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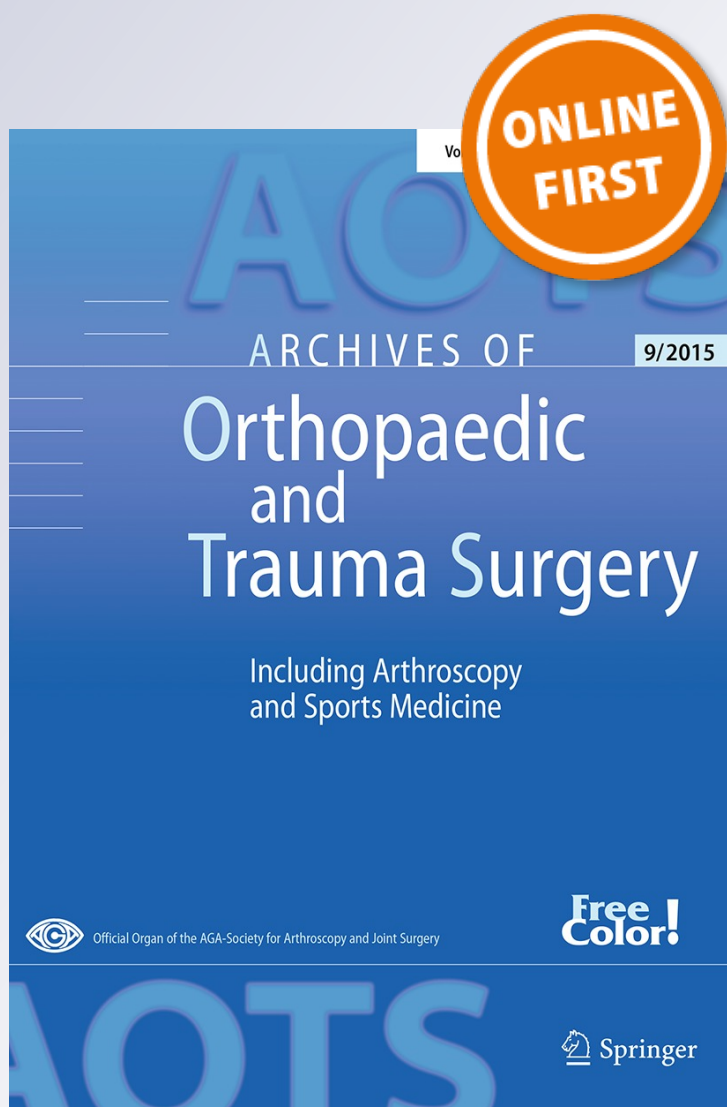
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Cephalomedullary nails: factors associated with impingement of the anterior cortex of the femur in a Hispanic population

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Abstract

Introduction Impingement and penetration of the anterior cortex of the femur have been reported as complications after cephalomedullary nailing. The purpose of this study was to determine factors related to nail impingement in our population of Hispanic patients.

Materials and methods A non-matched case-control study was carried out and 156 patients who underwent cephalomedullary nailing from 2010 and 2013 were included; 78 cases with anterior cortical impingement and 78 control cases without impingement were documented. Demographic variables and specifications of the nails such as manufacture and radius of curvature were recorded. The presence of impingement, angle of incidence on radiographs—indirect measurement of the femoral bow on the sagittal plane—and nail entry site were determined. Bivariate and multivariate logistic regression analyses were performed to identify the factors associated with cortical impingement.

Results The distribution by sex corresponded to 87 females (56 %) and 69 males (44 %) with a mean age of 75 years [SD 18.2]. Cortical impingement was presented in 78 cases (50 %) and 6 (3.8 %) patients evidenced penetration of the anterior cortex of the femur. On the bivariate analysis the posterior nail start site is highlighted, which showed a positive association with impingement (OR 4.3; 95 % CI 1.1–36 and $p = 0.04$). After the multivariate analysis, the factors associated with anterior cortical

impingement included female gender (OR 2.2; 95 % CI 1.1–4.6 and $p \leq 0.038$), straight nails—short nails—(OR 4.9; 95 % CI 2.2–10 and $p \leq 0.001$) and angle of incidence $\geq 7^\circ$ (OR 4.9; 95 % CI 2.2–10 and $p \leq 0.001$), the latter showing a likelihood of 57 % for impingement, increasing to 90 % with an angle of incidence of 11° .

