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Clinical Study

A prospective multicenter randomized controlled trial on safety and procedural competency in SI joint fusion performed by interventional pain physicians trained by a spine surgeon

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Abstract

BACKGROUND CONTEXT: Sacroiliac joint (SIJ) fusion was traditionally performed exclusively by spine surgeons using a minimally invasive direct lateral approach. With advancements in technology, SIJ fusion has evolved into percutaneous techniques which have been adopted by interventional pain management (IPM) physicians due to their expertise in interventional techniques. However, this expansion has raised safety concerns among spine surgeons regarding "practice creep" and procedural competency gaps. Furthermore, the lack of uniform outpatient credentialing has created an environment where safety oversight may be inconsistent.

PURPOSE: To evaluate and compare the safety and procedural competency of percutaneous posterior-oblique SIJ fusions performed by trained IPM physicians using titanium screws plus a synthetic bioactive glass flowable biologics under direct spine surgeon supervision versus nonspine surgeon supervision.

STUDY DESIGN/SETTING: A prospective multicenter randomized controlled trial conducted across multiple ambulatory surgery centers between 2020 and 2022.

PATIENT SAMPLE: About 276 adult patients (mean age 56.7 years; 72.1% female) scheduled for SIJ fusion.

OUTCOME MEASURES: The primary outcome measures were surgical complications, deviations, and revisions. These were assessed through medical records and radiographs for at least 6 months post operative.

METHODS: About 276 patients were in this study and were randomly assigned to Group 1 or Group 2. Sixty-six patients (Group 1; spine surgeon supervised). Sixty-seven patients, clinical specialist supervised, plus 143 assigned to sales representatives/independent distributors supervised (Group 2; nonspine surgeon supervised). All primary procedures were performed by 47 IPM physicians who received structured training on the percutaneous posterior-oblique technique by a board-certified orthopedic spine surgeon. Surgical complications, deviations, and revisions were recorded, with follow-up data collected for at least 12 months.

RESULTS: A total of 9 complications (3.3%), 4 deviations (1.4%), and 5 revision cases (1.8%) were observed. Group 1 experienced no complications, deviations, or revisions. In Group 2, 9 complications (4.3%) and 4 deviations (1.9%) occurred between the second and fifth operative days. 5 cases were revised (2.4%).

CONCLUSIONS: Spine surgeon training equipped IPM physicians to safely performed percutaneous posterior-oblique SIJ fusions with titanium screws plus biologics, achieving low complication and revision rates. These findings highlight the importance of incorporating standardized surgeon-led training and certification programs to bridge the competency gap and ensure safe adoption of interventional spine surgery practices by IPM physicians.

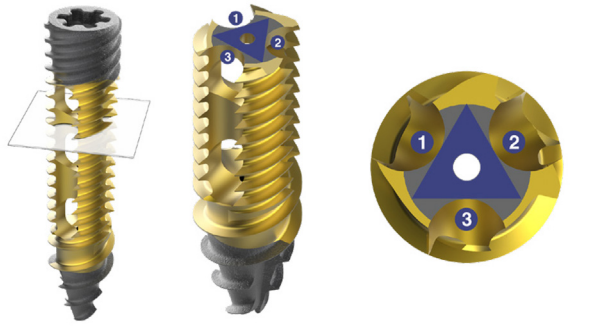
Keywords: iFuse; Interventional pain medicine; NanoFuse biologics; Posterior-oblique; Sacrix®; Sacroiliac joint fusion; SI-bone; SIJ fusion; Titanium triangular implant

Introduction

Sacroiliac joint (SIJ) pain, often indistinguishable from lower back pain, affects 15% to 30% of chronic back pain cases, with over 40% occurring postlumbosacral fusions [1–5]. The SIJ is the largest axial joint in the body and is vital for load transfer from the spine to the lower extremities [6]. This complex joint exhibit limited mobility and is susceptible to instability under shear loads [6,7] and pain, particularly when instrumentation is extended to the pelvis [8]. Traditionally, board-certified fellowship-trained spine surgeons exclusively performed SIJ fusions using a minimally invasive direct lateral approach to place 3 triangular titanium implant (TTI) wedges (iFuse Implant System, SI-BONE, Inc., San Jose, CA, USA). Multiple randomized clinical trials have demonstrated the efficacy of SIJ fusion compared to nonoperative treatments for patients with SIJ dysfunction [9–12].

