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Randomized controlled trial of accelerated rehabilitation versus standard protocol following surgical repair of ruptured Achilles tendon

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Abstract

Background: There is no consensus regarding the optimal management of the acutely ruptured Achilles tendon (TA). Functional bracing alone achieves outcomes similar to those of surgical repair. Surgical repair combined with immediate mobilization may improve the clinical outcome further. The purpose of our study was to determine if an accelerated rehabilitation programme following surgical repair of the ruptured TA could improve clinical outcome, relative to the standard protocol.
Methods: Patients with an acutely ruptured TA were randomly allocated to undergo an accelerated programme (AP) or standard programme (SP), following surgery. Outcome was assessed at 12 months post-surgery using the Achilles tendon Total Rupture Score (ATRS), the heel-raise height and the time taken to return to running.
Results: Fifty-one patients completed the study, 25 in the AP group and 26 in the SP group. At 12 months post-surgery, the ATRS results were similar in the two treatment groups (87.46 in AP with standard error (SE) of 0.735 versus 87.12 in SP with SE of 0.75) while the AP group had less lengthening of the TA (0.385 cm, SE 0.166 versus 1.00 cm, SE 0.169) and a more rapid return to running (17.231 weeks, SE 0.401 versus 21.08 weeks, SE 0.409), than the SP group.
Conclusion: The accelerated rehabilitation programme resulted in less tendon lengthening, more rapid return to running, but similar ATRS relative to the standard rehabilitation. Immobilization following TA repair may prolong recovery.

Introduction

Achilles tendon (TA) rupture is a common injury and is associated with a prolonged period of rehabilitation. Irrespective of treatment chosen, recovery may be incomplete. Strength deficits of 10–30% are common and may be permanent.[1,2] This weakness is most pronounced towards the end range of plantar flexion and this is responsible for the gait abnormalities, commonly seen up to 2 years following surgical repair.[3]

Mechanical stimulation during the reparative phase of tendon healing has been shown to be beneficial and the most effective form of mechanical stimulation is early motion.[4] During TA healing, tendon separation has been demonstrated to occur up to 4 months post-surgery, and poor clinical outcome correlates with tendon lengthening.[5,6] Concern over potential elongation may be responsible for the post-operative regimes, which include a period of immobilization. However, workers have demonstrated that early mobilization is as important as surgical repair of the TA.[7]

Surgical techniques have improved, and the introduction of suture material of high tensile strength, combined with the ability to place locking sutures in a tendon, results in a more robust repair. This surgical technique may permit immediate safe mobilization of the tendon post-surgery. Previous workers have published favourable, but uncontrolled data, using a similar surgical technique with no post-operative orthosis.[8]

This study was designed to determine if immediate mobilization following surgical repair of the ruptured TA could improve the clinical outcome, relative to a standard post-operative regimen.

Methods

During the period April 2009 to October 2011, patients presenting to the main author with a ruptured TA, who satisfied the inclusion and exclusion criteria shown in Table 1, were invited to take part in the study. All patients were informed of the rationale behind the study

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
First-time Achilles tendon rupture	Recurrent rupture, compound injury
Mid-zone rupture	Part of a combined injury
Presentation within 3 days of injury	Previous treatment with intra-tendinous or paratendinous injection of corticosteroid or prolotherapy
Clinically diagnosable (positive Symmond's test)	Unfit for surgery or general anaesthesia
Age: 18–65	Unable to complete either rehabilitation programmes
Written informed consent	

and were willing to be randomized to either arm of the study. Ethical approval was obtained from the surgical centre's quality, safety and ethics committee.

Each patient underwent the surgical repair using the technique described below. On completion of surgery, patients were randomized using a single toss of a coin, to either follow the standard rehabilitation regimen (SP group), or an accelerated regimen (AP group). These protocols are detailed in Table 2.

