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ORIGINAL REPORT

A NEW ORTHOSIS FOR SUBLUXED, FLACCID SHOULDER AFTER STROKE FACILITATES GAIT SYMMETRY: A PRELIMINARY STUDY

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Objective: **The aims of this study were: (*i*) to evaluate the immediate effects on subluxation and gait pattern of a new shoulder orthosis, developed for treatment of painful shoulder syndrome in subacute stroke patients; and (*ii*) to evaluate patients' and therapists' opinions about its fit and benefits after 4 weeks.**

Methods: **A total of 40 subacute in-rehabilitation stroke patients with non-functional arm and painful shoulder were included in the study. Of these, 12 subjects underwent shoulder radiography and gait analysis with and without the orthosis to determine the immediate effects of the orthosis. All 40 patients wore the orthosis during the daytime for 4 weeks before completing a survey. Outcome measures were: repositioning of the humeral head, gait cycle parameters, and qualitative lower limb muscle activation patterns. Patients and therapists rated wearing comfort, odour nuisance, effect on pain and performing gait and mobility-related activities.**

Results: **When using the shoulder orthosis the humeral head was repositioned in 10 of 12 patients, patients walked more symmetrically due to a prolonged hemiparetic stance phase ($p < 0.01$), and the paretic quadriceps muscle activity was higher and more appropriately timed. The majority of patients and therapists rated the wearing comfort positive, the odour nuisance minimal, and that the orthosis helped with performing activities. However, less than half of patients and therapists reported improvement in pain.**

Conclusion: **The well-tolerated shoulder orthosis improved gait quality and repositioned the subluxated humeral head, offered a good fit, and eased performing activities, but did not reduce pain. This preliminary study does not warrant any definite conclusions on the effectiveness of the orthosis; more studies are needed to compare its effect with other models.**

Key words: stroke; orthosis; shoulder; pain; hemiparesis.

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INTRODUCTION

The annual incidence of stroke in the industrialized world is approximately 180 per 100,000 inhabitants, and it is the most common cause of persisting disabilities (1). Painful shoulder syndrome (PSS) occurs in 15–40% of subacute stroke patients, and is associated with an extended length of stay and a worse rehabilitation outcome (2).

The aetiology of PSS has been ascribed to the biomechanical compromise of the post-stroke glenohumeral joint, subluxation due to paresis of the shoulder girdle, shoulder spasticity, rotator cuff tears, and a limited range of motion (ROM) of the shoulder (3, 4). In early rehabilitation, a flaccid, rather than a spastic, type of PSS predominates, mainly characterized by paresis of the shoulder girdle, with shoulder subluxation, shoulder microtrauma and soft tissue inflammation (4–6).

Many different types of treatment (joint mobilization, steroidal and non-steroidal anti-inflammatory agents, therapeutic ultrasound, strapping, functional electrical stimulation (FES) of the shoulder girdle muscles, botulinum toxin injections of the pectoralis and subscapularis muscles, intra-articular steroid injections and suprascapular nerve blocks (5, 7–13)) have been used, and the failure of any to become universally adopted illustrates their limited benefits.

Many designs of shoulder orthoses and slings are commercially available, and are used to various degrees in different units. They share the intention of supporting the weight of the upper limb, repositioning the humeral head and preventing sudden uncontrolled movements of the paretic arm. A Cochrane meta-analysis reported: insufficient evidence of effect in preventing subluxation and pain; the potential for restricting shoulder range of movement; concern that elbow flexor spasticity may increase; and that discomfort and unpleasant odour discouraged many from using the orthoses and slings (14). Recently, Hartwig et al. reported that wearing a functional shoulder orthosis helped to reduce the development of clinical symptoms of shoulder-hand syndrome in subacute stroke patients (15).

The authors, together with a commercial partner (Otto Bock Health Care company, Duderstadt, Germany), developed a

new orthosis, aiming comfortably to support the weight of the flaccid upper limb, reposition the subluxed humoral head, and avoid restriction of passive shoulder movement, elbow spasticity and odour. A tight fitting in case of an atrophic shoulder girdle was another goal. It consisted of a shoulder part with a belt running under the contralateral axilla. The belt could be individually adjusted with the help of Velcro straps, adjustable both on the chest and the back. This extended to a cuff around the upper arm and an additional forearm cuff, which encouraged elbow extension (Fig 1).

