Clinical Device-Related Article
Osteotomy of Distal Radius Fracture Malunion Using a Fast Remodeling Bone Substitute Consisting of Calcium Sulphate and Calcium Phosphate

Antonio Abramo,1 Mats Geijer,2 Philippe Kopylov,1 Magnus Tägil1
1 Department of Orthopaedics, Hand Unit, Clinical Sciences, Lund University, Lund S-221 85, Sweden
2 Department of Radiology, Lund University Hospital, Lund S-221 85, Sweden

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Abstract: Malunion after a distal radius fracture can be treated with an osteotomy of the distal radius. Autologous iliac crest bone graft is often used to fill the gap, but the procedure is associated with donor site morbidity. In this study a novel fast resorbing biphasic bone substitute consisting of a mixture of calcium sulphate and calcium phosphate is used (Cerament™ BoneSupport AB, Sweden). Fifteen consecutive patients, with a mean age of 52 (27–71) years were included. All had a malunion after a distal radius fracture and underwent an osteotomy. A fragment specific fixation system, TriMed® (TriMed, Valencia, CA), consisting of a Buttress Pin® and a Radial Pin Plate® were used for fixation and a calcium sulphate and calcium phosphate mixture as bone substitute. The patients were followed for 1 year. Grip strength increased from 61 (28–93)% of the contralateral hand to 85 (58–109)% of the contralateral hand, p < 0.001. DASH scores decreased from 37 (22–61) to 24 (2–49) p = 0.003. Radiographically all osteotomies healed. An increase of ulnar variance was noted during healing from 1.8 mm immediately postoperatively to 2.6 mm at final follow up. Osteotomy can increase grip strength and decrease disability after a malunited fracture. In the present series the bone substitute was replaced by bone, but a minor loss of the achieved radiographic correction was noted in some patients during osteotomy healing. A more rigid fixation may improve the radiographic outcome with this kind of bone substitute. © 2009 Wiley Periodicals, Inc. J Biomed Mater Res Part B: Appl Biomater 92B: 281–286, 2010

Keywords: calcium sulphate; calcium phosphate; osteotomy; distal radius; bone substitute

INTRODUCTION

Malunion after a distal radius fracture is a major cause for residual symptoms. It appears in about 5% of the fractures1 and the patients may suffer from decreased grip strength, poor hand and arm function and poor cosmetic appearance. To correct the deformity and relieve the symptoms, an osteotomy can be performed.2–4 The malunited fracture is cut at the fracture site and the length and/or angle is corrected using an opening wedge technique. An iliac crest bone graft is most often used to fill the gap, either as a structural single block of cortico-cancellous bone or as a nonstructural cancellous graft.5 A high incidence of donor site morbidity has been reported,6 most commonly in the form of pain but also as wound infection or even fracture of the iliac crest.

To avoid donor site morbidity, a bone substitute can be used instead of bone graft. Fast resorbing calcium sulphate has been used, and although being highly biocompatible,7 the resorption rate has been too rapid to be used in fracture treatment. Without rigid fixation, the risk of mechanical failure during the remodeling is obvious but at the same time a rigid fixation decreases the bone formation stimulus.8 Instead a nonresorbable bone substitute, such as calcium phosphate paste can be used. The injectable bone substitute is deposited into the fracture or osteotomy and sets in situ to carbonated hydroxyapatite (HA), which retains its mechanical properties during healing. HA has been used both in surgery of distal radial fractures9 and in osteotomies of malunited distal radius fractures.10–12 However, it takes years,13 if ever, to resorb and ideally a bone substitute should be resorbed within reasonable time but still maintain the strength until bone has formed. In the present study a novel injectable bone mixture containing
both a calcium sulphate, resorbing during 6–12 weeks and
a nonresorbing HA will combine the two resorption
extremes with the hypothesis that the HA will provide
structural support during the remodeling and the calcium
sulphate will be remodeled swiftly into bone. The aim of
this study was to evaluate the feasibility of using the cal-
ccium sulphate/calcium phosphate substitute as gap filler in
distal radius osteotomies in combination with the fragment
specific fixation technique, which has previously been used
as fixation in combination with a nonresorbing HA.11

MATERIALS AND METHODS

Fifteen patients were included prospectively as a feasibility
study of a biphasic bone substitute. The study was
approved by the regional research ethics committee and the
Swedish Medical Products Agency.

Patient Selection

Inclusion criteria for this study were a malunited distal ra-
dius fracture, healed with a dorsal or volar angulation and/
or shortening and with a clinically manifesting symptom
such as pain at rest, pain at activity or decreased range of
motion. Patients were enrolled from two hospitals in the
southern region of Sweden. Between October 2005 and No-
vember 2006, 15 consecutive patients with a malunion after
a distal radial fracture underwent an osteotomy using the
fragment specific system for fixation and the biphasic bone
substitute as gap filler. The mean age in the study group
was 52 (27–71) years; four patients were men and 11
women. Eight patients were operated on their left wrist and
seven on their right. Eight were operated on their dominant
wrist.

