Patient-Reported Outcomes and Computed Tomography Review After Minimally Invasive Fusion of the Sacroiliac Joint With Aggressive Joint Decortication and Joint Compression

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abstract

The sacroiliac joint (SIJ) is a common, underrecognized source of low back pain. We evaluated outcomes in patients undergoing sacroiliac joint fusion (SIJF) using a novel, minimally invasive SIJF system emphasizing compressive forces across an aggressively debrided SIJ. We retrospectively reviewed data from a continuous set of patients presenting to a large, tertiary care hospital from September 2017 to August 2019. All patients received the novel SIJF device. Outcomes were assessed at 8 weeks, 6 months, and 12 months using the Oswestry Disability Index (ODI) score, Numerical Rating Scale (NRS) score, Single Assessment Numerical Evaluation (SANE) score, and Patient-Reported Outcomes Measurement Information System (PROMIS) measures, plus radiographic evaluation of fusion status. Data from 75 patients were analyzed. At 8 weeks, 6 months, and 12 months, the ODI score improved by 10.5 points (P=.002), 17.4 points (P<.0001), and 23.6 points (P<.0001), respectively, while the NRS score improved by 4.6 points (P<.0001), 4.4 points (P<.0001), and 4.6 points (P<.0001), respectively. SANE scores indicated high levels of patient satisfaction (81.0%, 92.18%, and 89.2%, respectively). PROMIS physical function scores improved by 2.65 points, 3.30 points, and 3.63 points, respectively, while PROMIS mental health scores showed changes of -1.93 points, 1.57 points, and -0.47 points, respectively. A review of computed tomography scans demonstrated grade 3 fusion (complete) in 81% of cases at a mean of 371 days postoperatively. There was one revision case for a malpositioned implant. The use of a novel SIJF device emphasizing compressive forces provided early, durable improvements in patient-reported outcomes and extremely high patient satisfaction. [*Orthopedics*. 202x;4x(x):xx-xx.]

Chronic low back pain (LBP) remains a common form of musculoskeletal pain and a leading cause of disability in the United States.[1-3] For the majority of adults, the condition is self-limiting.[4] However, for a subset of patients unresponsive to treatment, recalcitrant LBP evolves to chronic LBP,[5] the financial costs of which approach $96 billion annually in the United States.[6] LBP is multifactorial and presents varyingly depending on etiology, with hip and/or sacroiliac joint (SIJ) contributions common but underappreciated as causal pathologies.[7]

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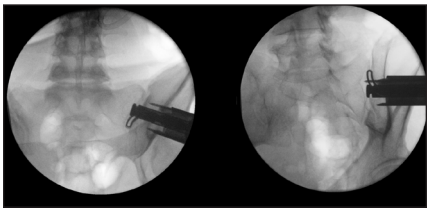

Figure 1: Sacroiliac joint decortication with a deployable, rigid blade. The spinning blade is deployed while the device is within the sacroiliac joint space (left). The stiff blade permits aggressive decortication of the dense, sclerotic, subchondral bone, allowing for cancellous-to-cancellous bone exposure (right).

The literature increasingly recognizes SIJ dysfunction as a significant contributor to chronic LBP, with reports suggesting that 15% to 40% of patients presenting with LBP may have SIJ dysfunction as their primary pain generator.[7,8] SIJ pain presents unique challenges to practitioners, as diagnosis is often difficult due to the lack of correlation between radiographic findings and symptomatology,[9] and the typical non-surgical treatment regimen, while effective in mild or early cases, is less effective in chronic SIJ pain.[10] Assistive devices may provide temporary relief but are often unsuccessful in alleviating chronic symptoms.[10-12] As such, for patients whose condition does not respond to these treatments and whose pain becomes limiting, surgical management may represent the only remaining option.

Surgical options for SIJ fusion (SIJF), while generally associated with improvements in pain, vary in technology and are associated with drawbacks. There is a scarcity of evidence using patient-reported outcome measures (PROMs) to evaluate treatment success. Regarding fusion outcomes, the correlation between fusion and treatment success is not well understood.[12] While significant focus is given to radiographic fusion as an indicator of success, few current devices employ the fundamental principles of bony fusion outlined by the AO Foundation, namely, aggressive joint preparation with decortication, percutaneous autograft delivery, joint compression, and stability.[13]

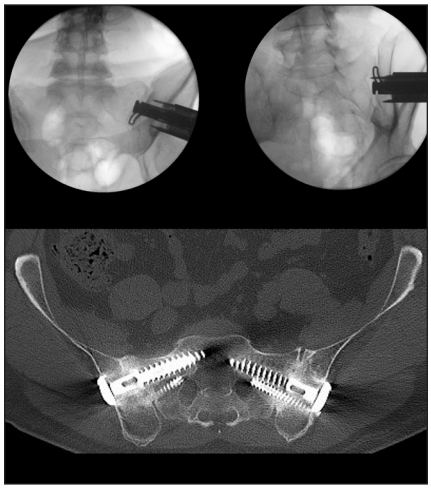

Figure 2: Filling of the sacroiliac joint fusion zone with autograft and bone graft extender. The bone graft applicator is inserted within the minimally invasive tube system (top left), using stabilization pins. The void is then filled with autograft mixture, with the graft positioned within the cancellous bone on the iliac and sacral sides (top right). At 1-year follow-up, radiographic fusion is evident (bottom).

