Biomechanical Analysis of Polyester Silicone-coated Artificial Tendon and Accompanying Suture Anchors

A Dissertation Presented for the

Doctor of Philosophy

Degree

The University of Tennessee Knoxville

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December 2024

ACKNOWLEDGEMENTS

In his book *The Righteous Mind*, moral psychologist Jonathan Haidt wrote “the reason we express gratitude is not to repay debt but to strengthen relationships.” I could not have come this far in my academic journey without the help and support of many people, my relationships with whom I want to strengthen. I am filled with gratitude in my heart that our paths have crossed and wish to bring them honor by praising them publicly in this dissertation. The following paragraphs are a collection of *thank you* for people who have helped me in distinctive ways through this journey.

First, I wish to thank my advisor, Dustin Crouch, PhD, for being supportive through these years of working with him. I am profoundly grateful to you for providing me with feedback in a timely manner and for your kindness and patience with me through the difficult times. I thank former colleague Caleb Stubbs and his family for their hospitality during my early days in Knoxville after arriving to commence my PhD. I am also thankful to Katrina Easton, PhD, Jalen Barker, Fisher Adkisson and Madison Smith, for their contributions to the research presented in this dissertation.

I thank Jeffrey Reinbolt, PhD and Andrew Dickerson, PhD, for serving on my PhD qualifying examination committee as well as on my dissertation committee. During my qualifying examination, you both provided me with enriching insights from your personal experiences which gave me a clearer idea of how to approach my research. I am grateful for your time and for your generosity with sharing knowledge.

I thank Dr David Anderson, DVM, for accepting to serve on my PhD committee but equally for making his laboratory at the University of Tennessee College of Veterinary Medicine

(UTCVM) readily available to me for use every time that I needed to. Most importantly, I acknowledge each time that he stopped by to check on me while I was carrying out my experiment on the MTS. You did not have to, but you always chose to. I thank Elizabeth Croy and Lori Terrones for being great companies at the laboratory at UTCVM. They always made me feel welcomed to work at their lab. I thank Dr Pierre-Yves Mulon for contributing to parts of my research.

I wish to acknowledge Dr Bryce Burton, Dr Kelsey Finnie, Chris Carter and Amy Sanderson and the staffs of Mossman Animal Housing Facility at the University of Tennessee, Knoxville, for their contributions to the research studies presented in this dissertation.

In my first semester at the University of Tennessee, Knoxville, I was enrolled in three classes where I met three friends – Andrew Strick, Viet Nguyen and Kaileigh Estler. Andrew and Viet were my go-to guys for brainstorming difficult class assignments and they were always generous with their time to go through projects with me. They supported me so much that after the semester, they had become such a huge support network for me at the University of Tennessee, Knoxville. Kaileigh was a huge source of social support. Having been in similar situation, she understood how difficult it can be to be far away from your family. She invited me to many social events and I enjoyed socializing and getting away from the stressful academic challenges – at least momentarily. These relationships somehow helped me settle well into life in Knoxville. This is a *thank you* to all three of you.

I thank Prof Isaac Adeyemi, former Vice Chancellor at Bells University of Technology, Ota, who took a chance with me when he appointed me a Teaching Assistant in the Biomedical Engineering program at the university. My desire to pursue a PhD in Biomedical Engineering received a big boost with that opportunity. I also thank Messrs. Mike Ogunniran and Julius

Olowo who helped me with getting a job when I needed one so I could save money to pursue my bachelor's degree.

I thank Ephraim Nwoye, PhD, for being my teacher and mentor and for supporting me with countless recommendation letters while I was applying to PhD programs. I thank every teacher who ever taught me at any stage of my life. I learnt something from each of you to get me to this stage. I thank my brother and friend Babatunde Ogunlade, PhD, for all the love and support I received from him throughout this PhD journey. I am glad that I can count on you.

I thank my mom and dad for making innumerable sacrifices for me, many of which I may never fully understand. I honestly look back with gratitude knowing that my parents put me and my siblings first, before themselves. I am here today partly because of those sacrifices, and partly because of God’s love. I thank my siblings with whom I shared my childhood. What would life be without them?

Finally, what can I offer the Lord for all he has done for me? I will lift up the cup of salvation and praise the Lord’s name for saving me (Psalms 116:12-13, NLT). Praise the Lord!

ABSTRACT

The incidence of Achilles tendon rupture has increased from 11 to 37 per 100,000 population in recent decades with these ruptures causing pain, swelling and disability in the patient. Critically sized tendon gaps, which are too large to heal spontaneously, are currently treated with tendon grafts, but the use of grafts have some challenges such as donor site morbidity, risk of disease transmission, and potential mismatches in length and size. An artificial tendon can address these challenges and may be customizable for each patient. If the whole tendon is replaced with an artificial tendon, suture anchors are one option for attaching the artificial tendon to bone. The mechanical characteristics of the suture anchor used in musculoskeletal reconstructions (e.g. to attach an artificial tendon) can limit the strength of the attachment and lead to premature failure. The objectives of this dissertation were to (1) investigate the reasons for in vivo failures of suture anchors used to attach artificial Achilles tendons in a rabbit model, (2) quantify the maximum failure load of suture anchors identified as suitable for attaching artificial tendons in rabbit, and (3) evaluate the effects of artificial Achilles tendon on hindlimb biomechanics and muscle morphology in rabbits. We observed that neither suture size (1 or 5) nor time of implantation (delayed or immediate) was a causative factor for the failures. In addition, suture anchors with raised eyelets decreased suture strength compared to those with embedded eyelets, irrespective of loading condition. We also found that artificial Achilles tendon preserved average ground contact area, peak vertical force and vertical impulse. It improved muscle cross-sectional area (CSA) and could potentially mitigate loss of muscle mass and length. These outcomes can help surgeons improve their choice of anchors for soft tissue reconstructions, reduce the risk of revision surgeries which are painful and costly to patients, and address the challenges associated with the use of tendon grafts for treating tendon ruptures.

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LIST OF ABBREVIATIONS

ACL	anterior cruciate ligament
ADL	activity of daily living
ANOVA	analysis of variance
cm	centimeter
CSA	cross-sectional area
CRI	constate rate infusion
ECM	extracellular matrix
ED	extensor digitorum
FD	(superficial) flexor digitorum
IM	intramuscular
LG	lateral gastrocnemius
MG	medial gastrocnemius
mm	millimeter
MTP	metatarsal phalangeal
MTS	mechanical testing system
NZW	New Zealand white
SC	subcutaneous
Sol	soleus
SPSS	statistical package for social sciences
TC	tibialis cranialis
TE	tendon excision
PDS	polydioxanone suture
PET	polyester
PET-SI	polyester silicone-coated
PO	*per os* (by mouth)
UHMWPE	ultra-high molecular weight polyethylene
UTCVM	University of Tennessee College of Veterinary Medicine

CHAPTER I. Introduction

Tendon injuries are common musculoskeletal conditions with a worldwide incidence of tendon ruptures between 80 and 90 persons per 100, 000 population per year; occurring more in males and in ages between 30 – 46 years (Bergamin et al., 2023; Manent et al., 2019; Wang et al., 2023). Achilles tendon rupture is the most frequent tendon rupture in humans primarily due to long-term overuse and repetitive activities, despite the Achilles tendon being the strongest and largest tendon in the body (Kauwe, 2017; Wu et al., 2017). Achilles tendon rupture is also one of the most common soft tissue injuries, reported to be just behind the ACL tear in terms of incidence (Ponkilainen et al., 2022). The incidence of Achilles tendinopathy among competitive athletes is 24 percent and about 18 percent among athletes aged 45 years and below. In the general population, among people who do not participate in sporting activities, Achilles tendon rupture is about 1 percent (Wu et al., 2017). Other tendons prone to higher possibility of injury in humans include rotator cuff, forearm extensors, quadriceps tendon, and tibialis posterior.

A single episode of stress exceeding the tendon's threshold for intolerance or a direct mechanical damage can result in tendon tear or laceration (Bergamin et al., 2023). A tendon tear or laceration can lead to loss of muscle function, inability to plantarflex the ankle, difficulty in extending the knee, and can significantly limit the ability to walk, stand and climb stairs (Agres, 2018). Tendon ruptures also cause joint instability, joint weakness and can result in bone dislocation at a joint. Tendon ruptures are often accompanied by severe and sudden pain at the injury site due to tearing of the tendon fibers. Swelling, bruising and bleeding into the surrounding are also common with these ruptures. When a tendon ruptures, it is common to have the associated muscles retract leading to possible deformities on the affected part of the body.

The overall implication of a tendon rupture is that the individual's ability to perform activities of daily living (ADL) is profoundly negatively impacted.

A. TENDON ANATOMY AND PHYSIOLOGY

The tendon is the link between a muscle and a bone, and is responsible for the transmission of tensile loads from the muscles to the bone, thereby facilitating movement of the skeletal structure (Lin et al., 2004). A tendon is attached at one end to a bone at the osteotendinous junction (enthesis) and at the other end to a muscle at the myotendinous junction (James et al., 2008; Magnusson & Kjaer, 2003). A healthy tendon when viewed under a microscope should have a bright white color (Wu et al., 2017). Tendons are dense connective tissues and mainly contain parallel, closely packed collagen fibers and cells within a well-ordered extracellular matrix (ECM). Type I collagen makes up 65% to 80% of the dry mass of a tendon, with about 2% to 3% of other collagen types (Docheva et al., 2015). The smallest collagen unit is the tropocollagen and is synthesized inside the tendon cell, aggregates into a self-assembled triple-helix polypeptide, responsible for the wave-like appearance of a tendon, and consisting of two alpha-1 chains and one alpha-2 chain, and is secreted into the ECM. The triple-helix polypeptide organizes into parallel organized collagen fibers, which are about 100 nm to 500 nm in diameter and rotates about 90 degrees, in the Achilles tendon, descending into the calcaneus.

The tendon fiber is surrounded by a thin reticular network of connective tissue, known as the endotenon. The whole tendon tissue is covered by a fine loose connective tissue sheath called epitenon, ensuring vascular, lymphatic and nerve supply (**Figure I-I**). When the tendon bends around a joint, it often comes enclosed in a tendon sheath with synovial fluids to reduce sliding friction. The paratenon provides the vascularization of the epitenon and endotenon, reduces

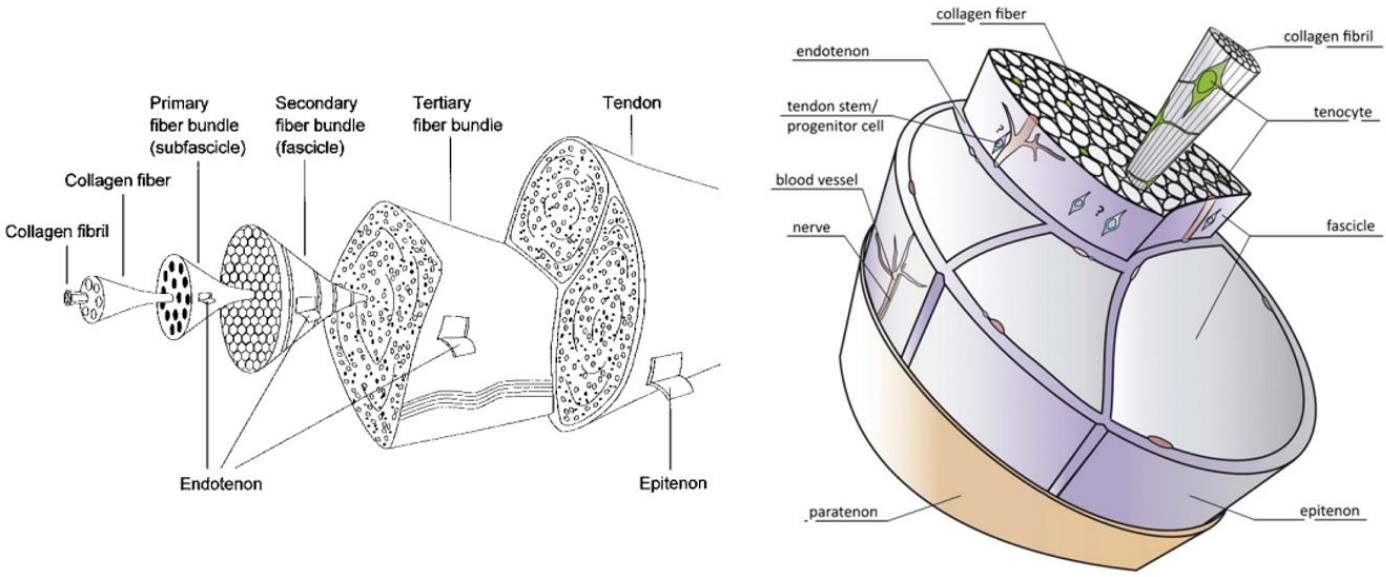

Figure I-I. Basic structure of the tendon. Fibrils, fibers, and fascicles are hierarchically arranged units of collagen. Terminally developed cells, known as tenocytes, comprise the majority of cellular composition. The precise location of progenitor and stem cell populations inside the tendon remains unclear. Along with the blood arteries and nerves, other sheets, including endotenon and epitenon (loose connective tissues) and paratenon (fatty areolar tissue), are shown. Sources: (Docheva et al., 2015; Kannus, 2000).

friction and permits free tendon movement against surrounding tissues (Sharma & Maffulli, 2008; Wu et al., 2017).

The ground substance of the ECM on tendons is composed of 1% to 5% proteoglycans and glycoproteins (such as tenascin C, cartilage oligomatrix protein, decorin and fibromodulin), 2% elastin and about 0.2% inorganic molecules such as copper and manganese (Docheva et al., 2015; Lin et al., 2004). Elastin, in conjunction with collagen functions in elastic stretch and recoil especially for tensile resistance, and regulates the interactions between cells and ECM.

Tenoblasts and tenocytes make up about 90% to 95% of the cells in a tendon. Chondrocyctes, synovial cells, and vascular cells make up the remaining 5–10% (Kannus, 2000). Tenocytes are long spindle-shaped cells that originate from tenoblasts, which are juvenile tendon cells. Tenocytes are essential for controlling synthesis and maintenance of the ECM. These cells allow for adaptive modifications by reacting to the mechanical stimuli applied to the tendon. Tenocytes are structurally arranged in longitudinal arrays and communicate extensively with adjacent cells across the cell membranes, mostly through gap junctions (Stanley et al., 2007; Subramanian et al., 2018; Zhang et al., 2019). Other cell types found in a tendon include the tendon stem/progenitor cell, perivascular cell, intra-fascicular matrix cell (Wu et al., 2017).

Tendons are poorly vascularized, and many tendons may show regions of reduced vascularity (Schmidt-Rohlfing et al., 1992). Blood supply to the tendon arises from the myotendinous junction, the osteotendinous junction as well as the tendon sheaths (Fenwick et al., 2002). Different tendons may also depend on certain arteries for their blood supply, leading to significant differences in blood supply to different tendons (Rathbun & Macnab, 1970). Although tendons have a limited amount of direct blood supply, especially in the middle

portions, they are able to obtain vital nutrients by diffusion from the surrounding synovial fluid (Fenwick et al., 2002; Schmidt-Rohlfing et al., 1992).

Tendons are supplied with nerve fibers by muscular nerve branches, peritendinous nerves (which surround the tendon), and cutaneous nerves. The nerve fibers pass over into the endotenon (inner tendon layer) and paratenon (outer tendon sheath) at the myotendinous junction. Compared with the myotendinous junction area, the middle portion of some tendons, such as the Achilles tendon, exhibits relatively poor innervation. Between their origin and insertion, tendon compression can occur at several points, which may affect the nerve supply in these regions (Ackermann et al., 2001; Lephart et al., 1997; Stilwell Jr., 1957).

B. TENDON INJURIES AND DISEASES

Tendinopathy, a state in which a tendon is injured or malfunctions, includes tendinitis or inflammation of the tendon as well as tendon ruptures or tears and is characterized by pain, swelling, tenderness, reduced range of motion and disability (Gaut & Duprez, 2016) . Overuse, repeated activities, and age-related tendon degeneration are the common causes of tendon injuries. Acute tendon tears can also result from sudden traumas (Wu et al., 2017). Acute tendon ruptures/tears (partial or complete tear of the fibers), tendon strain (overstretching or twisting of the tendon) and tendinosis (chronic degeneration of the tendon without inflammation) are other conditions that can negatively affect the tendon (**Figure I-II**). Tendons recover according to the standard wound healing process after acute injury, which entails an early inflammatory phase, cell migration, cell proliferation, and remodeling stages. As recovered tendons never regain their biomechanical qualities, the healing process is never fully achieved (Gaut & Duprez, 2016; Lin et al., 2004).

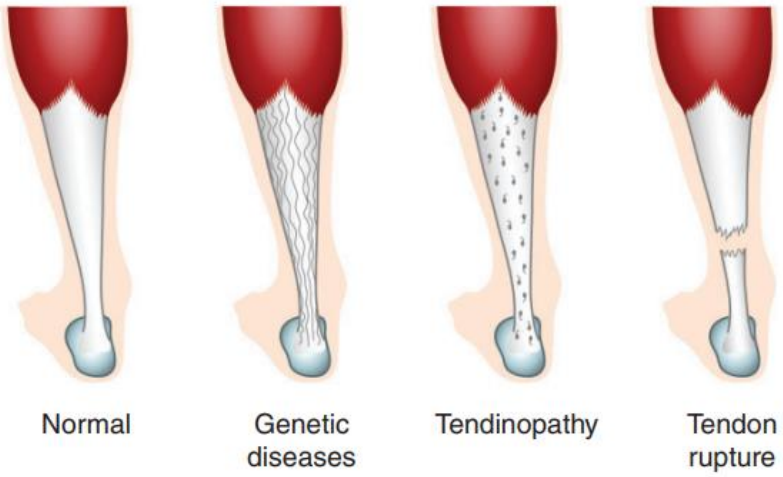

Figure I-II. A representation of tendon pathologies. (A) A normal tendon. (B) Genetic diseases affecting genes coding for proteins involved in type I collagen fibrillogenesis lead to tendon defects. (C). Tendinopathy. (D). Tendon rupture. Source: (Gaut & Duprez, 2016)

C. TREATMENT AND MANAGEMENT OF TENDON INJURIES.

Treatment for tendon injuries can include non-surgical, conservative treatments such as load modification, eccentric exercises, orthoses, massage, electrotherapy, cryotherapy, nonsteroidal anti-inflammatory drugs, extracorporeal shockwave therapy (ESWT), high volume and sclerosing injections. Tendon ruptures can be treated by primary repair (surgically joining the torn ends). However, critically sized tendon ruptures (with big gaps between the torn ends) are treated with the use of tendon grafts (Lohrer et al., 2016). For some individuals, surgery may be the right course of action, but recovery from surgery can be painful and uncomfortable (Sharma & Maffulli, 2008). With surgical repairs, re-rupture can be a problem. Achilles tendon re-rupture following surgery to repair a tear is between 1.7% to 5.6% (Hanada et al., 2011), while the re-rupture rate for rotator cuff repair is between 20% to 25% (Longo et al., 2021; Shin et al., 2018). These tendon re-tears typically result in revision surgeries which are costly and burdensome to the patients.

Tendon grafts are used for treating critically sized tendon injuries. A graft can be obtained from a different part of the patient's body (autograft), a donor individual (allograft) or an animal of a different species (xenograft). There are challenges associated with this treatment method. Difficulty in harvesting tendon graft, variability in graft size especially with allografts, potential mismatch between graft length and size and the patient's anatomy, and donor site morbidity (pain and weakness) and limited availability of the tissue have been identified as prominent problems associated with tendon grafts (Zein et al., 2017).

The difficulties described with regard to the current methods of treating critically sized tendon ruptures highlight the significance of developing new techniques to mitigate the complexity of these injuries, as the current methods for managing tendon lacerations and

tendinopathy have limited success (Sharma & Maffulli, 2008). Innovative solutions to these problems, such as the development and use of biocompatible artificial tendon have become necessary.

D. RESEARCH OBJECTIVES

The overall objective of this dissertation is to develop and analyze the biomechanical capability of polyester suture-based silicon-coated artificial tendons, to repair or fully replace biological tendons having large (critically sized) defects. Towards the development of effective artificial tendons and reliable tendon anchorage for humans and animals, the overall objective of this dissertation is to: 1) examine in vivo data for previously implanted artificial tendons in rabbits, 2) perform mechanical testing of suture anchors whose sizes are compatible with the rabbit model for attaching artificial tendons and 3) investigate the effect of polyester suture-based silicone-coated artificial Achilles tendon on musculoskeletal function (hindlimb biomechanics) and musculoskeletal form (muscle mass, length and cross-sectional area) in New Zealand White (NZW) rabbits. The research activities are divided into three research focus areas:

Research objective 1: Investigate the factors associated with outcomes of replacing biological tendons with polyester suture-based artificial tendons in rabbits. The results of this study showed that anchor eyelet geometry was a probable cause of failure whereas timing of implantation and suture size had no effect on suture anchor failure.

Research objective 2: Quantify the strength of different suture anchors whose sizes are compatible with the rabbit model for attaching artificial Achilles and tibialis cranialis tendon. This study quantified the maximum failure strength of suture anchors and the % reduction of suture strength of the different anchors due to eyelet geometry.

Research objective 3: Analyze the effect of polyester artificial Achilles tendon on musculoskeletal form and function. This study evaluated peak vertical force, vertical impulse, average ground contact area and joint angles of rabbit hindlimb during the stance and swing phases of hopping gait. It also measured changes in muscle mass, length and cross-sectional area following artificial tendon implantation in the rabbits compared to an excision-only group.

E. CHAPTER SUMMARY

In Chapter 2, an overview of previous attempts at developing artificial tendons, as well as an introduction to polyester suture-based artificial tendon design are presented.

In Chapter 3, an investigation is launched into the factors responsible for the premature failure of multiple suture anchors used to attach artificial Achilles tendons in rabbits.

In Chapter 4, a study to quantify the maximum tensile strength of suture anchors used for attaching artificial tendons and the effect of eyelet geometry on suture strength are presented.

In Chapter 5, a study of the effect of artificial Achilles tendons on hindlimb biomechanics and muscle morphology in NZW rabbits is presented.

In Chapter 6, conclusions from the main findings, limitations and future directions of the studies in this dissertation are presented.

CHAPTER II. Background

A. ARTIFICIAL TENDON

The current standard treatment for critically sized tendon defects is a tendon graft, which may be autologous or allogenic (Crossett et al., 2002; Sarzaeem et al., 2012). However, there are situations when the use of tendon graft may be undesirable such as in the case of long tendons running through close-fitting tunnel structures that are supposed to change the direction of operation of the tendon, or when a damaged muscle needs to be disconnected and its function assumed by a muscle with less important function in the vicinity of the damaged muscle. In the former case, grafting will generate scar tissue which will cause the graft to fail. In the latter case, the availability of tendon prosthesis removes the need for the second muscle to be in the vicinity of the first muscle (Murray & Semple, 1979).

There are no reliable pharmaceutical treatments for critically sized (large) tendon injuries and viable tissues for tendon transplantation are limited (Zein et al., 2017). Injections and other medications only temporarily relieve pain and are not effective in repairing significant tendon defects. Autograft tendon transplantation may result mechanical mismatch, donor-site morbidity, and other complications. When utilized for extensive tendon defects, allografts and xenografts have significant failure rates, risk of rejection, and potential for disease transmission (Hafeez et al., 2021). Therefore, there is an urgent need for new treatment methods, one potential alternative been the use of biocompatible and durable artificial tendon.

