

A randomized controlled trial of strapping to prevent post-stroke shoulder pain

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Objective: To determine whether strapping the shoulder in hemiplegic stroke patients: (1) prevents the development, or reduces the severity, of shoulder pain, (2) preserves range of movement in the shoulder, and (3) improves the functional outcomes for the arm and patient overall.

Design: A prospective, randomized, single-blind controlled trial of shoulder strapping versus no strapping.

Setting: Care of the elderly wards in a teaching hospital, Christchurch, New Zealand.

Subjects: All patients admitted with an acute hemiplegic stroke, who had persisting weakness of shoulder abduction.

Intervention: The treatment group had their affected shoulder strapped for six weeks from randomization in addition to standard physiotherapy.

Main outcome measures: All subjects were assessed at entry (week 0), at end of the treatment phase (week 6) and two months later (week 14). A visual analogue scale (VAS) was used to assess shoulder pain severity whereas shoulder range of movement to the point of pain (SROMP) assessed passive range of movement and pain. Functional Independence Measure (FIM), Motor Assessment Scale (MAS) and Rankin Disability Index measured functional outcomes.

Results: Ninety-eight subjects participated (49 strapped, 49 controls). Intention to treat analysis showed no significant difference in pain, range of movement or functional outcomes after the intervention phase or at the final assessment. However there were trends for less pain at six weeks (VAS, $p = 0.11$) and better final upper limb function (MAS, $p = 0.16$) in strapped patients. Skin reactions were uncommon (6.1%). The presence of neglect or sensory loss, but not subluxation, at baseline was independently associated with poor outcome. Range of movement was lost early (mean difference SROMP between hemiplegic and contralateral shoulders at baseline = 15.2° (95% CI 10.9-19.5)) and continued throughout the study. Shoulder strapping did not alter the rate at which range of movement was lost.

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Conclusions: No significant benefit with shoulder strapping was demonstrated and reasons for this are discussed. Range of movement in the hemiplegic shoulder is lost very early and any preventive treatments need to begin within the first 1–2 days after a stroke.

Introduction

Post-stroke shoulder pain (PSSP) is a common and debilitating complication after stroke.^{1,2} Estimates of the prevalence of PSSP vary widely from 16 to 80% depending on how and when it is measured,^{1–10} but it is clear that its prevalence increases with time since the stroke.² The development of PSSP has serious consequences; it not only causes discomfort to the patient, but is also associated with poor functional recovery, reduced range of movement, depression, disturbed sleep, reduced quality of life and possibly increased length of stay in hospital.^{1,2,11,12}

It is important to note that pre-existing shoulder pain is common in elderly people living in the community^{13–15} and so any insults caused by the stroke may exacerbate these problems. Forster¹ recently reviewed possible causes of PSSP which include subluxation, abnormal tonal patterns (both flaccidity and hypertonicity), scapular retraction, sensory loss, hemi-neglect, the effects of immobilization and poor handling. There is no clear consensus on the relative importance of these factors. Some authors have found PSSP to be associated with subluxation, sensory loss or neglect, but others have been unable to replicate these findings^{3,5,6,8–10,16,17} These inconsistent findings reflect the small select samples of stroke patients studied at different times after their stroke. It is highly probable that PSSP is multifactorial with different factors contributing at different stages of the illness.^{1,9} As an example, early flaccidity may cause subluxation of the glenohumeral joint, which in turn causes stretching of the shoulder capsule and ligaments. Abnormal tonal patterns of the rotator cuff and scapula develop which, when combined with poor handling and the effects of immobilization in a sling, continue the PSSP. Later, sympathetically mediated pain may occur.¹⁷

Whilst preventative measures for PSSP are limited, treatment of PSSP once it has developed is even more restricted. Some prevention options

include careful positioning, passive movement,¹ external supports such as slings^{6,18–20} and strapping,^{18,21} Functional Electrical Stimulation (FES)^{22,23} and facilitation of active movement. Unfortunately the evidence supporting any modality is limited as most trials have been too small, nonrandomized or unblinded.^{1,24} A variety of slings have been used, to support the arm, and to prevent subluxation and trauma to the shoulder joint.^{6,18–20} Despite the widespread use and broad acceptance of slings, there is no evidence that they reduce PSSP¹ and some evidence that they may be counterproductive.^{6,19} Most slings hold the arm in a position of internal rotation and adduction at the shoulder that encourages disuse, tonal changes and muscle shortening. Furthermore, they fail to adequately reduce shoulder subluxation²⁰ and are not worn at all times, thus leaving the limb unprotected.

