SCIENTIFIC ARTICLE

Prospective Randomized Clinical Trial Comparing 3-point Prefabricated Orthosis and Elastic Tape Versus Cast Immobilization for the Nonsurgical Management of Mallet Finger

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Purpose The purpose of this randomized trial was to compare the outcomes of using a 3-point prefabricated orthosis with elastic tape versus cast immobilization for the management of nonsurgical mallet finger.

Methods This study was conducted in a single center. Individuals with a mallet injury requiring nonsurgical management were randomized to 6 weeks of full-time immobilization with either a 3-point prefabricated orthosis and elastic tape or a cast for distal interphalangeal joint extension. Outcomes were assessed at 12 weeks after the initiation of full-time immobilization and 6 months after injury.

Results A total of 70 individuals agreed to participate in the study between April 2017 and April 2021. No statistically or clinically significant differences were found between the groups regarding distal interphalangeal joint extension lag, distal interphalangeal joint flexion deficits, function according to the brief Michigan Hand Outcome Questionnaire, and pain on the Numeric Pain Rating Scale. The overall findings for both treatment groups included means of <15° of extensor lag and minimal pain (mean, <1.2 of 10) at the 6-month outcome assessment.

Conclusions The use of a 3-point prefabricated orthosis with elastic tape and cast are both appropriate immobilization options for the management of nonsurgical mallet finger. *(J Hand Surg Am. 2022;■(■):1.e1-e9.*

Type of study/level of evidence Therapeutic II.

Key words Casting, mallet injury, DIP joint extension lag, nonsurgical treatment, three-point prefabricated orthosis with elastic taping.

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MALLET FINGER IS AN INJURY to the terminal extensor tendon of the finger incurred via forced flexion of the distal interphalangeal (DIP) joint.[1,2] Mallet finger may be a result of an extensor tendon rupture just distal to the DIP joint or an avulsion at the tendon insertion on the distal phalanx.[1,2] The classic symptom of mallet finger is an extensor lag at the DIP joint. If this is left untreated, greater deformity and functional concerns

may result from the retraction of the central tendon at the proximal interphalangeal (PIP) joint, resulting in a swan neck deformity.[3]

Nonsurgical management is traditionally recommended for tendinous mallet injuries and for bone avulsions involving less than one-third of the distal phalangeal articular surface and without volar subluxation.[4,5] In some cases, nonsurgical treatment may be an option with greater fracture involvement and with delayed treatment.[6,7] A common treatment program of nonsurgical management is full-time immobilization of the DIP joint in full extension for 6−8 weeks, with night time extension immobilization for an additional 4 weeks.[8] Although there are many options for immobilization of the DIP joint, systematic reviews on the nonsurgical management of mallet injury do not define a superior option.[4,8] Nevertheless, 2 clinical trials have suggested advantages to the use of casting versus custom DIP extension orthoses. Tocco et al[9] found a statistically significant difference with less extensor lag at a 12-week follow-up for individuals with mallet injury treated with casting versus those treated with a low-profile custom thermoplastic lever orthosis. The authors noted less edema in the cast group and suggest that decreased edema from casting may correlate with less extension deficit.[9] Cavanaugh et al[10] also found that individuals treated with casting experienced less pain from the immobilization device and fewer skin complications compared with a traditional thermoplastic custom-fabricated orthosis.

In general, the use of a material for immobilization that considers patients' needs and lifestyle is recommended.[8] Appropriate compliance with treatment is associated with a greater rate of excellent outcomes than noncompliance (61.5% vs 9.1%).[11] To our knowledge, the use of a 3-point prefabricated orthosis with waterproof elastic tape, a method of immobilization that allows the material to get wet and does not necessarily require removal by the patient, has not yet been studied to determine clinical outcomes. The comparison of this method of immobilization to casting, for which there is evidence to suggest less DIP joint extension lag and less pain and complications compared with a custom orthosis, is warranted to provide evidence for the most appropriate method of immobilization for nonsurgical mallet injury.[9,10] It may be hypothesized that a method of immobilization that is able to tolerate getting wet and does not require patient removal for hygiene may allow for improved outcomes because of better compliance and fewer complications.[10,11] The purpose of this randomized clinical trial was to compare the outcomes of using a 3-point prefabricated orthosis with elastic tape versus cast immobilization for the management of nonsurgical mallet finger.

