Product Design Specifications (PDS)

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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° (Pylios, 2007)
ii. Extension Range of Motion: 0-20° extension (Pylios, 2007)
iii. Abduction/Adduction Range of Motion: Ideally a total of 30° (Pylios, 2007)
iv. Implant lifetime: 310 million cycles of varying movement angles (Fowler, 2001)
v. Power grip strength: withstand 464 N external load (Beevers, 1995)
vi. Pinch Strength: withstand 70 N external load (Irwin, 2003)
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).

References

Beevers, D. J. et al. "Design of a non-constrained, non-cemented, modular, metacarpophalangeal prosthesis." IMechE, 209: 185-195, 1995.

Fowler, NK et al. "Long-term measurement of metacarpophalangeal joint motion in normal and rheumatoid hand." IMechE, 215(H): 549-553, 2001.

Irwin, CB. Radwin, RG. A new method for estimating biomechanical loading in grip. Proceedings of the Human Factors and Ergonomics Society 47th Annual Meeting 1126-1130, 2003.

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, vol 7 issue 2, p. 163-174, 2007.