NextGen Ligament Replacement
Synthetic ACL Graft

BIOE 5850

Device Design Term Paper

Design Team

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April 25, 2022

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Unmet Clinical Needs

Anterior cruciate ligament (ACL) injuries are one of the most common knee injuries. In the United States alone, there are anywhere between 100,000 and 200,000 incidents per year [1]. They are more common in athletes, and beyond that, female athletes are up to five times more likely to suffer a chronic or acute ACL injury [1]. For this reason, partial and total knee arthroplasty, and ACL replacement surgery have all become far more common, especially among younger, healthier individuals.

There are a couple different treatment options for an ACL injury, but both involve removing the damaged ligament and replacing it. The more common procedure is to take a tendon from elsewhere in the body to use as a graft, or to use a tendon from a donor, normally someone deceased at that point. These are known as autografts and allografts, respectively. The other option is to use an implantable artificial ligament as the graft, which is steadily becoming a more common choice.

These grafts are not without issue. First, they have a short lifespan, especially when compared against an actual ACL replacement. According to a literature review of 14 different studies, after a clinical follow-up of 10 years, reported ACL graft rupture rate was at 6.2%, and a total clinical failure rate of 10.3%. While there are artificial ligaments currently on the market, they are not FDA-approved, so they are not widely used in the United States. Additionally, the most commonly-used one has a failure rate of 4.4% and a complication rate of 2.2% after at least a 7-year follow-up [2]. While these numbers are slightly better than the autografted or allografted ligaments, there is still a need for a longer device lifespan. As we advance as a society, mortality rate keeps decreasing, and average life expectancy has been climbing for some time now. An implant with a 20-year lifetime is impressive, but if the patient receives it when they are 40 years old, there is a good chance they are going to need a new one eventually. Therefore, artificial ligaments with extended lifetimes are of greater importance than ever before.

Beyond these, there is also an issue of adoption by healthcare providers. Orthopedic surgeons tend to shy away from them due to the high procedure cost and poor reimbursement situations [3]. This also tends to affect the insurance coverage as well. An ACL reconstruction is normally covered by insurance, but they are more reluctant to cover the cost of an expensive artificial ligament rather than just a graft. This demonstrates that there is a clear market need for an inexpensive artificial ligament that preforms just as well, if not better, than the real thing.

Prior Art

Current Fiber Based Grafts

Ligament Augmentation and Reinforcement System (LARS) is a fiber-based synthetic graft made of polyethylene terephthalate (PET) fibers and consists of woven extra-articular fibers and intra-articular longitudinal fibers [4]. The woven extra-articular ends are then secured into bone, femur and tibia, with screws. The device can be used either as a standalone graft or to reinforce autografts, usually the quadricep tendon [5]. Biocompatibility data for ten years post implantation shows that the device allows for ongrowth and adhesion of fibroblasts [6]. Below in Figure 1 is the LARS graft, the difference between the woven extra-articular and longitudinal intra-articular fibers can be seen.

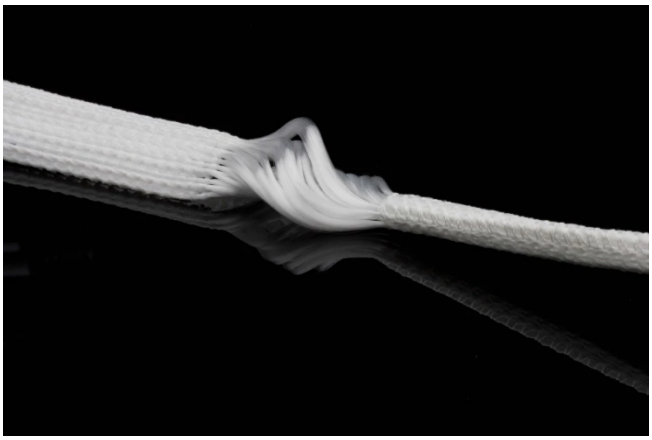

Figure 1: LARS ligament graft [6]

Previous Fiber Based Grafts

A series of fiber-based grafts were proposed in the 1980s, these included: GORETEX (polytetrafluoroethylene (PTFE)), Stryker Dacron Ligament Prosthesis (polyester), Versigraft carbon (caprolactone and lactic acid copolymer coated filamentous carbon), Kennedy LAD (polypropylene (PP)), Xenograft (bovine tendon), Leeds-Keio (polyester) [7]. All grafts resulted in synovitis, the swelling of the joint [5]. The synovitis was due to wear particles causing a foreign body response, in severe cases this response resulted in caseous necrosis [7]. Failure rates for these devices often reached 60%.

Patents

While no complete synthetic ACL grafts exist on the US market, it was still important to ensure the device did not encroach on existing patents. Patents from the full graft, including attachments, to components, intra- and extra-articular and attachment devices. The patent WO2017164754A1 is a complete synthetic graft that consists of ultra-high molecular weight polyethylene fibers in a knotless weave conformation in a flattened tube shape. To encourage osteoblast ingrowth, intraosseous sections have a hydroxyapatite coating [8]. Another patent, US10,493,180B2, contains just the graft without attachment devices. The main prototype in the patent consists of a mono to multi polyether ether ketone (PEEK) filament core, as a mechanical reinforcing component, and a collagen containing outer scaffold to encourage cell growth [9]. Instead of being design specifically for the ACL, but instead ligaments in general. Another route taken in patents is to create a graft that contains degradable polymers and biocompatible nondegradable polymers. The patent US8758437B2 uses poly(L-lactic acid) (PLLA) or poly(DL-lactic-co-glycolic acid) (PLGA) as the degradable component and a biocompatible polyester as the biocompatible nondegradable component in a braided structure [10]. This framework allows for the ingrowth of tissue and results which overtime replaces the degradable polymer.