MATERIALS AND METHODS

Study design and enrollment

This study was a prospective, single-center, randomized clinical trial involving patients treated by the hand team at a large orthopedic practice. All procedures were in accordance with the ethical standards of the institutional and national ethics compliance committees, and the Declaration of Helsinki of 1975, as revised in 2008. The study was approved by the institutional review board at St. Vincent's Medical Center (a part of Hartford HealthCare in Bridgeport, CT). The study is also registered at ClinicalTrials.gov (NCT04830917).

All individuals referred to hand therapy between April 2017 and April 2021 for nonsurgical management of a mallet finger injury and who met the inclusion criteria were invited to participate. The inclusion criteria were patients with a mallet injury determined by a physician or physician's assistant to be appropriate for nonsurgical immobilization at the DIP joint, those aged at least 18 years of age, and those able to understand and complete forms in English. The exclusion criteria were individuals with previous injury of the involved digit and individuals who desired to select their treatment. The participants were randomly allocated to a treatment group and were permitted to change treatment groups at any point in time.

Methods

All participants were determined to be candidates for nonsurgical management by 2 board-certified orthopedic surgeons with subspecialty certificates in hand surgery and 2 orthopedic physician assistants who worked under their direct supervision. The nonsurgical status was determined through clinical and radiographic examination. Individuals with a bony mallet injury with an avulsion fragment involving >40% of the distal phalangeal articular surface or DIP joint subluxation were referred for surgery and excluded from the study.

All study participants were treated with full-time immobilization with either a cast made from Quickcast (Preston Medical) or elastic tape (Kinesiotape) and an Oval 8 (3 Point Products) to maintain the DIP joint in full extension. Regardless of group assignment, each participant was encouraged to be seen 1 time per week in hand therapy (as per routine

nonsurgical mallet treatment at this facility) for a change of the tape or cast and to ensure good fit and full DIP extension in their immobilization device. All participants were immobilized full time at least 6 weeks and then were encouraged to use a DIP extension orthosis for an additional 6 weeks for at-risk activities and during sleep. Full-time immobilization was extended for 2−4 weeks for individuals who had an extensor lag of >20° at 6 weeks after the initiation of immobilization. Any participant who presented with PIP joint hyperextension in the involved digit related to their mallet injury (based on comparison to the contralateral same digit and physician determination) had the PIP joint blocked at approximately 30° of flexion using the casting material or an extra 3-point prefabricated orthosis (allowing the PIP to fully flex, but not extend past 30° of flexion) during the full-time immobilization period. Three occupational therapists (2 certified hand therapists) and 1 physical therapist/certified hand therapist provided the weekly treatment. All were experienced in treating mallet finger injuries and together reviewed protocols for the application of cast and the 3-point prefabricated orthosis with elastic tape before enrolling the first participant. Individuals with a bony mallet that involved a substantial avulsion fragment underwent repeat radiographs at 3 weeks to confirm no subluxation, and all bony mallets had radiographs at 6 weeks to assess healing. Soft tissue mallets were seen by the physicians or physician assistants at the 6-week mark.

The individuals in the elastic tape and 3-point prefabricated orthosis group were treated with elastic tape from volar to dorsal DIP to apply a slight pull into DIP joint extension (Fig. 1A), a well-fitting 3-point prefabricated orthosis adjusted for best fit and full extension (Fig. 1B), and elastic tape on the orthosis to ensure that the orthosis was secure (Fig. 1C).[12] The participants were permitted to change the elastic tape on top of the orthosis between sessions if needed and were permitted to get the involved hand wet. The individuals in the cast group were casted in full extension using 2−3 pieces of cast material to ensure sturdy immobilization (Fig. 2A). Self-adherent wrap (Coban, 3M) was placed on the cast to assist with keeping the cast clean between changes (Fig. 2B), and the participants were permitted to change the self-adherent wrap as needed. A piece of elastic tape was used at the dorsal DIP joint as needed under the cast for comfort. The participants in the cast group were instructed to keep the cast dry.

Outcomes and evaluation

All assessments and data collection were completed unblinded by 1 of the hand therapists mentioned above. Baseline data were collected from participants at their initial presentation when enrolling in the study. Baseline data included age, sex, involved digit, hand dominance, days since injury, mechanism of injury, DIP joint extension lag (if immobilization was not already started), smoking status, pain on the Numeric Pain Rating Scale, and brief Michigan Hand Outcome Questionnaire (MHQ).