We sought to evaluate the effect of a novel, minimally invasive SIJF system that employs the AO Foundation principles of joint fusion and compression on patient-related outcomes and radiographic fusion rates in patients undergoing SIJ arthrodesis for chronic, recalcitrant LBP.

Materials and Methods

We retrospectively reviewed prospectively collected data from a large, tertiary care facility specializing in surgical treatment of chronic SIJ pain. We collected data from patients who underwent SIJF surgery performed by a single surgeon between September 2017 and August 2019. Institutional review board approval was received prior to beginning data collection, and the study was performed in accordance with the Helsinki Declaration of 1975 (revised 1983).[14]

Study Population

Patients who presented with chronic SIJ pain and fulfilled all of the following criteria were eligible for inclusion in the study: SIJ pain unresponsive to conservative treatment; at least three positive examination findings consistent with SIJ-mediated pain (positive SIJ distraction, FABER test, compression test, Gaenslen's test, or thigh thrust); a demonstrated positive response to a documented intra-articular injection in the SIJ; and minimum 1-year follow-up.

Surgical Technique

Surgeries were performed using a novel, minimally invasive SIJF system (Integrity-SI Fusion system; OsteoCentric Technologies). The system employs a threaded, 10- or 12-mm screw that includes a pre-assembled washer to facilitate joint compression, a fenestrated "fusion zone" that sits across the SIJ, and an optional 6.5-mm screw for additional rotational stability. The SIJ was accessed percutaneously using fluoroscopy, followed by aggressive decortication with a deployable, rigid blade (**Figure 1**). The fusion zone was then irrigated and joint debris was suctioned, after which a combination of autograft and bone graft extenders were placed percutaneously into the joint cavity (**Figure 2**). The autograft was obtained from a 12-mm, deep-fluted drill with an average yield of 1 to 4 cm^3. Bone graft extenders included 5 cm^3 of demineralized bone matrix (AlloSync; Arthrex Inc) and 1.05 mg of recombinant bone morphogenetic protein-2 (Infuse; Medtronic), which was used off-label with preoperative patient consent. A cannulated system was then used to place the implant across the SIJ. Implant placement was aided by biplanar fluoroscopy using inlet, outlet, and lateral views. The distal portion of the implant was inserted to engage the dense bone in the vertebral body of the upper or lower sacral segment (S1 or S2). Final implant seating and adequate compression across the SIJ was verified via an anteroposterior view with a 20° to 40° tilt to match the slant of the pelvic outer table (**Figure 3**).

The techniques employed to accomplish this predictable and durable SIJF,

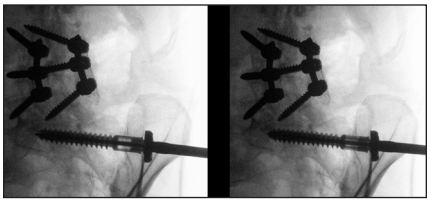

Figure 3: Sequential fluoroscopy images demonstrating compression across the sacroiliac joint. Compression with the final implant is sequential. This ensures proper placement of the fusion device (left) and that, in the final construct, the washer is securely seated on the outer table of the pelvis (right).

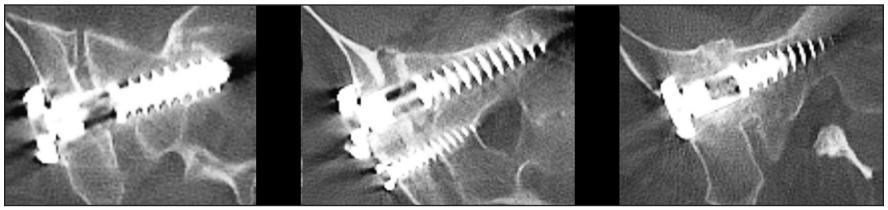

Figure 4: Grades of radiographic fusion. Grade 1: no discernible bridging bone from ilium to sacrum (left). Grade 2: some bone formation present but no definitive evidence of bridging bone from ilium to sacrum (middle). Grade 3: clear and definitive evidence of bridging bone from ilium to sacrum (right).

