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FASCIA SCIENCE AND CLINICAL APPLICATIONS: EXPERIMENTAL STUDY

Fascial manipulation vs. standard physical therapy practice for low back pain diagnoses: A pragmatic study

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ABSTRACT

Background: Connective tissue mobility alters motor unit recruitment, but the restoration of fascial mobility allows for optimal motor function. The Fascial Manipulation® (FM®) method is a multiplanar approach that assesses and treats the mobility of deep fascia in specific anatomical locations where motor units converge.
Objectives: To assess the effects of FM® vs. standard physical therapy treatment (SPT) in patients with low back pain (LBP).
Design: Six-months controlled clinical trial.
Method: 102 participants with LBP received SPT or FM®. Numeric Pain Rating Scale (NPRS), 15- point Global Rating of Change (GROC), and Oswestry Disability Index (ODI) were used to monitor progress.
Results: The FM® group had a significantly lower ODI ($p < 0.009$) and NPS scores ($p < 0.0001$) and significantly higher GROC scores ($p < 0.003$) once their means were adjusted for initial scores. When comparing the SPT to FM®, the final ODI decreased by at least 1 category in 48.9% of the SPT cases, while in 36.2% of the cases was no change. ODI minimal clinical importance difference (MCID) change of 10% decrease in scores occurred in 70.2% of the SPT group compared to 96% of the FM® group ($p = 0.003$). ODI MCID change of 50% decrease in scores occurred in 40% of the SPT group compared to 64.6% of the FM® group ($p = 0.02$) 44.7% of the participants in the SPT group had final GROC values above +5 at discharge, compared to 92% of the participants from the FM® group ($p = 0.0001$). The FM® subjects had almost three times the change in NPRS compared to SPT counterparts *(-4.3 ± 2.2 to -1.5 ± 2.4, p=0.0001).*
Conclusions: FM® appears to improve NPRS, GROC, and ODI more than SPT. FM® may provide an effective treatment technique for LBP.

1. Introduction

Approximately 70–80% of all people will have some type of back pain during their lifetimes. Annually, back pain prevalence ranges from 15% to 45% (Praemer et al., 1999). In the United States, back pain is the most common factor limiting activity in people younger than 45 years of age (Chaiamnuay et al., 1998; Hart et al., 1995; Taylor et al., 1994). It is the third most common cause of surgical intervention, the fifth most common reason to visit hospital emergency departments, and the second most frequent reason for physician visits (Chaiamnuay et al., 1998; Hart et al., 1995; Taylor et al., 1994). However, low back pain (LBP) is not simply a Western-culture phenomenon; it is a global issue with a similar prevalence in other less developed countries (Hoy et al., 2010; Jin and SorockTheodore, 2004; Luo et al., 2004; Ory et al., 1997). Approximately 24–80% of those who experience LBP will have another episode of back pain within one year (Luo et al., 2004). Health care costs for back pain range from $30 billion to $90.7 billion dollars in the United States (Waterman et al., 2011). The primary interventions for LBP are varied and lack consensus, and currently there is no “gold” standard of intervention procedure for low back pain (LBP) (Straton and D.G., 2011). Furthermore, a majority of cases lack an underlying pathoanatomic diagnosis and are classified as non-specific LBP (Bhatia et al., 2008).

All connective tissues within the body, contractile and non-contractile, are joined in some way by broad sheets of fibrous tissue called fascia. In a normal system, fascia provides stability to the body structures while also allowing necessary mobility. When there is an alteration in the fascia, dysfunction can occur, in which mobility can be impaired and pain may result (Stecco et al., 2013).

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For example, myofascial pain syndrome (MPS) is a descriptive diagnosis that refers to dysfunction of the fascia found within and around muscle tissue (Stecco et al., 2013). It has also been reported that through its myotendinous insertions and its innervation, fascia can influence proprioception and motor control (Schleip, 2003a, 2003b; Schleip et al., 2010).

