Article

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Functional orthosis in shoulder joint subluxation after ischaemic brain stroke to avoid post-hemiplegic shoulder–hand syndrome: a randomized clinical trial

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Abstract

Objective: To examine whether the use of a shoulder joint functional orthosis over four weeks can mitigate the development or progression of the shoulder–hand syndrome in patients with shoulder joint subluxation after stroke.

Design: Two-armed randomized controlled trial.

Setting: Rehabilitation unit of a neurological hospital, single centre.

Subjects: Forty-one patients with caudal subluxation of the glenohumeral joint and hemiparesis of the upper extremity after ischaemic brain stroke.

Interventions: Support by functional orthosis Neuro-Lux (Sporlastic, Nürtingen, Germany) on top of usual care according to current guidelines (experimental, $n = 20$) versus usual care alone (control, $n = 21$).

Main measures: Weekly shoulder–hand syndrome scores (severity of clinical symptoms ranging from 0 to 14), discomfort caused by the orthosis, and its usage rate. The primary outcome was the average shoulder–hand syndrome score on days 14, 21 and 28, adjusted for the baseline shoulder–hand syndrome score.

Results: The adjusted mean shoulder–hand syndrome score was lower by 3.1 in the intervention compared to the control subjects (95% confidence interval 1.9 to 4.3, $P < 0.0001$). Marginal or no discomfort from treatment with the orthosis was reported in 15 patients (75%), and only a single patient (5%) felt severe discomfort during the entire treatment. Use of the orthosis during the prescribed time was 89%.

Conclusions: The orthosis examined in this trial has been successfully shown to reduce and prevent the development of clinical symptoms of shoulder–hand syndrome. Timing and duration of application of the orthosis as well as its combination with other therapeutic measures should be investigated in future clinical trials.

Keywords

Ischaemic brain stroke, shoulder joint subluxation, shoulder–hand syndrome, painful shoulder, neurological rehabilitation

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Introduction

The shoulder joint is particularly vulnerable to deterioration and injury due to its anatomy. Its stability is predominantly assured by muscular and ligamental structures.[1] Paralysis of the muscles may lead to a subluxation of the shoulder joint, a common secondary complication after ischaemic stroke followed by central hemiparesis. Such cumulative incidences were reported in 17–81% of stroke patients.[2] Glenohumeral subluxation is an alteration of the mechanical integrity of the shoulder joint. Atonic paresis of the shoulder musculature leads to a palpable gap between the acromion and the head of the humerus.[3] In the latter, shoulder–hand syndrome may develop.[4–7] Incidence in the European population was estimated at 26.2 cases per 100 000 individuals per year,[8] corresponding to 20 000 annual cases in Germany. The shoulder–hand syndrome is characterized by pain, oedema and restricted flexibility of the shoulder and hand, as well as changes in skin temperature, turgor and colour.[4,9–12] Spontaneous healing is possible in the absence of further complications.[13] However, even when pain and impaired function are adequately treated, up to 50% of patients may experience delayed rehabilitation and persisting impediment.[14]

Although the pathophysiology of the shoulder–hand syndrome is not yet completely understood, various therapeutic measures have been proposed to prevent or treat it, including supportive devices. Several devices have been described in literature, but only a few trials have examined efficacy against glenohumeral subluxation.[15–17] These studies were confined to the immediate mechanical effect when the devices were attached to the patients' arms. Neither of the studies included a follow-up to assess clinical benefit. A Systematic Cochrane Review[18] concluded that there is insufficient evidence regarding the contribution of such devices to heal or prevent shoulder joint subluxation after stroke, as evidence is lacking for treatment of the shoulder–hand syndrome in general.[19] This situation has remained unchanged in recent years.[20,21] The objective of the present study was to examine the efficacy of the use of a shoulder joint functional orthosis over four weeks to prevent the onset and progression of symptoms of shoulder–hand syndrome.

