The Journal of Foot & Ankle Surgery 000 (2021) 1–5

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

Original Research

Functional Gains Using Radial and Combined Shockwave Therapy in the Management of Achilles Tendinopathy

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ARTICLE INFO

Level of Clinical Evidence: 3

Keywords:
Achilles tendinopathy
eccentrics
focused shockwave
radial shockwave
sports medicine

ABSTRACT

Achilles tendinopathy is a common condition and many patients have functional limitations after initial conservative treatment. Shockwave therapy has been shown to improve function within patients; however, comparative outcomes for different forms of shockwave are poorly described. In this retrospective cohort study, we describe findings from a quality improvement initiative evaluating safety and functional outcomes after treatment with radial shockwave therapy (n = 58) or combined radial and focused shockwave therapy (n = 29) for patients with Achilles tendinopathy refractory to exercise therapy. All patients were prescribed an eccentric exercise program. We hypothesized both groups would see improvements in function quantified using the Victorian Institute of Sports Assessment-Achilles with similar safety outcomes. Overall, the minimal clinically important difference (defined at 7 for insertional and 12 for noninsertional Achilles tendinopathy) was met in a greater proportion of patients treated with combined shockwave compared to radial shockwave (26 [89.7%] vs 37 [63.8%], $p = .022$). The change in Victorian Institute of Sports Assessment-Achilles from baseline to final treatment was not different between combined and radial-only groups (23.3 ± 12.6 vs 19.9 ± 18.7, $p = .2$). Within group differences from baseline to final follow-up measures (mean duration 17.9 ± 14.8 weeks) demonstrated overall functional improvement for both groups (both $p < .0001$). No serious adverse effects were observed. Our findings suggest combined radial and focused shockwave therapy may provide more predictable functional gains for treatment of Achilles tendinopathy compared to radial shockwave therapy.

Achilles tendinopathy (AT) is one of the most frequently reported injuries to the foot and ankle amongst a multitude of sporting activities (1). The prevalence of this injury has been reported as high as 52% in runners (2). The condition is also seen in nonathlete populations, with estimates that one-third of those with AT lead a sedentary lifestyle (3). AT can be further classified as insertional or noninsertional. Initial conservative management strategies include physical therapy (often utilizing progressive eccentric heel-drop exercises through the Alfredson protocol), heel lifts, oral anti-inflammatories, and nitroglycerin patches. Unfortunately, up to one-half of patients receiving conservative treatment for Achilles tendinopathy may have persistent symptoms and desire further treatment (4).

A variety of interventions have been proposed in management of AT. Recently, a network meta-analysis compared interventions for noninsertional AT (5). This review evaluated short term (<3 months) and longer-term outcomes (3-12 months) for management of mid-portion AT and quantified differences using the Victorian Institute of Sports Assessment – Achilles (VISA-A). While high-volume injection with steroid plus eccentrics was shown to have good outcomes, corticosteroid injections are less commonly used due to concerns for tendon toxicity and limited long-term efficacy (6). Eccentric loading showed benefits in longer-term outcomes, with stronger effect seen combining eccentric exercises with extracorporeal shockwave therapy (ESWT) suggesting potential synergy in benefits.

ESWT can be classified as either "focused" (F-SWT) or "radial" (R-SWT) based on the characteristics in waveform generated and effects on target tissue. R-SWT uses pressure waves generated through pneumatic device and is sometimes referred to as a soundwave therapy. In contrast, F-SWT creates a higher amplitude phase wave through electromagnetic, electrohydraulic, and piezoelectric sources to achieve higher energy flux density levels (7). The differences in wave characteristics may affect tissue differently. While the exact mechanism of action for ESWT remains unknown, proposed mechanisms for the positive effects observed in tendinopathy include facilitating collagen synthesis

Financial Disclosure: The authors have no financial disclosures to report.
Conflict of Interest: The authors have no conflicts of interest to report.
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https://doi.org/10.1053/j.jfas.2021.06.014

and upregulation of growth factors that promotes proliferation of tenocytes (8,9). The analgesic effect may arise from multiple factors affecting pain neurotransmission and nociceptor hyperstimulation (10).

