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ORIGINAL ARTICLE

W. M. Franck · M. Olivieri · O. Jannasch · F. F. Hennig

An expandable nailing system for the management of pathological humerus fractures

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Abstract *Background:* People with metastatic fracture of the humerus are of poor general health. Often they are not able to compensate the handicap of an impaired extremity. Standard osteosynthetic techniques are not always applicable. To reduce the trauma of the operation, we used the Fixion® expandable nail system. *Methods:* At two centers, 23 metastatic fractures of the humerus (in 22 patients) were stabilized with a new nailing system. The nail expands under hydraulic pressure up to 150% of its uninflated diameter, gaining long frictional contact to the bone. All patients were followed up until osseous healing occurred or until they died. *Results and conclusions:* The operative time was approximately 32 min, including 1.4 min fluoroscopy time. Nail insertion is brief and therefore not very stressful to the group of debilitated patients who require this intervention. Immediately postoperatively, the upper extremity is stable to permit physiotherapy. In these few patients, we saw no complications. The advantages of the surgical approach appear to outweigh those of conservative management options if a simple and safe surgical technique makes the humerus stable enough to resist normal daily loads.

Keywords Bone metastases · Pathological fracture · Nailing system · Osteoporosis · Humerus

Introduction

Other than young trauma patients, tumor patients whose general health is poor experience more difficulties in using the unaffected limbs to compensate for a functionally impaired extremity. Any treatment should therefore permit postoperative mobilization. Patients will usually have experienced an extended phase of illness with subsequent osteoporotic changes and reduced bone strength before any metastases lead to a fracture. The standard osteosynthetic techniques are therefore not always applicable or may require modification.

When the often poor general health of these patients and their limited life expectancy are taken into account, it

Fig. 1 Fracture through a metastasis of a plasmacytoma after 6 months of conservative management at an outside hospital. The patient had not appeared stable enough to tolerate conventional management

W.M. Franck (✉) · O. Jannasch · F.F. Hennig
Friedrich Alexander University Department of Surgery,
Trauma Surgery Division,
Krankenhausstr. 12, 91054 Erlangen, Germany
e-mail: Wolfgang.Franck@chir.imed.uni-erlangen.de,
Tel.: +49-9131-8533272, Fax: +49-9131-8533300

M. Olivieri
Marien Hospital, Trauma Surgery Division,
Böheimstr. 37, 70199 Stuttgart, Germany

Fig. 2 Same patient as in Fig. 1

seems mandatory to use an approach that guarantees immediate primary osseous stability, even under conditions of absent or severely delayed bone healing. It is particularly difficult to secure screws in bone which is affected by numerous metastases and which is often also osteoporotic (Figs. 1, 2). One should not wait until a conservative management approach – such as a fracture brace plus radiation therapy – fails, because full function of the arm might not be regained during the patient's residual life span.

Classically, humeral shaft fractures were managed by application of a plaster cast which can be replaced by a fiberglass cast at a later stage. Prerequisites for this treatment are a slender upper arm with well-developed muscles and a cooperative patient. Frequently, these requirements are not met in tumor patients whose general health is often impaired, and operative management is often needed. Placement of an intramedullary implant is the therapy of choice. Today's standard technique requires a minimum of 2 – or better up to 4 – interlocking screws to control rotation and to prevent longitudinal displacement, usually referred to as 'telescoping'. In bone replete with metastases, interlocking screws do not hold very well, and the goal to make the bone stable enough to permit early physiotherapy may not be met. The implant diameter cannot exceed 10 mm. Even if multiple locking screws are utilized, significant play between the nail and shaft may result if the the medullary canal is widened by osteoporosis. In such cases, the canal can be up to 15 mm in diameter. Only during the early phase can play be counteracted by interlocking compression, but the effect does not persist because the bone is soft, replete with metastases, and often osteoporotic. These problems prompted us to utilize a novel nailing system which 'self-locks' inside the medullary canal and which remains secure because of its large frictional surface area.

