

van der Eng DM, Schepers T, et al. Rerupture rate after early weightbearing in operative versus conservative treatment of Achilles tendon ruptures: a meta-analysis. J Foot Ankle Surg 2013;52(5):622-8.

Design: meta-analysis of randomized clinical trials

Purpose of study: to compare the rerupture rate of Achilles tendon ruptures treated with surgical repair and early weightbearing with the rerupture rates of ruptures treated conservatively with early weightbearing

PICOS:

- Patient population: patients with acute ruptures of the Achilles tendon
- Interventions: surgical repair followed by early weightbearing
- Comparison interventions: conservative care followed by early weightbearing
 - o Conservative treatment could include casting, bracing, orthosis, or bracing
- Outcomes
 - o Primary outcome was the rerupture rate
 - o Secondary outcomes: major and minor complications
 - Minor complications included superficial infection, transient pain, and painful or hypertrophic scars
 - Major complications included deep vein thrombosis, pulmonary embolus, deep infection, and sural nerve injury
- Study types: randomized clinical trials only

Study selection:

- Databases included MEDLINE and the Cochrane Library from January 2001 through December 2012
- Two authors independently assessed studies for inclusion and for methodologic quality and used a random effects model to combine the relative risks of adverse events from the included studies
 - o The guidelines of the Cochrane Bone, Joint, and Muscle group were used for assessing study quality

Results:

- 32 potentially relevant studies were considered, and 7 studies with 624 patients were included in the meta-analysis
 - o In 6 of the studies, surgery was open; in the seventh, surgery was done with a minimally invasive operation (an incision less than 5 cm)

- All 7 studies reported rerupture dates, and the authors analyzed separately studies with early weightbearing (before 4 weeks, n=4) and later weightbearing (after 4 weeks, n=3)
 - o In both early and late weightbearing, there were no statistical differences in rerupture rates between operative and conservative treatment; the pooled risk ratios for rerupture had 95% confidence intervals which included the null value of 1.0
 - o In the pooled analysis of all 7 studies, the rerupture rate was lower for operated than for conservative interventions, but again the 95% confidence interval included the null value of 1.0
 - That is, the pooled risk ratio for rerupture for all 7 studies was 0.50, with 95 confidence interval from 0.25 to 1.0
- Analysis of complications other than rerupture were divided into major and minor complications as described above
 - o For both major and minor complications, the complication rates were higher for surgery than for conservative treatment, but as with the rerupture rates, the 95% confidence intervals for the risk of complications included the null value of 1.0

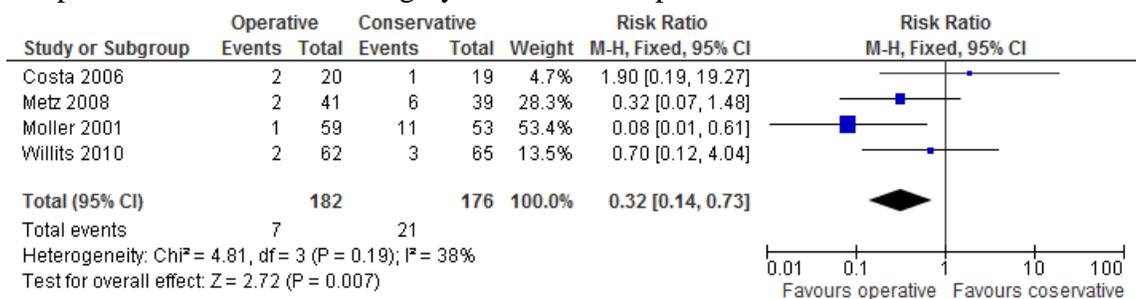
Authors' conclusions:

- The present meta-analysis showed no significant differences in rerupture rates between patients treated surgically and those treated conservatively
- No differences were seen in the incidence of minor or major complications after early weightbearing between surgically and nonsurgically treated patients, but for the total group of patients, there were significantly more complications with surgery than with nonoperative treatment; no less than 1 in 6 surgical patients had complications, compared with 1 in 13 conservatively treated patients
- Future randomized trials should be done with greater methodological rigor than in the studies which were available for this analysis, with adequate concealment and blinding of outcome assessors and with large patient numbers

Comments:

- Most of the studies analyzed in this analysis were also analyzed in an earlier Cochrane Review (Khan 2010), but the conclusions differ
- Khan reported more reruptures with conservative treatment than with surgery
- Khan included some studies published prior to 2000, and this study did not include those studies
 - o However, excluding those earlier studies did not change the effect that Khan calculated for rerupture rates; the rate was still lower with surgical than with operative treatment

