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A randomized, placebo-controlled study

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Tendoscopic peritendon shaving of midportion Achilles tendinopathy: A randomised, placebo-controlled study

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Abstract

Achilles tendinopathy is among the most frequent tendon injuries in sport. Despite evidence-based management, a significant proportion of patients continue to experience symptoms. This is the first randomised trial to investigate the effect of tendoscopic treatment of midportion Achilles tendinopathy compared with placebo at baseline, 3, 6 and 12 months.

Patients with midportion Achilles tendinopathy (non-responsive to more than 6 months of nonsurgical treatments) were randomly assigned to receive either tendoscopic peritendon shaving or placebo tendoscopic treatment. The primary outcome measure was the total score of the Victorian Institute of Sport Assessment Achilles (VISA-A) questionnaire. Due to three adverse events (sural nerve injuries), in the group receiving tendoscopic treatment, the trial was stopped short of the planned 48 participants. All 23 patients included completed 3 months' follow-up (100%), 22 (96%) 6 months' and 19 (83%) completed 12 months' follow-up. The between-group estimates favoured endoscopic treatment and ranged from 19 points (95% CI: 1–38) at 3 months, 14 points (-7 to 34) at 6 months and 5 points (95% CI: −19 to 28) at 12 months. After 12 months, the tendoscopic group improved 47 points (95% CI: 29–65) versus 40 points (95% CI: 22–57) in the placebo operated group. Despite a smaller sample size due to adverse events, VISA-A indicate faster recovery from tendoscopic treatment compared to placebo. These data suggest that tendoscopic treatment of midportion Achilles tendinopathy should be tested in further research; however, the technique needs to be refined to avoid sural nerve injuries.

Registration: N-20100077 Scientific ethics committee Region of Northern Jutland. The project was initiated before 2016 and was therefore not required to be prospectively registered at clinical trials. Full protocol can be obtained from first author.

Key Terms: Achilles ; midportion, tendinopathy; tendoscopic, placebo operation, double blinded, randomised.

Conflict of interest statement: None

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303

Introduction

If you run, move or in any other way use your body, you risk sustaining common overuse injuries such as Achilles tendinopathy. Chronic midportion Achilles tendon pain (midportion Achilles tendinopathy, m-AT) is one of the most common overuse injuries. The prevalence of Achilles tendinopathy is up to 9% among runners (1,2). Tendon tissue is designed to withstand considerable forces to produce joint movement (3). Such repetitive high magnitude loads with inadequate recovery can result in tendinopathy, a painful and disabling tendon injury that can persist for months or even years (4-6). Symptoms include pain, swelling and impaired performance. Pain in Achilles tendinopathy is commonly located 2–7 cm proximal to the insertion on the calcaneus. An injury to the Achilles tendon can have a severe impact upon recreational and everyday activities and lead to a reduction in overall physical activity levels and reduced quality of life (6).

Due to the prolonged pain and poor prognosis associated with this condition, many different treatments have been evaluated for patients with m-AT (7). Despite these different treatment options, there is still a subgroup of patients that are non-responsive to typical exercise or injection-based treatment. These severe cases can bring athletes' careers to an end and make habitual physical activity difficult.

Tendoscopic treatment of m-AT is a new treatment and is described as a safe method with a quick recovery (8). At present, this treatment has only been documented in case-series or retrospective studies without a control group (8,9). Thus, it is not known whether there is any further benefit of tendoscopic treatment of m-AT beyond what can be expected from placebo. There is therefore a need to evaluate its efficacy in an appropriately designed randomised controlled trial. The aim of this study was to compare tendoscopic surgical treatment with a placebo surgery in patients with longstanding m-AT. The hypothesis was that tendoscopic treatment of m-AT was more effective than placebo surgery after 3 months measured with the total score of the Victorian Institute of Sport Assessment - Achilles.

Materials and methods

This prospective randomised placebo-controlled trial was approved by the local ethics committee. The trial was not prospectively registered at clinical trials as this was not mandatory at the time the trial was initiated. Primary outcome and endpoints were defined a priori in the protocol approved by the ethics committee. All patients received written and oral information before they completed an informed consent form. The study is reported according to CONSORT guidelines (10).

Settings and locations

Patients were recruited from a private Orthopaedic Clinic in Aalborg and from Silkeborg Regional Hospital. Patients referred to the clinic or hospital were asked to participate in the trial.

Participants

We included patients suffering from long-standing m-AT (minimum 6 months) that were non-responsive to non-surgical treatments. These treatments typically consisted of exercise-based programmes instructed by a physiotherapist followed by a trial of steroid injection. m-AT was diagnosed by clinical assessment and musculoskeletal ultrasound by a specialist in rheumatology. Height and weight were measured and patients were asked to self-report symptom duration at baseline.

Inclusion criteria for the patients were as follows during a clinical examination:
1: Insidious onset of pain in the Achilles tendon region aggravated by weight-bearing activities and worse in the morning, and/or during the initial stages of weight-bearing activities.
2: Pain and swelling located 2–7 cm proximal to the Achilles tendon insertion (as described by patient and palpated by the investigator).
3: Ultrasound imaging of the Achilles tendon showing local spindle-shaped increased thickening (anterior-posterior) of more than 20% compared to the opposite asymptomatic side or more than 7 mm.

