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## Conservative treatment of Rockwood type III acromioclavicular joint separation: a randomized controlled trial sling vs. brace

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**Background:** Management of Rockwood III acromioclavicular joint separations is a matter of ongoing debate, with nonoperative treatment being favored in recent literature. The aim of this study is to compare clinical and radiological outcomes of nonoperative treatment with a brace, which elicits a direct reduction force to the distal clavicle, to a sling. We hypothesized the brace might yield in better acromioclavicular joint (ACJ) reduction and cosmesis.

**Methods:** In this dual center prospective randomized controlled trial, all patients sustaining an acromioclavicular joint separation Rockwood III between July 2017 and August 2020 were included. Patients with previous ipsi- or contralateral ACJ injury or surgery were excluded. Randomization occurred in the emergency department to either the sling or brace group. Patients were followed up at 1, 6, and 12 weeks. Patient-reported outcome measures included subjective shoulder value (SSV) and American Shoulder and Elbow Surgeons (ASES) score at each follow-up and Constant Score at 6 and 12 weeks. Vertical distal clavicle displacement was assessed on bilateral non-weighted panoramic anteroposterior radiographs using coracoclavicular (CC) distance to calculate the CC-index.

**Results:** Thirty-five consecutive patients were included across the 2 sites, 18 (all male) in the brace and 17 (14 male) in the sling group. Baseline characteristics did not differ significantly between groups, the average age was 40 years, and body mass index 25.5 kg/m<sup>2</sup>. Analysis revealed no statistical difference in CC-index between groups at the time of injury, 6 weeks and 12 weeks postinjury ( $P = .39$ ,  $P = .11$ , and  $P = .21$ ). SSV improved from 30 and 35 postinjury to 81 and 84 at 12 weeks in the sling and brace group, respectively ( $P = .59$ ). ASES improved from 48 and 38 to 82 and 83, respectively ( $P = .84$ ). Similarly, Constant Score improved from 64 and 67 to 82 and 81, respectively ( $P = .90$ ). One patient in the brace group underwent ACJ stabilization with hamstring autograft at 4 months due to persistent pain.

**Conclusion:** This randomized controlled trial shows no statistically significant difference between the brace and sling group in clinical (SSV, ASES, Constant Score) or radiological (CC-index) outcomes after conservative treatment of Rockwood III injuries.

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Acromioclavicular joint separations (ACJS) account for up to 41% of athletic shoulder injuries,<sup>11</sup> mainly affecting young men. ACJS have been classified by the Tossy et al<sup>30</sup> and Allman in the 1960s<sup>1</sup>

Ethical approval was obtained from Swiss ethics EKNZ 2017-00670 and the trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) NCT03261778. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

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and were updated by Rockwood in 1989.<sup>35</sup> While low-grade ACJS (Rockwood I-II) are commonly treated conservatively, high grade injuries (Rockwood IV-VI) are traditionally surgically repaired with a multitude of techniques described.<sup>18</sup> There is an ongoing debate of optimal treatment of Rockwood III injuries,<sup>6,12,32</sup> where coracoclavicular (CC) and acromioclavicular (AC) ligaments are ruptured resulting in a vertical proximal displacement of the distal clavicle and visual cosmetic deformity especially in slender patients. Conservative treatment of Rockwood III injuries is being favored over surgical intervention<sup>10</sup> for most patient groups in the recent literature due to quicker return to work and similar outcomes in terms of pain and function, while avoiding surgical

complications.<sup>2,4,14,16,23,26,27</sup> Furthermore, it is more cost effective than surgical treatment.<sup>7</sup> However, cosmetic deformity is better addressed by surgery and remains an issue in some conservatively treated patients.<sup>4,29</sup>

The literature has reported multiple options of maintaining reduction of the lateral clavicle. These include the traditional spica cast,<sup>30</sup> bracing,<sup>31,36</sup> and taping.<sup>20</sup> While casting and braces of the “Kenny Howard” type are restrictive and bulky, taping can lead to skin reactions and therefore reduce patient compliance.<sup>3</sup> Furthermore, there is no guarantee that the acromioclavicular joint (ACJ) will remain reduced.<sup>33,36</sup> With the aim to restore function, current conservative treatment consists of short shoulder immobilization in a sling for 1–2 weeks, followed by early range of motion, physiotherapy, and functional training.<sup>19</sup> Even though multiple studies have shown good functional outcomes<sup>14,23,25</sup> the anatomy of the ACJ is not restored and a prominent, potentially cosmetically disturbing or unstable distal clavicle will remain.<sup>4</sup> Recently, a case report<sup>15</sup> on the conservative treatment of a high-grade Rockwood V injury with a brace eliciting depression on the distal clavicle and humeral elevation showed healing of the injury in a reduced Rockwood II position, suggesting the efficacy of such a brace when worn for 6 weeks in combination with a restrictive physiotherapy protocol. Up to date, there is no study looking at the effect of this modern brace in the treatment of Rockwood III injuries in comparison to the standard sling treatment.

