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Does three months of nightly splinting reduce the extensibility of the flexor pollicis longus muscle in people with tetraplegia?

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ABSTRACT **Background and Purpose.** *The extensibility of the paralysed flexor pollicis longus (FPL) muscle is an important determinant of an effective tenodesis grip in people with C6 and C7 tetraplegia. Therapists believe that splinting can reduce the extensibility of the FPL muscle and thus improve hand function. However, there remains much controversy around the optimal position of splinting and its effectiveness is yet to be verified. The aim of the present study was to determine whether a three-month thumb splinting protocol reduces extensibility of the FPL muscle in people with tetraplegia.* **Method.** *An assessor-blinded, within-subject, randomized controlled trial was undertaken. Twenty people with tetraplegia and bilateral paralysis of all thumb muscles were recruited from a sample of convenience. One randomly selected hand of each subject was splinted each night for three months. The splint immobilized the FPL muscle in a relatively shortened position by positioning the carpometacarpal and metacarpophalangeal joint of the thumb in flexion. The other hand remained unsplinted for the duration of the study. Carpometacarpal angle was measured with the application of a standardized torque by a blinded assessor at the beginning and end of the three-month study period. A device specifically designed for this purpose that stabilized the wrist and other joints of the thumb in full extension was used.* **Results.** *No subject withdrew from the study. The three-month splinting protocol had a mean treatment effect on carpometacarpal joint angle of 0° (95% CI, −6° to 6°).* **Conclusion.** *Splinting the FPL muscle in a relatively shortened position each night for three months does not reduce its extensibility. Copyright © 2006 John Wiley & Sons, Ltd.*

Key words: extensibility, flexor pollicis longus, splinting, tenodesis, tetraplegia

INTRODUCTION

The extensibility of the paralysed flexor pollicis longus (FPL) muscle is an important determinant of an effective tenodesis grip in people with C6 and C7 tetraplegia (Harvey, 1996; Johanson and Murray, 2002). If the FPL muscle is too extensible then active wrist extension will not increase the passive tension in the FPL muscle and the thumb will not be pulled into flexion. Excessive extensibility of the FPL muscle is a common clinical problem that is routinely managed with surgery. However, therapists believe that a judicious splinting protocol can also reduce the extensibility of the FPL muscle and thus improve hand function (Curtin, 1994; Harvey, 1996; Johanson and Murray, 2002). However, the optimal position of splinting and the effectiveness of any splinting protocol for this purpose is yet to be verified (Curtin, 1993; Sutton, 1993; DiPasquale-Lehnerz, 1994; Doll et al., 1998).

There is good animal evidence to support the belief that prolonged and sustained splinting of the FPL muscle in its shortened position (for example, thumb carpometacarpal and metacarpophalangeal flexion) will induce muscle shortening in the FPL muscle (Curtin, 1994; Harvey, 1996). Animal studies indicate that immobilization of a muscle in a shortened position promotes serial loss of sarcomeres and decreases muscle extensibility (Tabary et al., 1972; Williams and Goldspink, 1978; Witzmann et al., 1982; Herbert and Balnave, 1993). However, no randomized controlled trial has yet verified whether human muscles respond to immobilization in a shortened position in the same way as the muscles of animals. More specifically, no study has yet determined whether splinting the FPL muscle in its shortened position reduces its extensibility. Only one randomized controlled trial has yet attempted to verify the effectiveness of a hand splinting regimen in the tetraplegic population but it did not examine the extensibility of the FPL muscle (DiPasquale-Lehnerz, 1994).

The aim of the present study was, therefore, to determine whether three months of splinting the FPL muscle in a relatively shortened position (thumb carpometacarpal and metacarpophalangeal flexion) decreases FPL extensibility in people with tetraplegia. The thumbs of people with tetraplegia provide a rare opportunity to study interventions designed to reduce muscle extensibility. The findings of the study therefore have clinical implications for therapists working in the area of spinal cord injuries as well as for scientists interested in understanding the response of muscles to immobilization in a shortened position.

