ABSTRACT

COMPARING PAIN AND DISABILITY OUTCOMES OF INSTRUMENTAL VERSUS HANDS ON MYOFASCIAL RELEASE IN INDIVIDUALS WITH CHRONIC LOW BACK PAIN: A META-ANALYSIS

Background: There are many treatment techniques for those with chronic low back pain(CLBP), a common treatment is Myofascial release (MFR), which manually applies a direct stretch to long standing tissue restrictions. An alternative MFR technique, is instrumental assisted (IA), which uses various firm instruments to release tissue restriction. Instrumental assisted MFR has been found to increase superficial blood flow and fibroblast reaction to provide healing effects.

Objective: To compare pain and disability outcomes when using instrumental assisted MFR techniques compared to hands on MFR techniques performed on patients with CLBP.

Methods: Performed a meta-analysis by collecting studies that analyzed IA or hands on MFR on those with CLBP. Studies that met the criteria were then analyzed with mean and standard deviation, Q statistics, and I^2 statistic, grand effect size with 95% CI.

Results: There was no difference between instrumental and hands on MFR for the VAS analysis (ES=-.12, 95% CI (-1.21, .97). Instrumental assisted MFR did show greater improvements of the ODI compared to hands on myofascial release (ES=-1.5, 95% CI (-1.95,-1.01).

Conclusion: This meta-analysis concluded that both instrument and hands on MFR improve pain, although instrument MFR showed greater improvements of disability.

MaryBeth Williams
May 2017

COMPARING PAIN AND DISABILITY OUTCOMES OF INSTRUMENTAL VERSUS HANDS ON MYOFASCIAL RELEASE IN INDIVIDUALS WITH CHRONIC LOW BACK PAIN: A META-ANALYSIS

by

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BACKGROUND

Low back pain (LBP) is one of the most common disabling disorders that effects 68% to 81% of the world's population.[1] It is projected that 30% of all LBP cases will lead to chronic low back pain (CLBP).[2] In developed countries, CLBP is the leading cause of disability and work absences for those under 45 years old.[3] Chronic low back pain is equally prevalent in both men and woman with an average age onset between 30 and 50 years.[4] The risk factors that do contribute to CLBP are: heavy lifting and twisting, bodily vibration, obesity and poor conditioning.[5] Physical, emotional, and psychosocial (depression and anxiety) factors are associated with CLBP that eventually cause a decline quality of life.[6] In America, the cost is astronomical, with CLBP responsible for an average of $70 billion each year arising from medical costs, disability, law suits, and work absence.[7,8] Considering the indiscriminate and far reaching effects on the cost of medical care for those affected, CLBP is considered an epidemic comparable to cardiovascular disease, infectious disease, and cancer as it carries major social, emotional, and economic burden.[9]

The potentially complex nature of the LBP process is a challenge for the individual and clinician. Considering the extensive effects of LBP, it is important to look at the breadth of variance in the evidence-based treatments for LBP. In other words, there is no single treatment that heals LBP, especially as continued treatment without much success will be an increased economic burden and detriment to a person's life.[5] Since treatment is not singular, acute low back pain transitions to sub-acute low back pain within 6 weeks, then another transition occurs at 12 weeks to CLBP, which exceeds the normal healing time.[10]

Physical therapy treatment choices for CLBP range from modalities such as transcutaneous electrical nerve stimulation (TENs), interferential therapy, laser, and short wave diathermy; exercise; and massage are the most recently researched to be useful in treating CLBP.[13] Chronic low back pain includes numerous structures, however most CLBP individuals with an unknown pathology include musculoskeletal dysfunction, so soft tissue should be addressed in the course of treatment. Given that the musculoskeletal system is the most involved structure, the purpose of this meta-analysis is to compare pain and disability outcomes when using instrumental assisted myofascial release techniques compared to hands on myofascial release techniques performed on patients with CLBP.

Development of Chronic Low Back Pain

Physical therapy and the use of myofascial techniques target reduction of muscular strain, connective tissue restrictions for those with CLBP, thus reduce the potential for ongoing pathology. The pathogenesis of CLBP is an increased sensitivity from initial injury with repetitive injury and microtrauma after the fact, thus leading to the chronic condition.[11] As a consequence, long term muscular strain, connective tissue fibrosis, and reduced flexibility are a major factors in the pathogenesis.[12] Furthermore, tissue and cellular changes occurs from the initial acute phase and greatly contribute to the chronic pain. Therefore, there is an ongoing revolution in cells, chemistry, tissue formation, and structural integrity leading to chronic pain. Therefore, it’s clinically important to review the pain process from acute to chronic pain.

When an acute injury occurs, an inflammatory process begins. There is an increased production of histamine and cytokines released from mast cells, monocytes, and endothelial cells. Substance P, a neuropeptide is also released from sensory C-fibers.[14,15] Increased transforming growth factor beta-1(TGFb-1) production, which is stimulated by tissue injury and histamine release, enhances fibroblast collagen synthesis and tissue fibrosis.[16] These chemical mediators, especially substance P, alter the transitional properties of the free nerve endings.[15] During the inflammatory process, the highly innervated connective tissue is modified. The damaged cells release chemical mediators, activating nociceptor nerve endings, causing pain signals to be sent to the brain. A peripheral stimulus involving pain, is carried through C fibers or A delta fibers. The painful stimulus is sent to the spinal cord (SC) which crosses the SC at the lateral spinothalamic tract. The signal is sent through the thalamus and taken to the somatosensory cortex for interpretation. The perception of pain is further analyzed by connections to the insular cortex, amygdala, hypothalamus, and anterior cingulate cortex.[17]

However, there are significant differences in the modulation of brain activity when comparing CLBP to acute low back pain. Both acute and CLBP show dysfunction in the nociceptive system to non-painful stimuli by distortion of cortical processing. The distinction in CLBP occurs because of negative neuroplasticity, which shows thinning of cortical gray matter in the bilateral dorsolateral prefrontal cortex (DLPFC), thalamus, brainstem, primary somatosensory cortex, and posterior parietal cortex. Alternatively, there are positive changes in prefrontal cortical thickness in individuals with CLBP reporting decreased pain.[18]

Simultaneously, as CLBP evolves, individuals will avoid pain and as a result, perform less movement, thus tissue fibrosis ensues leading to altered muscle activity. Since the muscle is unable to support mechanical loads the adjoining connective tissue transforms, causing further adhesions.[13] Passive muscle stiffness results from the cross bridging of myosin and actin, which spontaneously form under resting states, contributing to muscle tension. Therefore, mobilizing and stretching muscular and connective tissue with myofascial release improves pain.[19]

Tissue Response to Pain

Connective tissue contributes to the processing of chronic pain and movement dysfunction. Connective tissue is divided into 3 layers: a superficial layer, a layer of potential space, and a deep layer. Connective tissue is believed to be one continuous piece of tissue that works in connected chains to create tension integrity in the body. Because the fibers of the fascia run in many directions, there is an inherent in flexibility, thus the surrounding tissue moves and changes with the damaged tissue.[13] The damaged tissue is mobilized creating increased tension as the site, expands the injury site to the healthy tissue.[13] In individuals with CLBP, prolonged and continuous strain exerted on the surrounding soft tissues creates hypersensitivity to pain, reduces mechanosensory and proprioception, and alters deep tissue nociceptive perception. [14] Nociceptor activation alone contributes to tissue misalignment and inflammation, causing even more connective tissue stiffness and movement impairment.[15] Chronic injury evolves from new connective tissue fibers forming over time to reunite, resulting in irregular collagen fiber arrangement with increased random cross-links between fibers, resulting in movement dysfunction [16,17] In order to restore mobility, fascial restrictions are treated with manual therapy techniques such as myofascial release.[18]

Myofascial Release

Myofascial release is “the facilitation of mechanical, neural, and psychophysiological adaptive potential as interfaced via the myofascial system.”[19]

Hands on myofascial techniques in literature consist of relaxation massage, therapeutic massage, and deep tissue massage. Massage is reported to be one of the most popular treatments for back pain and is defined as “a mechanical manipulation of body tissues with rhythmical pressure and stroking for the purpose of promoting health and well-being.”[20] Likewise, therapeutic massage has a focus for health improvements with relaxation of whole body soft tissue manipulation.[21] Deep tissue massage uses the most effective and-efficient way to interact with each tissue layer for relaxation, release of tension, lengthening musculature, and breakage of fibrosis.[22] The analgesic effects of myofascial release transform pain perception by contributing to stimulation of afferent pathways. Myofascial release stimulates large diameter, A delta fibers, and modulation through the activation of descending pain inhibiting systems.[23] The inhibiting system is explained through the Gate Control Theory, which predicts that the faster and larger A beta fibers carrying touch and proprioception have an inhibitory effect on lymphocyte T cells. The A beta fibers send sensory signals to the substania gelatinosa in the brain, which inhibit slow C fibers or nociceptive afferent information at the T cells in the spinal cord. Kerr et al.[24] presented a theory that predicts touch has the ability to renormalize the cortical somatosensory central pathways that add to the painful perception in chronic pain. It is proposed that human touch is thought to reverse the distorted perception of pain, in turn minimizing the secondary pathology of CLBP such as the unorganized somatosensory cortex mapping, enlarged activated area in the brain, and increased amplitude of neural responses found in those with CLBP.

