Trigger point dry needling, manual therapy and exercise versus manual therapy and exercise for the management of Achilles tendinopathy: a feasibility study

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ABSTRACT

Objectives: The effects of trigger point dry needling (TDN) on myofascial trigger points (MTP) in Achilles tendinopathy (AT) are unknown. We conducted a study to test the feasibility of a large randomized controlled trial (RCT) to compare the effects of TDN to MT and exercise in a patient population with AT.

Methods: Twenty-two subjects were randomly assigned to a control (MT+Ex) or experimental group (TDN+MT+Ex) and completed eight treatment sessions over 4 weeks with follow up at 3 months. TDN was performed to MTPs in the gastrocnemius, soleus or tibialis posterior each session. The same MT and exercise program was conducted in both groups.

Results: Two of three criteria for feasibility were met. The attrition rate at 4-week and 3-month follow-up was 18.1% and 68%, respectively. Significant differences ($p < .05$) reported for within group analysis for FAAM, NPRS, pain pressure threshold and strength in both groups at 4 weeks and 3 months. The GROC was significant for MT + Ex at 3 months. No between group differences were found. The MCID for the FAAM, GROC was surpassed in both groups at 4 weeks and 3 months and NPRS for the MT + Ex group at 4 weeks.

Discussion: A large RCT to investigate the effects of TDN on MTP in AT is not feasible without modifications due to low recruitment and high attrition rate. Modifications to study design should give consideration for closed or national health-care system for access to large patient populations and reduced financial burden to subjects.

Trial Registration: ClinicalTrials.gov identifier: NCT03261504F.

ARTICLE HISTORY

Received 26 March 2019

Accepted 18 December 2019

KEYWORDS

Trigger point dry needling; myofascial trigger points; feasibility; Achilles; eccentric

Introduction

Achilles tendinopathy is the most prevalent pathology to the Achilles tendon. [1] Tendinopathy is classified as degenerative disorder with several contributing factors leading to the development [2–4]. Midportion tendinopathy is the most common pathology of the Achilles tendon and estimated to account for 55–65% of all incidences, while insertional tendinopathy follows with 20–25% [1]. The incidence of Achilles rupture is rising in the US and abroad, with evidence indicating tendinopathy is present prior to the rupture and may increase the rate of occurrence [5]. Achilles tendinopathy affects people with a sedentary or active lifestyle [6–9].

Mechanical loading through eccentric strengthening can stimulate a healing response in tendons [10,11]. Treatment programs for Achilles tendinopathy including eccentric exercise have reported improved pain and function [12] but the healing rate and functional improvements are slow with gradual improvements over a span of 4–5 years [13–16]. Other treatment options including extracorporeal shockwave therapy, tendon needling, platelet-rich plasma or corticosteroid injections have either modest benefit or questionable efficacy [12,16–19].

Pain from myofascial trigger points (MTPs) can refer to distant regions [20]. Active MTPs in the gastrocnemius, soleus and tibialis posterior have been shown to refer pain to the posterior heel [21]. Renin-Ordine reports a significant improvement in posterior heel pain following soft tissue mobilization to the MTPs in the lower leg in patients with posterior heel pain. Treatment for MTP with trigger point dry needling (TDN) has been reported to be effective and the number of studies reporting beneficial effects of TDN to MTPs is rapidly growing for several diagnoses. [22–24] These results occur in much shorter timeframes than what has been reported for eccentric exercise and other interventions for Achilles tendinopathy [15,16,25]. There are no studies in the published literature that have investigated the effects of TDN for myofascial trigger points in Achilles tendinopathy.

Despite these reported benefits, there are still unanswered questions regarding TDN and the effectiveness compared to other interventions [26]. At present, there is questionable reliability for diagnosing MTPs with clinical examination procedures [27] as well as concerns related to the recommended screening examination for performing TDN [28]. Furthermore, there is inconsistency with the parameters for TDN procedures, the importance of the

local twitch response to outcomes [29] and insufficient data to determine if superficial or deep needling is more effective for long-term benefits [30].

