



Anterior column acetabulum fracture fixation with a screw-augmented acetabular cup—a biomechanical feasibility study

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ABSTRACT

Background: The beneficial effects of unrestricted postoperative full weight bearing for elderly patients suffering hip fractures have been demonstrated. However, there is still existing disagreement regarding acetabular fractures. The aim of this biomechanical study was to evaluate the initial load bearing capabilities of different fixation constructs of anterior column fractures (ACFs) in osteoporotic bone.

Methods: Artificial pelvises with ACFs were assigned to three groups ($n = 8$) and fixed with either a 7.3 mm partially threaded antegrade cannulated screw (group AASS), an anteriorly placed 3.5 mm plate (group AAPF), or a press-fit acetabular cup with screw augmentation (group AACF). All specimens underwent ramped loading from 20 N preload to 200 N at a rate of 18 N/s, followed by progressively increasing cyclic testing at 2 Hz until failure performed at a rate of 0.05 N/cycle. Relative displacements of the bone fragments were monitored by motion tracking.

Findings: Initial stiffness (N/mm) was 118.5 ± 34.3 in group AASS, 100.4 ± 57.5 in group AAPF, and 92.9 ± 44.0 in group AACF, with no significant differences between the groups, $p = 0.544$. Cycles to failure were significantly higher in groups AACF (8364 ± 2243) and AAPF (7827 ± 2881) compared to group AASS (4440 ± 2063), $p \leq 0.041$.

Interpretation: From a biomechanical perspective, the minimally invasive cup fixation with screw augmentation demonstrated comparable stability to plate osteosynthesis of ACFs in osteoporotic bone. The results of the present study do not allow to conclusively answer whether immediate full weight bearing following cup fixation shall be allowed. Given its similar performance to plate osteosynthesis, this remains rather an utopic wish and a more conservative approach deems more reasonable.

1. Introduction

The beneficial effects of unrestricted postoperative full weight bearing following hip fractures in elderly patients have repeatedly been demonstrated (Baer et al., 2019; Kuru and Olcar, 2020; Ottesen et al., 2018; Pfeufer et al., 2019a; Pfeufer et al., 2019b). While there seems to be a unanimous agreement on this advancement, the situation is entirely different with regard to acetabular fractures (AF). There is a lack of evidence-based studies on the postoperative management for unstable

AFs (Meys et al., 2019). Anterior column fractures (ACF) account for up to 15–22.2% of all AFs (Boudissa et al., 2017; Firoozabadi et al., 2017). Following open reduction and internal fixation (ORIF) with plate osteosynthesis of AFs, partial weight bearing for several weeks is the standard procedure. The same applies to minimally invasive alternatives such as percutaneous screw fixations. Full weight bearing in the early postoperative stage can endanger the reconstruction stability and therefore the surgical result (Rüedi et al., 2000). However, immobilization, bed rest, or wheelchair mobilization can initiate well-known

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complications such as thromboses, pneumonia, pressure ulcers, a deterioration of diabetes, and degeneration of muscle mass (Dirks et al., 2016; Kamel et al., 2003; Wall et al., 2013). Acute total hip arthroplasty (THA) is respected by some authors to be the only surgical treatment method that may qualify for immediate postoperative full weight bearing following an acute AF (Cochu et al., 2007; Wenzel et al., 2022). Currently, the ideal therapy utilizing either a hip revision cup alone, a THA plus an addition of ORIF, or treatment in a one-step or two-step approach, could not yet be determined (Becker et al., 2021). Comparable investigations regarding cup and plate fixations of the acetabulum in artificial bone specimens showed promising results, yet to our knowledge, the specific question of full weight bearing for ACF fixation has not been investigated (Culemann et al., 2010; Nam et al., 2023; Tabata et al., 2015).

Therefore, the aim of this biomechanical study was to evaluate the initial load bearing capabilities of different fixation constructs of ACFs in osteoporotic bone and test the hypothesis that an ACF, treated with a screw-augmented cup, would show comparable results versus two other treatment options—standard plate osteosynthesis and standard screw fixation.

2. Materials and methods

2.1. Specimens

Twelve artificial pelvises were used (Model LSS4055®, Synbone, Zizers, Switzerland). The models were manufactured from polyurethane foam featuring closed porotic cells with varying densities, namely a low density in the core representing cancellous bone, and a higher density near the surface, representing a harder, yet thin cortical shell. Whereas the density of the ilium was 28.32 pounds per cubic foot (PCF), it amounted to 21.44 PCF in the sacrum to represent cadaveric specimens with low bone quality. Moreover, in previous studies these models were associated with pullout forces of instrumented sacroiliac screws similar to cadaveric anatomic preparations featuring low bone mineral density (Grechenig et al., 2015; Zderic et al., 2021). The chosen fracture model in all specimens was an ACF according to the Letournel classification (Letournel, 2007). For a reliable comparability of the data, only one type of AF was investigated. The ACF was created by an osteotomy with a 1 mm sawblade and a custom cutting template to ensure standardization. Each pelvis was considered for instrumentation and testing on both the left and right side, resulting in twenty-four available hemipelvis constructs which were assigned to three groups of eight specimens each ($n = 8$) corresponding to the given treatment. In group anterior acetabulum standard screw (AASS), the ACF was treated with a standard cannulated screw, 7.3 mm in diameter, partially threaded (32 mm), and 90 mm in length (DePuy Synthes, Zuchwil, Switzerland). In group anterior acetabulum plate fixation (AAPF), the ACF was fixed using a standard 3.5 mm 14-holes reconstruction plate, low profile, curved (R108), and 182 mm in length (DePuy Synthes, Zuchwil, Switzerland). In group anterior acetabulum cup fixation (AACF), the ACF was treated with a press-fit, screw-augmented acetabular cup (Mpact, two holes, 58 mm) with two 6.5 mm cancellous screws, both 70 mm in length (Medacta International, Strada Regina, Switzerland).

