

Efficacy and Safety of Percutaneous Sacroplasty for Painful Osteoporotic Sacral Insufficiency Fractures

A Prospective, Multicenter Trial

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Study Design. A prospective observational cohort study of consecutive osteoporotic patients with sacral insufficiency fractures (SIFs).

Objective. Assess the safety and efficacy of sacroplasty in treating osteoporotic SIFs.

Summary of Background Data. SIFs can cause low back pain in osteoporotic patients. Symptomatic improvement may require up to 12 months. Treatment includes limited weight-bearing and bed rest, oral analgesics, and sacral corsets. Significant mortality and morbidity are associated with pelvic insufficiency fractures. Percutaneous sacroplasty is an alternative treatment for SIF patients, and initial reports have documented its safe and effective performance. Yet, follow-up intervals have been short, and study cohorts small precluding definitive assessment of sacroplasty's safety and efficacy.

Methods. Baseline Visual Analogue Scale (VAS), analgesic usage, and duration of symptoms were recorded. Subsequent VAS ratings were assessed at 30 minutes and at 2, 4, 12, 24, and 52 weeks postprocedure. Analgesic usage and patient satisfaction were assessed at final follow-up. Each procedure was performed under intravenous conscious sedation using fluoroscopy. Two bone trochairs were inserted between the sacral foramen and sacroiliac joint through which 2 to 3 mL of polymethylmethacrylate was injected.

Results. Thirty-seven patients, 27 females, were treated. Mean age was 76.6 years, and mean symptom duration was 34.4 days. All patients were available at each follow-up interval except 1 patient who died due to unrelated pulmonary disease before the 4-week follow-up. The mean VAS score at baseline was 7.7 and 3.2 within 30 minutes, and 2.1 at 2, 1.7 at 4, 1.3 at 12, 1.0 at 24, and 0.7 at 52 weeks postprocedure. Improvement at each interval and overall was statistically significant using the Wilcoxon Rank Sum Test. One case of transient S1 radiculitis was encountered.

Conclusions. Sacroplasty appears to be a safe and effective treatment for painful SIF. The rate of improvement is rapid and sustained through 1 year.

Key words: sacroplasty, sacral fracture, osteoporosis, low back pain. **Spine 2007;32:1635–1640**

Sacral insufficiency fractures (SIFs) are a consequence of the imposition of undue stresses onto weakened bone and are common cause of low back pain in the elderly population. Risk factors for SIFs include osteoporosis, osteopenia, rheumatoid arthritis, corticosteroid use, radiation therapy, renal osteodystrophy, osteomalacia, Paget's disease, hyperparathyroidism, joint arthroplasty, and lumbosacral fusion.¹ Among these, osteoporosis, the most common metabolic bone disorder affecting 25 million people in the United States, is the leading cause and is the most common.² Osteoporotic bone is prone to fracture due to decreased bone mineralization and mass. Spontaneous fracture of the osteoporotic sacrum was first described in 1982 by Lourie³ and manifests clinically as low back or buttock pain with or without referred pain into the lower limb.^{3–5} Although common in the elderly,^{4,5} SIFs may escape detection by the treating practitioner due to a low clinical suspicion and poor sensitivity of plain radiography,³ thus delaying appropriate therapeutic interventions.

The traditional therapeutic algorithm for SIFs consists of limited bed rest,^{4–6} partial weight-bearing and early mobilization,⁷ analgesic medications, and lumbosacral or pelvic corsets.⁸ Deep venous thromboses⁹ and pulmonary emboli,¹⁰ reduced muscle strength,¹¹ postural hypotension,¹¹ pneumonia,¹¹ skin breakdown,⁷ and constipation⁷ are known complications of periods of inactivity. The overall 1-year mortality rate associated with pelvic insufficiency fractures is 14.3%, and 50% of affected patients will not return to their prior level of function.¹² Although initial clinical improvement may occur rapidly, complete resolution of symptoms may not occur for up to 9 to 12 months.^{5,13} Despite a favorable natural history, more aggressive treatments may benefit certain patients who are incapacitated by painful SIFs.

