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How comparable is so-called standard fracture fixation with an identical implant? A prospective experience with the antegrade femoral nail in South Africa and Europe

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ABSTRACT

Background: The utilisation and consequences of standardised operative procedures may importantly differ between different healthcare systems. This is the first investigation comparing the treatment and outcome of femoral shaft fractures stabilised with an identical implant between trauma centres in 2 continents (Europe, EU and South Africa, SA).
Methods: Following standardised introduction of the technique, the prospective, observational multicentre study enrolled 175 patients who underwent intramedullary fracture fixation using the antegrade femoral nail (AFN) for femoral shaft fractures. Eleven EU hospitals recruited 86 patients and 1 SA centre 89 patients in the study period. Comparison of epidemiologic data, operative characteristics as well as subjective (e.g., pain, SF-36) and objective (e.g., X-ray, range of motion [ROM]) 3-month and 1-year outcomes were performed ($p < 0.05$).
Results: Compared to EU centres, several significant differences were observed in SA: (1) on average, patients operated on were younger, had less concomitant diseases and had more severe open fractures; (2) operative stabilisation was more often undertaken by young, unsupervised residents, with shorter operating and intraoperative fluoroscopy times; (3) mean hospital stay was shorter, with less recorded complications, but a higher loss to follow-up rate. Non- or malunion rates and subjective outcomes were similar for both groups, with the physical component of the SF-36 at the 1-year follow-up not fully restoring to baseline values.
Conclusions: Our investigation demonstrates the importance of several major differences between 2 different regions of the world in the treatment of femoral shaft fractures, despite involving only high level trauma centres and using an identical implant. The intercontinental comparison of results from clinical studies should be interpreted very carefully considering the heterogeneity of populations and clinical settings.

Introduction

The healthcare disparity between developed and developing countries can be very large. Differences between low- and middle-income countries (LMIC) and high-income countries (HIC) have been reported in type of trauma care offered from the prehospital period until recovery of patients.[30,35,44] In addition, there are also differences in mechanisms of injury. In general, LMIC such as South Africa (SA) demonstrate a much higher burden of injuries due to homicide or interpersonal violence in comparison to Europe (EU).[19,28,46] Some of the specific problems in surgical care faced by LMIC are lack of equipment and resources,[1,24,27] poorly standardised classification of surgical operations,[27] poor reporting,[24,27] poor follow-up rate,[2,17] and lack of access to medical literature.[26]

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Intramedullary nailing of femoral fractures is a standard procedure in orthopaedic surgery.[9,10,16,34,36] However, typical for surgical interventions, factors such as different injury types, patient populations, surgical experience and approaches or the type of implant used may have an important impact on the operation and the subsequent outcome of patients. This may be especially valid in the comparison of interventions between highly developed and developing countries.

There are very few publications specifically on the treatment of femoral shaft fractures in low- and middle-income countries (LMIC) and we could not find any intercontinental comparison between LMIC and HIC in this context. Studies that compare data from different regions in the world can help to better understand clinical settings in terms of healthcare and study implementation.

The prospective study was designed to investigate the stabilisation of femoral shaft fractures with the antegrade femoral nail (AFN), which was a new implant at the time of the study and was accordingly introduced in all centres. The objective of this evaluation was to elucidate on important differences regarding the basic characteristics of patients and fractures, their treatment and 1-year objective and subjective outcomes between trauma centres in EU and SA, nevertheless executing a well-standardised procedure such as intramedullary nailing with an identical implant.

Patients and methods

The prospective multicentre study included patients from 11 trauma centres in EU and 1 centre in Johannesburg, SA in the introduction period of the antegrade femoral nail (AFN). It was conducted according to Good Clinical Practice guidelines, approved by the Institutional Review Boards of all collaborating centres, and monitored by the Arbeitsgemeinschaft für Osteosynthese – Clinical Investigation and Documentation (AOCID), Davos, Switzerland. All participants provided written informed consent.

One hundred and seventy-five ($n = 89$ in SA; $n = 86$ in EU) patients (average age 37.5; range 18–95 years) who sustained a femoral shaft fracture (AO type 32), either as a monotrauma, within multiple fractures or multiple trauma cases and with any severity of soft-tissue injury (closed as well as any grade of open fractures) were enrolled in the study. Patients had to receive definitive surgical repair with the AFN within 7 days after occurrence of the fracture; conversion from emergency external fixation to the AFN was allowed. Patients with existing implants of the fractured hip and femur, those younger than 18 years, unable or unlikely to cooperate, or patients who had participated in any other clinical device or drug trial within the previous month were excluded.

