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This article describes first clinical and gait analysis data on the orthosis OmoNeurexa, a new shoulder orthosis to prevent and treat a painful shoulder (PS) after stroke. A shoulder brace of soft material connects to a forearm cuff to promote elbow extension and supination. Out of 13 subjects, ten patients used the device continously for four weeks and three put the orthosis off within three days (too tight, no effect anticipated, fear of flexor spasticity). The comfort was good, transpiration minimal, and seven patients reported a beneficial effect of the orthosis on their activities, e.g. they felt more secure during transfer tasks and mobility. Five patients reported a relevant pain reduction. Gait analysis revealed a more dynamic gait pattern reflected by a significant reduction of the relative double stance phase. Furthermore the paretic quadriceps muscle was facilitated during the initial stance phase in selected patients. The therapists reported that they could intensify their functional therapy approach in seven subjects. The shoulder subluxation decreased, spasticity of the initially plegic patients only slightly increased, and the shoulder range of motion did not change. The orthosis is an interesting component in the prevention and treatment of PS after stroke, controlled trials are justified.

Introduction

Stroke is the most frequent cause of permanent impairment in the industrialized world. In Germany, the annual incidence of stroke is approx. 180 patients per 100,000 people. A painful shoulder (PS) occurs in about 15 to 40 percent of patients in early rehabilitation [8]. It is associated with an unfavorable and longer period of rehabilitation.

Several factors are discussed in the etiopathogenesis. For example, PS is correlated in particular with subluxation of the humeral head, the underlying causal paresis of the shoulder region, spasticity, and limited shoulder movement [10]. The distinction between the flaccid and spastic form has proven helpful; the former is more frequent in early rehabilitation and is generally associated with extreme weakness of the shoulder girdle, subluxation, and resulting injuries to the soft tissues [6, 9]. These injuries occur in particular when the paretic arm is lifted without protection; the lack of movement of the shoulder blade causes the humeral head to strike the acromion. This results in microtraumas, inflammation of soft tissues, and bursitis and by today's understanding is a major factor in the pathogenesis of the flaccid form of PS [1].

Correct shoulder handling, administration of non-steroidal pain medication, physical therapy including ultrasound, less frequently electrostimulation [7], and in recent times injections of botulinum toxin A into the subscapularis and pectoral muscles [5, 12] have proven to be effective therapy for PS. Although many shoulder orthoses are available, they have not been widely used. All orthoses share a common goal of recentering the humeral head through traction and/or reducing the weight of the arm (one twelfth of body weight) in the event of subluxation. Another aspect is protecting the paretic arm from abrupt movements during walking. Arguments against prescribing a shoulder orthosis are that it promotes a flexed position of the forearm, risks limiting shoulder movement, is impractical to use, does not fit well, is uncomfortable to wear on bare skin, and may cause an unpleasant odor.

In this situation, the author's team collaborated with Otto Bock with the intent to design a new orthosis and test it in an initial pilot study in early rehabilitation of patients with severe flaccid paresis of the shoulder girdle. An instrumented gait analysis was conducted with and without the orthosis to examine the effect the orthosis had on gait pattern and muscle activation while walking.

The Orthosis

The shoulder orthosis weighing approx. 300 g comes in five sizes

and for either shoulder (Fig. 1) and consists of a shoulder section with a belt that fits under the contralateral armpit. The belt can be adjusted in the front and back with Velcro fasteners. The second part of the orthosis is a forearm cuff that also has Velcro fasteners. The two adjustable straps connecting the two parts have different colored snaps to avoid mix-ups.

The orthosis is made of a soft, supple material. All parts that could slip on bare skin are lined with a one-cm strip of silicone. The snaps embedded in the soft Velcro fasteners are padded on the body side to prevent pressure points on bare skin. The outer edges of the orthosis are trimmed with soft bias tape and are very elastic. A webbing strap stitched onto the orthosis provides the desired fit and necessary stability.

Nine photographs with written instructions show how the shoulder orthosis is put on. The orthosis is worn on bare skin. After the proper size is selected (based on the circumference of the thorax under the armpits) the shoulder part is put on so that it lies smoothly over the shoulder joint. Next the underarm strap is fastened either from the front or the back and adjusted if necessary to ensure a proper fit. The perspiration protection must fit under the armpit. The forearm cuff is closed in such a manner that the olecranon is not covered and circulation is not restricted. In the next step, the two parts are connected so that the forearm is slightly supinated and extended. Finally, the fit is optimized once again in a standing position. The orthosis is taken off at night.

