

Navigated percutaneous screw fixation of the pelvis with O-arm 2: two years' experience

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ABSTRACT

Aim To evaluate the case series of the patients operated with percutaneous fixation by the navigation system based on 3D fluoroscopic images, to assess the precision of a surgical implant and functional outcome of patients.

Methods A retrospective study of pelvic ring fractures in a 2-year period included those treated with the use of the O-Arm 2 in combination with the Stealth Station 8. Pelvic fractures were classified according to the Tile and the Young-Burgess classification. All patients were examined before surgery, with X-rays and CT scans, and three days after surgery with additional CT scan. The positioning of the screws was evaluated according to the Smith score, the outcome with the SF-36.

Results Among 24 patients 18 were with B and six with C type fracture according to Tile, while eight were with APC, 10 LC, and six with VS type according to Young-Burgess classification. All patients were treated in the supine position, except two. A total of 41 iliosacral or transsacral screws and five anterior pelvic ring screws were implanted. The medium surgical time per screw was 41 minutes. There was a perfect correspondence of screw scores value from post-operative CT and intraoperative fluoroscopy. The mean screw score value was 0.92. There were no cases of poor positioning. The median follow-up was 17.5 months. The patients were satisfied with their health condition on SF-36.

Conclusion The use of the O-arm guarantees great precision in the positioning of the screws and reduced surgical times with excellent clinical results in patients.

Key words: 3D-fluoroscopic navigation, fragility fracture of pelvis, iliosacral fixation, O-arm Stealth Station S8, pelvic ring fractures

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INTRODUCTION

Fractures of the pelvic ring account for 3% of all fractures with an incidence of about 20-40 cases per 100,000 citizens (1-2). Pelvic ring fractures have a bimodal distribution by age, with peaks in the 15-30- and 50-70-years age groups. In the young population, fractures mostly involve males, victims of high-energy trauma (road accidents or falls from great heights), while in the elderly osteoporotic population, females are prevalent and following low-energy trauma (falls from the standing position or bed) (3).

Pelvic ring surgery is complex and requires deep knowledge of the anatomy of the pelvis and a long learning curve for the surgeon, as well as a hospital able to guarantee assistance to patients, often hemodynamically unstable. Open reduction and internal fixation of the pelvic ring requires extensive approaches and long operating times, which can lead to various early and long-term complications for the patient (4-5). Therefore, in recent years, increasing attention has been directed towards minimally invasive or percutaneous techniques that allow less blood loss, neurovascular risks, and a lower rate of infections (6-7). In parallel with their increased use, the available surgical instrumentation has improved, with the introduction of navigation techniques using high-quality fluoroscopy or CT with 3D reconstructions. Those technologies assist the surgeon in all phases of surgery, from the confirmation of the preoperative planning to the evaluation of the reduction obtained, up to the execution of the surgical procedure, reducing the operating time and increasing the surgeon's confidence (8-9). The aim of this study was to retrospectively evaluate the case series of the patients operated with percutaneous fixation guided by the navigation system based on 3D fluoroscopic images (O-arm 2 Medtronic), judging the precision of the performed surgical procedure and the functional outcome of the patients.

PATIENTS AND METHODS

Patients and study design

We conducted a retrospective study of all surgically treated pelvic ring fractures in the Department of Orthopaedics, A. Gemelli University Hospital Foundation IRCCS Level II Trauma Centre, Rome, between February 2018 and February 2020, before

the SARS-CoV-2 pandemic began and our Hospital became involved (10). Of the pelvic ring fractures treated, we included only those treated with the use of the O-Arm 2 system (Medtronic Inc., Louisville, Colorado, USA) in combination with the Stealth Station 8 navigation system (Medtronic Navigation) without exclusion criteria.

Pelvic fractures were classified according to the Tile classification (11) based on the stability of the pelvic ring (type A: Stable fracture, type B: rotationally unstable and vertically stable, fractures, type C: rotationally and vertically unstable fractures), and the Young-Burgess classification (12) based on the direction of the forces causing the injury (anterior posterior compression - APC, lateral compression - LC, vertical shear - VS).

