Midterm Radiographic and Functional Outcomes of the Anterior Subcutaneous Internal Pelvic Fixator (INFIX) for Pelvic Ring Injuries

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Objective: To describe our experience using the anterior internal pelvic fixator (INFIX) for treating pelvic ring injuries.

Design: Case Series.

Setting: Level 1 Trauma Center.

Patients: Eighty-three patients with pelvic ring injuries were treated with INFIX. Follow-up average was 35 months (range 12–80.33).

Intervention: Surgical treatment of pelvic ring injuries included reduction, appropriate posterior fixation, and INFIX placement.

Outcome Measurements: Reduction using the pelvic deformity index and pubic symphysis widening, Majeed functional scores, complications; infection, implant failure, heterotopic ossification (HO), nerve injury, and pain.

Results: All patients healed in an appropriate time frame (full weight bearing 12 weeks postoperation). The average pelvic deformity index reduction (injury = 0.0420 ± 0.0412 , latest FU = 0.0254 ± 0.0243) was 39.58%. The average reduction of pubic symphysis injuries was 56.92%. The average Majeed score of patients at latest follow-up was 78.77 (range 47–100). Complications

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were 3 infections, 1 case of implant failure, 2 cases implantation too deep, 7 cases of lateral femoral cutaneous nerve irritation, and 3 cases of pain associated with the device. HO was seen in >50% of the patients, correlated with increased age (P < 0.007), injury severity score (P < 0.05) but only 1 case was symptomatic.

Conclusions: The pelvic injuries had good functional and radiological outcomes with INFIX and the appropriate posterior fixation. The downside is removal requiring a second anesthetic, there is a learning curve, HO often occurs, the lateral femoral cutaneous nerve may get irritated which often resolves once the implants are removed. Surgery-specific implants need to be developed.

Key Words: pelvic fracture, internal fixator, Majeed, symphyseal disruption, anterior fixatior, ramus fracture, pelvic fixation, functional outcomes, heterotopic ossification, pelvic deformity index, lateral femoral cutaneous nerve

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

The use of an anterior external fixator (Exfix) in the treatment of pelvic injuries is effective and may be lifesaving.¹⁻¹⁹ Exfix is associated with pin-tract infections (25%–50% of pts),^{1,2,4,10–15,17,19,20} osteomyelitis (7%),^{1,2,10,11,14,17} lossening (10%),^{10,11,14,15,17} loss of reduction (up to 33%),^{2,4,10} is difficult to use in obese patients,⁷ and can be restrictive to movement.

The anterior subcutaneous internal pelvic fixator (INFIX)²¹ attempts to address these issues and has been used by several groups with good early results for reduction, fracture healing, patient mobility, comfort, and has acceptable complication rates.^{21–26} The reported complications include heterotopic ossification (HO), lateral femoral cutaneous nerve (LFCN) irritation, loss of fixation,^{21,22,27} and recent reports of femoral nerve palsy.²⁸ The construct is biomechanically superior to the anterior 2 pin external fixator in stiffness when tested in single leg stance in an anterior–posterior compression type 3 (APC3) pelvic model,²⁹ as strong as a femoral distractor for compressing the sacroiliac joint in an APC injury,³⁰ equivalent to an external fixator in repetitive motion testing of translational stiffness and superior to an external fixator in repetitive motion testing of rotational stiffness.³¹

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The purpose of this report is to evaluate our experience with INFIX, quantifying the results using radiographic measures, ^{32–34} functional outcomes,³⁵ complications, and technical issues we have encountered and learned from.

PATIENTS AND METHODS

An institutional review board-approved retrospective study was performed on 83 consecutive patients who underwent implantation of an INFIX between November 2007 and September 2014 at our institution and had a minimum of 12 months follow-up. Twenty-six patients in our database were not included because of loss of follow up (21) or early death (4). The surgical technique, reduction of the injury and, equipment for implantation, was previously described^{21,36} and demonstrated on the Orthopaedic Trauma Association video gallery^{37,38} (Fig. 1). The INFIX apparatus in this article was made with long pedicle or Schanz screws and rods from Johnson and Johnson Depuy Synthes (Paoli, PA).

We recorded demographic information including body mass index (BMI), fracture classifications, associated injuries with the injury severity score (ISS), timing of treatment, mechanism of injury, comorbidities and complications. Functional outcomes were assessed using the Majeed score, and radiographic outcomes were measured using the pelvic deformity index (PDI)^{32,34} and distraction of the pubic symphysis (PS).