Patients of the Pilot Study

Thirteen hemiparetic patients participated in the pilot study (ten men, three women, mean age 61.7 ± twelve years, six patients with hemiparesis on the right and seven on the left, mean interval since stroke before the orthosis was prescribed was 8.3 ± 3.8 weeks, height 173.5 ± 11.4 cm, and weight 75.8 7 ± 9.1 kg), who fulfilled the following criteria:

- First-time stroke with treatment in inpatient early rehabilitation,
- Non-functioning paretic upper extremity,
- Mobilized in wheelchair, stance and gait already practiced in therapy,
- Able to give verbal or written information in a short interview,
- No major impairment of sensory perception in the affected upper extremity,
- Consent given to participation in the study.

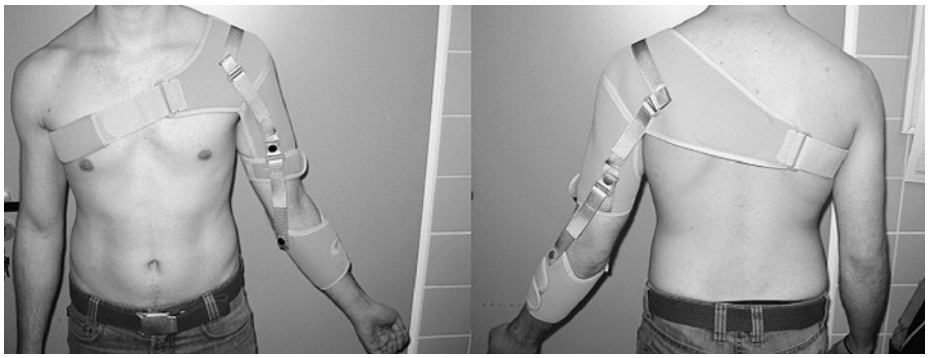

Fig. 1 *OmoNeurexa shoulder orthosis*

The patient was fitted with an orthosis if

- He or she complained of shoulder pain on his own,
- The team reported on shoulder pain,
- There were clear clinical signs of subluxation (more than one finger width).

At the time they were included in the study, ten of the thirteen patients complained spontaneously of shoulder pain and the team of physicians and therapists described three cases of acute shoulder pain.

Dependent Variables of the Pilot Study

An experienced examiner determined the size of the shoulder luxation, the passive range of motion using the Fugl-Meyer Score (Fugl Meyer 1975), and the proximal strength and tone of the upper extremity. With the help of the MRC strength scores (zero to five: 0 = plegia, 5 = full strength), shoulder elevation and abduction and elbow flexion and extension were measured and resistance to passive elbow flexion and extension was tested using a modified Ashworth score (zero to five, 0 = no increase in muscle tone, 5 = rigid). The examinations were made before daily use of the orthosis and four weeks afterwards. The patients assessed the effect of the orthosis in a "patient-reported outcome" with respect to

- Shoulder pain (impairment dimension)
- Use of the arm for daily activities, participation in physical therapy, competence in activities of daily life, and mobility in the clinic (activities dimension)
- Mood and social contacts (participation dimension)

The patient could respond to each question with "clearly worse" (-2), "worse" (-1), "unchanged" (0), "somewhat better" (1), or "clearly better" (2).

Patients and therapists were also requested to assess the wearing comfort and potential unpleasant odor. An X-ray of the shoulder with and without the orthosis was made for one patient.

Results of the Pilot Study

Three out of thirteen patients discontinued use of the orthosis prematurely. The reasons given were unfulfilled expectations (one patient), feeling of constriction (one patient), and the fear, conveyed by the therapist, of developing flexor spasticity. All three patients discontinued use of the orthosis within the first three days.

The other ten patients all assessed wearing comfort as good with minimal odor build-up. The demonstration X-ray images showed that subluxation was reduced; in seven patients, the joint space

was reduced by an average of 2.5 cm during the four-week intervention (Fig. 2). Passive shoulder movement deteriorated for only one patient and improved for three patients. The MRC strength grades of the shoulder-elbow musculature showed increased shoulder strength for three out of ten patients (by one point in two cases and two points in one case) and increased elbow muscle strength for four of ten patients. Four patients developed flexor spasticity in the elbow with the Ashworth score increased by one (two cases), two, and three points respectively; for each of three patients it decreased by one point.

