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Retrospective Study

Posterior Sacroiliac Fusion Surgery: A Retrospective Single Center Study

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Background: Chronic sacroiliitis has variable etiologies with numerous treatments of varying efficacy. In recent years, a novel posterior approach utilizing bone matrix has been developed although to date, there is limited data in the literature regarding efficacy and safety through this approach. Benefits described include reduced adverse outcomes and quicker recovery when compared to the lateral approach.

Objective: The present investigation focused on sacroiliac joint fusion through the posterior approach and outcomes including disability, pain, and use of analgesics post-surgery.

Study Design: This retrospective, single-center study was conducted evaluating safety and efficacy of sacroiliac fusion allograft implants (LinQ Implant System from PainTEQ; PsiF System from Omnia Medical).

Methods: A total of 72 posterior approach sacroiliac joint fusions were performed. Fifty-three individuals were enrolled and followed at LSU Health Shreveport as the sole investigational site between August 2020 and June 2024. Selected participant age ranged between 28 and 79 years, with a mean age of 53.4 years. The LinQ Implant System was the primary surgical hardware selected for implantation (83.0%), with the PsiF System chosen in the remaining cases.

Outcome Measures: VAS Scores, disability changes, adverse outcomes, and analgesic use were compared after sacroiliac joint fusion via the posterior approach.

Results: Mean VAS Scores for SIJ Pain Intensity significantly decreased by 3.6 cm from a baseline score of 9.5 cm by the Specified End (June 1st, 2024). In this regard, 65.4% of patients experienced a 20% or greater improvement in pain, 38.5% of patients experienced a 50% or greater improvement in pain, and 26.9% of patients experienced a 70% or greater improvement in pain. Zero (0) procedure-related adverse events nor intra- or post-operative complications occurred throughout the duration of the investigation.

Limitations: Retrospective nature of the study without a control group. Fifty-four percent (39 of 72) completed minimum one year follow up. Further, the withdrawal rate was 26%.

Conclusion: The results of the present investigation demonstrated effective outcomes with minimal adverse effects and improvements in disability over a three-year period in the largest single center study to date involving posterior approach sacroiliac joint fusion.

Key words: Sacroiliac joint fusion, posterior approach, sacroiliitis, pain, disability, lower back pain

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Low back pain stands as a significant health concern, exerting a notable influence on both quality of life and healthcare expenses (1-3). Statistically, it has been observed that roughly 70% to 85% of individuals will experience back pain at some point in their lives (4-7). Annually, this prevalence fluctuates between 15% and 45%, with an average point prevalence around 30% (4-7). In the United States, back pain is the leading cause of activity limitation among individuals under 45 years old. It ranks second as the most common reason for medical consultations, fifth in terms of hospital admissions, and sits in the third position as the most prevalent reason for surgical procedures (1-7).

Pain stemming from the sacroiliac joint (SIJ) is commonly recognized as a contributing element to low back pain, constituting around 15% to 30% of all documented cases (8-12). The SIJ, a diarthrodial joint opposing articular surfaces with synovial space and fibrous capsule, has a large surface area and a multi-faceted joint interface. Patients can present with complex and variable pain related to posterior and anterior innervation. The posterior innervation includes the dorsal ramus L5, lateral branches of the dorsal rami S1-3, and the L4 medial branch and S4 lateral branch. The anterior innervation consists of the ventral rami of L5-S2 and can also include L4. Variable presentations of pain include the buttock, lower lumbar region, the lower extremity and can radiate to the knee and/or foot.

Causes of sacroiliac pain include traumatic events such as falls, motor vehicle accidents, pregnancy, infection, repetitive injury including repetitive lifting, running, altered gait, idiopathic, post lower back surgical procedures, and rheumatologic processes (8-12). In cases where patients experience moderate to severe pain, functional limitations, or when nonoperative interventions yield unsatisfactory results, surgical stabilization and/or SIJ fusion may be considered (13). In this regard, conservative management with lidocaine patches, nonsteroidal antiinflammatory drugs (NSAIDs), transcutaneous electrical nerve stimulation, SIJ belt, orthotics, shoe lifts, and adjuvant medications typically can provide some benefit for patients with acute or chronic sacroiliitis.

Interventional pain procedures have been performed for decades to alleviate SIJ pain with fair results (8-10). In this regard, sacroiliac injection (Level 3 evidence) (9), regenerative medicine (Level IV evidence) (14), sacral lateral branch injections and ablations (Level 3 evidence) (10) have been shown to be beneficial for 3-6 months.

