Effect of Calcium Phosphate Bone Cement Augmentation on Volar Plate Fixation of Unstable Distal Radial Fractures in the Elderly

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Background: Calcium phosphate bone cement increases the stability of implant-bone constructs in patients with an osteoporotic fracture. The purpose of this randomized study was to determine whether augmentation of volar locking plate fixation with calcium phosphate bone cement has any benefit over volar locking plate fixation alone in patients older than sixty-five years of age who have an unstable distal radial fracture.

Methods: Forty-eight patients (fifty unstable distal radial fractures) were recruited for this study. The mean patient age was seventy-three years. Surgical procedures were randomized between volar locking plate fixation alone (Group 1) and volar locking plate fixation with injection of calcium phosphate bone cement (Group 2). The patients were assessed clinically at three and twelve months postoperatively. Clinical assessments included determinations of grip strength, wrist motion, wrist pain, modified Mayo wrist scores, and Disabilities of the Arm, Shoulder and Hand (DASH) scores. Radiographic evaluations were performed immediately postoperatively and at one year following surgery. The adequacy of the reduction was assessed by measuring radial inclination, volar angulation, and ulnar variance.

Results: The two groups were comparable with regard to age, sex, fracture type, injury mechanism, and bone mineral density. No significant differences were observed between the groups with regard to the clinical outcomes at the three or twelve-month follow-up examination. No significant intergroup differences in radiographic outcomes were observed immediately after surgery or at the one-year follow-up visit. Furthermore, no complication-related differences were observed, and there were no nonunions.

Conclusions: Augmentation of metaphyseal defects with calcium phosphate bone cement after volar locking plate fixation offered no benefit over volar locking plate fixation alone in elderly patients with an unstable distal radial fracture.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

The incidence of distal radial fractures increases with age, and, with longer life expectancy, these fractures are likely to become more common[1]. Fractures of the distal radial metaphysis are known to be strongly related to osteoporosis[2], and the management of distal radial fractures in elderly patients may be difficult[3].

Recently, the benefits of more aggressive fracture fixation in the elderly have attracted research interest, in the hope of improving patients' outcomes and preserving their ability to live independently. The introduction of the volar locking plate system has increased this interest[4]. This system is a fixed-angle construct and has been effective in maintaining good anatomic reduction, even in the elderly[4,5]. However, the potential complications from metaphyseal defects remaining after reduction of osteoporotic distal radial fractures remain of concern.

Injectable calcium phosphate bone cement has been used to augment metaphyseal defects after reduction of fractures, including distal radial fractures, especially in osteoporotic elderly patients[6-8]. The purpose of this randomized study was to evaluate whether augmentation of volar locking plate fixation with calcium phosphate bone cement has any benefit over volar locking plate fixation alone in patients older than sixty-five years who have an unstable distal radial fracture. The null hypothesis was that patients older than sixty-five years who had been treated

Disclosure: In support of their research for or preparation of this work, one or more of the authors received, in any one year, outside funding or grants of less than $10,000 from Ewha Womans University. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity.

with a volar locking plate alone for an unstable distal radial fracture and those treated with a volar locking plate plus calcium phosphate bone cement would show no difference in terms of wrist function, radiographic outcomes, or complications.

Materials and Methods

Our institutional review board approved this study. All patients older than sixty-five years who had an acute distal radial fracture were considered for inclusion. The inclusion criterion was unacceptable fracture alignment after one attempt at closed reduction. Unacceptable closed reduction was defined as dorsal angulation of >10°, volar angulation of >20°, an articular gap or step-off of >2 mm, radial inclination of <10°, or radial shortening of >5 mm. The exclusion criteria were a preexisting severe illness, a previous wrist injury, a surgical delay of more than two weeks, and a concomitant ulnar neck fracture.

Between March 2007 and October 2008, forty-eight patients (fifty distal radial fractures) were recruited for this study. There were forty female patients (83%) and eight male patients (17%) with a mean age of seventy-three years (range, sixty-five to eighty-nine years). Twenty-nine fractures (58%) were in the right wrist, and twenty-one (42%) were in the left wrist.

Of the fifty fractures, forty-two (84%) resulted from a fall from a standing height. The other eight (16%) resulted from a high-energy injury: three (6%) were caused by a fall from a height above the level of the head, and five (10%) were sustained in a motor-vehicle accident. Twenty-three fractures (46%) involved the ulnar styloid. Two fractures were classified as grade-I open fractures according to the Gustilo and Anderson classification system[9].

