Acute Achilles tendon rupture
Treatment strategies and outcomes

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Acute Achilles tendon rupture
Treatment strategies and outcomes

Acute achillespees ruptuur; behandel strategieën en uitkomsten
(met een samenvatting in het Nederlands)

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door

Roderik Metz

geboren op 18 april 1973 te Ede

Promotor:	Prof. dr. Chr. van der Werken
Co-promotoren:	Dr. G.J.M.G. van der Heijden
	Dr. E.J.M.M. Verleisdonk

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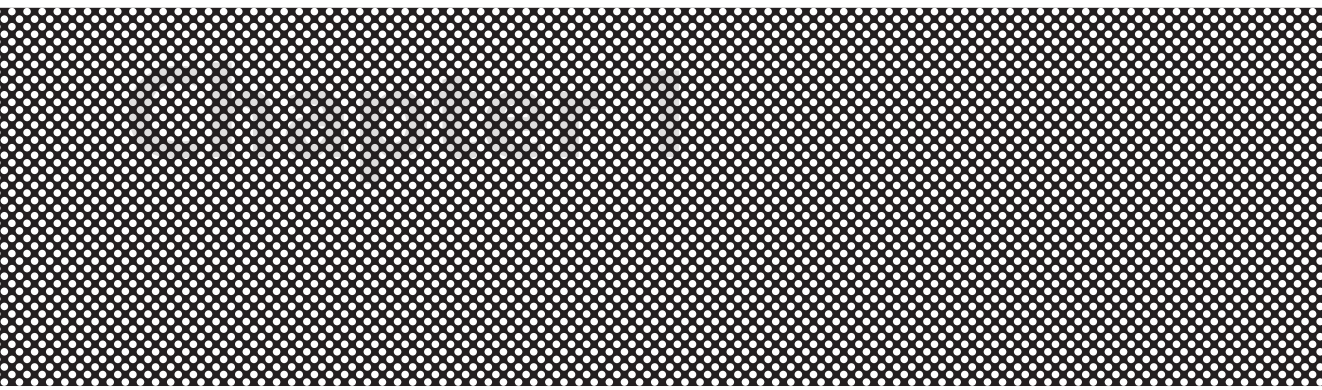
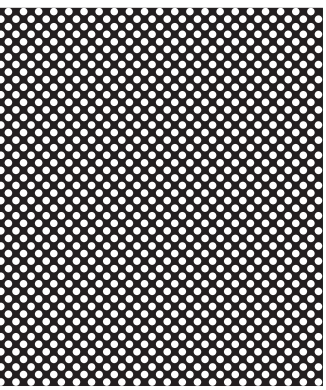


General introduction and aims of the thesis



General introduction and aims of the thesis

In Greek mythology, Achilles was a hero of the Trojan War and the central figure in Homer's Iliad. According to the incomplete poem Achilleis written by Statius in the first century AD, Achilles mother Thetis tried to make him immortal by dipping him in the river Styx. However, he was left vulnerable at the part of the body she held him by, his heel. These legends state that Achilles was killed in a battle by an arrow in the heel, and so an Achilles heel has become an expression used for "area of weakness" or "vulnerable spot". The first written proof for the expression "the cord of Achilles" or "Achilles tendon" to describe the combined tendon of the gastrognemius and soleus muscles dates from the seventeenth century.

Injuries to the Achilles tendon

The Achilles tendon is the largest tendon in the human body and has the capacity to withstand high tensional forces created by movements during walking, running and jumping. Despite these qualities the Achilles tendon is remarkably susceptible to injury. [3] One of these injuries, the acute Achilles tendon rupture, is the subject of this thesis.

Achilles tendon ruptures are most likely to occur in sports requiring sudden stretching, such as sprinting and (racquet) ball sports. [13] Its etiology has been studied extensively but the true cause of acute Achilles tendon rupture has not yet been identified. Treatment can be classified into surgical repair (open surgical reconstruction or minimally invasive surgical techniques) and conservative treatment (cast immobilization or functional bracing). Traditionally, open surgical repair has been the preferred method of treatment, mainly due to a low re-rupture risk compared to conservative treatment by cast immobilization. But surgery is associated with a high risk of wound healing complications. Minimally invasive surgical repair techniques are designed to reduce this risk and have become increasingly popular since their introduction in 1977. [4,6] The development of functional bracing systems has renewed interest in conservative treatment. [1,6,7,9,10] Unfortunately, a meta-analysis of all available randomized trials has not been able to identify one single superior treatment strategy so far. [4] Trial results do reveal that post-surgical functional rehabilitation protocols are superior to prolonged immobilization as these shorten sick leave from work and reduce complications risk. [14]

Preventing complications that arise from treatment of acute Achilles tendon ruptures provides a challenge to the surgeon. Nerve damage, wound infections, tendon lengthening, re-rupture and loss of function are known examples. In trial reports, complications are regularly denoted as "minor" or "major", suggesting they are of minor or major importance to the patient and functional recovery. But these qualifications are subjective, some complications resolve completely without any interference and others have long-lasting impact on outcome. [8,11] Further insight in the effect of complications on recovery in needed.

Frequently debated is the prevention of potentially hazardous venous thrombo-embolic complications in below-knee immobilization, and thus in Achilles tendon rupture treatment as well. Thrombosis prophylaxis during treatment is not recommended based on the conclusions from consensus meetings but a quantitative analysis of results from randomized trials on the efficacy of prophylaxis has not been undertaken so far. [2,5,12]

This thesis aims to contribute to the identification of optimal treatment strategies for acute Achilles tendon ruptures and to study the impact of complications on outcome. The following research questions are addressed and answered:

1. Does conservative treatment by functional bracing of acute Achilles tendon ruptures reduce the risk of complications compared to minimally invasive surgical repair. Chapter 2, 3 and 4.
2. Is conservative treatment of acute Achilles tendon ruptures by functional bracing equally effective as minimally invasive surgical treatment in achieving functional recovery, expressed as (early) return of calf muscle strength. Chapter 5.
3. What is the impact of complications, in particular re-rupture, on long-term outcome after minimally invasive surgical treatment of an acute Achilles tendon rupture. Chapter 6 and 7.
4. Do patients treated for an acute Achilles tendon rupture need thrombosis prophylaxis during immobilization. Chapter 8.

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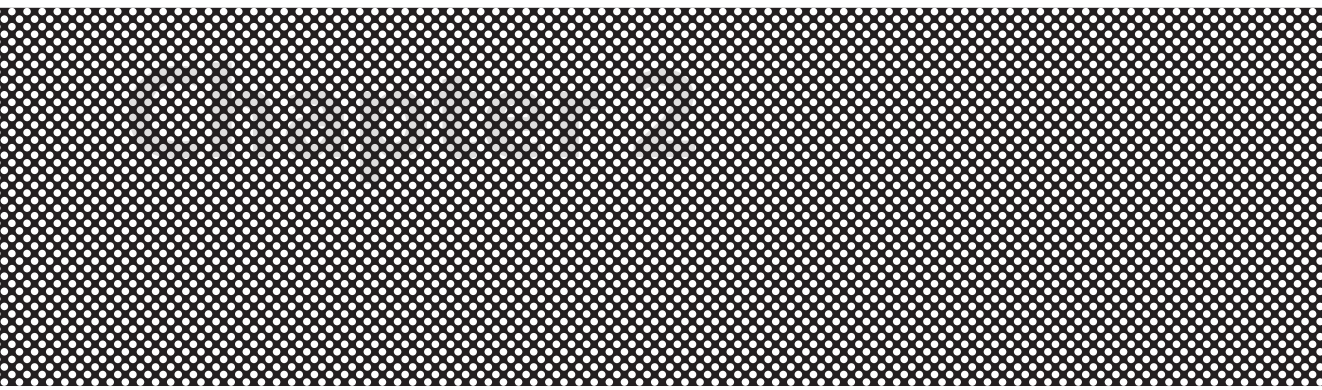
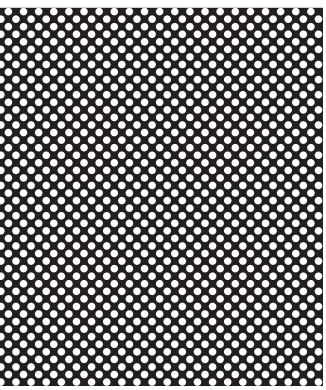


Acute Achilles tendon rupture treatment: towards an evidence bases guideline?



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Abstract

The acute Achilles tendon rupture is a typical sports injury that most commonly occurs in a male population. The diagnosis can be made easily, yet, there is no evidence based practical guideline for treatment of acute Achilles tendon ruptures. Historically, open surgical repair is the preferred over conservative treatment by cast immobilisations since it reduces the risk of a re-rupture. Nowadays, minimally invasive surgical treatment appears to be superior to open surgical repair, particularly in reducing the risk of (severe) wound infection. Still, evidence for this superiority from rigorously designed trials is limited. Independent from the surgical technique chosen, after-treatment should be functional. Early mobilisation increases speed of recovery and patient satisfaction and reduces complication risk. Functional conservative treatment (functional bracing) has not proven to be an effective treatment method yet. On the basis of the current evidence on acute Achilles tendon rupture treatment, it's too early for an evidence bases practical guideline.

Introduction

An acute rupture of the Achilles tendon is typical sport injury of which the observed increased incidence is attributed to the increased popularity of (recreational) sports. In the eighties it was noted this injury was misdiagnosed regularly. [26] At present time the acute Achilles tendon rupture attracts our attention again as new treatment methods have been introduced.

Epidemiology

The distinction between an acute or chronic Achilles tendon rupture has not been clearly defined. Generally, a 4-week period is apprehended, past this period the rupture is termed chronic, neglected or missed. [4] This distinction is important because treatment of acute ruptures differs from chronic ruptures; in chronic ruptures a surgical reconstruction of the tendon gap is mandatory. This discussion limits itself to acute Achilles tendon ruptures.

Acute Achilles tendon ruptures are particularly encountered during ball sports and although Dutch data are lacking, an increase in incidence of 22.1 persons per 100,000 inhabitants in 1991, to 32.6 per 100,000 inhabitants in 2002, is reported in Denmark. [5,20,22] The peak incidence lies at an age between 30 and 50 years. [5,20]

Etiology and risk factors

Concerning the cause of acute Achilles tendon rupture, two main theories exist. The first and most going declaration is that degenerative changes weaken the tendon, until it eventually tears. [5,10] This degeneration is caused by repeated micro traumas that, because of the marginal blood supply in middle the part of the tendon, badly heal. [23] Histological examinations of Achilles tendons have subscribed the existence of these degenerative changes. [6] The second theory assumes a biomechanical cause. It is adopted that a healthy tendon can tear at violent muscle tension in the presence of certain functional and anatomical conditions. Moreover, strength partitioning is not symmetrically due to a 90 degrees rotation of the tendons fibers along its course. This could explain why the tendon is more susceptible to rupture at peak performance. [5,10]

Injections of corticosteroids in the Achilles tendon as well as oral use of fluoroquinolones, such as ciprofloxacillin, have been associated with an increased risk of an Achilles tendon rupture. [5,20] Associations with blood group, inflammatory- and autoimmune disease, collagen disorders and neurological disease have been suggested but have never been proven. [5]

Diagnosis

Acute Achilles tendon rupture can be diagnosed simply by means of clinical investigation. A frequently used test is the so-called calf muscle squeeze test or Simmonds/Thompson test: the patient is lying in prone position with both feet over the research bench. When plantar flexion of the foot by squeezing the calf muscles fails, the test is regarded positive for rupture. [19,24] This test has 96% sensitivity and 93% specificity. [11] A falsely positive test can be found in the presence of an intact musculus plantaris function. Notably, active plantar flexion of the foot is still possible due to the deep flexor muscles of the foot. When in doubt, ultrasound examination or MR imaging can be used to confirm the diagnosis but this is seldom necessary.

Treatment

Treatment methods for acute Achilles tendon rupture are subdivided in surgically (open surgical reconstruction or minimally invasive surgical techniques) or conservative (cast immobilization or functional bracing). In 2004, a Cochrane meta-analysis of randomized trials on these treatment methods was published. [7] With this review in mind acute Achilles tendon rupture treatment is further discussed.

Open reconstruction versus cast immobilization

In surgical repair by open reconstruction the Achilles tendon is explored over nearly its full length. The V-Y reconstruction technique or braid technique according to Bunell are well known. Open tendon reconstruction reduces the chance of re-rupture in comparison to conservative treatment by means of cast immobilization (3% re-rupture risk versus 10% re-rupture risk). [5] However, the most serious complication in open reconstruction is a severe wound infection, occurring in approximately 2% of the patients. [5] In sum, 36% of the patients suffer a complication after open repair. [5] These numbers are, among others, reason for the development of less invasive repair techniques. [9]

Open reconstruction versus minimally invasive repair

In 1977, the first description of a minimally invasive repair technique for acute Achilles tendon ruptures was reported. [9] A Bunell type suture was placed through the Achilles tendon using stab incisions through the skin proximal to the rupture after which the suture was subcutaneously tunneled to the calcaneus bone. The tendon itself was not explored. The aim of this operation is to guarantee that the ruptured tendon ends unite and not to make a firm connection between them. Since this publication various minimally invasive repair techniques have been presented. [15] With the use of these techniques a 2% re-rupture is reported without serious wound infections. But these figures are based on two studies with in sum 94 patients. [5] Since the appearance of the Cochrane review one additional comparative study was published in which none of the 20 minimally invasive

surgically treated patients suffered a re-rupture. [3] Remaining data are obtained from case series. [1,8]

A potential disadvantage of minimally invasive surgical repair techniques is the increased chance of lesion of the sural nerve, with loss of sensation on the lateral foot edge. [10] In randomized trials though, no difference in nervus suralis injury risk between open and minimally invasive repair techniques was found. [5] Recently, sural nerve injury was reported in four out of 42 patients after minimally invasive tendon repair in a randomized trial comparing to conservative treatment by functional bracing. These lesions were discovered during follow-up without spontaneous complaint from the patients themselves. [11] Little is known on the long-term outcome of nervus suralis injury. A part of these injuries probably relies on neuropraxia and are therefore likely to be temporarily. Moreover, a carefully carried out operative technique seems to prevent this injury. [8]

Conservative treatment: Cast immobilization versus functional bracing

Renewed interest in the conservative treatment of the Achilles tendon ruptures has arisen with the introduction of functional braces. This type of conservative treatment allows early (partial) weight bearing during rehabilitation. The advantages of early weight bearing are commented in the rehabilitation paragraph. Pooling the results of two small trials produces a 2.4% risk of re-rupture with functional bracing versus 12,2% with cast immobilization. [5] These promising results are supported by a more recently published randomized trial of small statistical power and two prospective cohort studies. [2,12,17] However, in the previously cited study that compared minimally invasive surgery to functional bracing a 12% re-rupture risk was reported in the functional bracing group. [13]

Rehabilitation

Post-surgical treatment of acute Achilles tendon ruptures can be subdivided in complete (cast) immobilization and functional after-treatment. With a functional after-treatment the cast is replaced by a tape dressing or functional brace after a short period of time (i.e. approximately two weeks) and the patient is allowed early weight bearing. [2,13] The potential advantage of functional rehabilitation is the prevention of muscle atrophy and joint stiffness and as a result, faster recovery. In meta-analysis of 6 randomized trials with more than 300 participants this comes to expression in a shorter sick leave from work. [22] Moreover, this type of after-treatment is better appreciated by the patient compared to cast immobilization and there is a statistical trend towards a lower complication risk, including re-ruptures. [22] Once a faster calf muscle strength recovery (by isokinetic strength testing) was found with functional after-treatment in comparison with long-term immobilization. [7] Since the publication of this meta-analysis, the advantages of functional after-treatment have been reported repeatedly. [21,25]

Prognosis

Generally, outcome after an acute Achilles tendon is considered good. Approximately three-quarter of the patients returns to their pre-rupture level of sport. [13] Fear for a re-rupture seems to be an important reason to stop. [13] It is striking however, that objective strength measurements by means of dynamometry show a distinctive loss of calf muscle strength of the injured leg up till 2 years after the rupture. [14]

The outcomes after a re-rupture are less favorable in comparison to those after an uncomplicated post-operative course, but still considered reasonable. [16,18] The outcomes after a severe wound infection are regarded as poor. [16] Concerning the long-term impact of less serious complications and sural nerve injury hardly any knowledge exists.

In summary, surgical treatment of acute Achilles tendon ruptures is preferred over conservative treatment by cast immobilization, particularly because of the lower re-rupture risk. Less invasive surgical treatment methods have gained popularity in acute Achilles tendon rupture treatment, which seems justified on the basis of the current evidence. If conservative treatment by functional bracing will play an important role in the treatment of acute Achilles tendon ruptures in the future remains unclear at this stage. Independently from treatment type chosen, the patient should not be denied the advantages of functional rehabilitation. It is concluded that current evidence is insufficient to introduce an evidence based treatment guideline.

Literature search strategy

The publications that are involved in this literature overview were traced on the basis of the following snowball method. Randomized trials were traced on the basis of literature lists of editorials, systematic reviews and meta-analyses incorporated in Pubmed. Relevant citations from the literature lists of the thus traced randomized studies were assessed on suitability. Of all suitable publications in Pubmed the related articles were assessed as well.

Acknowledgement: We thank prof dr Chr van der Werken for his comments on our manuscript.

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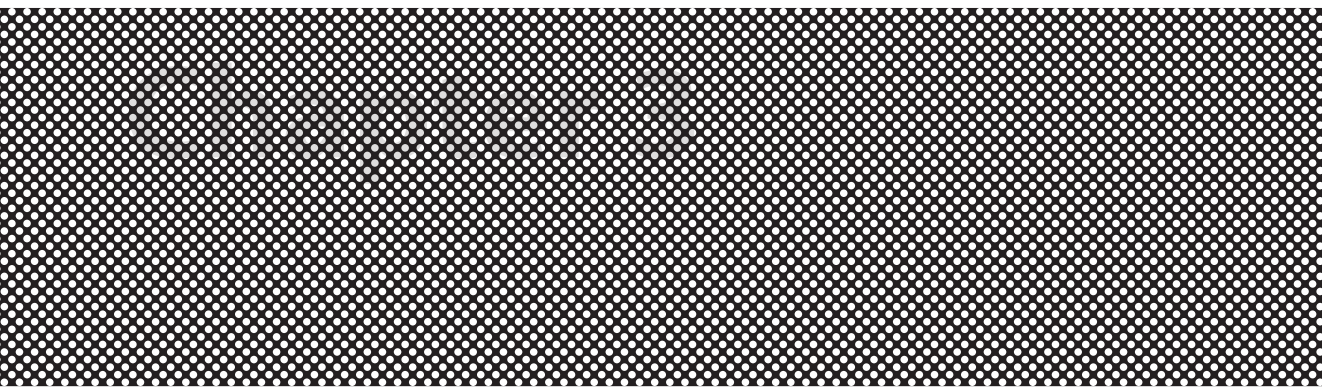
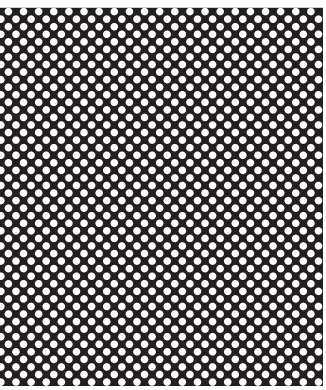


Acute Achilles tendon rupture: Minimally invasive surgery versus non operative treatment, with immediate full weight bearing. Design of a randomized controlled trial.



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BMC Musculoskelet Disord 2007; 8(1):108

Abstract

Background: We present the design of an open randomized multi-centre study on surgical versus conservative treatment of acute Achilles tendon ruptures. The study is designed to evaluate the effectiveness of conservative treatment in reducing complications when treating acute Achilles tendon rupture.

Methods/Design: At least 72 patients with acute Achilles tendon rupture will be randomized to minimally invasive surgical repair followed by functional rehabilitation using tape bandage or conservative treatment followed by functional rehabilitation with use of a functional bracing system. Both treatment arms use a 7 weeks post-rupture rehabilitation protocol. Four hospitals in the Netherlands will participate. Primary end-point will be reduction in complications other than re-rupture. Secondary end-point will be re-rupturing, time off work, sport participation post rupture, functional outcome by Leppilahti score and patient satisfaction. Patient follow-up will be 12 months.

Discussion: By making this design study we wish to contribute to more profound research on Achilles tendon rupture treatment and prevent publication bias for this open-labelled randomized trial.

