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Tendoscopic peritendon shaving of midportion Achilles tendinopathy

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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272 Abstract

273 Achilles tendinopathy is among the most frequent tendon injuries in sport. Despite evidence-based
274 management, a significant proportion of patients continue to experience symptoms. This is the first
275 randomised trial to investigate the effect of tendoscopic treatment of midportion Achilles
276 tendinopathy compared with placebo at baseline, 3, 6 and 12 months.
277 Patients with midportion Achilles tendinopathy (non-responsive to more than 6 months of nonsurgical
278 treatments) were randomly assigned to receive either tendoscopic peritendon shaving or placebo
279 tendoscopic treatment. The primary outcome measure was the total score of the Victorian Institute of
280 Sport Assessment Achilles (VISA-A) questionnaire. Due to three adverse events (sural nerve
281 injuries), in the group receiving tendoscopic treatment, the trial was stopped short of the planned 48
282 participants. All 23 patients included completed 3 months' follow-up (100%), 22 (96%) 6 months'
283 and 19 (83%) completed 12 months' follow-up. The between-group estimates favoured endoscopic
284 treatment and ranged from 19 points (95% CI: 1–38) at 3 months, 14 points (-7 to 34) at 6 months and
285 5 points (95% CI: -19 to 28) at 12 months. After 12 months, the tendoscopic group improved 47
286 points (95% CI: 29–65) versus 40 points (95% CI: 22–57) in the placebo operated group. Despite a
287 smaller sample size due to adverse events, VISA-A indicate faster recovery from tendoscopic
288 treatment compared to placebo. These data suggest that tendoscopic treatment of midportion Achilles
289 tendinopathy should be tested in further research; however, the technique needs to be refined to avoid
290 sural nerve injuries.

291

292 Registration: N-20100077 Scientific ethics committee Region of Northern Jutland. The project was
293 initiated before 2016 and was therefore not required to be prospectively registered at clinical trials.

294 Full protocol can be obtained from first author.

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

297

298

299 Conflict of interest statement: None

300

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302 design or interpretation of the study results).

303

Accepted Article

304 **Introduction**

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

315

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

321

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

331

332 **Materials and methods**

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

338

339 Settings and locations

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

342

343 Participants

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

350

351 Inclusion criteria for the patients were as follows during a clinical examination:

352 1: Insidious onset of pain in the Achilles tendon region aggravated by weight-bearing activities and
353 worse in the morning, and/or during the initial stages of weight-bearing activities.

354 2: Pain and swelling located 2–7 cm proximal to the Achilles tendon insertion (as described by patient
355 and palpated by the investigator).

356 3: Ultrasound imaging of the Achilles tendon showing local spindle-shaped increased thickening
357 (anterior-posterior) of more than 20% compared to the opposite asymptomatic side or more than 7
358 mm.

359 4: Achilles tendon pain for more than 6 months.

360 5: Above 18 years of age.

361 6: No effect of exercise therapy for a minimum of 6 months

362 7: No effect of injection-based treatments for a minimum of 6 months

363

364 Exclusion criteria for the patients were as follows:

365 1. Previous Achilles tendon surgery in the symptomatic lower limb.

366 2. Previous Achilles tendon rupture in the symptomatic lower limb.

367 3. Known medical conditions such as diabetes mellitus or rheumatic diseases.

368 4. BMI above 30.

369 5. Pregnant or planning pregnancy.

370 6. Injury or pathology of the foot, knee, hip and/or back or any condition that, in the opinion of the

371 investigators, may interfere with participation in the study.

372 7. Glucocorticoid treatment within 4 months of inclusion.

373

374 Outcomes and endpoints

375 Primary outcome

376 The primary outcome measure was the total score of the Victorian Institute of Sport Assessment

377 Achilles (VISA-A) questionnaire at the primary endpoint of 3 months. Additional endpoints were at 6

378 and 12 months. The VISA-A questionnaire was developed primarily to assess the clinical severity of

379 AT (11). The VISA-A questionnaire evaluates three domains that are clinically relevant to patients:

380 pain, function and activity. The VISA-A questionnaire has been validated (construct validity) and

381 shows good test-retest reliability (11). Other strengths of the VISA-A questionnaire are that it can be

382 self-administered, is likely to be sensitive to small changes occurring over a medium duration of time

383 and has previously been used to monitor the clinical severity of m-AT in response to treatments (12-

384 14). The VISA-A scores are summed to give a total out of 100. Higher scores indicate less severe

385 symptoms.

