Norian SRS Cement Compared with Conventional Fixation in Distal Radial Fractures

A RANDOMIZED STUDY

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Background: A prospective, randomized multicenter study was conducted to evaluate closed reduction and immobilization with and without Norian SRS (Skeletal Repair System) cement in the management of distal radial fractures. Norian SRS is a calcium-phosphate bone cement that is injectable, hardens in situ, and cures by a crystallization reaction to form dahlite, a carbonated apatite equivalent to bone mineral.

Methods: A total of 323 patients with a distal radial fracture were randomized to treatment with or without Norian SRS cement. Stratification factors included fracture type (intra-articular or extra-articular), hand dominance, bone density, and the surgeon’s preferred conventional treatment (cast or external fixator). The subjects receiving Norian SRS underwent a closed reduction followed by injection of the cement percutaneously or through a limited open approach. Wrist motion, beginning two weeks postoperatively, was encouraged. Control subjects, who had not received a Norian SRS injection, underwent closed reduction and application of a cast or external fixator for six to eight weeks. Supplemental Kirschner wires were used in specific instances in both groups. Patients were followed clinically and radiographically at one, two, four, and between six and eight weeks and at three, six, and twelve months. Patients rated pain and the function of the hand with use of a visual analog scale. Quality of life was assessed with use of the Short Form-36 (SF-36) health status questionnaire. Complications were recorded.

Results: Significant clinical differences were seen at six to eight weeks postoperatively, with better grip strength, wrist range of motion, digital motion, use of the hand, and social and emotional function, and less swelling in the patients treated with Norian SRS than in the control group (p < 0.05). By three months, these differences had normalized except for digital motion, which remained significantly better in the group treated with Norian SRS (p = 0.015). At one year, no clinical differences were detected. Radiographically, the average change in ulnar variance was greater in the patients treated with Norian SRS (+2.0 mm) than in the control group (+1.4 mm) (p < 0.02). No differences were seen in the total number of complications, including loss of reduction. The infection rate, however, was significantly higher (p < 0.001) in the control group (16.7%) than in the group treated with Norian SRS (2.5%) and the infections were always related to external fixator pins or Kirschner wires. Four patients with intra-articular extravasation of cement were identified; no sequelae were observed at twenty-four months. Cement was seen in extraosseous locations in 112 (70%) of the SRS-treated patients; loss of reduction was highest in this subgroup (37%). The extraosseous material had disappeared in eighty-three of the 112 patients by twelve months.

Conclusions: Our results indicate that fixation of a distal radial fracture with Norian SRS cement may allow for accelerated rehabilitation. A limited open approach and supplemental fixation with Kirschner wires are recommended. Additional or alternate fixation is necessary for complex articular fractures.

Level of Evidence: Therapeutic study, Level I-1a (randomized controlled trial [significant difference]). See Instructions to Authors for a complete description of levels of evidence.
methacylate bone cement. In 1989, Schmalholz demonstrated the efficacy of polymethylmethacrylate in the management of distal radial fractures. Other authors have advocated the use of cement in the treatment of distal radial fractures, particularly in older patients. Despite these encouraging reports, polymethylmethacrylate cement fixation of fractures has not been embraced, presumably because the compound is neither remodeled nor incorporated and it cures through an exothermic reaction, potentially impairing fracture-healing.

The Norian Skeletal Repair System (SRS; Norian, Cupertino, California) is a biocompatible cement that has a higher compressive strength than cancellous bone. It is an injectable, fast-setting paste that cures in vivo at physiologic pH and temperature to form an osteoconductive carbonated apatite with chemical and physical properties similar to those of bone mineral. The potential value of SRS in managing distal radial fractures has been demonstrated in two small series with use of percutaneous and open techniques. More recently, a larger, prospective study comparing SRS and cast treatment demonstrated superior clinical and radiographic results in the SRS-treated patients.

The objective of this randomized, prospective multicenter clinical trial was to determine the safety and effectiveness of Norian SRS cement compared with conventional treatment in patients with unstable and/or displaced fractures of the distal end of the radius. The two treatment groups were compared with use of standardized clinical and radiographic outcome measures.