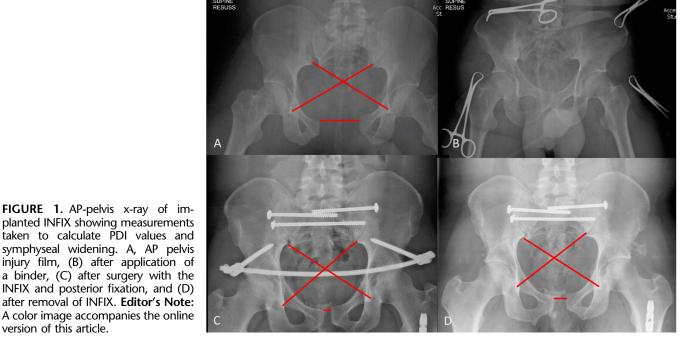
Patients

The indications for surgery included an unstable pelvic fracture (OTA/AO classification 61-B or C 76 pts) as a result of a motor vehicle collision or pedestrian hit by a vehicle, falls, or crush injury; a painful pathologic fracture unresponsive to pain medications and failing to heal (6 patients); and an insufficiency

fracture which was chronic and painful to the point of preventing ambulation (1 patient) (Table 1). The average age of the patients was 41.67 ± 15.9 years (median 42 years, range 14–86 years). There were 57 (68.7%) men and 26 (31.3%) women. The average ISS was 22.75 \pm 11.2 (median 21, range 5–57) and BMI was 27.6 ± 7.4 (median 26.3, range 17.03–48.0). The average time from fixation to survey was 33.29 months (range 12.15-80.33). Eighty of the 83 patients also required posterior fixation and 11 had temporary external fixators/femoral distractors placed before definitive treatment with INFIX. In all cases, the conversion was performed within a week.

Pelvic fractures were graded separately by an orthopaedic surgery resident and 2 fellowship-trained orthopaedic trauma surgeons using the OTA/AO³⁹ and Young and Burgess⁴⁰ classification systems. AP-pelvis radiographs were used in conjunction with computed tomography and fluoroscopic manual examination under anesthesia to classify the fractures. In the case of disagreements, a consensus was reached after a discussion. The fracture asymmetry was measured on anterior posterior pelvis x-rays using the cross measurement method first described by Keshishyan³² and later modified by Lefaivre^{33,34} (PDI Fig. 1). Measurement of PS displacement was performed using the largest width of the PS for disruptions. These measurements were performed preoperatively, postoperatively, after INFIX removal and at latest follow-up. Functional outcomes were assessed using the scoring system described by Majeed.³⁵ This was obtained at the latest clinic visit (47 patients) or by phone survey (36 patients).

HO in the soft tissues surrounding the implants was determined on x-rays at 3 months postoperation before INFIX removal and at latest follow-up. The severest grade of the 2 x-rays was used. HO was graded based on size and appearance as none, some HO (wispy or diffuse <30 mm),