Solution

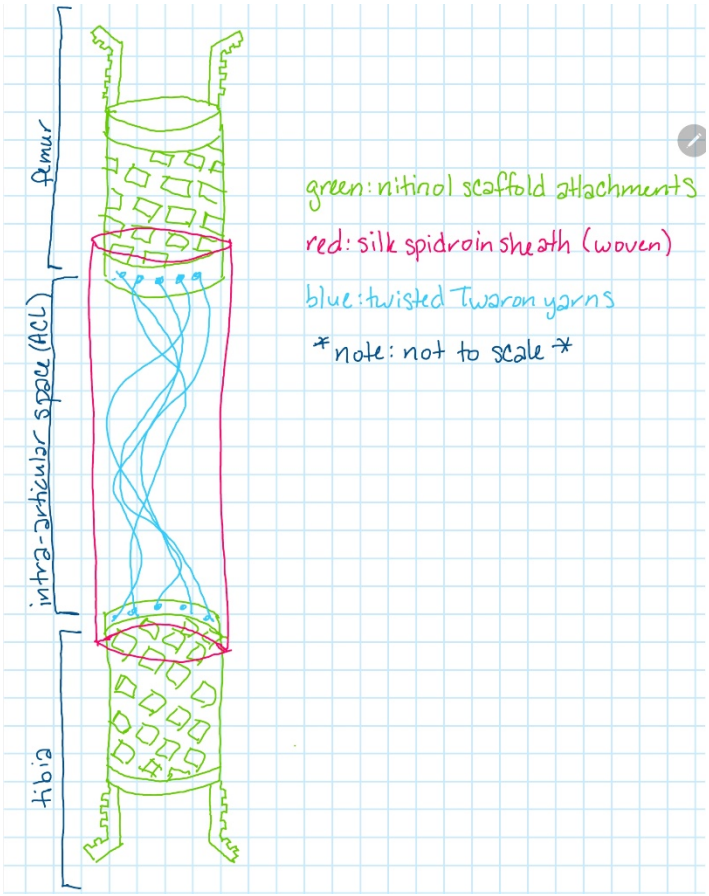

Figure 2: Sketch of ACL graft device

Twaron Fibers:

The main part of our artificial ligament will be made of Twaron. Twaron is a strong, lightweight synthetic fiber made from aramid polymer. Aramids have 5-10% higher mechanical properties than other synthetic fibers [11]. The unique characteristics of Twaron are the result of a 100% paracrystalline structure with molecular chains preferentially oriented along the yarn filament axis. In Figure 3 is demonstrated the chemical structure of Twaron.

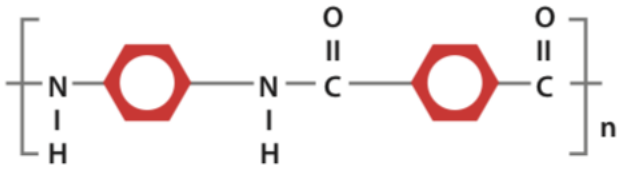

Figure 3: Chemical structure of Twaron

The structure of aramids comprises rigid polymer chains with linked benzene rigs and amide bonds. Aramid fibers represent unique fatigue damage mechanisms as compared to other fibers typically used as reinforcements in composites [12].

They are maintaining their properties at high temperatures because of their heat resistant nature. Other properties are high specific tensile modulus, tenacity and dimensional stability, and thermal/oxidative stability [13]. Twaron yarns are very strong, in Figure 4, the stress/strain curves are visualized of Twaron and other materials [14].

