Fixion™ nails for humeral fractures

A. Jovanovic, M. Pirpiris, H. Semirli, S.G. Doig*

Alfred Hospital, Commercial Road, Prahran, Australia

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Introduction

The internal fixation of long bone fractures is the most effective form of treatment in the setting of multi-trauma.1,12,15 It allows immediate mobilisation and functional recovery. There is controversy between nailing and plating as to which is the most effective operative form of humeral fracture treatment.3,9,10 We prefer humeral nailing because it is minimally invasive, relatively fast, results in less blood loss compared to plating3 and allows easy positioning of the multiply-injured patient on the operating table.3,4

Despite the operative advantages of humeral nailing, we have found that distal cross-bolting may be challenging and time consuming as opposed to proximal cross-bolting which is relatively straightforward. This may be detrimental to patient care in the multi-trauma setting where multiple fractures demand rapid fixation. Recent advances in nail designs have attempted to come to terms with this issue.5,13 Nails have been developed that do not require distal cross-bolting.

This is the first, prospective, consecutive study of the use an inflatable nail (Fixion™, Intramedullary-Nail DicoTech, Medical Technology, Herzliya, Israel) in the management of multiple trauma. This nail permits the rapid, stable fixation of fractures with minimal dissection and no distal cross-bolting.5,13

Materials and methods

Nine patients with a mean age of 43 years (range: 18–87 years), were enrolled in the study from November 2000 to January 2002. There were six males and three females. All multiply-injured patients with a concurrent middle third humeral shaft fracture were enrolled. Written, informed consent was obtained from the patients and their families. There were no refusals to participate. Ethical committee approval was not sought for the study, as the results of the device have been well reported in the literature.5,13

There were nine fractures of which five were right-sided. All were closed injuries. The associated injuries included five upper limb fractures, nine lower limb fractures, two pelvic fractures, two cranial fractures and one thoracic fracture.

Summary

Humeral fractures in the setting of multi-trauma are usually managed with internal fixation. We prospectively followed nine patients treated with an expandable nail (Fixion™, DiscoTech, Medical Technologies, Herzliya, Israel), until union. Internal fixation rapidly stabilises the injured limb, and the lack of distal cross-bolting in this device markedly reduced our operative time. There were no complications in our series and there was evidence of clinical and radiological union within 6 months. We found the nail easy to use and effective in this clinical setting.

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two splenic ruptures and two patients with significant chest injuries. There were no significant head injuries.

The patients were assessed on admission, post-operatively, and at 6 weeks, 6 months and 12 months. A comprehensive, standardised clinical examination, including measurement of range of motion of shoulder and elbow, fracture site assessment and neurological examination was performed. Antero-posterior and lateral radiographs were taken. All assessments were performed by one of the authors.

The technique used for insertion of the nail was the same in all patients. A two centimeter long transverse antegrade approach was used. The deltoid was split. No guide wires were inserted. The entrance site, which is just lateral to the acromion over the greater tuberosity, was opened using an awl. The proximal humerus was reamed using instruments supplied with the set, and the position of the reamer screened on image intensifier to ensure correct placement. Nail length and diameter were determined according to pre-operative templating. This was done on the injured limb, and then modified intraoperatively if necessary. The selected nail was inserted and inflated under image intensifier control. The nail is inflated using a calibrated pump supplied with the set, and the limb was then screened to ensure proper inflation. There was no distal cross-bolting.

Results

All fractures were middle-third humeral fractures (see Fig. 1). There were five A2 and three A3 fractures according to the A.O. classification. There was also one segmental fracture that was both a proximal and middle third fracture.

The nail diameters used ranged from 6.7 to 8.5 mm in the collapsed state.

The average operating time per humeral fracture was 30 min (range: 16—35 min). There were no infections. All patients complained of pain in the area of insertion at 6 weeks.

No patient had shoulder pain at 6 months. Furthermore, no patient had pain at the fracture site to deep pressure or to angulatory stress at this time. There were no sagittal or rotatory malunions on clinical examination. There were no neurological abnormalities. All of the fractures had united on radiological grounds by this time (see Fig. 2).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Shoulder range of movement at the 6-month post-operative review</th>
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<tbody>
<tr>
<td>Movement</td>
<td>Range (°)</td>
</tr>
<tr>
<td>Flexion</td>
<td>170 ± 6</td>
</tr>
<tr>
<td>Abduction</td>
<td>173 ± 4</td>
</tr>
<tr>
<td>External rotation</td>
<td>35 ± 4</td>
</tr>
<tr>
<td>Internal rotation</td>
<td>42 ± 12</td>
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</tbody>
</table>

Figure 1 Radiograph depicting a typical midshaft fracture of the humerus treated with this method.

Figure 2 Radiographs depicting radiological union at the 6-month post-operative review.
At 6 months post-operatively shoulder range of motion is shown in Table 1. The mean range of elbow flexion was 140° ± 5°.

Discussion

There is some controversy as to whether humeral fractures should be fixed with plates and screws or an intramedulally nail.3,8,9 At our centre, the busiest trauma centre in South-Eastern Australia, where the rapid stabilisation of multiply-injured patients is a priority, the practice of intramedullary nailing with its favourable biomechanical profile, is becoming more widely used. Whilst some fractures are not amenable to nailing including fractures associated with nerve palsies and fractures that are too proximal, or too distal to allow adequate fixation, mid-shaft humeral fractures are ideal candidates for this technique.

Commonly cited concerns with this technique include the potential interference with the rotator cuff and long-term dysfunction2,6,7,11,14 and the time-consuming practice of distal cross-bolting. Neither of these were apparent in our series, although our series is small. The inflatable nail that we used did not require distal cross-bolting, therefore, shortening operating time markedly, and reducing radiation exposure. It is an unreamed device, and because it inflates, fixation is obtained at multiple points along the intramedullary canal. There was no clinical evidence of rotator cuff dysfunction at the sixth post-operative month.

This series is the largest to our knowledge in multiple trauma patients dealing with the management of humeral fractures using an inflatable intramedullary nail. Whilst other papers have demonstrated this nail effectiveness in the management of isolated humeral fractures, this is the first paper to demonstrate its effectiveness in the management of this patient group.5,13

Conclusion

We have found that this particular nail is easy to use, can be inserted rapidly, and has a good clinical outcome at 6 months. We recommend the use of this nail for the management of uncomplicated fractures of the middle third of the humeral shaft in multiply-injured patients. Further modifications to the nail, including the ability to proximally cross-bolt, will extend the indications to the more proximal fracture patterns, without significant increases in operative time.

References