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Inter and Intra Operator Reliability of Motor and Palpation Evaluation in Fascial Manipulation in individuals with coxarthrosis

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ABSTRACT

Objective: An inter and intra rater reliability (INTERR and INTRAR) study was designed.

Methods: 71 subjects, with primary hip coxarthrosis, were included and randomly divided in a study group (SG= 36) and a control group (CG= 35) to assess the efficacy of the Fascial Manipulation® (FM®) method. The primary objective was the assessment of INTERR and INTRAR about movement verification (MV) and palpation verification (PV) of FM® performed by two physiotherapists (PtA and PtB). The secondary objective was evaluate the efficacy of FM® through MV, PV and pain score. Pain was assessed using the Numeric Rating Scale (NRS). SG received three weekly sessions of FM® byPtA. PtB re-evaluated all the subjects at the end of the study.

Results: Results of the INTERR analysis showed for SG: MV (ICC= 0.92, k= 72.7%); PV (ICC= 0.91, k= 75.7%). For CG : MV (ICC= 0.95, k= 84.2%); PV (ICC= 0.90, k= 75%). Results of the INTRAR analysis for SG reported: MV (ICC= 0.82, k= 74,8%); PV (ICC= 0.60, k= 46.8%); for CG: MV (ICC= 0.93, k= 78.7%); PV (ICC= 0.84, k= 53.3%). Statistical significance were reported in NRS ($p = 0.001$), MV ($p = 0.0003$) and PV ($p < 0.0001$) with better results for SG using "Intention To Treat" method.

Discussion: This study demonstrates that FM® assessment procedures have a high reliability even if applied by practitioners with basic experience. Furthermore FM® treatment can improve pain and ROM in individuals with primary coxarthrosis

KEYWORDS

Fascial manipulation; Inter reliability; intra reliability; movement evaluation; motor evaluation; palpation evaluation; coxarthrosis; pain

Introduction

There are many manual techniques used for the treatment of musculoskeletal disorders [1]. Different manual approaches apply a specific method to identify areas, joints, or tissues that need to be treated. These methods use a clinical reasoning and specific assessment with respect to postural observations, motion tests, and direct palpation evaluations to the soft and/or skeletal tissues of the locomotor system [2–6]. Some techniques take into consideration the general picture of the subject, looking for the possible origin of the problem even in areas not involved in the actual pain while others focus on the painful segment. Identifying the structure to treat and applying the most appropriate manual treatment are fundamental, considering pain a multidimensional phenomenon where both central and peripheral sensitization plays a critical role [7]. The combination of peripheral stimuli and increased central sensitization could be the key to justify the chronicity of pain [8]. Manual therapies act in an attempt to affect the descending modulation of pain, although their effects are not yet well explained [9].

What is well documented in MRI studies in the literature is the strong relationship between a greater level of painful peripheral tissues (of varying pathogenicity) with a greater level of hyperechogenicity and therefore a greater thickness of fascial tissues [10,11]. It has been shown that fascia thickening is mostly due to an increase of loose connective tissue that is mainly composed of hyaluronan. Cowman et al. [12] have shown that an increase of hyaluronan within the interface, as within fascial layers, can stimulate the aggregation of the hyaluronan that increases the viscosity of the loose connective tissue. This reaction can also affect joint mobility and the muscle spindle's stretch reflex of the muscles in the same region [13,14].

Some manual techniques look for these thick and rigid fascial areas, where a feeling for a resistance to sliding and a rough surface between the various tissue planes can be easily found by the physiotherapist [15,16]. Some authors suggest that these areas of non-tissue flow, called centers of coordination (CC) [17], are located within the deep fascial tissue planes and are identified as regions demonstrating a lack of

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gliding in comparison with the nearby or contralateral areas.

Other authors attribute the presence of these thickenings as the stiffness of the muscular fibers or contracted muscle bands (taut bands), named trigger points (TrPs) [18–20], that are identified through palpation. From their first description, already in the nineteenth century [21], the presence of these muscular nodules or fibroses has interested numerous researchers, who have found common pathophysiological characteristics of these muscular rigidities and given them a fundamental role in the pathogenesis of myofascial pain syndrome [22]. Other authors, using advanced imaging technologies, such as ultrasound and elastonosography, have described the presence of these rigid areas within the muscle [23,24]. However, a critical review of the literature on these TrPs has raised strong doubts about their real presence based on several factors. The hypothetical mechanism of the onset of the TrPs has not been shown to date. The presence of TrPs is detected through criteria such as the triggering of an acute, local, or radiating pain. These indications have never been attributable to a single interface. Above all, their palpation-based research shows limited and inhomogeneous levels of inter-operator reliability even among expert clinicians [25–27]. In a work of 2017, Rathbone concludes that manual palpation alone is not reliable for identifying TrPs, finding an inter-operator agreement equal to $k = 0.452$ (95% CI 0.364–0.540) [28]. It was also noticed that no studies with both inter- and intra-operative reliability that evaluated TrPs localization were found in the literature, except for the upper trapezius muscle [29] proving a lack of research on this topic.

