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Intra-Articular Corrective Osteotomy for Distal Radial Intra-Articular Malunion Using Patient-Matched Instruments

A Prospective, Multicenter, Open-Label, Single-Arm Trial

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Background: Corrective osteotomy for intra-articular malunion is a challenging procedure. However, recent advancements, including patient-matched instruments created on the basis of preoperative computer simulation, enable accurate intra-articular correction. We hypothesized that intra-articular corrective osteotomy using patient-matched instruments for the treatment of distal radial intra-articular malunion would reduce intra-articular deformity and restore wrist function at 12 months of follow-up.

Methods: This prospective study included 12 patients with distal radial intra-articular malunion who underwent intra-articular corrective osteotomy external to the joint using patient-matched instruments. The primary end point was the maximum step-off on the articular surface of the distal radius, measured with use of computed tomography (CT), with an expected postoperative value of ≤1.5 mm. The secondary end points included the gap of the articular surface; range of motion; grip strength; pain evaluated using a visual analog scale (VAS); patient satisfaction; Disabilities of the Arm, Shoulder and Hand (DASH) score; and Patient-Rated Wrist Evaluation (PRWE) score. A mean postoperative step-off of ≤1.5 mm for the primary end point was assessed with use of the 1-sample t test. The secondary end points were assessed with use of the Dunnett multiple comparison test.

Results: The average step-off significantly improved from 3.75 ± 1.04 mm preoperatively to 0.51 ± 0.40 mm at the 52-week postoperative follow-up and was maintained within 1.5 mm. The average wrist and forearm range of motion, VAS score, grip strength, DASH score, and PRWE score significantly improved. Eleven patients were either very satisfied or satisfied with their outcomes.

Conclusions: The use of patient-matched instruments could contribute to improving postoperative outcomes of intra-articular corrective osteotomy procedures involving the distal radius.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Distal radial fractures are common skeletal injuries. Although several randomized controlled trials have shown that unreduced distal radial fractures with malunion, including those associated with intra-articular deformity, do not significantly affect wrist function in older individuals on average[1-4], malunions after unreduced fractures sometimes cause impaired wrist and forearm function with pain, restricted range of motion, and decreased grip strength[5-10]. Extra-articular distal radial malunion can be managed with an osteotomy to achieve deformity correction and functional recovery[11-14]. Recently, three-dimensional (3D) corrective osteotomy using a patient-matched instrument created on the basis of computer simulation has improved the outcomes for patients with extra-articular

Disclosure: This study was supported by national grants from the Japan Agency for Medical Research and Development (AMED) and JSPS KAKENHI (No. JP 22H03199). The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A661).

malunion[15-18]. However, intra-articular malunion treatment remains challenging because intra-articular corrective osteotomy through an arthrotomy is highly invasive and is associated with the risks of intra-articular fibrosis, fragment necrosis, and nonunion[19,20]. Accurate intra-articular corrective osteotomy remains difficult, even with arthroscopic techniques[21,22]. Hence, salvage procedures, such as wrist arthrodesis and arthroplasty, are often used to manage pain and osteoarthritis[23-28].

Favorable clinical outcomes have been reported for patients with malunited distal radial fractures that were treated with intra-articular corrective osteotomy using patient-matched instruments created on the basis of preoperative computer simulations[29-35]. However, to our knowledge, no prospective studies have examined the effectiveness of this procedure. We hypothesized that intra-articular corrective osteotomy with use of patient-matched instruments for the treatment of distal radial intra-articular malunions would reduce the intra-articular deformity and restore wrist function at 12 months of follow-up.

Materials and Methods

Study Design

This study was approved by the institutional review board of our institution and was registered with the Japan Registry of Clinical Trials (jRCT2052200081). The study adhered to Good Clinical Practice guidelines and was conducted according to the Helsinki Declaration of 1975, as revised in 2000. Oral and written informed consent was obtained from all patients. Research coordinators supported data collection. Data monitoring was outsourced to clinical trial monitors of an external site management organization. A team of biostatisticians conducted data management and performed statistical analyses. All institutions used for data handling and analysis were independent of the researchers.

Participants

This prospective study included volunteer patients, 18 to 75 years of age, with distal radial intra-articular malunion following a distal radial fracture from April 2020 to March 2022. The study was conducted at 5 registered institutions. The inclusion criteria were the presence of a step-off of >2 mm on the articular surface of the distal radius on computed tomography (CT) resulting from a malunited fracture; ≥3 months from the time of the initial fracture to study inclusion; and functional impairment, such as restricted range of motion, pain, and no or early osteoarthritic changes of grade 0 or 1 according to the Knirk-Jupiter system (grade 0 = none, grade 1 = slight joint-space narrowing, grade 2 = marked joint-space narrowing, and grade 3 = bone-on-bone)[8]. Patients with highly complex intra-articular deformities resulting from severe comminuted fractures with ≥4 parts that were deemed unmanageable through this approach, and those with advanced or severe (grade-2 or 3) osteoarthritis, were excluded. Two board-certified orthopaedic hand surgeons with >20 years of experience who were not part of this study (Image Evaluation Committee) determined the osteoarthritis grade. In case of disagreement, a third evaluator determined which of the 2 grades should be assigned.