Surgeons in the 12 centres were advised to perform the operative procedure following a standard protocol prepared by the implant manufacturer and the 2 principal investigators (TG and PM), illustrated by an educational video.[23] Standard perioperative treatment followed international AO as well as hospital guidelines, with the aim of achieving postoperative movement and weight-bearing as early as possible.

Patient data were collected at baseline, 6 and 12 weeks and 12 months after surgery using identical datasheets in all participating centres. Baseline assessments included demographics, body mass index (BMI), American Society of Anaesthesiologists (ASA) risk scores, and fracture characteristics based on the AO classification. Soft-tissue injuries in closed fractures were graded according to Tscherne and Oestern.[42] Open fractures were classified according to Gustilo and Anderson.[13] Patients underwent radiographic examination of the femoral shaft with the adjacent joints in the anteroposterior and lateral views at study entry and during scheduled follow-up visits. Details of the procedure including the surgeon's general (resident vs. consultant level) and specific experience (number of previous interventions undertaken with the proximal femur nail [PFN], a similar implant), or need of supervision (intervention was instructed/assisted by a more experienced surgeon vs. independent responsibility without supervision), open or closed reduction, reamed or unreamed insertion, surgery and fluoroscopy times were documented.

Complications were recorded throughout the study follow-up of 1 year. All complications and radiographs were reviewed by the principal investigators (TG and PM). Distinction was made between local (e.g., surgical site infection [SSI], delayed, mal- and nonunion) and systemic complications. The definitions for fracture healing were adapted from McLaren et al.[22], with the presence of bridging callus and the ability of the patient to bear his or her own weight without pain indicating union. Nonunion was assumed in case of (a) a delayed union, i.e. insufficient healing in the first 6 months after the AFN procedure where the surgeon decided for early reoperation; or (b) failed union/absence of bridging callus after >6 months. Malunion was defined using Ricci et al.'s definition of malalignment.[34] Further objective outcome assessments included the length of hospital stay, any reoperation over time and the range of motion (ROM) at follow-up visits.

Subjective criteria included (a) patient-reported pain registered by a visual analogue scale (VAS 0–10) as well as graduation following the Harris Hip Score at 12 weeks and 1 year and (b) the quality of life assessment using the Short Form 36 (SF-36) questionnaire, comparing in particular patients' self-assessment of their preoperative status (interviewed during the initial hospital stay) with the 12-month follow-up assessment.

Data management, including data entry, plausibility checks, and query generation was performed by AOCID. Data were processed with Qualicare Version 9.1a25 database (Qualidoc, Trimbach, Switzerland) and linked with the digitised radiographic images. All statistical analyses were conducted with the software Intercooled Stata Version 10 (StataCorp LP, College Station, TX, USA). EU and SA population baseline characteristics were compared; continuous variables were described using means, standard deviations (SD) and ranges (or medians and inter-quartile ranges as appropriate) and compared using the *T*-test; categorical variables were tabulated with absolute and relative frequencies and compared using the Fisher's exact test. Patient baseline factors were compared between the group of patients examined 1 year postsurgery and the group of patients lost to follow-up at 1 year as above; factors associated with 1-year loss to follow-up using univariable statistics at a significant level of 0.10 were examined together in a multivariable logistic regression model with a backward selection procedure. The significant level for selection in the final model was set to 0.05. Relative risks (RR) were derived by multivariable binomial regression. Outcome parameters were compared similarly between EU and SA patient groups; however continuous outcomes were analysed using multivariable linear regression. The following potential influencing factors were investigated: EU (vs. SA), age <65 years, BMI >30, single injury (vs. multiple fracture or trauma), open fracture, ASA score III–V (vs. ASA score I + II), surgeon experience, nail reaming, centre enrolling at least 10 patients, occurrence of a local complication and occurrence of delayed or nonunion. All comparative analyses were exploratory without a predetermined sample size or power calculation; 95% confidence intervals (CI) were computed for difference in proportions or means as appropriate to support interpretation of clinical relevance. In addition, outcome changes between 3-month and 1-year follow-up (e.g., ROM parameters) or between baseline and 1-year follow-up (e.g., SF-36) were examined by paired *T*-test. To examine potential biases in data collection, all analyses were reimplemented by excluding EU centres which have enrolled <10 patients. These results are