DESIGN AND VALIDATION OF A FULLY-CONSTRAINED METACARPOPHALANGEAL JOINT REPLACEMENT

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ABSTRACT

Current metacarpophalangeal (MCP) joint replacements are designed for patients who have functional ligaments to support and stabilize the joint. Available implants may not provide adequate supports for patients with missing or damaged ligaments due to congenital hand defects, severe trauma, or rheumatoid arthritis. A fully-constrained, osteointegratable MCP joint replacement has been designed for these patients. The prosthesis has been validated using finite element analysis to confirm its ability to support the loads experienced at the MCP joint. The results revealed that this design can withstand physiological loading experienced during a pinch grip. *In vivo* testing and a complete pre-market approval process will need to be conducted to gain FDA approval.

INTRODUCTION

In healthy hands, the metacarpophalangeal (MCP) joint is stabilized by ligaments. Two sets of ligaments support the joint: the collateral ligaments prevent tensile dislocation, and the volar plate prevents hypertension (Figure 1). However, many patients who receive MCP replacements do not have functional ligaments.

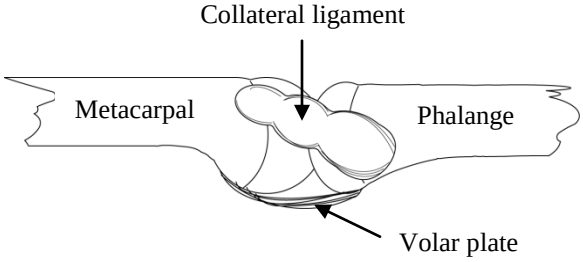

Figure 1: Anatomy of a healthy hand.

There are two types of MCP joint replacements on the market: semi-constrained implants and Swanson implants. Current semi-constrained implants, which consist of two unattached parts, rely on ligaments to prevent dislocation and stabilize the joint. Swanson implants consist of a single silicone part and also require functioning collateral ligaments. Furthermore, over half of all silicone implants fracture within 11 years (Trail et al., 2004) and can cause bone erosion at the bone-implant interface (Burgess et al., 2007). A fully-constrained, osteointegratable MCP joint would greatly benefit patients receiving joint replacements.

DESIGN CONSIDERATIONS

Several important design considerations were developed to ensure that the device will function properly after implantation. While the following section is not an exhaustive list, the most important considerations are discussed below.

MATERIAL SELECTION

The implant should be made from FDA-approved materials. Three major categories of materials considered were metals, polymers, and ceramics. The materials were selected to minimize wear at the articulating surface, providing longevity to the implant.

JOINT STABILITY

The implant must accommodate patients without functioning ligaments by providing stability to the joint. Therefore, the prosthesis must be fully constrained in order to prevent dislocation.

RANGE OF MOTION

The implant should provide a functional range of motion. It must allow 90º of flexion and 20º of extension (Pylios and Shepherd, 2007). Abduction and adduction must be limited to 40º or less, ideally with minimal adduction and abduction at full flexion (Pylios and Shepherd, 2007). Additionally, the device must restrict undesired movements, including rotation about the axis that runs through the canal of the bone.

FAILURE MODE

The failure mode of the implant determines the difficulty of any necessary repair surgeries. If the implant fails by pulling out of the bone, then new stems would have to be inserted. The joint would have to be immobilized while the implant osteointegrates again. The stem of the implant may also shatter the bone as it pulls out of the canal, which may cause irreparable damage. Therefore, the implant must be designed to fail at the articulating surface. In this case, the articulating surface could be replaced while still preserving osteointegration.

DESIGN DESCRIPTION

A fully-constrained hinge design was selected to best fulfill the previously mentioned considerations. The design will have a metacarpal component, a phalangeal component, and a pin to connect the two halves (Figure 2).

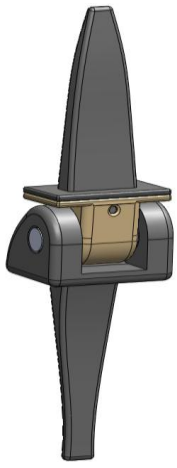

Figure 2: Hinge MCP prosthesis at zero degrees flexion.

