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CT-guided pelvic fracture osteosynthesis in the elderly – a retrospective observational monocentric trial.

Dissertation zur Erlangung des Grades eines Doktors der Medizin
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Key

AO/OTA	Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma association
ASA	American Society of Anaesthesiology
BEST	Bone Evaluation Study
cm	Centimeters
CT	Computed Tomography
DXA	Dual X-ray-Absorptiometry
FFP	Fragility Fracture of the Pelvis
IQR	Interquartile Range
SD	Standard deviation
SIJ-Screw	Sacroiliac joint screw
mGy*cm	Milligrays per centimetres
mm	Millimeters
MRI	Magnetic Resonance Imaging
NRS	Numerical rating scale
PTH	Parathyroid Hormone
PMMA	Polymethylmethacrylate
SOP	Standard operating procedure
QoL	Quality of Life
VAS	Visual Analogue Scale
WHO	World Health Organization

1 Summary

Patients with Fragility Fractures of the Pelvis experience immobilising pain. In the population aged >65 years, being bedridden for a prolonged period commonly leads to a cascade of complications, including immobility and decreased independence, resulting in a reduced quality of life. Hence, the primary treatment goal is pain control and early mobilisation to restore the patient's independence.

A conservative approach to these fractures may seem to carry the least risk, as no surgery or general anaesthesia is necessary. However, this approach often leads to the aforementioned complications. Meanwhile, the indication for an operative approach must be carefully considered as extensive and invasive surgery often leads to long periods of hospitalisation and rehabilitation. A minimally invasive surgical intervention is suitable for patients who may not be eligible for extensive operations yet will benefit significantly by restoring mobility.

This retrospective study analysed the risks and benefits of a minimally invasive computed-tomography-guided percutaneous operative approach in 28 cases. Patients aged 67–91 years who presented with fragility fractures between August 2015 and September 2021 were included. The primary focus resides on the postoperative outcomes, including the assessment of the quality of life. The limitations of our study include the relatively high number of patients lost to follow-up and small cohort size.

Our study shows that this operative method is safe to use in daily practice and has many advantages over other or conventional surgical approaches; it does not require extensive resources, as it is conducted using a standard computed tomography scanner, a device available in most hospitals. It also makes the intervention quick and relatively easy to learn, with an average operation time of 32.4 ±9.6 minutes for unilateral and 50.7 ±17.4 for bilateral procedures and no significant difference between individual surgeons (p=0.12). The method is very precise and minimises the risk of severing the sensitive structures of the pelvis. Postoperative computed tomography scans showed just one case of cortex penetration; however, this did not require revision surgery. All the above methods allow surgeons to apply this method even in smaller, resource-constrained healthcare facilities.

Furthermore, this minimally invasive procedure enables early postoperative mobilisation and effective pain management. Consequently, this leads to relatively brief hospitalisation periods (mean 12.1 ±4.6 days), diminishing the potential complications associated with extended hospital stays and enhancing the prospects of elderly patients maintaining their independence

and enjoying a higher quality of life in their later years. A total of 57.1% of patients were discharged home or to rehabilitation clinics.
An average score of 55.6 on the visual analogue scale of the EQ-5D-3L questionnaire represented overall satisfactory health.

In the future, more prospective studies with larger cohorts are needed to improve the treatment of these cases, which are continuously increasing in number owing to our aging society.

2 Zusammenfassung

Titel: CT gesteuerte zementaugmentierte Schraubenosteosynthese des Ileosakralgelenks am osteoporotischen Becken – eine retrospektive monozentrische Beobachtungsstudie.

Patienten, die sich Insuffizienfrakturen des Beckens zuziehen, leiden häufig unter stärksten Schmerzen, die eine deutliche Bewegungseinschränkung zur Folge haben. Besonders in der Altersgruppe >65 Jahren führt die vermehrte Bettruhe nicht selten zu einer Abfolge von Komplikationen, die von Immobilität über reduzierte Lebensqualität bis hin zu schwindender Selbstständigkeit reicht. Infolgedessen stehen eine suffiziente Schmerzkontrolle und frühzeitige Mobilisation im Mittelpunkt der Therapie.

Da diese Frakturen nicht immer zwingend eine operative Intervention benötigen, scheint ein konservativer Behandlungsansatz auf den ersten Blick das geringste Risiko zu bergen. Dennoch führt dieser oft zu den oben genannten Folgen. Anderseits sind invasive Operationen häufig mit langen Krankenhausaufenthalten und umfassenden Rehabilitationsmaßnahmen verbunden, was letztendlich zu ähnlichen unerwünschten Ergebnissen führen kann. Für Patienten, bei denen eine umfangreiche Operation möglicherweise zu belastend ist, sie aber von der Aufrechterhaltung der Mobilität erheblich profitieren würden, zeigt sich der minimalinvasive chirurgische Eingriff besonders geeignet.

Diese retrospektive Studie analysiert die Vorteile und Risiken eines minimalinvasiven, Computertomografie-gesteuerten perkutanen operativen Ansatzes. Hierfür wurden die Daten von 28 Fällen mit Patienten im Alter von 67 bis 91 Jahren analysiert, die zwischen August 2015 und September 2021 behandelt wurden. Ein besonderes Augenmerk liegt hierbei auf den postoperativen Ergebnissen unter Einbeziehung der Lebensqualität. Zu den Limitationen der Studie zählen die begrenzte Fallzahl sowie die unregelmäßige Nachverfolgung.

Die Ergebnisse verdeutlichen die Sicherheit und großen Vorteile dieses operativen Ansatzes in der klinischen Anwendung im Vergleich zu anderen Therapieoptionen. Er zeichnet sich durch die vergleichsweise einfache Erlernbarkeit aus und erfordert keine umfangreichen Ressourcen. Die durchschnittliche Operationszeit für einen einseitigen Eingriff betrug 32.4 ±9.6 Minuten und 50.7 4 ±17.4 für einen beidseitigen Eingriff, ohne signifikanten Unterschied zwischen verschiedenen Chirurgen ($p=0.12$). Die Nutzung der Computertomografie, die in nahezu jedem Krankenhaus zur Verfügung steht, ermöglicht eine kurze Eingriffszeit und liefert präzise Ergebnisse, die das Risiko von Verletzungen an sensiblen Strukturen des Beckens

minimieren. The postoperativen Computertomographiebilder zeigten eine Penetration des Cortex in einem Fall, ohne Notwendigkeit einer Revision.

Zusammenfassend könnte dieses Verfahren von einer breiteren Gruppe von Chirurgen effizient umgesetzt werden, selbst in kleineren, ressourcenbeschränkten Gesundheitseinrichtungen. Es ermöglicht eine frühe postoperative Mobilisation und effektive Schmerzkontrolle. Somit ist der Krankenhausaufenthalt verkürzt (durchschnittlicher Krankenhausaufenthalt 12.1 ±4.6 Tage) und mögliche Komplikationen, die mit längeren stationären Aufenthalten verbunden sind, minimiert. Dies verbessert die Aussicht auf Wahrung der Unabhängigkeit und erhöht die Lebensqualität in späteren Lebensjahren. 57.1% der Patienten wurden nach Hause oder in Rehabilitationskliniken entlassen. Die Datenerhebung mittels des EQ-5D-3L Fragebogens ergab eine durchschnittliche Punktzahl von 55.6 und somit eine zufriedenstellende Gesundheit.

Künftig sind umfangreichere prospektive Studien erforderlich, um diese Behandlungsoption zu optimieren, da ihre Anwendung aufgrund der kontinuierlichen alternden Gesellschaft stetig zunehmen wird.

3 Introduction

Typically, pelvic fractures occur due to high-energy trauma such as car accidents or falls from great heights. However, in the elderly population, they can arise from only a minor impact, such as a fall from a sitting or standing position. In some instances, a traumatic event may not even be memorable [3,9,18,53,64]. Due to demographic changes, the number of these so-called “fragility fractures” is constantly increasing [59]. Furthermore, the age of this particular patient group is associated with a greater risk of complications. Owing to multiple comorbidities, poor preoperative mobility, and polypharmacy, these patients are at risk of significant morbidity and mortality [7]. Therefore, a multidisciplinary treatment approach is crucial for achieving satisfactory outcomes for patients, families, and healthcare professionals.

The traumatology department of Marienhaus Klinikum Hetzelstift in Neustadt an der Weinstraße, Germany, regularly treats patients with fragility fractures of the pelvis. In this thesis, the outcome of a minimally invasive CT-guided treatment approach performed between 2015 and 2021 was evaluated.

3.1 Demographic changes and their impact on the German healthcare system

The proportion of older adults (aged 65 years and above) in the German population has been continuously increasing in recent decades. This is due to both an increasing life expectancy and a declining birth rate, resulting in aging of the general population. According to data from the Federal Statistical Office, in 2015, 21% of the total population of Germany (82.2 million total) was aged 65 years or above, compared to 14% (78.1 million total) in 1970. Projections indicate that this trend is likely to continue, with estimates suggesting that the proportion of seniors in the population will reach nearly 30% within the next decade [70]. This demographic shift is likely to significantly impact healthcare services because of an increase in geriatric patients requiring more frequent in-hospital treatment and long-term care.

Therefore, orthogeriatrics is becoming an increasingly important field as the number of geriatric fracture entities continues to rise [33,59]. In 2018, more than 400,000 patients with geriatric fractures were treated in Germany. This not only places a burden on traumatology departments in hospitals, but also on other parts of the healthcare system, such as rehabilitation clinics and nursing homes. According to data collected by the Federal Statistical Office, the number of patients requiring care in nursing homes rose from 2 million in 1999 to 3.4 million in 2017, and is estimated to reach 5 million by 2050 [71,72]. While the number of patients is constantly increasing, the number of trained staff is declining. Consequently, innovative solutions are needed that require less personnel and conserve resources while maintaining a high quality of care [71].

3.2 Osteoporosis and Fragility Fractures

The World Health Organization (WHO) defines fragility fractures as fractures caused by trauma that would otherwise be insufficient to break bones in healthy individuals [67].
Patients with malignant diseases or conditions that affect bone mineral density, such as osteoporosis, are predisposed to such fractures. Correspondingly, these illnesses are more prevalent in the elderly [7,59].

Osteoporosis is a chronic metabolic bone disease characterised by decreased trabecular and cortical bone mass (bone mineral density), resulting from an imbalance between bone resorption and formation. This, in turn, leads to reduced bone strength and increased susceptibility to fractures (**Image 1**) [9,34,67].

The maintenance of bone density is a dynamic equilibrium regulated by the activity of osteoblasts and osteoclasts, paired with hormonal influences.
Osteoblasts are responsible for bone formation and mineralisation using calcium.
Osteoclasts, on the other hand, are bone-resorbing cells that facilitate the removal of old or damaged bone matrix, thereby helping maintain the correct serum calcium concentration.
Calcium is further absorbed from the small intestine. Vitamin D facilitates this process; hence, vitamin D deficiency can decrease serum calcium concentration.
The endocrine system regulates this process via hormones, such as Parathyroid Hormone (PTH) and Oestrogen. PTH, secreted by the parathyroid glands, regulates the calcium homeostasis. As serum calcium levels decrease, PTH is released, stimulating osteoclast activity and resulting in bone resorption. This is essential for maintaining correct serum calcium levels. However, prolonged elevation can contribute to bone loss, and consequently, osteoporosis. Oestrogen has a protective effect on bone health because it inhibits the activity of osteoclasts [10,43].

The risk factors for osteoporosis include both genetic and environmental factors. These include increased prevalence of certain ethnicities, inherited disorders, increased age, low body weight, malnutrition (low calcium and vitamin D intake), sedentary lifestyle, prolonged use of certain medications (e.g. glucocorticoids, anticonvulsants, selective serotonin reuptake inhibitors, proton pump inhibitors, or aromatase inhibitors), and menopause [7,35,43,50].
After menopause, a decline in oestrogen levels accelerates bone loss owing to increased osteoclast activity. Additionally, reduced sunlight exposure and poor nutrition affect calcium

and vitamin D metabolisms. The combination of these factors puts postmenopausal women at greater risk for developing osteoporosis [18,28].

A study known as the “Bone Evaluation Study” (BEST), conducted between 2009 and 2013, found a prevalence of osteoporosis in 24% of women and 6% of men over the age of 50 years. Furthermore, the study revealed that within four years, 50% of these patients experienced at least one fracture [21].

The prevention of such fractures is another important topic. Methods such as FRAX score calculation or Dual X-ray-Absorptiometry (DXA) aim to detect and forecast the likelihood of an osteoporotic fracture [9]. However, owing to insufficient screening, osteoporosis often goes unnoticed until a fracture occurs. The most common sites of such fractures are the vertebrae, neck of the femur, wrist and pelvis [34].

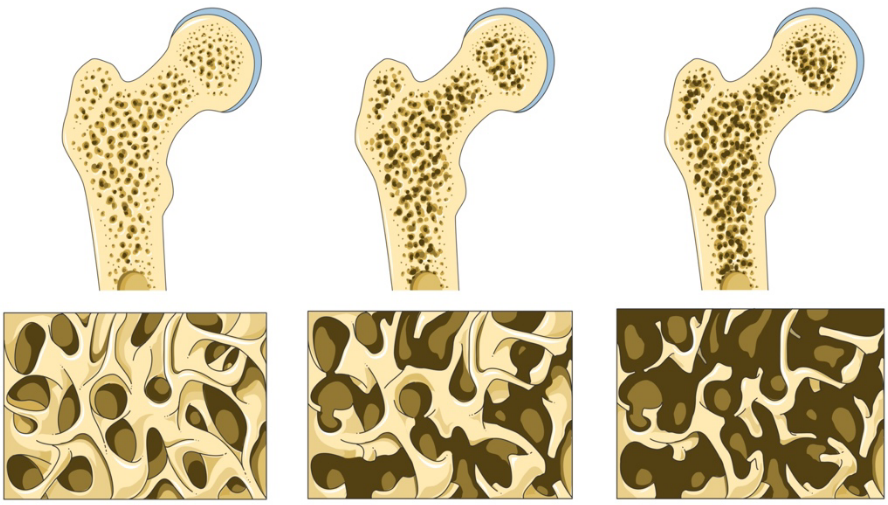


Image 1: Visualisation of structural changes in the bone matrix in osteoporosis. Left: Healthy bone matrix. Right: Osteoporotic bone matrix [69].

3.3 Anatomy of the pelvis

The pelvis connects the axial skeleton to the lower extremities. It is composed of multiple bones, joints, and ligaments and provides stability by supporting the weight of the upper body. In addition, the bony structure of the pelvis protects several internal organs and blood vessels. Owing to this complex 3-dimensional anatomy, pelvic fractures and subsequent surgical repair are prone to complications [64].