Surgical technique

All surgery was performed within 10 days of the injury. The procedure was performed under general anaesthesia in an operating theatre, under standard sterile conditions. A tourniquet was used in all cases with the patient in a 'lazy-lateral' position. A medial-sided para-tendon incision and approach was used, with sharp dissection to the tendon and preservation of the paratenon. The tendon ends were cleared of blood clot and debris. Tendon repair was planned to produce a resting length similar to that of the non-injured side. The repair was performed using a locking Krackow suture with a minimum of four locking loops on each side of the rupture and four strands crossing the rupture and a no. 2 fibrewire. A cross-stitch using 0-PDS (Ethicon, Somerville, NJ, USA) was used to over-sew the repair, before closing the paratenon and subcutaneous fascia with 2-0 vicryl and a tension-free, running subcutaneous 3-0 monocryl and steristrips to the skin.

Post-operative rehabilitation

Those patients randomized to the SP were placed in a dorsal plaster-of-Paris slab in the resting position until 10 days post-surgery. Their rehabilitation was similar to that used by Twaddle and Poon[7] (Table 2). At the first post-operative review, patients were placed in an extension-blocking orthosis set at 20 dg plantar flexion. The orthosis was removed for active range of motion exercises and hygiene only. At 4 weeks post-surgery, the orthosis was adjusted to block extension to neutral while the range of motion exercises were continued. At 6 weeks, weight bearing as tolerable with or without crutch assistance was commenced, and the orthosis was removed at night. At 8 weeks post-surgery, the use of the orthosis was discontinued and the patient encourage to wean from the use of the crutches. Strengthening work was introduced at this stage, and progression to double leg calf raises with the uninjured calf supporting the operated side.

Those randomized to the AP followed a protocol similar to that used by Yotsumoto *et al*.[8] (Table 2). These patients were placed in a heavy crepe bandage following surgery and encouraged to commence active range of motion exercises from neutral to full plantar flexion as soon as possible. At the initial post-operative review, these patients were placed in an orthosis and allowed to begin partial weight bearing. The orthosis was removed at night and whenever non-weight bearing. The number of 10-mm heel wedges used was dependent upon the tension in the calf muscles. A heel wedge was removed every 2 weeks until the ankle was held in neutral within the orthosis. Weight bearing and range of motion were progressed as tolerable with the introduction of strengthening when 6 weeks post-surgery.

No patient was allowed to attempt a return to running until strength was similar to that of the opposite uninjured calf.

Follow-up

All patients were reviewed 10–14 days following surgery. Patients were then placed in the TA boot and given instructions appropriate for their rehabilitation programme. Those patients in the AP group were instructed to only wear the boot while mobilizing, and to remove it all other times, as long as comfortable to do so. The SP group, only removed the boot for washing, but was instructed to commence active plantar flexion exercises while in an extension-blocking device.

Patients were routinely reviewed at the following scheduled time intervals post-surgery; 6 weeks, 3 months, 6 months and 12 months.

Outcomes of interest

The Achilles tendon Total Rupture Score (ATRS) is a validated patient scored outcome assessment tool.[1] It consists of 10 subscales, each of which is scored out of a maximum score of 10 points. The scores are tallied to produce a final score out of the maximum possible score of 100, and a 10-point difference in the score is regarded as clinically relevant. All patients were asked to complete this score at 12 months post-surgery.

The heel-rise height (HRH) is a validated measurement of TA lengthening.[9] Each patient performed this test, under the supervision of the lead author, 12 months post-surgery. Following restoration of muscle strength, side-to-side differences in the HRH are a validated measure of TA lengthening.[9]

The rehabilitation was supervised by a physiotherapist, and each patient was allowed to return to running only after restoration of muscle strength and endurance. They were asked to record at how many weeks post-surgery they were able to return to continuous running for a minimum of 5 min.

The occurrence of any complications was recorded by the surgeon.

