ORIGINAL RESEARCH

Efficacy of Fascial Distortion Model Treatment for Acute, Nonspecific Low-Back Pain in Primary Care: A Prospective Controlled Trial

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ABSTRACT

Context • Low-back pain (LBP) is a prevalent and potentially crippling condition for which treatment is often unsatisfactory from the perspectives of physicians, patients, and payers. The application of the fascial distortion model (FDM), an integrated concept for the diagnosis and manipulative treatment of musculoskeletal disorders, is conceptually promising for LBP but has not been investigated systematically.

Objective • The study intended to provide proof of concept to establish the noninferiority of the FDM treatment as opposed to the therapy recommended by the German National Disease Management Guideline (NDMG) for acute LBP.

Design • The study was a prospective, nonrandomized, controlled, parallel-group trial.

Setting • The study took place in a private practice for surgery and orthopedics.

Participants • Seventy-seven outpatients with acute LBP with an average age of 42.6 ± 13.5 y, 50.6% of whom were male, took part in the study.

Intervention • Participants in the intervention group (FDM group) received osteopathic manipulative treatments according to the FDM, whereas the control group (NDMG group) received an active control treatment following the NDMG.

Outcome Measures • Comparing the FDM group (n = 39) and the NDMG group (n = 38), the study measured pain (visual analog scale, patient diary), functional (FFbH-R) and self-reported vocational status, and use of medication (patient diary) at baseline and after 1, 4 and 12 wk of treatment.

Results • The study found marked improvements of the symptoms in both groups, with a faster onset of efficacy and significantly less medication under the FDM treatment.

Conclusions • FDM appears to be effective with regard to pain relief and functional improvement for LBP. (*Altern Ther Health Med.* 2017;23(5):24-32)

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Nonspecific low-back pain (LBP) is a prevalent and potentially disabling condition that causes a substantial economic burden due to direct and indirect costs. Irrespective of regional and social differences, expenditures for diagnosis and treatment as well as loss of productivity and disability payments are significant,[1] and the indirect costs outweigh the direct costs by a substantial margin, rendering more effective treatment modalities economical even if they are more expensive in the short term.[2,3]

A broad range of treatment modalities for acute and chronic LBP is available, comprising a variety of pharmaceutical, physical, interventional, surgical, and psychological methods, and, clearly, one therapy that fits all patients does not exist. The broad choice of treatment options does not remotely imply that an effective and tolerable, let alone economical, choice is available for everybody; on the contrary, many patients deal

Table 1. Definitions of Fascial Distortions and Their Symptoms and Signs

Distortion	Definition	Body Language	Subjective Description
Trigger band	Twisted, banded fascia	Finger sweeping along a painful line	Burning/dragging pain
Herniated trigger point	Protrusion of tissue through a fascial layer	Finger, thumb, or knuckle pressed into the affected area	Dull pain
Continuum distortion	Alteration of a transition zone between bone and tendon or ligament	Finger points at a painful spot	Pain at a circumscribed point
Folding distortion	Three-dimensional alteration of fascial tissue, mostly joint capsule, interosseous membrane, or intermuscular septum	Extremities: 1. Clasping of a joint with the hand or placing a hand on the joint (unfolding) 2. Sweeping motion with hand or finger across joint (refolding) Trunk: Laying on of the hand	Pain deep within the spinal column
Cylinder distortion	Torsion of circular superficial fasciae of the cylinder fascia	1. Repeated kneading or massaging of the affected tissue 2. Broad sweeping of the hand over a larger painful area	Deep-seated pain, tingling, numbness, or temperature sensations
Tectonic fixation	1. Loss of sliding ability of fascial surfaces 2. Loss of quantity and quality of synovia	Low-back pain: 1. Placing hands over iliac crest 2. Twisting or jerking torso In general: Moving joint with great force	Stiffness

with severe and crippling pain despite the best efforts of their physicians and a sizeable armament of diagnostic and therapeutic measures.

The choice of the most appropriate treatment depends on the patient's age, history of illness, and somatic and psychological comorbidities as well as the personal preferences of the patient and therapist; however, the treatment should not be chosen arbitrarily but should be based on the best available evidence.

The assessment of the available evidence, however, is a major task in itself; a plethora of randomized controlled trials (RCTs) and systematic reviews exist, and little robust evidence is available beyond the efficacy of analgesics and strengthening physical therapy. Therefore, treatment algorithms should be derived from evidence- and consensus-based guidelines, such as that provided in the German National Disease Management Guidelines (NDMGs)[4]; the joint clinical practice guideline from the American College of Physicians and the American Pain Society[5]; and the European guidelines for the management of acute, nonspecific LBP in primary care.[6] The results of novel treatment modalities should be evaluated using the guideline-adherent therapy as a benchmark.

