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A biomechanical study comparing minimally invasive anterior pelvic ring fixation techniques to external fixation

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ABSTRACT

Introduction: INFIX and Pelvic Bridge are two new minimally invasive surgical techniques for unstable pelvic ring injuries, and they have demonstrated early clinical success in small, single-center case-series. The primary objective of this study is to gather evidence speaking to the biomechanical stability of internal bridging methods relative to external fixation, with the expectation of biomechanical equivalence.

Methods: Ten human cadaveric pelvic specimens were dissected free of all skin, fat, organs, and musculature and were prepared with a partially unstable pelvic ring injury (OTA/AO 61-B). The specimens were randomized to two groups and were repaired and tested with anterior pelvic external fixation (APEF) and INFIX sequentially, or APEF and Pelvic Bridge sequentially. Testing was performed with each specimen mounted onto a servo-hydraulic testing frame with axial compression applied to the superior base of the sacrum under five axial loading/unloading sinusoidal cycles between 10 N and 1000 N at 0.1 Hz. Relative translational motion and rotation across the osteotomy site was reported as our primary outcome measures. Outcome measures were further analyzed using a Wilcoxon signed-rank test to determine differences between non-parametric data sets with significance defined as a p value < 0.05.

Results: We found no statistical difference in translation ($p = 0.237, 0.228$) or rotation ($p = 0.278, 0.873$) at the fracture site when comparing both new constructs to external fixation. Under the imposed loading protocol, no episodes of implant failure or failure at the bone-implant interface occurred.

Discussion: Our study provides the biomechanical foundation necessary to support future clinical trial implementation for pelvic fracture patients. While biomechanical stability of these newer, subcutaneous techniques is equivalent to APEF, the surgeon must take into account their technical abilities and knowledge of pelvic anatomy, patient-specific factors including body habitus, and the potential complications associated with each implant and the ability to avoid them.

Introduction

Pelvic ring injuries are complex injuries to treat and are associated with significant morbidity and mortality [1,2]. These injuries occur frequently in high-energy trauma and can render the pelvis unstable for physiological weight-bearing. Stabilization of the pelvis early in the trauma patient's management is critical to their survival. Although the current treatment protocol using anterior pelvis external fixation (APEF) with adjunct posterior fixation for stabilization of the pelvic ring and control of hemorrhage has been shown to effectively reduce mortality, these fixators cause a high frequency of new morbidities [3–5].

APEF is quickly and easily applied by the orthopaedic surgical team and has demonstrated a reduction in morbidity and mortality to rates comparable with those in patients sustaining stable pelvic injuries [6]. Although this technique is in current, widespread, global use, it is associated with multiple complications including pin site infection, fixator loosening, and impingement of the fixator on the skin. The incidence of these complications range from 10% to 62% [7–10].

Additional aspects associated with APEF are counterproductive to the healing needs of these severely injured individuals. Aside

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from the clinical complications, these external fixators impair the nursing staff's ability to bathe and mobilize the patient during hospitalization. During the later phases of recovery, they impede the patient's ability to wear clothes, sit upright, lay prone, or have sexual intercourse. Furthermore, patient satisfaction of external fixators worn 4–12 weeks for recovery is extremely low in spite of their potential life-saving function. Subcristal pelvic external fixation has been described in the literature as an alternative technique demonstrating success in small clinical trials with lower rates of pin loosening and pin tract infections. The thoughtful positioning of pins also facilitates walking, sitting, and dressing for patients. Although complications are decreased and mobility is improved with this technique, pin tract infections occurred in 20% and activities such as laying prone and engaging in sexual intercourse are not facilitated [11].

New surgical techniques for unstable pelvic ring injuries utilizing readily-available spine implants have been described in the literature with early clinical success in small, single-center case-series [12–17]. The newly proposed subcutaneous internal bridging fixation constructs differ in their designs by either fully bridging the anterior pelvic ring from left to right ilium (INFIX) or by fully bridging the anterior pelvic ring and engaging the pubis with adjunctive fixation (Pelvic Bridge) (Figs. 1 and 2). Prior to widespread adoption of either of these new concepts, a critical step in the systematic investigation of any new fixation strategy involves comparative biomechanical efficacy in a cadaveric model [18]. The primary objective of this study is to gather evidence speaking to the biomechanical stability of internal bridging methods relative to external fixation, with the expectation of biomechanical equivalence.

