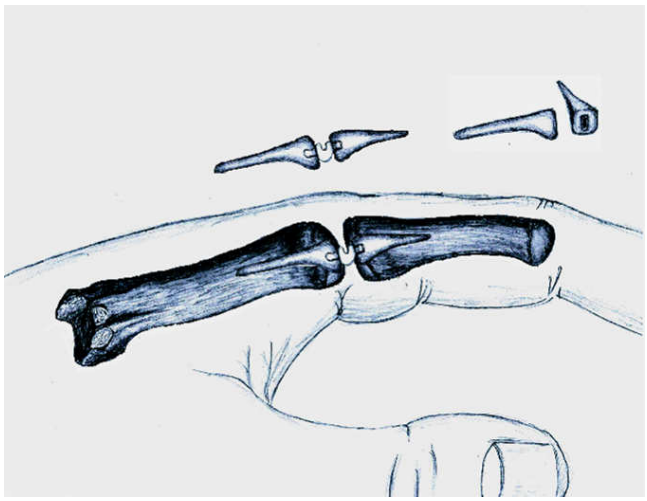
Figures 7 and 8: Sloppy Hinge design in sagittal and frontal views

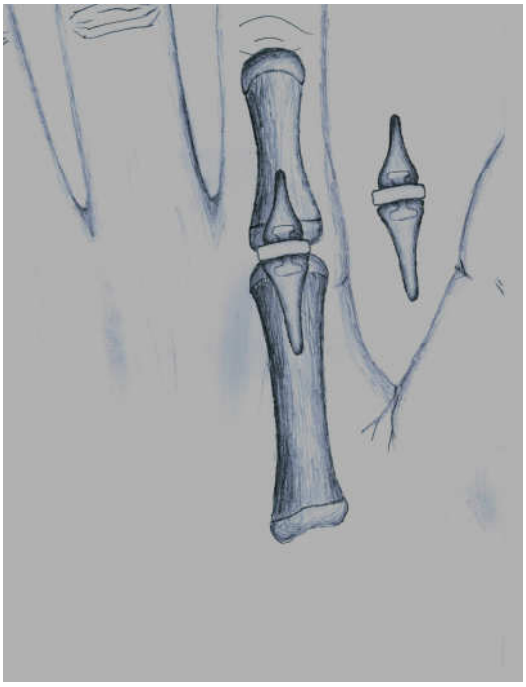
Silicone-metal Hybrid

The silicone-metal hybrid is a modification of existing silicone implants that would be suitable for the required application. The implant consists of three components. One CoCr stem connects with the metacarpal, and another CoCr stem connects with the phalange. A silicone bridge, whose geometry limits the range of motion, joins the stems. The silicone is thickest in medial/lateral direction and thinner in the dorsal/volar direction. This allows for a smaller force to result in larger deflection in the flexion/extension direction than the adduction/abduction direction. By this mechanism, a greater range of motion is present in the flexion/extension direction than the adduction/abduction direction. More flexion is possible than extension because the device has a u-like cross section when viewed from the side. The silicone begins to compress itself in extension, whereas it encounters no such limitation in flexion.

Device implantation begins with stem insertion into the canals of the metacarpal and phalange. The silicone is next inserted in a lock and key fashion into each stem. The flared ends of the silicone component would be rotated 90 degrees from their resting position to fit into the complimentary slots on the exposed stem ends. After inserting the ends, the silicone would be rotated to its final position. A small amount of quick curing silicone or adhesive would ensure the position of the silicone component. An alternate realization of this design may include a pre-attached version where the silicone is attached to the stems by interlocking geometry directly in the molding process. This design would involve simultaneous insertion of both stems. This insertion would be easier, but firmly anchoring both of the stems may prove to be more difficult since they are attached.

One large difference between the silicone design and the other designs is its variable range of motion. The extent of motion is partially constrained because of device geometry, but since silicone has a lower elastic modulus, it will deform substantially more with the same applied load. However, its lower elastic modulus allows the silicone to absorb an impulsive load by momentarily deforming past the otherwise acceptable limits rather than fracturing. Frequently, stressed silicone implants are prone to wear debris that can result in fibrous capsule buildup, which interferes with device function as mentioned in the materials section. Manufacture of the device would be straightforward. Likely, several iterations would be needed to optimize the geometry to provide the best range of motion (Figures 9 and 10).





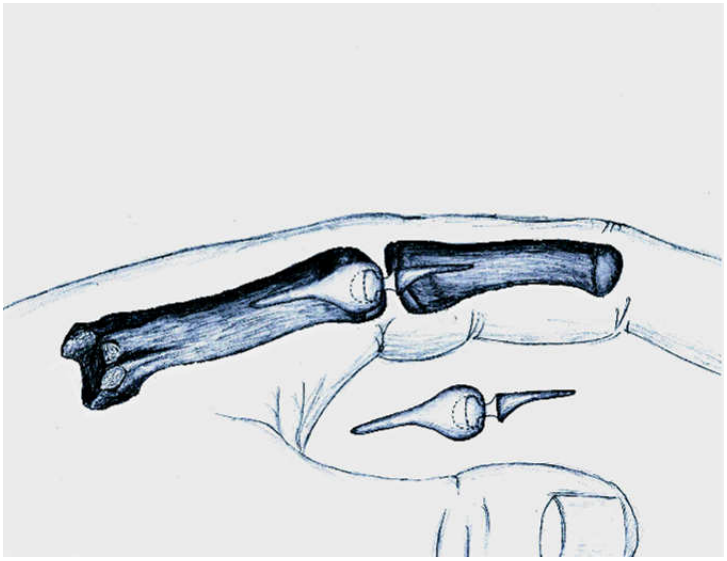
Figures 8 and 9: Silicone-metal Hybrid design in sagittal and frontal views

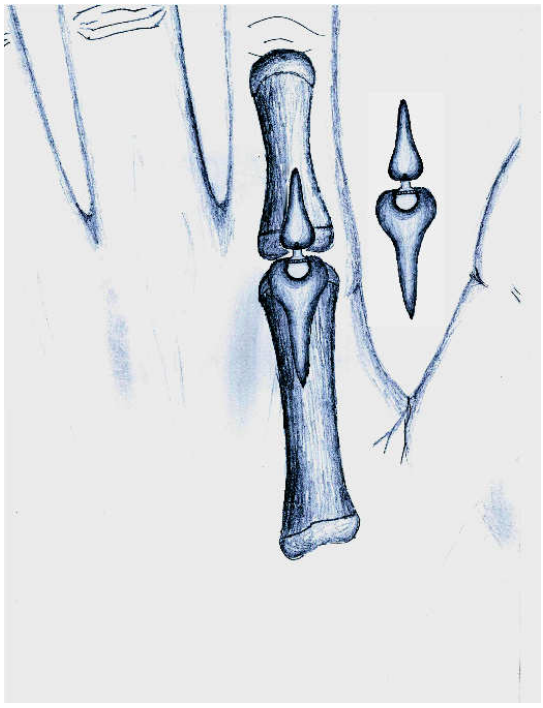
Ball and Socket

The ball and socket design has two main components. The metacarpal section has a smooth disc shaped socket into which the ellipsoidal head of the phalange section tightly fits. The disc shaped socket and ellipsoidal ball are favored here over the classic spherical ball and socket to avoid rotation about the axis parallel to the bones. The geometry of the opening through which the neck of the distal component protrudes, limits the ranges of motion in both the flexion/extension and adduction/abduction directions. The opening is wider on the dorsal side than the volar to reflect the increased adduction/abduction when the finger is not flexed. The proximal half of the device is entirely CoCr. The distal portion has three subcomponents. The stem is CoCr, and the head and neck portion of the distal component are made of UHMWPE. This polyethylene component is attached to the distal stem with a pin or screw.

Implantation occurs in two steps. The first step is insertion of the stems into their respective bone canals. The second step is connection of the head and socket. The dorsal surface of the socket is open, and the head fits neatly in. After it is in, a pin or screw secures the opening so that the head cannot be removed. The device is designed to fail at the polyethylene head, thereby preserving the more expensive CoCr socket, and the valuable osteointegration present with the stems. Therefore, repair of a broken device involves replacement of the single failed component.

This design allows excellent control of range of motion in all directions. The detachable head designed to fail first is attractive for limiting catastrophic failure, and for easily repairing implants. The major drawbacks to this design are the unusual geometry and the tight tolerances required by the close contact between the ball and socket. These factors combined with the small size make manufacture difficult (Figures 10 and 11).





