Norian SRS versus external fixation in redisplaced distal radial fractures

A randomized study in 40 patients

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We compared Norian SRS, an injectable calcium phosphate bone cement, with external fixation in the treatment of redisplaced distal radial fractures by a prospective randomized study in 40 patients (women 50–80 years or men 60–80 years). After rereduction, the fracture was either stabilized by injection of SRS and immobilized with a cast for 2 weeks, or externally fixed with Hoffman's bar for 5 weeks. Each patient was evaluated at 2, 5, 7 weeks and at 3, 6 and 12 months. Functional parameters were grip strength, range of motion and pain. Radiographic parameters were radial angle, ulnar variance and dorsal tilt. The chosen primary effect variable was grip strength at 7 weeks. Patients treated by injection of SRS apatite had better grip strength, wrist extension and forearm supination at 7 weeks. There was no difference in functional parameters at 3 months or later. None of the methods could fully stabilize the fracture: radiographs showed a progressive redislocation over time. The results indicate that SRS can be used in the treatment of unstable distal radial fractures. The more rapid recovery of grip strength and wrist mobility in the SRS group appears to be due to the shorter immobilization time.

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Secondary displacement of distal radial fractures in the elderly can occur because of compaction of metaphyseal bone support to the distal radial joint surface. External fixation with ligamentotaxis may distract the fractures fragments and bone grafting, bone cement or injection of hydroxyapatite can be used to stabilize the fracture by filling the cancellous bone defect that appears after reduction. Hydroxyapatite may provide mechanical strength for stabilization through healing of the fracture. It also eliminates potential problems associated with autogenous bone transplantation or related to the exothermic reaction of the bone cement (Mjöberg et al. 1984, Constantz et al. 1995). We have previously described a treatment protocol for unstable distal radial fractures, using Norian SRS, an injectable calcium phosphate bone cement (Kopylov et al. 1996). We have now compared Norian SRS, with external fixation for treatment of redisplaced distal radial fractures.

Patients

All distal radial fractures treated with closed reduction and cast at the Department of Orthopedics in Lund are examined between 7 and 10 days after injury and fracture reduction. Patients were invited to participate in the study if radiographs at this examination showed one or more of the following criteria: 20° dorsal angulation, 2 mm or more of axial compression, 2 mm or more of incongruity in the radio-carpal or distal radio-ulnar joints. Inclusion criteria were: men between 60 and 80 years of age and women between 50 and 80 years. 40 consecutive patients, who agreed to participate after verbal and written information, were enrolled during a period of 1.5 years (1995–1997). Randomization between the 2 treatments was performed in the operating room, after rereduction and the groups were stratified according to sex and fracture type (extra- or intraarticular). There were 18 women and 2 men in each group. The mean age was 69 years in the SRS group and 66 in the external fixation group. In both groups, there were 11 articular and 9 extraarticular fractures. The patients were examined at 1 day, 2, 5 and 7 weeks, and 3, 6 and 12 months after the operation. All patients were operated on by one of us (PK). Grip strength was measured with the JAMAR dynamometer (Asimow Engineering Co., Los Angeles, USA) and wrist motion by a physiotherapist (KR) with a goniometer. All patients were asked

to assess their pain, residual disability and treatment satisfaction on three visual analogue scales (VAS) where 0 mm represented perfect result and 100 mm unbearable problems. Radiographs were taken with a posterior-anterior and a lateral view on each occasion. The measurements of the radial angle, the volar angle, the ulnar variance and the lateral angle between the scaphoid and the lunate were done by the same radiologist (KJ) and compared to the contralateral wrist. All data collection was checked by an external controller (Uthne Consulting, Stockholm, Sweden). The study was approved by the Ethics Commitee of Lund University.

Methods

Norian Skeletal Repair System (SRS) is an injectable bone mineral substitute that cures in vivo to form a carbonated apatite, with chemical and physical characteristics similar to the mineral phase of bone. 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 by approximately 12 hours. The reaction allows a working time of 5 minutes, after a mixing time of 2.5 minutes. The SRS hardening begins immediately after injection, due to the higher temperature in the tissue. During the 10-minute setting time after injection, all movements must be avoided, not to disturb the crystallization process.

In both groups, the fractures were rereduced in traction, with fingertraps and the arm in 60° of abduction, using an extension table. This method of fracture reduction ensured rigid stability during the SRS setting time. The entire procedure was controlled with an image intensifier. In the Norian group after closed re-reduction, the fractures were partially exposed through a dorsal incision less than 5 cm long and, if necessary, further reduced through the wound. Hematoma, callus and debris were scraped out of the defect, which was flushed with saline. SRS was then injected, filling the defect from palmar to dorsal. A short-arm dorsal splint was applied, kept for 2 weeks, and thereafter the wrist was mobilized.

