Lo SCALPELLO (2020) 34:154-159
doi number: 10.36149/0390-5276-186

The role of computer-assisted navigation in intramedullary nailing of pertrochanteric fractures: a prospective multicentre comparative study between EBA2 standard and EBA NAV nails

Vincenzo Caiaffa[1], Andrea Leone[2], Mario Manca[3], Alberto Momoli[4], Biagio Moretti[5]

[1] Orthopaedic &Trauma Unit, Di Venere Hospital, Bari, Italy; [2] Orthopaedic &Trauma Unit, Delle Murge Hospital, Altamura (BA), Italy; [3] Orthopaedic &Trauma Unit, Versilia Camaiore Hospital, Lido di Camaiore (LU), Italy; [4] Orthopaedic &Trauma Unit, San Bortolo Hospital, Vicenza, Italy; [5] Orthopaedic &Trauma Unit, School of Medicine, University of Bari "Aldo Moro", AOU Policlinico Consorziale, Department of Basic Medical Sciences, Neuroscience and Sense Organs, Bari, Italy

Received: October 25, 2020
Accepted: December 1, 2020

Correspondence
Andrea Leone
Orthopaedic &Trauma Unit, Delle Murge Hospital, Strada Statale 96 per Gravina in Puglia, km 74, 800, 70022 Altamura (BA), Italy
E-mail: andrea.leone@asl.bari.it

Conflict of interest
The Authors declare no conflict of interest

How to cite this article: Caiaffa V, Leone A, Manca M, et al. The role of computer-assisted navigation in intramedullary nailing of pertrochanteric fractures: a prospective multicentre comparative study between EBA 2 standard and EBA NAV nails. Lo Scalpello Journal 2020;34:154-9. https://doi.org/10.36149/0390-5276-186

Summary

Background. Computer-assisted navigation surgery has been gaining increasing importance in several orthopaedic fields in the last decade. However, none of the previous studies has described a navigated system in the intramedullary nailing of pertrochanteric femoral fractures.

This prospective comparative study aims to compare, for the first time, a navigated pertrochanteric intramedullary nailing system (EBA NAV) to a traditional cephalo-medullary nail (EBA2).

Materials and methods. 100 patients with 31-A1 or 31-A2 pertrochanteric femoral fractures were recruited from January to September 2020. Twenty patients were managed using the EBA-NAV system, whereas 80 patients were treated using a traditional cephalomedullary nail (EBA2) implanted under fluoroscopic guidance.

The set-up time of the operating room (ST-OR), surgical time, exposure time to ionising radiation and the dose area product (DAP) were compared in the two groups.

Results. Although the ST-OR was longer in patients managed with EBA NAV compared with EBA2 system, shorter surgical time and radiation exposure time was observed during EBA NAV surgery. Furthermore, significant DAP reduction was observed during the EBA NAV procedure.

Conclusions. This preliminary study shows that EBA NAV navigated pertrochanteric intramedullary nail allows standardisation of the surgical technique, regardless of the surgeon's experience, and significantly reduces exposure to ionising radiation, both in terms of time and DAP. EBA NAV could also play a key role in improving the learning curve of residents.

Key words: computer-assisted navigation surgery, intramedullary nail, pertrochanteric femoral fractures, ionising radiation, navigated nail

Introduction

Over the years, minimally invasive surgery has gained increased popularity in daily orthopaedic clinical practice thanks to the development of imaging technology.

Most fractures require the intraoperative reconstruction of axis, rotation and length; all these outcomes can be achieved by using traditional fluoroscopy and anatomic landmarks.

In recent years, the development of computer-assisted surgery, allowing real-time three-dimensional(3D) reconstruction and tracking of surgical instruments and devices within a surgical field [1], has revolutionised several surgical procedures.

Two adjectives, i.e. real and virtual, can easily summarise the innovation provided by a navigation system. The fractured patient, surgeon and navigated device are real. The navigated system, on the other hand, thanks to sensors, virtually reproduces the three-dimensional spatial location of the device.

Computer-assisted navigation systems have been successfully used in several orthopaedic surgical procedures, including spine [2] and total hip/knee replacement [3]. It has been also studied in some trauma surgical procedures, i.e. percutaneous screw implant for medial femoral neck fractures [4] and acetabular fractures.

