



Rate and maintenance of improvement of myofascial pain with dry needling alone vs. dry needling with intramuscular electrical stimulation: a randomized controlled trial

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ABSTRACT

Study design: Prospective, randomized

Objectives: To determine the difference in rate and maintenance of improvement of pain and disability for Dry Needling (DN) compared to Dry Needling with Intramuscular Electrical Stimulation (DN/IMES), in Myofascial Pain Syndrome (MPS).

Background: DN and neuromuscular electrical stimulation (NMES) have been shown to be efficacious in treating MPS. DN/IMES for MPS treatment has not been studied extensively, but initial results are promising.

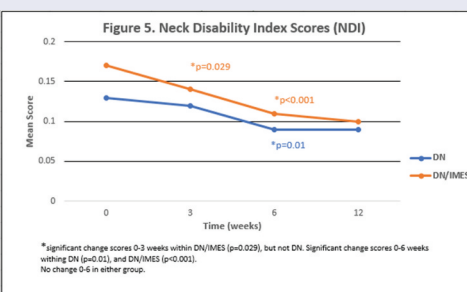
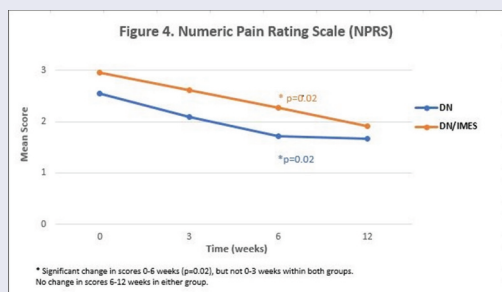
Methods: Forty-five subjects were randomly assigned to the DN (n = 25) or DN/IMES (n = 20) group. Both groups received six consecutive weekly treatments and completed NDI and NPRS questionnaires (week 0, 3, 6, and 12).

Results: Both DN and DN/IMES groups showed significant improvement between weeks 0–6 on NDI (p = 0.008 and 0.00002, respectively) and NPRS scores (p = 0.017 and p = 0.018, respectively). DN/IMES group showed significant within group changes on the NPRS between weeks 0–3 (p = 0.029). No changes were noted in the DN or DN/IMES groups between week 6–12 on NDI (p = 0.497 and p = 0.714, respectively) or NPRS (p = 0.801 and p = 0.164, respectively).

Conclusion: DN and DN/IMES demonstrated improvement and maintenance in disability and pain for 6 weeks. No differences in improvement of disability or pain existed between the groups at week 6 or 12.

KEYWORDS

Trigger point dry needling; upper trapezius; neck Pain; shoulder pain



Introduction

Myofascial Pain Syndrome (MPS) is one of the most prevalent causes of pain in the United States today[1]. MPS is defined as the presence of sensory, motor, and/or autonomic symptoms caused by the presence of myofascial trigger points (MTrPs), which are defined as hyperirritable nodules located within a taut band of muscle. These are often thought to be caused by motor endplate dysfunction, in addition to biochemical and vascular changes that lead to MPS [2–10].

Some of the symptoms of MPS include deep muscle pain, pain when the muscle is stretched or activated,

reduced ROM, and/or weakness[1]. MTrPs located in the upper trapezius (UpTr) muscle have been shown to be a common clinical finding in patients with neck pain [1,5,11–15].

One study identified MPS as the cause of neck pain in 100% of individuals examined and 93.75% had an active MTrP present[16]. Evidence suggests that 85% of people experience MPS at some point in their lifetime, and over 14% of the general population has chronic musculoskeletal pain[1]. Of these individuals, 21–54% report symptoms consistent with MPS [1,11,17]. With the high prevalence of MPS and the annual financial cost of pain on society estimated to be approximately

560 USD to 635 USD billion each year, identifying effective methods of managing and treating MPS is paramount [18].

DN has demonstrated mechanical, biochemical, vascular and neurophysiological effects [7–10,19–30]. Studies identified DN to be an effective technique to reduce pain, disability, and range of motion (ROM) deficits, while increasing pain pressure thresholds (PPT) [13,23,29,31–41]. In a randomized trial of 65 subjects with nonspecific low back pain, Griswold et al [33] compared segmental and distal DN without needle manipulation to non-thrust manipulation (NTM) after 6 sessions over 3 weeks. Outcome measures were the Oswestry Disability Index (ODI), Patient Specific Functional Scale (PSFS), Numerical Pain Rating Scale (NPRS), and PPT. The DN group demonstrated significant improvement in the ODI, PSFS, and NPRS; $p < 0.001$, $p < 0.001$, and $p < 0.001$, respectively. Tekin et al [39] demonstrated better improvement in pain and quality of life with DN in 46 subjects with MFP of the neck and shoulder randomly assigned to a DN or sham treatment. Treatments were performed 6 times over 4 weeks. While both groups improved in pain over the 4 weeks (DN $p = 0.000$, Sham $p = 0.0170$), the DN group improved ($p < 0.05$) in all domains of the SF-36, while the sham group only improved in 1 of 10 domains of the SF-36. In a systematic review and meta-analysis of 14 studies, Liu et al [14] reported significant pain relief in subjects with neck and shoulder pain with DN compared to sham in the short term ($p = 0.002$) and medium term ($p = 0.009$), but not long term ($p = 0.30$).

Multiple studies support the use of DN in improving neck and/or shoulder pain with DN in the UpTr muscle specifically [13,23,32,34,36–38,40]. Cerezo-Tellez et al [13] compared Visual Analog Scale (VAS), MTrP status, PPT, active cervical ROM (CROM) and muscle strength outcomes in subjects with neck pain who underwent DN with passive stretching (DDN+passive stretch) to those who underwent passive stretching alone (CG). The researchers randomized 44 subjects into the 2 groups, and performed the interventions 5 times over 3 weeks. Results indicated superior responses in the DDN+ passive stretch group in all outcomes compared to CG. Gerber et al [29] investigated the number of subjects whose active TrPs became latent or resolved after DN, and secondarily analyzed CROM, pain, PPT, and disability in 52 subjects. Forty-one of the 52 subjects' TrPs changed from active to latent or resolved ($p < 0.001$), and all subjects with unilateral TrPs demonstrated improvement in CROM, PPT, SF-26 and ODI ($p = 0.001$, $p = 0.006$, and $p = 0.019$, and $p = 0.003$, respectively).