4: Achilles tendon pain for more than 6 months.

5: Above 18 years of age.

6: No effect of exercise therapy for a minimum of 6 months

7: No effect of injection-based treatments for a minimum of 6 months

Exclusion criteria for the patients were as follows:

1. Previous Achilles tendon surgery in the symptomatic lower limb.
2. Previous Achilles tendon rupture in the symptomatic lower limb.
3. Known medical conditions such as diabetes mellitus or rheumatic diseases.
4. BMI above 30.
5. Pregnant or planning pregnancy.
6. Injury or pathology of the foot, knee, hip and/or back or any condition that, in the opinion of the investigators, may interfere with participation in the study.
7. Glucocorticoid treatment within 4 months of inclusion.

Outcomes and endpoints

Primary outcome

The primary outcome measure was the total score of the Victorian Institute of Sport Assessment Achilles (VISA-A) questionnaire at the primary endpoint of 3 months. Additional endpoints were at 6 and 12 months. The VISA-A questionnaire was developed primarily to assess the clinical severity of AT (11). The VISA-A questionnaire evaluates three domains that are clinically relevant to patients: pain, function and activity. The VISA-A questionnaire has been validated (construct validity) and shows good test-retest reliability (11). Other strengths of the VISA-A questionnaire are that it can be self-administered, is likely to be sensitive to small changes occurring over a medium duration of time and has previously been used to monitor the clinical severity of m-AT in response to treatments (12-14). The VISA-A scores are summed to give a total out of 100. Higher scores indicate less severe symptoms.

Secondary outcomes

Worst pain and pain during walking was collected with a numerical rating scale going from 0 (indicating no pain) to 10 (worst imaginable pain). For ultrasonographical assessment of the Achilles tendon, we used a Hitachi Ascendus with an 18 Hz linear transducer. Ultrasonographical measures were collected due to their potential association with patient symptoms (15,16). Doppler settings were the same for all patients, with a gain setting just below the noise level and pulse repetition frequency set to 1.0. Tendon thickness was measured at the thickest point in a longitudinal scan perpendicular to the greatest width of the tendon (the true thickness) in accordance with earlier recommendations (17). All included patients had ultrasonographically determined spindle-shaped thickening, inhomogeneity and hypoechogenicity of the symptomatic tendon with increased Doppler activity. Doppler settings were the same for all patients, with a gain setting just below the noise level and the V scale set to 350. We ranked the colour Doppler activity from grades 0 to 4, where grade 0 = no activity, 1 = single vessel, 2 = Doppler activity in >25%, 3 = Doppler activity in 25% to 50%, and 4 = Doppler activity in > 50% (18). The same experienced specialist in rheumatology performed both the measurements before and after the surgery and was blinded to the treatment.

Adverse events

Patients were instructed to report any type of adverse events to the primary investigator. The primary investigator then reported any adverse events to the ethics committee and made a note describing the event in the patient record. The sural nerve injuries were diagnosed clinically at the control appointment at the clinic.

Randomisation and allocation concealment

Patients were randomly assigned to either of the two groups by 1:1 allocation by a computer-generated randomisation schedule. The randomisation sequence was made using the open source software MinimPy 0.3. The primary investigator, assessors and administrator of the randomisation procedure did not have access to the randomisation list to ensure allocation concealment. Only after recruitment and baseline measurements was the allocation completed by a secretary, who then informed the surgeon performing the treatment.

Interventions

All patients were given the same information regarding treatment. Randomisation occurred after patients received all information. Surgical procedures were performed by an experienced orthopaedic surgeon (SK) who did not have contact with the patient after the operation. The follow-up assessments were performed at another public hospital, and both the assessor (SGK) and patients were blinded to the treatment allocation at all follow-ups (operation/placebo operation).

Tendoscopic operation: The patient was placed in prone position with the face placed so that only the screen with the arthroscopic picture was visible (Figure 1). The region of the Achilles tendon was sterilised. Xylocaine (15 ml) was injected 1 cm from the Achilles insertion and 5 cm proximally intraperitendiously. Two incisions were made near the insertion. One lateral and one medial was made in the anterior part of the tendon. Two incisions, one lateral and one medial, were made near the insertion of the tendon. The scope with water pump and shaver was inserted. When the shaver was identified in the peritendon, it was shaved away. Suture with nylon 4-0. After the first two nerve injuries we tried through the same incisions to shave more medial when ascending along the Achilles tendon, but we still experienced one more suralis damage and decided to stop the trial.

Figure 1 here

Placebo operation: Similar to the above, the patient was placed in prone position with the face placed so that only the screen with the arthroscopic picture was visible. The region of the Achilles tendon was sterilised. 15 ml Xylocaine (15 ml) was injected 1 cm from the Achilles insertion and 5 cm proximally. 2 incisions were made near the insertion. One lateral and one medial was made in the anterior part of the tendon. Two incisions, one lateral and one medial, were made near the insertion of the tendon. Scope and shaver were placed on the skin and the operative procedure was performed. During the operation, the patient watched another patient's video of a tendoscopic treatment of m-AT in the belief that it was the patient's own surgery that appeared on the video. This also ensured that the time of intervention was identical in both groups. We used a suture with nylon 4-0.