The aims of the study were: (*i*) to evaluate the immediate effects of the shoulder orthosis on subluxation and gait pattern; and (*ii*) to evaluate the patients' and therapists' opinion about its fit and benefits after 4 weeks. Shoulder radiography and gait analysis with and without the orthosis was planned; previous work had shown that other orthosis models had repositioned the humeral head (16) and improved the walking pattern, as reflected by the assessment of gait cycle parameters, weight acceptance onto the paretic leg and oxygen uptake (17, 18). The hypothesis was that the shoulder orthosis improved the position of the humeral head and had a positive effect on the patients' gait, including the activity pattern of the weight-bearing lower limb muscles of the affected side, which, to the authors' best knowledge, had not yet been investigated. In the additional survey, the patients wore the orthosis during the daytime for 4 weeks, in order to assess its wearing comfort, odour and its effect on pain and performing mobility-related activities. It was expected to show a good fit and wearing comfort, and to benefit the performance of activities, but not to benefit shoulder pain.

METHODS

Subjects

A total of 40 patients (27 men, 13 women, mean age 60.3 years (standard deviation; SD 16.7)) from 2 in-patient stroke rehabilitation units were recruited to the study. Of these, 17 had a right hemiparesis and 23 a left hemiparesis. The mean stroke interval was 6.3 weeks (SD 3.3 weeks), the mean height (body weight) was 175 cm (SD 12 cm) (78 kg (SD 13 kg). All patients met the following inclusion criteria:

- First-time supratentorial stroke and participating in a comprehensive in-patient rehabilitation programme.
- Non-functional upper extremity (i.e. no ability to perform Box and Block Test (19).
- Subluxated shoulder, tested clinically while standing with the arm unsupported.
- Pain in the affected shoulder reported spontaneously by the patient and/or noticed by the team during manipulation.
- Ability to walk at least 20 m, with or without a therapist's help, corresponding to Functional Ambulation Category (FAC 0–5) of 2 or 3 (20).
- Ability to answer a short interview.
- No relevant impairment of pain sensation in the arm.
- No known history of shoulder impairment before stroke onset.
- Signed consent in the study approved by the local ethics committee.

Radiography and gait analysis in a subgroup of patients

In 12 of the 40 patients (all of whom came from 1 of the 2 participating centres and had worn the orthosis for at least 1 week, fulfilled the above-mentioned criteria, did not differ with respect to their clinical data from the 28 patients from the other centre, and had a comparable rehabilitation programme) a conventional anterior-posterior X-ray of the affected shoulder with and without the orthosis was carried out, while the patient was standing. Two experienced radiologists independently measured to what extent the orthosis repositioned the shoulder head vertically, and a mean was calculated. Two reference points were identified: the most inferolateral point of the acromion and the apex of the humeral head, a line was drawn between these two points, and the distance measured using a ruler (mm) (Fig. 2). The measurement error was ±1.5 mm, a relevant subluxation reduction was assumed when the difference was at least 3 mm, corresponding to 2 SDs.

Instrumented gait analysis was performed with and without the orthosis in the same 12 patients. Initially, patients performed the 10-m test twice without any instrumentation, in order to determine their self-selected walking velocity. During the subsequent instrumented gait analysis with and without the orthosis, the patients were instructed to walk at their self-selected speed, cued by a metronome, to minimize the known influence of walking velocity on gait parameters (21). Gait analysis was performed on a floor 100-m long, the instrumented patients familiarized themselves to the conditions, the actual sample time was 30 s, and the order of conditions changed from patient to patient. All patients had worn the orthosis for at least 1 week, the 2 conditions were assessed within one measurement sequence including a 10-min break, with the instrumentation remaining in place throughout, in order to minimize its influence, particularly on the recording of the dynamic electromyography.

