



A newly designed shoulder orthosis for patients with glenohumeral subluxation: a clinical evaluation study

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Abstract

Background: Shoulder complaints from glenohumeral subluxation are a common problem and limit patients during daily activities.

Objective: To assess the clinical pros and cons and usability of a newly developed shoulder orthosis (Roessingh Omo Support [ROS]) in patients with chronic shoulder complaints.

Study design: Retrospective cross-sectional study.

Methods: All patients older than 18 years who received the ROS were invited. Medical information was collected from medical records. Two questionnaires were sent to the patient: The "Shoulder Rating Questionnaire" (SRQ, max 100 points) for evaluation before and during use and a custom orthosis usability questionnaire.

Results: In total, 28 patients (34 orthoses) participated in the study. Neuralgic amyotrophy was the most common diagnosis (64.3%). The SRQ showed a significant positive change of 8.9 points (from 35.0 [SD 12.6] to 43.9 [SD 14.3]). The most described goal was pain reduction (76.5%). 47.1% of the patients achieved their goal(s), and 71.4% were still using the orthosis. The mean satisfaction rate was 7.1 (SD 1.4).

Conclusion: The use of the ROS shows a significant functional improvement (SRQ), a decrease of pain, and a high degree of satisfaction, although the individual experiences of the patients are highly variable. Some modifications to the design to improve comfort may be needed.

Keywords

shoulder, orthosis, glenohumeral subluxation, shoulder pain, neuralgic amyotrophy

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Background

The shoulder is a complex joint in which pain and functional problems can arise because of various causes. Pain and limitations in range of motion and loss of strength can lead to serious limitations in activities of daily living.^{1,2} In the general population, the prevalence of shoulder complaints is high: the point prevalence ranges from 6.9% to 26%.³ One of the causes of these shoulder complaints can be glenohumeral subluxation. Glenohumeral subluxation is usually caused by muscle imbalance.⁴ This occurs in neuralgic amyotrophy, plexus injury, and muscular injuries (rotator cuff), after a stroke or different muscular diseases. Neuralgic amyotrophy (Parsonage Turner syndrome) is a disorder of the plexus brachialis nerve and is characterized by attacks of neuropathic pain and subsequent paresis or paralysis, or sensory deficits in the affected upper extremity.⁵

Because of muscle dysfunction, a subluxation of the glenohumeral joint can occur. Recovery can take months or even years, and many patients do not fully recover.⁵ Shoulder pain after subluxation is caused by stretching of the joint capsule and tendons, microdamage of the glenohumeral joint, or overloading of the residual muscles of the rotator cuff.^{4,6,7} This expression of shoulder subluxation is regardless of the etiology.

Frequently prescribed treatments include physical therapy, strapping, and orthoses (also referred to as braces or slings). Strapping is a technique in which tape applied to the skin is used to lift the arm. Strapping is often used to reduce glenohumeral subluxation and pain. A systematic review by Appel et al concluded that the efficacy of strapping is unclear, whereas a systematic review of Arya stated that strapping is not an effective method.^{8,9} There are some disadvantages associated with this method, such as the risk of skin reaction and related irritation, which limits the applicability of strapping for a long period.⁴ Shoulder orthoses intend to support the weight of the arm, reposition the head of the humerus, and prevent uncontrolled movement of the arm.^{7,10} Most commercially available orthoses are only available in specific sizes. Below, some advantages and disadvantages of frequently used shoulder orthoses are described.

The simplest orthoses are slings, which consist of an arm tray and a strap wrapped around the neck. Slings are easy to use, but several studies show variable results and disadvantages. For example, all the weight of the arm is carried by the strap that is wrapped around the neck, and the sling immobilizes the shoulder.