Figures 10 and 11: Ball and Socket design in sagittal and frontal views

Locking Groove

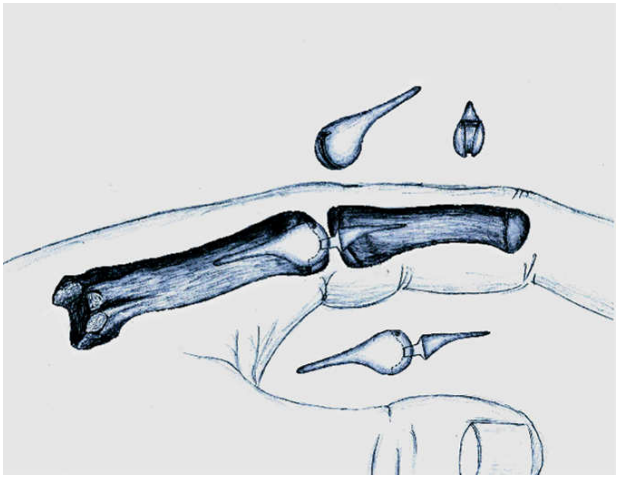
The locking groove design is comprised of two main components: one secured to the distal portion of the metacarpal and the other the proximal portion of the phalange. The portion connected to the metacarpal contains the groove into which the other component in secured. The joining components are of matched male and female geometries, with the phalangeal component having a male trapezoidal head and the metacarpal component a groove with a trapezoidal cross section. The phalangeal component is allowed to translate along the length of the curved groove, rotating about an axis inside the head of the metacarpal component. This mimics how the proximal articulating surface of the phalange translates along the distal portion of the metacarpal physiologically in the normal MCP joint.

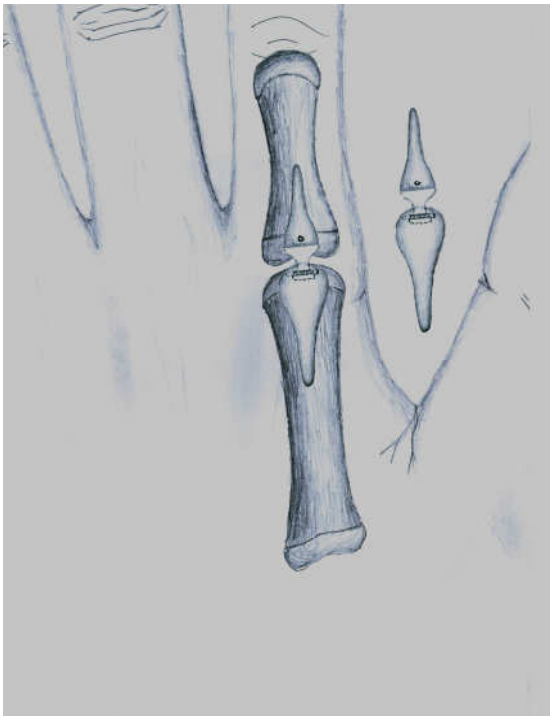
The length of the groove geometrically constrains the flexion and extension to physiologically relevant ranges. The design allows for range of motion in the adduction/abduction direction by scaling the opening of the groove slightly larger than the corresponding locking component. Along the length of the groove, the size of the opening changes to limit abduction/adduction when the finger is fully flexed. The locking of the phalangeal and metacarpal components does not allow rotation about an axis passing through both bones.

The metacarpal component in this design is made of CoCr. The phalangeal component is comprised of three pieces. The head will be made of UHMWPE because it will contact the CoCr metacarpal surface. The stem of the phalangeal component will be made of CoCr, and will be attached to the head with a screw.

. The implant is designed to fail at the phalangeal head. Failing first at this location allows for preservation of the bone implant interfaces of the metacarpal component. The surgeon can remove and replace the broken phalangeal component, which will interface with the preserved metacarpal component. During the initial implantation, the surgeon implants the two halves of the device independently. The metacarpal component is first inserted into the medullary canal. The distal portion of the device is then fixed to the phalange's canal, hyperextended, and inserted into to proximal end. A screw is used to close the insertion slot in the metacarpal head, which ensures the two halves do not dislocate.

This design constrains the joint's range of motion to normal physiological values. Furthermore, the phalangeal component translates along the metacarpal as in the normal hand. The need to replace only one half of the device is a useful feature in limiting the severity of failure. The general size and geometry of this design make it challenging to manufacture. Additionally, stress concentrations at the neck may shorten the lifespan of the device (Figures 12 and 13).





Figures 12 and 13: Locking Groove design in sagittal and frontal views

Design Matrix

The aforementioned designs were evaluated on a number of criteria. The device must constrain the range of motion, as this is a function normally performed by the ligaments. Flexion at the MCP joint is the most important attribute; hence the proper flexion and extension ranges are weighted highly. Adduction and abduction are less important. The most important aspect of the range of motion in this direction is the prevention of ulnar dislocation. In order for surgeons to adopt the device and to avoid complications associated with longer surgeries, the device must be easy to implant. The method of failure is important to preserve the integrity of the bone and to simplify any necessary repairs. Therefore, devices where only one component needs to be replaced are scored more highly. Manufacturability is another important factor that was considered. Table 1 summarizes points that were previously discussed. Because the locking groove design received the highest score, it was pursued for the remainder of the semester.

Table 1: Design Matrix

Criterion	Weight	Rigid Hinge	Sloppy Hinge	Ball and Socket	Silicone Hybrid	Locking Groove
ROM: Flexion/ Extension	35	35	35	35	30	35
ROM: Abduction/ Adduction	20	15	15	20	15	20
Ease of Implantation	20	10	10	15	10	15
Consequence of Failure	20	15	12	15	18	15
Manufacturability	5	5	2	1	5	3
Total	**100**	**80**	**74**	**86**	**78**	**88**

Final Design

Materials

As previously mentioned, a CoCr-on-UHMWPE articulating surface was desired for this implant due to its excellent wear characteristics. When deciding which parts would be made out of each material, the design requirement of having the phalangeal component fail before the metacarpal component was noted. The metacarpal implant is a single component fabricated from CoCr. Therefore, the phalangeal head was fabricated from UHMWPE to provide the proper articulating surface. However, because UHMWPE has poor osteointegration capabilities, a CoCr sheath was added around the UHMWPE core. The two pieces of the phalangeal implant will be connected by a CoCr pin located on the stem (Figure 14).

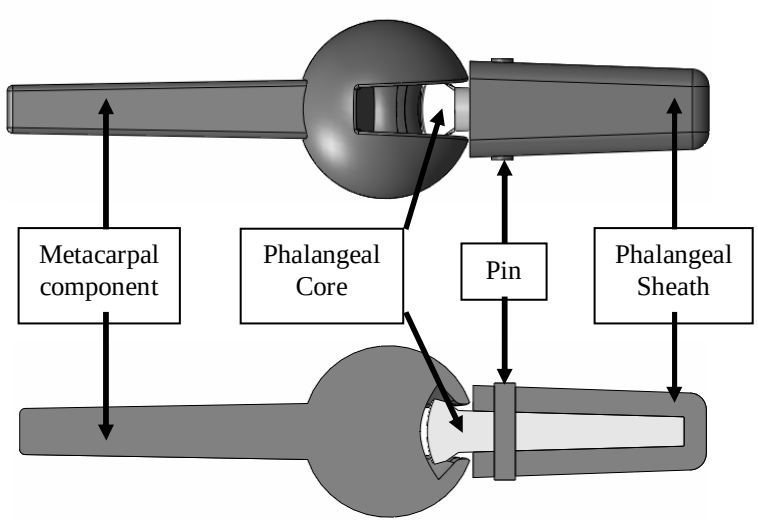


Figure 14: An external (top) and cross-sectional (bottom) view of the assembled implant.

Unique Design Features

Because this design will be used in patients without collateral ligaments, special features were added to restore the functionality normally provided by ligaments.

1. **Fully constrained design:** The device is fully constrained, which implies that it only restricts motion to normal ranges of motion. The fully constrained nature of the interlocking groove prevents tensile and ulnar dislocation.
2. **Narrowing groove:** The groove width is wider at 0º of flexion, and gradually narrows as it approaches 90º of flexion. The narrowing groove allows the design to mimic the natural adduction/abduction range of motion at varying degrees of flexion provided by the ligaments.
3. **Hyperbolic paraboloid articulating surface:** The articulating surface of the phalangeal head has a hyperbolic paraboloid surface. The abduction/adduction surface is convex, while the flexion/extension surface is concave. The opposite concavities of the two surfaces (resulting in a saddle-shaped geometry) prevent rotation about the long axis of the bone, a feature normally accomplished by the ligaments (Figure 15).

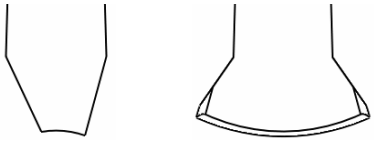


Figure 15: The flexion/extension surface (left) is concave while the abduction/adduction surface (right) is convex.

Surgical Implantation

This device will not significantly affect the surgical implantation techniques employed with current MCP joint replacements. The surgeon will implant the two halves of the device using the current procedure (see Appendix for Surgical Implantation section). To insert the interlocking head of the phalangeal component into the metacarpal groove, the joint will be hyperextended to 45º and placed into the insertion slot that opens into the groove (Figure 16). This position is shown in Figure 16. After the phalangeal head is inserted into the groove, a pin will be used to close the insertion slot to prevent the joint from dislocating if it hyperextends.

