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**EOS stereographic assessment of femoral shaft malunion after intramedullary nailing.
A prospective series of 48 patients at 9 months' follow-up.**

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Abstract

Introduction: The aim of the present study was to assess femoral shaft malunion following anterograde intramedullary nailing, using low-dose EOS stereoradiography. The study hypothesis was that our surgical technique is associated with radiological rotation disorder rates equivalent to those reported in the literature.

Methods: All patients with unilateral femoral shaft fracture treated by anterograde nailing between January 2014 and December 2016 and followed up in our structure were included in a single-center prospective study. The main endpoint was $\geq 15^\circ$ transverse malrotation compared to the contralateral side as measured on EOS stereoradiography. Correlations between malrotation and Harris Hip and SF12 functional scores were assessed, as were risk factors for onset of shaft malunion in rotation. Forty-eight patients with a mean age of 31.4 years were analyzed at a mean 9.3 months' follow-up.

Results: Stereoradiographic malrotation was found in 29.2% of patients. Mean anteversion was $18.5 \pm 13.8^\circ$. In 2.1% of patients, symptomatic rotation disorder required revision surgery. No correlations emerged between transverse malrotation and functional scores ($p > 0.05$). Risk factors for malrotation comprised multi-site fracture ($p = 0.04$), surgeon's inexperience ($p = 0.04$), and open reduction ($p = 0.01$).

Conclusion: The present radiologic malrotation rate was comparable to those reported in the literature, using the EOS stereoradiographic system, which provides precise assessment of rotation disorder following closed nailing of femoral shaft fracture.

Level of evidence: III; prospective study without control group

Keywords: Femoral shaft fracture; Femoral nail; EOS; Malunion; Femoral version; Rotation disorder

1. Introduction

Intramedullary nailing is the treatment of choice in femoral shaft fracture. One weakness is the risk of transverse, frontal or sagittal malunion. The most frequent deformity is transverse rotation disorder, with incidence of 20-30% [1–4].

To our knowledge, there have been few studies of malrotation in femoral shaft nailing, and measurement methods were poorly reproducible [1–4]. None used EOS stereoradiography [5,6].

The aims of the present study were 1) to identify and quantify malrotation after transverse femoral shaft intramedullary nailing, using the EOS system; 2) to assess functional impact; and 3) to determine risk factors. The study hypothesis was that our surgical technique is associated with radiological rotation disorder rates equivalent to those reported in the literature.

2. Material and method

2.1. Population

A single-center continuous prospective study included patients aged >15 years, treated between January 2014 and December 2016 for unilateral femoral shaft fracture by anterograde intramedullary nailing. Joint fractures, floating knee and bilateral fractures were excluded, as were patients followed up elsewhere.

Ninety-six patients were eligible. Forty-eight were included: 12 female, (25%), 36 male (75%); mean age, 31.4 ± 14.8 years (range, 15.4-72.4 years). The inclusion flowchart is shown in figure 1. Mean body-mass index (BMI) was 23.6 ± 3.2 kg/m² (15.9-31,8). Fracture and surgery data are shown in Table 1.

2.2. Surgical technique

Patients were positioned on an orthopedic table with pubic support and boot traction of the foot. A titanium anatomic locking nail (T2, Stryker, Pusignan, France) was implanted. Femoral neck anteversion was assessed in the transverse plane as the angle between the axis of the proximal femoral neck and the distal posterior bicondylar plane, as described by Bråten et al. [7]: fluoroscopy situated the femoral neck in relation to the ground after fracture

reduction; strict lateral knee view superimposing the 2 condyles situated the bicondylar plane and thus the transverse axis of the knee, with respect to the ground; and subtracting the two axes gave the femoral neck anteversion value. The target value was 15-20° [7]. Varus-valgus (frontal plane) and genu recurvatum-flessum (sagittal plane) were assessed by aligning fragments according to the nailing principle. The entry point was at the summit of the greater trochanter. The reaming guide was positioned at the center of the condyles, frontally and laterally. Limb length restoration was checked by realigning the fragments.

After reaming and hardware introduction, static locking was performed proximally and freehand dynamic locking distally. Anteversion was adjusted, following Bråten, ahead of distal locking [7]. Immediate resumption of weight-bearing was at the surgeon's discretion.

