Early mobilization versus plaster immobilization of simple elbow dislocations; results of the FuncSiE multicenter randomized clinical trial

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ABSTRACT

Background/Aim To compare outcome of early mobilization and plaster immobilization in patients with a simple elbow dislocation. We hypothesized that early mobilization would result in earlier functional recovery.

Methods From August 2009 to September 2012, 100 adult patients with a simple elbow dislocation were enrolled in this multicenter randomized controlled trial. Patients were randomized to early mobilization (n=48) or three weeks plaster immobilization (n=52). Primary outcome measure was the Quick Disabilities of the Arm, Shoulder, and Hand (*Quick*-DASH) score. Secondary outcomes were the Oxford Elbow Score, Mayo Elbow Performance Index, pain, range of motion, complications, and activity resumption. Patients were followed for one year.

Results *Quick*-DASH scores at one year were 4.0 [95% CI 0.9 to 7.1] points in the early mobilization group *versus* 4.2 [95% CI 1.2 to 7.2] in the plaster immobilization group. At six weeks early mobilized patients reported less disability (*Quick*-DASH 12 [95% CI 9 to 15] points *versus* 19 [95% CI 16 to 22]; $p<0.05$) and had a larger arc of flexion and extension (121° [95% CI 115 to 127] *versus* 102° [95% CI 96 to 108]; $p<0.05$). Patients returned to work sooner after early mobilization (10 *versus* 18 days; $p=0.020$). Complications occurred in 12 patients; this was unrelated to treatment. No recurrent dislocations occurred.

Conclusions Early active mobilization is a safe and effective treatment for simple elbow dislocations. Patients recovered faster and returned to work earlier without increasing the complication rate. No evidence was found supporting treatment benefit at one year.

BACKGROUND

With an incidence of 5.2 to 6.1 per 100,000 person years, the elbow joint is the second most common major joint to dislocate in adults.[1-3] An elbow dislocation without associated fractures is considered a simple dislocation.[4-6]

Traditionally, the elbow is immobilized in a long arm cast after closed reduction. However, immobilization may result in stiffness and contracture of the elbow joint.[4,7-10] Simple dislocations may also be treated with early mobilization following closed reduction.[11-16] Although elbow experts appreciate and acknowledge the importance of early mobilization, it is not common practice worldwide yet. In the Netherlands more than 60% of simple elbow dislocations are still treated with plaster immobilization for at least three weeks.[17]

Current evidence on the merits of early mobilization over immobilization in a long arm cast has a low level of scientific evidence. Moreover, some physicians fear persistent instability after early mobilization. A systematic review including only one RCT (n=50) found no difference in flexion-extension arc at one year; less extension limitation was observed at three months in the early mobilization group.[8,14] Observational retrospective studies showed better results for pain and range of motion (ROM) at six months following early mobilization.[8,15,16]

The low scientific level of evidence and methodological issues with the previous studies stress the need for more clinical studies. The FuncSiE trial (FUNCtional treatment *versus* plaster for SImple Elbow dislocations) was designed to compare patient-reported outcome after early mobilization versus three weeks of plaster immobilization in patients with a simple elbow dislocation. Primary outcome measure was the *Quick* Disabilities of the Arm, Shoulder, and Hand (*Quick*-DASH) score. We hypothesized that early mobilization would result in earlier functional recovery without increase in recurrent dislocation or persistent instability.

METHODS

Setting and participants

The FuncSiE trial was a multicenter, parallel group randomized study. Twenty-two hospitals in The Netherlands participated. All patients aged 18 years or older with a simple elbow dislocation and successful closed reduction were included after provision of written informed consent. Patients were excluded if they 1) were polytraumatized; 2) had a complex (*i.e.*, associated with fractures), recurrent, or open dislocation; 3) had additional traumatic injuries of the affected arm; 4) required surgical intervention; 5) had a history of impaired elbow function (*i.e.*, stiff or painful elbow or neurological disorder); or 6) had fractures or surgery of the affected elbow in the past. Patients with expected problems in maintaining follow-up or with insufficient comprehension of the Dutch language were also excluded. The trial was approved by the Medical Research Ethics Committees or Local Ethics Boards of all participating centers. The study protocol is available online.[18]

Randomization and masking

Eligible patients were informed about the trial while being in the Emergency Department. Patients who signed informed consent were randomly assigned in a 1:1 ratio to receive early mobilization or plaster immobilization. The randomization sequence, stratified by center and with random block sizes, was computer generated at the coordinating hospital. Randomization was done by an independent central telephone operator, concealing treatment allocation from the recruiting investigator. Masking participants or investigators to the allocated treatment was not possible. In order to reduce bias, the follow-up measurements were standardized. Radiographs were blinded and evaluated independently by two assessors (GITI and DDH).

Intervention

The dislocated elbow was reduced under local, regional, or general anesthesia or without anesthesia, depending upon the preference of the surgeon. In the early mobilization group, the affected arm was put in a bandage for up to seven days. Patients were allowed to use a sling to relieve pain during the first few days. Early active movements within the limits of pain were started after two days according to a predefined protocol.[18] During the first three weeks, passive stretching was not allowed. In the plaster group the elbow was immobilized for three weeks in full above elbow cast. After removal of the plaster physical therapy was initiated according to a standardized protocol.

