

CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In adults with Achilles tendinopathy, do gastroc/soleus eccentric exercises or corticosteroid injections have better outcomes in decreasing pain?

AUTHOR

Prepared by	Mark Boles	Date	November 22, 2014 Revised February 5, 2015
Email address	mark_boles@med.unc.edu		

CLINICAL SCENARIO

Achilles tendinopathy is a relatively common pathology seen in the clinic, especially in active older adults. One of the most, if not *the* most, common complaints of Achilles tendinopathy is pain. In the clinic I have observed how this pain often limits an individual's ability to participate in the physical activities that they enjoy.

Historically, physicians have often relied on corticosteroid injections to treat patients with Achilles tendinopathy due to an effective relief of patient reported pain and decreased swelling. However, my clinical experience is that recurrence of pain is common, leading me to suspect that this method of treatment might not target the root problem causing Achilles tendinopathy. Moreover, corticosteroid injections may also have deleterious effects on tendon leading to further pathology.⁵

Eccentric exercises are often included in the physical therapy treatment of Achilles tendinopathy. I would like to investigate this more in detail to determine if it is truly an effective treatment in decreasing patient report of pain. I have encountered a patient in the clinic (via direct access) who asked me if she should seek a physician for management of her Achilles tendinopathy and if I would recommend a corticosteroid injection for relief of pain. Through this evidence-based search, I hope to find a valid answer to this question. Moreover, if the literature indicates corticosteroids as being more beneficial than eccentric exercises in decreasing pain, this would prompt me to research other common physical therapy treatments for the management of a patient with Achilles tendinitis.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- Fourteen studies were located that met the inclusion/exclusion criteria, including 10 randomized controlled trials, 1 systematic review of randomized controlled trials, 2 case series, and 1 retrospective study. Three studies were reviewed in detail.
- There were significant improvements in pain, both statistically and clinically, with the use of an eccentric exercise protocol or repetitive low-energy shock-wave therapy over a 12-week period.
- There were no statistical or clinically significant improvements in pain with the use of a steroid injection.

CLINICAL BOTTOM LINE

Current best evidence suggests that an eccentric exercise protocol results in greater pain reduction than a steroid injection in Achilles tendinopathy. Patients who performed eccentric exercises on a daily basis for a 12-week period demonstrated significant reductions in pain and increased activity levels. Conversely, limited research indicates that steroid injections have no benefit in pain reduction over 12 weeks. Eccentric exercises delivered through a physical therapist protocol are an appropriate, non-invasive alternative to steroid injections. Further research of high methodological quality is required to study the benefits of steroid injections in pain reduction in this population.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	Intervention (or Assessment)	Comparison	Outcome(s)
Active Run* Achilles tendinitis Achilles tendinosis Achilles tendinopathy	Eccentric exercise* Eccentric* Eccentric decline Eccentric loading Physical therapy Physiotherapy Rehabilitation Load	Corticosteroid injection* Injection Corticosteroid* Steroid Cortisone Triamcinolone Kenalog Betamethasone Celestone Methylprednisolone Depo-Medrol	Pain Discomfort

Final search strategy:

(achilles OR triceps surae) AND (tendinitis OR tendinosis OR tendinopathy) AND (eccentric OR physical therapy OR physiotherapy OR rehabilitation OR load* OR decline)

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
PubMed	465	- Published within past 10 years - Human studies - 251
SPORTDiscuss	323	- Published from Jan 2002 – Sep 2014 - 268
Cochrane Library	1	- Once allowed trials, revised number of 58

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
<ul style="list-style-type: none"> • Studies with a protocol including eccentric exercises or corticosteroid injection for the treatment of Achilles tendinopathy. • Studies that used an outcome measure to assess pain. • Studied a population of adults with a diagnosis of midportion (non-insertional) Achilles tendinopathy. • Randomized controlled trials, case series or case reports relating to corticosteroids.

Exclusion Criteria

- Studies involving patients with a prior history of partial or complete rupture of the Achilles tendon.
- Studies with an eccentric exercise protocol published prior to the year 2000 or after September 2014.
- Any study other than a randomized controlled trial relating to eccentric exercise.
- Any study including patients with ankle or foot fracture, or soft tissue calcification.
- Studies involving participants reporting prior history of surgery for treatment of Achilles tendinopathy.

RESULTS OF SEARCH

A total of 14 relevant studies were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011)

- PEDro Scale: used to score all included articles with exception to the one systematic review, two case series and one retrospective study. Score from 0-10; 10 indicating highest quality. "Eligibility score" does not contribute to the total score.
- R-AMSTAR checklist: used to score systematic review. Score from 0-44; 44 indicating highest quality.
- The two case series and one retrospective study were rated subjectively for quality. Good, fair, and poor were the possible scores.

Summary of articles retrieved that met inclusion and exclusion criteria.

Author (Year)	Study quality score	Level of Evidence	Study design
Rompe JD (2007) – Eccentric	7/10	2b	RCT
Roos EM (2004) – Eccentric	6/10	2b	RCT
DaCruz DJ (1988) – Steroid	7/10	2b	RCT
Chan O (2008) – Steroid	Poor	4	Case Series
Mafi N (2001) – Eccentric	5/10	2b	RCT
Peterson W (2007) – Eccentric	6/10	2b	RCT
Rompe JD (2009) – Eccentric	7/10	2b	RCT
Yu JH (2013) – Eccentric	7/10	2b	RCT
Knobloch K (2008) – Eccentric	6/10	2b	RCT
De Vos R (2006) – Eccentric	5/10	2b	RCT
Tumilty S (2012) – Eccentric	9/10	2b	RCT
Gill SS (2004) – Steroid	Poor	4	Case Series
Read MTF (1992) – Steroid	Poor	4	Retrospective Study
Coombes BK (2010) – Steroid	34/44	1a	Systematic Review of RCTs

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Eccentric Loading, Shock-Wave Treatment, or a Wait-and-See Policy for Tendinopathy of the Main Body of Tendo Achillis (Rompe JD, et al. 2007).**
- **Clinical improvement after 6 weeks of eccentric exercise in patients with mid-portion Achilles tendinopathy – a randomized control trial (Roos EM, et al. 2004)**
- **Achilles Paratendonitis: An Evaluation of Steroid Injections (DaCruz DJ, et al. 1988)**
- The first two papers by Rompe, et al and Roos, et al relating to eccentrics were chosen because they had higher study quality scores than many of the other eccentric papers. The other two articles that scored a 7/10 were not chosen because one of them (Yu, 2013) had significantly different baseline pain scores between the two groups, and the other (Rompe, 2009) had fewer participants in their study.
- The study by DaCruz, et al was chosen because it was the only RCT found that discussed Achilles tendonopathy specifically. The systematic review of RCTs that was graded as the best evidence, while

demonstrating a high level of evidence (1a), primarily discussed the outcomes of steroid injections with other tendinopathies in the body (e.g. patellar tendon, rotator cuff tendon, lateral elbow tendon).

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Eccentric Loading, Shock-Wave Treatment, or a Wait-and-See Policy for Tendinopathy of the Main Body of Tendo Achilles by Rompe JD, Nafe B, Furia JP, et al. (2007)

Aim/Objective of the Study/Systematic Review:

The aim of this study was to determine if eccentric calf strengthening, repetitive low-level shock-wave therapy (SWT), or rest is the most effective treatment method for mid-portion Achilles tendinopathy

Study Design

- Randomized controlled trial
- Participants were randomly assigned (block randomization in blocks of 3) using a concealed allocation method to one of three 12-week interventions and were assigned to treatment groups using a computerized random-number generator. An assistant unaware of block sizes allocated interventions using opaque sealed envelopes marked based on the allocation schedule.
- The interventions were eccentric calf strengthening (n=25), SWT (n=25), and rest (n=25).
- Participants completed baseline assessment by the lead author (Rompe JD) prior to randomization. Observer-blinded outcome assessments were also performed 16 weeks after the baseline assessment. Outcome assessments were not performed immediately following the 12-week intervention because midportion Achilles pain has a noninflammatory characteristic requiring at least 4 months for collagen turnover and remodelling.^{1,4}

Setting

Participants were diagnosed with Achilles tendonopathy by one of 3 orthopaedic physicians involved in the study in a primary care setting. After diagnosis, the participants were then referred to the primary care clinic of the lead author in this study. The lead author practices at an OrthoTrauma Clinic in Gruenstadt, Germany, which is where participants received treatment.

