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Early mobilisation versus plaster immobilisation of simple elbow dislocations: results of the FuncSiE multicentre randomised clinical trial

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ABSTRACT

Background/aim To compare outcome of early mobilisation and plaster immobilisation in patients with a simple elbow dislocation. We hypothesised that early mobilisation 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 multicentre randomised controlled trial. Patients were randomised to early mobilisation (n=48) or 3 weeks plaster immobilisation (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 1 year.
Results *Quick*-DASH scores at 1 year were 4.0 (95% CI 0.9 to 7.1) points in the early mobilisation group versus 4.2 (95% CI 1.2 to 7.2) in the plaster immobilisation group. At 6 weeks, early mobilised patients reported less disability (*Quick*-DASH 12 (95% CI 9 to 15) points vs 19 (95% CI 16 to 22); p<0.05) and had a larger arc of flexion and extension (121° (95% CI 115° to 127°) vs 102° (95% CI 96° to 108°); p<0.05). Patients returned to work sooner after early mobilisation (10 vs 18 days; p=0.020). Complications occurred in 12 patients; this was unrelated to treatment. No recurrent dislocations occurred.
Conclusions Early active mobilisation 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 1 year.
Trial registration number NTR 2025.

BACKGROUND

With an incidence of 5.2–6.1/100 000 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 immobilised in a long arm cast after closed reduction. However, immobilisation may result in stiffness and contracture of the elbow joint.[4 7–10] Simple dislocations may also be treated with early mobilisation following closed reduction.[11–16] Although elbow experts appreciate and acknowledge the importance of early mobilisation, it is not yet common practice worldwide. In the Netherlands, more than 60% of simple elbow dislocations are still treated with plaster immobilisation for at least 3 weeks.[17]

Current evidence on the merits of early mobilisation over immobilisation in a long arm cast has a low level of scientific evidence. Moreover, some physicians fear persistent instability after early mobilisation. A systematic review including only one randomised controlled trial (RCT; n=50) found no difference in flexion–extension arc at 1 year; less extension limitation was observed at 3 months in the early mobilisation group.[8 14] Observational retrospective studies showed better results for pain and range of motion (ROM) at 6 months following early mobilisation.[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 vs plaster for SImple Elbow dislocations) was designed to compare patient-reported outcome after early mobilisation versus 3 weeks of plaster immobilisation in patients with a simple elbow dislocation. Primary outcome measure was the *Quick* Disabilities of the Arm, Shoulder and Hand (*Quick*-DASH) score. We hypothesised that early mobilisation would result in earlier functional recovery without increase in recurrent dislocation or persistent instability.

METHODS

Setting and participants

The FuncSiE trial was a multicentre, parallel group randomised 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 polytraumatised; (2) had a complex (ie, 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 (ie, 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 centres. The study protocol is available online.[18]

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Randomisation and masking

Eligible patients were informed about the trial while in the Emergency Department. Patients who signed informed consent were randomly assigned in a 1:1 ratio to receive early mobilisation or plaster immobilisation. The randomisation sequence, stratified by centre and with random block sizes, was computer-generated at the coordinating hospital. Randomisation was carried out 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 standardised. Radiographs were blinded and evaluated independently by two assessors (GITI and DDH).

Intervention

The dislocated elbow was reduced under local, regional or general anaesthesia, or without anaesthesia, depending on the preference of the surgeon. In the early mobilisation group, the affected arm was put in a bandage for up to 7 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 2 days according to a predefined protocol.[18] During the first 3 weeks, passive stretching was not allowed. In the plaster group the elbow was immobilised for 3 weeks in full above elbow cast. After removal of the plaster, physical therapy was initiated according to a standardised protocol.

Assessments and follow-up

Follow-up data were obtained during outpatient visits at 1, 3 and 6 weeks, and at 3, 6 and 12 months after randomisation. At each visit, the investigators ascertained clinical data from the patient files and patients completed a questionnaire on the level of pain. From 6 weeks onwards, the investigators measured the elbow ROM on both sides. During these visits, patients were asked to complete a set of patient-reported outcome measures (PROMs), and to complete a questionnaire with additional questions on healthcare consumption (eg, 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 1 week and 1 year. The X-ray at 12 months was used for determining the amount and location

