

# No difference between two splint and exercise regimens for people with osteoarthritis of the thumb: A randomised controlled trial

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The purpose of this study was to compare the effects of two 6-week splint and exercise regimens for patients with trapeziometacarpal osteoarthritis. Forty participants were enrolled in a randomised, controlled clinical trial. The experimental group received a newly designed thumb strap splint and an abduction exercise regimen, whereas the control group received current clinical practice consisting of a short opponens splint and a pinch exercise regimen. Outcome measures included pain (VAS at rest in cm), strength (tip pinch in kg), and hand function (Sollerman Test of Hand Function scored out of 80), measured by a blinded assessor at Weeks 0, 2, and 6. By Week 6 there was no significant difference in the extent of mean improvement between the groups in: pain, 0.5 cm (95% CI -1.1 to 2.1); strength, 0.1 kg (95% CI -0.8 to 0.9); or hand function, 0.7 points (95% CI -3.6 to 5.0). While both groups improved, neither regimen is superior to the other in patients with trapeziometacarpal osteoarthritis. [Wajon A and Ada L (2005): No difference between two splint and exercise regimens for people with osteoarthritis of the thumb: A randomised controlled trial. *Australian Journal of Physiotherapy* 51: 245-249]

Key words: Splints, Osteoarthritis, Thumb, Physiotherapy

## Introduction

Clinical symptoms of trapeziometacarpal osteoarthritis include pain, stiffness, and weakness at the base of the thumb, which cause considerable interference to overall function of the hand (Menon 1995, Roberts et al 2001). Typically, patients report disability during a variety of occupations, domestic tasks, hobbies, and sports. Specific aggravating activities include writing, gardening, turning taps, and opening jars, with pain frequently localised to the volar surface of the joint (Flatt 1995). Symptoms develop when ligamentous laxity at the trapeziometacarpal joint causes dorso-volar translation and recurrent synovitis (Glickel 2001, Poole and Pellegrini 2000). The radiological severity of trapeziometacarpal osteoarthritis may be graded according to the staging system of Eaton and Glickel (1987), and it is generally accepted that people with severe degenerative changes (Stage IV) will be less likely to respond to conservative management. Therefore, conservative management aims to decrease pain, weakness and contracture, and improve function, in those with Stage I-III trapeziometacarpal osteoarthritis.