Patients and methods

Under hydraulic inflation, a new, already market-approved nailing system 'self-locks' inside the medullary canal. The nail is manufactured by Disc-O-Tech Medical Technologies, Israel. The brandname is Fixion (Figs. 3, 4). After the nail is inserted into the medullary canal, its original diameter can be expanded by up to 50% by inflating the system with Ringer's solution through an unidirectional valve. The required pressure of up to 70 bar is generated with a small manual pump. The nail's cross-section is characterized by 4 external longitudinal bars which are forced against the cancellous and cortical bone (Fig. 5), matching the medullary canal which is hourglass-shaped on longitudinal section. This deformation will cause the nail to 'self-lock'. The large frictional contact area avoids localized pressure peaks. The bars' ridges prevent rotation. The entire length of the nail provides frictional contact, which differs from the very localized forces created by locking screws securing a standard interlocking nail. Hydraulic inflation provides a kind of stability resembling a full, sealed can which cannot be deformed manually. The entire diaphysis of the bone affected by metastases becomes stable, i.e., all forces are distributed over the entire bone corpus, similar to healthy bone. This device lets one expect a sim-

Fig. 3 Expanded fixion nail with one-way valve

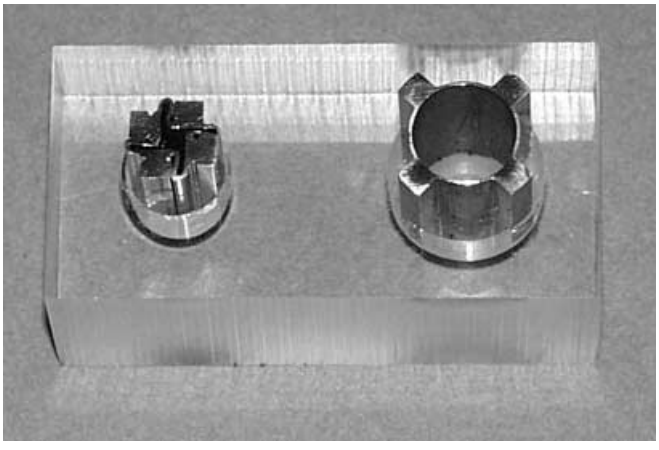

Fig. 4 Cross-section of fixion nail – before and after inflation

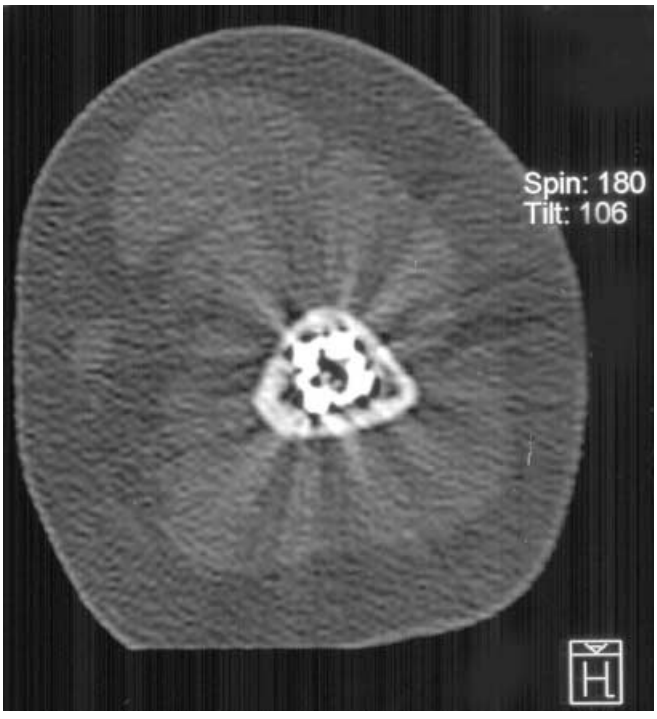

Fig. 5 Computed tomographic section proximal to the fracture: The nail adapts to the canal and the cortical bone. The rarified cancellous bone is seen to be compressed between the longitudinal struts

pler fracture management and increased reliability with respect to early physiotherapy. The elimination of locking screws reduces X-ray exposure for both operating room personnel and patients, and shortens the operative time.