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Patient	Age	Sex	Mechanism of Injury	ISS	OTA/AO Class	Young + Burgess Class	Pre-Op PDI	Post-Op PD
1	21	F	MVP	14	61-C1.3a1c1	VS	0.0097	0.0225
2	32	М	MVA	29	61-C1.2a2c3	VS	0.0103	0.136
3	27	F	MVA	34	61-C1.3a1c3	VS	0.0203	0.0337
4	23	М	MCA	18	61-C1.2a2c5	VS	_	0.0270
5	42	F	MVA	41	61-B3.2c3	LC3	0.1616	0.0303
5	22	F	MVA	14	61-B2.2(1)c1	LC2	0.0196	0.0060
7	50	М	MVP	21	61-C3.1(a4)c3	VS	0.0098	0.0068
3	21	М	MCA	25	61B3.2a2b1c1	LC3	0.1090	0.0584
)	48	F	MVA	34	61C2.3a1b1	VS	0.0324	0.0326
10	64	М	MCA	14	61B3.1c4	APC2	0.0331	0.0283
11	63	М	Tractor acc	22	61B3.2a4b1c8	LC3	0.0761	0.0457
12	46	М	Indust acc	17	61C2.3a1b1c1	VS	0.0153	0.0710
13	71	М	MVA	21	61C3.1a4b4c9	APC3	0.0145	0.0147
14	28	М	Fall	27	61C1.3a2c1	VS	0.0086	0.0100
15	27	F	MVA	22	61C1.3a1c3	VS	0.0006	0.0072
16	35	F	MVA	33	61C1.2a1c1	VS	0.0317	0.0004
17	44	М	MVA	45	61C3.1a2b2c4	VS	0.0307	0.0042
18	46	М	Fall	18	61C3.1a2c4	VS	0.0479	0.0362
19	42	М	MVP	27	61B3.1(1)c4	APC2	0.0074	0.0534
20	55	М	MVP	13	61B1(1)C4	APC2	0.0068	0.0083
21	21	F	MVA	21	61C3.1c4	APC3	0.0320	0.0327
22	53	М	MVA	5	61B2.2c3	LC2	0.0307	0.0151
23	21	F	MVA	17	61B2.2c3	LC2	0.0207	0.0370
24	52	М	Path fx	12	61B2.3(1)c2	LC2	0.0648	0.0132
25	71	F	Sac insuff fx	4	61-B2.1c1	LC1	0.0152	0.0070
26	63	М	MVA	20	61-C1.1c3	СМ	0.0754	0.0240
27	53	М	MVP	10	61-C1.2a1c1	СМ	0.0349	0.0319
28	26	М	MVP	12	61-A2.2(1)	LC2	0.0201	0.0208
29	27	F	MCA	29	61-C1.3a2c3	LC2	0.0575	0.0430
30	50	М	MVA	17	61-B2.1(1)c1	LC2	0.0108	0.0162
31	44	М	MCA	41	61-B3.2(3)a3b1.1c7	LC3	0.0232	0.0230
32	23	M	MVA	18	61-B2.1(1)c1	LC2	0.0369	0.0274
33	21	M	MVP	9	61-C1.2a3c1	VS	0.0024	0.0112
34	44	F	MVA	9	61-B2.2(1)c1	LC1	0.0041	0.0018
35	22	F	MVA	30	61-C1.2a2c9	VS	0.1339	0.0389
36	42	M	MVP	18	61-C1.2a1c1	VS	0.0296	0.0153
37	21	F	MVA	27	61-B2.1(1)c8	LC3	0.0148	0.0072
38	33	F	MVA	57	61-B2.1(1)c3	LC3	0.0164	0.0269
39	60	M	Fall	22	61-B1(1)	LC2	0.0282	0.0194
40	60	M	MVP	29	61-C1.2a2c1	LC2	0.0311	0.0113
41	55	M	MVP	34	61-B2.1c3	LC2	0.0031	0.0384
42	19	M	MVA	27	61-B2.1c4	LC2	0.0406	0.0089
43	19	F	MCA	21	61-B3.3(2)a2b3c3	LC2 LC3	0.0071	0.0167
44	35	F	MVP	36	61-C2.1b1.1c3	CM	0.0770	0.0568
45	57	F	MVA	41	61-B3.2(1)a1b4c10	LC3	0.0266	0.0009
46	22	M	Fall	9	61-B2.1(1)c1	LCJ LC1	0.0200	0.0003
40 47	25	M	MVA	50	61-B2.1(1)c1	LC1 LC2	0.0167	0.0043
					61-B3.2(3)a2b1c1			
48 49	62 50	M M	MVA MVP	14 14	(<i>'</i>	LC3 LC3	0.0932 0.0278	0.0421 0.0172
			MVP	14 20	61-B3.2(3)a2b1c1			
50 51	24	M M	MVP	29 20	61-C1.2a1c9	LC2	0.0557	0.0050
51	41	M	Indust acc	20	61-C1.3a2c8	APC3	0.0989	0.0431
52	33	M	MPC	22	61-C1.2a2c4	CM	0.0337	0.0271
53 54	68 27	M M	Horse Riding MVA	20 57	61-B1.1(1)c5 61-C1.2a1c10	APC2 APC3	0.0127 0.0600	0.0018 0.0371

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Patient	Age	Sex	Mechanism of Injury	ISS	OTA/AO Class	Young + Burgess Class	Pre-Op PDI	Post-Op PD
55	26	М	MCA	21	61-B1.1(1)4	APC3	0.0205	0.0204
56	49	F	MVP	13	61-B2.2c3	СМ	0.0753	0.0557
57	86	Μ	MVP	9	61-B3.1(1)a1b1.1c5	APC2	0.0012	0.0118
58	57	М	Fall	14	61-A2.3(1)	LC1	0.0249	0.0042
59	48	F	Path fx	4	61-B2.1	LC1	0.0866	0.0340
60	61	Μ	MVP	17	61-B2.2(1)c1	LC2	0.0119	0.0853
61	46	Μ	MVA	24	61-B1.1c5		0.0163	0.0105
62	53	F	Fall	18	61-C1.2a1c1	СМ	0.1254	0.0394
63	42	Μ	MVA	27	61-C1.3a1c9	VS	0.0551	0.1145
64	31	Μ	MCA	24	61-C2.2a2b1.1c5	APC3	0.0206	0.0060
65	52	F	MVP	9	61-B2.1c3	LC2	0.1075	0.0649
66	21	Μ	MVA	19	61-B3.2a1b2c2	LC3	0.0819	0.0485
67	53	F	MVP	34	61-B1	APC2	0.0269	0.0003
68	41	Μ	MCA	18	61-B1.1(1)c5	APC1	0.0152	0.0029
69	58	Μ	MVP	25	61-C1.3a2	VS	0.2110	0.0989
70	24	F	MVP	22	61-C1.2a2c2	VS	0.0610	0.0202
71	25	Μ	Fall	33	61-B1.1c7	APC2	0.0691	0.0195
72	62	Μ	MVP	18	61-B3.1(1)	LC3	0.0611	0.0131
73	49	М	Crush	9	61-A2.2(1)	LC1	0.0104	0.0121
74	31	М	MVA	18	61-C2.2a2b1.1c3	APC3	0.0195	0.0025
75	46	Μ	MVA	25	61-B1.1(3)	APC3	0.0691	0.0385
76	44	Μ	MVA	21	61-C1.2a2c1	LC1	0.0186	0.0273
77	41	F	MVA	21	61-B1.1(1)	LC2	0.0277	0.0273
78	59	М	MVP	25	61-C1.1c2	LC3	0.0414	0.0117
78	50	Μ	MVP	10	61-C2.1b1.1c8	LC3	0.1436	0.1235
80	25	Μ	MVA	28	61-C1.3a2c2	LC3	0.1146	0.0723
81	33	М	MVA	18	61-C2.3a3c1	APC3	0.0048	0.0394
82	31	F	MVA	25	61-B1.2c3	LC2	0.0214	0.0041
83	14	М	MVA	25	1B2.2a2b1.1c8	APC3	0.0824	0.0095