An artificial tendon is a tendon prosthesis that links a muscle to a bone and provides a permanent load-bearing interface with the muscle at one end and a simple mechanical fastener at the other end (Melvin et al., 2012). Artificial tendon implants could prevent the need to harvest

the patient's tendon, eliminating donor-site morbidity. Biocompatible artificial tendons made from synthetic biomaterials (such as polyester) can mitigate the risks of rejection and disease transmission associated with allografts and xenografts. Artificial tendon implants can provide structural reinforcement and bridge large tendon gaps that cannot be repaired with pharmaceutical treatment. Biocompatible and biodegradable artificial tendons can act as temporary scaffolds to guide and facilitate the regeneration of new tendon tissue.

The nature of tendons requires that an artificial tendon be strong to withstand high loads, be flexible to permit turning and twisting around tissues and structures in the body and has the apparatus for attachment to the remains of a biological tendon (or to a muscle) on one end, and to a bone on the other end, mimicking the myotendinous junction and osteotendinous junctions of biological tendons. It should also have a smooth surface to facilitate sliding over tissues in its vicinity in addition to a small cross-sectional area which enables it fit in place. A presentation of previous efforts to develop artificial tendons is summarized in **Table II-I**.

B. POLYESTER (PET) SUTURE-BASED ARTIFICIAL TENDON

A number of materials have been used for making artificial tendons including polyester, Teflon, and nylon. However, polyester has been demonstrated to be more resilient and less inflammatory than Teflon and nylon (Murray & Semple, 1979). Beyond the choice of material for making the artificial tendon, the technique for anchoring the tendon to bone is equally important and a major determinant of the success of the musculoskeletal reconstruction. Different methods have been used previously to attach soft tissues (such as tendons) to bone with suture anchors providing better mechanical strength and durability compared to pins, screws and staples (Barber et al., 1993).

Table II-I. Artificial tendon studies between 1900 and 1975 with the main accomplishments and limitations of each study. Source: (Murray & Semple, 1979).

S/n	Author (Year)	Study Description	Accomplishment/Limitations
1	Lange (1900 & 1902)	Tendon lengthening and shortening using silk cords, in human ankles of paralyzed legs.	Fibrous tissues large or larger than the replaced tendon was a main challenge in this studies.
2	Delbet (1928)	Paralyzed muscle-tendon unit was substituted with a tensioned rubber.	The attachment to tendon or aponeurosis pulled out or elongated.
3	Arkin & Siffert (1953)	Sections of tendons in dogs and rabbits were replaced with braided tantalum using cotton sutures as attachment/anchorage to the tendon and to bone, in a 3-month study.	Fibrous tissues covered the braids at the tendon and bone junctions. No ingrowth of bone in the braids.
4	Sarkin (1956)	Nylon monofilament covered with polyethylene tubes replaced the FDP tendons in humans. The mechanical testing of the FDP muscle-tendon/bone yielded average load of 55kgf, with failure at the osteotendinous junction in all cases.	A 15-year follow-up shows that 14 out of 21 patients has retained the original movements.
5	Grau (1958)	Achilles tendon was replaced in 5 dogs with prosthetic tendons, some made with silk, and some made with metal wire.	Anchorage was weak in the muscle. Fibrous tissue growth around the prosthesis.
6	Williams (1960)	Artificial tendon made of woven Teflon and attached to a biological tendon at both ends, in dogs.	A well-developed pseudo-sheath formed around the artificial tendon within which the prosthesis glides. Adhesion at prosthesis-tendon junction was a challenge.
7	Bowen & Dyer (1962)	Dacron reinforced silicone elastomer was used to replace tendons in the eyes of dogs, using silk sutures.	Adhesion were present although to a lesser extent in longer term studies.
8	Flynn (1965)	'beaded Teflon' was used for making tendons and tested in dogs.	Only reported evaluation has it to cause proliferation of tendon-like tissues in the dogs.
9	Bader and Curtin (1968)	A silicon and polyester prosthesis was installed as radialis tendons in dogs.	In 8 out of 10 dogs, the prosthesis held fully but in the remain 2, scar tissues maintained the union. Got a patent in 1972.
10	Homsy (1972)	A carbon fiber/PTFE porous composite was inserted in the calcaneal tendon and gluteal muscle in rabbits.	The pull out strength per bonding area averaged 2.5 kgf cm^{-3}
11	King, Dunn & Bolstad (1974)	Braided polyester with silicone coating sandwiched into the gastrocnemius of dogs and through the calcaneum.	Scar tissue formation was a complication but in one dog without this complication, the prosthesis was functional up to 3 years.
12	Murray & Semple (1975)	Polyester cord coated with polyurethane elastomer with porous titanium as an anchorage to bone, and used as Achilles tendon replacement in dogs.	Both ends of the prosthesis were intact up to end of study (8 months) with bone formation around the porous titanium.

In recent years, polyester-based artificial tendons (**Figure II-I**) have been studied in goats for up to 180 days (Melvin et al., 2011; Melvin et al., 2010; Melvin et al., 2012). In vitro testing demonstrated that the prosthesis exhibited mechanical reliability and durability, withstanding forces of up to 350 N. In the goat model, there was successful integration with the muscle tissue, providing strength exceeding the predicted muscle contractile force and showing tissue integration without compromising vascularity. Histological analysis revealed fully vascularized integrated tissue around the prosthesis, supporting its potential long-term strength and clinical applications. However, a major shortcoming of these studies is that it did not include the effect of the artificial tendon on the movement biomechanics in the goat, considering that an important function of the tendon is to transmit muscle force and help facilitate movement.

As part of advancing the development of durable and reliable polyester suture-based artificial tendons and addressing the gaps in previous studies on this subject, the Upper Limb Assist Laboratory at the University of Tennessee, Knoxville, embarked on the design and testing of artificial tendons made from braided polyester sutures and coated with biocompatible medical-grade silicone (**Figure II-I**). The artificial tendon design was adapted from an existing device (Melvin et al., 2010; Melvin et al., 2012) using customized USP size 0 braided polyester sutures (RK Manufacturing Corp, Danbury, CT, USA). The sutures were cut to a length of 12 inches, double-armed with swaged 3/8-circle tapered point needles (0.028-inch wire diameter). Artificial Achilles tendons were made using three suture strands that were folded in half to form a loop at the mid-point, then braided to the desired length, yielding 6 suture threads for muscle attachment; tibialis cranialis artificial tendons included 2 suture strands, folded in half to form a loop, then braided to the desired length yielding 4 suture threads for muscle attachment. To prevent tissue adhesion, medical-grade biocompatible silicone (BIO LSR M340, Elkem

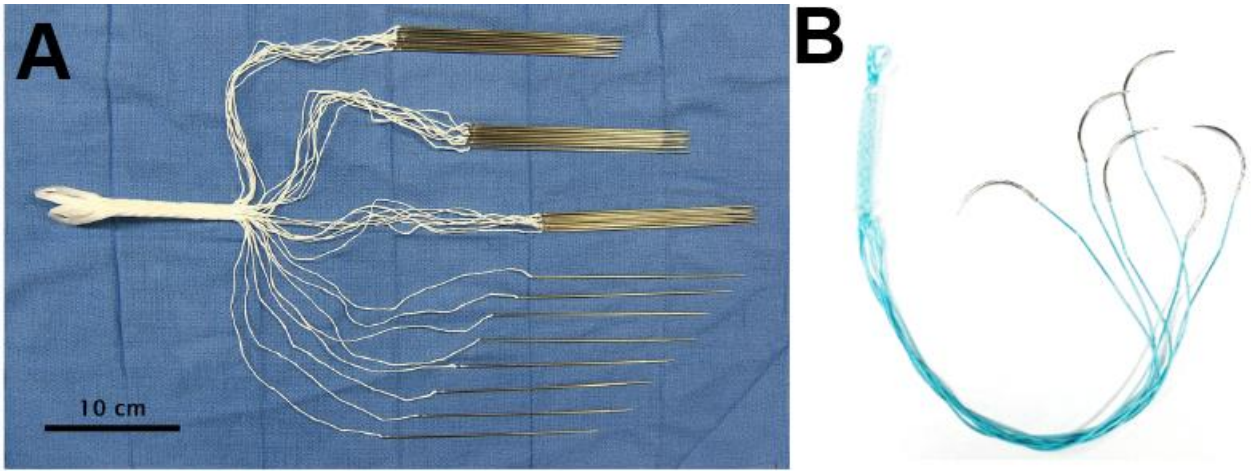

Figure II-I. (A) Braided polyester suture material used as artificial tendon and implanted in goats (Melvin et al., 2010). (B) Sample Achilles tendon prosthesis from the Upper Limb Assist Laboratory, an evaluation of which forms the central synopsis of the studies presented in this dissertation. Braided portion of artificial tendon is coated with biocompatible silicone.

Silicones, Lyon, FR; LSR-4301 silicone elastomer, Factor II, Inc., Lakeside, AZ) was applied to the braided portion of the tendon. The tendons were then cleaned and sterilized with hydrogen peroxide gas before implanted in the rabbits.

Artificial Achilles tendon (n=2) and artificial tibialis tendon (n=2) were implanted in NZW rabbits as part of a feasibility study to test the effect of the artificial tendons on movement biomechanics in the rabbits (Hall et al., 2023). Rabbits with artificial tendons either maintained or recovered their locomotor functions. The Achilles group exhibited biomechanical impairment from week 0 to week 2 post-surgery, followed by some biomechanical recovery from week 2 to week 6. The tibialis cranialis (TC) group exhibited near-normal locomotor biomechanics throughout the test sessions. The Achilles group had substantially smaller ankle and foot angles than the TC group and healthy controls. The ankle remained dorsiflexed throughout most of the stance in the Achilles group. The mechanical load is expected to be greater in the Achilles tendon than in the TC tendon during stance, which may explain the differences in biomechanical outcomes between the two groups. This study had limitations, including a small sample size, did not include the effect of the artificial tendon on muscle properties as well as a limited measurement of biomechanics only during the stance phase of gait.

As part of efforts to address the limitations of the study described above, artificial Achilles and tibialis cranialis tendon (TC) were implanted in another group of NZW rabbits (n = 12). In nine out of twelve rabbits, the suture anchor used to attach the artificial Achilles tendons failed in vivo within 10 weeks of implantation, as seen from radiographs taken every other week post-surgery, and confirmed with post-mortem hindlimb dissection. The suture anchor used to attach the artificial TC tendons did not fail in any of the twelve rabbits. The premature failures of the suture anchors of the Achilles tendon implied that the effect of the artificial tendon on

movement biomechanics in the rabbits could not be investigated fully. Investigations into the factors associated with these premature failures motivated the first and second research focuses of this dissertation.

Taking advantage of the success of the TC tendons, another study (Easton et al., 2024) was conducted to investigate the effect of artificial polyester suture-based TC tendon on movement biomechanics in NZW rabbits. The TC tendon of the rabbits (n=5) was surgically replaced with a polyester, silicone-coated artificial tendon (PET-SI), while five control rabbits underwent complete surgical excision of the biological tendon with no replacement. The length of the artificial tendons closely approximated that of the native tendon, which is important for maintaining proper joint function. The artificial tendon effectively preserved the biomechanical function of the native tendon, as there were no significant changes in joint kinematics over time in the group that underwent tendon replacement with the PET-SI artificial tendon.

The success of the artificial TC tendon motivated the study to investigate the effect of artificial Achilles tendon on movement biomechanics in NZW rabbits, which forms the third research focus of this dissertation.

C. FOCUS OF THE DISSERTATION

Critically sized tendon ruptures cause pain, swelling, tenderness, reduced range of motion and disability in the patients. Unfortunately, damaged tendons heal slowly and seldom recover their structural integrity and mechanical strength. This implies that such tendons are prone to re-rupture, the consequence of which is costly revision surgeries that are often burdensome to patients. Among professional athletes, tendon ruptures can reduce participation and performance,

leading to early retirement from the sports. In the general population, tendon ruptures reduce performance of ADLs.

The objectives of this research are 1) to investigate the factors associated with outcomes of attaching artificial tendons to bone using suture anchors for replacement of biological tendons in rabbits. 2) to quantify the strength of different suture anchors whose sizes are suitable for attaching artificial Achilles and TC tendons in a rabbit model, as well as determine the effect of cyclic loading on the anchoring strength. 3) quantify the in vivo hindlimb biomechanics (ground contact pressure and sagittal-plane motion) during hopping gait of rabbits having an excision of the Achilles tendon and either with or without repair using a PET-SI artificial tendon.

In a previously implanted models of artificial Achilles tendon, we evaluated the hindlimb radiographs to estimate the timing of failures of the suture anchors used to attach the artificial tendons. We measured the gap between the head of the anchor and the lowest point of artificial tendons to inform the gap length; and noted which gap lengths increased beyond 5 mm with no return to the previous shorter gap length, and the time of this increase. Based on this data, we performed a survival analysis of the suture anchor using Kaplan-Meier method. We also performed analysis of variance (ANOVA) to determine any effect of tendon implantation timing or suture size on either the timing or frequency of suture anchor failure.

Toward investigating the root cause of the premature in vivo failures of the suture anchors used to attach the artificial Achilles tendons, we carried out tensile tests of the suture anchors to inform the maximum tensile force at failure for each of the suture anchors we have used to attach artificial tendons till date. We also investigated the effect of cyclic loading on the strength of the suture that accompanied each anchor, to determine which of the suture anchor combination was most suitable for attaching artificial tendons in rabbits. Taken together, these studies helped to

improve the chances of success on the study to understand the effect of artificial Achilles tendon on rabbit hindlimb biomechanics.

The specific aims of the dissertation are:

Specific Aim 1: Estimate the timing and determine the mode of failure of suture anchors used to attach artificial Achilles tendons in NZW rabbits, from the hindlimb radiographs taken approximately every other week post-surgery.

Specific Aim 2: Determine the effect of eyelet design and cyclic loading on suture strength for four metallic screw-type suture anchors, two with raised eyelets and two with embedded eyelets, whose sizes are compatible with the rabbit model.

Specific Aim 3: Measure the biomechanics of the unilateral hindlimb throughout the complete hopping gait cycle in rabbits with Achilles tendon loss, in comparison to rabbits in which the defect was repaired using an artificial PET-SI Achilles tendon.

Specific Aim 4: Quantify important muscle properties (muscle mass, muscle length and muscle cross-sectional area) in rabbits with Achilles tendon loss, in comparison to rabbits in which the defect was repaired using an artificial PET-SI Achilles tendon.

CHAPTER III. Attaching artificial Achilles and tibialis cranialis tendons to bone using suture anchors in a rabbit model: assessment of outcomes

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This manuscript is currently under review in PeerJ and has been published in bioRxiv, an online preprint server.

A. INTRODUCTION

A suture anchor consists of a suture and an anchor with an eyelet on the anchor through which the suture passes. Suture anchors are frequently used in human and veterinary musculoskeletal reconstruction to reconnect soft tissues, such as tendons and ligaments, to bones (Cho et al., 2021; Visscher et al., 2019). Suture anchors can offer quick, reliable, and stable fixation (Burnham et al., 2020; Ravin et al., 2005), and can achieve close apposition between the soft tissue and bone (Altiparmak & Uckan, 2013). An intimate interface between the anchor and suture is needed to ensure that the soft tissue is securely connected to the bone to facilitate healing (McFarland et al., 2005). Compared to other techniques for fixation of soft tissues to bone, the strength of suture anchors has been shown to be superior to other means of fixation such as bone tunnels, staples, screws, washers, or tapered plugs, (Barber et al., 1993).

Anchors can be classified as either screw-type or non-screw-type (Barber et al., 1995), with screw-type anchors having greater load-to-failure resistance compared with non-screw-type designs (Barber et al., 2006; Barber et al., 2003). The eyelets in screw-type anchors can be either raised above the screw or embedded within it. Anchors may also be bioabsorbable, nonmetallic, or metallic (Barber et al., 1993). Metallic anchors are relatively affordable with minimal

undesirable biological reactions, ensuring safe and long-term fixation of the anchor within the bone while the tissue heals (Longo et al., 2019).

Mechanical failure of a suture anchor is a potential complication for clinical concern as it compromises the stability and integrity of the surgical reconstruction (Meyer et al., 2002). When failure occurs, the connection between soft tissue and bone becomes weak or ineffective, resulting in the need for revisions. Revision surgeries are often complex, costly, and burdensome for the patient. Sometimes, revisions may lead to more loss of bone tissue, depending on the nature of the reconstruction, as the bone is prepared to hold the anchor (Panegrossi et al., 2014). This highlights the importance of developing reliable and durable suture anchors to minimize the risk of failure. Several factors may affect the durability of suture anchors, including suture anchor design, material composition, and surgical techniques (Fleischli, 2018; Schanda et al., 2022).

Sutures associated with suture anchors tend to fail in one of two ways: at the knot, which is considered the weakest point of a tied suture, or at the eyelet of the anchor (Meyer et al., 2002). Using a model of bovine infraspinatus tendon repair, suture breakage at the eyelet was the most common mode of failure for metallic suture anchors with eyelets raised above the screw, when the anchor head was flush with the surface of the bone, and when the anchor head was raised above the bone (Bynum et al., 2005). Suture breakage also was the predominant mode of failure for two metallic screw type suture anchors evaluated in a human cadaveric shoulder using an arthroscopic Bankart method; although the study did not state if the sutures failed at the knot or around the eyelet (Barber et al., 1993). In an extensive study of the mechanical properties of suture-anchor interactions, fourteen different sutures were used in combination with thirty-one

anchors; suture breakage at the midpoint of the tested strands was the failure mode for all the suture anchors (Barber et al., 2006; Barber et al., 2003).

In a previous study, a metallic screw-type anchor (part no. 60-27-09, 2.7 mm x 9 mm, IMEX Inc., Longview, TX) was used to attach artificial tendons in rabbits. The suture failed away from the knot in multiple rabbits, prematurely. Mechanical testing of the anchor using a size 5 suture yielded a failure load of 437.24 ± 42.35 N with cycling and 498.13 ± 18.20 N without cycling (Fidelis et al., 2024). Therefore, the objective of our study was to investigate the timing and mode of failure of metallic screw-type suture anchors used to attach artificial tendons to bone in an in vivo New Zealand White rabbit model. We hypothesized that suture size and timing of tendon replacement surgery would have significant effects on the timing and frequency of suture anchor failure. The results of our study will inform the design and selection of suture anchors for clinical applications.

B. MATERIALS AND METHODS

Artificial tendon fabrication

We fabricated custom polyester suture-based artificial tendons to replace the biological Achilles and tibialis cranialis tendons, as previously described (Hall et al., 2023). The artificial tendon design was adapted from an existing device (Melvin et al., 2010; Melvin et al., 2012) using customized USP size 0 braided polyester sutures (RK Manufacturing Corp, Danbury, CT, USA). The sutures were cut to a length of 12 inches, double-armed with swaged 3/8-circle tapered point needles (0.028-inch wire diameter). Artificial Achilles tendons were made using three suture strands that were folded in half to form a loop at the mid-point, then braided to the desired length, yielding 6 suture threads for muscle attachment; tibialis cranialis artificial

tendons included 2 suture strands, folded in half to form a loop, then braided to the desired length yielding 4 suture threads for muscle attachment (**Figure III-I**). To prevent tissue adhesion, medical-grade biocompatible silicone (BIO LSR M340, Elkem Silicones, Lyon, FR) was applied to the braided portion of the tendon. Two parts (ratio 1:1) of the silicone was manually mixed by stirring for up to 5 minutes in a cup. The mixture was transferred into a syringe and centrifuged at 4900 rpm for 4 minutes to eliminate air bubbles and achieve a homogenous mixture. The mixture was then applied to the braided section of the artificial tendon to create a thin and uniform silicone coating on the braided suture. The tendons were cleaned in an ultrasonic cleaner (Model: JPS-08A) and sterilized using hydrogen peroxide gas to prepare them for surgery. We applied a silicone coating on the braided polyester sutures to deter tissue adhesion and encourage the formation of a pseudo-sheath to allow the tendon to slide relative to surrounding tissues (Melvin et al., 2011).

In Vivo Study

All animal procedures were approved by the Institutional Animal Care and Use Committee at the University of Tennessee, Knoxville (Protocol #2726). The study included twelve female New Zealand White rabbits (Robinson Services Inc, USA), with an average age of 19.9 ± 2.17 weeks and an average body mass of 3.52 ± 0.35 kg at the time of first surgery. All rabbits were part of a larger study to determine the effect of tendon replacement timing, immediate versus delayed (5 weeks), on hindlimb movement biomechanics. We housed the rabbits individually and allowed them to acclimate for a minimum of 2 weeks prior to surgery. They received daily positive human interaction and enrichment in addition to being fed *ad libitum* with regular laboratory diet, Timothy hay, and greens. In addition, rabbits were given playpen time twice a week for at least ten minutes before surgery and beginning two weeks after

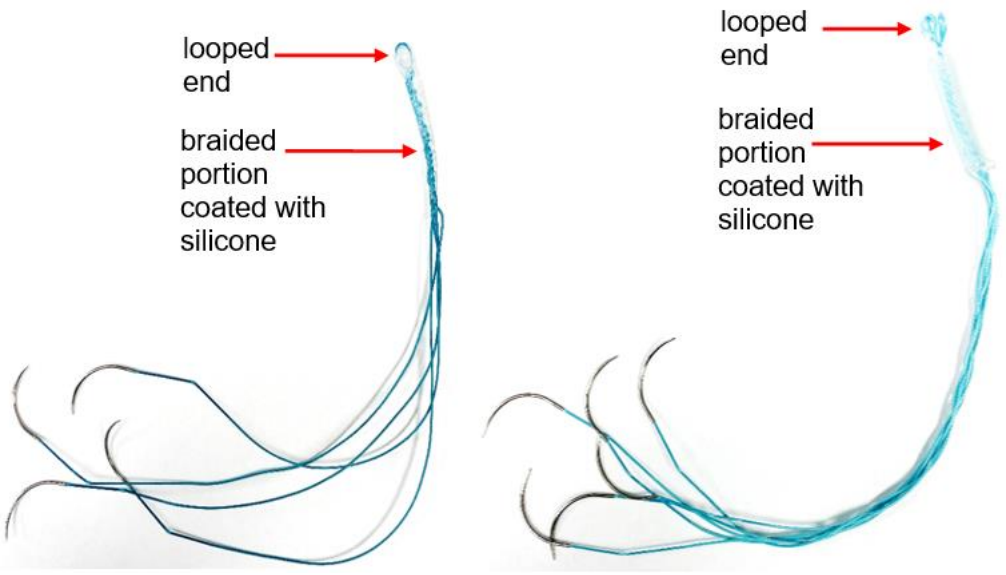

Figure III-I. Sample artificial tendons implanted in this study. Left – artificial tibialis cranialis tendon. Right – artificial Achilles tendon.

the procedure, when the bandages had been taken off. Surgeries were performed iteratively, on multiple days over a 35-week period (**Figure III-II**) under general anesthesia. The rabbits were administered hydromorphone (0.1 mg/kg IM) as an analgesic and midazolam (1 mg/kg IM) as sedative prior to surgery; with additional dose of hydromorphone (0.1 mg/Kg IM) post-surgery if necessary, as part of pain management. We applied silver sulfadiazine to the incision and the operated limb was bandaged for at least three days with splint bandage. Isoflurane was administered during surgery via face mask to induce general anesthesia. To maintain general anesthesia, isoflurane gas was evaporated in 100% oxygen.

First, the biological Achilles and tibialis cranialis tendons were excised from the musculotendinous junction to the tendon enthesis in the left hindlimb. To reduce the number of animals, no control group was used. Artificial Achilles and tibialis cranialis tendons were then implanted in the left hindlimb, either at the time of (immediate, n=8) or 5 weeks after (delayed, n=4) biological tendon excision (**Table III-I**). The proximal ends of the artificial tendons were sewn into the distal end of the respective muscle. The tibialis cranialis tendon implant had 4 strands of suture material with swaged-on needles. The sutures were folded at their mid-point, to create the distal loop used for attachment to the bone anchor. The free-ends with the swaged-on needles remained unbraided and were used to attach the tendon implant to the muscle. Muscle attachment was established using 1-pair of free sutures to create two pairs of modified single-locking loops in the muscle and tying these 2 sutures together (Rawson et al., 2013). This was repeated for the second pair of suture free ends.