METHOD

Study design

An assessor-blinded, within-subjects, randomized controlled trial was undertaken. Experimental thumbs were splinted each night for three months and control thumbs received no intervention. Extensibility of the FPL muscles was measured in all thumbs at the beginning and end of the three-month splinting period.

Subjects

Outpatients from a Sydney spinal unit were contacted via telephone and invited to participate in the study. To be eligible for inclusion, subjects had to have sustained an American Spinal Injury Association (ASIA) motor C4 to C7 symmetrical cervical spinal cord injury at least one year earlier. Subjects

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were only included if they had paralysis of the thumb muscles (grade 0/5 or 1/5 voluntary strength) and excessive extensibility in the FPL muscle as demonstrated by no contact or minimal contact between the thumb and first finger with the wrist passively extended. Subjects were excluded if they had a history of trauma to either thumb, hand or wrist, were unable to tolerate wearing a thumb splint, were unlikely to co-operate, had joint contractures of the wrist or thumb, or were already wearing hand splints at night.

Twenty subjects took part in the study. This sample size provided a 90% probability of detecting a 10° change in carpometacarpal angle, assuming a standard deviation (SD) of 5°, loss to follow-up of 10%, and alpha of 0.05. A minimal clinically worthwhile treatment effect of 10° was determined a priori and decided upon after quantifying carpometacarpal angles in a group of subjects with tetraplegia (Harvey et al., 2005). Ten degrees was an estimate of the magnitude of change needed to see an associated change in hand function.

One subject had a C4 lesion, three subjects had a C5 lesion, 12 subjects had a C6 lesion and four subjects had a C7 lesion (according to ASIA motor classification; ASIA, 1992). All subjects had varying amounts of spasticity in their FPL muscles. The median (interquartile range) time since injury and age of subjects was 10 years (5.8–15.3 years) and 37 years (31–47 years), respectively. All but four subjects were male (*see* Table 1).

The study received ethical approval from the appropriate institutions and informed consent was obtained from all subjects. The authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of the research.

TABLE 1: Subjects' characteristics at baseline, including age, sex, time since injury, ASIA motor level, carpometacarpal angle of experimental and control thumbs with the application of 0.044 Nm

Age	37 (31–47)
Sex:	
male	16
female	4
Time since injury (years)	10 (5.8–15.3)
ASIA motor level:	
C4	1
C5	3
C6	12
C7	4
Carpometacarpal angle	
control	62 (54–78)
experimental	65 (56–73)

ASIA = American Spinal Injury Association; Nm = Newtons per metre.

Materials and procedure

The extensibility of the FPL muscle was measured initially. Upon completion of these measurements, one thumb of each subject was randomly allocated to the experimental (splint) group and the other thumb to the control (non-splint) group. A computer-generated random allocation schedule was determined prior to the study by an independent person otherwise not involved in the study. The use of random allocation ensured that there was an equally probable chance of subjects' dominant hands being allocated to the treatment group as to the control group without systematic bias. To ensure concealment, the independent person placed allocations in sealed, opaque, sequentially numbered envelopes which were not opened until after baseline measurements had been obtained. Subjects were considered to have

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entered the study when the envelope was opened.

The thumb allocated to the experimental group was splinted each night for three months. The splint was custom made for each subject by an occupational therapist. The splint held the carpometacarpal and metacarpophalangeal joints of the thumb in flexion. The splint was initially fabricated from a thermoplastic material (Eziform™) that encompassed the base of the thumb and the lower part of the hand. However, the first five subjects reported problems with comfort and fit, so subsequent subjects were provided with a different type of splint (*see* Figure 1) fabricated from thermoplastic (Orfit™) and strapping (Softstrap™) material. The strapping material looped around the base of the thumb and attached to the thermoplastic palmar splint. This splint was well tolerated. Both types of splints held the thumb in the same position and neither splint encompassed the interphalangeal joint of the thumb. All other aspects of subjects' hand management remained constant and subjects continued to use push mitts and adapted equipment for activities of daily living as required.

