

Evaluation Of Comfort And User-Friendliness Of Immobilizing Internal Rotation-Adduction Shoulder Braces

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Internal rotation-adduction shoulder braces are commonly used to immobilize the shoulder following surgery. This prospective, interventional study aimed to evaluate the comfort and user-friendliness of four such braces frequently employed in postoperative care. Four braces—Shoulder Support[®], Actimove Umerus Comfort[®], Shouldfix II[®], and Shoulder Fix[®]—were assessed across four medical centers. Patient comfort was evaluated using a 14-item Likert scale questionnaire (maximum score: 70). Additionally, 53 healthcare professionals rated each brace’s user-friendliness using a separate 5-question survey. A total of 166 patients were included in the analysis. All four braces received favorable comfort ratings. Shoulder Support[®] achieved the highest comfort score (60.73), significantly outperforming Actimove[®] (56.12) and Shouldfix II[®] (56.38). Regarding user-friendliness, Shoulder Support[®] (3.89) and Actimove[®] (3.79) were rated significantly higher than Shoulder Fix[®] (2.99) by healthcare professionals. To conclude, all braces demonstrated good overall comfort, with Shoulder Support[®] emerging as the most preferred by patients. In terms of ease of use, both Shoulder Support[®] and Actimove[®] were favored by healthcare providers. These results highlight the dual importance of patient comfort and clinical practicality in selecting postoperative shoulder braces.

Keywords: Shoulder surgery, brace, user-friendliness.

INTRODUCTION

Following shoulder surgery, temporary immobilization of the shoulder joint is often necessary to support healing and improve patient comfort. Internal rotation-adduction braces are commonly used for this purpose, providing effective immobilization not only during postoperative recovery but also in the non-operative management of acromioclavicular and glenohumeral (sub)luxations, as well as fractures of the clavicle or proximal humerus¹⁻¹².

The primary objective of using internal rotation-adduction braces is to ensure optimal immobilization of the shoulder joint in the correct anatomical position. In addition to their functional effectiveness, the comfort and user-friendliness of these orthotic devices are critical factors influencing patient satisfaction and adherence to prescribed use¹³⁻¹⁸. Notably, previous studies have revealed a substantial gap -up to 80% - between expected and patient-reported compliance rates¹⁹. This discrepancy is often attributed to commonly

reported issues such as nocturnal discomfort, neck pain, skin irritation, muscle weakness, and difficulties with donning or doffing the brace^{20,21}.

Despite the clinical importance of these factors, there is a notable lack of research specifically evaluating the comfort and usability of different internal rotation-adduction shoulder braces. Therefore, the aim of our study was to systematically assess and compare the comfort and user-friendliness of four widely used internal rotation-adduction braces in the postoperative context. This evaluation integrates feedback from both patients and healthcare professionals to offer a comprehensive perspective on the practical aspects of brace application and wearability.

METHODS

In a prospective interventional study with a cross-sectional design, four distinct shoulder braces (Shoulder Support[®], Actimove[®], Shouldfix II[®], and Shoulder Fix[®], see Figure 1) were evaluated across

			
Shoulder Fix® Medi Price: +/- € 80 Image source: https://www.medi.nl/producten/medi-arm-fix/	Actimove Umerus Comfort® BSN Medical Price: +/- € 27 Image source: https://www.actimove.com.au/products/shoulder-and-arm/professional-line-umerus-comfort-shoulder-immobilizer	Shouldfix II® Orthoservice RO+TEN Price: +/- € 40-55 Image source: https://www.orthoservice.com/en/products/1692/shouldfix-ii	Shoulder Support® Promedionics Price: +/- €30
Product name, manufacturer and estimated prices for private buyers based on online research at the time of the study.			

Fig. 1 — Overview of the four shoulder braces used in this study.

four centers in a multicenter setting. The participating centers included Ghent University Hospital, AZ Sint-Lucas Ghent, AZ Sint-Jan Bruges, and AZ Sint-Lucas Bruges. The study focused on two main groups: patients requiring shoulder surgery (open or arthroscopic) for shoulder pathology (bone injury, joint injury, and/or musculotendinous injury) with a postoperative immobilization period of at least one week using an internal rotation–adduction brace, and healthcare professionals (orthopaedic surgeons, residents, nurses) responsible for applying the brace postoperatively. Only elective cases in patients aged 18 or older were consecutively included, and basic demographic information was collected at admission. The randomization method employed was based on chronology, as a randomized controlled trial design was not feasible due to practical reasons. Hospital 1 started with brace 1, first 12 patients received brace 1; next 12 patients received brace 2, hospital 2 started with brace 2, first 12 patients received brace 2; next 12 patients received brace 3, ... last 12 patients received brace 1, ...). Patients had to wear the shoulder brace continuously for at least 3 consecutive days after surgery.

A patient questionnaire comprising 14 statements, including ten related to wearing comfort and user-friendliness and four addressing the physical burden of the brace, was developed based on frequently reported comfort problems in literature and expert opinion^{14,16-18,22-29}. Participants rated these statements on a Likert scale from 0 to 5, with an overall maximum

score of 70. To minimize scoring bias, positive and negative statements were alternated, and patients completed the questionnaire in the postoperative period through a structured telephone interview.

