Journal of Bodywork & Movement Therapies 22 (2018) 112–117

Contents lists available at ScienceDirect

Journal of Bodywork & Movement Therapies

journal homepage: www.elsevier.com/jbmt

FASCIA SCIENCE AND CLINICAL APPLICATIONS: CRITICAL SURVEY: PERSPECTIVE STUDY

A fundamental critique of the fascial distortion model and its application in clinical practice

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ARTICLE INFO

Article history:
Received 23 January 2017
Received in revised form
18 July 2017
Accepted 19 July 2017

Keywords:
Fascial distortion model
Fasciae
Manual therapy
Reductionism
Typaldos
Validity

ABSTRACT

Introduction: The therapeutic techniques used in the fascial distortion model (FDM) have become increasingly popular among manual therapists and physical therapists. The reasons for this trend remain to be empirically explored. Therefore this paper pursues two goals: first, to investigate the historical and theoretical background of FDM, and second, to discuss seven problems associated with the theory and practice of FDM.
Materials and methods: The objectives of this paper are based on a review of the literature. The research mainly focuses on clinical proofs of concept for FDM treatment techniques in musculoskeletal medicine.
Results: FDM as a treatment method was founded and developed in the early 1990s by Stephen Typaldos. It is based on the concept that all musculoskeletal complaints can be traced back to three-dimensional deformations or distortions of the fasciae. The concept is that these distortions can be undone through direct application of certain manual techniques. A literature review found no clinical trials or basic research studies to support the empirical foundations of the FDM contentions.
Discussion: Based on the absence of proof of concept for FDM treatment techniques along with certain theoretical considerations, seven problems emerge, the most striking of which include (1) diagnostic criteria for FDM, (2) the biological implausibility of the model, (3) the reduction of all such disorders to a single common denominator: the fasciae, (4) the role of FDM research, and (5) potentially harmful consequences related to FDM treatment.
Conclusion: The above problems can only be invalidated through high-quality clinical trials. Allegations that clinical experience is sufficient to validate therapeutic results have been abundantly refuted in the literature.

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1. Introduction

Treating orthopedic and trauma patients using the manual therapy techniques of the fascial distortion model (FDM) has become increasingly popular among manual practitioners in general and physical therapists in particular (EFDMA, 2012; Typaldos, 2002) over the past few years. FDM is one of several types of fascial therapy; others include myofascial release (Chila, 2003; Ward, 2003), Rolfing (Rolf, 1977), and visceral manipulation (visceral osteopathy) (Barral and Mercier, 2005). Common to these therapies is that they all assign to fasciae a prominent role in the origin and persistence of a variety of complaints. The differences between these therapies can be found in the assertions made about them, and in their diagnostic and therapeutic procedures. The exact reasons for the recent high interest in FDM are a matter of speculation since, to date, no empirical studies have been conducted. It might be that FDM promises quick treatment success (EFDMA, 2012:23f.) and is relatively easy to apply?

The present paper should be viewed as a critical survey study on FDM. The focus is on seven problem areas associated with the theory and practice of the FDM manual therapy approach. The arguments will be based on a specific, systematic search of the literature on the clinical effectiveness of FDM treatment techniques.

2. Materials and methods

2.1. Literature review

Searches included the databases PubMed, The Cochrane Library, PEDro (Physiotherapy Evidence Database) and the research study

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http://dx.doi.org/10.1016/j.jbmt.2017.07.009
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register of the *World Health Organization International Clinical Trials Registry Platform* (WHO ICTRP, apps. who.int/trialsearch) and ClinicalTrials.gov up until 5 October 2016. In addition, the references given in all articles, relevant textbooks and FDM professional association websites were also searched for relevant sources. The fundamental PICO question for the literature review was: Have any clinical studies been conducted (in any patient subgroup) on the effectiveness of FDM as a treatment method for various musculoskeletal complaints? The keywords used in the searches are listed in Table 1.

Keywords within each box were linked by the Boolean operator OR and the contents of the three boxes were linked by the Boolean operator AND. No restrictions applied as to date of study or language of publication. The literature review focused on clinical studies on the effectiveness of FDM as a treatment method for various musculoskeletal complaints.

Since the present paper is not a systematic review, the results of the specific literature review are not presented in a PRISMA-type flowchart (Moher et al., 2009), but are instead directly incorporated into the text.