Chronic symptoms and disability related to osteoporotic insufficiency fractures are thought to be due to fracture non-union, micromotion, or resultant deformity related to the anemic attempts of the weakened bone to heal.¹⁴ The percutaneous injection of polymethylmethacrylate (PMMA) into fractured vertebral bodies (vertebroplasty) has been safely performed to successfully treat painful osteoporotic compression fractures.^{15–18} A natural extension in the application of vertebroplasty is the percutaneous injection of synthetic bone cement into the fractured sacrum (sacroplasty) to treat persistent symptoms and disability. Sacroplasty was first reported in 2001 as treatment of symptomatic sacral metastatic lesions,^{19,20} and subsequent reports have documented its safe and effective performance.^{21–23}

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Figure 1. Sacral MRI through the coronal plane highlighting increased T2-weighted signal in both sacral ala indicating sacral edema.

However, although provocative, the short follow-up intervals^{21–23} and small study cohorts²³ preclude a more definitive commentary regarding the safety of the procedure and the durability of initial results. We designed this study to assess the safety and efficacy of sacroplasty to better define the incidence of complications and to evaluate the clinical utility of percutaneous sacroplasty in treating painful osteoporotic SIFs.

■ Materials and Methods

A prospective, observational cohort study was conducted of consecutive osteoporotic patients presenting with low back or gluteal pain. Inclusion criteria were: incapacitating lumbar and/or gluteal pain due to a SIF, documented osteoporosis, magnetic resonance imaging evidence of the sacral fracture and or increased radiotracer uptake on nuclear imaging (Figures 1, 2), and failure of or intolerance to conservative measures, such as analgesics, corsets, or bed rest. Patients were excluded if their imaging findings suggested malignant insufficiency fracture or if their pain was manageable or improving.

Patient gender, age, preprocedure pain duration, analgesic usage, pain level, and patient satisfaction were recorded at baseline and postprocedure follow-up intervals at 2, 4, 12, 24, and 52 weeks. Additionally, each patient was assessed for postprocedure complications before discharge and at each follow-up evaluation. Pain duration was compiled in days, analgesic use described as narcotic, non-narcotic, and over-the-counter, pain level was assessed by the pain Visual Analogue Scale (VAS), and patients were asked if they were satisfied with their outcome, and if so, by how much. Statistical analyses were performed using the Wilcoxon Rank Sum Test, using a *P* value of <0.05 as significant.



Figure 2. Whole-body bone scan of the same patient illustrating increased radiotracer uptake in both sacral ala.

Each procedure was performed by a fellowship-trained interventional spine physiatrist (M.F., S.M.B.) and one interventional pain physician (J.S.D.), whose combined vertebroplasty experience surpassed 500 cases. Each sacroplasty procedure was completed under light, intravenous conscious sedation using fluoroscopic guidance. One gram of cefazolin, or 600 mg of clindamycin if there was a penicillin or cephalosporin allergy, was administered intravenously 30 minutes before the procedure. After an oblique view aligning the entire sacroiliac joint, two 13-gauge bone trochars were placed between the sacral foramen and sacroiliac joint on the side of the fractured ala at a 45° angle toward the sacroiliac joint. The needles were then inserted approximately to midpoint of the sacrum, under lateral view, maintaining the 45° angle (Figure 3). After mixing the cement (Spineplex), using the precision cement mixing system (Stryker, Kalamazoo, MI) under anteroposterior imaging, 2 to 5 mL of PMMA was injected through each trochar, monitoring the spread of the bone cement, to avoid medial extension toward the sacral nerve roots (Figure 3). Each patient was maintained in the prone position for 30 to 45 minutes after the procedure before discharge. The VAS rating was determined after the patient stood for 30 seconds on their affected side (Frey's test). If the patient had bilateral SIF, then the patient stood on each leg and the total VAS score was obtained.

