Twelve weeks of nightly stretch does not reduce thumb web-space contractures in people with a neurological condition: a randomised controlled trial

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Question: What is the effectiveness of 12 weeks of nightly stretch in reducing thumb web-space contracture in people with neurological conditions? ***Design***: Assessor-blinded, randomised controlled trial. ***Participants***: Forty-four (one dropout) community-dwelling patients with a neurological condition (14 stroke, 7 traumatic brain injury, 23 spinal cord injury) who had uni- or bilateral thumb web-space contractures (60 thumbs). ***Intervention***: The experimental thumbs were splinted into a stretched, abducted position each night for 12 weeks. The control thumbs were not splinted. ***Outcome measures***: Thumb web-space was measured as the carpometacarpal angle during the application of a 0.9 Nm abduction torque before and after intervention. ***Results***: The mean increase in thumb web-space after 12 weeks was 1 deg (95% CI, –1 to 2). ***Conclusion***: Intensive stretch administered regularly over three months does not reduce thumb web-space contractures in neurological conditions. **[Harvey L, de Jong I, Goehl G, Marwedel S (2006) Twelve weeks of nightly stretch does not reduce thumb web-space contractures in people with a neurological condition: a randomised controlled trial. *Australian Journal of Physiotherapy* 52: 251–258]**

Key words: Contracture, Rehabilitation, Thumb, Hand Deformities, Splints, Physiotherapy

Introduction

Contractures are a common complication of neurological conditions and are undesirable for many reasons (Bryden et al 2004, Dalyan et al 1998, McDonald et al 2005, Scott and Donovan 1981, Yarkony et al 1985). In particular, they limit function and predispose patients to pain, sleep disturbances, and unsightly deformities (Cooper et al 1993, Dalyan et al 1998, Grover et al 1996, Scott and Donovan 1981, Silfverskiold and Waters 1991, Waring and Maynard 1991). Contractures are due to neurally-mediated and non-neurally mediated factors (Dietz 2000, Herman 1970, Lamontagne et al 1998, O'Dwyer and Ada 1996, Sinkjaer and Magnussen 1994, Sinkjaer et al 1993). They are typically managed with stretch that is administered manually by therapists or through weight-bearing, positioning, or splinting programs. However, there is uncertainty about the effectiveness of stretch for this purpose. There are strong anecdotal reports and low-quality evidence from different patient populations supporting its effectiveness (Cherry and Weigand 1981, Conine et al 1990, Harvey et al 2002, Kent et al 1990, MacKay-Lyons 1989, McDonald 1989, Scott et al 1981). Animal studies also indicate that soft tissue structures are highly adaptable and remodel in response to stretch (Tabary et al 1972, Tardieu et al 1981). The underlying morphological changes include increases in the number of muscle sarcomeres, changes in the amount and orientation of the intramuscular connective tissue, as well as changes in the biochemistry of the extracellular matrix of connective tissues (Akeson et al 1977, Amiel et al 1985, Evans et al 1960, Tabary et al 1972, Williams 1988).

In contrast to the anecdotal and animal evidence, there are a growing number of randomised controlled trials in people with neurological conditions that throw doubt on assumptions about the efficacy of stretch for the prevention and reduction of contractures (Ben et al 2005, Harvey et al 2000, Harvey et al 2003, Lannin et al 2003, Turton and Britton 2005). The clinical trials in this area have mostly examined the effects of a two- or four-week intensive stretch, although one trial examined the effect of 1.5 hours per week of stretch over a three-month period (Ben et al 2005). These trials have included people with spinal cord injuries (Ben et al 2005, Harvey et al 2000, Harvey et al 2003), stroke (Ada et al 2005, Turton and Britton 2005), and traumatic brain injury (Lannin et al 2003) and have administered stretch to ankles (Ben et al 2005, Harvey et al 2000), hips (Harvey et al 2003), shoulders (Ada et al 2005, Turton and Britton 2005), and hands (Lannin et al 2003). Stretch has been applied to increase, maintain, or prevent the loss of tissue extensibility, and although the underlying rationale may be different, no trial provides convincing evidence that stretch is effective for any of these purposes. This is despite the application of stretch for considerably longer than typically carried out in the clinical setting (ie, at least 20 minutes per day).

