Fixation of fractures of the shaft of the humerus by dynamic compression plate or intramedullary nail

A PROSPECTIVE, RANDOMISED TRIAL

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We randomised prospectively 44 patients with fractures of the shaft of the humerus to open reduction and internal fixation by either an intramedullary nail (IMN) or a dynamic compression plate (DCP). Patients were followed up for a minimum of six months. There were no significant differences in the function of the shoulder and elbow, as determined by the American Shoulder and Elbow Surgeons' score, the visual analogue pain score, range of movement, or the time taken to return to normal activity. There was a single case of shoulder impingement in the DCP group and six in the IMN group. Of these six, five occurred after antegrade insertion of an IMN. In the DCP group three patients developed complications, compared with 13 in the IMN group. We had to perform secondary surgery on seven patients in the IMN group, but on only one in the DCP group ($p = 0.016$).

Our findings suggest that open reduction and internal fixation with a DCP remains the best treatment for unstable fractures of the shaft of the humerus. Fixation by IMN may be indicated for specific situations, but is technically more demanding and has a higher rate of complications.

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When uncomplicated diaphyseal fractures of the humerus are treated conservatively by reduction and subsequent immobilisation of the arm, successful healing occurs in over 90% of cases.¹⁻⁴ Open reduction and internal fixation, however, is preferred for open, segmental and pathological fractures. Surgical stabilisation is also considered to be the best treatment for bilateral fractures of the humerus and ipsilateral fractures of the humerus and forearm, as well as in cases of polytrauma, progressive neurological deficit, vascular injury and failed conservative treatment.^{2,3,5,6} Usually, fixation is achieved by a dynamic compression plate (DCP), and it is generally accepted that this gives satisfactory results.^{5,7,8}

Use of this plate, however, requires extensive dissection and is complicated by the proximity of the radial nerve and the risk of mechanical failure in osteopenic bone. As a result of recent technical advances, there is growing interest in the use of the humeral intramedullary nail (IMN).^{6,9,10} Browner et al¹¹ and Rockwood and Green¹² recommend fixation of diaphyseal fractures of the humerus by an IMN which can be inserted into the humerus antegrade, from the shoulder, or retrograde, from the elbow. In theory, fixation by an IMN requires less invasive surgery, and reaming can yield autograft material. The biomechanics are improved, with higher moments of inertia and load-sharing capabilities.

We are not aware of any previous published prospective, randomised comparisons of fixation by the DCP or locked IMN and none of the existing studies^{13,14} assesses functional outcome.

Patients and Methods

Between 1994 and 1996, 44 patients with a fracture of the humeral shaft requiring surgical stabilisation were prospectively randomised to undergo fixation by either a DCP or locked IMN at three tertiary care centres in Canada. The five surgeons involved were all experienced in both procedures. The fractures were located from 5 cm distal to the surgical neck to 5 cm proximal to the olecranon fossa. The indications for operation included open fractures, polytrauma, instability and early failure of conservative treatment. All the patients were skeletally mature. We excluded those with a history of previous fractures of the humerus or

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pathology of the upper limb and those with pathological fractures, grade-III open fractures and injuries more than 21 days old. In addition, we did not include patients who might be unable to co-operate in the assessment of function because of head injuries.

Patients randomised to fixation by DCP had plating through an anterolateral or posterior approach. The length of the plate and the necessity for autogenous bone grafting were dependent on the pattern of the fracture, comminution, and at the discretion of the surgeon. Russell-Taylor locked humeral IMNs (Smith & Nephew, Memphis, Tennessee) were used. Reaming was done only if necessary for insertion of the smallest IMN of 7 mm diameter. Our protocol initially specified antegrade insertion, but later we inserted the IMN retrograde whenever possible. This change was based on an interim analysis and on the reports of Chapman et al¹³ and Wagner et al,¹⁴ who reported problems in the shoulder after antegrade insertion. Eight IMNs were inserted retrograde. Reaming was done in ten of the 13 antegrade insertions.

There were 23 patients in the DCP group and 21 in the IMN. Table I gives details of gender, age and Injury Severity Score (ISS). One patient in each group (ISS of 30 and 64, respectively) died in hospital after surgery.

Most of the patients (18 in the DCP and ten in the IMN fixation group) sustained their injuries in motor-vehicle accidents. Falls were the second most common cause of injury with four patients in the DCP and seven in the IMN fixation group. Table II shows the distribution of the types of fracture.¹⁵ There were five open fractures (four grade I, one grade II) in the DCP group and one (grade II) in the IMN group.

