EDITOR'S CHOICE

Nonsurgical Treatment Versus Surgical Treatment in Displaced Metacarpal Spiral Fractures: Extended 4.5-Year Follow-Up of a Previously Randomized Controlled Trial

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Purpose Spiral or oblique fractures of the metacarpals of rays II–V are common and often managed nonsurgically. Surgery is typically recommended for fractures with displacement or rotational deformity. In a recent randomized controlled trial of displaced fractures, nonsurgical treatment with early unrestricted mobilization was found to be noninferior to surgical treatment at the 1-year follow-up. However, long-term outcomes comparing these approaches have not been reported. This study evaluated whether treatment differences emerge at the midterm follow-up, hypothesizing that nonsurgical treatment will remain noninferior.

Methods Of 42 patients with displaced spiral/oblique metacarpal shaft fractures enrolled in our previous randomized controlled trial, 34 were analyzed at a mean of 4.5 years postinjury (range: 3.1–6.6 years). The primary outcome was grip strength of the injured hand relative to the uninjured hand, with and without adjustment for hand dominance. Secondary outcomes included the Disabilities of the Arm, Shoulder, and Hand score, range of motion, rotational deformity, complications, and patient-rated pain.

Results Nonsurgical treatment remained noninferior within the predefined margin. The mean grip strength was 95% of the uninjured hand in the nonsurgical group and 95% in the surgical group. After adjusting for hand dominance, the mean grip strength was 103% of the uninjured hand in the nonsurgical group and 96% in the surgical group. Secondary outcomes were similar between the groups.

Conclusions Nonsurgical treatment with early unrestricted mobilization remains noninferior to surgical treatment at the midterm follow-up. These findings support the viability of this treatment option for displaced single spiral or oblique metacarpal shaft fractures of rays II–V in patients who prefer nonsurgical treatment.

Type of study/level of evidence Therapeutic II.

Key words Early mobilization, metacarpal fracture, noninferiority, RCT.

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FRACTURES OF THE METACARPALS constitute almost one-third of hand fractures, which in turn represent approximately one-fifth of all fractures.[1,2] For spiral and oblique metacarpal shaft fractures (MSFs) of rays II−V, surgical treatment has traditionally been the recommended treatment whenever notable shortening or rotational deformity is present. This stems from the finding that metacarpal shortening decreases grip strength and causes extensor lag in biomechanical models.[3,4] Whether these experimental findings are relevant in actual clinical practice has recently been investigated, with the hypothesis that nonsurgical treatment, together with early and unrestricted mobilization, will yield noninferior clinical outcomes while avoiding the risks associated with surgical treatment.

We tested this hypothesis using grip strength as the primary outcome in a randomized controlled noninferiority trial and found noninferiority of grip strength at the 1-year follow-up, despite shortening of the fractured metacarpal.[5] However, it is unknown if changes resulting from the nonsurgically treated fractures may cause changes over a longer period of time. Shortening of the bone may exert an effect on all surrounding tissue and alteration of biomechanical forces, possibly causing previously undiscernible weakness or extensor lag. With more time after the completion of formal rehabilitation within a trial setting, any temporary effects of therapy could be expected to diminish. Whether such factors could influence outcomes has, to our knowledge, not been previously explored for this type of injury.

To address this knowledge gap, we conducted an extended follow-up of the same patient cohort at 3−6 years. Our hypothesis remained that nonsurgical treatment with early unrestricted mobilization would be noninferior to surgical treatment using open reduction and internal fixation for spiral and oblique MSFs of rays II−V, even at the midterm follow-up.

MATERIALS AND METHODS

This study and the original trial were approved by the Swedish Ethical Review Authority. All patients agreed to participate and gave their written informed consent. The study followed the Declaration of Helsinki and the Consolidated Standards of Reporting Trials guidelines. Registration at clinicaltrials.gov (NCT05869331) was completed before recruitment was initiated.

Trial design and participants

This was an extended, midterm follow-up of a previously completed, prospective, randomized controlled trial of two equally sized parallel groups. Only patients previously included and evaluated in the original trial were eligible for participation in this analysis. All 42 patients from the previous trial were invited back to the outpatient clinic at Uppsala University Hospital or the Regional Hospital of Falun between May 29, 2023 and February 5, 2024. Inclusion and exclusion criteria were the same as in the original trial (Table 1). For a detailed flowchart, see Figure 1, and for representativeness of study participants, see Table S1, available online on the *Journal*'s website at www.jhandsurg.org.