In the external fixation group, 2 pins were drilled in the second metacarpal and 2 pins in the radius, and the fracture immobilized with an external fixator (Hoffman™, Howmedica, Malmö, Sweden). After 5 weeks, pins were removed and the wrist was mobilized. All patients had physiotherapy after both types of treatment.

Statistics

The study was designed to use grip strength at 7 weeks as the primary outcome variable. The results were analyzed with the Student's t-test. The other outcome variables are described using the 95% confidence interval for the differences between the two groups.

Results

There was no loss to follow-up, except 2 patients who refused to return at 1 year. Fewer than 2% of all visits were missed. More than 94% of the information was collected and the follow-up visits were done within 2 weeks from the scheduled time.

Complications

In the SRS group, 1 patient presented with a rupture of the extensor pollicis longus tendon. She had no complaint and declined a tendon transfer. 3 patients developed a carpal tunnel syndrome, one of them had to be operated on.

In the external fixation group, we noted 3 cases of pin-tract infection and 3 cases of skin adhesion. 4 patients had swelling of the wrist, and finger stiffness persisting up to 1 year in 2 cases.

Clinical parameters

At 7 weeks, the wrists treated with SRS showed almost half of the grip strength on the contralateral side. This was better than in the external fixation group, whose grip strength was less than a third of the contralateral wrist. The absolute values were 108 N and 65 N, respectively ($p = 0.002$). The intraarticular fractures treated with SRS had 38% of the contralateral grip strength versus 29% in those treated with external fixation. In extraarticular fractures, the grip strengths were 56% and 32%, respectively. At 3 months, both groups had improved and no significant difference was found (Figure 1).

Wrist motion in the SRS group, compared to the contralateral wrist, was also better than the external fixation group at 7 weeks, especially for wrist extension and supination. The absolute values were 43 and 27 degrees, respectively, for extension ($p = 0.009$) and 69 and 53 degrees for supination ($p = 0.001$). In both groups, mobility improved over time (Figure 1).

The pain VAS score did not differ significantly at any time-point. At 7 weeks, it was 22 mm for external fixation and 16 mm for Norian SRS. At 1 year, the pain score was 7 mm for external fixation and 8 mm for SRS.