One patient treated by IMN fixation was lost early to follow-up. This left 22 in the DCP group and 19 in the IMN series. Routine follow-up examinations, including clinical and radiological assessments, were carried out for a mean of 14.3 months (6 to 33). We chose a minimum follow-up of six months because by the end of that time healing of the fracture would normally have taken place and functional improvement would be starting to level off. Although we realised that there may be some further functional improvement after six months, we calculated that with a prospective, randomised design any difference would be the same in both groups. We recorded the time to union, but decided to concentrate on the more objective endpoint of nonunion requiring surgical intervention.

The primary outcomes measured were function and pain. To assess function, we used the American Shoulder and Elbow Surgeons' (ASES) shoulder score for 13 activities of daily living¹⁶ requiring full shoulder and elbow movement (Table III). The maximum possible score is 52 points. We quantified pain using visual analogue scales, with zero being no pain and 10 extreme pain. Secondary outcomes of the study were the incidence of complications (Table IV) and the need for further operation (Table V).

Table I. Details of the patients in both groups

	Plate	Nail
Number	23	21
Gender		
Male	15	13
Female	8	8
Age in years (range)	49 (20 to 81)	40 (19 to 82)
Injury Severity Score (range)	18 (4 to 41)	18 (4 to 64)

Table II. Distribution of the types of fracture in both groups

Comprehensive classification	Plate	Nail	Total
A	8	10	18
B	11	8	19
C	4	3	7
Total	23	21	44

Table III. Details of the American Shoulder and Elbow Surgeons' (ASES) score (4 = normal; 3 = mild compromise; 2 = difficulty; 1 = with aid; 0 = unable; NA = not available)

Back pocket	Perineal care
Wash opposite axilla	Eat with utensil
Comb hair	Use arm at shoulder level
Carry 10lb at side	Dress
Sleep on affected side	Pull
Use hand overhead	Throw
Lift	

Table IV. Details of the complications in both groups

	Plate	Nail
Iatrogenic palsy of the radial nerve	0	3
Late fracture	0	1
Nonunion	1	2
Intraoperative comminution	1	2
Infection	0	1
Severe impingement	0	3
Adhesive capsulitis (shoulder)	0	1
Minimal loss of fixation	1	0
Total	3	13

Table V. Details of secondary surgery required in both groups

	Plate	Nail
Nonunion	1	2
Infection	0	1
Nerve palsy	0	1
Failure of fixation	0	1
Impingement	0	2
Total	1	7

Results

The two-tailed *t*-test revealed no significant difference in pain ($p = 0.574$) or ASES function scores ($p = 0.713$) in the two groups. All fractures healed with less than 10° of angulatory or rotatory deformity and less than 1 cm of shortening. Blood loss and time in theatre were similar for the two groups (Table VI).

IMN fixation. Table IV lists the complications. Three patients sustained iatrogenic injury to the radial nerve. In one, a 26-year-old woman, there was a deficit of the radial nerve after reamed antegrade nailing, but the nerve was found to be intact and not entrapped in the fracture site. The patient was lost to follow-up. The other two patients had neurapraxia: one recovered fully in 12 hours, the other within six months. Four months after surgery, one patient sustained a fracture at the level of the distal locking screw on moderately forceful rotation of the arm. This was treated by DCP fixation. Because of nonunion, we substituted DCP for IMN fixation in two patients. In one a type-C3 fracture had been nailed without reaming and in the other a type-B2 had been reamed and nailed. There were three cases of severe impingement, in two of which removal of the IMN was required during the follow-up period. Both patients regained nearly normal function of the shoulder. We removed another IMN because of infection, and the symptoms resolved. After six months, one patient with adhesive capsulitis needed manipulation under anaesthesia. At follow-up at one year, this patient still had restricted movement. In two patients iatrogenic comminution occurred during retrograde insertion of the IMN, but this did not affect the outcome.

DCP fixation. There was one nonunion which required revision of the plate fixation and bone grafting at one year. One patient had minimal loss of fixation, with the plate pulling away from the bone. Another had intraoperative comminution with a slightly displaced fracture at the distal end of the plate. Both patients were treated conservatively and the complications did not affect the outcome. It was not necessary to remove hardware from any patient in the DCP group.

As Table V shows, only one secondary surgical procedure was necessary in the DCP group, but seven patients treated with an IMN required secondary surgery. This difference was significant (Fisher's exact test, $p = 0.0162$).