Assessments and follow-up

Follow-up data were obtained during outpatient visits at one, three, and six weeks, and at three, six, and 12 months after randomization. At each visit, the investigators ascertained clinical data from the patient files and patients completed a questionnaire on the level of pain. From six weeks onwards, the investigators measured the elbow ROM at both sides. At those times, patients were asked to complete a set of patient reported outcome measures (PROMs) and to complete a questionnaire with additional questions on health care consumption (*e.g.*, physical therapy) and resumption of activities of daily living (including work and sports). Radiographs of the elbow were made at the time of presentation to the hospital (baseline), after reduction, and at the follow-up visits at one week and one year. The X-ray at 12 months was used for determining the amount and location of heterotopic ossification and the grade of degenerative joint changes. All data were collected prospectively and were entered into a central database.

The primary outcome measure was the *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score.[19 20] Secondary outcome measures were the Oxford Elbow Score (OES),[21-23] the Mayo Elbow Performance Index (MEPI),[24] pain level (Visual Analog

Scale, VAS), Range of Motion of the elbow joint, and the rate of secondary interventions and complications. A detailed description of these questionnaires can be found in the trial protocol.[25] Heterotopic ossifications were classified from X-rays at one year according the classification of Broberg and Morrey.[26]

At baseline, intrinsic variables such as age, gender, American Society of Anesthesiologists' (ASA) classification, tobacco and alcohol consumption, comorbidities, dominant side, medication use, and work and sports participation were collected. Also, injury related variables (such as the affected side, mechanism of injury, and type of dislocation) and intervention related variables (such as the time between dislocation and reduction) were recorded.

Statistical analysis

Sample size calculation was based upon the assumption that the mean *Quick*-DASH would be 12.5 (SD 15.0) in the plaster immobilization group.[15] The FuncSiE trial was designed to enrol 100 patients, yielding 80% power to detect a treatment difference of at least 7.5 points (mean 5.0, SD 7.5) with a two-sided significance level of 0.05 and anticipating a 20% loss to follow-up.

Since there were hardly any missing data imputation was not needed. Normality of continuous data was assessed by inspecting the frequency distributions and the homogeneity of variances was tested with the Levene's test.

Chi-squared analysis was used for statistical testing of categorical data. Continuous data were analyzed using a Mann-Whitney U-test. P-values <0.05 were regarded as statistically significant.

Continuous outcomes that were repeatedly measured over time were compared between treatment groups using linear mixed-effects regression models. These multilevel models included random effects for the intercepts of the regression model and time coefficient of individual patients. Since the outcome measures were not linearly related with time, the time points were entered as factor. The models included fixed effects for treatment group, involvement of the dominant side, and gender. The effect of age was non-significant in all models and age was therefore not included. As the participating hospitals used similar treatment strategies, site was also not included in the model. The interaction between treatment group and time was included in the model to test for differences between the groups over time. For each follow-up moment, the estimated marginal mean was computed per treatment group and compared post hoc using a Bonferroni test to correct for multiple testing. Absence of overlap in the 95% confidence interval around the marginal means was regarded as significant at $p<0.05$.

Analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 20. Analysis was by intention to treat and all statistical tests were two-sided. The trial is registered at the Netherlands Trial Register (NTR2025).

RESULTS

Patient and injury characteristics

Between August 25, 2009 and September 18, 2012, 108 patients were screened for eligibility, of which 100 were included; 13 hospitals included <5 patients, seven included 5 to 10 patients, and two included 10 or more patients. Of the included patients, 48 patients were assigned to early mobilization and 52 to plaster immobilization (Figure 1). All patients received the allocated treatment. One patient in the plaster group was lost to follow-up after six months, and six patients did not show up at one follow-up moment (four in the early mobilization and two in the plaster group; Figure 1). Randomization resulted in similar baseline and injury characteristics in the two groups (Table 1), except for a relative predominance of patients with comorbidities in the plaster group, and the dominant side was affected more frequently in the early mobilization group.

