Randomized Controlled Trial of Daily Total End Range Time (TERT) for Capener Splinting of the Stiff Proximal Interphalangeal Joint

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OBJECTIVE. Capener splinting is a common treatment for extension deficit of the proximal interphalangeal (PIP) joint. This study compared the effect of daily splint total end range time (TERT) of 6–12 hr versus 12–16 hr.

METHOD. Twenty-two participants with extension deficits of the PIP joint were randomly allocated to a daily TERT of 6–12 hr or 12–16 hr. Progress after 8 wk of splinting was evaluated.

RESULTS. No significant difference was found in change in extension range of motion (ROM) between groups (active ROM, $F[4, 17] = 2.19$, $p = .13$; passive ROM, $F[4, 17] = 0.95$, $p = .46$; torque ROM, $F[4, 17] = 1.49$, $p = .26$). Considerable crossover between groups resulted in a similar average daily TERT (9.5 hr for the 6–12 hr group vs. 11.5 hr for the 12–16 hr group).

CONCLUSION. Further research with a larger sample is needed to determine whether longer daily TERT is beneficial. Our results suggest, however, that most patients find it difficult to wear splints >12 hr/day.

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Joint stiffness and joint contracture are secondary complications of traumatic hand injury resulting in loss of active range of motion (AROM) and passive range of motion (PROM; American Society for Surgery of the Hand, 2006; Colditz, 2004; Creighton & Steichen, 1994; E-Hand. Com, 2009; Michlovitz, Harris, & Watkins, 2004; Page & Stern, 1998). This loss of joint motion impairs hand function and results in difficulty participating in normal activities of daily living (ADLs) such as dressing, eating, and work-related tasks (Schneider et al., 2008). Consequently, occupational therapists are frequently challenged with the task of improving range of motion (ROM) to facilitate restoration of function after hand trauma (Michlovitz et al., 2004).

Proximal interphalangeal (PIP) joint extension deficits are a common pattern of deformity resulting from hand injury (Creighton & Steichen, 1994; Page & Stern, 1998; Prosser, 1996). The anatomy of the PIP joint and its tendency to sit in flexion in the presence of edema postinjury create a predisposition toward loss of extension PROM. After trauma, changes occur within the collagen matrix of the soft tissues encapsulating the PIP joint that result in shortening and disorganization of fibers and contracture formation (Brand, 1995; Brand & Hollister, 1999).

Dynamic Capener splints are a common treatment used for improving PIP joint extension (Capener, 1967; Fess & McCollum, 1988; Li-Tsang, Hung, & Mak, 2002; Prosser, 1996; Wilton, 1997b). A dynamic extension-mobilizing force is applied via the splint through spring coils that sit on either side of the PIP joint. The splint is designed to encourage PIP extension while allowing the distal interphalangeal joint to move freely (Figure 1). Growth and reorganization of contracted soft tissues are promoted as a result of extended periods of splint use (Brand, 1995; Fess & McCollum, 1988; Flowers &

Figure 1. Dynamic Capner splint used to improve proximal interphalangeal joint extension.

LaStayo, 1994; Glasgow, Fleming, & Tooth, 2008).

The term *total end range time* (TERT) was developed by Flowers and LaStayo (1994) and is used to describe the number of hours that a joint is held at the end of available ROM under light tension over days, weeks, or even months using a splint or cast (Wilton, 1997a). *Daily TERT* refers to the total number of hours per day that the splint is used (i.e., the daily wearing regimen, such as 6 hr per 24 hr; Glasgow, Wilton, & Tooth, 2003). Clinically, the concept of an optimal daily TERT is important for several reasons. First, the detrimental effects of prolonged joint immobilization have been well documented (Akeson, Amiel, Abel, Garfin, & Woo, 1987; Akeson, Woo, Amiel, Coutts, & Daniel, 1973; Salter & Field, 1960). Holding a joint still with the goal of improving PROM may result in some of the negative changes associated with immobilization if not counteracted with regular active motion. Second, joint contracture after trauma rarely presents as an isolated problem. More frequently, patients experience deficits in other areas of hand function as well, such as active motion, grip strength, and dexterity. Sufficient time to participate in an exercise program and ADLs without the splint in situ is needed to address these other functional deficits and to maintain healthy joint function.

