NIH Grant Sample

SIGNIFICANCE

In the past ten years, significant progress has been made in the development of prosthetic limbs. State-of-the-art prostheses are electrically powered and controlled using muscle sensors placed over the residual limb of the user. These devices are heavy, uncomfortable, dependent on batteries, and most significantly, they lack proprioceptive feedback (a person's ability to know the position and movement of their body at any given time). As a result, users rely primarily on vision to know the position and orientation of their prosthesis. Surveys have reported this over-dependence on vision as one of the largest contributors to prosthesis abandonment (Peerdeman, 2011). To solve this, PSYONIC proposes to create a biointegrated prosthesis that connects to the patient's residual tendons and bone (**Fig. 1**). This will be accomplished by developing an anatomically accurate (both biomechanically and anthropometrically), osseointegrated, artificial tendon-driven prosthesis; initially to replace a human finger. **The contributions of this project are significant because it will be the first prosthesis that enables users to control their prosthesis directly from their muscles, battery-free, with proprioception, in a biomechanically natural way.** PSYONIC has a patent pending on this prosthetic technology (Akhtar, 2021).

A study conducted in 2005 (Ziegler-Graham, 2008) identified 1.6 million people living with the loss of a limb in the United States. Upper limb amputees accounted for 35% of this number (560,000 persons) and finger amputees accounted for 92% of all upper limb amputees (515,000 persons). It is projected that by 2050, the number of amputees will grow to 3.6 million, with 1.16 million having finger amputations. We intend to create an innovative prosthesis for these finger amputees in the United States and many more worldwide. For these amputees, their current prosthetic options are both limited and over-priced for the technology available. This project aligns with PSYONIC's overall vision of lowering the barrier of access to advanced prosthetic technology for over 10 million people with upper limb amputations worldwide by creating a next-generation prosthesis that is affordable for all amputees.

INNOVATION

With our proposed prosthesis, after receiving their amputation, the patient would undergo a single 2-stage surgery to attach the artificial tendon system (ATS), implant the osseointegration (OI) abutment and construct the infection mitigation system. Once the ATS has successfully tissue-integrated with the existing tendon or muscle (~6 months), the abutment has sufficiently osseointegrated (~4.5 months), and the infection mitigation system has been properly integrated with the OI abutment, the prosthetic finger can then be attached. The OI abutment and ATS designs allow eligibility for all finger amputees irrespective of amputation type or time since amputation. The OI abutment's unique design adapts for amputations across any finger or phalanx. If tendinosis is present in the residual tendons, the ATS will attach to the forearm muscle corresponding to the phalanges of interest. If tendinosis is not present, the ATS will attach directly to the residual tendons just proximal to the transverse carpal ligament. As part of the rehabilitative process, varying degrees of muscle retraining will be necessary for all patients. Since

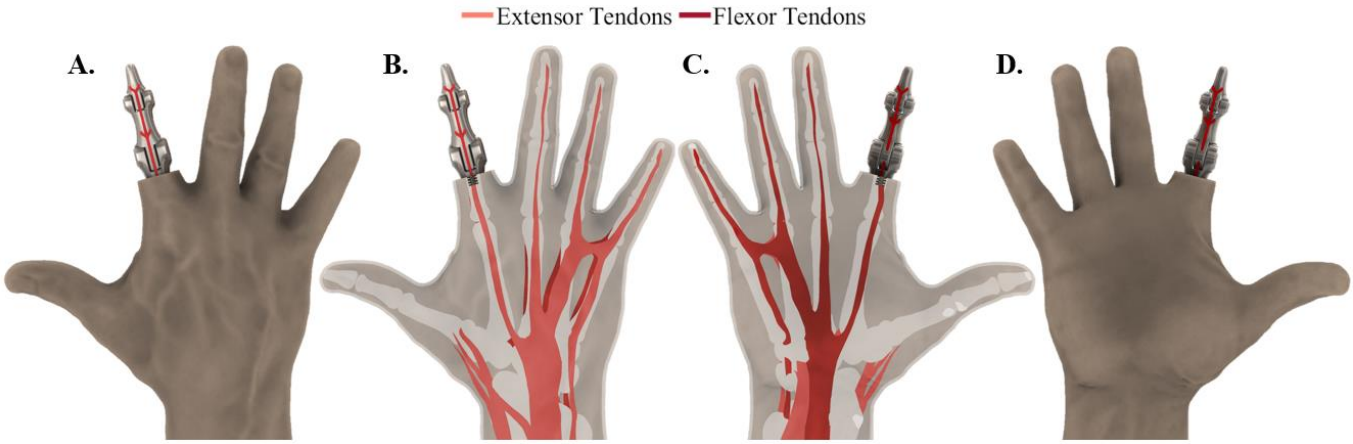

Figure 1. Concept rendering for proposed osseointegrated, artificial tendon-driven prosthesis. (A) Posterior and (D) anterior view of implanted finger prosthesis into real-view hand. (B) Posterior view accentuating extensor tendon connection and (C) anterior view accentuating flexor tendon connection into finger prosthesis and artificial tendon system.

the prosthesis is simple in construction and modular in design, if a piece of the prosthesis breaks, it is easily replaceable without requiring surgery. PSYONIC will re-manufacture the broken finger, to which can be easily reattached to their ATS. By providing users with a battery-free, biomechanically accurate prosthesis, users will potentially be able to return to the workforce and perform activities of daily living that would have been challenging using electric prostheses currently available.

