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Evaluating the clinical effects of a dynamic shoulder orthosis

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Abstract

Background: Shoulder orthoses reduce the gravitational pull on the shoulder by providing an upward force to the arm, which can decrease shoulder pain caused by stress on the glenohumeral structures.

Objective: In this interventional study, the clinical effects of a recently developed dynamic shoulder orthosis were assessed in 10 patients with chronic shoulder pain. The shoulder orthosis provides an upward force to the arm with 2 elastic bands. These bands are arranged to statically balance the arm, such that the supportive force is always directed toward the glenohumeral joint and shoulder movements are not impeded.

Study design: Clinical effect study.

Methods: The study population was provided with a dynamic shoulder orthosis for 2 weeks. In the week before the orthosis fitting, the participants had no intervention. The primary outcome measures were the mean shoulder pain scores before and during the intervention, and the distance between the humeral head and the acromion without and with orthosis.

Results: Ultrasound evaluation showed that the shoulder orthosis resulted in a reduction of the distance between the acromion and humeral head at different levels of arm support. In addition, it was demonstrated that the mean shoulder pain scores (range 0–10) decreased from 3.6 to 3 (in rest) and from 5.3 to 4.2 (during activities) after 2 weeks of orthosis use. In general, patients were satisfied with the weight, safety, ease in adjusting, and effectiveness of the orthosis.

Conclusions: The results of this study show that the orthosis has the potential to reduce shoulder complaints in patients with chronic shoulder pain.

Keywords

shoulder, shoulder pain, orthosis, assistive device

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Introduction

The shoulder joint permits a large range of motion (RoM), at the expense of its stability. Decreased muscle tone or a lesion of the rotator cuff muscles may cause glenohumeral subluxation (GHS) which is defined as a, inferior, partial dislocation of the humeral head from the glenoid.[1] Reported incidences of GHS vary from 17% up to 67% in cerebrovascular accident.[2] Other causes of GHS include shoulder trauma and operative procedures,[3] neuromuscular disorders such as cerebral palsy and brachial plexus injury,[4] and brachial neuritis (also called neuralgic amyotrophy).[5]

The passive stabilizing structures such as the capsule and ligaments become more dominant because of the reduced tone in 1 or more shoulder muscles. A continuous, passive stretch of these structures due to the weight of the arm can provoke pain, even if no GHS is present.[6]

Patients suffering from chronic shoulder pain are frequently prescribed a shoulder orthosis to reduce the gravitational pull on the shoulder by providing an upward force to the arm.[7] Other treatments include physical therapy or strapping. Studies assessing the effects of shoulder orthoses on shoulder pain only show low to modest improvements in pain measures.[8-10] In addition, many available shoulder orthoses limit the remaining RoM of the arm to stabilize the glenohumeral joint.[11]

In previous research, a dynamic shoulder orthosis was developed to reduce the stress on the passive structures surrounding the glenohumeral joint by applying an upward force to the arm with 2 elastic bands that are attached between an upper arm cuff and a shoulder bracket.[12] The unique feature of this device is that the elastic bands statically balance the arm, such that the supportive force is always directed toward the center of rotation of the glenohumeral joint. Therefore, this force will not impede the remaining RoM of the arm because no additional moment around the shoulder joint in the sagittal plane is introduced. A prototype was designed and tested with 2 patients to subjectively assess the immediate effects of the orthosis on shoulder pain, glenohumeral stability, and the RoM. This pilot clinical evaluation showed promising results.

The aim of this interventional study was to assess the clinical benefit of the shoulder orthosis for patients with chronic shoulder pain after 2 weeks of use. In the week before the orthosis fitting, the participants had no intervention. The primary outcome measures were the mean shoulder pain scores before and during the intervention, and the distance between the humeral head and the

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acromion (AC) without and with orthosis. The secondary outcome measures included the pain-free active RoM, shoulder function and arm activity before and during the intervention, the orthosis wear time, and user satisfaction with the orthosis.

We first present the redesign of the orthosis, followed by the patient selection, the study outline, and a detailed description of the chosen outcomes measures. Then the results of the interventional study, reporting the clinical effects of the shoulder orthosis, are presented, followed by the discussion and the conclusions.

Methods

Shoulder orthosis

In this study, we redesigned the dynamic shoulder orthosis to increase the robustness, usability, and level of comfort of the device without altering the working principle of the orthosis, Figure 1. In addition, the weight was reduced from 605 to 247 g. Elastic bands suspended at the anterior and posterior side of the shoulder provide an external, upward force to the arm. Proximally, these bands are connected to a rigid wireframe construction supported on the shoulder. Straps around the waist and the chest hold this construction in place. Two main differences between the previous and current version of the orthosis are as follows:

1. A thin, metal wireframe was used at the lateral side of the body, instead of a large aluminum construction.
2. The silicone arm cuff of the previous prototype relied on friction that is associated with warmth and perspiration and contributes to discomfort.[13] In the current prototype, we therefore used a fabric arm cuff that locks itself around the forearm due to its conical shape.

Participants

Adult patients (≥18 years) with chronic shoulder pain (>6 months) that was probably caused by stress on the glenohumeral structures were recruited from the Roessingh, Center for Rehabilitation (Enschede, the Netherlands) and Radboud University Medical Center (Nijmegen, the Netherlands). Patients who reported that supporting the affected shoulder with the unaffected hand reduced pain complaints were considered eligible for the study. Exclusion criteria were defined as an inability to sit upright in a chair without supporting the arm for at least 15 minutes consecutively, an irritated skin in the application area of the orthosis, recent shoulder or arm surgery (<6 months before participation in the study), or inability to understand and follow simple verbal instructions. Ethical approval for the study was granted by the Committee on Research involving Human Subjects, region Arnhem-Nijmegen (number NL74819.091.20). Written informed consent was obtained from all subjects before the start of the study.

The patients' age, sex, weight, height, dominant arm and affected shoulder, diagnosis, and time since the onset of their shoulder complaints were recorded before the start of the study. Ten participants (1 male and 9 female) with a median age of 48 years (range 19–60) were recruited (Table 1).