The metacarpal component (Figure 3) will be made out of a cobalt chromium alloy (CoCr) which is capable of osteointegration (Hunt et al., 2005). The osteointegration capability will be enhanced by applying a hydroxyapatite coating (Suh , 1998).

Figure 3: The metacarpal component is made of CoCr.

The phalangeal component (Figure 4) will be an assembly of three parts: a stem, a head, and a connecting pin. The stem will also be made out of CoCr coated with hydroxyapatite. The alumina (Al_2O_3) head will allow for reduced wear patterns with the CoCr metacarpal articulating surface of the joint (Firkins et al., 2001). The parts will be connected by a press-fit CoCr pin.

Figure 4: The phalangeal component is a three-part subassembly with a CoCr stem, alumina articulating head, and a connecting pin.

The final component of the hinge will be a deformable polyoxymethylene (POM) pin. POM was selected because it will elastically deform and return to its original position when the deforming load is released (DuPont, 2010), allowing the pin to dampen loads. Dampening of the load will help promote osteointegration (Perez del Palomar et al., 2005). Everyday forces from movements of the hand range from 0-14 N (Tamai et al., 1988). The pin was

Table 1: Material properties used in analyses.

Property	Units	Cobalt Chromium (Arcam, 2009)	POM (Delrin 500 AF) (DuPont, 2010)	Alumina (Munro, 1997)
Properties applied to:		Metacarpal component, phalangeal stem, connection pin	Damping pin	Phalangeal head
Elastic Modulus	N/mm^2	230,000	1,000	416,000
Poisson's ratio	Not applicable	0.33	0.35	0.231
Shear Modulus	N/mm^2	85,900	66	Not listed
Mass density	kg/m^2	8,387	139	3,984
Tensile Strength	N/mm^2	655	66	267
Yield Strength	N/mm^2	450	66	3,000

designed to bear loads up to 50 N, which will cause a 0.45 mm deflection. After 0.45 mm of deflection, the metacarpal and phalangeal components will be in contact and any incremental load will be carried by this contact surface.

The geometry of the metacarpal component limits the flexion and extension of the joint. The metacarpal component will have geometry such that the head of the phalange will come into contact with the articulating surface of the metacarpal component, stopping motion at 90º of flexion and 20º of extension (Figure 5).

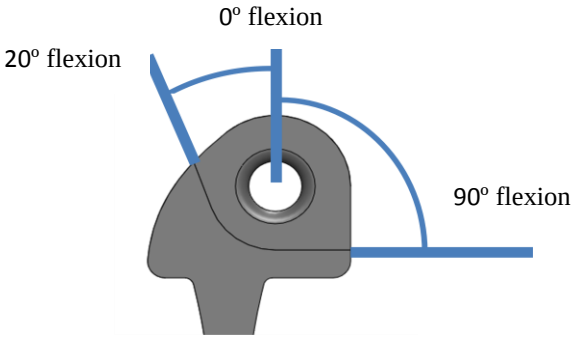

Figure 5: Flexion and extension are restricted by the articulating surface of the metacarpal component.

Modifications were made to introduce 9.5º each of adduction and abduction, for a total range of motion of 19º. The inner surface of the phalange head was curved (Figure 6) and additional clearance was added between the metacarpal and phalangeal components.

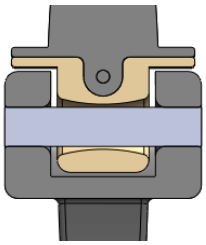

Figure 6: The curved inner surface of the phalangeal head allows for 19º of adduction and abduction.

MATERIALS AND METHODS

Four finite element analyses (FEA) were performed: two studies of the metacarpal component in compression, and one study each for the phalangeal head and phalangeal stem in compression. The POM pin was not tested using FEA because the constraints could not be properly simulated. In this case, theoretical calculations were used to validate the pin.

