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ORIGINAL ARTICLE

Early clinical experience with resorbable poly-5D/95L-lactide (PLA95) plate system for treating distal radius fractures

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distal radial fracture;
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Abstract *Background/purpose:* Distal radius fractures are amongst the most common musculoskeletal bone injuries treated in emergency departments. The objective of this study was to evaluate the functional and radiologic outcomes of treating distal radius fractures with a resorbable volar polymeric implant system.
Materials and methods: We applied the volar poly-5D/95L-lactide (PLA95) plate/screw system (Bonamates, BioTech One, New Taipei City, Taiwan) for intraosseous fixation after open reduction of distally displaced radius fracture in four patients (three males and one female, ages range: 7–67 years). Another four patients [three females and one male, ages 68–70 (68.8 ± 1.0)] were treated with 3.5-mm metal volar T locking plates (Synthes, Paoli, PA, USA) as the control group. The minimum follow-up period was longer than 2.5 months for all cases.
Results: At final functional and radiologic assessment, all of the distal radius fracture sites were united and one patient achieved excellent results, two patients had good results, and one had a fair result. All patient outcomes were satisfactory, and no major material-related infections or allergies were found.

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Conclusion: Within the limitations of this early clinical experiment, we conclude that the volar PLA95 copolymer plate/screw system can be used to treat distal radial fractures.

Introduction

Biodegradable fixation devices have gained much attention recently due to their advantages, which include radio translucencyto X-ray, low stress-shielding effects, good biocompatibility, and no need for secondary operation, in comparison with metallic implants.[1] Typical bioresorbable devices are manufactured by copolymers of poly-L-lactide (PLLA), poly-DL-lactide (PDLA), or polyglycolic acid (PGA), because of the adverse events associated with pure PLLA and PGA.[2] Among these polymers, a copolymer composed of poly-5D/95L-lactide (PLA95) has been successfully used in craniomaxillofacial applications like skull flap fixation,[3] mandibular fracture fixation,[4] and facial fracture fixation,[5] due to its relatively strong mechanical properties. The feasibility of using PLA95 resorbable implants in moderate-load orthopedic areas is worth exploring.

Distal radius fracture is one of the most common bone injuries to the musculoskeletal system and represents approximately one-sixth of all fractures treated in emergency departments.[6] Postmenopausal women are susceptible to fractures of the distal radius on account of fragility of the distal forearm due to low bone mineral density resulting from osteoporosis. The lifetime risk of sustaining a distal radius fracture is 15% for women and 2% for men.[6–8] Operative management is the treatment of choice for the majority of displaced fractures, and the surgical options depend on the fracture pattern and the amount of displacement. Many treatment modalities are available, including closed reduction and cast immobilization,[9] percutaneous pinning and external fixation,[10–13] open reduction and internal fixation,[14–18] and intramedullary pinning.[19]

Open reduction with internal fixation is one method of surgically repairing a fractured bone. Generally, this involves the use of plates and screws to stabilize the bone. The two most widely used internal fixation methods are dorsal and volar plating. In the majority of distal radius fracture cases, volar plating gives the most satisfactory result.[20] It leaves more space for volar aspect of the distal radius and also helps avoid dorsal dissection, which can injure the extensor tendons and blood supply to the dorsal metaphyseal fragments.[21–23]

Internal fixation of comminuted, distal radius fractures with metal implants has shown promising clinical outcomes. However, complications resulting from of the metal plates may include infection, tenosynovitis, radiocarpal arthrosis, stiffness of the phalanges, or tendon rupture.[24] Due to the incidence of such complications, most patients prefer to have the implant removed when the fracture sites have united. Early removal of the hardware is sometimes necessary and may bring the risk of severe pain, weakened grip, or even refracture of the distal radius (from screw holes or the previous fracture site).[25] These potential disadvantages of using metal devices to treat distal radius fractures have provided an opportunity to develop improved methods. Bioresorbable distal radius plating systems have been developed to stabilize the fracture site while eliminating most of the disadvantages that metal implants present.

Bioresorbable fixation systems have been developed as a reasonable alternative in orthopedic surgery without showing adverse effects on bone healing.[26] Various commercially available bioresorbable distal radial plate systems are summarized in Table 1. One clinical study of the Reunite bioabsorbable plating system (ReUnite Distal Radius, Biomet U.K., Ltd., Bridgend, UK) showed functional results comparable with metal plates in the majority of cases; however, five of 26 patients lost reduction between 6 and 12 weeks postoperatively, due to the severity of dorsal comminution.[27] With improvements in production and design, the Bonamates system (BioTech One, New Taipei City, Taiwan), which is composed of copolymer of PLA95, has unique three-point bending strength performance.[28] The bending strength of the PLA95 plates first increases up to

Table 1 Summary of commercially available bioresorbable distal radial plate systems.

