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Randomized trial for the treatment of post-traumatic elbow stiffness: surgical release vs. rehabilitation

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Background: There are no previous randomized trials comparing surgical to conservative treatment for post-traumatic elbow stiffness. The aim of our study was to compare elbow range of motion (ROM) and clinical outcomes among patients undergoing surgical treatment or a standardized rehabilitation for post-traumatic elbow stiffness.

Methods: Randomized clinical trial of patients with post-traumatic elbow stiffness for more than 6 months who failed conventional physical therapy for 4 months. Patients were randomized into 2 treatment groups. The conservative group underwent the rehabilitation protocol associated with the use of orthoses (static progressive for extension and dynamic for flexion) and continuous passive motion. The surgical group underwent surgical release by a posterior approach without triceps detachment, followed by a rehabilitation protocol similar to the conservative group. The primary outcome of the study was flexion-extension ROM at 6 months of follow-up. Secondary outcomes included the visual analog scale for pain, the Mayo Elbow Performance Score, the Disabilities of the Arm, Shoulder, and Hand score, absolute and relative increase in flexion-extension ROM, and complication rates.

Results: Thirty patients were analyzed in the study, 15 in each group. The mean elbow flexion-extension ROM at the end of 6 months of follow-up was 108° in the surgical group and 88° in the conservative group ($P = .002$). The mean absolute and the relative increase of elbow flexion-extension at 6 months were, respectively, 17° and 27% in the conservative group and 41° and 59% in the surgical group ($P < .001$).

Conclusion: Surgical elbow release associated with the rehabilitation protocol resulted in a greater flexion-extension ROM, as well as a greater absolute and relative increase compared with rehabilitation alone at 6 months of follow-up. The groups did not differ regarding clinical scores and complication rates.

Level of Evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Randomized controlled trial; recovery of function; surgery; orthosis; comparative study; elbow; range of motion; stiffness

This study was approved by the Ethics Committee of the University of São Paulo (no. 15631) and registered on the clinicaltrial.gov website, under the responsibility of the National Institutes of Health of the United States, under identification code NCT03015415.

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It is widely accepted that the functional elbow range of motion (ROM) is between –30° of extension to 130° of flexion.[20] Post-traumatic elbow stiffness is defined as the loss of any degree of movement after trauma, but most authors consider it an indication for treatment only when functional ROM loss occurs.[14,28]

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Both conservative and surgical release are available options for patients with elbow stiffness without deformities, such as malunion, nonunion, intra-articular metal hardware, and heterotopic ossification.[11,22]

There are several variations for the conservative treatment, including dynamic and static orthoses and continuous passive motion (CPM). In a meta-analysis[22] evaluating the increase in elbow ROM with rehabilitation protocols associated with the use of orthoses, the average increase varied from 20°-40°. The authors were unable to observe a statistically significant difference between dynamic and static progressive orthoses.[22]

Several surgical techniques have been described, from the most aggressive, with extensive release associated with the external fixator,[19] to the minimally invasive or arthroscopic release.[10,13] In a systematic review[14] of different surgical techniques, an average increase in ROM of 51° for open releases was observed. However, most studies are retrospective case series,[1,6,17,18,24] and there is a lack of prospective randomized trials.

Our goal was to compare clinical outcomes and complication rates among patients undergoing surgical treatment or a standardized rehabilitation protocol with orthoses and CPM.

Methods

Study design

We conducted a prospective, parallel, randomized clinical trial with a blinded evaluator involving patients with post-traumatic elbow stiffness.

Participants

Patients were included in the study from January 2014–April 2018, after signing the informed consent. Inclusion criteria were age between 18 and 65 years and previous history of trauma (>6 months) that developed elbow stiffness, despite previous rehabilitation for at least 4 months and without the use of orthoses or CPM. We included patients with flexion-extension ROM of less than 100° or maximum extension less than –30° or maximum flexion less than 130°.

Patients with elbow ankylosis (ROM equal to 0°), neurologic injury of the affected upper limb, mental illness or inability to understand questionnaires, previous elbow infection, and heterotopic ossification were not included.

Interventions

Surgical group

All patients were operated on by the same 2 surgeons (M.G. and C.G.) as previously published by the authors.[9] Physical examination under anesthesia was performed to confirm the elbow stiffness.