The mean ulnar variance was plus 2.4 mm (0–9.2), the
mean dorsal angulation was 17.9° (−9.4 to 38.2) and
the mean radial inclination was 19.2° (8.8–30.2). All the
patients had had their fractures treated by closed reduction
and fixation in a below elbow cast as primary fracture
treatment.

Presurgical Preparation

Blood samples were collected preoperatively and at each
follow up, analyzing the platelet count, thyroid hormone,
thyroid stimulating hormone, calcium and CRP to monitor
any potential side effect of the dissolving bone substitute.
Preoperative radiographs including a lateral and an ante-
ierior–posterior view were taken A clinical examination was
performed with measuring of the grip strength and preoper-
ative pain level and patients filled out a preoperative
DASH-from.

Surgical Protocol

All operations were performed by two surgeons (A.A. and
P.K.). The technique has been described previously but
with the use of Norian SRS, a single phase substitute
consisting of a HA (dahlite), as a bone substitute instead of
this novel biphasic CS/HA material.11 In all osteotomies
the fragment specific fixation system was used for fixation
and the biphasic bone substitute as gap filler. The fixa-
tion system is a fragment specific fixation device for distal
radial fractures consisting of plates and pins. In the osteot-
omy technique in the present study a Radial Pin Plate
and a dorsal Buttress Pin were inserted using two separ-
ate incisions. A dorsal incision was made through the styloid
and the first extensor tendon compartment to allow for
placement of the radial pins and the Radial Pin Plate.
Once a correct level for the osteotomy was established, the
radius was cut with an oscillating saw, leaving the perioste-
um intact at the volar side. The dorsal and radial mal-
alignment were corrected. The osteotomy was temporarily
secured by the Buttress Pin, which could be slid to cor-
rect the axial deformity. The Buttress Pin screw was
tightened, the radial pins inserted and the correction con-
trolled in the fluoroscope. Before injecting the bone substi-
tute, the Radial Pin Plate was applied to secure full
stability. Postoperatively the wrist was immobilized in a
plaster cast for 2 weeks and thereafter active mobilization
was encouraged in a removable soft splint.

Bone Substitute

A novel bone substitute has been developed allowing new
bone tissue to grow into the bone defect made possible by
certain porosity.14 It is an injectable bone substitute and
consists of 60% calcium sulphate (CS) and 40% HA.15
This ratio gives the mixture a compressive strength of 35–50 MPa comparable to trabecular bone and a better strength than with a 50/50 ratio of CS and HA. Both the CS and the HA are synthetically made to control quality and purity of the mineral phases. The HA is of medical grade and tested according to American standard, ASTM F1185. The HA particles are small (<100 μm) and high temperature sintered to give a round shape and smooth surface for optimal handling characteristics.

The bone substitute powder is mixed with Omnipaque (GE HealthCare) a low osmolar, nonionic, iodinated contrast agent (iomeprol), to form an injectable paste. The working time and injectability of the substance is 7 minutes using a 16G cannula and the final setting time is 25 minutes. The setting temperature is 39 centigrade.

Follow-up

Clinical follow ups were performed at 2 weeks, 7 weeks, 3 months and at 1 year. These follow ups include clinical examination, blood samples, radiographic examination and the DASH form.

The subjective and objective outcomes were followed prospectively to monitor the clinical improvement by the operation per se.

Radiographs

Radiographs were obtained preoperatively, postoperatively and at every follow-up to monitor the mechanical integrity of the bone substitute during remodeling. A radiologist (M.G.) measured all radiographs. Radial shortening was measured as ulnar variance from the distal radial surface to the distal ulnar surface according to the method of perpendiculars on AP radiographs of the wrist obtained in the neutral position. The radial inclination angle was measured on the AP radiographs and the dorsal angulation on the lateral view, expressed as the angle of joint surface relative to the radial length axis. The resorption of bone substitute was evaluated in the radiographs, by estimating the amount of remaining radio-opaque material in the gap. The degree of radiographic healing of the osteotomy was also appreciated in no healing, partial healing and definite healing.

Tests

Grip strength was measured using a dynamometer (Jamar; Preston Corp, Jackson, MI). The mean preoperative grip strength was 61% (28–93%) of the contralateral, uninjured side.

The patients rated their pain at activity and at rest on a 10 cm visual analog scale (VAS) and the functional outcome was evaluated using the Swedish version of the validated outcome score disability of the arm, shoulder and hand (DASH). DASH is a self-administered questionnaire developed by the AAOS and the Institute for Work and Health in Canada. The Swedish version was validated for general use in upper extremity disorders but not specifically for distal radius fractures.