CM, combined mechanism; Fall, Fall from height >6 ft; F, female; LC, lateral compression; MCA, motorcycle accident; MVA, motor vehicle accident; MVP, motor vehicle versus pedestrian collision; M, male; VS, vertical shear.

and severe HO (>30 mm) (Fig. 2). The patients' left and right sides were evaluated separately, with the side having the most severe grade determining the overall HO classification.

Other complications were tabulated. Lessons learned from technical failures and improvements to the original technique are described and demonstrated.³⁷

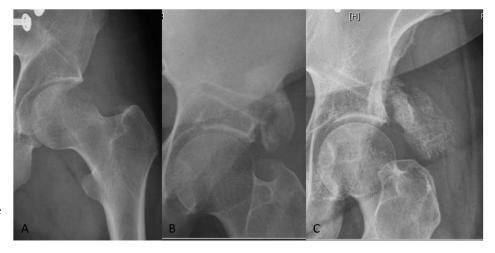


FIGURE 2. HO. A, None. B, Some HO < 3 cm in any direction. C, Severe HO > 3 cm in any direction.

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All statistical analyses were performed using Pearson correlation coefficients, the *t* test, or analysis of variance (ANOVA) in Microsoft Excel, where applicable. Statistical significance was determined as P < 0.05.

RESULTS

Fracture Healing

The pelvic injury was deemed to be healed when the patient was allowed to fully weight bear. In our study, all patients were allowed to be full weight bearing by 12 weeks postoperation without difficulty. Four patients did not weight bear at 12 weeks because of spinal cord injury (2) and 2 who had pathological fractures with multiple other conditions preventing weight bearing. There has been no case of nonunion from a traumatic fracture in this case series.

Fracture Reduction

The average reduction was 39.6% of the original injury (PDI). Patients who suffered injuries to the PS (30) experienced a 56.9% reduction of the injury after reduction and implantation of INFIX. Of these injuries, 17 had an original displacement greater than 25 mm, 9 between 15 and 25 mm, and 4 less than 15 mm. With the INFIX in place, there were 26 (PS < 14 mm) very good, 4 (15–25 mm) good symphyseal reductions (see **Table**, **Supplemental Digital Content 1**, http://links.lww.com/BOT/A845). Loss of reduction occurred in one case where the implants were improperly secured by one of our surgeons during the early stages of the study. This case was reinstrumented with the same implants the next day with C-rings to reinforce the construct and led to a good outcome.

Implant Retention

INFIX is typically removed after 3 months or when the fracture has demonstrated healing on x-ray. The average time of removal was 5.3 \pm 5.4 months (median 3.7, range 0.3– 49.5 months). The average time to removal was greater than 3 months as often patients are scheduled for the removal but patient or scheduling issues delayed the procedure and this number also includes several patients who did not want to have it removed when we suggested (including one who decided on removal at 49.5 months postoperation). Three patients had the device removed early because of the development of an infection. Seventy-three of the 83 implants were removed. Six patients died before removal (all had cancer, implant retained >12 months), 1 was unable to be removed because of complications with anesthesia, and 3 declined. Neither of these 3 patients complained about any discomfort from the INFIX. One patient had the implant in for 49.5 months and delivered 2 children vaginally with the bar in place.41

Outcome Scores

The average follow-up was 35 ± 12.4 months (range 12-80.33 months) and the average Majeed score was 78.8 ± 13.8 (median 78.5, range 47–100). Majeed scores were collected and analyzed by individual category (Table 2). Pearson correlations

were used to test for correlations between Majeed score and several other factors. In this series, a higher ISS was correlated with a poorer Majeed score (P < 0.0001 ANOVA). There was little correlation between the Majeed Score and age ($\rho = -0.19$) or reduction (PDI $\rho = -0.15$). Majeed scores verses length of follow-up <24 months (75.72) and >24 months (78.61) showed no significant difference (P = 0.50 t test).