There are many possible explanations for the failure of clinical trials to detect an effect of stretch. For example, it may be that stretch is more effective for reduction rather than prevention of contractures, or more effective for some joints and some conditions than for others. However, the most likely explanation is not that stretch is ineffective, but rather that stretch needs to be applied for many hours a day and/or applied over many months. To explore this possibility, we looked at the effectiveness of stretch applied for eight hours a day over 12 weeks to people with thumb web-space contractures and neurological conditions. The thumb was used because it can be stretched for prolonged periods of time without excessive discomfort or disruption to patients' lives and independence. In this way, it provides a pragmatic

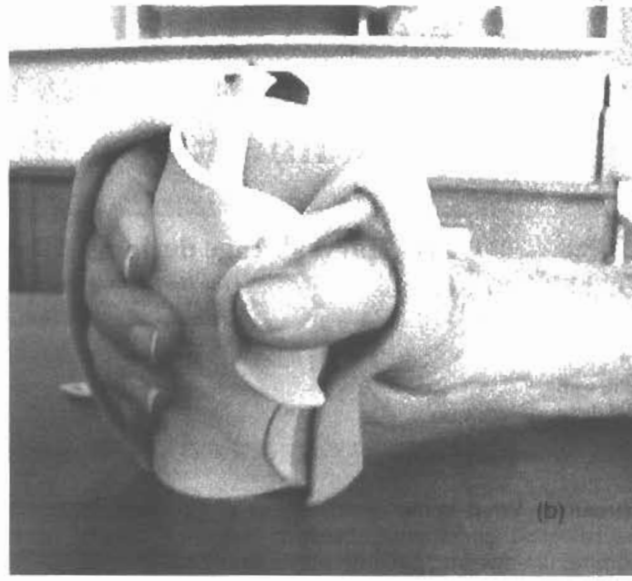

Figure 1. One of two types of splints was used. Both stretched the thumb into abduction, the first (a) with a C-bar and the second (b) with a cone-shaped piece.

model to explore tissue adaptability that is superior to the typically-used animal model. Patients suffering spinal cord injury, stroke, or traumatic brain injury were included because they commonly have contractures that are managed with stretch. It was hypothesised that eight hours of stretch applied each day over a 12-week period would reduce thumb web-space contractures in patients with neurological conditions.

Method

Design A randomised, controlled trial was carried out with a combination of a within-participants and between-participants design. That is, for participants with bilateral thumb web-space contractures, the intervention was applied to one thumb and the contralateral thumb acted as a control (as determined by random allocation). The thumbs of participants with unilateral thumb web-space contractures were either randomly allocated to the control (no splint) or experimental (splint) condition. Consequently, different random allocation schedules were used for the unilateral and bilateral participants. In addition, participant allocation was blocked according to diagnosis, namely spinal cord injury, traumatic brain injury, or stroke. The size of each block was varied randomly and was unknown to those responsible for participant recruitment and testing. An independent person used a computer to generate the random allocation schedules. These were placed in opaque, sequentially-numbered envelopes which were sealed and kept off site. As each participant was recruited, and following his/her initial assessment, the research assistant contacted the independent person for the subject's allocation. The participant was considered to have entered the trial once the envelope was opened. Final measures were retaken one day after completion of the 12-week intervention. Participants were instructed not to wear the splint, nor apply any stretch to the thumb for 24 hours preceding the final measures. Four assessors were used for the initial measures but only two assessors for the final measures. The assessors were blinded to participant allocation and participants were asked not to discuss any aspect of the trial with the assessors in order to maintain blinding. The success of blinding was recorded by asking assessors to indicate whether group allocation had been revealed. If it had not, assessors were then asked to indicate which group they thought participants had been allocated to. The trial received ethical approval from the relevant institutions and informed consent was obtained from all participants.

