ORIGINAL ARTICLE

Computer-assisted navigation for intramedullary nailing of intertrochanteric femur fractures: a preliminary result

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ABSTRACT

Aim To demonstrate a reduction of risk factors ray-depending in proximal femur nailing of intertrochanteric femur fractures, comparing standard technique with computer-assisted navigation system.

Methods One hundred patients hospitalised between October 2021 and June 2022 with intertrochanteric femur fractures type 31-A1 and 31-A2 were prospectively enrolled and divided randomly into two groups. A study group was treated with computer-assisted navigation system ATLAS (Masmec Biomed, Modugno, Bari, Italy) (20 patients), while a control group received the standard nailing technique. The same intertrochanteric nail was implanted by a single senior surgeon, Endovis BA 2 (EBA2, Citieffe, Calderara di Reno, Bologna, Italy). The following data were recorded: the set-up time of operating room (STOR; minutes); surgical time (ST; minutes); radiation exposure time (ETIR; seconds) and dose area product (DAP; cGy·cm2).

Results Patients underwent femur nailing with computer-assisted navigation system reported more set-up time of operating room (24.87±4.58; $p<0.01$), less surgical time (26.15±5.80; $p<0.01$), less time of radiant exposure (4.84±2.07; $p<0.01$) and lower dose area product (16.26±2.91; $p<0.01$).

Conclusion The preliminary study demonstrated that computer-assisted navigation allowed a better surgical technique standardization, significantly reduced exposure to ionizing radiation, including a reduction in surgical time. The ATLAS system could also play a key role in residents improving learning curve.

Key words: computer-assisted surgery, fluoroscopy, internal fixation, intertrochanteric fracture, nailing

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INTRODUCTION

Intertrochanteric fractures represent the most frequent elderly fractures that an orthopaedic surgeon may encounter in his daily practice (1), more than wrist and shoulder fractures (2). Elderly people (> 65 years old) are most affected by this fracture and the simultaneous presence of other comorbidities, such as osteoporosis, makes the management more complicated (3-5). Obesity also represents an important risk of fracture than normal-weight due to metabolic factors and increased risk of falls (6). Due to the biomechanical advantages and the soft tissue respect, intramedullary nailing has proven to be the most widely used device in the treatment of the disease (7, 8). Bone healing, early mobilization and full weight bearing restored as soon as possible are the main surgery goals (9, 10). Over the years, the need for less invasive, faster procedures and concerns about the effects of radiation exposure (11) have been the main drivers for the evolution of computer-assisted surgery, which is finding various fields of application (7).

Computer-assisted navigation systems have been successfully used in several orthopaedic surgical procedures, including spine and total hip/knee replacement (12-14). It has been also studied in some trauma surgical procedures, i.e. percutaneous screw implant for medial femoral neck fractures and acetabular fractures (15-17). Three-dimensional (3D) reconstruction surgical instruments tracking real time and novel devices within a surgical field are just some of the salient features of computer assisted surgery, which often simplify some surgical phases as in achieving a correct positioning of the guide wire through the femoral neck (18).

The aim of this study was to describe the preliminary results of a new navigated intramedullary system and to compare it with fluoroscopy guided traditional procedure as a proximal femur treatment, highlighting the differences between the two procedures in terms of preoperative setting and variations in ionizing radiation received.

PATIENT AND METHODS

Patient and study design

All patients hospitalized at the Orthopaedic and Traumatology Unit, “Di Venere" Hospital in Bari, due to intertrochanteric femur fractures during the period from October 2021 to June 2022, were involved in this prospective observational study according to the recommended STROBE guidelines (19). Inclusion criteria were: diagnosis of an intertrochanteric femur fracture (AO Classification 31-A1 or 31-A2) (20) and low energy mechanism of injury (i.e. fall from standing, twist). Exclusion criteria were: less than 18 years, high energy mechanism of injury (e.g. motor vehicle accident, fall from height), open fracture, multiple injuries to the lower extremity, refused to give written consent, need for open reduction. The patients were divided into two groups using a predefined program (http://www.randomization.com). Prior to the surgery, the circulating nurse reviewed the random-numbers list. A study group was represented by patients who were treated with computer-assisted navigation of intramedullary nailing and a control group included patients treated with the standard nailing technique.