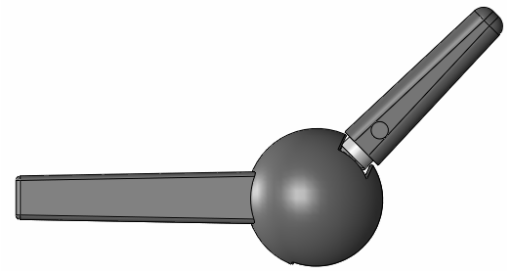


Figure 16: The phalangeal head is inserted into the groove at a hyperextended position (45º extension).

Dimensions

The device was scaled to fit the index finger of a normal male hand. This was done for two reasons. First, the expected power grip and pinch force for a person with symbrachydactyly are unknown. Second, the detailed bone dimensions of symbrachydactyly patients are also unknown. Calculating the joint reaction forces without bone dimensions and external loads is impossible. Bone dimensions are known from literature for the average adult male, as are the

maximum external loads and estimated joint reaction forces. For these reasons, the implant was sized to fit the normal adult male index finger and the reaction forces applied are the maximum the average male can generate. As the implant gets smaller, generally the loads it experiences are expected to decrease, although this relationship may not be linear. Since it is unlikely that research in the near future will document the detailed bone dimensions and loading of such a small population segment, it is best to overdesign the implant for bearing loads.

The device was dimensioned using literature measurements from existing implants and male anatomical data. The diameter of the metacarpal head was based off of the outer dimensions of the distal metaphysis [31]. The stem lengths were based off of an existing MCP joint replacement [19]. The stem widths were based off of anatomical bone dimensions of the metacarpal and proximal phalange (specifically, midshaft dimensions of the medullary canal) [31, 32]. These dimensions are shown in figures 17 and 18.

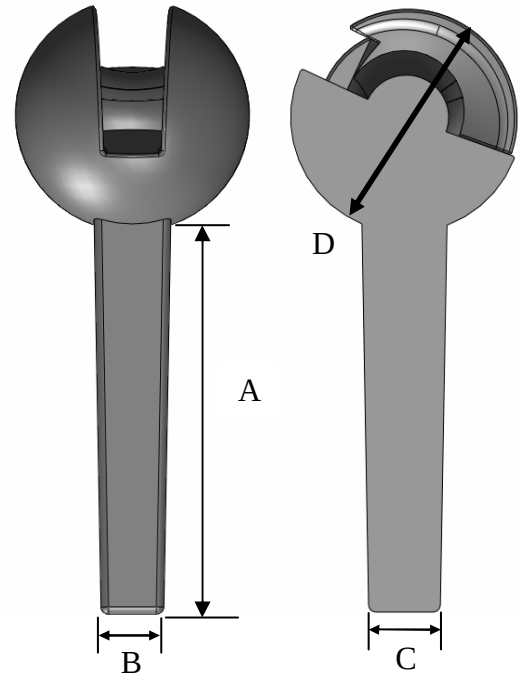
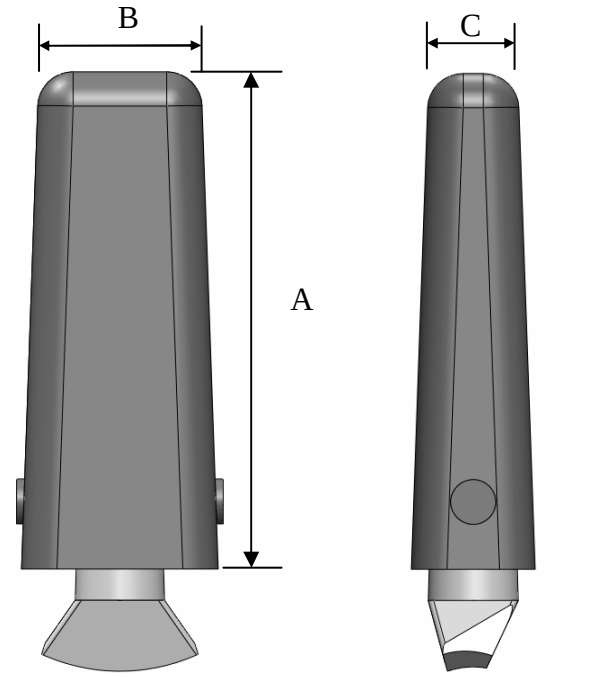


Figure 17: Metacarpal Dimensions

	Dimension	Value
A	Stem length [19]	25 mm
B	Sagittal stem tip width [31]	4.2 mm
C	Frontal stem tip width [31]	4.8 mm
D	Head diameter [31]	15.5 mm



	Dimension	Value
A	Stem length [19]	18 mm
B	Sagittal stem tip width [32]	3.74 mm
C	Frontal stem tip width [32]	6.86 mm

Figure 18: Phalangeal Dimensions

Testing

As this idea was a novel one, testing was of the utmost importance. Loads were applied to the device through finite element analysis to test pinch and power grips (Figure 19). The range of motion was tested using the SolidWorks motion simulator.

Figure 19: Pinch grip (left) and power grip (right) [33]

Finite Element Analysis

After the joint reaction forces were calculated, they were applied to the model through the finite element analysis (FEA) application of SolidWorks software. For the joint reaction forces, literature values from an article by Beevers et al. were used [7]. These values in were adapted from an earlier study by Chao et al. [33]. The pinch grip value was 490 N [7], which is within the range of other literature values. The grip value of 980 N is the highest seen in any source and much higher than the value calculated in the free body diagram section. Upon later investigation, it is believed Beevers et al. interpreted the data by Chao et al. in obtaining the 980 N power grip value, resulting in an unusually large joint reaction force. Due to time constraints, the FEA testing was not repeated with another value. However, a more realistic value will be used for future testing. Overdesigning the implant will not have negative consequences provided the other specifications are still met.

Models of metacarpal and phalangeal bones were created (Table 2) with the material properties of cortical bone. Additionally, the material properties for Cobalt Chrome [25] and UHMWPE (RAM extruded GUR 1050 highly cross-linked UHMWPE) [34] were applied to appropriate implant components. These material properties are summarized in table 3. Each half of the implant was then implanted into its corresponding bone model such that the inner surface of the bone was bonded with the outer surface of the implant (Figure 20). The outside surface of the bone was then fixed. The loads were applied to each half on the implant individually, since the reaction forces are equal and opposite on each component. The loads were applied as pressures over an area, whose size matched the contact area between the two halves of the implant. The pressure acts normal to the surface upon which it is applied; however, the free body diagrams suggest that there are components of the force acting tangent to the surface. One limitation of the FEA application in SolidWorks was the inability to apply pressures at an angle. The corresponding angle of flexion of the joint determined where the pressure was applied on the metacarpal. The pressure was applied to the only articulating portion of the phalangeal component in both loading scenarios.

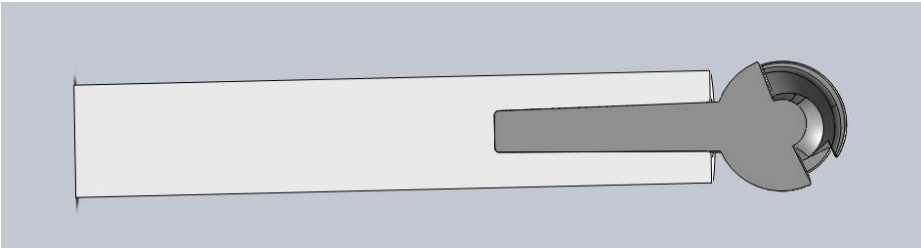


Figure 20: Potting of the metacarpal component

Table 2: Bone dimensions

Phalange Dimensions [32]	Length [mm]	Outer Diameters [mm]					
		Frontal			Sagittal		
		PM	MS	DM	PM	MS	DM
	41.65	17.17	10.12	12.15	12.35	6.91	8.91
Metacarpal Dimensions [31]	Length [mm]	Outer Diameters [mm]					
		Frontal			Sagittal		
		PM	MS	DM	PM	MS	DM
	69.22	18.83	8.34	15.79	17.37	9.28	15.26

PM-proximal metaphysis, MS-midshaft, DM-distal metaphysis

Table 3: Material properties

Cobalt Chrome

Mass Density [SolidWorks default]	8.397 g/cm^3
Elastic Modulus [SolidWorks default]	230 GPa
Shear Modulus [SolidWorks default]	85.9 GPa
Poisson's Ratio [SolidWorks default]	0.33
Ultimate Strength (Tensile) [25]	655 MPa
Yield Strength (Tensile) [25]	450 MPa

UHMWPE [34]

Mass Density	1.020 g/cm^3
Elastic Modulus	1.06 GPa
Shear Modulus	377.2 GPa
Poisson's Ratio	0.46
Ultimate Strength (Tensile)	37 MPa
Yield Strength (Tensile)	19.6 MPa