The outcomes were collected at 12 weeks and 6 months following the start of immobilization. The DIP joint extension lag was the primary outcome measure. This was measured using a finger goniometer and assessed dorsally during composite extension of the involved finger.[13] The actual measurement of extension was recorded without rounding and was compared with that of the noninvolved contralateral digit. If the contralateral noninvolved digit had any lag without previous injury, the number of degrees in lag was subtracted from the involved side assuming symmetry in extension before injury. The DIP joint flexion deficit was determined via the number of degrees of DIP joint flexion on the noninvolved contralateral digit minus the number of degrees of DIP joint flexion on the involved digit measured during composite flexion and with dorsal placement of a finger goniometer.[13] The brief MHQ was used to assess function. The brief MHQ is an efficient outcome measure specific to hand disability that retains psychometric properties of the full MHQ and has categories including function, activities of daily living, aesthetics, and satisfaction.[14] Although the brief MHQ has not been specifically studied with mallet finger, the full MHQ has been found to be able to describe functional limitations for hand fractures.[15] The participants who did not return for outcome assessment were contacted on the phone and offered the completion of the brief MHQ and Numeric Pain Rating Scale via verbal communication.

Statistical analysis

To determine whether there was a difference in DIP joint extensor lag between groups, an *a priori* sample size estimate indicated that 25 participants were needed in each group to provide 80% statistical power ($\beta = 0.20$ and $\alpha = 0.05$) based on a difference of a 5-degree residual lag between groups and a standard deviation of 6.2 degrees. This was based on a combination of expert opinion and a pilot study

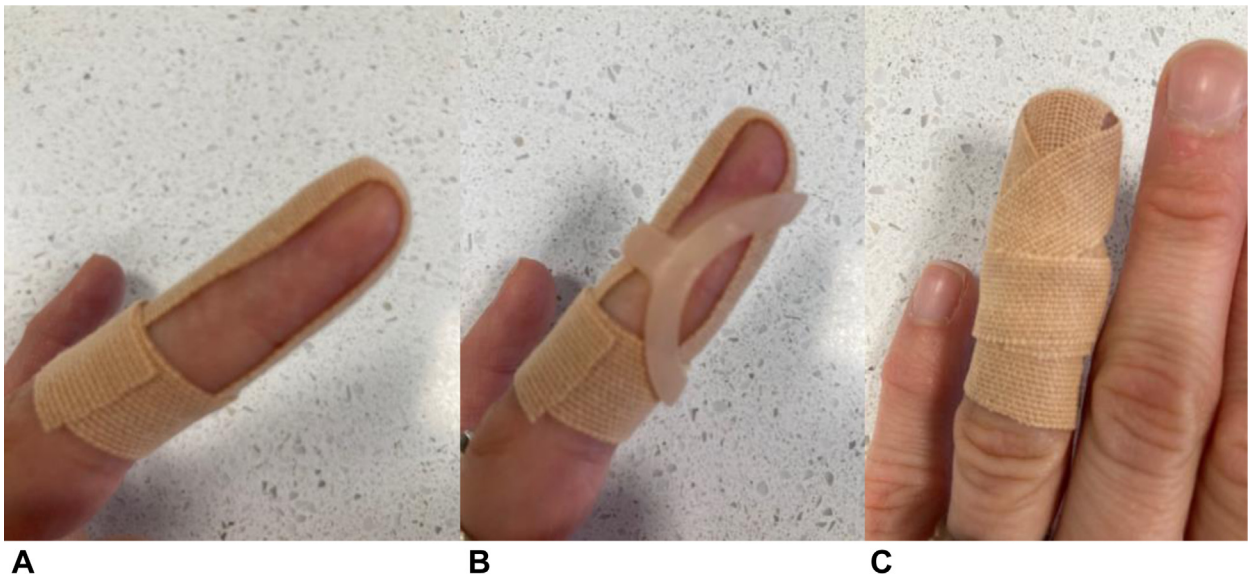

FIGURE 1: Three-point prefabricated orthosis with elastic tape for mallet finger. **A** Elastic tape applied volar to dorsal with slight pull to DIP joint extension and secured. **B** Well-fitting 3-point prefabricated orthosis applied in full DIP joint extension. **C** Elastic tape applied over the orthosis to ensure that it remains intact.