ISRCTN50141196

Background

Controversy continues with regard to the optimal treatment for acute subcutaneous Achilles tendon (AT) ruptures. Treatment can be classified into operative and non-operative. Postoperative splintage can be divided into cast immobilisation and functional bracing. Traditionally open surgical repair of a ruptured Achilles tendon has been the first choice of treatment due to low re-rupture rates and the possibility for functional post-operative splintage. [1-4] But, 34% of patients treated with open repair suffer from complications other than re-rupture, especially wound infection and adhesions. [1-5] In general, the outcome after treatment of a re-rupture is poor, but results following treatment of a severe infection are devastating. [6] Therefore an effort should be made to prevent infectious complications. Many articles on different types of minimally invasive repair techniques (using limited incisions or performed percutaneously) of ruptured AT's have been published. [7-14] But to date, only two 2 randomized trials have been reported. [4,15] In Khan's review on randomized trials, complications other than re-rupture were substantially reduced with percutaneous repair techniques. But data were very limited. Data on complications using limited incision techniques are even more scant. As minimally invasive techniques differ it is hard to compare other techniques with these numbers. An advantage of most minimally invasive techniques is smaller scars and less damage to the delicate blood supply of the AT. Importantly, in most patients minimally invasive surgery does allow functional rehabilitation. [7] Patients treated by functional rehabilitation after operation rather than cast immobilisation are reported to have a shorter in-patient stay, less time off work and a quicker return to sporting activities. In addition, lower complication rates, including re-ruptures, are reported. [1-5]

The main advantage of conservative, i.e. non-operative treatment is elimination of wound complications and intra-operative sural nerve damage. Complications other than re-rupture are reported to reduce to 3%. [5] But, conservative treatment with cast immobilisation has shown to increase the re-rupture rate and cast immobilisation induces delayed recovery due to calf muscle weakness as a result of long immobilisation of the ankle joint. [1-5] In contrast, conservative treatment by functional bracing does allow immediate weight bearing, preventing calf muscle weakness and enabling fast recovery. In three studies conservative treatment of AT rupture with functional bracing did not result in increased re-rupture rates. [16-18] But since only one of these is a randomized trial, more high quality data from randomized prospective studies are needed. [17] We hypothesized that compared to surgical treatment, conservative treatment with functional bracing will reduce the absolute risk of complications other than re-rupture with 30%.

Methods/Design

Design of study

Context: The efficacy of minimally invasive surgery versus functional conservative treatment of acute subcutaneous Achilles tendon ruptures will be studied in a randomized trial. Four hospitals in the Netherlands will participate in the study, one of them being a university medical centre. The Medical Research Ethics Committee of all the participating hospitals approved the study protocol.

Patient selection and informed consent: All patients who report to the emergency department of one of the participating hospitals with an acute Achilles tendon rupture will be considered for entering the study protocol. Inclusion and exclusion criteria are listed in table 1 and will be checked by an emergency room doctor, surgical resident or surgeon. All eligible patients are asked to provide written informed consent.

Inclusion Criteria	**Exclusion criteria**
Achilles tendon rupture.	Re-rupture / bilateral rupture / open rupture.
Treatment starts within 72 hours.	Combination with fracture of foot or ankle.
Diagnoses by physical examination: palpable gap and calf muscle squeeze test.	Former application (injection) of local corticosteroids in tendon area.
Age 18-65 years.	Contra-indications for surgery.
Written informed consent.	Physical or mental handicaps that do not allow functional treatment or otherwise interfere with the ability to follow-up on the study protocol.

Table 1. Inclusion and exclusion criteria

Randomisation and concealment: Randomisation is concealed by a specially designed internet site. Randomisation is in blocks (4 blocks) and stratified by centre. The treatment nature is open labelled for patients, physicians and physiotherapists. During follow-up visits physical examination reveals the allocated treatment to patient and assessor.

Interventions: Surgical therapy consists of a minimally invasive technique (figure 1). [7] The same protocol for the operative procedure was used by all surgeons and residents in the participating hospitals. Also, before study participation, all surgeons were familiar with the operative procedure. A less than 5 cm longitudinal incision is made over the posterior aspect of the affected leg just proximal to the rupture site. The incision is slightly medially placed. The subcutaneous fat is divided and the peritendineum opened. Then a Bunell type suture is placed though the proximal end of the Achilles tendon (PDS® 1.0). With a hollow mandarin the suture is tunnelled to the lateral aspect of the calcaneal bone and guided out through a 5 mm stab incision. A hole is drilled through the calcaneal bone 1 cm distal to the tendon insertion (exit through 5 mm stab incision

medially). The PDS® in guided though the hole. Now the mandarin is used to guide the suture back to the proximal site of the tendon. After the foot is placed in plantar flexion the suture is tied. After wound closure a cast is applied with the foot still in plantar flexion. After one week a tape bandage is applied for a total period of 6 weeks. In the first two weeks the tape bandage is supported by a 2 cm heel raise. The following 2 weeks the heel raise is reduced to 1 cm. The last two weeks the heel raise is removed (tape bandage will be renewed every time the heel raise is changed). Full weight bearing is allowed during the 6 weeks of tape bandage, not allowing sporting activities or walking stairs on tiptoes. Crutches are advised in the first week of casting, thereafter for maintenance of balance, but only if necessary.

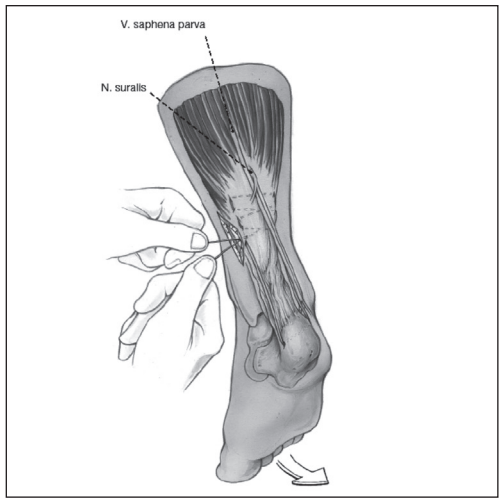

Figure 1. Surgical repair technique. Taken from "Operative treatment of Achilles tendon rupture: a minimally invasive technique allowing functional after treatment". Orthop Traumatol. 2000; 8:285-90.

Figure 2. Vacoped.

Conservative therapy consists of a cast in plantar flexion for one week. After one week a functional bracing system (figure 2) is applied for 6 weeks. [19] The Vacoped® bracing system (Company OPED, Valley, Germany) is a multifunctional splint consisting of several components. The essential parts are the dorsal and ventral shell, the vacuum cushion with changeable terry cloth covers, the belts with security locks and the removable sole. Prior to study use the brace was successfully used in a small pilot series and an instructions meeting on brace application was held in all participating hospitals. In the first two weeks the brace is fixed in 30º plantar flexion. The following 2 weeks in is in rigid 15º plantar flexion. The last two weeks the brace is dynamic from neutral position to 30º plantar flexion. Full weight bearing is allowed during the 6 weeks of bracing, not allowing sporting activities or walking stairs on tiptoes. Crutches are advised in the first week of casting, thereafter for maintenance of balance, but only if necessary.

After tape or brace removal patients were advised further rehabilitation with physiotherapist and were allowed sports 3 months after rupture. Patients were free to choose their physiotherapist.

Design of collection of data

Primary endpoint: Complications other than re-rupture, i.e. infection, disturbed wound healing, sural nerve injury, scar adhesions, deep vein thrombosis and all other complications per treatment group. During follow-up all complications will be documented by a surgeon or resident according to a standardised procedure using the definitions of complications presented in the table 2. All complications will be included in the final analysis of results.

Secondary endpoint: Re-rupturing (clinical diagnosis supported by ultrasound), time off work, sporting activity post rupture and patient satisfaction. The Thompson test is used for clinical diagnosis of re-rupture. Failure in plantar movement of the foot during calf muscle squeeze is considered a positive sign for re-rupture. Ultrasound evaluation for re-rupture is performed in neutral ankle position. Complete tendon rupture with tendon gap was considered a re-rupture. Time off work will be registered by a patient diary. Complete return to profession was used as endpoint. Stratification to type of profession (sedentary and non-sedentary) will be performed afterwards. A visual analogue scale (VAS) on patient satisfaction with treatment will be measured at 7 weeks, 3 and 12 month. Patient outcome will also be evaluated by the Leppilahti scoring method, a clinical scoring system, including subjective assessment of symptoms and evaluation of ankle range of motion and isokinetic measurement of ankle plantar flexion and dorsifexion strengths (table 3). [20]

Follow-up: Follow-up visits for assessment of primary and secondary endpoints will be scheduled every week during the first 7 weeks. Thereafter, follow-up visits will be planned at 3, 6 and 12 month. Any other consultation for complaints concerning the Achilles tendon area will be documented.

Complication	**Definition**
Infection	Clinical signs of wound infection, i.e. redness, swelling, pain and functional impairment. Severe infection is defined as an infection beyond skin or subcutaneous fat needing surgical treatment in the operating theatre.
Disturbed wound healing	Keloid formation or hypertrophic scar, secondary wound healing, protruding PDS knot.
Sural nerve injury	Any sign of altered sensibility in the sural nerve area diagnosed by surgeon or surgical resident (using touch and pin prick test).
Scar adhesion	Clinical signs of adhesion of skin to underlying tissue layers. Clear wound retraction at ankle movement.
Deep vein thrombosis	Clinical and ultrasonographic signs of deep vein thrombosis of the ipsilateral lower leg.
Other complications	Any complication met during follow-up.

Table 2. Definitions of complications.

Clinical factors	**Scores (points)***
Pain	
None	15
Mild, no limitations on recreational activities	10
Moderate, limitations on recreational, but not daily activities	5
Severe, limitations on recreational and daily activities	0
Stiffness	
None	15
Mild, occasional, no limitations on recreational activities	10
Moderate, limitations on recreational, but not daily activities	5
Severe, limitations on recreational and daily activities	0
Calf muscle weakness (subjective)	
None	15
Mild, no limitations on recreational activities	10
Moderate, limitations on recreational, but not daily activities	5
Severe, limitations on recreational and daily activities	0
Footwear restrictions	
None	10
Mild, most shoes tolerated	5
Moderate, unable to tolerate fashionable shoes, modified shoes tolerated	0
Active range of motion (ROM) difference between ankles	
Normal (<6°)	15
Mild (6°-10°)	10
Moderate (11°-15°)	5
Severe (>15°)	0
Subjective result	
Very satisfied	15
Satisfied with minor reservations	10
Satisfied with major reservations	5
dissatisfied	0
Isokinetic muscle strength (score)	
Excellent	15
Good	10
Fair	5
poor	0
* Maximum overall score 100. An overall score of 90-100 rates excellent, 75-85 is good, 60-70 is fair and <55 is poor.	

Table 3. Leppilahti score.

Design of analysis

Results will be analysed according the intention-to-treat principle.

Data analysis: The study groups will be compared for their baseline characteristics. The number of complications will be calculated for the primary endpoint. Distribution measures will be calculated for the secondary endpoints at the different moments of follow-up. Differences between groups for the number of complications and distribution of other endpoints will be calculated for each outcome measure with a 95% confidence interval. The study groups will be compared with the chi-square test for categorical outcome variables and the independent sample

Student *t* test for continuous outcome variables. The dropouts and withdrawals will be summarized and analyzed by treatment groups. A listing of subject with withdrawal with the date and reasons for termination will be provided.
Because we standardised the intervention procedures we do not anticipate important differences between centres. So we do not stratify our primary analysis for centre. However, when eventually differences may occur we will explore their effect in a secondary analysis (Mantel-Haenszel). All analysis in SPSS (SPSS Inc, Chicago Illinois).
Sample size: Sample size is calculated on the basis of complication other than re-rupture. With conservative treatment using this new type of functional bracing we hypothesized a 30% reduction in the absolute risk for complications other than re-rupture. This risk reduction is similar to the risk reduction obtained in the systematic review on open versus conservative treatment by Khan: risk of complications for open repair being 34%. [5] Prospective data on the risk of complications of minimally invasive repair is very scant. The Khan review provides the best empirical estimate for the complication risk associated with surgical repair. Therefore we decided to use this risk estimate of complications of open repair for the sample size calculation. With a one-sided α of 0.05, a statistical power of (1-β) of 0.80, and an attrition rate of 10% we need to randomize at least 36 patients per treatment arm.

Discussion

This study is primarily designed to evaluate the effectiveness of conservative treatment of acute AT ruptures, using a functional bracing system, in reducing complications other than re-rupture. A comparison is made between this functional bracing system and a minimally invasive operative repair of acute AT ruptures. Both treatment options used in this comparison allow immediate full weight bearing so none of the patients is denied the purported advantage of a functional after treatment. [2, 5, 21-24]

There have been randomized clinical trials on treatment of acute Achilles tendon rupture but the methodological rigour is often low. There is a need for more rigorous designed studies on AT rupture treatment as this subject is still very much under debate. By publishing our protocol we wish to show our care for a profound design and methodological quality of our protocol. Moreover, when the design of a study is published it will help to achieve transparency about why and how studies are undertaken. The publication of a study design may help to reduce the problem of publication bias, i.e. selective publication of positive associations and disregarding negative and weak associations, prevent unnecessary duplication of research efforts and duplicate publication. [25]
To our knowledge, there has never been a design study published regarding treatment of AT ruptures. By making this design study we wish to contribute to more profound research on AT rupture treatment and prevent publication bias for this open-labelled randomized trial.

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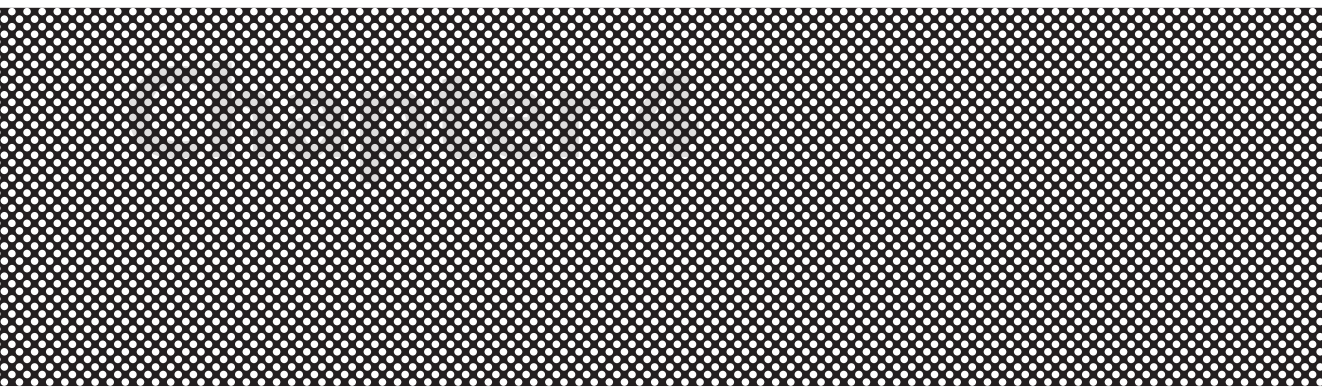
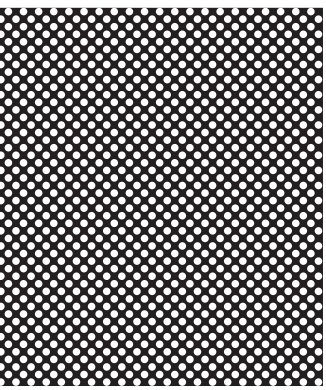


Acute Achilles tendon rupture: Minimally invasive surgery versus nonoperative treatment with immediate full weight bearing. A randomized controlled trial.



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Am J Sports Med 2008; 36:1688-94

Abstract

Background: Surgical repair of acute Achilles tendon ruptures is considered superior to conservative treatment, but complications other than re-rupture range up to 34%. Conservative treatment by functional bracing seems a promising alternative.

Hypothesis: Conservative treatment of acute Achilles tendon ruptures by functional bracing reduces the number of complications compared to surgical treatment with a minimally invasive technique.

Study design: Randomized controlled clinical trial. Level of evidence, 2.

Methods: Using concealed random allocation, 83 patients with acute Achilles tendon rupture were assigned to conservative treatment by functional bracing or minimally invasive surgical treatment followed by tape bandage. Patients were allowed full weight bearing and follow-up was one year.

Results: Complications risk other than re-rupture by intention-to-treat analysis was 9 in 42 patients (21%) for surgical treatment and 15 in 41 patients (36%) for conservative treatment (risk ratio: 0.59; 95% confidence interval 0.29; 1.19). Re-ruptures risk was 5 in 41 patients after conservative treatment and 3 in 42 patients for surgical treatment (risk ratio: 0.59; 95% confidence interval 0.15; 2.29). The average time of work was 59 days (SD 82) after surgical treatment and 108 days (SD 115) after conservative treatment (difference 49 days; 95% confidence interval 4; 94. $p<0.05$). The difference between treatments for return to sports (risk ratio 0.55; 95% confidence interval 0.23; 1.29), pain and treatment satisfaction did not reach statistical significance.

Conclusion: There appears to be a clinically important difference in the risk of complications between minimally invasive surgical treatment and conservative treatment for acute Achilles tendon ruptures, but this was not statistically significant.

ISRCTN50141196

Introduction

Surgical repair of acute Achilles tendon (AT) ruptures is generally considered superior to conservative treatment as it reduces re-rupture rates and allows functional after treatment. [4,9,20,22] However, postoperative complications other than re-rupture (e.g. wound infection, scar adhesion, surgery related sural nerve injury) have been reported to range up to 34%. [9] Minimally invasive surgical techniques (using limited incisions or percutaneous techniques) are considered to reduce the risk of operative complications and appear successful in preventing re-rupture in cohort studies. [1-3,5,11,14,16,26,28] But to date, evidence from randomized trials is very limited. [9,13] On the other hand, non-operative treatment by cast immobilisation eliminates the risk of wound complications and intra-operative sural nerve damage, but has a considerable risk of re-rupture. [9,20] A major disadvantage of cast immobilisation is delayed recovery due to calf muscle weakness. [7,8,15,21,25] Functional bracing allows exercise and training therewith preventing calf muscle atrophy and enabling faster recovery. At the same time, a low risk for re-rupture and a low overall complications rate have been reported for functional bracing. [17,23,24,27]

The goal of this randomized trial is to compare the results of minimally invasive surgical repair to those with conservative treatment by functional bracing of acute ruptures of the AT. The design of this trial has been published previously. [18]

Materials and methods

The study was conducted in four teaching hospitals in the Netherlands. Eligible were patients with an acute AT rupture who visited the Accident & Emergency departments of one of the four hospitals. Treatment was initiated (surgery or cast application) within 3 days from AT rupture. Inclusion and exclusion criteria are listed in table 1.

Inclusion criteria	**Exclusion criteria**
Primary Achilles tendon rupture (mid-zone tear)	Re-rupture / bilateral rupture / open rupture.
Treatment starts within 72 hours.	Combination with fracture of foot or ankle.
Diagnoses by physical examination: palpable gap and positive calf muscle squeeze test.	Former application (injection) of local corticosteroids in tendon area.
Age 18-65 years.	Contra-indications for surgery.
Written informed consent.	Physical or mental handicaps that do not allow functional treatment or otherwise interfere with the ability to follow-up on the study protocol.

Table 1. Inclusion and exclusion criteria

The surgeon, surgical resident or emergency department doctor allocated treatment to patients. This was done in a concealed manner via a specially designed internet site for which treatment randomisation was stratified by hospital in blocks of 4 to balance groups over hospitals. The treatment nature was open to patients, physicians and physiotherapists.

Sample size

Prospective data on the risk of complications of minimally invasive repair are very scant.
The systemic review by Kahn provides the best empirical estimate for the post-surgical risk of complication (excluding re-rupture) for any surgical treatment. [9] Based on this post-surgical risk of 34%, a statistical power (1-β) of 0.80, and an attrition rate of 10% at least 36 patients per treatment arm are needed for this balanced group trial to reach statistical significance (one-sided $\alpha = 0.05$) for a risk difference of 30%. (figure 1)

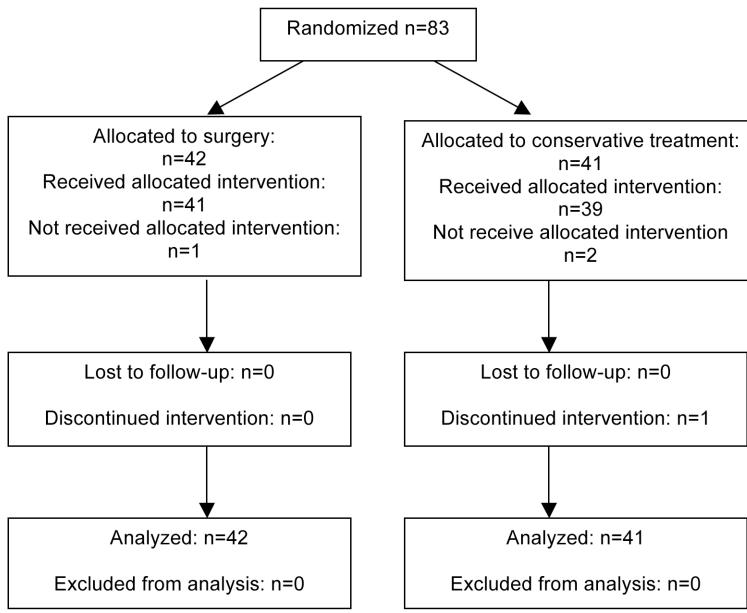

Figure 1. Diagram of patient flow through the trial.

Treatment

In all hospitals physicians were familiar with the surgical technique before trial participation. Surgery was performed under supervision of one of four surgeons (EV, GC, EH, MV). Surgery was performed under regional or general anaesthesia, with the patient in prone position. No tourniquet was used. The minimally invasive surgical repair started with a less than 5 cm longitudinal incision over the postero-medial aspect of the affected leg just proximal to the rupture area. [3] A Bunell type suture was placed through the proximal end of the Achilles tendon (atraumatic PDS® 1.0).