Fifteen patients with radiographic evidence of intra-articular malunion of the distal radius were enrolled. Two patients were excluded because of an intra-articular step-off of ≤2 mm on screening CT, and 1 patient withdrew consent

TABLE I Data on the Patients*

Patient	Affected Side	Sex	Age *(yr)*	Interval from Injury to Surgery *(mo)*	Initial Treatment	Chief Symptom	Intra-Articular Malunited Fragment	Type of Extra-Articular Deformity
1	L	M	61	7.3	Pinning	Pain	DLF	Dorsal
2	L	F	67	10.7	Bandage	Pain	DSF	—
3	R	M	45	14.9	Splint	Pain	EVS	—
4	L	F	53	6.9	Cast	Pain	DLF	Dorsal
5	R	F	59	9.7	Cast	Pain	DLF	Dorsal
6	R	M	46	9.1	Cast	Limitation of range of motion	VLF	Volar
7	R	M	58	18.4	ORIF	Limitation of range of motion	VLF	—
8	R	F	51	14.7	Cast	Pain	EVS	—
9	L	M	64	5.6	Cast	Pain	EVS	—
10	L	M	18	8.5	ORIF	Pain	EDS	—
11	L	M	21	9.8	ORIF	Limitation of range of motion	EVS	—
12	R	M	42	5.0	Cast	Pain	EVS, DLF	—
Average			48.8	10.1				

*DLF = dorsal lunate fossa, DSF = dorsal scaphoid fossa, EVS = entire volar surface, VLF = volar lunate fossa, ORIF = open reduction and internal fixation, EDS = entire dorsal surface.

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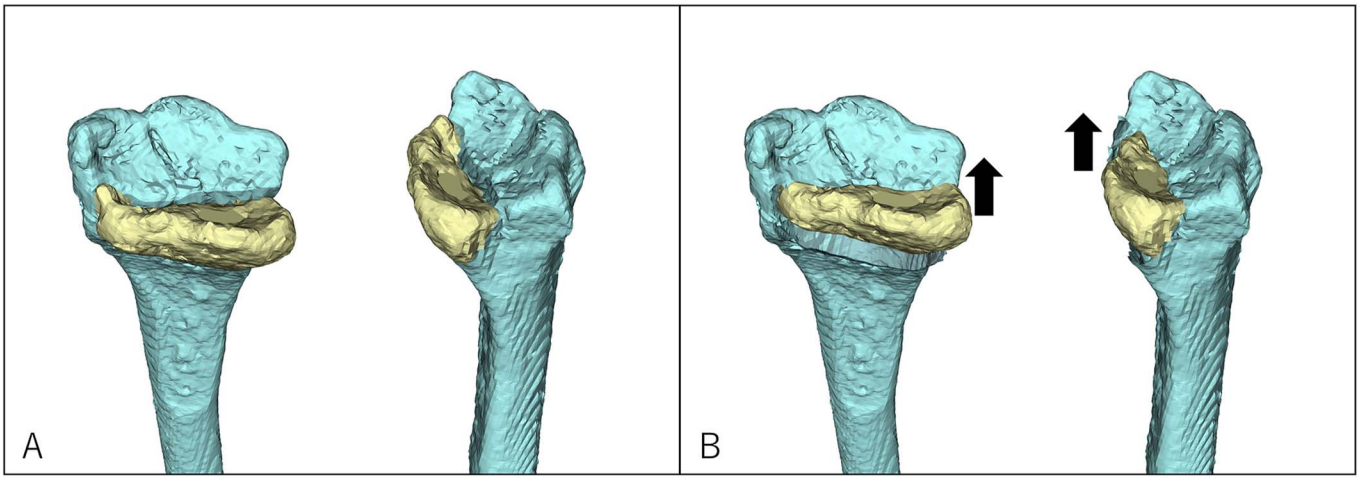

Fig. 1

Figs. 1-A and 1-B Computer-aided simulation of intra-articular corrective osteotomy. **Fig. 1-A** Three-dimensional bone model showing intra-articular malunion. The entire volar fragment (yellow) is proximally displaced and is malunited with the distal radius (blue). **Fig. 1-B** The entire volar fragment is separated and corrected (black arrows) to create a smooth articular surface.

to participate before surgery. The remaining 12 patients participated. Four malunions were accompanied by extra-articular deformities that required extra-articular correction. The duration of follow-up was 52 weeks for all patients. Patient data, including the intra-articular malunion type, are shown in Table I.

Surgical Planning

Both wrists were scanned with use of a CT scanner with a low radiation setting[36]. During image acquisition, both arms were elevated and extended overhead and were placed in the prone position to reduce radiation exposure to the head and eyes. Bilateral 3D bone surface models of the distal radius and ulna were created using 0.5-mm-slice CT data, and intra-articular corrective osteotomy was simulated using commercially available software (BoneViewer and BoneSimulater; Teijin Nakashima Medical). The malunited fragment was manually separated along the step-off direction and was corrected to create a smooth articular surface. The simulation was performed carefully with consideration of the anatomical attachments of the joint capsule and capsular ligament to the fragment (Fig. 1).