Materials and Methods

Study Design

This randomized, prospective, active, concurrently controlled clinical trial was initiated in January 1995 to evaluate the treatment outcomes of matched cohorts of patients with distal radial fractures managed with either Norian SRS cement (study) or conventional (control) treatment. A total of 323 patients were enrolled at twenty-three investigative centers. The institutional review board at each center approved the study protocol and randomization process. The investigators were required to attend a bioskills workshop on the application of Norian SRS cement. A detailed consent form was signed by each patient prior to enrollment.

Patient Selection

Patients who sustained a displaced and/or unstable (comminuted) distal radial fracture and were at least forty-five years old and living independently were considered for inclusion in the study. All patients were volunteers. Inclusion and exclusion criteria were intended to limit the distal radial fractures to isolated, low-energy displaced fractures that would require manipulative reduction and some form of immobilization. The inclusion and exclusion criteria are listed in the Appendix.

Randomization

The patients were assigned to a treatment group (SRS or conventional therapy) according to a stratified and blocked randomization schedule designed to ensure matching and balance between the groups at each site and overall. The randomization was based on four parameters: fracture type (intra-articular or extra-articular), bone mineral density (average or below average), side of injury (dominant or nondominant hand), and the type of designated conventional immobilization (cast or external fixator). The fracture type was classified as intra-articular if any fracture line extended into the radiocarpal or distal radioulnar joint. The Older et al. classification systems were used to further define the fracture. Bone mineral density was determined by dual-x-ray absorptiometry of the uninjured distal radius. Patients were classified as having either “average” (values of ≥0.57 g/cm²) or “below average” bone quality. The involved limb was defined as dominant or nondominant. The fourth randomization parameter was the designation of a cast or an external fixator for immobilization. For each fracture, the investigator preoperatively assigned his or her preferred control treatment. Fractures that then were randomized to the control group received the preselected treatment (cast or external fixator). Fractures that were randomized to the study group and received SRS cement received a designation indicating which form of conventional treatment they would have received had they been randomized to the control group (SRS-designated cast or SRS-designated external fixator). This randomization method was implemented to attempt to control for fracture severity while permitting the investigator to treat the control subjects with his or her preferred method.

Sample Size

Radial length and grip strength data were used to perform a power analysis. In order to detect a mean difference (and standard deviation) in radial length of 0.75 ± 1.9 mm and a mean grip strength difference of 5% ± 10% with 90% power, a sample size of 145 patients per treatment group was needed. A target of 162 enrolled patients per treatment group was adopted to accommodate an assumed 10% attrition rate.

Treatment

All procedures were performed in the operating room with the patient under regional or general anesthesia, within five days after the injury. SRS treatment included a closed reduction under image intensification, followed by injection of SRS cement into the metaphyseal bone defect either through a dorsal percutaneous or a limited open technique. Early in the study, the percutaneous method was favored for its apparent simplicity. However, many investigators had difficulty injecting the cement into the fracture site, encountering obstructions such as hematoma, cancellous bone fragments, and inadequate space in which to inject. In addition, the rate of extravasation was quite high. Consequently, beginning with the thirteenth study patient, a limited open technique was used exclusively. A 1.5 to 2-cm dorsal incision was made directly over the metaphyseal component of the fracture between the third and fourth extensor compartments under tourniquet hemostasis. The so-called fracture void was prepared by evac-
uating the fracture hematoma and impacting the crushed metaphyseal bone to a stable rim with a small elevator or tamp. The cement was then injected under fluoroscopic control, excess cement was removed with a sponge, and the tourniquet was then released. The limb was not manipulated for ten minutes to allow the cement to set. The wound was closed, and a short arm cast was worn for two weeks. The patient then wore a removable splint for four additional weeks.

