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Functional rehabilitation of patients with acute Achilles tendon rupture: a meta-analysis of current evidence

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Abstract
Purpose The optimal treatment for acute Achilles tendon rupture (ATR) is continuously debated. Recent studies have proposed that the choice of either operative or non-operative treatment may not be as important as rehabilitation, suggesting that functional rehabilitation should be preferred over traditional immobilization. The purpose of this meta-analysis of randomized controlled trials (RCTs) was to compare functional rehabilitation to immobilization in the treatment of ATR.
Method This meta-analysis was conducted using the databases: PubMed, EMBASE, Rehabilitation and Sports Medicine Source, AMED, CINAHL, Cochrane Library and PEDro using the search terms: "*Achilles tendon,*" "*rupture,*" "*mobilization*" and "*immobilization*". Seven RCTs involving 427 participants were eligible for inclusion, with a total of 211 participants treated with functional rehabilitation and 216 treated with immobilization.
Results Re-rupture rate, other complications, strength, range of motion, duration of sick leave, return to sport and patient satisfaction were examined. There were no statistically significant differences between groups. A trend favoring functional rehabilitation was seen regarding the examined outcomes.
Conclusion Functional rehabilitation after acute Achilles tendon rupture does not increase the rate of re-rupture or other complications. A trend toward earlier return to work and sport, and increased patient satisfaction was found when functional rehabilitation was used. The present literature is of low-to-average quality, and the basic constructs of the examined treatment and study protocols vary considerably. Larger, randomized controlled trials using validated outcome measures are needed to confirm the findings.
Level of evidence II.

Keywords Achilles tendon · Rupture · Functional rehabilitation · Mobilization · Immobilization

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Introduction

Acute Achilles tendon rupture can be treated both surgically and non-surgically. Rehabilitation can be functional (mobilizing) or non-functional (immobilizing). Functional rehabilitation can be further divided into controlled early motion, controlled early weight-bearing or a combination of the two.

In some regions, it is common practice to treat young active people surgically and elderly patients non-surgically [2]. Rehabilitation of both surgically and non-surgically treated patients has traditionally been completed by 8–10 weeks of non-weight-bearing immobilization [8]. However, over the past few decades, functional rehabilitation has gained increasing popularity, and today, it is a well-accepted treatment modality used as the standard of care by approximately half of hospitals in some regions [2].

This shift toward functional rehabilitation has been driven by a series of randomized controlled trials comparing surgical and non-surgical treatment protocols using functional rehabilitation [16–18, 20, 26, 28]. The studies by Nilsson-Helander et al. [17], Nistor et al. [18], Olssen et al.

[20], Twaddle et al. [26] and Willits et al. [28] all showed a low rate of re-rupture in both the surgically and the non-surgically treated groups. The low rate of complications has been attributed to the functional rehabilitation regimes even though this was not investigated in the trials. In a meta-analysis by Soroceanu et al. [23], surgically and non-surgically treated patients were compared. Looking at all studies together, they found possible benefits from surgical treatment. Looking only at studies using functional rehabilitation, no statistically significant differences between surgical and non-surgical treatment were found. This again led the authors to opt for the use of functional rehabilitation even though it was not investigated in the included trials.

In 2006, a meta-analysis of randomized and quazi-randomized trials was performed, investigating whether an early functional protocol was superior to cast immobilization after surgical repair of acute Achilles tendon rupture [25]. They found that early functional protocols led to more excellent rated subjective responses and no difference in the re-rupture rate.

It is the authors' perception that a general shift from immobilization toward functional rehabilitation is taking place at the moment in treatment of acute Achilles tendon rupture. This shift may not be supported by sufficient evidence as few randomized clinical trials have investigated the field of functional rehabilitation. A meta-analysis of current evidence is needed to investigate whether functional rehabilitation is safe and beneficial.