Design and Production of Patient-Matched Instruments

We designed patient-matched instruments to reproduce preoperative simulations during surgery. The patient-matched instrument was shaped to fit the bone surface of the distal radius and had multiple sleeves to bore holes leading toward the intra-articular malunited fracture line. We used a smooth

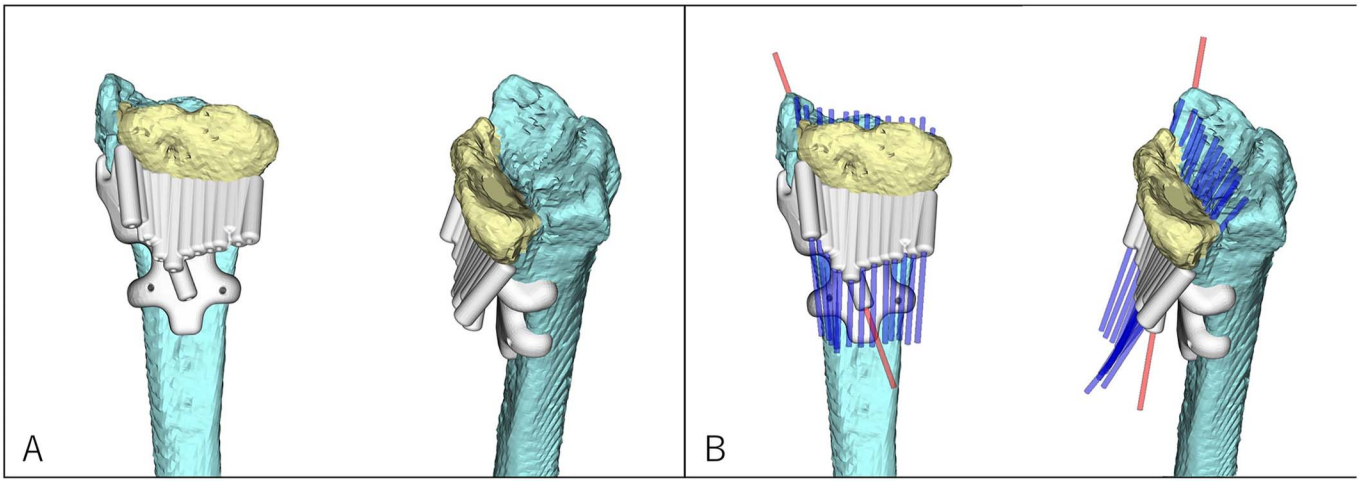

Fig. 2

Figs. 2-A and 2-B Computer-aided simulation of the design of a patient-matched instrument. **Fig. 2-A** A patient-matched instrument (white) that fits on the bone surface and is equipped with multiple sleeves is designed**. Fig. 2-B** The placement can be confirmed by inserting a reference Kirschner wire (red) pointing at the tip of the radial styloid. Multiple drillings are performed by passing Kirschner wires (blue) through the sleeves.