Fusion of the SIJ can be pursued though 3 avenues: a lateral, posterior, or posterior oblique approach. Existing medical literature underscores the effectiveness of minimally invasive surgical techniques for SIJ, offering pain relief and improvement in functional capacity (15-26). The present investigation, therefore, evaluated a posterior approach SIJ fusion, evaluating effectiveness, disability, and adverse effects over a 3-year period. The results of the investigation also measured the number of patients taking opioids, NSAIDs, and other analgesics post SIJ fusion procedure.

Methods

Study Design and Objectives

This retrospective, single-center study was conducted to evaluate safety and efficacy of sacroiliac fusion allograft implants (PsiF System from Omnia Medical; LinQ Implant System from PainTEQ [Figs. 1-3]) via a novel posterior approach to treat chronic, low back pain associated with sacroiliac disease. Additionally, this study aims to demonstrate that the posterior approach is comparable to and preferred over the current standard of care offered through the lateral approach. Reduced disability and pain are represented by lower scores in the Oswestry Low Back Disability Questionnaire and Index (ODI) and Visual Analog Scale (VAS), respectively. Pain management and medication reliance are represented by post-operative opioid and NSAID usage, while the Quality-of-Life Survey assesses improvements in sleep, fatigue, anxiety, and depression.

Ethical Considerations

All documents related to the present investigation were submitted for review to, approved by, and registered with the Institutional Review Board at LSU Health Shreveport (STUDY00002746) in compliance with local and state legal requirements. All patients were informed about the study's purpose and voluntarily agreed to participate of their own accord.

Trial Population

Patients were eligible for consideration for this study if they had chronic sacroiliitis (greater than 6 months) after being diagnosed by a positive response to three of the following five exam findings including: the FABER Test, Gaenslen Test, Compression Test, Thigh Thrust, and the Distraction Test. The diagnosis was established with controlled comparative local anesthetic blocks with 75% relief as the criterion standard.

Fig. 1. *PsiF System Implant is visualized within the right sacroiliac joint by a minimally invasive technique. PsiF Device contains carved out, distinctive "channels" within the underlying subchondral bone (Source: Omnia Medical).*

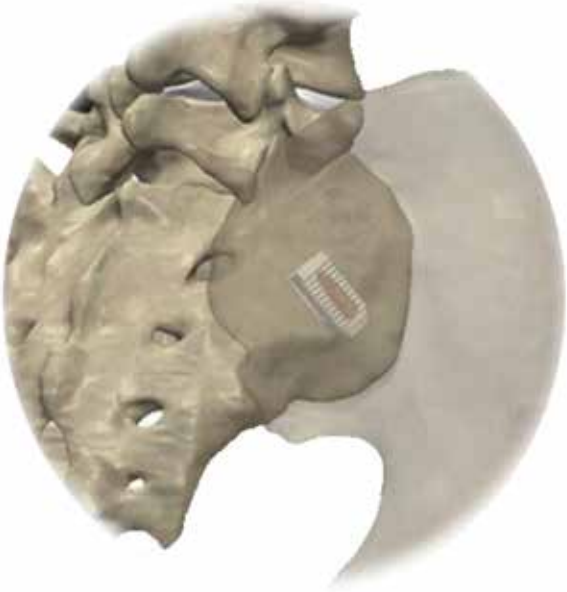

Fig. 2. *LinQ Implant System is implanted within the right sacroiliac joint by a minimally invasive technique. LinQ Device contains a window in the center, filled with bone allografts. (Source: PainTEQ).*