A posterior approach to the elbow was performed. The ulnar nerve was identified, released and protected, followed by lateral and medial dissection of the triceps brachii muscle to the humerus, without disinsertion of the triceps tendon. The extensor mass of the forearm was elevated from the anterior capsule, followed by the release of its humeral insertion together with the lateral collateral ligament. Next, the posterior portion of the medial collateral ligament was released. We performed the release of joint adhesions between the triceps brachii and the posterior humerus, with excision of periarticular osteophytes, débridement of the olecranon fossa, and release of the anterior capsule of the distal humerus. After complete release and total increase of ROM, metal implants, if present, were removed. The lateral and medial collateral ligaments were reinserted with nonabsorbable transosseous sutures. External fixation was not performed. Anterior subcutaneous transposition of the ulnar nerve was performed and a vacuum drain was used in all cases.

The patients were hospitalized for 3 days for pain control and early mobilization. They were observed by an occupational therapist and subjected to a standardized rehabilitation protocol. On the first postoperative day, an anterior polyethylene orthosis was applied and used full-time for the first week; it was removed only for the home-based exercises and for cleaning. After this period, it was worn only during sleep. They underwent daily CPM for 1 hour during hospitalization and twice a week after hospital discharge. They were encouraged to perform daily activities and instructed to perform daily home exercises every 2 hours for 5-10 minutes. One month after surgery, they started using a dynamic orthosis for flexion gain 3 times a day for 30 minutes. The orthoses are shown in Fig. 1.

Conservative group

Patients underwent a similar elbow rehabilitation protocol as performed in the surgical group. They participated in two 1-hour occupational therapy sessions per week and underwent CPM during the sessions. Serial static orthoses were used to the maximum extent during sleep. For flexion gain, dynamic orthoses were used 3 times a day for 30 minutes. No forced manipulation was performed in any patient.

Outcomes

The primary outcome of the study was elbow flexion-extension ROM after 6 months of initiation of treatment. Secondary outcomes were Mayo Elbow Performance Score, Disabilities of the Arm, Shoulder, and Hand score, visual analog scale for pain, pronosupination ROM, relative ROM increase, incidence of clinical and radiographic complications, and the need for revision surgery. Mayo Elbow Performance Score results were categorized as excellent (>90 points), good (between 75 and 89 points), regular (between 60 and 74), and poor (<60).

The evaluation of the elbow flexion-extension range was performed in degrees with a manual goniometer. The patient was kept in orthostatic position, with the shoulder flexed to 90° and the arm parallel to the ground. The evaluation of the pronosupination was performed with the patient in an orthostatic position with the elbow flexed in 90°. The patient held a

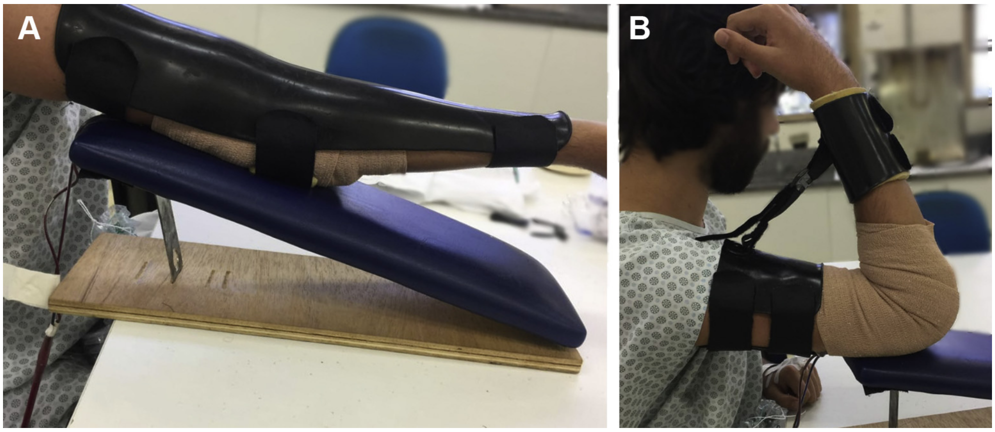

Figure 1 (A) Static progressive extension orthoses and (B) dynamic orthoses for flexion.

rod over his palm and a manual goniometer was used to measure it in degrees. It was considered 0° with the rod perpendicular to the ground.

