

No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial

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Question: Is wearing a night splint as effective as standing on a tilt table in preventing ankle dorsiflexion contracture and promoting the ability to stand up early after stroke? **Design:** Randomised trial with concealed allocation, assessor blinding, and intention-to-treat analysis. **Participants:** 30 patients undergoing rehabilitation who were not yet walking and within three weeks of their first stroke. **Intervention:** For four weeks, one group wore a splint with the affected ankle at plantargrade, 7 nights per week, while the other group stood on a tilt table for 30 min with the ankle at maximum dorsiflexion, 5 times per week. This was followed by a period of no intervention for six weeks. Both groups received inpatient and outpatient rehabilitation emphasising mobility. **Outcome measures:** The primary outcome was contracture measured as maximum passive ankle dorsiflexion. **Results:** The night splint group had the same amount of ankle dorsiflexion as the tilt table group by Week 4 (mean difference 1 deg, 95% CI -5 to 7), and by Week 10 (mean difference 3.5 deg, 95% CI -3 to 10). **Conclusion:** When added to early rehabilitation, wearing a night splint on the affected ankle in stroke patients appears to be as effective as standing on a tilt table in preventing contracture at the ankle. However, since there was no control group, the prevention of contracture may have been due to other factors. [Robinson W, Smith R, Aung O, Ada L (2008) No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Australian Journal of Physiotherapy* 54: 33–38]

Key words: Randomised Controlled Trial, Hemiplegia, Splints, Ankle, Contracture, Physical Therapy Techniques, Rehabilitation, Treatment Outcomes

Introduction

Contracture of the ankle is a common impairment following stroke. Stroke patients who are not yet walking in rehabilitation units may spend up to 58% of their day sitting with their calf muscles in shortened positions (Mackay et al 1996), which could contribute to contracture of the plantarflexors. This in turn limits ankle dorsiflexion and consequently affects activities, such as standing up from a chair and descending stairs, which rely on large amounts of ankle dorsiflexion (Moseley et al 2003). A review of animal studies suggest that muscles immobilised in shortened positions lose extensibility and length (Herbert 1993). It is perhaps not surprising that loss of 10 to 15 degrees of ankle dorsiflexion has been reported years after stroke (Chung et al 2004, Rydahl and Brouwer 2004, Vattanasilp et al 2000). However, a loss of 14 degrees of ankle dorsiflexion has been reported within a few months after stroke (Grissom and Blanton 2001, Keating et al 2000), suggesting that adaptive changes occur early.

When this study was planned, there was little evidence to guide clinical practice in the prevention of contracture after stroke. Although animal studies suggested that 30 min of positioning muscles in a lengthened position was enough to prevent contracture (Williams 1990), there were no randomised trials of prevention of contracture after stroke. However, there was some evidence to suggest that

prolonged stretching may prevent contracture in other neurological populations. Tardieu et al (1988) found that ankle dorsiflexion was maintained in cerebral-palsied children when they spent an average of 6 hr/day in some dorsiflexion. Grissom et al (2001), in an uncontrolled trial, reported improvements in ankle dorsiflexion of 20 degrees using an orthosis that provided a constant low load stretch over only 2 weeks in people after stroke and traumatic brain injury, but skin breakdown was a problem. Hyde et al (2000) reported 23% less dorsiflexion contracture with the addition of night splints over 1 year compared with passive stretches alone in subjects with muscular dystrophy. A systematic review recommended the use of casting and/or splinting for both prevention and reduction of lower limb contractures for people following traumatic brain injury (Watson 2001). Despite the lack of evidence in the stroke population, it seemed obvious that prevention of contracture should be an important part of rehabilitation, so that there is enough joint range to perform everyday activities.

