

## Prospective Study



## Sacroplasty: A Ten-Year Analysis of Prospective Patients Treated with Percutaneous Sacroplasty: Literature Review and Technical Considerations

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**Background:** The treatment of sacral fractures has evolved since its first description in 1982. Several techniques for sacral augmentation have been developed since 2001, and the rate of improvement is rapid with over 50% reduction in pain achieved prior to post-procedure discharge of the patient. Pain reduction occurs primarily within the first 3 months and is sustained at 12 months; however, the long-term outcomes have not previously been studied.

**Objectives:** We aim to evaluate the long-term efficacy of sacroplasty versus non-surgical management (NSM) in treating sacral insufficiency fractures (SIFs), including the effect on pain relief, opioid and other analgesic use, patient satisfaction, and complication rates. Additionally, we aim to review the most current sacroplasty literature.

**Study Design:** A 10-year prospective, observational cohort study of patients with SIFs treated with sacral augmentation.

**Setting:** A single-center interventional pain management private practice.

**Methods:** Two-hundred and forty-four patients with SIFs were treated with sacroplasty (210 patients) or NSM (34 patients) beginning in January 2004 and then followed for 10 years. The patients' gender, age, pre-procedure pain duration, analgesic use, pain level, and satisfaction were recorded at baseline and at post-procedure follow-up intervals of 2, 4, 12, 24, 52 weeks, and 2 years. The experimental group was then contacted at 10 years. Post-procedure complications before discharge and at each follow-up were also evaluated.

**Results:** Both NSM and sacroplasty resulted in statistically significant drops in visual analog scale (VAS) scores from pre-treatment to 2-year follow-up ( $P < 0.001$ ). When measured from follow-up to follow-up, the NSM group's only significant decrease in the mean VAS score was between pre-treatment and 2 weeks ( $P = 0.002$ ). The experimental group had significant decreases over the periods pre-op through post-op ( $P < 0.001$ ), post-op through 2 weeks ( $P < 0.001$ ), 12 weeks through 24 weeks ( $P = 0.014$ ), and 24 weeks through one year ( $P = 0.002$ ). The experimental cohort experienced statistically significant drops in the mean VAS scores between follow-ups for a longer period of time. Opioid and non-opioid analgesic use was markedly decreased preoperatively to postoperatively and was sustained at the 10-year follow-up.

**Limitations:** Patients were placed into the control group, NSM, if they did not meet inclusion criteria for sacroplasty. However, the baseline characteristics of the sacroplasty versus NSM group were not statistically different. Additionally, the control group was only followed through 2 years and was not contacted at the 10-year follow-up.

**Conclusions:** Our results and those reported in previous studies establish that sacroplasty allows for decreased use of medications and results in pain relief, greater patient mobility, and improved patient satisfaction. In addition to the published body of literature, our results show strong evidence in support of sacroplasty as a safe and efficacious treatment of SIFs.

**Key words:** Sacroplasty, sacral fracture, fracture, osteoporosis, insufficiency, radiology

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**S**acral insufficiency fractures (SIFs) are a common but often underdiagnosed and undertreated source of low back pain in the elderly osteoporotic patient (1-3). Insufficiency fractures result from normal stresses on abnormally weak bone, and patients presenting with these fractures usually have low back, groin, posterior thigh, or hip pain depending on the location of the fracture and whether it is associated with any other fractures such as pubic rami fractures. Osteoporotic fractures of the sacrum have similar etiologies as do vertebral compression fractures (VCFs), but the patients with SIFs typically have more severe osteoporosis than patients with VCFs. In addition to primary osteoporosis, other factors that may contribute to sacral fragility fractures include osteomalacia, Paget's disease, hip arthroplasty, and lumbosacral fusion (4). Radiation therapy also substantially increases the incidence of pelvic and sacral insufficiency fractures with a 5-year cumulative incidence of insufficiency fractures of nearly 20% in patients who have undergone radiation therapy for cervical carcinoma (5). This is due in part to the demineralizing effect of radiotherapy on bone matrices. Consequently, pelvic irradiation for gynecologic malignancies has yielded a 2 – 89% pelvic fracture rate (6). Apart from radiation-induced insufficiency fractures for cervical carcinoma, there is also a strong female predominance (10:1) (5,7). Other at-risk groups for SIFs include those suffering from rheumatoid arthritis, diabetes, renal failure, or long-term corticosteroid use, all of which contribute to decreased osseous elasticity and demineralization. Recent literature has suggested that in these at-risk groups, insufficiency fracture prevalence is somewhere between 9.5% and 11.4% (8).

The reported incidence of SIFs is approximately 1 – 2% of pathologic fractures involving the spine and pelvis, but given the low rate of recognition and diagnosis of these fractures this number could be lower than the actual prevalence (9,10).