Conclusions Posterior entry site should be avoided and an anterior site should be used. Female gender, straight nails and greater angle of incidence of the femur were associated with cortical impingement. A specific intramedullary nail design is needed for the Hispanic population due to high impingement and anterior cortical penetration rates seen with conventional nails. Short curved nails and long nails with a lower radius of curvature are required.

Keywords Cephalomedullary nails · Impingement · Hispanic population

Introduction

Hip fracture is an international public health problem occurring at a rate of approximately 1.5 million per year in the world, and roughly 340,000 in the USA in individuals older than 65 years [1]. It is estimated that the worldwide number of hip fractures will increase from 1.26 million in 1990 to 2.6 million in 2025 and 4.5 million in the 2050 [2, 3]. In addition, the increased risk of death after hip fracture has been well documented [4], showing a mortality rate of 2–5.3 % and 12–33 % in in-hospital mortality and 1-year mortality, respectively [4–8].

Hip fractures can be treated with different cephalomedullary implants including the Gamma nail and the trochanteric fixation nail (TFN), with specific clinical indications. The first device developed was the Gamma

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nail in the mid 1980s and was first brought into clinical use in 1988, with the first generation [9] evolving into the third generation in 2004 [10]. Similarly, TFN was developed by the AO Foundation and became available in the USA in 2001 [11]. It was later introduced in Colombia in 2006. Cephalomedullary nails are indicated in unstable fractures including pertrochanteric, intertrochanteric, basal neck fractures and the combination of them. Long implants are used in subtrochanteric and pertrochanteric fractures with extension to the femoral shaft [10, 12–14].

The devices have similar technical specifications by which they have to fit the human anatomy, specifically in terms of curvature and length. The nail curvature is determined by the radius of curvature (ROC) expressed in meters (m) or in centimeters (cm) and its longitude denominated in millimeters (mm); a greater radius of curvature refers to a straighter nail. Short nails from both brands show no ROC, meaning that they are completely straight, but differ in length, with the Gamma3™ nail being 180 mm and TFN 170 mm or 235 mm. On the contrary, long nails have different ROC, namely 2.0 m or 1.5 m in Gamma3™ nail and 1.5 m in TFN. At the same time, the length of long nails shows increments of 20 mm up until 460 mm in both nails; however, Gamma3™ starts at 280 mm and TFN starts at 300 mm [10, 12, 13]. Based on the nail features, they attempt to follow the human femoral bow. The femoral bow or curvature is easily measured on a lateral radiograph of the femur through the “angle of incidence”, which provides an indirect estimation of the femoral ROC on the sagittal plane [15].

Recently, there have been reports regarding different complications related to cephalomedullary nailing, such as impingement and penetration of the anterior cortex of the femur. In the USA, studies have shown a frequency of impingement of 7–25 % and penetration with a range between 0.47 % and 2 % [15–18]. Similarly, in the German population, penetration has been found in 1.1 % [19]. The purpose of this study is to determine the frequency and associated factors with impingement of the anterior cortex of the femur in a Hispanic population after cephalomedullary nailing. It was hypothesized that a higher angle of incidence of the femur and cephalomedullary nails without a radius of curvature or with a greater radius of curvature would have a higher rate of impingement.

Materials and methods

A non-matched case–control study was conducted including all patients with proximal femoral fractures treated with cephalomedullary nails between 2010 and 2013 at a

referral teaching hospital. A case was defined as a femoral cortical impingement, which was defined as a nail tip that contacts or runs through the anterior cortex of the femur on a postoperative lateral radiography of the femur (Fig. 1a). A control was defined as a patient without contact or penetration of the nail tip with the anterior cortex of the femur. Patients with pathologic fractures, previous post-traumatic femoral deformities, ipsilateral distal femoral fracture and lack of or poor quality of radiographs in special patients without a perfect axiolateral hip projection (ALHP) or perfect lateral femoral X-ray (LFXR) were excluded.