Historically, the earliest published study that explored daily TERT was described by Kolumban in 1969. In a sample of 29 patients with PIP joint flexion contractures resulting from leprosy, Kolumban examined the difference between the use of a cast 11 hr/day versus 22 hr/day. Casts were changed on a daily basis after a period of heat and exercise, and this process was continued for up to 6 weeks. Kolumban found that patients who used their cast for 22 hr/day made greater gains in PROM than those using a cast for 11 hr/day; however, this difference was not statistically significant ($p = .38$). The relatively small sample size may in part account for the lack of significant findings.

Luster et al. (1990) examined daily TERT with dynamic splinting in 20 stiff metacarpophalangeal (MCP) joints (4 participants) after burn injury. Participants were divided into two groups, with one group wearing their splint 1 hr/day and the other group wearing their splint 2 hr/day. Progress was evaluated over 3 days of treatment. Luster et al. found no significant difference between a daily TERT of 1 hr versus 2 hr. Once again, the very small sample size of this study may have contributed to this negative finding. It is also possible that there was no observable difference between a daily TERT of 1 hr versus 2 hr because both are insufficient to significantly affect joint contracture.

Glasgow et al. (2003) conducted a prospective sequential clinical trial to investigate the concept of an optimal daily TERT in splinting for contracture resolution. Thirty-two participants with joint contracture in the

hand secondary to upper-limb trauma completed the 4-wk study. Participants were randomly allocated to a daily TERT of <6 hr (Group A) or 6–12 hr (Group B). Participants with both flexion and extension deficits were included in the study sample. The participants in Group B (daily TERT 6–12 hr) made twice the gains in ROM over 4 wk of splinting than those in Group A (daily TERT < 6 hr; $p < .05$). The average increase in ROM for participants in Group B was 21.9° versus 10.2° for those in Group A. Glasgow et al. recommended that further research explore the use of daily TERT beyond the 12-hr level. Hence, the purpose of our study was to assess whether participants using splints for 12–16 hr/day made greater progress with contracture resolution than those using splints for 6–12 hr/day over 8 wk of treatment.

Method

Research Design

A randomized controlled trial (RCT) design was used to implement the study. Participants were randomly allocated to daily TERT of 6–12 hr or 12–16 hr. Ethics approval was obtained from the University of Queensland Institutional Review Board and from the recruitment site (Hand and Upper Limb Clinic, EKCO Occupational Services, Brisbane, Queensland, Australia). All participants provided informed voluntary consent.

Participants

Twenty-two participants with an extension deficit in one PIP joint were recruited from the hand clinic at EKCO Occupational Services from November 2004 to May 2008. This sample was a subset of a larger cohort of patients with deficits in either MCP or PIP joints involved in a prospective splinting project we conducted (Glasgow, Tooth, Fleming, & Peters, 2011).

Participants were included in the study if they had a history of traumatic injury resulting in extension deficit of the PIP with PROM ≤ 80% that of the unaffected side (to justify the use of dynamic Capener splinting). Patients who had previously used dynamic splinting for the presenting injury were

excluded from the study, as were those with abnormal tone or paralysis associated with central nervous system dysfunction. Patients with acute complex regional pain syndrome, inflammatory arthritic conditions, infection, or artificial joints were also excluded from the study. Seven potential participants were excluded, resulting in the final sample of 22. Figure 2 provides further detail on the study sample, including recruitment, treatment allocation, and data analysis (CONSORT Group, 2010).

Study Variables

Clinical variables assessed included age (yr), diagnosis (e.g., fracture, soft tissue injury, volar plate), gender, pretreatment joint stiffness (modified Weeks Test; Flowers, 2002; Glasgow et al., 2011), time since injury (wk), digit, and insurance status (workers' compensation, non–workers' compensation). The extent of contracture resolution was measured using three outcome variables: (1) change in AROM (degrees), (2) change in PROM (degrees), and (3) change in torque range of motion (TROM; degrees) from baseline to after 8 wk of dynamic splinting. TROM was measured in addition to PROM because of its high reliability (Glasgow et al., 2003).

Materials

A standard silver finger goniometer (Smith & Nephew, Inc., Germantown, WI) was used to take all AROM, PROM, and TROM measurements. A Haldex tension gauge (JID Tools, Jonard Industries, Tuckahoe, NJ) was used to take TROM measurements and to set splint tension.