Randomization, allocation concealment, and blinding

A description of the initial randomization protocol and blinding can be found in the original report.[5] Recruitment for this extended follow-up was conducted by F.P. and C.S.O. following a mail or telephone invitation. All patients were compensated with 500 Swedish Kronor (approximately 45 US dollars) for participation.

Interventions

Patients in the nonsurgical group were mobilized upon inclusion, allowing unrestricted use of the injured hand. Patients were initially assisted by a physiotherapist (Uppsala) or an hand therapist (Falun), who introduced them to a standardized mobilization regime consisting of making a closed fist five times, on five occasions each day. They were offered an optional resting splint to be used between training sessions or buddy taping for comfort.

Patients in the surgical group were operated on using a standard longitudinal dorsal approach; fractures were reduced and stabilized with at least two interfragmentary compression screws (2 mm) or a dorsally placed variable angle locking compression plate and screws (LCP Compact Hand 2.0, DePuy Synthes). A plaster splint immobilizing the wrist and metacarpophalangeal joints was applied after surgery and removed at 2 weeks, simultaneous with suture removal, followed by active mobilization assisted by a physiotherapist or hand therapist. Details of both interventions are in sections B and C of Appendix 1, available online on the *Journal*'s website at www.jhandsurg.org.

Outcomes

Both groups were initially assessed at 6 weeks, 3 months, and 1 year (patients in the surgical group had an additional visit at 2 weeks for splint removal). For the extended follow-up, patients were examined again during an additional visit 3−6 years after

TABLE 1. Inclusion and Exclusion Criteria for the Original Trial

Inclusion Criteria	Exclusion Criteria
• Diaphyseal, single spiral and oblique fractures of the index-to-little finger metacarpals. • Fracture line at least twice the length of the diameter of the bone at the level of the fracture. • At least 2 mm displacement or shortening of the fracture or malrotation. • Normal hand function before the injury. • Fracture <10 d old at possible randomization.	• Multiple metacarpal fractures. • Open fractures. • Inability to follow instructions. • Fracture line not twice the length of the diameter of the bone at the level of the fracture. • Abnormal hand function before the injury. • Previous ipsilateral hand fractures. • Fracture >10 d old at possible randomization.

recruitment. Grip strength was measured using a dynamometer (JAMAR, Patterson Medical Ltd) set at second position for three consecutive measurements, calculating the mean value.[6] Strength was reported as a percentage of the mean grip strength of the opposite, uninjured hand. Strength was also reported, taking hand dominance into account, assuming a 15% difference in favor of the dominant hand in right-handed individuals. Finger joint ranges of motion (ROMs) were measured using a finger goniometer at the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints, recording to the nearest 5°; hyperextension was recorded as a negative value. Total active motion was calculated and reported as a percentage value of the uninjured hand total active motion. Flexion deficit was measured from the distal flexion crease of the palm in centimeters. Extension deficit was defined as any measurable difference in extension calculated by comparing the combined goniometer measurements of all three joints with the opposite hand. Rotational deformity was defined as visible rotational asymmetry between the injured finger and the same finger on the opposite hand during a full arc of flexion, also noting the presence of finger scissoring over or under a neighboring finger.

The Disability of the Arm, Shoulder, and Hand (DASH) score was used in conjunction with patient-reported numeric rating scale quantification of pain (range: 1−10, with 1 representing best and 10 representing worst).

Sample size calculation

Expecting a normal variation in grip strength between the hands of 10% to account for hand dominance and allowing an additional 5% difference in grip strength between measurements, the noninferiority margin (NIM) was set at a 15% decrease relative to the uninjured hand. The same threshold was used to define a successful treatment outcome; sample size was calculated assuming that 97% of patients would achieve a successful outcome. To achieve a one-sided 97.5% confidence interval (CI) with 80% power, 21 patients per treatment group were needed.