The artificial tendon implant was attached to the muscles of the Achilles tendon in similar fashion, except that these tendon implants were composed of 6 strands of sutures resulting in 3

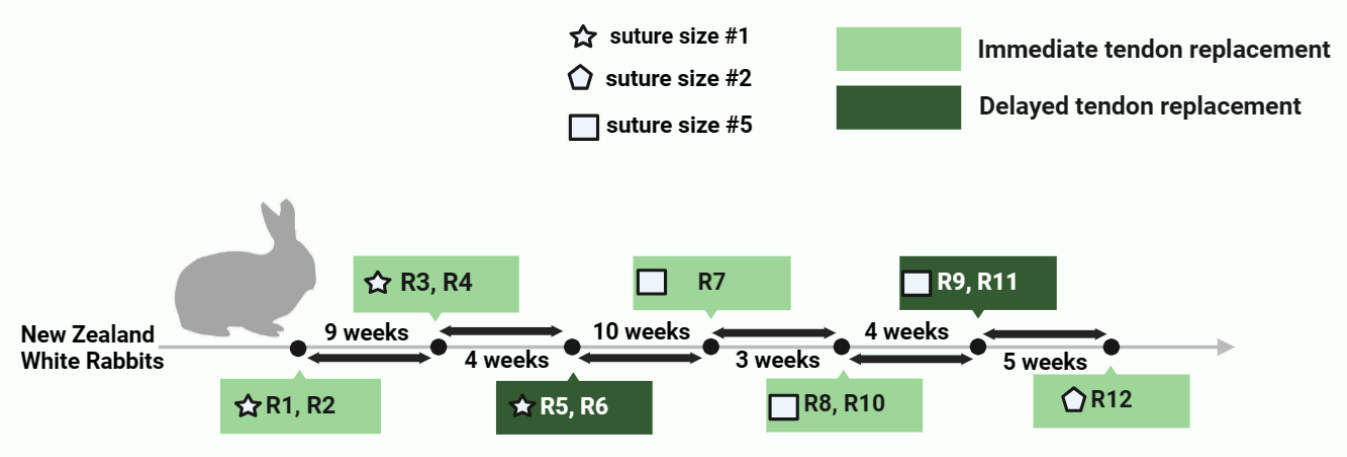

Figure III-II. Timeline of surgeries in the study showing the tendon replacement timing (immediate or delayed) and the suture size used for the Achilles tendon suture anchor for rabbits R1 through R12.

Table III-I. Summary of results for Achilles artificial tendon suture anchors.

Rabbit ID	Study Group based on tendon replacement timing (Immediate or Delayed)	USP suture size for Achilles tendon suture anchors	Postoperative radiographic timepoint at which suture anchor failure was first suspected (weeks post-surgery)	Location of suture breakage	Gap length on the day of surgery (mm)	Gap length at suspected failure timepoint or end of study (mm)
R1	Immediate	1	2 weeks	Mid-section	0.000	6.312
R2	Immediate	1	4 weeks	Mid-section	0.720	6.312
R3	Immediate	1	No failure	-	1.760	2.410
*R4	Immediate	1	No failure	-	4.827	4.442
R5	Delayed	1	6 weeks	Mid-section	0.673	13.179
R6	Delayed	1	4 weeks	Mid-section	0.821	3.612
R7	Immediate	5	No failure	-	0.564	0.991
R8	Immediate	5	7 weeks	Mid-section	0.344	4.463
R9	Delayed	5	5 weeks	Mid-section	1.057	12.932
R10	Immediate	5	6 weeks	Mid-section	0.815	4.784
R11	Delayed	5	10 weeks	Mid-section	0.798	5.466
#R12	Immediate	2	4 weeks	unknown	1.023	5.126

**The tendon of the superficial flexor digitorum was replaced with an artificial tendon instead of the Achilles tendon, as such, this rabbit was excluded in the statistical analysis.*

#This rabbits was also excluded in the statistical analysis because it was the only rabbit with a suture anchor having a size 2 suture.

pairs of locking loops placed in the muscles. The distal ends of the artificial tendons were attached near the respective biological tendon insertion points on the bone using metallic screw-type anchors with eyelets located within a raised post.

Two bone anchors, manufactured for use in veterinary surgery and commercially available, were chosen based on their size and ability to select suture sizes to be used. The anchor (**Figure III-III**) for the artificial Achilles tendon (part no. 60-27-09, 2.7 mm x 9 mm, IMEX Inc., Longview, TX) was inserted in a proximal to distal angle through the cranial aspect of the calcaneus close to the point of insertion of the biological tendon. Either USP size #1 (n = 6), #2 (n = 1) or #5 (n = 5) braided composite suture (Fiberwire, Arthrex Inc., Naples, FL) was passed through the eyelet for use to secure the artificial tendon to the anchor. The anchor for the tibialis cranialis artificial tendon (2 mm x 6mm, Jorgensen Laboratories LLC., Loveland, CO) was inserted in the proximal, dorsal aspect of the 2nd metatarsus (MT II) at the point of insertion of the tendon and accompanied with either a size #1 or #2 suture.

Radiographs of the operated limbs were taken at the time of surgery and approximately once every other week post-surgery to monitor the placement and integrity of the suture anchors and artificial tendons. Radiographs of both the lateral and cranial-caudal views were taken at each timepoint. Potential confounders such as order of treatment and measurements were not controlled. All authors were aware of the rabbit group allocations at all stages of the study.

At the end of the study (16 weeks post-surgery), the rabbits were humanely euthanized by intravenous overdose of pentobarbital (390 mg/ml, minimum 1 ml/10 lbs). The hindlimbs were collected via disarticulation of the limb at the level of the hip joint, fixed in 10% phosphate-buffered formalin for at least 5 days, and then stored in 70% ethanol. Following fixation,

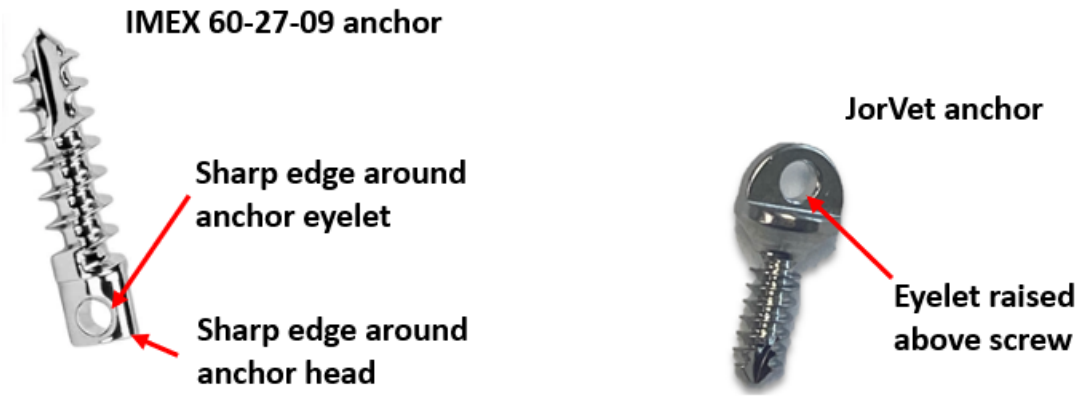

Figure III-III. IMEX 60-27-09 anchor (left) used to attach artificial Achilles tendon. A second raised eyelet design (JorVet 2 mm x 6 mm) used to attach artificial tibialis cranialis tendon is also shown (right).

the hindlimbs were dissected to permit visual inspection of the suture anchor and confirmation of suture breakage in all rabbits. We also determined the mode of suture failure, either at the knot or at the mid-section (i.e., away from the knot).

Data Analysis

The artificial tendon and metallic anchor were visible on radiographs, but not the connecting suture. Thus, failure of the tendon suture anchors by suture breakage was suspected when, qualitatively, the gap length between the artificial tendon and anchor was substantially longer than that observed immediately after surgery. From the digital radiographs, we used image processing software (ImageJ, NIH) to measure the tendon-anchor gap length, defined as the length from the head of anchor to the most distal visible point on the artificial tendon. No tibialis cranialis suture anchor failures occurred; thus, gap lengths were only measured for the Achilles tendon suture anchors. Post-surgery gap lengths were compared to those at the time of surgery to estimate the timing of suture anchor failure, defined as the first radiographic timepoint at which gap length had increased substantially (> 5 mm) compared to the previous timepoint with no return to the previous shorter gap length.

The estimated time of Achilles tendon suture anchor failure was used to perform a survival analysis to determine the probability of failure as a function of time post-surgery. For all samples, we defined suture-anchor failure as the timepoint at which a large gap distance was detected radiographically. The exact time of failure could not be determined because of the pre-determined radiography timepoints. The number of events, cumulative survival, and cumulative failure (1 – cumulative survival) was calculated for each time point using equation 1.

$$cumulative\ survival = \frac{survivals\ at\ time\ point - number\ of\ failures\ at\ time\ point}{survivals\ at\ time\ point} \qquad Eq.1$$

The survival distribution function was calculated by multiplying the cumulative survival rates and plotted against time to obtain a Kaplan-Meier survival curve. We applied the fundamental assumptions of the Kaplan-Meier survival analysis (Etikan et al., 2017).

A non-parametric analysis (two-tailed Mann-Whitney U test) was used to determine the potential effect of two key variables, surgery type (immediate and delayed tendon replacement) and suture size (#1 and #5), on the timing of suture anchor failure. Additionally, the possible effect of surgery type and suture size on the frequency of suture anchor failure was investigated using a Fisher's exact test with the data grouped as number of failures associated with each surgery type and with each suture size. It should be noted that the tendon of the superficial flexor digitorum (SFD) was unintentionally replaced in one rabbits (R4), instead of the Achilles tendon. This rabbit was excluded in the statistical analyses. We also excluded a second rabbit (R12) having a suture anchor with a size 2 suture. Only 8 rabbits with failed suture anchors were included in the statistical analyses (**Table III-I**). For all statistical comparisons, a p-value < 0.05 was considered significant.

C. RESULTS

Radiographs were inspected qualitatively to identify suspected suture failures. Based on this inspection, in vivo failure of the suture used to attach the artificial Achilles tendons was initially

suspected in 9 of the 12 rabbits (**Figures III-IV** and **III-V**). Conversely, there was no qualitative evidence of failure of the suture anchors used for attaching the tibialis cranialis artificial tendons. All specimens were inspected post-mortem by gross dissection. For all available specimens, the failure states (failed or not) of all suture anchors determined by post-mortem dissection were consistent with those determined radiographically (**Figure III-VI**). For all failure cases, the mode of suture anchor failure was suture breakage at the mid-section, i.e., away from the knot (**Table III-I**).

The timepoint at which the substantial increase in gap length was first observed was designated as the failure timepoint. The earliest failure (R1) occurred only 2 weeks after implantation. Three sutures failed at 4 weeks post-implantation (R2, R6, and R12), one at 5 weeks (R9), two at 6 weeks (R5 and R10), and one each at 7 weeks (R8) and 10 weeks (R11) (**Figure III-VII**). In three rabbits (R3, R4 and R7), the suture of the suture anchor did not fail. In some rabbits, gap length continued to increase over time after the suspected failure timepoint. Of the nine suture that failed, the mean failure timepoint was 5.3 ± 2.3 weeks post-surgery, with a range of 2-10 weeks. It should be noted that the tendon of the superficial flexor digitorum (SFD) was unintentionally replaced in R4, instead of the Achilles tendon. This tendon was resected along with the Achilles tendons and placement of the tendon implant failed to sufficiently incorporate the Achilles tendon muscles in this rabbit.

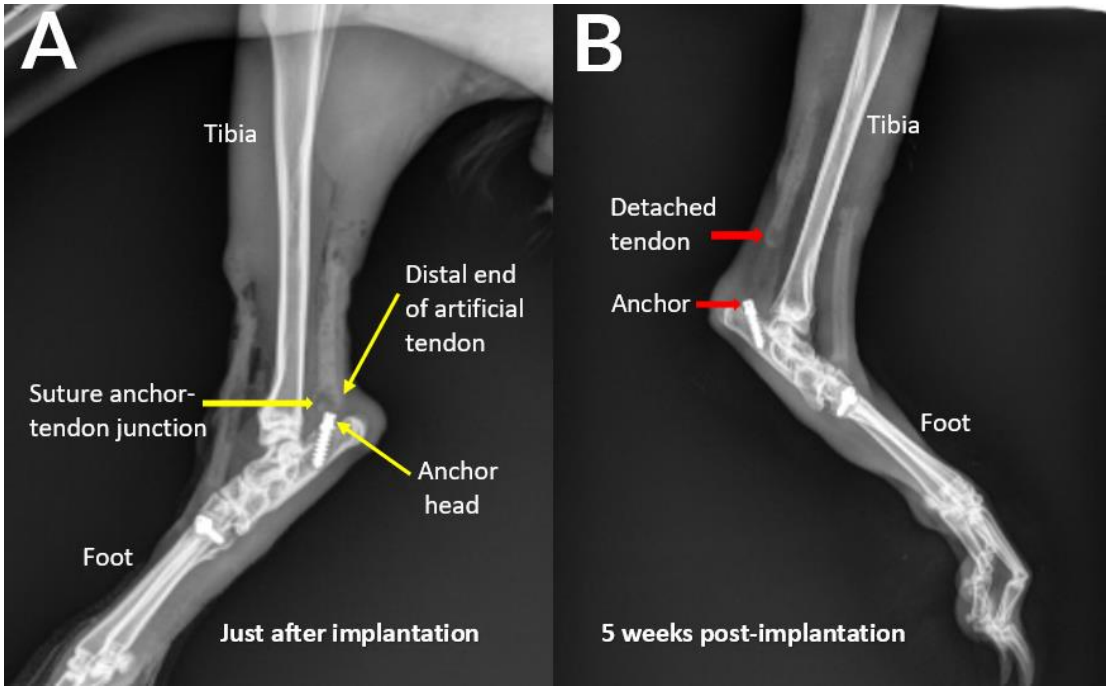

Figure III-IV. Exemplary hindlimb radiographs showing attachment of the artificial tendon just after surgery and detachment of the tendon from the anchor following failure of the suture anchor after five weeks for rabbit R9.

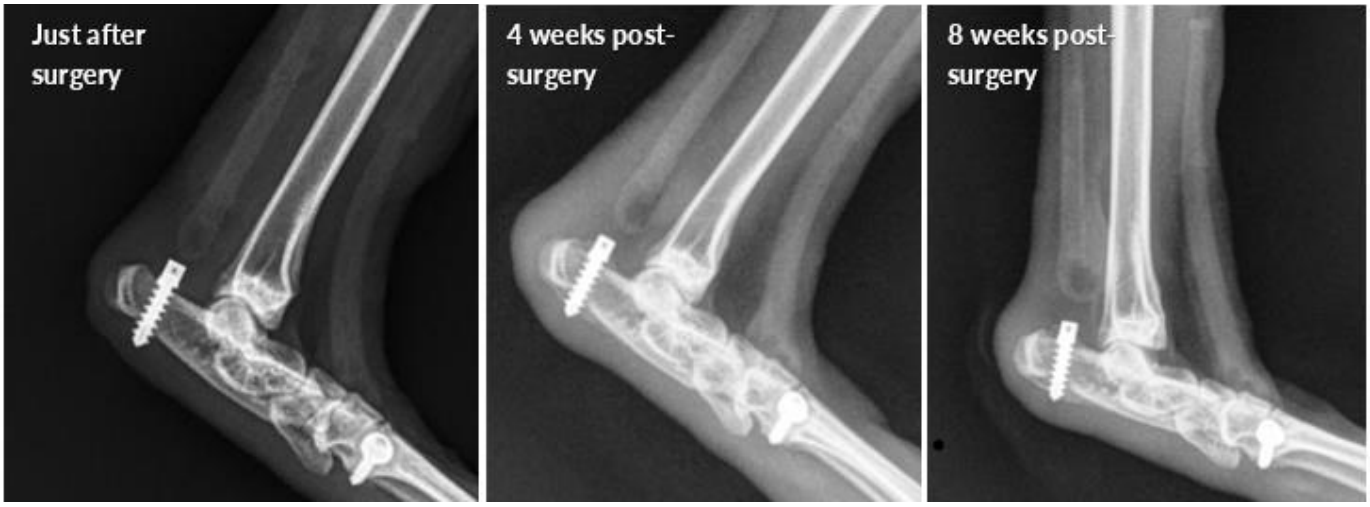

Figure III-V. Hindlimb radiographs from rabbit R11 showing a gradually increasing gap length between the anchor and Achilles artificial tendon.

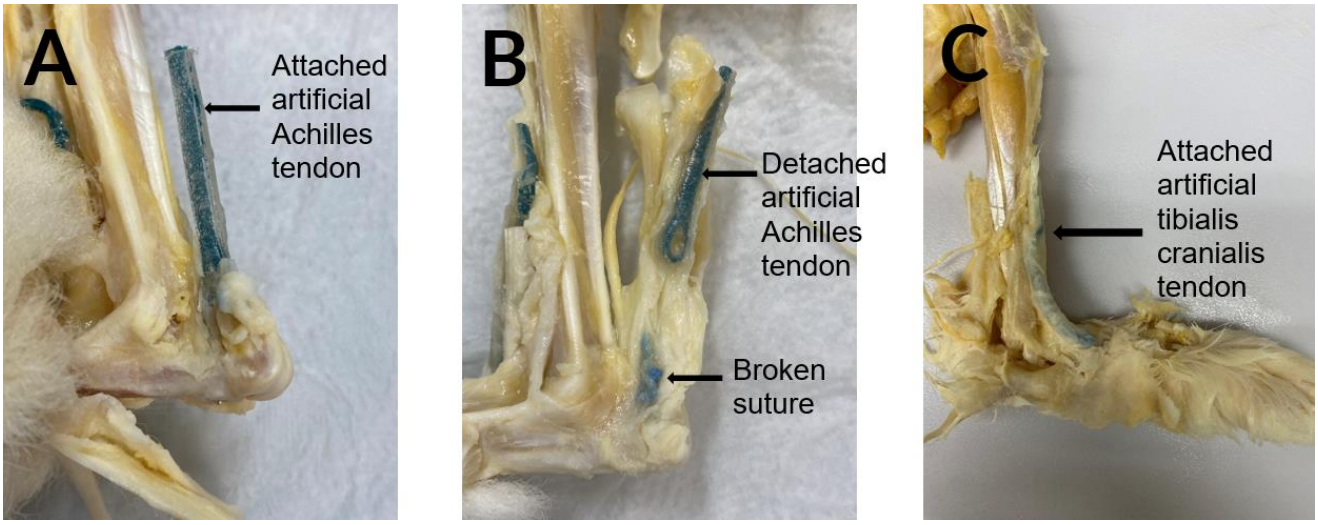

Figure III-VI. (A) Artificial Achilles tendon securely attached to the calcaneus by an intact suture anchor (B) Artificial Achilles tendon detached from a broken suture in a rabbit (C) Artificial tibialis cranialis (TC) tendon still attached to the MT II at end of study. None of the suture anchors used for attaching the artificial TC tendon failed in the rabbits.

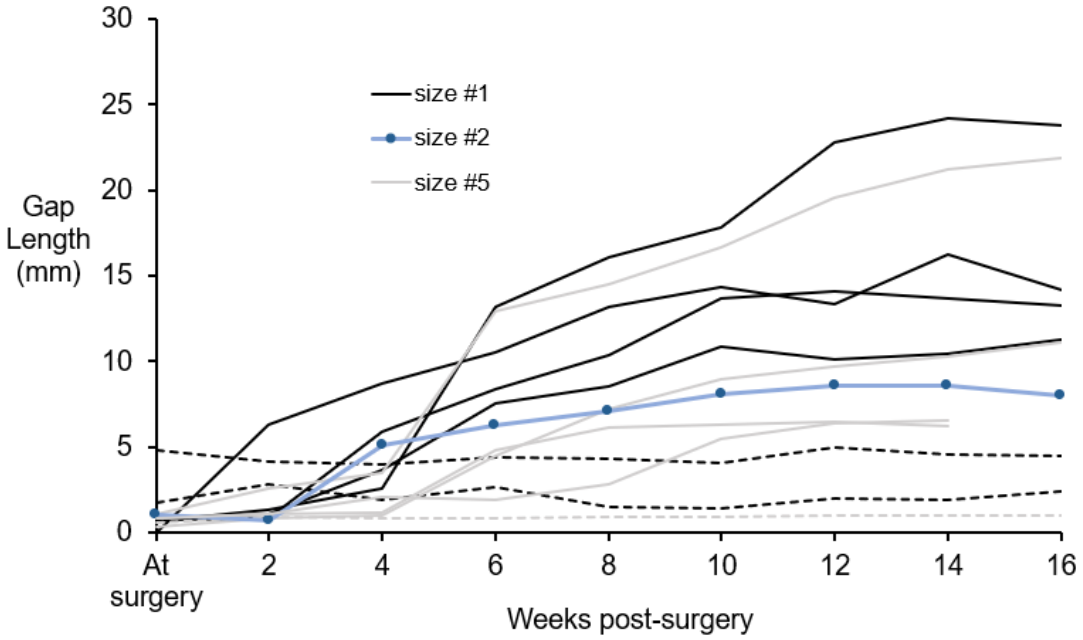

Figure III-VII. Gap length between the anchor and Achilles artificial tendon as measured from radiographs. In nine rabbits, the gap length increased by at least 5mm between two consecutive radiographic timepoints (solid lines); these rabbits were suspected to have suture anchor failure. The gap length remained about the same in three rabbits (dashed lines); these were suspected to have intact suture anchors throughout the entire study. *In R4, the tendon of the superficial flexor digitorum was replaced, instead of the Achilles tendon.

The Kaplan-Meier survival analysis (**Table III-II**, **Figure III-VIII**) revealed that 92 percent of the suture anchors survived beyond the initial two weeks. As time progressed, the survival rate decreased gradually, with 67 percent of the anchors surviving beyond 4 weeks, 58 percent of the anchors surviving beyond 5 weeks, 42 percent surviving for 6 weeks, and 33 percent of the suture anchors surviving beyond seven weeks. Finally, 25 percent of the anchors survived up to the end of the study at 16 weeks.

The two-tailed Mann-Whitney U test revealed no significant difference in effect of implantation timing between the delayed implantation and immediate implantation, $U=8.0$, $p=0.05$, with both groups having the same median score (median = 18). Furthermore, the test also showed no significant difference in effect of suture size between the suture anchors with suture size 1 and suture size 5, $U=2.5$, $p=0.05$, with the suture size 5 group having higher median scores (median = 23.5) than the suture size 1 group (median = 12.5). Similarly, Fisher's exact test indicated no significant effect of implantation timing on frequency of failure ($p=0.071$) and no significant effect of suture size on frequency of failure ($p=0.556$).