For these reasons, some investigators have used strapping or a subaxillary cushion to prevent PSSP.^{10,18,21} These measures, if used at all times, have the theoretical advantages of being able to reduce subluxation whilst allowing free movement of the upper limb. They may also provide some sensory stimulation. The subaxillary cushion¹⁰ does not allow for adequate axillary hygiene and pressure effects may preclude its use. In a small pilot study, a different strapping technique delayed the onset of PSSP, but suffered the same hygiene problems.²¹ Morin and Bravo¹⁸ showed that strapping is more effective than a conventional sling at reducing subluxation, but the tape stretched after 3–5 days, reducing much of its effectiveness. Thus for strapping to be useful, it needs to be able to be worn at all times, including showering, to allow access to the axilla for hygiene, yet support the glenohumeral joint adequately. In addition re-strapping is necessary at least every three days to minimize the effects of stretching. One of the authors (RC) started using a version of the current strapping technique whilst in the United Kingdom. It appeared to meet all the above conditions. Anecdotally we

were impressed by its efficacy, but could find no evidence to support its use.

The aims of the current study were to determine whether shoulder strapping:

- 1) Prevents the development of, or reduces the severity of, PSSP in patients with hemiplegia.
- 2) Preserves range of movement in the shoulder after stroke.
- 3) Alters the functional outcome of the arm, and the patient overall, after a hemiplegic stroke.

Methods

The study was undertaken in the five assessment, treatment and rehabilitation wards for older people (135 beds) at the Princess Margaret Hospital, Christchurch, New Zealand. Stroke patients are either admitted directly from the community or as transfers from the nearby acute general hospital (ratio 30:70). Every elderly person (age >65 years) who has an acute stroke in Christchurch and who needs ongoing inpatient rehabilitation is admitted to one of these wards. Whilst the median length of stay for the service is 17 days (mean 22.1), stroke patients stay longer (median 25 days, mean 32.3 days).

The study was a prospective, single-blind, randomized controlled trial comparing shoulder strapping with no strapping (control) to include as many stroke patients as possible. Both groups received rehabilitation in an interdisciplinary team setting. Whilst an eclectic approach to physiotherapy was the norm, the emphasis was on task-specific re-education for function. Positioning, maintenance of range of movement, and the provision of adequate support for the arm (which could include the use of a sling when mobilizing) were used and encouraged in both groups.

Subjects were randomly allocated to strapping or control groups, with stratification into two groups according to the severity of disability at baseline. Randomization was by computer-generated random number sequence with each code sealed in an opaque envelope prior to the beginning of the study. Stratification occurred prior to randomization, using the four-point FIM.²⁵ Different sets of envelopes were used for those with

an initial score of 25 or less, and those with a score greater than 25.

Patients in the treatment group had their affected shoulder strapped. All other interventions between the two groups were similar. Strapping was continued (1) for a total of six weeks, or (2) until they were able to achieve active abduction of the affected arm to 90° against gravity for 2 seconds, with the elbow flexed, or (3) until discharge from hospital, whichever was the soonest. Shoulder strapping was applied by the patient's usual ward-based physiotherapist immediately after their baseline assessment and randomization. The strapping remained on all the time, including in the shower, and was replaced every 2–3 days (maximum 3 days) to minimize the effects of stretching. At each change of strapping, the skin was thoroughly cleaned before re-strapping.

Strapping technique

The technique consisted of three lengths of nonstretch tape (Elastoplast Sports tape) applied over an 'undertape' (Hypafix) to prevent skin reactions (Figure 1). The arm was supported under the elbow by a second person. The two main 'supporting' tapes were applied first. Both were applied using a lifting action, starting 5 cm above the elbow, and moving up the arm front and back, crossing at the top of the shoulder. The posterior arm tape was then anchored down past the clavicle whereas the tape from the anterior aspect of the arm came across the shoulder and down past the spine of the scapula. They were both supported at the lower end by a short tape to prevent them peeling off. The third main tape was applied from the medial third of the clavicle, around the surgical neck of humerus and along the spine of scapula to its medial third. When correctly applied, the soft tissues of the upper arm appeared to 'crumple' into folds under the tape.