Table 1: Characteristics of trial participants by treatment group

		Early mobilization N=48	Plaster immobilization N=52
Patient characteristics			
Male[1]		22 (46%)	20 (39%)
Age[2] (year)		43 (16)	47 (14)
BMI[2] (kg/m^2)		25.0 (4.7)	26.4 (4.4)
Smoking[1]:	Current	10 (21%)	12 (23%)
	Past	13 (27%)	13 (25%)
	Never	25 (52%)	27 (52%)
Alcohol consumer[1]		34 (71%)	35 (67%)
Alcohol consumption (units/week)[3]		3 (0-10)	3 (0-7)
Comorbidities[1]		12 (25%)	24 (46%)
	Number of comorbidities[3]	1 (1-1)	1 (1-2)
Medication use[1]		11 (23%)	19 (37%)
	Number of medications[3]	2 (1-2)	2 (1-4)
Independent living[1]		44 (92%)	50 (96%)
Household composition[1]:	Alone	10 (21%)	10 (19%)
	Alone with children	1 (2%)	3 (6%)
	With partner	18 (38%)	19 (37%)
	With partner and children	13 (27%)	17 (33%
	With family/student house	6 (13%)	3 (6%)
Activities of daily living			
Work participation (N patients)		32 (67%)	32 (62%)
Exertional level:	Light, mainly sedentary	13 (41%)	11 (34%)
	Medium work	3 (9%)	7 (22%)
	Heavy or very heavy work	16 (50%)	14 (44%)
Work participation (hours/week)[3]		36.0 (24.0-40.0)	36.0 (24.0-40.0)
Sports participation (N patients)		37 (77%)	36 (69%)
Sports participation (hours/week)[3]		6.0 (3.5-8.8)	6.0 (3.1-7.8)

Injury characteristics			
Right side affected[1]		26 (54%)	27 (52%)
Dominant side affected[1]		24 (50%)	22 (42%)
Type of dislocation	Posterolateral	27 (56%)	29 (56%)
	Posterior	8 (17%)	10 (19%)
	Lateral	5 (10%)	5 (10%)
	Posteromedial	3 (6%)	3 (6%)
	Medial	0 (0%)	1 (2%)
Low energy trauma[1]		45 (94%)	48 (92%)
Accident scene[1]:	Sports/recreation	21 (44%)	20 (38%)
	Accident at home	14 (29%)	13 (25%)
	Traffic accident	10 (21%)	15 (29%)
	Accident at work	2 (4%)	4 (8%)
	Violent assault	1 (2%)	0 (0%)
Treatment characteristics			
Number of reduction attempts[3]		1 (1-2)	2 (1-2)
Reduction in operating room[1]		5 (10%)	1 (2%)
Reduction anesthesia[1]:	IV valium	21 (44%)	17 (33%)
	General anesthesia	10 (21%)	8 (15%)
	Intra-articular	3 (6%)	12 (23%)
	None	6 (13%)	9 (17%)
	Other	6 (13%)	6 (12%)
	Regional/plexus	2 (4%)	0 (0%)

Data are presented as [1] N (%), [2] mean (SD), or [3] median (P_{25}-P_{75}).
* In six patients for whom stability was tested, the pivot shift test was not performed (three in each group).

Patient-reported functional outcome and pain

The *Quick*-DASH, OES, MEPI, and pain scores improved over time in both treatment groups (Figure 2). Table 2 shows the results of the mixed-effects regression model for the interaction of treatment with time (indicating difference in speed of recovery between the groups) as well as the estimated marginal mean scores for the efficacy outcomes at six weeks; at that time a difference between the groups was expected. The mean *Quick*-DASH score diminished from 12 points at six weeks to 4 points at 12 months in the early mobilization group, and from 19 to 4 points in the plaster group (Figure 2A). The difference was significant ($p<0.05$) at six weeks follow-up, but not at later time points. The interaction between treatment and time, representing a change in treatment effect over time (and thus in recovery speed) was also significant ($p_{interaction}=0.002$). A similar change in treatment effect over time was found for the *Quick*-DASH work module score ($p_{interaction}=0.003$; Figure 2B).

Table 2. Treatment effect over time and outcome at six weeks follow-up by treatment group

		Treatment effect over time		Outcome at six week follow-up	
		F-value	**P interaction**	**Early mobilization N=48**	**Plaster immobilization N=52**
Patient reported outcome measures:					
Quick-DASH	Overall score	**5.103**	**0.002**	**12 (9-15)**	**19 (16-22)**
	Work	**4.731**	**0.003**	**20 (14-26)**	**35 (29-41)**
	Sports	1.449	0.229	41 (33-49]	52 (44-60)
MEPI		2.397	0.068	89 (86-92)	84 (81-87)
OES	Overall score	**3.662**	**0.013**	72 (68-76)	66 (62-70)
	Pain	1.343	0.261	74 (70-79)	73 (68-77)
	Function	**6.952**	**<0.001**	**86 (82-89)**	**73 (70-76)**
	Psychosocial	1.102	0.349	57 (51-63)	52 (47-58)
VAS (1 week)	Affected side	**2.353**	**0.040**	**3.1 (2.7-3.6)**	**2.2 (1.8-2.6)**
VAS (6 weeks)	Affected side	**2.353**	**0.040**	1.2 (0.7-1.6)	1.2 (0.8-1.7)
Range of motion (degrees):					
Angle	Flexion	2.021	0.111	133 (130-137)	127 (124-131)
	Extension*	**11.858**	**<0.001**	**12 (9-15)**	**25 (22-29)**
	Pronation	0.100	0.960	86 (85-88)	86 (84-88)
	Supination	**3.014**	**0.030**	**87 (85-89)**	**83 (81-85)**
Arc	Flexion-Extension	**7.715**	**<0.001**	**121 (115-127)**	**102 (96-108)**
	Pronation-Supination	0.819	0.484	173 (170-177)	169 (165-172)
Loss of ROM	Flexion-Extension	**5.692**	**0.001**	**21 (15-27)**	**39 (34-45)**
	Pronation-Supination	**3.026**	**0.030**	**0 (-1-2)**	**4 (2-5)**