Study outline

Three assessment and 2 monitoring sessions were performed per participant, Figure 2. The participants performed their normal daily routine at home for a period of 3 weeks (1 week without orthosis and 2 weeks with orthosis). The first week provided a baseline to which the second and third weeks (with orthosis) were compared.

During the initial assessment (day 0), the pain-free RoM (PF-RoM) during shoulder anteflexion (forward flexion) and abduction movements was measured, and general patient characteristics were noted. In addition, the initial orthosis fitting was performed by customizing a standard brace to the participant's body and determining the required adjustments.

During the intermediate assessment (day 7), several questionnaires were conducted regarding arm activity and shoulder pain, and the PF-RoM was measured. In addition, the acromiohumeral distance (AHD), ie, the distance between the AC and humerus, was measured.

Figure 1. Left: Prototype of the dynamic shoulder orthosis. (1) Elastic bands. (2) Rigid construction. (3) Forearm cuff. (4) Tensioning mechanism. (5) Strap around contralateral side of the chest. Right: Close-up of the arm cuff and tensioning mechanism with flexed elbow. (6) Forearm cuff with soft Velcro straps. (7) Ring aligned with elbow joint center of rotation. (8) Upper arm part to guide the force from the elastic bands (1) to the forearm cuff.

Table 1. Subject characteristics.

ID	Sex	Age (y)	Weight (kg)	Diagnosis	Height (m)	Dominant Arm	Affected Shoulder	Time since Complaints (y)
S1	F	23	68	Plexus trauma	1.69	Left	Right	8
S2	F	50	98	NA	1.70	Right	Right	6
S3	F	52	75	NA	1.70	Right	Right	23
S4	F	46	64	NA	1.63	Right	Left	8
S5	F	55	58	NA	1.71	Right	Left	23
S6	F	59	110	NA	1.76	Right	Right	6
S7	F	35	75	NA	1.77	Right	Left	5
S8	M	60	84	CVA	1.86	Right	Left	<1
S9	F	43	90	Iatrogenic nerve injury	1.78	Right	Left	6
S10	F	19	70	Erb palsy	1.71	Right	Left	19

Abbreviations: CVA, cerebrovascular accident; F, female; ID, subject ID; M, male; NA, neuralgic amyotrophy.

Both the PF-RoM and AHD measurements were performed without and with orthosis, and at 3 levels of supportive force (40%, 80%, and 120% of the arm weight) to assess the immediate effects of the orthosis. These values were chosen to represent a wide range of supportive force conditions that could be chosen by the participant during the 2-week assessment. At the beginning of this session, final adjustments were made to the shoulder orthosis.

During the final assessment (day 21), the same tests were performed as on day 7. In addition, the Dutch version of the Quebec User Evaluation of Satisfaction (D-QUEST) regarding user satisfaction and a short interview were conducted. The latter contained custom questions about the type of activities the participants performed with the orthosis.

Shoulder pain

The shoulder pain was measured with a 10-cm visual analog scale (VAS).[14,15] All subjects reported their daily average shoulder pain over the last 24 hours in rest and during activities for a period of 3 weeks (1 week before and 2 weeks during the intervention). Subjects were asked to mark their response on the scale, where the ends of the scale represent extreme limits of the pain, orientated from left (no pain at all) to right (worst pain imaginable).

AHD

The AHD was assessed with diagnostic ultrasound without and with the shoulder orthosis to measure the immediate effect of the orthosis on the AHD (Figure 3). The change in AHD caused by shoulder supports is most often assessed using radiography.[16] However, exposure to radiation and high costs limit the clinical application of this technique.[17] Diagnostic ultrasound does not involve exposure to radiation and was therefore adopted in this research. The AHD was defined as the shortest distance from humeral head to the tip of the AC.[18]

The ultrasound examination was performed with an ACUSON S1000 system (Siemens Healthineers, Erlangen, Germany) and a 5–14 MHz (14L5) linear array transducer. A custom preset was defined to optimize image quality. The transducer was placed over the lateral border of the AC. This placement does not interfere with the position of the orthosis.

Subjects were examined while seated upright in a chair (hips and knees in 90 degrees flexion). They were instructed to keep their arm in a neutral position, and elbow in 0 degree flexion, while keeping their trunk still. First, the AHD of the (unsupported) affected and unaffected shoulder was measured to be able to compare both shoulders. Then, the orthosis was fitted to the patient and the AHD

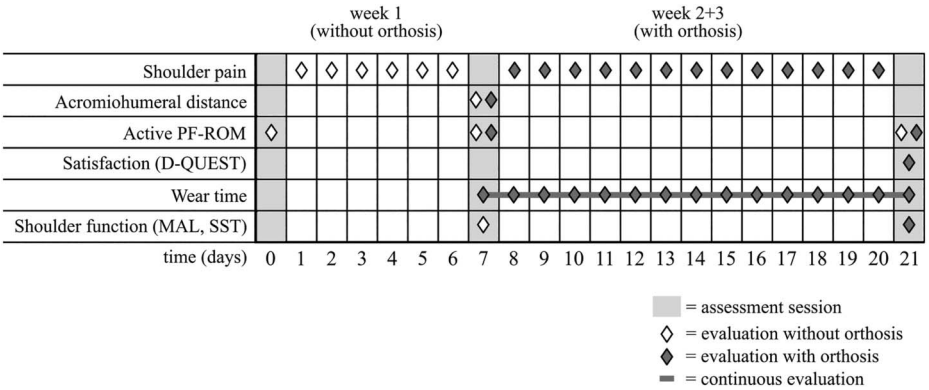

Figure 2. Schedule depicting the tests that are conducted throughout a period of 3 weeks. Each row represents a different test. On days 0, 7, and 21, the assessments were conducted.