All patients admitted to the Princess Margaret Hospital with an acute hemiplegic stroke (excluding subarachnoid haemorrhage) in the preceding four weeks were eligible for the study. Exclusion criteria were (1) inability to give informed consent, (2) previous shoulder surgery precluding passive external rotation, (3) ability to abduct the affected shoulder to 90° and hold it for 2 seconds already, or (4) residence outside the greater

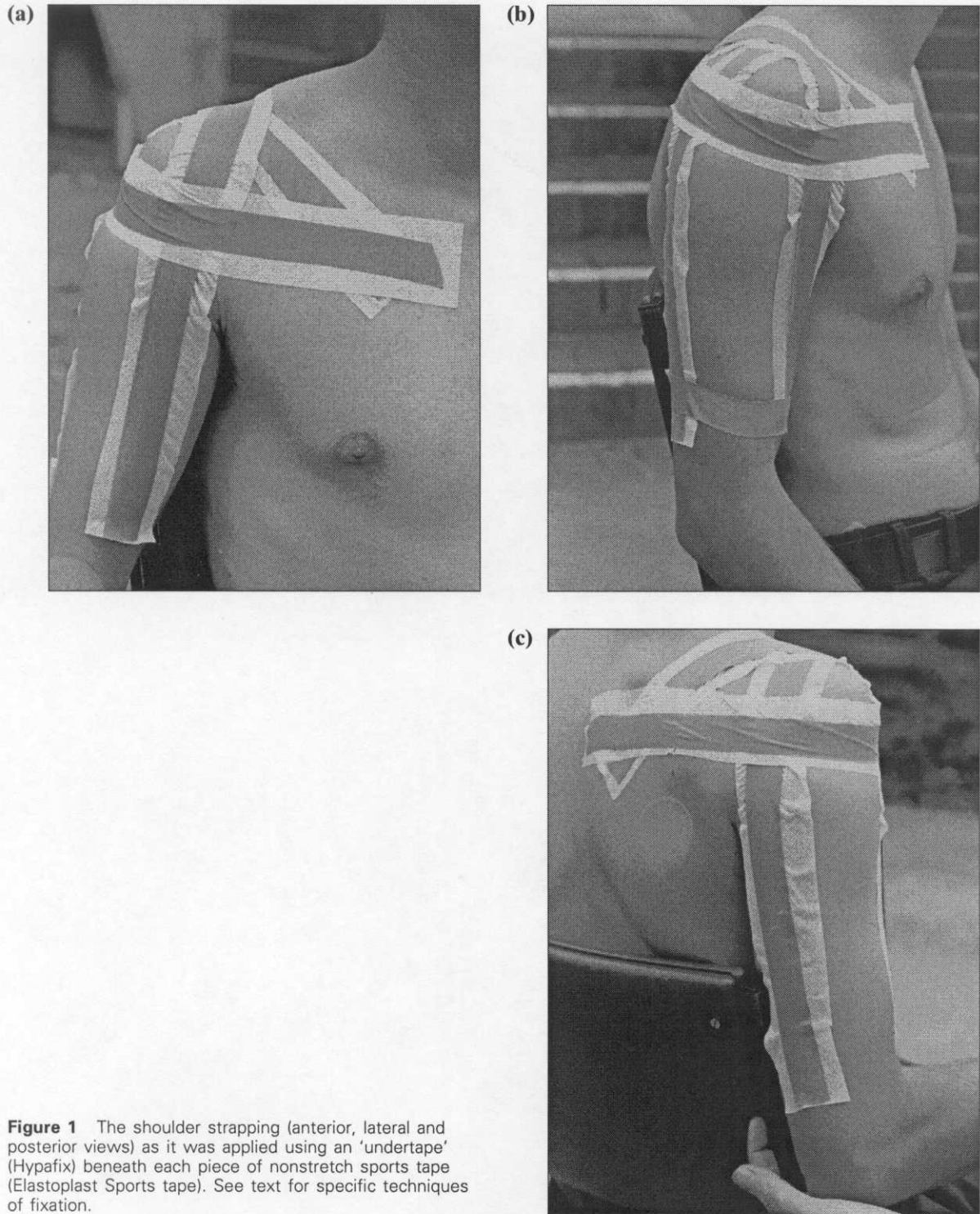


Figure 1 The shoulder strapping (anterior, lateral and posterior views) as it was applied using an 'undertape' (Hypafix) beneath each piece of nonstretch sports tape (Elastoplast Sports tape). See text for specific techniques of fixation.