Supplemental Kirschner-wire fixation was permitted in specific instances, including displaced articular fractures that remained unstable following reduction or nondisplaced articular fractures at risk of displacement during injection. The wires were intended to be used to resist only noncompressive loads (shearing or tensile forces) and were not to be used as the principal fixation of the metaphyseal component of the fracture. Intrafocal (Kapandji) pinning was not permitted. The protocol specified that the Kirschner wires be placed prior to SRS injection and that they be maintained for a minimum of twenty-four hours to avoid disruption of the cement during its curing period.

The control group underwent a closed reduction of the fracture, followed by the application of a short arm cast or an external fixator, depending on the preference of the individual investigator. Percutaneous pins were placed at the discretion of the investigator according to previously described methods; any configuration except intrafocal pinning was permitted. Immobilization was discontinued at six to eight weeks postoperatively, as determined by the treating surgeon.

Prior to discharge, all patients were instructed in digital range-of-motion exercises and limb elevation to reduce edema. Occupational therapy, including wrist and forearm range-of-motion exercises, was initiated at two weeks for the SRS group and at the time of removal of the cast or external fixator for the control group.

Evaluations
Follow-up evaluations were specified at one, two, four, and between six and eight weeks, and at three, six, and twelve months after treatment for all patients. At each visit, designated subjective, objective, and radiographic data were obtained, and complications were recorded.

Clinical Evaluation
The patient was asked to assess both wrist pain and hand function with use of a visual analog scale at each follow-up visit. Interim pain medication usage was documented. During follow-up evaluations at one week and six to eight weeks and at six and twelve months, the patient completed the standard validated Short Form-36 (SF-36) health status questionnaire.

Functional measurements of digital, wrist, and forearm motion were obtained at each visit by designated occupational therapists with use of standardized techniques. Grip strength was measured with use of the Jamar dynamometer (Therapeutic Equipment, Clifton, New Jersey) at the six to eight-week and the three, six, and twelve-month follow-up visits.

Edema was measured in both groups at the one, two, and six to eight-week follow-up intervals. Circumferential measurements were obtained at the forearm (10 cm distal to the olecranon process), wrist, and proximal and middle phalanx of each finger. For patients managed with a cast, the wrist and forearm measurements began at the time of cast change or removal. Digital circumferences were averaged for the proximal and middle phalanx. Edema was expressed as a percentage of the measurements of the contralateral limb.

The Jebsen dexterity test was administered at the six to eight-week and the three, six, and twelve-month intervals. The time needed to perform each activity was recorded and compared with that for the uninjured limb. The clinical outcome at twelve months was also assessed with use of the scoring system of Green and O’Brien, as modified by Cooney et al. In this 100-point scale, pain, functional status, range of motion, and grip strength are assigned equal weight. The visual analog scale for pain was used to calculate the pain score.

Radiographic Evaluation
Standard posteroanterior and lateral radiographs were made at each follow-up visit. Independent bone radiologists reviewed the radiographs and measured radial length, radial angle (ulnar inclination), volar/dorsal angle, ulnar variance, radial shift, and articular step-off. Radiographic parameters were compared with those of the uninjured wrist, with the difference expressed as the change in millimeters or degrees as appropriate.

Radiographic criteria were established for assessing failure (loss of reduction). These included a change in the radial length of >5 mm compared with the contralateral side, a dorsal angle of >10° and/or a change in the volar/dorsal angle of >20°, and an articular step-off of >2 mm. Patients who had loss of reduction were considered to have had a treatment failure, and they were considered in the final analysis regardless of whether any secondary interventions had been required.

Statistical Methods
Statistical analysis was completed with the SAS statistical software package (version 6.12; SAS Institute, Cary, North Carolina), the JMP statistical software package (version 3.2.1; SAS Institute), and StatXact (version 4; Cytel Statistical Software, Cambridge, Massachusetts). Demographic characteristics of the study groups were compared with the use of univariate analysis of variance for the continuous variables and with the use of chi square for the categorical variables. Univariate analyses of variance were used to identify differences between treatment groups with respect to functional and radiographic outcome, swelling, pain, use of pain medication, and health survey results. To control for possible confounding factors, covariate adjustment was used for study stratification and demographic biasing variables. Repeated-measures analysis of variance with covariate adjustment was used to compare the study groups over time with respect to functional and radiographic outcomes. The adverse events of the two study groups were compared with...
the use of chi-square and Fisher exact tests. The frequencies of individual and combined radiographic failure and individual and combined functional failure as well as overall failure, including reoperations, were calculated as exact binomial confidence intervals. All failure frequencies of the study groups were compared with the use of the Fisher exact test. Logistic regression with covariates was used to analyze the influence of covariates in the failure analysis. All reported p values are two-sided; p values of <0.05 were considered to be significant.

