Adjuvant Arthroscopy Does Not Improve the Functional Outcome of Volar Locking Plate for Distal Radius Fractures: A Randomized Clinical Trial

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Purpose: To evaluate the outcomes of adding arthroscopy to osteosynthesis of distal radius fractures (DRF) with volar locking plate (VLP), by Patient-Rated Wrist Evaluation (PRWE) 1 year after surgery. **Methods:** In total, 186 functionally independent adult patients who met the inclusion criteria (DRF and a clinical decision for surgery with a VLP) were randomized to arthroscopic assistance or not. Primary outcome was PRWE questionnaire results 1 year after surgery. For the main variable, PRWE, we obtained the minimal clinically important difference based on a distribution-based method. Secondary outcomes included Disabilities of the Arm, Shoulder and Hand and 12-Item Short Form Health Survey questionnaires, range of motion, strength, radiographic measures, and presence of joint step-offs by computed tomography. Data were collected preoperatively and at +1 and +4 weeks, +3 and +6 months, and +1 year after surgery. Complications were recorded throughout the study. **Results:** In total, 180 patients (mean age: 59.0 ± 14.9 years; 76% women) were analyzed by modified intention to treat. A total of 82% of the fractures were intra-articular (AO type C). No significant difference between arthroscopic (AG) and control (CG) groups in median PRWE was found at +1 year (median AG: 5.0, median CG: 7.5, difference in medians 2.5; 95% confidence interval [CI] −2.0, 7.0, $P = .328$). The proportion of patients who exceeded the minimal clinically important difference of 12.81 points in the AG and CG was 86.4% vs 85.1%, $P = .819$, respectively. Percentage of associated injuries and step-offs reduction maneuvers was greater with arthroscopy (mean differences: 17.1 95% CI −0.1, 26.1, $P < .001$) and 17.4 (95% CI 5.0, 29.7, $P = .007$). The difference in percentage of residual joint step-offs at the postsurgical computed tomography in radioulnar, radioscaphoid, and radiolunate joints was not significant ($P = .990$, $P = .538$, and $P = .063$). Complications were similar between groups (16.9% vs 20.9%, $P = .842$). **Conclusions:** Adjuvant arthroscopy did not significantly improve PRWE score +1 year after surgery for DRF with VLP, although the statistical power of the study is below the initially estimated to detect the expected difference. **Level of Evidence:** Level I, randomized controlled trial.

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Distal radius fracture (DRF) is one of the most common fractures in adults, with a bimodal incidence curve by age and sex[1] (peaking in young male and older female patients) and is expected to increase in the future due, among others, to a projected greater incidence of osteoporotic fractures in the older age

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The authors report the following potential conflicts of interest or sources of funding: This work is partially funded by Institute of Health Carlos III (Instituto de Salud Carlos III − ISCIII [grant number PT17/0017]), co-financed by the European Regional Development Fund (FEDER) "A way to make Europe." Instituto de Salud Carlos III is a Spanish public body assigned to the Ministry of Science and Innovation that manages and promotes public clinical research related to public health. Full ICMJE author disclosure forms are available for this article online, as supplementary material.

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Received November 29, 2022; accepted June 22, 2023.

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0749-8063/221520/$36.00

https://doi.org/10.1016/j.arthro.2023.06.036

group.[2] There is a clear tendency to treat DRF surgically, and the open reduction and internal fixation with volar locking plate (VLP) is the most frequently used surgical method.[3] A meta-analysis showed that the VLP for DRF in adult patients offered the best results compared with external fixation, intramedullary nailing, K-wires, or plaster casting.[4]

The use of adjuvant arthroscopy is proposed to improve diagnosis and treatment of associated injuries,[5] reduce joint step-offs,[6] and avoid the presence of intra-articular screws,[7] although there is no consensus on whether adjuvant arthroscopy improves the functional outcome of this surgery.[8,9] A recent meta-analysis suggests that arthroscopic assistance for DRF osteosynthesis with VLP is useful for step-offs reduction and treatment of soft-tissue injuries, but it has not found significant differences in functional outcomes, so further research is needed to assess this statement more closely.[10]

Nowadays, using patient-reported outcome measures (PROMs) to assess study outcomes is essential, and the Patient-Rated Wrist Evaluation (PRWE) questionnaire is the most responsive one for DRF when compared with other PROMs, as stated by MacDermid et al. and recently confirmed Mark.[11,12]

The main purpose of the study is to evaluate the outcomes of adding arthroscopy to osteosynthesis of DRF with a VLP, by PRWE 1 year after surgery. Our hypothesis was that adding arthroscopy to the open reduction and internal fixation treatment of DRF with a VLP would improve the functional outcomes at 1 year, as measured by the PRWE questionnaire.

Methods

Design and Ethics

The study is a multicenter, randomized, open clinical trial, with a parallel assignment and superiority design. The trial was developed in 3 tertiary hospitals in the same city, with 2 main surgeons of the Hand and Wrist Surgery Unit in each one, between September 2017 and February 2021. Seven visits were performed: baseline, surgery, +1 and +4 weeks, +3 and +6 months, and +1 year after surgery.

The study was developed in accordance with GCP and Declaration of Helsinki rules and approved by the CEIC of the Hospital Clínico San Carlos (No. 16/206-P_BD) and by the board of directors of each of the participating hospitals. The study followed the CONSORT statement recommendations, adjusted for non-pharmacological treatments.[13] Registered at ClinicalTrials.gov (No. NCT02911610; August 29, 2017).

Inclusion and Exclusion Criteria (Patients)

Inclusion criteria included patients aged older than 18 years, functionally independent or who needed assisted support by crutches/walker for walking, with a DRF and a clinical recommendation for surgery with a VLP. Exclusion criteria included severe open fractures (type III of the Gustilo classification); bilateral or ipsilateral associated fractures of the affected upper limb (except distal ulnar fracture); previous ipsilateral major wrist fracture or injury; injuries secondary to tumor processes, congenital osseous metabolic processes, and others that imply a poor prognosis; pregnant patients, according to the usual clinical criteria in the management of patients with these traumas; and medical criteria that contraindicate surgery. Full study information was given, and informed consent was signed by every patient.

Surgical criteria were radiographic unacceptable parameters after 1 attempted closed reduction in the emergency department (dorsal angulation $>0°$ or volar angulation $>15°$, measured from lateral radiograph; ulnar variance >3 mm, compared with the uninjured side; radial inclination $<15°$ on the posteroanterior radiograph; articular step-offs >1 mm) or unstable fracture, defined as a fracture with loss of reduction during the first 3-week follow-up.

