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FASCIA SCIENCE AND CLINICAL APPLICATIONS: SYSTEMATIC REVIEW

Effectiveness of myofascial release: Systematic review of randomized controlled trials

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Summary *Introduction:* Myofascial release (MFR) is a form of manual therapy that involves the application of a low load, long duration stretch to the myofascial complex, intended to restore optimal length, decrease pain, and improve function. Anecdotal evidence shows great promise for MFR as a treatment for various conditions. However, research to support the anecdotal evidence is lacking..

Objective: To critically analyze published randomized controlled trials (RCTs) to determine the effectiveness of MFR as a treatment option for different conditions.

Data sources: Electronic databases: MEDLINE, CINAHL, Academic Search Premier, Cochrane library, and Physiotherapy Evidence Database (PEDro), with key words *myofascial release* and *myofascial release therapy*. No date limitations were applied to the searches.

Study selection: Articles were selected based upon the use of the term *myofascial release* in the abstract or key words. The final selection was made by applying the inclusion and exclusion criteria to the full text. Studies were included if they were English-language, peer-reviewed RCTs on MFR for various conditions and pain.

Data extraction: Data collected were number of participants, condition being treated, treatment used, control group, outcome measures and results. Studies were analyzed using the PEDro scale and the Center for Evidence-Based Medicine's Levels of Evidence scale.

Conclusions: The literature regarding the effectiveness of MFR was mixed in both quality and results. Although the quality of the RCT studies varied greatly, the result of the studies was encouraging, particularly with the recently published studies. MFR is emerging as a strategy with a solid evidence base and tremendous potential. The studies in this review may help as a respectable base for the future trials.

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Introduction

Myofascial release (MFR) is a widely employed manual therapy treatment that involves specifically guided low load, long duration mechanical forces to manipulate the myofascial complex, intended to restore optimal length, decrease pain, and improve function (Barnes., 1990). MFR when used in conjunction with conventional treatment is said to be effective to provide immediate relief of pain and tissue tenderness (Hou et al., 2002; McKenney et al., 2013). It has been hypothesized that fascial restrictions in one region of the body cause undue stress in other regions of the body due to fascial continuity. This may result in stress on any structures that are enveloped, divided, or supported by fascia (Schleip., 2003). Myofascial practitioners claim that by restoring the length and health of restricted connective tissue, pressure can be relieved on pain sensitive structures such as nerves and blood vessels.

MFR generally involves slow, sustained pressure (120—300 s) applied to restricted fascial layers either directly (direct MFR technique) or indirectly (indirect MFR technique). Direct MFR technique is thought to work directly over the restricted fascia: practitioners use knuckles or elbow or other tools to slowly sink into the fascia, and the pressure applied is a few kilograms of force to contact the restricted fascia, apply tension, or stretch the fascia. Indirect MFR involves a gentle stretch guided along the path of least resistance until free movement is achieved (GOT, 2009). The pressure applied is a few grams of force, and the hands tend to follow the direction of fascial restrictions, hold the stretch, and allow the fascia to loosen itself (Ajimsha et al., 2014a) The rationale for these techniques can be traced to various studies that investigated plastic, viscoelastic, and piezoelectric properties of connective tissue (Schleip., 2003, 2012; Pischinger., 1991; Greenman., 2003).

Recent Fascia Research Congresses (FRC) define fascia as a 'soft tissue component of the connective tissue system that permeates the human body' (Huijing and Langevin, 2009). One could also describe them as fibrous collagenous tissues that are part of a body-wide tensional force transmission system (Schleip et al., 2012). The complete fascial net includes dense planar tissue sheets, ligaments, tendons, superficial fascia and even the innermost intramuscular layer of the endomysium. The term fascia now includes the dura mater, the periosteum, perineurium, the fibrous capsular layer of vertebral discs, organ capsules as well as bronchial connective tissue and the mesentery of the abdomen (Schleip et al., 2012). Fascial tissues are seen as one interconnected tensional network that adapts its fiber arrangement and density, according to local tensional demands (Schleip et al., 2012).

Authors such as Day et al. (2009); Stecco et al. (2013) and Langevin et al. (2011) and colleagues, have suggested that connective tissue could become tighter/denser in overuse syndromes, or after traumatic injuries, but it is unclear if this is due to an alteration of collagen fiber composition, of fibroblasts, or of ground substance. The same authors suggest that the alteration of fascial pliability could be a source of body misalignment, potentially leading to poor muscular biomechanics, altered structural alignment, and decreased strength and motor coordination. MFR practitioners claim to be clinically efficacious in providing immediate pain relief and to improve physiologic functions that have been altered by somatic dysfunctions (Hou et al., 2002; McKenney et al., 2013). MFR directs force to fascial fibroblasts, as well as indirect strains applied to nerves, blood vessels, the lymphatic system, and muscles. Laboratory experiments suggest that fibroblasts, the primary cell type of the fascia, adapt specifically to mechanical loading in manners dependent upon the strain magnitude, duration and frequency. Meltzer et al. (2010), in their in-vitro modeling study demonstrated that treatment with MFR, after repetitive strain injury, resulted in normalization of apoptotic rate, and reduction in production of inflammatory cytokines.

