SCIENTIFIC ARTICLE

Three-Dimensionally Planned and Printed Patient-Tailored Plates for Corrective Osteotomies of the Distal Radius and Forearm

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Purpose We evaluated the 1-year postoperative clinical and patient-reported outcomes in patients who had a 3-dimensional planned corrective osteotomy of their distal radius, radial shaft, or ulnar shaft using a printed, anatomical, patient-tailored plate to determine the feasibility and effectiveness of this methodology.

Methods Simulations in computer-assisted preoperative planning of corrective osteotomies resulted in 3-dimensionally printed surgical guides, surgical models, and anatomically customized plates for application at the distal radius and forearm. Patients with malunions of the distal radius or forearm who underwent fixation with the custom-made plates were documented in our registry. Grip strength and range of motion assessments were made before surgery (baseline), as well as at 6 weeks and 3 and 12 months. Additionally, patients rated their wrist-related pain and disability using the Patient-Rated Wrist Evaluation.

Results Fifteen patients underwent corrective surgery, and the 1-year follow-up data of 14 patients with a median age of 56 years (interquartile range, 24−64 years) were available for analysis. The median baseline Patient-Rated Wrist Evaluation score improved from 47 to 7 after 1 year. The flexion-extension arc of motion of the wrist increased from 90° at baseline to 130° at 1 year and the pronation-supination arc of motion of the wrist increased from 135° to 160° in the same time period. Differences in radiological measurements for palmar and radial inclinations, as well as for ulnar variance between the affected and contralateral wrists, were reduced with the osteotomy. In 1 case, the plate was removed 11 months after the osteotomy. No severe adverse events were reported.

Conclusions Three-dimensionally planned and printed patient-tailored plates offer a reliable method for correcting even complex malunions of the distal radius and forearm. *(J Hand Surg Am. 2022;■(■):1.e1-e8. Copyright © 2022 by the American Society for Surgery of the Hand. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).)*

Type of study/level of evidence Therapeutic IV.

Key words Custom-made plate, patient-reported outcome, patient-specific implant, 3-dimensional planning, 3-dimensionally printed implant.

Online Exclusive

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Received for publication October 22, 2021; accepted in revised form June 23, 2022.

Drs Schindele and Herren receive royalties from KLS Martin, the manufacturer of the implants. Parts of the study have been funded by KLS Martin.

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0363-5023/22/■■-0001
https://doi.org/10.1016/j.jhsa.2022.06.021

Posttraumatic malunions of the radius and/or ulna can lead to considerable disability because of limitations on the biomechanics of the distal radioulnar and radiocarpal joints and pain associated with this condition.[1,2] To minimize worsening pain and to improve arcs of motion, precise surgical corrective osteotomies are often considered to restore the normal anatomy of the forearm or wrist. Since more precise bone realignment is directly related to better functional outcomes, comprehensive preoperative planning is important.[1,3]

With current advances in computer-assisted 3-dimensional planning and printing technologies, more accurate preoperative simulations are possible and 3-dimensionally printed, patient-specific guides are increasingly used for corrective osteotomies.[1,4–8] The capability to manufacture personalized implants has also seen an increase in popularity, particularly in trauma surgery because, in contrast to conventional plates, patient-tailored implants can be fitted to the patient's exact bone contour.[9,10] In craniomaxillofacial surgery, 3-dimensionally printed implants are very popular and have been proven effective.[11] For the treatment of distal radius and forearm malunions, this 3-dimensional process of tailoring plates for the individual patient is yet to be extensively discussed in the literature.[12] There are only 3 case reports that investigated patient-tailored plates for the treatment of malunited diaphyseal forearm fractures in children and adults with distal radius malunions.[10,13,14]

Therefore, the aim of the current study was to evaluate the 1-year postoperative clinical, radiological, and patient-reported outcomes in patients after a planned 3-dimensional corrective osteotomy for posttraumatic malunions of the distal radius or forearm using patient-tailored plates and to determine the feasibility and effectiveness of this methodology.