Statistical analysis

The primary outcome of grip strength was reported first as an unadjusted mean calculated from individual grip strength fractions to percentage values ([injured hand/uninjured hand] × 100). Second, adjustment for hand dominance was calculated using the formula (dominant hand × 0.85) for right-handed individuals with injury to their nondominant hand and (nondominant hand × 1.15) for right-handed individuals with injury to their dominant hand. The normality of grip strength data was verified using the Shapiro-Wilk test and compared using the Student *t* test. Two-sided 95% CIs were used to quantify estimation uncertainty, and the lower 95% CI of grip strength percentage was compared with the NIM to assess noninferiority. *P* values of <.05 were considered significant. Secondary outcomes are reported as calculated means and not subjected to hypothesis testing because of expected inadequate power.

RESULTS

Characteristics of the study population

Thirty-five (83%) patients attended the follow-up at a mean of 4.5 years (range: 3.1−6.6) after injury; seven patients were lost to follow-up. One patient relocated in the interim between the trials and was examined at the hospital closest to the patient's new home. Baseline characteristics of patients are shown in Table 2. All patients in both groups were right hand-dominant. One patient attended but was excluded because of loss of most of the function of the uninjured hand because of an unrelated medical condition, making the comparison between hands impossible, leaving 34 (81%) patients for the analysis.

For a detailed account of the patients lost to follow-up, see Figure 1. As reported in the original

