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Computer-assisted navigation in intramedullary nailing of intertrochanteric femoral fractures treated with EBA2 nailing system: a single center retrospective study

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Summary

Aim. This study aims to present a single-center experience with the ATLAS system, a new computer-assisted navigation system for intramedullary nailing of intertrochanteric femoral fractures. We compare its effectiveness with the standard nailing technique.

Methods. A retrospective analysis was conducted at the Orthoaedic and Traumatology Department of San Bortolo Hospital in Vicenza (Italy), focusing on the use of the ATLAS system (Masmec Biomed, Modugno, Bari, Italy) in treating intertrochanteric fractures with the EBA2 nail (Citieffe, Calderara di Reno, Bologna, Italy). Between September 2021 and March 2022, 9 patients were treated using the ATLAS system (ATLAS group), and were compared with 9 patients treated with the standard EBA2 nail system in 2021 (control group). All patients in both groups had intertrochanteric femur fractures classified as type 31-A1 and 31-A2 according to the AO/OTA classification system. The data collected included the setup time of the operating room (STOR; minutes), surgical time (ST; minutes), radiation exposure time (ETIR; seconds), dose area product (DAP; cGy·cm2), presence of a senior surgeon *versus* a surgeon in training, 6-month survival rates and complications.

Results. Patients who underwent femoral nailing using the ATLAS system experienced longer setup time in the operating room (27.22 minutes) and longer surgical time (58.22 minutes) compared to the standard technique. However, they had reduced radiation exposure time (27.44 seconds) and lower dose area product (1148.67 cGy*cm^2). Additionally, in the ATLAS group, shorter surgical times were observed when the procedure was performed by a resident surgeon and fewer complications were reported. No deaths were recorded in the first 6 months.

Conclusions. The preliminary findings from our study indicate that the ATLAS system allows for improved standardization of surgical technique, a significant reduction in radiation exposure, enhanced accuracy in implant positioning, reduced learning curve, and decreased complications. However, it should be noted that the use of the ATLAS system has a longer setup time in the operating room and increased surgical duration, which could be reduced if this technique becomes routine.

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

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Introduction

Intertrochanteric fractures represent the most frequent fractures in the elderly that an orthopedic surgeon may encounter in daily practice, in fact, these fractures occur more frequently than those involving the wrist or shoulder [1]. These fractures predominantly affect elderly people (> 65 years old) and their management is further complicated by the presence of comorbidities, such as osteoporosis [2]. Obesity also represents an important risk for fractures due to metabolic factors and increased risk of falls [3]. Due to the biomechanical advantages and soft tissue preservation, intramedullary nailing has proven to be the most widely used device in the treatment of this type of fracture [4]. Bone healing, early mobilization, and early weight bearing are the main goals of surgery [5]. In recent years, there has been a growing demand for less invasive and expedited surgical procedures to minimize patient discomfort and reduce recovery time. Additionally, concerns regarding the potential adverse effects of radiation exposure have prompted the development and advancement of computer-assisted surgery techniques, which have found applications across various medical fields [4,6]. The development of computer-assisted surgery enabled real-time three-dimensional (3D) reconstruction and tracking of surgical instruments and devices within the surgical field, bringing significant transformation in several surgical procedures, enhancing surgical precision, improving outcomes and expanding the possibilities of minimally invasive approaches [7,8]. Computer-assisted navigation systems have been successfully used in several orthopedic surgical procedures, including spinal surgery [9] and total hip/knee replacement [10]. It has also been employed in some surgical procedures for trauma, i.e. percutaneous screw implant for medial femoral neck fractures [11,12], acetabular fractures [13] and distal locking of long nails in the femur, humerus, and tibia. Recently, two studies by Caiaffa et al. and Coviello et al. [14,15] described the use of the ATLAS System in intramedullary nailing for intertrochanteric femoral fractures. Building upon this research, the objective of this study is to provide a description of a single-center experience (San Bortolo Hospital, Vicenza, Italy) with the utilization of the ATLAS System and to compare outcomes of the ATLAS System with the traditional intramedullary nailing system guided by fluoroscopy in terms of operative time, radiation exposure, surgical outcomes, and surgeon's learning curve. By examining these parameters, this study aims to contribute valuable insights into the potential benefits and effectiveness of the ATLAS System compared to conventional techniques in the treatment of intertrochanteric femoral fractures.