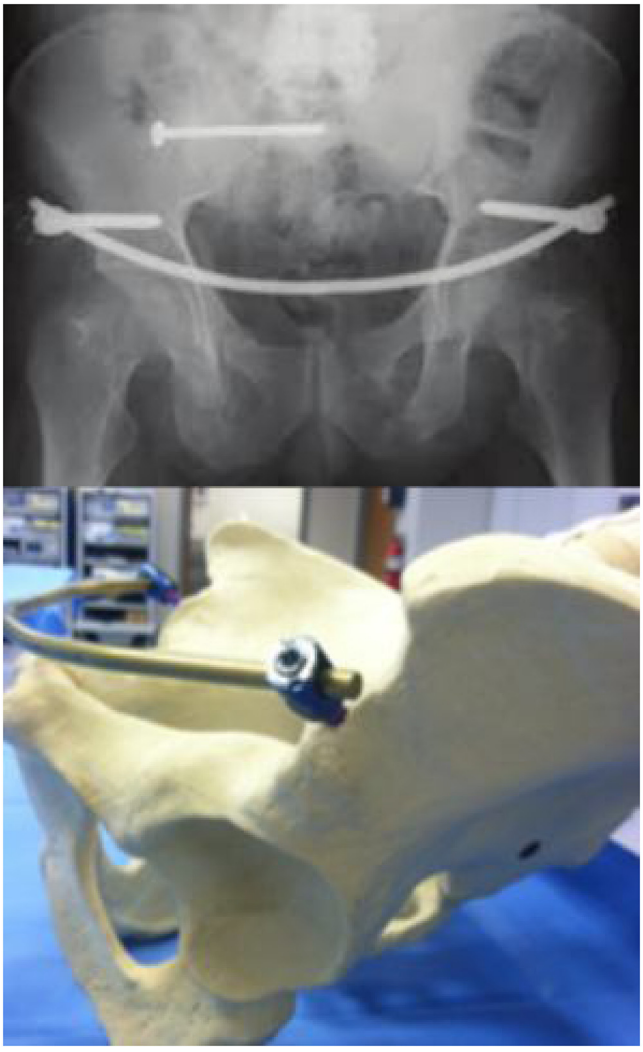

Fig. 1. Radiograph and pelvis model demonstrate placement of INFIX. Two pedicle screws inserted into bilateral supraacetabular bone and interconnected by a 6 mm curved, titanium rod.

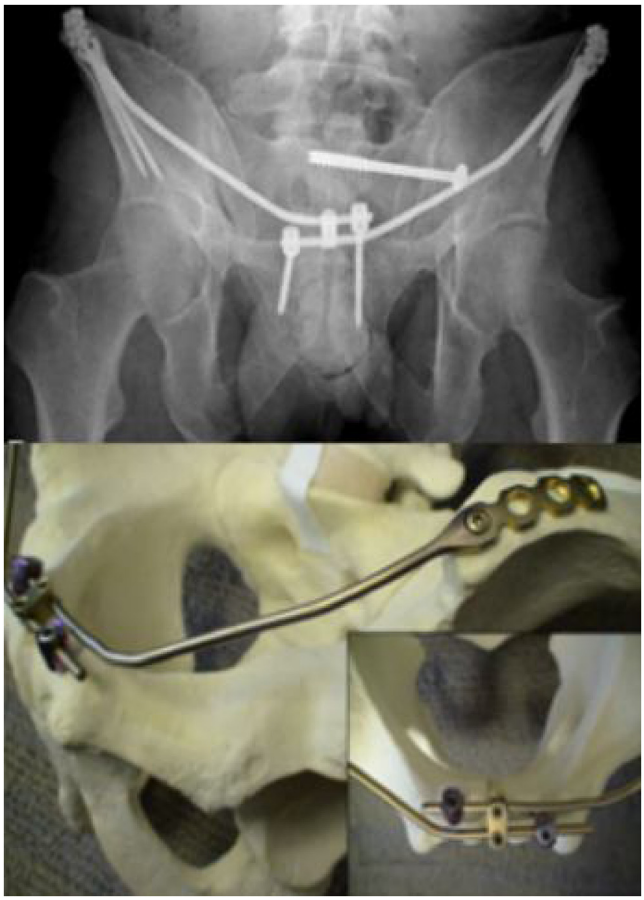

Fig. 2. Radiograph and pelvis model demonstrate placement of Pelvic Bridge. A rod-plate construct spans the iliac crest to the contralateral superior pubic rami, and utilizes pedicle screw fixation in the pubic rami and a rod-to-rod connector midline.

Methods

Ten human cadaveric pelvic specimens were acquired from our university Bequest Program, which, in cooperation with the IRB, provides research oversight for cadaveric studies. The fresh human pelvis specimens were dissected free of all skin, fat, organs, and musculature while ligaments and hip joint capsule were left intact. They were then prepared with the following partially unstable pelvic ring injury (OTA/AO 61-B): osteotomy of the right superior and inferior pubic rami and disruption of ipsilateral sacrospinous, sacrotuberous, and anterior sacroiliac ligaments.