Despite this indeterminacy, the habit of physiotherapists to look for areas of rigidity to release with various strategies has generated a large interest in clinicians. Many clinical studies and systematic reviews, not always of good quality, have shown uneven levels of validity for the resolution of the dysfunctions examined when the study is based only on pain and disability components [30]. It can be hypothesized that a possible cause of a limited effectiveness of these treatments turns out to be the strong subjectivity of the palpation-based investigation, making it difficult to determine, in a reliable way, the presence and localization of these rigidities.

Clinical trials referring to the treatment of CCs, although numerically inferior, seem to demonstrate a better clinical efficacy of FM® [11,31,32].

Based on the hypothesis that clinical improvement was due to a better ability to identify the presence and consistency of CCs, the aim of this study was to evaluate the inter- and intra-operator reliability of the movement verification (MV) and palpation verification (PV) in FM® with particular attention paid to the variation of palpation record over the CCs before and after treatment. To better prove the ability of the physiotherapist to recognize an altered point and to better prove the variation of the tissue before and after FM treatment, the reliability test was performed at T0 between two physiotherapists (PtA and PtB) for the inter-operator reliability, and after one month at T4, when PtB re-tested the same subjects after their randomization in two groups, half of them received no treatment (CG), while the SG were exposed to three sessions of FM® treatment performed by PtA. PtB was blinded with respect to SG or CG of subjects. The second aim of the study was to investigate the effectiveness of FM® in regard to pain rate, quality of range of motion (ROM), and change of the tissue quality over the CCs after treatment, comparing data of the outcome measures (NRS, MV, and PV) at T0 and T4 between groups.

Methods

This study is part of a randomized, blind, parallel-group clinical trial. The study project was approved by the Rizzoli Orthopaedic Institute (I.O.R) ethics committee in the session of 27 May 2014 Prot. Gen. 0018810 and registered on linicaltrial.gov NCT02305108.

In order to define a homogeneous group of subjects, people diagnosed with coxarthrosis by the orthopedic specialist and on the waiting list for total hip replacement surgery at the Operative Unit of 'Orthopedics-Trauma Surgery, Prosthetic Hip and Knee Regimens', were chosen for this study. This population was selected, thanks to the collaboration with I.O.R. that guaranteed the recruitment of a large number of subjects in a relatively short time frame. All patients who agreed to participate in the study signed the informed consent and followed inclusion and exclusion criteria. In order to participate in the study, subjects had to present a diagnosis of primary coxarthrosis, a self-reported pain score of ≥5 on NRS, age between 40 and 80 years, and a resident in the province of Bologna (to facilitate access to various assessments and treatments). The exclusion criteria were prosthetic replacement/revision, prostheses for secondary injuries, cognitive impairment, and diagnosis of concomitant severe diseases (rheumatic, neurological, and cardiovascular). The various phases of the study are summarized in Figure 1.

Randomization

Another physiotherapist (PtC) collected the informed consents, verified the presence of the selection criteria, and then randomized the subjects through the random extraction of an envelope, remaining unaware of the group to which the subjects belonged [33]. Ten envelopes were available, five for the study (SG) and five for the control (CG) groups, containing the phone

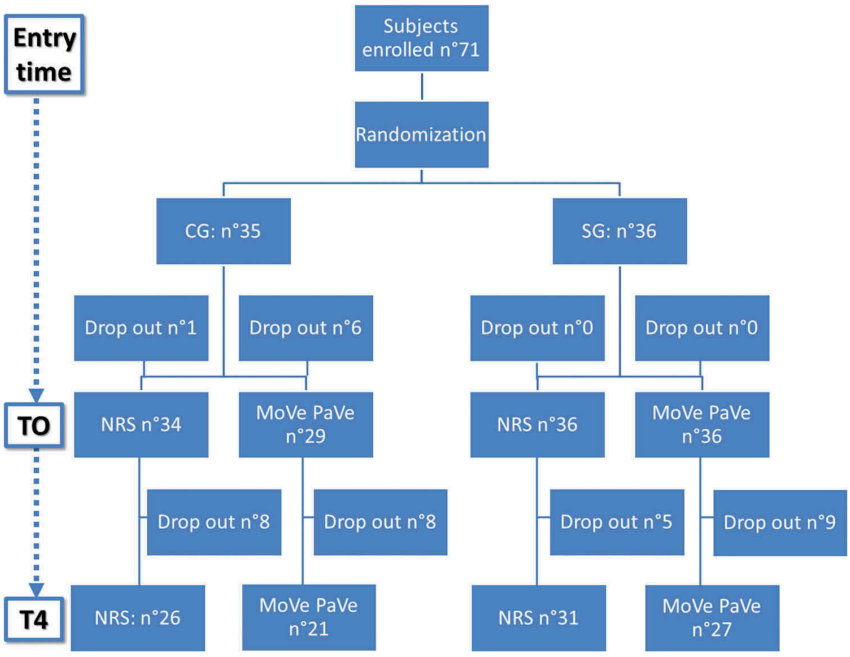

Figure 1. Diagram of study phases. NRS: Numeric Rating Scale; CG: control group; SG: study group; MoVe: movement verification; PaVe: palpatory verification; T0: first assessment of outcome measures: pain, MoVe, and PaVe; T4: last assessment of outcome measures: pain, MoVe, and PaVe.

