OTA HIGHLIGHT PAPER

A Prospective Clinical Trial Comparing Surgical Fixation Versus Nonoperative Management of Minimally Displaced Complete Lateral Compression Pelvis Fractures

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Objective: To compare the early pain and functional outcomes of operative fixation versus nonoperative management for minimally displaced complete lateral compression (LC; OTA/AO 61-B1/B2) pelvic fractures.

Design: Prospective clinical trial.

Setting: Two academic trauma centers.

Patients: Forty-eight adult patients with LC pelvic ring injuries with <10 mm of displacement were treated nonoperatively and 47 with surgical fixation. Sixty percent of participants were randomized. Seventy-three percent of the fractures were displaced <5 mm, and 71% were LC-1 patterns.

Intervention: Operative fixation versus nonoperative management.

Main Outcome Measurements: The primary outcome was patient-reported pain using the 10-point Brief Pain Inventory. Functional outcome was measured using the Majeed pelvic score. Outcomes were analyzed using hierarchical Bayesian models to compare the average treatment effect from injury to 12 and 52 weeks postinjury. The probability of the mean treatment benefit exceeding a clinically important difference was determined.

Results: The 3-month average treatment effect of surgery compared with nonoperative management was a 1.2-point reduction in pain [95% credible interval (CrI): 0.4–1.9] and an 8% absolute improvement in the Majeed score (95% CrI: 3%–14%). Similar results persisted to 1 year. Patients with initial fracture displacement ≥5 mm experienced a larger reduction in pain (2.2, 95% CrI: 0.9–3.5) compared with those patients with less initial displacement (0.9, 95% CrI: 0.1–1.8).

Conclusion: On average, surgical fixation likely provides a small improvement in pain and functional outcome for up to 12 months. Patients with ≥5 mm of posterior pelvic ring displacement are more likely to experience clinically important improvements in pain.

Key Words: pelvis, lateral compression fracture, operative, nonoperative, pain, function, Bayesian

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

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INTRODUCTION

Lateral compression (LC) pelvic ring injuries constitute the most common type of pelvic fracture. The optimal management of minimally displaced LC fractures remains uncertain[1–5]—particularly for complete posterior pelvic ring fractures with less than 10 mm of displacement.[6–8] Although previous research has demonstrated good long-term results from nonoperative management of these injuries,[7] it is possible that surgical fixation could improve early outcomes of pain, function, and time to mobilization compared with nonoperative management.

We sought to determine whether surgical fixation reduces early pain and improves early function for minimally displaced LC pelvis injuries with a complete posterior fracture. We hypothesized that there would be no difference in pain or physical function within 3 months postinjury in patients treated with surgical fixation compared with nonoperative management. Secondarily, we sought to determine if any early outcome differences seen within the initial 3 months would persist to 1 year postinjury.

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METHODS

Study Design

This study was designed to compare surgical fixation versus nonoperative management of minimally displaced LC fractures. The study was registered at ClinicalTrials.gov (NCT02625766) and received Institutional Review Board approval at both recruiting sites. The trial was coordinated by the Department of Orthopaedics at the University of Maryland School of Medicine, and recruitment occurred at the R Adams Cowley Shock Trauma Center and Indiana University Health Methodist Hospital. No external funding was obtained for the research, and the authors maintained full oversight of the data, analysis, and manuscript preparation.

Enrollment

Patients with a Young-Burgess lateral compression pelvic fracture (OTA/AO 61-B1/B2) were screened for study participation. Study eligibility required a fracture pattern with a complete posterior pelvic ring fracture with less than 10 mm of displacement based on static injury axial computerized tomography scan and standardized plain radiographs with anterior–posterior, inlet, and outlet pelvis views. Patients with a spinal cord injury and patients who were nonambulatory before their pelvis fracture were excluded. Eligible English-speaking patients, ages 18–80 years, were approached for study consent and randomization. For patients who were intubated and temporarily unable to provide consent, a legally authorized representative was contacted.