Before randomization, computed tomographic scans and radiographs were performed in all patients. Radiographs were also performed 6 months after inclusion to assess complications.

Sample size calculation

Sample size was calculated based on flexion-extension ROM, according to a subjective clinically important difference of 13° between groups, assuming a standard deviation of 9° in each group.[14,22] A 2-tailed test with a 95% confidence interval and 80% power indicated a sample size of 15 patients in each group.

Randomization

Randomization was generated on the website http://www.randomization.com/, with random blocks, and stratified in 4 levels: previous surgical treatment or not and severity of stiffness (ROM >60° or ≤60°).

Allocation was performed by a collaborator, nonparticipant of the study, using a password-protected database.

Blinding

The evaluator of primary clinical outcomes was blinded to patient allocation and treatment. To ensure blinding, patients were instructed not to inform the evaluator about previous treatment. In addition, they wore a long sleeve so as not to expose the surgical scar.

Statistical analysis

Because of the small sample size, nonparametric tests were chosen, regardless of the normality of the data. The primary and secondary clinical outcomes for both groups were compared using a Mann-Whitney *U* test. For analysis of evolution over time, the Friedman test was performed. Complications were analyzed using Fisher exact test. The intention-to-treat principle was used, but all patients were treated according to the group in which they were allocated. All patients underwent scheduled evaluations, and no data imputation technique was required. All statistical analyses were performed using SPSS version 23.0 (IBM, Armonk, NY, USA) and the alpha level (type I error) was set at 0.05 and beta level at 80%.

Results

Participant flow

Sixty-three patients were assessed for eligibility. Thirty-one individuals did not meet the inclusion criteria. A total of 30 patients were analyzed, 15 in each group (Fig. 2). One patient from each group was excluded after randomization before receiving the treatment.

Baseline characteristics

Baseline characteristics were similar between the groups, both clinical and radiologic (Table I). The causes that led to elbow stiffness in the surgical group were as follows: 5 patients for radial head fracture, 3 for terrible triad, 2 for elbow dislocation, and 5 for other causes (a blunt wound, a lateral condyle fracture, a radius head fracture associated with a capitellum fracture, a proximal ulna fracture associated with radius head dislocation, and a coronoid fracture associated with elbow dislocation). In the conservative group, the causes were as follows: 6 patients for radial head fracture, 4 for terrible triad, 2 for elbow dislocation, 2 for olecranon fracture, and 1 for olecranon fracture associated with lateral condyle fracture.

Outcomes

The flexion-extension ROM at 6 months was 108° in the surgical group and 88° in the conservative group (P =