number of the respective physiotherapists (PtA or PtB) in charge of the group. The patients were invited to open the envelope at home after T0 and T1 assessments were completed. After eight patients were recruited, the two remaining envelopes were substituted with the other 10 envelopes, five for each group, in order to maximize the randomization. All subjects were free to leave the study at any time, for any reason, but, by participating in the study, they agreed to avoid other types of medical or physiotherapy treatment for the duration of the trial. Each subject was included in the study 1 month before the scheduled date for hip prosthesis surgery.

Treatments

The SG underwent 3-weekly FM® sessions, carried out by PtA.

The CG had not undergone any kind of treatment.

Evaluations

All subjects were evaluated at study entry (T0) by PtA and PtB for the MV and the PV. For MV, we intend the active ROM according to FM® textbook; for the PV, the research of the consistency of the CCs is described in Figure 2. The evaluations were conducted independently and subsequently by the two operators, using closed and reserved offices. PtC also calculated the NRS score for pain of each participant at T0. PtA and PtB were students of the Physiotherapy Course. They both had completed the training in FM® (participating at first and second FM® level courses), and therefore, we can state that they had the same training experience and manual competence.

FM® treatments were administered to all SG subjects by PtA, collecting their pain rate before T2 (after 1 week) and at T3 (after 2 weeks). Due to logistics, T0 and T1 took place on the same day; therefore, the NRS before T1 was considered the same as T0 that were collected by PtC.

At T4, one month after entry in the study, PtB reassessed the entire sample of the participants, administering MVs and PVs, while PtC recorded the NRS. PtC and PtB were not aware of the group to which the subjects belonged.

MV and PV were performed following the standard FM® criteria which involve the use of functional motor tests (for MV) and palpation evaluations (for PV) over CCs. The presence of a palpable alteration, within tissue planes, indicates, that the point has to be treated.

Motor tests were performed following FM® guideline that defines six tests (two for each opposite directions in every single plane of movement) for each body segment. The subjects were individually instructed to carry out specific movements in concentric, eccentric, or isometric activities which involve each segment in every specific direction [34]. The segments of lumbar, pelvis, hip, and knee were evaluated with the methodology reported in Table 1. The palpation tests were performed looking for the possible lack of multiplanar sliding within the deep fascial planes in the areas

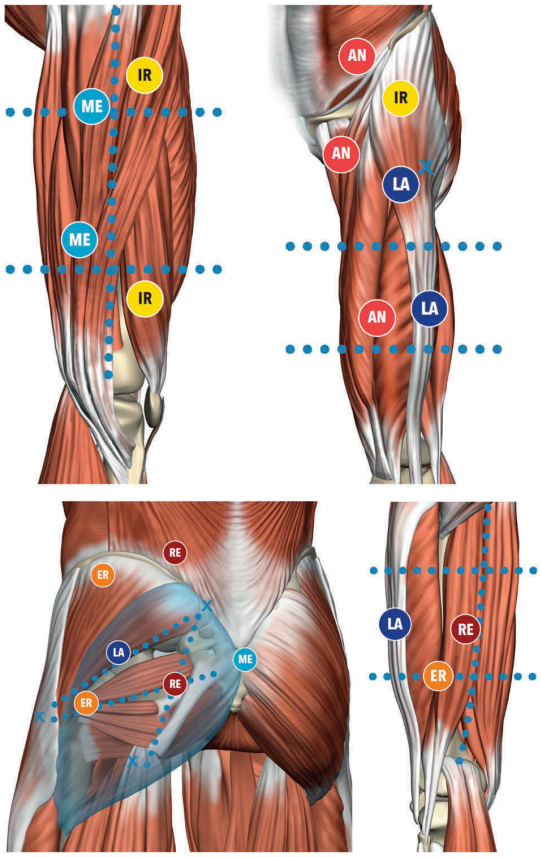

Figure 2. Center of coordinations in the body segments of Pelvi (PV), Hip (CX), and Knee (GE). AN: antemotion; RE: retromition; ME: mediomotion; LA: lateromotion; ER: extramotion; IR: intramotion.

where CCs are located. These CCs were evaluated for the pelvis and hip segments as described, in accordance with the standard criteria and methodology of Luigi Stecco, author of the FM® method [34] (Figure 2).

