



Original Research—CME

Fascial Manipulation Associated With Standard Care Compared to Only Standard Postsurgical Care for Total Hip Arthroplasty: A Randomized Controlled Trial

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Abstract

Background: Postsurgical physiotherapy programs after total hip arthroplasty (THA) show important differences between types and numbers of treatment sessions. To increase functional recovery in postsurgical patients, manual therapy can be added to traditional physiotherapy programs. Fascial manipulation (FM) has been demonstrated to be effective in decreasing pain and increasing muscular capacity.

Objective: To compare the effectiveness of FM when added to a standard protocol of care.

Design: Randomized controlled trial.

Setting: Rehabilitation center.

Patients: A total of 51 patients were recruited after total hip arthroplasty. Inclusion criteria were first THA surgery, posterior-lateral access, and onset of pain within a maximum 2 years. Exclusion criteria were previous hip or knee prosthesis, congenital hip dysplasia, elective THA secondary to trauma, real leg-length discrepancy (≥ 1.5 cm), cognitive impairment, concomitant rheumatic pathology in acute phase, and serious comorbidities such as cardiac, respiratory, and/or neuromuscular pathologies.

Methods: Patients were randomized into 2 groups; both followed a standard protocol based on 2 daily sessions of active exercises for 45 minutes. In the study group, 2 sessions were replaced by FM. The clinical trial was registered at clinicaltrials.gov (NCT02576028).

Main Outcome Measures: Functional outcome measures were collected before and after treatment and at the end of the rehabilitation program. The measures included the Harris Hip Score; Timed Up-and-Go test; articular range of motion in abduction, flexion, extension, and bilateral external rotation with heels together; and verbal numerical scale.

Results: Statistically significant differences were observed in degrees of flexion between the study and control group with 25.4 (± 11.3) and 18.7 (± 9.5), respectively ($P = .04$); for abduction with 16.8 (± 7.0) and 11.1 (± 6.1), respectively ($P = .005$); for extension with 16.2 (± 4.9) and 9.3 (± 3.8), respectively ($P = .001$); for bilateral external rotation with heels together with 8.3 (± 4.3) and 5.5 (± 4.6), respectively ($P = .04$); for the Harris Hip Score 23.3 (± 8.9) and 14.5 (± 8.5), respectively ($P = .002$); and for verbal numerical scale score 1.1 (± 2.1) and 0.5 (± 1.1), respectively.

Conclusions: This study demonstrates that 2 FM sessions are able to significantly improve several functional outcomes in patients compared to usual treatment after THA.

Level of Evidence: II

Introduction

Total hip arthroplasty (THA) is a routine procedure performed in patients with severe coxarthrosis. According to the Registro Italiano ArtroProtesi (RIAP), based on data from 2001 to 2010, the annual increase in total hip replacements in Italy is 3%, with about 60,000 operations having been performed in 2010 [1].

In the United States, according to the National Center for Health Statistics (NCHS), between 2000 and 2010 the number and rate of total hip replacements among in-patients aged 45 years and more increased from 138,700 to 310,800, for a rate of 142.2 to 257.0 per 100,000 population [2].

The aim of postsurgical physiotherapy programs is primarily pain reduction to facilitate a quick return to

patient autonomy, along with improved functional activities of daily living and ambulation. The objectives currently reported in the literature [3,4] regarding the early postsurgical rehabilitation include improvement and return to physiological values of the following parameters: joint movement [5,6], muscle strength [7,8], elasticity of tissues, decrease in pain, prevention of complications including deep vein thrombosis and luxation [9], maximum autonomy of the patient in the shortest amount of time possible, earliest weight bearing, and correct and pain-free ambulation. Treatment approaches show variations with regard to frequency of care, functional activities, and exercises [10]. Rehabilitation programs are supported by evidence of effectiveness in the presurgical hospitalization [11] and at home [12,13] and in the postsurgical period as early and intensive [14], long-term [15], and at home [16]. There is currently limited evidence supporting any specific approach over another in the early postsurgical period.