The bones of the pelvis consist of the sacrum, coccyx and two identical pelvic bones that are formed by three parts (os ilium, pubis and ischium). The sacrum articulates superiorly with the lumbar vertebrae, forming the lumbosacral joint, and inferiorly with the coccyx. The sacrum and coccyx are comprised of five and four fused vertebrae, respectively. The pelvic bones articulate posteriorly with the sacrum at the sacroiliac joint and anteriorly with the pubic symphysis. These fibrous joints allow minimal movement, thereby increasing stability. [13,61,66]. The anatomy of the bones and ligaments is shown in **Image 2**.

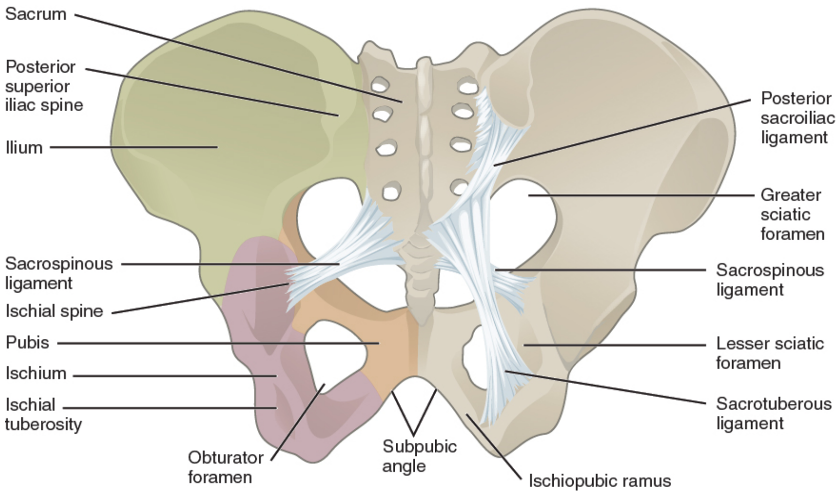


Image 2: Pelvic bone anatomy [39].

When bony injuries are classified, the pelvis is separated into two parts: The anterior and posterior pelvic ring. The structures conveying stability and weight-bearing capacity make up the posterior pelvic ring. Conversely, the anterior pelvic ring, comprising the pubic symphysis and the pubic and ischial rami, only plays a minor role in stability [13,66].

When fractures of either of these bones occur, injury to the internal structures, that is, organs, large blood vessels, and nerves residing within the pelvis, is not uncommon. The common iliac artery begins at the level of the fourth lumbar vertebra where the abdominal aorta bifurcates. This further bifurcates, forming the internal and external iliac arteries at the level of the sacroiliac joint. The external iliac artery then passes anteriorly along the pelvic brim, whereas the internal iliac artery runs near the sacroiliac joint [55]. Large venous plexuses, such as the vesical venous and rectal venous plexus, are found in the posterior part of the pelvis, accounting for the majority of haemorrhages associated with pelvic ring injuries [16]. The anatomy is further visualised using **Image 3**.

Urethral injuries occur in up to 10% of pelvic fractures in adults [12]. This can occur directly as the urethra passes in close proximity to the pelvic bone in front of the sacroiliac joint, causing it to tear or indirectly incur damage due to swelling of soft tissue or haemorrhage, resulting in compression of the urethra. Compared to injury of the blood vessels, urethral injuries are rarely life-threatening in the acute phase but may lead to severe long-term complications [25].

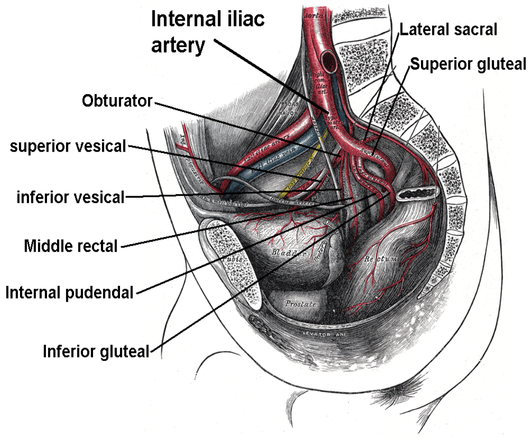


Image 3: Anatomy of the Blood vessels in the Pelvis [22].

3.4 Pelvic Fractures

Pelvic fractures often occur due to high-energy trauma, such as car accidents or falls from great heights. Patients commonly present with severe pain, reduced range of motion, and haematoma. Pelvic stability checks are often performed during the initial injury assessment. Due to the complex pelvic anatomy, instability may result in injury to the urethra, nerves, or major blood vessels. Consequently, this may lead to extensive intraperitoneal and retroperitoneal bleeding, haemorrhagic shock, or even death [48,50,64]. Whereas these severe cases most frequently occur due to high-energy impact, they are rarely observed in geriatric fractures [11]. Furthermore, the preserved integrity of the ligamentary structures in these low-impact traumas benefits the overall stability and reduces the potential for injury to intraperitoneal structures [11,50]. However, owing to a higher prevalence of cardiovascular comorbidities such as atrial fibrillation, elderly patients are more commonly on anticoagulant medication, consequently resulting in an increased risk of bleeding [24].

The history of pelvic fracture treatment dates back to the 19th century, when the French surgeon Joseph-François Malgaigne first published several manuscripts describing different types of fractures [42,57]. In recent years, several fracture classifications have been developed, including the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification, which has been adapted for various parts of the body. However, more specific classifications that focus on multiple aspects of pelvic fractures exist. The Tile classification is based on the stability of the pelvic ring [68]. In comparison, the Young-Burgess classification focuses on the mechanism of injury, specifically, the direction of the force. Both are related to the severity of injury and consider soft-tissue damage [2,37,49].

Fragility fractures of the pelvis do not necessarily fit either of these classifications. Such fractures are mainly characterised by the disruption of bony structures with intact soft tissue. The fragility fractures of the pelvis classification (FFP) also assesses the degree of instability and bone disruption, but it is adapted to this specific patient group [32,49].

3.4.1 Fragility fractures of the pelvis (FFP)

This classification was developed by Rommens and Hofmann in 2013 [49]. It describes the type of fracture most commonly encountered by elderly patients due to low-energy falls: pelvic fractures [49,51].

As previously established, such fractures require only a minor impact. Due to demographic changes, these so-called fragility fractures are constantly increasing in number, and significant morbidity and mortality ensue [3]. They markedly impair mobility and independence, and subsequently impair the quality of life [17,38]. Approximately 224 per 100,000 people over the age of 60 years experience pelvic fragility fractures due to osteoporosis each year [38].

Geriatric patients with pelvic fractures often present with great pain and immobility, and conventional X-ray examinations miss this fracture entity in approximately 50% of cases [8]. Computed tomography (CT) is the gold standard for diagnosing and assessing fractures [36]. Applying the FFP classification aids in deciding the appropriate treatment [38].
The FFP classification allocates fractures into four main groups, which are explained in detail below [38,49].

FFP Type I: These are isolated fractures of the *anterior* pelvic ring with the following subgroups (**Figure 1**):

- Type Ia: Unilateral fractures
- Type Ib: Bilateral fractures

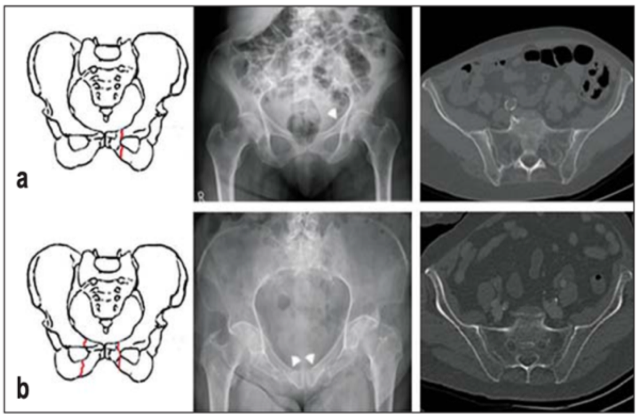


Figure 1: FFP Type I Fractures, including subtypes a and b. Left to right: Anatomical sketch, plain radiograph (AP), and CT image (axial plane) [49].

FFP Type II: These are non-displaced fractures of the *posterior* pelvic ring with the following subgroups (**Figure 2**):

- Type IIa: Isolated dorsal fractures
- Type IIb: Compression fractures of the anterior portion of the lateral mass of the sacrum, associated with instability of the anterior pelvic ring
- Type IIc: Non-displaced complete sacral/sacroiliac/iliac fractures with instability of the anterior pelvic ring

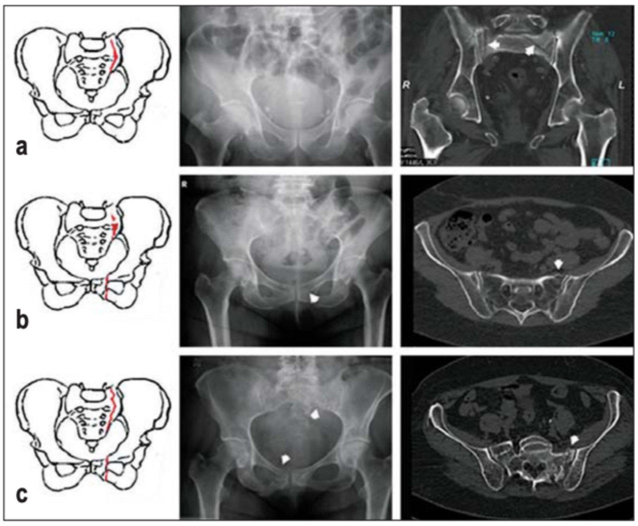


Figure 2: FFP Type II Fractures, including subtypes a, b, and c. Left to right: Anatomical sketch, plain radiograph (AP), and CT image (axial plane) [49].

FFP Type III: These are displaced unilateral fractures of the posterior pelvic ring *and* instability of the anterior pelvic ring, with the following subgroups (**Figure 3**):

- Type IIIa: Displaced fracture of the ilium
- Type IIIb: Displaced unilateral iliosacral injury
- Type IIIc: Displaced unilateral sacral injuries

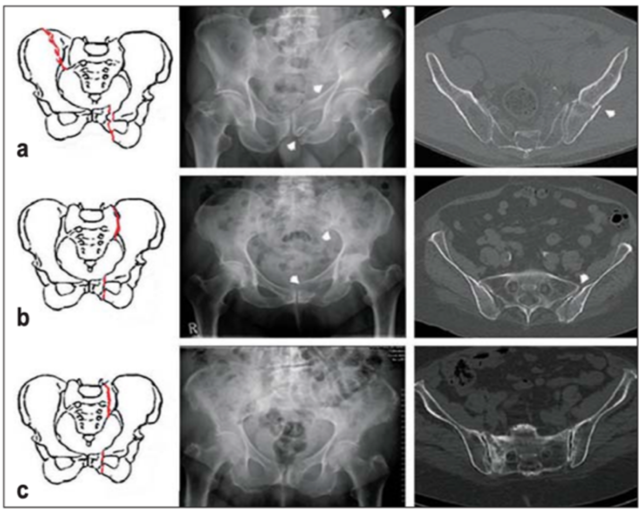


Figure 3: FFP Type III Fractures, including subtypes a, b, and c. Left to right: Anatomical sketch, plain radiograph (AP), and CT image (axial plane) [49].

FFP Type IV: These are *bilateral* displaced fractures of the posterior pelvic ring, with the following subgroups (**Figure 4**):

- Type IVa: Bilateral ilium or bilateral iliosacral injury
- Type IVb: Spinopelvic burst fractures with bilateral vertical lesions of the lateral mass of the sacrum and a simultaneous horizontal component connecting the two vertical lesions (known as “U” or “H” fractures)
- Type IVc: A combination of multiple displaced instabilities of the posterior pelvic ring

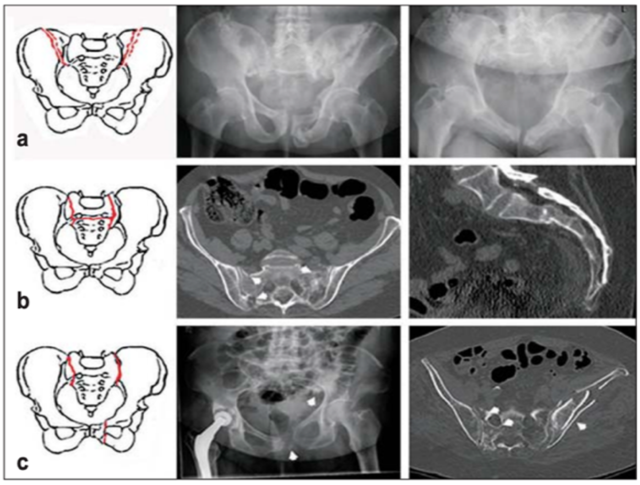


Figure 4: FFP Type IV Fractures, including subtypes a, b, and c. Left to right: Anatomical sketch, plain radiograph (AP), and CT image (axial plane) [49].

Types I and II are stable fractures that do not necessarily require operative stabilisation, whereas unstable fractures (Types III and IV) do. The overall treatment goal should always be early mobilisation with adequate pain relief to ensure the ability of the affected individual to live an autonomous life [35,38,40]. These aspects are explained in more detail below.

3.5 Diagnostics and Management of Fragility Fractures of the Pelvis

All patients initially presenting with pelvic or sacral pain following trauma underwent conventional X-ray imaging. Owing to many overlying structures, such as the bowel and bladder, the posterior part of the pelvis can be difficult to interpret. Fragility fractures are particularly difficult to identify due to altered bone mineralisation, making the bone appear less dense and are therefore often missed. Only 20-38% of sacral fragility fractures are identified in the initial evaluation [56]. Therefore, more detailed CT or MRI-imaging should be performed for all elderly patients presenting with persistent pain to exclude posterior pelvic ring fractures [18,41].

Different treatment approaches are available, depending on the FFP subtype (I-IV). Type I and II fractures are regarded as stable and can, thus, be managed conservatively. However, operative treatment is still a viable option and is sometimes favoured for pain control and mobility. For Type III and IV fractures, surgical treatment is the most frequently chosen management mode because of the mechanical instability of the bony pelvis (**Figure 5**) [38].