Participants A sample of convenience was recruited. Potentially suitable in and outpatients from a rehabilitation centre in Sydney were identified and contacted by staff. Patients were then screened for inclusion if they expressed a willingness to participate in the trial. Participants were included if they had sustained a cervical spinal cord injury, traumatic brain injury or stroke that affected one or both upper limbs, and also had a contracture of their thumb web-space (assessed by clinical examination). Participants were excluded if they had a contracture deemed unlikely to respond to stretch. This decision was based on a subjective clinical assessment of the duration of the contracture and the 'end-feel', as is routine clinical practice.

Intervention Experimental thumbs were stretched by splinting them into abduction. The splints were custom-made from thermoplastic material[a] by two experienced occupational therapists. One of two splints was used. The first splint was a volar splint with a C-bar to position the thumb into palmar abduction (Figure 1a). This splint was used by 26 of the participants. In 12 of the 26 participants the splint was extended to incorporate the wrist and other fingers but the important aspect of the splint was the same for all 26 participants, namely the C-bar for the thumb. A cone splint was used with four participants where it was difficult to get a good stretch with the thumb C-bar piece (Figure 1b). This splint sat in the palmar aspect of the hand with the fingers wrapped around it. It was also moulded to ensure that the thumb was stretched into palmar abduction. Care was taken with all splints to ensure that the stretch was primarily applied proximal to the metacarpophalangeal joint of the thumb so as to avoid over-stretching the metacarpophalangeal collateral ligaments.

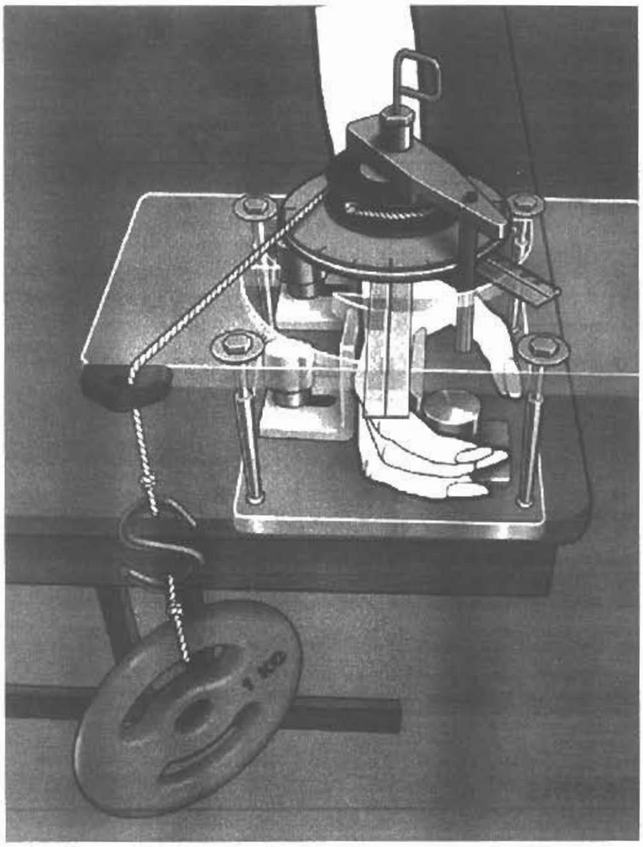

Figure 2. The device used to measure carpometacarpal angle. (Image used with permission from www.physiotherapyexercises.com)

The splints were reviewed one week after fabrication. At this time they were modified if necessary. They were then remoulded approximately 4 and 8 weeks later to increase the stretch on the thumb. Participants were instructed to wear the splint 8 hours per night for 12 weeks. Participants and their carers were initially taught how to apply the splint, and photographs and instructions of correct splint application were left with each participant. The application of the splints was not monitored directly although each experimental participant was rung every 1–2 weeks to monitor compliance and identify problems necessitating further follow-up. In addition, they were visited at least every 4 weeks. Participants were instructed to record in a diary when the splint was applied and removed each night. The diaries were checked each time the participant was contracted (either in person or by phone).

