ABSTRACT

LASER THERAPY TREATMENTS VERSUS DRY NEEDLING IN THE TRAPEZIUS FOR MYOFASCIAL PAIN SYNDROME: A META ANALYSIS IN PAIN OUTCOMES AND A SYSTEMATIC REVIEW ON CERVICAL RANGE OF MOTION

Context: with numerous physical therapy modalities for myofascial pain syndrome (MPS), it is important to compare the efficacy of recently used modalities such as low level laser therapy (LLLT) with popular interventions, such as dry needling (DN).

Objective: The purpose of this meta-analysis is to compare the short-term, long-term, and independent-of-time effects of LLLT and DN on pain and a systematic review on cervical range of motion (CROM) in adults diagnosed with MPS.

Data Sources: Search procedures followed PRISMA guidelines using the databases PubMed, CINAHL, PEDro. The search was limited to randomized controlled trials from 2000 to 2015 in the English language.

Study Selection: Adults ages 18-65 years, MPS, LLLT treatment, DN treatment, visual analog scale and numeric pain rating scale for pain outcome measure. Goniometer and cervical range of motion instrument used to measure CROM.

Data Extraction: Titles, abstracts and full text articles were screened by one reviewer.

Results: A fixed and random effects model compared the use of LLLT and DN for pain. DN was favorable for short-term pain [ES (95% CI) = -0.14 (-0.46, 0.19) P = 5.91E-11, Q = 50.61556] and LLLT was favorable for long-term pain.
[ES (95% CI) = 0.48 (0.06, 0.89) P = 2.25E-27, Q = 122.7181] and independent-of-time pain [ES (95% CI) = 0.23 (-0.09, 0.54) P = 2.6472E-32, Q = 154.1335668].

**Conclusion**: DN has better short-term effects and LLLT has better long-term and independent effects on pain for adults diagnosed with MPS.

**Key Words**: Low level laser therapy, Dry Needling, Pain, CROM

Daniel Valverde Valdez
May 2016
LASER THERAPY TREATMENTS VERSUS DRY NEEDLING IN THE TRAPEZIUS FOR MYOFASCIAL PAIN SYNDROME: A META ANALYSIS IN PAIN OUTCOMES AND A SYSTEMATIC REVIEW ON CERVICAL RANGE OF MOTION

by
Daniel Valverde Valdez

A project submitted in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy in the Department of Physical Therapy College of Health and Human Services California State University, Fresno May 2016
APPROVED

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TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>LIST OF TABLES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>vii</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIST OF FIGURES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>viii</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BACKGROUND</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Incidence and Prevalence</td>
<td>1</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>2</td>
</tr>
<tr>
<td>Etiology and Pathology</td>
<td>3</td>
</tr>
<tr>
<td>Treatment</td>
<td>3</td>
</tr>
<tr>
<td>Dry Needling</td>
<td>5</td>
</tr>
<tr>
<td>Low Level Laser Therapy</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>METHODS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Search Criteria</td>
<td>9</td>
</tr>
<tr>
<td>Eligibility Criteria</td>
<td>9</td>
</tr>
<tr>
<td>Definitions</td>
<td>10</td>
</tr>
<tr>
<td>Methodological Quality Assessment</td>
<td>11</td>
</tr>
<tr>
<td>Outcome Measures</td>
<td>11</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RESULTS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13</td>
</tr>
<tr>
<td>Short-Term Laser Therapy Versus Dry Needling on Pain Intensity</td>
<td>13</td>
</tr>
<tr>
<td>Long-Term Laser Therapy Versus Dry Needling on Pain Intensity</td>
<td>13</td>
</tr>
<tr>
<td>Independent-of-time Laser Therapy Versus Dry Needling on Pain Intensity</td>
<td>14</td>
</tr>
<tr>
<td>Laser Therapy and Dry Needling on Cervical Range of Motion</td>
<td>14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DISCUSSION</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
</tr>
<tr>
<td>Title</td>
<td>Page</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Heterogeneity in Short-Term Pain Comparison</td>
<td>17</td>
</tr>
<tr>
<td>Heterogeneity in Long-Term Pain Comparison</td>
<td>20</td>
</tr>
<tr>
<td>Heterogeneity in Independent-of-time Pain Comparison</td>
<td>21</td>
</tr>
<tr>
<td>Limitations</td>
<td>25</td>
</tr>
<tr>
<td>Conclusion</td>
<td>26</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>29</td>
</tr>
<tr>
<td>TABLES</td>
<td>39</td>
</tr>
<tr>
<td>FIGURES</td>
<td>44</td>
</tr>
<tr>
<td>APPENDIX: PEDRO SCALE</td>
<td>49</td>
</tr>
</tbody>
</table>
LIST OF TABLES

Table 1. Meta-Analysis Study Characteristics ......................................................... 40
Table 2. Long-Term Study Characteristics .............................................................. 41
Table 3. Characteristics of the Participants Included in This Systematic Review ................................................................. 42
Table 4. PEDro Scores for Included Meta-Analysis and Systematic Review Studies ........................................................................ 43
LIST OF FIGURES

Page

Figure 1. Search method flow chart of article inclusion and exclusion for statistical analysis.................................................................................................................................................. 45

Figure 2. Data analysis of short-term VAS/NPRS comparing LLLT and DN studies with effect sizes and confidence intervals ................................................................. 46

Figure 3. Data analysis of long-term VAS/NPRS comparing LLLT and DN studies with effect sizes and confidence intervals ................................................................. 47

Figure 4. Data analysis of independent-of-time VAS/NPRS comparing LLLT and DN studies with effect sizes and confidence intervals ........................................................................... 48
BACKGROUND

Introduction

Myofascial pain syndrome (MPS) is a common source of musculoskeletal pain seen in clinical practice.\(^1\) MPS is characterized by acute or chronic pain resulting from one or more hyperirritable spots in a palpable, taut band of muscle fibers (shortening of injured muscle fibers) known as myofascial trigger points (MTrPs).\(^2\) MTrPs are classified as active or latent. Active MTrPs cause spontaneous pain (noticeable pain that occurs unexpectedly) while latent MTrPs have no spontaneous pain but require palpation or motion/activity to cause pain.\(^1\)\(^-\)\(^3\) Compression of active MTrPs can cause localized tenderness or pain at a distant site from the MTrPs such as the neck, mandible, mandibular joint, head, etc.\(^1\)\(^,\)\(^4\) The painful presence of MTrPs and their ability to refer pain to distant sites is a key feature of MPS.\(^1\)\(^,\)\(^5\)\(^-\)\(^7\) MTrPs can occur within one or more muscles and affects the connective tissues of muscles anywhere in the body, causing pain and sometimes inflammation.\(^8\)\(^,\)\(^9\) The muscle and nerve components of MPS can involve sensory, motor, and on rare occasions, the autonomic nervous system.\(^9\) Symptomatic MTrPs can lead to muscle spasms, pain, weakness, sensitivity, and limited range of motion (ROM).\(^7\) The exact etiology and pathogenesis of MPS is unknown, except that MTrPs seem to be involved. As a result, MPS remains a medical mystery.\(^2\)\(^,\)\(^8\)