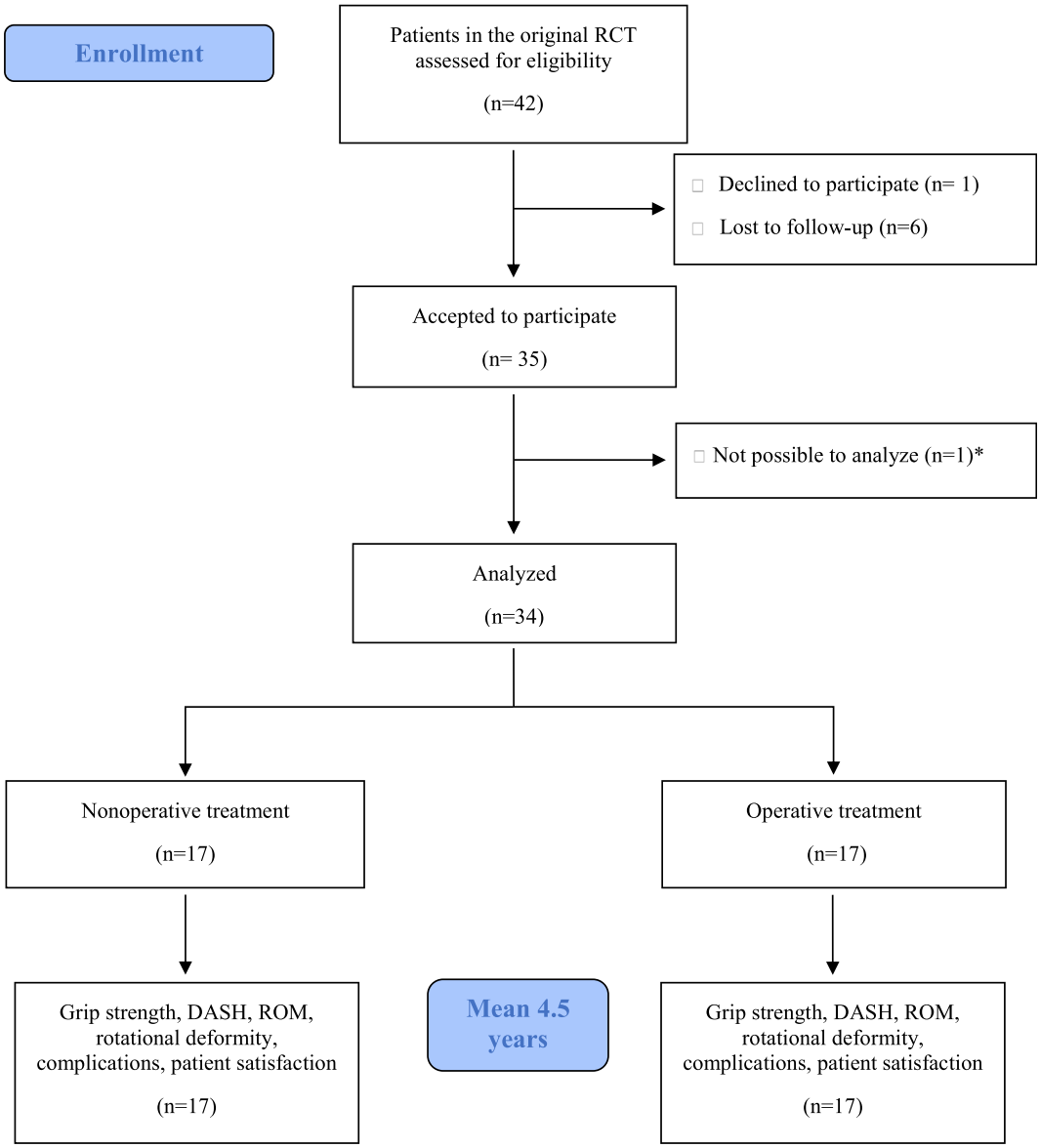

FIGURE 1: Consolidated Standards of Reporting Trials (CONSORT) flowchart. *One patient had lost all active motion of the contralateral hand because of inclusion body myositis, making grip strength analysis impossible.

article, the first surgeon had an experience level of at least 3.[7]

Primary outcome

The mean grip strength of the injured hand relative to the uninjured hand did not differ significantly between the groups, but absolute value grip strength was higher in the surgical group, approaching the threshold for significant difference. In patients who received nonsurgical treatment, the lower limit of the calculated 95% CI remained within the predefined noninferiority margin, regardless of correction for hand dominance (Table 3; Fig. 2).

Secondary clinical outcomes

The DASH scores were low in both groups, and ROMs were similar. Rotational deformity on clinical examination was seen with a similar frequency in both groups, but no patient in either group experienced finger scissoring when making a fist. The maximum amount of flexion deficit of 1.3-cm pulp-to-palm distance was seen in a patient treated nonsurgically; the frequency of flexion deficit was similar between the groups. Measurable extension lag was seen in both groups, with the maximum deficit of 15° recorded in one patient in the nonsurgical group and two patients in the surgical group. No patient in either group reported symptoms related to a lack of either

TABLE 2. Baseline Patient Characteristics

	Nonsurgical, n = 17	Surgical, n = 17
Age in y (mean and range)	50 (18–83)	42 (23–69)
Woman sex (biological sex, no. and %)	8 (47%)	5 (29%)
Injury to the dominant hand (no. and %)	5 (29%)	9 (53%)
Fractured metacarpal		
Second n = 1	1	0
Third n = 4	2	2
Fourth n = 16	8	8
Fifth n = 13	6	7
Rotational deformity at inclusion	8 (1 missing value)	2 (1 missing value)
Injury from the same-level fall	7	5
Sports injury	3	7
Smoker		
Active smoker	0 (1 missing value)	2 (1 missing value)
Previous smoker	2	1
Occupation type		
Manual labor	3	8
Nonlabor or student	9	8
Retired	5	1

extension or flexion. Seven patients in the nonsurgical group and four patients in the surgical group had better finger extension in the injured hand compared with the uninjured hand (maximum 25° difference). Further details on secondary outcomes are presented in Table 3.

Complications

One patient who received surgical treatment underwent revision surgery for implant removal for local discomfort since the last reported follow-up in the original trial, and two additional patients requested implant removal at the midterm follow-up. Three cases of revision surgery were reported in the original trial (two because of early osteosynthesis failure, and one implant removal because of local discomfort at 3 months after surgery). No additional minor or major complications were reported in this extended follow-up beyond those reported in the original trial.[5] A detailed report of complications is in section E of Appendix 1, available online on the *Journal*'s website at www.jhandsurg.org.

DISCUSSION

This midterm follow-up indicates that the outcomes previously reported at 1 year remained largely unchanged up to 3–6 years after the treatment of single spiral or oblique MSFs. Comparing the lower limit 95% CI for patients treated nonsurgically with the NIM, noninferiority of nonsurgical treatment remains plausible (Fig. 2).

The concept of nonsurgical treatment with early mobilization of spiral MSF is not entirely novel; to our knowledge, it was first proposed by Al-Qattan et al[8] and later expanded on by Khan and Giddins.[9] Other authors have proposed nonsurgical treatment for various types of MSFs with different types of limited bracing using short casts while allowing mobilization of the fingers.[10,11] MacDonald et al[12] published a prospective case series of 61 patients presenting with nonscissoring spiral metacarpal fractures treated with splinting for 3 weeks, allowing careful mobilization after 1 week. Their analysis, although methodologically lacking and weakened by only evaluating 13 patients, suggested good clinical outcomes following nonsurgical treatment.