The expected longevity of clinical improvements related to DN has not been well established. In a recent study, Gerber et al [41] examined the impact of dry needling on reduction and maintenance of pain

in 45 subjects with cervical pain and aMTrPs noted in the UpTr muscles. Subjects underwent 3 DN treatments and were reevaluated 6 weeks post treatment. Outcomes included VAS, Brief Pain Inventory (BPI), and MTrP status. They concluded that subjects did sustain improved pain scores for 6 weeks post treatment ($p < 0.003$). Ziaieifar et al [32] examined the long-term clinical effectiveness of DN in comparison to TrP compression in the UpTr. Thirty-three subjects were randomly assigned to DN ($N = 16$) or TrP compression ($N = 17$) groups. Data were collected immediately after treatments, at 2-weeks, and at 3-months following treatments. Pain and disability remained improved following DN ($p < 0.0001$) and TrP compression ($p < 0.01$) at 3 months. On the contrary, Liu et al [14] did not find pain reduction in the long term when performing a meta-analysis comparing DN to control/sham intervention. More studies are needed to investigate the longevity of treatment effects of DN, but the current body of results is encouraging.

The effects of DN with intramuscular stimulation (DN/IMES) as a form of treatment is being explored in the MTrP literature. More recently, this technique has been called electrical DN, electrical intramuscular stimulation (EIMS), and percutaneous electrical neural stimulation (PENS). Theoretically, DN/IMES combines the physiological effects of NMES with those of DN in order to decrease pain and improve function. By delivering a direct current directly into the target muscle, treatment can be focused to the MTrP, and impedance by more superficial tissue can be avoided [42]. Additionally, studies have shown positive changes in the neural mechanisms of pain and disability associated with MFPS [22,43,44]. In a cross-over study of 29 subjects with chronic headaches, Chassot et al [43] demonstrated significantly better resolution of pain per VAS with electroacupuncture (EA) than sham intervention ($p = 0.005$), regardless of which intervention was first, and increased serum levels of brain-derived neurotrophic factor (BDNF) when the EA was applied in the first round of intervention. Neural sensitization is likely related to BDNF, since it affects the excitatory/inhibitory balance in the central nervous system, and its serum levels have been inversely related to abnormal sensitization [45]. Bothello [22] investigated the use of EIMS compared to sham in affecting serum BDNF, pain, and motor cortex excitability in 24 female patients with MFP of the upper body. After 10 treatment sessions, VAS was lower ($p < 0.001$) and the BDNF levels higher ($p < 0.05$) in the EIMS group than the sham group. The MEPs of the group receiving EIMS decreased ($p = 0.02$) relative to the sham group.

In addition to neurochemical and neuromotor changes, DN/IMES has shown good clinical potential to improve pain, PPT, blood flow, disability, and ROM [22,30,31,42,44,46–49]. Lee et al [30] studied the effects

of needle EIMS (NEIMS) on pain (VAS), PPT, CROM (goniometer), and regional bloodflow (Doppler) in 40 patients with MPS involving the UpTr or levator scapulae. After one treatment a week for 4 weeks, improvements were noted in all outcome measures as follows: VAS ($p < 0.001$), PPT ($p < 0.001$), superficial skin blood flow ($p < 0.001$), and CROM in all planes ($p < 0.039$). Dunning et al [46] examined 111 subjects with plantar fasciitis and compared the effects of adding electrical DN to a program of manual therapy, exercise, and ultrasound on pain. Subjects were divided into groups receiving electrical DN with manual therapy exercises and ultrasound ($N = 58$), or manual therapy with exercise and ultrasound ($N = 53$) once or twice a week over 4 weeks. Improvement in NPRS ($p < 0.001$), Lower Extremity Functional Scale ($p < 0.001$), Foot Function Index ($p < 0.001$) and Global Rating of Change Scale ($p < 0.001$) were noted in the group receiving electrical DN compared to the group that did not. Dunning also reported evidence suggesting good maintenance of improved results 3 months later in the electrical DN group. Contrary to Dunning, Lopez-Martos et al [50] found immediate, but not sustained, improvement in pain and maximal interincisal opening in subjects with MFP of the mandible with the addition of electrical current to needles when compared to DN alone. They conducted a randomized, double-blind clinical trial investigating the effect of percutaneous needle electrolysis (PNE; $n = 20$) on pain and mandibular mobility compared to deep DN (DDN; $n = 18$) and sham needling procedure (SNP; $n = 19$) in 57 subjects with MFP of the mandible. The procedures were performed once a week for 3 consecutive weeks, and data were collected at baseline, day 28, day 42, and day 70. At day 28, both the PNE and DDN groups demonstrated improvements in pain ($p < 0.001$ and $p < 0.001$, respectively) and mobility ($p < 0.0001$ and $p < 0.001$, respectively). By day 70, PNE showed no improvement in mobility ($p = 0.36$), but DDN did ($p = 0.02$). The sham group demonstrated no improvement in either measure at any time point. Further research is needed to indicate whether pain and/or disability reduction through DN/IMES are sustainable over the mid to long term for patients with MPS.

Unpublished data collected by the principal investigator (KLB) demonstrated higher rates of improvement in pain and disability in subjects with neck pain associated with aMTrPs in the UpTr at 3 weeks, but no difference in improvement at 6 weeks when comparing DN/IMES to DN alone. This suggests the addition of electrical current does not produce sustained advantages over DN alone, but overall the research has not reached a consensus. The purpose of this study was to examine the differences in the rate of improvement for aMTrPs in the UpTr treated with DN only and those treated with DN/IMES, and to see if improvements are maintained 6 weeks post-treatment. We hypothesized

that DN/IMES would not demonstrate a difference in the rate of improvement compared to DN alone, and both treatment groups would maintain improvements in pain and disability 6 weeks post-treatment.

Methods

Participants

Participants ($N = 53$) were recruited from the University of Mary Hardin-Baylor (UMHB) and the surrounding community via flyers. All participants were treated by a licensed physical therapist between September 2018 and November 2018 on the UMHB campus. Inclusion criteria were being between the ages of 18 and 59, having an active e-mail account, having at least one palpable active trigger point located in one or both UpTr muscles, English speaking, and providing written informed consent to participate. Participants were excluded from the study if they were unable to pass an upper quarter screen, were currently being treated for cancer, diabetes, active infection, connective tissue disease and/or an autoimmune disorder, had current neck/shoulder pain continuously for over 3 months on one or both sides, currently smoke tobacco, or had previously participated in other dry needling treatments within 6 weeks of the study start date.

