Chapter 3

The incidence of non-union following unreamed intramedullary nailing of femoral shaft fractures

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Abstract

Introduction: Stabilization of fractures with an intramedullary nail is a wide-spread technique in the treatment of femoral shaft fractures in adults. To ream or not to ream is still debated. Primary objective of this study was to determine the incidence of non-union following unreamed intramedullary stabilization of femoral fractures. Secondary objectives were intra- en postoperative complications and implant failure.

Methods: Between March 1995 and June 2005, 125 patients with 129 traumatic femoral shaft fractures were treated with the unreamed femoral nail. From this retrospective single center study, 18 patients were excluded due to insufficient follow up data, including one patient who died within 2 days after severe head injury. Sixty-six patients had suffered multiple injuries. 21 Fractures were open. According to the AO classification, there were 54 type A, 42 type B, and 14 type C fractures. Dynamic proximal locking was performed in 44 cases (36 type A and 8 type B fractures).

Results: Non-union occurred in 2 patients (1.9%; one type B and one type C fractures). Intraoperative complications were seen in 3 patients (2.8%). Postoperative in-hospital complications occurred in 29 patients (27%). Local superficial infection occurred in 2 patients (1.9%), there were no cases of deep infection. Implant failure occurred in 3 patients (2.8%): nail breakage was seen in 2 patients.

Conclusion: In this study, the incidence of non-union following unreamed intramedullary nailing is low (1.9%) and comparable with the best results of reamed nailing in the literature.
Introduction

Intramedullary nailing has become the standard treatment for diaphyseal femoral fractures. Proximal and distal locking of the intramedullary nail provides length- and rotation stability. Antegrade reamed femoral nailing is popular. It has a high rate of union and low rates of infection and malunion\textsuperscript{2,8,39,41,42,43,44}.

Several concerns have risen regarding the local and systemic effects of reaming. Reaming disrupts the cortical blood flow\textsuperscript{36} and may cause variable degrees of thermal necrosis\textsuperscript{20,31}. With reaming procedures, the elevated intramedullary pressure\textsuperscript{37} can result in intravasation of fat and bone marrow contents\textsuperscript{4,28,38}. Reamed femoral nailing is associated with greater impairment of immune reactivity\textsuperscript{12} and with an increased consumption of coagulation factors\textsuperscript{34}. Intramedullary nailing also results in stimulation of the inflammatory system\textsuperscript{25}.

These systemic changes may contribute to pulmonary morbidity in patients with trauma. To address these disadvantages of the reaming technique, solid nails with a smaller diameter were developed. Proponents of the unreamed nailing technique state that unreamed nails are faster to insert, i.e. less operation time, and have favourable results similarly to the reamed nails\textsuperscript{15,30,33}.

Whether to ream or not is still debated. Comparative studies give conflicting results and have small numbers of patients\textsuperscript{10,13,15,30,32,33,35}.

We report our single center results of treating femoral fractures using unreamed femoral nails (UFN). Primary objective of this study was to determine the rate of non-union. Secondary objectives were intra- and postoperative complications and implant failure.

Patients and Methods

Between March 1995 and June 2005, 125 patients with 129 acute, traumatic femoral shaft fractures were treated by antegrade unreamed femoral nailing (UFN) at the University Medical Centre Groningen, The Netherlands. All patients were skeletally mature. Patients with a pathologic fracture of the femur and patients who underwent secondary operations with an UFN were excluded.