Given the prevalence of Achilles tendinopathy and slow progress with eccentric training, as well as the reported effectiveness of TDN, a large randomized controlled trial is warranted to investigate the effect of TDN on pain and functional outcomes, although the feasibility to conduct a large RCT for Achilles tendinopathy is questionable. Changes in the health-care delivery model and rising out-of-pocket costs for medical care may negatively affect the opportunities to recruit subjects for clinical research [31–35]. In addition, TDN is not included in the physical therapy practice act of all states, limiting the regions that data collection may occur. Barriers to subject participation including aversion to needles [36] and attrition rate are additional factors that can limit the total number of subjects completing a study. Therefore, this preliminary study was developed to assist in the determination of the feasibility of a large RCT investigating the effects of TDN on posterior heel pain in patients with Achilles tendinopathy.

The primary objectives of the current feasibility study were to report on subject recruitment and practicality of conducting this study design while maintaining normal operations in physical therapy clinics. These objectives include:

- (1) Report the access to participants with Achilles tendinopathy in private, outpatient physical therapy clinics.
- (2) Identify barriers for subject participation (injury severity, fear of needles, cost of care, time to complete study protocol and follow-up).
- (3) Describe the practicality of subject recruitment during normal clinic operations in physical therapy clinics.

The secondary objectives for this study were developed to describe the outcomes of this study and determine if the treatment protocol is worthwhile to include or redesign. These include:

- (1) Report participant's adherence to treatment.
- (2) Report and describe any adverse responses to treatment.
- (3) Report the attrition rate with follow-up data collection at 4 weeks and 3 months.
- (4) Report within, and between group treatment effects.

The determination of the feasibility for a randomized controlled trial will be based on the supporting data for each of the primary and secondary objectives [37–39]. Analysis of the primary objectives will be qualitative, while the secondary objectives will be

quantitative. The determination of the feasibility of the treatment protocol as described in the secondary objectives was adopted from a feasibility study reported by Tough et al. [37]. The treatment protocol for a randomized controlled trial will be feasible if 1) the 4-week attrition rate is less than 20%; 2) no adverse responses are reported; and 3) at least 75% of patients complete follow-up assessment data.

Methods

This feasibility study was conducted with a single-factor, pretest-posttest control group design. CONSORT guidelines with extension for randomized feasibility and pilot studies were followed for reporting the results of this study [40]. Consecutive patients presenting to data collection facilities were eligible to participate in the study. All data were collected in a total of seven private outpatient physical therapy clinics in North Carolina, Tennessee and Iowa by physical therapists. The primary investigator has over 20 years of clinical practice and over 10 years of experience performing TDN. There were seven additional physical therapists who contributed to the data collection. The clinical experience ranges from 2 to 20 years and all clinicians were certified to perform TDN for over 1 year at the time of data collection. All but one of the investigators were orthopedic clinical specialists and one was dual credentialed with orthopedic and sports.

The following conditions had to be met for the participants to be eligible to participate in the study:

- (1) Participants were between the ages of 18–70 years
- (2) Subjective report of the primary location of pain at any point along the Achilles tendon
- (3) Pain present ≥ 4 weeks
- (4) Positive Achilles palpation test
- (5) Positive Royal London test [2]
- (6) Decreased plantar flexion endurance test vs non-involved leg

The initial inclusion criteria were limited to non-insertional Achilles tendinopathy in the first year of data collection. However, the inclusion criteria were revised to include insertional Achilles tendinopathy due to low subject recruitment. The treatment protocol was not revised.

Patients with any of the following conditions were excluded from participating in the study:

- (1) fear of needles or unwilling to have needling performed due to fear or personal beliefs [41]
- (2) vascular or sensory disturbances in the lower leg which included but was not limited to injury to the nerve root or peripheral nerve in the

affected lower leg, inflammatory diseases, bleeding or clotting disorders, lymphedema, peripheral vascular or peripheral arterial disease. Diabetes was included in this group due to the progressive changes to the sensation and circulation in the lower extremities.

- (3) recent infection
- (4) previous surgery to the foot/ankle
- (5) steroid by injection or transdermal delivery to the posterior heel within three months
- (6) full rupture of the Achilles tendon
- (7) pregnant or may be pregnant
- (8) Tampa Scale for Kinesiophobia >37 [15]
- (9) participants with a work-related injury insured by the bureau of worker's compensation or involved in litigation related to injury of the lower leg, foot or ankle

The study was approved by the IRB at Nova Southeastern University and all patients provided informed consent prior to their participation. There was no compensation for the participants in this study.