Sacroplasty was first performed in 2001 for the treatment of metastatic lesions to the pelvis (11,12). The first large study that was performed demonstrated that sacroplasty was a safe and effective treatment for painful SIFs. The rate of improvement is rapid, with over 50% reduction in pain achieved prior to post-procedure discharge of the patient. Pain reduction occurs primarily within the first 3 months but is sustained at 12 months following the treatment (2). Since that initial study, many articles have been published on the evaluation, anatomical description, and treatment of SIFs but

none have focused on the long-term outcomes of this procedure.

## **OBJECTIVES**

The objective of this study is to evaluate the long-term efficacy of sacroplasty versus non-surgical management (NSM) in treating SIFs, including the effect on pain relief, opioid and other analgesic use, patient satisfaction, and complication rates. Additionally, we aim to provide an up-to-date review of the sacroplasty literature.

## **METHODS**

A prospective, observational cohort study was conducted of 244 consecutive patients with osteoporotic SIFs. Data was collected at a single-center, private practice pain management center from December 2003 to August 2015. Patients had to present with low back, sacral, or buttock pain. The inclusion criteria were: incapacitating pain due to a SIF, radiological imaging documenting evidence of sacral fracture with either magnetic resonance imaging (MRI) or increased radiotracer uptake on nuclear imaging (Fig. 1, Fig. 2), physical exam signs and symptoms consistent with SIFs, and failure of NSM. NSM was defined as analgesics including opioid analgesics, corsets, and/or bed rest for at least 3 weeks. Patients were excluded if their NSM plan was successful, if they refused treatment, had sepsis or infection, had neurologic deficits, or had uncorrected coagulopathy. The 34 patients falling within the exclusion criteria were placed into a control group. The remaining 210 patients underwent sacroplasty. The patients' gender, age, pre-procedure pain duration, analgesic use, pain level, and satisfaction were recorded at baseline and post-procedure follow-up intervals of 2, 4, 12, 24, 52 weeks, and 2 years. The sacroplasty group was also evaluated at 10 years. Additionally, each patient was assessed for post-procedure complications before discharge and at each follow-up evaluation. Pain duration was compiled in days, analgesic use was described as opioid, non-opioid, or over-the-counter (OTC), and pain level was assessed using the visual analog scale (VAS). The 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  $\leq 0.05$  as significant.

The patients included in this evaluation had the procedure performed with light intravenous conscious sedation and fluoroscopic guidance. Antibiotics were administered intravenously 15 – 30 minutes before

