Clinical Case Series

Meshworks Patient-Specific Corrective Osteotomy Plates for the Distal Radius

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Introduction

Fracture of the distal radius is one of the most common injuries of the human skeleton, comprising 17% of all fractures (1). Surgical treatment often involves corrective osteotomy which can present with unpredictable clinical outcomes (1). Stinton et al. reported a complication rate of 10% in patients who underwent distal radius osteotomy using conventional plate implants (2), but other reports have demonstrated a complication rate as high as 50% (3). Complications can include infection, nonunion, loss of reduction, implant failure, nerve injury, tendon injury, and complex regional pain syndrome (3). Patient-specific plates for distal radius osteotomy have been found to improve functional and clinical outcomes in particularly complex distal radius and forearm corrections (4).

Traditionally, distal radius osteotomies are performed using off-the-shelf solutions and can present considerable challenges. A study from 2013 found that existing volar locking plate designs have a significant discrepancy in their volar cortical tilt compared to the normal patient anatomy, which can result in repeated under correction of the fractured radius (5). In malunited cases with multiplanar deformity (Figure 1), intraoperative correction using standard fracture instruments can also be technically difficult. Once the osteotomy is made, controlling the exact inclination, tilt and rotation of the distal fragment using a combination of forceps, retractors and laminar spreaders can take considerable surgical time even for the most experienced surgeon.

Figure 1. Radiographs of an initial distal radius fracture (top) and its progression 8-months post fracture (bottom).

The present work describes the outcomes from a single-centre case series of patient-specific corrective osteotomy plates for the distal radius. We explore the design approach, surgical technique, post-operative management, and clinical outcomes from three cases. Data for the patient-rated wrist evaluation score (PRWE) and range of motion (ROM) were given as the standardised outcome measures.

Design Approach

With the advent of 3D printing technologies, custom-made surgical guides and implants can now be produced to simplify the surgical workflow (6). By performing bilateral forearm computed tomography (CT) scans, of both the injured and unaffected limbs, a surgical guide and corrective implant unique to the patient can be planned and manufactured.

Research has shown that, during surgery, it is essential to replicate the surgical plan accurately and consistently to achieve good postoperative outcomes (7). The use of patient-specific tools not only reduce the risk of under correcting the planned osteotomy, but can also significantly decrease surgical time by eliminating the need for fine intra-operative adjustments of the osteotomised fragments (7).

Following acquisition of the forearm CT-images, a virtual planning meeting is arranged with Meshworks' engineers to plan the surgical treatment. In each case, we aimed for a volar opening wedge osteotomy based on the findings of Schurko et al. who demonstrated a volar approach can result in better functional outcomes and a reduced rate of complications compared to a dorsal approach (8).

Initially, the position of the radial osteotomy cut was designed by virtually superimposing the malunited radius onto the patient's mirrored contralateral radius. The osteotomised distal radial fragment could then be virtually manoeuvred to achieve the optimum length, tilt, inclination, and rotation to match the contralateral arm (Figure 2). Once the surgeon and the design team were satisfied with the new alignment of the deformed radius, a custom corrective fixation plate was virtually placed onto the 3D model of the virtually osteotomised radius, in the desired position, for in vivo fixation of the bone fragments. The surgeon would verify the size, type, and position of the plate, as well as the screw locations for fixation. Finally, the virtual locations of the screw holes were reverse engineered onto the pre-osteotomy

