No Difference in Clinical Effects When Comparing Alfredson Eccentric and Silbernagel Combined Concentric-Eccentric Loading in Achilles Tendinopathy

A Randomized Controlled Trial

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Background: Alfredson isolated eccentric loading and Silbernagel concentric–eccentric loading have both shown beneficial effects on clinical symptoms in midportion Achilles tendinopathy (AT), but they have never been compared directly.

Purpose: To test for differences in clinical effects at 1-year follow-up between Alfredson and Silbernagel loading in midportion AT. **Study Design:** Randomized controlled trial; Level of evidence, 2.

Methods: A total of 40 recreational athletes were allocated to the Alfredson group (AG) or the Silbernagel group (SG). The primary outcome was the difference in the Victorian Institute of Sports Assessment–Achilles (VISA-A) at 1-year follow-up. Secondary outcomes were the visual analog scale for pain during activities of daily living (VAS-ADL) and sports activities (VAS-sports), the EuroQol 5 Dimensions instrument (EQ-5D), and global perceived effect score. Measurements were performed at baseline and 12-week, 26-week, and 1-year follow-up. Analysis was performed using a linear mixed-regression model with intervention (AG vs SG), time (12 weeks, 26 weeks, and 1 year postoperatively), and intervention-by-time interaction.

Results: The VISA-A score improved for both AG and SG, from 60.7 ± 17.1 at baseline to 89.4 ± 13.0 at 1-year follow-up and from 59.8 ± 22.2 to 83.2 ± 22.4 , respectively (P < .001 for both). Because the interaction term did not significantly improve the model, we reported a treatment effect without interaction term, indicating a constant difference at each follow-up. The linear mixed model with correction for baseline VISA-A and confounders revealed a nonsignificant treatment effect (2.4 [95% CI, -8.5 to 13.3]; P = .656). In addition, after adjustment for the respective baseline values and confounders, nonsignificant treatment effects were found for the VAS-ADL (-2.0 [95% CI, -11.3 to 7.3]; P = .665) and VAS-sports (1.3 [95% CI, -12.8 to 15.3], P = .858). The EQ-5D subscales improved in both groups. After 1 year, significantly more SG participants considered themselves improved (77.3% [SG] vs 50.0% [AG]; P = .04).

Conclusion: No differences in clinical effects were found between Alfredson and Silbernagel loading at up to 1-year follow-up. Both programs significantly improved clinical symptoms, and given their high adherence rates, offering either of them as a home-based program with limited supervision appears to be an effective treatment strategy for midportion AT.

Registration: NTR5638 (Netherlands Trial Register number).

Keywords: Achilles tendon; concentric; eccentric; exercise; loading; tendinopathy

In recent decades, loading programs have become the cornerstone of treatment for midportion Achilles tendinopathy (AT), mainly based on the work of Alfredson et al. ¹ These authors showed that recreational runners who performed 12 weeks of eccentric heel-lowering exercises daily

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demonstrated significantly larger pain reduction compared with a group who did not exercise. Although these promising results were not always confirmed in later studies, ^{25,31} the effectiveness of the Alfredson program for treating midportion AT in an active population is well-documented within the literature. ^{9,30}

Silbernagel et al^{34,35} showed that a combination of multiple concentric and eccentric heel-raising exercises performed once daily for 12 weeks also effectively improved

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clinical symptoms in individuals with AT. The Silbernagel program involved uni- and bipedal exercises, as well as progression to faster concentric-eccentric exercises and finally plyometrics. In a systematic review, Malliaras et al²¹ concluded that this Silbernagel program yields equivalent clinical results to the Alfredson eccentric program. However, their conclusion was based on heterogeneous study populations, hampering a firm conclusion regarding superiority of any program. To date, no studies have directly compared both loading programs.

In the present study, we aimed to test for differences in clinical effects between the Alfredson isolated eccentric and the Silbernagel combined loading program in recreational athletes with midportion AT in a randomized controlled trial with a 1-year follow-up. In line with extant yet inconclusive research, ²¹ we hypothesized that the 2 programs would yield comparable results.