Treatment Allocation

Patients were randomized with a 1:1 ratio using a computer-generated central randomization schedule. Randomization was stratified based on the recruiting center, patient intubation, and narcotic use in the previous month. For patients who refused to have their treatment randomly allocated, the patient was approached to participate in the prospective observational cohort of the trial. Patients who were enrolled in the observational cohort selected their treatment group without surgeon's recommendation. In all cases, the clinical team had treatment equipoise, and the surgeon did not make the decision between operative and nonoperative management.

Treatment Details

The study protocol did not dictate a mandatory surgical technique. The surgical management included standard open and percutaneous reduction and fixation techniques at the discretion of a fellowship-trained orthopaedic trauma surgeon. The technique used for closed reduction was similar to the percutaneous techniques. When a closed or percutaneous reduction was performed, an external rotation force was placed on the hemipelvis to manually manipulate the anterior superior iliac spine or iliac crest. For fractures with minimal or no displacement, fixation was performed without reduction to stabilize the fracture in situ and prevent potential displacement. Both treatment groups were instructed to be protected weight-bearing (foot-flat or non–weight-bearing) for a minimum of 6 weeks postinjury.

Clinical Outcomes

The primary outcome was patient-reported pain severity, as measured by the mean of the 4 pain severity items of the Brief Pain Inventory (BPI).[10] The BPI uses a 0–10 level visual analog scale (VAS) with a 24-hour recall period, where 0 anchors "no pain" and 10 anchors "pain as bad as you can imagine." The minimum clinically important difference (MCID) is not definitively established for the BPI in a trauma population; however, the MCID for other 10-point VAS pain scales has been reported between 1.0–2.5 points.[11–13] Secondary functional outcome was measured by the Majeed pelvic score. The Majeed pelvic score is a seven-item patient-reported outcome instrument that measures pain, work status, sitting comfort, sexual intercourse, use of walking aids, gait disturbance, and walking distance. The score is reported as a percentage of the highest possible score to adjust for participants who were not employed before their injury.[14] Higher scores represent better function, and a score of $>85\%$ has been suggested to represent excellent function.[14,15] The primary outcome was prospectively assessed at 96 hours, 2, 6, and 12 weeks postinjury at routine clinic visits. The functional outcome was assessed at the 2-, 6-, and 12-week clinic visits. Secondarily, we also assessed the pain and functional outcomes at 6 and 12 months. Other secondary outcomes included in-hospital to time mobilization and hospital length of stay.

Sample Size and Statistical Analysis

Based on a 2-point pain reduction and a SD of 3 points, enrolling 124 patients would have provided 90% power with an alpha of 0.05, an allocation ratio of 1:1, and up to 20% participant withdrawal or lost to follow-up. As the study was not externally funded, it was determined that after 5 years of enrollment, the initial target was not feasible. Therefore, the sample size was reduced to 94 patients to achieve 80% power. On completion of study recruitment, it was noted that participant attrition was only 4%, and therefore, the revised sample size retained 89% power to detect a 2-point difference in pain with a SD of 3 points.

All analyses were based on the intent-to-treat principle. The analyses used each patient's multiple outcome assessments to compare the average pain and function experienced over the 12-week period between the treatment groups. Our secondary analyses of the pain and function outcomes extended the models to 52 weeks. For all analyses, we used a Bayesian hierarchical model that applied a previous probability of no treatment difference based on the conflicting evidence in the previous literature.[3–6] This is akin to an initial assumption that there is "no difference" in pain or functional outcome between the treatment groups. The regression models adjusted for the patient's preinjury narcotic history and narcotic use at each time point. Multivariable quantile regression was used to analyze the treatment effect on the median hospital length of stay and median time to mobilization. Outcome data were missing in 16% of the sample at 2 weeks and 14% of the sample at 6 weeks and 12 weeks; multiple imputation was used for missing data in the final models.[16] A detailed Statistical Analysis Plan is provided as

Supplemental Digital Content (see **SDC 1**, http://links.lww.com/JOT/B354).