With advancements in imaging technologies such as fluoroscopy and computerized tomography (CT) [13], Interventional Pain Management (IPM) physicians have become well-established in performing spine-related procedures, such as steroid injections and radiofrequency ablation (RFA) [14]. Over time, their role has expanded into implantation procedures, including kyphoplasty, vertebroplasty, intrathecal pumps and spinal cord stimulators, which were historically performed only by spine surgeons. This trend, termed "practice creep", has now extended to the implantation of medical devices in the spine field. Vertiflex Superion Interspinous Spacer (Boston Scientific Inc., Marlborough, MA, USA) was one such device which was initially studied in Investigational Device Exemption (IDE) trials by orthopedic spine surgeons for spinal stenosis and has since been widely adopted by IPM physicians. Building on their proficiency in accessing the SIJ with fluoroscopy, IPMs transitioned to performing SIJ fusion using a similar direct posterior approach to place percutaneous intra-articular cortical allograft implants and have begun publishing their experiences [15,16]. However, these allografts are not United States Food and Drug Administration (FDA) regulated and are subject to failures [17] requiring revisions but there are currently no established methods for revisions by IPM, leading to referrals to spine surgeons.

In November 2019, Sacrix® Limited Liability Company (LLC) (LESspine Innovations, Burlington, MA, USA), introduced its FDA approved variable threaded triangular titanium screw with internal triangular features that also contribute to the functional strength of the implant [18] (Figs. 1 and 2), and a 2-step 100% fluoroscopic percutaneous transfixation lateral-to-medial posterior-oblique SIJ fusion technique [19–21]. The technique is 100% fluoroscopic, does not require an open incision to expose the posterior superior iliac spine, eliminates the need for a drill or tap and the screw is fully recoverable through the same incision. Aligned with the ability to rescue concept in anesthesia, where practitioners are trained to rescue a patient from an unintended progression to deeper sedation levels [22], the implants were designed to allow removal using the same steps in reverse as those used for initial insertion.



The Sacrix® titanium triangular implant (TTI) uses a 3 axial bone graft reservoir design

Fig. 1. Sacrix® descriptive triangular titanium implant's inner design with 3 axial bone graft reservoirs running along its length. (Source: MySacrix.com).

The expansion of SIJ fusion procedures by IPM physicians in outpatient and ambulatory surgery center (ASC) settings has revealed competency gaps. These procedures require technical skills and safety measures that highlight the need for IPM training to perform spine surgery and manage complications that are not addressed during residency or fellowship. Although spine surgeons learn new techniques and technologies after their residencies and fellowships, there is a general assumption that they are equipped with foundational skills to adopt new techniques. A similar argument could be made for IPM physicians who have learned procedures like kyphoplasties and are already familiar with accessing the spine. As such, a study assessing the value of standardized competency training on new techniques and technologies for both spine surgeons and IPM physicians is warranted. To date, no studies have specifically assessed the competency of IPM physicians performing SIJ fusions following structured training by a spine surgeon.

This study is the first to investigate the safety and procedural competency of IPM physicians trained by a spine

Fig. 2. Variable threaded titanium screw with self-harvesting channels.

surgeon to perform percutaneous posterior-oblique SIJ fusions with titanium screws plus a synthetic bioactive glass flowable biologics. It compares outcomes based on supervision type, spine surgeon versus nonspine surgeon, and emphasizes the importance of spine surgeon-led structured training programs in bridging competency gaps. By evaluating real-world outcomes, this study aims to provide evidence to suggest that physicians intending to perform spine procedures should receive training from a competent spine surgeon, and its findings could guide credentialing practices and mitigate risks associated with practice creep and expansion across traditional specialty lines.