Distal radial fractures were classified with use of the Orthopaedic Trauma Association Fracture Classification[10]. Two of the authors (J.K.K. and Y.D.K.) classified all fractures, and disagreements were settled by consensus. There were twenty A3 fractures, three B3 fractures, five C1 fractures, eighteen C2 fractures, and four C3 fractures (Table I).

Study Protocol

The surgical procedures were performed by one surgeon (J.K.K.) after patient randomization. A permutated block randomization method was adopted with blocks of four allocations. Each block contained two allocations of volar locking plate fixation alone (Group 1) and two allocations of volar locking plate fixation plus injection of calcium phosphate bone cement (Group 2). A computerized random-number generator was used to formulate an allocation schedule. The randomization scheme was generated with a web site[11] by an independent research assistant.

Methods of Treatment

Group 1 (Volar Locking Plate Fixation)

Twenty-five distal radial fractures (Group 1) were stabilized with volar locking plate fixation alone. The distal radial fractures were reduced with use of a volar approach and were stabilized with a 3.5-mm (until June 2007) or 2.4-mm (after July 2007) volar locking compression plate (Synthes, Paoli, Pennsylvania).

Group 2 (Volar Locking Plate Fixation Plus Injection of Calcium Phosphate Bone Cement)

Twenty-five distal radial fractures (Group 2) were stabilized with volar locking plate fixation with the addition of an injection of calcium phosphate bone cement. The calcium phosphate bone cement powder (Calcibon; Biomet Merck, Darmstadt, Germany) consisted of 61% α-tricalcium phosphate, 26% calcium hydrogen phosphate ($CaHPO_4$), 10% calcium carbonate ($CaCO_3$), and 3% precipitated hydroxyapatite. The cement is prepared by mixing the cement powder with cement liquid (a 4% aqueous solution of disodium hydrogen phosphate [Na_2HPO_4]). The surgical exposure and plate types were the same as those used in Group 1, as described above.

Calcium phosphate bone cement was injected through cortical defects on the radial side of the distal radial fracture, while metaphyseal defects were directly visualized. Soft tissues were visualized on both the radial and the ulnar side of the distal part of the radius during injection of the cement to allow direct visualization of extraosseous cement extrusion and to prevent contact between the cement and the surrounding soft tissues.

Postoperative Management

Postoperative management was the same for the two groups. A short arm splint was applied and worn for two weeks. During weeks two through four, a removable short arm brace was used but was removed for active wrist motion exercises.

Outcome Measurement

Patients were assessed clinically and radiographically during the early postoperative period and three and twelve months postoperatively. Forty-seven distal

TABLE I Demographic Data

	Baseline		12 Months	
	Group 1	Group 2	Group 1	Group 2
No. of cases	25	25	20	21
AO/OTA classification *(no.)*				
A3	11	9	9	8
B3	2	1	2	1
C1	2	3	1	2
C2	8	10	7	8
C3	2	2	1	2
Mean age *(yr)*	74	72	72	71
Male *(no.)*	3	5	2	4
Female *(no.)*	21	19	17	16
Mean bone mineral density *(T-score)*	−2.4	−2.3	−2.3	−2.3
Injury mechanism *(no.)*				
Low energy	21	21	17	17
High energy	4	4	3	4

radial fractures (twenty-three [92%] of those in Group 1 and twenty-four [96%] of those in Group 2) were available for follow-up at three months, and forty-one cases (twenty [80%] of those in Group 1 and twenty-one [84%] of those in Group 2) were available at twelve months (Fig. 1).

Clinical Evaluation

Assessment was performed independently by a trained physiotherapist who was unaware of the treatment details. Clinical assessments included determination of grip strength, wrist range of motion, subjective wrist pain, modified Mayo wrist scores (MMWS)[12], and Disabilities of the Arm, Shoulder and Hand (DASH) scores[13]. Grip strength was measured with use of a Jamar dynamometer (Sammons Preston, Bolingbrook, Illinois) with the elbow flexed 90° and the forearm in neutral rotation. Values are expressed as the percentage of the strength on the contralateral (uninjured) side. For grip strength calculations, we allowed for 10% greater strength of the dominant hand when the right hand was dominant, but we did not compensate when the left hand was dominant[14,15]. The wrist and forearm ranges of motion (extension, flexion, supination, and pronation) were measured with use of a handheld goniometer and are expressed as a percentage of the motion on the contralateral side. Wrist pain during daily activity was recorded with use of a visual analog scale (VAS), on which 0 indicated no pain and 10 indicated the most severe pain imaginable. The MMWS was calculated on a 100-point scale, with 100 points representing normal wrist function. The MMWS was based on separate ratings for pain (25 points), range of motion (25 points), grip strength (25 points), and functional status (25 points). The DASH questionnaire consists of thirty items; twenty-one address abilities to perform specified activities, and nine address symptoms. The DASH scores range from 0 to 100 points, with higher scores indicating greater disability.