Incidence and Prevalence

The prevalence of MPS varies from 21 to 85% among individuals experiencing musculoskeletal pain, and up to 85% of the general population will experience MPS once in their lifetime.\(^10\)\(^,\)\(^11\) It accounts for 30% of the patient population seeking pain consultation in a primary care setting.\(^10\) and is the primary
cause of pain in 85% of patients seen at a pain center.\textsuperscript{5,10,12} Active MTrPs are the most common cause of musculoskeletal pain experienced by 54% of women and 45% of men.\textsuperscript{11} A study performed by Gerwin,\textsuperscript{13} which differentiated between MPS and fibromyalgia, reported MTrPs as the primary source of musculoskeletal pain in 74% of 96 patients seen by a neurologist in a community pain center, and in 85% of 283 patients from a comprehensive pain center.\textsuperscript{12} One of the most common locations of MTrPs is the trapezius muscle. As a result, neck pain is a common complaint because of the involvement of MTrPs in the trapezius muscles, resulting in decreased cervical range of motion (CROM) with a lifetime prevalence of 30-50\%.\textsuperscript{14} Borg-Stein, an associate professor of physical medicine and rehabilitation at the Harvard Medical School, performed a study supporting upper back and neck pain as the most common complaint of MPS due to the involvement of the trapezius muscle in most cases.\textsuperscript{15}

**Diagnosis**

There is no consensus in diagnosing MPS due to an ongoing active debate about whether MTrPs are required in the diagnosis of MPS. Diagnosis is further confounded by the debate as to whether MTrPs should be targeted for pain relief.\textsuperscript{2,16,17} Despite a lack of consensus in diagnosing MPS, the following criteria are used to diagnose active MTrPs in the trapezius: presence of palpable taut band in the skeletal muscle; presence of an exquisitely tender spot in the taut band; recognition of the elicited pain as the patient’s pain; and a painful limit induced by the full-stretch ROM. A positive MTrP was diagnosed when 3 out of the 4 criteria were met.\textsuperscript{18,19} Furthermore, diagnosis of MPS can be based on a detailed patient history and physical examination involving muscle palpation and movements that provoke pain.\textsuperscript{1}
Etiology and Pathology

There is no definite etiology or pathology for MPS. It has been theorized that MTrPs develop in muscles in any part of the body as a result of response to sudden injury or muscle load involving parafunctional habits (uncommon habitual usage of a body part), poor posture, or occupational/recreational activities. As a result, some authors have hypothesized that trauma causes the sarcoplasmic reticulum to rupture, leading to the release of calcium ions into the sarcoplasm that can contribute to MTrPs.

Treatment

Knowing the potential cause of MPS is crucial when developing an effective treatment approach. However, due to a poor understanding of the underlying mechanisms of action, and in addition to the lack of consensus when diagnosing MPS, there is no consensus in the literature regarding the best form of interventions for treating MPS. As a result, various treatments have been utilized. Subsequently, MPS treatment continues to be an active topic for clinical research. Suggested treatments include nonsteroidal ant-inflammatory drugs (NSAIDS), ethyl chloride spray and stretching techniques, ultra sound (US), application of pressure or massage, e-stim (ES), acupuncture, dry needling (DN), and low level laser therapy (LLLT).

With the exception of DN and LLLT, the aforementioned traditional treatments can increase adverse effects to patients, the environment, or therapists. For example, NSAIDS have demonstrated a lack of pain relief and yet continue to be prescribed in the treatment of MPS, despite adverse effects that are known to cause upper and lower GI tract injuries. ES treatments also demonstrate vague evidence for treating MPS. Consequently, the application of ES can predispose the patient to increased risk of electrical burns, skin irritation, and mild
autonomic responses. Additionally, the use of ES on pregnant women is contraindicated. This can be problematic because the prevalence of MPS is higher in women than men. Moreover, US treatments reported conflicting evidence as a form of treatment to effectively treat MPS as stated in a systematic review conducted by Vernon et al. Additionally, US treatments pose a risk for patients with an intolerance for heat. Then in a study comparing US to LLLT for treating MPS, Kannan reported that LLLT had shown superior increments in the study variables (pain and ROM).

Acupuncture has been used with MPS, however, needles are not directly inserted into the MTrPs. Instead, acupuncture focuses on the insertion and stimulation of needles at specific points on the body and not directly into the MTrPs. Literature suggests that a needle must be directly inserted into MTrPs in order for the treatment to be most effective. To conclude, although ethyl chloride spray and stretch techniques, along with application of pressure or massage, have been found to be effective techniques for treating MTrPs, these techniques pose risks. First, the effects of the chemicals used in the spray degrade the ozone layer, so such treatments should be used sparingly. And second, application of pressure or massage requires more physical exertion by the therapist, contributing to wear and tear by placing excess stress on the therapist’s hands, wrists, and back.

Conversely, LLLT and DN do not have the adverse effects as described for the usage of the abovementioned interventions and, in addition, studies reported effective results in treating MPS with LLLT and DN. A meta-analysis performed by Kietrys et al recommended DN for immediate pain reduction in patients with MPS. Simunovic used LLLT on MTrPs of 243 MPS patients and reported a decrease in spontaneous pain and pain at activity. Moreover, literature supports
that LLLT and DN provide a safe approach that carries low risks, which are not seen with the traditional MPS treatments as stated above. As a result, LLLT and DN treatments appear to be some of the most effective and safest for deactivating MTrPs.

**Dry Needling**

Research has shown evidence supporting DN as an effective approach for MPS management. Cummings and White performed a systematic review for DN in the management of myofascial pain syndrome and reported that dry needling of MTrPs appears to be an effective treatment. DN is defined as a procedure in which a needle is inserted into the skin and muscle in the MTrP without the introduction of any drug. The aim in applying the DN into the MTrP is to elicit a local twitch response, which indicates MTrP activation. Once the MTrP is activated, the needle is removed. Hypothetically, the muscle twitch response may interrupt motor end-plate noise, promoting an analgesic effect. Hong et al. reported the needling procedure is most effective when a local twitch response occurs within the affected muscle. Furthermore, when a local twitch response is elicited, an immediate and complete pain relief can be achieved.

