

Mechanical Testing of a Synthetic Canine Gastrocnemius Tendon Implant

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Objective: To test a polyethylene terephthalate prosthesis (STIF, Chenove, France) for gastrocnemius tendon repair in dogs (cadaver model).

Study Design: In vitro mechanical study.

Animals: Pelvic limbs (n = 8) from 4 recently euthanatized adult dogs (weighing 30–45 kg).

Methods: Proximally the implant was sutured at the myotendinous junction of the gastrocnemius and distally secured in a 4.5 mm blind ending tunnel in the medullary cavity of the calcaneus using an interference screw (STIF, Chenove, France). Proximal and distal fixation were tested independently using an electrodynamic testing machine (Electropuls 3000, Instron, UK).

Results: Mean \pm SD failure loads for the proximal fixation (266.13 ± 43.88 N) was significantly less than for the distal fixation (649.25 ± 210.36 N; $P = .042$, paired *t*-test). Mean stiffness of the proximal and distal constructs were 19.08 ± 8.16 N/mm and 139.76 ± 24.51 N/mm, respectively.

Conclusions: Failure loads exceeded the values reported after experimental repair of chronic gastrocnemius tendon injuries using other methods involving suturing tendon to bone. Failure of this repair method clinically is predicted to occur proximally at the level of the myotendinous junction.

In dogs, gastrocnemius tendon rupture secondary to chronic degeneration at the insertion (a type IIc lesion¹) is a common cause of disruption to the common calcaneal tendon mechanism.² Progressive failure of the tendon results in fibrous tissue formation between the torn tendon ends and the tuber calcaneus, and may eventually lead to complete separation. Resection of this fibrous tissue and re-attachment of the tendon to the calcaneus are essential for restoration of function. In some cases, chronic contracture of the gastrocnemius, in addition to resection of fibrous tissue, makes re-apposition of the tendon to the tuber calcaneus difficult. After resection, current repair techniques rely on suturing the remaining tendon to the calcaneus avoiding any gap. Securing the tendon to bone can be difficult and, of the sutures described, a 3-loop pulley suture provides the greatest strength and is more resistant to gap formation than a locking loop suture.³ Gall and others reported repair augmentation with polypropylene mesh, but found this resulted in unacceptable gap formation and reduced gliding function.⁴ Other augmentation methods include semitendinosus⁵; small intestinal submucosa⁶; fascia lata⁷; and bone plates.⁸

Postoperatively, immobilization of the talocrural joint is required to protect the tendon during healing because repair techniques are not immediately strong enough to withstand weight-bearing forces.⁹ Immobilization techniques such as

casting,¹⁰ splinting, external skeletal fixation and placement of a calcaneal-tibial screw may not prevent tendon loading potentially allowing gap formation. These techniques are also associated with many secondary complications.^{11,12} Use of synthetic implants to augment repairs of both acute and chronic Achilles tendon injuries has been reported in people.¹³

Our purpose was to test the strength and fixation of a synthetic ligament implant using a cadaver model, to determine its suitability for gastrocnemius tendon repair in dogs. Maximum load at failure as well as stiffness of the proximal and distal fixation was evaluated. The implant is manufactured from polyethylene terephthalate (Soft Tissue Internal Fixation [STIF], Chenove, France) and is based on a human implant system called Ligament Augmentation & Reconstruction System (LARS, Arc sur Tille, France). The human Achilles tendon implant is too large for dogs, so a modified human patellar ligament prosthesis was used. Use of this implant should aid in repair of chronic gastrocnemius tendon injuries by bridging gaps (thus allowing maximal fibrous tissue resection), restoring a functional length, and allowing tissue ingrowth.¹⁴ We are unaware of reports in dogs of fixation of an implant to the calcaneus with an interference screw. Because the implant is enclosed within the paratenon, tendon gliding should not be compromised.