Christchurch area. Dysphasic patients were included wherever possible, with verbal consent from the patient and written consent from the next of kin. Patients who had a premorbid shoulder condition (e.g. rotator cuff lesion or glenohumeral osteoarthritis) were not excluded for that reason alone.

All strapping was removed by the treating physiotherapist, prior to any assessment. Assessments occurred at (1) entry (week 0), (2) end of 'treatment' (week 6), and (3) two months after the second assessment (week 14). Each assessment was made by an independent physiotherapist (PW or GB) who was not involved in treating these patients and was blind to the randomization code. The same assessing physiotherapist made all three (entry, exit and final) assessments in any given patient, and did so without access to the measurements at the previous assessment(s). Outcomes measured at each assessment were:

- A) Clinical assessments for sensory loss (any impairment of light touch or proprioception in upper limb defined as sensory loss), sensory inattention or neglect and glenohumeral subluxation. Subluxation was assessed at the bedside²⁶ without radiological investigations.
- B) Pain measures:
 - 1) Shoulder lateral range of movement measured at the point of pain (SROMP)²⁶. Both shoulders were measured, with the unaffected side measured first.
 - 2) The response to the question 'How would you rate the pain in your left/right shoulder as experienced over the last 24 hours on this line?' was recorded on a vertical 10-cm visual analogue scale (VAS).
- C) Arm function by the arm and hand subsections (sections 6, 7, and 8) of the Motor Assessment Scale (MAS).²⁷
- D) Overall functional status by the FIM (four-point scale²⁵) and the Rankin Disability scale.²⁸

A clinically useful response was estimated at a 12° difference in the SROMP. Based on data from a pilot study (unpublished), a sample size of 100 (50 per group) was calculated as having an 80% chance of detecting such a difference

($\alpha = 0.05$). An intention to treat (ITT) analysis, as well as a post hoc 'on treatment' analysis, was undertaken. The SROMP data was analysed using repeated measures ANOVA. The VAS, Rankin, FIM and MAS were analysed using non-parametric statistics, including the Mann-Whitney *U* and Wilcoxon tests. Paired testing was used for comparisons over time, and unpaired tests were used for comparisons between the treatment and control groups.

Patients gave informed consent, which was supplemented by consent of their next of kin, if the patient was dysphasic or confused. The Canterbury Ethics Committee (protocol no. 96/03/020) approved the study.

Results

A total of 103 patients were eligible for this study, of whom 98 (95% response rate) participated (Figure 2). Reasons for nonparticipation included terminal illness (2), inability to give consent (1), unwillingness to participate (1) and one patient not randomized due to an administrative error. Both groups were comparable at baseline (Table 1) with the exception of the type of stroke using the Oxfordshire classification²⁹ (Table 2). The strapped group had a greater number of intracerebral haemorrhages than controls. Eighteen people died during the study (nine in each group). Eight people withdrew from the trial, five of whom were in the strapped group. A skin reaction to the tape caused withdrawal in three people and a herpes zoster infection precluded taping in another. The onset of the skin reactions occurred at days 3, 15 and 39 and settled quickly on removal of taping.

There were no significant differences in the two groups for any of the outcome measures using ITT analysis (Table 3). However using an explanatory analysis, the strapped group had a trend to less pain at exit (VAS mean (median, SD) 1.8 (0, 3.1) versus 2.5 (2, 2.7) respectively, $p = 0.09$), and better arm/hand function (MAS mean (median, SD) 5.5 (3.5, 5.9) versus 2.8 (1.0, 4.5) respectively, $p = 0.12$) at final assessment. There was no evidence that strapping reduced the prevalence of subluxation.