Materials and methods

This was a retrospective, single-center comparative study. We used as a model the study of Coviello et al. [15] to be able to compare the results in further studies.

The study included patients with 31-A1 and 31-A2 fractures, according to the OTA/AO classification system [16], who were hospitalized at the San Bortolo Hospital of Vicenza and underwent anteroposterior and axial hip x-rays before surgery. The surgical procedures were performed within 48 hours after admission according to recommendations of the Italian Society of Orthopedics and Traumatology.

The only exclusion criterion was cases in which the fracture required open reduction.

Prior to surgery, all patients provided informed written consent. In all surgical procedures, the EBA2 intramedullary nail (Citieffe, Calderara di Reno, Bologna, Italy) nail was implanted. The operating room staff varied for each procedure, and patients were treated by both senior surgeons and residents.

The ATLAS system (Masmec Biomed, Modugno, Bari, Italy) is a computer-assisted navigation for intramedullary nailing. The surgical steps are the same as those of the standard technique, but does not require fluoroscopy, and it needs only two radioscopic images (AP and axial view) acquired after reduction maneuvers. The ATLAS system is composed of an infrared ray emitter and receiver, sensors that reflect infrared rays affixed on the surgical instruments, and a computer that elaborates data acquired by infrared rays, which locates the patient and surgical instruments in space, and give a coherent image on a display [15].

We analyzed all cases treated with the ATLAS system, and thus the the initial learning curve of medical staff must be considered.

We treated 9 patients with intertrochanteric femoral fractures with the ATLAS system between September 2021 and March 2022 (ATLAS group). Additionally, we randomly selected 9 cases treated in 2021 with the standard (fluoroscopy guided) technique using the EBA2 nail (control group).

The data assessed in this study were: patient age; setup time of the operating room (STOR; minutes), which refers to the time it takes to prepare the surgical environment before a procedure begins and includes tasks such as arranging surgical instruments, positioning the patient and ensuring the availability of necessary supplies; surgical time (ST; minutes), which refers to the duration of the actual surgical procedure from the initial incision to wound closure and includes all the necessary steps involved in the surgical intervention to exposure to closure; radiation exposure time (ETIR; seconds), which refers to the length of time during which a patient is exposed to ionizing radiation during a specific procedure; dose area product (DAP; $cGy \cdot cm^2$), which is a measure of the total amount of radiation delivered to a specific area of the patient's body during a radiological procedure and provides valuable information regarding the cumulative radiation exposure experienced by the patient; the execution of the procedure by a senior surgeon versus the execution by a surgeon in training, allowing for an evaluation of the impact of experience and skill level on surgical results; 6-month survival rates, providing valuable information about

the overall impact and success of the intervention; complications, especially postoperative infections, wound dehiscence, implant failure, and peri-implant fractures.
All data were collected and analyzed using Excel.
For the statistical analysis we used Student's T test and compared STOR, ST, ETIR, DAP in both groups.