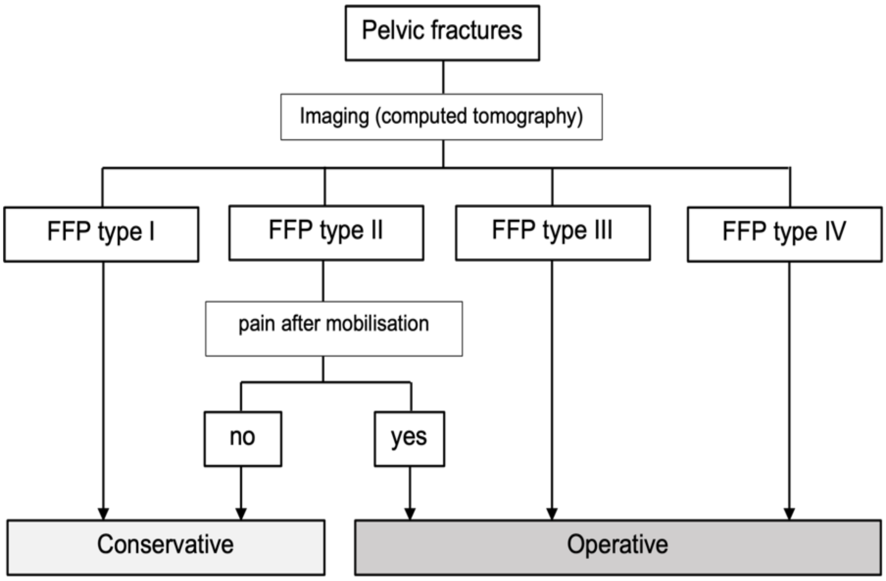


Figure 5: Management pathway according to the Fragility Fractures of the Pelvis (FFP) classification.

Both the conservative and operative treatment options have risks and benefits. On the one hand, the non-operative approach carries the risk of long-term immobilisation, which may cause pneumonia, urinary tract infections, and muscle wasting (bed rest causes a 1-1.5% loss of muscle strength per day [54])[17]. A study conducted by Studer et al. clearly shows a 13% mortality rate within 30 days post-injury in patients treated conservatively following pelvic fracture. According to published data, this was primarily due to exacerbation of underlying cardiovascular disease, and no further complications were discussed [58]. On the other hand, the operative approach carries the risk of anaesthesia- and surgery-related complications, such as haematoma, infection, postoperative delirium, and impaired wound healing. However, the key benefits of early mobilisation must be highlighted.

Most geriatric patients with these types of fractures have been conservatively treated in recent years. This was primarily because only open surgical repair was available in most hospitals. This was linked to significant peri- and postoperative risks, which commonly outweighed the benefits of early mobilisation. Less invasive operative approaches seemed to require costly imaging machinery, which was too expensive for smaller institutions [6]. However, the consequential bedriddenness of patients managed conservatively results in permanent immobility in several cases [30]. A minimally invasive approach using a CT scanner was first described by Taller et al. in 1995 [60]. Over time, this was further refined, providing both an adequate intraoperative overview of screw placement and making minimally invasive treatment approaches financially feasible, even for smaller trauma departments.

3.5.1 Conservative management

This treatment has been the treatment of choice for many years and is still frequently used for stable pelvic fractures. It mainly includes initial bed rest and minimal weight bearing for 6-8 weeks, pain management, physiotherapy and the use of assistive devices after some recovery time. This approach often takes months and may lead to permanent bedriddenness, and consequently, the associated complications discussed previously [9,17,49].

3.5.2 Operative management

There are two types of operative treatment approaches: open and minimally invasive. Both have their own benefits and drawbacks. In general, an open approach may result in prolonged in-hospital treatment; however, it reduces the risk of loosening implants, and therefore, the need for surgical revision. This minimally invasive approach aims to minimise tissue damage as much as possible. It allows for quicker discharge from the hospital and thereby has a lower risk of complications shortly after surgery [19]. The decision regarding the operative approach should be made on an individual basis and should always consider all associated risks and benefits. One aspect that cannot be emphasised enough is the quality of life following pelvic injuries and subsequent surgical treatment.

Several minimally invasive approaches have been developed:

- **Sacroplasty** involves placing cement into the fractured bone using a needle, analogous to vertebroplasty. This aims to form a cast-like structure that stabilises the fracture internally [17,40]. However, Richards et al. showed that in many cases, the strength or stiffness of the sacrum is not fully restored, and the cement distribution is poorly controlled [45].
- Conversely, **minimally invasive screw placement** across the sacroiliac joint has proven sufficiently stable. Some surgeons prefer to introduce a transsacral bar to improve stability [35]. However, a study conducted by Gänssler et al. clearly shows that unilateral screw placement conveys sufficient [19].

3.5.2.1 Intraoperative Imaging

All minimally invasive procedures require intraoperative imaging to ensure adequate screw placement. To date, the most widely used imaging mode in the operating theatre is the C-arm (**fluoroscopy**). It is readily available in most hospitals, cost-effective, and does not expose

patients to high levels of radiation. However, because it only provides a two-dimensional view, it is more time-consuming and has an increased risk of screw misplacement [20]. A study conducted by Gras et al. reported 6% screw misplacement in postoperative CT scans following the use of fluoroscopy for intraoperative imaging [20].
Alternatively, the **CT-*navigated*** approach uses an expensive navigation system. These either reconstruct 3D images using preoperative CT scans, use augmented reality to project into the surgeon's field of view, or use CT-fluoroscopy [5,29,65], thereby indicating the perfect screw position throughout the procedure. Owing to its cost, it is unavailable to most surgeons [6].
As described in this thesis, a simpler alternative is the **CT-*guided*** approach, where the intraoperative visualisation of screw osteosynthesis is performed with a standard CT scanner available in most clinics [44]. All the patients included in this study were treated using the CT-*guided* approach. This method is explained in detail below:

3.5.2.2 Minimally invasive CT-guided sacroiliac screw osteosynthesis

For this operation, the patient was placed under general anaesthesia and positioned on their side (fractured side facing upward). This was performed using a computed tomography (CT) scanner under sterile conditions. Following 3-fold skin disinfection and sterile draping, the operative field was covered with Betadine-Foil®. After preparation was completed, a primary scan was performed to determine the most suitable plane for the screw entry point and angle. The anterior superior iliac spine and the femoral shaft axis were marked as anatomical landmarks. A short skin incision (approximately 1 cm) was made and a bone cannula was inserted along the intended screw path. Control scans were performed until an adequate positioning was achieved. This cannula was then replaced with a guiding wire, the position of which was controlled again with another scan. The cannulated screw, including the washer, was manually introduced over the guidewire. After wire removal, augmentation with Polymethylmethacrylate (PMMA), a polymerising bone cement, was performed in most cases, and wound suturing was performed (**Figure 6**). Postoperatively, CT scans were reconstructed routinely in three planes (axial, coronal, and sagittal) to evaluate and document the final screw position (**Figure 7**).

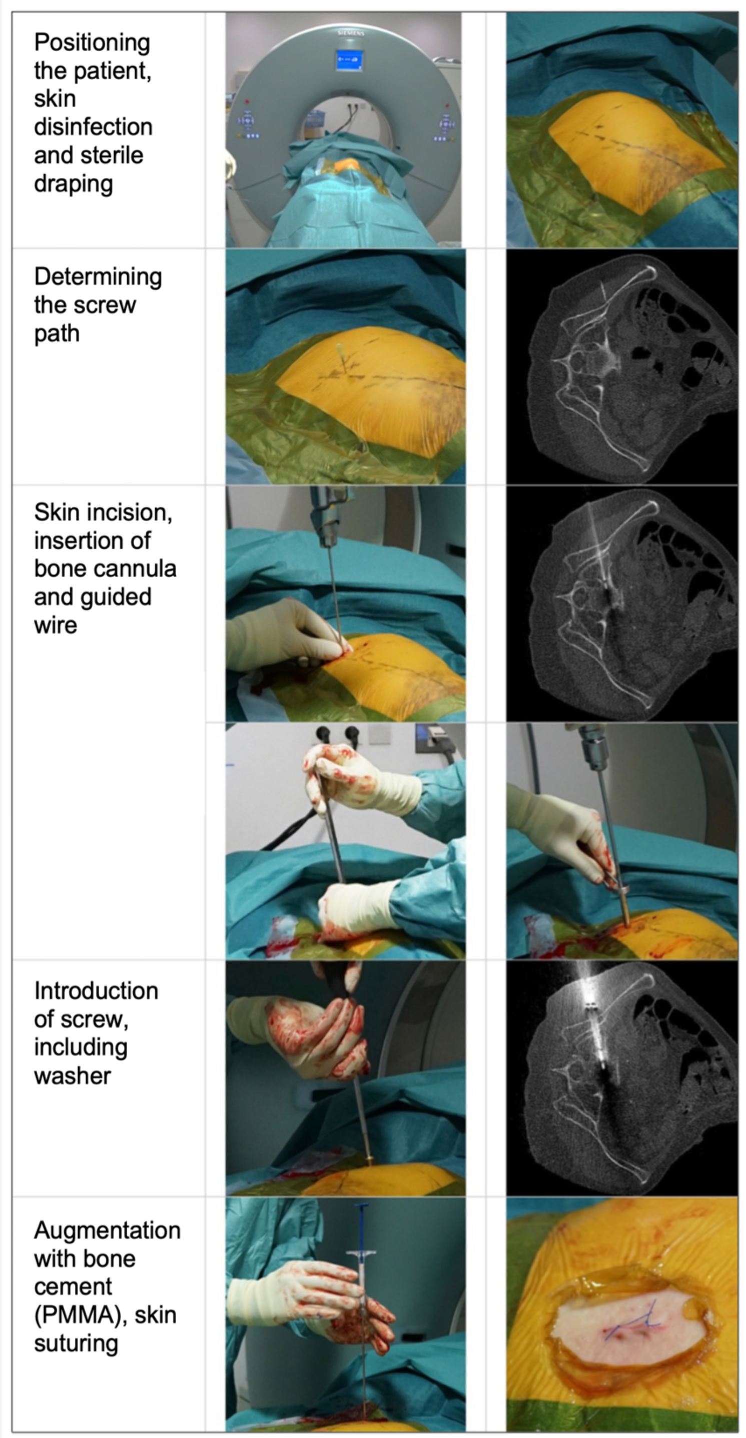


Figure 6: Images of the individual steps of the operational procedure [31].

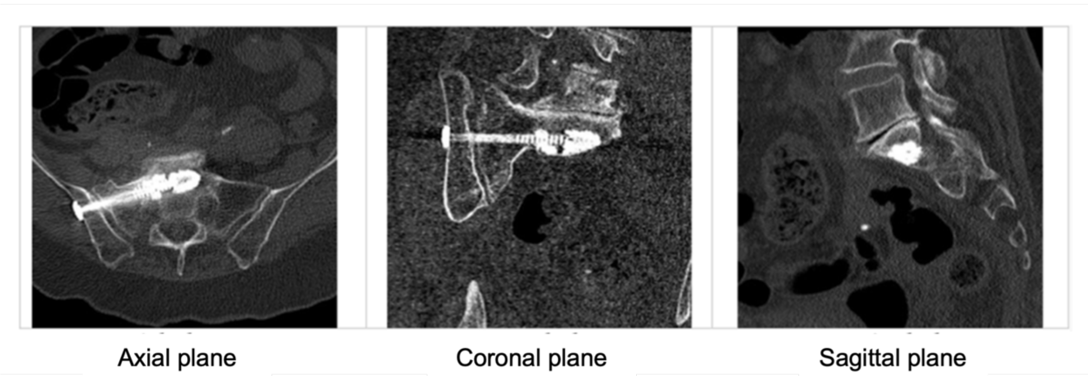


Figure 7: Postoperative CT images in three planes [31].

3.6 Objective of this thesis

This retrospective evaluation aims to compare the CT-guided approach with alternative operative and conservative approaches. The primary outcome is the assessment of the safety and efficacy of the CT-guided method, specifically in the geriatric population. The secondary outcome encompasses examining resource utilisation and the impact on the overall quality of life experienced by individual patients.

4 Material & Methods

4.1 General information

This retrospective cohort study analyses the medical records as well as peri- and postoperative CT imaging of patients who received surgical treatment for fragility fractures of the pelvis at the trauma department of the Marienhaus Klinikum Hetzelstift in Neustadt an der Weinstrasse, Germany, from August 2015 to September 2021. Data were collected solely for scientific research purposes, and all patients included in the study provided written consent for their data to be used anonymously. A sample of the information sheet and consent form are displayed in the appendix.

The data used for this thesis has previously been published under the title “Sacroiliac Screw Placement with Ease: CT-Guided Pelvic Fracture Osteosynthesis in the Elderly” in the 2022 special edition of the Medicina journal titled “Treatment of Spine and Pelvic Fractures in Patients with Osteoporosis” (PMID 35744073).

During the process of writing this thesis, ChatGPT Version GPT-3 and GPT-3.5 (OpenAI, San Francisco, California, USA) were used to assist with phrasing and to facilitate the execution of functions and statistical tests in Excel.

4.2 Operational procedure

4.2.1 Indication

For every geriatric patient presenting to the clinic with suspected pelvic fracture, plain radiography of the hip and pelvis was performed for diagnostic reasons. A CT scan was additionally performed when the radiograph was inconclusive or showed a suspected fracture of the pelvic bone. These scans were then used to diagnose and classify fractures according to the FFP classification [49]. All the patients with FFP I fractures were treated conservatively. FFP III-IV fractures were treated surgically and underwent the operative procedure outlined in the following paragraph. FFP type II fractures received the same surgical repair if the benefits of mobility outweighed the risks of surgery itself. Hence, a patient who had been bedridden previously and had no potential to regain mobility and independence would receive a conservative approach.

4.2.2 The surgical procedure

The surgery was performed on-site in the CT suite using a Siemens Somatom Definition DS 2 x 64 computed tomography machine. The operative procedure itself has been described in detail in the Introduction and is shown in **Figure 6**. The cannulated sacroiliac joint (SIJ) screw (6.5 or 7.5 mm in diameter and 65 - 100 mm in length), and the washers used were manufactured by Marquardt Medizintechnik, Germany.

4.2.3 Postoperative management

Immediately following the operation, patients were transferred to the recovery room before returning to the ward. During the first few days after surgery, patients were treated with a standard postoperative analgesia protocol, including pain-adapted analgesia, subcutaneous low-molecular-weight heparin for thrombosis prophylaxis, and physiotherapy to promote early mobilisation.
If required, the department's social workers ensured post-discharge management, including rehabilitation, ambulatory care services, and care-level classification.

Most patients were directly discharged into rehabilitation clinics to ensure the continuity of physiotherapy and to facilitate a smooth transition back to their homes. Patients were also instructed to avoid heavy lifting for a period of six weeks and to continue thromboprophylaxis until complete mobilisation was achieved. Additionally, a bone density scan was recommended after complete recovery, and if necessary, appropriate treatment targeting osteoporosis was initiated to prevent the occurrence of further fractures.

4.3 Study design

This study retrospectively evaluates the outcomes of minimally invasive CT-guided osteosynthesis with cement augmentation in pelvic fragility fractures.

4.4 Study cohort

A total of 164 patients with FFP type II-IV fractures underwent percutaneous CT-guided repair between August 2015 and September 2021. After applying the inclusion criteria, 88 patients were eligible for the study, and the remaining 76 were excluded. Of these 88 patients, 61 did not consent to participate in the study or passed away prior to the start of the study period. The remaining 27 patients consented to the inclusion of their data. One patient presented twice with fractures on either side, with an interval of only 22 days, resulting in a total of 28 cases. The Consort diagram in **Figure 8** provides a visual representation of the number of patients included in the study.

