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Intramedullary Stabilization of Pubic Ramus Fractures in Elderly Patients With a Photodynamic Bone Stabilization System (IlluminOss)

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Abstract

Introduction: A photodynamic bone stabilization system (PBSS) is a percutaneous operating method that provides intramedullary stabilization. The purpose of the study was to assess the clinical and radiological outcome after treatment of pubic ramus fractures with the PBSS. **Materials and Methods:** In a retrospective study, patients with osteoporotic pubic ramus fractures were included. The patients were treated with the PBSS in a percutaneous method. In the routine follow-up examination, pain was measured with the visual analog scale (VAS) and the type of mobilization was verified. Computer tomography of the pelvis was carried out in the follow-up examination (mean of 7.5 months after surgery) to investigate bone healing. **Results:** A total of 32 patients (25 females and 7 males) were included in the study. The average hospital stay was 16.5 $\pm$ 7.9 days (range: 5-37 days) and the mean operation time was 116.8 $\pm$ 47.1 minutes (range: 33-255 minutes). Two cases of wound infections and 1 case of misplacement of the PBSS implant with revision surgery have been documented. The mean VAS score for pelvic/hip pain at the day of inpatient discharge was 4.4 $\pm$ 1.4 (range: 2-7). A total of 25 patients could attend the follow-up examination 7.5 $\pm$ 1.7 months (range: 6-14) after the procedure, reporting a mean VAS for pelvic/hip pain of 3.0 $\pm$ 2.2 (range: 0-8). A total of 11 patients could walk without an orthopedic walking device, 7 patients needed underarm crutches, 6 patients used a walker-rollator, and 1 patient was immobilized. Consolidated pubis ramus fractures were described in 24 (96%) cases. **Discussion:** The results of our study reveal adequate clinical and radiological outcomes after treatment of osteoporotic pubic ramus fractures with the PBSS. This is the first study investigating the outcome after treating pubic ramus fractures with the PBSS. **Conclusion:** Based on our findings, the PBSS is an alternative to known techniques for the stabilization of the pubic ramus.

Keywords

photodynamic bone stabilization system, pubic ramus fracture, osteoporotic pelvic fracture, IlluminOss, fragility fracture pelvis

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Introduction

The photodynamic bone stabilization system (PBSS) was developed in 2010 for the treatment of fractures. This system allows for a minimally invasive approach using a photodynamic and light-curable polymer contained within an inflatable balloon catheter. This method offers intramedullary stabilization of the fracture. The purpose of this device is the treatment of osteoporotic or pathological long bone fractures. Both diaphyseal and metaphyseal fractures of long bones can be stabilized with this method, combining the stability of intramedullary nailing and the flexibility of the balloon catheter. Clinical and experimental studies present adequate results and safe application after the treatment of long bone osteoporotic fractures with this photodynamic stabilization device.[1-4]

An increased frequency of osteoporotic pelvic ring fractures has been observed in industrialized countries in recent years, as a result of growing elderly populations.[5,6] Isolated fractures of the pubic ramus are usually stable and can be treated

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conservatively. However, because of the rigidity of the pelvic ring, a pubic ramus fracture is often associated with a fracture at a second point of the pelvis, causing potential instability.[7] In the case of additional affection and interruption of the posterior pelvic ring or substantial dislocation of an isolated pubic ramus fracture, operative treatment is indicated.[8,9] Nonoperative treatment can lead to dislocation, injuries of the internal organs, and nonunion. Nonunion of a pubic ramus fracture can cause chronic pain and limited mobility.[10] Furthermore, long-term conservative treatment can cause pain and immobilization of the patient. In this case, the strategy of the therapy should be reevaluated and operative treatment can be considered.[11]

Operative treatment of pubic ramus fractures requires fixation of the anterior arch. Pubic ramus screws and plates have been developed to fix these types of fractures. Pubic ramus screws can be inserted in a percutaneous or open technique. The screw fixation allows an intramedullary fixation of the pubic ramus. The screw can be inserted anterograde or retrograde in a percutaneous method. However, a satisfactory closed reduction is required.[12]