Results

Eighteen patients were enrolled in this study, 9 in the ATLAS group and 9 in the control group.
The mean age was 81.2 years (range 75-90) in the ATLAS group and 87.0 years (range 81-95) in the control group.
ATLAS had a mean set-up time of the operating room (STOR) of 28.11 minutes (range 8-65), which was higher than that of the control group, corresponding to 24.67 minutes (range 10-38) (p-value > 0.05). We also recorded higher mean surgical time (ST) in the ATLAS group, which was 58.22 minutes (range 42-80) *vs* 49.44 minutes (range 20-95) for the control group (p-value > 0.05). On the other hand, there was a lower mean exposure time to ionizing radiation (ETIR) in the ATLAS group, 27.44 seconds (range 11-59) *vs* 76 seconds (range: 39-213) for the control group (p-value < 0.05) and a lower mean dose area product (DAP): 1148.67 cGy*cm^2 (range: 161-3460) in the ATLAS group *vs* 3663.67 cGy*cm^2 (range: 947.3-14860) in the control group (p-value > 0.05) (Tabs. I-II).
In both groups 4 of 9 cases were treated by residents (44%). It is important to consider that the mean surgical time of residents in the ATLAS group was considerably lower than the senior surgeon's mean surgical time (50.5 min *vs* 64.4 min), while in in the control group a reversal of this trend can be observed (58.25 min *vs* 42.4 min).
W did not observe any decease within the first 6 months in either group.
Regarding complications, in the ATLAS group, there were 2 cases of postoperative complications: a peri-implant fracture that required a revision of the internal fixation using a long intramedullary nail (Figs. 1-3) and a malunion due to a malpositioning of the nail that did not need any further treatment. In the control group we noted complications in 3 cases: two malunions with a varus displacement at 6 months which did not require any treatment and one infected pseudoarthrosis which needed removal of the infected implant (Figs. 4-7).

Table I. ATLAS group results.

	Age	STOR	ST	ETIR	DAP
1	81.00	65	55	20	574
2	76.00	40	40	11	161
3	86.00	40	65	28	1580
4	90.00	28	65	33	178
5	83.00	26	42	17	742
6	76.00	26	52	15	685
7	75.00	10	65	24	918
8	86.00	10	60	40	2040
9	78.00	8	80	59	3460
Mean	**81.22**	**28.11111**	**58.22222**	**27.44444**	**1148.667**

STOR: set-up time of the operating room, ST: surgical time, ETIR: Exposure time to ionizing radiation, DAP: Dose area product.

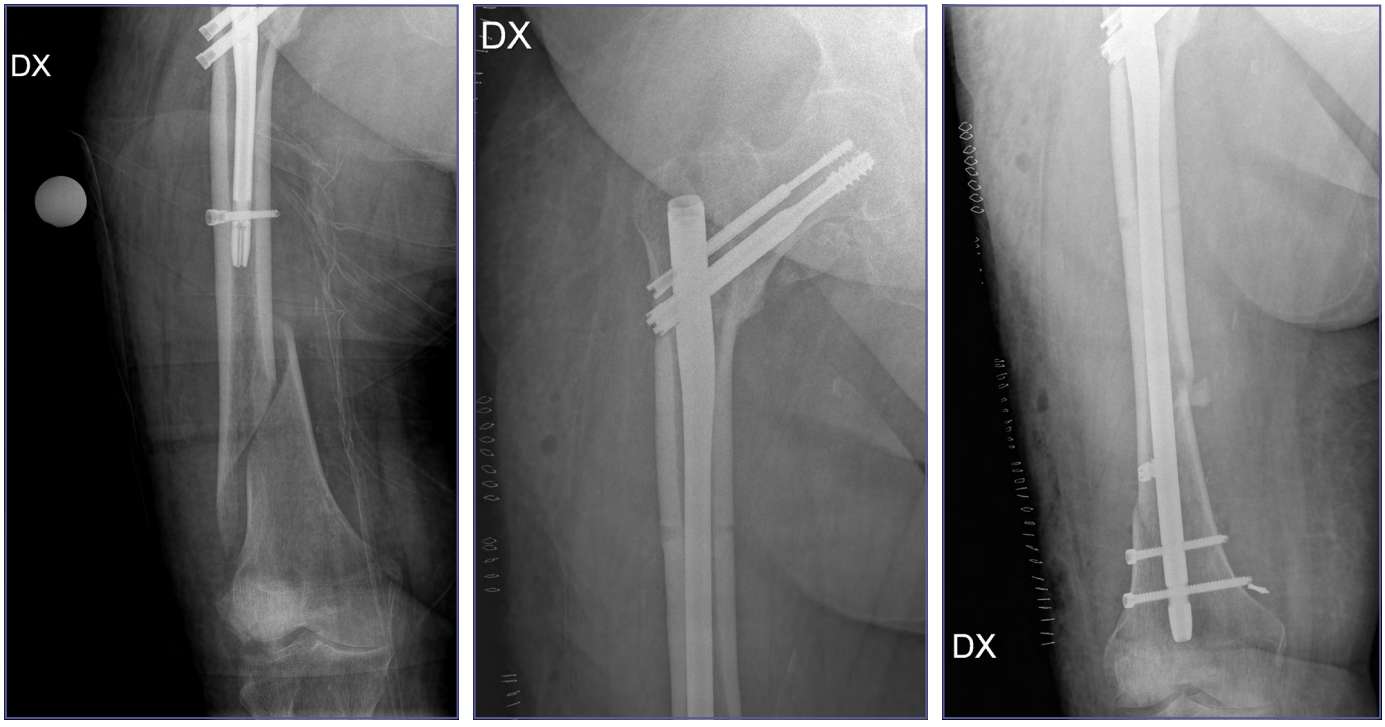
Table II. Control group results.