Of these 28 cases, 25 were female patients, and three were male. The ages of the patients ranged from 67 to 91 years (mean 80.5 years).

4.4.1 Inclusion and Exclusion criteria

Patients presenting with FFP II-IV fractures who underwent CT-guided percutaneous osteosynthesis of the posterior pelvic ring were included. The exclusion criteria included patients under 65 years of age, thus not fitting the geriatric patient group. Patients meeting the eligibility criteria were contacted via telephone or mail, and if they provided informed consent by returning the signed consent form, they were included in the study cohort. The presence of comorbidities did not result in exclusion from the study.
Additionally, patients were excluded from individual measurements and evaluations when data were missing from the documentation.

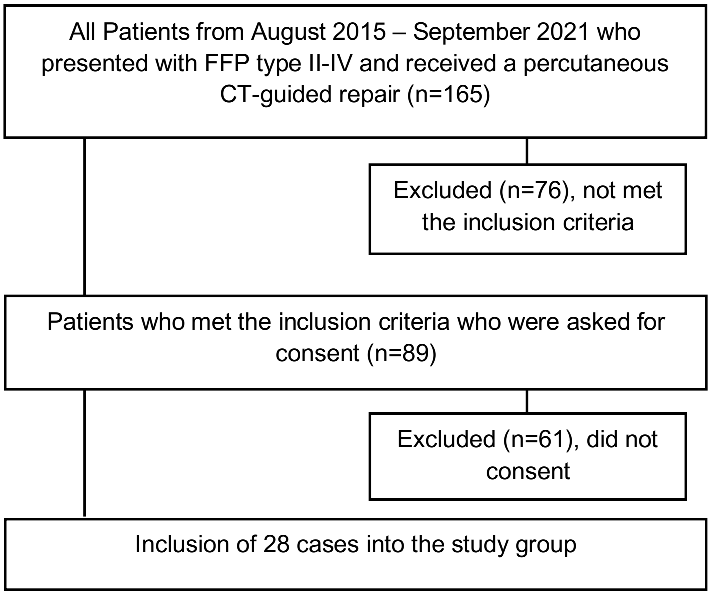


Figure 8: Consort diagram.

4.5 Data collection

Demographic data, as well as information extracted from discharge letters, operation protocols, ward round notes, and drug charts, were obtained using the hospital computer software (iMedOne, Deutsche Telekom Clinical Solutions GmbH), while the CT-imaging was analysed using the software at the radiology department's workstation (NEXUS / RIS^{NG}, NEXUS / CHILI GmbH). Quality of life (QoL) data were collected using a standardised questionnaire (EQ-5D-3L) [15]. The collected data were specified as follows:

4.5.1 Demographic data

- Gender
- Age

4.5.2 Operative Data

Preoperative:

- Information on the mechanism of injury
- Fracture type (FFP classification)
- American Association of Anaesthesiology (ASA) classification
- Comorbidities at admission

Intraoperative:

- Duration of Operation
- Individual surgeon
- Type of screw used during surgery
- Cement volume applied
- Radiation dose (mGy*cm)

Postoperative:

- In-hospital complications (i.e. infection, hematoma, pressure ulcers, etc.)
- Revision surgeries
- Total and postoperative hospitalisation time
- Postoperative pain (using the numeric rating scale (NRS))
- Analgesia requirement additionally to the standard pain medication defined by the standard operating procedure (SOPs)
- Destination following the discharge
- Quality of Life

4.5.3 Analysis of CT-Images

The fractures were classified using CT images obtained at admission and Fragility Fractures of the Pelvis (FFP) classification [49].

Furthermore, CT imaging was used during and at the end of the surgery to assess the following:

- Screw position
- Distance from the cortical bone and neuroforamina
- Possible cement leakage and extent of leakage

Additionally, the radiation exposure (mGy*cm) was calculated for every operation.

The CT images obtained at the end of the operation were assessed in the axial and sagittal planes.

- An axial scan was used to measure the distance of the screw from the neuroforamina at its closest point (**Figure 9**).

- The sagittal plane was used to measure the distance from the screw to the anterior and posterior, as well as to the caudal and cranial borders of the bone. The measurement point was determined by drawing a cross through the centre of the screw (**Figure 10**).

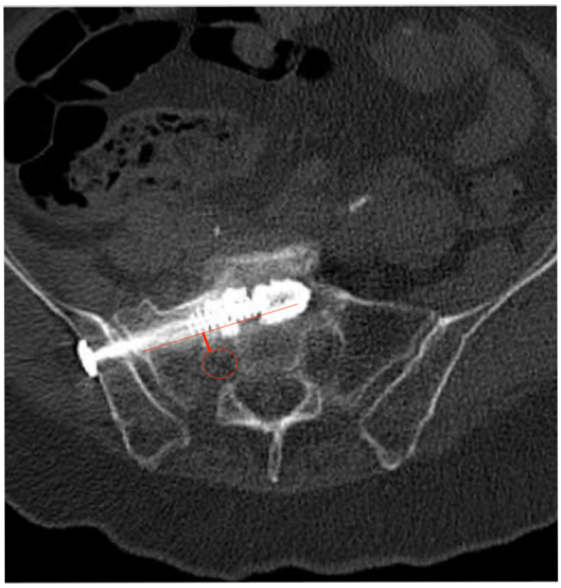


Figure 9: Measurement of the distance of the screw from the neuroforamina on an axial plane CT image. The red markings show how the measurements were performed during data collection.

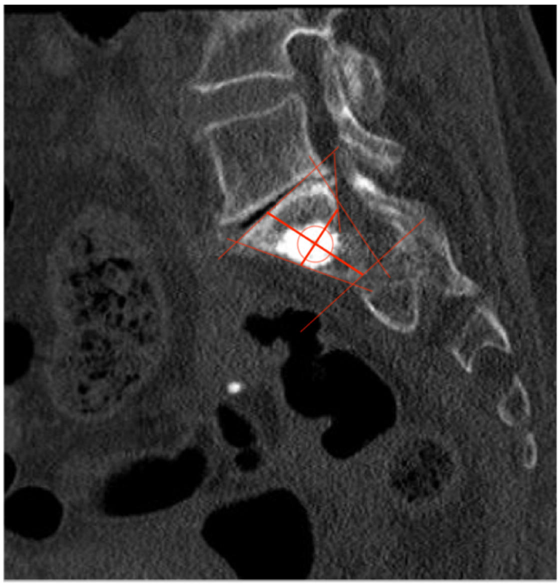


Figure 10: Measurement of the distance of the screw to the anterior, posterior, cranial and caudal border of the bone. Red markings show how the measurements were performed during data collection.

4.6 Quality of life after discharge

The standardised EQ-5D-3L questionnaire assessed the patient's quality of life and was distributed at least six months after the intervention [15,23]. The items enquire about five aspects of an individual's independence in daily living (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Patients provided their responses, which were scored on a scale where one indicated independence in the activity, two indicated limited independence, and three indicated reliance on extensive help. Additionally, the questionnaire included a visual analogue scale (VAS); here, patients could rate their overall health from 0 (representing extremely poor health) to 100 (representing best health) [31]. The complete questionnaire is presented in the Appendix.

4.7 Data Processing and statistical tests

Data were collected using Microsoft® Excel for Mac (version 16.59). All data was arranged in tables and processed accordingly. The following statistical tests were performed using Microsoft® Excel for Mac (version 16.59): percentage, mean, standard deviation, median, and interquartile range (IQR). P-values were calculated using the one-way ANOVA test; if a significance was found, the Turkey HSD test was applied. These analyses were performed using Prism 9 for macOS software (version 9.5.1, GraphPad Software, LLC).

All statistical calculations, except the ones concerning the operative data, were performed using the absolute number 28 (cases) as “Total”. The evaluation of the screw size, the cement volume employed, and the distance measured on CT images used the absolute number 33 (surgical incisions) as “Total”. This number was obtained because 21 patients were operated on one side (absolute number 21), while six patients were operated on two sides simultaneously (absolute number 12), yielding an absolute value of 33. One patient who underwent bilateral surgery was excluded because of missing values.

Demographic data were evaluated using mean, range, and percentage values based on the total and absolute values. To facilitate outcome comparison and assess whether the treatment approach leads to increased complications among older individuals, the cohort was sorted into three distinct age groups: group 1 (aged 65-74 years), group 2 (aged 75-84 years), and group 3 (aged 85-94 years). These groupings were employed in several subsequent analyses to assess the impact of the treatment approach across a spectrum of healthcare parameters, including complications, duration of hospitalisation, and post-discharge care.

The ASA (American Society of Anaesthesiologists) physical status classification system is a widely used medical assessment tool designed to evaluate a patient’s overall physical health and suitability for anaesthesia and surgery. In this instance, it was used to gain a better understanding of the patient’s general health status apart from the list of comorbidities. It was expressed using median values, and fracture type and mechanism were expressed as percentages and absolute values.

The operative data, including screw size and cement volume, were also expressed using percentages and absolute values. The operation duration, radiation, and distance between the screw and cortical bone were expressed using the mean and standard deviation. The p-value was calculated to evaluate whether there was a significant time difference between the procedures performed by different surgeons. The time interval between hospital admission and surgery was expressed as the median.

The total and postoperative hospitalisation times were evaluated using the mean and standard deviation. A p-value was calculated to determine whether there was a significant difference between the hospitalisation times of patients with no and multiple comorbidities. Statistical significance was set at $p \leq 0.05$.

Complications encountered in the postoperative phase were expressed as absolute values and percentages. Pain levels were expressed using the NRS (numeric rating scale), where higher scores indicate more severe pain. The obtained values were displayed as means with standard deviations. The number of patients requiring additional analgesic medication was indicated as a percentage.

The day of discharge post-operation was expressed as a median value with range and interquartile range, and the destination after discharge as a percentage. Quality of Life data were assessed using the mean, standard deviation, median, and interquartile range. The time (in months) that passed between the intervention and data collection was displayed as the median and range.

5 Results

The data displayed in the Results section have been partially published in the MDPI Medicina 2022 journal [31].

5.1 Demographics

Twenty-eight fractures that occurred between August 2015 and September 2021 were included in the analysis. Of these, 25 were female patients (89.3%), and three were male patients (10.7%). The youngest patient was 67 years old and the oldest was 91 years old. The mean age was 80.5 ±6.54 years. The demographic data are also displayed in **Table 1** and **Figure 11**.

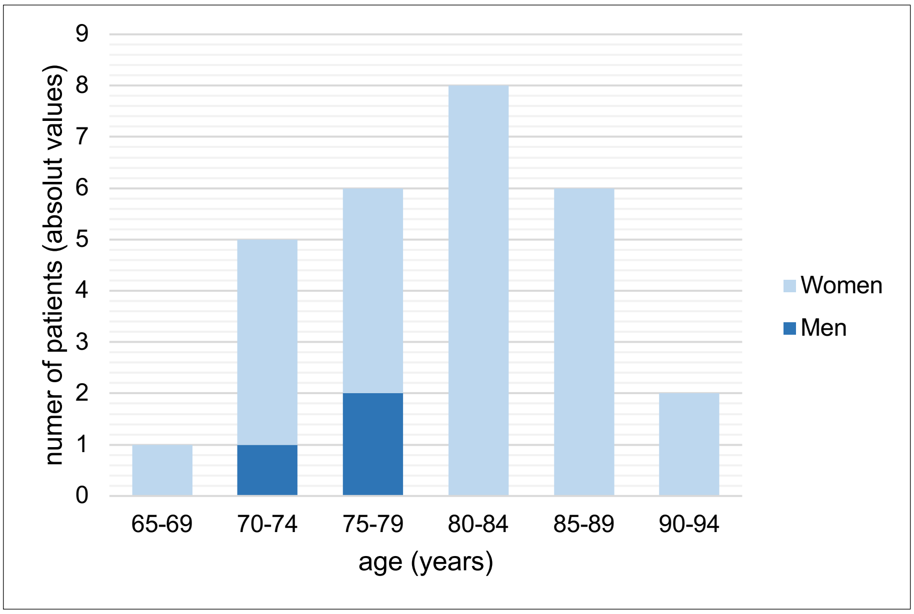
5.2 Comorbidities

Owing to the advanced age of the cohort, every patient presented with at least one comorbidity, and 16 patients (57.1%) had three or more comorbidities. A comorbidity was counted as such if it was mentioned in the discharge letter or listed in the previous medical notes. Cardiovascular conditions and, in particular, hypertension were the most common comorbidities, affecting 23 patients (82.1%). The median ASA score was 3 **(Table 1).**

Table 1: Demographic data, ASA score and co-morbidities, arranged in different age groups and in total. Data is demonstrated in absolute values, percentages, mean and standard deviation.

age (years)		**65-74**	**75-84**	**85-94**	**Total**
gender	male	1 (3.6%)	2 (7.1%)	0 (0.0%)	3 (10.7%)
	female	5 (17.9%)	12 (42.9%)	8 (28.6%)	25 (89.3%)
ASA score	1	0	0	0	0 (0.0%)
	2	1	6	1	8 (28.6%)
	3	5	8	7	20 (71.4%)
	4	0	0	0	0 (0.0%)
	5	0	0	0	0 (0.0%)
comorbidities	average number of comorbidities	3.7 ±1.5	3.1 ±1.5	3.6 ±1.5	3.6 ±1.5
	arterial hypertension	3	13	7	23 (82.1%)
	chronic pain	3	2	1	6 (21.4%)
	coronary heart disease	1	2	6	9 (32.1%)
	diabetes mellitus	2	1	1	4 (14.3%)
	obesity	2	4	3	9 (32.1%)
	atrial fibrillation	1	1	2	4 (14.3%)
	others	5	7	6	18 (64.3%)

Figure 11: Bar diagram visualising the distribution of age and gender within the patient cohort.