To determine whether the effects of surgical fixation differ based on the amount of initial fracture displacement or the surgical fixation strategy, we performed additional heterogeneity of treatment effect analyses. The initial degree of displacement was stratified for patients with ≥5 mm of displacement and patients with <5 mm of displacement. The effect of different fixation strategies was analyzed comparing posterior-only fixation versus operative fixation with anterior and posterior fixation. All analyses were performed using R version 3.6.1 (Vienna, Austria) with the packages *lme4, rstan, brms,* and *mice*.

RESULTS

Study Participants

Five hundred ninety-five patients with LC fracture were screened for study participation. Incomplete sacral fractures and sacral fractures displaced ≥1 cm were the most common reasons for study exclusion. Ninety-nine patients met the eligibility criteria and consented to participate in the study (Fig. 1). Sixty-one patients consented for randomization, and another 38 patients consented for the observational cohort. Four patients in the randomized arm who were allocated to operative treatment withdrew from the study before receiving their allocated treatment. The final analysis included 47 patients (49%) who received operative treatment and 48 patients (51%) who received nonoperative treatment.

Participant Characteristics

The mean age of the study participants was 44 years (SD: 18), and 63% (n = 60) were women (Table 1). Most of the participant was White (80%, n = 76) and 78% (n = 74) had a history of comorbidities. Seven percent of the sample reported regular preinjury narcotic use, and 45% (n = 43) reported regular preinjury nonsteroidal anti-inflammatory drug use. Most patients had LC type 1 injuries (71%, n = 67) with <5 mm of fracture displacement (73%, n = 69). Of those who received operative treatment, most received closed reduction (53%, n = 25) and posterior-only fixation (72%, n = 34) (Table 2). The operative group had 3 unplanned reoperations: 2 events related to implant loosening and one wound seroma requiring drainage. Four participants in the nonoperative group experienced unplanned surgical fixation: 2 participants had an early loss of reduction and 2 participants experienced delayed fracture healing.

Posttreatment Pain

The mean pain score at 96 hours from injury was 5.8 (SD: 2.1). The mean pain score declined to 2.4 (SD: 2.4) at 12 weeks from injury (Table 3, **Supplemental Digital Content 1**, http://links.lww.com/JOT/B354). Over the initial 12 weeks, patients treated with surgical fixation had an average pain score that was 1.2 points lower than the nonoperative treatment group [95% credible interval (CrI): 0.4 to 1.9]. Assuming a pain reduction of ≥1.0 as an important clinical difference (MCID) between the treatments, there is a 67% probability that surgical fixation achieves this benefit. Table 3 also lists the posterior probabilities of surgical fixation achieving a wider range of pain reduction magnitudes. For example, it is highly improbable that surgery can reach an average 2-point pain reduction compared with nonoperative management.

When the sample was stratified into the randomized and observational cohorts similar results were obtained: operative treatment reduced the mean pain score by 1.0 point (95% CrI: −2.1 to 0.1) in the observational arm and by 1.2 points (95% CrI: 1.9 to 0.5) in the randomized arm (Fig. 2, **Supplemental Digital Content 1**, http://links.lww.com/JOT/B354**)**. In addition, the magnitude of pain reduction seemed to be sustained across the entire 52-week study period (0.9 point pain reduction, 95% CrI 0.2 to 1.7).

Posttreatment Function

The mean Majeed function score of the sample at 2 weeks postinjury was 35% (SD: 11%). By 12 weeks postinjury, the average function had increased to 68% (SD: 22%) (Table 3, **Supplemental Digital Content 1**, http://links.lww.com/JOT/B354). Operative treatment increased the patient's average function by 8% (95% CrI: 3%–14%) over the initial 12 weeks from injury compared with nonoperative management. Assuming a ≥10% average improvement in the Majeed

