The Ruptured Achilles Tendon Elongates for 6 Months After Surgical Repair Regardless of Early or Late Weightbearing in Combination With Ankle Mobilization: A Randomized Clinical Trial

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The ruptured Achilles tendon elongates for 6 months after surgical repair regardless of early or late weight bearing in combination with ankle mobilization in a randomized clinical trial.

Running title: Achilles tendon elongation after tendon rupture.

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ABSTRACT

Background: There is a considerable variation in the treatment strategy for Achilles tendon rupture, and clinical outcome may depend on the magnitude of tendon elongation after surgical repair. The aim of this project was to examine if tendon elongation, mechanical properties and functional outcomes during rehabilitation of surgically repaired acute Achilles tendon ruptures were influenced by different rehabilitation regimens during the early post surgical period.

Hypothesis: Restricted early weight bearing that only permits limited motion about the ankle in the early phase of tendon healing limits tendon elongation and improves functional outcome.

Study design: Randomized controlled trial.

Methods: 75 consecutive patients with an acute Achilles tendon rupture were included. They underwent surgical repair and had tantalum beads placed in the distal and proximal parts of the tendon and thereafter randomized into three groups: The *LWB+IMMOB group* were completely restricted from weight bearing until week seven. The *LWB+MOB group* were also completely restricted from weight bearing until week 7, but performed ankle joint mobilization exercises. These 2 groups were allowed full weight bearing after week 8. The *EWB+MOB group* was allowed partial weight bearing from day one and full weight bearing from week 5. All patients received the same instructions in home exercise guidelines starting from week 9.

Results: The rehabilitation regimen in the initial 8 weeks did not significantly influence any of the measured outcomes including tendon elongation. Achilles tendon elongation and tendon compliance continued for up to six months post surgery, and muscle

strength, muscle endurance and patient reported functional scores did not reach normal values at 12 months.

Conclusion: Differences in rehabilitation loading pattern in the initial 8 weeks after the repair of an Achilles tendon rupture did not measurably alter the outcome. The time to recover full function after an Achilles tendon rupture is at least 12 months.

Key words: Achilles tendon rupture, tendon strain, tendon healing, tendon elongation, weight bearing

INTRODUCTION

The Achilles tendon is the strongest tendon in the human body and yet it is susceptible to complete rupture, which most frequently occurs in men 30-50 years of age that participate in recreational sports periodically.[18, 30, 36] The prevalence has been reported to be ~18 per 100,000 individuals per year with an incidence that appears to be on the rise. [18, 29, 30, 36]

The ruptured Achilles tendon can be treated surgically or non-surgically followed by a rehabilitation regimen with varying emphasis on loading. However, there is no consensus in the literature regarding the optimal rehabilitation protocol and there is a considerable variation of treatment strategy for Achilles rupture in clinical practice. [4, 32] Surgical repair of Achilles tendon ruptures is known to significantly reduce the risk of re-rupture in the long term, and to accelerate the return to activity compared with non-surgical treatments, which is why it has been advocated by some but not all.[21, 50] Data from animal models suggest that short episodes of loading may be beneficial for the healing tendon without inducing tendon elongation.[2] Furthermore, load on the tendon can stimulate the tendon cells (fibroblasts) to synthesize collagen and other extracellular components,[31] and therefore early motion of the ankle might be beneficial for the rupture repair.

The repair sutures themselves permit the tendon to withstand up to 550 N of force prior to failure,[7, 14, 17, 19] which is a mere fraction of the load placed on the Achilles tendon during walking (~1500 N) and running (up to 8000 N).[11, 12, 23, 24] Moreover, already after 10 cycles of low force loading there has been a significant separation of the repair site.[17] Yet, accelerated rehabilitation with early loading following surgical repair is commonly recommended [6, 41, 43, 51, 53] in an attempt to curtail the persistent long term muscle weakness, atrophy, dysfunction and frequent incomplete return to pre-injury sports

level.[1, 5, 16, 22, 28, 33, 35, 39, 48, 49, 52] It should be noted that there is currently no available data that identifies how early the repaired tendon can withstand any given loading without sustaining structural changes that yield permanent elongation.

The reason for the frequently observed inadequate recovery of calf muscle function remains a conundrum and while there has been considerable focus on accelerated rehabilitation and muscle strength, the length of the repaired Achilles tendon has attracted more attention recently. Following both surgical and conservative treatment it appears that the tendon may elongate.[16, 20, 34] In fact, the magnitude of the lengthening can be substantial and has been reported to occur in the initial 6-12 weeks post surgery.[20, 34, 42, 47] Importantly, it has been observed that the clinical outcome appears to be related to the magnitude of elongation, such that those with less elongation achieved a better clinical outcome.[20] This implies that efforts to prevent elongation in the initial months following tendon rupture repair may be critical.

The aim of this project was to examine tendon elongation (primary outcome), mechanical properties and functional outcomes during rehabilitation of surgically repaired acute Achilles tendon ruptures, and to determine if different rehabilitation regimens during the early rehabilitation period (0-8 weeks post surgery) influenced the outcome. We hypothesized that restricted early weight bearing that only allowed limited motion about the ankle in the early phase of tendon healing would yield better tissue regeneration and minimal chronic tendon elongation, and enhance long-term functional outcome.