Postoperative procedure for both groups: Patients were mobilised weight bearing but with crutches and allowed active movement of the ankle joint. No supervised training program was given to patients. Paracetamol and ibuprofen were given to all as postoperative pain treatment. Fourteen days to 4 weeks postoperatively, full weight bearing and walking on toe and heel were allowed. Four to 12 weeks after the operation, weight training, cycling and balance training were allowed. After 12 weeks, the patients were individually instructed to increase loads and return to their previous activity level.

Sample size

A pilot study was performed in which the sample size calculation was determined. This pilot study included seven patients (eight operations, one on both Achilles tendons) with chronic m-AT treated with endoscopic removal of peritendon tissue. The seven patients included four males and three females aged 38–60, with duration of symptoms from 13 to 572 months. The pilot study demonstrated a reduction in pain (measured on a numerical rating scale) from an average of 7.4 to 1.9 after 3 months. We interpreted this as a potential large effect of the tendoscopic surgery.

There is no established minimal clinically important change (MCID) in the VISA-A score for the mid-portion m-AT (19). However, the MCID for insertional Achilles tendinopathy has been found to be 6 points (20). Based on the pilot study we wanted to power this trial for a large effect and decided on between-group difference of 15 points at the primary endpoint at 3 months. With a common standard deviation of 18, a type I error rate of 5% and a type II error rate of 20% (80% power), we would need at least 23 patients in each arm. Based on this, we aimed to include 24 patients in each group to allow for a small loss to follow up.

Statistics:

Because we had to discontinue the study before all participants had been recruited, there were not enough participants to allow valid power assessment of statistical hypotheses. We therefore present all results descriptively with the mean values and 95% confidence intervals (95%CIs).

Results

During a period of 41 months, we included and randomised 23 patients with chronic m-AT (Figure 2). All patients included received either the allocated surgical or placebo intervention. There was a protocol deviation as the trial was stopped before the planned 48 patients had been recruited due to three serious adverse events (sural nerve injury) in the group receiving surgical treatment. The first sural nerve injury consisted of hyposensitivity distal and lateral to the tendon that did not affect activities of daily living or sport. The second patient had both hyposensitivity and dysesthesia in the same area. The third consisted of a patient with a large hyposensitive area lateral to the tendon and down beneath the heel and foot. All patients walked normal and continued work and daily activities. Follow-up was done on 23/23 patients at 3 months (100%), 22/23 at 6 months (96%), and 19/23 at 12 months (83%) (Figure 2). Two patients in the surgical intervention group received the surgical treatment on the opposite side between the 6- and 12-month follow-ups.

The average age, height, weight, worst pain, pain during walking, symptom duration and VISA-A in the treatment group and the placebo treatment groups are shown in Table 1.

Table 1 here

Figure 2 here

Primary outcome

The between-group estimates favoured endoscopic treatment and ranged from 19 points (95% CI: 1–38) at 3 months, 14 points (-7 to 34) at 6 months and 5 points (95% CI: −19 to 28) at 12 months. After 3 months, the group receiving endoscopic treatment improved 34 points (95% CI: 17–51) versus 16 points (95% CI: 4–28) in the group receiving endoscopic placebo treatment (Figure 3). After 6 months, the surgical group had improved 40 points (95% CI: 26–55) versus 28 points (95% CI: 11–

44) in the placebo group. After 12 months, the surgical group improved 47 points (95% CI 29-65) versus 40 points (95% CI: 22–57) in the placebo group.

Figure 3 here

Secondary outcomes

The between-group differences in pain during walking favoured endoscopic treatment and ranged from -1.6 NRS points (95% CI: -3.5 to 0.3) at 3 months, -1.5 points (-3.7 to 0.8) at 6 months and -0.4 points (95% CI: −3.0 to 2.2) at 12 months. After 3 months, the mean pain intensity during walking was 2.7 points (95% CI: 1.8–3.7) in the surgical group versus 4.4 points (95% CI: 2.6–6.1) in placebo group (Figure 4). After 6 months, pain was 2.0 points on a VAS (0.7–3.3) in the surgical group versus 3.5 points (1.6–5.3) in the placebo group. At 12 months, it was 1.8 points (95%CI 0-3.6) in the surgical group versus 2.2 (95%CI 0.1-4.3) in the placebo group. There was neither relevant difference in Achilles tendon thickness nor Doppler activity at any time point (table 2).

Figure 4 here

Discussion

This is the first double blinded, randomised placebo-controlled study to evaluate endoscopic treatment of m-AT. Due to adverse events (sural nerve injuries), we ended up with a smaller sample size than planned for. We therefore refrained from conducting statistical hypothesis testing. Despite a smaller sample size, the forest plot of both VISA-A and pain during walking indicated a potentially clinically relevant effect of the tendoscopic treatment compared to placebo. The effect appears to diminish over time, so that after 12 months there was only a minimal difference between the two groups in favour of

the group that had undergone tendoscopic surgery. This should not be interpreted as definitive evidence but highlights that endoscopic treatment should be tested in a new, larger randomised trial with a refined technique that avoids sural nerve injuries.