Patients with CLBP are found to exhibit a significantly diminished pain threshold.[14] As stated before the injured muscular and connective tissue adheres to the surrounding tissue causing irregular performance. The adhesions in CLBP causes pain as the free nerve endings that lie in the connective tissue, are substance P-containing receptors, commonly assumed to be nociceptive. The connective tissue is densely innervated by myelinated nerve endings that serve a proprioceptive function are involved and, result in altered movement. Movement dysfunction also occurs due to the restriction around the paciniform corpuscles, Golgi tendon organs, and Ruffini endings that are embedded in the fascia. Myofascial release proposes to treat the underlying cause of CLBP by breaking the fibrotic tissue and preventing the continued signals of pain and undesirable proprioception to the brain.[25] Myofascial release improves the mobility of soft tissues and advances the sliding of the connective tissue layers against each other, by applying a direct tissue stretch which provides relief to long-standing fibrotic stiffness.[19]

In practice, the interventional focus of myofascial release is to effectively break down the tissue resistance and restore proper body movements.[26] The proposed mechanism for myofascial release techniques is based on studies that analyze the plastic, viscoelastic, and piezoelectric properties of connective tissue.[27] Myofascial release therapy takes advantage of the plastic tissue properties by mobilizing and re-organizing the fibrotic tissue.[15] Myofascial release techniques are based upon the physiologic structure of fascia, that in restoring the length and health of restricted connective tissue, pain can be relieved from sensitive structures such as nerves and blood vessels.[28] Myofascial release of the scar tissue matrix is accomplished by redistributing internal fluids, breaking down restrictive intermolecular cross-links, and elongating collagenous tissue.[29]

The proposed mechanism of soft-tissue mobilization is to offer symptomatic relief of pain through the release of endorphins. A major ascent of myofascial release is the act of human touch coupled with deep pressure through the tissues. Akin to massage with deep continuous pressure applied to skin tissue and muscle increases the serotonin levels and decreases substance P, which is one of the primary activators of pain. One key components of moderate pressure in massage is the effect the autonomic nervous system (ANS) creating physical and mental relaxation, allowing a shift from a state of sympathetic response to a state of parasympathetic response.[30] During a study conducted by Ryan et al.[31], benefits of tactile acuity training were analyzed, the placebo group which received massage had improved pain levels compared to the treatment group. The study's explanation for the outcome was the relaxation component of massage. The physiological and biochemical effects of touch include decreasing heart rate, blood pressure, and cortisol levels and increasing oxytocin. It is thought that since tactile stimulation is encoded in the right orbitofrontal cortex, but also cingulate cortex and insular cortex, areas closely related to the perception of emotion and empathy, thus potentially effecting the afferent nervous system.[32] Human touch feeds into emotional wellbeing and a sense of being cared for within many different conditions.

Instrumental Assisted Soft Tissue Mobilization

Instrument assisted soft tissue mobilization (IASTM) is currently gaining popularity in the physical therapy profession. Fifty-six percent of physical therapists complain of pain to multiple areas in the body which arises from the amount of massage and manual therapy they perform.[33] Therefore, the benefits of injury reduction is a potential benefit to the profession. Benefits of IASTM consist of: a mechanical advantage allowing greater force transmission than with hands alone; less time needed to accomplish adequate tissue mobilization; and decreased strain of clinician's hands.[34] The IASTM technique incorporates transverse friction massage to improve realignment of the fascia by increasing vasodilation and breaking tissue adhesions.[35,36] Although it is progressively clearer that the use of IASTM is becoming popular, the literature has not brought attention to the difference in hands on myofascial release and instrument assisted myofascial release. Both interventions have a goal to release the thickened soft tissues of a healed injury, but the human touch is able to elicit relaxation while an instrument is able to reorganize the tissue more efficiently.

Instrumental assisted myofascial release consists of several friction types of techniques depending on the use of specific instruments. Instrumental utilization myofascial release differs from other soft tissue techniques by implementation specialty instruments to apply greater pressure.[42] The Graston Technique uses 6 stainless steel instruments to mobilize soft tissue by behaving like a transverse friction massage creating an inflammatory response.[37] Similarly, Gua sha, a traditional Chinese technique, also uses tools such as: a Chinese soup spoon; an edge-worn coin; a slice of water-buffalo horn; a cow rib; honed jade; and a simple metal cap with a smooth round lip with oil or water.[38] Gua sha technique consists of pressure that is applied along the lubricated skin which purposely produces temporary visible redness called petechiae."[36] Roptrotherapy uses deep friction technique with a bronze T-bar that initiates 5 to 10 kg/cm2 of force to the deep tissue.[39]

Before treatment, the instruments are moved along the skin in a longitudinal fashion to assess the quality of the musculotendinous structures. Changes in soft tissue consistency are detected by the clinician through vibrations of the instrument when it slides on areas of irregular fibrosis of the underneath connective tissue.[40] Once an adhesion is discovered, strokes are repeated for a range of 40 seconds to 20 minutes.[41,42] A study conducted by Nielsen et al.[36]

utilized Gua sha instruments and showed increased microcirculation in the treated area. The purple-red skin tint that instruments cause to the treated area, is due to the damaged superficial capillaries. While the superficial capillaries are damaged. the capillary bed is thought to be vasodilated, allowing inflammatory substances to reach the chronic injury. Even though the capillary bed has not been proven to be conserved it is hypothesized through instrumental assistant myofascial release showing the same blood flow reaction as injections of Acetycholine, meaning the vessels are vasodilated.

Animal research finds, that there are distinct benefits of IASTM by Davidson et al.[43], the results showed an increased fibroblast count in the rats that received IASTM treatment. The importance of fibroblasts is its major influence in the inflammatory process. First, fibroblasts generate fibronectin, which assists in blood clot formation at the injury site, preventing further bleeding and acting as a shield to the underlying tissue. In this inflammatory stage, fibroblasts replace proteins from the blood clot with a matrix that is similar to normal tissue. With controlled application of IASTM, microtrauma and an inflammatory response occurs, and stimulates healing by increasing the amount of fibroblast recruitment.[40] Instrument Assisted Soft Tissue Mobilization breaks down cell matrix adhesions, increases proliferation of fibroblasts, and improves the flow of ions. Furthermore, IASTM aligns the fibroblasts in a stress direction maintaining the healthy collagen and improves interfiber gliding.[44] Instrument assisted myofascial release demonstrates increased effectiveness to realign the tissue of a chronic injury, and thus contributing to the end of the pain cycle.

Purpose

It is clear that the literature has not brought attention to the distinctions in hands on myofascial release versus hands on myofascial release. Both interventions have an overall intent to release soft tissue fibrosis and thus reduce pain. There is however, a dilemma in the implementation of instrument versus hands on myofascial release. The human touch is able to elicit relaxation, provide difference in pressure, and procedure based on tactile information while an instrument is able to reorganize the tissue more efficiently, although lacks the subtle influence of the hand. More importantly, is the aspect of inflammatory response as this may prolong the pain cycle and inflict unwarranted responses. Even though, instrumental assisted myofascial release is an aggressive technique it may contribute to less pain and greater function than hands on myofascial release.