At the institution, when patients' comorbidities were stable, they usually underwent surgery within the first 48 h after hospital admission. Otherwise, the surgical procedure was delayed to optimize the medical status. Implant selection depended on surgeon preference and availability. Procedures were performed by 12 different surgeons with experience in trauma and cephalomedullary nailing. In general terms, the surgical technique of cephalomedullary fixation consisted initially of fracture reduction and alignment on a fracture table under fluoroscopic guidance, determination of the entry point, nail length and diameter, following reaming and nail insertion manually. Then insertion of the lag screw or blade and distal lockings were performed, and a final intraoperative radiological assessment was carried out with fluoroscopy [20].

Under anesthesia and before the patient left the operating room, an ALHP and an LFXR were obtained. A perfect ALHP had to demonstrate the following: (1) the lesser trochanter in profile medially, (2) the greater trochanter

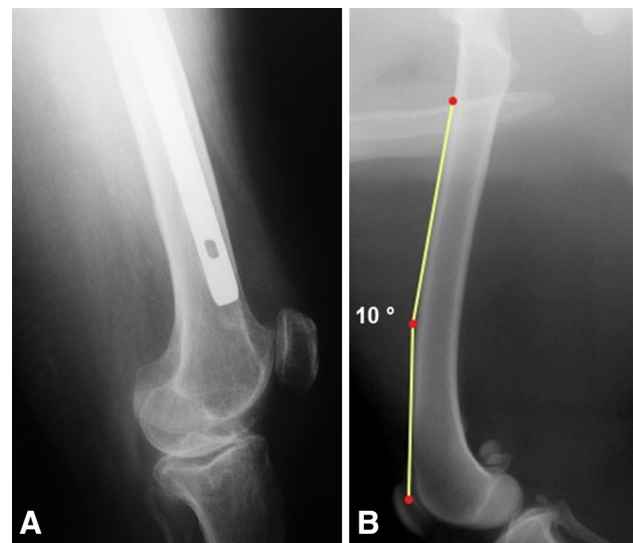


Fig. 1 **a** Image that represents cortical impingement, showing the nail tip contacting the anterior cortex of the femur. **b** Measuring the angle of incidence, providing an indirect estimation of the radius of curvature of the femur

superimposed on the femoral shaft, (3) the femoral neck at the center of the collimated field and not foreshortened and (4) the articulation of the acetabulum with the head of the femur entirely demonstrated and well penetrated [21]. Similarly, a perfect LFXR had to prove symmetry of the epicondyles with the femoral condyles in profile. The intercondylar eminence of the tibia is seen within the intercondylar fossa of the femur. The medial and lateral femorotibial joint is demonstrated open with good spacing between the femur and tibia [22].

Medical records were reviewed to collect demographic variables, mechanism of trauma and laterality of the fracture. Surgical records were reviewed to check the type and manufacturer, radius of curvature, length and diameter of the nail implanted. The mechanism of trauma was classified into two categories, low and high energy. Low-energy trauma included fractures secondary to a fall from standing height, and high-energy trauma included motor vehicle accidents, falls from significant heights or auto-pedestrian accidents.

All femoral radiographs were analyzed to determine the presence of impingement, angle of incidence and the nail start site in the proximal femur according to the definitions by Jason et al. [15]. The angle of incidence (AI) was measured along the femoral shaft using two tangential lines drawn parallel to the anterior cortex of the femur proximal and distal to the most bowed point of the femur (Fig. 1b). Nail entry site was grouped into anterior, middle and posterior by measuring the center of the nail in the proximal femur on the lateral view of the hip, and the endomedullary canal diameter was taken at the isthmus on the lateral postoperative radiographs. The measurements of AI and nail entry site were taken manually by an orthopedic surgeon from the Department of Orthopaedics.

Sample size estimation

A pilot study was performed and Epidat 4.0 was used to calculate the minimum sample size needed to detect significant differences for the outcome of interest, impingement. Given the pilot study results and using a power of 80 %, α of 0.05 and a ratio of 1:1 cases to controls, for the $AI \geq 7$ variable the proportion used in cases and non-cases was 67 % and 32 %, respectively, determining a sample size of 31 patients per arm. For straight nails without ROC, the exposure proportion used in non-cases was 9 % and in cases 30 %, requiring a sample size of 62 controls and 62 cases. Consequently, it was decided to use the highest sample size calculation between the two variables measured to carry out this study.