Complications during follow-up were recorded by the first author (J.K.K.), who was not blinded to the type of treatment.

Radiographic Evaluation

All radiographs were evaluated by two authors (J.K.K. and S.H.K.). Radiographs of the wrists were obtained immediately after surgery and at the one-year follow-up visit. The volumes of metaphyseal defects were estimated from radiographs obtained immediately after surgery. We hypothesized that the metaphyseal defect was a rectangular hexahedron and calculated it by measuring the length and width on the posteroanterior radiograph and the height on the lateral radiograph. The degree of reduction was assessed radiographically by measuring radial inclination, volar angulation, and ulnar variance. Radial inclination and volar angulation were measured with use of the method described by Goldfarb et al.[16], and ulnar variance was measured with the method described by Medoff[17]. A loss of reduction was defined as dorsal angulation of >10°, volar angulation of >20°, an articular gap or step-off of >2 mm, or radial inclination of <10°. We evaluated whether the injected calcium phosphate bone cement was incorporated into host bone on the one-year postoperative radiographs.

Lumbar spine (L2-L4) bone mineral density was measured in all study subjects perioperatively with dual x-ray absorptiometry (Prodigy Advance; GE Healthcare, Madison, Wisconsin).

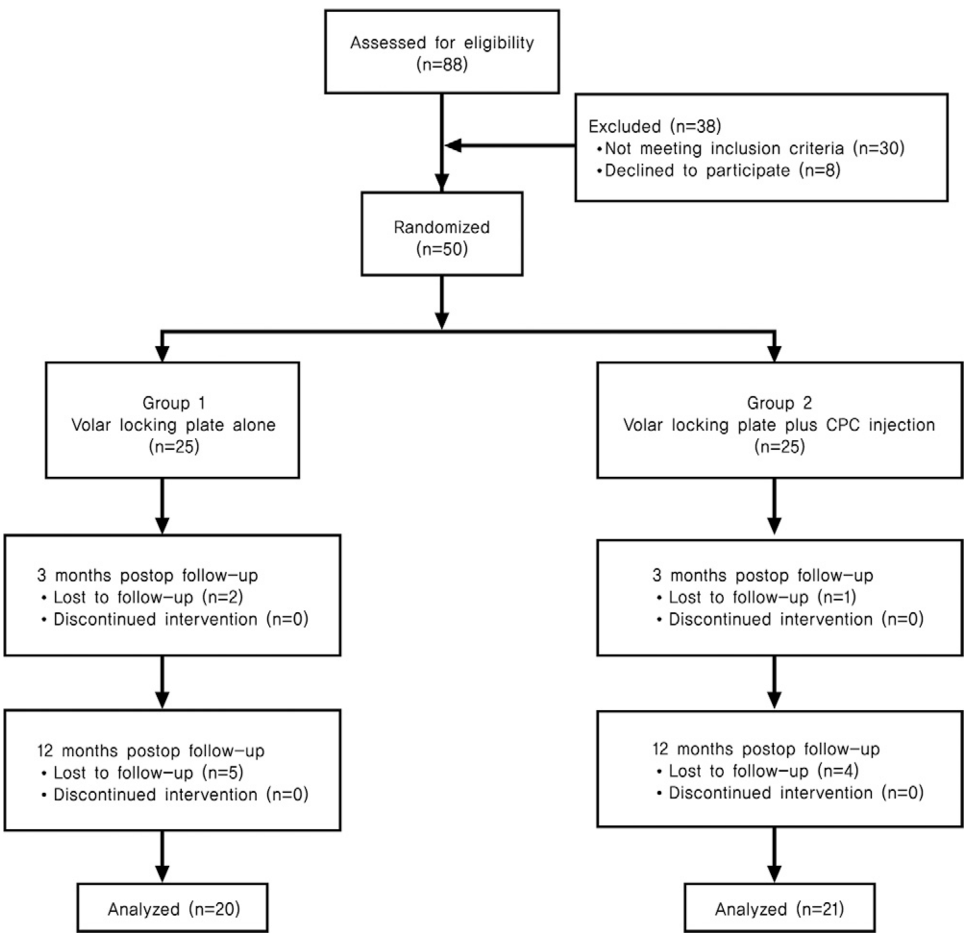

Fig. 1

A flow diagram according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines. CPC = calcium phosphate bone cement.