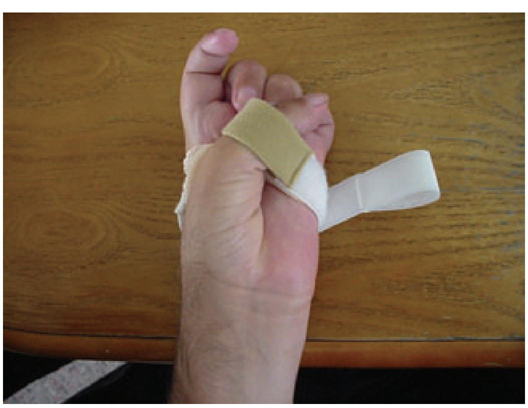

FIGURE 1: Splint worn by subjects. The first five subjects wore a different style of splint although it also immobilized the carpometacarpal and metacarpophalangeal joints of the thumb in flexion.

Subjects were instructed to put the splint on when they went to bed each night and to remove the splint in the morning. They were not directly supervised but compliance was closely monitored. Subjects were provided with diaries in which they (or their carers) were instructed to record when the splint was worn. Subjects were encouraged to report real compliance though this could not be verified. A research assistant either rang or visited subjects once a week, and at this time the diary entries were checked.

The primary outcome measure was the extensibility of the FPL muscle. This was reflected by measuring carpometacarpal joint extension with the application of a standardized thumb extension torque whilst stabilizing the wrist and other joints of the thumb in full extension. Carpometacarpal angle measured in this way can be used to reflect the extensibility of the FPL muscle in much the same way as hip flexion can be used to reflect the extensibility of the hamstring muscles when the knee is extended. A measurement device specifically designed and previously tested for reliability was used for this purpose (Harvey et al., 2005; *see also* Figure 2). Pre- and post-testing always followed the same format with all post-study measurements taken at least 24 hours after the cessation of the splinting protocol. In this way, measurements did not reflect the immediate response of the FPL muscles to immobilization in a shortened position, but rather its sustained response to this intervention. The right thumb was tested before the left thumb and subjects were tested in their wheelchairs except in two subjects who were unable to sit and were therefore tested in lying. The device was positioned on a testing table next to the subject. The height of the testing table was adjusted to ensure that the upper arm was positioned beside the subject's body with the forearm parallel to the

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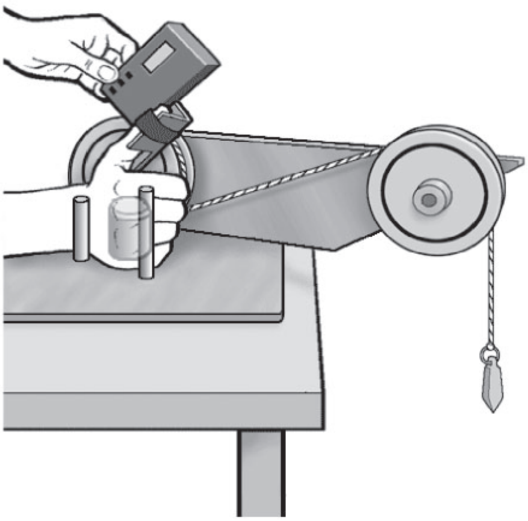

FIGURE 2: The testing device. Carpometacarpal angle was measured with an inclinometer (represented by the black box). The thumb extension torque was applied by suspending weights from the top of the device. The force from the weights was applied to the thumb by a rope wrapped around the wheel. The centre of the wheel was aligned with the carpometacarpal joint. In this way thumb extension torque was a product of the radius of the wheel and the mass of the suspended weight. Reprinted by permission. Copyright 2005. Harvey L, Simpson D, Glinsky J, Pirronello D and McLean S (2005) Quantifying the passive extensibility of the flexor pollicis longus muscle in people with tetraplegia. *Spinal Cord* 43: 620–624.

floor. Carpometacarpal angle was measured using a digital inclinometer and with the application of three extensor torques (0.027 Newtons per metre (Nm), 0.035 Nm and 0.044 Nm). Each torque was applied for one minute prior to measuring. In this way reflex activity around the thumb and wrist, if present, was minimized, and most viscous deformation exhausted (Bohannon, 1984; Magnusson et al., 1995). All measurements were taken by one of three research assistants — all of whom were blinded to hand allocation.

