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# Treatment of Distal Radius Bone Defects with Injectable Calcium Sulphate Cement

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## 1. Introduction

In the treatment of distal radius fractures, bone grafting for subchondral bone defects is often used in order to avoid articular surface collapse and radial shortening. At present, the bone graft materials used regularly include autogenous bone, allogeneic bone or heterogenous bone and synthetic materials. Autogenous bone graft has been the gold standard for bone grafting and is the ideal implant bone substitute, but its source is limited<sup>[1]</sup> <sup>[2]</sup>. Moreover, opening reduction to expose the fracture segment and the donor site of bone will increase blood loss, surgery time and the possibility of infection. Allogeneic bone, although solving the problem of insufficient amount, has the disadvantage of the lack of sources and has the potential for immune response, infection and re-fracture <sup>[3]</sup><sup>[4]</sup>. Synthetic calcium sulphate graft has the advantage of good biocompatibility, it is biodegradable and injectable and will set in situ, which makes it an excellent choice for the clinical application of the treatment of distal radius fracture, particularly suitable to be implanted by injection. Its' relatively rapid resorption time and complete resorption will minimize the risks associated with any intra-articular migration, which could be a problem with the much slower resorbing calcium phosphate cements. The authors present a retrospective analysis of the clinical outcome on the treatment of distal radius fractures using calcium sulphate cement.

## 2. Material and operating technique

### 2.1 Patient selection

Over a period of four years, from January 2006 to January 2010, data from 60 patients was reviewed; 42 males and 18 females, ages from 46-68 years old (mean age 56 years old). Fractures were classified to A3 (12 cases), C2 (28 cases) and C3 (20 cases) using AO classification and all had some degree of subchondral bone defects. There were 8 cases treated with closing reduction and 52 cases treated with external fixation. In all cases fractures were implanted with calcium sulfate cement (Stimulan Kit, Biocomposites Ltd., UK) without autogenous bone graft.

## 2.2 Calcium sulphate cement filling

After appropriate fixation, the size of the bone defect was preliminarily measured before cement injection. Puncture needles were inserted into the gaps of fracture defect under fluoroscopic control. Once the needle position was satisfactory the calcium sulphate powder and diluent were mixed. The paste was extruded into the defect cavity until full when viewed under fluoroscopy. The implantation was made in different directions to access all gaps. In all cases 3 - 5cc of paste was used and the whole implantation procedure was completed within 6 minutes.

## 3. Clinical result

Fractures healed in all cases. All patients were followed up for 4 to 18 months (mean 8 months) and X-ray images were taken for review. The study found that callus appeared in all cases within 2 to 4 months. Most of the calcium sulphate had absorbed within 2 months and all was completely absorbed in 3 months post surgery.

X-ray images for 57 patients demonstrated that the reduction of the fracture was stable and satisfactory, with no fracture side collapse and/or displacement found. 3 cases showed slight collapse which may be a result of the adjustment of the external fixator too early after the surgery.

No foreign body reactions or infection were found in all 60 patients. No complications such as pin loosening dislocation of fixators, injury of blood vessels and radial nerves, pin track infections occurred. According to McBride scoring, the results were excellent in 50 cases, good in 7 cases, fair in 1 case and poor in 2 cases, the excellent and good rate being 95%. Two cases had traumatic arthritis and 1 case had wrist joint stiffness.

## 4. Complications

Significant complications have been rare. In most cases of this group, the external fixators were applied. One case showed slight collapse since corrected the external fixator earlier after reduction, which may be a result of the adjustment of the external fixator too early after the surgery (Fig 1,2). The authors recommend that correcting the external fixator should pay attention to avoid the distal end re-displacement and collapse.

Two patients had radial shortening. Yang D.F<sup>[5]</sup> analyzed the causes of postoperative radial shortening includes: (1) patients older than 60 years; (2) severe osteoporosis; (3) preoperative displacement and comminuted fractures; (4) inappropriate fixation methods; (5) inadequate bone graft; (6) premature load. The key points to enhance the treatment outcomes include precise judgement of the fracture type and bone quality, sufficient bone graft, firmly fixed after anatomical reduction and an appropriate plan for early loadless functional exercise. Traumatic arthritis may be avoided or delayed if the above-mentioned causes can be taken into consideration or preventive measures can be taken. (Fig 3)

Sometimes the calcium sulphate cement out of the bone defect area, even outside of the medullary cavity of bone, and the cement may be overflow into soft tissue. It may be a stimulant to irritate cellulitis of soft tissue. Kelly Cynthia<sup>[6]</sup> et al reported in a prospective, nonrandomized, multicenter study, and 109 patients with bone defects were treated with a surgical grade calcium sulfate preparation as a bone graft substitute. There were 13

complications; however, only four (3.6%) were attributable to the product. Joseph<sup>[7]</sup> et al reported complications included persistent nonunion (four patients), wound drainage (five patients), wound drainage and cellulitis (one patient) and cellulitis alone (one patient).

