Online version at http://www.minervamedica.it
European Journal of Physical and Rehabilitation Medicine 2017 August;53(4):630-1
DOI: 10.23736/S1973-9087.17.04732-3

Evaluation of fascial manipulation in carpal tunnel syndrome: a pilot randomized clinical trial

Dear Editor,

Carpal tunnel syndrome (CTS) is the most common nerve compression syndrome, accounting for 90% of all compressive neuropathies.[1] Despite its high incidence, CTS remains challenging to treat. Fascial manipulation (FM) [2] involves deep friction over specific points, namely the center of coordination (CC) and the center of fusion (CF), *i.e*., where the vector forces of the myofascial expansions of synergic muscles occur (Figure 1). This technique has demonstrated to reduce pain symptoms in other musculoskeletal conditions such as painful shoulder syndrome,[3] patellar tendinopathy [4] or post traumatic neck pain.[5] A recent study comparing FM to conventional laser therapy in CTS showed that FM had better effects than laser therapy on pain relief and disability of the upper limb.[6] However, there was no sham comparator, and therefore we cannot disentangle the effects of the intervention from a placebo effect. In the present pilot study, we aimed to assess the efficacy of FM applied over the CCs and CFs compared to a sham intervention that looks like FM but applied over other areas of the skin, in patients with CTS.

The study was approved by the Ethics Committee of the Institute of Physical Medicine and Rehabilitation, Sao Paulo, Brazil. Patients signed an informed consent according the Declaration of Helsinki. Registration number: NCT02495298. Fourteen women (age: 18-65 years old) were enrolled and completed the trial. Before starting the treatment, all patients received an educational program regarding appropriate behaviors to avoid upper limbs overuse or incorrect movements during daily activities together with an exercise program to complete at home. Medication was kept unchanged during the study protocol. Patients allocated to the FM group received 5 sessions of 30-45 minutes, 1 session per week for 5 weeks. The most dysfunctional CC's and CF's, in the hand, forearm, arm, chest, and neck, were submitted to a comparative palpation following the FM guidelines.[2] After the selection of the points, friction was applied for 2 to 4 minutes.[7] Patients allocated to the sham group received the exact same protocol except that the frictions were applied outside the points used in the FM method. Duration of treatment was equal in both groups. Clinical outcomes encompassed the Visual Analog Scale (VAS),[8] both the Symptom Severity Subscale (BS) and the Functional Status Subscale (BF) of the Boston Carpal Tunnel Questionnaire (BCTQ, Brazilian translation),[9] and the Disability of the Arm Shoulder and Hand (DASH) Scale.[10] All evaluations were performed at baseline (T0), ten days (T1) and three months after the last treatment session (T2). Electromyographic median nerve conduction velocity and latency were also recorded at T0 and T1. Patients and assessors were blinded from the allocated treatment. Patients were randomized into two treatment groups: Fascial Manipulation (N.=7) and sham manipulation (N.=7). We first used paired *t*-test to compare FM versus sham groups at the end of treatment for all assessments. The effect size (Cohen's *d* effect size) was calculated from the difference in values between baseline (T0) and post-treatment (T1) comparing FM with sham. We then conducted a one-way analyses of variance (ANOVA) to compared the longitudinal effect of treatment (real *versus* sham) on the absolute change (*i.e*., delta, which equals to post-treatment minus pre-treatment values) to account for baseline differences, at T1 (*i.e*., scores at T1 minus scores at T0) and at T2 (*i.e*., scores at T2 minus scores at T0). For every analysis, the significance level was set at $P<0.05$. Although this was a pilot study, we did estimate a sample size considering the results of a previous study.[6] Using an effect estimate of 0.91, α level at P=0.05, and power was of 80%, power analysis indicated that 7 participants per group would provide sufficient power.

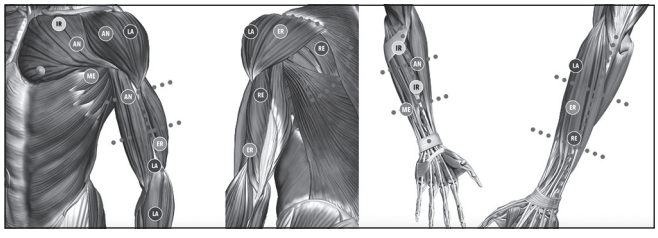

Figure 1.—Treated centers of coordination.
AN: antemotion; RE: retromotion; LA: lateromotion; ME: mediomotion; IR: intrarotation; ER: extrarotation.