MATERIAL DATA

Table 1 above summarizes the material data used in FEA testing and theoretical calculations.

SOFTWARE AND HARDWARE

SolidWorks 2009 software was used model the parts and perform the FEA. This system contains features for creating finite element meshes, running the analysis, and analyzing the results. A PC computer was used to model the parts and perform the analysis.

Model Preparation and Fixation

The models were created in SolidWorks using the dimensions of the average adult male hand. After the models were completed, their material properties were applied according to Table 1. From these models, fine grain surface meshes were created containing approximately 14,500 nodes each.

Constraints were applied to the model during FEA. To represent physiological loading, the surfaces of the stems were fixed to mimic the bone canal environment.

When testing the phalangeal component, each part was tested separately. The head was fixed on the surface that would contact the stem, and the stem was fixed on the surface that would contact the head. Loads were applied to each of the components to verify that they would withstand the anticipated physiological loading. Three loading scenarios were tested: compressive loading, tensile loading, and adduction/abduction impact loading.

Applied Loads

Compressive Loading

The model was tested using pinch grip reaction forces because this loading pattern produced the largest joint reaction forces (Weightman and Amis, 1982). For the adult male index finger, the literature showed a range of 287 N to 616 N reaction forces for a 70 N applied force (Weightman and Amis, 1982). FEA was performed on the phalangeal and metacarpal components by subjecting each to a 616 N force. The metacarpal component was loaded at both 0º of flexion and 90º of flexion (Figure 7). The 50 N force carried by the pin is distributed evenly between the pin holes. The remainder of the reaction force (568 N) was uniformly distributed along a line perpendicular to the articulating surface.

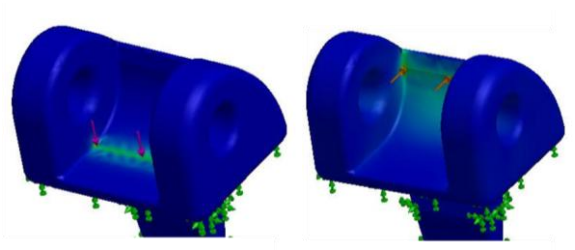

Figure 7: Compressive loading of the metacarpal stem at 0º of flexion (left) and 90º of flexion (right).

Only one test was required on the phalangeal component since it experiences the same loading patterns at any angle of flexion. The phalangeal head was loaded at the line of contact at which it articulates on the metacarpal component. The stem was loaded with a distributed force applied on the surface that would contact the head. Both loading patterns are shown in Figure 8.

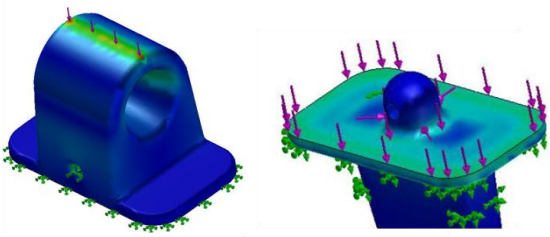

Figure 8: Compressive loading of the phalangeal head (left) and stem (right).

Due to inability to accurately fix the component in SolidWorks, stresses experienced by the deformable pin during compression were calculated theoretically. A 3 mm pin was analyzed using cantilever/roller constraints and beam bending equations.

Tensile Loading

Tensile loading occurs infrequently in synovial joints, so it is not a primary concern. However the pin should fail before the implant is pulled out of the bone canal if tensile loading were to occur. The maximum tensile load was calculated to verify the pin fails before the stems pull out of the bone.

Adduction/Abduction

The design was analyzed for failure in adduction and abduction. Since failure occurs at the CoCr pin securing the phalangeal head to the stem, the maximum applied load to the distal end of the phalange was calculated based on the strength of this pin.

RESULTS

COMPRESSIVE LOADING

The results of the FEA are shown in Table 2. All parts passed with a factor of safety of at least 1.3.

Table 2: Results of FEA.