MATERIALS AND METHODS

Pelvic limbs ($n = 8$) were collected from 4 recently euthanized adult dogs (weighing 30–45 kg). None of the dogs were euthanized because of musculoskeletal disease, and no obvious signs of musculoskeletal disease were identified on examination of the distal aspect of the pelvic limb when stripped of tissues before testing. Use of the cadavers was approved by University of Liverpool Veterinary Research Ethics Committee.

Cadavers were chilled and stored at 4°C for ~72 hours, then before testing were thawed until they reached room temperature. Each limb specimen was stripped of the most of the muscular tissue, preserving only the gastrocnemius muscle and tendon. The ligaments around the stifle and tarsus were initially preserved to provide stability, aiding implant placement.

The implant has 3 components: a flat proximal part designed to be sutured at the myotendinous junction of the gastrocnemius; a central section containing open fibers to be placed at the tendon defect; and a cylindrical distal section which is secured into the calcaneus using an interference screw (Fig 1). The proximal section measured 80 mm, the central section 40 mm, and the distal section, 100 mm. Both the proximal and distal sections of the implant can be trimmed in length depending on dog size/conformation.

The proximal and distal fixations were tested independently. For assessment of the proximal fixation, the flat portion of 1 implant was trimmed to a standardized length of 40 mm and placed at the level of the myotendinous junction, sandwiched between the medial and lateral sections of the gastrocnemius and secured with 8 evenly-spaced simple interrupted sutures of 3.5 metric polydioxanone. Each suture passed through both sections of the gastrocnemius and the implant (Fig 2).

To assess the distal fixation, the gastrocnemius tendon was detached from its insertion and a 4.5 mm diameter blind-ending tunnel was drilled distally beginning at the tuber calcaneus, into the medullary cavity of the calcaneus to a depth of 30 mm. The distal (cylindrical) woven end of a 2nd implant was trimmed to 25 mm and inserted into the tunnel, ensuring that the section

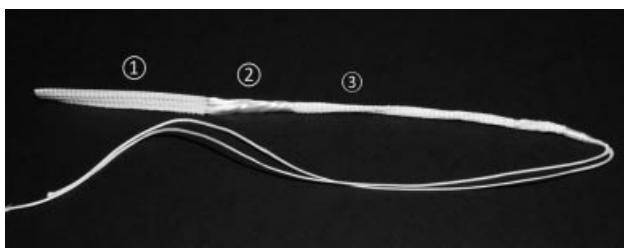


Figure 1 Canine gastrocnemius implant (STIF, Chenove, France) before trimming. The implant comprises 3 sections: (1) a flat proximal section designed to be sutured at the myotendinous junction of the gastrocnemius, (2) a central section containing open fibers, to be placed at the tendon defect, and (3) a cylindrical distal section that is secured into the calcaneus using an interference screw. (Image courtesy of Karen Simpson-Jones, Vetlig, UK.)



Figure 2 Cadaver limb before final dissection showing the implant sutured proximally between the medial and lateral portions of the myotendinous junction.

with free fibers remained outside the tunnel. The implant was then secured into the calcaneus with a titanium interference screw (5 mm diameter, 20 mm length; STIF, Chenove, France). All interference screws were inserted dorsal to the implant (Fig 3). All calcanei were radiographed (mediolateral and dorsoplantar projections) before mechanical testing to allow evaluation of implant position (Fig. 4). Radiographs were also taken after testing to assess failure mode.

After implantation, the talocrural joint was disarticulated and the calcaneus dissected from the tarsus, isolating the calcaneus with attached implant to test the distal fixation. The stifle was disarticulated, leaving the femur with the gastrocnemius and implant attached to test the proximal fixation. To prevent iatrogenic trauma to the origin of the gastrocnemius, the origin of the superficial digital flexor muscle was preserved. Separate implants were used to test the proximal and distal fixation in each limb.