Prior work has studied either F-SWT or R-SWT for management of AT, with a majority of studies demonstrating improvement in pain and function (7). However, 2 recent studies have evaluated combined R-SWT and F-SWT in treatment of AT, we will refer to this as combined SWT (C-SWT). One study randomly assigned 43 participants to 4 weekly treatments of C-SWT (n = 22) or placebo (n = 21) (11). Over 16 weeks, both groups demonstrated reduced pain using visual analog scale (VAS) and improved function using the American Orthopaedic Foot and Ankle Society at study endpoint, without greater gains observed in C-SWT. A separate report describes longer-term outcomes in 24 patients receiving C-SWT to 24 months and reports good outcomes based on improvement in VAS and Roles and Maudsley (12). Limitations in both reports include small sample sizes and they do not use an Achilles tendon specific validated outcome measure. The relative effects of R-SWT compared to C-SWT for treatment of AT were not assessed.

Collect research suggests shockwave may be helpful in management of AT, but the comparative effects of R-SWT to C-SWT has not been described. Safety concerns for tendon rupture are documented in a randomized control trial for AT using F-SWT (13); similar outcomes have not been reported for R-SWT. Treatment outcomes may be improved with F-SWT compared to R-SWT in management of tendinopathy (14). To address these aims, the purpose of this report was to describe the safety and functional outcomes using R-SWT and C-SWT for the management of AT. We hypothesized that patients receiving R-SWT and C-SWT would both see improvements in function quantified using VISA-A with similar safety outcomes. As an exploratory aim, we described outcomes in patients who elected to receive C-SWT after not achieving satisfactory outcomes in R-SWT.

Patients and Methods

This quality improvement initiative was approved by the Department of Physical Medicine and Rehabilitation at Spaulding Rehabilitation Hospital, and Institutional Review Board (IRB) approval was waived for this study. We used the SQUIRE-2 guidelines for reporting quality improvement data (15). Data were extracted by 2 authors (D.R., A.S.T.) using chart review from August 2017 to September 2020 for all patients receiving R-SWT or C-SWT for either insertional or mid-portion AT at the senior authors' (A.S.T.) outpatient sports medicine clinic. Abstracted data included clinical and treatment characteristics, demographics, and functional outcome measures of VISA-A. The diagnosis of Achilles tendinopathy was primarily based on history and physical examination, with imaging obtained when indicated to exclude alternative pathologies. Inclusion criteria were: (1) primary diagnosis of Achilles tendinopathy, either insertional or mid-portion, (2) prior treatment with physical therapy or previously saw a medical provider and completed prescribed eccentric heel drops, (3) symptoms greater than 3 months, and (4) available baseline and follow-up functional outcome measures. Exclusion criteria were: (1) previous Achilles tendon surgery, (2) myotendinous Achilles pain, (3) known connective tissue or inflammatory disease (e.g., rheumatoid arthritis), (4) presence of other lower extremity injury at time of treatment (e.g., known ankle arthritis, plantar fasciitis, or combined other lower extremity injury such as patellar tendinopathy). All patients fulfilling these criteria were deemed eligible for inclusion in this study.

Treatment Procedure

Patients received either R-SWT or C-SWT. The clinic performing ESWT used R-SWT solely as the treatment offered from August 2017 to January 2019. C-SWT was introduced to clinic in January 2019 and was offered to patients as an alternative to R-SWT. As ESWT is not covered by most commercial insurers in the United States, patients paid a one-time fee for treatment. ESWT was performed over a minimum of 3 weekly sessions, with additional sessions as needed to maximize clinical response. Those in the R-SWT group who did not have satisfactory response were offered C-SWT at no additional cost.

R-SWT treatments were performed using the Storz Extracorporeal pulse activation technology (EPAT®) device (Storz Medical, Tägerwilen, Switzerland). The R-SWT used 2 applicator heads each for a minimum of 3000 strikes at 15 Hz and set for a minimum pressure was 1.8 (range 1.8-4.5) Bar applied over areas of pain, including the calcaneal-tendon attachment, tendon, myotendinous junction and associated muscles of soleus and gastrocnemius. C-SWT was provided using F-SWT (Storz Duolith, Tägerwilen, Switzerland) set at a minimum of 1000 shocks at energy of 0.1 (range 0.1-0.45) mJ/mm^2 targeting primarily the Achilles tendon and R-SWT over the myotendinous region and affected muscles for a minimum of 3000 strikes at 15 Hz and set for a minimum pressure of 2 (range 2-4.5) Bar.