Part	Loading situation	Pass/ fail	Factor of safety
Metacarpal stem	0º of flexion	Pass	2.3
Metacarpal stem	90º of flexion	Pass	1.3
Phalange stem	n/a	Pass	23.6
Phalange head	n/a	Pass	10.5

Theoretical calculations of the pin showed that under the 50 N compressive load, the factor of safety is 1.5. Figure 9 shows the relationship between deflection and applied load. Note that the solid line representing compression does not deflect any further at loads above 50 N because the incremental load is carried at the contact surface of the metacarpal and phalangeal components.

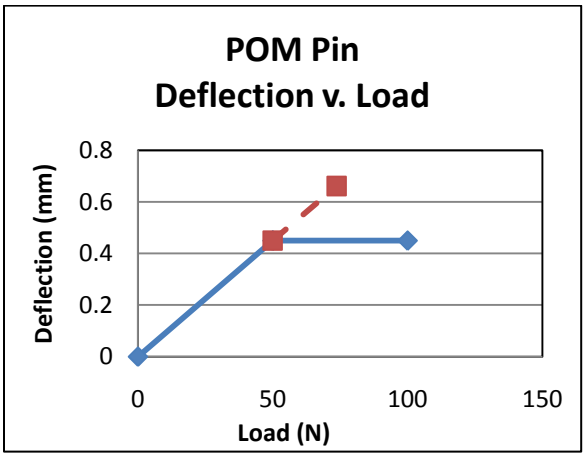

Figure 9: The relationship between the maximum deflection and applied load. During compression (solid line) the maximum deflection is reached at 0.45 mm when the phalangeal and metacarpal components contact. During tensile loading (dashed line) the pin fails at 74 N.

TENSION

The calculated load to break the POM pin is 74 N in tension.

ABDUCTION AND ADDUCTION

The failure of the implant during ad/abduction occurs at the CoCr pin. The maximum load that can be applied to the distal end of the phalange bone is 99 N.

DISCUSSION

FAILURE METHOD OF THE PIN

Based on the surface areas of the stems and values for pull out forces, it would take 930 N to pull the metacarpal component out of the canal and 1350 N to pull the phalangeal component out of the bone (adapted from Feighan et al., 1995).

APPLIED FORCES AND CONSTRAINTS

Since synovial joints nearly exclusively bear compressive as opposed to tensile loads, analysis focused on compression seen in pinch grip. The large literature range seen for internal joint reaction force in pinch grip is a result of different assumptions, different dimensions, and different applied loads. Conservatively the highest literature values were used here for simulation. Since the largest loads are experienced by the index finger, the device will see even higher factors of safety when placed in other MCP joints (Radwin et al., 1992).

The constraints used to fix the geometry of the implant were also conservative assumptions. The stems were fully constrained along the bone-implant interface; this simulated the implant being implanted into a completely rigid environment. The properties of bone are relatively elastic and would absorb strain energy from the implant when loaded. Therefore, *in vivo* we would expect to see lower maximum stresses and higher factors of safety in our stem components than what we observed in the FEA results.

ALIGNMENT

In order for the joint to function properly post-operation, the implants must be precisely aligned. The stem holes must be drilled at a defined angle to ensure the alignment, which would require proper surgical instrumentation. Misalignment of the joint may result in scissoring, where fingers overlap

when the hand is closed. Current devices have more flexibility for alignment errors because they are only semi-constrained. Therefore, precise alignment instruments need to be developed for this implant.

CUTTING ANGLE

During surgical implantation, the current design requires surgeons to cut the metacarpal bone at a point that removes the insertion points of the collateral ligaments (Figure 10). This is not important for patients who lack collateral ligaments, but could unnecessarily eliminate ligament functionality in patients where it is present. Therefore, the shoulders of the metacarpal implant should be thinner and cut at an angle to allow collateral ligament retention. The phalangeal component is sufficient as designed.