Ultimately, 25 participants completed the study in the DN group (22 F, 3 M) and 20 in the DN/IMES group (15 F, 5 M), with a total of 70 UpTr muscles were treated. Participant demographics are presented in Table 1. The study was approved through the UMHB Institutional Review Board (IRB). All participants provided verbal and written informed consent prior to their enrollment in the study and their rights remained protected throughout the study. This research study was registered through www.clinicaltrials.org (Identifier: NCT03638388). Participant flow is outlined in Figure 1.

Table 1. Demographic and Baseline Characteristics.

Variable	Dry Needling (DN)	Dry Needling with Intramuscular Electrical Stimulation (DN/IMES)
Location of s/sx (%)		
Unilateral	8 (32)	12 (40)
Bilateral	17 (68)	8 (20)
Laterality of Treatment (%)		
Right	7 (87.5)	5 (41.67)
Left	1 (12.5)	7 (58.33)
Sex* (%)		
Male	3 (12)	5 (25)
Female	22 (88)	15 (75)
Age (Years \pm SD)	26.32 \pm 8.94	28 \pm 9.99
BMI * (kg/m ² \pm SD)	26 \pm 5.54	24.63 \pm 6.8
NDI Score*	0.14 \pm 0.09	0.17 \pm 0.10
NPRS Score *	2.59 \pm 1.25	2.95 \pm 1.52

*No differences were found between groups ($p = 0.56, 0.435, 0.172, 0.551$ for age, gender, BMI, NDI, and NPRS, respectively)

Randomization/blinding

The participants were randomized into either a DN or DN/IMES group (n = 20 per group). Block randomization in blocks of 4 was used to maintain balance in case

of early study termination and to determine participant allocation based on order of entry into the study. Once the participant was screened for study inclusion, a co-investigator assigned the participant to a group according to the randomized list. The principal

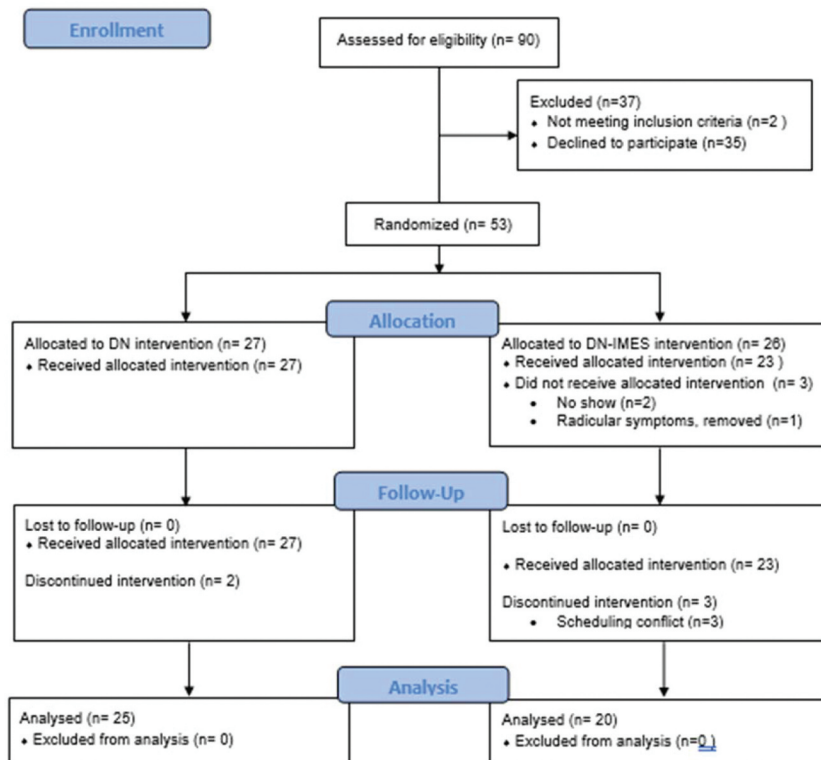


Figure 1. Participant Flow.



Figure 2. Dry Needling.

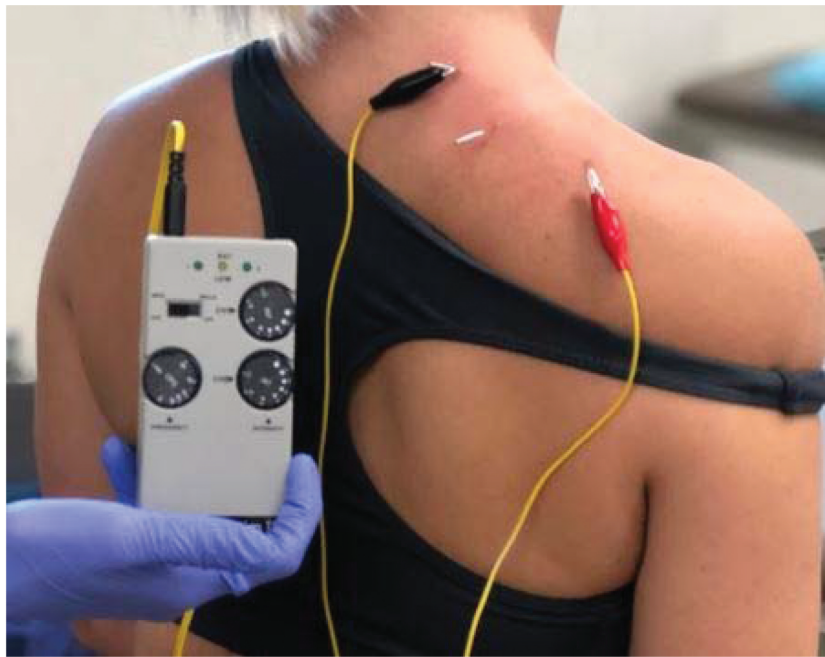


Figure 3. DN with IMES.