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In addition, the sling keeps the elbow in a flexed position, which may increase the muscle tone of the flexors in hemiplegia and obstruct the arm swing while walking.^{4,11} Another study shows that slings cannot neutralize the glenohumeral subluxation.⁶

Other commonly used orthoses in the Netherlands for stabilizing the shoulder are the Wilmer orthosis (Ambroise, the Netherlands) and OmoTrain (Bauerfeind, Germany). The Wilmer orthosis uses the weight of the forearm as a counterweight to push the head of the humerus upward in the direction of the glenoid.¹² A drawback is that the arm cannot be used during daily activities because of its design that keeps the elbow in a flexed position. The manufacturers of the OmoTrain claim a stabilizing effect.¹³ However, the orthosis does not reposition the humeral head into the glenoid. The Omo Neurexa Plus (Ottobock, Germany) can stabilize and reposition the humeral head by tensioning straps between a shoulder cuff and forearm cuff, but encompasses the elbow joint, which may hamper the user during activities of daily living (ADL).

Because of the disadvantages of these orthoses, a new type of shoulder orthosis was developed on the basis of clinical experience: the Roessingh OMO Support (ROS). Since the beginning of 2016, this orthosis has only been prescribed to patients who visited the neuromuscular outpatient clinic of Roessingh Centre for Rehabilitation. The goal of this custom-fitted device is to approximate the humeral head to the glenoid, thereby decreasing pain complaints and improving the function of the arm. The magnitude of the approximation force can easily be adjusted by the patient depending on the type of activity he or she performs.

The aims of this study were (1) to present the design of the new shoulder orthosis and (2) to evaluate the clinical experience of the users who used the new shoulder orthosis according to the ICF model (International Classification of Functioning, Disability and Health) by looking at aspects such as pain, daily activities, work, and usability.

Methods

ROS

The ROS (Figure 1) consists of several components: a shoulder pad, an upper arm sleeve, an adjustable strap around the contralateral

shoulder, and two adjustable straps with one end connected to the upper arm sleeve with Velcro and the other end to a BOA closure system, which is secured to the shoulder pad with Velcro. The amount of supportive force can be regulated by adjusting the length of the straps with the BOA closure. Both the shoulder pad and the upper arm sleeve are made from 6-mm-thick liner material composed of a thermoplastic elastomer gel with mineral oils (WillowWood). Microhook and loop fabric are glued to the back of the sleeve and shoulder pad. The mineral oils of the liner material keep the skin smooth. The high friction coefficient between the arm sleeve and skin gives the sleeve a good grip on the upper arm without slipping. The shoulder pad maintains its position because of this high friction. The friction forces applied to the upper arm are evenly distributed to the skin because of the large surface area of the upper arm sleeve (approximately 10 cm height times the circumference of the upper arm), which limits skin irritation. Another advantage of using a high-friction coefficient material is that the arm sleeve does not have to apply much radial pressure to the skin, which may constrict blood flow. The lifetime of the orthosis is approximately 2 years. All parts can be replaced or adjusted if necessary. Because of the materials used, a high level of comfort is expected.

Subjects

All adult patients with shoulder complaints who received the ROS between January 2016 and December 2018 in Roessingh Centre for Rehabilitation in the Netherlands were invited to participate in the study.

Measuring instruments

Patient characteristics were obtained from the medical records in the rehabilitation center. These data were collected retrospectively by an independent researcher until January 2019. The collected data (if available) concerned sex, age, diagnosis, (dominant) side, patient medical history, goals of the patient, previous treatment(s), time of delivery, and experiences with previous treatment(s).

Two types of questionnaires were sent to the participants by the researchers in December 2018. One questionnaire was the validated Dutch version of the “Shoulder Rating Questionnaire” (SRQ).^{14,15} This questionnaire consists of 21 questions that are