MATERIALS AND METHODS

Patients

Between March 2016 and July 2020, all patients who underwent a corrective osteotomy of the distal radius or forearm using an Individual Patient Solutions (IPS) plate (KLS Martin) in our clinic were documented in a single-center registry. The IPS registry was managed with a web-based electronic database using REDCap software.[15] Fifteen patients who completed a 1-year clinical follow-up examination were included in this analysis. Informed consent was obtained from all patients before surgery, and the local ethics committee approved the data analysis, which was conducted according to the REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement.[16] Because 1 patient declined further use of their data, clinical and/or patient-reported 1-year follow-up data were analyzed from the remaining 14 patients.

Three-dimensional surgical planning

For the 3-dimensional planning of the corrective osteotomy, a thin-layer computed tomography (CT) scan of both forearms was made for each patient. For isolated distal radius malunions, the CT scan included the wrist and distal third of the forearm; for combined or diaphyseal malunions of either the radius or ulna, the CT scan covered the entire forearm length, including the wrist and elbow (according to the specific protocol). The effective radiation dose from CT scans of the forearm with arms held above the head is relatively low, with Iordache et al[17] finding mean effective doses of 0.21 mSv in this position and 0.15 mSv for wrist CT scans. The corresponding lifetime-attributable risks of cancer per 1,000 patients were 0.01 for males and 0.02 for females for elbow CT scans and 0.01 for both males and females for wrist CT scans. Using the manufacturer's web-based platform (IPS Gate), designed for documentation of each case and ordering, planning, and fabrication of the patient-tailored plates, a new case dossier was created for each patient and all raw digital imaging and communications in medicine data were uploaded. Data of the contralateral side were digitally mirrored and projected onto the affected side (Fig. 1), which resulted in an anatomical template that could be used for planning the osteotomy correction. Using the healthy radius as a template is theoretically valid, since both radii have been shown to be symmetrical in healthy people.[18] The localization, alignment, and number of cutting planes were then checked, whereby the technical feasibility regarding surgical access and positioning of the guide was assessed by the surgeon. The plate position and design, as well as the locations, alignment, number, and lengths of the screws, were also defined. Furthermore, the case documentation also included the drilling and marking of jigs (Fig. 2).

The anatomical models, as well as drilling and marking guides, were made by the manufacturer from a biocompatible, plastic material in a 3-dimensional printer. Both the models and the guides helped to visualize the bone situation and the accuracy of the fitted plate. The final patient-specific plates were

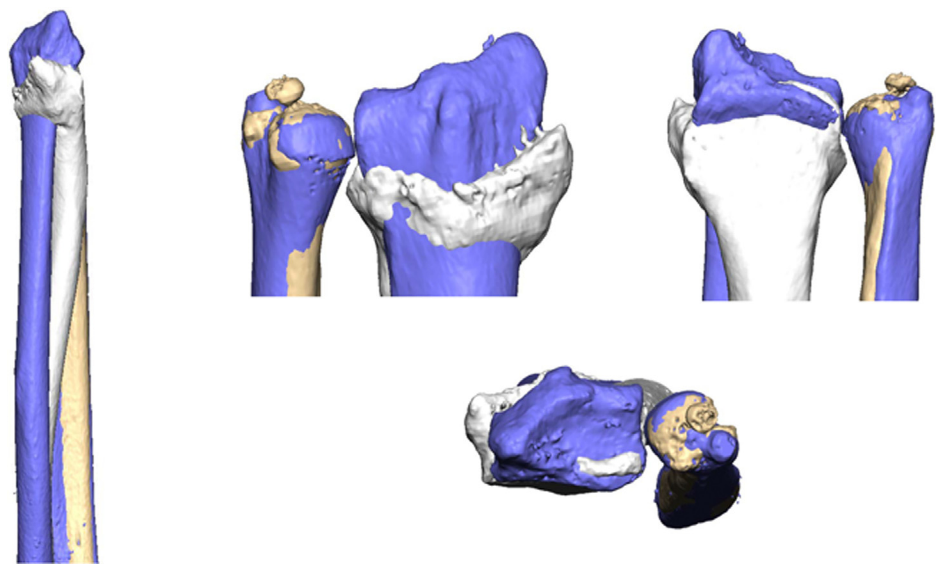

FIGURE 1: Forearm and distal radius projections of the contralateral side (purple) onto the affected side (white and beige) from multiple angles.

manufactured using titanium in a layer-by-layer assembly process.