Mechanical Testing

Testing was performed with an electrodynamic materials testing machine (Electropuls 3000, Instron Ltd, High Wycombe, UK). In each test, the calcaneus or femur was secured with a 10 KN pneumatic grip (Instron Ltd) with the implant secured in a mechanical grip (Instron Ltd). After pre-loading to 30 N, each specimen was tensioned until failure at a rate of 25 mm/min. Because of the uniplanar design of the testing machine, the proximal fixation was tested by pulling the implant perpendicular to the long axis of the femur, whereas the distal fixation was tested by pulling the implant in line with the long axis of the calcaneus. Experimental design and testing methodology was based on that reported by Moores et al.³ To ensure no slippage occurred, both the specimen and the load displacement curve were monitored in real time and load-displacement curves were reviewed after testing.

Construct load and displacement were recorded at 100 Hz during tests. Load was recorded with a 3000 N load cell. Displacement was recorded from the actuator. The stiffness of the proximal and distal constructs was calculated from the

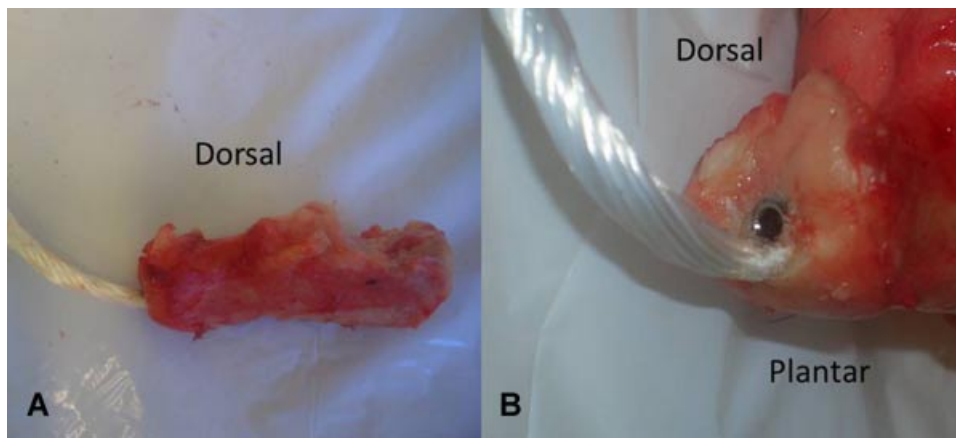


Figure 3 Calcaneus after final dissection before testing. The distal portion of the implant has been secured in the calcaneus. (A) Lateral view with the implant exiting the tuber calcaneus and (B) the interference screw placed dorsal to the implant.

slope of the initial linearly elastic region of the respective load-displacement curves. The construct yield point (Y) was determined at the point of first deviation from linearity of each load-displacement curve. The corresponding yield load and displacement were considered specimen failure load and displacement because further increases in load would cause specimen elongation because of unrecoverable plastic deformation and the clinical inability to resist loading. Failure mode was recorded.

Statistical Analysis

Differences in failure load of distal and proximal fixations were compared using Student's paired t-test (Graphpad InStat, San Diego, CA) and significance set at $P \leq .05$. When left and right limbs of a cadaver were used a mean of proximal values, and a mean of the distal values was used to account for non-independent values.

RESULTS

Figure 5 shows representative load displacement curves for load to failure for proximal and distal specimens.

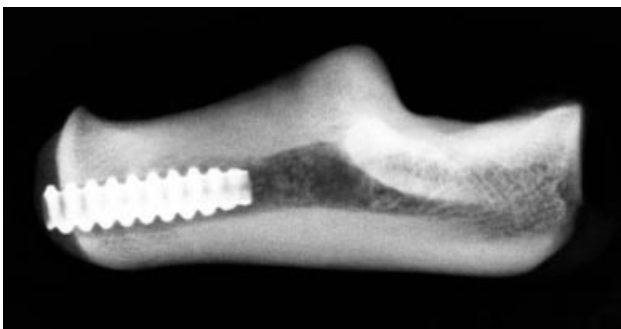


Figure 4 A pre-testing lateral radiograph of the calcaneus showing the interference screw and radiolucent implant *in situ*.