Early after stroke, physiotherapists use therapy time performing interventions aimed at contracture prevention (Mackey et al 1996). In Sydney hospitals, a common intervention for preventing dorsiflexion contractures is standing on a tilt table with a wedge under the affected foot so that the ankle is in maximum dorsiflexion (Bohannon and Larkin 1985). This is time-consuming and therefore reduces time spent in active rehabilitation. An alternative

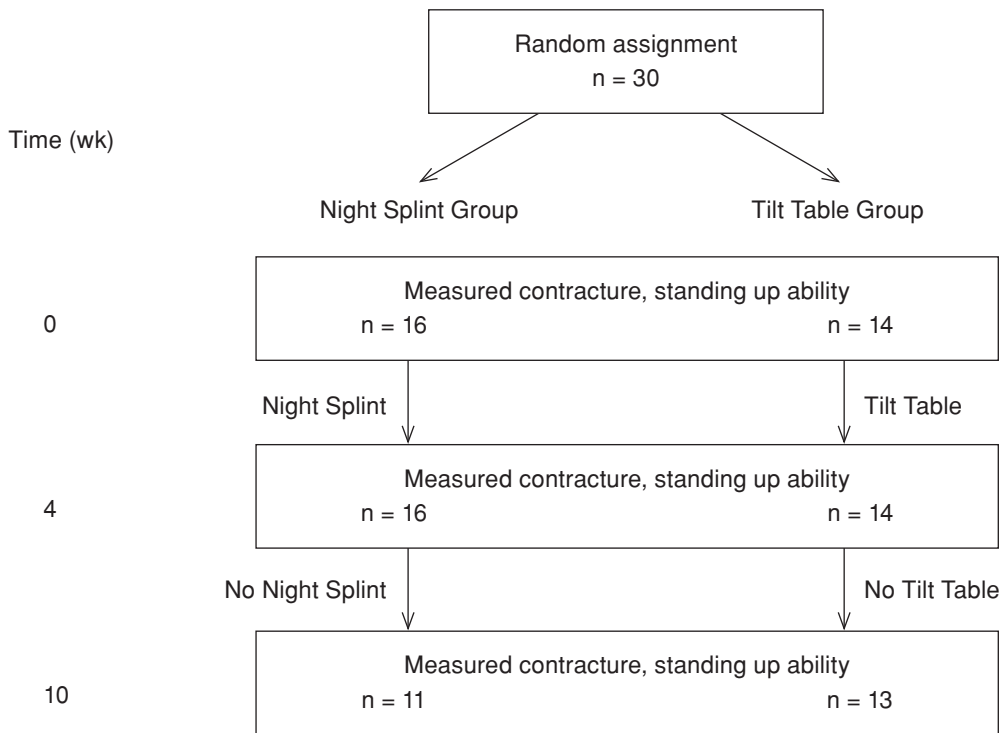


Figure 1. Design and flow of participants throughout trial.

intervention which would be more efficient of therapists' time is wearing an ankle splint overnight. Although the ankle is not usually positioned in maximum dorsiflexion in an ankle splint, the extra time spent at plantargrade may achieve the same result. The purpose of this study, therefore, was to compare the efficacy of these two interventions in patients who were not yet walking early after stroke. The specific research questions were:

1. Is 4 weeks of wearing a splint with the affected ankle at plantargrade overnight as effective as standing on a tilt table with the ankle at maximum dorsiflexion for 30 min/day in preventing ankle dorsiflexion contracture and promoting the ability to stand up in patients early after stroke who were undergoing rehabilitation?
2. Would any gains in efficacy of one intervention over the other still be apparent after 6 weeks of no prevention?

