Anterior internal fixator versus a femoral distractor and external fixation for sacroiliac joint compression and single stance gait testing: a mechanical study in synthetic bone

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Abstract

Purpose The purpose of this study was to evaluate the biomechanical stability and compressive forces across the sacroiliac (SI) joint of an anterior internal fixator compared to the femoral distractor and external fixator for vertically unstable pelvic fractures.

Methods Five composite pelvises with a simulated APC type III injury fixed with a femoral distractor, external fixator, or anterior internal fixator were tested. A pressure-sensitive film (Tekscan) was placed in the disrupted SI joint recording the magnitude of force. Then, in a single-leg stance model (Instron machine), a load was applied through

the sacrum. We recorded displacement at the pubic symphysis and SI joint using high-speed video. Peak load and displacement were measured, and axial stiffness was calculated. Values were compared using a Student's *t*-test ($p < 0.05$).

Results The SI joint was compressed significantly ($p < 0.001$) more using the anterior internal fixator (18.9 N) and femoral distractor (18.6 N) than the two-pin external fixator (2.5 N). There was no significant difference between the anterior internal fixator and the femoral distractor in displacement at the SI joint. The pubic symphysis displaced less with the femoral distractor than the anterior internal fixator (5.5 mm vs. 4.1 mm; $p < 0.05$).

Conclusions The anterior pedicle screw internal fixator allows for indirect compression across the sacroiliac joint that is superior to two-pin external fixation and comparable to the femoral distractor. The anterior internal fixator may be an option for temporary anterior pelvic fixation in situations where external fixation or the femoral distractor have otherwise been used.

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Introduction

The external fixator (ex-fix) plays an important role in the initial management of high energy pelvic ring injuries [1–3]. Its application allows the closure and compression of the anterior and posterior ring, reducing pelvic volume, causing a tamponade for the pelvic haematoma and venous plexus bleeding, minimises movement at the fracture sites which stabilises the clot, and ultimately aids in resuscitation [2, 4–6].

The complications associated with external pelvic frames include pin tract infection (2.5–50 %), osteomyelitis (0 to 7 %), loosening (0 to 19 %), skin compression (8 %), nerve

damage (0–7 %), loss of reduction in up to 33 % of rotationally unstable injuries and up to 95 % of vertically unstable injuries when used as a stand-alone device [7]. This improves to 0 to 8 % when combined with posterior fixation [7, 8]. An anterior pelvic external fixator limits patient mobility, especially when sitting and when being rolled from side to side.

Gardner et al. [9] have shown that the universal femoral distractor (Synthes, Paoli, PA, USA) is biomechanically superior to a two-pin anterior external fixator in its ability to compress the SI joint (Fig. 1a,b,c). The problem with using this operative room tool for this purpose is that most hospitals have one or two of these devices and they should remain in the operating theatre for routine use in fracture care.

We have developed an anterior supra-acetabular pedicle screw pelvic internal fixation construct (ASPIF), which combines the benefits of the ex-fix, while having the device entirely under the skin [10]. In a recent multicentre report of 91 patients, we found that ASPIF is effective in the treatment of unstable pelvic fractures and avoids many of the complications associated with external fixation [7] (Fig. 1d).

The purpose of this study was to evaluate the biomechanical stability of the ASPIF and compare it to traditional external fixation and a femoral distractor. We chose to test the three systems in single leg stance and to test their ability

to compress the SI joint in an APC 3 pelvic injury. We postulate that ASPIF will provide as good or greater stability than both the two-pin anterior ex-fix and femoral distractor in this unstable pelvic model.

Materials and methods

The fourth generation composite pelvis model (Sawbones, Vashon, WA, USA), was used to examine a vertically and rotationally unstable pelvic ring injury with a pure sacroiliac (SI) joint dislocation (AO/OTA type 61-C1.2.a2.c5). The SI joint dislocation model was shipped from the company with an intact left SI joint, and disrupted right SI joint and pubic symphysis. The composite pelvis model has been shown to allow for more controlled and repeatable testing, as each specimen has the same properties [11, 12]. The model simulates natural cortical bone using short e-glass fibres and epoxy resin pressure injected around a foam core to represent the cancellous bone of an average-sized adult male [12, 13]. Five pelvises were tested, and each with three stabilisation methods. We used the five millimetre Schanz pins with the femoral distractor or the external fixator construction in random order first and then replaced these with the seven millimetre pedicle screws to test the ASPIF device, as the same location in the AIIS is used for all three devices.