Explanation of findings

One of the hypotheses regarding m-AT is that neovascularisations and accompanying ingrowth of nerve fibres are associated with chronic pain. Steenstra and van Dijk hypothesised that release of the paratenon could, therefore, relieve pain due to the denervation (21). Another hypothesis is based on our observations during the endoscopic treatment. In the peritendon we often observed a layer of thin fibrotic tissue surrounding the tendon. As described by ultrasound (17), the Achilles tendon is thickened, and if the surrounding tissue is non-elastic, the tendon might be strangulated causing pain. The removal of the fibrotic tissue might be an explanation for the effect on pain. Another more recent treatment of m-AT is high volume injection (HVI), which has shown superior effects compared to placebo (22, 23). One of the proposed mechanisms behind HVI is the mechanical effect the injection has on neurovascular ingrowth and adhesions between the tendon and peritendinous tissue (22, 23). The hypervolume injection might expand the fibrotic tissue, solving the strangulation issue similar to that achieved by the endoscopic treatment. However, removing the corticosteroid from the hypervolume injection may decrease effect suggesting an isolated effect of corticosteroid as well (22, 23).

Comparison to previous studies

In this trial, we only included patients non-responsive to at least 6 months of exercise-based programmes and injection-based therapies. On average, they had a symptom duration of 34 months, which can be considered long-standing and considered the severe end of the spectrum. Comparison of this population to previous studies including a greater variety of patient presentations should therefore be done with care. The latest systematic review highlights that treatment of m-AT should include some form of loading exercises, e.g., eccentric exercises or heavy slow resistance exercises (7). Level 1 evidence supports the efficacy of loading-based programmes (e.g. heavy slow resistance exercises

or eccentric exercises) combined with some form of load/activity management (7, 22, 23). These studies are typically performed on patients with a shorter duration of symptoms. To date, endoscopic treatment of m-AT has only been evaluated in retrospective studies. The most recent and largest study with 45 patients found that endoscopic release of the paratenon in combination with transection of the plantaris tendon was associated with high patient satisfaction and good functional outcomes after 5 years in patients affected by m-AT. However, only 40% of patients were completely free of symptoms. Overall satisfaction was high and supported by 83% of patients stating that they would undergo the endoscopic treatment again for the same condition.

Strength and limitations

This trial was stopped prematurely due to injuries to the sural nerve. The sural nerve complication is well described after surgery for m-AT (21,24) After two nerve injuries, we tried to perform the procedure only medially but still had one nerve injury, after which we stopped the study. We know from studies that our frequency of sural nerve injuries is not uncommon (24). Two of the patients with this complication accepted performance of the procedure on the other side despite the complication. Future studies may wish to perform an ultrasound examination to determine the position of the sural nerve as described by Bianchi et al (25) and operate just distal to the nerve and then downward towards the insertion of the Achilles tendon. This could possibly prevent nerve lesions in the future. While both patients and assessors were blinded to treatment allocation, we have no measurement of the success of the blinding procedures. Tendoscopy of the Achilles tendon should be performed with care and respect until the surgical techniques have been developed to reduce risk of adverse events.

Perspective

Due to adverse events (sural nerve injuries), we ended up with a smaller sample size than planned for. Despite a smaller sample size, the forest plot of both VISA-A and pain during walking indicated a greater effect of the tendoscopic treatment compared with the placebo operation during the first 3-6 months after treatment. It is unclear if the potential effect is clinically important for patients. This should be tested in new trials in which the surgical interventions are refined to avoid sural nerve injuries.

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Tables

Table 1

Variable	Placebo surgery (N=11)	Surgery (N=12)
Age (years)	51 (42-55)	46.5 (44.5-54.5)
Height (cm)	180 (165-186)	175 (167-184)

Weight (kg)	85 (80-98)	83.5 (74.5-91.0)
Worst pain [NRS]	9 (8-9)	9 (8-10)
Pain during walking [NRS]	5 (5-8)	6.5 (5.5-7.5)
Symptom duration [months]	25 (24-48)	36 (26-41)
VISA-A at baseline	28 (24-41)	31 (16-50)

Table 2

Variable	Placebo surgery (N=11)	Surgery (N=12)
Thickness of Achilles Tendon		
3 months	10.8 (3.4)	11.4 (2.1)
6 months	10.2 (3.0)	10.2 (2.1)
12 months	9.4 (2.5)	9.1 (1.5)
Doppler activity		
3 months	2 (2-2)	2 (1.75-2)
6 months	2 (1-2)	2 (1-2)
12 months	1 (0-2)	1 (0-1)

Figure legends:

Figure 1: Access portals for tendoscopic treatment

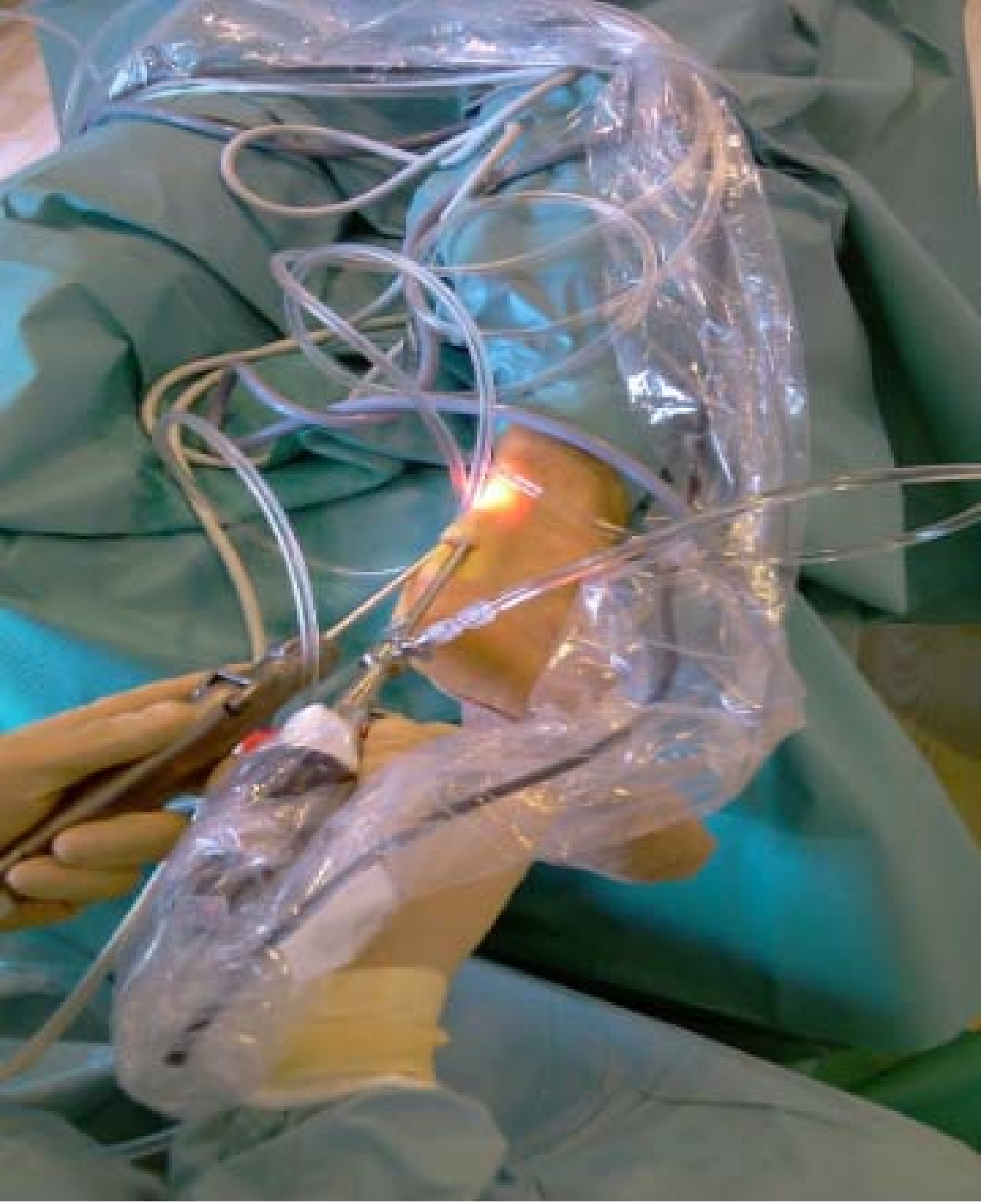
Figure 2: Flowchart

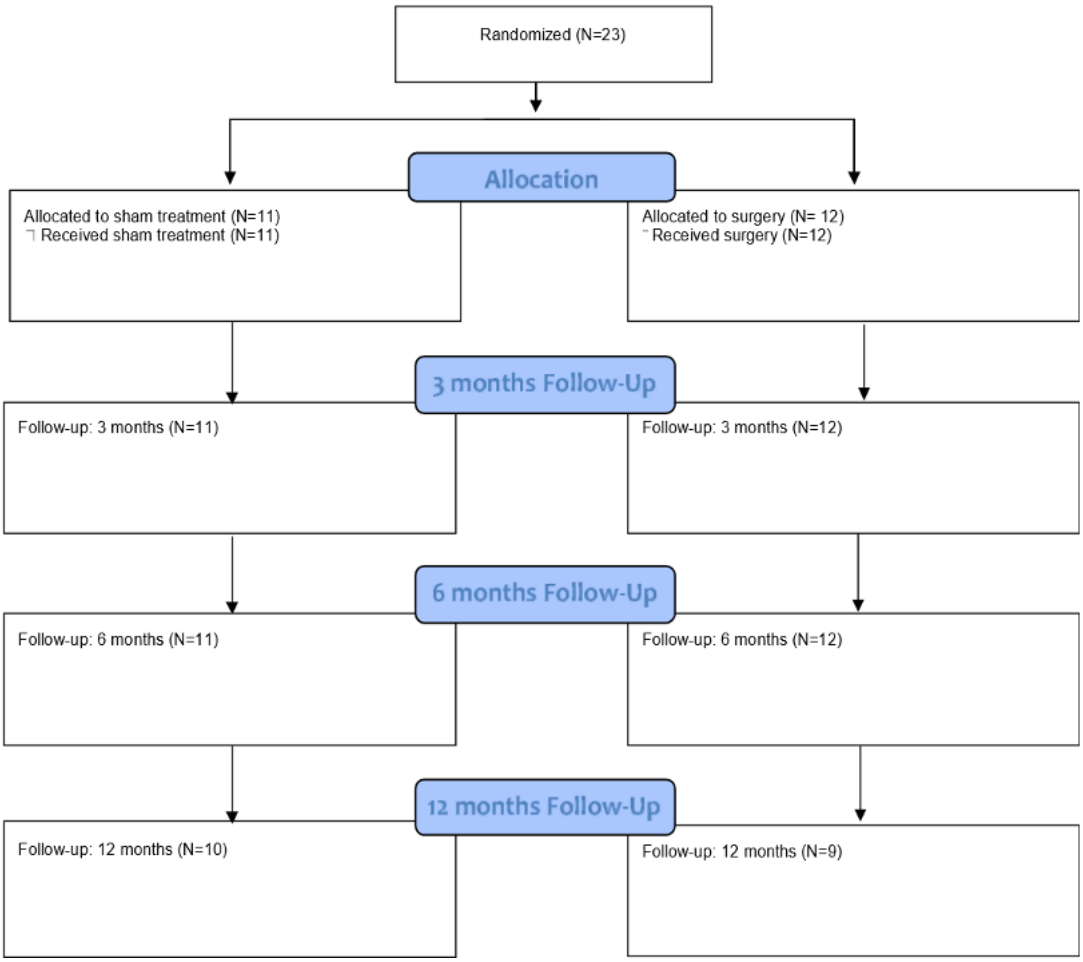
Figure 3: VISA-A score from baseline to 12 months' follow-up.