Clinical records and radiographs were reviewed by two authors (MM and KWW). From this retrospective single center study, 18 patients were excluded due to insufficient follow up data, including 11 patients who were transferred to other hospitals, one patient died in the early postoperative period after severe head injury, 3 patients died during follow up within 4
months due to reasons not related to their trauma and 3 were excluded for other reasons. There were 83 male and 24 female patients with an average age of 27 years (range 16-74 years). Fractures were caused by traffic accidents in 95, by fall in 5, by sports/recreational activities in 4, and by other causes in 3 patients. Three patients sustained bilateral femoral fractures. 66 Patients (62%) had multiple injuries. The average Injury Severity Score (ISS) was 15.6. Forty-two patients (39%) had an ISS ≥ 16. According to the AO classification, we identified 54 type A, 42 type B, and 14 type C fractures. Ten fractures were localized in the proximal third of the femur, 98 in the middle third, and 2 in the distal third. Open fractures were seen in 21 patients (19%). According to Gustilo grading, there were 13 grade I, 6 grade II, and 2 grade III soft-tissue injuries. All implants used were 9 mm solid nails of titanium alloy (Synthes®). Primary dynamic proximal locking was performed in 44 cases (36 type A and 8 type B). In these patients full weight bearing was permitted after 7-10 days. The nails were statically locked in 66 patients. These patients were allowed progressively full weight bearing after six weeks. Dynamization was performed in 42 cases to assist union. There is no universally accepted definition of non-union. We defined non-union as failure of clinical and radiological union at one year.

**Results**

Non-union was seen in 2 patients (1.9%). The first nineteen years old male had a closed type C1 midshaft fracture. His tobacco use may have negatively affected bone healing. Although the nail was dynamized, union was not achieved. After bone grafting, the non-union subsequently healed. The second 74 years old male with a history of cardiac diseases had a closed type B2 midshaft fracture. The use of calcium carbasalate (nonsteroidal anti-inflammatory drug) and smoking may have been risk factors for non-union. After the UFN was exchanged for a reamed retrograde femoral nail (Distal Femoral Nail (DFN), Synthes®), the fracture united. Intra-operative complications occurred in 3 patients (2.8%). One patient sustained neuropraxia of the ischiadic nerve that resolved spontaneously. In another patient, an iatrogenic fracture of the neck of the ipsilateral femur had to be treated with cannulated screws (Miss-A-Nail locking). A drill bit broke during the operative procedure in a third patient and was removed.
In total, 29 patients (27%) sustained postoperative in-hospital complications. Local superficial infection occurred in 2 patients (1.9%). There were no cases of deep infection. Although pulmonary complications were seen in 10 patients, including pneumonia, pulmonary embolism, pneumothorax, laryngeal oedema, laryngeal spasm, and retention of sputum, no cases with an obvious relation to the intramedullary nailing procedure like adult respiratory distress syndrome (ARDS) or fat embolism syndrome were seen. Implant failure was seen in three patients (2.8%). Two nails broke, one after a new trauma. In a third patient, one of the distal locking screws broke without compromising fracture healing.

Discussion
The rate of non-union in our study is 1.9%. A non-union rate of less than 2% is comparable to the best results in the series in which the femoral shaft was reamed²,⁴¹,⁴³. Several retrospective single center studies of unreamed intramedullary nailing have reported non-union rates ranging from 0% to 2.1%¹,¹⁸,¹⁹. Hammacher et al¹⁷ reported in their multicenter UFN trial a non-union rate of 5.1%. Comparative studies of reamed and unreamed intramedullary nailing give conflicting results and have included relatively small numbers of patients¹⁰,¹⁵,³⁰,³²,³³,³⁵. Reynders³⁰ and Giannoudis et al¹⁵ found no difference in the rate of non-unions in their studies. Both authors recommend the use of an unreamed technique as it is quicker to insert and perform similar to the reamed technique. Several prospective, randomized trials¹⁰,¹³,³²,³³,³⁵ have been published comparing reamed and unreamed antegrade femoral nailing. The rate of non-union ranged from 1-2% in the reamed group and from 0-8% in the unreamed group¹⁰,³²,³⁵. Clatworthy et al¹³ discontinued their trial because of high rate (13%) of implant failure in both groups. Nonetheless, they reported that the time to union was more than 9 months in 18% of the reamed group (n=23) compared to 57% of those in the unreamed group (n=22). Tornetta and Tiburzi³⁵ analyzed eighty-three fractures that had reamed nailing and eighty-nine fractures that had nailing without reaming. They found a significant shorter time to union for the reamed group compared to the unreamed group. This was most evident in the distal femoral fractures. Selvakumar et al³² randomized one hundred and two consecutive patients with closed femoral shaft fractures into two groups, one reamed group (n=52) and
another unreamed group (n=50). They found that the rate of non-union was 0% and 8%, respectively. In a multicenter clinical trial\textsuperscript{10}, the Canadian Orthopaedic Trauma Society enrolled 224 patients to compare the rate of non-union after reamed and unreamed femoral nailing. They reported that 7.5\% of the 107 fractures in the unreamed group had a non-union compared to 1.7\% of the 121 fractures in the reamed group (p=0.049).

