A prospective randomized controlled trial comparing night splinting with no splinting after treatment of mallet finger

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Published online: 22 January 2014
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Abstract

Background The effectiveness of night splinting after treatment of mallet finger is unknown. We tested the hypothesis that there is no difference in extensor lag between patients with mallet finger that wear a night splint for an additional month after 6 to 8 weeks of continuous splinting and patients that do not wear a night splint.

Methods Fifty-one patients were enrolled in this randomized controlled trial. At enrollment, range of motion was measured for the injured and contralateral uninjured finger. The follow-up was conducted approximately 4 weeks later in person (41 patients) or by phone (10 patients). Analysis was by intention to treat.

Results There were no significant differences in final extensor lag between patients that did and did not receive a night splint. Among the 41 patients with a final in-person evaluation, the final average extensor lag was 14°, and 34 % (14 of 41 patients) had a lag of 20° or greater. Final extensor lag correlated significantly with age, enrollment distal interphalangeal joint (DIP) flexion and extensor lag, and final DIP flexion, with the latter two accounting for 28 % of the variation in final lag in the final multivariable model ($p < 0.001$). There were no differences

in disability ($p = 0.67$) or treatment satisfaction ($p = 0.48$) between patients that did and did not use night splints.

Conclusions Supplemental night splinting does not improve the outcome of mallet finger in terms of extensor lag, disability, or satisfaction with treatment. Patients with worse initial extensor lags should expect worse final lags; residual lags of 20° or greater are commonplace.

Keywords Tendon · Mallet fracture · Extensor lag · Nonoperative treatment · Night splinting

Introduction

Rupture of the terminal extensor tendon at its insertion onto the distal phalanx (mallet finger) is very common. Adverse outcomes include a residual extensor lag, a dorsal bump, or a swan neck deformity [8, 15] but these are largely aesthetic. Based on rationale and tradition rather than scientific evidence, some surgeons recommend night splinting after conservative treatment of mallet finger to limit the potential for these adverse outcomes [2, 5–7].

This randomized clinical trial addressed whether (1) there is a difference in extensor lag between patients that night splint for an additional month after ceasing continuous patients that do not night splint, (2) there are predictors of extensor lag, disability, and satisfaction with treatment at the final evaluation.

Patients and Methods

Study Design

This single-center prospective, randomized controlled trial with a 1:1 allocation ratio was approved by our Institutional

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Review Board and registered on Clinicaltrials.gov (NCT01388751). Inclusion criteria were mallet finger with or without fracture, age 18 years or greater, English fluency, and treatment with a period of continuous splint or cast immobilization in neutral or slight hyper-extension for 6 weeks or greater (typically 6 weeks for bony and 8 weeks for tendinous mallet fingers). Exclusion criteria included open lesions, mallet fractures with delayed treatment of more than 2 weeks, and mallet fractures with subluxation of the distal interphalangeal joint. Subjects were recruited in one outpatient clinic of our hospital. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all patients included in the study.

Patients were enrolled after a course of full-time splint or cast wear. For those randomized to night splinting, we prescribed custom-made thermoplastic splints that positioned the injured distal interphalangeal joint in neutral or a slightly hyperextended position. Patients were instructed to wear the splint at night only and to return 1 month later for follow-up. Subjects in the control group did not receive a splint. Patients in both groups were asked to return 1 month later for reassessment.

The primary outcome measure was extensor lag approximately 1 month after enrollment: the extension of the distal interphalangeal joint (DIP) of the injured finger measured with a handheld goniometer. A trained research assistant not involved in the care of the patient took all measurements.

Evaluation

At enrollment, DIP flexion and extension and proximal interphalangeal joint (PIP) flexion and extension of the injured and contralateral uninjured finger were measured and recorded. The Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire was used to measure patient-rated disability from 0 to 100, with higher scores reflecting greater arm-specific disability [1]. Aspects of illness behavior that can affect pain and disability were measured with the Pain Catastrophizing Scale (PCS) [3, 4], the Center for Epidemiological Studies Depression Scale (CES-D) [5], and the Whiteley Index [14].

At the follow-up visit, approximately 4 weeks later, range of motion measurements were repeated and the DASH questionnaire was administered. Using an ordinal scale, patients rated their satisfaction with the treatment from 0 to 10. Patients who did not return for the follow-up evaluation were contacted to complete the DASH and ordinal scale for treatment satisfaction over the phone.