System (company)	Polymer composition (%)	*In vivo* degradation	
		Strength profile	Complete resorption (mo)
ReUnite Distal Radius, Biomet U.K., Ltd.	PLLA: ~ 82 PGA: ~ 18	6–8 wks – retain its strength	12
Inion OTPS Bioabsorbable Distal Radius System, Inion Oy.	PLLA: ~ 75 PDLLA: ~ 25 TMC: ~ 5	9–14 wks – 70% 18–36 wks—lost most of strength	9–36
Bonamates, Biotech-One Inc.	PLLA: ~ 90 PDLLA: ~ 10	8 wks—179% 16 wks—32%	≥36

PDLLA = poly-DL-lactic acid; PGA = polyglycolic acid; PLLA = poly-L-lactic acid; TMC = trimethylene carbonate.

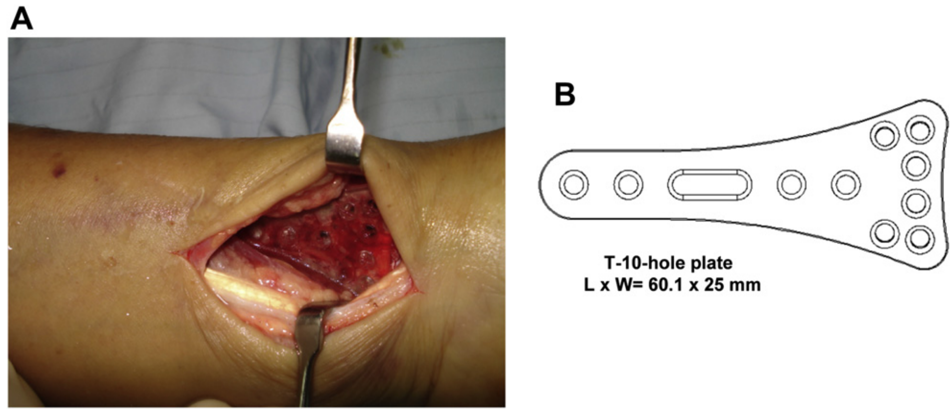

Figure 1 Fixation with volar poly-5D/95L-lactide copolymer distal radial plate system. (A) surgical site; (B) specification of distal radial plate.

Week 8, until the healing of fractured bones, and decreases over time from then on. While the resorbable PLA95 plate stabilized the fractured bone and assisted with the bone-healing process, the load of the fractured bone transferred to the PLA95 bone plate to enhance its bending strength. These physical and biomechanical cross-interaction phenomena can shed some light on the possibility of using resorbable implants for certain high load-bearing fractured sites. The potential of using the PLA95 plate system for distal radius fractures needs to be verified.

We conducted this study to assess outcomes using a resorbable distal radial plate system to treat distal radius fractures as a way of eliminating the need for a second operation. This study used the volar Bonamates PLA95 plate/screw system for this purpose, assessing patients' functional recovery and radiographic changes that occurred at the distal part of the radius at specific time-intervals after fixation.

Materials and methods

Between December 2009 and January 2011, we treated the experimental group of four patients with distal radius fractures, with or without combination distal ulna fractures, with open reduction and internal fixation using a bioresorbable plate/screw system designed for optimal alignment and stabilization. They were also protected with short arm splint or cast for periods ranging from 6 weeks to 3 months. We used the bioresorbable Bonamates plate/screw system, which is composed of copolymer in the following ratios: PLA95 or expressed as poly-L/DL-lactide (90/10). Plates were adapted to the shape of a volar small T-shaped compression plate by heating in a water bath containing 70° C sterile water for 7–10 seconds. The patients' ages ranged from 7 to 67 years of age. Of these patients, two received 2 cc xenograft Sinbone HT (Purzer Pharmaceutical, Taipei, Taiwan) in the fracture site, which consists of 63% hydroxyapatite and 37% tricalcium phosphate, to enhance healing related to osteoporosis. As a control group, we treated another four patients with 3.5 mm metal volar T locking plates (three females and one male) with a mean age of 68.8 ± 1.0 years (range, 68–70 years). X-ray analysis with interexaminer calibration was performed.