SROMP in the affected shoulder was lost early

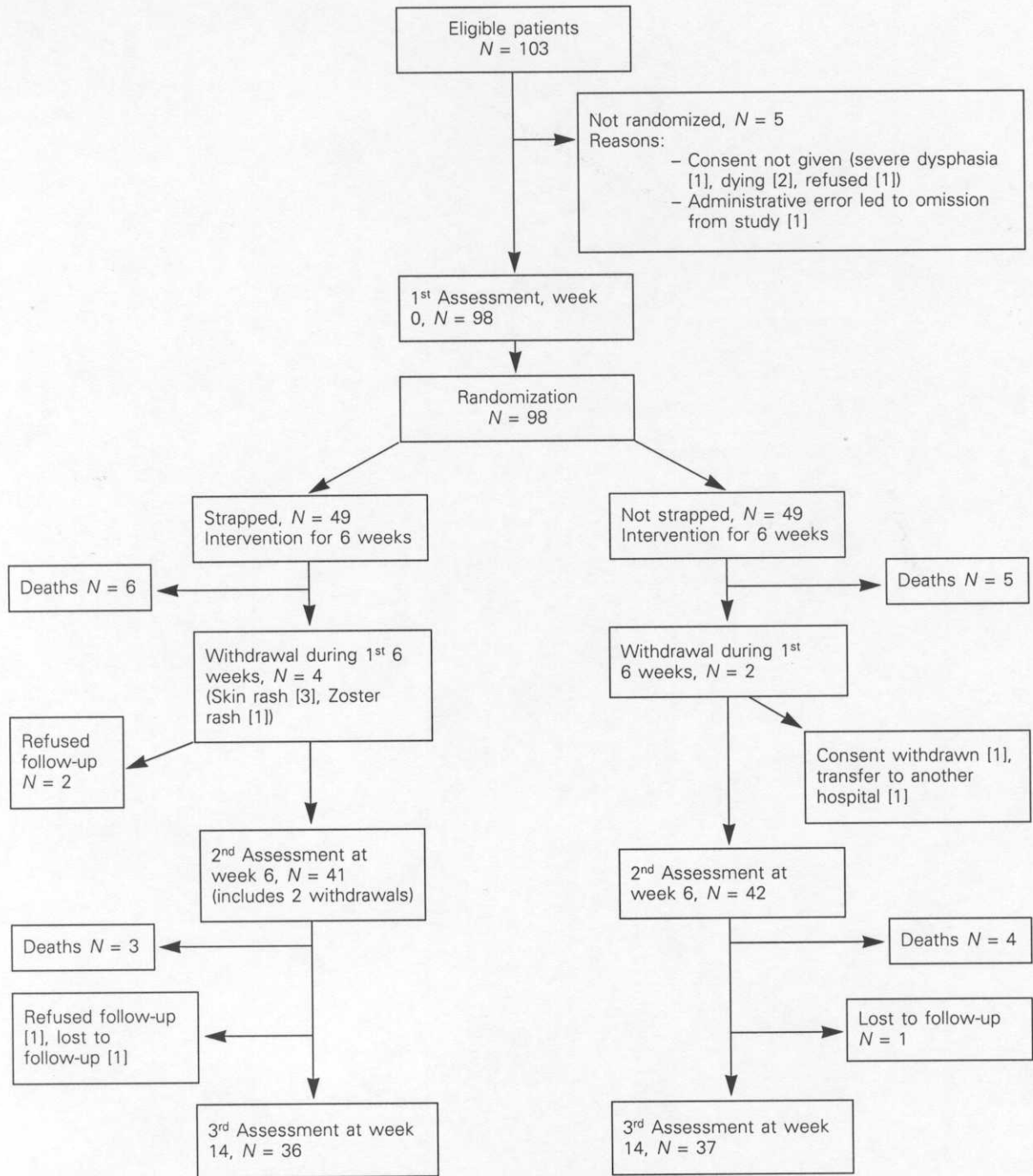


Figure 2 Flow diagram of patients who were eligible for the study with numbers of patients who participated, were excluded, died, or withdrew at each phase.

Table 1 Demographic characteristics of treatment and control groups

	Control (n = 49) Mean (SD)	Strapping (n = 49) Mean (SD)	p-value
Age (years)	77.8 (7.3)	79.1 (8.2)	0.43
Gender M/F	19/30	20/29	0.84
Side of stroke L/R	25/24	22/27	0.54
Stroke onset to admission to rehabilitation wards time (days)	12.4(6.9)	12.2 (7.9)	0.93
Stroke - study entry time (days)	15.4 (8.0)	15.1 (8.3)	0.93
SROMP ^a			
Affected shoulder - median	60.0 (21.8)	55.0 (22.6)	0.31
Unaffected shoulder - median	70.0 (18.5)	75.0 (14.2)	0.13
Shoulder clinically subluxed on entry ^b Y/N	18/28	17/31	0.71
Neglect present ^b Y/N	34/15	34/11	0.50
Sensory loss ^b Y/N	19/21	15/27	0.28
Total length hospital stay	76.0 (34.3)	76.3 (32.9)	0.97

^aShoulder range of movement at the point of pain²⁶ -expressed as degrees of external rotation from neutral. Data was not normal distribution, so median (not mean) is presented, along with SD.