2.3. Assessment

Patients were followed up at 45 days, 3 months, 6 months and 1 year, with standard AP and lateral femoral X-ray. At 6 months, clinical and radiological assessment including systematic EOS stereoradiography was performed by an independent observer. Data comprised epidemiological parameters, fracture characteristics, accident-to-surgery time, operator experience (senior or trainee), day or night surgery (emergency surgery after 6 pm), and clinical and radiological data comprising hip and knee ranges of motion, clinical measurement of morphological parameters including limb-length discrepancy, return to work, pain on VAS, and postoperative low back pain.

Radiologic assessment used EOS stereoradiography (EOS Imaging, Paris, France) [6,8]. The dedicated sterEOS software, version 1.6.4 (EOS Imaging, Paris, France) generated femur, tibia and fibula models for a 3D lower-limb skeleton model [8–10]. The software automatically measured femoral torsion disorder: anteversion (°) with respect to the posterior bicondylar plane, limb-length discrepancy, valgus/varus, and flessum/genu recurvatum [9,10]. On the anteroposterior axis, varus malrotation was defined by Hip-Knee-Ankle (HKA) angle <177° and valgus malrotation by HKA >183° [11,12]. On the mediolateral axis, normal alignment was defined by an 177-183° angle between the femoral axis (femoral head center to knee center) and the tibial axis (knee center to ankle center); angles >183° defined genu recurvatum compensating the malunion in flessum, and angles <177° defined flessum compensating malunion in genu recurvatum. There was assumed to be no anteroposterior translation, given the intramedullary nail design.

On the longitudinal axis, positive ($\geq 15^\circ$) or negative ($\leq -15^\circ$) differential axial rotation with respect to the healthy side defined malrotation (ΔR), the main endpoint. Axial rotation was also analyzed as $< 0^\circ$ or $> 0^\circ$, with respect to the surgical target of $15 \pm 5^\circ$ (ΔT). Limb-length discrepancy was measured as negative with respect to the contralateral length. Stereoradiographic interpretation was validated by a single independent radiologist experienced in bone and joint imaging.

2.4. Statistics

Sample size for the main endpoint was 30 patients. Analyses used Stata 14.2 and R software version 3.4.1. The α risk was set at 5%. Normal distribution for quantitative variables was checked on Shapiro-Wilks test, and correlations were assessed on Pearson or Spearman correlation coefficient (ρ) accordingly. Means were compared on Student test or non-parametric Mann-Whitney-Wilcoxon test. For qualitative variables with > 2 modalities, ANOVA or non-parametric Kruskal-Wallis test was applied.

The study conformed to the Declaration of Helsinki, and had local IRB approval. All patients provided consent.

3. Results

3.1 Radiographic results

Fourteen patients (39.2%) showed malrotation (ΔR): 11 with positive ΔR (mean, $27^\circ \pm 9.1$ (range, 15-44)), 3 with negative ΔR ($-23.1^\circ \pm 2.1$ (-22 to -26°)) (figure 2).

The target (ΔT) was not met for 32 patients (67%). Mean pathological side anteversion was $18.5^\circ \pm 13.8$ (range, -17 to 63°). Twenty-four showed positive ΔT (mean, $29.3^\circ \pm 8.0$ (21-63)), and 8 negative ΔT ($-2.6^\circ \pm 8.7$ (-17 to 6)) (figure 3).

Fifteen patients (31.2%) showed limb-length shortening (max., -13 mm) and 33 lengthening (68.8%) (max., +26 mm). Clinical limb-length discrepancy correlated with EOS measurements (ρ 0.57; $p < 0.01$).

On EOS, there was no significant difference between sides for frontal ($p=0.22$) or sagittal ($p=0.42$) rotation.

3.2 Clinical results

Clinical assessment was made at a mean 9.2 ± 5.1 months (range, 2.7-23.2) (Table 2). Five patients (10.4%) resumed sports activity at 3 months, 12 (25%) at 3-6 months, 9 (18.8%) at 6-9 months, and 22 (45.9%) did not return to sport. None returned to competitive sport. There was no clinical impact of limb-length discrepancy.