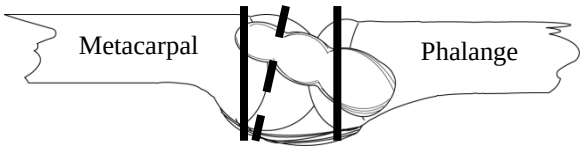

Figure 10: The current design requires the bone to be cut at the solid lines shown above, which would cut through the insertion points of the collateral ligaments. The redesign would ideally allow the metacarpal bone to be cut at the dashed line, preserving ligament insertion points.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the following people for their help in the design and testing of the device: Professor Heidi Ploeg and students, Professor Darryl Thelen, Dr. Curt Irwin, Professor Ed Bersu, Professor Tim Osswald, Dr. Bill Checovich, and Professor Jay Samuel, all from the University of Wisconsin-Madison. Funding for the prototype was provided by the UW-Madison Department of Biomedical Engineering.

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APPENDIX 1: IMPLANTATION PROCEDURE

Purpose: To assess ease of implantation and range of motion for the device relative to a commercial product in a cadaveric hand.

Procedure:

Presurgery

- Characterize the hand: s m l xl

- photograph the hand with scale bar ___

- ligament quality/comments _____

Assess range of motion on one finger:

Insert pins

Pose	Photo label
Neutral	
Adduction at full extension	
Abduction at full extension	
Adduction at 0 degrees flexion	
Abduction at 0 degrees flexion	
Adduction at 30 degrees flexion	
Abduction at 30 degrees flexion	
Adduction at 60 degrees flexion	
Abduction at 60 degrees flexion	
Adduction at 90 degrees flexion	
Abduction at 90 degrees flexion	
Full Flexion	
Full Extension	

- Setup camera

Ascension Device

A2

Start time_____

End time_____

Assess range of motion

Pose	Photo label
Neutral	
Adduction at full extension	
Abduction at full extension	
Adduction at 0 degrees flexion	
Abduction at 0 degrees flexion	
Adduction at 30 degrees flexion	
Abduction at 30 degrees flexion	
Adduction at 60 degrees flexion	
Abduction at 60 degrees flexion	
Adduction at 90 degrees flexion	
Abduction at 90 degrees flexion	
Full Flexion	
Full Extension	

Cut collateral ligaments and volar plate

Assess range of motion

Pose	Photo label
Neutral	
Adduction at full extension	
Abduction at full extension	
Adduction at 0 degrees flexion	
Abduction at 0 degrees flexion	

Adduction at 30 degrees flexion	
Abduction at 30 degrees flexion	
Adduction at 60 degrees flexion	
Abduction at 60 degrees flexion	
Adduction at 90 degrees flexion	
Abduction at 90 degrees flexion	
Full Flexion	
Full Extension	

Assess range of motion on one finger:

Insert pins

Pose	Photo label
Neutral	
Adduction at full extension	
Abduction at full extension	
Adduction at 0 degrees flexion	
Abduction at 0 degrees flexion	
Adduction at 30 degrees flexion	
Abduction at 30 degrees flexion	
Adduction at 60 degrees flexion	
Abduction at 60 degrees flexion	
Adduction at 90 degrees flexion	
Abduction at 90 degrees flexion	
Full Flexion	
Full Extension	

A4

Implanting our device:

Start time_____

End time_____

Assess range of motion

Pose	Photo label
Neutral	
Adduction at full extension	
Abduction at full extension	
Adduction at 0 degrees flexion	
Abduction at 0 degrees flexion	
Adduction at 30 degrees flexion	
Abduction at 30 degrees flexion	
Adduction at 60 degrees flexion	
Abduction at 60 degrees flexion	
Adduction at 90 degrees flexion	
Abduction at 90 degrees flexion	
Full Flexion	
Full Extension	

