ABSTRACT

The aim of this study was to determine the difference in functional outcomes after open reduction and internal fixation (ORIF) with and without arthroscopic debridement in adults with displaced intra-articular distal radius fractures. In this multicenter trial, 50 patients were randomized between ORIF with or without arthroscopic debridement. The primary outcome measure was the Patient-Rated Wrist Evaluation (PRWE) score. Secondary outcome measures were Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, pain scores, range of wrist motion, grip strength, and complications. Median PRWE was worse for the intervention group at 3 months and was equal for both groups at 12 months. The secondary outcome measures did not show consistent patterns of differences at different time-points of follow-up. We conclude that patients treated with additional arthroscopy to remove intra-articular hematoma and debris did not have better outcomes than those treated with ORIF alone. We therefore do not recommend arthroscopy for removal of hematoma and debris when surgically fixing distal radius fractures.

INTRODUCTION

Arthroscopy of the wrist has proven instrumental in identifying associated ligament and chondral lesions after distal radius fractures[1]. However, there is still no consensus on the benefit of arthroscopically assisted treatment of intraarticular distal radius fractures. Patients treated with arthroscopically assisted reduction appear to have a greater range of motion (ROM) [2]. With regard to functional outcomes or radiographic parameters, however, arthroscopic reduction does not appear advantageous[3]. Hemarthrosis may lead to inflammation, damage of articular cartilage and eventually to destruction of the entire joint[4]. We hypothesized that arthroscopically assisted removal of intra-articular fracture hematoma and debris may improve the functional outcomes after operative treatment of intra-articular distal radius fractures due to improvement of the synovial joint mobility[2,5-7]. Moreover, during arthroscopy, the quality of the reduction and the presence of associated ligament injuries can be assessed[8,9]. The purpose of this randomized controlled trial was to determine the difference in functional outcome, assessed with the Patient-Rated Wrist Evaluation (PRWE) score with a follow-up of 12 months, after open reduction internal fixation (ORIF) with and without arthroscopy in adults with displaced intra-articular distal radius fractures.

METHODS

Study design and patient randomization

This study was a multicenter randomized controlled trial in which adult patients with displaced intra-articular distal radius fractures were randomized between ORIF with wrist arthroscopy to remove fracture hematoma and debris (intervention group) and conventional ORIF (control group). Study approval was obtained from the ethics committee and institutional board of our hospital and the boards of directors of all participating centers. All patients provided written informed consent before randomization. The results were reported according to the Consolidated Standards for Reporting Trials (CONSORT). The study protocol has been published[10].

The study was conducted in three centers in the Netherlands. Two are academic hospitals and one is a regional teaching hospital. All consecutive patients aged 18 years with displaced intra-articular distal radius fractures (AO/OTA type C) where ORIF was deemed necessary were included in the study. The decision for ORIF was based on the Dutch guidelines for unacceptable alignment of the distal radius: radial inclination ≤ 15^{o}, loss of radial height ≥ 5 mm, dorsal angulation ≥15^{o}, palmar angulation ≥20^{o}, and

gap or step-off > 2 mm [11]. Patients with open distal radius fractures or other fractures of the affected extremity (except for a fracture of the ulnar styloid process), patients with impaired wrist function before the recent fracture and multiply injured patients (Injury Severity Score 16) were excluded. Patients unable to understand the study information and informed consent forms, as judged by the treating physician, were also excluded.

After obtaining informed consent, patients were randomized 1:1 to ORIF with arthroscopy: ORIF without arthroscopy. Randomization was performed using a secured online computer randomization procedure, with the use of permuted blocks of four, six and eight patients. We stratified randomization according to age into two strata: 18–64 years; and 65 years and older.

Surgical techniques

Open reduction and plate fixation, as well as wrist arthroscopy were performed by a certified (orthopedic) trauma surgeon of at least Level 3 expertise, according to criteria of Tang and Giddins in both ORIF of distal radius fractures and wrist arthroscopy[12]. An additional dorsal approach was allowed only when the dorsal capsule was not opened and thus leaving the radiocarpal joint closed to facilitate comparison between patients. The approach was at the discretion of the treating surgeon.