Filling the gap in the literature may assist physical therapist in the most effective method for CLBP. This is the first literature analysis utilizing pain and disability outcome measures to compare the difference among instrumental assisted and manual myofascial release techniques in patients with CLBP. On the other hand, there is a need to reorganize what the literature has to offer regarding new trend in the physical therapy profession of instrumental assisted myofascial release. There is a gap in the literature as to the benefits and effectiveness of either IASTM versus myofascial release for CLBP and therefore will be the first literature analysis assessing pain and disability to compare the difference among instrumental assisted and manual myofascial release technique in patients with CLBP

This meta-analysis was formulated by the following PICO question: In patients with CLBP which of the following interventions IASTM compared to hands on myofascial release improve the outcome measures of pain and disability.

The null hypothesis states there will be no differences in pain and disability outcomes in individuals with CLBP with the use of IASTM techniques compared to hands on myofascial release. The alternative hypothesis states that the use of IASTM will demonstrate a significant difference when compared to hands on myofascial release to improve pain and disability in patients with CLBP.

METHODS

The study's procedures were generated using the framework presented by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Beginning in August 2015, a comprehensive electronic search was conducted systemically in the following database: CINHAL, SPORTDIscus, Pubmed, Google Scholar, and Science Direct. The search was limited to studies from 2000 to 2016 concerning the effect of instrumental myofascial release verse hands on myofascial release in individuals with CLBP. Searches were limited to randomized control trials, English language, peer-reviewed, and human studies. The following search terms were used: Chronic low back pain AND massage, Chronic low back pain AND myofascial release, Chronic low back pain AND Graston, Chronic low back pain AND Gua sha, Chronic low back pain AND scraping, Chronic low back pain AND soft tissue mobilization, and Chronic low back pain AND instrument assisted. Secondary searches were performed reviewing references of acceptable studies. The first screening of articles was through reviewing of abstracts and titles.

The analysis first found the prevalence of studies on instrument assisted myofascial release for individuals with CLBP. Four were found that met the criteria. Only 2 of the 4 instrument-assisted myofascial release studies included a disability outcome measure. Next, 17 hands on myofascial release studies were collected from the literature databases that met the criteria. Four of the hands on myofascial release studies were chosen to best match the instrument myofascial release studies.

Eligibility Criteria

Once the first screening with the search from databases was complete, inclusion and exclusion criteria sorted through the obtained studies. Inclusion criteria for the studies include: use of the Visual Analog Scale (VAS), Pain Numeric Rating Scale (PNRS), Roland Morris Disability Questionnaire (RMDQ), Quebec Back Pain Disability Scale (QBPDS), or Oswestry Back Disability Index (ODI) as an outcome measure; subjects with CLBP (3 months or longer); subjects age 18 years old to 75 years old; and published no later than the year 2000. Studies were excluded if study's exclusivity pertained to any one gender, acupuncture use, a focus on trigger points, use of cupping as an instrument, or back pain for less than 12 weeks. Literature reviews, conference abstracts, and case reports were excluded.

Data Collection Process

Statistical data including means and standard deviations were collected from tables and graphs that obtained the VAS, PNRS, RMDQ, and ODI (outcome measures displayed in Appendices A, B, and C). Since none of the articles that met the criteria included the QBPDS there was no collection of this outcome measure. A statistical analysis was performed from the gathered data giving the effect size of treatment outcomes, homogeneity, and heterogeneity analysis between the studies.

Outcome Measures

Pain level and disability was measured using the VAS and ODI. The VAS was utilized to assess subjective pain on a straight horizontal line of fixed length of 100 mm measured from 0 signifying no pain and 100 signifying extreme pain. The subject is shown the scale and through visual and auditory directions, the subject chooses a point on the horizontal line that matches their pain level.[45] The VAS has been proven to be reliable and valid for measuring pain intensity. It has not been tested in those with low back pain, although it is most commonly tested in patients with rheumatoid arthritis. Romanowski et al.[51] used the Pain Numeric Rating Scale (PNRS) which was converted to the VAS, due to the high correlation between the 2, the PNRS score was able to be used with the VAS scores. The construct validity between the PNRS and VAS ranged from .86 to .95 while tested in those with chronic and rheumatic pain.

The main disability outcome measure chosen was the ODI which assesses severity of symptoms and of low back pain during functional activities. There are 10 questions regarding functional activities with 6 statements that represent the subject's symptoms with activity. The statements are gauged from 0 to 5, 5 representing the higher functioning statement. The score is out of 50, it is doubled and becomes a percentage of disablement. Payares et al.[47] found excellent construct validity of the ODI for CLBP with P=.409 and no difference between acute and chronic low back pain. The ODI and RMDQ have excellent correlation of .66 for patients with CLBP. Arguisuelas et al.[52] obtained the RMDQ and not the ODI at this point with evidence of correlation ability the RMDQ was calculated to be a percentage.[48]

Data Extraction/Statistical Analysis/Meta-Analysis

The effect size was calculated to quantify the treatment effect for each intervention group and each outcome measure. Cohen's standards for effect size was used and classified as small, moderate, or large with the correlating values being <.30, .30-.80, and >.80. The Q statistic, I^2, and associated P-value were calculated to determine statistical homogeneity or heterogeneity between studies.

This then indicated whether a random or fixed effects model would be used. Forest plots were created to give a visual representation of the effect size, with the grand effect size and 95% CI for the final results. Results were deemed significant if the confidence intervals did not cross zero and the p-value was less than .05.

RESULTS

A total of 313 studies from 2000 to 2016 were found through database searches using key words: myofascial release, soft tissue mobilization, chronic low back pain, chronic back pain, Graston, Gua sha, scraping, and instrumental assisted (CINHAL, SPORTDIscus, Pubmed, Google Scholar, and Science Direct). A review of titles and abstracts left 68 studies that were appropriate for screening. Following the screening, 15 studies were not experimental and 3 were case studies, so they were excluded. Fifty studies were examined to meet inclusion and exclusion eligibility in the meta-analysis. Twenty-nine studies were eliminated because: the full study was not available; the results were not completed; or the studies did not fit the inclusion or exclusion criteria. Out of the 21 studies that met the criteria, only 4 remained that were instrumental and the other 17 included hands on myofascial release. Four studies all included the VAS but only 2 out of the 5 included the ODI or RMDQ. An examination of the 17 studies that included hands on myofascial release was perform to best match the instrumental assisted with the hands-on myofascial release studies for an analysis between the 2 interventions (see Figure 1 for Consort).

The studies were evaluated utilizing the PEDro scale and the critical appraisal sheet from Duke University (refer to Table 1and Appendix D). The Pedro scales ranked from 3 to 9 out of 10 points. The areas that were most commonly rejected were: blinding subject, blinding therapists, blinding assessors, concealed allocation, and intent to treat.

Meta-Analysis-Study Characteristics

Articles included in this meta-analysis were the following authors, Lauche et al.[42], Wang et al.[49], Hernandez-Reif et al.[50], Romanowski et al.[51], Arguisuelas et al.[52], Lee et al.[41], Field et al.[53], and Yoon et al.[54] All of these studies met the standards of the presented PICO criteria and included based on type of population, type on intervention, study design, outcome measures, and available statistical means and statistical standard deviations. Eight studies were included in the meta-analysis (see Table 2 for study characteristics). Four studies examined the effect of instrumental assisted myofascial release and were compared to 4 hands on myofascial release studies analyzed the effects on pain. The functional outcomes were analyzed between 2 instrumental and 2 hands on myofascial release studies.

Lee et al.[41] was compared to Field et al.[53] due to the amount of subjects tested, the duration of treatment, and the pre-test values similarities. Lee et al.[41] included the confounding variable of general exercise at which the Garston group was compared to the general exercise group. The general exercise was compromised of a 10 to 15 minute bike ride and stretching. Field et al.[53] was chosen due to the stretching entailing of "flexing of the thighs and knees". Both of the studies included myofascial release of the back and the lower extremities. Both of these studies scored a 3/10 on the PEDro scale. Between the studies the outcome measure examined was the VAS. After 4 weeks of treatment, the Graston group showed a small statistical reduction of pain compared to the 5 week massage group. Keeping in mind the low PEDro scores, according to these studies hands-on myofascial release and instrumental myofascial release seems to have no real difference in pain.