Literature reports the mechanism of action involved in DN reveals no conclusive evidence. One theory put forth is that DN functions by destroying the contractile elements, either sensory or motor, of the nerve endings that contribute to the MTrPs activity. According to Tsai and Hsieh, DN is an effective method to decrease MPS. Their study results found that DN could significantly inhibit the irritability of MTrPs in comparison to a placebo group. The DN group showed significant improvements in pain, pain pressure threshold (PPT), and ROM in comparison to the placebo group. In another study, Martin and Aguilera
reported that the effectiveness of DN directly into the MTrP showed significant results in comparison to DN next to the trigger point. One study concluded that the application of DN in a MTrP promoted significant changes in improvements in pain as indicated using a visual analog scale (VAS).\

Although needling is considered a safe, minimally invasive procedure, there are some precautions: care should be taken with patients presenting a needle aversion or phobia; patients need to be able to give consent for the treatment with DN; local skin lesions must be avoided with DN; local or systemic infections are generally considered to be contraindicated; some patients may be allergic to certain metals in the needle, such as nickel or chromium; patients with significant cognitive impairment, an abnormal bleeding tendency, and/or those who may not be willing to be treated with DN must also be considered.

**Low Level Laser Therapy**

In addition to moderate evidence supporting the use of DN, studies also provide confirmation that LLLT used for MPS management is generally a positive approach for the effectiveness on pain and functional outcomes. Vernon and Schneider reported LLLT as generally positive with improvements in functional outcomes and pain while showing superiority to placebos. Hakguder et al and other studies reported LLLT has shown satisfactory effects in deactivating MTrPs. Manca and Limonta et al completed a study reporting that laser treatments showed significant results for pain and CROM improvement in comparison to a placebo LLLT. Additionally, a study by Gur and Jale Sarac found significant improvements in self-reported pain (rest and activity), Neck Pain and Disability Scale, and depression outlook and quality of life score (Nottingham Health Profile) in patients treated with laser when compared to patients treated...
with a placebo. Although there is moderate evidence in support of LLLT, there are other studies that report varying results and one study reported no significant difference while comparing laser to placebo in persons with MPS.

Laser therapy mechanisms of action are not clear. Proposed explanations reported that laser therapy mediates the inflammatory process, promotes analgesia, promotes angiogenesis, and enhances the tissue repair process. Laser therapy ideally increases local microcirculation and assists the supply of oxygen to cells with hypoxia. Theoretically, this promotes the removal of waste products that result from cell metabolism, which carries over to decreases in pain and muscle spasms. The proposed positive effects of laser are myorelaxant tissue healing, anti-inflammatory effects, and analgesic effects for decreasing MPS. Although LLLT does not offer the risk of tissue damage that DN can cause, nonetheless, there are some precautionary measures for LLLT. The following are some precautionary measures for LLLT: avoid direct laser on a fetus if the patient is pregnant; children under 2 years of age should not be irradiated, and one should avoid irritating the epiphyseal line in children; avoid irradiating areas with hemorrhage or with no hypoesthesia for heat and/or pain, areas of sympathetic ganglia or vagus nerve, the heart region in patients with heart problems, the gonad area, and infected areas; and avoid irradiating tumors directly to avoid stimulating tumor growth.

Indeed, there are various treatments available for treating patients diagnosed with MPS; however, many are associated with conflicting results, contraindications, and adverse effects. It is important to clinically assess therapies in an attempt to establish more effective treatments for managing MPS. However, many of these treatments have provided insufficient evidence of a particular treatment approach.
LLLT has been utilized for over 30 years and is one of the most recently employed treatments. While at the same time, needle therapies are by far one of the most common forms of treatment for MPS. Despite the regularity usage of LLLT and DN, only one study, Ilbuldu et al, compared LLLT to DN. This study found significant differences in favor of the laser group with decreases in pain at rest, pain during activity, increase in PPT, and improvements in Nottingham Health Profile. Despite these findings, further studies comparing these treatments need to be performed in order to determine which of the 2 (DN or LLLT) is significantly effective in treating MPS.

As a result, the aims of this study are to first compare 2 low-risk promising modalities that have rarely been compared for MPS treatment and second, to determine if LLLT or DN will be effective as a standalone treatment for MTrPs in the trapezius muscle. Standalone treatments are important for research because combined interventions lead to conflict attributions, making it difficult to evaluate the role of each single intervention. A third aim of this study is to compare LLLT to DN across various time periods and independent-of-time.

Therefore, the purpose of this study is to compare LLLT to DN in patients with MPS located in the trapezius muscle by performing a meta-analysis for outcome of pain and a systematic review for CROM. The null hypothesis of this meta-analysis is that there will be no difference between the short-term, long term, and independent time variable of LLLT and DN with regards to pain. The alternative hypothesis is that the use of LLLT will reveal improved short-term, long term, and independent-of-time frame effects on pain when compared to DN.
METHODS

Search Criteria

The study design was developed with PRISMA guidelines. The following databases were accessed for this meta-analysis: EBSCO Information Services using the following search terms: “trapezius AND dry needling AND chronic myofascial pain,” “dry needling AND mechanical neck pain,” “trapezius myofascial pain AND LLLT,” “cervical myofascial pain AND low level laser therapy,” and “neck myofascial pain AND low level laser therapy”; the U.S. National Library of Medicine National Institutes of Health (PubMed); and the Cumulative Index of Nursing and Allied Health Literature (CINAHL). The search was limited to randomized control trials published in peer-reviewed articles from the years 2000 to 2015 in the English language. Secondary searching was performed by reviewing reference lists of qualified papers. The search began in August 2014 and concluded October 2014. The search was held to the inclusion and exclusion criteria to the specific population of 18-65 year-old adults diagnosed with MPS in the trapezius muscle.

Eligibility Criteria

Peer-reviewed, randomized controlled trials, nonrandomized control trials, case-control studies, and single-group trials were all considered. Inclusion criteria involved adults ages 18-65 years old, neck or trapezius pain, preferably for 3 months or longer but not required for inclusion, presence of one or more palpable taut bands in the trapezius muscle (upper, mid or lower), elicitation of pain by compression of the active taut band, recognition of the elicited pain as the patient’s pain, visual analog scale (VAS) for pain outcome measures looking at longer term and short term effects, and a systematic review of cervical range of motion.
(CROM) to provide a summary of current literature relevant to the effects of laser therapy in comparison to dry needling. Studies were excluded if participants exhibited or participated in any of the following criteria: cervical radiculopathy; symptoms of fibromyalgia; no evidence of palpable taut bands in the trapezius muscles, palpable taut bands in regions other than the trapezius, and dry needle treatments not directly inserted into the active taut band of the trapezius.