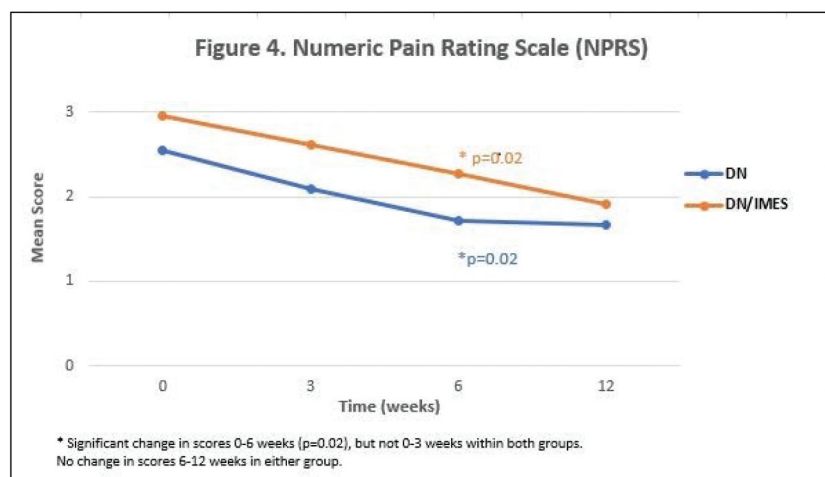


Figure 4. Numeric Pain Rating scale(NPRS). *Significant change in scores 0–6 weeks ($p = 0.02$), but not 0–3 weeks within both groups.No change in scores 6–12 weeks in either groups.

investigator and co-investigators were not blinded to group assignments. Participants in the study were not told which treatment group they were placed in; however, due to the nature of the study, participants were still able to identify their group assignment. For this reason, the subjects in the study were not blinded to their group assignment.

Outcome measures

The outcome measures used in this study included the Neck Disability Index (NDI: 0–50) and the Numeric Pain Rating Scale (NPRS: 0–10) at week 0, week 3, week 6 and week 12. The NDI allows the patients to identify their level of pain/difficulty with 10 tasks. The patient was instructed to circle the description, for each task,

that they most related to (A-E), and these categorical identifiers were later associated with numerical scores (0–5 respectively). The scores for each task were added together and then divided by the total number of possible points (50). The NPRS allows the patients to rate their pain on a scale of 0 (no pain) to 10 (maximum amount of pain) in their neck and shoulder/s. Additionally, height and weight measurements were collected at intake. All outcome measures and intake forms were either collected in person or via e-mail.

Time frame for measurements

Outcome measurements were collected within 24 hours of the initial screening and treatment session (week 0) and at 3, 6 and 12 weeks after the initial

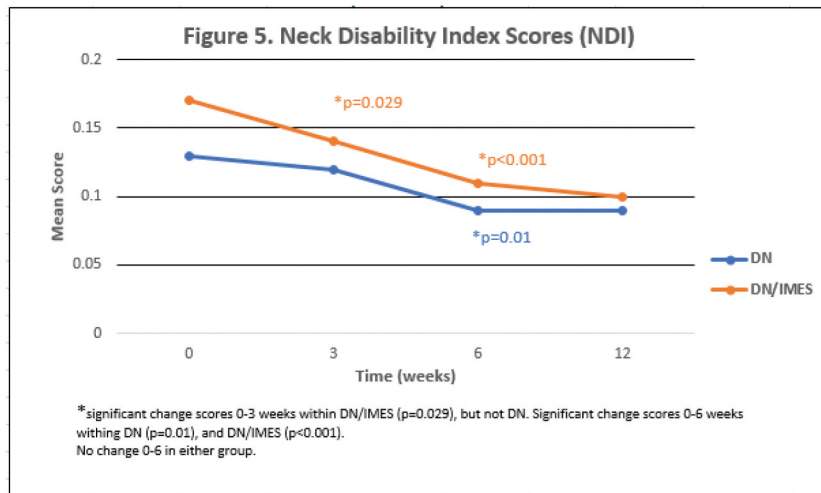


Figure 5. Neck Disability Index Scores (NDI). *Significant change in scores 0–3 weeks within DN/IMES($p = 0.029$), but DN. Significant change scores 0–6 weeks within DN ($p = 0.01$), and DN/IMES ($P < 0.001$).No change 0–6 in either group.

treatment. Baseline data were collected in person just prior to the initial treatment and follow up data were collected in person or through e-mail. All participants completed outcome measures in person at the initial testing session where the outcome scales were verbally explained to each participant by a co-investigator. For subsequent data collection sessions, if the participant completed the outcome measures via e-mail, then the instructions were included on each outcome measurement form.

Treatment groups

Dry Needling (DN)

Treatment was initiated week 0. The location of the needle placement was determined by the principal investigator and was based on palpation testing using the criteria described by Fernandez-de-las-Penas and Dommerholt[6]. These criteria being two of the following three: a taut band/nodule, hypersensitivity of the band/nodule, and/or pain recognition/referral. The DN procedure is outlined and pictured in Table 2 and Figure 2. Each subject in this group was treated by the same clinician, who has been licensed for 23 years and practicing DN for 9 years. Participants received one DN treatment per week for a total of 6 weeks, and DN was the only form of treatment administered throughout the course of this trial.

Dry Needling with Intramuscular Electrical Stimulation (DN/IMES)

Treatment was initiated week 0. The procedure was the same as the DN group, however, after placement of the needles, an e-stim unit was attached to the needles (Table 3, Figure 3). DN/IMES was performed by the same clinician as DN. Patients received one DN/IMES

Table 2. Details of the dry needling intervention.

Variable	Description
Brand of Dry Needles	Myotech Dry Needles (iDryNeedle; Kirkland, WA)
Muscles Dry Needled	The patient’s left and/or right Upper Trapezius m. was assessed first included those containing MTrPs that may have been contributing to the participant’s pain.
Needle Length and Diameter	Varied based on muscle size. Needle length typically ranged from 30–60 mm with a diameter of 0.25 mm to 0.30 mm. Length was based upon depth of TrP, patient body habitus, and whether or not a ropey band was going to be addressed with a single needle thread through the length of the muscle in the direction of fiber orientation (specifically for TrP2 and TrP6 ¹).
Needle Insertions per Muscle	The number of needle insertions for each muscle depended on the number of palpable MTrPs to be dry needled, the patient’s tolerance of needles, and responsiveness of the tissue to the dry needling.
Response elicited	Dry needling of an MTrP attempted to elicit sensation such as aching, pressure and the reproduction of symptoms and possibly a localized twitch response.
Manipulation of the Needle	Following the insertion of the needle, the needle was repeatedly partially withdrawn and advanced repeatedly. The soft tissue was always lifted superiorly away from the clavicle with 1–2 fingers on each side of the tissue, the needles were never advanced at an angle perpendicular to the horizontal axis, and the muscle was manipulated with the palpating/ lifting hand to bring the TrP closer to the needle.
Needle Retention Time	The needles were in the muscle for as long as it took to produce a response that was tolerated by the patient; The needle was then left in situ for approximately 10 minutes.