The nail is available in different diameters (6.7 mm/10.0 mm, 7.4 mm/11.0 mm, 8.0 mm/12.7 mm, 8.5 mm/13.5 mm [reduced/inflated]) and lengths (from 180 mm to 280 mm). This allows adaptation to different anatomic situations. Mechanical testing showed an average strength in the 4-point-bending test of 43.15±3.0 Nm and an average torsional stiffness of 2.78±0.27 Nm/m. Testing procedures were performed using a 7.4/11.0 mm nail expanded by a pressure of 70 bar. These results exceed those of conventional locking nails (data supplied by the manufacturer).

This is a summary of our initial clinical experience with this system.

Between March 1, 2000, and January 31, 2001, 23 humeral fractures were managed with this system in 22 patients (Table 1) at two hospitals. One patient suffering from metastatic lung cancer had nails placed in both humeri (Fig. 6). Six patients had pathological fractures and also severely osteoporotic bone. No fractures were open or associated with radial nerve damage. Each individual presentation favored a nonconservative approach.

The exclusive purpose of the procedure was to maintain or to improve the patient's quality of life. Whenever possible, scheduling of the operative procedure was synchronized with the chemotherapy regimen by postponing the surgery until the blood cell counts became acceptable; alternatively, surgery was scheduled 2 weeks prior to the next cycle. If nonoperative management did not bring adequate pain control, any current or planned chemotherapy was ignored, and the operation scheduled for the next feasible date.

An anterior approach through a small rotator cuff incision was used for 15 humeri (Fig. 7), and a retrograde approached for 8. No significant intraoperative or postoperative complications were seen.

Table 1 Patients' data

Procedure no.[a]	Age (years)	Associated diagnosis	AO fracture classification	Additional procedures	Operative time (min)	Fluoroscopy time (min)
1 (Figs. 1, 2)	73	Plasmacytoma, osteoporosis	12 A2		37	2.4
2	66	Metastatic lung cancer	12 C2		39	2.3
3	81	Plasmacytoma	12 A3		32	1.4
4	72	Metastatic breast cancer	12 B1	Radiation therapy	28	1.3
5	77	Plasmacytoma, osteoporosis	12 A2		31	1.4
6	65	Plasmacytoma	12 C2		35	1.4
7	82	Metastatic lung cancer, osteoporosis	12 A3		34	1.1
8	55	Metastatic lung cancer	12 C2		35	1.3
9	72	Plasmacytoma	12 B2		36	1.5
10	58	Metastatic breast cancer	12 B1	Radiation therapy	33	1.2
11	45	Metastatic lung cancer	12 A2		35	1.0
12	45	Metastatic lung cancer	12 C1		40	1.3
13	57	Metastatic lung cancer	12 B2	Resection of metastases and filling with methyl methacrylate	40	1.8
14	86	Metastatic breast cancer, osteoporosis	12 C2	Radiation therapy	60	2.1
15	63	Plasmacytoma	12 A3	Radiation therapy	27	1.4
16	71	Plasmacytoma	12 A3	Radiation therapy	32	1.3
17	80	Plasmacytoma, osteoporosis	12 C1		30	1.2
18	63	Metastatic breast cancer	12 A3	Radiation therapy	28	1.1
19	51	Metastatic breast cancer	12 A2	Radiation therapy	26	1.2
20	75	Plasmacytoma, osteoporosis	12 B2		30	1.3
21	64	Metastatic lung cancer	12 C3		38	1.2
22	78	Plasmacytoma	12 B3		29	1.0
23	67	Metastatic lung cancer	12 A2		27	1.1

[a]Procedure nos. 11 and 12 were done in the same patient

Fig. 6 Patient with metastatic breast cancer and bilateral pathological humeral fractures: signs of healing on the right; left side directly after nail placement. An antegrade approach had been used on both sides. Unrestricted bilateral shoulder motion

Operative technique

In 15 cases, an anterior approach to the humerus was used; a retrograde approach (patients in the prone position) was chosen in the remaining 8 cases.