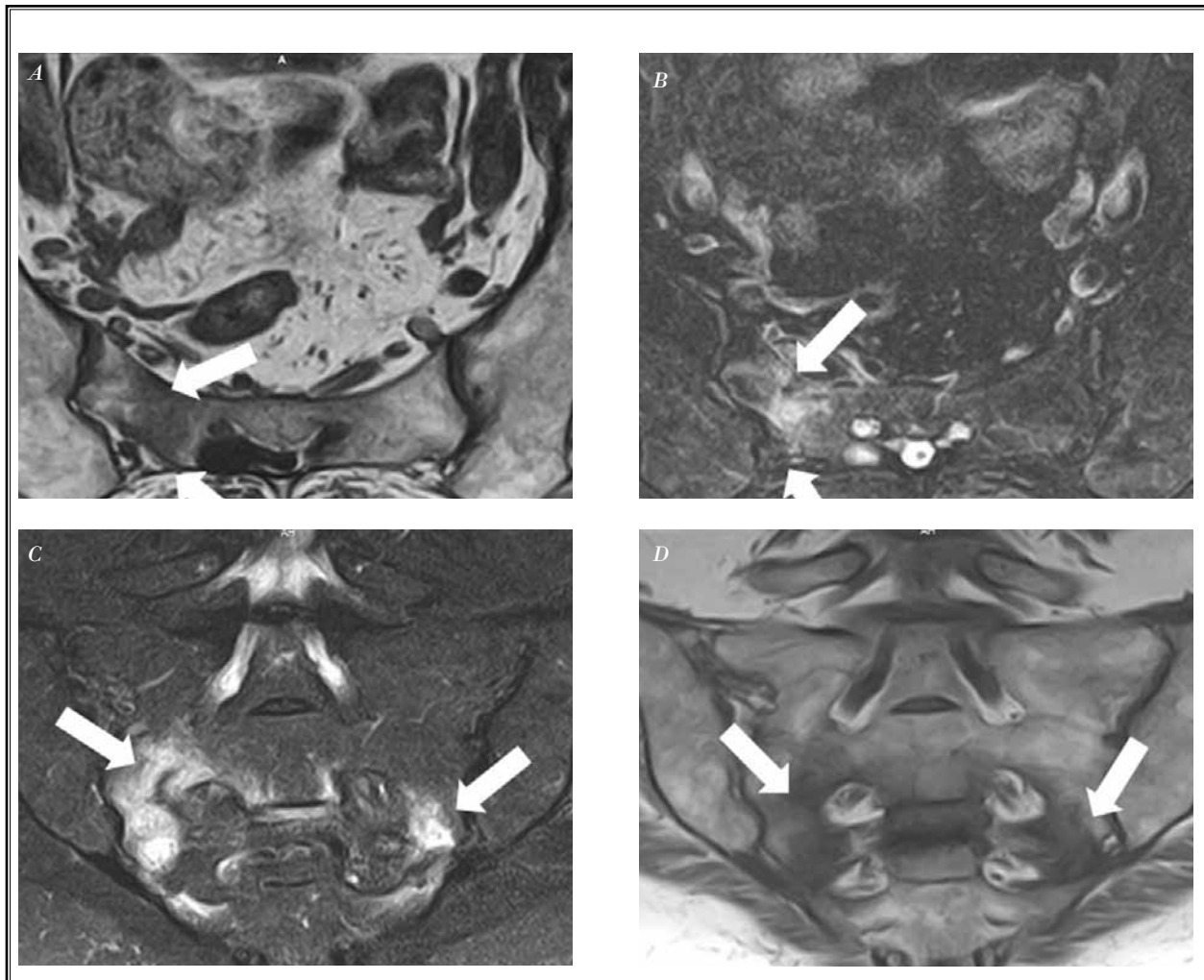


Fig. 1, A. Axial T1-weighted MR image shows a small focal region of decreased signal through the mid sacrum on the right (white arrows); due to its relative linear pattern, this most likely represents edema from an insufficiency fracture. B. Axial short tau inversion recovery (STIR) MR image shows increased signal within the small right mid sacrum on the right (white arrows) corresponding to the low signal seen on the T1-weighted image. The combination of findings, under the appropriate clinical conditions, most likely represents an insufficiency fracture. C. Coronal STIR MR image shows increased signal within the sacral ala bilaterally (white arrows) most consistent with edema. Linear low signal seen within the areas of edema are consistent with fracture lines. D. Coronal T1-weighted MR image shows the decreased signal within the sacral ala bilaterally (white arrows) most consistent with edema, which under the appropriate clinical conditions most likely represents insufficiency fractures. Notice that the fracture lines seen in C are not well-differentiated from the edema on this T1-weighted image.

the procedure. The procedures were performed by 2 fellowship-trained interventional physicians (M.F. and S.M.B.) and one interventional pain physician (J.S.D.) during the first 4 years of the study. During the subsequent 6 years, the majority were performed by one physician (M.F.). Over several years, different approaches were used to perform the sacroplasties. One approach was described in the 2007 and 2009 articles by Frey et al (2,10) where 2 13-gauge needles were

placed between the sacral foramen and sacroiliac joint on the side(s) of the fractured ala at a 45-degree angle cranially. The needles were inserted approximately to the midpoint of the sacrum, under lateral view, maintaining the 45-degree angle (Fig. 3a). After mixing the cement, using the Precision Cement Delivery System (Stryker, Kalamazoo, MI), 2 – 5 mL of polymethylmethacrylate (PMMA) was injected into the sacral ala through each trochar, monitoring the spread of the