PtA and PtB, who were trained in FM®, shared the criteria indicated for the resultant scores of each test (see Table 1 for the grading of MV and PV in FM®).

Outcomes

The primary outcome refers to the inter-operator (at T0) and intra-operator (between T0 and T3) reliability of FM® MV and PV. The secondary outcome refers to the efficacy of the treatment with respect to pain and ROM between groups.

For the primary outcome, following the guideline of the method, the first interphalangeal knuckle of the second finger was used, with a grading of positiveness from 0 (absence of alteration) to 3 (maximum alteration). Table 1 summarizes the scores of the MV and the PV.

Calculation of sample size

The sample size was calculated with $\alpha = 0.05$, $\beta = 0.20$ and following the indication of Walter et al. [35] for: 'n' = 2, '$\rho 0$' = 0.4, and '$\rho 1$' = 0.8, where 'n' represents the number of raters or the repeated measurements, $\rho 0$ is the null hypothesis, based on a low level of reliability, and $\rho 1$ is the expected value of reliability, in this case, estimated as very good. The values of $\rho 0$ $\rho 1$ were calculated with intraclass correlation coefficient (ICC). Due to these parameters, the sample size was calculated for 15 subjects.

Calculating the sample size for the secondary objective (setting α and β as above and expecting a difference of 1.5 points of the NRS with an SD of 2 points), we would have needed a sample of 58 subjects. Considering a high dropout (see Limit section), we decided to recruit at least 70 subjects.

Blinding

Only the patients were not blinded in this study, while assessor, evaluator, and data analyzer were. Inter-operator assessment in T0 was performed independently by PtA and PtB as the data were transmitted separately to PtD. Intra-operator assessment at T4 were carried out by PtB who was blinded to the group belonging to the subjects. Equally, NRS values were recorded at T0 and T4 by PtC, also unaware if the subject belonged to SG or CG.

Data analysis

Data collected by PtA, PtB, and PtC were transmitted to PtD who created an electronic database and proceeded with the statistic analysis. The study sample was analyzed to identify homogeneity criteria referring to the demographic characteristic and to the various T0 study outcome.

For the primary objective of the study, an inter-operator reliability analysis was performed at T0, correlating the MVs and PVs of PtA and PtB. An intra-operator correlation analysis was performed comparing PtB MVs and PVs assessments at T0 and T4.

The secondary objective of the study was to compare the mean of the differences at T0 and T4 of the two separated groups for the outcomes: pain, MV, and PV. This outcome was managed with the 'intention to treat' procedure: for NRS, missing data were used the 'worst case scenario' imputing '0' for missing data at T4 in control group and '10' for study group.

For missing data in MV and PV at T4, we have chosen the 'last observation carried forward' ITT method considering the different width scales (NRS 0–10; MV 0–117; PV 0–72).

Table 1. Grading for movement verification (MV) and palpatory verification (PV) in fascial manipulation. .

	Movement verification						Palpatory verification		
	Flexion	Extension	Adduction	Abduction	Intrarotation	Extrarotation	Description		Grade
LU	Patient prone; it is requested to extend the rachis by resting on the hands with outstretched arms.	The patient is required to bend forward with extended knees; measure the distance between fingers and ground.	No test request	Lateral bending of the trunk with arms extended along the sides. Measure the distance finger lateral condyle.	Sitting; hugging is required an active trunk torsion and passively complete the movement.	Sitting; hugging is required an active trunk torsion and passively complete the movement.	No articular limitation; ability to perform movement against manual resistance.	The palpation of the CC does not cause pain; the physiotherapist does not perceive alteration to tissue flow; there is no radiation.	0
PV	Patient supine with 90° flexion hip. It is required to keep the position against resistance. Test one leg at a time.	In standing; it requires the patient to put his hands on the gluteus and to bring forward the pelvis.	No test request	Standing without support for upper limbs; abduction of the contralateral limb of the evaluated side.	Patient standing in front of the therapist with hands each on the shoulders of the other. Torsion of the pelvis is required.	Standing up and touch the contralateral foot with his hand.	Mild joint limitation (less than 50% of the ROM allowed by the articular segment); ability to move against gravity but not against manual resistance.	The palpation of the CC causes pain; the physiotherapist does not perceive alteration to tissue flow; there is no radiation.	1(*)
CX	Standing up and quick extension of the inferior limb.	Standing; a hip quick flexion is required with strait knee.	Fists of the physiotherapist between the thighs and a resistance is applied to the adduction.	Fists of the physiotherapist placed externally to the thighs of the patient.	Sitting; patient is required to cross the legs putting the knees on the same vertical line.	Sitting; patient is request to bring the heel on the contralateral knee.	Important joint limitation (greater than 50% of the AROM allowed by the articular segment); ability to perform gravity movement in the allowed ROM.	The palpation of the CC causes pain; the physiotherapist perceives a slight reduction of tissue flow; there is no radiation.	2(**)
GE	Supine with squared legs and 90° flexed knee. Ask to keep the knee at 90° against a resistance downwards.	Prone with 90° flexed knee. Ask to keep the knee at 90° against a resistance downwards.	Fists of the physiotherapist between the legs of the patient and a resistance is applied to the adduction.	Fists of the physiotherapist externally to mid-leg and applies a resistance to abduction.	Prone with 90° flexed knee. Knee intrarotation is performed.	Prone with 90° flexed knee. Knee extrarotation is performed.	Severe joint limitation (active movement just mentioned); no ability to oppose gravity.	The palpation of the CC causes pain; the physiotherapist perceives an important limitation to tissue flow; radiation.	3(***)

