



Clinical application of a minimally invasive cement-augmentable Schanz screw rod system to treat pelvic ring fractures

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Abstract

Purpose The purpose of this study is to analyze the results using the USS fracture MIS system (DePuy Synthes) to treat instable pelvic ring fractures. As its outstanding feature, it is the only Schanz screw and rod system at present that combines angular stability, perforation/fenestration of the screws for cement-augmentation, a variable screw length, and a large screw diameter.

Materials and methods Retrospective investigation of 134 pelvic ring fractures treated in 2012–2013. Twenty-five patients obtained the abovementioned implant. Besides baseline characteristics of the included patients and the surgical procedure, a clinical/radiological follow-up of six months was analyzed.

Results Dividing the collective into two groups, I high-energy trauma and II fragility fracture of the pelvis, the following results were recorded: group I: ten patients, six male, age 48.4 ± 19.7 years. Mean ISS 41 ± 22.5 , fracture classification: AO/OTA type 61 B₁/C₁/C₃ = 1/5/4. Operative treatment: three transiliac internal fixator, seven iliolumbar fixation, one implant was cement-augmented. Group II: 15 patients, 14 female, age 77.5 ± 10.1 years. Fracture classification according to Rommens: FFP_{II/III/IV} = 6/1/8. Operative treatment: eight transiliac internal fixator, seven iliolumbar fixation, 14 implants were cement-augmented. Overall surgical side complications: 16%. Radiological examination: correct positioning of all ilium screws. Follow-up after six month (16 patients): all showed fracture consolidation. One ilium screw was broken close to the connecting clamp.

Conclusion The investigated Schanz screw rod system is a suitable implant to broaden the established procedures to stabilize dorsal pelvic ring fractures.

Trial registration The study is registered at the Clinical Trial Registry University of Regensburg (Number Z-2017-0878-3).

Keywords Fracture · Pelvis · Internal fixation · Cement augmentation · TIFI · Schanz screw

Introduction

In case of displaced or considered unstable pelvic ring fracture, an operative treatment is inevitable. The following methods for stabilization of dorsal pelvic ring fractures are established so far: sacro-iliac (SI) and trans-sacral-transiliac (TSTI) screw fixations [1–6]; trans-sacral positioning bars as

a bridging technique [7, 8]; osteosynthesis by using large fragment (locking) plates inside or outside the pelvic ring [9, 10]; transiliac internal fixator (TIFI) [11, 13]; iliolumbar fixation [14, 15]; and triangular osteosynthesis combining iliolumbar and SI-screw fixation [16–18]. Due to an increasing amount of fragility fractures of the pelvis (FFP) [19–21] which show a different kind of instability as well as a different kind of progress new classification systems [21], treatment strategies [13, 22] and innovative implants are necessary to adjust for the nature of these fractures.

The USS fracture MIS system (DePuy Synthes, Zuchwil, Switzerland) is a minimally invasive Schanz screw rod system for posterior thoracolumbar stabilization of the spine in skeletally mature patients. The Schanz screws are made out of titanium alloy with a threaded length of 35–60 mm and a diameter of 4 to 7 mm. In addition, they are cannulated and perforated for optional cement augmentation. A straight rod

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made of pure titanium with a diameter of 6 mm and a length of 30–350 mm is used to connect the Schanz screws. The connecting rod and Schanz screws are fixed in an angular stable fashion with a special clamp. The clamp can be positioned 360° around the axis of the Schanz screw. The connecting rod can be attached to each clamp at a variable angle of 80°–110°. The screws can be inserted percutaneously, whereas 2–3-cm-long skin incisions are needed to apply the clamps and the connecting rods.

The objective of this investigation is to analyze the first clinical results obtained by the use of the USS fracture MIS to treat pelvic ring fractures irrespective of the fracture entity.

Materials and methods

We retrospectively analyzed all patients with pelvic ring fractures in our clinic for trauma surgery (level 1 trauma centre) treated with a minimally invasive cement-augmentable Schanz screw rod system in the period from December 2012 to December 2014. In accordance with the 1964 Helsinki Declaration, the local institutional review board approved the study (IRB-Number 15-101-0092).

Surgical procedure Using the USS fracture MIS system, unstable dorsal pelvic ring fractures were stabilized. According to the assumed grade of instability, a transiliac internal fixation (TIFI) [11–13] or an iliolumbar fixation (ILF) [14, 15] was performed (Fig. 1). After safe percutaneous placement of the Schanz screws under fluoroscopic control, the fixation of the implant in osteoporotic bone can be increased by cement augmentation. Using a cement kit (Vertecem V, Synthes) and a sterile Luer-Lock adapter, the cement can be applied via the 1.6-mm inner diameter of the cannulated Schanz screw.