386

387 Secondary outcomes

388 Worst pain and pain during walking was collected with a numerical rating scale going from 0
389 (indicating no pain) to 10 (worst imaginable pain). For ultrasonographical assessment of the Achilles
390 tendon, we used a Hitachi Ascendus with an 18 Hz linear transducer. Ultrasonographical measures
391 were collected due to their potential association with patient symptoms (15,16). Doppler settings were
392 the same for all patients, with a gain setting just below the noise level and pulse repetition frequency
393 set to 1.0. Tendon thickness was measured at the thickest point in a longitudinal scan perpendicular to
394 the greatest width of the tendon (the true thickness) in accordance with earlier recommendations (17).
395 All included patients had ultrasonographically determined spindle-shaped thickening, inhomogeneity
396 and hypoechogenicity of the symptomatic tendon with increased Doppler activity. Doppler settings
397 were the same for all patients, with a gain setting just below the noise level and the V scale set to 350.
398 We ranked the colour Doppler activity from grades 0 to 4, where grade 0 = no activity, 1 = single
399 vessel, 2 = Doppler activity in >25%, 3 = Doppler activity in 25% to 50%, and 4 = Doppler activity in
400 > 50% (18). The same experienced specialist in rheumatology performed both the measurements
401 before and after the surgery and was blinded to the treatment.

402

403 Adverse events

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

408

409 Randomisation and allocation concealment

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

416

417 Interventions

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

423

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

433

434 Figure 1 here

435

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

445

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

452

453

454 Sample size

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

461

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

469

470 Statistics:

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

474

475 **Results**

476 During a period of 41 months, we included and randomised 23 patients with chronic m-AT (Figure 2).
477 All patients included received either the allocated surgical or placebo intervention. There was a
478 protocol deviation as the trial was stopped before the planned 48 patients had been recruited due to
479 three serious adverse events (sural nerve injury) in the group receiving surgical treatment. The first
480 sural nerve injury consisted of hyposensitivity distal and lateral to the tendon that did not affect
481 activities of daily living or sport. The second patient had both hyposensitivity and dysesthesia in the
482 same area. The third consisted of a patient with a large hyposensitive area lateral to the tendon and
483 down beneath the heel and foot. All patients walked normal and continued work and daily
484 activities. Follow-up was done on 23/23 patients at 3 months (100%), 22/23 at 6 months (96%), and
485 19/23 at 12 months (83%) (Figure 2). Two patients in the surgical intervention group received the
486 surgical treatment on the opposite side between the 6- and 12-month follow-ups.

487

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

490

491 Table 1 here

492

493 Figure 2 here

494

495 **Primary outcome**

496 The between-group estimates favoured endoscopic treatment and ranged from 19 points (95% CI: 1–
497 38) at 3 months, 14 points (-7 to 34) at 6 months and 5 points (95% CI: -19 to 28) at 12 months.

498 After 3 months, the group receiving endoscopic treatment improved 34 points (95% CI: 17–51) versus
499 16 points (95% CI: 4–28) in the group receiving endoscopic placebo treatment (Figure 3). After 6
500 months, the surgical group had improved 40 points (95% CI: 26–55) versus 28 points (95% CI: 11–

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

503

504 Figure 3 here

505

506 Secondary outcomes

507 The between-group differences in pain during walking favoured endoscopic treatment and ranged
508 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
509 points (95% CI: -3.0 to 2.2) at 12 months. After 3 months, the mean pain intensity during walking
510 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
511 group (Figure 4). After 6 months, pain was 2.0 points on a VAS (0.7–3.3) in the surgical group versus
512 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
513 surgical group versus 2.2 (95%CI 0.1-4.3) in the placebo group. There was neither relevant difference
514 in Achilles tendon thickness nor Doppler activity at any time point (table 2).