With a hollow mandarin the suture was tunnelled to the lateral aspect of the calcaneus and guided out through a 5mm stab incision. A hole was drilled through the calcaneus 1 cm distal to the tendon insertion (exit through 5 mm stab incision medially). The PDS® was guided though the hole and with the mandarin back proximally. Finally, the suture was tied with the foot in relaxed equine position (approximately 30 degrees plantar flexion). After wound closure a cast was applied with the foot in plantar flexion for one week. In the following six weeks tape bandage was applied, the first two weeks supported by a 2 cm heel raise, thereafter the height was reduced to 1 cm. The last two weeks the heel raise was removed.

Conservative therapy consisted of a cast in plantar flexion for one week, thereafter a functional bracing system (Vacoped) was applied. The Vacoped® bracing system (Company OPED, Valley, Germany) is a multifunctional below-knee splint consisting of several components. The essential parts are the dorsal and ventral honeycomb-shaped plastic shell, the vacuum cushion with changeable terry cloth covers, the belts with security locks and the removable sole. [19] Prior to the trial the brace was successfully used in a small pilot series to test feasibility of technical aspects of design and protocol. An instructions meeting on brace application was held in all participating hospitals. In the first two weeks the brace was fixed in 30° plantar flexion. The following 2 weeks bracing was in 15° plantar flexion. The last two weeks the brace was applied in a dynamic status enabling movement from neutral position to 30° plantar flexion. The braces were sealed to reveal illicit removal outside of protocol.

In both treatment groups crutches were advised in the first week of casting, thereafter the use of crutches was left at discretion of treating physician. Full weight bearing when walking on flat surface was allowed.

Follow-up and endpoints

The primary endpoint was all complications other than re-ruptures. Re-rupture rates were expected to be equal for both treatment groups. Secondary endpoints were time to work resumption, participation in sports and patient satisfaction with treatment and pain, both measured on a 0-10 visual analogue scale (VAS). Follow-up visits were planned at 1, 3, 5 and 7 weeks and at 3, 6 and 12 month.

At a minimum of six months follow-up patient outcome was evaluated by the Leppilahti scoring method, a clinical scoring system including subjective assessment of symptoms and evaluation by independent physiotherapists of the range of motion and isokinetic muscle strength of plantar flexion and dorsiflexion of the ankle. [12]

Data analysis

Both study groups were compared for their baseline characteristics. The number of complications was calculated for the primary endpoint. Distribution measures were calculated for the secondary endpoints at the different moments of follow-up. Differences between groups for the number of complications and distribution of other endpoints were calculated for each outcome measure with a 95% confidence interval (CI). The study groups were compared with the chi-square test for categorical outcome variables and the independent sample Student t test for continuous outcome variables. During the analysis the intention-to-treat principle was adhered, i.e. all patients were analysed according to their randomized treatment. A listing of dropouts and withdrawals, including date and reason, was summarized by treatment group. Because the intervention is standardised no important differences between centres was anticipated. The Mantel-Haenszel procedure was used to explore the effect of possible between-centre differences.

Results

Between January 2004 and September 2005 83 patients with an acute Achilles tendon rupture were included: 42 were allocated to minimally invasive surgical treatment and 41 to conservative treatment by functional bracing. Both groups were comparable at baseline (table 2). The AT rupture occurred mainly during sports, notably ball sports like tennis, squash and volleyball. Most patients were in their third or fourth decade of life.

Baseline characteristics	**Surgery Number**	**Conservative Number**	**Total Number (%)**
Number of patients	42	41	83
Age (years)	40 (range 23-63)	41 (range 25-62)	-
Gender: Male	31	35	66 (79.5)
Body mass index (mean)	25.9	26.3	-
Smoking	8	10	18
Diabetes Mellitus	0	2	2
Cause: Sports	37	33	70 (84)
Side: Left	28	21	49 (59)

Table 2. Baseline characteristics.

For all patients follow-up data on treatment complications were obtained (table 3). Re-ruptures occurred in 5/41 (12%) patients after conservative treatment and 3/42 (7%) patients after surgical treatment. Consequently the reduction in absolute risk of re-rupture in favour of surgical treatment

was 5%, whereas the relative risk reduction was 41% (risk ratio 0.59; 95% CI 0.15; 2.29). One of the re-ruptures in the surgical treatment group occurred in a patient who, after refusing allocated surgical treatment, received conservative treatment. In addition, 2 patients consenting to trial participation refused allocated conservative treatment and subsequently received surgery. Consequently, according to treatments-as-received re-rupture occurred in 6/40 patients (15%) with conservative treatment and 2/43 patients (5%) with surgery, resulting in a risk ratio of 0.31 (95% CI 0.07; 1.45. p=0.11). Re-ruptures were diagnosed clinically and by ultrasound examination in the Achilles tendon mid-zone, approximately 2-5 cm from the calcaneus. For 6 re-ruptures (1 after primary surgical and 5 after primary conservative treatment) patients underwent surgery. Both remaining patients (1 after primary surgical and 1 after primary conservative treatment) were treated conservatively. The re-rupture in the conservative treatment group occurred in a patient suffering severe dermatitis during bracing. It was treated conservatively by cast immobilisation, as the skin had not yet completely healed. One re-rupture in the surgical treatment group was a partial re-rupture on clinical and ultrasound examination and was treated conservatively by tape bandage.

Of all complications in both treatment groups, many were skin related: 5/12 (42%) for surgical treatment and 13/20 (62%) for conservative treatment. Most skin related complications (e.g. fungal infections, pressure sources and blisters) resolved quickly when brace or tape bandage was removed 7 weeks after treatment initiation. All post-operative wound adhesions documented by surgeons at follow-up were reported as asymptomatic. One of the two patients, who were operated after refusing conservative treatment, had short-term post-operative sensibility loss in the sural nerve area. Three other patients suffering sural nerve injury still had partial sensibility loss at one-year follow-up. One surgically treated patient developed a complex regional pain syndrome 3 month after surgery. Although improving, this patient was not fully recovered at one-year follow-up.

The total number of complications on the intention-to-treat basis was 12/42 (29%) for surgical treatment and 20/41 (49%) for conservative treatment. Consequently, the absolute risk reduction in favour of surgical treatment was 20% while the relative risk reduction was 41% (risk ratio 0.59 with a 95% CI 0.33; 1.04). The total number of complications other than re-rupture on the intention-to-treat basis was 9/42 (21%) for surgical treatment and 15/41 (36%) for conservative treatment. Consequently, the absolute risk reduction in favour of surgical treatment was 15% while the relative risk reduction was 41% (risk ratio 0.59; 95% CI 0.29; 1.19).

Complications	**Surgery (n=42) Number (%)**	**Conservative (n=41) Number (%)**	**Risk data**
Re-rupture	3 (7.1)	5 (12.2)	RR 0.59 (0.15; 2.29) *p* = 0.44 RD 0.05 (-0.08; 0.18)
Sural nerve injury	3	1	
Deep vein thrombosis lower leg	0	1	
Complex regional pain syndrome	1	0	
Skin related complications [1]	2	13	
Deep wound infection	0	0	
Scar adhesion	3	0	
Total complications other than re-rupture	9 (21.4)	15 (36.6)	RR 0.59 (0.29; 1.19) *p* = 0.13 RD 0.15 (-0.04; 0.34)
Total	12 (28.6)	20 (48.8)	RR 0.59 (0.33; 1.04) *p* = 0.06 RD 0.20(-0.003; 0.41)

Table 3. Complications of treatment (intention-to-treat analysis). 1: Skin related complications include fungal infection, pressure sores, blisters and superficial wound infection.

For all patients follow-up data were obtained for time to resumption of work and participation in sports. Five out of 83 patients included had no paid work and 14/83 patients did not participate in any sport at randomization. In table 4, the numbers of data available per group are presented for each variable. All but one patient returned to their former job. The one patient who did not was still suffering from a complex regional pain syndrome. The average time off work was 59 days (SD 82) for the surgically treated patients and 108 days (SD 115) for the conservative treated patients (difference 49 days; 95% CI 4; 94. p<0.05). In the surgery group 24/36 patients (67%) returned to their former level of sports within one year versus 27/33 patients (82%) in the conservative treatment group (risk ratio 0.55; 95% CI 0.23; 1.29). Eleven patients (4 in the surgery group and 3 in the conservative group) had reasons other than their AT rupture for not returning to or changing type of sports (e.g. for example job or family reasons).

Recovery to work and sports	**Surgery**	**Conservative**	
Return to work:			
Average in days (SD)	59 (82)	108 (115)	Difference 49 days
Median (days)	39	63	95% CI 4; 94
Not returned to work (n)	1	0	p < 0.05
No job (n)	2	3	
Sports *Pre-rupture*:			
Active in sports (n)	36/42	33/41	
Sports *Post rupture*:			
Retuned to sports (n)	24/36	27/33	RR 0.82 (0.23; 1.29)
Changed sport (n)	4	4	p = 0.16
Stopped sports (n)	8	2	RD 0.15 (-0.35; 0.05)

Table 4. Return to work and sports.

Follow-up data were complete for post-treatment VAS scores for pain and patient satisfaction. In figure 2, the two variables are given per patient group at 3 follow-up moments. At 7 weeks surgically treated patients were more painful and were less satisfied than conservatively treated patients. At 3 month and at one year it was the other way around.

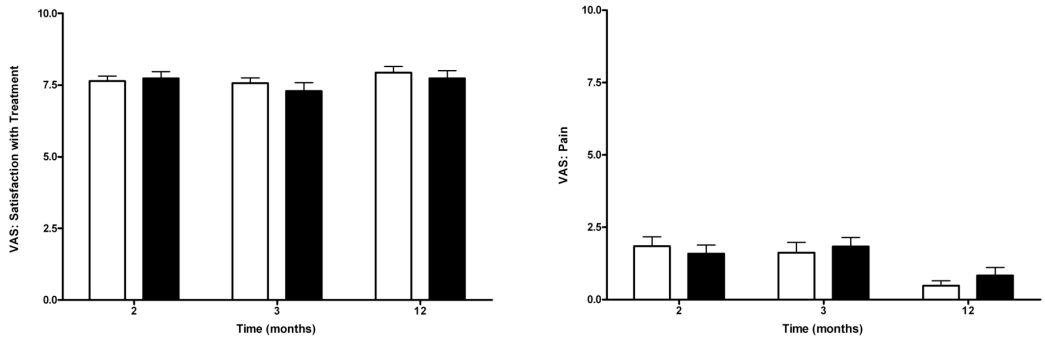

Figure 2. Visual Analogue Scores for patient satisfaction and pain at 2,3 and 6 month. □ surgical treatment group, ■ conservative treatment group.

Because 30% of all patients did not wish to participate in measurement of isokinetic strength and range of motion, the Leppilahti scores could be calculated for 59 (70%) of patients. There were fewer patients assigned to surgery and more smokers among patient with incomplete Leppilahti scores (table 5). There were neither clinical important nor statistical significant differences between the treatment groups regarding isokinetic strength or range of motion (data not shown). In the surgery group 26/32 of patients (81%) had good or excellent Leppilahti outcome scores; in the conservative treatment group 24/27 of patients (89%) had good or excellent Leppilahti outcome scores (table 6). This difference did not reach statistical significance.

Baseline characteristics	**Complete**	**Incomplete**
Number of patients	59	24
Age (years)	40	42
Gender: Male	47 (80%)	19 (79%)
BMI (body mass index)	25.9	26.3
Smoking	11 (19%)	7 (29%)
Diabetes Mellitus	0	2 (8%)
Surgical treatment	32 (54%)	10 (42%)
Side: Left Right	36 (61%) 23	13 (54%) 11

Table 5. Baseline characteristics of patients with complete or incomplete results on Leppilahti score

Leppilahti score	Surgery (n)	Conservative (n)
Number of patients	32 (76%)	27 (66%)
Excellent / Good	26	24
Fair	6	2
Poor	0	1
Complications in tested patients:		
Re-rupture	1	2
Sural nerve injury	3	0
Skin complication	3	10

Table 6. Leppilahti score.

Discussion

We observed a 15% lower risk of complications other than re-rupture after minimal invasive surgical treatment of acute Achilles tendon rupture with an absolute risk reduction favouring surgery of 41% compared to conservative treatment, but this difference did not reach statistical significance. For our sample size calculation we anticipated an absolute risk reduction of 30% favouring conservative treatment with a 34% risk of complications other than re-rupture after surgical treatment. [9] The lower risk after surgical treatment might be explained by the applied less invasive operative technique as the anticipated 34% risk of complications other than re-rupture was derived from data on conventional open repair techniques. [9]

Most complications other than re-rupture in the conservative treatment group were skin related, notably fungal infections, pressure sores or blisters. This bracing system is generally used in post-operative fracture treatment and not continuously worn. In this trial patients were not allowed to remove the brace in between follow-up appointments. This might contribute to the high incidence of skin related complications.

In contrast to previous studies, we experienced a higher (non-statistical significant) number of re-ruptures after conservative treatment by functional bracing. [17,23,24,27] But, comparison to the other studies is difficult because we used a different type of bracing system. In all patients, treatment was started within 72 hours as concerns have been expressed over initiating conservative treatment beyond this period. In some series on conservative Achilles tendon rupture treatment measuring tendon gap adaptation in plantar flexion by ultrasound is claimed to reduce re-rupture risk, only patients without tendon gap in plantar flexion are considered for conservative therapy. [6,10] But there is no proper randomized trial on surgical versus conservative treatment in patients with Achilles tendon rupture with no tendon gap at ultrasound investigation. For those without re-rupture functional bracing appears to produce good results according to Leppilahti outcome scores.

All but one of the trial participants returned to their former profession. Therefore we conclude that Achilles tendon rupture does not influence patients professional life substantially. The higher number of complications might explain the longer sick leave from work in the conservative treatment group. In contrast, almost a quarter of all participants (18/69 patients) did not return to their pre-injury level of sport. Some patients claimed their AT rupture was not the actual reason for chancing or quitting sport, therefore comparison between treatment groups is difficult. We can confirm conclusions from previous studies that Achilles tendon rupture is an injury greatly influencing post-rupture recreational sporting activity.

Conclusion: Our data show that minimally invasive surgical treatment of acute Achilles tendon ruptures has a lower risk of complications than conservative treatment by functional bracing, although this difference is not statistically significant. Surgery does result in earlier return to work.

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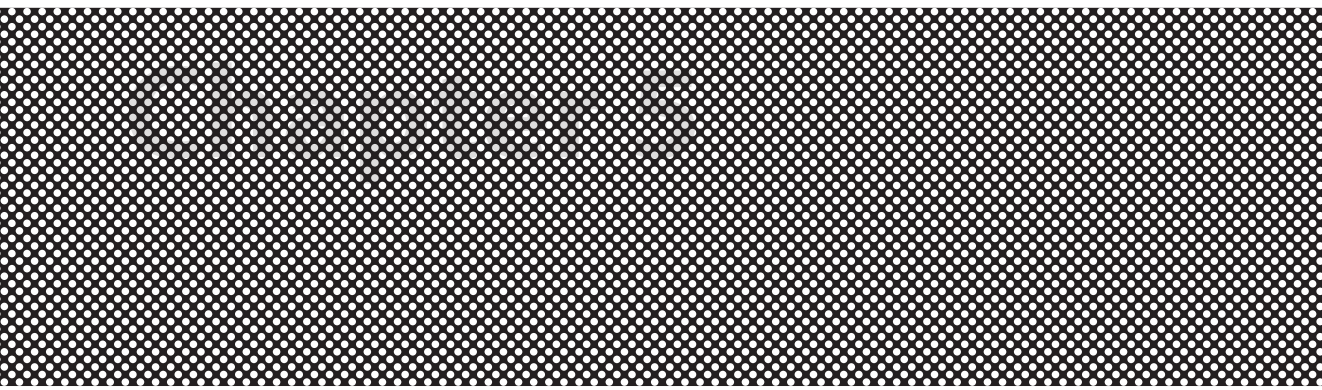
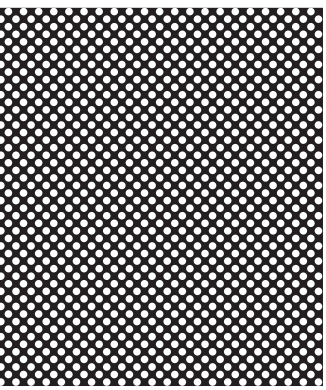


Recovery of calf muscle strength following acute Achilles tendon rupture treatment. A comparison between minimally invasive surgery and conservative treatment.



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Submitted

Abstract

Background: The aim of this study is to measure the effect of treatment of acute Achilles tendon ruptures on calf muscle strength recovery. Minimally invasive surgery is compared to conservative treatment by functional bracing.
Methods: From January 2004 to September 2005, 83 patients with acute Achilles tendon rupture were randomly allocated to either minimally invasive surgery with functional after-treatment or conservative treatment by functional bracing. Calf muscle strength using isokinetic testing was evaluated at 3 months and after 6 or more months post-treatment. To exclusively investigate the effect of treatment on outcome, patients with major complications were excluded from the analysis.
Results: In 31 out of 39 patients without relevant complications in the surgical treatment group and 25 out of 34 patients in the conservative treatment group isokinetic strength tests were performed. In the analysis of differences in mean peak torque of the injured leg, and on strength differences between injured and uninjured leg, no statistically significant differences were found between surgery and conservative treatment, except for plantar flexion strength at 90 degrees per second at the second measurement favouring conservative treatment. After 8 to 10 months follow-up, loss of plantar flexion strength at low angular velocities was still present in the injured leg in both treatment groups.
Conclusion: With isokinetic muscle strength tests we were not able to detect a statistically significant difference between minimally invasive surgical treatment with functional after-treatment and conservative treatment by functional bracing of acute Achilles tendon ruptures.

Introduction

In meta-analysis it is shown that surgical treatment of acute Achilles tendon (AT) ruptures reduces the risk of major complications (i.e. re-rupture) compared to conservative treatment by cast immobilization. [7] These conclusions are supported by our recently published randomized trial on acute AT rupture treatment comparing minimally invasive surgical repair to conservative treatment, this time using functional bracing. [11] But this increase in major (and minor) complications using functional bracing is in contrast to earlier reports. [9,16,17] Since it is likely the quest for effective conservative treatment method will continue we wished to evaluate the outcome of treatment without the negative impact of (major) complications. So we analysed the result of uncomplicated cases from the trial with the hypothesis that if major complications are avoided, functional bracing is equally effective in acute AT rupture treatment as minimally invasive surgical repair. Recovery of calf muscle strength is used as primary outcome measure.

Materials and Methods

The original trial was conducted in four teaching hospitals in the Netherlands. The Medical Research Ethics Committee of all the participating hospitals approved the trial protocol and its design and results have been described previously. [10,11] Eligible were patients with an acute Achilles tendon rupture who met the inclusion and exclusion criteria listed in table 1. Treatment allocation was done in a concealed manner via an Internet site and treatment nature was open to patients, physicians and physiotherapists. The primary interest in the current report is to exclusively measure the effect of treatment on outcome. Therefore, trial participants with a relevant complication (i.e. re-rupture, complex regional pain syndrome, deep vein thrombosis, deep wound infection, sural nerve injury) and those with protocol violation (e.g. refused allocated therapy) were excluded from the analysis. Isokinetic strength testing is the primary outcome measure. Notably, the principal endpoint of the complete trial was complications of treatment.

Inclusion criteria	**Exclusion criteria**
Primary Achilles tendon rupture (mid-zone tear)	Re-rupture / bilateral rupture / open rupture.
Treatment starts within 72 hours.	Combination with fracture of foot or ankle.
Diagnoses by physical examination: palpable gap and positive calf muscle squeeze test.	Former application (injection) of local corticosteroids in tendon area.
Age 18-65 years.	Contra-indications for surgery.
Written informed consent.	Physical or mental handicaps that do not allow functional treatment or otherwise interfere with the ability to follow-up on the study protocol.

Table 1. Inclusion and exclusion criteria.

Treatment and rehabilitation protocol

The minimally invasive surgical repair technique is described extensively in the original paper. [11] In summary, a Bunell type suture is placed through the proximal end of the Achilles tendon and guided to the calcaneus with a hollow mandarin. A hole is drilled through the calcaneus through which the suture is guided back proximally. The suture is tied with the foot in relaxed equines position. A cast is applied for the first post-operative week; thereafter a 6-week tape bandage protocol is used with a heel raise of decreasing height. [1]

Conservative therapy also started with a cast in plantar flexion for one week. Thereafter, a functional bracing system was applied for 6 weeks (Vacoped®, Company OPED, Valley, Germany). In the first 2 weeks of bracing, a 30º plantar flexion heel raise was used followed by 2 weeks in 15 degrees plantar flexion. In the last 2 weeks a dynamic status enabling movement from neutral position to 30 degrees plantar flexion is used. Importantly, although treatment protocols differ, both allowed for early weight bearing and mobilisation and are therefore considered functional treatment methods. [19]

Outcome measurements

Isokinetic strength testing was tested for plantar and dorsal flexion of the ankle at three angular velocities (as described by Leppilahti). [8] Each time 4 consecutive strength tests were performed and the highest recorded peak torque (in Newton-meters; Nm) was used for the analyses. Active range of motion for plantar and dorsal flexion of the ankle was tested as well. Three independent physiotherapists collected data from these measurements. Two different dynamometers were available at the participating centres: the Biodex Multi joint System 3® (Biodex Medical) and the Cybex Norm® (CSMI Solutions). All were serviced and calibrated before the first measurement. In three centres, patients were tested in seated position in a chair with a flexed knee. In one centre, using Cybex, patients were tested in prone position with extended knee. Patients were tested twice, first at 3 month post-rupture and the second test was performed after 6 or more months post-rupture (full recovery of calf muscle strength was anticipated after 6 month in uncomplicated cases). Absolute calf muscle strength and loss of strength compared to the uninjured side were calculated, with their 95% confidence intervals.