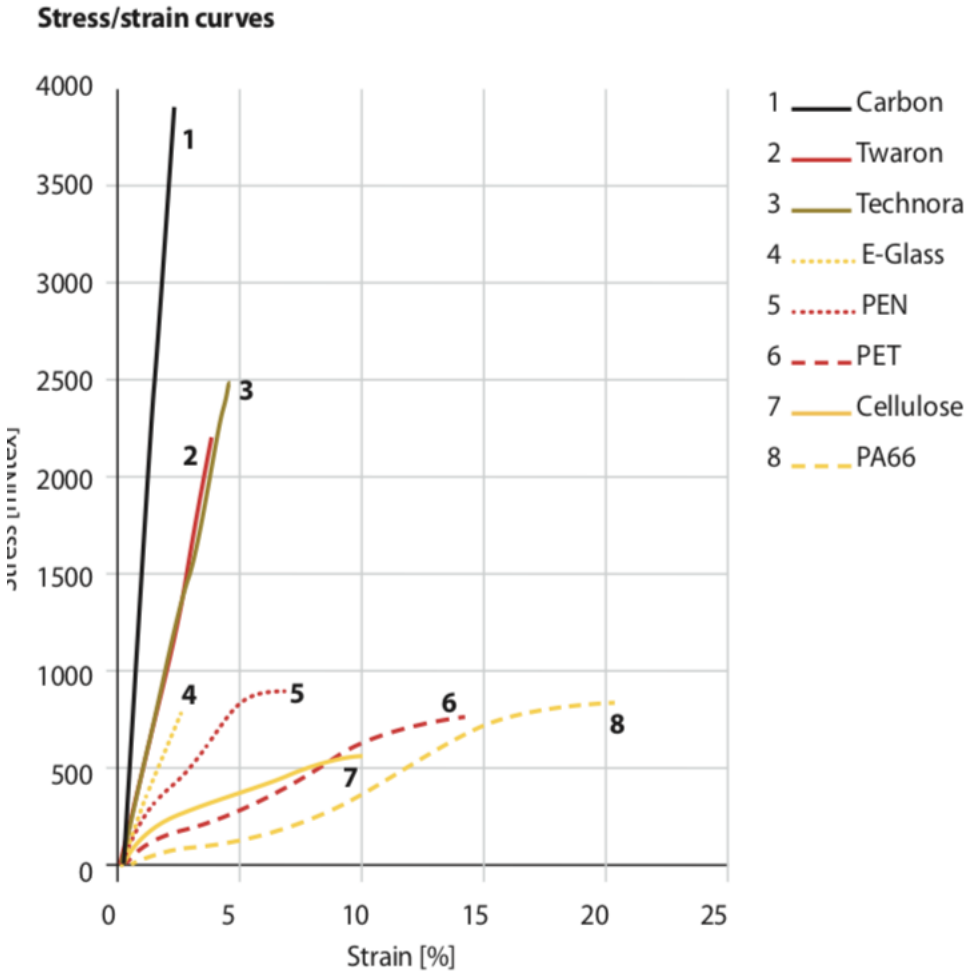

Figure 4: Stress/Strain curves

There are different types of Twaron yarns with different properties. Yellow filament yarn is the most used in the industry for optical fiber cables, tires, belts and other. Twaron black filament yarn is a high modulus filament yarn. In Tables 1 and 2 below are the properties of the two types of Twaron yarns [14].

Table 1: Twaron black filament yarn properties

Twaron black yarn types	Linear density (dtex)	Tenacity (mN/tex)	Modulus (GPa)	Elongation at break (%)
Standard	3,360*	1,828 - 1,950*	64 - 81*	3.2 - 3.8*
High-modulus	1,210 - 1,610*	2,000*	100*	2.8*

** preliminary values*

Table 2: Twaron yellow filament yarn properties

Twaron yellow yarn types	Linear density (dtex)	Tenacity (mN/tex)	Modulus (GPa)	Elongation at break (%)
Standard	420 - 3,360	1,650 - 2,200	60 - 80	3.0 - 4.4
High-modulus	420 - 24,150	2,100 - 2,300	100 - 120	2.2 - 3.0
High-tenacity	420 - 3,360	2,350 - 2,500	85 - 95	3.3 - 4.0

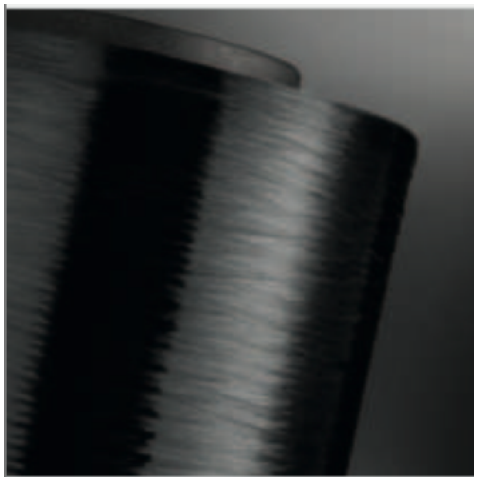

Figure 5: Twaron black filament yarn

Our solution will contain twisted Twaron black yarn high-modulus type (Figure 5) attached to the bottom of our anchor through specific holes to keep the fibers in place. There will be two sizes of the length and the width of the fibers, one according to the average size of a normal ACL and one a little bit smaller. For length our traditional ligament will be 31mm and for the thickness 6mm while the shorter ligament will be 26mm long and 5 mm wide [15] [16]. The size of the ligament will be chosen by the doctor before the surgery. With the use of imaging techniques, the knee will be landscaped and identified the anatomic femoral and tibial position to determine the distance that the ligament must cover to be similar like the original ACL.

Spider Silk:

To encapsulate the Twaron fibers from the external environment, a spider silk sheath will be applied. Spider silk is a very biocompatible, hydrophobic, and strong material which makes it a perfect candidate to be used in the application of serving as a boundary between the fibers and the synovial fluid around the knee. Spider silk is composed of proteins which can even be broken down by the body if they were to be absorbed [17], which is why a leno-weaving pattern will be used to tightly hold the silk strands preventing uncoiling and prevent fluid from interacting with the Twaron fibers. There have been no cases reported of spider silk being rejected by the immune response in humans [2], which makes this material a suitable candidate in terms of biocompatibility. In addition, spider silk has anti- bacterial, fungal, and microbial properties which may reduce post-surgical complications [18].