Discussion

In previous reports of DCP fixation, the incidence of nonunion has ranged from 2% to 10%, of infection from 2% to 4%, and of iatrogenic palsy of the radial nerve from 2% to 5%.^{5,7,8} With few exceptions, patients regained a full range of pain-free movement.^{5,7,8} In our DCP group, there was one nonunion (4%), and iatrogenic palsy of the radial nerve or decrease in the range of movement of the shoulder or elbow was not seen.

Table VI. Details of the results in both groups

	Plate	Nail
ASES functional score (52 points)	48	47
Visual analogue scale for pain (0 to 10)	1.0	1.5
Impingement symptoms	1	6
Time in theatre (min)	84	95
Blood loss (ml)	259	213
Primary bone graft	4	0
Postoperative brace (mean weeks)	8 (3)	2 (1)

Table VII. Details of the complications and problems in antegrade and retrograde nailing and DCP fixation

	Antegrade	Retrograde	DCP
Fracture	13	8	23
Complication	10	3	3
Secondary surgery	6	1	1

Retrospective studies of locked IMN fixation quote incidences of nonunion ranging from 0% to 8%, and reports of the function of the shoulder and elbow differ widely.^{6,9,17-20} In a study of 50 fractures of the humeral shaft, which included pathological fractures, Hems and Bhullar¹⁷ found that 30% of the non-pathological fractures had failed to unite after eight months and that a similar percentage of their patients had poor or unsatisfactory function. In five patients (10%) comminution of the fracture occurred on insertion of the IMN which required removal of the nail in three. They had one case of deep infection and two of intraoperative palsy of the radial nerve in both of which there was complete recovery. They concluded that IMNs should be used cautiously in treating acute non-pathological fractures.

Rommens et al²⁰ retrospectively reviewed DCP fixation of the humerus and then prospectively reviewed IMN fixation. They achieved better results with a retrograde IMN than with an antegrade IMN or DCP fixation; they recorded that 90% of their patients regained excellent function in the shoulder and elbow, and found that only 5% required secondary surgery. Unfortunately, their functional assessments were qualitative and their indications for primary surgery broader than is generally accepted.

Despite the higher rate of complications and need for secondary operations in our IMN group, there was no significant difference in pain and function scores between the two groups.

Despite theoretical concerns about stress risers at the end of the plates, our experience is consistent with the findings of McKee et al²¹ that such problems may be greater at the distal locking screws and tip of the IMN, possibly because they are in diaphyseal cortical bone. The benefits of IMN fixation in the femur and tibia do not seem to apply to the humerus, probably because of problems associated with reaming.²²

The two cases of nonunion in the IMN group occurred

after antegrade nailing, only one of which was reamed. Hems and Bhullar¹⁷ suggest that antegrade nailing adversely affects healing by distracting the fracture and the soft tissues. Of a total six cases of impingement in our IMN group, five occurred after antegrade insertion. Our study confirms that antegrade insertion can lead to problems with shoulder function and range of movement, probably because of damage to the rotator cuff.^{6,13,14,17,19,20}

A rate of injury to the radial nerve of 5% has been reported with DCP fixation.⁸ In the 24 acute fractures treated by this method, iatrogenic injury to the radial nerve was not seen but three patients in the IMN group had this complication.

We are aware that by inserting IMNs both retrograde and antegrade, and using variable degrees of reaming, we introduced variables which weakened direct comparison with DCP fixation. We also recruited fewer patients than we anticipated into the study. The small numbers limit comparison between the groups but Table VII suggests that there were more complications with the antegrade than with the retrograde technique, although open reduction and internal fixation by a DCP still remains the safest method. Fractures of the humeral shaft account for approximately 5% of all fractures,⁹ most of which are treated conservatively, and our inclusion/exclusion criteria were strictly applied. With $p = 0.574$ for the difference in pain and $p = 0.713$ for the difference in function, it would take a very large number of patients to show a significant difference in these primary outcomes. When the notable differences in secondary outcomes began to emerge, we found it difficult to justify further recruitment. Complications in the IMN group were more common, more severe and needed more secondary surgery ($p = 0.016$).

In specific situations, such as pathological or segmental fractures, IMN fixation may be better than DCP fixation,^{9,17,19} but we did not study the former. We suggest that DCP fixation should continue to be regarded as the best treatment for fractures of the humeral shaft which require surgical stabilisation.

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