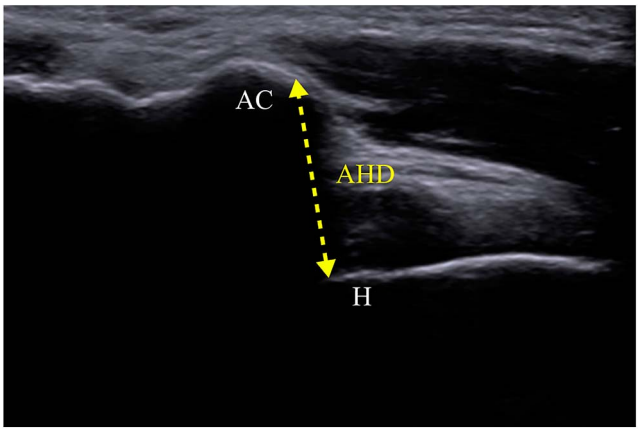

Figure 3. Example of AHD measurement with the arm in a neutral position. Indicated are the AC, H, and AHD. H, humerus.

of the affected shoulder was measured again, this time with the orthosis. To investigate the influence of the magnitude of the supportive force on the AHD, 3 supportive force conditions were defined. The tension of the elastic bands was set to support 40%, 80%, and 120% of the arm weight. The arm weight was estimated from the total body weight, according to the values presented by de Leva.[19] Each condition was repeated 3 times.

The ultrasound device was operated by a researcher who received training from an expert with over 20 years of experience in ultrasound examination. The operator was also the rater of the ultrasound images. The AHD was measured from the ultrasound images with Matlab 2019a (Mathworks, Natick) using a custom script. The rater was masked to the supporting force condition. The recorded images were presented in a random order to the rater. Each image was presented 3 times to the rater, from which the mean AHD could be calculated. In addition, 2-sample *t* tests were performed to investigate whether the mean AHD significantly changed between conditions ($P < 0.05$).

Active PF-RoM

A decreased shoulder RoM can adversely affect a person's ability to perform tasks and independent functioning in daily life. Many shoulder supports hold the arm internally rotated and adducted at the shoulder, discouraging arm use which in turn may lead to muscle shortening and/or changes in muscle tone.[20] Application of any shoulder orthosis should at least preserve, and preferably increase, the remaining shoulder RoM. As pain is often a movement-limiting factor for patients with shoulder pain, in this study we adopted the definition of the active RoM until the point of pain, or PF-RoM, for the examination of the shoulder RoM.[21,22]

The PF-RoM measurements were performed without the orthosis and with the elastic bands tensioned to 40%, 80%, and 120% of the total arm weight, for both anteflexion and abduction movements. The PF-RoM measurement without orthosis was conducted at the beginning of the session. In case the participants indicated fatigue of their shoulder muscles after measurements with orthosis, the measurement without orthosis was repeated at the end of the session and both results were inspected for large differences. The measurements at 40%, 80%, and 120% arm weight support were conducted in a randomized order.

Subjects were seated on a chair (hips and knees in 90 degrees flexion), while fully extending their elbow and keeping their wrist in a neutral position. The thumb was leading in the sagittal plane. The goniometer app Clinometer (Plaincode, Munich, Germany), validated for shoulder anteflexion and abduction movements, was used to measure the RoM.[23] For anteflexion movements, the smartphone screen was aligned with the longitudinal axis of the humerus, perpendicular to the sagittal plane. Subjects were instructed to move their arm in the sagittal plane while keeping their trunk still until they reached the threshold of pain or the end of their active RoM. At this point, the inclination angle was read from the goniometer app. The same procedure was repeated for abduction movements, only the movement now occurred in the frontal plane, and the smartphone screen was oriented perpendicular to the frontal plane. Both anteflexion and abduction angle measurements were repeated 3 times for each condition and the mean PF-RoM was calculated. With these data, 2-sample *t* tests were performed to investigate whether the mean PF-RoM for anteflexion and abduction movements significantly changed between conditions ($P < 0.05$).

User satisfaction

The Quebec User Evaluation of Satisfaction with assistive Technology 2.0[24] is the only validated questionnaire available in Dutch to evaluate the satisfaction regarding assistive devices.[25] This questionnaire was conducted at the end of the intervention to assess the user's satisfaction with the provided shoulder orthosis. Eight items of this questionnaire that were related to the assistive device were rated by the subject on a scale from 1 (not satisfied at all) to 5 (very satisfied). In addition, all subjects were asked about how they used the orthosis and about the type of activities they performed the most while wearing the orthosis.

Orthosis wear time

To gain insight in the usage of orthotics and prosthetics in daily life, often questionnaires or logbooks are used to measure the time that the devices are worn by patients.[26] These results might be biased because they rely solely on the accuracy of reporting.[27] Therefore, we recently proposed a new method to objectively estimate orthosis wear times using miniature temperature loggers and a trained classification algorithm.[28] A temperature logger was attached to the chest strap of the shoulder orthosis and the temperature was automatically logged every 5 minutes during the 2 weeks of unsupervised orthosis use. After this period, the sensor was retrieved from the orthosis and the temperature data were transferred to the computer for further processing with the algorithm. The algorithm provides an estimated device state (*on* or *off*) for every temperature sample. The number of *on* states was multiplied with the sample time (5 minutes) to obtain the estimated wear time. From the data, the total wear time and mean wear time per day were calculated.

Shoulder function

Objective assessment of shoulder function is possible in a clinical setting. However, a patient's capacity to perform specific clinical tests (eg, maximum active RoM) may not reflect their motor performance in daily life.[29] Instead, we proposed to assess the