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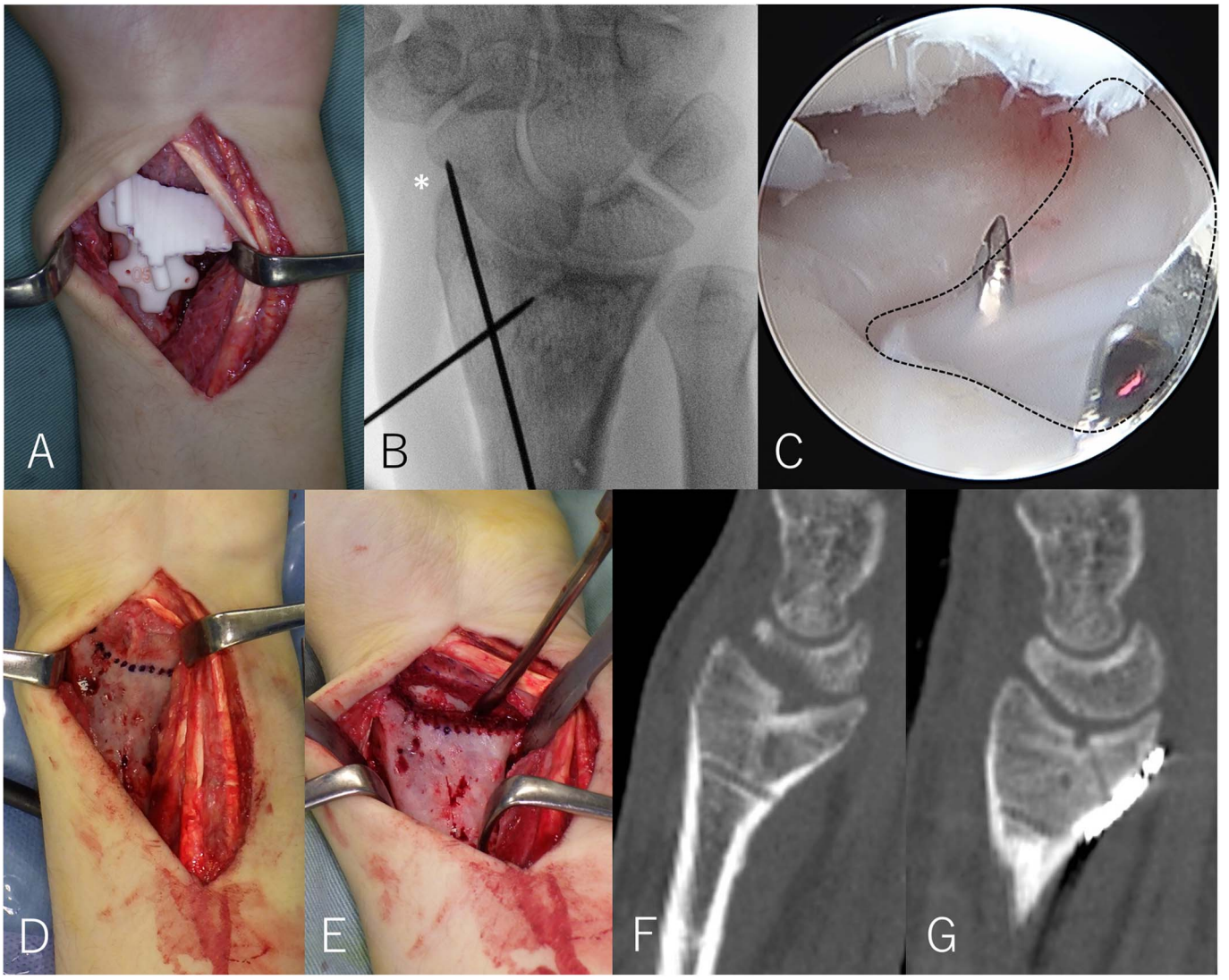

Fig. 3

Figs. 3-A through 3-G Images illustrating the surgical procedure for intra-articular corrective osteotomy using a patient-matched instrument. **Fig. 3-A** The patient-matched instrument is placed on the bone surface through the volar approach to the distal radius. **Fig. 3-B** The placement is confirmed by inserting a reference Kirschner wire (*) through the guide, pointing at the tip of the radial styloid, using fluoroscopy. **Fig. 3-C** A depressed volar fragment (dotted-line region) forms an intra-articular step-off. Then, 1.2-mm Kirschner wires that are passed through sleeves on the patient-matched instrument are confirmed to reach the articular deformity line under arthroscopic visualization. **Fig. 3-D** The entrances of multiple perforations made using the patient-matched instrument are marked. **Fig. 3-E** With radiocarpal ligaments and the articular capsule still attached, the malunited fragment is separated from the radius using a chisel to reduce the step-off at the articular surface. **Fig. 3-F** Preoperative sagittal CT scan showing the intra-articular step-off. **Fig. 3-G** Postoperative sagittal CT scan showing that the step-off was completely corrected.

Kirschner wire with a diameter of 1.2 mm to separate the malunited fragment from the outside of the joint (Fig. 2). The patient-matched instrument was a plastic model that was made of medical-grade resin polyamide 12 (PA 2200; Evonik Industries) using rapid prototyping technology (Formiga P; EOS GmbH Electro Systems).

Surgical Technique

First, the bone surface of the distal radius was exposed with use of a volar approach for malunion with a volar fragment, a dorsal approach for malunion with a dorsal fragment, and both approaches for malunion with volar and dorsal fragments. Then, the patient-matched instrument was placed on the bone surface to fit the morphology of the bone cortex. Placement was further confirmed by inserting a reference Kirschner wire through the guide, with the wire pointing to the tip of the radial styloid or either of the 2 ends of the sigmoid notch, using an x-ray image intensifier. Multiple drillings were then performed by inserting 1.2-mm Kirschner wires through sleeves on the patient-matched instrument while confirming the

TABLE II Treatment Protocol*

Examination Item	Obtaining Consent	Screening	Day of Surgery		Postop. Examination Week								
			Preop.	Postop.	1	4	8	13	17	21	26	39	52
Obtaining consent	✓												
Physical examination													
Wrist and forearm range of motion		✓				✓	✓	✓	✓	✓	✓	✓	✓
Grip strength		✓				✓	✓	✓	✓	✓	✓	✓	✓
Pain		✓				✓	✓	✓	✓	✓	✓	✓	✓
Vital signs													
Blood pressure		✓	✓	✓	✓	✓		✓			✓		✓
Pulse rate		✓	✓	✓	✓	✓		✓			✓		✓
Body temperature		✓	✓	✓	✓	✓		✓			✓		✓
Laboratory tests													
Blood cell count		✓		✓	✓	✓		✓					✓
Blood biochemistry		✓		✓	✓	✓		✓					✓
Clotting time		✓											
Pregnancy test		✓											
Electrocardiogram		✓											
Radiographic imaging tests													
Chest radiograph		✓											
CT		✓			✓								✓
Wrist radiograph		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient-reported outcomes													
DASH		✓						✓			✓		✓
PRWE		✓						✓			✓		✓
Satisfaction													✓
Adverse events				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

