**Minimally-Invasive Achilles Suture Trial (MIAST):**

**Non-Absorbable vs. Absorbable**

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**Background & rationale for the study:**

 Operative repair of the ruptured Achilles tendon leads to improved ankle plantar flexion strength, less tendon elongation [Lantto] and reduced time to return to work [Soroceanu] than non-operative management. Minimally-invasive repair of the tendon shows similar outcome to operative repair however has reduced risk of complications such as infection and wound breakdown [Grassi].

 Both absorbable and non-absorbable suture materials have been used to repair the Achilles tendon and have resulted in good outcome although differing suture techniques, sizes, type of suture and rehabilitation methods make comparison difficult. The Carmont and Maffulli modified percutaneous repair technique was first described in 2007 and since then has shown good outcome in many patient groups [Carmont, Carmont, Carmont, Carmont, Maffulli, Al Mouazzen, Maffulli]. The original technique used Maxon sutures, an absorbable monofilament suture. Since then Fiberwire and Vicryl braided sutures have been used but patient outcomes have not been directly compared in a single study.

Braided sutures are easier to tie than monofilament, producing tighter knots which may not slip. Advantages of a non-absorbable suture e.g. Fiberwire, a blend of polyester and polytetrafluoroethylene, are that it is permanent and therefore the suture maintains it’s strength within the tendon. Disadvantages of a permanent foreign material are that it may be a site for infection, give a palpable prominent knot, lead to adhesions and may be associated with tendon thickening as the tendon remodels with loading following the repair.

An absorbable suture such as polyglycolic acid, will breakdown in 6-8 weeks following insertion. Advantages of the absorbable suture e.g. Vicryl, made of polyglactin 910, include a lack of permanent foreign material if infection occurs, if sural nerve entrapment occurs the ensnaring suture will be broken down and this may permit neural recovery in the long-term. Similarly, prominent knots may reduce in size. After breakdown of the suture this also means that there is no longer any intra-tendinous foreign suture material within the substance of the tendon. Over time this may permit improved remodeling and subsequent function compared with the permanent suture. The absorption process may also be detrimental as the breakdown of the suture involves an inflammatory process which may weaken the tendon. The suture is absorbed by hydrolysis in 56-70 days and 25% of its strength remains by the 4-week time point. The inflammatory response of absorption and the reduction in strength may lead to an increased rate of re-rupture and that the tendon may elongate resulting in weakness [Yilidrim].

**Aims/Objective:**

The aim of this study is to compare the functional outcome of patients who had sustained a rupture of the Achilles tendon and had this repaired using a minimally -invasive repair using either absorbable or non-absorbable suture material.

The null hypothesis is that there would be no difference in the plantar flexion strength at one year following repair.

**Design/methodology:**

A prospective randomized controlled study into the outcome of patients suffering from an Achilles tendon rupture treated by minimally invasive repair using either absorbable or non-absorbable sutures.

Multiple surgeon, single Trust SATH (2 hospital: PRH & RSH) using the same surgical technique, post-operative rehabilitation and physiotherapy instructions.

**Population - inclusion/exclusion criteria**

Inclusion-

Mid-substance Achilles tendon rupture, diagnosed clinically by the presence of a palpable gap to the Achilles tendon, and increased Achilles Tendon Resting Angle and a calf squeeze test

Ages 18-65yrs,

Active patients with Tegner ≥5 (Generally participates in sports on regular basis and is recreationally competitive

Presenting <15 days following rupture

Able to understand the spoken and written English language

After consultation wishes to have operative repair of the Achilles tendon rather than non-operative management.

Available for 12 months follow up at SATH

Exclusion-

Distal Achilles tendon rupture, identified by palpation of the distal stump ending <2cm proximal to the Achilles insertion

Musculotendinous Achilles tendon ruptures

Patients with Diabetes Mellitus, chronic inflammatory conditions, and musculoskeletal conditions preventing a single heel-rise prior to rupture

A previous ipsilateral or contralateral Achilles tendon rupture

Patients >110Kg & BMI >30 owing to obesity giving an increased risk of wound, cast and functional brace complications

**Data collection:**

Where possible data collection will be performed by a specialist nurse practitioner, blinded as to suture randomization. This will aim to ensure there is no observational bias and improve the methodology of the study. Contemporaneous data collection at routine/current evaluation at 2 weeks, 3, 6, 9 and 12 months following repair. This would be the same as current practice.

The primary outcome measure is plantar flexion strength determined by the Heel-Rise Height Index (HRHI), comparing maximal sustained heel-rise of the injured side to the non-injured side at 12-months following repair [Grävare Silbernagel]. Secondary outcome measures include the Relative Achilles Tendon Resting Angle (RelATRA at 3 & 12 months) [Carmont], the Achilles tendon Total Rupture Score (ATRS at 12 months) a patient reported outcome measure [Nilsson-Helander], Tegner Score [Tegner], Patient Perception of Performance [Carmont] at 12 months, the patient’s acceptability of the received suture at 12 months and the occurrence of complications.

Health economic analysis will also be performed consisting of two forms patient outcomes and economic costs as used by Westin et al. [Westin]. The economy of patient outcome data will be assessed using differences in health-related quality of life in the form of the EuroQol-5D questionnaire incorporating mobility, self-care, usual activities, pain/discomfort and depression or anxiety, being graded as none, moderate or severe. The answers will be scored on an index scale based on the UK tariff range of -0.59-1(Dolan algorithm) and will reflect a change from baseline, 3, 6, and 12 months.

