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Scaphoid fractures: anatomy, diagnosis and treatment

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Chapter

12

Cast immobilization with and without immobilization of the thumb for nondisplaced scaphoid waist fractures: a multi-center randomized controlled trial

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CAST Trial Collaboration*



J Bone Joint Surg Am., in revision.

Abstract

Background Conservative treatment of scaphoid waist fractures usually consists of a thumb-spica cast. The aim of this study was to test the null-hypothesis that there is no difference in union or arm-specific disability between patients with nondisplaced scaphoid waist fractures treated in a below-elbow cast including or excluding the thumb.

Methods Sixty-two patients with a CT or MRI-confirmed nondisplaced fracture of the scaphoid were enrolled in a prospective multi-center randomized controlled trial comparing treatment in a below-elbow cast including the thumb with a below-elbow cast excluding the thumb. There were 55 waist and 7 distal fractures. We adhered to intention-to-treat principles. The primary outcome was the extent of union on CT performed after 10 weeks of cast treatment, expressed as a percentage of the fracture line that had bridging bone by musculoskeletal radiologists blinded to treatment. Secondary study outcomes included wrist motion, grip strength, the Mayo Modified Wrist Score (MMWS), the Disabilities of the Arm, Shoulder and Hand (DASH) score, a visual analogue scale (VAS) for pain, and radiographic union at six months after injury.

Results There was a significant difference in the extent of union on CT at ten weeks (85% vs. 70%; $p=0.048$) favoring treatment with a cast excluding the thumb. The union rate was 98% overall when adhering to intention-to-treat (1 nonunion in the thumb-cast group) and 100% with nonoperative treatment; as one patient with a waist fracture treated with the thumb immobilized elected operative treatment one week after enrollment, subsequently used crutches and developed nonunion. There were no significant differences between the groups for wrist motion, grip strength, MMWS, DASH score, VAS for pain, or union.

Conclusion Immobilization of the thumb appears unnecessary for CT or MRI-confirmed nondisplaced fractures of the scaphoid.

Level of Evidence Level I – Randomized Controlled Trial

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Introduction

Scaphoid fractures occur in young active patients and have become notorious for their potential for nonunion. Factors associated with nonunion of a scaphoid waist fracture include fracture displacement, delay in diagnosis, and inadequate protection.¹⁻³ Nondisplaced scaphoid waist fractures can be treated successfully if diagnosed promptly and adequately protected in a cast.⁴ However, there is no agreement on whether or not the thumb needs to be immobilized in the cast.

It is our impression that most surgeons worldwide immobilize the thumb when treating a patient with a scaphoid fracture, although there are regions, particularly in the UK where a below-elbow cast without immobilization of the thumb is preferred.⁵⁻⁷ There is evidence from one randomized clinical trial comparing cast immobilization with and without immobilization of the thumb) that there is no difference in the rate of union.⁸ However, that study included displaced fractures and the overall nonunion rate (10%) was higher than most studies of cast treatment (0-5%).⁹⁻¹³ Furthermore, radiographs may be unreliable for the diagnosis of union at least early on.¹⁴

Our aim was to compare below-elbow casting with and without immobilization of the thumb for CT or MRI-confirmed nondisplaced scaphoid waist fractures in a randomized controlled trial. The primary null-hypothesis was that there is no difference in the extent of union on CT performed after 10 weeks of treatment in a cast with or without immobilization of the thumb.

Material and Methods

This study was designed and reported according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines.¹⁵ Our respective Institutional Review Boards approved the study and all patients gave written informed consent. This was a multicenter, stratified (thumb versus no thumb immobilization with balanced randomization [1:1]), single-blind, controlled, parallel-group study conducted in the United States (2 sites) and the Netherlands (5 sites).

Eligible participants were all adults aged 18 or over with an acute nondisplaced fracture of the scaphoid waist. Displacement was defined as either ≥ 1 mm of gapping or translation between fracture fragments on MRI¹⁶ or CT¹⁷ using reconstructions in the planes of the long axis of the scaphoid.¹⁸ Exclusion criteria were pregnancy, delayed presentation (more than 4 weeks after injury), and any associated ligament injury or fracture of the ipsilateral upper extremity.

Due to a miscommunication at 3 of the 7 sites that joined at a later stage, seven patients with a fracture of the distal third of the scaphoid were inadvertently included.



We adhered to strict intention-to-treat principles and the data from these patients were included in the analysis.