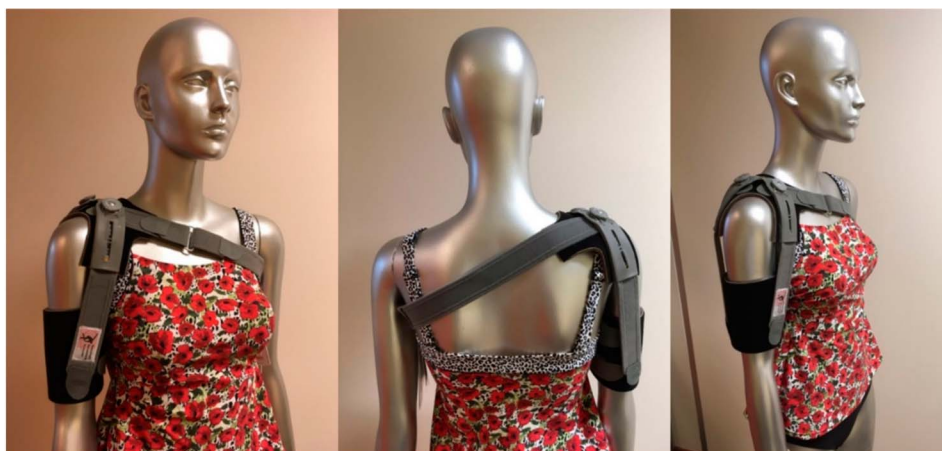


Figure 1. Front, back, and side views of the shoulder orthosis.

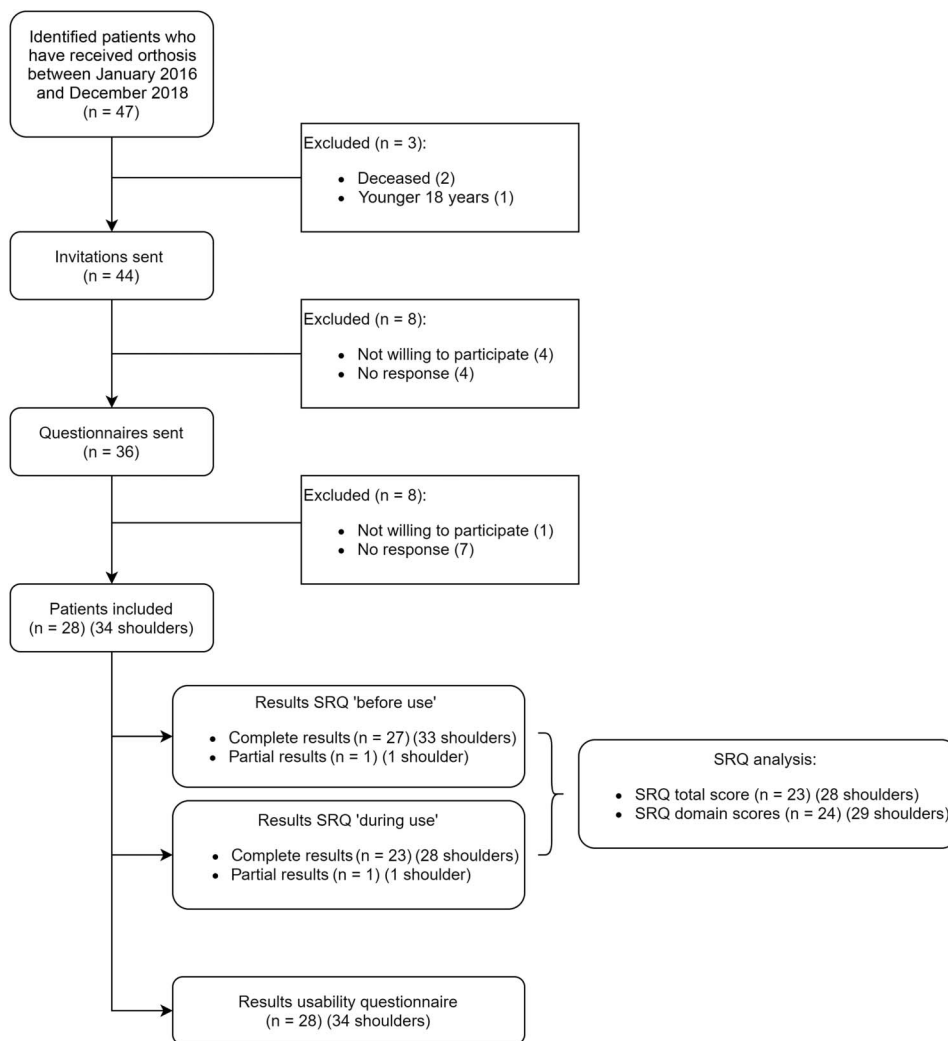


Figure 2. Flow chart patient selection.

