

University of Tennessee
Knoxville, TN 37996
May 14, 2024

Dr. Anderson
2407 River Dr.
Knoxville, TN 37996

Dear Dr. Anderson,

The following report includes an overview of OrthoTech's design that seeks to fulfill your predetermined project needs. The overall purpose of this report is to detail the development and finalization of our current bone implant design. This report begins with a summary of background information regarding the importance and applicability of this device, alongside a description of the specific problems and needs this project will address. Next, this report outlines the project plan, concept development, and manufacturing process. Finally, we go into detail in regards to the standards on the market, and a detailed look into our finalized project. This report will conclude with a proposed plan for future work if the work is continued by others who are completing the project.

As this project has come to a close, OrthoTech wishes you the best and thanks you for your mentorship and guidance along the way.
Sincerely,

Joe Brown



Rachel Ivy



Kate Pierce



Kailynn Deck



Final Design Report: Device for the Bone Fixation of Tendon Prosthetics

Dr. David Anderson, Associate Dean for Research and Graduate Studies at
the UT College of Veterinary Medicine

May 14th, 2024



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Executive Summary

OrthoTech has designed a bone anchor intended to attach synthetic tendons and bone tissue. This bone anchor is composed of four parts: a cap, a screw body, an inner nylon shell, and an outer nylon shell. In use, the screw body will be drilled into the cortical bone, creating a strong and secure attachment attributed to the wide, spaced threads of the screw. The synthetic tendon, or sutures attaching a synthetic tendon, will be fed through the engaging cap, after which the cap will be screwed onto the screw body. Both the cap and screw will have compatible interfaces of nylon to protect the synthetic tendon from damage as it is held between interlocking threads. This design is intended to fulfill the stakeholder's needs by maintaining a durable connection between bone and synthetic tendons that restores the function of a tendon enthesis while also presenting a simple design with few components. OrthoTech's design presents numerous advantages over existing products. Specifically, this implant eliminates points of stress concentrations associated with suture-dependant devices and provides greater stability for physical therapy. Moreover, the chosen materials for the device, as well as its simple assembly, allow it to be safely and easily implanted at an affordable price. As mentioned, this device is intended to connect synthetic tendons to bone; specifically, it is designated to allow tendons from the supraspinatus muscle in the rotator cuff to attach to the head of the humerus. To form this connection, OrthoTech's product has been made to a total length of 31.1 mm, a screw diameter of 7 mm, and a cap diameter of 14.33 mm. These dimensions allow the bone anchor to maintain a small profile to easily embed into bone while still generating a high degree of resistance to tensile and shear forces. When inserted into the humerus, this implant must withstand at least 676 N of tensile force generated by the supraspinatus muscle. When testing this implant, OrthoTech found that the screw body was able to withstand approximately 900 N of force. However, when testing the effectiveness of this device when holding sutures, the sutures could only withstand ~45 N in shear and ~90 N in tensile loading. Since only two sutures were used when testing shear and tensile loading, the completed implant device may be able to withstand high forces if more sutures are included, but future testing will need to be conducted to verify this claim. Given that approximately \$409 million per year is spent on flexor tendon surgeries alone, OrthoTech's design presents a great opportunity for profit gain once it has been fully realized. This opportunity is heightened by the fact that this device only requires four separate components, making it relatively easy to assemble and install in a short amount of time. Overall, OrthoTech is confident that the finalized design in this report is more than capable of fulfilling the needs of Dr. Anderson while also serving as a promising solution to greatly improve patient livelihood in an incredibly lucrative industry.

Background

Tendons are complex structures that require multifunctional performance over long periods, remaining compliant under millions of loading cycles. Numerous surgeons and researchers affiliated with the UT College of Veterinary Medicine have performed investigative surgeries to evaluate novel tendon replacement procedures. A notable challenge of the investigation has been successfully attaching the tendon to the bone with experimental or off-the-shelf devices, such as specialized suturing and bone anchors. The junction of the soft tendon to the hard bone frequently results in tissue damage or compromised structural integrity of the implant. Implanted devices may pull out of the bone under tension, and synthetic tendons or sutures often snap when securing knots are tied. For these reasons, stakeholder Dr. David Anderson requested that a new device be developed that improves the outcomes of artificial tendon repair surgeries.

There are two groups most affected by the need for improved bone implant devices. First, the patients suffering from tendon rupture-based injuries who struggle with implant complications and failure. Second, the orthopedic surgeons who are invested in providing the most effective treatments for their patients. For patients, positive patient impacts of OrthoTech's proposed system include a statistical reduction of bone damage caused by contemporary synthetic tendon replacement and improved physical therapy outcomes. For surgeons, positive impacts of OrthoTech's proposed system include access to an effective, affordable, and easy-to-use product for artificial tendon implantation surgeries.

Current solutions take a variety of forms. One researched method required that the prosthetic tendon be sutured to a soft bone anchor using an intermediate membrane. The anchor and tendon are then secured to the cortical bone layer opposite the site of rupture by drilling a hole through the proximal cortical bone layer and medullary cavity. In other methods, standard or expanding screws are used to engage both the cortical and cancellous bone. These screws contain embedded sutures that are used to attach the tendon prosthetic to the device. The most significant challenge with these devices is their reliance on sutures for attachment. Sutures frequently break under the high tensile loading induced by muscle/tendon use, particularly at points where the thread is knotted.

Problem Definition

The purpose of this project is to design a device that provides long-term fixation of prosthetic tendons to bone. Based on the challenges the stakeholder identified with existing surgical procedures and devices, OrthoTech constructed a list of stakeholder needs to be met. From these needs, a series of device functions and requirements were established. The minimum forces required for qualification were determined by calculating the forces required to support the supraspinatus muscle, most commonly affected by tendon-related injuries. Specifically, based on results from *Review of Human Supraspinatus Tendon Mechanics* by Kyle M. Griffith et al, the

supraspinatus muscle is capable of generating approximately 676 N (newtons) of tensile force on its tendon that inserts into the head of the humerus.

Need: Restore the function of the muscle/tendon unit

1. *Function: Create a Strong Connection Between Screw System and Synthetic Tendon*
 - a. Requirement: Prevent Synthetic Tendon Damage: Evaluated using mechanical testing. The prosthesis must not be weakened by the device under a minimum load of 676 N.
 - b. Constraint: Synthetic Tendon Properties: The proposed screw system does not include a synthetic tendon as a component of the design. the dimensions and materials of the tendon cannot be altered. Only the device component of the tendon-device interface can be modified to mitigate the disparity in mechanical properties.
2. *Function: Create a Strong Connection Between Screw System and Bone*
 - a. Requirement: Remain Implanted within Bone: Evaluated using mechanical testing. The device must remain in bone when a minimum force of 676 N is applied.
 - b. Requirement: Stress Shielding Prevention: Device material in contact with bone should not exceed the Young's Modulus of bone, within the range of 16.7-20.5 GPa.
 - c. Constraint: Size of Device: While a larger surface area of the device may improve the connection to bone, exceeding a diameter of 15mm could prevent the device from sitting flush with the uneven bone surface.
 - d. Constraint: Position of Implant: Tendon insertions may be located in bone regions with or without medullary cavities. The device should be optimized for high cortical engagement, even if a portion of the device interacts with medullary tissue.

