ANTEROGRADE FEMORAL NAILING WITH A REAMED INTERLOCKING TITANIUM ALLOY NAIL

S. DEBRAUWER, K. HENDRIX, R. VERDONK

Intramedullary nailing has become the gold standard for treatment of femoral diaphyseal fractures. Between March 1995 and December 1998 we performed 40 intramedullary nailings using the ACE femoral nail (De Puy). The patients were followed for an average of 27.9 months (range: 6-54 months).

The mean age was 33.2 years (range: 17-87 years); the sex distribution was 33 males and 7 females. All fractures were unilateral (right 18, left 22). Most of the fractures were caused by traffic accidents (35), the others originated from sports, work and gunshot (1).

Thirty-five fractures were closed and 5 were open: 1 was grade I, 2 were grade II and 2 grade IIIa according to Gustilo's classification. According to the AO classification 18 fractures were type A, 13 type B and 9 type C.

The majority of patients had associated injuries: neurotrauma 2, chest trauma 2, and other fractures e.g. of the clavicula, lumbar spine, patella, tibia. Immediate surgery was performed in 34 cases, delayed surgery in 6 cases. All fractures were treated on a fracture table, with closed reduction, reaming of the intramedullary canal, proximal and distal locking and intraoperative control of rotation and length. The mean time to healing was 17.85 weeks (range: 18-50 weeks). The following complications were observed: 3 delayed unions, which united after dynamisation, one malunion, which required corrective osteotomy, and one nonunion, which healed after exchange nailing. We encountered no rotational deformity and no clinically relevant shortening. Six nails were removed due to irritation by locking screws.

These results are comparable with those of larger series in the literature with other types of interlocking nails. The union rate in this series was 97.5%.

Keywords: femoral diaphyseal fractures; nailing; intramedullary; anterograde.

Mots-clés : fractures diaphysaires fémorales ; enclouage ; intramédullaire ; antérograde.

INTRODUCTION

The introduction of Küntscher's intramedullary nailing technique (5) was a milestone in femoral shaft fracture treatment. Küntscher's original Vshaped nail was based on the fact that an elastic deformable nail, when inserted into a slightly smaller medullary canal, will be deformed, therefore providing fixation for the fracture fragments. It was subsequently changed to a cloverleaf cross-sectional nail with anterior bowing, ideally suited for transverse isthmus fractures. Preliminary intramedullary reaming enlarged longitudinally the area of contact between the nail and the bone, thus allowing to treat also short oblique fractures of the middle third of the femur. The development of interlocking nails (4) extended the indication of intramedullary nailing to fractures of the proximal and distal part of the diaphysis and to longer oblique and comminuted fractures. Second-generation nails, such as the reconstruction nail (Smith Nephew Richards, Memphis, TN, USA) or the

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short and long gamma nail (Howmedica Pfizer, New York, NY, USA) made it possible to treat subtrochanteric fractures and ipsilateral fractures of the shaft and neck of the femur. Experimental evidence that hollow nails appeared to support infection and the recognition that further dead bone from the reaming could result in further infection, led to the development of solid unreamed nails.

The lesser surgical exposure and the earlier rehabilitation with weight-bearing have made the intramedullary fixation technique the gold standard for treatment of fractures of the femoral shaft.

The ACE femoral nail is made of titanium alloy (Ti-6A1-4V), treated with a proprietary surface treatment. This material has the highest fatigue strength of all implant alloys, which is of particular importance for the locking screws. It contains only trace amounts of iron, which allows to use MRI and CT scans without significant interference. The modulus of elasticity is approximately one-half that of stainless steel, which may contribute to promote bone formation at the fracture site and more rapid fracture healing. These material characteristics made us decide to make a clinical trial with titanium alloy nails instead of the stainless steel nails which we used previously.

MATERIAL AND METHODS

From March 1995 to December 1998, 40 femoral shaft fractures were treated using the ACE Anterograde Femoral Nail (DePuy, Warsaw, Ind., USA). All fractures were unilateral, 18 on the right side and 22 on the left side. Most of them were unifocal, 6 were bifocal. The male:female ratio was 33:7 with a mean age of 33.2 years (range 17 – 87 years).

Road traffic accidents were the most important cause of injury (35 cases), others included sports (1), industrial accidents (2), accidents at home (1) and gunshot injury (1).