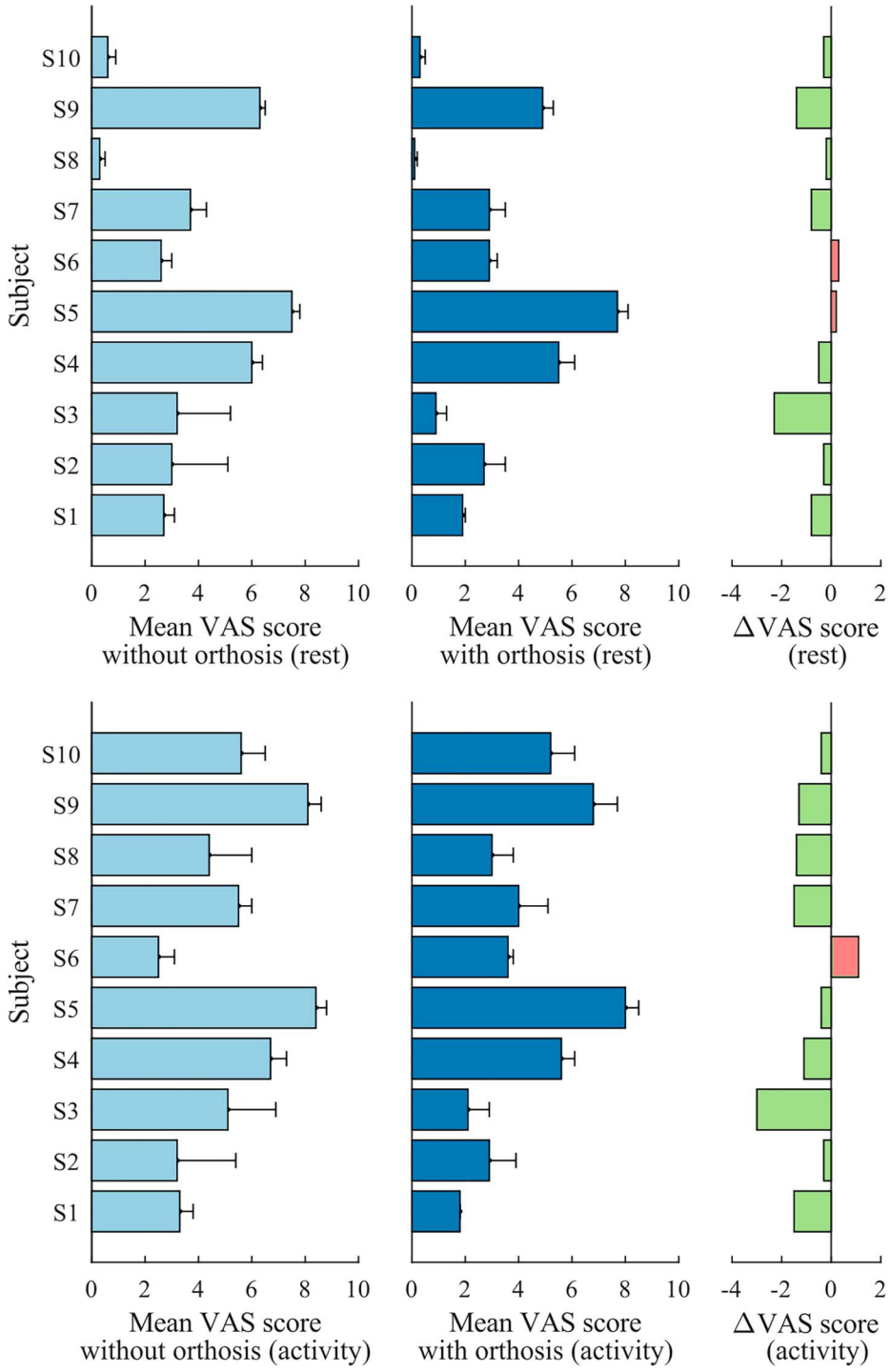

Figure 4. VAS scores in rest (top) and during activities (bottom). Left: mean VAS without shoulder orthosis. Middle: mean VAS after wearing the shoulder orthosis. Right: differences in VAS scores without and with orthosis. A decrease in the VAS score is marked in green and an increase is marked in red. Error bars represent the standard deviation of the mean.

patient's perceived performance of their affected shoulder in daily life with and without the shoulder orthosis using the Motor Activity Log (MAL)[30,31] and the Simple Shoulder Test (SST).[32] For the MAL, the participants were asked to rate the Quality of Movement (QOM) and Amount of Use (AOU) of their affected arm during several functional daily tasks. All 26 items were rated on an ordinal scale from 0 (affected arm was never used) to 5 (ability to use the affected arm was as good as before the shoulder complaints) on the QOM subscale and from 0 (affected arm was never used) to 5 (affected arm was always used during the activity) on the AOU subscale. The SST consists of 12 items to assess the functional limitations of the affected shoulder. Each item was scored as either 0 (no) or 1 (yes). The summed scores were divided by 12 and multiplied by 100 to obtain the total score (range 0–100

Table 2. AHD measured with ultrasound for different conditions.

ID	N (mm), mean (SD)	UA (mm), mean (SD)	A40 (mm), mean (SD)	A80 (mm), mean (SD)	A120 (mm), mean (SD)	Δ(N-UA) (mm)	Δ(UA-A40) (mm)	Δ(UA-A80) (mm)	Δ(UA-A120) (mm)
S1	—	9.7 (0.3)	8.5 (0.2)	10.5 (0.3)	—	—	1.2	0.5	—
S2	—	11.3 (1.1)	11.6 (0.7)	10.5 (1.0)	—	—	−0.3	0.8	—
S3	13.0 (0.6)	13.5 (0.3)	11.5 (0.6)	12.0 (0.8)	11.4 (0.3)	−0.5	2.0	1.5	2.1
S4	10.2 (0.2)	10.0 (0.4)	9.8 (0.3)	9.6 (0.4)	9.9 (0.5)	0.2	0.2	0.4	0.1
S5	—	13.7 (0.2)	11.5 (0.2)	11.3 (0.2)	11.4 (0.7)	—	2.2	2.4	2.3
S6	12.2 (0.4)	12.0 (0.4)	10.6 (0.3)	12.0 (0.3)	12.1 (0.3)	0.2	1.4	0.0	−0.1
S7	15.0 (0.8)	14.5 (1.0)	11.4 (0.8)	10.7 (0.5)	9.9 (1.3)	0.5	3.1	3.8	3.0
S8	13.4 (0.8)	12.8 (0.9)	9.4 (0.6)	9.5 (0.4)	9.0 (0.5)	0.6	3.4	3.3	3.8
S9	15.5 (0.4)	12.2 (0.6)	10.1 (1.3)	9.4 (1.3)	9.6 (1.0)	3.3	1.4	2.8	2.3
S10	11.9 (0.3)	9.2 (0.3)	8.9 (0.3)	9.7 (0.5)	8.9 (0.4)	2.7	0.3	−0.5	0.3
	13.0 (1.8)	11.9 (1.8)	10.3 (1.2)	10.5 (1.0)	10.3 (1.2)	1.0 (1.3)	1.5 (1.2)	1.5 (1.4)	1.7 (1.4)

Abbreviations: A40, affected shoulder with 40% arm weight support; A80, affected shoulder with 80% arm weight support; A120, affected shoulder with 120% arm weight support; ID, subject ID, N, nonaffected shoulder; SD, standard deviation.
The last row presents the mean and SD across all participants.

points). A higher score represents less functional limitations of the affected shoulder.