Statistical analysis

The results were analysed using the SPSS package (v21; SPSS, Inc., Chicago, IL, USA). The outcomes in the two groups were compared using a generalized linear model with multivariate dependent outcomes. We considered both parametric and non-parametric analyses. A probability of 5% was used throughout and a Bonferroni adjustment for multiple comparisons was performed. A power analy-

Table 2 Accelerated and standard rehabilitation protocols

	Standard protocol	Accelerated protocol
Immediate post-surgery	Hanging equinus POP slab	Heavy crepe bandage and immediate ROM exercises
Post-operative review (10–14 days)	Dorsiflexion blocking orthosis at 20–30 dg plantar flexion x 2 weeks	Removable TA boot, PWB with crutches, boot removed when NWB, number of heel wedges required for resting position, one wedge removed per week
4 weeks	Dorsiflexion blocking orthosis at neutral × 2 weeks	Most patients will be using two heel wedges and FWB with the boot is allowed
6 weeks	Begin PWB with crutches and the orthosis	Most patients will be FWB with no wedges, and weaning from the boot is commenced, resistance strengthening work introduced
8 weeks	Progress to FWB as tolerable with the orthosis	Progressive strengthening work
10 weeks	Wean off the orthosis for mobilizing, commence resistance strengthening	Progressive strengthening work
12 weeks	Passive stretching if indicated to regain ROM	Passive stretching if indicated
Return to running	When strength and muscle endurance have been restored to at least that present on the uninjured side	When strength and muscle endurance have been restored

FWB, full weight bearing; NWB, nil weight bearing; POP, plaster-of-Paris; PWB, partial weight bearing; ROM, range of movement.

sis calculation was performed for the ATRS and required a total of 46 patients for the study, to achieve a power of 0.80 and an alpha value of 0.05. The study was more powerful for both the HRH test and time to return to running (TTR).

Results

Fifty-four patients were enrolled in the study. Twenty-eight were randomized to the standard regimen, and 26 to the accelerated regimen. Three patients were lost to follow-up, all from the standard rehabilitation group. At 12 months follow-up, there were 25 in the standard group, M : F = 20:5, and average age 36.2 years (range 19–46). There were 26 in the accelerated group, M : F = 22:4, and average age 32.2 years (range 19–45). The three patients lost to follow-up had all relocated, and could not be contacted. Prior to their withdrawal from the study, they had no known complications and no data had been entered into the study. For this reason, they were not included in the final analysis.

At 12 months post-surgery, the ATRS results were similar in the two treatment groups. The mean total ATRS was 87.46 in AP group (SE of 0.735), while that in the SP group was 87.12 (SE of 0.75). With regard to the HRH test, the AP group had a mean lengthening of 0.385 cm (SE 0.166), and that of the SP group was 1.00 cm (SE 0.169). The AP group were able to return to running at a mean of 17.231 weeks post-surgery (SE 0.401), while the time taken for the SP group was 21.08 weeks (SE 0.409).

The results of the ATRS scores for both groups are shown in Table 3, along with their mean values and standard errors. The results of the HRH test and TTR results for both treatment groups are shown in Table 4.

Statistical analysis

Table 5 details the results of the statistical analysis. Similar results were obtained for both parametric and non-parametric analysis.

In summary, both groups had similar ATRS total scores at 12 months. The accelerated group had significantly higher scores in sub-scales of the ATRS scores for strength, fatigue, stiffness, stairs/slopes, running and jumping. The accelerated groups had less difference in HRH compared with uninjured side, and thus lengthening of the repaired TA. The accelerated group also had lower TTR, or in other words, a quicker return to running following surgery.

Table 3 The mean subscale and total ATRS results for the two treatment groups

Subscales and total ATRS	Standard protocol	Accelerated protocol
Strength	8.0 (0.177)	9.3 (0.174)
Fatigue	7.6 (0.189)	9.2 (0.185)
Stiffness	8.9 (0.149)	9.5 (0.146)
Pain	9.6 (0.106)	9.6 (0.106)
Activities of daily living	9.2 (0.295)	9.8 (0.289)
Uneven surfaces	9.6 (0.099)	9.7 (0.097)
Stairs and slopes	8.3 (0.139)	9.6 (0.136)
Running	7.6 (0.167)	9.2 (0.163)
Jumping	8.2 (0.186)	9.4 (0.182)
Heavy physical labour	9.6 (0.114)	9.7 (0.112)
Total	87.12 (0.75)	87.46 (0.735)

Standard error in parentheses. ATRS, Achilles tendon Total Rupture Score.