Methods

All patients were examined before surgery with pelvic specific X-ray views (anteroposterior, inlet, outlet) and with thin-slice CT with multiplanar reconstructions. Three days after surgery, additional CT scan was obtained to assess the position of the screws. The radiolucent carbon table was used to allow intra-operative radiological visualization without interference, and the position taken by the patient on the operating bed during the surgery was reported. All patients were treated by the same surgeon and with the O-Arm 2 system in combination with the Stealth Station navigation system S8. The O-Arm 2 System performs an intraoperative 3D fluoroscopic scan of the pelvis, which is visualized with the Stealth Station Navigation System showing the position of moving objects in three planes of space, with multiple imaging protocols (low or high dose) that allow the surgeon the flexibility to choose an appropriate dose for the patient based on individual clinical goals (Figures 1, 2). With this technology, the surgeon can virtually navigate each screw intraoperatively with a viewfinder centring system, from the entry point to the different planes and calculate, without any other measure, the length and diameter of the screw. Only after those virtual screw checks on the monitor, the surgeon can safely insert the k-wire, through a cannulated trocar, and then the cannulated real screw into the bone (13). During the acquisition of imaging, the surgical team was outside the operating room. The operative objective was to obtain the anatomo-

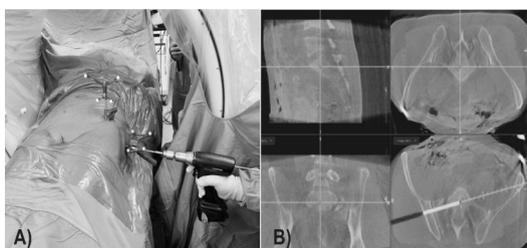


Fig 1. A) Navigated percutaneous fixation with O-Arm2 and Stealth station Navigation System. Once the trackers have been positioned on the iliac crest to locate the bone target, a cannulated trocar can be used for surgical navigation. **B)** The three-dimensional mode allows to obtain a simultaneous and complete multiplanar examination on the screen. The 3-window configuration highlights the axial, sagittal and coronal planes related to each other by a "crosshair" centring system (LiuZZA F, 2019)

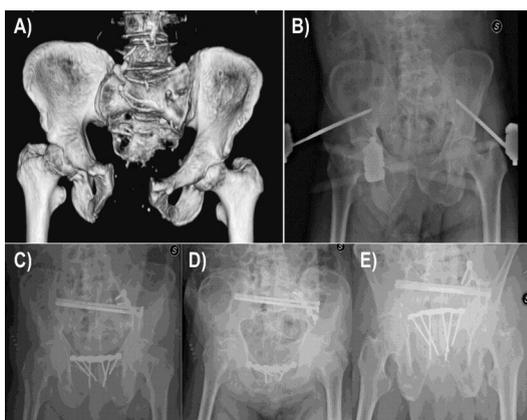


Figure 2. A) 3D CT reconstruction: pelvic ring B1 injury according to Tile and APC 2 injury according to Young Burgess. It is possible to appreciate sacral dysmorphism (Bertolotti's Syndrome) with hemisacralization of L5 on the left side; **B)** anteroposterior X-ray after damage control with supracetabular external fixator; **C-E)** post-operative X-ray: AP, inlet and outlet view after reduction and fixation with anterior 3.5 sacroiliac plate and two 7.3 trans-sacral screws; the pubic symphysis was fixed with a 3.5 dedicated plate and six screws (LiuZZA F, 2019)

mical reduction, with the least possible invasiveness, and to obtain a stable and strong fixation. Axial traction on the lower limb or a large distractor or external fixator could be used. It is also possible to obtain a solid and provisional fixation with the operating bed employing special frames, like Matta or Starr Frame (14-15).