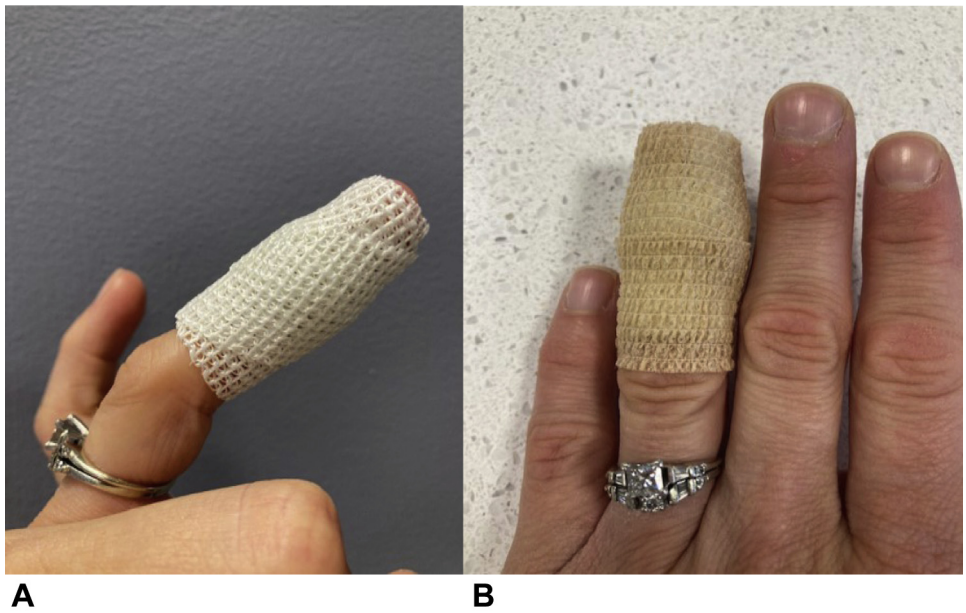

FIGURE 2: Cast for mallet finger. **A** Two to 3 layers of cast strips were used to cast the DIP joint in full extension. **B** A layer of self-adherent adhesive was then applied to the top to assist with keeping the cast clean.

completed by Pike et al[16] in a mallet injury randomized clinical trial. In addition, according to calculations, this study would have 80% power to detect a difference in continuous variables between any 2 groups equivalent to 1 standard deviation with a 2-sided P value of .05.[17] All data were analyzed via intention-to-treat; therefore, main calculations were completed with the participants in the group to which they were randomized and not the group in which they completed treatment. Data were not estimated for anyone who did not complete a study follow-up. The Student t test for independent samples was used to compare the means of the 2 groups in this study. Significance was set at $P < .05$.

RESULTS

Data were collected from participants from April 2017 to April 2021 and were continued until each group had

at least 25 individuals assessed for DIP joint extension at the 12-week outcome measurement. A total of 70 participants initially agreed to participate; however, 15 withdrew before any outcome assessment. (Fig. 3) Most of the withdrawals were lost to follow-up and not scheduled/unable to be reached to schedule for data collection. One participant in the cast group withdrew from the study during treatment because she was not tolerating nonsurgical management in her occupation as a physician. Another participant from the 3-point prefabricated orthosis and elastic tape group withdrew following the 12-week data collection because of functional concerns related to her extensor lag at that time. Both participants withdrew from the study to have an arthrodesis of the DIP joint.

Both groups were similar at the baseline. Both groups were also similar in the number of participants who switched treatment interventions during the study; 6 (20%) participants switched to the cast from the 3-point prefabricated orthosis and elastic tape group, and 5 (20%) participants also switched out of the cast group. Both groups were similar in the number of participants that did not fully adhere to the treatment protocol based on missed weekly appointments; 2 (6.7%) participants did not adhere to treatment in the orthosis group, and 3 (12%) participants did not adhere to treatment in the cast group. The groups also had a similar number of participants who required an extension of their full-time immobilization because of having a lag of at least 20° at the physician follow-up at 6 weeks after the initiation of immobilization; 4 (13.3%) participants extended immobilization in the orthosis group, and 3 (12%) participants extended immobilization in the cast group. There was 1 possible major complication in the 3-point prefabricated orthosis with elastic tape group: 1 participant was prescribed an antibiotic for a paronychia with uncertainty as to the relationship to the immobilization method and mallet injury (Table 1). One participant from each group had their PIP joint blocked from full extension in addition to the