Need: Product can be purchased by surgeons off-the-shelf

3. *Function: Manufacturing process is replicable*
 - a. Requirement: Compatibility with mass production methods: The final design must be compatible with at least 1 mass production method. Evaluated through consultation with the prototype manufacturing team.
 - b. Requirement: Prototype replicability: Evaluated using the prototype manufacturing methodology. Must be able to produce two separate, identical products.
4. *Function: Product design information is distributable*
 - a. Requirement: CAD modeling of the final product: The final model must be created using a common CAD program.

Need: Product is easy to use for surgeons

5. *Function: The device is easily held and manipulated*
 - a. Requirement: Minimal Parts: The final screw design should have no more than four individual components arrive at the user.

- b. Requirement: Easy Application: Device must be compatible with existing surgical practices, including tools and speed of current operation methods.

Need: Biocompatible Product

- 6. *Function: Offer low risk of foreign body response, corrosion, wear, or cytotoxicity in the body*
 - a. Requirement: FDA Approved material choices: The materials selected for the product must be cross-referenced with FDA standards for low health risks.
 - b. Constraint: Material availability and cost: Many cutting-edge medical device materials are expensive to acquire. The team may have to consider more readily available materials without benefits like enhanced osseointegration or growth factor stimulation.

Concept Development

Early Ideation

The original concept was determined by OrthoTech throughout several team meetings. In the original design, a tendon wrap was used to keep the tendon in place and threaded through a completely smooth “torus cap”, which was inspired by two-part dental implants (Fig. 1). Later, the tendon wrap was removed, as any proposed attachment methods to the muscle/tendon

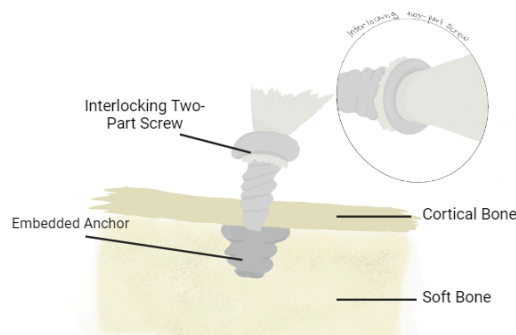


Fig. 1: Original design illustration

complex created greater weaknesses. The anchor was added to give the device lateral support within the bone, inspired by drywall anchors (Fig. 1). This element was later removed because the component was not a novel innovation. Furthermore, while a strong connection to bone was required, it is less common for the screw to separate from the bone than for the tendon to separate from the device.

During the early stages of the design process, the stakeholder invited Orthotech to observe a surgery in

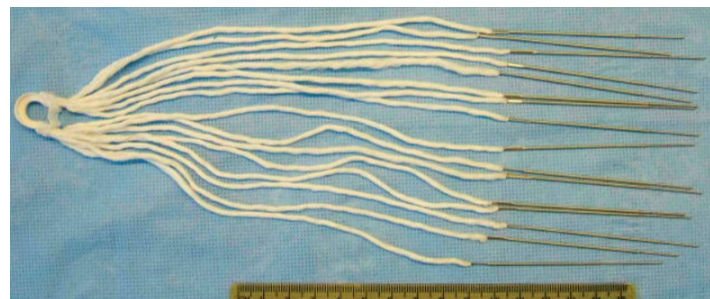


Fig. 2: OrthoCoupler Novel tendon prosthesis

which an artificial achilles tendon was installed in a rabbit model. The tendon used was composed of multiple strands of a coated polymer, rather than a single, thick band. Upon completing a literature review, it was noted that a similar, experimental device had been created for human implants, known as an OrthoCoupler (fig.2) Anticipating the future of the field, OrthoTech wanted to consider this type of device in the development of our prototype. Using these original ideas, the team assessed

existing patents to aid in building a device that would be best fit for the attachment of an artificial tendon to the bone.

Concepts Considered

During the design process, several patents were examined to determine specific weaknesses to address, and strengths to consider as a component in our new design. The team also sought to ensure our initial path did not infringe upon existing intellectual property. The most significant patents are evaluated below:

US9357991B2 - Method and Apparatus for Stitching Tendons: A patented system for attaching soft tissues to bone. The system requires the use of a soft polymeric interface and a soft bone anchor to pass the tendon through the bone and secure it to the opposite cortical wall using suturing technique.

Strengths:

- The elastic modulus of the intermediate member and sutures is similar to that of the artificial tendon
- The soft tissue intermediate member distributes tensile forces on sutures across a greater surface area

Weaknesses:

- Using knots in attachment systems creates a weakened point in the suture. All ruptures involving sutures occur at the knots.
- Passing the tendon through the medullary cavity of the bone may promote cartilage growth rather than bone growth due to the applied tensile forces.
- The difference between the tendon insertion hole and the soft suture support holes in both size and placement requires more surgical tools and precision than a single-hole device

Based on the weaknesses of the design, the team decided to create a system that largely used compressive forces to keep components in place, rather than tensile. A method that would compressively entrap the ends of sutures or a device like the OrthoCoupler was settled on. Additionally, the team decided that our final design should require a far less complicated installation process.

US20090149884A1- System and Method for Bridge Anchor Tendon Attachment. This design is composed of a bracket and a screw. The bracket has a top opening for the screw, two sharpened legs, and small holes for suturing. The tendon is passed underneath the bracket, which is then hammered into the bone. The screw is then pushed through the bracket and into the bone, piercing the tendon as it enters. Alternatively, the patent illustrates that the tendon may be anchored with the bracket alone.

Strengths:

- The presence of sutures in this design increased the stability of the synthetic tendon attachment to a bone anchor.
- The threading on the screw that is drilled into bone serves to provide a stronger attachment point between the bone anchor and the bone tissue.

Weaknesses:

- The threads present in the screw may rip the surrounding bone tissue and not provide adequate resistance to prevent the screw from pulling out of the bone. This problem arises since the screw system is drilled directly down into bone with no lateral extension for an increased surface area.
- The sutures present in this design may fail due to tearing at sharp edged or rupturing of suture knots under excessive loading.
- Since this design requires that the screw used is drilled through the tendon into bone, the strength and flexibility of the tendon may be compromised.
- Rather than drilling through the tendon, this design may alternatively secure the tendon to bone by compressing the tendon into bone. However, this compression may not serve as a sufficient attachment method if frequent use of this bone-tendon unit causes the tendon to slip out of the fastener.

Evaluation of this patent led the team to ensure that the assembly and anchoring methods of our final device did not require any piercing of the synthetic tendon, which greatly compromises its strength. Additionally, the team decided to use a silicone layer to protect the tendon/suture pieces from the shear effects of the steel interface.

AlphaVent: Hard-body screw-in anchor platform: The AlphaVent system is a threaded anchor with attachment sutures embedded within the device. The product is packaged with a screwdriver-shaped applicator that allows the user to cut threading into the bone as the anchor is inserted. The sutures are released from the hollow applicator for affixing to soft tissues such as tendons and ligaments.

Strengths:

- The device comes with a tool for easier and more comprehensive attachment.
- The device contains vents to allow for more cellular integration
- There are various anchor sizes for attachment in a variety of bone tissue.
- The anchor is composed of a biodegradable polymer for better cellular regeneration.
- The screw threading pattern alters between cortical and cancellous bone for better bone attachment.

Weakness:

- This design depends on knotted sutures which have been shown to rupture under tension.
- Since this device is not bi-cortical, the screw may present excessive lateral movement in the cancellous bone.