Statistical analysis

A descriptive analysis of the variables was performed and its results were expressed as percentages and proportions, or mean with standard deviation [SD]. Subsequently, a logistic regression model was built to explain the relationship between the outcome variable (impingement) and the set of independent variables, which were composed of the rest of the variables measured in our study. For that reason, an initial model was built taking into account the results of the bivariate analysis of each independent variable with the outcome variable. Upon completion of the bivariate analysis, the potential candidate variables to conform to the final model were selected based on a p value of <0.20 , which allowed to evaluated variables that were not statically significant, but that could have explained the anterior cortical impingement. Thereafter, a multivariate logistic regression was performed using the Wald test and an elimination scheme for removing variables until obtaining the final model. In addition, goodness-of-fit test was used to assess the final model's adequacy and check its fit, and good calibration was indicated with a p value of >0.05 [23].

Potential confounding variables were determined during the statistical analysis, and results from the bivariate and multivariate logistic regression analysis were presented with odds ratio (OR) and 95 % confidence interval (CI). Statistical significance was set at p of <0.05 , and the Stata 12 statistical package was used to perform all the statistical analysis.

Results

A total of 189 consecutive patients treated with cephalomedullary nails were identified from our surgical records, from which 33 patients were excluded: radiographs were not found in 12 patients, 3 patients presented ipsilateral distal femoral fracture and 1 patient had a previous post-traumatic femoral deformity. In the remaining 17 patients, the radiographs available were incomplete or did not allow appropriate assessment due to poor quality. No patients with pathological fractures were identified.

156 patients were included in this study, 78 cases of impingement and 78 controls, and their characteristics are presented in Table 1. All patients were Hispanic and sex distribution corresponded to 87 females (56 %), and 69 males (44 %) with a mean age of 75 years [SD 18.2]. Female gender was associated with cortical impingement (Tables 2, 3). The mean height was 158 cm [SD 8.4] and mean weight was 60 kg [SD 11.2].

Table 1 Patient characteristics ($n = 156$)

Variables	Impingement, $n = 78$	No impingement, $n = 78$
Gender, female (%)	53 (68)	34 (44)
Age, years [SD]	79 [11.6]	70.5 [22.2]
Height, cm [SD]	156 [7.8]	159 [8.8]
Weight, kg [SD]	59 [11]	62 [11]
Ethnicity, Hispanic (%)	78 (100)	78 (100)
Angle of incidence, [SD]	7.5 [2.2]	5.5 [2.4]
Nail type, (%)		
Gamma3 TM	37 (47)	30 (38)
TFN	41 (53)	48 (62)
Short nails, (%)		
Gamma3 TM , 180 mm	23 (29)	10 (12)
TFN, 170 and 235 mm	32 (41)	20 (26)
Long nails, (%)		
Gamma3 TM , ≥ 280 mm	14 (18)	20 (26)
TFN, ≥ 300 mm	9 (12)	28 (36)
Nail start site, (%)		
Anterior	5 (6)	15 (19)
Middle	65 (84)	61 (78)
Posterior	8 (10)	2 (3)
ROC of nails, (%)		
0 m	55 (70)	30 (38)
1.5 m	9 (12)	28 (36)
2.0 m	14 (18)	20 (26)

TFN trochanteric fixation nail, ROC radius of curvature

Table 2 Bivariate analysis for anterior cortical impingement

Variables	OR	95 % CI	p value
Female gender	2.7	1.3–5.5	0.002
Age >70 years	4.3	1.6–12	<0.001
Weight, ≤ 60 kg	2.32	1.1–4.8	0.012
Height, ≤ 160 cm	2	0.9–4.2	0.041
Endomedullary diameter, ≤ 14 mm	2.1	0.9–4.9	0.05
Low-energy trauma	9	2.5–18	<0.001
Side of fracture, left	1.5	0.8–3.1	0.14
Type of nail, Gamma3 TM	1.4	0.7–2.8	0.25
Nail start site, posterior	4.3	1.1–36	0.04
Gamma3 TM nail, 180 mm	2.8	1.1–7.2	0.010
Nail diameter, ≥ 11 mm	2.3	1.1–4.9	0.011
Angle of incidence, $\geq 7^\circ$	4.2	2.0–8.7	<0.001
ROC short nails, 0 cm	3.8	1.8–7.8	<0.001

OR odds ratio, CI confidence interval, ROC radius of curvature

Among the 78 patients with cortical impingement, nail tip that just contacted or penetrated the anterior cortical femur was found in 72 (92 %) and 6 (8 %), respectively. Nails longer than 300 mm represented the majority of cases of penetration in which Gamma3TM nails accounted

