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## Exchange nailing for femoral diaphyseal fracture non-unions: Risk factors for failure

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ABSTRACT

fracture non-unions. The study cohort comprised 40 patients with femoral diaphyseal non-unions treated by exchange nailing, of which six were open injuries. The median time to exchange nailing from primary fixation was 8.4 months. The main outcome measures were union, number of secondary fixation procedures required to achieve union and time to union. Multiple causes for non-union were found in 16 (40%) cases, with infection present in 12 (30.0%) patients. Further surgical procedures were required in nine (22.5%) cases, one of whom (2.5%) required the use of another fixation modality to achieve union after the exchange nailing was 9.4 months. Cigarette smoking and infection were risk factors for failure of exchange nailing. Multivariate analysis found infection to be the strongest predictor of exchange failure (p < 0.05). Exchange nailing is an effective treatment for aseptic femoral diaphyseal fracture non-union. However, 50% of patients undergoing exchange nailing in the presence of infection required at least one further procedure. It is important to counsel patients of this so that they

can plan for it and do not consider that the first exchange operation has failed.

The aim of this study was to identify risk factors for failure of exchange nailing for femoral diaphyseal

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### Introduction

Non-union can be a devastating consequence of a fracture and the cause of a massive amount of patient morbidity [1]. Nonunions also consume a vast amount of health care resources with estimates of treatment costs ranging from £7000 to £79,000 per case [2–5]. Approximately 200 long bone non-union cases per annum occur per million population [6], indicating an estimated total of 150,000 in Europe each year. Following reamed femoral nailing, the rate of non-union is low, particularly for closed fractures. Reported rates of secondary surgery to achieve union in femoral diaphyseal fractures range from 0 to 14%, with an average 2.4%. Even following nailing of open fractures, the rates of nonunion are low ranging from 0 to 4.8% [7]. Reamed secondary exchange nailing remains the procedure of choice in treating femoral diaphyseal non-unions [8–13]. It is considered to be a

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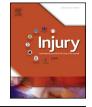
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http://dx.doi.org/10.1016/j.injury.2015.09.027 0020-1383/© 2015 Elsevier Ltd. All rights reserved. relatively simple procedure in which the fracture site is not exposed, with minimal blood loss, low surgical morbidity and a short hospital stay [14]. Reported union rates range from 72% to 100% for aseptic femoral diaphyseal non-unions [8–16]. However, other studies have reported that a significant number, up to 71%, required additional surgical procedures to achieve union following exchange nailing [9,10,14,16–23]. Cigarette smoking [12] and an atrophic pattern of non-union [12,19] have been previously identified as risk factors for failure of exchange nailing in femoral diaphyseal fracture non-union. This study aimed to identify additional risk factors for failure of exchange nailing and the relative importance of known risk factors in femoral diaphyseal fracture non-union surgery.

#### Methodology

All patients who had undergone exchange nailing for the initial management of femoral diaphyseal fracture non-union secondary to trauma between January 1992 and August 2010 were analysed. All fractures were AO/OTA classification 32-A, 32-B and 32-C subtypes [24]. The cohort included both local and tertiary referral







patients. Patients under the age of 16 and patients with pathological fractures were excluded. Primary fracture non-union was diagnosed if there were no signs of union after six months with no evidence of progression in the previous three months.

Information was obtained from the patient clinic visits and notes, radiographs and laboratory results. All records were analysed to identify risk factors for non-union. These were divided into four groups: host, mechanical, bone defect at non-union site and infection. All of the risk factors that were present in a case were included in the statistical analysis. Only host factors that were accepted risk factors for non-union were included [25]. Smoking was included as a host factor if the patient had a habit of 10 cigarettes or more per day, however details of patients smoking fewer cigarettes per day was also recorded. Non-steroidal antiinflammatory drugs (NSAIDs) were only included as a host factor if there was documented evidence of prolonged duration of use. Alcohol was included if weekly consumption exceeded 28 units for men and 14 units for women. Infection was deemed to be present if positive cultures were obtained or had previously been obtained from intra-operative specimens at the site of the non-union at the time of primary exchange nailing. An inappropriate mechanical environment was considered to be present if there was radiographic evidence of fracture fixation failure or a hypertrophic pattern of non-union. A non-union with minimal or no callus response was classified as an oligotrophic/atrophic non-union. Bone defect was recorded as a cause if either a distraction gap or bone loss which resulted in greater than 5 mm or more than 50% femoral circumference at the non-union site was demonstrated on plain radiographs.