Method

Design

A randomised trial comparing wearing a night splint with standing on a tilt table for the maintenance of dorsiflexion of the affected ankle in stroke patients undergoing rehabilitation was carried out (Figure 1). Ward therapists screened patients' files against the inclusion criteria and patients who met the inclusion criteria were invited to enter the trial. Group allocation was achieved via a table of computer-generated random numbers held off site. In this way, randomisation was concealed from the ward therapists. Participants then received 4 weeks of the allocated intervention followed by 6 weeks without that intervention. Measures were collected at entry to the trial (Week 0), following intervention (Week 4), and after intervention was withheld for six weeks (Week 10). All measures were collected by an assessor blind to

group allocation. Blinding was achieved in a number of ways. First, the assessor did not work in the area where the interventions took place and second, the participants were instructed not to reveal anything about the interventions they received. It was not possible to blind the participants and therapists to the interventions. The study was approved by the hospital area health services and university ethics committee. Informed consent was gained before data collection took place.

Participants

Patients within 3 weeks of having a stroke and undergoing rehabilitation were recruited from two public metropolitan hospitals. Patients were included if they were currently immobile, defined as scoring less than 3 points on Item 5 (Walking) of the Motor Assessment Scale (Carr et al 1985); had not yet developed an ankle contracture, defined as their affected ankle dorsiflexion being within 10 degrees of their intact ankle; and were able to walk before their stroke. Patients were excluded if they were diabetic, had pre-existing skin or circulatory problems contraindicating the application of splints, or had severe difficulty in communication affecting their ability to report adverse events.

Demographic data such as age, gender, and side of hemiparesis were collected. Item 3 (Sitting balance) of the Motor Assessment Scale was collected as a general descriptor of the level of disability of the participants. The time from the stroke to admission to the study was also collected.

Intervention

Participants allocated to the night splint group had their affected ankle splinted in a plantargrade position 7 nights per week. This was achieved either by wearing a prefabricated splint or, if not suitable, the therapist made a removable

Table 1. Participant characteristics.

Characteristic	Included participants		Loss to follow-up	
	NS n = 16	TT n = 14	NS n = 5	TT n = 1
Age (yr), mean (SD)	74 (12)	72 (8)	82 (6)	80
Gender M:F	8: 8	9: 5	2:3	1:0
Side of hemiplegia L:R	9: 7	6: 8	2:3	0:1
Admission to study (d), mean (SD)	12.6 (5.4)	11.5 (5.0)	10.0 (2.3)	17
Sitting balance Item 3 MAS (0 to 6), mean (SD)	2.7 (1.7)	3.2 (1.5)	2.6 (1.8)	2.0
Max passive DF of intact ankle (d), mean (SD)	12.6 (10.9)	12.0 (11.4)	7.9 (11.4)	12.0

NS = night splint group, TT = tilt table group, DF = dorsiflexion, MAS = Motor Assessment Scale

padded fibreglass splint which was held in position with a crepe bandage. The nursing staff or family applied the splint with the participants in supine and the affected knee extended after they were assisted to bed. This ensured that the gastrocnemius muscle was in a lengthened position initially, but participants were free to move throughout the night as desired. If the participant could not tolerate the splint for any reason, the splint was removed by nursing staff and later adjusted by the ward therapist in order to minimise adverse events. Otherwise, it was removed prior to being assisted out of bed in the morning. Compliance and adverse events were documented each night by the nursing staff and reviewed regularly by the ward therapist.

Participants in the tilt table group stood on a tilt table 5 days per week for 30–40 minutes with the affected ankle positioned at maximum dorsiflexion using an appropriately-angled wedge. The unaffected leg was placed on a stool so that they bore weight primarily on their affected leg. The affected hip and knee were maintained in extension using straps. Compliance and adverse events were documented by the ward therapist.

All participants received inpatient rehabilitation 5 days per week aimed at early weight bearing and regaining mobility. In addition, outpatient rehabilitation 1 to 2 times per week was available following discharge from the rehabilitation unit. No other intervention aimed purely at maintaining ankle dorsiflexion was given.

