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Immediate mobilization of distal radius fractures stabilized by volar locking plate results in a better short-term outcome than a five week immobilization: A prospective randomized trial

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Abstract

Objective: To evaluate the impact of immediate (first day after surgery) mobilization compared to standard five weeks cast immobilization on the functional outcome after volar locking plate fixation of distal radius fractures.

Design: Prospective randomized parallel group comparative trial.

Setting: Trauma Hospital, Austria.

Participants: Patients with isolated unstable distal radius fractures, stabilized with volar angular stable locking plate.

Interventions: The immediate mobilization group received a removable forearm splint for one week and active supervised group physiotherapy and home exercises for the shoulder, elbow, wrist, and fingers from the first postoperative day. The cast immobilization group received a non-removable cast for five weeks. In the first five weeks supervised group physiotherapy and home exercises were performed for shoulder, elbow, and fingers. Thereafter additional supervised and home exercises for the wrist were started.

Main measures: At regular intervals of six and nine weeks, three and six months, and one year post surgery range of motion, grip strength, and x-rays were evaluated. Additionally, the shortened disabilities

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of the arm, shoulder and hand (*Quick*DASH) score, Patient-rated Wrist Evaluation, Mayo Wrist score, and pain according to the Visual Analog Scale score were analyzed.

Results: One hundred and sixteen patients were prospectively randomized into two study groups. At the one-year follow-up, patients in the immediate mobilization group showed a significantly higher range of motion in extension/flexion (mean difference 10.2°, 99% confidence interval 0.6–19.8), grip strength (mean difference 5.1 kg, 99% confidence interval −0.5 to 10.7), and Mayo Wrist score (mean difference 7.9 points, 99% confidence interval 2.3–13.5) than the cast immobilization group. Range of motion in supination/pronation (mean difference 13.4°, 99% confidence interval 1.5–25.3) and in radial/ulnar deviation (mean difference 6.3°, 99% confidence interval 0.9–11.7) differed significantly up to nine weeks favoring the immediate mobilization group. The Patient-rated Wrist Evaluation revealed significantly better scores after three months (mean difference 9.3 points, 99% confidence interval 0.5–18.1) and *Quick*DASH after six months (mean difference 7.3 points, 99% confidence interval 0.3–14.3) in the immediate mobilization group. All other subsequent follow-up examinations indicated no significant differences in respect of pain, range of motion, and patient-reported outcome measurements between the study groups. There were no significant differences in respect of radiological loss of reduction and complications between the groups.

Conclusions: Immediate mobilization in combination with supervised physiotherapy of the wrist after volar locking plate fixation of unstable distal radius fractures results in a significantly improved range of motion and grip strength after one year compared to cast immobilization. No increased risk for loss of reduction and other complications was observed.

Keywords

Distal radius fracture, volar locking plate, mobilization, outcome, rehabilitation

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Introduction

Distal radius fractures are one of the most common fractures in the upper extremities and the incidences appear to increase worldwide.[1–3] Anatomical reconstruction, stable fixation, and early motion can be seen as the main principles in the treatment of articular fractures.[4–6] However, early mobilization has not entered standard care in operatively treated distal radius fractures.[7,8] Although there is a consensus in the literature that internal fixation requires shorter immobilization and thus allows an earlier return to daily life activities, only few studies evaluate the possible benefits of shorter immobilization.[9–14] Additionally, the published guidelines do not recommend early mobilization on a routine basis.[15,16]

Therefore, a single-center, prospective, and randomized clinical trial was established to evaluate the impact of immediate mobilization compared to standard five weeks cast immobilization on the functional outcome after volar locking plate fixation.

The primary study hypothesis was that an immediate mobilization starting on the first day after surgery leads to a better range of motion, grip strength, and patient-reported outcome measures one year after surgery compared to a cast immobilization for five weeks. The primary endpoint was defined one year after surgery, as this represents the minimum follow-up period to evaluate the functional outcome after distal radius fractures.[17]

The secondary study aim was to compare pain, range of motion, grip strength, and patient-reported outcome measures at six weeks, nine weeks, three months, and six months after surgery between the study groups.

Methods

Between January 2015 and July 2016, 116 patients were enrolled in this single center, two-group, prospective randomized controlled trial incorporating

concealed allocation. All patients suffered an unilateral unstable distal radius fracture, underwent internal stabilization using volar locking plate and gave written informed consent prior to inclusion. The study protocol was approved by the local Institutional review board (3/2010), registered at clinicaltrials.gov (NCT02312128), and followed the consolidated standards of reporting trials (Consort) guidelines.[18]

Patients were considered eligible if they suffered a displaced distal radius fracture with a dorsal tilt greater than 15°, an intra-articular step of more than 1 mm, or a radial shortening of more than 2 mm in the standard radiographs. Bone quality was not considered a relevant factor in this study. Further inclusion criteria were age between 18 and 75 years, isolated displaced distal radius fracture (A2–C3.2) and capability of giving consent.

Patients were excluded if they were pregnant, suffered open, pathological, C3.3 distal radius fractures, or associated fractures of the distal ulna (except fractures of the processus styloideus ulnae). Additionally, potential patients were excluded if they showed other concomitant fractures or bilateral distal radius fractures, were unable to answer the outcome questionnaires or to comply with postoperative therapy.

Primary analysis was performed as intention-to-treat. A detailed study flowchart is shown in Figure 1. Patients were randomly allocated (chronological depending on admission) into the immediate mobilization or cast immobilization group. Randomization with a block of 10 patients per group was performed by using 10 sealed permuted envelopes containing equal number of sheets for immediate mobilization and cast immobilization. Preparation and shuffling of the envelops was performed by one of the authors. An arbitrary person, not involved or familiar with the study, was chosen to select a random envelope. The surgeon was not aware of the group allocation during the operation. Opening of the envelope and allocation of the patient in the study group was performed by one of the authors after surgery.

Owing to the study design blinding was not possible in all aspects of the study. Blinding of surgeons and hand therapists, as care providers, was not possible during the study. But the surgeons did not know the group allocation of the patient during the surgery. Clinical assessment was performed by an independent examiner, blinded to the patient's allocation group.

Analysis of the radiological outcome was done by an unbiased surgeon not involved in the patient's care, blinded to the functional outcome, but not to the method of treatment. Blinding to method of treatment was not possible as the postoperative immobilization method could be seen on the x-rays.