Statistical methods

Independent-samples t-test was used for the analysis of the differences between treatment groups (SPSS 15.0, SPSS Inc. Chicago, Illinois USA). Histograms were made to assure normality of distribution. If Levene's test reached significance equality of variances was not assumed. A p-value of 0.05 was considered statistically significant. All the significance tests were two-tailed.

Results

In the original trial report, 42 patients were allocated to surgery and 41 to conservative treatment. In the current analysis, 4 patients in the surgery group (3 re-ruptures and 1 CRPS) and 7 in the conservative treatment group (5 re-ruptures, 1 deep vein thrombosis and 1 sural nerve injury) were excluded from the analysis on the basis of having suffered a major complication. Hence, 39 patients in the surgical group and 34 patients in the conservative group qualified for the analysis. Of these, 25 out of 39 patients in the surgical group and 24 out of 34 in the conservative group were willing to be tested at 3 months. At the subsequent measurement (at 6 or more month after treatment) 31 out of 38 patients in the surgical group and in 25 out of 34 in the conservative group were willing to be tested (figure 1). The mean time from injury to the first strength test was 3 month as planned previously, the mean time from injury to the second strength test was 10 months (range 6 to 28 months) in the surgery group and 8 months (range 6 to 28 months) in the conservative group. Baseline characteristics for (non)-participants at the second measurement are given in table 2.

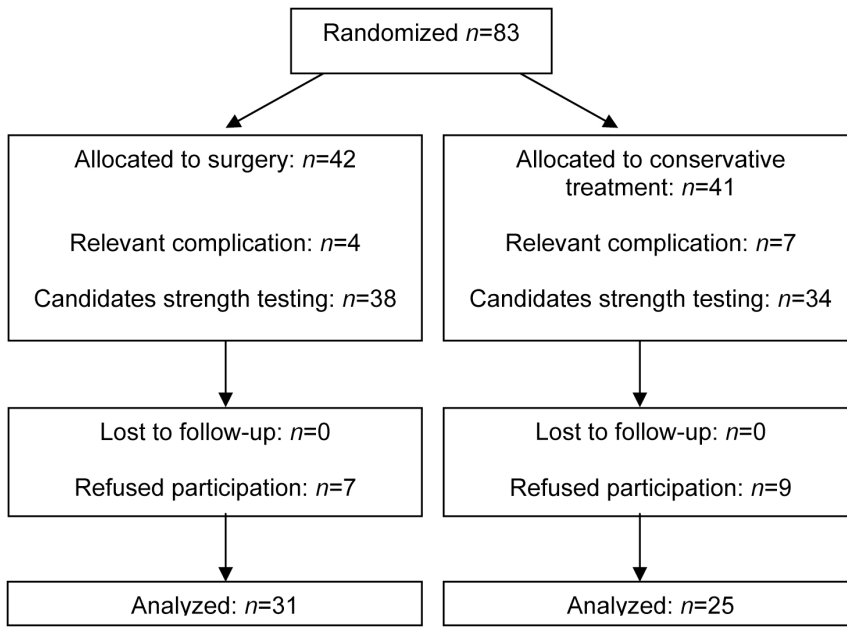

Figure 1. Diagram of patient participation for the second strength test (after > 6 month).

Baseline characteristics	**Surgery**	Surgery Missings	**Conservative**	Conservative Missings
Number	**31**	7	**25**	9
Age in years (range)	**39 (24-63)**	39 (26-49)	**41 (27-62)**	43 (25-61)
Male	**22**	6	**22**	7
Body Mass index (mean)	**25.7**	26.7	**25.9**	26.2
Current smoker	***4***	3	**6**	2
Diabetes Mellitus	**0**	0	**0**	2
Side: Left	**22**	4	**13**	6

Table 2. Baseline characteristics of patients with isokinetic strength tests at ≥ 6 months. Missings are those patients refusing to undergo strength testing.

With the numbers available, no statistically significant differences in absolute calf muscle strength between surgery and conservative treatment could be detected, except for plantar flexion strength at 90 degrees per second at the subsequent measurement in favour of conservative treatment (figure 2 and 3, full data in separate tables 3 and 4). In the analysis of strength differences between the injured and uninjured leg, again, no statistically significant differences between the two treatments could be detected (figure 4 and 5). In 13 cases (7 after surgery and 6 after conservative treatment) tests were performed with patients in prone position and not sitting in a chair. If these 13 cases were excluded from the analysis, no change in outcome was detected (no data shown).

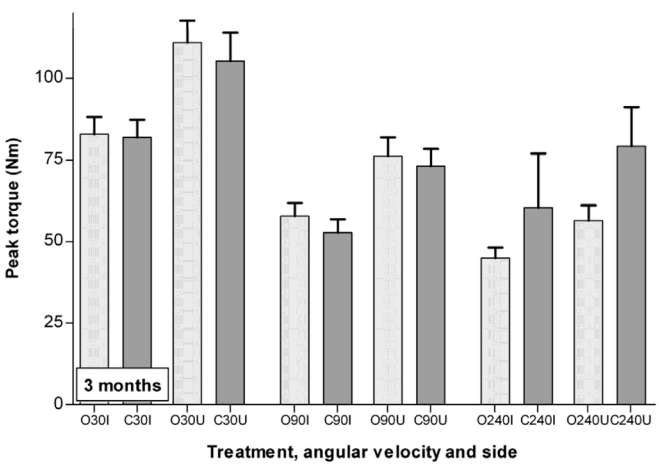

Figure 2: Absolute strength at 3 months. O = surgical, C = conservative, I = injured side, U = uninjured side, 30/90/240 = angular velocity

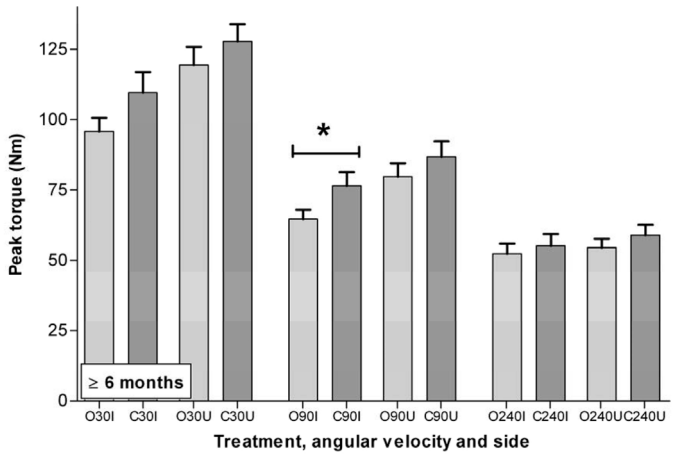

Figure 3: Absolute strength at subsequent measurement.
O = operative, C = conservative, I = injured side, U = uninjured side, 30/90/240 = angular velocity.
** statistically significant difference*

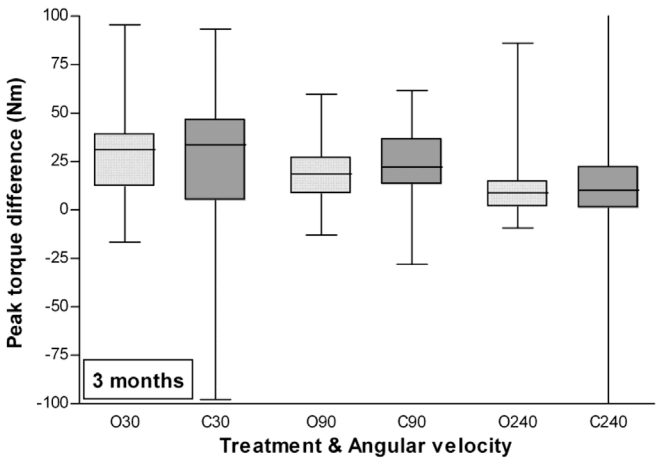

Figure 4: Strength difference (uninjured minus injured leg) at 3 months.
O = operative, C = conservative, 30/90/240 = angular velocity

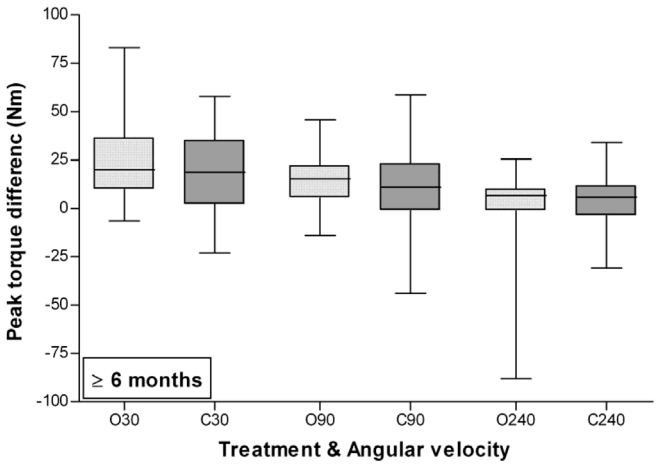

Figure 5: Strength difference (uninjured minus injured leg) at subsequent measurement. O = operative, C= conservative, 30/90/240 = angular velocity

Discussion

In the primary analysis of the trial from which data for this study were extracted, more complications were encountered with conservative treatment than with surgical treatment.[11] These complications (e.g. re-rupture) influence recovery substantially and conservative treatment is only justified if they can be avoided.[15] If so, the result of our current analysis show conservative treatment of acute AT ruptures by functional bracing is equally effective in recovery of calf muscle strength as minimally invasive surgical repair.

Previous randomized trials on surgical versus conservative AT rupture treatment subscribe these conclusions based on isokinetic strength testing.[13, 14, 21] Isokinetic strength testing is regarded as an accurate tool for evaluating acute AT rupture treatment outcome, and is a validated testing method.[2, 6, 12] Remarkably though, only one out of 14 randomized trials on AT rupture treatment that reported on isokinetic strength testing found a statistically significant difference between treatment groups.[3, 4, 5, 7, 18, 21] Moller et al. did find that even after a considerable rehabilitation time, there is substantial loss of calf muscle strength in the injured leg compared to the uninjured leg, regardless of treatment method chosen.[13] The latter appears to be the case in our analysis as well.

We realise lack of statistical power could be the reason for the inability to show a (statistical) difference in our analysis. Several patients who were invited for strength testing refused, reducing group sizes. But although these numbers are large, analysis of baseline characteristics proves that there is no indication that missing data have occurred in a selective pattern. Moreover, there are no differences at baseline between patients with and without isokinetic strength tests (table 2). Missing data are therefore likely to be completely at random. In general, completely random missing data reduce precision, which will result in wider confidence intervals but a change in the magnitude of effect or its direction is unlikely.

In 13 cases (7 after surgery and 6 after conservative treatment) tests were performed with patients in prone position and not sitting in a chair. We performed a separate analysis excluding those tested in prone position. Results of this analysis did not show a statistically significant difference between treatment groups either. After stratification of our data for test position, no effect was shown for prone or sitting position.

On the basis of the results of this study, conservative treatment by functional bracing is a potentially effective treatment method for acute Achilles tendon ruptures, provided major complications are avoided (in particular re-rupture). An attempt to reduce re-rupture was made by Thermann et al. using ultrasonographic criteria.[20] Only those patients with tendon adaptation in plantar flexion were regarded for conservative treatment. But its use has to be proven in a trial with more rigorous methodology. It is likely the search for effective conservative treatment methods will continue as surgical treatment is frustrated by wound healing disturbances. When successful, satisfactory functional results can be expected.

Angular velocity 3 months	**Surgical** Originally 39 patients	**Conservative** Originally 34 patients	**Difference (95%CI)** Surgical minus conservative	**p**
Plantar 30dg/sec	n = 25	n = 24		
Injured side	82.91 (26.41)	83.37 (27.16)	-0.46 (-15.69; 14.77)	ns
Non-injured side	110.97 (33.73)	108.08 (43.99)	2.89 (11.09; -19.40)	ns
Difference	-28.06 (22.01)	-24.71 (39.39)	-3.35 (-21.51; 14.81)	ns
Plantar 90dg/sec	n = 25	n = 24		
Injured side	57.83 (20.07)	53.0 (19.3)	4.83 (-6.36; 16.03)	ns
Non-injured side	76.21 (28.83)	73.89 (25.78)	2.32 (-13.23; 17.88)	ns
Difference	-18.38 (15.55)	-20.89 (20.58)	2.51 (-7.78; 12.80)	ns
Plantar 240dg/sec	n = 25	n = 24		
Injured side	44.99 (15.94)	59.29 (79.16)	-14.30 (-46.77; 18.17)	ns
Non-injured side	56,45 (23.28)	77.75 (57.73)	-21.30 (-46.67; 4.07)	ns
Difference	-11.46 (17.85)	-18.46 (67.11)	7.00 (-20.92; 34.92)	ns
Dorsal 30dg/sec	n = 25	n = 24		
Injured side	28.62 (18.03)	26.59 (14.3)	2.02 (-7.23; 11.28)	ns
Non-injured side	27.41 (14.37)	28.74 (17.65)	4.55 (-10.48; 7.82)	ns
Difference	1.21 (21.14)	-2.15 (8.31)	3.36 (-5.76; 12.46)	ns
Dorsal 90dg/sec	n = 25	n = 24		
Injured side	14.2 (7.61)	15.64 (9.43)	-1.43 (-6.30; 3.44)	ns
Non-injured side	13.92 (8.03)	16.3 (13.63)	-2.38 (-8.75; 3.98)	ns
Difference	0.28 (4.57)	-0.66 (6.95)	0.95 (-2.34; 4.25)	ns
Dorsal 240dg/sec	n = 25	n = 24		
Injured side	10.57 (9.59)	20.2 (39.13)	-9.63 (-25.83; 6.57)	ns
Non-injured side	11.03 (9.21)	63.86 (137.84)	-52.84 (27.63;-108.4)	ns
Difference	-0.46 (3.65)	-43.66 (140.2)	43.20 (-13.60; 100.0)	ns

Table 3. Results of isokinetic strength tests at 3 months. Peak torque in Newton-meters and standard deviation (SD) are given. Difference in left column is injured minus uninjured leg. ns: not significant.

Angular velocity ≥ 6 months	**Surgical** Originally 38 patients	**Conservative** Originally 34 patients	**Difference (95%CI)** Surgical minus conservative	**p**
Plantar 30dg/sec	n = 31	n = 25		
Injured side	95.81 (26.55)	109.49 (36.78)	-13.67 (-30.65; 3.30)	ns
Non-injured side	119.45 (35.6)	127.7 (31.02)	- 8.25 (-26.38; 9.88)	ns
Difference	-23.64 (20.25)	-18.21 (22.49)	-5.42 (-16.89; 6.04)	ns
Plantar 90dg/sec	n= 31	n= 25		
Injured side	64.59 (19.04)	76.44 (24.37)	-11.84 (-23.46; -0.22)	<0.05
Non-injured side	79.72 (26.29)	86.76 (27.21)	-7.03 (-21.42; 7.36)	ns
Difference	-15.13 (14.24)	-10.32 (21.08)	-4.81 (-14.30; 4.68)	ns
Plantar 240dg/sec	n = 30	n = 25		
Injured side	52.28 (19.69)	55.09 (21.09)	-2.81 (-13.86; 8.23)	ns
Non-injured side	54.4 (17.44)	58.85 (18.57)	-4.44 (-14.27; 5.38)	ns
Difference	-2.13 (18.81)	-3.76 (13.10)	1.63 (-7.31; 10.58)	ns
Dorsal 30dg/sec	n = 31	n = 25		
Injured side	27.75 (11.98)	27.69 (9.83)	0.06 (-5.78; 5.90)	ns
Non-injured side	25.14 (11.14)	36.88 (55.69)	-11.74 (-32.24; 8.76)	ns
Difference	2.62 (5.76)	-9.18 (52.74)	11.80 (-7.29; 30.89)	ns
Dorsal 90dg/sec	n = 31	n = 25		
Injured side	16.06 (8.8)	15.67 (7.47)	0.39 (-4.05; 4.83)	ns
Non-injured side	14.15 (7.22)	13.74 (9.63)	0.40 (-4.11; 4.92)	ns
Difference	1.91 (5.52)	1.92 (6.06)	-0.01 (-3.12; 3.09)	ns
Dorsal 240dg/sec	n = 30	n = 25		
Injured side	10.82 (10.79)	14.3 (19.79)	-3.48 (-11.92; 4.95)	ns
Non-injured side	9.66 (9.61)	8.7 (12.12)	2.93 (-4.91; 6.84)	ns
Difference	1.16 (4.82)	5.60 (14.58)	-4.45 (-10.68; 1.79)	ns

Table 4. Results of isokinetic strength testing at 6 months. Peak torque in Newton-meters and standard deviation (SD) are given. Difference in left column is injured minus uninjured leg. ns: not significant.

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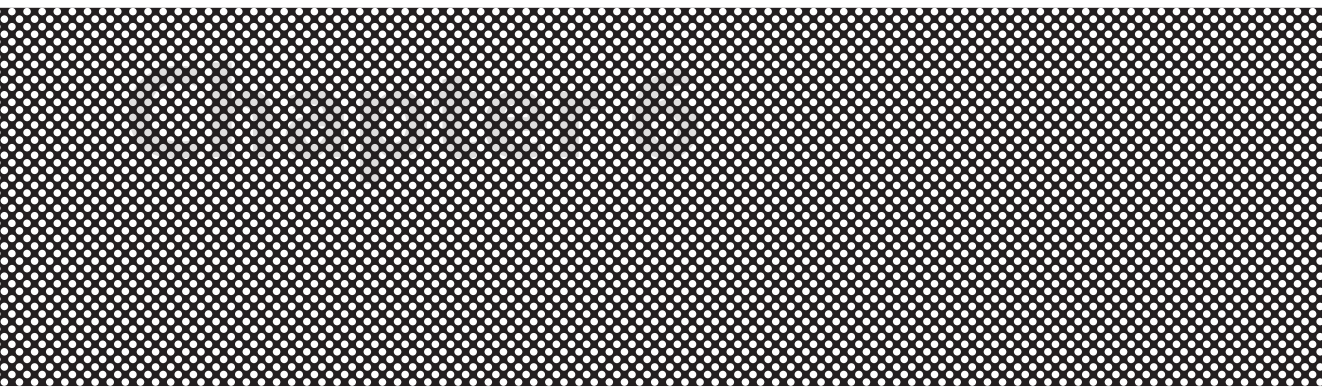
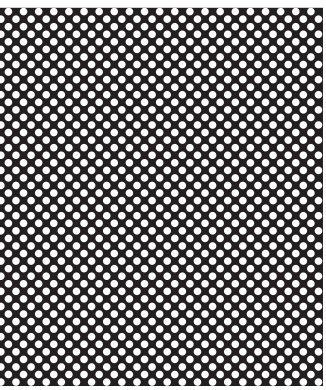


Impact of complications after minimally invasive surgical repair of acute Achilles tendon ruptures. Report on 211 cases.



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Abstract

Introduction: Complications of acute Achilles tendon rupture treatment are considered to negatively influence outcome. But, the relevance of these effects is largely unknown. In this study, the Achilles Tendon Total Rupture Score (ATRS) is used to determine level of disability in minimally invasive surgical Achilles tendon rupture repair with a complicated post-operative course.

Methods and materials: The charts of 340 consecutive patients treated for an acute Achilles tendon rupture by minimally invasive surgical repair were reviewed. Complications were categorised in re-rupture, severe wound infection, sural nerve injury and other. Level of disability was evaluated by the 10-item ATRS with a sum score of minimum 0 to maximum 100 points.

Study design: Follow-up study.

Results: 211 (62%) patients returned a completed questionnaire. Mean follow-up was 6.2 years (range 3 to 10 years). The average ATRS for the 135 (64%) uncomplicated cases was 89 out of 100 points, 71 points for the 17 (8%) patients with a re-rupture (95% confidence interval 63; 79, $p<0.0001$), 79 points for the 41 patients (19%) with a sural nerve injury (95% confidence interval 74; 85, $p=0.0008$) and 75 points for the 17 patients (8%) with an other complication (95% confidence interval 67; 83, $p=0.001$). Out of these other complications, 13 patients (6%) suffered a wound healing complication considered minor. Their average ATRS score was 80 points (95% confidence interval 71; 88.7, $p = 0.0445$). One patient suffered a severe wound infection as well, scoring 28 out of 100 points. Re-rupture significantly increased the risk of quitting or changing sport participation on the long term.

Conclusion: Re-rupture and severe wound infection have a significantly larger negative impact on long term outcome than minor wound healing complications or sural nerve injury. It justifies the use of re-rupture as relevant outcome measure in treatment evaluation.