D. DISCUSSION

The frequent failures of the Achilles suture anchor-tendon implant linkage were surprising and characterized by a sudden, radiographically apparent, large increase in gap length, followed by gradual continued increase in gap length. The gradual increase in gap length may have been due to shortening of the muscle fibers (Maffulli, 1999; Meyer, Farshad, et al., 2011). Muscles retract after tendon ruptures, with the degree of retraction depending on the muscles involved and the severity of the rupture(Gil-Melgosa et al., 2021; Meyer, Gerber, et al., 2011). Mean gap length of up to 6.0 cm has been reported in cases of distal biceps tendon ruptures

Table III-II: Kaplan-Meier survival rate and distribution function for 12 suture anchors

Time when failure occurred (weeks)	Number of failed suture anchors	Number of censored data	Survival rate of suture anchors	Survival distribution function
0	0	0	1.0000	1.0000
2	1	0	0.9167	0.9167
4	3	0	0.7272	0.6667
5	1	0	0.8750	0.5833
6	2	0	0.7140	0.4165
7	1	0	0.8000	0.3332
10	1	0	0.7500	0.2499
16	0	3	1.0000	0.2499

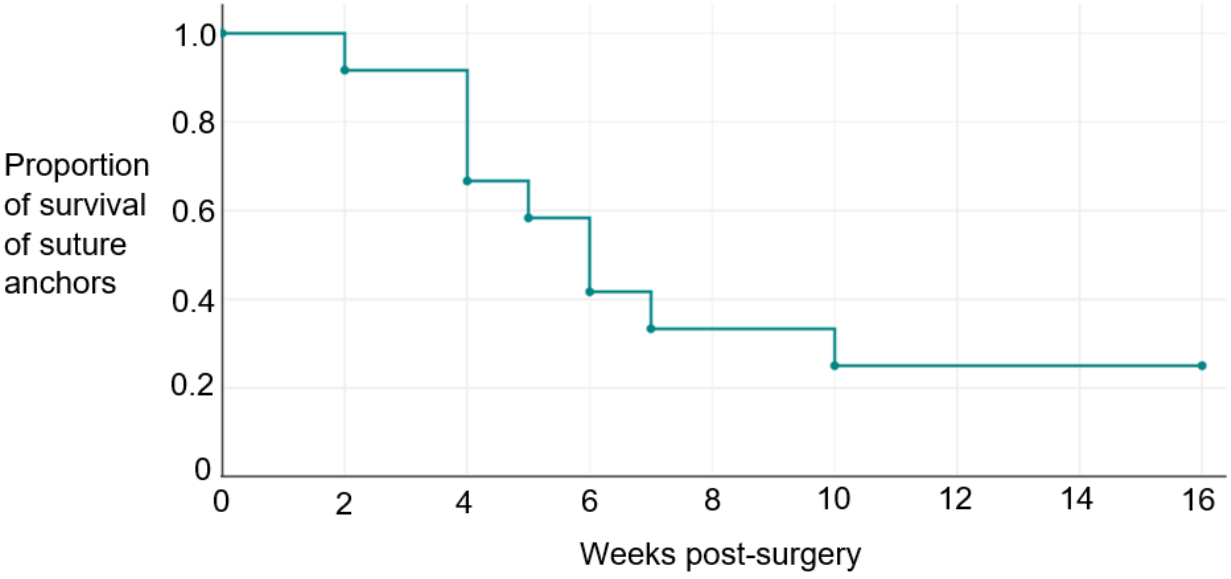

Figure III-VIII. Kaplan-Meier survival curve showing the probability of suture anchor failure at the respective time intervals.

(Samra et al., 2019) and up to 4.8 cm gap length in cases of supraspinatus tendons ruptures (Meyer, Farshad, et al., 2011). The implications of muscle retraction include muscle atrophy, loss of muscle mass and strength, muscle weakness and a loss of tissue quality and quantity, which increase the risk of complications and decrease the success rate of surgical repair (Lakemeier et al., 2010).

The reported suture anchor failures in the study is specific to artificial tendon implantation and may not be generalized to other applications of the suture anchor. The location of suture failure (at the mid-section, away from the knot, in all 9 cases of failure) provides important clues about the cause of failure. The knot is considered the most severe stress point with sutures, and therefore, a weak link in a suture anchor. Therefore, failures at the knot are usually attributed to excessive loading. Conversely suture anchor failure away from the knot suggests wear or abrasion of the suture against part of the anchor. This mode of failure can reduce suture strength by as much as 73% (Meyer et al., 2002). The reduction in strength was presumably more pronounced in our rabbit model when using size #5 sutures, given that the reported in vivo Achilles tendon loading (57.7 ± 0.5 N) was 80% lower than the reported strength of the suture (295 N) (Arthrex Inc, 2014; West et al., 2004).

Suture anchor design, especially the design of the eyelet through which the suture passes, likely played a significant role in the observed failures. The eyelets of suture anchors are generally configured in two ways: either raised above the screw or embedded within the screw. Anchors with raised eyelet designs offer greater versatility because they can accommodate sutures of various sizes. However, this design has drawbacks; a raised eyelet allows relatively unrestricted freedom of suture movement through the eyelet. Conversely, the embedded eyelet design (e.g., Mini Corkscrew AR-1319FT, 2.7 mm x 7 mm, Arthrex Inc., Naples, FL, and the

Anika 2.5 mm MiTi, 2.5 mm X 5.7 mm, Parcus Medical, LLC, FL), while limiting the range of suture sizes that can be accommodated, restricts suture motion through the eyelet. Therefore, sutures may wear more rapidly in suture anchors with raised eyelets than with embedded eyelets; future studies should quantify the effect of suture motion on the extent and rate of suture wear. For long-term fixation, bioabsorbable anchors could be a good alternative to metal anchors. The suture would be integrated with the bone and would not have to rely on the metal anchor for fixation.

With either raised or embedded eyelets, another factor that likely affects suture failure is the sharpness of the eyelet edges. Here we define sharpness as the radius of a corner feature, where a lower radius corresponds to a sharper edge; previous finite element simulations have shown a strong relationship between cutting force and edge radius, though in a different context (blade cutting into soft material) (McCarthy et al., 2010; Schuldt et al., 2016). One study noted that, due to the small size of suture anchors, many have eyelets with sharp edges because their eyelets must be narrow and thin (Meyer et al., 2002), which may cause the suture to wear more rapidly. The suture anchor used in the rabbits had two edges that could be both considered sharp and contacted by the suture in vivo: the edges around the eyelet and the edge around the oval-shaped top of the screw (**Figure III-III**). In previous mechanical tests of suture anchors, edge radius or other potential aspects of sharpness (e.g., wedge angle (McCarthy et al., 2010) were not measured. Future studies should quantify the effect of edge sharpness on suture failure conditions, such as failure load, to inform the design of suture anchors.

Despite having a similar eyelet configuration as the Achilles tendons suture anchor but smaller suture, the tibialis cranialis suture anchors did not fail in any of the 12 rabbits. There are several factors that potentially explain the difference in failure rates between the suture anchors

for the two different artificial tendons. For one, the Achilles tendon is expected to experience greater biomechanical loads than the tibialis cranialis tendon. The triceps surae-Achilles tendon unit provides body weight support against gravity and propels the body during locomotion (Machado et al., 2021); conversely, the tibialis cranialis muscle-tendon unit contributes to foot motion during the swing phase of locomotion (Viidik, 1969). In vivo motion of the artificial tendon and suture relative to the anchor, which could affect wear of the suture against the anchor eyelet, could have been greater for the Achilles tendon than for the tibialis cranialis tendon. Finally, the eyelet design and material characteristics, including the radii (sharpness) and smoothness of edges, could have been more averse to suture durability for the Achilles tendon anchor, but this could be verified in future studies using optical profilometry.

The results of the Mann-Whitney U (non-parametric) and Fisher's exact tests provided further evidence to suggest that the suture breakage was caused in part by wear or abrasion of the suture against the anchor rather than exclusively due to biomechanical overload. These statistical tests found no effect of suture size on the timing or rate of failure. If overloading was the cause of failure, one may expect that failures would occur possibly later or at a lower rate for anchors with larger suture. This is especially true given that, as previously mentioned, the expected in vivo load ((57.7 ± 0.5 N, (West et al., 2004)) was substantially less than the strength of the largest suture used (295 N, (Arthrex Inc, 2014)). Additionally, the Mann-Whitney U and Fisher's tests indicated no effect of the type of surgery (immediate vs. delayed replacement); this result suggests that the failure conditions were similar between the two surgery types.

In the present study, the survival analysis provided information about the likelihood of failure for the suture anchor used in the study along with their corresponding survival rates. The survival analysis of the suture anchors showed that only about 25 per cent of the suture anchors

survived up to 16 weeks post implantation, as verified by postmortem dissection of the limbs. These findings provide valuable insights into the durability and performance of the suture anchors over time, showing the proportion of anchors that effectively withstood the loading conditions in the rabbits post-implantation and for the duration of the study. By incorporating both tabular and graphical representations, this analysis offers a comprehensive understanding of the survival patterns and outcomes of the suture anchors under investigation. It will also assist in making important decisions about our choice of suture anchors for future research.

In order to reattach soft tissues, such tendons and ligaments, to bone, physicians and veterinary surgeons now frequently use suture anchors. Often times, these suture anchors are used in veterinary surgery on the basis of clinician judgement rather than on the recommendations of the manufacturers. In humans and animals, as in our rabbit model, suture anchors are mostly expected to be loaded in a dynamic manner, with changes in both magnitude and orientation of load relative to the anchor. The results of this study shows that the anchors used for attaching the artificial Achilles tendon may not be suitable for this specific application, based on the multiple failures of the sutures of the suture anchors. This observation that could assist surgeons to make important decisions in both human and veterinary surgery so as to prevent costly revision surgeries which may be painful and burdensome to patients.

The primary purpose of a suture anchor is to provide a stable attachment of a soft tissue (such as tendon) to a bone. In the light of this, there are very few studies that have attempted to secure an artificial tendon to bone in an animal model using a suture anchor. More importantly, to the best knowledge of authors, there are limited studies that have secured an artificial Achilles tendon to bone in an animal model, including one in which the tendon prosthesis was secured with a MyoCoupler (Melvin et al., 2003). Therefore, our study forms an important basis for

future research that may attempt to replace the biological Achilles tendon in an animal. Our results highlight some of the challenges in using one type of metallic screw-type anchor for this application. Some studies that have (re)attached soft tissues in animals and the suture anchor they used are presented in **Appendix 1**. In the appendix, we present methods used for bone-tendon attachment for previous polyester artificial tendon studies. However, to the best of authors' knowledge, our study is the first to use a suture anchor for such attachment in animal model.

This study has some limitations. The small sample size may have affected the outcome. Non-standard radiographic positioning may have affected gap measurement. The range of timepoints over which failure occurred (2-10 weeks post-surgery) as well as the standard deviation of the mean failure timepoint (standard deviation was 43% of the mean) were both relatively large. Additionally, the earliest failure timepoint (2 weeks post-surgery) may seem too soon for wear to have occurred. However, previous in vitro mechanical tests observed that, for some suture anchors and loading conditions, the number of loading cycles to failure had similar variability and was low (<10 cycles) (Bardana et al., 2003). The radiographic evaluation time points were pre-planned based on the overall project goals and with the desire to reduce radiation exposure. Given the length of study, imaging every 2 weeks was considered appropriate. The current study of suture anchor failure was retrospective and, thus, we had limited control over the study variables. Variable initial gap length is a potential confounding factor that complicates our comparisons. There was no time-to-failure data upon which to plan more frequent imaging. This is an important consideration for future study planning. Lastly, the study was not designed in such a way as to rigorously compare performance among suture anchors.

The suture anchor we used to attach artificial Achilles tendon to bone failed in 9 of 12 rabbits; no failures were observed for a different suture anchor used to attach tibialis cranialis artificial tendons. All failures of the Achilles tendon suture anchor were characterized by suture breakage at the mid-section (i.e., away from the knot). Based on this failure mode and other aforementioned factors, we suspect that the failures were caused by wear of the suture against an edge of the suture anchor, which reduced the suture strength below in vivo loads. The failures may be partly attributed to the anchor design and to loading conditions. Therefore, the next steps in our study will include (1) measurement of suture anchor design features such as edge radii and (2) replication of the in vivo failures through laboratory testing of the strength of different suture anchors compatible with the rabbit model for attaching artificial tendons. The silicone coating may affect artificial tendon mechanical properties and future studies should investigate this effect.

Chapter IV. Effect of suture anchor type, eyelet configuration, and loading condition on suture failure: an in vitro study

Obinna P. Fidelis, Pierre-Yves Mulon, David E. Anderson, Dustin L. Crouch

This manuscript is currently under review with Veterinary Surgery and has been published in bioRxiv, an online preprint server.

A. INTRODUCTION

Clinically, suture anchors are used to reconnect soft tissues, such as tendons and ligaments, to bone. They can provide fast, dependable, and stable anchoring of the soft tissue, facilitating healing and reunion to the bone (Burnham et al., 2020; Cho et al., 2021; Ravin et al., 2005). The strength of suture anchors is superior to alternative methods for fixing soft tissues to bone, such as bone tunnels, staples, screws, washers, and tapered plugs (Barber et al., 1993). Suture anchors have different designs and use different materials including metals and polymers. They also can be classified as screw-type and non-screw-type (Barber et al., 1995). The screw-type anchors often have larger load-to-failure limits than their non-screw-type equivalents (Barber et al., 2006; Barber et al., 2003). Metallic screw-type suture anchors are frequently used because they are biocompatible, relatively inexpensive, and provide long-term stabilization as the tissue heals (Longo et al., 2019).

Suture anchor failure, either via anchor pullout or suture breakage, is a clinically important concern because failure can result in devasting complications and pose a challenge to the success of orthopaedic surgeries (Ntalos et al., 2021). In a recent study (Fidelis. et al., 2024) we used a veterinary metallic screw-type anchor (2.7 mm x 9 mm, Part No. 60-27-09, IMEX Veterinary

Inc., Longview, TX) with either USP size 1, 2 or 5 braided composite sutures (Fiberwire, Arthrex, Inc., Naples, FL) to attach artificial Achilles tendons to the calcaneus bone in rabbits. In nine of twelve rabbits, the suture failed; the timing of failure were determined to occur within the first 10 weeks after implantation based on radiographic observation and confirmed by post-mortem dissection. In eight of nine specimens with failure, the suture broke at the mid-section, away from the knot. The knot is considered the weakest part of tied sutures and the failure mode distant from the knot suggested that the failure was caused by the suture either wearing or cutting on the edge of the anchor eyelet. This hypothesis is further supported by the fact that the reported average peak Achilles tendon force in laboratory rabbits during hopping (57.7 N, West et al., 2004) is much lower than the reported knot strength (295 N) of the size 5 suture (Arthrex Inc, 2014). Based on our studies and the available literature, further engineering analysis is needed to evaluate risk factors for failure modes.

Several factors, acting either independently or interactively, may have caused the observed suture failures. Two of these factors can be generally categorized as (1) eyelet design and (2) loading conditions. The eyelet is the hole in the anchor through which the suture passes. In most metallic screw-type anchors, the eyelet is either raised above or embedded within the screw. The geometry of the eyelet, including the radius of edges, also can vary among anchors. These eyelet features can affect the relative motion between the suture and anchor as well as the concentration and magnitude of reaction forces (e.g., normal, shear, friction) on the suture. The IMEX veterinary anchor we used in our previous study to attach the artificial Achilles tendon had a raised eyelet, and some edges on the raised post of the anchor near the eyelet have relatively acute, “sharp”, angles. Sharp edges reportedly reduce the failure loads of sutures around the

eyelet by up to 73 percent compared to suture contact with a smooth surface (Meyer et al., 2002; Wasik et al., 2013).

Previous studies investigated the effects of eyelet design and loading conditions on suture anchor strength, but not for select anchors whose sizes we have identified as being compatible with rabbit models used for attaching artificial Achilles tendons to the calcaneus. Since design characteristics and mechanical properties can vary widely among suture anchors, results from a subset of suture anchors may not be able to be generalized to all. Therefore, the objective of our study was to determine the effect of eyelet design and cyclic loading on suture strength for four metallic screw-type suture anchors, two with raised eyelets and two with embedded eyelets, whose sizes are compatible with the rabbit model. An eyebolt with a smooth cylindrical cross-section was used as a control. We hypothesized that 1) the suture anchors with a raised eyelet would have an adverse effect on maximum tensile force at failure (F_{max}) when compared with suture anchors having an embedded eyelet; and 2) cyclical loading would have a more pronounced adverse effect on F_{max} for the suture anchors with a raised eyelet than for the suture anchors with an embedded eyelet; 3) a greater percentage of failure mode would occur at the suture mid-section (i.e., distant from the knot) in the suture anchors with a raised eyelet than in the suture anchors with an embedded eyelet.

B. MATERIALS AND METHODS

Suture Anchors

We tested four screw-type, metallic suture anchors that are of suitable size for attaching artificial Achilles tendons to the calcaneus of a rabbits (**Table IV-I**). Two anchor types had raised eyelets and two anchor types had embedded eyelets. The two anchors with raised eyelets,

Table IV-I. Specifications and features of suture anchors tested in this study.

Category	**Clinical Anchor+Suture Combinations**				**"Best-Case" Reference**
Anchor photo					
Number of samples tested	n=10 (n=5 per loading condition)	n=10 (n=5 per loading condition)	n=10 (n=5 per loading condition)	n=10 (n=5 per loading condition)	n=10 per suture type tested in the clinical anchors (n=30 total)
Approved application	Human or Animal	Human or Animal	Animal only	Animal only	N/A
Anchor name in paper	Arthrex	Anika	IMEX	Jorvet	Eyebolt Screw
Manufacturer	Arthrex, Inc.	Parcus Medical, LLC.	IMEX Veterinary, Inc.	Jorgensen Laboratories, LLC	unknown (sold by Home Depot)
Part number	AR-1319FT	10433	60-27-09	J0836D	unknown
Anchor material	titanium	titanium	stainless steel	stainless steel	stainless steel
Anchor screw dimensions (width x length)	2.7 mm x 7 mm	2.5 mm x 5.7 mm	2.7 mm x 9 mm	2 mm x 6 mm	4 mm x 16 mm
USP suture size	0	2	5		n=10 samples per suture type tested with the clinical anchors
Suture material	*UHMWPE, polyester	UHMWPE, polyblend	UHMWPE, polyester		
Eyelet position	embedded	embedded	raised	raised	raised
Bone block hole diameter (inches)	5/64	5/64	5/64	3.125/64	9/64

*UHMWPE = ultra-high molecular weight polyethylene

both marketed for veterinary use only and made of stainless steel, were used in our previous in vivo rabbit study: one (2.7 mm x 9 mm, Part No. 60-27-09, IMEX Inc., Longview, TX, **Figure IV-I**) to attach an Achilles artificial tendon to the calcaneus bone and the other ("Jorvet" 2 mm x 6mm suture screw, cortical, SKU J0836D, Jorgensen Laboratories LLC., Loveland, CO) to attach a tibialis cranialis artificial tendon to the 5th metatarsal bone. The two anchors with embedded eyelets were made of titanium and marketed for use in humans. Since we suspected that the edges of the raised eyelets may contribute to suture wear during cyclic loading, we used an eyebolt screw (4 mm x 16 mm, Home Depot, Atlanta, GA) whose eyelet had a smooth, circular cross-section (**Table IV-I**) as a control group; the radius of curvature of the eyebolt eyelet was ~3.375mm.

In all anchors, we used the largest suture size that the anchor could accommodate. The Arthrex Mini Corkscrew anchor is typically packaged with a USP size 2-0 braided composite suture, but we manually changed the suture to the largest size that the anchor could accommodate (size 0). For the Anika anchor, we used the suture that was supplied with the anchor (Parcus Braid #2 suture, Anika, Bedford, MA); the suture is composed of ultra-high molecular weight polyethylene (UHMWPE). In all other anchors, we used a #5 braided composite suture composed of a UHMWPE core with a braided polyester covering (Fiberwire, Arthrex, Inc., Naples, FL). All 3 suture sizes were tested using the control eyebolt screw.

Study Design and Sample Population

Each of the four anchors and eyebolt screw listed in **Table IV-I** were subjected to two different loading conditions (n=5 samples per condition): (1) cyclic loading followed by load to failure and (2) single cycle loading to failure. For the Jorvet anchor, five different samples were tested in both loading conditions, due to a relatively short supply of the anchor. For the

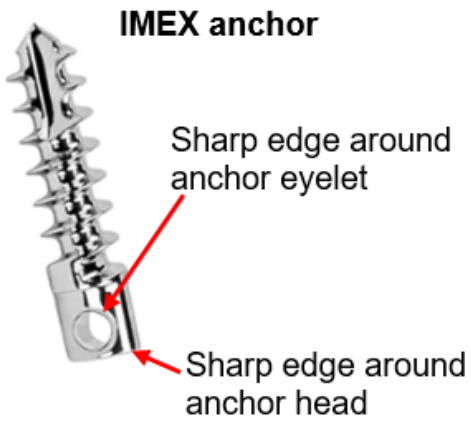

Figure IV-I. IMEX anchor highlighting the sharp edges around the anchor's eyelet and head.

remaining anchors, ten different anchors were used so that each anchor was tested only once. The same five eyebolt screws were used to test both loading conditions for all three suture sizes. The order of anchor or loading condition was not randomized.

The number of samples tested in the study are as follows:

- Arthrex anchor with size 0 suture was tested with cycling (n=5) and without cycling (n=5).
- Anika anchor with size 2 suture was tested with cycling (n=5) and without cycling (n=5).
- IMEX anchor with size 5 suture was tested with cycling (n=5) and without cycling (n=5).
- Jorvet anchor with size 5 suture was tested with cycling (n=5) and without cycling (n=5).
- Eyebolt screw with size 0 suture was tested with cycling (n=5) and without cycling (n=5).
- Eyebolt screw with size 2 suture was tested with cycling (n=5) and without cycling (n=5).
- Eyebolt screw with size 5 suture was tested with cycling (n=5) and without cycling (n=5).
- Total number of samples tested in the study equals to 70.

Mechanical Testing Procedure

Each anchor was screwed into pre-drilled holes (hole diameter listed in **Table IV-I**) on a simulated bone block (PCF 50, density=0.8 g/cm^3, Sawbones, Vashon, WA); the holes were drilled perpendicular to the block surface. We used one hole per anchor per test to avoid poor block-anchor grip. Each anchor was accompanied with a braided composite suture according to the size listed in **Table IV-I**. The suture was tied around a braided polyester rope that represented the artificial tendon but whose diameter (6.5 mm) was substantially larger than that of the artificial tendon to ensure that the suture would fail first, as observed in vivo. The suture was tied with six throws of square knots (Tidwell et al., 2012). All samples were clamped and

tested on a universal material testing machine (Model 5965, Instron Inc., Norwood, MA), that has a load cell with static rating ± 5kN and deflection at force capacity of 0.12 mm.

All loading was applied in line with the central long axis of the suture anchor (180^{o}) as shown in **Figure IV-II**. The suture anchors were preloaded to 60 N, the approximate peak Achilles tendon tensile force in rabbits during hopping gait (West et al., 2004). The samples were then unloaded and preloaded to approximately 1 N prior to testing. For single cycle to failure loading tests, the samples were loaded to failure under continuously increasing force until failure. For samples subjected to the cyclical loading condition, samples were loaded uniaxially for 1000 cycles from 0 N to 60 N, then ramped up to failure. The extension rate for all tests, 4.5 mm/s, was approximately the greatest extension rate that the testing machine could apply and still track the target cyclic load limits accurately. This extension rate was chosen to mimic the rapid extension/loading rate expected in the rabbit hindlimb Achilles tendon during hopping gait.