It is increasingly recognized that fascia may be implicated in the production of pain, the limitation of range of movement, and a variety of musculoskeletal conditions [17]. Fascial manipulation (FM) [18] is a manual therapy that focuses on deep muscular fascia. This technique considers the fascia as a 3-dimensional continuum [19]. The mainstay of this manual technique lies in the identification of specific localized areas of the fascia, defined as the center of coordination (CC), where the gliding of the subcutis should be preserved to avoid biomechanical incoordination of the surrounding muscles. The method is performed by applying deep friction over the CCs that are more altered in the area of the clinical palpation. For this reason it was decided to assess the effectiveness of FM intervention within a standard rehabilitation program for postsurgical THA patients using the outcomes of reported pain, joint range of motion, and functional improvement. The null hypothesis was that there would be no difference in outcome in patients going through standard rehabilitation and FM treatment compared to standard rehabilitation only.

Methods

Study Design and Patient Selection

This study was a prospective, single-blinded, parallel-group, randomized, controlled trial. It was approved by the Ethics Committee of "Azienda Ospedaliera Bolognini" di Seriate, Bergamo, Italy (ref. no. 518 of 4 July 2011). The clinical trial is registered at clinicaltrials.gov (NCT02576028).

Participants were recruited from patients undergoing THA surgery from October 2011 to July 2013 in the Unit of Neuromotor Rehabilitation of the Bolognini hospital, Seriate, Italy. Inclusion criteria were first THA surgery, posterior-lateral access, onset of pain with a maximum

2 years. Exclusion criteria were patients with previous hip or knee prosthesis, congenital hip dysplasia, revision THA, elective THA secondary to trauma, real leg-length discrepancy (≥ 1.5 cm), cognitive impairment, concomitant rheumatic pathology in acute phase, serious comorbidities as cardiac, and respiratory and/or neuromuscular pathologies.

The first contact with the patients were 7 days after surgery; all patients had received the same rehabilitation program at that point. Patients were evaluated by a physiatrist and, when all the inclusion and exclusion criteria were met, were invited to participate in the study. Patients received verbal and written information about the trial (background, procedure, randomization, and potential risks) and, upon acceptance, provided signed informed consent.

Randomization and Treatment Groups

At baseline, the participants were randomized into a study group (SG) and control group (CG) by a computer-generated randomization list; both groups received 2 daily treatment sessions of standard care. All patients were evaluated by the same blinded observer (physiotherapist [PT A] with more than 5 years' experience in FM) on 5 separate occasions: t0, before the first treatment of day 2; t1, before the second treatment of day 2; t2, before the first treatment of day 7; t3, before the second treatment of day 7; and t4, after the first treatment of standard care of day 10 (day of patient discharge from the study). The standard protocol of

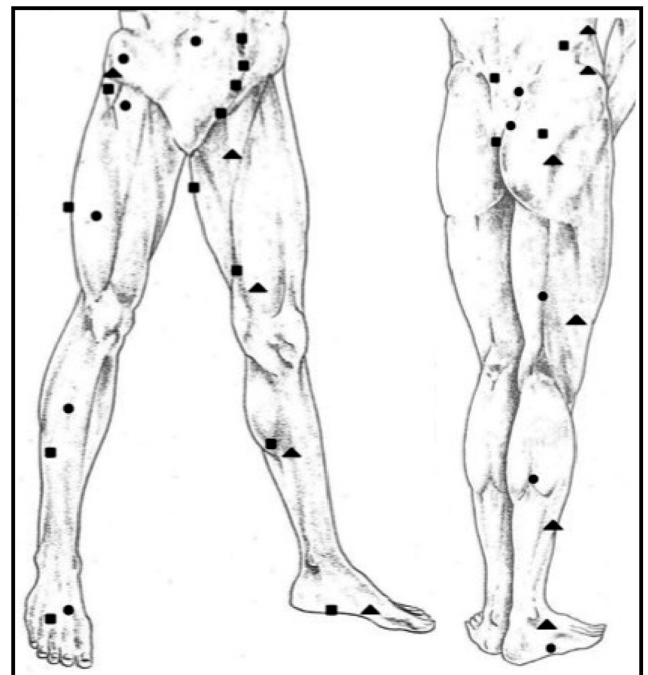


Figure 1. Centers of coordination in the lower limbs in fascial manipulation.