All procedures were performed under general anesthesia and from the volar approach by dissection between the flexor carpi radialis tendon and the median nerve. We

Table 2 Demographic data.

Patients enrolled ($N = 8$)		
Poly-5D/95L-lactide plate system (4 patients)	Age (yr)	48.5 ± 28.1 (7–67)
	Arbeitsgemeinschaft fur Osteosynthesefragen classification	
	Type A (extra-articular fracture)	
	A1 (ulna, radius intact)	0
	A2 (radius, simple and impacted)	1
	A3 (radius, multifragmentary)	3
Metal plate system (4 patients)	Age (yr)	68.8 ± 1.0 (68–70)
	Arbeitsgemeinschaft fur Osteosynthesefragen classification	
	Type A (extra-articular fracture)	
	A1 (ulna, radius intact)	0
	A2 (radius, simple and impacted)	2
	A3 (radius, multifragmentary)	2

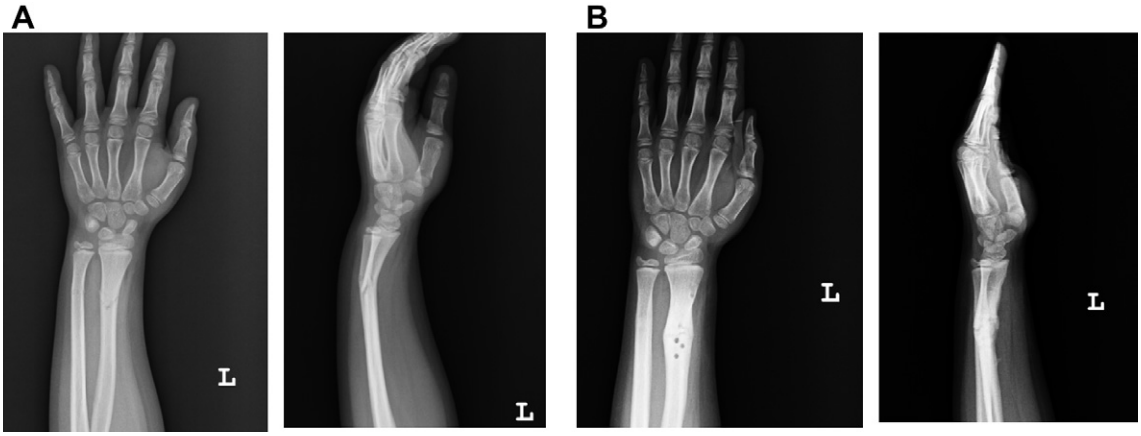

Figure 2 Distal radial and ulna shaft fracture in a 7-year-old boy. Radiographs showing fracture healing and good radiological alignment after poly-5D/95L-lactide copolymer plates and screws fixation for 2 months. (A) preoperative radiography; (B) postoperative radiography.

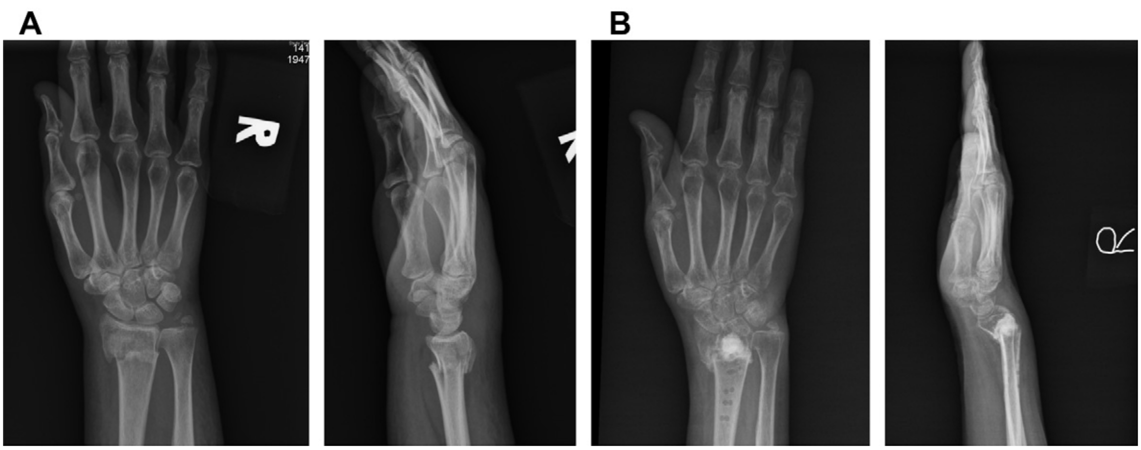

Figure 3 Radiographs showing the unstable dorsally displaced fracture of the distal radius with loss of reduction and progressive volar angulation 2.5 months after poly-5D/95L-lactide copolymer plates and screws fixation. (A) preoperative radiography; (B) postoperative radiography.