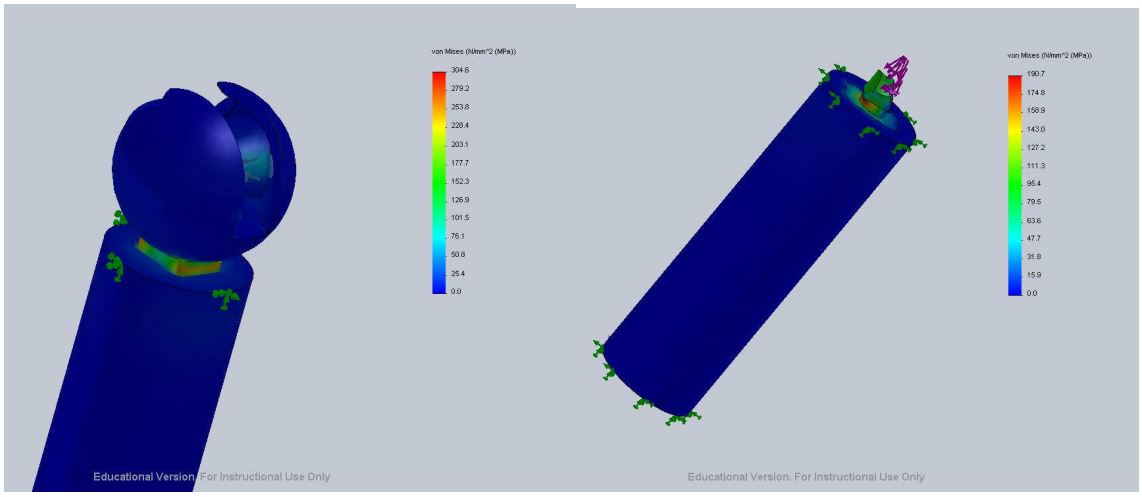
Cortical Bone [35]

Mass Density [53]	1.85 g/cm^3
Elastic Modulus	18.6 GPa
Poisson's Ratio	0.3
Ultimate Strength (Tensile)	120 MPa
Yield Strength (Tensile)	100 MPa

Results

Power Grip

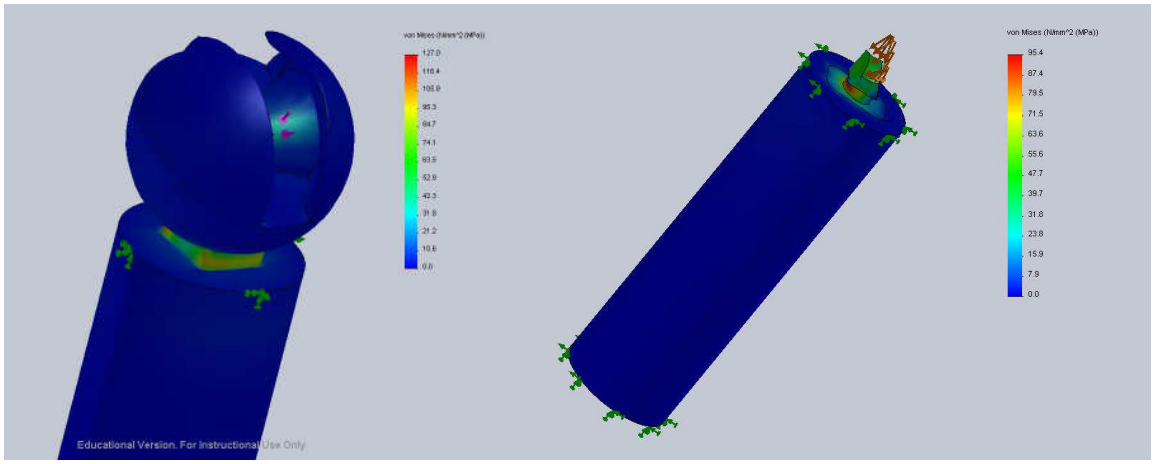
The metacarpal component withstood the reaction forces applied, with the largest stress concentrations occurring at the neck of the device opposite the applied load as seen in figure 21. The largest stress seen was 67.69% the yield strength of CoCr (factor of safety=1.47). The implant's maximum deformation was elastic with a value of 0.05269 mm. The phalangeal component endured stresses that exceeded its yield strength. The largest stress seen was 190.7 MPa, which is 973% the yield strength of UHMWPE (factor of safety=0.103) and major stress concentrations occurred at the neck of the component as seen in figure 22. The largest deformation seen was 0.7163 mm.



Figures 21 and 22: FEA stress testing of the metacarpal and phalangeal components during power grip.

Pinch

The metacarpal component withstood the reaction forces applied with the largest stress concentrations occurring at the neck of the device opposite the applied load as seen in figure 23. The largest stress seen was 22.28% the yield strength of CoCr (factor of safety=3.54). The implant's maximum deformation elastic with a value of 0.02186 mm. The phalangeal component endured stresses that again exceeded its yield strength. The largest stress seen was 95.4 MPa which is 486% the yield strength of UHMWPE (factor of safety=0.205) and major stress concentrations occurred at the neck of the component as seen in figure 24. The largest deformation seen was 0.3582 mm.



Figures 23 and 24: FEA stress testing of the metacarpal and phalangeal components during pinch.

Range of Motion Testing

One client requirement was a functional range of motion. Testing was performed for both flexion/extension and adduction/abduction to ensure that the design would meet this requirement. Range of motion testing was performed using the "Move Component" function in SolidWorks. The test results are summarized in Tables 4 and 5 below.

Table 4: Range of Motion in the Flexion/Extension

Motion	Design Specification	Design Capability
Flexion	90°	92.59°
Extension	20°	44.95°
Insertion angle	n/a	44.95°

Table 5: Range of Motion in the Abduction/Adduction Direction

Degree of Flexion	Design Specification	Design Capability
0°	40°	9.56°
90°	0°	0.88°

For flexion/extension, an appropriate range of motion was achieved. The degree of flexion of the model was an acceptable range, and could be easily modified in the future. The maximum angle of extension was larger than the design specification; however, the future addition of a pin in the insertion slot of the metacarpal implant (as previously discussed) will decrease this range of motion.

This design proved to have a smaller range of motion in the abduction/adduction direction than was required for functional range of motion. Although appropriate restriction of abduction/adduction motion was achieved at 90° of flexion, the range of motion at 0° of flexion was significantly smaller than the functional requirement. This difference may be due to a limitation of the "move component" function in SolidWorks. It only allows the user to either translate or rotate the component until it collides with another surface. Essentially, artificial constraints were required to actuate the model, but these constraints would not be present in a physical model.

Budget

This project did not require prototype fabrication because testing was completed theoretically. Therefore, no costs were incurred during the semester. A scaled-up version of the design was made out of plastic by a rapid prototyping machine housed in the mechanical engineering building. Professor Ploeg used a grant for orthopedics research to fund the fabrication of a scaled-up rapid prototype. In order to get a stainless steel version of the design fabricated by the Physics shop, it would cost $2,700 +/- $500. At this time, funding has not been pursued but will be in the future as seen in the budget proposal found in the appendix.

Intellectual Property

At the beginning of the semester, a problem to design a MCP joint replacement in patients lacking ligamentous support was presented. The client conceptually developed the idea for an interlocking groove, which would provide stability for the patient. The design and its features appeared novel, useful, and nonobvious so it was decided that the design should be brought to the Wisconsin Alumni Research Foundation (WARF) to determine its patentability. To do so, an invention disclosure report (IDR) was completed and can be viewed in the appendix. The design idea was continually refined throughout the semester and a few limitations were discovered. By modifying the design to combat these limitations, it became more similar to a patent found during the original patent search performed early in the semester [36]. After close inspection of the patent, some of the claims overlapped with the design presented here. Therefore, a WARF disclosure was not pursued at this time.

Ethical Considerations

The goal of this project is to eventually use this implant in humans lacking the ligamentous support required for currently available implants. Before the implant can be commercialized, however, the implant must be tested in animals and then later in humans. To do so, all guidelines provided by the Institutional Animal Care and Use Committee as well as the Institutional Review Board will be followed. In development, it is important to not cut any

corners and make sure all tests are completed thoroughly. On the other hand, developing the device too slowly would not be beneficial to the inventor, investors, or patients.

Ergonomics

In designing the implant, it was important to account for the method of surgical implantation. The joint replacement should in no way be difficult for the surgeon to implant or require the surgeon to learn a significantly different procedure. Also, as the MCP joint replacement will eventually be used in patients with a variety of bone sizes, the implant must be available in a variety of sizes to accommodate each patient.

Future work

Through testing, limitations of the design were discovered. The first major limitation is the inability of the phalangeal component to support the reaction forces without failing. Increasing the surface area of the load bear articulating surface will address this concern. The most intuitive way to do this is adding "shoulders" to the device that contact the metacarpal component outside the groove. This would also help ensure that the phalangeal component is not pushed deeper into the medullary canal by the compressive forces at the joint. Also, in the current design the extensor tendon currently rests on the convex head of the metacarpal. In the normal hand a fibrous sheath secures this tendon in place. A concave track could be added to help ensure proper position of this tendon. Another limitation of the current design is that it does not allow for full abduction/adduction at zero degrees of flexion. Also, the current axis of rotation for adduction and abduction is located on the phalangeal component, and in the normal hand it lies within the metacarpal head. Similarly, in the current design the axis of rotation for flexion and extension is centered along the stem of the design. In the normal hand the axis is slightly offset in the volar direction from the stem. This could have the biomechanical consequence of adjusting moment arms, changing the function of the finger [37]. Future designs should bring these axes into proper position.