MFR is being used to treat patients with a wide variety of conditions, but there is little research to support its efficacy. According to Kidd (2009) the application of MFR is inherently not evidence-based medicine since it relies on clinician—patient interaction, it cannot be a neutral treatment; therefore, the subjectivity of the interaction cannot be removed when we try to determine its outcome. Kidd indicated that much of the effect of MFR relies on the skill of the clinician and his or her ability to sense the changes in the tissue. In addition, biological effects of touch can change the effectiveness of the treatment, depending on the state of either the clinician or the patient. This variability means that interrater reliability is low, and therefore, according to Kidd, prevents MFR from being considered evidence-based. Yet the same arguments have been applied to other manual therapies in the past that now are considered part of evidence-based practice. Although MFR is a popular therapy and anecdotal reports describe positive outcomes from MFR treatments, research is necessary to demonstrate its effectiveness to refute Kidd's argument. Therefore, the purpose of this systematic review was to critically analyze previously published literatures of RCTs to gather the documented effectiveness of MFR.

Methods

We searched the following electronic databases with no date limitations: MEDLINE, CINAHL, Academic Search Premier, Cochrane library, and Physiotherapy Evidence Database (PEDro) by adhering to the systemic review process followed by McKenney et al. (2013) in their study. Two reviewers performed independent searches in September 2013 which was later updated in May 2014. Key words used for the search were *myofascial release* and *myofascial release therapy*. Each reviewer identified articles as relevant based on the use of the term myofascial release in the abstract or key words. The lists were compared, and articles identified by both reviewers were collected in full text. A total of 133 articles were identified as relevant by both reviewers.

The 2 experienced reviewers with sound knowledge in the PEDro and CEBM's scales, screened the full-text articles for inclusion based on a set of inclusion and exclusion criteria. The inclusion criteria were as follows: (1) RCTs published in a scientific peer-reviewed journal, (2) studies with 10 or more participants, (3) contained sufficient information to complete an analysis, (4) used direct or indirect and passive MFR as an experimental treatment, (5) published in English, (6) studied human participants, and (7) included adult participants only (18 years and older). Articles were excluded if published as case studies, editorials, expert opinions, or instructive articles; used trigger point therapy; or did not use MFR as defined. Studies on myofascial trigger-point therapy, proprioceptive neuromuscular facilitation (PNF) and MFR used as a conventional treatment without distinct explanations were also excluded. Subsequently, 19 articles met the criteria for inclusion in our analysis.

Next, the reviewers assessed all studies meeting the inclusion criteria using 2 scales: the PEDro scale (2012) (Table 1) and the Centre for Evidence-Based Medicine's (CEBM's) Levels of Evidence scale (Phillips et al., 2009) (Table 2). The PEDro scale assesses methodological quality and consists of a checklist of 11 criteria, 10 of which are scored. For each criterion the study met, 1 point was awarded. The points were tallied and presented as a score out of 10. The scale applies only to experimental studies. For this review, investigations with PEDro scores of 6–10 were considered high quality, of 4–5 were considered moderate quality, and of 0–3 were considered low quality. The PEDro scale does not evaluate clinical usefulness. The CEBM Levels of Evidence scale assesses quality based on study design, which categorize the studies in a scale ranging from 1 to 5 with further subdivision for each.

Systemic reviews with homogeneity of RCTs are ranked in the highest levels while expert opinions rank the least (Table 2). In both scales, RCTs receives higher rankings, particularly with long-term follow-up and narrow confidence intervals. The reviewers solved any rating discrepancies through verbal discussion. A consensus was reached regarding all studies during the first meeting, which were documented in the review process.

Results

Of the 133 studies identified in the original search, 19 were eligible as per the inclusion criteria (Fig. 1). The PEDro scores of the studies ranged from 5 of 10 to 8 of 10. Five studies rated as 1b and 14 studies as 2b in the CEBM ratings. The most common reason for a 2b rank was that the study had a small sample size and/or no long-term follow-up to treatment. The key characteristics and methodological details are provided in Table 3.

Data synthesis

The quality of research on MFR as a treatment varies widely. The recent published studies are appreciable in their adherence to near normal RCT guidelines. Of the 19 studies included in our analysis, we ranked the 5 RCTs at levels 1b and 14 at level 2b on the CEBM scale, indicating a relatively high quality study design. Scores on the PEDro scale indicated moderate- to high-quality study designs. The lowest score was 5 of 10 and the highest was 8 of 10.

Hanten and Chandler (1994) conducted a moderate-quality study that was rated at level 2b on the CEBM scale and 6 of 10 on the PEDro scale. The purpose of the study was to compare the effect of MFR and PNF in increasing the straight leg raise (SLR) in the management of hamstring tightness. The study highlighted the point that, though MFR is effective in increasing the SLR angle against a control group receiving no treatment, the effect is inferior to a PNF treatment. The study itself had positive outcomes (see Table 3), but it lacked random selection of participants and follow-up.