COMPLICATIONS

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No sign of HO was seen in 32.5% of patients, some HO was found in 32.5%, and 35% had developed severe HO. Only 2 patients had symptoms related to HO. One patient had severe HO and complained for 4 months after removal of implants, did not let us remove it and the patient stopped complaining about it. A second patient had severe HO unrelated to the INFIX but to a massive soft tissue injury. This patient had multiple upper and lower extremity injuries including a proximal femur fracture.

ANOVA tests were performed to ascertain a relationship between HO: Majeed scores, duration of fixation, ISS, GCS, sex, race, and age. Older age and HO classes were statistically significant with a P value of 0.007. The relationship between higher ISS and HO development was found to be statistically significant with a P value of 0.05 using a t test. The length of time the INFIX was in place, GCS, sex, race, Majeed scores showed no significant relationship with the development of HO.

Infection

Infection at the surgical site was noted in 3 cases. One patient had a bladder injury with the suprapubic catheter placed above the bikini line at the time of INFIX placement. However, the urological team decided to reposition the catheter later that week and placed the catheter through the area of the INFIX bar (see Figure, Supplemental Digital Content 2, http://links.lww.com/BOT/A844). They were unfamiliar with the INFIX device and we failed to communicate its location. This led to an infection which required removal of the implant at 3 weeks. No loss of reduction was encountered as there was good posterior fixation. A second patient was noncompliant; he walked right away on the fracture and developed a posterior infection which presented 4 months after insertion. The third patient was obese, had a Morel-Lavallee lesion, and developed a superficial infection at the surgical site which eventually infected the hardware. We removed the implants, preformed serial irrigation and debridements's with eventual resolution after 6 weeks of intravenous antibiotics. At latest follow-up, there has been no recurrence of infection.

Persistent irritation of the LFCN was observed in 7 cases, none of which were problematic and resolved once the implants were removed. Our feeling is that as many as 25% of the patients have some irritation of the LFCN, most are minor and can be from numbness to paresthesia that resolve quickly. Persistent irritation was felt to be complaints that are still present at the time of implant removal. One patient developed

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Score	Maximum Score	Mean	Median	Range	Median Classification
Pain	30	27	30	15-30	Slight/none
Work	20	8.65	6	0–20	Light work/no work
Sitting	10	9.62	10	6-10	Pain free
Sexual intercourse	4	3.26	3	0–4	Uncomfortable
Walking aids	12	10.72	12	4–12	No sticks
Unaided gait	12	10.38	12	4-12	Normal
Walking distance	12	9.14	10	4-12	1 h without sticks or limp
Total	100	78.77	78.5	47-100	Good/excellent

TABLE 2. Breakdown of Majeed Scores by Subsection

numbness and dysesthesia at removal. These did not lead to any long-term difficulty.

Implant revision occurred in 3 of the early cases. In one case, the rods and caps were improperly secured, resulting in loss of reduction requiring revision as with the addition of C-Clamps.³⁸ In 2 morbidly obese patients, the INFIX bar was placed too deep, causing discomfort, a crease in the lower abdomen, and swelling in the legs and occurred in our first series that we reported.²¹ The screws were too short and sunk too far into the iliac wing at the anterior inferior iliac spine. The implants were removed and replaced with 110 mm screws which protruded from the anterior inferior iliac spine almost 50 mm so that the heads sat at the level of the subcutaneous rod. No further problems occurred in these individuals and they healed uneventfully.

Three cases of discomfort clearly caused by the device were observed all in very thin women. Each tolerated the situation and had the device removed at 3 months.

DISCUSSION

Physicians are always seeking better ways to provide treatment to their patients. It was this spirit that led to the development of the INFIX device as an alternative to the widely used external fixator for definitive fixation of anterior pelvic ring injuries. The INFIX technique was developed with obese individuals in mind, but as we became more confident, we expanded our indications. As such, our patients had a mean BMI of 27.6 (median 26.3, range 17.03–48.0), and we

do not restrict its use to obese patients. Patients find INFIX comfortable and are able to sit and move without limitation. 21,22