MATERIALS AND METHODS

Patients 18-65 years of age with an acute Achilles tendon rupture scheduled for surgery at Bispebjerg-Frederiksberg Hospital, Copenhagen were recruited to participate in this

randomized controlled trial. A total of 75 patients with an acute Achilles tendon mid-substance rupture were included between August 2012 and November 2015. Patients with prior Achilles tendon rupture or other injuries affecting their lower limb functions were excluded. Other exclusion criteria included systemic diseases that potentially could influence tendon healing (e.g. autoimmune disease, genetic connective tissue disorders), immunosuppressive treatment including systemic corticosteroid treatment and inability to complete rehabilitation or follow-ups due to travel distance from the hospital. All the patients were given verbal and written information about the study and gave written informed consent to participate in the study. Ethical approval was obtained from the regional Ethics Committee (number H-3-2012-060). The trial was a single center, controlled, parallel-group study using block randomization and was registered (www.clinicaltrials.gov; trial number NTC02422004). Based on tendon elongation data [20] it was estimated that a sample of n=18 was needed in each group to detect a 3 mm difference in tendon elongation with an 80% power, and therefore a total of n=25 were included in each group to account for possible drop outs.

Surgery and rehabilitation

Patients were positioned prone with their feet hanging freely at the end of the operation table. A longitudinal incision was made slightly medial to the midline at the level of the rupture. The peritendon was incised and the rupture identified. The tendon was sutured with the Kessler technique with Vicryl size 1 while attempting to achieve an anatomical length by tightening sutures until the two feet had an equal resting position and the tendons on both sides felt equally tight when the foot was manually dorsal flexed. After tendon suture, four tantalum metal beads with a diameter of 1.0 mm were implanted with a

cannula in the tendon on either side of the rupture (two beads in each end)(Figure 1).[46]

Therafter the peritendon and the subcutaneaous tissue was closed with Vicryl 2-0, and the

skin was closed with Nylon 4-0. However, the first five patients in the trial had the beads

implanted percutaneously one week post surgery under ultrasound guidance. After surgery

an orthosis (Nextep Contour II Walker, DonJoy® Nordic, Denmark) that inhibits ankle-joint

movement was applied and worn for six weeks. To keep the foot in plantar flexion three

heel wedges were worn the first four weeks and patients were instructed to remove one

heel wedge every week thereafter. Randomization to three separate rehabilitation regimens

was performed postoperatively using block randomization with six in each block (see

CONSORT diagram, Figure 2). The persons responsible for obtaining the primary outcome

data (tendon elongation) were blinded, but the persons responsible for the other follow up

tests were not systematically blinded. All data analysis was performed in blinded fashion.

In the *late weight bearing with immobilization group* (LWB+IMMOB) the

patients were completely restricted from weight bearing until week seven. Partial weight

bearing with the use of crutches was allowed week 7-8 and full weight bearing after week 8.

The aim of the LWB+IMMOB group was to minimize tendon lengthening. In the *late weight*

bearing with mobilization group (LWB+MOB) the patients were also completely restricted

from weight bearing until week 7. Partial weight bearing with the use of crutches was

allowed week 7-8 and full weight bearing after week 8. These patients were also instructed

to perform ankle joint mobilization exercises without any load (25 repetitions, 5 times/day)

beginning week 3. The aim of the ROM group was to provide limited mechanical stimulation

without any lengthening of the tendon. In the *early weight bearing with mobilization*

group (EWB+MOB) the patients were instructed in the currently accepted rehabilitation

regimen at Bispebjerg-Frederiksberg Hospital, which includes partial weight bearing from

day one and full weight bearing from week 5. This protocol closely resembles commonly accepted accelerated rehabilitation regimens.[53] Similar to the LWB+MOB group, EWB+MOB were instructed in ankle joint range of motion exercises. The aim of EWB+MOB group was to maximize mechanical stimulation. All patients received the same instructions in home exercise guidelines starting from week 9 (see table 1). Patients were allowed heel-rise exercise after 16 weeks, jogging after 22 weeks and return to sports 34 weeks after surgery.

Follow-up evaluation

The primary outcome was tendon elongation at rest. Secondary outcomes were tendon strain during isometric plantar flexion, ankle joint range of motion, maximal plantar flexion muscle strength, tendon cross-sectional area, muscle cross-sectional area, heel-rise test and patient reported outcomes (Achilles tendon Total Rupture Score (ATRS), Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A)).

Tendon elongation

Two-dimensional x-ray was used to measure the distance between the tantalum beads inserted during surgery as a measure of tendon elongation. The patients were positioned prone with the feet in a relaxed position outside the table during the x-ray. The distance between the radiographic source and the film plate was fixed at 120 cm and the radiograph was focus perpendicular on the midpoint of the Achilles tendon. X-rays were obtained at weeks 2, 6, 12, 26 and 52. ImageJ 1.47 (National Institutes of Health, USA) software was used to calculate the distance between two of the four tantalum beads, and the same two beads were used at all time points. An x-ray calibration sphere of known diameter was

placed in the image during x-ray and all measured distances were calibrated to the diameter of the sphere in the image (see figure 1).

