

Use of Injectable Calcium Phosphate in the Treatment of Intra-Articular Distal Radius Fractures

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Abstract

This study reviewed 19 patients with intra-articular fractures of the distal end of the radius treated with augmented external fixation and injectable calcium phosphate (Norian SRS; Norian Corp, Cupertino, Calif) between November 1997 and July 2000. Average patient age was 52 years, and average follow-up was 16.3 months. Patients

were evaluated clinically and radiographically using the modified Mayo Wrist Score and Knirk and Jupiter's criteria, respectively. Overall results are comparable to those from other studies of intra-articular distal radius fractures in which other grafts have been used.

Intra-articular distal radius fractures usually are the result of high-energy trauma1 and deserve special attention because of the distortion of the articular surface and the concomitant collapse of the metaphyseal cancellous bone. Closed reduction seldomly restores the articular congruity, and redisplacement is possible. Therefore, surgical intervention is necessary to restore and stabilize the fragments and to offer structural support. This is achieved by open reduction and stabilization of the fragments and grafting of the metaphyseal defect. Surgical intervention includes pins and plaster,2 percutaneous pin fixation,3 open reduction and internal fixation,4 external fixation,5 and augmented external fixation with Kirschner wires.6

Autologous cancellous bone graft has been used to supplement external fixation of unstable distal radius fractures.⁷ However, the source of bone graft, usually the iliac crest, is limited, a second procedure is required, and harvesting is related to donor site morbidity (6%-30%),⁸ which includes infection, pain, nerve injury, and pathologic fractures. These problems led to the development of synthetic grafts, one of which is Norian SRS (Skeletal Repair System) (Norian Corp, Cupertino, Calif).

Norian SRS is an injectable bone mineral substitute that cures in vivo to form carbonate apatite with chemical and physical characteristics similar to the mineral bone phase. Calcium and phosphate sources are mixed with the addition of a buffer solution to form an injectable material of paste-like consistency that conforms to the bone defect and then hardens and achieves its maximum compressive strength in approximately 12 hours.⁹

Norian SRS has been used in fractures of various bones and multicenter trial results are encouraging for extraarticular fractures. 10 This study evaluated the use of Norian SRS in the treatment of intra-articular distal radius fractures.

MATERIALS AND METHODS

Between November 1997 and July 2000, 19 patients (9 men and 10 women) with intra-articular distal radius fractures were surgically treated at our institution (Table 1). Average patient age was 52 years (range: 20-83 years). All patients were available for follow-up.

The indications for surgery were intraarticular fractures that met one of two criteria: 1) any step-off or gap in the articular surface >1 mm, or 2) radial inclination $<19^{\circ}$ or $>30^{\circ}$, radial length <8 mm or >17 mm, or volar tilt $<0^{\circ}$ or $>21^{\circ}$ (Figure 1). Patients who presented 5 days after injury were not included in the study.

All patients were treated within 48 hours of admission. Fifteen patients were treated with augmented external fixation, two with external fixation without K-wires, and two with plate and screws. Calcium phosphate (Norian SRS) was

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TABLE 1
Patient Data

Patient No./ Sex/Age (y)	Side	Follow-up (mo)	Fracture Type (AO)	External Fixation	Radial Length*	Radial Inclination*	Volar Tilt*	MAYO Score†	Complications
1/M/39	Right	12	C1	DRS	10/13	16/27	14/19	85 (20/25/25/15)	
2/F/57	Right	11	C1	DRS	9/10	15/21	18/10	80 (25/25/15/15)	
3/F/61	Left	30	C2	Mini AO‡	10/11	26/20	12/12	75 (20/25/15/15)	
4/M/20	Right	14	C1	DRS	3/10	6/16	19/19	90 (25/25/25/15)	Ulna subluxation; rupture of capito- lunate ligament
5/M/63	Left	13	C1	DRS	0/8	10/18	13/18	60 (10/20/15/15)	SLD
6/F/39	Right	12	C2	DRS	13/12	3/10	30/6	90 (25/25/15/25)	
7/F/65	Right	18	C1	Palmar plate§	11/11	20/18	30/24	60 (10/20/15/15)	Missed SLD, slack wrist
8/M/47	Right	13	C3	DRS	9/12	13/14	4/12	90 (25/25/15/25)	
9/M/24	Left	14	C3	DRS	8/12	22/20	28/10	80 (25/25/15/15)	
10/F/60	Left	13	C3	DRS	10/12	20/18	10/10	75 (25/20/15/15)	Norian SRS, intra- articular
11/F/73	Right	12	C2	DRS	7/11	18/22	10/8	80 (25/25/15/15)	
12/F/55	Right	13	C1	DRS	15/13	22/23	6/21	85 (20/25/15/15)	SLD
13/F/83	Left	13	C1	DRS	8/11	15/18	12/10	85 (25/20/15/25)	
14/M/46	Right	14	C3	Palmar plate, DRS	6/10	9/19	32/10	70 (20/20/15/15)	Failed reduction, reoperation
15/M/50	Right	12	C2	DRS	3/12	12/22	33/8	100 (25/25/25/25)	
16/F/42	Left	14	C2	DRS‡	5/10	2/22	26/8	85 (25/20/25/15)	Norian SRS, intra- articular
17/F/78	Right	28	C1	DRS	8/10	8/18	30/6	75 (20/25/15/15)	
18/M/40	Right	17	C1	DRS	11/16	26/19	3/18	70 (20/20/15/15)	Reoperation, ulna shortening 6 mo later
19/M/52	Right	13	C3	DRS	5/9	20/17	11/10	80 (25/25/15/15)	