Follow-up examinations were carried out for both groups at six weeks, nine weeks, three months, six months, and one year after surgery. At each examination, range of motion, grip strength in kilograms (minimal clinical important difference: 6.5 kg or 19.5% decrease)[19] and pain according to the Visual Analog Scale (ranging from 0 (no pain) to 10 (worst possible pain) over the past week) were measured. All clinical values were compared to those of the uninjured hand. For calculating the duration of physiotherapy and sick leave, the beginning and end dates were documented.

Self-assessment by patients was registered on the shortened disabilities of the arm, shoulder, and hand (*Quick*DASH) score (0–100 points; minimal clinical important difference: 10 points[20]),[21] Patient-rated Wrist Evaluation (0–100 points; minimal clinical important difference: 11.5 points[22]),[23] and Mayo Wrist score (0–100 points).[24]

Details for range of motion, grip strength measurement, and patient-reported outcome measurements are given in the Appendix.

Each follow-up appointment included a standard radiological check in two planes (anteroposterior and lateral view). Additionally, the primary (prereduction) and immediate postoperative radiographs were checked for alignment and intra-articular step-off. Fractures were classified according to the Arbeitsgemeinschaft für Osteosynthesefragen classification by Müller et al.[25] In the anteroposterior radiographs, radial inclination and ulnar variance according to Gelberman were measured.[26] In the lateral radiographs the palmar tilt was measured.[26] Fracture healing was defined as bone bridging of the radial, ulnar, and dorsal cortical aspects of the distal part of the radius.[27]

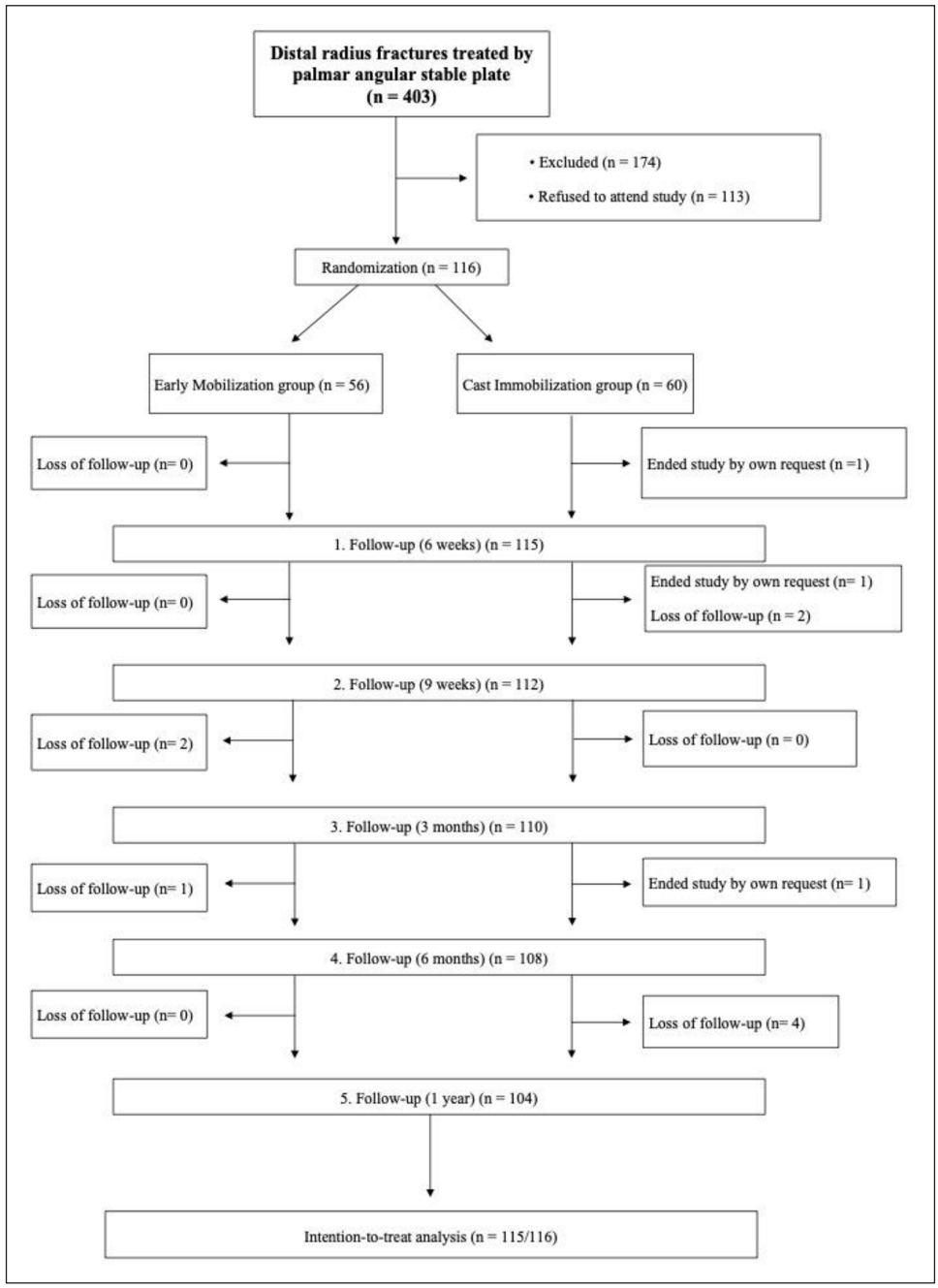

Figure 1. Study flow-chart.
A total of 403 patients with distal radius fractures were treated operatively during the investigation period. Of these, 174 did not meet inclusion criteria, 113 refused to participate in the study. Therefore the sample size of 116 patients was established. Primary analysis was performed as intention-to-treat. Three patients ended the study by their own request and nine patients were lost during the follow-up. One patient in the cast immobilization group ended the study in the first five weeks. Due to this, no functional or radiological data was available and the patient was excluded from analysis.

Complications during the study were reported and included loss of reduction, carpal tunnel syndrome, nonunion, tendon irritation or rupture, deep or superficial infection, and neuropathy. Complex regional pain syndrome was diagnosed clinically on the basis of the Veldman et al.[28] criteria. Complications that required additional surgery were defined as an adverse event.

Complications after distal radius fractures are well reported in the previously published literature ranging between 8% and 39%.[29–33] The most common are carpal tunnel syndrome (up to 15%),[30,33] complex regional pain syndrome (up to 6%),[31,32] tendon irritation/rupture (3.8%),[32] and loss of reduction (1.0%).[32]

Surgery was performed under general or regional anesthesia in a supine position. The arm was placed on a radiolucent table and the image intensifier positioned cranially. A pneumatic tourniquet was applied to the upper arm and inflated to 250 mmHg. In all cases a standard volar-radial approach between the flexor carpi radialis tendon and arteria radialis according to Henry was carried out. The flexor carpi radialis tendon was retracted ulnar and the forearm fascia was opened. After releasing the pronator quadratus muscle the fracture site was exposed. Using the image intensifier, the fracture was reduced and, if necessary, temporarily fixed with K-Wires.