2.2. Surgical procedure

Anatomical reduction of the ACF was achieved with two supra-acetabular Weber reduction clamps and two infraacetabular Kirschner (K-) wires placed from anterior to posterior and posterior to anterior. The plate was bent according to the anatomical conditions of each specimen, such that it came to rest completely flush on the bone without protruding from it. Subsequently, four bicortical screws of appropriate length were placed in the most distal region of the superior pubic ramus. For increased plate stability, three bicortical interfragmentary screws were placed through the cranial supraacetabular part of the acetabular

corridor into the ilium. Lastly, four bicortical screws were placed in the most proximal holes under direct visualization to achieve satisfactory fixation, and tightened appropriately. An attempt was made to insert all eleven screws in identical position in all pelvises of group AAPF. After removal of the reduction clamps, the fracture reduction was maintained.

The ACF in group AACF was addressed using a cementless press-fit acetabular cup with two holes for screw augmentation. An anatomical reduction was achieved in the same manner as in group AAPF. The acetabulum was reamed in stages, starting with 50 mm and ending with 58 mm. The cup was implanted with gentle hammer blows in an ideal position concerning inclination (45°) and anteversion (15°). The cup itself was additionally stabilized by using the two available screw fixation holes in the acetabulum dome. One screw was placed medially and one laterally to the fracture line.

In group AASS, a 2.8 mm guide wire was placed in the acetabulum across the fracture and cephalad to the superior pubic ramus according to the AO Surgery Reference in an antegrade fashion (Nambiar et al., 2017). The starting point for the K-wire placement was radiologically determined at the proximal ilium and its placement was continuously monitored under fluoroscopy, avoiding any perforations, via falsa, or cortical disruptions that could influence the outcome. Following pilot drilling, the cannulated screws were inserted over the K-wires and tightened according to the operator's best practice.

All surgical procedures were performed following the surgical guidelines of the implant manufacturer as well as following the AO Surgery Reference recommendations in order to minimize the interobserver variability (Medacta, 2023; Nambiar et al., 2017). An experienced surgeon with senior attending status performed all procedures. After instrumentation, anterior-posterior, obturator oblique, and iliac oblique views were attained via X-rays for documentation and verification of implant positioning. (Fig. 1).

2.3. Biomechanical testing

Biomechanical testing was performed on a servohydraulic material test system (Mini Bionix II 858; MTS Systems, Eden Prairie, MN, USA) equipped with a 4 kN load cell (HUPPERT 6, HUPPERT GmbH, Herrenberg, Germany). The setup used to mount the specimen for testing was implemented from previous studies investigating acetabulum fracture fixation (Wenzel et al., 2022). Accordingly, each hemipelvis was tested and aligned in an inverted upright standing position. In order to achieve this, the specimen rested on an aluminum base plate, which was rigidly connected to the machine base, and inclined by 20° in the coronal plane, following the protocol according to Morosato et al. (Morosato et al., 2018) to position the medial aspect of the symphysis as well as the sacroiliac joint flush with the base plate. The sacroiliac joint was further constrained to the base plate via two molded polymethylmethacrylate (PMMA, SCS-Beracryl D-28, Suter Kunststoff AG/Swiss-Composite, Fraubrunnen, Switzerland) blocks, which allowed a consistent mounting for all specimens. (Fig. 2).

Axial compression along the machine axis was applied to the acetabulum via a ceramic ball (28 mm radius). A homogenous load transfer to the specimens in groups AASS and AAPF was achieved by a molded PMMA hemispherical cavity—a negative imprint of the acetabulum simulating the femoral head—resting in the acetabulum. In group AACF, the load transfer was realized through the polyethylene liner of the cup. Both the PMMA cavity and the acetabular cup acted as substitutes of the femoral head, and—considering their similar diameter—an equivalent load transfer to the acetabulum was assured. Furthermore, this configuration simulated the force trajectory acting at the time point of heel strike during walking, when the hip joint reaction forces reach their peak, as previously described by Bergmann et al. (Bergmann et al., 2001).

