Reamed *versus* unreamed femoral nails

A RANDOMISED, PROSPECTIVE TRIAL

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We performed a randomised, prospective trial to evaluate the use of unreamed titanium nails for femoral fractures. Of 48 patients with 50 femoral fractures 45 were followed to union; 23 with an unreamed and 22 with a reamed nail. The study was stopped early because of a high rate of implant failure.

The fractures in the unreamed group were slower to unite (39.4 weeks) than those in the reamed group (28.5 weeks; $p = 0.007$). The time to union was over nine months in 57% of the unreamed group and in 18% of the reamed group.

In the unreamed group 14 secondary procedures were required in ten patients to enhance healing compared with three in three patients in the reamed group. Six implants (13%) failed, three in each group. Four of these six fractures showed evidence of delayed union.

To achieve quicker union and fewer implant failures we recommend the use of reamed nails of at least 12 mm in diameter for female patients and 13 mm in males.

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A symposium on the pathophysiology of intramedullary nailing¹ has highlighted the dangers of reaming for fractures of the long bones. Very high intramedullary pressures are generated by the reamer, which acts as a hydraulic piston.² This causes disruption of the vascular supply due to obliteration of Haversian canals,^{3,4} causing bone infarction which can extend over 66% of the cortical thickness⁵ and may well delay fracture healing.⁶

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Transoesophageal echocardiography has shown large configured emboli in the right atrium during reaming which increase in number with higher intramedullary pressures.^{7,8} In addition, the infiltration of coagulation-promoting substances and the breakdown products of macrophages may cause generalised pulmonary impairment.⁹ There is reported to be an increased incidence of acute respiratory distress syndrome (ARDS) and mortality in patients with thoracic trauma who have reamed femoral nailing within 24 hours of injury.¹⁰ There is less deterioration in lung function if an unreamed nail is used.¹¹

Femoral nails made of titanium are reported to have increased strength, flexibility and biocompatibility,¹² and it has been postulated that the increased strength of nails of smaller diameter enables them to be inserted without reaming to avoid such dangers.

We report a randomised, prospective clinical trial comparing the use of unreamed titanium nails of small diameter with similar reamed titanium nails.

Patients and Methods

Between March 1995 and February 1996 all skeletally mature patients who had had a fracture of the femoral shaft over 6 cm above the knee or below 4 cm from the lesser trochanter were included in our study. Ethical approval was obtained. There were 48 patients with 50 fractures. Five patients were lost to follow-up; four could not be traced and one was known to have left the country. This left 43 patients (45 fractures) in the study; 23 fractures were treated with an unreamed nail and 22 with a reamed nail. Table I shows that the only statistically significant differences between groups were in age and Injury Severity Score (ISS).¹³ The unreamed group was on average nine years younger and had higher trauma scores, but these scores were generally low. Analysis of covariance showed no correlation of age and the ISS with time to union, indicating that they were not confounding factors.

Fracture configuration was classified according to Winquist and Hansen¹⁴ and again there was no statistically significant difference between the two groups ($p = 0.1699$; Fig. 1).

Both groups had similar operating techniques, rehabilitation programmes and postoperative evaluation. The method

Table I. Details of the patients in both groups

	Unreamed	Reamed	p value
Mean ($\pm$ SD) age in years	24.77 $\pm$ 15.09	33.73 $\pm$ 11.63	0.031
Mean ($\pm$ SD) ISS	23.65 $\pm$ 14.45	15.50 $\pm$ 10.91	0.039
Closed injury (%)	74	86	NS
Open injury (%) ³³	6 (26)	3 (14)	NS
Grade I	1	1	
II	4	2	
IIIa	1	0	
Site of fracture (%)			
Proximal	13	6	NS
Midshaft	78	85	NS
Distal	9	9	NS
Mean time from injury to operation (hr)	11.1	10.1	NS

Fig. 1

Configuration of the fractures according to Winquist and Hansen¹⁴ in both groups.

Fig. 2

Variation in the diameter of the nail in both groups.

of nail insertion was decided by the opening of a sealed envelope. Patients were reviewed at four-weekly intervals, with fracture healing defined as the time when it appeared to be clinically stable, the patient could walk without pain or external support, and trabeculation was seen to cross the fracture on radiographs of three of the four cortices.

Delayed union was defined as a fracture healing time which exceeded 39 weeks.

The implant chosen was the Alta nail, a titanium fluted nail. The 9 mm nail is solid; larger nails are cannulated, but except for this all the nails had the same characteristics.

Operative technique. The nails were inserted with the patient supine on a fracture table. In the unreamed group the diameter of the nail was determined by measurement made from preoperative templates of the intramedullary canal and measurement made at the operation. For the reamed group, reaming was stopped when cortical chatter was encountered and a nail inserted which was 1 mm smaller than the reamer. Two proximal and two distal locking screws were inserted. The variation in nail diameter is shown in Figure 2.