No side effects were reported for any of the patients. Patients' baseline characteristics can be found in Supplementary Table I. When analyzing the main endpoint and comparing both groups, we found a significant difference at T1 for the BS (P=0.021; effect size: 1.04) and a trend for BF (P=0.051; effect size: 1.11). None of the other scales, neither electromyographic measurements, demonstrated any significant differences between the groups at T1 (Table I). When analyzing the longitudinal effects, we did not find a significant interaction for group *vs*. time for any of the scales (P>0.05) (Supplementary Table II).

Even considering this study as a pilot study, we identified a significant effect of FM in patients with CTS after 5 weeks of treatment. The effect size was also bigger than the one we expected (1.11 *versus* 0.91). These findings provide additional data supporting the efficacy of FM in improving CTS patients' symptoms. This technique has the advantage to be safe, with no adverse event and needs to be applied once a week. However, it should be underlined that the effects did not last over time. Therefore, further trials trying to optimize the methods and including a bigger sample size should

TABLE I.—*Results of the t-tests for the VAS, the BS and FB of the BCTQ, and the DASH.*

Variable	FM	Sham	t	P value	Cohen's *d* effect size
VAS T0	7.29±1.78	7.90±1.55	0.69	0.503	
VAS T1	2.50±2.18	3.71±1.25	-1.28	0.225	0.21
VAS T2	2.29±2.23	4.00±3.37	-1.12	0.284	0.35
BS T0	3.40±1.00	3.38±0.50	0.06	0.952	
BS T1	1.71±0.76	2.83±0.82	-2.65	0.021*	1.04
BS T2	1.94±0.89	2.56±00.66	-1.48	0.166	0.62
BF T0	3.46±0.99	3.29±0.44	0.43	0.672	
BF T1	1.75±1.14	2.86±0.74	-2.17	0.051†	1.11
BF T2	2.00±1.02	2.79±1.23	-1.29	0.219	0.79
DASH T0	66.96±10.02	51.79±24.40	-1.52	0.154	
DASH T1	40.17±29.94	53.57±17.25	1.03	0.325	0.55
DASH T2	40.17±33.24	45.53±32.41	0.30	0.765	0.15

VAS: Visual Analog Scale; BS: Symptom Severity Subscale of the Boston Carpal Tunnel Questionnaire (Brazilian translation); BF: Functional Status Subscale of the Boston Carpal Tunnel Questionnaire (Brazilian translation); DASH: Disability of the Arm Shoulder and Hand Scale.
*Significant P value (>0.05); †trend to significance (P=0.051).

be performed. Interestingly, the BCTQ was the only measurement able to capture a difference between the real and the sham interventions. Overall, this scale can be considered as the most accurate questionnaire that reflects patients' improvement. As compared to the VAS and the DASH, the BCTQ requires more objective reports (*e.g.*, by giving specific tasks to evaluate) from patients and therefore, is less likely to be affected by patients' expectations.

In conclusion, the results of this pilot study do underscore the need to perform randomized clinical trials to understand the real effect of FM. Although results were positive, they do need to be replicated in larger studies. Further clinical trials should also power the study to detect long lasting effects. In this trial, the effect sizes at T2 for BS and BF were 0.62 and 0.79 respectively; thus, larger clinical trials should consider smaller effect sizes when designing the protocol. We also suggest that BCQT may be the best outcome to detect the effects of FM in patients with CTS.

Marco PINTUCCI [1], Marta IMAMURA [2] *, Aurore THIBAUT [3], Lucas M. de EXEL NUNES [4], Mylene MAYUMI NAGATO [1], Helena H. KAZIYAMA [1], Satiko TOMIKAWA IMAMURA [1], Antonio STECCO [5], Felipe FREGNI [3], Linamara RIZZO BATTISTELLA [2]

[1]Center for Clinical Research, Institute of Physical Medicine and Rehabilitation, Hospital das Clínicas, São Paulo, Brazil; [2]Department of Legal Medicine, Medical Ethics, Social and Occupational Medicine, Medical School, University of São Paulo, Brazil; [3]Neuromodulation Center, Spaulding Rehabilitation Hospital, Harvard Medical School, Boston, MA, USA; [4]Electrophysiology Clinic, Institute of Physical Medicine and Rehabilitation, Hospital das Clínicas, São Paulo, Brazil; [5]Rusk Rehabilitation School of Medicine, New York, NY, USA

*Corresponding author: Marta Imamura, Department of Legal Medicine, Medical Ethics, Social and Occupational Medicine, Medical School, University of São Paulo, São Paulo, Brazil. E-mail: marta.imamura@fm.usp.br

