Research Proposal

POBRAT-Post-Operative Bracing following Repair of the Achilles tendon

Comparison of methods and duration of post-operative bracing following repair of acute Achilles tendon rupture.

Michael R Carmont, Consultant Trauma & Orthopaedic Surgeon.

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Background:

The aim of management of patients with Achilles tendon rupture is to restore function and preserve push off strength, with the minimum of complications. Rupture of the Achilles tendon results in reduced ankle plantar flexion strength [Olsson, Brorsson, Lantto]. This weakness, in the form of reduced single heel-rise height, correlates with elongation of the Achilles tendon [Grävare Silbernagel]. Research has focused on reducing elongation of the tendon during rehabilitation, minimising weakness.

Percutaneous and minimally-invasive repair followed by immediate weight-bearing and early range of motion exercises has shown good outcome following Achilles tendon rupture [Carmont, Carmont, Maffulli, Al Mouazzen]. The post-operative regime in these studies involves the use of an anterior protective shell permits weight-bearing on the meta-tarsal heads with active ankle plantar flexion and yet prevents dorsiflexion for 6 weeks duration [Carter]. A small number of patients have lost balance during mobilisation and inadvertently borne all their weight on the injured foot, dorsiflexed their ankle resulting in traumatic re-ruptures of the tendon.

Varying the number of sutures and suture material to repair the tendon using the same rehabilitation method, has revealed similar changes in the Achilles Tendon Resting Angle (ATRA) and no difference in patient reported outcome or heel-rise height following rupture [Carmont, Carmont]. When the ATRA was observed over the period of rehabilitation and recovery, the repaired ankle the adopted increased resting dorsiflexion compared with the non-injured side following repair up to approximately 6 weeks whilst weight-bearing on the metatarsal heads only. Dorsiflexion then increased significantly further with normal weight-bearing on the whole of the foot over the subsequent 6 weeks, 3 months following repair and then did not significantly change [Carmont]. A recent study using the same suture

configuration using absorbable suture but with a prolonged period of 11 weeks of wedged brace use, showed low relative ATRA values at one year following repair and lower re-rupture rates [Maffulli].

Eliasson et al. also found no difference in outcomes using different regimes of weight-bearing and ankle immobilisation for 8 weeks. Tendons were repaired with a single absorbable Kessler suture and then ankle protected with a walker boot with wedge. Tendon elongation continued for up to 6 months following surgery irrespective of early or late weight-bearing and movement [Eliasson].

A recent meta-analysis has shown that 8 weeks is a common period of protected mobilisation in non-operated rehabilitation [Harrington]. A recent study of minimally-invasive repair using absorbable suture with subsequent prolonged wedged brace use showed low relative ATRA values at one year following repair [Maffulli].

The aim of this study is to compare the outcome of patients following minimally-invasive Achilles tendon repair mobilising for 6 weeks of weight-bearing in an anterior shell with those mobilising for 8 weeks in an anterior shell and heel wedges.

Methods:

This study is a non-randomized cohort comparison design, comparing the outcomes of two cohorts of patients following minimally-invasive surgery followed by immediate weight-bearing and early range-of-movement exercises following mid-substance rupture and repair of the Achilles tendon.

The study cohort of patients will be prospectively evaluated and will receive two weeks in a synthetic cast in plantar flexion, weight-bearing on the meta-tarsal heads. Subsequently the patient will receive 6 weeks with an anterior cast shell in plantar flexion and a boot with wedges, weight-bearing on the sole of the walker boot.

The comparison cohort of patients were retrospectively managed however received the same surgical technique, in terms of suture configuration and material, and post-operatively received two weeks in a synthetic cast. After two weeks this historical retrospective cohort used the synthetic anterior cast shell in plantar flexion only, with continued weight-bearing on the meta-tarsal heads. For both cohorts, weight-bearing was performed together with crutches.

Patients will be recruited from those presenting to Shrewsbury & Telford Hospital NHS Trust with an Achilles tendon rupture. Diagnosis would be made based upon the history of a sensible pop to the Achilles during plantar flexion usually during sports or activities of daily living. Clinical features include a palpable gap in the tendon, a loss of the normal resting posture to the ankle and the absence of plantar flexion on calf squeeze test. Imaging is not used to confirm the diagnosis of mid-substance rupture.

All patients received or will receive, a minimally-invasive repair using a similar surgical technique consisting of a six-strand repair using Number 2 Fiberwire® (Arthrex, Naples, Fl) in the configuration of a modified Bunnell suture proximally and a Kessler suture distally. The sutures were tied with the ankle held in maximal plantar flexion [Carmont].