**Definitions**

A laser is an instrument utilized to increase the velocity of the spinning atom electrons by passing the photon energy through a medium. This allows a new light to be sent at different wavelengths in one direction. As a result, the wavelength produced with laser treatments can promote analgesic, wound-healing, and anti-inflammatory effects. Researchers have shown that laser therapy can cause an increase in motility, cell proliferation, and synthesis of collagen.\(^{70-72}\)

Clinical application of low level laser therapy (LLLT) is known to be performed in 3 ways: direct exposure of the skin overlying the injury, direct exposure of MTrPs or acupuncture points, and direct exposure of nerves inside or outside the painful area.\(^{14}\)

Trigger point dry-needling is a procedure commonly used to treat MPS.\(^{16,45}\) Clinicians frequently use a 32-guage needle inserted into the MTrP using a superficial (20 mm) or deep (25-40 mm) needling technique. When the needle is inserted into the skin and muscle, in the location of the MTrP, the needle remains until there is elicitation of one or more local twitch responses. Once the MTrP is activated, evidenced by the twitch response, the needle is removed.\(^{73}\) Studies report that the localized twitch response assists in relaxing the actin-myosin bonds in the tight bands, hence reducing pain. It has been suggested that
the decrease in pain may partially be attributed to the gate control theory of pain.\textsuperscript{74} Other theories suggest that DN may help to decrease pain by promoting a mechanical destruction of dysfunctional end plates.\textsuperscript{2,41} Ideally, deactivation of these endplates terminates the contraction of the muscle fiber and nociceptive input to the CNS.\textsuperscript{75}

**Methodological Quality Assessment**

All studies selected and reviewed with extraction of their data for this meta-analysis were selected utilizing the 11-point PEDro scale (see Appendix A). The purpose of the PEDro scale was to evaluate and determine the quality of randomized control trials (RCTs) to assist in evaluating physical therapy interventions by establishing the studies’ significance and any risk for bias.\textsuperscript{76} Each satisfied item contributed 1 point to the total PEDro score; however, item 1, which pertains to external validity, was not included because it is only used to assess external validity. As a result, items 2-11 were included because they pertain to internal validity. Therefore, the final PEDro score is out of 10 points. All data were composed from the results section (intervention tables) from the studies selected. The mean and standard deviations were used in the statistical analysis portion of this meta-analysis.

**Outcome Measures**

The visual analog scale (VAS)/numeric rating scale (NRS) were used by all studies to evaluate the change in pain following treatment. Respectfully, patients were asked to gauge their pain numerically from 0 to 10, indicating no pain or the most excruciating pain. Researchers reported\textsuperscript{77,78} the VAS/NRS are superior because they have greater sensitivity to change and thus are considered reliable and valid. Pain outcome measure is a self-reported outcome measure that is
frequently used for those with MPS. Lower self-reported scores in the outcome measures signify a decrease in participant pain. Furthermore, a systemic review for DN and LLLT was performed to assess cervical range of motion (CROM). An intratester reliability (ICC= 0.87-0.96) and a change of 5-10 degrees would be needed in order to suggest a real change in CROM in participants with MPS stemming from the trapezius.⁷⁹

**Statistical Analysis**

Continuous variables were analyzed using the weighted mean difference of the studies. A statistical significance of a P-value <0.05 was determined and the 95% confidence interval (CI) was reported for the outcome measure. VAS/NPS were obtained and analyzed from selected studies to assess them individually and a thorough review was conducted to select studies appropriate for CROM outcome measures to conduct and present a systematic review. The pain outcome was sub-grouped under 3 within-subjective variables: short-term, long-term, and no time constraints. Each sub-group was analyzed in order to determine the confidence interval and effect sizes that are derived from mean and standard deviations within each study. The following effect sizes for this study were categorized accordingly: small, < 0.3, medium, 0.3-0.8, and large, > 0.8. In order to determine the homogeneity or heterogeneity of the combined studies, a calculation of the Q statistic was performed. In regards to VAS/NPS, a decrease in score for these measures shows a decrease in pain.⁷⁷,⁷⁸
RESULTS

The initial data base search produced 948 studies. However, 7 were appropriate for full text review with only 1 study found comparing LLLT to DN. See Figure 1 for the study selection process. The characteristics of this meta-analysis for each study (involving short-term and independent-of-time) are presented in Table 1. For studies only comparing the long-term portion of this meta-analysis, refer to Table 2. Refer to Table 3 for articles analyzed in the systematic review on CROM.

Short-Term Laser Therapy Versus Dry Needling on Pain Intensity

The data indicated that DN was minimally better than LLLT application with short-term treatment for decrease in pain intensity when the results were combined in a fixed-effects model: [ES (95% CI) = -0.14 (-0.46, 0.19) P = 5.91E-11, Q = 50.61556]. A high Q value with a low P value shows heterogeneity throughout the studies compared, indicating that the studies are not comparable, and that the result may be deemed inconclusive from this meta-analysis.

Long-Term Laser Therapy Versus Dry Needling on Pain Intensity

The data indicated that LLLT was minimally better than DN application with long-term treatment for decrease in pain intensity when the results were combined in a fixed-effects model: [ES (95% CI) = 0.48 (0.06, 0.89) P = 2.25E-27, Q = 122.7181]. A high Q value with a low P value shows heterogeneity throughout the studies compared, indicating that the studies are not comparable, and that the result may be deemed inconclusive from this meta-analysis.
Independent-of-time Laser Therapy Versus Dry Needling on Pain Intensity

The data indicated that DN was better than LLLT application with independent-of-time treatment for decrease in pain intensity when the results were combined in a fixed-effects model: \[ \text{ES (95\% CI) = 0.23 (-0.09, 0.54)} \, P = 2.6472E-32, \, Q = 154.1335668. \] A high Q value with a low P value shows heterogeneity throughout the studies compared, indicating that the studies are not comparable, and that the result may be deemed inconclusive from this meta-analysis.

Laser Therapy and Dry Needling on Cervical Range of Motion

The principal findings of this review indicated that the use of LLLT and DN is attributed to better improvements in CROM. Ilbuldu et al,\(^47\)Gerber et al,\(^3\) and Ramos et al\(^80\) measured CROM in flexion, extension, rotation, and lateral flexion. Manca et al\(^56\) and Altan et al\(^81\) measured CROM outcomes in lateral flexion (see Table 3).