Methods

Patients were eligible for the trial if they were over 18 years of age, had an ischaemic brain stroke proven by computed tomography within the last 21 days, exhibited caudal subluxation of the glenohumeral joint and hemiparesis of the upper extremity with muscle strength 0–2 (grading recommended by the Medical Research Council,[22,23] see Table 1 for details), had been admitted to the rehabilitation unit and could be mobilized for at least 4 hours daily. Exclusion criteria were high-grade neglect, severe aphasia, symptomatic transitory psychotic syndrome, treatment with opioids or analogous substances, contraindications to the use of the orthosis, planned thermic treatment or electrostimulation, any conditions (physical, mental or logistic) jeopardizing compliance with the protocol and participation in another interventional trial. Informed written consent was obtained from each participant prior to inclusion.

All patients received conventional care consisting of various passive and active movement exercises of the affected extremity under individual guidance of a therapist. Six training units of 30 minutes each were prescribed every week. Supportive and symptomatic treatments of the subluxed shoulder were provided. All measures of conventional care adhered to current guidelines applicable in Germany.[24]

In addition to usual care, patients randomly allocated to the intervention group received the functional orthosis Neuro-Lux (Sporlastic GmbH, Nürtingen, Germany), designed to reposition the affected joint and reduce subluxation (Figure 1). This orthosis is available in three sizes and can be individually adapted to the patient's body. Patients were advised to carry the orthosis between 8 a.m. and 6 p.m. during normal daily activity.

Patients were randomized in a ratio of 1 : 1 to the intervention and control groups. Blocked randomization lists were generated at the Clinical Trial

Table 1. Definition of classifications: Components of the shoulder–hand syndrome score and description of muscle strength

Criteria	Score value
Components of the shoulder–hand syndrome score[a]	
Sensory: pain, hyperalgesia	
None	0
Mild	1
Moderate	2
Distinct	3
Severe	4
Spontaneous	5
Autonomic: distal oedema	
None	0
Mild	1
Distinct	2
Severe	3
Motoric: painless passive range of motion	
Humeral abduction	
≥120 degrees	0
≥90 to <120 degrees	1
≥45 to <90 degrees	2
<45 degrees	3
Humeral external rotation	
≥30 degrees	0
≥20 to <30 degrees	1
≥10 to <20 degrees	2
<10 degrees	3
Muscle strength[b]	
No muscle activity	0
Discernable contraction without movement	1
Movement through range without gravity resisting	2
Movement through range against gravity	3
Movement through range against resistance	4
Normal power	5

[a]According to Braus et al.,[25] as recommended by current guidelines.[24]
[b]Grading as recommended by the Medical Research Council.[22,23]

Centre in Leipzig. Patients were consecutively allocated according to the lists upon request, and investigators were not made aware of the sequence in advance. Randomization was stratified by the affected side (dominant hand side or contralateral) and the muscle strength[22,23] at inclusion.

Patients underwent scoring of pain, hand oedema and limitations of humeral abduction and humeral external rotation, according to the shoulder–hand syndrome score defined by Braus et al.[25] (see Table 1), anthropometric measurement of subluxation (with the orthosis removed in the intervention group),[26] and examination of muscle strength,[22,23] all immediately prior to randomization and on days 7, 14, 21 and 28 following randomization. In addition, patients of the intervention group were asked to report discomfort caused by the orthosis (on a scale of none, mild, moderate or severe) and the average daily time the orthosis had been used. The observer was unblinded, as blinding was found to be unfeasible without additional staff.

The primary endpoint was defined as the average of the shoulder–hand syndrome scores on days 14, 21 and 28. The reason for this choice was that a sufficiently prominent effect was expected after two weeks, and an attempt was made to reduce variance by averaging over repeated measurements. The last valid observation was used to estimate missing values whenever at least one follow-up measurement after baseline was available. Assuming predominantly monotonous development of the shoulder–hand syndrome scores within patients, this approach was expected to favour conservative test results. The major secondary endpoint was the shoulder–hand syndrome score on day 28. The primary and the major secondary endpoints were evaluated by analysis of covariance[27] with treatment as the factor and baseline shoulder–hand syndrome score as the covariate.