The Keshishyan cross method was chosen to analyze reduction because of its reliability compared with other methods described in the literature.⁴² Our average reduction was 39.6% and an average reduction in PDI of 0.0166 \pm 0.0343. A limitation of this method is that it frequently underestimates the severity of the fracture and the quality of the reduction in AP compression (APC) injuries as the disruption may be symmetric and thus give a very low PDI. Thus diastasis of the PS is important in assessing the severity and reduction of these APC injuries. A 56.9% reduction was seen in these 30 patients with 26 (PS < 14 mm) very good, 4 (PS 15-25 mm) good. There was loss of reduction in one case which required revision as reported above because of unfamiliarity with the implants. Loss of reduction has been reported with the use of polyaxial pedicle screws in APC3 injuries.^{22,27} We performed a biomechanical study to test this issue and found that polyaxial screws failed in distraction at about 150N, whereas monoaxial screws did not.³¹ Another study confirmed this.⁴³ If polyaxial systems are chosen, we recommend the use of C-Clamps outside these screws to reinforce the construct (Fig. 1C) or using the Universal Spine System fracture module (Synthes Spine, Paoli, PA) which is very strong.31,37

We chose to use the Majeed functional outcomes score as it is easy to perform, but shows similar validity when compared with other accepted methods of evaluating



FIGURE 3. The rod should be placed very superficial. The USS fracture module (Synthes Spine) has pins that are 150-mm long and in really obese individuals, they are very useful. **Editor's Note:** A color image accompanies the online version of this article.

functional outcomes of pelvic fractures.33 Median Majeed scores for pain, sitting, standing, and unaided gait all had scores within the highest range (Table 2). Sexual intercourse and walking distance score medians were within the second highest score. The only set of scores not within the highest 2 ranges in terms of median and mean were work scores. This discrepancy in work scores could reflect economic or personal factors such as the high rate of unemployment within our city (24% according to the Bureau of Labor Statistics). Overall, the Majeed scores indicate positive long-term results for the patients. We performed statistical analysis to ascertain significant relationships and correlations between different factors and Majeed scores. Most results were statistically inconclusive. However, greater ISS, which denote greater and more traumatic injuries, were found to have worse functional outcomes or lower Majeed scores score (P < 0.0001 ANOVA).

The complications associated with the INFIX procedure have previously been described,^{21,22} and most of these complications are not unique to INFIX. They can occur with other fixation methods. Pin-tract infections are common in anterior external fixators (25%–50% of pts),^{1,2,4,10–15,17,19,20} and the INFIX procedure also had infections in our hands although much reduced 3/83 (3.6%) because of the internal position. In patients who had an external fixator using supra-acetabular pin placement, we used a new screw path to place the INFIX after removing the external fixator pins.

Parasthesias in the distribution of the LFCN is a common occurrence with the INFIX and in our series was persistent in 7 patients. It may occur with an external fixator when using supra-acetabular pin placement as well due to the proximity of the device to the LFCN.⁴⁴ Removal of the device at the end of treatment solved the issue in each one of the patients except one but it was not found to be a problem as reported by this patient. Femoral nerve palsies have been reported in the literature as a complication of INFIX.²⁸ We have not experienced this in our patients. We feel that placing the screws too deep can lead to compression of the underlying structures. In our early series, this happened on 2 occasions and led to discomfort and leg swelling. However, it was recognized fairly quickly and revised with longer screws.²¹ The cases of femoral nerve palsy in an article by Hesse et al²⁸ all occurred in patients operated by surgeons early in their experience with the procedure.

HO around the device seems to be unique to INFIX, as it has not been reported in the literature for external fixation. In our series, it was related to increased ISS (P < 0.05) and age of the patient with older patients suffering more HO (P =0.007). It was asymptomatic in all patients even at latest follow-up, except in one patient as mentioned in the results. No specific treatment was performed. During hardware removal, one always has the opportunity to remove HO as well. We have conducted this several times when it was present but have not made it a routine practice.

Technical lessons: placing the screw heads too deep in obese patients can lead to compression of the underlying structures, and we recommend to keep the bar very superficial. We have switched from the use of pedicle screws to Schanz pins and the Universal Spine System fracture module (Synthes Spine) which has pins that are 150-mm long and in obese individuals they are useful (Fig. 3). In cases of APC3 injuries, there is sometimes force which exceeds the capability of the polyaxial pedicle screw caps and may lead to failure.^{22,27} In these cases, we have used monoaxial screws that have a very strong connection, the Schanz pins from the Universal Spine System fracture module, or have placed C-Clamps on the outside of both pedicle screws to reinforce the construct. These are all very strong constructs.³¹ The ultimate solution for this problem is to have implants specifically for this method which are designed to withstand the loads of a pelvis and have extremely long lengths.