Results

The study was stopped early due to an unacceptably high rate of implant failure (13%).

Time to union. All 45 fractures had healed within 69 weeks of injury. In the unreamed group the mean time to union was 39.4 $\pm$ 15.27 (SD) weeks (8 to 69). This group included two patients who had head injuries; these fractures united in eight and 17 weeks. In three cases the nails failed before union. In the reamed group the mean time to union was 28.5 $\pm$ 9.83 weeks (13 to 45). Three nails failed early and the fractures were treated by exchange nailing; they healed at 30, 37 and 45 weeks.

Fractures treated with an unreamed nail took a statistically significant longer time to heal (Student's *t*-test, *p* = 0.007).

In general, open fractures did not take longer to heal: in the unreamed group the mean time for open fractures was 39.5 weeks and in closed fractures 39.4 weeks. In the reamed group the mean time for open fractures was 33.7 weeks as against 27.8 weeks for closed fractures. In the unreamed group 13 fractures (57%) showed delayed union compared with four (18%) in the reamed group.

In the unreamed group 14 secondary procedures were performed in ten patients (39%). Five patients had

Fig. 3

Radiographs of a femoral fracture in a 24-year-old man which was treated with a reamed 12 mm nail. The nail bent at 22 weeks.

Fig. 4

Radiographs of a femoral fracture in a 22-year-old man which was treated with an unreamed 11 mm nail which broke at 30 weeks.

Table II. Details of the six cases in which the nails failed

Case	Group	Nail diameter (mm)	Fracture configuration class*	Gustilo class†	Isthmus/nail ratio	Time to failure (mth)
1	Unreamed	11	4	Open II	1.1	30
2	Unreamed	11	3	Closed	1.18	50
3	Unreamed	11	1	Closed	1.4	46
4	Reamed	10	2	Open II	1.4	22
5	Reamed	10	3	Open II	1.1	21
6	Reamed	12	1	Closed	1.5	22

* Winquist and Hansen¹⁴

† Gustilo and Anderson³³

exchange nailing, three had bone grafting and six had dynamisation. Only three patients (14%) in the reamed group needed a secondary procedure; two had dynamisation and one had exchange nailing.

Implant failure. Six implants (13%) failed before the fracture healed, three in each group. Three nails bent at the fracture site (Fig. 3) and three broke, two at the fracture site (Fig. 4) and one at the level of insertion of a proximal locking screw. None of the failures was due to high-energy trauma. Possible factors which may have predisposed to implant failure are shown in Table II.

Time to union. The implant failed in two patients after 39 weeks (Fig. 5). Another two patients showed no significant callus formation at 30 and 22 weeks, respectively. Three of these four fractures were in the unreamed group (Fig. 6).

Fracture configuration. Half of those with implant failure had had comminuted fractures.

Open fractures. Half of the implant failures occurred in open fractures and one-third of open fractures was asso-

ciated with implant failure.

Nail diameter. None of the solid 9 mm nails failed, but cannulated nails of 10 mm ($n = 2$), 11 mm ($n = 3$) and 12 mm ($n = 1$) did so.

Mismatch between the nail and the intramedullary canal.

The ratio of the diameter of the intramedullary canal measured at the isthmus to the nail diameter was assessed from the anteroposterior and lateral radiographs and the disparity was determined. In three patients whose implants failed there were canal:nail mismatch ratios of 1.5, 1.4 and 1.4. When all 45 patients were evaluated, however, there was no significant correlation between canal and nail diameter and implant failure.

Discussion

Unreamed titanium nails performed poorly in comparison with the reamed nail: fracture union was slower and the rate of implant failure was higher.

Fig. 5a

Fig. 5b

Radiographs of a femoral fracture in a 68-year-old man treated with an unreamed 11 mm nail (a) which broke at 50 weeks (b).

In theory, fractures treated with an unreamed nail should unite more rapidly because reaming disrupts the circulation to the inner two-thirds of the cortex. It has been shown that only one-third is disrupted if there is no reaming.¹⁵ In experimental models cortical revascularisation is reported to occur twice as rapidly with unreamed nails¹⁶ and callus formation is faster and more prolific.^{17,18}