Changes in recovery pattern were assessed in the multivariable model. Results are shown by the F-value of the interaction term in the model (treatment * FU moment) and its p-value ($P_{interaction}$). Data of the outcome at six weeks are shown as the estimated marginal mean with 95% confidence interval after six weeks follow-up adjusted for involvement of the dominant side and gender. If the intervals did not overlap, this is indicated in bold face. The Arc of ROM is shown for the affected side, loss of ROM is calculated by subtracting the angle of the affected side from the contralateral side.
Quick-DASH, Disabilities of the Arm, Shoulder, and Hand; MEPI, Mayo Elbow Performance Index; OES, Oxford Elbow Score; ROM, Range of Motion; VAS, Visual Analog Scale.
* Extension is measured as deficit from neutral position (0°).

The OES increased from 72 points at six weeks to 93 points at 12 months in the early mobilization group and from 66 to 95 points in the plaster group (Figure 2C). Significantly higher OES function scores were noted in the early mobilization group at six weeks (86 *versus* 73 points; $p<0.05$) but not at later time points (Figure 2D). Patients in the early mobilization group recovered faster ($p_{interaction}=0.013$ for overall score and <0.001 for function).

The MEPI was consistently between 84 and 97 points in both groups (Figure 2E; $p_{interaction}=0.068$).

Patients reported significantly more pain at the affected arm in the early mobilization group at one week only (mean VAS 3.2 [95% CI 2.7 to 3.6] *versus* 2.2 [95% CI 1.8 to 2.6] for the plaster group; $p<0.05$) (Figure 2F). Analgesics use was similar in both groups; 16 (33%)

patients in the early mobilization group and 12 (24%) patients in the plaster group used analgesics ($p=0.372$).

Range of motion

Figure 3 shows changes in ROM. The corresponding estimated marginal means at six weeks and results of the regression model are shown in Table 2. The mean flexion-extension arc increased from 121° [95% CI 115 to 127] at six weeks to 142° at 12 months [95% CI 136 to 148] in the early mobilization group. In the plaster group, the arc increased from 102° [95% CI 96 to 108] to 138° [95% CI 133 to 144]; Figure 3A). A significant difference was noted only at six weeks, which was mainly attributable to differences in the angle of extension (Figure 3C). Likewise, the loss of ROM of flexion and extension (compared with the contralateral side) was significantly larger in the plaster group at six weeks (39° [95% CI 34 to 45] *versus* 21° [95% CI 15 to 27] after early mobilization; $p<0.05$; Figure 3E). At longer follow-up the motion limitation had resolved. Flexion-extension improved faster in the early mobilization group ($p_{interaction}<0.001$ flexion-extension arc, <0.001 for extension, and 0.001 for loss of flexion extension).

The pronation-supination arc was consistently between 169° and 174° in both treatment groups (Figure 3B). At six weeks follow-up, the mean angle of supination was significantly larger in the early mobilization group (mean 87° [95% CI 85 to 89] *versus* 83° [95% CI 81 to 85] in the plaster group; $p<0.05$; Figure 3D). The plaster group also showed a significantly greater loss of ROM of pronation and supination at six weeks (3.8° [95% CI 2.4 to 5.2] *versus* 0.2° [95% CI -1.3 to 1.6]); Figure 3F). Supination and ROM loss improved faster in the early mobilization group ($p_{interaction}=0.030$ for both).

Resumption of work and sports

Table 3 shows the patients' resumption of work and sports. Forty-eight patients reported sick due to their injury. Although the rates of work and sports resumption at one year after early mobilization did not differ significantly from that after plaster immobilization, the early mobilization group returned to work earlier (median 10 *versus* 18 days; p=0.027).

Table 3. Resumption of work and sports by treatment group

	Early mobilization N=48	Plaster immobilization N=52	P-value
Work participation:			
Work absenteeism (N patients) [1]	22 (69%)	25 (78%)	0.572
Resumption at 12 months (N patients) [1]:			
No	0 (0%)	1 (4%)	0.637
Partial	1 (4%)	1 (4%)	
Fully	21 (96%)	23 (92%)	
Time-full resumption (days) [2]	10 (5-16)	18 (8-41)	0.027
Percentage of baseline hours resumed at 12 months (%)[2]	100 (100-100)	100 (100-100)	0.376
Sports participation:			
Resumed activities at 12 months (N patients) [1]	28 (76%)	27 (75%)	1.000

Data are presented as [1]number (%) or as [2]median (P_{25}-P_{75}) and were analyzed using a Chi-squared test and Mann-Whitney U-test, respectively.