However, none of the previous studies has described a navigated system in the intramedullary nailing of pertrochanteric femoral fractures. Therefore, thanks to the cooperation between the DiVenere Hospital Orthopaedic team (Bari) and Citieffe and Masmec Biomed, a navigated pertrochanteric intramedullary nail, the Endovis Bio Advanced NAVigator (EBA NAV) system, was developed. Citieffe, the society that introduced the EBA nail system, applied variations of the nail adapting sensors to the device; Masmec supplied the viewer, the processing and display unit.

This study aims to describe the EBA-NAV intramedullary nail and compare it with traditional intramedullary nail guided by fluoroscopy (EBA2), in terms of operative time and radiation exposure.

Materials and methods

Patients

This was a prospective multicentric comparative study. We selected 100 patients with pertrochanteric femoral fractures. The mean age was 86 years (range: 66-102).

Inclusion criteria were: 1) 31-A1 fractures 2)31-A2 fractures according to the OTA/AO classification [5]).

The only exclusion criterion was pertrochanteric femoral fractures needing open reduction.

All patients underwent anteroposterior and axial hip x-rays before surgery and underwent surgery within 48 hours from trauma. All patients gave informed written consent before surgery.

In all surgical procedures, the EBA intramedullary nail (Citieffe) nail was used, but two different systems were employed:

- the EBA2 standard nail was implanted, under fluoroscopic guidance, in 80 patients, from January to July 2020;
- the EBA-NAV computer-assisted navigation system was used in 20 patients, from May to September 2020.

Surgical technique

EBA2 standard nail [6]:

1. The patient is positioned supine on a radiolucent table, with the affected limb placed on a leg holder. The contralateral hip and knee are flexed at 90° to facilitate the use of the image intensifier. The trunk is turned 20-30° towards the healthy limb;
2. The fracture is reduced in the best possible way, with moderate traction against a well-padded perineal post, adduction and internal rotation if necessary;
3. The skin incision is about 4 cm extending proximally from the apex of the greater trochanter;
4. Insert the trochanteric drill, on the apex of the greater trochanter, and ream it;
5. Insert the wire in the medullary canal through the trochanteric drill;
6. Insert the nail through the wire;
7. Check correct positioning of the nail;
8. Insert the guidewire for the distal cephalic screw and check that it is correctly positioned (a-p and axial);
9. Check the screw length;
10. Perforate the lateral cortex and insert the proximal cephalic screw;
11. Perforate the lateral cortex and insert the distal cephalic screw;
12. Insert the distal block screw if necessary.

All these steps (except for the first) require fluoroscopy.

EBA NAV nail

The EBA-NAV has the same surgical steps of the EBA2 standard, but does not require fluoroscopy, except for the step 2. Hence, the navigation system scans the two radiographic images acquired after reduction (i.e., anteroposterior and axial hip views).

The EBA NAV system is composed of a viewer (i.e., an infrared rays 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 (Fig. 2), patient (Fig. 3) and C-ARM (Fig. 4).

The system uses infrared rays to visualise the patient and surgical instruments in space. The processing unit uses the fluoroscopic images acquired after the reduction (step 2) to navigate the subsequent surgical steps.

Parameters

The following outcomes were recorded and compared in the two groups: 1) the set-up time of operating room (STOR); 2)

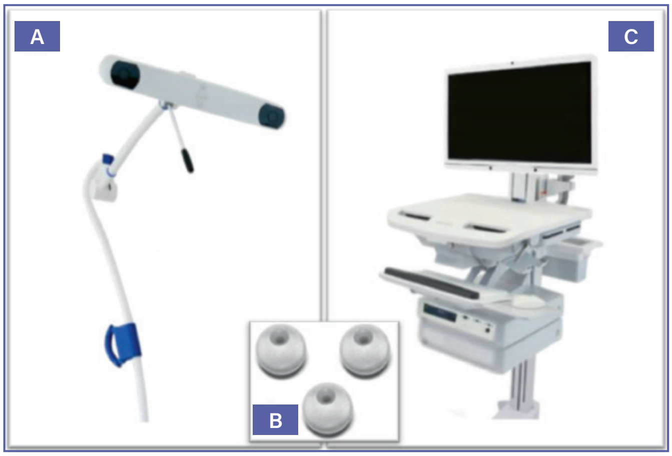

Figure 1. a. viewer; b. sensors; c. processing unit.

surgical time (ST); 3) radiation exposure time (ETIR); 4) dose area product (DAP).
For statistical purposes, the first 10 EBA-NAV nail data were not analysed, since we considered the initial learning curve of the surgical and engineering teams, as well as the technical improvements of the system.
All the data were collected and analysed with Excel.