One of the reasons why spider silk has hydrophobic properties is because its composition is made up of "large quantities of nonpolar and hydrophobic amino acids like glycine or alanine" [19]. One of the main

factors for the spider silk having better hydrophobic properties compared to other insects is upon the secretion of the silk from the spinning gland, the "polyalanine segments expose an increasingly hydrophobic surface which triggers the formation of β-pleated structures with numerous intra- and interchain hydrogen bonds" [20]. During the spinning process, the α-helices fold towards the center of the structure and the β-pleated sheets are pushed outwards, giving it a highly hydrophobic surface. The β-pleated sheets do not only play a role in the hydrophobic properties of spider silk, but also has a great role in providing strength. Spider silk is composed of proteins, the structural integrity of the materials occurs when the "Protein assembly involved phase separation into concentrated coacervates, with subsequent conformational switching from disordered structures into β-sheets" [17].

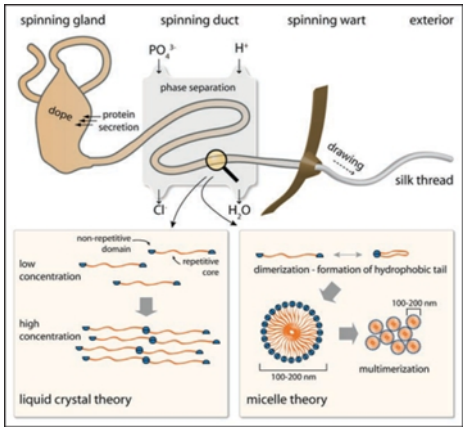

Figure 6: Spider Silk Process

Spider silk has been shown to have a relatively similar tensile strength to materials such as Kevlar which is used to make bulletproof vests. Another property that that spider silk has is that elongate a significant amount before experiencing permanent deformation, making it an excellent candidate for an artificial ligament, as they undergo constant strain. In fact, "Spider silk is shown to possess strength as high as 1.75 GPa at a breaking elongation of over 26%" [17]. The thing that makes spider silk the perfect candidate compared to other insects that secret silk is that the protein sericin is absent which provides it with more favorable mechanical properties. For example, comparing silkworm silk and spider silk it was shown that, "depending on spinning conditions, silkworm silk is either strong or elastic, whereas spider silk combines both properties." [21]. Given that spider silk has great biocompatibility, strength and is hydrophobic it makes this material a suitable candidate for the purpose of adding structural strength and protecting the Twaron from the external environment.

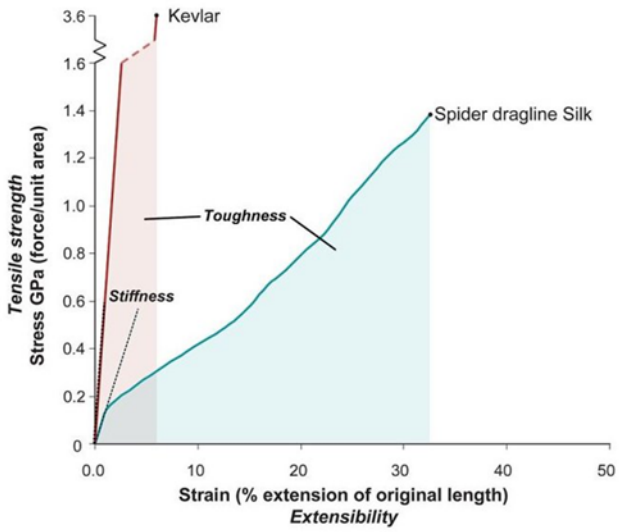

Figure 7: Comparing Mechanical Properties of Silk vs Kevlar [22]

Anchor:

The base of the anchor component for our solution is a porous rod mirroring the porosity of cancellous bone. This rod will be made of Nitinol as porous nitinol has mechanical properties close to that of cancellous bone. Figure 8 shows that the stress and strain of bone fits within the hysteresis of nitinol.

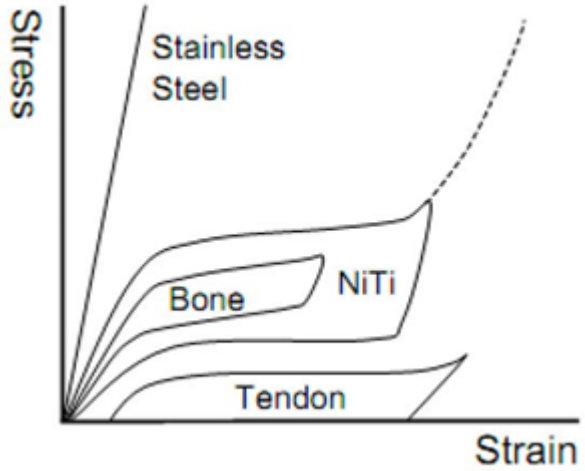

Figure 8: Stress-Strain curves for dense Nitinol (NiTi), Bone, Tendon, and Stainless Steel [23]