Our hypothesis was that this modern brace leads to superior cosmetic results, better radiological reduction of ACJS as well as better pain control and clinical scores. We therefore aimed to compare patient satisfaction, radiological outcomes as well as subjective and objective shoulder function in a randomized controlled trial between a sling and a brace group.

## Materials and methods

We conducted this dual center prospective randomized controlled trial between July 2017 and August 2020 in 2 trauma center hospitals in Switzerland. The trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03261778) and ethical approval was

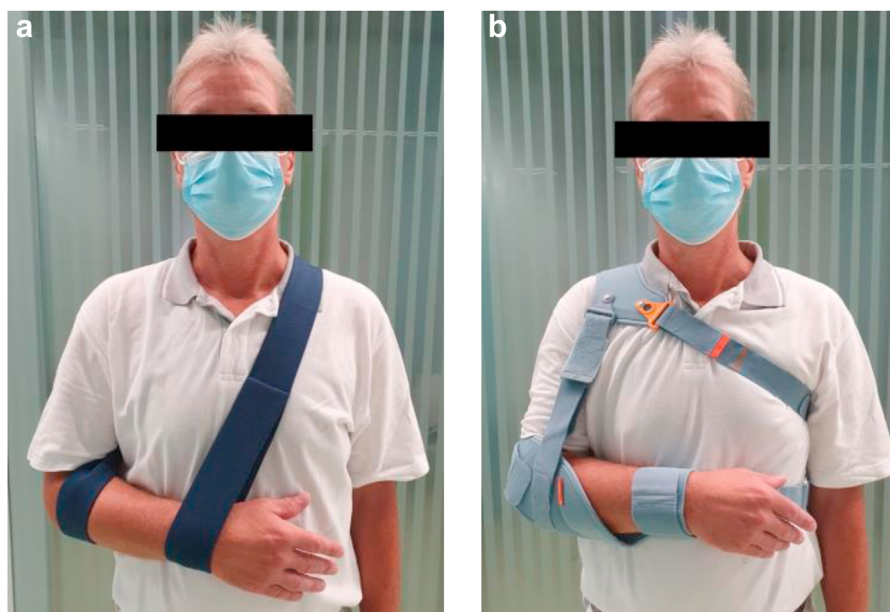
obtained through Swiss Ethics prior to patient enrollment (EKNZ 2017-00670).

Adult patients (>18 years) with an acute (within 7 days) Rockwood III AC joint separation were included in the study. Upon presentation in the emergency department, the patients were seen by junior medical staff and discussed with one of the authors (M.F., M.L.D.T, D.H.) to confirm the diagnosis for inclusion in the study. Exclusion criteria were higher grade injuries, previous injury and/or surgery to the same or contralateral ACJ, pregnancy, and allergy to brace/sling material.

Treatment options (surgical and non-surgical) were discussed with all eligible patients. Based on current literature, our standard practice is to treat all grade III injuries conservatively and proceed with surgical treatment only in case of persistent significant symptoms. After obtaining informed consent to participate in the study, patients were randomized into the brace or sling group after by picking an enclosed envelope in the emergency department.

The sling (Fig. 1, a) or brace (Acromion 2.0; Orthoservice AG, Chiasso, Switzerland) (Fig. 1, b) were then fitted by an orthopedic technician. The brace included a broad shoulder pad which is connected to the elbow by an adjustable strap, allowing ACJ reduction through depression of the distal clavicle and elevation of the humerus. Patients were discharged with appropriate oral analgesia, instructed to tighten the brace as tolerated and to wear it day and night for 6 weeks. They were allowed to take it off to shower, range their elbow and perform gentle pendulum exercises of the shoulder for 30 minutes/d. The sling group was instructed to wear the sling for comfort and start gentle range of shoulder and elbow once pain allowed. Adverse events were recorded.