References

1. Ibrahim I. Carpal Tunnel Syndrome: A Review of the Recent Literature. Open Orthop J 2012;6:69-76.
2. Stecco L, Stecco C. Fascial Manipulation: Practical Part. Padua, Italy: Piccin; 2009.
3. Day JA, Stecco C, Stecco A. Application of Fascial Manipulation© technique in chronic shoulder pain-Anatomical basis and clinical implications. J Bodyw Mov Ther 2009;13:128-35.
4. Pedrelli A, Stecco C, Day JA. Treating patellar tendinopathy with Fascial Manipulation. J Bodyw Mov Ther 2009;13:73-80.
5. Picelli A, Ledro G, Turrina A, Stecco C, Santilli V, Smania N. Effects of myofascial technique in patients with subacute whiplash associated disorders: A pilot study. Eur J Phys Rehabil Med 2011;47:561-8.
6. Pratelli E, Pintucci M, Cultrera P, Baldini E, Stecco A, Petrocelli A, *et al.* Conservative treatment of carpal tunnel syndrome: Comparison between laser therapy and fascial manipulation®. J Bodyw Mov Ther 2015;19:113-8.
7. Ercole B, Antonio S, Julie Ann D, Stecco C. How much time is required to modify a fascial fibrosis? J Bodyw Mov Ther 2010;14:318-25.
8. Younger J, McCue R, Mackey S. Pain outcomes: A brief review of instruments and techniques. Curr Pain Headache Rep 2009;13:39-43.
9. de Campos CC, Mastrocola Manzano G, de Andrade LB, Castelo Filho A, Maciel Nóbrega JA. Tradução e validação do questionário de avaliação de gravidade dos sintomas e do estado funcional na síndrome do túnel do carpo. Arq Neuropsiquiatr 2003;61:51-5.
10. Orfale A, Araújo P, Ferraz M. Translation into Brazilian Portuguese, cultural adaptation and evaluation of the reliability of the Disabilities of the Arm, Shoulder and Hand Questionnaire. Braz J Med Biol Res 2005;38:293-302.

Authors' contributions.—Marco Pintucci, Marta Imamura, and Aurore Thibaut contributed to this study equally.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Article first published online: May 2, 2017. - Manuscript accepted: April 21, 2017. - Manuscript received: March 10, 2017.

For supplementary materials, please see the online version of this article.

(*Cite this article as:* Pintucci M, Imamura M, Thibaut A, de Exel Nunes LM, Mayumi Nagato M, Kaziyama HH, *et al*. Evaluation of fascial manipulation in carpal tunnel syndrome: a pilot randomized clinical trial. Eur J Phys Rehabil Med 2017;53:630-1. DOI: 10.23736/S1973-9087.17.04732-3)

SUPPLEMENTARY MATERIALS

SUPPLEMENTARY TABLE I.—*Characteristics of included patients at baseline.*

Variables	FM (N.=7)	Sham (N.=7)	P value
Age, years	53±10.21	49.85±10.30	0.984
Affected side, left (%)	5 (71.4%)	2 (28.57%)	0.109
Weight, kg	79.1±29.65	69.35±9.16	0.012
Height, cm	1.61±0.09	1.56±0.04	0.119
Duration of pain before treatment, months	38.57±38.55	29.14±16.40	0.057
VAS	7.29±1.78	7.90±1.55	0.503
BS	3.40±1.00	3.38±0.50	0.952
BF	3.46±0.99	3.29±0.44	0.672
DASH Scale	66.96±10.02	51.79±24.40	0.154

Data are presented as mean±SD, where not otherwise specified.
VAS: Visual Analog Scale; BS: Symptom Severity Subscale of the Boston Carpal Tunnel Questionnaire (Brazilian translation); BF: Functional Status Subscale of the Boston Carpal Tunnel Questionnaire (Brazilian translation); DASH: Disability of the Arm Shoulder and Hand Scale.

SUPPLEMENTARY TABLE II.—*ANOVA results for the VAS, BCTQ (BS and BF) and the DASH.*

Tools	Statistical significance
VAS	
Group (T1-T0)	*F*=0.15; P=0.701
Group (T2-T0)	*F*=0.43; P=0.526
BS	
Group (T1-T0)	*F*=3.78; P=0.076
Group (T2-T0)	*F*=1.33; P=0.271
BF	
Group (T1-T0)	*F*=4.33; P=0.059
Group (T2-T0)	*F*=2.2; P=0.164
DASH	
Group (T1-T0)	*F*=0.12; P=0.738
Group (T2-T0)	*F*=0.12; P=0.738

VAS: Visual Analog Scale; BS: Symptom Severity Subscale of the Boston Carpal Tunnel Questionnaire (Brazilian translation); BF: Functional Status Subscale of the Boston Carpal Tunnel Questionnaire (Brazilian translation); DASH: Disability of the Arm Shoulder and Hand Scale.