*CT = computed tomography; DASH = Disabilities of the Arm, Shoulder and Hand; PRWE = Patient-Rated Wrist Evaluation.

penetration of their ends into the malunited fracture line under arthroscopic visualization. After patient-matched instrument removal and marking of the penetration entrances, the malunited fragment was separated along multiple drill holes using a bone chisel. Next, the fragment was separated from the radius, while the radiocarpal ligaments and the capsule remained contiguous. The fragment was corrected to reduce the step-off on the articular surface under fluoroscopy or arthroscopy, depending on the surgeon's preference. The small fragments were fixed with double-threaded screws, whereas a locking plate was used for the large entire volar or dorsal fragment; multiple fragments were fixed with a combination of both (Fig. 3, Video 1). Subsequently, locking plates were also used in 4 cases in which combined intra-articular and extra-articular corrective osteotomies were performed. Extra-articular corrective osteotomy was performed first, followed by intra-articular corrective osteotomy (see Appendix Figs. 1 and 2).

Finally, cast immobilization was maintained for 2 to 4 weeks postoperatively. After cast removal, the patient was encouraged to perform active wrist and forearm exercises under the supervision of a physiotherapist.

Measurements

All patients were clinically and radiographically evaluated according to the protocol (Table II). CT was performed to measure the maximum step-off and gap on the articular surface of the distal radius during preoperative screening and at 1 and 52 weeks postoperatively. A CT image with the maximum step-off in any sagittal or coronal plane was selected, and the step-off and gap were measured using the arc method, which is highly reliable for quantifying articular surface incongruities (Fig. 4). The intraclass correlation coefficients for intrarater and interrater reliabilities were 0.96 to 0.97 and 0.69 to 0.83, respectively[37]. The time of osseous union was recorded when the callus was bridged on radiographs. The step-off and gap were measured and osseous union was judged by 2 evaluators of the Image Evaluation Committee. The mean values of the measurements obtained by the 2 evaluators were used.

All patients were assessed for range of motion of the wrist and forearm and grip strength (recorded as a percentage of that on the normal, contralateral side). The surgeons in charge of each case examined physical findings with the help

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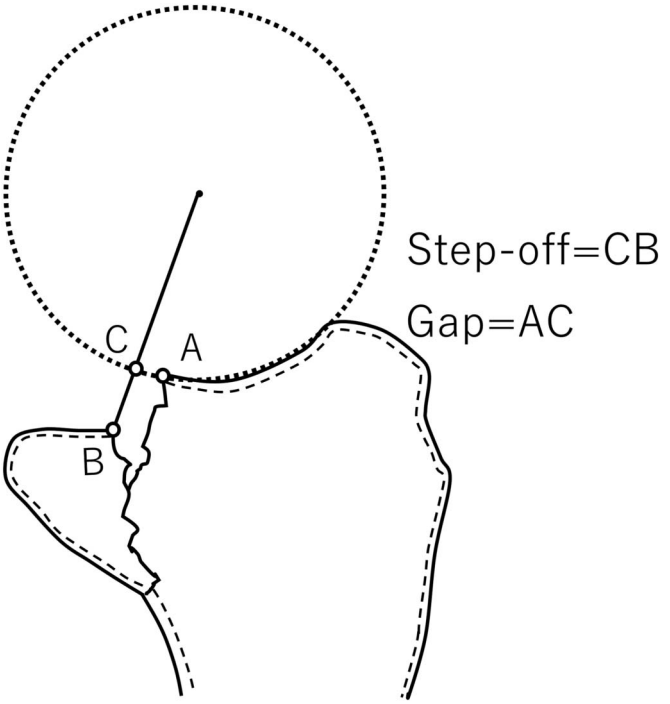

Fig. 4

Illustration depicting the step-off and gap measurements on the CT image. An approximate circle is marked on the articular surface of the distal radius. Point B is the articular edge of the malunited fragment separated from Point A. Point C is the intersection of the approximate circle and a line connecting the center of this circle and Point B. The distances CB and AC are defined as the step-off and gap, respectively.

of a clinical research coordinator. Patient-reported outcome measures were solicited by the coordinator to be authored by each patient. The Disabilities of the Arm, Shoulder and Hand (DASH) and Patient-Rated Wrist Evaluation (PRWE) self-administered questionnaires were used to assess patient-reported outcomes[38,39]. The DASH and PRWE scores range from 0 (no disability) to 100 (most severe disability) and from 0 (no pain or disability) to 100 (most severe pain or disability), respectively. We used a visual analog scale (VAS) to assess pain, determined by measuring the distance on a 10-cm line between 0.0 (no pain) and the patient's mark. Patient satisfaction with treatment was rated on a 5-level scale: very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, or very dissatisfied[40]. The surgeons who performed the procedures were also asked about the difficulty of intra-articular osteotomy using the patient-matched instrument compared with that without a patient-matched instrument in 5 categories: very easy, easy, equal, difficult, and very difficult.