An isolated fracture occurred in 11 cases (27%), but since femoral fractures are the result of high-energy trauma, most patients had concomitant injuries. We noted neurological injury (2), chest injury (2), clavicular fractures (3), humeral fractures (2), forearm fracture (1), and lumbar spine fractures (2) of which one could be treated conservatively; the second was an L1 burst fracture with paraplegia which had to be stabilized operatively. There were also one hip fracture, one hip dislo-

cation, one greater trochanter fracture and three pelvis fractures, all treated conservatively, three patellar fractures and eight tibial fractures . All concomitant fractures were treated, if necessary and if possible, in the same operative session as the femoral fracture.

Fractures were graded using the AO-ASIF classification system (table I), and open fractures were graded according to the Gustilo classification. (table II) (3).

Table I. — Classification of fractures according to AO-ASIF

AO	N
Type A	18
Type B	13
Type C	9

Table II. — Classification of fractures according to Gustilo (3)

Gustilo	N
Closed	35
Open I	1
Open II	2
Open III	2

Immediate surgery, within the first 12 hours, was performed in the majority of cases (34). Surgery was delayed when the patient's general condition had to be monitored in the Intensive Care Unit, due to neurological or chest injury. Condylar traction was applied until nailing could be performed. The mean delay was 2 days (range: 1-4 days).

In the event of open fractures, immediate external fixation was the treatment of choice for grade III fractures and it was also used for one out of two grade II fractures. Once the soft tissue lesions were healed, the external fixation was removed and intramedullary nailing was performed, after 3 to 4 weeks.

Patients were positioned on a fracture table, with condylar traction on the affected limb and the contralateral limb in a gynaecologic leg holder.

All operations were carried out under antibiotic prophylaxis, using a 3-dose regimen of cephazolin, 2 grams preoperatively, followed by 2 grams at six and 12 hours postoperatively. In open fractures this prophylaxis was extended until 5 days after surgery.

After skin preparation and draping, a longitudinal incision was made proximal and somewhat posterior to the greater trochanter, and a bone awl was inserted into the tip of the trochanter. We prefer this entry point

because of previously experienced complications, such as fracture at the base of the femoral neck or hip arthritis, when the entry point was at the fossa.

Moreover, this entry point, being more lateral to the fossa and located vertically up to the femoral diaphysis, offers additional benefit, creating some sort of 3-point fixation in the proximal femur.

A guide wire was passed down across the fracture into the distal femoral metaphysis. Reaming was performed over the length of the femoral shaft, but was often kept to a minimum. The intramedullary canal was reamed 1.0 mm larger than the diameter of the nail to be inserted.

The ACE nail is a circular, non slotted nail with anterior bowing and exists in different diameters ranging from 9 to 15 mm. Only the 9-mm diameter nail is solid, the larger diameter nails are cannulated. In most cases an 11-mm diameter nail was placed.

The femoral nail was tapped into place while the fracture was manually reduced, taking care to avoid rotational malalignment and shortening. For this purpose, an assistant held the lower leg in correct alignment with the upper leg and gave more or less additional traction using the condylar traction device on the fracture table. All nails were proximally locked with one 6.5-mm diameter screw and distally locked with two 4.5-mm diameter screws.

Low-molecular weight beparin and nonsteroidal antiinflammatory drugs were administered during the period of hospital stay. Mobilization was started as soon as possible, weight-bearing was determined by the stability of the fracture, the degree of discomfort and the presence of concomitant injuries.

RESULTS AND COMPLICATIONS

After discharge, the patients were followed up at intervals of two to four weeks until fracture healing. The mean follow-up was 27.9 months (range 6-54 months). The overall mean time to radiological union was 17.8 weeks (range 8-50 weeks) (fig. 1). In cases of isolated femoral fractures, the mean time to resumption of full activities was 20 weeks.

No deep infections were noted in this series. Superficial wound infection at the insertion site was observed in one case. This problem could be resolved with oral antibiotics and local wound care.

Clinically relevant shortening or rotational malalignment were not noted, obviating the need



Fig. 1. — Femoral diaphyscal fracture treated successfully with the ACE femoral nail.

for standard radiological scaniometry or CT evaluation of rotational deformity. There were no clinical arguments for investigating compartment syndromes by means of pressure measurement. Clinical signs of deep vein thrombosis were absent. One patient presented a pulmonary embolism 15 days after surgery, requiring heparinization and several mouths of oral anticoagulants.