Material and methods

Patient enrollment

A total of 276 patients scheduled for unilateral SIJ fusion at multiple ambulatory surgery centers (ASCs) were enrolled between 2020 and 2022. All primary procedures were conducted by 47 fellowship-trained IPM physicians who participated in a customized training and mentoring apprenticeship program led by a board-certified fellowship-trained orthopedic spine surgeon, the primary author. Western Institutional Review Board (IRB) approval was granted through Protocol #20181251.

Inclusion and exclusion criteria

Patients meeting the inclusion criteria had a history of back or radiating pain to the buttocks and anterior hip area, at least 3 positive provocative SIJ tests, positive diagnostic SIJ injections, and failed response to at least 6 weeks of conservative treatment. Bilateral SIJ fusion and performed by orthopedic spine surgeons and neurosurgeons were excluded.

Group allocation

Patients were randomized by the scheduling team to either Group 1 (spine surgeon supervised) or Group 2 (nonspine surgeon supervised). Randomization was based on the availability of the supervising surgeon at the time of scheduling during the study period, ensuring the process was independent of the research team and blinded to both the patients and the surgeon. Group 2 was further divided into Subgroup 2A (supervised by a clinical specialist) and Subgroup 2B (supervised by independent distributors or sales representatives), all of which were trained by the spine surgeon.

Postprocedure assessment

Postprocedure assessments included independent clinical evaluations conducted in the recovery room, with patients discharged the same day. Follow-up data was collected for at least twelve months through postoperative radiographs, including anterior-posterior (AP), Ferguson and lateral views, as well as clinical records. On postoperative AP radiograph, satisfactory implant placement was determined when the tip of the screw was lateral to the lateral border of the sacral foramen. On lateral radiograph, the tip of the screw was considered appropriately if it did not extend beyond the sacral alar. CT scans were recommended to improve accuracy in detecting implant position, particularly in cases of complex sacral anatomy, such as transitional vertebrae.

Data collection

Data were collected from medical records and operative notes. Surgical complications were defined as "any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped" [23], such as the placement of long implants, misplaced implants, broken guidewires, and implants. On the other hand, a deviation was defined as any aberration from the expected surgical technique without complications such as a single implant placement or correction of a misplaced implant.

Training and mentoring apprenticeship program

The training and mentoring apprenticeship program for the SIJ fusion surgery was devised and led by the primary author, a board-certified orthopedic spine surgeon, and included webinars, didactic sessions, and hands-on training with fresh-frozen cadavers and sawbone models. The posterior-oblique technique and implant were selected because they enable IPM physicians to perform the procedure entirely percutaneously, with the ability to insert and revise the implant using the same steps in reverse. Emphasis was placed on patient selection, risks, benefits, outcomes, and surgical techniques. This mentorship relationship extended beyond the training lab, allowing ongoing communication directly between the IPM physician and the training spine surgeon as members in the Less Exposure Spine Surgery (LESS) Society (a 501(c)(3) Florida, USA, www.lessociety.org) secured and encrypted WhatsApp group. This platform was used to discuss upcoming surgeries and to share knowledge.