performed dissection of the pronator quadratus muscle and open reduction with the aid of intrafocal leverage (Fig. 1). Sometimes an assistant performed traction to facilitate reduction. We determined the need for allograft with Sinbone HT intraoperatively based on the level of subarticular support and bone quality. After applying the bioabsorbable plates, we fixed the long slot screw hole first and checked with a c-arm image intensifier under a guide of

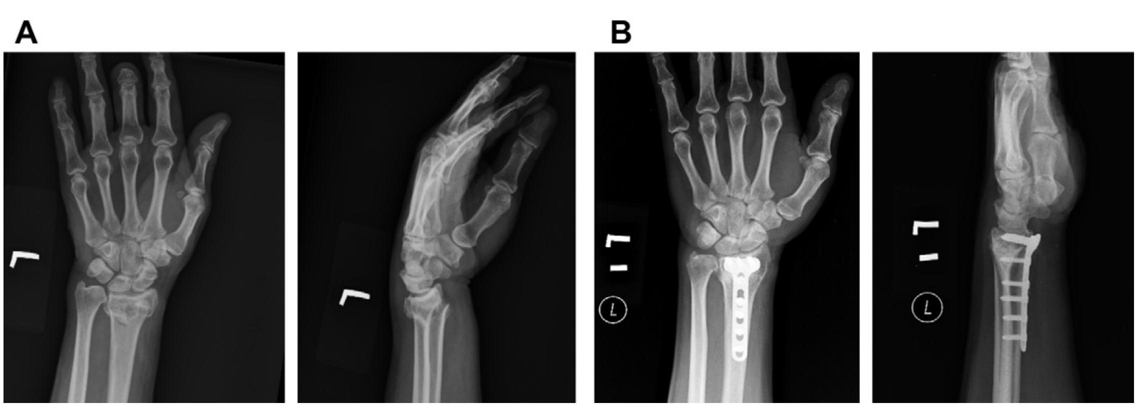

Figure 4 Case of a 68-year-old man with Colles fracture treated with small metal T-locking plates and 2 cc bone substitute, union of fracture site 2.5 months later. (A) preoperative radiography; (B) postoperative radiography.

Table 3 Postoperative hand functions and mean range of motion 3 months following fixation.

Case	Test					
	Wrist extension (injured/normal)	Wrist flexion (injured/normal)	Forearm supination (injured/normal)	Forearm pronation (injured/normal)	Grip power (kg), injured/normal	Pinch power (kg), injured/normal
Poly-5D/95L-lactide plate system						
1	70°/70°	80°/80°	80°/85°	90°/90°	7/8	4/5
2	34°/41°	50°/55°	70°/80°	80°/85°	13/16	6/8
3	70°/70°	70°/75°	65°/90°	80°/90°	11/14	8/10
4	60°/75°	42°/60°	80°/85°	90°/90°	8/12	4/6
Test kit: Sammons Preston Hand Dynamometers. Metal plate system						
1	71°/73°	75°/76°	75°/80°	90°/90°	14/15	8/8
2	69°/71°	65°/73°	73°/78°	89°/90°	13/14	8/9
3	68°/70°	67°/72°	70°/80°	85°/90°	12/15	7/9
4	65°/69°	70°/75°	73°/76°	83°/85°	16/18	11/12

Kirschner wire to make sure that the screw would not interfere with the carpal joint.

The standard posteroanterior, oblique, and lateral views were the basis for the initial radiographic examination. Follow-up radiographs of the wrists were taken to assess reduction and bony union. We measured radiological parameters—including radial inclination, radial length, and volar tilt—before and after surgery, as well as at the final follow-up. We graded subjective and objective functional results using the Gartland and Werley point system. Objective evaluation consisted of grip power, range of wrist joint motion, and complications such as wound infection, finger contracture and median nerve injury.