Three cases of delayed union occurred, in which callus formation was insufficient after six months. After removal of the proximal or distal locking screws, union was achieved within 6 weeks (fig. 2a-b). Dynamisation by removing proximal or distal locking screws was never performed systematically while using the ACE nail.

One late progressive valgus deformity occured in a distal femoral fracture, after weight bearing resumption, requiring removal of the nail, varisation osteotomy and renailing.



Fig. 2a. — Type B femoral fracture, treated with intramedullary nail. Delayed union after 6 months.



Fig. 2b. — Consolidation of the fracture after removal of the distal interlocking screws.

In one patient an exchange nailing procedure, involving extensive reaming and exchange to a thicker interlocking nail, was performed for hypertrophic nonunion after 22 weeks. Union then occurred after 2 months.

Six patients had complaints of irritation from the hardware, either at the proximal insertion at the tip of the trochanter or at the distal screws. After union of the femoral fracture, these nails were removed and the complaints disappeared.

DISCUSSION

Little controversy now exists about the optimal treatment for femoral shaft fractures. Intramedullary nailing is now considered to be the best treatment option for closed femoral fractures, and even in grade I and grade II open fractures, nailing can be considered a safe procedure (2). In our series the time to union was 17.8 weeks and the union rate was 97.5%. These figures are consistent with those of larger series in the literature. Pintore *et al.* (7) reported a union time of approximately 4 months in their series of 71 femoral fractures treated with interlocking nails according to Grosse and Kempf. In a series of 551 femoral fractures treated with interlocking nails, Wolinsky *et al.* (11) obtained a union rate of 98.5% with a low rate of malunion, infection and hardware failure.

By computed tomography, Bonevialle *et al.* (1) retrospectively determined torsional abnormalities and length discrepancies after diaphyseal femoral

fractures treated by intramedullary nailing. The mean difference in torsion was 9.9°, the mean femoral length discrepancy was 6.3 mm, which was clinically irrelevant. Although length and torsion were not routinely measured in our patients, we believe that, with a good reduction technique and peroperative assessment of length and alignment, good results can be achieved. Clinically relevant length discrepancies or torsional abnormalities were absent in our series.

Distal interlocking screws and only rarely thicker proximal interlocking screws have shown signs of failure using other intramedullary nailing material.

Such implant failures may give rise to difficulties for implant removal, particularly in the event of delayed union, preventing easy rerodding.

In our series using titanium alloy ACE nails and screws, no implant breakage occured during the follow-up period, even though full weight bearing was encouraged as tolerated, even in cases with obvious gaps at the fracture site.

CONCLUSION

The goal of femoral diaphyseal fracture treatment should be quick functional recovery.

Intramedullary nailing may be performed swiftly and requires no extensive fracture exposure, therefore reducing postoperative complications and allowing early rehabilitation. We would like to suggest the tip of the greater trochanter as the optimal entry point. It decreases the potential risk of a basicervical hip fracture as well as the risk of avascular necrosis of the femoral head and septic arthritis, in the rare event of a wound infection proximally. Orler et al. (6) acknowledged the complication of avascular femur head necrosis in children and adolescents, when the entry point was located at the femoral neck basis, but these findings may also be extrapolated to adults. Strand et al. (10) investigated two groups of patients in which the entry point was made either at the fossa piriformis or at the tip of the greater trochanter. They concluded that reaming through an entry point at the piriformis fossa weakened the femoral neck and created a localizing point for fracture.

This approach to anterograde femoral nailing enjoys the added benefit of 3-point fixation in the proximal femur, increasing rotational stability together with the proximal locking.

Dynamisation to promote fracture healing, was not performed as a rule in this series, but was only performed in cases of delayed union. Because of the high fatigue strength of the ACE femoral nail and its locking screws, we decided to encourage full weight bearing in all types of fractures. So far, the ACE nail has lived up to our expectations, as we had no fatigue breakage of the nail or screws. We found the ACE anterograde femoral nail to be a reliable device, giving good clinical results and few complications.

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SAMENVATTING

S. DEBRAUWER, K. HENDRIX, R. VERDONK. Anterograde nageling van de femur met een geriemde vergrendelde Titanium Allov nagel.

Sinds zijn ontstaan is de Küntscher IM-nagel progressief de voorkeursbehandeling geworden voor diafysaire femurfracturen.