Surgical technique

With the patient in the prone position, the fluoroscope was angled to visualize the S1 endplate, SIJ and Sacrix® line [19] to determine the starting point on the lateral border of the iliac crest. The fluoroscope was positioned at least a 30-degree caudal tilt to visualize the anterior cortex of the sacral ala. Under fluoroscopic guidance, a Jamshidi needle was obliquely inserted across the SIJ and directed into the sacral ala, cephalad, and lateral to the sacral foramen. A smooth, flexible, blunted-tip Nitinol guidewire was then inserted through the Jamshidi needle and securely positioned within the bone. A less than 1 inch skin incision was made, and a tissue dilator and working cannula were

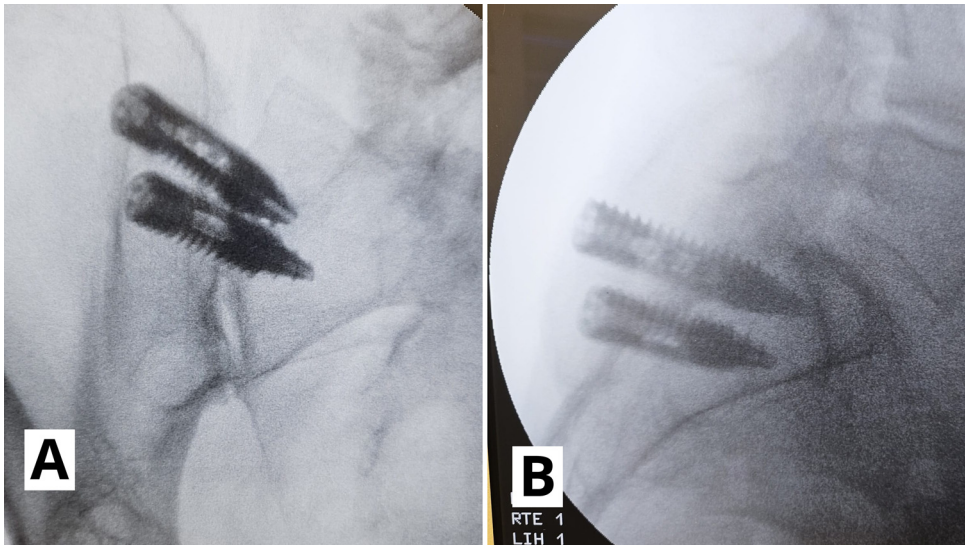


Fig. 3. Intraoperative fluoroscopy of the percutaneous posterior-oblique SIJ fusion using 2 titanium screws on (A) Anteroposterior (AP) View and (B) Lateral view placed by interventional pain management (IPM) supervised by a nonsurgeon.

inserted over the guidewire. A 10- or 12-mm x 50- or 60-mm variable threaded titanium screw, prepacked with NanoFuse Biologics 45S5 bioglass flowable putty (NanoFuse Biologics LLC, Burlington, MA, USA), was introduced over the guidewire to transfix the SIJ at the S1 level. This procedure was repeated to place a second implant at the S2 level. Final screw placement was confirmed on fluoroscopy (Fig. 3).

Statistical analysis

We employed descriptive statistics to summarize the outcomes of Group 1 and Group 2. Key measures, including the number and percentage of complications, deviations, and revisions, are presented without inferential statistical tests. Percentages and frequencies are used to highlight differences between groups, focusing on the practical implications of supervision during SIJ fusion procedures.

Software and tools

Descriptive statistics were calculated using Microsoft Excel and Python with basic data manipulation and visualization packages using Microsoft Visual Studio (VS) Code (version 1.83.1), the anaconda3 (Python 3.11.4) kernel within VS Code, and packages including 'pandas' and 'matplotlib'.

Results

A total of 276 patients underwent percutaneous posterior-oblique SIJ fusion by 47 IPM physicians across various ambulatory surgery centers (mean [SD] age, 56.7 [13.9] years; 72.1% females, 27.9% males) (Table 1). Mean [SD]

Table 1
Summary of complications, revisions and deviations by groups

Complications, revisions, and deviations	Group 1 (n=66)	Group 2 (n=210)	Subgroup 2A (n=67)	Subgroup 2B (n=143)
Complications	0	9		
Broken guidewire				1
Broken implant			1	1
Long implant			2	1
Misplaced L5 implant				3
Revisions	0	5		
Long implant			2	1
Misplaced implant				2
Deviations	0	4		
Corrected long implant intraoperatively				1
Single implant			1	
Single implant (one no space)				2

Group 1, spine surgeon supervised; Group 2, nonspine surgeon supervised; Subgroup 2A, supervised by a clinical specialist; Subgroup 2B, supervised by an independent distributor or sales representative.