The ease with which this device is installed was something that Orthotech decided to retain in our own device. Additionally, the stakeholder noted that a completely smooth torus cap would be impossible to tighten in surgery. The external profile of the cap was then adjusted to be hexagonal, compatible with surgical drivers.

Morphix® Suture Anchor System - DJO (djoglobal.com): This device is made of a biodegradable polymer and, similarly to the AlphaVent system, is installed using a prepackaged device with enclosed sutures. The device has an outer shell that expands once the device is inserted.

Strengths:

- The device comes with a tool for easier and more comprehensive attachment.
- There are various anchor sizes for attachment in a variety of bone tissue.
- The anchor is composed of a biodegradable polymer for better cellular regeneration.

Weaknesses:

- This design depends on knotted sutures which have been shown to rupture under tension.
- Since this device is not bi-cortical, the screw may present excessive lateral movement in the cancellous bone.
- Pullout forces were measured in line with the insertion of the device during testing. Device response to lateral forces, such as widening of the insertion cavity with applied friction forces, appear to be unknown

While the biodegradable material choices are most ideal for the Morphix device design, Orthotech did not believe this technology would translate well to the previously developed ideas. Alternative, non-degrading polymers were kept in mind for future works.

Final Modifications

Further changes were made during the development of the first prototypes (fig.3). It was quickly realized that adhering a uniform layer of silicone to threaded stainless steel would be impractical and near impossible. After consulting with university faculty specializing in biomaterials and material sciences, the team switched to a nylon cap interface. In an effort to maintain compatibility with surgical tools, as well as to preserve the strength of the bone anchor, it was decided that nylon shells should be added to create the interface, rather than changing the materials of the whole device. Finally, the initial nylon cap caused suture tears during testing. The team reintroduced the rounded edges of the “torus cap” design

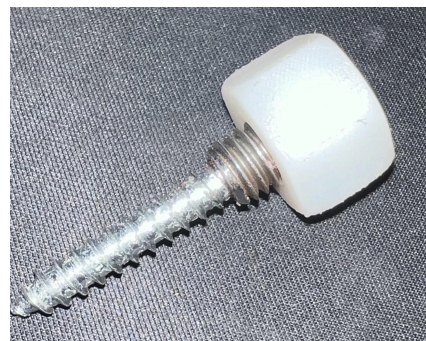


Fig.3 First prototype of OrthoTech's design

just on the internal opening of the suture cap to eliminate this issue.

Survey of Related Standards

FDA standards for medical device classifications are most relevant to OrthoTech's product development. The American Society for Testing and Materials (ASTM), and the International Organization for Standardization (ISO) also contribute standards relevant to the production of a long-term implantable medical device.

FDA 21CFR888.3640

Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis

This standard classifies permanent devices installed in the bone at the shoulder with a combination of polymer and metallic components as a class III medical device. This standard indicates the levels of testing and approval qualifications needed for our device to reach the market. The standard states that "A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint...This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene...*Classification*. Class III."

ASTM F981-23

Standard Practice for Assessment of Muscle and Bone Tissue Responses to Long-Term Implantable Materials Used in Medical Devices

This standard is used for the testing of biocompatibility for implanted devices. There is a strict protocol of what needs to be tested if it is a new material, and even if it's not a new material, a strict protocol still needs to be followed to ensure that the device is safe for implantation of patients. In particular this standard is "The experimental protocol is not designed to provide a comprehensive assessment of the systemic toxicity, immune response, carcinogenicity, or mutagenicity of the material since other standards address these issues. It applies only to materials with projected applications in humans where the materials will reside in bone or skeletal muscle tissue in excess of 30 days"

ISO 13402 First edition 1995-08-01

Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure

This standard is to test surgical tools to ensure they are autoclavable to resist the large amounts of heat against the device. This is important for our device because it needs to be sterilized prior to packaging and shipping to the surgeons, therefore resisting this process is important. Additionally, if any special tools are made for our device to be implanted, they will need to resist the high heats as well making this an important standard.

ISO 5832-1 Fifth edition 2016-07-15

Implants for surgery - Metallic materials - Part 1: Wrought stainless steel

This is a standard that defines the needs and testing requirements of any stainless steel that is implanted. As half of our design is made of stainless steel, it is vital that an analysis is completed of its profile and composition to ensure safety of the patients. Our device, being an implant and fixed, will fall under class 2 and regulation number §872.4880.

Product Description

OrthoTech's current design is a four-part screw system that will secure artificial tendons to bone. The device is designed to be inserted into the cortical bone, with an exposed end on the surface for tendon attachment. The complete assembly includes a screw with a male-threaded nylon face and a suture-engaging cap with a female-threaded nylon face.

Material Choices

For the product, 316L stainless steel, grade 66 Nylon, and medical-grade epoxy were chosen for finalized manufacturing and distribution. Each of these materials were researched and confirmed to meet FDA biocompatibility standards for long-term implanted devices. Other benefits of these materials are outlined in "Significance of Product Elements".

Component Breakdown

Suture Cap: The Suture Cap is a hexagonal-shaped stainless steel cap lined internally with nylon threading. The upper opening of the cap is smoothed and rounded to provide a low-friction surface for the active end of the sutures or prosthesis to move against. The proposed cap dimensions are 10.5mm/5.5mm in outer/inner diameter and 5mm in height with standard national threading.

Screw Body: The screw is designed with two sections, each with a different diameter, threading profile, and material choice. The lower section of the screw body is intended to be drilled into cortical bone, with wide buttress threading and a self-tapping end. The upper section of the screw is a combination of a stainless steel core and an outer nylon shell. This threading of the upper section will be compatible with the nylon threading of the cap. Proposed dimensions include a 5.5mm in diameter and 5mm in length upper section, with cut standard national threading. The lower section of the screw is proposed to be 4.5mm in diameter, 12mm in length, and cut with customized wide threading.

Component Integration

The two components are derived from four total pieces: two nylon shells and two stainless steel bodies. In finalized manufacturing and distribution, the device will be assembled and packaged so that the user receives only the two complete components described above. In use, an orthopedic surgeon will drill the screw into the bone at the desired insertion point, leaving the

nylon upper section of the screw exposed at the bone's surface. Once the artificial tendon is affixed to the affected muscle, the prosthesis, or connecting sutures, will be passed through the cap from top to bottom. The surgeon will then use a hexagonal driver to tighten the cap over the

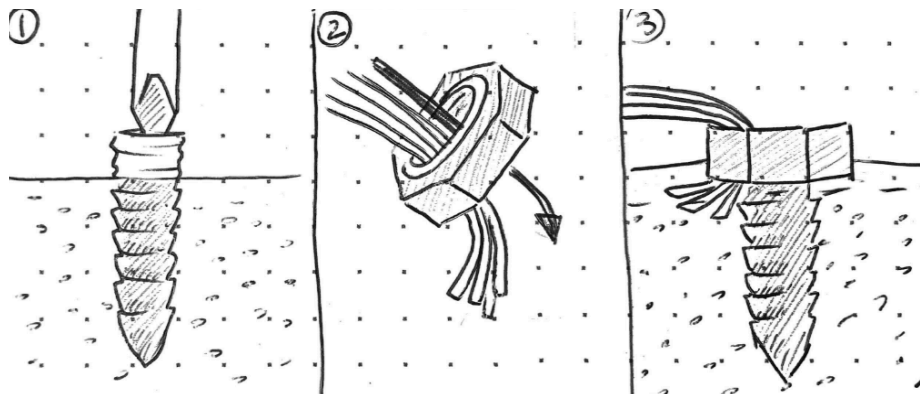


Fig.4: Assembly of the device, 4.1) Cross-section of the screw body drilled into bone, 4.2) Suture bundle/synthetic tendon passed from top through the cap, 4.3) View of the fully assembled device; sutures rest on the surface of the bone while the lower screw remains embedded

exposed end of the screw, applying slight tension to the ends of the prosthesis.