Statistical Analysis

To determine if there was a difference in extensor lag between patients that used a night splint and those that did not, an a priori power analysis indicated that a total sample of 42 patients (21 in each group) would provide 80 % statistical power ($\beta=0.20$ and $\alpha=0.05$) for a large effect size (0.8 of a standard deviation or 12° , estimating that the standard deviation in lag would be 15°). Anticipating loss of 20 % of patients, we planned to enroll 26 patients in each cohort. The actual loss of patients was 10 of 51 patients (20 %).

After informed consent, participants were randomized 1:1 according to a sequence generated by a computer random-number function (Windows Excel; Microsoft, Redmond, WA) to either 1 month of night splinting or no additional splinting. A total of 51 patients were enrolled from March 2009 until May 2012.

The chi-square test was used to find the differences in categorical variables between the treatment groups. The Fisher's exact test was used to compare the smoking status between the cohorts. Independent t-tests were used to compare continuous variables.

In bivariate analysis, Pearson correlation was used to determine the correlation of continuous outcome variables with the final DASH score, satisfaction, and extensor lag. Independent t-tests and one-way ANOVA were employed for dichotomous and categorical variables, respectively.

All variables with $p<0.10$ in the bivariate analysis were inserted in a stepwise backward multivariable regression analysis in order to determine the strongest predictors of DASH, satisfaction, and extensor lag. We planned not to insert the patient satisfaction in the regression for DASH since we consider these two response variables to be measuring similar things.

This pragmatic trial followed strict intention-to-treat principles using mean imputation for missing data. In other words, patients were analyzed based upon their original group assignment regardless of adherence, which is representative of actual practice [10].

Results

Participant Flow and Recruitment

Of the 59 invited patients, seven declined and one was found ineligible after enrollment due to delayed treatment. Twenty-five patients were randomized to night splinting and 26 to no splinting. Forty patients returned to the office for the final evaluation: 20 (80 %) in the night splint group and 20 (77 %) in the no-splint group, and seven patients completed the

outcome measures over the phone (2 in the night splint group and 5 in the no-splint group), for a total of 47 patients who had either an in-person or phone follow-up. One subject had returned, but a study evaluation was not performed. The final extensor lag was extracted from this subject's medical record, resulting in a total of 41 final motion measurements. Three patients in the night-splint group and one in the no-splint group were lost to follow-up and had no final evaluation. The final in-office evaluation occurred in an average of 5.7 weeks after enrollment (median 4.9 weeks, range 2.9 to 17 weeks), and the final phone evaluation occurred in an average of 23 months after enrollment (median 25 months, range 12 to 34 months).

Baseline Comparison

Fifteen subjects presented with a bony mallet and 36 with a tendinous mallet (Table 1). There were no significant differences in baseline variables (Table 1), measurements, or questionnaire scores (Table 2) between the cohorts.

Numbers Analyzed/Missing Data

We used group mean imputation for the following missing data: 3 DIP and 4 PIP flexion values for the affected finger at enrollment. We also used mean imputation for the missing measurements of patients that did not return to the office for final evaluation, and 5 of 51 final DASH and treatment satisfaction scores.

Analysis

At the follow-up evaluation, there were no significant differences between the cohorts in the average extensor lag, DASH, or treatment satisfaction scores (Table 2). The average final extensor lag was 14° (median 11, range 0 to 42). Among the 41 patients with a final extensor lag measurement, 14 (34 %) patients had a 20° or greater final extensor lag (6 treated with night splint, 8 not; 5 bony, 9 not).