At 5 weeks, when the external fixator was removed,

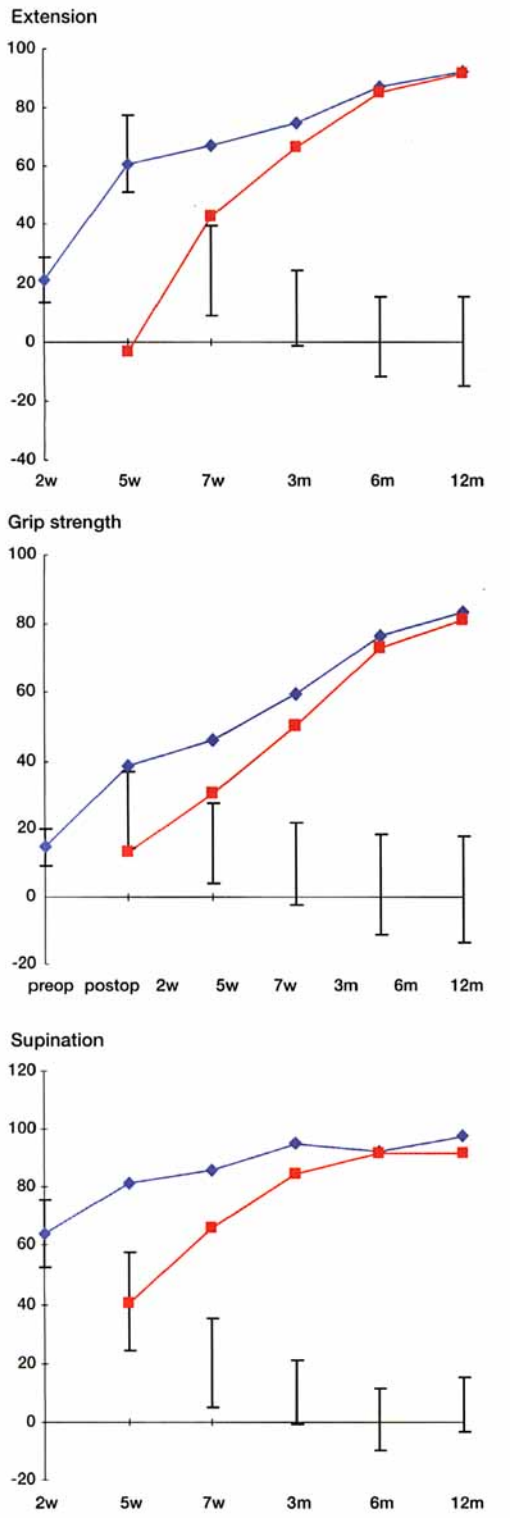


Figure 1. Clinical measurements at follow-up expressed as percent of uninjured hand. Vertical lines show the 95% confidence interval for the difference between the groups.

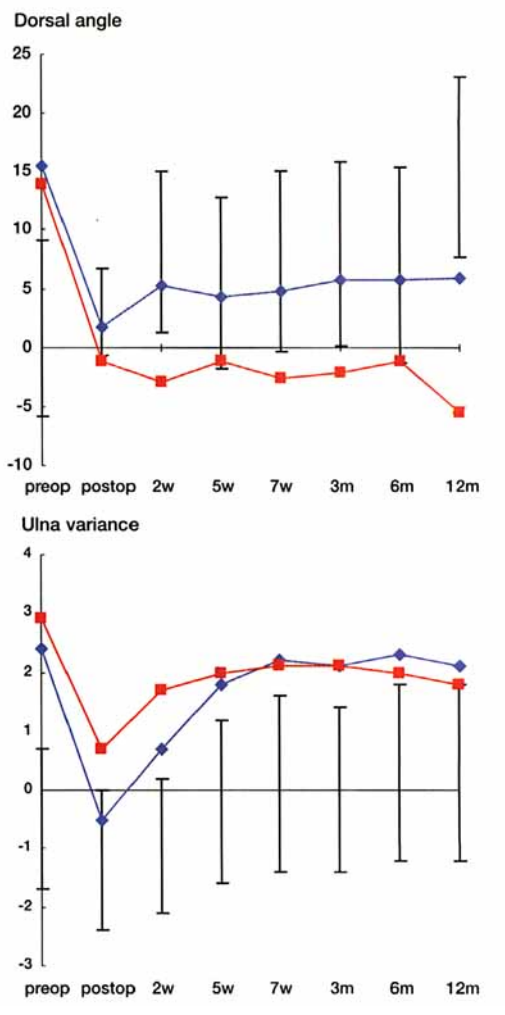


Figure 2. Radiographic measurements at follow-up. Ulnar variance in mm and dorsal angulation in degrees. Vertical lines show the 95% confidence interval for the difference between the groups.

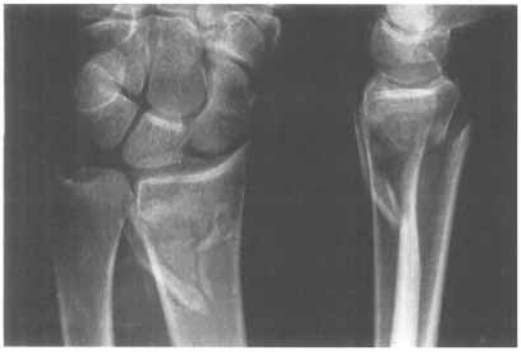
the VAS rating for impairment of the hand function was 66 mm for external fixation and 33 mm for SRS. Thereafter, the rating was similar to that for pain, with higher values for external fixation at 7 weeks. At 1 year, the mean values were 11 mm and 9 mm, respectively.

Radiographs

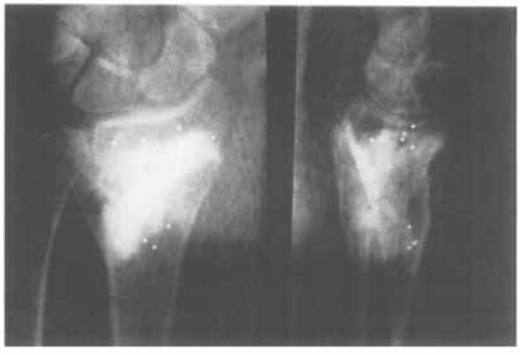
In both groups, the repeat fracture reduction was successful with a mean radial angle, dorsal angle and ulnar variance of 22°, 2° and –0.5 mm, respectively, in the SRS group and 19°, –1° and 0.7 mm in the external fixation group (Figure 2).