Statistical Analysis

From the time-series force data for each test, we extracted the maximum tensile force at failure (F_{max}). The Kolmogorov-Smirnov test was used to determine if the standardized residuals of the failure loads for each suture category were normally distributed. An initial two-way analysis of variance (ANOVA) was performed for each suture size category (size 0, 2, and 5) with factors ‘anchor type’ and ‘loading condition’ followed by Tukey HSD pair-wise comparison between each anchor and eyebolt of similar suture size for anchor types and loading conditions. To permit direct comparison among suture anchors with different suture sizes, for each loading condition, we calculated the percent difference in F_{max} for each suture anchor test sample

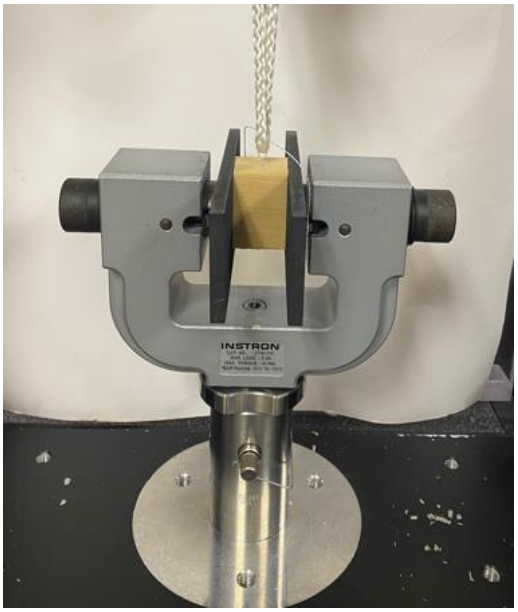

Figure IV-II. Prepared test specimen clamped in the universal material testing machine.

($F_{max,anchor}$) with respect to the mean F_{max} of the eyebolt screw ($\bar{F}_{max,eyebolt}$) with the corresponding suture size:

$$\%\Delta F_{max} = \frac{F_{max,anchor} - \bar{F}_{max,eyebolt}}{\bar{F}_{max,eyebolt}} \times 100 \qquad \text{Equation IV-I}$$

$\%\Delta F_{max}$ indicates the extent to which the suture anchor affects F_{max} relative to the "ideal" eyebolt screw. Using the data calculated from **Equation IV-I**, we performed a second two-way ANOVA test across all anchors with factors "anchor type" and "loading condition", followed by Tukey HSD post-hoc pairwise comparisons. We used IBM SPSS statistics (v.28) to perform the normality test and ANOVA. Fisher's exact test was used to compare the proportion of suture failure modes (suture breakage at "knot" vs "mid-section") among groups. For all statistical comparisons, $p<0.05$ was considered significant.

C. RESULTS

All samples completed 1000 cycles without failure. Furthermore, all suture anchors failed by breakage of the suture rather than anchor pull-out from the bone block. In this way, the failure mode (suture breakage) was consistent with that observed in our previous in vivo study. The results show that for all samples in both loading conditions, the tensile force (load) increased to the maximum and then rapidly dropped after suture breakage (**Figure IV-III**).

The results show that data for F_{max} for each suture category was not significantly different (suture size 0, p=0.084; suture size 2, p=0.200; sutures size 5, p=0.200) from a normal distribution. For the % reduction in suture strength using the F_{max} of the eyebolt corresponding

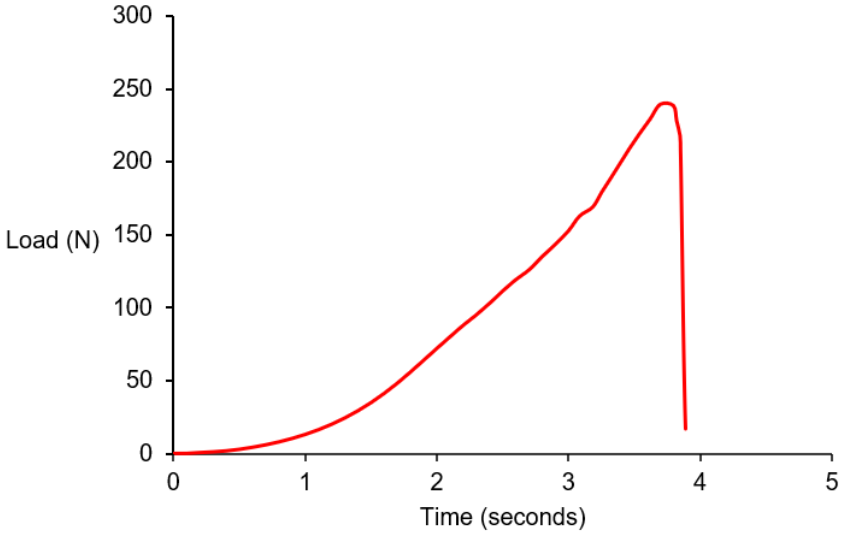

Figure IV-III. Load-time curve of a sample of the Anika anchor loaded to failure without cycling. The maximum tensile force at failure for this sample equals 239.51 N.

to each anchor, the data also was not significantly different from a normal distribution for Arthrex (p=0.138), Anika (p=0.200), IMEX (0.190) and Jorvet (p=0.200).

F_{max} for all anchors and loading conditions exceeded the reported peak Achille tendon force in rabbits during hopping gait (57.7 N, West et al., 2004) (**Figure IV-IV**). As expected, failure loads generally increased with suture size for both loading conditions, from Arthrex through Anika, IMEX and Jorvet (**Figure IV-IV**). The results of the ANOVA of F_{max} for the four anchors with 'anchor' and 'loading conditions' as factors, showed a significant effect of anchor on F_{max} (suture size 0, p<0.001, F=108.825; suture size 2, p=0.001, F=15.394, suture size 5, p<0.001, F=14.861), but no significant effect of loading condition (p=0.862, F=0.031; p=0.373, F=0.841; p=0.212, F=1.644, for suture sizes 0, 2 and 5 respectively). When we compared the suture anchors to the eyebolt screw with corresponding suture sizes, the ANOVA results showed that F_{max} of the anchors were significantly less for the IMEX anchor (with cycling, p=0.002; without cycling, p=0.007) and Jorvet anchor (with cycling, p<0.001; without cycling, p=0.012), but not significantly different for the anchors with embedded eyelets (**Figure IV-IV**).

All $\%\Delta F_{max}$ values were negative, indicating that F_{max} for all suture anchors was always less than that of the eyebolt screw with the corresponding suture size (**Figure IV-V**). There was a significant effect of anchor design (p=0.003, F=5.623) but not loading condition (p=0.808, F=0.060) on $\%\Delta F_{max}$. From post-hoc comparisons, $\%\Delta F_{max}$ was significantly less for the Anika anchor than for the Arthrex (p=0.015), IMEX (p=0.004) and Jorvet (p<0.001) anchors.

All suture anchors failed via suture breakage. For anchors with embedded eyelets (Anika and Arthrex) and the eyebolt screw, the suture broke at the knot in all samples (**Figure IV-VI**).

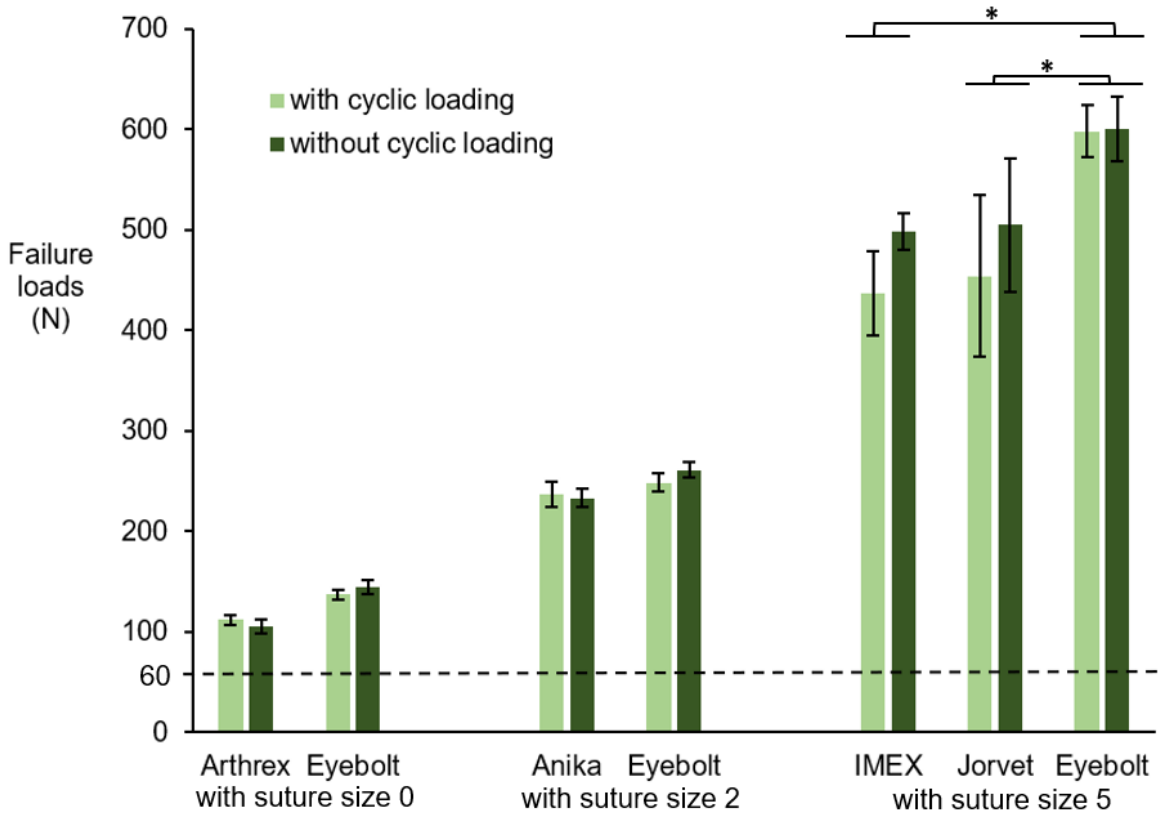

Figure IV-IV. Failure loads of suture anchors compared with eyebolt screws, with accompanying suture sizes (n=5 per device and loading condition). Error bars represent standard deviations. Dashed line represents the reported peak Achilles tendon force in rabbit during hopping gait (West et al., 2004). The suture size used with each device is listed under the anchor name. *p<0.05

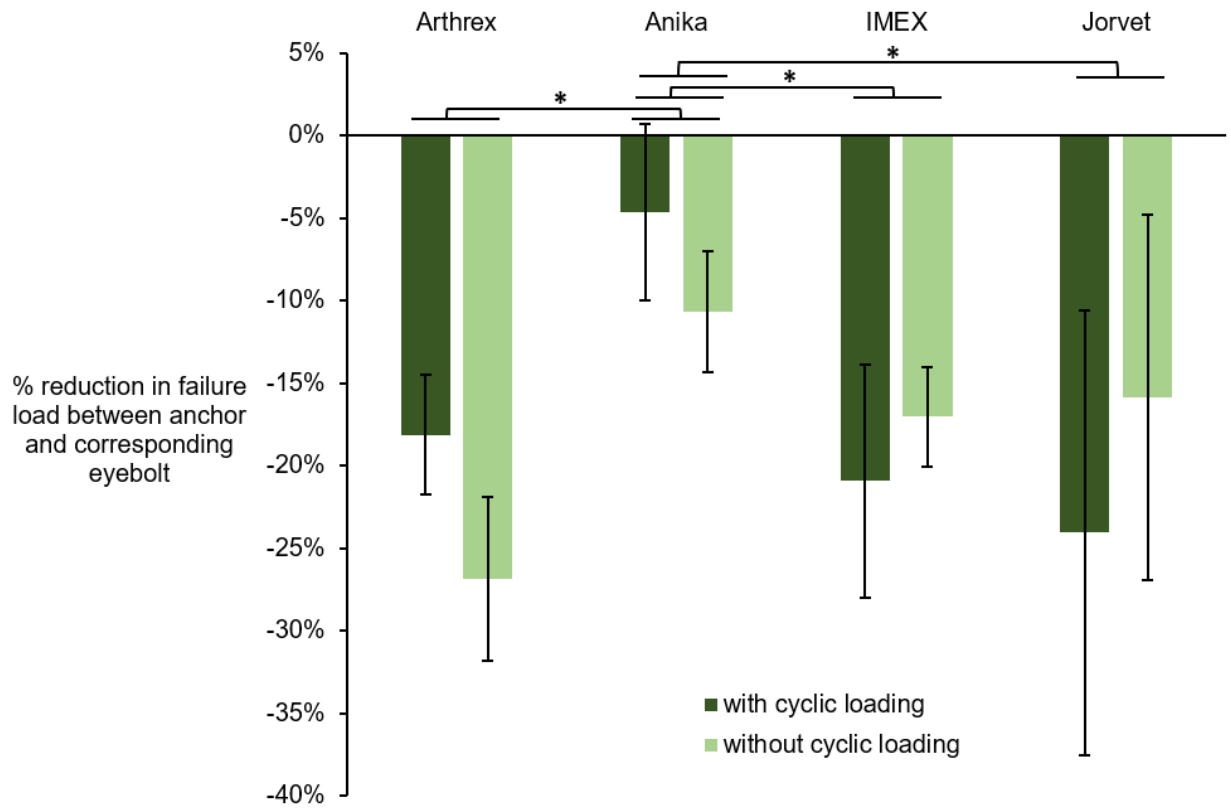

Figure IV-V: Percent difference in failure load between anchor and corresponding eyebolt using matched suture sizes (see Equation 1). Error bars represent standard deviations. *p<0.05

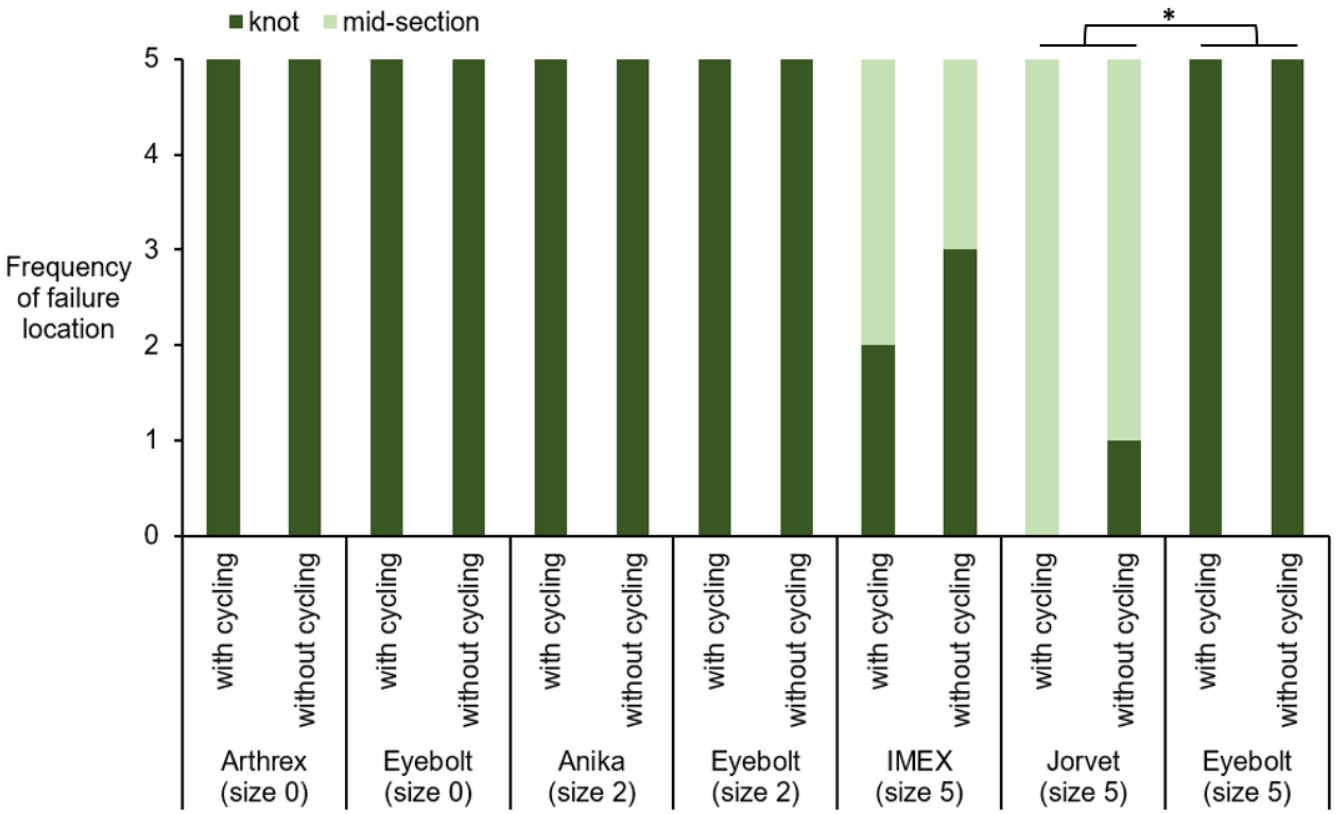

Figure IV-VI. Frequency of suture failure mode (n=5 per device and loading condition). *p<0.05.

However, for the IMEX anchor, the suture failed at the mid-section under cyclic loading (n=2) and without cyclic loading (n=3); the remaining samples failed at the knot. For the Jorvet anchor, the suture broke at the mid-section for all five samples with cyclic loading and four samples without cyclic loading. The proportion of suture failure mode for the Jorvet anchor was significantly different from the corresponding eyebolt, both with cycling ($p=0.024$) and without cycling ($p=0.004$). Conversely, the proportion of suture failure mode for the IMEX anchor was not significantly different from the corresponding eyebolt, both with cycling ($p=0.083$) and without cycling ($p=0.222$).

D. DISCUSSION

Suture anchors are widely used in veterinary medicine (Kunkel et al., 2013; Logothetou et al., 2022; Robb et al., 2005; Rochat, 2016; Simonis et al., 2024; Yoon et al., 2013). In terms of size, the tested anchors were suitable for attaching an experimental artificial Achilles tendon in a rabbit model and, likewise, would be suitable for many other species and applications. Clinical reports of suture anchor failures are limited and highlight other modes of failure, such as anchor pull-out from the bone (Kaar et al., 2001). One possible reason for this gap in the veterinary literature is the challenge of long-term follow-up (Edwards et al., 1993). Nonetheless, the risk of failure by wear and breakage of suture against the anchor eyelet is appreciated in the veterinary literature (Aktay & Kowaleski, 2011; Kunkel et al., 2013). Furthermore, many studies have been dedicated to mechanical testing of suture anchors for veterinary applications (Aktay & Kowaleski, 2011; Balara et al., 2004; GILES III et al., 2008; Kunkel et al., 2013; Robb et al., 2005). Our own previous experience revealed the concerning potential suture breakage for a clinically relevant use case of a veterinary suture anchor (Fidelis. et al., 2024).

Our results generally supported our hypotheses that, compared to anchors with embedded eyelets, anchors with raised eyelets will have a greater adverse effect on F_{max}, a greater effect of cyclic loading (Figure 5), and more frequent failures at the suture mid-section. One notable exception was that $\%\Delta F_{max}$ for the Arthrex anchor was significantly greater than that of the Anika anchor and about the same as that of the two anchors with embedded eyelets. Nonetheless, anchors with raised eyelets may have design features that have a greater adverse effect on suture wear and strength than the anchors with embedded eyelets, depending on the application. For example, the suture path through raised eyelets is less tortuous than through embedded eyelets. Thus, sutures in raised eyelets may experience more relative motion, greater focused points of strain, and friction against edges leading to more rapid suture wear. Given the more tortuous path, sutures in embedded eyelets may contact the anchor over a larger surface area and, thus, have greater load distribution (i.e., less load concentration). Finally, the tested anchors with raised eyelets may have had edges with smaller radii, which would also cause greater load concentration on the suture. Greater concentration of load on the suture is expected to result in greater suture wear due to greater friction force and increased probability of mid-section failure of the suture. To confirm these hypotheses, future studies should quantify the geometry of the suture anchors and relative motion between the suture and anchor during cyclic loading. Additionally, computational finite-element analysis may enable estimation of suture force magnitude, direction, and distribution for different anchors and loading conditions.

The clinical implications of our results may be case-dependent. For example, if the suture anchor is used to support high but relatively static loads, anchors with raised eyelets may be better since they can accommodate larger suture. Conversely, for applications in which load magnitude and/or direction are relatively dynamic, anchors with embedded eyelets may be

preferred. The ideal anchor design would be one with a large, embedded eyelet that can accommodate a large suture. However, such anchors may be contraindicated in applications requiring anchors with small diameters. Additionally, anchors with embedded eyelets are more complex and expensive to manufacture and, thus, may be cost-prohibitive for some veterinary applications.

Our results only partly explain the suture anchor failures experienced in our previous in vivo study (Fidelis. et al., 2024). The mechanical testing showed that IMEX suture anchors may be more prone to suture failure at the mid-section. However, the IMEX failure load exceeded those expected during in vivo peak Achilles tendon load by a factor of 8, and with no significant effect of cyclic loading. There are a few factors that may explain the discrepancy between the in vivo study and mechanical tests. For example, in our mechanical tests, the direction of the load was static. Conversely, in vivo, the suture anchors likely experienced more dynamic loading conditions, including simultaneous changes in magnitude and/or direction of tendon force relative to the suture anchor, due to dynamic ankle motion, muscle force, and external loads (i.e., ground reaction forces). Such dynamic loading may cause considerably more rubbing and wear of the suture against the anchor than we observed in our mechanical tests. A related factor is the orientation of the suture anchor relative to the bone, which affects the direction of tendon load on the suture anchor; significant detrimental effects of anchor angulation and rotation on suture abrasion have been reported in a previous study (Bardana et al., 2003). In our in vivo model, the anchors were typically inserted at an angle to the calcaneus bone surface, though it is not clear if and by how much the anchors rotated in the bone.

An important consideration for selecting a suture anchor is the application or conditions for which it is designed, tested, and used. Limited manufacturer information exists for individual products regarding use of suture anchors marketed for veterinary applications. Detailed information regarding case outcomes is lacking and the use of raised eyelet suture anchors may need to be more specifically studied relative to indications and applications best suited to their use. (IMEX Veterinary Inc.) In our experience, use of these anchors may not be suitable for (re)attachment of the Achilles tendon to the calcaneus. Previous research had indicated a connection between application and anchor strength (Barber et al., 1993), stating for example that when immobilization following surgery is required and possible, the initial strength requirement of the suture anchorage may be small compared to those situations were immediate motion is required.

Several studies have characterized the ultimate strength or fatigue strength of suture anchors and in different applications including repair of anterior Bankart lesions, stabilization of anterior labral lesions, stabilization of canine hip joint luxation, rotator cuff repair and glenoid labral repair (Burkhart et al., 1997; Cummins & Murrell, 2003; Mueller et al., 2005; Nho et al., 2010; Rudzki et al., 2004). These tests were either with cyclic loading or without cycling. Failure in cyclic loading occurs due to material fatigue caused by repeated loading and unloading cycles and this test is used to determine the fatigue strength and fatigue life of a material whereas uniaxial load to failure is used to assess the acute mechanical strength of a material (McFarland et al., 2005). In humans and animals, as in our rabbit model, suture anchors are mostly expected to be loaded in a dynamic manner, with changes in both magnitude and orientation of load relative to the anchor. However, in most laboratory testing of these anchors, the loading conditions are static and uniaxial, with or without cycling (Bardana et al., 2003; Deakin et al.,

2005; Meyer et al., 2003). One study that involved dynamic loading did not measure strength of the anchor but rather evaluated two surgical techniques, with different number of anchors and anchor orientation (Garcia et al., 2013). To ensure that suture anchors are safe and effective, more research is needed to quantify the in vivo dynamic loading conditions for different clinical applications of suture anchors and the effect of such dynamic loading conditions on suture anchor construct strength and durability.

Use of a synthetic bone block for testing the suture anchor is well established (Bardana et al., 2003; Green et al., 2014; Lo et al., 2004; Meyer et al., 2003). Compared to biological bone specimens, bone blocks have fewer variable properties, eliminate animal and cadaver use, and make the results more generalizable rather than specific to the tested species and tissue. Additionally, in both the bone blocks and our previous in vivo study, we did not observe any failures or displacement at the bone-anchor interface. Therefore, the use of bone block is suitable for use in studying the suture-anchor interface in mechanical testing.