Outcome measures

The primary outcome was contracture measured as maximum passive dorsiflexion in degrees according to Moseley and Adams (1991). Surface markers were applied to the lateral malleolus, the head of the fifth metatarsal, and the head of the fibular. Participants were positioned

in supine with a 10-cm cylinder placed under the knee whilst a force of 12 kilograms, standardised with a spring gauge, was applied over the metatarsal heads to produce dorsiflexion at the ankle. This method has been found to be highly reliable with an intra-class correlation coefficient of 0.97 (Moseley and Adams 1991). A Polaroid photograph of the lateral view of the leg was taken from a distance of 1 metre and at the same height as the ankle to avoid parallax error. Ankle dorsiflexion was measured on the photograph using the intersection between a line joining the lateral malleolus and the head of the fibular, and the line of best fit with the sole of the foot. Plantargrade was set as 0 degrees, with dorsiflexion given a positive value, and plantarflexion a negative value. An intra-rater reliability check performed on our quantification of dorsiflexion from the photographs produced an intra-class correlation of 0.98 (95% CI 0.90 to 1.00).

The secondary outcome was the ability to stand up from a 45 centimetre height chair measured using Item 4 (Standing up) of the Motor Assessment Scale on a scale from 0 to 6 where 0 is poor performance and 6 is good performance with even weight bearing. Limitation of ankle dorsiflexion, particularly from shortening of the soleus muscle, interferes with the ability to move the foot backwards under the knee preventing even weight bearing. Also shortening of the gastrocnemius muscle interferes with even weight distribution for final standing alignment.

Data analysis

Consensus amongst the authors determined that 10 degrees difference in ankle dorsiflexion range of motion between the groups was the smallest effect worthwhile detecting. Initial power calculations were based on the mean standard deviation (9.1 deg) of ankle dorsiflexion for the first 10 participants. Therefore, in order to have an 80% chance

Table 2. Mean (SD) for each group, mean (SD) difference within groups, and mean (95% CI) difference between groups for all outcomes.

Outcome	Group						Difference within groups			Difference between groups				
	Week 0		Week 4		Week 10		Week 4 minus Week 0		Week 10 minus Week 0		Week 4 minus Week 0		Week 10 minus Week 0	
	NS n = 16	TT n = 14	NS n = 16	TT n = 14	NS n = 11	TT n = 13	NS	TT	NS	TT	NS minus TT	TT	NS minus TT	TT
Contracture	14.0	15.9	14.1	15.0	12.9	9.8	0.2	-0.8	-2.4	-5.9	1.0	3.5	1.0	3.5
Max passive DF (deg)	(9.0)	(8.6)	(6.4)	(12.6)	(8.6)	(11.5)	(8.8)	(7.2)	(7.0)	(7.7)	(-5.1 to 7.1)	(-2.8 to 9.8)	(-5.1 to 7.1)	(-2.8 to 9.8)
Standing up ability	0.8	1.2	2.7	2.6	4.1	3.4	1.9	1.4	3.3	2.2	0.5	1.1	0.5	1.1
Item 4 MAS (0 to 6)	(0.7)	(1.1)	(1.7)	(1.5)	(2.3)	(2.1)	(1.5)	(0.9)	(2.1)	(1.5)	(-0.4 to 1.4)	(-0.4 to 2.6)	(-0.4 to 1.4)	(-0.4 to 2.6)

NS = night splint group, TT = tilt table group, DF = ankle dorsiflexion, MAS = Motor Assessment Scale

of detecting a 10-degree difference in ankle dorsiflexion, we needed 26 participants. We recruited 30 participants to allow for 10–15% loss of participants to follow-up.

Examination of the size of the effect (95% CI) was used to determine whether there was a greater effect of wearing a night splint compared with standing on a tilt table in the maintenance of dorsiflexion and promotion of standing up ability. Analysis of data from Weeks 0 to 4 compared the immediate effect of wearing a night splint with standing on a tilt table, while analysis of data from Weeks 0 to 10 determined whether any benefits of one intervention over the other were maintained.