Post-operative mobilization of the patients In case of a stable general condition, the patient was mobilized from the first day after operative treatment under physiotherapeutic advice. Crutches or a walking aid were used to ensure partial weight bearing. Geriatric patients were mobilized with full weight bearing as tolerated.

Design of the study Inclusion criteria are shown in Fig. 2. Age, gender, body mass index (BMI), and physical status according to the American Society of Anesthesiologists (ASA classification) were recorded. The trauma mechanism, additional injuries, and the Injury Severity Score (ISS) in case of multiple injuries were registered. The morphological appearance of pelvic ring fractures was analyzed using conventional standard X-rays and computer tomography (CT) scans. The fractures were classified according to the worldwide accepted classification for pelvic ring fractures of the AO Foundation and the Orthopedic Trauma Association [23]. In

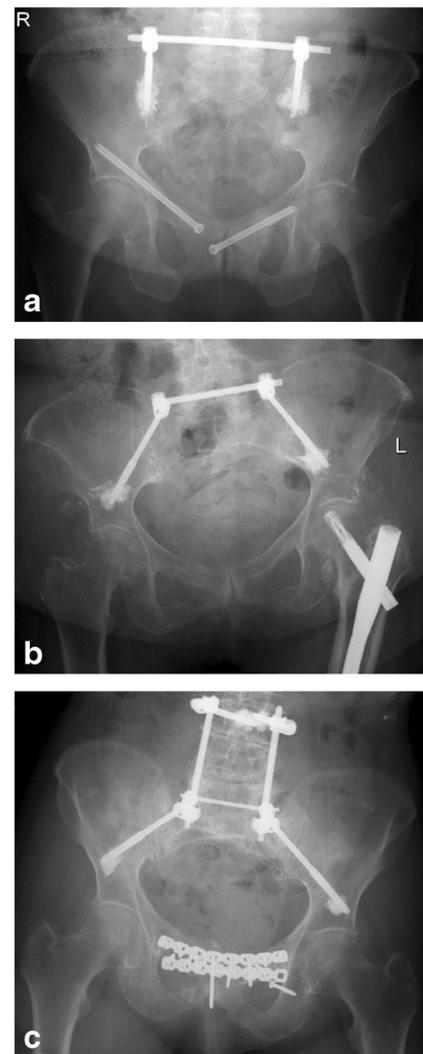


Fig. 1 Post-operative X-rays (pelvic AP-view): different surgical procedures to stabilize dorsal pelvic ring fractures. **a** Cement-augmented transiliac internal fixator in cranio-caudal position (TIFicc). **b** Cement-augmented transiliac internal fixator in dorso-ventral position (TIFIdv). **c** Cement-augmented iliolumbar fixation

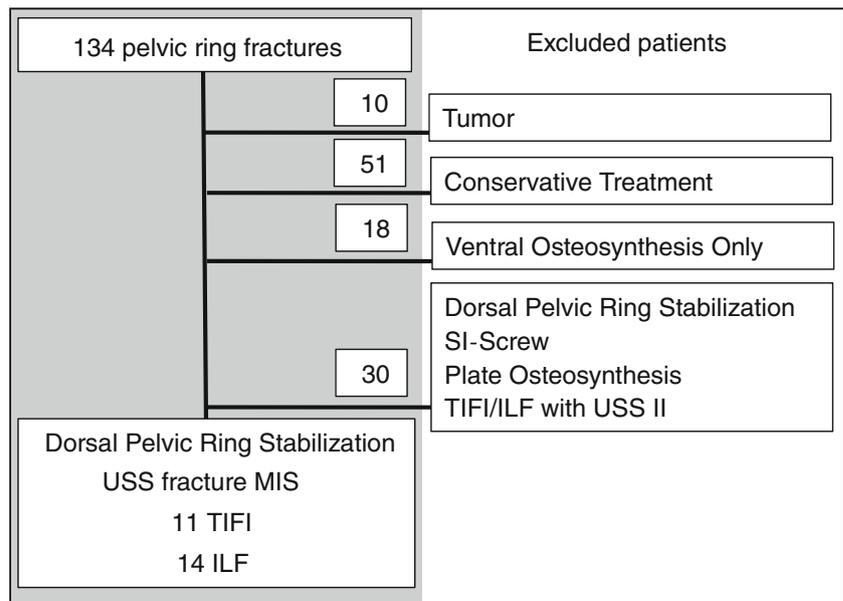
case of a diagnosed FFP, the comprehensive classification of fragility fractures of the pelvis proposed by Rommens et al. was used [21].