The limitations of this study include the lack of a control group with fractures treated by the same surgeons using more traditional methods and leaves us with no way to compare INFIX directly with other methods. This is a retrospective study and several prospective comparative studies with INFIX and plates are now starting. Majeed scores were compared in patients who were at different stages of recovery, and although there was no correlation with the length of follow-up (<24 vs. > 24 months), we do believe a more homogenous group of patients would show improvement in scores over time or if we had followed outcome scores during the entire recovery period, this trend may have become apparent in the recovery of each patient. It is still unclear to us from this data set when improvement in outcome begins to plateau. Our study is a larger single-center sample of patients than previously seen in the literature regarding INFIX.

CONCLUSIONS

The pelvic injuries had good functional and radiological outcomes with INFIX and the appropriate posterior fixation. The downside is removal requiring a second anesthetic, there is a learning curve, HO often occurs, the LFCN may get irritated which often resolves once the implants are removed. Surgery-specific implants need to be developed.

REFERENCES

- Arazi M, Kutlu A, Mutlu M, et al. The pelvic external fixation: the mid-term results of 41 patients treated with a newly designed fixator. *Arch Orthop Trauma Surg.* 2000;120:584–586.
- Bellabarba C, Ricci WM, Bolhofner BR. Distraction external fixation in lateral compression pelvic fractures. J Orthop Trauma. 2000;14: 475–482.
- Rockwood CA, Green DP, Bucholz RW, et al. Rockwood and Green's Fractures in Adults. Philadelphia, PA: Lippincott Williams & Wilkins; 2006.
- Gansslen A, Pohlemann T, Krettek C. A simple supraacetabular external fixation for pelvic ring fractures [in German]. *Oper Orthop Traumatol.* 2005;17:296–312.
- Gardner MJ, Nork SE. Stabilization of unstable pelvic fractures with supraacetabular compression external fixation. *J Orthop Trauma*. 2007; 21:269–273.
- Haidukewych GJ, Kumar S, Prpa B. Placement of half-pins for supraacetabular external fixation: an anatomic study. *Clin Orthop Relat Res.* 2003;269–273.
- Hupel TM, McKee MD, Waddell JP, et al. Primary external fixation of rotationally unstable pelvic fractures in obese patients. *J Trauma*. 1998; 45:111–115.
- Kellam JF. The role of external fixation in pelvic disruptions. *Clin* Orthop Relat Res. 1989;66–82.
- Lefaivre KA, Starr AJ, Barker BP, et al. Early experience with reduction of displaced disruption of the pelvic ring using a pelvic reduction frame. *J Bone Joint Surg Br.* 2009;91:1201–1207.

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- Lindahl J, Hirvensalo E, Bostman O, et al. Failure of reduction with an external fixator in the management of injuries of the pelvic ring. Long-term evaluation of 110 patients. *J Bone Joint Surg Br.* 1999;81: 955–962.
- Mason WT, Khan SN, James CL, et al. Complications of temporary and definitive external fixation of pelvic ring injuries. *Injury*. 2005;36: 599–604.
- Mears DC, Fu FH. Modern concepts of external skeletal fixation of the pelvis. *Clin Orthop Relat Res.* 1980;65–72.
- Riemer BL, Butterfield SL, Diamond DL, et al. Acute mortality associated with injuries to the pelvic ring: the role of early patient mobilization and external fixation. J Trauma. 1993;35:671–675. discussion 6–7.
- Scaglione M, Parchi P, Digrandi G, et al. External fixation in pelvic fractures. *Musculoskelet Surg.* 2010;94:63–70.
- Solomon LB, Pohl AP, Sukthankar A, et al. The subcristal pelvic external fixator: technique, results, and rationale. J Orthop Trauma. 2009;23:365–369.
- Tile M. The management of unstable injuries of the pelvic ring. J Bone Joint Surg Br. 1999;81:941–943.
- Tucker MC, Nork SE, Simonian PT, et al. Simple anterior pelvic external fixation. J Trauma. 2000;49:989–994.
- Kim WY, Hearn TC, Seleem O, et al. Effect of pin location on stability of pelvic external fixation. *Clin Orthop Relat Res.* 1999;237–244.
- 19. Majeed SA. External fixation of the injured pelvis. The functional outcome. *J Bone Joint Surg Br.* 1990;72:612–614.
- Wild JJ, Jr, Hanson GW, Tullos HS. Unstable fractures of the pelvis treated by external fixation. J Bone Joint Surg Am. 1982;64:1010–1020.
- Vaidya R, Colen R, Vigdorchik J, et al. Treatment of unstable pelvic ring injuries with an internal anterior fixator and posterior fixation: initial clinical series. J Orthop Trauma. 2012;26:1–8.
- Vaidya R, Kubiak EN, Bergin PF, et al. Complications of anterior subcutaneous internal fixation for unstable pelvis fractures: a multicenter study. *Clin Orthop Relat Res.* 2012;470:2124–2131.
- Merriman DJ, Ricci WM, McAndrew CM, et al. Is application of an internal anterior pelvic fixator anatomically feasible? *Clin Orthop Relat Res.* 2012;470:2111–2115.
- Kuttner M, Klaiber A, Lorenz T, et al. The pelvic subcutaneous crossover internal fixator [in German]. *Der Unfallchirurg*. 2009;112:661–669.
- 25. Muller FJ, Stosiek W, Zellner M, et al. The anterior subcutaneous internal fixator (ASIF) for unstable pelvic ring fractures. Clinical and radiological mid-term results. *Int Orthop.* 2013;37:2239–2245.
- Scheyerer MJ, Zimmermann SM, Osterhoff G, et al. Anterior subcutaneous internal fixation for treatment of unstable pelvic fractures. *BMC Res Notes.* 2014;7:133.
- Owen MT, Tinkler B, Stewart R. Failure and salvage of "INFIX" instrumentation for pelvic ring disruption in a morbidly obese patient. *J Orthop Trauma*. 2013;27:e243–e246.
- Hesse D, Kandmir U, Solberg B, et al. Femoral nerve palsy after pelvic fracture treated with INFIX: a case series. *J Orthop Trauma*. 2014;29: 138–143.
- 29. Vigdorchik JM, Esquivel AO, Jin X, et al. Biomechanical stability of a supra-acetabular pedicle screw internal fixation device (INFIX) vs