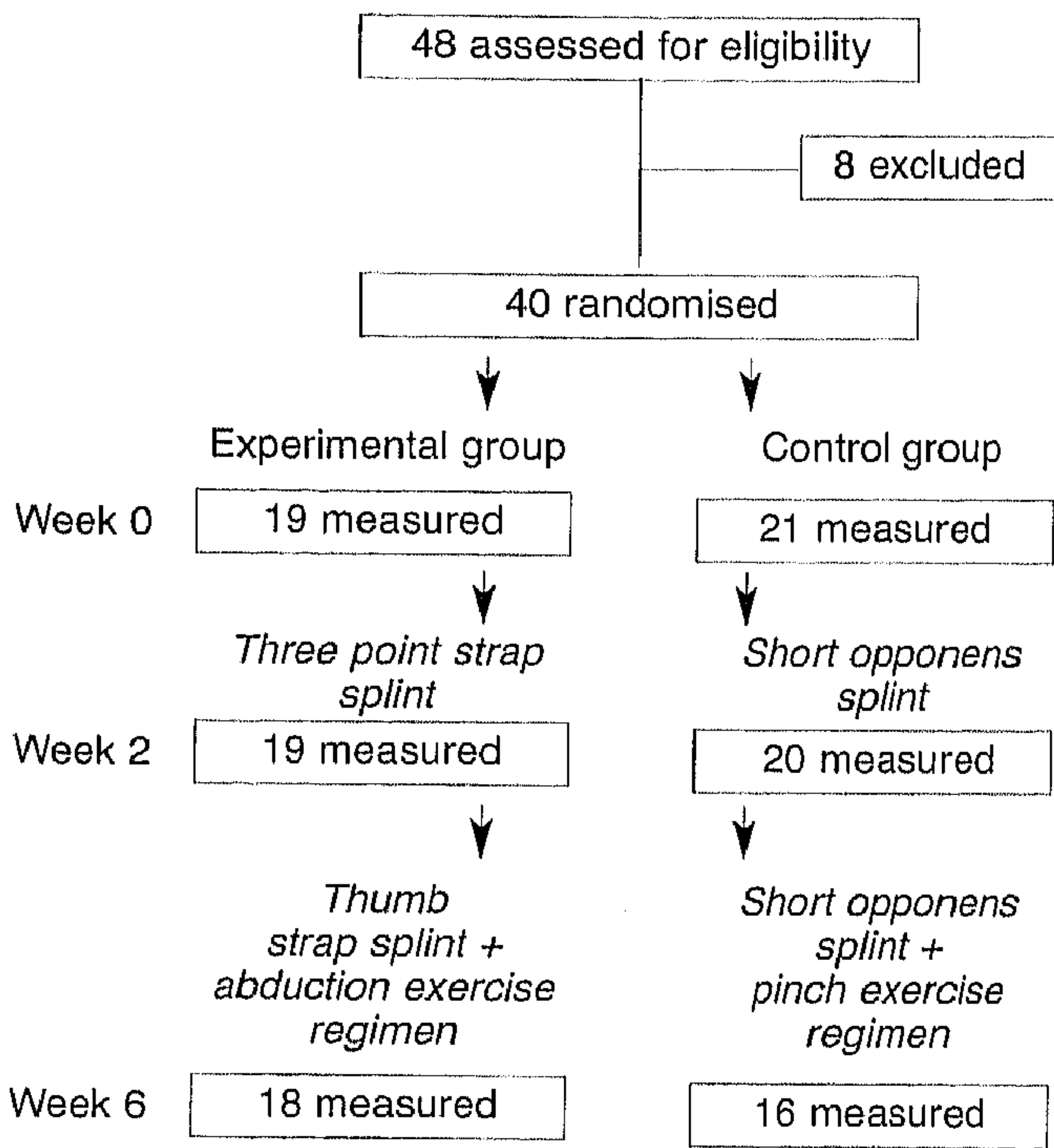
Current physiotherapy for trapeziometacarpal osteoarthritis consists of a period of splinting traditionally with either a short (Poole and Pellegrini 2000) or long opponens (Swigart et al 1999) splint to allow acute pain to settle, followed by exercises for the thenar musculature – traditionally pinch exercises. A new splint (thumb strap splint) and exercise regimen (abduction exercise regimen) was developed with the intention of addressing more specifically the tendency of the thumb to collapse with advancing osteoarthritis (Flatt 1995). The thumb strap splint (Wajon 2000) (Figure 1) was designed to prevent flexion and adduction of the metacarpal, dorsoradial subluxation of the base of the first metacarpal, and subsequent metacarpophalangeal hyperextension. In



Figure 1. Thermoplastic splint provided to experimental group: thumb strap splint.

addition, an abduction exercise regimen was designed to provide reinforcement of the palmar beak ligament, since the degeneration of this ligament has been associated with advanced trapeziometacarpal osteoarthritis (Pellegrini 1991).

In order to test the efficacy of this new splint and exercise regimen against current practice, a prospective, randomised controlled trial was conducted. It was designed to mimic clinical practice and therefore consisted of a 2-week period of splinting followed by a 4-week period incorporating the addition of an exercise regimen (Figure 2). The research questions were: In participants with pain at the base of the