Distal Fixation

Two calcanei were excluded: 1 because of a poorly positioned drill tunnel exiting the plantar aspect of the calcaneus and 1 because of a fracture caused by the pneumatic grip. Mean \pm SD load at failure was 649.25 ± 210.36 N ($n = 4$). The implant failed in the central (open fibered) section in 4 specimens (Fig 6A) and pulled out of the calcaneus leaving the screw *in situ* in 2. Implant pull-out (mean, 347.50 N) occurred at less than half the load of implant failure (mean, 749.83 N). Mean stiffness of the distal construct was 139.76 ± 24.51 N/mm ($n = 4$). Radiographic evaluation identified no change in screw position in any construct when pre and post testing radiographs were compared.

Proximal Fixation

Each femur fractured because of the compressive force of the pneumatic grip before testing; however, this did not result in any slippage in 5/6 specimens. In 1 construct with slippage, the gastrocnemius was dissected from the femur and the fabellae used as an anchor point in the grip. This resulted in a secure fixation without slippage. Mean failure load was 266.13 ± 43.88 N. Failure occurred by tearing of the myotendinous junction proximal to the implant and sutures in all constructs (Fig 6B). No implant failure or suture pull out was identified. Failure of proximal fixation was significantly lower than distal fixation ($P = .042$; paired t-test). Mean stiffness of the proximal construct was 19.08 ± 8.16 N/mm ($n = 4$).

DISCUSSION

Using similar methodology, failure loads of constructs (both proximal and distal fixation) exceeded the values reported by Moores et al.³ (mean, 72.9 N) and Gall et al.⁴ (mean, 145.1 N) when suture fixation alone was used to attach the tendon to the calcaneus of similarly sized dogs. The myotendinous junction was the weakest part of the repair construct. Our results predict

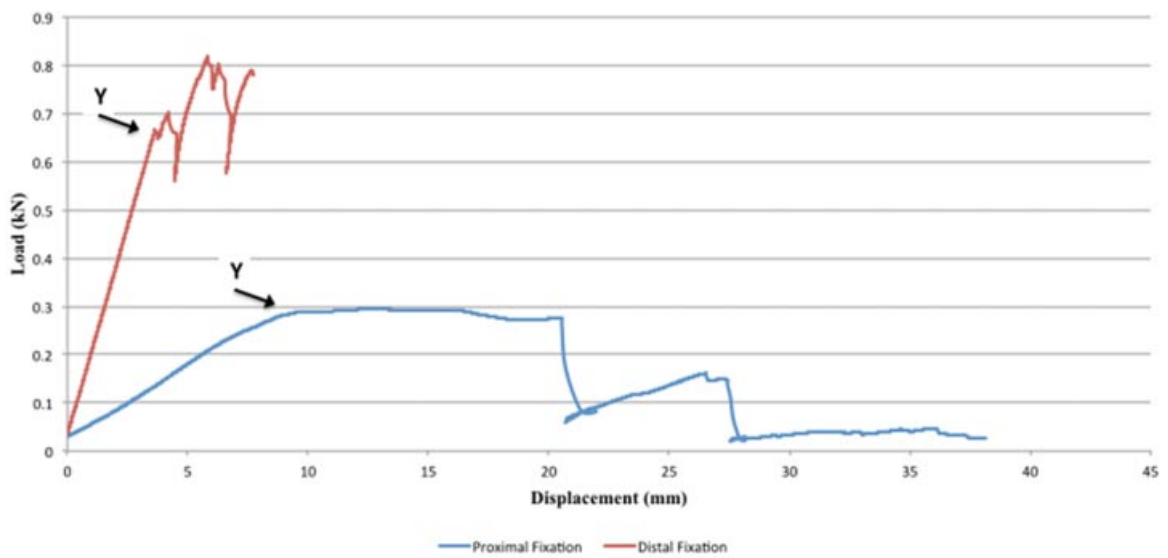


Figure 5 Representative load displacement curves for proximal and distal tests. 1 = the straight portion of each graph where stiffness was calculated. Point Y shows the yield point at which failure was determined.