Table 4 The mean results of the HRH test and TTR for the two treatment groups

	Standard protocol	Accelerated protocol
HRH (cm)	1.0 (0.169)	0.38 (0.166)
TTR (weeks)	21.08 (0.409)	17.23 (0.401)

Standard error in parentheses. HRH, heel-rise height; TTR, time to return to running.

Complications

There were two recorded complications, and both of these occurred in the SP group. Both patients complained of a limp 12 months following surgery because of clinical lengthening of the TA and weakness of push off during gait. At final follow-up, neither patient's functional limitation warranted any further treatment.

Table 5 Results of the statistical analysis comparing the two treatment groups

Dependent variable	SP	AP	Mean difference	SE	*P*-value	95% CI
ATRS (total score)	87.12	87.46	0.342	1.05	0.746	1.769–2.452
Strength	8.0	9.3	1.268*	0.248	<0.001	0.769–1.767
Fatigue	7.6	9.2	1.552*	0.265	<0.001	1.02–2.084
Stiffness	8.9	9.5	0.658*	0.208	0.003	0.24–1.077
Pain	9.6	9.6	0.02	0.152	0.88	0.328–0.282
ADLs	9.2	9.8	0.568	0.413	0.176	0.263–1.398
Uneven surfaces	9.6	9.7	0.094	0.139	0.502	0.185–0.373
Stairs and slopes	8.3	9.6	1.295*	0.194	<0.001	0.905–1.686
Running	7.6	9.2	1.592*	0.233	<0.001	1.123–2.061
Jumping	8.2	9.4	1.223*	0.26	<0.001	0.7–1.746
Heavy physical labour	9.6	9.7	0.054	0.159	0.737	0.267–0.374
TTR (weeks)	21.1	17.2	3.849*	0.572	<0.001	2.699–4.999
HRH (cm)	1.0	0.3	0.615*	0.237	0.012	0.139–1.092

*Statistically significant at $P < 0.05$. ADL, activities of daily living; ATRS, Achilles tendon Total Rupture Score; CI, confidence intervals; HRH, heel-rise height; TTR, time to return to running.

Discussion

This study has demonstrated how appropriate post-operative rehabilitation may be able to capitalize on the improved mechanical strength of a surgically repaired construct, analogous to stable fixation of intra-articular fractures followed by early mobilization.

The immediate mobilization protocol for the repaired TA used in this study resulted in less lengthening of the tendon and a faster return to running. Although the overall ATRS results were similar, there were significantly higher scores in those subscales more specific to function, that is, strength, fatigue, stiffness, stairs/slopes, running and jumping. A 10-point difference in the total score is regarded as clinically significant, and therefore, if each of the 10 subscales is equally weighted, a 1-point difference within a subscale may be significant. If this is the case, then there may have been a clinically relevant and significantly better outcome in the AP group, relative to the SP group for strength, 9.3 versus 8.0 ($P < 0.001$); fatigue, 9.2 versus 7.6 ($P < 0.001$); stairs and slopes, 9.6 versus 8.3 ($P < 0.001$); running, 9.2 versus 7.6 ($P < 0.001$); and jumping, 9.4 versus 8.2 ($P < 0.001$).

Although the 'time to return to running' is not a validated measure of functional outcome, patients recovered quicker following the accelerated programme. This measure relies on the patient accurately recording the number of weeks before they were able to complete a continuous 5-min run. The speed of running was not specified, nor the terrain.

The HRH test has been validated as a measure of TA lengthening, following the restoration of muscle strength. In our study, it was performed 12 months post-surgery, when muscle strength had been restored.