Results

The set-up time of operating room (STOR)

The mean STOR was 20.2 minutes (range: 14-32) for EBA2 standard nail and 27 minutes for EBA NAV (range: 25-30) (Tables I-II).

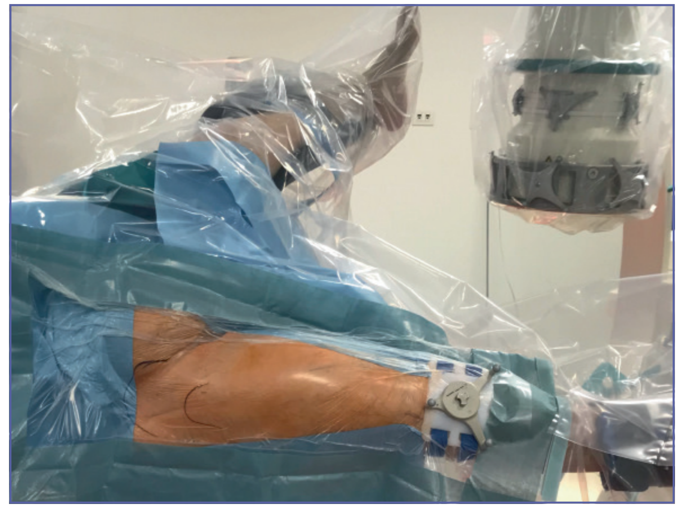

Figure 3. Specific sensors' supports for patient.

Surgical time (ST)

The mean surgical time was 35.3 minutes (range: 16-90) for EBA2 nail and 26 minutes (range: 20-30) for EBA NAV.

Exposure time to ionizing radiation (ETIR)

The mean ETIR was 53.5 seconds (range: 25-140) for EBA2 standard and 4.2 seconds for EBA NAV (range: 3-5).