Introduction & Review of Relevant Literature

Cadaver Models During Phase I of the proposed project, we intend to test the relevant biomechanical properties of our systems in a human cadaver model. Phase II of the project will include canine animal testing and human clinical trials of our prosthesis, as the proposed prosthesis will be an FDA class II/III device. Currently, flexor tendon research uses a canine model since canines have anatomical and biomechanical similarities to humans (Kadar, 2017). In the canine model, we created a prosthetic hindlimb connected to residual extensor tendons; and in the human model, we created a prosthetic finger connected to the residual flexor digitorum profundus tendon. Both prostheses can connect to all residual flexor/extensor tendons in the residual limb responsible for motion.

Prosthetic Technologies Current finger prostheses are either electrically- or body-powered but have inherent limitations. Electrically powered options, such as Ossur I-digits, rely only on feedforward commands from myoelectrical signals and cannot provide proprioception (Saunders, 2011). While body powered prostheses, such as Naked Prosthetics, mitigate the lack of proprioception, only amputees with an intact joint proximal to the site of amputation are eligible (Young, 2019). To grant proprioceptive feedback irrespective of the prosthesis, Clites et al. has developed and implemented an agonist-antagonist myoneural interface for above- and below-knee amputations (Clites, 2019). While this option is currently only available for lower extremity amputees, strides have been taken towards granting proprioception to upper extremity amputees. The Krukenberg procedure has been used to grant full proprioception but at the cost of cosmetic appearance (Nathan, 1977). Tunnel cineplasty has been explored for controlling an external prosthesis through skin graft-lined tunnels in the muscles of the residual limb (Weir, 2001, Childress, 2022). While finger prostheses have been extensively researched in the past (Difonzo, 2020, Kim, 2019), a system that grants proprioception by combining artificial tendons, osseointegration and an infection mitigation strategy, has not. The most relevant research to our proposed work is by Hall et al. through permanently attaching an artificial limb comprising a prosthesis in combination with an artificial tendon attachment for lower extremity animal amputees (Hall, 1976, Hall, 1979); however, this approach required excessive movement of the skin at the skin-abutment/tendon interface, which would too easily break down.

Artificial Tendon Systems (ATS) To date, <u>there is no ATS that can replace or attach an external prosthesis to existing tendons</u> (Melvin, 2011). Fully implanted artificial tendons made of polyester that biologically integrate with the tendon have been reported, such as OrthoCoupler (Melvin 2011, Melvin, 2009, Melvin, 2016) and the commercially available Neoligaments Poly-Tape (Abdullah, 2015); however, these systems are limited to repairing limbs that are still present. In most situations of tendon repair, a tendon transfer is performed, in which a piece of tendon is gathered from elsewhere in the body (Gardenier, 2020).

Osseointegrated (OI) Systems Although osseointegration is relatively new in the clinical setting, in 2019 Resnik et al. showed that in a national sample, 41% of veterans with upper limb loss would already consider receiving OI (Resnik, 2019). Currently, the only clinically available prosthetic OI systems are the Integrum OPRA (Hoellwarth, 2020), OrthoDynamics ILP (Frolke, 2017), and Osseointegration Group of Australia OPL (Haque, 2020) systems. The majority of finger OI research, such as Lundborg et al. (Lundborg, 1996), Manurangsee et al. (Manurangsee, 2021), and Sierakowski et al. (Sierakowski, 2010), use similar techniques using intramedullary screws or press fit rods. However, recent successful finger OI systems have been developed by Manrique et al. (Manrique, 2017) by screwing a tripod mini-plate around the bone.

FDA Pathway We plan to use the same Humanitarian Device Exemption (HDE) pathway used by the Integrum OPRA osseointegration system with specific designation being 21 CFR 814 Subpart H (Zhuang, 2019).

<u>APPROACH</u>

Aim 1: Develop a scalable CAD model for the prostheses that accounts for measurements and biomechanics of the human cadaver model. The goal of this aim is to mathematically characterize the joint biomechanics for the human model to refine our prosthesis design such that a scalable CAD model can accommodate different test subjects' unique anthropometry. Each model's joint biomechanics will be characterized using inverse dynamics,

Dynamic Force Analysis (DFA) and OpenSim simulations on each joint of interest for each cadaver model. With this, we can customize our CAD model for any test subject in a cost-effective manner.

Preliminary Study To date, we developed CAD models for individual cadaver specimens that will serve as the foundation for our scalable prosthesis design. The finger prosthesis has been scaled to fit the anatomy of the human finger **(Fig. 2A)**, while the canine prosthesis has been scaled to fit the anatomy of the canine hindlimb **(Fig. 3A)**. The current iteration of the prosthesis uses a version of the "living hinge" design first used in PSYONIC's patented multiarticulated Ability Hand prosthesis (Akhtar, 2018). The living hinge comprises two materials: one rigid piece centrally located and discontinuous at the joint, and two flexible continuous lateral bands simulating "ligaments". This design allows the same range of motion (ROM) as a typical hinge joint while providing the bones a shock-absorbing capacity to withstand high shear loading indicative of blunt forces to the finger. A network of four channels was cut into the finger prosthetic bones **(Fig. 2B)** and a network of five channels was cut into the hindlimb prosthetic bones **(Fig. 3B)** to incorporate their respective artificial tendons and accommodate the flexor/extensor tendons. The location of the loops within the prosthetic bones are anatomically accurate with respect to each tendon's tendon-to-bone insertion point. Each artificial tendon loops through its designated channel so both ends of the tendons can be attached to the residual tendons through a system outlined in Aim 3.