The control thumbs received no intervention and no contact was made with these participants over the 12 weeks. Prior to the commencement of the trial, 10 control participants had been wearing hand splints. These splints had not been prescribed to stretch the thumb web-space but rather to place the hand in a 'resting' position. The splints of these participants were modified to either remove the thumb from the splint or ensure the thumb was not placed in any kind of stretched position so that no torque or force was applied to the carpometacarpal joint or thumb web-space. Participants were then allowed to continue wearing the splint. Both control and experimental participants were instructed to refrain from self-administering any stretch and no participant received any type of regular hand therapy.

Outcome measures Palmar abduction of the carpometacarpal joint was the primary outcome. It was measured with a device specifically designed for the purpose which uses a wheel to apply a standardised torque to the carpometacarpal joint (Figure 2). The carpometacarpal angle was measured with a goniometer, the centre of which was fixed to the centre of the wheel. Palpation was used to identify the carpometacarpal joint and a metal guiding pin dropped from the centre of the wheel and goniometer to ensure they were aligned over the carpometacarpal joint. The device consists of a base that stabilises the forearm in a mid-pronated position. The wrist and metecarpophalangeal joints of the fingers were held in a neutral position. The device has been shown to be reliable (ICC 0.78, 95% CI 0.56 to 0.90) and further details can be found in Harvey et al (2006). The carpometacarpal angle was measured with a 0.9 Nm torque after a one minute pre-stretch. The pre-stretch was applied at 0.3 Nm, then 0.6 Nm and finally 0.9 Nm for 20 seconds each. Participants were tested in sitting with their elbow at 90 deg next to their body and their arm supported on a table (except in four participants that needed to be testing in lying due to sacral pressure areas). Both thumbs were measured in all participants, including those with unilateral lesions.

Participants' attitudes towards the effectiveness and convenience of the splinting regime was a secondary outcome and was measured by asking five questions. The questions were designed by the investigators and were not formally tested for consistency, validity, or reliability. Participants with bilateral lesions answered the questions separately for their control and experimental thumbs. The first three questions were administered at the beginning and end of the trial to both experimental and control participants. Participants were asked to answer each question using a 10-point visual analogue scale where one was 'not at all happy' and 10 was 'extremely happy'. These questions were:

1. How happy are you to wear a splint each night if you get no change in the extensibility of your thumb web-space?
2. How happy are you to wear a splint each night if you get a small increase in the extensibility of your thumb web-space?
3. How happy are you to wear a splint each night if you get a large increase in the extensibility of your thumb web-space?

Questions 4 and 5 were administered at the end of intervention to the experimental participants only. Participants were asked to provide a 'yes' or 'no' response. These questions were:

4. Will you continue to wear the splint after the completion of the trial?
5. Do you think that the splinting regime has increased your thumb web-space extensibility?

The effect of the splinting regime on participants' self-selected goals was an additional secondary outcome and was measured using the Canadian Outcome Performance Measure. However, it was discontinued when it became apparent that very disabled participants (and their carers) were unable to set meaningful goals. The participants in this trial were chosen because their thumbs provided a good model to explore the response of soft tissues to stretch, not because thumb web-space contractures were limiting their daily lives.

Table 1. Characteristics of participants.

Characteristic	Unilateral participants		Bilateral participants	
	Con n = 14	Exp n = 14	Con n = 16	Exp n = 16
Age (*yr*), mean (range)	64 (50 to 71)	58 (49 to 67)	47 (37 to 51)	
Gender, number				
Female	8	3	1	
Male	6	11	15	
Type of lesion, number				
Stroke	7	7	0	
TBI	3	4	0	
SCI	4	3	16	
Thumb, number				
Right	4	8	8	8
Left	10	6	8	8
Total	14	14	16	16

Con = control, Exp = experimental

Data analysis The minimal clinically-worthwhile effect for the primary outcome measure (ie, carpometacarpal angle) was set *a priori* at 5 deg. This decision was based on consensus from a group of clinicians as well as the preliminary results of a study that quantified carpometacarpal angle in participants with and without contracture (Harvey et al, 2006). The best available evidence indicated that a sample size of 60 thumbs would provide a 90% probability of detecting a 5 deg effect of stretch on carpometacarpal angle, assuming a standard deviation of 5 deg, a loss to follow-up of 10%, and an alpha level of 0.05 (Harvey et al 2006).