Figure 4: Mean pain intensity during walking [Numerical Rating Scale, 0-10]

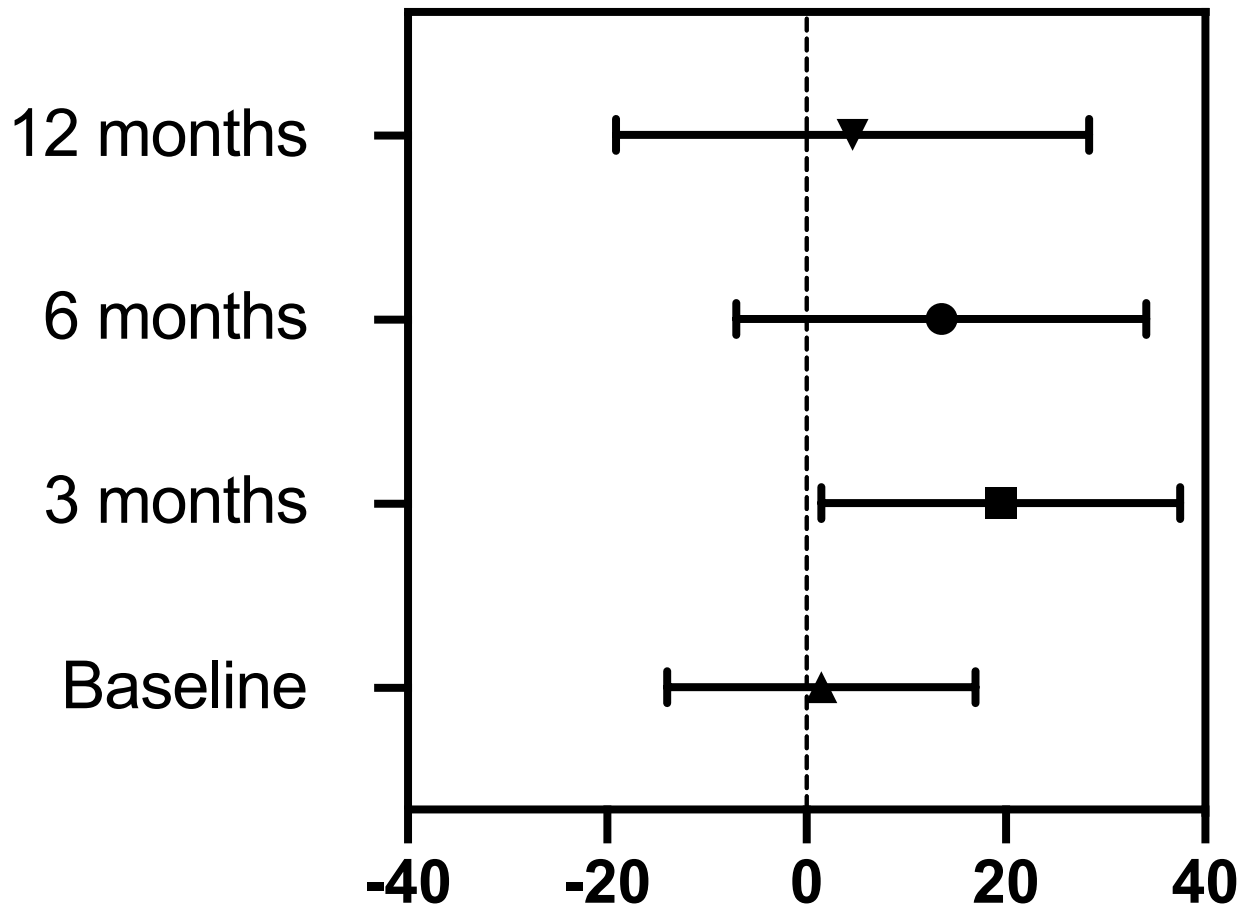
Figure 5: Achilles tendon thickness [mm] from baseline to 12-month follow-up. Error bar show 95% confidence interval