Settings of each shockwave device were adjusted for patient comfort and used the principle of clinical focusing (targeting areas of pain during treatment). Therefore, all patients reported pain during treatment, no topical or regional anesthetic was applied. Each patient was instructed to not use nonsteroidal anti-inflammatories and to avoid icing during their treatment course. Activities including running were allowed as tolerated with R-SWT and within 2 to 3 days with C-SWT unless pain was worse after treatment. Heel lifts, orthotics, and immobilization were not prescribed. Patients were recommended to resume formal physical therapy. Patients who recently completed physical therapy were recommended to continue their home exercise program. All patients were instructed to perform eccentric calf raises with a goal of 3 sets of 30 eccentric calf raises daily, modified to heel drop to the floor for insertional AT (16).

Typical treatment included 3 to 4 weekly shockwave treatment sessions. Treatment session number was determined based on combination of clinical judgement and patient response to treatment. Follow-up visits were scheduled at 6 to 8 weeks to evaluate for effect of initial treatment program. At repeat clinic visits, further ESWT was offered to all patients who did not report sufficient clinical relief. For patients initially treated with R-SWT, each was offered further treatment with R-SWT or C-SWT. For patients with C-SWT, further treatment primarily with R-SWT was offered to help optimize treatment effects. VISA-A measures were obtained on date of first ESWT treatment, at clinical visit follow-up, and after further treatment with shockwave.

Outcome Assessment

The VISA-A was used to assess functional outcomes. VISA questionnaires are comprised of 8 questions assessing limitation in one's ability to participate in sport. Scores range from 100 (asymptomatic) to 0 points (17). A change of 7 points was used for the minimal clinically important difference (MCID) in patients with insertional AT, and 12-point MCID for mid-portion AT (18,19). VISA-A was collected on date of first treatment, after completion of initial series of treatment, and at each follow-up visit.

Statistical Methods

Descriptive statistics are presented for demographics and patient populations, presenting mean and standard deviations for continuous data, and frequencies with percentages for qualitative data. After verification of normal data distribution using the Kolmogorov-Smirnov normality test, unpaired 2-tailed *t* tests were used to compare means of continuous demographic variables between the 2 groups. Mann-Whitney U Tests were used when data were not normally distributed. Chi-squared tests with Yates' continuity correction were used to evaluate the primary outcome of whether or not the number of patients in each group who met the MCID differed across groups (C.O.T). A repeated measures ANOVA model was used with time point (pretreatment vs final follow-up) and pretreatment x SWT interaction, to test for significant difference in VISA-A score from pre- to post-treatment across the 2 groups. To assess whether there was a temporal trend of R-SWT, we used a linear regression model with the pre-/post-treatment difference in VISA-A as the dependent variable and the actual sequence of each treatment as the independent variable. For those treated with R-SWT who later crossed-over to C-SWT, outcomes reported are based on their baseline and final VISA-A score after solely R-SWT treatment. Thus, all statistical analyses on R-SWT patients depict their outcomes after only R-SWT. We descriptively present the functional outcomes for those who crossed-over from R-SWT to C-SWT. Statistical significance was defined a priori at the 5% ($p \leq .05$) level.

Results

Chart review of a single provider who performs shockwave in clinic (A.S.T.) identified 111 patients with AT treated with shockwave during the study period. Nine of these patients were excluded for not completing a follow-up functional outcome, 11 were excluded for the presence of additional lower extremity injuries, and 4 were excluded for a diagnosis of myotendinous Achilles pain, leaving 87 patients available for analysis (Fig. 1). Most (n = 58, 67%) were initially treated with R-SWT and 29 (33%) with C-SWT. Demographics and clinical characteristics were similar by treatment group (Table 1). Overall, the population was primarily male, on average was in fifth decade of life, and a majority were runners (n = 63, 72%). Eighty-four patients (96.6%) had previously completed formal physical therapy, and the other 3 (3.4%) had seen a different medical provider previously and completed prescribed eccentric heel drops. The mean duration of symptoms was 18 months.