The loading protocol commenced with an initial nondestructive quasi-static ramp from 20 N preload to 200 N at a rate of 18 N/s, followed by progressively increasing cyclic loading in axial compression

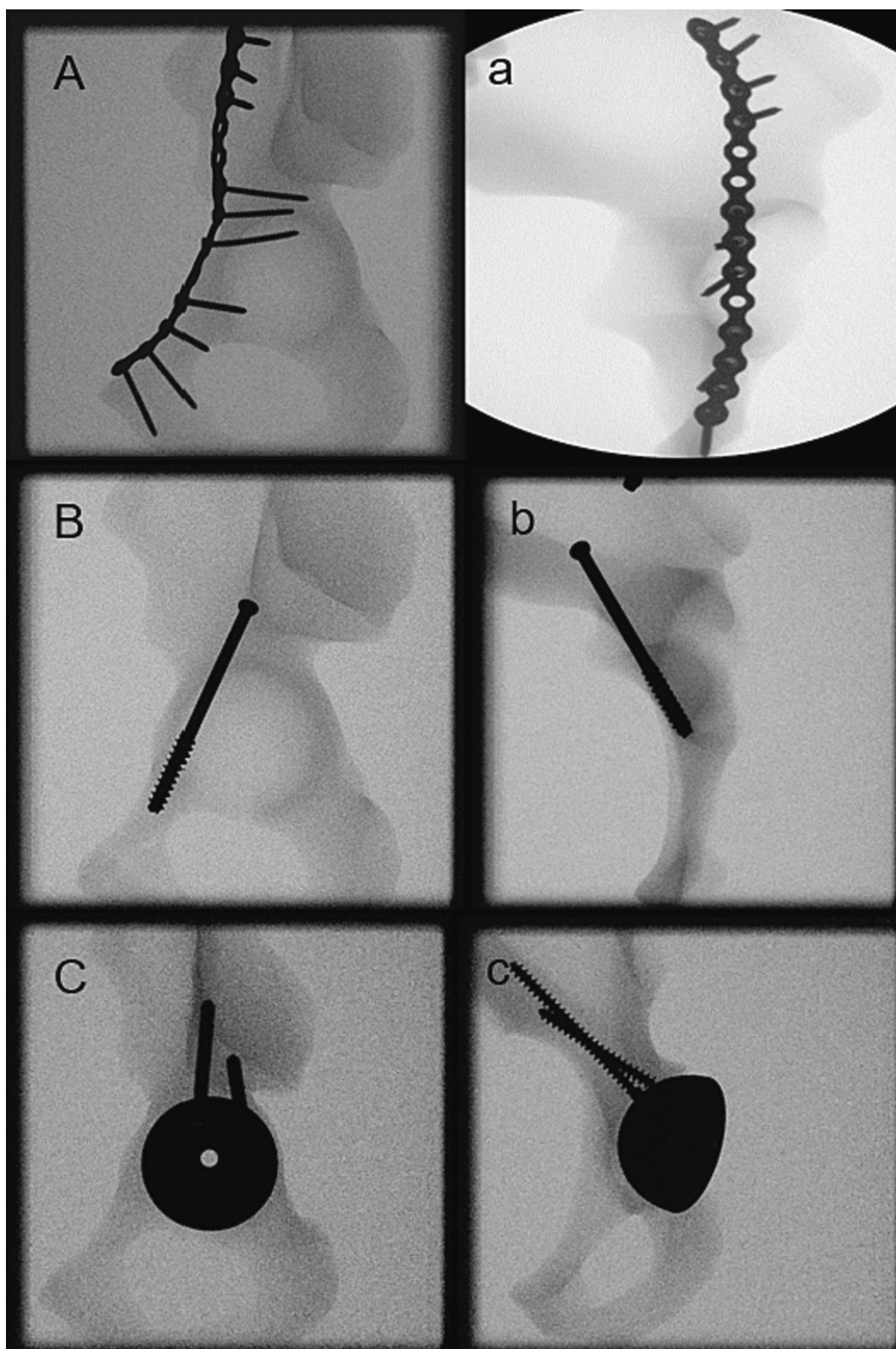


Fig. 1. Anterior-posterior and inlet X-rays after instrumentation showing exemplified specimens from group AAPF (A,a), AASS (B,b) and AACF (C,c).

with a double-peaked physiological profile of each cycle at a rate of 2 Hz, simulating the two peaks at heel strike and toe off during the stance phase of a walking cycle (Bergmann et al., 2001). Keeping the minimal load at a constant level of 20 N, the peak load, starting at 200 N, was monotonically increased cycle by cycle at a rate of 0.05 N/cycle until the test stop criterion of 10 mm actuator displacement was achieved with

respect to its position at the beginning of the loading protocol, which was found adequate to provoke catastrophic failure of the specimens (Gueorguiev et al., 2011; Windolf et al., 2009). Whereas the start peak load reflected the prescribed limited and gradually increasing toe-touch weight bearing (Management Apof, 2001), the walking frequency resembled the one of normal walking (Nguyen et al., 2011).