Procedures

The initial evaluation and all subsequent treatment were conducted by the principal researcher (Celeste Glasgow). After recruitment and completion of informed voluntary consent, a verbal history was taken and baseline cold AROM, PROM, and TROM were recorded. TROM was assessed at 500 g using the Haldex tension gauge (Glasgow et al., 2003), and demographic data were collected for the predictor variables. A dynamic Capener splint was then fabricated, and the mobilizing force was set to 200–250 g. The modified Weeks Test assessment of joint stiffness was then conducted (Glasgow et al., 2011); that is, the splint was applied for 30 min and change in AROM was recorded as the estimate of stiffness. We had previously found that the modified Weeks Test predicted

outcome with splinting (Glasgow et al., 2011).

Participants were randomly allocated to a daily TERT of either 6–12 hr or 12–16 hr. The randomization sequence was developed from a table of random numbers by an associate researcher (Jenny Fleming) not responsible for conducting the initial assessment or providing intervention. This sequence was stored off site, and the principal researcher was advised by telephone of each participant's treatment allocation only after completion of the initial assessment and splint construction. Participants were advised of their own allocated daily TERT but were blinded to the existence of the alternative daily TERT group. Participants were provided with a splint diary and instructed to accurately record the actual number of hours per day they used their splint.

Participants attended therapy every 1–2 wk so that their progress could be monitored. Splint biomechanics and tension were checked and, if necessary, adjusted at each therapy session. All participants received a standard core treatment program including dynamic splinting, AROM and assisted ROM, and edema management. An independent
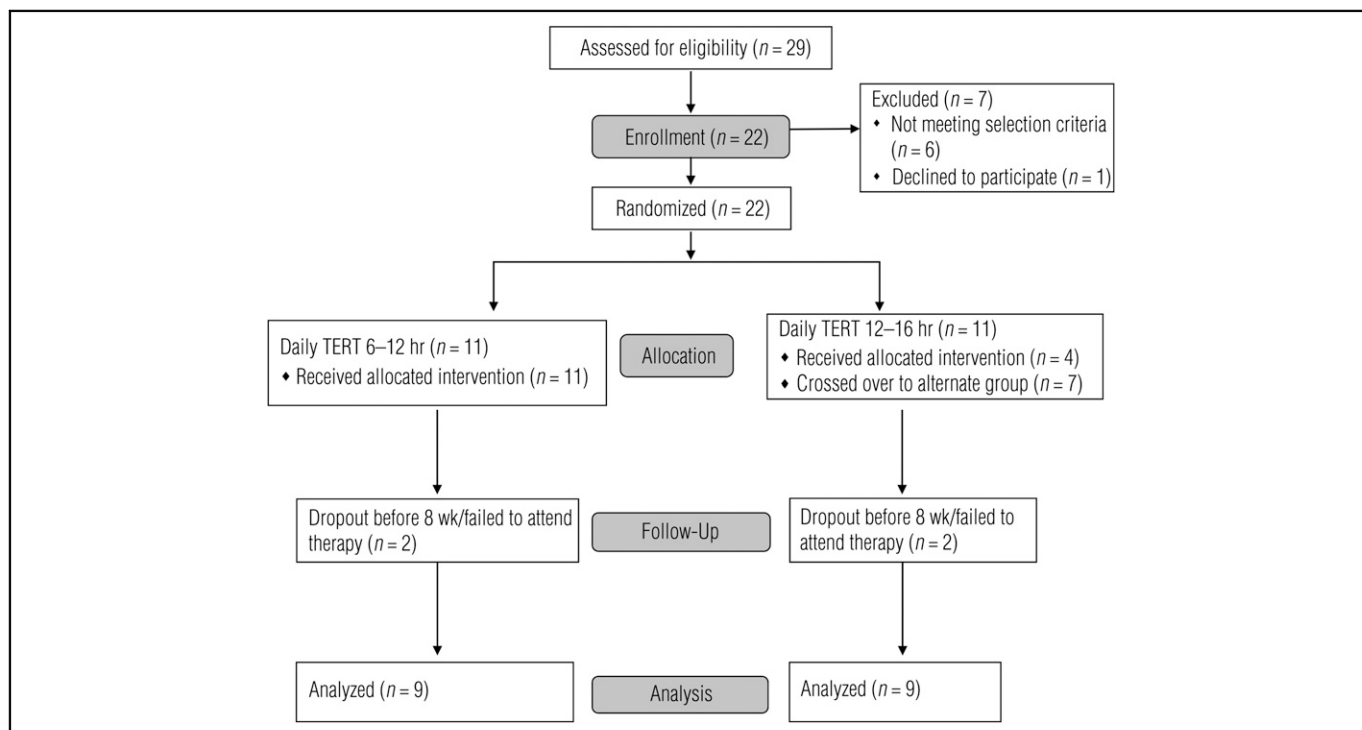

Figure 2. CONSORT diagram outlining recruitment process and treatment allocation (CONSORT Group, 2010).