The results of our analysis are consistent with these previous publications, indicating that nonsurgical treatment of spiral or oblique MSFs can produce equivalent results to surgical treatment with open reduction and interfragmentary screw fixation. Although some patients had slight residual malrotation of their injured finger on clinical examination or had a difference in finger extension measurable with a goniometer, these findings were generally not noticed by the patients and caused no functional loss. Surgical treatment also carries the risk of complications and, in some cases, secondary surgery for implant removal. In our previous trial, the number of cases needing revision surgery for failed osteosynthesis was unexpectedly high (12%), which we believe to be a random effect in a small sample.[13] Allen et al[14] analyzed a series of 138 MSFs and found a fairly high rate of osteosynthesis failure (11.6% of MSFs treated with screw fixation demonstrated loss of reduction), but only 5% rate of revision surgery. Having chosen to compare nonsurgical treatment only with the method of fixation that was considered standard at the time of study inception, we do not know how nonsurgical treatment would compare to fixation using minimally invasive fixation with intramedullary cannulated screws. This method has gained increasing popularity in recent years and has the advantages of stable fixation, allowing for early mobilization, thus far comparing favorably to open reduction with screw or plate fixation.[15]

TABLE 3. Outcome at the Midterm Follow-Up*

Outcome	Nonsurgical n = 17	Surgical n = 17	*P* Value
Grip strength as a percentage of the contralateral hand (mean and 95% CI)	94.9% (90.1%–99.8%)	94.5% (89.7%–99.2%)	.88
Grip strength as a percentage of the contralateral hand adjusted for hand dominance (mean and 95% CI)	102.5% (95.7%–109.3%)	95.6 (87.3%–103.9%)	.18
Grip strength in kg (mean and 95% CI)	33.8 (27.4–40.2)	41.1 (35.3–46.9)	.08
Grip strength ≥85% of contralateral hand (no. and %)	16 (94%)	15 (88%)	
Rotational deformity	3	2	
Flexion deficit	2	1	
Extension deficit	5	4	
Total active motion percentage	97.1% (93.3%–100.8%)	97.9% (95.3–100.5)	
Pain under load (NRS, 1–10, 1 best)	1.1 (1–1.4)	1.8 (1.3–2.3)	
DASH score (0–100) (mean and 95% CI)	1.9 (0.5–3.6)	2.3 (1.0-4.0)	
Time to final follow-up in y (mean and range)	4.5 (3.3–6.4)	4.5 (3.1–6.6)	
Revision surgery (including implant removal)	0	6	

*Continuous data are given as mean with 95% CI. Grip strength: measured using a JAMAR dynamometer; Rotational deformity: number of patients exhibiting any degree of rotational deformity on clinical examination; Flexion and extension deficit: number of patients with any degree of deficit in the injured hand; TAM: total active motion, shown as percentage relative to the contralateral hand; NRS: numeric rating scale; DASH: Disabilities of the Arm, Shoulder and Hand outcome measure.