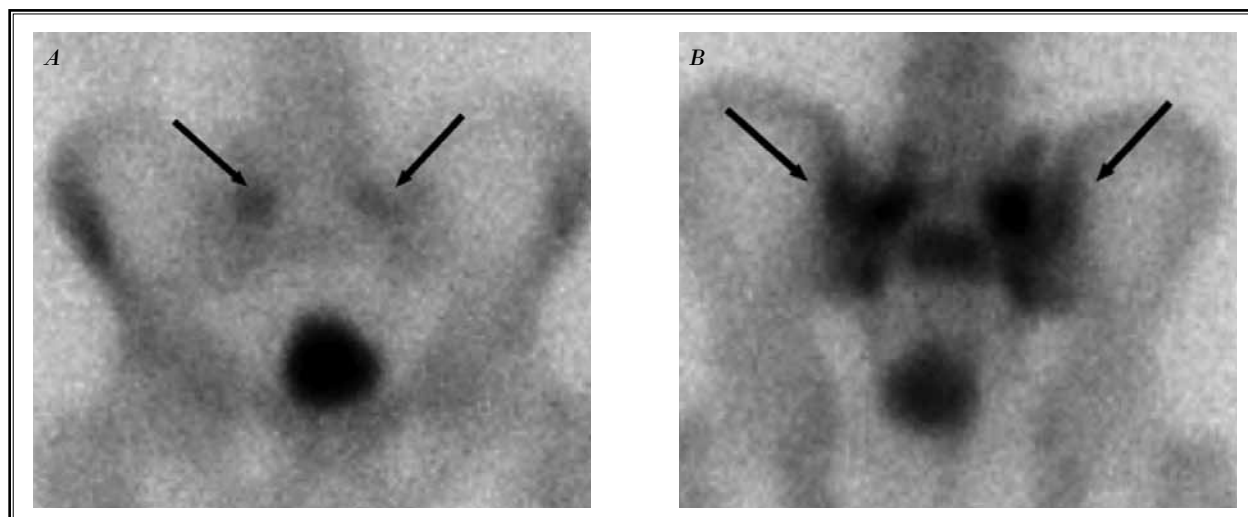


Fig. 2. A. Anteroposterior view of the pelvis taken after an intravenous injection of 25.1 mCi of Tc99m-MDP demonstrates areas of increased radiotracer uptake in the sacral ala bilaterally (black arrows). B. Posteroanterior view of the pelvis taken after an intravenous injection of 25.1 mCi of Tc99m-MDP shows prominent areas of increased radiotracer uptake in the sacral ala bilaterally (black arrows). The “H” configuration of the tracer uptake is a pattern most consistent with SIFs.

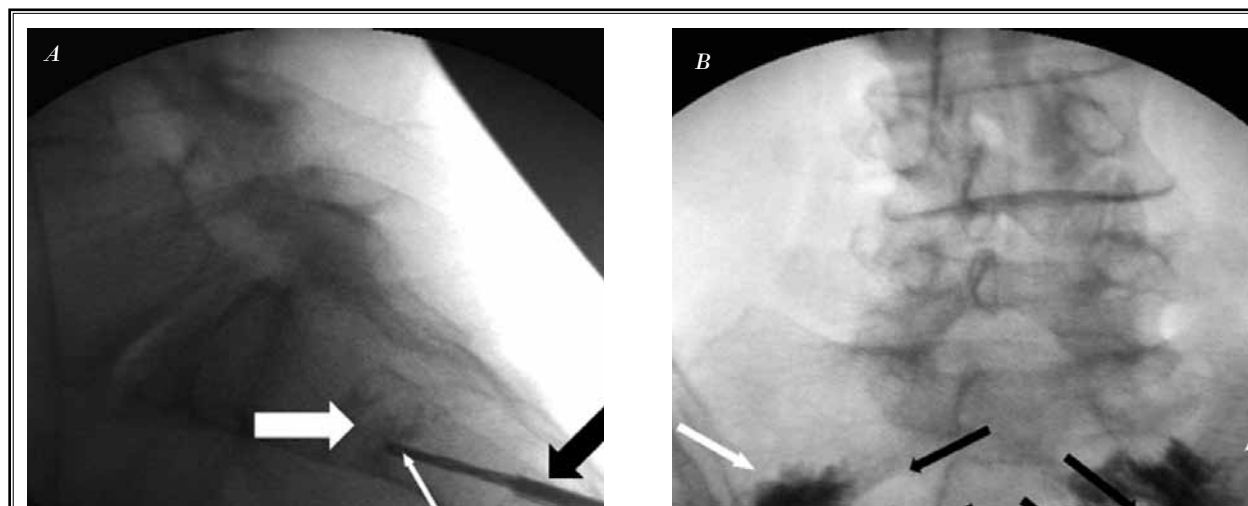


Fig. 3. A. Lateral fluoroscopic view demonstrates the needles entering the inferior portion of the S2 posteriorly (black arrows), a drill placed into the upper portion of the S2 vertebral body (thin white arrow), and the cement injected into the center of the upper S2 vertebral body (thick white arrow). B. Anteroposterior fluoroscopic view demonstrates the PMMA within the sacral ala (white arrows) and extending around, but not significantly into, the sacral foramen (black arrows).

bone cement primarily on the anteroposterior fluoroscopic view to avoid medial extension toward the sacral nerve roots (Fig. 3b). Another approach was the long-axis approach first described by Smith (13). The long-axis approach was performed by M.F. and J.D., but strictly under fluoroscopic guidance and not computed tomography (CT) guidance. The final approach was a “down the beam” approach first described by

Frey et al (14). After the procedure, each patient was maintained in the prone position for 30 to 45 minutes before being allowed to move prior to 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 SIFs, then the patient stood on one leg followed by the other leg and the total VAS score was then obtained.



**RESULTS**

A total of 244 patients were evaluated with 210 participants receiving sacroplasty in the experimental group and 34 control patients receiving NSM. Baseline characteristics including age and sex of the patients were comparable for the 2 groups. The average age of the experimental group was 75.7 years (81.9% female) and 72.3 years (76.5% female) for the control group. In the experimental group 117 patients (55.7%) completed the follow-up to 10 years, 82 patients (39%) were followed-up to 2 years, and the remaining 11 patients (5.2%) were followed for one year or less. All of the 34 control patients completed follow-up to 2 years. The control patients were not contacted at the 10-year follow-up.