Results

Flow of participants through the trial

Thirty participants (13 female, 17 male) with a mean age of 72 (SD 10) years, who were 12 (SD 5) days post stroke (hemiparesis left = 15, right = 15) consented to participate in the study between August 2002 and May 2006. As an indication of the severity of their stroke, their mean score was 3.0 points (SD 1.7) on Item 3 (Sitting Balance) of the Motor Assessment Scale. Initially, passive dorsiflexion of the affected ankle was 15 degrees (SD 9), compared with 12 degrees (SD 11) on the intact ankle. Standing up ability was 1.0 point (SD 1.0) on the Motor Assessment Scale, indicating the need for assistance in order to stand up from a chair. At baseline, the groups were similar in terms of characteristics such as sex, age, days from stroke to admission to the study, side of hemiparesis, and sitting balance (Table 1). They were also similar in terms of the amount dorsiflexion and ability to stand up from a chair (Table 2).

The flow of participants through the trial is summarised in Figure 1. All participants were still inpatients and therefore available for the post-intervention assessment (Week 4). By Week 10, six participants had withdrawn from the study (five from the night splint group and one from the tilt table group). Reasons for dropping out were: death (n = 1), moved out of the area (n = 3, 1 from the tilt table group), refused measurement (n = 1), and fracture secondary to a fall (n = 1).

Compliance with trial method

Intervention was documented as being given, documented as not being given (with reasons), or undocumented and therefore unknown. Compliance with wearing a night splint was documented as happening 73% of the time, documented as not happening 10% of the time, and undocumented 17% of the time. Reasons for non-compliance included: complaints of leg pain/tightness/heat (n = 5), refusal (n = 3), and pressure sores caused by the splint (n = 2). Compliance with the standing on a tilt table was documented as happening and well tolerated 87% of the time, documented as not happening 10% of the time, and not documented 3% of the time. Reasons for non-compliance included: insufficient time by the therapist (n = 7), illness of the participant (n = 3), unstable blood pressure (n = 2), refusal (n = 1), unrelated surgery (n = 1), and bowel accident (n = 1).

Effect of intervention

Group data for contracture and standing up ability are presented in Table 2 while individual data are presented in Table 3 (see eAddenda for Table 3). By Week 4, both groups had lost very little dorsiflexion and there was no difference between them (mean difference 1 deg, 95% CI -5 to 7). By Week 10, although both groups had lost a small amount of

dorsiflexion, there was still very little difference between them (mean difference 4 deg, 95% CI -3 to 10).

Since there was no difference between the groups, the data of all the subjects were pooled to examine the development of ankle contracture. At Week 4, participants had maintained ankle dorsiflexion to within 0.3 degrees (SD 8) of entry to the study. Between Week 4 and 10 when no ankle contracture prevention occurred, participants lost 3 degrees (SD 7) of ankle dorsiflexion.

Discussion

The overall aim of this trial was to determine if wearing a night splint was a viable alternative to the more established intervention of standing on a tilt table in preventing ankle dorsiflexion contracture in the early stages of rehabilitation after stroke. Over the four weeks of intervention, both groups maintained maximum passive dorsiflexion and there was no difference between the interventions in terms of maintaining maximum passive dorsiflexion or improving the ability to stand up from a chair. As the investigators had agreed that a difference of 10 degrees in ankle dorsiflexion was the smallest clinical effect worth detecting, the 95% confidence interval demonstrates that a clinical effect was not achieved. It would therefore appear that wearing an overnight splint is as effective as standing on a tilt table.

Each intervention had its advantages and disadvantages. The advantages of wearing a night splint are: it uses the overnight period for intervention which allows therapy time to be spent on active retraining of everyday tasks, it is easy to apply, and, perhaps most importantly, it can be sustained in the long term following discharge from hospital. The disadvantages are the risk of pressure sores, particularly when patients have compromised vascular supply and/or sensation in the area. Even with the exclusion of patients with sensory loss, peripheral vascular disease, and diabetes from the current study, a pressure sore occurred in one of the participants. The advantage of standing on a tilt table is the ability to position the ankle in maximum dorsiflexion thereby necessitating only a short duration of intervention. It had been thought that standing on a tilt table had the added advantage of maintaining bone mineral density, but this has recently been disproved in a high quality trial of 3 months duration (Ben et al 2005). The disadvantages are that it is poorly tolerated by those patients with unstable blood pressure, and takes up time that therapists see as being spent more effectively in active retraining of everyday tasks. Given that there was no obvious superiority of one intervention over the other, the choice of intervention to prevent contractures should be based on the individual characteristics of the patient and the resources available.