Following parameters related to the operative treatment were recorded:

1. Posterior stabilization (TIFI, ILF),
2. Cement augmentation,
3. Anterior stabilization (plate osteosynthesis, percutaneous screw fixation, supra-acetabular fixator),
4. Quality of reduction according to Matta and Tornetta [24].

General complications, adverse events associated with the operative treatment, and implant failure were registered. Reduction of the pelvic fracture and implant positioning were analyzed by post-operative CT scans. A clinical and

Fig. 2 Flow shard. SI-screw, sacro-iliac-screw; TIFI, transiliac internal fixator; ILF, iliolumbar fixation; USS II, Universal Spine System II (DePuy Synthes); USS fracture MIS, minimally invasive Schanz screw system for complete spinal fracture reduction (DePuy Synthes)



radiological follow-up at 6, 12, and 24 weeks were performed to analyze the following parameters: persisting pain, localization of pain, state of mobilization, neurologic status of lower extremities, and consolidation of the fracture.

Results

Twenty-five patients (5 males and 20 females) with an unstable posterior pelvic ring fracture were treated operatively using the USS fracture MIS system. Baseline characteristics of the treated patients are listed in Table 1. According to trauma mechanism, the collective was divided into two groups. Those who suffered from a high-energy trauma (motor vehicle

accident, fall from ≥3-m height) (Group 1) and those who suffered from a fragility fracture of the pelvis (insufficiency fracture, fall from standing height) (Group 2). Eight of the high-energy trauma patients were poly-traumatized with an ISS of 41 ± 22.5 (range 29–75). Their age was 48 ± 19.8 years (range 20–75 years). The age of patients who suffered from a FFP was 77.5 ± 10.1 years (range 47–89 years). The mean BMI of all patients was 25 ± 3.6 kg/m².

Classification of the pelvic ring fractures and operative treatment

The classification of the pelvic ring fractures according to the AO/OTA classification system [23] (Group 1) and the

Table 1 Baseline characteristics of the included patients, fracture classification, and treatment. *m*, male; *f*, female; *BMI*, body mass index; *ASA*, physical status according to the American Society of Anesthesiologists; *ISS*, Injury Severity Score; *FFP*, fragility fracture of the pelvis; *TIFI*, transiliac internal fixator; *ILF*, iliolumbar fixation

		Group 1 High-energy trauma (n = 10)	Group 2 Fragility fracture of the pelvis (n = 15)
Age	[years]	48.4 ± 19.7	77.5 ± 10.1
Gender	m/f	4/6	1/14
BMI	[kg/m] ²	25 ± 3.2	25 ± 3.8
ASA		3 ± 1.2	3 ± 0.5
ISS		41 ± 22.5	
Fracture classification		AO 61-B2 = 1 AO 61-C1 = 5 AO 61-C3 = 4	FFP II = 6 FFP III = 1 FFP IV = 8
Ventral osteosynthesis		10	13
Dorsal osteosynthesis	TIFI	3	8
	ILF	7	7
Cement augmentation		1	14

comprehensive classification of fragility fractures of the pelvis according to Rommens et al. [21] (Group 2) is shown in Table 1. All patients of Group 1 received a dorsal and ventral osteosynthesis of the pelvic ring whereas in Group 2, 1 patient achieved a stable pelvic ring even without a ventral osteosynthesis. Due to the osteoporotic bone structure, 1 patient of Group 1 and 14 patients of Group 2 needed a cement augmentation (Traumacem, DePuy Synthes, Oberdorf, Switzerland) of the implant.

Duration of operative treatment and intra-operative fluoroscopy The duration of the dorsal instrumentation with TIFI (45 ± 19 min) was significantly lower in comparison to that with the ILF (118 ± 41 min, $p = 0.0020$). Approximately five minute additional time was needed for cement augmentation of two Schanz screws inserted in the ilium and two Schanz screws in a vertebral body.

Similarly, the duration of the intra-operative fluoroscopy for TIFI osteosynthesis (10 ± 6 seconds) was significantly lower in comparison to that for the ILF (77 ± 35 seconds, $p = 0.0177$).

General complications In Group 1, two patients developed a SIRS and two patients—a pneumonia during the time of intensive care, whereas in Group 2, one patient sustained a deep vein thrombosis and one patient a pulmonary embolism without any sign of a deep vein thrombosis. Neurological deficits were detected in six patients and were related to the trauma and not to the operative treatment.

Adverse events associated to the operative treatment The overall complication rate associated to the dorsal pelvic ring stabilization was 16% (Table 2).