Significance of Product Elements

There are several elements of the design that lend themselves to the desired function. First, it was requested that the device provide an improved connection between the tendon prosthesis and the anchor. To fulfill this need, the product features the unique interface of two nylon shells for the suture/prosthesis to be entrapped. By using the compression of two wide, smooth interfaces to hold the tendon in place, rather than a series of knots, the device eliminates the risk of stress concentration-induced ruptures. To further minimize the risk of rupture at the site of repair, the device was designed with nylon as the chosen material for the entrapment interface. Nylon offers greater plasticity and softer edges for the sutures to rest against than the stainless steel used by the rest of the device. These characteristics enable some conformation of the interface to the profile of the added sutures, limiting shear forces and pinch points at the apex of each thread.

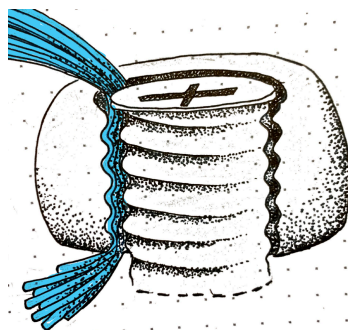


Fig.5: Cross-section illustration of suture/prosthesis placement

Another significant need the product fulfills is creating a strong connection between the product and the bone at the point of insertion. Specifically, stability under a tensile force of approximately 676 N based on the PCSA and optimal muscle force of the supraspinatus muscle in the rotator cuff is required. This is achieved through the use of extra wide threading along the lower screw shaft. This style of threading will provide upward compression and a significant

area of engagement essential to retaining the environment of the dense, mechanically strong bone tissue. Additionally, the wider lower surface area of the cap compresses downward on the surface of the bone once it is fully tightened. This combination of forces creates a “sandwiching” effect with the local bone, reducing the likelihood of the device pulling out after installation.

The further benefits of this installation are two-fold. The choice of 316 L steel provides similar mechanical properties to bone; a Young’s modulus of approximately 16.7-20.5 GP (Giga-Pascals). Combined with the relatively large surface area of the device in contact with the bone, and the environmental mimicry through applied compression, these elements lend themselves to improved osseointegration and thus, improved long-term stability of the device. More significantly though, this instantaneous application of forces makes the device more suitable for cases in which physical therapy shortly after surgery is desired. Withstanding loading of the muscle-tendon complex without waiting for complete healing and osseointegration was an additional need outlined by the stakeholder that is addressed by the device.

As a veterinary surgeon, the stakeholder further emphasized that the product should be easy to use for the practitioners installing the device. The product’s simple construction and three-step assembly described previously satisfy this need. The screw body was manufactured with screwdriver slots on the top face for compatibility with medical-grade drivers. For this same reason, the device cap was designed with a hexagonal profile and a steel outer section for good strength against the high torque produced by the driver. The self-tapping end of the screw component will eliminate any need to pre-drill into the patient’s bone. An added bonus of this configuration is that the time spent securing the device in surgery will be significantly less than that spent on tendon repair surgeries that require pilot holes, more complex assemblies, or numerous passages of individually knotted sutures.

Lastly, the stakeholder requested that the product be designed for off-the-shelf sales to medical centers and surgeons, rather than custom-made for each patient. The product was modeled entirely in CAD software during the prototype manufacturing process of the team’s project. The resulting files and material choices are compatible with numerous mass production methods, including additive manufacturing using nylon melt electro writing and stainless steel powder sintering, or nylon injection molding, and steel forging. The nylon and stainless steel parts of each component are designed to fit snugly together with a thin layer of medical-grade epoxy securing the connection. This assembly could easily be automated for inexpensive, rapid production. Furthermore, nylon and stainless steel may be safely sterilized using ethylene oxide gas prior to packaging and distribution, a process for which many medical device manufacturing facilities have equipment.

Manufacturing Overview

In order to design and perfect the anchor system, CAD was used to model the parts. The pieces were created with low tolerances ($\pm 0.1\text{mm}$) (millimeters) to ensure that the interface shells pressed into their steel counterparts with a snug fit. To initiate final prototype manufacturing, the team consulted with the staff at the UTK Innovation and Collaboration Studio (ICS). Stock stainless steel and nylon were purchased. The exterior of the suture cap required a 12 in (inch) long, 1 in. diameter 316 stainless steel rod. The hexagonal shape was cut using a milling machine, leaving an empty, circular interior for the nylon shell. To make the screw body, a 9/32 in. diameter, 12 in. a long stainless steel rod was milled in the MABE Maker Space to reduce the length to 1.225 inches. The Maker Space staff then used a lathe to cut 12 threads per inch (TPI) to the lower shaft of the screw; custom threading was not available at the time of prototype manufacturing. While the team initially purchased nylon stock, ICS staff faced insurmountable challenges creating the shells with the bulky tools at their disposal. To complete the prototype, the team instead 3D printed the shells with PLA filament. The unthreaded surfaces of the shells were coated in industrial grade two-part epoxy and pressed onto their stainless steel counterparts. While the ICS struggled to create the shells, OrthoTech is confident that mass production with nylon is possible with mass production manufacturing methods.

Design Evaluation

The requirements for our device were both quality and quantity based. The team established a combination of processual assessments and mechanical testing qualification procedures for the device based on the needs provided by the stakeholder (table 1).

Table 1. Qualification Results

Requirement	Qualification Test	Results
Compatible with off-the-shelf purchasing and use	Create multiple devices using the same manufacturing methods. Assess for similarities	Some variations in the quality of threading. Device size and component compatibility is thoroughly consistent
Easy to use for surgeons	Installation in synthetic bone using medical tools	Prototype successfully and repeatedly screwed into synthetic bone for mechanical testing with existing tools
Biocompatible	Reference FDA literature to verify material choices	316 Stainless Steel: highly corrosion and wear resistant, low likelihood of device complications Nylon 66: Bioinert, low risk of allergic reaction and device complications Non-toxic epoxy approved for in-vivo use
Device retains tendons/sutures under shear stress of at least 4.19(megapascals)	(1) Instron mechanical testing machine used to apply tensile forces to sutures engaged in the device, pulling at a 30.9° angle (2) Instron machine used to apply tensile forces to sutures engaged in the device, pulling at a 90° angle	(1) When using two size 0 sutures, the sutures withstood ~45 N of tensile force before tearing (0.279 MPa). (2) When using two size 2 sutures, the sutures withstood ~100 N of tensile force before tearing (0.558 MPa).
Device remains embedded in bone under at least 676N	Instron machine used to apply tensile forces directly to the screw while embedded in synthetic bone	While under tensile load in the sawbone, the screw withstood ~900 N before pulling out of bone.

To begin the mechanical testing, OrthoTech drilled the prototype into a cube of synthetic bone. The synthetic bone was secured using the lower vise grips of the Instron machine, while the top of the device was held by the upper vise grip of the Instron (fig.6a). The machine was powered on and the upper grip of the machine applied a tensile force to the device. The ultimate pull-out strength of the device significantly exceeded the minimum of 676 N.