although not widespread, are straightforward with appropriate training and understanding of the relevant anatomy. There are two standard ways in which the authors have performed these fusions. With the first technique, after templating the case with PACS imaging software, fluoroscopy is used primarily with outlet and inlet views of the sacrum. This allows for adjustments in the cranial/caudal plane and anterior/posterior plane, respectively. A lateral view of the sacrum is often used to ensure safe pin placement posterior to the iliac cortical density.[15-17] Using these views and placing the implants in the predetermined pathways will allow reproducible and safe screw placement across the SIJ and optimizes the compressive force across the SIJ perpendicular to its native alignment. This maximizes stability while minimizing any shear effect from oblique screw or implant placement across the SIJ.

The second technique (which is used more occasionally) employs intraoperative navigation using the Stealth navigation system with the O-Arm (Medtronic).[18-20] With this method, the guide pin is placed in accordance with preoperative templating, using the navigation system and a predetermined but safe length. After guide pin placement with navigations, fluoroscopy is then used with outlet as the primary view to optimize guide pin length and identify the SIJ for adequate decortication depth and diameter.

It is critical to note that proper templating is mandatory for every patient and is used for every patient in the primary author's practice. Failure to template the SIJF procedure properly may result in nerve damage or inadequate stability and compression. Preoperative outlet and inlet plain radiographs and axial, sagittal, and coronal oblique computed tomography (CT) scans of the pelvis are used for templating. A concentrated effort at measuring the "safe zone" is critical. The safe zone is defined as the corridor of bone extending from the lateral wall of the iliac wing across the SIJ and into the S1 or S2 vertebral bodies, depending on the morphology of the sacrum.[16]

Physical and Radiographic Evaluation

The diagnostic strategy used at our SIJ clinic involves 4 primary criteria: (1) a history consistent with SIJ pain where pain is off-midline, below L5, and not typically associated with neuropathic signs; (2) a positive SIJ examination with 3 or more positive tests reproducing or worsening their pain; (3) imaging consistent with SIJ disease, although this is the least influential criterion; and (4) a positive injection response. A comprehensive triage form is completed by patients prior to their appointment, allowing the treatment team increased sensitivity in diagnosing SIJ-mediated pain. The physical examination, including 5 core provocative SIJ maneuvers, is employed to both diagnose and aggravate the SIJ. These maneuvers include the FABER test, PSIS sulcus pain (Fortin finger test), PSIS distraction test, combined FABER/PSIS distraction (ie, the Mayo SI Joint test), Gaenslen's test, and sacral thrust. Finally, an image-guided intra-articular injection is administered by our radiology or pain medicine colleagues. These images are closely inspected to ensure perfect placement into the joint. If fluoroscopy cannot guarantee the injection placement, the injection is "auto-elevated" to CT-guided injection where ideal placement is optimized. In our practice, patients typically must demonstrate 50% or greater pain relief to be considered candidates for minimally invasive SIJF surgery.

In our study, pre- and postoperative radiographs were obtained for all patients. Preoperative anteroposterior pelvic, inlet, outlet, and single leg stance views (to identify preoperative pelvic ring instability) were obtained. Preoperative CT scans were also obtained to help determine the etiology of the SIJ pain and allow for surgical planning. At 12 months post-procedure, plain radiographs and a CT scan were obtained.

Outcomes

The primary outcomes of this study were scores for pain (via the Numerical Rating Scale [NRS]) and functional abilities (via the Oswestry Disability Index [ODI]). Secondary outcomes included PROMs including the Single Assessment Numerical Evaluation (SANE) scoring system[21-23] and the Patient-Reported Outcomes Measurement Information System (PROMIS)-10 T-scores (physical function [PF] and mental health [MH]).[24,25] Radiographic fusion of the SIJ at 12 months post-procedure was assessed via independent radiographic review. Fusion was evaluated as follows: grade 1, no evidence of bone growth across the SIJ; grade 2, bone

Table 1

Summary of Demographic Data (N=75)

Characteristic	Value
Age, mean (SD; range), y	58.0 (14.6; 31-87)
Sex, No./total no. (%)	
Female	45/75 (60)
Male	30/75 (40)
Body mass index, mean (range), kg/m^2	29 (19-40)
Smoking status, No./total no. (%)	
Yes	2/60 (3.3)
No	58/60 (96.7)
Laterality, No./total no. (%)	
Left	28/75 (37.3)
Right	24/75 (32.0)
Bilateral	23/75 (30.7)