Results

Demographic data and Arbeitsgemeinschaft fur Osteosynthesefragen classification for four patients (two men, one boy, and one woman) with a mean age of 48.5 years (range, 7—67 years) are listed in Table 2. Between December 2009 and November 2010, we performed four procedures using the volar PLA95 copolymer plate and screw system. Radiographs for the distal radial and ulna shaft fracture in the 7-year-old boy show fracture healing and good radiological alignment after PLA95 copolymer plate and screw fixation for 2 months (Fig. 2). In the case of a 64-year-old woman, radiographs show the unstable dorsally displaced fracture of the distal radius with loss of reduction and progressive volar angulation 2.5 months after PLA95 copolymer plate and screw fixation (Fig. 3).

Fig. 4 is of a 68-year-old man with a typical Colles fracture treated with small metal T-locking plates and 2 cc of bone substitute, showing union of the fracture site 2.5 months later. Patients with unstable, dorsally displaced fractures of the distal radius treated with metal volar fixed-angle devices generally have good or excellent functional outcomes.

Follow-up duration varied from 2.5 to 11 months. Half the patients had a fracture in the dominant limb. Injuries were caused by a fall or slip ($n = 3$) and falling while riding a bicycle ($n = 1$). All had closed fractures. Preoperative radiographic evaluation showed that the mean volar angulation was 18.5 degrees (range, 1—43), mean radial inclination 12.3 degrees (range, 10—15), and mean radial shortening of 4 mm (range, 2—5). One patient had a negative ulna variance of about 3 mm. The mean interval between injury and surgical stabilization was less than 1 day. Two patients received bone substitute (Sinbone HT) due to osteoporosis of the fracture site and difficulty restoring the height of the articular surface.

The final mean range of motion was wrist flexion 60.5 degrees (range, 42—80), extension 58.5 degrees (range, 34—70), supination 73.8 degrees (range, 65—80), and pronation 85 degrees (range, 80—90), and the mean grip power was 9.8 kg with a pinch power of 5.5 kg on the injured side. The normal side of mean wrist flexion was 67.5 degrees (range, 55—80), extension 69 degrees (range, 41—75), supination 85 degrees (range, 80—90), and

Table 4 Postoperative radiographic data for injured side 3 months following fixation.

Case	Outcomes		
	Radial inclination (degrees)	Volar tilt (degrees)	Radial length (mm)
Poly-5D/95L-lactide plate system			
1	17	8	10
2	20	20	13
3	10	16	9
4	4	40	4
Metal plate system			
1	19	5	11
2	16	2	7
3	23	16	12
4	18	6	9

Table 5 Functional scores of the four patients at final follow-up.

Excellent	Good	Fair	Poor
Poly-5D/95L-lactide plate system			
1	2	1	0
Metal plate system			
3	1	0	0

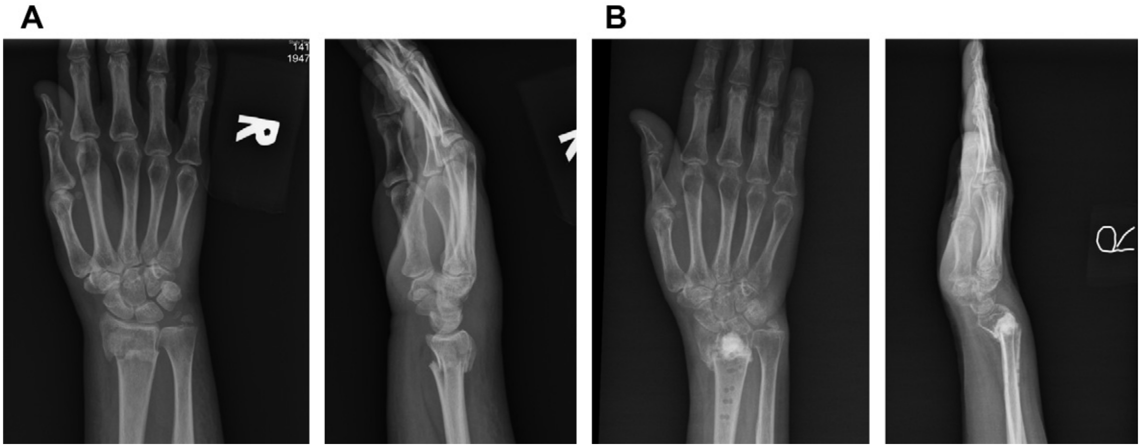

Figure 5 Radiographs showing the unstable dorsally displaced fracture of the distal radius with loss of reduction and progressive volar angulation 2.5 months after poly-5D/95L-lactide copolymer plates and screws fixation. (A) preoperative radiography; (B) postoperative radiography.