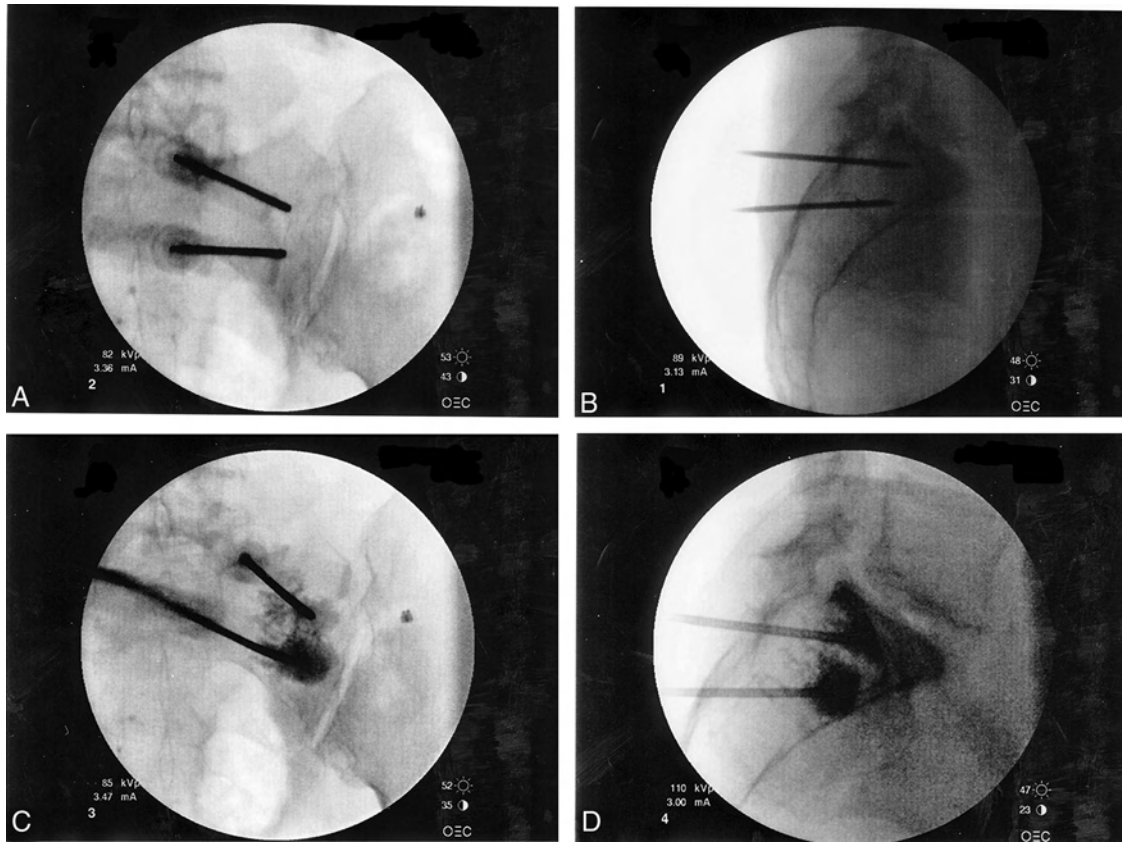


Figure 3. Anteroposterior (A, top) and lateral (B, bottom) fluoroscopic views of two 13-gauge bone trochars in the right sacral ala. Anteroposterior (C, top) and lateral (D, bottom) fluoroscopic views of PMMA injected into the right sacral ala. The injected bone cement is positioned medial to the sacroiliac joint and lateral to the sacral foramen while not breaching the anterior sacral wall.

Results

Thirty-seven patients were enrolled in the study with a mean age of 76.6 years (range, 61–92 years). Twenty-seven females and 11 males were treated after no symptomatic improvement with conservative care for a mean of 34.4 days (range, 13–82 days). Nineteen patients had bilateral sacral ala fractures and underwent sacroplasty on both ala. All patients were available at all follow-up intervals. One patient, however, died due to unrelated, preexisting pulmonary disease just before the 4-week follow-up. This patient’s VAS score was 0 at the 2-week follow-up. The mean VAS score at baseline was 7.7, 3.2 within 30 minutes after the procedure, 2.1 at 2, 1.7 at 4,

1.3 at 12, 1.0 at 24, and 0.7 at 52 weeks (Figure 4). At 30 minutes after the procedure, 5 patients reported complete pain relief, increasing to 10 pain-free patients at 2 weeks and 25 pain-free patients at 52 weeks after the procedure. At 2 weeks postprocedure, 20 patients reported a VAS score of 1 to 3, while 11 patients reported a VAS rating between 1 and 3 at the 52-week follow-up (Table 1). Improvement at each follow-up interval and overall was statistically significant ($P \leq 0.05$). Differences between bilateral and unilateral fracture patients mean VAS scores did not reach statistical significance. Excluding the patient that died, all but 2 patients reported 75% to 100% satisfaction at the time of the last