Proposed Study In this aim, we will standardize the prosthesis development process for test subjects of arbitrary anthropometry, eliminating trial-and-error guesswork involved in replicating joint biomechanics iteratively. Two biomechanical models will be created to

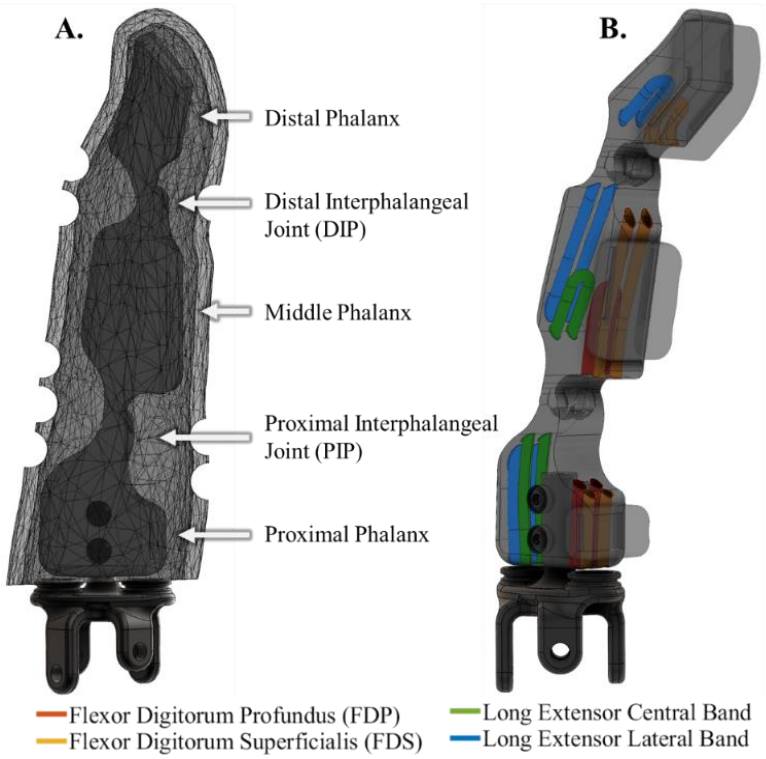

Figure 2. Proposed human finger prosthesis. (A) Finger prosthesis bone embedded in silicone sleeve; joints of interest depicted. (B) The finger prosthesis features four internal sterile channels for each tendon of interest.

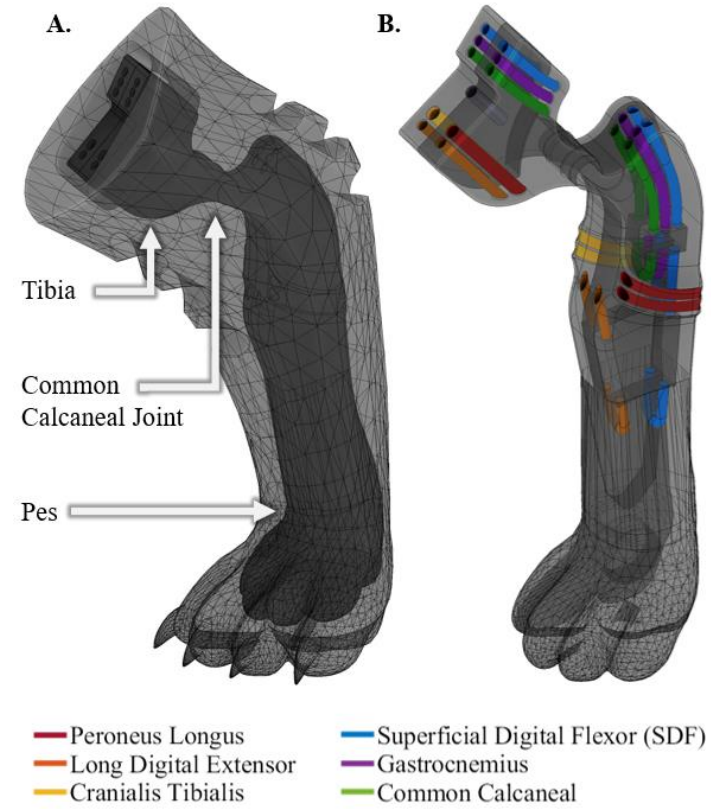

Figure 3. Proposed canine hindlimb prosthesis. (A) Canine hindlimb prosthesis bones implanted into silicone sleeve; joints of interest depicted. (B) The canine hindlimb prosthesis features five internal sterile channels for each tendon of

characterize the joint torque of the sound limb and its relationship to the compliance of the prosthetic joint. In-vivo, finger motion is mainly dependent on the moment arms of the tendons as determined by joint size, tendon insertion point and flexor pulley system (Greenwald, 1994). The tendon force required for finger motion is dependent on the size of the tendon, stiffness of the joints, and the friction of the tendon against the surrounding tissues (Amadio, 2005). Similarly, the prosthetic joint torque is directly related to the anthropometric dimensions of the finger bones, moment arm between tendon and point of joint articulation, and resistance of the joint to bending. While natural joint resistance in-vivo can be attributed to the surrounding tissues, in the prosthesis it can be controlled by varying the thickness of flexible material at each hinge.

Natural joint resistance will be obtained by creating anatomically accurate, modifiable, and scalable CAD models from measurements of the human hand. Each prosthesis design can be evaluated virtually before cadaver testing, improving time and cost-efficiency, while ensuring proper scalability and accurate joint biomechanics. After creating models of the joint of interest, biomechanical analyses will be conducted. The models will output the desired torque given the anthropometric measurements and body weight of a specific subject, allowing us to modify the stiffness of our prosthetic joint to replicate their unique joint biomechanics. To test the model's accuracy, we will compute the root mean square error (RMSE) and coefficient of determination (R^2) comparing the joint angles and grip strength of our models to the individual cadaver specimens. RMSE and R^2 are standard metrics used to assess the performance of joint angle estimation (Kaliki, 2008, Akhtar, 2017). The lower the RMSE value, the better the fit to the data. R^2 values indicate the amount of variance explained by the estimation model ranging from 0 to 1; values higher than 0.7 indicate a strong fit to the data (Kaliki, 2008, Akhtar, 2017). To determine if there is a statistically significant difference ($p<0.05$) between the models and the experimental values, we will conduct a repeated measures ANOVA. For the human finger model, it will be a 3-way ANOVA (Distal Interphalangeal Joint (DIP) angle, Proximal Interphalangeal Joint (PIP) angle, grip strength).