METHODS

Study Design

A prospective, multicenter, 2-arm, single-blind, randomized clinical trial (RCT) was conducted in agreement with the CONSORT (Consolidated Standards of Reporting Trials) statement. Participants were allocated either to the Alfredson isolated eccentric program (Alfredson group; AG) or the Silbernagel concentric-eccentric exercise program (Silbernagel group; SG). Researchers involved in data collection and analysis were blinded to group allocation. Measurements were performed at baseline and after 12 weeks, 26 weeks, and 1 year. Detailed information on the study design has been published previously. 10

Participants

Recreational athletes with chronic (ie, ≥ 3 months) unilateral midportion AT were eligible for inclusion if they were aged between 18 and 65 years and participated in sports that involved Achilles tendon loading. Exclusion criteria were (1) bilateral symptoms, (2) insertional AT, (3) washout period of less than 4 weeks from other treatments, (4) corticosteroid injections in the region of the Achilles tendon in the previous 12 months, (5) other lower-limb injuries of the affected limb in the previous 12 months, (6) musculoskeletal surgery of the affected limb in the previous 12 months, (7) history of Achilles tendon rupture in the affected limb,

and (8) systemic diseases that could interfere with rehabilitation (eg, rheumatoid arthritis or diabetes).

The diagnosis of midportion AT was established by one of the researchers (B.H.), who has more than 12 years of experience in tendon rehabilitation. Diagnosis was based on the following criteria: subjective as well as palpation pain 2 to 7 cm proximal to the calcaneal insertion, ¹² pain during tendon loading sports activities, swelling, and morning stiffness. ²⁶ No imaging modalities were used to assist in establishing the clinical diagnosis. ⁶

An a priori sample size calculation was performed based on the differences on the Victorian Institute of Sports Assessment–Achilles (VISA-A) obtained in previous studies. ^{28,34} These studies found a mean (\pm SD) improvement of 22.4 (\pm 19)²⁸ and 34 (\pm 17)³⁴ points on the VISA-A for the Alfredson and the Silbernagel program, respectively. With 0.80 power and α (2-sided) of .05, and taking a dropout rate of 9% into account, we needed 86 participants to detect a difference of 11.6 points on the VISA-A.

Recruitment and Randomization

A detailed description of our recruitment strategy has been published previously. 10 Participants were primarily recruited through sports physicians and physiotherapists from Sports Medical Center Papendal and the University Medical Center Utrecht (both in the Netherlands). To enhance enrollment of participants, 3 Dutch private clinics for physiotherapy were added as participating centers (FysioHolland Medicort, Academie Instituut, and Van Tongeren Fysiotherapie). After being informed, participants made an appointment with one of the researchers (B.H.) to check for the diagnosis of midportion AT and the other criteria for inclusion in this study. Before participation, participants signed informed consent. Thereafter, baseline assessment was performed, and an independent secretary randomly assigned the participants into the AG or SG by choosing an opaque, sealed envelope from a box. Envelopes were consecutively numbered according to a computergenerated randomization table. Within 1 week after baseline assessment, participants were scheduled for an appointment with one of the supervising physiotherapists, who were informed about the allocated program by the secretary. During this appointment, the respective program was explained so participants could correctly perform the exercises at home. Two and 6 weeks later, an appointment with the same supervising physiotherapist was scheduled,

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Ethical approval for this study was obtained from University Medical Center Utrecht (16-158/M).

with the aim of motivating participants to continue their exercises and adjust the program according to the protocol.

Interventions

The AG participants performed 12 weeks of home-based, heavy-load, eccentric heel-lowering exercises on the edge of a stair, using the noninjured limb to concentrically return to the starting position. Exercises were performed twice daily, for 3 sets of 15 repetitions with a straight knee, and 3 sets of 15 repetitions with a bent knee. Pain during exercises was allowed, and load was increased by adding weight in a backpack in increments of 5 kg once exercises could be performed without pain.