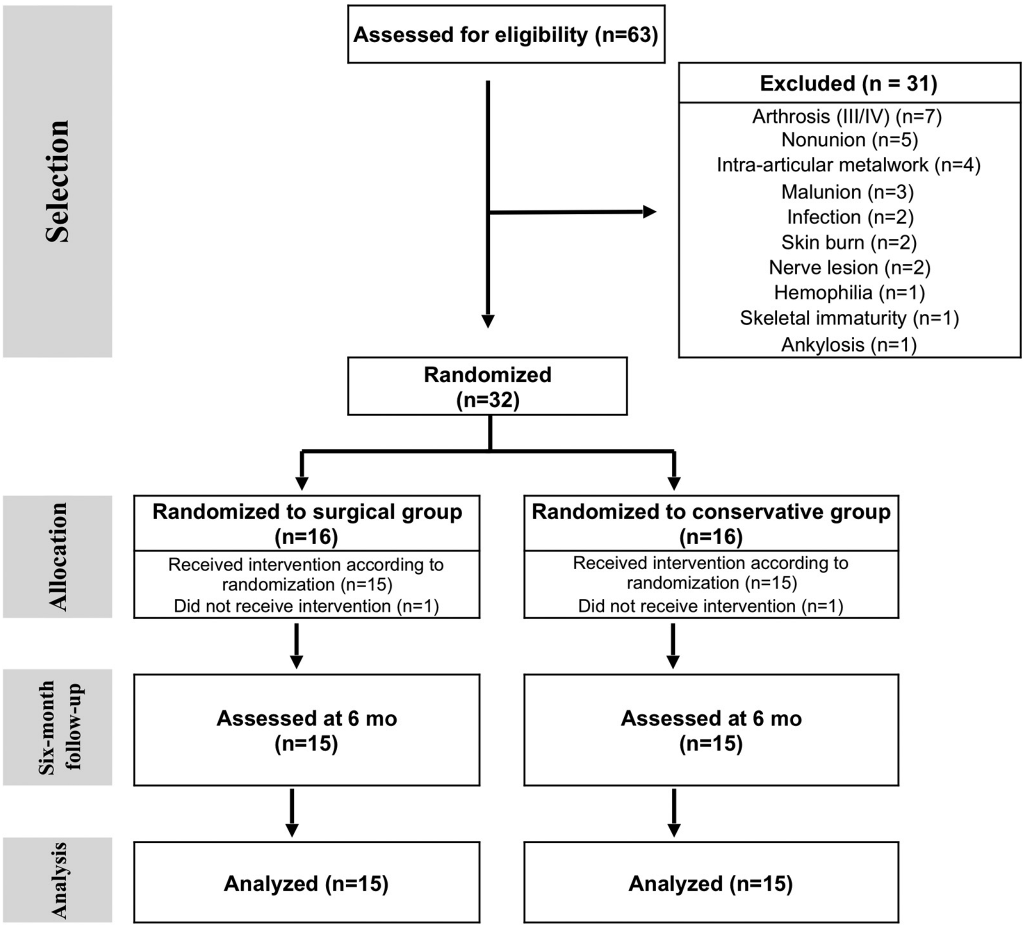

Figure 2 Consolidated Standards of Reporting Trials (CONSORT) flowchart of the trial enrollment and analysis.

.002). The absolute and relative increase of elbow flexion at 6 months were, respectively, 17° and 27° in the conservative group and 41° and 59° in the surgical group ($P < .001$) (Table II and Fig. 3). Temporal analysis showed that both groups showed a statistically significant improvement at 6 weeks and 3 and 6 months of follow-up ($P < .001$). Eleven patients in the conservative group did not reach functional ROM, vs. 6 in the surgical group ($P = .139$).

There were no statistically significant differences between treatment groups for the scores (Mayo Elbow Performance Score, Disabilities of the Arm, Shoulder and Hand, and visual analog scale for pain) at individual time points (Table III).

Five complications were recorded, 4 in the surgical group (2 transient ulnar nerve neuropraxia, 1 radial head subluxation, and 1 superficial infection) and 1 in the conservative group (transient ulnar nerve neuropraxia). Complications occurred in 4 patients, 3 in the surgical group and 1 in the conservative group, as 1 patient from the surgical group had 2 complications. One patient from the conservative group and 2 from the surgical group had transient ulnar nerve neuropraxia. The patient in the conservative group showed improvement in symptoms as soon as he discontinued use of the orthoses at 6 months of follow-up, whereas both in the surgical group showed improvement before 3 months of follow-up. One patient in the surgical group with preoperative limitation of pronation presented with radial head subluxation during passive exercises to increase pronation. He was treated with interruption of exercises for pronation, with a final 25° of pronation ROM (10° increase from preoperative). One patient presented a superficial infection, resolved with oral antibiotics for 1 week. No patient required a reoperation due to complications. Eleven patients from the conservative group did not reach the functional ROM. However, at final follow-up, only 3 intended to undergo surgical treatment.

Discussion

Our findings showed that surgical release yielded better results for flexion-extension ROM at 6 months when compared to rehabilitation alone. We did not find statistically significant differences for clinical scores and complication rates.