OrthoTech completed two more tests for which the device was fully assembled with two size 2 sutures secured in the cap. The first test required the device be secured into the Instron as shown in figure 6b, before applying a vertical tensile load on the sutures until failure occurred. Shown in figure 7b, the sutures were able to withstand a tensile force of roughly 90 N before tearing, falling short of the 676 N requirement. This tensile force leads to roughly 0.558 MPa based on the cross-sectional area of the nut of 0.00016 m^2 . Notably, when the sutures ruptured, they did not tear at a point of contact with the implant. The site of tearing occurred above the implant, indicating that failure was caused by the type and number of sutures used, rather than a defect of the device. However, for this testing, only two size 2 sutures were placed inside the implant device. While the team hoped for better initial results, this failure mechanism opens the door for future works. If seven size 2 sutures were incorporated instead, the bundle theoretically will withstand the 676 N. This further testing was desired during the qualification procedure, however, time constraints and availability of testing machinery prevented this from occurring.

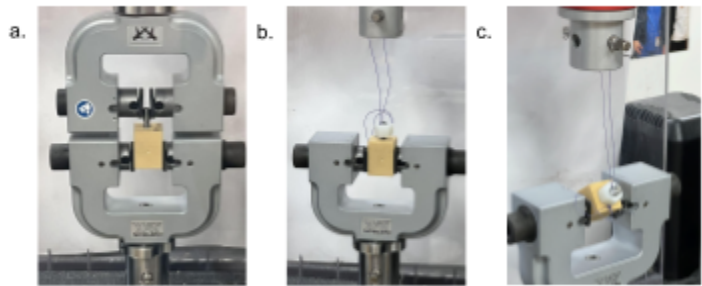


Fig.6: a) Instron setup for the bone-device interface test, b) Instron setup for the vertical device-suture interface strength test, c) Instron setup for the angled device-suture interface strength test

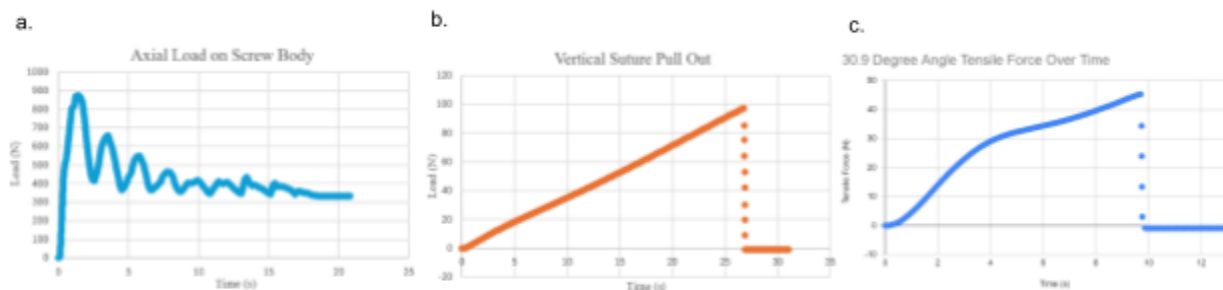


Fig. 7: Raw Instron data of tests evaluating a) device-bone attachment strength, b) vertical device-suture attachment strength, c) angled device-suture attachment strength

The final test used two size 0 sutures secured in the device cap. This test repeated the procedure of the previous, but the synthetic bone and device were angled 30.9° from the tensile load. The

purpose of this orientation was to more accurately simulate the angle at which a muscle/tendon unit pulls against bone. The sutures were only able to withstand approximately 45 N before failure, falling short of the expected results. This tensile force leads to roughly 0.279 MPa based on the cross-sectional area of the nut of 0.00016 m². Similar to the previous test, the sutures ruptured above the implant. Because the device was able to protect the sections of the sutures entrapped in the cap, OrthoTech believes the results of this test are promising for further development.

When analyzing specific areas of OrthoTech's design that may fail, several potential failure modes were highlighted. The first two failure modes—which have previously been addressed—include shear failure of the sutures in the implant and tensile failure which would cause the screw to pull out of bone. Both failure modes would prevent secure attachment of the synthetic tendon to bone and, therefore, lead to a complete or partial loss of motor function in the upper arm. In response to shear failure, previous testing demonstrated that tensile loading of the sutures at an angle of 30.9° caused these size 0 sutures to fail at ~45 N. Even though this angle does not lead to complete shearing, it does mimic the realistic shear forces acting on the implant while inside the body. When this failure occurred, however, the sutures ruptured above the implant rather than inside the implant, suggesting that this failure was due to the size and number of sutures rather than the mechanics of OrthoTech's implant. Moreover, when testing the tensile strength acting directly on the screw, this screw was able to resist ~900 N which exceeds the desired force of 676 N. Despite this success, bodily conditions may greatly reduce the tensile strength of the screw. Thus, future testing incorporating more sutures would need to be conducted in vivo prior to commercial use of OrthoTech's device.

In addition to these two failure modes, other potential failure modes include the synthetic tendon tearing in the body, rejection of the implant due to a foreign body response, and separation of the implant components while inside the body. These failure modes would potentially lead to systemic or acute health complications, loss of arm motor function, and a degraded device that becomes unusable over time. Currently, OrthoTech is unable to determine the extent of the potential failure modes since our team does not have the means to conduct clinical trials of the implant device. Therefore, future clinical testing will need to be conducted to determine possible health complications associated with the device as well as the overall effectiveness of the implant device.

In addition to the need for further mechanical testing, OrthoTech has identified a few other areas for further evaluation, including in-vivo assessments and replicability assessments using injection molding or laser sintering technology. Prototype replication to perform this further testing will be relatively affordable, at approximately \$219 per unit (see Appendix C for cost breakdown). Evaluating the overall performance of the device thus far against the qualification criteria, OrthoTech believes the device meets stakeholder expectations.

Survey of Standards Used

As previously mentioned, there are a number of important safety characteristics and standards that must be met to deem a project as FDA and ISO-approved. The following lists specific standards alongside their application to OrthoTech's design and manufacturing processes.

ISO 5832-1: Implants for Surgery - Metallic Materials - Part 1: Wrought Stainless Steel

When applying this standard to OrthoTech's manufacturing process, ISO 5832-1 references ISO 377: steel and steel products - location of preparation of samples and test pieces for mechanical testing. Through this reference, ISO 5832-1 highlights the importance of minimizing superficial heating or hardening of the stainless steel material used during manufacturing. While OrthoTech did not directly manufacture the final prototype, our team was still able to observe a majority of the manufacturing process. OrthoTech reports that no unnecessary heating or hardening of the stainless steel was performed while milling or threading the steel used.

Moreover, ISO 5832-1 highlights the importance of marking both the steel component used for testing as well as the location of insertion for this component. While OrthoTech has identified the insertion point of the rotator cuff tendon in the head of the humerus as the final location of our device, our team was not able to perform testing on this location. Thus, during simulation testing with sawbone, OrthoTech made sure to make the location of the sawbone where insertion of our steel screw would occur. During this testing, OrthoTech also drilled one inch holes into the sawbone to mark the location of the inserted steel screw.