The intervention group was treated with wrist arthroscopy directly after ORIF. Arthroscopic debridement of hematoma and debris was performed. A detailed description of the arthroscopic procedure has previously been described[10]. No corrections of reduction were allowed and all additional soft-tissue injuries were left untreated according to study protocol. A delay of at least 5 days before performing arthroscopy was mandatory to enable visualization due to the organization of the hematoma[13]. The operation was performed within 3 weeks after the initial trauma. For both the intervention and control groups, patients started exercise immediately after the operation. For the first 6 weeks, only non-weight-bearing exercises were allowed. Physiotherapy was recommended at the discretion of the surgeon, as this was the nearest reflection of daily practice.

Outcome assessment

The primary outcome measure was the PRWE score at 3 months. In addition, the PRWE questionnaire was completed after 3 and 6 weeks, and 6 and 12 months of follow-up. The PRWE is a validated tool for assessing functional outcome in patients with distal radius fractures. The highest score, indicating severe impairment, is 100; the best score, indicating no impairment, is zero. In the intervention group, the quality of reduction, associated ligament injuries and cartilage damage was assessed. Ligament injuries were divided into triangular fibrocartilage complex (TFCC) injuries, classified according to the Palmer classification, and scapholunate (SL) ligament and lunotriquetral (LT) injuries, graded according to the Geissler classification.

Secondary outcome measures were the arthroscopic findings, the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, postoperative pain as indicated on the visual analogue scale (VAS), ROM, grip strength and complications during 1-year follow-up. ROM included active wrist flexion and extension, radial and ulnar deviation, and pronation and supination, measured with a handheld goniometer. Grip strength was measured with a hydraulic hand dynamometer (Baseline, Fabrication Enterprises, White Plains, NY, USA). ROM and grip strength of the injured side were compared to the uninjured side. A complication was defined as any adverse event for which additional treatment was required.

Statistical analysis

The sample size was calculated based on the primary outcome, the PRWE at 3 months. With an a ¼ 0.05%, a sample size of 46 was required to provide 80% power to detect a difference of 18 points in the PRWE score. For safety measures and with an expected lost-to-follow-up of 5%, 25 patients in each arm were included.

All analyses were based on the intention-to-treat principle. General descriptive statistics on patient characteristic at baseline were performed including factors such as sex and age. Normality was determined by visually inspecting the plotted data distribution in a histogram and boxplot. Normally distributed data were reported as mean and standard deviation (SD) and non-normally distributed data were reported as median with interquartile range (IQR). To compare continuous non-normally distributed baseline characteristics such as age and operation duration, the Mann–Whitney U-test was used. For the analysis of the categorical baseline characteristics, the chi-square test was used.

Differences between the two groups in PRWE and DASH scores, VAS pain sores, ROM and grip strength at the follow-up intervals were analyzed using a linear mixed model. The best covariance structure for each linear mixed model was determined using the smallest Akaike information criterion[14]. All outcome measures were corrected for age, because this was a stratification factor in the design of the study. Differences in complication rates between the two treatment groups were analyzed using the chi-square test. An additional per-protocol analysis was performed.

RESULTS

Patient demographics

Between February 2016 and October 2017, 93 patients were screened for eligibility. Patients were excluded if they did not meet inclusion criteria (n=23), declined to participate (n = 10) or because no arthroscopy set was available (n= 9). In the period that the arthroscopy set was not available, patients were not included in the study. In total, 25 patients were assigned to the intervention group and 26 patients were assigned to the control group. One patient in the intervention group was excluded after randomization because this patient did not meet the inclusion criteria. In each group, 25 patients were analyzed for the primary outcome (Figure 1).

The median age of the 50 study participants was 59 years (IQR 44–66) and 33 (66%) participants were women. Baseline characteristics were evenly distributed between the two treatment groups (Table 1). The baseline characteristics of the included patients did not differ from the eligible but not included patients. Patients were operated within a mean of 1.5 weeks (SD 0.4). Operation duration was significantly longer for the intervention group than the control group, 98 minutes vs. 64 minutes (p ¼ 0.002).

Three patients in the intervention group did not receive arthroscopy. This was because the dorsal joint capsule had already been opened during surgery before the intervention could take place.

Primary outcome

The PRWE scores were not significantly different for the arthroscopy group at 3 weeks or at 6 weeks. The PRWE scores were significantly worse for the arthroscopy group at 3 months (p = 0.008) and at 6 months (p = 0.01). In the mixed-model analysis used for this study, these scores were statically different at the two time-points, due to the large spread in range. However, the mean differences are none or too small; therefore, they are not clinically significant (Table 2). The median PRWE score at 12 months was equal for both groups (Table 2).