	Age	STOR	ST	ETIR	DAP
1	87.00	25	50	45	1660
2	95.00	24	95	213	14860
3	80.00	23	20	39	947.3
4	86.00	20	55	106	4250
5	95.00	38	47	66	4040
6	81.00	27	33	54	1914.3
7	83.00	35	55	60	1789.2
8	95.00	20	50	59	2361.1
9	81.00	10	40	42	1151.1
Mean	**87.00**	**24.66667**	**49.44444**	**76**	**3663.667**

STOR: set-up time of the operating room, ST: surgical time, ETIR: Exposure time to ionizing radiation, DAP: Dose area product.

Discussion

The present study shows the ATLAS system has some advantages compared with conventional fluoroscopy-guided nailing. In terms of operative time, the ATLAS group had a longer set-up time of the operating room (STOR) compared to the control group: this can be attributed to the additional time required for the preparation and setup of the ATLAS system, which includes the real-time three-dimensional (3D) reconstruction and tracking of surgical instruments within the surgical field and the inexperience of the operating room staff due to the small number cases treated with this method in our department. The ATLAS group also exhibited a significantly higher mean surgical time (ST) compared to the control group. This may be caused by various factors, such as the learning curve associated with implementing the ATLAS system and the additional steps involved in utilizing computer-assisted surgery. In contrast, Caiaffa et.al and Coviello et al. [14,15] obtained lower surgical times with ATLAS, which could be explained by their greater experience with this system for the single surgeon. We believe that both STOR and ST could be considerably decreased over



Figures 1-3. Complication in the ATLAS group - Peri-implant fracture (PIF) occurred 6 months after the trauma (Fig. 1); the patient was hospitalized for the removal of the short nail and fracture stabilization with a long nail and a cerclage in polyethylene (Figs. 2-3).