One model of fascial treatment, the Fascial Manipulation® (FM®) Method, was developed by Luigi Stecco (Stecco, 2004; Stecco and Stecco, 2009), and uses an integrated biomechanical model (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012). The FM® model looks at the relationship between muscle and the deep fascia, consisting of systematic assessment in relation to pain patterns, movement impairments, and associated alterations identified in the deep fascia. Instead of thinking in terms of muscle origin, insertion and general action, this theory focuses on triplaner interrelationships (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012) and regional interdependence, both at the site of symptoms and regionally along the kinetic chain where unrelated impairments in a distant anatomical region may play a part in the patients primary symptoms (Wainner et al., 2007; Sueki et al., 2013). If fascia is not gliding it can influence movement, resulting in dysfunctional movement patterns. The FM® method provides an objective movement analysis system by which to evaluate fascial mobility through and between the three cardinal planes of movement while taking into account regional influences from musculoskeletal and fascial connections. In order to do this, the body is separated into myofascial units (MFUs), which are defined as: 1) motor units that activate muscle fibers pertaining to biarticular (e.g. 2-joint) and monoarticular (e.g. 1-joint) muscles that work together to move a body segment in a specific direction, 2) the joint where movement occurs, 3) nerves and vessels that supply or cross the segment, and 4) the fascia that connects these components together (Day et al., 2012). Monoarticular fibers stabilize the segment while the biarticular fibers synchronize movement between adjacent distal and proximal joints via their myotendinous expansions. This arrangement permits them to link MFUs together, forming unidirectional movement sequences. As an example, the sequence responsible for moving the upper limb anteriorly in the sagittal plane, consists of tendinous expansions in the anterior aspect of the arm. These expansions include the pectoralis major onto the anterior aspect of the brachial fascia involving the biceps brachii contributing to shoulder flexion. An expansion from the biceps brachii (lacertus fibrosus) onto the antebrachial fascia contributing to elbow flexion. Next, the antebrachial fascia provides an origin for the flexor carpi radialis (FCR) and continuity with the palmaris longus (PL) contributing to wrist flexion. Finally, from the antebrachial fascia and the PL aponeurosis, there is a myotendinous expansion on to the flexor retinaculum and the thenar muscles in the hand contributing to both wrist and finger flexion (Stecco et al., 2007) (See Fig. 1.).

Initial research of treatment utilizing this theoretical model has resulted in subjective reports of decreased pain, objective measurements of increased range of motion, and increased strength for conditions involving patellar tendinopathy (Pedrelli et al., 2009), whiplash (Picelli et al., 2011), chronic ankle sprain (Masiero et al., 2011), chronic shoulder pain (Day et al., 2009), LBP (Branchini et al., 2015), and carpal tunnel syndrome (Pratelli et al., 2015). The purpose of this study was to compare and assess the effects of FM® versus standard physical therapy (SPT) in patients with low back pain (LBP) related diagnoses.

2. Methods

The design of this study was a controlled clinical trial lasting six-months. It was a pragmatic (Patsopoulos, 2011; Roland and Torgerson, 1998; Treweek and Zwarenstein, 2009) study, specifically designed to evaluate the effectiveness of interventions in real-life routine practice conditions. Pragmatic studies are designed to test interventions in the full spectrum of everyday clinical settings in order to maximize applicability and generalizability (Patsopoulos, 2011; Roland and Torgerson, 1998; Treweek and Zwarenstein, 2009).