By conducting the MAL and SST twice (after the first week and after 3 weeks), we were able to investigate the influence of the shoulder orthosis on the perceived shoulder performance. The mean AOU and QOM subscale scores of the MAL and the total score of the SST were reported without and with the orthosis.

Results

Shoulder pain

The mean VAS scores in rest and during activities (Figure 4) were calculated from the daily VAS scores without orthosis and with orthosis for each subject. Days without reported VAS scores (due to incomplete subject logs) or without shoulder orthosis use were not taken into account during the analysis. The mean shoulder pain in rest, represented by the VAS score, across all subjects was 3.6 (range 0.3–7.5) without orthosis and 3.0 (range 0.1–7.7) with orthosis. The mean shoulder pain during activities across all subjects was 5.3 (range 2.5–8.4) without orthosis and 4.3 (range 1.8–8.0) with orthosis. To see whether the use of the shoulder orthosis led to a decrease in shoulder pain, the difference (ΔVAS) between the mean VAS scores without and with shoulder orthosis was also determined in rest and during activities (Figure 4, right). For 8 of 10 subjects, the mean shoulder pain in rest decreased when the subjects wore the shoulder orthosis, whereas for 9 of 10 subjects, the mean shoulder pain during activities decreased. ΔVAS across all subjects was −1.0 in rest and −0.6 during activities.

Table 3. Anteflexion PF-RoM of the unsupported shoulder and with 40%, 80%, and 120% of the arm weight supported by the shoulder orthosis, measured during the initial, intermediate, and final assessments.

	Initial	Intermediate				Final			
ID	UA (degrees), mean (SD)	UA (degrees), mean (SD)	A40 (degrees), mean (SD)	A80 (degrees), mean (SD)	A120 (degrees), mean (SD)	UA (degrees), mean (SD)	A40 (degrees), mean (SD)	A80 (degrees), mean (SD)	A120 (degrees), mean (SD)
S1	76 (2.0)	71 (3.2)	76 (6.9)	82 (3.9)	—	—	—	—	—
S2	70 (4.6)	70 (3.7)	82 (2.6)	83 (3.9)	—	86 (2.6)	87 (2.0)	87 (1.2)	—
S3	69 (15.7)	50 (4.0)	37 (2.4)	53 (0.7)	42 (8.3)	57 (8.9)	49 (11.4)	61 (4.7)	47 (10.8)
S4	82 (4.1)	68 (2.4)	72 (4.8)	70 (2.4)	65 (1.8)	66 (1.0)	72 (1.6)	67 (2.4)	63 (3.1)
S5	74 (2.3)	59 (0.7)	67 (3.6)	77 (4.4)	74 (2.1)	75 (0.6)	69 (0.6)	68 (0.5)	56 (1.0)
S6	98 (8.2)	81 (4.0)	76 (4.4)	77 (2.6)	66 (3.5)	—	56 (4.9)	69 (1.7)	53 (1.4)
S7	84 (1.6)	80 (3.9)	74 (2.8)	67 (3.4)	70 (3.0)	72 (3.9)	75 (3.0)	69 (3.2)	69 (1.9)
S8	—	—	—	—	—	—	—	—	—
S9	12 (1.1)	11 (1.4)	13 (0.6)	14 (1.8)	9 (1.3)	25 (1.8)	24 (1.7)	16 (2.7)	12 (1.2)
S10	79 (4.7)	83 (6.8)	67 (2.9)	75 (1.8)	65 (1.1)	69 (1.6)	69 (0.5)	76 (2.1)	72 (2.5)
	72 (23)	64 (21)	63 (21)	66 (20)	56 (32)	64 (18)	63 (18)	64 (20)	53 (19)

Abbreviations: A40, affected shoulder with 40% arm weight support; A80, affected shoulder with 80% arm weight support; A120, affected shoulder with 120% arm weight support; Final, final assessment; ID, subject ID; Initial, initial assessment; Intermediate, intermediate assessment; SD, standard deviation.
The last row presents the mean and SD across all participants.

Table 4. Abduction PF-RoM of the unsupported shoulder and with 40%, 80%, and 120% of the arm weight supported by the shoulder orthosis, measured during the initial, intermediate, and final assessments.

	Initial	Intermediate				Final			
ID	UA (degrees), mean (SD)	UA (degrees), mean (SD)	A40 (degrees), mean (SD)	A80 (degrees), mean (SD)	A120 (degrees), mean (SD)	UA (degrees), mean (SD)	A40 (degrees), mean (SD)	A80 (degrees), mean (SD)	A120 (degrees), mean (SD)
S1	68 (7.0)	76 (4.1)	77 (0.8)	84 (1.4)	—	—	—	—	—
S2	75 (2.1)	75 (4.1)	75 (0.8)	79 (1.6)	—	85 (1.2)	89 (1.2)	85 (0.6)	—
S3	30 (9.6)	32 (5.8)	24 (3.6)	44 (7.3)	40 (7.8)	33 (8.3)	31 (6.5)	37 (6.5)	36 (3.5)
S4	73 (4.6)	62 (2.2)	60 (2.1)	59 (1.9)	60 (2.6)	59 (2.5)	57 (0.8)	56 (1.1)	59 (1.8)
S5	66 (0.6)	55 (5.2)	51 (1.3)	64 (1.8)	66 (2.0)	68 (3.5)	66 (1.7)	62 (3.2)	55 (2.0)
S6	66 (2.6)	56 (3.4)	51 (2.6)	62 (1.2)	51 (3.1)	—	46 (6.3)	51 (0.7)	49 (1.8)
S7	67 (3.5)	55 (1.7)	47 (1.3)	49 (2.9)	53 (0.6)	44 (10.4)	43 (3.8)	47 (1.2)	46 (1.5)
S8	—	—	—	—	—	—	—	—	—
S9	16 (0.4)	14 (1.5)	20 (0.8)	21 (1.1)	25 (1.4)	12 (1.2)	15 (1.5)	13 (0.0)	17 (0.6)
S10	64	46	62	61 (4.0)	55 (2.6)	59 (5.8)	58 (1.3)	63 (3.6)	62 (0.7)
	58 (21)	52 (20)	52 (20)	58 (19)	50 (14)	51 (24)	51 (22)	52 (21)	46 (16)