Further secondary endpoints were the components of the shoulder–hand syndrome score on day 28, the binary variable indicating the presence of all three shoulder–hand syndrome criteria (denoted by SHS-3, set ‘yes’ if pain, oedema and limitation of movement – impaired abduction or rotation – were all reported to occur at the same time, otherwise ‘no’), anthropometric subluxation and muscle strength on day 28, and the need for analgesic medication due to shoulder–hand syndrome within the study period. These endpoints were analysed by *t*-test (quantities) and Fisher’s exact test (frequencies).

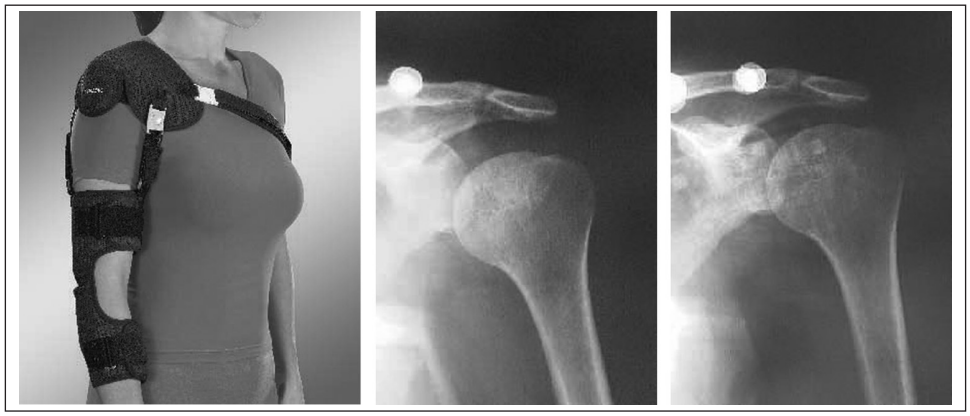

Figure 1. The Neuro-Lux shoulder joint functional orthosis in situ (left). The glenohumeral joint of a patient without (middle) and with orthosis (right). Reproduced with kind permission from Sporlastic.

A descriptive post-hoc subgroup analysis examining the changes of the shoulder–hand syndrome scores in patients with lower and higher baseline scores (median split) was also carried out in order to obtain information about whether the benefit from the orthosis is related to the severity of shoulder–hand syndrome symptoms at the onset of the treatment.

In the intervention group, the time spent free from discomfort as well as compliance with the orthosis were estimated at 95% confidence intervals (CI). Compliance was expressed by the percentage of the prescribed time the orthosis was used. Eight hours of daily use or more was set at 100%, assuming an interval of use from 8 a.m. and 6 p.m. minus 2 hours of rest. The relationship between discomfort and compliance with clinical outcomes was examined by correlation analysis (Kendall's coefficient).

All analyses were performed according to the intention-to-treat principle. SPSS 15 (SPSS Inc., Chicago, IL, USA) was used as statistical software.

Sample size calculation was based on shoulder–hand syndrome scores of patients observed in clinical routine, simulations based on these data and the assumption that the orthosis may reduce the percentage of patients experiencing significant worsening of the shoulder–hand syndrome score from 45% to 5%. Primary endpoint means of 2.6 and 5.0 and standard deviations of 1.6 and 3.1 in the intervention and control groups, respectively, were anticipated. To achieve a power of 0.8 (preferably 0.9) at a type I error level of 0.05, 19 (preferably 25) patients per group needed to be evaluated. It was therefore decided to cease recruitment at the point where 25 patients per group had been included, or after six months of recruitment had passed provided that at least 20 patients per group were included, or after inclusion of 20 patients per group where the duration of recruitment exceeded six months.

The study protocol was approved by the Ethics Committee of the Medical Association of Bavaria (Germany).

Results

Of 151 patients considered for inclusion, 41 were eligible (Figure 2). Of the eligible patients, 20 were randomly allocated to the intervention group and 21 to the control group. One patient in the intervention group died on day 8 after initial improvement of the shoulder–hand syndrome score from 6 to 2. Another patient of the same group was discharged on day 15 after improvement of the shoulder–hand syndrome score from 8 to 4. The last observations of these patients were carried forward, and all eligible patients were analysed. Demographic data and baseline variables are summarized in Table 2.