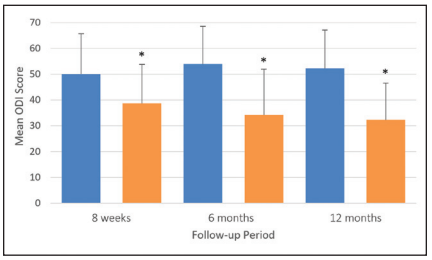

Figure 6: Mean Oswestry Disability Index (ODI) scores at 8-week, 6-month, and 12-month follow-up (orange) compared with baseline (blue). *Statistically significant difference vs baseline (*P*<.0001).

growth evident but no definitive bridging bone identified; and grade 3, bone growth and clearly demonstrated bridge of the SIJ (**Figure 4**). Implant loosening, subsidence, and neural foramen penetration were also assessed at radiographic follow-up. Outcomes were collected at baseline and at 8-week, 6-month, and 12-month follow-up visits.

Statistical Analysis

Alpha was set a priori at *P*<.05 for all statistical comparisons. Continuous variables were presented as mean and range; categorical variables were presented as proportion. Mean values were compared using the Student's *t* test. Statistical analysis was performed using Excel (Microsoft Corp).

For PROMs data, the proportion of patients who achieved a minimal clinically important difference (MCID) at each follow-up visit was calculated. For ODI and NRS score, improvements of 15 and 2 points, respectively, were considered clinically important.[26] For PROMIS-10, no consensus on what constitutes a MCID has been reached in the literature; ranges from 3 to 23 points have been reported in studies of patients with spinal conditions.[27-29] Given this, we chose an improvement of 3 points for each of the PF and MF domains as clinically important, consistent with published data for studies in this field.[29]

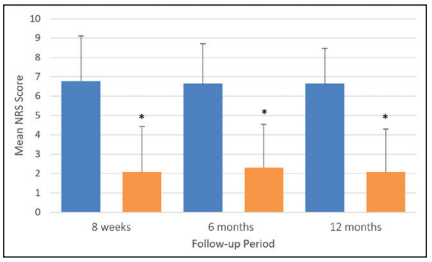

Figure 5: Mean Numerical Rating Scale (NRS) scores at 8-week, 6-month, and 12-month follow-up (orange) compared with baseline (blue). *Statistically significant difference vs baseline (*P*<.0001).

Results

Demographic Data

Seventy-five patients were evaluated during the study period and included in the study, with a mean age of 58.0 years (SD, 14.6 years; range, 31-87 years). Females comprised 60% (45 of 75) of the study cohort. The mean follow-up period was 14.2 months. SIJF was bilateral in 31% (23 of 75) of cases, with the remaining procedures similarly distributed between right-sided (32%, 24 of 75) and left-sided (37%, 28 of 75) unilateral fusion (**Table 1**).

PROMs

NRS

At 8 weeks post-procedure, patients reported a 69% improvement in pain scores over baseline (2.1±2.3 vs 6.8±2.4 points, *P*<.0001). Similar improvements were noted at the 6-month (65% improvement: 2.3±2.24 vs 6.6±2.1 points, *P*<.0001) and 12-month (68% improvement: 2.1±2.2 vs 6.6±1.8 points, *P*<.0001) follow-ups (**Figure 5**). At the 12-month follow-up, 88% of patients (43 of 49) had achieved a MCID improvement in pain scores.

ODI

At 8-week follow-up, patients reported a significant improvement of 23% in ODI scores when compared with baseline (38.7±15.1 vs 50.1±15.6 points, *P*=.002). Similar improvements were also noted at 6 months (37% improvement: 34.2±17.8 vs 53.9±14.7 points, *P*<.0001) and 12 months (38% improvement: 32.3±14.2 vs 52.3±14.8 points, *P*<.0001) (**Figure 6**). At 12 months, 66% of patients (33 of 50) had achieved a MCID improvement in ODI scores.

PROMIS-10

Statistically significant improvements in PROMIS-10 PF scores were noted at all time points. At 8 weeks, a 2.7-point improvement over baseline was noted (35.9±0.1 vs 38.5±0.4 points at baseline, *P*=.05). Significant improvements continued to be noted at 6 months (3.3-point improvement: 35.8±0.1 vs 39.1±0.5 points, *P*=.006) and 12 months (3.6-point improvement: 36.2±0.4 vs 39.8±0.4 points, *P*=.001). At 12 months, 38% of patients (14 of 37) had achieved a MCID improvement in PF scores. PROMIS-10 MH scores remained stable at all time points, with changes from baseline of -1.9 points at 8 weeks (*P*=.21), +1.6 points at 6 months (*P*=.18), and -0.5 points at 12 months (*P*=.37). At 12 months, 27% of patients (10 of 37) had a MCID in MH scores (**Figure 7**).