The questionnaire consists of 30 questions evaluating physical activities, symptom severity and the effect of the injury on social activities. A score is calculated and the disability of the patient is estimated on a scale from 0 to 100, with 100 being the worst result that is reflecting the highest degree of disability. At study entry, the mean pain as measured on a visual analogue scale (0–10 cm) was 5.5 (3–10) and the mean DASH score was 37 (22–61).

Statistics

Student’s paired t-test was used to compare pre- and postoperative data as well as to evaluate radiographic changes within the first year. Repeated measures ANOVA was used for repeated measures within the group and Wilcoxon’s rank sum test to compare pre- and postoperative DASH and pain scores. The SPSS program (SPSS, Chicago, IL) version 14.0 was used for the statistical analyses.

RESULTS

All patients were admitted as outpatients. Eleven of the 15 patients could return home the same day and the others the morning after. One patient had the pins and plate removed at 8 months postoperatively due to pain from the Radial Pin Plate. The osteotomy was healed at that time. There were no adverse events correlated to the bone substitute at follow up, neither by clinical examination nor in the blood samples. There were seven adverse events correlated to the surgery or to the fixation device. One patient had a rupture of the extensor pollicis longus tendon (EPL) treated by an extensor indices proprius tendon (EIP) transfer. One patient had a carpal tunnel syndrome treated by carpal tunnel release. One patient had a postoperative wound infection which was treated successfully with antibiotics and healed uneventfully. Three patients had local pain and tenderness due to the Radial Pin Plate, in one patient due to a pin which had to be removed and in two patients due to a transient irritation of the tendons in the first dorsal compartment and the radial nerve branches.

Objective

The mean operation time was 75 (58–91) minutes. Grip strength increased from 61% (28–93%) of the uninjured side preoperatively to 85% (58–109%, p < 0.001) at 1 year (Figure 2).

Subjective

The preoperative pain at rest as measured on a visual analogue scale (0–10 cm) was 5.5 (3–10) and decreased to 2.4 (1–6) at 1 year (p < 0.001). The mean DASH score was 37 (22–61) preoperatively and improved to 24 (2–53) already at 3 months postoperatively (p = 0.011). The score
improved further and was 20 (2–49) at 1 year ($p = 0.003$) (Figure 3).

**Radiology**

Radiographically, all the osteotomies healed. One patient fell due to a minor cerebral infarction, traumatized her wrist and the pins broke with a loss of correction. As expected a high rate of early decrease in radiolucent material in the gap was noted. The mean ulnar variance for the whole group was $+2.4$ mm (0–9.2) preoperatively, $+1.9$ mm ($-1.0$ to 7.8 mm) immediately postoperatively and $+2.6$ mm ($-0.6$ to 9.4 mm) at the final follow up. These changes were statistically not significant. The mean radial inclination was $19.3^\circ$ (8.8–30.2) preoperatively, $22.9^\circ$ (14.9–30.8) postoperatively and $24.3^\circ$ (18.0–32.6 $p = 0.002$) at 1 year. The mean dorsal angulation was 17.9 ($-9.4$ to 38.2) preoperatively, $-1.1^\circ$ ($-15.0$ to 12.2) postoperatively and $-2.2^\circ$ ($-19.3$ to 17, $p = 0.001$) at the final follow up (Figure 4, Table I). In three patients, there was a more than 1 mm loss of ulnar variance correction from immediately postoperatively (mean 4.6 mm, range 2.8 to 7.8 mm) to the 1 year follow-up (mean 6.4 mm, range 4.6–9.4 mm). One additional patient who had one of the radial

![Figure 2](image1.png)

**Figure 2.** Mean grip strength expressed as a percentage of the contralateral wrist; preoperatively and at follow up. Error bars represent 95% confidence interval.

![Figure 3](image2.png)

**Figure 3.** DASH score and VAS pain (cm) at rest, preoperatively and at follow up. Error bars represent the 95% confidence interval.

![Figure 4](image3.png)

**Figure 4.** Radiographic appearance at follow up. An improvement is seen in dorsal angulation and radial inclination but there is no significant change in ulnar variance. Error bars represent 95% confidence interval.
TABLE I. Radiographic Results