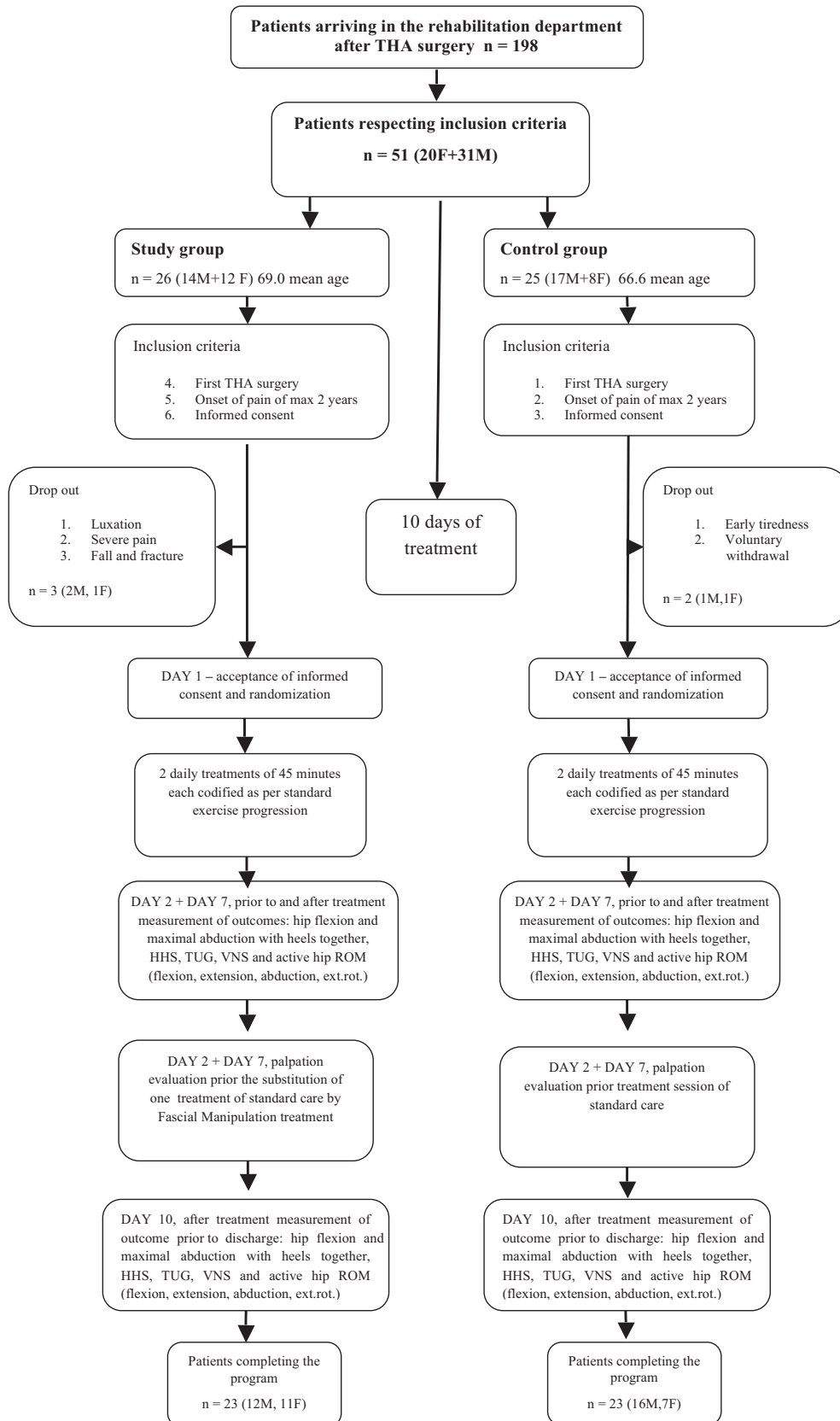


Figure 2. Patient flow chart. THA = total hip arthroplasty; F = female; M = male; HHS = Harris Hip Score; TUG = Timed Up-and-Go; VNS = verbal numeric scale; ROM = range of motion; ext.rot. = external rotation.