The nitinol can then be made porous to closely match the mechanical properties of bone. The elastic modulus of cancellous bone ranges from 0.7-3 GPa, the range of porous nitinol depends on pore size and % of open space, but for the intended use case ranges from 0.7- 1.3 GPa [24]. To make nitinol, equal amounts of powdered nickel and titanium are mixed and then heated using high temperature synthesis (SHS). To make the nitinol porous, nonreactive salt is added prior to SHS and dissolved with water once the material has been synthesized [25]. The reason SHS was chosen compared to other methods is due to its similar porosity result to cancellous bone, and the good pore connectivity [26]. When the porous structure of the implanted material is like that of cancellous bone it promotes: osteointegration, reduces recovery time (4 months until bone is grown into pores), has capillary properties, and reduces

osteoporosis [27]. This will prevent any loosening over time that other ligament anchors have. The main body of the anchor will have two sizes because of the memory shape feature in nitinol. The heated austenite phase will expand the radius of the anchor by 5% compared to the anchor in its martensite phase this is to ensure that the anchor cannot slip, as a screw-based solution would loosen over time. Implants changing in shape and size can be seen in Figure 9.

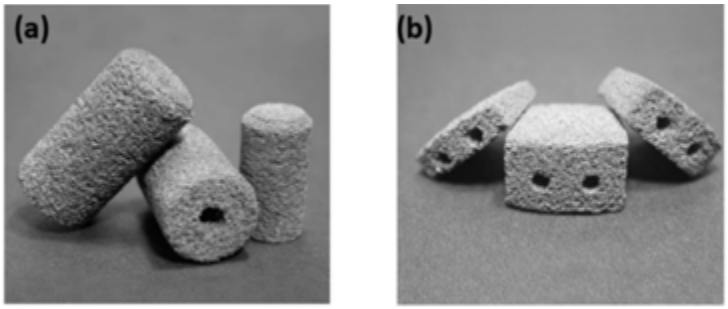

Figure 9: **Nitinol shape memory feature. a) Room temperature nitinol b) Heated nitinol [26]**

The top end of the anchor is closed as this is where the fastening tabs protrude. These tabs are straight when inserted but change shape to have a 75˚ angle with the top face. As well as a 135˚ angle for the tips of the tab. These tabs are also grooved on the outside edge to ensure no slipping when initially implanted. These nitinol tabs are initially in a straight upright position for easy insertion of the anchor, but once inserted into the body enough heat is introduced to spread the tabs to their austenite state. This nitinol feature is a mixture of nitinol staples for fusing bones together and the Morphix suture anchor [28]. A diagram of the expanded state for the anchor can be seen in Figure 10.

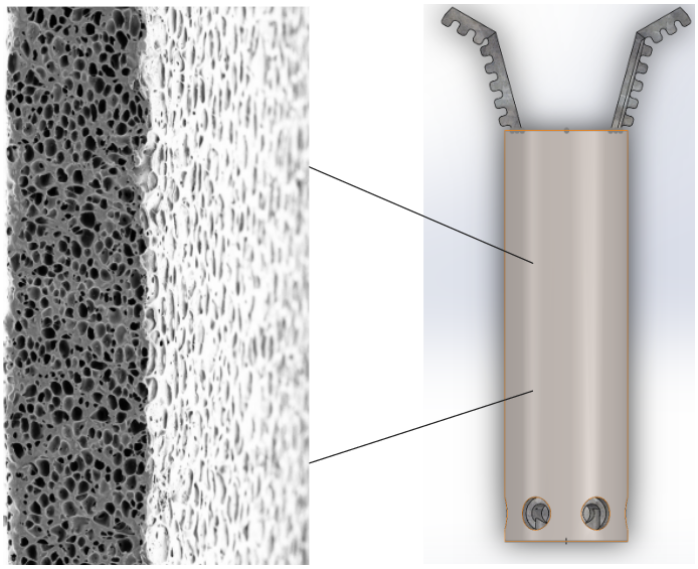

Figure 10: **Expanded state of porous anchor.**

Once the anchor has been cleaned (further discussed in human factors) it is ready to have the fibers attached. The bottom end of the anchor allows for the fibers to be fastened to it via holes for the strands of fibers to be looped through.

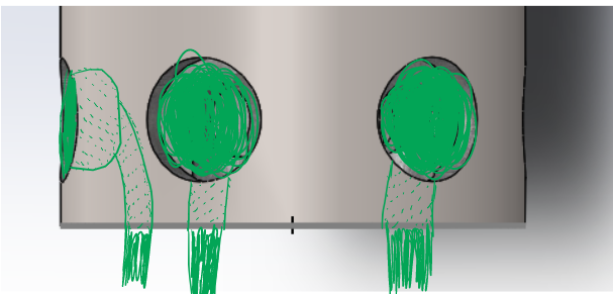

Figure 11: **Fibers tied at the end of the anchor.**

Previous iterations of the anchor (Figure 12) consisted of a titanium stent like base with the nitinol tabs at the end to ensure the anchor stays in bone. This design was avoided due to increased osteointegration property found in porous nitinol [26].