Mobility and duration of hospitalization The mean duration of patients' hospitalization was 20.8 ± 9.1 days. There was no significant difference between Group 1 and Group 2. According to the standard procedures in our clinic, all patients were mobilized from the first day post-operative treatment under sufficient pain medication and physiotherapeutic advice. For 24 patients, the status of mobility at the day of discharge was recorded (Table 3).

Post-operative radiological results Sufficient reduction according to the criteria of Matta [24] was achieved in 24 patients. One patient needed revision surgery due to insufficient reduction and simultaneous pedicle screw displacement. No malposition of Schanz screws in the sciatic notch nor in the acetabulum did appear. No cement leakage into the spinal canal nor the sacro-iliac joint was observed (Table 2).

Clinical and radiological evaluation (6-month follow-up: 16 patients)

Mobility Fourteen patients attained a good mobility with full weight bearing. Four patients with FFP did not attain the same mobility as prior to the injury. Two of them were just able to be mobilized in a wheelchair due to their geriatric general condition (Table 3).

Pain Four patients complained about persisting pain in the pelvis, the hip, or a lower extremity. One of these and 3 other patients complained about tenderness on palpation at the area of dorsal pelvic ring instrumentation.

Table 2 Adverse events associated to the surgical treatment. *HET*, high-energy trauma; *FFP*, fragility fracture of the pelvis; *nn*, revision surgery not necessary due to no or low-rated complains

	Group 1 HET	Group 2 FFP	Therapy
Subcutaneous hematoma	1	1	Conservative
Subfascial hematoma			
Disturbance of wound healing			
Superficial wound infection		1 ^a	Local debridement
Deep wound infection			
Neurological deficiency			
Insufficient fracture reduction	1* ^a		Revision + reduction
Ilium screw malposition			
Pedicle screw malposition	1* ^a		
Implant failure		1 ^a	nn
Cement leakage into soft tissue		2	nn
Cement leakage into the SI-joint			
Cement leakage into spinal canal			

*Same patient

^a Considered as complication

Table 3 Mobility of the patients at day of discharge and after 6 months

	Day of discharge		6-month follow-up	
	Group 1 HET (n = 10)	Group 2 FFP (n = 15)	Group 1 HET (n = 5)	Group 2 FFP (n = 11)
Not registered		1		
Immobile	1			
Wheelchair	2	2		2
Mobile on ward	4	8		3*
Stair case	3	4	5 (1*)	6 (3*)

*Number of patients that needed a walking aid at date of follow-up

Wound healing No prolonged wound healing or disturbance of the wound healing appeared in the period of clinical follow-up. Neither did a decubitus appear in the area of dorsal instrumentation.

Evaluation of the radiographs Fracture healing of the pelvic ring fracture was seen in all patients. A loss of reduction did not appear in any of the patients. In one patient, a breakage of a Schanz screw, placed in the ilium occurred close to the connecting clamp (Fig. 3). Revision surgery was not necessary due to low clinical complaints. Removal of the implant was refused by the patient. Four out of 15 cement-augmented implants showed a radiolucent line between the tip of the Schanz screw and the bone cement (Figs. 1b, c and 3).

Discussion

During the last five decades, the quality of operative treatment of instable pelvic ring fractures could be improved after numerous anatomical, biomechanical, and clinical investigations. Whereas standardized protocols for the treatment of the haemodynamically unstable pelvic ring fracture have been established [6, 25], the definitive treatment of vertical shear pelvic fractures is controversial and the selection of fixation technique remains the choice of each individual surgeon [6].



Fig. 3 Breakage for the right ilium screw close to the connecting rod

The surgical approaches to the pelvis changed from large incisions to minimally invasive approaches. Simultaneously, innovative instruments and implants were developed to account for the complex anatomy of the pelvis and the unique three-dimensional shape of the pelvic bone. Recent scientific investigations focus on the increasing amount of fragility fractures of the pelvis [13, 20, 21]. Even though the pelvic ring is disrupted, a partial stability remains in the geriatric patient due to the intact pelvic ligaments [10]. This new aspect of pathoanatomy, the poor osteoporotic bone stock, and the individual demands of geriatric patients with a high amount of comorbidities challenge the established therapeutically methods. Besides the specific treatment of the cause (osteoporosis) for FFP, innovative surgical techniques and new implants have to be developed and investigated to account for the increasing relevance of fragility fractures.

For the treatment of fragility fractures of the extremities and the spine, several implants have been developed to avoid an early failure such as screw cut-out and secondary loss of reduction [26]. Especially, the combination of cement augmentation with an angular stable implant proved clear biomechanical advantages [27]. Nonetheless, up to now, cement augmentation at the pelvis is just established for SI-screw osteosynthesis [4, 28].