Patient Cohort

A total of 323 patients were enrolled in the study. Of those patients, 161 were randomized to treatment with Norian SRS (study patients) and 162 were randomized to conventional treatment (control subjects) (Table I). Two hundred and seventy-two patients (84%) were women and fifty-one (16%) were men, and the average age was sixty-four years. With the exception of gender, no differences were identified between the treatment groups. The proportion of women in the control group (88%) was higher than that in the SRS group (80%) (p = 0.04). Comorbidities were comparable. Nearly 90% of the total study population was white, and no differences with respect to race were noted between the two groups. The numbers of intra-articular fractures were equivalent for both groups, with seventy-five intra-articular fractures in the study group and seventy-three in the control group (p = 0.78). In addition, no significant differences between groups were noted with respect to the fracture types classified by any of the three methods (Table II).

Table II Distribution of Fractures According to the AO Comprehensive Classification Scheme

<table>
<thead>
<tr>
<th>Fracture Type</th>
<th>No. (%) of Fractures Treated with Norian SRS</th>
<th>No. (%) of Fractures in Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>A 2.1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A 2.2</td>
<td>41 (25.5)</td>
<td>32 (19.8)</td>
</tr>
<tr>
<td>A 3.1</td>
<td>18 (11.2)</td>
<td>26 (16)</td>
</tr>
<tr>
<td>A 3.2</td>
<td>26 (16.1)</td>
<td>27 (16.7)</td>
</tr>
<tr>
<td>A 3.3</td>
<td>5 (3.1)</td>
<td>5 (3.1)</td>
</tr>
<tr>
<td>C 1.1</td>
<td>34 (21.1)</td>
<td>30 (18.5)</td>
</tr>
<tr>
<td>C 1.2</td>
<td>13 (8.1)</td>
<td>15 (9.3)</td>
</tr>
<tr>
<td>C 1.3</td>
<td>2 (1.2)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>C 2.1</td>
<td>19 (11.8)</td>
<td>24 (14.8)</td>
</tr>
<tr>
<td>C 2.2</td>
<td>2 (1.2)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>C 3.3*</td>
<td>1 (0.6)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>161 (100)</td>
<td>162 (100)</td>
</tr>
</tbody>
</table>

*AO C 3.3 was not a fracture designated for study inclusion. One investigator classified a multifragmentary articular fracture as a C 3.3.
Subjective Evaluation
The study patients reported less pain on the average than the control patients did at all follow-up visits, with a significant difference at two weeks (p = 0.02) and four weeks (p = 0.02). On the average, the study patients required less postoperative pain medication than the control patients did at all follow-up visits. The differences were significant only at two weeks (p = 0.004). The patient-reported rating of the hand was significantly greater for the study patients at both four weeks (p = 0.007) and six weeks (p = 0.0001) compared with that of the control patients. No other significant differences were observed.

The SF-36 health status questionnaire showed significant differences in function at the six to eight-week time-point. The study patients scored significantly higher than the control patients did in five of the eight domains, including fewer limitations due to pain, less limitation of role due to physical or emotional problems, a better state of mental health, and an improved ability to perform normal social activities (p < 0.05). No other significant differences were noted at any other time-points.

Objective Evaluation
At six to eight weeks, the study patients exhibited a greater mean grip strength than did the control patients (18 lb [8 kg] compared with 10 lb [4.5 kg], or 37% compared with 21.5% of that of the contralateral side, respectively) (p < 0.0001). The study patients also demonstrated a greater mean range of wrist and forearm motion in all planes at this time-point (see Appendix). By three months, grip strength and wrist motion parameters were equivalent for the two groups. The average grip strength and motion continued to increase in both groups at similar rates for the remainder of the study period.