Two criteria were used to decide which approach to use:

1. Does the overall clinical status permit repositioning of the patient into the prone position?
2. Does the rotator cuff appear intact on sonographic examination?

All patients expected to tolerate repositioning without undue burden were selected for the retrograde approach if their rotator cuffs appeared intact.

For the antegrade approach, a stab incision was made and the rotator cuff split longitudinally under fluoroscopic control. The cortex was penetrated with an awl. The nail was preselected based on the maximum and minimum width of the medullary canal where the nail was to be anchored as well as the canal's length. The nail was inserted with ease. The fracture was reduced and the nail guided through the fracture site just like a standard locking nail. Instead of being locked with screws, the nail was then inflated if both the reduction and nail position were satisfactory. This was accomplished by filling the nail with Ringer's solution through a one-way valve under manometric control. Upon reaching the maximum pressure of 70 bar, the cross-section was maximized and the nail secure. Finally, the rotator cuff was reapproximated and the incision closed.

For the retrograde approach, the patients were brought into the prone position. An approximately 5-cm-long skin incision was made proximal to the elbow joint and the tendon of the triceps muscle divided in the fiber direction. Initially, a triangular-shaped drill hole was created in the dorsal cortex proximal to the olecranon fossa, and enlarged in steps with milling heads of increasing size, until the nail could be inserted into the medullary canal without tension. The nail was placed as usual, reducing the fracture.

Independent of the operative approach, motion exercises for the shoulder and elbow joint were started on the 1st postoperative day. There was no need for any immobilization.

In this series, no hardware removal was performed because of the patients' overall status – their advanced age in particular. In other patients in whom fractured healthy bones had been treated, hardware removal proved straightforward and free of complications.

Fig. 7 Same patient as in Fig. 8: 1.5 cm stab incision for the antegrade approach to the shoulder joint

After relieving the pressure inside the nail, the nail's outer shell, which measures just 0.3 mm will recoil to such an extent that the nail becomes loose enough to slide out under traction.

Results

Postoperative radiological assessment showed good alignment in all cases. There was no need for any revisions and also no evidence for any intraoperative damage to the radial nerve.

Even massively weakened cortical bone withstood the nail's expansion forces at the maximum inflation pressure of 70 bar. No fractures related to fissures or fragments occurred. No cases of nail dislodgment or telescoping were observed throughout the treatment course.

Postoperatively, all patients regained their preexisting shoulder and elbow range of motion. This statement is based on the patients' own assessment. Postoperatively, the antegrade approach did not result in any range of motion limitations or in increased shoulder pain. Because of age-related and in many cases severe preexisting pathology, we abstained from evaluating the functional result with the Constant score. The frequent functional limitations due to preexisting age-related degenerative changes of the shoulder joint would not have permitted a meaningful assessment.

All patients were followed until osseous healing occurred or until they expired. All treated fractures became immediately stable enough for physiotherapy and for activities of daily living, such as food intake, body hygiene,

Fig. 8 At 8 weeks after treatment with the Fixion expanding nailing system: good callus formation

Fig. 9 Same patient as in Fig. 8

dressing, etc. Considering the general clinical status or the advanced age, none of the implants was removed.

No complications occurred in this small patient group. There were no wound infections, despite the patients' advanced age and the effect of the tumor on the patients' overall health. No cases of secondary fracture displacement were seen, especially no rotational instability or telescoping phenomenon.

On radiological assessment, callus formation was observed in all cases (Figs. 8, 9), except around the methyl methacrylate plug in one case where this composite type of osteosynthesis had been used. In all patients who survived long enough, complete bone healing was seen. There were no cases of secondary displacement, in particular no rotator cuff instabilities or any telescoping phenomenon.

Discussion

L. Böhler's historic statement [3] that humeral fractures are not to be operated upon needs to be considered a reflection of the operative techniques available in his day. The good results obtained with the use of occupational therapy and a functional Sarmiento fracture brace [20] can only be accomplished in cooperative and nonobese patients. Therefore, unreamed interlocking nails have become today's gold standard [19].