In 2004, Füchtmeier et al. proposed the TIFI to treat instable dorsal pelvic ring fractures [11]. In 2015, Schmitz et al. published a new technique placing the ilium screws in a dorsoventral direction (TIFIdv) increasing the bone screw interface of up to 120 mm [13]. It has to be mentioned critically that the stabilization of some patients in this study by ILF is probably over utilized since the same amount of stability can be achieved by two SI-screws. Whereas the ILF scarifies, SI-screws preserve the motion of L5–S1. A recent published surgical procedure called “Within ring”-based sacro-iliac rod fixation (SIRF) was developed to overcome the weakness of ILF [22]. The SIRF combines the TIFI with a S1 pedicle screw on the injured side of the pelvis. For the TIFI as well as for the SIRF and the ILF basically, any internal screw-rod system for posterior thoracolumbar spine fixation can be used. Different manufacturers provide long ilium screws (uCentum™ Comprehensive

Posterior System, Ulrich GmbH & Co. KG, Ulm, Germany; Viper Sacral-Alar-Iliac Fixation, DePuy Synthes, Zuchwil, Switzerland; CD Horizon Longitude™, Multi-Level Percutaneous Fixation System, Metronic, Memphis, USA). Besides, special features of each different implant screws can be obtained in diameters up to 10.5 mm and a length up to 140 mm. All of them are perforated and can be positioned in a minimally invasive manner guided by a long K-wire. But only the Schanz screws used and analyzed in this study are perforated/fenestrated at the tip of the screw. In this way, they can be cement-augmented after safe placement in the iliac bone. Furthermore, a unique feature of the Schanz screws is a direct reduction and even fracture compression by manipulation on the screws prior to fixation of the connecting rod.

Limitations of the Schanz screw rod system to treat pelvic ring fractures Since it is a system to provide a segmental posterior stabilization for the thoracolumbar region (T1–S2) due to its design, the connecting clamps are configured polyaxial with a large range of motion offering an easy positioning of a longitudinal connecting rod. Performing the TIFI procedure by placing a transverse connecting rod between a right and a left ilium screw, the motion of the clamps sometimes is not enough so that the rod still needs to be bent to facilitate proper rod placement. Another limitation of the system is that the Schanz screws are perforated only at the tip. Unfortunately, this way just a short bone implant interface can be cement-augmented. In four out of 15 cases, we saw a radiolucent line between the screw and the bone cement after six months. If the cement augmentation of the whole screw rather than just the tip of the screw would be a biomechanical advantage, still it has to be investigated.

The aims of the study were to emphasize on the outcome after treatment and to focus on the advantages and disadvantages of the implant rather than comparing different surgical methods or different patient cohorts. In order not to miss any potential failure of the implant, not just patients with FFP but also patients with a high-energy trauma were included. Nonetheless, the heterogeneity of the patient collective is one of the limitations of this study. Further limitations are the limited amount of patients and the retrospective design accountable for the low rate of follow-up.

An overall rate of 16% adverse events associated to the operative stabilization technique has to be analyzed. Five out of seven were minor complications without any need for further intervention. One patient just needed a local debridement due to a wound infection. To avoid this minor problems especially in the elderly patient, a thorough wound closure of the muscle-fascia above the implant and the posterior superior iliac spine (PSIS) has to be performed. Therefore, the insertion of the ilium screw should be located at the ventromedial area of the PSIS rather than at its prominence. Implants with a lower profile certainly would make wound coverage easier. The

pedicle screw malposition as well as the insufficient reduction of the pelvic ring fracture at the same patient could be ascribed to an unexperienced surgeon. Besides one screw breakage without need for revision due to low clinical complaints, no major complication associated to the TIFI/ILF procedure nor to the implant occurred. Fracture healing occurred in all patients at the follow-up after six months.

Conclusion

A minimally invasive cement-augmentable Schanz screw rod system can be used to provide sufficient stability in patients with dorsal pelvic ring fractures and has some advantages compared to other pedicle screw systems. A stable fixation of the implant to the bone can be achieved using Schanz screws with a length of up to 120 mm and a large diameter with up to 7 mm. Additional stability in osteoporotic bone can be achieved by cement augmentation. Nevertheless, some adjustments of the implants which are designed for spinal surgery rather than for pelvic ring surgery, such as a lower profile, even larger diameter screws for iliac screws or a higher range of angulation in the connecting clamp would increase the suitability for pelvic applications.

Compliance with ethical standards

In accordance with the 1964 Helsinki Declaration, the local institutional review board approved the study (IRB-Number 15-101-0092).

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