Fixing these limitations in the ways described will bring the design even closer to the previously mentioned patent [36]. Future attempts will be made to contact the patent owner to discuss his design. The patent was issued in 1999, and it is unknown why the design is not

commercially available or if it has been licensed. If contact cannot established with the patent owner, he is unwilling to cooperate, or another route is deemed more promising, novel ideas will be generated and old design alternatives refined. This approach will address limitations to the current design or present new ways of satisfying the design specifications.

Whichever route is pursued, the new design will first be modeled, theoretically tested, and optimized. Different theoretical testing programs such as ANSYS will be explored in an attempt to apply the loads more realistically. Also, new theoretical testing methods for range of motion will be explored. If the budget can be procured, the design will be fabricated and implanted into a cadaveric hand to test the functional range of motion and ease of implantation. If the budget affords the correct materials, wear testing will be conducted to establish a lifetime for the device. Next intellectual property and licensing will be addressed in order to push the design toward FDA approval and eventual market share. See Table 6 project schedule for the predicted timeline for the spring 2010 semester.

Table 6: Project schedule

Tasks	Winter Break	January		February				March				April					May	
		22	29	5	12	19	26	5	12	19	SB	2	9	16	23	30	7	14
Research and Development																		
Brainstorm																		
Contact current patent owner																		
Finalize design																		
Simulated Testing																		
Explore new motion testing techniques																		
Learn ANSYS																		
SolidWorks modeling																		
Range of motion testing																		
FEA testing with ANSYS																		
Model Optimization																		
Physical Testing																		
Manufacture Prototype																		
Cadaveric hand testing																		
Deliverables																		
Mid Semester Presentation																		
Final Presentation																		
Final Report																		
Outreach Report																		
Progress Reports																		
Website																		

References

1. Pylios T, et al. A new metacarpophalangeal joint prosthesis. Proceedings of the World Congress on Engineering 2007; 2.
2. Herman IP. “Physics of the Human Body”. New York: Springer, 2007.
3. Modified from: Kleinert HE, Sunil TM. Use of volar plate for reconstructing the radial collateral ligament after metacarpophalangeal arthroplasty of fingers in rheumatoid arthritis: Surgical technique. The Journal of Hand Surgery 2005; 30(2): 390-393.
4. Netter FH. "Atlas of Human Anatomy." Philadelphia, PA: Saunders Elsevier, 2006.
5. Shehadi R. conversation. September 14, 2009.
6. Children’s Hospital Boston. “Symbrachydactyly.” 2009. <http://www.childrenshospital.org/az/Site1108/mainpageS1108P0.html>.
7. Beevers DJ, *et al*. Design of a non-constrained, non-cemented, modular, metacarpophalangeal prosthesis. IMechE 1995; 209: 185-195.
8. Irwin CB, Radwin RG. A new method for estimating biomechanical loading in grip. Proceedings of the Human Factors and Ergonomics Society 2003; 47th Annual Meeting: 1126-1130.
9. Fowler NK, *et al*. Long-term measurement of metacarpophalangeal joint motion in normal and rheumatoid hand. IMechE 2001; 215(H): 549-553.
10. Trail, *et al*. Seventeen-year survivorship analysis of silastic metacarpophalangeal joint replacement. The Journal of Bone & Joint Surgery 2004; 86-B: 1002-1006.
11. Burgess SD, Kono M, Stern PJ. Metacarpophalangeal Joint Surgery in Rheumatoid Patients Following Previous Silicone Arthroplasty. The Journal of Hand Surgery Volume 2007; 32(10): 1506-1512.
12. Madden, *et al*. A rational postoperative management program for metacarpophalangeal joint implant arthroplasty. Journal of Hand Surgery 1977; 2A(5): 358–366.
13. Bobyn JD, *et al*. Producing and Avoiding Stress Shielding: Laboratory and Clinical Observations of Noncemented Total Hip Arthroplasty. Clinical Orthopaedics and Related Research 1992; 274: 79-96.
14. Wolff J. Das Gesetz der Transformation der Knochen. Berlin Hirschwald 1892.
15. Bobyn JD, Stackpool G, Toh K-K, et al. Bone ingrowth characteristics and interface mechanics of a new porous tantalum biomaterial. J Bone Joint Surg. 1999; 81-B: 907-914.
16. Willert HG, Semlitsch M. Reactions of the articular capsule to wear products of artificial joint prostheses. Journal of Biomedical Materials Research 1976; 11(2): 157-164.
17. Bobyn JD, Hacking SA, Krygier JJ, et. al. Characterization of a new porus tantalum biomaterial for reconstructive surgery. 66th AAOS, Anahem, CA 1999.
18. Deglurkar M, et al. Evaluation of machining methods for trabecular metal implants in a rabbit intramedullary osseointegration model. Journal of Biomedical Materials Research 2006; 80B(2): 528-540.
19. Cook SD, Beckenbaugh RD, Redondo J, Popich LS, Klawitter JJ, Linscheid RL. Long-Term Follow-up of Pyrolytic Carbon Metacarpophalangeal Implant**s.** The Journal of Bone and Joint Surgery 1999; 81: 635-48.
20. Ploeg H. conversation. October 2, 2009.

21. Kurtz SM. "The UHMWPE handbook: ultra-high molecular weight polyethylene in total joint Replacement". Academic Press, 2004.
22. Liu, X, *et al*. Surface modification of titanium, titanium alloys, and related materials for biomedical applications. Materials Science and Engineering R 2004; 47: 49-121.
23. Brown SA, Lemons JE. "Medical applications of titanium and its alloys: the material and biological issues". Page: 6. ASTM International, 1996.
24. Merritt K, Brown SA. Distribution of Cobalt Chromium Wear and Corrosion Products and Biologic Reactions. Clinical Orthopaedics 1996; 329: 233-243.
25. Arcam ASTM F75 CoCr alloy. <http://www.arcam.com/CommonResources/Files/www.arcam.com/Documents/EBM%20Materials/Arcam-ASTM-F75-Cobalt-Chrome.pdf> 2009.
26. Foliart, DE. Swanson Silicone Finger Joint Implants: A Review of the Literature Regarding Long-term Complications. J. Hand Surg. 1994; 20A: 445-449.
27. Ryan, G, *et al*. Fabrication of porous metals for use in orthopaedic applications. Biomaterials 2006; 27: 2651-2670.
28. Nasatzky E, Gultchin J, Schwartz Z. The role of surface roughness in promoting osteointegration. Refuat Hapeh Vehashinayim. 2003; 20(3): 8-19, 98.
29. De Bruijn JD, van Blitterswijk CA, Davies JE. Initial bone matrix formation at the hydroxyapatite interface *in vivo*. Journal of Biomedical Materials Research 2004; 29(1) 89-99.
30. Gschwend N, Simmen BR, Matejovsky Z. Late complications in elbow arthroplasty. Journal of Shoulder and Elbow Surgery 1996; 5(2): 86-96.
31. Lazar GT, Schulter-Ellis FP. Intramedullary Structure of Human Metacarpals. J Hand Surg Am. 1980; 5(5): 477-481.
32. Schulter-Ellis FP, Lazar GT. Internal morphology of human phalanges. J Hand surgery, 1984; 9A: 490-495.
33. Chao EY, Opgrande JD, Axmear FE. Three dimensional force analysis of finger joints in selected isometric hand functions. Journal of Biomechanics 1976; 9: 387-396.
34. Lewis G. Properties of crosslinked ultra-high-molecular-weight polyethylene. Biomaterials 2001; 22: 371-401.
35. Reilly DT, Burstein AH. The Mechanical Properties of Cortical Bone. J. Bone Joint Surg Am. 1974; 56: 1001-1022.
36. Lippincott AL et al. Constrained prosthesis for replacement of joints between long bones in the hand. US Patent 5938700, 1999.
37. Simmen BR, Stanley J. Hand Arthroplasties. Informa Health Care, 2000.
38. Napier JR. The prehensile movements of the human hand. J Bone and Joint Surgery 1956; 38B: 902-913.
39. Landsmeer JMF. Power grip and precision handling. Annals of the Rheumatic Diseases. 1962; 21: 164-170.
40. Brand PW, Hollister A. Clinical Mechanics of the Hand. Mosby – Year Book Inc, 1993.
41. Nordin, M. Frankel, V.H. "Basic Biomechanics of the Musculoskeletal System". Lippincott Williams & Wilkins, 2001.
42. Moore KL, Dalley AF. Clinically Oriented Anatomy. Lippincott Williams & Wilkins, 1999.