In operation, surgery should pay attention to avoid the cement out and into the soft tissue. If the cement mass close to the major blood vessel and nerve, getting them out by surgery recommended.



Fig. 1. Female, 68 years old. Postoperative anteroposterior and lateral image shown good alignment.



Fig. 2. At 8 weeks after operation, the picture showed collapse and shortening of distal radius which may be a result of the adjustment of the external fixator too early after the surgery.



Fig. 3. Male, 54 years old. Distal radius fracture and plaster splint was used after injury. No bone grafting and fixator were giving. Three months later, distal radius collapse and malunion, and traumatic arthritis occurred. Distal ulna-ectomy was given for improve the function of the wrist.

## 5. Discussion

The routine clinical treatment of distal radius fractures is closed reduction and/or external fixation. As the fracture is commonly to the metaphyseal joint, particularly in the elderly, it is easy to cause fracture displacement, collapse, distal radioulnar joint instability and shortening of the radius following reduction because of unstable fixation. Although open reduction can help reduce the occurrence of fracture re-displacement with internal fixation, it is difficult to achieve anatomical reduction on complex and comminuted fractures. Also there is risk of infection. The ability to carry out closed reduction, effectively maintaining bone fragment stability and good alignment of the distal radioulnar joint is a key issue. In recent years, many surgeons prefer to use external fixation plus metaphyseal bone grafting to treat distal radius bone fractures<sup>[8,9,10]</sup>, such as leverage reduction and bone graft. intramedullary implant with bone graft, insert pin with bone graft etc, and this technique has achieved satisfactory results. The authors retrospectively analyzed 60 patients who sustained such fractures and showed that external fixation combined with minimally invasive injection of calcium sulphate bone cement is an excellent method to treat distal radius bone defects.

### 5.1 Synthetic calcium sulfate cement

In recent years, many biomedical scientists have carried out research to find the ideal bone substitute with mechanical strength, excellent biocompatibility, and with osteoconductive and osteoinductive properties. The bone substitute should be fully biodegradable with an absorption rate similar to the rate of new bone formation. Commonly used bone graft substitutes include heterogeneous bone, polymers and biologically active ceramics (hydroxyapatite and tricalcium phosphate) which have no osteoinductive activity and some

implant material combined with BMP claiming osteoinductive activity. The characteristics of calcium sulfate can meet the criteria of an ideal bone substitute and is therefore of value in clinical application.

For larger bone defects caused by trauma, the routine treatment involves bone grafting. When filling with calcium sulfate or other synthetic bone materials (pellet or granules are used commonly), the method of implantation is the same as the traditional bone grafting. However, for irregular shaped defects, pellets/granules tend to be filled by an open procedure, and also are difficult to fill into every corner. Only tightly filling can maximize the likelihood of consolidation of fracture fragments, by providing an effective scaffold for bone conduction. As calcium sulphate cement can be shaped and adapted to any irregular shapes of defect, it can overcome the disadvantages presented by granular materials. In addition, when set, it helps the defect area resist loading forces. In this study, all 60 patients with distal radial fractures combined with subchondral bone defects were treated by using injectable calcium sulphate cement to fill the defects. It was simple to inject the calcium sulphate cement and the results were satisfactory. In addition, because of the use of a minimally invasive technique, it minimized disturbing the fracture site blood supply and interference with the fracture region, and supported the biological basis of fracture healing as scheduled. Bavonratanavech<sup>[11]</sup> *et al* has also recently reported on the use of injectable cement (calcium phosphate) to treat fresh distal radius fractures, and concluded that it has the advantages of convenient use of injection, supporting metaphysis, reducing both operation time and the risk of infection with reliable healing results. The authors would not recommend any adjustment to the external fixation equipment between 1.5 and 2 months after surgery as the mean absorption time of the injectable calcium sulphate cement was 2.5 months and there is a potential risk of displacement of fracture segments prior to healing.

In this study, one case presented with a slight distal radius collapse at 6 weeks after surgery when adjusting the external fixator. It was speculated it may be related with the time of adjustment in addition to the serious degree of comminuted fractures and insufficient cement filling.