Expected Outcomes The outcome of this task would be a biomechanical model that relates the body weight of the specimen and the dimensions of the sound limb to the tendon moment arm and joint stiffness of our prosthetic bone with no statistically significant difference between the model and actual cadaver measurements. This model would enable attaining a biomechanically accurate ROM and grip strength in the prosthesis per patient.

Potential Problems/Alternative Strategies Accurately characterizing the masses and moments of inertia of the bones of interest as required for the DFA may be challenging to accomplish. Our current models simplify the bones by characterizing them as cylinders with arbitrary masses, but these simplified assumptions can lead to calculation errors. These errors can be resolved through extensive bone measurements during cadaver testing or by implementing OpenSim modeling.

Aim 2. Develop prostheses with the ATS and OI abutment that can accurately replicate the finger biomechanics of the human cadaver. The goal of this aim is to determine if the proposed prosthesis can return mechanical functionality to the cadaveric finger models, i.e., the prosthetic digit can achieve a normal ROM and grip strength for a given applied tendon excursion and force, as in an unimpaired digit. We will test the digit's ROM as being dependent on the tendon's excursion, and the digit's strength as being dependent on the applied force on the tendon. This will grant the ability to determine each tendon's contribution during motion, leading to a more effective prosthesis design. Another goal of this aim is to determine the mechanical properties of the proposed ATS and OI abutment. The testing conducted in this aim will characterize the strength of our devices without tissue integration/OI by quantifying their mechanical properties in comparison to our previous cadaver results (ATS) and data found in literature (OI abutment).

Preliminary Study In our preliminary research, we conducted testing on canine cadaver models, focusing on the hock joint (canine analog to human ankle) and extensor tendons. Our results showed through R^2 value analysis that the prosthetic system can accurately replicate the biomechanics of the sound hindlimb when actuating all extensor tendons, with an R^2 value greater than 0.7 indicating a strong fit between the prosthesis and sound limb data (Kaliki, 2008). The canine data showed a ROM R^2 value of 0.88 and paw strength R^2 value of 0.76 between the prosthesis and sound limb data **(Fig. 4)**. These results indicated the canine prosthesis design was ready to be adapted for human testing.

In our preliminary human research, we focused on two major joints of the finger (PIP and DIP) and one of the finger's flexor tendons (flexor digitorum profundus (FDP)). Two experiments were performed on the specimen's index finger and then repeated on the middle finger with the hand in a neutral position (~15° of wrist flexion). The protocol for both experiments have previously been done by Greenwald et al. (Greenwald, 1994) and Sapienza et al. (Sapienza, 2012). The first experiment applied an increasing tensile force to the FDP tendon, articulating the specimen's finger. The joint angles were measured and compared to the amount of FDP tendon excursion. The results showed a linear relationship, which was expected as this shows the tendons in our experimental apparatus follow the same linear trend as tendons within the body (Wagoner Johnson, 2019). In the second experiment, we isolated the finger of interest, applied an increasing tensile force to the FDP tendon, and placed a grip force transducer in the specimen's palm to record the finger's individual grip strength (**Fig. 5A**). The data showed similar grip strength and tendon load values to that of the FDP tendon in the sound limb documented by Greenwald et al. (Greenwald, 1994). The two experiments were then repeated with our prosthesis implanted into the residual cadaver limb (**Fig. 5B**). The results from these tests produced R^2 values >0.7 threshold for ROM, indicating a strong fit between the prosthesis and the sound limb (**Fig. 5C-F)**. As the FDP tendon was actuated, the prosthesis was able to bend in a way biomechanically similar to that of the sound limb (**Fig. 6**). Additionally, the amount of tendon force necessary for full ROM of the prosthesis had a maximum value below the mean tendon force of 18.63 N reported by Schuind et al. (Schuind, 1992) for active flexion of the distal and interphalangeal joints of the finger. While the ROM results were promising, the grip strength results indicated the prosthesis still needs