The aim of this meta-analysis was to compare functional rehabilitation (mobilization) and non-functional rehabilitation (immobilization) in the treatment of acute Achilles tendon rupture.

Materials and methodology

The primary search was carried out in May 2013. The study was performed in accordance with the PRISMA guidelines.

Eligibility criteria

Only randomized, controlled trials were included in the search. All languages were included, and studies were translated into English if necessary. Only studies with participants with an acute unilateral rupture were included. An acute rupture was defined as being maximum of 14 days old. Studies that included participants with diabetes or neurological conditions were excluded.

Information regarding the orthosis, when it was put to use and for how long it was worn, was required, as was the information regarding length of time of allowed weight-bearing and range of motion in the orthosis. If the intervention did not meet the above-mentioned criteria, the study was excluded. Both operatively and conservatively treated patients were included.

Primary outcome for this meta-analysis was the rate of re-rupture. Secondary outcome measures were the rate of complications, strength, range of motion, sick leave, return to sport and patient satisfaction.

Information sources

The search was employed in the following databases: PubMed, EMBASE, CINAHL, Cochrane Library, AMED, Rehabilitation and Sports Medicine Source and PEDro. The final search was performed on May 5, 2013.

A secondary search to assess unpublished randomized, controlled trials was carried out using the databases "Current Controlled Trials" and "International Clinical Trials Registry Platform," but neither of these databases revealed any relevant studies to include in the meta-analysis. A hand search was also performed by scrutinizing the reference list of relevant systematic reviews and meta-analyses.

Search

The keywords used to identify relevant studies within the databases were: "Achilles Tendon," "Rupture" and "Mobilization." Three different search strategies were carried out in each of the seven databases.

The first search strategy (the combination search) only used MeSH terms (where possible) to identify relevant studies. Relevant MeSH terms were found using the above-mentioned keywords.

The second search strategy was a free text search where the words were truncated to allow different spelling of the key words. This search strategy was employed due to the assumption that recent published studies may not have been assigned a MeSH term yet. Due to the huge amount of hits in this search, a secondary limit was set to only include studies published in 2012 or later. Older studies were expected to have been given one or more MeSH terms.

The third search strategy was a combination of the first two search strategies. This was employed as a supplement to the two other search strategies. The keywords "Achilles tendon" and "Rupture" were essential for the relevance of the search results, but the intervention ("mobilization") could be described in many ways. Therefore, this search used "Achilles Tendon" and "Rupture" as MeSH terms, and the other words (intervention words) were truncated such as described in the second search strategy.

Study selection

Two hundred and sixty-five records were identified during the three searches. The records within each database were