Radiographic Evaluation (Figs. 1-A through 1-F)
At one week postoperatively, the SRS-treated fractures were in slightly better position, compared with the uninjured wrist, than were the fractures in the control group, with significant differences (p < 0.05) with respect to loss of radial length (1.3 compared with 2.6 mm), loss of radial angle (2.7° compared with 4.2°), radial shift (1.7 compared with 2.1 mm), change in volar/dorsal angle (7.3° compared with 10.6°), and change in ulnar variance (0.2 compared with 0.4 mm). The fractures in both groups tended to settle with time, but more so in the study group such that, by six to eight weeks, the groups were radiographically equivalent with the exception of the change in ulnar variance, which was higher in the study group (2.2 compared with 1.5 mm) (see Appendix). The results at twelve months were similar, including loss of radial length (4.5 compared with 3.7 mm), loss of radial angle (4.5° compared with 4.6°), radial shift (2.7 compared with 2.4 mm), change in volar/dorsal angle (10.3° compared with 10.5°), and change in ulnar variance (2.0 compared with 1.4 mm). Only the change in ulnar variance was significant (p = 0.02).

Covariate adjustment indicated that, for both groups, extra-articular fractures were associated with greater loss of radial length, loss of radial angle, change in volar/dorsal angle, and radial shift than were intra-articular fractures (p < 0.05). The cast or external fixator treatment designation also showed a significant difference. Within the control group, the patients managed with a cast, compared with those managed with an external fixator, had a greater loss of radial length (4.5° compared with 1.9 mm), loss of radial angle (6.0° compared with 1.9 mm), radial shift (2.1 compared with 1.9 mm), change in volar/dorsal angle (13.0° compared with 5.6°), and change in ulnar variance (1.5 compared with 1.1 mm).

Gender appeared to exert an independent effect only with respect to ulnar variance: men had a larger change in mean ulnar variance (2.5 mm) than did women (1.5 mm) (p = 0.0465). There were significantly more men in the study
group. When controlled for gender, the two treatment groups demonstrated no significant difference with respect to ulnar variance. Neither hand dominance nor the dual x-ray absorptiometry score appeared to have an independent effect on the radiographic result.

With respect to articular step-off, no significant differences were noted between the two groups. At the time of the three-month evaluation, eight of the seventy-four intra-articular fractures treated with SRS had a detectable step-off, with a mean value of 0.9 mm. None of the study patients had a step-off of >2 mm. In the control group, eleven of the sixty-nine intra-articular fractures had a detectable step-off, with a mean value of 1.1 mm. One of the control patients had a step-off of >2 mm.

As reported by the investigators, loss of reduction occurred in forty-six (29%) of the study patients and in forty (25%) of the control patients; the difference was not significant. Secondary treatment was performed in nine (20%) of the study patients and seventeen (43%) of the control patients following loss of reduction (p = 0.0209). Interventions included open reduction with internal fixation, autogenous bone-grafting, osteotomy, or a repeat closed reduction and cast application. These patients, who were considered to have had failure of treatment, remained in the study for twelve months.

**Complications**

There were no systemic complications specifically related to the use of SRS. Seventy-four (46%) of the 161 study patients experienced complications compared with eighty-two (51%) of the 162 control patients (p = 0.403) (see Appendix). There were a total of 101 complications in the study group and 121 in the control group. There were no significant differences in the occurrence of the specific events reported with the exception of infection, which occurred in four (2.5%) of the SRS-treated patients and twenty-seven (16.7%) of the control patients (p < 0.001). Within the SRS-treated group, infection occurred exclusively in patients with supplemental Kirschner wires. One of these patients had development of osteomyelitis, requiring removal of the SRS cement, intravenous antibiotics, and application of an external fixator. He had no persistent or recurrent osteomyelitis, and the final result was considered satisfactory. In the control group, eighteen infections were related to the external fixator and nine infections were related to the Kirschner wire. No control patient had development of osteomyelitis.