Lauche et al.[42] implemented the IASTM and Romanowski et al.[51] used the hands on myofascial release for CLBP comparing. In the VAS scores between these 2 studies, the hands on myofascial release showed minimal decrease in pain compared to the instrumental. Although, keep in mind Lauche et al.[42] was a onetime treatment while the comparison Romanowski et al.[51] had 10 consistent days of intervention.

For the functional outcome measure Romanowski et al.[51] was compared to Yoon et al.[54] due to the scarce amount of literature with a small amount of subjects and a functional scale. Romanowski et al.[51] included 10 days of treatment for CLBP while Yoon et al.[53] included only 6 days. The hands on myofascial release presented with 12 points higher on the ODI, however with a greater standard deviation. In the between group analysis, Yoon et al.[53] showed a significant decrease in pain within the study and when compared to Romanowski et al.[51] results. For the purpose of the pain analysis Yoon et al.[54] was compared to Hernandez-Reif et al.[50] Hernandez-Reif et al.[50] which was compromised of 30 minutes twice a week for 5 weeks, demonstrates a moderate significant improvement in pain when compared to Yoon et al.[54], which included 20 minute, 3 times a week for 2 weeks of treatment.

Wang et al.[49] with a 6/10 PEDro scale and Arguisuelas et al.[52] with a 9/10 PEDro scale was compared to each other. Arguisuelas et al.[52] used RMDQ and Wang et al.[49] used ODI which is a possible explanation for 10 percent difference between pre-test functional outcomes. Wang et al.[48] performed 10 minutes for 4 days of instrument myofascial release while Arguisuelas et al.[52] performed hands on myofascial release for 40 minutes, 2 times a week, for 2 weeks. Overall, Wang et al.[49] showed significant improvements in pain and in function when compared to Arguisuelas et al.[52]

All instrument myofascial release studies when compared to hands on myofascial release showed significant improvements in disability outcomes. When reviewing the effects of pain between the 2 groups, the results were scattered.

Three demonstrated only minimal significance with one comparison showing moderated significance of hands on myofascial release.

Meta-Analysis-Synthesis of Results

Primary Analysis

VAS:

Combined effect size of -.21 shows a small effect favoring the instrument assisted myofascial release (see Table 3 and Figure 2 for results). The overall confidence interval crosses zero, showing weak statistical significance for the results of this meta-analysis. A meta-analysis with a Q-value of 10.9, larger than 4 degrees of freedom and a P-value of .03 indicates a variable between studies signifying heterogeneity, thus the random model was used, I^2 showed 88% confirming heterogeneity. The grand effect size confidence interval crosses zero indicating statistical insignificance for the one group comparison of the VAS.

ODI:

The grand effect size of -1.48 validates a large effect which favors instrumental myofascial release when compared to hands on myofascial release (see Table 4 and Figure 3 for results). The overall confidence interval does not cross zero and p-value is less than .05, indicating statistical significance for the results of this meta-analysis. A meta-analysis with a Q-value of .19 being smaller than 2 degrees of freedom, a P-value of .6 greater than .05, and a I^2 of 0% indicating no variability between studies and homogeneity. The fixed effects model was used for the analysis.

Secondary Analysis: Instrumental Myofascial Release

VAS:

The within study instrumental myofascial release analysis showed a grand effect size of -2.2 indicating a large effect favoring instrumental myofascial release. The results demonstrated heterogeneity with (Q=101.5, p=7.56E-22) large variance between studies. These results are conflicting with the between study analysis of instrumental and hands on myofascial release that gave minimal support that instrumental myofascial release decreases pain (see Figure 4 for results).

ODI:

The within one study analysis of instrument myofascial release indicates a large grand effect size of -3.1 indicating that instrument myofascial release does improve functional ability, supporting the results of instrument myofascial release and hands on myofascial release which showed a small effect size still favoring the instrumental myofascial release. The results demonstrated homogeneity with (Q=21,9, p=2.8E-06) minimal to moderate variance between studies (see Figure 5 for results).

Secondary Analysis: Hands on Myofascial Release

VAS:

The one-group analysis of hands on myofascial release showed a large grand effect size of -1.57. The results demonstrated heterogeneity with (Q=9.33, p=.03) large variability between studies (see Figure 6 for results).

ODI:

The one-group analysis of hands on myofascial release indicates a moderate grand effect size of -.82 indicating that hands on myofascial release does improve disability. The results demonstrated homogeneity with ($Q=.28$, $p=.596$) small variance between studies (see Figure 7 for results).

DISCUSSION

The purpose of this meta-analysis was to determine if instrumental myofascial release demonstrated greater effectiveness in decreasing pain and disability compared to hands on myofascial release. The null hypothesis was partially accepted with no difference in instrumental versus hands on myofascial release to improve pain in individuals with CLBP. The alternative hypothesis was partially accepted with instrumental improving disability greater than hands on myofascial release for individuals in individuals with CLBP. Participants with CLBP showed no difference in subjective pain intensity when comparing instrumental versus hands on myofascial release, however disability showed a greater effect size when utilizing instrumental myofascial release compared to hands on myofascial release. The discussion will summarize the results based on the grouping of studies, threats to validity, the limitations of the meta-analysis, ideas for future research, and clinical relevance of results.

Pain Intensity

The meta-analysis demonstrated that both the instrumental and hands on demonstrates similar effects in reducing pain in subjects with CLBP. The studies used for the analysis resulted in heterogeneity, which indicated that when combined, the studies had variability between each other in comparing the effect size. Results of the meta-analysis for pain showed a small effect size of -.12. The forest plot determined heterogeneity indicating the use of a random effects model. The results varied among the 4 combined studies, 2 were in favor of instrumental and 2 were in favor of hands on myofascial release. In performing a within group analysis of instrumental myofascial release and hands on myofascial release independently, the effect sizes showed -2.2 for instrumental and -1.52 for hands on respectively, corresponding with the 2 group analysis results.

Disability Level

The meta-analysis indicates that instrumental myofascial release showed an increase in improving disability in subjects with CLBP. The analysis revealed homogeneity between studies indicating a fixed effects model being performed. Results of the disability meta-analysis showed a large effect size of -1.5 favoring instrumental assisted myofascial release. The ability of the instruments to apply larger pressure and the evidence that shows increased blood flow and fibroblast proliferation largely contributes to the results of decreased disability. [54]

As a one group analysis was performed for pain, a disability one-group analysis was also performed for instrumental and hands on myofascial release. These analyses concurred the 2-group analysis results. The instrumental had a larger effect size of -3.3, while the hands on had an effect size of -.82. Both one-group analyses had homogeneity and statistically significant.

Dosage

One of the systematic issues with many rehabilitation interventions including both myofascial release protocols is the lack of standardized dosage for any diagnoses, including CLBP. A systematic review that was published in 2016 by Cheatham et al.[56] has found that the lack of standardized rehabilitation protocols make it hard to compare and analyze the effectiveness of one compared to the other.[55] In terms of the meta-analysis, the treatment duration between studies had large variations, especially in the myofascial release interventions. In the instrumental studies, the interventions ranged from 40 seconds to 20 minutes with length of treatment duration varying from a one-time frequency to 4 weeks (refer to Table 2). Alternatively, the hands on myofascial release plan of care ranged from 30 to 40 minutes, a much smaller range of time (refer to Table 2). Although the protocol frequency was not clear for hands on or instrument assisted myofascial release, the instrumented dosage showed shorter treatment sessions than hands on myofascial release. An advantage for cost is to complete a treatment intervention in 40 seconds rather than 20 or 40 minutes. Furthermore, the clinician is able to apply other approaches that could potential be beneficial to the patients healing process.