Economic costs will be determined in the form of direct costs and indirect costs. Direct costs will be the actual cost of healthcare determined from the number of clinic and physiotherapy department visits made, whether day surgery or inpatient beds were used and the materials used in for the treatment as used in the cost effectiveness study by Carmont et al. [Carmont]. Indirect costs will be determined due to the production loss related to the impact of a patient’s injury in terms of a loss in the ability to work and will be based on the number of sick leave days taken. The patient’s occupational activities and their ability to work from home will influence this data. This will also be influenced by the occurrence of complications.

The cost-effectiveness will be determined from an incremental cost-effectiveness ratio determined from ICER= Cost Ab-Cost Non-Ab/QALY Ab-QALY Non-Ab.

The patient acceptability of the study will also be studied. This will be determined from the number of patients enrolled into the study, compared with the number of patients approached for recruitment into the study.

**Complications will be defined as follows:**

Re-rupture: Divided into traumatic & spontaneous

Traumatic re-rupture is a forcible fall onto the foot in the first 8 weeks following repair resulting in complete separation of the repaired tendon ends.

Spontaneous re-rupture is defined as an acute pain, snapping or popping to the Achilles tendon with push off.

Elongation: An increase of the ATRA to that of the original resting position of the tendon following rupture or a relative Achilles Tendon Resting Angle of -12˚.

Infection: the presence of redness, swelling, warmth and discharge from the surgical site and/or the presence of a positive culture on wound swab and/or the presence of a positive culture of removed suture material.

**Potential risks and how they will be managed:**

Re-rupture: Previous published cohort studies performed using the same surgical technique using an absorbable monofilament suture showed the following outcome measures and risk profile.

Complications would be managed as per current management:

Re-rupture > re-repair

Infection > Oral antibiotics, ± surgical suture removal

Adhesion > Endoscopic debridement

Prominent knot > surgical suture removal

Healing with elongation > tendon shortening

**Potential benefits:**

The potential benefit of having an absorbable suture is that over time the suture will be completely absorbed. This may have 2 benefits: in the early stage of rehabilitation from 3 to 6 months the tendon may hypertrophy and thicken, making it less compliant, more prone to adhesions and thicker as the tendon elongates and remodels with the intra-tendinous suture knot. If the suture is absorbable, the suture may have been completely absorbed, reducing this potential intra-tendinous irritation and cause of hypertrophy.

**Ethical considerations:**

The Researcher has considered the ethical matters and feels that these are minimal. Both sutures have been shown to be safe and effective however have not been compared directly in a PRCT. The follow up and management will be identical whether patients choose to be included or not. The Researcher’s main problem is that a patient does not want to be part of the study but wishes to have operative repair which suture to use since both sutures have produced similar results. The default will be that the Fiberwire suture would have to be used as this is the material for which the Researcher has completed the greatest number of cases (n=150).

One aspect is the potential for tendon elongation although this did not occur in the Researcher’s 2015 paper [Carmont] or Maffulli et als’ recent paper [Maffulli].

**Statistical review of study: recruitment target, how it was arrived at, how the data will be analysed**

The Minimal Important Clinical Difference of HRHI is considered to be primary outcome measure.

Data analysis will be performed on the SPSS programmes on the computers from the University of Staffordshire at the library on the RSH site.

The sample size will be determined using the freely available G\*Power programme [G Power].

Power calculations have been performed based on what we may find e.g. a 10-15% different in HRHI. Using students t test with Alpha 0.05, and ß 0.2, giving a power of 0.8, and a SD of 20% based upon 2 previous studies:

Large effect size 15% 0.75, gives a total of 58 patients, 29 per group.

Moderate effect size 10% 0.5, gives a total of 128 patients, 64 per group.

Therefore, based upon current presentation rates following Achilles tendon ruptures of 25 per year PRH site only, overall SATH potentially 50 allowing for loss to follow up of 20%, including re-rupture recruitment could take 1.5-2 years.

Randomisation to use a computer-generated binary sequence and sealed envelope allocation. The envelopes will be stored in my locked office. The envelope will be opened at the team brief prior to surgery. The suture material will not be documented in the operative notes. The type of suture used will be emailed to the Research Nurse along with the patient’s hospital number and this can be stored on an entirely separate spreadsheet and computer.

Suture materials will be selected prior to and discussed at Team Brief so that suture will be available during the case. Patients will be blinded as to which suture material has been used. The surgeon will have knowledge of the suture material that was inserted and this was then recorded on a separate spread sheet on Microsoft Excel immediately following surgery. Post-operative evaluation details would be entered into a different spread sheet. Unblinding would only need to occur after data analysis or if wound infection occurred to determine if the suture would need to be removed. This means that the researcher would be unlikely to have recollection of the suture material.

**Missing Data:**

Those patients whom were not available to be evaluated at the 12-month time point would be considered to be lost to follow up. Given the progressive nature of the recovery of patients following Achilles tendon rupture the inclusion of a patient’s values from an earlier time point would not be acceptable. Patient’s outcomes could not be analysed on an intention to treat basis.

**Information governance/data protection requirements:**

Any data will be stored according to the GDPR principles and anonymized.

This will be stored on a secure NHS laptop.

**Funding:**

This study should not require funding. Both suture materials are in common usage within SATH. Follow up occurs within routine clinics.

**Resources and costs – how this will be managed:**

Patients will be treated identically if they are enrolled or not, other than having a suture on a randomized basis. This is exactly the same surgery, the same number and duration of follow ups.

The only difference is the difference in cost of the suture material, assuming that the same number of strands are used i.e. 5 per repair

Using Vicryl (W9378 £35.88 per box of 12) the cost = £14.95

Using Fiberwire (AR-7233 £191.94 + VAT per box of 12) the cost = £95.97

**Dissemination-communication of results:**

Presentation internationally and publication.

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