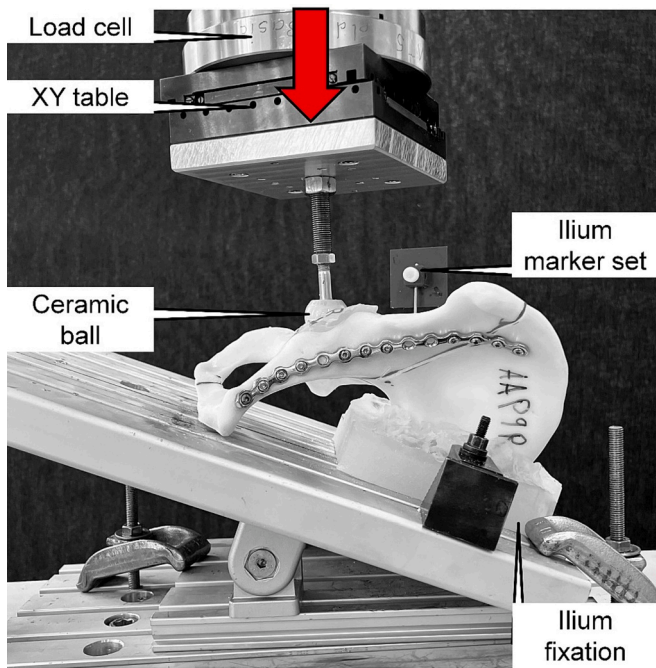


Fig. 2. Test setup with a specimen mounted for biomechanical testing. Vertical arrow denotes loading direction.

2.4. Data acquisition and analysis

The relative displacements between the fracture fragments were continuously monitored at 20 Hz throughout the tests in all six degrees of freedom by optical motion tracking. The sampling frequency was well above the Nyquist frequency requiring at least twice the highest signal frequency to prevent aliasing (Kester, 2009). For this purpose,

individual marker sets, consisting of multiple single optical markers, were attached to the superior and inferior fragments adjacent to the fracture line with K-wires. The most posterior and most inferior points lying in the fracture plane were virtually determined using a dedicated touch probe. In addition, two local coordinate systems were constructed, originating in either of the two virtual points, with their x and y axes spanning a plane parallel to the superior marker set, and the x axis oriented parallel to the line connecting the two most superior marker points of the latter (Fig. 3). The coordinates of all markers, including the virtual ones, were then tracked with a stereographic optical camera system (Aramis SRX, Carl Zeiss GOM Metrology GmbH, Braunschweig, Germany) within these two coordinate systems. Based on these measurements, the relative displacements of the most posterior and most inferior virtual fracture points were calculated as the Euclidean normal distance of the translational displacements along the three principal axes and defined as total displacement posterior and total displacement inferior, respectively. The combined angular displacement was calculated as the gap opening between the two initially reduced fracture surfaces adjoining each other in the fracture gap and defined as gap angle. Furthermore, the angular displacement between the fragments in the fracture plane was defined as torsional displacement. Machine data in terms of axial displacement and axial load were continuously acquired from the machine transducer and load cell throughout the tests at 200 Hz. Based on these, initial stiffness was calculated from the ascending load-displacement curve of the quasi-static ramp within the linear loading range between 80 N and 180 N. Similarly, dynamic stiffness was evaluated within the same loading range of the 3rd and 5000th cycle.

The outcome measures were calculated at five intermediate time points of cyclic testing after 1000, 2000, 3000, 4000, and 5000 test cycles. The latter represented the highest rounded number of cycles when none of the specimens had failed catastrophically so that dropouts could not artifactually influence the results. The values were considered with respect to the beginning of the cyclic test and were calculated in