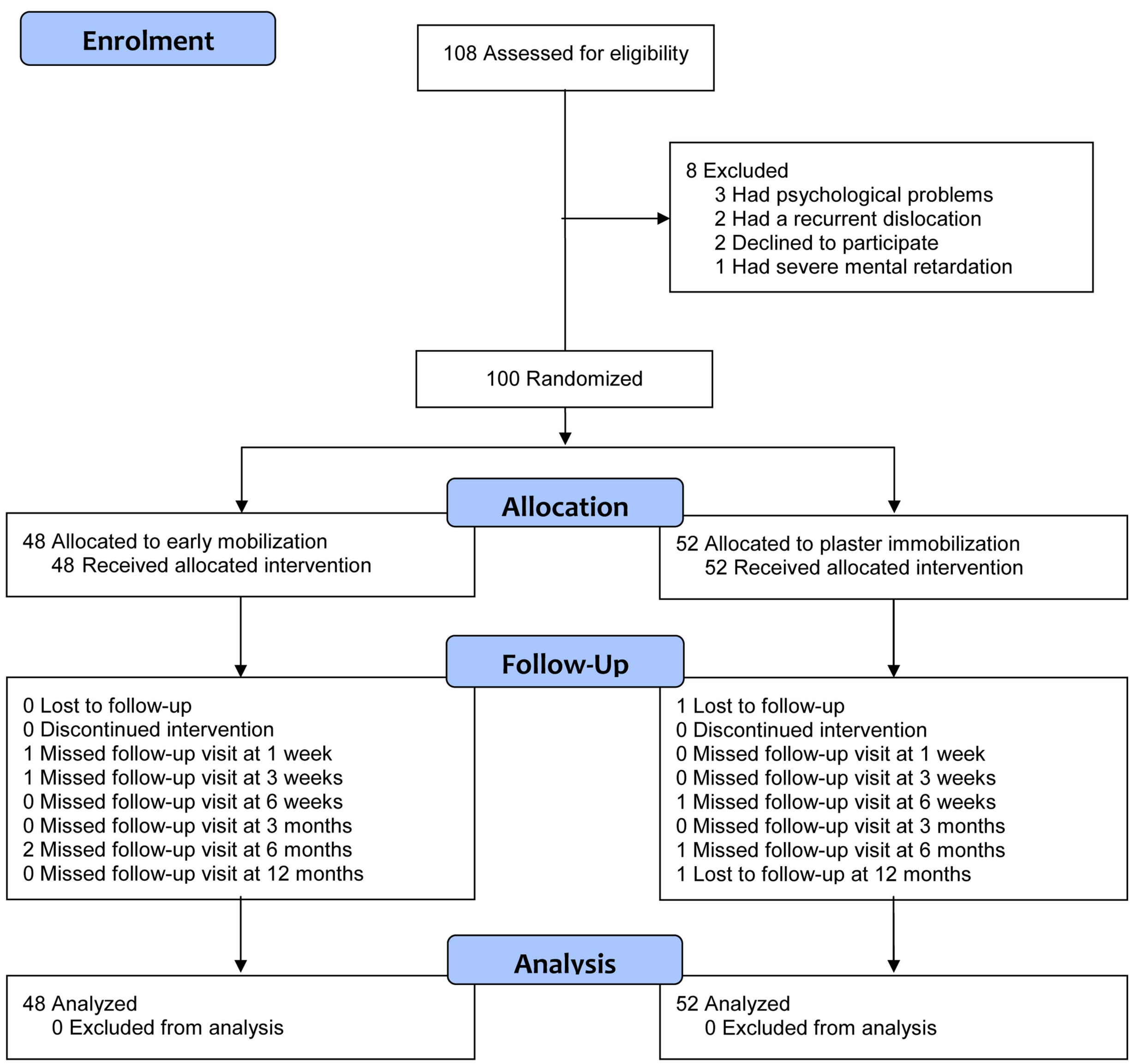

Figure 1 Flow chart of the study.

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 score.[19 20] Secondary outcome measures were the Oxford Elbow Score (OES),[21–23] the Mayo Elbow Performance Index (MEPI),[24] pain level (visual analogue scale, VAS), ROM 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.[18] Heterotopic ossifications were classified from X-rays at 1 year according the classification of Broberg and Morrey.[25]

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 on the assumption that the mean *Quick*-DASH would be 12.5 (SD=15.0) in the plaster immobilisation 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.

The χ^2 analysis was used for statistical testing of categorical data. Continuous data were analysed 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% CI around the marginal means was regarded as significant at $p<0.05$.