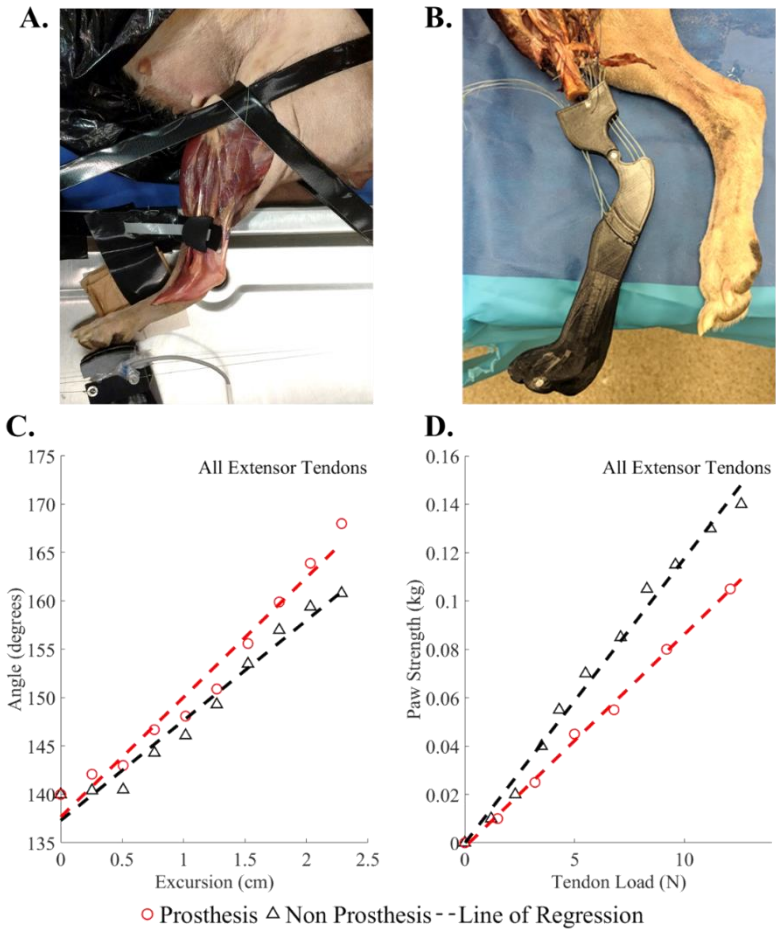

Figure 4. Canine prosthesis testing. (A) Sound canine hindlimb during paw strength testing. (B) Canine hindlimb prosthesis implantation. (C) Canine hindlimb calcaneal joint ROM results between sound limb and prosthesis when actuating all extensor tendons (R^2 = 0.88). (D) Canine hindlimb grip strength

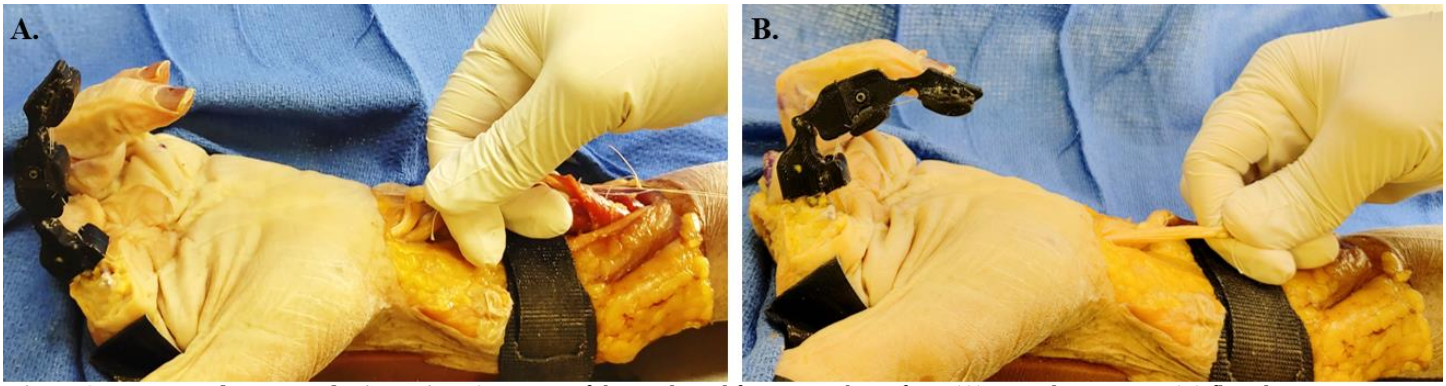

Figure 6. Human cadaver prosthesis motion. Actuation of the implanted finger prosthesis from (A) neutral position to (B) flexed position.

iteration, as the index finger R^2 values recorded <0.7 while the middle finger R^2 values were >0.7 (**Fig. 5G-H**). Addressing such variation between data sets is an objective in our proposed study.

We implanted our prosthesis into the human cadaver by first amputating the finger just proximal to the midpoint of the proximal phalanx. The prosthesis was then connected to the residual bone using an OI abutment **(Fig. 7)** based on the method by Manrique et al. (Manrique, 2017), who developed a tripod titanium mini-plate for an osseointegrated digit prosthesis. The mini-plate anchored into the distal end of the residual finger through three equidistant axes with 1.5 mm mini-plates and screws (Manrique, 2017). This construction allows a more stable implant concerning lateral torque movements and prevents loosening during insertion/removal of the prosthetic finger (Manrique, 2017). The absence of an intramedullary component also means that stress within the phalanx is decreased over time, ultimately preventing fractures/weakening of the residual bone which would compromise prosthesis integrity (Manrique, 2017). Our abutment has been modified to accommodate the loading conditions of the prosthesis and further improve fixation to the bone. Our abutment features a quadrupod design with each anchoring screw attached to the bone at different depths from the amputation site (5, 6, 7, and 8 mm) to prevent bone fracturing. The abutment is also designed to accommodate the ATS and infection mitigation system through two ports cut into the OI abutment base. The abutment is designed to use the 1.5 mm of cortical bone around the finger perimeter for fixation, since finger bones lack the necessary amount of usable space within the intramedullary canal to use conventional OI methods. By using this method for fixation, the OI abutment has the capacity to be used by all finger amputees irrespective of amputation site across any phalanx.