3.3 Complications

By end of follow-up, there had been 6 revision surgeries (12.5%): 1 correction of >20 mm limb-length discrepancy, 4 for non-union (at 7, 8, 11 and 13 months), and 1 femoral derotation procedure (at 4 months). There were 3 gluteus medius tendinites associated with bursitis. One patient showed symptomatic gluteus medius calcifications. Two showed signs of psoriasis due to mechanical irritation by the proximal locking screw.

3.4 Multivariate analysis and radio-clinical correlations

Table 3 shows risk factors for malrotation: multi-site fracture ($n=3$) ($p=0.04$), surgeon inexperience ($p=0.04$), and open reduction ($p=0.01$). No factors emerged for limb-length discrepancy or frontal or sagittal malunion.

Clinical and EOS femoral anteversion correlated ($\rho=0.53$; $p<0.01$). Clinical internal rotation of the hip and EOS femoral anteversion correlated ($\rho=0.39$; $p<0.01$).

There were no correlations between transversal, frontal or sagittal malrotation and SF12 or Harris scores ($p>0.05$). In the 11 patients with positive ΔR , mean SF12 was 7.6 ± 1.1 (range, 6-9), and mean Harris score 90 ± 8.9 (75-100). In the 3 patients with negative ΔR , mean SF12 was 7.3 ± 0.6 (7-8), and mean Harris score 71 ± 31 (36-96).

4. Discussion

At a mean 9 months' follow-up, 14 of the 48 patients showed $\geq 15^\circ$ malrotation on EOS with respect to the healthy side (29.2%). This is in agreement with the literature, with rates of 20-30% [1,13,14].

One limitation of the present study was the large rate of loss to follow-up, due to patients changing residence. The use of EOS stereoradiography for assessment was also debatable, CT being the current gold-standard [1,15]. The interest of EOS imaging to assess femoral torsion has been demonstrated [16,17], with no significant difference with respect to CT [17,18] or even superiority of EOS according to Morvan et al. [19]. Radiation dose to the pelvis is 18.8-fold lower than with classical X-ray [6], and, compared to CT, dose to the testicles is 24-fold lower, and 14-to-30-fold lower for the knee and ankle [5]. The EOS system also enables simultaneous weight-bearing measurement of limb-length discrepancy, so that the healthy side can serve as reference. The limitations lie in interpretation and the evaluation system [20]. For this reason, interpretation was made by an experienced independent radiologist. The evaluation software has been constantly upgraded since the report by Knafo et al. in 2016 [20].

Natural femoral anteversion is agreed to average 15° , with physiological variation between 0° and 30° [1,3,21]. In the present study, mean postoperative anteversion was 18.5° , associated with a 29.2% rate of malrotation. This value was close to the 16° anteversion reported by Patel et al. after nailing for gunshot wound, but where the prevalence of malrotation was lower, at 12.3% [22]. In the present series, 67% of patients were off the target $15 \pm 5^\circ$, suggesting that the method described by Bråten et al. is not very reproducible or reliable [5]. There was a tendency for hyper-anteversion, with 50% of patients over the target, although without impact on SF12 or Harris functional scores.

There are several intraoperative methods intended to limit malrotation, without consensus [22,23]. Some authors use preoperative external fixation, intraoperative CT control, or intraoperative navigation, with encouraging results [23–25].

There was a weak correlation between clinical assessment and EOS confirmation. All clinical methods are poorly reproducible, with up to 20° error in the hip [26,27]. The present study found a correlation between internal rotation of the limb and femoral anteversion, an excess in one being associated with an excess in the other. Moreover, given a mean 30° physiological external tibial torsion, a phenomenon of adaptation to gait patterns in both

pelvis and knee compensates malrotation [28]. Compensation for excess external rotation by the patient increases posterior acetabular and medial femorotibial stress, with risk of osteoarthritis of the hip and knee. Clinical findings of excess internal rotation indicate screening for malrotation following nailing. The absence of clinical impact of limb-length discrepancy exceeding 10 mm (max., +26mm) was unexpected [29], and may be due to short follow-up. Disturbed gait, partial functional recovery, recent trauma and hardware still in place are possible explanations; this requires longer-term analysis.