Tendon and muscle cross sectional area

Magnetic resonance imaging (MRI) was used to assess cross-sectional area (CSA) of the Achilles tendon and muscles of triceps surae on the injured side at 6, 26 and 52 weeks (Sigma horizon LX 1.5T, Wauwatosa, Wisconsin, USA). The MRI parameters used in the tendon scans were; T1 weighted SE, TR/TE of 400/16 ms; FOV of 12 cm; matrix 320x320; slice 6 mm and spacing of 2 mm. The ankle was maintained at 90 degrees during the scan using an HD foot ankle coil. The open source software, OsiriX 4.19 for MAC OS (http://www.osirix-viewer.com) was used to analyze the MRI scans. The Achilles tendon CSA (see figure 3) was measured by manually outlining the tendon in the axial plane of four images and a mean was calculated. The most distal image without any visible calcaneus bone was defined as the starting image. To optimize the measurement both grey-scale and National Institute of health (NIH) color scale were used during outlining. This procedure has been described in details elsewhere and has shown to reduce the underestimation of CSA with 2.8 % compared to only using grey-scale.[8]

For the muscle CSA 20 images were obtained distal to the tibia plateau. The protocol for the axial MRI scans was the following; T1 weighted SE, TR/TE of 440/12.7 ms; FOV of 28 cm; matrix 256 x 256; slice 10 mm and spacing of 5 mm. The lean muscle mass of triceps surae (subcutaneous and intermuscular tissue were not included in the measurement) was manually outlined using the open source software, OsiriX 4.19 for MAC OS (http://www.osirix-viewer.com). The CSA was measured for medial and lateral gastrocnemius and soleus by first determining the axial plane where the muscle was thickest

at 52 weeks, then manually outlining each muscle in the same plane at each time point (see

figure 3). An average of three measurements was made on each section.

Mechanical testing

A previously reported method to measure Achilles tendon elongation during isometric

plantar flexion contraction was used coupled with x-ray.[26] Briefly, the patient was seated in

a rigid frame with the knee flexed to 90 degrees and the ankle at 0 degrees. The foot was

fixed on a footplate and a strain gauge was attached to the footplate to register plantar

flexion force (N). A steel bar was tightly positioned behind the distal femur to prevent any

movement. The patient was instructed to produce plantar flexion with only the ball of the

foot to maintain a prescribed load by visual feedback, and an x-ray image was recorded

simultaneously. A wireless transmitter (8-channel, TeleMyo 2400T G2, Telemetry System,

Noraxon Inc.) was used for force recording. The position of the film plate was fixed relative

to the foot and X-ray images were recorded in the same manner as described for tendon

elongation. The x-ray analysis was used to calculate tendon elongation by measuring the

distance between the tantalum beads under different predefined loads. Elongation was

measured at loads of 0, 200 and 1200 N (1200 N only at week 26 and 52). Strain was

calculated as change in distance between beads from the neutral position with 0 N of force

on the tendon.

Patient-Reported Outcome

Self-reported perception of disability was evaluated using the Achilles tendon Total Rupture

Score (ATRS),[38, 40] and The Victorian Institute of Sport Assessment-Achilles questionnaire

(VISA-A) was used to assess symptoms, function, and pain during sporting activities.[38] These questionnaires were completed prior to functional testing at 12, 26 and 52 weeks

Functional evaluation

Plantar flexion muscle strength was measured during maximal voluntary isometric contraction (MVC) with ankle flexion at 0° and thereafter at 12° of plantar flexion. Strength tests were conducted in the same custom-made rigid steel frame used during the tendon mechanical evaluation (see above). Four isometric contractions of ~8 s were conducted on each side. The first contraction on each side was considered as a familiarization to the test and the remaining three were used for calculations. A ratio between the injured and the non-injured side was calculated. Muscle endurance was evaluated on both sides independently with single-leg standing heel-rise test on a step, as previously described[48]. The test was conducted to the pace of a metronome with the concentric and eccentric phases each lasting 1 s. The test ended when the patient stopped due to fatigue, was unable to maintain the rate or was unable to elevate at least 5 cm. The MuscleLab® (Ergotest Technology, Oslo, Norway) computer software and a linear encode sensor attached to the heel was used for evaluation[48] The average height and the total work (the body weight times total distance) in joules were used for data analysis and a percentage of the non-injured side was calculated. The maximum dorsiflexion range of motion was assessed by using the weight-bearing lunge test were we measured the maximum distance away from the wall with each foot meanwhile the patient could still touch the wall with the knee.[27] A percentage of the non-injured side was calculated.

Statistical analysis

Demographic baseline data were analyzed using a one-way ANOVA. Outcome parameters where analyzed using two-way ANOVA's with rehabilitation regimen (group) and time as main factor followed by Tukey's multiple comparisons post hoc test in case of significance unless otherwise noted (GraphPad Prism version 7.00 for Windows, GraphPad Software, La Jolla California USA, www.graphpad.com). All analyses were performed as intention to treat. Results are reported as mean±sem unless otherwise noted.

RESULTS

There were no significant differences between the groups with respect to gender, age, BMI and days from rupture to surgery (Table 2). The majority (97%) obtained their rupture during sports-related activities.

Tendon Elongation

There was no significant interaction or group effect with respect to tendon elongation, but there was a significant main effect of time (P<0.0001)(Figure 4); Elongation increased from 6 to 12 weeks (P<0.01) and from 12 to 26 weeks (P<0.001), but not from 26 to 52 weeks. For strain at 200 N there was no significant interaction or group effect, but a significant main effect of time (P<0.0001)(Figure 5A); strain decreased from 6 to 26 weeks (P<0.001), but not from 26 to 52 weeks. For 1200 N there was no significant interaction or group effect, but a significant effect of time (P<0.0001)(Figure 5B). For tendon CSA there was no interaction or group effect, but a significant effect of time (P<0.0001)(Figure 5C); Tendon CSA increased from 6 to 26 weeks (P<0.001), and decreased from 26 to 52 weeks (P<0.001).