Abbreviations: MTrP, myofascial trigger point.

¹ David G. Simons, Janet G.Travell, Lois S. Simons. *Myofascial Pain and Dysfunction. The Trigger Point Manual. Volume 1. Upper Half of the Body.* Vol 1. 2nd ed. Williams and Wilkins; 1999.

treatment per week for a total of 6 weeks, and DN/IMES was the only form of treatment administered throughout the course of this trial.

Table 3. Details of the dry needling with intramuscular stimulation intervention.

Variable	Description
Brand of Dry Needles	Myotech Dry Needles (iDryNeedle; Kirkland, WA)
Muscles Dry Needled	The patient's left and right Upper Trapezius m. was assessed first included those containing MTrPs that may have been contributing to the participant's pain.
Needle Length and Diameter	Not specified but the needle length typically ranged from 30–60 mm with a diameter of 0.25 mm to 0.30 mm. Length based upon depth of TrP, patient body habitus, and whether or not a ropey band was going to be addressed with a single needle thread through the length of the muscle in the direction of fiber orientation (specifically for TrP2 and TrP6 ¹).
Needle Insertions per Muscle	The number of needle insertions for each muscle depended on the number of palpable MTrPs to be dry needled, the patient's tolerance of needles, and responsiveness of the tissue to the dry needling.
Response elicited	Dry needling of an MTrP attempted to elicit sensation such as aching, pressure and the reproduction of symptoms and possibly a localized twitch response.
Manipulation of the Needle	Following the insertion of the needle, the needle was repeatedly partially withdrawn and advanced repeatedly. The soft tissue was always lifted superiorly away from the clavicle with 1–2 fingers on each side of the tissue, the needles were never advanced at an angle perpendicular to the horizontal axis, and the muscle was manipulated with the palpating/lifting hand to bring the TrP closer to the needle.
Electrical Stimulation Unit	E-Stim II, Dual-Channel Milli-Amp/Micro-Current (Lhasa Oms, Inc; Weymouth, MA)
Electrical Stimulation Frequency	The unit was turned on and the intensity increased to a level that was strong but tolerable to the subject; approximately 10 Hz*
Needle Retention Time	The needles were in the muscle for as long as it took to produce a response that was tolerated by the patient; Electrode leads were attached to two needles using alligator clips and were then left in situ for approximately 10 minutes.

Abbreviations: MTrP, myofascial trigger point

¹David G. Simons, Janet G.Travell, Lois S. Simons. *Myofascial Pain and Dysfunction. The Trigger Point Manual. Volume 1. Upper Half of the Body.* Vol 1. 2nd ed. Williams and Wilkins; 1999.

*At the time of study conception, there were no trends in the physical therapy literature to support one frequency over another. The principle investigator was using 10 Hz clinically at the time to elicit a distinct, but comfortable muscle contraction. Many studies published in the last couple years use 2 Hz. Chassot et al [2] fluctuated between 2 Hz and 10 Hz.

Sample- size determination

Based on the literature [51,52] the 1 week change in NRPS was estimated to be roughly 2, with a standard deviation (of the change) of about 2.1. Assuming a similar change at both weeks 3 and 6, we noted that to detect these differences with a two-sided one sample t-test with an alpha of 0.05 and 95% power requires 17 subjects. To detect a between group difference of 2, with each within group standard deviation of 2, at an alpha of 0.05 and 80% power, requires 17 subjects per group.

Adverse events

The most common AEs associated with DN are bleeding, bruising, and pain during and/or after treatment [53,54]. All of these are considered mild AEs and were not recorded in our study. More serious, but very rare, AEs include fainting, pneumothorax, needles breaking off, and infection have been reported [54–56]. Concerns have been expressed about needles in the UpTr migrating into the apical lung during IMES, but we found nothing documented in the literature describing this event. Nevertheless, precautions were taken during intervention (Tables 2 and 3). Adverse events were recorded in the data file for each subject along with the type of event and details (i.e. symptoms, duration, research team response).

Data analysis

Data within each group were analyzed using a paired t-test, looking at changes from baseline to 3 and 6 weeks. Baseline values were compared between the two groups, using a t-test. To answer the primary question, outcomes were compared between groups at 3 and 6 weeks using an unpaired t-test. To answer our secondary question, within group outcomes were compared between week 6 and 12 using a paired t-test.

Results

There were no significant differences between the two groups at baseline in terms of demographics (Table 1). There was also no observable difference between the groups in terms of baseline NDI (0.13, SD 0.08 in DN, 0.17, SD 0.1 in DN/IMES, $p = 0.12$) (Figure 4) or NPRS (2.55, SD 1.3 in DN, 2.96, SD 1.59 in DN/IMES, $p = 0.37$) (Figure 5). The DN group and the DN/IMES group each received 7 treatments over the course of 6 weeks. The average NDI scores at baseline were 0.14 ± 0.09 and 0.17 ± 0.10 for DN and DN/IMES respectively. The average NPRS scores at baseline were 2.59 ± 1.25 and 2.95 ± 1.52 for the DN and DN/IMES respectively. These average baseline scores are outlined in Table 4.

The DN group showed improvement in NDI from baseline to week 6: mean decrease of 0.04, with a 95% confidence interval for the change of -0.062 to -0.01 , p -value 0.01. There was also an improvement in NPRS: decrease of 0.84, with a 95% confidence interval for the change of -1.521 to -0.16 , p -value 0.02. The changes from baseline to week 3 were not significant. In the DN/IMES group, by contrast, the NDI changes were significant at both 3 and 6 weeks: -0.03 , 95% confidence interval -0.058 to -0.004 , p -value 0.03, and

Table 4. Numeric Pain Rating Scale and Neck Disability Scores, Averaged.