The subject's allocation to treatment was determined by computer-generated randomization (REDCap random-order table, ratio of 1:1). All the surgeons were extensively experienced in wrist arthroscopy and hand and wrist surgery.

Surgical Open Procedure

A modified Orbay volar approach was performed at the wrist without opening the flexor carpis radialis tendon sheath. Osteosynthesis with a VLP was performed and checked by fluoroscopy (adding a lateral projection with radial inclination of 20° to visualize the radiocarpal articular surface without the overlapping of the radial styloid, to also assess the presence of intra-articular screws, and a dorsal tangential view when needed, to determine screw articular length. To check scapholunate (SL) instability after osteosynthesis of the distal radius, axial compression and radial/ulnar deviation maneuvers were performed under fluoroscopy control, considering the widening of the SL space and scaphoid flexion as unstable (Fig 1). The intraoperative distal radioulnar (DRU) instability was assessed by comparing with the contralateral side. The postoperative treatment, depending on the surgical findings (quality of bone, fracture pattern, and/or associated lesions), was compressive bandaging or immobilization with brachial/antebrachial splint for 4 or 8 weeks. The associated acute SL instability was treated with Kirschner pins and splint immobilization for 8 weeks. In case of DRU instability, it was stabilized with a Kirschner wire, 3 weeks with brachial splint and another 3 weeks with antebrachial splint, delaying

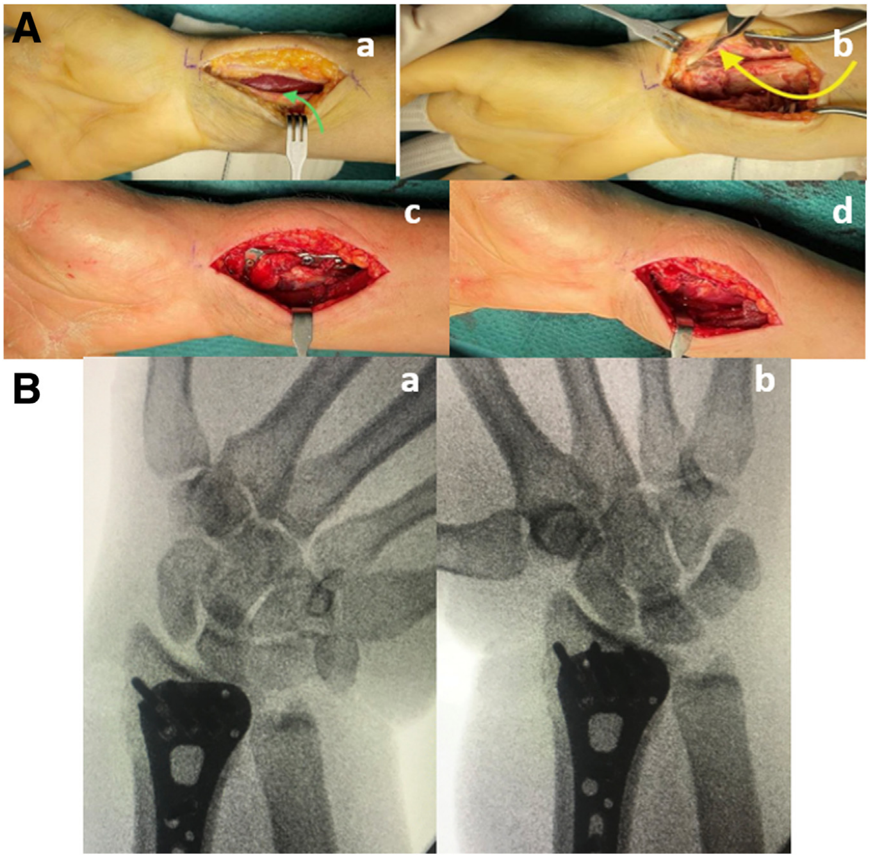

Fig 1. The images above (A) show the main step-offs of open volar plate osteosynthesis: the green arrow shows the intact FCR sheath (a), the yellow arrow shows the BR tendon (b), and the following photos show the PQ muscle before (c) and after suturing the PQ muscle covering the plate (d). The images below (B) show dynamic intraoperative fluoroscopy to assess scapholunate unstability with compression and ulnar (a) and radial deviation (b). (FCR, flexor carpis radialis.)

rehabilitation to 6 weeks after surgery. In any case, rehabilitation began after removal of the splint or at 4 weeks.

Arthroscopic Wrist Procedure

After open reduction and temporary fixation of the fracture with the VLP and K-wires, radiocarpal and/or midcarpal arthroscopy was performed with 10-pound joint traction using the Geissler tower. Arthroscopy is usually performed through dorsal portals, but occasionally volar portals may be used at the surgeon's discretion and depending on the preoperative findings. Joint step-offs >2 mm were reduced as anatomically as possible with the aid of a hook or narrow chisel, using maneuvers to lift or lower the displaced fragment. Kirschner pins and splint immobilization for 8 weeks were used to address the concomitant acute SL instability (Geissler grades III-IV). An acute foveal triangular fibrocartilage complex lesion was treated with a suture anchor. Finally, the definitive osteosynthesis of the fracture was performed with the VLP, with arthroscopic assessment for possible intra-articular screws in the radiocarpal joint (Fig 2). As in the control group, closure and postoperative treatment depended on the surgical findings (quality of bone, fracture pattern, and/or associated lesions) and was either compressive bandaging or immobilization with a brachial or antebrachial splint for 4 or 8 weeks. In any case, rehabilitation began after removal of the splint or at 4 weeks.

Data Collection

We evaluated the functional outcomes with validated PROMs (PRWE, Disabilities of the Arm, Shoulder and Hand [DASH], and 12-Item Short Form Health Survey [SF-12]), particularly for DRF. The primary variable was the PRWE questionnaire score at +1year postsurgery. This questionnaire consists of 15 questions, divided into a pain and a function section, with a score range from 0 to 100, being 100 the worst possible score.

Secondary functional outcomes were the PRWE at the other visits, DASH and SF-12 questionnaires.

The DASH questionnaire consists of 30 compulsory questions, a work module, and an optional sports/music module. The score ranges from 0 to 100, being 100 the worst score. The SF-12 consists of 12 questions that assess the patient's perceived physical and mental health.