TABLE II Clinical Outcomes*

	3 Months Postop.				12 Months Postop.			
	Group 1		Group 2		Group 1		Group 2	
	Mean and Stand. Dev.	% of Contralat. Side	Mean and Stand. Dev.	% of Contralat. Side	Mean and Stand. Dev.	% of Contralat. Side	Mean and Stand. Dev.	% of Contralat. Side
Range of motion *(deg)*								
Flexion	51 ± 10	80	53 ± 15	82	61 ± 13	86	61 ± 14	86
Extension	54 ± 11	85	53 ± 10	84	60 ± 15	85	60 ± 15	85
Supination	84 ± 7	95	83 ± 9	84	85 ± 9	95	85 ± 8	97
Pronation	86 ± 5	96	85 ± 6	95	86 ± 5	96	86 ± 6	95
Grip strength *(kg)*	17 ± 9	67	18 ± 12	69	22 ± 13	82	22 ± 15	83
VAS score *(points)*	3.2 ± 2		3.0 ± 2		1.2 ± 2		1.0 ± 2	
MMWS *(points)*	69 ± 11		71 ± 13		80 ± 11		81 ± 13	
DASH score *(points)*	24 ± 15		23 ± 12		10 ± 8		10 ± 7	

*There was no significant difference between groups for any outcome measure.

TABLE III Radiographic Outcomes*

	Immediate Postop.†		12 Months Postop.†	
	Group 1	Group 2	Group 1	Group 2
Radial inclination *(deg)*	22 ± 3	21 ± 4	22 ± 4	22 ± 3
Volar angulation *(deg)*	5.6 ± 4	5.2 ± 5	4.7 ± 4	4.4 ± 3
Ulnar variance *(mm)*	1.0 ± 2	0.8 ± 2	1.0 ± 2	1.0 ± 2

*There was no significant difference between groups for any outcome measure. †The values are given as the mean and standard deviation.

Sample Size

To detect a minimum difference of 3° in radiographic outcomes and with distal radial fracture reduction status represented with a standard deviation of 3, a 20% loss to follow-up, a type-I error rate of 0.05, and a power of 0.8, twenty-three cases of distal radial fracture were needed per group.

Statistical Analysis

The Mann-Whitney U test was used to evaluate significant differences between the two study groups for continuous variables, and the Fisher exact test was used to evaluate significant differences for categorical variables. All statistical tests were two-sided, and p values of <0.05 were considered significant.

Source of Funding

There was no external funding source for this study. This study was supported by a grant from Ewha Womans University.

Results

Group 1 (volar locking plate fixation alone) and Group 2 (volar locking plate fixation plus calcium phosphate bone cement) were comparable with regard to age, sex, fracture type, injury mechanism, and bone mineral density (Table I).

Table II shows the clinical outcomes in both groups. No significant differences were found between the groups for any clinical parameter (mean range of motion [flexion arc, extension arc, supination arc, and pronation arc], grip strength, VAS scores, MMWS, and DASH scores) at three or twelve months postoperatively.

No significant differences were observed between the two groups with regard to any radiographic parameters in the initial postoperative period or at twelve months postoperatively (Table III). The mean approximate volumes (and standard deviation) of the metaphyseal defects in Groups 1 and 2 were 7.2 ± 2.4 and 7.0 ± 1.9 cm^2, respectively, which were not significantly different. All patients (twenty-one fractures) in Group 2 who returned for the twelve-month follow-up visit had radiographic evidence of incorporation of the calcium phosphate bone cement into host bone.

Complications

Loss of reduction occurred in one wrist in each group, and both patients refused a reoperation. Two superficial skin infections developed (one in each group), and both responded to intravenous antibiotics without surgical debridement.

All fractures healed uneventfully. There were no tendon-related complications, and no patient required a second operation.