Analyses were performed using the Statistical Package for the Social Sciences (SPSS) V.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 25 August 2009 and 18 September 2012, 108 patients were screened for eligibility, of which 100 were included; 13

Table 1 Characteristics of trial participants by treatment group

	Early mobilisation N=48	Plaster immobilisation N=52
Patient characteristics		
Male*	22 (46%)	20 (39%)
Age† (year)	43 (16)	47 (14)
BMI† (kg/m^2)	25.0 (4.7)	26.4 (4.4)
Smoking*		
Current	10 (21%)	12 (23%)
Past	13 (27%)	13 (25%)
Never	25 (52%)	27 (52%)
Alcohol consumer*	34 (71%)	35 (67%)
Alcohol consumption (units/week)‡	3 (0–10)	3 (0–7)
Comorbidities*	12 (25%)	24 (46%)
Number of comorbidities‡	1 (1–1)	1 (1–2)
Medication use*	11 (23%)	19 (37%)
Number of medications‡	2 (1–2)	2 (1–4)
Independent living*	44 (92%)	50 (96%)
Household composition*		
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*	13 (41%)	11 (34%)
Light, mainly sedentary		
Medium work	3 (9%)	7 (22%)
Heavy or very heavy work	16 (50%)	14 (44%)
Work participation (hours/week)‡	36.0 (24.0–40.0)	36.0 (24.0–40.0)
Sports participation (N patients)*	37 (77%)	36 (69%)
Sports participation (hours/week)‡	6.0 (3.5–8.8)	6.0 (3.1–7.8)
Injury characteristics		
Right side affected*	26 (54%)	27 (52%)
Dominant side affected*	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*	45 (94%)	48 (92%)
Accident scene*		
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‡	1 (1–2)	2 (1–2)
Reduction in operating room*	5 (10%)	1 (2%)
Reduction anaesthesia*		
IV valium	21 (44%)	17 (33%)
General anaesthesia	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 *N (%), †mean (SD), or ‡median (P_{25}–P_{75}).
BMI, body mass index; IV, intravenous.

hospitals included <5 patients, 7 included 5–10 patients and 2 included 10 or more patients. Of the included patients, 48 patients were assigned to early mobilisation and 52 to plaster immobilisation (figure 1). All patients received the allocated treatment. One patient in the plaster group was lost to follow-up after 6 months, and six patients did not show up at one follow-up moment (four in the early mobilisation and two in the plaster group; figure 1). Randomisation 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 mobilisation 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 6 weeks; at that time, a difference between the groups was expected. The mean *Quick*-DASH score diminished from 12 points at 6 weeks to 4 points at 12 months in the early mobilisation group, and from 19 to 4 points in the plaster group (figure 2A). The difference was significant ($p<0.05$) at 6 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).

The OES increased from 72 points at 6 weeks to 93 points at 12 months in the early mobilisation group and from 66 to 95 points in the plaster group (figure 2C). Significantly higher OES function scores were noted in the early mobilisation group at 6 weeks (86 vs 73 points; $p<0.05$) but not at later time points (figure 2D). Patients in the early mobilisation 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 mobilisation group at 1 week only (mean VAS 3.2 (95% CI 2.7 to 3.6) vs 2.2 (95% CI 1.8 to 2.6) for the plaster group; $p<0.05$) (figure 2F). Analgesics use was similar in both