For each patient, the following data were recorded: age, gender, BMI (body mass index), side of surgery, time to surgery, fracture classification (20), American Society of Anesthesiologists Score (ASA) (21), the set-up time of operating room (STOR), surgical time (ST), radiation exposure time (ETIR) and dose area product (DAP).

Demographic data were recorded at patient admission, while studied outcomes were collected after surgery.

The study was approved by the local Ethics Committee of the Faculty of Medicine, University of Bari. An informed consent was obtained from all study participants before the data collection.

Methods

All procedures were done by single senior orthopaedic trauma surgeons with more than 10 years of intertrochanteric procedures experience. All procedures were performed under spinal anaesthesia. The patient was placed on a traction bed. The closed reduction was performed, under C-arm control, to restore the anatomical position of fragments. The control group received standard EBA2 nailing (Citieffe, Calderara di Reno, Bologna, Italy). The first step of the surgical procedure was a small proximal incision at the greater trochanter level. Using manufacturer’s instruments, the trochanteric hole was made to insert the guide pin and successively the femur nail. Two cephalic screws were inserted after measurements. The distal locking screw was applied if necessary. The final position of the fragments and the implant were controlled with uniplanar fluoroscopy in AP and lateral views. The same views were used for the first postoperative radiographs. A standardized operative technique was used following the manufacturer's instructions. All these steps require fluoroscopy.

The ATLAS system (Masmec Biomed, Modugno, Bari, Italy) is a computer-assisted navigation for intramedullary nailing using the same surgical steps of the EBA2 standard, but does not require fluoroscopy, except for the correct close initial reduction. Firstly, the navigation system scans two radiographic images acquired after reduction (i.e. anteroposterior and axial hip views). The ATLAS system is composed of a viewer (i.e. an infrared ray's emitter and receiver), sensors (spheres that reflects infrared rays), a processing and display unit (a computer that elaborates data acquired (Figure 1) and supports for specific sensors for each surgical instrument (Figure 2A), the patient (Figure 2B) and C-ARM (Figure 2C).

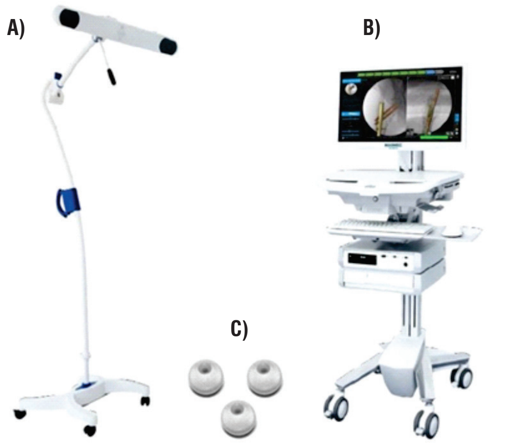

Figure 1. Computer-assisted navigation system. A) viewer; B) sensors; C) processing unit (Di Venere Hospital, 2022)

Due to infrared rays the system locates the patient and surgical instruments in space. The processing unit elaborates the fluoroscopic images acquired after the reduction to navigate the subsequent surgical steps without further fluoroscopic rays.

The Endovis BA 2 (EBA2) Citieffe nail is made of titanium alloy and is 180 mm long with a metaphyseal angle of 5° a proximal diameter of 13.5 mm and a distal diameter of 10 mm. It has two oblique screws with a self-drilling cervico-cephalic angle of 130° for proximal locking, thereby preventing

Figure 2. Computer-assisted navigation system. A) specific sensors implemented for each instrument; B) support for patient specific sensors; C) support for C-ARM specific sensors (Di Venere Hospital, February 2022)

the rotation of the femoral head and neck. The distal end of the nail consists of a 4-ray 30-mm "diapason", which offers gradual reduction in stiffness and reduces stress shielding (22).

Preoperative and postoperative x-rays as an example of the procedure are illustrated in Figure 3.