Introduction

There is an ongoing debate on best management for acute Achilles tendon (AT) ruptures. Historically, open surgical repair has been preferred because of low re-rupture risk. But overall complication risk is up to 36%. [3] Minimally invasive repair techniques followed by functional after treatment reduce this complication risk and are therefore increasingly popular. [1,2,3,5,7,8,12] Complications of treatment, in particular re-rupture, are used in literature to compare different treatment methods. They are considered to negatively influence outcome. However, the magnitude of these negative effects is largely unknown.

Outcome measures for patients with acute Achilles tendon ruptures are based on a mixture of objective and subjective parameters. [4,6] Recently, a validated easy to use outcome questionnaire was introduced: The Achilles Tendon Total Rupture Score (ATRS). This score consists of 10 questions with a sum score of minimum 0 to maximum 100 points. [9] It is designed to evaluate treatment outcome, compare patient groups, and measure severity of disability. In this study, the ATRS is used to evaluate long-term outcome after minimally invasive surgical repair of acute AT ruptures and to quantify the impact of post-operative complications.

Methods and materials

The medical records of all patients operated between January 1997 and January 2004 for an acute AT rupture in three teaching hospitals in the Netherlands were reviewed. In the participating hospitals, minimally invasive surgical repair was the first treatment choice for all acute AT ruptures. The charts were screened for baseline patient characteristics (i.e. gender, age, cause of rupture, time between rupture and surgery), complications of treatment and duration of follow-up. Complications were grouped in 4 categories, i.e. re-rupture, severe wound infection (a wound infection was considered severe if surgical debridement and/or reconstruction of a tendon defect were necessary), sural nerve injury and "other". Surgeon registrars or surgical residents familiar with the operative technique performed surgery. Patients were operated in prone position under regional or general anaesthesia and no tourniquet or antibiotic prophylaxis was used. The minimally invasive surgical repair technique started with 4 stab wounds or a small longitudinal incision over the postero-medial aspect of the affected leg proximal to the rupture area. A Bunell type suture was placed through the proximal end of the AT (atraumatic PDS® 1.0). With a hollow mandarin the suture was tunnelled to the lateral aspect of the calcaneus and guided out through a 5mm stab incision. A hole was drilled through the calcaneus 1 cm distal to the tendon insertion (exit through 5 mm stab incision). The PDS® was guided though the hole and with the mandarin back proximally. Finally, the suture was tied with the foot in relaxed equine position. [2,7] After wound closure a cast was applied for approximately 2 weeks with the foot in plantar flexion. In the following 4 weeks tape bandage was used, in the first 2 weeks supported by a heel raise. Post-operative tre-

atment was functional in all cases, i.e. patients were allowed full weight bearing after cast removal.

Follow-up

All 340 patients selected for chart review received a written questionnaire, for which consent has been waived. Patients with a known complication from chart review were contacted by telephone if the questionnaire was not returned. Outcome was primarily evaluated using the Achilles Tendon Total Rupture Score. [9] Additionally, questions on post-operative complications and recovery to work and sports were included.

Statistics

Baseline characteristics of questionnaire responders and non-responders were compared. For the analysis of influence of complications on ATRS, linear regression model was used in SPSS 15.0. Table 5 was created using Office Excel (Microsoft Corporation, USA).

Results

Medical record review

During the study period, 340 consecutive patients with an acute AT rupture were treated by minimally invasive surgical repair. Most patients were male and in their third or forth decade of life when tearing their AT. A vast majority of AT ruptures occurred during sport, in particular (racket) ball sports (table 1). Mean follow-up from chart review was 5.3 months (range 0 to 81 months). According to medical records, 56 patients (16.5%) had suffered a complication; re-rupture occurred in 20 (5.9%) patients, 2 patients (0.6%) suffered a serious wound infection while 9 patients (2.6%) were recorded to have a sural nerve injury (table 2). "Other" complications found during chart review include superficial wound infection (10), scar adhesions (2), pain at suture knot site (5), skin laceration due to tape bandage (1), tendon lengthening (2), Complex Regional Pain Syndrome (CRPS) (3) and pulmonary complications (2).

Baseline characteristics	Responders	Non-responders	p	Total
Number	211	129		340
Male	167 (79%)	107 (83%)	ns	274 (81%)
Age (years)	40 (20 to 74)	36 (20 to 68)	ns	38 (20 to 74)
AT rupture caused by sport	187 (89%)	100 (78%)	0.006	287 (84%)
Left side	116 (55%)	64 (50%)	ns	180 (53%)
Median time from rupture to surgery (days)	1 (0 to 32)	0 (0 to 10)	ns	1 (0 to 32)

Table 1. Baseline characteristics of patients after surgery for an acute AT rupture (operated between January 1997 and January 2004).

Complications	Responders (n=211)		Non-responders (n=129)	Total (n=340)
	chart only	after questionnaire	chart only	chart only
None	170	135	114	284
Re-rupture	16	17	4	20 (5.9%)
Infection*	1	1	1	2 (0.6%)
Nerve injury	7	41	2	9 (2.6%)
Other	17	17	8	25 (7.4%)
Total complications	41	76	15	56 (16.5%)

Table 2. Complications of patients after surgery for an acute AT rupture. (* infection = severe wound infection).

Questionnaire responders

211 (62%) patients returned a completed questionnaire after a mean follow-up of 6.2 years (range 3.8 to 10 years). Baseline characteristics are given in table 1. In total, 76 (36%) out of the 211 patients suffered one or more complications (table 2). One additional re-rupture and 34 additional sural nerve injuries were identified. All 41 patients with a sural nerve injury indicated (temporarily) altered sensibility of the skin at the lateral foot border. The 34 new nerve injuries identified in the questionnaire were the not clinically verified. In table 3 complications classified as other are listed.

Complication	Number (total 17)
Superficial wound infection	6
Scar adhesion	2
Temporarily pain at suture knot site	4
Skin laceration due to bandage	1
Tendon lengthening	2
Complex Regional Pain Syndrome	1
Pneumonia	1

Table 3. Specification of complication category "other" for patients after surgery for an acute AT rupture. CRPS: Complex Regional Pain Syndrome.

Achilles Tendon Total Rupture Score

The mean ATRS and the mean ATRS per item for the 211 responders is displayed in table 4 and 5. The items loading most on the ATRS were 1, 8 and 9, and loading least on ATRS were 2, 4 and 5 (table 5). The average ATRS for the 135 (64%) uncomplicated cases was 89 out of 100 points and for the 76 complicated cases this was 13 points lower (on average 76 points, 95% confidence

interval (CI) 71; 80, p < 0.0001). The average ATRS for the 17 (8%) patients with a re-rupture was 71 points (95% CI 63; 79, p<0.0001), 79 points for the 41 patients (19%) with a sural nerve injury (95% CI 74; 85, p=0.0008) and 75 points for the 17 patients (8%) with an "other" complication (95% CI 67; 83, p=0.001) (table 4, figure 1). If CRPS, tendon lengthening and pneumonia are eliminated from the other complications category, 13 patients (6%) with complications generally considered minor wound complications remain (table 4). Their average ATRS score was 80 points (95% CI 71; 88.7, p = 0.0445). One patient suffered a severe wound infection as well, scoring 28 out of 100 points.

	n	ATRS	95% CI	p-value
Uncomplicated	135	89.16	86.54 to 91.86	
Re-rupture	17	71.42	63.32 to 79.22	p < 0.0001
Severe wound infection	1	28		
Nerve injury	41	79.37	73.76 to 84.92	p = 0.0008
Other	17	75.42	67.32 to 83.52	p = 0.0010

Table 4. Mean ATRS score by complication type for patients after surgery for an acute AT rupture. A 100 point score is maximum, zero points minimum.

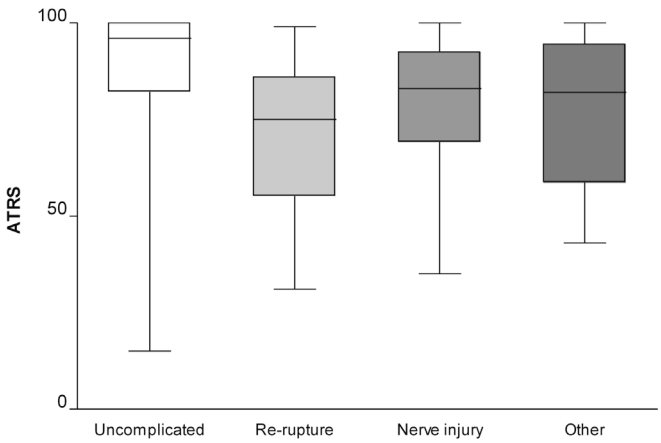

Figure 1. Mean ATRS score by compliction type in patients after surgery for an acute AT rupture. A score of 100 points is maximum

Return to work and sports

Table 6 displays results on recovery to work and sports. Only one patient, who suffered from a sural nerve injury, had to limit his workload permanently after the AT rupture. All others were able to return to their previous profession although some patients reached age of retirement or changed jobs for other reasons then their AT rupture.

ATRS		Uncomplicated	Re-rupture	Severe wound infection	Sural nerve injury	Other
1. Are you limited because of decreased strength in the calf/Achilles tendon/foot?	Mean (SD)	8.82 (1.74)	6.47 (2.90)	4	7.90 (2.03)	7.41 (2.58)
	Median (P25; P75)	10 (8; 10)	7 (5; 8)		9 (5; 8)	8 (5; 10)
2. Are you limited because of fatigue in the calf/Achilles tendon/foot?	Mean (SD)	9.01 (1.62)	8.06 (1.98)	2	8.06 (1.98)	7.47 (2.85)
	Median (P25; P75)	10 (8; 10)	9 (7; 10)		9 (6; 10)	8 (5; 10)
3. Are you limited because of stiffness in the calf/Achilles tendon/foot?	Mean (SD)	8.59 (1.86)	7.12 (2.12)	7	7.37 (2.20)	7.76 (2.36)
	Median (P25; P75)	9 (8; 10)	7 (6; 9)		8 (6; 9)	8 (6; 10)
4. Are you limited because of pain in the calf/Achilles tendon/foot?	Mean (SD)	9.30 (1.38)	8.29 (2.49)	3	8.32 (2.11)	8.71 (1.79)
	Median (P25; P75)	10 (9; 10)	9 (8; 10)		9 (8; 10)	9 (8; 10)
5. Are you limited during activities of daily living?	Mean (SD)	9.48 (1.18)	8.47 (1.87)	4	8.78 (1.72)	8.35 (2.00)
	Median (P25; P75)	10 (10; 10)	9 (8; 10)		9 (8; 10)	9 (8; 10)
6. Are you limited when walking on uneven surface?	Mean (SD)	9.13 (1.52)	7.88 (2.19)	4	8.32 (1.72)	7.65 (2.40)
	Median (P25; P75)	10 (9; 10)	8 (7; 10)		9 (8; 10)	8 (5; 10)
7. Are you limited when walking quickly upstairs or uphill?	Mean (SD)	8.82 (1.95)	7.71 (2.11)	4	7.85 (2.25)	7.18 (2.77)
	Median (P25; P75)	10 (8; 10)	8 (7; 10)		8 (7; 10)	7 (5; 10)
8. Are you limited during activities that include running?	Mean (SD)	8.72 (2.06)	6.06 (3.13)	0	7.83 (2.16)	7.06 (3.15)
	Median (P25; P75)	10 (8; 10)	6 (4; 8)		8 (7; 9)	9 (4; 10)
9. Are you limited during activities that include jumping?	Mean (SD)	8.28 (2.29)	4.76 (3.27)	0	7.12 (2.22)	6.18 (3.32)
	Median (P25; P75)	9 (7; 10)	5 (3; 7)		8 (6; 9)	7 (3; 10)
10. Are you limited in performing hard physical labour?	Mean (SD)	9.01 (1.62)	7.06 (2.73)	0	8.00 (1.94)	7.65 (2.23)
	Median (P25; P75)	10 (9; 10)	7 (6; 9)		8 (7; 9)	8 (6; 10)
Total score	Mean (SD)	89.16 (14.48)	71.41 (20.46)	28	79.37 (17.04)	75.41 (20.53)
	Median (P25; P75)	96 (82; 100)	75 (59; 86)		83 (70; 92)	82 (60; 91)

Table 5. ATRS per item and per complication category.

The impact of complications on post-treatment sport participation is illustrated in figure 2. The relative risk (RR) for quitting or changing sport activities after any complication is 1.27 (95% CI 0.94; 1.72, p = 0.127). If analysed by category, re-rupture significantly increased the chance of quitting or changing sport participation compared to uncomplicated cases (RR 2.05, 95% CI 1.55; 2.71, p=0.0008). Sural nerve injury and other complications did not.

	Uncomplicated n = 135	***Re-rupture*** n = 17	***Nerve injury*** n = 41	***Other*** n = 17
Work Post-rupture				
Retired*	5	1	1	1
Other job**	4	1	2	1
Same job	126	15	38	15
Sport pre-rupture	117	16	37	17
Sport post-rupture				
Stop	26	4	4	3
Other sport	24	10	12	5
Same sport	67	2	21	9

Table 6. Return to work and sports by complication type in patients after surgery for an acute AT rupture.
**** Patients reached retirement age during follow-up***
***** One patients in the nerve injury group works less hours than before due to complaints after AT rupture.***

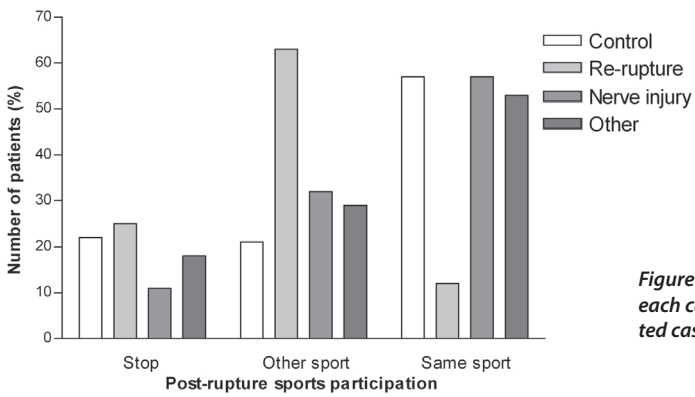

Figure 2. Post-rupture sport participation for each category (%). Controls are the uncomplicated cases.

Discussion

The primary interest in this study was to investigate long-term outcome of minimally invasive surgical repair of acute Achilles tendon ruptures, and quantify the impact of complications. In general, patients were satisfied with their recovery as the average ATRS was 84 out of 100 points. Complications unmistakably influenced long-term outcome. As anticipated, re-rupture and severe wound infection have a larger negative impact on long-term outcome than sural nerve injury or "other" complications, such as minor wound complications. This conclusion is supported by a twofold increase in the risk of quitting or chancing post-treatment sport participation after a re-rupture. Most severely affected by a complicated post-operative course was calf muscle strength with limitations in running and jumping as a result (item 1,8, and 9 of the ATRS). The ability to perform daily activities was barely altered in complicated cases (item 5 of the ATRS). Previously, two studies reported a similar clinically important negative effect of re-rupture and severe wound infection on outcome. These studies used different outcome measures combining perceived disability with functional impairment tests. [10,11]

Although the baseline characteristics of responders and non-responders are alike, response bias cannot be ruled out. By actively tracking down patients of whom we knew they suffered a complication, based on chart review, selection bias was introduced. These biases could explain the high incidence of complications in the 211 analysed cases. Sural nerve injuries were anticipated based on complaints of altered sensibility of the lateral foot border. Strikingly, in 34 out of the 41 patients complaining of altered sensibility of the lateral foot border, no record of sural nerve injury was found in their medical chart. These 34 supposed sural nerve injuries were not clinically verified.

To our knowledge, this is the first study to analyse long-term outcome after AT rupture treatment using a validated standardised patient perceived disability score. This study is unique for measuring the effect of even minor complications on outcome. Our data justify the use of re-rupture as important outcome measure in studies on AT rupture treatment. Results confirm that re-rupture and severe wound infection have a more serious negative impact on outcome than other complications.

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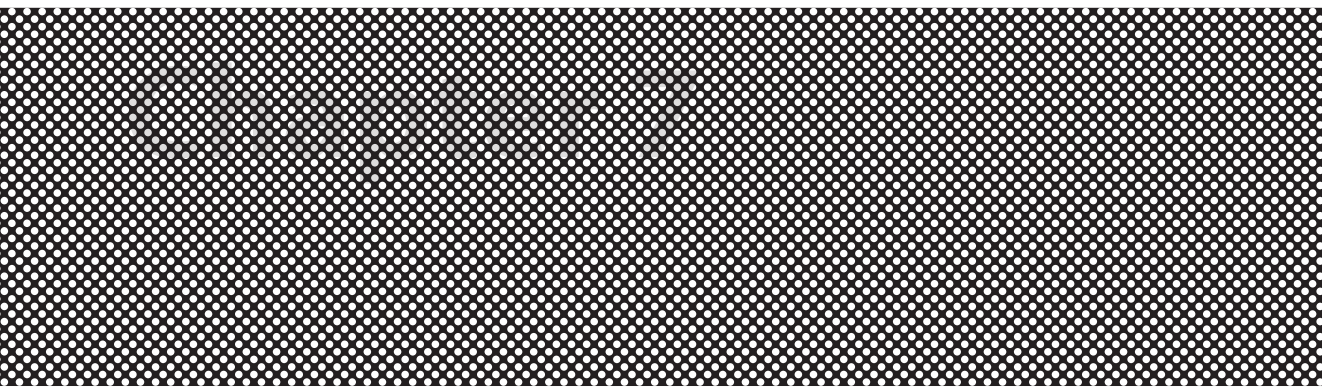
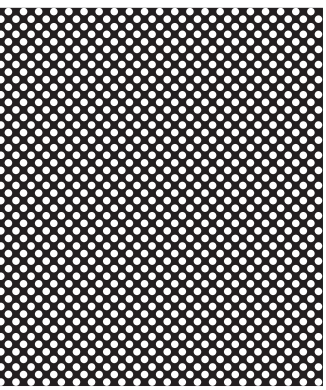


Persistent disability despite sufficient calf muscle strength after re-rupture of surgically treated acute Achilles tendon ruptures.



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Abstract

Introduction: Re-rupture after surgical or conservative treatment of acute Achilles tendon rupture is considered to be a serious complication. This study was performed to evaluate the long-term impact of re-rupture on outcome after primary minimally invasive surgical Achilles tendon rupture repair.

Methods and materials: The functional outcome in thirteen patients with a re-rupture following minimally invasive surgical Achilles tendon rupture repair was evaluated by Leppilahti score and resumption of work and sport. One of these patients suffered a severe wound infection as well. Mean follow-up was almost nine years. Results were compared to those of a reference group of 23 uncomplicated cases with a follow-up of at least 1 year.

Study design: Follow-up study.

Results: The relative risk for a fair/poor outcome by Leppilahti score after a re-rupture in comparison to uncomplicated cases is 2.83 (95% confidence interval 1.17; 6.87, p = 0.0185). Although re-rupture did not affect ultimate resumption of professional life, the relative risk for quitting sport or resuming sport at a lower level after a re-rupture is 3.33 (95% confidence interval 1.71; 6.51, p = 0.0001). In contrast, the plantar flexion strength deficit is 5-10% in the re-rupture group and up to 20% in the reference group. This calf muscle strength difference is explained by the relatively short follow-up period in the reference group.

Conclusion: Despite sufficient recovery of calf muscle strength, re-rupture after acute Achilles tendon rupture treatment results in significant long-term functional disability.

Introduction

Historically, open surgical repair of acute Achilles tendon (AT) ruptures is preferred over conservative treatment because of a lower re-rupture risk. [2] Re-ruptures indicate failure of treatment and are considered severe adverse events. Therefore, re-rupture risk is frequently used as primary outcome measure in clinical research. [2] Surgical treatment however bears the risk of wound infection as a serious complication. Severe wound infections, although rather rare, may have a detrimental effect on outcome. [8] In treating AT ruptures surgically, a lower re-rupture rate is preferred over a low risk of infection. This is only justified when re-rupture is indeed a serious adverse event with lasting negative impact on outcome. So far, the impact of re-ruptures on long-term outcome after AT rupture is poorly documented. [8,9] Therefore, this study was performed to evaluate the long-term impact of re-rupture on outcome after primary minimally invasive surgical AT rupture repair.

Methods and materials

Patient selection

Patients with a re-rupture were selected from the medical records of 340 patients who had an acute AT rupture repair by minimally invasive surgery in one of three teaching hospitals in the Netherlands between 1996 and 2003. The applied minimally invasive surgical repair technique started with a small longitudinal skin incision or four stab incisions proximal to the rupture area. A Bunell type suture was placed through the proximal end of the AT (atraumatic PDS® 1.0) and with a hollow mandarin the suture was tunnelled to the lateral aspect of the calcaneus and guided out through a stab incision. A hole was drilled through the calcaneus 1 cm distal to the tendon insertion. The PDS® was guided though the hole and with the mandarin back proximally. The suture was tied with the foot in relaxed equine position. [1,4] Post-operative treatment of all cases consisted of a cast applied for approximately 2 weeks with the foot in relaxed plantar flexion, followed by full wait bearing with 4 weeks of tape bandage supported by a heel raise the first 2 weeks.

