Original Article

Efficacy of a Newly Designed Custom-Fitted Shoulder Subluxation Orthosis for Stroke Patients: A Single-Blinded Crossover Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the efficacy of a newly designed custom-fitted shoulder subluxation orthosis (SSO) with a commercial Bobath sling for shoulder subluxation in stroke patients.

Study design: A single-blinded crossover randomized controlled trial.

Setting: Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

Subjects: Sixteen post-stroke patients with hemiplegia/hemiparesis

Methods: A radiologist measured the acromiohumeral (AH) distance in anterior-posterior view radiographs of normal and affected shoulders of patients in a sitting position when not using any orthosis, when wearing a Bobath sling which supports the proximal humerus only, and when wearing an SSO. Comparison of the AH distance was conducted using the paired t-test.

Results: Without any orthosis, the mean (SD) of the affected and normal shoulders were 47.9 (7.5) and 36.2 (4.6) mm, respectively. The AH distance of the affected shoulder while wearing SSO was reduced to 36.8 (4.7) mm which is not statistically significant different from the normal shoulder distance ($p = 0.49$), whereas the mean AH distance wearing a Bobath sling was only reduced to 44.9 (7.7) mm., statistically significantly greater than the normal shoulders ($p < 0.01$).

Conclusions: The newly designed custom-fitted proximal-distal type shoulder subluxation orthosis for hemiplegia/hemiparesis patients, can reduce the AH distance significantly closer to that of a normal shoulder than a Bobath sling.

Keywords: shoulder subluxation, radiograph, orthosis, stroke, rehabilitation

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Introduction

Stroke is a major health problem in Thailand, with an incidence of up to 250,000 cases per year. It results in approximately 50,000 deaths per year and is the leading cause of death and disability in Thailand.[1]

Shoulder pain is a common stroke complication, found in up to 33.9% of stroke patients.[2,3] Multiple causative factors for shoulder pain have been proposed due to the complex anatomy and biomechanics of the shoulder. Shoulder subluxation is often a suspected cause. In some studies, a higher prevalence of post stroke shoulder pain was found in patients with shoulder subluxation.[4-6] Both the shoulder pain and subluxation interfere with rehabilitation and negatively affect quality of life,[7-11] making prevention of shoulder subluxation and the reduction of shoulder pain and its complications an important goal.

Currently, there are many methods to help prevent and reduce shoulder subluxation in stroke patients, e.g., shoulder orthosis, positioning of shoulder, and neuromuscular electrical stimulation. Shoulder orthosis support methods can be divided into 3 main types according to the point of support. The first type is proximal humeral support (P-S) which supports only proximal part of the upper extremity. The second type is whole arm with elbow flexion support (Wh-S) which supports the entire upper arm and keeps the elbow in the flexed position. The last is the proximal distal support (P-D-S) which supports both the proximal and distal parts of the upper extremity.[11]

A systematic review of published reports found that the shoulder orthoses that provide the greatest shoulder subluxation reduction is the Wh-S, followed by the P-D-S and, finally, the P-S type. Although the P-D-S type reduces subluxation slightly less than the Wh-S type, unlike the Wh-S orthosis, it does not limit elbow motion,[11,12] allowing the elbow to move more naturally. However, the P-D-S type shoulder orthoses are not available in Thailand and imported P-D-S orthoses are expensive.

At our institute, only the Bobath sling (P-S type) is widely available and generally prescribed for stroke patients in spite of its limitations, i.e., according to several studies, the P-S shoulder orthosis is unable to clinically significantly reduce shoulder subluxation.[13] An occupational therapist (BC) on

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our rehabilitation team recently designed a custom-fitted shoulder subluxation orthosis (SSO). The SSO, classified as a P-D-S type, can be made from locally available materials, making it both easily accessible and inexpensive. The objective of this study was to evaluate the efficacy of the SSO and to compare it with the Bobath sling in reducing shoulder subluxation in hemiplegic/hemiparetic stroke patients.

Methods

Study design

This single-blinded crossover randomized controlled trial was approved by the Institutional Review Board, Faculty of Medicine, Ramathibodi Hospital (approval number ID 12-60-02).

Participants

Post-stroke patients at our hospital with the following characteristics were recruited during March to December 2018: shoulder subluxation more than 5 mm as measured by physical examination; able to sit without support for at least 30 minutes and willing to participate in the study, including giving written informed consent. Patients were excluded if they had bilateral hemiplegia, were unable to communicate, had neurological, muscular or bone conditions other than stroke that affected movement of the shoulder, or declined participate in the study. The sample size was calculated with the power of 0.8, 5% type I error and 20% type II error, resulting in total of 16 subjects.