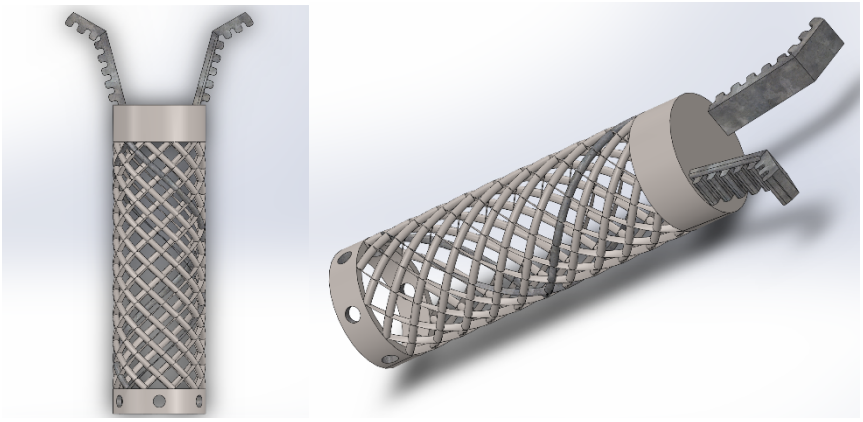

Figure 12: Previous version of the anchor

The installation of the anchor will be similar to that of a bone staple. A single vertical hole with an acute angle to the center of the bone will be drilled out of the femur and tibia where the anchors will be inserted.

Competitors

Ligament Augmentation and Reinforcement System (LARS)

Ligament Augmentation and Reinforcement System (LARS) is a synthetic, fiber-based graft that can be used either as a complete graft or to reinforce an insufficient autograft [5]. The graft is made of polyethylene terephthalate (PET) fibers that can withstand traction forces of 1500N to 4700N. Additionally, the fibers are minimally elastic with an elongation of 1.5% after a force of 1500N was applied for 24 hours [5]. Post implantation studies have shown osteoblast and fibroblast ongrowth and no synovitis [5]. LARS is threaded through bone tunnels on the femur and tibia and the ends are then held in place with screws. Using screws introduces the possibility of instability caused by device loosening. Overall, LARS has a relatively low complication failure rate (4-5%) on the short term scale, but has

conflicting results on the long term scale [2]. LARS is not FDA approved and is mostly used in France and Australia [2].

Bridge-Enhanced ACL Repair (BEAR) Implant

Bridge-Enhanced ACL Repair (BEAR) Implant is a resorbable collagen scaffold that is sutured to the remaining ACL on the tibial by absorbable sutures and held against the femur by nonabsorbable sutures that are threaded through bone tunnels. The scaffold is then filled with the patient's blood [29]. This allows for the patents own tissue to grow into the scaffold to heal the ACL. In order to receive the BEAR implant, the patient must be at least fourteen years old and the tear must have occurred within 50 days of surgery [30]. The BEAR implant eliminates the need for a graft, however an ACL stump attached to the tibia is needed [31]. FDA marketing approval was recently granted in December 2020 [31].

ACL Repair Surgery (Auto- and Allo- grafts)

Although not a device, the device would also compete against the current standard of care which is replacement with either the patient's own tissue, autograft, or donor tissue, allograft. In autografts, a portion of the hamstring, quadriceps or patellar tendon is used [32]. Allografts commonly use the Achilles, hamstring, or patellar tendon [33]. In both surgeries the existing ACL is removed, bone tunnels are drilled, and the graft is attached to the femur and tibia with screws [34]. Concerns with allografts include: contamination, disease transmission and structural compromise from irradiation. Additionally, allografts are not suggested for active people under 25 due to an increased rate of failure, up to 7.7x. Autograft concerns include increased postoperative pain and increased complications due to graft harvest [33].

Human Factors

Twaron Fibers: Twaron is made of aramid fibers. The tissue response to implantation of aramid fiber indicates that aramid is a biocompatible material [35]. Twaron seems to be biocompatible and will not create any problems with the synovial fluid.

Spider Silk: Given that spider silk is composed of proteins, it provides low immune rejection response. The silk serves as a boundary to protect any Twaron particles that suffer from abrasion from entering the surrounding environment, which could lead to inflammation and other health implications. The main goal of the spider silk is to make the device biocompatible and add support to the system, thus improving the patients long term experience and effectiveness of the ligament replacement.

Anchor: One component that brings the biocompatibility of the anchor into question is nickel. Nickel in large doses (> 0.5g) can cause nickel poisoning, 10-20% of the population is nickel sensitive [36]. To prevent issues of biocompatibility the anchor will go through Micro-arc oxidation (Figure 13); the anchor is placed in an electrolytic solution which is electrically charged. This promotes oxidation and forms a TiO_2 layer [37]. Small amounts of NiO_2 can also formulate so it is important to minimize the amount of nickel found in the oxide layer by thoroughly washing to ensure there are minimal free floating Nickel particles in the system. Nitinol implants do not produce a lot of nickel due to corrosion, with the TiO_2 layer, nitinol implants are safe with the formulation of some small fibrous capsules as the only noticeable adverse effect. Porous nitinol has been known to be a good component of osteointegration.

