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ORIGINAL STUDY

The Fixion® nailing system for stabilising diaphyseal fractures of the humerus : A two-year clinical experience

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Previous studies have shown that the expandable nail system (Fixion®) can provide rapid stabilisation of long bone fractures with reduced operative time and low complication rates. Patients with humeral shaft fracture were treated consecutively over a two-year period in our institution with the Fixion® nail.

Nineteen Fixion® nailings were performed in 16 patients over a 2 year period. All fractures were diaphyseal and closed. Eight primary fracture stabilisations were performed and we recorded 2 non-unions in this group, both associated with rotational instability at the fracture site.

Six nailings were performed in 4 patients for fracture non-union with a mean operative time of 127.5 minutes. One case did not unite despite 3 separate Fixion® nailing procedures. Five operations were performed for a pathological fracture, with a mean operative time of 79 minutes ; they all united.

We did not experience advantages of this nail as mentioned in previous studies and the complication rate was higher than previously stated.

Keywords : humerus ; Fixion® nail ; inflatable nail ; non-union ; pathological fracture.

INTRODUCTION

There is growing interest in treating humeral shaft fractures operatively in order to allow for early mobilisation and return to work (*13*). Plating osteosynthesis and intramedullary nailing have been established as methods of stabilising diaphyseal fractures of the humerus (*12,14*).

The Fixion® expandable nail (Disc-o-Tech, Herzeliya, Israel) was introduced in 1999 for the stabilisation of long bone shaft fractures. This device does not require the use of a distal locking screw because of the unique facility to inflate the nail whilst inside the medullary cavity of the bone ; fracture stabilisation is achieved via this manner. This is seen as a recognised benefit of this implant as it can potentially reduce operative time and exposure to radiation (*3,17*). We present the results of our experience with humeral shaft fracture fixation using the Fixion® nail system in 16 patients treated in our institution over a 24 months period, with respect to operative experiences, fracture healing and post-operative complications.

MATERIAL AND METHOD

From January 2002 to September 2005, we treated 16 consecutive patients with humeral shaft fractures, using

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the Fixion® nail. The decision to stabilise the humeral shaft fracture was made according to indications widely published in the literature. We divided the patients into 3 categories : primary fracture fixation, treatment of fracture non-union, pathological fractures. The medical records, operative notes and serial radiographs were reviewed for each case. Patient demographics were recorded, in addition to mechanism of injury ; relevant medical history and fractures were classified via the AO comprehensive system. It was also noted whether the fracture was open or closed, with or without associated neurovascular injury at presentation.

The Fixion intramedullary self-locking nail is a device that limits the need for interlocking screws. The stainless steel nail is composed of a solid core shaft, surrounded by an outer metallic sheath and four perpendicular reinforcement bars. The uninflated nail is inserted into the reamed or unreamed intramedullary canal. Ease of insertion is related to its inherent malleability when uninflated. The distal tip is conical in shape, aiding direct intramedullary advancement without the use of a guide wire. Once in position, the nail is inflated with pressurised sterile saline using a manual hand-cranked pump fitted with a one-way valve. Controlled inflation is carried out to 70 atmospheres with continued monitoring of the system's pressure via a pressure gauge affixed on the pump. Once inflated, the pump mechanism is detached, leaving the injected saline within the nail's core. The nail is expandable up to approximately 160% of its original size. We utilised the implants with a diameter range of 6.7-10 mm and 8.5-13.5 mm. As it expands, the nail conforms to the contour of the intramedullary canal. In this manner, the nail secures itself along the entire length of the bone in a snug anatomic fit, providing rotational stability and proper fragment alignment by its interference fit.

Nails were inserted retrograde or antegrade according to the surgeons' preference and experience. Two consultant orthopaedic surgeons within our institution carried out the procedures. For antegrade nailings, the patient was in the beach chair position and an anterolateral deltoid splitting approach was used. A 1-2 cm opening was created in the rotator cuff over the greater tuberosity and access into the medullary cavity of the humerus was achieved with an awl. Retrograde nailings were performed with the patient prone. Access into the medullary cavity was made 1-2 cm above the olecranon fossa. A hole was created in the diaphysis around 2 cm in diameter to allow for nail insertion.