Data collection

All selected patients were invited for follow-up. The primary outcome measure was the Leppilahti score. [3] This is a 6 item functional impairment score combining questions on recovery with isokinetic calf muscle strength testing. The overall score ranges from 0 to 100 points. An overall score of 90-100 rates excellent, 75-85 is good, 60-70 is fair and 55 or below is poor. Isokinetic calf muscle strength tests were performed for active plantar and dorsal flexion of the ankle at three angular velocities (30, 90 and 240 degrees per second) for the injured and uninjured leg. Patients were tested in seated position in a chair with a flexed knee using a Biodex Multi joint System 3® (Biodex Medical). This system was serviced and calibrated before measurement. The highest recorded

peak torque (in Newton-meters; Nm) of 4 consecutive strength tests was used for the analyses. Return to work and sport were also used as outcome parameters.

Reference values for the Leppilahti score, isokinetic calf muscle strength and return to work and sports were calculated in a reference group of patients selected from a recently published randomized trial. [6] These were patients, treated in the same three teaching hospitals in the Netherlands, with uncomplicated recovery in the year following minimally invasive surgical repair for their acute AT rupture. In this reference group, isokinetic strength testing and Leppitahti score were documented between 6 and 12 months after surgery, and return to work and sports at one year. One independent physiotherapist collected the isokinetic calf muscle strength data (in Newton-meter) in all patients and in the reference group.

Data analysis

The population distribution measures were calculated: mean, standard deviation for the Leppilahti score and isokinetic strength; proportions for return to work and sports. Between group differences and ratio, with their 95% confidence intervals (CI), were calculated using Rothman's Episheet. [10] Mann-Whitney U test was used for the analysis of the differences between treatment groups (SPSS Version 15.0). A p-value of 0.05 was considered statistically significant. All the significance tests were two-tailed.

Results

The medical records of 340 consecutive patients treated by minimally invasive surgical repair of an acute AT rupture were reviewed. Among the 340 patients, 22 (6%) were identified with a re-rupture of whom 13 were willing to participate in the follow-up measurements. The mean time from primary repair to re-rupture was 10 weeks (range 2 to 31 weeks). All re-ruptures were diagnosed clinically and confirmed by ultrasound. They occurred as a result of a fall or tripping in 10 patients, during walking in 2 patients, and in 1 patient a re-rupture was diagnosed during follow-up without an explanatory event. Ten patients with a re-rupture were treated by open surgical repair and three patients were treated conservatively. Non-weight bearing rigid 6-week below-knee cast treatment was chosen in these three patients in the absence of a gap between tendon ends in relaxed plantar flexion at ultrasound control. One patient suffered from a severe wound infection after open repair for re-rupture, for which surgical repeated wound debridement was mandatory. This resulted in AT tissue necrosis and skin loss. Reconstructive surgery was necessary to repair the tendon and cover the skin defect. The median time to follow-up for the 13 patients with re-rupture was 8.7 years (range 5 to 11.3 years).

For the reference group of 23 uncomplicated cases, isokinetic calf muscle strength testing and Leppitahti score were documented at a mean time of 11 months after surgery (range 6 to 28

months). All patients visited the one-year clinical follow-up moment as planned in the trial design. [5] Descriptive characteristics of both groups are given in table 1.

	Re-rupture (N = 13)	Control (N = 23)
Age (median)	45 (range 31 to 56)	40 (range 23 to 57)
Male	11	16
Left side	6	15

Table1. Baseline characteristics

Outcome by Leppilahti score

In the re-rupture group, 8 out of 13 patients had a fair or poor outcome by Leppilahti score compared to 5 out of 23 patients in the reference group with uncomplicated cases (table 2). Therefore, the relative risk for a fair/poor outcome after re-ruptures compared to uncomplicated cases is 2.83 (95% CI 1.17; 6.87, p = 0.0185). This difference remains statistically significant after exclusion of the patient with the severe wound infection from the analysis.

	Re-rupture (N = 13)	Control (N = 23)
Excellent	2	8
Good	3	10
Fair	4	5
Poor	4	0

Table 2. Leppilahti score

Return to work and sport

All patients employed prior to the injury resumed professional life except for one (table 3). This one patient resigned from work because he suffered from persisting pain after a severe wound infection. Notably, none of the 13 patients in the re-rupture group returned to their previous level of sports, 4 of them decided to quit definitively. In contrast, four out of the 20 patients without complications participating in sport prior to their injury resigned form sport; others resumed sport within a year, in whom 2 at a lower level. The reasons for adjusted sport participation were variable and often a combination of fear for re-rupture, loss of calf muscle strength and endurance after the AT rupture and busy private life, professional life or both. The relative risk for quitting sport after a re-rupture is 1.54 (95% CI 0.46; 5.09, p = 0.49); the RR for quitting sport or resuming sport at a lower level after a re-rupture is 3.33 (95% CI 1.71 to 6.51, p = 0.0001).

		Re-rupture (N = 13)	Control (N = 23)
Work:	Resumed	12	23*
	Stop	1	0
Sport:	Resumed	0	14
	Stop	4	4
	Different level	9	2
	n.a.	0	3

*Table 3. Work and Sports. * One patient was retired but resumed normal activities at home.*

Outcome by isokinetic plantar flexion calf muscle strength testing

The absolute plantar flexion strength of the calf muscles of the injured leg is higher in the re-rupture group compared to uncomplicated cases, in particular at low angular velocities (i.e. 300 and 900 per second) (figure 1). Although their follow-up is many years shorter the absolute plantar flexion strength of the uninjured leg is similar for both groups (figure 2). The difference in plantar flexion strength between the injured and uninjured leg however ranges up to 20% in the reference group, while this range is 5% to 10% in the re-rupture group (figure 3). Table 3 displays full data on isokinetic plantar flexion strength testing.

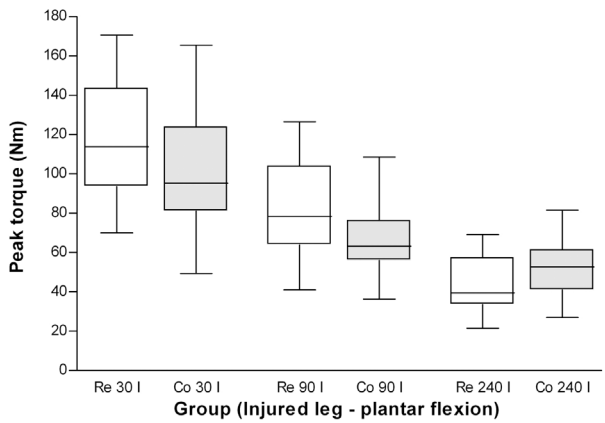

Figure 1. Absolute isokinetic plantar flexion strength (Nm) for re-rupture group (Re) and controls (Co) at 3 angular velocities, injured leg.

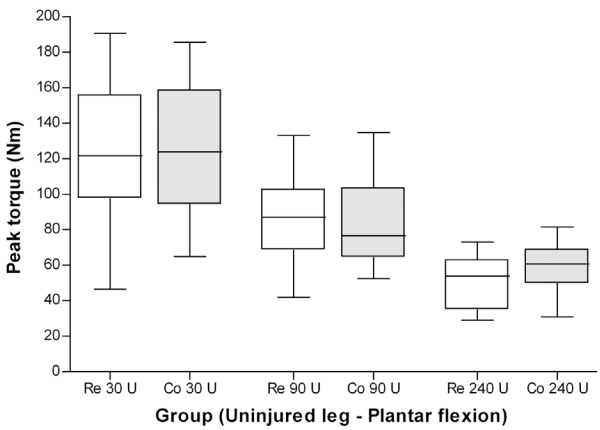

Figure 2. Absolute isokinetic plantar flexion strength (Nm) for re-rupture group (Re) and controls (Co) at 3 angular velocities, uninjured leg.

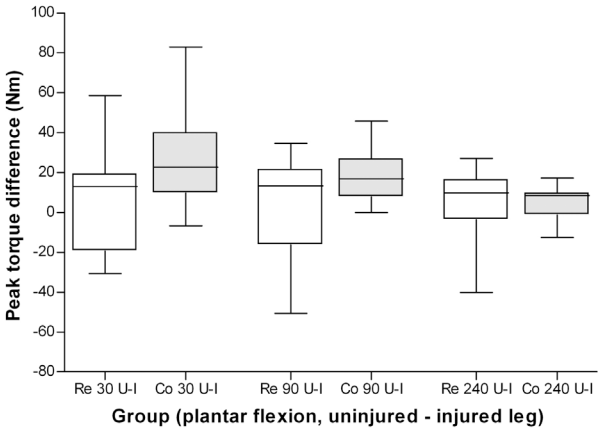

Figure 3. Difference in isokinetic plantar flexion strength (Nm) between injured and uninjured leg for re-rupture group (Re) and controls (Co) at 3 angular velocities.

Angular velocity in Nm	**Re-ruptures** n = 13	**Control group** n = 23	**Difference (95%CI)**	**p**
Plantar 30°/sec				
Injured side	118.97 (31.06)	99.02 (28.20)	-19.95 (-40.57; 0.67)	0.068
Non-injured side	125.06 (37.96)	125.49 (36.99)	0.43 (-25.90; 26.75)	0.961
Difference*	6.09 (26.03)	26.47 (21.87)	20.38 (3.86; 36.90)	0.024
Plantar 90°/sec				
Injured side	83.77 (25.34)	67.40 (19.11)	-16.37 (-31.54; -1.20)	0.040
Non-injured side	86.70 (25.40)	85.30 (26.10)	-1.40 (-19.63; 16.84)	0.633
Difference*	2.93 (25.04)	17.91 (13.13)	14.98 (-0.86; 30.82)	0.143
Plantar 240°/sec				
Injured side	45.24 (14.78)	53.50 (14.21)	8.27 (-1.90; 18.43)	0.078
Non-injured side	50.82 (14.94)	58.78 (14.14)	7.96 (-2.22; 18.13)	0.143
Difference*	5.58 (17.16)	5.28 (7.25)	-0.31 (-10.98; 10.37)	0.383

*Table 4. Results for isokinetic plantar flexion strength tests (mean and standard deviation). Nm = Newton-meter. * Difference between uninjured and injured leg.*

Discussion

We describe the long-term outcome in a cohort of 13 patients with a re-rupture after minimally invasive surgical AT rupture repair. Their results were compared to a reference group of cases with an uncomplicated post-operative course. Follow-up in the re-rupture group was 8.7 years (5 to 11 years). Follow-up in the reference group follow-up was 11 months (6 to 28 months) for Leppilahti score and isokinetic strength testing; follow-up for clinical outcome and return to sport was one year. This ensures patients in the reference group did not suffer a re-rupture within the first year post-treatment.

Re-rupture clearly has a negative impact on the Leppilahti score and return to sport, despite an on average small (ranging up to 10%) loss of isokinetic plantar flexion calf muscle strength in comparison to the uninjured leg. More than half of our patients with a re-rupture had a fair or poor outcome by Leppilahti score, which was a statistically significant worse result than the outcome in uncomplicated cases. None of the patients resumed sport at their previous level after re-rupture. In uncomplicated cases only four of 20 patients did not resume sport. Of those who resumed sport 88% was able to do this at their previous level. Our data on Leppilahti score and calf muscle strength recovery confirm findings by Pajala et al and Scott et al.[8,9] Pajala et al reported an average isokinetic plantar flexion calf muscle strength deficit (injured compared to uninjured side) of 10% at long-term follow-up.[8]

The mean follow-up was one year in the control group, and more than eight years in the re-rupture group. Despite this difference, the Leppitahti score and post-injury sport participation was clearly better in the reference group. In contrast, the measured loss of isokinetic plantar flexion calf muscle strength in the reference group ranged up to 20%, which on average is twice as big than in the re-rupture group. Our data from the reference group thereby confirm earlier findings of Moller et al, reporting a strength deficit up to 20% in comparison to the uninjured side up to two years in uncomplicated cases of AT rupture repair.[7] Still, given the marked difference in follow-up, strength differences were expected to be largest for the cases in the re-rupture group and loss of calf muscle strength was expected to translate in more functional disability and decreased satisfaction with outcome. However, our data did not confirm our prior expectations on recovery of isokinetic plantar flexion strength.

The difference in follow-up time most likely explains the diverging pattern between re-rupture and reference group in strength difference between injured and non-injured side. Spurious findings due to limited sample size cannot be ruled out, but our selective sample of patients with re-rupture is likely to be representative. Strength measurement error is also unlikely to explain all our results, because we standardised our measurements, which were all performed by a single physiotherapist with a well-calibrated system.

In summary, isokinetic plantar flexion calf muscle strength after AT re-rupture is sufficient at long-term follow-up, but disability persists. In contrast, although a remarkably large strength difference between the injured and non-injured side is found in uncomplicated cases at one-year follow-up, the last group is clearly less disabled. Isokinetic plantar flexion calf muscle strength is expected to improve at long-term follow-up in uncomplicated cases, which will probably even increase their satisfaction with long-term outcome.

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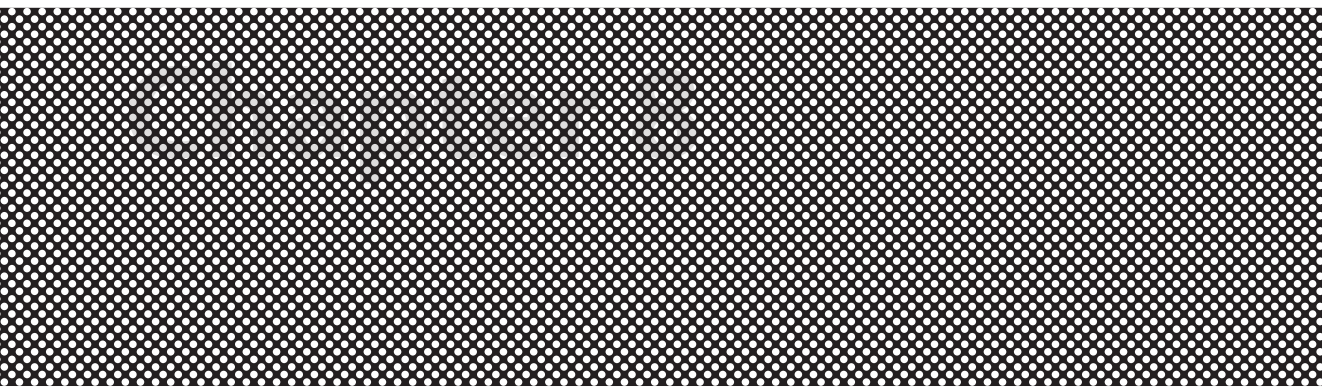
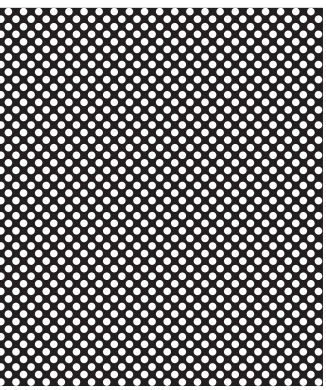


Insufficient evidence for routine use of thromboprophylaxis in ambulatory patients with an isolated lower leg injury requiring immobilization. Results of a meta-analysis.



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Abstract

Background: There are no generally accepted guidelines for the prevention of venous thromboembolism in ambulatory patients requiring immobilization after an isolated lower leg injury. Our objective was to evaluate the effectiveness and safety of pharmacological interventions for preventing venous thromboembolism in these patients.

Study design: Meta-analysis of randomized controlled trials.

Materials and Methods: We searched Pubmed/Medline, EMBASE and the Cochrane Central Register of Controlled Trials for trials with random allocation of thromboprophylaxis, notably low molecular weight heparin (LMWH) versus no prophylaxis or placebo, in ambulatory patients with below-knee or lower leg (including the knee joint) immobilization. Outcome was analysed using MIX to calculate the pooled risk ratio/relative risk (RR) for each outcome, with its 95% confidence interval (CI).

Results: The RR of asymptomatic deep vein thrombosis (DVT) is 0.66 (95% CI: 0.44; 1.02) for below-knee immobilization and 0.51 (95% CI: 0.37; 0.70) for lower leg immobilization. Evaluated is low molecular weight heparin (LMWH) versus no prophylaxis or placebo. The incidence of symptomatic DVT and PE is too low to show any statistically significant difference between thromboprophylaxis and controls in both groups. Although only 1 adverse bleeding event is considered major, the RR for any adverse bleeding event is 1.94 (95% CI: 1.03; 3.67).

Conclusion: There is insufficient evidence to warrant routine use of thromboprophylaxis in ambulatory patients with below-knee or lower leg immobilization after an isolated lower leg injury. The incidence of symptomatic VTE is too low to show a relevant clinical benefit from thromboprophylaxis.

Background

Venous thromboembolism (VTE) is a common complication in hospitalised bed-ridden patients after major trauma and after hip-arthroplasty. [1,2] Thromboprophylaxis is therefore provided in most of these patients. However, to date there are no generally accepted recommendations for the prevention of VTE in ambulatory patients requiring below-knee or lower leg (i.e. including the knee joint) immobilization after an isolated lower leg injury. The reported incidence of symptomatic deep vein thrombosis (DVT) after lower leg injury varies substantially, from 0.22% in patients operated on foot or ankle injuries to 7.6% after surgical treatment of Achilles tendon ruptures. [3,4] In a large cohort on nonsurgical isolated limb injures treated with below-knee immobilization an incidence of 1.0% was found. [5] At the seventh ACCP Conference on antithrombotic and thrombolytic therapy, it was suggested that thromboprophylaxis should not be used in patients with isolated lower leg injuries since it is uncertain whether prophylaxis similarly reduces the risk of clinically important VTE, or is cost-effective. [6] A quantitative analysis of results from randomized trials was not presented. A survey of current practice on the use thromboprophylaxis during lower leg immobilization in the United Kingdom, results showed substantial variation among physicians and most of them were not aware of any existing guidelines in this regard. [7] Therefore, a critical analysis of literature is warranted, knowing below-knee/lower leg immobilization is frequently used in treatment of Achilles tendon ruptures, ligament sprains and lower leg fractures. In this meta-analysis we assess the effectiveness and safety of pharmacological interventions for preventing deep vein thrombosis (DVT) or pulmonary embolism (PE) in patients with below-knee/lower leg immobilization by cast or brace after an isolated lower leg injury.

Materials and Methods

Search strategy for identification of studies

The following electronic databases were searched: Pubmed, from 1966 to July 2007; EMBASE, from 1980 to July 2007; The Cochrane Central Register of Controlled Trials (Clinical Trials). We constructed a topical search filter for PubMed and combined this topical search filter with the broad, sensitive PubMed clinical query for treatment. We also constructed a topical search filter for Embase (appendix). In the Cochrane Central Register of Controlled Trials we searched with: Leg injuries AND thrombosis. In addition, we searched the reference lists of identified studies. There were no restrictions on language. If the inclusion criteria were met, full text articles were obtained (figure 1).

Selection of studies

The titles and abstracts of the retrieved records were checked by RM. Selection of records was based on the following criteria: (1) clinical trials with random allocation (2) of pharmacological thromboprophylaxis (e.g. heparin, low molecular weight heparin, coumarins and antiplatelet treatment) (3) in ambulatory patients over 16 years old (4) with below-knee or lower leg (i.e. including patients

with immobilized knee joints) immobilization after an isolated lower leg injury (5) in which the outcomes were deep vein thrombosis and pulmonary embolism. This selection was cross checked by GH. Any disagreements were resolved by a third author (EV).

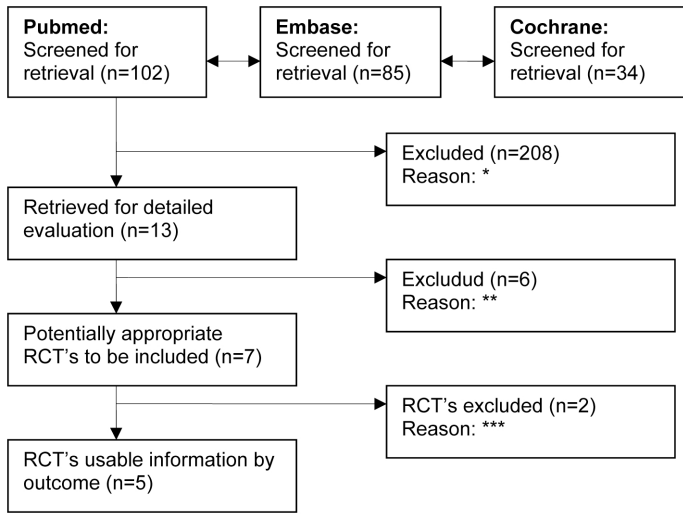

Figure 1. Flow diagram representing the search and selection of trials. * No lower leg immobilisation / injuries, no ambulatory patients / outpatients, non pharmaceutical thromboprophylaxis, non-randomized trials, overlap in databases. ** Duplicate data, selection bias [23,25-29] *** Abstract only / insufficient data [20] or comparing two interventions with no control group. [22] Two studies were retrieved by manual reference search and were excluded after detailed evaluation. [21,24]

Quality assessment

The methodological quality of the trials included was graded on six items, notably randomization, concealment of allocation, blinding of treatment and endpoints, dropouts and completeness of data (table 1). [8,9]

Study	Randomization	Concealment of allocation	Blinding of treatment	Blinding of outcome	Withdrawals	Missing data
Jorgensen	+	?	-	+	+	-
Kock	+	?	-	-	+	-
Kujath	+	?	-	-	+	-
Lapidus	+	?	+	+	+	-
Lassen	+	+	+	+	+	-

Table 1. Quality assessment of included randomized clinical trials. + reported to be performed, - reported not to be performed, ? not reported/unknown. Missing data (on DVT by diagnostic procedure): + reported and < 10 %, - not reported or reported and > 10 %.