Participants

- To be included in the study the participants had to be aged 18-70 years. This study included 75 patients, 46 females and 29 males, with a diagnosis of chronic midportion (noninsertional) Achilles tendinopathy. Eccentric training group (n=25): mean age 48.1, SD 9.9. Shock-wave therapy group (n=25): mean age 51.2, SD 10.3. Rest group (n=25): mean age 46.4, SD 11.4.
- Participants were eligible if they demonstrated local thickening of the tendon and/or irregular tendon structure with hypoechoic areas and/or irregular tendon fiber orientation via ultrasound.
- Symptoms of chronic midportion Achilles tendinopathy were present in all participants for at least 6 months (mean duration of symptoms in included participants: 10.8 months). Furthermore, all participants had previously received unsuccessful nonoperative treatment for greater than 3 months.
- A nonprobabilistic sampling method was used - purposive.
- Participants were recruited by one of 3 participating orthopaedic physicians who identified their patient as having Achilles tendon complaints. The physician then referred their patient to the clinic of the lead author to be evaluated. The lead author then decided if the patient was eligible.
- All three groups were comparable at baseline based on key demographic variables.
- 5 patients were lost to follow-up leaving 70 patients available for follow-up.

<p>Intervention Investigated</p>
<p><i>Control – Rest group</i></p>
<ul style="list-style-type: none"> • Rest group (RG): • Patients were seen once more by their orthopaedic physician during the 12-week intervention period. • Modification of training, basic ergonomic advice, and stretching exercises were discussed with patient. • Medication was prescribed if patient required it for pain. • Patients were instructed to wait for spontaneous recovery.
<p><i>Experimental – eccentric group and shock-wave therapy group</i></p>
<ul style="list-style-type: none"> • Eccentric group (EG): • The lead author demonstrated the eccentric loading exercise program to each patient and each patient was given a written manual on how to progress. • Eccentric loading was performed standing upright on a step with full body weight on the forefoot of the affected leg. The starting position was full plantarflexion of the ankle, and then the calf was loaded by lowering the affected limb into full dorsiflexion. They were to return to full plantarflexion of the affected leg by using their unaffected leg and upper extremities, ensuring no concentric loading was performed. • Exercises were performed with the knee in full extension to eccentrically load the gastrocnemius, as well as partially flexed to eccentrically load the soleus. The goal was to complete 3 sets of 15 with a 1-minute rest between sets, 2 times per day, 7 days per week for 12 weeks. • Patients were encouraged to continue exercises if they experienced mild or moderate pain, but to discontinue if the pain was unbearable. • Initially, the patient eccentrically loaded the calf with only their body weight. If the patient reported no pain at the end of the third set of body weight loading, they were to progress by adding a 5 kg book bag. Patients were instructed to continue adding weight in multiples of 5 kg if they reported no pain at the end of the third set. • An assistant reassessed each patient after 6 weeks to ensure proper form/technique of the intervention. • SWT group: • Was performed by the lead author in three sessions at weekly intervals using a radial shock-wave device. • 2000 pulses were applied with a pressure of 3 bars and a treatment frequency of 8 pulses/second at each session. • The area of maximal tenderness was treated using a circumferential pattern.
<p>Outcome Measures (Primary and Secondary)</p>
<p>All outcome measures were performed before randomization and at 16 weeks after baseline assessment by a blinded observer in the primary care clinic.</p> <ul style="list-style-type: none"> • VISA-A score (primary efficacy endpoint at 4 months): (0-100); has been validated for Achilles tendon problems. Contains 8 questions covering 3 domains: pain, function, and activity. Scores are summed to give a total out of 100, with a score of 100 indicating an asymptomatic person. • Likert scale (secondary): (1-6); used to measure general assessment based on how much the person agrees or disagrees with a statement. A score of 1 indicates being completely recovered; a score of 6 indicates much worse when compared to baseline. • Load-induced pain (secondary): (0-10); measured with 11-point numeric rating scale (NRS) (0 indicates no pain, 10 indicates very severe pain). • Pain threshold (secondary) [kg]: measured with an algometer using a 1-cm² tip. The pain threshold was identified as the minimum pressure that elicited pain in the tenderest area of the Achilles tendon. • Tenderness: measured with an algometer using a 1-cm² tip. Patient rated pain according to the 11-point NRS (0-10) when a pressure of 3 kg was applied to the tenderest area of the Achilles tendon. • Tendon diameter (secondary) [mm]: measured AP diameter of the Achilles tendon of the affected and unaffected leg with ultrasound.
<p>Main Findings</p>
<p>[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under 'critical appraisal' on next page]</p>
<ul style="list-style-type: none"> • 5 patients were lost to follow-up; outcome analysis was completed using the last set of data provided by these 5 patients.