The study by Barnes (1997) on pelvic symmetry was ranked as level 2b and earned a PEDro score of 8 of 10. Overall, it was a high quality study; however, a few concerns lowered the CEBM ranking, including the small sample size and the lack of follow-up. Only 10 participants were involved, and the authors acknowledged that 23 participants were needed in the treatment group and 15 in the control group to meet the assumptions for parametric data analysis. Overly, the follow-up measurements were conducted immediately after the treatment. Despite these limitations, the 8 of 10 ranking on the PEDro scale indicated that the study was well designed.

Hsieh et al. (2002) investigated the relative effectiveness of three manual treatments including MFR for patients with subacute low back pain (SALBP). The study was rated as a high-quality one, ranked at level 1b on the CEBM scale and earned 7 of 10 points on the PEDro scale. The 1b rating reflects a study that was well designed, with a sufficient number of participants and adequate long-term follow-up. The PEDro score indicates that the study design was strong. The back pain improved in all groups, but there were no differences between the groups. Because the Hsieh et al. study was high quality, the results are relevant to use of MFR as an adjunct to a formal treatment for SALBP.

Another level 2b study was performed by Kuhar et al. (2007), who used MFR to treat plantar fasciitis. This study

Table 1 Physiotherapy evidence database (PEDro) scale scores.

1	Eligibility criteria were specified (no points awarded)
2	Subjects were randomly allocated to groups
3	Allocation was concealed
4	The groups were similar at baseline regarding the most important prognostic indicators
5	There was blinding of all subjects
6	There was blinding of all therapists who administered the therapy
7	There was blinding of all assessors who measured at least one key outcome
8	Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated
10	The result of between-group comparisons are reported for at least one key outcome
11	The study provides both point measures and measures of variability for at least one key outcome

Table 2 Centre of evidence-based medicine: Levels of evidence.

Level	Definition
1a	Systematic reviews of randomized controlled trials
1b	Individual randomized controlled trial
1c	All-or-none studies
2a	Systematic reviews of cohort studies
2b	Individual cohort studies or low-quality randomized controlled trials
2c	Outcomes research
3a	Systematic reviews of case—control studies
3b	Individual case—control studies
4	Case series, poorly designed cohort or case—control studies
5	Animal and bench research, expert opinion

scored 7 of 10 points on the PEDro scale. Patients were evaluated at the beginning of the treatment and then once more on the final day of treatment. However, no measurements were taken as follow up, which lessened the study quality to level 2 on the CEBM scale. As a result, we know only the immediate effects of MFR and cannot comment on long-term effectiveness. Significant reduction in pain and improvement in foot function was reported as the short term effect.

Arroyo-Morales et al. (2008) in their RCT studied the effects of MFR after high-intensity exercise, which scored level 2b in CEBM scale with a quality of 6/10 in PEDro scale.