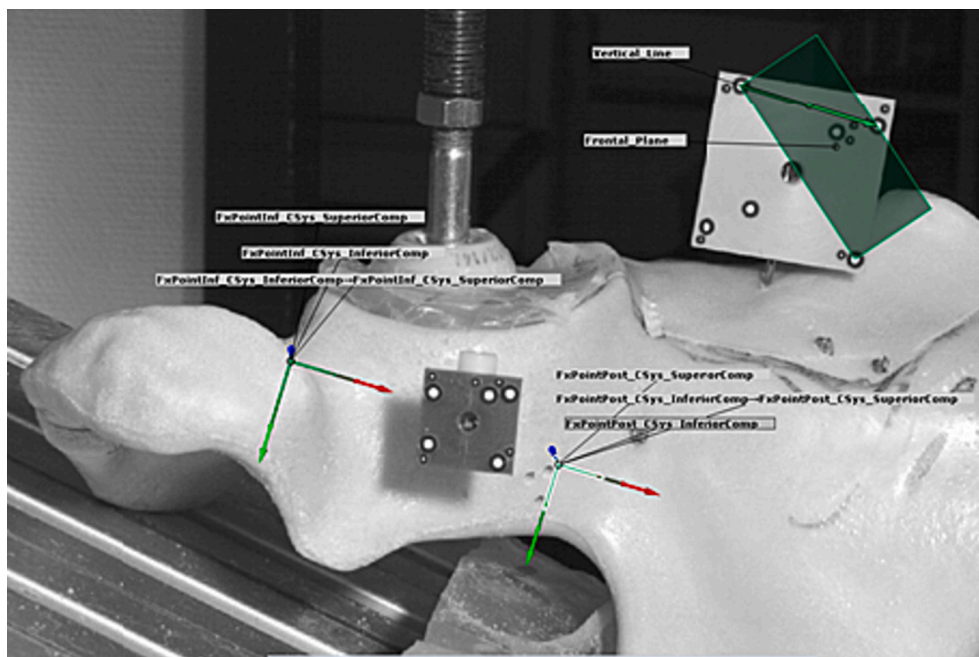


Fig. 3. Print screen taken from the motion tracking software, denoting the tracked most posterior and most inferior virtual points lying on the fracture line of a left hemipelvic specimen, together with the attached marker sets on the superior and inferior fragments. Fracture displacement was defined as the magnitude of the fracture points displacements along the three principal axes (x axis – red, y axis – green, z axis – blue) of the coordinate systems that have been aligned with the fracture plane. Whereas gap angle was considered as the combined movement of the fracture plane around the x and y axes, torsion was calculated as the angular displacement of the fractured fragments around the z axis, the latter being normal to the fracture plane. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

peak loading condition. Furthermore, a criterion for specimen failure was set at 3 mm total displacement posterior and the corresponding number of cycles until fulfillment of this criterion—defined as cycles to failure—was calculated together with the respective peak load—defined as failure load.

Statistical analysis among the outcome measures was performed with SPSS software (v.27, IBM SPSS, Armonk, NY, USA). Normality of data distribution was confirmed with the Shapiro-Wilk test. Mean value and standard deviation (SD) were calculated for each parameter of interest and group separately. General Linear Model Repeated Measures test with Bonferroni post-hoc test for multiple comparisons were conducted to detect significant differences between the groups for the outcome measures of the parameters of interest evaluated over the time points during cyclic testing after 1000, 2000, 3000, 4000, and 5000 cycles. Initial and dynamic stiffness, as well as cycles to failure and failure load were compared among the groups with One-Way Analysis of Variance (ANOVA) with Bonferroni post-hoc test. Progression over time of the dynamic stiffness was screened with Paired-Samples *t*-test. Level of significance was set at 0.05 for all statistical tests.

3. Results

Values for initial and dynamic stiffness are summarized in Fig. 4. Initial stiffness (N/mm) was 118.5 ± 34.3 in group AASS, 100.4 ± 57.5 in group AAPF, and 92.9 ± 44.0 in group AACF, with no significant differences between the groups, $p = 0.544$. Dynamic stiffness within the 3rd loading cycle was significantly higher in group AAPF versus group AACF, $p = 0.021$, with no further significant differences between the groups, $p \geq 0.332$. In contrast, the dynamic stiffness within the 5000th cycle remained without significant differences between the groups, $p = 0.266$. In addition, the dynamic stiffness significantly increased between the 3rd and the 5000th cycle in each group, $p \leq 0.023$.

Total displacement inferior and gap angle were significantly higher in group AASS versus group AAPF, $p \leq 0.027$, with no further significant differences between the groups, $p \geq 0.112$. However, total displacement posterior and torsional displacement remained not significantly different between the groups, $p \geq 0.119$ (Fig. 5). Cycles to failure and failure load in both groups AACF (8364 ± 2243 cycles; 618.2 ± 112.2 N) and AAPF (7827 ± 2881 cycles; 591.4 ± 144.1 N) were significantly higher compared to group AASS (4440 ± 2063 cycles; 422.0 ± 103.2 N), $p \leq 0.041$, with no significant differences between groups AACF and AAPF, $p > 0.999$ (Fig. 6). Catastrophic failure modes were expressed by either a total displacement of the fracture gap itself due to a pullout of the screws, or a supraacetabular horizontal fracture.

4. Discussion

The aim of this biomechanical study was to evaluate the

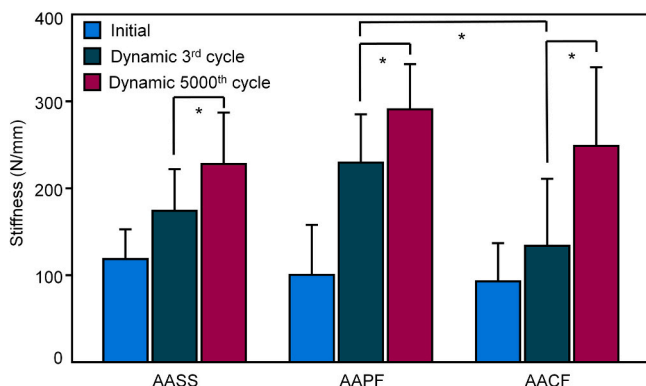


Fig. 4. Initial and dynamic stiffness presented for each group separately in terms of mean value and SD. Stars indicate significant differences.

biomechanical competence of three different techniques for fixation of anterior column acetabulum fractures. The following two main important points can be identified:

1. Cup fixation was associated with comparable fracture displacements versus plate fixation regarding the parameters total displacement inferior and gap angle.
2. Cycles to failure and failure load were significantly higher for both cup and plate fixations versus screw fixation.