The combined costs of the CT scans (1 side, 300 CHF = $323 USD; both sides, 450 CHF = $485 USD) and the entire process, including planning, printing guides, and printed titanium plates, amounted to 4,000 CHF ($4,300 USD) for the correction of distal radius malunions and 6,500 CHF ($7,000 USD) for the correction of both the radius and the ulna.

Surgical technique

Four experienced hand surgeons performed the surgeries. If reduction of the fragments after osteotomy resulted in lengthening and a gap of more than 1 cm, a cortico-cancellous bone graft corresponding to the bone defect was harvested from the iliac crest before the upper-arm tourniquet was inflated. Using a 3-dimensionally printed model, the bone graft was carved by hand. For cases in which the lengthening resulted in a gap less than 1 cm, only cancellous chips from the osteotomy site were prepared.

At the distal radius, we used the extended flexor carpi radialis approach according to Henry,[19] which permitted a clear view of the bone and guide attachment. As the extensor tendons on the dorsal side must be protected during an osteotomy, radial and dorsal release of the brachioradialis tendon, as well as all tendons of the first extensor compartment up to the fourth compartment, is mandatory. The dorsal compartment was released through the osteotomy in all cases. On the volar side, the pronator muscle was dissected radially in an L-shaped manner and reflected ulnarly. Using the 3-dimensionally printed model on the operating table as a reference, anatomical landmarks were dissected and all remaining soft tissue was removed. This step is paramount for the accurate positioning of the drilling and marking guides.

For diaphyseal corrections of both the radius and ulna, 2 separate incisions were made, as required, depending on the location of the planned osteotomy.

The drilling guide was placed and fixed with Kirschner wires before making a fluoroscopic check of the positioning. Especially at the diaphysis, correct positioning of the guide can be difficult because there are no landmarks on the bone itself. In these cases, the guides were equipped with distally protruding arms. The guides could then be moved in the longitudinal axis under fluoroscopic control until a Kirschner wire inserted at the distal end of the arms was exactly at the level of the radial styloid or the ulna styloid. Once correct placement of the guide was assured, the screw holes were drilled and the osteotomy was performed.

For simple and reliable fragment reduction of distal radius malunions after mobilization, the distal part of the plate was first tightly screwed to the distal fragment, after which the screws could be fixed in the intended shaft holes to accurately fit the anatomical bone surface.

When both the ulna and radius had to be corrected, the order of plate fixation was determined by the individual correction in the shaft area. All fixation

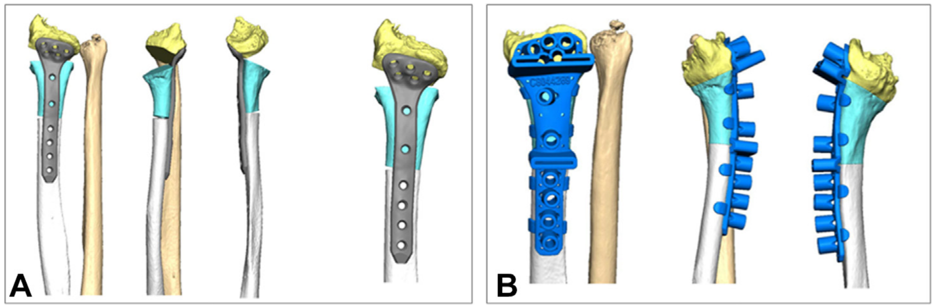

FIGURE 2: Case documentation including **A** the alignment of the plate and bone fragments and **B** the 3-dimensional guide, including drilling and marking holes, as well as the osteotomy planes. Visualization is from multiple angles.

steps were finally checked both clinically and under fluoroscopy (Figs. 3 and 4), followed by standard closure of the surrounding soft tissues. Postoperative rehabilitation of the treated arm involved 6–8 weeks of unloaded mobilization without an orthosis, in conjunction with scheduled clinical and radiological assessments.