There are many studies in the literature that support and correlate the treatment dosage of certain myofascial instruments. Roptrotherapy has been successful in functional and pain improvements with a consistent dosage in those with LBP, although the dosage takes a longer time than the other 2 instruments. Yoon et al.[54] incorporated a frequency and duration of 20 minutes, 2 times a week for 3 weeks of Roptrotherapy, which improved pain and disability for individuals with CLBP. Similarly, Farasyn et al.[57] used Roptrotherapy with individuals with subacute LBP, implementing a 30 minute one-time treatment session and found a significant decrease in pain at a week follow up. Studies that used Graston technique did not produce dosage consistency with sessions ranging from 40 seconds to 15 minutes. To be clear, there is evidence that short bursts of IASTM can result in significant pain and disability improvements as found in a related study by Laudner et al.[58] The study used Graston to the posterior shoulder in baseball players with previous UE injuries. Laudner et al.[58] used the same treatment duration, of 40 seconds as Lee et al.[41], the results showed significant increases in shoulder range of motion. Furthermore, Lee et al.[41] measured lumbar range of motion and found great improvements in function. Up to 2 minutes of Graston technique has showed improvements, as in Markovic et al.[59] Although in other studies that included dosages reaching 3, 5, and 8 minutes which were combined with other interventions, resulted in minimal improvements.[44,60,61] Additionally, Graston technique was controlled as an intervention alone and applied to patients with spine pain for 10 to 15 minutes, for 10 treatments in 3 to 4 weeks noting that pain did not improve as much as Lee et al.[42] using the duration of 40 seconds.[62]

Even though the Gua sha and Graston technique both use instruments and have the same effect on tissue there is a cultural aspect that seems to be a large contributor to the goal of treatment. Gua sha technique strives for symptomatic relief, improved state of health, and sympathetic response. While Graston technique strives from greater function. Graston is an American made product that is influenced by our health system to achieve outcomes and provide rapid results so insurance is not responsible for more pay. Gua sha was established in China first and then other European countries that don't necessarily recognize those factors as significant, so 10 to 30 minutes is clinically relevant duration.[54] Both of the studies, Wang et al.[49] and Lauche et al.[42] used a duration of 10 minutes. Also, Lauche et al.[42] included subjects with chronic neck pain in their study which were given treatment for 10 minutes. Another study similar to Lauche et al.[42], a study constructed by Braun et al.[63], 2011 utilizing Gua sha on individuals with chronic neck pain for a one-time 30 minute treatment, measured a week later. These studies that used 10 to 30 minute instrumental assisted myofascial release treatments may have influenced a sympathetic response, influencing pain levels.

Location

The location and dosage that myofascial release was applied, varied amongst the studies. The variation of hands on myofascial location became apparent while reviewing reasons and contributes to the heterogeneity in the 2-group pain analysis. Arguisuelas et al.[52] differed from the other hands on myofascial release studies in one way, the therapists applied myofascial release to the psoas major and quadratus lumborum. The other myofascial release studies applied myofascial release to the entire back with a focus on the posterior legs. Romanowski et al.[51] did not specify the location of treatment, leaving it up to the therapist to choose the appropriate location, and this showed in the results with Romanowski et a.l[51] obtaining the largest confidence interval.

Arguisuelas et al.[52] stated that they were particular in the location of treatment, because past evidence found changes of soft tissue on magnetic resonance imaging of lumbar fascia, quadratus lumborum, psoas, and multifidus. Other studies have connected these abnormalities with compensatory movement and posture from altered proprioception, the injury, or location of pain. Lordotic posture represents greater activation of the posterior psoas major and quadratus lumborum. Alternatively, greater activation of the erector spinae led to less activation of the psoas major.[64] Healthy individuals who demonstrated an increase anterior pelvic tilt during prone hip extension also showed delayed activation of bilateral multifidi and contralateral erector spinae.[65]

Additionally in CLBP, hip extension displays an altered muscular activation, confirmed by Bruno and Bagust[66] who showed delayed gluteus maximus activity during prone hip extension. Although this finding has been contradicted in 3 other studies Guimarães et al.[67], Masse-Alarie et al.[68], and Suehiro et al.[69], showing that the gluteus maximus was not found to have a delayed onset of activity. In Masse-Alarie et al.[68] the one difference in the CLBP versus the healthy individuals was the delayed activation of semitendinosus. Suehiro et al.[69] and Guimarães et al.[67] showed delayed activation of the multifidi and erector spinae. Although, Suehiro et al.[69] and Guimarães et al.[67] excluded subjects with tight hip flexors. Masse-Alarie et al.,[68] Bruno, and Bagust[66] did not control for tight hip flexors in their study, which could be the result of less delayed activation of the erector spinae and multifidi, gluteus maximus and hamstrings, which are antagonistic muscles of the psoas major. Therefore, the hands on myofascial release studies seemed to be limiting their treatments with no intervention to the hip musculature. These findings all collaborate to propose that myofascial release should be applied to the psoas major and the back musculature. As clinicians, the evaluation should include examination of which muscles are over activated which will direct the location of treatment.

Blood Flow

To address the scar tissue in CLBP it is important to improve blood perfusion to decrease tissue hypoxia progress. Graston, Gua sha, and hands on myofascial release have been recognized to improve blood flow in the treatment area. A study performed by Portillo-Soto et al.[70] compared massage to Graston measuring the skin temperature to discover which of the interventions produced deeper blood flow. Massage showed a higher temperature than the instrumented device. Furthermore, Gerritis et al.[71] has revealed that temperature of the muscle and pressure in which the instrument is applied effects blood perfusion. Graston resulted in a 6 Celsius change and massage showed an 8 Celsius change. Both treatments showed a 5 to 6 Celcius change in skin temperature post treatment, lasting for 60 minutes after the treatments. The massage treatment leg ended with a mean temperature of 33 Celsius verses the untreated leg, resulting in a temperature of 31 Celsius. The Graston technique ended with a 31 Celsius with 30 degrees Celcius for the untreated leg. These studies concurs with previous literature affirming blood flow increasing on the contralateral limb because of triggering of the cutaneovisceral reflexes, causing a sympathetic autonomic response.[70] There is mixed evidence, as a previous publication revealed that deep massage increases temperature in muscle. Tiidus et al.[72] detected changes in the large artery and vein using a Doppler ultrasound, but did not detect in microcirculation of muscle. Contrariwise, another study shows that massage effects muscular temperature up to 1.5 to 2.5 cm, which is a sign of increased blood flow.[73]

Loghmani et al.[74] showed instrument assisted cross fiber massage increases tissue perfusion and alters microvascular morphology near healing knee ligaments. Nielsen et al.[36], found that superficial blood flow increases by 400%, with Gua sha treatment, which amount to a capillary reaction and acts similar to Acetylcholine injections. Instrumental assisted myofascial release has been found in 2 studies to show only a local response and no global microvascular perfusion.[74,75] Loghmani et al.'s[75] study showed that tissue perfusion was not apparent until the 24 hour mark after the 4th and 9th visit. Also, results in Loghmani et al.[75] indicated that instrumental assisted cross friction massage treated ligaments were 43% stronger, 40% stiffer, and able to absorb 57% more energy than contralateral, nontreated, injured ligaments at 4 weeks following injury. Davidson et al.[43], conducted a study showing IASTM administered to chemically-induced injured rat achilles tendon resulted in fibroblast proliferation and activation, which may be associated with enhanced healing. Instrument assisted soft tissue mobilization resulted in better aligned collagen orientation and decreased fibroblastic activity when compared to tendons not treated. In a proceeding study, using the same model to investigate various IASTM pressures, a significant increase in fibroblast proliferation and activation was found at a greater pressure (1.5 N·mm-2) compared to light pressure (.5 N·mm-2).[76] This could possibly be the reason why hands on myofascial release is unable to reach the results of instrumental myofascial release.

The gathered studies reviewing blood flow and the outcomes between hands on myofascial release indicate that hands on myofascial release can give a whole-body relaxation effect, although without greater pressure less blood flow to the localized effected area causes pain in CLBP to occur. To treat the injured area causing the ongoing painful process instrumental has been shown to increase blood flow as well as fibroblast proliferation.