ROM: range of motion; AROM: active range of motion; CC: center of coordination; LU: lumbi; PV: pelvis; CX: hip; GE: knee.

Statistical analysis

Data analysis was performed with the STATA software, version 14 [36]. The correlation of the various measurements of the MVs and PVs was considered using the ICC (model 3, form 1) and Cohen 'k' coefficient test with the agreement percentage.

Analysis was performed both including all the tests simultaneously as independently to better underline the reliability value of each single movement and palpatory test.

The efficacy of the treatment through the variation of the NRS score and MV and PV tests was treated as an ordinary variable, using statistical tests by ranks (Mann–Whitney *U* test)

Results

Seventy-one subjects (31 men and 40 women), of average age 64, were recruited (±9.9 SD). Randomization created an SG with 36 subjects (mean age 65 ± 11.04 SD) and a CG with 35 subjects (mean age 63 ± 8.72 SD). The mean NRS indicated 6.58 (±1.46 SD) for SG and 6.4 (±1.46 SD) for CG at T0. The statistical analysis for these data indicated that the distribution of the subjects was homogeneous both for the characteristics of age and the intensity of the pain (Table 2).

For logistical and organization reasons, it was not possible to detect all the subjects in all the programmed visits (see Limits section). Each subject was assessed with 39 MV and with 24 PV. At T0, we collected data of 65 enrolled subjects (36 SG and 29 CG) for a total of 2535 MV and 1560 PV. At T4, we collected data of 48 subjects (27 SG and 21 CG) for a total of 1872 MV and 1152 PV. NRS data were collected for 70 subjects at T0 (36 SG and 34 CG) and for 57 at T4 (31 SG and 27 CG). Pain measurements were performed by PtC for both the groups at T0 (71 subjects) and T4 (58 subjects). All subjects tolerated assessments and treatments with no adverse or unforeseen events.

Table 3 summarizes the statistical analysis of the efficacy outcomes, related to the secondary objective. Statistical analysis was carried out using the grading of the movement and palpatory verification tests to rate the mobility limitation of each single test as described in Table 1 (from 0 = no limitation to 3 = severe limitation).

The statistically significant difference was reached in the pain evaluation as well as in movement and palpatory verification between T0 and T4 (NRS = 0.001; MV = 0.0003; PV = <0.0001).

As previously indicated in Data Analysis, missing data were inputted with ITT methods. Nevertheless, the average value of the difference T0–T4 remains appreciably to the advantage of the SG. The Mann–Whitney *U* test analysis confirms a statistically significant difference between the two groups in favor of the SG for NRS, MV, and PV values.

The analysis of the inter- and intra-operator correlations of the MVs and PVs is summarized in Table 4, subdividing the MVs and PVs carried out, respectively, in the SG and CG. The ICC was chosen as the main statistical indicator of reliability to calculate simple size. We also performed Cohen's kappa test in order to calculate the agreement percentage and to facilitate the comparison of the present data with other studies of palpation reliability.

While the inter-operator reliability measurements (MV of CG = 0.95; of SG = 0.92; PV of CG = 0.90; of SG = 0.91) have shown excellent results in both SG and CG, the intra-operator values (MV of CG = 0.93; of SG = 0.82; PV of the CG = 0.84, of the SG = 0.60), even if they are very satisfactory values, deserve a differentiated analysis between the two study groups. In fact, while the values of the CG were similar to those of the inter-operator detection, the measurements carried out in the SG subjects have decidedly lower values, in particular on the PV (SG: MV inter: 0.92; intra 0.82; PV inter: 0.91; intra: 0.60).

We found a similar trend in the single test analysis, as shown in Table 5, where the best reliability values are represented in the inter-operator and in the intra-operator for control group analyses.

Discussion

The principal purpose of this study was to demonstrate the inter- and intra-operator reliability of the assessment

Table 2. Homogeneity analysis between SG and CG at baseline.