FDA 21CFR888.3640: Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis

FDA 21 CFR888 identifies and characterizes prosthetic devices designed to be implanted into the shoulder joint. Specifically, this standard relates to metal/polymer implants constituting class III devices that replace portions of the shoulder joint while attaching to the humeral head. For OrthoTech's design, our final prototype is intended to be implanted into the cancellous bone of the humeral head and attach to the supraspinatus of the rotator cuff in the shoulder joint. Thus, OrthoTech's design must comply with the standards outlined in this FDA standard. Namely, this standard dictates that PreMarket Approval (PMA) alongside completion of a product development protocol (PDP) are required before this device can be utilized commercially. As of now, OrthoTech has completed a PDP outlining specifications of the prototype. However, since clinical trials with this device have not yet been performed, and comparisons between OrthoTech's device and other implants currently on the market have not been conducted, FDA PMA has not yet been met.

ASTM F1147-05: Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

This ASTM standard discusses the use of several metallic coatings during tensile testing of implant devices. Specifically, this standard covers tensile testing procedures regarding the degree of adhesion between coatings and metals when performing testing on the two bound materials. Since OrthoTech's device heavily relies on the implementation of epoxy coating to adhere the stainless steel components to the nylon pieces, OrthoTech must follow this standard during testing and manufacturing. Namely, in adherence to this standard, OrthoTech must ensure that the epoxy utilized during testing is the same as the epoxy coating that will be implemented into the final in vivo design. Additionally, this standard highlights the importance of determining the effect of various temperatures on the effectiveness of coating adherence. Even though the epoxy coating used during testing allowed for strong adherence between materials at room temperature ($\sim 22^{\circ}\text{C}$), testing has not been performed at bodily temperatures ($\sim 37^{\circ}\text{C}$). Thus, this ASTM dictates that future testing at body temperatures will be required prior to bodily applications.

ISO 10993-16: Biological Evaluation of Medical Devices - Part 16: Toxicokinetic Study Design for Degradation Products and Leachables

This ISO standard discusses principles regarding toxicology studies of various implanted materials while also highlighting the importance of performing specific toxicology studies for an implanted device. Since OrthoTech's device is intended to implant into the humeral head of the human body, toxicology reports on the materials incorporated into this design should be assessed. The materials OrthoTech has chosen to incorporate into the implant device—nylon 66, 316 stainless steel, and two-part medical epoxy—have previously been FDA and USDA approved for biological use, rendering these materials safe for bodily implantation. However, in order to assure biocompatibility in line with ISO 10993, OrthoTech may need to conduct a toxicology study directly on the finalized product prior to commercial use.

Recommendations and Future Works

OrthoTech would like to continue efforts to improve the team's promising prototype. As mentioned previously, we would like to expand upon device qualification. We recommend first identifying a relationship between the tensile forces sustained by different suture and prosthetic sizes, and how many sutures of that size fit comfortably within the cap. This evaluation will indicate theoretical device and suture couplings ideal for different sizes of tendon insertions. These calculations can be used as a benchmark for final mechanical testing of the device. Further device evaluation should include in vitro and in vivo assessments to affirm biocompatibility and device effectiveness in use. OrthoTech also recommends additional assessment of device manufacturing methods.

A significant challenge in the production of a prototype was the small size of the device. The available hand tools and shop equipment were intended for much larger fabrications, forcing the

team to size-up our device. While the materials and design methodologies used are known to be compatible with additive manufacturing, injection molding, machining, and other mass production techniques, each method should be tested at the original scale of the device design. This will help OrthoTech and investors determine which method produces the highest quality results at reasonable prices. OrthoTech expects to complete these additional efforts within 1 year with a budget of approximately \$2000.

There are some risks associated with investment in a new artificial tendon-to-bone anchor. Specifically, the materials utilized to construct this anchor alongside the location of implantation may lead to systemic or acute health complications. While OrthoTech has chosen materials that currently meet FDA standards for biocompatibility, the actual bodily effects of this implant cannot be properly identified and addressed until in vivo testing occurs. Moreover, while various tests described previously mention the feasibility of the bone anchor for resisting strenuous tensile loading, these tests only involved a handful of trials. Therefore, when the implant is embedded in the body and is under a high degree of continuous loading, the effectiveness of the implant may be diminished over time. Even though there are various unknown and potentially dangerous outcomes associated with the use of OrthoTech's bone anchor, OrthoTech is willing to perform the necessary testing to gauge the device's effectiveness, and our team is confident that the device will exceed expectations.

In summary, OrthoTech's design offers unique features superior to those of competing products. The suture entrapping cap provides a first-of-its-kind mechanism for anchoring tendon prosthetics that eliminates the frequent ruptures seen in common practice. All evaluated competitors require some form of knot to secure the artificial tendon. The "sandwiching" effect created by the cortical bone threads and bottom surface of the cap provides enhanced device stability unseen in the existing market. While the Morphix and Alphavent anchors offered specialized threading, there are no elements to introduce downward force. Furthermore, investment in OrthoTech's device is a financially viable choice. Currently, United States companies involved in tendon repair device manufacturing and sales comprise a \$645.7 million market. Assessing competitor costs was not possible, as the companies require medical license submission to view pricing information. However, the affordable production costs of \$219 per unit for our device certainly indicates an opportunity for healthy profits.