3. Results

3.1. Historical background and basic principles of FDM

The treatment method of FDM was developed and established in the early 1990s by US physician Stephen Typaldos, D.O. (1957–2006) (EFDMA, 2012:29ff). It has been taught in Europe by the *European FDM Association* (EFDMA) since 2006. Other professional associations include the *American FDM Association* (AFDMA) in the US, the *FDM Asian Association* (FAA) in Japan, and the *Société Africaine du Modèle de Distorsion Fasciale* (SAMDF) in Africa. Since the demise of its founder, no significant methodological advances have been made in FDM diagnostics or therapy (EFDMA, 2012; Typaldos, 2002). It is reasonable to assert that FDM methodology is based on expert assessment, rather than on external evidence.

FDM is rooted in the hypothesis that all musculoskeletal complaints can be traced back to three-dimensional deformation or distortion of a specific connective-tissue structure: the fasciae. Manual techniques applied directly to these distortions purportedly reverse them. Based on the published manual therapy literature (Chaudhry et al., 2008; Seffinger et al., 2004), this assumption must be considered biologically implausible. It is important to note that FDM therapy is usually intensely painful for patients.

3.2. Definition of the term 'fascia'

A serious discussion on this topic needs a common definition, especially since the term *fascia* is itself rather vague (Benjamin, 2009). Therefore any analysis of FDM first requires terminological clarification. Schleip et al. (2012a) compared three established nomenclatures that differ in regard to the scope of meaning of the term *fascia*, in which the *Federative International Committee on Anatomical Terminology* (FICAT, renamed in 2008) applies the strictest criteria, while the *Fascia Research Congress* has the broadest definition. For instance, the *Fascia Research Congress* includes the annulus fibrosus of spinal discs, along with tendons and ligaments and even the dura mater under the umbrella term *fasciae*, whereas the FICAT and the 40th edition of *Gray's Anatomy* both use narrower definitions. In *Gray's Anatomy*, for example, fascia is defined as "… masses of connective tissue large enough to be visible to the unaided eye" (Standring, 2008). This narrower definition of fascia comprises the sheaths of nerves and vessels, muscular septi, organ capsules and joint capsules, among other anatomical structures. Not included in the narrower definition are the fibers of the annulus fibrosus of spinal discs, tendons and ligaments as well as perimysium and endomysium (Schleip et al., 2012a,b). Each of these definitions has its advantages and drawbacks. Schleip et al. (2012a) recommend identifying the fascial structure in question as precisely as possible and then choosing from one of the three nomenclatures above in order to best meet the specified objective (e.g., for anatomical or therapeutic studies) (Langevin and Huijing, 2009; Schleip et al., 2012a; Stecco and Schleip, 2016). We may reasonably assume that these three definitions provide different perspectives on one and the same concept.

3.3. Diagnostics within the context of FDM

FDM therapists in clinical practice consider a detailed medical history to be of central importance, the main focus being on the body language ("signature presentation") with which patients communicate their complaints (EFDMA, 2012). By observing and differentiating the gestures patients use to specify their ailments, the attending physician or therapist can deduce to which of the six classes of 'fascial distortions' the symptoms belong: trigger bands, herniated trigger points, continuum distortions, folding distortions, cylinder distortions, and tectonic fixations. The issue of construct validity remains to be explored. That said, construct validity does not seem to be a priority among FDM practitioners (EFDMA, 2012:34) and therefore the diagnostic accuracy of the above classification system has not yet been evaluated either. One problem might be that there is no accepted reference test by which to independently verify the construct validity and clinical diagnostics of FDM. A number of different technical options have been pointed out, including high-resolution ultrasonography, real-time elastography, shear wave elastography, myometrics and bioelectrical impedance analysis (Klingler et al., 2014; Schleip et al., 2012a; Schleip et al., 2012b), but so far none of these has proven useful for verifying the construct validity and diagnostic accuracy of FDM diagnostic criteria.

Inter-rater reliability concerning these diagnostic criteria was analyzed in one master's thesis (Anker, 2011) and one bachelor's thesis (Stechmann, 2011), but neither study was published in a professional journal. Both used videos to check inter-rater reliability. While this is an elegant method to eliminate bias resulting from individual clinical interaction between FDM therapists and patients, it does not reflect the actual clinical situation. The external validity of video-based data on inter-rater reliability must therefore be regarded as low, so the values for inter-rater reliability found by Anker (2011) (κ overall index according to Siegel and Castellan of 0.51) and by Stechmann (2011) (κ coefficient of 0.61) are thus likely to be in fact even lower.