The SG participants followed 12 weeks of home-based, concentric-eccentric loading. Various heel-raising exercises were performed once daily, with 3 sets of 15 repetitions for each exercise. Progression was made from bipedal to unipedal exercises, from floor level to the edge of a stair, by increasing weight in 5-kg increments and increasing speed (plyometrics) in the last phase. A more detailed description of the programs is published elsewhere.³⁴

Participants in both study arms were asked to refrain from other treatments during the intervention period, yet if they received other treatments, they were requested to register that in a logbook. Furthermore, they were asked to register exercise adherence in the logbook weekly. During the first 3 weeks of their program, participants were advised not to engage in tendon-loading sports activities, such as running and jumping. After the first 3 weeks, they could resume their sports activities with a pain-monitoring model; that is, pain during activities should not exceed 5 on a 0 to 10 numerical rating scale, and symptoms should have subsided within 24 hours after the respective activity.³⁴ After the intervention, participants were encouraged to continue loading exercises according to their allocated program, but this was not further monitored.

Outcome Measures

The primary outcome measure was the valid and reliable Dutch version of the VISA-A,³² which consists of 8 questions and covers the domains of pain, daily activities, and sports. Scores range from 0 to 100, with 100 being equivalent to asymptomatic.27

As secondary outcome measures, we included a 100-point pain visual analog scale (VAS; 100 represented maximal pain), on which participants could indicate their pain during daily activities (VAS-ADL) and sports activities (VASsports) during the previous week. Participants also completed the EuroQol 5 Dimensions instrument (EQ-5D) for quality of life (QOL), 11 in which they rated 5 dimensions of health on a 3-point scale (no problems, some problems, or extreme problems) and a VAS for self-rated health. Last, participants rated their global perceived effect (GPE) on a 7-point ordinal scale, ranging from worse than ever to recovered completely.

Demographic data collected at baseline were age, sex, body height and weight, body mass index, and duration of symptoms. In addition, we collected waist circumference

with a flexible tape measure,8 ankle dorsiflexion range of motion (ROM) of the talocrural joint using the weightbearing lunge test, 17 and dorsiflexion ROM of the first metatarsophalangeal joint using a goniometer (Fysiosupplies).² A detailed description of all measurement procedures has been published previously. 10

Statistical Analysis

Patient characteristics were presented as means \pm SDs or numbers (percentage). In line with current recommendations, 22 statistical comparison of baseline characteristics between the groups was not performed. All statistical analyses were performed using SPSS, Version 23.0 (IBM), based on intention-to-treat principles. Testing was performed 2-sided, with significance level set at $\alpha \leq .05$.

The adherence rate was defined as the proportion of prescribed exercises actually performed and was divided into 4 categories: when less than 25%, 25% to 50%, 50% to 75%, or more than 75\% of the exercises were performed. Adherence was rated as poor, moderate, good, or excellent, respectively. Between-group difference in adherence rate was analyzed using the Pearson χ^2 test. Before further analysis, normality was examined, and a graphical representation of observed mean scores and 95% CI was composed.

Our primary aim was to test for differences in VISA-A score between the AG and the SG participants at 1-year follow-up. As a secondary aim, we assessed differences in the VAS-ADL and VAS-sports at 1-year follow-up. Because some of the follow-up measurements were missing from our data, we decided to use a linear mixed-regression model for analysis of our primary and secondary outcomes instead of the repeated-measures analysis of variance we intended to apply. 10 We included an unstructured residual covariance type (generalized estimating equations type) to correct for repeated measurements within participants. For the main analysis, we used a linear model that included intervention (AG vs SG), time (12-week, 26-week, and 1-year follow-up), and intervention-by-time interaction. We evaluated the intervention-by-time interaction effect for all outcomes and tested these with likelihood ratio tests. In case the interaction did not significantly improve the model fit, an additional step was performed in which we excluded the interaction from the analysis to test an assumption of a constant difference between AG and SG at each follow-up. Validity of the model was assessed using residual

Regression analyses were performed with the VISA-A, the VAS-ADL, and VAS-sports during follow-up as dependent variables. For each analysis, the baseline value of the respective outcome was included as a covariate. Sex, age, and duration of symptoms were also included as covariates, since these were considered potential confounders. 14,18

For completeness, we report the results for the initial model (intervention, time, and intervention-by-time interaction), the model with correction for baseline, and the model with correction for baseline and confounders. Results for each follow-up measurement are presented as treatment effects (mean [95% CI]) with the AG as reference, based on estimated marginal means. In addition, because