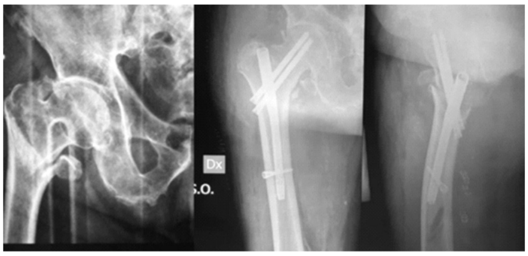

Figure 3. Preoperative and postoperative x-ray views of intertrochanteric femur nailing (Di Venere Hospital, 2022)

As a primary endpoint, the radiation exposure time was analysed to detect if computer-assisted navigation reduces the radiation risk for the patient and surgical team. The set-up time of operating room, surgical time and dose area product were assessed as a secondary endpoint.

Statistical analysis

Descriptive statistics were calculated for the overall sample and for follow-up. Categorical variables were presented as numbers or percentages. Continuous variables were presented as mean and standard deviation (SD). Due to the non-homogeneous distribution of the values using the Kolmogorov-Smirnov test ($p>0.05$), non-parametric tests were considered. To compare average values between the groups at the same times, the U Mann–Whitney test or Fischer's test were used, when appropriate.

RESULTS

One hundred consecutive patients who underwent intertrochanteric femur fractures were enrolled in this study and allocated into two groups, 20 patients in the study group and 80 patients in the control group. The study group mean age was 84.42±9.68 years with 13 (65%) females, and BMI of 22.38±4.84 kg/m^2. The control group was made up of 80 patients, mean age 83.48±9.23 years, 54 (67.5%) females, and BMI of 24.25±5.87 kg/m^2 (Table 1). No statistical differences emerged between the groups according to preoperative features.

Table 1. Characteristics of the study population

Variable	Study group (20 patients)	Control group (80 patients)	p
Age (mean±SD) (years)	84.42±9.68	83.48±9.23	0.53
Gender (female) (No; %)	13 (65)	54 (67.5)	0.51
BMI (mean±SD) (Kg/m2)	22.38±4.84	24.25±5.87	0.17
Side (left) (No; %)	9 (45)	41 (51.2)	0.80
Surgical time (minutes) (mean±SD)	38.67±4.12	40.19±3.26	0.12
Fracture classification (No; %)			0.60
31-A1	8 (40)	32 (40)	
31-A2	12 (60)	48 (60)	
ASA Classification	2.91±0.59	3.06±0.49	0.26

BMI, body mass index; ASA Classification, American Society of Anesthesiologists Classification

All the patients were treated within 48 hours after admission according to the Italian Society of Orthopaedics and Traumatology recommendation (23).

The study group had more set-up time of operating room (24.87±4.58) ($p<0.01$), less surgical time (26.15±5.80) ($p<0.01$), less time of radiant exposure (4.84±2.07) ($p<0.01$) and lower dose area product (16.26±2.91) ($p<0.01$) (Table 2).

Table 2. Differences in studied outcomes between the groups*

Outcome	Study group	Control group	p
STOR (minutes)	24.87±4.58	18.08±3.66	< 0.01
ST (minutes)	26.15±5.80	33.40±8.58	< 0.01
ETIR (seconds)	4.84±2.07	58.08±21.99	< 0.01
DAP (cGy·cm2)	16.26±2.91	149.58±55.60	< 0.01

*mean±SD
STOR, the set-up time of operating room; ST, surgical time; ETIR, radiation exposure time; DAP, dose area product

None of the patients experienced any skin complications. None of the patients needed revision surgery due to infection or mechanical complication in the early period. No intraoperative complication was recorded.