According to the Wilcoxon Rank Sum Test, the difference between the pre-treatment VAS averages for the experimental (8.29) and control (7.47) groups was not statistically significant. The experimental group average pre-procedure VAS score of 8.29 dropped to 3.63 post-procedure, (a 56.2% decrease) (Fig. 4a, Table 1). At 2 weeks, the pain reduction had continued to decrease to 2.82 (66% decrease from baseline). The control group, however, achieved only a 27.2% decrease at the same 2-week interval (Fig. 4b, Table 2). A 2-year follow-up showed a 92% decrease in pain in the experimental group and an 85% decrease for the control group. The patients in the experimental group followed-up from 2 to 10 years exhibited a stable drop in pain from 92% to 94% as compared with their pre-procedure pain level. Decreases in pain from year 1 to year 2, and year 2 to year 10 were found to be statistically insignificant, however, they were significant relative to all of the other time-points. No data was available for the control group at 10 years.

Both NSM and sacroplasty resulted in statistically significant drops in VAS scores from pre-treatment to the 2-year follow-up ( $P < 0.001$ ). However, when measured from follow-up to follow-up, the control group's only significant decrease in the mean VAS score was between pre-treatment and 2 weeks ( $P = 0.002$ ), whereas the experimental group had significant decreases over the periods pre-op

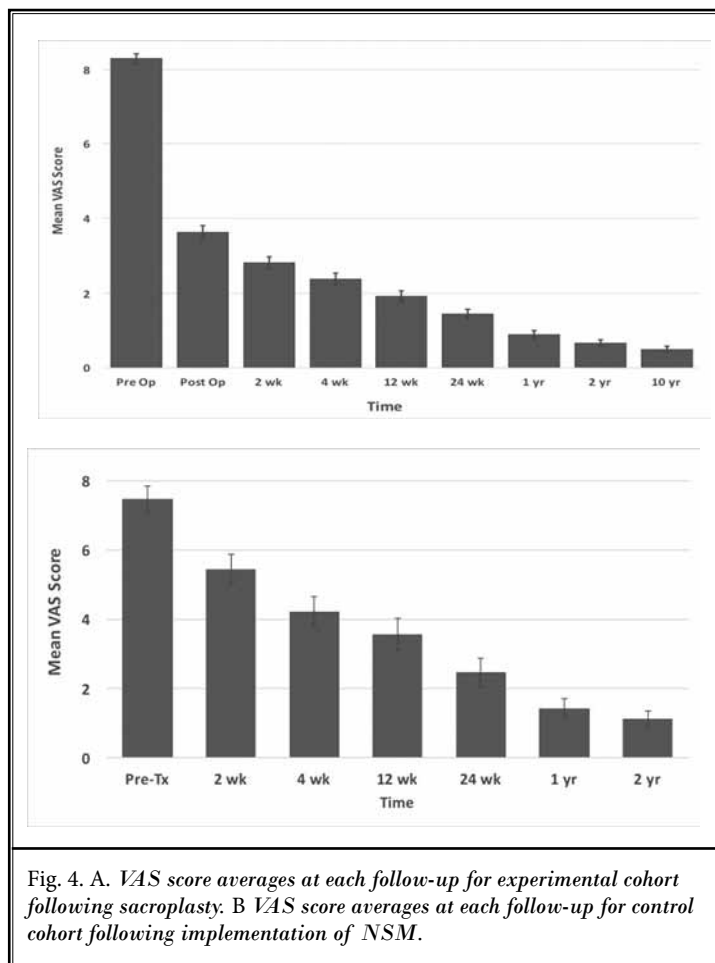


Fig. 4. A. VAS score averages at each follow-up for experimental cohort following sacroplasty. B VAS score averages at each follow-up for control cohort following implementation of NSM.

through post-op ( $P < 0.001$ ), post-op through 2 weeks ( $P < 0.001$ ), 12 weeks through 24 weeks ( $P = 0.014$ ), and 24 weeks through one year ( $P = 0.002$ ). Additionally, the experimental cohort experienced statistically significant drops in mean VAS scores between follow-ups for a longer period of time.

In the experimental group 77% of patients were using opioids pre-operatively, which decreased to 33% post-operatively. Non-opioid use and OTC analgesic use dropped from 31% to 0.005% and from 21% to 0.07%, respectively (Table 2). A small subset (15 of 140) of the patients was not able to immediately discontinue their post-operative opioids. The period these patients required to discontinue narcotics ranged from 4 – 12 weeks with an average of 5.7 weeks. Of the 33% of patients who were classified as continued post-operative narcotic users, 26 of the 69 patients had discontinued narcotics immediately post-operatively and relapsed on average at 11.9 weeks (range 2 – 24 weeks). After 10 years, of the 117 patients contacted from the experimental group, all had completely discontinued the use of medication for sacral pain.