The patients assessed the orthosis as follows:

- Five patients each described shoulder pain as reduced or unchanged,
- Use of the arm in everyday activities: better for seven, unchanged for three,
- Participation in physical therapy: better for six, unchanged for four,
- Mobility in everyday activities: better for six, unchanged for four,
- Performing activities of daily life: better for five, unchanged for five,
- Participation and mood: better for three, unchanged for seven.

Instrumented Gait Analysis

In addition, a gait analysis [3] was performed for all ten patients, with and without the orthosis. The Infotronic system was used. It

consists of overshoes in the proper sizes; by means of contact switches embedded in the soles, cycle parameters, stance, swing, and double stance periods are measured separately for each side. The data are saved in a portable data logger. The ten-meter test was used to determine the basal cycle parameters, namely speed, cadence, and stride length. The dynamic electromyogram of selected leg muscles on the paretic side (tibialis anterior, gastrocnemius, vastus medialis, vastus lateralis, gluteus medius, and erector spinae muscles) was recorded from superficial electrodes applied to the body of the muscle following proper cleansing of the skin, pre-amplified, and then also saved in the data logger. The patient walked with and without the orthosis for 30 seconds each, and then the data were transmitted to a computer for further analysis. The cycle parameters for each side were then standardized to the gait cycle (100 percent), symmetry quotients were calculated for the stance and swing phase periods using the formula: stance (swing) right/ stance (swing) left times 100 if the right was less than the left side, otherwise vice versa. The EMG data were rectified, standardized to the gait cycle and filtered. An experienced examiner analyzed the envelope curves determined in this manner quantitatively with respect to amplitude and qualitatively with respect to the pattern.

Results of the Gait Analysis

There was no difference in the basal cycle parameters between the two conditions; there was a tendency toward a greater stride length and lower cadence with the orthosis. With the orthosis, the relative double stance phase was significantly shorter (-17 percent on average, $p<0.05$), while the relative stance and swing periods of both sides as well as the symmetry quotients were not significantly different. The analysis of the dynamic EMGs did not yield a uniform result; in four of the ten patients, there was more pronounced activity of the quadriceps femoris muscle, simultaneously, activity in the stance phase began earlier (Fig. 3).

Discussion

The orthosis proved to be practicable in the clinical setting – fit and wearing comfort were good and there was minimal unpleasant odor from the orthosis worn on the bare skin. No side effects such as chafing or allergies occurred.

The clinical routine quickly showed that ongoing training of the therapy team, especially of nursing personnel, was indispensable for ensuring the desired functionality of the orthosis.

Initially, the most frequent mistakes were loose fit, incorrectly fastened straps, and wearing the orthosis over clothing. It proved to be practicable for therapy that the separate forearm cuff could be taken off quickly, allowing unrestricted mobilization of the upper extremity.

Three patients had discontinued use of the orthosis prematurely – one patient due to a feeling of constriction, one patient did not consider it to be useful after only two days, and one patient, after discussing with his therapist, feared developing flexor spasticity in his elbow.

However, the studies did not justify the fear of developing flexor spasticity; passive resistance against extension of the elbow increased slightly in four patients and was even reduced in three patients.

This result must be viewed in the context that acute patients were initially flaccid and thus the development of varying degrees of flexor spasticity would not be unusual.

The specifications of this orthosis recommend extension and supination of the elbow to prevent the

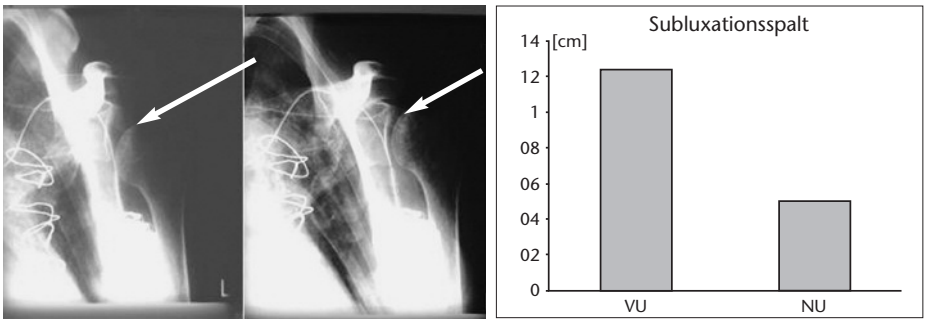

Fig. 2 *X-ray images of a subluxated shoulder; a) without the shoulder orthosis (left) and b) with shoulder orthosis (center). Note the large gap between the socket and the humeral head in the left image and the improved position of the humeral head with the shoulder orthosis (center). The diagram shows the average size of the subluxation gap at the beginning and end of the study in centimeters.*

development of flexor spasticity.