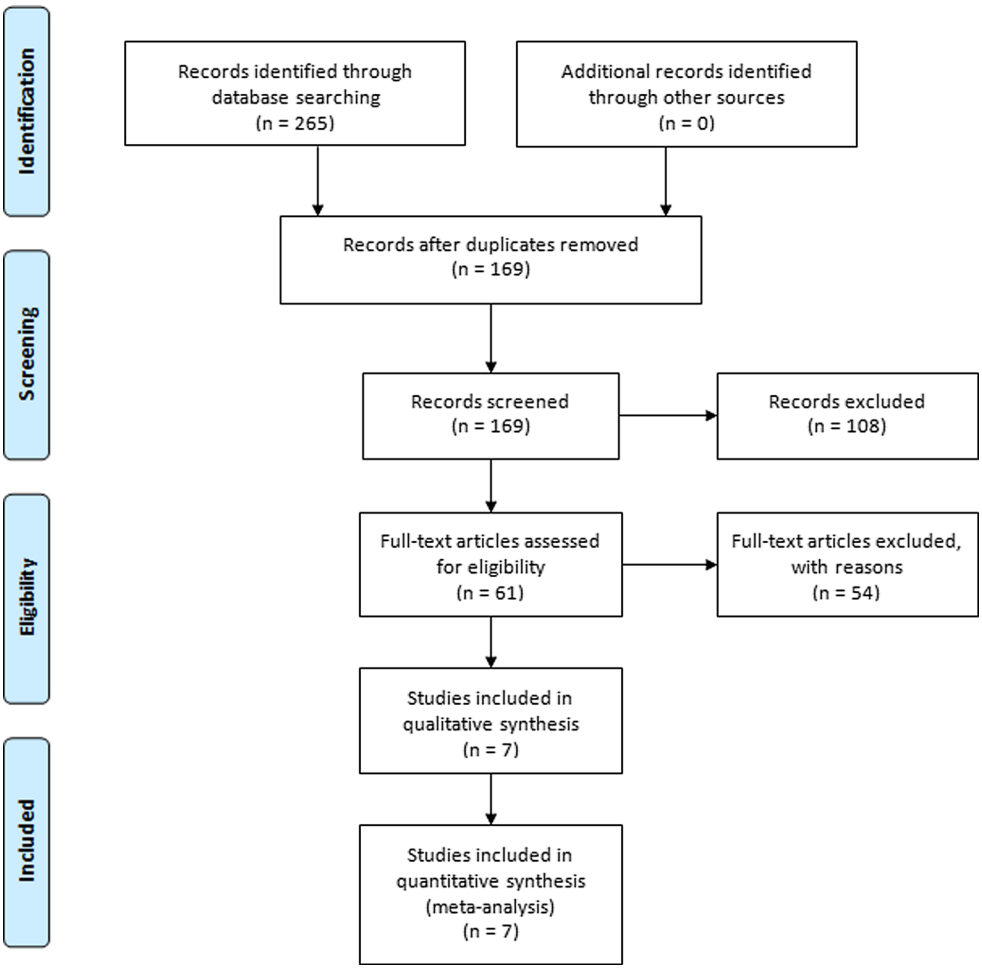

Fig. 1 Flow chart of study selection, following PRISMA recommendations

examined for duplicates. The remaining number of different articles was 169 (Fig. 1), which was screened. No unpublished or ongoing trials were found. Of these records, 108 were excluded based upon the title, therefore 61 articles remained.

The remaining articles were assessed for eligibility and included primary research of 44 randomized, controlled trials and 17 secondary literatures such as meta-analysis or systematic reviews. The primary literature was examined by one assessor (TMC) for eligibility by reading the abstracts; 13 met the overall inclusion criteria. A reference search within the secondary literature revealed two relevant articles, which were not included in the primary literature search.

Two of the remaining 16 trials could not be located electronically [1, 29]. The authors of the two trials were contacted by mail with the intent to locate the articles, but these communications remained unanswered. The remaining 14 trials were read in full length. One trial [4] was describing temporary results of larger studies already included in the search and therefore excluded. One trial [9] was a part of an earlier, lager trial and therefore excluded. Furthermore, six studies [7, 11–14, 21] were excluded, as they did not meet the inclusion criteria for this meta-analysis. One article [5] described two independent randomized, controlled trials and is therefore accounted as two trials. Seven randomized, controlled trials remained [4, 5, 10, 15, 22, 24] to be included in this meta-analysis.

Study appraisal

The six trials were independently assessed for inclusions by two reviewers (TMC and KWB) using the Jadad score (Table 1). The Jadad score is the most widely used scale to assess the quality of randomized controlled trials [19]. It includes three different aspects within a randomized, controlled trial: randomization, blinding and the account of all patients. The maximum score is five points. Disagreements between the assessors were resolved by discussion.