Other studies have also shown that the use of an unreamed nail may result in an increased time to fracture union. A retrospective review of diaphyseal femoral fractures treated with reamed or unreamed AO nails was reported to show that fractures treated with an unreamed nail had a mean healing time of 26.9 weeks compared with 20.5 weeks after a reamed nail ($p = 0.009$).¹⁹ A randomised, prospective trial of femoral fractures treated with stainless-steel nails showed an increased time to union of distal fractures after unreamed nailing (130 days *v* 84 days, $p = 0.0490$), and a rate of nonunion of 25%.²⁰ In another study, Tscherne C1 tibial fractures healed in 15.4 weeks in the reamed group compared with 22.4 weeks in the unreamed group, with a higher reoperation rate in the unreamed group.²¹ Another retrospective study of tibial nailing showed healing in 242 days in the unreamed cases compared with 158 days in the reamed, with a fivefold greater incidence of nonunion in the unreamed group.²²

Earlier non-randomised studies of unreamed titanium femoral nails showed rapid union. The ACE nail was shown to allow uneventful consolidation at a mean of 3.8 months.²³ Another series of 108 femoral fractures treated with an AO unreamed nail had a mean union time of 10.4 weeks. These results differ from our findings: the reason for this difference is difficult to define, other than the type of

Fig. 6

Radiograph of a femoral fracture in a 62-year-old woman 42 weeks after the insertion of an unreamed 11 mm nail showing delayed union.

implant and the design of the studies. The relative effectiveness of the three different nails requires a randomised, prospective trial.

The more rapid union seen in our reamed group may be due to several factors. These include the autografting provided by reaming, the sixfold increase in periosteal blood flow which is reported to follow reaming²⁴ and the improved mechanical purchase of a reamed nail which provides greater stability.²⁵ We consider that the most important factor is the increase in fracture stability. The femur has a short isthmus, and there is therefore only a small area for endosteal purchase by an unreamed nail. Reaming increases this area and provides greater stability.

It is not known whether titanium has any effect on fracture healing. We found slower times to union than those reported for larger numbers of patients after the use of stainless-steel nails.^{20,26-28} Mechanical tests suggest that titanium is very suitable for the construction of nails. Bending tests show that titanium nails 4 mm less in diameter are equivalent to first-generation steel alloy nails.²⁹ The fatigue strength of titanium is greater than that of stainless steel³⁰ and its modulus of elasticity is lower so that it is more flexible, which may have physiological advantages.³¹

We had a higher rate of implant failure than previously reported. AO implants have shown very low incidences of implant failure,^{6,19} as have ACE nails,²³ reamed Gross Kempf nails and unreamed Delta femoral nails.²⁰ A review of the literature on the use of reamed stainless-steel nails found implant failure rates of 0.5% to 3.3%.³²

In our series the failure rate was the same in both the reamed and unreamed groups and there was a wide variation in the diameters of the nails which failed. As regards failure, the time to union, the presence of an open wound and the configuration of the fracture were the most critical predisposing factors. The combination of a comminution, a smaller diameter nail (9 to 12 mm) and an open injury gave a high risk of implant failure.

Conclusions. Our results suggest that reaming aids fracture healing. We therefore recommend the use of a reamed nail, with an implant diameter chosen according to the weight of the patient, the degree of comminution and the diameter of the intramedullary canal. We suggest that the nail should have a minimum diameter of 12 mm in female and 13 mm in male patients.