Abbreviations: A40, affected shoulder with 40% arm weight support; A80, affected shoulder with 80% arm weight support; A120, affected shoulder with 120% arm weight support; Final, final assessment; ID, subject ID; Initial, initial assessment; Intermediate, intermediate assessment; SD, standard deviation.
The last row presents the mean and SD across all participants.

AHD

The mean AHD of the nonaffected shoulder (N); unsupported affected shoulder (UA); and affected shoulder with 40% (A40), 80% (A80), or 120% (A120) of the arm weight supported is shown in Table 2. For 2 subjects (S1 and S2), no recordings were available from the nonaffected side and the 120% support condition because these conditions were added to the measurement protocol after the first 2 participants. For subject S5, the data were not correctly stored for the nonaffected shoulder. The mean AHD of the nonaffected shoulder across all subjects was 13.0 mm (range 10.2–15.5 mm). The mean AHD of the affected, unsupported shoulder across all subjects was 11.9 mm (range 9.7–14.5 mm). The difference in mean AHD between the nonaffected and affected unsupported shoulder was not statistically significant ($P = 0.11$).

The differences in mean AHD between the affected, unsupported condition and the conditions at 40% ($P = 0.003$), 80% ($P = 0.011$), and 120% ($P = 0.015$) arm weight support were all statistically significant. For the 3 supported conditions, the mean AHD was smaller than that for the unsupported condition.

A statistically significant reduction in AHD was measured between the affected unsupported and supported force conditions (Δ[UA-A40], Δ[UA-A80], and Δ[UA-A120]), although for none of the patients a GHS could be confirmed. A comparison between the different supported force conditions revealed no statistically significant differences.

Active PF-RoM

We assessed the PF-RoM during anteflexion and abduction movements of the affected unsupported shoulder, and with 40%, 80%, and 120% of the arm weight supported during the initial, intermediate, and final assessment, Tables 3 and 4. For 2 participants (S1 and S2), no measurements were available for the 120% arm weight condition because this condition was added to the protocol after the first 2 participants were measured. For S1, the final assessment was not completed as the subject was unable to travel to the measurement location. S8 could not actively lift his arm against gravity.

The shoulder orthosis had no instantaneous effect on the active PF-RoM for both anteflexion and abduction movements because no significant differences were found between the mean PF-RoM of the unsupported and supported affected shoulder at 40%, 80%, and 120% arm weight support.

In addition, wearing the orthosis for 2 weeks did not affect the active PF-RoM because no statistically significant differences were found between the intermediate and final assessment.

User satisfaction

Overall, the 10 subjects reported a high level of satisfaction with the assistive device (mean 4.1, range 3.3–4.9), Figure 5. Subjects were most satisfied with the weight (247 g) of the device (4.5), the safety (4.3), the ease in adjusting (4.2), and the effectiveness (4.2). Of all aspects, comfort was rated lowest (3.4). The downward force pressing on the shoulder arc, required to lift the arm, was mentioned by several subjects as a factor that decreased the comfort of the orthosis.

Subjects reported that they used the orthosis both at home and outdoor. Most subjects wore the orthosis over their clothing. A wide range of activities were performed with the orthosis. Among frequently reported activities are walking (×6), cooking (×4), and gardening (×3). Two participants (S4 and S10) reported that they used the orthosis during their work. Apart from these participants, only S1 was employed. For most of the participants, the level of comfortable arm weight compensation ranged between 40% and 80%, depending on the type of activity that was performed.

Orthosis wear time

For 9 subjects, the sensor data were processed with the wear time estimation algorithm. For 1 subject (S10), the temperature data could not be retrieved from the data logger. Instead, the self-reported wear times were used during the analysis. On average, subjects used the orthosis 9.5 days (range 3–14 days) for 155 min/d