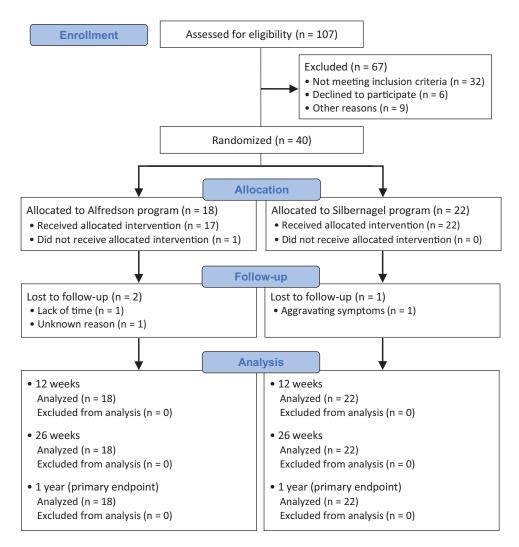


Figure 1. Flowchart of the study population throughout the study.

the intervention-by-time interaction term did not improve our model fit, we present a constant treatment effect (95% CI) with the AG as reference, corrected for baseline and confounders, but without the intervention-by-time interaction.

For the EQ-5D subscales, the percentage of participants reporting each level of each problem was calculated for all measurements, and for the EQ-5D VAS score we calculated mean \pm SD for all measurements. 37 Differences between the groups for the GPE were assessed using the Pearson χ^2 test.

RESULTS

Owing to a much slower than expected inclusion rate as well as the COVID-19 outbreak, we decided to terminate enrollment of new participants in April 2020, before reaching the targeted sample size. Planned follow-up measurements after this date were performed as scheduled. From December 2016 to April 2020, a total of 107 potential participants were screened for eligibility (Figure 1). Of these,

40 participants were included and randomly assigned into the AG (n=18) or the SG (n=22). Two participants in the AG withdrew from the study, 1 because of lack of time and 1 for an unknown reason. In the SG, 1 participant decided to withdraw because of aggravation of symptoms after a running race. Data from these participants were included in the analyses.

Baseline characteristics of the study sample are presented in Table 1. Participants in the AG were younger (45 years) than the SG (50 years) and experienced a shorter duration of symptoms (9.4 months) than participants in the SG (15.1 months). Furthermore, the AG consisted of fewer runners (5.6%) than the SG (27.3%).

In the AG, 1 participant was treated once with dry needling and kinesiotape, 2 participants received inlays, and 2 participants used paracetamol for 1 week. In the SG, 1 participant received massage of the calf musculature (once weekly for 4 weeks), 1 participant received heel lifts, 1 participant was treated once with shockwave therapy, and 3 participants used nonsteroidal anti-inflammatory medication or paracetamol for a short term.

Adherence

The mean adherence rate during the intervention period was $74.1\% \pm 21.6\%$ in the AG and $77.3\% \pm 16.2\%$ in the SG. In the AG, 20% showed "good" and 53% showed "excellent" adherence. For the SG, these percentages

 ${\it TABLE~1} \\ {\it Baseline~Characteristics~of~the~Study~Population}^a$

	$\begin{array}{c} Alfredson \\ Group \\ (n=18) \end{array}$	$\begin{array}{c} Silbernagel \\ Group \\ (n=22) \end{array}$
Age, y	44.7 ± 9.0	49.9 ± 10.1
Sex, female	8 (44.4%)	10~(47.6%)
Height, cm	179.7 ± 8.6	175.4 ± 9.8
Weight, kg	84.7 ± 15.6	81.3 ± 15.4
BMI	26.1 ± 3.6	26.3 ± 4.1
Injured limb, left side, n (%)	12(66.7)	11 (50.0)
Duration of symptoms, mo	9.4 ± 8.2	15.1 ± 24.0
Sports type, n (%)		
Walking	8 (44.4)	6(27.3)
Running	1 (5.6)	6(27.3)
Ball sports	9 (50.0)	7 (31.8)
Other sports	0	1(4.5)
No current sports	0	2(9.1)
Weekly time spent on sports, h	4.7 ± 4.7	5.1 ± 3.5
Waist circumference, cm	94.3 ± 11.5	94.8 ± 12.6
ROM dorsiflexion TCJ, cm		
Injured limb	12.4 ± 3.0	10.5 ± 2.6
Noninjured limb	12.5 ± 3.7	10.1 ± 3.5
ROM dorsiflexion MTP1, deg		
Injured limb	44.7 ± 14.2	43.1 ± 10.9
Noninjured limb	46.2 ± 13.8	43.6 ± 11.2
VISA-A	60.7 ± 17.1	59.8 ± 22.2
VAS-ADL	28.6 ± 22.1	28.6 ± 31.8
VAS-sports	44.8 ± 26.8	46.6 ± 32.6