To lock the tip of the nail, fluoroscopy is mandatory. This is often difficult when attempting a retrograde approach in obese patients, because the extremity needs to be at the edge of the operating room table to avoid superposition on fluoroscopy. Because of the anatomical proximity, proximal locking is associated with a high risk of damage to the axillary nerve, and also to the brachial plexus if the medial cortex is drilled [8, 15].

In solid small-diameter nails, drill holes for interlocking screws weaken the material. Thicker nails are contraindicated because of the age-dependent waist in the middle of the humeral shaft. Nail fractures will cause instabilities and further pseudarthrosis as well as failure of the locking screw. Farragos et al. described secondary fractures which occurred after fracture healing and began where rotational forces acted on the tracks of the locking screws [8]. Another consideration is the additional technical problem of play when a narrow nail resides in a wide lumen. Various methods address these problems [12]. Nevertheless, fluoroscopy is still essential for these techniques.

The same type of instability seen when the nail or screws fracture is also observed when locking screws migrate in soft osteoporotic bone [14]. Bone replete with metastases is quite comparable, especially in cases of osteoclastic metastases. Large size differences between the diameter of the nail and the inner diameter of the humerus are predisposing factors. Despite interlocking in two orthogonal planes, some instability will remain if the medullary canal is not completely filled. Daily movement will gradually widen such canals. Fracture compression [2, 19] increases the load on the locking screws. In patients no. 1 and 2, the smallest internal diameter of the humerus was 15 mm. An 8 mm diameter nail would have resulted in 3.5 mm of play in each direction. In cases of distal interlocking, Moran mentions injuries to the antebrachial cutaneous nerve [16] and considers dissection of the cortex mandatory, as its shape can make the screw move to a minor extent, so that the locking hole is missed.

The big problem of securely anchoring the implant in osteoporotic bone made Palmer et al. bend a dynamic compression plate into the shape of an angulated plate [17], so that the small leg of the plate would reach the humeral head. He placed an additional screw, which runs diagonally inside the angle – just like a roof support strut – thus achieving a high degree of stability at the cost of maximal invasiveness. Stable bone healing resulted eventually.

Other noninterlocking intramedullary osteosynthetic techniques did not gain much acceptance because of their high complication rate. Intramedullary wiring frequently led to head perforations, nail migration with cutaneous inflammation, and secondary fracture displacement [5, 11, 13, 18]. The initial encouraging results made with the Seidel nail [6, 7] could not be duplicated [7, 8, 10]. Insufficient locking around the distal spreading mechanism was the primary reason for this instability. Barnes and Schuler reported complications in 46%, including cases of shaft disruption and nail displacement [1]. The acutely angulated and star-shaped profile of the True-Flex nail cuts into the cortex in order to provide good rotational stability. The nail is not well supported, however, in the proximally wider segment of the medullary canal [4]. Only a small number of cases are documented in the literature [9].

Ikpeme reports on 39 patients who were treated with the Russel-Taylor nail [14]. Some 12% of these patients complained of persisting pain despite otherwise good results. In all these cases, the underlying reason was migration of the locking screws into the deltoid muscle, because the thread was not sufficiently supported in the thin cortical bone of the humeral head.

After it is expanded, the Fixion nail will completely obliterate the medullary canal by adapting to the canal's shape. As the nail expands by 50% of its original diameter, it fits easily into the relative isthmus in the middle of the shaft. This isthmus becomes less pronounced in the elderly. With expansion, any axial and sideways displacement is completely reduced, as the medullary cavity is totally filled. The large frictional contact surface between nail, cortical and cancellous bone results in a self-locking effect without weakening the cortex through drill holes. Forces acting on the outside of the bone are distributed over a large area and are not concentrated on small, localized connections, such as locking screws.