The volar angular stable plate was placed on the volar aspect of the distal radius and initially fixed at the gliding hole using a cortical screw. In all cases a Medartis® Aptus 2.5 trilock distal radius locking plate (2 fracture, 105 correction, and 9 FPL plates) was used. Consequently, the remaining plate holes were filled with angular stable screws. Care was taken that the screws under the articular surface were placed subchondral to prevent dorsal protrusion. The pronator quadratus was reinserted in all cases. Surgery was not limited to a particular surgeon. All operations were performed by members of the trauma department, trained in orthopedic surgery.

The immediate mobilization group received a removable thermoplastic forearm splint for one week and conducted supervised physiotherapy and home exercises of the wrist starting on the first day after surgery. The cast immobilization group received a non-removable plaster cast for five weeks and performed supervised physiotherapy and home exercises of the adjoining (not fixed) joints for the first five weeks. After cast removal the same physiotherapy program as the immediate mobilization group was started. A detailed description of the postoperative therapeutic interventions for both groups can be found in the Appendix and Tables A1–A3.

Prior to the study a sample size analysis was performed (G*Power 3.1). Sample size calculation was performed on the basis of the most important patient-reported outcome parameter for wrist activity limitation (*Quick*DASH)[34] after distal radius fractures. Based on previously published studies, a difference in *Quick*DASH score of 10 points was considered as the minimal clinical important difference, taking into consideration, that reported thresholds have not been evaluated specifically for distal radius fractures.[20,35–37] Therefore, 51 patients per group were required, to achieve 90% power with an alpha of 0.05 and to detect a difference of 10 points in *Quick*DASH and standard deviation of 12 points[38] for an effect size of 0.60. The target enrollment was 116 patients to account for a loss of patients during the investigation of approximately 15%.

The Shapiro-test was used to test the assumption of normal distribution of scaled parameters. Since this assumption could not be maintained, the outcome was analyzed non-parametrically using the Mann–Whitney *U* test to compare the two groups. Chi-square was used for testing categorical data.

Due to multiple testing of range of motion, *Quick*DASH, Patient-rated Wrist Evaluation, Mayo Wrist Score and grip strength and the distribution of the parameter, the threshold for statistical significance was corrected according to Bonferroni to $P < 0.01$. Data is presented in mean, median, and standard deviation, differences between the groups are reported as mean difference and 99% confidence interval.

Results

Clinical results

Patient demographic characteristics are summarized in Table 1 and the study flow in Figure 1. Primary outcome analysis one-year after surgery

Table 1. Patients demographic and fracture classified according to the Arbeitsgemeinschaft für Osteosynthesefragen classification.

	Study group		
	Immediate mobilization	Cast immobilization	*P* value
	Group *n* = 56	Group *n* = 60	
Age in years*	56 (25–75)	58 (24–75)	0.42
Duration sick leave (weeks)*	6 (0.7–16)	10 (0.7–19)	0.02
Duration physiotherapy (weeks)*	12 (3–27)	14 (3–27)	0.03
Sex			
F/M	39/17	45/15	0.52
Injured hand			
R/L	26/30	29/31	0.84
Dominant/non-dominant hand			
D/N	25/31	25/35	0.75
Co-morbidities			
Y/N	23/33	22/38	0.63
Hypertension	16	15	
Diabetes	3	3	
Gastritis	1	1	
Hypothyroidism	5	9	
Chronic renal failure	0	1	
Hyperlipidaemia	1	5	
Depression	1	1	
Coronary heart disease	0	1	
BMI (kg/m^2)*	27 (19 to 40)	25 (15 to 36)	0.10
Workman's compensation			
Y/N	9/47	10/50	0.93
Ability to work			
A/I	32/24	32/28	0.68
Profession			
White-collar worker	14	16	
Official	1	2	
Gastronomy	1	1	
Medical profession	4	2	
Musician	1	0	
Taxi driver	0	2	
Student	0	1	
Retiree	21	28	
Unemployed	6	6	
Teacher	3	1	
Housewife	3	1	
Workman	2	0	
Fracture ulnar styloid			
Y/N	23/33	34/26	0.09
Season (winter/spring/summer/fall)	22/12/11/11	23/17/10/10	

(Continued)

Table 1. (Continued)

	Study group		
	Immediate mobilization	Cast immobilization	*P* value
	Group *n* = 56	Group *n* = 60	
AO classification			
A2	1	2	0.55
A3	13	7	
C1	5	5	
C2	13	15	
C3	24	31	

AO: Arbeitsgemeinschaft für Osteosynthesefragen; F: female; M: male; R: right; L: left; D: dominant/N: non-dominant hand; Y: yes/N: no; BMI: body mass index; kg: kilograms; m^2: square meter; A: working/I: inactive.
*Values are given as mean (range).

revealed a significant better range of motion in extension/flexion (mean difference 10.2°, 99% confidence interval 0.6–19.8), grip strength (mean difference 5.1 kg, 99% confidence interval −0.5 to 10.7) and Mayo Wrist score (mean difference 7.9 points, 99% confidence interval 2.3–13.5) in the immediate mobilization group compared to the cast immobilization group.

However, no significant differences could be found in the *Quick*DASH (mean difference 5.6 points, 99% confidence interval 0.5–11.6), Patient-rated Wrist Evaluation (mean difference 5.0 points, 99% confidence interval −1.5 to 11.4), range of motion in supination/pronation (mean difference 0.01°, 99% confidence interval −0.7 to 0.7), and radial/ulnar deviation (mean difference 0.6°, 99% confidence interval −2.3 to 3.5) between the groups one year after surgery.

Secondary outcome analysis revealed a significant difference in range of motion in supination/pronation (mean difference 13.4°, 99% confidence interval 1.5–25.3) and in radial/ulnar deviation (mean difference 6.3°, 99% confidence interval 0.9–11.7) up to nine weeks favoring the immediate mobilization group. Postoperative *Quick*DASH showed significant better results for the immediate mobilization group up to six months (mean difference 7.3 points, 99% confidence interval 0.3–14.3) and Patient-rated Wrist Evaluation up to three months (mean difference 9.3 points, 99% confidence interval 0.5–18.1) after surgery. Range of motion for each follow-up examination is presented in Table 2. Patient-reported outcome measures, pain, and grip strength for each follow-up visit are presented in Table 3.