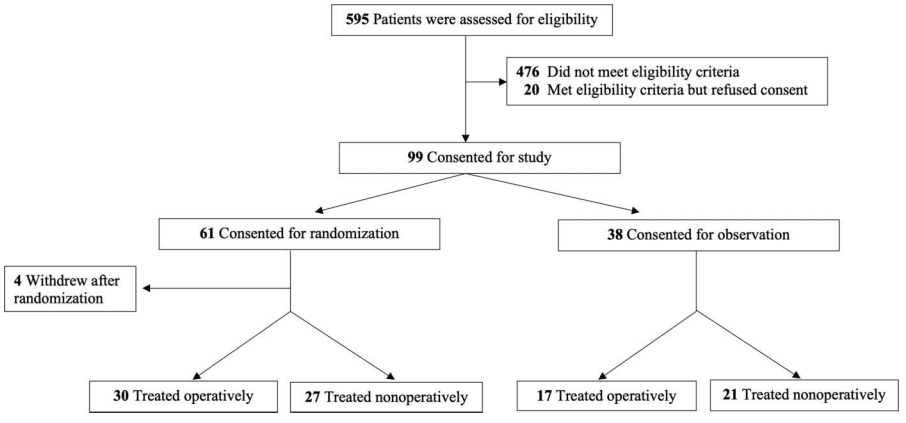

FIGURE 1. CONSORT flow diagram.

TABLE 1. Participant Characteristics

	Operative (n = 47)	Nonoperative (n = 48)	Total (N = 95)
Age, y, mean (SD)	43.6 (18.9)	43.5 (17.9)	43.5 (18.3)
Sex, female, n (%)	28 (60%)	32 (67%)	60 (63%)
Race, n (%)			
White	37 (79%)	39 (81%)	76 (80%)
African American	6 (13%)	6 (13%)	12 (13%)
Hispanic	1 (2%)	0 (0%)	1 (1%)
American Indian or Alaskan Native	2 (4%)	0 (0%)	2 (2%)
Asian	1 (2%)	3 (6%)	4 (4%)
Education, n (%)			
High school or less	23 (49%)	24 (51%)	47 (50%)
Some college, associates, or bachelor's degree	19 (40%)	18 (38%)	37 (39%)
Some graduate school or graduate degree	5 (11%)	5 (11%)	10 (11%)
Smoking history, n (%)			
Never smoked	24 (51%)	18 (38%)	42 (44%)
Current smoker	15 (32%)	26 (54%)	41 (43%)
Former smoker	8 (17%)	4 (8%)	12 (13%)
Body mass index, (Kg/m^2), n (%)			
Underweight (<18.5)	2 (4%)	0 (0%)	2 (2%)
Normal weight (18.5–24.9)	23 (49%)	29 (60%)	52 (55%)
Overweight (25–29.9)	15 (32%)	11 (23%)	26 (27%)
Obese (>30)	7 (15%)	8 (17%)	15 (16%)
History of comorbidities, n (%)	38 (81%)	36 (75%)	74 (78%)
Regular preinjury narcotic use, yes, n (%)	3 (6%)	4 (8%)	7 (7%)
Regular preinjury NSAID use, yes, n (%)	20 (43%)	23 (48%)	43 (45%)
Mechanism of injury, n (%)			
Motor vehicle	36 (77%)	38 (79%)	74 (78%)
Fall	10 (21%)	9 (19%)	19 (20%)
Other	1 (2%)	1 (2%)	2 (2%)
Injury Severity Score, mean (SD)	17 (9)	18 (10)	17 (9)
Fracture type, n (%)			
Lateral compression type 1*	31 (66%)	36 (75%)	67 (71%)
Lateral compression type 2†	16 (34%)	12 (25%)	28 (29%)
Initial fracture displacement, n (%)			
<5 mm (not displaced/minimal)	36 (77%)	33 (69%)	69 (73%)
5–10 mm (displaced)	11 (23%)	15 (31%)	26 (27%)

*OTA/AO 61-B1/B2.
†OTA/AO 61-B2.
NSAID, nonsteroidal anti-inflammatory drug.

score function as clinically important, there is only a 25% probability that surgical fixation achieves this benefit over nonoperative management (Table 3). Table 3 also reports the probabilities of surgical fixation achieving various MCID thresholds. In the stratified analysis, operative treatment increased mean function by 13% (95% CrI: 7%–19%) for patients in the randomized cohort; whereas, operative treatment only increased function by 2% (95% CrI: −7 to 11%) in the observational cohort (Fig. 2, **Supplemental Digital Content 1**, http://links.lww.com/JOT/B354). Secondary analysis of the entire 52-week period suggests a similar magnitude of functional improvement compared with the initial 12 weeks (8% improved function, 95% CrI 3%–13%).