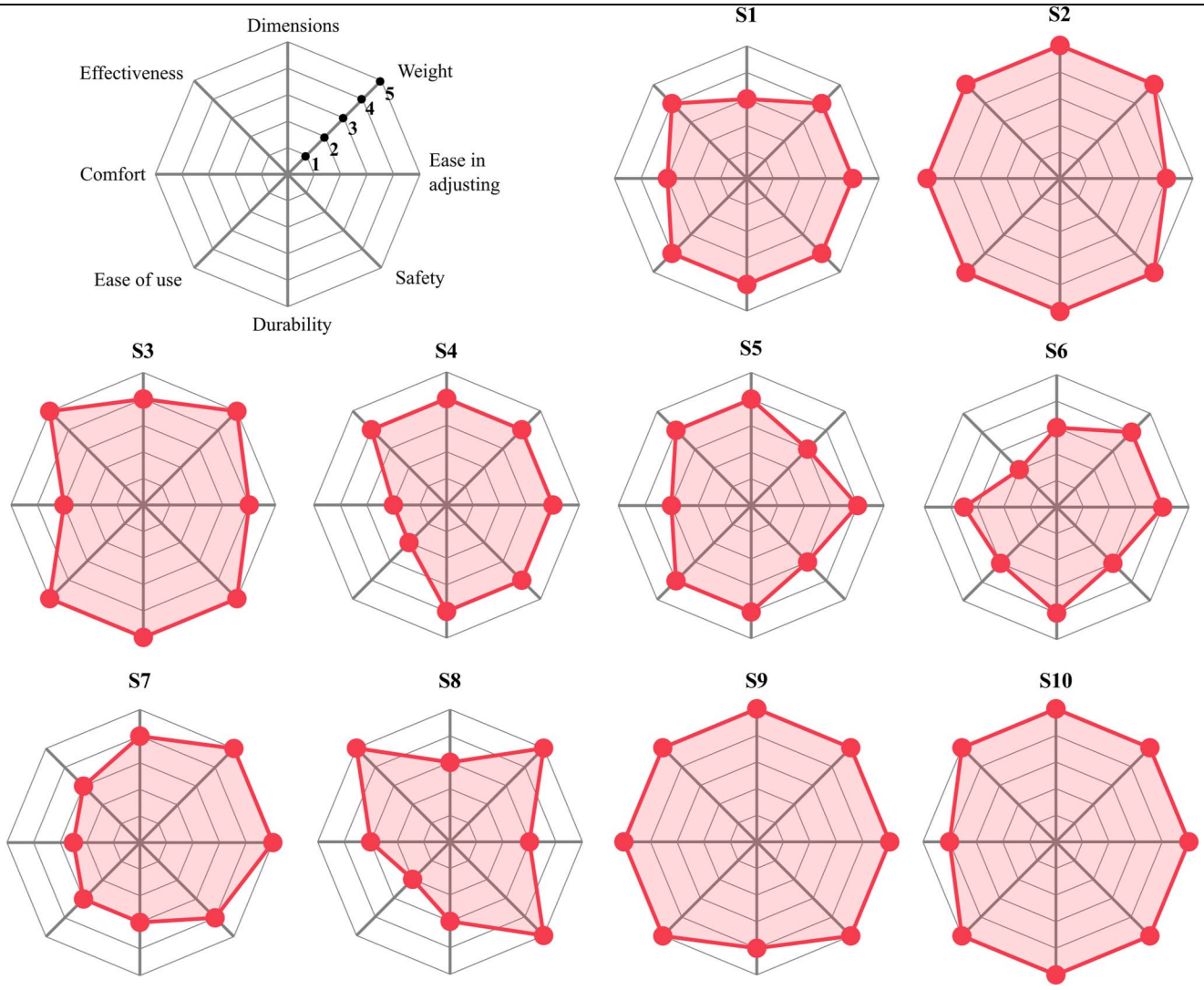

Figure 5. Results of the D-QUEST questionnaire, showing the satisfaction with the shoulder orthosis for the aspects "dimensions," "weight," "ease in adjusting," "safety," "durability," "ease of use," "comfort," and "effectiveness" per subject. The further away from the center, the higher the score (1–5).

(range 63–397 min/d), Figure 6. In general, subjects who were more satisfied with the orthosis, used the orthosis more. S1 used the orthosis the least (270 min across 3 days) due to a lack of comfort and stopped wearing the orthosis after 1 week. S6 was not satisfied with the effectiveness, ease of use, and the dimensions. This was also reflected as she used the orthosis only during 8 days, with an average wear time of 63 min/d. S7 reported a low effectiveness and comfort level. From the wear time results, it can be seen that her orthosis usage dropped significantly after 1 week. S8 used the orthosis the most (4760 min across 12 days). Although this subject indicated that he could not don the orthosis without help, he reported a high effectiveness score.

Shoulder function

The MAL and SST scores are presented in Table 5. The mean amount of use (AOU) and QOM of the affected arm across all participants improved from 3.3 to 3.6 (AOU) and from 3.0 to 3.3 (QOM). For none of the subjects, the SST scores decreased after wearing the orthosis. For 5 subjects, the SST score remained the same, whereas for the other 5 subjects, the score improved. The mean improvement on the SST questionnaire across all participants was 7.5 points. This was mainly attributed to an increased comfort level of the arm at rest for 4 of 5 subjects with improved SST scores.

Conclusions and discussion

Limitations of the study included a lack of participants with objectively established GHSs, large individual differences in baseline shoulder pain and RoM, limited sample size, and the relatively short duration and uncontrolled nature of the intervention period.

Nadler et al reported pooled data about the reduction of vertical subluxation caused by 3 main orthosis design types.[16] Because of a different methodology (radiography vs. ultrasound) and target population (stroke vs. neuralgic amyotrophy, and degree of subluxation), these results cannot be directly compared with our results. We hypothesized that continuous stress on the glenohumeral joint contributes significantly to shoulder pain instead of GHS and therefore did not include an (objectively) established GHS as inclusion criteria. It turned out that none of the participants in our

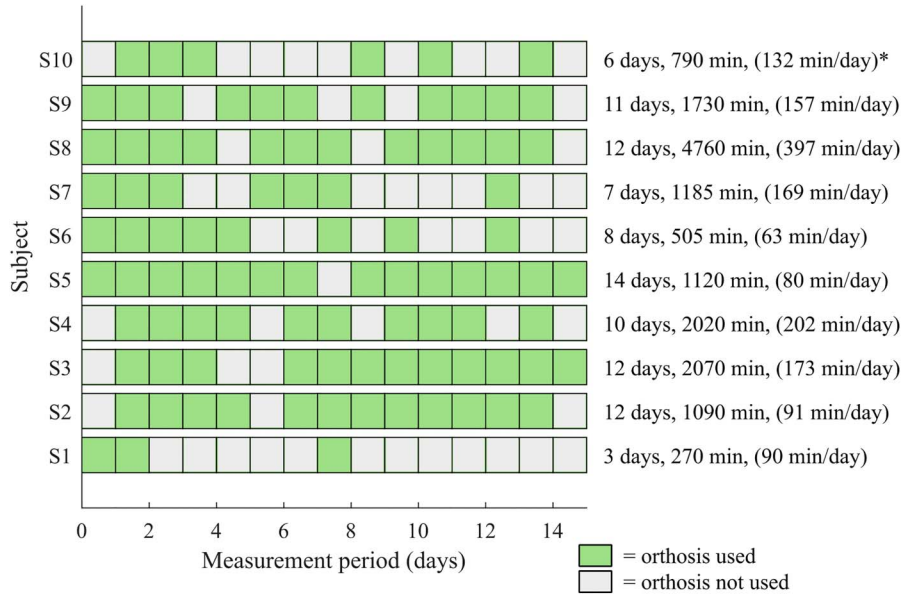

Figure 6. Overview of the days when each subject used (green) or did not use (gray) the orthosis during the measurement period, including the total estimated wear time from the miniature temperature loggers and the average wear time per day that the orthosis was used. *Indicates self-reported wear times.

study suffered from GHS because the AHD measured at both the nonaffected and affected shoulder was not statistically different and was in the range of healthy controls.[33] Therefore, the reduction in AHD was also expected to be less than if the shoulder was subluxated because the maximal reduction is dependent on the level of subluxation. This could also explain the fact that supporting the arm more (with 80% or even 120% of the arm weight) did not further decrease the AHD. Even so, we did see a slight reduction in AHD due to application of the shoulder orthosis. This means that the upward force created by the elastic bands caused the arm to move slightly toward the glenoid.