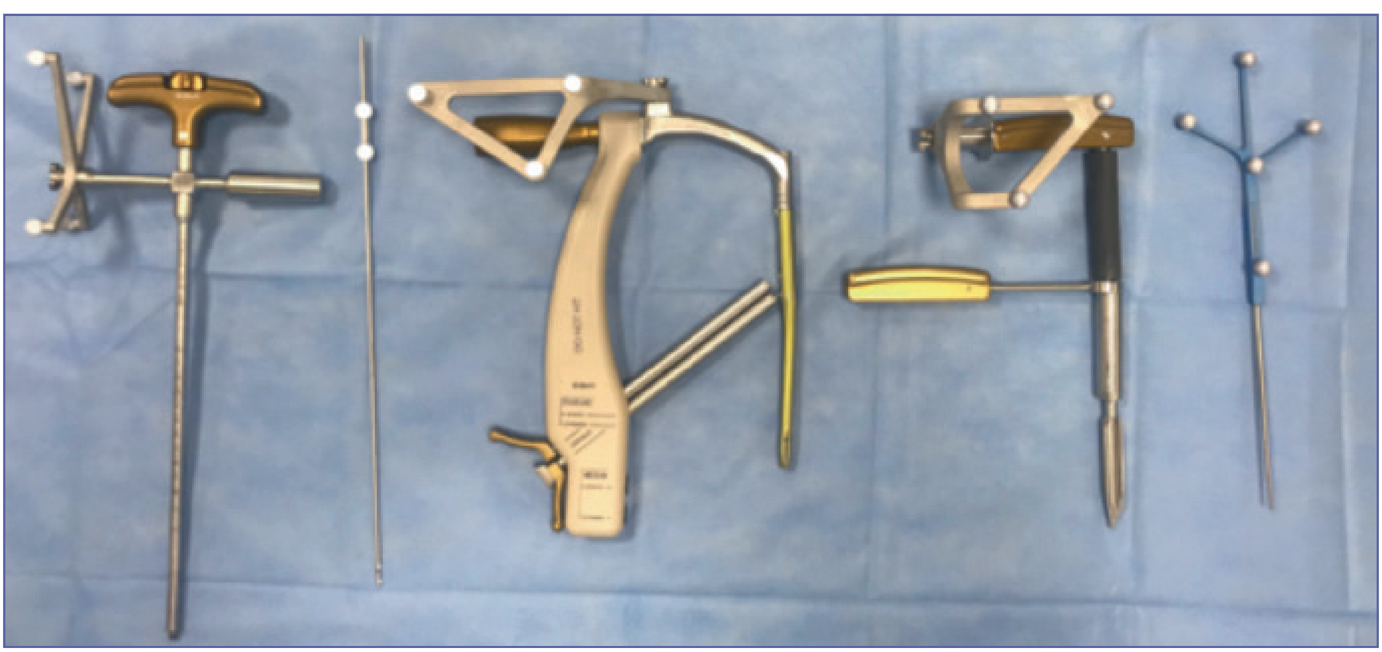

Figure 2. Specific sensors' supports for each instrument.

Figure 4. Specific sensors' supports for C-ARM.

Dose area product (DAP)

The mean DAP was 140.1 cGy*cm^2 (range: 50-305) for EBA2 standard and 16.6 cGy*cm^2 (range: 12-20) for EBA NAV.

Discussion

The purpose of a surgical device system is to help the surgeon achieve the desired surgical plan in a shorter surgical time and without risks for either the patient or surgeon.

The intramedullary nailing of pertrochanteric femoral fractures is successful when the intramedullary nail is correctly implanted, thus maintaining the fracture reduction and fixation and, at the same time, a short time of radiation exposure [7].

The present study shows the EBA NAV system has some advantages compared with conventional fluoroscopy-guided nails. Although the set-up time of the operating room was higher in EBA NAV surgical procedure, because of the more complex preparation of surgical instruments, the computer-assisted navigated procedure showed shorter radiation exposure time and DAP. These findings highlight a significant risk reduction for patient and surgical team.

Hayda et al. [8], in a review, highlighted a significant correlation between radiation exposure time, DAP and cancer or cataract risk in orthopaedic surgeons. According to the literature, surgeons should continue following the principle of *as low as reasonably achievable* to minimise occupational radiation exposure.