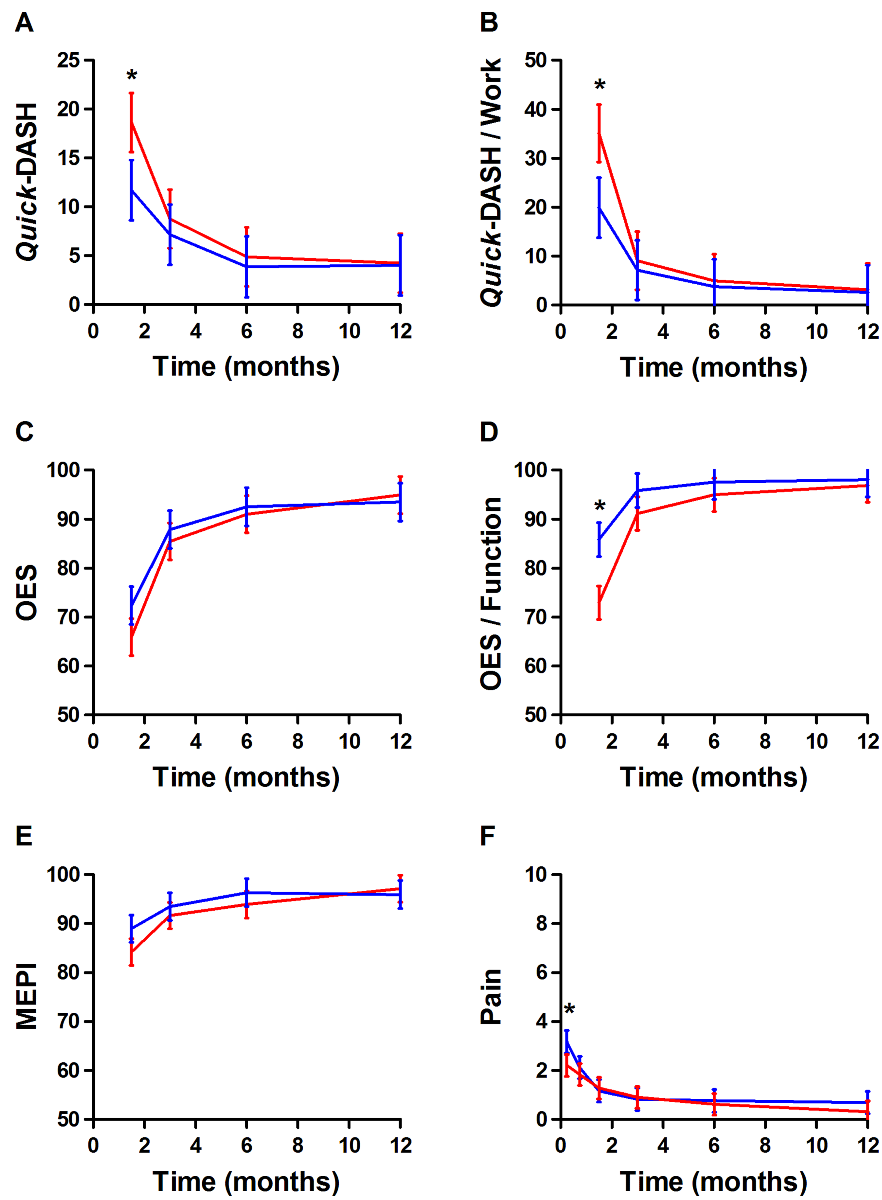

Figure 2 Changes in functional outcome scores and pain over time by treatment group. (A) Disabilities of the Arm, Shoulder and Hand (*Quick*-DASH) overall score, (B) *Quick*-DASH score for the work optional module, (C) Oxford Elbow Score (OES) overall score, (D) OES score for the subdomain function, (D) Mayo Elbow Performance Index (MEPI) and (F) pain (VAS, visual analogue 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% CI, adjusted for involvement of the affected side and gender. Black lines represent the early mobilisation group; grey lines represent the plaster immobilisation group; *p<0.05 (Bonferroni test).

Table 2 Treatment effect over time and outcome at 6 weeks follow-up by treatment group

	Treatment effect over time		Outcome at 6-week follow-up	
	F value	$p_{interaction}$	Early mobilisation N=48	Plaster immobilisation N=52
Patient reported outcome measures				
Quick-DASH				
Overall score	**5.103**	**0.002**	**12 (9 to 15)**	**19 (16 to 22)**
Work	**4.731**	**0.003**	**20 (14 to 26)**	**35 (29 to 41)**
Sports	1.449	0.229	41 (33 to 49)	52 (44 to 60)
MEPI	2.397	0.068	89 (86 to 92)	84 (81 to 87)
OES				
Overall score	**3.662**	**0.013**	72 (68 to 76)	66 (62 to 70)
Pain	1.343	0.261	74 (70 to 79)	73 (68 to 77)
Function	**6.952**	**<0.001**	**86 (82 to 89)**	**73 (70 to 76)**
Psychosocial	1.102	0.349	57 (51 to 63)	52 (47 to 58)
VAS (1 week)				
Affected side	**2.353**	**0.040**	**3.1 (2.7 to 3.6)**	**2.2 (1.8 to 2.6)**
VAS (6 weeks)				
Affected side	**2.353**	**0.040**	1.2 (0.7 to 1.6)	1.2 (0.8 to 1.7)
Range of motion (degrees)				
Angle				
Flexion	2.021	0.111	133 (130 to 137)	127 (124 to 131)
Extension*	**11.858**	**<0.001**	**12 (9 to 15)**	**25 (22 to 29)**
Pronation	0.100	0.960	86 (85 to 88)	86 (84 to 88)
Supination	**3.014**	**0.030**	**87 (85 to 89)**	**83 (81 to 85)**
Arc				
Flexion–extension	**7.715**	**<0.001**	**121 (115 to 127)**	**102 (96 to 108)**
Pronation–supination	0.819	0.484	173 (170 to 177)	169 (165 to 172)
Loss of ROM				
Flexion–extension	**5.692**	**0.001**	**21 (15 to 27)**	**39 (34 to 45)**
Pronation–supination	**3.026**	**0.030**	**0 (−1 to 2)**	**4 (2 to 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×follow-up moment) and its p value ($p_{interaction}$). Data of the outcome at 6 weeks are shown as the estimated marginal mean with 95% CI after 6 weeks of 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.
*Extension is measured as deficit from neutral position (0°).
Quick-DASH, Disabilities of the Arm, Shoulder and Hand; MEPI, Mayo Elbow Performance Index; OES, Oxford Elbow Score; ROM, range of motion; VAS, visual analogue scale.