Materials

The newly designed custom-fitted SSO was made using ethylene vinyl acetate (EVA) foam sheet, canvas fabric, cloth straps, elastic bands, 3 oval loop rings, Velcro straps, a tape measure, scissors and a sewing machine. The device is divided into proximal and distal parts (Fig. 1). The proximal part rests on the weak or hemiplegic shoulder and the strap from the posterior crosses under the opposite axilla to the front. The distal part wraps around the forearm and is connected to the proximal part by anterior and posterior straps. The posterior strap also passes behind elbow. All straps are adjustable. The cost is about 400-500 baht and requires about 45-60 minutes to make. A petty patent has been applied for with the Department of Intelletual Property, Ministry of Commerce, Thailand (application number 2103000837 Date March 19th, 2021).

The commercial Bobath slings used in the study are available in 3 sizes, small, medium and large, with the appropriate size is determined based on the circumference of the mid arm.

Intervention

The objectives of the study and the research methods were explained to all participants. Patients were randomly assigned to first apply either the SSO or the Bobath sling to the affected shoulder, then later to apply the other type. Randomization was done using a sealed envelope method. Application of both orthoses was done by the same occupational therapist assistant who had been previously trained by a qualified occupational therapist. The rest time between each orthosis application was 5-10 minutes during which participants sat with their arm hanging at the side of their body.

Four anteroposterior radiographs of both shoulders in sitting position (Fig. 3) were taken, the first and the second without any shoulder orthosis, the third and the fourth with either the SSO or the Bobath sling according to the randomization. The acromiohumeral (AH) distances were measured by a radiologist who was blinded to the type of orthosis used.

Demographic data, including age, gender and medical history, were collected. Participants assessed their level of pain using a visual analog scale (VAS), and the researcher (PP), a physiatrist, assessed shoulder range of motion (ROM), muscle tone using modified Ashworth Scale (MAS) and the muscle strength of the deltoid muscle.

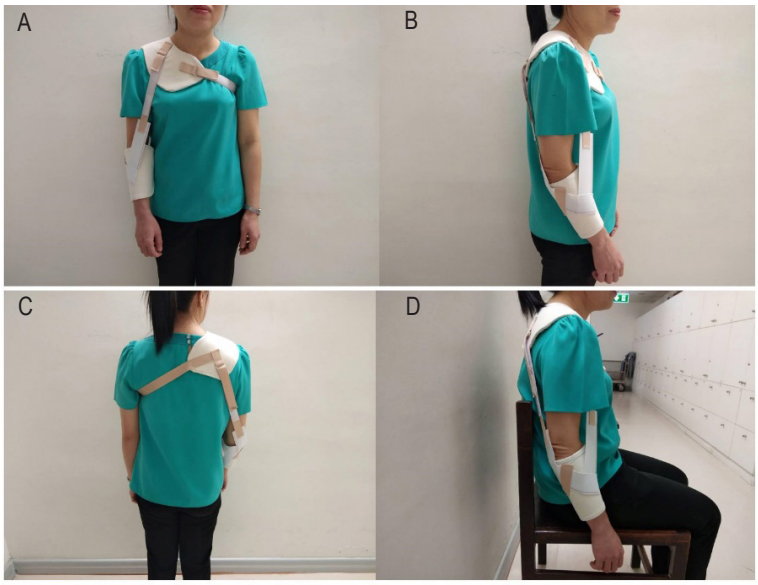

Figure 1. The newly designed shoulder subluxation orthosis in anterior (A), lateral (B) and posterior view (C), and sitting position for radiographs (D)

Figure 2. The Bobath sling in anterior (A), lateral (B) and posterior view (C), and sitting position for radiographs (D)