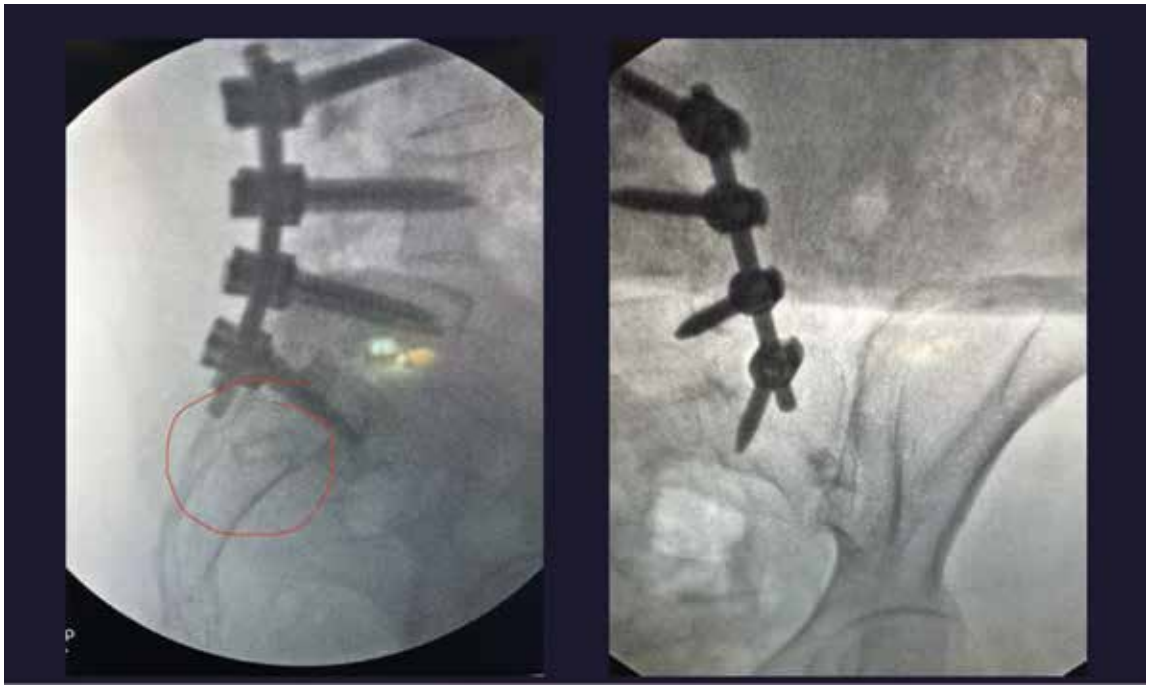

Fig. 3. *Fluoroscopic views of implanted sacroiliac joint allograft.*

Patients with severe osteoporosis were excluded from this study, however, patients with obesity, lumbar facet arthritis, degenerative disc disease, osteoarthritis, and lumbar disc herniation were included and accounted for. Selected participant age ranged between 28 and 79 years, with a mean age of 53.4 years.

Study Procedures

Age, gender, weight, medication usage, and other relevant data for this study were collected through the EPIC Electronic Medical Database, as well as through voluntary ODI and VAS Questionnaires. ODI Scores were taken at one month, 3 months, 6 months, and when possible, one year, 2 years, and 3 years after each participant's procedure. VAS scores were taken prior to each participant's procedure and by the specified end (June 1, 2024). Eligible patients received either the LinQ Implant System or the PsiF System, which utilized a posterior approach. The results presented in this study include all data collected from the complete participant cohort.

Outcome Measures

Primary outcomes were measured by individual improvements in ODI and VAS scores from baseline, as well as the absence of implant-related serious adverse events (SAEs) and the absence of neurologic worsening related to the lumbosacral nerve roots. VAS Scores (0 – 10 cm) were measured by the reduction percentage between a participant's pain level prior to their procedure and at the specified end, while ODI scores (0 – 50 points) were measured by the reduction percentage between the time periods described previously.

Secondary outcomes were measured by a participant's reliance on opioid analgesics and prescribed NSAIDs at 6 months, the latter including: meloxicam, diclofenac, naproxen, celecoxib, indomethacin, and aspirin. Furthermore, the Quality-of-Life Survey measured improvements in sleep, fatigue, anxiety, and depression.

Safety Outcomes

Safety was measured by the amount of SAEs as a result of the implant. SAEs include prolonged hospitalization or a life-threatening event as a result of the implant, whether during the procedure itself or associated with recovery and rehabilitation. Procedure-Related SAEs were calculated by dividing the number of events by the total number of implants (n = 53).

Statistical Methods

Data analysis was conducted to determine statistical significance amongst primary outcomes. ODI and VAS data were imputed into Analysis ToolPack through Microsoft and computed using Paired T-Test Analysis. All statistical analyses were performed and completed in July 2024, with all tests being 2-sided with a significance level of 5%, unless otherwise denoted. All other data is reported descriptively as appropriate (i.e., means, proportions, etc.).