Outcome measures

Clinical and patient-reported outcomes were collected before surgery (ie, at baseline) and then at 6 weeks, 3 months, and 1 year after surgery. Wrist-related pain and disability was assessed using the Patient-Rated Wrist Evaluation (PRWE).[20,21] The score ranges from 0 to 100, with lower scores indicating lower pain and disability. Active range of motion of the wrist was calculated by measuring both the pronation-supination and flexion-extension arcs of motion using a goniometer. Maximal grip strength was measured in a standardized sitting position using a Jamar dynamometer (Saehan Corporation). Anteroposterior and lateral radiographs of the wrist and forearm taken prior to the first clinical visit, after intraoperative placement of the plate and before the postsurgical follow-ups, were analyzed for palmar and radial inclinations and ulnar variance.

All complications and events of plate removal were recorded throughout the 1-year postoperative period.

Statistics

All study parameters were described using standard descriptive statistics, including medians and interquartile ranges (IQRs).

RESULTS

The median age of our 14 patients at the time of surgery was 56 years (IQR, 24–64 years), and 9 patients were female (Table 1). The median surgery time was 92 minutes (IQR, 83–105 minutes), and reconstruction times differed when solely treating the radius, as was done in 12 cases, compared with concurrent fixation of the radius and ulna, which was the case in 2 patients. In all cases, the printed guides and plates fit well and, from the authors' experiences, their placement was less complicated at the distal radius compared with the long forearm bones, as expected.

The baseline PRWE score improved from a median of 47 (IQR, 23–78) to 7 (IQR, 0–55) after 1 year. Baseline flexion-extension and pronation-supination arcs of motion were 90° (IQR, 35° to 133°) and 135° (IQR, 100° to 165°), respectively; the respective 1-year values increased to 130° (IQR, 100° to 140°) and 160° (IQR, 143° to 185°). Grip strength increased from a baseline median of 26 kg (IQR, 18–42 kg) to 28 kg (IQR, 18–52 kg) at 1 year.

The radiographic measurements showed that the differences between the affected and unaffected sides in palmar inclination, radial inclination, and the ulnar variance decreased from 16° to 1°, 6° to 0°, and 2 mm to 1 mm from baseline to 1 year, respectively (Table 2).

One plate was removed 11 months after surgery because the patient had developed pressure sensitivity on the palmar side of the hand, probably due to the plate.

One adverse event comprising wound dehiscence with increased swelling was reported for 1 patient within the first 2 weeks after surgery, without any signs of infection. The patient underwent a secondary hematoma evacuation 2 weeks after the osteotomy. The wound healed successfully within the following 3 months without any further complications.

DISCUSSION

This study showed that planned 3-dimensional corrective osteotomies of the distal radius and

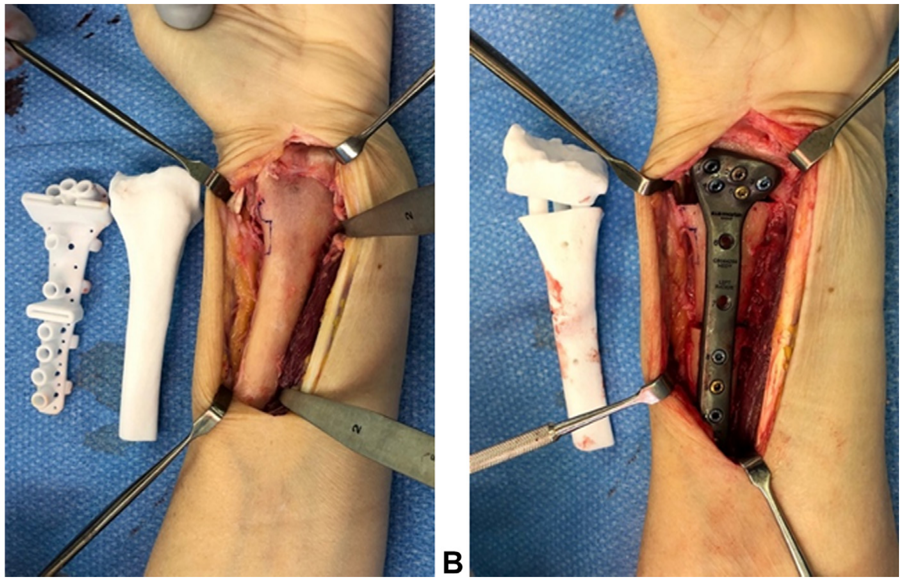

FIGURE 3: **A** Printed 3-dimensional model and surgery guide beside the exposed distal radius. **B** Inserted plate using cortical screws, as well as locking screws.