Abbreviations: DRS=Distal Radius System (Richards) and SLD=scapholunate dissociation.

*Expressed as preoperatively/postoperatively.

‡No K-wire

§K-wire.

injected under direct vision in all patients (Figure 1).

Patients were placed under general or regional anesthesia. Closed reduction was not attempted intraoperatively. A mini AO external fixator (AO/ASIF; Synthes, Switzerland) with 2.5-mm diameter pins or a Distal Radius System (Richards, Memphis, Tenn) with 3-mm diameter pins was used. Two pins were placed in the radius 3 cm proximal to the fracture site through a 2- to 3-cm skin incision with meticulous preparation of the sensory nerve branches. Two other pins were placed in the second metacarpal with stab incisions.

In all but two patients—treated with palmar incision and plate and screws—a longitudinal dorsal incision of 6-7 cm was made at the distal radius. The retinaculum was opened with an incision

at the third dorsal compartment and the extensor pollicis longus displaced radially. The second and fourth compartment and their tendons were subperiostally elevated, and the fracture site was identified. The joint was then incised vertically and copiously irrigated. Under direct vision and traction of the wrist through the index and thumb, any articular step-off was restored with a small freer. The fragments were stabilized with K-wires or were not stabilized as indicated. The frame was then applied with moderate traction of the wrist (ie, enough to keep the articular surface of the radius and scaphoid and lunate apart).

If ligamentous rupture was indicated on preoperative radiographs, the wrist was checked under image intensifier and any ruptures were repaired accordingly. This was necessary in three patients: two patients with scapholunate dissociation (patients 5 and 12) and one with capitolunate rupture (patient 4). In patient 4, distal radioulnar subluxation also was found and was reduced and stabilized with a K-wire for 6 weeks. The remnants of the ligaments were sutured and additional Mitec bone anchors (Johnson & Johnson, Westwood, Mass) were used as necessary.

In all 19 patients, a cavity of various size in the metaphyseal cancellous bone was observed that enlarged when the articular fragments were elevated. The remaining loose cancellous bone at the metaphysis was carefully impacted to create a firm cancellous bed in which Norian SRS was injected without pressurization within 2 minutes. The injection was not observed by the image

[†]Total score reported and broken down as pain/satisfaction/range of motion/grip strength.



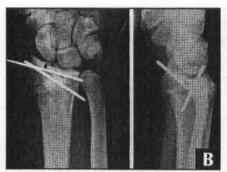




Figure 1: Patient 1. Preoperative AP and lateral radiographs show a C1 type intra-articular fracture of the distal end of the radius (A). Postoperative AP and lateral radiographs show reduction of the intra-articular fracture using augmented external fixation with K-wire and Norian SRS (B). AP and lateral radiographs at 1-year follow-up show healing of the fracture and partial absorption of Norian SRS (C).

intensifier. No more than 5 cc of the product were needed in each patient. After removing Norian SRS from the soft tissues, the remainder was left to harden for 10 minutes. No movement was allowed during hardening.

Patients were advised to move their hand, elbow, and shoulder as soon they could. Serial radiographs were obtained. Between postoperative weeks four and six, the external fixator was removed when there was radiographic evidence of union and lack of pain on palpation of the fracture site.

Patients were reassessed clinically and radiographically (Figure 1). At most recent follow-up, grip strength was obtained using a Jamar dynamometer (Preston Corp, Jackson, Miss), and the modified Mayo Wrist Score questionnaire was submitted to patients (Table 2). Clinical outcome was graded accordingly. Standard posteroanterior and lateral radiographs of most recent follow-up were obtained and compared with initial radiographs. Radial inclination, volar tilt, and radial length were measured in the radiographs by one of the authors (A.P.) who was not involved in the initial treatment. Any signs of incongruity were assessed according to Knirk and Jupiter's criteria (Figure 2).