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References

1. Pape HC, Weller S, Sturmer KM, et al. Pathophysiology of intramedullary nailing. *Injury* 1993;24:Suppl 3:1-103.
2. Sturmer KM. Measurement of intramedullary pressure in an animal experiment and propositions to reduce the pressure increase. *Injury* 1993;24:Suppl 3:7-21.
3. Danckwardt-Lilliestrom G, Lorenzi GL, Olerud S. Intramedullary nailing after reaming. *Acta Orthop Scand* 1970;134:1-78.
4. Kessler SB, Hallfeldt KKJ, Perren SM, Schweiberer L. The effects of reaming and intramedullary nailing on fracture healing. *Clin Orthop* 1986;212:18-25.
5. Olerud S, Stromberg L. Intermedullary reaming and nailing: its early effects on cortical bone vascularisation. *Orthopaedics* 1986;9:1204-8.
6. Krettek C, Schulte-Eistrup S, Schandelmaier P, Rudolf J, Tschern H. Osteosynthesis of femur shaft fractures with the unreamed AO-femur nail: surgical technique and initial clinical results with standard lock fixation. *Unfallchirurg* 1994;97:549-67.
7. Wenda K, Runkel M, Degreif J, Ritter G. Pathogenesis and clinical relevance of bone marrow embolism in medullary nailing: demonstrated by intraoperative echocardiography. *Injury* 1993;24:Suppl 3:73-81.
8. Pell ACH, Christie J, Keating JF, Sutherland GR. The detection of fat embolism by transoesophageal echocardiography during reamed intramedullary nailing: a study of 24 patients with femoral and tibial fractures. *J Bone Joint Surg [Br]* 1993;75-B:921-5.
9. Strecker W, Gonschorek O, Fleischmann W, et al. Thromboxane-co-factor of pulmonary disturbances in intramedullary nailing. *Injury* 1993;24:Suppl 3:68-72.
10. Pape HC, Regel G, Dwenger A, Sturm JA, Tschern H. Influence of thoracic trauma and primary femoral intramedullary nailing on the incidence of ARDS in multiple trauma patients. *Injury* 1993;24:Suppl 3:82-103.
11. Pape HC, Regel G, Dwenger A, et al. Influences of different methods of intramedullary femoral nailing on lung function in patients with multiple trauma. *J Trauma* 1993;35:709-16.
12. Zardiackas LD, Disegi J, Givan D. Torsional properties of implant grade titanium. *J Biomed Mater Res* 1991;25:281-93.
13. Baker SP, O'Neill B, Hadden W Jr, Long WB. The injury severity score: a method for describing patients with multiple injuries and evaluating emergency care. *J Trauma* 1974;14:187-96.
14. Winquist RA, Hansen ST Jr. Comminuted fractures of the femoral shaft treated by intramedullary nailing. *Orthop Clin North Am* 1980;11:633-48.
15. Klein MP, Rahn BA, Frigg R, Kessler S, Perren SM. Reaming versus non-reaming in medullary nailing: interference with cortical circulation of the canine tibia. *Arch Orthop Trauma Surg* 1990;109:314-6.
16. Schemitsch EH, Kowalski MJ, Swionkowski MF, Senft D. Cortical bone blood flow in reamed and unreamed locked intramedullary nailing: a fractured tibia model in sheep. *J Orthop Trauma* 1994;8:373-82.
17. Runkel M, Wenda K, Ritter G, Rahn B, Perren SM. Bone healing after unreamed intramedullary nailing. *Unfallchirurg* 1994;97:1-7.
18. Pape HC, Remmers D, Regel G, Tschern H. Pulmonary complications following intramedullary stabilization of long bones: effect of surgical procedure, time and injury pattern. *Orthopade* 1995;24:164-72.
19. Giannoudis PV, Furlong AJ, Macdonald DA, Smith RM. Reamed against unreamed nailing of the femoral diaphysis: a retrospective study of healing time. *Injury* 1997;28:15-8.
20. Tornetta P, Tiburzi D. The treatment of femoral shaft fractures using intramedullary interlocked nails with and without intramedullary reaming: a preliminary report. *J Orthop Trauma* 1997;11:89-92.
21. Court-Brown CM, Will E, Christie J, McQueen MM. Reamed or unreamed nailing for closed tibial fractures: a prospective study in Tschern C1 fractures. *J Bone Joint Surg [Br]* 1996;78-B:580-3.
22. Anglen JO, Blue JM. A comparison of reamed and unreamed nailing of the tibia. *J Trauma* 1995;39:351-5.
23. Kropff A, Naglik H, Primavesi C, Hertz H. Unreamed intramedullary nailing of femoral fractures. *J Trauma* 1995;38:717-26.
24. Reichert ILH, McCarthy ID, Hughes SP. The acute vascular response to intramedullary nailing: microsphere estimation of blood flow in the intact ovine tibia. *J Bone Joint Surg [Br]* 1995;77-B:490-3.
25. Fairbank AC, Thomas D, Cunningham B, Curtis M, Jinnah RH. Stability of reamed and unreamed intramedullary tibial nails: a biomechanical study. *Injury* 1995;26:483-5.
26. Kempf I, Grosse A, Beck G. Closed locked intramedullary nailing: its application to comminuted fractures of the femur. *J Bone Joint Surg [Am]* 1985;67-A:709-20.
27. Winquist RA, Hansen ST Jr, Clawson DK. Closed intramedullary nailing of femoral fractures: a report of five hundred and twenty cases. *J Bone Joint Surg [Am]* 1984;66-A:529-39.
28. Brumback RJ, Uwagie-Ero S, Lakatos RP, et al. Intramedullary nailing of femoral shaft fractures. Part II. Fracture-healing with static interlocking fixation. *J Bone Joint Surg [Am]* 1988;70-A:1453-62.
29. Latta L. *Biomechanics of femoral nails: symposium current concepts in trauma care*. 1992:55-63.
30. Roth DL. *ASM handbook*. 10th ed. American Society of Metals, 1992;8:240-58.
31. Litsky AS, Spector M. Biomaterials. In: Simon SR, ed. *Orthopaedic basic science*. 1 ed. AAOS, 1994:468-70.
32. Franklin JL, Winquist RA, Benirschke SK, Hansen ST Jr. Broken intramedullary nails. *J Bone Joint Surg [Am]* 1988;70-A:1463-71.
33. Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analysis. *J Bone Joint Surg [Am]* 1976;58-A:453-8.