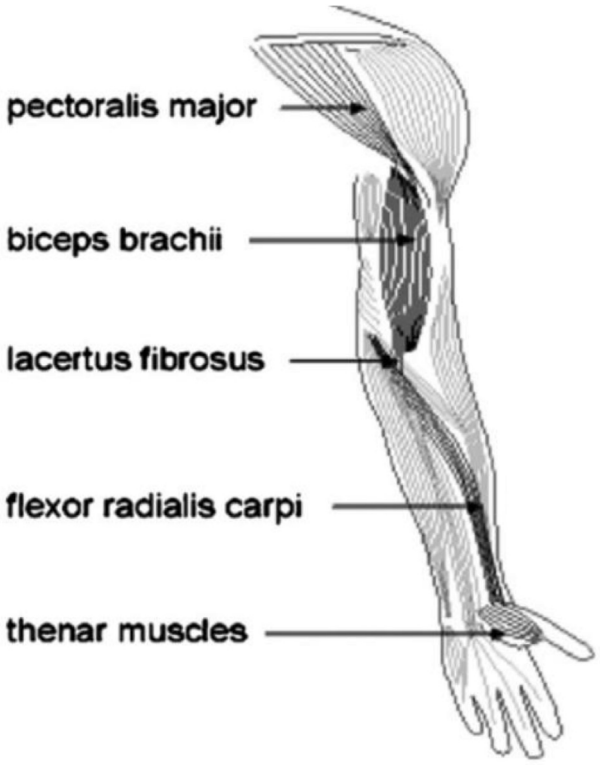

Fig. 1. Movement sequence responsible for moving the upper limb anteriorly in the sagittal plane. Adapted from "Anatomical study of myofascial continuity in the anterior region of the upper limb," by Antonio Stecco et al. (2009) Journal of Bodywork and Movement Therapies, 13(1), 53-62. Copyrighted in 2009 by Antonio Stecco. Figure was reprinted with permission.

Institutional Review Board (IRB) approval was achieved and informed consent was obtained from participants in this study. The inclusion criteria included a low back related diagnosis referred by a medical physician with a target population between 18 and 70 years of age, all acuity levels (i.e. acute, sub-acute, and chronic), with any low back pain related diagnoses. The most common physician diagnoses included low back pain, lumbar radiculopathy, lumbar sprain, failed back syndrome, degenerative disc disease, fracture "not otherwise specified", congenital spondylolisthesis, sacroliitis, and osteoarthritis pelvic. There were 102 subjects that were divided between the FM® (n = 53) and SPT (n = 49) groups (See Fig. 2). The testing location for this study was an outpatient clinic in the state of Georgia. Subjects were recruited for this study on the patient's first day of physical therapy services. Subjects were excluded from the study if they had a fever, severe immunodepression, dermal lesion in the region of treatment, thrombophlebitis/thrombosis, lymphedema (Stage III or more), history of cancer, recent trauma without analysis, severe bleeding disorder, chronic corticosteroid therapy, or chronic opioid therapy. Following consent, the subjects completed objective data measures, which included the Numeric Pain Rating Scale (NPRS), the Global Rating of Change (GROC) score, and the Modified Oswestry Low Back Pain Disability Index (ODI). NPRS is an 11-point scale to measure the