Physical examination

On the first appointment, the physical therapist conducted a comprehensive examination to the lower leg, ankle and foot to verify the diagnosis of Achilles tendinopathy, presence of myofascial trigger points and study eligibility. A palpation exam was conducted for detecting myofascial trigger points as it has been found to be a reliable measure [37,38] but the controversy with reliability is noted [27, 42].

Data were collected at three intervals including baseline at the initial examination, at the conclusion of treatment at 4 weeks and follow-up at 3 months. The primary dependent variable was the Foot and Ankle Ability Measure (FAAM) while the secondary dependent variables were pain pressure threshold (PPT) measured with an algometer, global rating of change (GROC), numeric pain rating scale (NPRS) and strength. The FAAM is a self-report functional measure with subscales for ADL and sports. Only the ADL subscale was used in this study. This is a valid measure with an MCID of 8 points [43]. Pain threshold on the most painful site of the Achilles tendon was assessed with the FPK 20 PainTest™ algometer by Wagner Instruments [44]. The protocol for PPT measure was adopted from Renan-Ordine [21]. Pain pressure threshold measures were taken at the same location on the Achilles at the initial examination, at discharge as well as the 3-month follow-up examination. The GROC is a 15 point scale with an MCID of 3 points [45]. The NPRS is a valid measure with the MCID of 2 points [46]. The Tampa Scale of Kinesiophobia (TSK) was used for the exclusion criteria only with a cutoff score of 37 as recommended by Silbernagle [15]. Strength was measured with a single

leg heel raise and is a reliable test for Achilles tendinopathy. [15,47]

Random group assignment

Data were collected in eight outpatient physical therapy clinics located in North Carolina, Tennessee and Iowa. The process for random assignment was the same for each clinic and done independent of each respective clinic. A blocked randomization procedure was used to balance the participants among groups with a computer-generated blocked randomization sequence [48]. Each participant was randomly assigned to the dry needling or exercise group according to the blocked randomization sequence. A concealed envelope with the group allocation was presented to the patient by an assistant to the evaluating physical therapist and opened in their presence.

Interventions

Participants began treatment on the day of the examination, immediately after randomization. If the participant was unable to complete the treatment on the day of the examination, then treatment began on the day of the next scheduled appointment. For these participants no interventions were performed, and no exercise was instructed for an independent home program until the participant returned for the next treatment. This session was their second visit to the clinic, but it was recorded as treatment number one.

Participants in both groups were treated in the clinic twice a week for 4 weeks for a total of eight treatment sessions. Each treatment session for Group 1 (MT + Ex) and group 2 (TDN + MT + Ex) included the interventions in order as shown in Figure 1. Exercises are shown in Figure 2. The treatment protocol was the same for participants with insertional and non-insertional tendinopathy.

The needling technique began with pistoning in a cone fashion around the trigger point. When a twitch was elicited, pistoning continued at that precise location until the twitch was exhausted. Once the cone was completed, the needle was rotated until there was sufficient needle grasp that would not allow the needle to be easily removed from the tissue. The needle remained until the grasp released and the needle was easily removed by the physical therapist.

A discharge examination was completed immediately following all interventions during the eighth treatment session. At this visit, participants completed the FAAM, PPT, TSK, GROC, NPRS and muscle endurance testing. Participants were instructed to continue with the exercise program independently and return for a follow-up examination at 3 months after the completion of the last treatment session. The 3-month follow-up examination included the FAAM, PPT, TSK, GROC, NPRS and strength tests.

Figure 1. Sequence of Interventions for Each Treatment Session.

Data analysis

The independent variable in this study was trigger point dry needling and time while the primary dependent variable was the FAAM and the secondary dependent variables were PPT, GROC, NPRS and strength utilizing the plantar flexion endurance test. Descriptive statistics were used to analyze data including participant adherence to treatment, attrition rate and baseline demographics. Categorical variables were calculated with frequency counts while continuous variables were calculated with measures of central tendency.

Friedman's Test/Two Way Analysis of Variance by Ranks was conducted to assess effect size, changes in

FAAM, PPT, GROC, NPRS and plantar flexion endurance measures for within group interaction and Mann Whitney U to assess between group analysis was performed at baseline, 4 weeks and 3 months [38]. The level of significance was set at $p < .05$. Data analysis was performed with SPSS 25. An intention to treat analysis was utilized for dropouts with the last value forward method being used to replace any missing data.