3.4. Controlled clinical studies on the efficacy of FDM

Fink et al. (2012) conducted the only published randomized controlled clinical trial to study the efficacy of FDM treatment. In this study, 60 patients with adhesive capsulitis of one glenohumeral joint were randomized to receive either four sessions of FDM treatment or four sessions of passive manual therapy over a

Table 1
Search table.

PICO	Keywords
Patients	adult*, child*, musculoskeletal
Intervention	"fascial distortion model", "fascial distortion", distortion, Typaldos, fascia*
Outcome	physical function, effect*, reliab*, valid*, pain, outcome

course of two weeks. All patients were assumed to be in the freezing (phase 1) or frozen stage (phase 2) of this condition. The primary outcome measure was pain-free, active abduction of the involved joint. Secondary outcome measures included pain (measured on a visual analogue scale) and function, using the DASH questionnaire and the Constant-Murley-Score. Both the primary outcome measure as well as pain were assessed at eleven different points in time. The study found that all endpoints showed improvement in both treatment groups. As the authors note, effects occurred faster and were more pronounced in the FDM group. However, major flaws were associated with this study: imprecise definition of inclusion/exclusion criteria, short follow-up period (6 weeks), lack of intention-to-treat analysis, and limited number of cases (n = 60).

Schulze et al. (2014) published a descriptive (non-controlled) before-and-after study. The study included 32 soldiers diagnosed with medial tibial stress syndrome. All participants received a variable number of FDM treatments on their crural fascia. FDM treatment was continued until full exercise tolerance or painlessness was achieved. The primary outcome measure was "painless exercise tolerance" (running and jumping). On average, participants received four treatment sessions. Pain was shown to be reduced in all subjects. 53% of participants were pain free at the end of the study whereas 60% could run 3.000 m without any complaints. The results of this study are at risk of significant bias due to serious quality issues such as the nonspecific method used for blinding endpoint assessors, attrition bias, extremely short follow-up period (<3 weeks) and lack of control group.

In addition, the efficacy of FDM for a variety of musculoskeletal indications was the focus of one doctoral dissertation (Stein, 2008) and several master's theses (http://www.fdm-europe.com/en_US/fdm/science/).

All of the clinical studies on FDM referenced above suffer from major flaws relating to their internal and external validity. Furthermore, Ellis (2012:110) points out that "[s]ome would even say that individual studies have no value at all except as data points in future meta-analyses (Schmidt, 1996). The implication of this extreme view is that authors of individual studies need not waste their time drawing conclusions or testing significance since these will be ignored by meta-analysts. While this view is certainly controversial, most would agree that meta-analysis provides the best means for generalizing the results of replication studies."

4. Discussion

A variety of theoretical reasons have been put forth to explain why FDM techniques *might* be effective, though none can consistently be linked with actual results to verify that they *are effective*. This section identifies seven issues that both FDM practitioners and clinical research on FDM must consider in order to justify widespread use of this treatment method in the clinical setting.

4.1. Seven issues associated with FDM

4.1.1. Issue #1: what is the therapeutic object?

Which of the fasciae (e.g. superficial fasciae, intramuscular fasciae, visceral fasciae, tendons) itemized by Langevin and Huijing (2009) and Schleip et al. (2012a) are being treated by FDM therapists? FDM practitioners should be capable of precisely specifying the fasciae that they intend to treat. It is not enough to name a therapeutic construct of questionable validity. If the object of therapy cannot be clearly identified, the competence of the practitioners is equally questionable. FDM therapists are usually rather vague about this and remain non-committal when asked to provide the exact anatomical location of the fascia they are treating (Schleip et al., 2012a). A good first step would be high-quality inter- and intra-rater reliability studies, especially verification of construct validity.