Osteopathy and manipulative treatment of LBP has gained some interest in the past decade[7-12]; however, it is difficult to judge the merits of the approach due to the variety of methods and the overall scanty evidence. Therefore, the therapist needs to establish the efficacy and safety of a given method by appropriate research.

One relatively novel method of manipulative diagnosis and treatment is the fascial distortion model (FDM), developed by the American osteopath Stephen Typaldos.[13-16] It is based on the concept of the fasciae as sensitive, pain-permitting organs[17-19] and uses the patient's body language as an indicator of the underlying functional disturbance as well as guidance for the appropriate manipulative treatment. The FDM decodes categorized manual gestures (ie, pain-related body language) to 6 pathophysiological mechanisms involved in the etiology of pain (Table 1).[16] The treatment is subsequently guided by those nonverbal expressions.

The intervention mainly consists of high-velocity and low-amplitude manipulations, so-called thrusts, of the affected joints, and specific massaging procedures at the surrounding connective tissue.[20] Those procedures are based on the concept of a maladaptation of the crosslinks along the subcutaneous fasciae and a subsequent tension-free readaptation after manipulation.

Two of the most prevalent gestures in patients with LBP indicate distortions, called the *herniated trigger point* and the *trigger band*.

Herniated Trigger Point. The patient's symptom is a dull pain in the gluteal region or the trigonum lumbale. Typically, as the sign of the condition, the patient presses his or her thumb or the knuckle of a finger into the area affected by the pain, and that pressure causes some relief, which, however, is only transient. The therapeutic solution is to follow the patient's body language and apply increased pressure in the same area. The pressure is held until the patient experiences relief (ie, after approximately 2 min). The relief is often lasting, and the patient may not require further treatment.

Trigger Band. As the sign of the condition, the patient makes a sweeping motion with 1 or more fingers along an imaginary, painful, linear pathway. In LBP, that pathway typically starts in the paravertebral region of the thoracolumbar spine and extends over the gluteal region to the lateral or dorsal thigh. The fascial band is treated with a sweeping motion of the tip of the thumb that follows the imaginary line

shown by the patient. The intervention typically loosens the restrictions of motion often associated with LBP. Patients often perceive the intervention as rather painful but report quick and substantial relief shortly afterward.

Systematic clinical trials of the FDM are scarce[13,21,22] but indicate efficacy that is superior to that of a placebo. The only comparative study published so far found the FDM to be more efficacious than conventional manipulative treatment in patients with frozen shoulders.[21]

The application of the FDM in LBP is therefore promising but has not been systematically investigated. The present study is a prospective, nonrandomized, controlled, parallel-group trial intended to provide proof of concept to establish the noninferiority of the FDM treatment compared to the NDMG-guided therapy for acute LBP.

The study's nonrandomized design is due to the complex nature of the patient-therapist interactions in FDM, as in all other manipulative methods of treatment. A reliable randomization would have required sample stratification according to a number of criteria, and, consequently, the required sample size would have been prohibitive for an early-phase evaluation of the method. A successful demonstration of noninferiority against the conventional guideline-adherent treatment might be a rational basis for a future RCT.

MATERIALS AND METHODS

Participants

The study took place in a private practice for surgery and orthopedics of 1 member of the research team. The participants were recruited at that private practice between July 2012 and December 2013.

To be included, prospective participants needed to be (1) seeking treatment at the investigator's private practice for acute, nonspecific, LBP of up to 2 weeks in duration; (2) aged older than 18 years; (3) able and willing to understand the trial's purpose and to communicate with the investigator; and (4) willing to provide written informed consent for participation after detailed information about the purpose and methods of the study.

Prospective participants were excluded if they (1) showed signs of inflammatory and/or rheumatic spinal diseases; (2) showed signs of anatomical alterations such as spondylarthritis or hereditary malformations; (3) had had traumata or operations of the pelvis, hip, or spine within the 3 months prior to enrollment; (4) had neurological diseases or signs of nerve compression; (5) had spinal hypermobility or instability; (6) had clinically significant arthritis; (7) had malignancies; (8) had coagulation disorders; or (9) were pregnant.

Upon visiting the clinic, eligible patients were informed about the study's design and about the potential benefits and risks of the 2 treatment alternatives. Only patients who did not express a preference between the FDM- and the NDMG-based treatment were enrolled.