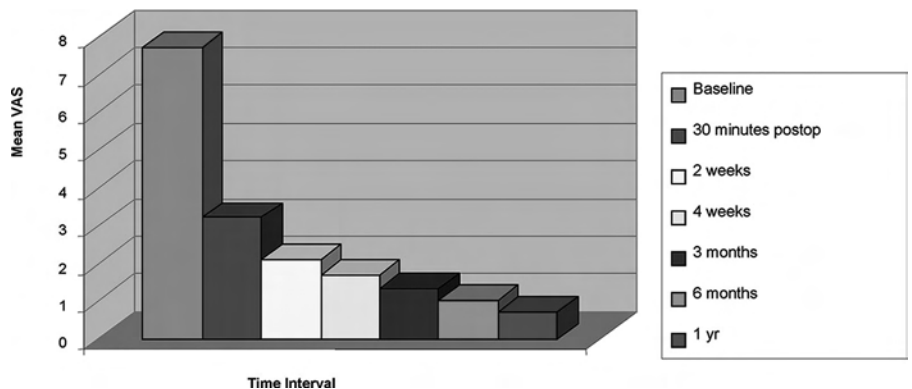


Figure 4. Mean visual analog score versus time interval for patients undergoing percutaneous fluoroscopic sacroplasty.

Table 1. Number of Patients Reporting VAS Score of 0 or 1–3 at Each Time Point Postprocedure

Time Period	VAS Score 0	VAS Score 1–3
Post	5	17
2 wk	10	20
4 wk	13	19
12 wk	16	18
24 wk	20	15
1 yr	25	11

follow-up visit. Twenty patients were using narcotic analgesics at baseline and only 12 at the last follow-up, with 6 patients using narcotics only at 2 to 8 weeks postprocedure (Figure 5). No catastrophic complications were encountered immediately or during the follow-up intervals. One patient, however, did develop S1 radicular pain during the procedure, necessitating termination of injection of the PMMA. Although the primary sacral pain was alleviated, the patient experienced persistent inferior buttock and posterior thigh pain that was completely relieved 7 days later by perineural instillation of 2.0 mL of preservative-free betamethasone (6 mg/mL) and 1.0 mL of 1.0% lidocaine.

■ Discussion

Mechanical failure of osteoporotic bone occurs due to both a reduction bone mineral density and trabecular thinning. The former occurs due to osteoporosis, which is then compounded by the latter occurring with advancing age.^{24,25} The compressive mechanical strength of trabecular bone is proportional to the apparent density squared. Thus, a decrease in the latter will cause a disproportionate reduction in trabecular bone strength.²⁴ Consequently, sacral strain is increased by 40% to 70% in osteoporotic elderly patients.²⁵ Mechanical differences between vertebral body and sacrum may help explain the consequence of such strain. The vertebral body is primarily under simple compression²⁵ as opposing vertebral bodies

and intervertebral discs are in series. The sacrum, however, articulates superiorly and laterally with lumbar spine and ilium, respectively, suggesting that superomedial forces are left to contend with inferiorly directed load from the lumbar spine. Sacral osseous characteristics may provide an additional explanation of the pathophysiology of sacral insufficiency fractures.

In independent investigations, de Peretti *et al* using computed tomography (CT)²⁶ and Smith *et al* using quantitative CT,²⁷ have documented a higher trabecular density in the sacral body than the sacral ala. In a subsequent study combining cadaveric sections, faxitron imaging, and CT reconstructions, Peretz *et al*²⁸ demonstrated a cruciate trabecular pattern of highest density and reproducibility in the proximal sacral body. These findings imply that a higher load is borne by the central sacrum and that trabecular thinning first occurs at the ala-body junction.²⁸ A relative void of trabeculae was consistently discovered in the sacral ala of the studied specimens.²⁸ Leroux *et al* have previously suggested that sacral insufficiency fractures arise as an axial load is transmitted into the sacrum,²⁹ implying that a vertical force is imposed through the weakened sacral ala.²¹ Corroborative experimental evidence produced by Kayanja *et al*, in a cadaveric, biomechanical study, demonstrated that sacral alar strain is higher than iliac wing strain, and alar defects increased alar strain and reduced pelvic stiffness.³⁰ Simulated osteoporosis, *via* a finite element model, has been shown to linearly increase sacral strain.²⁵ The presence of advanced degenerative discogenic changes may lead to greater transfer of axial compressive loads through the sacrum, leading to vertical shearing of the weakened ala-body junction.

