# **Original Article**

# Early Mobilization Versus Splinting After Surgical Management of Distal Radius Fractures

Results of a Randomized Controlled Study of Postoperative Care in Older Patients

Christian Zeckey\*, Anton Späth\*, Sebastian Kieslich, Christian Kammerlander, Wolfgang Böcker, Maximilian Weigert, Carl Neuerburg

# **Summary**

<u>Background</u>: After the surgical management of distal radius fractures (DRF) in older patients, further treatment with a splint often follows. It is unclear whether early mobilization might be superior to splinting in this group of patients, as it is in others. In this prospective, randomized, controlled trial, we attempted to determine whether early mobilization yields better outcomes.

Methods: 50 patients over age 70 with DRF were included in the trial. Group A (the splint group) was treated with postoperative immobilization, group B with early mobilization. Clinical follow-up examinations were performed at 2, 6, and 12 weeks and at 6 and 12 months. X-rays were obtained preoperatively, postoperatively, at 6 weeks, and at 6 months. The primary outcome parameter was the modified Mayo Wrist Score (MMWS) at 6 weeks.

Results: At 6 weeks, the functional outcome was better to a statistically significant extent in group B (MMWS; 65/100 vs. 55/100 [q25: 55/40 - q75: 70/70; p = 0.025]). No difference between the two groups was demonstrable in their further clinical course. The estimated regression model revealed a statistically significant effect of the method of treatment (p = 0.023). There were no differences in hand strength or in x-ray findings.

<u>Discussion</u>: Early mobilization is associated with better wrist function on initial follow-up, without any demonstrable disadvantage with respect to secondary dislocation. The psychological benefit and protective function of wrist splinting in patients who are in danger of falling should nonetheless be investigated in further studies.

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istal radial fractures (DRFs) are the most common upper extremity fracture and often associated with underlying osteoporosis in older patients (1). In view of the demographic trend in our aging society, a 38% increase in DRFs is expected by 2050 (2). This highlights the importance of this injury entity and the significance of optimal fracture management.

Surgical treatment—particularly in elderly patients—has repeatedly been called into question (3). However, it has been shown that surgical treatment using volar locking plate osteosynthesis achieves significantly better outcomes in terms of reduction and function (4, 5). In particular, delayed surgical management in the setting of secondary fracture displacement following initial conservative therapy shows poorer outcomes (6).

This surgical technique of DRF management, although more aggressive particularly in older patients, could offer advantages in fragile patients in terms of returning to everyday activities and early functional mobilization, thereby reducing immobility-related complications (7).

Irrespective of the discussion on the advantages of conservative or operative therapy, the question arises of the benefits of immobilization for operated patients following surgery.

A prospective randomized study showed that shorter immobilization times can have a positive effect on treatment outcomes in younger patients (8). Thus, shorter immobilization appears to have less of an effect on the treatment outcome (9). Another study—also in younger patients—demonstrated that early mobilization represents a safe approach. In addition, better outcomes were observed with early mobilization (10).

In the light of these results, prescribing wrist immobilization following surgical fracture stabilization appears to be paradoxical. Nevertheless, post operative immobilization is recommended and carried out time and again in the literature (11, 12). However, the authors are not aware of any prospective randomized studies in older patients with surgically managed DRF.

The aim of the current randomized controlled study is to investigate whether dispensing with





Figure 1: Top: commercially available wrist orthosis in a functional position: postoperative radiographic follow-up after management of a right distal radial fracture using locking plate osteosynthesis

postoperative follow-up treatment using a wrist orthosis leads to an improvement in the functional and radiological treatment outcome.

## **Methods**

For the present study, a prospective randomized investigation was carried out including patients that had undergone surgical stabilization of a distal radial fracture (DRF) by means of conventional volar locking plate osteosynthesis. Postoperatively, patients in group A received a commercially available wrist orthosis (Figure 1) in a functional position for 4 weeks (standard treatment), while patients in the intervention group (group B) underwent early functional rehabilitation without immobilization. This was performed at the patients' own training frequency with early mobilization and a pain-adapted increase in weight-bearing.

All patients were prescribed between two and three physiotherapy sessions per week.

Randomization was performed by the software application List Randomizer (Randomness and Integrity Services Ltd., Premier Business Centres, Dublin, Ireland; www.random.org). For further details, the reader is referred to the *eMethods* section. The study was carried out in accordance with Good Clinical Practice guidelines, and approval was obtained from the Ethics Committee of the Ludwig Maximilian University (LMU) Munich, Germany (AZ 17–209). The study was registered online in an international study registry (DRKS-00016418). Due to a change in principal investigator, the study was registered retrospectively.