related to pain, daily activities, leisure or sport, work, and satisfaction. Nineteen questions are multiple-choice questions, and for two questions, a grade had to be given. Each domain has a different weighting factor. A total score could be calculated (range 17–100).¹⁶ The patients were asked to complete the SRQ twice for each affected shoulder: once for the period before the orthosis prescription and once for the period during orthosis use. To get more insight into the goals, time of delivery, satisfaction (range 0–10), and pros and cons, a custom questionnaire was developed consisting of open-ended and multiple-choice questions (see Supplemental Digital Content 1, <http://links.lww.com/POI/A44>).

The research protocol has been assessed by the local Ethics Committee of Medisch Spectrum Twente in the Netherlands, and they considered the study exempt. All patients provided written informed consent.

Statistics

A descriptive analysis has been performed. For the total score of the SRQ and the satisfaction of the custom usability questionnaire with the orthosis, mean scores could be calculated. A paired *t*-test

was used to detect a significant change ($p < 0.05$) between the total score of the SRQ before and during use. A 95% confidence interval of the difference was calculated.

Results

Subjects

Between January 2016 and December 2018, 55 orthoses were prescribed to 47 patients. In total, 28 patients were enrolled in the study, of which six patients had an orthosis on both sides (also see the flow chart in Figure 2). The mean age of the patients is 50.0 years (range 21–73 years). The most common diagnosis was neuralgic amyotrophy (64.3%). The dominant side was mainly affected (67.9%). The treatments received before inclusion were diverse and included strapping, other orthoses (mostly Wilmer or OmoTrain), dry needling, transcutaneous electrical nerve stimulation (TENS), physical therapy, and occupational therapy. Patients who participated in the study had the orthosis on average of 10.8 months (range 1–28 months) in possession.

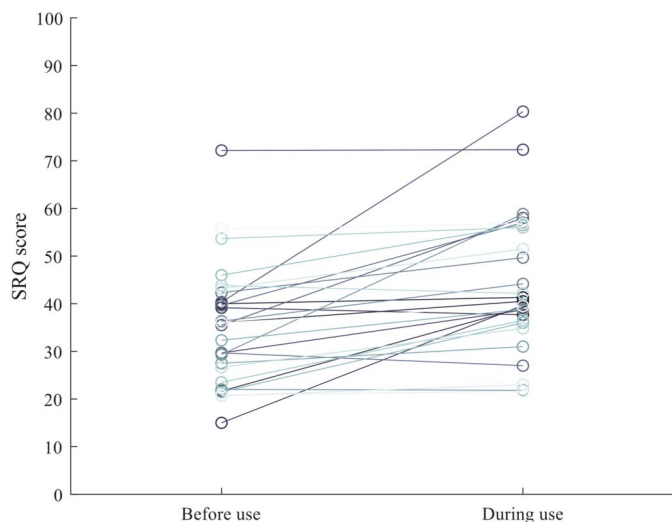


Figure 3. Change in SRQ score. Each line indicates the change in SRQ score of one patient.

Questionnaires

SRQ

The SRQ scores were calculated for 23 participants (28 shoulders), from which the complete results of both questionnaires (before and during use) were available. The SRQ score improved for 24 shoulders (85.7%), whereas for the other four shoulders (14.3%), a minor decrease was reported. The SRQ scores before and during use are plotted in Figure 3 for each shoulder. A paired *t*-test was performed. The mean score before use (*t*₁) was 35.0 ± 12.6 (range 15–72.2) points and during use (*t*₂) 43.9 ± 14.3 (range 21.7–80.3) points. This improvement of 8.9 points is statistically significant (*p* < 0.001). The 95% confidence interval of the difference is 4.9–13.0 points.