The present study best compares to the one performed by Wenzel et al. (Wenzel et al., 2022) investigating the biomechanical effect of stand-alone total hip arthroplasty or its combination with plating in simulated anterior column acetabular fractures. However, load trajectory and used protocol, as well as investigated implants and bones were different. Using human anatomic specimens, the authors reported that by application of a less-invasive press-fit revision cup—featuring an extension flange—similar biomechanical stability can be achieved as with use of a standard cup with additional suprapectal plating. In the biomechanical study of May et al. (May et al., 2018) the authors explored four different augmentation techniques of anterior column acetabulum fractures, fixed with a quadrilateral plate in artificial bone models, to conclude that periarticular screws provided superior stability compared to infrapectal plates. To our knowledge, a controversy remains in the literature regarding postoperative full weight bearing recommendations following acetabular fractures and further studies may provide benefits for future patient care.

For acetabular fractures, there is strong evidence that the loss of reduction results in development of posttraumatic arthritis and therefore leads to poor patient outcomes (Tannast et al., 2012). Osteomalacia or manifest of osteoporosis are common comorbidities in patients suffering from such fractures, that can correspondingly lead to early failures of osteosynthesis and therefore to advancing osteoarthritis of the hip joint (O'Toole et al., 2014; Weaver et al., 2018).

The results from the current study demonstrated that the numbers of cycles to 3 mm total posterior displacement were highest for cup fixation, followed by plate fixation, however, with no significant difference between these two techniques. The main advantage of THA in ACFs is that secondary fracture dislocation can be tolerated to a certain degree without direct negative consequences for joint preservation, as in case of plate osteosynthesis. This could lead to a possible compromise for the aftercare with respect to the prescribed mobilization. Instead of strict partial weight bearing, which is often prescribed after plate osteosynthesis, cup fixation could form the basis for full weight bearing, but under walking distance limitation.

Von Rudena et al. stated: “The primary aim of operative treatment in elderly individuals is the avoidance of immobilization of the patient” (von Rudena and Augat, 2016). The present results do not qualify cup fixation eligible for immediate full weight bearing. It has been reported that restriction of weight bearing increases the energy required for ambulation by four-fold, in comparison to full weight bearing (Westerman et al., 2008). This could be an explanation for the fact that for geriatric patients with reduced muscle mass, comorbidities and an increased rate of complications, partial weight bearing is often barely possible to comply with. In a study analyzing compliance with weight bearing restrictions following surgical treatment of proximal femur fractures, only 2.94% of the follow up cohort were compliant (Kammerlander et al., 2018). A different study on geriatric patients with operatively treated hip fractures concluded that these patients seemed to be unable to comply with weight-bearing restrictions, which could then potentially result in immobility, loss of autonomy, and was also associated with a higher one-year mortality rate (Pfeuffer et al., 2019a). At times, an unavoidable alternative to partial weight bearing in clinical practice is a wheelchair mobilization. However, after 8–12 weeks bound to a wheelchair, the loss of muscle mass and mobility can be very challenging to restore in order to achieve the pre-incident level of