Patients were followed up by one of the local authors (M. F., M.L.D.T, D.H.) clinically and radiologically at 1-, 6-, and 12-weeks post injury. Patient-reported outcome measures included subjective shoulder value (SSV), with 0% being worst and 100% best values, American Shoulder and Elbow Surgeons (ASES) score,<sup>17</sup> ranging from 0 to 100 (50% visual analog scale pain score weighing plus a 10 item 4-point likert scale) at each follow-up and Constant Score,<sup>5</sup> ranging from 0 as worst and 100 as best shoulder function (including pain, function, strength, and range of motion) at 6 and 12 weeks.



**Figure 1** (a) Patient wearing sling. (b) Patient wearing Brace.

**Table I**  
Demographics.

	AC brace	Mitella	P value
N	18	17	
Male: female	18:0	14:3	
Age (y)	39 ± 13	41 ± 16	.712
Height (cm)	180 ± 6	176 ± 10	.221
Weight (kg)	82 ± 11	79 ± 12	.548

AC, acromioclavicular.

Standard anteroposterior and axial radiographs of the injured side as well as bilateral non-weighted panoramic anteroposterior views as described by Zanca<sup>37</sup> were obtained at initial presentation and standard follow-ups without patients wearing the brace or sling. An independent radiographer blinded to the patients group allocation measured CC distance bilaterally and calculated CC-index (CC injured/CC healthy) at each visit. As defined by Rockwood,<sup>21</sup> a grade III injury corresponds to a 25%-100% increase in CC distance. The used measurements have been reported to be reliable and reproducible.<sup>8,24</sup>

**Statistical analysis**

A sample size of minimum 16 per group was calculated to detect a minimal clinically important difference for the Constant Score of 10.4<sup>13</sup> and ASES score of 6.4<sup>17</sup> with a power of 80% and alpha 0.05. Statistical analysis has been performed using SPSS Statistics (SPSS; IBM Corp., Armonk, NY, USA). Continuous variables were reported as average and standard deviation. Categorical variables are reported as numbers and percentages. P values < .05 were considered statistically significant for all statistical tests.

**Results**

We included 35 patients, 18 (18 male) in the AC brace and 17 (14 male, 3 female) in the sling group. All patients received treatment within 3 days of sustaining the injury. One female patient in the sling group had to be excluded, because she turned out to have a Rockwood V injury diagnosed only at the 6-week follow-up. There was no statistical difference in age (39 years vs. 41 years, P = .71), height (180 cm vs. 176 cm, P = .22), and weight (82 kg vs. 79 kg, P = .55) (Table I) at baseline. Comparing the CC-index at time of injury, 6 weeks and 12 weeks postinjury, there was a more pronounced tendency toward temporary reduction of the CC-index at 6 weeks in the AC brace group but without statistical difference compared to the sling group (P = .39, P = .11, and P = .21) (Table II). No significant difference was found comparing the SSV preinjury, 1 week, 6 weeks, and 12 weeks postinjury (P = .34, P = .47, P = .90, and P = .59). For the ASES score, we observed a slightly better score at one week post injury in the AC brace group compared to the sling group, but without statistical significance (48 ± 14 vs. 38 ± 19, P = .100). At 6 weeks and 12 weeks postinjury, the ASES and the Constant Score showed no statistical difference between the AC brace and the sling group (P = .75, P = .84, P = .64, and P = .90) (Table III).

One patient treated with the AC brace underwent operative stabilization with autologous gracilis tendon 4 months postinjury due to persistent pain. Another patient in the AC brace group suffered from prolonged pain after 3 months, which was explained by an additional not displaced intra-articular lateral clavicle fracture seen in the magnetic resonance imaging performed 2 months postinjury. No adverse events related to the injury or to the immobilization technique was reported.

**Table II**  
CC-index.

CC-index	Time of injury	6 weeks	12 weeks
AC brace	2.03 ± 0.46	1.78 ± 0.50	1.95 ± 0.53
Sling	2.20 ± 0.69	2.12 ± 0.65	2.21 ± 0.66
P value	.386	.111	.214

AC, acromioclavicular; CC, coracoclavicular.