The limb-dependent cycle parameters (stance, swing, double support durations) were recorded by the Infotronic system (Infotronic, Tubbergen, The Netherlands), consisting of overshoe slippers with 8 insole force sensors and a portable data logger. The logger sampled the data of 30 s at 100 Hz, and amplified and recorded them. Elec-

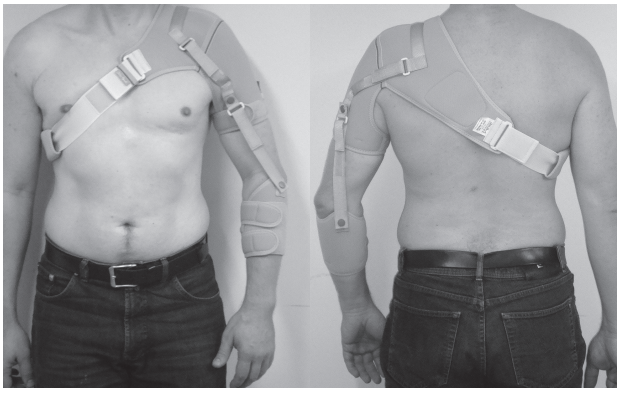

Fig. 1. Shoulder orthosis.

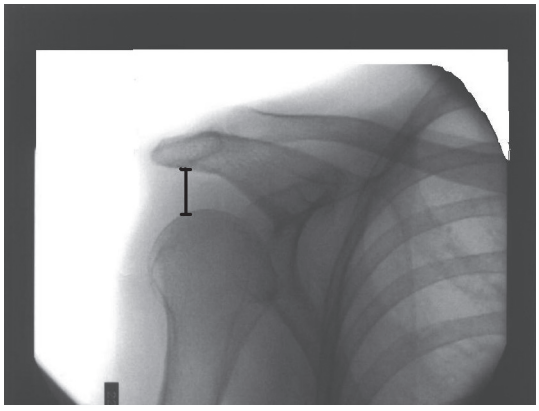

Fig. 2. Reference points for measurement of the vertical and horizontal displacement of the glenohumeral joint.

tromyographic activity (EMG) was detected by self-adhesive surface electrodes, which were attached 2 cm apart on the muscle bellies. The impedance was checked and kept below 5 kOhm. On each subject's affected side, we obtained recordings for the following muscles: tibialis anterior, medial head of the gastrocnemius, vastus lateralis, vastus medialis, rectus femoris, biceps femoris, gluteus medius and erector spinae. Signals (1,000 Hz sampling rate) were pre-amplified with standard Infotronic preamplifiers attached to the limbs and recorded by the same data logger.

All gathered signals (limb-dependent cycle parameters and EMG signals) were transmitted to a personal computer after the end of the measurement, and further processed by Infotronic software.

Limb-dependent cycle parameters were averaged over 30 s, and normalized with respect to the gait cycle (= 100%). Symmetry ratios were calculated for stance and swing durations (duration of the left-side divided by that of the right if the duration of the left was shorter, or vice versa). The electromyographic data were digitally filtered (band-pass, 10–300 Hz), full-wave rectified, averaged over at least 20 strides, and time-normalized to the mean cycle duration set to 100%. Two raters, who were unaware of the experimental condition, together checked the muscle activation patterns qualitatively for obvious, orthosis-related pattern changes. As the electromyographic data were gathered in one session, the qualitative comparison of the electromyographic activities within subjects was appropriate, assuming stable conditions.

Intervention

All 40 patients wore the orthosis during the daytime for 4 weeks, The therapy team, helped with putting it on in the morning, and with re-adjustment during the day, when necessary. The actual wearing time (in h) was noted every day.

The in-patient rehabilitation programme consisted of individual physio-, occupational and physical therapy (e.g. massage, heat, electrotherapy, ultrasound), and locomotor training for all patients on a regular basis, and other therapies were individually administered. All team members had been instructed on the PSS aetiology and the preventive shoulder handling on a regular basis. In case of any PSS, the commonly decided treatment algorithm, independently of the orthosis' prescription, included the prescription of a steroidal and non-steroidal pain medication, therapeutic ultrasound, electrical stimulation, and suprascapular nerve block. Aggressive ROM exercisetas (i.e. pullies), resulting in a markedly increased incidence of painful shoulder (22), were to be avoided in all cases.

Assessment

Wearing comfort, odour nuisance, pain, and effect on activities. At the end of the intervention, patients and the individually treating physiotherapists ($n = 14$) rated the wearing comfort (0 = very bad, 10 = excellent, a value > 7 was rated as a positive response), and the odour nuisance (0 = absent, 10 = intolerable, a value < 3 was rated as tolerable odour nuisance) with the help of a visual analogue scale (0–10).