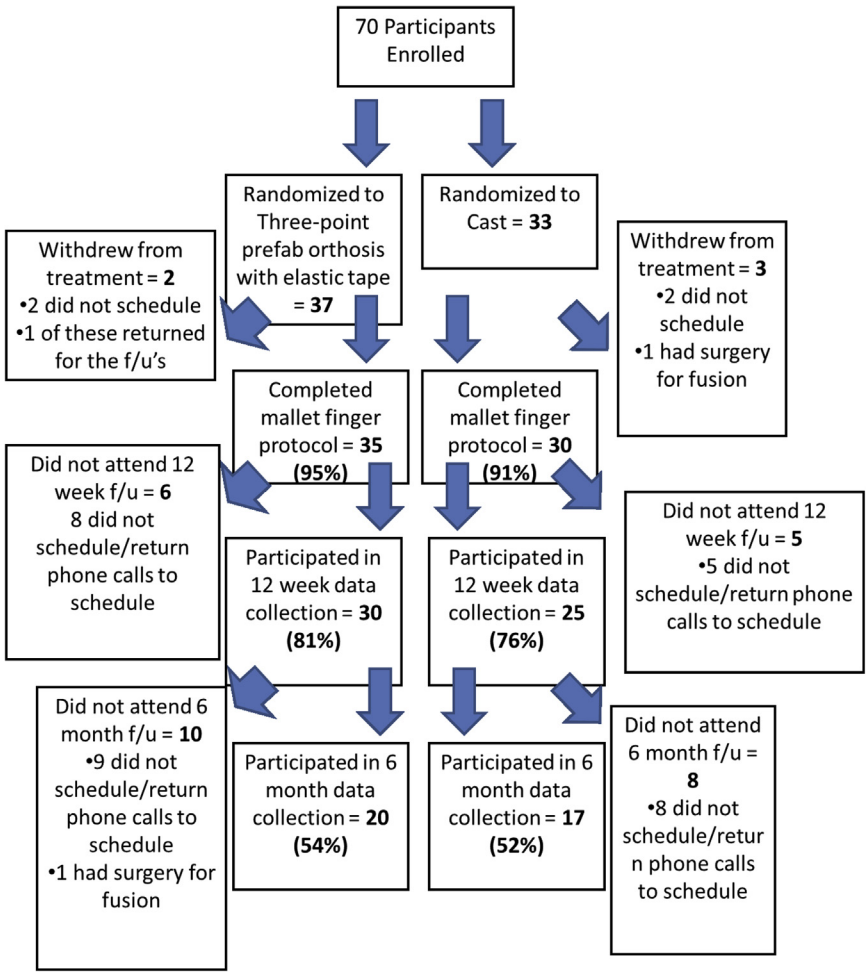

FIGURE 3: Participant flow through the study. f/u, follow-up.