Fig. 1 A haemodynamically unstable patient with an APC3 injury (**a**, **b**) treated acutely with the femoral distractor (**c**) followed by definitive fixation with the anterior supra-acetabular pedicle screw pelvic internal fixation construct (ASPIF) and posterior fixation (**d**)

Description of fixation

The external fixation construct was a standard two-pin pelvic external fixator, with two supra-acetabular five millimetre Schanz pins and an 11-mm carbon fibre rod (Synthes, Paoli, PA, USA) placed under fluoroscopy and direct visualisation. The Schanz pins were each inserted to 70-mm and the clamps placed five centimetres from the bone. The construct was compressed indirectly through manipulation of the pins and pressure on the iliac wings until visual subluxation of the SI joints and then slightly backed off. The femoral distractor was a standard AO Large Universal Distractor (Synthes, Paoli, PA, USA) with two supra-acetabular five millimetre Schanz pins placed in the same manner.

The ASPIF uses two 7.0-mm×80-mm titanium polyaxial pedicle screws and a six millimetre titanium rod (Click'X Pedicle Screw System, Synthes, Paoli, PA, USA) [10]. The pedicle screws were inserted in the previous holes made by the Schanz pins (of note: there was no loosening noted in any construction at the screw–model interface at the time of removal). The two screws were seated so that the bottom of the pedicle screw heads were 15-mm from the level of the AHS in all specimens which approximates to their position in a human of average weight [10]. A titanium rod of appropriate length, contoured with an anterior bow, was placed in the screw heads and locking caps applied. The construction was compressed using a small c-clamp attached to the rod and compressor instruments from the spinal system; the locking caps were then tightened with a seven inch–pound torque screwdriver. Care was taken to cause no deformation at the SI joint or pubic symphysis during compression of the construction. Thus the device was tightened until visual subluxation of the SI Joint and then slightly backed off.

Compressive testing

A pressure-sensitive film (Tekscan Inc., Boston, MA, USA) was placed in the pubic symphysis and the disrupted sacroiliac joint of each sawbones pelvis with each construct was mounted. This electroresistive film determined the pressure distribution of contact forces with a reported accuracy and repeatability of 2–4 %. The sensors used for this study had a sensing area of 55.9×55.9 mm and a thickness of 0.1 mm. The sensors were calibrated according to the manufacturer's guidelines. Calibration was completed using a pressure bladder provided by the manufacturer. This setup was similar to one described by Gardiner et al. [9].

Biomechanical testing

For stability testing, we created a single-leg stance model based on previous reports [14–16]. Each pelvis was securely

mounted through the sacrum at the S1 level to a servohydraulic testing machine (Instron Model 8500, Canton, MA, USA). The sacral mount was free to pivot in all planes to eliminate loading artifact. The anatomical standing vertical relationship of the anterior-superior iliac spine and pubic symphysis was maintained. For the hip, we used a 52-mm hemiarthroplasty, which freely articulated with the acetabulum. The femoral component was potted using Bondo putty (3M, St. Paul, MN, USA) in a position of 15° of adduction and 15° of anteversion to simulate single-legged stance, and the distal femur was rigidly fixed to a mobile base plate. The abductor musculature and vectors were simulated using cables attached to the pelvis with two drill holes at the gluteus ridge, and a pulley system at the level of the greater trochanter on the prosthesis [17, 18]. The chains were tightened manually and stabilised the hemipelvis against rotation (Fig. 2).

Markers were placed at each side of the SI joint and at the pubic symphysis. The markers were small white dots, placed at the superior and inferior aspects of both SI joints, and at the superior and inferior portion of the anterior pubic symphysis. A high-speed digital video camera (HG-2000, MotionXtra Inc., San Diego, CA, USA), aimed at the markers, recorded images at 125 frames per second.