Furthermore, patients answered 3 questions: How do you rate the effect of the orthosis: (*i*) on shoulder pain, (*ii*) on ability to perform walking, and (*iii*) on ability to perform basic activities of daily living, namely dressing, personal hygiene, transfers and toilet; on a scale of –2 to +2, where: –2 = definitely worse; –1 = worse; 0 = unchanged; +1 = better; and +2 = definitely better. The therapists answered questions (*ii*) and (*iii*) only.

The individually treating physiotherapists based their assessment on the patients' observation during treatment, with the arm both at rest and during movement. Their criteria for wearing comfort were: a good fit, no shifting, and no skin redness. A pre-study workshop had developed, tested and modified the questionnaires.

Arm impairment

Before and after the intervention, an experienced physiatrist assessed the subluxation cleft (in cm) while the patient was standing with the arm unsupported, i.e. patients did not wear the orthosis, and the passive ROM of the shoulder, based on the corresponding Fugl-Meyer Test (0–24) (23). With the help of Medical Research Council grades (MRC, 0–5) the voluntary muscle strength was tested for shoulder elevation, abduction, elbow, wrist and finger flexion and extension a sum score (0–40) was calculated (24). The Modified Ashworth Scale (MAS 0–5) helped to rate the muscle tone, tested for shoulder elevation and abduction, elbow, wrist and finger flexion and extension and forearm pronation and supination, a sum score (0–50) was calculated (25).

Statistics

To detect a significant change ($p < 0.05$) in the selected variables over conditions and over time, a non-parametric Wilcoxon test for paired samples was applied. In addition, 95% confidence intervals (CI) were calculated. The ordinal scaled values of the questionnaires (–2, –1, 0, +1, +2) were presented descriptively.

RESULTS

Immediate effects of the orthosis

X-ray revealed that the orthosis repositioned the humeral head in the vertical axis to a relevant extent in 10 of the 12 patients (Fig. 3), the distance (in cm) between the point of the acromion and a perpendicular vertical line through the central point of the humeral head decreased significantly, by a mean of 0.8 cm (SD 0.6; 95% CI –0.93 to –0.48).

Instrumented gait analysis showed that the stride length and cadence did not differ between the two walking conditions, and that the walking velocity remained constant according to the protocol. The relative stance phase duration of the affected leg ($p < 0.001$) and the stance symmetry ratio ($p < 0.05$) increased significantly, i.e. the patients walked more symmetrically while wearing the orthosis. The remaining relative limb-dependent cycle parameters (the relative double-stance phase, swing symmetry ratio), did not differ between the two conditions (Table I). The qualitative analysis of the dynamic EMG revealed a more normal phasic pattern of activation of the vastus lateralis muscle in the early stance phase, seen in 8 out of 12 patients (Fig. 4). For the vastus medialis and biceps femoris, the same pattern change was seen in 6 of the 8 patients. The gluteus medius muscle became more active in the early stance phase in 5 patients. The shank muscles and the erector spinae revealed no discernible alterations of their muscle activation patterns.

Wearing comfort, odour nuisance, pain, and effect on activities

Thirty-eight subjects wore the orthoses for 4 weeks, the mean wearing time was 6.8 h (SD 1.8 h) per day. Two subjects stopped wearing the orthosis in the first week, due to unfulfilled expectations and a sensation of constriction. The assessment continued in those cases (intention-to-treat).

At the end of the intervention, 32 rated the wearing comfort ≥ 7, with a mean value of 8 (SD 1.3) on the VAS; and 34 patients the odour ≤ 3, with a mean value of 1.1 (SD 1.2) on the VAS. The corresponding values for the therapists were 29 (VAS 7.3 (SD 2.1)) and 33 (VAS 1.2 (SD 0.9)), respectively.

With respect to pain, 18 patients reported an improvement (+2 or +1), 19 patients an unchanged condition, and 3 patients a change for the worse (–1 or –2). (Table II).