Of 483 patients who called the practice for an appointment during this period, 224 were excluded because of complaint duration in excess of the prespecified 2-week threshold. A total of 181 of the remaining 259 patients met 1 of the exclusion criteria, most frequently because of longer pain duration upon close scrutiny (n = 80) or signs of specific causes of back pain (eg, inflammatory or rheumatic signs, disc herniation, lumbar fractures; n = 67). One patient was lost to follow-up after the first intervention, leaving 77 patients for evaluation.

The choice of treatment by the investigator was sequential (ie, the first 38 patients who were eligible and provided informed consent to participate were treated according to NDMG and the latter half according to FDM).

Patients were stratified for age, gender, and crude prognosis assessment (ie, the presence of LBP in the 12 months before enrollment and their functional capacity)[24] to provide sufficient sample sizes for pertinent subgroup analyses.

The study's materials and methods are reported according to the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement.[23] The study's protocol was approved by the ethics committee of the Medical School Hanover (approval No. 5846).

Procedures

Patients' statuses were evaluated at baseline and after 1, 4, and 12 weeks of treatment. At baseline only, the research team recorded the anamnestic duration and intensity of symptoms for the patient and his or her previous incapacitation(s) related to work. At 1, 4, and 12 weeks of treatment, the research team measured the primary, coprimary, and secondary outcome endpoints described in the following.

The primary endpoint for the efficacy analysis was the percentage of patients who were completely free of symptoms at the final examination. The coprimary endpoint was the percentage of responders at 1, 2, and 12 weeks after treatment onset.

The following parameters were analyzed as secondary endpoints: (1) pain-free range of motion of the spine—finger-floor distance and lateral flexibility; (2) incapacitation related to work in days; (3) use of analgesics, including frequency and dosage; (4) frequency of specialist consultations; and (5) pain scores according to the patient diaries

Interventions

Patients in the intervention group (FDM group) were treated according to the FDM once per week for a prespecified maximum of 4 weeks, which was, however, not fully exploited due to early treatment response. In addition to the FDM treatment, the patients were allowed to receive all required guideline-conformant modalities, such as analgesic medications, topical applications, and active exercises. To provide specific information on the FDM's efficacy, all concomitant interventions were meticulously recorded, and both treatment arms were statistically controlled for possible confounding effects of those interventions. Patients with a persistent treatment demand beyond the 4 weeks of the intervention or with 6 weeks of symptoms were classified as nonresponders.

The active control treatment was performed according to the German NDMG[4] and included all modalities recommended therein with the exception of FDM treatment. The recommendations herein are derived from international guidelines and are mostly identical with those given in pertinent American[5] or European[6] guidelines. Accordingly, the treatment included the following interventions in varying, patient- and investigator-driven combinations: (1) analgesic and anti-inflammatory pharmacotherapy, (2) active exercises, instead of immobilization, (3) thermotherapy, and (4) relaxation/psychoeducation.

Like for the intervention group, all treatments were recorded, and patients with persisting treatment demands beyond the 4 weeks of therapy or 6 weeks of symptoms were deemed nonresponders.

Outcome Measures

The study protocol and study report include a number of outcome criteria for further analysis (eg, subjective experience of the treatment, current complaints, FABQ[26]) that are not referred to in this study.

Absence From Work. This measurement was self-reported and expressed in days of work missed by the participant. Each reporting opportunity collected only those days missed since the participant's most recent visit to the clinic.

Physical Examination. In the examination, the research team measured the finger-floor distance (in maximal pain-free anteflexion) and the Schober sign, both in centimeters.

Hanover Functional Ability Questionnaire. The questionnaire provided a score of a patient's functional capacity. It was specifically developed for LBP.[25]

Pain Intensity Questionnaire. The study measured pain on a 10-cm visual analogue scale (VAS) with a range between 0 (no pain at all) and 10 (excruciating, unbearable pain). A reduction of 33% in pain intensity was employed as a threshold for response analyses.

Patient Diaries. These included pain, medication, interference with activities of daily living and sleep. Patients recorded pain intensity (VAS) and any intake of analgesic agents (with substance and dosing) as well as interference of their back pain with activities of daily living and sleep in a diary throughout study duration.

Statistical Analyses

The required sample size for the present trial was calculated based on a noninferiority hypothesis with respect to the endpoint of chronification of the acute LBP (ie, persistence of symptoms beyond 3 months after the onset of treatment). A difference of 10% regarding that endpoint was considered clinically meaningful and socioeconomically relevant[29] and, thus, was chosen as the predefined difference (D) for the statistical testing for noninferiority. However, due to the very low risk of side effects for the FDM treatment in the previous experience of the research team, an extension of the noninferiority margin to 20% was considered acceptable and approved by the ethics committee.