43. Thelen D. conversation. November 17, 2009.
44. An, KN, Ueba Y, Chao EY, Cooney WP, Linscheid RL. Tendon excursion and moment arm of index finger muscles. Journal of Biomechanics 1983; 16(6): 419-425.
45. Radwin RG, Oh S, Webster JG, Jensen TR. External finger forcesin submaximal five-finger static pinch prehension. Ergonomics 1992; 35(3): 275-288.
46. Irwin CB. conversation. November 23, 2009.
47. Weightman B, Amis AA. Finger Joint Force Predictions Related to Design of Joint Replacements. Journal of Biomedical Engineering 1982; 4: 197-205.
48. Dennerlein JT, Diao E, Mote CD, Rempel DM. Tensions of the flexor digitorum superficialis are higher than a current model predicts. Journal of Biomechanics 1998; 31: 295-301.
49. Valero-Cuevas FJ. An integrative approach to the biomechanical function and neuromuscular control of the fingers. Journal of Biomechanics: 2005; 38: 673-684.
50. Ash *et al*. Biomechanics of the upper limb. Current Orthopaedics 1996; 10(1): 25-36.
51. Pylios T, *et al*. Biomechanics of the normal and diseased MCP Joint: Implications on the design of joint replacement implants. J Mechanics in Medicine and Biology 2007; 7(2): 163-174.
52. Bone Innovations, Inc. "Surgical Technique: SR™ MCP Implant System." 2008.
53. Barkmann R, Luesse S, Stampa B, Sakata S, Heller M, Gluer CC. Assessment of the geometry of human finger phalanges using Quantitative Ultrasound in vivo. Osteoporosis Int 2000; 11: 745-755.

Appendix

WARF IDR

UW-Madison Invention Disclosure Report Date: WARF Case No.
Information in this report is supplied by the investigators pursuant to obligations of researchers specified in the UW-Madison, Graduate School, Intellectual Property Policies and Procedures for University Research: (http://info.gradsch.wisc.edu/research/ip/ippolpro.doc).- If you have questions about completing this document contact your WARF Intellectual Property Manager, 263-2500 or Sarah Castello, UW Graduate School, 263-2877. Please distribute copies to all individuals who worked on this invention as identified in the inventor information section of this document.

Invention Summary
Title of invention: Stable Metacarpophalangeal Joint Replacement
Technical abstract of the invention (or attach a publication or draft). This will be provided, when required, to sponsoring agencies. This invention is a stable metacarpophalangeal joint replacement. The replacement is used as a substitute or replacement for the joint between the proximal phalanx and the metacarpal particularly in cases where functional collateral ligaments are absent. The design is comprised of two main components, one secured to the distal portion of the metacarpal, and the other the proximal portion of the phalanx. The portion connected to the metacarpal contains a groove into which the other component in secured. The phalangeal component is allowed to translate along

the length of the curved groove, rotating about an axis inside the head of the metacarpal component, as the proximal articulating surface of the phalanx translates along the distal portion of the metacarpal physiologically in the normal hand. The flexion and extension are limited to physiological values by the length of the groove. Maximum adduction and abduction limited by the width of the groove. The implant is intentionally designed to fail at the neck of the distal portion prior to the bone/implant interface or the bone itself to avoid complicated failure.

What makes this invention superior to existing technology?

Metacarpophalangeal(MCP) joint replacements are most commonly used in cases of rheumatoid arthritis typically found in older patients. The most frequently used implants are made of silicone and targeted to the needs of this group. The lifespan of such devices is not appropriate for younger patients. Available metacarpophalangeal joint replacements require good support from the collateral ligaments and volar plate. This becomes a problem when the ligaments are absent from congenital defect, destroyed from injury, or stretched beyond usefulness with arthritis. The new design does not require the presence of collateral ligaments, making it a viable option for replacement in these populations. Even in cases where the ligaments are intact, the surgeon must use care and occasionally extra steps to preserve the ligaments through the implantation process. A device that does not require ligaments would simplify the surgery.

The invention was conceived of at least as early as:

2006

When was the invention shown to work?

The device has not yet been shown to work.

Have you disclosed this invention to anyone in a non-confidential manner?

If so, when and to whom?

If not, do you anticipate such a disclosure in the next six months (when and to whom)?

The design was disclosed to students and faculty at the midsemester Biomedical Engineering project presentations on October 16, 2009. Intention was made clear in the presentation and by a show of hands prior to the presentations that the meeting was not a public disclosure and ideas discussed within would remain confidential. The IDR is being filed now in anticipation of public disclosure at the final presentation December 4, 2009.

Inventor Information

Note: Should royalty payments be made to the department(s) at any point, the distribution will be determined based on the departments listed below and any additional information provided by inventors, as this is expected to reflect the unit in which the work was done.

Is any inventor employed by or affiliated with:

	Yes	No
USDA		**x**
USDA/Forest Products Lab		**x**
Veterans Administration		**x**
UW Hospitals and Clinics		**x**
Howard Hughes Medical Institute		**x**
Any organization or company other than the UW Madison	**x**	

Dean Health System

Funding and Materials

To look up your funding sources see http://www.rsp.wisc.edu/services/admin/awards.cfm

A grant, contract or cooperative agreement is a source of funds if the invention was conceived or reduced to practice in the performance of work sponsored by the funding agreement.

Which federal funds (144-accounts) contributed to making this invention?

	Sponsoring Agency	Grant, Contract or Agreement Number	UW Account

			Number
Primary	n/a	n/a	144-
Secondary	n/a	n/a	144-

(expand as needed for more sources)

Which non-federal funds contributed to making this invention?

Sponsoring Agency	Grant, Contract or Agreement Number	UW Account Number
n/a		
n/a		
n/a		

(expand as needed for more sources)

Check if any other agreements are relevant to this invention (list):

Check Here	**Agreement Type**	**Other parties to agreement, and description of agreement**
	Material transfer agreement	
	Confidentiality agreement	
	Collaboration agreement	
	Research agreement	
	Consortia agreement or funding	
	Consulting agreement	
	Other	

If none, check here____x_____

(expand as needed for more sources)

Name of person completing this form:	Nate Cira
Phone:	(414)-916-0216
e-mail address:	ncira@wisc.edu

In submitting this form you are accepting the responsibility for the accuracy of the information supplied and for ensuring that all inventors will be provided with copies of this form.

Submit this report to the Wisconsin Alumni Research Foundation:

- By e-mail to the appropriate Intellectual Property Manager
- Through WARF's website at http://www.warf.org/contact/idr.jsp
- By mail Attn: Docket Clerk P.O. Box 7365 Madison, WI 53707

Free Body Diagrams

In order to estimate the loads the implant will bear, free body diagrams (FBD) were developed for the index finger. A number of assumptions were made statically determinate manageable calculations while reflecting the anatomy of the finger. These assumptions and their rationale are listed below. Two common loading situations the pinch and power grasp were analyzed. [38,39]

Assumptions:

The finger remains static since it is not moving during the grip.

Gravity is negligible since the weight of the entire hand is only about 1/40 the smallest tendon force. [2]

Forces are applied at single points to simplify calculations.

Tendons are the only soft tissue that exerts forces on the bone since the forces from other soft tissues are unknown and these other tissues do not function to exert forces.

Moment arms are valid at all joint geometries distal to the joint of interest since the positions of the distal bones does not affect the distance from the center of rotation to line of action of the tendon force.

Tendons are ideal frictionless cords. [40]

Bones are ideal rigid members since they are not broken or substantially bent during pinch or power grip. [40]

Joints are simple 2D hinges to simplify modeling the system. [40]

Tendons crossing a bent knuckle exert forces on that knuckle as if it were an ideal pulley with no size . [41]

The force from this “pulley” is supported half by each bone at the joint. [42]

Tendon forces at the insertion are parallel to the bone of insertion since the tendons track along the bone. [42]

Co-contraction of extensor tendons is ignored since the position acts to produce flexion. [43].

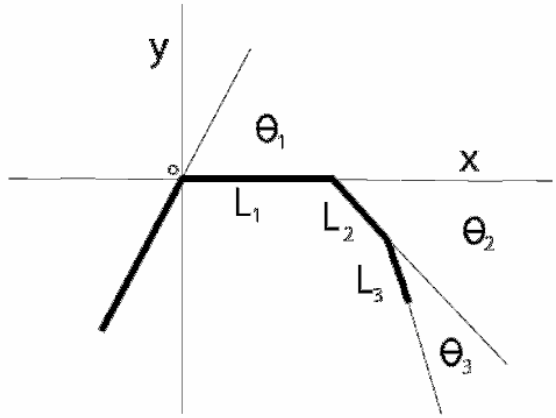


Figure 25: shows the coordinate system used. Point o is the MCP joint. L_1 = 4.357 cm, L_2 = 2.467 cm, L_3 = 1.967 cm [44]

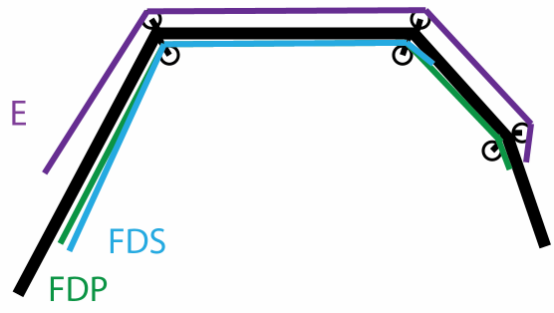


Figure 26: shows how the tendons were represented in the system. They are ideal cords tracking over minute pulleys at each joint. E stands for extensor, FDP for flexor digitorum profundus, and FDS for flexor digitorum superficialis. They are parallel to each bone as they pass along them.