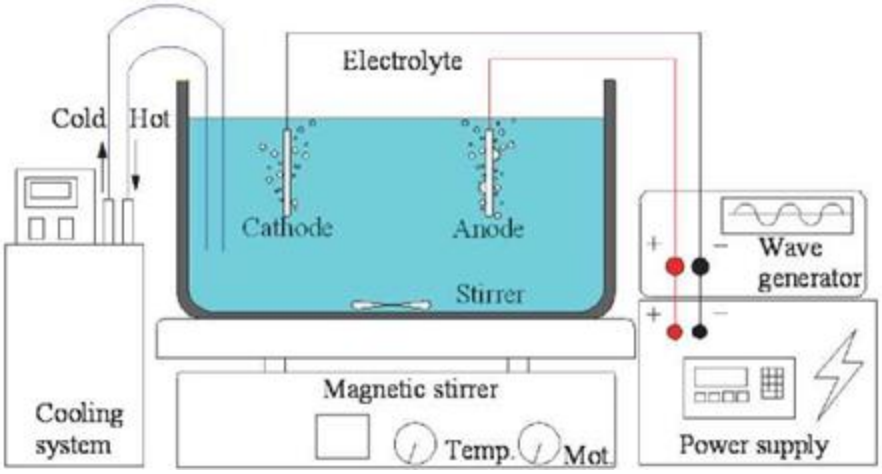

Figure 13: **Micro-arc Oxidation [38]**

Achilles Heels

Twaron: Twaron structure makes it very strong and unbreakable even in the most difficult conditions. The only environment that Twaron fibers are unprotected is moisture. The fibers can absorb moisture and then get destroyed in time.

Anchor: The fastening mechanism of the Anchor is time based. There are no screws or adhesives designed into the anchor because the intent is to have minimal steps for the surgeon. This means there is potential for the anchor to slip out if the expansion is slower than expected or if the magnitude of expansion is not enough to fill the hole the surgeon made.

Silk: The issues with using spider silk is that since its composed of proteins it can degrade. The degradation rate is dependent upon the structure and the biological conditions its placed in. While altering the structure and production process of the silk can prolong the silks integrity, it will face degradation at some point in its lifecycle. When the spider silk sheath degrades, this will affect the biocompatibility and performance of the device as it will allow that unwanted interaction between the Twaron fibers with the synovial fluid and will impair the structural performance that it provides to the overall system.

Affordability

Twaron: Teijin Aramid began producing Twaron after it was invented about three decades ago. Depends on the specific filament type the price range changes. On average the price is around 56 dollars a kilogram. After buying the yarn there will be a cost of cleaning the product and sterilize it before attaching it to the artificial ligament.

Anchor: PorOsteon is a version of porous nitinol created by Phusion Metal Technology. Depending on the price of the mold the price of the anchor may vary, but through an initial quote of a mold, a single anchor can be manufactured for ~$200 [24]. Another way to approximate the price is to take the cost per pound on nitinol ($11/lbs), while a whole pound of nitinol will not be used for an anchor we will use the $11 price point for a worst case [39]. The time to machine a small component like this can range from 1-5

hours with an hourly rate of $60. This means the total cost of the anchor can be up to $311, assuming it takes the full 5 hours to machine [40].

Silk: According to the chemical and engineering news source, an organization named Bolt threads, "is targeting a cost of $100 per kg." [41] This price is targeted towards commercial use. To purify and prepare spider silk for implantation purposes, there could be an additional cost towards verifying that the material is clean and processed correctly to avoid any external bacteria/factors from compromising the devices biocompatibility.

Surgery and rehab: Surgeon, anesthesia, and faculty fees can add to be $20,000-$50,000; if you have insurance the price can lower to the price range of $800-$3,000 (surgical costs contain the cost of the implant itself). Other medical equipment along with physical therapy can cost as much as $1500 [42].

Regulatory

Due to the invasiveness of the device, it will be classified as a Class III. There are currently no synthetic ligament grafts that are FDA approved which eliminates the option to go through the 510(k) process. This will require the device to go through the premarket approval (PMA) process. The PMA process is the most stringent pathway FDA device marketing application [43]. Included in a PMA is non-clinical laboratory data, clinical human trial data, and a summary section. The summary section contains the device description, alternative practices and procedures, marketing history, summary of studies, and conclusions from studies [44]. Once the application has been submitted and the filing has been accepted by the FDA, they will conduct an in-depth review and potentially a panel review. During the review process, FDA field agents will inspect the manufacturing site of the device and an audit of the study data are conducted. The outcome of a PMA has four options: an approval order, approval letter, a not approvable letter, or an order denying approval. Amendments can be made to the PMA until an approval order is reached [45]. The PMA approval process takes significantly longer due to the amount of information needed before the application is filed which leads to a longer review process post filing.

Manufacturing

Scalability

The materials within the device are readily available. There could be an issue sourcing silk spidroin depending on the number of devices produced. Weaving the silk sheath and attaching the Twaron fibers and silk sheath can be done in house. Manufacturing the nitinol attachments would have to be outsourced to another company. A manufacturer that is able to attach the anchors to fibers would be desirable. Assembling the three components would occur in house in a clean room environment to keep the components sterile.