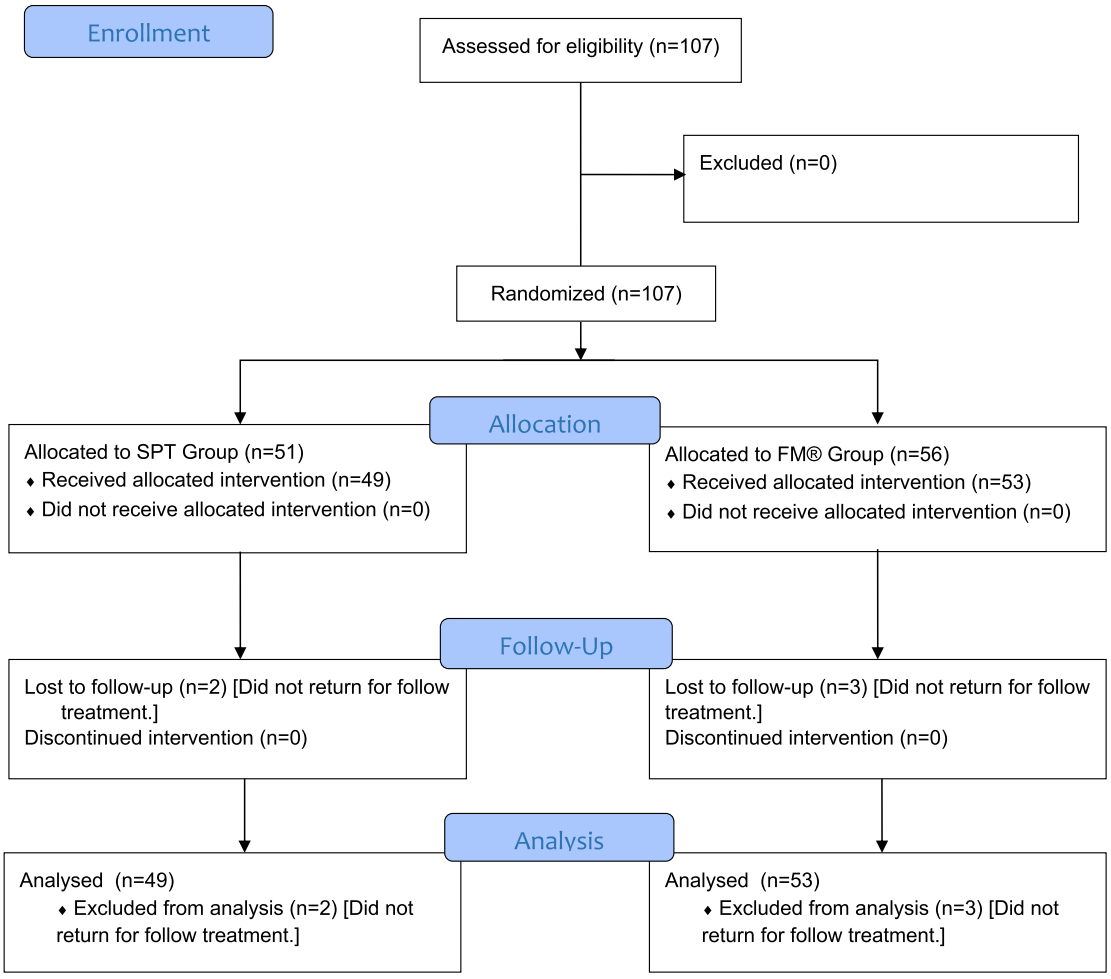

Fig. 2. Study design flow chart.

intensity of pain from 0 to 10. This scale has been shown to be reliable and valid in both healthy people and those with low back pain (Childs et al., 1976; Herr et al., 2004). Minimal clinical importance difference (MCID) was set as a change of $\geq$2 on the NPRS (Childs et al., 1976; Herr et al., 2004). GROC scale is a 15-point Likert scale that assesses a subject's overall change from the initial evaluation to the day of discharge. Ratings range from -7 (A very great deal worse) to 0 (About the same) to $+7$ (A very great deal better), all of which correlate to the 15-point numerical scale (Jaeschke et al., 1994; Kamper et al., 2009). The GROC has been shown to have high reliability, validity, and clinical importance with potential significance (MCID) likely associated with a 2 point change (Jaeschke et al., 1994; Kamper et al., 2009). ODI is a 10-item questionnaire that assesses the symptoms and severity of low back pain in regard to functional activities of daily living using a scale from 0 to 5. ODI has excellent reliability and validity for assessing low back pain (Frost et al., 1976; Miekisiak et al., 2013). A single agreed-upon MCID cutpoint score for the ODI is not yet established, but 10% and 50% are commonly utilized (Alrwaily et al., 2016; Brennan et al., 1976; Fritz et al., 1976, 2005; Sheeran et al., 2015). Therefore, the ODI MCID was evaluated as a change in at least one disability category, at a 10% change, and at a 50% change.

The subjects were asked to complete the NPRS and ODI during the initial physical therapy evaluation. Subjects completed the NPRS, the GROC, and the ODI on their 3rd visit, 6th visit, and at discharge.

Prior to intervention, subjects were sequentially allocated into one of two groups: (1) a fascial manipulation (FM®) group and a (2) standard physical therapy (SPT) group, according to the next clinician's availability. SPT group interventions may have included spinal and pelvic mobilization and/or manipulation, lumbar mechanical traction, and general soft tissue mobilization. Both groups, SPT and FM®, received thermal and/or electrical modality and a continuum of exercises from movement preference to strategic strengthening of identified weaknesses in the trunk and lower limbs to general fitness with aerobic and generalized strength training. Each subject was given interventions specific to the findings of each individual's examination and evaluation based on the therapist's clinical judgment. SPT interventions for low back pain were based off the Clinical Practice Guidelines for low back pain which included: manual therapy (graded mobilization, thrust manipulation and/or soft tissue mobilization), trunk coordination/strengthening/endurance exercises, directional preference and centralization exercises, neurodynamic exercises, patient education, general body strengthening, and progressive aerobic activity (Alrwaily et al., 2016; Delitto et al., 2012). The FM® group also received FM® assessment and treatment. There were three examiners that participated in this study. All examiners were licensed physical therapists. Those providing SPT without FM® interventions had over 31 years of combined experience (26 and 5 years). The examiner providing fascial manipulation (FM®) was certified in facial manipulation with over 30 years of experience.