Results

Participant Demographics

Participant cohorts are shown in Table 1. Seventy-two (72) individuals met inclusion criteria and were enrolled at LSU Health Shreveport as the sole investigational site between August 2020 and June 2024. All 72 patients were implanted, with 53 completing the one month visit, 46 completing the 3 month visit, 42 completing the 6 month visit, 39 completing the 12 month visit, 17 completing the 24 month visit, and 5 completing the 36 month visit. Nineteen (19) patients withdrew from the study after implantation, with specific reasons for study withdrawal included in Table 2.

Participant demographics are highlighted in Table 3. The mean (SD) age across the 53 patients was 53.4 (12.1) and 88.7% were women. Average (SD) pain duration was 8.8 (7.6) years and baseline VAS and ODI scores were 9.5 (0.8) and 29.9 (8.7) at one month postoperative, respectively. Surgical considerations relating to the SIJ fusion are detailed in Table 4. Most implants were placed bilaterally (56.6%), with right side placements preferred in unilateral cases (32.1%). Mean (SD) surgical time for the procedure was 112.5 (28.6) minutes and all cases were performed under general anesthesia. The LinQ Implant System was the primary surgical hardware selected for implantation (83.0%), with the PsiF System chosen in the remaining cases. Secondary diagnoses contributing to chronic lower back pain are listed in Table 5. Amongst the 53 patients, 71.7% met the body mass index (BMI) criteria to be classified as obese, 28.3% were diagnosed with lumbar facet arthritis, 15.1% were diagnosed with degenerative disc disease, 5.7% were diagnosed with osteoarthritis, and 1.9% was diagnosed with lumbar disc herniation.

Efficacy

Mean VAS scores for SIJ pain intensity had significantly decreased by 3.6 cm from a baseline score of 9.5

Table 1. *Participant Cohorts*

	Number of Patients
Implanted	72
1 M follow-up	53
3 M follow-up	46
6 M follow-up	42
12 M follow-up	39
24 M follow-up	17
36 M follow-up	5
Completed study	53
Study withdrawals	19

Table 2. *Study withdrawal reasons (n = 19).*

Withdrawn after implant	19
Lost to follow-up	16
Participant withdrew consent	2
Determined to be ineligible for participation	1

Table 3. *Patients demographics and baseline characteristics (n = 53).*

Age (in years), Mean (SD)	53.4 (12.1)
Women, n (%)	47 (88.7%)
Body mass index (BMI), Mean (SD)	35.3 (8.8)
Pain duration (in years), Mean (SD)	8.8 (7.6)
Visual analog scale (VAS) score for SIJ Pain, Mean (SD)	9.5 (0.8)
Oswestry disability index (ODI) score at 1 M, Mean (SD)	29.9 (8.7)

Table 4. *Surgical characteristics (n = 53).*

Bilateral, n (%)	30 (56.6%)
Right Side, n (%)	17 (32.1%)
Surgical time (in minutes), Mean (SD)	112.5 (28.6)
Anesthesia type general, n (%)	53 (100%)
Implanted surgical hardware PainTEQ LinQ Omnia Medical PsiF	44 (83.0%) 9 (17.0%)
Hospital length of stay in days, Mean (SD)	0
Procedure-Related SAEs, n (%)	0
Intra- and post-operative complications, n (%)	0

Table 5. *Secondary diagnoses (n = 53).*

Obesity, n (%)	38 (71.7%)
Lumbar facet arthritis, n (%)	15 (28.3%)
Degenerative disc disease, n (%)	8 (15.1%)
Osteoarthritis, n (%)	3 (5.7%)
Lumbar disc herniation, n (%)	1 (1.9%)

Table 6. *VAS Outcomes*

Outcome	Specified end (n = 26)×
Mean improvement from baseline, Mean (SD)	3.6 (3.4)*
Mean percentage improvement from baseline, Mean (SD)	37.9% (36.2)
> 0% Improvement, n (%)	20 (76.9%)
≥ 20% Improvement, n (%)	17 (65.4%)
≥ 50% Improvement, n (%)	10 (38.5%)
≥ 70% Improvement, n (%)	7 (26.9%)

Notes: ×Specified end was June 1, 2024, to establish uniformity when measuring VAS outcomes across time. *Denotes statistical significance, *P* value < 0.0001.

cm by the specified end (June 1, 2024) (Table 6). Paired t-test analysis regarding both the completed case data set and imputed data set revealed similar effects for VAS scores describing SIJ pain intensity. Regardless of the data set or time since receiving the SIJ fusion compared to the specified end, significant reductions in VAS Scores were reported (*P*-value < 0.0001), indicating that participant withdrawal had an inconsequential impact on the results. Furthermore, by the specified end, 65.4% of patients experienced a 20% or greater improvement in pain, 38.5% of patients experienced a 50% or greater improvement in pain, and 26.9% of patients experienced a 70% or greater improvement in pain (Fig. 4).