				Hip range of motion					
				Flexion		Abduction		Extrarotation	
Outcome	Age	NRS	Sex	Right	Left	Right	Left	Right	Left
SG mean (±SD)	65 (±11.04)	6.58 (±1.46)	M: 15 W: 21	1.24 (±0.82)	0.94 (±0.92)	0.56 (±0.99)	0.38 (±0.78)	2.06 (±0.85)	1.79 (±1.09)
CG mean (±SD)	63 (±8.72)	6.4 (±1.46)	M: 16 W: 19	1.17 (±0.87)	0.93 (±1.08)	0.27 (±0.52)	0.30 (±0.65)	1.97 (±0.96)	1.33 (±1.12)
p Value	0.58	0.60	0.74	0.78	0.96	0.17	0.69	0.90	0.07
Effect size (Cohen's d)	0.20	0.12	-	0.08	0.01	0.37	0.11	0.01	0.42
95% CI	−6.04 to 3.40	−0.87 to 0.51	−0.28 to 0.20	−0.37 to 0.49	−0.50 to 0.47	−0.66 to 0.19	−0.42 to 0.28	−0.47 to 0.42	−1.01 to 0.048

SG: study group; CG: control group; SD: standard deviation; NRS: Numeric Rating Scale; W: woman; M: men.

Table 3. Mean of the difference between T0 and T4, of SG and CG, of the Numeric Rating Scale (NRS), movement verification (MoVe), and palpatory verification (PaVe).

	SG	CG		
Outcome	Mean of the differences T0–T4 (±SD)	Mean of the differences T0–T4 (±SD)	*p* Value	Effect size Cohen's d
NRS[a]	3.42 (±3.06)	1.4 (±2.8)	0.001	0.69
MoVe[b]	−5.03 (±8.64)	0.97 (±4.06)	0.0003	0.89
PaVe[b]	−8.5 (±8.68)	3.67 (±7.44)	<0.0001	1.51

[a]ITT with 'worst case scenario'.
[b]ITT with 'last observation carried forward'.

Table 4. Correlation of results of motor and palpation evaluation, inter- and intra-operator.

Interrater reliability		Intrarater reliability	
MV	ICC: 0.92 (95% CI: 0.92–0.93)	MV	ICC: 0.82 (95% CI: 0.80–0.84)
SG	A: 72.7% K: 0.57 SE: 0.02	SG	A: 74.8% K: 0.6 SE: 0.02
MV	ICC: 0.95 (95% CI: 0.95–0.96)	MV	ICC: 0.93 (95% CI: 0.91–0.93)
CG	A: 84.2% K: 0.75 SE: 0.02	CG	A: 78.7% K: 0.66 SE: 0.02
PV	ICC: 0.91 (95% CI: 0.90–0.92)	PV	ICC: 0.60 (95% CI: 0.54–0.66)
SG	A: 75.7% K: 0.65 SE: 0.02	SG	A: 46.8% K: 0.23 SE: 0.02
PV	ICC: 0.90 (95% CI: 0.89–0.92)	PV	ICC: 0.84 (95% CI: 0.81–0.86)
CG	A: 75% K: 0.64 SE: 0.02	CG	A: 52.3% K: 0.37 SE: 0.03

ICC: intraclass correlation; 95% CI: 95% confidence interval; A: agreement; K: Kappa di Cohen; SE: standard error; SG: study group; CG: control group; MV: movement verification; PV: palpatory verification.

Table 5. Intraclass correlation (ICC) reliability tests.