SANE

Patients generally rated their level of improvement as very high. Mean SANE scores for all cases were 81.0% at 8 weeks, 92.1% at 6 months, and 89.2% at 12 months.

Radiographic Evaluation

One-year postoperative CT scans were available for 78% (47 of 60) of patients

(63 joints), obtained at a mean follow-up of 371 days. Based on radiographic review, 1 joint (2%) had grade 1 fusion, 11 joints (17%) had grade 2 fusion, and 51 joints (81%) had grade 3 fusion. No radiographic lucencies, implant subsidence, or implant fractures were observed.

Complications

One patient reported L5 radicular symptoms exceeding 10 days post-procedure. Subsequent CT scans revealed the implant anterior to the right sacral ala, impinging on the L5 nerve root. The patient underwent revision surgery to reposition the implant; symptoms resolved and no further symptoms were reported. At 12-month follow-up, no ongoing symptoms were reported by the patient and radiographic evaluation determined that the fusion was grade 3. No other complications were reported.

Discussion

SJI pain unresponsive to conservative treatment often benefits from joint fusion surgery; however, data on patient-reported outcomes are lacking. Data on fusion devices that use the principles of joint fusion—aggressive joint preparation with decortication, percutaneous autograft delivery, joint compression, and stability—are limited, as current systems focus on joint stability rather than joint compression. Our study found that a fusion device that capitalized on these fusion principles was associated with significant and clinically relevant improvements in pain- and function-related PROMs and achieved grade 3 fusion in a majority of cases at 12-month follow-up. Our findings provide treatment guidance for patients with severe SIJ-mediated disease by supporting an intervention associated with improvements in both joint fusion and PROMs.

Although there is a growing body of published evidence regarding SIJF surgery, the nature of the fusion hardware used is variable. Predominant technologies focus on joint stabilization and/or transfixation, rather than true fusion.[11,30-32] As a result, few current offerings adhere to the principles of joint fusion and bone healing set out by the AO Foundation, specifically, aggressive joint preparation with decortication and percutaneous autograft delivery followed by joint compression and stability.[13] Joint compression combined with decortication is the gold standard for joint fusion or arthrodesis surgery within the field of orthopedic surgery. These are sound principles held deeply within the field of orthopedic surgery in areas such as ankle fusions, midfoot fusions, and fusions of many other joints.[13,33,34] Decorticating the joint and removing articular cartilage and a selected area of subchondral bone allows for exposed cancellous surfaces to fuse from the ilium to the sacrum. This fusion is enhanced with the addition of an osteoconductive and osteoinductive bone graft technique. Indeed, in comparison with fusion without compression, we observed greater improvements in pain scores at 12 months (65% over baseline vs 37%) and similar improvements in disability scores.[35] In the authors' opinion, avoiding the critical steps of decortication and compression and relying on immobilization and grafting to lead to fusion in cartilaginous surfaces is ultimately detrimental to good patient outcomes.

In our study, joint compression was central to our approach, which is hypothesized to lead to physiologic states that can exceed the stability imparted by currently available fusion devices and the stability of the native joint itself.[36] The benefits of this approach are evident in our rates of radiographic fusion, with independent radiographic review revealing at least partial signs of radiographic fusion in 98% of joints and definitive bone bridging (grade 3 fusion) in 81% of joints at 12-month follow-up. In contrast, other studies using non-compressive hardware have been associated with significantly lower rates of fusion. One recent study of 159 patients observed a 12-month grade 3 fusion

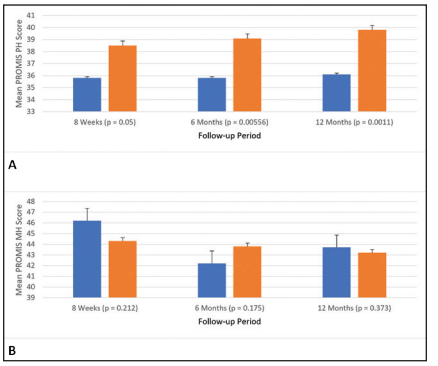

Figure 7: Mean Patient-Reported Outcomes Measurement Information System (PROMIS)-10 physical function (top) and mental health (bottom) scores at 8-week, 6-month, and 12-month follow-up (orange) compared with baseline (blue). *Statistically significant difference vs baseline (*P*<.05).

rate of only 15%.[31] Another study of 43 patients with 198 implants using a triangular, non-compressive fusion system noted a lucency rate of 1.5% to 2%.[30] An assessment of bone bridging was not provided because of the need for an extended follow-up period that was unavailable. In contrast, Cross et al[12] reported a 74% rate of solid fusion in 19 patients using a screw design with flexible decortication, which mirrors findings of our study. As such, the use of fusion hardware with a threaded design that facilitates compression of the joint rather than only stabilization may be key in establishing high rates of solid fusion of the SIJ. These data, combined with the low rate of revision surgery (n=1) in our study and the lack of observed lucencies or subsidence, reinforce the hypothesis that joint compression, guided by the AO Foundation principles, is essential for establishing a stable construct.

