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# Introduction of a new shoulder orthosis to treat shoulder pain (PS) in the severely affected arm in patients during early rehabilitation after stroke

S. Hesse<sup>1</sup>, A. Bardeleben<sup>2</sup>, J. Grunden<sup>2</sup>, I. Rembitzki<sup>2</sup>, C. Werner<sup>2</sup>

<sup>1</sup>Medical Park Berlin, Humboldtmühle, <sup>2</sup>Klinik Berlin, Neurological Rehabilitation, Charité, Campus BF

## Zusammenfassung

We report on a new shoulder orthosis to treat shoulder pain (PS) in the severely affected arm after stroke. The patient wears the orthosis directly on the skin. It consists of two pieces: a shoulder and a forearm part, which are connected by straps to ensure that the forearm can perform extension and supination. To date, the orthosis was fitted to twelve early-rehabilitation patients with a severely paretic arm who either suffered from PS already or presented with a distinct subluxation. The patients reported high wearing comfort with no unpleasant odour emanating from the orthosis. The seven patients who had initially presented with PS reported a relevant reduction of shoulder pain. However, this feedback was not consistent with the rater's findings. In three of the five patients who were included in the trial due to a diagnosed subluxation, the gap closed completely after four weeks. The remaining two patients reported a gap reduction. None of these patients developed PS during the intervention period. In conclusion, the orthosis is considered an interesting option for the prevention or treatment of PS. Further studies are required.

**Schlüsselwörter:** shoulder luxation, orthosis, stroke, hemiparesis

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## Introduction

Incidence rates of the painful shoulder (PS) in early rehabilitation after stroke are reported to range from 15 to 40% [13]. The painful shoulder is associated with an unfavourable, protracted rehabilitation process. In conjunction with a swollen hand it is referred to as shoulder-hand syndrome [8].

Several contributing factors are discussed in aetiopathogenesis. PS is particularly associated with a subluxation of the head of the humerus, the paresis of the shoulder girdle that causes this subluxation, spasticity and reduced shoulder movement [15]. There is a proven distinction between flaccid and spastic types; with the former being more frequent during early rehabilitation. It is usually associated with severe weakness of the shoulder girdle, subluxation and consecutive soft tissue injuries [11, 14].

Soft tissue injuries result from the impaired shoulder kinematics seen in patients with hemiparesis. If a sound person lifts his/her arm, the scapula and the humeral head move in a synchronized way, i. e. the scapula slides upwards and forwards along the thorax resulting in the head of the humerus and the glenoid surface remaining congruent. In

a patient with hemiparesis, on the other hand, there is no scapular movement. This phenomenon is associated with the clinical manifestation of a scapula alata [2]. When the paretic arm is lifted above the patient's hand, the humeral head strikes against the acromion. This results in microtraumas that cause inflammation of the soft tissue and bursae. According to current knowledge, these symptoms are key factors that contribute to the pathogenesis of the flaccid PS type [3]. *P. Davies* clearly recognised this fact and taught shoulder mobilisation derived from these phenomena in her textbooks and seminars [4]. In the Klinik Berlin the incidence of painful shoulder declined dramatically after a lecture on the aetiology of shoulder pain held by *P. Davies* in the early 1990s.

Treatment thus far has been based on appropriate shoulder handling, administration of non-steroidal pain medication, physical therapy including ultrasound, occasionally electrical stimulation [12], and more recently, injection of botulinum toxin A into the subscapular and pectoral muscles [10, 17]. Although many orthoses are also available, fitting patients with them has not yet led to convincing outcomes. All of these orthoses attempt to reposition the head of the humerus

by traction and/or reduction of the arm's weight (1/12 of body weight) in the event of subluxation. Another aspect is to protect the paretic arm from abrupt movements. Depending on the specific model, arguments against the prescription of orthoses include the promotion of forearm flexion, complicated handling, inadequate fit, discomfort when worn directly on the skin, malodour and lack of evidence [1].

In this situation, the team headed by the author defined the objective of designing a new orthosis in cooperation with Otto Bock HealthCare, and tested it in an initial pilot phase in the early rehabilitation of patients with a severe flaccid paresis of the shoulder girdle. This pilot stage was intended to create the basis for a subsequent controlled study.

### The orthosis

The shoulder orthosis (Fig. 1) consists of a shoulder piece with a strap, which is placed underneath the contralateral axilla. The system includes a hook and loop closure to adjust the strap on the front and rear side. The second part of the orthosis is a forearm cuff, also fitted with hook and loop closures. The two pieces are connected by two adjustable straps. Their push buttons appear in different colours to prevent confusion.