NeuroNetwork

It is known that patients with CLBP have a movement dysfunction. Eriksson et al.[77] suggested that abnormal movement patterns are the result of CLBP, because of the pathological changes of the muscle. In Suehiro et al.[69], individuals demonstrated a delay in activity onset of the bilateral multifidi and contralateral erector spinae muscles during prone leg extension. Della Volpe et al.[78] utilized dynamic posturography which is reliable and sensitive enough to differentiate a CLBP patient from healthy patient. The dynamic posturography found increased postural sway in the anterior posterior direction with a greater dependence on visual input under dynamic stance conditions in those with CLBP. This pattern reveals adaptive postural strategy to maintain equilibrium under such as restricted musculature and altered movement from poor receptors, challenging stability conditions.

As the fascia thickens and increases cross-links, nerves becoming adhered in the fascia, altering movement. Burke et al.[79] tested the sensory and motor nerve conduction on the subjects with carpal tunnel syndrome, then performed Graston myofascial release on forearm, wrist, and hand. The treatment resulted in improved conduction of the nerves, pain, range of motion and strength. Furthermore, a study conducted by Schaefer and Sandrey[61] analyzed the effects of Graston Technique with an ankle stability program for individuals with chronic ankle instability. Those who received the Graston and ankle stability program showed greater improvements in ankle range of motion and the Star Excursion Balance Test than the sham treatment group and control group. Thus, leading to a possible connection between instrumental myofascial release and improved proprioception.

The most applicable research on IASTM was a study performed by Lauche et al.[80] Pressure pain threshold was increased, but more appropriately mechanical detection threshold was improved by Gua sha treatment in patients with CLBP. Fascia is densely innervated by mechanoreceptors, and it is thought that myofascial release has effects on the mechanoreceptors. A proposed conceptual model that is more applicable to hands on myofascial release, as slow deep pressure is an important part of the applied technique in order to change tonus and produce relaxation changes to the fascia. The mechanoreceptor that is thought to be responsive to the slow deep pressure is Ruffini fascia receptors.[81] While Graston technique is a rather quick treatment duration, Gua sha which uses a longer treatment duration may use the deep slow pressure technique promoting breaking up of fibrotic tissue and decreasing tissue tension.

Limitations

There were limited studies that examined instrumental myofascial release as a treatment intervention for CLBP. The sheer small number of overall studies, when discussing the implications of their results is a concern and a cause for some caution. Giving there was no one study that compared instrumental to hands on myofascial release in this meta-analysis, led to difficulty comparing the studies and contributed to the heterogeneity between groups. The studies that were included in this meta-analysis had small sample sizes attributing to low validity of results. There were 2 studies included in the meta-analysis that had within study threats against validity. Lauche et al.[42] recorded low pre-test scores and measure post-test scores a week later making it difficult to compare with a hands on myofascial release study. Wang et al.[49] also altered the validity of the meta-analysis, using patient preference and resulted in the largest effect size. Chronic low back pain is complex and involving an individualized approach that may result in patient preference as shown in Wang et al.[49]

The element of the PEDro scale that were not met in the studies were the blinding of the therapist, blinding of the subject, and blinding of the assessor. Without blinding, there are threats to validity to control the therapist, subject, or assessors. Only one study in the pain and disability analysis had a strong PEDro score of 9/10, 3 studies had moderate PEDro scores of 5-6/10, and 4 had weak PEDro scores of 3-4/10. The low PEDro scores give a sense of cautiousness to the results (refer to Table 1).

Future Research

Future studies with increased subject size and awareness to threats of validity supporting a higher PEDro score would further contribute to the reliable of this meta-analysis. Although of the same importance, future research should also include a study that compares hands on myofascial release to instrumental myofascial release with the VAS and ODI for those with CLBP. Then, research should grow to compare the different instruments and the results for patients with

CLBP. Another important outcome that should be identified in literature is patient's sensory, postural control, and proprioceptive function after myofascial release. Instruments should also be compared to each other, since dosage varies among each instrument and technically each one seems to be distinctly different from one another, due to the cultural association.

Dosage has been revealed as a main topic that is lacking in the literature. Longer duration has been advocated for those with longer lasting injuries. To find convincing literature that recommends a myofascial release protocol with a shorter duration would be beneficial. Evidence supporting a shorter time frame comes from Drust et al.[73] who found that the differences in massage duration of 5, 10, 15 minutes did not greatly influence the muscle or skin temperature. Additionally, Eriksson et al.[77] found that a 7-minute massage has been shown to decrease muscle stiffness albeit only for a short period of time.

The location of treatment was also shown to vary in literature, however recent research seems to be targeting into the direction of myofascial restrictions of the multifidi, erector spinae, gluteus maximus, and psoas major. Given these recommendation, myofascial release studies that consider the research and treat to these areas for consistent literature would be beneficial to promote accurate protocols.

Clinical Implications

In physical therapy practice, limitations of time, patient independence, and quality of care are concerning and pressed to all be achieved. Chronic low back pain is a complicated condition that varies among each individual. The findings show that hands on myofascial release and instrumental do not differ in pain relief. This concludes that therapist have a choice of which myofascial release technique to use. The duration of hands on myofascial release ranged from 30 to 40 minutes. Direct patient care includes not only myofascial release, but soft tissue massage, traction, stretching, joint mobilization, instrument assisted soft tissue mobilization and muscle energy techniques, or soft tissue mobilization. The number of patients that would be receiving is 16 patients a day, for a 5 day per week work period, with each patient would have 30 minutes of direct patient care. This is clinically relevant, but unrealistic, since physical therapists perform more than hands on technique and as a result, more than half of physical therapist's experience pain from increased manual techniques.[82] Hands on myofascial release is still an effective intervention as it produces a large effect on the sympathetic nervous system response with whole body increase in blood flow. On the other hand, instrumental assisted myofascial release requires less time and improves disability outcomes at a higher level than hands on myofascial release. Therefore, instrumental myofascial release should be strongly considered as an intervention, to the physical rigors when there are excessive adhesions, and when time there is limited for treatment.

A dissertation performed by Heyer[55] found that after employing the Graston Technique strokes alone an almost 8% increase in range of motion was identified. However, the addition of the stretching and exercise activities only provided a minimal, 3%, increase in range of motion. Although, stretching does not result in greater range of motion it may lead to lasting effects, Graston Technique was designed to follow a protocol that includes examination, warm-up, IASTM, and post treatment stretch, strengthening, and ice. It is problematic to compare studies with different IASTM protocols and attempt to draw conclusions regarding its efficacy in clinical practice. Another factor that contributes to certain outcomes from instrumental assisted myofascial release is the amount of pressure applied with the instrument. Heyer[55] also recognized that less pressure applied with the instrument, no “sha” or the visible redness occurred, resulting in less gains of range of motion. Since movement impairments are a large aspect of CLBP, combined interventions and amount of pressure applied with instruments should be considered with the use of instrumental myofascial release. All things considered, instrumental assisted myofascial release can provide clinicians with an advanced technique to supplement their manual skills to provide a method of manipulating the myofascial.

Conclusion

Instrumental and hands on myofascial release have both been shown to decrease pain of patients with CLBP. Although if the purpose of treatment is to improve disability, then literature shows that instrumental assisted myofascial release demonstrates significant greater improvements compared to hands on myofascial release. Improved and greater research will clarify the benefits of instrumental assisted myofascial release on CLBP.