Typical physical therapy sessions ranged from 60 to 90 min and the duration was dependent on multiple factors, including physical

prescription based on the physical therapist's clinical judgment. This study did not impact the services nor did it alter the plan of care (POC) developed by the clinicians at the practicing facility. If a subject missed a treatment session and did not return, the subject was contacted via phone interview with a care extender to complete the NPRS, GROC, and ODI.

Statistical analyses of the data were completed. Test of normality using the Shapiro-Wilk test was conducted to determine if data were normally distributed. Independent samples t-tests or Mann-Whitney tests were performed to examine a potential difference between the groups on the baseline data. An analysis of covariance (ANCOVA) was used to examine between-group differences with pretest scores as covariates. Categorical variables were compared using Pearson's chi-square or Fisher's exact test. Differences between groups and time points were determined with a 2-way repeated-measures analysis of variance. When significant *F* was observed, Bonferroni test was used for post-hoc comparisons. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, version 22, Armonk, NY, USA) and significance was set at P level < 0.05.

3. Results

The participants of both groups were similar in gender, age, and chronicity of low back pain ($p > 0.05$) (Table 1). There were 2 participants lost to follow-up from the SPT group and 3 from the FM® group, $p > 0.05$. The SPT group had 10.1 ± 6.7 visits compared to 7.5 ± 3.5 visits that the FM® group experienced ($p = 0.01$). Subject's clinical results are summarized in Table 2.

3.1. ODI

Following treatment, the FM® group had significantly lower overall ODI scores once their means were adjusted for initial ODI scores, $p = 0.009$. Chronicity of the LBP did not alter this difference, $p = 0.11$. The final ODI decreased by at least 1 category in 48.9% of the SPT cases, while in 36.2% of the cases there was no change. This was similar with the FM® group, as 60% of the cases decreased and 38% did not change their category. Another approach to analyzing the ODI responses was to consider the minimal clinical importance difference (MCID) of 10% decrease in scores after treatment. This occurred in 70.2% of the SPT participants compared to 96% of the FM® participants, $p = 0.003$. We took the analysis a step further and compared the groups in relation to a 50% decrease in ODI scores. In the SPT group, 40% of the participants experienced a 50% decrease in ODI compared to 64.6% participants of the FM® group, $p = 0.02$. Interestingly, there were participants who reported worsening ODI scores for both groups. However, only 2 participants from the FM® group increase their ODI scores, compared to 12 SPT participants (4.0% and 25.5% respectively, $p = 0.003$).

Table 1
Subject characteristics.

	SPT (N = 49)	FM® (N = 53)
Gender (males)	46.9%	47.2%
Age (years)	58.1 ± 13.6	61.1 ± 9.3
Acute	8.2%	9.4%
Sub-acute	24.5%	24.5%
Chronic	67.3%	66.1%

Data is presented as percentages (%) or mean ± standard deviation.
SPT, standard physical therapy; FM®, fascial manipulation.

Table 2
Clinical variables between the groups.

		SPT (N = 49)	FM® (N = 53)
ODI score	Pre	35.5 ± 14.9	32.8 ± 15.8
	Post	24.9 ± 15.9*	14.4 ± 12.6*#
NPRS	Pre	6.2 ± 2.5	7.0 ± 2.2
	Post	4.5 ± 2.8*	2.7 ± 1.8*#
GROC	Pre	2.5 ± 1.8	4.1 ± 1.6
	Post	3.7 ± 2.5*	5.9 ± 1.0*#

Data is presented as mean ± standard deviation.
SPT, standard physical therapy; FM®, fascial manipulation; ODI, Oswestry Disability Index; NPRS, Numeric Pain Scale; GROC, Global Rating of Change.
*Statistically significant at 0.05 level compared to pre-values.
Statistically significant at 0.05 level compared to SPT.

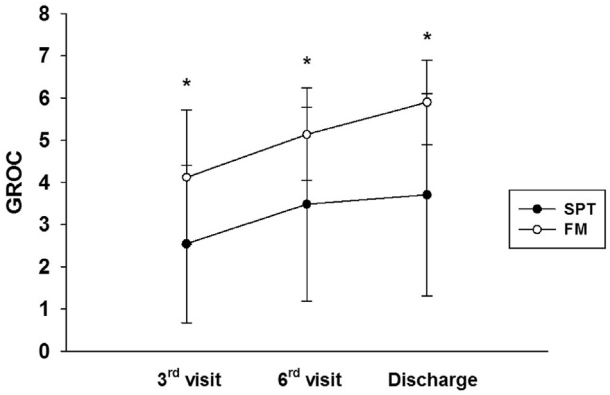

Fig. 3. GROC Changes Throughout Treatment. SPT, standard physical therapy; FM®, fascial manipulation; GROC, Global Rating of Change. *Statistically significant at 0.05 level compared to SPT.