Table 1. A *This table describes the mean VAS scores for patients who underwent sacroplasty, standard error for each value, and % decrease from baseline.*

Experimental Group	Pre-Op	Post-Op	2 wks	4 wks	12 wks	24 wks	1 yr	2 yrs	10 yrs
Mean VAS	8.29	3.63	2.82	2.39	1.93	1.45	0.89	0.66	0.50
Std. Error	.1273	.1684	.1661	.1543	.1429	.1267	.0998	.0847	.0805
% Decrease from Baseline	N/A*	56.2%	66%	71.2%	76.7%	82.5%	89.3%	92%	94%

\* Not Applicable

Table 2. *This table describes the mean VAS scores for patients who underwent NSM, standard error for each value, and % decrease from baseline.*

Control Group	Pre-Op	Post-Op	2 wks	4 wks	12 wks	24 wks	1 yr	2 yrs	10 yrs
Mean VAS	7.47	N/A*	5.44	4.24	3.47	2.47	1.44	1.12	N/A*
Std. Error	.3758	N/A*	.4351	.4223	.4629	.4185	.2775	.2453	N/A*
% Decrease from Baseline	N/A*	N/A*	27.2%	43.2%	53.5%	66.9%	80.7%	85%	N/A*

\* Not Applicable

## Discussion and Review

The sacroplasty procedure involves injecting stabilizing material (usually PMMA) into the cancellous portion of the sacrum at the S1 and S2 levels. These levels are the most commonly fractured portions of the sacrum and are also the largest sacral vertebral levels that provide the greatest amount of structural support. Sacroplasty is similar to a vertebroplasty procedure and may be performed under fluoroscopy, CT, or a combination of both modalities. Sacroplasty was first reported in 2001 with the treatment of symptomatic metastatic sacral lesions (11,12) and subsequent contributions to the literature have documented its safety and efficacy (15,16). Although these studies indicate the strong potential for effective percutaneous stabilization and treatment of SIFs, the lack of larger randomized control trials and cohort analyses with long-term follow-up periods are a major limitation when trying to objectively provide a more definitive assessment of the durability of the safety and efficacy of percutaneous sacroplasty (17). In 2007, a prospective multicenter study assessing the safety and effectiveness of sacroplasty was published by Frey et al (2), which better outlined the clinical utility of sacroplasty in the treatment of osteoporotic SIFs along with accurately categorizing the incidence of procedural complications. The authors reported a mean patient age of 76.6 years and stipulated that they had to have had a failure of NSM. The mean baseline VAS score was 7.7, which decreased to 3.2 immediately following the procedure and was 0.7 at 1 year. There were no persistent complications resulting from the procedure and the patients' opioid use dropped substantially.

The potential risks for the sacroplasty procedure are similar to those of vertebroplasty and include cement extravasation around the nerve roots, cement emboli, and leakage into the epidural space. Some potential complications specific to sacroplasty include penetration of/extrusion of cement around the lumbosacral plexus and sacral nerve roots. Despite the potential complications, this is a safe procedure with very few reported complications.

In 2008, Frey et al (10) published an additional study with similar outcomes of patients treated with percutaneous sacroplasty. This manuscript reported that greater than 75% of the patients had their pain reduced by more than half within 30 minutes following the procedure. The authors also reported follow-up information from some of their former patients.

In 2009, a meta-analysis by Bayley et al (18) on sacroplasty literature between 2002 and 2008 was published, including a total of 15 publications (18). The criteria for inclusion in their study were manuscripts published in the English language evaluating osteoporotic SIFs. Analysis of the literature included information regarding patient numbers, surgical technique, and procedural outcomes.

Cumulatively, the 15 studies amounted to data on 108 patients, with the largest single study including 52 patients. The average patient age was 75.5 years and there was a minimum follow-up time of 2.5 months and a mean follow-up time of 9.1 months.

The majority of procedures involved posterior percutaneous entry, as opposed to posterolateral entry across the sacroiliac joint. The short- and long-axis

techniques were discussed, and although no consensus was found as to which technique was optimal, the ease of direct injection via long-axis approach was noted. In 2008, Waites et al (19) suggested that neither posterior nor posterolateral cement augmentation of the sacrum yielded enhanced pelvic strength or stability. In the same year, Tjardes et al (20) also suggested that sacroplasty did not sufficiently stabilize the pelvis. There was concern over the lack of long-term sacroplasty data, so the authors suggested that iliosacral screw fixation might be a good alternative. However, one criticism of Waites' study was that a relatively small amount (4 mL) of PMMA was used in their sacroplasties as compared with 4 – 6 mL as reported by Frey et al (2,10). In the 15 studies, the VAS was used to assess the patients' pain in 62 of 108 patients. In these patients, mean VAS scores dropped from 8.9 to 2.6, a > 75% decrease in pain. Frey et al (10) observed that these low VAS scores were maintained at one year after the procedure.