Following recreation of the injury, each specimen was randomly assigned to Group A or Group B. Group A included five specimens repaired and tested with APEF and INFIX, with the order of implants tested alternating with each specimen. Group B included five specimens repaired and tested with APEF and Pelvic Bridge in a likewise fashion. This repeated-measures approach enabled each internal bridging fixation method to be compared to external fixation in a manner that controls for inter-specimen differences because each specimen served as its own control, thereby maximizing statistical power and the informational utility of each

specimen. Pelvic Bridge and INFIX instrumentation was applied in the manner described in respective published surgical techniques [19,20]. Supra-acetabular APEF was applied in the method described by Calafi and Routt [21]. Fluoroscopy was not utilized due to the lack of cadaver skin, subcutaneous tissue, and muscle that allowed us to observe that the Schanz pins remained within the iliac tables. All implants were placed by the same author (LM). APEF implants included two 11.0 mm (mm) diameter × 200 mm length carbon fiber rods, two 5.0 × 150 mm Schanz screws, and associated clamps. INFIX implants included a contoured 6.0 × 400 mm titanium rod and two 7.0 × 75 mm polyaxial pedicle screws. Pelvic Bridge implants included two 4.0 × 240 mm titanium plate-rods, four 4.0 × 70 mm locking screws, two 4.5 × 50 mm polyaxial pedicle screws, and a rods connector. A new set of implants was utilized for each specimen, and each set of implants was completely removed prior to assembling and testing the second set of implants.

After surgical fixation, each specimen was mounted onto a servo-hydraulic testing frame (MTS, Eden Prairie, MN) as described by Simonian et al [22]. With bilateral femora potted, mounting occurred centrally through the sacrum at the level of S1 in anterior tilt with an inclination of 45 degrees with respect to vertical to simulate erect stance (Fig. 3). Reflective optical marker triads (MKR-6.4, B&L Engineering, Santa Ana, CA) were positioned on the sacrum, right ilium, and right pubis. The two optical markers on the right pubis were placed on either side of the osteotomy. The anterior-superior apex of each side of the fracture site were registered using an optical marker stylus, serving as the origins of the two coordinate systems representing the bony structures on the left and right side of the fracture site. Data collected from our infrared motion measurement system has been used in numerous published studies and the accuracy of displacement measurements is 0.1 mm [23–26].

Biomechanical testing was also carried out in a similar manner as described by Simonian et al [22]. Axial compression was applied to the superior base of the sacrum via an aluminum rod with semi-spherical head connected to the MTS actuator. The pelvis was tested under five axial loading/unloading sinusoidal cycles between 10 N and 1000 N at 0.1 Hz, during which the motion of the optical markers was measured via a motion capture system (Nexus V1.0, VICON, Oxford, UK) at a sampling rate of 50 frames per second.

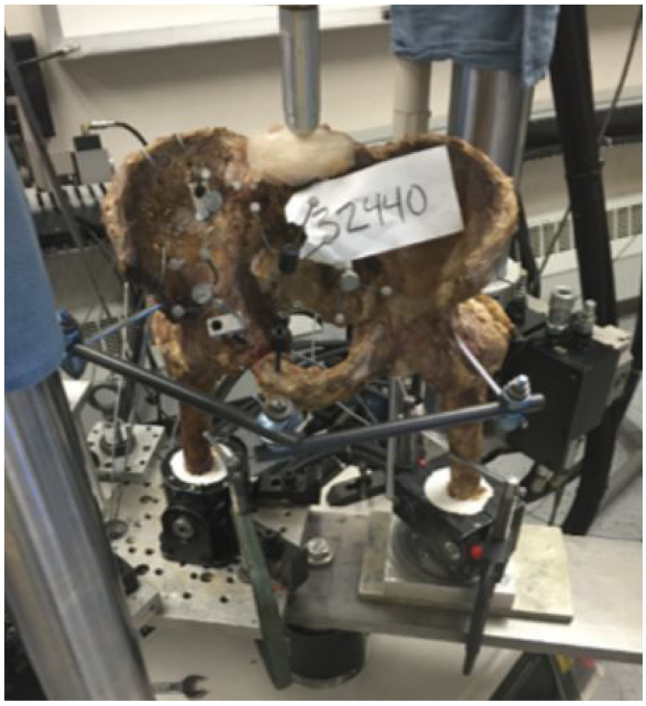

Fig. 3. Pelvis specimen mounted on testing frame after osteotomy created and implants (APEF) placed. Motion sensors in place on sacrum, right iliac wing, and pubis.