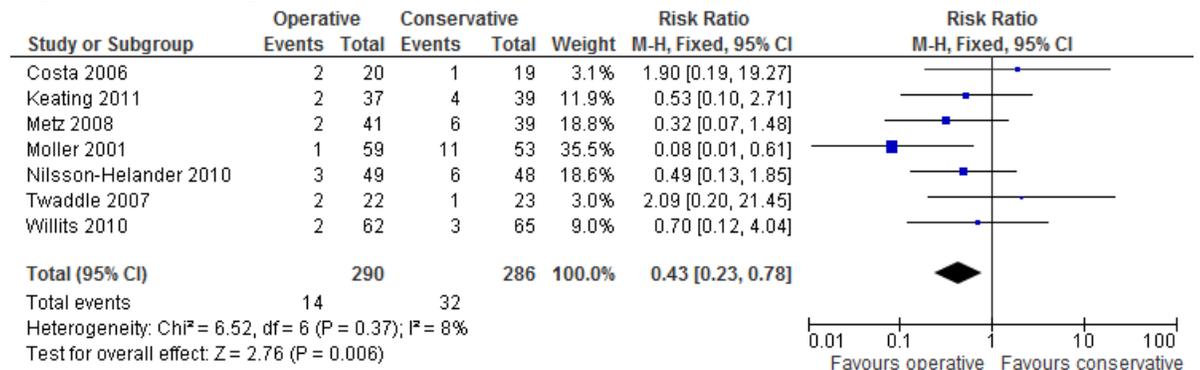
- The current meta-analysis used a random effects model rather than the fixed effect model which Khan used in the Cochrane Review, based on a judgment that the studies were heterogeneous and that this was the more appropriate model to use
- The authors used I^2 as a measure of heterogeneity, with values greater than 30% considered heterogeneous
 - o This is a fairly low I^2 to consider as heterogeneous, since 50% is more commonly used for this definition
 - o The only rerupture rate for which I^2 was greater than 30% was in Figure 2 where the early weight bearing had a I^2 of 38%; for the late weight bearing and for the 7 studies combined, I^2 was less than 30%, and for all 7 studies it was in fact 0%
- A random effects model will tend to have wider confidence intervals than a fixed effect model, due to assuming that there are two sources of variation among studies rather than only one
 - o A fixed effect model assumes that all variation between studies is due to sampling error (due to chance)
 - o A random effects model assumes that the variation between studies arises from sampling error (as with the fixed effect model) and also from genuine differences between studies such as type of patient, type of operation, severity of case, intensity of conservative treatment, and other unknown factors
 - o This means that a statistically significant result is less likely with a random effects model than with a fixed effect model
- Because the heterogeneity is actually quite low, a fixed effect model would have been a more appropriate choice of analysis, especially since the authors have used the lack of statistical significance (95% confidence intervals including the null value of 1.1) to support the conclusion that rerupture rates are not greater with conservative than with operative treatment
- A fixed effect model analysis of the data in Figure 2 supports the conclusion that for early weight bearing, delayed weight bearing, and for all 7 studies combined, the rerupture rate is lower with surgery than with nonoperative treatment



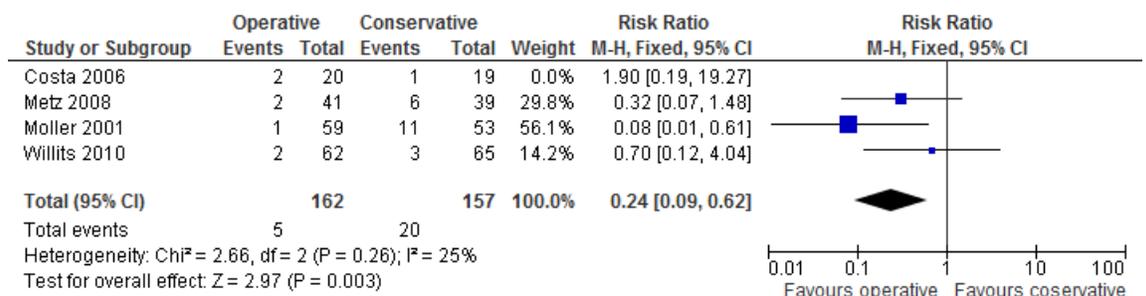
- This analysis of the top of Figure 2 shows that the pooled risk ratio for the four studies is 0.32 with confidence intervals from .014 to 0.73, which excludes the null

value of 1.0 as reported by the authors, whose risk ratio of 0.40 had confidence intervals from 0.12 to 1.32

- For the second part of Figure 2, the three delayed weight-bearing studies, the fixed and random effects models are very similar
- However for the 7 studies combined, the fixed effect model has a lower risk of rerupture with operative than with nonoperative treatment, with a risk ratio of 0.43 and a 95% CI from 0.23 to 0.78, even though the total number of events analyzed (14 out of 290 with operative and 32 out of 286 with conservative) is identical between Figure 2 and the figure below:



- On other consideration is that the inclusion of Costa 2006 in Figure 1 is not appropriate, since Costa conducted two separate randomized studies of early versus late weightbearing in two separate patient populations, one treated with surgery and the other treated conservatively; the randomization was not between surgery and conservative treatment
 - o It is likely that the surgically treated patients differed from those treated conservatively, and it is likely that the difference is associated with the severity of injury, or with other factors which could increase the risk of rerupture
 - o Costa 2006 therefore did not belong at the top of Figure 2, and its removal from the figure further reduces the risk ratio for rerupture to 0.24 with a 95% CVI from 0.09 to 0.62



- Therefore, the earlier analyses showing lower rerupture rates with operative treatment are better supported by appropriate analysis of the data than that used by the authors here

Assessment: inadequate for evidence that there is no difference in rerupture rates between surgically and conservatively treated Achilles tendon ruptures (inappropriate use of a random effects model which obscures clinically and statistically significant differences in rerupture rates between randomized groups)

References:

Costa ML, MacMillan K, et al. Randomised controlled trials of immediate weight-bearing mobilisation for rupture of the tendo Achillis. *J Bone Joint Surg [Br]*2006;88-B:69-77.

Khan RJ, Carey Smith RL. Surgical interventions for treating acute Achilles tendon ruptures. *Cochrane Database Syst Rev*. 2010 Issue 9 Art #:CD003674. doi: 10.1002/14651858.CD003674.pub4