To account for the influence of pain and shoulder functionality on the comfort scores reported by patients, a Patient Reported Outcome Measure (PROM) was conducted using the Simple Shoulder Test (STT) before shoulder surgery^{30,31}. Statistical analysis, executed using SPSS software version 28, involved the Shapiro-Wilk test to assess normal distribution, the Kruskal Wallis test to compare means between different groups or question-related differences per brace, and a Pearson correlation coefficient was used to analyze correlation between STT score and total questionnaire scores. The level of statistical significance was set at $p < 0.05$.

A parallel questionnaire, consisting of 5 statements, was designed for healthcare professionals to assess the user-friendliness of the shoulder brace when applied postoperatively. A one-way ANOVA analysis was used to compare means of the overall score on this questionnaire, followed by a Tukey post-hoc test. The level of statistical significance was set at $p < 0.05$.

RESULTS

A total of 166 patients were analyzed (30 patients lost for follow-up) (Table I). No significant differences were found between the four different braces regarding participants' age, BMI, weight, height, score on the

Table I. — Demographic data and variables: mean (standard deviation).

	Total	Actimove Umerus Comfort	Shoulder Fix	Shouldfix II	Shoulder Support
Number of patients (n (%))	166 (100%)	40 (24,1%)	45 (27,1%)	39 (23,5%)	42 (25,3%)
Sex (male/female)	81/85	21/19	19/26	20/19	21/21
Age (years)	54,01 (13,09)	52,85 (13,62)	55,27 (13,81)	52,51 (12,86)	56,07 (11,90)
BMI (kg/m ²)	27,25 (4,71)	27,06 (4,34)	27,53 (4,80)	26,70 (4,81)	27,70 (4,99)
SST score	4,45 (2,81)	4,57 (3,38)	4,29 (2,70)	4,81 (2,79)	4,33 (2,79)
Righthanded (yes/no)	145/13	39/1	39/2	31/6	36/4
Brace side (right/left)	91/68	17/23	29/12	16/22	23/17
Brace on dominant arm (yes/no)	99/59	23/17	31/10	20/17	25/15

Note: Missing data for BMI (4,8%, n=7), right/left handed (4,8%, n=8), brace side (4,2%, n=7), brace dominant arm (4,8%, n=8), SST score (9,9%, n=15). Abbreviations: BMI = body mass index, SST = simple shoulder test.

SST, gender, dominant arm, brace arm, or surgery taking place on the dominant side.

No significant correlation was found between the scores on the SST questionnaire and the overall score on the comfort questionnaire (Pearson Correlation coefficient 0,154 ; $p=0,058$)

The overall score of The Shoulder Support[®] (42 patients) (60.73; SD 8,35) was significantly better than the Actimove[®] (40 patients) (56.12; SD 8,98, $p = 0,007$) and the Shouldfix II[®] (39 patients) (56.38; SD 7,61, $p = 0,005$), and not significantly better than the Shoulder fix[®] (45 patients) (57,76; SD 8,41, $p = 0,057$). After further analysis, there was no significant difference between the Shouldfix II[®], Actimove[®], and Shoulder Fix[®]. When comparing individual scores per question (on 5 points), the question regarding comfort during the night and the question on freeing the forearm to move the elbow was significantly better in patients with the Shoulder Support[®]. Patients with the Shouldfix II[®] had significantly less difficulty putting on the brace.

The analogous questionnaire (5 questions) analysing user-friendliness for healthcare providers was filled in by a total number of 53 healthcare professionals, of which 46 in Ghent University Hospital, 3 in AZ Sint-Lucas Bruges and 4 in AZ Sint-Jan Bruges. Of these questionnaires, 14 were completed by orthopaedic surgeons, 20 by orthopaedic surgery residents, 6 by candidate residents and 13 by nurses. The average score means score out of 5 points for user-friendliness from the perspective of the healthcare professional was significantly different between the four braces. Post-hoc analysis showed that the Shoulder Fix (2,99, SD 0,85) scored significantly lower than both the Actimove Umerus Comfort (3,79. SD 0,61; $p=0,022$) and the Shoulder Support (3,89; SD 0,39; $p=0,008$). Also, the Shoulder Support scores higher than the Shouldfix II (3,10; SD 0,86; $p=0,038$). No other

significant differences in mean scores between the four braces were found for this questionnaire.

DISCUSSION

This study aimed to assess the user-friendliness and comfort of four distinct commercially available internal-rotation adduction shoulder braces in Belgium, providing valuable insights for orthopedic surgeons in choosing appropriate shoulder braces for post-operative immobilization. Notably, no prior studies have explored the comfort of immobilizing internal rotation-adduction shoulder braces, preventing direct comparisons with existing research. Consequently, the results of this study lack a comparative reference to previous investigations.