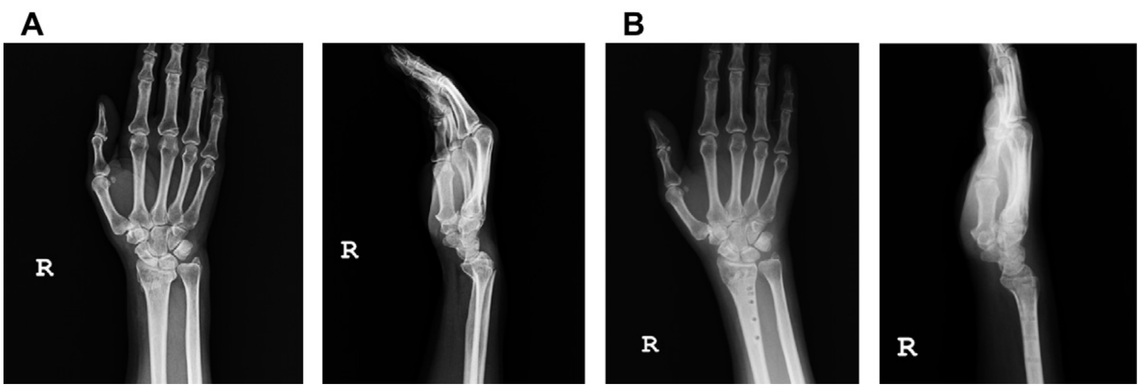

Figure 6 Distal radial fracture in a 56-year-old man. The preoperative radiography (left two) and the final union status (right two). (A) preoperative radiography; (B) postoperative radiography.

pronation 88.8 degrees (range, 85–90), and the mean grip power was 12.5 kg with a pinch power of 7.3 kg (Table 3).

The final follow-up radiologic evaluation showed that the mean volar angulation of the distal radius was 21 degrees (range, 8–40), mean radial inclination 14.3 degrees (range, 10–20), and the mean radial shortening 3.5 mm (range, 0–9 mm). One poor mean radial shortening result was from secondary volar displacement and collapse of fracture site at final assessment. The average time to union was 3.5 months (range, 2.5–4.5; Table 4).

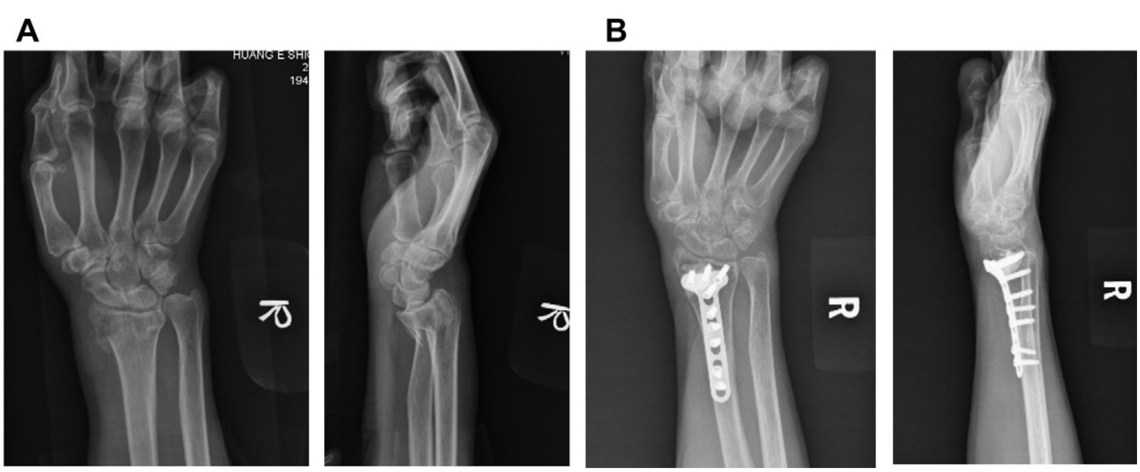

Figure 7 Case of a 69-year-old woman with Smith fracture had received ORIF with small metal T-locking plates and 2 cc bone substitute, union of fracture site 4 months later. (A) preoperative radiography; (B) postoperative radiography.