**Figure 2.** Flow of participants through the trial showing timing of intervention and measurement.

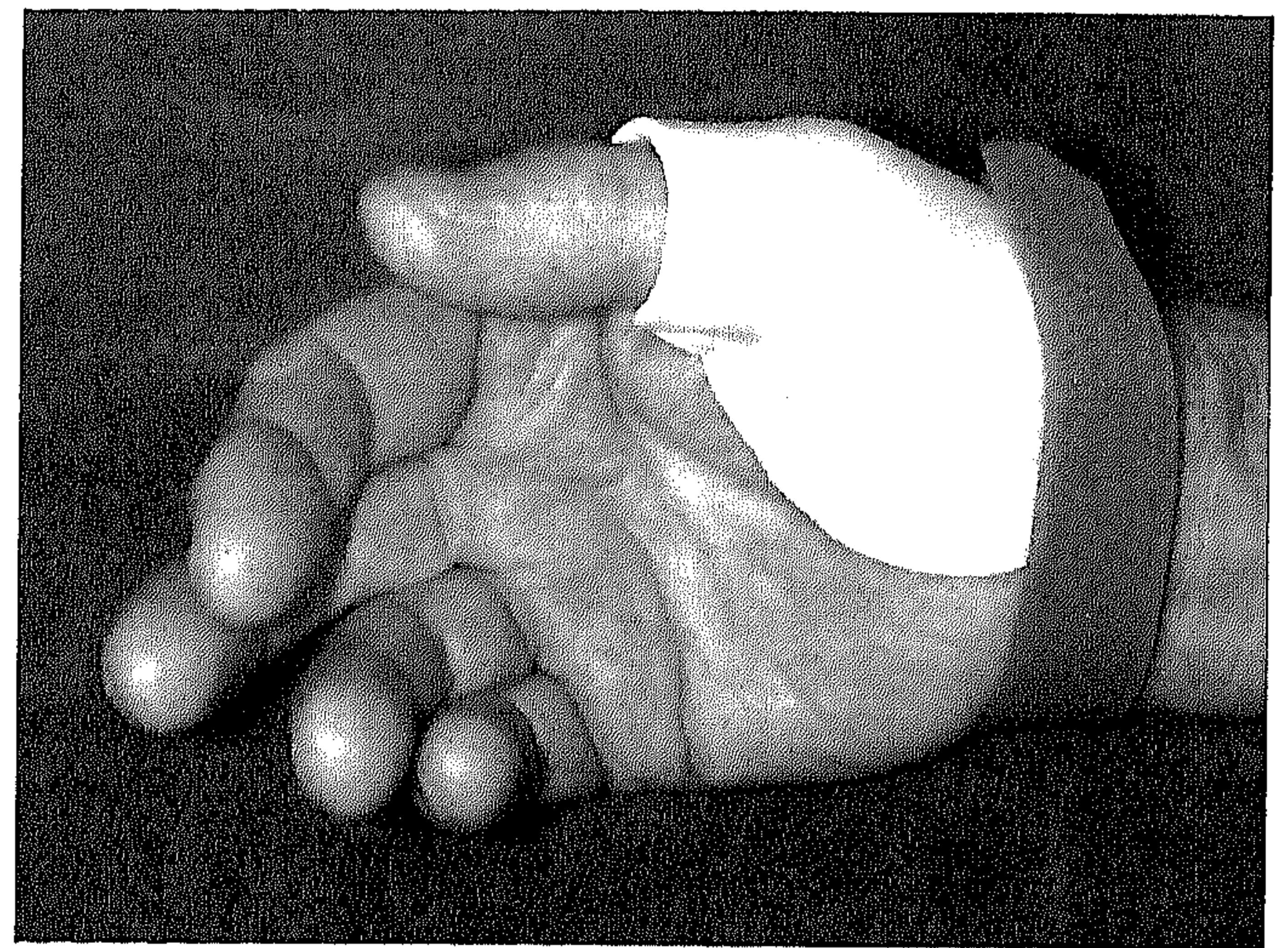
thumb: (a) is two weeks of splinting with a thumb strap splint more effective at decreasing pain, increasing strength, and improving hand function than two weeks of splinting with a short opponens splint, and (b) is six weeks of splinting with a thumb strap splint and four weeks of an abduction exercise regimen more effective at decreasing pain, increasing strength and improving hand function than six weeks of a short opponens splint and four weeks of a pinch exercise regimen?