In both groups, there was a mild loss of fracture reduction over time. The SRS group lost 4° of radial angle, 4° of dorsal angle and 2.7 mm of ulna variance

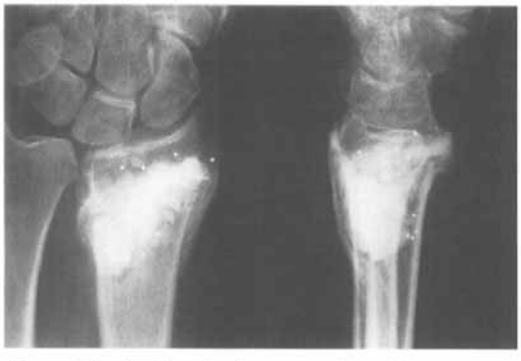
Figure 3. A case treated with Norian SRS.



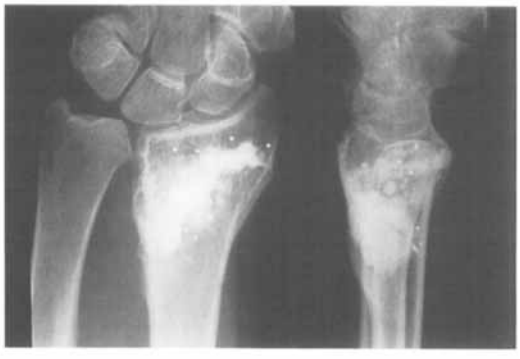
Before rereduction.



Postoperative control.



After mobilization 7 weeks after surgery. Note ulna +.



At 1 year.

between the postoperative and the 6-month examinations. The corresponding figures for external fixation were 1°, 0.5° and 1.3 mm, respectively. The loss of ulna variance during treatment was significant ($p = 0.001$) in each group. The loss of ulna variance was higher in the SRS group than with external fixation ($p = 0.03$).

Discussion

If the the main goal of the treatment of distal radial fractures is return of mobility and grip strength as soon as possible, our findings are in favor of SRS treatment. Similar results have been shown with other methods which allow early mobilization (Mac Auliffe et al. 1987, Schmalholz 1988). However, we found no difference between the 2 groups in the long term, and our results are in accordance with other studies using a long immobilization time (Cooney et al. 1979, Abbaszadegan et al. 1989).

If the main goal of the treatment of distal radial fractures is to obtain good radiographic alignment, with minimal ulna positive variance, to avoid risk of osteoarthritis, none of these methods is better than the others. In both groups, the fracture was not perfectly stabilized and a mild recurrence of the radius shortening occurred. At 1 year, the dorsal angle was better than our inclusion criteria, but the ulna variance was close to the preoperative value. We noted that the SRS group lost 2.7 mm of ulna variance during the healing period, in spite of our attempts to create a clean interface between bone and SRS. The SRS group had reached a better initial reduction position than the external fixation group because of the open reduction. This better starting position compensated for the greater shortening of the radius in the SRS group, so that the final positions were equal in both groups. Such compensation will probably not be achieved if the Norian SRS is introduced through a closed procedure. Loss of reduction during treatment has been observed by several authors (de Bruijn 1987, Hutchinsson et al. 1995, Mac Queen et al. 1996). No consensus has been reached about the need for rereduction of the distal radial fracture in the osteoporotic patient.

In terms of morbidity during and after the treatment, no advantage could be found in favor of one method or the other. Pin-tract problems in external fixation were relatively few and similar to other studies (Raskin and Melone 1993). Stiffness in relation to

the device is reported in the same proportion. Rupture of the extensor pollicis longus tendon is a well known complication of a distal radial fracture (Trevor 1950, Engkvist and Lundborg 1979); various mechanisms have been proposed. In our case (Helal et al. 1982), the reason may have been tendon attrition by the hydoxyapatite and we recommend careful removal of any extraosseous hydroxyapatite at the dorsum of the wrist. Volarly, the tendons and median nerve are protected by the pronator quadratus and no complication occurred because of extraosseous hydroxyapatite at this location. Carpal tunnel syndrome is also a well known complication of distal radial fractures. The frequency in our study was not higher than previously reported (Cooney et al. 1980) but we note that all cases were in the SRS group, and we emphasize the need to prevent postoperative edema.

Our findings indicate that SRS can be used to treat unstable distal radial fractures with clinical success. No important difference from external fixation could be demonstrated in the long term. With neither treatment could the postoperative position be fully maintained. The shorter immobilization time with SRS permitted earlier return of hand function. The question remains whether early mobilization by itself is enough to reach a good final result, even in the absence of fixation with SRS. That question is addressed in an ongoing study.

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