After informed consent participants were randomized 1:1 using computerized random numbers using a web based application at www.random.org. Allocation was concealed. Patients were randomly assigned to receive a below-elbow cast with or without inclusion of the thumb. Instructions for the cast including the thumb were immobilization of the wrist in neutral position, the thumb in palmar abduction leaving the interphalangeal joint free and extension of the cast to the proximal forearm. Instructions for the cast not including the thumb were to leave the entire thumb free to the trapeziometacarpal joint. Patients and care providers were aware of the allocated arm.

The primary outcome variable was the extent of union on CT performed after 10 weeks of cast treatment and expressed as a percentage of the fracture line that had bridging bone following a published protocol.¹⁹ The extent of union was calculated by one of four experienced musculoskeletal radiologists as an average of two axes: the sagittal and coronal longitudinal axis of the scaphoid. The musculoskeletal radiologists were blinded for the type of cast immobilization.

Secondary outcome variables were radiographic union and or arm-specific disability at six months after the injury. Radiographic union was evaluated on radiographs of the wrist with four views of the scaphoid: posteroanterior, lateral, posteroanterior with ulnar deviation, and oblique with 45° of pronation. The treating surgeon and treating radiologist reached consensus on union (defined as crossing trabeculae at the fracture site) and nonunion (defined as a persistent lucency at the fracture site) and this was confirmed by the authors at final review. Arm-specific disability was evaluated by the range of wrist motion (measured with a hand-held goniometer), grip strength (measured with a grip dynamometer as an average of three attempts), the Disabilities of the Arm Shoulder and Hand (DASH) score²⁰, the Mayo Modified Wrist Score (MMWS)²¹ and a visual analogue scale (VAS) for pain. Range of motion and grip strength were measured bilaterally and were also expressed as a percentage of the contralateral side.

This study was designed to determine a 20% difference in the extent of union of the fracture line on CT between groups after ten weeks of cast immobilization. We assumed a standard deviation of 10 percent, which translates into an effect size of 1.0 ($\delta = 20/20$). A power analysis indicated that a total sample size of 46 patients randomized to each of the two groups would provide 90% statistical power to detect a significant difference between the groups ($\alpha = 0.05$, $\beta = 0.10$) using an unpaired Student t-test. To account for a possible loss to follow-up of 20-25%, we chose a sample size of 30 patients per group.

Statistical methods included the two-tailed unpaired Student t-test and the Mann Whitney U test. The level of significance of the primary outcome was set at $p < 0.05$.

For secondary outcome variables a Bonferroni adjustment was used to correct for multiple outcome variable testing, with the level of significance set at $p < 0.005$. Missing data were handled by imputation of the mean. A subgroup analysis of the fifty-five scaphoid waist fractures solely has been performed.²²

Source of Funding

No funds were received in direct support of this study.

Results

Fifty-five patients with a nondisplaced fracture of the scaphoid waist were enrolled in this prospective multi-center randomized controlled trial as well as seven patients with a nondisplaced fracture of the distal scaphoid which were enrolled during the early part of the trial (Figure 1). Demographic and clinical characteristics for each study group were comparable (Table 1). Suspected scaphoid fractures were diagnosed on