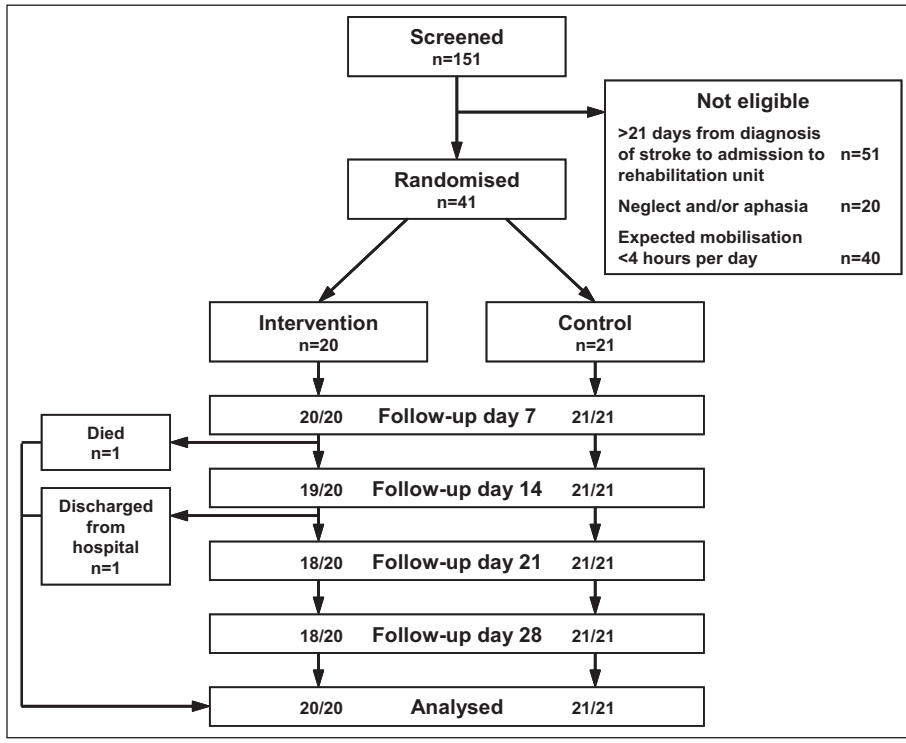

Figure 2. Flowchart.

Table 2. Demographic data and baseline examination

Variable	Treatment group	
	Orthosis	Control
Number of subjects	20	21
Female sex	10 (50%)	8 (38%)
Age (years)	64 ± 16	65 ± 13
Days from hospital admission to randomization	8.2 ± 5.3	7.7 ± 5.3
Stratification variables		
Writing hand affected	6 (30%)	7 (33%)
Muscle strength		
0	10 (50%)	10 (48%)
1	8 (40%)	9 (43%)
2	2 (10%)	2 (9%)
Subluxation, anthropometric measurement (cm)	2.2 ± 0.5	1.6 ± 0.5
Shoulder–hand syndrome score	6.0 ± 2.6	3.2 ± 2.2
Pain	1.8 ± 1.1	1.0 ± 1.0
Oedema	1.3 ± 0.5	0.8 ± 0.5
Limitation of movement (abduction + rotation)	2.9 ± 1.5	1.4 ± 1.3
SHS-3 (three criteria fulfilled)	16 (80)	9 (43)

Values are frequencies (percentages) or mean ± standard deviation. SHS, shoulder-hand syndrome.

