Resorbable cement for the augmentation of internally-fixed unstable trochanteric fractures

A PROSPECTIVE, RANDOMISED MULTICENTRE STUDY

We undertook a multicentre, prospective study of a series of 112 unstable trochanteric fractures in order to evaluate if internal fixation with a sliding screw device combined with augmentation using a calcium phosphate degradable cement (Norian SRS) could improve the clinical, functional and radiological outcome when compared with fractures treated with a sliding screw device alone. Pain, activities of daily living, health status (SF-36), the strength of the hip abductor muscles and radiological outcome were analysed.

Six weeks after surgery, the patients in the augmented group had significantly lower global and functional pain scores (p < 0.003), less pain after walking 50 feet (p < 0.01), and a better return to the activities of daily living (p < 0.05). At follow-up at six weeks and six months, those in the augmented group showed a significant improvement compared with the control group in the SF-36 score. No other significant differences were found between the groups. We conclude that augmentation with calcium phosphate cement in unstable trochanteric fractures provides a modest reduction in pain and a slight improvement in the quality of life during the course of healing when compared with conventional fixation with a sliding screw device alone.

A standard surgical procedure for trochanteric fractures is internal fixation with a sliding screw device. This implant allows controlled telescoping and impaction of the fracture during weight-bearing and an improved rate of healing when compared with that of earlier, rigid implants. Stable two-part trochanteric fractures usually heal well, irrespective of the fixation device used with a rate of complications of less than 5%. Unstable trochanteric fractures, defined as fractures with three fragments or more are more often associated with complications such as cut-out or excessive slippage, particularly in patients who are unable to restrain from full weight-bearing during the early healing period. The re-operation rate is approximately 10%. Various methods, such as valgus osteotomy, valgus reduction with tension-band wiring and a variety of other techniques of internal fixation have been developed in an attempt to reduce the rate of complications in the management of these fractures.

Previously polymethylmethacrylate (PMMA) cement has been successfully used for structural augmentation of unstable trochanteric fractures but the technique has not gained wide acceptance. The drawbacks of using cement include thermal necrosis, disturbances of healing due to the interposition of cement and difficulty removing the cement if revision surgery is required. In recent years new types of cement which are susceptible to remodelling and replacement by host bone have been introduced and may be used for the augmentation of fractures in order to improve stability and outcome. Of the various degradable cements available, the use of Norian SRS (Skeletal Repair System; Norian Corp., Cupertino, California), a calcium phosphate cement, is probably the most widely documented. It is injectable, biocompatible, non-exothermic, hardens in situ and is claimed to be replaced by host bone over time. After injection, an osteoconductive, carbonated apatite is formed with chemical and physical characteristics similar to those of the mineral phase of bone. It has a compressive strength of 55 MPa, which is higher than that of cancellous bone.

We undertook a prospective, randomised multicentre study in order to evaluate whether the augmentation of an internally-fixed, unstable trochanteric fracture with calcium phosphate cement could improve the outcome when compared with conventional internal fixation alone.
Patients and Methods
The study was performed at three orthopaedic departments between 1997 and 2000. The inclusion criteria were as follows: an unstable trochanteric fracture (Jensen types 4 to 5 or AO 31 to A235), age more than 65 years, walking with or without support, less than 72 hours between the fracture and surgery and signed informed consent. The exclusion criteria were: dementia, serious concomitant illness or mental instability, neurosensory, neuromuscular or musculoskeletal deficiency which limited the ability to perform objective functional tests, soft-tissue infection at the operation site, ongoing radiotherapy or chemotherapy for malignancy, pathological fracture, a clotting disorder, corticosteroid treatment exceeding 5 mg/day, a concurrent fracture which would affect the post-operative functional outcome or an earlier operation on the contralateral hip.

After inclusion the patients were randomised using a closed-envelope system to be treated either by closed reduction and internal fixation with a sliding screw device alone or using the same device combined with calcium phosphate for augmentation. Randomisation was stratified according to age (above or below 80 years of age), gender and pre-fracture mobility (with or without a walking aid). The authors performed all the surgical procedures, 98 being under spinal anaesthesia with sedation and 14 under general anaesthesia. After reduction of the fracture a sliding screw device (Dynamic Hip Screw (DHS), Stratec, Obersdorf, Switzerland) was inserted using the standard technique although the most proximal screw hole in the plate was left without a screw since it was used for the injection of cement. A separate cortical drill hole was made in the anterolateral aspect of the femur just distal to the base of the barrel. A curved probe was used to clear the fracture of small bone fragments, which were then impacted into the side of the fracture in order to create an empty space. The cement was injected using curved needles with the same curvature as the probe. The goal was to achieve complete filling of the posteromedial gap and thereby create a mechanically competent medial arch which would share load between the bone and the implant. Typically, 20 ml of cement were used to fill this gap (Fig. 1). All the patients were allowed immediate weight-bearing after surgery and were followed by clinical and radiological examination immediately after surgery and at one and six weeks and six months after the procedure. Specially-assigned physiotherapists undertook the clinical and functional evaluations. The intention was to keep the randomisation status of the patients as masked as possible to the physiotherapists. From a practical standpoint this was difficult to achieve fully, although the physiotherapists did not have access to the medical records or radiographs.