Statistical analysis

Categorical variables are presented as numbers (%), while normally distributed continuous variables and nonparametric continuous variables are presented as mean (standard

Table 1 study appraisal

Trials	Randomization	Blinding	Account of all patients	Overall	Critical appraisal
Cetti et al. [3]	1	1	1	3	Underpowered
Kangas et al. [10]	1	0	1	2	Underpowered
Mortensen et al. [15]	2	0	1	3	Inconsistent follow-up
Saleh et al. [22]	1	0	0	1	Unclear inclusion criteria
Costa et al. [5] operative	2	0	1	3	Selection bias at inclusion
Suchak et al. [24]	2	0	1	3	Missing data of patients

This study appraisal was carried out using the Jadad scale for reporting randomized controlled trials. The maximum score is 5 points (2 points for appropriate randomization, 2 points for appropriate blinding and 1 point if the fate of all patients of the trial is known). If the randomization or the blinding is inadequate, points are abducted

deviation) or median (range), respectively. Dichotomous outcomes were compared by pooled odds ratios (95 % confidence intervals, CI) using the Mantel–Haenszel estimator and chi-squared test, while mean differences (95 % CI) were calculated for normally distributed outcomes employing Student's *t* test. One trial displayed a zero event in re-rupture. Typically, this implies the use of risk difference instead of odds ratio, as the zero-event trials are not included in the calculation when using odds ratio. The study presents the pooled odds ratio as it is intuitively easier to understand. Nonparametric data not directly applicable for meta-analysis were transformed to the parametric counterpart using the methods described by Hozo et al. [6].

Weighted estimates are presented on forest plots assuming fixed effects in the absence of significant heterogeneity, defined as $I^2 > 50$ % or a Chi-squared p value <0.05. Publication bias was ascertained by funnel plots. A p value <0.05 was considered statistically significant in all analyses, using RevMan 5.2 (Cochrane Collaboration, Nordic Cochrane Center, Denmark).

Results

The seven included randomized, controlled trials compared functional rehabilitation and immobilization after acute Achilles tendon rupture. Three trials [3, 10, 15] investigated the effect of controlled early motion, one trial [24] investigated the effect on controlled early weight-bearing, and three trials [5, 22] investigated the combined effect of controlled early motion and weight-bearing. The selected trials were of low-to-moderate methodological strength, with Jadad scores of three or below (Table 1). The funnel plots regarding "re-rupture rate" and "major complications" showed a symmetric inverted funnel shape, making publication bias unlikely.

Five trials (339 participants) investigated operative treatment [3, 5, 10, 15, 24] and two trials conservative treatment (88 participants) [5, 22]. They included 344 men, 82 women and 1 not specified. The age range of the participants was 17 years to 79 years. Two hundred and eleven participants were treated with functional rehabilitation and 216 participants with immobilization.

Participants were followed for a minimum of 6 months [10, 24] to a maximum of 24 months [15]. Primary outcome measures of the trials were the re-rupture and complication rate. Secondary outcomes were strength, range of motion, atrophy, tendon separation, tendon thickness, adhesions, questionnaires, patient's satisfaction, pain, sick leave, return to sport and functional outcomes such as walking and standing on tiptoes.

All trials reported the re-rupture rate (Fig. 2). In the group treated with functional rehabilitation, 3.5 % (7/200) sustained a re-rupture. In the group treated with immobilization, 3.9 % (8/204) sustained a re-rupture. Odds ratio for re-rupture was 0.91 (n.s.).

Major complications are reported among 27 of all the trials participants; 5 % (9/180) reported a complication within the functional rehabilitated group (6 infections). All of these complications occurred in operatively treated participants. Within the immobilized group, 10 % (18/184) reported a complication (infections, paresthesia, rupture of the contralateral leg, wound slough, nonunion and deep vein thrombosis). The odds ratio was 0.53 (n.s.) (Fig. 3).

Strength was commonly measured at the 6 and 12 month follow-up. No significant differences were found between groups in 5 of the trials. One trial [3] showed a significant difference at the twelfth month follow-up ($p < 0.001$) favoring functional rehabilitation. The measuring technique and the equipment differed substantially between the trials.