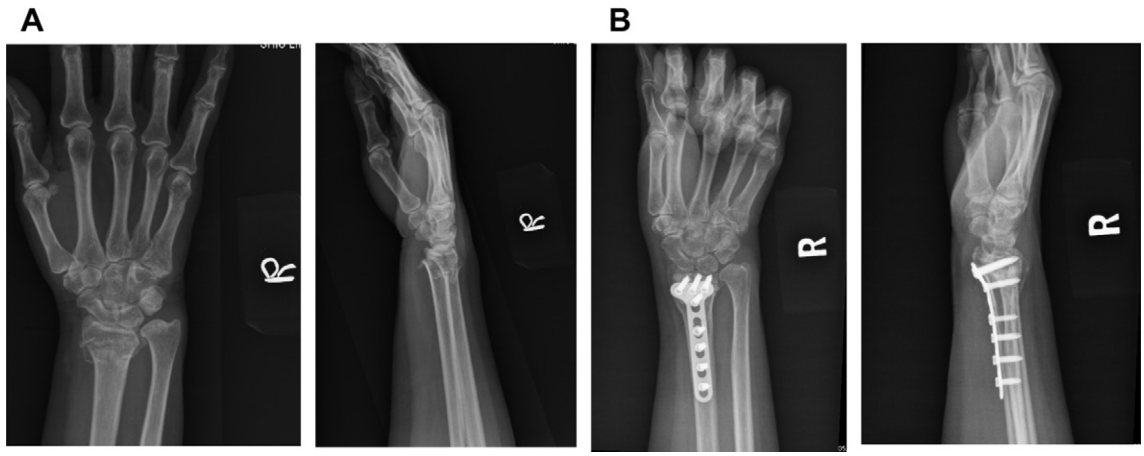

Figure 8 Case of a 70-year-old woman with Colles fracture s/p ORIF with small metal T-locking plates and 2 cc bone substitute. (A) preoperative radiography; (B) postoperative radiography.

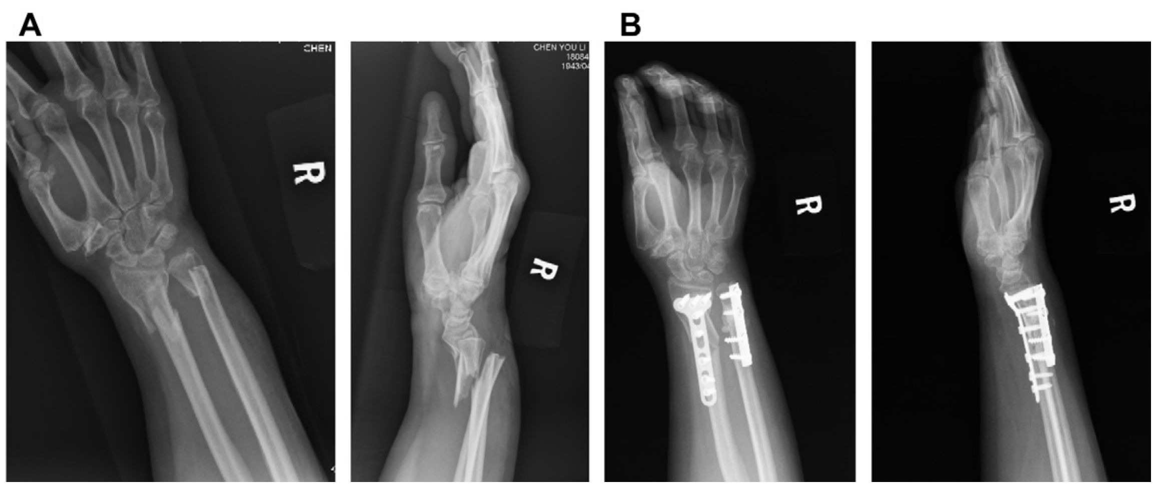

Figure 9 Case of a 68-year-old woman with distal radial and ulna shaft comminuted fracture treated with small T-locking plate and one third tubular plate, callus formation of fracture site after 6 weeks later. (A) preoperative radiography; (B) postoperative radiography.