The total number of patients included in the study was 112, 55 in the cement augmented group (augmented) and 57 in the group treated with a sliding screw device alone.
(controls). Of all the screened patients, 29 (10%) were excluded because of senile dementia, 85 (30%) because of a stable two-fragment fracture or an intact lesser trochanter, 41 (15%) because of earlier surgery to the contralateral hip and 13 (5%) for other reasons.

Seven patients in each group were lost to follow-up because of concurrent illness or weakness which made it impossible for them to attend for review. Five patients died, three in the augmented group and two in the control group. No death was related to the surgical procedure. The remaining 93 patients were followed up according to the study protocol.

Pain was evaluated at each follow-up visit using a 100 mm linear visual analogue scale (VAS) with 0 indicating no pain and 100 the most severe pain possible. Patients were asked to mark the degree of pain on the scale. Three different pain modalities were evaluated at each visit. Global pain was measured by the response to the question “How is your hip pain today?”. Functional pain was assessed after the subject had walked ten feet and completed the VAS, and then after walking 50 feet.

Health status was assessed using the short form-36 questionnaire (SF-36). This has been validated among healthy individuals and those with various chronic and acute medical conditions. Each subscore totals between 0 and 100, a higher score indicating better function. Health transition was also measured; the patients compared their general health at each time point with that one year earlier.

Six parameters reflecting the activities of daily living (ADL) were evaluated. These were: 1) walking ten feet; 2) walking 50 feet; 3) getting in and out of bed; 4) rising from an armless chair; 5) getting on and off a toilet and 6) climbing a 15 cm-high step. The use of a walking aid was reported as a percentage of the unaffected side. Each patient therefore served as his own control.

The radiological outcome included assessment of reduction of the fracture, the adequacy of fixation, failure of the implant, sliding of the lag screw and healing of the fracture. Reduction was considered to be adequate if the femoral neck angle was < 10° of varus or < 15° of valgus when compared with the uninjured, contralateral hip and the displacement was < 5 mm on both anteroposterior (AP) and lateral post-operative radiographs. The position of the lag screw was assessed from the mapping of the femoral head described by Kyle, Gustilo and Premer and the tip apex distance (TAD) described by Baumgaertner and Solberg. Fixation was deemed to be adequate if the lag screw was placed central/central (AP/lateral view), inferior/central, or inferior/posterior. Placement in the superior and/or anterior third of the femoral head was considered inadequate. A TAD of less than 20 mm was considered to be adequate. Sliding was measured along the lag screw. A fracture was assessed as healed if trabeculae were visible across the fracture line. Nonunion was defined as the absence of bridging bone at the line of the fracture by follow-up at six months. Signs of avascular necrosis were assessed according to the classification of Ficat.

The ethical committees at each participating centre reviewed and approved the protocol for this study.

**Statistical analysis.** In order to test the null hypothesis of no difference between the two treatment groups for continuous outcomes, generalised linear models (GLM) analysis was employed using SAS Institute software, version 8.0 (SAS, Cary, North Carolina).

In order to assess the independence of the treatment groups for categorical outcomes, two methods were employed. For 2 x 2 and for non-ordered 2 x r contingency tables, the chi-squared test was used for expected cell frequencies greater than or equal to 5.0. Fisher’s exact test was used for the 2 x 2 and for non-ordered 2 x r contingency tables for expected cell frequencies of less than 5.

For ordered 2 x r contingency tables, the asymptotic Mantel-Haentzel chi-squared test was used when the expected frequency was greater than or equal to 5.0. The exact Mantel-Haentzel chi-squared test was used for ordered 2 x r tables when the expected value was less than 5.

A power analysis was made to estimate the sample size. Based on the assumption that the augmented group would have a reduced screw shortening of 20% compared with the control group (15 vs 12 mm) a sample size of 44 completed subjects for each study group was assumed in order to detect a significant difference between the two groups with $\alpha = 0.05$ and $\beta = 0.20$ (i.e. power 0.8). Values for $p < 0.05$ were regarded as significant.

**Results**

There was no statistical difference between the two groups in terms of age, gender, affected hip and walking-aid requirements at the time of fracture (Table I).

The mean operating time was longer for the augmented group (68.7 vs 56.9 minutes) although the difference was
not statistically significant. The mean blood loss during surgery was significantly greater in the augmented group (405 ml vs 281 ml, p < 0.05).

There was no difference in the reduction of the fracture and positioning of the implant between the groups as assessed on the immediate post-operative radiographs. Reduction was considered to be adequate in 43 (78%) of the augmented hips and 42 (74%) of the control group. The positioning of the implant was considered to be adequate in 52/55 (95%) of the augmented hips and 52/57 (91%) of the control group. Inadequate placement was because of the position of the tip of the lag screw in the superior third of the femoral head in one hip from each group and in the anterior third in two augmented and four control hips. The mean TAD was 18 mm (SD 2) in the augmented hips and 16 mm (SD 2) in the control group. In three hips (one augmented and two control), the TAD was > 25 mm.