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TABLES

Table 1. Study Pedro Scale

Criterion[24]	Lee et al,	Field et al.	Wang et al,	Arguisuelas et al.	Yoon et al.	Hernandez et al.	Lauche et al.	Romanowski et al.
1. Random allocation of subjects		✓	✓	✓	✓	✓	✓	
2. Allocation concealment			✓	✓			✓	
3. Similar groups at baseline	✓	✓	✓	✓	✓	✓	✓	
4. Subjects blinded				✓				
5. Therapists administering treatment blinded								
6. Assessors blinded	✓			✓				
7. One key outcome obtained from 85% of subjects initially allocated to groups			✓	✓	✓		✓	✓
8. 'Intention to treat' used for analysis of one key outcome				✓				✓
9. Between-group statistics for one key outcome reported	✓		✓	✓	✓	✓	✓	✓
10. Point measures and measures of variability for one key outcome		✓	✓	✓	✓	✓	✓	
Total Score	3	3	6	9	5	4	6	3

Table 2. Study Characteristics

Studies	Instrument and Therapist	Location of treatment	Dosage
Lee et al.	Graston group performed IASTM using the DR. YOUSTM,	To posterior fascia, sacrum, hip lateral rotators, and hamstring bilaterally and general exercise (stretching exercises and stationary bicycling for 10–15 min)	40 sec, 4wks
Field et al.	A massage therapist applied kneading, pressing, pressing and releasing, rubbing, and long gliding strokes	Entire back ,abdomen, neck muscles, and entire legs with added flexion and traction of lower extremities in techniques	30 min, 5 weeks
Wang et al.	Scraping therapy (scraper)	Along channels or between acupoints until appearance of skin eruptions“, on the back	10min, 4 days
Arguisuelas et al.	Physical therapists	Longitudinal sliding of lumbar paravertebral muscles, myofascial release of the thoracolumbar fascia, myofascial release of quadratus lumborum, and myofascial release of the psoas muscle	40 min 2 xwk,2 wks
Yoon et al.	Deep cross-friction massage with the HT-bar	At both the thoracolumbar regions (T6-L3) and hip muscles including the region where the patients complained of pain.	20 min,3 x wk, 2wks
Hernandez et al.	Massage therapist: kneading pressing, rubbing, and long glide strokes	To the entire back and legs	30 min 5 wks, 2 x wk
Lauche et al.	Gua sha instrument. The strokes were repeated in one location until “Sha” (petechiae) became visible	Paravertebral strokes were applied from C7 to L5, followed by horizontal strokes between C7 and L5 and further strokes along the dorsal part of the gluteus maximus muscle	10-15 min, 1 x wk
Romanowski	Qualify massage therapist performed: therapeutic massage, gliding or sliding movement and kneading motion, or pressing or rolling to	Non-specified area	10 days, 30 min

Table 3. Two Group Analysis of the Visual Analogue Scale

Instrumental Studies	n	Mean pre test	SD pre test	Mean post-test	SD Post-test	Hands on Studies	n	Mean pre-test	SD Pre-test	Mean post-test	SD post-test
Wang et al.	39	65	6	6	7	Arguisuelas et al.	27	63	17.4	27.1	20.1
Lauche et al.	10	.4334	24	21	19	Romanowski et al.	13	43.1	17.6	29.54	16.55
Yoon et al.	12	56.67	15.13	31	16.15	Hernandez et al.	13	56	22	17	23
Lee et al.Z	15	50.6	12.7	25.5	7.3	Field et al.	15	51	29	14	16

Table 4. Two Group Analysis of the Oswestry Disability Index

Instrumental Studies	n	Mean pre test	SD pre test	Mean post-test	SD Post-test	Hands on Studies	n	Mean pre-test	SD Pre-test	Mean post-test	SD post-test
Wang et al.	39	55.9	10.9	7.6	7.2	Arguisuelas et al.	27	46.7	17	31.25	22
Yoon et al.	12	34.06	8.8	20.83	11.55	Romanowski et al.	13	46.61	14.61	37.15	12.36

FIGURES

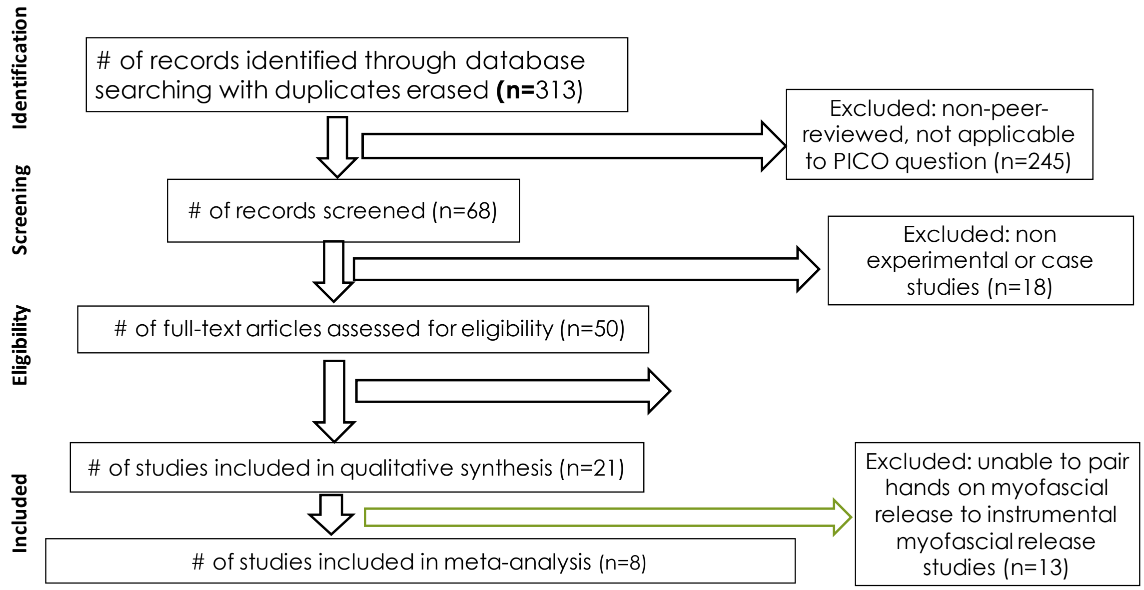


Figure 1. Consort: Study selection

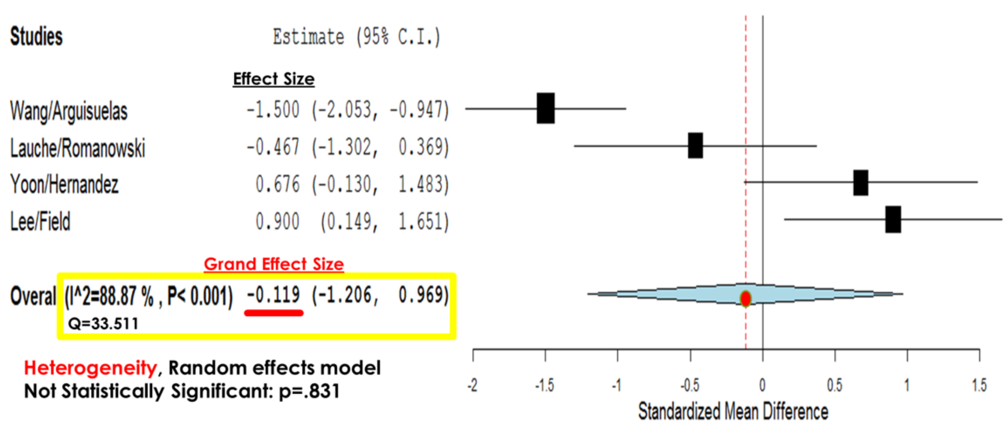


Figure 2. VAS instrumental versus hands on myofascial release two group analysis

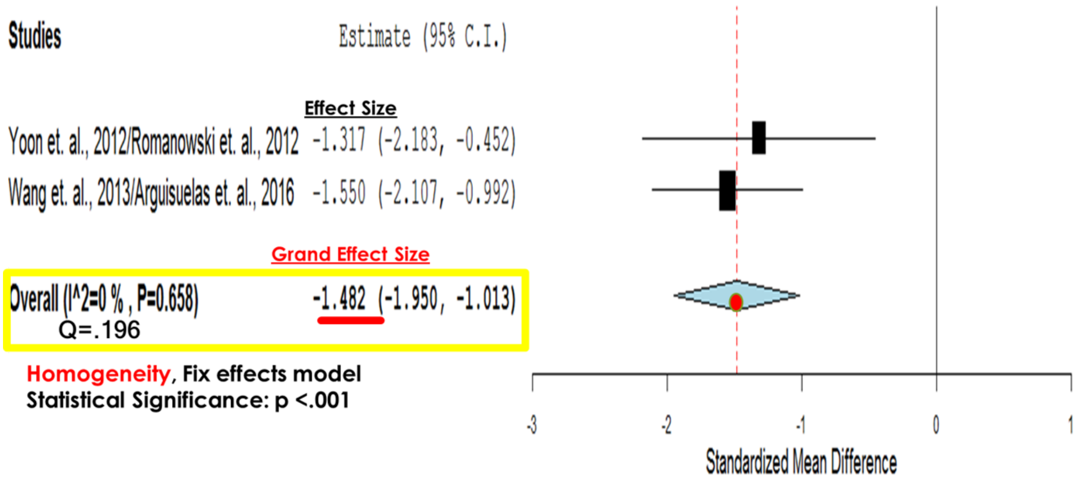


Figure 3. ODI instrumental versus hands on myofascial release two group analysis

Grand Effect Size	-2.20
SE combined	.25
CI lower	2.70
CI upper	-1.71
Q- statistic	101.46
P-value	<.001