RESULTS

All fractures were classified according to the AO/ASIF system. Nine fractures were C1 (complete articular fracture, articular simple, metaphyseal simple), five were C2 (complete articular,

articular simple, metaphyseal multifragmentary), and five were C3 fractures (complete articular fracture, multifragmentary).

Average follow-up was 15.1 months. Thirteen patients without concomitant injuries were hospitalized for an average 3.8 days. The remaining six patients with concomitant injuries were admitted for 4-10 days.

Clinical Results

The Modified Mayo Wrist Score System was used for clinical assessment. Eleven patients had no pain and 6 had mild pain with vigorous activities or weather changes. No patient had moderate pain with activities of daily living or pain at rest. Twelve patients were very satisfied and 7 were moderately satisfied; no patient was dissatisfied. Range of motion and grip strength were evaluated as a percentage of the normal wrist. Four patients had regained full range of motion (ie, 70° flexion, 70° extension, 20° radial inclination, and 30° ulnar inclination). The remaining 15 patients had achieved 75%-99% of normal range of motion and grip strength. Overall, 12 patients had good and excellent results, 5 had fair, and 2 had poor results.

Radiographic Results

Radial length, volar tilt, and radial inclination were measured. Preoperatively, mean radial length was 7.9 mm (range: 0-15 mm), mean volar tilt was 13° dorsally (range: 19° volarly to 30° dorsally), and average radial inclination was 14.8° (range: 2°-26°). At follow-up,

mean radial length was 11 mm (range: 8-16 mm), mean volar tilt was 11.3° (range: 6°-24°), and average radial inclination was 17.9° (range: 10°-27°).

Radiographs obtained preoperatively and at most recent follow-up were assessed for articular incongruity and classified using the Knirk and Jupiter system. Preoperatively, 12 patients had grade 0, 5 had grade 1, and 2 had grade 2. At most recent follow-up, 15 patients had grade 0, 3 had grade 1, and 1 had grade 2 (Figure 2).

Two patients underwent reoperation. Patient 14 underwent reoperation 7 days after initial surgery because of inadequate initial reduction. Palmar plate and screws were removed, and augmented external fixation with Norian SRS applied on the dorsal surface was performed. Patient 18 had excessive fragmentation of the articular surface and severe collapse of the radius that could not be restored. Six months after initial treatment, ulnar shortening was performed.

There were no nonunions, infections, or sensory nerve irritation. Between postoperative weeks 8 and 10, all fractures had united radiographically. Partial resorption of Norian SRS was noted in the radiographs of all patients at most recent follow-up. In two patients (10 and 16), intra-articular extrusion of the product was detected in immediate postoperative radiographs and at most recent follow-up (Figure 3). Patient 16 was unable to flex the distal phalanx of her thumb 2 months postoperatively. Late rupture of the flexor pollicis longus was diag-

TABLE 2

Modification of the Mayo Wrist Scoring Chart

25 20 15 10 5 0 25 20	No pain Mild pain with vigorous activities Pain only with weather changes Moderate pain with vigorous activities Mild pain with activities of daily living Moderate pain with activities of daily living Pain at rest Very satisfied Moderately satisfied
20 15 10 5 0 25 20	Pain only with weather changes Moderate pain with vigorous activities Mild pain with activities of daily living Moderate pain with activities of daily living Pain at rest Very satisfied Moderately satisfied
15 10 5 0 25 20	Moderate pain with vigorous activities Mild pain with activities of daily living Moderate pain with activities of daily living Pain at rest Very satisfied Moderately satisfied
10 5 0 25 20	activities Mild pain with activities of daily living Moderate pain with activities of daily living Pain at rest Very satisfied Moderately satisfied
5 0 25 20	living Moderate pain with activities of daily living Pain at rest Very satisfied Moderately satisfied
0 25 20	daily living Pain at rest Very satisfied Moderately satisfied
25 20	Very satisfied Moderately satisfied
20	Moderately satisfied
777	Moderately satisfied
10	
10	Not satisfied but working
0	Not satisfied, unable to work
25	100
15	75-99
10	50-74
5	25-49
0	0-24
25	100
15	75-99
10	50-74
5	25-49
0	0-24
cellent 90-100 od 80-89 r 65-79	
	25 15 10 5 0 25 15 10 5 0 cellent 90-100 od 80-89

nosed, which was probably caused by attrition to a mass of Norian SRS on the palmar surface of the metaphysis. She has not consented to further treatment.

In patient 7, scapholunate dissociation, undiagnosed before surgery, remained untreated. The patient failed to appear at the first two scheduled follow-up visits and when she finally presented after 18 months, a scapholunate advanced collapse wrist grade I was diagnosed. She refused further treatment.