Complications and secondary interventions

Complications occurred in 12 patients and three underwent a secondary surgical intervention; no association with treatment was observed for both complications (p=0.640) or surgical interventions (p=1.000). In the early mobilization group, two patients reported pain without evident cause; one of these patients received five days of plaster immobilization, and one patient underwent arthrolysis to resolve motion restriction and pain. Another patient in the early mobilization group had a brachialis muscle rupture, and two patients had an ulnar nerve palsy; all three were treated non-operatively. In the plaster group five patients reported with discomfort or pain due to the plaster. One patient reported with an ulnar nerve palsy which was treated with ulnar nerve release, and one patient complained of persistent wrist pain requiring a diagnostic arthroscopy. The latter revealed cartilage degeneration, without instability of the distal radial-ulnar joint.

Radiological evaluation

Table 4 shows the radiological evaluation by treatment. At one year after trauma, radiographs were taken for 83 patients. Fifty (60%) of these showed heterotopic ossifications (55% in the early mobilization group versus 65% in the plaster group (p=0.377). Only three grade 3 ossifications were found, all occurred in the plaster group.

Table 4. Radiological outcome at one year by treatment group

	Early mobilization N=40*	Plaster immobilization N=43*	P-value
Joint incongruency	0 (0%)	0 (0%)	1.000
Heterotopic ossifications	22 (55%)	28 (65%)	0.377
Grade 1 (small, immature)	2 (9%)	1 (4%)	0.221
Grade 2 (small, mature)	20 (91%)	24 (86%)	
Grade 3 (large, mature)	0 (0%)	3 (11%)	
Grade 4 (ankylosis)	0 (0%)	0 (0%)	

Data are presented as N (%) and were analyzed using a Chi-squared test.
* Radiographs were not made for eight patients in the early mobilization group and nine in the plaster immobilization group.
Heterotopic ossifications were classified according to Broberg and Morrey.[26]

DISCUSSION

This study showed that treating a simple elbow dislocation with early mobilization resulted in earlier recovery and work resumption than immobilizing the elbow joint for three weeks. At six weeks follow-up, patients in the early mobilization group reported significantly better *Quick*-DASH and OES functional outcome scores, and a larger arc of ROM of flexion and extension. No evidence supporting treatment benefit at one year was found. Complications and secondary interventions were similar in both treatment groups. No residual instability, subluxation, or secondary dislocations were found.

Comparison with other studies

Functional outcome of simple elbow dislocations is generally good; however, residual stiffness may occur.[10,27-29] The only RCT comparing early mobilization and plaster immobilization showed a significantly higher percentage of patients with a normal extension at three months in the early mobilization group.[14] The ROM values in the current study were in line with other studies.[28,29] Absence of treatment effect at one year was also noted by Riel *et al.*, who found no difference in ROM after eight years of follow up.[7]

The functional outcome scores of our study were equivalent with Anakwe *et al.*.[28] De Haan *et al.*, however, reported slightly inferior *Quick*-DASH, MEPI, and OES scores. This is likely attributable to the inclusion of patients with complex elbow dislocations (49%) in their study.[29] The observation that early mobilization resulted in less disability and better function than plaster immobilization during the early phases of recovery was in line with the hypothesis and with previous studies.[8,14-16] Given similar outcome scores at one year in the current study, superiority of early mobilization on the long term, as shown by Maripuri *et al*. (better *Quick*-DASH and MEPI scores at 2-5 years) and others is not to be expected.[8,15]

Another finding supporting superiority of early mobilization was the shorter period until full-time work resumption. This difference, which could not be attributed to differences in exertional levels, emphasizes the relevance of early mobilization from a patient's perspective and has also been described before.[15] Earlier work resumption will reduce societal costs.

Patients in the early mobilization group reported a 1-point higher pain score only at one week. As analgesics use was the same in both groups, this small difference can be considered to be of little clinical relevance.

As expected, none of our patients showed recurrent instability. In 11 published studies (502 patients),[4,7,9,10,13-16,28-30] only three recurrent dislocations (0.6%) were reported; two occurred after plaster immobilization and one after early mobilization.[13,15,29]

Strengths and limitations

The current study had some limitations. In addition to eight excluded patients, at least seven more patients have been missed during the enrolment period, possibly due to unfamiliarity of local hospital staff with the trial. A second limitation is that the ROM was measured from six weeks onwards. The six weeks visit was chosen since it was the first standard of care visit moment after removal of the plaster. For future studies, earlier measurement of the ROM would be recommended; it would provide baseline data for the plaster group as well as a more detailed view on the early recovery pattern. A final limitation relates to other sources of bias. Patients completed questionnaires on work absence and health care use at fixed time points. Should recall bias have occurred, it will be limited and non-selective. It was not possible to blind patients, physicians or researchers for the allocated treatment, which may run a risk of ascertainment bias. The blind (and duplicate) review of radiographs, the use of a standardized ROM protocol, and keeping the statistician blinded for treatment was meant to prevent this bias as much as possible.

An important strength of this study is the exceptionally high follow-up rate which can be explained by the fact that all follow-up moments at all sites were attended by the researcher. If patients declined coming to the hospital, a meeting was arranged at their home or work.