- The authors report no serious complications of all patients participating in this study. (Rompe et al., 2007, p. 380)
- Authors calculated that 25 subjects must be treated in each group to determine a statistically significant treatment effect size of 3.0 points on the NRS, assuming a standard deviation of 2.0. The sample size accounted for a 10% loss to follow-up, a type I error rate of 0.05, and a power of 0.8.
- **VISA-A Score:** Mean scores at baseline demonstrated no significant differences in all groups: (eccentric group (EG), 50.6 ± 11.5; SWT, 50.3 ± 11.7; RG, 48.2 ± 9.0). EG and SWT groups showed significantly better results (all P<.01) at 4-month follow-up compared to baseline (EG, 75.6% ± 18.7%; SWT, 70.4% ± 16.3%; RG, 55.0% ± 12.9%), and both groups had significantly better results than patients in the rest group (RG), all P<.001; power=0.99). The between-group difference mean at 4-month follow-up of EG and SWT was 5.2 (95% confidence interval; CI=-3.9 to 14.3; P=.259; power=0.13), indicating that there was no statistically significant difference in outcomes between these two groups.
- **General assessment:** Mean scores on the Likert scale at baseline were (EG, 5.3 ± 0.8; SWT, 4.8 ± 0.9; RG, 4.8 ± 0.8). Mean scores on the Likert scale at 4-month follow-up were (EG, 2.7 ± 1.5; SWT, 2.9 ± 1.5; RG, 4.3 ± 1.6). The between-group difference mean at 4-month follow-up of EG and SWT was -0.2 (95% confidence interval; CI = -1.0 to 0.5); P=.557); EG and RG was -1.6 (95% confidence interval; CI = -0.8 to 2.4; P<.001); SWT and RG was -1.4 (95% confidence interval; CI = -2.2 to 0.6; P=.001). These findings indicate that patients from EG and SWT groups demonstrated significantly better results than patients from RG (P<.001; P = .001). Between 60% of patients in EG, 53% of patients in SWT, and 24% of patients in RG reported a 1 (completely recovered) or 2 (much improved) on the Likert scale at 4-months follow-up.
- **Load-induced pain:** Mean scores on the NRS at baseline were (EG, 7.0 ± 0.8; SWT, 6.8 ± 0.9; RG, 7.9 ± 0.6), demonstrating no significant difference between all groups. Mean scores on the NRS at 4-month follow-up were (EG, 3.6 ± 2.3; SWT, 4.0 ± 2.2; RG, 5.9 ± 1.8), showing statistically significant improvements from the pre-treatment level in all groups (all P<.001). The between-group difference mean at 4-month follow-up of EG and SWT was 0.5 (95% confidence interval; CI = -0.8 to 1.6; P=.494); EG and RG was 2.4 (95% confidence interval; CI = 1.3-3.5; P<.001); SWT and RG was 2.0 (95% confidence interval; CI = 1.0-3.0; P<.001). These findings indicate that patients from EG and SWT achieved significantly better results than patients from RG (all P<.001).
- **Pain threshold [kg]:** Mean pain threshold values at baseline were (EG, 1.5 ± 0.6; SWT, 1.4 ± 0.8; RG, 1.6 ± 0.8), demonstrating no significant difference between all groups. Mean pain threshold values at 4-month follow-up were (EG, 3.1 ± 1.1; SWT, 2.8 ± 0.9; RG, 2.1 ± 1.0), and improvements from baseline were only statistically significant in EG and SWT (all P<.001). The between-group difference mean at 4-month follow-up of EG and SWT was 0.4 (95% confidence interval; CI = -0.1 to 0.9; P=.181); EG and RG was 1.0 (95% confidence interval; CI = 0.5-1.5; P<.001); SWT and RG was 0.7 (95% confidence interval; CI = 0.2-1.2; P=.008). These findings demonstrate that patients from EG and SWT had statistically better results than RG (P<.001; P = .008).
- **Tenderness:** Mean scores on the NRS at baseline were (EG, 7.1 ± 3.6; SWT, 6.4 ± 4.4; RG, 6.8 ± 3.1), showing no significant difference in all groups. Mean scores on the NRS at 4-month follow-up were (EG, 1.7 ± 3.9; SWT, 2.6 ± 4.2; RG, 4.3 ± 7.0), which show that improvements from baseline were statistically significant in all groups (all P<.001). The between-group difference mean at 4-month follow-up of EG and SWT was -0.9 (95% confidence interval; CI = -2.9 to 1.2; P=.393); EG and RG was -2.6 (95% confidence interval; CI = -5.5-0.3; P=.076); SWT and RG was -1.7 (95% confidence interval; CI = -4.7-1.3; P=.260). None of these between-group differences were statistically significant.
- **Tendon diameter [mm]:** Mean diameters of affected leg at baseline were (EG, 12.8 ± 4.1; SWT, 11.8 ± 4.7; RG, 11.3 ± 3.8). Mean diameters of unaffected leg at baseline were (EG, 5.3 ± 2.1; SWT, 5.5 ± 1.7; RG, 5.9 ± 2.0). These changes in tendon diameter were not significant in all three groups.

Original Authors' Conclusions

"Spontaneous recovery after more than 6 months of symptoms of tendinopathy of the main body of the Achilles tendon is unlikely in the vast majority of patients. Our results show that the likelihood of recovery after 4 months was comparable after both eccentric loading and SWT, as applied. Success rates were 50%-60%." (Rompe et al, 2007, p. 382).

Rompe et al. (2007) found that eccentric training or SWT for the treatment of chronic tendinopathy of the main body of the Achilles tendon can be effective and successful alternatives to surgical intervention.

Critical Appraisal

Validity

[Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]

Comment on missing information in original paper.

- PEDro Score: 8/10 based on Eligibility Criteria: Yes; Random Allocation: yes; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: No; Blind Therapist: No; Blind Assessors: Yes; Adequate Follow-up: Yes; Intention-to-treat analysis: Yes; Between Group Comparison: Yes; Point Estimates and Variability: Yes. (Eligibility score does not contribute to total score.)

Although this study performed observer-blinded outcome assessments before randomization and at 16 weeks after baseline assessment, the author states that it is still difficult to implement a blinded and unbiased assessment of outcomes in the primary-care setting.¹ This leads to the possibility of the independent observer becoming aware of the treatment being received by patients in some instances.¹ However, the author continues to explain that this likely would not have biased the results because the assistant was not directly involved in the management of patients.¹ Also, the blinding of subjects and therapists was not possible due to the inability to blind these interventions, as all interventions are visually identifiable to participant and therapist. This inability to blind interventions could have led to potential bias and/or a placebo effect. Even though power was excellent in regards to the NRS when comparing EG or SWT with RG, there was still a small number of patients included in this study. The authors found that power was weak when comparing EG and SWT, and in order to reach a power greater than 80%, a sample size of 140 patients per group would be required for adequate statistical analysis.¹ Nevertheless, all outcome measures used in this study were appropriate. The interventions used were well designed by the authors; however, there was a lack of standardization of the eccentric exercise group. The eccentric group was given instructions on their exercise protocol at baseline, and assessed once again after 6 weeks. This may lead one to question the true clinical significance of this intervention, seeing as many patients are treated by their therapist on a weekly basis. Although it was implicated that participants documented each treatment session on standardized forms, compliance to the eccentric intervention was not reported. This leaves one to wonder how much exercise the patients performed during this intervention. If the compliance forms demonstrated a lack in compliance, it would be plausible to conclude that the results for EG are lower than what is presented in this article. Follow-up measures of tendon diameter were also missing in the original paper. Of the 5 patients lost to follow-up, the last set of data provided by each patient was used to complete outcome analysis. There is one aspect of the article that is particularly confusing, possibly due to the wording: one of the outcomes assessed was "load-induced pain," which was not defined in great detail. In one section of the article they describe pain assessment as the severity of the patient's main complaint, pain during the day, and inconvenience, but load-induced pain was never mentioned. Lastly, it should be noted that the intervention period was 12-weeks long but the follow-up occurred at 16 weeks. This leaves 4 weeks after the intervention period in which we are unsure of what activities the participants are doing. An assessment of outcome should have been performed immediately after the 12-week intervention period, as well as at 16 weeks.

Interpretation of Results

[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean.

- This study provides evidence that eccentric loading and SWT have superior results compared to rest, and demonstrated significantly better results on the VISA-A score, general assessment, load-induced pain, and pain threshold at 4-months follow-up.
- Improvements from baseline in tenderness were statistically significant in all three groups ($P < .001$).
- MCID was estimated for each outcome by using half of the baseline standard deviation. The MCID scores indicate the smallest change in the outcome measure that is needed to demonstrate benefit to the patient. For example, the MCID for the VISA-A outcome in the EG is 9.35. This would indicate that the patient needs to improve their score by at least 9.35 points to be considered as having a beneficial change from the intervention.
- **VISA-A:** EG and SWT obtained significantly better results than patients from RG (all $P < .001$; power=0.99), telling me that EG and SWT are more effective than RG in producing better results according to the VISA-A. The Cohen's effect size was large ($d=1.28$) between EG and RG; large between SWT and RG ($d=1.05$); small between EG and SWT ($d=0.30$). This tells me that the magnitude of difference between EG and SWT were greater compared to RG. Furthermore, it indicates that there was not much difference in magnitude between EG and SWT, therefore not clinically meaningful. MCID: EG = 9.35; SWT = 8.15; RG = 6.45
- **General assessment:** EG and SWT obtained significantly better results than patients from RG ($P < .001$; $P = .001$), telling me that EG and SWT are more effective than RG in producing better results according to Likert scores on the general assessment. There was a large Cohen's effect size ($d=-1.03$) between EG and RG; large between SWT and RG ($d=-0.99$); and no effect between EG and SWT ($d=-0.13$). This tells me that the magnitude of difference between EG and SWT were greater compared to RG and that there was no difference in magnitude between EG and SWT, therefore not clinically meaningful. MCID: EG = 0.75; SWT = 0.75; RG = 0.8.
- **Load-induced pain:** EG and SWT demonstrated significantly better results than patients from RG (all $P < .001$), telling me that EG and SWT are more effective than RG in decreasing pain during loading according to the NRS. The Cohen's effect size was large ($d=-1.11$) between EG and RG; large between