Motor and palpatory reliability: intraclass correlation analyses							
	Motor verification				Palpatory verification		
MFU	Inter at T0	Intra CG	Intra SG	CC	Inter at T0	Intra CG	Intra SG
AN-LU	0.93	0.96	0.82	AN-PV rt	0.94	0.87	0.52
RE-LU	0.94	0.94	0.74	AN-PV lf	0.95	0.66	0.55
LA-LU rt	0.91	0.73	0.72	RE-PV rt	0.93	0.82	0.17
LA-LU lf	0.9	0.60	0.60	RE-PV lf	0.86	0.83	0.71
ER-LU	0.84	0.86	0.86	LA-PV rt	0.86	0.81	0.29
IR-LU	0.85	0.93	0.82	LA-PV lf	0.91	0.81	0.74
AN-PV rt	0.91	0.9	0.75	ME-PV a	0.84	0.84	0.63
AN-PV lf	0.91	0.87	0.88	ME-PV r	0.86	0.92	0.58
RE-PV	0.88	0.87	0.86	IR-PV rt	0.91	0.67	0.78
LA-PV rt	0.9	0.93	0.87	IR-PV lf	0.85	0.68	0.58
LA-PV lf	0.93	0.96	0.9	ER-PV rt	0.83	0.88	0.58
IR-PV rt	0.78	0.9	0.47	ER-PV lf	0.94	0.84	0.66
IR-PV lf	0.84	0.86	0.48	AN-CX rt	0.93	0.83	0.58
ER-PV rt	0.92	0.92	0.57	AN-CX lf	0.89	0.75	0.8
ER-PV lf	0.95	0.94	0.71	RE-CX rt	0.87	0.88	0.15
AN-CX rt	0.88	0.88	0.7	RE-CX lf	0.91	0.91	0.41
AN-CX lf	0.91	0.92	0.68	ME-CX rt	0.9	0.76	0.49
RE-CX rt	0.92	0.9	0.57	ME-CX lf	0.87	0.82	0.72
RE-CX lf	0.92	0.92	0.7	LA-CX rt	0.94	0.83	0.65
ME-CX rt	0.85	0.65	0.51	LA-CX lf	0.86	0.89	0.56
ME-CX lf	0.84	0.58	0.54	IR-CX rt	0.94	0.83	0.4
LA-CX rt	0.95	0.82	0.53	IR-CX lf	0.94	0.75	0.64
LA-CX lf	0.9	0.91	0.82	ER-CX rt	0.93	0.84	0.64
IR-CX rt	0.96	0.9	0.73	ER-CX lf	0.94	0.94	0.67
IR-CX lf	0.95	0.89	0.93				
ER-CX rt	0.91	0.97	0.72				
ER-CX lf	0.94	0.86	0.86				
AN-GE rt	0.96	0.9	0.64				
AN-GE lf	0.97	0.89	0.93				
RE-GE rt	0.94	0.96	0.7				
RE-GE lf	0.92	0.94	0.87				
ME-GE rt	0.95	0.9	0.44				
ME-GE lf	0.95	0.96	−0.7				
LA-GE rt	0.91	0.83	0.83				
LA-GE lf	0.9	0.9	0.78				
IR-GE rt	0.88	0.64	0.76				
IR-GE lf	0.8	0.79	0.64				
ER-GE rt	0.89	−0.5	0.79				
ER-GE lf	0.9	0.95	1				

CC: center of coordination; MFU: myofascial units; CG: control group; SG: study group; a: anterior; r: retro.

procedures of the FM® method, as standardized on a double movement and palpatory verification. Due to the secondary objective of this study, the efficacy of the FM® treatment, we enrolled a homogeneous group of people with a diagnosis of coxarthrosis and surgery indication for hip arthroplasty at the Rizzoli Orthopaedics Institute in Bologna. Both assessment and treatment procedures were carried out by undergraduate students in physiotherapy who attended the training of first and second FM® level. We could, therefore, state that their level of clinical and manual experience could be considered equivalent, and the results of both assessments and treatments were not influenced by a inhomogeneous level of competence.

The 71 subjects enrolled in the study were tested not only in their symptomatic hip but also on the unaffected side as in other asymptomatic segments, from lumbar to knees. As the findings of a normal or altered CC are usually not related to the symptomatic area, we can consider that assessment results were not conditioned in MV and PV by symptoms or pain of the subjects.

Concerning to the secondary outcomes, we got very interesting improvement of the SG with a significant diminishing of pain (NRS scale) ($p = 0.001$), increasing of ROM ($p = 0.0003$), and diminishing of PV ($p < 0.0001$). As the intra-operator reliability analysis shows that tissue consistency has changed in the SG compared to the CG, we could assume that there is a correlation between the tissue modification due to the FM treatment and the clinical results about pain and ROM.

Unfortunately, some subjects did not complete the study due to logistic problems such as transportation, distance to the hospital, or caregiver availability. There was no reaction to any evaluation or treatment procedures.

To avoid a small number of subjects due to a predicable high dropout, a larger number of subjects (see Table 3), than simple size calculation, were recruited.

Following the principles of the 'intention to treat', the missing data of the NRS at T4 were charged using the 'worst case scenario' method. This allowed calculation of the statistical significance of the 71 subjects included in the research. These values allowed us to conclude that FM® treatment is able to significantly modify both clinically and statistically pain in subjects for whom the orthopedic specialist never indicated alternative therapeutic solutions other than prosthetic replacement surgery. Due to ITT, CG managed to overcome the value of minimal clinically important difference (MCID) [37] (=1.4). Furthermore, SG, despite the same ITT, abundantly doubled MCID (=3.42; see Table 3). Also, the inferential statistical analysis between groups showed a statistically significant difference ($p = 0.01$). We considered these results very interesting in clinical practice

for two major reasons: a small number of treatments were performed (n = 3) over the duration of the study (=30 days); FM® targeted the fascial tissue and not the articular components that are commonly reputed to be the origin of the symptoms.

Pain, imaging, and joint mobility are the criteria for prosthetic surgery [38]. Furthermore, pain limits the subjects' mobility, influences their activities of daily living (ADL) and attitudes to avoid the symptoms (escape mechanisms, reduction of walking and motor performance in general, increasing assistance requests), and negatively affects their quality of life [39].