Range of motion (ROM) was as an outcome measure in all trials. The contralateral leg was used as reference, but again the method for measuring varied between the trials. At 1-year follow-up, only Saleh et al. [22] found a

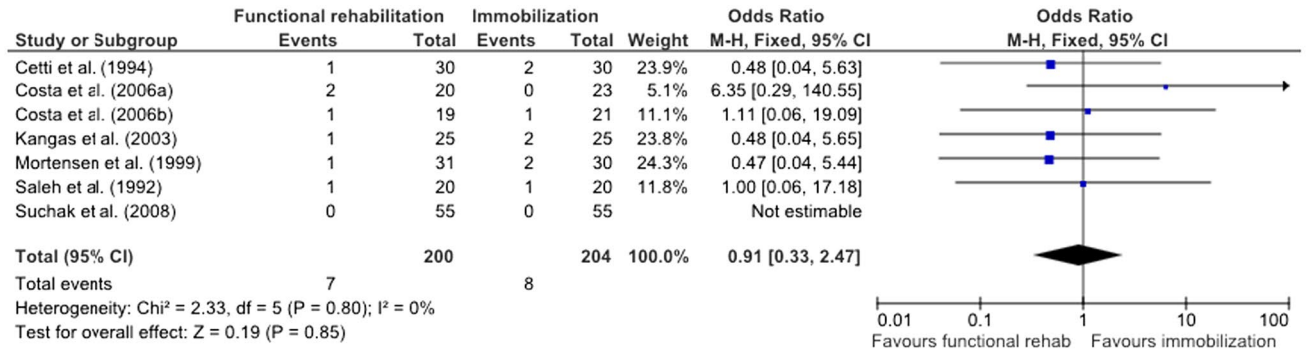

Fig. 2 Re-rupture rate compared by odds ratio (95 % CI). Costa et al. [5] and Mortensen et al. [15] are here set as the number of patients at the last follow-up. The missing patients are due to loss to the last follow-up

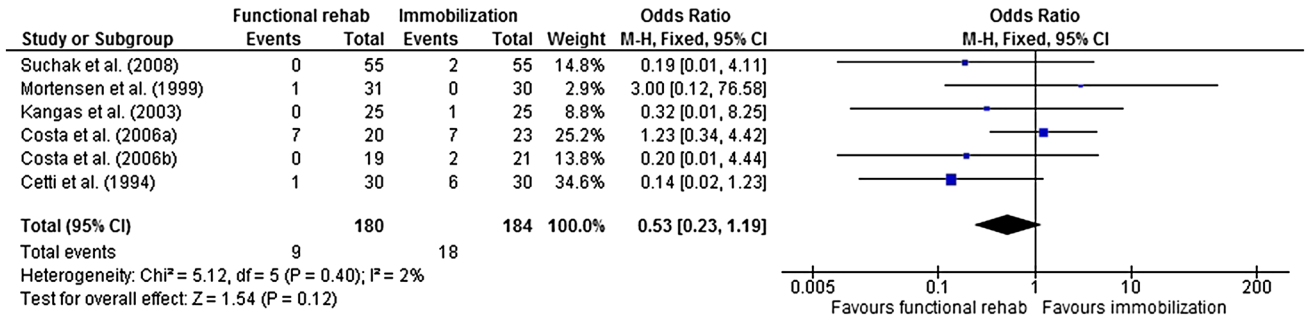

Fig. 3 Rate of major complications besides re-rupture calculated with fixed odds ratio (95 % CI)