Taking the inclusion and exclusion criteria into account, trauma surgery patients aged >70 years that were treated on an inpatient basis for distal radial fractures at the Department of General, Trauma, and Reconstructive Surgery at the LMU, Munich, between March 2017 and July 2019 and who consented to participate in the investigations were enrolled in the study.

Patients with dementia, additional fractures to the same extremity, or bilateral fractures, as well as patients with ligament injuries in the wrist area, were excluded. In a first step, two independent investigators classified fractures according to the AO classification (*Arbeitsgemeinschaft für Osteosynthesefragen*, AO; Association for the Study of Internal Fixation) on the basis of preoperative two-plane radiographs. Subsequently, additional two-plane radiological evaluations were performed on postoperative day 1, as well as at 6 weeks and 6 months. For radiographic evaluation, the Böhler angle was digitally measured, in addition to the Soong score, and evaluated with regard to the anatomical outcome of reduction and any secondary displacement.

To evaluate the functional outcome, established outcome parameters were recorded at the time of follow-up examinations at 2 and 6 weeks, as well as at 3, 6, and 12 months. To evaluate wrist function, the internationally established Modified Mayo Wrist Score (MMWS) was used (0 = lowest, 100 = highest)score) (13, 14). For this study, the time of follow-up examination at 6 weeks was defined as the primary outcome parameter. The other times of follow-up examination were set as secondary outcome parameters. The neutral-0 method initially specified in the study protocol as the primary outcome parameter was corrected to the MMWS, and the power analysis was applied to this. Due to the fact that the difference between the two groups could no longer be measured after 3-month follow-up, subsequent statistical analysis at 12 months was dispensed with.

In addition, function of the affected upper extremity was recorded using the DASH (Disabilities of the Arm, Shoulder and Hand) score (100 = worst, 0 = best score). Wrist range of motion (ROM) was recorded using the neutral-0 method.

### **Statistics**

The study investigated the hypothesis that group B had better wrist function at 6 weeks according to the MMWS after surgically treated distal radial fracture compared to group A. Sample size planning using a-priori power analysis was carried out by a platform available online (www.powerandsamplesize.com, HyLown Consulting LLC, Atlanta, USA). Statistical analysis was performed using the R (Version 3.6.2) and SPSS (Version 25.0.0.1) programs. To test the hypotheses, statistical tests on significance level  $\alpha = 0.05$  and linear mixed models were used. Sample size planning and statistical analysis are discussed in more detail in the *eMethods* section.

#### Results

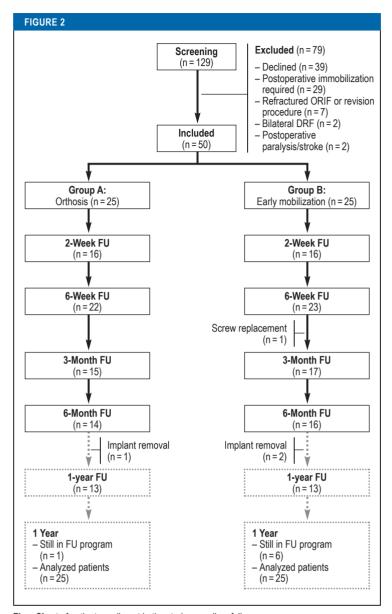
A total of 50 patients were included in the study, comprising 25 with a median [q25; q75] age of 82.0 (78.5; 84.5) years in group A and 25 patients with a median age of 80.0 (76.5; 83.5) years in group B. The flowchart shows the recruiting process (*Figure 2*).

Table 1 shows the demographic and other data of the included patients. Both in terms of radiographic fracture classification and when taking into account the basic demographic data and comorbidity index, group distribution was homogeneous with no significant differences. The prolonged hospitalization of patients with wrist braces can be attributed to external circumstances, such as a search for a care facility/rehabilitation places.

MMWS as the primary outcome parameter showed statistical differences in hand function at 6 weeks postoperatively between the groups (p = 0.025), with better functional values in group B. No difference could be seen in the further follow-up.