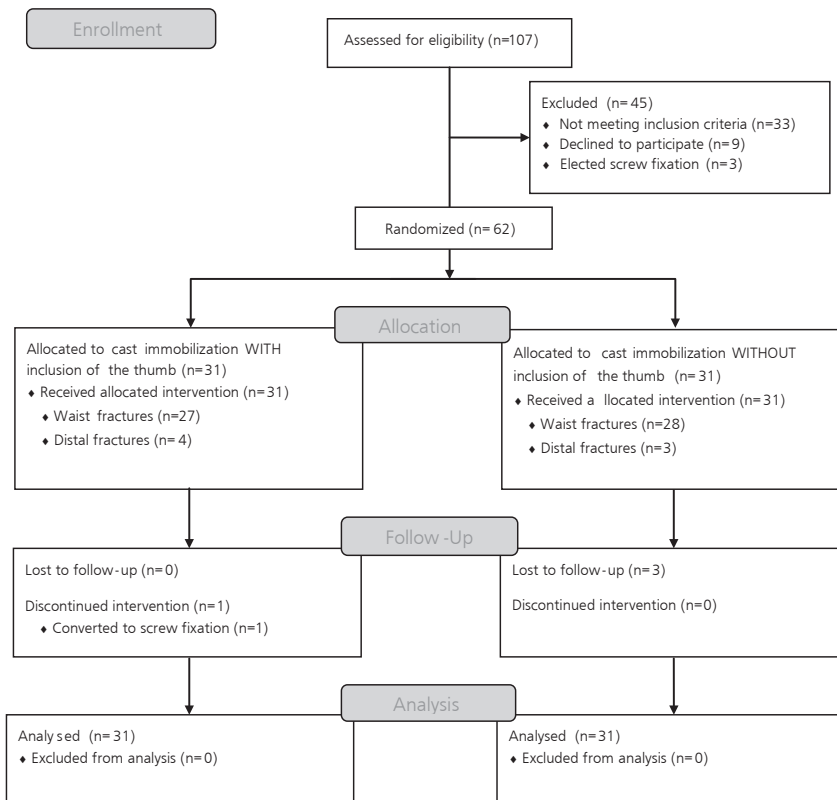


Figure 1. CONSORT Study Flow Diagram



CT or MRI after an average of 10 days after injury (range, 0 to 28 days). For each group, there were thirty-one patients included in the analysis. Three patients (5%) changed address within 6 weeks of injury and could no longer participate in the study, and were considered lost to follow-up. Another six patients (four in the no-thumb cast group and two in the thumb cast group) did not return for the six-month assessment (usually due to perceived complete recovery).

There was a significant difference in the extent of union on CT at ten weeks (85% vs. 70%) favoring treatment with a cast without immobilization the thumb (Tables 2 and

Table 1. Demographic and injury characteristics		
	No-Thumb Cast	Thumb Cast
Gender		
Male	21	22
Female	10	9
Injured hand		
Dominant	15	18
Non-dominant	15	12
Ambidextrous	1	1
Age (years)	42.2 (18.3)	32.8 (14.5)
Fracture Type		
waist	28	27
distal	3	4
Comminuted fractures	0	2
Enrolment delay (days)	9.2 (6.5)	10.9 (8.2)
Occupation		
Laborer	12	9
Desk-based	10	11
Retired	4	3
Unemployed	1	1
Student	4	7

Numeric values are presented as means and standard deviations in brackets

Table 2. Extent of union on CT after ten weeks of cast immobilization					
	Extent of union				
	0-24%	25-49%	50-74%	74-99%	100%
No-Thumb Cast	1	2	3	11	11
Thumb Cast	4	0	8	12	7

3A). One patient with a scaphoid waist fracture treated with the thumb immobilized elected operative treatment 1 week after enrollment, subsequently used crutches and developed nonunion (98% union overall according to the intention-to-treat principle; 100% union with nonoperative treatment). There were no significant differences between the groups for wrist motion, grip strength, DASH score, MMWS score, pain score, or union (Table 3A).

Subgroup analysis of scaphoid waist fractures only revealed no significant difference in the extent of union on CT nor in any of the secondary outcome measures (Table 3B).

Table 3A. Comparison of cohorts at ten weeks (primary outcome) and six months (secondary outcomes)					
	No-Thumb Cast (n=31)		Thumb Cast (n=31)		p-value
	Mean	SD	Mean	SD	
Primary Outcome					
Extent of Union (%)	85	24	70	30	0,048*
Secondary Outcomes					
Flexion (°)	72	9	76	12	0,130
Flexion (% of value on uninjured side)	97	7	96	8	0,692
Extension (°)	67	14	68	15	0,811
Extension (% of value on uninjured side)	92	16	98	7	0,057
Ulnar Deviation (°)	32	8	38	13	0,026
Ulnar Deviation (% of value on uninjured side)	99	9	100	11	0,643
Radial Deviation (°)	19	7	20	9	0,604
Radial Deviation (% of value on uninjured side)	98	9	95	13	0,264
Grip Strength (kg)	37	21	40	12	0,954
Grip Strength (% of value on uninjured side)	86	13	95	12	0,008
DASH (points)	5,6	8,5	5,2	7,5	0,842
MMWS (points)	87	19	92	9	0,201
VAS Pain (points)	0,8	1,3	1,1	1,4	0,533

* significant ($p < 0.05$)

Discussion

For treatment of acute CT or MRI-confirmed nondisplaced scaphoid waist fractures the present study shows a significant, but small and likely clinically irrelevant difference in the extent of union on CT ten weeks after treatment, favoring treatment with a cast excluding the thumb. In subgroup analysis of scaphoid waist fractures only the