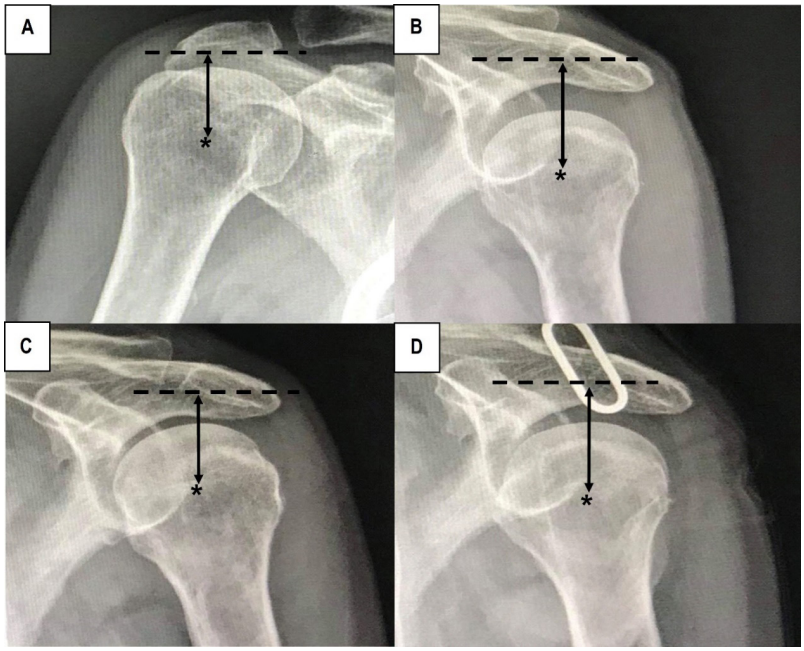

Figure 3. The acromiohumeral (AH) distance measurement in anteroposterior view of a shoulder radiograph: (A) normal shoulder, (B) affected shoulder without orthosis, (C) affected shoulder wearing a shoulder subluxation orthosis (SSO), (D) affected shoulder wearing a Bobath sling. In the figures, an asterisk * marks the center of the humeral head, a double arrow line represents the AH distance, and a horizontal dotted line shows the most inferolateral level of the acromioclavicular joint.

Outcome measurements

The primary outcome of this study was the AH distance, the vertical distance from the most inferolateral surface of acromioclavicular joint to the center of humeral head (Fig. 3).[16]

Statistical analysis

SPSS version 21 was used for data analysis. The demographic data were defined using descriptive statistics, i.e., frequency, mean and standard deviation (SD). The AH distance between the normal and affected shoulders, the AH distance of the affected shoulder without a shoulder orthosis and wearing each type of shoulder orthosis, and the difference in AH distance between the two orthoses was analyzed using the paired t-test. The statistical significance level was set at a $p < 0.05$.

Results

Table 1 shows the demographic characteristics and clinical findings of the 16 stroke participants.

The normal and the affected shoulders had a mean AH distance (SD) of 36.2 (4.6) and 47.9 (7.5) mm, respectively. Table 2 shows the AH distance while wearing the different orthoses. The AH distance of the affected shoulder was reduced significantly when wearing both orthoses; however, the AH distance with the SSO approached that of the normal shoulder ($p = 0.49$), but not with the Bobath sling ($p < 0.01$). The mean distance reduction was significantly greater with the SSO than with the Bobath sling (11.1 vs 3.0 mm, $p < 0.01$).

Discussion

In this study, the efficacy of the SSO, our newly designed custom-fitted P-D-S shoulder orthosis, was evaluated and

Table 1. Demographic data (n = 16)

Characteristics	
Age (years)[1]	61.5 (12.1) [37.0-77.0]
Sex (male : female)[2]	10 : 6
Affected side (right : left)[2]	4 : 12
Shoulder pain VAS score[3]	2.7 (2.2)
Etiology of stroke (ischemic : hemorrhagic)[2]	12 : 4
Affected shoulder ROM[3]	
Flexion : abduction	137.5 (31.7) : 140.6 (31.3)
Internal rotation : external rotation	65.0 (24.2) : 71.9 (28.2)
Affected shoulder spasticity[2]	
MAS 0-1	8
MAS 1+	8
Manual muscle test of deltoid muscle[2]	
Grade 0-1	5
Grade 2	11
Time since diagnosis (months)[3]	5.8 (3.8)

[1]Mean (SD) [range], [2]number, [3]mean (SD)

MAS, modified Ashworth scale; ROM, range of motion; SD, standard deviation; VAS, visual analog scale

Table 2. Acromiohumeral (AH) distance in millimeters (mm) of the normal and affected shoulders and AH distance reduction while wearing the shoulder subluxation orthosis (SSO) and the Bobath sling

AH distance (mm)				AH distance reduction (mm)	
Normal shoulder	Affected shoulder			Affected shoulder	
	Without orthosis	With SSO	With Bobath sling	With SSO	With Bobath sling
36.2 (4.6)	47.9 (7.5)	36.8 (4.7)[a,b] $p < 0.01$[a] $p = 0.49$[b]	44.9 (7.7)[a,b] $p < 0.01$[a] $p < 0.01$[b]	11.1 (5.2)[c] $p < 0.01$[c]	3.0 (2.4)

Mean (SD)