A statistical treatment effect (p = 0.023) was demonstrated using a mixed linear regression model, whereby the differences between the two groups became apparent in the further postoperative course. For example, a higher expected MMWS was evident in the intervention group in the early postoperative phase (up to the 6-week point). At the later time point (at 6 months), the expected scores were comparable in the two groups (Figure 2). Since the expected Mayo wrist score was already approximately aligned in the two groups at 6 months, the model was only considered up to this measurement point.

In terms of the mobility of the affected wrist, a continuous improvement was seen over the observation period in both study groups for flexion/extension as well as pronation/supination (Table 2). Here, again, a visible treatment effect was demonstrated in the mixed linear model. The differences between the two groups became smaller as follow-up time progressed (Figure 3). On radiographic examination, no differences in terms of Soong index and volar tilt were detected between the two groups. The data are shown in the eTable. Surgical complications occurred in four patients in the further course. Due to screw loosening (intervention group B), one screw needed to be re-



**Flow Chart** of patient enrollment in the study as well as follow-up course DRF, distal radial fracture; FU, follow-up, ORIF, open reduction and internal fixation

placed in one case at around 8 months. In two other patients, the metal needed to be removed prematurely (at nine and at 10 months, respectively) due to pain in the region of the plate. In the final case, the metal was prematurely removed at 11 months only at the patient's request. The patient was not experiencing pain, nor was there any other medical indication. In all of these cases, the patients were excluded at the time of revision (Figure 2).

# **Discussion**

The positive treatment outcomes for the surgical management of distal radial fractures even in older patients have led to a paradigm shift towards surgical treatment (8). The concept of postoperative follow-up treatment

IMPLE I
Averaged basic demographic data of patients in the individual investigation groups at the time of recruiting. Presented as median (q25; q75) or number (relative frequency)

	Total population	Group A	Group B	p-Value
Age (years)	80.5 (78.0; 84.0)	82.00 (78.5; 84.5)	80.0 (76.5; 83.5)	0.161
Sex Female Male	47 (94%) 3 (6%)	23 (92%) 2 (8%)	24 (96%) 1 (4%)	1
Body mass index (BMI)	23.0 (21.0; 27.0)	23.0 (22.0; 27.0)	23.0 (20.0; 26.5)	0.369
Time from diagnosis to OP (days)	5.0 (3.0; 7.0)	5.0 (2.5; 7.0)	4.0 (3.0; 5.0)	0.232
Charlson comorbidity score (CCI)	4.00 (3.00; 5.00)	4.00 (3.00; 5.50)	4.00 (3.00; 5.00)	0.254
ASA classification 1 2 3	0 (0%) 29 (58%) 21 (42%)	0 (0%) 13 (52%) 12 (48%)	0 (0%) 16 (64%) 9 (36%)	0.567
AO classification  A1  A2  A3  B1  B2  B3  C1  C2  C3	0 2 (4%) 4 (8%) 1 (2%) 0 2 (4%) 13 (26%) 14 (28%)	0 2 (8%) 2 (8%) 0 0 1 (4%) 5 (20%) 7 (28%) 8 (32%)	0 0 2 (8%) 1 (4%) 0 1 (4%) 8 (32%) 7 (28%) 6 (24%)	0.680
Duration of hospitalization (days)	4.0 (3.0; 6.0)	4.00 (3.0; 12;0)	3.0 (2.0; 5.0)	0.016
Discharge management:  Discharge home  Discharge to STC  Discharge to GRB	43 (86%) 6 (12%) 1 (2%)	19 (76%) 5 (20%) 1 (4%)	24 (96%) 1 (4%) 0 (0%)	0.120

AO, Arbeitsgemeinschaft für Osteosynthesefragen (Association for the Study of Internal Fixation); ASA, American Society of Anesthesiologists; GRB, geriatric rehabilitation; OP, operation; STC, short-term care

for surgically managed patients currently remains unclear. Immobilization in plaster or using a brace is often recommended following surgical management. This is remarkable inasmuch as the very advantage of surgical fracture stabilization is that it should enable early functional rehabilitation, and early mobilization/rehabilitation has proved to be clearly superior for other anatomical regions particularly in older patients (15, 16). The advantages of prompt functional rehabilitation following osteosynthetic treatment of the wrist are also becoming the focus of ever more attention in industrialized countries and are increasingly the subject of structured studies (10, 17). To the best of the authors' knowledge, there are no prospective randomized studies investigating the effect of postoperative followup treatment after distal radial fractures in older patients.