Our study had several limitations. The number of suture anchors and number of samples of each anchor included in our study were relatively small. Also, the number of loading cycles was based on a rough estimate of the number of hopping gait cycles in rabbits (Bohannon, 2007; Dutta & Sengupta, 2018); in future studies, we plan to obtain a better estimate by instrumenting the rabbits with motion sensors. We tested anchors with different suture sizes, which was a confounding factor for comparing F_{max} across anchor-suture combinations and limited our statistical comparisons. Though we observed some suture failures at the mid-section away from the knot, we did not visualize or record the failures to determine whether the failure point was against the anchor eyelet or elsewhere. Additionally, the depth of insertion of the anchor in the simulated bone block may have differed from depth used in our previous in vivo work (Barber et

al., 2006). Anchor depth has been implicated in the mechanical performance of suture anchors with deep sitting anchors reported to have higher failure loads and significantly different modes of failure compared with anchors with eyelets sitting above the bone (Bynum et al., 2005). Current raised eyelet suture anchors are difficult, if not impossible, to fully insert into small bones and in many applications in small sized animals. Lastly, the conditioned and controlled laboratory conditions under which the mechanical testing was performed differ from the biological environment in which suture anchors are used clinically.

Of the tested anchors, the Anika anchor had the least adverse effect on the strength of the accompanying suture. It may also be inferred that raised eyelets are more likely to fail at the suture mid-section, which is indicative of suture wear or cutting against the anchor eyelet, compared with embedded eyelets. Our results did not explain the premature suture anchor failures we observed in our previous study since, for all anchors, F_{max} exceeded the measured Achilles tendon force in rabbits during level hopping. Future studies of suture anchors are needed to determine the influence of dynamic loading and its interaction with other factors such as eyelet position and geometry, on the strength and durability of the suture.

CHAPTER V. Replacing biological Achilles tendon with polyester suture-based silicone coated artificial tendon: effects on hindlimb movement biomechanics and muscle morphology in rabbits.

A. INTRODUCTION

The Achilles tendon is the strongest and largest, yet most frequently ruptured, tendon in humans, accounting for up to 20 percent of all large tendon ruptures (Gillies & Chalmers, 1970; Park et al., 2020; Ponkilainen et al., 2022). Approximately 80 percent of all Achilles tendon ruptures can be attributed to participation in sports. In the general, non-athletic population, the prevalence of Achilles tendon rupture is approximately 1 percent (Wu et al., 2017). Tendon ruptures are treated with primary repair. However, critically sized ruptures (with gaps too large to bridge through primary repair), are treated surgically and with the use of tendon grafts (Ahmad et al., 2016; Lin et al., 2016). Between 2005-2011, about 5.5% of Achilles tendon ruptures in the United States was treated with tendon grafts (Erickson et al., 2014). About 78% of patients treated with grafts following Achilles tendon ruptures were reported to have no activity limitations while 48% returned to sports at an average of 22.6 weeks post-surgery (Maffulli et al., 2023). However, challenges including donor site morbidity, risk of disease transmission, unavailability of tendon graft and potential mismatch of graft length and size may limit the outcome of this method (Maffulli et al., 2023; Shearn et al., 2011).

For repairing critically sized tendon defects, artificial tendons are a potentially attractive alternative to tendon grafts for many reasons. For example, artificial tendons could avoid many of the problems associated with tendon grafts such as rejection, disease transmission, donor site morbidity, and limited donor availability. Additionally, the size of the artificial tendon can be customized for each patient. Development and testing of artificial tendons dates as far back as

the early 1900s and have been made from materials such as silk, rubber, braided tantalum, nylon monofilament covered with polyethylene, woven Teflon, Dacron, carbon fiber and polyester (Murray & Semple, 1979). In many of the previous studies on tendon prosthesis, fibrous tissue formation which eventually led to implant failure, weak anchorage, adhesion at tendon-prosthesis junction, all constituted major challenges (Grau, 1958; King et al., 1975; Williams & August, 1964). In previous studies (Melvin et al., 2011; Melvin et al., 2010; Melvin et al., 2012), artificial tendon consisting of braided strands of polyester microfiber suture was used to replace the quadricep tendon in a goat. The tendon formed a myotendinous junction, which was reported to be stronger than the biological myotendinous junction, and did not compromise vascularity in the goat for up to 180 days. It also facilitated tissue integration without microencapsulation.

A major limitation of the previous in vivo studies on polyester artificial tendons is that they did not investigate the effect of artificial tendons on movement biomechanics or muscle properties. Tendons have various effects on musculoskeletal biomechanics, including the ability to store and release elastic energy, function as shock absorbers to protect muscles from injury, and transmit forces from muscles to bones to enable joint mobility (Jin & Dowson, 2013; Kirkendall & Garrett, 1997; Wang et al., 2012). Because muscle function is affected by the mechanical characteristics of tendons, assessing movement biomechanics and muscle properties in experimental models would provide a quantitative evaluation of the performance of the artificial tendon. In a recent study (Easton et al., 2024), biological tibialis cranialis tendons in New Zealand White (NZW) rabbits were replaced with polyester silicone-coated (PET-SI) artificial tendons and the movement biomechanics was quantified for the rabbits that had tendon excision and replacement with artificial tendons compared with rabbits that had tendon excision

only. Overall, the results suggest that the artificial tendon successfully replaced the biomechanical function of the native tendon.

The purpose of the current study was to examine how the functional biomechanics and muscle properties of the hind limb in NZW rabbits are affected by critically sized Achilles tendon defects treated with artificial tendon. Since the Achilles tendon is an ankle plantar flexor, we hypothesized that rabbits with an artificial Achilles tendon would have greater ankle range of motion and maximum ankle plantarflexion angle during the swing phase of gait, compared to rabbits with Achilles tendon excision only. We also hypothesized that muscle cross-sectional area, muscle mass and muscle length would be greater in the rabbits with artificial Achilles tendon compared to the rabbits with tendon excision only.

B. MATERIALS AND METHODS

Artificial Achilles tendon

The artificial Achilles tendon consisted of three strands of custom double-armed size 0 braided polyester suture (RK Manufacturing, Danbury, CT, USA) and is based on a previously published design (Melvin et al., 2012). Artificial Achilles tendons were made using three suture strands that were folded in half to form a loop at the mid-point, then braided to the desired length, yielding 6 suture threads for muscle attachment. The proximal end had swaged needles on each strand for suturing the tendon to muscle, while the folded distal end created a loop to aid attachment to bone using a suture anchor (**Figure V-I**). At the start of braiding, the sutures were fastened around a cylindrical pipe to create the looped end of the tendon. The length of the biological tendon that we measured during previous surgeries was used to estimate the length of the braided portion of the artificial Achilles tendon. We made artificial tendons of different

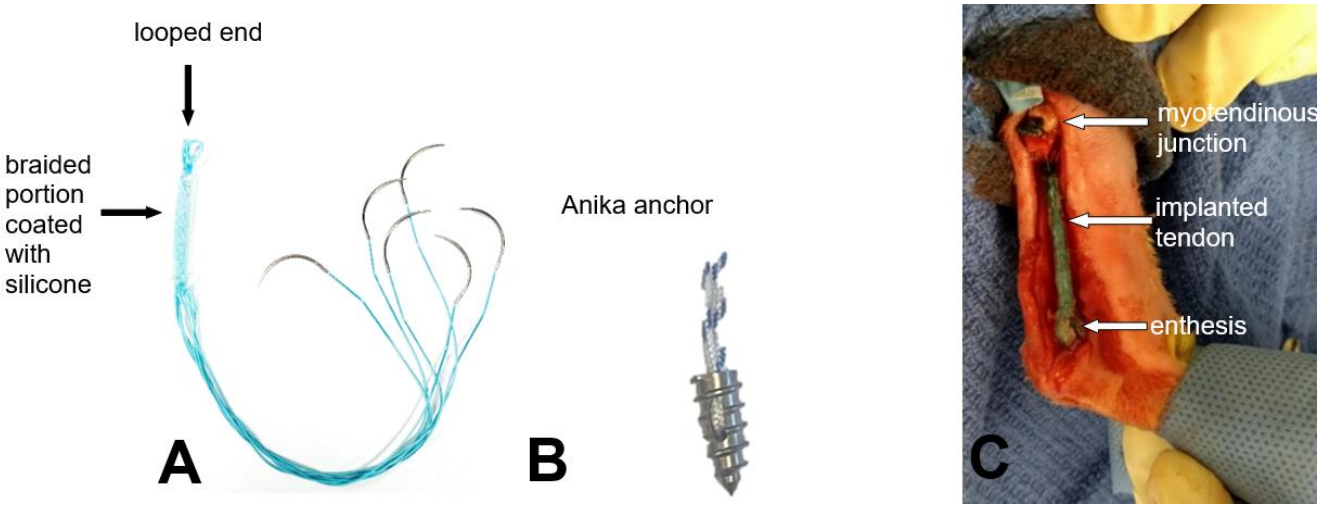

Figure V-I. (A) Polyester silicone-coated artificial Achilles tendon prior to implantation. (B) Anika anchor used to attach artificial tendon to calcaneus. (C) Artificial Achilles tendon implanted in the left hindlimb of a rabbit.

lengths. Medical-grade biocompatible silicone (LSR-4301 silicone elastomer, Factor II, Inc., Lakeside, AZ, USA) was applied to the braided portion of the artificial tendon in order to prevent tissue adhesion in vivo. Two parts of the silicone were manually combined in a cup (ratio 1:1) and stirred for up to five minutes. To remove air bubbles, the silicone mixture was centrifuged at 4900 rpm for 4 minutes. The mixture was then applied to the braided section of the artificial tendon, covering the braided suture with a thin, consistent layer of silicone. Preparatory to surgery, we cleaned the artificial tendons in an ultrasonic cleaner (Model: JPS-08A) and sterilized them with hydrogen peroxide gas.

Animal Handling and Surgery

The study included ten female NZW rabbits (Robinson Services Inc, USA) with mean age at surgery = 18.18 ± 1.89 weeks and body weight = 3.34 ± 0.21 kg and randomly assigned to either the "tendon excision only" group (TE, n=5) or the group with excision and replacement with the polyester, silicone-coated artificial tendon (PET-SI, n=5). The Institutional Animal Care and Use Committee at the University of Tennessee Knoxville approved all animal procedure (protocol #2726). We housed the rabbits individually, allowed acclimatized for a minimum of 2 weeks prior to surgery and ensured that they were fed *ad libitum* with a standard laboratory diet, Timothy hay, and daily greens; and given daily positive human interaction and enrichment. In addition, the rabbits received playpen time twice weekly for at least 10 minutes prior to surgery and starting 2 weeks post-surgery.

Prior to surgery, the rabbits were given hydromorphone (0.1 mg/kg IM) as a pre-operative analgesic, sedated with midazolam (1 mg/kg IM), and induced into general anesthesia with isoflurane via face mask. Then they were intubated while positioned in right lateral dorsal

oblique recumbency. General anesthesia was maintained with isoflurane gas vaporized in 100% oxygen. We administered a loading dose of lidocaine (2 mg/kg IV), followed by a lidocaine CRI (50 mcg/kg/min IV) with isotonic fluids at a rate of 30 ml/h IV throughout the procedure. After shaving, the left hind limb was suspended, and aseptically prepared for surgery with 70% isopropyl alcohol and 2% chlorhexidine scrub. Just before the start of surgery, a second dose of hydromorphone (0.05 mg/kg IM) was administered.

In the TE group, a caudolateral longitudinal skin incision was made over the Achilles tendon using a #10 scalpel blade, extending from mid-tibia to the calcaneus. The skin was retracted to expose the tendon and the calcaneus. The Achilles tendon (fused tendons of the Gastrocnemius and Soleus muscles) was released by cutting it at its insertion, taking care to preserve the overlying tendon of the superficial digital flexor muscle. The Achilles tendon was then excised by cutting it at the musculotendinous junction. The subcutaneous layer was closed with a simple continuous pattern with 4-0 PDS. The skin was then closed with an intradermal pattern with 4-0 PDS.

In the PET-SI group, a caudolateral longitudinal skin incision was made over the Achilles tendon, extending from mid-tibia to the calcaneus. The skin was retracted to expose the tendon and the calcaneus. The gap length between the musculotendinous junction and the tendon point of insertion was measured intraoperatively and we selected an artificial tendon that was about 15% shorter than the biological tendon. The Achilles tendon (fused tendons of the gastrocnemius and soleus muscles) was released by cutting it at its insertion, taking care to preserve the overlying tendon of the superficial digital flexor muscle. A guide hole was pre-drilled with a 1.7 mm drill bit into the dorsal aspect of the calcaneus at the insertion of the Achilles tendon. A

Parcus Anika bone anchor (2.5 mm MiTi, 2.5 mm x 5.7 mm, Parcus Medical, LLC, Sarasota, FL, **Figure V-I**), with 2 pre-threaded #2 custom suture, was screwed into the hole until finger tight. The looped, distal end of an artificial tendon coated with silicone (6 strands of silicone coated braided #0 polyester suture) was sutured to the anchor using the pre-threaded size 2 Fiberwire suture. The free ends of the artificial tendon were inserted through the distal end and passed through the muscle using a single suture loop pattern in the gastrocnemius and soleus muscles and exited from the side of the muscles about 1 cm proximal to the distal ends (Rawson et al., 2013). Adjacent suture strings were tied together using six throws. The excess suture was cut and removed. The biological Achilles tendon was excised by cutting it at the musculotendinous junction (**Figure V-I**). The cut distal cut edge of the muscles were sutured around the proximal end of the artificial tendon with 4-0 PDS. The subcutaneous layer was closed with a simple continuous pattern with 4-0 PDS. The skin was then closed with an intradermal pattern with 4-0 PDS.

Post-surgical laser therapy was performed with a MultiRadiance ACTIVet Pro: 1000 Hz for 1 min, 50 Hz for 1 min, and 1000-3000 Hz for 1 min. A bandage was then placed on the limb. Hindlimb radiographs were taken immediately post-surgery and approximately every 2 weeks post-surgery.

The rabbits were administered meloxicam (1 mg/kg SC) and enrofloxacin (5 mg/kg SC, diluted in 6 ml of sterile saline) immediately following surgery. We bandaged the operated limb for three days post-operatively, with silver sulfadiazine topical cream applied to the surgical incisions. Post-operative care included hydromorphone (1 mg/kg IM, every 6 hours for 3 days), enrofloxacin (5 mg/kg PO, every 12 hours for 7 days), and meloxicam (1 mg/kg PO, every 24

hours for 7 days). Additionally, lactated Ringer's solution (150 ml SC) was administered twice daily, beginning the day after surgery and continuing for a total of 5 doses.

Data collection

Hindlimb kinematics and ground contact pressure were measured once pre-surgery and every other week post-surgery. Prior to surgery and data recording, rabbits were trained to hop along a 2.6 m-long walkway for approximately 2 weeks. For each data collection session, we shaved the left lateral side of the rabbits, then placed reflective, flat circular markers (7.5 mm diameter) on the lateral side of the left limb at the hip (greater trochanter), knee, ankle (lateral malleolus), and 5th metatarsophalangeal (MTP) joint (**Figure V-II**). Hindlimb kinematics were captured by video of the rabbits hopping on the walkway with seven high-speed cameras (Prime 13, OptiTrack, NaturalPoint, Inc, Corvallis, OR, USA) that were placed equally spaced apart along one side of the walkway in order to capture sagittal plane motion as the rabbit hopped from one end of the walkway to the opposite end. Ground contact pressures were recorded along the walkway using a pressure sensitive mat that had an active high-resolution pressure sensing area of 1.3 m (2-Tile High-Resolution Strideway System, Tekscan, Norwood, MA, USA). Pressure and video data were recorded synchronously at 240 Hz.

We used medical diagnostic ultrasound imaging to record pictures and videos of the tibialis cranialis and lateral gastrocnemius muscles in the left (operated) hindlimb. The muscles were imaged four days before surgery (baseline) and approximately every other week post-surgery, until the end of study. The hindlimb was first shaved to allow improved scanning with the ultrasound probe. An ultrasound gel was applied to the probe to increase visibility of the internal muscles. For each muscle and imaging session, we collected at least three images that were clear and captured the entire muscle cross-section.

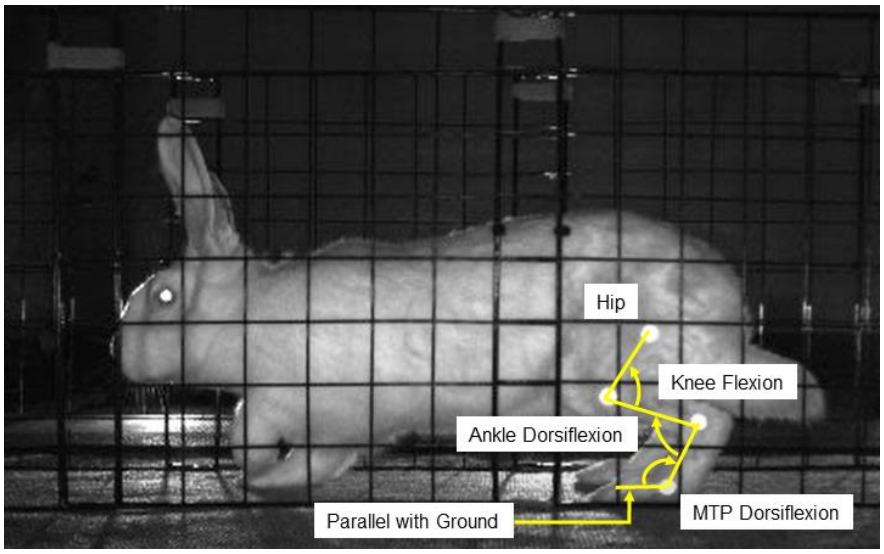

Figure V-II: A rabbit hopping on the walkway. Flat circular markers located at the hip, knee, ankle, and MTP are depicted by bright white dots. Arrows indicate direction of joint flexion (Easton et al., 2024).

At the end of the study (8-weeks post-surgery), the rabbits were humanely euthanized. The hindlimbs were collected via disarticulation of the limb at the level of the hip joint, fixed in 10% phosphate-buffered formalin for at least 5 days, and then stored in 70% ethanol. Following fixation, the hindlimbs were dissected to permit visual inspection of the suture anchor and confirmation (or not) of suture breakage in all rabbits. The involved muscles [lateral gastrocnemius (LG), medial gastrocnemius (MG), and soleus (Sol)] and select uninvolved muscles [tibialis cranialis (TC), extensor digitorum (ED) and superficial flexor digitorum (FD)] crossing the ankle were dissected from their origin to the myotendinous junction (**Figure V-III**). For each muscle, mass and length were normalized by body mass and tibia length, respectively.

Data analysis

We used pressure analysis software (Strideway 7.80, Tekscan, Norwood, MA, USA) and custom written MATLAB scripts (MATLAB 2024a, MathWorks, Natick, MA, USA) to process pressure data. The videos were exported from the motion capture software (Motive: Tracker 1.9, OptiTrack, NaturalPoint, Inc. Corvallis, OR, USA) and converted into Tekscan-readable format using a custom written python script. The purpose of this conversion was to synch the videos with rabbit paw pressure map in Tekscan. Joint angles (knee, ankle and metatarsal phalangeal (MTP)) during stance and swing were calculated in the Motive software using the dot products of joint markers and a ground plane. Joint angles for the knee, ankle and MTP in the stance and swing phase of gait were calculated from joint angle timeseries data, measured for each gait cycle and averaged across cycles. The joint angles are presented as maximum angle (i.e., joint angle at maximum stance/swing), minimum angle (i.e., joint angle at minimum stance/swing) as well as range of motion (ROM, the difference between the maximum angle and minimum angle).

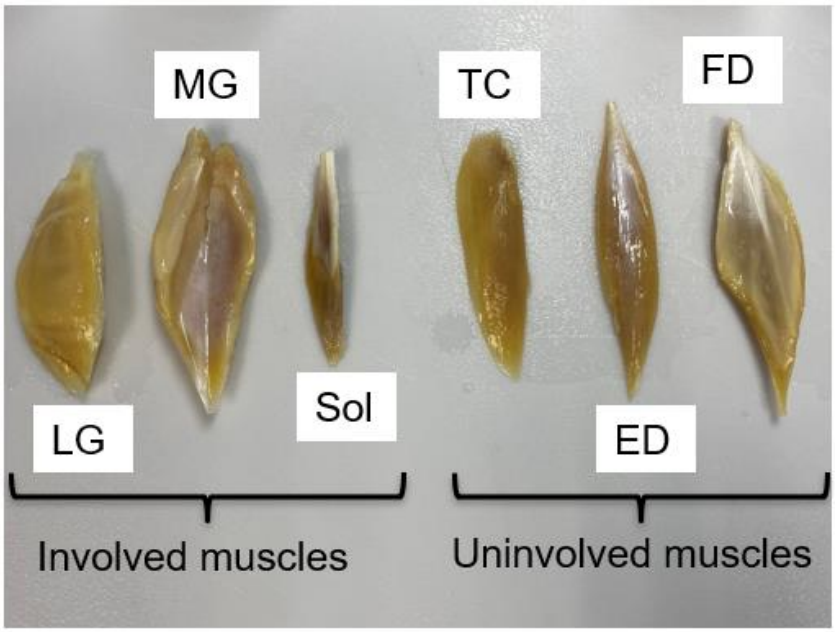

Figure V-III. Muscles dissected from the rabbit's hindlimbs for which mass and length were measured.

Statistical analysis software (SPSS IBM Statistics v.28) was used to perform a two-factor (group, timepoint, and their interaction) analysis of variance (ANOVA) with repeated measures (rabbit). A p-value < 0.05 was used to determine any significant differences. Groups included "TE" and "PET-SI", and timepoint included "baseline" (pre-surgery), "2 weeks post-surgery", and 8 weeks post-surgery". Tukey HSD test was used for post-hoc pairwise comparisons. A total of ten different comparisons were made between the groups and timepoints as follow:

- Weeks Post-Surgery
    - Baseline vs. 2 weeks post-surgery
    - Baseline vs. 8 weeks post-surgery
    - 2 weeks post-surgery vs. 8 weeks post-surgery
- Group x Weeks Post-Surgery
    - TE baseline vs PET-SI baseline
    - TE baseline vs. TE 2 weeks post-surgery
    - TE baseline vs. TE 8 weeks post-surgery
    - TE 2 weeks post-surgery vs. TE 8 weeks post-surgery
    - PET-SI baseline vs. PET-SI 2 weeks post-surgery
    - PET-SI baseline vs. PET-SI 8 weeks post-surgery
    - PET-SI 2 weeks post-surgery vs. PET-SI 8 weeks post-surgery

Muscle cross-sectional area CSA was measured from the ultrasound image using image processing software (ImageJ, NIH) and was analyzed using a two-way ANOVA with factors 'group' and 'timepoint' and their interactions, to determine the effect of the artificial tendon on the cross-sectional area of the muscles. We measured muscle CSAs from a minimum of three

image samples for each muscle, rabbit, and timepoint. The data were averaged across samples, then normalized by the rabbit's body mass measured at each respective timepoint. We hypothesized that the artificial tendon (PET-SI) group will have muscle cross-sectional areas similar to the baseline and significantly different from the excision-only (TE) group.

Muscle mass and length data was also compared using a 3-way ANOVA with factors 'side' (operated vs non-operated), 'group' (PET-SI vs TE), and 'muscle' (LG, MG, Sol, TC, ED, FD); the Tukey HSD test was used for post-hoc pairwise comparison, with $p<0.05$ considered significant. We hypothesized that there would be a significant effect of group ('TE', 'PET-SI') on muscle mass and length.