Note. TERT = total end range time.

Table 1. Comparison of Baseline Clinical Characteristics, by Group

Characteristic	Group 1 (6–12 hr/day) Mean (*SD*, range)	n	%	Group 2 (12–16 hr/day) Mean (*SD*, Range)	n	%	*p*
Age, yr	41.0 (11.2, 30.0–72.0)			35.3 (11.4, 20.0–56.0)			.17
Race or ethnicity							NA
White		11	100		10	90.9	
Asian		0	0		1	9.1	
Time since injury, wk	11.1 (3.7, 7.0–20.0)			9.6 (4.5, 5.0–18.0)			.29
>8		2	18.2		6	54.5	
8–12		6	54.5		2	18.2	
<12		3	27.3		3	27.3	
Modified Weeks Test, degrees	11.8 (3.6, 7.0–17.0)			9.8 (6.0, 2.0–24.0)			
Gender							.09
Female		6	54.5		2	18.2	
Male		5	45.5		9	81.8	
Digit							NA
Index		1	9.0		1	9.0	
Middle		2	18.2		3	27.3	
Ring		4	36.4		2	18.2	
Little		4	36.4		5	45.5	
Insurance status							.50
Workers' compensation		1	9.1		2	18.2	
Non–workers' compensation		10	90.9		9	81.8	
Diagnosis							.01
Fracture		0	0		4	36.4	
Volar plate		4	36.4		5	45.4	
Soft tissue		7	63.6		2	18.2	

Note. NA = χ^2 analysis not appropriate; *SD* = standard deviation. Percentages are rounded to the nearest decimal point.

evaluation of change in AROM, PROM, and TROM was conducted 8 wk into the splinting program by a colleague blinded to treatment allocation.

Data Analysis

Descriptive statistics (means, *SD*, medians, and percentages) were initially calculated on all data. Participants were analyzed in the groups to which they were randomized following an intention-to-treat principle. Baseline similarities between the groups on demographic and clinical factors were analyzed using nonparametric statistics when possible because of the small numbers. We used three simple linear regression analyses using the generalized linear procedure in SPSS Version 17 (SPSS, Inc., Chicago) to predict change in AROM, PROM, and TROM (in degrees). Predictors were randomization group (6–12 hr, 12–16 hr) and baseline ROM for each of the three outcomes. Because of the small sample size, other covariates were included only if they were significantly different by randomization group. Cronbach's α was set at $p \leq .05$.

Results

Baseline characteristics of the participants and data showing whether randomization resulted in equal distribution of these characteristics across the two groups are presented in Table 1. The only significant difference between the groups was found for diagnosis; most patients randomized to wear their splint for 6–12 hr had soft tissue injuries. Because of the small cell sizes, however, these results must be treated with caution. Of the 22 participants randomized, 4 dropped out of the study because of work or family commitments, leaving a final sample of 18.

The average daily TERT for both groups was similar (6–12 hr/day group = 9.5 hr; 12–16 hr/day group = 11.5 hr) because 78% of the participants in the 12–16 hr/day group did not use their splint for more than an average of 12 hr/day and subsequently crossed over into the 6–12 hr/day group. All participants allocated to the 6–12 hr/day group used their splint for the correct amount of time each day. We found no significant differences in

improvement in AROM, PROM, or TROM at the 8-wk assessment (Table 2).

Discussion

The purpose of this study was to examine the benefit of using dynamic Capener splints to improve extension at the stiff PIP joint for more than 12 hr/day. Previous research (Glasgow et al., 2003) indicated that 6–12 hr/day of splint use is better than <6 hr; however, limited evidence is available examining splint use beyond 12 hr. Some observable differences between groups existed at baseline, but overall the combined sample appeared to be representative of the wider population of hand-injured patients undergoing PIP joint extension splinting (i.e., mostly men, little finger most commonly affected, average time since injury 10–11 wk; Glasgow et al., 2003; Glasgow, James, O'Sullivan, & Tooth, 2004; Prosser, 1996).