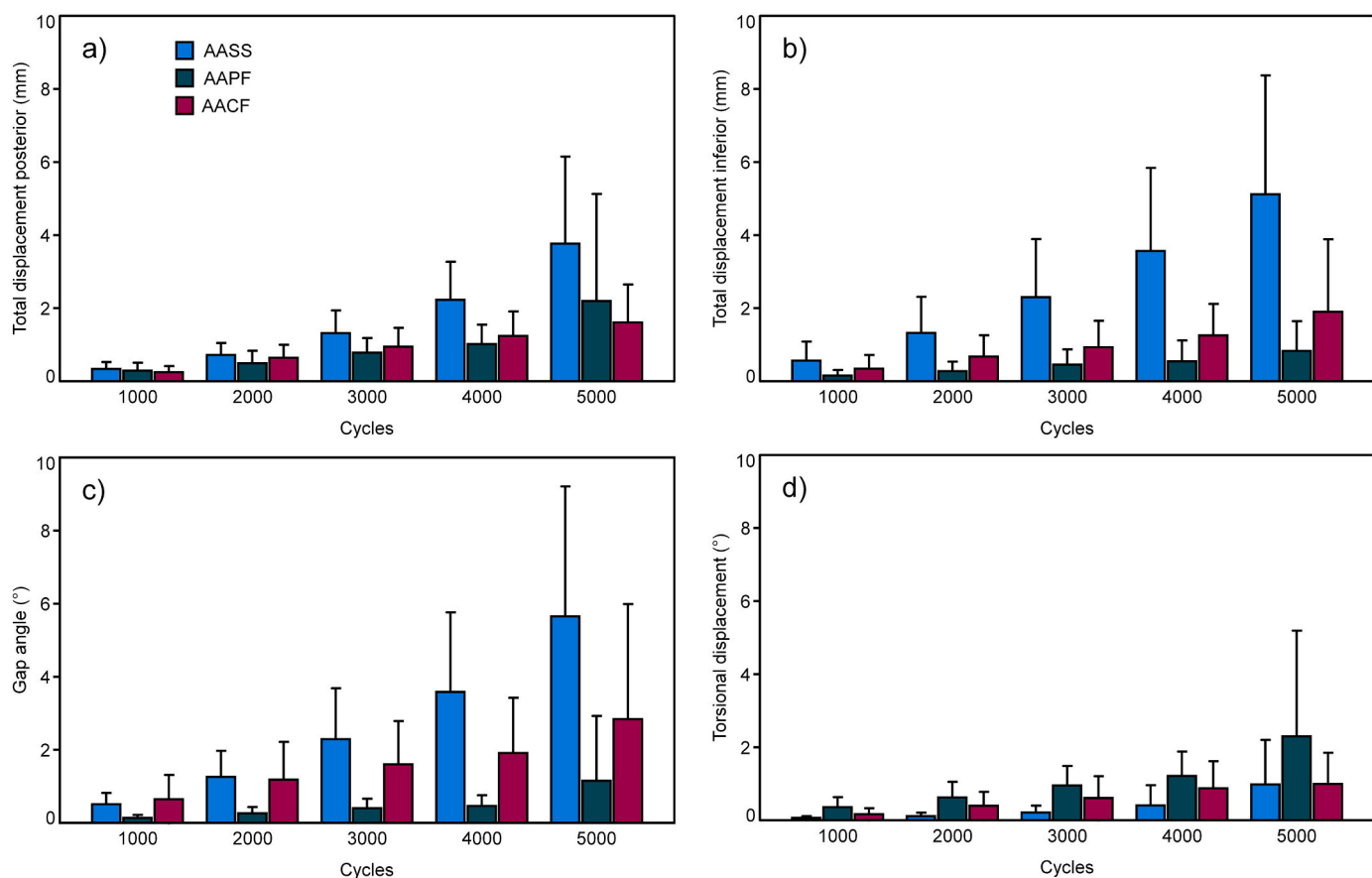


Fig. 5. Total displacement posterior (a), total displacement inferior (b), gap angle (c), and torsional displacement (d), over the five time points during cyclic loading after 1000, 2000, 3000, 4000, and 5000 test cycles, presented for each group separately in terms of mean value and SD.

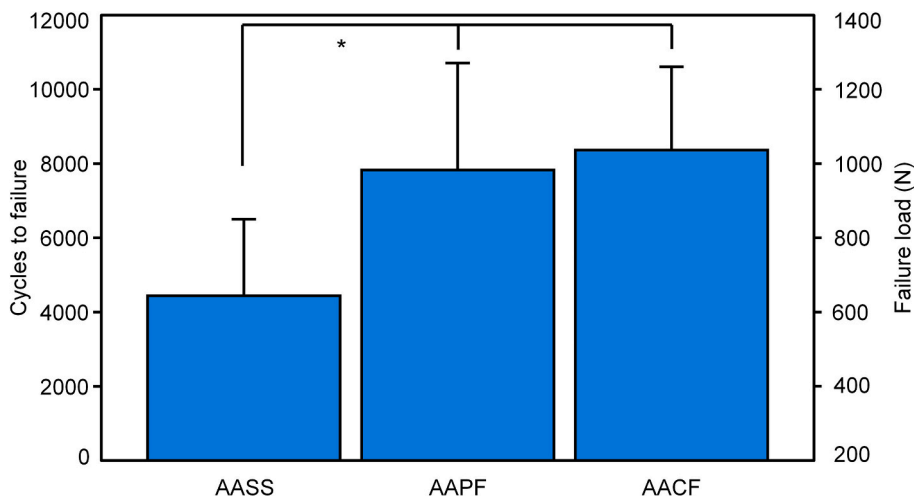


Fig. 6. Cycles to failure and corresponding failure load presented for each group separately in terms of mean value and SD. Star indicates significant differences.

mobilization.

Group AACF in the present study demonstrated the highest number of cycles to 3 mm total posterior displacement, being significantly higher when compared to group AASS, yet without significant difference when compared to group AAPF. Approximately 600 steps per day are reported for older slower walkers (Perry and Burnfield, n.d.). Based on the results of this investigation, it can not be conclusively answered whether the number of cycles to failure in group AACF is sufficiently high to allow full weight bearing. However, at least a mobilization out of the

wheelchair into a standing position, into the bathroom or within the confines of the home and a more active participation in standing physiotherapy could be at least conceivable.

In the current study, the initial and the dynamic stiffness after 5000 cycles was statistically insignificant between the three groups. However, within the 3rd loading cycle, plate fixation was associated with significantly higher dynamic stiffness compared to cup fixation. Moreover, the dynamic stiffness significantly increased between the 3rd and the 5000th loading cycle. These non-intuitive results can be ascribed to material

hardening during cyclic loading. However, despite the increasing stiffness, the fracture displacement gradually increased. Therefore, to interpret this behavior, it is hypothesized that within each cycle the constructs are loaded in their settled position within a linear range and then undergo a certain plastic deformation when the load reaches its peak value.