## Method

**Participants** Participants were recruited from patients referred to a hand physiotherapy practice. People were eligible for the study if they complained of pain at the base of the thumb and had Stage I–III trapeziometacarpal osteoarthritis. They were excluded if they had DeQuervains tendonitis, carpal tunnel syndrome, scapholunate instability, trigger thumb, had received a steroid injection to the trapeziometacarpal joint in the preceding six weeks, or had previous surgery. The study was approved by the Human Ethics Committee of the University of Sydney.

Where available, radiographs were viewed to determine the stage of osteoarthritis (Eaton and Glickel 1987). Where radiographs were not available, a clinical diagnosis was made through palpation and the grind test (Prosser and Conolly 2003). Local pain and tenderness at the scaphotrapezium joint was suggestive of Stage IV osteoarthritis, and in the absence of radiographic confirmation, these patients were excluded from the study.

**Intervention** From Weeks 0 to 2, participants in the *experimental* group wore a thumb strap splint described by Wajon (2000) (Figure 1). They were instructed to wear it full



**Figure 3.** Thermoplastic splint provided to control group: short opponens splint.

**Table 1.** Characteristics of participants.

Characteristic	Experimental group (n = 19)	Control group (n = 21)	Drop-outs (n = 6)
Age (years): Mean (SD)	59.7 (9.0)	61.2 (12.5)	54.7 (15.6)
Gender M:F	5:14	4:17	1:5
Handedness	18:1	21:0	5:1
Affected side R:L	11:8	11:9	3:3
Duration of disease: Years (SD)	3.9 (5.2)	3.3 (3.6)	3.0 (3.2)
Severity of disease: Mean stage (SD)	2.6 (0.5)	2.3 (0.8)	1.8 (0.8)

time, removing it for personal hygiene only. The splint was custom-made and fabricated from 3.2 mm thermoplastic splinting material. From Weeks 2 to 6, participants continued to wear the thumb strap splint and began an abduction exercise regimen. They were instructed to perform palmar abduction against gravity in a smooth, controlled motion, avoiding any aggravation of pain for three sessions per day, increasing from 5 to 10 repetitions per session as endurance and pain permitted. At Week 4, the splint and exercises were checked and any modifications made as necessary. At Week 6, participants were discharged from treatment with advice regarding joint protection (Wolfe 2000), encouraged to wear their splint for any persistently aggravating activities and to continue to perform their exercises.

From Weeks 0 to 2 participants in the *control* group wore a short opponens thumb splint which included the metacarpophalangeal joint (Figure 3). They were instructed to wear it full time, removing it for personal hygiene only. The splint was custom made and fabricated from 3.2 mm thermoplastic splinting material. From Weeks 2 to 6, participants continued to wear the short opponens splint and began a pinch exercise regimen. They were provided with a yellow, extra-soft Foam Block<sup>®</sup> and instructed to perform three sessions per day, increasing from 5 to 10 repetitions of

**Table 2.** Mean (SD) scores, mean (SD) differences within groups, and mean differences between groups (95%CI) for all outcomes

Outcome	Scores						Differences within groups				Differences between groups			
	Wk 0 (n = 40)		Wk 2 (n = 39)		Wk 6 (n = 34)		Wk 2-Wk 0		Wk 6-Wk 0		Wk 2-Wk 0 Exp-Con		Wk 6-Wk 0 Exp-Con	
	Exp (n = 19)	Con (n = 21)	Exp (n = 19)	Con (n = 20)	Exp (n = 18)	Con (n = 16)	Exp	Con	Exp	Con	Exp	Con	Exp	Con
VAS (cm)	3.0 (1.9)	2.9 (2.2)	2.1 (1.8)	1.8 (1.8)	1.3 (2.2)	0.9 (1.2)	-0.9 (2.1)	-1.3 (1.7)	-1.8 (2.5)	-2.3 (2.0)	0.4	(-0.8 to 1.6)	0.5	(-1.1 to 2.0)
Tip pinch (kg)	4.0 (1.8)	3.5 (1.4)	4.5 (1.7)	4.1 (1.7)	4.7 (2.2)	4.0 (1.7)	0.4 (0.8)	0.6 (0.7)	0.7 (1.6)	0.6 (0.6)	-0.2	(-0.7 to 0.3)	0.1	(-0.8 to 0.9)
Sollerman test (/80)	67.9 (6.5)	69.7 (3.9)	72.3 (4.0)	72.0 (4.4)	74.8 (6.1)	75.6 (3.3)	4.3 (5.6)	2.4 (3.0)	6.8 (8.0)	6.1 (2.7)	2.0	(-0.9 to 4.9)	0.7	(-3.6 to 5.0)