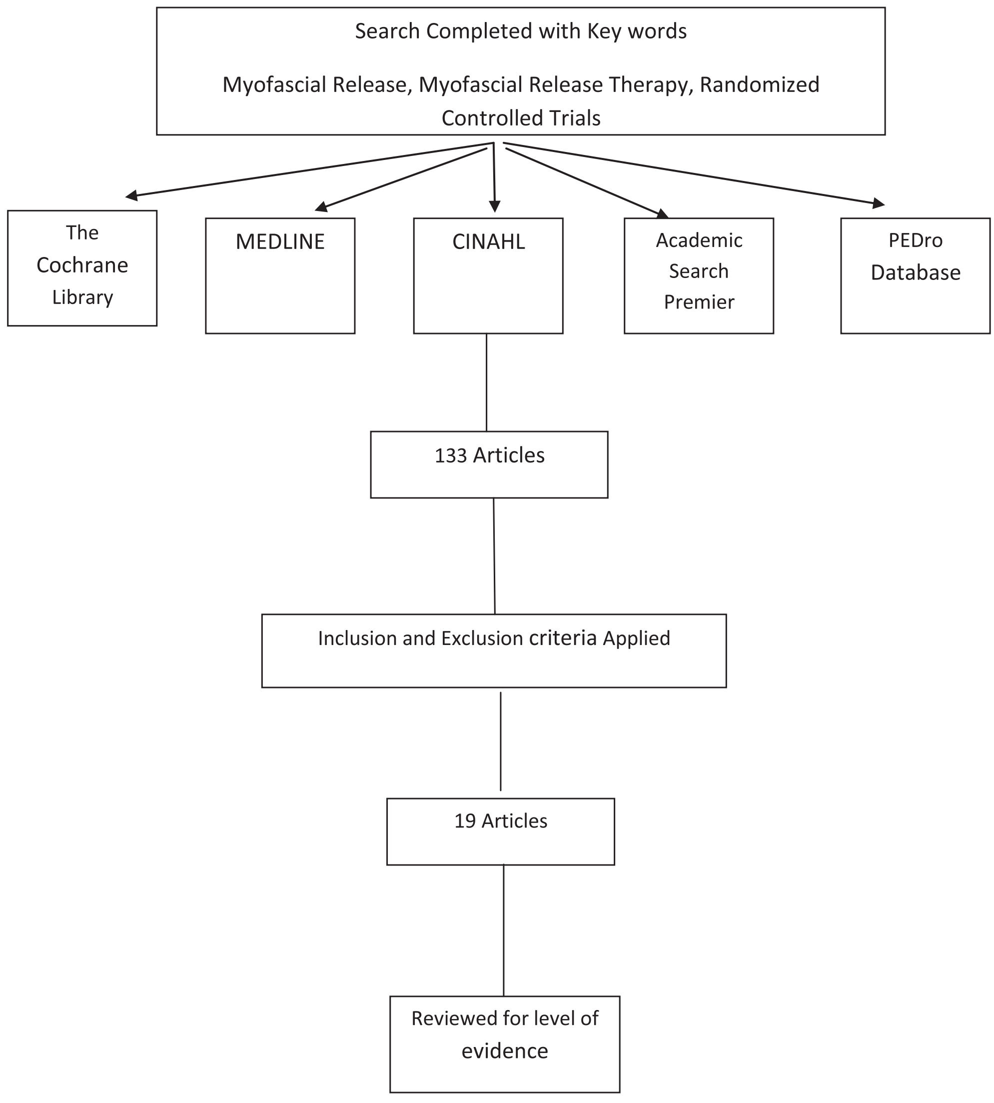

Figure 1 Study flow diagram.

Table 3 Study results & grading included in the systematic review.

First author, year	Condition	Sample Size	Treatment	Control	Treatment Schedule	Main Outcome Measures	Results	PEDro Score	Level of Evidence (CEBM)
Hanten, 1994	Hamstrings tightness	75	MFR to leg × 10-15 min, Contract- relax PNF × 4 min	Supine rest × 5 min	Single session	Passive hip flexion ROM	Post treatment gains PNF: 10.4° MFR: 6.6° Control: 0.9°	6/10	2b
Barnes, 1997	Unilateral Pelvic Rotation	10	MFR pelvic region, 10 min	Rest × 10 min	Single session	Pelvic Position	Better pelvic alignment post MFR	8/10	2b
Hsieh, 2002	Sub acute Low Back Pain	200	Back school program, MFR, joint manip or combined MFR + joint manip	NA	Back school : 1/week × 3, MFR, joint manip & combined MFR + joint manip: 3/week × 3	VAS, Roland Morris activity scale	Back pain improved in all. No difference between groups	7/10	1b
Kuhar, 2007	Plantar fasciitis	30	Ultrasound × 5 min, contrast bath 20 in, exercises, MFR × 15 min	Ultrasound × 5 min, contrast bath 20 in, exercises	10 consecutive days	FFI, VAS	Significant reduction in VAS and FFI	7/10	2b
Arroyo-Morales et al., 2008	Healthy active individuals	62	MFR × 40 min	Sham treatment with disconnected ultrasound and magnetotherapy × 40 min	Single session	HRV & BP	Favors the recovery of HRV and diastolic BP after high-intensity exercise	6/10	2b
Tozzi, 2011	Non-specific cervical (NP) or lumbar pain (LBP)	120	NP: MFR × 6 min LBP: MFR × 12 min	NP: Sham MFR × 6 min LBP: Sham MFR × 12 in	Single session	Dynamic ultrasound (US)	MFR improved fascial mobility& pain in people with non-specific NP or LBP	7/10	2b
Kalamir, 2010	Chronic myogenous temporomandibular disorders	30	MFR × 15 min, MFR 15 min with self care & exercises	Waist list	2 sessions/ week × 5	ROM & Pain	MFR alone or with self-care is beneficial	8/10	2b
Kain, 2011	Healthy individual	31	indirect tri-planar MFR × 3 min	Hot pack × 20 min	Single session	Passive shoulder range of motion	MFR is as effective as hot packs in increasing range of motion	5/10	2b