Sample-size calculations were based on that wider range of noninferiority and yielded a minimum of 34 patients per group, with $\alpha = .05$ and a power of 80%. Statistical testing of metric and discrete parameters for significance was performed employing established nonparametric methods, with $P < .05$.

The outcomes for the intervention were statistically tested for noninferiority in comparison with the therapy that followed the NDMG.[4] Efficacy limits for primary and secondary endpoints were chosen according to published studies versus a placebo, and statistical testing for noninferiority was performed according to the Consolidated Standards of Reporting Trials (CONSORT) methodical principles.[30,31]

RESULTS

Baseline

Seventy-seven outpatients, 38 females (49.4%) and 39 males (50.6%), participated in the trial. Their mean age was 42.6 ± 13.5 years, with a range from 19 to 75 years, and the patients were on average slightly overweight, with a mean body mass index (BMI) of 26.4 ± 5.2 and a range from 18.5 to 43.9. Patients in the 2 treatment groups showed no significant differences with respect to sociodemographic and baseline data (Table 2).

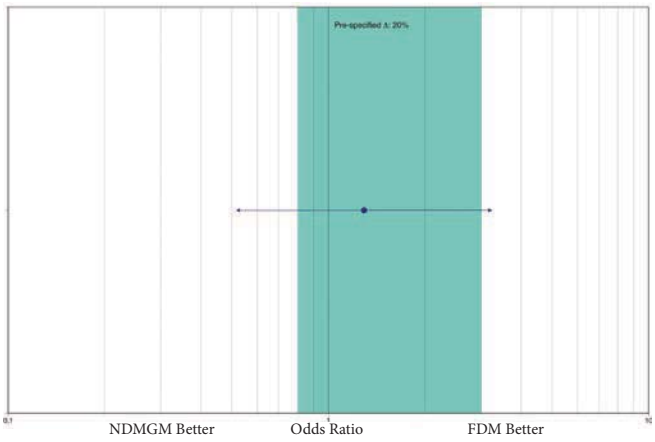
After the start of treatment, follow-up examinations were performed at approximately 1 week, with a mean of 7.5 ± 2.9 days (T2); at approximately 4 weeks, with a mean of 30.4 ± 4.2 days (T3); and at approximately 12 weeks, with a mean of 86.7 ± 6.7 days (T4) after the initial evaluation, and no significant group differences existed regarding the time between treatment and assessment. The slight deviations of the actual assessment date from exactly 1, 4, and 12 weeks were owing to practical considerations (public holidays, appointment availabilities, etc) in the private practice study setting.

Table 2. Participants' Baseline Data

Parameter	All Participants N = 77	FDM Group N = 39	NDMG Group N = 38
Age, y			
Range	19 to 75	19 to 75	20 to 69
Mean ± SD	42.6 ± 13.5	40.3 ± 14.8	45.0 ± 11.8
Gender, n (%)			
Male	39 (50.6%)	20 (51.3%)	19 (50.0%)
Female	38 (49.4%)	19 (48.7%)	19 (50.0%)
BMI			
Range	18.5 to 43.9	18.5 to 37.3	19.4 to 43.9
Mean ± SD	26.4 ± 5.2	25.5v± 4.7	27.4 ± 5.6
Duration of acute pain, days			
Range	1 to 18	1 to 18	1 to 14
Mean ± SD	6.9 ± 4.4	6.6 ± 4.3	7.3 ± 4.5
Pain within the past 12 mo, n (%)	63 (81.8%)	34 (87.2%)	29 (76.3%)

Abbreviations: FDM, fascial distortion model; NDMG, German National Disease Management Guideline; SD, standard deviation; BMI, body mass index

Figure 1. Results of Statistical Testing for Noninferiority of the Primary Endpoint



Note: The endpoint had a prespecified Δ requiring 10% or 20% of patients to be completely symptom free at the end of observation, respectively. If the lower 95% confidence interval would have been within the green area (depicting the more "generous" 20% interval), noninferiority would have been demonstrated. Both intervals were prespecified and tested, but only the 20% interval is shown in the figure.

Abbreviations: NDMG, German National Disease Management Guideline; FDM, fascial distortion model.