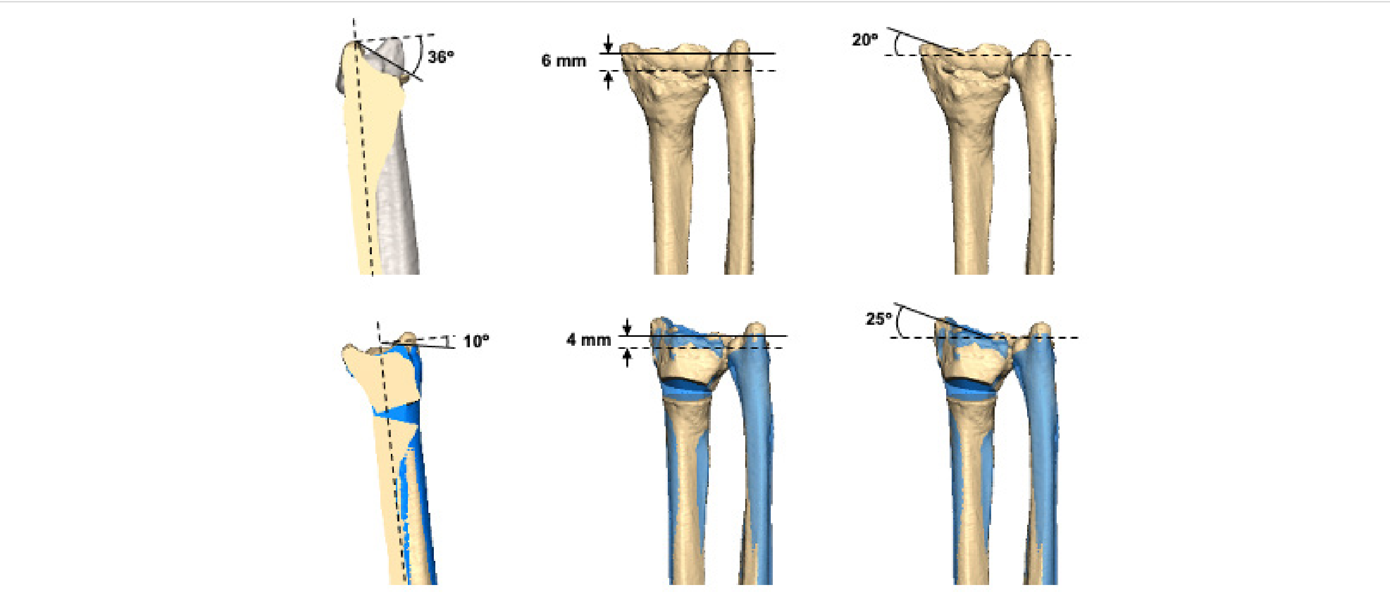

Figure 2. Virtual osteotomy design (Top) pre-osteotomy and (Bottom) virtual planning with mirrored contralateral radius (blue), showing radial tilt, ulnar variance, and radial inclination.

osteotomy 3D model of the radius, and custom instrument guides were designed to pilot the screw holes and orient the osteotomy to match the positions of the final fixation. The guides were made with protruding clips designed to grip the shaft and metaphyseal flare of the radius to allow stable positioning at the single designed reference position. The guides can be designed either as [1] separate drilling and cutting guides which use k-wires as rails to sequence the procedure, ensuring the resection location has been optimised without impinging on the drill sleeves (Figure 3) or as [2] a single-combined drilling and cutting guide (Figure 4).