Patients in the immediate mobilization group showed a significantly shorter duration of sick leave (mean difference 3.9 weeks, 99% confidence interval −0.2 to 8.0) and period of physiotherapy (mean difference 1.9 weeks, 99% confidence interval −0.6 to 4.4) than patients in the cast immobilization group. Additionally, patients in the immediate mobilization group needed significantly lesser physiotherapy sessions than patients in the cast immobilization group (mean difference 8.4 sessions, 99% confidence interval 0.5–16.2).

Clinically important differences between the immediate mobilization and cast immobilization group were found up to three months for the *Quick*DASH and nine weeks for the Patient-rated Wrist Evaluation favoring the immediate mobilization group. Although grip strength differed significantly up to one year between the groups, mean differences were under the minimal clinical important difference at all follow-up examinations.

Radiological results

No significant differences in frequency of ulnar styloid fracture ($P = 0.09$) or AO fracture type ($P = 0.55$) could be found between the groups. All distal radius fractures showed union at the six

Table 2. Range of motion (mean, median (standard deviation)) and percentage of uninjured side (%).

	Study group		MD (99% CI)
	Immediate mobilization	Cast immobilization	
	Group ($n = 56$) (%)	Group ($n = 59$) (%)	
Six weeks			
Extension (deg)	61.1, 70.0 (SD 20.9) (72)	43.3, 45.0 (SD 18.4) (51)	17.9 (8.2–27.5)*
Flexion (deg)	50.0, 50.0 (SD 21.3) (59)	31.0, 30.0 (SD 15.0) (39)	18.4 (9.4–27.5)*
Extension/flexion (deg)	110.9, 120.0 (SD 38.5) (66)	74.1, 70.0 (SD 29.9) (43)	36.8 (19.8–53.8)*
Supination (deg)	79.5, 90.0 (SD 16.6) (90)	68.4, 80.0 (SD 24.8) (76)	11.1 (0.7–21.5)*
Pronation (deg)	81.3, 90.0 (SD 16.6) (92)	69.1, 80.0 (SD 23.9) (86)	12.2 (2.1–22.3)*
Supination/pronation (deg)	160.7, 170.0 (SD 28.3) (91)	137.2, 140.0 (SD 37.8) (76)	23.5 (7.1–39.8)*
Radial deviation (deg)	12.1, 10.0 (SD 4.9) (90)	8.1, 10.0 (SD 5.8) (59)	4.0 (1.4–6.7)*
Ulnar deviation (deg)	28.0, 30.0 (SD 8.7) (81)	21.4, 20.0 (SD 10.5) (62)	6.6 (1.8–11.3)
Radial/ulnar deviation (deg)	40.1, 40.0 (SD 10.1) (83)	29.5, 30.0 (SD 11.9) (61)	10.6 (5.1–16.1)*
Nine weeks			
Extension (deg)	74.6, 80.0 (SD 19.0) (86)	60.3, 60.0 (SD 16.1) (69)	14.4 (5.5–23.3)*
Flexion (deg)	62.4, 70.0 (SD 23.9) (74)	46.9, 45.0 (SD 19.6) (57)	15.5 (4.5–26.5)*
Extension/flexion (deg)	137.0, 140.0 (SD 39.3) (81)	107.2, 110.0 (SD 31.5) (61)	29.8 (11.8–47.8)*
Supination (deg)	84.2, 90.0 (SD 13.0) (94)	76.3, 90.0 (SD 19.0) (86)	7.9 (−0.4–16.1)*
Pronation (deg)	85.3, 90.0 (SD 13.0) (97)	79.7, 90.0 (SD 15.2) (94)	5.6 (−1.6–12.7)*
Supination/pronation (deg)	169.5, 180.0 (SD 20.1) (95)	156.0, 170.0 (SD 26.4) (87)	13.4 (1.5–25.3)*
Radial deviation (deg)	13.3, 10.0 (SD 4.9) (99)	9.5, 10.0 (SD 5.5) (83)	3.8 (1.2–6.4)*
Ulnar deviation (deg)	29.2, 30.0 (SD 8.9) (85)	26.6, 30.0 (SD 10.0) (75)	2.6 (−2.3–7.4)
Radial/ulnar deviation (deg)	42.5, 50.0 (SD 9.3) (88)	36.2, 35.0 (SD 11.9) (76)	6.3 (0.9–11.7)*
Three months			
Extension (deg)	80.7, 90.0 (SD 13.8) (91)	68.6, 70.0 (SD 18.8) (80)	12.2 (3.9–20.5)*
Flexion (deg)	70.6, 80.0 (SD 23.9) (81)	59.2, 60.0 (SD 20.8) (77)	11.4 (0.1–22.6)*
Extension/flexion (deg)	151.3, 170.0 (SD 35.5) (86)	127.7, 130.0 (SD 35.8) (73)	23.6 (5.7–41.5)*
Supination (deg)	86.9, 90.0 (SD 7.3) (97)	81.3, 90.0 (SD 17.7) (92)	5.7 (−1.2–12.5)
Pronation (deg)	87.3, 90.0 (SD 6.4) (97)	81.6, 90.0 (SD 13.2) (92)	5.7 (0.5–10.9)
Supination/pronation (deg)	174.3, 180.0 (SD 10.8) (97)	162.9, 180.0 (SD 25.5) (92)	11.4 (1.5–21.2)
Radial deviation (deg)	12.9, 10.0 (SD 5.3) (97)	10.7, 10.0 (SD 4.2) (87)	2.1 (−0.3–4.6)
Ulnar deviation (deg)	30.0, 30.0 (SD 7.7) (86)	29.7, 30.0 (SD 10.0) (83)	0.3 (−4.2–4.8)
Radial/ulnar deviation (deg)	42.8, 40.0 (SD 8.2) (88)	40.4, 40.0 (SD 10.2) (83)	2.4 (−2.2–7.1)
Six months			
Extension (deg)	85.5, 90.0 (SD 9.1) (96)	73.0, 80.0 (SD 17.7) (85)	12.5 (5.4–19.6)*
Flexion (deg)	80.2, 90.0 (SD 16.6) (92)	68.2, 70.0 (SD 19.5) (85)	12.0 (2.9–21.1)*
Extension/flexion (deg)	165.9, 180.0 (SD 24.1) (94)	141.2, 150.0 (SD 34.6) (82)	24.7 (9.6–39.7)*
Supination (deg)	89.7, 90.0 (SD 1.5) (100)	88.0, 90.0 (SD 5.3) (98)	1.8 (−0.2–3.7)
Pronation (deg)	89.9, 90.0 (SD 0.69) (100)	86.6, 90.0 (SD 13.5) (98)	3.3 (−1.6–8.2)
Supination/pronation (deg)	179.6, 180.0 (SD 1.9) (100)	176.2, 180.0 (SD 9.3) (98)	3.4 (−0.01–6.9)
Radial deviation (deg)	12.7, 10.0 (SD 4.5) (97)	11.3, 10.0 (SD 4.4) (91)	1.4 (−0.8–3.7)
Ulnar deviation (deg)	33.5, 30.0 (SD 7.4) (95)	34.0, 40.0 (SD 10.0) (96)	0.5 (−5.0–4.0)
Radial/ulnar deviation (deg)	46.2, 50.0 (SD 7.0) (95)	45.2, 50.0 (SD 9.6) (93)	1.0 (−3.2–5.3)