The coordinate system used can be seen in figure 25 and tendon positions can be seen in figure 26. Two different approaches were used in determining the joint reaction forces. The first approach involved isolation of the distal three bones and a diagram of forces on this free body (figure 28, 30). With this approach it is easy to see exactly where each force is applied since the tendon is not included in the free body. The second approach isolates the distal three bones and includes part of the tendon in the free body diagram (figure 27, 29, 31). This approach hides the forces between from the tendon on the bone as it passes over the distal two knuckles. This simplifies the calculations. Here both methods and corresponding equations are included and yield the same result. The general approach was to use moment equilibrium to find the tendon forces then force equilibrium to find reaction forces at the joint.

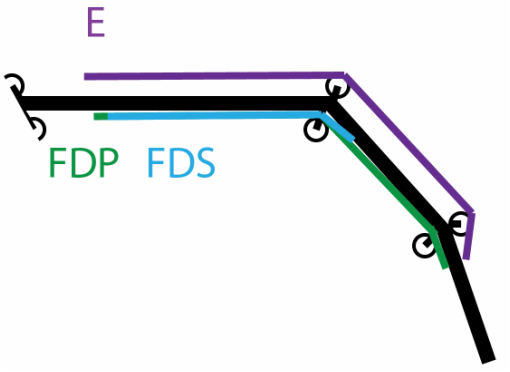


Figure 27: shows how the tendons were represented in the system. They are ideal cords tracking over minute pulleys at each joint. E stands for extensor, FDP for flexor digitorum profundus, and FDS for flexor digitorum superficialis. They are parallel to each bone as

Power Grip:

Maximum grasp strength = 464 N [8]

Index and middle fingers each support 32% of load [45]

Distal phalange supports ⅔of the load for each finger [45]

Middle and proximal phalanges each support ⅙ of the load [45]

F_1 = 24.75 N

F_2 = 24.75 N

F_3 = 99 N

$M_E(\theta_1 = 62°)$ = -0.8 cm [44]

$M_{FDP}(\theta_1 = 62°)$ = 1.3 cm

$M_{FDS}(\theta_1 = 62°)$ = 1.4 cm

$\theta_1 = 62°$

$\theta_2 = 48°$ (Chao)

$\theta_3 = 23°$

$T_{FDS} = .6T_{FDP}$ [46]

$$\sum M_o = 0 = \frac{1}{2}L_1F_1 + \left(\frac{1}{2}L_2 + L_1\cos\theta_2\right)F_2 + \left(\frac{1}{2}L_3 + L_2\cos\theta_3 + L_1\cos(\theta_2 + \theta_3)\right)F_3 - M_{FDS}T_{FDS} - M_{FDP}T_{FDP}$$

The tendon forces resulting from the moment equilibrium are:

T_{FDS} = 173.613 N

T_{FDP} =289.355 N

The magnitude of the forces of the tendon on the bones at the knuckles are:

$$J_1 = \cos\left(\frac{180-\theta_1}{2}\right)(T_{FDP}+T_{FDS}) = 238.4463\ N$$

$$J_2 = 2\cos\left(\frac{180-\theta_2}{2}\right)(T_{FDP}+T_{FDS}) = 376.6123\ N$$

$$J_3 = 2\cos\left(\frac{180-\theta_3}{2}\right)(T_{FDP}) = 115.3762\ N$$

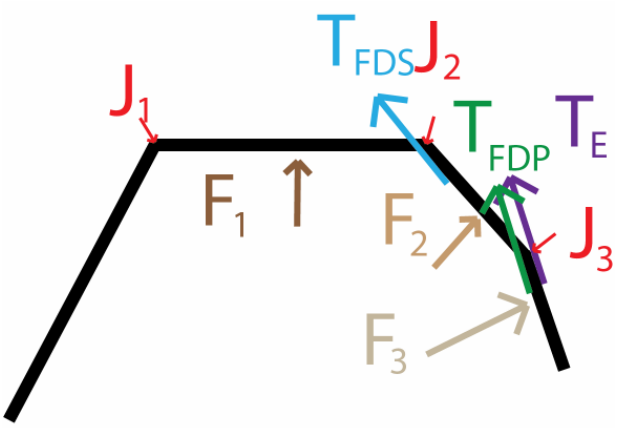


Figure 28: shows the forces acting on the phalanges during power grip. Not shown are the internal joint reaction forces found at the MCP joint.

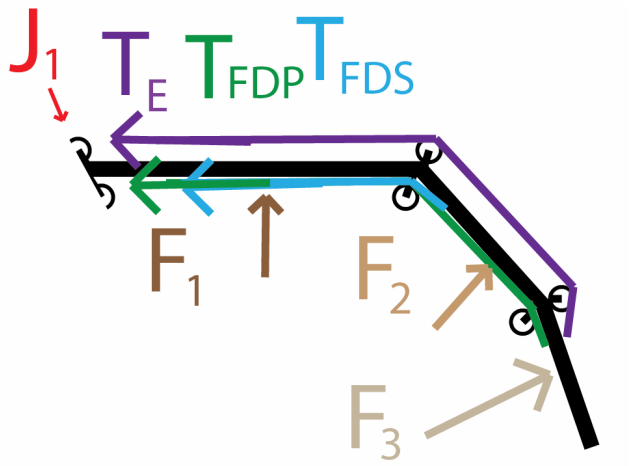


Figure 29: shows the forces acting on the distal three phalanges and a potion of the tendon during power grip. Not shown are the joint reaction forces at the MCP joint.

The force equilibrium equations from figure 28 are:

$$\sum F_x = 0 = F_2\sin\theta_2 + F_3\sin(\theta_2+\theta_3) - T_{FDP}\cos(\theta_2+\theta_3) - T_{FDS}\cos(\theta_2) + J_1\cos\left(\frac{180-\theta_1}{2}\right) - J_2\cos\left(\frac{180-\theta_2}{2}\right) - J_3\cos\left(180-\theta_2-\frac{180+\theta_3}{2}\right) + R_x$$

$$\sum F_y = 0 = F_1 + F_2\cos\theta_2 + F_3\cos(\theta_2+\theta_3) + T_{FDP}\sin(\theta_2+\theta_3) + T_{FDS}\sin(\theta_2) - J_1\sin\left(\frac{180-\theta_1}{2}\right) - J_2\sin\left(\frac{180-\theta_2}{2}\right) - J_3\sin\left(180-\theta_2-\frac{180+\theta_3}{2}\right) + R_y$$

The equivalent force equilibrium equations from figure 29 are:

$$\sum F_x = 0 = F_2\sin\theta_2 + F_3\sin(\theta_2+\theta_3) - T_{FDP} - T_{FDS} + J_1\cos\left(\frac{180-\theta_1}{2}\right) + R_x$$

$$\sum F_y = 0 = F_1 + F_2\cos\theta_2 + F_3\cos(\theta_2+\theta_3) - J_1\sin\left(\frac{180-\theta_1}{2}\right) + R_y$$

The reaction forces determined by either set of equations are:

R_x = 228 N

R_y = 131 N

or

R = 263 N @ 30° north of east

<u>Pinch:</u>

$M_E(\theta_1 = 48)$ = -0.8 cm [44]

$M_{FDP}(\theta_1 = 48)$ = 1.1 cm

$M_{FDS}(\theta_1 = 48)$ = 1.2 cm

$T_{FDS} = .6T_{FDP}$ (Irwin)

$T_E = 0$

F = 70 N parallel to the metacarpal [7]

θ_1 = 48°

$\theta_2 = 50°$ [33]

$\theta_3 = 25°$

$$\sum M_o = 0 = (L_1 \sin\theta_1 + L_2 \sin(\theta_1 + \theta_2) + L_2 \sin(\theta_1 + \theta_2 + \theta_3))F + M_E T_E - M_{FDS} T_{FDS} - M_{FDP} T_{FDP}$$

The tendon forces resulting from the moment equilibrium are:

$T_{FDS} = 169.1746$ N

$T_{FDP} = 281.958$ N

The magnitude of the forces of the tendon on the bones at the knuckles are:

$$J_1 = \cos\left(\frac{180 - \theta_1}{2}\right)(T_{FDP} + T_{FDS} + T_E) = 183.492 \text{ N}$$

$$J_2 = 2\cos\left(\frac{180 - \theta_2}{2}\right)(T_{FDP} + T_{FDS} + T_E) = 381.314 \text{ N}$$

$$J_3 = 2\cos\left(\frac{180 - \theta_3}{2}\right)(T_{FDP}) = 122.054 \text{ N}$$

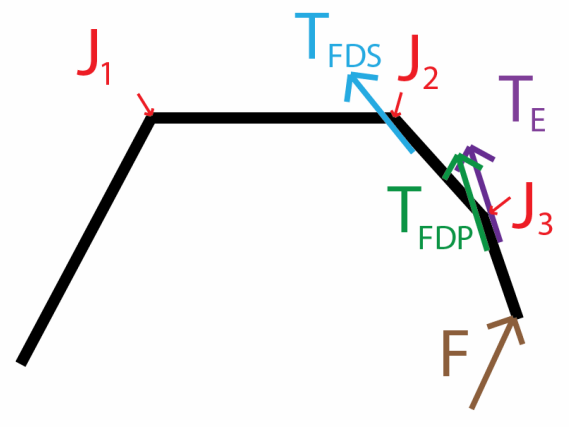


Figure 30: shows the forces acting on the phalanges during pinch. Not shown are the internal joint reaction forces found at the MCP joint.