C. RESULTS

One rabbit died during surgery due to anesthetic complications; all remaining rabbits in the study (n = 9) were included in the data analysis. There were no significant differences in age or body weight at time of surgery, weight at euthanasia, or length of the biological tendon between the two groups **(Table V-I**). The length of the artificial tendons ranged from 84% to 87% (mean 85.75 ± 1.09%) of the length of the biological tendon (**Table V-I**).

Biomechanics: Kinematics

The ANOVA results showed no significant effect of group (TE and PET-SI) on the knee angle (p=0.704), ankle angle (p=0.651), and MTP angle (p=0.550) during the stance phase of gait. However, there was a significant effect of timepoint on the knee angle (p<0.001), ankle angle (p<0.001) (i.e., ankle was more dorsiflexed), and MTP angle (p<0.001). In the swing phase of gait, we found no significant effect of group on knee angle (p=0.969) and ankle angle (p=0.564) but found a significant effect of timepoint on the knee angle (p<0.001) and ankle angle

Table V-I. Rabbit demographics and biological and artificial tendon lengths for the tendon excision and excision with replacement groups. NA = not applicable. std = standard deviation.

	Age (weeks)	Weight at surgery (kg)	Weight at euthanasia (kg)	Biological tendon length (mm)	Artificial tendon length (mm)	Percent of biological tendon (%)
Tendon excision (TE) only group						
TE 1	17.3	2.85	3.15	40	NA	NA
TE 2	17.4	2.84	3.36	33	NA	NA
TE 3	17.4	2.83	3.45	37	NA	NA
TE 4	17.4	3.13	3.71	44	NA	NA
Mean (std)	17.38 (0.04)	2.91 (0.13)	3.42 (0.2)	38.50 (4.03)	NA	NA
Tendon excision and replacement with polyester silicone-coated (PET-SI) tendon group						
PET-SI 1	23.4	2.76	3.05	35	30	86%
PET-SI 2	18.7	2.78	3.03	--	27	--
PET-SI 3	17.3	2.97	3.44	38	33	87%
PET-SI 4	17.3	2.88	3.41	35	30	86%
PET-SI 5	17.4	3.00	3.45	32	27	84%
Mean (std)	18.83 (2.35)	2.87 (0.10)	3.28 (0.2)	35 (2.12)	29.40 (2.24)	85.75 (1.09)

($p<0.001$) during the swing phase of gait. The detailed (p-values) pairwise comparisons of kinematic variables across groups, and timepoints are presented in **Table V-II**. We also present the statistical results (p-values) of kinematics variables showing how the joint angles changed across timepoints within each group, as well as the results (p-values) for the test for data normality of kinematic variables in **Table V-III**.

In the stance phase of gait, maximum and minimum knee angles were significantly greater (knee was more extended) at 2 and 8 weeks post-surgery compared to baseline ($p<0.001$). The knee ROM was significantly higher at baseline compared to 2 weeks post-surgery ($p<0.001$) and at 8 weeks post-surgery compared to 2 weeks post-surgery ($p=0.005$) (**Figure V-IV, Table V-II**). In the swing phase, maximum knee angle was significantly greater (i.e., more extended) at 8 weeks post-surgery compared to baseline ($p=0.015$). The minimum knee angle was significantly greater (i.e., more extended) at 2 and 8 weeks post-surgery compared to baseline ($p<0.001$). The ROM was significantly greater at baseline compared to 2 weeks post-surgery ($p=0.024$).

The maximum ankle angle during stance was significantly less (i.e., more dorsiflexed) at 2 and 8 weeks post-surgery compared to baseline ($p<0.001$). The minimum ankle angle was also significantly less (i.e., more dorsiflexed) at 2 and 8 weeks post-surgery compared to baseline ($p<0.001$) (**Figure V-V, Table V-II**). Ankle ROM was significantly less at 2 weeks post-surgery compared to baseline ($p<0.001$) and 8 weeks post-surgery ($p=0.001$). In the swing phase of gait, the maximum and minimum ankle angles were significantly less (i.e., more dorsiflexed) at 2 and 8 weeks post-surgery compared to baseline ($p<0.001$). The were no significant differences in ankle ROM among timepoints during swing.

Table V-II. Statistical results (p-values) of 2-factor ANOVA with repeated measures for each kinematic variable for knee, ankle and MTP joints during stance and swing phase of gait.

Variable	Gait phase	Group	Timepoint	GxT	B vs 2	B vs 8	2 vs 8
Knee							
Max angle	Stance	0.588	<0.001	<0.001	0.007	<0.001	0.231
	Swing	0.193	0.017	<0.001	0.289	0.015	0.380
Min angle	Stance	0.525	<0.001	<0.001	<0.001	<0.001	0.989
	Swing	0.035	<0.001	<0.001	<0.001	<0.001	0.556
Avg angle	Stance	0.704	<0.001	<0.001	<0.001	<0.001	0.873
	Swing	0.969	<0.001	<0.001	0.016	<0.001	0.532
Ankle							
Max angle	Stance	0.271	<0.001	<0.001	<0.001	<0.001	0.177
	Swing	0.147	<0.001	<0.001	<0.001	<0.001	0.912
Min angle	Stance	0.403	<0.001	<0.001	<0.001	<0.001	0.390
	Swing	0.822	<0.001	<0.001	<0.001	<0.001	0.603
Avg angle	Stance	0.651	<0.001	<0.001	<0.001	<0.001	0.984
	Swing	0.564	<0.001	<0.001	<0.001	<0.001	0.992
MTP							
Max angle	Stance	0.148	<0.001	<0.001	0.040	<0.001	0.012
	Swing	-	-	-	-	-	-
Min angle	Stance	0.123	<0.001	<0.001	<0.001	<0.001	0.297
	Swing	-	-	-	-	-	-
Avg angle	Stance	0.550	<0.001	<0.001	<0.001	<0.001	0.486
	Swing	-	-	-	-	-	-

The result shows effect of group, timepoints and their interaction (GxT) for each variable and each joint across the groups.

Table V-III. Statistical results (p-values) for multiple comparison for maximum, minimum and average joint angles for knee, ankle and MTP joints during stance and swing phases of gait for each timepoints and within each group.

			Knee				**Ankle**				**MTP**			
Groups	Variable	Gait phase	B vs 2	B vs 8	2 vs 8	Normality	B vs 2	B vs 8	2 vs 8	Normality	B vs 2	B vs 8	2 vs 8	Normality
TE	Max angle	Stance	0.032	0.008	0.164	0.080	<0.001	<0.001	0.910	0.022	0.033	0.062	0.459	0.192
		Swing	0.187	0.062	0.354	0.069	<0.001	<0.001	0.869	0.200	-	-	-	-
	Min angle	Stance	<0.001	<0.001	0.145	0.064	<0.001	<0.001	0.755	0.080	<0.001	<0.001	0.850	0.200
		Swing	0.008	<0.001	0.132	0.200	<0.001	<0.001	0.091	0.012	-	-	-	-
	Avg angle	Stance	<0.001	<0.001	0.172	0.104	<0.001	<0.001	0.972	0.041	<0.001	<0.001	0.527	0.200
		Swing	0.082	0.009	0.163	0.080	<0.001	<0.001	0.763	0.049	-	-	-	-
PET-SI	Max angle	Stance	0.057	0.006	0.127	0.004	<0.001	<0.001	0.034	0.195	0.033	<0.001	<0.001	0.200
		Swing	0.532	0.089	0.052	0.132	<0.001	<0.001	0.530	0.200	-	-	-	-
	Min angle	Stance	<0.001	0.005	0.012	0.002	<0.001	<0.001	0.099	0.200	<0.001	<0.001	0.075	0.077
		Swing	0.007	0.002	0.987	0.004	<0.001	<0.001	0.670	0.200	-	-	-	-
	Avg angle	Stance	0.009	0.003	0.466	<0.001	<0.001	<0.001	0.740	0.200	<0.001	<0.001	0.399	0.200
		Swing	0.096	0.036	0.436	0.061	<0.001	<0.001	0.816	0.025	-	-	-	-

Results for normality of data using Kolmogorov-Smirnov test is also shown.

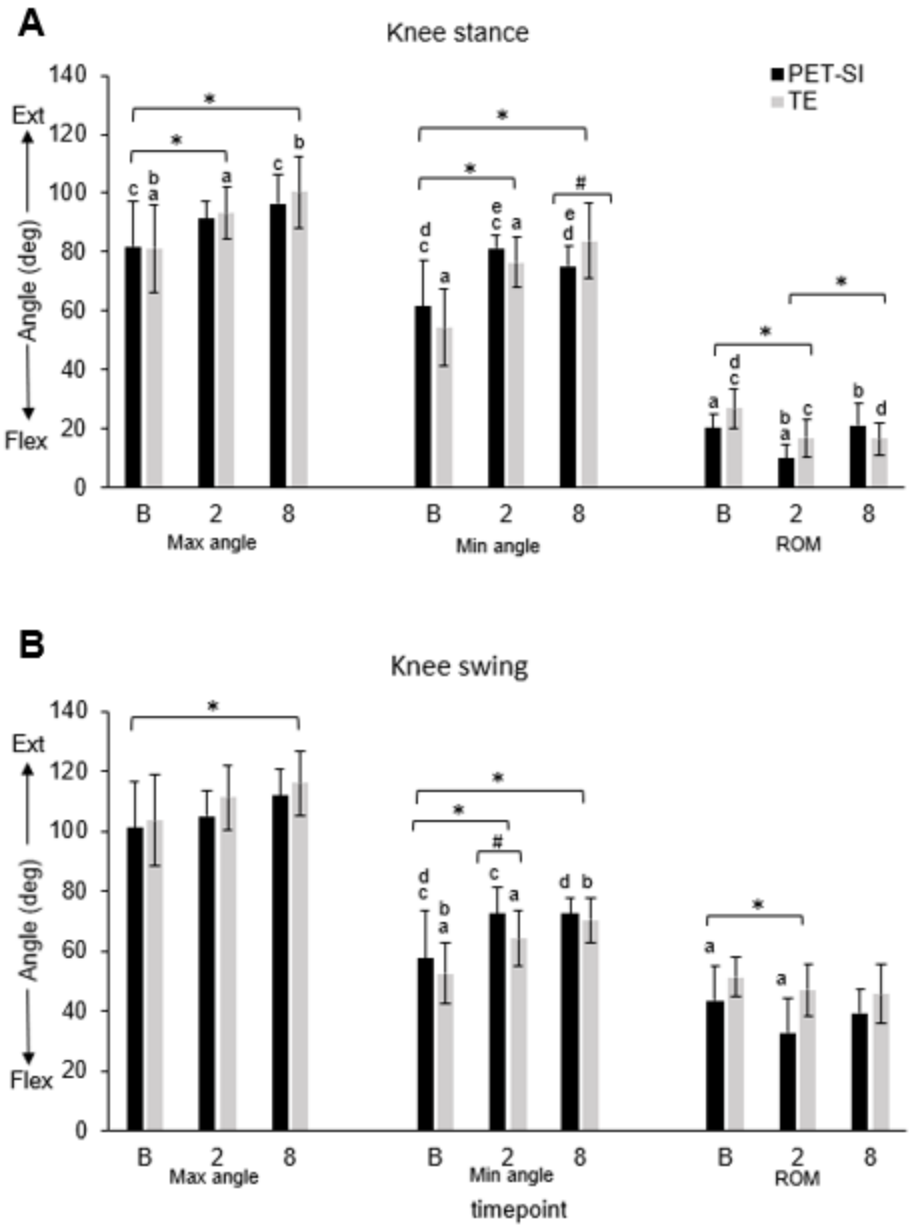

Figure V-IV. Maximum and minimum knee flexion (Flex) and extension (Ext) angles and range of motion (ROM) during the stance (A) and swing (B) phases of gait. * indicates a significant difference between timepoints. # indicates a significant difference between groups at specific timepoints. Letters a-d represent significant differences within groups. Differences for which $p<0.05$ are considered significant. Error bars represent standard deviation.

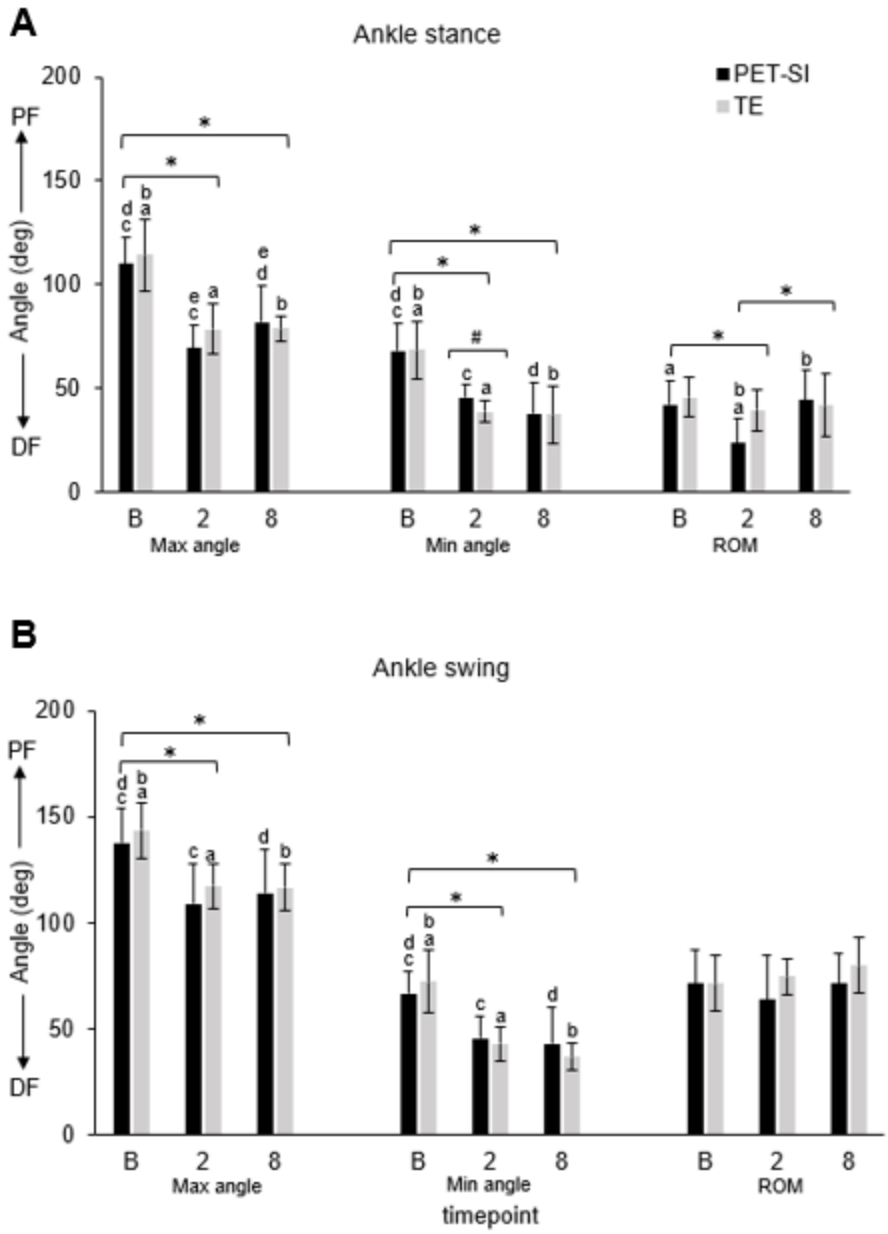

Figure V-V. Maximum and minimum ankle angles in plantarflexion (PF) and dorsiflexion (DF) and ankle angle range of motion (ROM) during the stance (A) and swing (B) phases of gait. * indicates a significant difference between timepoints. Letters a-e represent significant differences within groups. Differences for which $p<0.05$ are considered significant. Error bars represent standard deviation.

In stance, maximum MTP angle was significantly greater at 2 weeks ($p=0.040$) and 8 weeks ($p<0.001$) post-surgery compared to baseline and greater at 8 weeks post-surgery compared to 2 weeks post-surgery ($p=0.012$) (**Figure V-VI**). The ROM was significantly greater at baseline compared to 2 weeks post-surgery ($p<0.001$) and compared to 8 weeks post-surgery ($p=0.039$) and significantly greater at 8 weeks post-surgery compared to 2 weeks post-surgery ($p=0.002$).

Biomechanics: Pressure data

We found a significant effect of group ($p<0.001$) as well as timepoint ($p<0.001$) on the peak vertical force (**Figure V-VII**). The maximum peak vertical force was significantly greater at 8 weeks post-surgery compared to baseline ($p<0.001$) and 2 weeks post-surgery ($p<0.001$), but not significantly different at 2 weeks post-surgery compared to baseline ($p=0.711$). At 2 weeks post-surgery, the maximum force was significantly greater in the TE group compared to the PET-SI group ($p=0.003$).

We found a significant effect of group ($p=0.004$) and timepoint ($p<0.001$) on vertical impulse. Vertical impulse was not significantly different at 2 weeks post-surgery compared to baseline ($p=0.439$) but was significantly greater at 8 weeks post-surgery compared to baseline ($p<0.001$) and 2 weeks post-surgery ($p<0.001$). At 2 weeks post-surgery, the vertical impulse was significantly greater in the TE group compared to the PET-SI group ($p=0.001$).

We found no significant effect of group ($p=0.641$) but a significant effect of timepoint ($p<0.001$) on the average ground contact area. The average ground contact area at 2 weeks post-surgery was significantly less compared to baseline ($p<0.001$) and compared to 8 weeks post-surgery ($p<0.001$). However, baseline average ground contact area was not significantly different

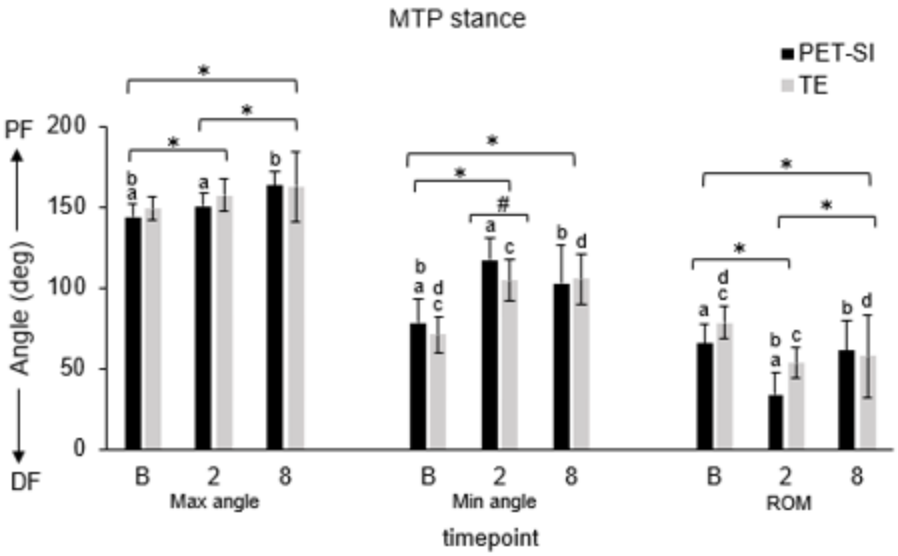

Figure V-VI. Maximum and minimum metatarsophalangeal (MTP) joint angles in plantarflexion (PF) and dorsiflexion (DF) and MPT joint range of motion during the stance phase of gait. * indicates a significant difference between timepoints. # indicates a significant difference between groups at specific timepoints. Letters a-d represent significant differences within groups. Differences for which $p<0.05$ are considered significant. Error bars represent standard deviation.

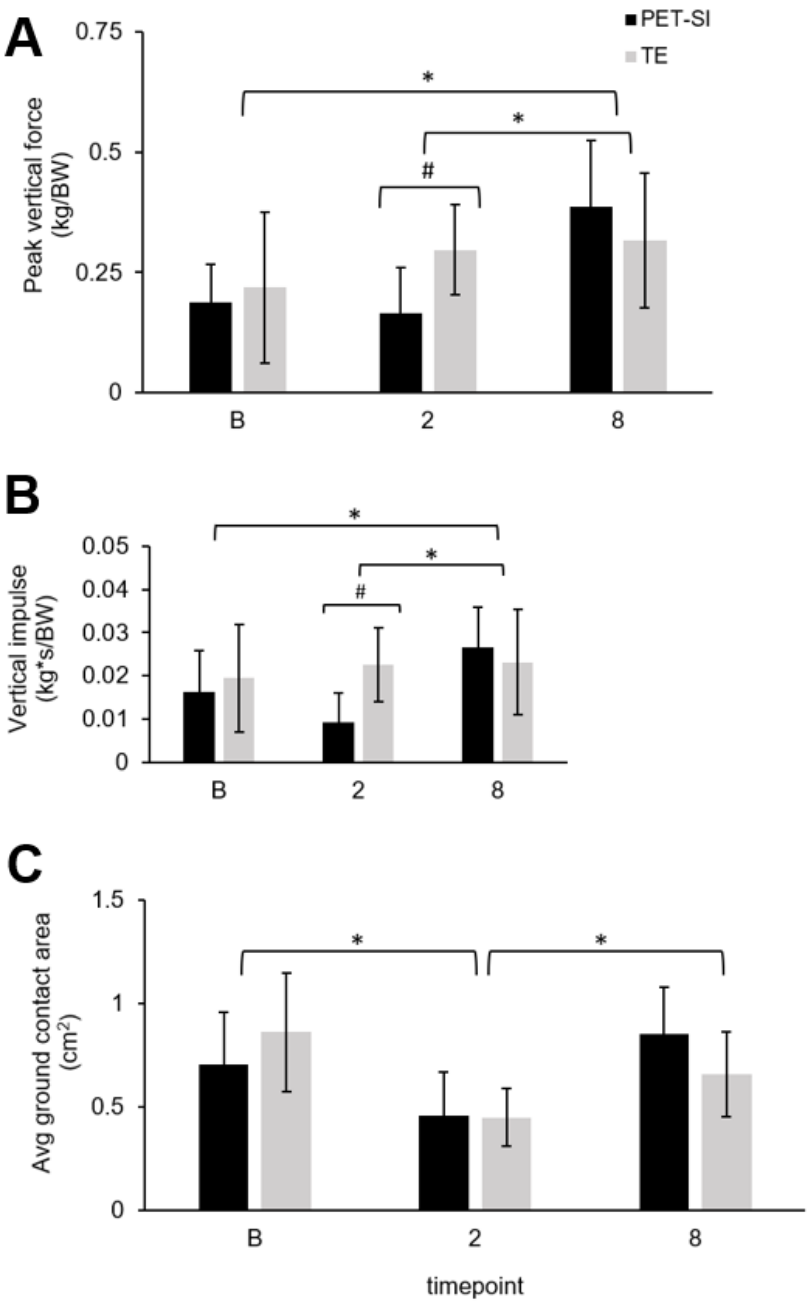

Figure V-VII. Mean values at baseline, B (pre-surgery), 2 weeks and 8 weeks post-surgery for the operated limb for TE and PET-SI groups for (**A**) peak vertical force (kg/BW) at maximum, minimum and average stance (**B**) vertical impulse (kg*s/BW) and (**C**) average ground contact area (cm^2) at maximum, minimum and average stance. Error bars represent standard deviation.

from the 8 weeks post-surgery (p=0.932).