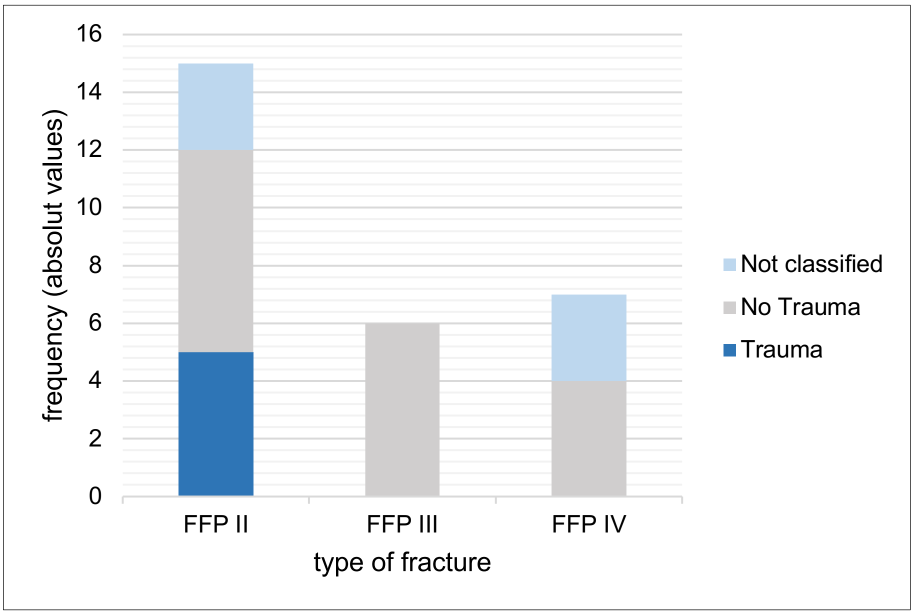
5.3 Fracture type and mechanism of injury

Of the cases admitted, 21 (75.0%) presented with unilateral and seven (25.0%) had bilateral fractures. Fifteen fractures (53.6%) were classified as FFP II, six (21.4%) as FFP III, and seven (25.0%) as FFP type IV. Of these 28 fractures, five occurred following conscious trauma (17.9%) and 17 (60.7%), with no relevant trauma being recalled. In the remaining 6 cases (21.4%), it could not be determined retrospectively whether the fracture had occurred due to trauma. (**Table 2, Figure 12**)

Table 2: Type of fracture and mechanism of injury, arranged in different age groups, including absolute values and percentages.

age (years)		65-74	75-84	85-94	Total
fracture type	FFP II	4	8	3	15 (53.6%)
	FFP IIa	0	0	0	0 (0.0%)
	FFP IIb	4	8	3	15 (53.6%)
	FFP IIc	0	0	0	0 (0.0%)
	FFP III	0	2	4	6 (21.4%)
	FFP IIIa	0	1	1	2 (7.1%)
	FFP IIIb	0	1	1	2 (7.1%)
	FFP IIIc	0	0	2	2 (7.1%)
	FFP IV	2	4	1	7 (25.0%)
	FFP IVba	0	0	0	0 (0.0%)
	FFP Ivb	0	1	1	2 (7.1%)
	FFP Ivc	2	3	0	5 (17.9%)
mechanism of injury	trauma	2	3	0	5 (17.9%)
	no trauma	3	6	8	17 (60.7%)
	not classified	1	5	0	6 (21.4%)

Figure 12: Bar diagram visualising the fracture type and corresponding mechanism of injury.



5.4 The operative procedure

After admission, the operation was performed at a median of six days (IQR 4–8.5 days). This timing was mainly due to the availability of the CT scanner. All patients underwent percutaneous osteosynthesis of the posterior pelvic ring, performed by five different surgeons.

All fractures of the anterior pelvic ring were treated conservatively. There were variations in the screw size used and whether the cement was implanted. The screw size ranged from 6.5x75 mm to 7.5x100 mm. The most used size was 7.5x75 mm (in 39.4% of the cases). PolymethylmethacrylateIn (PMMA) cement was employed in 24 of 33 (72.7%) operative incisions. One patient was excluded due to missing documentation regarding the screw used during the procedure. On average, the duration of the operation was 32.4 ±9.6 minutes for unilateral and 50.7 ±17.4 minutes for bilateral procedures. There was no significant difference in the duration of unilateral procedures among the surgeons (p=0.12) (**Table 3**).

The average intraoperative radiation exposure during the unilateral procedure was 265.2 ±142.7 mGy*cm, while for the bilateral procedure, this almost doubled to 393.4 ±201.3 mGy*cm (**Tables 3**).

Table 3: Comparing the average operative time and radiation exposure between different surgeons and uni-/bilateral procedures. Data is demonstrated in absolute values and mean including standard deviation.

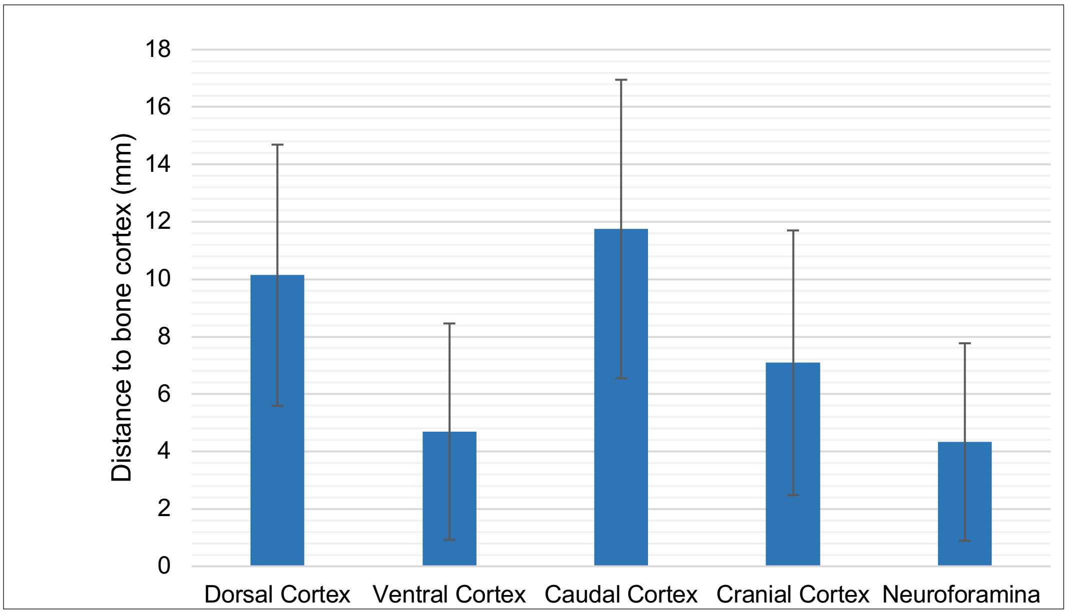
surgeon	**1**	**2**	**3**	**4**	**5**	
unilateral						
number of procedures	5	0	14	2	0	
average time (min)	40	n/a	30	30	n/a	mean 32.4 ±9.6 p=0.12
radiation exposure	558.1	n/a	264.7	236.6	n/a	mean 265.2 ±142.7 p=0.61
bilateral						
number of procedures	2	1	2	1	1	
average time (min)	40	55	45	75	55	mean 50.7 ±17.4
radiation exposure	379.0	780.0	267.5	287.0	n/a	mean 393.4 ±201.3

Skrew placement was evaluated by measuring the relevant distance to the surrounding bony cortices using computed tomography scans conducted at the end of the procedure. The mean distance to the dorsal cortex was 10.1 ±4.5 mm; there was no instance of penetration. The mean distance to the ventral cortex was 4.7 ±3.8 mm, with one case exhibiting a 1 mm cortex penetration. However, this did not necessitate revision surgery. The mean distance to the caudal border was 11.8 ±4.6 mm and 7.1 ±4.6 mm to the cranial border, with no case of cortex penetration observed. The mean distance to the cortex of the neuroforamina was 4.3 ±3.4 mm with no instance of penetration. Cement leakage was detected in 5 of the 24 (20.8%) cases in which it was applied, but none led to nerve injury. None of the cases required revision surgery during the postoperative period. Due to missing CT images from the database, the distance to the cortices and neuroforamina could not be calculated for three and one cases, respectively. (**Table 4, Figure 13**).

Table 4: Measurements of the distance (in mm) from the bone cortex, gained from the operative CT-imaging, demonstrated as mean, including standard deviation.

distance to (mm)	dorsal cortex	ventral cortex	caudal cortex	cranial cortex	neuroforamina
mean ±standard deviation (mm)	10.1 ±4.5	4.7 ±3.8	11.8 ±4.6	7.1 ±4.6	4.3 ±3.4

Figure 13: Distance of the screws to the bone cortex and neuroforamina, visualised as a bar chart including standard deviations.



5.5 Postoperative course

The mean length of total hospitalisation time was 12.1 ±4.6 days, ranging from four to a maximum of 21 days. There was no significant difference between patients who presented with several (≥2) and fewer (<2) comorbidities regarding total (p=0.87) and postoperative hospitalisation (p=0.35) (**Table 5**). Similarly, no significant difference was found between patients presenting with unilateral or bilateral fractures (postoperative hospitalisation, p=0.50; total hospitalisation, p = 0.49) (**Table 5**). However, a significant difference (p=0.04) could be found regarding postoperative hospitalisation between age groups 2 (75-84 years) and 3 (85-94 years), with a reported mean of 6.7 days ±3.8 and 3.0 days ±2.0, respectively (**Table 6**).

Table 5: Comparing the total and postoperative hospitalisation in relation to the number of comorbidities the patients present with at admission and mode of operation (unilateral and bilateral) . Data is demonstrated in mean including standard deviation and p-value.

		total hospitalisation	postoperative hospitalisation
≤2 comorbidities	mean ±SD	12.1 ±4.2	6.4 ±4.3
>2 comorbidities	mean ±SD	12.1 ±5.0	4.5 ±2.7
	p-value	p=0.87	p=0.35
unilateral operation	mean ±SD	12.4 ±4.3	5.5 ±3.7
bilateral operation	mean ±SD	11.0 ±5.6	4.4 ±2.6
	p-value	p=0.49	p=0.50

Table 6: Comparing the total and postoperative hospitalisation of the different age groups. Data is demonstrated in mean including standard deviation and p-value.

age (years)		group1 (65-74)	group 2 (75-84)	group 3 (85-94)	total
total hospitalisation	mean ±SD	10.2 ±6.5	13.4 ±4.2	11.3 ±3.3	12.1 ±4.6
					group 1 & group 2 p=0.36 group 1 & group 3 p=0.90 group 2 & group 3 p=0.58
postoperative hospitalisation	mean ±SD	5.8 ±2.7	6.7 ±3.8	3.0 ±2.0	5.2 ±3.5
					group 1 & group 2 p=0.40 group 1 & group 3 p=0.60 group 2 & group 3 p=0.04

Evaluation of the patient's postoperative well-being included assessing complications, measuring pain levels, and identifying the requirement for additional analgesic medication.
On the first day following surgery, patients reported an average pain rating of 1.3 ±1.0 out of 10 on the numeric rating scale (NRS). Five (17.9%) patients required supplementary analgesics.

The most common complications experienced by 18% of patients during the recovery period after surgery were urinary tract infections, decubitus, and mild cases of delirium. However, the overall length of hospital stay remained unaffected (p=0.87) (**Table 7**). Notably, there were no cases of in-hospital mortality, and no neurological palsy or vascular lesions were reported after surgical intervention.

Table 7: Comparing the total hospitalisation (in days) with regards to complications encountered in the postoperative phase. Values given as mean including standard deviation.

total hospitalisation (days)	complications encountered	no complications encountered	total
mean ±SD	12.4 ±5.9	12.0 ±4.4	12.1 ±4.6 p=0.87

5.6 Discharge

Following the completion of the surgical procedure, the patients were discharged from the hospital after a median duration of 4 days (range 1 - 14 days, interquartile range of 3 - 7.5 days). To quantify patients' recovery, their post-discharge destinations were documented. Ten patients (35.7%) were transferred directly to rehabilitation clinics. In comparison, twelve patients (42.9%) were transferred to geriatric clinics, and five patients (21.4%) were discharged to their pre-admission place of residence.

To assess the long-term overall outcome, the patients were asked to complete the EQ-5D-3L QoL (Quality of Life) questionnaire. This was sent via post at least six months after discharge from the hospital. Out of the 28 cases, 18 patients returned the questionnaire. The median time for questionnaire completion was 19.5 months after discharge, with the most extended interval being 76 months and the shortest the minimum required six months.
Answers were scored on a scale from one to three. Patients provided a mean score of 1.6 ±0.6 out of 3 regarding their general mobility. Independent self-care was rated with a mean score of 1.6 ±0.7, whereas activities of daily living achieved a score of 1.8 ±0.8. Pain was rated at 1.8 ±0.6, and general anxiety at a score of 1.8 ±0.8.
The Visual Analogue Scale (VAS), included in the questionnaire, measured overall health on a score from zero to 100 and yielded a mean score of 55.6 ±25.6, and a median of 60.0 ranging from 10 to 95 (IQR 0–60). **Table 8** displays the data obtained from the ED-Q5 questionnaire. No significant differences were found between the different age groups.

Table 8: Comparing the results of the ED-Q5 Questionnaire between the three different age groups. Values given as mean including standard deviation.

age (years)	group 1 (65-74)	group 2 (75-84)	group 3 (85-94)	total
mobility	2.0 ±1.0	1.3 ±0.5	1.7 ±0.5	1.6 ±0.6
self-care	2.3 ±1.2	1.4 ±0.5	1.5 ±0.6	1.6 ±0.7
usual activities	2.3 ±1.2	1.6 ±0.7	1.8 ±0.8	1.8 ±0.8
pain/discomfort	2.3 ±0.6	1.7 ±0.7	1.7 ±0.5	1.8 ±0.7
anxiety depression	2.3 ±1.2	1.7 ±0.5	1.7 ±1.0	1.8 ±0.8
visual analogue scale (VAS)	38.3 ±40.7	63.1 ±25.9	54.2 ±15.0	55.6 ±25.6

6 Discussion

Fractures of the posterior pelvic ring are a common fracture entity encountered by elderly patients [3,18,53]. Operative management of fragility fractures of the pelvis using CT-guided osteosynthesis of the posterior pelvic ring has several advantages. It has been proven to be a precise, quick, and safe method for treating fragility fractures of the pelvis in the elderly. This retrospective study analysed the perioperative and postoperative outcomes of 28 geriatric cases. However, several treatment approaches exist, including conservative and alternative surgical methods. In the following section, the outcomes of this study are discussed and compared with those of similar studies that have been previously published and studies that evaluate alternative treatment approaches.

6.1 Demographics

The demographic characteristics of our patient cohort exhibit similarities to the participants enrolled in the study conducted by Rommens et al. in 2021 and Eckardt et al. in 2017, both of which focused on the operative management of geriatric patients. They reported an average age of 77.4 and 79.1 years, respectively, with females representing the majority at 89.3% and 86.0% [14,52]. However, overall, our patient cohort displayed a relatively advanced age compared to most studies analysing the outcome of this specific operative technique, with an average age of 57.4 years in these studies [4,17,29,44,46,63].

The markedly higher proportion of female participants in this study, as well as in other study cohorts, is attributed to a combination of factors, including a higher life expectancy and increased risk of osteoporosis [18,28].

6.2 Precision

The assessment of the CT scans of our patient cohort revealed comparable outcomes regarding screw position and the rate of cortical bone or neuroforamen perforation in the study conducted by Reuther et al. [44]. They evaluated a similar CT-guided approach; however, they did not limit the patient group to geriatric patients. Their investigation reported only a few cases where the screw lay within the cancellous bone, but reported no penetration. There was only one case (5.6%) of cortical bone penetration in our cohort.