Muscle strength

For plantar flexion strength at both 0° and 12° there was no interaction or group effect, but a significant main effect of time (P<0.001)(Table 3); Similarly, for heel-rise index and height there was no significant interaction or group effect, but a significant main effect of time (P<0.0001)(Table 3). For range of motion there was also no interaction or group effect, but a significant main effect of time (P<0.001)(Table 3). All of these parameters increased from 26 to 52 weeks.

Muscle size

For the CSA of the medial gastrocnemius there was a significant interaction (P<0.05) and time effect (P<0.0001), but no group effect (Table 4); CSA increased from 6 to 26 weeks but not 26 to 52 weeks. For the lateral gastrocnemius there was no significant interaction or group effect, but a significant effect of time (P<0.0001); CSA increased from 6 to 26 weeks but not 26 to 52 weeks. For the soleus muscle there was no significant interaction effect, but a significant main effect of both group (LWB+MOB and EWB+MOB differed, P<0.05) and time (P<0.0001); CSA declined from week 6 to 26, but not from 26 to 52 weeks.

Outcome scores

There was no significant interaction or group effect for ATRS, but a significant main effect of time (P<0.001)(Table 5); ATRS increase from week 12 to 26 and from week 26 to 52 (P<0.01). There was a significant interaction and main effect of time (P<0.0001) for VISA-A, but no group effect (Table 5); VISA-A increased from week 12 to 26 and from week 26 to 52 (P<0.01).

The time to return to full time work was 6 weeks and 2 days±10 days for LWB+MOB, 6 weeks and 4 days±11 days for LWB+IMMOB and 5 weeks and 2 days±7 days for EWB+MOB without any between group differences. The time to return to some level of sporting activity was 24 weeks and 2 days±29 days (n=15) for LWB+MOB, 26 weeks and 6 days±28 days (n=15) for LWB+IMMOB and 26 weeks and 2 days±19 days (n=22) for EWB+MOB. At the 52-week follow-up 17 patients (24%) reported that they were back to pre-injury sporting level. There were a total of seven complications in the 75 patients that were included: two re-ruptures (2.7 %, both in the LWB+MOB group), one re-surgery due to adhesion, one DVT, and four skin infections. The re-ruptures occurred due to miss steps and fall on the injured side both at 7 weeks after repair.

DISCUSSION

The principal finding of this randomized control trial was that Achilles tendon elongation was significant and continued for up to 26 weeks post surgery (Figure 4). Data on secondary outcomes show that the Achilles tendon CSA increased from 6 to 26 weeks, but then decreased from 26 to 52 weeks. Tendon compliance, which was measured by elongation during isometric contractions, also decreased over the course of a year after surgery at which time muscle strength, endurance and patient reported functional scores had not yet reached normal values. Collectively, these data suggest that the time to recover full function after rupture is at least one year. Notably, our hypothesis was not supported since different loading pattern during rehabilitation of the tendon in the initial eight weeks post surgery did not significantly influence the primary outcome or any of the measured outcome parameters.

While there has been considerable attention to preventing muscle atrophy and strength loss following Achilles tendon rupture, much less focus has been placed on the length of the tendon. Previous investigations have shown that the Achilles tendon elongates substantially (5-11 mm) in the initial 6-7 weeks,[20, 34, 42, 47] and some studies, [34, 42] but not all [20] show that the elongation appears to continue up to 12 weeks (8-14 mm). However, the elongation appears to have halted about one year post rupture.[20, 42] Similar to previous studies the present data show that the tendon elongates in the initial six weeks (0.8-1.9 mm) and 12 weeks (2.6-4.2 mm) albeit with seemingly smaller magnitudes and this might be related to strong repairs or perhaps overtightening of the repair during surgery. However, the present data extend on previous findings by showing that the tendon continues to elongate (5.5-8.2 mm) up to 26 weeks after surgery. In fact, only ~ 50% of the total elongation takes place in the initial three months after surgery and the remaining 50% in the subsequent three months. It is noteworthy that the rehabilitation regimen in the initial eight weeks does not appreciably influence the elongation, which corroborates earlier studies.[20, 34, 45] To what extent loading in the first six months influences elongation remains unknown but should be considered since elongation may relate to the clinical outcome.[20] For logistical and ethical reasons it was not possible to measure strain or absolute length on the uninjured side, which would have contributed further insight into the data. We could therefore not measure any of the mechanical parameters on the uninjured side to evaluate how the recovery of this has progress during the first year after rupture. However the true purpose of the study was to find out if the timing of the initiation of weight bearing and ankle mobilization influenced the elongation process after tendon rupture which we found that it didn´t even if we don´t have the elongation compared to the uninjured side.

In the present study the CSA of the Achilles tendon was 154-169 mm^2 at the

first measurement six weeks post surgery. It was not possible to obtain an MRI to determine the CSA of the contralateral side. However, it has been reported that the tendon on the uninjured side in patients with Achilles tendon rupture is ~ 101 mm^2, [25] suggesting that there had been a sizeable increase in CSA in the present study. This increase may be related to inflammation and the repair process, in which hydrophilic proteoglycans and glycosaminoglycans aggregate. It is perhaps unlikely, but it can´t be excluded that these processes also affects the size in the longitudinal direction as well and thereby have an impact on the elongation of the tendon as well. The CSA was at a maximal at 26 weeks and was then reduced at the 52-week follow-up, which is a similar temporal pattern to that reported by others.[45-47] The CSA at one year post surgery was >100% larger than reported normal values for the Achilles tendon,[25] but since did not follow-up beyond 1 year it is unknown if the reduction in CSA continued. Interestingly, it has been shown that cellular activity measured by the glucose uptake associated with ambulation is higher in repaired than in intact Achilles tendons at three months (6x), six months (3x) and 12 months (1.6x) indicating that tendon response to loading is not normalized until some time after one year.[9]