There are several methodological limitations to the quality of these randomized studies. None of these trials included the 420 patients that were needed to provide acceptable power (80\%) to detect a difference in non-union rate without the risk of a type I error\textsuperscript{10}. In one study\textsuperscript{32}, the method of randomization was not mentioned, other studies\textsuperscript{33,35} were pseudo-randomized. Only two trials\textsuperscript{33,35} stated that the outcome observers were blinded to the treatment. Another limitation is the absence of a clear definition of non-union in the literature. Only one of these randomized studies\textsuperscript{10} clearly defined non-union. Furthermore, several risk factors for non-union were not quantified.

According to the Detsky\textsuperscript{14} quality scale for randomized trials, there is only one\textsuperscript{10} high quality study and 4 moderate quality studies\textsuperscript{13,32,33,35}. From these studies, the grade of recommendation could only be "probably do it", indicating that a majority of surgeons would ream the femoral canal before nailing but a substantial minority would not, based on different patient scenarios or population\textsuperscript{29}. Based on our experience and reflecting the literature with a non-union rate of 1.7\%, we find no indication to ream the medullary canal in cases of traumatic femoral shaft fractures.

Reaming of the femoral canal has been shown to increase the intramedullary pressure, including intravasation of bone marrow and fat into the venous blood system\textsuperscript{4,28,37,38}. The elevated pressure can result in fat embolism syndrome (FES), adult respiratory distress syndrome (ARDS), and even sudden death. In our study with unreamed femoral nailing there were no cases of FES or ARDS. To what extent reaming increases the risk for pulmonary complications is still unclear. Pape et al\textsuperscript{24,26} have suggested that reaming the femoral canal may have a detrimental effect on pulmonary function and recommended nailing without reaming to reduce the risk of ARDS. Buckley et al\textsuperscript{9} reported in a prospective, randomized study of 153 patients with isolated femoral fractures no difference in pulmonary complications for reamed versus unreamed intramedullary nails. In a large prospective, randomized, multicenter study, the Canadian Orthopaedic Trauma Society\textsuperscript{11} found no significant difference in ARDS between the reamed and unreamed groups. They also
reported that the ARDS rate was too low to detect a significant difference. Bosse et al reported in a retrospective, comparative study no significant difference regarding the incidence of ARDS, pneumonia, pulmonary embolism, multiorgan failure, or death between the reamed and unreamed groups. Bone et al confirmed these findings and made the recommendation that patients with pulmonary injuries and femoral fracture should have reamed intramedullary stabilization unless they are hemodynamically unstable. In these latter cases, they recommended early stabilization, but with use of an unreamed nail or plating technique. In a prospective, randomized study, Anwar et al suggested that the severity of initial pulmonary injury is the most important factor in determining which patient will have a pulmonary complication. The contribution of reaming to pulmonary morbidity is probably small, but might be clinically significant.

In this study, the incidence of infection is low (1.9%). This is comparable with other studies. The reported incidence of infection complicating reamed intramedullary nailing varies from 0% to 3.3%. The infection rate in patients treated with unreamed nailing ranges from 0% to 2.9%. However, in open femoral fractures the risk of infection is increased and varies from 2.4% to 4.8%. Retrospective and prospective comparative studies reported no significant difference in infection rate between reamed and unreamed nailing.

Our study is limited since it is a retrospective analysis. Furthermore, there is no control group and several risk factors for non-union, such as nicotine abuse, use of NSAID’s and traumatic bone loss, were not quantified. However, the sample size is acceptable. This study does suggest, however, that the incidence of non-union following unreamed intramedullary nailing is low in a selected trauma center and is comparable with the best results of reamed nailing in the literature. The debate of whether to ream or not still continues. A large multicenter, randomised, controlled trial with sound methodology is needed to make a solid recommendation.

**Conflict of interest**

The authors have no conflict of interest with regards of this manuscript.
Reference List