^aData are reported as mean \pm SD or n (%). BMI, body mass index; MTP1, first metatarsophalangeal joint; ROM range of motion; TCJ, talocrural joint; VAS-ADL, visual analog scale for activities of daily living; VAS–sports, visual analog scale for sports activities; VISA-A, Victorian Institute of Sports Assessment–Achilles.

were 40% and 50% respectively. Analysis revealed no significant difference in adherence rates between both groups ($\gamma^2 = 4.8$; P = .197).

Primary Outcome Measure

In the AG, the VISA-A score improved from 60.7 ± 17.1 at baseline to 89.4 ± 13.0 at 1-year follow-up (P<.001) (Figure 2A), whereas in the SG, the VISA-A score increased from 59.8 ± 22.2 to 83.2 ± 22.4 (P<.001). Table 2 reports the estimated marginal means for each follow-up measurement (12 weeks, 26 weeks, and 1 year), with correction for baseline and confounders and using the intervention-by-time interaction. Because the interaction term did not improve the model fit, we report a treatment effect without the interaction term, indicating a constant difference at each follow-up up to 1 year. Linear mixed-model analysis without the interaction term showed a nonsignificant treatment effect (2.4 [95% CI, -8.5 to 13.3]; P=.656) (Table 3) for the AG after correcting for baseline VISA-A and confounders.

Secondary Outcome Measures

The VAS-ADL showed a decrease of 28.6 ± 22.1 at baseline to 5.8 ± 8.3 at 1-year follow-up for the AG (P=.004) (Figure 2B). In the SG, VAS-ADL decreased from 28.6 ± 31.8 to 9.0 ± 23.0 (P=.004). The estimated marginal means at the different follow-up measurements are shown in Table 2. After correction for baseline VAS-ADL and confounders, the linear-mixed model analysis without the group-by-time interaction revealed a constant nonsignificant treatment effect (-2.0 [95% CI, -11.3 to 7.3]; P=.665; see Table 3).

In the AG, VAS–sports decreased from 44.8 ± 26.8 at baseline to 13.1 ± 20.2 at 1-year follow-up (P = .027) (Figure 2C), whereas in the SG, VAS–sports improved from 46.6 ± 32.6 to 12.8 ± 24.6 (P = .027). Without including the intervention-by-time interaction, a non-significant treatment effect (1.3 [95% CI, -12.8 to 15.3];

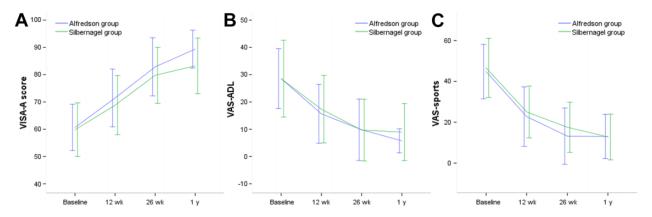


Figure 2. Observed mean scores with 95% CI of the (A) VISA-A, (B) VAS-ADL, and (C) VAS-sports from baseline to 1-year follow-up. VAS-ADL, visual analog scale for activities of daily living; VAS-sports, visual analog scale for sports activities; VISA-A, Victorian Institute of Sports Assessment-Achilles.