<table>
<thead>
<tr>
<th></th>
<th>Mean (range)</th>
<th>SD</th>
<th>p-Value&lt;sup&gt;a&lt;/sup&gt;</th>
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</thead>
<tbody>
<tr>
<td>Ulnar variance</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Preop</td>
<td>2.4 (0.9-2.2)</td>
<td>2.4</td>
<td></td>
</tr>
<tr>
<td>Postop</td>
<td>1.9 (1.7-7.8)</td>
<td>2.3</td>
<td>1</td>
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<tr>
<td>2 week</td>
<td>2 (1-1.6-8.6)</td>
<td>2.5</td>
<td>0.9</td>
</tr>
<tr>
<td>7 week</td>
<td>2.4 (1.2-9.2)</td>
<td>2.7</td>
<td>1</td>
</tr>
<tr>
<td>3 month</td>
<td>2.8 (1.4-10)</td>
<td>2.8</td>
<td>1</td>
</tr>
<tr>
<td>1 year</td>
<td>2.6 (0.6-9.4)</td>
<td>2.4</td>
<td>1</td>
</tr>
<tr>
<td>Radial inclination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preop</td>
<td>19.3 (8.8-30.2)</td>
<td>5.1</td>
<td></td>
</tr>
<tr>
<td>Postop</td>
<td>22.9 (14.9-30.8)</td>
<td>4.5</td>
<td>0.2</td>
</tr>
<tr>
<td>2 week</td>
<td>23.8 (19.4-35)</td>
<td>5.1</td>
<td>0.001</td>
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<tr>
<td>7 week</td>
<td>24.4 (16.9-32.5)</td>
<td>4.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3 month</td>
<td>24.8 (18.9-32.6)</td>
<td>4.0</td>
<td>0.004</td>
</tr>
<tr>
<td>1 year</td>
<td>24.6 (8-38.2)</td>
<td>4.4</td>
<td>0.002</td>
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<tr>
<td>Dorsal angulation</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Preop</td>
<td>17.9 (-9.4-38.2)</td>
<td>12.9</td>
<td></td>
</tr>
<tr>
<td>Postop</td>
<td>-1.1 (-15-12)</td>
<td>8.7</td>
<td>0.001</td>
</tr>
<tr>
<td>2 week</td>
<td>-3 (-7-17.8)</td>
<td>9.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>7 week</td>
<td>-3 (-19.9-19.7)</td>
<td>11.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3 month</td>
<td>-3.9 (-19.7-19.3)</td>
<td>13.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1 year</td>
<td>-2.2 (-19.3-18.2)</td>
<td>9.9</td>
<td>0.001</td>
</tr>
</tbody>
</table>

<sup>a</sup>p-value compared to preoperative values. Repeated measures ANOVA with Bonferroni correction.

The mixture of a solid and a soluble phase of the bone substitute allow manipulation of the bone healing and remodeling. Drugs can be added to the soluble phase to be released during the four first weeks. Besides antibiotics, theoretically a bone morphogenetic protein (BMP) or another osteoinductive peptide can be added to increase bone formation. A further advantage might be that the elasticity modulus of the biphasic bone substitute (0.3–0.4 GPa) is equivalent to cancellous bone and will decrease the shear forces at the bone substitute to bone interface. HA has a higher modulus and with a stiffer material, stress shielding of the bone surrounding the bone substitute might lead to resorption.

As Demonstrated in this Study, the Reduction can be Lost in Some Patients During the Remodeling

With a fast resorption of the bone substitute, such as with the present bone void filler, the fixation becomes more important and more rigid solutions are necessary. Without being bulky, the Fragment specific fixation system is more rigid than pins alone and the same fixation strength is reached as with a volar angle stable plate, at least in cadaver studies.<sup>21</sup> In vivo, when diverging muscle forces are added as in the present study, the fixation in some cases does not seem to be rigid enough. Although the dorsal angulation was unaffected, axial compression occurred during the remodeling in four patients. A delicate balance thus exists between on one hand the wish to speed up the remodeling, but at the same time without losing the mechanical integrity during the remodeling.

The objective results in the present study regarding increased grip strength and pain relief are good and equivalent to previous studies in osteotomies of the distal radius using bone grafts.<sup>22,23</sup> In the present series grip strength increased to 85% of the uninjured side which is better or comparable to other studies with plating and a conventional bone graft<sup>22</sup> or a bone substitute.<sup>10,12</sup> Also subjectively, a substantial improvement was recorded using the DASH outcome score. DASH decreased from 37 preoperatively to 20 at the final follow up. The results all implicate that the operation offers a substantial improvement of the symptoms but no normalization. A faster resorbing bone substitute like this biphasic CS/HA substitute can be used as a safe alternative to bone graft. Still 4 of 15 patients lost some radial length during the remodeling period and although no correlation was found between radiographical and subjective outcome in the present study, it has previously been shown to influence the outcome.<sup>24</sup> In the authors’ opinion a careful choice of fixation is recommended with the relatively fast resorption of the calcium sulphate component of the biphasic bone substitute and more rigid fixation may be necessary. This might be obtained by adding an Ulnar Pin Plate or by a complete change of fixation device to a volar fixed angle plate to prevent the loss of reduction.

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