On the third postoperative day, patients underwent radiographs and thin-slice CT with multiple control reconstruction examinations, by a team of musculoskeletal anatomy radiologists. They evaluated accuracy of the positioning of the implanted screws and compared the results of the three-dimensional reconstruction performed in the operating room with the postoperative CT.

The positioning of the screws was evaluated according to the Smith score (16), which produces

a "screw score" ranging from a minimum of 0 points (in case of perfect positioning) up to a maximum of 6 points (in case a revision is necessary) based on deviation from ideal screw position. In the Smith score, each screw was assigned a numerical score that was the sum of each perforation and angular grade. Perforations were graded as grade 0 - no perforation, grade 1 - perforation less than 2 mm, grade 2 - perforation between 2 and 4 mm, and grade 3 - perforation more than 4 mm. The angle of each screw relative to the respective superior endplate was measured and assigned a grade: grade 0 for an angle less than 5°, grade 2 for an angle of 5°–10°, grade 3 for an angle of 11°–15°, and grade 4 for an angle more than 15°. Each screw was assigned a numerical score that was the sum of each perforation and angular grade.

Functional outcome was assessed with the use of the SF-36 (Short-Form 36 items health Survey). We compared the measurements obtained from post-operative CT and intraoperative fluoroscopy using O-arm. The SF health survey 36 (standard questionnaire test) was administered 6 months after surgery (17-18).

Patients began physiotherapy, with passive and active-assisted mobilization starting from the second postoperative day, and began weight-bearing in a personalized way based on the type of fracture and the type of patient. The functional evaluation was done with a periodic clinical and radiological follow-up at 1, 3, 6, and 12 months, then annually.

RESULTS

Of 120 pelvic ring fractures treated surgically between February 2018 and February 2020, we considered only 24 (17 males and seven females) for which we used the O-Arm 2 system in combination with the Stealth Station 8 navigation system (Table 1). The mean age was 48.9 years with a maximum age of 89 and a minimum of 18. According to the Tile classification the patients were classified as B1 (five cases), B2 (13 cases), and C1 (six cases), while according to the Young-Burgess classification there were eight APC, 10 LC, and 6 VS. All patients were treated in the supine position, except two prone. In one case, a patient was treated in two surgical stages, first supine and then prone. In all cases of anterior and posterior fixation, anterior surgical time was performed first and

Table 1. Characteristics of 24 patients with fractures treated using the O-Arm 2 system in combination with the Stealth Station 8 navigation system

Patient	Gender	Age	Tile*	Young-Burgess*	Implants	Position
1	M	33	61B2.3	APC III	Symphysis plate, Iliosacral screw	Supine
2	M	50	61B2.3	APC II	Symphysis plate, Iliosacral screw	Supine
3	M	28	61B2.3	APC II	Symphysis plate, Iliosacral screw	Supine
4	F	51	61B2.2	LC I	Pubic ramus screw, Iliosacral screw	Supine
5	M	52	61B1	LC I	Iliosacral screw, InFix	Supine
6	M	38	61B2.1	LC I	Transsacral screw, Iliosacral screw, Symphysis plate	Supine
7	F	79	61B2.1	LC I	Pubic ramus screw, Iliosacral screw	Supine
8	F	51	61B2.1	LC I	Transsacral screw, InFix	Supine
9	M	89	61B2.3	APC III	Symphysis plate, Transsacral screw	Supine
10	M	46	61B1	APC I	Pubic ramus screw, Iliosacral screw, Transsacral screw	Supine
11	M	58	61C1.3	VS	Transsacral screw, Iliosacral screw, Neutralization plate, Suprapectineal plate	Supine/Prone
12	F	35	61B2.1	LC I	Iliosacral screw, Transsacral screw	Prone
13	M	18	61B1	APC III	Iliosacral screw, Transsacral screw	Supine
14	M	69	61C1.3	VS	Symphysis plate, RECON plate, Transsacral screw	Supine
15	F	30	61C1.3	VS	Iliosacral screw, Transsacral screw, Lumbopelvic fixation with pedicle screws and rod	Prone
16	M	65	61C1.3	VS	Symphysis plate, RECON plate, Transsacral screw	Supine
17	M	44	61B2.1	LC I	Transsacral screw, Iliosacral screw, Symphysis plate	Supine
18	M	33	61B1	APC III	Iliosacral screw, Transsacral screw	Supine
19	M	50	61B2.1	LC I	Transsacral screw, Symphysis plate	Supine
20	M	48	61B1	APC III	Transsacral screw	Supine
21	F	35	61C1.3	VS	Symphysis plate, Transsacral screw	Supine
22	M	56	61B2.1	LC I	Transsacral screw, Iliosacral screw, Symphysis plate	Supine
23	F	67	61C1.3	VS	Symphysis plate, RECON plate, Transsacral screw	Supine
24	M	52	61B2.1	LC I	Transsacral screw, Iliosacral screw, Symphysis plate	Supine