A vertical compressive displacement of seven millimetres was applied through the sacral mount at the rate of ten millimetres per second. This was chosen based on previous studies [19, 20] and pilot data showing a more reproducible measurement of construct stiffness. The exfix and femoral distractor were applied in random order followed by the ASPIF. Five specimens were tested for each system. The testing was repeated five times per construct to look for any degradation in the mechanical properties of the device with repeated testing of the same pelvis. Each construct was re-tightened between tests.

For each loading cycle, force and displacement data were recorded by a 32-bit Instron MAX V9.3 at 1 kHz, and connected to a Pentium Dual-Core E5300 personal computer. Force-displacement curves were generated for each test. The displacement at the pubic symphysis and SI joint were analysed using TEMA (Photo-Sonics, Burbank, CA, USA) motion analysis software.

Statistical analysis

Compressive loads at the SI joint and pubic symphysis were recorded by Tekscan software. Displacement and load were recorded and total axial stiffness was calculated as the slope of the linear portion of the force-displacement curve. All data were compared by 2-way ANOVA with LSD adjustment for multiple comparisons using SPSS software ($p<0.05$).

Fig. 2 A single-leg stance model was created by securely mounting the synthetic pelvis through the sacrum at the S1 level to a servohydraulic testing machine (Instron Model 8500, Canton, MA, USA)

Results

All five pelvic specimens were tested with each system five times, with no degradation of data and no mechanical failures of either the pelvis or the constructs. At the end of testing the screws were removed from the pelvic models. We found no loosening of the Schanz or Pedicle screws at the end of testing.

The SI joint was compressed significantly ($p < 0.001$) more using the ASPIF (18.9 N) and femoral distractor (18.6 N) than the two-pin external fixator (2.5 N) (Fig. 3). There was no statistically significant difference in compressive force at the SI joint between the ASPIF and the femoral distractor ($p = 0.88$). At the pubic symphysis, the ASPIF and femoral distractor compressed significantly more than the two-pin external fixator ($p < 0.05$). There was no significant difference in force at the pubic symphysis between the ASPIF and the femoral distractor ($p = 0.39$).

There was no significant difference in displacement at the SI joint or the pubic symphysis between the ASPIF and the femoral distractor during axial loading (5.5-mm vs. 4.1-mm). There was a trend that indicated that peak load (103.5 N v 50.6 N; $p = 0.057$) and stiffness (16.5 N/mm v 6.7 N/mm; $p = 0.077$) were higher for the femoral distractor when compared with the ASPIF but was not significant in the limited samples we used (Fig. 4).

Fig. 3 The SI joint compressed significantly ($p < 0.001$) more using the anterior supra-acetabular pedicle screw pelvic internal fixation construct (ASPIF) (18.9 N) and femoral distractor (18.6 N) than the 2-pin external fixator (2.5 N)

Discussion

Decreasing pelvic volume has long been thought to help prevent death from haemorrhagic shock in pelvis fractures. Many devices have been used acutely to accomplish this goal, including pelvic binders and circumferential sheets in both the pre-hospital setting and resuscitation bay, to external fixation and C-clamp fixation. The reduction in pelvic volume causes a tamponade for the pelvic haematoma and venous plexus bleeding, minimises movement at the fracture sites to prevent clot disruption, and ultimately aids in resuscitation [2–5, 8]. External fixation is preferred in the acute setting due to its relative ease and speed of application [2–5, 8]. However, complications associated with external fixation are numerous [7, 8].

The purpose of this investigation was to compare the posterior pelvic compression of three anterior pelvic fixation systems, an external fixator, a novel internal fixation (ASPIF), and a femoral distractor applied anteriorly. We also examined load, displacement, and stiffness of the femoral distractor and ASPIF in single-leg stance gait. Many previous studies have been performed testing internal fixation techniques for anterior pelvic ring injuries [15, 16, 18, 21, 22]. It is difficult to extrapolate data across studies as many different fixation methods and loading techniques were examined: various external fixation devices have

Fig. 4 There was no significant difference ($p=0.077$) in overall axial stiffness between the anterior supra-acetabular pedicle screw pelvic internal fixation construct (ASPIF) and femoral distractor

been studied, as well as numerous plating options for the pubic symphysis. All have been examined in single and double leg stance [18, 23–25] models with varying loads, from 250–2000 N. Different injury patterns have also been tested, with or without stabilisation of the posterior pelvis [23]. Between studies and between systems, no significant differences in stability have been shown. However, all methods of fixation are inferior to the intact pelvis [25].