Table I Baseline characteristics according to treatment group

	Surgical group (n = 15)	Conservative group (n = 15)	*P* value
Age, yr	34.8 (10.6)	39 (10.6)	.383
Male	10 (66.6)	9 (60)	.705
Involvement of the dominant arm	11 (73.3)	7 (46.6)	.264
Previous fracture	10 (66.7)	14 (93.3)	.169
Previous surgery	4 (26.7)	5 (33.3)	.690
Months with stiffness	15.9 (8.2)	14.9 (11.6)	.567
Presence of metal hardware	2 (13.3)	5 (33.3)	.390
Arthrosis*			
0	5 (33.3)	9 (60.0)	.281
I	5 (33.3)	2 (13.3)	
II	5 (33.3)	4 (26.7)	
Radial head			
Normal	7 (46.7)	6 (40.0)	.935
With deformity	5 (33.3)	7 (46.7)	
Excised	2 (13.3)	1 (6.7)	
Arthroplasty	1 (6.7)	1 (6.7)	

Continuous data are presented as means ± standard deviations and categoric data as absolute numbers (%).
* According to de Jäger classification.

Table II Results of ROM evaluation according to treatment groups

	Surgical group (n = 15)				Conservative group (n = 15)				*P* value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR	
Flexion-extension ROM, degrees									
Preoperative	68	16	65	22	71	19	70	27	.560
6 weeks	72	24	70	45	74	18	76	26	.819
3 mo	97	25	105	32	82	17	82	20	.017
6 mo	108	16	112	25	88	19	85	30	.002
Absolute increase in flexion-extension ROM, degrees									
6 weeks	4	20	8	20	3	8	0	13	.692
3 mo	29	18	30	31	11	10	10	16	.004
6 mo	41	13	45	23	17	12	15	13	<.001
Relative increase in flexion-extension ROM, %									
6 weeks	5	31	12	33	5	12	0	19	.663
3 mo	42	25	38	39	16	15	11	17	.004
6 mo	59	16	64	20	27	21	24	16	<.001
Pronosupination ROM, degrees									
Preoperative	113	50	125	100	118	47	115	70	.739
6 weeks	123	44	140	90	136	46	140	55	.324
3 mo	130	44	150	80	140	45	160	45	.439
6 mo	134	42	150	80	143	45	160	45	.487
Flexion, degrees									
Preoperative	106	19	110	20	115	14	120	30	.162
6 weeks	104	21	110	30	118	13	120	20	.045
3 mo	114	20	122	25	118	13	120	20	.983
6 mo	124	10	125	12	122	12	120	12	.722
Extension, degrees									
Preoperative	–39	17	–35	22	–43	10	–40	12	.268
6 weeks	–34	18	–35	30	–44	10	–40	12	.083
3 mo	–17	11	–18	15	–33	12	–35	22	.002
6 mo	–15	11	–15	20	–31	13	–35	22	.002

ROM, range of motion; *SD*, standard deviation; *IQR*, interquartile range.