#### **Operative technique**

The patient was positioned on a traction table as for a primary nailing procedure and the original nail or a table with a radiolucent top and cross-screws were removed through the original surgical incisions. In this cohort, if a significant bone defect was identified pre-operatively; the non-union site was exposed, taking care not to strip the periosteum from the healthy bone, sclerotic bone excised and autologous bone graft packed into the non-union site. In cases of suspected infected non-unions the fracture site was debrided and irrigated with samples sent for microbiology culture. In these cases (and current cases) antibiotics were withheld until the microbiological samples had been obtained. No frozen sections were sent intra-operatively, however in the recent cases in the series samples were routinely sent for routine histopathological examination. No antibiotic-loaded spacers were used in this cohort. Systemic antibiotic choice was based on organism sensitivity. Antibiotic therapy was commenced following intraoperative sample collection. Where no positive microbiological cultures were available empirical antibiotics were started in accordance to local antimicrobial policies. The intramedullary canal was then reamed, starting with a drill bit of the same size as the extracted nail. Sequential reaming, by 0.5 mm increments, was undertaken to remove endosteal fibrous tissue until healthy bone was seen on the end of the drill bit. This usually occurred at about a diameter of 1 mm greater than the original reaming. More reaming was required if the original nail had been of an inappropriately small diameter. The new nail was introduced and locked both distally and proximally. For the more recent cases, the nails were first locked distally, then tapped backwards with the nail removal apparatus to compress the non-union site and then statically locked proximally. If it was felt that there remained distraction at the facture the nail was dynamically locked. Post-operatively patients were mobilised with full weight-bearing encouraged [26]. Follow-up was performed post-operatively with check plain orthogonal radiographs at two weeks, six weeks, 12 weeks, six months and 12 months or until union was achieved both clinically and radiographically. If union was not progressing additional outpatient reviews were arranged

#### **Outcome measures**

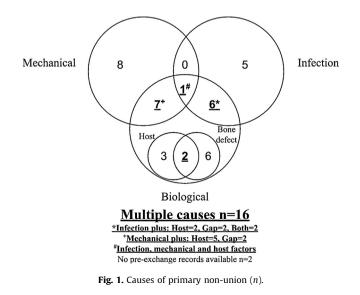
Outcome measures included, fracture union, exchange nail failure and time to union. Union was defined using well-recognised radiographic criteria, i.e. radiographic fracture healing was considered to be present if radiographs demonstrated bridging callus on at least three cortices on standard antero-posterior and lateral radiographs. Exchange nail failure was defined as the requirement for further surgical intervention to achieve union. Time to union was determined from initial exchange nailing using the radiographic criteria defined above.

### Statistical analyses

Data were analysed using SPSS statistical software version 21.0 (SPSS Inc., Chicago, IL). The probabilities of union and associated comparisons were estimated using the Kaplan–Meier test and logrank analysis. Risk factor analysis was performed using a chi-squared test for categorical data, Pearson's correlation for continuous data and multiple regression modelling. A *p*-value <0.05 was considered statistically significant. Risk factors analysed were age at time of exchange nailing, time to exchange nailing from primary fixation, Gustilo type at initial injury, cigarette smoking, excessive alcohol use, excessive NSAID use, Weber and Cech classification of primary non-union, presence of mechanical cause of non-union, presence of host cause of non-union, presence of a bone defect, and infection. A univariate analysis of the risk factors was initially performed followed by multiple regression analysis of significant factors (Fig. 1).

## Results

A total of 40 patients with 40 femoral fractures underwent exchange nailing for non-union. The mean age of the patients at the time of the exchange nailing was 37.5 years (standard error  $(SE) \pm 2.4$ , range 16.6–65.6 years). The median time to exchange nailing from primary fixation was 8.4 months (95% confidence intervals (CI) 7.0–9.7 months). Patient, injury and primary surgery characteristics are presented in Table 1. The attributed causes of the primary non-union are presented in Fig. 2. Multiple causes for the



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