In contrast, plate fixation requires an open procedure. The open technique allows an open reduction and reconstruction of the fracture. According to a biomechanical study, both techniques provide equal anterior pelvic stability, and the decision is based on the pelvic injury pattern, the preference of the surgeon, and the nature of the ramus fracture.[13] However, according to the biomechanical study of Acklin et al, plate osteosynthesis provides better stabilization compared to retrograde screw fixation in bone with low mineral density.[14]

The purpose of this study was to examine and describe the clinical and radiological outcomes after stabilization of pubic ramus fractures with the PBSS. Furthermore, the purpose was to investigate whether this technique represents an alternative to the established methods (screw and plate osteosynthesis) for operative treatment of osteoporotic pubic ramus fractures.

Materials and Methods

Study Design

Between August 2014 and January 2017, consecutive patients with an osteoporotic pelvic ring fracture with the pubic ramus involved were included in this retrospective study. The detailed inclusion and exclusion criteria are described in Table 1. Because of the retrospective design of the study, an ethical approval was not necessary. Diagnosis and fracture classification were based on preoperative X-rays and computed tomography (CT) scans. All pubis ramus fractures were treated with the photodynamic stabilization system IlluminOss (IlluminOss Medical Inc, East Providence, Rhode Island). Stabilization of the posterior pelvic ring was achieved with one percutaneous sacroiliac joint screw. After the operation, patients were mobilized with full weight bearing of the injured side.

Table 1. Inclusion and Exclusion Criteria of the Study.

Inclusion Criteria	Exclusion Criteria
Type IIc, IIIa, IIIb and IIIc FFP classification fractures[15]	Inoperability
Failed conservative treatment of type I, IIa, and IIb FFP classification fractures.[15] In this case, patients were treated conservatively with pain medication and mobilization. If the patients were immobilized due to the pain after 1 week of conservative treatment, we recommended the surgical stabilization of the fracture.	Type IV FFP classification fractures[15]

Abbreviation: FFP, fragility pelvic fracture.

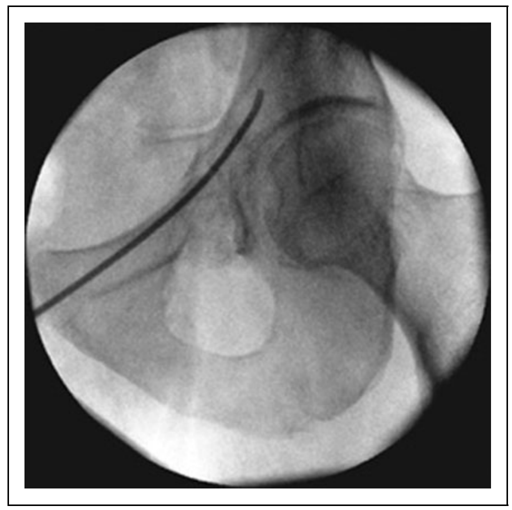

Figure 1. Intraoperative fluoroscopy image: control of the position of the elastic wire titanium elastic nail.

Radiological Data

A CT scan was performed for every patient included in the study. All fractures were classified regarding the fragility pelvic fracture (FFP) classification[15] according to the CT scan. The fractures were classified by the authors of this article. The patients were subjected to radiographs directly after the operation. A CT scan was carried out in the routine follow-up examination 6 months after the operation or later.

Surgical Technique

All surgeries were performed in the supine position under general anesthesia. Closed reduction was performed under fluoroscopy guidance in anterior–posterior, inlet, and outlet X-rays. A percutaneous anterior approach superior of the symphysis to pubic ramus was chosen. After identifying the pubic ramus and opening the cortical bone with an awl, an $\sim$3-mm elastic wire (titanium elastic nail) was inserted retrograde to the pubic ramus under fluoroscopy guidance (Figure 1). The position of the wire was controlled with an intraoperative fluoroscopy scan