(Continued)

Table 2. (Continued)

	Study group		MD (99% CI)
	Immediate mobilization	Cast immobilization	
	Group ($n=56$) (%)	Group ($n=59$) (%)	
One year			
Extension (deg)	87.9, 90.0 (SD 5.7) (99)	82.2, 90.0 (SD 11.4) (92)	5.8 (1.1–10.5)*
Flexion (deg)	85.6, 90.0 (SD 11.3) (98)	80.6, 90.0 (SD 14.2) (99)	5.0 (−1.7–11.6)
Extension/flexion (deg)	173.5, 180.0 (SD 15.4) (99)	163.3, 170.0 (SD 21.3) (94)	10.2 (0.6–19.8)*
Supination (deg)	89.8, 90.0 (SD 1.4) (100)	90.0, 90.0 (SD 0.0) (100)	−0.2 (−0.7–0.3)
Pronation (deg)	90.0, 90.0 (SD 0.00) (100)	89.8, 90.0 (SD 1.4) (100)	0.2 (−0.3–0.7)
Supination/pronation (deg)	179.8, 180.0 (SD 1.4) (100)	179.8, 180.0 (SD 1.4) (100)	0.01 (−0.7–0.7)
Radial deviation (deg)	13.0, 10.0 (SD 4.6) (100)	13.1, 10.0 (SD 11.7) (100)	−0.1 (−4.7–4.4)
Ulnar deviation (deg)	36.1, 40.0 (SD 6.6) (100)	37.9, 40.0 (SD 10.3) (100)	−1.8 (−6.2–2.6)
Radial/ulnar deviation (deg)	49.2, 50.0 (SD 5.5) (100)	48.5, 50.0 (SD 5.7) (100)	0.6 (−2.3–3.5)

SD: standard deviation; deg: degree; MD: mean difference; CI: confidence interval.
*Statistical significant by a threshold of $P < 0.01$.

Table 3. Mean, median (standard deviation) pain, grip strength, and patient-reported outcome measures.

	Study group		MD (99% CI)
	Immediate mobilization	Cast immobilization	
	Group ($n=56$)	Group ($n=59$)	
Six weeks			
VAS	0.7, 0.0 (SD 1.3)	2.7, 3.0 (SD 2.1)	1.9 (1.0–2.8)*
Grip strength (kg)†	16.2, 14.6 (SD 7.2) (50%)	10.4, 8.0 (SD 7.8) (34%)	5.8 (2.0–9.6)*
*Quick*DASH score	32.6, 30.0 (SD 17.8)	51.1, 54.8 (SD 18.7)	18.6 (9.4–27.7)*
Mayo Wrist score	62.3, 65.0 (SD 14.3)	42.8, 47.5 (SD 18.0)	19.5 (11.4–27.6)*
PRWE score	29.2, 27.4 (SD 18.3)	46.6, 43.9 (SD 21.3)	17.4 (7.4–27.3)*
Nine weeks			
VAS	0.3, 0.0 (SD 0.9)	1.5, 1.0 (SD 1.8)	1.2 (0.4–1.9)*
Grip strength (kg)†	19.8, 18.0 (SD 8.4) (62%)	14.8, 12.0 (SD 8.0) (50%)	5.0 (0.8–9.2)*
*Quick*DASH score	20.1, 15.9 (SD 16.5)	35.3, 38.6 (SD 17.5)	15.2 (6.5–23.9)*
Mayo Wrist score	72.6, 75.0 (SD 13.2)	57.7, 60.0 (SD 14.5)	14.9 (7.8–22.0)*
PRWE score	19.2, 15.6 (SD 16.5)	31.2, 26.0 (SD 20.1)	12.0 (2.7–21.4)*
Three months			
VAS	0.3, 0.0 (SD 0.8)	0.9, 0.0 (SD 1.4)	0.6 (0.03–1.2)
Grip strength (kg)†	22.6, 20.0 (SD 9.9) (70%)	18.9, 16.0 (SD 10.2) (62%)	3.8 (−1.3–8.9)*
*Quick*DASH score	13.9, 9.6 (SD 13.8)	24.1, 20.0 (SD 18.6)	10.2 (1.9–18.5)*
Mayo Wrist score	79.1, 80.0 (SD 13.0)	67.7, 70.0 (SD 12.7)	11.4 (4.8–18.0)*
PRWE score	13.1, 9.0 (SD 14.7)	22.4, 17.0 (SD 19.7)	9.3 (0.5–18.1)*
Six months			
VAS	0.2, 0.0 (SD 0.7)	0.9, 0.0 (SD 1.7)	0.8 (0.1–1.4)
Grip strength (kg)†	28.4, 26.0 (SD 9.5) (88%)	23.4, 20.0 (SD 10.7) (78%)	5.0 (−0.1–10.2)*
*Quick*DASH score	8.3, 4.6 (SD 11.8)	15.6, 11.4 (SD 15.2)	7.3 (0.3–14.3)*
Mayo Wrist score	88.3, 90.0 (SD 10.9)	77.3, 80.0 (SD 12.8)	11.0 (4.9–17.1)*
PRWE score	8.0, 4.0 (SD 12.1)	14.4, 9.0 (SD 15.4)	6.5 (−0.7–13.6)

(Continued)

Table 3. (Continued)

	Study group		MD (99% CI)
	Immediate mobilization	Cast immobilization	
	Group ($n=56$)	Group ($n=59$)	
One year			
VAS	0.0, 0.0 (SD 0.2)	0.2, 0.0 (SD 0.5)	0.1 (−0.1–0.3)
Grip strength (kg)†	30.6, 26.0 (SD 10.7) (95%)	25.5, 22.0 (SD 11.1) (86%)	5.1 (−0.5–10.7)*
*Quick*DASH score	5.2, 2.3 (SD 7.9)	10.8, 4.6 (SD 14.5)	5.6 (0.5–11.6)
Mayo Wrist score	92.9, 100.0 (SD 8.9)	85.0, 85.0 (SD 12.6)	7.9 (2.3–13.5)*
PRWE score	4.9, 2.0 (SD 8.8)	9.8, 4.0 (SD 15.3)	5.0 (−1.5–11.4)