3.2. GROC

Following treatment, the FM® group had a significantly higher GROC scores once their means were adjusted for initial GROC scores, $p = 0.003$. Chronicity of the LBP did not alter this difference, $p = 0.46$. ANCOVA results showed statistically significant GROC values between the groups when accounted for the number of visits ($p = 0.01$). FM® subjects had higher GROC scores throughout the study and they increased more towards discharge ($p = 0.02$). Right after the third session, their GROC scores were almost double compared to SPT (4.1 ± 1.6 vs. 2.5 ± 1.9, $p = 0.0001$) (See Fig. 3).

When GROC values were analyzed for clinical relevance, 44.7% of the participants in the SPT group had values $\geq +5$ at discharge, compared to 92% of the participants from the FM® group ($p = 0.0001$). In addition, 19.1% of the SPT group experienced the extreme changes of GROC scores $\geq +6$, compared to 72% of the FM® group ($p = 0.0001$). When GROC was analyzed for MCID significance where subjects were grouped for changes, based on two and four point change, there was no difference between the groups ($p = 0.07$) (See Table 3).

3.3. NPRS

Following treatment, the FM® group had significantly lower NPRS scores once their means were adjusted for initial NPRS scores, $p = 0.0001$. Chronicity of the LBP did not alter this difference, $p = 0.23$.

At discharge, the FM® subjects had almost three times the change in NPRS compared to SPT counterparts (-4.3 ± 2.2 to -1.5 ± 2.4, $p = 0.0001$). Overall, 94% of the subjects in the FM®

Table 3
GROC changes according to [MCID] clinical significance.

		Decreased	Did not improve	Improved by 2	Improved by 4
SPT	After 6 visits	12.5%	50.0%	27.5%	10.0%
	At discharge	14.9%	46.8%	23.4%	14.9%
FM	After 6 visits	8.1%	40.5%	37.8%	13.5%
	At discharge	2.0%	38.8%	38.8%	20.4%

group decreased their NPRS by at least 2 points compared to 57.4% of the SPT group ($p = 0.0001$). Moreover, when data were analyzed based on NPRS change of at least 4 points, 58.0% of the FM® patients experience the decrease, compared to just 17.0% of the SPT patients ($p = 0.0001$).

4. Discussion

The FM group demonstrated the greatest statistically significant NPRS changes ≥2 (94% FM vs. 57.4% SPT) and ≥4 (58% FM vs. 17% SPT). Cook et al. (2012) used NPRS to evaluate pain changes that occurred after two treatment sessions of lumbar manipulation for those with low back pain. They then compared those values to NPRS and ODI at discharge. They found that a two point or greater NPRS change after the second treatment session was associated with decreased pain reports and lower ODI scores at discharge and that an NPRS change equal to or greater than two points predicted a 50% reduction in pain at discharge with an 87.3 sensitivity, 42.2 specificity, and 5.0 odds ratio, which was accurate in 67% of the subjects. The current study demonstrated that almost all patients receiving FM had 2 points or greater change in NPRS score, which correlated with positive and greater changes in ODI and GROC at discharge. A potential reason for this effect may be due to the restoration of fascial mobility and the quality of sliding motion between the fascial layers (Langevin, 2006) at specific anatomical sites, known as centers of coordination (CCs) and centers of fusion (CFs), which may restore optimal motor unit recruitment (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012). It has been hypothesized that this loose connective tissue layer permits mobilty in a specific direction determined by collagen fiber orientation. In a pathological state, alterations in any of the loose connective tissue layers can impede the normal gliding (sliding) (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012; Pratelli et al., 2015). FM®'s tangential oscillations can cause an outward flow of hyaluronic acid (HA) which can restore HA viscosity/homeostasis and increase lubrication which has been shown to lead to a thicker fluid gap between fascial layers and a restoration of normal sliding (fascial gliding) (Roman et al., 2013; Chaudhry et al., 2013). In addition, this normalization of movement patterns and muscle function (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012) can impact the biotensegrity via the neural mechanisms of central sensitization, neuroplasticity, and somatosensory reorganization (Langevin and Sherman, 2007; Flor, 2003; Ji and Woolf, 2001; Boal and Gillette, 2004; Coderre et al., 1993; Lotze et al., 2001; Hodges and Tucker, 2011). Deep fascia is richly innervated and primed to perceive variations in tension while assisting movement pattern organization (Day et al., 2012; Stecco et al., 2007, 2010). The central nervous system (CNS) likely applies spatial significance to myofascial sequences based on predetermined anatomical vectors that influence biomechanical movement patterns.