Data extraction

The number of events and number of patients randomized for each treatment group in each trial were extracted. Events included: prevention of proximal and distal DVT, both clinical and by diagnostic

procedure i.e. venography or duplex/ultrasound; pulmonary embolism, both diagnosed by V/Q lung scan, spiral computer tomography (CT), pulmonary angiography or autopsy; death related to embolic events. In addition, data on adverse events were extracted, notably for major bleeding, i.e. requiring transfusion of red blood cells or surgical interventions, minor bleeding i.e. did not meet the major criteria for intervention and bleeding related death. Data on baseline characteristics, i.e. risk factors for thrombosis and intervention characteristics such as administration, dosage and duration, were also extracted (table 2 and 3). [5,10] Data extraction was performed by one reviewer (RM) cross checked by another (GH). Disagreements were resolved by consensus discussion.

Baseline characteristics (pooled)	**LMWH**	**No Prophylaxis**
N	719	716
Male	405 (56%)	430 (60%)
Smoking	286 (40%)	299 (42%)
Oral contraceptives	47 (7%)	56 (8%)
Previous DVT / venous thomboembolism	17 (2%)	14 (2%)
Varicose veins	69 (10%)	88 (12%)

Table 2. Available baseline characteristics of patients analysed (pooled).

Statistical Analysis

The data analysis was performed using MIX to calculate the pooled risk ratio (RR) for each outcome, with its 95% confidence interval (CI) according to the Mantel-Haenzel method. [11] To overcome the unwarranted exclusion from the analysis of studies without an event in both groups we added 0.001 events to the control group.

Results

Five trials met our search criteria. [4,12-15] All 5 trials compared thromboprophylaxis by low molucular weight heparin to no prophylaxis or placebo. Patients selected in these studies had isolated lower leg injuries varying from ligament sprains to fractures. Three studies (Kock, Kujath, Lapidus) used ultrasound/duplex to screen for DVT, 2 studies (Jorgensen, Lassen) used venography. Study characteristics are given in table 3. Importantly, 2 studies reported on below-knee immobilisation (Jorgensen, Lapidus) and 3 studies reported on lower leg immobilisation (Kock, Kujath, Lassen). These last 3 studies included patients with an immobilized knee joints as well. Kock described the subgroup of patients with below-knee immobilisation separately in his report and these data were used for analysis of VTE in below-knee immobilisation as well.

	Number*	Participants**	Type of injury	Duration of immobilisation	Operation	Intervention	Duration of intervention	Outcome
Jorgensen	300	Below-knee immobilisation	Fractures: 73% Lig/tendon injuries: 27%	> 3 weeks	Yes / No	Tinzaparin 3.500 IU anti-Xa	Total plaster period	DVT / PE / AE
Kock	391	Lower leg immobilisation	Fractures: 21% Lig/tendon injuries:79 %	Depending on trauma	No	Mono-Embolex® 0,3 ml anti-Xa	Total plaster period	DVT / AE
Kujath	279	Lower leg immobilisation	Fractures: 30% Lig/tendon injuries: 70%	> 7 days	No	Nadroparin 0,3 ml anti-Xa	Total plaster period	DVT / PE / AE
Lapidus	105	Below-knee immobilisation	Fractures: none Achilles tendon: 100%	6 weeks	Yes	Dalteparin 5000 U anti-Xa	6 weeks	DVT / PE / AE
Lassen	440	Lower leg immobilisation	Fractures: 81% Lig/tendon injuries: 19%	> 5 weeks	Yes / No	Reviparine 1750 IU anti-Xa	Total plaster period	DVT / PE / AE

Table 3. Characteristics of included studies. *Numbers of patients randomized are given. ** Participants are ambulatory patients with lower leg fracture or soft tissue injury requiring immobilisation. Lig: ligament. DVT: deep vein thrombosis, PE: Pulmonary embolism, AE: adverse events.

VTE in below-knee immobilization:

The RR of asymptomatic DVT (proximal and distal) in below-knee immobilization after an isolated lower leg injury obtained from pooling data from 3 studies with a total of 587 patients is 0.66 with a 95% CI from 0.44 to 1.02 favouring prophylaxis (Jorgensen, Kock, Lapidus) (figure 2). Evaluated is low molecular weight heparin (LMWH) versus no prophylaxis or placebo. The RR for asymptomatic proximal DVT alone, obtained from pooling data from 3 studies with a total of 640 patients is 0.24 (95% CI: 0.05; 1.12) favouring prophylaxis (Jorgensen, Kock, Lapidus) (figure 3). The RR of asymptomatic DVT in Achilles tendon ruptures treatment obtained from pooling data from 2 studies with a total of 167 patients is 0.73 (95% CI: 0.44; 1.21) favouring prophylaxis (Lapidus, Lassen). In the studies on below-knee immobilisation none of the participant suffered a symptomatic DVT or PE (Jorgensen, Kock, Lapidus). Therefore, an analysis of pooled data was not performed.

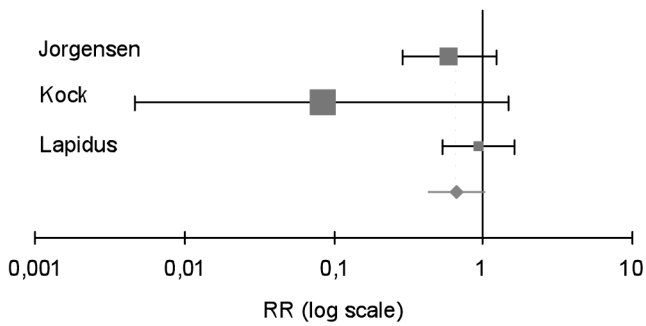

Figure 2. The effect of Low Molecular Weight Heparin on asymptomatic deep venous thrombosis in below-knee immobilization.

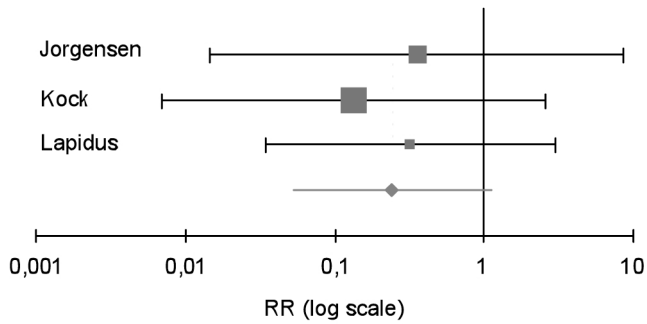

Figure 3. The effect of Low Molecular Weight Heparin on proximal asymptomatic deep venous thrombosis in below-knee immobilization.

VTE in lower-leg immobilization:

Kock, Kujath and Lassen reported on patients with lower leg immobilisation. Pooling their results with those of Jorgensen and Lapidus, altogether including 1259 patients, resulted in a RR of asymptomatic DVT for lower leg immobilization of 0.51 (95% CI: 0.37; 0.70) (figure 4). As stated before, this RR concerns a mixed group of patients with ankle joint (below-knee) and/or knee joint immobilization.

The RR of symptomatic DVT in lower leg immobilization obtained from pooling data from 3 studies with a total of 667 patients is 0.28 (95% CI 0.05; 1.69) favouring prophylaxis (Jorgensen, Lapidus, Lassen) (figure 5). In the study by Lassen clinical signs of DVT for each subgroup were described. In 4 out of 11 patients with clinical suspicion of DVT the diagnosis was confirmed by venography. All 4 patients were in the placebo group. In the studies by Jorgensen and Lapidus, none of the analysed patients had any clinical sings of DVT. Kock and Kujath did not report sufficiently on clinical DVT. The pooled absolute risk of symptomatic DVT in the control group is 1.2% versus 0% in the prophylaxis group.

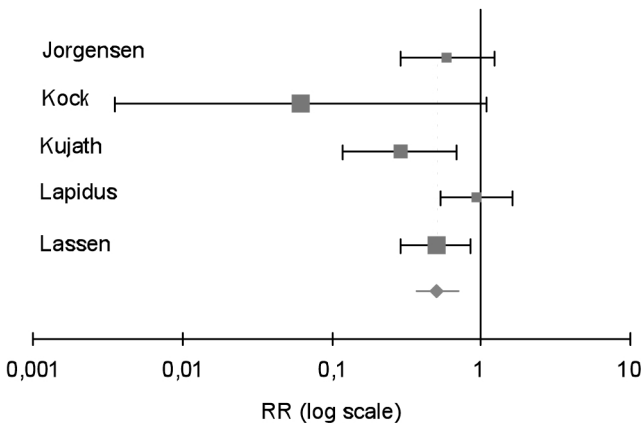

Figure 4. The effect of Low Molecular Weight Heparin on asymptomatic deep venous thrombosis in lower-leg immobilization.

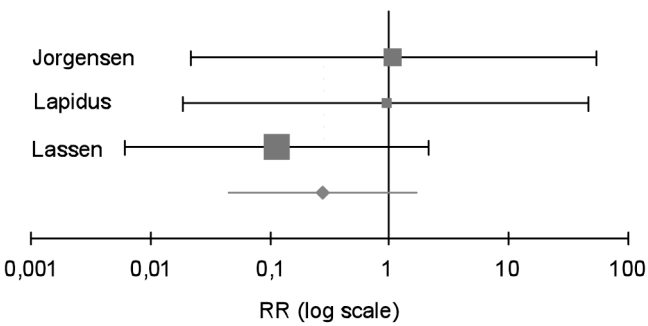

Figure 5. The effect of Low Molecular Weight Heparin on symptomatic DVT in lower leg immobilization.

Pulmonary embolism was conformed by ventilation-perfusion scan after clinical suspicion in two patients in the placebo group in the study by Lassen. In 2 studies, none of the patients had any clinical suspicion for PE (Jorgensen, Lapidus). Therefore, the RR for PE is 0.44 (95% CI: 0.06; 2.94) favouring prophylaxis and including 3 studies with a total of 843 patients.

Adverse events (in lower leg immobilization):

Adverse events are reported in all studies (Jorgensen, Kock, Kujath, Lapidus, Lassen). The RR for any adverse events in lower leg immobilization is 1.94 (95% CI: 1.03; 3.67) favouring no prophylaxis or placebo including 5 studies with a total of 1435 patients (figure 6). One bleeding event (retroperitoneal bleed) described in the study by Lassen is considered major. All other bleeding events were minor (e.g. nose bleed, haematoma at injection site). Seven patients discontinued allocated study medication (LMWH of placebo) due to minor bleeding, one due to metrorrhagia. None of the studies reported deaths. None of the studies reported any change in platelet count or signs of heparin-induced thrombopenia.

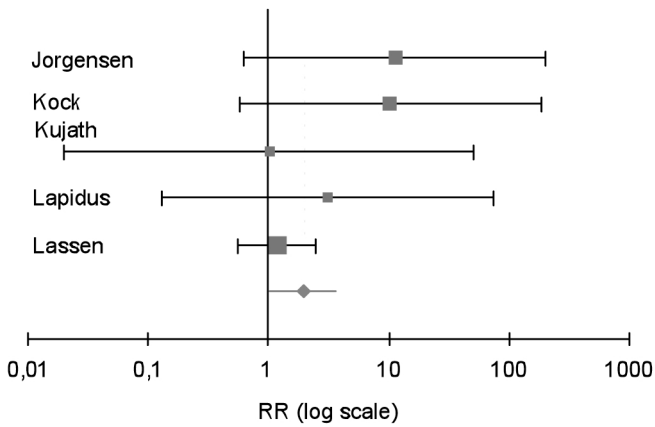

Figure 6. The effect of Low Molecular Weight Heparin on all adverse events in lower-leg immobilization.

Discussion

The 34% RR reduction in asymptomatic deep vein thrombosis in patients with below-knee immobilization using LMWH and the 76% RR reduction of potentially more dangerous proximal asymptomatic DVT are not statistically significant. The 49% RR reduction in asymptomatic DVT in patients with lower leg immobilization is. However, the aim of thromboprophylaxis is the prevention of symptomatic VTE (i.e. symptomatic DVT and post-thrombotic syndrome, PE and death by thromboembolic event). The incidence of symptomatic DVT after pooling data is 1.2% and is too low to show a statistically significant difference between groups. Much larger numbers are needed to clearly identify the benefit of prophylaxis (pooling the result of symptomatic DVT and PE is impossible as more patients were available for the outcome PE). Still, asymptomatic DVT is accepted as a surrogate endpoint for VTE in hip and knee surgery. [16,17] A parallel relative risk reduction of asymptomatic DVT and symptomatic VTE is found when thromboprophylaxis is used in these patient categories. [17] If this parallel reduction also exists in below-knee

immobilization, a 49% reduction of a 1,2% absolute symptomatic DVT risk would mean treating over 150 patients to prevent 1 symptomatic DVT. The number needed to treat to prevent a PE would be much higher. But is the 1.2% symptomatic DVT risk realistic? In trials where DVT screening is used, knowledge of the results of these screening tests can affect the true incidence of symptomatic DVT (and VTE) due to diagnostic decision bias. [16] None of the included studies in our analysis reported the number of patients who were treated. Mizel et al. did not use screening methods and found a less than 1% incidence of symptomatic DVT in patients after foot or ankle surgery with post-operative immobilization. [3] These results also suggest that the incidence of symptomatic DVT and even more so PE is probably very low. We cannot explain the high incidence of DVT reported by Lapidus, as investigational data are unpublished. [4] The included studies provide indirect evidence for a large effect (RR reduction) of thromboprophylaxis on symptomatic VTE in lower leg immobilization. This effect of prophylaxis is not doubted; a clinically relevant effect of thromboprophylaxis on the incidence of symptomatic DVT or PE in patients with lower leg immobilization is questionable though, and probably even more so in below-knee immobilization. The incidence of symptomatic VTE seems too low to legit routine use of prophylaxis. The results from our meta-analysis do show thromboprophylaxis using LMWH can be considered safe. Although thromboprophylaxis significantly increases the RR of adverse bleeding events, these events were all minor except for one retroperitoneal bleed.

The results of this meta-analysis itself deserve some further considerations as well. First, the number of included studies is limited, while the allocation of concealment and the completeness of data analysed are reported in an insufficient manner. There were several patients in the included studies for whom outcome could not be determined. The main reasons for missing outcome values were patients refusal of venography or technical impossibility of venography. 83% of randomized patients were used in the analysis to calculation of the RR for asymptomatic DVT, as outcome was unknown in others. Most of these patients were not lost to follow-up and so were included in the analysis of risk of pulmonary embolism and adverse events.

Second, variation of baseline risk across clinical trials included in a meta-analysis is common and may have impact on the treatment benefit for individual patients. [18] The included studies varied regarding the risk factors for thrombosis, such as type of injury, operation, hospitalisation and duration and type of immobilization. A rigid non-weight bearing cast with knee joint immobilization is considered a bigger risk to development of thrombosis than non-rigid weight bearing below-knee immobilization. [5] Increasing age and age-related (co)morbidities are considered to be risk factors as well but age was consistent at baseline across studies. [10] Furthermore, as no trials on coumarines for the prevention of VTE were found, no conclusions can be drawn regarding the efficacy and safety of this antithrombotic agent. Finally, venography is considered the gold standard diagnostic test for DVT but has largely been replaced by ultrasonographic modalities. [19] Kock, Kujath and Lapidus use ultrasound for measuring outcome, if DVT is suspected venography is performed. According to study protocol Kock verified all DVT's venographically. Kujath reported 22 out of 27

DVT's seen during compression ultrasound could be verified venographically. Lapidus verified all DVT's venographically, except for 2 proximal DVT's because duplex/sonography was considered to have high sensitivity and specificity for proximal DVT.

In conclusion, there is insufficient evidence for routine use of thromboprophylaxis in ambulatory patients with below-knee or lower leg immobilization after an isolated lower leg injury. Future studies should include large numbers of patients with stratification of risk factors; only then a selected patient group might be found than can clearly benefit from pharmacological thromboprophylaxis during immobilization of an injured leg.

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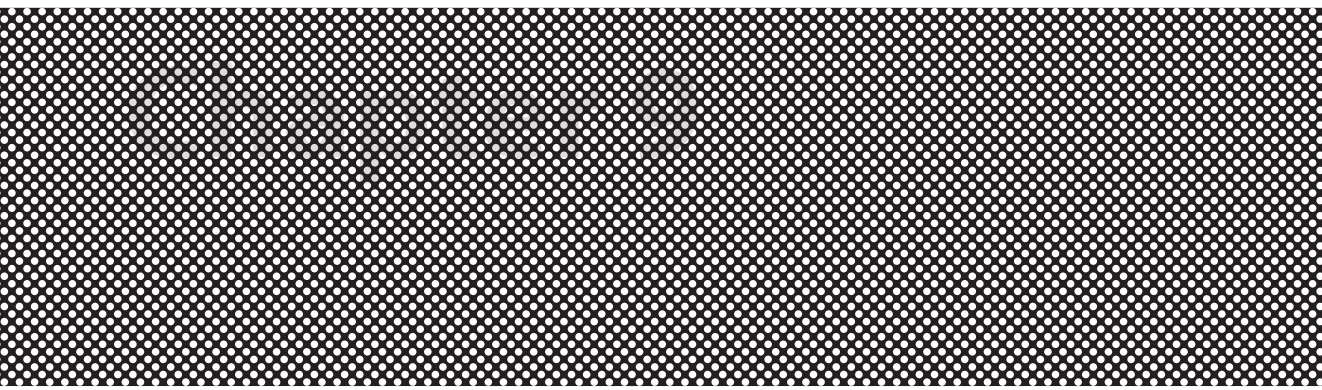
Appendix:

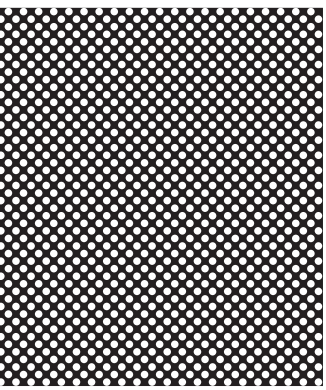
Topical search filter for PubMed
((“Immobilization”[Mesh]) OR “immobilizing”[All Fields] OR “immobilized”[All Fields] OR “immobilization”[All Fields] OR “immobilisation”[All Fields]) AND (((“lower extremity”[All Fields] OR “leg”[All Fields] OR “limb”[All Fields]) AND (“Embolism and Thrombosis”[Mesh] OR “embolism”[All Fields] OR “thrombosis”[All Fields]). Topical search filter with the broad, sensitive PubMed clinical query for treatment: AND (randomized controlled trial [Publication Type] OR (randomized [Title/Abstract] AND controlled [Title/Abstract] AND trial [Title/Abstract])).

Topical search filter for Embase

(immobilising OR immobilizing OR ('immobilisation'/exp) OR ('immobilization'/exp) OR immobilized OR immobilised OR injuries) AND (('leg'/exp OR 'leg') OR ('limb'/exp OR 'limb')) AND ('thrombosis' OR Thromboprophylaxis OR ('thromboembolism'/exp) OR ('thrombosis'/exp)) AND (Randomized OR Randomisation OR ('randomization'/exp) OR (Clinical AND Trial)).



Summary and conclusions



Summary and conclusions

Despite the high incidence of acute Achilles tendon (AT) ruptures and the amount of clinical research on its treatment, no single treatment strategy is currently considered best. [4] Goal of treatment of an acute AT rupture is to return patients to their original level of professional and athletic activities as soon as possible, without the burden of complications. In this thesis various studies are described to compare the results of conservative treatment of acute AT ruptures by functional bracing with those of minimally invasive surgical repair. The impact of complications on long-term functional recovery is studied as well. A number of research questions are answered.

Does conservative treatment by functional bracing of acute Achilles tendon ruptures reduce the risk of complications compared to minimally invasive surgical repair and is functional bracing equally effective as minimally invasive surgical treatment in achieving functional recovery, expressed as (early) return of calf muscle strength.

In **chapter 3** the design of a prospective clinical trial to study the potential benefits of conservative acute AT rupture treatment by functional bracing over minimally invasive surgical treatment is presented. Results, discussed in **chapter 4**, clearly showed that surgical treatment is superior in preventing complications, including re-rupture. In sum, 83 patients were included and randomly allocated to one of the treatment methods. Early full weight bearing was allowed in both treatment arms. Re-rupture risk was 15% versus 5% favouring surgical treatment (treatment-as-received analysis). Overall complication risk was 49% versus 29%. This difference was mainly caused by skin related complications, which are considered of minor importance. [10] Sick leave was significantly shorter after surgical treatment. No difference between treatment groups was found for post-treatment sport participation or VAS-scores for pain and patient satisfaction.