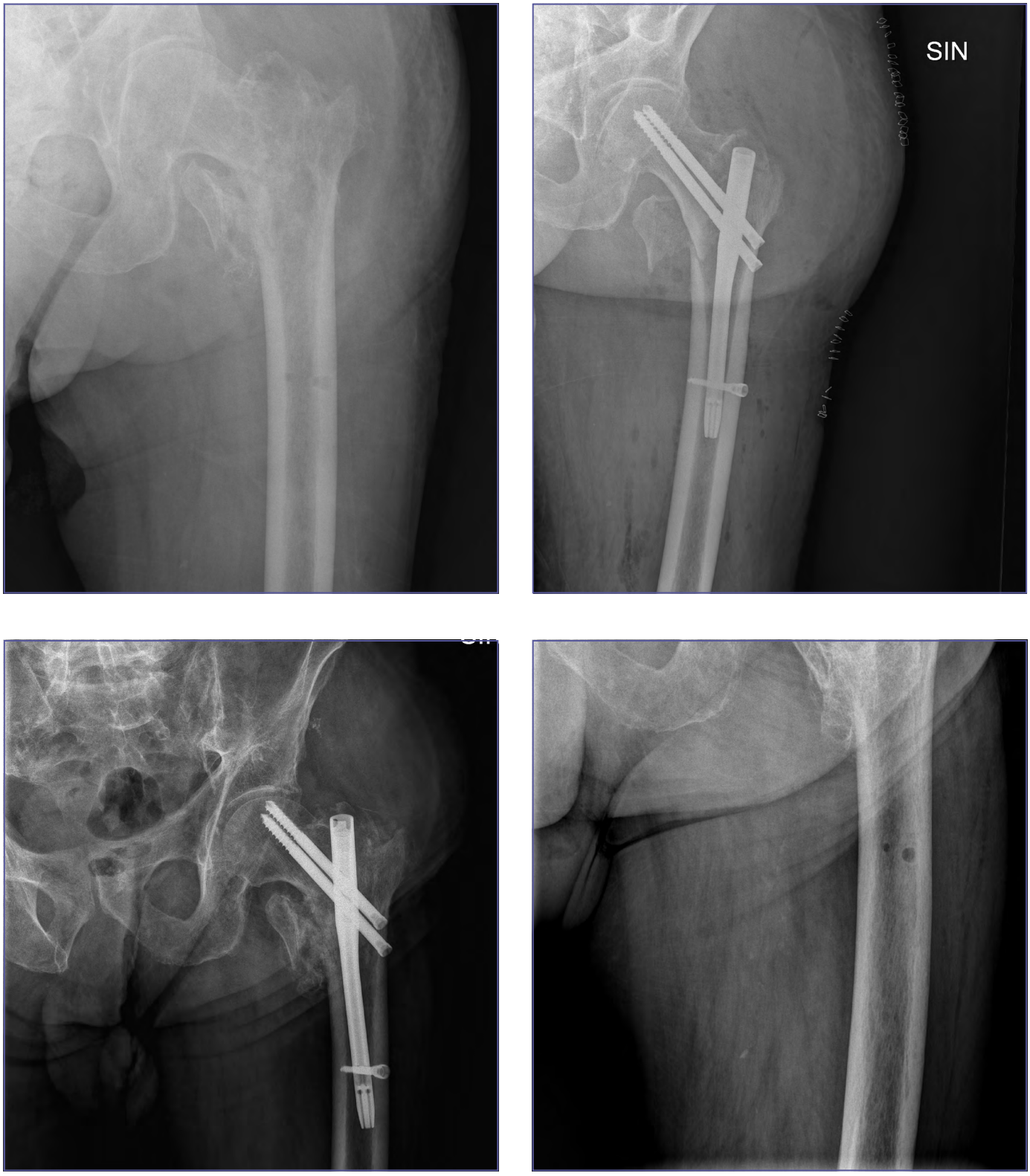
time as the surgeons and the operating room staff gain experience.

One noteworthy advantage of the ATLAS system was the reduction in radiation exposure time (ETIR) and dose area product (DAP) compared to the control group. The ATLAS system's ability to provide real-time 3D navigation and tracking of surgical instruments allowed for more precise and efficient implant placement, potentially minimizing the need for repeated scopies and reducing overall radiation exposure. This is particularly crucial, considering the potential adverse effects of radiation exposure on patients and healthcare professionals. In fact, Hayda et al. [17] and Matityhau et al. [18] highlighted a significant correlation between ETIR and DAP and cancer or cataract risk in orthopedic surgeons. It is important to underline that the only statistically significant result is that concerning ETIR.