Exp, experimental group; Con, control group; VAS, visual analogue scale pain score

pinch per session, as endurance and pain permitted. At Week 4, the splint and exercises were checked and modifications made as necessary. At Week 6, participants were discharged from treatment with advice regarding joint protection (Wolfe 2000), splint wearing and exercise performance.

**Outcome measures** Three variables were measured: pain, strength, and hand function. Pain at rest (at the time of assessment) was measured using a 10 cm VAS, with 0 corresponding to no pain, and 10 the worst pain imaginable (Tollison 1989). Strength of tip pinch was measured in kilograms in the standard position (Fess and Moran 1981) using a pinch gauge<sup>b</sup>. The best of three trials was recorded, unless the participant expressed reluctance to repeat the test due to increased pain levels. Hand function was measured using the Sollerman Test of Hand Function (Sollerman and Ejekkar 1995). This test includes 20 standardised activities of daily living including opening jars, turning keys, hand-writing, using a knife and fork, and pouring liquids from various containers. Each task was measured on a four-point scale, providing a maximum score of 80 for a participant who can complete each task with the correct hand-grip in less than 20 seconds without any pain or disability. All measurements were taken at Weeks 0, 2 and 6 by another physiotherapist in the practice who was blind to group allocation.

**Statistical analysis** Two-tailed independent t-tests of the change scores were used to determine whether there was a greater effect of the experimental interventions on pain, strength, and hand function than the control interventions. One analysis conducted on data from Weeks 0 to 2 compared the immediate effect of the thumb strap splint with the short opponens splint, while a second analysis of the change from Weeks 0 to 6 compared the effect of the combined splint and exercise regimens. Data are presented as means (SD) and effect sizes (95% CI). Differences were considered significant at  $p < 0.05$ .