515

516 Figure 4 here

517

518

519

520

521 **Discussion**

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

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

531

532 Explanation of findings

533 One of the hypotheses regarding m-AT is that neovascularisations and accompanying ingrowth of
534 nerve fibres are associated with chronic pain. Steenstra and van Dijk hypothesised that release of the
535 paratenon could, therefore, relieve pain due to the denervation (21). Another hypothesis is based on
536 our observations during the endoscopic treatment. In the peritendon we often observed a layer of thin
537 fibrotic tissue surrounding the tendon. As described by ultrasound (17), the Achilles tendon is
538 thickened, and if the surrounding tissue is non-elastic, the tendon might be strangulated causing pain.
539 The removal of the fibrotic tissue might be an explanation for the effect on pain. Another more recent
540 treatment of m-AT is high volume injection (HVI), which has shown superior effects compared to
541 placebo (22, 23). One of the proposed mechanisms behind HVI is the mechanical effect the injection
542 has on neurovascular ingrowth and adhesions between the tendon and peritendinous tissue (22, 23).
543 The hypervolume injection might expand the fibrotic tissue, solving the strangulation issue similar to
544 that achieved by the endoscopic treatment. However, removing the corticosteroid from the
545 hypervolume injection may decrease effect suggesting an isolated effect of corticosteroid as well (22,
546 23).

547

548 Comparison to previous studies

549 In this trial, we only included patients non-responsive to at least 6 months of exercise-based
550 programmes and injection-based therapies. On average, they had a symptom duration of 34 months,
551 which can be considered long-standing and considered the severe end of the spectrum. Comparison of
552 this population to previous studies including a greater variety of patient presentations should therefore
553 be done with care. The latest systematic review highlights that treatment of m-AT should include
554 some form of loading exercises, e.g., eccentric exercises or heavy slow resistance exercises (7). Level
555 1 evidence supports the efficacy of loading-based programmes (e.g. heavy slow resistance exercises

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

564

565 **Strength and limitations**

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

577

578 **Perspective**

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

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652 Tables

653

654 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)

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656 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)

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660 Figure legends:

661 Figure 1: Access portals for tendoscopic treatment

662 Figure 2: Flowchart

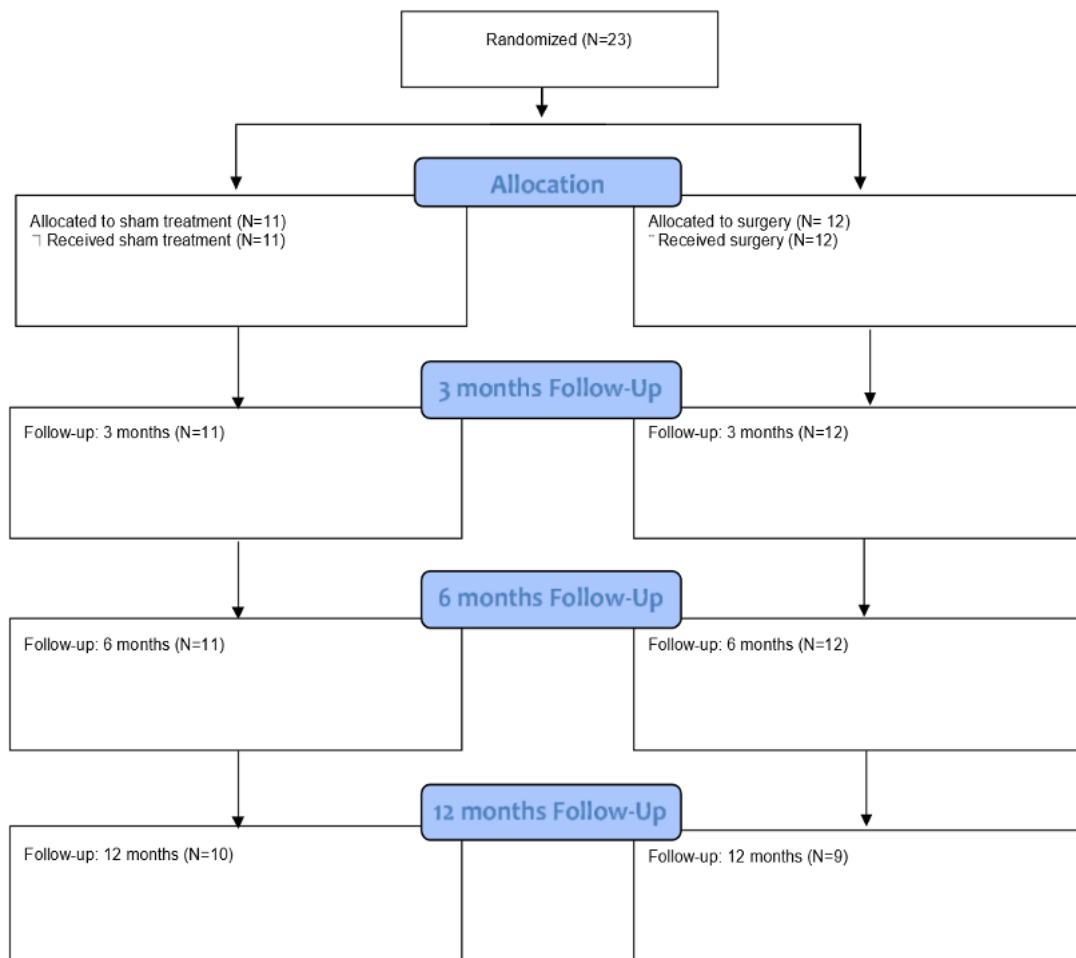
663 Figure 3: VISA-A score from baseline to 12 months' follow-up.