Proponents of acute surgical repair of the ruptured TA cite the reduced risk of recurrence as the indication for surgical intervention, while the proponents of non-operative treatment cite the lower morbidity as the justification for non-operative treatment. Nistor's research in 1981 confirmed these relative risks and, based on the data at that time, he concluded that non-operative treatment was superior.[10] Since then, both operative and non-operative treatments have evolved with shorter periods of immobilization. Nonetheless, more recent data from individual studies and meta-analyses confirms the higher re-rupture rate in those patients managed without surgery and the greater risk of complications in those managed with surgery.[2]

Twaddle and Poon drew attention to the fact that the apparently superior outcome and lower risk of recurrence with surgery may be attributable to the negative effect of the longer period of immobilization used during non-operative treatment of TA rupture. In their level 1 study, they demonstrated that early motion was as influential, with regard to both clinical outcome and recurrence rate, as surgical repair.[7]

The advent of braided polyethylene-blend suture material with high tensile strength, combined with effective locking suture technique, has generated the possibility safe post-operative rehabilitation, without any form of immobilization.[8,11–13] Biomechanical studies have confirmed that the epitendinous augmented four-strand locking Krackow technique, was superior to the four-strand Krackow technique in terms of both pull-out strength and gap resistance.[14] This technique was found to withstand forces comparable with those generated while full weight bearing with a 1-inch heel lift in place.

It is on the basis of these studies that the lead author chose to use a #2 fibrewire four-strand locking Krackow core suture, augmented with an epitendinous 0-PDS cross-stitch.

Although Yotsumoto *et al*. generated the hypothesis that an immediate mobilization protocol may improve the outcome following surgical repair of the TA, this has not been tested with the rigor or a randomized controlled trial.[8] These researchers reported a safe, rapid and more economical management of ruptured TA without the use of any period of immobilization. However, there was no comparison group in their case series of 20 patients. The results of our study demonstrated that the more active protocol reduced the amount of lengthening that occurs in the ruptured tendon, improved some functional outcomes and reduced the time required to return to running.

Kangas *et al*. also found that early motion resulted in less TA lengthening, and this correlated with improved clinical outcome measures.[6] The early motion protocol in their study used a dorsiflexion blocking splint at neutral, and patients were allowed to move the ankle between neutral and full plantar flexion.

Surgical repair of the ruptured TA is often followed by separation of the tendon ends by 0.5–1.0 cm, and progression until 4 months post-surgery.[5,6,15] However, the whole tendon appears to be affected by the injury and its treatment. Lengthening has been demonstrated to occur both proximal and distal to the rupture site,[15] and workers have confirmed pathological changes within the tendon on both sides of the rupture.[16]

Studies on tendon separation found that when the length of the entire tendon was considered, most of the lengthening occurs in the first 3 months. It may be assumed that this period is the most influential with regard to minimizing the lengthening that occurs. Early mobilization has been shown to reduce the amount of tendon separation that occurs.[6] Animal studies have confirmed the beneficial effect of mechanical stimulation on tendon healing, but have also demonstrated that it has to be applied during the early stages of healing to avoid permanent damage.[4,17]

Tendon lengthening following surgical repair occurs in two phases, each of which may have different aetiology.[6] The first phase occurs during weeks 0–5 and this is thought to be due to tightening of the suture loops and/or tissue necrosis. This may be reduced by using a locking suture technique, using small tight loops and high tensile strength suture material. The second phase occurs during weeks 5–60 and this phase of lengthening can be reduced and possible reversed by early mobilization. The mechanism has been theorized to be due to stretching of the entire tendon, rather than the site of repair. Early mechanical stimulation of the repaired tendon may reduce the later phase of lengthening by encouraging 're-rotation' of the damaged tendon, as suggested by Kangas *et al*.[6]

The use of modern surgical suture techniques and suture material, combined with a rehabilitation programme that incorporates immediate mobilization, may be effective in reducing both of these phases of lengthening. The combined treatment package may address the entire tendon, rather than purely the site of rupture.

The weaknesses of the current study include its relatively small sample size, albeit of adequate power, and the lack of blinding. The latter may have introduced potential bias in favour of the newer treatment. There was no means by which the authors could accurately monitor or ensure compliance with the post-operative guidelines, and/or physiotherapy; however, the study was designed to compare these treatment regimens in the clinical setting.

Despite these weaknesses, this study has demonstrated that an immediate mobilization programme, following acute surgical repair of the ruptured TA, improves the clinical outcome in terms of the tendon lengthening and time required to return to running, with similar overall ATRS scores.

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