# The main results of the present study are:

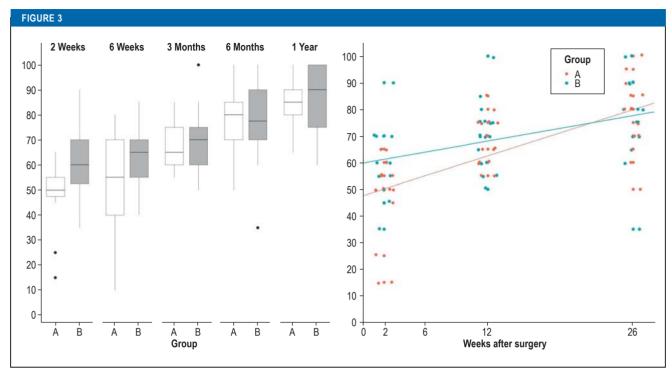
- Postoperative follow-up treatment without orthosis results in significantly better function in the first 6 weeks following surgically managed distal radial fractures; this function aligns with the orthotic approach in the further course.
- An orthosis does not confer a protective effect with regard to the radiological outcome.

The results of our investigation yield important insights regarding the concept of postoperative follow-up treatment in older patients with distal radial fractures. In the context of the available literature with a similar level of evidence, a recently published prospective randomized study investigated the effect of a shorter period of immobilization in extra-articular fractures. No difference was seen between the patients (average age, 55 years) that either wore a plaster splint for 2 weeks or underwent immediate physiotherapy (9).

To date, these findings could not be sufficiently extrapolated to older patients. Our data make it possible, for the first time, to extrapolate findings to intra-articular fractures also in older patients.

A prospective randomized study by Stuby et al. showed, in addition to improved functional parameters, subjectively greater comfort when wearing a dynamic orthosis compared to a plaster splint. It was not possible to make a comparison of functional post-operative treatment (18).

Other studies investigated the effect of wrist orthoses—particularly over the short-term course in younger patients—and showed better range of motion and pain reduction in the group with early functional rehabilitation, thereby underscoring the basic concept



MMWS (points: < 65 = poor, 65–79 = satisfactory, 80–89 = good, 90–100 = very good) (left) and as a function depending on the time to the 6-month time point (right). MMWS at the 6-week time point is defined as the primary outcome parameter in this study MMWS, Modified Mayo Wrist Score

of successful volar locking plate osteosynthesis (19). In young patients with surgically treated DRF, post-operative treatment with a plaster cast actually showed poorer functional outcomes and grip strength compared to early mobilization at comparable radiographic healing results (10).

On the basis of our data, the intended postoperative treatment approach should be the main consideration when selecting the treatment strategy especially in older patients with distal radial fractures. Bearing this in mind, a high level of stability of osteosynthesis is required (20).

In the present study, the evaluation of radiological findings revealed no difference between the two groups. Therefore, one can conclude that immobilization following surgical management does not confer a reduction in risk of secondary displacement. As such, our data do not substantiate the frequently expressed concern regarding secondary displacement in the absence of postoperative immobilization following surgical treatment.

The overriding goal in the management of older trauma surgical patients is a return to everyday activities. As in other investigations (21), the current study found better functional outcomes especially in the first 6 postoperative weeks in the patient group treated with early mobilization.

The overall somewhat better DASH scores in our study—at comparable grip strengths—compared to other studies could be due to the cohorts investigated

(22). For example, older age could affect the level of impairment perceived by the individual patient; the same applies to the perception of pain.

The superiority of early functional rehabilitation may be of particular importance especially in older patients, since even shorts periods of restricted function and everyday activity in frail patients can lead to irretrievable loss of function (23).

A possible reason for prescribing postoperative wrist orthoses may also be the risk of falls. Investigations to evaluate the risk for second fractures following initial hip fracture demonstrate that advanced patient age in particular is associated with a higher risk for second hip fractures (24).

Likewise in the current study, the mean patient age was relatively high; nevertheless, geriatric comorbidity assessments, such as the chronic critical illness (CCI) and the American Society of Anesthesia (ASA) scores, indicate a patient collective that is still robust with a comparatively low risk for second falls. However, studies on hip fracture patients in the same age group showed that 56% of patients suffer further falls within the first year following a hip fracture (25). Therefore, taking into account the data on patients at risk of falls, the psychological effect of postoperative wrist orthosis also needs to be borne in mind.