Other secondary outcomes were clinical examination and radiographic findings. Active range of motion (ROM) was measured with a goniometer and assessed

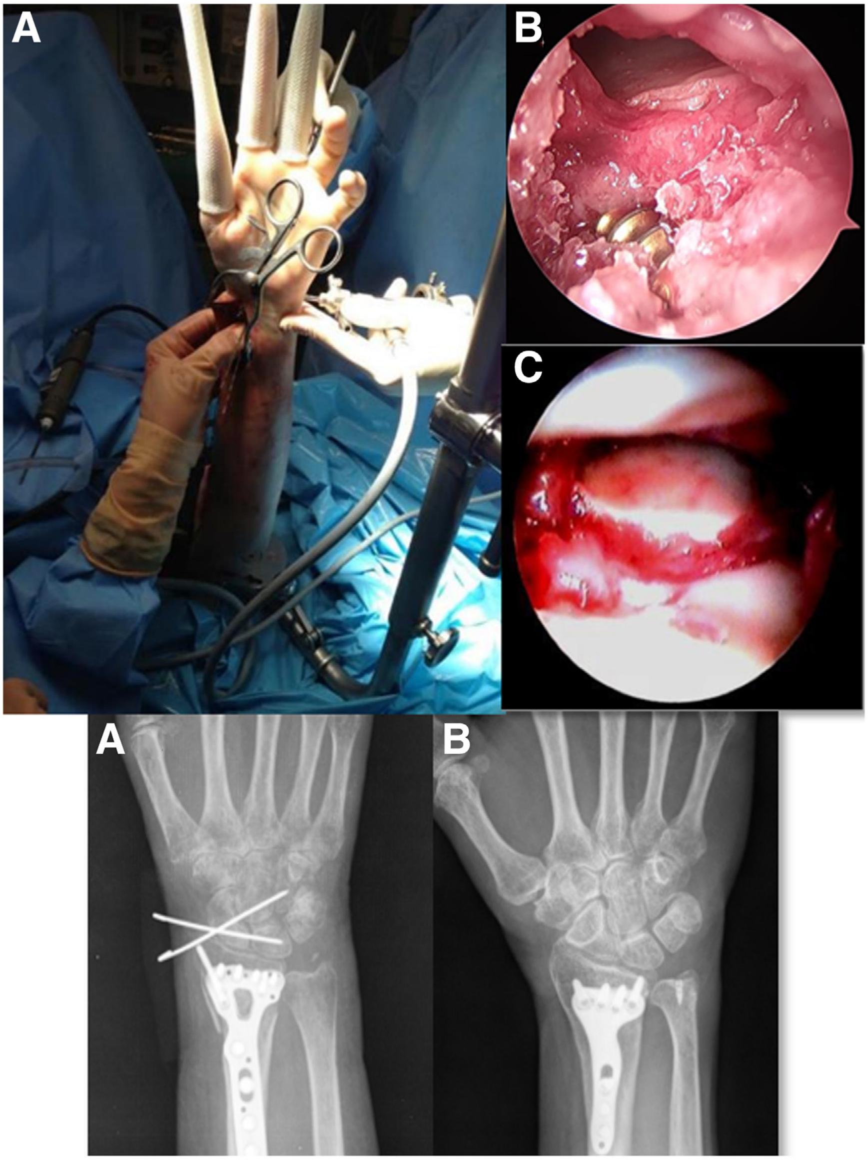

Fig 2. The photos above show (A) an intra-articular step-offs reduction maneuver in a left DRF, (B) an intra-articular screw in the lunate fossa, viewed from the dorsal 3-4 radiocarpal portal, and (C) a joint step-offs in the scaphoid fossa, viewed from the dorsal 4-5 radiocarpal portal. The images below show (A) an associated SL ligament treatment with K-wires and (B) a TFCC lesion treated with a suture anchor.

using the MacDermid scale, which is scored from 0 to 30, 1-point equals 10° of mobility and gives a maximum of 4 points for full fist closure.[12] Active mobility and postoperative PROMs were evaluated by an external assessor from the Rehabilitation Department.

Strength was measured using a dynamometer (JAMAR) in its second handle position. Grip strength was reported as a percentage of the unaffected side, considering dominance (10% more for the dominant hand if right-handed, but without compensation in left-handed people). Fracture types were classified according to AO classification for the distal radius and with the Jupiter classification for the associated distal ulna fracture.[14] The radiographic extra-articular parameters were the same as for surgical criteria, measured in the posteroanterior and lateral radiographs, as well as the SL gap compared with the uninjured wrist (Fig 3).

The radiographic intra-articular assessment was the percentage of patients with joint step-offs on the radiographs and on the preoperative and postoperative CT included in the study, differentiating the radioscaphoid, radiolunate (RL), and/or DRU joint areas.

Demographics (age and sex) and patient-specific factors (active work status, manual hobbies, dominant side) were collected preoperatively as secondary variables. The number of days patients took off work in an active professional situation was recorded to indirectly assess the socioeconomic impact of suffering a DRF. Mechanism of injury was collected and classified as low