DISCUSSION

Studies have shown that articular incongruity of the distal radius predisposes to increased symptoms, decreased range of motion and grip strength, 11 and post-traumatic osteoarthritis 12 if left untreated. Open reduction and stabilization with K-wires combined with external fixation is an effective method of treatment of intra-articular distal radius

fractures.¹³ Supplementary grafting of the metaphyseal cavity is necessary as clinical studies have shown improved outcome due to earlier removal of the external fixation and initiation of motion.¹⁴

Autologous bone graft has the highest biological activity, integrates rapidly, offers structural support that maintains fracture reduction, and provides an osteoconductive matrix with osteoinductive factors to promote healing. The "gold standard" bone graft, however, is available in limited quantity only and is related to donor site morbidity. This has led surgeons to use structural bone "substitutes" of which Norian SRS (ie, bone cement) has been used in metaphyseal fractures.

Compared with cancellous bone, Norian SRS has higher compressive strength (55 MPa) and lower tensile and shear strength.¹⁶ To create a cavity in the metaphysis with firm walls, in which Norian SRS would be injected, the loose cancellous bone was impacted as much as possible. However, whether the product adequately supported each single fragment was unknown.

Yetkinler et al,17 in a study with human cadaveric radii, reported fixation of an intra-articular distal radius fracture with calcium phosphate bone cement that produced results biomechanically comparable to those produced by Kwire fixation. The clinical relevance is that calcium phosphate bone cement with high compressive strength may provide adequate stability of the fracture and therefore serves as an alternative to K-wires. However, their model was a three-part type "T" intra-articular fracture with two major intra-articular fragments. Their model did not resemble the comminuted pattern of most of the fractures in the present series. Therefore, osteoconductive properties of Norian SRS were relied on rather than loading properties. Consequently, intra-articular fragments were stabilized with K-wires and external fixation was retained for at least 4 weeks.

No relation was found between fracture type and pain score according to the Mayo Wrist Score. The worst result, ie, mild pain with daily activities, was present in two patients with concomitant rupture of the scapholunate ligament. The rupture remained in patient 7 and was treated with augmented suture of the remnants in patient 5. However, patient 12 with scapholunate rupture and patient 4 with radioulnar subluxation had no pain. Patients had equally good results regarding range of motion and grip strength. No patient had <75% range of motion and grip strength compared to the normal wrist. Satisfaction score was not related to the fracture type. Patients who complained of pain, those with extrusion of Norian SRS in the joint, and those who underwent reoperation had low satisfaction scores. One patient with no pain was only moderately satisfied.

Overall, results were comparable with those of other series¹⁸ although follow-up was much shorter in the present

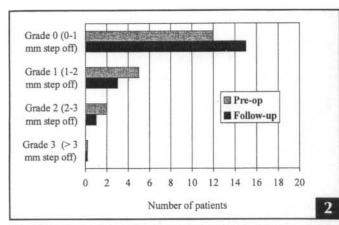






Figure 2: Articular incongruity of the patient population according to Knirk and Jupiter's classification. Figure 3: Patient 10. Postoperative AP (A) and lateral (B) radiographs show intra-articular placement of Norian SRS.

study. Postoperative radiographic examination revealed corrected radial length, radial inclination, and volar tilt, which remained at most recent follow-up. Improvement also was noted according to Knirk and Jupiter's criteria.

There was a slight alteration of Norian SRS either within the bone or in the joint on the last follow-up radiographs. This alteration is related to replacement of the product by host bone. Correlation of radiographic and histologic analyses have shown that regions implanted with Norian SRS have radiographic density that may not accurately reflect replacement of the apatite because this replacement is coupled with new bone deposition. Norian SRS in the joint space is a matter of concern but given the intra-articular extension of the fracture, it was noted in only two patients postoperatively. Range of motion was normal but grip strength was reduced in these two patients. Grip strength weakening is not entirely related to the presence of the product within the joint; one patient had articular stepoff postoperatively and the second flexor pollicis longus was ruptured. In the latter patient, irritation of the adjacent soft tissues and the median nerve particularly cannot be excluded in the future. Longterm follow-up is needed.

Early signs of osteoarthritis were not seen in this series because of the short length of follow-up. Because intra-articular step-off was detected in some patients, it is reasonable to suggest that signs of osteoarthritis will be seen in the future. However, as Catalano et al¹⁸ reported, these signs are not necessarily related to deterioration of clinical results.

Therefore, Norian SRS may be used in intra-articular distal radius fractures along with other means of stabilization as it is used in extra-articular fractures. Special attention should be paid to surgical technique. Extrusion of the product in the joint space or soft tissues should be avoided because of unknown long-term results.

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