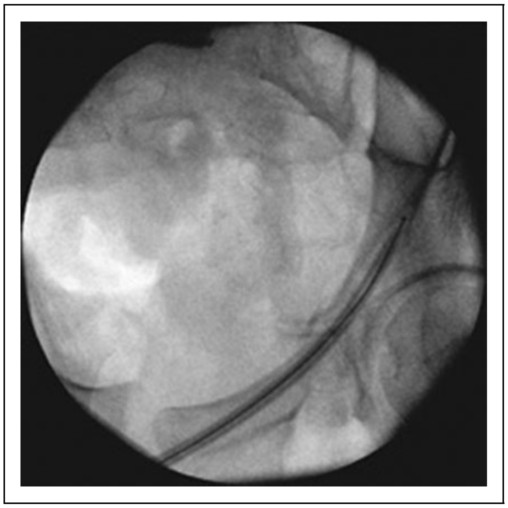

Figure 2. Intraoperative fluoroscopy image: control of the position of the balloon catheter of the IlluminOss system.

Figure 3. Intraoperative fluoroscopy image: the inflated IlluminOss system.

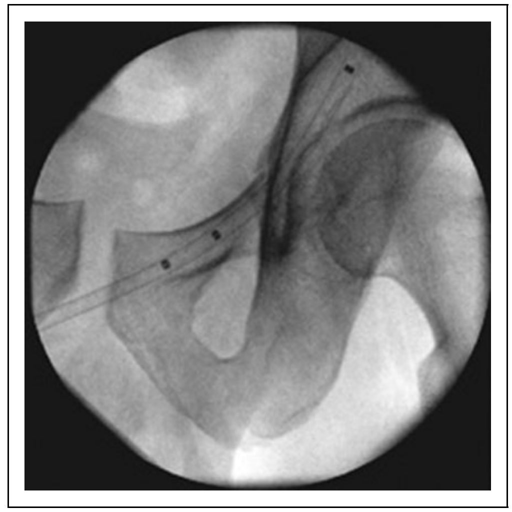

Figure 4. Connection of the photodynamic curing system with the balloon catheter.

Figure 5. Implant with continuous spirally X-ray marker.

(Arcadis Orbic 3D; Siemens, Erlangen, Germany). After controlling the sufficient position of the wire, the intramedullary space was drilled so that the balloon catheter of the IlluminOss system (∼9 mm × 160 mm) could be inserted in the pubic ramus (Figure 2). The next step was to fill the balloon catheter with the photodynamic monomer causing the catheter to expand. After connecting the balloon catheter to the photodynamic curing system, the photodynamic monomer converts to a polymer (Figure 3). This procedure leads to the hardening of the implant and stabilization of the fracture (Figure 4). The hardening procedure lasts for 4 minutes. Final X-rays in anterior–posterior, inlet, and outlet view were performed to control the position of the implant. The implant was equipped in both ends and in the middle with an X-ray marker, helping the surgeon to identify its position in the bone. Newer implants are equipped with an X-ray marker along the entire implant (Figure 5), providing exact identification of the position of the implant.

Clinical Data and Outcome Values

Demographic and clinical data, such as operation time, time of hospital stay, american society of anesthesiologists (ASA) classification, postoperative complications, and postoperative type of mobilization, were recorded and documented. Pain was measured with the visual analog scale (VAS) at the day of inpatient discharge and in the routine follow-up. The type of mobilization was also verified and categorized directly at the day of inpatient discharge and in the follow-up examination (Table 2).

Table 2. Categories of the Type of Mobilization.

Type of mobilization
1. Without orthopedic device
2. Underarm crutches
3. Walker-rollator
4. Immobilization

Table 3. Distribution of the FFP Classification.

FFP Classification	Number
Ia	1
Ib	0
IIa	0
IIb	17
IIc	5
IIIa	0
IIIb	0
IIIc	9
Iva	0
IVb	0
IVc	0

Abbreviation: FFP, fragility pelvic fracture.