Castro-Sánchez, 2011	Fibromyalgia	74	MFR × 90 min	Disconnected Maganetotherapy × 30 min	1 session/ week × 20	VAS, STAI, BDI, PSQI	MFR improved pain & quality of life in patients with fibromyalgia	7/10	1b
Castro-Sánchez, 2011	Fibromyalgia	86	MFR × 60 min	Sham short-wave and ultrasound treatment × 30 min	2 sessions/ week × 20	Number of tender points, MPQ and postural stability.	MFR improved pain, sensory, and affective dimensions without change in postural stability	7/10	1b
Ajimsha, 2011	Tension headache	63	Direct MFR × 60 min Indirect MFR × 60 min	Slow soft stroking × 60 min	2 sessions/ week × 12	Numbers of days with headache	MFR is effective than a control intervention	6/10	2b
Fernández-Lao 2012	Breast cancer	20	Neck and shoulder MFR × 40 min	Special attention & Education × 40 min	2 sessions separated by 2 weeks	Salivary flow rate, immunoglobulin A (IgA) concentrations,	Immediate increase in salivary flow rate & IgA	6/10	2b
Cantarero-Villanueva, 2012	Breast cancer	78	Multimodal exercise and MFR × 90 min	Usual care advises	3 sessions/ week × 8	POMS	Multimodal program with MFR reduced fatigue, tension, depression, & improved vigor & muscle strength	7/10	2b
Ramos-González, 2012	Venous insufficiency in postmenopausal women	65	MFR × 50 min × 2 session/week Venous return kinesiotherapy 2 times daily	Venous return kinesiotherapy 2 times daily	10 weeks	Blood pressure, venous velocity, skin temperature, pain	Improvement in venous return blood flow, pain and quality of life noted	8/10	2b
Ajimsha, 2012	Lateral Epicondylitis (LE) in Computer Professionals	68	MFR × 30 min	Sham ultrasound therapy × 30 min	3 sessions/ week × 4	PRTEE	MFR is effective for LE in Computer Professionals	7/10	Ib-
Ajimsha et al., 2014a	chronic low back pain(CLBP) in nursing professionals	80	Specific back exercises (SBE) & MFR × 60 min	SBE & Sham MFR × 60 min	3 sessions/ week × 8	MPQ, QBPDS	MFR with SBE is effective for CLBP	7/10	1b
Kuruma, 2013	Healthy individuals	40	MFR to hamstring × 8 min. MFR to Quadriceps × 8 min. stretch for quadriceps	Lay supine × 8 min	Single session	ROM, muscle stiffness, and Reaction Time	Improved ROM & ease of movement	5/10	2b

(*continued on next page*)

Table 3 (*continued*)

First author, year	Condition	Sample Size	Treatment	Control	Treatment Schedule	Main Outcome Measures	Results	PEDro Score	Level of Evidence (CEBM)
			8 min,						
Khuman, 2013	Chronic Lateral Epicondylitis	30	MFR forearm × 30 min, Ultrasound × 5 min Stretching and strengthening exercise	Ultrasound × 5 min Stretching and strengthening exercise	3 sessions/ week × 4	pain, functional performance & grip strength	Significant decrease in pain, improvement in functional performance & grip strength	7/10	2b
Ajimsha et al., 2014b	Plantar heel pain (PHP)	66	MFR × 30 min	Sham ultrasound therapy × 30 min	3 sessions/ week × 4	FFI & PPT	Significant decrease in pain & functional disability, improvement in pressure pain threshold	8/10	2b

Abbreviations: Myofascial Release (MFR), Not Applicable (NA), Range of Motion (ROM), State- Trait Anxiety Inventory (STAI), Beck Depression Inventory (BDI), Pittsburgh Quality of Sleep Index Questionnaire (PSQI), McGill Pain Questionnaire, (MPQ), Profile of Mood State (POMS) questionnaire, Quebec Back Pain Disability Scale (QBPDS), Chronic Low Back Pain (CLBP), Patient-Rated Tennis Elbow Evaluation (PRTEE). Minutes (Min), Manipulation (Manip), Center for Evidence-Based Medicine (CEBM), Proprioceptive Neuromuscular Facilitation (PNF), Visual Analogue Scale (VAS), Foot Function Index (FFI), Heart rate variability (HRV), Blood Pressure (BP), Foot function index (FFI), Pressure pain threshold (PPT).

The study included 62 healthy, active individuals. After baseline measurements, the subjects performed standardized warm-up exercises followed by three 30-s Wingate tests. After completing the exercise protocol, the subjects were randomly assigned to MFR or a placebo group for a 40-min recovery period. Holter recording and BP measurements were taken after exercise protocol and after the intervention and found that MFR favors the recovery of heart rate variability and diastolic BP after high-intensity exercise to pre exercise levels. Short duration and lack of follow up along with normal, healthy individual were considered as the limitation of the study with an assumption that high-level sports people might possibly show a different behavior which makes the study into the 2b level.

Tozzi et al. (2011) studied pain perception and the mobility of fascial layers by using a dynamic ultrasound (US) in patients with neck pain (NP) and low back pain (LBP). Sixty patients with nonspecific neck pain and 60 with nonspecific back pain were divided into experimental and control groups who were evaluated in the area of complaint, by 'Dynamic US Topographic Anatomy Evaluation', before and after MFR were applied in situ, in the corresponding painful region, for not more than 12 min. The effects were compared with those from the respective sham control group of 60 cases. The result highlighted that MFR can be effective in releasing area of impaired sliding fascial mobility, and to improve pain perception over a short term duration in people with non-specific NP or LBP. The study obtained 2b level evidence with a quality of 7/10. The study is important because it suggested that 'dynamic US evaluation' can be a valid and non-invasive instrument to assess effective sliding motion of fascial layers in vivo. Main limitations noted were that pain assessment was for a short period of time following treatment and on a relatively small study population without a follow up.