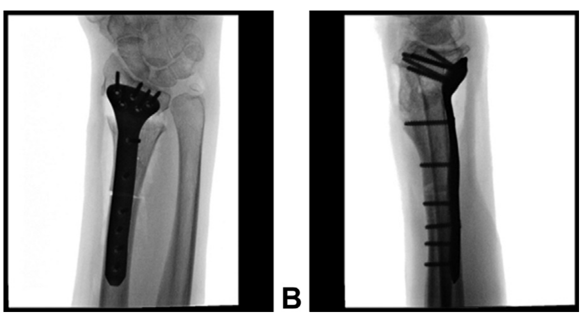

FIGURE 4: Fluoroscopic images (**A** anteroposterior and **B** lateral views) of the patient-tailored plate after the corrective osteotomy.

forearm using patient-specific guides and patient-tailored, printed titanium plates are feasible for correcting malunions in the distal radius and forearm. Our patients showed considerable improvements in function and pain 1 year after surgery. Furthermore, the alignment of the bones could be corrected to that of the unaffected side, and we saw only 1 minor, wound-related complication. In the authors' experience, the advantage of printed, patient-tailored titanium plates lies in the accurate placement on deformed bone, especially at the diaphyseal forearm, where anatomical landmarks for correct plate placement are technically difficult to determine. Moreover, bone fragments can be reduced in a simpler and more reliable way, and the surgical guides are helpful in providing the surgeon with direct visual and haptic feedback on the accuracy of the correction achieved.

Only 3 case reports have documented the technique of printing titanium plates for stable fixation in corrective osteotomies of the radius and ulna.[10,13,14] These reports included 1, 5, and 7 cases, all of which resulted in satisfactory outcomes. Dobbe et al[10] also compared the 3-dimensional preoperative planning and intraoperative fixation with a patient-specific plate to conventional planning using 2-dimensional images and standard plates. They found that the 3-dimensional technique led to significantly better plate positioning and alignment. Alignment is correlated to patient-reported and functional outcomes, which implies that 3-dimensional preoperative planning and use of patient-tailored plates could potentially lead to better outcomes over traditional methods.[10,22] A biomechanical study showed that 3-dimensionally printed, volar-locking, titanium plates provided significantly higher stiffness compared with conventional distal radius plates.[23] Further comparative studies investigating the clinical outcomes after both methods are still required.[10] Since more precise bone realignment is directly related to better functional outcomes, we assume that using this 3-dimensional planning technology with patient-specific, titanium plates would lead to superior outcomes than those achieved using traditional planning and standard plates.[1,3] Although the outcomes of 3-dimensional technology on our small case series are encouraging, it is yet to be clarified whether the clinical results are actually better or whether the complication rates are lower when compared with freehand osteotomy.[3,6,24,25] Only 1