Table 3B. Subgroup analysis of scaphoid waist fractures only at ten weeks (primary outcome) and six months (secondary outcomes)					
	No-Thumb Cast (n=28)		Thumb Cast (n=27)		p-value
	Mean	SD	Mean	SD	
Primary Outcome					
Extent of Union (%)	84	25	70	32	0,099
Secondary Outcomes					
Flexion (°)	73	8	77	11	0,094
Flexion (% of value on uninjured side)	98	6	96	8	0,329
Extension (°)	72	8	69	14	0,354
Extension (% of value on uninjured side)	97	6	97	7	0,921
Ulnar Deviation (°)	31	7	38	12	0,005
Ulnar Deviation (% of value on uninjured side)	99	10	99	11	0,956
Radial Deviation (°)	21	7	21	9	1,000
Radial Deviation (% of value on uninjured side)	98	9	94	13	0,254
Grip Strength (kg)	41	14	39	10	0,560
Grip Strength (% of value on uninjured side)	91	10	96	12	0,107
DASH (points)	4,2	7,4	4,7	6,0	0,751
MMWS (points)	88	19	92	9	0,360
VAS Pain (points)	0,6	1,2	1	1,4	0,261

difference in the extent of union was similar but not significant, likely due to a smaller sample size. The present study also shows that the rate of union with nonoperative treatment six months after injury was 100%, regardless of thumb immobilization. A single patient with a scaphoid waist fracture treated with the thumb immobilized and who elected operative treatment 1 week after enrollment developed nonunion. Possible reasons for this nonunion were the use of crutches and heavy smoking. Arm-specific disability six months after injury was minimal regardless of immobilization of the thumb. These results are comparable to previous studies of operative and non-operative treatment of CT-confirmed nondisplaced scaphoid waist fractures.^{12,13} The major difference of the present study with the previous randomized controlled trial on thumb immobilization of scaphoid fractures⁸ is that we excluded both displaced and proximal fractures – both risk factors for nonunion. These additional exclusion criteria in our study may explain the higher total rate of union (100%) as compared to the previous study which found a 90% total rate of union in both groups.⁸ Of note, two fractures with no signs of fracture union on CT performed 10 weeks after treatment and two fractures that were rated as <24% of bony bridging, all four

fractures were diagnosed clinically and radiographically as united 24 weeks after injury without additional treatment. These findings are consistent with previous studies^{19,23,24} A recent interobserver study suggested that CT scans are accurate and reliable for diagnosis of union but inadequate for predicting nonunion of scaphoid waist fractures between 6 and 10 weeks after injury.²³ Therefore it may be unnecessary to operate on patients with scaphoid fractures that show no sign of union on CT after 12 weeks of cast immobilization, which is a commonly applied management strategy.^{12,25}

The results of the current study should be interpreted in light of several limitations. First, 11% (7 of 62) fractures involved the distal third, a location where fracture healing is expected to be less problematic.⁸ Second, the reliability of percent union on CT has not—to our knowledge—been studied. Third, there was a considerable loss to follow-up, three patients at 10 weeks follow-up and another six at 24 weeks follow-up. We addressed this by using the mean imputation technique to account for missing data. The strengths of the present study included the prospective multi-center design, a blinded primary outcome, a reliable and accurate method to diagnose fracture displacement, CT scanning to diagnose union, and validated outcome measures.

There is ongoing debate about operative versus non-operative treatment of patients with nondisplaced scaphoid waist fractures. The primary advantage of operative treatment is avoidance of immobilization.²⁵⁻²⁷ Cast immobilization is a more appealing option when the elbow and thumb are not included in the cast. A recent meta-analysis showed that above-elbow thumb-spica cast immobilization is not superior to below-elbow thumb-spica cast immobilization.²⁸ Our study and the study of Clay et al.⁸ suggest that immobilization of the thumb is not also required. A shorter duration of cast immobilization might also be appealing and is being investigated in some centers.^{24,29} One study of 26 patients with a nondisplaced scaphoid waist fracture treated in a below-elbow cast without immobilization of the thumb documented trabeculae crossing at least 50% of the fracture site on CT scans obtained 4 weeks after injury in 25 fractures (96%).²⁴ Four patients were splinted for another 2 weeks, and all 26 fractures healed.

In our opinion, a key factor in determining treatment strategy is documenting that the scaphoid waist fracture is nondisplaced using computed tomography. Radiologically nondisplaced fractures are usually stable and probably require less protection than is traditionally advised. Given the growing evidence that nondisplaced fractures do not benefit from immobilization of the elbow and thumb, additional study is merited to confirm that these less cumbersome approaches to immobilization are safe and effective. In conclusion, our data suggest that immobilization of the thumb is unnecessary for CT or MRI-confirmed nondisplaced fractures of the scaphoid. The authors now offer patients with a nondisplaced fracture of the scaphoid a short arm cast without immobilization of the thumb.



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