Immediately after the third session, the FM's GROC scores were almost double that of the SPT group (Fig. 3), and continued to be higher throughout their episode of care. There was no difference between the groups for a 2 point or 4 point change in GROC score, however, this may be caused by the higher scores registered by the FM group initially [See Table 3].

In the current study, it is probable that these changes in NPRS and GROC are due to histological changes within the connective tissues. The fascial organization identified through histological studies shows an organized multi-layered structure of parallel collagen fibers each separated by a loose connective tissue layer. An extracellular matrix (ECM)/loose connective tissue with low pH (<6.6) may result in a fragmentation of hyaluronic acid (HA) leading to an increase in ECM viscosity which results in decreased fascial gliding, thus may be a source of muscle stiffness. These areas of increased viscosity can be identified by palpation and have been labeled areas of "densification" (Stecco et al., 2006, 2007, 2010, 2013). Densification is a result of viscoelastic changes within the ground substance of the deep muscular fascia. Differentiation is made between the alterations in the ECM/loose connective tissue versus alteration in the collagen fiber component (Stecco, 2004; Day, 2011; Day et al., 2012). When palpated, hallmark findings may include hardness, roughness, or a thickened appearance (Stecco, 2004). FM intervention normalizes these tissue textures through the stimulation of HA, thereby abolishing the densification.

In the present study, a change of 10% in ODI occurred in 96% of the FM group and 70.2% of the SPT group ($p = 0.003$). Furthermore , when analyzed for a 50% change in ODI, there was 64.6% for the FM group and 40% for the SPT group ($p = 0.02$). In a double-blind randomized controlled trial, Ulger et al. (2017) studied the effects of manual therapy methods vs. spinal stabilization exercises on pain and quality of life in those with low back pain. Manual therapy procedures included soft tissue mobilization (e.g. myofascial stretching or transverse friction), muscle energy technique (e.g. post isometric contract relax), and joint mobilization/manipulation (e.g. sacroiliac mobilty) while spinal stabilization exercises included transversus abdominus (TA) and multifidus activation in conjunction with other general exercises for the core musculature. The authors concluded that manual therapy and exercises had the same effects on quality of life (i.e ODI), but that manual therapy was more effective at decreasing pain. Learman et al. (Learman et al., 2013) compared spinal thrusting manipulation (i.e. high-velocity low-amplitude thurst) vs. non-thrust manual procedures (i.e. low-velocity oscillatory movements within physiological range) with both groups receiving a standardized exercise program. The results demonstrated that both groups improved and neither intervention was superior to the other. In our study, the FM and SPT groups received exercises and manual therapy interventions. Contrary to the studies discussed above, we found significant differences in outcomes when FM was added to the treatment interventions.

A potential explanation for the statistically significant and dramatic changes may be the specificity of the FM approach. FM® consists of targeted or strategic application of manual medicine directed towards the deep fascia. By studying muscle conformation and their tensional vectors, Dr. Luigi Stecco has hypothesized that whenever muscle fibers within an MFU are activated to bring about movement, tension could be conveyed via this intramuscular fascial skeleton to a specific point on the deep fascia. These small focal areas on the deep fascia were called 'centers of coordination' (CC) and were mapped for each MFU (Day et al., 2012). Stecco has