	Baseline	Intervention		Post- Intervention
	Week 0 (Score \pm SD)	Week 3 (Score \pm SD)	Week 6 (Score \pm SD)	Week 12 (Score \pm SD)
NPRS				
DN	2.59 \pm 1.25	2.09 \pm 1.07	1.71 \pm 1.47	1.67 \pm 1.45
DN/IMES	2.95 \pm 1.52	2.62 \pm 1.59	2.27 \pm 1.80	1.92 \pm 1.63
NDI				
DN	0.14 \pm 0.09	0.12 \pm 0.09	0.09 \pm 0.10	0.09 \pm 0.09
DN/IMES	0.17 \pm 0.10	0.14 \pm 0.11	0.11 \pm 0.09	0.10 \pm 0.11

Abbreviations: NPRS, numeric pain rating scale; DN, dry needling; DN/IMES, dry needling with intramuscular stimulation; NDI, neck disability index

−0.06, 95% confidence interval −0.088 to −0.04, p-value <0.001. The week 3 NPRS changes were not significant, but the six-week changes were: −0.69, 95% confidence interval −1.239 to −0.13, p-value 0.02.

In the current study, a vasovagal response was our only type of AE. Three participants had a vasovagal response, and all were transitioned to prone or supine, depending on their preference. All fully recovered within 30 minutes. Remaining treatments for these individuals were carried out in prone.

At no time point did NDI or NPRS differ significantly between groups, and the change from baseline to each intermediate point did not differ significantly between groups. Finally, the changes between 6 and 12 weeks, for both NDI and NPRS, were not significant in either DN or DN/IMES groups.

Discussion

The primary objective of this study was to investigate if DN/IMES would reduce neck pain and disability at a faster rate than DN alone in patients with MPS across 6 consecutive weeks of treatment. Secondly we aimed to investigate if DN and DN/IMES provided sustained improvements in the reduction of pain and disability for patients 6 weeks following the completion of the DN intervention. Our results indicated that both DN and DN/IMES result in improvement in pain and disability between weeks 0–6, with a questionable difference in rate of improvement. The DN/IMES group showed improvement in NDI scores from baseline to 3 weeks, while the DN group did not, but the mean score for NDI between groups was not different. The DN and the DN/IMES groups showed no regression in pain and disability scores 6 weeks following the cessation of treatment, indicating that the reduction in pain and disability obtained from both was maintained.

The current study provided evidence of improved pain and function with the use of DN/IMES in keeping with Lee et al [30] and Lopez-Martos et al [50]. Like the results of Lopez-Martos et al, our data also suggest that overtime DN alone is as effective as DN/IMES. However, comparison to these studies is difficult. Lee et al [30] did not have a control group, so while they demonstrated significant improvement with the use of IMES, they could not conclude that it was superior to DN

alone. The study conducted by Lopez-Martos et al [50] was well designed, in that it had a group receiving electrical current through a needle, a DN group without electrical current, and a sham needling group; furthermore, the study was double blinded. The difficulty in comparison lies in the technique/device in which the current and needling were provided. This study used Intratissue percutaneous electrolysis (IPE®); an ultrasound-guided technique which uses a single needle device to deliver galvanic current through the needle. This was not the device or technique used by our study or any of the others referenced.

While our study was similar to Dunning et al [46] in noting positive changes in clinical outcomes, other aspects of our data vary from theirs. We did not find evidence of improved or faster clinical progress beyond 3 weeks when compared to DN alone. One reason for the difference may be that Dunning et al were targeting fascia, not muscle, and used a technique that appears to follow/surround the posterior tibial nerve and its branches. Their study also had roughly twice the sample size, lending greater statistical power.

While the mechanisms of neurophysiological, biomechanical, biochemical and vascular changes associated with DN are not well understood, the current literature, including this study, does support DN as an effective method for the treatment of MPS [8–10,16,19–27,29–33,41]. The role of added electrical current to the procedure is promising, but has yet to be elucidated. Intermediate term longevity of improved outcomes following DN with and without IMES was demonstrated in this study and supported by others, but more investigation into intermediate and long-term follow-up is warranted.

To date data published on the effectiveness of DN/IMES to reduce MTrP pain, disability, and range of motion are promising, but not consistent [22,30,46,47,50]. The current study contributes to the growing body of literature which supports DN with and without IMES as an effective treatment for pain and disability in patients with MPS.

Limitations

There are a few limitations to this study. First, our sample, while statistically powerful, is not

representative of the overall population. Additionally, the methodology of the treatment was not performed exactly to the clinical standard. A majority of subjects were treated sitting, rather than lying (with the exception of those who reported previous vasovagal response with exposure to needles). Evidence suggests that performing this technique in sitting can lead to a vasovagal response which can alter the patient's outcomes[56]. Sitting was chosen for pragmatic reasons, but subjects were treated in prone if they had a fainting history or fear of needles. Finally, and most importantly, we discovered a ceiling effect with the NDI, because baseline NDI scores were 6.5/50 and 8.5/50 for the DN and DN/IMES groups, respectively. Scores of < 5.0 out of 50 are classified as 'no disability', leaving little room for improvement. We recommend future studies exclude subjects with NDI scores <6/50.

Conclusion

Our data support the use of DN with or without IMES to improve pain and disability in patients with neck pain associated with aMTrPs, and the improvements were maintained 6 weeks following cessation of both treatments. We did not find robust evidence that one treatment improves outcomes at a faster rate. While DN continues to be a promising intervention for pain and disability associated with MPS, the additional benefit of IMES is less clear. More studies are needed to investigate whether IMES is a worthy adjunct to DN, and to report intermediate and long-term follow-up outcomes of DN and DN/IMES in this population.

Key points

- **Findings:** Dry needling is an effective treatment for MPS. Both DN and DN/IMES are effective at intermediate term maintenance of improvements in neck pain and disability.
- **Implications:** Dry Needling treatment continues to demonstrate promise for the treatment of MPS.
- **Caution:** This study was limited by the small sample size utilized and the ceiling effect observed with the outcome measures.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author, KLB. The data are not publicly available due to their containing information

that could compromise the privacy of research participants.

Disclosure statement

No potential conflict of interest was reported by the authors.