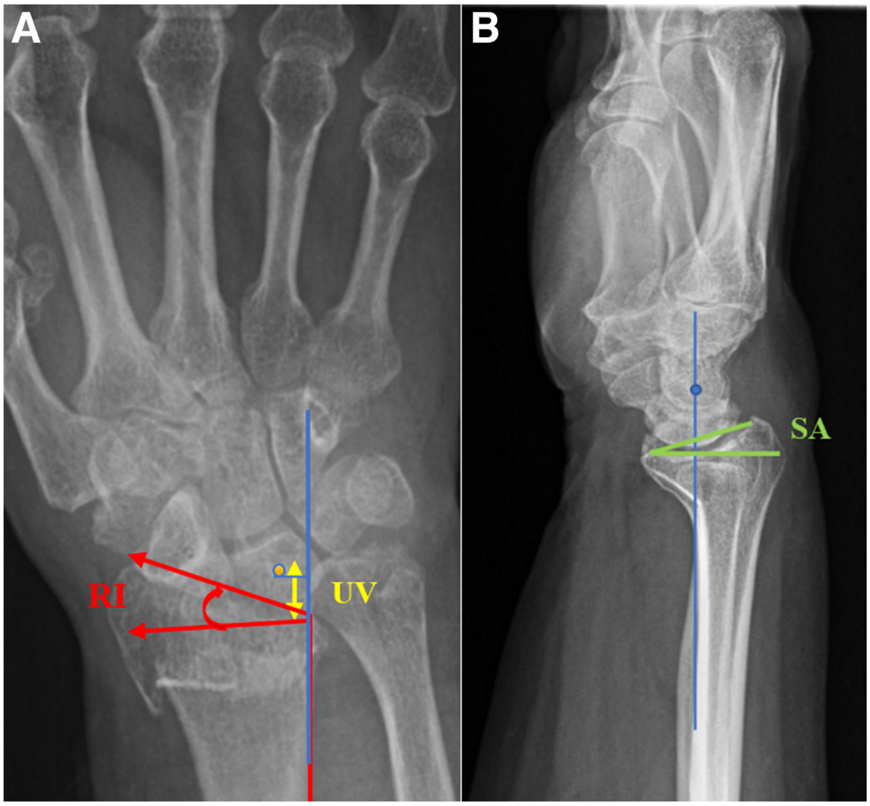

Fig 3. The images show the three main extra-articular radiographic parameters: RI = radial inclination (red), UV = ulnar variance (yellow), SA = sagittal angulation (green). (A) The blue line marks the reference of the frontal translation of the carpus on the PA radiograph (the ulnar cortical of the radius must be in line with the center of the lunate bone), and (B) the blue line in the lateral radiographs marks the reference of the sagittal translation of the carpus (the volar cortical must be in line with the center of the capitate bone).

(fall from own height), medium (sports fall including running, fall from a height >50 cm up to 1 meter), or high energy (traffic accident, run over, precipitation >1 meter, bicycle/skateboard at >20 km/hour).

Surgical and postoperative data collected as secondary outcome measures were elapsed time between fall and surgery or fall-surgery time, surgery time, ischemia time; associated surgical procedures such as joint step-offs reduction maneuvers, grafting at the fracture site (with cancellous bone allograft) or percutaneous k-wires; percentage of associated injuries diagnosed in each treatment group (acute SL ligament injury and/or acute TFCC injury); percentage of patients immobilized with a splint after surgery, the postoperative immobilization time, and the number of physiotherapy sessions each patient received, with the criteria for ending the sessions being uniform for all patients. Outcomes were measured at different times during the scheduled study visits (Table 1). Complications were noticed and registered throughout the study and were classified as major when a secondary surgery was needed.

Statistical Analysis

The sample size was calculated to detect a 10-point difference in the mean PRWE score between groups and the highest standard deviation (SD) of 23 points[15] (significance level: .05, β: 0.2), resulting in 93 patients per group considering an estimated 10% dropout rate. The minimum clinically relevant difference of 10 points was established according to what is considered clinically relevant in our center in routine clinical practice and in accordance with what patients have shown to be meaningful in other studies found in the literature.[16] The software used was GRANMO, version 7.12. Data were processed and analyzed by a blinded investigator.

Statistical analysis was performed primarily on a modified intention-to-treat (ITTm) basis for all the described outcomes. The ITTm population included randomized patients who received their assigned treatment. Secondarily, an analysis was performed on the per-protocol (PP) population, defined as the patients with 80% of the scheduled visits completed, including the primary outcome.

Qualitative variables were summarized as a frequency distribution and normally distributed quantitative variables as mean ± SD. The continuous non-normally distributed variables were summarized as median and interquartile range (IQR). To assess the skewness of quantitative variables, a graphical inspection of histograms and box plots, together with quantile-quantile normality plots, was performed.

A description of the baseline characteristics between the 2 groups was performed to assess homogeneity. The association between qualitative variables was evaluated by the χ^2 test or by Fisher exact test when more than 25% of the expected values showed a

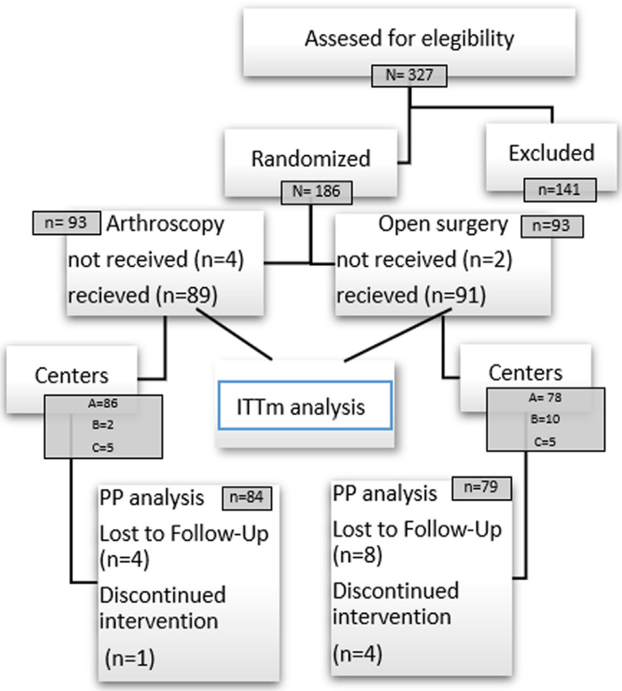

Fig 4. Patient flow chart. Centers are tertiary hospitals; a, b and c are the three different hospitals; (ITTm, modified intention-to-treat; PP, per protocol.)

frequency lower than 5. Quantitative variables that fit a normal distribution were compared with the Student's *t*-test. For variables that did not fit this distribution, the nonparametric Mann−Whitney *U* test was used.

Given the non-normal distribution of the primary and secondary outcomes variables PRWE and DASH the difference in medians and it's 95% confidence interval was estimated using quantile regression (median regression).

To assess the superiority of the treatment for the main variable PRWE, we obtained the minimal clinically important difference (MCID) based on a distribution-based method calculated by ½ SD of the delta from the post-immobilization visit (+4-8 weeks) to the final visit (+1 year) and compared the percentage of patients

Table 1. Outcomes Measured at the Scheduled Study Visits

Visits	DASH PRWE	SF-12	Clinical Radiography	Strength	ROM
V-basal	X	X	X		
4-8 weeks	X		X		X
3 months	X		X	X (Optional)	X
6 months	X		X	X (Optional)	X
1 year	X	X	X	X	X

DASH, Disabilities of the Arm, Shoulder and Hand; PRWE, Patient-Rated Wrist Evaluation; ROM, range of motion; SF-12, 12-Item Short Form Health Survey.

who met at least the MCID as a clinically meaningful difference between groups.[17] A complete case analysis was performed without treatment of the missing values. The statistical programs used for the analysis were SPSS 26.0 (IBM Corp., Armonk, NY) and STATA 15.0 (StataCorp LLC, College Station, TX).