At six months after surgery the mean sliding distance of the screw in the augmented group was 13.5 mm (SD 3.3) compared with 15.9 mm (SD 4.1) in the control group. There was no major displacement of the fracture in any patient during the study. All fractures healed although two in the augmented group had not healed completely as nonunion. By nine months both fractures had healed without any additional procedure.

The mean hospital stay was 10.5 days (SD 3.9) for the augmented group and 10.0 days (SD 3.3) for the control group. This difference was not significant.

There were no re-operations in any of the patients during the study. By six months, two cases of loosening of the plate were seen in the augmented group. In one, the screws securing the plate had broken and in the second they had pulled out. In both, the fractures healed and further surgery was not indicated. There was no breakage or pull-out of screws or other complications of hardware in the control group. There were no cut-outs or screw penetrations in either group.

At six weeks, patients in the augmented group had significantly lower global pain scores (p < 0.003) and lower functional pain scores after walking ten feet (p < 0.003) and 50 feet (p < 0.01). There was no difference between the augmented and control groups for global or functional pain when walking ten or 50 feet at one week or at six months (Table II).

Patients in the augmented group showed an improvement at six weeks compared with the control group in: rising from an armless chair (p < 0.003), getting on/off a toilet (p < 0.05) and climbing a 15 cm-high step (p < 0.03). There was no statistical difference between the two groups for any of the six elements at one week and six months.

At six weeks patients in the augmented group showed significant improvement compared with the control group on three SF-36 subscales: pain (p < 0.02), general health (p < 0.006) and vitality (p < 0.004). Health transition was also significant in favour of the augmented group at six weeks (p < 0.02). In addition, at six months, patients in the augmented group showed significant improvement for five SF-36 subscales compared with the control group: physical functioning (p < 0.04), vitality (p < 0.02), social functioning (p < 0.002), mental health (p < 0.03), and general health (p < 0.02) (Table III).
groups. There was no significant difference in the amount of pain experienced during the isometric testing for the two groups at any time point.

Discussion
The management of patients with unstable trochanteric fractures is a continuing challenge, in part because of the frequency of osteoporosis in these individuals which may make it difficult to achieve stable fixation with conventional metal implants. In elderly patients, who may not be able to take weight through their upper limbs, successful rehabilitation often depends upon immediate weight-bearing being allowed after surgery. Augmentation of the bone surrounding a metal implant therefore seems to be an attractive option. Although clinical reports using PMMA have shown favourable results, it has not become widely used in this situation.14-17 Our aim was to evaluate augmentation with a cement which had been specifically developed for the task. Calcium phosphate hardens without generating heat and, based upon preclinical studies and human biopsies, will resorb over time, although the timetable for this resorption in man is not known. The compressive strength of calcium phosphate appears to be adequate but its bending and shear strengths are low. Because of this, the metal implant should be considered to neutralise the shearing and bending forces.

Augmentation added another step to the surgical procedure and prolonged our operating time by approximately 12 minutes. Perioperative bleeding is in part related to the operating time and perhaps explains the increased perioperative blood loss in the augmented group. Reduced pain will allow earlier mobilisation and return to the activities of daily living. A stable fixation will clearly help with this. Sliding screw devices allow impaction of the fracture in order to achieve better load-sharing and healing when compared with rigid implants. Unfortunately, the initial impaction is associated with pain on weight-bearing. In our study pain was significantly reduced at six weeks in the augmented group probably because of the more stable fixation offered by the augmentation. At one week and six months, there was no significant difference in pain between the two groups. At one week this might in part have been because of pain being created by both the bony and soft-tissue components of the injury and subsequent surgery. At six months the fractures were healed and the pain, if present, was low in both groups.

For the different ADLs which were examined, the difference between the groups was most pronounced at six weeks, while that at one week and six months was less obvious. Because of the strict inclusion and exclusion criteria, the included patients represented a healthy subpopulation of those suffering a trochanteric fracture. It has been shown that a patient’s general health, activity level and especially rotation at the site of the fracture, is low. In a previous study using roentgen stereophotogrammetric...
analysis which is a very precise radiological technique, with similar treatment groups as in our study, augmented trochanteric fractures were significantly more stable when compared with trochanteric fractures fixed with a sliding screw device alone. An important radiological measure of the success of fracture surgery is the adequacy of reduction of the fracture. In our study there was no difference in this between augmented and control hips on the immediate post-operative radiographs. This suggests that any differences in outcome were because of the presence or absence of the augmentation rather than surgical technique.

Our findings suggest that augmentation of unstable trochanteric fractures using calcium phosphate cement provides modest improvement during healing compared with those treated by conventional fixation alone.

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References

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