An Implanted, Skin-Covered Prosthetic Thumb

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INTRODUCTION**:** In 2017, there were 6 million digit amputations worldwide, one third of which included loss of the thumb [1]. The thumb is arguably the most important digit on the hand and is responsible for approximately 40% of hand function [2]. The human thumb's unique position and structure allows for opposition, the ability to trace the tip of the thumb along the tips of the remaining four digits. Opposition motion is crucial for fine motor skills such as firmly grasping, pinching, and holding. Mid-thumb amputations, which sacrifice the interphalangeal (IP) joint, leave a bony structure that is often unable to complete opposition-dependent tasks. Current prostheses are external devices that articulate with the patient's hand to improve function and aesthetic appearance; however, these devices do not integrate with the patient's bony anatomy and do not restore sensation and tactile feedback that are integrated in biological skin. As an alternative to conventional external thumb prostheses, we present a linkage-driven osseointegrated prosthetic thumb that is designed to be fully encapsulated in a vascularized, innervated autologous skin flap (Fig. 1A). The device's mechanical linkage couples motion of the IP joint to that of the intact biological metacarpal phalangeal (MCP) joint, allowing the reconstructed thumb to closely replicate the relationship between biological MCP and IP joint angles. In this abstract, we describe a complete design pipeline for this thumb, including optimization of device mechanics, design of a surgical procedure to implant the thumb and cover it with autologous skin, and validation of the soft-tissue plan in an animal model.

METHODS**: Device Mechanics:** The prosthetic device was designed such that motion of the IP joint is driven entirely by bony attachment to the residual proximal phalanx and the distal metacarpal. The 4-bar linkage mechanism rigidly ties IP joint motion to motion of the biological MCP joint (Fig 1A); as the MCP joint moves via contraction of the native flexor and extensor muscles, the linkage transmits this motion to the IP joint. The fixed relationship between the MCP and IP joint angles is governed by the geometry of the linkage mechanism. We first parameterized the implant geometry and optimized the key features to match as closely as possible the natural relationship between MCP and IP joint angles during natural opposition across all four fingers (i.e. to minimize residual error in the angle relationships). This design is referred to as the "ideal" device. We then constrained our optimization to avoid any mechanical elements that would protrude into the thumb's soft tissue, as these would likely cause breakdown of the skin envelope and extrusion. We refer to this constrained design as the "feasible" device. **Surgical Technique**: In a series of cadaver dissections, we designed a surgical technique for implantation of this device in the human hand. In short, the device will be wrapped in a tubularized reverse radial forearm flap, which will be elevated as rotation flap from the ipsilateral side. After a period of healing, the *de novo* thumb-tip will then be covered in a first dorsal metacarpal artery (FDMA) flap from the posterior aspect of the index finger. We modeled this technique in three human cadavers to assess feasibility and extrusion risk. During these dissections, a 3D-printed dummy implant was placed in each cadaver, and range of motion of the reconstructed thumb was confirmed. **Soft Tissue Viability**: The skin-facing titanium parts of the prosthetic device (except near the *de novo* IP joint) are covered with porous polyethylene, to promote skin ingrowth and limit relative motion between the skin and the device. To test this, we developed a rat model to explore the reaction of a rotated, tubularized skin-flap to an implant of comparable shape, in an area of high motion. An implant was 3D printed in porous high density polyethylene (HDPE) that mimicked the shape of the prosthesis at a feasible scale for assessment in a rat (15 mm x 5 mm x 4 mm). In 20 skeletally mature male lewis rats, an epigastric skin flap was elevated, tubularized, and rotated to a point near the hind leg that would ensure motion during rat walking. Implants were placed in the flaps of 10 of these rats, and the other rats were used as non-implant controls. Skin flaps, as well as skin samples from the contralateral epigastric region were harvested at various time points for histological analysis and assessed for skin thickness and ingrowth. The animal protocol was approved by the UCLA IACUC.