TABLE 1. Description of Participant Variables

Participant Variable	Three-Point Prefabricated Orthosis With Elastic Tape N = 30	Cast N = 25
Sex (female/male)	10 (33.33%)/20 (66.67%)	7 (28%)/18 (72%)
Age, y; mean (SD)	54.53 (13.40)	48.92 (15.31)
Digit involved		
Index	2 (6.67%)	0 (0%)
Middle	10 (33.33%)	6 (24.0%)
Ring	10 (33.33%)	9 (36.0%)
Small	8 (26.67%)	10 (40.0%)
Dominant hand (yes/no)	15 (50%)/15 (50%)	17 (68%)/8 (32%)
Days since the injury, mean (SD)	10.53 (8.65)	16.96 (24.83)
Pain at baseline via NPRS mean (SD)	2.10 (2.34)	2.00 (1.83)
DIP joint extension at baseline, mean (SD)	−31.21 (13.35)	−27.81 (13.49)
Type of injury (tendon/bone)	24 (80%)/6 (20%)	20 (80%)/5 (20%)
Smoking status (current/previous/never)	2 (6.67%)/5 (16.67%)/23 (76.67%)	1 (4.00%)/4 (16.0%)/19 (76%)
Adherence to treatment (yes/no)	28 (93.33%)/2 (6.67%)	22 (88.0%)/3 (12.0%)
Brief MHQ score at baseline, mean (SD)	69.12 (14.29)	65.80 (16.02)
No. of participants who switched groups during the immobilization period (switch/no switch)	6 (20.0%)/24 (80.0%) Switch reasons: 2 participants: unable to achieve fit with the 3-point prefabricated orthosis 1 participant: distal migration of the orthosis with PIP flexion 2 participants: desire for stronger/greater protection 1 participant: dorsal bar of the orthosis was uncomfortable	5 (20.0%)/20 (80.0%) Switch reasons: 2 participants: desired to get the involved digit wet 3 participants: casts were loosened
Major complication	1 (3.3%)/29 (96.7%)	0 (0%)/25 (100%)
Extended immobilization	4 (13.3%)/26 (86.7%)	3 (12%)/22 (88%)

NPRS: Numeric Pain Rating Scale.

TABLE 2. Outcomes of the Intention-to-Treat Analysis at the 12-Week Follow-Up

Outcome	Three-Point Prefabricated Orthosis and Elastic Tape Mean (SD)	Cast Mean (SD)	*P* Value
DIP joint extension lag, °	−12.87 (16.00)	−14.08 (13.94)	.768
DIP joint flexion deficits, °	13.93 (17.82)	13.95 (17.91)	.997
Brief MHQ score	81.84 (15.86)	79.37 (15.73)	.590
Pain	1.57 (1.68)	1.73 (2.03)	.756

immobilization of the DIP joint in full extension related to physician orders for this and a clinical judgment that the PIP joint hyperextension was related to the mallet injury.

According to the calculated *P* values for each outcome measure at the 12-week and 6-month assessments, there were no statistically significant differences between the use of the 3-point prefabricated orthosis and elastic tape versus cast for any of the outcomes assessed in this study (Tables 2–4).

DISCUSSION

This study suggests that no statistically significant differences were observed in outcomes for range of

TABLE 3. Outcomes of the Intention-to-Treat Analysis at the 6-Month Follow-Up

Outcome	Three-Point Prefabricated Orthosis and Elastic Tape Mean (SD)	Cast Mean (SD)	*P* Value
DIP joint extension lag, °	−9.75 (12.29)	−14.12 (14.19)	.323
DIP joint flexion deficits, °	7.26 (10.09)	9.36 (17.89)	.672
Brief MHQ score	92.76 (10.63)	88.47 (16.79)	.370
Pain	0.5 (0.95)	1.13 (1.67)	.165

TABLE 4. Difference Between Group Means at Each Follow-Up

Outcome	Difference Between Group Means at the 12-Wk Follow-Up	Difference Between Group Means at the 6-Mo Follow-Up
DIP joint extension lag	1.21	4.37
DIP joint flexion deficits	0.02	2.10
Brief MHQ score	2.47	4.29
Pain	0.16	0.63

motion, pain, and function measured by the brief MHQ for individuals treated with a 3-point prefabricated orthosis and elastic tape versus cast for nonsurgical mallet injury. The findings suggest that outcomes of both treatment groups were good (overall mean extensor lag of <15° and minimal pain) at the 6-month outcome assessment. The 3-point prefabricated orthosis with elastic tape and cast were both found to be appropriate immobilization options for the management of nonsurgical mallet finger.

There have been 2 previous mallet finger studies that included casting.[9,10] In a randomized trial, Tocco et al[9] found that at 12 weeks after injury, the subjects in the cast group had 5° greater DIP joint extension than individuals in a lever-type custom orthosis. Cavanaugh et al[10] performed a randomized trial comparing casting and a custom DIP joint extension orthosis and did not find a statistically or clinically significant difference in DIP joint extension outcomes between groups. They did find that pain with the use of the orthosis and skin complications were significantly less in the cast group.[10] These findings suggest an advantage of casting as an immobilization method for nonsurgical mallet injury, which has not been found for other methods of immobilization that have been studied.[8–10,16–18] To our knowledge, the use of a 3-point prefabricated orthosis with elastic tape has not been studied in nonsurgical mallet injury, and our study suggests that this approach can perform comparably. This is important because this orthosis option offers the benefit of allowing the patient to get the involved finger wet when it is worn and does not require removal, which can possibly decrease complications and increase compliance.[10,11] In addition, mallet injury is often perceived as an injury that is difficult to treat with immobilization options that have been found to cause varying degrees of skin maceration and complications; thus, it is important to study additional nonsurgical methods of mallet finger management.[9,19]