Besides the total SRQ scores, the SRQ domain scores are also investigated. Table 2 lists the number of participants with major improvements (++) , minor improvement (+) , no improvement (0) , minor decrease (-) , or major decrease (--) for each domain of the SRQ. Improvements are calculated by comparing the difference between average domain scores before and during orthosis usage. For the global assessment domain, a change ≥ 3 points is defined as a major improvement and an improvement >0 and <3 is defined as a minor improvement. For the domain pain, ADL, sports, and work, a major improvement is defined as a change in the average domain score ≥ 1.5 points and a minor improvement is defined as a change in the average domain score >0 and <1.5 points. In the domain “work,” subscores could only be calculated for seven patients, because the other 17 participants did not work. Thirteen patients (54.2%) indicated that they did not work because of their shoulder complaints. For one patient, the orthosis allowed him to resume his job. Three patients (12.5%) performed paid work. Four patients (16.7%) were retired.

Custom orthosis usability questionnaire

The custom usability questionnaire was completed by 28 patients (34 shoulders). Twenty patients are still using the orthosis (71.4%). Four of them have an orthosis on both sides. Eight patients (10 shoulders) no longer used the orthosis

(28.6%). The main reason for discontinuing the orthosis was discomfort. In three cases (10.7%), the orthosis was no longer needed, through either shoulder surgery or sufficient recovery of the shoulder. The duration of use ranged from a few hours per week to daily usage. An average wear time of 6.3 h/d ± 3.7 was reported by patients who still used the device.

Pain reduction is the most frequently mentioned goal to start using the orthosis. This goal was mentioned for 26 shoulders (76.4%). Thereafter, more support (19 shoulders [55.9%]), a subjective reduction of arm weight (15 shoulders [44.1%]), and more stability (11 shoulders [31.0%]) were mentioned. For 16 shoulders (47.6%), patients indicated that all their goal(s) had been achieved. However, for eight shoulders, none of the goals were reached, for seven shoulders, the goals were reached only partially, and for three shoulders, it is unknown.

The highest benefit was experienced during walking- and standing-related activities. Nineteen patients (67.9%) had less shoulder pain, seven patients (25.0%) were able to do activities they could not do before, and the arms of three patients (10.7%) felt lighter. Two patients (7.1%) did not report any benefits at all. Discomfort was mentioned by 16 patients (57.1%) as a disadvantage. Twelve patients (42.9%) reported the feeling of warmth and perspiration as another disadvantage. Patients also reported arm obstruction during an activity (seven patients [25.0%]) and wear of the orthosis (one patient [3.6%]). Many patients had trouble in independently donning the orthosis. In addition, cosmetics are mentioned by two patients (7.2%) as a disadvantage. One patient (3.6%) reported no disadvantages.

Patients were asked to give a grade for their satisfaction with the orthosis. The mean satisfaction was 7.1 ± 1.4 (range 4–10).

Table 1. Patient characteristics from medical records.	
	Total
Total	28
Men/women	8 (28.6%)/20 (71.4%)
Mean age (years)	50.0 (21–73)
Diagnosis	NA: 18 (64.3%) FSHD: 2 (7.1%) PSMA: 1 (3.6%) Distal arthrogryposis: 1 (3.6%) Mitochondrial myopathy: 1 (3.6%) Linear deep morphea with myositis: 1 (3.6%) Traumatic plexus brachialis injury: 2 (7.1%) Erbs palsy: 1 (3.6%) Chronic shoulder complaints: 1 (3.6%)
Affected side	Left: 6 (21.4%) Right: 16 (57.1%) Both: 6 (21.4%)
Dominant side affected	Yes: 19 (67.9%) No: 8 (28.6%) Unknown: 1 (3.6%)
<i>FSHD: facioscapulohumeral muscular dystrophy; NA: neuralgic amyotrophy; PSMA: progressive spinal muscular atrophy.</i>	

Table 2. The change in average domain score before and during use.