1 y

	Without Correction		With Correction for Baseline		With Correction for Baseline and Confounders a	
	Treatment Effect $(95\% \text{ CI})^b$	P	Treatment Effect $(95\% \text{ CI})^b$	P	Treatment Effect $(95\% \text{ CI})^b$	P
VISA-A score						
12 wk	2.1 (-12.2 to 16.4)	.772	2.1 (-10.7 to 14.8)	.741	0.9 (-11.9 to 13.8)	.885
26 wk	2.2 (-11.4 to 15.8)	.741	2.2 (-10.4 to 14.8)	.728	1.1 (-11.8 to 14.0)	.867
1 y	5.6 (-6.6 to 17.9)	.360	5.5 (-6.5 to 17.5)	.361	4.3 (-8.0 to 16.6)	.479
VAS-ADL						
12 wk	-1.3 (-16.9 to 14.3)	.866	-1.6 (-13.2 to 10.0)	.784	-0.9 (-12.4 to 10.6)	.874
26 wk	3.2 (-11.2 to 17.7)	.653	3.6 (-8.5 to 15.6)	.552	4.5 (-8.1 to 17.0)	.475
1 y	-1.3 (-13.2 to 10.6)	.825	-0.8 (-10.7 to 9.1)	.864	-0.1 (-10.3 to 10.1)	.986
VAS-sports						
12 wk	-1.8 (-19.6 to 16.1)	.843	-1.6 (-19.0 to 15.7)	.849	-0.7 (-18.3 to 16.9)	.936
26 wk	-1.9 (-18.5 to 14.6)	.816	-1.8 (-18.2 to 14.6)	.824	-1.0 (-17.6 to 15.7)	.908

TABLE 2
Comparison of Primary and Secondary Outcomes in the Alfredson Versus the Silbernagel Group^a

2.0 (-12.8 to 16.7)

.789

TABLE 3 Treatment Effect Between the Alfredson and Silbernagel $Groups^a$

2.0 (-12.9 to 16.9)

	With correction for baseline and confounders $\!\!\!^a$		
	Treatment effect $(95\% \text{ CI})^b$	P	
VISA-A score	2.4 (-8.5 to 13.3)	.656	
VAS-ADL	-2.0 (-11.3 to 7.3)	.665	
VAS-sports	1.3 (-12.8 to 15.3)	.858	

^aBaseline measurement of respective outcome, sex, age, and duration of symptoms. VAS-ADL, visual analog scale for activities of daily living; VAS-sports, visual analog scale for sports activities; VISA-A, Victorian Institute of Sports Assessment-Achilles.

P = .858; see Table 3) was found after adjustment for baseline VAS-sports and confounders.

The results for the EQ-5D are shown in Appendix Figure A1. In both groups, the percentage of participants reporting "no problems" on the domains mobility, usual activities, and pain/discomfort increased between baseline and 1 year follow-up. In the SG, more than 25% of the participants encountered some problems with anxiety/depression at baseline, but this percentage decreased from 27.3% to 14.3% at 1-year follow-up. In the AG, none of the participants reported any problems with anxiety/depression during the study. The EQ-5D VAS-score changed from 77.2 \pm 13.1 at baseline to 77.9 \pm 23.4 at 1-year follow-up in the SG, and from 82.6 \pm 8.7 to 81.0 \pm 20.3 in the AG, indicating no improvement in the self-rated health of the participants up to 1-year follow-up.

The GPE showed that, at 1-year follow-up, 50% of the participants in the AG reported "much" or "very much" improvement, whereas this percentage in the SG was 77.3%. This difference was statistically significant ($\chi^2 = 10.3$; P = .04).

DISCUSSION

.788

In this RCT, we found that both the Alfredson and the Silbernagel programs yielded significant improvement of clinical symptoms up to 1-year follow-up in recreational athletes with midportion AT, but no significant differences between both programs were found. QOL and perceived effect also improved in both groups, with significantly more participants in the SG considering themselves improved at 1-year follow-up in comparison with the AG.