Statistical Analysis

All statistical analyses were conducted using the SPSS statistical program (IBM SPSS version 20, 76, Chicago, Illinois). Descriptive and frequency statistics have been used to analyze the demographic, clinical data, and outcome. Moreover, descriptive statistics have been used to analyze the distribution of posterior and anterior pelvic ring fractures. The Student *t* test for paired samples was used to compare the VAS at discharge and at the follow-up examination. A P value < .05 was considered statistically significant. Bar diagrams were used to describe the distribution of the posterior and anterior pelvic ring fractures.

Results

Demographics

A total of 32 patients fulfilled the inclusion criteria, with 25 female patients and 7 male patients. The average age of the patients was 79.6 ± 7.8 years (range: 61-93 years).

Clinical Data

The distribution of the FFP and ASA classification is described in Tables 3 and 4, respectively. In Figures 6 and 7, the distribution of the posterior and anterior pelvic ring fractures is described. The average hospital stay was 16.5 ± 7.9 days (range: 5-37 days), and the mean operation time was 116.8 ± 47.1 minutes (range: 33-255 minutes). During the hospitalization, wound infections with revision surgery were reported in 2 cases. In one case, a misplacement of the PBSS implant following revision surgery was documented. Major complications, such as nerve or vessel injury, did not occur.

Table 4. Distribution of the ASA Classification.

ASA Classification	Number
ASA 1	0
ASA 2	8
ASA 3	21
ASA 4	3

Abbreviation: ASA, american society of anesthesiologists.

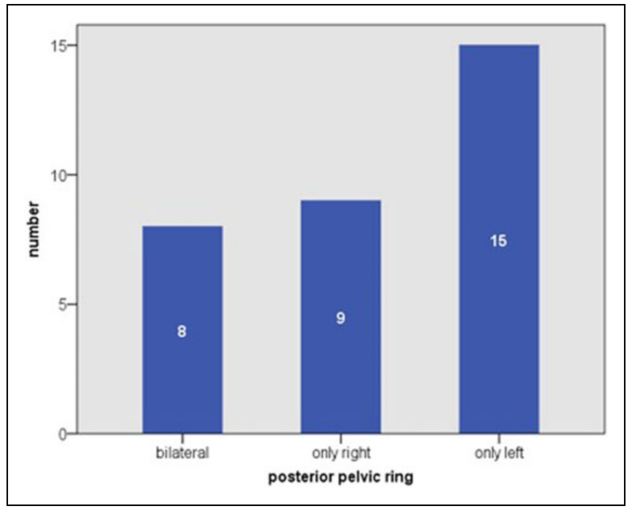

Figure 6. Bar diagram showing the distribution of the posterior pelvic ring fractures.

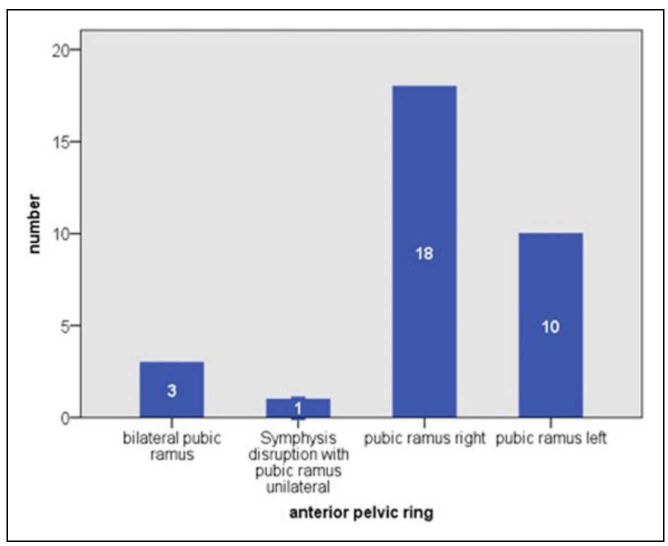

Figure 7. Bar diagram showing the distribution of the anterior pelvic ring fractures.

Furthermore, 2 patients developed pneumonia and 4 other patients developed urinary tract infection during hospitalization. No misplacement of the sacroiliac screws was reported.

