**Article Full Title**

Short-Term Effects of Manual Therapy in Patients After Surgical Fixation of Ankle and/or Hindfoot Fracture: A Randomized Clinical Trial

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**Paper Abstract**

Background: Patients with surgical fixation of ankle and/or hindfoot fractures often experience decreased range of motion and loss of function following surgery and postsurgical immobilization, yet there is minimal evidence to guide care for these patients.

Objectives: To assess whether manual therapy may provide short-term improvements in range of motion, muscle stiffness, gait, and balance in patients who undergo operative fixation of an ankle and/or hindfoot fracture.

Methods: In this multisite, double-blind randomized clinical trial, 72 consecutive patients who underwent open reduction internal fixation of an ankle and/or hindfoot fracture and were receiving physical therapy treatment of exercise and gait training were randomized to receive either impairment-based manual therapy (manual therapy group) or a sham manual therapy treatment of light soft tissue mobilization and proximal tibiofibular joint mobilizations (control group). Participants in both groups received 3 treatment sessions over 7 to 10 days, and outcomes were assessed immediately post intervention. Outcomes included ankle joint range of motion, muscle stiffness, gait characteristics, and balance measures. Group-by-time effects were compared using linear mixed modeling.

Results: There were no significant differences between the manual therapy and control groups for range of motion, gait, or balance outcomes. There was a significant difference from baseline to the final follow-up in resting gastrocnemius muscle stiffness between the manual therapy and control groups (−47.9 N/m; 95% confidence interval: −86.1, −9.8; P = .01). There was no change in muscle stiffness for the manual therapy group between baseline and final follow-up, whereas muscle stiffness increased in the control group by 6.4%.

Conclusion: A brief course of manual therapy consisting of 3 treatment sessions over 7 to 10 days did not lead to better short-term improvement than the application of sham manual therapy for most clinical outcomes in patients after ankle and/or hindfoot fracture who were already being treated with exercise and gait training. Our results, however, suggest that manual therapy might decrease aberrant resting muscle stiffness after ankle and/or hindfoot surgical fixation.

**NIH Risk of Bias Tool**

Quality Assessment of Controlled Intervention Studies

1. **Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT**

Yes

1. **Was the method of randomization adequate (i.e., use of randomly generated assignment)?**

Yes

1. **Was the treatment allocation concealed (so that assignments could not be predicted)?**

Yes

1. **Were study participants and providers blinded to treatment group assignment?**

No

1. **Were the people assessing the outcomes blinded to the participants' group assignments?**

Yes

1. **Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?**

Yes

1. **Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?**

Yes

1. **Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?**

Yes

1. **Was there high adherence to the intervention protocols for each treatment group?**

Cannot Determine, Not Reported, or Not Applicable

1. **Were other interventions avoided or similar in the groups (e.g., similar background treatments)?**

No

1. **Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?**

Yes

1. **Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?**

Yes

1. **Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?**

Yes

1. **Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?**

Yes

**Key Finding #1**

There were no significant differences between the manual therapy and control groups outcomes, except for resting gastrocnemius stiffness.

**Key Finding #2**

Participants were already attending physical therapy prior to the start of the study and were instructed to continue their HEP (withholding from new exercises) with the addition of the manual therapy intervention sessions.

**Key Finding #3**

The ankle lunge test improved statistically in both groups from baseline to the final follow-up. Although, only the manual therapy group improved greater than the MDC of 1.38 cm.

**Key Finding #4**

Outcomes were only recorded short-term; at baseline, at 2nd session, and 7 to 10 days after participants final 3rd visit.

**Please provide your summary of the paper**

Due to the lack of clear guidelines for management, the goal of this study was to observe the short-term effects of manual therapy on individuals with ankle and hindfoot fractures. This study compared two groups that each received manual therapy, the treatment group being a more specific treatment based on the type of fracture and the control group receiving soft tissue and grade I/II proximal tibiofibular mobilizations. Although not significantly different, both groups saw statistical improvements in outcome measures including ROM, gait, and balance. The study also found an increase in stiffness in the control group which indicates the potential for manual therapy to be used for decreasing undesirable neuromotor effects. Limitations included the number of sessions being limited to 3, inadequate blinding of the control group (only 53% guessed they were in the manual therapy group as compared to 90% in the manual therapy group), and not randomizing participants by their fracture type. The manual therapy group included a greater number of total fractures and fixations when compared to the control group, potentially impacting outcomes.

**Please provide your clinical interpretation of this paper. Include how this study may impact clinical practice and how the results can be implemented.**

This study suggests that manual therapy may be beneficial for individuals with ankle or hindfoot fractures who are immobilized for 10-16 weeks, but not any more than standard physical therapy treatment alone. It is hard to say if these results came from the additional manual therapy sessions, as the participants all continued their assigned home exercise programs from prior physical therapy. A factor of this study that may impact its clinical use is that both groups received some form of manual therapy. While the two interventions were different, it cannot be said that this study compared manual therapy to treatment without manual therapy. While this study demonstrated some short-term benefits of manual therapy, more research is needed to determine the benefits for those who are immobilized for longer periods of time and if the number of manual therapy treatments impacts the results.