Table 2
Demographics and clinical characteristics of patients undergoing sacroiliac joint fusion with Sacrix®

Characteristic	Total (n=276)	Group 1 (n=66)	Group 2 (n=210)
Age, mean (SD), y	56.7 (13.9)	56.9 (12.4)	56.64 (14.2)
Gender, n (%)			
- Female	199 (72.1%)	51 (76.9%)	148 (71.1%)
- Male	77 (27.9%)	15 (23.1%)	62 (28.9%)
Complications, n (%)	9 (3.3%)	0 (0%)	9 (4.2%)
Deviations, n (%)	4 (1.4%)	0 (0%)	4 (1.9%)
Revisions, n (%)	5 (1.8%)	0 (0%)	5 (2.4%)

SD, standard deviation.

number of procedures per IPM was 6 [12]. The mean total operative time was 1 hour (mean [SD] procedure time, 30 [10] minutes). Overall, we identified a total of 9 complications (3.3%), 4 deviations (1.4%), and 5 revision cases (1.8%). Table 2 summarizes the total number of specific complications, revisions, and deviations.

Group 1 comprised 66 patients (mean [SD] age, 56.9 [12.4] years; 76.9% females), with no reported complications, deviations, or revisions. Group 2 (mean [SD] age, 56.64 [14.2] years; 71.1% females) consisted of 67 patients from Subgroup 2A plus 143 patients in Subgroup 2B. In Group 2, 7 IPM physicians reported 9 complications (4.3%), 4 deviations (1.9%), and 5 revisions (2.4%) between their second and fifth operative days, out of a total of 185 operative days. Most complications occurred on the fourth operative day, accounting for 5 of the 9 complications. Subgroup 2A reported 3 complications (4.5%), 2 revisions (3.0%), and 1 deviation (1.5%), while Subgroup 2B reported 6 complications (4.2%), 3 revisions (2.1%), and 3 deviations (2.1%). Of the 5 revisions in Group 2, 3 revisions (2 due to long implants and 1 from a misplaced implant) were performed by IPMs with spine surgeon supervision, and 2 revisions (one from a long implant and one from a misplaced implant) were performed by spine surgeons at an outside facility, not affiliated with the study.

Of the 9 complications in Group 2, placement of long implants (Fig. 4A) and misplaced implants at L5 in patients with Bertolotti syndrome (Fig. 4B) accounted for the majority of complications (67%). The remaining complications were 2 cases of broken guidewires (22%) within the ilium, and 1 case of a broken implant (11%). A relative risk of 1 (95% CI, 0.31−3.14) suggested that there was no significant difference in the risk of complications, deviations, or revisions between the subgroups.

Discussion

The percutaneous fluoroscopic posterior-oblique transfixation technique was developed to place 2 threaded titanium screws obliquely across the SIJ through a small incision minimizing dissection and the risk of neurovascular injury [24]. Our findings demonstrate that, with structured training programs by a spine surgeon, IPM physicians can be trained to safely and competently perform percutaneous SIJ fusions using the technique with low complication and revision rates regardless of the type of supervision. While this study was not powered to detect statistical significance, the descriptive findings suggest a trend toward improved outcomes across both groups. This result supports the idea that IPMs can expand their scope of practice to include SIJ fusion as part of broader interventional spine procedures, provided appropriate spine surgeon-led mentorship and credentialing systems are in place.