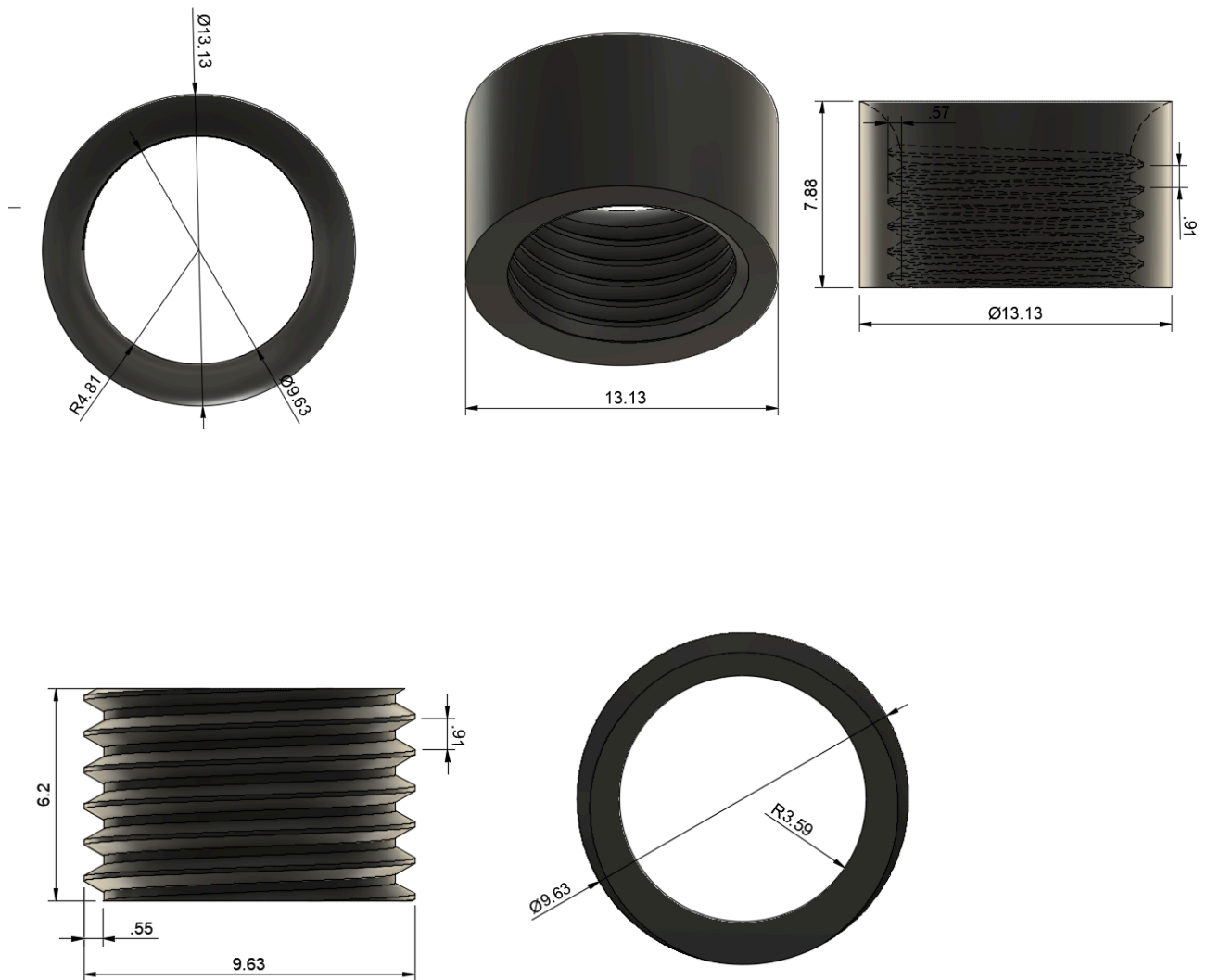
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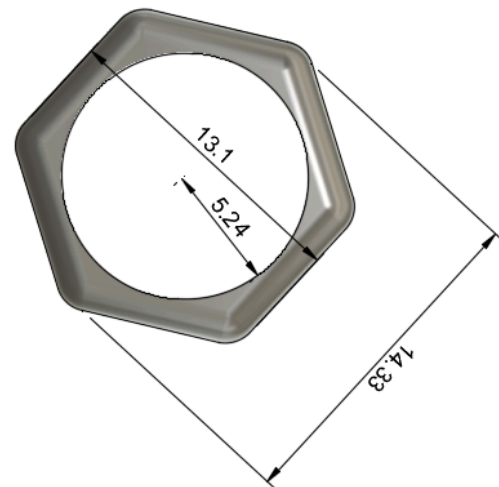
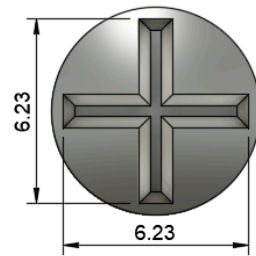
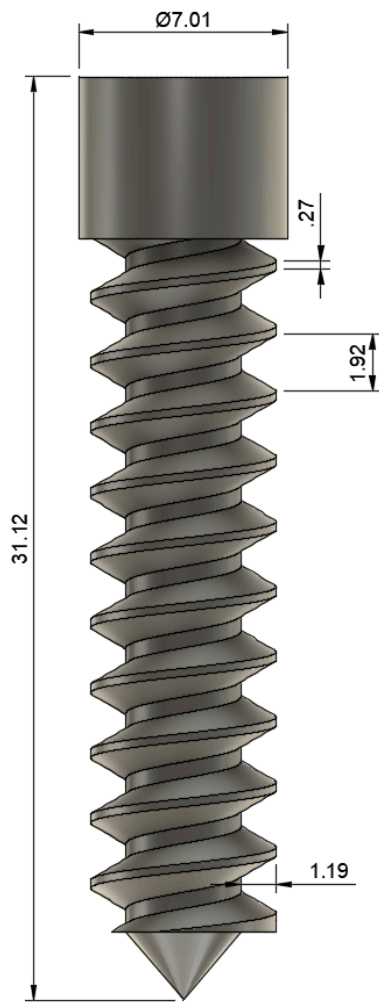
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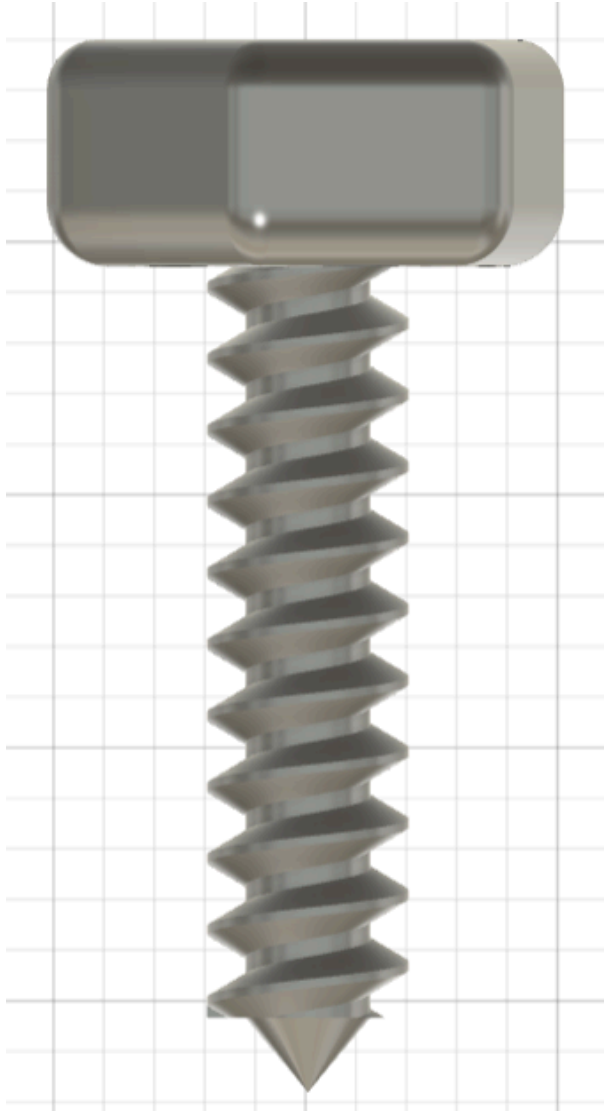
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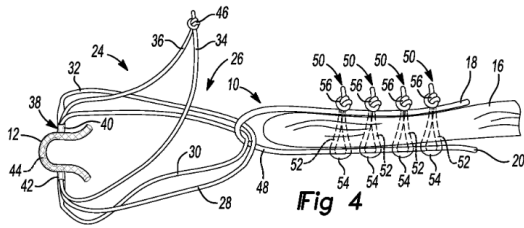
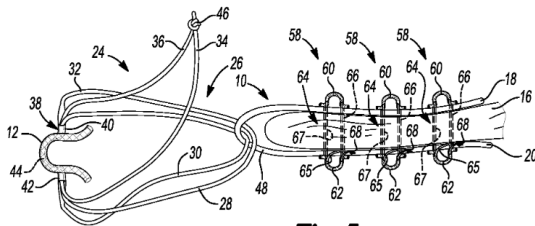
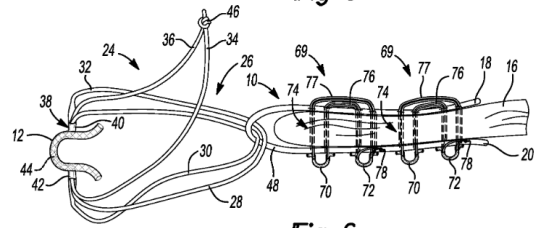
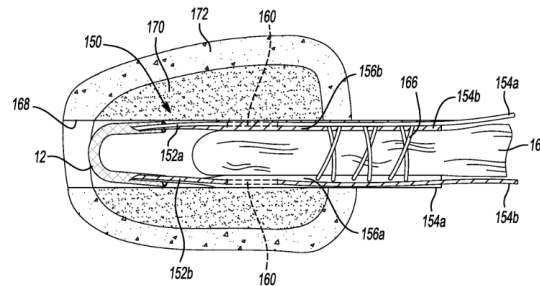
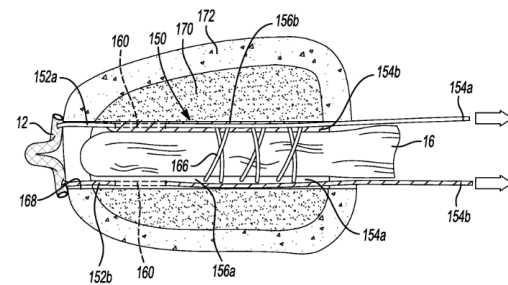
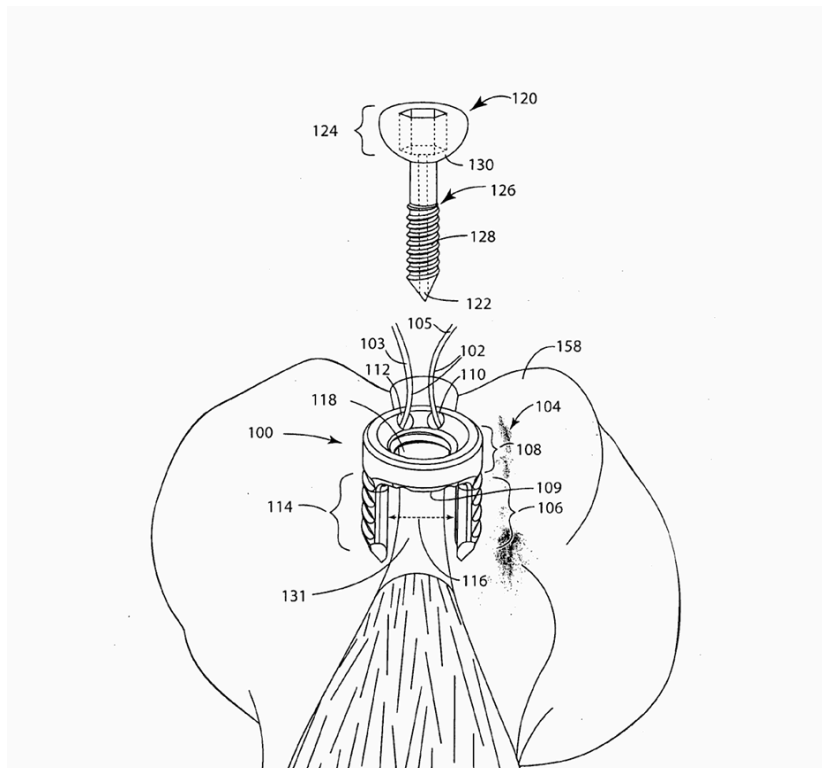
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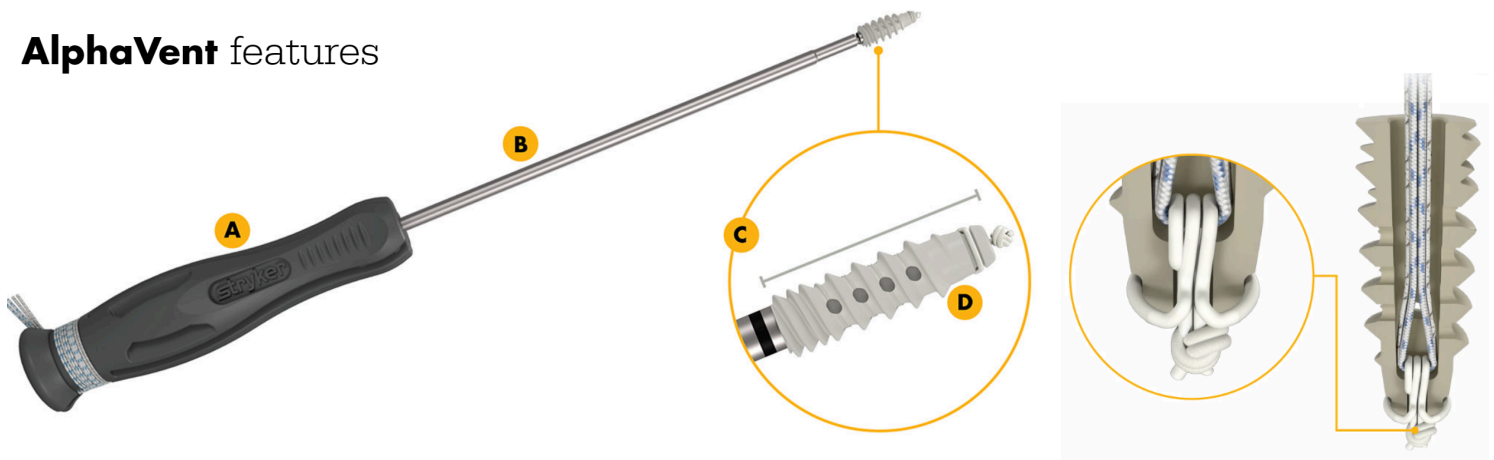
Appendix A: Part CAD Models