Length of Stay and Mobilization

Other secondary outcomes did not differ between the 2 treatment groups. The median length of stay was 6.6 days for nonoperative patients [interquartile range (IQR) 3.4–12.4] and 6.9 days for those who received operative treatment (IQR: 3.6–12.2). After adjusting for treating center, smoking status, and mechanism of injury, operative treatment was not

TABLE 2. Treatment Characteristics and Complications

Surgical Technique	Operative (n = 47)	Nonoperative (n = 48)
Type of reduction, n (%)		
Closed	25 (53%)	
Percutaneous	18 (38%)	
Mini open (small lateral window)	1 (2%)	
Full open	3 (6%)	
Fixation, n (%)		
Anterior only	—	
Posterior only	34 (72%)	
Anterior and posterior	13 (28%)	
Complications		
Unplanned reoperation, n (%)		
Loss of fixation—implant removal	2 (4%)	—
Delayed healing treated with surgical fixation	—	2 (4%)
Loss of reduction treated with surgical fixation	—	2 (4%)
Wound seroma evacuation	1 (2%)	—

associated with hospital length of stay (median difference 0.4 days; 95% CI: −3.1 to 3.8, $P = 0.83$). The median time to first mobilization for operative patients was 3 days after injury (IQR: 2 to 5) compared with 3 days (IQR: 2 to 4.3) for nonoperative patients. The median difference was 0 days (95% CI: −1.2 to 1.2, $P = 1.00$), after adjusting for the treating center and 3-day morphine use during hospitalization.

Heterogeneity of Treatment Effect

Operative treatment reduced pain within 12 weeks of the injury for patients with both <5 mm of displacement and ≥5 mm of displacement. However, the average pain reduction effect from operative treatment was greater in patients with more displaced fractures (2.2, 95% CrI: 0.9 to 3.5) compared with those patients with less initial displacement (0.9, 95% CrI: 0.1 to 1.8). Patients with ≥5 mm of displacement had an 80% higher probability of achieving a 1.5 point average pain reduction during the study period (88% vs. 8%, see **Supplemental Digital Content 1**, http://links.lww.com/JOT/B354). Fracture type did not seem to differentially affect the pain benefit of fixation (LC-1: 1.1 points less pain, 95% CrI 0.2 to 2.1; LC-2: 0.8 points less pain, 95% CrI −0.6 to 2.3). Finally, within operatively treated patients, posterior-only fixation had 0.7 points less pain compared with anterior and posterior fixation within 12 weeks postinjury (95% CrI: −1.8 to 0.3). However, the credible interval suggests this estimate is unstable.

DISCUSSION

This prospective trial sought to compare the early clinical results of operative fixation versus nonoperative management for LC pelvic ring injuries with minimally displaced complete posterior fractures. In our study population, surgical fixation with primarily percutaneous techniques resulted in an early and sustained small average improvement in pain and function for up to 12 months postinjury.

The potential short-term benefits of surgical fixation for minimally displaced pelvis fractures have been a longstanding controversial topic. Although authors frequently debate the clinical significance of small treatment benefits, it should be noted that our results are consistent with previous studies. A recent observational study conducted at 16 trauma centers prospectively measured short-term VAS pain scores in 194 patients with unilateral sacral fractures (less than 5 mm of displacement).[6] The treatment decision (surgical fixation or nonoperative management) was left to the discretion of the surgeon, and 74% of fractures were treated nonoperatively. Despite the potential for indication bias to treat the more displaced fractures surgically, operative patients reported less mean pain at all time points within the 3-month study duration. When assessing posterior pelvic pain, patients treated with surgical fixation reported 2.7 points less pain at 24 hours postinjury ($P = 0.01$) and 1.1 points less pain at 3 months ($P = 0.02$).