The LLLT study\(^47\) and DN studies\(^3,47,80\) measuring cervical flexion revealed improvements, with the exception of Gerber et al,\(^3\) which reported no improvements with cervical flexion after DN. The Ilbuldu et al study\(^47\) revealed significant improvements when LLLT was compared to DN with cervical extension. Ramos et al\(^80\) had results in conflict with Gerber et al.\(^3\) Ramos et al found improved cervical extension in response to DN, while Gerber et al\(^3\) found no improvements with cervical extension. Two DN studies\(^3,80\) out of 3 DN studies\(^3,47,80\) that measured cervical rotation reported significant improvements, while the other study\(^47\) reported no difference. Only 1 LLLT\(^47\) study out of 3 LLLT studies\(^47,54,56\) measured cervical rotation. This LLLT study\(^47\) reported no difference with cervical rotation. Also, Ilbuldu et al\(^47\) had better results using
LLLT in comparison to DN for lateral flexion. On the whole, all LLLT studies\textsuperscript{47,56,81} and DN studies\textsuperscript{3,47,80} reported significant improvements with lateral flexion. Conversely, LLLT showed no improvements with cervical rotation in comparison to DN, which demonstrated improved cervical rotation. Furthermore, LLLT and DN demonstrated improved cervical flexion and extension, with the exception of one study,\textsuperscript{3} which reported no improvement with cervical flexion or extension.
DISCUSSION

The objective of this meta-analysis was to evaluate the short-term, long-term, and independent-of-time effects in persons with MPS, comparing LLLT to DN with an outcome measuring pain. Results from this meta-analysis indicate that the short-term use of DN has a small effect size in comparison to LLLT in improving pain, and the long-term use of LLLT has a small effect size in comparison to DN in improving pain. Moreover, LLLT has a small effect size in comparison to DN, independent-of-time, in improving pain. The short-term results reject the alternative hypothesis of this meta-analysis and accept the null hypothesis. The long-term and independent-of-time results reject the null hypothesis of this meta-analysis and accept the alternative hypothesis. However, the overall view of the effect sizes must be carefully reviewed due to the heterogeneity of these studies.

With the exception of Ilbuldu et al\textsuperscript{47} (the only study discovered comparing LLLT to DN), LLLT and DN data were pooled within the different studies selected for this meta-analysis. Since only one study was discovered comparing DN and LLLT, it was necessary to pool data in order to compare the 2 interventions with the attempts to determine which was most effective in reducing pain. All studies were compared according to number of weeks of treatment and mean pain levels as an attempt to acquire homogeneity. Differences in these studies were the sample sizes and number of treatments received.

Sample size may have been the biggest contributing factor for heterogeneity among the short-term, long-term, and independent-of-time study comparisons. The resulted heterogeneity likely occurs because confidence intervals in smaller sample sizes are expected to have a greater positive or
negative influence on the mean scores when compared to outliers in larger sample sizes.

**Heterogeneity in Short-Term Pain Comparison**

Compared short-term LLLT and DN studies resulted in overall heterogeneity (see Table 1). The Manca et al\(^{56}\) and Ilbuldu et al\(^{47}\) studies indicated that LLLT was effective in reducing pain in comparison to DN evidenced by a 2.94 effect size. The Manca et al\(^{56}\) and Martin et al\(^{54}\) studies indicated that DN was effective in reducing pain in comparison to LLLT evidenced by a -1.70 effect size. An effect size of -0.37 in favor of DN over LLLT was evidenced between the Manca et al\(^{56}\) and Gerber et al\(^{3}\) studies. And the Gur et al\(^{14}\) and Ramos et al\(^{80}\) studies indicated that DN was minimally effective in reducing pain in comparison to LLLT evidenced by a -0.06 effect size. The grand effect size of this meta-analysis is -0.14 in favor of short-term dry needling. Thus, the short-term results reject the alternative hypothesis of this meta-analysis and accept the null hypothesis. Based on this short-term meta-analysis, LLLT is not superior to DN for reducing pain in 1-2 weeks. However, the overall small grand effect size (-0.14) must be viewed with caution because of the heterogeneity that can be attributed to sample size and variables in the studies such as number of treatments, response to treatment, and age. Although one group of compared studies\(^{47,56}\) indicated an effect size of 2.94 favoring LLLT, this effect size must be viewed with caution. For example, the DN study\(^{47}\) had a total of 4 sessions and the compared LLLT study\(^{56}\) had 10 sessions; this increase in treatment sessions of LLLT may have some placebo effects.\(^{82}\) Moreover, the DN group did not report a local twitch response within the muscle. As previously mentioned, Hong et al\(^{51}\) reported that the needling procedure is most effective when a local twitch response
occurs within the affected muscle. Most importantly, Ilbuldu et al\textsuperscript{47} incorporated daily stretching exercises and permitted participants to take paracetamol when needed, making it difficult to determine which intervention played the greatest role for the LLLT effect size. Stretching may have played the greatest role according to Dundar et al.\textsuperscript{61} who reported that stretching exercises alone are known to decrease muscle tightness and shortening, which can eliminate or decrease pain.

Furthermore, the DN group\textsuperscript{47} consisted of older females (mean age 35.29) while the LLLT group\textsuperscript{56} consisted of younger men and women (mean age 24) who were physiotherapy university students. This results in a threat to external validity due to sample sizes, age ranges, and gender biases of the sample, so results should be taken with caution since studies reported that confounding variables in the interpretation of pain can involve age and sex.\textsuperscript{83}

Although Manca et al\textsuperscript{56} and Martin et al\textsuperscript{54} demonstrated an effect size of -1.70 in favor of DN, the results should also be interpreted with caution due to heterogeneity of the effect size. While both studies demonstrated good internal validity evidenced by randomized control double blinded studies, variables should be considered. For instance, Martin et al\textsuperscript{54} reported participants with pain existing for 3 months or longer while Manca et al\textsuperscript{56} reported a pain duration of 4 weeks. Patients who experienced longer duration of pain periods with MPS may have poorer outcome results with treatment. Studies supported that patients who suffer from MPS for long durations might develop anxiety and depression.\textsuperscript{84-87} As a result, patients may not efficaciously respond to treatment. However, this was not the case in the Martin et al study which demonstrated a longer duration of pain compared to Manca et al\textsuperscript{56}. Furthermore, despite Manca et al\textsuperscript{56} administering 10 LLLT sessions in comparison to Martin et al, which only performed 1 DN session, DN had better outcomes on pain. Once again this may be due to an elicited local
twitch response as implied by Martin et al\textsuperscript{54} by reporting that DN techniques were similar to that used by Hong et al\textsuperscript{51}

Although Gerber et al\textsuperscript{3} demonstrated a greater effect on pain with DN evidenced with an effect size of -0.37 in comparison to the LLLT group,\textsuperscript{56} results may be ambiguous due to the non-randomized study performed by Gerber et al, which can threaten internal validity.