Table 1
Baseline characteristics of study group (SG) and control group (CG)

t ₀	SG Mean (±SD)	CG Mean (±SD)	P Value, z Value	95% CI
VNS	1.13 (±2.16)	0.7 (±1.18)	.34	
Flexion	55.7 (±13.7)	57.7 (±13.1)	.61	−5.911393 9.99835
Abduction	17.4 (±6.8)	19.1 (±9.3)	.48	−3.147616 6.53892
Extension	7.0 (±4.4)	7.9 (±5.6)	.54	−2.069006 3.895093
External Rotation	15.2 (±6.4)	16.7 (±6.8)	.47	−2.508505 5.37807
Bilateral hip flexion and external rotation with heels together	46.7 (±10.1)	48.5 (±10.0)	.56	−4.210524 7.732264
TUG	31.7 (±12.0)	29.4 (±13.9)	.56	−9.917272 5.470316
HHS	55.5 (±12.2)	61.8 (±7.5)	.05	
Age	69.0 (±9.5)	66.6 (±5.9)	.30	−7.127707 2.258142

SD = standard deviation; CI = confidence interval; VNS = verbal numeric scale; TUG = Timed Up-and-Go; HHS = Harris Hip Score.

care designed for THA rehabilitation spanned more than 10 days with two 45-minute sessions per day, followed by the CG. The same protocol was followed by the SG except on days 2 and 7 where the first treatment was replaced with FM treatment. SG patients received 2 FM treatments on 3 CCs by a physiotherapist (PT B, with more than 5 years' experience in FM) on the points recorded as more altered by PT A during evaluation. PT A was blinded to treatment allocation along with PT C, the data analyst.

The FM treatment took the same amount of time as the standard protocol treatment. The only requirement was for the physiotherapist to be trained in the specific manual therapy FM, with no additional costs for the rehabilitation unit.

Outcome Measures

The verbal numeric scale (VNS) was recorded with the patient supine during active movement of hip flexion and maximal external rotation with heels together; the distance between the medial condyle of the femurs was measured in the above position with a tape measure. Active range of motion (AROM) of the operated hip in flexion, abduction, extension, and external rotation with a bubble inclinometer was also measured. PT A had experience using this instrument [20]. The palpation evaluation of the 24 CCs was performed in all participants on the operated lower limb (Figure 1) according to the methodology of FM [21,22]. The functional Harris Hip Score (HHS), validated in Italian with a total score from 0 to 100, was administered, along with the functional part of the questionnaire [23]. The Timed Up-and-Go (TUG) test was also performed along a straight corridor with floor markings using the same chronometer [24,25].

Statistical Analysis

Data were analyzed by PT C using STATA version 10 [26]. The statistical analysis was conducted assessing the differences between groups for each evaluation

(mean ± SD); statistical significance was reached for values of <.05. The slope of the trend lines was calculated to assess the interval of the greatest improvement between different measurements. The Student *t* test was used for continuous data including means and standard deviations (ROM, TUG, age), and the Wilcoxon rank-sum (Mann-Whitney) test was used for VNS and HHS data. Baseline comparison was performed to check the homogeneity between groups. No adjusted analysis were conducted, because of the equality of the groups at baseline.

Results

A total of 198 patients were screened for eligibility between October 2011 and July 2013. Figure 2 shows the patient flow during the study. A total of 51 patients met the inclusion criteria; only the variable "age" met the normal distribution of the sample. A total of 46 patients completed the study; there were 3 dropouts in the SG and 2 dropouts in the CG. The reasons for which patients dropped out were not directly related to the rehabilitation program or the treatment of FM. Table 1 shows that baseline data were similar between groups. Gender distribution was not homogeneous, with 17 male and 8 female participants in the CG compared to 14 male and 12 female participants in the SG. After dropping out occurred, 16 male and 7 female participants were included in the CG, and 12 male and 11 female participants were in the SG ($z = .23$).