Previous studies were only able to relate a change in shoulder pain to a change of the vertical displacement of the glenohumeral joint because of the type of orthosis used.[8-10] These shoulder orthoses are position-controlled. Position-controlled orthoses[8-10] do not allow researchers to precisely control the applied force during the investigation. Our shoulder orthosis is force-controlled, meaning that the amount of upward force is always equal, irrespective of the arm position. The tensioning mechanism allows for an easy adjustment of supporting force. To the best of our knowledge, our study is the first to investigate the relationship between different levels of stress reduction, the repositioning of the humeral head (AHD), and the shoulder pain.

Table 5. MAL subscale scores and SST scores of each participant during a typical week without shoulder orthosis and after 2 weeks of orthosis use. Δ indicates the difference in test scores without and with orthosis.

	AOU (0–5)		ΔAOU	QOM (0–5)		ΔQOM	SST (0–100)		ΔSST
	Without	With		Without	With		Without	With	
S1	3.3	3.3	0.0	3.6	3.5	−0.1	67	67	0
S2	5.0	5.0	0.0	4.3	4.4	0.1	67	67	0
S3	1.8	2.0	0.2	2.2	2.2	0.0	17	33	17
S4	2.4	2.9	0.5	2.9	3.0	0.1	8	8	0
S5	2.5	2.3	−0.2			0.0	8	25	17
S6	4.8	4.1	−0.8	3.9	3.6	−0.3	30	30	0
S7	4.6	4.4	−0.2	3.3	3.7	0.4	42	42	0
S8	5.0	5.0	0.0	2.0	2.0	0.0	8	17	8
S9	2.3	4.7	2.3	2.0	4.7	2.7	0	8	8
S10	1.7	2.4	0.7	2.3	2.8	0.5	58	83	25
	3.3 (1.4)	3.6 (1.2)	0.3 (0.8)	2.9 (0.9)	3.3 (0.9)	0.3 (0.9)	31 (26)	38 (26)	7.5 (9.2)

Abbreviations: ID: subject ID; SD, standard deviation.
The last row presents the mean and SD across all participants.

Our study confirms that wearing the shoulder orthosis reduced shoulder pain, despite the lack of participants with GHS. This supports the hypothesis that shoulder pain reduction may be more dependent on a stress reduction of the structures surrounding the shoulder joint than an actual translation of the humeral head toward the glenoid. To confirm this hypothesis, future research should include a more diverse patient population for baseline characteristics (diagnosis, degree of subluxation, etc). In our study, pain scores improved for 8 of 10 participants (80%) in rest, and for 9 of 10 participants (90%) during activities. Subject S5 used the orthosis extensively and scored high on effectiveness, but her pain scores in rest showed a slight increase while wearing the orthosis. This increase was negligible compared with the average pain level of this participant. Subject S6 scored low on orthosis effectiveness and comfort. This may have been caused by a poor brace fitting due to a mismatch between the brace size and the subject's oversized body dimensions. She reported a low usage, which may have limited the effect of the brace and making the pain scores less reliable. The effects of the orthosis on the pain scores were largest among patients with VAS scores between approximately 3 and 6.

Our findings of pain score improvements are similar to comparable studies where the effects of shoulder orthoses are investigated. Across 3 studies found in the literature, 57% of the patients reported improved pain scores after wearing a shoulder orthosis for several weeks.[8,9,16,34] In the study by Hesse et al,[9] patients described the improvement as better (10 of 40 patients) or definitely better (8 of 40 patients), and in the study by Hartwig et al, sensory pain scores were provided as a subset of the shoulder-hand syndrome score, ranging from 0 (no pain) to 5 (spontaneous pain). Here, the mean pain scores improved from 1.8 ± 1.1 to 0.4 ± 0.6 (n = 20).[8]

Most participants reported an unpleasant feeling in the glenohumeral joint region when large arm weight compensation forces (>80%) were applied by the orthosis to the arm. The discomfort could have been caused by impingement of the muscle between the AC and humeral head as the arm was pushed toward the glenoid more.

The clinical benefit of the shoulder orthosis can be assessed by comparing the results to the minimally important differences (MIDs). Minimally important differences represent the minimal change in outcome that are important to the patient.[35] Typical MIDs are 0.5–3.0 for the VAS,[36-39] 0.5 for the MAL,[31] and 17 for the SST.[40] The improvements in shoulder pain (VAS) were in the range of the MID. For the MAL and SST, the MIDs were not achieved. This might be caused by the relatively short use period (2 weeks). Therefore, we suggest to extend the orthosis use period to a few months in a future study.

In clinical practice, the amount of pain relief, assessed by VAS, is often considered as a measure of the efficacy of treatment. In our study, the arm activity scores showed similar trends as the reported VAS scores. Periods of high arm activity were reflected in the daily VAS scores. As we did not want to intervene in the subjects' daily activities, this could have affected the results. However, as many people schedule their activities on a regular basis, we accounted for this effect because the measurement periods included both working days and weekends. In a future study, we will extend the period of orthosis use to further reduce these effects.

Author Contributions

C.J.W.H.: Conceptualization of prototype, methodology, investigation, writing – original draft, visualization. E.E.G.H.: Methodology, writing – review & editing. H.v.d.K: Methodology, writing – review & editing. JR: Methodology, writing – review & editing.

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Supplemental material

No supplemental digital content is available in this article.

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