Muscle cross-sectional area (CSA)

At 8 weeks post-surgery, the CSA of the LG was significantly higher in the PET-SI group than in the TE group (p=0.006) (**Figure V-VIII**). There was no significant difference in the CSA of the TC between the TE and PET-SI groups at any timepoint. However, there were several significant differenes in CSA between timepoints. For example, in the TE group, TC CSA was significantly greater at baseline (B) compared to 8 weeks post-surgery (p=0.022) as well as greater at 2 weeks post-surgery compared to 8 weeks post-surgery ($p<0.05$). There were no significant differences in the CSAs of the TC within the PET-SI group at any timepoint ($p<0.05$). There were timepoints with significant differences in the CSA of the LG within the TE group, including baseline compared to 2 weeks post-surgery (p=0.010), baseline compared to 8 weeks post-surgery ($p<0.001$), and 2 weeks post-surgery compared to 8 weeks post-surgery (p=0.003). Compared to baseline, CSA of the LG was significantly less at 2 weeks post surgery (p=0.007) and at 8 weeks post-surgery (p=0.003) in the PET-SI group.

Muscle mass and length

Muscle mass and length were less in the operated limb compared to the non-operated limb for most of the muscles across the two groups (TE and PET-SI), but with no significant between-group differences in muscle mass or length for any of the muscles. There was a trend of less between-limb differences in muscle mass and length of the involved muscles (LG, MG, and Sol) in the PET-SI group compared to the TE group (**Figure V-IX**). We also observed that the mass of the FD was greater in the operated limb compared to the non-operated limb in the two groups; the between-group difference in FD mass was greater in the TE group than in the PET-SI group

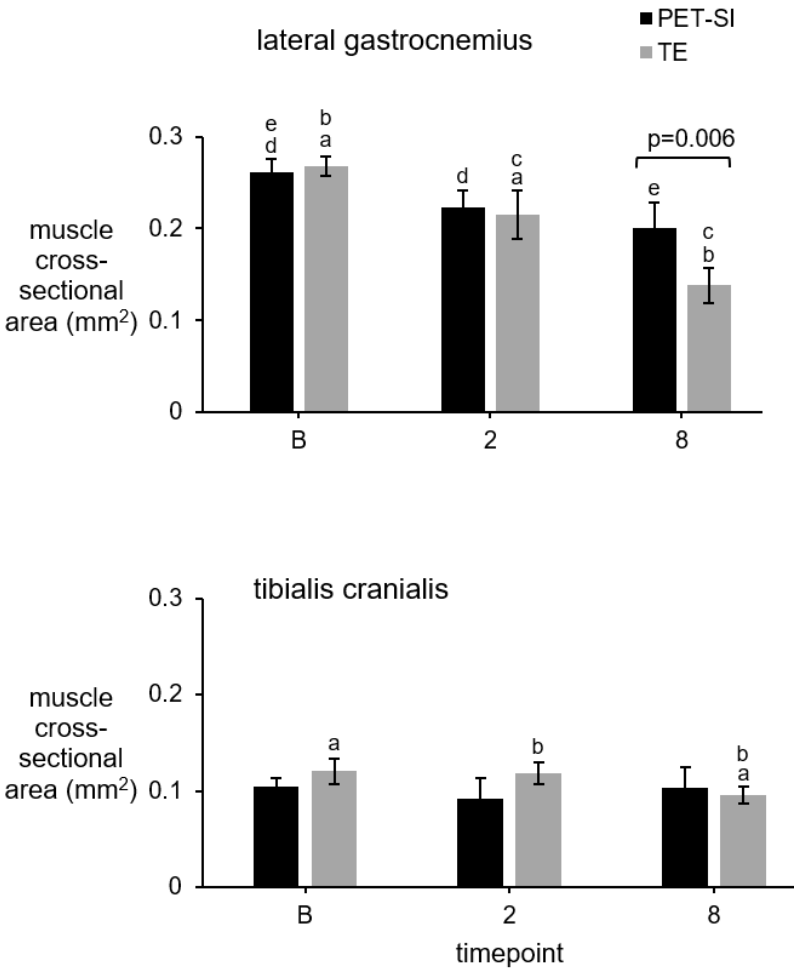

Figure V-VIII. Cross-sectional areas (CSAs) of lateral gastrocnemius (LG) and tibialis cranialis (TC) at baseline (B), at 2 weeks post-surgery and at 8 weeks post-surgery. Letters a-e represent significant differences within groups ($p<0.05$). Error bars represent standard deviations.

($p<0.05$).

In the TE group, muscle mass was significantly less for the involved muscles (LG, MG, Sol) in the operated limb than in the non-operated limb (**Figure V-IX**). In the PET-SI group, even with the artificial tendon, muscle mass of LG, MG, and Sol were 16.7 ± 21.0% ($p=0.503$), 39.2 ± 9.1% ($p<0.001$), and 53.9 ± 15.7% ($p=0.333$) less, respectively, in the operated limb compared to the non-operated limb. In the operated limb, muscle length was significantly less for MG and Sol in the TE group but only for MG in the PET-SI group, compared to the non-operated limb. There was no significant effect of group for either mass ($p=0.267$) or length ($p=0.941$), although there was a consistent trend of less bilateral difference in the involved muscles of the PET-SI group than in the TE group (**Figure V-IX**).

D. DISCUSSION

The Achilles tendon plantarflexes the ankle joint and helps to maintain joint angle during gait (Wong et al., 2023). Joint angles influence range of motion, muscle activation, and force distribution and, thus, are crucial for effective movement and injury prevention (Ugbolue et al., 2021). In both rabbit groups (TE and PET-SI), the ankle was more dorsiflexed in both the stance and swing phases of gait at 2 and 8 weeks post surgery compared to baseline (**Figure V-V**). This kinematic change in ankle angle is not surprising since the surgical intervention affected the triceps surae ankle plantarflexor muscle-tendons and, therefore, it is reasonable to expect plantarflexion weakness leading to a more dorsiflexed ankle angle during gait. Plantarflexion weakness was apparently not overcome by the artificial Achilles tendon combined with post-surgical rehabilitation in the PET-SI group.

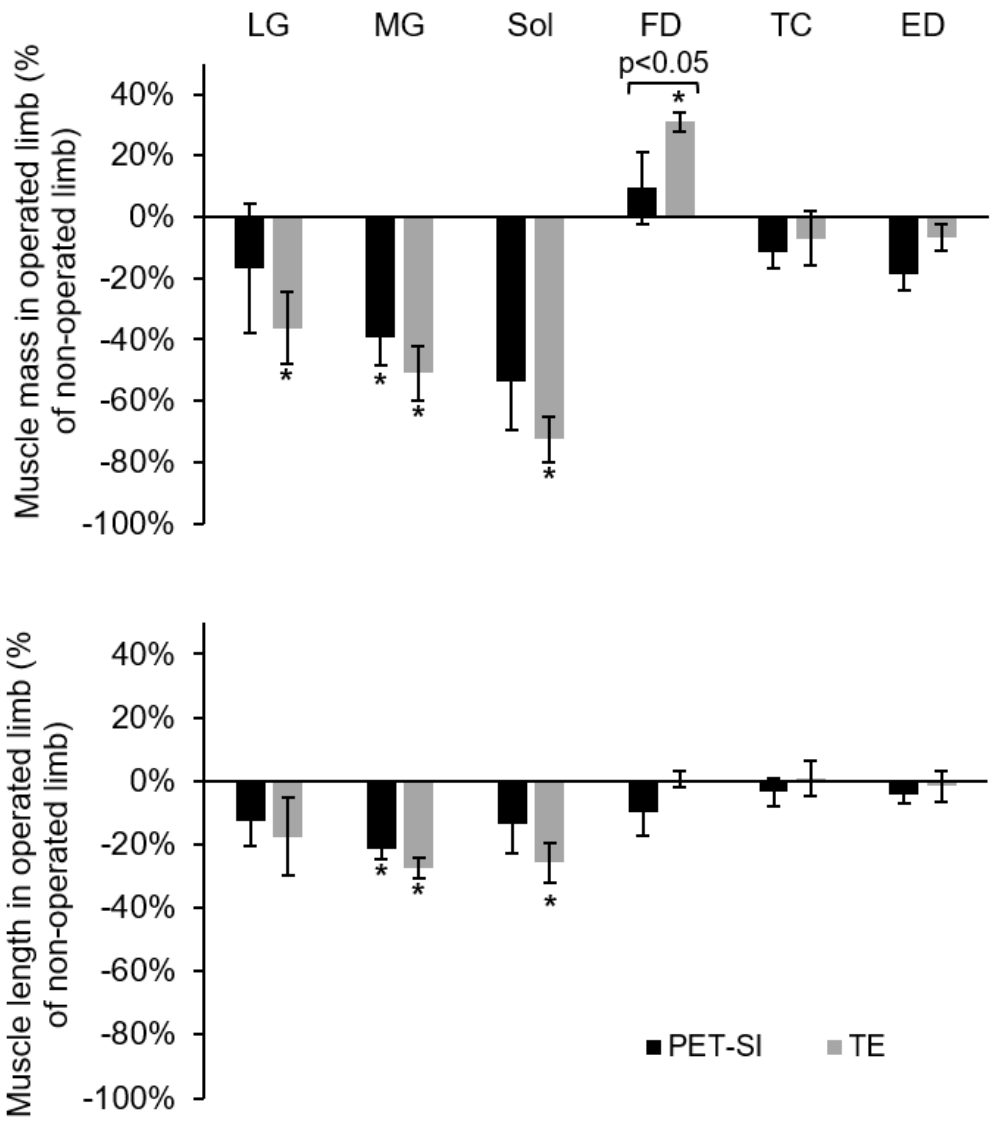

Figure V-IX. Mass (top) and length (bottom) of muscles in the operated limb as a percentage of values in the non-operated limb. *Bilateral differences between sides were significant ($p<0.05$). LG = lateral gastrocnemius; MG = medial gastrocnemius; Sol= soleus; FD = superficial flexor digitorum; TC = tibialis cranialis and ED = extensor digitorum. Error bars represent standard deviations.

The muscle morphology data provided evidence that the artificial Achilles tendon provided some biomechanical benefit compared to tenectomy only. Specifically, muscle cross-sectional area for the lateral gastrocnemus was significantly greater in the PET-SI group compared to the TE group ($p=0.006$). Additionally, there was a trend of greater muscle mass in the operated limb (compared to the nonoperated limb) in the PET-SI group than in the TE group. These between-group differences and trends were likely due to greater loading of the involved muscles in the PET-SI group. However, the benefit was marginal as muscle mass decreased by up to 53.9% in the involved muscles.

Interestingly, in both groups, the flexor digitorum (FD) muscle mass was greater in the operated limb than in the non-operated limb, on average (**Figure V-IX**). This suggests that the flexor digitorum, which contributes to ankle plantarflexion based on its moment arm, compensated for weakness of the involved triceps surae muscles. Notably, the bilateral difference in FD muscle mass wassignificantly greater in the TE group than in the PET-SI group; this provides further support that the artificial Achilles tendon provided some biomechanical contribution to ankle plantarflexion.

A possible reason for the modest functional benefit of the artificial Achilles tendon may be due to the accumulation of scar tissues around the implant or muscle-tendon junction as a result of the so-called foreign body reaction (Noskovicova et al., 2021). The silicone coating around the braided portion of the artificial tendon was used in the original PET-SI tendon design intended to prevent tissue adhesion (Melvin et al., 2011; Melvin et al., 2010; Melvin et al., 2012). In a previous study, we observed the formation of a functional pseudo-sheath that allowed an artificial tibialis cranialis tendon to slide relative to surrounding tissues (Easton et al., 2024). However, immediately post-mortem in the current study, we did not observe sliding of the

artificial Achilles tendon in a pseudo-sheath. Additionally, there was qualitatively more scar tissues around the artificial Achilles tendon and muscle-tendon junction than we observed in the previous study. Scaring may have limted the transmission of mucle force and hence the movement of the ankle joint in the PET-SI group, resulting in little functional benefit of the artificial tendon. The reason for the difference in pseudo-sheath and scar tissue formation between studies is unclear and should be investigated in future studies.

Our study had some limitations. The artificial tendons may not have exactly matched the length of the biological tendons. We used tendons with lengths that closely approximated the length of the biological tendons, and the total length from the myotendinous junction to the enthesis was measured as the sum of the length of the braided artificial tendon and suture of the suture anchor. Additionally, it is possible the artificial tendon was basically plastically deformed when first loaded so that its resting length increased in vivo after implantation. We observed such plastic deformation in some of the preliminary mechanical tensile tests, indicating that artificial tendons may need to be pre-loaded before implantation. Also, our study had a small sample size, which may have underpowered the study and affected the results of the statistical analysis. Lastly, the duration of the study (8 weeks) was relatively short; a longer study may reveal more extensive neuromuscular and functional recovery in the PET-SI group and greater between-group differences.

The artificial tendon has could be a potential substitute for the biological Achilles tendon, preserving essential muscle properties, such as mass and cross-sectional area. This preservation is critical because it maintains the muscle's capacity to generate force and contributes to functional movement patterns. For optimal recovery of biomechanical function, further improvements in the integration of artificial tendons with surrounding tissues are

necessary, as effective tendon-tissue integration is crucial for efficient force transmission and the preservation of natural limb biomechanics. Specifically, minimizing scar formation at the interface between the artificial tendon and the native tissue may play a pivotal role in preventing mechanical complications. Therefore, addressing these challenges in tendon-tissue integration and scarring could enhance the functional outcomes and long-term viability of artificial tendon implants, making them more suitable for clinical applications aimed at restoring full biomechanical function post-injury.

CHAPTER VI. Conclusions, Limitations and Future Work

A. Conclusions

Anchor eyelet design is an important factor affecting suture anchor performance as evident from the results of our study. Anchor eyelet geometries, when optimized, can reduce stress concentrations and provide smooth suture gliding surfaces leading to improve tensile strength of the suture anchor. On the other hand, suboptimal designs may lead to premature failure at lower loads, as seem when we compared the anchors with eyebolt screw with smoother eyelet geometry. We also think that anchor eyelet geometry might have caused the premature failures of the suture anchors in multiple rabbits when we used a certain anchor type for attaching artificial Achilles tendon in the rabbits. Also, eyelet design and geometry influences the mode of failure observed during mechanical testing. Our data suggest that raised eyelet designs are more prone to failure via suture breakage at the mid-section, away from the knot, whereas the embedded eyelet designs mostly failed via suture breakage at the knot. Understanding these failure modes may be important for predicting anchor behavior under physiological loading conditions and for guiding future design improvements.

Another important factor that might contribute to the effectiveness of suture anchors in orthopedic reconstruction is the anatomical point of application of the suture anchor. As we have seen with the IMEX anchor, its use for Achilles tendon re(attachment) might not be its best application, although there is currently no information from the anchor's manufacturer indicating its best application. We predict that if the anchor was used in applications with less/limited biomechanical loading compared to the Achilles tendon, the prevalence of suture breakage may have been less. Therefore, in future studies, the specific area of application should be considered when making the choice of anchor/eyelet design for the orthopedic reconstruction.

The results of the studies in this dissertation show that eyelet designs and eyelet geometry in particular tend to reduce suture strength under tensile forces, either with cycling or without cycling. However, we see that the negative effect was more evident in the two raised eyelet designs than with the embedded eyelet design. It is also evident from our results that no significant effect of loading condition (with cycling or without cycling) on the maximum failure loads of the suture anchors exists. To the best knowledge of the author, there are no published studies detailing the mechanical strengths of the anchors that were tested and reported in this dissertation. Also, there are no publicly available information by the manufacturers of these anchors with respect to the strength of anchors. This studies are therefore important to surgeons for making important decisions in orthopedic reconstructions involving the use of these anchors. We also encourage other scientists to conduct similar studies with these anchors to further verify and improve the acceptability of our results.

The primary purpose of the mechanical testing of suture anchors presented in this dissertation is to establish what combination of anchor and suture is best for attaching artificial tendons in rabbits. Our results suggests that using a small anchor with embedded eyelet design and the largest possible suture size that the anchor could accommodate would present the most effect result for the orthopedic application. Hence, the use of the Anika anchor for attaching the artificial Achilles tendon and the subsequent biomechanical analysis presented in the dissertation. We see that the artificial tendon seem to restore biomechanical function, although without any significant differences compared to the group that did not get an artificial tendon placement. Several factors including the formation of fibrotic tissues may have hampered the effectiveness of the artificial tendon in this application.

B. Limitations

The sample sizes used in all the studies contained in this dissertation were relatively small. We investigated the causes of suture anchor failure in rabbits (n=12), then we tested the strength of four groups of suture/anchor configurations in two loading conditions (n=5 per group) and lastly we quantified the effect of tendon excision and replacement with artificial Achilles tendon on hindlimb biomechanics and muscle morphology in a group of rabbits compared to a second group of rabbits that had tendon excision only (n=5 rabbits per group). It is not clear whether our sample sizes have affected the power of the research in terms of detecting an effect that truly exists. However, in the rabbits studies, we used minimally possible sample size that are large enough to detect a significant difference between groups and to reduce the number of animals used in the studies, which is an important ethical consideration research.

In the study to test the mechanical strength of suture anchors, we used synthetic bone blocks rather than cadaveric bones for the tests. Although synthetic bones are universally accepted as test platforms for orthopedic devices, they are not exactly the same in terms of properties as biological or cadaveric bones. Synthetic bones lack the natural variability in density, porosity, and mechanical properties of biological bones which can provide a more realistic testing environment, it is generally acceptable for use in testing orthopedic implants because it offers consistent and repeatable results because the block is manufactured with identical material properties. Synthetic bone models also eliminate variations due to biological factors such as age, or bone health, ensuring that differences in results are due to the suture anchors or test conditions, and not the test bones.

C. Future Work

The tendon designs presented in this dissertation consist of two strands (for the artificial tibialis cranialis tendon) and three strands (for the artificial Achilles tendon) of polyester suture. In human applications, more strands of the sutures may be required depending on the size of the biological tendon to be replaced. In addition, it will be important to reduce the formation of fibrose tissues around the artificial tendon when implanted in the patients. In the group of rabbits (n=12) in which we investigated the cause of suture anchor failures, we observed the formation of fibrous tissues in multiple rabbits when the limbs were dissected to physically confirm failure (or not) and mode of failure of the suture anchors. Fibrotic tissues have been reported to have negative impact on implant function, sometimes resulting in implant failure. Therefore, improving tendon design and implantation to reduce fibrose tissue formation to its minimum will be important for the overall success of the artificial tendon project.

Tendon testing and characterization to inform important mechanical properties such as stiffness and wear needs to be conducted. It is not yet known what the mechanical properties of the PET-SI we have presented in this studies are. These important properties needs to match those of the biological tendons as much as possible. Conducting this tests and using the initial data to improve tendon (re) design will ensure that the eventual product can mimic the biological tendon as much as possible.

In the studies presented in this dissertation, we excised and replaced the biological tendon . However, in most real-life scenarios of tendon ruptures requiring tendon grafts, the entire length of tendon is not replaced rather only a part of the length is replaced with a graft. In future studies, it will be important to use the artificial tendon in the way a graft is applied in a model of tendon replacement with a tendon graft.

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Appendix

Appendix I

Table APX1. Previous studies involving artificial tendons and the method of attachment used.

S/n	Year	Authors	Focus of the study	Suture anchor	Outcome
1.	2010	(Melvin et al., 2010)	Replaced goat semitendinosus tendon with an artificial material (OrthoCoupler)	The method of attachment was not specifically stated.	Fatigue strength of the OrthoCoupler was several times the contractile force of the semitendinosus muscle.
2.	2012	(Melvin et al., 2012)	Replaced quadriceps tendon with the OrthoCoupler in a goat.	The OrthoCoupler was attached to a stainless steel bone plate on the tibia.	Mechanical testing of the myotendinous junction showed superior strength compared with the biological myotendon interface after 180 days.
3.	2024	(Easton et al., 2024)	Replaced tibialis cranialis biological tendon with polyester silicone-coated artificial tendon in rabbits.	2 mm × 6 mm bone suture anchor (Jorgenson Laboratories, Loveland, CO, USA) , with a size 2 FiberWire suture (Arthrex Inc. Naples, FL).	The suture anchors held the artificial tendon securely to the bone in the rabbits and the artificial tendon restored normative biomechanical function in the rabbits.
4.	2024	(Hsu et al., 2024)	Rotator cuff repair surgery on goat shoulders.	Custom-made MgF_2-coated ZK60 suture anchor	Reestablished the connection between the detached infraspinatus tendon and the humeral head, with demonstrable osseointegration.

Appendix II

Table APX2: Maximum tensile strength at failure of suture anchor tested with suture size 5

IMEX (n=5 per test condition)			Jorvet (n=5 per test condition)		
	With cycling	Without cycling		With cycling	Without cycling
	504.5853	492.9014		354.3179	412.8633
	432	481.2616		413.8906	536.0646
	510.735	503.6444		404.7531	589.265
	412.02	482.172		539.3816	442.7802
	506.87	530.6861		559.6168	544.9985
Mean	473.2421	498.1331	Mean	454.392	505.1943
Std dev	42.35093	18.20356	Std dev	80.51672	66.37131

Table APX3. Maximum tensile strength at failure of Arthrex anchor tested with suture size 0 and Anika anchor tested custom and suture 2. (n=5 per anchor per test condition)

Arthrex (with suture size 0)			Anika (with suture size 2)		
	With cycling	Without cycling		With cycling	Without cycling
	108.0688	108.6894		237.0936	239.5091
	108.3258	98.65972		239.1659	221.5885
	118.5619	104.1217		231.4074	221.9744
	108.4925	99.69374		259.1961	242.4262
	118.3789	118.3338		218.4361	241.8044
Mean	112.3656	105.8997	Mean	237.0598	233.4605
Std dev	4.986749	7.162138	Std dev	13.21547	9.586085

Table APX 4. Maximum tensile strength at failure eyebolt screw tested with suture size 0, 2 and 5 (n=5 per anchor per test condition)

	Suture size 0		Suture size 2		Suture size 5	
	With cycling	Without cycling	With cycling	Without cycling	With cycling	Without cycling
	129.814	148.6884	233.5359	262.2241	565.598	599.1495
	144.4564	145.9594	243.7983	266.5857	580.9529	574.9227
	138.7343	137.8469	258.5054	247.0311	592.4752	653.3746
	140.2971	154.9552	256.7182	268.2068	617.0143	560.3575
	133.1527	136.7229	250.5494	263.3068	636.385	614.8456
Mean	137.2909	144.8346	248.6214	261.4709	598.4851	600.53
Std dev	5.205639	6.828924	9.141156	7.536284	25.31715	32.46214

VITA

Obinna Peter Fidelis hails from Umuahia, Abia State, Nigeria. He obtained a Bachelor of Technology degree in Biomedical Technology from the Federal University of Technology, Owerri, Nigeria, in 2011 and a Master of Science degree in Biomedical Engineering from the University of Lagos in 2016. He worked briefly with Deux Projects Nigeria Limited, managing medical technologies in hospitals before accepting a Teaching Assistant position at Bells University of Technology, Ota, Nigeria, in 2012. He joined the Federal University of Technology, Akure, Nigeria, as an Assistant Lecturer in 2016 and rose to the rank of Lecturer I before moving to the University of Tennessee, Knoxville, USA, where he worked with Dr Dustin Crouch to advance the development of artificial tendons and earned a PhD in Biomedical Engineering in 2024. He has co-authored research papers published in peer-reviewed journals and presented abstracts at conferences including the Biomedical Engineering Society conference (San Antonio, Texas, 2022; Seattle, Washington, 2023) and the American Society of Biomechanics conference (Knoxville, Tennessee, 2023; Madison, Wisconsin, 2024). He is a recipient of many awards including the Biomechanics Initiative Inc./American Society of Biomechanics Outreach Award (2021), Diversity Travel Awards of the American Society of Biomechanics (2021, 2023) and the Orthopedic Research Society (2023) and the Graduate Fellowship Award at the University of Tennessee, Knoxville (2022). He is a member of the Biomedical Engineering Society, Orthopedic Research Society, American Society of Biomechanics and the International Society for Technology in Arthroplasty.