Final extensor lag correlated significantly with age ($r=0.38$, $p=0.006$), final DIP flexion ($r=0.39$, $p=0.005$), enrollment extensor lag ($r=0.43$, $p=0.001$), and enrollment DIP flexion

Table 1 Patient demographics

Parameter		Total <i>n</i> =51	Splint <i>n</i> =25		No splint <i>n</i> =26		
			Range	Mean±SD	Range	Mean±SD	<i>p</i>
Age (years)		50±14	24–78	49±14	24–78	51±14	0.64
Self-rated health		2.2±2.5	0–10	2.4±2.6	0–8	2.0±2.4	0.54
Education (years)		16±2.5	12–25	17±2.6	12–25	16±2.2	0.27
		Numbers				<i>p</i>	
Sex	Women	17		7		10	0.43
	Men	34		18		16	
^a Smoking	Yes	5		2		3	0.99
	No	46		23		23	
Marital status	Single	18		9		9	0.81
	Married	28		14		14	
	Separated/divorced	4		2		2	
	Living with partner	1		0		1	
Work status	Full-time	35		18		17	0.44
	Part-time	6		3		3	
	Homemaker	2		2		0	
	Retired	5		1		4	
	Unemployed, able to work	2		1		1	
	Unemployed, unable to work	1		0		1	
Type of injury	Bony	15		7		8	0.83
	Tendinous	36		18		18	

^a Calculated with Fisher's exact test

Table 2 Outcome measures

Parameter	Cohort <i>n</i> =51			Splint <i>n</i> =25		No splint <i>n</i> =26		<i>p</i>
	Mean	SD	Range	Mean	SD	Mean	SD	
DASH initial	16	11	0–63	14	9.2	18	13	0.29
DASH follow-up	8.8	10	0–54	8.1	8.5	9.4	12	0.67
CESD	6.5	9.3	0–43	8.2	11	4.9	7.1	0.21
PCS	1.2	2.8	0–16	0.92	1.8	1.4	3.6	0.53
Whiteley	1.6	1.7	0–8	1.5	1.7	1.6	1.7	0.84
Months to follow-up	4.9	8.5	0.67–34	4.0	8.1	5.9	8.9	0.24
Treatment satisfaction	8.2	2.5	0–10	8.5	2.2	8.0	2.9	0.48
Motion analysis at enrollment after 6–8 weeks of splint immobilization								
Injured								
DIP flexion	43	18	0–85	39	16	47	19	0.12
DIP extension	7.6	10	0–40	7.1	9.6	8.1	11	0.73
PIP flexion	77	20	20–110	77	20	76	21	0.87
PIP extension	0.4	3.2	–10–12	0.2	2.8	0.58	3.6	0.68
Uninjured								
DIP flexion	74	14	35–90	75	13	74	15	0.84
DIP extension	0.55	3.3	–5–13	0	2.0	1.1	4.1	0.24
PIP flexion	95	12	50–115	97	9.3	92	14	0.14
PIP extension	0.14	1.4	–5–7	0.2	1.0	0.08	1.7	0.76
Motion analysis at follow-up								
Injured								
DIP flexion	63	14	0–90	61	17	65	12	0.37
DIP extension	14	12	0–42	11	11	16	12	0.22
PIP flexion	93	10	60–120	92	10	94	10	0.47
PIP extension	–0.2	1.4	–10–0	–0.40	2	0	0	0.33
Uninjured								
DIP flexion	77	11	40–90	80	10	74	11	0.044
DIP extension	0.2	3.2	–10–15	0	2.5	0.38	3.7	0.67
PIP flexion	99	6.9	80–120	100	3.9	99	8.9	0.61
PIP extension	0	0	0–0	0	0	0	0	^a

DASH disabilities of arm, shoulder, and hand; CES-D Center for Epidemiologic Studies Depression Score; PCS Pain Catastrophizing Scale

^a could not be calculated

($r=0.34$, $p=0.014$) (Table 3). The final multivariable model included enrollment lag and follow-up DIP flexion and accounted for 28 % of the variation in final extensor lag ($p<0.001$).

Final DASH averaged 8.8 (range from 0 to 54). Final satisfaction averaged 8.2 (range from 0 to 10). In bivariate analysis, no explanatory variables were significantly associated with final DASH or satisfaction (Table 3).

Discussion

The benefits of wearing a night splint for an additional month after standard conservative treatment of mallet finger are

unknown. This study addressed whether night splinting led to better outcomes in terms of extensor lag, patient-rated disability, or satisfaction with treatment compared with no night splinting and sought to determine predictors of residual lag, disability, and satisfaction.