Results

Data collection began in May 2015 and terminated on August 1st, 2018. During this time 70 subjects were

Figure 2. Exercises for both groups. Top Right: right leg eccentric lowering with knee flexed; Bottom Right: right leg eccentric heel lowering with knee extended; Bottom Left: resisted ankle adduction; Top Left: towel crunches.

referred with Achilles tendinopathy and 34 subjects met the inclusion criteria. There were 36 subjects (51.6% of referrals) who were not eligible to participate in the study. There were 34 subjects (48.6%) who met the inclusion and 22 subjects (31.4%) who agreed to participate and provided informed consent. The flow diagram of subject recruitment and retention is described in [Figure 3](#).

There were 12 patients (17.1% of referrals) eligible to participate in the study that declined. These patients declined participation due to averse to needle stick to painful trigger points (4), time commitment (2) and finances (6).

Each physical therapist collecting data was interviewed to determine if the study protocol was manageable during normal clinic operations. There was an average patient volume of 14 or more patients per 8-h day. All physical therapists rated the protocol to be manageable and were able to maintain their typical patient schedule without allotting additional time to complete the study protocol.

There were four subjects who voluntarily discontinued participation in the study resulting in an end of treatment drop out rate of 18.1%. Reasons for drop out included family emergency that resulted in extended delay upon return to treatment; time commitment due to family responsibilities; slow progress and returned to referring provider; one subject did not return for the final treatment session and discharge data collection despite reports of improved pain and functional activity tolerance. No serious adverse events were reported.

The attrition rate for the 3-month data collection was 61%. There was a total of seven subjects who returned for the 3-month follow-up while 11 subjects did not return across both groups. When factoring in the four subjects who dropped out of the study, the attrition rate increases to 68%.

Data analysis

A within group analysis for both groups included means and Friedman's Two-Way Analysis of Variance by Ranks test were computed for all dependent variables. A mean of the demographic data on participants in each group is available in [Table 1](#). The within group means, and significance for all tests and measures are provided in [Table 2](#), while between group means are in [Table 3](#). A statistically significant improvement with the within group analysis was achieved for all variables in both groups except for the GROC in the TDN+MT+Ex group.

A between group analysis was performed with Mann Whitney U. There were no statistically significant differences between groups for any of the dependent variables ([Table 3](#)).

Change scores for baseline to discharge at 4 weeks and baseline to 3-month follow-up were compared to the MCID for the FAAM, NPRS and GROC. The change score means for the FAAM between the baseline to the discharge at 4 weeks as well as the baseline to 3-month follow-up exceeded the MCID of 8 [43] for both data collection points in both groups. The individual subject results for the FAAM are reported in [Figures 2 and 3](#). The

Figure 3. Consort flow diagram for subject recruitment and retention.

MCID for the NPRS is 2 [46]. The change score means for the NPRS between the baseline to the discharge at 4 weeks as well as the baseline to 3-month follow-up exceeded the MCID for MT+Ex group. The TDN+MT+Ex group means for change exceeded the MCID for only the baseline to 3-month follow-up. The NPRS significantly improved for both groups. The MCID for the GROC is +4

[45]. The means for both groups exceeded the MCID at both the 4-week and 3-month measures in both groups.

Comparison of results between participants with insertional and non-insertional tendinopathy within each group is found in Table 4. Results at the 4-week and 3-month data collection reveal similar outcomes for each variable.

Table 1. Demographic Data.

	Group 1 (MT+Ex)			Group 2 (TDN+MT+Ex)		
	NON	INS	Combined	NON	INS	Combined
Age (yrs)	49.4	41	45.7	36.7	44.5	41.9
Height (inches)	68.4	71.75	69.9	65.7	67.5	66.9
Weight (lbs)	184.2	192.5	187.9	216.7	175.7	189.3
BMI	27.9	26.5	27.3	34.8	27.2	29.7
Pain Duration (months)	40.6	19	31	82.0	20.8	41.2

Key: NON: non-insertional tendinopathy; INS: insertional tendinopathy.

The effect size was calculated for groups 1 and 2 by using Kendall's Coefficient of Concordance. Kendall's W can be used for effect size calculations in SPSS [49]. The effect size was 0.663 for the MT + Ex group and .416 for the TDN+MT+Ex group.