In the present study, the surgical revision rate was 12.5%, with 2.1% for femoral derotation. The nonunion rate was 8.4% , in agreement with literature rates of up to 14.2% [30]. One reason could be soft-tissue incarceration in fractures with large initial displacement, which is difficult to assess on standard X-ray or intraoperatively on the traction table. There were no cases of cortical breach or screw breakage.

Risk factors for malrotation comprised: surgeon inexperience, or learning curve; multi-site fracture in multiple trauma; and open reduction. In our experience, open surgery does not prevent malrotation. A need for a sub-vastus approach on traction table testifies to difficulty in introducing the guidewire, and thus probably poor initial reduction. Associating traction and open reduction does not enable anatomic reduction following difficult intraoperative exposure.

5. Conclusion

EOS stereography assesses malrotation following closed nailing for femoral shaft fracture. Risk factors for malrotation comprised multi-site fracture, surgeon inexperience, and open reduction. Intraoperative bilateral comparative clinical and radiological assessment gives a better picture of native femoral version. This in-theater screening under fluoroscopy or CT can avoid certain severe rotation disorders in patients with natural hyperversion or retroversion.

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Author contributions:

B. Orfeuvre: follow-up, article writing

J. Tonetti: project supervision

G. Kerschbaumer: article re-editing for publication

R. Barthelemy: radiographic analysis

A. Moreau-Gaudry: statistical analysis

M. Boudissa: article supervision, re-editing and submission

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Table 1: Fracture characteristics and surgical data

| <i>Characteristics</i> | <i>Population, n (%) (N=48)</i> |
|-----------------------------------------|---------------------------------|
| Type of accident | |
| - road | 28 (58.3) |
| - sport | 12 (25) |
| - other | 8 (16.7) |
| Emergency surgery | |
| - no | 6 (12.5) |
| - yeas | 42 (87.5) |
| Surgeon's experience | |
| - junior | 28 (58.3) |
| - senior | 20 (41.7) |
| Open fracture | |
| - no | 39 (81.2) |
| - yes | 9 (18.8) |
| Side | |
| - right | 17 (35.4) |
| - left | 31 (64.6) |
| Type | |
| - unifocal | 38 (79.2) |
| - bifocal | 7 (14.6) |
| - multifocal | 3 (6.2) |
| Form | |
| - short spiroid | 7 (14.6) |
| - long spiroid | 7 (14.6) |
| - transverse | 34 (70.8) |
| Location on shaft | |
| - proximal | 7 (14.6) |
| - medial | 39 (81.2) |
| - distal | 2 (4.2) |
| Isolated osteoligamentous lesion | |
| - no | 15 (31.2) |
| - yes | 33 (68.8) |
| Multiple fracture | |
| - no | 29 (60.4) |
| - yes | 19 (39.6) |
| Open reduction | |
| - no | 44 (91.7) |
| - yes | 4 (8.3) |

Table 2: Clinical results

| <i>Clinical parameters</i> | <i>N=48 (range)</i> |
|----------------------------------------|-----------------------|
| Femoral anteversion | 10.6 ± 10.2° (0 - 50) |
| Scores | |
| - SF12 (/10 points) | 7.2 ± 1.7 (3 - 10) |
| - Harris (/100 points) | 85 ± 17.5 (36 - 100) |
| Pathologic hip range of motion | |
| - flexion | 122.7 ± 15.9° |
| - extension | -15.8 ± 8.9° |
| - abduction | 44.9 ± 6.2° |
| - adduction | 25.1 ± 11.1° |
| - external rotation | 50.9 ± 19.3° |
| - internal rotation | 32.0 ± 15.2° |
| - pain on FABER | 6 (12.5%) |
| - pain on FADIR | 8 (16.7%) |
| Pathologic knee range of motion | |
| - flexion | 143.6 ± 14.1° |
| - extension | -1.1 ± 3.1° |
| Meniscal pain | |
| - medial | 6 (12.5%) |
| - lateral | 6 (12.5%) |
| Knee extension | |
| - flossum (≥ 5°) | 1 (2.1%) |
| - genu recurvatum (-5 to -15°) | 14 (29.2%) |
| Frontal disorder | |
| - normal alignment | 21 (43.8%) |
| - varus | 21 (43.8%) |
| - valgus | 6 (12.5%) |
| Limb-length discrepancy | |
| - equality | 20 (41.7%) |
| - shortening | 5 (10.4%) |
| ✓ mean | -8 ± 6.7mm |
| ✓ maximum | -20 mm |
| - lengthening | 23 (47.9%) |
| ✓ mean | 10.4 ± 4.9mm |
| ✓ maximum | 20 mm |
| Acetabular pain syndrome | |
| | 1 (2.1%) |