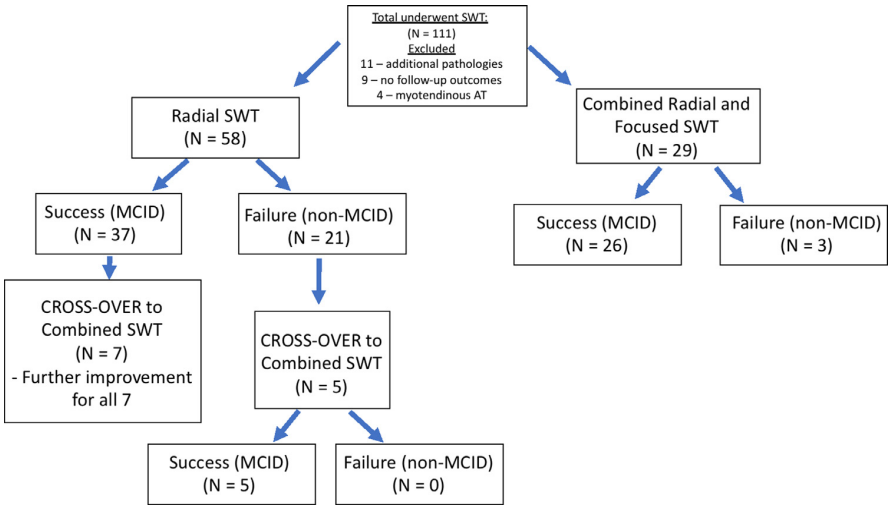

Fig. 1. Patient population and treatment outcomes (N = 87). Flowchart of patients treated with radial or combined radial and focused shockwave therapy (SWT), including number of patients in each group who met the minimal clinically important difference (MCID) for their Victorian Institute of Sports Assessment-Achilles score.

Baseline VISA-A scores were not different by treatment type nor location of AT (Table 2). Overall, the MCID was met in a greater proportion of patients treated with C-SWT compared to R-SWT (26 (89.7%) vs 37 (63.8%), p = .022: Table 2). The improvement in change of VISA-A score was not different between C-SWT and R-SWT (23.3 ± 12.6 vs 19.9 ± 18.7, p = .2). At final follow-up measure (mean duration from start of treatment 17.9 ± 14.8 weeks), changes were significantly different within both R-SWT (p < .001) and C-SWT (p < .001). Mean number of treatment sessions before final VISA-A was 4.6 ± 1.9 for R-SWT and 4.3 ± 1.4 for C-SWT (p = .51). Proportion of patients meeting the MCID were not different between runners and nonrunners (46 (73%) vs 14 (58%)) across the entire cohort (p = .19).

For R-SWT, 23 (39.7%) patients had 3 initial treatment sessions and 35 (60.3%) patients had 4 initial treatment sessions. For C-SWT, 10 (34.5%) patients had 3 initial treatment sessions and 19 (65.5%) patients had 4 initial treatment sessions. Proportion of patients initially receiving 3 or 4 treatment sessions was not different between the 2 groups (p = .64). No differences in proportion meeting the MCID were found within either the R-SWT or C-SWT groups depending on if they had 3 or 4 initial treatment sessions (p = .46; p = .55).

Recognizing that R-SWT was offered initially and C-SWT was performed later during clinical practice, time effect was evaluated to account for potential confounders including provider experience or patient characteristics. No temporal trend in outcomes with shockwave treatment success was found (p = .19). Five patients who initially completed R-SWT but did not meet the MCID elected to complete C-SWT, and all subsequently achieved the MCID (Fig. 2). For these 5 patients, the mean time between their last R-SWT treatment and starting C-SWT was 11.3 ± 7.5 weeks and the mean time from starting C-SWT to final VISA-A score was 15.8 ± 8.2 weeks. Outside of expected pain during the procedure, no complications were observed including tendon rupture.

Table 1
Demographics and clinical characteristics (N = 87)

	Radial (n = 58)	Combined (n = 29)	p Value
Age (years)	45.3 ± 14.3	44.8 ± 12.5	.87
Male	33 (56.9%)	22 (75.9%)	.08
Body mass index	25.0 ± 4.4	24.9 ± 3.8	.98
Pathology			.22
Insertional	24 (41.4%)	16 (55.2%)	
Mid-portion	34 (58.6%)	13 (44.8%)	
Laterality			.56
Left	26 (44.8%)	13 (44.8%)	
Right	23 (39.7%)	9 (31.0%)	
Bilateral	9 (15.5%)	7 (24.2%)	
Duration of symptoms (months)	16.8 ± 10.9	18.5 ± 11.1	.52
Runner	39 (67.2%)	24 (82.8%)	.13
Previous formal physical therapy	56 (96.6%)	28 (96.6%)	.53
Prior imaging	35 (60.3%)	15 (51.7%)	.44

Mean and standard deviations or frequencies with percentages are reported.