Relative translational motion and rotation across the osteotomy site was reported as our primary outcome measures. Bulk motion of the pelvis under axial compression can still occur. However, the motion reconstruction algorithm was able to extract the motion of the left hemipelvis relative to the right hemipelvis utilizing several steps. First, frame-to-frame coordinate transformation matrices were calculated, which contained both relative translational and rotational components. Then, frame-to-frame change in spatial distance between origins of the coordinate systems were calculated based on the translational components of the matrices. Meanwhile, a plane was formed by the unit vectors of the coordinate system at a given frame, and its normal vector was calculated. Orientation of such plane changed during the testing, defining a plane-to-plane angle from frame-to-frame. Plane-to-plane angle was calculated and reported as the relative rotational motion that occurred at the osteotomy site. Such change in spatial distance between the two anterior-superior apexes and the change in the plane-to-plane angle defined above were reported. The first four loading cycles served as pre-conditioning soak cycles, and the motion data of the last cycle was calculated and reported. Outcome measures were further analyzed using a Wilcoxon signed-rank test to determine differences between non-parametric data sets with significance defined as a p value < 0.05.

Results

We found no statistical difference in translation ($p = 0.237$, 0.228) or rotation ($p = 0.278$, 0.873) at the fracture site when comparing both new constructs to external fixation. INFIX averaged 1 mm less translation at the fracture site on average compared to APEF, and Pelvic Bridge averaged 0.52 mm more translation than APEF. However, mean translation for each construct was less than two millimeters. Mean rotation at the fracture site was within 0.2 degrees for all constructs and overall less than 2 degrees (Table 1).

Translation, and to a lesser degree rotation, differed between different specimens fixed with the same implant. Specimens fixed with APEF, INFIX, or Pelvic Bridge had translation that ranged from 0.29 to 4.93 millimeters, 0.48–1.36 millimeters, and 1.16–4.09 millimeters respectively (Table 2).

Under the imposed loading protocol, no episodes of implant failure or failure at the bone-implant interface occurred.

Discussion

This study addresses a gap in the scientific knowledge regarding the mechanical competence of new techniques of treating pelvic ring injuries subcutaneously. Both new techniques have demonstrated biomechanical stability equivalent to APEF. Our results also demonstrate the benefit of performing biomechanical pelvic testing using the same implants on one specimen in order to control for inter-specimen differences in bone quality and ligamentous laxity.

Several limitations of our study should be considered. Our biomechanical testing was performed on a limited number of specimens. However, we feel that our repeated-measures approach allowed us to maximize statistical power and the informational utility of each specimen. Also, lack of functional musculature on cadaveric specimens affects the normal physiology and support of a human pelvis. We feel that this does not

Table 1
mm = millimeters.

		Translation (mm)			Rotation (degrees)		
		Mean	Range	p value	Mean	Range	p value
Group A	APEF	1.87	0.40–4.93	**0.188**	0.94	0.32–2.10	**0.188**
	INFIX	0.87	0.48–1.36		0.78	0.24–1.40	
Group B	APEF	1.42	0.29–4.45	**0.313**	1.20	0.32–3.05	**0.989**
	Pelvic Bridge	1.94	1.16–4.09		1.26	0.35–2.69	

negatively affect our results because dissections were performed in an identical manner for all specimens, and we based our methodology on a previously validated, reproducible method of pelvis biomechanical testing [22]. In addition, we do recognize that variability exists from one construct to another based on surgical decision making. All implants were placed in a manner that would be appropriate for an individual with a normal body mass index. Therefore, the results of our study do not necessarily apply to patients treated with APEF with an elevated body mass index that would require an increase in bar-to-bone distance to accommodate body habitus. Similarly, INFIX requires the use of longer pedicle screws in obese patients in order to avoid the possibility of a femoral nerve palsy. On the contrary, biomechanical stability of Pelvic Bridge reported in our study is generalizable to all body types due to the subcutaneous nature of these implants and lack of proximity to major neurovascular structures. In regards to INFIX instrumentation, we felt it most appropriate to use polyaxial pedicle screws for several reasons. Recently, biomechanical testing on synthetic bone models has shown that monaxial screws increase the stiffness of the construct, but polyaxial screws are illustrated in published techniques of this instrumentation and are most commonly utilized clinically as it allows for easier passage of the connecting rod [20,27]. Kowalski et al. studied the difference between metal and carbon fiber rods in external fixation. They found that metal rods create a stiffer frame compared to carbon rods, which is thought to be due to motion at the clamp-rod connection [28]. However, we utilize carbon rods for APEF in a clinical setting due to their lighter weight and radiolucent nature, and therefore chose this implant in our testing. Furthermore, we acknowledge the difference between placement of the constructs in the clinical environment, which does not mimic the ideal circumstances of placing the hardware on cadaver bones in a visually optimal position. Lastly, we acknowledge that INFIX and the Bridge constructs are not ideal head to head comparisons of technique in that the bars and screws were wider diameters than for the pelvic bridge, but we sought to compare what has been described previously, clinically in the literature.