^bSome patients did not have this data recorded at entry.

Table 2 Stroke type by the Oxfordshire Community Stroke Project Classification²⁹

	Oxfordshire Classification ²⁹					Total
	Lacunar syndrome	Partial anterior circulation syndrome	Posterior circulation syndrome	Total anterior circulation syndrome	Primary intracerebral haemorrhage	
Control	6	12	1	28	2	49
Strapping	1	16	0	22	10	49

$\chi^2 = 11.2$, $df = 4$, $p = 0.02$.

before entry to the study (at mean of 15.4 days post stroke). At entry there was a mean difference of 15.2° (95% CI 10.9–19.5°) SROMP between the hemiplegic and unaffected shoulders. Further losses of SROMP in the hemiplegic shoulder occurred over the whole study (mean further loss of SROMP (95% CI) strapped 23.4° (14.1–32.7), controls 23.4° (13.9–32.7)) compared to the unaffected shoulder which showed no change with time (strapped group 0.0° (-5.5–+5.4), controls + 3.1 (-1.4–+7.5)). Strapping made no difference to this rate of loss of external rotation. The mean total loss of SROMP (loss before entry and during study) was 45.9° (95% CI 38.0–53.8) which equates to a mean decline of 2.5° (95% CI 2.1–2.0) per week.

We considered whether the presence of sen-

sory loss, neglect or subluxation at baseline could independently predict poor outcome at final assessment (Kruskal-Wallis ANOVA). The presence of sensory loss was independently associated with lower FIM ($p = 0.01$), Rankin score ($p = 0.03$), and MAS ($p = 0.03$) scores. Neglect was associated with a lower FIM and Rankin scores ($p = 0.0001$ and $p = 0.003$ respectively). However, the presence of shoulder subluxation was not independently associated with poor outcome in any of the measures, including SROMP.

Discussion

Pain in the shoulder following a hemiplegic stroke is common, persistent and distressing to

Table 3 Differences (intention to treat analyses) between strapped and control groups at entry, end of six weeks treatment and final (week 14) assessments

	Entry			End of treatment			Final		
	Controls	Strapped	Difference	Controls	Strapped	Difference	Controls	Strapped	Difference
SROMP ²⁶									
Median	60	55	0.31	44	45	0.84	40	35	0.15
SD	21.8	22.6		22.5	21.1		26.9	19.5	
VAS									
Median (mean)	0 (0.27)	0 (0.68)	0.4	1.6 (2.4)	0 (1.7)	0.11	2 (2.7)	0 (2.3)	0.34
SD	1.6	2.1		2.7	3		2.9	3.3	
MAS ²⁷									
Median	0	0	0.87	1	3	0.48	1	3	0.16
SD	1.6	2.1		5	5.6		4.5	5.9	
FIM ²⁵									
Median	31.5	29.5	0.12	41	35	0.31	41	47	0.71
SD	8.6	8.3		13.6	11.4		15.2	12.7	
Rankin ²⁸									
Median	4	4	0.31	4	4	0.7	4	3.5	0.64
SD	0.6	0.6		0.78	0.8		1.1	1	

Clinical messages

- Shoulder pain is common after stroke, but proven preventative strategies are few.
- Strapping the shoulder in this study did not prevent shoulder pain, nor maintain range of movement.
- Loss of range of movement in the shoulder begins very early (within days) so treatment needs to start immediately.

patients.^{1,2} Unfortunately, there is only scanty evidence supporting any form of treatment, thus emphasizing the importance of preventing this condition. Recent literature suggests that shoulder strapping has considerable potential to reduce the incidence and/or severity of PSSP, but the studies were small or uncontrolled.^{10,18,21} There are a number of different techniques of strapping, each of which aims to reduce subluxation whilst allowing freedom to move the upper arm actively and passively. Furthermore, because strapping is left on continuously, unlike slings, it should ensure support to the soft tissues of the shoulder at all times. In addition, the strapping may provide some limited sensory stimulation on the affected side. Despite these theoretical benefits, we found no evidence that this particular strapping technique does work, either in reduc-

ing pain, maintaining range of movement or improving functional outcome using an ITT analysis. However, the efficacy of technique may be better assessed by an explanatory analysis. Using this analysis there was less pain in the strapped group at the end of the treatment phase, and better upper limb function at final assessment. However these results did not reach statistical significance ($p = 0.09$ and $p = 0.12$ respectively).