The fracture site was opened if closed reduction was unsuccessful and for the purposes of augmenting fracture fixation, for example with cerclage wires. For the fracture non-unions the site was routinely opened to clean the bone ends, free interposed soft tissue and insert bone graft. Autologous bone graft and allograft was used at the surgeons' discretion. Following successful reduction, a guide wire was introduced across the fracture site. If reaming of the medullary cavity was performed, it was done over the guide wire and the canal was progressively enlarged. The Fixion® nail was then inserted and the implant was inflated with normal saline or Hartmann's solution to the desired diameter, in order to achieve a stable fixation. With antegrade nailings, one or more proximal locking screws were inserted using a guide, which is part of the assembly.

Wounds were then irrigated and closed in a standard fashion with absorbable braided filament sutures to fascia/ rotator cuff and subcutaneous tissue, followed by clips, vicryl or non-absorbable sutures to skin. If there was doubt with regards to stability of the fracture post nail insertion, a humeral cast brace was considered. Patients were then appropriately discharged and followed up in the outpatient fracture clinic. They were all assessed clinically and radiologically for fracture healing and complications post-op.

RESULTS

Primary fracture group

There were 8 patients who underwent primary fracture fixation, with a mean age of 48 years (range : 28 to 60). Five were males and 3 females. One patient was assaulted while the remainder sustained a fracture through a fall of less than 5 ft. All fractures were closed, with no distal neurovascular deficit. Mean follow-up for the primary fracture fixation group was 24 months (range : 12 to 48). Six (75%) fractures united with a mean time to appearance of callus of 8.25 weeks (range : 5 to 12) and a mean time to union of 16.5 weeks (range : 15 to 27). Operative record, follow-up details and complications in this group of patients are shown in tables I and II. In summary we encountered 7 complications in 7 patients. This included 2 non-unions, 2-intra operative device failures, 2 radial nerve palsies, and one patient had shoulder pain due to proximal nail migration. Two patients with fracture non-unions had continuing pain and mobility at the fracture site, described as rotational instability in

Table I. — Operative record of patients in the primary fixation group including demographics, AO type, operation time and any per operative problems noted (MUA : manipulation under anaesthesia)

Pt No	AO Fracture Type	Injury To Op (Days)	Retrograde /Antegrade	Operation Time (Mins)	No. of Locking Screws Used	Fracture Reduction (Intra-Operative)	Additional Procedures/Note
1	12.A2	14	antegrade	80	× 2 proximal	Satisfactory	Nil
2	12.A3	1	retrograde	160	nil	Satisfactory	Jig broken at tip of nail
						Reduction difficult	
3	12.A2	3	retrograde	135	nil	Satisfactory	Partial inflation only-device failure
							MUA prior to nailing
4	12.A2	1	antegrade	130	× 1 proximal	Minimal rotational instability	Humeral cast brace 6 weeks
						Alignment acceptable	Post-op
5	12.A2	3	retrograde	65	nil	Satisfactory	Nil
6	12.A3	2	antegrade	105	× 1 proximal	Satisfactory	Slight nail prominence intra-op
7	12.A1	2	antegrade	110	× 3 proximal	Reduction not anatomical	Rotator cuff repaired
8	12.A3	3	retrograde	150	nil	Satisfactory	MUA prior to nailing
							Exploration radial nerve

Table II. — Follow-up of patients, the complications encountered and their management in the primary fixation group