A study with 30 chronic myogenous temporo mandibular disorder (TMD) patients by Kalamir et al. (2010) investigated the effectiveness of intra-oral MFR therapy (IMT) by randomizing into three groups; IMT, IMT plus 'self-care' and a wait list control with pain and ROM as the primary outcome measures. The measurements were taken at baseline, 6 weeks post-treatment, and 6 months post-treatment. They concluded that IMT with or without self-care may be beneficial in chronic TMD over the short-medium term and advocated a larger scale study over a longer term. The study obtained high quality rating on the PEDro scale (8/10) and 2b rating in CEBM.

Kain et al., in 2011 compared an indirect tri-planar MFR technique and a hot pack for increasing gleno-humeral joint range of motion on 31 healthy individuals. Both the hot pack application and the MFR technique were found to be as efficacious in increasing passive range of motion of the gleno-humeral articulation. The tri-planar MFR could be considered more effective as an intervention in terms of time spent with a patient and the number of patients seen in a 20-min period and lack of equipment needed for MFR compared to hot pack use. The speed of the MFR technique and the lack of equipment would suggest that it is a more time efficient type of intervention, provided the therapist is trained in this technique. Improper blinding, concealing and follow-up grade the quality of the study as moderate (5/10 in PEDro) and level 2b in CEBM.

Castro-Sánchez et al. conducted two (2011 a,b) high quality studies in fibromyalgia. Both studies were rated as 7/10 in PEDro scale and 1b in CEBM due to their methodological standards. The first one; was to determine whether MFR therapy can improve pain, anxiety, quality of sleep, depression, and quality of life in patients with fibromyalgia. Seventy four fibromyalgia patients were randomly assigned to MFR and placebo groups. The intervention period was 20 weeks. Pain, anxiety, quality of sleep, depression, and quality of life were determined at baseline, after the last treatment session, and at 1month and 6 months. Right away after treatment and at 1 month, anxiety levels, quality of sleep, pain, and quality of life were improved in the experimental group over the placebo group. Even so, at 6 months post intervention, there were only significant differences in the quality of sleep index. They have documented the exclusion of 35 of the 231 eligible participants due to incompatibility with their work schedules as their major limitation and commented that patients with less severe pain may have been able to improve more rapidly. The second study was with 86 fibromyalgia patients to find out the effect of a 20 week MFR on pain, physical function, and postural stability over a placebo group. MFR improved pain, sensory, and affective dimensions without change in postural stability. They concluded that MFR techniques can be a complementary therapy for fibromyalgia syndrome. The authors attributed that lack of a postural stability test with a higher level of difficulty might have an effect on the result. Lack of blinding of therapists and patients and the absence of a 'hands-on' component in the sham treatment was another drawback. They recommended further research to compare outcomes with other manual therapies.

A study by Ajimsha (2011) on 63 tension headache patients compared the direct MFR technique and indirect MFR technique with a sham control receiving slow soft stroking. The study was of moderate quality (6/10) on PEDro with 2b level of evidence. The techniques consisted of 24 sessions per patient over 12 weeks with the difference in number of days with headache at baseline and post test as the outcome measure. Patients in the direct MFR group, the indirect MFR group and the control group reported a 59.2%, 54% and 13.3% reduction respectively in their headache frequency in post test compared to the baseline. Lack of follow up, blinding of the therapists and the patient were the major limitations of the study.

Two moderate to high quality studies were found on quality of life of breast cancer survivors (BCS). The first study was by Fernández-Lao et al. (2012) on the influence of patient attitude towards massage on pressure pain sensitivity and immune system after application of MFR. Twenty BCS, in a two week study, received MFR or control (special attention) intervention. Salivary flow rate, immunoglobulin A concentrations & the attitude toward massage scale were the outcome measures. MFR led to an immediate increase in salivary flow rate in BCS with cancer-related fatigue. The authors suggested that the effect of MFR on immune function was modulated by a positive patient's attitude toward massage. Lack of therapist blinding and follow ups were the main drawbacks of the study. The authors acknowledged that alterations of stress response to cancer related fatigue could reduce the ability of MFR in changing salivary cortisol concentrations and α-amylase activity and placebo effect associated with hands-on techniques might have influenced the outcome.

The second study was conducted by Cantarero-Villanueva et al. (2012). Seventy eight BCS participated in effectiveness of core stability exercises and recovery MFR on fatigue with the Profile of Mood State questionnaire as the main outcome measure. The experimental group received core stability exercises & MFR while the control group received usual health care advices for a period of 8 weeks. Mood state, fatigue, trunk curls endurance, and leg strength were determined at baseline, after the last treatment session, and at 6 months of follow up. The multimodal program with MFR reduced fatigue, tension, depression, improved vigor & muscle strength. The study was of moderate to high quality (7/10) with level 2b evidence. The main drawback was that the control group was allowed to freely increase physical activity during the study. They reasoned that this possible bias was controlled as the control group did not demonstrate substantial gains in physical activity during the study.