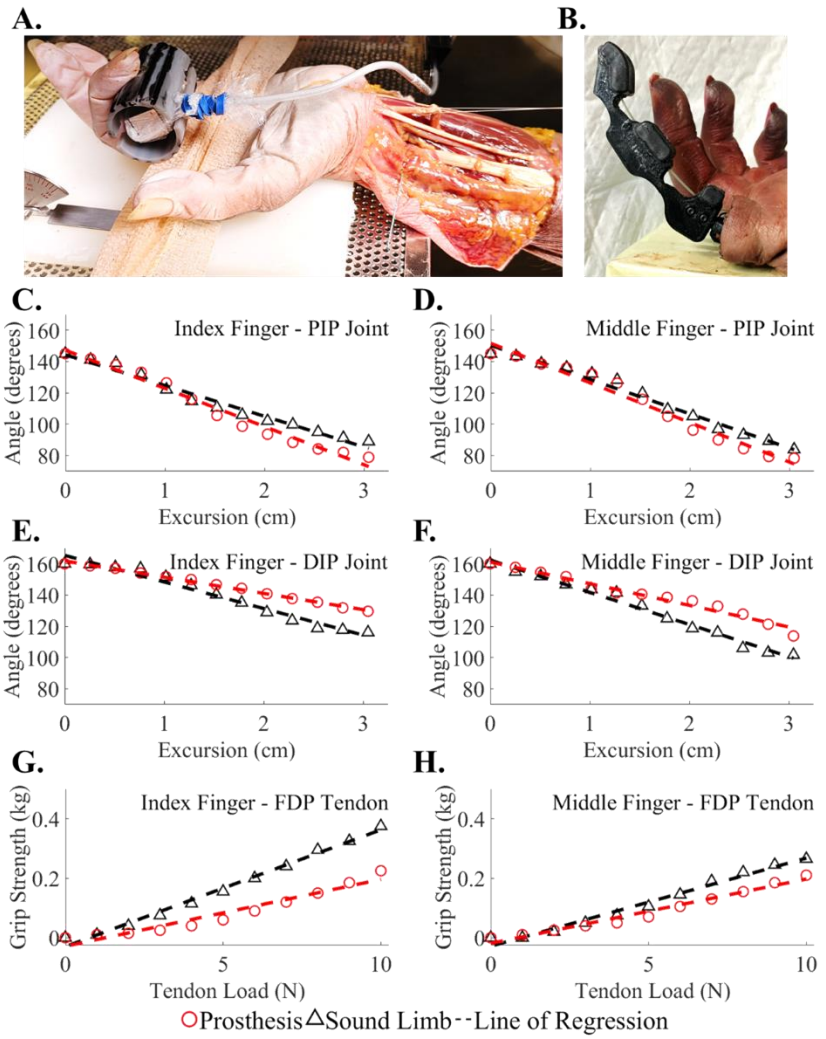

Figure 5. Human prosthesis testing. (A) Sound human index finger during grip strength testing. (B) Human index finger prosthesis implantation. Joint ROM results between sound limb and prosthesis when actuating FDP tendon of (C,E) index finger (PIP joint $R^2 = 0.93$, DIP joint $R^2 = 0.69$) and (D,F) middle finger (PIP joint $R^2 = 0.96$, DIP joint $R^2 = 0.68$). Grip strength results between sound limb and prosthesis data when actuating FDP tendon of (G) index finger ($R^2 = 0.37$) and (H) middle finger ($R^2 = 0.82$).

At this stage in the project, we have developed rough prototypes for the ATS **(Fig. 8A)**. The system is similar in design to the OrthoCoupler (Melvin 2011, Melvin, 2009, Melvin, 2016), with tendon fibers less than 50 μm in diameter composed of material with the required biocompatibility and tensile properties. The integrity of two potential artificial tendon materials (braided Polyethylene terephthalate (PET) and Nylon monofilament) were compared against commercially available artificial ligaments (Neoligaments Poly-Tape) **(Fig. 8B)** through tensile and Dynamic Mechanical Analysis (DMA) testing. Tensile testing results indicated the PET tendons are capable of achieving higher tensile loads, while the nylon tendons have higher displacements **(Fig. 8C)**. At a 1 mm diameter, both ATS designs recorded maximum tensile forces over 100 N which is above the 75 N threshold Urbaniak et al. identifies as being within the human physiologic range (Urbaniak, 1975). Both curve trends were also indicative of

normal tendon behavior (Felder, 2016). DMA testing results indicated both artificial tendons demonstrated highly viscoelastic properties, pointing favorably (Greenwald, 1994).

Proposed Study We will continue comparing our preliminary results to tests conducted after prosthesis implantation into cadaver models to validate that the prostheses are behaving in a biomechanically accurate way. The experimental protocols will be similar to those outlined in our preliminary study as we expand our tests to include all flexor and extensor tendons in the human finger model. This process will entail testing on ten human cadavers (five male, five female). We will attempt to characterize the contribution of each flexor and extensor tendon **(Fig. 2)** in MCP, PIP, and DIP flexion/extension for all fingers, comparing our results to literature for validation. We will also expand our tests to characterize each tendon's contribution in total hand motion and grip strength using 25%, 35%, 26% and 15% for the index, middle, ring and little fingers, respectively, as a basis (Talsania, 1998, MacDermid, 2004). We will then adapt our prosthesis to accommodate this new data and further refine the design for patient use. To determine the accuracy of our prosthetic system, we will follow similar statistical methods as outlined in Aim 1. We will compute RMSE and R^2 values to compare the joint angles and grip strength of our prosthesis to the sound limb. Low RMSE values and R^2 values above 0.7 will be used to determine the goodness of fit of our results. We will perform an R^2 analysis and conduct a repeated-measures, three-way ANOVA (R^2 for excursion v. PIP angle, excursion v. DIP angle, and tendon load v. grip strength).