Results

A total of 186 patients complying the inclusion/exclusion criteria were enrolled among the 327 screened (Fig 4) and randomized to arthroscopic group (AG) or control group (CG). Of them, 4 patients in the AG and 2 in the CG did not receive the assigned surgery (AG: 1 withdrew consent, 1 moved to another center, 1 tested positive for coronavirus disease 2019, 1 due to breakage of the arthroscope optic; CG: 1 change in the surgeon's criteria, 1 exclusion criterion detected during surgery [ipsilateral lunate fracture]). The primary analysis was on ITTm population (N = 180; AG: 89, CG: 91). Five patients in AG and 12 in CG were lost to follow-up (the number of patients per group and follow-up period for each variable is specified in the results). For the primary outcome, available patients (AG/CG) were 89/91 for ITTm and 84/79 for PP analysis, yielding a statistical power of 82.45 and 78.48%, respectively, for the sample size estimation. The main study groups had comparable baseline characteristics and fracture type (Table 2).

Function

The difference in the median PRWE score distribution at the end of the study was not statistically significant ($P = .328$) between groups of treatment, with a median (IQR) of 5.0 (0.0-14.0) in the AG vs 7.5 (0.0-18.5) in the CG, differences in medians of 2.5 (95% CI −2.0 to 7.0). Similarly, the PP analysis failed to show differences, with a median (IQR) of 5.0 (0.0-14.5) in the AG vs 7.5 (0.0-18.5) in the CG ($P = .374$), differences in medians 2.5 (95% CI −1.9-6.9).

The MCID in the PRWE score after applying the formula of the distribution method was 12.81 points and comparing the percentage of subjects that met at least the MCID in the change in PRWE score at the end of the study the result was not statistically significant (86.4% in the AG vs 85.1% in the CG; $P = .819$).

No statistically significant differences were found for the other postoperative PROMs at each follow-up point (Table 3). Considering the PRWE-function score at +3 months, the difference of medians was 13 points (95% CI −0.1 to 26.1), favoring the AG, although not statistically significant ($P = .315$) (Fig 5).

ROM and strength were similar between study groups (Fig 6). The percentage of professionally active patients was 54.7% of the total (98 patients) and, from retired patients, 46.9% were engaged in manual hobbies, meaning that 76.9% of the entire study

Table 2. Comparison of Baseline Demographic and Radiographic Characteristics

	Total (N = 180)		AG (N = 89)		CG (N = 91)	
Mean age, y, (SD, range)	59.0 (14.9, 20-89)		60.5 (13.4, 21-87)		57.6 (16.1, 20-89)	
Female	137 (76.1)		72(80.9)		65(71.4)	
Active work status	98 (54.7) (n = 179)		43 (48.8) (n = 88)		55 (60.5) (n = 91)	
Manual hobbies	87 (48.3)		44(49.4)		43(47.3)	
Dominant side fracture	90 (50.6) (n = 178)		45(51.1) (n = 88)		45(50.0) (n = 90)	
Mechanism of injury						
Low energy	124 (69.7)	N = 178	65 (73.9)	N = 88	59 (65.6)	N = 90
Medium energy	36 (20.2)		17 (19.3)		19 (21.1)	
High energy	18 (10.1)		6 (6.8)		12 (13.3)	
AO type fracture C	147 (82.6)	n = 178	74 (84.1)	n = 88	73 (81.2)	n = 90
Distal ulnar fracture	96 (54.2)	n = 177	47 (53.4)	n = 88	49 (54.1)	n = 89
Preoperative radiography joint step-offs	105 (58.7)	n = 179	55 (62.5)	n = 88	50 (54.9)	n = 91
PRWE BASAL*			0 (0-0)	88	0 (0-0)	85
DASH BASAL*			0.0 (0.0-7.3)	86	0.8 (0.0-5.2)	87
SF-12 physical BASAL†			51.5 (±8.7)	88	52.6 (±8.1)	82
SF-12 mental BASAL†			50.3 (±10.1)		48.3 (±10.8)	

NOTE. N/n indicates number of patients with data collected.

AG, arthroscopic group; CG, control group; DASH, Disabilities of the Arm, Shoulder and Hand; PRWE, Patient-Rated Wrist Evaluation; SD, standard deviation.

*Median (interquartile range).

†Mean (standard deviation).

population were high-demand active patients. Regarding the time off from work, we had a high percentage of data loss, 35% (30% in the AG and 38% in the CG), caused in part by loss of employment after the fracture. The median (IQR) time off from work for the total study group was 102 (72-160) days, with a difference of medians between groups of 21 days more in the CG (91.5 vs 112.5; 95% CI 8.4-33.6, P = .014). In the CG, the percentage of manual workers, and therefore more demanding in function, was greater (36% vs. 23% in the TG), although not statistically different.

Surgical Data

Some of the surgical data showed significant differences, as reflected in the table (Table 4). The percentage of associated lesions recorded (SL tears and TFCC acute lesions) was greater in the AG, which was reflected in a greater percentage of splint immobilization and longer immobilization time. There was also a significant

Table 3. Comparison of Patient-Reported Outcomes (PROs)

Questionnaire	AG		CG		Difference (95% CI)*	P Value
Postimmobilization (4-8 wk)						
PRWE†	60.0 (32.5-76.5)	83	62.5 (42.0-75.5)	77	2.5 (−9.5 to 14.5)	.606
DASH†	56.7 (35.8-71.7)	83	58.6 (41.7-75.0)	75	2.0 (−8.3 to 12.2)	.336
3 MO						
PRWE†	23.0 (8.5-50.1)	82	31.0 (12.0-47.4)	74	7.5 (−3.3 to 18.3)	.432
DASH†	25.8 (8.3-40.0)	79	25.0 (9.6-38.6)	77	−0.8 (−10.3 to 8.7)	.789
6 MO						
PRWE†	10.8 (1.9-28.5)	78	13.8 (4.9-26.8)	70	3.0 (−5.1 to 11.1)	.608
DASH†	10.8 (0.8-23.1)	76	11.3 (5.0-24.8)	72	0 (−7.0 to 7.0)	.181
1 Y						
PRWE†	5.0 (0.0-14.0)	85	7.5 (0.0-18.5)	79	2.5 (−2.0 to 7.0)	.328
DASH†	5.8 (0.0-13.3)	83	5.0 (1.3-13.8)	81	−0.8 (−4.3 to 2.6)	.405
SF-12 physical‡	49.8 (±9.9)	85	49.2 (±9.3)	76	0.6 (−2.4 to 3.6)	.715
SF-12 mental‡	50.8 (±10.6)		49.7 (±10.7)		1.1 (−2.3 to 4.4)	.528

NOTE. N = number of patients with data collected.