Discussion

The primary aim of this study was to test the feasibility of a randomized controlled trial investigating the effects of TDN to myofascial trigger points, manual therapy and eccentric exercise compared to manual therapy and eccentric exercise alone for individuals with Achilles tendinopathy. Feasibility is determined by meeting the primary and secondary objectives.

Analysis of the primary objectives pertaining to subject recruitment is concerning. Primary objective #1 was not met. Subject recruitment for this study was slow with a total of 34 subjects eligible to participate in a 3-year time span. The initial study inclusion criteria were limited to mid-portion Achilles tendinopathy but were revised after the 1st year to include insertional tendinopathy to improve subject recruitment. Recruitment did increase in the second year of data collection but then dropped over the next year for a total of 22 subjects entering the study.

There were two key factors that were attributed to the low recruitment: rising out-of-pocket costs and changes in referring provider health system networks. Health insurance deductibles and co-pays for physical therapy services increased significantly in the first year of data collection in the regions of data collection.

Additionally, several data collection sites had referring providers for Achilles tendinopathy changing health-care networks leaving these clinics out of network and thus a higher cost for care. Communication from referring providers indicated that their patients were not willing to pay the higher cost for treatment at clinics out of network. However, these data were not collected.

Additional factors contributing to low recruitment were related to the barriers to participation. A total of 12 subjects were eligible but declined participation. This amounts to 17.1% of the total subjects evaluated for the study (n = 70) but 35.3% of the subjects eligible

Table 3. Between group analysis.

Variable	Sig
FAAM at 4 weeks	0.388
FAAM at 3 months	0.834
NPRS at 4 weeks	0.548
NPRS at 3 months	0.1
GROC at 4 weeks	0.063
GROC at 3 months	0.348
PPT at 4 weeks	0.257
PPT at 3 months	0.526
Strength at 4 weeks	0.916
Strength at 3 months	0.673

Table 4. Insertional vs Non-insertional Comparison.

Variable	Group	IE	DC	3 month
FAAM	1 -NON	66%	84%	85%
	1 - INS	49%	82%	84%
	2 - Non	62%	78%	79%
	2- INS	50%	73%	77%
NPRS	1 -NON	5.5	2.7	2.3
	1 - INS	6.3	2.8	0.8
	2 - Non	4.9	3.1	2.9
	2- INS	6	3.7	4
GROC	1 -NON		1.4	1.6
	1 - INS		1.1	1.9
	2 - Non		1.4	1.6
	2- INS		1.7	1.3
PPT	1 -NON	1.2	2.5	2.3
	1 - INS	1	2.1	2.9
	2 - Non	1.4	2.1	2.3
	2- INS	1	2.3	2.7
Strength	1 -NON	1.5	2.2	2.3
	1 - INS	1.1	2.1	2.5
	2 - Non	1.4	2.1	2.3
	2- INS	1.5	2.2	2.3

Key: Group 1: MT+Ex; Group 2: TDN+MT+Ex; NON: non-insertional tendinopathy; INS: insertional tendinopathy.

Table 2. Group 1 (MT +Ex) and Group 2 (TDN + MT + Ex) mean scores for tests and measures, change scores from baseline to 4 weeks and baseline to 3 months.

Tests and Measures	Baseline	4 week	3 month	Mean within group change (Baseline to 4 weeks)	Mean within group change (Baseline to 3 months)	p-value
Group 1						
FAAM (%)	59	86	85	24	28	*0.002
NPRS	5.8	2.7	1.7	3.1	4	*0.001
GROC	NA	4.8	6.1	NA	1.3	*0.046
PPT (kg)	2.3	4.7	5.3	2.4	3.3	*0.000
Strength (reps)	17.2	24.5	26.2	7.3	9	*0.008
Group 2						
FAAM (%)	59	78	78	19	19	*0.006
NPRS	5.2	3.3	3.2	1.9	2.0	*0.018
GROC	NA	5.3	5.3	NA	0	1
PPT (kg)	2.5	4	4.8	1.8	2.3	*0.006
Strength (reps)	9.4	15.3	17.6	5.9	8.2	*0.007

* P < .05

to participate ($n = 34$). Barriers to their participation included aversion to needle penetration to painful trigger points, financial constraints and limited time available to complete the treatment protocol. In this study, 4 of the 70 patients (5%) eligible to participate declined due to an aversion of needles.