Clinical and Radiological Outcome

The mean VAS score for pelvic/hip pain at the day of inpatient discharge was 4.4 ± 1.4 (range: 2-7). Moreover, 10 patients

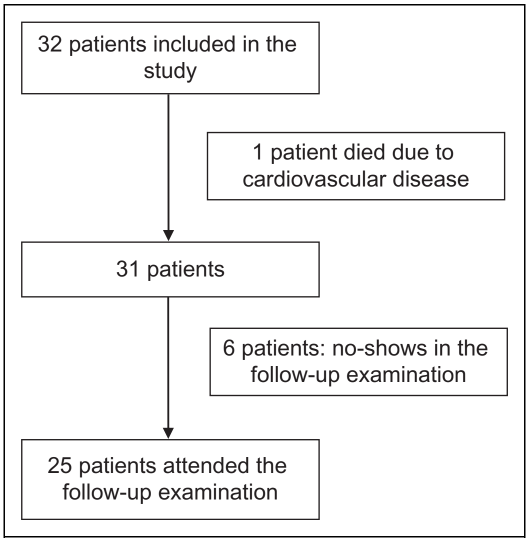

Figure 8. Flow diagram describing the lost to follow-up.

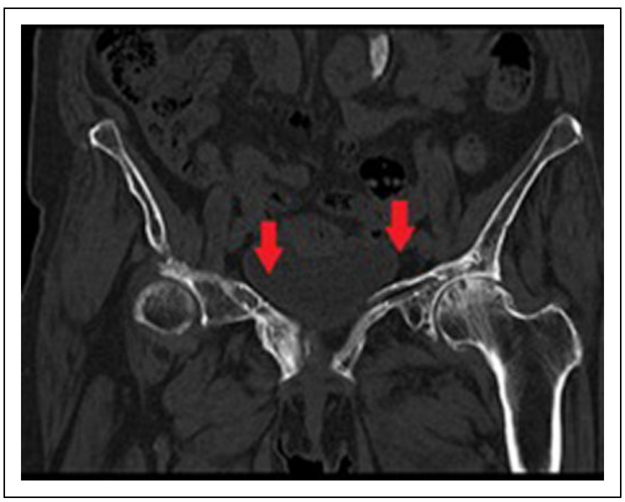

Figure 9. Computed tomography (CT) scan 6 months after the procedure (A, coronal; B, sagittal): The red marker points to the consolidated fractures of both pubic rami.

could walk with underarm crutches, 21 with a walker-rollator, and 1 was immobilized at the day of inpatient discharge.

Twenty-five (78.1%) patients could attend the follow-up examination. A loss to follow-up of 7 patients (21.9%) was reported (Figure 8). The mean time of the follow-up examination was 7.5 $\pm$ 1.7 months (range: 6-14 months) after the procedure. The mean VAS score for pelvic/hip pain in the follow-up examination was 3.0 $\pm$ 2.2 (range: 0-8), showing a statistically significant reduction ($P < .05$). A total of 11 patients could walk without an orthopedic walking device, 7 patients needed underarm crutches, 6 patients used a walker-rollator, and 1 patient was immobilized. In the CT scan, consolidated pubis ramus fractures were reported in 96% of the cases (n = 24; Figure 9). In one case, implant breakage and dislocation with development of a nonunion were recorded (Figures 10 and 11). In this case, the dislocated part of the

Figure 10. Radiological examination of the pelvis: The red marker points to the dislocated PBSS implant. PBSS indicates photodynamic bone stabilization system.

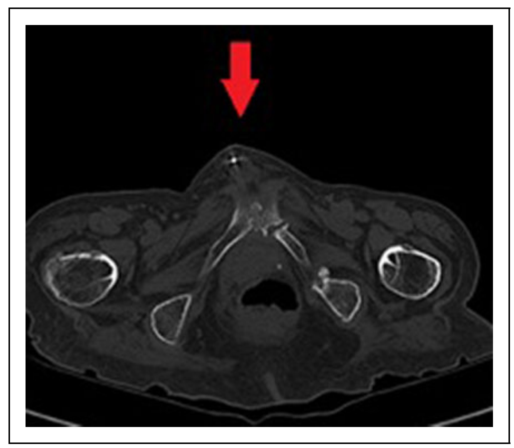

Figure 11. Computed tomography (CT) scan of the pelvis: The red marker points to the dislocated photodynamic bone stabilization system (PBSS) implant and the nonunion.

implant was removed. Moreover, one patient died due to cardiovascular disease during the follow-up.