Key findings

Overall, our study revealed low complication (3.3%), revision (1.4%), and deviation (1.8%) rates among spine surgeon trained IPM physicians performing percutaneous posterior-oblique SIJ fusion. Notably, all complications, revisions and deviations occurred in Group 2, where complication rates reached 4.3%, revisions 2.4% and deviations 1.9%. These complications included placement of long implants, misplaced implants, broken guidewires, and a

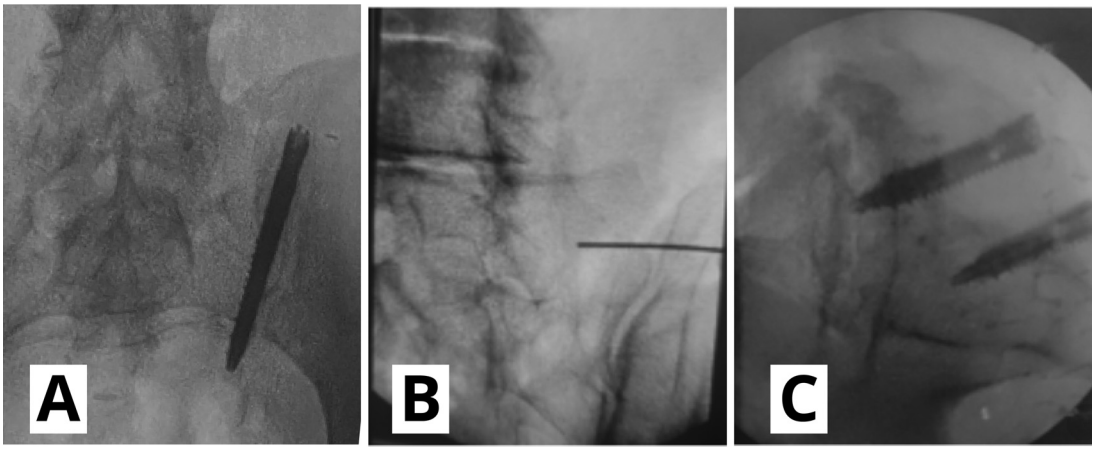


Fig. 4. Complications: (A) Long implant at S1 requiring revision, (B and C) Misplaced implant placed at L5 in a patient with Bertolotti syndrome.

broken implant. In contrast, Group 1 reported no complications, deviations, or revisions.

Complications related to the long implants (Fig. 4A), which risk injuring neurovascular structures along the anterior surface of the alar, were associated with starting the insertion of the implant inferior to the iliac crest level, emphasizing the need for careful fluoroscopic views and adjustments. Misplaced implants were noted in patients with sacral dysmorphism, described as "Bertolotti syndrome" [25], who had an increased risk of iatrogenic injury with screw placement due to their unusual sacral anatomy [26]. Preoperative plain Ferguson radiographs of the sacrum should be carefully assessed for sacral dysmorphism, such as sacralized L5 (Fig. 4B), as established by Castellvi et al. [27]. Concerns for transitional anatomy should be further evaluated with a CT scan to understand the variety that exists within these transitional segments. Broken guidewires occurred when the implant was inserted over a bent guidewire and stressed the significance of maintaining guidewire alignment with frequent fluoroscopic checks during insertion. Premature guidewire removal before the implant was securely positioned beyond the SIJ coupled with the application of angular torque on the inserter and implant was attributed to the broken implant.

Of the reported complications, 5 required revisions, and the IPM successfully performed 2 under the supervision of the spine surgeon. All complications occurred within the IPM's first 5 operative days performing SIJ fusion cases, emphasizing the importance of supervision within the first 5 operative days by a spine surgeon or a trained nonsurgeon. Trained clinical specialists and independent distributors/sales representatives avoided catastrophic events but failed to appropriately adjust the implant length for patients with a small sacral anatomy and to identify those with sacral dysmorphism.