*classification M, male; F, female;

then percutaneous posterior fixation with O-arm, as we described previously (13). Anterior fixation was performed open, with Pfannenstiel approach, in 13 cases, while in five cases it was performed percutaneously with O-arm.

A total of 41 iliosacral or transsacral screws, three ramus pubic-screws, and two in-fix were implanted. In 16 cases an iliosacral screw was placed for fixation of the posterior arc of the pelvis, six without any other posterior fixation. A transiliac screw was used in 18 cases, 10 with another iliosacral screw and eight without other posterior fixation. To fix the anterior arc of the pelvis a symphysis plate in 13 cases was used, a retrograde screw in the pubic ramus in three cases, and an in-fix in two cases (Figure 2).

Surgical time per screw of 41 minutes on average (± 12.5) was observed.

In all cases, there was a perfect correspondence of the perforation and angle values; so there was a perfect correspondence of screw score values. The mean value was 0.92 (± 0.76). A perfectly located screw corresponds to a screw score of 0, obtained in seven patients. There were no cases of poor positioning in any of the implanted screws, no screw score more than 2 in all cases. The screws were found to be completely intraosseous without any penetration in all cases (Smith grade 0) except in

two cases (Smith grade 1) with perforation less than 2 mm. The angle of each screw relative to the respective superior endplate in 13 cases was between 5° and 10° (Smith grade 1), and between 5° and 10° (Smith grade 2) in three cases. The other seven screws have an angulation less than 5° (Smith grade 0). In 3rd day post-operative CT, the grade of perforation and angulation were comparable to those evaluated on intraoperative CT scans. No implant breakage was observed. Screw revision was not necessary. The radiation dose received by the operative team outside the operating room, during the imaging acquisition, was considered null. There were no complications due to the placement of the screws.

The median follow-up was 17.5 (± 6.7) months. Nine of 24 (37.5%) patients were followed up at 2 years, two were followed up at 6 months, the others after almost one year. At the last follow-up, the patient was satisfied with his health condition (SF-36: 120% for the physical component summary score, 85% for the mental component summary score compared to the age and gender controlled German population (18).

DISCUSSION

Pelvic surgeons use traditional fluoroscopy for percutaneous and mini-open procedures. Traditi-

onal fluoroscopy uses specific projections (anteroposterior view, inlet view, outlet view, Judet's views and lumbosacral spine views) that allow the surgeon to safely place the screws within the bony corridors of the pelvic ring (19,21). This imaging is the most popular among surgeons because it is inexpensive and widely used; however, it presents some technical difficulties which may concern the positioning of the patient on the operating table, in the case of severe thoracic injury with concomitant sternal or rib fractures or pneumothorax that prevent the patient from assuming the prone position (19,20). Also, some characteristics of the patient can cause interference such as obesity or intestinal gas, or urinary and abdominal viscera, which would deserve some preoperative preparations that are not always possible (20,21). Other disadvantages are the exposure of the surgical team to radiation and the inability to obtain simultaneous images on different planes (22). To overcome these difficulties, new technologies have been introduced in recent years, capable of helping the surgeon to increase the precision and safety of screw placement, with similar surgical times (23,26). They also make it possible to navigate bony corridors otherwise difficult to synthesize, such as pubic branches (27).