Most studies of SIJF report pain scores rather than PROMs. Dengler et al[30] examined ODI and visual analog scale scores in 52 patients who had non-compressive fusion and observed clinically important improvements in both for 79% of patients. In another study, an 18.8-point improvement in ODI scores at 12 months was noted in 66% of patients and an 83.1% improvement in visual analog scale scores was noted at 24 months.[32] In a German

study of 2-year PROM results in a cohort of 171 patients, mean decreases in ODI scores of 16 points at 12 months and 18 points at 24 months were reported.[37] Similarly, we noted a 20-point improvement in ODI scores at 12 months and a 4.5-point improvement (68%) on the 10-point NRS, with clinically important improvements realized in 66% and 88% of patients, respectively. These results are similar to those of an earlier study with the same fusion technology that reported a 54% improvement in pain scores and a 20-point improvement in ODI scores at 6-month follow-up.[12] The similar pain scores in these studies of two different technologies are perhaps not surprising, but the greater improvements in ODI scores noted with compression-based fusion systems may speak to the impact of the greater biomechanical stability they offer. The minimally invasive nature of surgery may also contribute to improvements in PROM scores. However, the data from our study strongly suggest that the benefits of compression-based fusion are seen not only in pain reduction but also in improved functional ability. This may have contributed to the high patient satisfaction scores in our study, as patients with fewer limitations of their activities of daily living are more likely to have a positive outlook on their procedure.

The retrospective nature of our review and the relatively small sample are limitations; however, our sample size mirrors that of similar studies.[12,38] Similarly, due to loss to follow-up, PROM data were not available for all patients at all follow-ups. These limitations are representative of the challenges associated with the real-world experience. However, the high response rates at our earlier time points and our use of a variety of PROM scales to provide more robust findings, as well as the high percentage of patients with 1-year radiographic findings (78%), may offset the limitations faced in real-world settings. Finally, the lack of 2-year follow-up data may traditionally be viewed as a limitation. However, recent evidence indicates that there is no appreciable change in outcome scores between 1- and 2-year follow-ups in musculoskeletal research,[39] suggesting that 2-year data, although anecdotally desirable, may not be critical in evaluating treatment success.

Conclusion

Our study demonstrated that a SJIF system based on the principles of joint fusion—aggressive decortication, autogenous bone grafting, and joint compression—was associated with early and durable improvements in both radiographic fusion and patient-related outcomes. The results of this study support the growing body of evidence that SIJF surgery benefits patients with SIJ dysfunction. Future studies will focus on evaluation of PROMs in a larger cohort of patients with longer-term follow-up data.