Primary Endpoint

Overall, 38 of the 77 patients (49.4%) were completely free of symptoms at the time of the final examination at 12 weeks after initiation of the treatments (Table 3). The primary endpoint was met in 20 of the 39 patients (51.3%) in the FDM group and in 18 of the 38 patients (47.4%) in the NDMG group (odds ratio [OR], 1.29; 95% confidence interval [CI], 0.52 to 3.21), with the difference not being statistically significant. Statistical testing for noninferiority with a prespecified Δ of 20% yielded an inconclusive result with regard to the primary endpoint (Figure 1).

According to the primary response criterion of ≥33% pain reduction on the VAS, the FDM group consistently scored slightly better than controls, but the difference was statistically not significant throughout the observations.

Secondary Endpoints

The evaluation of participants' pain diaries showed that their complaints—pain intensity and frequency, impairment of activities of daily living, and interference with sleep—declined in both groups, but the improvements occurred noticeably faster under FDM when compared to the NDMG-guided treatment. The differences were not statistically different and diminished beyond the first week, so that toward then end of observation, both groups showed more or less identical behavior. A slow further improvement of the aforementioned complaints occurred until approximately week 6, after which the patients' statuses remained largely

Table 3. Outcome of Primary and Selected Secondary Endpoints

Parameter	All Participants N = 77 Mean ± SD	FDM Group N = 39 Mean ± SD	NDMG Group N = 38 Mean ± SD
Freedom from symptoms at 12 wk after treatment onset, n (%)	38 (49.4%)	20 (51.3%)	18 (47.4%)
Response after, n (%)			
1 wk	71 (92.2%)	37 (94.9%)	34 (89.5%)
4 wk	76 (98.7%)	39 (100.0%)	37 (97.4%)
3 mo	75 (97.4%)	39 (100.0%)	36 (94.8%)
Finger-floor distance (cm)			
baseline	35.4 ± 21.5	34.1 ± 22.8	36.7 ± 20.4
after 1 wk	13.9 ± 12.2	13.9 ± 13.9	13.9 ± 10.4
after 4 wk	9.0 ± 10.0	8.7 ± 12.0	9.3 ± 7.6
after 3 mo	8.9 ± 12.5	10.1 ± 12.6	7. 7 ± 12.4
Schober sign (cm)			
baseline	1.92 ± 0.66	1.95 ± 0.65	1.89 ± 0.69
after 1 wk	3.00 ± 0.73	2.87 ± 0.66	3.13 ± 0.78
after 4 wk	3.22 ± 0.74	3.21 ± 0.74	3.23 ± 0.75
after 3 mo	3.88 ± 0.80	3.18 ± 0.68[a]	3.59 ± 0.86[a]
FFbHR (%)			
baseline	60.5 ± 22.9	61.5 ± 20.6	59.5 ± 25.3
after 1 wk	78.6 ± 17.7	77.2 ± 19.4	80.0 ± 15.9
after 4 wk	85.5 ± 16.0	85.7 ± 17.3	85.3 ± 14.6
after 3 mo	87.7 ± 15.6	86.3 ± 16.2	89.1 ± 15.0
Inability to work (d)			
baseline	1.81 ± 3.34	1.41 ± 3.23	2.21 ± 3.44
after 1 wk	2.51 ± 4.68	1.97 ± 4.51	3.05 ± 4.85
after 4 wk	2.99 ± 5.84	2.38 ± 5.09	3.61 ± 6.52
after 3 mo	3.26 ± 5.91	2.69 ± 5.23	3.84 ± 6.56

[a] $P < 0.05$ for comparison between groups

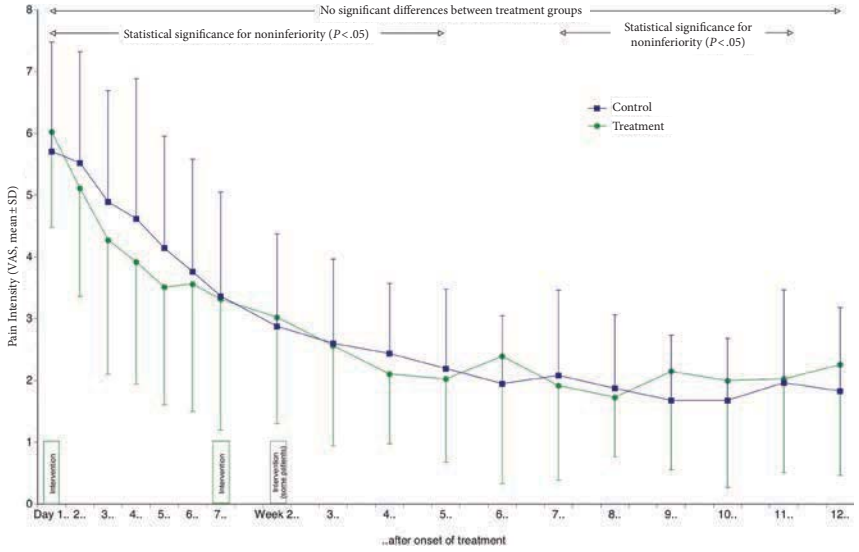
Abbreviations: FDM, Fascial Distortion Model; NDMG, German National Disease Management Guideline; SD, standard deviation; FFbHR, Hanover Functional Ability Questionnaire