# Limitations

When designing the study, the available scores were critically questioned. In particular, the feasibility of the

TABLE 2					
Mobility of the affected wrist*					
MMWS	Group A	Group B			
2 Weeks	50 (47.5; 55)	60 (52.5; 70)			
6 Weeks*	55 (40; 70)	65 (55; 70)			
3 Months	65 (60; 75)	70 (60; 75)			
6 Months	80 (70; 85)	77.5 (70; 90)			
12 Months	85 (80; 90)	90 (75; 100)			
ROM extension/flexion	Group A	Group B			
2 Weeks	20/0/20 (10; 22.5); (10; 20)	30/0/30 (20; 32.5); (13.8; 40)			
6 Weeks	20/0/25 (16.3; 30); (20; 38.8)	30/0/40 (30; 40); (30; 50)			
3 Months	40/0/30 (30; 50); (25 ;47.5)	40/0/50 (30; 40); (40; 50)			
6 Months	55/0/40 (40; 60); (32.5; 48.8)	42.5/0/40 (40; 50); (40; 50)			
12 Months	50/0/40 (40; 60); (30; 60)	50/0/50 (40; 72.5); (40; 65)			

MMWS, Modified Mayo Wrist Score;

ROM range of motion according to the neutral-zero method;

# Key messages

- Postoperative follow-up treatment without an orthosis results in significantly better function in the first 6 weeks following surgically managed distal radial fractures; this level of function aligns with the orthotic approach in the further course.
- According to radiological evaluation, there were no signs of secondary loss of reduction at the same grip strength compared to the group immobilized with a wrist orthosis.
- However, whether or not wrist orthoses of this kind serve a possible psychological
  protective function or contribute to re-fracture prevention in older high-risk groups
  remains unclear and should be investigated in further studies.

score in this specific patient population (> 70 years) was considered. The MMWS is widely used in the literature and offers the advantage of rapid evaluation (26, 27). Furthermore, the items assess not only function as such, but also the variable "pain." The great advantage of the score lies in the fact that it is straightforward to carry out (28). Therefore, we chose the score taking into particular account the patient group to be evaluated. In the future, it would be interesting to see how the acceptance and feasibility of an—ideally webbased—PROMs (patient reported outcome measures) is in this patient group and how this affects the quality of the PROMs. We assume that, with the wider use of the PROMs also as a quality control measure, this aspect will play an important role. Analysis of the PRWE

(patient-rated wrist evaluation) could increase comparability in subsequent studies.

The present study with a group size comparable to other randomized DRF studies recorded no postoperative falls or anxiety in patients that permit a reliable assessment of the psychological effect of temporary postoperative wrist immobilization.

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#### Conflict of interests

The authors state that no conflicts of interest exist.

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<sup>\*</sup>Presented as median (q25; q75), p = 0.025, significance in MMWS at the 6-week time point

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#### ► Supplementary material

eMethods, eTable: www.aerzteblatt-international.de/20m0445

# CLINICAL SNAPSHOT

# Vesicular Skin Reactions After Stress ECG

A 43-year-old man presented with acute skin lesions on his chest that were sensitive to touch with a slight burning sensation. The lesions had formed after a stress ECG examination the day before. Clinical examination found several skin lesions, positioned exactly at the sites of application of the electrodes, composed of precisely annular, transparent, tightly filled vesicles on an erythematous background. Further questioning revealed that the stress ECG had been interrupted because of a technical defect, but the electrodes, which had been moistened with a disinfectant spray, had not been removed during the delay. The result was that the electrodes were on the patient's skin for about 2.5 h. On the basis of this history and the clinical findings, the cutaneous vesicular reaction pattern, atypical for stress ECG, was classified as irritant–toxic contact eczema. The cause in this case was the prolonged contact time of the alcohol-based disinfectant in occlusive conditions under



**Figure:** Vesicular skin lesions restricted to the sites of application of the electrodes

the suction pads of the electrodes. The skin lesions healed completely within a few days after drainage of the vesicles and application of topical steroids under wet-wrap dressings.

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# Supplementary material to:

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# **eMETHODS**

# Randomization

Randomization was performed by the software application List Randomizer (Randomness and Integrity Services Ltd., Premier Business Centres, Dublin, Ireland; www.random.org).