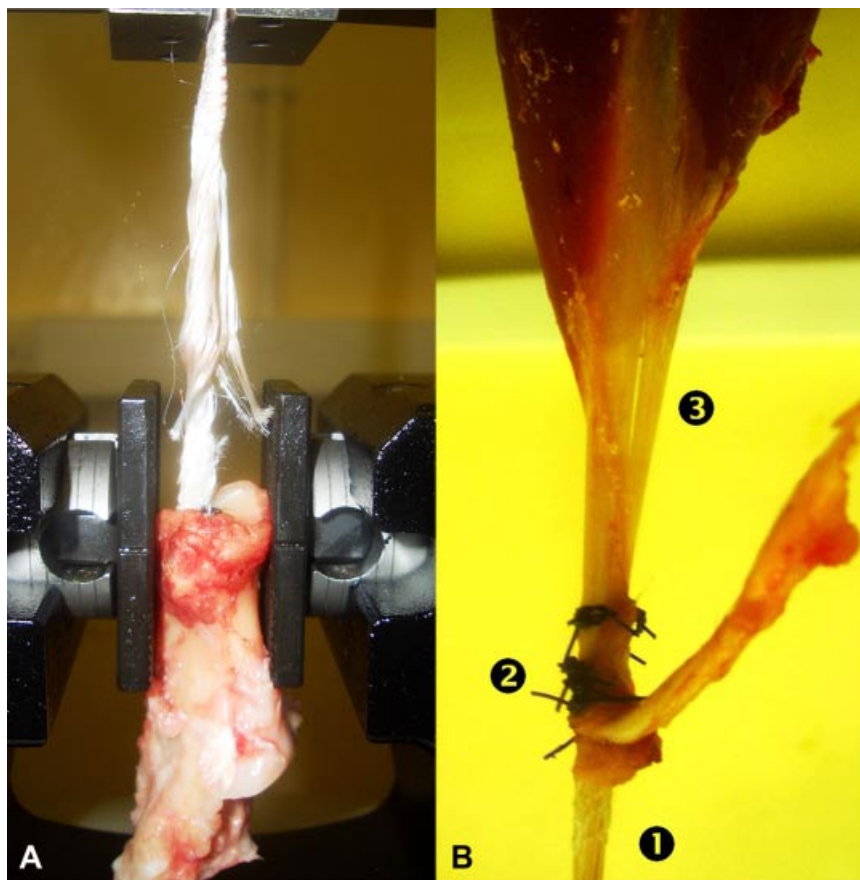


Figure 6 (A) Calcaneus and failed implant after testing distal fixation. (B) Implant and gastrocnemius showing myotendinous junction failure after testing the proximal fixation. 1 = central portion of the implant, 2 = sutures holding the implant, and 3 = failure of the myotendinous junction.

that failure of this repair in clinical cases would most likely occur proximally, at the level of the myotendinous junction, rather than by failure of the implant or its fixation. Gall et al.⁴ found a combination of polypropylene mesh and 3 loop pulley suture to have the greatest load to failure (mean, 376.95 N) and concluded that this combination was unsuitable for use clinically because of unacceptable gap formation, and possible problems with reduction of tendon gliding.⁴