Evaluation of Safety

Leukocyte counts and C-reactive protein levels were determined to detect infections, toxic effects, and allergic reactions. All adverse events were recorded from the time of surgery to the latest follow-up, regardless of causality related to this study.

Primary End Point

Residual step-off on the articular surfaces in patients with intra-articular malunion of the distal radius is related to wrist dysfunction and osteoarthritis progression and is used as a metric for intra-articular fractures of the distal radius[8,12,41,42]. Therefore, the maximum step-off on the articular surface of the distal radius, as measured with use of CT at 52 weeks postoperatively, was used as the primary end point. Although the goal should be to reduce the residual step-off to as close to zero as possible, the cutoff value for residual step-off was established as ≤1.0 mm on radiographic measurements in this study as a clinically acceptable value[19,21,33,41,43]. Although the target step-off value was ≤1.0 mm, previous studies have shown the step-off value measured with CT to be >50% greater than that measured with radiographs[37,44]. Therefore, this prospective clinical study was designed to verify that the postoperative maximum step-off does not exceed 1.5 mm on CT images.

Statistical Analysis

Assuming that the null hypothesis in this clinical trial was that the primary end point of the mean value of maximum step-off is >1.5 mm and the alternative hypothesis was that the mean step-off is ≤1.5 mm, evaluation was performed using a 1-sample t test. Additional analysis of the primary end point, with a threshold of 1.0 mm, was also performed using a 1-sample t test.

We used a preliminary report on intra-articular corrective osteotomy of distal radial malunion for a sample size calculation using a patient-matched instrument as a reference[29]. As the maximum postoperative step-off in the preliminary study (and standard deviation) was 1.0 ± 0.2 mm, the expected maximum postoperative step-off was set at 1.0 mm. As the present study was a multicenter study, we set the standard deviation at 0.5 mm, assuming higher variability in postoperative outcomes than in the preliminary study. A power analysis performed to determine the necessary sample size, given the expected mean under the alternative hypothesis of 1.0 mm with a standard deviation of 0.5 mm, a one-sided significance level of 2.5%, and a power of 80%, indicated that the minimum required sample size for this clinical trial was 10 cases. The sample size determined for this study was 12, accounting for potential dropouts during the study period. Secondary end points, such as step-off, gap, range of motion of the wrist and forearm, VAS score, grip strength, and DASH and PRWE scores at each follow-up visit, were also examined using repeated-measures analysis of variance with the Dunnett multiple comparison test. Statistical analyses were performed with use of SAS (version 9.4; SAS Institute). The level of significance for all statistical analyses was set at $p < 0.05$.

Results

Study Patients

All patients who received the intervention successfully completed the 52-week postoperative follow-up. Intra-articular corrective osteotomy using a patient-matched instrument was

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TABLE III Clinical Results*

Assessment	Preop.	Latest Follow-up	P Value†
Step-off *(mm)*	3.75 ± 1.04	0.51 ± 0.40	<0.001
Gap *(mm)*	2.93 ± 1.59	2.04 ± 1.42	0.268
Wrist ROM *(deg)*			
Flexion	33.3 ± 14.2	58.3 ± 19.6	<0.001
Extension	53.8 ± 16.8	72.5 ± 14.2	<0.001
Radial deviation	19.2 ± 7.3	25.0 ± 6.7	0.019
Ulnar deviation	22.9 ± 8.1	31.7 ± 10.3	<0.001
Forearm ROM *(deg)*			
Pronation	69.6 ± 15.0	80.4 ± 6.9	0.012
Supination	73.3 ± 17.6	84.6 ± 7.8	0.001
VAS *(cm)*	5.19 ± 2.47	1.47 ± 1.66	<0.001
Grip strength *(%)*	51.5 ± 15.9	85.3 ± 16.3	<0.001
DASH score	32.4 ± 19.6	15.5 ± 23.0	<0.001
PRWE score	47.3 ± 23.6	20.0 ± 26.5	<0.001
Satisfaction *(no. of patients)*			
Very satisfied	—	8	—
Satisfied	—	3	—
Neither satisfied nor dissatisfied	—	1	—
Dissatisfied	—	0	—
Very dissatisfied	—	0	—

*The values are presented as the mean and the standard deviation, except as noted. ROM = range of motion; VAS = visual analog scale for pain; DASH = Disabilities of the Arm, Shoulder and Hand; PRWE = Patient-Rated Wrist Evaluation. †Dunnett multiple comparison test.

performed as planned, without major technical difficulties, for the volar fragment in 6 cases, the dorsal fragment in 5 cases, and both fragments in 1 case. Double-thread screws were used in 2 cases, locking plates were used in 5, and both were used in 5. Surgeons found the surgical technique using the patient-matched instrument to be very easy in 11 cases and difficult in 1 case that required both intra-articular and extra-articular osteotomy.