Cut collateral ligaments and volar plate

Assess range of motion

Pose	Photo label
Neutral	
Adduction at full extension	

A5

Abduction at full extension	
Adduction at 0 degrees flexion	
Abduction at 0 degrees flexion	
Adduction at 30 degrees flexion	
Abduction at 30 degrees flexion	
Adduction at 60 degrees flexion	
Abduction at 60 degrees flexion	
Adduction at 90 degrees flexion	
Abduction at 90 degrees flexion	
Full Flexion	
Full Extension	

Dr. Shehadi fills out ease of implantation survey

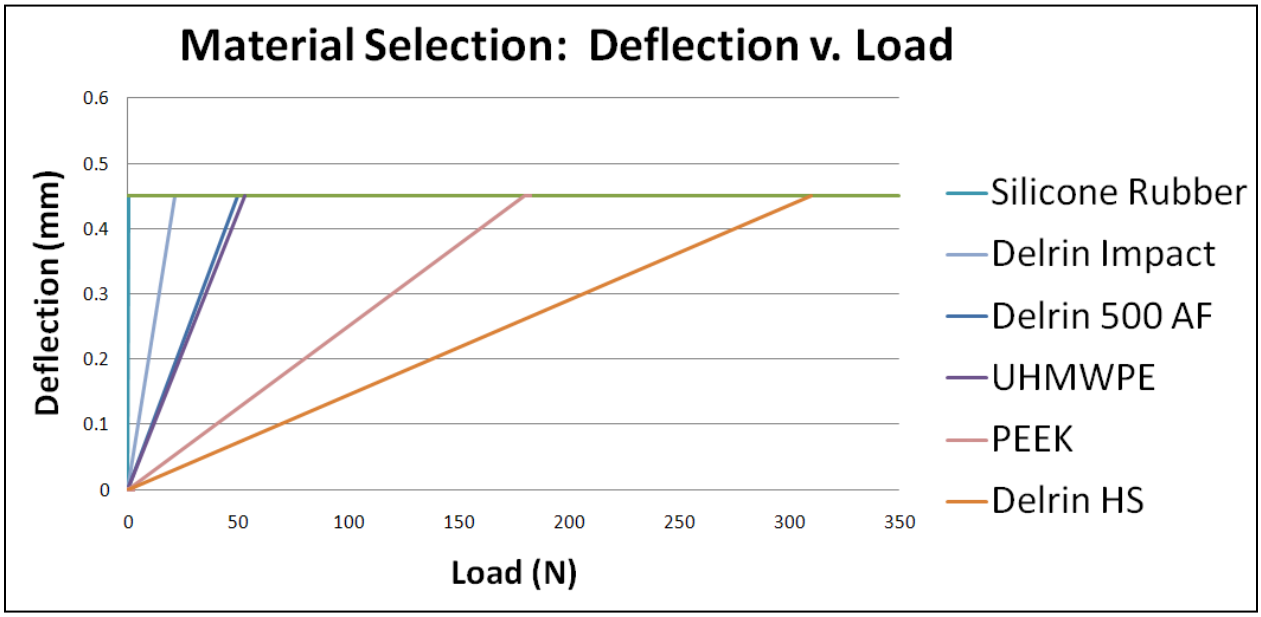
Clean up

APPENDIX 2: EASE OF IMPLANTATION SURVEY

	Ascension	New Prototype
Which implant preserved the most bone?	1 2 3 4 5	1 2 3 4 5
Which implant was easier to align?	1 2 3 4 5	1 2 3 4 5
Is the joint anatomically correct?	1 2 3 4 5	1 2 3 4 5
Are the tendons tracking properly?	1 2 3 4 5	1 2 3 4 5
Does the surrounding soft tissue get pinched?	1 2 3 4 5	1 2 3 4 5
Were special tools needed?	1 2 3 4 5	1 2 3 4 5
How easy was it to make the cuts in the bone?	1 2 3 4 5	1 2 3 4 5

How does your lack of experience with the new prototype contribute to your answers to the question? Would more practice change any of your answers?

APPENDIX 3: GRAPH ON POSTER



This graph illustrates how the material was chosen for the dampening pin. A constant pin geometry of 3 mm diameter was used. Since common loads applied to the finger range from 0-14 N, a material that stays below the deflection limit (.45 mm) until well past this loading range is desired. During static grip the metacarpal and phalangeal components should support additional loading.