Collagen fibrils are the principal tensile bearing structures of tendons,[31] but the mechanism and time course of fibril integration and reorganization following a rupture remains entirely unknown. The magnitude of strain at a low force (200 N) declined from six weeks to three months and continued to decline up to a year, and this increased stiffness was corroborated at a higher force (1200 N). In other words, this process of increased tendon stiffness continued for at least one year and was independent of the magnitude of loading in the initial eight weeks. These findings are in close agreement with a previous investigation.[45] Whether new collagen is deposited in the healing region or not is unknown,

but the fact that the CSA decreased from six to 12 months while the strain properties continued to improve suggest that CSA is not directly related to tensile properties in the healing phase. This may also indicate that tissue quality rather than quantity is responsible for the increase in stiffness, which could be caused by an improved fibril organization.

Muscle weakness can persist for a long time after surgery [1, 5, 16, 22, 28, 33, 35, 39, 44, 48, 49, 52] and may even be present a decade after the injury [28]. In the present study, the rehabilitation regimen in the initial eight weeks did not influence muscle strength recovery 52 weeks post surgery, which reached almost normal values (92-105 % of uninjured side). Interestingly the isometric strength deficit in the neutral position was 8-15 % at 26 weeks, but this deficit appeared to be greater (24-30 %) when tested at 12° of plantar flexion. Similarly, at 52 weeks the deficit was less in the neutral position compared to that at 12° plantar flexion. This strength deficit in the more plantar flexed position has been observed before.[35] In addition, the current results show that the average heel-rise height during the heel-rise test was 76-84 % of the injured side at 52 weeks, likely also reflecting a muscle-tendon functional deficit in a relative plantar flexion position. However, the average heel-rise height may be influenced by fatigue, and therefore we also examined the heel-rise height during the first three heel-rises, which corresponded to 75 % of the uninjured side (P<0.001, data not shown) at 52 weeks. Collectively, these data show that overall muscle function in a more plantar flexion position has far from recovered 52 weeks post surgery. The heel-rise index, which represents the overall muscle endurance capacity of the triceps surae muscle group, only recovered 63-70% of the uninjured side at 52 weeks, which also corresponds to previous reports.[3]

Because muscle function often does not recover fully after an Achilles tendon rupture, there has been some attention to what extent the muscle mass can recover. In the

present study it was not possible to obtain muscle CSA on the uninjured side for logistical reasons and therefore our analysis is limited to changes over time. The data of the present study suggest that for both gastrocnemii muscles there is an increase over time, which is in contrast to muscle volume changes reported by others.[16] Interestingly, the same study [16] showed a side-side difference of 15 % and 11 % for the medial and lateral gastrocnemii, respectively 18 months post surgery, indicating a practically permanent reduction in that muscle mass. In contrast to the gastrocnemii, the soleus muscle mass in the present study declined from week 6 to 26, and did not recover at 52 weeks, which corroborates previously reported 18 % deficit in muscle mass of the soleus 18 months after surgery.[16] This apparent incomplete recovery of the soleus muscle, which has a physiological CSA that is more than twice the size of the combined gastrocnemii,[13] may also explain the deficit in the heel-rise index at 52 weeks (63-70 %). Intriguingly, it has been shown that there may be an altered muscle activation strategy after an Achilles tendon rupture with a compensatory activation of flexor hallucis longus to achieve isometric plantar flexion moment,[10] which appears to be supported by the recent finding of compensatory hypertrophy in this muscle group 18 months post surgery.[16] It is possible that this is a protective strategy, and that it may stress shield the Achilles tendon. Furthermore, to what extent the timing and magnitude of loading influences this altered activation is unknown.

The ATRS scores showed that the patient's perception of disability improved significantly from week 26 (score 52-65) to week 52 (score 74-79). Previous reports of ATRS at the 12 months follow up after surgery ranges from 61 to 89.[3, 15, 37, 39] Importantly, healthy persons have a score that approach 100,[38] and it has been shown that there are no meaningful improvements beyond one year suggesting some remaining functional deficits compared with pre-injury.[39] It is noteworthy that at the one year follow up only 24%

reported that they were back to pre-injury sporting level. The VISA-A score showed a similar pattern with an improvement from 26 to 52 weeks, but did also not reach 100 %. Notably, the patient reported outcomes were unaffected by the difference in rehabilitation regimens. The overall re-rupture rate (2.7 %), the complication rate (6.7%), and the time to return to full time work (37-46 days) was similar to that reported by others.[3, 6]

We hypothesized that the LWB+MOB group would see benefits in the outcome parameter with less tendon lengthening. However, basically all the measured outcomes were similar in all three intervention groups. Similar to other studies on the effect of rehabilitation (reviewed in reference [6]) the present study focused on the initial 6-8 weeks. However, it should be noted that the results suggest increased tendon elongation and stiffness for at least 6 months after surgery, and since the healing process as determined by metabolic activity and vascularization is elevated for 6 to 12 months after injury,[9] rehabilitation and controlled loading paradigm may be important well beyond the initial 2-3 months.