Table 3. Primary and secondary endpoints

Variable	Treatment group		Difference orthosis–control	
	Orthosis	Control	Mean (95% CI)	*P*-value
SHS score, average of days 14, 21, 28 (primary endpoint)	2.7 ± 1.5	4.8 ± 2.1	−2.1 (−3.3 to −0.9)	0.0008
Adjusted for baseline SHS score[a] (analysis of covariance)			−3.1 (−4.3 to −1.9)	<0.0001
SHS score on day 28	1.8 ± 1.5	5.3 ± 2.4	−3.5 (−4.7 to −2.2)	<0.0001
Adjusted for baseline SHS score (analysis of covariance)			−4.1 (−5.5 to −2.8)	<0.0001
SHS score on day 28, components				
Pain	0.4 ± 0.6	1.8 ± 1.0	−1.4 (−2.0 to −0.9)	<0.0001
Oedema	0.6 ± 0.5	1.3 ± 0.7	−0.7 (−1.1 to −0.4)	0.0003
Limitation of movement (abduction + rotation)	0.9 ± 1.0	2.2 ± 1.0	−1.3 (−2.0 to −0.7)	0.0002
SHS-3 (three criteria fulfilled)	3 (15)	19 (90)	−75% (−97% to −54%)	<0.0001
Anthropometric subluxation (cm)[b]	1.7 ± 0.7	1.6 ± 0.9	+0.1 (−0.4 to +0.6)	0.7634
Muscle strength	1.7 ± 1.0	1.8 ± 1.0	−0.1 (−0.8 to +0.6)	0.8592
Analgesic medication due to SHS	0 (0)	1 (5)	n.a.	1.0000

Data are mean ± standard deviation or frequencies (percentages). CI, confidence interval.
[a]Primary analysis.
[b]In the intervention group, the orthosis was taken off for the examination. This is hence a measure of residual subluxation without support of a device, not an estimate of the repositioning achieved by the orthosis in situ.

Shoulder–hand syndrome scores improved in the intervention group and worsened in the control group. The average shoulder–hand syndrome scores on days 14, 21 and 28 (primary endpoint) were 2.7 ± 1.5 in patients treated with the orthosis and 4.8 ± 2.1 in the control group. Analysis of covariance estimated the gain by the orthosis to be a lowering of the shoulder–hand syndrome score by 3.1 points (95% CI 1.9 to 4.3, $P < 0.0001$). In addition, the intervention group had significantly lower levels on the shoulder–hand syndrome score, its components and the qualitative SHS-3 endpoint on day 28, despite less favourable scores at baseline. Muscle strength and anthropometric measurements of subluxation (with the device removed) were comparable in both groups at follow-up (Table 3).

Analysis of the changes in the shoulder–hand syndrome scores in the subgroups with low (0–4) versus high baseline score (>4, median split) showed that the benefit from treatment with the orthosis was independent of the initial severity of shoulder–hand syndrome symptoms (Figure 3). Intervention and control patients began treatment with comparable levels of the shoulder–hand syndrome score in both subgroups. The score of patients treated with the orthosis decreased to a low level regardless of the initial score. In contrast, control patients starting with low shoulder–hand syndrome scores continuously increased, and those starting with high scores exhibited no significant changes in their shoulder–hand syndrome score. Despite small sample sizes, the final shoulder–hand syndrome scores differed significantly between intervention and control groups in both subgroups.

Nine patients of the intervention group (45%) reported no discomfort caused by the orthosis at any time, and six patients (30%) felt at most mild discomfort. Four patients (20%) had occasional moderate (1) or severe (3) discomfort, and only one patient (5%) felt severe discomfort during the entire trial. The overall time spent free of any discomfort was 59% of the entire treatment period (95% CI 38% to 79%).

Thirteen patients (65%) were fully compliant with the intervention, meaning that they carried the