Figure 6: Doppler activity in the Achilles Tendon. Individual values are plotted on top the median and interquartile range (shown as solid line and error bars)




Randomized (N=23)
Allocation
Allocated to sham treatment (N=11)
Received sham treatment (N=11)
Allocated to surgery (N= 12)
Received surgery (N=12)
3 months Follow-Up
Follow-up: 3 months (N=11)
Follow-up: 3 months (N=12)
6 months Follow-Up
Follow-up: 6 months (N=11)
Follow-up: 6 months (N=12)
12 months Follow-Up
Follow-up: 12 months (N=10)
Follow-up: 12 months (N=9)

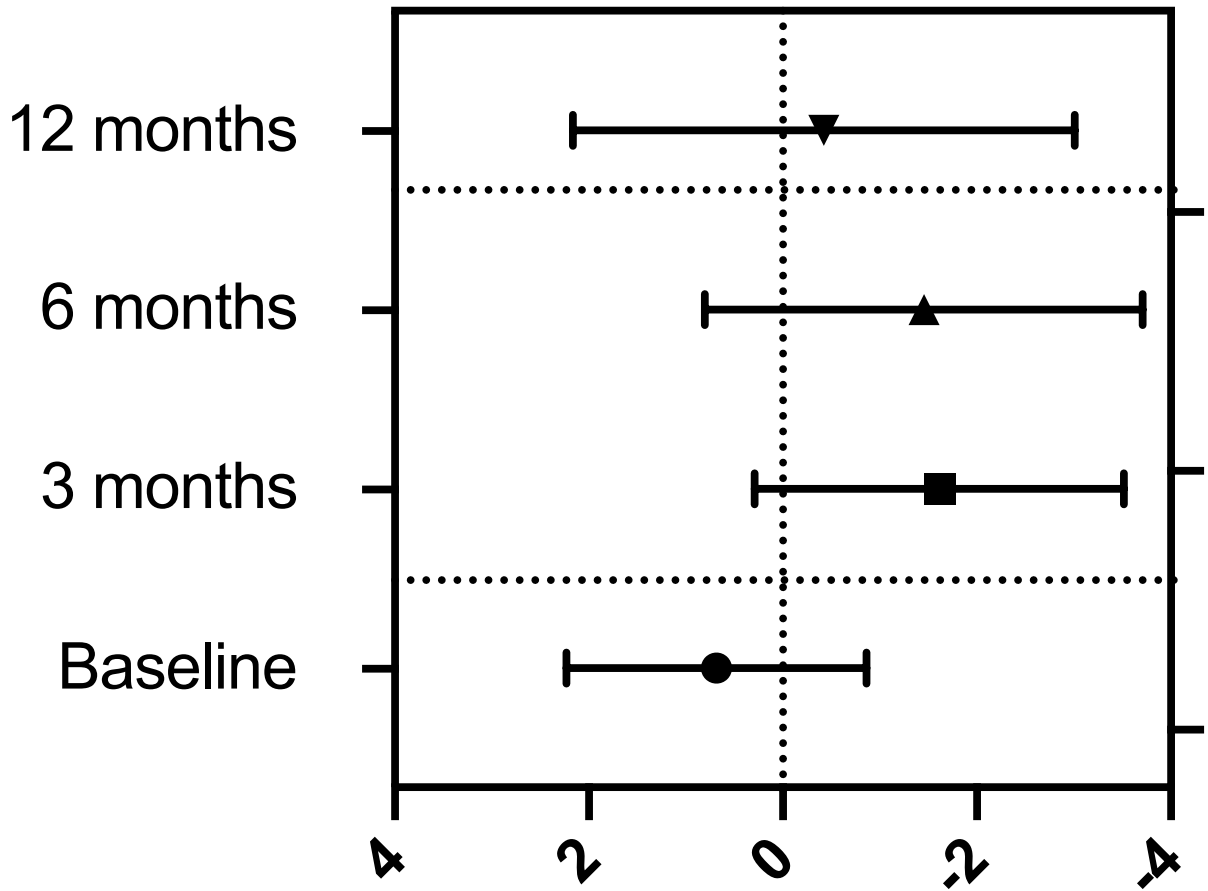
Difference between groups in VISA-A

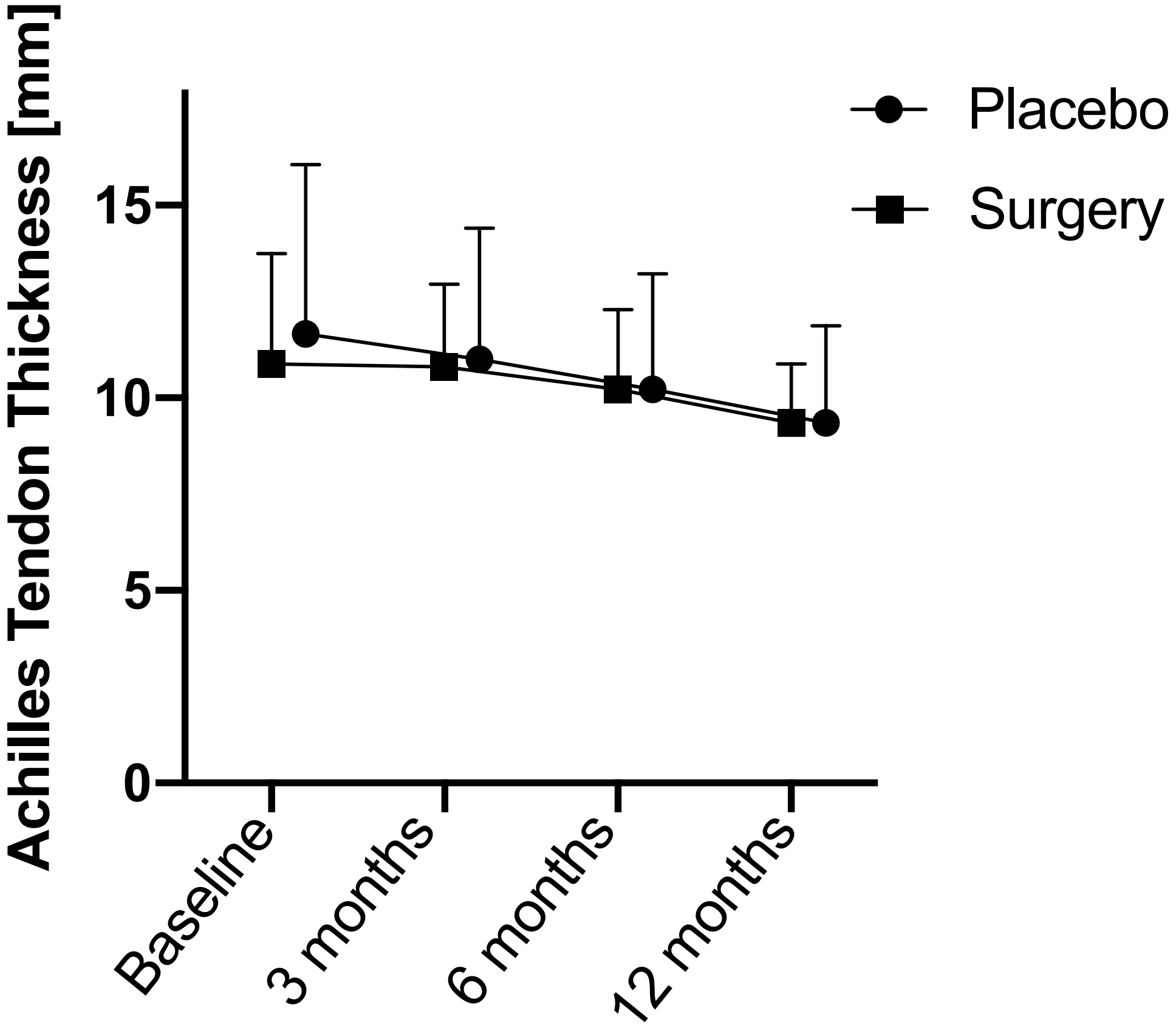


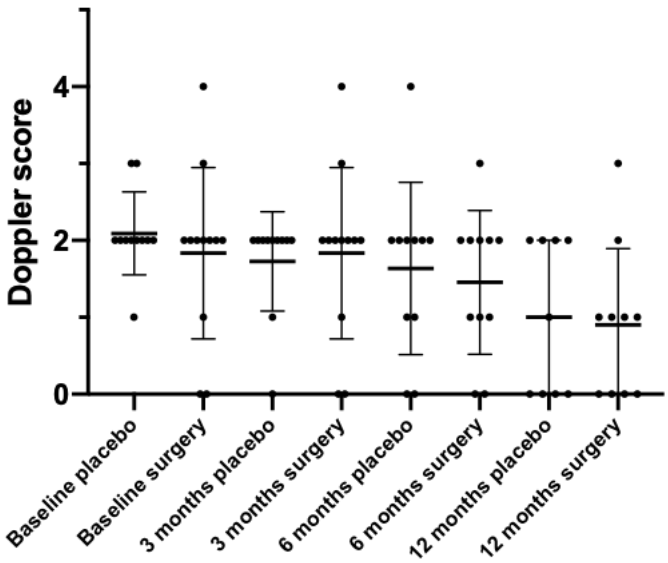
Favour placebo

Favour tendoscopic treatment

Difference between group in pain (VAS) during walking




Achilles Tendon Thickness [mm]
15
10
5
0
Baseline
3 months
6 months
12 months
Placebo
Surgery


Doppler score
4
2
0
Baseline placebo
Baseline surgery
3 months placebo
3 months surgery
6 months placebo
6 months surgery
12 months placebo
12 months surgery