Table 4. Number of Participants Taking NSAIDs and Ibuprofen Doses During the First Week

Parameter	All Participants N = 77 N (%)	FDM Group N = 39 N (%)	NDMG Group N = 38 N (%)	*P* Value
Ibuprofen				
Intake	67 (87.0%)	33 (84.6%)	34 (89.5%)	.737
Dose, mg/7 d, mean ± SD	7746 ± 3245	6872 ± 3523	8594 ± 2813	.052
Additional analgesic or anti-inflammatory medication for the 67 patients taking ibuprofen	10 (14.9%)	3 (9.1%)	7 (20.6%)	.305
Other analgesic or anti-inflammatory medication for the 10 patients not taking ibuprofen	3 (30.0%)	2 (33.3%)	1 (25.0%)	1.000

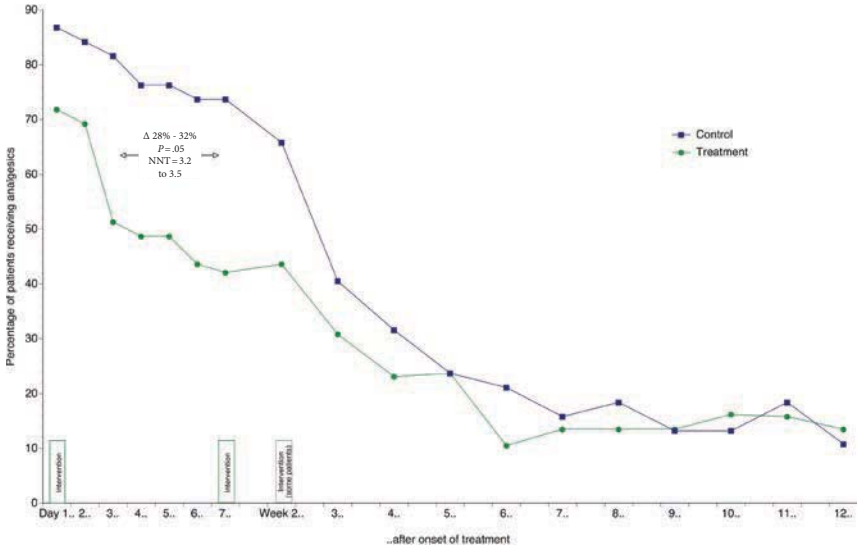
Abbreviations: NSAIDs, nonsteroidal anti-inflammatory drugs; FDM, fascial distortion model; NDMG, German National Disease Management Guideline; SD, standard deviation.

Figure 2. Pain Intensity on a VAS During Observation of Use of FDM Therapy and an NDMG-adherent Control Treatment



Abbreviations: VAS, visual analogue scale; FDM, fascial distortion model; NDMG, German National Disease Management Guideline; SD, standard deviation; FFbHR, Hanover Functional Ability Questionnaire.

Figure 3. Percentage of Patients With Analgesic Medication During the First Week of FDM Therapy and an NDMG-adherent Control Treatment



Abbreviations: FDM, fascial distortion model; NDMG, German National Disease Management Guideline; NNT, number needed to treat.

unchanged. No recurrence of complaints was observed within the observation period.

As an example, Figure 2 shows the VAS values for pain intensity in both groups. Between days 2 and 5, an appreciable, albeit insignificant, difference was found in favor of the patients under FDM treatment that then evened out from day 6 onward. More important than that slight difference was the fact that statistical testing yielded results showing noninferiority with regard to pain intensity, with a prespecified Δ of 1 cm, for all but 2 points of observation, with the latter 2 points of observation being inconclusive.