The orthosis is manufactured in five different sizes, making a distinction between left and right shoulder. The orthosis weighs 300 grams and is made of a soft, smooth material. The inner fabric consists of neoprene; the outer lining is made of a balanced blend of Lycra and polyester. This material is used commercially in the textile industry to produce underwear. A 1 cm wide silicone strip has been incorporated in all parts that may slip when worn directly on the skin. The push buttons integrated in the soft hook and loop closures are padded on the inside to avoid pressure sores on the skin. The external edges of the orthosis are lined with a soft oblique strip and provide a high degree of elasticity. The required fit and the corresponding stability of the orthosis are ensured by a belt quilted on top. The orthosis can be washed using fine fabric detergents.

Fitting the shoulder orthosis is made easy by "donning instructions" that contain captioned photographs. The orthosis is worn directly on the skin. After selecting the correct size, the shoulder piece is positioned. It should smoothly cover shoulder joint. In the next step, the axilla strap is closed either on the front or rear side and re-adjusted if required, with the aim of achieving the best possible fit. The sweatband must be firmly fixed under the axilla.

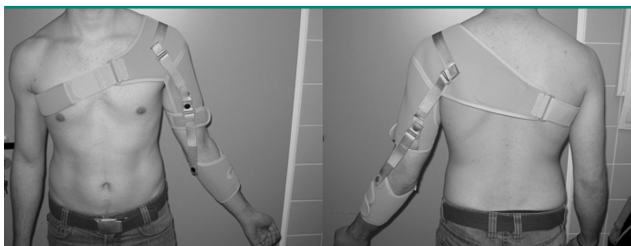


Fig. 1: Omo Neurexa shoulder orthosis

The forearm cuff is closed in such a way that the olecranon remains exposed in order not to compromise forearm circulation. In the next step, both pieces are connected and positioned in such way to ensure slight supination and extension of the forearm. Finally, the fit is optimised again if required while the patient is standing. The orthosis will not be used at night.

### Indication

To date, early-rehabilitation patients with hemiparesis and a severely affected arm have been selected. Patients were fitted with an orthosis if a significant subluxation was diagnosed or if they reported shoulder pain themselves or if the attending therapist determined the indication. All patients were able to walk, at least with aids, and underwent gait training for a minimum of one unit per workday. Patients confined to bed were not fitted with an orthosis. The patients' sensitivity was not compromised to a degree that they would not notice any pressure or abrasion sores. The patients were also able to take part in a brief interview to report on their condition.

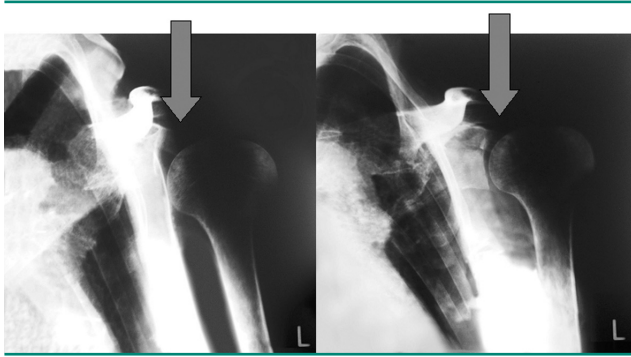
### Clinical experience

To date, twelve patients have used the orthosis over a four-week period. One patient discontinued its use prematurely due to lack of effectiveness. None of the highly paretic patients was able to don the orthosis without help. This task was always carried out by nursing staff. Re-adjustment was required two or three times per day, mainly after treatment. For the treatment sessions, only the forearm cuff needed to be removed in order to ensure full shoulder mobility.

Almost all patients perceived the direct contact between the material and the skin as comfortable. Unpleasant odour caused by perspiration was considered minimal. All but one patient who had previously presented with PS reported a relevant pain reduction ( $n=7$ ). These six patients were also encouraged to continue to use the orthosis. Out of the remaining five patients who were prescribed the orthosis only because of the subluxation to prevent pain, four patients did not develop any pain during the intervention phase. The subluxation gap closed completely in three patients. It proved difficult to develop an appropriate methodology to assess pain. A visual analogue scale and questionnaire were used, both of which were completed by the patient. In addition, a Fugl-Meyer subscore to assess pain (0.24) was performed by an investigator. The results were inconsistent – the above statement regarding pain reduction refers to the questionnaire data. Pain medication remained at an almost constant level in all patients.

The patients also reported in this questionnaire that they were able to better concentrate on gait rehabilitation due to the protection of the paretic arm.

The exemplary shoulder x-ray of a 45-year-old patient with left side hemiparesis, taken while standing with and without the orthosis, demonstrated a clear reduction of shoulder subluxation with the orthosis fitted (Fig. 2).