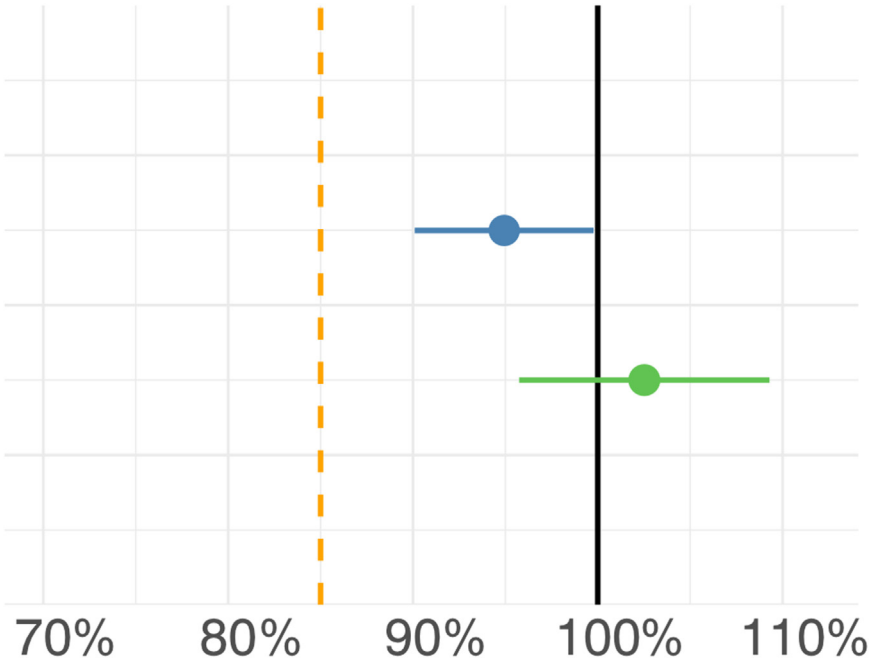

FIGURE 2: The blue bar represents two-sided 95% CI for grip strength percentage in the nonsurgical group versus noninferiority margin (−15% represented by the dotted yellow line). The green bar represents two-sided 95% CI for grip strength percentage in the nonsurgical group adjusted for hand dominance.

Secondary patient-rated outcomes were excellent and similar in both groups in terms of DASH scores, which were well below the published minimally important clinical difference of 14–16 points (nonsurgical: 1.9 and surgical: 2.3).[16] Although it is reasonable to conclude from these DASH scores that most patients had good hand function, the low scores may also indicate that DASH is inadequately responsive to identify all relevant differences between the groups for this condition. Similarly, pain under

load showed low scores in both groups (nonsurgical: 1.1 and surgical: 1.8), well below the published minimally important clinical differences and thus not favoring either group.[17]

The main limitation of this study is the small sample size. As expected, given the nature of an extended follow-up, patients were lost to follow-up or excluded, resulting in the final number of patients evaluated being lower than originally required by our sample size calculation. In the setting of a noninferiority design, the risk of a type II error (erroneously failing to identify the new treatment as being noninferior) increases with a widening of the CI, which would be the assumed result of underpowering of the study.[18] Despite this fact, we report a grip strength CI with a lower limit above the predefined NIM, which is still considered noninferior using this study design. Consequently, the choice of NIM is of great importance when planning a noninferiority trial, and the results must be interpreted in light of the chosen NIM.

The choice of NIM threshold was made, given the assumption of 10% grip strength variation between hands, allowing a further 5% decrease as could be expected with any fracture and treatment. This chosen level of accepted inferiority could be criticized as being too generous. The influence of hand dominance on grip strength, while still showing heterogeneity in the literature, has been reported to make up to a 15% difference, favoring the dominant hand in right-handed individuals.[19] In order to cover the spectrum of possibilities, we analyzed the data both without and with correction for hand dominance.

For practical reasons, neither the patient nor the examiner was blinded to treatment in either the original trial or this extended follow-up, introducing potential bias. Allocation to the study groups in the original trial was randomized and blinded for the patient and the physician until patients had consented to participate, eliminating the risk of allocation bias.

No patients were excluded because of an initial rotational deformity, and no patients experienced symptomatic scissoring at the follow-up; however, the number of patients with initial rotation was small. This means that the analysis is likely to be underpowered to detect potential problems in patients with severe rotation on the initial clinical examination.

The finding that some patients in both groups had slightly better finger extension in the affected ray of the injured hand is unexpected. Occurring in both young and old patients, we believe this to be a reflection of measurement inaccuracy rather than a true increase in the ROM. Measurement bias from rounding to the nearest 5° increment or from the lack of blinding is a possible explanation.

Despite randomizing patients to intervention or control treatment, baseline characteristics of patients differed in terms of occupation type between the groups. A higher proportion of manual laborers were randomized to the surgical group, and a higher proportion of retirees to the nonsurgical group. This is a likely reason for the higher absolute values for grip strength in the surgical group, but given that each patient's grip strength is analyzed relative to the contralateral hand, we believe this difference is compensated for. It remains possible that a larger sample would reveal grip strength differences between groups that contradict the results presented in our analysis.

The main strength of this study lies in its RCT design in combination with the relatively long follow-up time.

For clinicians and patients, the relative simplicity and promising outcomes of nonsurgical treatment with early mobilization may make it an appealing option compared with surgical treatment. Future studies with larger sample sizes and comparison with newer surgical techniques are necessary before definitive recommendations can be made.

CONFLICTS OF INTEREST

No benefits in any form have been received or will be received related directly to this article.

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