Secondary outcomes
All 22 patients who underwent arthroscopy had a hematoma that was removed; 11 patients had a loose piece of cartilage or bone floating freely in the joint. Anatomic reduction (no gap or step-off) was obtained in 13 patients (Table 3). All patients had additional ligament or chondral injuries. Twenty patients had TFFC injuries. SL injury and LT injury were present in half of the patients in the arthroscopy group (Table 4). No patients received postoperative plaster cast immobilization.

The DASH scores were significantly better for the arthroscopy group at 3 weeks ($p = 0.01$) (Table 2). At 3 months, the arthroscopy group had a significantly worse DASH score ($p = 0.046$). At the other follow-up time-points, no significant differences were found between the two groups. Patients treated with arthroscopy had slightly lower VAS scores overall compared to those treated with only ORIF from 1 day to 2 months (Table 2). ROM did not differ significantly between the groups. Grip strength was overall significantly better for the group with ORIF alone ($p = 0.003$), though the mean difference was small (15 kg vs 18 kg, at 3 months after surgery) (Online supplementary Table S1).

Complications
Complications occurred in five patients in the group without arthroscopy (Table 5). Four patients had implant removal due to tendonitis, of which one developed a superficial wound infection that was treated with oral antibiotics, which resolved the infection. Another patient had a superficial wound infection after ORIF that was treated with oral antibiotics. This same patient later had a flexor pollicus longus tendon rupture, which was reconstructed. In the arthroscopy group, six patients had complications. In five, the implant was removed due to tendonitis. One patient had extensor carpi ulnaris tendinitis. There is no significant difference in complication rate between the two groups (Table 5).

DISCUSSION

In this multicenter randomized trial, we found that patients with displaced intra-articular distal radius fractures treated with ORIF and additional arthroscopy to remove hematoma and debris did not have better clinically relevant functional outcomes than patients treated with ORIF alone. The differences in median scores of each outcome measure were small, though some show statistical differences. We therefore do not recommend performing additional arthroscopy with removal of hematoma and debris in patients with displaced intra-articular distal radius fractures.

Previous studies have explored the role of arthroscopy in the treatment of distal radius fractures. A study by Varitimidis et al. found that patients who underwent arthroscopically assisted reduction had better supination, extension and flexion[15]. Functional outcomes measured with the DASH score were similar in the two groups. This study was, however, underpowered, so no definitive conclusions could be drawn. Another retrospective study of 30 patients showed a better ROM for patients who underwent arthroscopic reduction compared to those treated with fluoroscopic reduction[2]. Patients in this study were, however, treated with external fixation and not with ORIF. Yamazaki et al. compared functional and radiographic outcomes of fluoroscopically and arthroscopically guided reduction of unstable intraarticular distal radius fractures and found no significant differences between the two techniques with regard to functional and radiographic outcomes[3].

In this study, we found soft-tissue injuries in all patients where arthroscopy was performed. This included different degrees of TFCC injuries in 90% of patients, SL ligament injuries in 50% of patients and LT ligament injuries in 50% of patients. Lindau et al. reported soft-tissue injuries in all patients[1]. This

percentage of soft-tissue injuries is comparable to that in other studies reporting TFCC lesions in up to 63% to 82%[1,16] (Abe et al., 2013; Lindau et al., 1997), and SL and LT ligament lesions in up to 88% and 61%, respectively[1,16,17]. In contrast to our study, Yamazaki et al. treated soft-tissue injuries and found significantly better functional results[3]. However, we find that most of these soft-tissue injuries do not require treatment. This recommendation is further supported by two studies that show that patients with untreated SL injuries and TFCC injuries, except one, had good functional outcomes measured with the DASH score at a follow-up of 13–15 years[18,19]. In our study, additional lesions were left untreated and these patients had good functional outcomes at 6-month and 12-month follow-ups with PRWE scores of 10 and 7. The long-term functional results of these patients are still unknown.

This study has several limitations. Patients and physicians were not blinded to the treatment group assignment. Being aware of the additional injuries sustained may have influenced the self-reported functional outcomes. The functional outcomes were evaluated during a 1-year follow-up period, but whether the patient returned to the same function as before the fracture is unknown. We can, however, compare the injured side to the uninjured side and assume that due to randomization this difference is divided equally in both groups.