In contrast, a study by Richter et al., which evaluated a computer-assisted approach using a C-arm to construct a 3D scan, reported a notably higher perforation rate of 16% [46].

Notably, radiation exposure in our patients during unilateral procedures was 28% lower than that reported by Reuther et al., while it was comparable to bilateral procedures conducted with

CT guidance [44]. The study conducted by Eckhardt et al. reported a mean radiation of 449.6 mGy*cm, according to 266.4 mGycm per screw [14], making their results comparable to our outcome with an average radiation of 265.2 mGy*cm per screw.

6.3 Duration of surgery

A shorter duration of surgery was observed compared with similar studies. Other authors reported operating times of up to 62 minutes per side using a non-augmenting technique, compared to a mean of 32 minutes in our study [20]. The study conducted by Eckardt et al. also reported a mean operation time of 63 min; however, it must be considered that they implanted two trans-sacral bars during the surgical procedure [14]. Reuther et al. reported a much shorter time, with an average of 23 minutes for unilateral and 35 minutes for bilateral CT-guided procedures [44]. The observed discrepancy in operating times can be attributed to various factors, including potentially different methods of documentation and data evaluation. We used the time recorded on the anaesthesiologists' protocols, while others relied on the time imprinted on the first and final CT scans.

Furthermore, our data demonstrated a 10% reduction in the operating time when comparing the data from August 2015 to August 2020 with that from September 2020 to September 2021. This decline suggests a continuous improvement in the individual surgeon's expertise and proficiency over time.

6.4 Safety

Owing to the increased age of our cohort, the frequency of comorbidities is also increased. This naturally puts patients at increased risk of in-hospital complications. The complications encountered in our patients were similar to those described in the studies by Rommens et al. and Jäckle et al., the most frequent being urinary tract infections and decubitus [26,52]. The complications found in our patients are also comparable to those of the general population, as the second most common medical condition experienced by geriatric patients is urinary tract infection [1]. Additionally, decubitus and delirium are the most common complications encountered by hospitalised geriatric patients [47], which were also experienced by patients in our cohort.

In our study, the procedure was performed by five different surgeons. The outcomes were similar for all patients, supporting the hypothesis that this approach is safe for use in various facilities and staff.

6.5 Clinical Outcomes

The postoperative pain levels reported by our patients were lower than those reported in similar studies published to date. Rommens et al. reported a median score of 4 on the NRS [52], while our patients reported a median score of 1.3. Compared with studies evaluating conservative treatment, our patients reported less pain. A study by Timmer et al. reported a mean NRS score of 3 for patients with combined anterior and posterior fractures and a score of 5 for isolated anterior fractures two weeks after the fracture was diagnosed [62].

Additionally, the length of postoperative hospitalisation was the same or shorter than that in comparable studies that examined patients who underwent minimally invasive procedures. The median total hospitalisation was reported to be between 12 and 17 days, compared with 12 days in our case [20,52].
In contrast, studies analysing open-operative procedures described extended hospitalisation periods, with Rommens et al. reporting an average of 18 days [52].

However, it must be considered that the duration of hospitalisation is influenced not only by the individual patient’s health status and recovery process but also by systemic factors. For example, the period preceding the intervention varied as the department in our study had to wait for the allocated time slots to use the CT suite. At the same time, postoperative hospitalisation varied significantly owing to the capacity of rehabilitation clinics and nursing homes. This may explain why the oldest patient group (85-94 years) had a significantly shorter postoperative hospitalisation period. A substantial proportion of patients had already been admitted to nursing homes or possessed adequate home-based care prior to hospitalisation. Consequently, these patients could be discharged much sooner without the need to wait for the availability of such facilities.

Overall, the observed distribution of post-discharge destinations provides good insight into the overall recovery process of individual patients. This highlights the success of the surgical procedure in achieving a level of recovery that allows a substantial proportion of patients to return to their pre-admission place of residence, indicating an essential accomplishment of the treatment goal.

6.5.1 Quality of life following surgery

The patients expressed overall satisfaction with their quality of life, which was effectively preserved through the operative intervention. Overall, the quality of life was scored < 2 for all parameters, indicating that most patients could independently perform activities of daily living and self-care without requiring assistance. This achievement highlights the successful realisation of the primary treatment objective.

In a study conducted by Janssen et al. in 2021, the results of the visual analogue scale (VAS) and ED-Q5 questionnaire were evaluated in a diverse population in Germany. Among the population aged ≥75 years, the VAS score was reported to be 62.8 [27]. In contrast, our patients obtained a VAS score of 55.6, demonstrating that their quality of life was well maintained and comparable to that of individuals of a similar age in the broad population.

6.6 Limitations

This study has several limitations that should be considered. Firstly, the small study cohort comprised of only 28 cases. This limited sample size affects the generalisability of our findings to a broader population.
Secondly, the retrospective study design itself. The lack of previously planned follow-up appointments makes it challenging to comprehensively assess patient outcomes over time. Also, this limits the possibility of comparing the data to other studies.
Additionally, there was poor participation in the Quality of Life (ED-Q5) questionnaire, with only 18 of the 28 patients returning the questionnaire. This may be due to the advanced age of the patients. However, owing to the long interval between surgery and data collection, several patients moved to another address and were hence lost to follow-up.
Lastly, this study was conducted within a single hospital, which limits the broader applicability of our results and makes it more prone to institutional bias.

Future studies are needed to further explore the important field of geriatric orthopaedics, focusing on a larger and more diverse cohort, prospective design, and multicentre investigations to enhance the robustness and generalisability of our findings.

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8 Publication

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(Article)

Sacroiliac screw placement with ease: CT-guided pelvic fracture osteosynthesis in the elderly

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Abstract:

Background and Objectives: The number of geriatric patients presenting with fragility fractures of the pelvis is increasing due to ageing Western societies. There are conservative and several operative treatment approaches. Many of which cause prolonged hospitalisation, so patients become bedridden and lose mobility and independence. This retrospective study evaluates the postoperative outcome of a CT-guided minimally invasive approach of sacroiliac screw osteosynthesis. The particular focus is to demonstrate its ease of use, feasibility with the equipment of virtually every hospital and beneficial outcomes to the patients.

Materials and Methods: 27 patients (3 men, 24 women, age 80.5 ±6.54 years) with fragility fractures of the pelvis types II-IV presenting between August 2015 and September 2021 were retrospectively reviewed. The operation was performed using the CT of the radiology department for intraoperative visualization of screw placement. Patients only received screw osteosynthesis of the posterior pelvic ring and cannulated screws underwent cement augmentation. Outcomes measured included demographic data, fracture type, postoperative parameters and complications encountered. The quality of life was assessed using the German version of the EQ-5D-3L.

Results: The average operation time was 32.4 ±9.6 minutes for the unilateral and 50.7 ±17.4 for the bilateral procedure. There was no significant difference between surgeons operating (p=0.12). The postoperative CT scans were used to evaluate the outcome and showed only one case of penetration (by 1 mm) of the ventral cortex, which did not require operative revision. No case of major complication was reported. Following surgery, patients were discharged after a median of 4 days (Interquartile range 3-7.5). 53.4 % of the patients were discharged home or to rehabilitation. The average score on the visual analogue scale of the EQ-5D-3L evaluating the overall wellbeing was 55.6 (IQR 0-60).

Conclusions: This study shows that the operative method is safe to use in daily practice, is readily available and causes few complications. It permits immediate postoperative mobilization and adequate pain control. Independence and good quality of life are preserved.

Keywords: fracture, osteoporosis, spine, pelvis

1. Introduction

Fractures of the pelvis often occur due to high energy trauma such as car accidents or falls from great heights. In the elderly population, however, they can arise after only a minor impact, such as a fall from a sitting or standing position. In some instances, a traumatic event may not even be memorable [1,2]. Due to the demographic change, these so-called insufficiency fractures are constantly increasing in number [3] and significant morbidity and mortality ensue [4].

Pelvic fractures in the elderly are also known as Fragility Fractures of the Pelvis (FFP) [5]. They arise due to low bone mineral density and are considered to be of the osteoporotic fracture entities [6]. Therefore, most patients suffering from these fractures are women of old age, as the female gender conveys a higher risk for osteoporosis [2]. Additionally, these patients have a greater chance of comorbidities, which naturally puts them at a higher risk for complications and early death.

Patients often present with great pain and immobility. When using conventional X-ray examination, this fracture entity is often missed. Computed tomography is essential for a thorough assessment and detection of complications. Different treatment approaches are available depending on the FFP subtype (I-IV). FFP type I describes fractures of the anterior pelvic ring only. FFP type II includes non-displaced fractures of the posterior pelvic ring. Whereas FFP type III are displaced unilateral fractures of the posterior pelvic ring, FFP IV are bilateral displaced fractures of the posterior pelvic ring [7].

FFPs can be handled either conservatively or operatively. Either approach should mainly focus on pain relief and early mobilization to reduce the rate of complications and improve the overall long-term outcome. Both treatment modes have risks and benefits. The non-operative approach, on the one hand, bears the risk of long-term immobilization, which may result in pneumonia, urinary tract infections and muscle wasting (bed rest causes a 1-1.5% loss of muscle mass every day [8]), resulting in loss of independence.

The operative approach, on the other hand, often results in earlier mobilisation but bears the risk of anaesthesia and the operation itself: hematoma, infection and impaired wound healing.

The latter favours operation modes with as minor tissue damage as possible. A minimally-invasive approach allows for a quicker discharge from the hospital and thereby has a lower risk of complications in the time shortly after surgery [9]. Several minimally-invasive approaches exist: Sacroplasty has been shown by Richards et al. to not fully restore strength or stiffness of the sacrum and cement distribution is poorly controlled [10]. Conversely, minimally-invasive screw placement across the sacroiliac joint has proven to be sufficiently stable. Some surgeons prefer introducing a transsacral bar (Bilateral screws and an additionally screw on the side of the fractures) to further improve stability [11]. However, a study conducted by Gänssler et al. clearly shows that unilateral screw placement is sufficient to achieve clinical improvement [12]. We used this method and augmented the screw after placement. One cannulated screw per fractured side was embedded in PMMA cement. This provides increased stiffness and pull-out resistance, as described by Wähnert et al. [13]. These minimally-invasive screw placements may be monitored using a C-arm (fluoroscopy) in the operation theatre. To date, this is the most widely-used mode of imaging, but as it only provides a two-dimensional view, it is more time-consuming and bears an increased risk of screw misplacement [14]. A study conducted by Gras et al. reported a 6 % screw misplacement in postoperative CT scans following fluoroscopy for intraoperative imaging [14]. Alternatively, placement can be performed as a CT-navigated approach. This uses an expensive navigation system that indicates the optimal screw position. Due to its cost, this is unavailable to most surgeons [15]. A more straightforward alternative, as described here, is the CT-guided approach, where the screw-osteosynthesis is performed in a standard CT scanner for intraoperative visualisation [9].

This paper analyses the outcome of osteosynthesis of FFPs type II-IV managed with the minimally- invasive CT-guided percutaneous surgical procedure.

There are many papers published on the outcome of the different surgical procedures and several papers analyzing data on pelvic fractures in geriatric patients. However, little research has been published about this operative technique solemnly used on fragility fractures.

2. Materials and Methods

This study retrospectively analysed the medical records and postoperative CT imaging of patients treated in the Department of Traumatology of the Marienhaus Klinikum Hetzelstift in Neustadt an der Weinstrasse, Germany, between August 2015 and September 2021. Patients who presented with an FFP II-IV fracture and received treatment using the CT-guided percutaneous osteosynthesis of the posterior pelvic ring were included. Patients under the age of 65 years and who did not consent to participate were excluded.

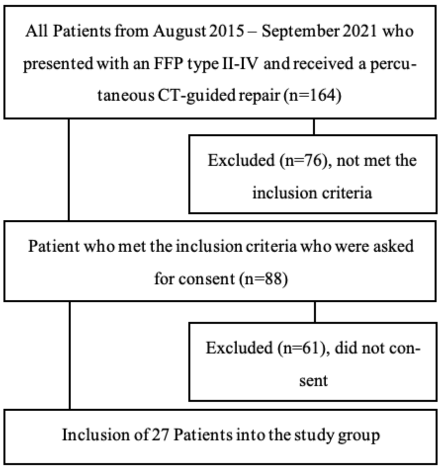

Figure 1. Consort Diagram

The fractures were classified using the Fragility Fractures of the Pelvis (FFP) classification published by Rommens and Hofmann [7]. All patients with FFP II-IV were treated surgically and received the operative procedure as described below.

The operation took place in the computed tomography (CT) scanner under sterile conditions in general anaesthesia. The patient was positioned sidewards. Following 3-fold skin disinfection and sterile draping, the first scan was performed. Thereby the most suitable plane for the screw entry point and –angle was determined. A short skin incision (approximately 1 cm) was made and a bone cannula inserted in the intended screw path. Control scans were performed until adequate positioning was achieved. Then this cannula was replaced by a guiding wire, the position of which was controlled again with another scan. The screw, including a washer, was introduced manually. After removing the guided wire, augmentation with PMMA was performed and wound suturing ensued (**Figure 2**).

The following demographical data were collected: gender, age and comorbidities at admission. The medical records were analysed for: further information on the mechanism of injury, American Association of Anesthesiology (ASA) classification, type of screw, cement volume applied, time of operation, total hospitalisation time, postoperative hospitalisation time, postoperative pain (using the numeric rating scale (NRS)) and analgesia requirement additional to the standard pain medication SOPs, rehabilitation institution after discharge, in-hospital complications (i.e. infection, hematoma, pressure ulcers, etc.), revision surgeries and whether the patients returned to their homes after discharge. The CT images were analysed for FFP classification, screw position, distance from the cortical bone and cement leakage. Additionally, the amount of radiation (mGy*cm) was collected for every operation. The axial scan was used to analyze the distance of the screw from the neuroforamina, the sagittal plane to analyze the distance to the anterior and posterior border and the distance to the caudal and cranial border of the bone. Additionally, the cases of cement leakage and the amount of leakage were analysed using the axial, sagittal and coronal planes.

Furthermore, the postoperative quality of life was assessed using the standardised EQ-5D-3L questionnaire [16,17]. The patients received this questionnaire at least six months after the operation. Its items enquire about five different aspects of their mobility and independence in daily living. The answers given by the patients were scored. One being independent in the activity and three being reliant on help. Patients were additionally asked to score their overall health on a visual analogue scale from 0 to 100 (zero being extremely poor health and 100 in best health).

The data was collected using Microsoft Excel®. The following statistical tests were retrieved: mean, standard deviation, median, interquartile range and the one-way ANOVA test was employed to calculate p values. A p-value <0.05 was considered statistically significant.