Mean changes from initial to final measures were calculated for both experimental (splint) and control (non-splint) hands. The t distribution was used to estimate 95% confidence intervals for between-hand differences in the change of carpometacarpal angle. Data were analysed by intention-to-treat (Pocock, 1983).

RESULTS

Outcome measures were obtained at the beginning and end of the study from all 20 subjects. There were some deviations from the study protocol. One subject ceased wearing his thumb splint for a 20-day period because of skin breakdown over the thumb. The splint was adjusted and the subject recommenced wearing the splint without any further problems. Another subject was hospitalized for three weeks due to an unrelated illness. He was unable to wear his splint over this time. So whilst the study protocol dictated that subjects wear the splint each night for three months (between 90 and 92 days), in practice the best estimation (as provided by subjects) indicated that subjects wore the splint on a median (interquartile range) of 77 nights (71–86 nights) over the three-month period. Subjects reportedly wore the splint each night for a median (interquartile range) of 7.0 hours (5.6–8.9 hours) with a total median (interquartile range) splinting time of 535 hours (352–692 hours).

The treatment and control hands of all subjects were similar at baseline with regard to FPL extensibility (*see* Table 1). FPL extensibility of individual subjects varied substantially (carpometacarpal angle of the control thumbs with the application of 0.044 Nm of torque ranged between 46° and 87°).

The splinting protocol did not significantly change the extensibility of the FPL muscle. The mean (95% CI) treatment effect

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TABLE 2: Mean (SD) pre- and post-carpometacarpal angle (°) with the application of 0.027 Nm, 0.035 Nm and 0.044 Nm torque. The mean (95% CI) overall treatment effect is also provided. A decrease in angle reflects a loss of extensibility in the FPL muscle

Torque (Nm)	*Control*		*Experimental*		*Treatment effect*	
	Pre-	*Post-*	*Pre-*	*Post-*	*Mean*	*95% CI*
0.027	55 (12)	53 (15)	54 (10)	54 (11)	–2	(−8 to 4)
0.035	61 (12)	60 (16)	61 (12)	60 (11)	0	(−6 to 6)
0.044	65 (13)	64 (16)	65 (12)	64 (12)	0	(−6 to 6)

Nm = Newtons per metre; FPL = flexor pollicis longus.

of the splinting protocol on carpometacarpal angle with the application of 0.027 Nm, 0.035 Nm and 0.044 Nm was –2° (−8° to 4°), 0 (−6° to 6°) and 0°degrees (−6° to 6°), respectively (*see* Table 2) where a positive difference in carpometacarpal angle reflects a positive treatment effect (i.e. shortening of the FPL muscle in the experimental hand). Post hoc analyses failed to detect any systematic differences in the response of subjects according to time since injury (p = 0.768; regression coefficient −0.15; 95% CI −0.27 to 0.20), pre-intervention extensibility (p = 0.111; regression coefficient 0.44; 95% CI −0.79 to 0.67) or compliance (p = 0.979; regression coefficient 0.00; 95% CI −8.27 to 8.48).

DISCUSSION

The results of the present study indicate that in people with tetraplegia, splinting the FPL muscle in its shortened position every night for three months does not reduce FPL extensibility. These findings have implications for the management of hands in people with tetraplegia, and also for therapists interested in understanding the response of human muscles to prolonged immobilization in a shortened position.

Excessive extensibility of the FPL muscle is a common clinical problem that hinders the hand function of people with C6 and C7 tetraplegia. Some therapists believe that the extensibility of this muscle can be reduced by an appropriate and judicious splinting programme (Curtin, 1994; Harvey, 1996; Johanson and Murray, 2002). Whilst there are different types of splints advocated, the one selected for the present study held the FPL muscle in a relatively shortened position with the carpometacarpal and metacarpophalangeal joints flexed. There is good evidence from animal studies to indicate that immobilizing muscles in their shortened positions is an effective way of inducing sustained decreases in extensibility (Tabary et al., 1972; Williams and Goldspink, 1978; Witzmann et al., 1982; Herbert and Balnave, 1993). It is not clear why we were unable to reproduce these findings in this study, although the most likely explanation is that the treatment dosage was insufficient. That is, the FPL muscle needed to be splinted in an even shorter position, or the splints needed to be worn for longer periods each day and for more than three months.