A comparative study was performed on the effectiveness of MFR and PT for venous insufficiency in postmenopausal women by Ramos-González et al. (2012), which is of high quality (8/10) with a 2b level of evidence. Sixty five postmenopausal women with stage I or II venous insufficiency were enrolled into two groups. The control and experimental group patients underwent physical venous return therapy (kinesiotherapy) for a 10-week period, during which the experimental group patients also received 20 sessions of MFR. Main outcome measures were blood pressure, cell mass, intracellular water, basal metabolism, venous velocity, skin temperature, pain and quality of life. The combination of MFR and kinesiotherapy improved the venous return, pain and quality of life in postmenopausal women with venous insufficiency. Lack of follow up and non blinding of the researchers were the primary limitations.

Ajimsha et al. (2012) in their study investigated whether MFR reduces the pain and functional disability of lateral epicondylitis in comparison with a control group receiving sham ultrasound therapy in computer professionals ($N = 68$) for 12 sessions per client over 4 weeks with the Patient-Rated Tennis Elbow Evaluation (PRTEE) as the main outcome measure. The study was of a moderately high quality on the PEDro scale (7/10) with 1b- level in CBEM. The MFR group performed better than the control group at weeks 4 and 12. Patients in the MFR and control groups reported a 78.7% and 6.8% reduction, respectively, in their pain and functional disability in week 4 compared with that in week 1, which persisted as 63.1% in the follow-up at week 12 in the MFR group. Lack of therapist blinding was the major limitation of the study. A slight improvement over time occurred in the control group at week 4 and the authors are attributing this to a meaning response.

A similar type of study was carried on by Khuman et al. (2013) on a smaller sample size of chronic lateral epicondylitis (CLE) subjects. Thirty CLE subjects were divided into MFR & conventional physiotherapy ($n = 15$) and conventional physiotherapy ($n = 15$) groups. Numerical pain rated scale, PRTEE and hand dynamometer were the outcome measures. They concluded that a 4 weeks MFR program was effective in improving pain, functional performance and grip strength in CLE subjects compared to the control group. Lack of follow up and improper blinding were the major limitations. The study scored 2b level of evidence with a quality of 7/10.

Another study by Ajimsha et al. (2014a) on the effectiveness of MFR in the management of chronic low back pain (CLBP) in nursing professionals falls under a high quality one with a PEDro score of 7/10 and CBEM level of 1b. The participants were nursing professionals ($N = 80$) with CLBP. The aim was to investigate whether MFR when used as an adjunct to specific back exercises (SBE) reduces pain and disability in CLBP in comparison with a control group receiving a sham MFR and SBE among nursing professionals. The McGill Pain Questionnaire (MPQ) was employed to assess subjective pain experience and Quebec Back Pain Disability Scale (QBPDS) was employed to evaluate the disability associated with CLBP. The primary outcome measure was the difference in MPQ and QBPDS scores between week 1 (pretest score), week 8 (posttest score), and follow-up at week 12 after randomization. The patients in the MFR group reported a 53.3% diminution in their pain and 29.7% decrease in functional disability as evidenced in the MPQ and QBPDS scores in week 8, whereas patients in the control group reported a 26.1% and 9.8% decrease in their MPQ and QBPDS scores in week 8, which persisted as a 43.6% reduction of pain and 22.7% reduction of functional impairment in the follow-up at week 12 in the MFR group compared to the baseline. The authors advocated examining other outcomes such as pain beliefs, mood, and quality of life in future studies.

Kuruma et al. conducted a study (2013) on the effects of MFR and stretching technique on range of motion (ROM) and reaction time (RT) with a medium quality procedure (5/10 PEDro) and 2b level in CBEM. Forty healthy individuals were randomly allocated to four groups: MFR for quadriceps; MFR for hamstrings; stretch for quadriceps; and controls. Active ROM was significantly increased in the two MFR groups and the stretch group. Passive ROM was significantly increased by MFR in the quadriceps and stretching groups. Premotor time was significantly reduced by MFR in the quadriceps and hamstrings groups. Compared to controls, RT was significantly lower after the interventions in the quadriceps and hamstrings groups. Lack of blinding, concealing and follow up were the main limitations of the study.

A recent study by Ajimsha et al. (2014b) investigated whether MFR reduces the pain and functional disabilities associated with plantar heel pain (PHP) in comparison with a control group receiving sham ultrasound therapy. Sixty six PHP patients, in a 4 week study, received MFR or control intervention. The study was a well designed and executed one, with sufficient number of participants and adequate follow-up, ranked level 2b on the CEBM scale and scored 8/10 on the PEDro scale. The primary outcome measure was the difference in foot function index scale at week 1, week 4, and follow-up at week 12 after randomization. Additionally, pressure pain thresholds (PPT) over the affected gastrocnemii and soleus muscles and over the calcaneus were assessed. The simple main effects analysis showed that the MFR group performed better than the control group in weeks 4 and 12 ($P < 0.001$). Patients in the MFR and control groups reported a 72.4% and 7.4% reduction, respectively, in their pain and functional disability in week

4, which persisted as 60.6% in the follow-up at week 12 in the MFR group compared to the base-line. The mixed ANOVA revealed a significant group-by-time interaction for changes in PPT over the gastrocnemii and soleus muscles, and over the calcaneus compared to the control group ($P < 0.05$). The short term follow up was mentioned as the major limitation of the study. The authors recommended future studies to compare the MFR with established treatments like arch supports, self stretching or even with surgical procedures.