Periprocedural cement extravasation was the primary complication, occurring in 8 of 108 patients. However, this extravasation was not clinically harmful to any individual. A significant limitation of this evaluation was that only 80 patients underwent CT combined with fluoroscopic imaging, while the other 28 patients had either one or the other. Because the presence of cement extravasation is more accurately determined using CT or CT and fluoroscopy, as opposed to fluoroscopy alone, it is likely that more than the observed 8 patients had the presence of cement extravasation. One patient experienced S1 radicular pain immediately following the procedure, but this was promptly treated effectively using an anesthetic injection around the nerve. One quadriplegic patient experienced no pain relief, but this refractory case was attributed to severe muscle dystrophia. While Gjertsen et al (21) suggested that infection, pulmonary emboli, and nerve damage are all potential complications of sacroplasty, no patients in this study experienced these problems. Ultimately, Bayley et al (18) concluded that while sacroplasty was deemed safe, a longer study would be necessary to determine if time affects cement distribution and placement and if any long-term complications occur with significant frequencies.

We also compiled a separate, more recent collection of sacroplasty literature, published between 2009 and 2016. The literature search involved the use of Medline via PubMed and ProQuest and yielded 10 publications. The keywords SIF and sacroplasty were used. Studies involving both cancerous pelvic lesions

and osteoporotic SIFs were included, so as to address the safety and efficacy of sacroplasty for treatment of both patient groups. These studies were analyzed for the number of cases, follow-up period, and clinical outcome. The clinical outcome was based on pain relief, affect on ambulation, and affect on analgesic use.

A total of 488 patients were included in the 10 publications identified. Four of the 10 studies had follow-ups of up to one year, and included data for 236 patients (22-25). Shorter follow-ups were conducted for 182 patients. In the remaining 70 patients, either no follow-ups were conducted or no data were recorded at their follow-ups. Talmadge et al (26) followed-up their 18 patients through 48 weeks. Gupta et al (27) followed-up 53 patients at an average of 27 +/- 3.7 days. Dougherty et al (28) conducted follow-ups at a median of 2.5 weeks for 45 of their total 57 patients. Pereria et al (29) conducted, on the average, a 1-month follow-up for all of their 58 patients. Kang et al (30) were able to follow-up each of their 8 patients in the short term, which they defined as "less than one month," and 5 of their patients for longer, which they defined as "more than one month." Lastly, Hassan (31), Naderi et al (32), Cho et al (33), and Trouvin et al (34) failed to include any information on their follow-ups.

With regard to pain relief, 7 of the 10 publications used VAS scores to measure pain relief. Studies by Kortman et al (22), Eichler et al (23), Pereira et al (29), Hassan (31), and Naderi et al (32) examined VAS scores from cohorts ranging between 3 and 243 patients. The decreases in short-term mean VAS scores for these studies ranged from 61.7% to 75.27%. Gupta et al (27) compiled VAS scores for only 27 of 53 patients, with a mean decrease of 67.67% in those 27 patients' scores. Kamel et al (25) had a lower level of mean pain relief, finding only a 50% post-op pain decrease in their 19 patients. However, this moderate decrease in pain improved to 80% over the course of one year. The Eichler et al (23) study also suggests that pain relief increases as time elapses, finding that a mean VAS score decrease of 61.7% post-procedure increased to 74.1% over the course of one year. While Kang & Lee et al (30) and Kang & Kim et al (24) did not note VAS scores, they found that cumulatively, 7 of their 9 total patients (77.78%) experienced significant pain relief postoperatively (30).

Another factor analyzed when considering the clinical outcome of sacroplasty is patient mobility. Gupta et al (27) used the Functional Mobility Scale (FMS) to determine procedural effect on mobility and ambulation. The average pre-procedure score of

Table 3. The number of patients using opioids, non-opioids, and OTC drugs, separated by treatment and pre-/post- distinction.

	Experimental	Control
Opioid Users (Pre-Treatment)	162 (77.1%)	24 (70.6%)
Opioid Users (Post-Op)	69 (32.9%)	N/A*
Non-opioid Users (Pre-Treatment)	65 (31%)	13 (38.2%)
Non-opioid Users (Post-Op)	1 (.005%)	N/A*
OTC Drug Users (Pre-Treatment)	43 (20.5%)	14 (41.2%)
OTC Drug Users (Post Op)	15 (.07%)	N/A*

\* Not Applicable

3.0 (2.0 – 3.0) decreased to 1.0 (0.25 – 2.8) ( $P < .001$ ). Talmadge et al (26) utilized the clinical mobility scale (CMS) to shed light on the effectiveness of sacroplasty on mobility. They reported that mean CMS scores significantly improved over the course of 48 weeks, indicating that patient mobility scores continue to improve even beyond 4 weeks post-procedure. While exact score measurements were not specified, other studies noted that their patients experienced improved mobility and/or ability to ambulate (25,29-31).