MD: mean difference; CI: confidence interval; SD: standard deviation; VAS: pain according to the visual analog scale; kg: kilogram; *Quick*DASH: shortened disability of the arm, shoulder, and hand; PRWE: Patient-rated Wrist Evaluation Score.
†Grip strength is given in mean ± SD and percentage of the uninjured hand (%).
*Statistical significant by a threshold of $P<0.01$.

months follow-up. Postoperative X-rays and the one-year follow-up examination showed no significant difference in palmar tilt ($P=0.39$), radial inclination ($P=0.63$), and ulnar variance ($P=0.10$). Furthermore, loss of reduction did not differ significantly between the groups (palmar tilt: $P=0.07$; radial inclination: $P=0.93$; ulnar variance: $P=0.12$). Radiological results are summarized in Table 4.

Complications

Complications were recorded in 16 out of 115 (14%) patients. No plate breakage or case of infection occurred. There was no significant difference in complication rate between the two groups (Relative Risk 0.82, 95% confidence interval 0.33–2.05).

Five patients (4.3%) had to undergo carpal tunnel release and plate removal for their carpal tunnel syndrome. Complex regional pain syndrome type-1 was seen in four patients (3.5%). Two patients (1.7%) developed extensor tendon synovitis due to dorsally protruding screws and required plate removal. One patient (0.9%) showed an intra-articular screw. In this case the plate was also removed. Extensor pollicis longus rupture occurred in one patient (0.9%), which necessitated reconstruction by indicis proprius transfer and plate removal. One patient (0.9%) showed impaired wound healing, which was treated conservatively without prolonged immobilization. In two patients (1.7%), loss of reduction occurred within the first five weeks. By prolonging the immobilization period additional surgery was prevented.

Complications divided into each study group are listed in Table 5.

Discussion

The results of this prospective randomized clinical trial prove that immediate (starting first day after surgery) wrist mobilization after volar locking plate stabilization of distal radius fractures leads to a significantly improved range of motion in extension/flexion, grip strength, and Mayo Wrist score compared to a five weeks cast immobilization one year after surgery. Additionally, no increased risk for loss of reduction or other complications were observed.

Clinically, patients in the immediate mobilization group benefited especially in the first three months according to the *Quick*DASH and nine weeks to the Patient-rated Wrist Evaluation with better results over the minimal clinical important difference.

The literature widely accepts open reduction and internal fixation in distal radius fractures, yet no consensus for the optimal rehabilitation after

Table 4. Radiological outcomes (mean (standard deviation)).

	Study group		MD (99% CI)
	Immediate mobilization	Cast immobilization	
	Group ($n = 56$)	Group ($n = 59$)	
Palmar tilt (deg)			
Before surgery/reduction	−21.2 (SD 30.3)	−15.6 (SD 18.2)	5.7 (−6.4–17.7)
Post surgery	3.6 (SD 5.7)	3.9 (SD 4.4)	0.2 (−2.3–2.7)
Latest follow up examination	3.1 (SD 7.3)	3.8 (SD 4.7)	0.6 (−2.4–3.6)
Loss of reduction	1.7 (SD 4.1)	0.4 (SD 1.2)	1.3 (−0.2–2.8)
Radial inclination (deg)			
Before surgery/reduction	14.1 (SD 11.3)	16.3 (SD 7.9)	2.2 (−2.6–6.9)
Post surgery	23.7 (SD 13.2)	21.7 (SD 5.0)	2.0 (−2.8–6.8)
Latest follow up examination	24.3 (SD 13.4)	22.3 (SD 5.0)	2.0 (−2.9–6.9)
Loss of reduction	0.8 (SD 2.1)	0.6 (SD 1.5)	0.2 (−0.7–1.1)
Ulnar variance (cm)			
Post surgery	−0.1 (SD 0.3)	0.1 (SD 0.2)	0.2 (0.0–−0.3)
Latest follow up examination	0.1 (SD 0.2)	0.1 (SD 0.2)	−0.1 (0.0–0.2)
Loss of reduction	0.2 (SD 0.3)	0.1 (SD 0.1)	0.1 (0.0–0.2)

CI: confidence interval; SD: standard deviation; VAS: pain according to the visual analogue scale; deg: degree; MD: mean difference. Statistical significant by a threshold of $P < 0.01$.

Table 5. Complications.

	Study group	
	Immediate mobilization	Cast immobilization
	Group ($n = 56$)	Group ($n = 59$)
CRPS	1	3
Loss of reduction	1	1
Impaired wound healing	1	0
Tendon irritation dorsally	1	1
CTS	2	3
Tendon rupture	0	1
Intra-articular screw	1	0
Total (16/115; 14%)	7/56 (13%)	9/59 (15%)

CRPS: complex regional pain syndrome; CTS: carpal tunnel syndrome.

surgery has been found.[39] Different protocols of postoperative mobilization and physiotherapy have been reported within present literature. However, none of these studies started with mobilization in combination with guided therapy on the first day after surgery.[37–39]

Lozano-Calderón et al.[9] compared wrist mobilization within two weeks after surgery and immobilization for six weeks. No significant differences could be found in respect of range of motion, grip strength, pain, radiological parameters, and patient-reported outcome measures. Watson et al.[12] investigated effects of a one, three or six weeks immobilization on function and pain after surgically treated distal radius fractures. Up to six weeks after surgery a significantly better Patient-rated Wrist Evaluation and extension/flexion arc between the "one-week"/"three-week" group compared to the "six-week" group was observed.

Clemenstsen et al.[14] randomized 119 patients with extra-articular distal radius fractures treated by surgery and compared an early mobilization with supervised physiotherapy including home exercises to a late mobilization with only home exercises. The early mobilization group showed a significant better *Quick*DASH six weeks and pronation three months

after surgery. However, these did not pass minimal clinical important difference.

Another prospective randomized trial compared immediate mobilization with cast immobilization after surgically treated distal radius fractures in a small group of 30 patients.[13] The immediate mobilization group started physiotherapy on the first day after surgery and the cast immobilization group after cast removal five weeks post-surgery. Range of motion in extension/flexion and grip strength was significantly better up to six months, radial/ulnar deviation up to nine weeks, and supination/pronation up to six weeks in the immediate mobilization group. *Quick*DASH and Patient-rated Wrist Evaluation differed significantly up to six weeks. However, the sample size was small, which hinders statistical interpretation.