Pt. No	No. Of Weeks Follow-Up	Callus Visible On X Ray (Wks Post-Op)	Time To Union (Weeks Post-Op)	Complications Documented	Management
1	53	5	-	Non-union diagnosed at 24 weeks post op.	Exchange nailing at 28 weeks post op.
				Rotational instability at # site.	Discharged at 53 weeks post-op
2	58	6	17	Radial nerve palsy - spontaneous recovery at 24 weeks	Discharged
3	52	12	16	Nil	Discharged
4	55	9	15	Nil	Discharged
5	54	8	10	Nil	Discharge
6	51	6	27	Proximal nail prominence - painful shoulder motion	For planned nail removal
7	54	8	-	Rotational instability ; continued pain at # site at 28 weeks	Exchange nailing for a T2 locked
					Distal humeral nail planned
8	55	12	24	Radial nerve palsy	(Recovery at 6 weeks post-op) ; discharged

Table III. — Operative record of patients in the non union group including demographics, AO type, operation time and any per operative problems noted

Pt. No	AO Fracture Type	Injury To Op (Days)	Retrograde /Antegrade	Operation Time (Mins)	No. of Locking Screws Used	Fracture Reduction (Intra-Operative)	Additional Procedures/Note
1	12.A2	86	Retrograde	75	Nil	Satisfactory	Exchange nailing
2a	12.c3	443	Retrograde	75		Satisfactory	Exchange nailing
2b			Antegrade	255	× 2 proximal	Satisfactory	Exchange nailing, fracture site opened
							Autologous bone graft
2c			Antegrade	100	× 2 proximal	Satisfactory	Nail protrusion proximally 1 cm
							Exchange nailing
3	12.B1	210	Antegrade	150	× 1 proximal	Satisfactory	Tutobone(allo) graft+ cerclage wire for non union
4	12.A1	84	Antegrade	127.5	Nil	Satisfactory	Tutobone(allo) graft + cerclage wire for non union

both cases, and no progressive signs of healing on serial radiographs (table II). Both patients underwent exchange nailings.

Non-union group

Six nailings were performed for fracture non-union in 4 patients (see table III). Their mean age was 68.5 years (range : 60 to 84), with 3 females and 1 male. In three patients, the decision to operate was following failed conservative treatment and in one case non-union occurred following a Fixion® nailing 28 weeks before. The mean time from injury/initial surgery to secondary treatment was 25 weeks (range : 15 to 28). Three cases united (2 within 24 weeks and 1 after 24 weeks). One patient (see table IV) underwent a retrograde Fixion® nailing for a fracture non-union at an extra-ordinary 443 days post injury. Following this, she failed to show signs of fracture union and underwent a further two separate antegrade fixion® nailing procedures with bone graft and cerclage wiring (fig 1 & 2). The non-union has persisted and further surgery with exchange nailing to a statically locked nail has been debated. Details of operative record, follow-up details and complications are tabulated in tables III and IV.

Pathological fracture group

Five patients, one male and 4 female, with a mean age of 73 years (range : 61 to 84), underwent Fixion® nailing for a pathological humeral fracture (see table V). The primary site of cancer was breast in 2 patients, lung in 1, prostate in 1 and kidney in 1. One patient had a period of cast bracing for 4 weeks post-operatively as the reduction at time of operation was deemed unsatisfactory by the surgeon (fig 3). All the patients achieved union with a mean time of 14 weeks (range : 10 to 16). Two patients in this group died at 6 months post surgery, secondary to metastatic cancer. Table VI shows detailed results.

DISCUSSION

Five to ten percent of all long bone fractures occur in the humerus, with 20% of these occurring in the diaphysis (*27*). Current literature reports 55% of the patients are female, with a mean age of 55 years and in 60% of the cases, the fracture is due to a simple fall (*31*). In our study, 68% of the patients were female, the mean age was 60 years (range : 25 to 84) and 56% occurred due to a fall. Simple humeral shaft fractures have been adequately

Table IV. — Follow-up of patients, the complications encountered and their management in the non union group

Pt.	No. Of Weeks Follow-Up	Callus Visible On X Ray (Wks Post-Op)	Time To Union (From Injury) Weeks Post-Op)	Complications Documented	Management
1	51	5	51	Non-union diagnosed at 24 weeks post op.	Exchange nailing at 28 weeks post op.
				Callus formation, rotational instability at fracture site	Discharged at 51 weeks post-op
2a	104	16	-	Hypertrophic non-union, 3 previous IM nailing attempts	Plan for statically locked IM nail
2b			-		
2c			-		
3	56	20	56	Nail migration proximally and rotational instability	Cast-bracing post-operatively. Fracture united at final follow-up No shoulder problems
4	53	12	20	Nil	Discharge

treated conservatively with encouraging results reported (*2,4,13,29*).