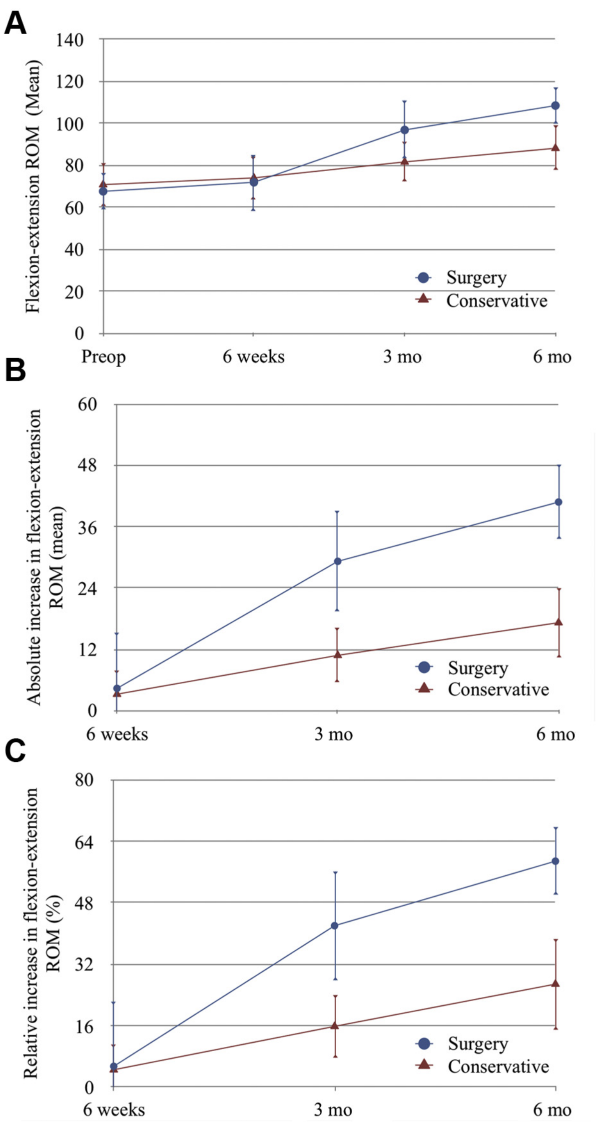

Figure 3 Results of flexion-extension range of motion for (A) absolute value, (B) absolute increase, and (C) relative increase.

The surgical group presented 108° for the flexion-extension ROM, slightly higher than the average found in the systematic review by Kodde et al[14] of 103° for open releases. In the conservative group, we observed a flexion extension ROM of 88° at 6 months, slightly lower than the values presented by Lindenhovius et al[16] of 92°. However, the preoperative treatment ROM in our study was 71° for the conservative group, whereas for Lindenhovius et al[16] it was 51°.

Regarding the increase of flexion-extension ROM, the surgical group presented the value of 41°, similar to those reported by Higgs et al[11] and Koh et al,[15] superior to the 17° increase in the conservative group. Ayadi et al[2] observed superior flexion-extension increases after surgical treatment, with an average of 51°. However, only 18% of this author's series reached functional ROM, which is less than the 60% observed in our study.

Because of this finding, it is important to highlight that ROM increase is inversely proportional to preoperative ROM.[15] Thus, in studies with lower initial ROM, patients will be prone to greater post-treatment ROM gains. This fact makes the comparison between the results of studies difficult to perform and interpret and may lead to mistaken conclusions. In an attempt to solve this problem, Cauchoix and Deburge[5] created a formula that takes into account the possible pretreatment gain and the obtained post-treatment increase, calling it the relative flexion-extension ROM. Our study achieved 59% relative ROM increase in the surgical group, similar to the 57% gain observed by Boerboom et al.[3] The conservative group had a relative increase of 27%, lower than the 47% gain presented by Lindenhovius et al.[16]

The conservative group had a 17° increase in flexion-extension ROM at 6 months after treatment, which was lower in comparison to other studies. Doornberg et al[7] reported an increase of 41°, but in their series almost half of the patients had undergone open surgical release before starting the rehabilitation protocol. When we limit the comparison to studies similar to ours, this difference narrows. Gelinas et al[8] and Ulrich et al[27] observed an increase of ROM of 24° and 26°, with an initial flexion-extension ROM of 76° and 81°, respectively. Both authors used progressive static orthoses in their rehabilitation protocols. Lindenhovius et al[16] conducted a prospective comparative study between the use of progressive static orthosis and dynamic orthosis. They report a gain of 39° and 40°, respectively, in the elbow flexion-extension ROM increase at 6 months of follow-up. The inclusion criteria were similar to our study, but they included patients with acute trauma and the time considered as failure of conventional physical therapy was only 1 month. Such a difference may increase the number of patients included without an established stiffness and, consequently, with less difficulty to increase their ROM.

The rehabilitation protocols applied to patients in both groups were similar. They were based on our institutional experience and available resources. Similar to Lindenhovius et al,[16] patients underwent active and light passive stretching exercises during occupational therapy sessions and were instructed to perform them daily at home. Unlike Tan et al,[26] no forced manipulation was performed at any time, as studies show risks for hematoma, heterotopic ossification, worsening of pain, and stiffness.[12,21] Although there is no evidence for CPM without surgery,[21] we decided to perform CPM in the conservative group to avoid differences between treatment protocols during rehabilitation.