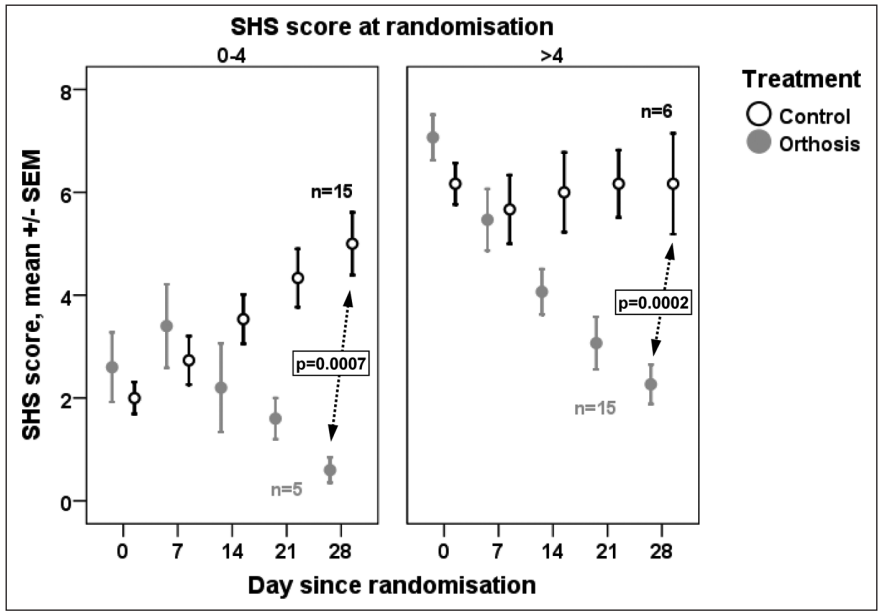

Figure 3. Changes of the shoulder–hand syndrome score from baseline to follow-up depending on baseline shoulder–hand syndrome score and treatment. Patients treated with the orthosis reached low scores after four weeks regardless of the initial levels, while controls starting with low scores continuously worsened and those with high baseline scores remained unchanged.

orthosis for 8 hours or more every day. Average usage of the orthosis over four weeks was 89% (95% CI 82% to 97%). The minimum compliance level per patient was 50%.

No significant associations between discomfort or compliance with the shoulder–hand syndrome score on day 28 were found (Kendall's $\tau_b = 0.14$, $P = 0.49$, and $\tau_b = 0.15$, $P = 0.46$, respectively).

One patient from the control group had severe pain of the affected shoulder and received an opioide (tilidin retard, 50 mg per day). This treatment was administered up to and including day 28, keeping pain at a moderate level.

All other administrations of potentially analgetic agents were prescribed before inclusion of the patients into the study, maintained unchanged over the study time, and were not associated with the shoulder subluxation. One patient of the intervention group received ibuprofen retard 800 mg twice daily for generalized pain syndrome. Fourteen patients of the intervention group and nine controls received aspirin to prevent thrombosis and embolism at doses not effective for pain treatment (50–100 mg daily).

Discussion

The present study demonstrated that the functional orthosis Neuro-Lux is efficacious in the reduction and prevention of pain, hand oedema and limitations of movement of the upper extremity in patients with a caudal subluxation of the glenohumeral joint after ischaemic brain stroke. Treatment using the orthosis was tolerated well by the patients. Only few symptoms of shoulder–hand syndrome were observed after four weeks of treatment, compared to a considerable burden of symptoms observed in the control group. The subgroup analysis (Figure 3) is of particular interest as it revealed that the orthosis is efficacious in the treatment (in patients with high initial shoulder–hand syndrome scores, left panel of

Figure 3) as well as in the prevention of onset or worsening of symptoms (patients with low initial scores, right panel of Figure 3).

This is, to our best knowledge, the first randomized trial demonstrating clinical benefit of a supportive device in treating symptoms of shoulder–hand syndrome. Previous studies on devices measured only the repositioning of the shoulder joint, without examining the change of clinical parameters over time. Existing evidence on treatments of the shoulder–hand syndrome provided by randomized trials has been considered poor,[18–21] hence the present study represents a significant contribution to this field.

Although only 41 (27%) out of 151 patients assessed for eligibility were included in the study, the results are likely to apply to a wider patient demographic. Heterogeneity in the study sample was intentionally minimized in this first efficacy trial examining the orthosis. Limitation to a time span of 21 days from diagnosis of stroke is certainly not essential for the development of subluxation and shoulder–hand syndrome, and hence, for the benefit arising from use of the orthosis. In addition, the minimum of 4 hours of daily mobilization could be relaxed, since the orthosis is potentially useful in every moment the patient spends in an upright position. In conclusion, 131 (87%) of patients screened would belong to the target population for orthosis treatment in clinical practice.