The final comparison of studies\textsuperscript{14,80} for short-term provided evidence of a small effect size (-0.06) in favor of DN.\textsuperscript{80} However, due to the heterogeneity of the short-term meta-analysis, the effect size may be misleading. Although Ramos et al\textsuperscript{80} demonstrated a small effect size favoring DN, these results may have revealed a larger effect size, if not for the postural education and ergonomics implemented in the Gur et al study.\textsuperscript{14} Furthermore, LLLT provided 10 sessions, in contrast to DN, which only provided 2 sessions, possibly contributing to a placebo effect due to an increased number of sessions. On the other hand, Gur et al’s\textsuperscript{14} participants reported a pain duration of greater than 1 year compared to Ramos et al’s participants, who reported a pain duration of 7.5 months. As previously mentioned, pain duration can adversely affect pain outcome results. For instance, Thorsen et al\textsuperscript{88} and Altan et al\textsuperscript{81} reported that a MPS duration of 4.5 to 5 years reported negative results with treatments. Therefore, researchers concluded that there may be an optimum time window following symptoms when MPS will respond to treatment.\textsuperscript{89}

All in all, the small grand effect size (-0.14) favoring DN for short-term may be unreliable due to the aforementioned moderate variables in each study that can contribute to the overall heterogeneity of this meta-analysis.
Heterogeneity in Long-Term Pain Comparison

The compared long-term LLLT and DN studies resulted in overall heterogeneity (see Table 2).\textsuperscript{47,54,80} The Ilbuldu et al\textsuperscript{47} and Martin et al\textsuperscript{54} studies suggested that LLLT is effective in reducing pain in comparison to DN, as evidenced by a 1.89 effect size. The Ilbuldu et al\textsuperscript{47} and Ramos et al\textsuperscript{80} analyses indicated that DN was effective in reducing pain in comparison to LLLT, as evidenced by a -1.92 effect size. Moreover, the Ilbuldu et al\textsuperscript{47} study favored LLLT over DN, as evidenced by an effect size of 4.55. The grand effect size of these studies is 0.48 in favor of long-term LLLT. Thus, the long-term results accept the alternative hypothesis of this meta-analysis and reject the null hypothesis.

According to the grand effect size (0.48) of this long-term meta-analysis, LLLT is superior to DN for pain reduction at 3-4 weeks. Despite the reported results, this grand effect size must also be viewed with caution because of the heterogeneity that can be attributed to moderate variables as previously mentioned. For example, the Ilbuldu et al\textsuperscript{47} and Martin et al\textsuperscript{54} analyses demonstrated an effect size (1.89) favoring LLLT over DN but the results may be due to number of treatments and an incorporated stretching exercise. The LLLT study\textsuperscript{47} had a total of 12 sessions while the DN study\textsuperscript{54} had 1 session/treatment. Furthermore, the LLLT study\textsuperscript{47} also included upper and middle trapezius and pectoral muscle stretching exercises, which had to be performed daily during the 4-week treatment period. Conversely, the DN participants\textsuperscript{54} did not participate in other interventions. It is likely that the increased LLLT treatment sessions combined with stretching exercises contributed to the treatment effects. Studies reported that stretching is a major and effective part of treating MPS and is known to restore normal activity by decreasing muscle tightness, thereby relieving pain.\textsuperscript{90-92} As a result, a combination
of LLLT and stretching exercises may have contributed to the effectiveness of the LLLT treatment.

The final comparison of studies for long-term\textsuperscript{47,80} provided evidence of an effect size (-1.92) in favor of DN. As with all aforementioned effect sizes of the various studies discussed, the effect size of the Ilbuldu et al\textsuperscript{47} and Ramos et al\textsuperscript{80} analyses may also be misleading. Surprisingly, despite the 12 sessions of treatments, paracetamol (when needed), and daily stretching exercises involved in the LLLT study,\textsuperscript{47} the DN study\textsuperscript{80}, which offered only 2 DN sessions, demonstrated greater pain reduction in comparison to LLLT. Several variables may contribute to these results. For instance, this may be the result of the DN study treating only 1 MTrP while the LLLT study treated 3 MTrPs bilaterally. Furthermore, a local twitch response occurred with every treatment, which could have contributed to the effect sizes in favor of DN as reported by Hong et al.\textsuperscript{51}

As reported, the grand effect size (0.48) favoring LLLT for long-term effects may be ambiguous due to the moderate variables mentioned in each study that can contribute to the overall heterogeneity of this meta-analysis.

\textbf{Heterogeneity in Independent-of-time Pain Comparison}

The compared independent-of-time LLLT and DN studies resulted in overall heterogeneity\textsuperscript{3,14,47,54,56,80} (see Table 1). The Ilbuldu et al\textsuperscript{47} study suggested that LLLT was effective in reducing pain in comparison to DN evidenced by a 4.55 effect size. Manca et al\textsuperscript{56} and Martin et al\textsuperscript{54} analyses indicated that DN was effective in reducing pain in comparison to LLLT evidenced by a -1.70 effect size. Manca et al\textsuperscript{56} and Gerber et al\textsuperscript{3} indicated that DN was effective in reducing pain in comparison to LLLT, as evidenced by a -0.37 effect size. LLLT was effective in reducing pain in comparison to DN evidenced by a 2.94 effect size as indicated by
Manca et al\textsuperscript{56} and Ilbuldu et al\textsuperscript{47} Furthermore, Gur et al\textsuperscript{14} and Ramos et al\textsuperscript{80} indicated that DN was minimally better in reducing pain in comparison to LLLT, as evidenced by a -0.06 effect size.

The grand effect size (0.23) for independent-of-time favors LLLT over DN. Thus, the independent-of-time results accept the alternative hypothesis of this meta-analysis and reject the null hypothesis. This small grand effect size of the independent-of-time analysis must also be viewed with careful consideration because of the heterogeneity attributable to sample size, length of pain, treatments, response to treatments, age, and gender as previously described in the short-term and long-term analysis. Since the independent-of-time analysis is an accumulation of the short-term and long-term analysis, the same moderate variables exist and contribute to heterogeneity of the independent-of-time meta-analysis.

Additional significant variables can further contribute to the heterogeneity of this meta-analysis. Significant variables of the selected studies include quality of studies, sample sizes, LLLT parameters, and DN techniques/methods that could have contributed to the significant heterogeneity of the effect sizes.

Six eligible studies that were selected for this meta-analysis utilized different variances for the studies ranging from sample size, baseline characteristic, and method of studies. As a result, the variances of these methods can lead to various sources of bias, which can threaten internal validity (see Table 1).\textsuperscript{3,14,47,54,56,80} Furthermore, the utilization of a PEDro scale\textsuperscript{76} revealed that PEDro scores for these studies ranged from 5-8, with Gerber et al\textsuperscript{3} scoring the lowest and Martin et al\textsuperscript{54} and Ramos et al\textsuperscript{80} scoring the highest. Because of the variant qualities between these studies, internal validity is threatened. Furthermore, since data had to be pooled within the LLLT and DN studies in order to compare the 2 interventions, study comparisons resulted in heterogeneous sample sizes, which
likely contributed to the heterogeneity of the effect sizes. Sample sizes ranged from 11 to 47, with Manca et al\textsuperscript{56} being the lowest and Ramos et al\textsuperscript{80} being the highest. Although the studies included in this meta-analysis had similar outcomes and interventions, this variation in method of studies and population groups likely influenced the effectiveness of the interventions.