Tables and Figures

Table 1: Patient characteristics

Patient information	**ORIF alone (N = 25)**	**ORIF with arthroscopy (N = 25)**
Age (years), median [IQR]	58 [47-65]	60 [36-66]
Gender		
Female	17	16
Male	9	9
Fracture of dominant side	11	8
Operation duration (minutes), mean ± SD	64 ± 37	98 ± 30

Table 2: Functional outcomes in PRWE,DASH, and VAS scores expressed as median [IQR]

Postoperative time-points	**ORIF alone**	**ORIF with arthroscopy**	**p-value**
1 day			
VAS	7 [5-8]	5 [3-7]	**0.001**
1 week			
VAS	4 [3-6]	3 [2-4]	0.11
3 weeks			
PRWE	58 [44-73]	48 [26-67]	0.07
DASH	45 [34-60]	34 [20-49]	**0.01**
VAS	3 [2-3]	2 [0-3]	**0.02**
6 weeks			
PRWE	39 [19-53]	37 [18-63]	0.65
DASH	23 [17-36]	27 [15-40]	0.87
VAS	2 [1-4]	1 [0-3]	0.31
3 months			
PRWE	13 [5-21]	23 [9-44]	**0.008**
DASH	9 [4-15]	19 [5-30]	**0.046**
VAS	2 [0-2]	0 [0-2]	0.13
6 months			
PRWE	10 [3-17]	10 [1-47]	**0.01**
DASH	8 [3-18]	6 [0-15]	0.75
12 months			
PRWE	7 [1-15]	7 [0-20]	0.26
DASH	6 [1-18]	8 [0-21]	0.16

Table 3: Quality of reduction

Quality of reduction	**N = 22**
Step-off	
None	16
1-2mm	4
≥ 2mm	2
Gap	
None	16
1-2mm	5
≥ 2mm	1