Conclusions

Early mobilization is a safe and effective treatment for simple elbow dislocations. It resulted in earlier recovery of elbow function and range of motion than after plaster immobilization. As a consequence, patients were able to resume work earlier. Early mobilization did not result in recurrent dislocation or persistent instability of the elbow. No evidence was found supporting treatment benefit at one year. The earlier recovery is relevant for patients but also from a societal perspective.

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Specified notice

COMPETING INTERESTS

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: all authors had financial support from the European Society for Surgery of the Shoulder and the Elbow (SECEC/ESSSE) for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

DATA SHARING

No additional data available.

CONTRIBUTORSHIP STATEMENT

NWLS acted as trial principal investigator. EMMVL, JDH, WET, NWLS, EFVB, and DDH designed the study and trial documents. GITI performed data acquisition. EMMVL, GITI, and EFVB performed the statistical analysis. GITI, EMMVL, and DDH drafted the manuscript. All authors critically revised the manuscript, and read and approved the final manuscript. All site principal investigators (JDH, RSB, MWGAB, MRDV, BJD, RH, SAGM, JWRM, KJP, WHR, GRR, IBS, MAS, JBS, SS, JGHVDB, FMVDL, HGWMVDM, EJMMV, JPAMV, MW, and WJW) participated in patient inclusion, critically revised the manuscript, and read and approved the final version. All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Figure 1. Flow chart of the study