All outcome measures improved in both groups during the course of the study; however the SG showed significant improvement compared to the CG during and at the end of the study. Table 2 reports the mean differences and standard deviations between groups after FM treatments were implemented compared to the SG. It should be noted that external rotation and TUG outcomes did not show significant difference in improvement between groups at the time of discharge. The VNS values were initially low (mean 1.3 and 1.1/10 for SG and CG, respectively) and improved to 0 and 0.2 for the SG and CG, respectively, at t4.

Table 2
Differences in study group (SG) and control group (CG) at various points in time

Groups	t0 Mean (\pm SD)		t1 Mean (\pm SD)		t2 Mean (\pm SD)		t3 Mean (\pm SD)		t4 Mean (\pm SD)	
	SG	CG	SG	CG	SG	CG	SG	CG	SG	CG
Flexion	55.7° (\pm 13.7)	57.7° (\pm 13.1)	65.4° (\pm 12.8)	60.0° (\pm 12.6)	73.0° (\pm 8.1)	68.7° (\pm 11.5)	77.7° (\pm 8.2)	71.2° (\pm 10.7)	81.1° (\pm 8.3)	76.5° (\pm 10.9)
Abduction	17.4 (\pm 6.8)	19.1 (\pm 6.3)	22.3 (\pm 6.6)	21.3 (\pm 10.2)	25.5 (\pm 6.9)	25.7 (\pm 8.5)	30.5 (\pm 6.6)	26.5 (\pm 8.8)	34.3 (\pm 6.1)	30.2 (\pm 7.8)
Extension	7.0 (\pm 4.4)	7.9 (\pm 5.6)	12.4 (\pm 4.2)	10.3 (\pm 6.2)	16.4 (\pm 5.1)	13.4 (\pm 5.7)	20.7 (\pm 3.7)	14.4 (\pm 5.8)	23.2 (\pm 4.2)	17.3 (\pm 4.9)
External rotation	15.2 (\pm 6.4)	16.7 (\pm 6.8)	19.6 (\pm 6.9)	18.9 (\pm 7.1)	22.3 (\pm 7.8)	22.3 (\pm 7.8)	25.0 (\pm 7.0)	23.2 (\pm 6.0)	26.9 (\pm 6.6)	25.6 (\pm 6.5)
Bilateral hip flexion and external rotation with heels together	46.7 (\pm 10.1)	48.5 (\pm 10.0)	51.0 (\pm 9.7)	50.0 (\pm 9.9)	52.2 (\pm 8.8)	52.5 (\pm 9.1)	54.0 (\pm 8.6)	53.3 (\pm 9.1)	55.0 (\pm 8.9)	54.0 (\pm 9.3)
TUG	31.7 (\pm 12.0)	29.4 (13.9)	26.5 (\pm 10.8)	27.6 (\pm 13.5)	20.8 (\pm 7.2)	19.5 (\pm 6.1)	18.6 (\pm 7.0)	18.0 (\pm 5.4)	16.0 (\pm 4.0)	16.8 (\pm 5.3)
VNS	1.13 (\pm 2.16)	0.7 (\pm 1.18)	0.5 (\pm 1.3)	0.5 (\pm 1.1)	0.2 (\pm 0.5)	0.4 (\pm 0.8)	0.1 (\pm 0.5)	0.3 (\pm 0.6)	0.0 (\pm 0.2)	0.2 (\pm 0.6)
HHS	55.5 (\pm 12.2)	61.8 (\pm 7.5)	61.3 (\pm 10.7)	63.5 (\pm 6.3)	71.2 (\pm 8.7)	72.7 (\pm 5.3)	73.1 (\pm 9.0)	73.2 (\pm 4.9)	78.7 (\pm 5.4)	76.2 (\pm 5.3)

SD = standard deviation; VNS = verbal numeric scale; TUG = Timed Up-and-Go; HHS = Harris Hip Score.