external fixation and plates for vertically unstable pelvic fractures. J Orthop Surg Res. 2012;7:31.

- Vigdorchik JM, Esquivel AO, Jin X, et al. 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. *Int Orthop.* 2013;37:1341–1346.
- Vaidya R, Onwudiwe N, Roth M, et al. Monoaxial pedicle screws are superior to polyaxial pedicle screws and the two pin external fixator for subcutaneous anterior pelvic fixation in a biomechanical analysis. *Adv Orthop.* 2013;2013:683120.
- Keshishyan RA, Rozinov VM, Malakhov OA, et al. Pelvic polyfractures in children. Radiographic diagnosis and treatment. *Clin Orthop Relat Res.* 1995;28–33.
- Lefaivre KA, Slobogean GP, Ngai JT, et al. What outcomes are important for patients after pelvic trauma? Subjective responses and psychometric analysis of three published pelvic-specific outcome instruments. *J Orthop Trauma*. 2014;28:23–27.
- Lefaivre KA, Blachut PA, Starr AJ, et al. Radiographic displacement in pelvic ring disruption: reliability of 3 previously described measurement techniques. J Orthop Trauma. 2014;28:160–166.
- Majeed SA. Grading the outcome of pelvic fractures. J Bone Joint Surg Br. 1989;71:304–306.
- Vaidya R, Oliphant B, Hudson I, et al. Sequential reduction and fixation for windswept pelvic ring injuries corrects the deformity until healed. *Int Orthop.* 2013;37:1555–1560.
- Vaidya R, Nasr K, Kanneganti P, et al. The anterior pelvic internal fixator "INFIX" technique. OTA Video Library 2016. Available at https:// vimeo.com/147862715. Accessed June 5, 2016.
- Vaidya R, Tonnos F, Nasr K, et al. The anterior subcutaneous pelvic fixator (INFIX) in an anterior posterior compression type 3 pelvic fracture. J Orthop Trauma. 2016;30(suppl 2):S21–S22.
- Marsh JL, Slongo TF, Agel J, et al. Fracture and dislocation classification compendium—2007: Orthopaedic Trauma Association classification, database and outcomes committee. *J Orthop Trauma*. 2007;21(10 suppl):S1–S133.
- Dalal SA, Burgess AR, Siegel JH, et al. Pelvic fracture in multiple trauma: classification by mechanism is key to pattern of organ injury, resuscitative requirements, and outcome. *J Trauma*. 1989;29:981–1000. discussion -2.
- Sethi A, Vaidya R, Schneider S, et al. Vaginal delivery after pelvic fracture fixation with a subcutaneous anterior fixator with review of literature of delivery mode in pelvic injuries. *Open J Obstet Gynecol.* 2014;4:836.
- 42. Lefaivre KA, Slobogean G, Starr AJ, et al. Methodology and interpretation of radiographic outcomes in surgically treated pelvic fractures: a systematic review. J Orthop Trauma. 2012;26:474–481.
- Eagan M, Kim H, Manson TT, et al. Internal anterior fixators for pelvic ring injuries: do monaxial pedicle screws provide more stiffness than polyaxial pedicle screws? *Injury*. 2015;46:996–1000.
- 44. Vaidya R, Oliphant B, Jain R, et al. The bikini area and bikini line as a location for anterior subcutaneous pelvic fixation: an anatomic and clinical investigation. *Clin Anat.* 2013;26:392–399.