SWT and RG ($d=-0.95$); and no effect between EG and SWT ($d=-0.18$). This tells me that the magnitude of difference between EG and SWT were greater compared to RG, and that EG and SWT had no difference in magnitude, therefore showed no clinical meaningfulness. MCID: EG = 1.15; SWT = 1.1; RG = 0.9

- **Pain threshold:** EG and SWT demonstrated significantly better results than patients from RG ($P<.001$; $P=.008$), which tells me that EG and SWT are more effective than RG in increasing pain tolerance when pressure is applied to the Achilles tendon. The Cohen's effect size was large ($d=0.95$) between EG and RG; large between SWT and RG ($d=-0.94$); and small between EG and SWT ($d=0.30$). This tells me that the magnitude of difference between EG and SWT were greater compared to RG, and that EG and SWT had similar sized differences and were not clinically meaningful. MCID: EG = 0.55; SWT = 0.45; RG = 0.50
- **Tenderness:** All groups showed improvements at 4-month follow up that were statistically significant (all $P<.001$); however, between-group differences were not statistically significant. The Cohen's effect size was moderate ($d=-0.46$) between EG and RG; small between SWT and RG ($d=-0.30$); and small between EG and SWT ($d=-0.22$). This tells me that the magnitude of difference was not clinically meaningful except for moderately between EG and RG. MCID: EG = 1.95; SWT = 2.1; RG = 3.5
- **Tendon diameter:** This data was not provided in the study; however, the author states, "no group showed significant changes of the dimensions of the Achilles tendon of the affected leg compared with baseline ultrasound measurement." (Rompe et al., 2007, p. 380)

(2) Description and appraisal of: Clinical improvement after 6 weeks of eccentric exercise in patients with mid-portion Achilles tendinopathy – a randomized trial with 1-year follow-up by Roos EM, Engstrom M, Langerquist A, et al. (2004)

<p>Aim/Objective of the Study/Systematic Review:</p>
<p>The aim of this study was to determine if eccentric calf exercises, prolonged stretching with the use of a night splint, or a combination of both is beneficial for decreasing pain and improving function in patients with mid-portion Achilles tendinopathy.</p>
<p>Study Design</p>
<ul style="list-style-type: none"> • Randomized controlled trial • Participants were randomly assigned using a concealed allocation method to one of three 12-week interventions. The examiner randomized the patients by selecting an envelope from a box holding 60 randomly ordered envelopes (20 envelopes for each treatment group). • The interventions were eccentric calf exercises (N=16), eccentric calf exercises and night splint (N=15), or night splint only (N=13). • A baseline clinical examination was completed by one examiner to ensure an accurate diagnosis of midportion (non-insertional) Achilles tendinopathy. This same examiner randomized the patients to treatment groups. • Outcomes were measured via patient-administered questionnaire at baseline, and at 6, 12, 26 and 52 weeks after start of the treatment.
<p>Setting</p>
<p>Patients seeking treatment for insidious onset of Achilles tendinopathy in the primary care setting were recruited by one of 23 primary care physicians in Helsingborg, Sweden. Once these recruiting primary care physicians determined that their patients met the written inclusion criteria for this study, they were referred to one examiner. The study does not indicated what setting the intervention was provided.</p>
<p>Participants</p>
<ul style="list-style-type: none"> • To be included in the study the participants had to be 20-60 years of age who normally participate in physical activity. Their symptoms of pain during physical activity were required to be present for more than 4 weeks. Furthermore, symptoms of pain were required to be 2-6cm proximal of the insertion to be identified as non-insertional (midportion) Achilles tendinopathy.

- A nonprobabilistic sampling method was used – purposive
- This study included 44 patients, 23 females and 21 males. All participants presented with pain and swelling 2-6cm proximally to the Achilles tendon, confirming a diagnosis of midportion Achilles tendinopathy. Eccentric calf exercise group (N=16), eccentric calf exercises and night splint group (N=15), and night splint only group (N=13).
- Mean age for all participants: 46 (range, 26-60 years). Mean ages for each group was not provided.
- Median symptom duration was 5.5 months (range, 1-180 months). 86% reported symptoms > 3 months.
- 65% of patients were involved in sports before current symptoms, 86% of patients reported pain daily or always, and 14% reported having pain on a weekly basis.
- There were no significant differences in key demographics at baseline (age, sex, activity level, or symptom duration between the groups). The only difference noted was seen in the patients randomized to the splint group who reported significantly better foot and ankle-related quality of life at baseline.
- 33 patients were available for follow-up at 12 weeks and 35 patients were available for follow-up at 52 weeks.

Intervention Investigated

Control – Eccentric exercises + night splint

- **Eccentric exercises + night splint group (ENS)**
- This group performed both interventions. The interventions are explained in greater detail below.

Experimental – Eccentric exercises and night splint

- **Eccentric exercise group (EE)**
- All patients were instructed how to perform the eccentric exercises by one physical therapist.
- Eccentric loading was performed standing upright on a step with full body weight on the forefoot of the affected leg. The starting position was full plantarflexion of the ankle, and then the calf was loaded by lowering the affected limb into full dorsiflexion. They were to return to full plantarflexion of the affected leg by using their unaffected leg, ensuring no concentric loading was performed.
- The patients progressively worked their way up to performing 3 sets of 15 of the eccentric exercises with a straight and bent knee, 2 times per day, 7 days per week for 12 weeks.
- In attempts to decrease delayed onset muscle soreness, the first 2 days the patients performed 1 x 15 repetitions; days 3-4 they performed 2 x 15 repetitions; days 5-7 they performed 3 x 15. The exercises were only performed with an extended knee for the first week. The patients were instructed to perform 3 x 15 repetitions with both extended and bent knees at each exercise occasion during weeks 2-12.
- Initially the patient eccentrically loaded the calf with only their body weight. Patients were encouraged to progress loading by adding books or other weight to a backpack if they were able to perform their exercises without discomfort.
- The patient saw the therapist after 1 week of treatment to discuss any issues with the regimen and to see how the program was performed.
- The therapist contacted the patient via phone after 6 weeks to discuss any issues with the regimen and progressing the intensity of the program. A manual was also given to the patients at baseline on how to progress the intensity of the program, including contact information for the physical therapist so they could call if they had any questions.
- **Night splint group (NS):**
- An anterior night splint was used to hold the foot in 90 degrees of dorsiflexion.
- Patients were instructed on proper donning and doffing of the splint, and to only use it at night while sleeping.
- They were encouraged to use the splint 7 nights per week for 12 weeks.
- Issues relating to possible side effects of wearing the splint were also discussed.

Outcome Measures (Primary and Secondary)

All outcomes were performed at baseline and at 6, 12, 26 and 52 weeks after initiation of treatment via a patient-administered questionnaire. The questionnaire was mailed to the patients and returned by mail to decrease investigator bias.