References

1. Centers for Disease Control and Prevention. Prevalence of disabilities and associated health conditions among adults: United States, 1999. *JAMA*. 2001;285(12):1571-1572. PMID:11302137
2. Stewart WF, Ricci JA, Chee E, Morganstein D, Lipton R. Lost productive time and cost due to common pain conditions in the US workforce. *JAMA*. 2003;290(18):2443-2454. https://doi.org/10.1001/jama.290.18.2443 PMID:14612481
3. Ricci JA, Stewart WF, Chee E, Leotta C, Foley K, Hochberg MC. Back pain exacerbations and lost productive time costs in United States workers. *Spine*. 2006;31(26):3052-3060. https://doi.org/10.1097/01.brs.0000249521.61813.aa PMID:17173003
4. Carey TS, Garrett J, Jackman A, McLaughlin C, Fryer J, Smucker DR. The outcomes and costs of care for acute low back pain among patients seen by primary care practitioners, chiropractors, and orthopedic surgeons: the North Carolina Back Pain Project. *N Engl J Med*. 1995;333(14):913-917. https://doi.org/10.1056/NEJM199510053331406 PMID:7666878
5. van Tulder M, Koes B, Bombardier C. Low back pain. *Best Pract Res Clin Rheumatol*. 2002;16(5):761-775. https://doi.org/10.1053/berh.2002.0267 PMID:12473272
6. Mehra M, Hill K, Nicholl D, Schadrack J. The burden of chronic low back pain with and without a neuropathic component: a healthcare resource use and cost analysis. *J Med Econ*. 2012;15(2):245-252. https://doi.org/10.3111/13696998.2011.642090 PMID:22136441
7. Sembrano JN, Polly DW Jr. How often is low back pain not coming from the back? *Spine*. 2009;34(1):E27-E32. https://doi.org/10.1097/BRS.0b013e31818b8882 PMID:19127145
8. DePalma MJ, Ketchum JM, Saullo TR. Etiology of chronic low back pain in patients having undergone lumbar fusion. *Pain Med*. 2011;12(5):732-739. https://doi.org/10.1111/j.1526-4637.2011.01098.x PMID:21481166
9. Eno JJ, Boone CR, Bellino MJ, Bishop JA. The prevalence of sacroiliac joint degeneration in asymptomatic adults. *J Bone Joint Surg Am*. 2015;97(11):932-936. https://doi.org/10.2106/JBJS.N.01101 PMID:26041855
10. Schmidt GL, Bhandutia AK, Altman DT. Management of sacroiliac joint pain. *J Am Acad Orthop Surg*. 2018;26(17):610-616. https://doi.org/10.5435/JAAOS-D-15-00063 PMID:30059395
11. Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. *Open Orthop J*. 2014;8(1):375-383. https://doi.org/10.2174/1874325001408010375 PMID:25352932
12. Cross WW, Delbridge A, Hales D, Fielding LC. Minimally invasive sacroiliac joint fusion: 2-year radiographic and clinical outcomes with a principles-based SIJ fusion system. *Open Orthop J*. 2018;12(1):7-16. https://doi.org/10.2174/1874325001812010007 PMID:29430266
13. Muller ME, Allgower M, Schneider R. *Manual of Internal Fixation: Techniques Recommended by the AO-ASIF Group*. Springer-Verlag; 1991. https://doi.org/10.1007/978-3-662-02695-3
14. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Bull WHO*. 2001;79(4):373-374. PMID:11357217
15. Graves ML, Routt ML Jr. Iliosacral screw placement: are uniplanar changes realistic based on standard fluoroscopic imaging? *J Trauma*. 2011;71(1):204-208. https://doi.org/10.1097/TA.0b013e31821e842a PMID:21818026
16. Miller AN, Routt ML Jr. Variations in sacral morphology and implications for iliosacral screw fixation. *J Am Acad Orthop Surg*. 2012;20(1):8-16. https://doi.org/10.5435/00124635-201201000-00002 PMID:22207514
17. Routt ML Jr, Simonian PT, Agnew SG, Mann FA. Radiographic recognition of the sacral alar slope for optimal placement of iliosacral screws: a cadaveric and clinical study. *J Orthop Trauma*. 1996;10(3):171-177. https://doi.org/10.1097/00005131-199604000-