AG, arthroscopic group; CG, control group; CI, confidence interval; DASH, Disabilities of the Arm, Shoulder and Hand; PRWE, Patient-Rated Wrist Evaluation.

*For variables expressed with medians, refers to the difference in medians and their 95% CIs, obtained through quantile regression; for variables expressed with means, refers to the mean difference together with its 95% CI.

†Median (interquartile range).

‡Mean (standard deviation).

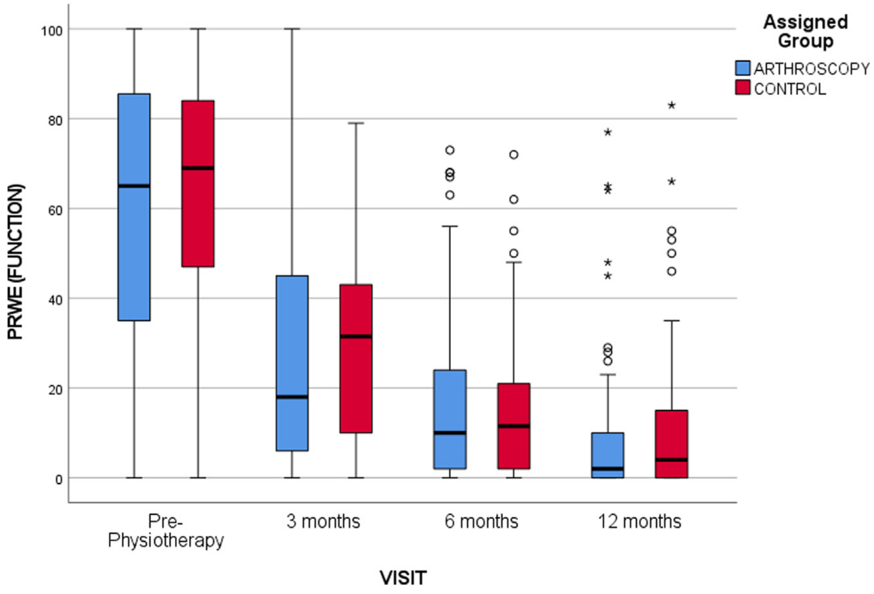

Fig 5. Box plot of the results of the function subscale of the PRWE questionnaire during the follow-up visits in both groups. (PRWE, Patient-Rated Wrist Evaluation.)

difference in the percentage of joint step-offs reduction maneuvers and 5 cases in the AG were treated with suture anchor for a TFCC lesion, resulting in a 20-minute longer mean surgery and ischemia time for the AG.

Radiologic Outcomes

All extra-articular radiographic parameters were similar between groups. The reduction of joint step-offs was similar between groups assessed by radiography, whereas by CT, the arthroscopic group reduced the percentage of joint step-offs in the radioscaphoid, RL, and RU joints but in the CG only in the RL joint (Fig 7), although not statistically significant ($P = .990$, $P = .538$, and $P = .063$).

Complications

The complication rate (including the need for additional surgery) was 18.9% in the whole study population (AG: 16.9%; CG: 20.9%; $P = .842$). The main reasons for additional surgery were hardware complaints (AG: 11.2%; CG: 11%) and neuropathic disorders, mostly carpal tunnel syndrome (AG: 3.4%; CG: 7.7%), both not statistically different. The percentage of intra-articular screws detected on the postoperative CT was greater in the CG (14.5% vs 9%, $P = .316$) but not all cases required additional surgery for screw removal. In AG, intra-articular screws were observed in 6 cases (3 due to postsurgical joint collapse with a very distal fracture site C3 type, only one case required additional surgery); in 2 cases, partial necrosis of the dorsoulnar fragment was observed, both very distal C3 type; and 1 case, a screw slightly invaded the distal RU joint with no clinical repercussions. The complex regional pain syndrome rate was 2.6% overall, with no significant difference between groups (2 cases in each group, Fisher exact test).

Discussion

In our trial, arthroscopy did not improve functional results 1 year after DRF, and the difference of the median PRWE score at the end of the study was not statistically significant between groups of treatment. The difference observed was not detectable as a clinically relevant improvement by the patient. This result is in line with recent publications,[9,18] while previously Ruch et al.[19] in 2004, had shown better results in terms of joint mobility with adjuvant arthroscopy (surgical technique with external fixation), or that of Varitimidis et al.[20] informed of better functional results in the arthroscopy-assisted group, measured by the Mayo Wrist Score (also mainly external fixation).

We chose the primary outcome at 1 year based on the study of Waljee et al.,[21] looking for a consensus about outcomes assessment for DRF of the Distal Radius Working Group of the International Society for Fracture Repair and the International Osteoporosis Foundation, which concluded that one year is enough to capture late clinical events.

In the prospective multicenter study by Jupiter and Marent-Huber,[22] with 150 cases operated on with VLP, the observed improvements in mobility, strength, and patient satisfaction between 6 months and 1 year did not increase after 2 years of follow-up. Perhaps after 1 year the results of the different treatments are equalized by the patient's own adaptation to the new functional