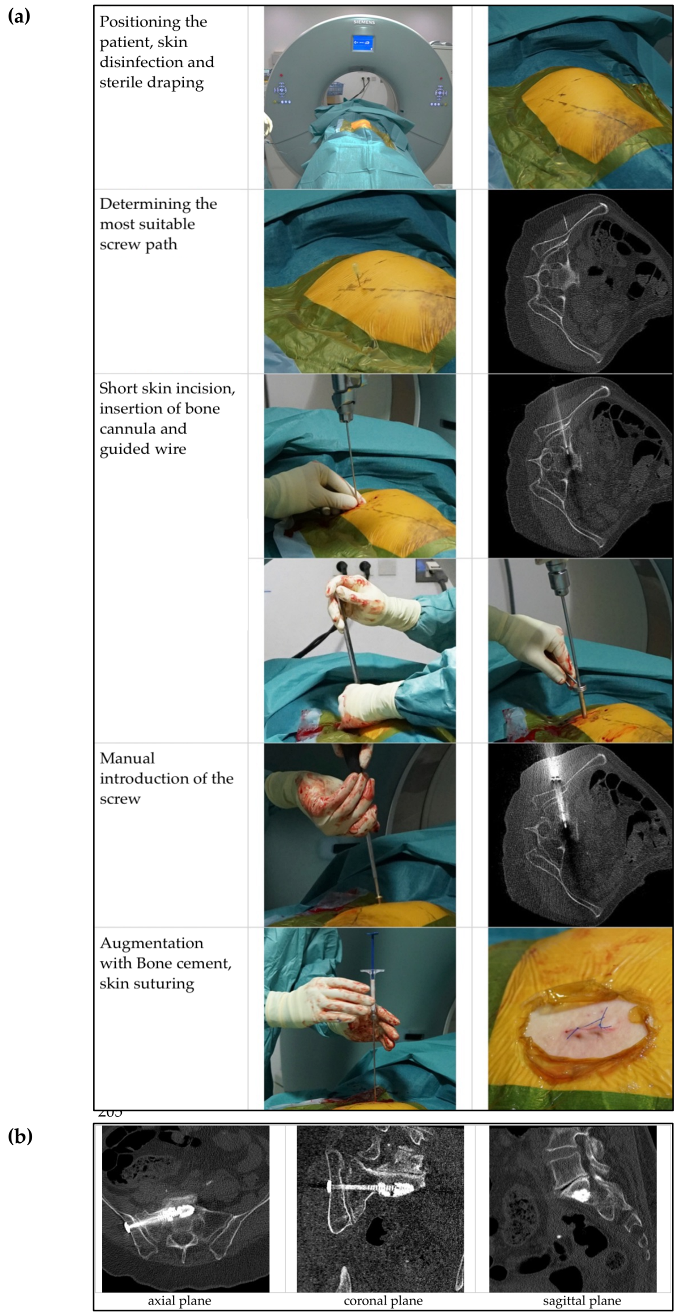

Figure 2. (a) Operational Procedure, (b) Post-operative CT-scans

3. Results

3.1 Demographics

Of the 28 fractures treated, 25 were of female (89.3 %) and 3 of male (10.7 %) gender. The mean age was 80.5 ±6.54 years (**Figure 3**). The youngest patient was 67 years old, whereas the oldest was 91 years old. All patients presented with at least one comorbidity and 16 patients (59.3 %) with three or more comorbidities. A comorbidity was registered as such as soon as it was mentioned in previous medical notes or the discharge letter. Previously diagnosed cardiovascular conditions were quite common conditions to be met. Hypertension was the most common, with 23 patients (82.1 %) affected. The median ASA score was 3 (mean 2.7, **Table 1)**.

Of the patients admitted, 21 presented with a unilateral fracture (75.0 %). Of these, one was readmitted just two weeks after discharge with a fracture on the other side and hence, was counted as two fractures/patients for evaluating the operative data. Seven patients presented with bilateral fractures. 15 incurred an FFP II (63.6 %), 6 an FFP III (21.4 %) and only 7 an FFP type IV fracture (25.0%). Of these 28 fractures treated, 5 followed a conscious trauma (17.9 %) and 17 were considered to have insufficiency fractures for which no relevant trauma was recalled (60.1%). In 6 cases (21.4 %), it could not be determined retrospectively whether the fracture occurred due to trauma or not. (**Table 1, Figure 4**)

Table 1. Demographic data, fracture subtype and type of injury of our patient cohort.

Age (years)		65-74	75-84	85-94	Total
Gender	Male	1 (3.57 %)	2 (7.14 %)	0 (0.00 %)	3 (10.71 %)
	Female	5 (17.86 %)	12 (42.86 %)	8 (28.57 %)	25 (89.29 %)
ASA score	1	0	0	0	0 (0.00 %)
	2	1	6	1	8 (28.57 %)
	3	5	8	7	20 (71.42 %)
	4	0	0	0	0 (0.00 %)
	5	0	0	0	0 (0.00 %)
Comorbidities	Average number of comorbidities	3.67 ±1.51	3.07 ±1.54	3.63 ±1.51	3.57 ±1.50
	art. hypertension	3	13	7	23 (82.14 %)
	chronic pain syndrome	3	2	1	6 (21.42 %)
	coronary heart disease	1	2	6	9 (32.14%)
	diabetes mellitus	2	1	1	4 (14.29 %)
	obesity	2	4	3	9 (32.14 %)
	atrial fibrillation	1	1	2	4 (14.29 %)
	Others	5	7	6	18 (64.29 %)
Fracture Type	FFP IIa	0	0	0	0 (0.00 %)
	FFP IIb	4	8	3	15 (53.47 %)
	FFP IIc	0	0	0	0 (0.00 %)
	FFP IIIa	0	1	1	2 (7.14 %)
	FFP IIIb	0	1	1	2 (7.14 %)
	FFP IIIc	0	0	2	2 (7.14 %)
	FFP IVa	0	0	0	0 (0.00 %)
	FFP IVb	0	1	1	2 (7.14 %)
	FFP IVc	2	3	0	5 (17.86 %)
Mechanism of Injury	Trauma	2	3	0	5 (17.85 %)
	No Trauma	3	6	8	17 (60.71 %)
	Not classified	1	5	0	6 (21.43 %)

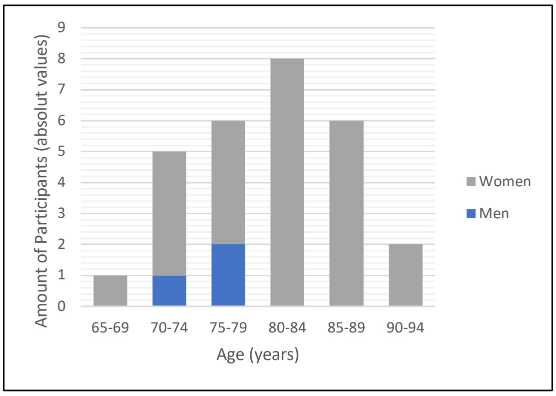

Figure 3. Bar diagram representing the distribution of gender and age within the study cohort

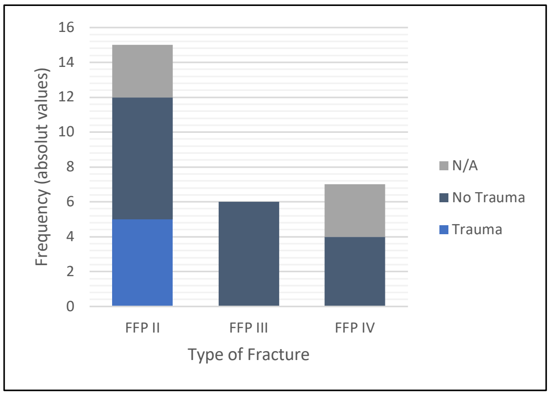

Figure 4. Bar diagram representing fracture classification and mechanism of injury encountered

3.2 The operative procedure

Regardless of the FFP subtype II-IV, all patients received percutaneous osteosynthesis of the posterior pelvic ring by 5 different surgeons. None of the patients received osteosynthesis of the anterior pelvic ring. However, there was variation in the screw dimensions and whether cement was implanted. The screws varied in size from 6.5x75 mm to 7.5x100 mm. Most commonly, the 7.5x75 mm screw was used (39.4 %). In 24 out of 33 operational procedures, PMMA (polymethylmethacrylate) cement was employed (72.7 %). One patient had to be excluded as there was no documentation on the screw used during the procedure. On average, the time taken for the operation was 32.4 ±9.6 minutes for one side and 50.7 ±17.4 minutes when both sides were operated upon. There was no significant difference in the time required to conduct the unilateral procedure between surgeons (p=0.12). The average radiation dose the patients were exposed to during the unilateral procedure was 274.0 ±138.3 mGy*cm and for the bilateral procedure 472.0 ±201.3 mGy*cm (**Tables 2.1** and **2.2)**.

The position of the screws was analysed using the CT scans taken at the end of the procedure. On average, the distance to the dorsal cortex was 10.1 ±4.6 mm; there was no penetration in any case. The average distance to the ventral cortex was 4.7 ±3.8 mm; there was a cortex penetration in one case by 1 mm. However, this did not require revision surgery. The average distance to the caudal border of the bone was 11.8 ±5.2 mm and to the cranial border 7.1 ±4.6 mm, with no case of penetration of the cortex. The mean distance to the cortex of the neuroforamina was 4.4 ±3.4 mm with no case of penetration. Cement leakage could be detected in 5 of 33 operations (15.2 %), but none affected nerves. Three patients had to be excluded due to missing CT-images. None of the cases required revision surgery (**Table 3**).

Table 2.1. Outcomes of unilateral surgery.

Surgeon	Number of procedures	Average Time (min)	Radiation exposure (mGy*cm)
1	5	40	558.14
2	0	N/A	N/A
3	14	30	264.72
4	2	30	236.60
5	0	N/A	N/A
		Mean 32.38 ±9.57 (p=0.12)	Mean 265.17 ±142.68 (p=0.61)

Table 2.2. Outcomes of bilateral surgery.

Surgeon	Number of procedures	Average Time (min)	Radiation exposure (mGy*cm)
1	2	40	379.00
2	1	55	780.00
3	2	45	267.54
4	1	75	287.00
5	1	55	N/A
		Mean 50.71 ±17.42	Mean 393.35 ±201.30

Table 3. Data gained from the postoperative CT-images. Measurement of distance from the cortex.

Distance (mm) to:	posterior cortex	anterior cortex	caudal cortex	cranial cortex	neuroforamina
Average values (mm)	10.14 ±4.54	4.69 ±3.77	11.75 ±4.61	7.09 ±4.61	4.33 ±3.44

3.3 Postoperative course

The median length of hospitalisation was 12 days, the shortest stay being just four and the longest 21 days (IQR 9–15.5 days). The operation was performed at a median of day six after admission due to the availability of the CT scanner. There was no significant difference between patients who presented with several comorbidities and patients with only one or no comorbidity regarding the total (p=0.87) and the postoperative hospitalisation (p=0.35) (**Table 4** and **Table 5**). 18 % of patients suffered from minor complications, the most frequent being urinary tract infections and bedsores. These did not influence the length of total hospitalisation. There was no in-hospital mortality, no neurological palsy or vascular lesion following surgery.

The patients' postoperative wellbeing was assessed by evaluating the complications encountered, the pain and the analgesia requirements. The average pain stated by the patients on the NRS (numeric rating scale) was 1.32 ±0.95 out of 10 on the first postoperative day. Only five patients (17.9 %) required additional analgesics.

Table 4. Total and postoperative hospitalisation in the different age groups.

Age		65-74	75-84	85-94	Total
Total hospitalisation (days)	mean	10.17	13.36	11.25	12.07
	standard deviation	±6.52	±4.24	±3.30	±4.59
	median	8.00	13.00	12.00	12.00
	IQR	5-16	11-16	9-14	9-15.5
					p = 0.32
	mean	5.83	6.71	3.00	5.21

Postoperative hospitalisation (days)	standard deviation	±2.73	±3.77	±2.00	±3.46
	median	3.50	9.50	3.00	4.00
	IQR	3-7	4-10	1-4.5	3-7.5
					p = 0.04

Table 5. Total and postoperative hospitalisation of patients who received unilateral compared to a bilateral surgery.

Age		Unilateral procedure	Bilateral procedure	Total
Total hospitalisation (days)	mean	12.43	11.00	12.07
	standard deviation	±4.30	±5.60	±4.59
	median	12.00	9.00	12.00
	IQR	9.5-15.5	7-16	9-15.5
				p = 0.50
Postoperative hospitalisation (days)	mean	10.17	13.36	5.21
	standard deviation	±6.52	±4.24	±3.46
	median	8.00	13.00	4.00
	IQR	5-16	11-16	3-7.5
				p = 0.50

3.4 Discharge

Following surgery, patients were discharged after a median of 4 days (1–14 days, IQR 3–7.5 days). To evaluate recovery, the post-hospital destination was assessed. Ten patients (35.7 %) directly went to rehabilitation, 12 patients (42.9 %) were first transferred to geriatric clinics and five patients (17.9 %) were discharged to the location they had been living before admission.

To assess the overall outcome over time, patients were asked to complete the QoL questionnaire at least six months after discharge from the hospital. Of 27 patients total, 18 returned the questionnaire. It was completed at a median of 19.5 months post-discharge. With the longest interval being 76 months and the shortest six months. When asked about general mobility, patients assessed this with a score of 1.59 ±0.62 out of 3. Independent self-care was rated with an average score of 1.61 ±0.71 out of 3 and activities of daily living with an average score of 1.78 ±0.83. The pain was rated with a score of 1.82 ±0.64 of 3 and general anxiety with 1.78 ±0.83. The Visual Analogue Scale of overall health was completed with a mean score of 55.6 (10-95, IQR 0-60).

4. Discussion

CT-guided SI-screw osteosynthesis has been shown to be a precise, quick and safe method to be used for the treatment of fragility fractures of the pelvis of the elderly.

4.1 Precision

The outcome of screw position and rate of cortical bone or foramen perforation found after assessing the CT scans of our patients are also comparable to the study conducted by Reuther et al.. They evaluated a similar CT-guided approach but did not limit the patient group to geriatric patients [9]. They described only a few cases where the screw lay within the cancellous bone but had no penetration. There was only one case (5.6 %) of penetration of the cortical bone in our cohort. In comparison, a study conducted by Richter et al. evaluating the Computer-assisted approach using c-arm to construct a 3D-scan reported a perforation rate of 16 % [18]. Of note, our patients' radiation exposure was 28 % less for unilateral procedures and similar for bilateral procedures conducted with CT-guidance [9].

4.2 Speed

We reported a shorter time for operations when compared to similar studies. Other authors report operating times up to 62 minutes per side using a non-augmenting technique [14]. We employ augmentation that takes approximately 5-10 minutes extra per screw. Furthermore, our data shows that operating time decreased by 10 % when comparing the data for August 2015 to August 2020 to the data for September 2020 to September 2021 reflecting increasing experience of the individual surgeon

4.3 Safety

Complications encountered in our patients are similar to those described in the study by Rommens et al., the most frequent being urinary tract infection and bedsores [19]. The complications found in our patients are also comparable to the general population, as the second most common medical condition experienced by geriatric patients is urinary tract infection [20].