Cleaning & Sterilization

Sterilization procedures for each component will vary therefore each will likely have to be cleaned and sterilized separately then assembled in a clean room environment. The degumming process of silk will clean the fibers by removing the outer sericin layer. Furthermore, the fibers will be sterilized before and after weaving. To sterilize silk autoclaving will be used as this saw a decrease in degradation rate [46]. Twaron can be cleaned with oxygen-based bleach, however chlorine-based bleach will cause the fibers to decompose [47]. The fibers would then have to be thoroughly rinsed and dried to prevent decomposition. Twaron is highly damaged by UV light, which removes the option for UV irradiation to sterilize [48]. The

nitinol stents would come cleaned and sterilized from the manufacturer chosen. Random testing of devices will be conducted for the presence of endotoxins and other microbes.

IP

The intellectual property of the device belongs to the authors. A notice of invention has been completed. However, at this point a patent will not be filed.

Exogenous Factors

There are a few different issues with the current design and construction of the artificial ligament and anchor previously laid forth. However, it is worth noting that most, if not all, of these issues are not specific to this design, but are present in artificial ligaments in general.

First, there is always a risk of the fibers rubbing together, which introduces friction and can slowly weaken the fibers over time. This causes degradation of the fibers, which can contribute to device failure after years and years. Additionally, this runs the risk of causing reactive synovitis, which is one of the pathologies that contribute to device failure rate later down the line.

Another big factor is the anchors detaching from the bone. If there is not sufficient bone ingrowth or osseointegration into the nitinol, the anchors could detach, causing the implant to fail. Though, even if there is sufficient ingrowth, the implant could still detach if the ACL is stressed too much or loaded too quickly. It is worth nothing that a stress this high would likely cause damage or failure to an actual organic ACL, so it does not necessarily constitute failure on the device's end.

Future Research

Materials

For the materials used, silk spidroin and Twaron, individual fiber mechanical properties are known. It not known what the properties of the fibers are in the conformation of the device. Further materials testing would be needed to both determine the properties of the Twaron fibers twisted together and the woven silk spidroin sheath. Spidroin based silk contracts in the presence of water, this needs to be accounted for in the design of the device [18]. The amount of contracture in the silk will affect both the total length of the sheath, there will be a difference in length between fabrication and post-implantation. The contracture will also affect the tightness of the weave because excess stress on the fibers post-implantation could cause breakage and in the worst-case scenario, rupture. In addition, the properties of the two materials together attached to the nitinol anchoring device is needed. This information would inform on the number of Twaron fibers necessary to withstand the normal forces on the knee while keeping a normal range of motion.

Degradation of silk spidroin is facilitated by enzymes within the body [18]. Within a year, a majority of the tensile strength is lost and within two or more years fails to be recognized [49]. To solve this issue engineers at Washington University in St. Louis have developed synthetic spider silk which could potentially solve the issue of degradation [50]. The synthetic silk is characterized as a polymeric amyloid fiber and is created from amyloid peptides and the glycine-rich silk sequence. The resulting fibers have comparable mechanical properties to silk fibers with similar molecular weights [51]. However, there have not been any clinical trials testing the biocompatibility or longevity and structural integrity of the

synthetic spider silk in a biological setting. More research must be done to determine whether it can be applied to our given solution.

Within the body, silk promotes cell proliferation and attachment [18]. The impact of this is unknown. Cell ingrowth is dependent on the porosity of the scaffold. The sheath likely has a lower than desired porosity due to its tightly woven conformation. In vivo research needs to be done to determine the cell on- or in-growth of cells into the silk and the impact this has on the functionality of the device.

One of the purposes of the silk sheath is to prevent the Twaron fibers from coming in contact with the body and the degradation of Twaron. Twaron is highly hydrolyzed in an alkaline environment, characterized by a pH greater than 7 [48]. The pH of healthy synovial fluid is 7.43 which is slightly alkaline [52]. In addition, Twaron fibers exhibit time dependent loss of aqueous environments which will likely have a greater impact than the pH if synovial fluid is able to penetrate the silk sheath or after the sheath degrades [48].

If a silk-based solution cannot be found, Halar could be a possible solution. Halar (ethylene chlorotrifluoroethylene) is a fluoropolymer that can be extruded into fibers. The high purity of Halar has resulting in its use in biotech and pharmaceutical applications [53]. However, there is no data on direct biocompatibility, so testing needs to be done.

Technology Improvements

To have the implant fully integrate into the body, the placement of the anchors into the bones is important. Additionally, the anchors dislodging from the bones is one of the causes of device complication and failure down the line, which contributes to a reduced overall lifespan. Also, if the ligament and anchors are not placed in a good location or position relative to the other anatomical landmarks of the patient, it can lead to the patient not trusting the implant fully. This can result in the patient not utilizing their new knee to the greatest extent possible, which can hinder rehabilitation and cause more issues down the line. To combat this, we are looking into taking MRI scans of the patient's knee beforehand, so that their specific anatomy can be studied and accounted for when designing the ligament anchors. OTISmed had a similar process when they developed their patient-specific surgical guides for total knee replacement surgery, though it is worth noting that their guides failed and caused malalignment of the prosthetic knee [54]. This was due to the guides warping after being the sterilization process. Assuming that the same issue is not repeated, a similar guide could potentially be developed and manufactured for placing the ligament anchors on the femur and tibia.

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