The surgical technique was the same for all patients in the surgical group. Similar to Koh et al,[15] the posterior approach was used because of the versatility of access to all elbow compartments, and it is our preferred approach for most cases. We do not perform the disinsertion of the triceps, and we believe it favors early rehabilitation. Similar to Higgs et al,[11] joint mobilization began on the first postoperative day with the use of CPM, but without the use

Table III Results of clinical scores according to treatment groups

	Surgical group (n = 15)		Conservative group (n = 15)		*P* value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
MEPS					
Preoperative	51.3 (15)	50 (30)	60.3 (19)	65 (35)	.107
3 mo	71 (22)	70 (30)	65.3 (20)	65 (25)	.404
6 mo	77.3 (11)	80 (20)	70.6 (20)	65 (30)	.342
DASH					
Preoperative	45.4 (17)	50 (23)	49.3 (22)	51.6 (37.5)	.468
3 mo	34.2 (24)	31.6 (39)	40.1 (22)	39.1 (37.5)	.52
6 mo	27.6 (18)	21.6 (28)	35.3 (23)	39.1 (32.5)	.361
VAS					
Preoperative	6.2 (2.3)	6 (3)	5.1 (2.9)	5 (4)	.281
3 mo	3.9 (3.1)	5 (6)	4.8 (3.3)	5 (7)	.527
6 mo	3.9 (1.7)	4 (2)	4.4 (3.2)	5 (8)	.486

MEPS, Mayo Elbow Performance Score; *DASH*, Disabilities of the Arm, Shoulder, and Hand score; *VAS*, visual analog scale pain score; *SD*, standard deviation; *IQR*, interquartile range.

of catheter for continuous brachial plexus block. The patients tolerated pain only with the use of analgesics and anti-inflammatories, and they were able to use the CPM uneventfully. We believe it is important to perform CPM in the presence of a vacuum drain on the first postoperative day, as drainage of the hematoma can be observed during the sessions.

Although some surgeons avoid posterior surgical release claiming a higher risk for wound complications such as dehiscence,[21] in a systematic review of complications, Cai et al[4] did not observe such a relationship. We observed only 1 case of wound complication—a superficial infection that was treated with oral antibiotic therapy for 7 days. Tan et al,[26] who used a medial and/or lateral approach, reported 3 cases (5.8%) of wound complications, but with deep infection and need for surgical cleaning, débridement, and intravenous antibiotic therapy.

Neurolysis and anterior transposition of the ulnar nerve was performed in all cases of the surgical group to avoid ulnar nerve injury or cubital tunnel syndrome in the postoperative period. Our study presented 3 cases (20%) of transient ulnar nerve neuropraxia in the surgical group with symptom improvement before 3 months of follow-up. There is no consensus in the literature as to which ulnar nerve approach is best for surgical release. Cohen and Hastings,[6] who performed isolated lateral surgical release without ulnar nerve approach, reported 3 cases (14%) of postoperative neuropraxia. They suggested a possible relationship between the severity of stiffness and the risk of developing neuropraxia, and advocate for prophylactic neurolysis in patients with maximal flexion below 100°. In the conservative group of our study, 1 patient (6.7%) had transient ulnar nerve neuropraxia. She reported worsening of symptoms while using the dynamic orthosis for flexion gain. Gelinas et al[8] report 2 patients (9%) not undergoing surgical treatment with transient ulnar nerve neuropraxia in their study with progressive static orthoses. Lindenhovius et al[16] reported 3 complications (10%) of ulnar nerve neuropraxia with the use of dynamic bracing and 3 (9%) with the use of progressive static bracing in a comparative study. Of the total of 6 cases, 3 required surgical approach.

Our study has some limitations. The 6-month period may be considered a short period, but studies have shown no statistically significant differences in elbow ROM from this period in the treatment of post-traumatic elbow stiffness.[1,23,25] Patient follow-up will continue until 5 years from the start of treatment to further understand the relationship of post-treatment time with elbow ROM and clinical scores. Another limitation is that the sample size is relatively small, which has low power for the analysis of secondary outcomes, such as clinical scores and complications, although our sample is similar to previous published studies and it was enough to demonstrate the difference between groups.

The main advantage of this study is that it is prospective and randomized with a blinded evaluator and is the first to compare these 2 treatment options. The strict inclusion criteria, not only including functional ROM limitation,[20] allowed a more homogeneous sample with greater internal validity. We also evaluated elbow flexion-extension ROM in several ways, which will allow a better comparison with other studies.

Conclusion

Surgical elbow release associated with the rehabilitation protocol resulted in a greater flexion-extension ROM, as well as a greater absolute and relative increase when compared to rehabilitation alone at 6 months of follow-up. The groups did not differ in clinical scores and complication rates.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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