Lobenhoffer<sup>[12]</sup> *et al* retrospectively analyzed 26 cases sustaining unstable tibial plateau fractures. 25 cases were open reduction with plates and screws for fixation and one case was closed reduction. In all cases calcium phosphate cement (Norian SRS, Synthes) was injected into the condyle bone defects. Mean follow-up time for all cases was 19.7 months. In all cases no re-displaced fracture was evident. The authors believed that the synthetic bone cement used has the advantage of high safety, good supporting strength and avoiding the need for autogenous bone graft. The cement could be arbitrarily shaped and completely fill the defect. In addition treatment allowed passive exercises of the limbs at an average of 4.5 weeks after surgery.

Calcium sulphate is not commonly expected to show bone induction ability as it is considered a simple inorganic salt. However, Walsh<sup>[13]</sup> *et al* used immunostaining methods and found that it increased the amount of BMP (bone morphogenic protein), IgG (immunoglobulin G), PDGF (platelet derived growth factor) and TGF- $\beta$  (transforming growth factor-beta) and other important factors in new bone formation sites. Following implantation of calcium sulfate in bone defects, it may promote the fracture healing process through a variety of ways and Gitelis<sup>[14]</sup> reported that calcium sulphate was a good substitute for autogenous bone. In this study, results have indicated that although the

calcium sulfate was absorbed in 2 or 3 months, strong bone healing capability was observed. Whether calcium sulphate possesses an osteoinductive function explaining why excellent bone healing is achieved in these patients is yet to be determined. Further *in-vitro* and *in-vivo* studies are required.

Distal radius fractures, especially classified by AO as A3, B3 and C-type of metaphyseal cancellous bone defect and articular surface collapse, were a good indication to use injectable calcium sulphate cement. In the author's experience, this injection method is suitable for patients who have collapse of the articular surface and a defect larger than 0.5cm and with the gap of cavities less than 2.5cm. An open reduction would be needed if the defect was greater than 2.5cm. The injection needle is usually introduced from the dorsal side, and great care should be taken to avoid over injection of cement to prevent neurovascular compression in the palm side (Fig 4, 5).



Fig. 4. The injection needle is usually introduced from the dorsal side, and great care should be taken to avoid over injection of cement to prevent neurovascular compression in the palm side.



Fig. 5. Postoperative image shown good alignment. Calcium sulfate filling the defect fully but the cement outside of bone defect between distal radius and ulna. Potential risk is irritating soft tissue cellulites.

## 5.2 Impact on fracture healing

Calcium sulphate, as a synthetic bone graft substitute, has demonstrated the capability to support fracture healing. All cases in this study showed callus by X-ray in 2 to 4 months. The average time of bone callus appearing was 2.9 months. Distal radioulnar joint had good alignment (Figure 6, 7, 8, 9).



Fig. 6. Preoperative anteroposterior and lateral X-ray image demonstrated significant dorsal fracture displacement and distal collapse.



Fig. 7. Postoperative anteroposterior and lateral X-ray image shown good alignment. Calcium sulfate filling the defect fully was evident radiographically.