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References

- [1] Tantanatip A, Chang KV. Myofascial Pain Syndrome (MPS) [Updated 2020 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK499882/>.
- [2] Xie P, Qin B, Song G, et al. Microstructural abnormalities were found in brain gray matter from patients with chronic myofascial pain. *Front Neuroanat*. 2016;10:122.
- [3] Gerwin RD, Dommerholt J, Shah JP. An expansion of Simons' integrated hypothesis of trigger point formation. *Cur Sci Inc*. 2004;8(6):468–475.
- [4] Simons DG, Travell JG, Simons LS. Myofascial pain and dysfunction. The trigger point manual. Volume 1. Upper half of the body. 2nd ed. Vol. 1. Baltimore, Maryland: Williams and Wilkins; 1999.
- [5] Simons DG. Clinical and etiological update of myofascial pain from trigger points. *J Musculoskelet Pain*. 2010;4(1–2):93–122.
- [6] Fernández-de-las-Peñas C, Dommerholt J. International consensus on diagnostic criteria and clinical considerations of myofascial trigger points: a delphi study. *Pain Med*. 2018;19(1):142–150.
- [7] Abbaszadeh-Amirdehi M, Ansari NN, Naghdi S, et al. The neurophysiological effects of dry needling in

- patients with upper trapezius myofascial trigger points: study protocol of a controlled clinical trial. *BMJ Open*. 2013;3:5.
- [8] Hsieh Y-L, Yang S-A, Yang -C-C, et al. Dry needling at myofascial trigger spots of rabbit skeletal muscles modulates the biochemicals associated with pain, inflammation, and hypoxia. *Evid Based Complement Alternat Med*. 2012;2012:342165.
- [9] Shah JP, Danoff JV, Desai MJ, et al. Biochemicals associated with pain and inflammation are elevated in sites near to and remote from active myofascial trigger points. *Arch Phys Med Rehabil*. 2008;89(1):16–23.
- [10] Shah JP, Gilliams EA. Uncovering the biochemical milieu of myofascial trigger points using in vivo microdialysis: an application of muscle pain concepts to myofascial pain syndrome. *J Bodyw Mov Ther*. 2008;12(4):371–384.
- [11] Deyo RA, Mirza SK, Martin BI. Back pain prevalence and visit rates: estimates from U.S. National Surveys, 2002. *Spine (Phila Pa 1976)*. 2006;31(23):2724.
- [12] Lluch E, Nijs J, De Kooning M, et al. Prevalence, incidence, localization, and pathophysiology of myofascial trigger points in patients with spinal pain: A systematic literature review. *J Manipulative Physiol Ther*. 2015;38(8):587–600.
- [13] Cerezo-Téllez E, Lacomba MT, Fuentes-Gallardo I, Mayoral Del Moral O, et al. Dry needling of the trapezius muscle in office workers with neck pain: a randomized clinical trial. *J Man Manip Ther*. 2016;24(4):223–232.
- [14] Liu L, Huang Q-M, Liu Q-G, et al. Effectiveness of dry needling for myofascial trigger points associated with neck and shoulder pain: A systematic review and meta-analysis. *Arch Phys Med Rehabil*. 2015;96(5):944–955.
- [15] Chiarotto A, Clijsen R, Fernandez-de-las-Penas C, et al. Prevalence of myofascial trigger points in spinal disorders: a systematic review and meta-analysis. *Arch Phys Med Rehabil*. 2016;97(2):316–337.
- [16] Cerozo-Tellez E, Torres-Lacomba M, Mayoral-Del Moral O, et al. Prevalence of myofascial pain syndrome in chronic non-specific neck pain: a population-based cross-sectional descriptive study. *Pain Med*. 2016;17(12):2369–2377.
- [17] Simons D, Travell J, Simons L. Myofascial pain and dysfunction: the trigger point manual, Vol. 1 - upper half of body. 2nd ed. Vol. 1. Baltimore, MD: LWW; 1998.
- [18] Gaskin DJ, Richard P The economic costs of pain in the United States. National Academies Press (US); 2011. [cited 2019 Dec 17]. <https://www.ncbi.nlm.nih.gov/books/NBK92521/>
- [19] Skorupska E, Rychlik M, Samborski W. Intensive vasodilatation in the sciatic pain area after dry needling. *BMC Complement Altern Med*. 2015;15:72.
- [20] Kubo K, Yajima H, Takayama M, et al. Effects of acupuncture and heating on blood volume and oxygen saturation of human Achilles tendon in vivo. *Eur J Appl Physiol*. 2010;109(3):545–550.
- [21] Inoue M, Kitakoji H, Yano T, et al. Acupuncture treatment for low back pain and lower limb symptoms-The relation between acupuncture or electroacupuncture stimulation and sciatic nerve blood flow. *Evid Based Complement Alternat Med*. 2008;5(2):133–143.
- [22] Botelho L, Angoleri L, Zortea M, et al. Insights about the neuroplasticity state on the effect of intramuscular electrical stimulation in pain and disability associated with chronic myofascial pain syndrome (MPS): a double-blind, randomized, sham-controlled trial. *Front Hum Neurosci*. 2018;12:388.
- [23] Mejuto-Vázquez MJ, Salom-Moreno J, Ortega-Santiago R, et al. Short-term changes in neck pain, widespread pressure pain sensitivity, and cervical range of motion after the application of trigger point dry needling in patients with acute mechanical neck pain: A randomized clinical trial. *J Orthop Sports Phys Ther*. 2014;44(4):252–260.
- [24] Cagnie B, Dewitte V, Barbe T, et al. Physiologic effects of dry needling. *Curr Pain Headache Rep*. 2013;17(8):348.
- [25] Chou L-W, Kao M-J, Lin J-G. Probable mechanisms of needling therapies for myofascial pain control. *Evid Based Complement Alternat Med*. 2012;2012:1–11.
- [26] Butts R, Dunning J. Peripheral and spinal mechanisms of pain and dry needling mediated analgesia: A clinical resource guide for health care professionals. *Int J Phys Med Rehabil*. 2016;04:02.
- [27] Kopenhagen SL, Walker MJ, Su J, et al. Changes in lumbar multifidus muscle function and nociceptive sensitivity in low back pain patient responders versus non-responders after dry needling treatment. *Man Ther*. 2015;20(6):769–776.
- [28] Fernández-de-Las-Peñas C, Nijs J. Trigger point dry needling for the treatment of myofascial pain syndrome: current perspectives within a pain neuroscience paradigm. *JPR*. 2019;12:1899–1911.
- [29] Gerber LH, Shah J, Rosenberger W, et al. Dry needling alters trigger points in the upper trapezius muscle and reduces pain in subjects with chronic myofascial pain. *PM&R*. 2015;7(7):711–718.
- [30] Lee S-H, Chen -C-C, Lee C-S, et al. Effects of needle electrical intramuscular stimulation on shoulder and cervical myofascial pain syndrome and microcirculation. *J Chin Med Assoc*. 2008;71(4):200–206.
- [31] Griswold D, Wilhelm M, Donaldson M, et al. The effectiveness of superficial versus deep dry needling or acupuncture for reducing pain and disability in individuals with spine-related painful conditions: a systematic review with meta-analysis. *JMMT*. 2019;27(3):128–140.
- [32] Ziaefar M, Arab AM, Mosallanezhad Z, et al. Dry needling versus trigger point compression of the upper trapezius: a randomized clinical trial with two-week and three-month follow-up. *J Man Manip Ther*. 2019;27(3):152–161.
- [33] Griswold D, Gargano F, Learman KE. A randomized clinical trial comparing non-thrust manipulation with segmental and distal dry needling on pain, disability, and rate of recovery for patients with non-specific low back pain. *J Man Manip Ther*. 2019;27(3):141–151.
- [34] Priyanka M, Francis TGT. Compare the effectiveness of dry needling therapy versus cryotherapy on patients with upper trapezius trigger. *Indian J Physiother Occup Ther*. 2017;11(3):183–186.
- [35] Llamas-Ramos R, Pecos-Martin D, Gallego-Izquierdo T, et al. Comparison of the short-term outcomes between trigger point dry needling and trigger point manual therapy for the management of chronic mechanical neck pain: a randomized clinical trial. *J Orthop Sports Phys Ther*. 2014;44(11):852–861.
- [36] Kamali F, Sinaei E, Morovati M. Comparison of upper trapezius and infraspinatus myofascial trigger point therapy by dry needling in overhead athletes with