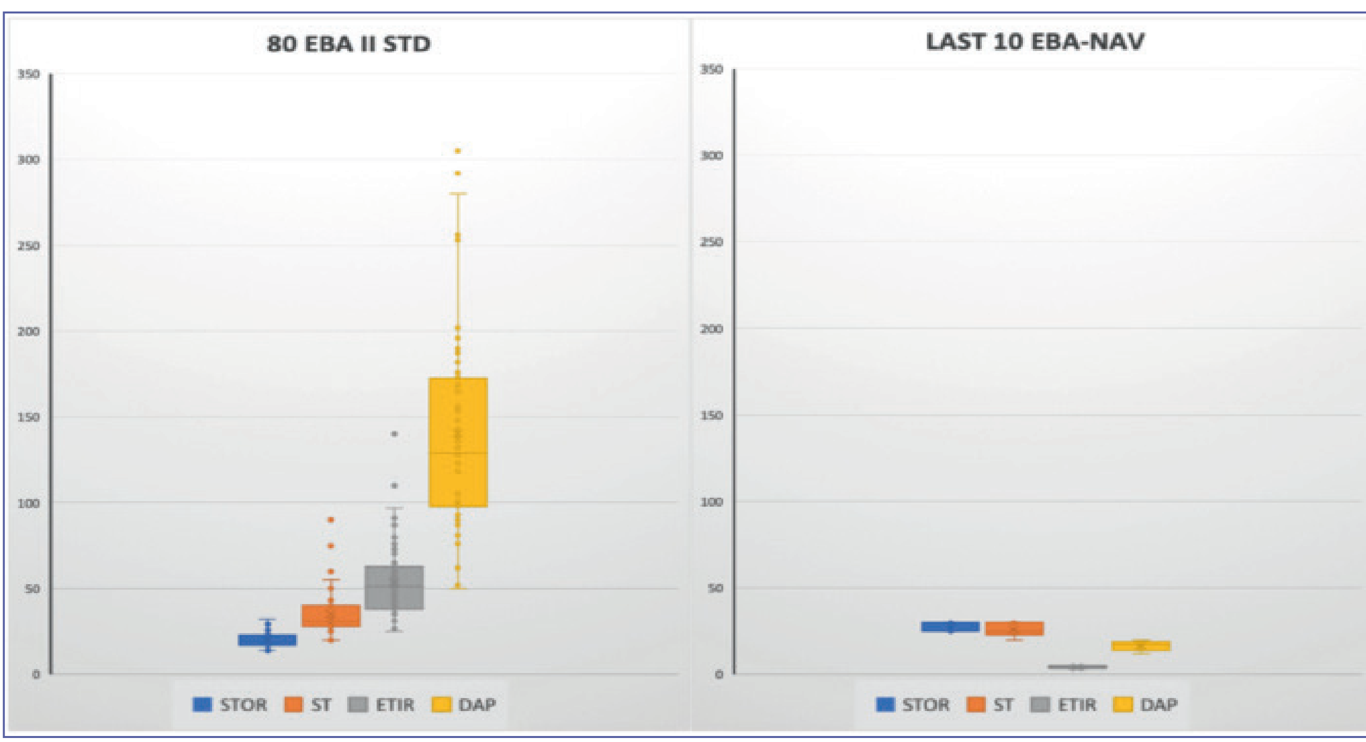

Figure 5. Comparison of data's distribution.

Table I. EBA2 Standard (STD) data.

80 EBA2 STD	AVERAGE	MIN	MAX
Set-up time of operating room (minutes)	20.2	14	32
Surgical time (minutes)	35.3	16	90
Exposure time to ionizing radiation (seconds)	53.5	25	140
Dose area product (cGy*cm^2)	140.1	50	305

Table II. EBA-NAV, last 10 data.

LAST 10 EBA-NAV	AVERAGE	MIN	MAX
The set-up time of operating room (minutes)	27	25	30
Surgical time (minutes)	26	20	30
Exposure time to ionizing radiation (seconds)	4.2	3	5
Dose area product (cGy*cm^2)	16.6	12	20

The EBA NAV nailing system significantly reduced the radiation exposure time of about 12-fold, and the DAP of about 8-fold. Interestingly, the highest DAP value recorded during EBA2 standard nail surgery is 305 cGy*cm^2, whereas during the EBA NAV implantation the maximum recorded DAP was 20 cGy*cm^2 (Fig. 5).

This study also demonstrates that the EBA NAV system provides a reduction in surgical time. Even if an experienced surgeon can obtain a shorter surgical time with EBA2 standard nail, compared with EBA NAV (the least recorded value was 16 minutes), the mean EBA2 standard nail surgical time was