Persistent pain and dysfunction due to an osteoporotic sacral insufficiency fracture may be related to chronic nonunion of the fracture site from the inability of the osteoporotic bone to heal under repetitive strain. Sacral augmentation normalizes alar strain without affecting the strain pattern.³⁰ Using a finite element model,

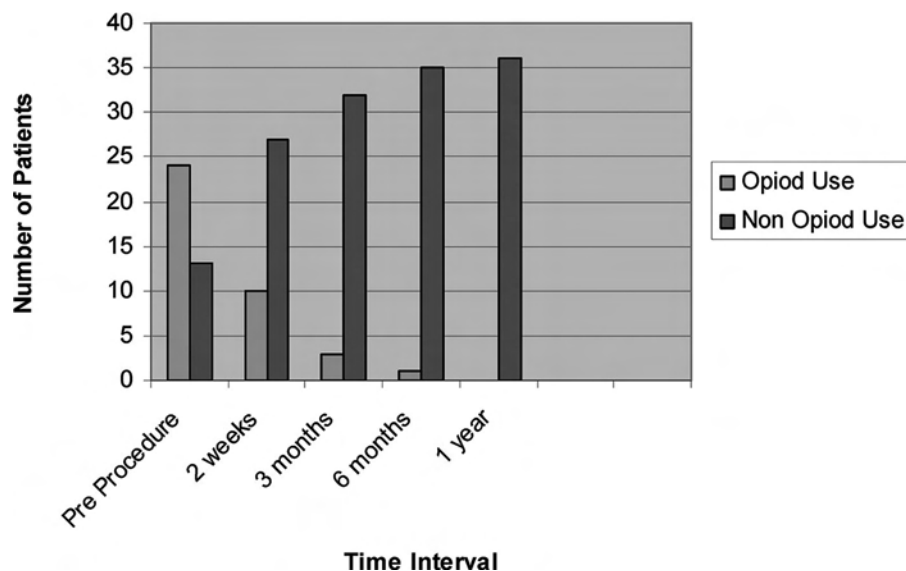


Figure 5. Opioid use *versus* time interval after percutaneous fluoroscopic sacroplasty.

Anderson demonstrated a reduction in sacral strain of 40% to 60% associated with minimal increase in pelvic stiffness, after augmentation of intact sacrum.^{25,30} The introduction of PMMA across the sacral fracture site may provide mechanical stabilization preventing painful micromotion.³¹ Sacral augmentation restores pelvic strength to 63% of baseline in fractured sacral ala.³² These findings suggest that the effects of sacroplasty are primarily related to local deposition of PMMA.²⁵

Five studies have investigated the safety and efficacy of sacroplasty.^{19–23} Dehdashti *et al*¹⁹ and Marcy *et al*²⁰ independently reported their positive experience performing sacroplasty for pelvic metastatic disease. Pommersheim *et al* later reported 3 case reports in which all 3 patients experienced significant pain reduction immediately and sustained at 14 to 16 weeks in 2 patients, while the third patient was lost to follow-up.²² In a larger case series, Butler *et al*²³ reported 6 cases in which sacroplasty was performed for painful osteoporotic fractures in 4 patients, radiation necrosis in 1 patient, and multiple myeloma in 1 patient. The osteoporotic and radiation necrosis patients experienced significant pain reduction at 2 weeks after the procedure. Although good outcomes and no complications were observed, the Butler *et al* study cohort was small and the follow-up period short. The current study confirms these preliminary results and provides prospective evidence that the percutaneous injection of PMMA into an osteoporotic sacral insufficiency fracture results in >50% reduction in pain level immediately, with gradual reduction of >80% at 2 weeks and 90% at 1 year. The improvement in pain level was mirrored by a reduction in narcotic analgesic requirement and an increase in patient satisfaction.