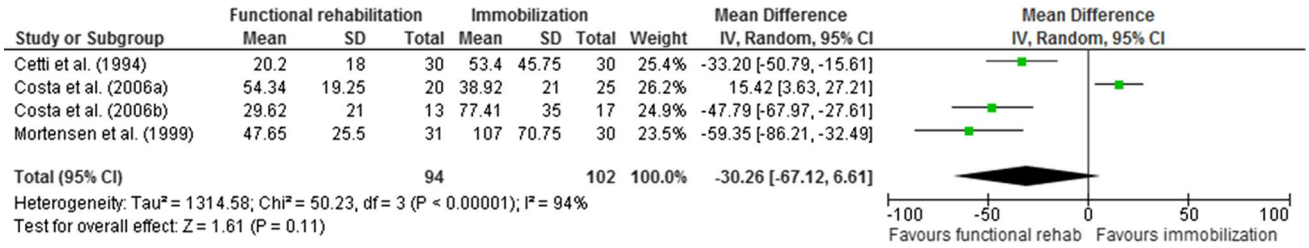

Fig. 4 Sick leave measured in terms of days away from work, calculated with mean difference using random effect (95 % CI). Costa et al. [5] recorded the sick leave in weeks. This was converted to days by multiplying the number with seven. The trials also used a 95 % confidence interval instead of range. Where the number of patients did not equal the total number of patients in each group, either the data were not recorded or the activity was not applicable to that individual

significant difference ($p < 0.001$) regarding range of motion of dorsiflexion between the groups, favoring the functional rehabilitation protocol. The other trials did not show significant differences.

Sick leave was described by Cetti et al., Costa et al. and Mortensen et al. [3, 5, 15] (Fig. 4). The mean difference for sick leave of 30 days was not statistically significant (p = n.s.). The analysis was performed using a random effects model due to heterogeneity of the data (Fig. 5).

Return to sport was described by Cetti et al., Costa et al. and Mortensen et al. [3, 5, 15]. Mortensen et al. [15] found that patients receiving controlled early motion returned at a median of 4 months (range 2–13), and the immobilization group returned at a median of 7.5 months (range 3–22). This difference was highly significant ($p \leq 0.001$). Results from Costa et al. [5] showed that patient treated with functional rehabilitation returned at a median of 39 weeks (range 18–60), and the immobilization group returned at a median of 26 weeks (range 40–90) (n.s.).

Patients' satisfaction was described by Cetti et al., Kangas et al., and Mortensen et al. [3, 10, 15] (Fig. 6). Overall, 72 % of patients treated with functional rehabilitation, and 52 % in the immobilized regime, thought the treatment was excellent (or were very satisfied).

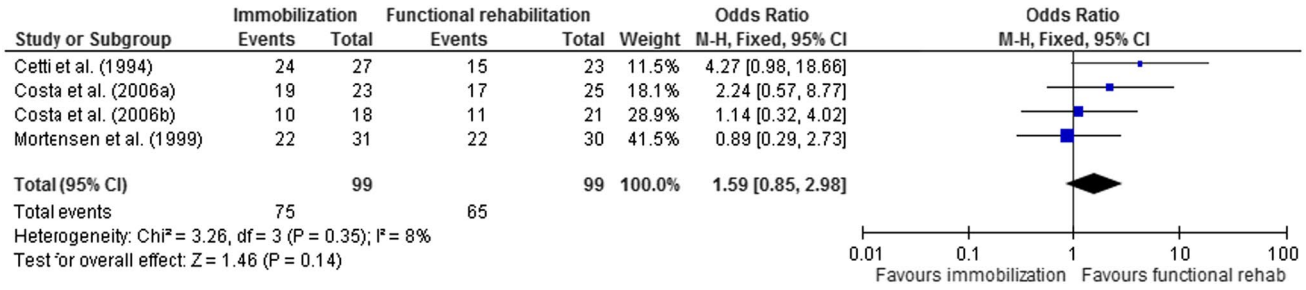

Fig. 5 Return to sport within 1 year of injury, using the calculated odds ratio (95 % CI). Only patients who had returned to the same level of sport activities as pre-injury are included here