Mean (SD) change in carpometacarpal angle from initial to final measure was calculated for both experimental (splint) and control (no splint) thumbs. A statistical method (the corrected t-method) that allows comparison of means attained from correlated (within-participant) and uncorrelated (between-participant) data was used to determine the mean effect of stretch (95% CI) for all participants (Looney and Jones 2003). In this approach, all data (correlated and non-correlated) were used without biasing the estimate of the variance of the mean change in carpometacarpal angle and without compromising the Type 1 error rate and statistical power (Looney and Jones 2003). All participants' data were analysed according to their group allocation including one non-compliant bilateral participant. That is, the data were analysed by 'intention-to-treat' (Pocock 1983). Results from the five questions were not analysed statistically since these data were only included to provide some insights into participants' attitudes about the effectiveness and convenience of the splinting regime.

In addition, the reliability of the torque-controlled device was determined using the initial and final measures of all control thumbs and the contralateral unaffected thumbs of participants with a unilateral lesion. Intra-class correlation coefficient (ICC) and percent close agreement (ie, % of time measure was within 6 deg) were calculated. (See Appendix 1 on the eAddenda for the complete details of the trial method.)

Results

Flow of participants through the trial Forty-four participants (60 thumbs) participated in the trial. See Table 1 for a breakdown of the characteristics of the participants. Overall, the median age of the participants was 54 years (IQR 43 to 65) and the median time since onset of the neurological condition was 4 years (IQR 2 to 10). Thumb spasticity and strength were variable. Fifty-five thumbs had either Grade 0/4 or 1/4, and five thumbs had Grade 2/4 or 3/4 spasticity in the adductor muscles (according to Ashworth scale, a standardised clinical assessment of spasticity that rates severity on a five-point scale: Johnson 2002). Thirty-nine hands had complete or near-complete paralysis of all thumb muscles (Grade 0/5 or 1/5 on manual muscle testing; Kendall and Kendall McCreary 1983) while eight hands had small amounts of strength around the thumb (Grade 2/5 or 3/5). The thumbs of the remaining 13 hands had moderate to normal strength in one or more thumb muscles (Grade 4/5 or 5/5). The amount of thumb web-space contracture was moderate but variable. The mean carpometacarpal angle was 45 deg (SD 7). In people without contracture, the median carpometacarpal angle with application of the same torque is 56 deg (IQR 53 to 60) (Harvey et al 2006). There were no significant differences between control and experimental thumbs at commencement of the trial.

The flow of participants through the trial is given in Figure 3. One participant with bilateral thumb web-space contractures withdrew from the trial. Therefore, outcome measures are presented for 98% of the participants and 97% of the thumbs.

Compliance with trial method On average, each participant's splint was reviewed by an occupational therapist 4.5 times (SD 1.3) over 12 weeks. The splints were remoulded only if the participant indicated willingness to tolerate a greater stretch and/or if clinical judgment indicated that this was necessary. Most participants had their splints remoulded into a more stretched position at least once, if not twice, in 12 weeks; this does not provide good evidence about change