Discussion

The results of our study report sufficient mobilization, low pain, and a low complication rate after treatment of pubic ramus fractures with the PBSS in a geriatric patient collective. In addition, a high rate of bone healing of the pubic ramus fracture was shown by the CT scans 6 months and later after the procedure. Current studies[1-4] present sufficient results after treatment of long bone fractures with a photodynamic stabilization system. However, only one case report describes the stabilization of a pubic ramus fracture with the PBSS.[16] This is the first study that reports the clinical and radiological outcome after stabilization of pubic ramus fractures with the PBSS in a geriatric patient collective. The results of this study are comparable to the results of other studies reporting surgical treatment of FFPs. Noser et al report, in a retrospective study with 60 patients with surgically treated FFPs, high mortality rates 62 months after the operation. However, they report that surviving patients had good functional outcomes. In this study, patients were treated with a percutaneous sacroiliac screw fixation.[17] A further study investigating the clinical and radiological outcome of surgically treated fragility fractures of the pelvis reported good functional outcome. Nonetheless, the authors report a high reoperation rate (20%). In this study, 36 of the patients were treated with a percutaneous sacroiliac screw and 14 patients with an additional fixation of the anterior pelvic ring (9 platings/5 external fixations).[18]

Stabilization of the pubic ramus with the PBSS provides intramedullary splinting. Because of its flexibility, the PBSS can bond exactly with the intramedullary space of the pubic ramus, increasing the bone–implant interface and leading to greater stability. This aspect is important for the osteoporotic bone. Two significant limitations are combined with the intramedullary stabilization of osteoporotic fractures: poor bonding of screws to the bone and poor anchoring of intramedullary implants due to enlarged intramedullary space.[19] A method to increase the bond strength of the implant (screw and nail) and bone is the introduction of bone cements. Bone cements provide a better implant–bone interface. Beall et al report a method of percutaneous augmentation of the superior pubic ramus with polymethyl methacrylate for traumatic and osteoporotic fractures.[20] However, the development of heat generated during the hardening process and the risk of embolism are drawbacks of this method.[21] Additionally, bone cement can leak, causing soft tissue damage. Moreover, the bone cement hardens to such a degree as to restrict revision surgery and removal of the stabilization implant.[22] The PBSS allows additional plate fixation, without removal of the implant needed, in the case of failed stabilization and revision surgery. The polymerized IlluminOss implant allows drilling and screw insertion. Biomechanical studies report high stability of screws inserted in the IlluminOss implant.[21] In addition, curved osseous fixation devices allow the implantation of larger, in diameter and length, implants than straight fixation devices.[23] The PBSS is a flexible implant that can be used in intramedullary curves of the bone.

The photodynamic implant also provides rotational stability of the fracture because it ensures cortical wall contact for the pubic ramus. The screw osteosynthesis cannot restore the rotational instability of the pubic ramus. To ensure rotational instability, a plate fixation is necessary. This ability of the photodynamic implant can increase the stability in rotation of unstable pubic ramus fractures.

Another important aspect of the stabilization of pubic ramus fractures with the PBSS is the reduction achieved in the hardening process. The implant can fit through, as a result of its flexibility, exactly in the intramedullary space. After filling with the photodynamic monomer and the hardening process, the implant fills the whole intramedullary space of the pubic ramus, achieving a reduction of the fracture. However, in the case of screw osteosynthesis, reduction of the pubic ramus fractures must be achieved prior to insertion of the intramedullary screw. The screw functions mostly to hold the reduction.[13,22]