Participants allocated to the 12–16 hr daily TERT group showed slightly greater improvement in both AROM and TROM than did participants in the 6–12 hr/day

Table 2. Improvements in AROM, PROM, and TROM After 8 Wk of Splinting: Mean Scores and Results of Linear Regression Analyses

Measure	Group 1 (6–12 hr/day)	Group 2 (12–16 hr/day)	F	p
Mean daily TERT, hr (95% CI)	9.5 (7.9, 11.1)	11.5 (9.1, 13.9)	$F(1, 17) = 2.67$	.12
Mean improvement in AROM, degrees (95% CI)	16.7 (8.7, 24.6)	19.1 (13.4, 24.8)	$F(4, 17) = 2.19$	.13
Mean improvement in PROM, degrees (95% CI)	18.4 (10.5, 26.3)	18.1 (14.1, 22.1)	$F(4, 17) = 0.95$	.46
Mean improvement in TROM, degrees (95% CI)	9.2 (4.6, 13.8)	12.8 (7.0, 18.5)	$F(4, 17) = 1.49$	.26

Note. AROM = active range of motion; CI = confidence interval; PROM = passive range of motion; TERT = total end range time; TROM = torque range of motion.

group (Table 2). However, these differences were small (2–3°) and, like Kolumban's (1969) finding, not statistically significant. The negative effects of prolonged immobilization associated with extended splint use may outweigh the potential benefit of increasing ROM by only a few degrees. But in some cases, those extra few degrees may be all a patient needs to achieve functional ROM.

Several factors may have contributed to the nonsignificant results. First, as in Kolumban's (1969) study, the small sample size limited the power of statistical analyses, increasing the risk of Type 2 error (i.e., inability to detect a true significant difference). Second, data for this study were collected as part of a larger splinting cohort study we conducted (Glasgow et al., 2011). This larger sample included both flexion and extension deficits of PIP or MCP joints, reflective of the majority of stiff joints presenting to the hand clinics at EKCO in Brisbane, Queensland, Australia, during the 3.5-yr data collection period. Because the PIP joint is frequently stiff in both flexion and extension after hand trauma, in some cases splinting to improve flexion rather than extension was the functional priority. Hence, when the main treatment goal was to improve PIP joint flexion using dynamic splinting, static extension splinting was used to control PIP joint extension within an acceptable range rather than dynamic Capener splinting.

Finally, the fact that 78% of participants allocated to the 12–16 hr/day group used their splints for <12 hr/day and consequently crossed over into the 6–12 hr/day duration may have contributed to the lack of difference in progress observed between the groups. As a result, the difference in mean daily TERT over the 8 wk of the study was small and possibly not large enough to detect any significant difference (mean daily TERT was 9.5 hr for the 6–12 hr/day group and 11.5 hr for the 12–16 hr/

day group). Participants in both groups reported that the splints were comfortable and easy to sleep in overnight. However, participants in the 12–16 hr/day group also needed to wear their splint for a reasonable time during the day to accrue 12–16 hr of splint use. Difficulty completing work, self-care, or domestic tasks while using the splint was the reason cited for inability to accrue the required daily TERT of 12–16 hr. Participants reported that they ran out of time in the day to meet the target TERT. This finding that most participants were unable to wear a fairly unobtrusive finger-based Capener splint for more than 12 hr per 24 hr—suggests that it may not be clinically practical to expect patients to comply with a daily TERT beyond 12–14 hr and that other factors need to be considered in the prescription of splint regimens (e.g., work and family commitments, time since injury, pretreatment joint stiffness; Glasgow et al., 2011; Wilton, 1997a).

Implications for Occupational Therapy Practice

Findings from this RCT of daily TERT with Capener splinting have the following implications for clinical practice:

- Capener splinting is an effective treatment for the management of PIP joint flexion contracture.
- Although longer daily splint use is considered desirable, patients may find it difficult to wear splints for more than 12 hr/day.
- Therapists need to be mindful of lifestyle factors that may influence patients' ability to use splints for long periods.

Conclusions

In our sample, daily TERT beyond 12 hr/day did not result in a statistically significant improvement in AROM, PROM,

and TROM compared with daily TERT of less than 12 hr/day. In many cases, it may not be practicable for patients to use splints for >12 hr/day. When prescribing splint-wearing regimens, therapists need to consider lifestyle factors that influence patients' ability to comply with the allocated daily TERT, as well as other factors such as length of time since injury and degree of pretreatment joint stiffness. Additionally, the benefit of small gains in ROM needs to be weighed against the need for prolonged immobilization in the splint. ▲

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