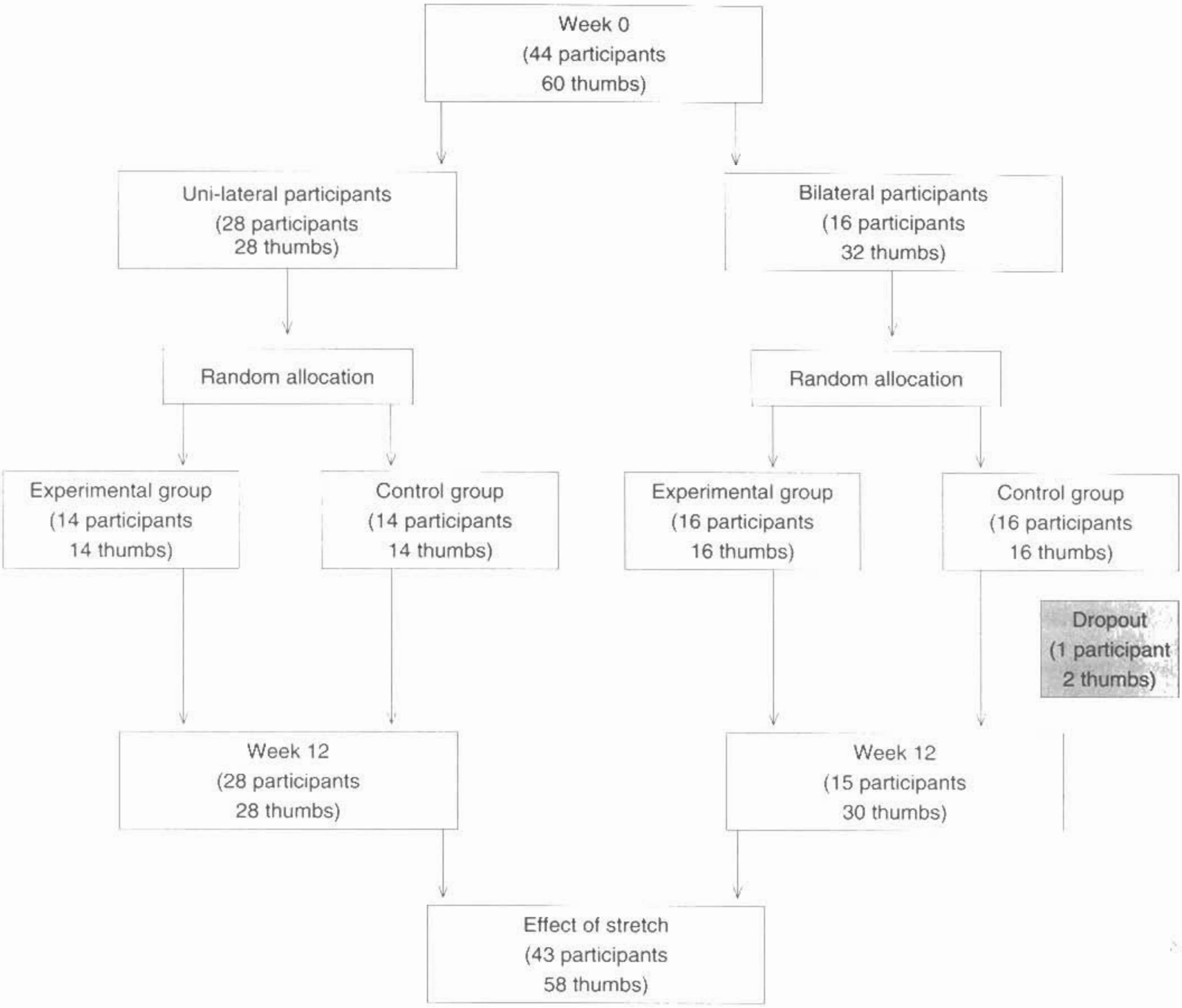

Figure 3. Flow of participants through the trial.

in tissue extensibility and may only reflect participants' willingness to tolerate a greater stretch.

The intervention protocol dictated that participants wear the splint for 8 hours a night on 84 nights over 12 weeks for a total of 672 hours. One participant was non-compliant and ceased wearing the splint after 3 days. Four other participants wore the splint on and off. In addition, a few participants sometimes failed to record precisely how long they had worn the splint. On these occasions, the hours of stretch were estimated based on participants' overall splint-wearing habits. Excluding the one non-compliant participant, participants wore the splint for a mean of 7.9 hours per night (SD 1.6) on 74 nights (SD 11.4) over 12.2 weeks (SD 0.6) for a total of 586 hours (SD 169) (ie, 87% of the intervention was delivered).