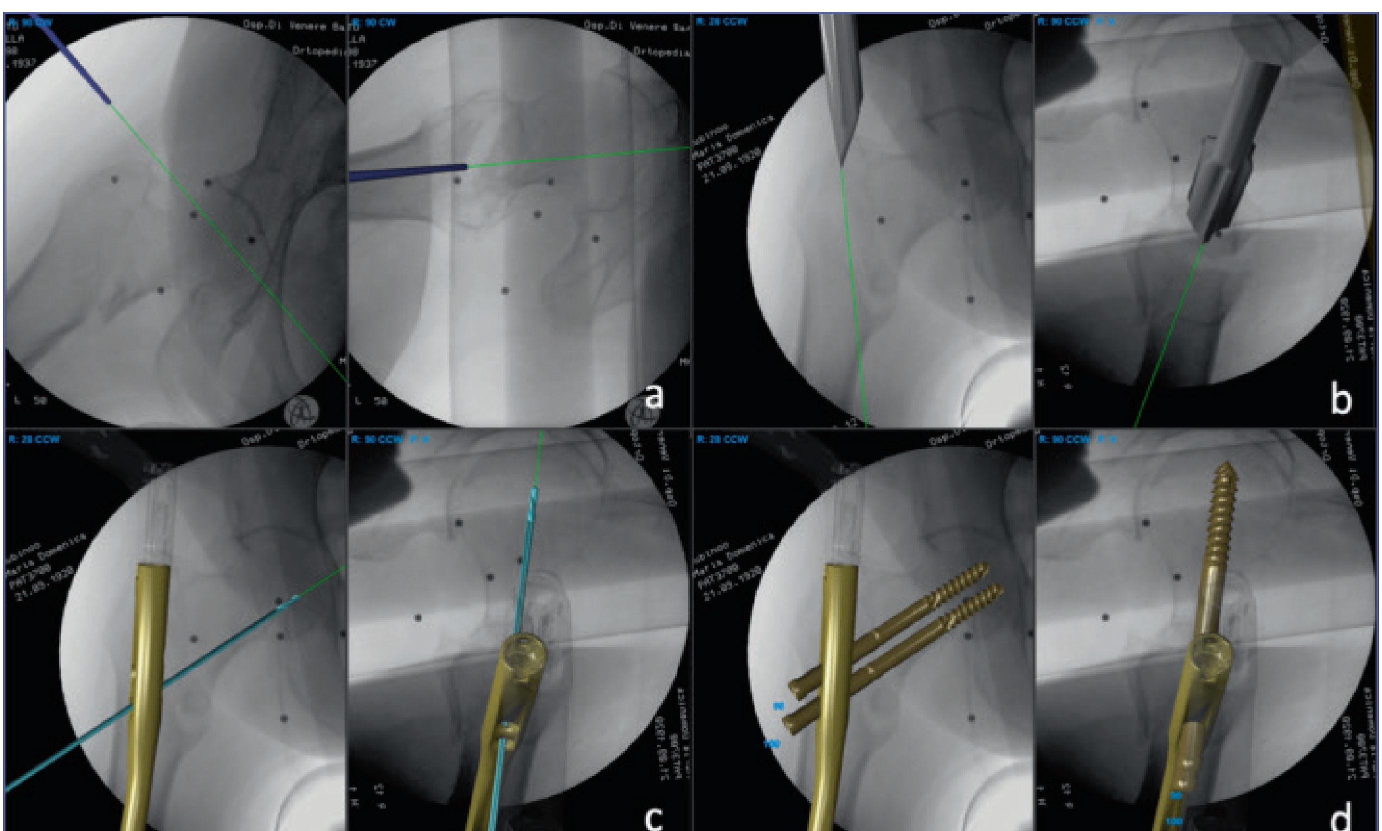

Figure 6. a. skin incision; b. entry point; c. nail and K-wire's position; d. Screw's position.

higher than the EBA NAV in the present study. The orthopaedic surgeon's experience plays a crucial role during traditional pertrochanteric nailing, whereas the navigation system standardises surgical time, regardless of the surgeon's skill level. Several studies have shown that the success of a computer-assisted navigated surgical procedure is independent of the surgeon's experience and skill level [9].

It is important to note the EBA NAV nailing system could have a key role in the residents' learning curve for intramedullary nailing of stable pertrochanteric fractures. Therefore, this computer-assisted navigated system allows memorisation of all surgical steps, thus avoiding intraoperative technical mistakes and complications. This leads to a reduction in surgical time, optimization of the surgical technique and, consequently, to a better functional outcome. The 3D experience acquired by the resident during the use of the EBA NAV nailing system can also be useful when he/she will start to use a traditional, fluoroscopy-guided, pertrochanteric nailing system.

Future studies will better investigate the role of EBA NAV nailing system in orthopaedic residents' learning curves, in order to fully understand the educational potential of this innovative surgical device.

One of the main advantages of EBA NAV is the possibility to monitor the progression of both nail and screws both in anteroposterior and axial hip views during their implantation [10] (Fig. 6). This a very useful and innovative feature compared to the static, uniplanar conventional fluoroscopy.

The EBA NAV system reduces the time lost in searching for the correct positioning of the device and improves implantation accuracy (Fig. 7). The double projection guarantees greater precision and less extension of the surgical incision, as well as a more precise entry point. Furthermore, the system allows accurate measurement of the cephalic and distal screws before their implantation.

Conclusions

Despite the small sample size and modest experience with navigation, the present study shows that navigation significantly reduces radiation exposure, without increasing the overall time in the operating room.