groups; 16 (33%) patients in the early mobilisation 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 6 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 6 weeks to 142° (95% CI 136° to 148°) at 12 months in the early mobilisation 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 6 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 6 weeks (39° (95% CI 34° to 45°) vs 21° (95% CI 15° to 27°) after early mobilisation; p<0.05; figure 3E). At longer follow-up, the motion limitation had resolved. Flexion-extension improved faster in the early mobilisation 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 6 weeks of follow-up, the mean angle of supination was significantly larger in the early mobilisation group (mean 87° (95% CI 85° to 89°) vs 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 6 weeks (3.8° (95% CI 2.4° to 5.2°) vs 0.2° (95% CI −1.3° to 1.6°)); figure 3F). Supination and ROM loss improved faster in the early mobilisation 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 1 year after early mobilisation did not differ significantly from those after plaster immobilisation, the early mobilisation group returned to work earlier (median 10 vs 18 days; p=0.027).

Complications and secondary interventions

Complications occurred in 12 patients and 3 underwent a secondary surgical intervention; no association with treatment was observed for either complications (p=0.640) or surgical

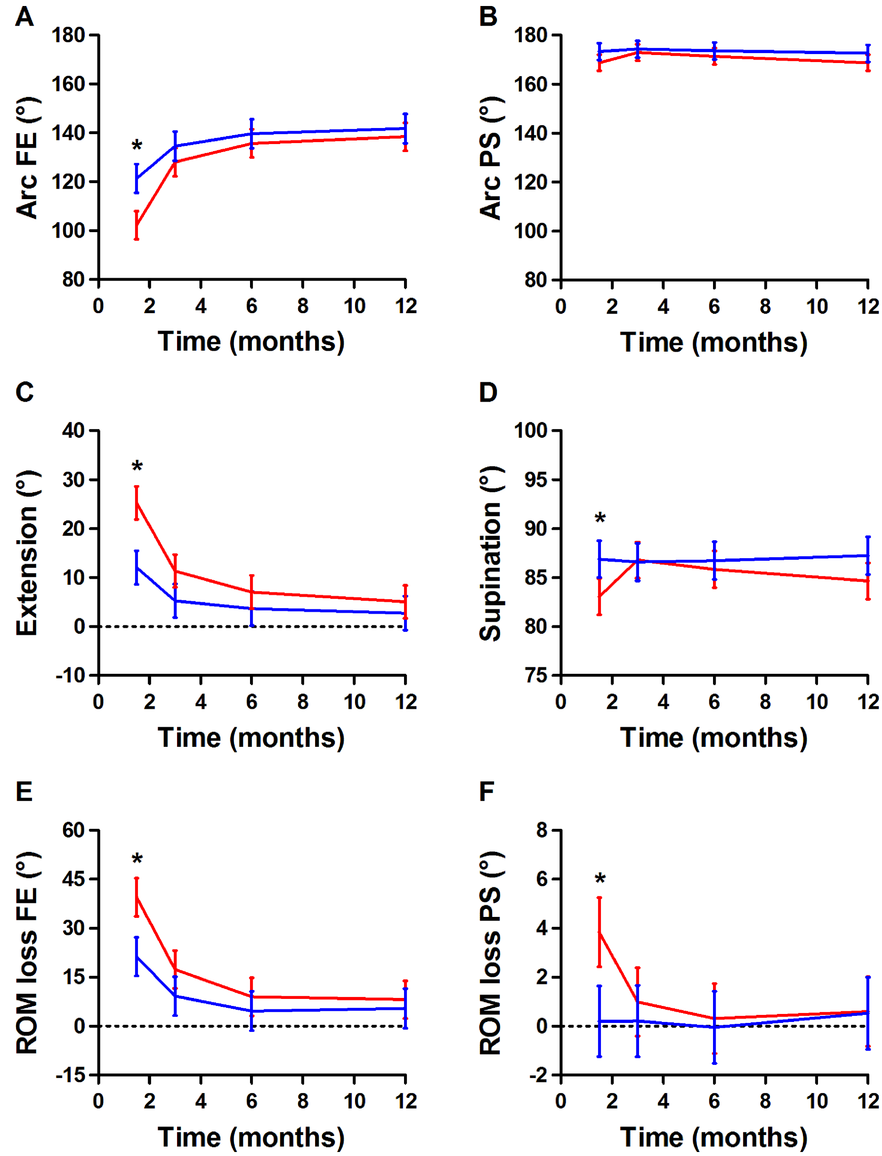

Figure 3 Changes in range of motion (ROM) over time by treatment group. (A) Arc of ROM of flexion and extension (FE), (B) arc of ROM of pronation and supination (PS), (C) angle of extension and (D) angle of supination over time are shown for the affected side. Higher arcs and angles represent better 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% CI, adjusted for involvement of the affected side and gender. Black lines represent the early mobilisation group; grey lines represent the plaster immobilisation group; *p<0.05 (Bonferroni test).

interventions (p=1.000). In the early mobilisation group, two patients reported pain without evident cause; one of these patients received 5 days of plaster immobilisation, and one patient underwent arthrolysis to resolve motion restriction and pain. Another patient in the early mobilisation group had a brachialis muscle rupture, and two patients had ulnar nerve palsy; all three were treated non-operatively. In the plaster group, five patients reported with discomfort or pain due to the plaster.

Table 3 Resumption of work and sports by treatment group

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

Data are presented as *number (%) or as †median (P_{25}–P_{75}) and were analysed using a χ^2 test and Mann-Whitney U test, respectively.

Table 4 Radiological outcome at 1 year by treatment group

	Early mobilisation N=40*	Plaster immobilisation 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 analysed using a χ^2 test.
Heterotopic ossifications were classified according to Broberg and Morrey.[25]
*Radiographs were not made for eight patients in the early mobilisation group and nine in the plaster immobilisation group.