In the presented study all patients conducted the same standardized supervised group physiotherapy program twice a week first for 30 than for 45 minutes. One group started active wrist exercises five weeks earlier (on the first day after surgery).

In a systematic review, Bruder et al.[40] identified that a shorter immobilization combined with early exercises has positive effects on participation, activity level, and impairment. Active mobilization and shortening of immobilization help to reduce pain, swelling and edema which possibly leads to scar tissue and decreased joint mobility. As guided physiotherapy has not shown to be more beneficial than home exercises alone,[40,41] shorter immobilization leads to earlier and improved use of their hand during daily-life activities.[40] The combination of a first day post-surgery supervised physiotherapy and reduced duration of cast immobilization may have benefited each other mutually and explains the better outcome in the immediate mobilization group over the cast immobilization group in the short-term of this study.

Supervised physiotherapy in both study groups was conducted by group therapy. Although physiotherapists cannot address all the individual needs of the patients within a group, it can work as a "peer group" of affected patients, where experiences are exchanged and patients learn by observation and motivate each other.[42] Additionally, this form of learning provides a high motivational factor and may increase effectivity of the therapy.

Study limitations

Still, there are several limitations that should be kept in mind before interpreting this study. Sample size calculation was based on the *Quick*DASH, showing minimal clinical important difference at a minimum of 10 points.[20] Values in *Quick*DASH showed significance up to six months, but with a mean difference of only 7.3 points. Thus, clinically the patients may not have been noticeably affected.

Pain was not measured in the first six weeks after surgery and baseline parameters directly after cast/splint removal were not collected. Further studies should consider these issues.

There was no defined endpoint (e.g. ending therapy by achieving 50% of the uninjured hand) regarding physiotherapy. Duration of physiotherapy was based on the individual needs of each patient, which was determined by the treating physician. If an endpoint would have been defined, most likely, the differences in duration between the study groups would be smaller. However, in this case, reality is probably reflected rather than study guidelines.

On one hand, patients received supervised group physiotherapy and adherence to the program was monitored, but on the other hand, adherence to the home exercises was not controlled. Therefore, the real number of carried out exercises at home cannot be determined.

The difference in length of sick leave may be biased and should be interpreted with caution, as employment status (e.g. part/full time or casual) and type of work after returning (e.g. full duties/modifications or partial duties) were not documented and may influence the return to work.

Conclusion

This prospective randomized clinical trial shows the benefit and safety of immediate (first day after surgery) mobilization in combination with supervised physiotherapy of the wrist after volar locking plate fixation of unstable distal radius fractures. Starting mobilization on the first day after surgery revealed no increased risk for loss of reduction or complications. Thus, the presented protocol of postoperative immediate mobilization represents

the standard of care at our institution and will hopefully enter the relevant guidelines in the future.

Clinical messages

- Immediate (first day after surgery) mobilization of the wrist after operatively treated distal radius fractures, in combination with supervised group physiotherapy leads to a better functional outcome after one year than an immobilization of five weeks.
- Wrist mobilization in a supervised group physiotherapy with home exercises starting the first day after surgery leads to no increased risk for loss of reduction or complications
- Shortening the immobilization time from five to one week does not lead to a significant increased risk of complications

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Trial registration

The Study was registered at the US National Institutes of Health (ClinicalTrials.gov): NCT02312128.

Ethical review committee statement

Institutional review board approval was obtained from the Austrian Workers' Compensation Board (AUVA) for this study. All patients signed an informed written consent prior to their inclusion.

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Appendix

Therapeutic interventions/exercises

Immediate mobilization group

Inpatient physiotherapy program (day 1–2 after surgery). Occupational therapists fitted all patients randomized into the immediate mobilization group with a removable thermoplastic splint for the forearm on the first day after surgery. The splint was worn for one week but patients were allowed to remove the splint during the supervised physiotherapy and at home to do the instructed wrist exercises (at least four times a day, 10 repetitions) by themselves. Patients were also encouraged to remove the splint for light activities of daily living (max lifting of 1 kg for the first eight weeks).[43]

Supervised physiotherapy was performed from the first postoperative day, with active wrist mobilization exercises in extension/flexion, pro-/supination, and radial-/ulnar deviation. Patients were instructed to start with small movements of the wrist within the painless range and increase movement range up to the pain threshold. Equally, exercises for the shoulder, elbow, and fingers in all movement directions were performed. Interventions for edema reduction were instructed (elevation of the affected hand, cool packs, manual edema mobilization[44] – light skin-traction massage of the upper extremity from distal to proximal, pumping movements with the fingers).

Outpatient physiotherapy program (day 2 after surgery). Supervised group physiotherapy was performed twice a week for 30 minutes for the first five weeks in the "immediate mobilization group" in our outpatient physiotherapy department. Active exercises for the wrist, shoulder, elbow, and fingers in all movement directions were performed. Additionally, all exercises were supposed to be carried out by the patients at home at least four times a day with 10 repetitions. Detailed review of the exercises for the "immediate mobilization group" are summarized in the Appendix Table A1.

From the sixth week after surgery the patients attended the "hand group" for 45 minutes twice a week.

Cast immobilization group

Inpatient physiotherapy program (day 1–2 after surgery). All patients randomized into the cast immobilization group received a non-removable plaster cast on the first postoperative day for five weeks. During the inpatient stay supervised physiotherapy was performed with active mobilization of the shoulder, elbow, and fingers. In addition, interventions for edema reduction as in the immediate mobilization group were instructed. All exercises were supposed to be performed by the patients at least four times a day with 10 repetitions at home.

Outpatient physiotherapy program (day 2 after surgery). Patients randomized into the cast immobilization group attended the supervised "cast immobilization group" physiotherapy twice a week for 30 minutes in our outpatient physiotherapy department. Active exercises for the shoulder, elbow, and fingers were performed. Exercises were supposed to be carried out at least four times a day with 10 repetitions at home.

The cast was worn for five weeks. After removal in the sixth week after surgery the patients attended the "hand group" for 45 minutes twice weekly, where they started with wrist exercises and continued with the exercises for shoulder, elbow, and fingers.

Detailed exercises for the immobilization group are given in Appendix Table A2.

Hand group physiotherapy program (both groups). From the sixth week after surgery, patients from both groups (immediate mobilization and cast immobilization) attended the "hand group." The intensity of all exercises from the first five weeks were increased. Additionally, coordination, stretch, strengthening exercises, and weight bearing activities for the wrist and upper extremity with different therapy devices (balls, ring, barbell, and bars) were conducted.[43,45]

Detailed exercises for the hand group are given in Appendix Table A3.