- **Foot and ankle outcome score (FAOS):** (0-100); has been validated in patients with lateral ankle ligament injury and demonstrated high test-retest reliability.⁶ Contains five separate subscales (pain, other symptoms, activities of daily living, sport and recreation function, and food and ankle-related

quality of life. A percentage of 0 to 100 is calculated for each of these subscales, 100 representing the best possible score. *Pain was considered the primary outcome in this study.*

- **Physical activity level:** (0-6); used to measure recreational activity. A score of 0 represents recreational activities such as watching TV, reading, and performing no household work. A score of 6 represents competitive sports, such as soccer, racquet sports, track and field, skiing, etc.
- **Difficulty during sporting activities:** (1-5); a 5-point Likert scale was used to assess difficulty during sporting activities (no, mild, moderate, severe, extreme). The answers were categorized into no or mild difficulty and moderate-to-extreme difficulty in order to compare difficulty between treatment groups.
- **Compliance & side effects:** patients recorded the treatments they performed on a daily basis, and compliance was assessed on a weekly basis. For the EE group, the authors determined that good compliance was reporting at least 75% (10 exercise sessions per week). For the NS group, compliance was also reporting at least 75% (5 nights per week). Patients in all groups were to also record any side effects, such as soreness, bruising, or sleep disturbances that they experienced during the 12 weeks. This was also evaluated on a weekly basis.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under 'critical appraisal' on next page]

- 10 patients were lost to follow-up at 6 weeks; 11 patients were lost to follow-up at 12 weeks (after treatment); 9 patients were lost to follow-up at 26 and 52 weeks.
- There were no serious side effects or complications of all patients participating in this study. One patient terminated the use of the night splint because of sleep disturbances.
- Authors determined that "60 patients were needed to detect a clinically significant mean score difference of 10 points in the FAOS subscale pain between groups with 80% power at $P = 0.05$." (Roos et al, 2004, p. 289).
- Friedman's test assessed post treatment change across all times. When Friedman's test was significant, Wilcoxon's signed rank test assessed post-treatment change at 6, 12, 26 and 52 weeks compared to baseline. To compare the three groups, the Kruskal-Wallis test was used. When comparing two groups, the Mann-Whitney U-test was used. To compare proportions, the X^2 test was used.
- **FAOS pain subscale:** mean scores at baseline demonstrated no significant differences in all groups: EE, 60 ± 19 ; NS, 61 ± 13 ; ENS, 60 ± 13 . All groups demonstrated a significant improvement across all follow-up times ($P < 0.05$), and at 1-year follow up all three groups reported between 35-42% ($P < 0.001$) reduction in pain when compared to baseline. EE demonstrated a rapid decrease in pain at 6 weeks (27%) compared to baseline (77 ± 14 , $P = 0.007$). This trend continued until 1-year follow-up, demonstrating a 42% decrease in pain from baseline (86 ± 17 , $P = 0.001$). The NS group showed the lowest reduction in pain out of the three groups (19% at 6 weeks, 73 ± 16 , $P = 0.005$; 13% at 12 weeks, 69 ± 20 , $P = 0.14$; 17% at 26 weeks, 72 ± 29 , $P = 0.14$ compared to baseline). The authors also report a significant improvement at 52 weeks. The ENS group demonstrated less pain reduction than the EE group, but more than the NS group (18% at 6 weeks, 71 ± 14 , $P = 0.14$; 22% at 12 weeks, 74 ± 16 , $P = 0.008$; and 22% at 26 weeks, 74 ± 22 , $P = 0.08$ compared to baseline). The authors also report a significant improvement at 52 weeks. The authors report similar results of improvement in the other FAOS subscales, but this data was not calculated. There were no statistically significant differences between groups at any time during the study ($P = 0.14-0.98$), but differences of >10 points in the mean pain scores at 12 weeks (82 vs. 69, $P = 0.04$) and 26 weeks (84 vs. 72) were present in the EE group compared to the NS group, which the authors considered to be clinically significant.
- **Physical activity level:** The authors report, "five out of eight patients in the EE group who were participating in sports before onset of Achilles tendinopathy returned to their pre-injury activity level after the 12-week intervention. Three out of eight patients in the ENS group returned to sports after the 12-week intervention. One out of 10 patients in the NS group returned to sports after the 12-week intervention" (Roos et al, 2004, p.291). The study authors did not provide data concerning the actual scores on the 0-6 scale used.
- **Difficulty during sporting activities:** The authors discovered that "more than 80% of patients in all three groups reported moderate-to-extreme difficulty participating in sporting activities at baseline. At 12 weeks, 27% of patients in the EE group, 58% of patients in the ENS group, and 50% of patients in the NS group reported moderate-to-extreme difficulty during sporting activities" (Roos et al, 2004, p.291). The study authors did not provide data regarding scores at 26 weeks; however, they state that the results were similar to the results at 12 weeks.
- **Compliance:** Compliance was good for EE during four out of the first five weeks then continued to decline over the remainder of the intervention. The authors noted that only 50% of patients reported good compliance with EE by week 12. According to the graph provided in the original article, it appears that there was poor compliance ($<75\%$) with EE for eight out of 13 weeks. Compliance with the night splint generally increased during the first several weeks of the intervention period, and remained over 75% for the majority of the study period. According to the graph provided in the original article, it appears that there was poor compliance for only three out of 13 weeks with use of the night splint (weeks 1, 12 and 13). The authors state that the association between compliance and outcome was not

calculated because the numbers were too small in each group. Although compliance was reported in this study, the authors did not provide sufficient detail of the data or analyse the collected data.

Original Authors' Conclusions

"We conclude that eccentric exercises seem to improve function and reduce pain because of Achilles tendinopathy in patients recruited from primary care. The effects were apparent already after 6 weeks of treatment and lasted for 1 year. Our results are in line with previous studies and strengthens the recommendation that patients, regardless of the duration or the severity of the problems, should undergo an eccentric exercise program prior to consideration of other treatments such as Achilles tendon surgery." (Roos et al, 2004, p. 294).

Critical Appraisal

Validity

[Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]

Comment on missing information in original paper.

- PEDro Score: 6/10 based on Eligibility Criteria: Yes; Random Allocation: Yes; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: No; Blind Therapist: No; Blind Assessors: No; Adequate Follow-up: No; Intention-to-treat analysis: Yes; Between Group Comparison: Yes; Point Estimates and Variability: Yes. (Eligibility score does not contribute to total score.)

It is noteworthy to consider that this study was unable to recruit 60 patients in order to demonstrate statistical significance. However, the authors determined that a mean score difference of 10 points on the FAOS would be considered as clinically relevant. The authors emphasize that they were only able to recruit 44 patients despite nearly a 3-year period of recruitment involving 23 primary-care physicians. This lack of participants (only 10-13 per group at 1-year follow-up) introduces a possibility that the results are narrowed to a very specific clinical population. As with many physical therapy studies, blinding of subjects, therapist and interventions was not possible due to all interventions being visually identifiable to participant and therapist. This lack of blinding may have led to potential bias or a placebo effect. Because the primary outcome of this study was pain, the authors deemed the FAOS as appropriate to measure this in this patient population. However, because the FAOS is adapted from the Knee Injury and Osteoarthritis Outcome Score (KOOS), which considers a 10% score change as representing clinical change,⁷ this same representation was used in this study for the FAOS. This leaves one to question if the representation for a score change based on an outcome assessing the knee is appropriate for the ankle. Mailing the questionnaires to the participants may have improved credibility in this study by possibly minimizing investigator bias. While this may have minimized investigator bias, one could speculate that this may have contributed to the follow-up loss seen in the study, which varied at each follow-up point. The interventions used in this study were appropriate, but there was a lack of standardization in the groups performing eccentric exercises. The authors mention that the participants were encouraged to increase weight as tolerated, but there was no information provided in the article as to how much the patients progressed. Although compliance was documented in this study, detail was lacking in the analysis of the collected data to be able to differentiate compliance trends between groups. This information would have been helpful for a clinician reviewing this study to know in order to improve compliance in clinical practice. For example, because of the limited information provided about compliance, it is difficult to distinguish if the EE group or the ENS group contributed more to the poor compliance demonstrated by week 12. Furthermore, the graph provided in the article on compliance is somewhat confusing. It demonstrates that there was a 13-week treatment period, while the authors state that the intervention was only 12 weeks. Lastly, the diagnosis of Achilles tendinopathy leading to an inclusion in the study was based on one examiner. The use of an objective measure, such as an MRI or ultrasound would have been beneficial in reducing the possibility of a patient presenting with symptoms of Achilles tendinopathy but not having structural damage being included in the study.