TABLE 1. Patient Characteristics (n = 14)*

Patient	Age at Corrective Osteotomy, y	Sex	Dominant Side	Time Between Fracture and Corrective Osteotomy, y	Prior Treatment at Radius	Osteotomy Location	PRWE Score, Baseline/1 y	ROM, ° Flex-Ext, Baseline/1 y	ROM, ° Pron-Sup, Baseline/1 y	Grip strength, kg, Baseline/1 y
1	60	F	L	0.5	Nonsurgical	Distal radius	./.	75/.	90/.	8/28
2	30	F	R	14	Nonsurgical	Distal radius	./9	145/.	180/.	./.
3	60	F	R	3	Nonsurgical	Distal radius	./25	140/140	180/185	21/24
4	17	M	R	13	Cyst excochleation at distal metaphysis of left radius	Distal radius	./0	./140	./140	./42
5	83	F	R	8	Nonsurgical	Distal radius	./0	65/100	50/160	10/18
6	61	M	R	14	Nonsurgical	Distal radius	54/.	80/.	100/.	20/30
7	75	F	R	14	Nonsurgical	Distal radius	78/18	70/.	135/.	25/.
8	20	M	R	4.5	2 prior operations	Distal radius	43/39	133/140	125/170	32/30
9	24	F	R	8	1 prior operation	Distal radius	56/55	130/130	./160	26/19
10	66	F	R	2	2 prior operations	Distal radius and radial shaft	36/3	35/115	165/160	18/18
11	52	M	R	1.5	2 prior operations	Distal radius	76/5	100/130	100/150	26/40
12	23	F	R	2	1 prior operation	Distal radius and ulnar shaft	31/17	110/130	155/155	30/30
13	64	F	L	10	Nonsurgical	Distal radius	47/7	90/110	165/160	24/26
14	49	M	R	1.5	1 prior operation	Radial shaft	23/8	90/140	135/160	42/52

*A period (.) represents a missing value. Flex, flexion; Ext, extension; Pron, pronation; PRWE, Patient-Rated Wrist Evaluation; ROM, range of motion; Sup, supination.

TABLE 2. Radiological Measurements of Affected Versus Contralateral Forearm for Patients With Complete Data at Baseline and 1 Year

	Baseline		1 y		Contralateral Side	
Measured Value	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)
Palmar inclination, °	10	−7 (−12−13)	10	8 (6−11)	10	9 (2−15)
Radial inclination, °	11	20 (13−25)	11	26 (23−28)	11	26 (24−26)
Ulnar variance, mm	11	3 (3−6)	11	2 (1−3)	11	1 (0−2)

study showed that computer-assisted, 3-dimensional planning and patient-specific guides (without patient-tailored plates) led to shorter operation times while providing similar clinical results to a conventional osteotomy.[7]

By only using x-rays of the forearm in 2 planes, the effective dose of freehand osteotomies, which amounts to 0.002 mSv, is lower when compared with the dose when using CT scans.[17] Additionally, the costs of using traditional reconstruction methods are much lower. For this reason, a cost-utility analysis would also be warranted to determine when using 3-dimensional technology would make the most sense.

However, we presume that the correction of intra-articular malunions and malalignments of the wrist using this 3-dimensional technology results in less joint degeneration in the long term over traditional reconstruction. A recent study by Singh et al[26] reported no osteoarthritic progression after a mean follow-up length of 6 years following 3-dimensionally guided corrective osteotomies in 15 patients. In addition, malunions of the radial und ulnar diaphyses usually show considerable deformities associated with restrictions in forearm rotation. For the treatment of these deformities, we see 2 specific advantages of the IPS. First, rotational deformities are difficult to recognize on standard radiographs. A preoperatively planned computer simulation in which the CT scan of the affected forearm is compared with that of the healthy, opposite side enables detection of the deformity and exact planning of the resection plane. Second, the placement of a standard plate on a severely deformed bone is technically very challenging, particularly at the diaphyses of the radius and ulna, where standard plates have to be contoured for a precise fit on the bone. In these complicated cases, the individually planned and printed plates can be helpful, whereas deformities that need only be longitudinally corrected (ie, with shortening or elongation) could be corrected using standard plates.

Our study has some limitations. Forearm placement during the imaging procedure was not standardized and we observed slight deviations in the radiographic measurements throughout the postoperative time points. Furthermore, the sample size was small, with a substantial part of the data missing, which limits the generalizability of our study. In addition, most of our patients had only extra-articular malunions and, therefore, our results should be cautiously extrapolated to more complex, intra-articular malunions. Lastly, as is often the case in studies aiming to evaluate clinical outcomes after 3-dimensional planned corrective osteotomy, we could not determine with certainty whether we were able to reconstruct our planned result with this technically demanding procedure, as this can only be clarified by taking postoperative CT scans, and these were not obtained.[22]

ACKNOWLEDGMENTS

We thank Melissa Wilhelmi, PhD, for the copy editing of this manuscript.

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