	++ (n)	+(n)	0 (n)	-(n)	--(n)
SRQ domains					
Global assessment (n = 28)	8 (28.6%)	12 (42.9%)	6 (21.4%)	2 (7.1%)	0 (0%)
Pain (n = 29)	3 (10.3%)	17 (58.6%)	6 (20.7%)	3 (10.3%)	0 (0%)
ADL (n = 29)	2 (6.9%)	6 (20.7%)	11 (37.9%)	10 (34.5%)	0 (0%)
Sports/recreational activities (n = 29)	1 (3.4%)	12 (41.4%)	12 (41.4%)	4 (13.8%)	0 (0%)
Work (n = 7)	1 (14.3%)	4 (57.1%)	2 (28.6%)	0 (0%)	0 (0%)

Number of patients are given with major improvements (++), minor improvements (+), no improvement (0), minor decrease in score (-), and major decrease in score (--).

Discussion

To our knowledge, this is one of the few studies that investigated the clinical aspects of a newly developed shoulder orthosis. Our results regarding shoulder pain reduction (67.9% of the patients experienced pain reduction) are in line with the results reported in previous studies (67%).⁷ However, the results regarding device comfort seem to be not in line with previous studies. Hesse et al reported that 80% of the patients rated the comfort with a grade >7 (on a scale from 0 to 10), whereas Hartwig et al reported that 75% of their patients experienced no to mild discomfort.^{10,17} A direct comparison between comfort ratings is not possible, because we did not ask the patients to grade the degree discomfort. However, the results suggest that patients in our study experienced more discomfort during orthosis usage. This may be (partially) caused by the design of our orthosis. The results of this study will therefore be used to improve the design, especially the aspects that could contribute to the comfort. Comfort may be significantly improved if a better fitting to the body can be achieved that reduces pressure points around the affected shoulder. In addition, different materials will be evaluated to reduce discomfort caused by perspiration and to reduce the wear of several components during use.

The reported improvement in shoulder function (represented by the change in SRQ score of 8.9 points across all subjects) is statistically significant. The minimal clinically important difference (MCID) is defined as the smallest changes in score that is associated with a clinically important change to the patient. Reported values for the MCID of the SRQ in patients with unspecified shoulder disorders range from 12 to 13 points, whereas for patients with shoulder instability, reported values for the MCID range from 4 to 5 points.¹⁸ Although there is a large variation in reported MCID values, we conclude that the improvements in SRQ score are not only statistically significant but also clinical significant.

Several methodological limitations can be mentioned related to this study. First, both SRQ questionnaires were completed at the same time. This might have led to less reliable results because the patients had to answer the questions for the situation before orthosis usage retrospectively. In addition, the duration of use was highly variable between patients, which might have affected the outcome of the questionnaires. It is unknown whether these aspects positively or negatively influenced the results. Therefore, it is recommended to set up a prospective study with measurements at fixed moments in time (e.g. immediately after delivery and after a few months). Second, the patients had to fill in the questionnaires independently without the researcher present. It is unknown

whether the patients correctly interpreted all questions and instructions. This study setup might have also affected the number of responses. From a large number of invited patients, no response was received. This might have led to a selection bias. Third, the orthosis was only prescribed to patients who visited the neuromuscular department of an outpatient clinic. As a result, no stroke patients were included, which is considered an important target population. Although a comparison between different target populations is possible because the expression of shoulder subluxation is regardless of the etiology, the inclusion of only patients with neuromuscular disorders is a limitation of the current work. In a future study, stroke patients will also be included. Possible differences to be expected when dealing with this population may be related to comfort (skin tolerance) or complications because of other impairments.

Conclusion

This retrospective cross-sectional study of the ROS in 28 patients with shoulder complaints showed a significant improvement in functioning (as indicated by the change in SRQ score) and a decrease of shoulder pain. Patients reported a high degree of satisfaction, although the individual experiences of the patients were highly variable. The design of the ROS may require some modifications to improve comfort.

Author contribution

The authors disclosed the following roles as contributors to this article: W.V. and C.H. contributed equally to this work.

Declaration of conflicting interest

The authors declared the following potential conflicts of interest for the research, authorship, and/or publication of this article: J.L.d.K. is employee of Roessingh Rehabilitation Technique, the manufacturer of the Roessingh Omo Support. The other authors have nothing to disclose.

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Supplemental material

Supplemental material is available via direct URL citations in the HTML and PDF versions of this article on the website (www.POIjournal.org).

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