Interpretation of Results

[Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean.

- MCID was not calculated for the FAOS because the study authors determined that a change in 10% indicated a clinical improvement in score.
- **FAOS pain subscale:** Patients in all groups improved significantly across all follow-up times ($P < 0.05$).

However, it should be noted that the EE group improved more rapidly than the ENS and NS group at 6 weeks. At 6 weeks the EE group demonstrated a 27% reduction in pain compared to 18% in the ENS group and 19% in the NS group. This is important to the clinician in that to achieve the best results in pain reduction quickly, an eccentric program should be considered. It is also important to note that the patients performing eccentric exercises had much better compliance during the first week than those using a night splint. At 12 weeks the EE group demonstrated a 37%* reduction in pain compared to 22% in the ENS group and 13% in the NS group. At 26 weeks the EE group demonstrated a 40% reduction in pain compared to 22% in the ENS group and 17% in the NS group. At 52 weeks the EE group demonstrated a 42% reduction in pain compared to 36%* in the ENS group and 36%* in the NS group. The effect size at baseline was none (-0.06) between EE and NS, none (0.00) between EE and ENS, and none (0.07) between ENS and NS. The effect size at 6 weeks was small (0.26) between EE and NS, moderate (0.43) between EE and ENS, and small (0.13) between ENS and NS. The effect size at 12 weeks was moderate (0.66) between EE and NS, moderate (0.47) between EE and ENS, and small (0.27) between ENS and NS. The effect size at 26 weeks was moderate (0.48) between EE and NS, moderate (0.50) between EE and ENS, and none (0.07) between ENS and NS. The effect size at 52 weeks was small (0.17) between EE and NS, small (0.22) between EE and ENS, and none (0.05) between ENS and NS. The only clinically significant differences in pain scores within the groups were between the EE group and the NS group at 12 and 26 weeks, in which there was more than a 10 point score difference in favour of the EE group.

- The above information shows a trend of eccentric exercises alone being more efficient in reducing pain than eccentric exercises + night splint or a night splint alone. The data also indicates that the use of a night splint diminishes the effect of eccentric exercises. Using a night splint alone demonstrates inferior pain reduction than either the EE or ENS groups. Overall, no strong conclusions can be made regarding the effectiveness of EE compared to ENS or NS in relieving pain.
- **Physical activity level:** 8 patients in the EE group, 8 patients in the ENS group, and 10 patients in the NS group participated in sports before onset of Achilles tendinopathy. At 12 weeks, 5/8, 3/8, and 1/10 patients returned to sports in the EE, ENS and NS groups respectively. Overall, while no statistical analysis was performed, there is a greater trend towards eccentric exercises being effective in return to sport.
- **Difficulty during sporting activities:** there was a greater trend of less patients (27%) in the EE group reporting moderate-to-extreme difficulty during sporting activities at 12 weeks compared to 58% in the ENS group and 50% in the NS group. This trend continued through the 52-week follow-up, in which 15%, 54%, and 56% reported difficulty during sporting activities in the EE, ENS and NS groups respectively. It was interesting to see that the NS group reported a greater percentage of difficulty at 52 weeks compared to at 12 weeks. This may have been a result of the fluctuation in loss to follow-up.
- **Compliance:** The study authors considered compliance to be good if the subjects performed at least 75% of the recommended exercises or wore the night splint at least 75% of the time during the week. For those performing eccentric exercises, about 95% of them reported good compliance in the first week. From weeks 2-7 about 80% of the patients had good compliance. Compliance started to progressively decrease following week 7, reaching around 50% by week 13. It is plausible to believe that outcomes would have been even greater in the groups performing eccentric exercises if compliance remained good throughout the intervention period. This is noteworthy in that a practicing clinician should advocate to their patients the importance of maintaining compliance in order to achieve optimal pain reduction. Compliance progressively increased in patients wearing the night splint during the first 7 weeks and then started to decrease thereafter. Overall, patients wearing the night splint reported good compliance throughout most of the intervention period. Because compliance in wearing the night splint was generally good throughout most of the study and was generally poor for those performing eccentric exercises, one may suspect that outcomes could have potentially been close to their peak for those wearing a night splint, while outcomes in those performing eccentric exercises could have potentially been better if greater compliance was achieved. However the authors state, "the numbers were too small in each group to calculate the association between compliance and outcome" (Roos et al, 2004, p. 291).

*I calculated these percentages because they were not calculated in the original article.

(3) Description and appraisal of Achilles paratendinitis: an evaluation of steroid injection by DaCruz DJ, Geeson M, Allen MJ, et al. (1988)

Aim/Objective of the Study/Systematic Review:

The aim of this study was to determine the effectiveness of a peritendonous injection of methyl prednisolone acetate (Depo Medrone) in the treatment of Achilles paratendonitis.

<p>Study Design</p>
<ul style="list-style-type: none"> • Prospective, randomized, double-blind study (RCT) • Patients were randomly assigned to one of two groups. There was no mention in the study regarding randomization procedures or allocation concealment. • Patients were assessed by a single physician at presentation, 3 weeks and 6 weeks, and then at 6-week intervals thereafter. Follow-up assessments were double blinded. • There was a crossover at 12 weeks for those who failed to respond to their treatment.
<p>Setting</p>
<p>Patients presenting to the Accident and Emergency Department, Leicester Royal Infirmary who met the inclusion criteria were admitted to the study. The study authors did not provide information as to where treatments were administered, where follow-up occurred, or where the patients had physical therapy.</p>
<p>Participants</p>
<ul style="list-style-type: none"> • To be included in the study patients were required to have midportion (non-insertional) Achilles tendinopathy, in which their complaint of pain was not localized to the musculotendinous junction or at the point of insertion. • This study initially enrolled 36 patients, but six refused to attend physical therapy and two refused further injection when they came to cross-over, thus leaving 28 total patients that were studied; 18 males and 10 females with an average age of 28 (22-46). • 20 patients were active in sports, running more than three miles per day, four regularly played racquet sports, and four participated in no sports. • The most common factor for onset of Achilles tendinopathy in this cohort was a sudden increase in training. • None of the patients demonstrated swelling or movement limitations in the ankle at baseline. Furthermore, no patient demonstrated any soft tissue calcification via radiographs. • Six patients had bilateral Achilles tendinopathy, leaving a total of 34 tendons that were studied. • Patients were divided into two groups; group 1 was the experimental group who received a locally administered peri-tendinous injection of 40 mgs methyl prednisolone acetate (steroid) in 1 ml of Marcaine (local anaesthetic) 0.25% (N=19 tendons), and group 2 was the control group who received just the local anaesthetic of 2 ml of 0.25% marcaine (N=15 tendons). At 6 and 12 weeks there were 13 and 10 tendons studied in the experimental and control groups, respectively. • The study authors indicate that the two treatment groups were comparable at baseline regarding age, sex, pain, tenderness and activity levels. However, the article did not provide information regarding the ages (and standard deviations) or gender for each group. • Information regarding duration of Achilles tendinopathy was not provided. • A nonprobabilistic sampling method was used – purposive.
<p>Intervention Investigated</p>
<p><i>Control – Local anaesthetic alone</i></p>
<ul style="list-style-type: none"> • Patients received a peri-tendinous injection of 2 ml of 0.25% marcaine alone. This served as the placebo group. • The injection was provided by the lead author (DaCruz DJ), in which he was careful not to penetrate the actual Achilles tendon. The injection was administered on either side of the palpable tendon with the patients lying in prone. • Patients underwent a standardized regimen of physical therapy by a single physical therapist, the second author (Geeson M). Patients attended physical therapy two times per week for four weeks. Physical therapy included application of ice, followed by ultrasound at a dose of 0.5 watts per cm for five minutes. Patients were given an orthopaedic felt heel insert at their first physical therapy session. Patients were encouraged to function normally within the limits of their pain; there was no formal restriction on activity level. When physical therapy intervention involved running, the patients ran at half pace on a soft surface with shock absorbing shoes and a sorbithane insert.
<p><i>Experimental – Steroid and local anaesthetic</i></p>
<ul style="list-style-type: none"> • Patients received a peri-tendinous injection of 40 mgs methyl prednisolone acetate (steroid) in 1 ml of Marcaine (local anaesthetic) 0.25%.