Various studies exist utilizing different parameters of LLLT because no scientific consensus supports a particular application dosage.\textsuperscript{57} Researchers suggest that in order to effectively judge the effectiveness of LLLT for treating MTrPs, the application parameters of LLLT is of great importance.\textsuperscript{57} Laser wavelengths within the range of 780-904 nm are suggested as the most suitable for deactivation of MTrPs since they have higher tissue penetration.\textsuperscript{59} Furthermore, pain reduction of MTrPs appears possible using power outputs of 0.95-120 mW and energy doses ranging from 0.275-8 J.\textsuperscript{46,89,93} LLLT studies\textsuperscript{14,56} selected for this meta-analysis used 904 nm and fell within the power output and energy dosage ranges. Ilbuldu et al.,\textsuperscript{47} however, used a range of 632.8nm with a dosage of 2 joules (energy dose) and achieved satisfactory results. This appears to confirm the hypothesis that a suitable dosage may be important for effective therapy.\textsuperscript{47} Conversely, a meta-analysis containing 36 randomized controlled studies\textsuperscript{94} reported that there was no relation between laser dose and the effectiveness of laser therapy after treating musculoskeletal and skin disorders. As a result, Ilbuldu et al’s\textsuperscript{47} selected dose and the role it had with the satisfactory results is difficult to determine since this study had a multi-intervention approach, hence making it difficult to determine the role of each intervention. Indeed, the Ilbuldu et al\textsuperscript{47} study should be cautiously considered since stretching exercises and paracetamol (when needed) were included with LLLT. As expected, it can be difficult to determine the LLLT parameters since there is little evidence in the literature
providing specific information in regards to the parameters for MPS treatment. Moreover, studies report that LLLT dose should be adjusted according to types of tissue pigmentation and amounts of subcutaneous fat. Studies suggest there should be a 50% increase over the usual dose for swarthy skin since melanin absorption is greater on the surface. Furthermore, researchers suggest dosages should be increased accordingly to levels of subcutaneous fat since fat may cause reflection leading to a decrease of radiation absorption by the tissue.46

Likewise, there is a lack of consensus approach for DN for the treatment of MTrPs.17 Factors such as method of needle insertion and presence of a twitch response can contribute to the effectiveness of treatment. Various DN techniques have been utilized throughout numerous studies. One technique involves inserting the DN into the MTrP and leaving it in position for different periods of time.47,95 Another technique known as “sparrow pecking” involves manipulating the needle in and out of the MTrP until a local twitch response is elicited.96 Additionally, a technique known as “grasping and winding” that may include or exclude “sparrow pecking” has also been utilized for deactivation of MTrPs. The theory behind “grasping and winding” is that it allows grasping of the MTrPs to produce stronger stimulation.97 Variances to these techniques can be included by determining needle placement, needle size, depth of insertion and elicitation of a twitch response.16 Twitch responses are seen as favorable results and researchers reported finding better improvements in pain scores of patients experiencing muscle twitch responses with DN.73,97 A comparison of DN studies3,47,54,80 of this meta-analysis appears to support the importance of the twitch response. The Ramos et al80 study included the twitch response, which demonstrated a greater pain change in comparison to the remaining DN studies that did not require a mandatory twitch response.3,47,54 However, due to the heterogeneity of this meta-
analysis, the effective outcome must be perceived with careful consideration. Moreover, since there appears to be a correlation between DN methods/techniques and LLLT parameters, further research should be conducted to determine a general consensus for the applications of these 2 interventions.

**Limitations**

One of the most significant limitations of this analysis is the heterogeneity between studies compared. However, the discussion of the variances attributed to the heterogeneity and the findings within each of the respective studies provide a rationale for further pursuit of this meta-analysis. Another limitation involves the wide confidence intervals contributing to high heterogeneity due to the small sample sizes in each of the studies. Small sample sizes can be challenging to interpret because they lead to large confidence intervals that can cross the line of no difference, leading to a high P value, suggesting no significant changes. Moreover, since all studies had to have pooled data within each in order to compare LLLT and DN, the age of participants, duration of pain, population samples, gender, and education level varied, which contributed to heterogeneous comparisons and likely resulting in heterogeneous meta-analyses. Moreover, one study incorporated an adjunct of stretching exercises and paracetamol use, making it difficult to evaluate and accept the LLLT effectiveness over DN when compared to studies that only utilized DN.

All the compared studies had methodological differences with varying PEDro scores (see Table 1). There is no consensus for optimal wave lengths and dosages due to a lack of evidence in the literature providing specific LLLT parameters. Only one LLLT study was performed as a standalone treatment. The parameters of LLLT varied. Two studies utilized the recommended wave
lengths, power, and dosages, \textsuperscript{46,89,93} while one study\textsuperscript{47} did not use the recommended wave lengths.\textsuperscript{59} Moreover, the parameters of DN techniques varied across the studies. Only one study\textsuperscript{80} reported that all participants required and had to demonstrate a local twitch response, while another single study\textsuperscript{47} made no mention of requiring a local twitch response. Martin et al\textsuperscript{54} implied they required a local twitch response by reporting the utilization of a DN technique performed by Hong et al.\textsuperscript{51} Gerber et al\textsuperscript{3} strived to elicit a twitch response; however, not all participants responded with a local twitch response. Furthermore, DN treatment techniques varied across the studies. DN techniques utilized different needle sizes, DN techniques, and depth of tissue penetration. One study\textsuperscript{47} made no mention of a DN technique while 2 DN studies\textsuperscript{54,80} used Hong et al.’s technique\textsuperscript{51} and one study\textsuperscript{3} used a 4-point compass technique.

Conclusion

In conclusion, this meta-analysis revealed mixed results for short-term, long-term, and independent-of-time treatment in trapezius myofascial pain syndrome. When comparing short-term LLLT to DN in patients with MPS, the overall results favored DN. While comparing long-term LLLT to DN, the overall results favored LLLT. And, during the comparison of independent-of-time LLLT to DN in patients with MPS, the overall results favored LLLT. Furthermore, both LLLT and DN revealed significant improvements with CROM, particularly with lateral flexion. However, it must be noted that despite the grand effect sizes indicating a preferred treatment within their respective time frames and improved CROM outcomes, these results must be viewed with caution due to variant confidence intervals, heterogeneous populations, and variant LLLT and DN specifications, which likely contributed to the heterogeneity of the studies.
This is the first meta-analysis attempting to demonstrate the efficacy of LLLT and DN for the deactivation of MTrPs. However, results of this meta-analysis and systematic review need to be perceived with caution due to large confidence intervals and poor consensus of LLLT and DN parameters contributing to the heterogeneity of these studies. The meta-analysis demonstrates that DN will be more effective for short-term treatment for improved pain outcomes compared to short-term LLLT. The goal of a successful DN treatment is rapid relief of pain. However, studies report that in order to achieve better pain outcome responses, a local twitch response may be required. Kietrys et al\textsuperscript{45} conducted a meta-analysis for the effectiveness of DN and reported that a local twitch response is an important component for DN. The importance of rapid pain relief allows the patient to progress to other forms of therapy, such as postural correction and exercise. Several studies in this review favored DN over LLLT for short-term pain outcomes.