Following surgery patients were placed in a synthetic below knee cast with the ankle in full plantar flexion. The cast was split and held in place using Velcro straps [Carmont]. Immediate weight-bearing on the metatarsal heads was permitted as comfort allows, using crutches. At two weeks following surgery, the wounds were inspected, sutures removed. At that time point active plantar flexion, inversion and eversion exercises of the ankle were commenced three times per day.

Study and Control groups:

At two weeks following surgery, the posterior half of the synthetic cast was discontinued, and the anterior shell was held in place with the Velcro straps.

Study group: In addition to the anterior shell, patients were fitted with a Walker boot with 4 heel wedges (Össur, Reykjavik, Iceland) enabling them to bear weight on the whole of the foot. This was to be used for the next 6 weeks until 8 weeks following repair. Crutches were to be continued for all weight-bearing. The Össur boot with wedges has been shown to produce satisfactory patient reported outcome measures following non-operative management [Maempel].

Control group: Patients continued the use of the anterior synthetic cast shell held in place using the Velcro straps. Patients were permitted to weight-bare on their meta-tarsal heads only for the next 4 weeks until 6 weeks following repair. Crutches were to be continued for all weight-bearing.

After the 6-week and 8-week time points respectively, patients were referred for physiotherapy for gait retraining and strengthening exercises. Stretching exercises and plyometric exercises were not recommended until 6 months. Patients were given a 1.5cm

heel-raise to place into the heel of both shoes to be worn for all weight-bearing until 3 months following repair.

Evaluation:

Contemporaneous data collection was performed at routine follow up at the completion of brace use at 6 and 8-weeks, and at 3, 6, 9 and 12-months following repair. The primary outcome measure is 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]. The HRHI is an indirect measure of tendon elongation [Grävare Silbernagel]. Secondary outcome measures include the ATRA [Carmont], a validated direct measure of tendon length [Hansen], the Achilles tendon Total Rupture Score (ATRS), a patient reported outcome measure [Nilsson-Helander], Tegner Score [Tegner], and the Patient Perception of Performance [Carmont 2017].

Enrolment:

Patients will be recruited from those presenting to Shrewsbury & Telford Hospital NHS Trust with an Achilles tendon rupture. Diagnosis would be made based upon the history of a sensible pop to the Achilles during plantar flexion usually during sports or activities of daily living. Clinical features include a palpable gap in the tendon, a loss of the normal resting posture to the ankle and the absence of plantar flexion on calf squeeze test. Imaging is not used to confirm the diagnosis of mid-substance rupture.

Patients in the study group will be those receiving a non-absorbable suture in the Minimally-Invasive Achilles Suture Trial (MIAST). These patients will have to be included retrospectively following their unblinding from MIAST at 12 months.

MIAST is a randomised prospectively controlled trial of absorbable versus non-absorbable suture usage with the same post-operative weight-bearing, early range of movement exercises and brace protection. Patients will be blinded as to the material of the suture they receive. Patients from MIAST who at unblinding who were found to have received a non-absorbable suture will have an explanation of the further analysis and consented for inclusion in this study.

Patients in the control group have already received their treatment and evaluation following Achilles tendon rupture. These patients have given informed consent for their anonymous data to be used for research and comparison purposes.

Being included in this study will only involve the use of the patient's medical records and assessments that have already been undertaken.

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

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, diagnosed by tenderness at the musculotendinous junction and on ultrasonography. Ultrasonography will be used for the confirmation of musculotendinous rupture rather than mid-substance rupture.

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

Statistical review of study:

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

In terms of sample size, a 1:2 ratio of study to control patients would reduce the effect size. As the control patients' data is being retrospectively analysed this would mean that recruitment for the study group would be likely to take 2 years. This would be based upon a presentation rate of 25 per year and these being randomised into non-absorbable or absorbable sutures within MIAST.

This is a cohort comparison study of prospectively collected data. All patients gave consent for data collection and anonymous analysis. Data will be analysed descriptively in terms of Mean (Standard Deviation) and Median (Minimum value-Maximum value). Following the assessment for normality, parametric data will be compared using the students t test. Non-parametric data will be analysed according to the Mann-Whitney U test.

Information governance/data protection requirements:

Any data will be stored according to the GDPR principles and anonymized. This will be stored on a secure password protected NHS laptop and a study file kept in a locked office.

Costs:

The use of the boot with wedges has been adopted in Royal Shrewsbury Hospital since 2019. I presented and received approval for the use of the Össur boot with wedges at the Devices, Products and Gases Meeting 1st December 2020. The continued audit of outcome and evaluation of the use of the boot with wedges was recommended.

Research application:

This study is a **cohort comparison study** and is not randomised. The outcomes will be analysed retrospectively to evaluate a change in treatment made on previous studies and recent published literature.

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