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

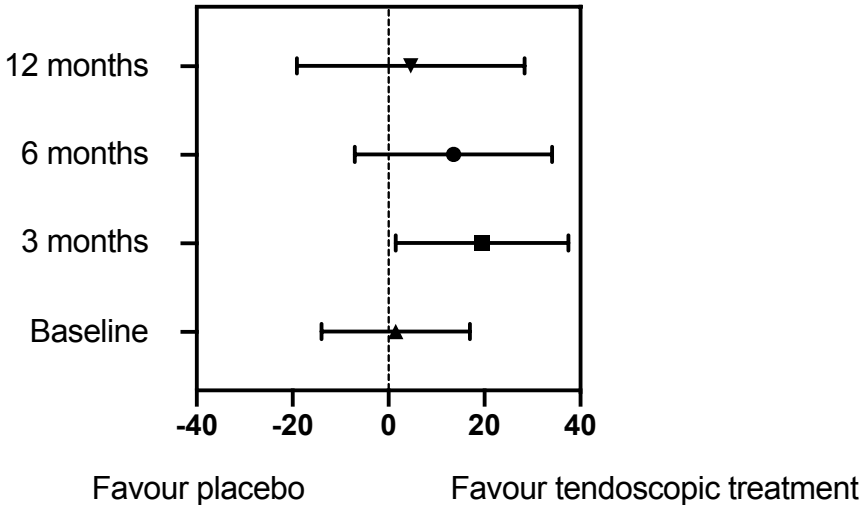
665 Figure 5: Achilles tendon thickness [mm] from baseline to 12-month follow-up. Error bar show 95%
666 confidence interval

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

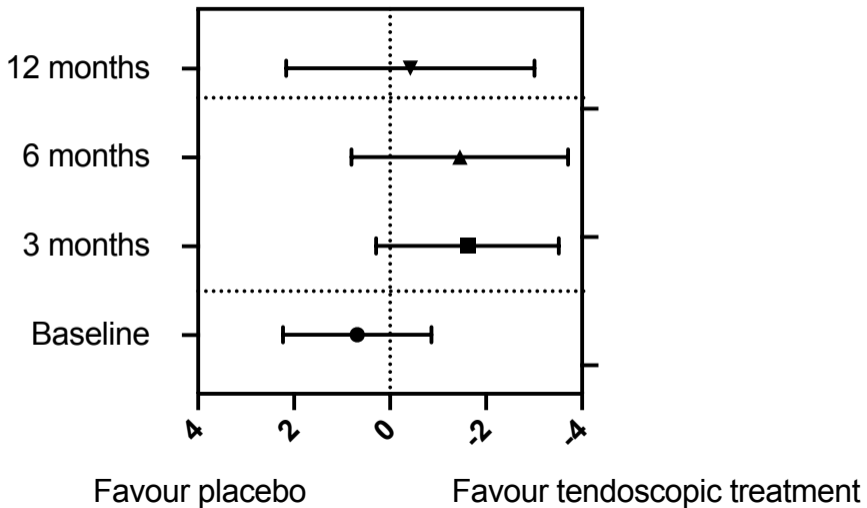




Difference between groups in VISA-A



Difference between group in pain (VAS) during walking



Achilles Tendon Thickness [mm]