Loss of reduction was by far the most common complication overall, involving forty-six patients (29%) in the SRS group and forty patients (25%) in the control group; the difference was not significant (p = 0.4). A total of twenty-three patients (14%) in the study group experienced neuropathies compared with thirty-two patients (20%) in the control group. In the study group, carpal tunnel syndrome developed in four patients and in each one it was associated with loss of reduction, with the onset of symptoms ranging from two weeks to twelve months postoperatively. In the control group,

![Fig. 1-A](image1.png)

**Figs. 1-A through 1-F** Radiographs of a fifty-two-year-old woman with a dorsally displaced distal radial fracture of the right wrist. **Fig. 1-A** Posteroanterior radiograph.

For both groups, the presence of Kirschner wires had a significant impact on maintenance of reduction. In the control group, loss of reduction occurred in eleven (13%) of eighty-two patients who had Kirschner wires and in thirty-eight (38%) of eighty patients who had not had wires (p ≤ 0.001). In the study group, loss of reduction occurred in twelve (19%) of sixty-four patients who had Kirschner wires and in thirty-four (35%) of ninety-seven patients who had not had wires (p ≤ 0.025).

**Influence of Supplemental Kirschner Wires**

In the control group, Kirschner wires were used in eighty-two patients (51%). An average number of 2.2 wires (range, one to five wires) were in place for a mean of fifty-one days. In the study group, supplemental Kirschner wires were used in sixty-four patients (40%). An average of 1.5 Kirschner wires (range, one to three wires) were in place for a mean of twenty-eight days. In two patients, intraoperative removal of the Kirschner wires following injection of the SRS resulted in fragmentation of the material and loss of reduction.

![Fig. 1-B](image2.png)

Lateral radiograph.
NORIAN SRS CEMENT COMPARED WITH CONVENTIONAL FIXATION IN DISTAL RADIAL FRACTURES

Tendinopathies (tendinitis, tendon adhesion, weakness, rupture, or stenosing tenosynovitis) were reported in twelve study patients and eight control patients. Tendon ruptures occurred in six patients in the study group and in two patients in the control group; all ruptures involved the extensor pollicis longus tendon. Each of the extensor pollicis longus tendon ruptures in the study group occurred in patients with extraosseous cement dorsally; the ruptures were identified an average of 161 days (range, thirty-six to 337 days) postoperatively. There was no apparent relationship between the volume of extraosseous cement and tendon rupture. Both of the extensor pollicis longus tendon ruptures in the control group occurred in patients managed with a cast, and the ruptures were identified forty-two and 281 days postoperatively.

SRS cement was observed radiographically within the soft tissues in 112 (70%) of the 161 study patients. The location of the extraosseous cement was dorsal in 101 patients, volar in seventy-one, ulnar in fifty-four, and radial in forty-seven. The amount of cement diminished with time in all instances. Complete resorption was observed in seventy (63%) of the 112 patients by six months and in eighty-three patients (74%) by twelve months.

A separate analysis of the patients with extraosseous SRS cement was identified radiographically within the soft tissues in 112 (70%) of the 161 study patients. None of the four patients had associated symptoms or clinical sequelae attributable to the intra-articular cement. The amount of cement within the joint diminished over time and was not associated with radiographic evidence of arthritis at the time of the most recent follow-up at an average of forty-eight months postoperatively (range, twenty-four to seventy-two months).

SRS cement was observed radiographically within the radiocarpal and/or radioulnar joint space in four of the 161 study patients. None of the four patients had associated symptoms or clinical sequelae attributable to the intra-articular cement. The amount of cement within the joint diminished over time and was not associated with radiographic evidence of arthritis at the time of the most recent follow-up at an average of forty-eight months postoperatively (range, twenty-four to seventy-two months).

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SRS cement was observed radiographically within the radiocarpal and/or radioulnar joint space in four of the 161 study patients. None of the four patients had associated symptoms or clinical sequelae attributable to the intra-articular cement. The amount of cement within the joint diminished over time and was not associated with radiographic evidence of arthritis at the time of the most recent follow-up at an average of forty-eight months postoperatively (range, twenty-four to seventy-two months).