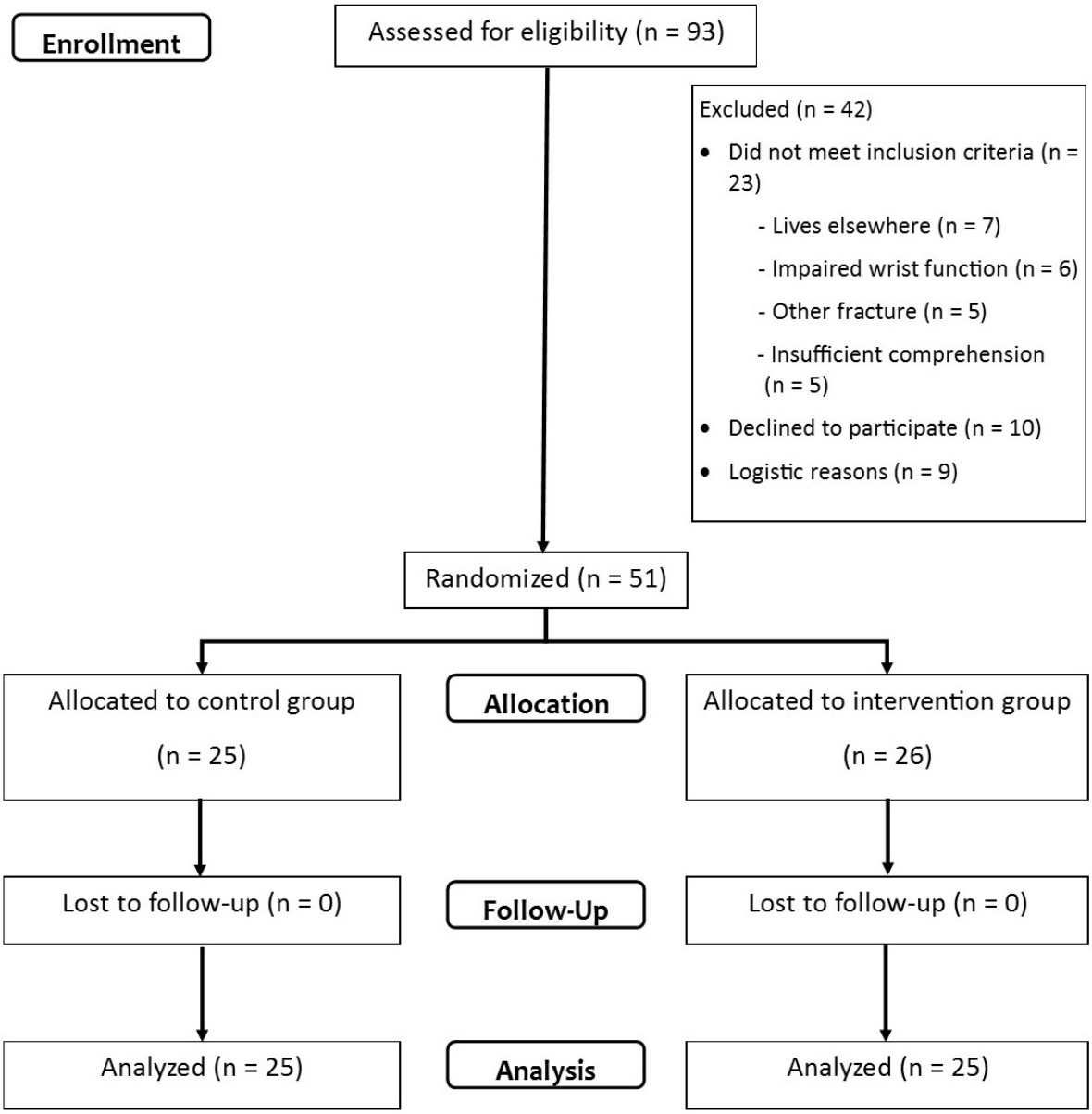
Table 4: Arthroscopic findings

Arthroscopic findings	**N = 22**
Triangular fibrocartilage complex injury (Palmer)	
none	2
A	8
B	10
C	1
D	1
Scapholunate injury (Geissler)	
none	11
grade 1	2
grade 2	1
grade 3	5
grade 4	3
Lunotriquetral injury (Geissler)	
none	11
grade 1	4
grade 2	4
grade 3	3
grade 4	0
Cartilage damage lunate fossa (Outerbridge)	
grade 0	7
grade 1	2
grade 2	6
grade 3	4
grade 4	3
Cartilage damage scaphoid fossa (Outerbridge)	
grade 0	10
grade 1	4
grade 2	6
grade 3	1
grade 4	1

Table 5: Complications

Complication	**ORIF alone**	**ORIF with arthroscopy**	**p-value**
Hardware related complaints	4	6	
Superficial wound infection	2	0	
ECU tendonitis	1	0	
FPL rupture	0	1	
Total	**7**	**7**	1.0

Figure 1: CONSORT flow diagram of this study



Online supplementary Table: Clinical outcomes in range of motion (degrees) and grip strength (kg), expressed as median [IQR] and (percentage of uninjured side)

	3 weeks		6 weeks		3 months		
Clinical outcome	**ORIF alone**	**ORIF with arthroscopy**	**ORIF alone**	**ORIF with arthroscopy**	**ORIF alone**	**ORIF with arthroscopy**	**p-value**
Radial deviation	*5 [5-10] (44%)*	*10 [5-13] (59%)*	10 [5-15] (74%)	10 [10-15] (77%)	10 [9-15] (86%)	15 [10-15] (90%)	0.13
Ulnar deviation	*10 [8-15] (49%)*	*15 [10-18] (63%)*	15 [10-20] (71%)	15 [11-20] (72%)	20 [18-20] (98%)	20 [18-25] (90%)	0.05
Pronation	*80 [70-83] (86%)*	*80 [75-85] (93%)*	80 [78-85] (92%)	85 [83-85] (98%)	85 [80-85] (97%)	85 [85-85] (100%)	0.16
Supination	40 [20-63] (49%)	50 [25-65] (52%)	65 [60-73] (77%)	65 [58-80] (76%)	75 [70-80] (87%)	85 [78-85] (92%)	0.71
Dorsoflexion	*25 [10-40] (37%)*	*40 [20-50] (49%)*	50 [30-64] (65%)	55 [43-70] (68%)	60 [60-73] (85%)	70 [60-80] (89%)	0.10
Palmarflexion	30 [30-43] (43%)	30 [25-39] (43%)	40 [35-60] (58%)	40 [35-58] (56%)	65 [50-70] (79%)	65 [50-75] (80%)	0.90
Grip strength	3 [1-7] (18%)	7 [2-12] (28%)	12 [6-19] (45%)	10 [2-17] (41%)	18 [12-28] (72%)	15 [11-25] (62%)	**0.003**