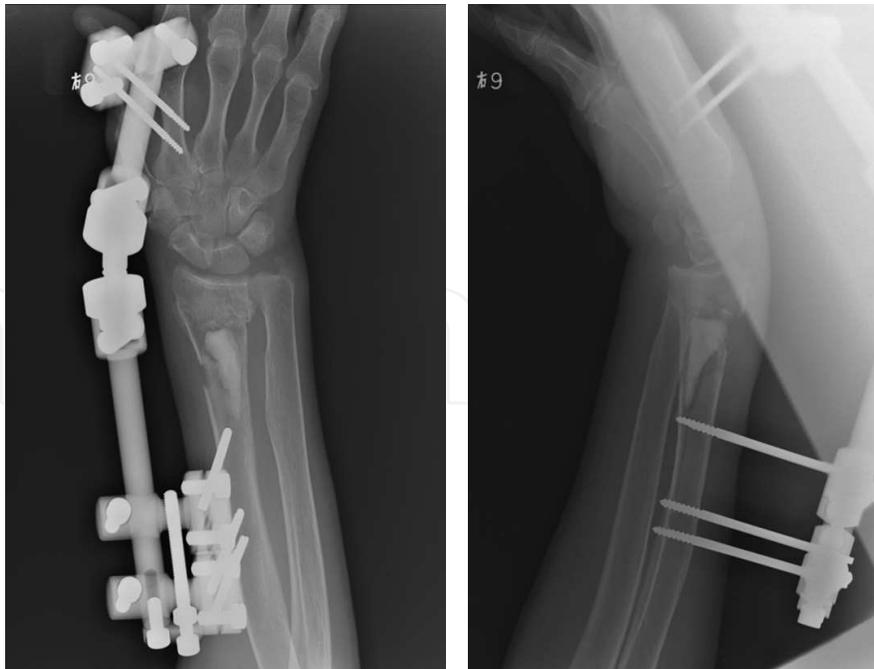


Fig. 8. Radiologic examination 4 weeks after surgery showed partial resorption of calcium sulphate.



Fig. 9. At 8 weeks after surgery the calcium sulphate was absorbed completely and callus formation and fracture stability was demonstrated. The external fixator was removed.

In the majority of cases it seems that the appearance of callus and new bone were later than the time for material absorption, which means the callus appeared after the cement was absorbed. In this study we found 86% of the patients with calcium sulphate were absorbed within 2 months with the complete absorption at 3 months.

Borrelli<sup>[15]</sup> et al assessed the calcium sulfate cement had bending and torsional strength comparable with autogenous bone in treated bone defects cases. The authors also observed that calcium sulphate had adequate mechanical strength and believe that the absorption of

calcium sulfate and bone callus formation in the implantation site is predictable and simultaneous. Therefore there should be reduced concern if the calcium sulphate is absorbed in 2 or 3 months after surgery if proper external fixation support is achieved.

## 6. Conclusions

It is recommended to use injection of calcium sulphate bone graft material in the treatment of comminuted distal radius fractures, especially in metaphyseal fracture defects. Minimally invasive approach causes reduced damage to the tissue, significantly decreasing the risk of infection and accelerating the bone healing. Overfilling or pressurizing the defect site should be avoided. There is the potential to cause a reaction if the bone graft material overflows into the soft tissue, in addition to potential articular cartilage damage if extravasation into the joint space occurs. Kelley and Borrelli reported that 3% to 7% of the site drainage and cellulitis are related to the product itself; such phenomenon requires further clinical investigation. In cases where sterile wound drainage occurs, changing dressings for a few days usually resolves the problem. Bacterial culture or giving prophylactic antibiotics are only needed if it is suspected that an infection is present.

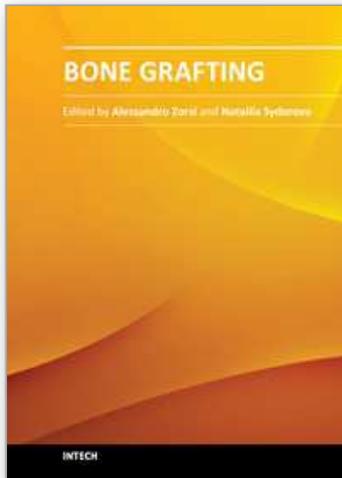
Synthetic calcium sulphate bone cement is an ideal choice of bone graft substitute for stabilization and repair of comminuted distal radius fractures by minimally invasive technique and external fixation. The capability to support new bone formation is excellent and the material absorption is 100%. Calcium sulphate also has the advantage of being mouldable such that it can be shaped to fill gaps in bone, in addition to setting hard within a convenient time frame (approximately 10 minutes), combined with good mechanical strength. It can also be injected for minimally invasive surgery. Calcium sulphate is now being used as a carrier for local delivery and slow release of antibiotics, so it is a material with a huge potential clinical application. The use of calcium sulphate to treat distal radial fracture defects coupled with external fixation appears safe and efficacious, if the articular surface defect is larger than 0.5cm or the gap of bone cavities is less than 2.5cm.

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## **Bone Grafting**

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Bone grafting is the surgical procedure in which new bone (bone graft) or a replacement material (graft substitute), is placed into bone fractures or bone defects to aid in healing. Bone grafting is in the field of interest of many surgical specialties, such as: orthopedics, neurosurgery, dentistry, plastic surgery, head and neck surgery, otolaryngology and others. In common, all these specialties have to handle problems concerning the lack of bone tissue or impaired fracture healing. There is a myriad of surgical techniques nowadays involving some kind of bone graft or bone graft substitute. This book gathers authors from different continents, with different points of view and different experiences with bone grafting. Leading researchers of Asia, America and Europe have contributed as authors. In this book, the reader can find chapters from the ones on basic principles, devoted to students, to the ones on research results and description of new techniques, experts will find very beneficial.

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