2.9 (-12.3 to 18.1)

.702

Improvement in the VISA-A and the VAS-scores between baseline and 1-year follow-up, which was found within both groups, exceeded the minimal clinically important difference (MCID) reported for these outcome measures. 19,24,38 These positive clinical results are frequently reported for both the Alfredson and the Silbernagel loading program in patients with midportion AT, 21,30 with the VISA-A score considered the most relevant patient-reported outcome measure. 19 For the Silbernagel program, an increase of 28 to 34 points in the VISA-A has been reported, 34 while the increase in VISA-A score for the Alfredson program ranged between 18 and 25 points. 4,29,39 Baseline VISA-A values in the present study were comparable with those reported in other studies, 34,39 but at 1-year follow-up our results were slightly different from data reported elsewhere. On one hand, improvement of VISA-A score for the SG in the present study (23.7 points) was slightly inferior to the 28 to 34 points found elsewhere.³⁴ On the other hand, improvement for the AG obtained in the present study (an increase of 29.3 points on the VISA-A) exceeded the results reported in other studies (an 18- to 25-point increase on the VISA-A). 4,29,39 The precision of the estimates found in the present study may be affected by our small sample size; comparison of effect sizes with other studies is therefore complicated. However, we feel that some explanations may account for the discrepancies in effect sizes found in other studies. Primarily, although load progression in the present study was applied according to the original protocols, we did not

^aBaseline measurement of respective outcome, sex, age, and duration of symptoms. VAS-ADL, visual analog scale for activities of daily living; VAS-sports, visual analog scale for sports activities; VISA-A, Victorian Institute of Sports Assessment-Achilles.

^bTreatment effect reported with the Alfredson group as reference group.

 $[^]b\mathrm{Treatment}$ effects reported with the Alfredson group as reference group.

exactly monitor the amount of weight that each participant added during the course of the exercise program. Therefore, there may be a discrepancy between the present study and other AT exercise trials in the amount of weight added. Second, the frequency of supervision in the present study (3 times in 12 weeks) differed from the frequency of supervision in the original study using the Silbernagel program (12 times in 12 weeks).³⁵ This may explain why higher VISA-A change scores were found in the original Silbernagel study³⁴ compared with our results. Last, differences in the follow-up period may account for differences in effect sizes. Rompe et al²⁹ assessed the Alfredson program using a 16-week follow-up, which was different from the follow-up terms used in the present study. The change score in VISA-A reported at 16 weeks' follow-up in their study was comparable with our findings at a 26-week follow-up, but inferior to our results at 1-year follow-up.

Our data showed that clinical symptoms continue to improve in the long term, for both the AG and the SG. This is in accordance with other research showing improvement of the VISA-A score up to 5 years after following these programs. However, despite a continuous improvement over the course of the study, our results illustrate that many participants still encountered mild symptoms at 1 year. In both groups, the mean VISA-A score at 1 year did not exceed 90 points, which is considered the lower limit for full recovery according to some authors. Previous research already showed that patients may encounter mild symptoms despite rehabilitation, 33,36 and in our opinion this is important to discuss early in rehabilitation to adequately manage patient expectations.

We could not find a significant difference in clinical improvement between the different contraction modes used in our study, and the magnitude of the differences was far below the MCIDs reported for the VISA-A and VAS. 19,24,38 This corresponds with other studies comparing different loading programs in AT^{3,21} and studies investigating loading programs for other tendinopathies^{5,15,16} and may suggest that contraction mode is not decisive for the effect of loading in AT rehabilitation. Yet, because both programs include eccentric contractions, it may also be that eccentric loading is the key for clinical improvement and that adding concentric exercises is of little value. To our knowledge, only 1 study showed that Alfredson isolated eccentric loading is superior to concentric loading.²⁰ However, in that study many of the involved concentric exercises were nonor partial weightbearing. Obviously, this is less demanding for the muscle-tendon complex than full weightbearing exercises and, therefore, supported by the present findings, we caution against the conclusion that eccentric loading is superior to concentric loading.

Although we could not demonstrate significant differences in terms of clinical improvement between the SG and the AG, we found some interesting findings on QOL and GPE. In both groups, QOL improved at 1-year follow-up, with fewer participants reporting problems with mobility, usual activities, and pain in both groups. However, in the SG, more problems with anxiety/depression were reported in comparison with the AG. Somewhat contrary to the latter findings, the number of participants who considered

themselves improved after 1 year (GPE) was significantly larger in the SG than in the AG (P=.04). This may be explained by the age differences between both groups. Participants in the AG were younger, and because age is suggested to be associated with patient expectations, ¹³ it can be hypothesized that participants in the AG had higher expectations and consequently were less satisfied with their improvement. However, because the age differences were limited, this explanation remains speculative. Although a firm conclusion cannot be drawn, our findings may indicate that some aspects of improvement are not fully captured by the VISA-A and VAS scores and that outcome measures evaluating QOL and GPEs should be included in AT intervention studies.