All participants, including the non-compliant participant, were measured at the end of the intervention. Assessor blinding was successful for 38 of the 43 participants (ie, for 88% of the time).

Effect of intervention Table 2 shows the change in carpometacarpal angle for the experimental and control thumbs over the course of the trial. The extensibility of the control thumb web-spaces increased slightly over 12 weeks from a mean of 45 deg (SD 7) to 47 deg (SD 6). These results were mirrored by changes in the experimental thumbs with a mean change from 45 deg (SD 7) to 47 deg (SD 7). Thus the mean difference between experimental and control thumbs over 12 weeks was 1 deg (95% CI –1 to 2). A similar finding was obtained when the non-compliant participant's data were excluded from the analysis (mean difference 0 deg, 95% CI –1 to 2). (See Table 3 on the eAddenda for the complete dataset.)

Problems of skin break down were minor. If red marks or painful spots developed, it was usually within the first week or after making an adjustment to the splint. In total, a median of 4 out of 84 nights (5%, IQR 2 to 14) of splinting were missed due to skin-related problems.

The results of Questions 1–3 are provided in Table 2. At

Table 2. Mean (SD) carpometacarpal angle, mean (SD) difference within groups, and mean (95% CI) difference between groups for the experimental group and the control group. Median (interquartile range) response to three questions about participant attitudes.

Outcome	Score*				Difference within groups*		Difference between groups*
	Week 0		Week 12		Week 12 minus Week 0		Week 12 minus Week 0
	Exp	Con	Exp	Con	Exp	Con	Exp–Con
CMC angle (*deg*)							
43 participants	45 (7) 29 thumbs	45 (7) 29 thumbs	47 (7) 29 thumbs	47 (6) 29 thumbs	2 (3)	1 (3)	1 (–1 to 2)
28 unilateral participants	47 (7) 14 thumbs	48 (5) 14 thumbs	49 (7) 14 thumbs	49 (5) 14 thumbs	2 (3)	1 (3)	1 (–2 to 3)
15 bilateral participants	43 (6) 15 thumbs	43 (7) 15 thumbs	45 (6) 15 thumbs	45 (5) 15 thumbs	2 (3)	2 (4)	0 (–3 to 3)
Participant attitudes							
Question 1 (0 to 100 mm) (43 participants)	50 (30 to 55) 29 thumbs	50 (20 to 55) 29 thumbs	0 (0 to 30) 29 thumbs	0 (0 to 50) 29 thumbs			
Question 2 (0 to 100 mm) (43 participants)	80 (60 to 95) 29 thumbs	78 (55 to 100) 29 thumbs	60 (50 to 80) 29 thumbs	60 (50 to 80) 29 thumbs			
Question 3 (0 to 100 mm) (43 participants)	100 (100 to 100) 29 thumbs	100 (95 to 100) 29 thumbs	100 (90 to 100) 29 thumbs	100 (85 to 100) 29 thumbs			

*data are rounded to nearest integer thereby giving an apparent error. Exp = experimental, Con = control, CMC = carpometacarpal

the end of intervention, 22 experimental participants (51%) stated that they would continue to wear the splint, including four participants with a bilateral lesion (27%) who requested a splint for their other (control) thumb. Twenty experimental participants (47%) believed that the splint had increased the extensibility of their thumb web-space.

The ICC between the initial and final carpometacarpal angle of the control and unaffected thumbs (28 thumbs) was 0.87 (95% CI 0.79 to 0.92). Measurements attained at the beginning of the study were within 6 deg of measurement attained at the end of the study, 82% of the time.

Discussion

The primary aim of this trial was to determine whether stretch applied for eight hours a day over 12 weeks changes tissue extensibility. The thumb was chosen as a model to explore this question for pragmatic reasons but also because thumb web-space contractures can be an important impairment worthy of attention. The results indicate that stretch applied over such a long period of time does not change tissue extensibility. Of course, it is not known whether other joints would respond to stretch in the same way.