Gardner et al. [9] examined the sacroiliac compression of several anterior fixation devices. They found that the standard two-bar external fixator did not provide any compression across the SI joint. This data is in agreement with ours, as we found only a 2-N compressive force in this construct. They also showed that pins inserted 70-mm achieved similar compressive forces compared with pins inserted fully to the PSIS. The pedicle screws used in the ASPIF device have a length of 80-mm and penetrated 65 mm in the composite model.

To test stability we chose a single-leg stance model, as this was the most unstable scenario, with greater shear, bending and rotational forces than a double-leg stance and has been postulated to be more relevant to the clinical situation [18]. Other studies have used strain gauges, inclinometers, linear voltage transducers, or electromagnetic motion sensors to measure displacements, rotations, and 3-dimensional movements [18, 20, 23, 25]. We chose high-speed video because it allowed us to evaluate in real-time the complex movements across the pelvis, and gave us an accurate (up to 0.8 mm) detection of displacement to measure the stiffness of each construct.

A limitation to this study was the small sample size for each device; however, there was a significant difference observed in pubic symphysis gapping, and throughout the testing of each system on each pelvis, there was no degradation of data. Another limitation is the use of a synthetic pelvic model. This model is a fourth generation composite pelvis model (Sawbones, Vashon, WA, USA) which supposedly behaves more like real bone [11, 12]. The fact that the same models were used between the tests hopefully minimises the variability between tests. We randomised the testing so that different models used different devices

in different sequences throughout our experiment and used five tests to assess for degradation and then averaged them to minimise this effect. We were unable to simulate exactly the soft tissues and ligaments of the pelvis, or the different bone qualities. However, this uniform material allowed for consistency in fixation and testing, and allowed for a more controlled evaluation of the biomechanical stability as used in previous studies [11–13]. Although cadaver pelvises are optimal it would be difficult to compare the two-pin external fixator and the ASPIF system in the same model due to a similar location of screw insertion and in different models because of the variability between specimens. We wanted to test the construct and did not want the bone screw interface to be an additional variable which is a huge disadvantage in a cadaver model. Additionally, unstable AO/OTA type C or Young and Burgess APC III [1] injuries are recommended to have both anterior and posterior fixation [2]. However, we used this biomechanical test model because it represents the worst-case scenario in terms of force transmission that would be seen clinically and provides a repeatable, previously-used biomechanical testing method to compare the stiffness of the constructs [6, 16, 17, 23]. We recommend anterior and posterior fixation for these injuries as is standard in the literature [2].

The downside to using this internal fixation device is that it has to be removed in the operating room whereas many external fixators are removed in a clinic. We have removed the device in most cases between three and six months and are unsure what happens with extended retention of the device. The ability to temporarily fix a pelvis and use the same implants for definitive fixation at a later date after adjustment and addition of posterior fixation is potentially useful [7, 10].

Conclusion

The ASPIF allowed for indirect compression of the SI joint superior to two-pin external fixation, and comparable to the femoral distractor. In single stance gait the ASPIF

demonstrated lower peak loads and stiffness than the femoral distractor. It is unclear whether these differences have clinical significance. Combined with the presumed benefit of minimising the complications associated with external fixation, the ASPIF may be an option for temporary anterior pelvic fixation.

Conflict of interest The authors declare that they have no conflict of interest in the preparation of this publication. We also declare that Dr. Vaidya has received payment for lectures from AO Trauma and Synthes Trauma for teaching courses; Dr. Vaidya has received payments for consulting with Stryker Corporation for implant development; and Dr. Vaidya is involved in developing an FDA approved product for Stryker Corporation which is not this fixator that is made from custom spinal implants.

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