reasoned a CC to be possible because 1) fascia is partially adhered to bone, 2) a portion of fascia is free to glide over muscle, and 3) is tensioned via fascia inserted into muscle, as well as, the muscular expansions onto the deep fascia (Day et al., 2012). Stecco also describes multi-planar myofascial vectors, called "centers of fusion" (CF) that are responsible for coordinating movements from one spatial plane to another. Similar to the sequence described above, the CF combines segments into diagonal and spiral patterns, similar to those seen in proprioceptive neuromuscular facilitation (PNF). The CCs and CFs are a summation of fascial vectoral forces influencing the six trajectories of human movement in three spatial planes. This theory explains the role of fascia in motor unit recruitment and proprioception, highlighting the interrelationship of contractile structures, the nervous system, the circulatory system, the skeletal system, and fascia. Therefore, according to Stecco, treatment should be directed towards the deep fascia (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012). A systematic biomechanical assessment method of the fascial system allows for a clinically reasoned approach to clinical decision-making, especially when it is consistent with regional interdependence and supported by anatomical studies. CCs and CFs may be considered anatomical "access points" or key anatomical locations to apply strategic intervention to the system. FM® treatment is performed over the CCs and/or CFs identified from a thorough history, movement screen (active, passive and resistive), and a palpation assessment (densified tissue, local or referred pain). CCs are typically smaller areas between 1 and 2 cm^2 in diameter over muscle bellies while CFs are larger fascial areas between 2 and 3 cm^2 in diameter typically located over tendons and retinacular structures. In the current study, FM® was applied manually to the specific centers via the examiner's elbow, knuckle, or fingertip based on the clinician's judgment on the size of the area targeted (Stecco, 2004; Stecco and Stecco, 2009; Day, 2011; Day et al., 2012). The average time to resolve a densification has been, on average, 3–4 min (Ercole et al., 2010). Incorporating a few minutes of FM® treatment into the plan of care has the potential to dramatically reduce the perception of pain and improve quality of life outcomes for those with low back pain.

Attempting to classify LBP signs and symptoms using a common clinical paradigm is debatable (Brennan et al., 1976; Sheeran et al., 2015; Apeldoorn et al., 1976). The primary clinical classification systems used presently include responses to repetitive movements (i.e. McKenzie Method) and treatment-based classification (TBC) (Alrwaily et al., 2016; Brennan et al., 1976; Delitto et al., 2012; Garcia et al., 2017; Halliday et al., 2016; Werneke et al., 2008). The interventions utilized in this study for those in the SPT group tended to be consistent with those found in the TBC method of clinical decision-making.

Cook et al. (Cook et al., 2017) studied individuals with chronic low back pain, evaluating changes in pain at two weeks compared with final outcomes at six months after receiving pragmatically prescribed manual therapy interventions. They found that if pain is reduced by $\geq$ 33% by the end of the first two weeks of treatment, the subjects had 6.98 times greater odds of having a 50% improvement in GROC scores and 4.74 times of having a 50% improvement on the ODI at six months. If subjects had greater pain reduction ($\geq$50%) at two weeks they had 5.98 times greater odds of having a 50% improvement in GROC scores and 3.99 times of having a 50% improvement on the ODI at six months. In the current study, over 92% of the FM® group had clinically relevant sustained and continual changes in all outcome measures, which included pain reduction NPRS scores, improved GROC scores, and ODI outcomes. These findings support the addition of FM® treatment into the plan of care for those with low back pain to maximize positive patient outcomes.

5. Limitations

Some of the limitations include the broad inclusion criteria, not being generalizable to a specific back pain diagnosis, and lack of objective anatomical findings in the connective tissue (i.e. Thickness Changes via Diagnostic Ultrasound) making it unable to evaluate whether pain changes are related to anatomical changes. Accepting these limitations, our study may be more generalizable and provide external validity to every day clinical practice situations of those with back pain who present to the clinic with a regional diagnoses and/or common cluster of signs and symptoms.

6. Conclusions

The FM® method emphasizes a clinically reasoned biomechanical assessment of the fascial system to understand its role in the movement system and to movement system dysfunction. Thus, FM® is an integrated anatomical biomechanical model where fascia and its component parts can be assessed in an organized manner in order to evaluate the myofascial system.

The generalizable findings of this pragmatic study indicate that when the fascial system is addressed (FM®) for those with LBP related conditions, regardless of diagnoses, gender, age, and chronicity, the outcome appears to result in significant pain reduction and perceived benefit with improvements in quality of life compared to standard physical therapy practice (SPT).

Disclosure of Interest

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