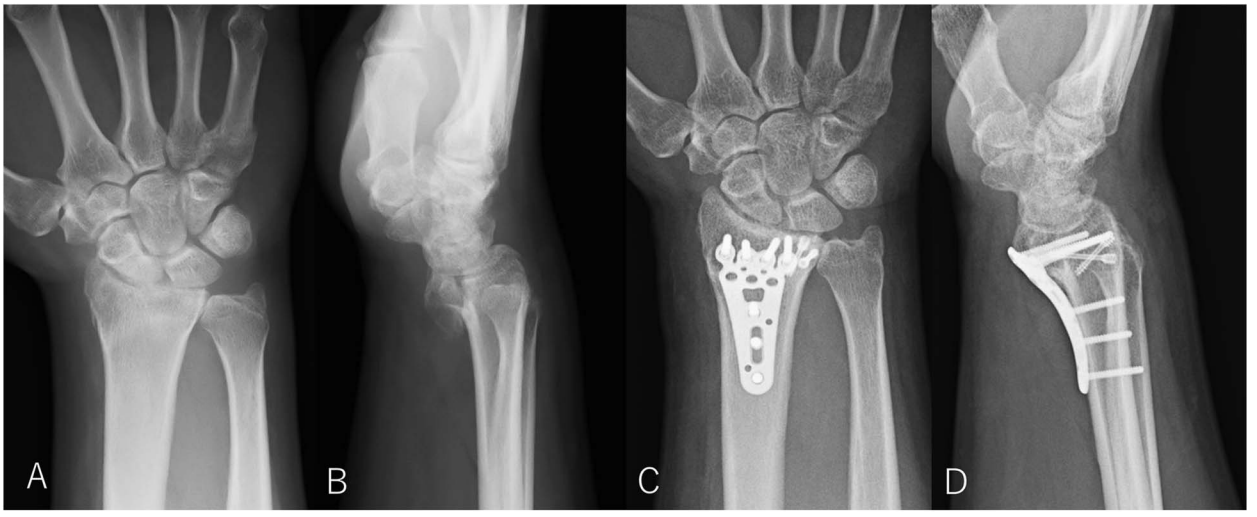

Fig. 5

Figs. 5-A and 5-B Preoperative anteroposterior (**Fig. 5-A**) and lateral (**Fig. 5-B**) radiographs showing intra-articular malunion of the volar fragment. **Figs. 5-C and 5-D** Postoperative anteroposterior (**Fig. 5-C**) and lateral (**Fig. 5-D**) radiographs showing correction of the articular surface of the distal radius.

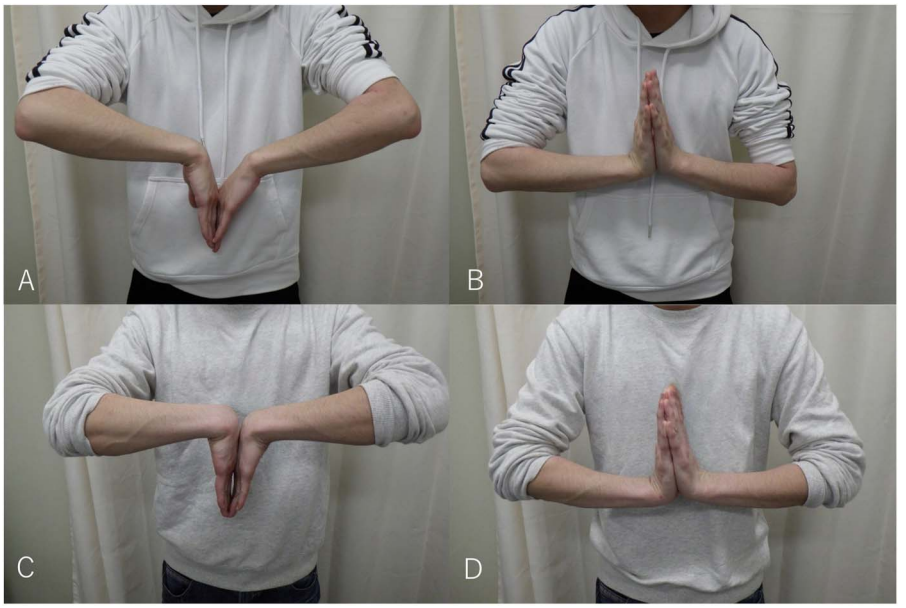

Fig. 6

Figs. 6-A through 6-D Preoperative and postoperative photographs showing the range of wrist motion in a patient with volar surface malunion. The flexion and extension of the left wrist improved from 20° and 60° preoperatively (**Figs. 6-A and 6-B**) to 80° and 80° postoperatively (**Figs. 6-C and 6-D**).

Primary End Point

The maximum step-off in 12 patients improved significantly ($p < 0.001$) from 3.75 ± 1.04 mm to 0.51 ± 0.40 mm (95% confidence interval [CI], 0.26 to 0.76 mm) at 52 weeks postoperatively, which was within 1.5 mm (Table III, Fig. 5; see also Appendix Fig. 3-A). It was also significantly maintained within 1.0 mm at 52 weeks postoperatively ($p < 0.001$).