- The injection was provided by the lead author (DaCruz DJ), in which he was careful not to penetrate the actual Achilles tendon. The injection was administered on either side of the palpable tendon with the patients lying in prone.
- All patients underwent the same physical therapy interventions as the control group, as described above. The second author also served as the single physical therapist in this group.

Outcome Measures (Primary and Secondary)

All outcome measures were performed at baseline, 3 weeks, 6 weeks, and at 6-week intervals thereafter. Outcome scores were only provided for baseline, 6 weeks and 12 weeks. Follow-up measures were conducted on a double-blind basis; however, the study authors did not mention who performed the follow-up assessments. This study considered patients to be fully recovered when they were back to normal activity, had no pain, and demonstrated no tenderness. It should be noted that the study authors did not address reliability and validity of all outcome measures used.

- **Pain:** (0-100); Patients graded pain by marking a section on a 10 cm linear analogue scale when asked "How bad is your pain when it is at its worse?" Patients were uninformed of previous pain scores at each follow-up. The lower the score on this scale indicates less pain (i.e. a 0 indicates no pain).
- **Swelling:** Was assessed by the lead author at baseline by measuring the thinnest diameter of the tendon with callipers. The symptomatic side was compared with the asymptomatic side if symptoms were unilateral.
- **Activity:** (25%, 50%, 75%); A self-report measure that was measured using an "activity level score". Patients ranked their current level of activity as 25%, 50% or 75% of normal including training.
- **Tenderness:** (grade 1-3); Measured based on the patient's response to gentle pinching between the assessor's pollex and finger. A grade 1 was classified as the patient neither wincing nor withdrawing when pressure was applied. A grade 2 was classified as the patient wincing but demonstrated no withdrawal. A grade 3 was classified as the patient both wincing and withdrawing when pressure was applied.
- **Ankle flexion:** Measured using a goniometer.

Main Findings

The study authors did not perform an a priori power analysis on any outcome. Furthermore, they did not report standard deviations or P values. Therefore effect sizes cannot be estimated to show clinical significance, and the lack of P values hinders the ability to know statistical significance. All outcomes were neither clinically nor statistically significant.

- **Pain:** At presentation the average pain score was 41 in the experimental group and 39 in the control group (a difference of 2 favouring the control group). At the 6-week follow-up the average pain score was 35 in the experimental group and 31 in the control group (a difference of 4 favoring the control group). At the 12-week follow-up the average pain score was 30 in the experimental group and 28 in the control group (a difference of 2 favoring the control group).
- **Swelling:** No patients demonstrated any swelling at baseline; therefore this measure was not assessed throughout the study.
- **Activity:** At presentation, 8 patients in the experimental group and 6 in the control group reported their activity level to be 25% of normal (difference of 2); 11 tendons in the experimental and 9 in the control reported activity level at 50% (difference of 2); 0 tendons in both groups reported activity level at 75%. At 6 weeks, 3 tendons reported activity levels at 25% in both groups; 6 in the experimental and 4 in the control reported their activity level at 50% (difference of 2); 4 in the experimental and 3 in the control reported their activity level at 75% (difference of 1). At 12 weeks, 3 tendons in each group reported activity level at 25%; 6 in the experimental and 4 in the control reported their activity level at 50% (difference of 2); 4 in the experimental and 3 in the control reported activity level at 75% (difference of 1).
- **Tenderness:** At presentation, 12 tendons in the experimental group reported tenderness as a grade 1 compared to 9 in the control group (difference of 3), 5 in the experimental reported grade 2 compared to 2 in the control (difference of 3), 2 in the experimental reported grade 3 compared to 4 in the control (difference of 2); at 6 weeks, 6 tendons in the experimental were at a grade 1 compared to 5 in the control (difference of 1), 5 reported a grade 2 in the experimental compared to 2 in the control (difference of 3), both groups reported 2 tendons at a grade 3; at 12 weeks, 6 in the experimental and 4 in the control reported a grade 1 (difference of 2); 6 in the experimental and 3 in the control reported a grade 2 (difference of 3), 1 in the experimental and 3 in the control reported a grade 3 (difference of 2).
- **Ankle flexion:** No patients demonstrated any limitation in ankle joint movement; therefore this measure was not assessed throughout the study.

Original Authors' Conclusions

"In this study only eleven out of 35* tendons studied (33%) responded to treatment. As six of these patients had received a steroid and five had not, it appears that locally acting steroids have no role to play. Patients who did respond to treatment had only minimal signs and symptoms when they presented and recovered within six weeks" (DaCruz et al, 1988, 65).

Considering the experience of Kvist H and Kvist M, 1980, and Clancy et al, 1986**, DaCruz et al³ notes that patients who don't respond to conservative treatment, such as rest and physical therapy, but want to continue living an active lifestyle have surgery sooner rather than later. Further, the study authors mention that 11 patients in this study ended up having surgery in which the thickened paratendon was stripped, and these patients have returned to normal activity and are no longer symptomatic.³

*Study authors reported here that 35 tendons were studied. According to the study and the percentage given, it is likely that this is a typing error in which they intended to report 34.

**Another likely typing error in which they indented to report 1976.

Critical Appraisal

Validity

- PEDro Score: 7/10 based on Eligibility Criteria: Yes; Random Allocation: yes; Concealed Allocation: No; Baseline Comparison: Yes; Blind Subjects: Yes; Blind Therapist: no; Blind Assessors: Yes; Adequate Follow-up: Yes; Intention-to-treat analysis: Yes; Between Group Comparison: Yes; Point Estimates and Variability: No. (Eligibility score does not contribute to total score.)

Although this study was well designed, there were many methodological flaws noted that hinder the credibility. Many of these flaws were a lack of reporting and calculation on the study authors' part. For example, no sample size calculation was reported. This limitation may have been compounded in that the study authors failed to report on the patients who were lost to follow-up. Hypothetically, the loss of 6 patients may have been do to an increase in tendon pain which could have skewed the authors predicted or desired outcome; therefore they may have chosen not to follow them. Furthermore, this study would have benefited from an increased number of participants. There were only 34 tendons total assessed in this study at baseline: 19 in the experimental group and 15 in the control group. This difference of 4 tendons may have skewed the data considering the limited amount of tendons studied total.

As previously mentioned, it is impossible to draw conclusions on the actual significance of this study without the report of p values, standard deviations or a power analysis.

The study authors make no mention of specific allocation concealment procedures; therefore, one would be unable to ascertain whether allocation was concealed or not. Without concealed allocation there is a risk of the researcher responsible for admitting patients into the study placing those with better prognosis in the experimental group and those with a poorer prognosis in the control group, or vice versa, which results in bias. For example, the authors mention that the four patients who were not active in sports (who also had minimal signs and symptoms at baseline) recovered after six weeks. Because the authors did not provide information as to which study group these four patients were in, one could assume, due to a lack of allocation concealment, that these patients were placed in the control group, thus showing that the placebo worked just as well as the steroids. The study authors also failed to report specifics regarding demographics of each study group. They report that demographics were comparable between the two groups at baseline, but the details of information were withheld. For example, I am unable to determine how many males versus females there were in each group.