Primary objective #3 was related to the practicality of enrolling subjects during normal clinic operations. All physical therapists reported average treatment volumes over 14 patients per 8-h day. They rated the protocol to be manageable and were able to maintain their typical patient schedule. Therefore, this protocol could be used in similar clinical practices for a future study.

The secondary objectives of this study were related to the clinical outcomes of the study.

Secondary objective #1 was met as the 4 week, end of treatment attrition rate was 18.1%. There were four subjects that dropped out of the study. Two subjects dropped out due to a family emergency and time commitment. There were two subjects who dropped out due to poor progress with treatment, one from each group, resulting in a 9.1% drop out rate due to poor progress.

Secondary objective #2 was also met. There were no serious adverse events reported in this study. Post-treatment soreness was commonly reported from subjects in both groups. Based on the criteria from Brady et al., soreness from TDN is considered a minor adverse event and was commonly reported in their study [50]. Post-exercise soreness is also a common report with eccentric training for patients with Achilles tendinopathy and may have contributed to the post-treatment soreness [11].

Secondary objective #3 was not met. The attrition rate for the 3-month follow-up for this study was poor at 68% when factoring in dropouts and is a major limitation for this study. Factors that may have attributed to this include the requirement of subjects to return to the participating clinic. There was an incentive for the subjects to attend each treatment session as they were receiving treatment that was effective in reducing their pain and improving their tolerance for functional activities. However, once they were discharged from treatment there was no further incentive to return aside from their obligation to the study.

Secondary objective #4 pertained to reporting treatment effects. The within group analysis resulted in statistically significant improvements for pain reduction, strength and functional outcomes for each group. However, there was no significant difference between groups for any dependent variables. The results of the within and between group analysis may be misleading due to the low recruitment and low power for the 4-week analysis as well as the poor follow-up response rate for the 3-month analysis.

The results of this study indicate a large randomized trial with the present treatment protocol may not be feasible due to the low subject recruitment combined with the barriers to participation and out-of-pocket costs

for physical therapy management. A large number of investigators would be needed to recruit subjects to meet the power analysis in an acceptable 1–2 year data collection period. These issues may be surmountable if the study can be conducted within a large health system with a wide referral network, a closed system such as the United States Department of Defense or in a country with a national health system where there may be greater access to eligible participants where out-of-pocket costs may not be problematic.

In the event that this study would be replicated, recommendations for modifications to this study design include:

- (1) It is recommended the study would be conducted in a closed system such as the Department of Defense or country with a national health insurance.
- (2) The study treatment protocol should be pragmatic to allow the data collection to be consistent with real-life conditions in clinical practice.
- (3) Treatment frequency and duration should not be standardized. This may enable subjects with financial constraints to participate in the study.
- (4) A financial incentive may increase subject recruitment and reduce the attrition rate for follow-up data collection.
- (5) Data collection for long-term follow-up should allow the option for subjects to complete self-report measures via video conference to verify identity. This would also allow the researcher to view the subject performing the heel raise exercise and record these data. This does eliminate the PPT variable from the follow-up data collection. Normative data have not been published for PPT to the Achilles tendon, nor has data correlating PPT measures to functional activity status. Therefore, the value of PPT to the results of future studies may need to be weighed against the importance of reducing the attrition rate by collecting follow-up data.

Conclusion

In conclusion, the results of this study indicate a large randomized trial with the present treatment protocol is not feasible due to low subject recruitment and retention. This study could be conducted in a region or health system with access to a larger patient population or where financial constraints may be overcome. The study design and treatment protocol could be modified for large RCT to investigate the effect of TDN on Achilles tendinopathy. Two of the three conditions for the feasibility of the treatment protocol were met. However, the issues surrounding recruitment and attrition overshadow these conditions. A within group analysis indicates a significant improvement that was also clinically meaningful

for pain, strength and functional outcomes in both groups. There was a large attrition for the 3-month follow-up data which increases the probability for a type II error [34]. Follow-up studies are needed to determine the effect of TDN for Achilles tendinopathy and to compare the results of the intervention to other treatment options available to people with this diagnosis.

Acknowledgments

The authors would like to acknowledge the following physical therapists for their contributions to this study: Matt Ware, Adam Autry, John Autry, Matt Tuttle, Blake Allen, Taylor Comford, Susan Daugherty, Kelli Brummer and Beth Dessner. The additional time and energy they devoted to this study is truly appreciated.

Disclosure statement

No potential conflict of interest was reported by the authors.

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