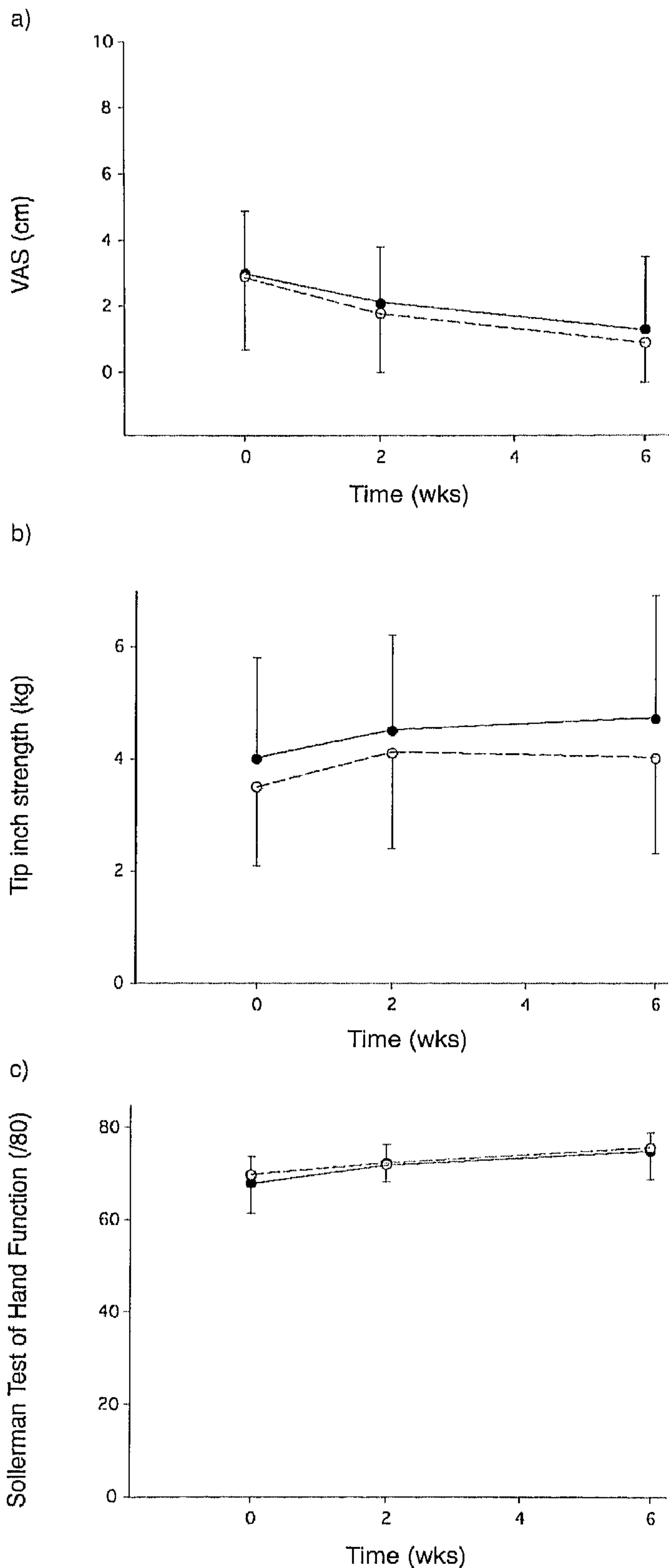
## Results

**Flow of participants through the trial** Forty-eight people were assessed for eligibility. Eight were excluded from the study for not meeting the inclusion criteria, six with Stage IV osteoarthritis and two with a steroid injection to the trapeziometacarpal joint the previous day. Therefore, 40 participants agreed to participate in the study and gave