In conclusion, differences in rehabilitation loading pattern in the initial 8 weeks after the repair of an Achilles tendon rupture did not alter the outcome. Importantly, Achilles tendon elongation and compliance continuous for up to six months post surgery, and muscle strength, endurance and patient reported functional scores did not reached normal values, indicating that the time to recover after rupture is at least 12 months.

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FIGURE LEGENDS

Figure 1. During surgery four tantalum metal beads with a diameter of 1.0 mm were implanted in the tendon on either side of the rupture (two beads in each end). Bottom right: a calibration sphere of known diameter was placed in the image.

Figure 2. CONSORT diagram.

Figure 3. MRI of the lower leg A) shows the tendon CSA in green, and B) muscle CSA for soleus (1), medial gastrocnemius (2) and lateral gastrocnemius (3).

Figure 4. The change in bead distance from week 2. Mean±sem.

Figure 5. Tendon strain measured in % at 200 N (A) and 1200 N (B) of tendon force as well as tendon CSA measured by MRI (C) Mean±sem.

Figure 1. During surgery four tantalum metal beads with a diameter of 1.0 mm were implanted in the tendon on either side of the rupture (two beads in each end). Bottom right: a calibration sphere of known diameter was placed in the image.

Operated for Achilles tendon rupture during the study period (n=129) → Excluded (n=54)

Enrollment

Randomized (n=75)

Allocation

LWB+MOB (n=25)

LWB+IMMOB (n=25)

EWB+MOB (n=25)

Follow-up 2 w

Lost to follow-up due to failures when implanting the beads (n=1)
• Discontinued intervention (n=0)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up due to x-ray failure (n=2) and repeatedly failing to attend the follow-ups (n=1)
• Discontinued intervention (n=1)

Follow-up 6 w

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Follow-up 12 w

Lost to follow-up (n=3) Two had a re-rupture, one had re-surgery
• Discontinued intervention (n=3)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Follow-up 26 w

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up (n=1) drop out not interested
• Discontinued intervention (1)

Lost to follow-up (n=1) repeatedly failing to attend the follow-up
• Discontinued intervention (n=0)

Follow-up 52 w

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Lost to follow-up (n=0)
• Discontinued intervention (n=0)

Analyzed

Analysed (n=23)
Excluded from analysis due to missing baseline value (n=2)

Analysed (n=25)
Excluded from analysis (n=0)

Analysed (n=22)
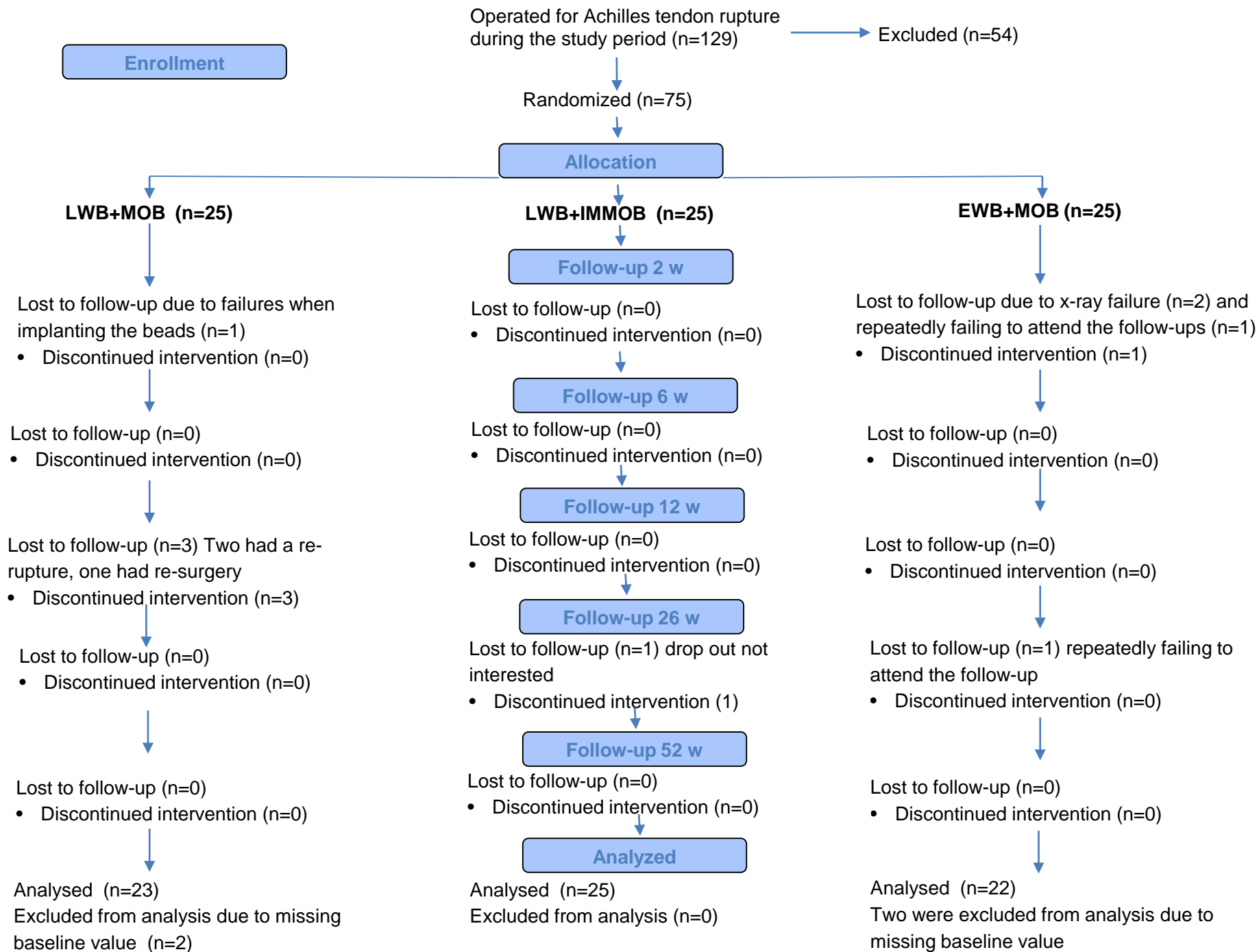Two were excluded from analysis due to missing baseline value