Lastly, there was no objective method of confirming the injection site, such as imaging. Rather, the injection was given based on the lead authors prediction of accurate placement, and the amount of experience the lead author has in delivering injections for this pathology is not given in the report. Nevertheless, to obtain maximal credibility when performing a research study, regardless of physician experience, an objective method should have been used. Literature even suggests that appropriate placement of an injection for this pathology is difficult to achieve without imaging.¹⁰ This proposes that the lack of imaging may have contributed to the minimal effects seen in this study.

Interpretation of Results

- **Pain:** Despite the lack of statistical analysis, the results imply that there is no benefit of steroids in decreasing pain when compared to an anaesthetic. Both groups appeared to have similar scores and improvements in pain throughout the study.
- **Activity:** Despite the lack of statistical analysis, the results imply that there is no benefit of steroids in improving activity when compared to an anaesthetic. Both groups appeared to have similar scores and improvements in activity levels throughout the study.
- **Tenderness:** Despite the lack of statistical analysis, the results imply that there is no benefit of steroids in decreasing tenderness when compared to an anaesthetic. Both groups appeared to have similar scores and improvements in tenderness throughout the study.
- Overall, with regards to this study it appears as though steroid injections have no benefit in outcomes for patients with Achilles paratendinitis. Again, one must take into account the lack of quality of this study.

IMPLICATIONS FOR PRACTICE and FUTURE RESEARCH

The review of the study by Rompe et al indicates that eccentric exercise for the treatment of chronic non-insertional Achilles tendinopathy has positive outcomes and supports the intervention of interest. Furthermore, shock-wave treatment for the treatment of this pathology also demonstrates positive outcomes. Clinically, this study provides evidence that either an eccentric loading program or a shock-wave therapy program should be used, and rest should not be used in the treatment of chronic non-insertional Achilles tendinopathy. Although a combined treatment of eccentric exercise and shock-wave therapy was not studied, this may be something to consider when treating a patient with this pathology. The authors of this study even mention "further studies should be performed to measure the benefits of combined eccentric training and SWT in the treatment of this condition." Due to the lack of documented compliance from participants of the eccentric group, future research should perform studies in order to analyse compliance data. This would help in determining the effectiveness of various amounts of eccentric exercises, thereby allowing clinicians to appropriately prescribe eccentric interventions. If this study demonstrated that compliance in the EG was low, a clinician reading this article would then be prompted to devise a way to promote compliance with their patients in the clinic. With regards to my PICO question, this study indicates that eccentric exercise works in decreasing pain in the patient with Achilles tendinopathy and is a potential alternative to steroid injections.

The review of the study by Roos et al indicates that eccentric exercise for the treatment of chronic non-insertional Achilles tendinopathy has positive outcomes and supports the intervention of interest. The study authors found great improvement in pain for those performing eccentric exercises by 6 weeks that lasted until 1-year follow-up. There was also evidence indicating that the use of a night splint alone or a night splint along with an eccentric exercise protocol has significant reductions in pain, although the effect was highest at 6 weeks and less at 12 and 26 weeks. Clinically, this study indicates that an eccentric exercise program for 12 weeks has greater effects on outcome than the use of a night splint alone or a night splint + eccentric exercises, and should be considered in treating pain associated with Achilles tendinopathy. Similar to the study performed by Rompe et al, this review indicates that there is a need for more studies with specific details regarding compliance with performing the eccentric exercise protocol. It would be helpful for the practicing clinician to know what reasons led to the participants' progressive decrease in compliance in order to devise methods to promote increased compliance. With regards to my PICO question, this study also provides evidence that eccentric exercise works in decreasing pain in the patient with Achilles tendinopathy and is a potential alternative to steroid injections.

The review of the study by DaCruz et al indicates that there is minimal benefit in the use of steroid injections for the treatment of Achilles tendinopathy. When compared to a placebo, steroid injections showed similar results. The minimal benefits demonstrated in both groups were possibly secondary to the physical therapy intervention that both study groups underwent. However, it is important to note that this study failed to report any statistical analyses, standard deviations or p-values, and there was a lack of specific information regarding allocation concealment, between-group patient demographics. Therefore, it is limiting to make any strong conclusions on the effects of steroid injections based on this study. Further research of better statistical quality is required to implicate the benefits, or lack thereof of steroid injections in the treatment of a painful Achilles tendinopathy.

Overall, this review indicates that a 12-week eccentric exercise protocol, shock-wave therapy, or a night splint is likely to demonstrate a better decrease in pain than a steroid injection for patients with non-insertional Achilles tendinopathy. The eccentric exercise protocol and shock-wave therapy interventions appeared to demonstrate the greatest improvements in pain. Considering the confines of this PICO question to eccentric exercises, training therapists on a basic eccentric exercise protocol would be very cost efficient, if not free. It would be easy to assume that all therapists know how to devise an eccentric exercise protocol for a patient with Achilles tendinopathy, but if not they may consider asking a co-worker, or hope that I am doing my next rotation there so they can listen to my in-service. It is important that practicing orthopaedic clinicians and current students understand how to perform these exercises so they can prescribe them to patients requiring them. The cost of this treatment for a patient would be no more than what is charged for therapeutic exercise.

Based on my clinical experience, similar eccentric exercise protocols are currently used in practice.

There is a lack in methodological quality of all three studies. As with most research studying physical therapy interventions, it will be impossible to blind subjects and therapists on the eccentric exercise interventions that the patients receive. Therefore, future studies will always show a lack in methodology. This presents the importance of future studies needing to be sound on all other aspects of methodology, such as detailed information on interventions, adequate sample size, and statistical analyses, to name a few. Furthermore, there is a dearth of literature supporting or opposing steroid injections in the reduction of pain in those with Achilles tendinopathy. It would be optimal for future studies to exhibit quality evidence on this topic, but at this point in time, any literature would be helpful.

REFERENCES

[List all references cited in the CAT]

- 1) Rompe JD, Nafe B, Furia JP, et al. Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis. *The American Journal of Sports Medicine*. 2007;35(3):374-83.
- 2) Roos EM, Engstrom M, Lagerquist A, et al. Clinical improvement after 6 weeks of eccentric exercise in patients with mid-portion Achilles tendinopathy – a randomized trial with 1-year follow-up. *Scand J Med Sci Sports*. 2004;14:286-95.
- 3) DaCruz DJ, Geeson M, Allen MJ, et al. Achilles paratendonitis: an evaluation of steroid injection. *Brit J Sports Med*. 1988;22(2):64-5
- 4) Khan KM, Cook JL, Kannus P, et al. Time to abandon the “tendinitis” myth. *BMJ*. 2002;324:626-7.
- 5) Speed CA. Corticosteroid injections in tendon lesions. *BMJ*. 2001;323:382-6.
- 6) Roos EM, Brandsson S, Karlsson J. Validation of the foot and ankle outcome score for ankle ligament reconstruction. *Foot Ankle Int*. 2001;22:788-94.
- 7) Roos EM, Lohmander LS. Knee injury and osteoarthritis outcome score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes*. 2003;1:64.
- 8) Kvist H and Kvist M. The operative treatment of chronic calcaneal paratendonitis. *Journal of Bone and Joint Surgery*. 1980;62B(3):353-7.
- 9) Clancy WG, Neidhart D, Brand RL. Achilles tendonitis in runners. *American Journal of Sports Medicine*. 1976;4(2):46-57.
- 10) Fredberg U, Bolvig L, Pfeiffer-Jensen M, et al. Ultrasonography as a tool for diagnosis, guidance of local steroid injection and, together with pressure algometry, monitoring the treatment of athletes with chronic jumper’s knee and Achilles tendonitis: a randomized, double-blind, placebo-controlled study. *Scand J Rheumatol*. 2004;33:94-101.