The questionnaires administered yielded high scores for all four braces (>56 out of 70 points) from the participating patients. Specifically, the Shoulder Support[®] achieved a significantly higher total score compared to the other three braces, although these three did not show significant differences in scores among themselves. However, it's essential to note that the statistically significant variance in total scores was less than 5 points on a 1 to 70 scale, which may not carry clinical significance.

No correlation was identified between the preoperatively calculated SST score and the outcomes from our patient comfort questionnaire (Figure 2). From this, we can infer that preoperative shoulder functionality did not exert any influence on the perceived comfort of a shoulder brace postoperatively. Both the Actimove[®] and Shoulder Support[®] significantly outperformed Shoulder Fix[®] and Shouldfix II[®] in terms of overall user-friendliness, as perceived by healthcare professionals. However, it's crucial to acknowledge a potential bias in this result, given that Actimove[®] and Shoulder Support[®]

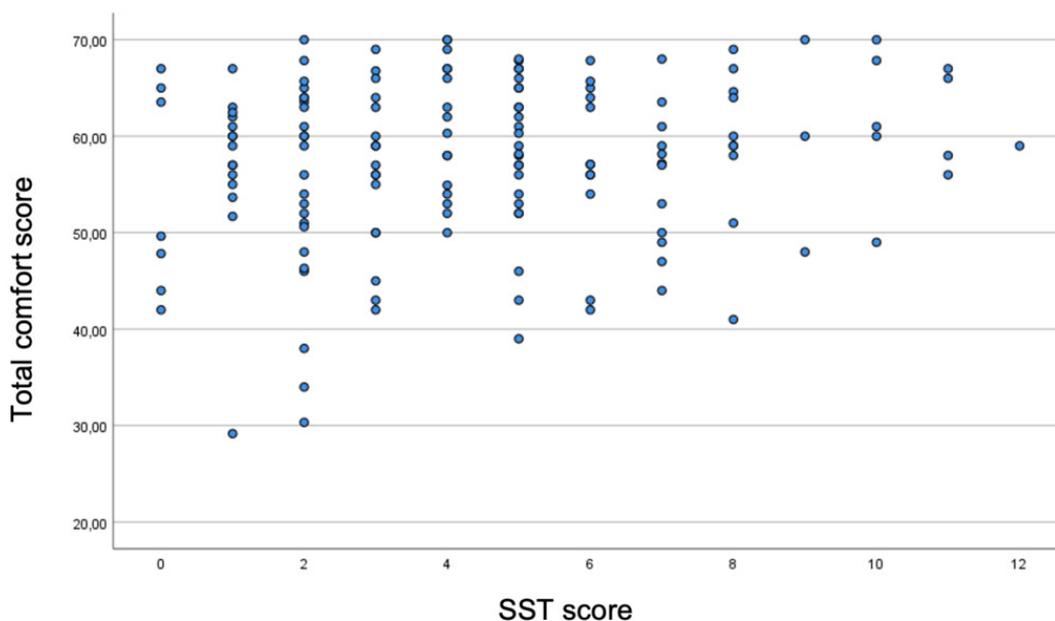


Fig. 2— Scatterplot showing no significant correlation between total score out of 70 on the comfort questionnaire and SST score out of 12 points.

were already familiar to healthcare personnel from the participating hospitals prior to the study.

A notable strength of this study is its exclusive focus on participants with shoulder pathology. In contrast, many previous studies often used healthy test subjects to evaluate orthopedic device comfort. The absence of surgery or pathology-related pain in healthy subjects could potentially interfere with their interpretation of comfort. Another strength lies in the extended duration over which participants wore and evaluated the braces. Monitoring comfort over a period of at least 3 days of use provides a more realistic perspective compared to the shorter wear times commonly used in similar studies, typically lasting only a few minutes to hours^{13,22,32,33}.

Patient groups for each of the four brace types were comparable in various aspects, including age, gender, BMI, weight, height, SST score, dominant arm, brace arm, and surgery on the dominant side. As a result, we believe that these characteristics did not influence the scores of the braces in the study.

The study’s findings may offer manufacturers of shoulder braces new insights into how their products are experienced by both patients and healthcare professionals. However, it’s important to note that the four shoulder braces discussed in this study represent only a limited selection from the extensive range of commercially available immobilizing shoulder braces. Different companies offer their own variations of several models, such as the “sling and swathe” model, exemplified by the Shouldfix II® in

this study. The results for Shouldfix II® should be interpreted specifically for this product and can only be partially generalized to similar models from other manufacturers, considering potential variations in materials and minor design differences that may affect comfort.

However, several limitations exist. The study concentrated on subjective factors, neglecting considerations like a brace’s impact on functional outcomes, recovery time, and financial costs. The exclusion of urgent or traumatic shoulder surgeries limits the study’s representativeness. Questionnaires, though developed for this study, lack prior validation, potentially overlooking crucial shoulder brace characteristics. Social desirability bias risk was higher due to telephone administration.

In conclusion, this study offers insights into patient and healthcare professional perceptions of shoulder braces, but its limitations underscore the need for comprehensive evaluations encompassing broader factors in practical settings.

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