Treating Non-Healing Stress Fracture in the Diabetic Population using a Minimally Invasive Surgical Technique and Synthetic β Tri-Calcium Phosphate/Calcium Sulfate Graft

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Introduction

Delayed-healing stress fractures are a common pathology presenting in the diabetic population. In both type 1 and 2 diabetes, bone turnover is decreased, and the microstructure and physical properties of the bone are compromised1. The reasons for this bone fragility are multi-factorial, complex and include impaired osteoclastogenesis, and an impaired response to mechanical loading2. These may be critical limiting factors of fracture remodeling in diabetic individuals, and often presents as a stress fracture that radiographically appears to be remodeling. However the fracture is still symptomatic (painful) even in patients with advanced neuropathy, but often lacks radiographic indication for rigid internal fixation techniques. Successful treatment must embrace effective fixation of the fracture, and the stimulation of bone growth at the site with the use of a suitable bone graft. Although autologous bone remains the gold standard bone graft, its' harvest may not be possible, and when it is, this can be associated with complications such as donor site morbidity. The use of a synthetic bone graft material is an attractive alternative. A synthetic, injectable β-Tri-Calcium Phosphate/Calcium Sulfate material* has been reported to demonstrate effective bone regenerative capacity and complete absorption3. This has been used with success in percutaneous internal fixation augmentation of scaphoid nonunions4. We believe this is the first reported use of this material in lower limb stress fractures.

Methods

A novel surgical approach was utilized in patients presenting with chronic pedal stress fractures. All patients were diagnosed with either type 1 or 2 Diabetes. Plain radiographs, MRI (Figure 1) and clinical symptoms confirmed the presence of stress fractures in all cases. Following standard preparation of the surgical site, a novel minimally invasive technique (key-hole incision technique) is utilized, with dissection down to the symptomatic bone, which was marked pre-operatively. The visualized fracture area is drilled with a 0.035 inch Kirschner wire, until bleeding/marrow extrusion is noted. Several drill holes are utilized to engage the entire symptomatic area. The β-Tri-Calcium Phosphate/Calcium Sulfate material is then prepared according to the manufacturers' instructions, by combining a powder and liquid, both supplied (Figure 2), to produce a smooth setting paste. The paste is transferred into a syringe and the graft material is implanted into the drill holes and surrounding bone (Figure 3). The use of the Kirschner wires to drill repeatedly across the fracture results in the exposure of bleeding bone, and the release of growth factors to stimulate the bone healing cascade. The placement of the graft material into this site is intended to further encourage new bone formation. Analogue pain scores were recorded for all patients pre and post operatively and at each subsequent follow-up. The patients were allowed to protective weight-bear, in a fracture boot immediately after the procedure for until symptoms resolve, with full weight bearing allowed after this time. Patients were assessed at 2-3 days, 2 weeks and 4 weeks, for healing and radiographic consolidation of the stress fracture.

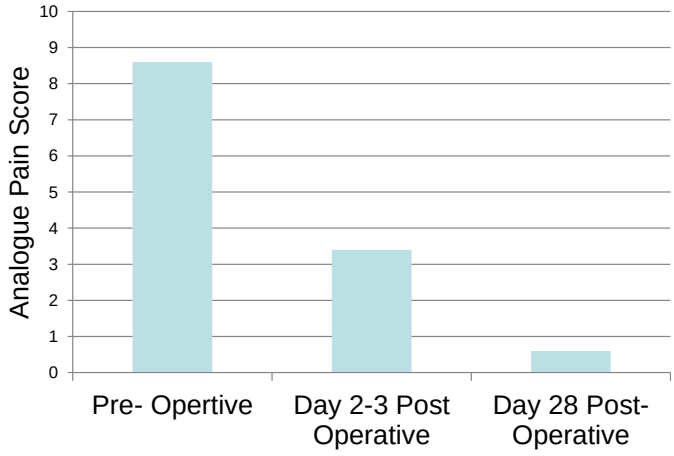
Figure 1. MRI confirming stress fracture

Figure 2. Synthetic bone graft, as supplied.

Results

To date, the technique has been used on 34 patients with a 100% success rate as defined by clinical resolution of pain and no radiographic indication of fracture or periosteal bone reaction. Analog pain scores reduced from an average of 8.7 pre- operatively to 3.4 two-three days post-operatively to 0.6 - 28 days post-operatively (Figure 4). No incidence of post-operative infection were noted in the patient population.

Figure 4- Analogue pain scores, pre and post operatively.



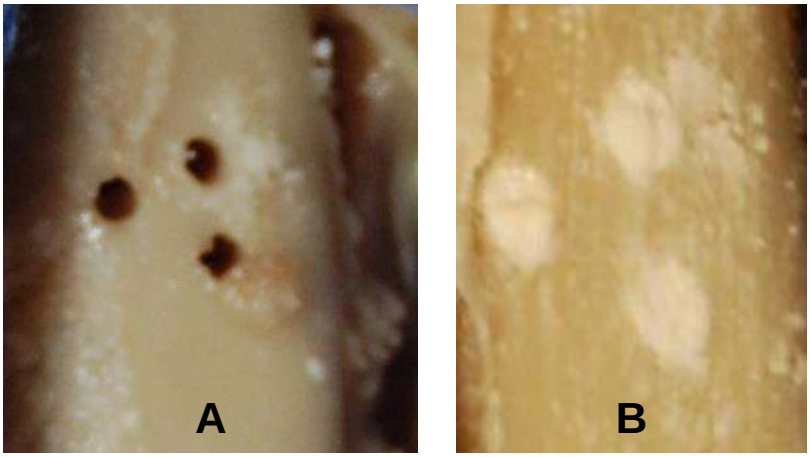


Figure 3. (A) Holes from drilling with Kirschner wire.
(B) Holes filled with synthetic graft material.

Conclusions

The application of this minimally invasive technique has demonstrated successful outcomes in a challenging patient population. The use of the technique in combination with the synthetic bone graft achieved radiographic healing of stress fractures in all 34 patients, and importantly, effective resolution of clinical symptoms in the majority of patients.

References

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*geneX, Biocomposites Inc, NC, USA.

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