Indications for operative treatment have included multiple fractures in the same patient, concomitant chest trauma, bilateral humeral fractures, floating elbow, intra-articular humeral fractures, fractures with an associated neurovascular injury, open fractures, pathological fractures, severely obese patients with a humeral fracture, and failed conservative fracture management (*12,28,30*). In addition, there is a growing interest in treating even simple humeral shaft fractures operatively, in order to allow for earlier mobilisation and rapid return to work (*11,14,33*).

A consensus regarding the ideal mode of operative stabilisation is yet to be reached. The most popular operative techniques in stabilising these fractures are open reduction and internal fixation with a plate and closed reduction with intramedullary nailing (*29*). Open reduction and plate osteosynthesis can require extensive soft tissue dissection, especially in comminuted, segmental type fractures. The integrity of plate fixation also relies upon accurate reduction and quality of the bone (*22*). Iatrogenic radial nerve palsy is a recognised complication ; its incidence ranges from 0-17% in the literature (*10,29*).

It has been documented that most humeral fractures can be treated with intra-medullary nailing except those in the distal 2-3 cm of the diaphysis (*24*). There are a variety of locking intramedullary nails available and the Fixion® nail is one example ; but the general principle remains that the implant provides relative stability as opposed to dynamic compression plating which allows for no movement at the fracture site.

In our institution, we began using the Fixion® nailing system based on evidence suggesting that this implant could provide a stable fixation of the fracture without the need for distal transverse locking screws and with a reduction in total operative time and fluoroscopy exposure (*3,17*). It is yet to be confirmed whether the Fixion® nail provides any great advantages over conventional locking nail systems, however, the current published series for its use in long bone fractures is positive for its continued use (*3,5,7,8,17*). Franck *et al* (*7,8*) showed almost 100% union rate and no complications in two separate studies using Fixion® nails to stabilise pathological and osteoporotic humerus fractures. However the follow-up in both these studies was 6 months. Dacert *et al* (*5*) and Panidis *et al* (*23*) have shown 90% union rates, but their indications for using the Fixion® nail are not mentioned.

Fig. 1. — Radiograph of a patient who underwent exchange Fixion nailing and bone graft for non-union. At 4 months post operatively, the radiograph shows nail protrusion and persisting non-union.

Fig. 2. — Radiograph of the same patient 6 month after a 2nd exchange Fixion Nailing. Radiograph shows persisting non-union.

Table V. — Operative record of patients in the pathological fracture group including demographics, AO type, operation time and any per operative problems noted

Pt. No	AO Fracture Type	Injury To Op (Days)	Retrograde /Antegrade	Operation Time (Mins)	No. Of Locking Screws Used	Fracture Reduction (Intra-Operative)	Additional Procedures/Note
1	12.A1	21	Antegrade	55	-	Satisfactory	Cast bracing for 4 weeks post-op
2	12.A2	0	Antegrade	60	× 1 proximal	Unstable reduction	Nil
3	12.A1	1	Antegrade	55	2 × proximal	Satisfactory	Nil
4	12.A2	1	Retrograde	105	Nil	Satisfactory	Nil
5	12.A1	1	Retrograde	120	× 2 proximal	Satisfactory	Nil

Primary fracture, non-union and pathological fracture have variable union rate (*9,10,13,24*). To group them together would not give a true picture of the treatment applied. Keeping this in mind we divided our group of patients in three sub groups i.e. primary fracture fixation, pathological fracture fixation and treatment for established fracture non-union. With regards to primary fracture fixation, our study showed a union rate of 75%. Published data on humeral nailing show union rates of 77-100% (*1,10,19,20,21,24*). Specifically with the Fixion® nail they have achieved 100% union rates (*7,8,23*).