The meta-analysis for long-term and independent-of-time treatments demonstrated better improvements in pain decrease with LLLT. However, these results must also be viewed with caution. Ilbuldu et al\textsuperscript{47} a study including LLLT, paracetamol, and stretching exercises, was compared with standalone DN treatments. In these studies it is possible that the stretching exercises contributed to the treatment effects. Moreover, the Ilbuldu et al\textsuperscript{47} study was compared often to DN standalone treatments that did not report local twitch responses, which may have been attributed to the treatment effects favoring LLLT. Indeed, these variances require a closer inspection to determine whether LLLT is superior to DN since this meta-analysis lacked a true comparison of standalone interventions. Although the results may be ambiguous, clinicians can opt to treat patients with
LLLT and stretching exercise since studies of meta-analysis demonstrated greater improvement with pain outcomes.

Kietrys et al\textsuperscript{45} reported that the provocation of a local twitch response does not appear to be common. As a result, it is cautiously suggested that if a local twitch response is not elicited, then ideally LLLT treatments with stretching will be most beneficial for long term pain outcomes. Furthermore, since clinicians typically treat patients with a multi-treatment approach, LLLT and stretching may seem like the ideal choice since this review is unable to determine whether DN with stretching exercises including a local twitch response is favorable over LLLT and stretching due to the results of this meta-analysis.

Future research comparing LLLT and DN should be performed due to the concerning high prevalence of MPS and lack of clinical trials comparing the 2 techniques as standalone treatments. Studies comparing LLLT to DN as standalone treatments for short-term and long-term response should be critically reviewed with the attempt to determine which is more efficacious. Most importantly, it appears that the local twitch response must be elicited in order to demonstrate greater or immediate decreases in pain representing short-term outcome effectiveness. Thus, future research should aim to improve the methodology of studies in order to provide evidence in favor of LLLT or DN to enable clinicians to treat their patients more efficiently and effectively.
REFERENCES
REFERENCES


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<table>
<thead>
<tr>
<th>Study</th>
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<td>(n=27) DN</td>
<td>35.8</td>
<td>1x/wk/3wks (3 visits total) DN tx</td>
<td>CROM: All Planes</td>
<td></td>
</tr>
<tr>
<td>Altan et al., 2003^81</td>
<td>Level 1 RCT</td>
<td>(n=23) LLLT</td>
<td>43.48±2.42</td>
<td>5x/wk/2wks (10 visits)</td>
<td>CROM: Lat. Flex.</td>
<td></td>
</tr>
<tr>
<td>Ramos et al., 2015^80</td>
<td>Level 1 Non-RCT</td>
<td>(n=47) DN (n=47) Manual therapy</td>
<td>31±3</td>
<td>1x/wk/2wks (2 visits total)</td>
<td>CROM: All Planes</td>
<td></td>
</tr>
</tbody>
</table>
Table 4. PEDro Scores for Included Meta-Analysis and Systematic Review Studies

<table>
<thead>
<tr>
<th>Scale</th>
<th>Manca, 2014&lt;sup&gt;56&lt;/sup&gt;</th>
<th>Ilbuldu, 2004&lt;sup&gt;47&lt;/sup&gt;</th>
<th>Martin, 2015&lt;sup&gt;54&lt;/sup&gt;</th>
<th>Gerber, 2015&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Gur, 2004&lt;sup&gt;14&lt;/sup&gt;</th>
<th>Ramos, 2015&lt;sup&gt;80&lt;/sup&gt;</th>
<th>Altan, 2003&lt;sup&gt;81&lt;/sup&gt;</th>
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<tbody>
<tr>
<td>Eligibility Criteria</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Random Allocation</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Concealed Allocation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline Comparability</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blind Subjects</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blind Therapists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Blind Assessors</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Adequate Follow-up</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Intention-to-Treat Analysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Between-group Analysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Point Estimates Variability</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>TOTAL SCORE</strong></td>
<td>7/10</td>
<td>6/10</td>
<td>8/10</td>
<td>4/10</td>
<td>7/10</td>
<td>8/10</td>
<td>7/10</td>
</tr>
</tbody>
</table>
Figure 1. Search method flow chart of article inclusion and exclusion for statistical analysis
Figure 2. Data analysis of short-term VAS/NPRS comparing LLLT and DN studies with effect sizes and confidence intervals
Figure 3. Data analysis of long-term VAS/NPRS comparing LLLT and DN studies with effect sizes and confidence intervals
Figure 4. Data analysis of independent-of-time VAS/NPRS comparing LLLT and DN studies with effect sizes and confidence intervals
APPENDIX: PEDRO SCALE
PEDro scale

1. eligibility criteria were specified
   no ☐ yes ☐ where:

2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated in an order in which treatments were received)
   no ☐ yes ☐ where:

3. allocation was concealed
   no ☐ yes ☐ where:

4. the groups were similar at baseline regarding the most important prognostic indicators
   no ☐ yes ☐ where:

5. there was blinding of all subjects
   no ☐ yes ☐ where:

6. there was blinding of all therapists who administered the therapy
   no ☐ yes ☐ where:

7. there was blinding of all assessors who measured at least one key outcome
   no ☐ yes ☐ where:

8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
   no ☐ yes ☐ where:

9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”
   no ☐ yes ☐ where:

10. the results of between-group statistical comparisons are reported for at least one key outcome
    no ☐ yes ☐ where:

11. the study provides both point measures and measures of variability for at least one key outcome
    no ☐ yes ☐ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41). The list is based on “expert consensus” and does not, for the most part, on empirical evidence. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to “weight” scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomized clinical trials (i.e. RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or “generalisability” or “applicability” of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the “quality” of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999
Notes on administration of the PEDro Scale:

All criteria Points are only awarded when a criterion is clearly satisfied. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.

Criterion 1 This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

Criterion 2 A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.

Criterion 3 Concealed allocation means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criterion, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".

Criterion 4 At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.

Criterion 4, 7-11 Key outcomes are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

Criterion 5-7 Blinding means the person in charge (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (e.g. visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.

Criterion 8 This criterion is only satisfied if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of these points in time.

Criterion 9 An intention to treat analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.

Criterion 10 A between-group statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group x time interaction). The comparison may be in the form of hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.

Criterion 11 A point measure is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. Measures of variability include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.
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Date