Paired t-test statistical significance level < 0.05, [a]comparison between with and without orthosis, [b]between the affected and normal shoulders, and [c]between using the SSO and the Bobath sling

compared to the Bobath sling which is a P-S type. We found that both types of shoulder orthoses could reduce shoulder subluxation in stroke patients. However, support from the SSO could reduce the AH distance much more than the Bobath sling, approaching the distance of the normal shoulder. The results of this study are in congruence with a previous systemic review study which reported that application of P-D-S and Wh-S shoulder orthoses for the hemiplegic shoulders can help in reducing shoulder subluxation better than P-S type orthoses.[11,12]

In our study, the Bobath sling was shown to reduce shoulder subluxation statistically significantly, but not clinically significantly, which is in line with a previous study.[13] The upward force to support the upper extremity relies only on the proximal support wrapped around the arm. The arm is cylindrical in shape and is composed predominantly of soft tissue. As a consequence, the upward force is not transferred to the bone effectively. This is probably the cause of the lower efficacy of the Bobath sling compared to the P-D-S type.

To the best of our knowledge, two designs of P-D-S are available, GivMohr® sling and OmoNeurexa, both of which have been studied for their efficacy. The GivMohr® sling can decrease shoulder subluxation better than the Rolyan humeral cuff, a P-S type, which cannot significantly reduce shoulder subluxation. The GivMohr® sling is also able to reduce the AH distance closer to that of the normal shoulder side.[17,18] The other P-D-S type shoulder support, OmoNeurexa, can also reduce shoulder subluxation by approximately 8 mm, statistically significantly more than the Bobath sling.[11,15,17]

The other type of shoulder orthosis, the Wh-S type, includes the Harris Hemi Sling and the ordinary triangular bandage. A systematic review showed that the Wh-S type can provide the greatest reduction in shoulder subluxation among the three types, but it restricts the elbow to the bent position which probably increases spasticity and may even cause elbow flexion contracture.[11,12,17] In contrast, the P-D-S and P-S types allow the elbow to move freely, thus permitting the upper extremity to swing naturally during ambulation. As a result, application of Wh-S is limited. Overall, the P-D-S shoulder orthosis seems to be the best for subluxation in hemiplegic shoulders. However, the GivMohr® sling and OmoNeurexa are not generally available in Thailand and the cost of importing these items is high. Our rehabilitation team designed a new P-D-S orthosis, the SSO, which provides good efficacy and can be custom made for each patient in less than an hour from available materials and at an affordable cost.

The probable mechanisms behind the superior efficacy of the SSO may include the following. The distal support grabs the forearm well because there is less soft tissue around the forearm bones so. That, together with the anterior and posterior straps connected to the proximal part providing upward force, transfers more of the orthosis support to the bone. The posterior strap, which passes behind elbow, pushes the elbow into extension, transferring the upward force to the shoulder more effectively. The upshot is that the shoulder joint is adequately supported and subluxation is reduced.

The SSO and the P-D-S type shoulder orthoses, GivMohr® sling and OmoNeurexa, both utilize a similar mechanism. The SSO is similar to the OmoNeurexa, but there are differences in the designs. The proximal and distal support of both types of orthoses have a large contact surface area, and hence provide good force distribution. However, the OmoNeurexa requires more adjustment to fit the device to the individual patient, thus making it potentially more problematic to put on. The GivMohr® sling, unlike the SSO, provides proximal support from the shoulder harness and distal support at hand. However, the proximal and distal support of GivMohr® sling both have less contact surface area and thus less distribution of force which may negatively affect wearer comfort. Each of these 3 P-D-S type shoulder orthoses are different in design, proximal and distal support, and points of adjustment. Only the SSO can be custom-made for each patient, making it fit more comfortably, even for patients with extremely small or large body size, and allowing easier adjustment during donning.

This research demonstrated only the immediate effects of the SSO. Previous studies of long-term effects of shoulder orthosis wear by stroke patients has revealed that wearing an appropriate shoulder orthosis continuously for more than 4 weeks can improve gait pattern by normalizing muscle activation and allowing more symmetrical walking.[11,15,19] Further research on the long-term efficacy of the SSO, including not only reduction of shoulder subluxation and pain, but also evaluation of patients' walking and balance, level of satisfaction, convenience in donning and doffing, and compliance with long term use recommendations as well as durability of the orthotic itself are suggested.

Conclusions

The newly designed custom-fitted shoulder subluxation orthosis, which is classified as a proximal-distal-support type, can significantly reduce shoulder subluxation both statistically and clinically more than the Bobath sling, a proximal-support type. The SSO can effectively support the affected upper extremity and can reduce the acromiohumeral distance close to that of the normal, unaffected shoulder.

Disclosure

The authors declare no conflict of interest of any kind.

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