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cement demonstrated greater loss of alignment radiographically than that seen in either the study patients without extrarossoseous cement or in the control group. Loss of reduction was noted in forty-one (37%) of the 112 patients with extrarossoseous SRS compared with five (10%) of the forty-nine study patients without extrarossoseous SRS and forty (25%) of the 162 control patients. In addition, total complications were more common in patients with extrarossoseous SRS cement. Sixty-three (56%) of the 112 study patients with extrarossoseous cement experienced complications in contrast to eleven (22%) of the forty-nine study patients without extrarossoseous cement and eighty-two (51%) of the 162 control patients.

**Discussion**

This investigation is the largest prospective, randomized, controlled study of distal radial fractures that has been reported to date, as far as we know. The patient cohorts were identical demographically in nearly every parameter including fracture type and severity. The size of the trial, the use of standardized outcome instruments, and the length and completeness of follow-up were intended to minimize problems noted in prior clinical studies.

While the importance of the final functional outcome following a distal radial fracture is indisputable, the time to return to function perhaps has been underappreciated. In a study of patients at least eight weeks following a distal radial fracture, Beaul et al. demonstrated substantial impairment across a spectrum of activities, including personal hygiene and domestic and social activities, particularly when the dominant limb was affected. Undoubtedly, their results would have been even more dramatic had the study examined earlier time-points. In a similar study, Morris found that older adults had substantially lower physical functioning during the period of immobilization. In the current study, the SRS-treated patients had the wrist immobilized for four to six weeks less than the control patients did. The earlier improvement in function in the study patients is therefore not surprising.

The pattern of recovery of wrist motion in this series parallels the findings in other prospective studies of early motion following stable fixation with either internal or non-bridging external fixation. The ultimate range of motion seems to be unaffected by early initiation of motion.

Despite the early wrist motion, the SRS-treated fractures behaved radiographically in a manner similar to those in the control group. Some settling of most fractures occurred during healing. Ultimately, the study patients lost slightly more length as measured by ulnar variance. The mean difference between the groups of 0.6 mm does not appear to be clinically significant. These radiographic results are equivalent to or better than those reported in the literature for similar fractures.

In what we believe is the only other randomized study of SRS cement in the treatment of acute distal radial fractures, Sanchez-Sotelo et al. demonstrated superior clinical and radiographic results in the SRS-treated group. However, several important differences between the studies deserve emphasis. Patients in their control group were treated with closed reduction and application of a cast alone. It has been fairly well established that cast treatment alone is often inadequate for unstable distal radial fractures. The relatively poor results in their control group (a 41.8% rate of malunion) substantiate this observation. In contrast, the present study attempted to reflect the current standard of care in the control group by including treatment with a cast, external fixation, and percutaneous pin fixation. Overall, the radiographic results in our control group were superior, minimizing differences between the control and study groups. Furthermore, in their series, the final radiographic result was compared with the immediate postreduction radiographs. Our radiographic results were measured relative to the normal wrist, thereby eliminating the variable of the quality of the initial reduction. This method, however, probably magnified the values of our radiographic changes.

A potential source of bias in the study was the treatment designation of a cast or external fixator. Surgeon preference, including factors related to the patient and the fracture, was considered in assigning a treatment designation of a cast or external fixator to a particular fracture. Nevertheless, there were no significant differences in fracture classification and severity between the groups or subgroups.

Failure to include carpal malalignment in the data analysis may be considered another potential weakness of this study. Bickerstaff and Bell demonstrated a strong correlation between function and dorsal carpal instability. Analysis of our clinical results demonstrated that dorsal angulation was associated with a reduction of grip strength. However, intercarpal angles were not routinely measured on follow-up radiographs.

The use of percutaneous pins was another confounding factor. While the presence of Kirschner wires did not influence the overall outcome of the study and control groups, the rate of loss of reduction was significantly higher within each group when Kirschner wires were not used. An in vitro biomechanical comparison of Kirschner wire and SRS fixation of intra-articular distal radial fractures has demonstrated the superiority of SRS cement in resisting compressive loads. In vivo, however, these fractures are also subjected to tensile and shear forces, which are poorly controlled by the cement. It is not yet clear which fracture patterns can safely be managed with SRS cement alone.

