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Scientific/Clinical Article

A randomized controlled trial of the effect of 2-step orthosis treatment for a mallet finger of tendinous origin

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ABSTRACT

Study Design: A randomized clinical trial, with patients treated either by new 2-step orthosis or by the figure–eight-type orthosis with the distal interphalangeal (DIP) joint extended.
Purpose of the Study: To report on our new orthosis and to evaluate the treatment efficacy of using a 2-step orthosis for the treatment of a mallet finger of tendinous origin compared with a conventional orthosis.
Methods: Forty-four patients were randomized into the 2-step or conventional orthosis groups. Primary outcomes were active DIP joint flexion and extensor lag, pain, and the Abouna–Brown criteria.
Results: The 2-step orthosis was associated with a smaller active DIP extensor lag, compared with the conventional orthosis ($-7.5 \pm 4.5^\circ$ vs $-16.4 \pm 6.9^\circ$, $P = .001$), combined with a significantly higher Abouna–Brown criteria ($\chi^2 = 14.57$, $P = .01$). No other between-group differences were identified.
Conclusion: The therapeutic effectiveness of the 2-step orthosis, over a conventional orthosis, was supported by a large effect size of the treatment in improving residual active extensor lag at the DIP and overall Abouna–Brown criteria. Our study thus suggested that the initial immobilization involved in new 2-step orthosis and is thus a good immobilization technique.
Level of Evidence: Ib.

Introduction

Loss of continuity of the conjoined lateral bands at the distal joint of the fingers results in a characteristic flexion deformity of the distal interphalangeal (DIP) joint called a mallet, baseball, or drop finger deformity. In most cases of a mallet finger of tendinous origin, treatment consists of immobilizing the DIP joint in an extended position. It is recommended that this immobilization technique be performed 24 hours a day for 6 weeks using an orthosis.[1-4] For the next 2-4 weeks, the use of an orthosis at night is recommended, and when a patient is performing activities that require finger strength, with use of the orthosis gradually phased out as strength improves.[5-9] Although treatment with an orthosis is successful in 80% of patients, with a residual extension lag of $\leq 10^\circ$, fair or poor results have been reported in patients who do not adhere to the treatment regimen and in those with inappropriate immobilization.[10] In their comparative study of 2 types of orthoses for the treatment of a mallet finger, Warren et al[11] reported improvement, defined as an extension lag $\leq 15^\circ$, in 52% of patients with a mallet finger treated using a stack orthosis and an overall improvement, evaluated using the Abouna criteria, in 53% of these patients. In comparison, O'Brien et al[12] did not identify a statistically significant difference in outcomes with the use of a stack orthosis, a custom thermoplastic orthosis, or a dorsal aluminum orthosis. Moreover, Pike et al[13] did not identify any difference in DIP extension, both on clinical and radiographic measurements, between patients treated with a dorsal aluminum, volar aluminum, or custom thermoplastic orthosis.

Immobilization of both the proximal interphalangeal (PIP) joint and the DIP joint using a plaster cast has also been reported to be effective.[14-17] In this type of immobilization, the plaster cast is applied to position the DIP joint in slight hyperextension and the PIP joint in approximately 60° flexion. According to Bunnell,[18] positioning of the PIP in flexion advances the lateral bands by 3 mm, which, along with hyperextension of the DIP joint, promotes an approximation of the torn extensor tendon at the DIP joint. In contrast, Kaplan[19,20] reported that, except in cases of swan neck deformity, immobilization of the PIP joint was not required for the treatment of a mallet finger. Smillie's method of immobilization

Conflict of interest: All named authors hereby declare that they have no conflicts of interest to disclose.