Discussion

The purpose of this quality improvement report was to evaluate the effectiveness of R-SWT and C-SWT in management of AT refractory to physical therapy. Using the VISA-A outcome measure, we identified a majority of patients met clinical improvement with treatment. We observed that the portion of patients meeting the MCID for VISA-A was higher in the C-SWT compared to the R-SWT group, although the mean change in VISA scores were not significantly different. Further, the individuals who received initial R-SWT and elected to additional treatment

Table 2
Victorian Institute of Sports Assessment-Achilles outcomes (N = 87)

All (Insertional + Mid-Portion)	Radial (n = 58)	Combined (n = 29)	p Value
Baseline	45.5 ± 20.3	47.3 ± 13.6	.67
Final	65.4 ± 19.9	70.6 ± 14.6	.22
Change	19.9 ± 18.7	23.3 ± 12.6	.19
Met MCID (Insertional = 7, Mid-portion = 12)	37 (63.8%)	26 (89.7%)	.022*
Insertional AT Only	Radial (n = 24)	Combined (n = 16)	p Value
Baseline	45.0 ± 21.2	47.0 ± 13.3	.74
Final	62.4 ± 20.9	67.4 ± 13.6	.41
Change	17.4 ± 19.6	20.4 ± 12.2	.59
Insertional AT met MCID of 7	15 (62.5%)	15 (93.7%)	NA
Mid-portion AT Only	Radial (n = 34)	Combined (n = 13)	
Baseline	45.8 ± 19.6	47.7 ± 13.8	.76
Final	67.6 ± 18.9	74.5 ± 14.6	.25
Change	21.7 ± 17.8	26.8 ± 12.2	.35
Mid-portion AT met MCID of 12	22 (64.7%)	11 (84.6%)	NA

Abbreviations: AT, Achilles tendinopathy; MCID, minimal clinically important difference; VISA-A, Victorian Institute of Sports Assessment-Achilles.
Mean and standard deviations or frequencies with percentages are reported.
* p value <.05.

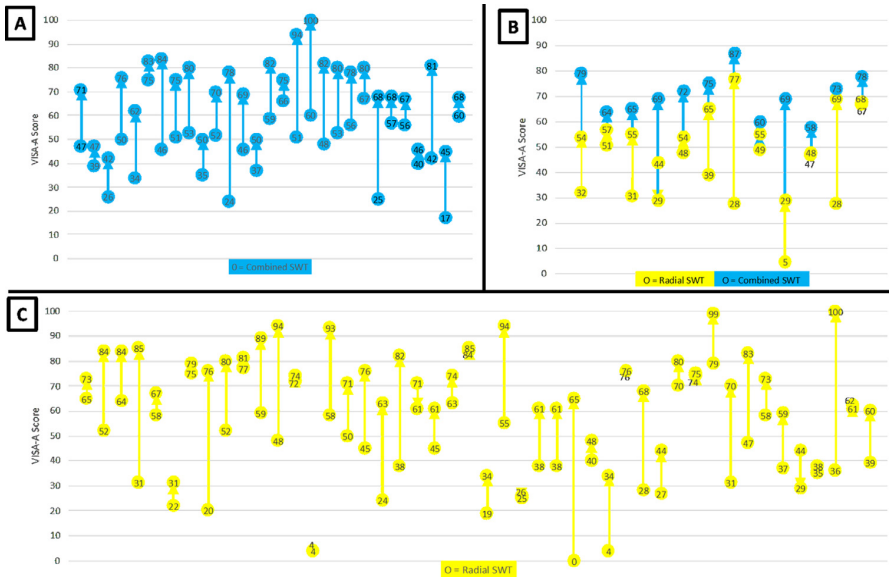

Fig. 2. Individual Victorian Institute of Sports Assessment-Achilles score changes by treatment type (N = 87). Dumbbell plot depicting individual patients' baseline and final Victorian Institute of Sports Assessment-Achilles scores: (*A*) patients who received only combined shockwave therapy, (*B*) patients who received radial shockwave therapy patients and later crossed-over to combined shockwave therapy, (*C*) patients who received only radial shockwave therapy.

with C-SWT all met the MCID. We did not observe any adverse outcomes. These findings collectively suggest that a majority of patients with chronic AT may achieve functional gains using ESWT.