A common complication of screw insertion in the pubic ramus is the penetration of the hip joint. In this case, cartilage damage and secondary osteoarthritis can occur. Gras et al report $\sim 6\%$ of screw misplacement in 29 pubic ramus screws inserted by 2-D fluoroscopic navigation.[24] The photodynamic implant is positioned in the intramedullary space of the bone and then filled with the photodynamic monomer, preventing penetration of the hip joint. Additionally, increased failure rates when using screw osteosynthesis have been reported in the case of osteoporosis, lateral fracture location, and retrograde insertion of the screw.[25]

Stabilization of the pubic ramus with a plate usually requires an open approach to the pelvic ring. Minimally invasive methods of subcutaneous plate fixation of pubic ramus fractures have been reported in the literature. However, systematic use of minimally invasive plate fixation of the pubic ramus has not yet been established.[26]

The implant allows a better intraoperative anatomical overview because it is X-ray permeable. This aspect can help the surgeon identify anatomical structures. In contrast, this feature can cause problems for the X-ray diagnostic in the postoperative follow-up. The exact location of the whole implant and implant failure, such as brake and dislocation of the implant, cannot be detected directly by X-ray examination. Indirect radiological and clinical signs, such as secondary dislocation, pain, and immobility, should indicate further examination, such as computer tomography scanning, resulting in delayed proof of an implant failure. In our study, a dislocation of the implant was described during the follow-up. New implants with continuous spirally X-ray markers have been developed (see Figure 5). These new implants allow for reliable detection of implant failure and dislocation during follow-up.

Current studies report an increase of pelvic ring fractures in elderly patients in the Western world caused by low-energy traumata.[5,27] Proper treatment of these fractures for the elderly is crucial. Excess mortality after osteoporotic pelvic fractures has been reported.[5,17,28,29] However, surgical management of these fractures is challenging, and there is still no established operating procedure.[30] The PBSS can provide sufficient stability of the pubic ramus combining the benefits of the minimally invasive approach, allowing early mobilization of elderly patients. The potential advantages of the minimally invasive stabilization of pubic ramus fractures may include reduced blood loss, lower infection rate, fewer soft tissue complications, and better pain control.[22]

This study has several limitations. The mean operating time described in the study was relatively long. A reason for this is that a learning curve is captured in this operating time. The introduction of novel operating techniques leads often to a learning curve. A further limitation of this study is the evaluation of pelvis and hip pain in the follow-up examination. Pain in this region can have many causes in elderly patients, such as arthritis of the hip joint or degenerative diseases of the lumbar spine. In this sense, the pain reported by the patient is not always associated with the pelvic fracture. A further limitation is that due to the combined dorsal–ventral procedure (sacroiliac joint screw and PBSS of the pubic ramus), both surgical techniques are accredited for the sufficient clinical outcome. On this basis, we cannot imply that use of the PBSS alone leads to a sufficient clinical result. However, this study reveals that the PBSS can be used for the operative treatment of pubic ramus fractures as an alternative method to screw or plate osteosynthesis. Moreover, a limitation of the study is that VAS was only documented at discharge, making a comparison of the pain development before and after the operation not possible. Finally, a relatively high percentage (21.9%) of the patients included in the study could not attend to the follow-up examinations. The reason for the relative high loss to follow-up could be the high age of the patients included in the study. Elderly patients with fragility fractures of the pelvis have high mortality rates even after hospitalization. Noser et al report in a retrospective study investigating patients with FFPs who were treated operatively about a 1-year mortality of 28.3%.[17] The percentage of the loss to follow-up in our study was 21.9%, 7.5 months after the operation. We can thus say that some of the patients who were loss to follow-up could have been deceased.

Conclusions

Photodynamic stabilization of pubic ramus fractures is a percutaneous operating method providing adequate intramedullary stabilization of the anterior pelvic ring. This is the first study investigating the clinical and radiological outcome after percutaneous stabilization of pubic ramus fractures in geriatric patients. Our study reports low morbidity when using the PBSS. This operating method can be combined with a percutaneous sacroiliac joint screw for stabilization of the posterior pelvic ring. We concluded that the PBSS is a safe method for the operating treatment of osteoporotic pelvic ring fractures.

Authors' Note

Informed consent was obtained from all individual participants included in the study.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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