One patient reported with ulnar nerve palsy that was treated with ulnar nerve release, and one patient reported 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 1 year after trauma, radiographs were taken for 83 patients. Fifty (60%) of these showed heterotopic ossifications (55% in the early mobilisation group vs 65% in the plaster group; p=0.377). Only three grade 3 ossifications were found; all occurred in the plaster group.

DISCUSSION

This study showed that treating a simple elbow dislocation with early mobilisation resulted in earlier recovery and work resumption than immobilising the elbow joint for 3 weeks. At 6 weeks of follow-up, patients in the early mobilisation 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 1 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 26–28] The only RCT comparing early mobilisation and plaster immobilisation showed a significantly higher percentage of patients with a normal extension at 3 months in the early mobilisation group.[14] The ROM values in the current study were in line with other studies.[27 28] Absence of treatment effect at 1 year was also noted by Riel and Bernett,[7] who found no difference in ROM after 8 years of follow-up.

The functional outcome scores of our study were equivalent with Anakwe *et al*.[27] 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.[28] The observation that early mobilisation resulted in less disability and better function than plaster immobilisation during the early phases of recovery was in line with the hypothesis, and with previous studies.[8 14–16] Given similar outcome scores at 1 year in the current study, superiority of early mobilisation in the long term, as shown by Maripuri *et al*[15] (better *Quick*-DASH and MEPI scores at 2–5 years) and others, is not to be expected.[8]

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

Patients in the early mobilisation group reported a one-point higher pain score only at 1 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 27–29] only three recurrent dislocations (0.6%) were reported; two occurred after plaster immobilisation and one after early mobilisation.[13 15 28]

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 6 weeks onwards. The 6-week 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 healthcare 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 standardised ROM protocol and keeping the statistician blinded for treatment were 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 mobilisation is a safe and effective treatment for simple elbow dislocations. It resulted in earlier recovery of elbow function and ROM than after plaster immobilisation. As a consequence, patients were able to resume work earlier. Early mobilisation did not result in recurrent dislocation or persistent instability of the elbow. No evidence was found supporting treatment benefit at 1 year. The earlier recovery is relevant not only for patients but also from a societal perspective.

What are the new findings?

- Early mobilisation 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 mobilisation does not increase the rate of complications.

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

- Plaster immobilisation 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.

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