There are three statistical notes. First, observed means and standard deviations of the primary endpoint were close to the underlying sample size calculations, hence the study was well powered.

Second, we defined the primary endpoint to be the average over three measurements in order to reduce variance and, thereby, to increase power. As a critical retrospective appraisal, note that the treatment effect increased continuously over time (Figure 3) and hence, the shoulder–hand syndrome score on day 28 would be a better and more simple choice for the primary endpoint in future trials.

Third, the reader may have noted the imbalance of baseline shoulder–hand syndrome scores in the intervention and control groups, which unfortunately occurred coincidentally despite randomization stratified by muscle strength. The results are nonetheless valid, as analysis of covariance adjusts for such imbalances at baseline,[27] and, moreover, results were consistent in the stratified analysis comparing subgroups of patients with similar baseline scores (Figure 3). A recommendation for future trials is, however, to stratify randomization by the baseline shoulder–hand syndrome score.

Because of the small sample size, the present study was limited in its chance of capturing a sufficient number of cases with severe shoulder–hand syndrome. In fact, only two patients of the control group had an shoulder–hand syndrome score of 8 or more after four weeks. Furthermore, this study was unblinded, which is generally considered a potential source of bias. However, note that blinding of patients was in this case impossible. Blinding of the observer would first require an independent observer who is sufficiently qualified but not involved in the clinical routine, and secondly a location for the study examinations which is well separated from the facilities visited by the patients during daily activity in order to ensure that the observer will never meet the patient incidentally. Third, procedures would need to be in place to ensure that the observer will not receive any clues from the patient about his or her group assignment during the examinations. Unfortunately, due to financial limitations these conditions could not be met in this study.

The results of this study imply that the orthosis is useful for mobilized patients with shoulder joint subluxation, regardless of whether or not symptoms of shoulder–hand syndrome are already present. At this stage, it is recommended that the orthosis be carried during all daily activities over at least four, but up to a recommended six weeks. The use of the orthosis should not be terminated abruptly, but rather the daily usage should be reduced incrementally, and the application should be continued whenever symptoms of the shoulder–hand syndrome resurface.

Following the first successful demonstration of efficacy of the orthosis in a randomized controlled trial, subsequent investigations should include patients at all stages of shoulder–hand syndrome, in a wider timespan after the diagnosis of stroke. Subsequent trials should include individuals with

low levels of mobilization, as well as reducing restrictions for eligibility of trial subjects.

Combinations with other therapeutic measures should also be studied to further optimize treatment. While the orthosis repositioned the shoulder joint during use, subluxation resumed as expected when the device was removed. It is hence a supportive device, and it would thus be of particular interest to study its combination with an 'active' treatment aiming to restore normal muscle function.

Clinical messages

- The functional orthosis Neuro-Lux proved to be efficacious for the prevention and treatment of the clinical symptoms of the shoulder–hand syndrome.
- Its application is well tolerated by the patients.

Authors' note

Maik Hartwig and Götz Gelbrich contributed equally to this work.

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The investigators received financial support for the conduct of the study from Sporlastic GmbH, Nürtingen, Germany (manufacturer of the orthosis). Representatives of the manufacturer were not involved in the development of the trial protocol, the conduct of the study, evaluation of data, writing of the manuscript or the decision to submit the paper for publication. The financial support was provided prior to the study, and hence was not dependant on the outcome. No further payment was received. No other conflict of interest declared. Registration: ISRCTN 61157551

Author's Contributors

MH and GG designed the trial and drafted the study protocol, case report forms and study guidelines. BG revised the study protocol critically. MH and BG were responsible for conduct of the study. GG performed the statistical analyses. MH and GG drafted the manuscript. BG revised the manuscript critically. BG is the guarantor. All authors had access to all study data and held final responsibility for the decision to submit for publication.

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