Discussion

Nineteen RCTs covering 1228 patients were included in this systematic review. The sample size varied from 10 to 200 with an average of 65 (SD $\pm$ 44). The methodological qualities of the included RCTs were moderate to high. Seventeen studies were with higher methodological quality and the remaining 2 were of moderate quality, which is appreciable for a relatively new approach with considerable amount of practice variations. The literature regarding the effectiveness of MFR was mixed in both quality and results. The quality of the RCT studies varied greatly, some were more substantial than others. The results of the studies were encouraging, particularly with the recently published studies. In many RCT's the MFR was adjunctive to other treatments and the potential-specific MFR effect cannot be judged.

Nine studies concluded that MFR may be better than no treatment or sham treatment for various musculoskeletal and painful conditions. Seven studies demonstrated that MFR with a conventional therapy is more effective than a control group receiving no treatment (3 studies), sham treatment (1 study) or with a conventional therapy. Hanten and Chandler (1994) have found in their study that, though MFR was effective in reducing hamstring tightness against a control group receiving no treatment, the effect was inferior to a PNF treatment. Two other studies highlighted MFR to be equally effective to conventional or "alternative" treatments (e.g., joint manipulation, back school or hot packs). These data suggest that the MFR can be a useful adjunct to the conventional therapies for various conditions.

It seems reasonable that in the authors' qualitative synthesis, the best evidence would be provided by the higher quality studies, which are less likely to have biased results. Although the levels of evidence in this review may be considered arbitrary, it seems unlikely that a different rating system would have resulted in different conclusions. It has to be remembered in this situation that, generally small sample sizes increase the possibility of type II error, where the likelihood of a study producing a false negative result will be high. (Sim and Wright, 2000). Although attempts were made to find all published RCTs, some relevant trials might have been overlooked. Due to resource and language constraints, only English language publications were included in the review and no effort was made to identify unpublished trials.

The included studies were very heterogeneous in terms of population included, type of MFR administered, control groups, outcome measures, timing of follow-up, and presentation of data. Like any other manual therapy interventions MFR also varies considerably in the technique, the pressure, individual treatment times and overall number of treatment sessions. Until evidence is available on the possible mechanism of action of MFR, or until different interventions have been compared directly, there is no logical basis for choosing the optimal intervention. The experience and training of the myofascial therapists who gave the treatments were mentioned in a few studies. No serious adverse events were reported in the trials included in this review. Seven studies have reported minor adverse events. The great variation in incidence of minor adverse events is probably due to different definitions of adverse reaction, research designs or styles of MFR in the various studies.

Some studies used a protocol of a fixed set of points for all patients while others used a flexible protocol where the points were selected for each individual. Both methods are considered to be valid and were analyzed together in this systematic review. There is evidence that MFR alone or added to other conventional therapies, relieves pain and improves function not lesser than conventional therapies studied. According to these results, MFR may be useful as either a unique therapy or as an adjunct therapy to other established therapies for a variety of conditions like sub acute low back pain, fibromyalgia, lateral epicondylitis, plantar fasciitis, headache, fatigue in breast cancer, pelvic rotation, hamstring tightness etc. It is also noticeable that the magnitudes of the effects were mostly retained.

The experimental studies in this review can serve as a starting point for future research by demonstrating the wide assortment of potential conditions that MFR may effectively treat. Although a wide variety of conditions are being treated with MFR, it is important to have evidence to support those actions. Anecdotal evidence is a good starting point, but it is time for scientific evidences on MFR to support its clinical use.

To attain the highest-quality evidences, good quality RCT designs should be utilized in the future researches. Participants should be randomized, the design should be double blinded, and the clinician performing the MFR should use it regularly in clinical practice. The subjective component of MFR must be addressed in future study designs. Because of the nature of the technique, the effectiveness of MFR can vary with the comfort level of the patient, so the patient and clinician should both feel at ease around one another. Only one medical condition should be studied at a time, and MFR should be used alone. As well, if possible, MFR should be compared with a control (no-treatment) group and with other established treatments. These guidelines will result in higher-quality studies that can help us determine the true effectiveness of MFR as a treatment for a wide variety of conditions.

Conclusions

The literature regarding the effectiveness of MFR was mixed in both quality and results. Although the quality of the RCT studies varied greatly, the result of the studies was encouraging, particularly with the recently published studies. MFR is emerging as a strategy with a solid evidence base and tremendous potential. The studies in this review may serve as a good foundation for the future trials.

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