Because both proximal and distal constructs were tested separately it is not possible to provide a figure for global stiffness of the repaired gastrocnemius unit. The proximal construct also incorporated both muscle and tendon as well the implant; the stiffness of each varies markedly. Further testing involving the whole gastrocnemius unit would be required to assess this. Assessment of stiffness is sensitive to the overall length of the test unit. Though the length of all implants used during testing was standardized, differences may have been present in the length of the gastrocnemius unit because of variations in dog conformation. This is a potential limitation of our study. Though the effect of this on our results is unknown but we attempted to minimize it by using dogs of similar size. Overall specimen length was also not reported in the study by Gall et al.⁴ Consequently comparison between these studies relies on the assumption of using dogs of similar size. Assuming that the repair tested by Gall et al.⁴ is a similar length to our distal construct, our distal construct is >12 times as stiff as the 3 loop pulley repair and >7 times as stiff of the suture and mesh repair they report. It is not possible to compare the stiffness of our proximal construct because we anticipate a significant difference in length between our proximal construct and the distal repair reported by Gall et al.⁴ We are unaware of data that allows comparison with the stiffness of the normal gastrocnemius myotendinous junction.

The difference between stiffness in the proximal and distal tests is explained by the greater displacement of the proximal section during testing, which occurred as the longer and inherently more compliant muscle and myotendinous junction stretched before failure. This is compared with the small amount of displacement of the shorter distal test segment and higher stiffness of the bone before implant failure in the distal test as well as the greater loads sustained. Clinical failure would occur when the gastrocnemius mechanism became too long to provide functional support. This value is likely to vary significantly depending on dog size. In our study, most failures under loading occurred with displacement of <15 mm. Therefore we believe load at failure to be a valid representation of clinical failure, as clinically the implant would resist substantial displacement before failure. Dog size (gastrocnemius length) will affect this and further investigation would be required to confirm this.

In any mechanical test, prevention of slippage is paramount. Use of pneumatic and mechanical grips with serrated faces, along with judicious intra-test monitoring, minimized slippage during this study. Use of cryoclamps was considered, though deemed unnecessary after preliminary work, and review of previous studies.^{3,4,9} Alternative fixation of the femur and calcaneus may have reduced fracturing. Testing was performed as soon as possible post-mortem to

minimize the effects on tissue structure and function. The effect of chilling on the specimen for a short period before testing is unknown, though we do not feel this affected results significantly. Hipara et al.¹⁵ showed no difference in the mechanical properties of tendons chilled before testing compared with frozen specimens. Failure loads *in vivo* would be anticipated to be higher than reported here if any tissue degradation did occur.

Our study lacks a control population of normal gastrocnemius tendons, and repairs with sutures only. Whereas matched pairs were considered, work evaluating normal tendons and repairs with suture only has been reported.^{4,9,16} Comparison of mechanical testing studies is limited by differences in experimental design. We acknowledge this limitation; however, our study design was based on previous work by Moores et al.³ to allow comparisons.

Although prevention of gap formation is essential for tendon healing, our aim was to evaluate immediate implant strength and fixation. Separate implants were tested both proximally and distally, which made a gap model difficult. Because of the uniplanar configuration of the mechanical testing machine, the implant was loaded parallel to the long axis of the calcaneus and interference screw. These factors introduce a major limitation of our study in that the testing model does not exactly replicate the clinical situation, where the forces of traction would act at a greater angle to the plane of the drill tunnel. Whereas the effects of this are unknown, it may be expected that when loaded anatomically, the strength of fixation in the calcaneus would be higher than we recorded because of increased friction at the interference screw interface with the implant and calcaneus. Zhang et al.¹⁷ have shown in a distal femoral model that resistance to implant pull out around interference screws increases significantly with greater angles of traction, though this may vary between materials. In our study, the implant itself failed before distal fixation in most constructs (4/6). Whereas altering the angle of loading (as would occur clinically) may increase the strength of fixation it is unlikely to affect the strength of the implant itself. Anatomic loading may increase shear on the implant, because of increased bone contact and result in earlier failure, though this was not demonstrated by Zhang et al.¹⁷ Testing by Gall et al.⁴ did incorporate a custom made jig which allowed the calcaneus to be positioned so that forces applied to the gastrocnemius repair replicated the clinical situation more accurately. Experimental design in any future work on this implant would benefit from replicating the methodology of Gall et al.⁴