APPENDIX 4: BUDGET PROPOSAL

BME Design 402 Budget Proposal

March 19, 2010

Team members: Nate Cira, Amanda Feest, Hallie Kreitlow, Ken Roggow
Client: Ramzi Shehadi, MD, Reconstructive and Plastic Surgeon for Dean Health Systems
Advisor: Professor Naomi Chesler, UW-Madison Department of Biomedical Engineering

Objective

This year, the goal of our design project is to effectively design a joint replacement for the metacarpophalangeal (MCP) 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.

Background

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 MCP 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.

Description of Design

This invention is a constrained MCP 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 three main components, one secured to the distal portion of the metacarpal, one to the proximal portion of the phalanx, and a third pin component to join the other two. The phalangeal component is allowed to rotate about the pin like a simple hinge. The geometry of the prosthesis limits the flexion, extension, and ad/abduction ranges of motion. Also, the device fails at the pin rather than at the stems preserving the osteointegration allowing less invasive follow-up surgeries.

Project Expenses

To complete this project, we must prototype a scaled-up version of our design out of plastic. We must purchase a to-scale version of our design to be rapid prototyped using stereolithography (SLA), which will be implanted into a cadaveric hand to test for ease of implantation and range of motion. We also will be fabricating one or more pins out of Delrin® to test its material properties. The following table provides each item with its respective cost:

Expense	Total
Scaled-up rapid prototyping (plastic)	Free through a grant obtained by the

	Mechanical Engineering Department
To-scale prototype material/labor costs	Quick Parts quote: $250
Possible costs for Delrin pin/implantation instrumentation	~$250
Total project expense	**$500**

Both models will be used for presentation purposes for proof of concept and will not be used as implants. Also, we plan on attempting to patent our device and if this grant proposal is accepted, we will require the following information:

Which federal fund (144- account) contributed to making this invention?

	Sponsoring Agency	**Grant, Contract or Agreement Number**	**UW Account Number**
Primary			144-

Which non-federal funds contributed to making this invention?

Sponsoring Agency	**Grant, Contract or Agreement Number**	**UW Account Number**

APPENDIX 5: BME START PROPOSAL

Metacarpophalangeal Joint Replacement

Team:
Nate Cira
Amanda Feest
Hallie Kreitlow
Kenneth Roggow
Advisor: Professor Naomi Chesler
Client: Ramzi Shehadi M.D.

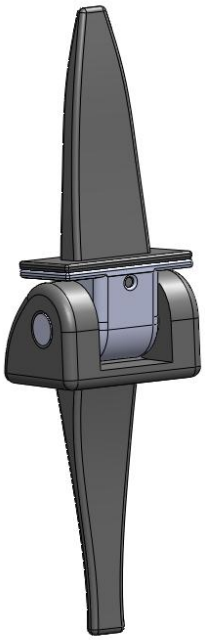
Summary

Existing metacarpophalangeal (MCP) joint replacements require collateral ligament support. The proposed design, an osteointegrated constrained joint replacement, makes it possible to reconstruct MCP joints of patients who do not have functional collateral ligaments. The design is made of a cobalt chromium metacarpal component, an alumina phalangeal component and a polyacetal pin used to connect the other two halves. The artificial joint is designed to fail at a replaceable interface, preserving osteointegration and simplifying secondary surgery. Osteointegration is further enhanced by dampening effects of the flexible pin. Lack of effective existing designs and an aging population contribute to market potential for this device.