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using a plaster cast is very useful for patients who may not comply with the treatment or who are unable to understand or consistently apply an orthosis correctly. Therefore, if there is doubt about a patient's reliability or ability to follow instructions, a plaster cast may be advantageous.[21]

The development of an immobilization-induced flexion contraction of the PIP is an important clinical issue. In an attempt to reduce the risk for postimmobilization flexion contracture, Evans[22] immobilized the PIP joint at a flexion angle of 30°-40°. However, a flexion contracture occurred at about the same rate when the PIP joint was immobilized at a flexion angle of 30°-40° as when the joint was immobilized at a flexion angle of 45°-60°. Based on this evidence, at our institute, we first restricted all periods of immobilization to 6 weeks, setting the PIP joint at an angle of 30°-40° and the DIP in slight hyperextension to provide sufficient immobilization to the DIP joint. Subsequently, we devised a 2-step method, wherein only the DIP joint was immobilized during the second half of the immobilization period. Our clinical impression is that our 2-step method improves extension lag, pain relief, and patient compliance. We have previously reported favorable outcomes using this 2-step orthosis technique (Fig. 1).[23] Therefore, the aim of our study was to evaluate the therapeutic benefit of the 2-step orthosis method for a mallet finger compared with traditional management. We undertook a prospective study to compare the efficacy of our 2-step orthosis method, wherein the first step involved immobilizing the finger with the PIP joint in flexion and the DIP joint in slight hyperextension and the second step involved immobilizing the finger with the DIP joint in extension, compared with a single-type orthosis immobilizing only the DIP joint in slight hyperextension.

Methods

Study design, participant enrollment, randomization, concealment, intervention, and control groups

Our prospective, parallel trial included patients from 2 centers. All procedures were performed in accordance to the ethical standards of the institutional and national ethics compliance committees, and the Declaration of Helsinki of 1975, as revised in 2008. The trial was registered as a randomized controlled trial with University Hospital Medical Information Network (UMIN) registration number UMIN-CTR (UMIN000019235). Informed consent was obtained from participants through their physician or hand therapist.

Prospective participants were selected using the following inclusion criteria: diagnosis of a mallet finger, with or without fracture; age $\geq$ 18 years; and no contraindications to continuous orthosis immobilization for 6 weeks or 12 weeks. Exclusion criteria included open lesions; mallet fractures with subluxation of the DIP; and delays in treatment >2 weeks. The first 44 consecutive patients eligible for the study were randomized to either the treatment group or the control group. Randomization was performed using a random number table, generated in Microsoft Excel (version 2010), in random permuted blocks of 4 patients to ensure equal distribution between the 2 groups, with stratification for sex and age to achieve an equal distribution of these 2 potential confounding factors between the groups. Allocation concealment was achieved by having treatment group information contained in consecutively numbered sealed opaque envelopes, which were prepared by the lead agency. Blocks of consecutively numbered envelopes were distributed to the different centers and patients were allocated in strict numerical sequence. The study therapist then provided and fitted the orthosis according to the randomized sequence.

The figure−eight-type orthosis (control) group underwent conventional immobilization using an orthosis with the DIP joint in slight hyperextension. The 2-step immobilization group underwent initial immobilization using an orthosis with the PIP joint in flexion and the DIP joint in slight hyperextension, followed by the use of a second orthosis that immobilized the DIP joint in slight hyperextension, as per the principles of conventional immobilization for a mallet finger (Fig. 1). The key features of the 2 programs of immobilization, conventional, and 2-step orthosis, are summarized in Table 1. The duration of immobilization was identical for the 2 groups, 6 weeks of immobilization with the conventional orthosis and, for the 2-step treatment, 3 weeks with the first orthosis and 3 weeks with the second. All orthoses were manufactured by the same hand therapist.

After 6 weeks of immobilization, all participants initiated a program of hand therapy, including gradual active DIP joint exercises. Thereafter, for 2-4 weeks, the orthosis was used at night and when patients' engaged in activities that required finger strength. The use of the orthosis was slowly phased out. Once the orthosis was removed, patients were reevaluated by a physician to ensure

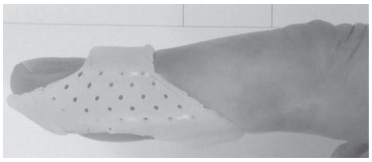
	First step	Second step
Appearance		
Position	DIP joint in a mildly extended position PIP joint at 30° flexion	DIP joint in a mildly extended position
Orthosis type	Cast	Figure-eight
Material thickness	1.3 mm	1.6 mm
Term	2–3 weeks from the initial visit	3–4 weeks from the initial visit
Mounting duration	Throughout the day	Throughout the day

Fig. 1. 2-step orthotic intervention.