An important aspect in this study was the experience and skill level of the surgical team, specifically comparing procedures performed by senior surgeons versus those performed by surgeons in training. Interestingly, in the ATLAS group the mean surgical time for residents was lower than that of senior surgeons, suggesting that the ATLAS system may have a more efficient surgical process for less-experienced surgeons, while the orthopedic surgeon's experience plays a crucial role during traditional intertrochanteric nailing. Several studies have shown that the success of a computer-assisted navigated surgical procedure is independent of the surgeon's experience and skill level as seen in our results [19,20]. It is notable that the ATLAS system could have a key role in the residents' learning curve for intramedullary nailing of stable intertrochanteric fractures (AO 31.A1 and 31.A2) [21], because this computer-assisted navigation system allows memorization of all surgical steps, thus avoiding intra-operative technical mistakes and complications. The 3D experience is also useful for the proper positioning of the nail from the entry level to the position of the screws in the femoral neck and their length, all characteristics that could significantly improve the patient outcomes.

Patient survival rates at 6 months were the same in the ATLAS and control groups.

The ATLAS group had a lower incidence of complications compared to the control group, which could be correlated with better positioning of the implant. In the ATLAS group one patient experienced a peri-implant fracture that necessitated a revision surgery that consisted in the removal of the short EBA2 nail and the implant of a long nail and a polyethylene cerclage to stabilize the fracture and a malunion; due to malpositioning of the nail which did not lead to clinical symptoms or hip ROM reduction to the patient we did not proceed with further treatment (Figs. 1-3). On the other hand, the control group had a higher complication rate, including two malunions with a varus displacement at 6 months which did not need treatment due to



Figures 4-7. Complication in the Control group – Post-op X-Ray showed a good reduction (Fig. 4); infected pseudarthrosis which became evident 1 month after the orthopedic procedure (Fig. 5); the patient underwent was treated with antibiotics and VAC therapy for 6 months in an attempt to reach fracture union – Once the fracture healed the nail was removed (Fig. 6); X-Ray 6 months from the nail removal (Fig. 7).

the advanced age of the patients, but there is the risk of a future implant failure. There was also one case of infected pseudoarthrosis with wound dehiscence which needed an initial treatment with intravenous antibiotic therapy and vacuum-assisted closure therapy for 6 months. Once the fracture healing was complete we removed the infected implant, allowing for complete healing with good clinical results (Figs. 4-7).

It is essential to consider the retrospective fashion and the limited sample size in this study and the potential influence of confounding factors such as patient age, sex, comorbidities, and other individual characteristics that may have contributed to the differences between groups. Moreover, we did not consider other perioperative complications such as blood loss or pulmonary infections that could be important in changing the patient's outcome. Further studies with larger sample sizes and rigorous controls are warranted to validate these findings.

Conclusions

Despite the limitations of a small sample size and limited experience with navigation, our study highlights the significant benefits of the ATLAS system in the management of intertrochanteric fractures. We found that navigation significantly reduces radiation exposure time (ETIR) and the dose area product (DAP), thereby prioritizing patient safety. Furthermore, the ATLAS system allows for standardized surgical techniques and improves the accuracy of implant positioning, enhancing overall surgical outcomes and accelerating the learning curve for residents. However, it is important to note that the implementation of the ATLAS system comes with increased costs and requires additional time for setup in the operating room, but this was also due to our team's unfamiliarity with the new setup. With increased familiarity and training, we can anticipate that setup time will decrease, making the ATLAS system more efficient in routine practice. The ATLAS system represents a promising and innovative surgical device, offering simplicity and intuitive usability. We envision that its integration into clinical practice has the potential to revolutionize the management of intertrochanteric femoral fractures in the future.

It is crucial to mention that further studies with larger sample sizes are necessary to comprehensively evaluate the accuracy and explore the full potential of the ATLAS system and to gain statistically significant results.

Conflict of interest statement

The authors declare no conflict of interest.

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Author contributions

All the authors contributed equally to this work; MR, CZ, SG: designed the research; JA: analysed the data; SG, NE, MC, CZ: wrote the paper; AM, JA: contributed to manuscript revision; all authors approved the final version of the manuscript.

Ethical consideration

All procedures in the study and involving humans were implemented in accordance with the ethical standards established by the Helsinki Clarification of 1975 and subsequent amendments. Informed consent was obtained from all patients included in the study.

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