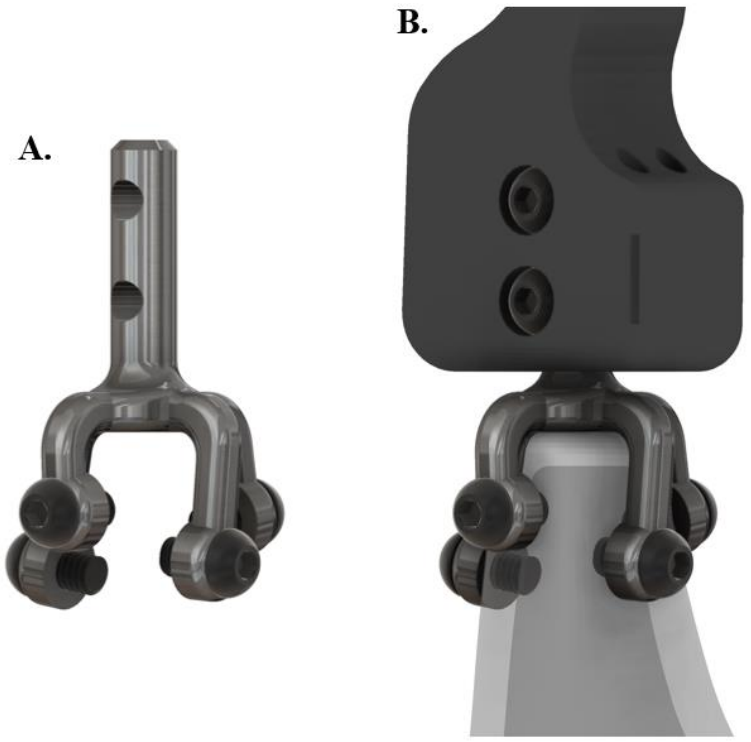

Figure 7. Osseointegration Abutment System. Human osseointegration abutment prototype (A) without implantation and (B) with implantation featuring four screws oriented at 45 degrees with respect to the axis of loading to anchor the abutment to the bone without risking stress shielding during the healing process.

In this aim, we will also further develop the OI abutment and ATS. The OI abutment will first be analyzed using Finite Element Analysis (FEA) to characterize the optimal screw orientation to prevent stress shielding for both

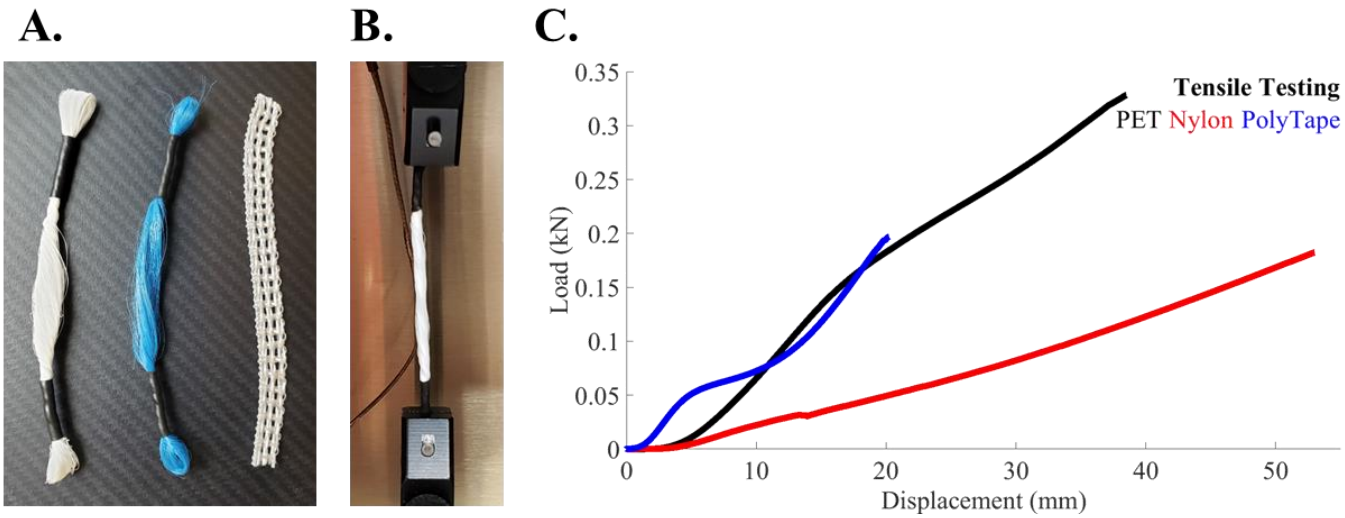

Figure 8. Artificial Tendon System Preliminary Study. (A) PET (left), Nylon (middle), PolyTape (right) artificial tendon prototypes comprising 300-50 μm fibers. (B) Tensile testing apparatus. (C) Tensile testing results (n=3) for PET (avg. peak load = 0.31 kN, avg. stiffness = 10 N/mm), Nylon (avg. peak load = 0.19 kN, avg. stiffness = 3.6N/mm) and PolyTape (avg. peak load = 0.19 kN, avg. stiffness = 13 N/mm) artificial tendons.

compressive and tensile loading. Stress shielding induced by improper force distribution between the implant and bone interface can lead to bone resorption and improper bone remodeling (Paio, 2014). We will initially conduct our FEA with the screws oriented at 45° with respect to the axis of loading (two pointing proximally for compressive forces and two pointing distally for tensile forces). Mechanical testing of the OI abutment will then be conducted by implanting the abutments into cadaver specimens and identifying the maximum loads withstood in tension, compression, and shear. These tests will be applied with successive increase until the observed loading is similar to that found in literature or until total failure of the abutment/bone. The ATS will then be mechanically tested in the laboratory through fatigue testing at 3 Hz for each of 10 load levels ranging from 30% to 75% of the maximum tensile load from preliminary testing, until failure or 10^7 cycles to meet FDA requirements (Melvin, 2011). After fatigue testing, a new ATS will be implanted into a cadaver specimen. The experimental procedure will be similar to our initial cadaver testing outlined in Aim 1. After completion of the mechanical tests, the ATS will be subjected to in-vitro biocompatibility testing following procedures laid out in Melvin, et al. (Melvin, 2011). Ingrowth and deposition of collagen and tenocytes will be evaluated. If human tenocyte proliferation is observed within the fibers of the artificial tendons and without scar tissue formation, this will provide convincing evidence into the viability of the ATS in a human test subject.