About 10% of all humeral fractures are due to metastasis and it is the second most common long bone to which tumours metastasise (*22*). They are usually simple Type A fractures and the most common primary sites are lung, prostate, kidney and breast. It is now widely accepted to treat these

Table VI. — Follow-up of patients, the complications encountered and their management in the non union group

Pt. No.	No. Of weeks Follow-up	Callus visible On x ray (wks Post-op)	Time to Union (from injury Weeks post-op)	Complications documented	Management
1	24	8	12	Died secondary to metastatic cancer, 7 months post-op.	
2	48	6	10	Brace for 4 weeks post op.	Fracture united. No shoulder problems
3	24	8	12	Developed spinal cord compression due to metastases, RT for palliation	
				Died 6 months post op.	
4	50	8	16	Nil	
5	56	14	14	Nil	

Fig. 3. — Pre operative and 3 months post operative radiographs of a pathological humerus fracture stabilised with a Fixion nail.

fractures operatively (*20,32*). Operative treatment does not improve the prognosis but provides better quality of life and nursing. The average survival time is between 4-15 months after a pathological fracture has occurred (*27*). Fixation with IM nails including the Fixion® nail has shown good results (*16,23*).

We stabilised 5 pathological humeral shaft fractures with the Fixion® nail. In our institution, all the pathological fractures stabilised with Fixion® nails united. Two of the patients died within 6 months of surgery but had clinical and radiological evidence of union. Tables III and IV show the operative details, follow-up and complications encountered in this group.

Non-union was defined in our study as persistent pain and no radiological signs of union in a series of radiographs as described by Weber and Cech (*34*). Although there is little disagreement that non-union after non-operative treatment requires operative intervention, the method is still arguable (*13,24*). Several authors have reported good union rates (80-96%) with ORIF but complication rates are higher (*6,13,28*). Union rates with humeral IM nailing vary from 77 to 95% but are not comparable to the results achieved with treating tibial or femoral non unions in a similar fashion (*13,15,25,28*).

In our study we achieved 100% union rate in treating non union with Fixion® nail following failed conservative treatment. Both the patients had atrophic non union and had bone grafting and cercalage wiring as additional procedures. Lin *et al* (*18*) has reported that 22 out of 23 patients achieved union after this procedure. Treating non union after primary IM nail fixation is challenging and various authors have reported variable results with exchange nailing (*26,35*). Two patients had exchange

nailing ; after primary Fixion® nail, this lead to non-union. One patient with hypertrophic non-union achieved union after exchange Fixion® nailing. One of our patients did not achieve union even after three attempts of exchange nailing with the Fixion® nail. Further treatment is considered.

In our experience, rotational instability and proximal nail migration has been a concern with the Fixion® nail. These problems have not been described in previous studies using this nail (*3,7,8,18, 23*). Out of 16 patients, 5 patients suffered complications (31%). There were 3 non-unions, 1 proximal nail migration and 1 transient radial nerve palsy. Three of these patients had a second procedure and 1 had three further procedures. Also there was device failure on two occasions, leading to increased operative times. These results are in contrast to previous studies with the Fixion® nail used to stabilise humerus diaphyseal fractures (*3,7,8,17, 23*). According to our knowledge this is the first study of the Fixion® nail with a minimum follow-up of 12 months, with patients categorised in sub groups with detailed explanation of each and showing problems with this new device.

CONCLUSION

Previously reported advantages of inflatable nails, of reduced operative time and high union rates were not seen in our study. We did not see any clear advantage of using the Fixion® nail for stabilising humerus fracture over other conventional nails. Also we encountered many problems not mentioned in earlier studies. However further research is needed to establish any advantage or disadvantage this device may have over other forms of stabilising humerus diaphysis fracture.

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