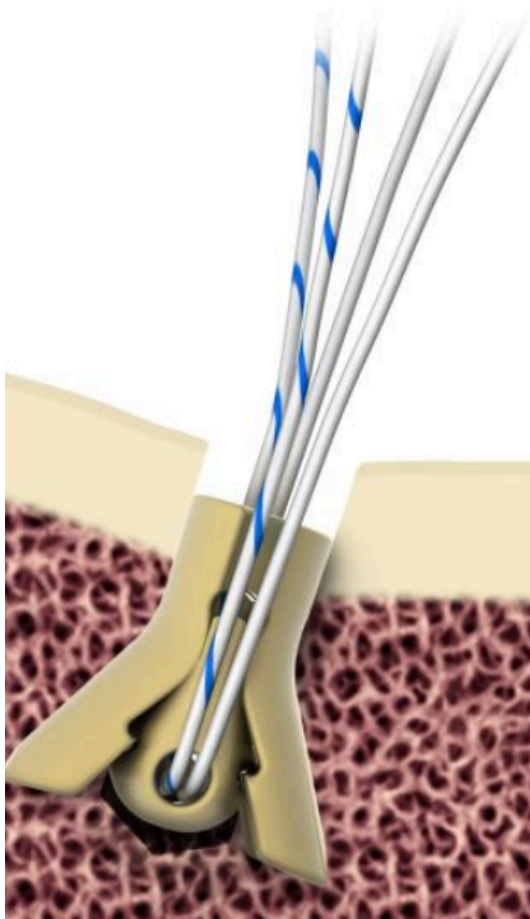




B1: US9357991B2 sample figures**Fig 4****Fig 5****Fig 6****Fig-13A****Fig-13B**B2: US20090149884A1 sample figure

AlphaVent features

B4: Sample Morphix Image



Appendix C: Cost Breakdown

Materials	OrthoTech Cost	Customer Parts Cost	Customer Total Cost
Epoxy	~\$47	~\$59	~\$188
Medical Grade Nylon	~\$72	~\$90	~\$288
Stainless Steel	~\$100	~\$125	~\$400