To monitor attendance to the physiotherapy program, each visit in our outpatient department was registered from the supervising physiotherapist.

Outcome measures

Range of motion and grip strength. Range of motion was measured with a standard manual goniometer in sitting position, adducted shoulder, the arm pressed against the torso, and the elbow held in 90° flexion.[46] To measure pronation, the goniometer was placed dorsally with pivot at the midcarpus and for supination volarly. Extension/flexion was measured with the goniometer positioned over the ulnar aspect of the wrist, the pivot in the carpal region, and the distal arm of the goniometer over the fifth metacarpal. For reporting radial/ulnar deviation the forearm was placed in pronation and the wrist in neutral position. The goniometer was placed at the midcarpal region, with the proximal arm in the center of the forearm and the distal arm over the third metacarpal.

Grip strength was measured bilaterally with the same Jamar hand dynamometer (Jamar, Sammons Preston Rolyan, Mississauga, Ontario, Canada) in position 2 with adducted and neutrally rotated shoulder, elbow flexed 90°, and the forearm and wrist in neutral position. One grip strength measurement was used, as it has been reported to be comparable with the average of three measurements[47] (minimal clinical important difference: 6.5 kg or 19.5% decrease[19]).

Patient-reported outcome measures. The 19-item shortened disabilities of the arm, shoulder and hand (*Quick*DASH) score is a self-administered, health-related quality-of-life questionnaire and measures disability, symptoms in a single or multiple conditions of the upper limb and has been shown to have good psychometric properties.[21,48] Patients are asked to rate their ability to perform upper limb tasks from 1 (no difficulty) to 5 (unable to perform). Higher scores indicating higher upper-extremity activity limitation[21] (minimal clinical important difference: 10 points[20]).

The Patient-rated Wrist Evaluation is a self-administered, 15-item health-related quality-of-life questionnaire and measures pain and disability in daily activities, whereby 5 assesses pain and 10 disability. The Patient-rated Wrist Evaluation was developed to assess wrist pain and disability from a patient's perspective and has been used in previous studies with patients with distal radius fractures and is proven to be a sensitive, valid, and reliable assessment tool. Higher scores indicate higher upper-extremity activity limitation[23,49] (minimal clinical important difference: 11.5 points[22]).

The modified Mayo Wrist Score assesses four domains: pain, grip strength, range of motion, and return to employment. Each domain is scored with 25 points. The Score is evaluated by a physician, but requires subjective evaluation of pain, which is reported by the patients. Higher scores indicate lower wrist activity limitation: 100–90 points are graded as "excellent," 80–89 points as "good," 65–79 points as "fair," and under 65 points as "poor."[50] Although the score is often used to assess wrist activity limitation, relativity, validity, or responsiveness is not evaluated in the literature.[51]

Table A1. Exercise program immediate mobilization group (week 1–5 after surgery – twice a week 30 minutes) – 10 patients/group/physiotherapist.

Therapeutic objectives	Minutes, including breaks	Exercises/intervention
Edema control	3‘	Elevation of the hand, activation of the muscle pump of both upper extremities, manual edema mobilization (MEM)[44] – light skin-traction massage of the upper extremity from distal to proximal – performed by the patients themselves, cold packs, skincare
Prevent adhesions of the scar	2‘	Mobilization and care of the scar (after sutures removed)
Free mobility of the finger joints	5‘	Active mobilization of the fingers in extension/flexion and of the thumb in retropulsion/opposition and abduction/adduction
		Lumbrical grip, straight and full fist, hook grip, precision grip, pinch grip, finger abduction/adduction (spread and close fingers) coordination exercises, bilateral exercises
Increasing mobility of the wrist	10‘	Active mobilization of the wrist in extension/flexion, pro-/supination, and radial/ulnar deviation up to pain threshold coordination exercises, bilateral exercises
	5‘	From week 3: stretching exercises in extension/flexion pro-/supination and radial/ulnar deviation
Maintain mobility of elbow and shoulder	5‘	Active mobilization of elbow and shoulder in all movement directions

Table A2. Exercise program cast immobilization group (week 1–5 after surgery – twice a week 30 minutes) – 10 patients/group/physiotherapist.

Therapeutic objectives	Minutes, including breaks	Exercises/intervention
Avoid narrow or loose cast	5‘	Plaster check
Edema control	5‘	Elevation of the hand, activation of the muscle pump of both upper extremities, manual edema mobilization (MEM)[44] – light skin-traction massage of the upper extremity from distal (proximal of the cast) to proximal – performed by the patients themselves, cold packs, skincare
Free motion of the finger joints	10‘	Active mobilization of the fingers in extension/flexion and thumb in retropulsion/opposition and abduction/adduction.
		Lumbrical grip, straight and full fist, hook grip, precision grip, pinch grip, finger abduction/adduction (spread and close fingers) Coordination exercises, bilateral exercises
Maintain mobility of elbow and shoulder	10‘	Active mobilization of elbow and shoulder in all movement directions

Table A3. Exercise program hand group (from week 6 after surgery – twice a week 45 minutes) – 10 patients/group/physiotherapist.

Therapeutic objectives	Minutes, including breaks	Exercises/intervention
Edema control	3‘	Elevation of the hand, activation of the muscle pump of both upper extremities, light skin-traction massage manual edema mobilization (MEM)[44] – light skin-traction massage of the upper extremity from distal to proximal – performed by the patients themselves, cold packs, skincare
Prevent adhesions of the scar	2‘	Mobilization and care of the scar
Free motion of the finger joints	5‘	Active mobilization of the fingers in extension/flexion and thumb in retropulsion/opposition and abduction/adduction. Lumbrical grip, straight and full fist, hook grip, precision grip, pinch grip, finger abduction/adduction (spread and close fingers). Coordination exercises, bilateral exercises
Free motion and function of the wrist	15‘	Active mobilization of the wrist in extension/flexion, pro-/supination, and radial/ulnar deviation with and without a therapy tools (ball, ring, dumbbell, bars) Exercises to increase endurance and coordination
	10‘	Passive stretching in extension/flexion, pro-/supination after week 8: weightbearing activities through the wrist up to the pain threshold
Wrist strength equal to the uninjured side	5‘	Strengthening exercises (week 6–8: 1 kg dumbbell, after week 8: 2 kg dumbbell, increasing up to the pain threshold)
Maintain mobility of elbow and shoulder	5‘	Active mobilization of elbow and shoulder in all movement directions