The current trial achieves a large incremental improvement toward understanding the potential short-term benefits of surgical fixation for these common pelvic fractures. Although the work of Bruce et al suggests certain fracture patterns are at increased risk of displacement after nonoperative management,[2] Gaski et al demonstrated that nonoperative management of LC pelvic ring injuries with complete sacral fracture and <10 mm of displacement result in good-to-excellent clinical outcomes in most patients.[7] Therefore, the current treatment controversy for these injuries has shifted to determining if surgical fixation can improve short-term outcomes such as pain, time to mobilization, discharge disposition, and physical function.[6] Many surgeons believe that a short-term benefit of decreased pain and improved mobilization with surgery may outweigh the minimal risks of percutaneous fixation.

TABLE 3. Primary and Secondary Outcomes: Adjusted Mean Difference and Posterior Probability of Treatment Benefit

Outcome		Operative (n = 47)	Nonoperative (n = 48)	Adj. Mean Diff (95% Credible Interval)	Probability of Better Outcomes with Surgical Fixation Compared With Nonoperative Treatment Across Increasing Magnitudes of Benefit	
Primary outcome	**Time Point**	**Mean (SD)**	**Mean (SD)**	**Weak Prior (Mean Diff, 0; SD, 3)**	**Magnitude of Benefit (MCID)**	**P-TB%**
Pain				−1.2 (−1.9 to −0.4)	Avg 3 mo decrease in pain (0–10)	
	96 h	5.3 (1.8)	6.2 (2.4)		>0.0	>99%
	2 wk	4.2 (2.0)	5.6 (2.3)		>0.5	93%
	6 wk	2.7 (2.6)	3.5 (3.1)		>1.0	67%
	12 wk	1.9 (2.0)	2.9 (2.7)		>1.5	13%
					>2.0	1%
Outcome		**Operative (n = 47)**	**Nonoperative (n = 48)**	**Adj. Mean Diff (95% Credible Interval)**	**Compared With Nonoperative Treatment Across Increasing Magnitudes of Benefit**	
Secondary Outcome	**Time Point**	**Mean (SD)**	**Mean (SD)**	**Weak Prior (Mean Diff, 0; SD, 0.3)**	**Magnitude of Benefit (MCID)**	**P-TB %**
Majeed score				0.08 (0.03–0.14)	Avg 3 mo improvement in Majeed (0%–100%)	
	2 wk	38% (11%)	31% (10%)		>0	99%
	6 wk	55% (18%)	50% (18%)		>5	94%
	12 wk	73% (20%)	62% (22%)		>10	25%
					>15	1%

Adj. mean diff, adjusted mean difference; Avg, average; P-TB, posterior probability of treatment effect; MCID, minimal clinically important difference.

In our study population, we were unable to detect any differences in time to mobilization or time to discharge between the treatment groups; however, a small improvement in pain and physical function was detected throughout the primary 3-month duration and persisted to 1 year. To better understand the significance of these differences, we adopted a Bayesian analysis approach to determine the probability of achieving various magnitudes of benefit from surgical fixation. Reported in Table 3, it is clear that surgical fixation results in lower pain and improved function; however, the magnitude of these benefits are unlikely to exceed commonly proposed MCID thresholds, and therefore, the potential treatment benefits may not be detected by most patients.