The strength of our study is its pragmatic nature and the clinical applicability of our design. By solely using home-based exercise interventions with minimal supervision, participants were largely responsible for their own recovery. The clinically relevant results and the rather high adherence rates found in both groups (74.1% and 77.3%) indicate that self-management is an appropriate management strategy for midportion AT, and that intensive supervision may not be required. It can be argued, however, that more frequent supervision may have improved the adherence rates and thereby could have yielded superior results.

The main limitation of our trial is that we did not reach our targeted sample size because of unforeseen circumstances and strict exclusion criteria (eg, regarding duration of symptoms, bilateral symptoms, and other musculoskeletal injuries). The latter increased the homogeneity of our study sample, but it also impeded us from reaching the targeted sample size. Consequently, our results are based on fewer participants than desired. This affects the precision of our estimates and increases the chance of a type II error. Several attempts to increase the inclusion rate unfortunately did not sufficiently affect the final sample size.

We did not include imaging modalities to establish the diagnosis of midportion AT, which may also be recognized as a limitation of our study. Although imaging is not considered necessary for diagnosing AT,⁶ it could have been useful in establishing the stage of tendinopathy and ruling out another confounding disease.

Although we emphasize that our conclusions should be interpreted with caution, we feel that the observed treatment effects still indicate there are no relevant differences in clinical effects between the included loading programs. However, future adequately powered studies are warranted to validate this statement and to further explore the relevance of contraction mode in rehabilitation of AT.

Clinical Implications

In this study we found that loading according to either the Alfredson or the Silbernagel protocol is effective in reducing clinical symptoms. However, our results did not demonstrate any difference in effects between both programs. Although underpowered, these findings suggest that contraction mode may not be a relevant factor for the clinical effect, and clinicians can confidently use both programs in the rehabilitation of their patients with AT.

CONCLUSION

Although both were effective in terms of improvement of clinical symptoms, we found no difference in clinical effects between the Alfredson isolated eccentric and the Silbernagel combined concentric-eccentric loading program at up to a 1-year follow-up. Given the high adherence rates that were found in this RCT, offering either the Alfredson or the Silbernagel programs as a home-based program with limited supervision appears to be an effective treatment strategy for midportion AT.

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APPENDIX

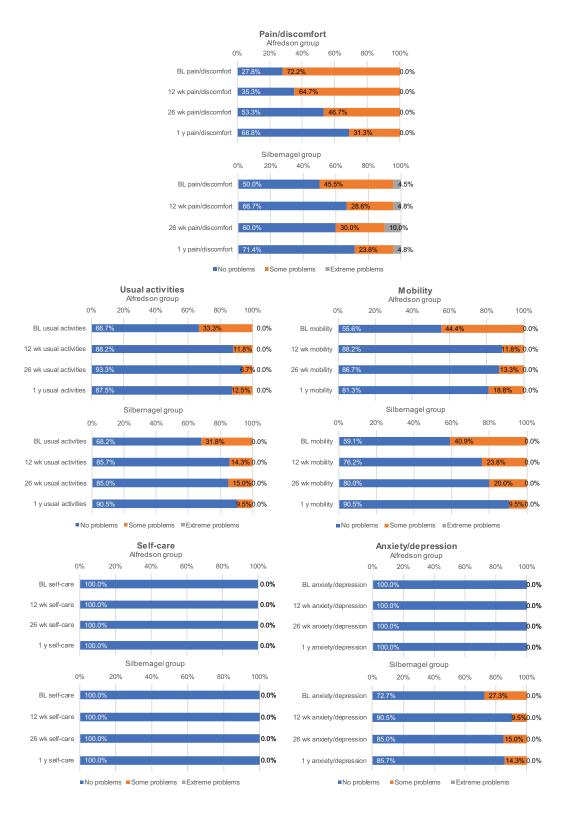


Figure A1. Proportion of participants responding as having no problems, some problems, or extreme problems on the EuroQol 5 Dimensions instrument questionnaire subscales for mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. BL, baseline.