Aside from one patient, there was no indication of limitation of passive shoulder movement. On the contrary, it was even improved in three patients, certainly the result of multi-professional, inpatient rehabilitation.

The X-ray confirmed that the orthosis when worn properly partially repositioned the humeral head, as previously described by Zorowitz et al. for four different models (including Bobath roll, mitra, and a comparable orthosis) [13].

The joint space was narrowed in seven of ten patients during the four-week intervention. Of course, the aim of therapy was to strengthen the shoulder girdle, but the MRC strength scores documented the known moderate regression of strength in the paretic upper extremity when severe paresis has occurred [2, 4]. Only three patients had minimal improvement of their voluntary shoulder strength, so that it can be assumed that the orthosis contributed to narrowing the joint space.

One important aim of the development of the shoulder orthosis was to reduce shoulder pain, but this was achieved for only half of the patients. However, subjective perception of pain is affected by many factors.

For some patients, fitting was carried out in the phase of uncritical euphoria (everything will be just fine) that is known to occur after brain damage. But the assessment was made four weeks later in a phase in which the patient becomes increasingly aware of the risk of permanent impairment, leading to negative views. This is most likely the reason that a Cochrane meta-analysis also reached the conclusion that no shoulder orthosis was completely convincing with respect to reduction of shoulder pain in controlled studies [7].

On the one hand, this result is an argument against the use of shoulder orthoses only for treating shoulder pain in stroke patients. On the other hand it could be seen as proof that determining pain in this patient group is a difficult task, dependent on many variables.

The patients gave a more positive assessment of the effect of the orthosis on the level of activity. When asked, the patients said that the affected arm was secured and held close to the body by the orthosis, making it lighter so that they were better able to concentrate on gait rehabilitation. They said that made walking safer, as already shown by Yavuzer and Ergin for a simple mitra-shaped device [11]. The existing results of the gait analysis showed that patients had a more dynamic gait with the orthosis. The relative length of the double-stance period was significantly reduced and the patients' strides also tended to become longer, both of which can be assessed as signs of greater gait security.

At the same time, some patients were apparently able to put more weight on the paretic leg. Unfortunately, ground reaction forces were not measured, but indirect indications were that there was earlier and greater activation of the quadriceps muscle on the paretic side in the initial stance phase. The muscle secures weight transfer in this phase; the results are consistent with the facilitation of the paretic quadriceps muscle by the orthosis.

In summary, the newly developed shoulder orthosis is an interesting component in the prevention and therapy of painful shoulder in severely paretic patients in multi-professional early rehabilitation.

Provided that the nursing staff is given extensive training, good fit, a high level of wearing comfort, and minimal amount of unpleasant odor can be ensured. The open study indicates that the orthosis reduces subluxation and promotes restoration of activity. The results of the gait analysis are consistent with a more secure and dynamic gait; there was also facilitation of the knee extensor on the affected side in some selected patients. A controlled study is indicated.

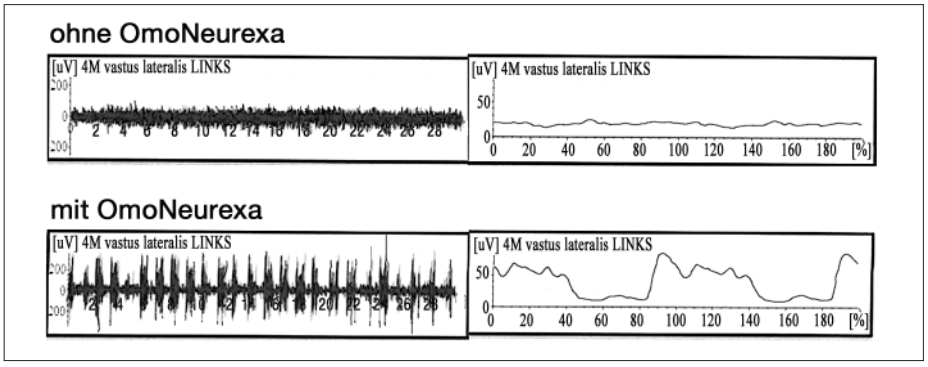

Fig. 3 *The EMG standardized to the gait cycle (left, raw EMG; right, envelope curve) of the paretic vastus lateralis muscle of a left hemiplegic patient without and with the orthosis. Note the increased activity and the earlier onset of the knee extensor in the stance phase (zero to 60 percent of the gait cycle) on the affected side. The finding is consistent with facilitation of the muscle.*

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