The main limitation of the current study was the lack of a control group who received no intervention. This means that, although ankle dorsiflexion was maintained and standing up ability improved in both the night splint and tilt table groups, we cannot be sure that this was not due to factors other than the intervention. For example, examination of loss of joint range in the control groups (ie, groups that received no intervention) of contracture prevention trials in patients undergoing 4 weeks of rehabilitation early after stroke (21 deg in Ada et al 2005, 5 deg in Horsley et al 2007, 9 deg in Lannin et al 2007, 9 deg in Turton and Britton 2005) suggests that modern rehabilitation, with its emphasis on active practice of everyday tasks, may be sufficient intervention to largely prevent contracture. The only one

of these trials where the control group lost any appreciable joint range over 4 weeks was the one where the amount of rehabilitation targeted at the joint under investigation was restricted to less than 10 minutes per day (Ada et al 2005). Furthermore, rehabilitation for the patients in the hospitals involved in the current study included many repetitions of standing up with the feet back, and this may have been sufficient stimulus to maintain ankle dorsiflexion. After the cessation of interventions to prevent contractures, the tilt table group (with only 1 dropout compared with the night splint group with 5) lost 6 degrees of ankle dorsiflexion over 6 weeks. However, the development of this small contracture may have been the result of the reduction in rehabilitation following discharge from the hospital rather than the cessation of stretching interventions. More importantly, this small contracture is likely to increase over time. It may be, in people with stroke who are susceptible to the development of contracture, that the challenge of prevention is bigger once they are discharged from rehabilitation. As also suggested by other authors, this question could be the focus of future studies (Harvey et al 2006).

eAddenda: Table 3 available at www.physiotherapy.asn.au

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Erratum

Correction to Volume 53 No 4

There was an error in Horsley et al (2007). The error was caused by unintentionally excluding one datum; it is small and does not affect the findings.

The text should be corrected as follows (corrected text in bold type):

Abstract: ‘The mean effect on passive range of wrist extension was **3.8** degrees (95% CI **–2.5 to 10.1**) after four weeks of daily stretch, 4.1 degrees (95% CI –4.0 to 12.3) after a week of no stretch, and 3.5 degrees (95% CI –4.6 to 11.7) after a further four weeks.

Page 242: ‘Over the intervention period, between Week 0 and 4, maximum passive wrist extension stayed the same in the experimental group and decreased slightly in the control group but there was no significant difference between groups ($p = 0.23$). The ANCOVA-adjusted estimate of the difference between groups was **3.8** degrees (95% CI **–2.5 to 10.1**) in favour of the experimental group.

Page 243: Table 2 should report the following mean (SD) for maximum passive wrist extension of the experimental group: Week 4 = **68.2 (13.0)**; difference within groups (Week 4 minus Week 0) = **–1.4 (10.4)**; difference between groups (Week 4 minus Week 0) = **3.8 (–2.5 to 10.1)**.

Page 243: ‘The best estimate of the effect of four weeks of daily stretch was that it increased range of motion by **4** degrees. However, given the precision of the estimate, it is quite possible that the true average effect of stretch could lie anywhere between a negative effect of **3** degrees and a beneficial effect of **10** degrees.’

Reference

- Horsley SA, Herbert RD, Ada L (2007) Four weeks of daily stretch has little or no effect on wrist contracture after stroke: a randomised, controlled trial. *Australian Journal of Physiotherapy* 53: 239–245.