Our study also differs slightly from the testing models used by Gall et al.⁴ and Moores et al.³ in that both of these studies only tested a tendon-bone repair method and used the gastrocnemius tendon for traction; the myotendinous junction was not included. Our results suggest that the myotendinous junction may also have failed before the mesh construct if this had been incorporated in the study of Gall et al.⁴ A previous mechanical study of the gastrocnemius tendon load-to-failure in similarly sized normal dogs, showed a greater mean load at failure distally than proximally (1107 N compared with 1031 N) although this was not statistically significant. The

myotendinous junction was not subjected to testing in that study.¹⁶ Whereas we acknowledge an anatomic testing position is preferable, no other investigator has, to our knowledge, tested the biomechanical properties of a canine gastrocnemius tendon unit or repair technique with incorporation of the origin as well as insertion. The implant in this study is biocompatible¹⁴; encourages anatomic ingrowth¹⁴; and is enclosed within the paratenon so that tendon gliding is not compromised. It may be used to bridge tendon defects after resection of scar tissue allowing restoration of functional length, which is a common problem with the treatment of chronic degenerative tendon failure.

Both implants that failed by distal prosthesis pull-out were from the same cadaver, which had the largest calcaneus. The screws remained *in situ* in both instances. It is likely this pull out would have been avoided if a larger diameter screw had been used. Further investigation is warranted to provide recommendations on screw size. Radiographically, the medullary cavity is wider in the dorsal to plantar aspect than in the medial to lateral aspect. Fixation may be more secure if screws are positioned medial or lateral to the implant, and this also provides a focus for future research. Any offset of the implant caused by a medial or lateral screw position is expected to be negligible and still within the footprint of the original gastrocnemius insertion. Though the effects of this are unknown it is not thought that this would affect the strength of the repair, or function significantly.

An ideal scenario for gastrocnemius repair would result in a construction strong enough to withstand normal weight bearing forces, negating the need for additional postoperative support and the associated complications. We found that the myotendinous junction of the gastrocnemius ruptured before reaching the predicted weight bearing loads that have been estimated in the Achilles mechanism of a 30 kg dog (399 N) at trot.⁹ Failure at this area may be explained stress concentration at the proximal end of the implant. This focal loading may have been magnified by the continuous loading in single load to failure test when compared with the normal cyclic loading experienced clinically. Distally, we have shown that both the fixation and implant exceed the weight-bearing forces on the whole Achilles' unit, estimated by Moores et al.⁹ to be 399 N in a 30 kg dog at a trot. Our study tested the gastrocnemius unit alone. It is possible that in clinical cases with load sharing proximally between the gastrocnemius, the combined tendon of the biceps, gracilis and semitendinosus, and the superficial digital flexor tendon, the construct would be sufficient to withstand anticipated weight bearing forces. A previous anatomic study showed the superficial digital flexor tendon to have a higher loads at failure than the gastrocnemius tendon of the same dog.¹⁶

In our clinical experience, the technique we tested is technically straightforward to perform, although a modification in implant design (incorporating a longer proximal section to aid implant positioning) has been made subsequent to this study. This will allow greater flexibility when implanting the prosthesis, improving suitability for use in dogs. Further *ex vivo*

assessment of gap formation using the modified implant in the whole gastrocnemius unit should be performed, using a larger number of samples and an anatomic testing positioning. Cyclic testing would also replicate more accurately the anticipated *in vivo* demands. However, considering the favorable mechanical testing data we report, further phase I testing in clinical cases is warranted.

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DISCLOSURE

Since this study, the primary author (MAM) has received remuneration from STIF related to publication of the surgical technique.

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