Analysis of further secondary endpoints such as analgesics demand confirmed the assessment derived from the remission/response and pain analyses. The faster onset of effects under FDM therapy became evident when the analgesic medication was studied (Table 4). Between day 3 and week 2, significantly fewer patients in the FDM group required analgesics and/or nonsteroidal anti-inflammatory drugs (NSAIDs). The difference was consistently in the order of magnitude of one third (ie, if 3 to 3.5 additional patients had been treated with FDM, 1 of them would have been able to cease medical treatment completely). See Figure 3. More specifically, Table 4 shows the number of patients under ibuprofen medication, a standard NSAID in NDMG-guided treatment, with the administered doses. The proportion of patients under medication was largely equivalent, with the patients under FDM requiring an appreciably smaller amount, and the difference of approximately 1700 mg/week only just failing to be statistically significant.

Functional parameters in Table 3 confirmed the tendency toward slightly better results for the FDM, largely without statistical significance. However, the consistent observation of a difference of approximately 1 day of incapacitation related to work might be economically, if not statistically, significant.

Influence of Baseline on Outcomes

Because of the very high percentage of patients who met the coprimary endpoint of response to treatment, the analysis of possible confounding factors did not promise to be informative and was therefore omitted. The results of the logistic regression for the primary endpoint of freedom from symptoms at 12 weeks after treatment are shown in Table 5. None of the baseline parameters showed a significant influence on the outcome in the multifactorial testing, and in particular, no tendency existed at all indicating a detrimental influence for patients with more severe symptoms at baseline. The tendency toward a slightly better outcome after FDM treatment was confirmed, with a 14% difference in the OR, and younger patients, females, and patients without pain within the 10 months

Table 5. Influence of Baseline Parameters on Treatment Outcome, the Primary Endpoint

		Unifactorial Evaluation		Multifactorial Evaluation	
Factor	**Group (unit)**	**Odds Ratio (95 % CI)**	***P* value**	**Odds Ratio (95 % CI)**	***P* value**
Treatment modality	FDM treatment	1.16 (0.47 to 2.86)	.73	1.14 (0.40 to 3.26)	.80
Gender	Male	2.20 (0.88 to 5.55)	.093	2.28 (0.80 to 6.51)	.12
Age	Per year	0.96 (0.93 to 1.00)	.048	0.97 (0.93 to 1.01)	.12
Duration of pain	Per day	0.97 (0.88 to 1.08)	.59	0.99 (0.88 to 1.12)	.93
Pain with the prior 10 mo	None	3.13 (0.87 to 11.2)	.081	3.10 (0.74 to 12.9)	.12
Pain upon diagnosis	Per unit VAS	0.96 (0.75 to 1.23)	.73	0.95 (0.71 to 1.28)	.75
FFbHR upon diagnosis	Per %	1.01 (0.99 to 1.03)	.57	1.00 (0.97 to 1.02)	.77

Abbreviations: CI, confidence interval; FDM, fascial distortion model; FFbHR, Hanover Functional Ability Questionnaire.

prior to enrollment fared slightly better than their respective counterparts.

Adverse Events

In addition to the known collateral effects of FDM treatment that were part of the consent form, such as pain and subcutaneous hematomas, no adverse events occurred in either group.

DISCUSSION

The unmet needs in the treatment of acute LBP are undeniable and substantial, both with regard to the individual patient's well-being and from a payers' perspective,[5] and, therefore, exploratory research such as presented in the present trial is well justified. Before the discussion of the present trial's results, the proof-of-concept character of the study has to be emphasized. The FDM as such has scarcely been investigated systematically,[21] and no evidence had been published on its application in LBP as of October 2015. Therefore, the current research team decided to gather some solid, albeit preliminary, evidence from a nonrandomized trial before launching a much more expensive RCT.

Against that background, the results of the present trial appear very conclusive, and the fact that the CONSORT-conformant test for noninferiority was inconclusive should not be given too much weight. In fact, although the primary endpoint could technically not be shown to be noninferior, the pain intensity for the intervention group on the VAS was noninferior at all but one points of assessment; moreover, the observation was confirmed with noticeably lower doses of analgesic medication being taken by the FDM patients. That observation is all the more remarkable because the patients were self-dosing the medication, (ie, taking it ad libitum) and the FDM intervention as such is rather painful in the short term. That pain might have prompted the patient to take the NSAID after treatment to alleviate the immediate effects.

Overall, the current research team's observations showed that the 2 examined interventions yielded a largely equivalent effect over the entirety of the observation period, but the beneficial effects occurred noticeably earlier in patients treated according to the FDM. It is remarkable that the same results—efficacy equivalent to established treatment but earlier improvement under FDM therapy—were observed in a study on use of the FDM for a frozen shoulder.[21] Even under full consideration of the methodological constraints of early exploratory research, that finding strongly indicates the ability of FDM treatment to exploit the individual patient's existing potential for quick and substantial improvement.