Table 3 Multivariate logistic regression model of associated factors for anterior cortical impingement

Variables	OR	95 % CI	p value
Female gender	2.2	1.1–4.6	0.038
AI $\geq 7^\circ$	5.9	2.7–13	<0.001
ROC short nails, 0 cm	4.9	2.2–10	<0.001

OR odds ratio, CI confidence interval, AI angle of incidence, ROC radius of curvature

Goodness-of-fit test: $p = 0.37$

for four cases (66 %) and TFN for one case (17 %). The other case was due to short Gamma3TM nail (17 %). Three of the patients with perforation did not require additional procedures due to slight elevation of the anterior cortex, the reason why weight-bearing was restricted during the postoperative period based on the surgeon criteria. The other three patients required revision. One of them suffered a fracture secondary to a short cephalomedullary nail, which was removed and replaced by a long implant 2 days later. The two remaining patients were treated with distal locking plate 2 days after the first intervention (Fig. 2). The revision procedures were performed in a secondary operation due to unavailability of resources to perform the

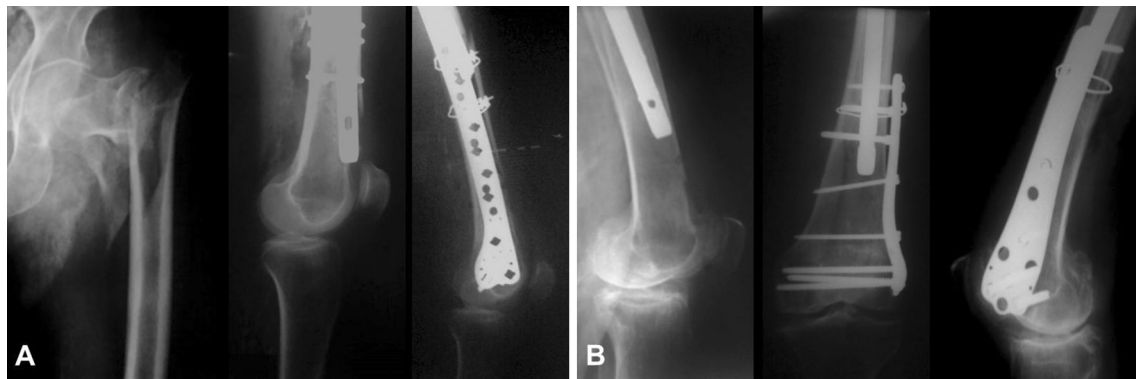


Fig. 2 A 70- (a) and an 85- (b) year-old patient treated with distal locking plate of the femur after cortical penetration. Long cephalomedullary nails with a radius of curvature of 2.0 m—less curved nails—were initially used

osteosynthesis or to the medical condition of the patients that did not allow extending the surgical time.

The initial model included the following variables: female gender; age, ≥ 70 years; weight, ≤ 60 kg; height, ≤ 160 cm; fracture side, left; posterior nail start site; Gamma3TM nail, 180 mm; endomedullary diameter, ≤ 14 mm; nail diameter, ≥ 11 mm; AI $\geq 7^\circ$ and ROC short nails, 0 cm (Table 2). Low-energy trauma was a statistically significant variable; however, that association was due to a confounding variable, which in this case was the angle of incidence. Therefore, it was excluded from the multivariate logistic regression analysis. The final model contained variables such as female gender, AI $\geq 7^\circ$ and ROC short nails, 0 cm (Table 3).

Angle of incidence

The mean AI [SD] was 6.5° [2.5] in all patients, but was higher in patients with cortical impingement with a mean of 7.5° [2.2]. Patients without cortical impingement had a mean of AI 5.5° [2.4]. A cutoff of 7° for the angle of incidence was selected, because it proved to demonstrate the best sensitivity and specificity to predict cortical impingement.

AI $\geq 7^\circ$ at bivariate analysis was associated with anterior cortical impingement, and similar results were found with logistic regression analysis (Tables 2, 3). The likelihood of cortical impingement for patients with an AI ≥ 7 was 57 %, and with an AI of 12 was 90 %. Increasing the angle of incidence was directly proportional to the probability of impingement of the anterior cortex of the femur.