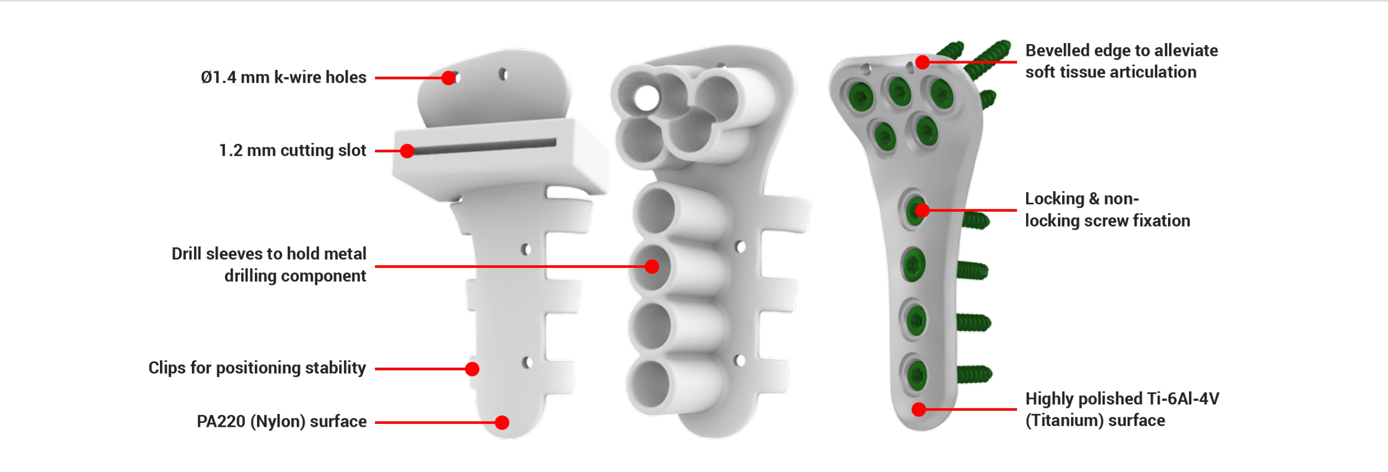

Figure 3. Example patient-specific cutting guide, drilling guide, and osteotomy plate designs and features.

Figure 4. Non-surgical 3D models of the cutting guide, implant & radius pre- & post-osteotomy (provided in pink). Two weeks prior to surgery, non-surgical models of the patient-specific cutting guides, implant & radius (pre- & post-osteotomy) were sent to the surgeon for familiarisation.

Surgical Technique

The surgeries were carried out under regional anaesthesia with an above elbow inflatable pneumatic tourniquet. A volar flexor carpi radialis (FCR) approach was used to reach the distal radius. It is important to release both volar and dorsal periosteum from the fracture site. Failure to thoroughly release the dorsal periosteum can hinder the subsequent osteotomy reduction and compromise the final position. With the radius suitably dissected, the cutting guide was placed onto the volar surface of the radius. It is designed to snugly conform to the contours of the malunited radius (Figure 5). Once in position, the cutting jig was affixed using four 1.4 mm K-wires. This could be checked fluoroscopically to ensure the guide is sitting flush with the radius. Every guide hole was drilled, after which the osteotomy was performed using a saw through the designated slot in the cutting guide.

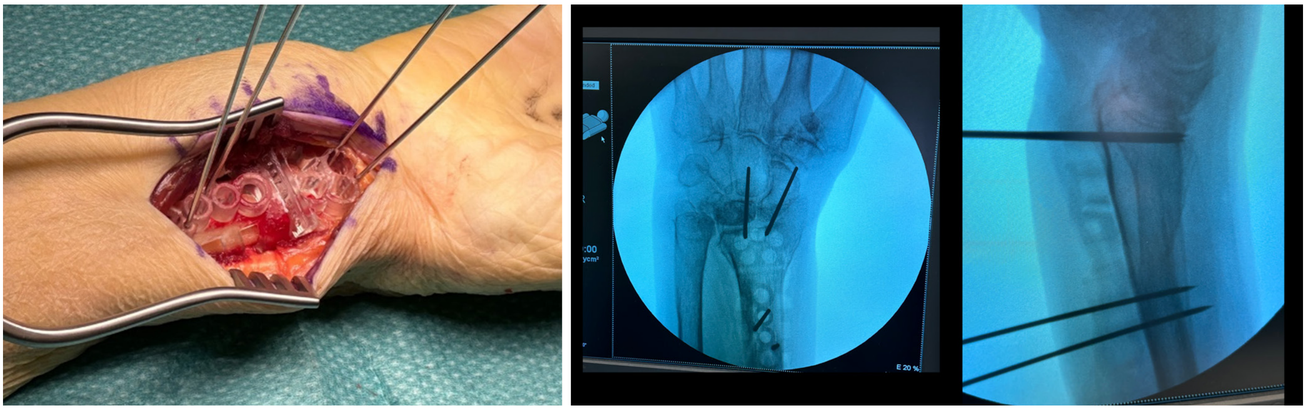

Figure 5. Photograph and radiographs of the cutting guide position.