Secondary End Points

Osseous union was attained within 13 weeks in all patients. The maximum gap on the articular surface was 2.93 ± 1.59 mm preoperatively and 2.04 ± 1.42 mm at 52 weeks postoperatively ($p = 0.268$) (see Appendix Fig. 3-B).

The physical and patient-reported outcomes (range of motion, VAS, grip strength, DASH, and PRWE) significantly improved at 52 weeks postoperatively (Table III, Fig. 6; see also Appendix Figs. 4, 5, and 6).

Minor adverse events, including pain around the surgical area and increased C-reactive protein levels and white blood-cell counts, were completely resolved at the latest follow-up in all patients. One patient underwent volar locking plate removal because of intra-articular protrusion of the screw due to atrophic changes in the fragment at 12 months postoperatively. One patient underwent shortening osteotomy of the ulna because of residual ulnar wrist pain caused by ulnar impaction syndrome at 6 months postoperatively. In both cases, wrist pain disappeared after the additional surgical treatment. No complications pertaining to nonunion or necrosis of fragments were identified.

Discussion

Intra-articular malunion after a distal radial fracture sometimes results in functional impairments, such as restricted range of motion and pain[7,8,45]. Although several randomized controlled trials have shown that some degree of intra-articular deformity does not affect wrist pain in older individuals[1-4], a greater residual articular step-off increases the risk of wrist osteoarthritis, especially in young and middle-aged individuals[19,46,47]. Therefore, surgical correction of the articular surface is often required. Intra-articular corrective osteotomy poses considerable challenges due to the technical complexities of intra-articular procedures, the potential for additional articular damage, and the risk of necrosis in small fragments[19]. Ring et al. reported that osteotomy via a direct open approach improved wrist function in patients with malunited articular fractures[19]. Favorable surgical outcomes, including enhanced grip strength and reduced wrist pain following intra-articular osteotomy with arthrotomy, have been reported, although recovery to the level of near-normal wrist function remains elusive[19]. To reduce the risk of joint contracture and bone fragment necrosis after arthrotomy, avoiding incision of the capsule and ligaments as much as possible is considered crucial.

Arthroscopic techniques represent a possible alternative to arthrotomy for intra-articular osteotomies. However, clinical investigations have been limited[21,22]. Furthermore, such techniques are not widely adopted because of their technical intricacies. Thus, we developed a 3D computer simulation system and a patient-matched instrument to establish reliable intra-articular corrective osteotomy. 3D simulation using computer bone models can detect the involved intra-articular malunited fracture line and enable precise 3D preoperative planning. Patient-matched instruments can assist precise intra-articular osteotomy outside the joint without the need for arthrotomy, minimizing damage to ligaments, the capsule, and articular cartilage[29,30,35].

Our results demonstrated that intra-articular corrective osteotomy using a patient-matched instrument provided highly accurate correction, with an average maximum step-off of 0.51 mm postoperatively. Functional parameters, such as range of motion, grip strength, pain, and patient-reported outcomes (DASH and PRWE scores), showed significant improvement, leading to high patient satisfaction, with no serious complications related to patient-matched instrument use. A smooth articular surface was maintained in 2 patients who required additional surgery for implant removal or ulnar shortening osteotomy, with a 0.5-mm intra-articular step-off at the latest follow-up in both. Therefore, these events were not classified as patient-matched instrument-related major adverse events. Both patients experienced relief of wrist pain after the additional procedures and were very satisfied with the outcome. In all except 1 case, in which both intra-articular and extra-articular corrective osteotomies were required, the surgeons rated the surgical technique using a patient-matched instrument as "very easy" compared with that without using a patient-matched instrument. The use of a patient-matched instrument can also streamline the complicated intra-articular corrective osteotomy procedure.

The present study has some limitations. First, a patient-matched instrument only assists in separating intra-articular malunited fragments. The determination to utilize fluoroscopy or arthroscopy during the procedure to correct the step-off was entrusted to the surgeon's discretion. It is undeniable that the surgical skills of surgeons with >20 years of specialized experience in hand surgery may contribute to good surgical outcomes. Second, this was a single-arm study without controls. A target step-off threshold was determined on the basis of previous findings, as establishing a control group for conventional procedures is ethically unacceptable because because intra-articular corrective osteotomy is highly invasive. Third, the use of multiple CT measurements raises concerns regarding patient radiation exposure. However, our CT protocol reduced radiation exposure to below one-tenth of the auto-exposure control[36]. Finally, computer simulations require approximately 2 hours, and the costs of manufacturing a patient-matched instrument and a patient-matched plate are approximately $600 and $2,000 USD, respectively, including labor charges. However, we believe that this surgical procedure, expected to restore optimum wrist function, would be a viable alternative treatment option to salvage arthrodesis surgery.

In conclusion, we demonstrated that intra-articular corrective osteotomy using a patient-matched instrument can result in accurate correction and satisfactory functional recovery of the wrist. The new technology for intra-articular corrective osteotomy using patient-matched instruments is beneficial for patients with intra-articular malunion.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A662). ■

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