Intramedullary nails

TFN was implanted in most cases, $n = 89$ (57 %), following by Gamma3TM nails $n = 67$ (43 %). Impingement was more frequent with the use of short nails than with long nails, 55 (70 %) and 23 (30 %), respectively. Long

nails with 200 cm radius of curvature had more cortical impingement than nails with radius of curvature of 150 cm (Table 1).

According to the bivariate and logistic regression analysis, absence of radius of curvature of short nails was associated with anterior cortical impingement (Tables 2, 3).

Discussion

In this analytical study, the proposed hypotheses such as association between nails without or with a greater ROC and a higher angle of incidence of the femur with the anterior cortical impingement were confirmed. Additionally, this study confirms the results found by other series [18]; however, our study showed that short nails, which are straight, had higher frequency of impingement compared to long cephalomedullary nails. Recently, this finding has been shown in Asian populations [24], but not in Hispanics. It differs from the findings in American or European populations in which only long nails produced cortical impingement [15–19].

As the Gamma3TM and TFN nails were designed for a different population with particular specifications, we feel that the demographic qualities of our Hispanic population, including short height and more curved bones than the European and North American population, account for the increased impingement rate in our series, being even two to seven times higher than in previously reported series [15, 16]. Even within our population and given our study findings, females had more cases of impingement, probably due to a more curved femur than males. Anatomical differences between populations have been described. Indeed, Egol et al. [25] reported femur differences between African Americans and Caucasian individuals in the USA, with African Americans donor femurs having less curvature than white donor femurs, but no Hispanic individuals were included in that study.

Table 4 Long cephalomedullary nails commonly used in Colombia

Cephalomedullary nail	Manufacturer	Radius of curvature (m)
Trochanteric fixation nail ^a	DePuySynthes	1.5
Gamma3 ^{TMa}	Stryker	1.5 ^b or 2.0
Proximal femoral nail	DePuySynthes	1.5
TRIGEN INTERTAN	Smith & Nephew	1.5 or 2.0
Gamma	Trauson	1.8
Peritrochanteric nail	Biomed	1.8
Phoenix TM	Biomed	1.8
Centronail	Orthofix International	2.5
Charfix	ChM company	2.8

^a Cephalomedullary nails used in our institution

^b Not available in Colombia

Furthermore, some anatomopathological studies have measured the radius of curvature of the femur in American and Spanish populations, finding an average ROC of 120 cm (± 36 cm) and 138 (± 11.8 cm), respectively [25, 26]. However, our findings showed a higher impingement rate, so we infer that in this Hispanic population the ROC could be lesser than expected [15, 16]; thus, the nails that we normally use mismatch with the femoral ROC of our patients (Table 4). Additionally, there are studies in Chinese population that evidence a mismatch between the geometry of their femur and the cephalomedullary nails as well [27]. Therefore, we postulate that cephalomedullary nails with different specifications are required for Hispanic populations. Specifically, short curved nails and long nails with a lower radius of curvature are demanded in order to decrease the frequency of impingement and penetration. In addition, it is also necessary to carry out cadaveric and radiographic studies to determine the exact specifications to develop nails for our Hispanic population.

The posterior nail start site was an incidental factor found in this study related with cortical impingement. Eighty nine percent of our patients with posterior nail insertion presented impingement, which translates into an association that bivariate analysis shows as 3.3 times higher (OR 4.3, 95 % CI 1.1–36). This was not statistically significant upon logistic regression analysis due to lack of sample size. Roberts et al. [15] postulate that a posterior starting point increases the angle at which the nail is inserted, through which the nail has to pass, leading to increased contact between the nail and the anterior cortex of the femur. Considering our results regarding higher impingement with short nails, nail entry site selection for those nails must be more rigorous than for long nails, so that the insertion of the nail through an anterior site should be used and posterior nail start site avoided (Fig. 3).