Following the osteotomy, the proximal two K-wires were removed, and the cutting jig removed by sliding off the two distal K-wires. The 3D printed osteotomy plate was then slid over the two distal K-wires and fixed to the distal fragment using locking screws through the pre-drilled holes, ensuring the plate was positioned flush with the volar cortex. Final reduction was easily performed using the plate, by inserting and tightening the shaft cortical screws to accurately fit the anatomical bone surface (Figure 6).

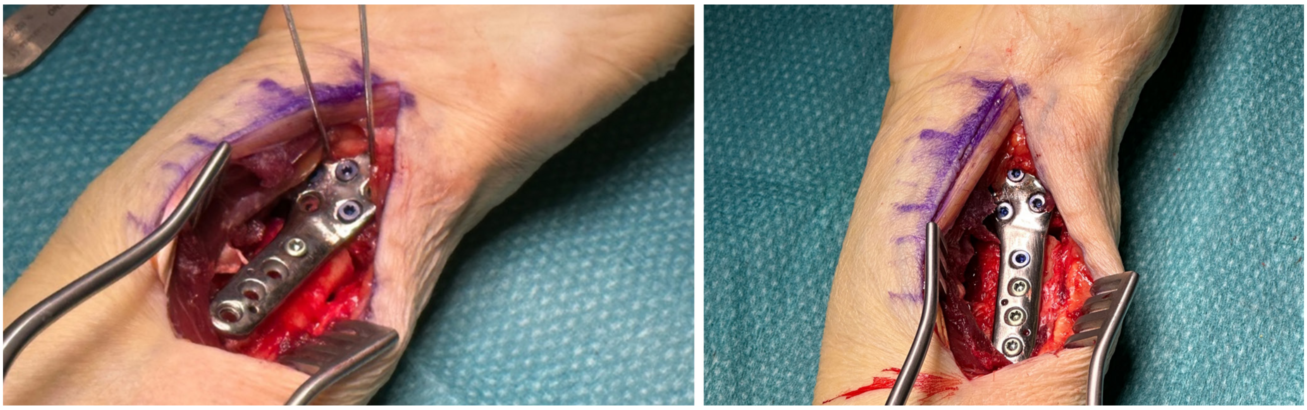

Figure 6. The radius was easily reduced by inserting and tightening a cortical screw between the plate and radial shaft

Post-Operative Management

Post-operatively, the arm was immobilised in a below elbow cast up to the metacarpophalangeal joint. After 6-weeks, a custom-moulded below-elbow thermoplastic splint was made for nighttime immobilisation. Finger ROM exercises were commenced with hand therapy at two weeks post-surgery and wrist movements were started after six weeks.

Results

In this pilot series of three patients, the median patient age was 72 years and follow-up was 10 months. Pre-operatively, there was a median dorsal tilt of 39°, radial inclination of 18°, and ulnar positive variance of 6 mm (Table 1). The wrists were typically held in a mid-prone position and were unable to be actively or passively supinated or pronated, owing to the malunited incongruence of the distal radial-ulnar joint (DRUJ). Given these findings, and following informed discussions, our three patients opted to undergo a patient-specific distal radius osteotomy in an effort to correct the abnormal anatomy and improve the severely restricted range of movement.

Figure 7. A radiograph at 8 weeks post-surgery. Synthetic graft was used in this case to bridge the gap between the osteotomy surfaces.

The planned corrections were to a median tilt of 0°, radial inclination of 22°, and ulnar positive variance of 4 mm (Table 1). Although distal radial tilt and inclination were aimed to be restored for each patient, distal radius length was not increased, as we planned to achieve a degree of cortical contact after the plate fixation to ensure bony union. Time-to-union was a median of 4 months. The baseline PRWE score improved from a median of 92 to 13.5. Wrist flexion-extension and pronation-supination demonstrated normal function at a median of 130° and 160°, respectively (Table 2). There were no intra-operative or post-operative complications.

Table 1. Radiological baseline and planned distal radius tilt, radial inclination, and ulnar variance.

	Baseline				Planned			
Case	Volar tilt (°)	Dorsal tilt (°)	Inclination (°)	Ulnar variance (mm)	Volar tilt (°)	Dorsal tilt (°)	Inclination (°)	Ulnar variance (mm)
1	-	36	20	6	-	10	25	4
2	-	39	16	6	-	0	20	6
3	-	40	18	4.5	-	0	22	1.5

Table 2. Patient reported outcome measures and functional outcomes.