In **chapter 5** the value of conservative AT rupture treatment by functional bracing in achieving functional recovery is evaluated. To exclusively measure the effect of treatment on functional recovery, isokinetic calf muscle strength test results in uncomplicated cases in both trial arms were compared. Isokinetic plantar and dorsal flexion strength was tested at 3 months and at least after 6 months post-treatment in 31 out of 39 patients with an uncomplicated recovery in the surgical treatment group and in 25 out of 34 patients in the conservative treatment group. No clinically relevant differences were found in recovery of calf muscle strength between treatment groups. In both groups, there was a remarkable loss of plantar flexion strength of the injured leg compared to the healthy leg at the second measurement (more than 6 months post-rupture). Apparently, an AT rupture itself has more impact on calf muscle strength recovery than the treatment method chosen. [9]

The results described in **chapter 4 and 5** were integrated in a review on AT rupture treatment in **chapter 2**. Treatment of acute Achilles tendon ruptures can be classified into surgical repair

(open surgical repair or less invasive surgical techniques) and conservative treatment (cast immobilization or functional bracing). Reviewing literature learned that open surgical repair limits the risk of re-rupture in comparison to conservative treatment by cast immobilization, but has a considerable risk of other complications; in particular wound related.[4] Less invasive surgical techniques reduce this risk and have become increasingly popular.[4,7,10] At the same time, evidence for their superiority from rigorously designed trials is limited.[2,4] There is profound evidence that early post-operative weight bearing with early motion will render better functional outcome and even reduce complication risk.[17] This seems to apply to functional conservative treatment (i.e. functional bracing) as well.[1,8,13,14] But the promising results from previous reports on functional bracing treatment of acute AT ruptures were not confirmed in our trial.

What is the impact of complications, in particular re-rupture, on long-term outcome after minimally invasive surgical treatment of an acute Achilles tendon rupture.

The impact of complications on functional outcome is outlined in **chapter 6 and 7**. Long-term outcome after minimally invasive surgical repair of acute Achilles tendon ruptures was studied with the use of the Achilles tendon total rupture score (ATRS) after a mean follow-up over 6 years in 211 patients. The ATRS is a validated questionnaire consisting of 10 questions on post-treatment disabilities with a sum score of 0 as minimum to 100 as maximum.[11] Complications were categorised in re-rupture, severe wound infection, sural nerve injury and "other" (merely "minor" wound healing disturbances). The average ATRS for the 135 (64%) uncomplicated cases was 89 out of 100 points. The average ATRS for 17 (8%) patients with a re-rupture was 71 points, for 41 patients (19%) with a sural nerve lesion 79 points and for 17 patients (8%) with "other" complications 75 points. For the 13 patients with minor wound healing complications from the category "other" it was 80 points. These differences all reached statistical significance at the conventional level. One patient suffered a severe wound infection (and a re-rupture), scoring 28 out of 100 points.

In **chapter 7** the impact of re-rupture was further analyzed in 13 patients (including the one with the severe wound infection) with the Leppilahti score, post-treatment sport participation and isokinetic strength testing.[6] Re-ruptures were treated by open repair followed by cast immobilization in 10 cases and conservatively by cast immobilization in 3 cases. The severe wound infection was treated by surgical debridement and tendon reconstruction. Mean follow-up was almost 9 years. Twenty-three patients with an uncomplicated post-operative course from the trial served as a reference group. Again, re-rupture caused significant disabilities (i.e. lower Leppilahti score and decreased participation in sport), despite quite satisfactory calf muscle strength recovery with on average 10% loss of strength in comparison to their uninjured leg.

The results given in **chapter 6 and 7** support the choice of surgical treatment of AT ruptures, therewith limiting the re-rupture risk in comparison to conservative treatment methods. They also justify the use of re-rupture as an important outcome measure in clinical research.[12,15]

Do patients treated for an acute Achilles tendon rupture need thrombosis prophylaxis during immobilization.

In **chapter 8**, a meta-analysis of available randomized trials on pharmacological prophylaxis for the prevention of venous thrombo-embolism (VTE) in patients with below-knee plaster immobilization is presented. The relative risk of asymptomatic deep vein thrombosis (DVT) with the use of low molecular weight heparin was 0.66 (95% confidence interval 0.44; 1.02) and the incidence of symptomatic venous thromboembolism is too low to show a clear benefit. Asymptomatic DVT is a surrogate outcome measure for symptomatic VTE, which in our opinion does not justify prophylaxis.[3,5] A parallel reduction in asymptomatic and symptomatic VTE is proven in orthopedic hip surgery, but this is not necessarily the same in below-knee immobilization.[16] The result of this meta-analysis show there is insufficient evidence to warrant routine use of thromboprophylaxis in ambulatory patients with below-knee immobilization after an isolated lower leg injury, including Achilles tendon rupture.[3]

Conclusions

Based on the results of the studies presented in this thesis it is concluded that minimally invasive surgical treatment of acute AT ruptures with functional after-treatment allows patients to return to their original level of their professional and athletic activities and should be regarded best treatment until otherwise proven. Conservative treatment by functional bracing might still be a potentially valuable alternative, but our studies failed to prove so, mainly because of a higher complication risk. More clinical trials with large statistical power and of rigorous methodology are needed to identify best management of acute Achilles tendon ruptures. Re-rupture and severe wound infection should be included as important outcome measure. Routine use of thromboprophylaxis is not warranted in patients with temporary below-knee immobilization.

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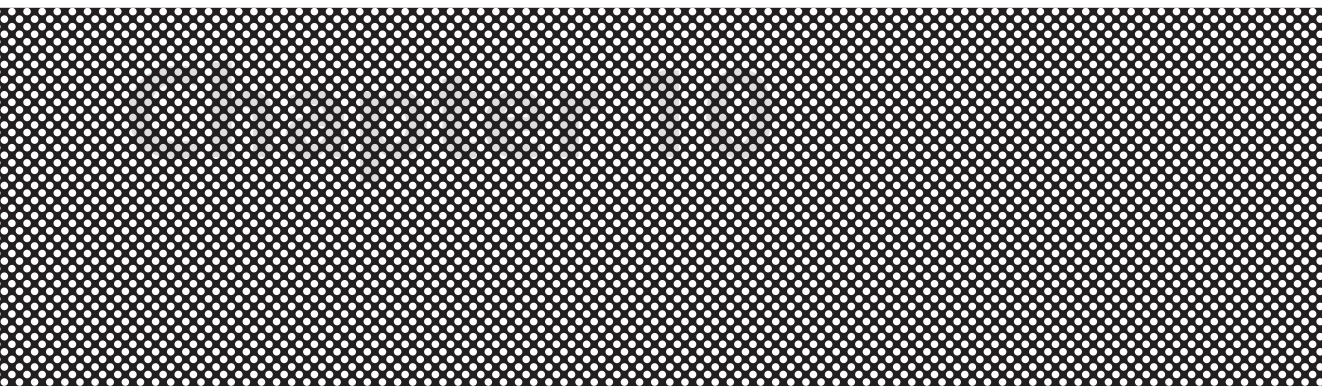
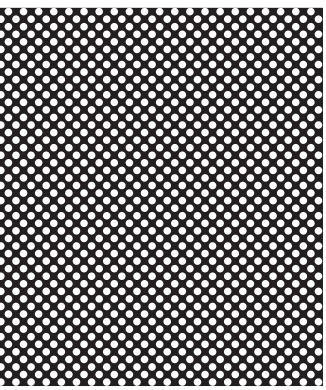


Samenvatting en conclusies



Samenvatting en conclusies

Ondanks het frequent voorkomen van acute achillespees rupturen en het grote aantal klinische onderzoeken naar de behandeling ervan bestaat er tot op heden geen consensus over de optimale behandelingsstrategie. [4] Het doel van de behandeling van acute achillespees rupturen is om patiënten zo spoedig mogelijk terug te brengen op hun oude niveau van professionele en sportieve activiteiten, zonder de nadelen van complicaties. In dit proefschrift worden een aantal studies beschreven die de resultaten van conservatieve functionele brace behandeling van acute achillespees rupturen vergelijkt met die van minimaal invasieve chirurgische behandeling. Daarnaast wordt het effect van complicaties van behandeling op het uiteindelijk functioneel herstel bestudeerd. Een aantal onderzoeksvragen wordt beantwoord.

Doet conservatieve functionele brace behandeling van acute achillespees rupturen het risico op complicaties verminderen in vergelijking met minimaal invasieve chirurgische behandeling en is functionele brace behandeling even effectief als minimaal invasieve chirurgische behandeling in het bereiken van functioneel herstel, uitgedrukt in herstel van kuitspier kracht.

In **hoofdstuk 3** worden het ontwerp van een prospectieve klinische studie naar de potentiële voordelen van conservatieve functionele brace behandeling van acute achillespees rupturen ten opzicht van minimaal invasieve chirurgische behandeling beschreven. De resultaten van deze studie worden in **hoofdstuk 4** besproken. In totaal werden 83 patiënten geincludeerd en gerandomiseerd voor één van de eerder genoemde behandelingsmethoden. Beide groepen werden functioneel (na)behandeld, dat wil zeggen met vroege mobilisatie en belasting. Het risico op een recidief ruptuur was 5% in de chirurgisch behandelde groep tegenover 15% in de conservatief behandelde groep (treatment-as-received analyse). Het totale complicatierisico was respectievelijk 29% en 49% (intention-to-treat analyse). Dit laatste verschil werd hoofdzakelijk veroorzaakt door huid gerelateerde complicaties (o.a. druk ulcera, wondgenezing stoornissen en blaren), die als minder belangrijk werden beschouwd. [10] Het ziekteverlof was beduidend korter na chirurgische behandeling. Er werd geen verschil tussen behandelingsgroepen gevonden voor sportparticipatie na behandeling of VAS-scores voor pijn en tevredenheid.

Minimaal invasieve chirurgische behandeling van acute achillespees rupturen vermindert dus de kans op complicaties in vergelijking met functionele brace behandeling. In **hoofdstuk 5** wordt een subgroepanalyse van deze klinische studie beschreven. Hierin wordt onderzocht of functionele brace behandeling een goed functioneel eindresultaat geeft, uitgedrukt in herstel van kuitspier kracht, bij uitblijven van complicaties. Daartoe werden de resultaten van isokinetische krachttesten van patiënten zonder ernstige complicaties uit beide groepen met elkaar vergeleken. Deze krachtmetingen (in plantair en dorsaal flexie) vonden plaats na drie maanden en na meer dan zes maanden na behandeling. Bij 31 van de 39 patiënten met een ongecompliceerd verloop in de chirurgisch behandelde groep en in 25 van de 34 patiënten in de conservatief behandelde

groep werden metingen verricht. Hierbij werden geen klinisch relevante verschillen gevonden in herstel van spierkracht tussen de behandelingsgroepen. In beide groepen was er echter wel een opmerkelijk verlies van plantair flexie kracht van het aangedane been in vergelijking met het gezonde been (meer dan zes maanden na ruptuur). Blijkbaar heeft een achillespees ruptuur zelf meer invloed op het functioneel herstel dan de gekozen behandeling. [9]

Hoofdstuk 2 is een overzichtsartikel over de behandeling van acute achillespees rupturen. De resultaten van **hoofdstuk 4 en 5** zijn hierin meegenomen. De behandeling van acute achillespees rupturen kan grofweg onderverdeeld worden in chirurgische therapie (open chirurgische reconstructie of minder invasieve chirurgische technieken) en conservatieve behandeling (gips immobilisatie of functionele brace behandeling). Studie van de beschikbare literatuur leerde dat open chirurgisch herstel het risico op een recidief ruptuur vermindert in vergelijking met conservatieve behandeling middels gips immobilisatie, maar een aanzienlijk risico geeft op andere complicaties, in het bijzonder wond gerelateerde complicaties. [4] Minder invasieve chirurgische technieken verminderen dit risico op wondcomplicaties en worden mede daarom in toenemende mate toegepast, ondanks het feit dat het bewijsmateriaal voor deze superioriteit beperkt is. [2,4,7,10] Wel is duidelijk dat vroege postoperatieve mobilisatie (functionele nabehandeling) een beter functioneel resultaat geeft met een hogere patiënt tevredenheid en zelfs een lager complicatierisico dan met langdurige immobilisatie. [17] De gunstige resultaten van conservatieve functionele behandeling met een brace, die in de literatuur gerapporteerd worden, konden in onze studie niet worden bevestigd. [1,8,13,14]

Wat is het effect van complicaties, in het bijzonder recidief ruptuur, op het functionele herstel na minimaal invasieve chirurgische behandeling van een acute achillespees ruptuur.

Het effect van complicaties op het functioneel herstel na minimaal invasieve chirurgische behandeling van acute achillespees rupturen wordt beschreven in **hoofdstukken 6 en 7**. Het herstel op lange termijn, en de invloed van complicaties hierop, werd allereerst bestudeerd middels de Achilles tendon Total Rupture Score (ATRS). De ATRS is een gevalideerde vragenlijst bestaande uit 10 vragen over het herstel na achillespees ruptuur behandeling met een score van 0 als minimum en 100 als maximum. [11] De uitkomsten van de enquêtes van 211 patiënten met een gemiddelde follow-up duur van meer dan zes jaar werden geanalyseerd. Complicaties werden daarbij gecategoriseerd in recidief ruptuur, ernstige wondinfectie, letsel van de nervus suralis en "overige". De laatste categorie bestond voornamelijk uit wondgenezing stoornissen die als minder ernstig werden beschouwd. De gemiddelde ATRS voor de 135 (64%) ongecompliceerde gevallen was 89 van de 100 punten. Gemiddelde ATRS voor de 17 (8%) patiënten met een recidief ruptuur was 71 punten, voor de 41 patiënten (19%) met een zenuwletsel 79 punten en voor de 17 patiënten (8%) met andere complicatie 75 punten. Voor de 13 patiënten met minder ernstige wond genezingsstoornissen uit de "overige" categorie was de ATRS 80 punten. De ATRS was na alle soorten van complicaties statistisch significant lager in vergelijking met ongecompliceerde gevallen. Één patiënt liep na een recidief ruptuur tevens een ernstige wondinfectie op en scoorde 28 van de 100 punten.

In **hoofdstuk 7** wordt het effect van een recidief rupturen op het functioneel herstel vervolgens nader geanalyseerd middels de Leppilahti score, isokinetische krachtmetingen en sportparticipatie na behandeling. [6] In totaal namen 13 patiënten met een recidief ruptuur na eerdere minimaal invasieve chirurgische ruptuur behandeling deel aan deze studie (waarvan er één tevens een ernstige wondinfectie doormaakte). In negen gevallen werd de recidief rupturen chirurgisch behandeld met open reconstructie, in drie gevallen met gips immobilisatie gedurende zes weken. De ernstige wondinfectie werd behandeld met een chirurgisch debridement, later gevolgd door open peesreconstructie. De gemiddelde follow-up duur was bijna 9 jaar. Drieëntwintig patiënten met een ongecompliceerd postoperatief beloop na eveneens minimaal invasieve chirurgische behandeling van hun acute Achillespees ruptuur (afkomstig uit de eerder beschreven klinische studie) dienden als controle groep. Zij hadden een gemiddelde follow-up duur van bijna een jaar. Ook met deze uitkomstmaten bleek een recidief achillespees ruptuur een langdurig negatief effect op het functioneren te hebben (d.w.z. lagere Leppilahti score en verminderde participatie in sport in vergelijking met ongecompliceerde controle patiënten), ondanks een bevredigend spierkracht herstel na de recidief ruptuur. De kracht in de kuitspieren van het aangedane been was gemiddeld 10% lager in vergelijking met het niet aangedane been. In de controle groep, met een aanzienlijk kortere follow-up duur, was dit krachtverschil veel prominenter. Desondanks was hun Leppilahti score dus hoger en hun sportparticipatie groter.

De resultaten die in **hoofdstuk 6 en 7** worden beschreven tonen aan dat een recidief ruptuur (en een diepe wondinfectie) een ernstige complicatie is met een langdurig negatief effect op het functioneren. Dit rechtvaardigt de keuze voor chirurgische behandeling van acute achillespees rupturen, aangezien die de kans op recidief rupturen vermindert ten opzichte van conservatieve behandeling. Tevens wordt hiermee het gebruik in onderzoeksverband van recidief rupturen als belangrijke uitkomstmaat gesteund. [12,15]

Dienen patiënten die voor een acute achillespees ruptuur behandeld worden met (tijdelijke) immobilisatie van het onderbeen farmacologische trombose profylaxe te krijgen.

In **hoofdstuk 8** wordt een meta-analyse van gerandomiseerde klinische studies beschreven naar het nut van farmacologische trombose profylaxe bij patiënten met immobilisatie van het onderbeen. Het gaat hierbij om ambulante patiënten met een geïsoleerd onderbeenletsel. Het relatieve risico van niet-symptomatische diep veneuze trombose (DVT) bij het gebruik van laag moleculair gewicht heparine, de meest gebruikte profylaxe, was 0.66 (95% betrouwbaarheidsinterval 0.44; 1.02). De incidentie van symptomatische DVT of longembolie was te laag om een voordeel van profylaxe aan te tonen. Hoewel trombose profylaxe het risico op niet-symptomatische DVT duidelijk doet afnemen, rechtvaardigt dit het routinematig gebruik van profylaxe niet. Niet-symptomatische DVT is namelijk een surrogaat eindpunt voor symptomatische trombo-embolische complicaties. [3,5] Een parallelle vermindering van niet-symptomatische en symptomatische trombo-embolische verschijnselen is weliswaar aangetoond in orthopedische chirurgie en heup operaties, maar dit

is niet vanzelfsprekend hetzelfde bij immobilisatie van het onderbeen. [16] Het resultaat van deze meta-analyse is ontoereikend om routinematig gebruik van trombose profylaxis bij ambulante patiënten met onderbeen immobilisatie na een geïsoleerd onderbeenletsel, waaronder acute achillespees ruptuur, te rechtvaardigen. [3]

Conclusies

Gebaseerd op de resultaten van de studies die in dit proefschrift worden beschreven is minimaal invasieve chirurgische therapie van acute achillespees rupturen de behandeling van eerste keus. Conservatieve behandeling met een functionele brace kan een waardevol alternatief zijn, maar de resultaten van onze studies kunnen de veelbelovende resultaten uit eerdere studies niet bevestigen, met name vanwege de vastgestelde verhoogde kans op complicaties. Uiteindelijk zijn meer degelijk uitgevoerde gerandomiseerde studies nodig om de optimale behandelingsstrategie voor acute achillespees rupturen te kunnen bepalen. Recidief ruptuur en ernstige wondinfectie zijn hierbij belangrijke uitkomstmaten. Het routinematig gebruik van trombose profylaxe is vooralsnog niet gerechtvaardigd in deze patiënten categorie.

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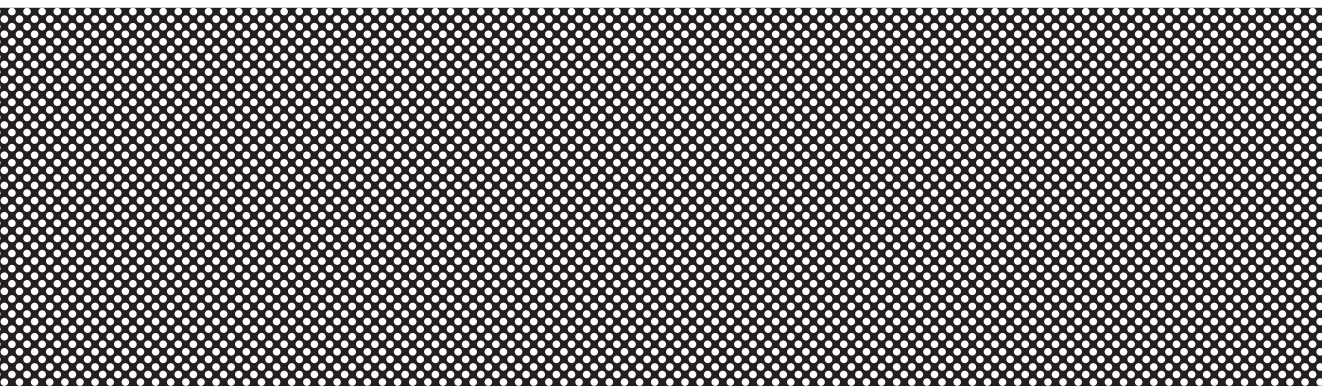

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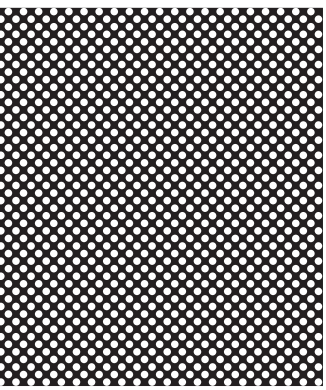

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Curriculum Vitae

Roderik Metz werd geboren op 18 april 1973 te Ede. Na het behalen van zijn eindexamen VWO aan het van Lingen College te Arnhem studeerde hij geneeskunde aan de Universiteit Utrecht. Eind 1999 werd het artsexamen behaald en aansluitend begon hij te werken als arts-assistent chirurgie (ANIOS) in het St Antonius ziekenhuis in Nieuwegein. In 2002 start hij de opleiding tot algemeen chirurg in het Diakonessenhuis te Utrecht (opleider Dr. GJ Clevers), welke wordt voortgezet in het Universitair Medisch Centrum Utrecht (opleider Prof. dr. IHM Borel Rinkes). Tijdens zijn opleiding begint hij onder leiding van Prof. dr. Chr van der Werken aan de onderzoeken die uiteindelijk tot dit proefschrift hebben geleid. Sinds 1 januari 2008 is hij algemeen chirurg en momenteel chirurg in vervolgopleiding tot vaatchirurg in het Erasmus Medisch Centrum te Rotterdam (opleider Prof. dr. HJM Verhagen).