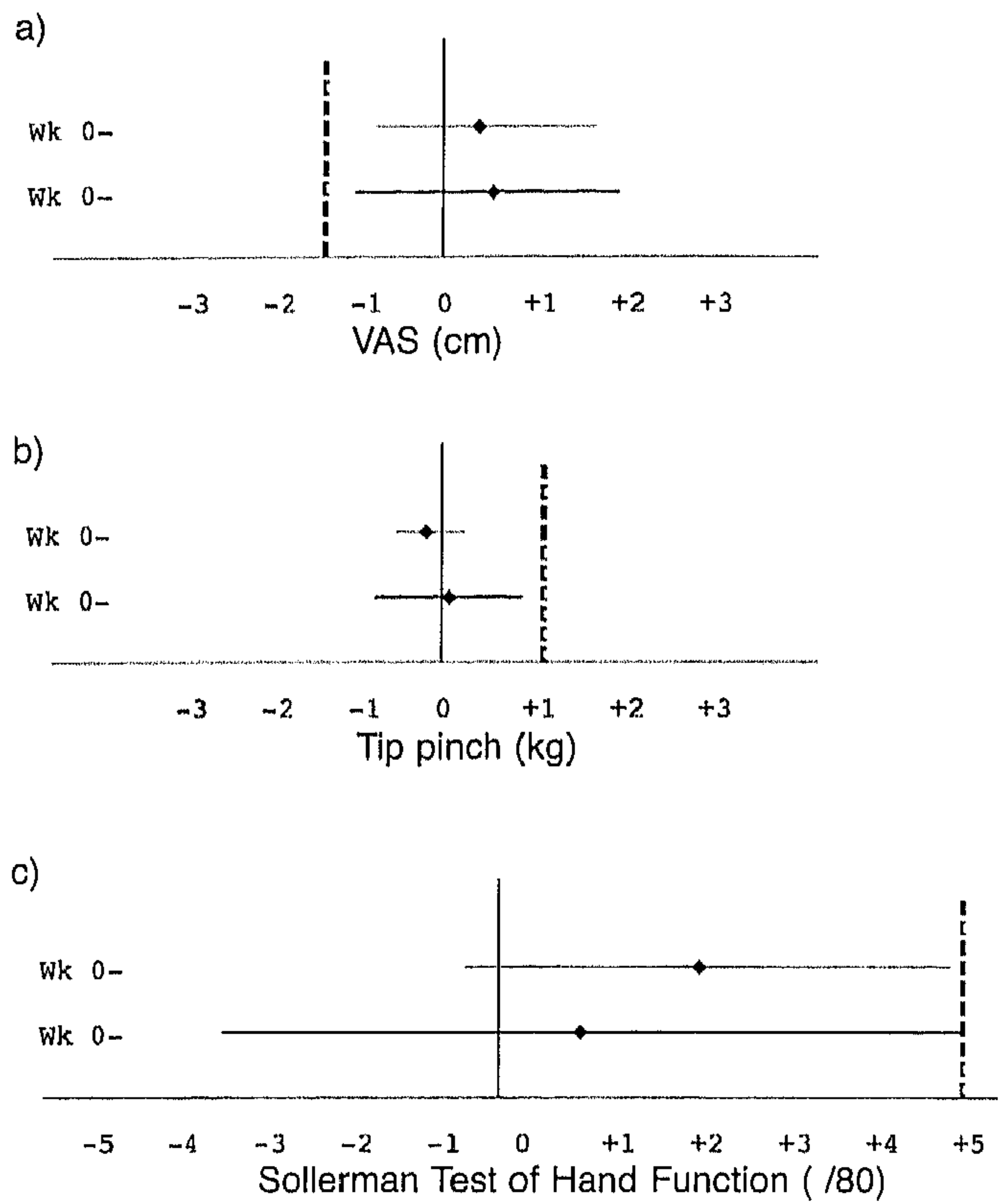
informed consent. To ensure concealment of allocation randomisation of participants to the experimental and control groups was performed by a person not involved in the trial. Nineteen were randomised to the experimental group and 21 to the control group (Figure 2). At Week 2, 19 participants were analysed in the experimental group and 20 in the control group. One participant in the control group was unable to be measured due to unexpected overseas travel. At Week 6, 18 participants were analysed in the experimental group, 16 in the control group. Of the five participants who were unavailable for the Week 6 measurement, two were unavailable due to overseas travel, one was unable to attend due to ill health, while two others withdrew from the study due to discomfort in the splint (one in each group) and declined to attend for measurement. The characteristics of the experimental group, control group and dropouts are summarised in Table 1, demonstrating that they were similar at baseline in terms of sex, age, handedness, affected side, duration, and severity of disease. Table 2 demonstrates that they were also similar at baseline in terms of the outcomes of pain (VAS), strength (tip pinch), and hand function (Sollerman test).

**Compliance** Participants were not required to keep a record of how many hours they wore their splint, or how many repetitions of their exercises were performed. However, the impression gained from the reports of participants at the Week 2 measurement was that they were wearing their splint full time. By Week 4, they had begun to leave the splints off when at rest, and were performing their exercises twice daily. By Week 6, the majority reported that they were wearing the splints only for specific aggravating activities, and were performing their exercises daily.

**Outcomes** By Week 2, after the participants had worn the splints for two weeks, there was no significant difference between the groups in: VAS scores, 0.5 cm (95% CI -0.8 to 1.6,  $p = 0.50$ ); tip pinch strength, -0.2 kg (95% CI -0.7 to 0.3,  $p = 0.46$ ); or Sollerman Test of Hand Function scores, 2 points (95% CI -0.9 to 4.9,  $p = 0.18$ ) (Figure 4, Table 2). By Week 6, after the participants had worn their splints for six weeks and exercised for four weeks, there was no significant difference between the groups in: pain, 0.5 cm (95% CI -1.1 to 2.1,  $p = 0.57$ ); tip pinch strength, 0.1 kg (95% CI -0.8 to 0.9,  $p = 0.86$ ); or Sollerman Test of Hand Function, 0.7 points (95% CI -3.6 to 5.0,  $p = 0.74$ ) (Figure 4, Table 2).