Figure 3. MRI of the lower leg A) shows the tendon CSA in green, and B) muscle CSA for soleus (1), medial gastrocnemius (2) and lateral gastrocnemius (3).
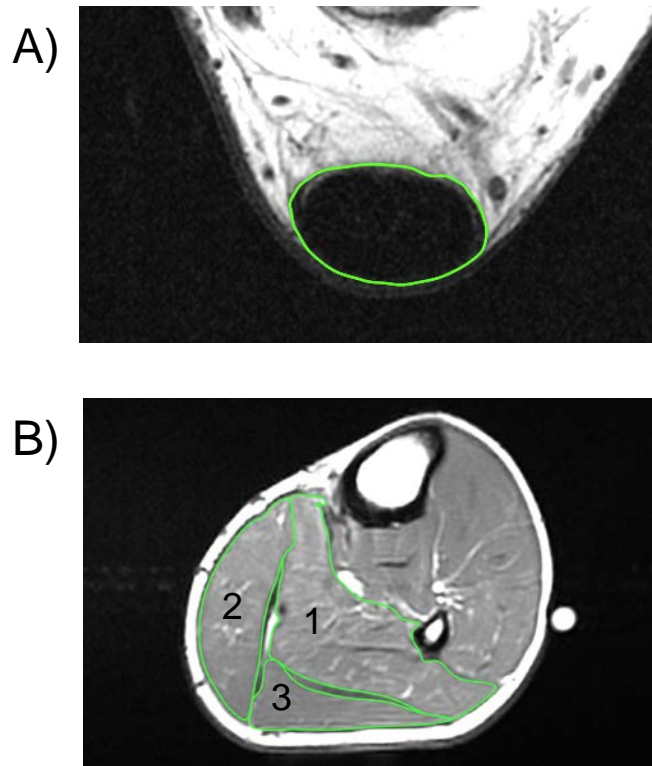
Figure 4. The change in bead distance from week 2. Mean±sem.

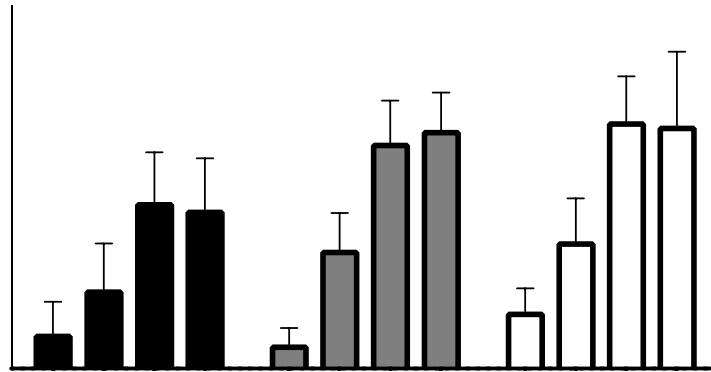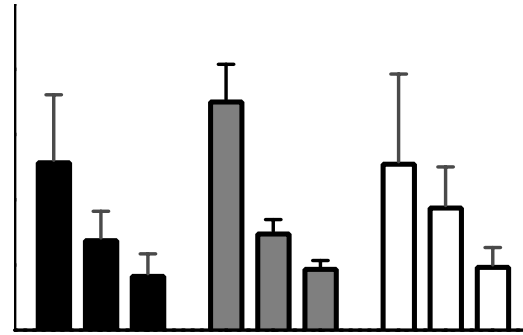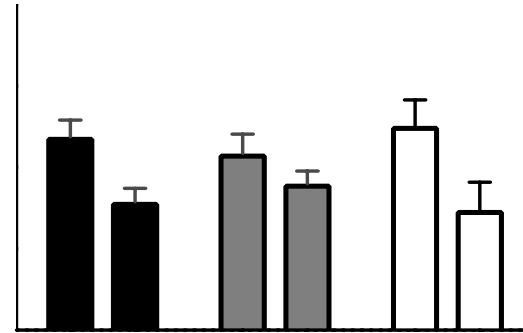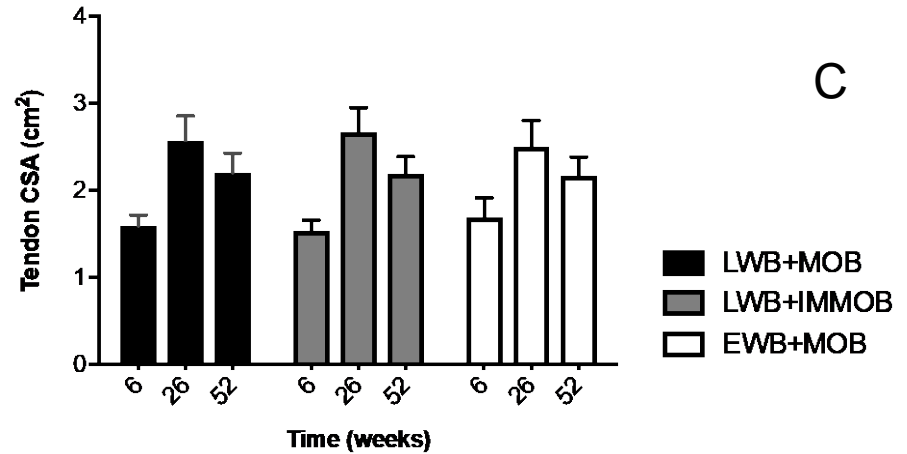**Figure 5**. Tendon strain measured in % at 200N and 1200N in tendon force as well as tendon CSA measured by MRI A) tendon strain at 200N B) tendon strain at 1200N C) Tendon CSA. Mean±sem.