Table 3: Risk factors for intraoperative malrotation

| <i>Risk factors</i> | <i>P-value</i> |
|---------------------------------------|----------------|
| Type of accident | |
| - road | 0.09 |
| - sport | 0.31 |
| - other | 0.98 |
| Emergency surgery | 0.10 |
| Surgeon's experience | 0.04 |
| Open fracture | 0.44 |
| Side | 0.39 |
| Type | |
| - unifocal | 0.21 |
| - bifocal | 0.57 |
| - multifocal | 0.90 |
| Form | |
| - short spiroid | 0.38 |
| - long spiroid | 0.62 |
| - transverse | 0.43 |
| Shaft location | 0.95 |
| Multisite orthopedic treatment | 0.04 |
| Open reduction | 0.01 |

Figure 1: Selection flowchart

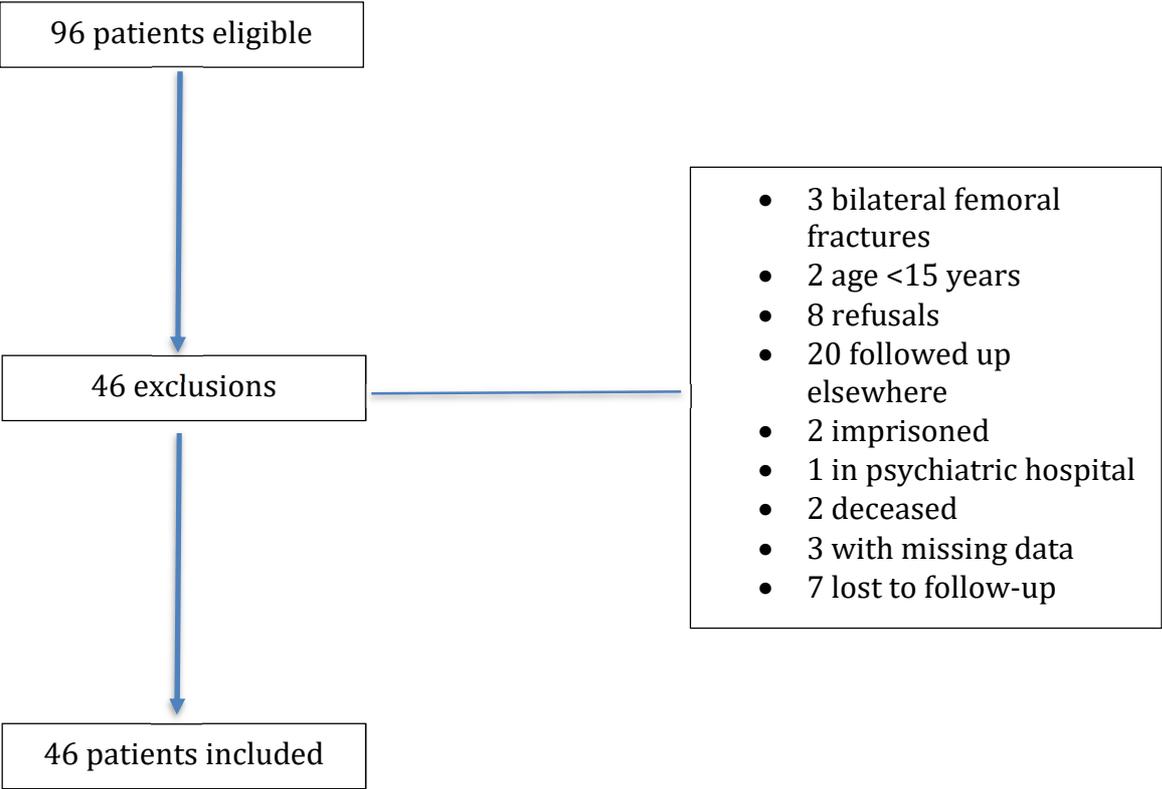


Figure 2: Malrotation with respect to the healthy side (ΔR). (Healthy side rotation = 0°)