The simple handling of the Fixion system keeps the operative procedures very brief. The average operative time was 32 min in all cases, which did not require adjunct measures such as resection of a metastasis and filling of the cavity with methyl methacrylate. The average fluoroscopy time of 1.4 min was also very short. In fact, one needs to consider that fluoroscopy was used in the first several cases throughout the expansion phase, because of the concern to over expand the medullary canal. With growing experience, fluoroscopy was abandoned during this phase: From then on, it was reserved for fracture repositioning and for checking the final result. The expansion process was checked by manometry alone. These operative and fluoroscopy times were identical to those achieved when comparable humeral fractures were treated with the Fixion system in osteoprorotic bone.

Based on this experience, the concept of treating humeral shaft fractures primarily in a conservative manner needs to be reassessed, at least with respect to the elderly and in the case of pathologic fractures or severely compromised bone due to osteoporosis. The advantages of the surgical approach appear to outweigh those of conservative management options if a simple and safe surgical technique makes the humerus stable enough to resist normal daily loads. This needs to be investigated in further studies.

References

1. Barnes CE, Schuler TE (1993) Complications associated with the Seidel nail. Orthop Rev 22: 699–706
2. Blum J, Rommens P, Janzing H (1997) The unreamed humeral nail – a biological osteosyntheses of the upper arm. Acta Chir Belg 97: 184–189
3. Böhler L (1964) Gegen die operative Behandlung von frischen Oberarmschaftbrüchen. Langenbeck's Arch Chir 308: 465–475
4. Dalton JE, Salkeld SL, Satterwhite YE, Cook SD (1993) A biomechanical comparison of intramedullary nailing systems for the humerus. J Orthop Trauma 7: 367–374
5. Durbin RA, Gottesman MJ, Saunders KC (1983) Hackethal stacked nailing of humeral shaft fractures. Clin Orthop 179: 168–174
6. Evans PD, Conboy V (1993) Locked nailing of humeral fractures. J Bone Joint Surg Br 75: 165
7. Evans PD, Habernek H, Orthner E (1991) A locking nail for fractures of the humerus. J Bone Joint Surg Br 73: 651–653
8. Farragos AF, Schemitsch EH, McKee MD (1999) Complications of intramedullary nailing for fractures of the humeral shaft: a review. J Orthop Trauma 13: 258–267
9. Garnavos C, Seaton J, Lunn PG (1998)The treatment of selected fractures of the humeral shaft with the True-Flex nail. Injury 29: 269–275
10. Habernek H (1998) A locking nail for fractures of the humerus. J Bone Joint Surg Br 80: 557
11. Hall R, Pankovich A (1987) Ender nailing of acute fractures of the humerus – a study of closed fixation by intramedullary nails without reaming. J Bone Joint Surg Am 69: 558–567
12. Harrington P, Howell F (1998) An aid to distal locking of the Russell-Taylor humeral nail. Injury 29: 732–733
13. Hoffmann R, Khodadadyan C, Raschke M, Melcher I, Maitino P, Haas N (1998) Die retrograde Markdrahtung bei proximaler Humerusfraktur des alten Menschen. Zentralbl Chir 123: 1232–1238
14. Ikpeme JO (1994) Intramedullary interlocking nailing for humeral fractures: experiences with the Russell-Taylor humeral nail. Injury 25: 447–455
15. Lin J, Hou SM, Inoue N, Chao EY, Hang YS (1999) Anatomic considerations of locked humeral nailing. Clin Orthop 368: 247–254
16. Moran MC (1995) Distal interlocking during intramedullary nailing of the humerus. Clin Orthop 317: 215–218
17. Palmer SH, Handley R, Willet K (2000) The use of interlocked 'customised' blade plates in the treatment of metaphyseal fractures in patients with poor bone stock. Injury 31: 187–191
18. Putz P, Pauwels P (1995) Hackethal's method of bundle nailing for proximal or diaphyseal fractures of the humerus. Acta Orthop Belg 61 [Suppl 1]: 162–165
19. Rommens PM, Verbruggen J, Broos PL (1995) Retrograde locked nailing of humeral shaft fractures. J Bone Joint Surg Br 77: 84–89
20. Sarmiento A, Kinman PhB, Galvin EG, Schmitt RH, Phillips KG (1977) Functional bracing of fractures of the shaft of the humerus. J Bone Joint Surg Am 59: 596–601