	EWB+MOB	LWB+MOB	LWB+IMMOB
	Early WB, early MOB	Late WTB, early MOB	Late WTB, late MOB
Orthosis week 0-6	x	x	x
3 heel wedges week 0-4	x	x	x
Remove one wedge per wk from week 5			
NWB		Wk 0-6	Wk 0-6
PWB	Wk 0-4	Wk 7-8	Wk 7-8
FWB	From wk 5	From wk 9	From wk 9
Early ankle mobilization	Wk 3-6	Wk 3-6	-
Visit to PT week 2, 6, 12	x	x	x
Rehab program after removal of orthosis			
ROM (active) from week 7	x	x	x
Exercise bike from week 9	x	x	X
Swimming from week 9	x	x	X
Stair climbing week 14	x	x	X
Heel raises & stretching from week 16	x	x	X
Jogging week 22	x	x	X
Return to sport week 32	x	x	x

Table 1. Rehabilitation program guidelines.

	LWB+MOB	LWB+IMMOB	EWB+MOB
Sex (male/female)	19/6	19/6	22/3
Ruptured side (right/left)	12/13	13/12	9/16
Age (years)	36.0±1.5	36.9±2.2	38.8±1.1
Weight (kg)	81.7±2.8	76.0±2.5	85.5±2.9
Height (cm)	181.1±1.7	178.0±1.6	181.3±1.6
BMI (kg/m^2)	24.8±0.6	23.9±0.5	26.0±0.8
Days from rupture to surgery	3.5±0.6	3.4±0.4	3.4±0.5

TABLE 2. Subject characteristics (Mean±sem).

	LWB+MOB	LWB+IMMOB	EWB+MOB	P group	P time	P group x time
Plantar flexion strength 0°						
26 weeks	87±5 %	96±5 %	85±3 %	0.08	0.0001	0.63
52 weeks	92±5 %	105±5 %	97±5 %			
Plantar flexion strength 12°						
26 weeks	70±5 %	76±5 %	72±4 %	0.74	0.0001	0.76
52 weeks	83±4 %	85±4 %	88±4 %			
Range of motion						
26 weeks	58±4 %	65±5 %	65±6 %	0.59	0.0001	0.21
52 weeks	74±3 %	80±5 %	72±6 %			
Heel rise index						
26 weeks	52±4 %	44±2 %	44±4 %	0.57	0.0001	0.84
52 weeks	67±4 %	70±3 %	63±3 %			
Heel rise height						
26 weeks	69±5 %	68±2 %	61±5 %	0.18	0.0001	0.76
52 weeks	84±2 %	79±2 %	76±4 %			

Table 3. Plantar flexion strength at 0° and 12° of plantar flexion, range of motion, heel rise index and mean heel rise height. All data are expressed as a % of uninjured side. Two-way ANOVA with rehabilitation regime (group) and time as main factors. P for p-value (Mean±sem).

	LWB+MOB	LWB+IMMOB	EWB+MOB	P group	P time	P group x time
Medial gastrocnemius						
6 weeks	10.9±0.6	12.4±0.7	11.8±0.7	0.32	0.0001	0.03
26 weeks	13.3±0.7	12.8±0.8	12.8±0.7			
52 weeks	14.0±0.7	13.1±0.8	13.2±0.8			
Lateral gastrocnemius						
6 weeks	5.2±0.4	5.5±0.4	5.4±0.4	0.49	0.0001	0.95
26 weeks	6.6±0.4	6.0±0.4	6.4±0.5			
52 weeks	6.0±0.4	6.2±0.4	6.6±0.5			
Soleus						
6 weeks	21.7±1.2	25.0±1.2	24.5±1.3	0.05	0.0001	0.61
26 weeks	21.3±0.9	22.4±1.1	23.2±1.2			
52 weeks	22.8±1.0	23.1±1.1	23.0±1.1			

Table 4. Muscle CSA (mm^2) of the three triceps surae muscles measured where the muscle was thickest (Mean±sem). Two-way ANOVA with rehabilitation regime (group) and time as main factors. P for p-value.

	LWB+MOB	LWB+IMMOB	EWB+MOB	P group	P time	P group x time
ATRS						
12 weeks	36±3	31±3	33±3	0.24	0.0001	0.23
26 weeks	65±3	52±5	54±4			
52 weeks	79±4	77±3	74±4			
VISA-A						
12 weeks	42±3	29±3	44±4	0.11	0.0001	0.02
26 weeks	73±3	63±4	65±4			
52 weeks	82±4	79±3	79±3			

Table 5. Patient reported outcomes of The Achilles tendon Total Rupture Score (ATRS) and The Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A). (Mean±sem). Two-way ANOVA with rehabilitation regime (group) and time as main factors. P for p-value.