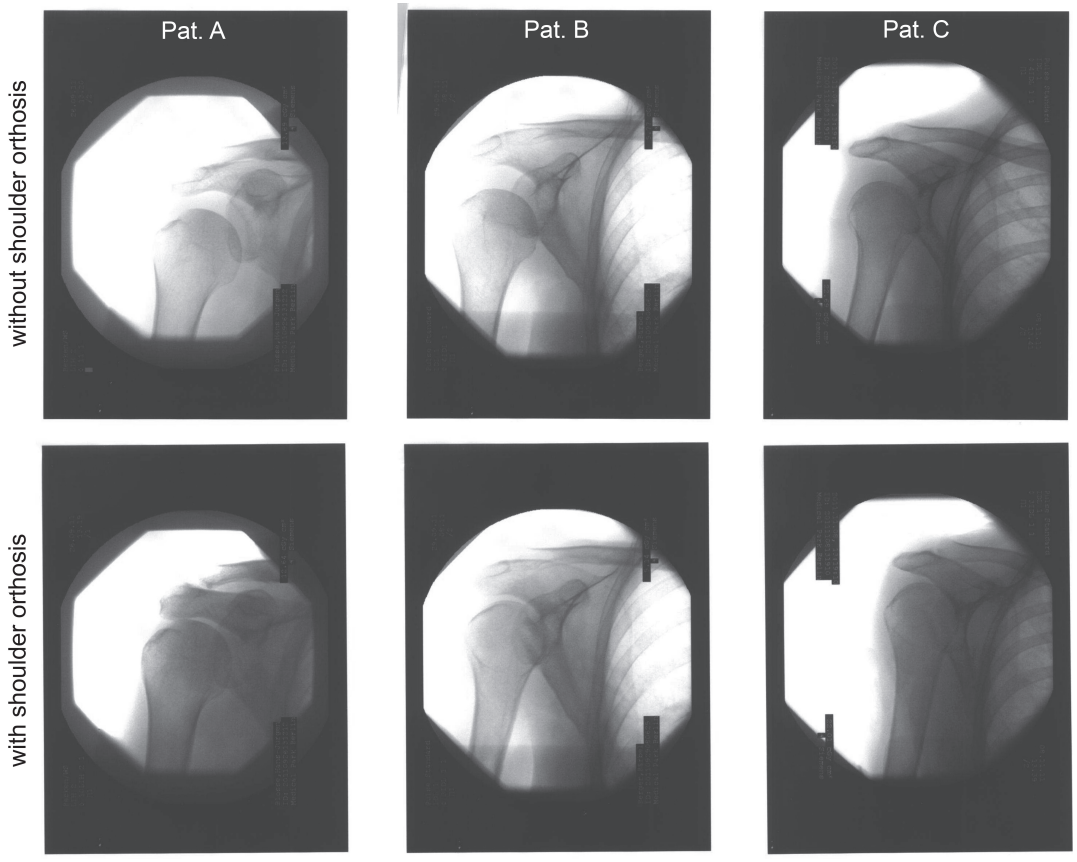

Fig. 3. Anterior-posterior X-rays in standing for 3 patients (A, B, C) without (*top figure*) and with the orthosis (*lower figure*). The orthosis reduced the vertical displacement of the glenohumeral joint.

Table I. *Results of quantitative gait analysis with and without the shoulder orthosis in a subgroup of 12 patients while walking on level ground*

	Without shoulder orthosis Mean (SD)	With shoulder orthosis Mean (SD)	*p*-value
Gait velocity (m/s)	0.62 (0.21)	0.63 (0.20)	n.s.
Cadence (steps/min)	72.7 (17.2)	74.0 (19.9)	n.s.
Stride length (m)	1.02 (0.34)	0.99 (0.33)	n.s.
Relative stance non-affected (%)	70.0 (2.3)	71.2 (2.8)	n.s.
Relative stance affected (%)	58.8 (13.1)	63.2 (14.5)	<0.001
Relative swing non-affected (%)	29.1 (2.8)	28.8 (2.8)	n.s.
Relative swing affected (%)	39.0 (5.5)	38.4 (4.6)	n.s.
Relative double support total (%)	37.8 (4.1)	38.0 (4.8)	n.s.
Stance symmetry as ratio of the absolute values	0.87 (0.04)	0.93 (0.05)	<0.05
Swing symmetry as ratio of the absolute values	0.77 (0.11)	0.81 (0.11)	n.s.

n.s.: non significant; SD: standard deviation.

Table II. *Patient's (therapist's[a]) evaluation of the questionnaire after 4 weeks of wearing the shoulder orthosis (*n = *40)*

	++ *n*	+ *n*	0 *n*	– *n*	— *n*
How do you rate the effect of the shoulder orthosis regarding your shoulder pain?	8	10	19	2	1
How do you rate the effect of the shoulder orthosis regarding relearning walking?	9 (13)	13 (15)	17 (11)	1 (1)	– (–)
How do you rate the effect of the shoulder orthosis regarding ADL activities (such as hand cleaning, dressing)?	8 (8)	15 (14)	15 (13)	2 (3)	– (2)

++: definitely better; +: better; 0: unchanged; –: worse; —: definitely worse.
[a]The team consisted of 14 therapists, all of whom rated their patients.
ADL: activities of daily living.