DISCUSSION

Over the past several years, an increasing number of intertrochanteric femur fractures has been reported with intramedullary fixation representing the gold standard treatment (24). The internal fixation with intramedullary nailing allows early mobilization and early weight-bearing of the patient due to the respecting the biology of the fracture (25, 26). Indeed, David et al. conducted a study comparing three different fixation methods in trochanteric fractures, finding higher inflammatory markers in a patient treated with dynamic hip screw (DHS) plate osteosynthesis despite the treatment of the patient with an intramedullary nail (27). Furthermore, Vitamin C also may have a key role in reducing the patient's inflammatory state (28). The fracture displacement, lack of fracture site direct visualization and unstable bare-handed operation can also make it difficult to select the trochanteric entry point (29,30). Repositioning the guide wire through repeated punctures can lead to the loss of fracture reduction (30), disruption of surrounding soft tissue structures and increased blood loss (31), although the use of intraoperative tranexamic acid may help in reducing bleeding (32). All these extra steps prolong the operation time, increase surgical complication rates and expose both surgeons and patient to more radiation (33). With the computer-assisted navigation system, internal fixation of the fracture can obtain the best surgical efficiency and accuracy, less surgical injury and reduction of radiation exposure (34). Although we demonstrated the set-up time of the operating room was higher in the study group due to the more complex preparation of surgical instrument, the guided system showed some advantages compared with conventional fluoroscopy-guided nails; the analysis conducted on the computer-assisted navigated procedure highlighted a statistically significant reduction of ETIR and DAP. These results were predictable because the only two fluoroscopy views were at the beginning of surgery. Hayda et al. reviewed a significant correlation between radiation exposure time, DAP and cancer or cataract risk in orthopaedic surgeons (35). This is in accordance with Matityhau et al. review identifying spinal surgery and intramedullary nailing as the procedure with the highest exposure to ionising radiation (36). We demonstrated the ATLAS nailing system significantly reduced the radiation exposure time of about 12-fold, and the DAP of about 9-fold if compared with control group. Interestingly, our results showed the highest DAP value recorded during EBA2 standard nail surgery is 205 cGy·cm2, whereas during the ATLAS implantation the maximum recorded DAP was 19 cGy·cm2; on the other hand, in the study group, set-up time was longer than standard procedures because of the installation of a sensor for each surgical instrument including C-Arm and the positioning of the viewer and display unit. Nevertheless, we assume that the set-up time may decrease over time as the surgeon and theatre operators gain experience, actually our last registered measurements were lower while the first were the highest.

We deliberately, included the first twenty records of each outcome in this preliminary study, avoiding biasing the results with a trial phase. The surgical time reduction within the study group reported by a single senior surgeon may be considered independent of operator's surgical skills. The mean EBA2 standard nail surgical time was higher than the ATLAS group in the present study. Similar results were found by Honl et al. which analysed how assisted navigation procedure was faster than the classic one (37). Furthermore, the navigated nailing system could have a key role in the residents' learning curve for intertrochanteric fractures intramedullary nailing (38). This system permits to avoid intra-operative technical mistakes and may provide real-time operative views and relative positioning of surgical instruments, thus better understanding the three-dimensional anatomy of the surgical procedure (39,40). Currently, we scheduled a study about the role of the ATLAS nailing system in orthopaedic residents' learning curves in order to fully understand the educational potential of this innovative surgical device.

This study has some limitations. The sample size was limited, and the groups were not homogeneous. Postoperative radiographic outcomes such as tip-apex distance or clinical scores at different follow ups were not evaluated.

On the other hand, we preliminarily presented a new computer-assisted navigation for intramedullary nailing never described before, which has proven effective and safe in the data observed. Furthermore, we reported the first twenty recorded measurements avoiding biasing due to a pilot phase, demonstrating the system reproducibility, and also we performed a rigorous method of patient selection with inclusion/exclusion criteria. Our results should be confirmed by a large sample size-controlled study.

Further studies will be necessary to assess the accuracy of the surgical procedure taking into account objective parameters such as tip-apex distance or tip-to-head-surface distance.

In conclusion, despite the small study group, the present preliminary study highlights a reduction in surgical time, exposure time to ionizing radiation and reduction of dose area product. The ATLAS system reduces the time lost in searching for the correct positioning of the device and improves implantation accuracy. In contrast, the assisted procedure requires more set-up time of operating room. The ATLAS system is a simple, intuitive and innovative surgical device that can revolutionise the management of intertrochanteric femoral fractures in the future. Furthermore, cost analysis is necessary to evaluate the feasibility of the computer-guided procedure and its impact on patient outcomes compared to the standard surgery.

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TRANSPARENCY DECLARATION

Competing interests: None to declare.

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