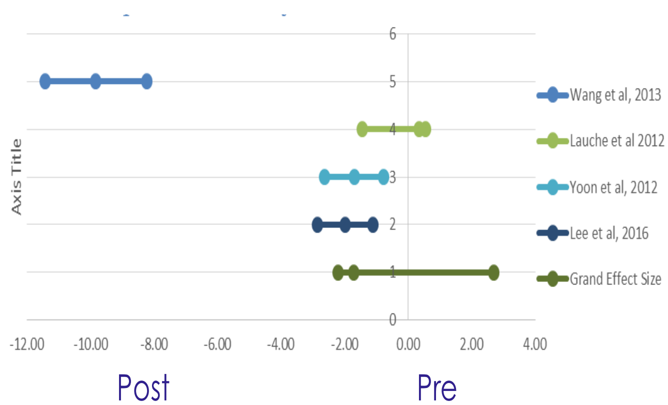


Figure 4. VAS instrumental myofascial release one group analysis

Grand Effect Size	-3.1
SE combined	.31
CI lower	-3.71
CI upper	-2.48
Q- statistic	21.93
P-value	<.001

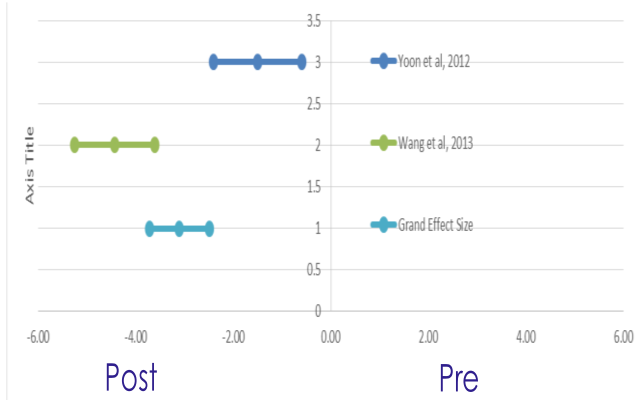
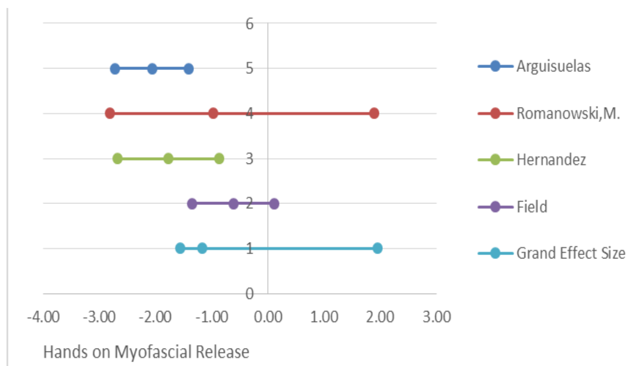


Figure 5. ODI instrumental myofascial release one group analysis

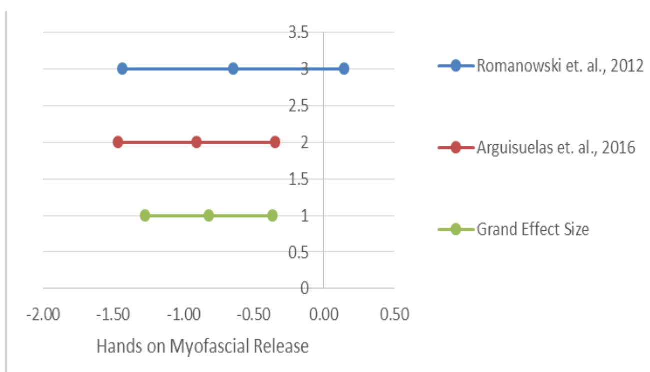
Grand Effect Size	-1.52
SE combined	.20
CI lower	-1.96
CI upper	-1.18
Q- statistic	9/32
P-value	.025



Post Pre

Figure 6. VAS hands on myofascial release one group analysis

Grand Effect Size	-.82
SE combined	.23
CI lower	-1.20
CI upper	-.36
Q- statistic	.28
P-value	.596



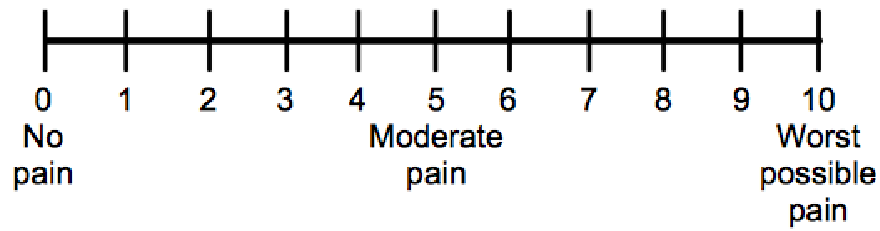
Post Pre

Figure 7. ODI hands on myofascial release one group analysis

APPENDICES

APPENDIX A: PAIN SCALES

0–10 Numeric Pain Rating Scale



Visual Analog Scale

APPENDIX B: ROLAND MORRIS DISABILITY QUESTIONNAIRE

The Roland-Morris Low Back Pain and Disability Questionnaire

Patient name: ______________________ File #__________ Date:__________

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

- ☐ I stay at home most of the time because of my back.
- ☐ I change position frequently to try to get my back comfortable.
- ☐ I walk more slowly than usual because of my back.
- ☐ Because of my back, I am not doing any jobs that I usually do around the house.
- ☐ Because of my back, I use a handrail to get upstairs.
- ☐ Because of my back, I lie down to rest more often.
- ☐ Because of my back, I have to hold on to something to get out of an easy chair.
- ☐ Because of my back, I try to get other people to do things for me.
- ☐ I get dressed more slowly than usual because of my back.
- ☐ I only stand up for short periods of time because of my back.
- ☐ Because of my back, I try not to bend or kneel down.
- ☐ I find it difficult to get out of a chair because of my back.
- ☐ My back is painful almost all of the time.
- ☐ I find it difficult to turn over in bed because of my back.
- ☐ My appetite is not very good because of my back.
- ☐ I have trouble putting on my sock (or stockings) because of the pain in my back.
- ☐ I can only walk short distances because of my back pain.
- ☐ I sleep less well because of my back.
- ☐ Because of my back pain, I get dressed with the help of someone else.
- ☐ I sit down for most of the day because of my back.
- ☐ I avoid heavy jobs around the house because of my back.
- ☐ Because of back pain, I am more irritable and bad tempered with people than usual.
- ☐ Because of my back, I go upstairs more slowly than usual.
- ☐ I stay in bed most of the time because of my back.

Instructions:

1. The patient is instructed to put a mark next to each appropriate statement.

2. The total number of marked statements are added by the clinician. Unlike the authors of the Oswestry Disability Questionnaire, Roland and Morris did not provide descriptions of the varying degrees of disability (e.g., 40%-60% is severe disability).

3. Clinical improvement over time can be graded based on the analysis of serial questionnaire scores. If, for example, at the beginning of treatment, a patient's score was 12 and, at the conclusion of treatment, her score was 2 (10 points of improvement), we would calculate an 83% (10/12 x 100) improvement.

APPENDIX C: OSWESTRY DISABILITY INDEX

Oswestry Low Back Pain Disability Questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self-care
- ☐ I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking*

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 1 mile
- ☐ Pain prevents me from walking more than 1/2 mile
- ☐ Pain prevents me from walking more than 100 yards
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10 – Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

References

1. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940-52; discussion 52.

APPENDIX D: 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 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 randomised 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" not, for the most part, on empirical data. 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 randomised clinical trials (ie 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.