RESULTS: **Device Mechanics:** The prosthetic device achieved sufficient range of motion. The "feasible" design's MCP and IP angles matched biological joint angle relationships with 19.89% error (Fig 1B). FEA studies confirmed the system did not mechanically fail under maximal load stresses sustained by a biological thumb, with a factor of safety greater than 1.5. **Surgical Technique:** Simulated surgeries were successfully completed in two of the three cadavers (the first was used for planning purposes only). The dummy device fit within the intended flap and had an appearance that approached that of the biological thumb. We also confirmed qualitatively that the thumb device restored opposition to each of the four fingertips (Fig 3). **Soft Tissue Viability:** Extrusion was not observed in any of the rats. Flap strain data confirmed that the flaps moved cyclically during gait, with an average peak strain of 26.5% proximally and 32.2 % distally. (Fig 2B). Histological analysis revealed adhesion to surrounding tissue and encapsulation around the implant (Fig 2C).

DISCUSSION: In this study, we designed and tested an osseointegrated, skin-covered prosthetic device that serves as a replacement for a biological thumb. The device closely replicates the kinetics and kinematics of a biological thumb, and scale models did not extrude in a rat model. One limitation of this study is the difference in scale between the rat and human models. If we do observe skin issues at the human scale, one potential solution is to prelaminate the device in the forearm prior to transferring the device and the skin-flap to the hand. This would allow the ingrowth to occur in a low-motion, native environment.

SIGNIFICANCE: This implanted prosthetic thumb has the potential to restore both function and sensation to patients who have lost their thumb. Together, the prosthesis and surgical techniques we developed illustrate a successful foundation for subcutaneous prosthetic devices that restore function and sensation.

References: **[1]** C. S. Crowe *et al.*, *Injury Prevention*, Oct. 2020. **[2]** D. L. Hart, S. J. Isernhagen *et al.*, *Journal of Orthopaedic & Sports Physical Therapy*, Dec. 1993. **[3]** Z.-M. Li *et al.*, *Journal of Biomechanics*, Jan. 2007.

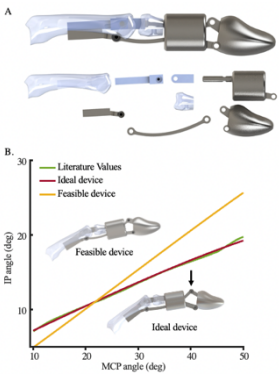

Fig. 1. A) Model of assembled device. Clear parts are biological bone. Blue metal parts are for modeling purposes only. Titanium metal parts make up physical device. C) MCP vs. IP angles for biological thumb vs. device. IP angle extrusion point indicated by arrow.

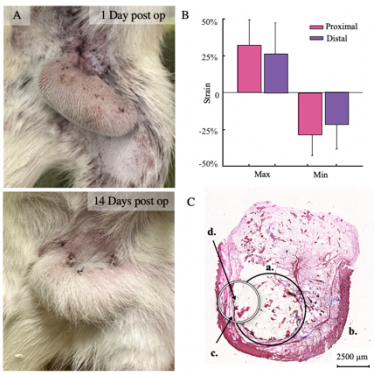

Fig. 2. A) Rat with implant post-op. B) Strain in rats' epigastric flap while walking. C) a: HDPE implant. b: tissue from skin flap. c: encapsulation around the implant. d: no adhesion or encapsulation between tissue and implant.

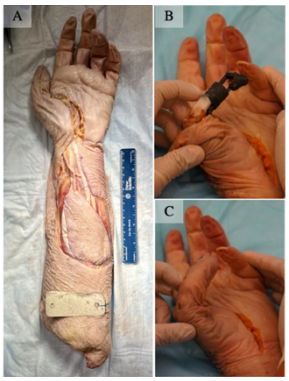

Fig. 3. A) Radial forearm flap. B) Opposition motion of the implant. C) Opposition of the implant under a skin flap.