Clinicians need to be aware of technical concerns that are specific to sacralplasty and not encountered in vertebroplasty, including the leakage of PMMA into the presacral space, spinal canal, sacral foramen, or sacroiliac joint.³³ Such complications may result in pelvic injection of PMMA, sacral nerve root or sacral spinal canal compromise, or sacroiliac joint dysfunction. As a measure to minimize these risks, sacroplasty should only be performed on zone 1 fractures³⁴ involving just the sacral ala. Only zone 1 fractures were treated in the current study and no permanent complications were encountered. One case of S1 radicular pain occurred and was successfully treated by the instillation of 2.0 mL of betamethasone and 1 mL of 0.5% Xylocaine around the S1 nerve root under fluoroscopic control. The presentation of post-sacroplasty S1 radicular pain may be due to irritation of the root by the exothermic reaction of the PMMA.³⁵ The cement was observed to migrate medially toward the S1 foramen, persuading the interventional spine specialist to terminate the injection.

Although CT guidance was not relied on to successfully perform sacroplasty on these 37 patients, the procedures were performed effectively and safely. However, each sacroplasty procedure was completed by a fellowship-trained interventional spine specialist with exten-

sive experience in vertebroplasty who had mastered procedural skills and knowledge regarding the percutaneous injection of PMMA. It would be irresponsible, therefore, to suggest that the injection of PMMA percutaneously to treat painful SIFs can be safely performed without underscoring the tremendous importance of knowledge of fluoroscopic anatomy, dextrous handling bone trochars in osteoporotic bone, knowledge of the properties of PMMA, and attention to the sacral fracture lines. Utilization of CT guidance may be wise until a practitioner's skill level is developed. The absence of CT evaluation in this study may present 2 drawbacks in the study. Specific identification of the fracture line may best be determined by CT as bone edema may obscure the fracture line on magnetic resonance imaging. However, the authors felt confident in each case of the location of the fracture line before treatment. Second, the true incidence of extraosseous PMMA extravasation may have been underestimated in this study because postprocedure CT scans were not obtained. However, the lack of clinical manifestations of any extraosseous cement would suggest these instances are largely inconsequential.

Although the rate and magnitude of improvement in pain appear to be impressive, no control group was randomized into our study protocol. The natural history of osteoporotic SIFs is gradual improvement, starting within 1 to 2 weeks of treatment initiation,¹³ requiring up to 6 to 12 months to become symptom-free.^{5,13} Spontaneous or natural recovery probably does not account for the rapid pain reduction experienced by the patients in our study, however, as 14% of patients had complete relief of pain within 30 minutes of the procedure, increasing to 27% pain-free at 2 weeks and 35% at 4 weeks after sacroplasty. Seven patients (3 with bilateral fractures) were candidates for our study but elected to continue conservative care for their SIFs. The mean VAS scores for these 7 patients were 7.4 at baseline, 6 at 2 weeks, 4.3 at 4 weeks, 2.7 at 12 weeks, 1.71 at 24 weeks, and 0.86 at 52 weeks. These patients likely represent the natural history of symptom resolution after SIF as the mean duration of symptoms before our initial evaluation was 20 days (range, 2–41 days) and demonstrated a much slower rate of pain reduction. One patient was pain-free at 4 weeks and only 2 patients were pain-free at 12 weeks. A placebo effect introduced by the sacroplasty procedure, however, cannot be excluded due to the absence of a sham control group. Therefore, randomized, controlled trials are warranted to confirm these preliminary results and prove the efficacy of sacroplasty in treating painful osteoporotic SIFs.

■ Conclusion

Sacroplasty appears to be a safe and effective treatment for painful osteoporotic SIFs. The rate of improvement is rapid, with over 50% reduction in pain achieved before postprocedure discharge of the patient. Pain reduction

occurs primarily within the first 3 months but is sustained through 12 months after treatment.

■ Key Points

- Sacroplasty can be performed safely in osteoporotic patients.
- Pain relief after sacroplasty is rapid and significant in patients with painful osteoporotic sacral fractures.
- The true incidence of cement extravasation during sacroplasty is still relatively unknown. However, clinically significant extravasation appears to be a rare occurrence.

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