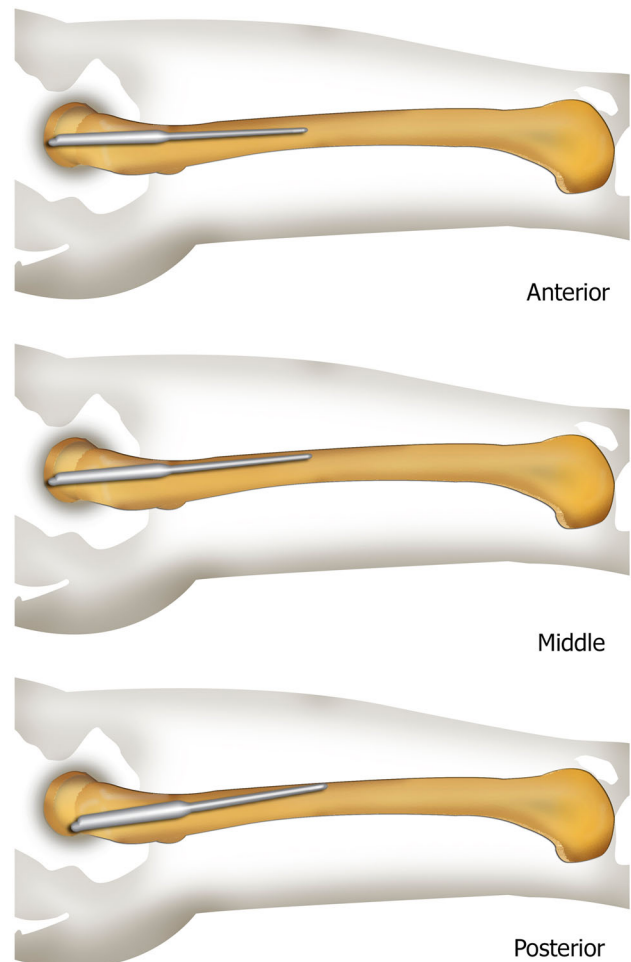


Fig. 3 Anterior, middle and posterior start sites for cephalomedullary nailing with short nails. Anterior site should be used and posterior nail start site avoided

On the other hand, there is limited evidence on the clinical relevance of impingement according to an author's extensive search of the literature. It has been reported that it can lead to a nonunion of the fracture, which is based on the principle that cortical impingement prevents the distal sliding of the nail within the diaphyseal canal and so it interferes with the compression during the healing process under fracture loading [28]. In the same way, moderate or severe claudication, and moderate or severe pain on the anterior face of the knee have been observed after 1 year of follow-up, with a statically significant relationship with cortical impingement. In that study, claudication was present in 60 % and pain on the knee in 52.6 % of the patients with impingement [29]. Moreover, we consider that the point on the femoral cortex where the impingement occurs can eventually serve as a lever arm where a fracture may occur or "a stress raiser point", especially considering the bone fragility that the geriatric population may have. For all the above mentioned, to clarify the findings reported in

the literature and to verify or reject the proposed hypothesis, it is necessary to carry out cohort studies or clinical trials to establish appropriately the clinical implications on hip or thigh pain, functional outcomes and secondary long-term complications such as fractures in the femur as well as breakage of the nail. A proper evaluation of outcomes must take into account factors that can interact with impingement or be a confounding variable. For instance, during the assessment of pain, positive medial cortical support should be considered because it could play a role in its occurrence, and while measuring the breakage of a cephalomedullary nail, factors such as an accurate preoperative planning and surgeon performance can be further factors involved [30, 31].

To our knowledge, this is the first study addressing these issues in a Hispanic population with a large number of patients and sufficient sample size calculation to find statistically significant differences in relation to impingement. Multiple orthopedic surgeons with formal training in trauma performed the surgical procedures, which allows for external validity. However, some limitations of this study should be addressed. The main limitation was the observational design, which is intrinsically prone to bias. In addition, there was a loss of 15 % of the radiographs for analysis, which could have affected the precision of the study results, though not the tendency of the results per se.

In conclusion, impingement and penetration of the anterior cortex of the femur can occur after cephalomedullary nailing. In the Hispanic population, anatomic characteristics such as a greater angle of incidence of the femur and nail particularities such as the absence or higher radius of curvature were associated with cortical impingement. A posterior nail start site was related with impingement, so it should be avoided. Cephalomedullary nails with specific features for the Hispanic population are required to reduce cases of impingement and penetration.

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Compliance with ethical standards

Funding source No external funding was used.

Ethical standards (1) The study was approved by both the Institutional Medical Review Board and Ethics Committee of the Hospital Research Center and was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments. (2) Since it was a retrospective study, the need for informed consent was waived by the Institutional Medical Review Board.

Conflict of interest The authors declare that they have no conflict of interest.

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