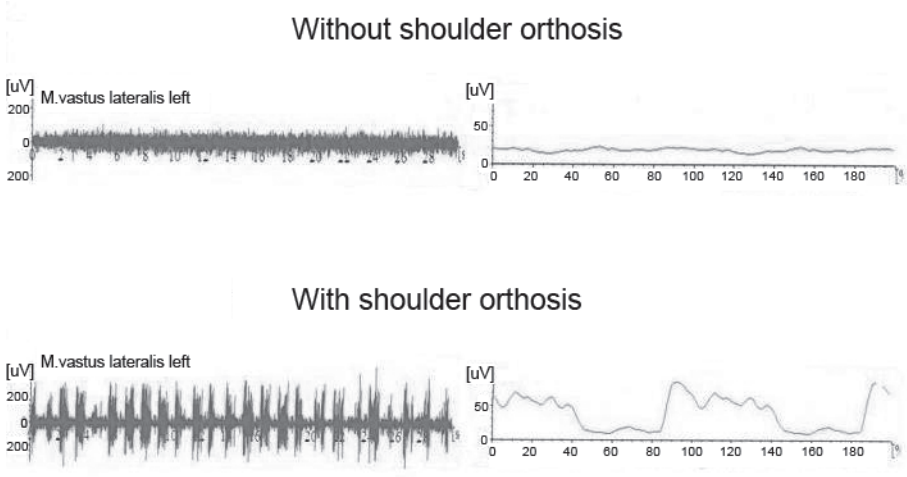

Fig. 4. Raw and averaged and normalized activity of the affected M. vastus lateralis of a left hemiparetic patient when walking without (*top figure*) and with the orthosis (*lower figure*). Note the more pronounced and more appropriately timed muscle activation, when walking with the orthosis.

On the activity level, 22 patients reported a positive effect (+2 or +1), 17 patients no effect, and 1 patient (–1 or –2) a negative effect of the orthosis on the ability to perform walking. The corresponding values for the therapists were 28, 11 and 1 (Table II).

Twenty-three patients reported a positive (+2 or +1), 15 patients no effect, and 2 patients (–1 or –2) a negative effect of the orthosis on the ability to perform mobility-related basic activities of living. The corresponding values for the therapists were 22, 13 and 5 (Table II).

Arm impairment

During the intervention, the subluxation cleft decreased significantly, by a mean of 0.8 cm (SD 0.6). Shoulder ROM tended to increase (mean 2.2 (SD 3.2)), the chosen significance level was not reached ($p > 0.05$). Muscle strength sum score (0–40) increased significantly, by a mean of 6.2 (SD 6.0). The elbow flexor and extensor muscle tone remained constant, the same applied to the other muscles tested, see the sum score in Table III.

DISCUSSION

Radiography and gait analysis in a subgroup of 12 out of 40 stroke patients revealed that the orthosis helped to reposition the subluxated humeral head, that they walked more symmetrically, and that the activity of the paretic quadriceps muscle was facilitated in a timely and correct manner. The majority of patients with a flaccid painful shoulder tolerated the orthosis well, found it comfortable, and were not troubled by odour. Their therapists reported that the orthosis helped patients to perform walking and other mobility-related tasks. However, it was not associated with a relevant reduction in shoulder pain.

The orthosis helped to reposition the humeral head in the vertical direction to a relevant extent, as reported previously for other models (16, 26). An excellent fitting in the atrophic shoulder region, straps firmly combining the shoulder and the forearm part, and partial relief of arm weight were the likely factors.

According to the gait analysis, wearing the orthosis resulted in a more symmetrical gait pattern due to a prolonged stance phase of the affected leg, indicating more weight acceptance onto the paretic leg, which, on the other hand, may explain the facilitated activity of the paretic quadriceps muscle, a finding not yet reported in the literature to the authors' knowledge. Yavuzer & Ergin (17) similarly reported that wearing a sling resulted in decreased double-stance phase, reduced excursions of the centre of gravity and increased weight-bearing of the paretic side in stroke patients. Han et al. (18) reported that an arm sling improved the gait efficiency of hemiparetic patients with a painful shoulder.