Table 2
mm = millimeters, deg = degrees.

Group	Specimen	Implant	Translation (mm)	Rotation (deg)
A	1	APEF	4.93	2.10
		INFIX	1.10	1.40
	2	APEF	1.74	0.48
		INFIX	0.93	0.50
	3	APEF	0.40	0.31
		INFIX	0.48	0.24
	4	APEF	0.88	0.61
		INFIX	0.48	0.54
	5	APEF	1.42	1.22
		INFIX	1.36	1.20
B	6	APEF	4.45	3.05
		Bridge	4.09	2.69
	7	APEF	1.36	1.38
		Bridge	1.16	0.42
	8	APEF	0.70	0.60
		Bridge	1.20	0.35
	9	APEF	0.29	0.32
		Bridge	1.78	1.49
	10	APEF	0.31	0.63
		Bridge	1.46	1.36

Our loading protocol was developed based on earlier studies evaluating physiologic loading of the pelvis, and a number of aspects were considered in order to appropriately translate in vitro cadaver testing to clinical patient care [29,30]. Standing, bending, and twisting create loads of 470–970 N through the human pelvis in vivo. However, loads greater than 1000 N occur with resisted hip flexion [29]. Greater loads likely occur in obese individuals as well, although there is currently no literature reported on this topic. In addition, a patient with a pelvic fracture will experience thousands of cycles of loading through their pelvis prior to the occurrence of bony healing. Our loading protocol, 1000 N for 5 cycles, was determined to be adequate to address our hypothesis which states that we expected new implants to demonstrate biomechanical equivalence to APEF. We did not feel load-to-failure testing was necessary due to adequate stability that APEF has demonstrated in a clinical setting. The rate of implant failure for definitive APEF is 12%. None of these failures were related to failure of the implants, and instead were due to pin loosening or pull out at the bone-implant interface [13]. Therefore, equivalent biomechanical efficacy of these new implants compared to APEF translates to stability that is safe and adequate for use in patients. A number of prior biomechanical pelvis studies have utilized similar loading protocols based on these concepts [22,31–34].

Our study is the first to report on biomechanical stability of the Pelvic Bridge, and our results for INFIX are consistent with prior studies. Several in vitro studies have demonstrated superior stability of the anterior pelvic ring with INFIX compared to APEF [35–37]. This was reproduced in our study as well, with slightly less translation occurring at the osteotomy site when compared to APEF.

Both INFIX and Pelvic Bridge have demonstrated promise in small, retrospective clinical case series with short- to mid-term follow up [16,17,38]. Complications related to each implant have also been reported. With the use of INFIX, rates of lateral femoral cutaneous neuropraxia have been reported as high as 48.3%, although it frequently is self-limited [39]. Early loosening or loss of fixation, pain related to impingement, and deep surgical site infections have also been reported and typically require revision surgery [39]. A recent case series of six patients described eight femoral nerve palsies, of which only one fully recovered after removal of implants [40]. Pelvic Bridge rates of complications have been reported as low as 4% overall, and have included transient lateral femoral cutaneous neuropraxia, pubic rami nonunion, and a superficial wound infection [13].

Our study provides the biomechanical foundation necessary to support future clinical trial implementation for pelvic fracture patients. While biomechanical stability of these newer, subcutaneous techniques is equivalent to APEF, the surgeon must take into account their technical abilities and knowledge of pelvic anatomy,

patient-specific factors including body habitus, and the potential complications associated with each implant and the ability to avoid them. The ultimate goal in advancing the treatment of pelvic ring injuries is to reduce complications, improve quality of life, and maximize functional status during the recovery and post-recovery period.

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Funding was received by Depuy-Synthes for this study. Depuy-Synthes did not have any involvement in the study design; collection, analysis and interpretation of data; the writing of the manuscript. They did review the manuscript prior to submission for publication, and they made no requests for changes in the original manuscript.

Conflicts of interest

L.M., P.C., and L.S. received a research grant from Depuy-Synthes in 2015 to assist with funding this study.

F.C. Employed by and receives compensation from Excelen and University of Minnesota.

J.G.: None.

S.K.: None.

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