Table 3 shows the differences in recorded parameters for both the CG and SG, along with their statistical significance before the first FM treatment (t0-t1), before the second treatment (t2-t3), and between the beginning and end of the study period (t0-t4).

Figure 3 shows the interpolation lines for flexion recorded in both SG and CG from t0 to t4. It can be observed that both groups show increasing slopes; however, the SG showed a steeper increasing slope and therefore greater improvement compared to the SG. A steeper increase was seen in the SG with a direct temporal relation (t0-t1 and t2-t3) to the FM treatment.

Table 4 shows the slope differences between the interpolation lines from the start to the end of the study. This table shows a higher inclination and therefore greater improvement in the group for which FM was added to standard care. The most important differences for all recorded parameters were observed on t0/t1 and t2/t3 after FM treatment was performed in the SG. The VNS on day 7 did not follow this trend, with the CG having a better improvement albeit minor compared to the SG.

Discussion

Two treatment sessions of FM associated with 17 sessions of a standard postsurgical rehabilitation spanning more than 10 days resulted in significant improvement in ROM, HHS score compared to 19 sessions of standard rehabilitation only. The null hypothesis was therefore rejected.

This is the first study to evaluate the effect of additional FM treatment on the functional improvement of patients with THA in the short term. In the hip joint, the work of Wojcik et al, although it lacked rigorous methodology, showed an increase in ROM, decreased VAS (or VNS), improved ADL, and decreased time to full functional recovery when implementing FM treatments.

Even in the presence of technically well-performed surgery, patients usually experience residual pain and limitations similar to the period before the intervention, especially in flexion, abduction, and external rotation [27]. The results of this study show a significant improvement in all outcomes, except VNS, after the first FM treatment in the SG compared with that in CG patients who followed the protocol for standard care of THA.

According to the outcome measures used in this study, the HHS is a validated instrument with good reliability and responsiveness for assessing hip surgery results [28]. It considers pain entity, functional activity, presence or absence of deformity, and articular ROM. FM treatment resulted in a significantly greater improvement in the SG, which may be directly correlated with the significant improvement of the observed ROM. Indeed, the HHS scale is based on ROM values, which showed a significant increase in the FM group. Moreover should be noted that, at baseline, the SG had a lower HHS score and therefore included patients with more limited abilities; however,

Table 3
Differences in outcomes between study group (SG) and control group (CG) at various points in time

Outcome	t0-t1 Mean (\pm SD)		t2-t3 Mean (\pm SD)		t0-t4 Mean (\pm SD)	
	SG	CG	SG	CG	SG	CG
Flexion	9.74 (\pm 6.60) <i>P</i> = .001	2.30 (\pm 8.01)	4.74 (\pm 4.48) <i>P</i> = .09	2.57 (\pm 3.91)	25.39 (\pm 11.34) <i>P</i> = .04	18.74 (\pm 9.54)
Abduction	4.83 (\pm 3.39) <i>P</i> = .009	2.13 (\pm 3.31)	5.00 (\pm 3.64) <i>P</i> < .0001	0.83 (\pm 1.61)	16.83 (\pm 6.95) <i>P</i> = .005	11.09 (\pm 6.15)
Extension	5.39 (\pm 2.69) <i>P</i> = .001	2.39 (\pm 2.78)	4.22 (\pm 3.84) <i>P</i> = .002	1.00 (\pm 2.54)	16.17 (\pm 4.89) <i>P</i> < .0001	9.35 (\pm 3.84)
External rotation	4.39 (\pm 3.41) <i>P</i> = .05	2.26 (\pm 3.67)	2.70 (\pm 3.62) <i>P</i> = .03	0.70 (\pm 2.38)	11.65 (\pm 4.71) <i>P</i> = .11	8.91 (\pm 6.51)
Bilateral hip flexion and external rotation with heels together	4.24 (\pm 4) <i>P</i> = .002	1.54 (\pm 1.86)	1.87 (\pm 1.71) <i>P</i> = .02	0.86 (\pm 0.87)	8.33 (\pm 4.29) <i>P</i> = .04	5.54 (\pm 4.61)
TUG	5.19 (\pm 4.65) <i>z</i> = .02	1.83 (\pm 5.02)	2.14 (\pm 2.58) <i>z</i> = .41	1.57 (\pm 1.94)	15.66 (\pm 9.93) <i>z</i> = .34	12.68 (\pm 11.00)
VNS	0.61 (\pm 1.20) <i>z</i> = .18	0.17 (\pm 0.89)	0.09 (\pm 0.29) <i>z</i> = .70	0.13 (\pm 0.69)	1.09 (\pm 2.15) <i>z</i> = .51	0.48 (\pm 1.12)
HHS	5.78 (\pm 6.40) <i>z</i> = .002	1.76 (\pm 3.48)	1.93 (\pm 2.93) <i>z</i> = .001	0.49 (\pm 1.33)	23.25 (\pm 8.91) <i>z</i> = .002	14.48 (\pm 8.48)