The FPL muscle was immobilized in a relatively shortened position with the carpometacarpal and metacarpophalangeal joints flexed. This, however, does not place the FPL muscle in its fully shortened position and may have been inadequate. Animal studies suggest that immobilization at intermediate

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lengths may still induce shortening, although the shortening is less marked (Herbert and Balnave, 1993). The fully shortened position of the FPL muscle can only be attained by also flexing the wrist and interphalangeal joint of the thumb. This position was not adopted because of the associated risk of promoting a flexion contracture of the wrist and interphalangeal joints (Harvey, 1996). In addition, flexion of the thumb interphalangeal joint was avoided in an attempt to encourage stiffness into extension of this joint. Stiffness into extension of the thumb interphalangeal joint is believed to promote hand function (Rieser and Waters, 1986; Moberg, 1987) and may be best attained by prolonged immobilization into extension, not flexion (Harvey, 1996).

It is possible that subjects needed to wear the splints for more than three months. Alternatively, it may be that subjects needed to wear the splints for longer periods each day and that uninterrupted immobilization is more important than the total time the splint is worn. However, we do not advocate that these types of splints be worn during the day in individuals with C6 and C7 tetraplegia because they limit upper limb function and independence.

Any beneficial effects of the splinting regime may have been negated by the hand activities subjects performed during the day. Subjects were encouraged to avoid activities that inadvertently stretched the FPL muscle; however, they were not supervised, nor were they blinded, so it is possible that they inadvertently stretched their FPL muscles during the day when the splints were removed. For instance, some subjects passively placed their thumbs in an extended position to turn on switches. The importance of avoiding self-administered stretch activities like this is not known, although three recent trials of our own (Harvey et al., 2000; Harvey et al., 2003; Ben et al., 2005b) suggest that the short duration stretches these individuals are likely to self-administer to their thumbs are not as deleterious to hand function as previously assumed.

Whilst the most likely explanation for our negative findings is an insufficient treatment dosage, there is also a possibility that there may be more important factors yet to be identified which trigger muscle shortening. Alternatively, it may be that muscle shortening can only be readily promoted in particular muscles or sub-groups of patients. For instance, it could be that muscle shortening is more readily promoted in certain types of muscles or in recently paralysed muscles. It is also possible that muscles affected by upper motor neuron lesions (with or without accompanying damage to the lower motor neuron) are less responsive to immobilization in a shortened position than neurally intact muscles, and particularly muscles of patients with chronic spinal cord injuries. While this issue has not been fully investigated in the animal model, there is evidence to indicate that denervated muscles (i.e. with lower motor neuron lesions) remodel in response to position of immobilization in a similar way as neurally intact muscles (Goldspink et al., 1974; Williams and Goldspink, 1976; Goldspink, 1978), albeit somewhat slower (Hayat et al., 1978). These responses may be further dampened by the secondary changes associated with chronic neurological injury, notably changes in the electrophysiological, biochemical, structural and enzymological characteristics of muscles (Hayat et al., 1978; Goldspink, 1978). However, clinical observations suggest that while we were unable to induce muscle shortening in the present study (when it is potentially useful), other muscles of people with spinal cord injuries are highly susceptible to shortening (when it is potentially

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detrimental), regardless of time since injury. These and similar anomalies between clinical observations about the response of muscles to position of immobilization and the results of animal studies and clinical trials are yet to be fully explained.

IMPLICATIONS

Three months of nightly splinting did not reduce the extensibility of the FPL muscle in the people with tetraplegia. It remains to be seen whether the same splinting protocol is effective if continued for more than three months, or if implemented with a different patient population.

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