4.4 Clinical outcomes

Additionally, the length of postoperative hospitalisation was shorter than in comparable studies looking at patients with minimally-invasive procedures, where the median hospitalisation was 12 and 17 days [14,19]. The pain reported by our patients after the operative procedure was less than in similar studies published to date [19]. Thereby the CT-guided operative method reduces the risk of complications caused by prolonged hospitalisation and supports the conservation of independent mobility.

Overall, quality of life was scored < 2 for all parameters, which means that most patients can complete activities of daily living and self-care without support. A study published by Janssen et al. in 2021 evaluates the results of the visual analogue scale (VAS) of the ED-Q5 questionnaire of a broad population of Germany. For the population ≥75 years, this is 62.8 [21]. Our patients scored 55.6. This shows that their quality of life is nearly maintained and comparable to the broad population of a similar age.

5. Conclusions

CT-guided placement of sacroiliac screws uses an intraoperative imaging mode that is easy to learn and grants excellent control of screw positioning and cement distribution. Stabilization of the posterior pelvic ring suffices to stabilise fragility fractures providing enough strength to allow for good pain relief even if the posterior and anterior pelvic ring is fractured. This method of osteosynthesis can be carried out in nearly every institution and deserves widespread use the increasing frequency this particular fracture entity calls for.

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Institutional Review Board Statement: The study protocol was approved by the Ethics Committee of Landesärztekammer Rheinland-Pfalz (reference Number: 2020-1519, approved on 30.07.2020).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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10 Appendix

10.1 Ethics vote

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Antragstitel: Charakterisierung des geriatrischen Patientengutes an der Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie am Marienhaus Klinikum Hetzelstift
Antragsnummer: 2020-15195-andere Forschung erstvotierend

Sehr geehrte Damen und Herren,

es konnte geklärt werden, dass es sich bei dem Vorhaben primär um eine Maßnahme der internen Qualitätssicherung handelt.

Eine weitere berufsrechtliche Beratung durch die Ethik-Kommission ist vor dem Hintergrund nicht erforderlich.

Sollten zukünftig Fragebögen ausgehändigt werden, sollten diese der Ethik-Kommission vorgelegt werden, damit überprüft werden kann, ob sich dadurch die Einordnung des Vorhabens als qualitätssichernde Maßnahme ändert.

Entsprechend § 9 der Geschäftsordnung der Ethik-Kommission wurde der Vorgang außerhalb einer Sitzung entschieden.

Mit freundlichen Grüßen

Dr. Andrea Wagner
Geschäftsführende Ärztin

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10.2 Patient Information

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b) den Initiator der Studie PD Dr. Christoph Wölfl

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Die Studie wurde der zuständigen Ethikkommission der Landesärztekammer Rheinland-Pfalz (Mainz) vorgelegt. Sie sah für das vorliegende Forschungsvorhaben keine Notwendigkeit eines Ethikratvotums.

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Sie werden durch Ihre Teilnahme an dieser Studie keinen Nutzen für Ihre Gesundheit haben. Die Ergebnisse dieser Studie können dazu beitragen, dass für andere Patienten, die an Ihrer Erkrankung leiden, die Versorgung verbessert wird.

Datenschutz

- Rechtsgrundlage für die Datenverarbeitung ist Ihre freiwillige Einwilligung (§ 6 Abs. 1 Buchst. b) KDG / Art. 6 Abs. 1 Buchst. c) DSGVO).
- Der Verantwortliche für die Datenverarbeitung ist der Studienleiter PD Dr. Wölfl und der Datenschutzbeauftragte der Marienhaus Kliniken GmbH (Winfried Kraatz)

Die Daten werden zu jeder Zeit vertraulich behandelt. Die Daten werden in anonymisierter Form an den Initiator der Studie bzw. von ihm beauftragte Stellen zum Zweck der wissenschaftlichen Auswertung weitergeleitet. Zugriff auf die personenbezogenen Daten haben nur die zuständigen Personen im jeweiligen Studienzentrum (PD Dr. Wölfl, Frau Hannah Kress). Anonymisiert bedeutet, dass nur ein Nummern- und/oder Buchstabencode verwendet wird. Eine nachträgliche Zuordnung der Proben/Daten zu einer bestimmten Person ist nicht mehr möglich.

Die Daten werden 10 Jahre nach Beendigung oder Abbruch der Studie aufbewahrt. Sie sind gegen unbefugten Zugriff gesichert. Sie werden gelöscht, wenn sie nicht mehr benötigt werden. Spätestens nach 10 Jahren werden sie gelöscht.

Zuständige und zur Verschwiegenheit verpflichtete Mitarbeiter des Initiators der Studie oder von ihm zum Zweck der wissenschaftlichen Auswertung

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NEUSTADT/WEINSTRASSE

Akademisches Lehrkrankenhaus der Universitätsmedizin Mainz

MARIENHAUS KLINIKUM HETZELSTIFT NEUSTADT/WEINSTRASSE
Stiftstraße 10 · 67434 Neustadt/Weinstraße

Studientitel: GeriNeu
Verantwortlicher Arzt: **PD Dr. Christoph Wölfl - Chefarzt -**
Marienhaus Klinikum Hetzelstift
Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie
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Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie Gelenk- und EndoProthetikZentrum Neustadt

Priv.-Doz. Dr. med. Christoph Georg Wölfl
Chefarzt

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Fax: 06321 859-2007
E-Mail: unfallchirurgie.new@marienhaus.de

EndoProthetikZentrum NEUSTADT

Patienteninformation

Studientitel: GeriNeu

Charakterisierung des geriatrischen Patientengutes an der Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie am Marienhaus Klinikum Hetzelstift

Sehr geehrte Patientin, sehr geehrter Patient,

wir möchten Sie fragen, ob Sie an einer wissenschaftlichen Studie teilnehmen möchten. Sie wurden in unserer Klinik behandelt. Durch diese Studie sollen die Bedürfnisse geriatrischer Patienten mit akuten Verletzungen beleuchtet werden. Uns interessiert der Behandlungsverlauf und die Ergebnisse von operativen Eingriffen und nichtoperativer Therapie bei Patienten in höherem Lebensalter.

Die Studie wird an der Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie auf Veranlassung von Chefarzt PD Dr. Christoph Wölfl durchgeführt und geleitet. Es werden insgesamt 5000 Patienten an dieser Studie teilnehmen.

Ihre Teilnahme an der Studie hat keinen Einfluss auf Ihre medizinische Behandlung, über die Sie bereits von Ihrem behandelnden Arzt aufgeklärt worden sind. Zusätzliche Besuche in der Klinik sind nicht erforderlich.

Im Rahmen der Studie sollen ausschließlich Daten Ihrer Routinebehandlung erfasst und ausgewertet werden. Wir möchten über 5 Jahre die im Verlauf der Routinebehandlung ermittelten Daten für unsere Studie verwenden und auswerten. Dabei handelt es sich um Daten wie Krankengeschichte, körperliche Untersuchung, Laborwerte, Messungen, Operationsverfahren, radiologische Bildgebung usw.
Ggf. werden Sie gebeten, zusätzlich zum üblichen medizinischen Vorgehen einen Fragebogen auszufüllen. Die genannten studienbedingten Maßnahmen erfordern ggf. einen zusätzlichen Zeitaufwand von insgesamt 10 Minuten während Ihres Krankenhausaufenthaltes.

10.3 Consent Form

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- Chefarzt -
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67434 Neustadt an der Weinstraße

Einverständniserklärung

Studientitel: GeriNeu

Charakterisierung des geriatrischen Patientengutes an der Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie am Marienhaus Klinikum Hetzelstift

Name des Patienten in Druckbuchstaben:......................

- Ich bin von Herrn / Frau ________________ über Wesen, Bedeutung und Tragweite der Studie sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text der Patientenaufklärung und dieser Einwilligungserklärung gelesen.
- Ich hatte ausreichend Zeit, Fragen zu stellen und mich zu entscheiden. Aufgetretene Fragen wurden mir vom Studienarzt beantwortet.

1. Ich willige ein, dass personenbezogene Daten über mich, insbesondere Daten zum Behandlungsverlauf, wie in der Informationsschrift beschrieben erhoben und in Papierform sowie auf elektronischen Datenträgern in der Klinik für Orthopädie, Unfallchirurgie und Sporttraumatologie, Klinikum Hetzelstift, Neustadt an der Weinstraße aufgezeichnet werden. Zu diesem Zweck entbinde ich die mich behandelnden Ärzte von der ärztlichen Schweigepflicht.

Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben werden:

a) an PD Dr. Wölfl oder von diesem beauftragte Stellen zum Zweck der wissenschaftlichen Auswertung,

b) im Falle unerwünschter Ereignisse: an PD Dr. Wölfl, an die jeweils zuständige Ethik-Kommission und zuständige Behörden sowie von dieser an die Europäische Datenbank.

Falls zutreffend: Außerdem willige ich ein, dass autorisierte und zur Verschwiegenheit verpflichtete Beauftragte des Initiators der Studie Einsicht in die Behandlungsunterlagen bei meinem behandelnden Arzt nehmen, soweit

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dies zur Überprüfung der Datenübertragung erforderlich ist. Für diese Maßnahme entbinde ich die jeweiligen Ärzte von der Schweigepflicht.

2. Ich bin darüber aufgeklärt worden, dass ich meine Einwilligung jederzeit widerrufen kann. Im Falle des Widerrufs werden keine weiteren Daten mehr erhoben. Ich kann in diesem Fall die Löschung der Daten verlangen. Bereits einer Veröffentlichung zugeführte Daten könnten nicht mehr gelöscht werden. Solche Daten lassen jedoch keinen Rückschluss auf einzelne Studienteilnehmer zu.

3. Ich willige ein, dass die Daten nach Beendigung oder Abbruch der klinischen Prüfung mindestens 10 Jahre aufbewahrt werden.

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MARIEN
HAUS

MARIENHAUS
KLINIKEN GMBH

MARIENHAUS KLINIKUM HETZELSTIFT
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Ich weiß, dass ich meine freiwillige Mitwirkung jederzeit beenden kann, ohne dass mir daraus Nachteile entstehen.

Ich erkläre mich bereit, an der Studie teilzunehmen.

Kontaktdaten des Hausarztes:

____

(Name und Vorname, Adresse)

Ich willige in die Verarbeitung der genannten Daten ein und weiß, dass ich die Einwilligung jederzeit bei PD Dr. Wölfl widerrufen kann.

Ein Exemplar der Informationsschrift und der Einwilligungserklärung habe ich erhalten. Ein Exemplar verbleibt im Prüfzentrum.

Unterschrift des Teilnehmers/der Teilnehmerin

_X____
Datum, Name und Vorname **Unterschrift**

Erklärung und Unterschrift des aufklärenden Arztes/Ärztin

Ich habe das Aufklärungsgespräch geführt und die Einwilligung eingeholt.

____

(Name und Vorname in Druckschrift)

________________________________ ________________________

(Datum) (Unterschrift)

________________ ____________ ______________

Name des Patienten **Unterschrift** **Datum**

____

Aufklärender Arzt

Mit freundlichen Grüßen

Priv.-Doz. Dr. med. Christoph G. Wölfl
Chefarzt der Klinik für Orthopädie, Unfallchirurgie
und Sporttraumatologie

10.4 Quality of Life Questionnaire (ED-Q5-3L)

EQ-5D-3L

Gesundheitsfragebogen

Deutsche Version für Deutschland

(German version for Germany)

Bitte kreuzen Sie unter jeder Überschrift DAS Kästchen an, das Ihre Gesundheit HEUTE am besten beschreibt.

BEWEGLICHKEIT / MOBILITÄT

Ich habe keine Probleme herumzugehen	❑
Ich habe einige Probleme herumzugehen	❑
Ich bin ans Bett gebunden	❑

FÜR SICH SELBST SORGEN

Ich habe keine Probleme, für mich selbst zu sorgen	❑
Ich habe einige Probleme, mich selbst zu waschen oder mich anzuziehen	❑
Ich bin nicht in der Lage, mich selbst zu waschen oder anzuziehen	❑

ALLTÄGLICHE TÄTIGKEITEN *(z.B. Arbeit, Studium, Hausarbeit, Familien- oder Freizeitaktivitäten)*

Ich habe keine Probleme, meinen alltäglichen Tätigkeiten nachzugehen	❑
Ich habe einige Probleme, meinen alltäglichen Tätigkeiten nachzugehen	❑
Ich bin nicht in der Lage, meinen alltäglichen Tätigkeiten nachzugehen	❑

SCHMERZEN / KÖRPERLICHE BESCHWERDEN

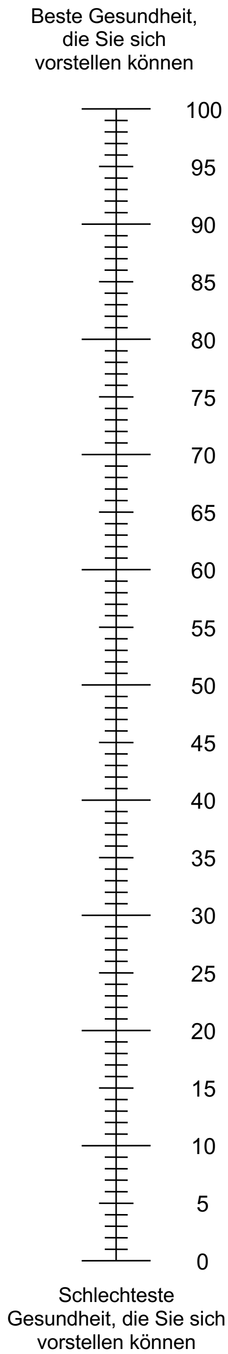
Ich habe keine Schmerzen oder Beschwerden	❑
Ich habe mäßige Schmerzen oder Beschwerden	❑
Ich habe extreme Schmerzen oder Beschwerden	❑

ANGST / NIEDERGESCHLAGENHEIT

Ich bin nicht ängstlich oder deprimiert	❑
Ich bin mäßig ängstlich oder deprimiert	❑
Ich bin extrem ängstlich oder deprimiert	❑

2

-



- Wir wollen herausfinden, wie gut oder schlecht Ihre Gesundheit HEUTE ist.
- Diese Skala ist mit Zahlen von 0 bis 100 versehen.
- 100 ist die beste Gesundheit, die Sie sich vorstellen können.
  0 (Null) ist die schlechteste Gesundheit, die Sie sich vorstellen können.
- Bitte kreuzen Sie den Punkt auf der Skala an, der Ihre Gesundheit HEUTE am besten beschreibt.
- Jetzt tragen Sie bitte die Zahl, die Sie auf der Skala angekreuzt haben, in das Kästchen unten ein.

IHRE GESUNDHEIT HEUTE =

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