It is unclear why this trial failed to find an effect when the anecdotal evidence supporting the effectiveness of stretch for this purpose is strong. The most plausible explanation relates to the frequency, intensity, and duration of the stretch intervention. The stretch was applied with the application of a splint, as is common clinical practice. However, there was no way to standardise the torque applied through the splint. While the two therapists who fabricated the splints were highly-experienced occupational therapists and the splints were remoulded every four weeks to maintain a stretch, it is possible that the splints did not administer a sufficiently large torque. It is also possible that while participants reported wearing the splint for eight hours per night, the splints were actually worn for less than this or were not applied effectively. However, both these scenarios mimic clinical practice and while they do not help answer mechanistic questions about tissue adaptability, they do answer pragmatic questions about the effectiveness of splints prescribed in this way.

The other possible explanation for the failure to find an effect relates to the specific characteristics of the participants. The sample was somewhat diverse although all had a neurological condition. Perhaps particular subgroups of patients respond more favourably than others. For instance it may be that recent contractures are more responsive to intervention than long-standing contractures. Alternatively, the presence or absence of spasticity or voluntary strength may influence outcome. It was our initial belief that type of neurological condition is the strongest predictor of outcome so experimental and control groups were balanced for this factor. Although there are many unknown but potentially important predictors of the response of soft tissue structures to stretch, the very tight 95% CI about the mean in this trial indicates that the response of all participants was reasonably consistent.

It was decided *a priori* that the smallest clinically-worthwhile effect was 5 deg. This decision was based on therapists' clinical judgments. Of course a clinically-worthwhile effect is a subjective judgement and while some may think that changes in carpometacarpal angle less than 5 deg are sometimes worthwhile, unless it is thought that an effect of 1 deg is worthwhile, the conclusions of this trial remain the same. In general, therapists view splints as a major inconvenience and their effect needs to be large to justify the inconvenience and discomfort. On the other hand, participants were happy to wear splints initially even if their effect was likely to be small. Not surprisingly though, they were less happy to wear the splints at the end of the study than at the beginning, presumably after they had experienced the associated inconvenience of hand splints. However, a number of participants were very disabled with little or no hand function or sensation and a splint may be less inconvenient and uncomfortable for them than for participants with some hand function.

The results of this trial are in line with at least five randomised controlled trials performed in recent years in similar neurological conditions that have all failed to demonstrate an effect of stretch (Ben et al 2005, Harvey et al 2000, Harvey et al 2003, Lannin et al 2003, Turton and Britton 2005). However, this trial is the first to apply a sustained stretch over such a long period of time. The results of animal studies suggest that such a stretch intervention should be sufficient to cause tissue remodelling. The failure to do so suggests that the soft tissues of people with neurological injuries are not as responsive to stretch as the soft tissues of animals.

The findings of this trial indicate that confidence about the effectiveness of stretch for the treatment and prevention of contractures in people with neurological conditions is not yet justified. The relevance of these results to other joints, different health conditions, and stretch applied in other ways and for longer periods of time is not known. However, the implications of contractures are profound, and the consequence of incorrect interpretation of research in this area is a concern. Larger studies that involve the regular application of stretch over many years are now required to resolve the issue conclusively.

Footnotes [(a)]Ezeform™, Smith & Nephew Rehabilitation.

eAddenda Table 3 and Appendix 1 available at www.physiotherapy.asn.au/AJP

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Statement regarding registration of clinical trials from the Editorial Board of *Australian Journal of Physiotherapy*

This journal is moving towards requiring that clinical trials whose results are submitted for publication in *Australian Journal of Physiotherapy* are registered. From January 2008, all clinical trials submitted to the journal must have been registered prospectively in a publicly-accessible trials register. We will accept any register that satisfies the International Committee of Journal Editors requirements. Authors must provide the name and address of the register and the trial registration number on submission.