SD = standard deviation; VNS = verbal numeric scale; TUG = Timed Up-and-Go; HHS = Harris Hip Score.

this trend was inverted when care was added. The results show that, in regard to most outcomes, statistical significance was reached in the SG. It could be considered that the effect of FM would be greater if corrective statistics had been performed. The TUG has a good predictive value for the functional recovery of patients following THA. TUG variations were significant at t1 but did not show significance after that time. This may be explained by the use of auxiliaries (crutches) to help ambulation so as to decrease excessive weight bearing on the operated limb but slowing down normal ambulation.

Other factors that might have limited improvement in the TUG include postsurgical connective tissue trauma and longer time needed to reintegrate a correct ambulation pattern after surgery. The VNS, even though it is considered a valid instrument to measure outcome [29], was found to be irrelevant in this study. The effects of analgic protocols may explain the low initial and final values reported. The inclinometer has good validity and reliability, as documented in the literature.

Significant improvements were observed between SG and CG on all outcomes except TUG (see above for

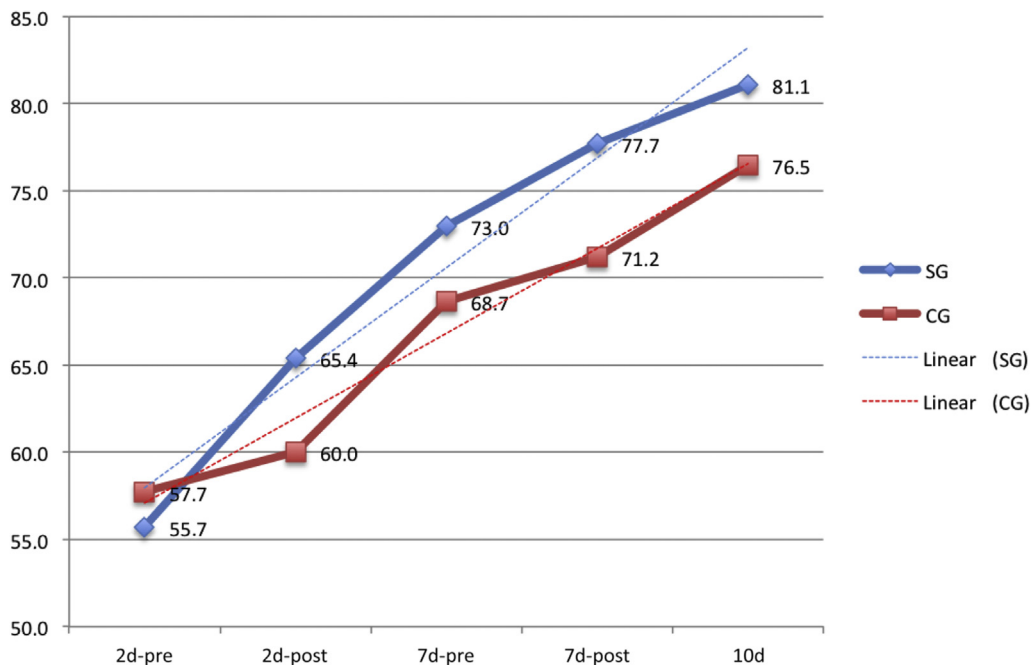


Figure 3. Interpolation lines for flexion: study group (SG) and control group (CG).