These preliminary data suggest the possibility to use a valid conservative treatment, such as FM®, to decrease pain, increase ROM, and possibly improve ADL, postponing or, in the best scenario, substituting surgery in subjects with coxarthrosis. It was already demonstrated that FM® was able to significantly restore motion immediately after total hip replacement [30].

The major outcome, the reliability analysis, attained excellent values that exceeded our expectations (see Table 4), even taking into consideration the anatomical variation encountered in the body segments evaluated. It is known that lumbar, pelvic, hip, and knee areas present major difference between subjects in relation to their BMI, amount of subcutis fat, and quality of the skin (cellulitis, dry skin, etc.) that challenge the ability of the practitioner to assess the CC through palpation [40]. Surprisingly, in both single, as reported in Table 5, and general test analyses, shown in Table 3, the reliability results were very good to excellent. Excluding the SG, where the differences are related to improvement after FM® treatment, between 126 evaluations, only 7 had a reliability below 0.7.

In literature, palpation reliability study can be found in particular inherent to TrPs. Only among experienced operators, a moderate-to-high-reliability TrPs detection is obtained [28], confirming the difficulty in objectifying manual palpation efficacy [41]. Comparing the above results with our research, two main factors should be emphasized:

(1) Localization: TrPs are not precisely localized as are CCs. This leaves room for arbitrariness and uncertainty for the physiotherapist searching for the altered tissues.

(2) The characterization of the perceived alteration: the palpation of a TrP, active or latent, is associated with a characteristic symptomatology (radiation pain in typical areas, local contraction response, jump sign) whose presence is obviously conditioned by the pain thresholds of the subjects palpated [41]. On the contrary, the CC is a stiff area with a lack of tissue gliding [11,42] that can also be associated with punctate or radiation type symptoms (Table 1). Comparing the pros and cons of TrPs versus CC evaluations, it seems easier to find the presence of an altered CC, knowing their exact location, but it seems more difficult to accurately connote the consistency of CC's alteration, attributing a grading from 0 to 3, in comparison to the simple decision of TrP presence or absence.

Another important finding of this study was the difference in intra-operator reliability values between SG and CG. While the values obtained by the MV and PV of the CG overlap those of the inter-operator reliability, the values of the SG were lower, especially for the PV. These data can be easily explained, considering that FM® treatment restores the sliding of fascial planes in altered CCs [11,42]. Therefore, the differences that PtB had found between CG and SG would suggest, even in the absence of imaging able to measure it objectively, that FM® treatment is effectively able to restore the sliding of the fascia tissue, maintaining its stability even at a time span of, at least, 30 days.

This could explain why PtB detected tissue changes with more consistency at T1 compared to T4 when CCs were already treated by PtA (see Table 1). The strength of these results was also due to the blind intra-operator evaluation, conducted over 1152 CCs with four different gradings, and the distance of about 30 days from the evaluations, that made it almost impossible for PtB to remember the initial findings.

Finally, in consideration of the limited clinical and manual experience of the involved operators, who did not even undergo a particular training period before this trial (as it is documented in other reliability studies [25,41]), we can state that FM® MV and PV strategies are easy to learn and apply.

Limits

The loss of subjects who underwent the various stages of study (a total of 22 people out of a total of 71 recruited = 31%) represents a dropout that is certainly greater than the 'physiological abandonment' that is found in clinical or reliability study. These dropouts were mainly due to organizational and personal logistic reasons (some subjects, for example, had difficulty in transportation, not being resident in the city where the study was carried out). Also, the hospital, that hosted the study, determined various dropouts, anticipating the date of admission of subjects' surgery, making T4 data collection impossible. No dropouts were caused by conditions related to evaluation or treatment.

Conclusion

This is the first study regarding the reliability of FM® evaluation procedures (MV and PV). The research produced a considerable number of evaluations (see Table 3) which allowed us to reach solid conclusions with respect to the pre-established outcomes.

Regarding the primary objectives of this study, it is shown that the inter-operator reliability results of MV and of PV in FM® were excellent (≥0.90). Intra-operator reliability also shows excellent results for CG (≥0.84) which had not undergone any treatment.

These appreciable results, however, are not in line with the extensive literature related to the reliability of motor tests and palpation findings of many other manual therapy techniques [25–28]. These differences may lie in the operational strategies adopted in FM® to identify the altered points involved in subject dysfunctions. These procedures allow the practitioner to choose the CCs that should be treated in each single session.

The improvement in the NRS pain scale (see Table 4) suggests that FM® procedure and analysis criteria can identify relevant and significant points (CCs) for the treatment of myofascial dysfunctions ($p = 0.01$).

It should be emphasized that the great number of collected and analyzed evaluations suggest that the results of this study were clinically meaningful (see Table 3).

These results confirm the very good to excellent reliability, demonstrated in less than expert evaluators, and the clinical efficacy of FM® in decreasing pain and restoration ROM in hip osteoarthrosis subjects.

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Consent

Written informed consent for publication of clinical details was obtained from the patients.

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