This study should be interpreted in light of the fact that we used strict intention-to-treat and mean imputation for missing data. This is ideal for limiting bias, but given that this is a small study, the results might have been different if the patients that did not return for measurements had important differences in final extensor lag than those that did return. In other words, this study applies best to the subset of patients that return as scheduled. It took some effort to coordinate and

Table 3 Bivariate analysis

Bivariate analysis	DASH		Satisfaction		Final DIP extension	
	Correlation	p-value	Correlation	p-value	Correlation	p-value
Pearson's correlation						
Satisfaction	−0.52	<0.001	x	x	x	x
Final DIP extension	0.26	0.067	−0.24	NS	x	x
Final DIP flexion	0.15	NS	0.015	NS	0.39	0.005
DIP extension at enrollment	0.038	NS	−0.050	NS	0.43	0.001
DIP flexion at enrollment	0.230	NS	−0.16	NS	0.34	0.014
Months to follow-up	−0.22	NS	−0.28	NS	0.026	NS
Age	0.060	NS	0.13	NS	0.38	0.006
Education (years)	−0.024	NS	−0.18	NS	0.022	NS
CES-D	0.092	NS	0.072	NS	0.052	NS
PCS	0.20	NS	−0.054	NS	0.077	NS
Whiteley	0.083	NS	0.10	NS	−0.009	NS
t-test						
Bony versus tendinous mallet		NS		NS		NS
Sex		NS		NS		NS
Night splint versus no night splint		NS		NS		NS
One-way ANOVA						
Work status		NS		NS		NS
Marital status		NS		NS		NS

DASH disabilities of arm, shoulder and hand; *CES-D* Center for Epidemiologic Studies Depression Score; *PCS* Pain Catastrophizing Scale; *NS* not significant; x not applicable

accomplish follow-up evaluations, resulting in a substantial variation in the time of final evaluation; however, there was no correlation between delay to final measurement and final extensor lag. The numbers of enrollment were powered for our primary study question, so some of the secondary study aims might be underpowered. This study was powered for a large effect size and was underpowered for smaller differences in average extensor lag.

Night splinting did not reduce extensor lag. It is notable that this was true for both bony and tendinous mallet fingers. Presumably, the bony mallets with displacement have some loss of mechanical advantage although we had too few bony mallets to test this hypothesis. It is also notable that 34 % (14 of 41 patients) with follow-up motion measurements had a final extensor lag of 20° or greater, including several patients with bony mallets. Final extensor lag averaged 14° and was associated with lag at enrollment. The final DIP motion was lower in our study than in prior trials, probably because we evaluated the result a median of just over a month after discontinuation of full-time immobilization. In one retrospective review of conservative treatment of 22 closed mallet fractures, the average final DIP extensor lag was 9° [9]. Another study that examined 31 patients approximately 5 years after splint treatment reported an average extensor lag of 8.3° [11]. A trial more consistent with our results found that

after 12 weeks, the mean lag on examination was 11° whereas the mean radiographic lag was 5.2° [12].

At 1 month evaluation, the average droop doubled from what was measured immediately after splint removal. One might speculate that the 8 weeks for tendinous and 6 weeks for bony mallet is insufficient, but that seems unlikely. Our impression—based on more prolonged splinting and even temporary pinning in some of these patients—is that a subset of patients does not heal a tendinous mallet, and that some of the displaced bony mallets have decreased mechanical advantage and more marked residual droop. What we learned from this study is that the patients we used to discharge at the end of full-time splint wear do not all maintain their extension.

Residual lag was associated with age, initial lag, and follow-up DIP flexion. The correlation between the increasing age and greater extensor lag is consistent with prior studies [2, 12]. The finding that residual lag does not correlate with satisfaction is also consistent with prior studies [11, 13, 15].

Based on these data, there is not much benefit to additional night splinting after completing the standard splinting protocol for mallet finger. The extra cost and time associated with obtaining a custom-made removable splint should be balanced with the patient's preferences. It is possible that a subset of patients might benefit from night splinting, although we did not find any such trends in our data. Patients should be aware that effective treatment of a mallet finger results in a slight extensor lag in most patients and a substantial probability of a

lag of 20° or greater. Future research can address whether other treatment approaches can improve these results.

Conflict of Interest David Ring declares that he has no conflict of interest.

Jillian S. Gruber declares that she has no conflict of interest.

Arjan G.J. Bot declares that he has no conflict of interest.

Statement of Human and Animal Rights All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Statement of Informed Consent Informed consent was obtained from all subjects, and all identifying details have been omitted from publication.

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