	Baseline			Postoperative		
Case	PRWE	ROM Flex-Ext	ROM Pro-Sup	PRWE	ROM Flex-Ext	ROM Pro-Sup
1	92	60°	40°	48	90°	160°
2	95	60°	50°	5	130°	160°
3	78	30°	50°	14	50°	90°

Discussion

In our case series of three patients, we demonstrated the safety and clinical efficacy of distal radius malunion treatment with Meshworks patient-specific corrective osteotomy plates. In this single-centre case series, operative time decreased from 90 minutes for the first case to 75 minutes for the final case. This finding demonstrates a relatively low learning-curve to fully master the surgical technique. Despite the residual ulnar positive variance following osteotomy, all patients were happy with their outcomes, and would recommend the procedure to others with severe distal radius malunions.

In the first and most extreme case, an 81-year-old lady fell onto her outstretched right hand and sustained a distal radius fracture during the height of the covid pandemic. She attended the emergency department and initial radiographs showed the fracture configuration to be dorsally angulated and intra-articular. This was manipulated and reduced in the emergency department and treated with cast-immobilisation for six-weeks. Unfortunately, cast immobilisation failed to sufficiently stabilise this injury. The fracture re-displaced with significant dorsal angulation and radial shortening (Figure 1). The patient attempted to manage her symptoms expectantly, by having physiotherapy led mobilisation and strengthening. Her symptoms did not improve, however, and she had worsening of her wrist pain, stiffness and weakness as the months progressed. After eight months, the patient was suffering from considerable disability from this injury. In addition to continuous pain, she never regained normal wrist rotation, and was incapable of performing basic tasks such as getting dressed or washing with the injured arm. The patient opted to undergo a distal radius osteotomy to correct the abnormal anatomy and improve her severely restricted range of movement.

To our knowledge, just three studies have published data on 3D-printed patient-specific titanium plates for corrective distal radius osteotomy (4,9,10). Schindele et al. reported the 1-year outcomes of 14 patients implanted with patient-specific distal radius and forearm plates (4). In their study, the median surgical time was 92 minutes, baseline PRWE improved from a median of 47 to 7, and median flexion-extension and pronation-supination improved to 130° and 160°, respectively. Despite our shorter median follow-up and higher baseline PRWE, their results were similar with a 6.5-point difference in median post-operative PRWE compared to the current series. A PRWE difference of >11.5 points is considered clinically significant (11).

Off-the-shelf osteotomy plates for the distal radius have demonstrated comparable outcomes to the patient-specific solutions previously reported, in addition to those presented in this case series (2). In their meta-analysis of 3,258 individuals, Stinton et al. reported an improvement in PRWE from 68.7 at baseline to 15.4 at 6-months and 12.2 at 1-year (2). Both the studies from Schindele et al. and Stinton et al. presented baseline PRWE lower than the baseline in our case series, which indicates less severe initial deformities compared to this series. Furthermore, age and fracture type have a significant effect on outcomes including PROMs and ROM, which may influence the interpretation of these results. Patient-specific plates are aimed at the pre-planning and treatment of particularly complex fracture types that are multi-planar in deformity compared with off-the-shelf designs.

This case series recognises several limitations. The single-centre focus and small sample size limits the strength of our findings. Further work is required in a multi-centre investigation, and reporting on a larger sample size, to fully understand the clinical outcomes across different uses cases. The present work can only be considered short-term in follow-up and may not represent the final outcomes for each patient. It is likely that PROMs and ROM will improve over time; however, longer-term data is required to fully validate this hypothesis.

Few studies have reported the results of patient-specific titanium plates for corrective osteotomy of the distal radius. The results of this white paper confer that patients and clinicians can expect clinically meaningful improvements in PRWE and ROM at a minimum of 6 months follow-up. These findings are comparable with both the previously published research on patient-specific and off-the-shelf solutions.

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