The final factor used to determine clinical outcomes for sacral augmentation was the affect on analgesic use. Kamel et al (25), Gupta et al (27), and Pereira et al (29) all noted significant reductions in analgesic and opioid use. Kortman et al (22) suggested that their patients exhibited a decrease in analgesic use as well, but provided no statistical analysis of this decrease.

Siggins et al (35) recently demonstrated similar results in their 2016 literature review of sacroplasty for sacral metastases. The 9 studies reviewed included 172 patients and an average follow-up of 6 months, ranging from 2 weeks to 12 months. The average VAS decreased from 8.43 pre-operatively to 2.8 post-operatively. Of the 9 reported cases of cement leakage, only 1.7% (3 of 172 patients) was clinically relevant.

In an effort to expand the body of literature on the long-term effects of sacroplasty, we performed a 10-year prospective study observing the effects of the treatment on osteoporotic patients. SIFs are indeed a source of significant pain and discomfort for patients, and though several treatment options exist (NSM, surgery, as well as sacroplasty), this study finds that sacroplasty is a viable and durable option for treating

patients with persistently painful SIFs. In our study, the patients treated with sacroplasty had an immediate decrease in pain with the mean pre-procedure VAS score of 8.29 decreasing to 3.63 post-procedure. Both the control group and experimental group demonstrated a significant reduction in VAS pain scores at 2 weeks, however, the sacroplasty group demonstrated a more marked decrease in pain scores: 2.82 (66%) compared to 5.44 (27%). Although, the decreases in pain from year 1 to year 2 and year 2 to year 10 were found to be statistically insignificant, they were significant relative to all the other time-points and demonstrate that the pain relief produced by sacroplasty is not only significant, but is maintained up to a decade after the procedure. Experimental group results demonstrate a greater decrease in VAS scores as compared to the control group, indicating lower pain levels and a higher positive affect following sacroplasty treatment.

While the VAS scores suggest that sacroplasty results in better outcomes in regard to both short- and long-term relief from sacral pain, this particular study was somewhat limited in terms of the sample size of the control group and no members of this group were able to be contacted regarding their 10-year outcomes. Moreover, we lack data on functionality and quality of life data which would allow for greater insight into the efficacy of sacroplasty.

We are, however, able to continue to find congruence with previous literature regarding the analgesic use in our patients. We measured opioid use, non-opioid use, and OTC use before and after the procedure. We found that not all patients were able to immediately stop their use of opioids, and some patients began reusing opioids after some period of time. Those who eventually discontinued their opioids were included in the patient group of opioid non-users, and those who eventually continued opioid use were included in the patient group of opioid users. Of the patients who were unable to immediately discontinue opioid use, the average time it took a patient to stop their opioid use was 5.7 weeks. The average time before patients who relapsed began to use again was 11.9 weeks.

Non-opioid use and OTC use were practically eliminated post-procedurally, dropping from 31% to 0.005% and from 21% to 0.07%, respectively (Table 3). After 10 years, of the 117 patients contacted from the experimental group, all had completely discontinued the use of medication for sacral pain. This indicates a significant effect on the reduction or elimination of the use of analgesics following sacroplasty treatment.



Our results and those reported in previous studies establish that sacroplasty allows for decreased use of medications and results in greater patient mobility and improved patient satisfaction.

Pain reduction is substantial in patients treated with sacroplasty and is consistently reported in the sacroplasty literature. In our study, it was determined that both NSM and sacroplasty resulted in statistically significant drops in VAS score from pre-treatment to 2-year follow-up. However, when measured from follow-up to follow-up, the control group's only significant decrease in mean VAS was between pre-treatment and 2 weeks. The experimental group had significant decreases over the periods pre-op through post-op, post-op through 2 weeks, 12 weeks through 24 weeks, and 24 weeks through 1 year. Not only was the overall pain relief greater in magnitude for the experimental cohort, but they also experienced statistically significant drops in mean VAS scores between follow-ups for a longer period of time. Interestingly, despite the significant reduction in patient pain in the control group up to year 2,

the difference between patient satisfactions remained statistically significant between the sacroplasty and control groups at this point in time ( $P < 0.001$ ).

## CONCLUSION

In conclusion, our long-term study of patients treated with sacroplasty supports previously reported data that shows a statistically significant reduction of pain and analgesic use and demonstrates that these results are durable for up to at least 10 years. Compared to a control group, the degree of pain relief for sacroplasty patients was greater and they had statistically significant decreases in pain scores at more time intervals for a longer period of time than did the patients in the NSM group. The 10-year follow-up also showed a high-rate of patient satisfaction with the sacroplasty procedure. Unfortunately, due to the vast age of the patients, death unrelated to the procedure was not uncommon. Our results, in addition to the published body of literature data, show strong evidence in support of sacroplasty as a safe and efficacious treatment of SIFs.

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