A fundamental requirement for the fixation of the pelvic ring is obtained an anatomical reduction, through a previous temporary reduction with K wires, large distractor, or external fixators. The only exception to achieving perfect anatomical reduction is fragility fractures of the pelvic ring, which require a compromise between the least possible invasiveness of the surgery and mechanically stable fixation (28,30).

Rommens et al. explained that fragility fracture of the pelvis requires patient-specific treatment, where fixation rigidity is more important than anatomical reduction and to achieve this, large exposures and long duration of surgery must be avoided; preferred percutaneous or minimally invasive approaches (28,30). We hope that these patients, who require multidisciplinary treatment, will be able to have targeted anaesthesia for the pelvic ring as those that already exists for acetabular fractures (31).

The increase in surgical precision in the positioning of pelvic screws with the support of CT navigated instruments has been reported in nu-

merous recent works (32). The complication rate and malpositioning of the screws with this technology vary from 0 to 15% against the 10-20% of placement with traditional fluoroscopy, which has an incidence of neurological damage between 0.5 and 7.7% (32,33). Our study shows that navigated percutaneous screw fixation of the pelvis with O-arm 2 is a safe and reliable surgical technique, which produces an intraoperative image comparable to that obtained with the postoperative CT scan; the functional outcome was judged satisfactory for all patients.

The biggest problem observed in our study concerns the sexual sphere and sexual dysfunctions of the patients following the trauma.

The limitation of our study is that it is a retrospective study, with a limited sample of patients and no control group. However, it produces the groundwork for targeted use of the O-Arm 2 in patients who require minimally invasive but mechanically stable surgery, particularly in difficult conditions such as in the presence of sacral dysmorphism, obesity, gas in the abdominal viscera, or a case of supine positioning by the patient. Kaiser et al. show that sacral dysmorphism was found in 41% of the pelvis and described a sacral dysmorphism score that quantifies the dysmorphism and can be used in preoperative planning of iliosacral screw placement. They also add that all patients with a sacral dysmorphism scored >70 do not have a safe corridor for percutaneous fixation of the first sacral vertebra (34,35). In those cases, it is strongly recommended to place ileosacral or trans-sacral screws with navigated procedures and we recommend the use of the O-arm 2 in combination with the stealth station navigation system S8. Furthermore, as demonstrated by a previous work of our group (36), it should be remembered that it is a procedure that exposes the patient to a radiation dose comparable to traditional fluoroscopy and lower than that of a CT scan, while it eliminates the radiation exposure by the surgical team that is outside the operating room during image acquisition.

In conclusion, surgical treatment of pelvic ring fractures is complex and requires a long learning curve. The increased attention given to percutaneous surgery in this type of fracture is justified by the increase in fragility fracture of the pelvis and by the improvement of diagnostic imaging

and surgical technology. The capacity to navigate with the support of 3D fluoroscopic or CT images turns into greater safety for the surgeon in the placement of difficult percutaneous screws such as trans-iliac screws, which can guarantee greater mechanical stability to fixation. It also allows for avoiding open approaches, long surgery time, and other complications related to open reduction and internal fixation (ORIF). The use of the O-arm in our experience guarantees us an instant precision in the positioning of the screws, a radiation exposure similar to the fluoroscopic technique for the patient and absent for the surgical

team, and reduced surgical time. The results of this study confirm the excellent clinical results in patients undergoing percutaneous navigation of the O-arm screws.

We hope that with the help of dedicated tools this intervention can be even more implemented and enhanced.

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TRANSPARENCY DECLARATION

Conflict of interest: None to declare.

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