REFERENCES

1. Lindau T, Arner M, Hagberg L. Intraarticular lesions in distal fractures of the radius in young adults. A descriptive arthroscopic study in 50 patients. *J Hand Surg Br.* 1997;22(5):638-643.
2. Ruch DS, Vallee J, Poehling GG, Smith BP, Kuzma GR. Arthroscopic reduction versus fluoroscopic reduction in the management of intra-articular distal radius fractures. *Arthroscopy.* 2004;20(3):225-230.
3. Yamazaki H, Uchiyama S, Komatsu M, et al. Arthroscopic assistance does not improve the functional or radiographic outcome of unstable intra-articular distal radial fractures treated with a volar locking plate: a randomised controlled trial. *Bone Joint J.* 2015;97-B(7):957-962.
4. van Meegeren ME, Roosendaal G, Jansen NW, Lafeber FP, Mastbergen SC. Blood-Induced Joint Damage: The Devastating Effects of Acute Joint Bleeds versus Micro-Bleeds. *Cartilage.* 2013;4(4):313-320.
5. Auge WK, 2nd, Velazquez PA. The application of indirect reduction techniques in the distal radius: the role of adjuvant arthroscopy. *Arthroscopy.* 2000;16(8):830-835.
6. Geissler WB, Freeland AE, Savoie FH, McIntyre LW, Whipple TL. Intracarpal soft-tissue lesions associated with an intra-articular fracture of the distal end of the radius. *J Bone Joint Surg Am.* 1996;78(3):357-365.
7. Lindau T. Management of Distal Radial Fractures. In: Geissler WB, ed. *Wrist Arthroscopy.* New York City: Springer; 2005.
8. Edwards CC, 2nd, Haraszti CJ, McGillivary GR, Gutow AP. Intra-articular distal radius fractures: arthroscopic assessment of radiographically assisted reduction. *J Hand Surg Am.* 2001;26(6):1036-1041.
9. Ono H, Furuta K, Fujitani R, Katayama T, Akahane M. Distal radius fracture arthroscopic intraarticular displacement measurement after open reduction and internal fixation from a volar approach. *J Orthop Sci.* 2010;15(4):502-508.
10. Mulders MAM, Selles CA, Colaris JW, et al. Operative Treatment of Intra-Articular Distal Radius Fractures With versus Without Arthroscopy: study protocol for a randomised controlled trial. *Trials.* 2018;19(1):84.
11. Surgery DSf. Distal Radius Fractures, diagnosis and treatment. Published 2010. Accessed 28/10 2016.
12. Tang JB. Re: Levels of experience of surgeons in clinical studies. *J Hand Surg Eur Vol.* 2009;34(1):137-138.
13. Slutsky DJ, Herman M. Rehabilitation of distal radius fractures: a biomechanical guide. *Hand Clin.* 2005;21(3):455-468.
14. Akaike H. Citation Classic - a New Look at the Statistical-Model Identification. *Cc/Eng Tech Appl Sci.* 1981(51):22-22.
15. Varitimidis SE, Basdekis GK, Dailiana ZH, Hantes ME, Bargiotas K, Malizos K. Treatment of intra-articular fractures of the distal radius: fluoroscopic or arthroscopic reduction? *J Bone Joint Surg Br.* 2008;90(6):778-785.
16. Abe Y, Yoshida K, Tominaga Y. Less invasive surgery with wrist arthroscopy for distal radius fracture. *J Orthop Sci.* 2013;18(3):398-404.
17. Mehta JA, Bain GI, Heptinstall RJ. Anatomical reduction of intra-articular fractures of the distal radius. An arthroscopically-assisted approach. *J Bone Joint Surg Br.* 2000;82(1):79-86.
18. Mrkonjic A, Geijer M, Lindau T, Tagil M. The natural course of traumatic triangular fibrocartilage complex tears in distal radial fractures: a 13-15 year follow-up of arthroscopically diagnosed but untreated injuries. *J Hand Surg Am.* 2012;37(8):1555-1560.

19. Mrkonjic A, Lindau T, Geijer M, Tagil M. Arthroscopically diagnosed scapholunate ligament injuries associated with distal radial fractures: a 13- to 15-year follow-up. *J Hand Surg Am.* 2015;40(6):1077-1082.