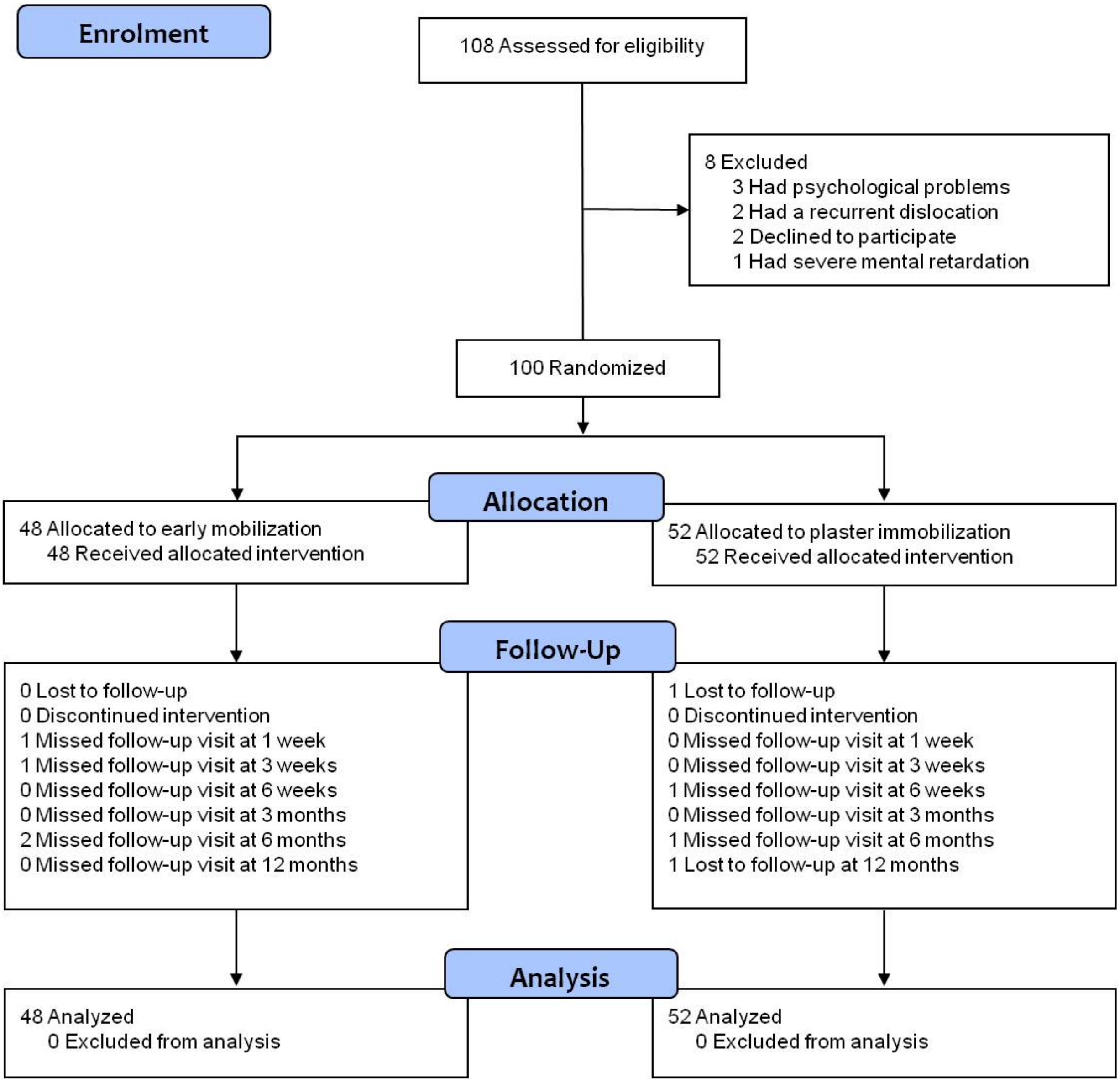
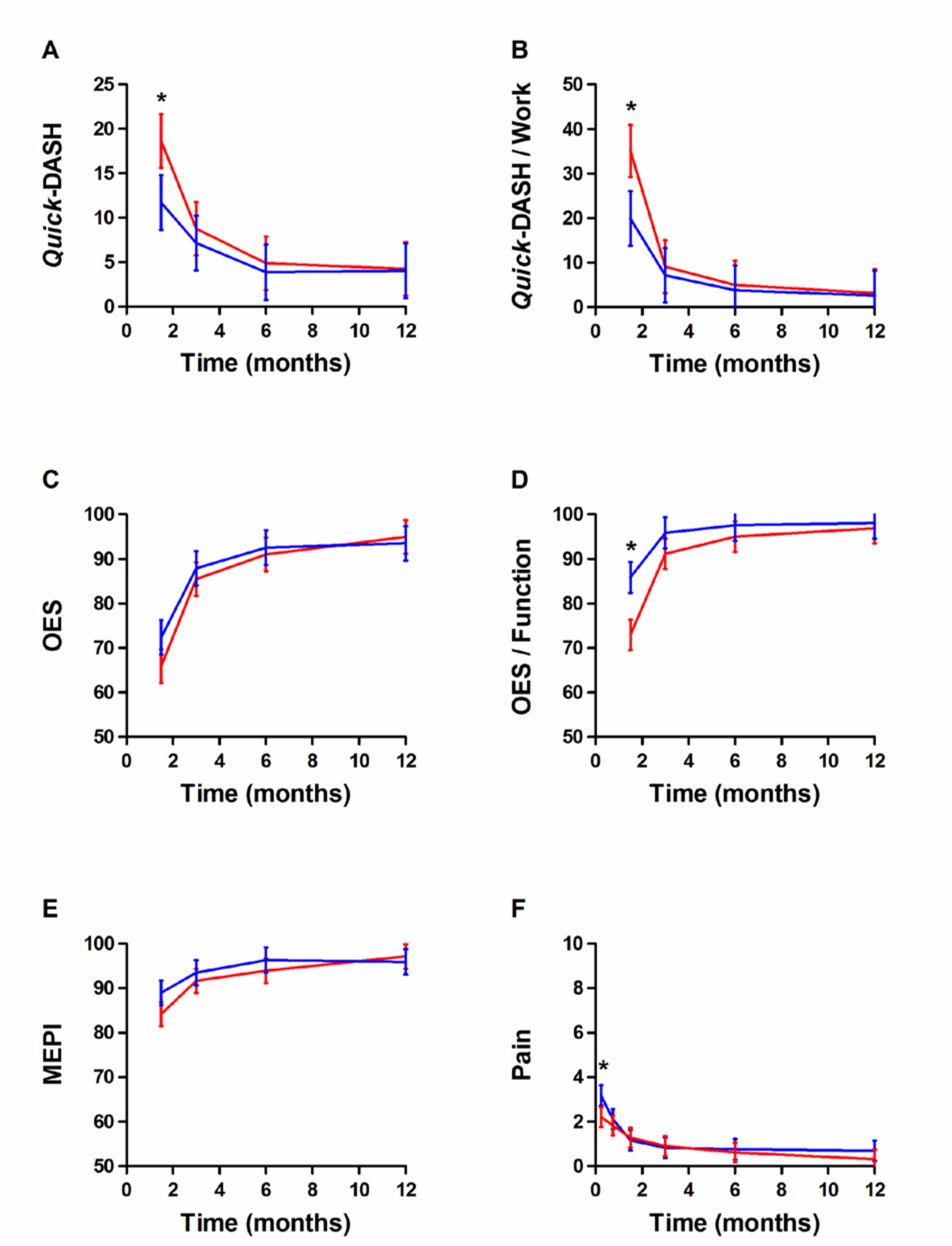


Figure 2. Changes in functional outcome scores and pain over time by treatment group