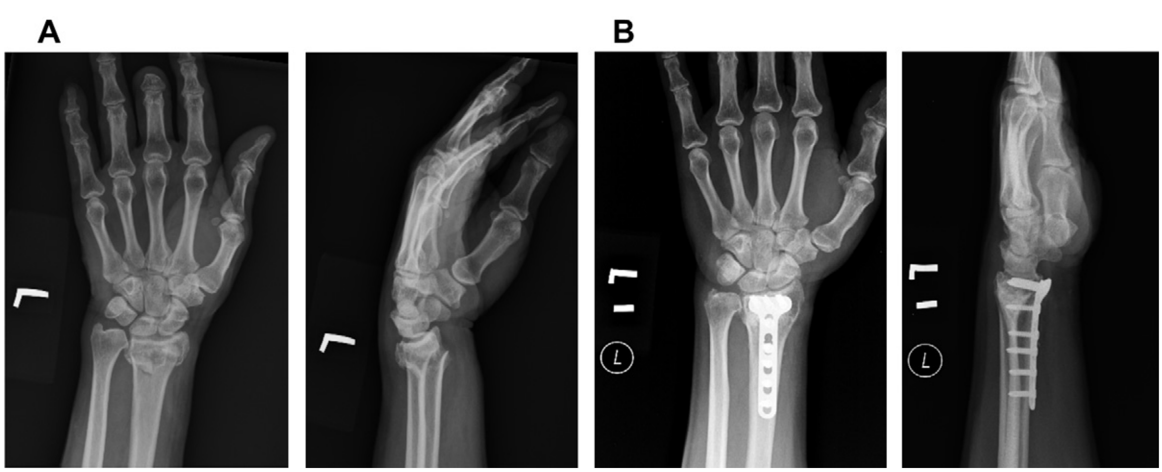

Figure 10 Case of a 68-year-old man with Colles fracture treated with small metal T-locking plates and 2 cc bone substitute; union of fracture site 2.5 months later. (A) preoperative radiography; (B) postoperative radiography.

We used Gartland and Werley's classification for the functional assessment,[9] and one patient achieved excellent functional scores, while two patients had good results and one had fair results (Table 5).

No complications such as wound infection or carpal tunnel syndrome were found during follow-up, (Figs. 5—10) except one patient had loss of reduction at the fracture site with progressive volar angulation and displacement. Even though the functional results are better for the metal plate fixation group, some patients still felt the sensation of a foreign body in the fracture site, and others felt irritation of the sliding tendon when they moved their wrist joints.

Discussion

Primary instability of distal radius fractures includes the following radiographic parameters: (a) more than 5 mm of radial shortening, (b) more than 20 degrees of lateral inclination, (c) more than 2 mm of articulator step-off, and (d) comminuting extending beyond the midaxial line.[29] We used a volar approach in these four distal radius fracture cases to avoid the common complications of extensor tenosynovitis and tendon rupture following dorsal plating.[30,31] With the properties of this PLA95 copolymer bioabsorbable plate and its low profile design, dorsal application of this plate can also be a biomechanical alternative to effectively buttress a dorsally displaced fracture of the distal radius. Using this bioabsorbable plate can avoid mechanical attrition to the extensor pollicis longus tendon caused by ordinary metal plates and screws. Concerned that the mechanical strength of the PLA95 bioabsorbable plate might be weaker than that of a metal plate, postoperative short arm cast or bivalve splint fixation was mandatory for 4—6 weeks.

Another disadvantage of the PLA95 copolymer bioabsorbable plate is that it is hard to check the distal screw position by fluoroscopy, so placement of a drill bit or Kirschner wire to identify the direction of the screw is necessary during the surgical procedure. But even if the tip of a screw touches the wrist joint, they do not appear to cause the irritation problem associated with metal screws.

Excellent results were obtained with the 7-year-old boy, even with residual volar angulation of distal radius fracture site of about 15 degrees (Fig. 2). This progressive angulation may be due to the short duration of cast protection of only 20 days. We noted the younger people had more daily activity and movement; therefore, longer cast fixation time needs to be considered even though these younger patients have good healing power.

The case with fair results was that of a 64-year-old woman with poor bone quality at the fracture site. Even with 2 cc Sinbone HT in the fracture site to support the medial cortex, loss of reduction was noted after scheduled follow-up at 42 days after operation (Fig. 3). The reason for displacement of the fracture site may be due to the fact that she removed the bivalve splint by herself 2 weeks after the operation. Skin itching and bad smell are common shortcomings, so most people who live in a tropical or subtropical climate cannot easily tolerate cast or splint fixation in the hot season. We always emphasize the importance of postoperative care and protection with cast or splint for sufficient time before patients are discharged, but sometimes they remove the splint when the pain subsides or they feel better. A short arm Scotch cast (3M, St Paul, Minnesota, USA) with a window for wound care may be the way to solve this problem.

These preliminary results of treating distal radius fractures with PLA95 copolymer bioabsorbable plates was encouraging for patients who did not want to receive a second operation to remove hardware after fracture healing. But, it is necessary to discuss protection with a cast for an appropriate period of time and physical therapy with patients before the surgery to achieve better results and functional outcomes. Within the limitations of this early clinical experience, we conclude that the volar PLA95 copolymer plate/screw system can be used for treatment of distal radius fractures.

Acknowledgments

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