**Abb. 2:** X-rays of a subluxated shoulder without (left) and with shoulder orthosis (right). Note the large gap between shoulder joint and humeral head on the left image and the improved position of the humeral head when the shoulder orthosis is worn (right).

No pressure sores, abrasion points or other side effects occurred. In particular, we did not observe any relevant increase in upper limb spasticity, shoulder stiffening, excessive swelling of the hand, skin reddening or allergies.

## Discussion

The new orthosis appears to achieve its development objectives: handling in everyday clinical practice, fit and wearing comfort were considered good. The orthosis worn directly on the skin caused only minimal malodour, the head of the humerus was centred, and most patients included in the pilot study reported pain reduction or prevention. These outcomes justify further investigations.

Training and education of the team of therapists, in particular the nursing staff, was indispensable in order to ensure the intended function of the orthosis. In the early phase of the study, loose fit, incorrectly fastened straps and wearing the orthosis over clothing were the most frequent shortcomings recorded. Moreover, it was necessary to re-adjust the orthosis several times during the day, especially after physiotherapy.

A potential alternative to the orthosis is the use of tapes, which also aims at correcting the position of the humeral head and protecting the shoulder joint. The work group of *Herrmann et al.* in Seesen/Germany repeatedly reported positive outcomes in the treatment of shoulder pain in patients with hemiparesis [7]. Two controlled studies demonstrated conflicting results [5, 6]. In the positive study conducted by *Griffin and Bernhardt* [5] taping was used for prevention, i. e. the authors had treated so-called patients “at-risk” for developing shoulder subluxation even before any pain occurred. However, the drawbacks of the taping method include an even higher amount of training and education to be provided to therapists, the fact that the patients may not take a shower, and the frequent occurrence of skin reddening and allergic reactions to the material. As both methods apply similar principles to the treatment of shoulder pain, a positive response to short-term taping could make it easier to determine the indication for the orthosis as long-term solution.

To date, the new orthosis has not been compared with other models in shoulder pain treatment. *Zorowitz et al.* compared four frequently used designs, including a simple shoulder sling, a Bobath roll and a model comparable to the new orthosis consisting of a shoulder and a forearm piece [19]. The primary dependent variable was the vertical and horizontal correction of the position of the humeral head in a comparison of both the hemiparetic and sound sides. On the group level none of the orthoses was clearly superior, but each of the four options was considered most favourable for single individual patients. The authors concluded that hospitals should have various orthoses available to ensure customised patient fitting. It should be noted, however, that the correction of the humeral head position, the reduction of shoulder pain desired by the patients and the improvement of rehabilitation progress do not necessarily correspond to each other.

In their Cochrane review, *Ada* and co-workers concluded that according to the available data none of the orthoses studied could prevent subluxation, relieve pain and improve function [1]. The only hint recorded was that the onset of shoulder pain could be delayed. Here the new orthosis will have to prove its effectiveness. On the other hand it is obvious, however, that an orthosis is only one of the elements of proper shoulder management in patients with hemiparesis as it will not be able to prevent inappropriate shoulder handling [4]. Moreover, the therapeutic benefit of successful motor rehabilitation of the severely affected arm should not be underestimated [9] because the reduction in subluxation achieved over a six-month period after stroke is closely correlated with an improvement of the motor function of the upper limb [19].

The article published by *Yavuzer et al.* [16] includes an interesting perspective regarding the positive effect of an orthosis on gait rehabilitation reported by patients. The vast majority of patients stated that they were able to walk more safely when wearing a triangular shoulder orthosis, which was confirmed in gait analysis. The arm was stabilised close to the body, and the patients were able to focus fully on walking. Only very few patients were able to swing the arm reciprocally without aids. Nor did they achieve the walking speeds required for this movement. From a clinical perspective, a justified counter-argument is that a simple shoulder sling, as used in the study conducted by *Yavuzer et al.*, promotes the flexion pattern of the upper limb [17]. For this reason, the newly developed orthosis should not only stabilise the arm in a position close to the body but also provide extension and discrete supination of the elbow joint consistent with common therapy objectives.

In summary, the newly developed shoulder orthosis is considered an interesting element in the treatment of shoulder pain in patients with severe paresis during early rehabilitation. The requirements in comparison to a conventional shoulder sling were good fit, high wearing comfort, minimal unpleasant odour and improved extension and supination of the elbow joint. Further studies are justified.

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## Competing interests:

Otto Bock HealthCare and the laboratory of the author SH jointly developed the orthosis described in this article. SH acts as a consultant to Otto Bock HealthCare.

## Correspondence to:

Cordula Werner  
Klinik Berlin  
Kladower Damm 223  
14089 Berlin, Germany  
Email: cowerner@zedat.fu-berlin.de

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