4.1.2. Issue #2: are the effects from FDM biologically plausible?

FDM does not appear to be biologically plausible. Three examples might serve to illustrate this assertion:

1. Some fasciae are very tight/hard, for which reason successful deformation through manual therapy is quite unlikely. For example, consider the compartment syndrome in the lower leg. These fasciae (intermuscular septa, Schleip et al., 2012a) are extremely firm, which means that in order for any manipulation to be achieved, adjacent muscles would be deformed, compressed, or even become necrotic. Nevertheless, FDM therapists claim that these fasciae (intermuscular septa) can be actively manipulated and thus "corrected" (EFDMA, 2012:194).
2. Other fasciae are so deeply situated that any manual manipulation would seem highly unlikely to succeed. Examples might include the interosseous membranes of the forearm and lower leg, or visceral fasciae deep within the body cavities (EFDMA, 2012).
   Current thinking holds that the probability of (a) even accessing these fasciae in a targeted manner through external pressure, and (b) deforming them in a desired direction must be considered to be extremely low (Chaudhry et al., 2008). Research on manual therapy has shown great variation in technique and the force applied by individual therapists (Harms and Bader, 1997; Levin et al., 2001; Seffinger et al., 2004; Simmonds et al., 1995), which is a fundamental problem.
3. FDM therapists claim that their methods can be used for causal treatment of pathologies for which there is no evidence so far that the fasciae are the main source of the complaints. Examples to be cited here include the treatment of bone fractures (EFDMA, 2012:43f.) and renal calculi (EFDMA, 2012:155).

4.1.3. Issue #3: reductionism 1—Is strict adherence to a biomechanical/structural paradigm justified?

FDM is based on a biomechanical/structural paradigm. However, it has not yet been established whether such a paradigm even makes sense for certain orthopedic problems that are alleged to be curable by means of FDM (Lederman, 2010; Moseley and Butler, 2015). In other words, there is no evidence that all musculoskeletal conditions are amenable to the laws of biomechanics and peripheral tissue pathology.

It will be no easy task over the next few years to ascertain what patient groups with musculoskeletal complaints do indeed primarily require a biomechanically/structurally oriented approach and for which patients a neurophysiological treatment (including a variety of psychotherapeutic methods) should take priority.

4.1.4. Issue #4: reductionism 2— how important are fasciae among organ systems? are fasciae the sole cause, or prime cause, of any musculoskeletal complaint?

FDM methodology attributes to fasciae a singular importance (EFDMA, 2012) which they do not possess. Anatomically, they are no more extraordinary than bones, muscles, or other tissues. While certain fasciae may have special functions, there is lack of evidence that they are of greater importance than other organ structures in any absolute sense. The argument that fasciae are especially important because they run through the entire body applies equally to other organ systems, such as the vascular, nervous, and lymphatic systems. This feature is not unique to the fascial system; for example, no angiologist would ever consider reducing all

disorders solely to vascular causes.

FDM seeks to reduce virtually all musculoskeletal complaints to fasciae (EFDMA, 2012), which is not only biologically implausible, but also potentially hazardous when such techniques are recommended for treatment of disorders such as neuropathic pain (EFDMA, 2012:154) or acute trauma (EFDMA:176; 202).

The approach of attributing all musculoskeletal complaints to a fascial cause calls to mind the "straight" philosophy that was historically prevalent among chiropractors; this original school of chiropractic also mistakenly believes that all disorders can be reduced to a single cause (in this specific case, it is not fasciae but "vertebral subluxations" that are viewed as "the root of all illness").

4.1.5. Issue #5: how does FDM address general logical concerns in structuring clinical/diagnostic research into musculoskeletal disorders?

The likelihood that a particular structure qualifies as a nociceptive generator in clinical practice depends on how many of Bogduk's four postulates are fulfilled (Bogduk, 2012:176):

1. Innervation;
2. Experimental induction of pain (in the fascia) in asymptomatic individuals;
3. Pathology;
4. Clinical induction AND/OR elimination of pain in individuals for whom the fascia has proven to be the nociceptive generator.

Bogduk (2012) posited these criteria in analogy to Koch's postulates for determining the cause of infectious disease (Koch, 1891).

4.1.5.1. Innervation. FDM therapists claim that fasciae play a key role in most if not all painful musculoskeletal conditions (EFDMA, 2012). In order for a structure to potentially be considered a nociceptive ("pain") generator, the structure must have nociceptive innervation, which has been demonstrated for several fasciae (Benjamin, 2009; Willard et al., 2012). However, too many unresolved issues remain to categorically state that all fasciae possess nociceptive innervation. The nonspecific presence of innervation is insufficient to conclude that clinical pain is produced.

There is no valid clinical test or reference test to identify a painful fascia, i.e. there is lack of evidence of appropriate diagnostic tests. However, there are highly specialized imaging methods for in vivo visualization of fasciae.

4.1.5.2. Experimental induction of pain (in the fascia) in asymptomatic individuals. The literature on this subject is sparse (Schilder et al., 2014, 2016). Studies show that the thoracolumbar fascia can be experimentally stimulated, but for other fasciae—using the narrower fascial classification criteria—no such studies are known.