Table III. *Means (standard deviation; SD) of the dependent variables and the 95% confidence interval (CI) for paired samples of all 40 patients at beginning and end of the survey*

	Study begin Mean (SD)	Study end Mean (SD)	Paired difference Mean (SD)	95% CI	*p*-value for paired differences
Shoulder subluxation cleft, cm	1.8 (0.9)	0.9 (0.7)	–0.8 (0.6)	–0.9320 to –0.4814	0.0001
Passive ROM as a subscore from Fugl-Meyer score, 0–24	19.3 (4.1)	21.3 (2.8)	2.2 (3.2)	0.990 to 3.344	0.176
MRC-Sum score, 0–40	5.2 (6.9)	11.3 (8.5)	6.2 (6.0)	3.894 to 8.406	0.0001
Sum Score of Modified Ashworth Scale, 0–50	3.8 (5.1)	3.9 (4.6)	0.1 (3.2)	–1.090 to 1.290	0.865

CI: confidence interval; ROM: range of motion.

It was, hence, not surprising, that most of the patients and therapists reported that the orthosis helped to perform walking and mobility-related basic activities of living. The patients may have felt more secure when walking with the orthosis, as the paretic arm was partially fixed and unloaded, thereby minimizing the risk of sudden uncontrolled arm movements provoking shoulder pain. Thus, the subjects could better concentrate on gait and mobility tasks. Yavuzer & Ergin (17) had similarly concluded that an arm sling improved gait, especially during gait training sessions with patients with hemiplegia who have impaired body image and insecurity-related excessive motion of the centre of gravity.

Less than half of the patients and therapists reported an improvement in pain. This finding is in line with a previous Cochrane report, that there was no clear evidence that shoulder slings prevented or treated shoulder pain effectively after stroke (14). Pain is a subjective sensation, and most of the patients were in the phase after stroke when they realize that their limb weakness is likely to be permanent, potentially giving rise to negative feelings. Furthermore, the correlation between glenohumeral joint subluxation and shoulder pain is a matter of debate, studies either supported (e.g. 3, 27), or failed to support the role of shoulder subluxation in pain. (e.g. 28–30). According to an MRI study by Shah et al. (31), rotator cuff tears and rotator cuff and deltoid tendinopathies were highly prevalent in post-stroke shoulder pain. Ultrasonography showed that acute stroke patients with poor upper limb motor functions, as selected in the present study, were more prone to soft-tissue injury of the shoulder during rehabilitation compared with less-affected patients (32).

On the arm impairment level, wearing the orthosis for 4 weeks resulted in a diminished subluxation cleft, and the strength of the shoulder girdle increased significantly, confirming the known correlation between muscle paresis and subluxation (3). The often expressed fear of elbow flexor stiffness could not be confirmed, the elbow muscle tone remained unchanged, and shoulder ROM even tended to increase. The orthosis held the forearm in slight extension and supination, and for the routinely applied therapeutic shoulder mobilization, the potentially impairing forearm cuff could easily be removed. Putting on the orthosis, however, required well-trained staff members. For a comparable model, Hartwig et al. reported that the use of the orthosis during the prescribed time was 89%, and that it prevented the development of clinical symptoms of shoulder-hand syndrome (15).

The major limitations of this survey are the lack of comparison with different models and follow-up. Information on the patients' ability to move the arm with and without the orthosis would supplement the assessment of the effect of the orthosis on activity level. X-rays and the gait analysis with and without the orthosis provide qualitative information only on the immediate effects of the orthosis.

In conclusion, the well-tolerated shoulder orthosis improved gait quality and repositioned the subluxated humeral head, offered a good fit, eased performing activities, but did not help reduce pain. The orthosis may be a clinical option for wheelchair-bound stroke subjects with PSS when re-learning walking and performing mobility-related activities. This preliminary study does not warrant any definite conclusions on the effectiveness of the orthosis; further studies are needed to compare its effect with other models.

Conflicts of interest

The shoulder orthosis was developed by the Berlin research lab for motion analysis and therapy, Medical Park Berlin, Germany (head Stefan Hesse) together with Otto Bock HealthCare, and royalties have been agreed. All authors state that the instrumental company had no influence on the interpretation of data and the final conclusions drawn.

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