In view of fracture displacement, the screw fixation in group AASS revealed significantly higher total inferior displacement and gap angle compared to the plate fixation in group AAPF. Concurring with the results of the present study, the known advantage of a minimally invasive surgical variant applying percutaneous screw fixation appears to be at the expense of overall stability. In contrast, the opposite can be attributed to the higher stability in group AAPF. Plate osteosynthesis with a total of eleven screws requires a pronounced soft tissue preparation with a large wound area, increased blood loss, and a longer operation time. In this regard, one should consider the conclusion of another study regarding the surgical treatment of acetabular fractures, namely that ORIF can lead to an altered anatomy, interfering hardware and scar tissue growths, which can significantly complicate a secondary hip joint replacement surgery (Templeman et al., 1999). Therefore, it is not unexpected that there is a high number of controversially performed surgeries reported in the literature, following joint preserving treatments of such fractures. Weaver et al. reported that 30% of the patients had a reoperation with a THA within two years following ORIF of the acetabulum (Weaver et al., 2018). Other authors reported 22% to 45% conversion rate to THA, following ORIF of acetabular fractures (Boelch et al., 2017; Daurka et al., 2014).

4.1. Strength & limitations

The main limitation of this study is based on the choice of artificial bone specimens, simulating less physiological conditions. In this regard, although a physiological hip joint reaction force trajectory (Bergmann et al., 2001) has been considered, the failure loads were significantly below the physiologically measured loads during walking, the latter amounting at least two-fold body weight. This represents a general limitation inherent in most biomechanical studies, where only the immediate postoperative situation can be simulated, and the temporal bone healing process is ignored. However, the applied loading protocol can be extrapolated to the clinical scenario where only gradually increasing toe-touch weight bearing is allowed. This makes the investigation of pelvis fractures challenging. Yet, since we conducted an experimental study with a unique approach, for which there is very little data available and therefore the outcome was unpredictable, the authors agreed on this first step approach. Only after a successful first step study it is ethically justifiable to proceed with a cadaveric study in the second step. Nevertheless, artificial bone specimens are commonly and efficiently used in biomechanical studies specifically related to the pelvis (Gardner et al., 2007; Gardner et al., 2010; Sahin et al., 2013; Yinger et al., 2003). Additionally, poor availability of cadavers can limit the sample size for biomechanical experimentations in general and it is known that sample sizes used in previous publications are small (Sagi et al., 2004). It is known that artificial pelvises allow standardized and comparable study groups, which overpowers the almost uncountable variations in cadaveric bone quality, while being more cost-effective (Elfar et al., 2014; Gardner et al., 2010; Zdero et al., 2008). Therefore, use of artificial bone models minimizes the variability of test results between specimens (Yinger et al., 2003). Nevertheless, it must be acknowledged that the used models were not validated biomechanically but were primarily made for orthopaedic educational purposes. Further, the chosen sample size was moderately small, yet retrospectively sufficient considering the detected significant differences between the groups and was in addition comparable to similar biomechanical studies investigating pelvic fixation techniques (Gardner et al., 2007; Sahin et al., 2013; Yinger et al., 2003). Lastly, the failure criterion, although minimally higher than in current literature (Kistler et al., 2014; Wenzel

et al., 2022) deemed relevant, because in some cases the specimens experienced a sudden drop in stability in close surrounding of this value. This failure criterion was applied in other studies, too (May et al., 2018).

5. Conclusion

From a biomechanical perspective, the minimally invasive cup fixation with screw augmentation demonstrated comparable stability to plate osteosynthesis of anterior column acetabulum fractures in osteoporotic bone. Yet, the results of the present study do not allow to conclusively answer whether immediate full weight bearing following cup fixation shall be allowed. Given its similar performance to plate osteosynthesis, this remains rather an utopic wish and a more conservative approach deems more reasonable.

Ethical approval

Not applicable

Good clinical practice

All methods were carried out in accordance with relevant guidelines and regulations. This study was performed in line with the principles of the Declaration of Helsinki.

Consent to publish/consent to participate

Not applicable

Authors contributions

Till Berk: study initiation, performing of instrumentations and tests, article writing.

Ivan Zderic: data evaluation and statistics, performing tests, article writing.

Peter Schwarzenberg: manuscript workup, literature review.

Roman Pfeifer: manuscript workup, literature review.

Tatjana Pastor: manuscript workup, literature review.

Sascha Halvachizadeh: manuscript workup, literature review.

R. Geoff Richards: manuscript workup, literature review.

Boyko Gueorguiev: study initiation, manuscript workup and literature review.

Hans-Christoph Pape: study initiation, manuscript workup and literature review.

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Availability of data and materials/code availability

The Codes are available upon reasonable request from the corresponding author

The collected data will be stored securely in our institute for 10 years. During this period, they are still available upon request. After 10 years, the data will be deleted, however, all the datasets analyzed or generated during this study will be available from corresponding author upon reasonable request.

Declaration of Competing Interest

None of the authors have any conflicts of interest to declare. *This study was performed in line with the principles of the Declaration of Helsinki.*

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