Shoulder strapping was well tolerated by the majority of patients. Only three withdrew due to skin reactions, one of whom had completed 39 of the planned 42 days active treatment. The under-tape facilitated good adherence of the tape, whilst minimizing the pain of tape removal. Potential stretching of the tape was avoided by replacing it regularly, at least every three days. There were no hygiene problems, but particular care was taken during each change to cleanse the skin thoroughly and remove any tape residues.

An important finding from this study was that pain-free ROM at the shoulder was lost very early after the stroke. There was already a 15° difference between the affected and unaffected shoulders at entry into the study (mean of two weeks post stroke). Chaco and Wolf³⁰ previously showed that subluxation can occur in the early (the first three weeks) flaccid stage after a stroke. Our study confirms that the changes within the shoulder girdle that cause loss of ROM and pain

also occur very early in the stroke illness. It is not clear how early these changes occur, but a recent study²³ measured SROMP using a similar technique to ours at 48 hours post stroke.²⁶ Their baseline SROMP measurements are remarkably similar to our two-week baseline figures (53.3° control, 45.0° treatment versus 57.9° control, 52.9° treatment respectively). Whilst they did not measure the unaffected arm, the similarities suggest that such changes may occur very early (i.e. within the first 24–48 hours). One factor that may have contributed to our negative findings was the inability to recruit patients earlier due to their admission to a different hospital for acute treatment. The sizeable early loss of movement, combined with the continued loss with time, means that any attempts to prevent PSSP must start as soon as possible after the stroke.²³

Our study was comparatively large ($n = 98$), had a high participation rate with few exclusions and thus is likely to be representative of all stroke patients needing inpatient rehabilitation. Despite this trial being larger than most other shoulder trials²⁴ a type II error is still possible. Recalculating the statistical power shows that we had an 80% chance of detecting a 15° difference in SROMP, but would need 33 additional patients to detect a 10° difference. The latter figure would still be clinically relevant as it represents approximately one-quarter of the total SROMP lost over the trial.

There are a number of other possible explanations why we were unable to demonstrate a benefit from the strapping: (1) The technique may be ineffective. (2) The strapping may not have reduced subluxation sufficiently. Clinically, the strapping did reduce subluxation and the strapping was replaced at frequent intervals to minimize the effects of stretching, but we did not seek radiological confirmation. (3) The strapping hypothesis may be sound, but the technique was incorrect. Our strapping came anteriorly across pectoralis major, which could have facilitated overactivity, thus encouraging internal rotation of the glenohumeral joint. (4) The measurements used may have been too insensitive to detect a clinically significant change. This seems unlikely as Linn *et al.*²³ used similar outcome measures and were able to demonstrate a change, albeit short term. It is quite possible that the disability

measures (FIM, Rankin) were too global and lacked sensitivity to change. (5) The intervention period (six weeks) may have been too short, following which the shoulder was left unprotected. However the time trends do not support this hypothesis. (6) Handling or some other aspect of care may have been inappropriate. Both treatment and control groups were allowed to use any conventional treatments, including slings. Indeed it is routine in our unit for all patients to use a sling (Cuff type arm sling³¹) whenever the arm is unsupported. It is possible that the negative effects of the slings^{6,18–20} counteracted any beneficial benefits of strapping. In hindsight, the study design may have been better to compare the effects of strapping (with no slings allowed) against conventional treatment, including slings. (7) The strapped and controls were not similar at entry for the type of stroke.²⁹ However, as survivors of intracerebral haemorrhages (ICH) tend to have better functional outcomes, this inequality would be expected to favour the strapped group. (8) Our patient group may have been too severely disabled and thus unlikely to benefit from any shoulder treatment. The high mean Rankin scores and comparative long hospital stay (mean 76 days) suggest that the study patients were a very disabled group. Parry *et al.* recently found that patients with severe arm impairment showed very little improvements in arm function irrespective of treatment given.³²

Although we have been unable to demonstrate that this form of strapping is beneficial, we believe that there is sufficient evidence to continue to investigate strapping as a potential preventative measure for this distressing condition. Combining strapping, to provide early shoulder stability, with other techniques such as maintenance of range of movement, FES^{22,23} or scapular stabilization^{33,34} seems to be the most promising line to investigate.

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