Tussen maart 1995 en december 1998 hebben we 40 intramedullaire nagelingen verricht met de ACE-nagel met een follow-up van 27,9 maanden (6-54). De gemiddelde leeftijd was 33,2 jaar (17-87). Alle gevallen waren unilateraal (rechts 18 – links 22). De verdeling volgens geslacht was 33 mannen en 7 vrouwen.

Het merendeel van de fracturen werd veroorzaakt door verkeersongevallen (35), de anderen door sportongevallen, arbeidsongevallen en revolverschot (1).

Volgens de Gustilo-classificatie waren 35 fracturen gesloten; 1 was graad I, 2 waren graad II en 2 graad IIIa. Volgens de AO classificatie waren 18 fracturen type A, 13 type B en 9 type C.

De femurfractuur was zelden het enige letsel, andere letsels zoals neurotraumata (2), thoraxtraumata (2) en andere fracturen b.v. ter hoogte van de clavicula, lumbale wervelzuil, patella en tibia waren er mee geassocieerd.

Chirurgie werd onmiddellijk verricht in 34 gevallen, verlaat in 6 gevallen.

Alle fracturen werden behandeld op een orthopedische tafel, met adequate reductie, reamen van het intramedullaire kanaal, proximale en distale vergrendeling, en peroperatoire controle van de rotatie en lengte.

De consolidatieduur was ongeveer 17,85 weken (8-50). Volgende complicaties kwamen voor: 3 gevallen van delayed union 3 (welke consolideerden na dynamisatie), 1 maal malunion (behandeld met correctieve osteotomie), en 1 geval van pseudarthrose (behandeld met exchange nageling).

We vonden geen klinisch relevante rotatie- of lengteafwijkingen.

Zes intramedullaire nagels werden verwijderd wegens irritatie veroorzaakt door het materiaal.

Onze resultaten zijn vergelijkbaar met deze van grotere series in de literatuur.

De graad van consolidatie bedroeg 97,5%.

RÉSUMÉ

S. DEBRAUWER, K. HENDRIX, R. VERDONK. Enclouage verrouillé du fémur après alésage au moyen d'un clou en alliage de titane.

Le clou de Küntscher est devenu le traitement de choix des fractures diaphysaires du fémur. Entre mars 1995 et décembre 1998, nous avons procédé à 40 enclouages intramédullaires avec le clou ACE fémoral, pour lesquels nous disposons d'un suivi moyen de 27,9 mois (6-54). L'âge moyen était de 33,2 ans (17-87). Les fractures étaient toutes unilatérales (côté droit : 18; côté gauche : 22). La répartition des sexes était de 33 hommes et 7 femmes.

La plupart des fractures ont été causées par des accidents de la route (35); les autres, par des accidents sportifs ou de travail ou une arme à feu (1).

D'après la classification de Gustilo, 35 fractures étaient fermées; 1 était grade I, 2 grade II et 2 grade IIIa. D'après la classification AO, 18 étaient de type A, 13 de type B et 9 de type C.

La fracture fémorale était rarement une lésion isolée; des lésions associées comme traumatisme du système nerveux central (2), traumatisme du thorax (2) et d'autres fractures p.ex. de la clavicule, la colonne vertébrale lombaire, la rotule et le tibia y étaient associées.

L'ostéosynthèse a été pratiquée immédiatement dans 34 cas, de façon différée dans 6 cas.

Toutes les fractures ont été traitées sur table orthopédique, avec réduction par manoeuvre externe et alésage du canal médullaire, fixation et immobilisation par verrouillage proximal et distal, avec contrôle peropératoire minutieux de la rotation et de la longueur du fémur.

La consolidation a été obtenue en moyenne après 17,8 semaines (8-50).

Les complications suivantes se sont produites : 3 retards de consolidation qui ont consolidé après dynamisation, un cal vicieux corrigé par ostéotomie, et une pseudarthrose guérie après réenclouage.

Nous n'avons pas relevé de déformation en rotation ni de raccourcissement significatif.

Six fois le clou intramédullaire a dû être enlevé en raison d'une irritation sur les vis de verrouillage.

Nos résultats sont comparables à ceux obtenus dans d'autres séries avec d'autres types de clous intramédullaires.

Notre taux de consolidation s'éléve à 97,5%.