Discussion

As a result of a longer life expectancy, the elderly have become the fastest growing subpopulation. The elderly now pursue more active lifestyles, so fractures in this age group require more orthopaedic attention[18]. Distal radial fractures are the most common upper-extremity fracture among the elderly (those aged sixty-five years or older). In fact, 15% of white women have a fracture of the distal part of the radius after the age of fifty[19].

Increasing age and a low bone mineral density are associated with instability and malunion of distal radial fractures[20-22]. The radiographic appearance, such as radial shortening and dorsal angulation, plays an important role in determining functional outcomes[18,23,24]. Therefore, the importance of radiographic outcomes and anatomic realignment has recently been emphasized in the elderly[5,25].

Two technical advances have been made in the treatment of unstable distal radial fractures in osteoporotic patients during the last decade. The first advance was the locking plate system, which has a mechanism of action similar to that of fixed-angled devices but has the mechanical advantage of multiple screw fixation points[26]. Because the fixed-angle construct does not affect the blood supply to the bone and does not require good bone quality to provide stability[27], the volar locking plate system produces good clinical results in elderly patients with an unstable distal radial fracture[3,28].

The second technical advance involves biomaterials that support and bring together bone fragments by filling voids after severe bone comminution or osteotomy[26]. At our institution, calcium phosphate bone cement is the most widely used biomaterial for treating distal radial fractures. Calcium phosphate bone cement is a second-generation hydroxyapatite bone substitute with nonceramic properties[29], and it has several advantages: biocompatibility and osteoconductivity, high compressive strength that is greater than that of cancellous bone, a rapid setting time, an injectable consistency, and proven compatibility with fluoroscopy and radiography; in addition, it is absorbed by and substitutes for woven bone[6,26,29-32]. For these reasons, several authors have treated distal radial fractures with injectable calcium phosphate bone cement, and they reported that it produces clinical outcomes that are similar to or better than those provided by conventional treatment, Kirschner wire fixation, or external fixation[30,33,34].

A large metaphyseal void often occurs after open reduction and plate fixation of a severely comminuted acute distal radial fracture in osteoporotic elderly patients. Bone graft or bone graft substitutes have sometimes been used to fill defects remaining after plate fixation of distal radial fractures[35,36]. However, in the present study on unstable distal radial fractures in patients more than sixty-five years of age, we were unable to demonstrate any outcome differences between patients treated with volar locking plate fixation alone and those treated with volar locking plate fixation plus augmentation with calcium phosphate bone cement.

Some authors have suggested that the injectable nature of calcium phosphate bone cement is its greatest merit because it facilitates percutaneous administration[37,38]. However, we believe that high pressure is required to inject calcium phosphate bone cement percutaneously because a hematoma at a fracture site could prevent adequate cement filling. Therefore, as a result of the high rates of extraosseous cement extravasation that we encountered, we have questioned the benefits of percutaneous administration of calcium phosphate bone cement[30,33] and have suggested the mini-open approach instead. In the present study, we administered calcium phosphate bone cement through an open volar approach while directly visualizing metaphyseal defects. Usually, after reduction of osteoporotic comminuted distal radial fractures, a cortical defect is present on the radial side of the fracture, which allows calcium phosphate bone cement to be injected without being obstructed by the plate. Under these conditions, low-pressure injection is enough to locate the calcium phosphate bone cement properly and small amounts of extraosseous cement around the fracture site can be removed under direct vision. Nevertheless, there is still a risk of extraosseous extravasation of the cement, especially when a patient has a severely comminuted acute intra-articular fracture, because of possible leakage of the cement into the radiocarpal joint[39].

This study has some limitations. First, the metaphyseal defect volumes that we compared between groups were only approximated. Nevertheless, we believe that the volumes were similar in the two groups because the mean ages, bone mineral densities, fracture types, and injury mechanisms were similar, and the approximate volumes of the metaphyseal defect were not significantly different. The second limitation concerns loss to follow-up. The intention-to-treat approach is prone to two common protocol deviations: namely, loss to follow-up and the switching of treatments[40]. Although treatment switching was not an issue during this study, five fractures from Group 1 and four from Group 2 were lost to follow-up before the twelve-month evaluation. Third, the surgeon was told whether injection of calcium phosphate bone cement was required at the start of the surgery, whereas ideally, for a rigorous double-blind study, he would have been unaware of the injection requirement until after plate fixation. ■

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