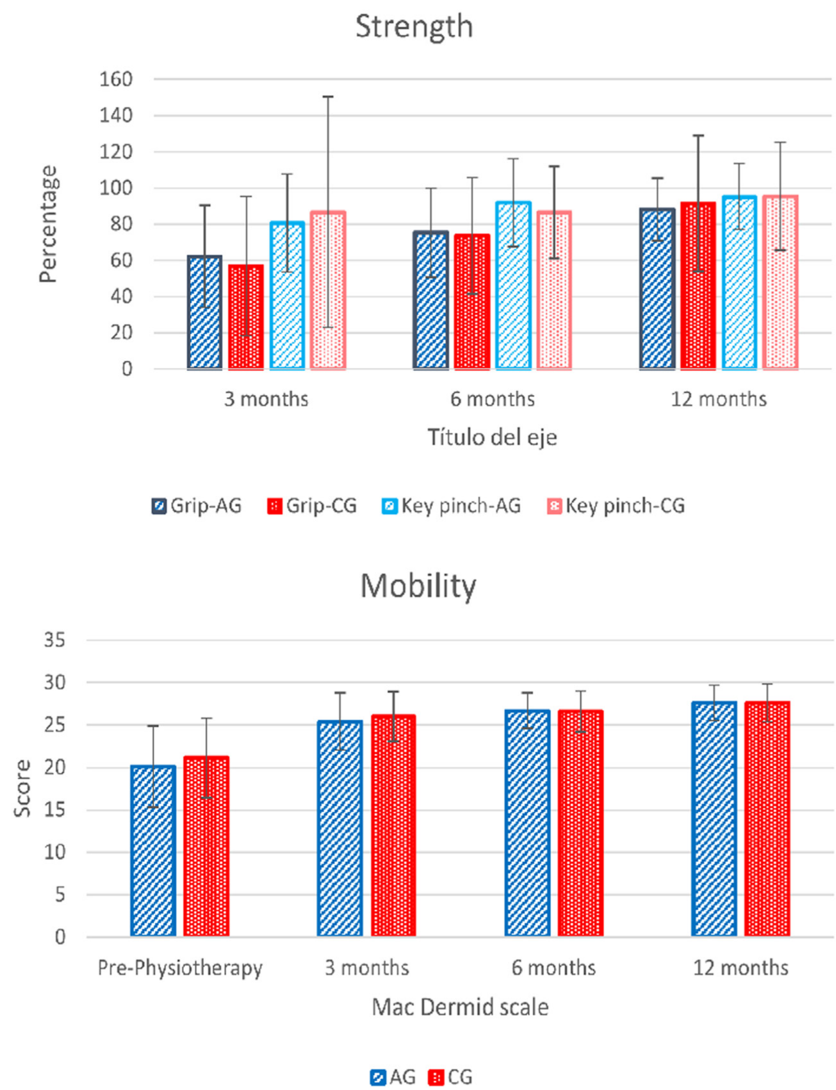

Fig 6. Bar chart comparing mobility and strength results throughout the study in both groups, with the 95% confidence interval included. (AG, arthroscopic group; CG, control group.)

situation, or even by bone remodeling of residual step-offs.

The evolution of functional outcomes during follow-up was similar in both groups to that observed by MacDermid et al.,[23] who described how in the first 2 months patients present a high level of pain with movement and severe difficulty in function, which recovers within the first 6 months and persists in only a few at 1 year. Maybe it is more appropriate to assess short-term results when evaluating the improvement of one treatment over another. Early functional improvement with a given treatment could have an important clinical and socioeconomic impact.[24]

In our study, the AG had a greater functional recovery at 3 months, with a difference in the median score of 13.5 points, considered clinically relevant in the study, though not statistically significant. This finding is especially important for working people, and in our study, time off from work was 21 days more in the CG and statistically significant. It is unknown which patients returned to the same work they had before the fracture so the real socioeconomic impact could be underestimated. Even for the retired population the socioeconomic consequences could appear in terms of autonomy, familiar caregiving ability, or requirement of external assistance. No other significant differences in the other PROMs, ROM, strength, or radiographic extra-articular alignment were found between groups.

The calculated sample size in our study is larger than that published in other similar trials. The recently published meta-analysis by Shihab et al.[10] on arthroscopy in wrist fractures selected 6 articles, of which only 2 were clinical trials and both with smaller sample sizes than our trial, with a maximum of 70 patients. Our study included the anticipated sample of 186 patients, although a few nonavoidable number of dropouts occurred. However, despite the losses, a power of 74.48% was available for the initially proposed

Table 4. Comparison of Surgical Data Between Groups

	TOTAL (n = 178)	AG (n = 88)	CG (n = 90)	Difference (95% CI)*	*P* Value†
Fall-surgery time, d	12.3 ± 6.4	12.9 ± 4.6	11.9 ± 7.8	1.0 (−0.9 to 2.9)	.308
Surgery time, min	98.4 ± 27.2	109.3 ± 24.2	87.9 ± 25.8	21.5 (14.1-28.9)	**<.001**
Ischemia time, min	73.2 ± 23.5	83.2 ± 19.2	63.3 ± 23.3	21.5 (13.6-26.3)	**<.001**
Joint step-offs reduction	43 (24.2%)	29 (33.0%)	14 (15.6%)	17.4 (5.0-29.7)	**.007**
Grafting at the fracture site	32 (19.2%)	16 (18.4%)	16 (20.0%)	1.6 (−13.6 to 10.4)	.792
Percutaneous k-wires	5 (3.0%)	2 (2.4%)	3 (3.5%)	1.1 (−6.2 to 4.0)	1.000
Associated lesions	19 (10.7%)	17 (19.3%)	2 (2.2%)	17.1 (8.3-25.9)	**<.001**
Postoperative splint immobilization	105 (59.0%)	61 (69.3%)	44 (48.9%)	20.4 (6.3-34.6)	**.006**
Post-operative immobilization time (days)	22 (6-29)	26 (7-30)	10 (5-28)	−16 (−24.1 to −7.9)	**.014**
Physiotherapy sessions	15 (10-30)	15 (11-30)	15 (5-30)	0 (−5.5 to 5.5)	.137

NOTE. N = number of patients with data collected. Statistical significance: *P* value <.05 (in bold).

AG, arthroscopic group; CG, control group; CI, confidence interval; IQR, interquartile range; SD, standard deviation.

*For variables expressed with medians, refers to the difference in medians and their 95% CIs, obtained through quantile regression; for variables expressed with means refers to the mean difference together with its 95% CI; for variables in percentages refers to the mean difference together with its 95% CI.

†Fisher exact test.

differences. Anyway, with a difference in medians for the primary outcome between the groups of 2.5 (not clinically relevant) the power of the study is less than the expected.