Description of Problem and Clinical Need

The proposed MCP joint replacement does not require patients to have collateral ligaments. Patients with congenital defects including symbrachydactyly lack collateral ligaments connecting the metacarpal and proximal phalange. Additionally rheumatoid arthritis, which has a prevalence of 1.3 million cases in the US [1], collateral ligaments are intact but are stretched beyond usefulness. The most frequently-used replacement is a ligament dependent flexible silicone elastomer. While this device has 75% of the US market for MCP implants [2], over half of silicone implants fractured in 11 years [3]. Furthermore, silicone implants can cause erosion at the bone/implant interface, weakening the patient's already fragile bones [4]. Another type of implant used is the semi-constrained finger prosthesis, which also 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 [5]. During current implant procedure, surgeons must be cautious not to damage surrounding ligaments. With a device that does not rely on these ligaments, this would be less of a concern and simplify primary surgery. 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.

Description of the design and novel features



This joint uses a hinge design to fully constrain the joint and therefore eliminates the need for ligaments. The device will be implanted as three components: a phalangeal component, a metacarpal component, and a pin to connect the two. The metacarpal component will be made of cobalt chromium. The phalangeal component consists of three parts: the stem, the articulating surface, and a connecting pin. The stem will be made of cobalt chrome to promote osteointegration, and the articulating surface will be made of alumina to allow for good wear characteristics against the cobalt chrome metacarpal implant. The phalangeal component will be assembled before the implant is shipped to hospitals. The phalangeal and metacarpal components are attached with a polyacetal (Delrin®) pin. The joint will fail at the pin, which will simplify any replacement surgeries because osteointegration of the stems will be preserved. Another novel feature of this design is the deformable Delrin® pin, which will enhance osteointegration and device longevity by absorbing impulsive loads.

Market

Patients with severe hand trauma, rheumatoid arthritis, and congenital defects such as symbrachydactyly stand to benefit from this device. Considering the US population, 1/32,000 people have symbrachydactyly (about 10,000 total) [6]. Of the 1.3 million rheumatoid arthritis sufferers, many have arthritis at the MCP joint (assume 50%). Data on severe trauma was not attained, and likely represents a small portion of the market. 26% of people with rheumatoid arthritis classified their condition as “severe” [7]. There are differing degrees of rheumatoid arthritis, and this group of 170,000 is most likely to receive surgery. Frequently MCP joints on both hands needs to be replaced. If each patient has on average 6 joints replaced then there are around 1.1 million candidate fingers. If each implant sells for $1,000 then there is a potential market of around $1 billion. A large portion of the potential market consists of rheumatoid arthritis sufferers. Since this is primarily a disease of the elderly, an effective MCP joint replacement is a timely improvement with an aging US population [7].

References

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6. Children’s Hospital Boston “Symbrachydactyly” 2005. <www.childrenshospital.org>.
7. Mintel Market Research, “Arthritis US 2009” <http://www.mintel.com/>.

APPENDIX 6: INVENTION DISCLOSURE REPORT

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. This joint uses a hinge design to fully constrain the joint. The device will be implanted as three components: a phalangeal component, a metacarpal component, and a pin to connect the two. The metacarpal component will be made of cobalt chromium. The phalangeal component consists of three parts: the stem, the articulating surface, and a connecting pin. The stem will be made of cobalt chrome to promote osteointegration, and the articulating surface will be made of alumina. The phalangeal and metacarpal components are attached with a polyacetal (Delrin®) pin. The joint will fail at the pin, which will simplify any replacement surgeries because osteointegration of the stems will be

preserved. Another novel feature of this design is the deformable Delrin® pin, which will enhance osteointegration and device longevity by absorbing impulsive loads.

What makes this invention superior to existing technology?

Metracarpophalangeal(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:

2-4-2010

When was the invention shown to work?

Plastic prototypes of the device have been made and implanted into a cadaver on April 15, 2010.

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 invention was disclosed to classmates and faculty at the midsemester Biomedical Engineering Design presentations on March 5, 2010. The device will be disclosed to the general public May 7, 2010 at the final BME design presentations.

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.

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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**	

Funding and Materials

To look up your funding sources see

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
BME Department Instructional Funds	n/a	101 A 19 4200
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
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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

- By mail Attn: Docket Clerk P.O. Box 7365 Madison, WI 53707