**Figure 4.** Mean (SD) for the experimental group (closed circles) and the control group (open circles) at Week 0, 2, and 6 for: a) pain (VAS in cm), b) strength (tip pinch in kg), and c) hand function (Sollerman Test of Hand Function).



**Figure 5.** Size of effects (means and 95% confidence intervals) of experimental splint regimen compared to the control splint regimen. Nominally clinically significant effects are shown as dashed vertical lines. a), pain, b), strength, c), function.

## Discussion

There was no greater effect of the experimental intervention on the decrease in pain, increase in strength, or improvement in hand function by Week 2 or Week 6. We considered the possibility that this may have been due to a lack of statistical power. If a reduction of 1.5 cm on the VAS, an increase of 1 kg tip pinch strength, and an improvement of 5 points on the Sollerman Test of Hand Function are considered the smallest clinical effects worth detecting, then the 95% confidence intervals for the effect on these outcome measures (Table 2, Figure 5) exclude a worthwhile effect. This suggests that we can be confident that the thumb strap splint and abduction exercise regimen provided to the experimental group was no more effective at reducing pain, increasing strength, or improving hand function than the short opponens splint and pinch exercise regimen provided to the control group.

Although no difference in outcomes was found between the groups, both groups improved. After 6 weeks of intervention, when both groups were considered together, pain had decreased by a mean of 2.1 cm on the VAS (95% CI -2.8 to -1.3,  $p < 0.01$ ) and strength had increased by a mean of 0.6 kg of tip pinch strength (95% CI 0.2 to 1.0,  $p < 0.01$ ). At the same time, hand function scores had improved by a mean of 6.5 points on the Sollerman Test of Hand Function (95% CI 4.4 to 8.6,  $p < 0.01$ ). It is possible that such improvements are

due to factors other than the intervention, such as statistical regression (Herbert et al 2005), the placebo effect (Mackenbach 2005), or the Hawthorne effect, whereby participants improved just because they were involved in the study (Verstappen et al 2004). Nevertheless, these results suggest that patients can expect an improvement in pain, strength, and hand function within six weeks of conservative intervention, regardless of the mechanism. Absence of any clinical improvement after six weeks of a splint and exercise regimen may be an indication for suggesting that the patient consider other options, such as surgery (Wajon et al 2005).

Both groups in this study received a hand-based thermoplastic splint and pain-free exercise regimen which resulted in improvement. Given that there was no obvious superiority of one over another, the choice of intervention (which splint and exercise regimen) can take into account other factors such as the individual's requirements, the extent of disease, and the demands placed on the trapeziometacarpal joint of the thumb by occupation, domestic tasks, hobbies, and sports. For example, occupational or avocational demands may influence the amount of mobility required while wearing the splint. The thumb strap splint permits active flexion at the metacarpophalangeal joint and greater mobility at the trapeziometacarpal joint, essential when playing stringed instruments. Conversely, the short opponens splint holds the metacarpophalangeal joint in a fixed position, and may be more appropriate for those patients who require stability, at the expense of mobility, with pinch and grasp. However, it is larger in size, and may be uncomfortable to wear for prolonged periods during hot weather. Ultimately, compliance with splint use will be determined by whether a patient perceives that a given splint relieves pain and enhances hand function (Colditz 2000).

The majority of people with Stage I–III trapeziometacarpal osteoarthritis are generally healthy and physically active, and find that the pain and dysfunction at the base of the thumb restricts involvement in activities of daily living. Our aim should be to provide individuals with the ability to control their symptoms, either through the use of splints, exercises, and/or joint protection advice. This study failed to find any additional benefit of one splint and exercise regimen over another, but identified improvements in pain, strength, and hand function when all participants with trapeziometacarpal osteoarthritis were considered together. While this finding does not provide evidence of effectiveness of the intervention, it nevertheless provides useful prognostic information (Herbert et al 2005).

**Footnotes** <sup>a</sup>Roylan R-lite Foam Block, Surgical Synergies, WI, USA <sup>b</sup>Pinch gauge model PG-30, B&L Engineering, Santa Fe Springs, CA, USA.

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