Table 4
Slope differences between the study group (SG) and control group (CG) at various points in time

	2d t0/t1	2d-7d t1/t2	7d t2/t3	7d-10d t3/t4	2d-10d t0/t4
HHS	4.10	0.70	1.50	2.50	2.20
TUG	3.40	-2.40	0.70	1.40	0.78
Flexion	7.40	-1.10	2.20	-1.90	1.65
Abduction	3.00	-1.00	5.00	-1.00	1.50
Extension	3.00	1.00	4.00	-1.00	1.75
Bilateral hip flexion and external rotation with heels together,	2.00	-1.00	1.00	0.00	0.50
External rotation	3.00	-2.00	3.00	-1.00	0.75
VNS	0.43	0.20	-0.04	0.00	0.15

d = days; HHS = Harris Hip Score; TUG = Timed Up-and-Go; VNS = verbal numeric scale.

explanation) and external rotation; statistical significance was not reached in the case of these parameters.

The most important improvement was observed after the first FM treatment; after the second and before discharge, the statistically significant improvement was a lower value. This study shows that interventions such as FM are able to improve joint movement and functionality in acute postsurgical patients, even though these patients had their functionality greatly decreased before surgery, and also to improve recuperation time after surgery. The immediate effect of additional therapy is shown by the increase in functionality observed on the same day as the FM treatment.

The biomechanical explanation of FM may explain the difference between groups. Fascia may present densifications [30] in which the normal gliding of this multilayered collagenous structure is impeded by aggregations (mainly hyaluronic acid) within the loose connective tissue; this affects its biomechanical properties. The hypothesis is that altered biomechanics of the fascia are able to influence muscular contraction and performance via their common anatomical connections [31,32]. This study supports this hypothesis, as it is assumed that the randomized design study provided equal distribution of potential confounding factors and that the improved outcomes (AROM and functionality) were directly correlated to the FM treatment.

This study does have several limitations. The results are applicable to patients with THA who meet all of the inclusion and exclusion criteria. Future research may be necessary to ascertain whether FM is a valid treatment option when using other criteria. Blinding of treatment allocation of patients, PTs for the CG, and PT B was not possible due to the nature of the interventions. However PT A, performing the assessments, was blinded with regard to therapy allocation, and PT C, performing the statistical analyses, was also blinded to group allocation. No sample size or number to treat was calculated, as no studies with similar designs were found in the literature. Follow-ups were not included in the study

design and were not performed; however further studies should include a follow-up period to help assess knowledge of long-term outcomes of FM in patients with THA.

Conclusions

This study indicates that the addition of FM to standard postsurgical care for THA can further increase the AROM in flexion, abduction, and extension of the operated hip compared to standard care alone. Functional outcomes such as the HHS also explain the difference in values between the SG to CG, whereas the TUG value was significant only for the first treatment.

The analgic protocols used in the hospital rehabilitation unit were most likely responsible for the lack of significant results observed for VNS values.

FM is therefore a valid form of manual therapy that may be implemented with a standard program to improve recovery of patients in the postsurgical period.

Furthermore, considering the recent international approach to decreasing the number of days of hospitalization following THA [33,34], a faster and more effective rehabilitation program needs to be applied. FM, because of its efficacy and the small number of treatment sessions required, can become a preferred treatment approach that can be used safely and can fulfill the aims of these new guidelines for THA rehabilitation.

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CME Question

In this study, what outcome measures showed statistical significance in improvements with the addition of 2 sessions of fascial manipulation to standard postsurgical care for total hip arthroplasty when compared to control group?

- a. External Rotation.
- b. TUG (Timed Up-and-Go).
- c. Flexion.
- d. VAS (visual analogue scale).

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