EBA NAV allows standardisation of surgical technique and time thanks to the continuous availability of the double hip views. Although EBA NAV is endowed with an increase in costs and a greater commitment in the OR setting up the operating room, it could be a very useful tool in fastening and improvising residents' learning curve.

The EBA NAV is a simple, intuitive and innovative surgical device that can revolutionise the management of pertrochanteric femoral fractures in the future. However, further studies, with a larger sample size, are needed to better evaluate the accuracy of the system.

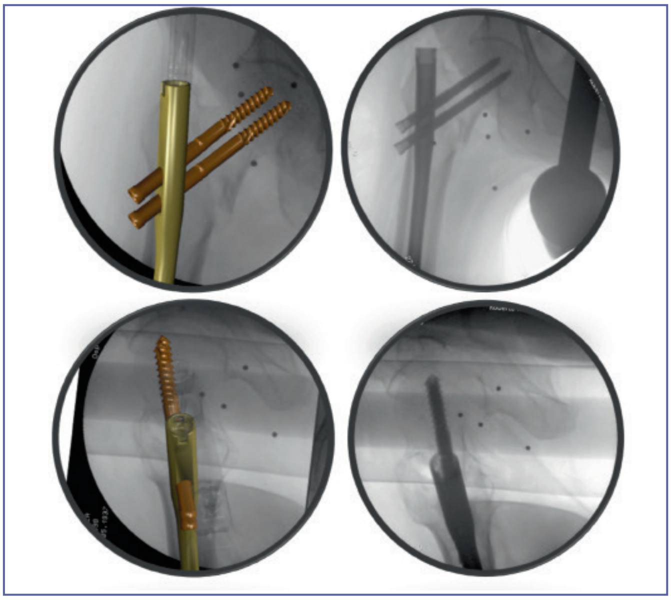

Figure 7. Accuracy of the navigated system.

References

1. Karkenny AJ, Mendelis JR, Geller DS, et al. The role of intraoperative navigation in orthopaedic surgery. J Am Acad Orthopaed Surg 2019;27:e849-58. https://doi.org/10.5435/JAAOS-D-18-00478
2. Huntsman KT, Riggleman JR, Ahrendtsen LA, et al. Navigated robot-guided pedicle screws placed successfully in single-position lateral lumbar interbody fusion. J Robot Surg 2020;14:643-7. https://doi.org/10.1007/s11701-019-01034-w
3. Figueroa F, Wakelin E, Twiggs J, et al. Comparison between navigated reported position and postoperative computed tomography to evaluate accuracy in a robotic navigation system in total knee arthroplasty. Knee 2019;26:869-75. https://doi.org/10.1016/j.knee.2019.05.004
4. He, M. et al. Evaluation of a bi-planar robot navigation system for insertion of cannulated screws in femoral neck fractures. Orthop Surg 2019;11:373-9. https://doi.org/10.1111/os.12450
5. AO Fundation, S. AO/OTA Fracture and dislocation classification. AOTrauma, 2014.
6. Caiaffa V, De Vita D, Laforgia R, et al. Treatment of pertrochanteric fractures with the Endovis BA cephalomedullary nail: multicenter study of 1091 patients. J Orthop Traumatol 2007;8:111-6 https://doi.org/10.1007/s10195-007-0172-y
7. Liebergall M, Ben-David D, Weil Y, et al. Computerized navigation for the internal fixation of femoral neck fractures. J Bone Jt Surg A 2006;88:1748-54. https://doi.org/10.2106/JBJS.E.00137
8. Hayda RA, Hsu RY, Mason DePasse, et al. Radiation exposure and health risks for orthopaedic surgeons. J Am Acad Orthopaed Surg 2018;26:268-77. https://doi.org/10.5435/JAAOS-D-16-00342
9. Honl M, Schwieger K, Gauck CH, et al. Comparison of total hip replacements cup orientation and position. Navigation vs conventional manual implantation of hip prostheses. Orthopade 2005;34:1131-6. https://doi.org/10.1007/s00132-005-0884-8
10. Hawi N, Haentjes J, Suero EM, et al. Navigated femoral shaft fracture treatment: current status. Technol Heal Care 2012;20:65-71. https://doi.org/10.3233/THC-2011-0652