4.1.5.3. Pathology. In a number of clinical situations, fasciae may indeed be involved in causing pain (Schleip et al., 2012b:ch.5), but the fascial distortions postulated by FDM proponents have yet to be demonstrated.

4.1.5.4. Clinical induction AND/OR elimination of pain in individuals for whom the postulated fascial distortion has proven to be the nociceptive generator. No such studies can be found regarding FDM.

4.1.6. Issue #6: is the transfer of results from basic research to the clinical setting justified?

In the context of fascial therapies, results from theory and basic research are frequently transferred to the clinical setting. Such transfer is not permissible since this strategy has often been shown to lead to false conclusions (Ioannidis, 2005; Guyatt et al., 2008:ch.9.2). An appropriate first step to rectify this situation would be to conduct randomized controlled clinical trials with appropriate long-term follow-up to verify whether FDM actually has a specific treatment effect. Only when such a specific effect has been discovered does it make sense to speculate about the plausible mechanisms of action underlying FDM treatment.

4.1.7. Issue #7: is it possible that painful manipulation of alleged fascial distortions contributes to the development, or maintenance, of pain related to central sensitization?

The theory of counterirritation, which states that pain relief can be achieved by applying a new painful stimulus, has been proposed to explain the effect of FDM treatment (Fink et al., 2012). This procedure stands in sharp contrast to traditional pharmacological approaches to pain management. Since no consistent proof has to date demonstrated that FDM treatment actually has a specific effect, there is no point in hypothesizing about its potential mechanisms of action.

A much higher priority, in light of its potential to cause patients harm, is the question of whether the nociceptive stimuli applied during FDM treatment promote development of central sensitization and whether this state is maintained in the central nervous system (Latremoliere and Woolf, 2009; Vierck, 2006; Woolf, 2011), but this question remains unresolved. Any direct test of this hypothesis through experimental intervention would be ethically unacceptable. Moreover, obtaining clinical evidence to support or refute this assumption would require considerably longer follow-up periods in clinical trials of FDM. Concerns regarding central sensitization could prove to be warranted, especially in patients with existing chronic pain (Moseley, 2012).

5. Conclusions

FDM has been in widespread use as a treatment method since the 1990s. Nonetheless, clinical trials to verify its efficacy have been few and far between, though some FDM therapists often promise amazing results. This paper addresses seven problem areas intended, on the one hand, to encourage contemplation and throw the unsubstantiated claims attributed to this comparatively new type of therapy into question. On the other hand, they might serve as suggestions for future studies on FDM treatment.

Manual therapy enthusiasts often hold that clinical trials and proof-of-concept studies are unnecessary since efficacy can be directly observed and patients provide reliable positive feedback on the effects they experience; however, the research literature has amply disputed this contention (Ernst, 2009; Grove, 2005; Sackett et al., 1991:174f.) and the relevant arguments need not be revisited here.

Indeed, some patients believe they really experience benefit from FDM treatment, but considering the seven problem areas addressed above any specific benefit from manual treatment of postulated fascial distortions must be called into question. The subjective changes attributed to FDM might well be due to nonspecific factors (Benedetti, 2009, 2011; Bland and Altman, 1994; Di Blasi et al., 2001; Ernst, 2009; Hall et al., 2010). Another explanation might be activation of neurophysiological modes of action caused by the experience of intense pain (see theory of counterirritation).

5.1. What is the solution to the problems stated above?

FDM as a treatment method for a variety of complaints currently relies more on anecdotal evidence than on external, controlled proof-of-efficacy studies. This does not mean that the clinical practice of FDM should be discontinued for the time being, since

the lack of evidence does not imply the non-existence of an effect. Therefore it is necessary to verify this treatment approach by means of methodologically sound clinical trials, attaching the highest priority to single-blinded, randomized controlled studies with sufficient numbers of subjects and long-term follow-up durations of at least one year. Careful documentation of any adverse events would be important as the FDM treatment, compared with other manual therapeutic procedures, involves direct application of substantial pressure to the patient, which is generally extremely painful. In addition, verification of the construct validity of the diagnostic criteria for FDM is needed, as is an independent assessment of inter- and intra-rater reliability. Research funding should not be wasted on studies of FDM that lack such high-quality methodology.

Conflict of interest

None.
This paper does not involve any studies on humans or animals.

Funding source

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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