**Table III**  
Functional outcome scores.

Functional outcome scores	Pre injury	1 week	6 weeks	12 weeks
SSV				
AC brace	99 ± 5	30 ± 19	64 ± 22	81 ± 16
Sling	100 ± 0	35 ± 20	63 ± 27	84 ± 15
P value	.339	.467	.909	.590
ASES				
AC brace	-	48 ± 14	67 ± 18	82 ± 22
Sling	-	38 ± 19	65 ± 24	83 ± 16
P value		.100	.751	.839
Constant Score				
AC brace	-	-	64 ± 21	82 ± 17
Sling	-	-	67 ± 21	81 ± 16
P value			.638	.901

AC, acromioclavicular; ASES, American Shoulder and Elbow Surgeons; SSV, subjective shoulder value.

**Discussion**

In this prospective randomized study, we compared the conservative treatment of Rockwood III injuries with a specific AC brace, which is designed to reduce the lateral clavicle, to a common sling and failed to show a difference in clinical and radiological outcomes between the methods of immobilization.

We hypothesized that the novel AC brace would allow for partial reduction of the ACJ deformity through depression of the lateral clavicle and elevation of the humerus not only in the acute stage, but also long-term. However, the radiological assessment with measurement of the CC index showed only a slight difference without statistical difference in the AC brace group compared to the group treated with a sling at any time of evaluation until 3 months post injury. Maleitzke et al<sup>15</sup> recently published a case report using the same AC brace in a 31-year-old male for a Rockwood V injury. In contrast to our results, they described a nearly anatomic reduction after 6 weeks of immobilization following the same treatment protocol. While a case report might not be compelling evidence, we could not find any further studies evaluating the outcome of a similar brace in the literature.

We further hypothesized that the added support with the AC brace compared to a sling immobilization would allow for better pain control and clinical outcomes. However, our clinical assessment with both patient-reported outcome scores (SSV and ASES) did not show statistical differences at any time of evaluation postinjury. Also, there was no difference in the functional assessment 6 and 12 weeks after injury measured with the Constant Score. We did however observe a non-significant better ASES score in the AC brace group at 1 week post injury, implying a marginal short-term benefit in this group.

The theory that an external force using a brace or taping can reduce Rockwood III or lateral clavicle fractures has not been proven in the literature. In contrast, most studies showed similar clinical and radiological outcomes irrespective of the type of sling, taping, or brace used.<sup>9,28,36</sup> This is consistent with the findings of our study.

According to the current literature, ACJ dislocations are difficult to reduce with external forces, however, overall good clinical

outcomes are reported through nonoperative therapies.<sup>9,28,36</sup> In compliant patients, reduction might be achieved over a questionable amount of time, but complications like skin irritation or even skin necrosis are reported.<sup>22,34</sup> Our presented series showed no complications. Nevertheless, patients should be counseled about possible skin irritation and pressure areas.

When comparing our results to patients treated with an AC Rockwood III injury nonoperatively only using a sling for comfort, we could show similar results.<sup>23</sup> The majority of our analyzed patients showed good and excellent functional results at follow-up.

A meta-analysis from 2011 comparing 6 retrospective studies showed that nonoperative management is poorly described and heterogenous. While it can achieve equivalent functional results and pain compared to the surgical treatment, surgery allowed for better cosmetic results with significantly longer sick leave.<sup>26</sup>

Considering the economic aspect of the conservative treatment of ACJ dislocations, the use of a sling is less expensive than the AC brace (4–9 vs. \$130–\$200 in Switzerland). However, in the context of the economic impact of the treatment costs and workers' compensation, these costs are negligible.

This study has some limitations. Firstly, despite a dual-center design only 35 patients with this specific injury could be recruited over a period of 3 years. Furthermore, the follow-up with 3 months is rather short and functional outcome scores might further improve over a longer period of time. Thirdly, the reduction of the lateral clavicle by the brace was not objectively verified by x-ray. Fourth, our brace group was entirely male which might limit generalizability to the broader population. Fifth, our study is inherently unable to be blinded, which could introduce patient bias in terms of treatment perception. Lastly, patient compliance with the AC brace might play an important role in the examined outcome and was not monitored in our study. This could explain the different results compared to the case report from Maleitzke et al,<sup>15</sup> where the patient was a compliant orthopedic resident.

## Conclusions

This prospective dual center randomized study could not show a beneficiary effect of a dedicated AC joint brace over a standard sling in the conservative treatment of Rockwood III ACJ dislocations with similarly good patient-reported and radiological outcomes at the latest follow-up. Even though not statistically significant, short-term benefits in pain control and radiological ACJ reduction were noted in the brace group which could be beneficial in a selected group of patients. To further investigate the potential benefit of such a brace, compliance with immobilization would need to be monitored.

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