As mentioned above, Cavanaugh et al[10] found less pain and skin complications in the cast group. The authors suggest that this could be related to the required weekly cast change.[10] In our study, both groups were checked weekly. This may have decreased complications and improved outcomes and satisfaction; however, it is unknown whether there is a relationship between these variables.[10] In our study, minor redness or inappropriate fit was addressed in weekly sessions. One participant in our study was diagnosed with a paronychia when she completed her full-time immobilization with uncertainty as to whether this was related to her immobilization method.

Although there is no consensus on a minimal clinically important difference (MCID) for range of motion at the DIP joint, Pike et al[16] suggested that a 5° change is clinically meaningful. Although this figure is obtained from a pilot study and expert opinion, it may arguably be small enough to be within measurement error because a systematic review did not establish real change and minimal detectable change for dorsally measured DIP joint range of motion.[16,20] However, the differences in means for DIP joint extension lag and DIP joint flexion deficits were <5° at both assessments in our study. The calculated MCID for pain on the Numeric Pain Rating Scale is 2, but the difference in pain

scores between groups at each assessment was <1.[21–23] There is not currently a calculated MCID for the brief MHQ. A previous study on the MCID for the full MHQ has suggested that the actual MCID varies by domain of the questionnaire and disease.[24] The difference in the brief MHQ score between the 2 groups at the 12-week follow-up was 2.5 and that at the 6-month follow-up was 4.3. The difference is also small, and the brief MHQ has not been validated specifically for mallet injury. The full MHQ has been validated for hand fractures but not specifically for mallet injury.[15]

Twenty percent of participants in each group switched treatments (Table 1). The reasons for the decisions to switch immobilization methods provide additional clinical information. Not all individuals can fit into a 3-point prefabricated orthosis appropriately to maintain DIP joint extension and allow PIP joint flexion, but the cast can be fit to everyone. The cast provides circumferential pressure when edema is present, whereas the dorsal bar on the 3-point prefabricated orthosis may be bothersome to edema; nevertheless, casting with edema may require a quicker follow-up than 1 week because of loosening. Casting may be perceived as sturdier immobilization, but the 3-point prefabricated orthosis with elastic tape allows exposure to water and less bulk in the immobilization method, which may be desirable.

Distal interphalangeal joint extension outcomes have been reported as 7.6° extension lag on average after nonsurgical intervention according to a systematic review versus a mean of 9.8° to 14.1° lag in our study.[4] Our DIP joint extension lag outcomes may be related to our choice to use an intention-to-treat analysis of data. Although values were not assigned to participants who did not attend follow-up sessions, those who did not complete the skilled treatment protocol were allowed to continue with participation and data collection. Noncompliance with treatment is likely to be related to outcome; thus, those who did not adhere to treatment may have potentially increased the size of the mean lag at outcome.[11]

In this study, both the treatment providers and the assessors were unblinded to study group assignment, which may have introduced bias.[25] This study did allow participants to complete the 12-week and 6-month follow-up despite any noncompliance with treatment, withdrawal from 6 weeks of full-time immobilization, or changing of the treatment group. This allows for the findings to be more clinically applicable but does not provide control for the impact of these variables. There is a possibility that the use of the intention-to-treat analysis and the variability in treatment (continued immobilization when the extension lag was >20° at the 6-week physician follow-up) contributed to the lack of a difference between groups. The use of intention-to-treat principles has been suggested as causing difficulty in interpreting data when too many participants cross over groups and may cause studies to be more susceptible to type II errors.[26] The study was also nonselective in the mallet injuries (time since injury, bone or tendon involvement, presence of PIP joint hyperextension) to be more clinically relevant. Additionally, although overall 93% of participants completed treatment and 79% overall completed the 12-week follow-up, only 53% overall completed the 6-month follow-up, causing a large dropout rate for data collection.

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