00005 PMID:8667109

18. Lieberman IH, Kisinde S, Hesselbacher S. Robotic-assisted pedicle screw placement during spine surgery. *JBJS Essential Surg Tech*. 2020;10(2):e0020. https://doi.org/10.2106/JBJS.ST.19.00020 PMID:32944411
19. Spatz JM, Conner AK, Young JS, Starr PA. Intraoperative stereotactic frame registration using a three-dimensional imaging system with and without preoperative computed tomography for image fusion. *Stereotact Funct Neurosurg*. 2020;98(5):313-318. https://doi.org/10.1159/000509312 PMID:32818947
20. Zhang P, Liu H, Sun Z, Wang J, Wang G. The application of O-arm and navigation system in precise localization of spinal cord lesions: a case series study. *Clin Neurol Neurosurg*. 2020;196:105922. https://doi.org/10.1016/j.clineuro.2020.105922 PMID:32622109
21. Williams GN, Gangel TJ, Arciero RA, Uhorchak JM, Taylor DC. Comparison of the single assessment numeric evaluation method and two shoulder rating scales: outcomes measures after shoulder surgery. *Am J Sports Med*. 1999;27(2):214-221. https://doi.org/10.1177/03635465990270021701 PMID:10102104
22. Williams GN, Taylor DC, Gangel TJ, Uhorchak JM, Arciero RA. Comparison of the single assessment numeric evaluation method and the Lysholm score. *Clin Orthop Relat Res*. 2000;373:184-192. https://doi.org/10.1097/00003086-200004000-00022 PMID:10810476
23. Sciascia AD, Morris BJ, Jacobs CA, Edwards TB. Responsiveness and internal validity of common patient-reported outcome measures following total shoulder arthroplasty. *Orthopedics*. 2017;40(3):e513-e519. https://doi.org/10.3928/01477447-20170327-02 PMID:28358978
24. Hays RD, Spritzer KL, Thompson WW, Cella D. U.S. general population estimate for "excellent" to "poor" self-rated health item. *J Gen Intern Med*. 2015;30(10):1511-1516. https://doi.org/10.1007/s11606-015-3290-x PMID:25832617
25. Lee AC, Driban JB, Price LL, Harvey WF, Rodday AM, Wang C. Responsiveness and minimally important differences for 4 patient-reported outcomes measurement information system short forms: physical function, pain interference, depression, and anxiety in knee osteoarthritis. *J Pain*. 2017;18(9):1096-1110. https://doi.org/10.1016/j.jpain.2017.05.001 PMID:28501708
26. Asher AL, Kerezoudis P, Mummaneni PV, et al. Defining the minimum clinically important difference for grade I degenerative lumbar spondylolisthesis: insights from the Quality Outcomes Database. *Neurosurg Focus*. 2018;44(1):E2. https://doi.org/10.3171/2017.10.FOCUS17554 PMID:29290132
27. Bernstein DN, Houck JR, Mahmood B, Hammert WC. Minimal clinically important differences for PROMIS physical function, upper extremity, and pain interference in carpal tunnel release using region- and condition-specific PROM tools. *J Hand Surg Am*. 2019;44(8):635-640. https://doi.org/10.1016/j.jhsa.2019.04.004 PMID:31126813
28. Okoroha KR, Lu Y, Nwachukwu BU, et al. How should we define clinically significant improvement on patient-reported outcomes measurement information system test for patients undergoing knee meniscal surgery? *Arthroscopy*. 2020;36(1):241-250. https://doi.org/10.1016/j.arthro.2019.07.036 PMID:31864584
29. Hung M, Saltzman CL, Kendall R, et al. What are the MCIDs for PROMIS, NDI, and ODI instruments among patients with spinal conditions? *Clin Orthop Relat Res*. 2018;476(10):2027-2036. https://doi.org/10.1097/CORR.0000000000000419 PMID:30179950
30. Dengler J, Kools D, Pflugmacher R, et al. Randomized trial of sacroiliac joint arthrodesis compared with conservative management for chronic low back pain attributed to the sacroiliac joint. *J Bone Joint Surg Am*. 2019;101(5):400-411. https://doi.org/10.2106/JBJS.18.00022 PMID:30845034
31. Duhon BS, Bitan F, Lockstadt H, Kovalsky D, Cher D, Hillen T; SIFI Study Group. Triangular titanium implants for minimally invasive sacroiliac joint fusion: 2-year follow-up from a prospective multicenter trial. *Int J Spine Surg*. 2016;10:13. https://doi.org/10.14444/3013 PMID:27162715
32. Polly DW, Swofford J, Whang PG, et al; INSITE Study Group. Two-year outcomes from a randomized controlled trial of minimally invasive sacroiliac joint fusion vs. non-surgical management for sacroiliac joint dysfunction. *Int J Spine Surg*. 2016;10:28. https://doi.org/10.14444/3028 PMID:27652199
33. Azar FM, Beaty JH, Canale ST. *Campbell's Operative Orthopaedics.* vol 1, ed 14. Elsevier; 2020.
34. Salter RB. *Textbook of Disorders and Injuries of the Musculoskeletal System: An Introduction to Orthopaedics, Fractures, and Joint Injuries, Rheumatology, Metabolic Bone Disease, and Rehabilitation.* Lippincott Williams & Wilkins; 1999.
35. Cleveland AW III, Nhan DT, Akiyama M, Kleck CJ, Noshchenko A, Patel VV. Mini-open sacroiliac joint fusion with direct bone grafting and minimally invasive fixation using intraoperative navigation. *J Spine Surg*. 2019;5(1):31-37. https://doi.org/10.21037/jss.2019.01.04 PMID:31032436
36. Cross WW III, Berven SH, Slater N, Lehrman JN, Newcomb AGUS, Kelly BP. In vitro biomechanical evaluation of a novel, minimally invasive, sacroiliac joint fixation device. *Int J Spine Surg*. 2018;12(5):587-594. https://doi.org/10.14444/5072 PMID:30364882
37. Fuchs V, Ruhl B. Distraction arthrodesis of the sacroiliac joint: 2-year results of a descriptive prospective multi-center cohort study in 171 patients. *Eur Spine J*. 2018;27(1):194-204.
38. Araghi A, Woodruff R, Colle K, et al. Pain and opioid use outcomes following minimally invasive sacroiliac joint fusion with decortication and bone grafting: the evolusion clinical trial. *Open Orthop J*. 2017;11(1):1440-1448. https://doi.org/10.2174/1874325001711011440 PMID:29387289
39. Seetharam A, Deckard ER, Ziemba-Davis M, Meneghini RM. The AAHKS Clinical Research Award: are minimum two-year patient-reported outcome measures necessary for accurate assessment of patient outcomes after primary total knee arthroplasty? *J Arthroplasty*. 2022;37(8S):S716-S720. https://doi.org/10.1016/j.arth.2022.02.016 PMID:35151810