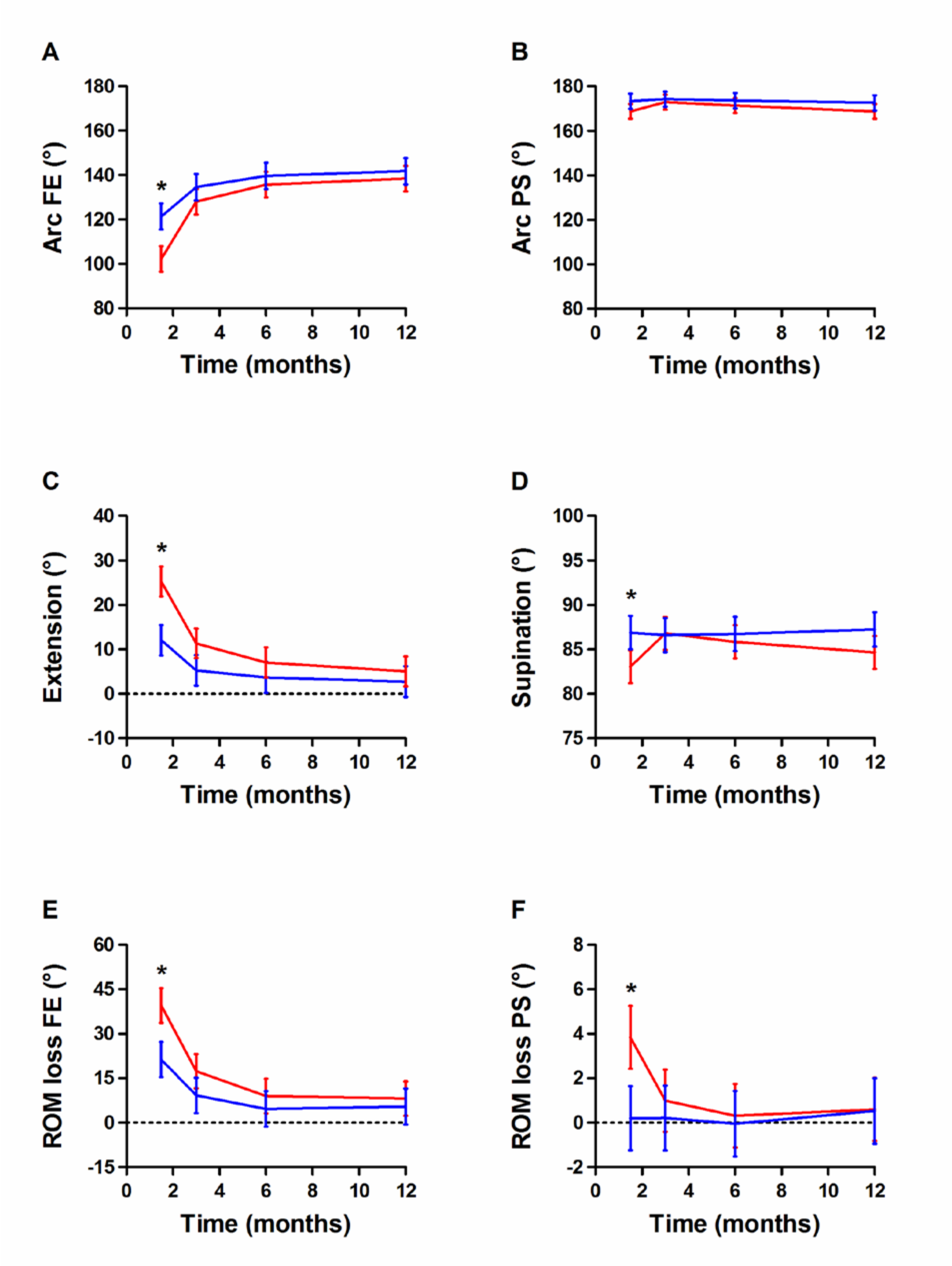


(A) Disabilities of the Arm, Shoulder, and Hand (*Quick*-DASH) overall score, (B) *Quick*-DASH score for the work optional module, (C) Oxford Elbow Score (OES) overall score, (D)

OES score for the sub-domain function, (D) Mayo Elbow Performance Index (MEPI), and (F) pain (VAS, Visual Analog Scale) over time. The VAS score is reported for the affected arm. Higher scores represent more disability (*Quick*-DASH), better functioning (OES and MEPI), or more pain (VAS).

Data are shown as mean with the corresponding 95% confidence interval, adjusted for involvement of the affected side and gender. Blue lines represent the early mobilization group; red lines represent the plaster immobilization group. *$p<0.05$ (Bonferroni test).

Figure 3. Changes in ROM over time by treatment group



(A) Arc of ROM (Range of Motion) of flexion and extension, (B) Arc of ROM of pronation and supination, (C) angle of extension and (D) angle of supination over time are shown for the affected side. Higher arcs and angles represent better ROM. (E) Loss of ROM of flexion and extension and (F) loss of ROM of pronation and supination are calculated by subtracting values for the affected side from the contralateral side. Lower values indicate less motion restriction compared with the contralateral side.

Data are shown as mean with the corresponding 95% confidence interval, adjusted for involvement of the affected side and gender. Blue lines represent the early mobilization group; red lines represent the plaster immobilization group. *$p<0.05$ (Bonferroni test).

SUMMARY BOX 1

What are the new findings?

- Early mobilization is a safe and effective treatment method for simple elbow dislocations.
- Patients recover faster which is relevant from both a patient's as well as a societal perspective.
- Early mobilization does not increase the rate of complications.

SUMMARY BOX 2

How might it impact on clinical practice in the near future?

- Plaster immobilization must be abandoned for the treatment of a simple elbow dislocation.
- Patients should be advised to start motion exercises as soon as possible.
- Motion exercises should preferably be supervised by a physical therapist.

EXCLUSIVE LICENCE

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