Randomization to the two groups was performed with equal probability (by randomly permuting the sequence of participants' IDs). Due to the study setting, blinding was not possible in the direct follow-up period due to the orthosis being clearly visible. After removal of the orthosis, follow-up was performed by two co-authors who had no specific knowledge regarding the group to which patients had originally belonged. In this way, bias could be largely reduced.

# Sample size determination

Sample size planning using a-priori power analysis was carried out by a platform available online (www.powerandsamplesize.com, HyLown Consulting LLC, Atlanta, USA).

The calculation was performed on the basis of function according to the Modified Mayo Wrist Score (MMWS). It was assumed that, at a difference of 10 points in the MMWS, an alpha-error of 5% and a power of 0.8 should be achieved. Determination of the sample size was powered by a comparison of two means on the basis of a t-test. This yielded a total sample size of 21 patients per group ( $\alpha = 0.05$ ).

# Statistical analysis

Statistical analysis was performed using the R (Version 3.6.2) and SPSS (Version 25.0.0.1) programs. Statistical tests at significance level  $\alpha$  = 0.05 and linear mixed models were used to test the hypotheses.

Depending on whether outcome parameters were normally distributed, as verified in graph form, either the t-test or the Wilcoxon test was used. An analysis was also performed of the outcome parameters over the study period up to measurement at 6 months with a linear mixed model (with time, treatment, and interaction effect, as well as a random intercept for the individual patients). Visualization over the course of time shows the estimated fixed effects. The significance of the treatment effect over time was tested with a likelihood ratio test.

#### eTABLE Soong index given as frequencies (n); volar tilt and grip strength given as median (q25; q75) Group B Soong index Grade 0 28 13 15 22 Grade 1 12 10 0 Grade 2 0 0 Total 50 25 25 Intraop 4.00 3.00 5.00 (0.25; 6.00)(1.00; 5.00)(-0.50; 8.50)Postop 5.00 5.00 7 00 (2.00; 7.50) (2.00; 9.00) (2.50; 9.00) 6 Weeks 0.00 0.00 2.00 (-4.50; 5.00)(-4.75; 3.75)(-4.50; 6.50)6 Months 1.00 -0.50 3.00 (-4.50; 6.00)(-4.75; 4.75)(-5.50; 8.50) Grip strength (kg) Group B 2 Weeks 6.20 5.50 7.90 (4.50; 8.48)(4.25; 7.20) (4.50; 10.50) 6 Weeks 9.65 8.25 10.45 (5.13; 12.48) (4.73; 11.95) (6.03; 13.33) 3 Months 13.75 13.50 13.65 (9.88; 16.05) (8.95; 16.13) (10.08; 16.15) 6 Months 16.35 18.60 14.45 (13.00; 21.58) (13.70; 23.75) (12.80; 18.80) 12 Months 19.00 18.80 19.00 (16.00; 21.65) (16.00; 23.25) (15.45; 20.98)

An analysis of differences between the groups yielded no statistically significant differences in either volar tilt or grip strength.

No p-values given due to of alpha-error accumulation through multiple tests.

On radiographic examination, no differences in terms of Soong index and volar tilt were detected between the two groups.

# Soong index:

Group A: grade 0 n = 13, grade 1 n = 12, grade 2 n = 0

Group B: grade 0 n = 15, grade 1 n = 10, grade 2 n = 0

Volar tilt medians (q25; q75) in °:

Intraop: group A: 3.00 (1.00; 5.00) vs. group B: 5.00 (-0.50; 8.50)

Postop: group A: 5.00 (2.00; 7.50) vs. group B: 7.00 (2.50; 9.00)

6 Weeks:

group A: 0.00 (-4.75; 3.75) vs. group B: 2.00 (-4.50; 6.50)

6 Months

group A: -0.50 (-4.75; 4.75) vs. group B: 3.00 (-5.50; 8.50)

Furthermore, also in hand grip measurement, no difference was seen between the two groups investigated

Grip strength medians (q25; q75) in kg:

2 Weeks

group A: 5.50 (4.25; 7.20) vs. group B: 7.90 (4.50; 10.50)

6 Weeks

group A: 8.25 (4.73; 11.95) vs. group B: 10.45 (6.03; 13.33)

3 Months

group A: 13.75 (8.95; 16.13) vs. group B: 13.50 (10.08; 16.15)

6 Months

group A: 18.60 (13.70; 23.75) vs. group B: 14.45 (12.80; 18.80)

12 Months

group A: 18.80 (16.00; 23.25) vs. group B: 19.00 (15.45; 20.98)