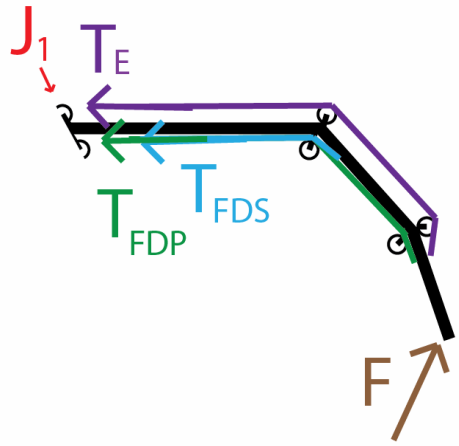


Figure 31: shows the forces acting on the distal three phalanges and a potion of the tendon during pinch. Not shown are the joint reaction forces at the MCP joint.

The force equilibrium equations from figure 30 are:

$$\sum F_x = 0 = F\cos(\theta_1) - T_{FDP}\cos(\theta_2 + \theta_3) - T_{FDS}\cos(\theta_2) - T_E\cos(\theta_2 + \theta_3) + J_1\cos\left(\frac{180 - \theta_1}{2}\right) - J_2\cos\left(\frac{180 - \theta_2}{2}\right) - J_3\cos\left(180 - \theta_2 - \frac{180 + \theta_3}{2}\right) + R_x$$

$$\sum F_y = 0 = F\sin(\theta_1) + T_{FDP}\sin(\theta_2 + \theta_3) + T_{FDS}\sin(\theta_2) - T_E\sin(\theta_2 + \theta_3) - J_1\sin\left(\frac{180 - \theta_1}{2}\right) - J_2\sin\left(\frac{180 - \theta_2}{2}\right) - J_3\sin\left(180 - \theta_2 - \frac{180 + \theta_3}{2}\right) + R_y$$

The equivalent force equilibrium equations from figure 31 are:

$$\sum F_x = 0 = F\cos(\theta_1) - T_{FDP} - T_{FDS} - T_E + J_1\cos\left(\frac{180 - \theta_1}{2}\right) + R_x$$

$$\sum F_y = 0 = F\sin(\theta_1) - J_1\sin\left(\frac{180 - \theta_1}{2}\right) + R_y$$

The reaction forces determined by either set of equations are:

R_x = 330 N

R_y = 116 N

or

R = 350 N @ 19° east of north

Comparison to literature values:

There have been many attempts at creating accurate models of the fingers to relate external loads to internal forces. Within these models there is large variation in the predicted internal reaction forces [47]. The one study measuring actual *in vivo* tendon forces contradicted the predicted values of pervious works [48]. Indeed a recent paper describes the inadequacy of current predictive models [49]. The literatures range of predicted values for pinch joint reaction

forces is 287 N to 616 N for a 70 N applied force [47]. The value found above of 350 N falls within this range. The one study that offered reaction forces for power grip found 387 N at the MCP joint [50]. The reaction force of 263 N found here is lower than this value. This discrepancy may be from differing assumptions, different dimensions, or different applied loads. The sources used for the magnitude, and distribution of the applied loads did not exist at the time of the literature reference. Some characteristics that validate the model described here are the near identical tendon forces in pinch and power grip. If a muscle has a maximum amount of force it can generate, and the same muscles are used for both flexing actions, then the tendon forces should be the same. For validating the pinch model, the ratio between the applied force and the FDS tension is 1:2.41, very close to 1:2.4 found experimentally but not accurately predicted by other models [48].

BME Design 400 Budget Proposal

Nate Cira, Amanda Feest, Hallie Kreitlow, Ken Roggow

Objective

This semester, the goal of our design project is to effectively design a joint replacement for the metacarpophalangeal joint in patients lacking collateral ligaments and a volar plate. In particular, we will be designing for our client's son who has symbrachydactyly, a congenital hand defect. Our client is Ramzi Shehadi, MD who is a reconstructive and plastic surgeon for Dean Health Systems.

Project Expenses

To complete this project, we must obtain funding for material and labor costs for fabrication of a to-scale version of our design to be completed by the Physics Instrument Shop at UW-Madison. The following table provides each item with its respective cost:

Expense	Total
To-scale prototype stainless steel/fabrication	$2,700 +/- 500
Total project expense	$2,200-3,200

The model will be used for implantation into a cadaveric hand to determine ease of implantation and range of motion.

Product Design Specifications (PDS)

Nate Cira, Amanda Feest, Hallie Kreitlow, and Kenny Roggow

12/8/09

Function:

The client would like an orthopedic joint replacement for the metacarpophalangeal (MCP) joint that can be used in patients who do not have collateral ligaments or a volar plate, including patients with severe trauma or congenital hand defects. The joint replacement will be implanted into younger patients, and should therefore have a long lifespan after implantation. Patients should be able to maintain appropriate grip strength and range of motion after the joint replacement is implanted. Finally, the stems should osteointegrate to prevent micormotion.

Design Requirements

1. **Physical and Operational characteristics**
    a. *Performance requirements:*
    The design should provide stability that is normally provided by the collateral ligaments and the volar plate. The design should maintain a normal anatomical range of motion for flexion/extension. Ideally, the design would also maintain a normal anatomical range of motion for abduction/adduction range of motion, but this is a secondary concern. The design should also be able to withstand physiological loads occurring during power grip and pinch grip functions.

    b. *Safety:*
    The joint replacement should not harm the patient. It should be designed to fail at the articulating surface instead of failing at the stems, which would put the patient at risk for fracturing or shattering of the bones.

    c. *Accuracy and Reliability:*
    The joint replacement should consistently provide stability in the operational range of motion.

    d. *Life in Service:*
    The joint replacement should have a 10 year lifespan after being implanted.

    e. *Shelf Life:*
    Not currently applicable. Eventually, the conditions of the sterile environment the device is packaged in will determine the shelf life.

    f. *Operating Environment:*
    The joint replacement will function in the body, with constant exposure to human synovial fluid.

g. *Ergonomics:*

The surgical procedure required for implantation should not exceed the complexity of the current surgery.

h. *Size:*

The joint replacement should be sized for the index finger of an average healthy hand. The dimensions of the implant should be similar to healthy bone dimensions to maintain proper tendon tracking. Future iterations of the design will test various sizes of the implant for different fingers and bone sizes.

i. *Materials:*

All materials should currently be FDA approved for use in other implants. The materials should be biocompatible and minimize wear at the articulating surface. The stems should have special materials or coatings to improve osteointegration.

j. *Aesthetics, appearance and finish:*

After implantation, the joint should default to a relaxed position.

2. Production characteristics

a. *Quantity:*

Ideally one prototype will be produced in the proper materials, which would be used for wear testing. However, if funding is not available, SolidWorks models and rapid prototypes are acceptable.

b. *Target Product Cost:*

Not currently applicable. Eventually, the implant must be comparable to existing implants in order to compete in the market.

3. Miscellaneous

a. Standards and Specifications:

i. Flexion Range of Motion: 0-90° [51]
ii. Extension Range of Motion: 0-20° extension [51]
iii. Abduction/Adduction Range of Motion: Ideally a total of 30° [51]
iv. Implant lifetime: 310 million cycles of varying movement angles [9]
v. Power grip strength: withstand 464 N external load [8]
vi. Pinch Strength: withstand 70 N external load [7]
vii. Method of Failure: lowest factor of safety at the articulating surface.

b. *Customer:*

The device will be implanted by a surgeon into a patient with congenital hand defects or severe trauma. The device market may also extend to patients who

have rheumatoid arthritis if the design is a significant improvement over current designs, which are acceptable for these patients.

c. *Competition:*

Ascension, Smith & Nephew, and Small Bone Innovations currently have prosthetic MCP joints on the market. There are two types of implants: silicone implants (which have poor osteointegration characteristics), and semi-constrained implants (which do not limit the range of motion and prevent dislocation).

Surgical Implantation

When designing a joint replacement, it is important to note the method of surgical implantation. Surgeons are looking for a replacement that is easy to implant quickly with minimum bone removal [7]. The current method of implantation begins with a longitudinal incision on the dorsal side of the MCP joint. Dissection continues until the metacarpal head and proximal phalange base are exposed. Next, a saw is used to remove the metacarpal head and preserve the collateral ligaments. The base of the proximal phalange is also sliced minimally to preserve the collateral ligamentous attachments. After this, a tool called an awl is used to create holes in both the metacarpal and phalange bones. The bone is then broached to ensure proper implant fit. Prior to implantation, trial placement occurs to ensure correct fit and position. Finally, the finger is ready for the joint replacement implantation. The distal component is inserted first and then the proximal component is inserted. The joint undergoes passive range of motion tests to make sure the prosthesis can flex and extend smoothly. Once the prosthesis is fixated, the collateral ligaments can be reattached and the closure of the finger can be completed [52].