The advantages of using wrist arthroscopy in the surgical treatment of DRF are improved diagnosis and treatment of associated injuries (mainly SL and TFCC lesions),[25] improved reduction of joint step-offs,[26] and the control of intra-articular screws in case the fracture is very distal and subchondral screws are required.[7]

The percentage of associated lesions diagnosed at surgery was statistically greater in the AG. Most cases were treated with splinting and further immobilization and 5 cases in the AG were treated with suture anchor for the TFCC lesion. The greater percentage of associated lesions diagnosed by arthroscopy was not subsequently reflected in the functional results obtained at 1 year. At the end of the study, only 2 cases of symptomatic SL instability were observed in the CG, which did not require additional surgery. However, the scientific literature reports high percentages of SL ligament involvement in distal radius fractures, from 21.5%[22] to 54%.[27,28] Perhaps most arthroscopically diagnosed injuries benefit from the same immobilizing treatment as the fracture and do not require further treatment or result in a worse prognosis. In fact, in the prospective study by Wang et al.,[29] 26.5% of DRF with untreated SL space widening had the same clinical outcome at 1 year as patients without SL space widening. According to the biomechanical study by Short et al.,[30] an extrinsic wrist ligament injury is also necessary for the development of SL instability. Another important source of residual pain in DRF is DRU instability. Maybe TFCC lesions are underdiagnosed in CG because there have been five cases treated with suture anchor in our AG but none in CG. Moritomo's biomechanical study,[31] however, addresses the distal interosseous membrane as a secondary stabilizer of the DRU joint. Despite the TFCC's complete disinsertion at the foveal level, his biomechanical study found that anatomical correction of the radius length in DRFs stabilizes the DRU joint by restoring distal interosseous membrane tension.

According to postsurgical CT imaging results, arthroscopy decreased the percentage of residual joint step-offs in the RC and DRU joints, whereas CG only in the RL joint, even though the difference was not statistically significant. Edwards et al.[26] also reported that arthroscopy could detect step-offs that fluoroscopy was unable to see in 33% of cases. The clinical manifestation of joint incongruence shows disparate results in different publications.[32,33] Incongruence in the dorsal or volar rim fragments (less than 2 mm from the articular surface) did not affect the functional outcome of intra-articular DRF, according to Lee et al.,[33] but the larger dorsal-ulnar fragments did affect the joint significantly. The affected articular regions in our trial weren't so specifically compared.

Biomechanical studies in cadaver models suggest subchondral placement of the distal screws of the plates for maximum stability in internal fixation with a VLP.[26] However, the risk of intra-articular screw placement increases. In our trial, the number of intra-articular screws was greater in the CG, although the difference was not statistically significant. Most of the AG cases with intra-articular screws were type C3, with a very distal fracture site that subsequently suffered collapse of the fracture or partial necrosis of articular fragments. In these cases, arthroscopy did not prevent the presence of intra-articular screws during the postoperative period. Other case had a slightly intra-articular screw in the DRU joint, but RC arthroscopy cannot avoid this and adding a DRU arthroscopy is more time-consuming.

Fig 7. Bar chart showing the results of extra-articular radiographic parameters in both groups and the difference in the pre- and postsurgical percentage of residual joint step-offs in the main articular fossae in both groups, with the 95% confidence interval included. (AG, arthroscopic group; CG, control group.)

Therefore, in fractures with a very distal fracture site, arthroscopy may be advisable to control the subchondral screws, although it cannot entirely prevent the postoperative collapse in some types of fractures.

Disadvantages of adding arthroscopy to volar plate surgery are an increase in surgical time, the need for trained and skilled personnel, and an increased risk of complications.[34] As in the Varitimidis clinical trial, surgery and ischemia time was longer in the AG,[20] a consequence of joint step-offs reduction maneuvers or the diagnosis and treatment of associated lesions. The percentage of complications in our study was similar across groups. All surgeons involved were skilled and familiar with the arthroscopic technique and there were no issues directly related to the portals of entry, or the arthroscopy technique.

In summary, the results of our study are in line with those obtained in the meta-analysis by Shihab et al.[10] regarding the improvement in the reduction of intra-articular step-offs and the diagnosis of associated lesions by adding arthroscopy to DRF surgery. However, longer-term studies are still needed to determine the evolution of these lesions and intra-articular incongruence. In the prospective study by Mrkonjic et al.,[35] 50 patients with untreated TFCC lesions were examined over a 13- to 15-year period. They did not observe DRU instability but acknowledge that the study may be underpowered. Although only 10% of cases with intra-articular step-offs in the study by Forward et al.[32] developed symptomatic osteoarthritis after a mean follow-up of 38 years, this was a retrospective study, and most fractures did not require surgery, so it is possible that the type of fracture is not comparable to our trial. The lack of more detailed short-term (3-month) trials in working-age patients makes it difficult to determine which factors contribute to a quicker recovery and minimize the socioeconomic impact of these fractures or identify the subtype of fracture that would benefit from adjuvant arthroscopic treatment. Future research could also consider standardizing postoperative treatment to reduce this potential confounding factor.

Limitations

As is inherent in other studies on surgical treatments due to ethical issues, one of our limitations is its unblinded nature. To reduce this bias, different evaluators outside the surgical team were included for some variables. Thus, in our trial the main variable was measured by the rehabilitation physician, as were the rest of the questionnaires (except for the baseline) and postoperative mobility.

Because of the coronavirus disease 2019 pandemic during the recruitment period of our randomized controlled trial, data on some variables were not possible to evaluate. The dropouts after 1 year were greater than initially expected, achieving a final power of 74.48% for the primary outcome, lower than the expected 80%, so the study is underpowered with a type II error greater than the expected, being this a considerable limitation.

Another limitation of the study was the wide age range included, accepted to allow extrapolation of the results to the general setting and thus increase external validity, as this also increases sample heterogeneity and can produce some confounding biases. Anyway, all the selected patients were functionally active. Another factor of heterogeneity was the postoperative treatment based on the surgical findings due to the higher sensitivity of the diagnosis of associated lesions in the AG. This variability may have affected the outcomes of the study.

Although baseline characteristics about the AO classification of DRF were similar between groups, we did not control for subtypes of intra-articular fractures (such as dye punch depressions or coronal plane shear fractures), which may affect the outcomes. Being a randomized study, these subtypes are expected to distribute homogeneously.

The follow-up time of 1 year is not sufficient to assess the long-term effects of the reduction of residual joint step-offs or the increased diagnosis of associated lesions achieved by arthroscopy.

Conclusions

Adjuvant arthroscopy did not significantly improve PRWE score +1 year after surgery for DRF with VLP, although the statistical power of the study is below the initially estimated to detect the expected difference.

Acknowledgments

We thank all the participating Centers and support units' staff, UICEC-HCSC, Spanish Clinical Trials Platform (SCREN, is a public network funded by the Instituto de Salud Carlos III), UAMI-HCSC, for their collaboration in the study. We especially thank Jorge-Mario Quiñonez-Silvero for the study monitoring and audit and Ana-Belen Rivas-Paterna and Amanda López-Picado for the study management.

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