Moreover, the validity of those observations was underlined by a reduced demand for analgesic medication and by the fact that patients under the FDM treatment returned to work one day before their NDMG-treated counterparts. Although the difference was not statistically significant, again owing to the current study using a proof-of-concept design resulting in low statistical power, its economic effect may potentially be substantial. It is well established that absence form work causes the majority of the overall economic burden of LBP,[1,32] and a gross expenditure of €150 to €300 per sick-leave day can be estimated from data of insurers, hospital operating companies, and published pertinent evidence.[33]

German health surveillance is notoriously sketchy and unreliable, and pain syndromes especially are therefore difficult to quantify.[34] However, the data of the largest payer in Germany showed approximately one million sick-leave cases, at approximately 14 days of absence, in 2008.[35] According to those figures, a savings of €150 million per year would be attainable in that insured population alone, even based on the lower margin of the aforementioned estimate, and that is an order of magnitude in which a payer should certainly be interested. From an economic standpoint, the systematic application of FDM instead of NDMG-guided treatment might save substantial amounts if the data in the present trial could be validated by a further study, and funding of pertinent research could be in the best interests of all stakeholders involved.

The major principle of FDM is the common reflection of the course of injury and the therapist's evaluation of the patient's body language and clinical symptoms, which altogether can lead to a diagnosis and an exactly defined therapeutic consequence. Therefore, the patient participates as a director of her or his own treatment.

The exact mechanism of action of the FDM method is currently elusive. The originator of the method assumed an

influence on fibroblast activity, and, consequently, alterations of the extracellular connective-tissue matrix.[13-16] Whereas that model is reasonably plausible to explain a slowing of the progress of inflammatory alterations in the periarticular tissue of the spinal column, it is hardly a sufficient concept for the quick pain relief and mobility gains observed in the current study's participants as well as those with a frozen shoulder in the previously published study.[21]

A leading characteristic of the FDM treatment is the significant discomfort/pain that patients experience during the manipulation. In contrast to some simplistic assumptions, inflicting pain as such is not an effective means to treat it[36]; however, a body of evidence is emerging concerning the modulation of pain-signal transmission and processing through counterstimulation.[37,38] Results of clinical trials have indicated that so-called sham interventions that inflict physical stimuli without following proposed therapeutic principles can show some efficacy in LBP and other painful musculoskeletal syndromes[39-43] and, therefore, a powerful counterstimulation that activates gate-control mechanisms needs to be considered as one potential mode of action for the FDM treatment.

The results of the present trial require confirmation by further study and are thus to be treated as preliminary for the time being. It also needs to be pointed out that no sufficient basis exists for treatment recommendations that divert from those in the German NDMG or other international guidelines. However, the current research team believes that the results of the present trial provide a sufficient basis for open-ended discussions with patients who actively seek alternatives to the mainly pharmacotherapy-driven principles of guideline-adherent treatment.

To further solidify the current research team also considers the present results to be a sufficient basis for the planning of an RCT that compares the same treatment groups as the present trial did. Because it is virtually impossible to establish a credible placebo modality, with a proven lack of efficacy, for FDM treatment and because the present trial established its efficacy, the step of placebo-controlled efficacy testing can and should be omitted.

At the same time, neither patient nor physician can be blinded against the treatment given to a participant, and blinded evaluation by a noninvolved investigator can only partly eliminate potential pitfalls in RCT evaluation. Therefore, a future RCT needs to include potentially confounding parameters as stratification variables for randomization to avoid bias and yield meaningful results. Together with the required statistical power to demonstrate noninferiority or superiority compared to established treatment standards, an appropriate study design must involve a sizeable patient population and prolonged recruitment time due to stratification of randomization. Feasibility of such a study can and will be assessed based on the data from the present trial.

The present study is only the third clinical trial involving the FDM, and, therefore, its evidence is limited to a proof-of-concept of the method's efficacy. Future studies should reach beyond that point and elucidate the mechanism of action of the method more specifically. Presently, it is open to debate as to the extent that the efficacy of the FDM, which has been convincingly demonstrated in the present trial, is owing to the specific methodological principles of FDM treatment.

CONCLUSIONS

FDM was shown to be efficacious with regard to specific pain relief and functional improvement in patients with LBP, and its results were comparable with guideline-adherent treatment. The potential of FDM to become part of the standard armament of treatment modalities for LBP should be elucidated in further RCTs.

AUTHOR DISCLOSURE STATEMENT

The research team received no funding in relation to the study and has no conflicts of interest.

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