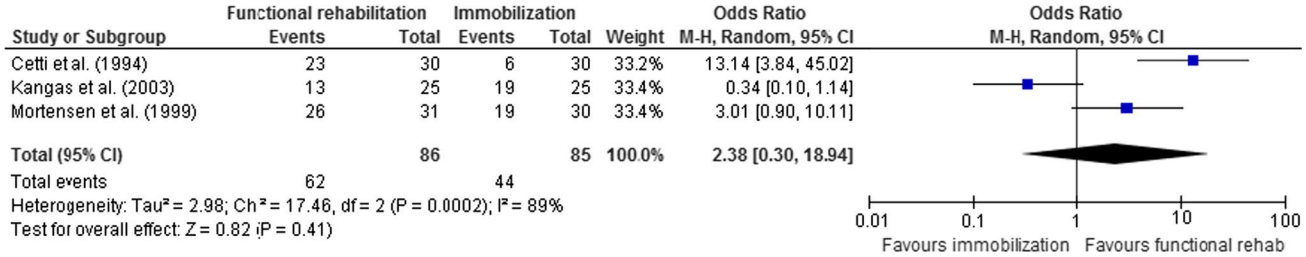

Fig. 6 Patient satisfaction regarding the overall treatment as "excellent," calculated with odds ratio (95 % CI)

Discussion

The most important finding of the present study was that no statistically significant differences were found comparing functional rehabilitation and immobilization in the treatment of acute Achilles tendon rupture. This finding is in contrast with the general recommendation in favor of functional rehabilitation supported by Nilsson-Helander et al. [17], Nistor et al. [18], Olsson et al. [20], Soroceanu et al. [23], Twaddle et al. [26] and Willits et al. [28].

The finding could be explained by several factors. It could be due to variation between the included studies in methodology, primary outcome and basic construct of the given treatment. Only the re-rupture rate and rate of complications were directly comparable across the trials.

Re-rupture rate was chosen as primary outcome measure as it is the most often used outcome measure in research concerning acute Achilles tendon rupture. It is, however, debatable whether re-rupture is a good primary outcome, as it does not include information concerning the function of the Achilles tendon. An alternative primary outcome, the Achilles tendon Total Rupture Score, has been suggested by Nilsson-Helander et al. [17]. It is a validated outcome measure doing a combined assessment of patient satisfaction and function.

Regarding major complications other than re-rupture, an insignificant difference in favor of mobilization was found. Only major complications were included in this review due to the availability of data. The influence of complications such as suture granuloma, keloid scar, pain and stiffness might also influence a successful rehabilitation.

A nonsignificant difference was found regarding self-reported patient satisfaction favoring the groups treated with functional rehabilitation (n.s.). This trend is supported by Wallace et al. [27] and Suchak et al. [24], who found similar results using a functional rehabilitation regime. The role of weight-bearing is of fundamental importance as it influences not only the quality of treatment but also the patient's ability to take care of himself/herself.

Looking at sick leave, a nonsignificant difference favoring controlled early motion was found. This finding is similar to the results found by Majewski et al. [14], where patients receiving controlled early motion returned 30 days earlier to work, compared with the immobilized patients' ($p = 0.042$). A possible explanation could be that controlled early motion encourages patients to move the affected limb more, and thus, the tendon can stand the tension of standing/walking and thereby recover faster than the immobilized patients. This meta-analysis is limited by the variability between treatment regime, outcome parameter and quality of the included trials.

When assessing the effect of functional rehabilitation one should ideally distinguish surgical and non-surgical treatment protocols as the conditions for healing are different. Also, controlled early motion should be distinguished from controlled early weight-bearing, as it is unknown how the two variables affect tendon healing

and how they interact. This distinction has not been possible due to the few available trials concerning functional rehabilitation.

Finally, it should be noted that all of the involved trials were designed as superiority trials, and as such they cannot claim the two rehabilitation regimes to be equal.

Conclusion

No statistically significant difference was found between functional rehabilitation and immobilization concerning re-rupture and major complications. The conclusion is limited due to the variation between the included studies. Larger, randomized controlled trials using validated outcome measures and stratifying for treatment regimens are needed to confirm the findings.

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Conflict of interest None.

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