- unilateral shoulder impingement syndrome. *J Sport Rehabil.* 2019;28(3):243–249.
- [37] Ziaiefar M, Arab AM, Karimi N, et al. The effect of dry needling on pain, pressure pain threshold and disability in patients with a myofascial trigger point in the upper trapezius muscle. *J Bodyw Mov Ther.* 2014;18(2):298–305.
- [38] Bron C, de Gast A, Dommerholt J, et al. Treatment of myofascial trigger points in patients with chronic shoulder pain: a randomized, controlled trial. *BMC Med.* 2011;9(1):8.
- [39] Tekin L, Akarsu S, Durmuş O, et al. The effect of dry needling in the treatment of myofascial pain syndrome: a randomized double-blinded placebo-controlled trial. *Clin Rheumatol.* 2013;32(3):309–315.
- [40] Wang CC, Huang TH, Chiou KC, et al. Therapeutic effect of superficial acupuncture in treating myofascial pain of the upper trapezius muscle: a randomized controlled trial. *Evid Based Complement Alternat Med.* 2018;2018:1–7.
- [41] Gerber LH, Sikdar S, Aredo JV, et al. Beneficial effects of dry needling for treatment of chronic myofascial pain persist for 6 weeks after treatment completion. *Pm R.* 2017;9(2):105–112.
- [42] León-Hernández JV, Martín-Pintado-Zugasti A, Frutos LG, et al. Immediate and short-term effects of the combination of dry needling and percutaneous TENS on post-needling soreness in patients with chronic myofascial neck pain. *Braz J Phys Ther.* 2016;20(5):422–431.
- [43] Chassot M, Dussan-Sarria JA, Sehn FC, et al. Electroacupuncture analgesia is associated with increased serum brain-derived neurotrophic factor in chronic tension-type headache: a randomized, sham controlled, crossover trial. *BMC Complement Altern Med.* 2015;15:1–10.
- [44] da Graca-tarragó M, Lech M, Angoleri LDM, et al. Intramuscular electrical stimulus potentiates motor cortex modulation effects on pain and descending inhibitory systems in knee osteoarthritis: a randomized, factorial, sham-controlled study. *J Pain Res.* 2019;12:209–221.
- [45] Kerr BJ, Bradbury EJ, Bennett DLH, et al. Brain-derived neurotrophic factor modulates nociceptive sensory inputs and NMDA-evoked responses in the rat spinal cord. *J Neurosci.* 1999;19(12):5138–5148.
- [46] Dunning J, Butts R, Henry N, et al. Electrical dry needling as an adjunct to exercise, manual therapy and ultrasound for plantar fasciitis: A multi-center randomized clinical trial. *PLoS ONE.* 2018;13(10):1–24.
- [47] Rock JM, Rainey CE. Treatment of nonspecific thoracic spine pain with trigger point dry needling and intramuscular electrical stimulation: a case series. *Int J Sports Phys Ther.* 2014;9(5):699–711.
- [48] Ahmed S, Haddad C, Subramaniam S, et al. The effect of electric stimulation techniques on pain and tenderness at the myofascial trigger point: a systematic review. *Pain Med.* 2019;20(9):1774–1788.
- [49] Garcia-de-Miguel S, Pecos-Martin D, Larroca-Sanz T, et al. Short-term effects of PENS versus dry needling in subjects with unilateral mechanical neck pain and active myofascial trigger points in levator scapulae muscle: a randomized controlled trial. *J Clin Med.* 2020;9:6.
- [50] Lopez-Martos R, Gonzalez-Perez L-M, Ruiz-Canela-Mendez P, et al. Randomized, double-blind study comparing percutaneous electrolysis and dry needling for the management of temporomandibular myofascial pain. *Med Oral Patol Oral Cir Bucal.* 2018;23(4):e454–e462.
- [51] Childs JD, Piva SR, Fritz JM. Responsiveness of the numeric pain rating scale in patients with low back pain. *Spine (Phila Pa 1976).* 2005;30(11):1331–1334.
- [52] Cleland JA, Childs JD, Whitman JM. Psychometric properties of the neck disability index and numeric pain rating scale in patients with mechanical neck pain. *Arch Phys Med Rehabil.* 2008;89(1):69–74.
- [53] Brady S, McEvoy J, Dommerholt J, et al. Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists. *J Man Manip Ther.* 2014;22(3):134–140.
- [54] Boyce D, Wempe H, Campbell C, et al. ADVERSE EVENTS ASSOCIATED WITH THERAPEUTIC DRY NEEDLING. *Int J Sports Phys Ther.* 2020;15(1):103–113.
- [55] Snyder DD. Acupuncture gone awry: a case report of a patient who required surgical removal of two single-use filament needles following acupuncture treatment. *J Man Manip Ther.* 2019;27(3):180–184.
- [56] Halle JS, Halle RJ. Pertinent dry needling considerations for minimizing adverse effects - part two. *Int J Sports Phys Ther.* 2016;11(5):810–819.