The nearly 50% complication rate for both groups in this series is substantially higher than the 20% to 31% complication rate reported in several large retrospective studies. The prospective nature of the current study and the rigorous reporting at each follow-up visit of any deviations from normal recovery permitted a comprehensive account of complications. This method of reporting is likely more accurate than a retrospective review. Some minor events, such as tenosynovitis, have not been included routinely in other series and may not generally be considered complications related to fracture treatment.

In what we believe is the largest series to date on complications related to distal radial fractures, Cooney et al. considered loss of reduction (which occurred in 27% of the patients)
a complication only if it went on to a malunion (5.3%) requiring subsequent treatment. In the current study, loss of reduction was defined by the investigators a priori with use of generally accepted radiographic criteria predictive of poor outcome\textsuperscript{17,23,38,45,31-34}. The majority of the patients who lost reduction radiographically did well clinically. Excluding the complications related only to radiographic findings, the overall complication rate for both groups would be approximately 22%, which is consistent with that in previous studies.

The loss-of-reduction issue highlights two important points. First, radiographic signs of loss of position were not uncommon in the control group, despite treatment by established and experienced surgeons with use of standard techniques. Second, with few exceptions, the clinical outcome of the patients in both groups was independent of the radiographic outcome.

The risk of extrusion of the SRS cement into undesirable locations has been a substantial concern. In the series described by Sanchez-Sotelo et al.\textsuperscript{19}, one patient had symptomatic intra-articular cement necessitating surgical removal. Of the seventy-five intra-articular fractures treated with SRS in our series, four had intra-articular extrusion. In each instance, the patient was asymptomatic, and the amount of intra-articular cement diminished with time. No arthritic changes were evident in any of the four wrists at twenty-four months, although clearly a longer follow-up period is necessary.

The infrequent presence of intra-articular SRS appears to be related to a combination of an adequate fracture reduction and the thixotropic properties of the material, which is of a toothpaste consistency and does not flow readily into narrow channels. Nevertheless, we currently recommend careful inspection of the postinjection radiographs and evacuation of any intra-articular cement identified intraoperatively.

The presence of extraosseous cement, seen in the majority of patients, was associated with a higher complication rate. Delivery of the SRS cement through a mini-open approach facilitated removal of excess dorsal material. Volar extrusion, although quite common, was not associated with any unique complications, and we did not remove it. Dorsal extrusion of cement can interfere with extensor tendon function. In our series, tendon ruptures exclusively involved the extensor pollicis longus tendon in both groups. This finding is consistent with those in other reports of tendon ruptures in association with distal radial fractures\textsuperscript{12,23,35-39}. Extraosseous SRS was identified dorsally in each study patient who sustained a tendon rupture; this finding is of some concern. However, the prevalence of extensor pollicis longus tendon ruptures in the SRS group was not significantly different from that in the control group or the historical prevalence of 1% to 5%. Longer follow-up of our study patients is required to determine the possible adverse effects of extraosseous extrusion of the cement.

Our data suggest that Norian SRS cement provides adequate fixation for the majority of distal radial fractures to permit early wrist mobilization. It is possible that the radiographic results would have been better with a longer period of postoperative immobilization. However, for the majority of patients, the earlier return of function following cement fixation appeared to outweigh the slightly inferior radiographic result. On the basis of our current understanding of this form of fixation, we make the following recommendations. A limited open approach for fracture site preparation should be used. Supplemental Kirschner wires should be placed prior to cement injection and should be left in place for a minimum of two weeks postoperatively. Whenever possible, extraosseous and intra-articular cement should be removed. The wrist should be immobilized for two weeks and protected for an additional four weeks. Complex articular fractures require additional fixation or another form of treatment.

Appendix

Tables showing all inclusion and exclusion criteria, clinical results, radiographic results, and complications are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on “Supplementary Material”) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).}

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