The findings from this report of high rate of success with shockwave therapy and eccentric exercises are consistent with prior studies in management of AT. Most studies for AT have evaluated effects using R-SWT. A 2009 randomized clinical trial evaluated 68 patients with refractory mid-portion AT (defined as >6 months of symptoms and failed conservative treatment) treated with either eccentric loading versus eccentric loading with 3 weekly sessions of R-SWT (20). Eccentrics were modeled after the Alfredson protocol and performed daily for 12 weeks. At 4-month follow-up, the combined R-SWT and exercise group demonstrated improved function (VISA-A) and pain (numeral rating scale) compared to eccentrics alone. On average VISA-A scores improved 14 points and NRS decreased 2 points more in the eccentrics combined with R-SWT group (p = .0016; p = .0045). The value of combined eccentrics with ESWT was also identified in a recent network meta-analysis evaluating treatments for mid-portion Achilles tendinopathy (5). Functional outcomes using VISA-A measure were observed at 3 to 12 months for eccentric exercises but not within shockwave as monotherapy. However, studies with combined eccentrics and shockwave demonstrated functional gains above eccentric exercise programs suggesting synergy of treatment. Notably, our patients were prescribed heel drops below neutral or to the floor depending on type of AT while many studies solely utilize the standard Alfredson protocol.

Despite the lack of difference in overall VISA-A score changes, the greater portion of patients meeting the MCID without any observed adverse effects suggests C-SWT to be a reasonable initial treatment strategy and adds to the limited reports on this treatment options. Vahdatpour et al demonstrated nonsignificant improvements in VAS and American Orthopaedic Foot and Ankle Society after treatment with C-SWT and eccentric exercises compared to sham SWT and eccentrics (11). Methodological issues previously mentioned, nonsteroidal anti-inflammatories (NSAID) usage, and lack of reporting on injury location and use of clinical focusing may further explain their findings. Additionally, lack of a comparison group limits interpretation of the C-SWT study by Saxena and Shou, despite good sustained relief identified in this study at close to 2 years for patients (12). The larger sample size in the latter study may have resulted in greater power to detect a difference in outcomes.

While this report is the largest to date to evaluate effects of C-SWT, limitations are noted to interpret these findings. The patient population from a convenience sample who elected to receive shockwave. No control group or alternative treatment arm of physical therapy was used to compare to each form of shockwave treatment. However, all patients had previously failed conservative treatment including prior physical therapy and the mean duration of symptoms suggests observed changes were unlikely to result from natural history of improvement. Additionally, we cannot exclude that the further improvements in VISA-A scores seen for those who initially received R-SWT and later elected to cross-over to C-SWT are not due to a delayed treatment response from R-SWT. Out of pocket costs associated with shockwave introduce potential for bias in population studied. Future studies are required to confirm these findings using a larger sample size and optimizing treatment protocol. Given our current results and the effect size (Cohen's d, 0.253), we estimate that at least 123 patients are needed to detect the same differences in proportions of patients meeting the VISA-A MCID between groups at a significance level of 0.05 with 80% power within the bounds of our study. Notably, the sample size resulting from this power calculation is based on our study duration, with mean treatment follow-up of 17.9 $\pm$ 14.8 weeks. Best practices include clinical focusing to guide treatment, restricting NSAID use, and use of tendon-specific outcome measures using a blinded, randomization treatment protocol.

In conclusion, the current study suggests a majority of patients with refractory AT benefit from both R-SWT and C-SWT combined with eccentric exercises regarding improved function. No major complications were observed. We did not observe any significant differences in improvement between insertional and noninsertional etiologies. C-SWT as initial treatment or for refractory pain following R-SWT may be reasonable to consider in management of AT. These results may aide the development of future randomized controlled trials or prospective cohort studies evaluating C-SWT use in AT.

Ethical Disclosure

Approval was obtained from our institution's quality improvement advisory board; IRB approval was thereby waived by the institution. The letter of approval has been attached to this submission.

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