The clinical implications of our results must also be interpreted in the context of the study's population. In the subgroup analysis, a larger benefit to surgical fixation occurred in patients with ≥5 mm of fracture displacement

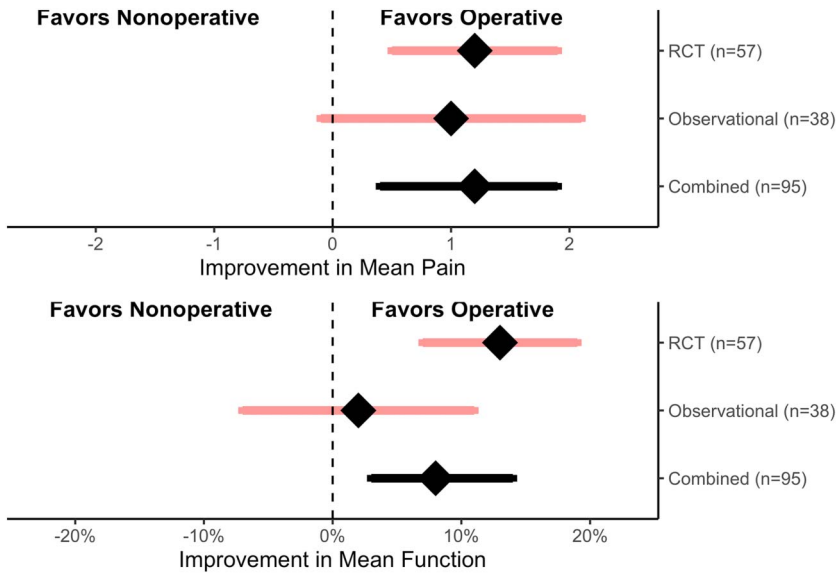

FIGURE 2. Forest plot comparing stratified analyses of RCT and observational data. RCT, randomized controlled trial. **Editor's Note**: A color image accompanies the online version of this article.

in the posterior pelvic ring. This observation might become an important deciding factor when considering indications for surgical fixation, particularly because the treatment benefit exceeds a 1.5-point pain reduction MCID. In addition, it is important to recognize that the mean age of the study participants was 44 years, the mean Injury Severity Score was 17, and most injury mechanisms involved motor vehicles. It is unclear whether our study results are generalizable to lower-energy geriatric fracture patients, particularly if the risks of surgery are increased in an elderly osteoporotic population. Finally, although the surgical fixation group had small benefits in pain and function, it is important to note that the probability of achieving a clinically significant benefit was much higher for reducing pain compared with improving function.

There are several other strengths of our clinical trial that merit discussion. To the best of our knowledge, this is the first prospective trial of pelvic fracture management. We used validated measures of pain and function, and all outcome data were collected prospectively from the study participants. Potentially confounding patient characteristics such as previous narcotic history and ongoing outpatient narcotic use were measured and included in our statistical models. Similarly, we used a repeated-measures longitudinal statistical model to determine the average treatment benefit over the primary 3-month postinjury period and, secondarily, the entire year post-fracture. This was performed instead of performing multiple time point comparisons, which can be difficult to interpret, vulnerable to issues of multiple testing, and erroneously contradictory.

The limitations of the trial are primarily related to its sample size and challenges with recruitment into a randomized controlled trial comparing operative versus nonoperative treatments. Sixty-two percent of study participants were willing to have their treatment decision randomized. This challenge was anticipated based on similar consent rates in several previous landmark orthopaedic trials.[17–19] The decision to enroll patients who refused randomization, but selected their treatment without surgeon's recommendation, was a study design decision carefully made to balance potential risks of bias with the benefits of increased study power from a larger sample size. Our sensitivity analysis confirmed a low risk of bias from combining the randomized controlled trial and observational cohort data (Fig. 2), and additional analyses methods support the credibility of our approach (see **Supplemental Digital Content 1**, http://links.lww.com/JOT/B354). Finally, we acknowledge that we were unable to obtain preoperative pain scores; instead, we assume those values to be similar between the treatment groups based on previous research and our study design.[6]

The treatment of pelvic ring fractures remains controversial because of significant injury heterogeneity and a lack of high-quality prospective research in this trauma population. Our results suggest that surgical fixation likely provides an early and sustained small average improvement in pain and function for up to 12 months, but these improved outcomes do not exceed most clinically important thresholds. Despite these overall findings, surgical fixation seems to have the largest effect on reducing pain in patients with fracture displacements ≥5 mm, and this likely represents the best operative candidates within the minimally displaced LC pelvis fracture population.

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