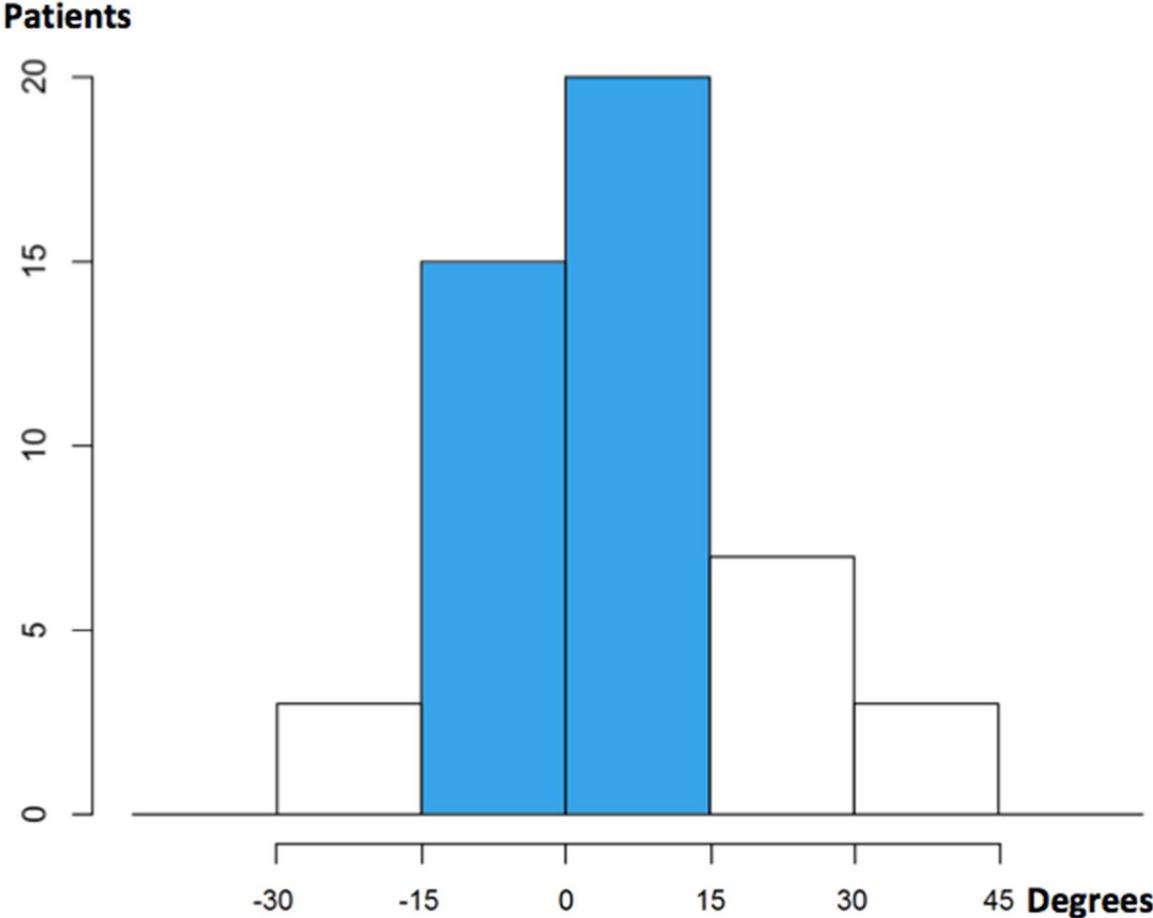


Figure 3: Axial rotation with respect to target (ΔC) 10-20° anteversion ($15^\circ \pm 5^\circ$) with respect to bicondylar plane