Comparisons with other studies

SIJ fusion using implants by spine surgeons using implants, such as TTI or screw fixation, has been well established in the literature. However, recent studies have reported positive patient outcomes with IPM performing SIJ fusion using intra-articular allografts through a direct posterior approach [15,28]. Kranerburg et al. found no radiographic evidence of fusion in cases treated with allograft SIJ fusion through distraction arthrodesis leading to revisions with TTIs or screw fixation due to continued or recurrence of pain due to implant failures such as implant malposition, failure to achieve fusion, and structural failures [17]. On the other hand, studies have reported radiographic evidence of fusion with posterior lateral or oblique placed screws [19,21,29,30]. Whang et al.[31] evaluated 3 SIJ fusion techniques (direct lateral, posterolateral, and posterior interpositional) and reported low complication rates across all methods. Acute implant malposition was observed in 0.43% of direct lateral cases, 0% in posterolateral, and 0.2% of posterior approach. Wound infections and bleeding requiring surgical intervention occurred in 0.15% and 0.04% of direct lateral cases, respectively, but was absent in the other 2 methods. In the LOIS (Long-Term Follow-up in INSITE/SIFI) study, revision rates for TTIs were reported to be 3% at 5 years [32].

Interpretation and implications

This study highlights the critical role of structured training programs and supervision in addressing competency gaps as IPM physicians expand their scope of practice into spine surgery. SIJ pain, identified as the source of pain in 43% of patients with prior lumbar fusions [33], has traditionally been managed by IPM through medications, steroid injections, and pain modulation. Dengler et al. [12] reported a statistically significant decrease in opioid use in patients treated with sacroiliac joint fusion, demonstrating the value of definitive treatment that targets the source of SIJ dysfunction. With this technique, IPMs can now perform percutaneous, less invasive, same-day outpatient procedure that minimizes blood loss, and allows for revision of implants if needed.

As more IPM physicians embrace and perform SIJ fusions using this technique, we anticipate that they will actively contribute to ongoing innovation in the field, thus collectively collecting more clinical data to further refine surgical methods and enhance patient outcomes. This evolution mirrors advancements in other interventional fields, such as interventional cardiologists, where physicians have expanded their capabilities to perform complex procedures that treat underlying cardiac conditions, opening access to patents and driving innovations for less invasive solutions than open-heart surgery [34]. The implication is that with time, IPM physicians and spine surgeons will also evolve and collaborate along similar lines.

These findings also have practical implications for credentialing in outpatient and ASC settings. The demonstrated safety and procedural competency of trained IPMs support the establishment of standardized credentialing protocols to ensure that SIJ fusion is performed only by adequately trained practitioners. Such protocols would bridge competency gaps, mitigate risks, and ensure high-quality, consistent care.

Limitations

Our study only focused on the percutaneous posterior-oblique technique to transfix the SIJ among IPM physicians. Our sample size could be larger. While sufficient to observe descriptive trends, may not adequately capture rare complications or long-term outcomes. It may introduce selection bias favoring more confident IPMs with adequate skill levels and a desire to learn. The absence of patient-reported outcomes limits the assessment of functional improvement and patient satisfaction. The lack of a comparison group of untrained IPMs limits direct assessment of the impact of

training on complications and revision rates. Future studies incorporating patient-reported outcomes, comparative groups, and longer follow up would provide further insights into the effectiveness of spine surgeon training for IPMs in interventional spine surgery.

Conclusion

This study demonstrates that a spine surgeon-led training program effectively equips IPM physicians with the safety and procedural competency required to perform percutaneous posterior-oblique SIJ fusions with titanium screws plus a synthetic bioactive glass flowable biologics, achieving low complication (3.3%) and revision (1.8%) rates. These findings suggest that structured, surgeon-led training programs can bridge competency gaps and support the safe expansion of interventional spine surgery practices by IPM physicians. The results provide a foundation to guide credentialing practices and address risks associated with practice creep and specialty expansion, ensuring consistent, high-quality care in outpatient and ASC settings.

Declaration of competing interest

One or more of the authors declare financial or professional relationships on ICMJE-TSJ disclosure forms.

CRediT authorship contribution statement

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