Expected Outcomes The outcome of this aim would generate two prostheses capable of replicating the biomechanical functionality of the sound cadaver limbs with no statistically significant difference. We expect the ATS to survive fatigue testing with no early signs of failure and that the maximum load endured by the artificial tendon will be within 20% of the control tendon maximum load. We also posit that the OI abutment will survive in tension and compression but will suffer failure in shear, since the testing conducted in this aim will not involve the tissue integration or OI factors that would drastically increase the overall strength of each component under these conditions.

Potential Problems/Alternative Strategies Variation in results is anticipated due to each cadaver's unique properties such as gender, age, underlying conditions, and condition after freeze-thaw cycles. We do not expect these properties will inhibit our ability to judge the overall success of our proposed prostheses. To mitigate the potential for failure of our OI abutment, FEA will be used during the design process to simulate loading parameters and ensure each design distributes forces correctly while withstanding the loading conditions of the fingers. A potential alternative strategy for our OI abutment system includes traditional lower extremity OI techniques utilizing an intramedullary canal screw or press-fit design. While these techniques limit the population of amputees that can use our prosthetic system, it remains an option.

Aim 3. Develop an effective infection mitigation system at the site that the artificial tendons interface between the internal and external environments of the body. The goal of this aim is to develop an infection mitigation system and the tests for its feasibility and durability. The system's feasibility will be assessed by its ability to be constructed in the operating room (OR) and durability to sustain mechanical forces incurred by artificial tendon translation during normal joint motion in human cadaver models. Construction of the system in the OR will be observed by the team and feedback from our hand surgeon will be collected to provide insight into areas for improvement. Mechanical testing will be conducted to characterize the durability of the system as being dependent on the applied force to the tendon. Knowledge gained from the results of this task will be vital to preventing infection in-vivo.

Preliminary Study To date, we constructed and preliminarily tested an infection mitigation system for our finger prosthesis in the OR (**Fig. 9**). Our design solution draws inspiration from a multifilament stainless steel cable crimp system for flexor tendon repair within the hand (Gordon, 2013). The disc has two connection points, an internal connection to the artificial tendon and an external connection to the prosthesis. Fastened around the disc is a non-porous material that extends distally to the external port of the OI abutment. The material is secured to create a seal around both the disc and OI abutment, thus creating a pocket within the finger. The length of this pocket is approximately 1.5-2 cm in length to accommodate the necessary tendon excursion for normal finger ROM. The

skin at the amputation site will be sutured around the external circumference of the OI abutment and left to heal (Kunutsor, 2018). This system creates two ports into the human body without risk of infection due to a non-porous, impermeable layer of material. After constructing the system in the cadaver model, it accomplished normal joint ROM by transferring internal tendon actuation to external tendon translation. The system showed promise in granting full finger ROM while sealing the amputation site to mitigate risk of infection.

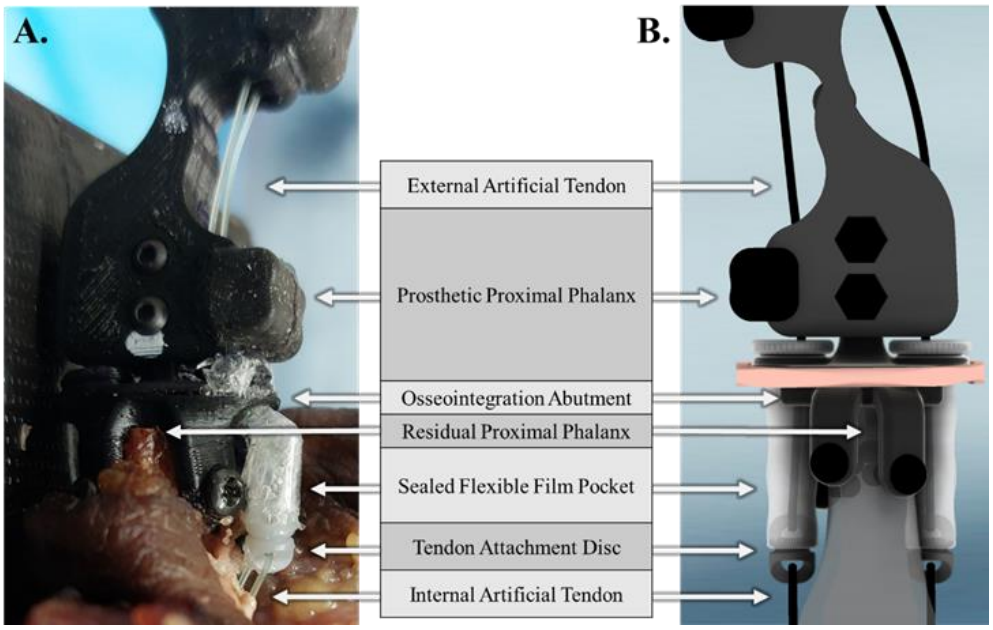

Figure 9. Proposed infection mitigation system. (A) Proposed infection mitigation system constructed and tested within the human cadaver model. (B) CAD model for the proposed system.

Expected Outcomes The outcome of this aim will generate an infection mitigation system that can be feasibly constructed in the OR and is durable enough to sustain the mechanical loading of the tendons at the interface between internal and external tendons. The infection mitigation system should be able to sustain the maximum loading of the tendons in both tension and compression. The system should also be able to withstand repeated loading up to 10^7 cycles.

Potential Problems/Alternative Strategies While tearing of the material within the body is a potential limitation of this system, we propose an added barrier of protection using a valve at the OI abutment ports, similar to a colostomy bag. If the material becomes compromised, the valve will act as an added barrier of protection until the material can be properly replaced. We are also exploring the option of inverting the system to which the disc exists completely in the external environment running parallel to the proximal phalanx of the prosthesis. This strategy may alter the biomechanics of the prosthesis and will create a dependency between the amount of tendon excursion and the length of the proximal phalanx.