Paired t-test analysis of ODI scores revealed significant improvements of 5.3, 7.4, 9.0, 11.0, and 14.8 points at 3-, 6-, 12-, 24-, and 36-months follow-up from a baseline score of 29.9 at one month (*P*-value < 0.0001; *P*-value = 0.0137). At 3 Months, 47.8% of patients had a clinically significant improvement in ODI score, defined as a 5 point or greater improvement, while 13.0% of patients had a clinically significant improvement defined as a 10 point or greater improvement (Table 7).

Improvement rates increased to 80.0% and 60.0% respectively for patients experiencing 5 and 10 point or greater improvements at 36 months follow-up. With respect to the ODI categories (Table 8), amongst the 53 patients, most were classified as either severely (56.6%) or completely (26.4%) disabled at one month post-operative. At 36 months, only 20.0% remained in either category, with the remaining 60.0% classified as mildly disabled after treatment. With a 43.0% reduction across the severe and complete disability catego-

ries, and a 52.5% improvement to mild disability, the posterior sacroiliac fusion procedure demonstrated a substantial shift in disability level at 36 Months compared to the one month post-operative baseline.

Opioid analgesic and prescription NSAID reliance drastically declined across all classifications at the 6 Month Follow Up, except amongst the completely disabled, which remained unchanged. Severely disabled patients had opioid and NSAID reliance rates of 26.1% and 56.5% respectively at 6 months post-operative, while mildly disabled patients had reliance rates of 25.0% and 50.0% for opioids and NSAIDs, respectively (Table 9). Patients with no disability had an opioid reliance rate of 33.3%, while patients with moderate disability had an opioid reliance rate of 18.2%, the lowest across all classifications (Fig. 5).

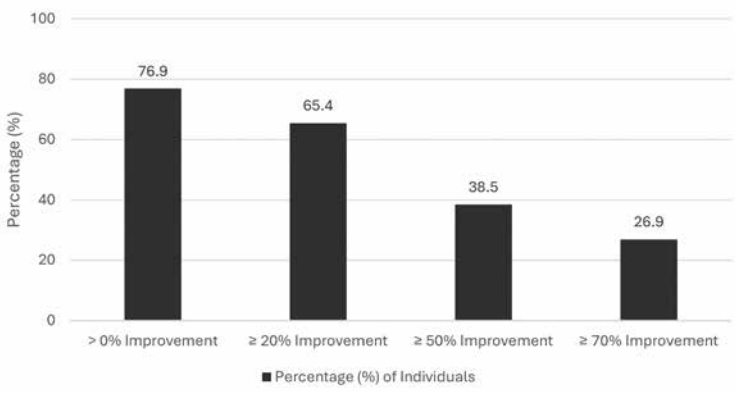

Fig. 4. *Bar graph of VAS score reduction from baseline pain at the specified end (June 1, 2024). Each Bar represents a percentile's improvement in VAS score, with the number above representing the percentage of individuals that met the corresponding percentile improvement.*

Safety

No procedure-related adverse events or complications occurred throughout the duration of the investigation, as presented in Table 4. Across 72 posterior SIJ fusion implants, the overall adverse event rate was 0%, with every patient discharged the same day as the procedure. In addition, of the patients who responded to the quality-of-life survey (n = 26), 34.6% reported mild to moderate improvements in sleep and fatigue after treatment. Rates of anxiety and depression, though, remained unchanged amongst surveyed patients.

Discussion

The present investigation evaluated the efficacy of posterior SIJ fusion over a 3-year period. These data demonstrate a reduction in pain scores, no adverse effects, improvement in disability, and a low percentage of patients taking opioids, NSAIDs, and analgesics for SIJ related pain after the procedure.

Compared to the posterior approach SIJ fusion, the lateral minimally invasive surgery (MS) SIJ fusion procedures involve a transiliac approach. This involves strategically placing devices to stabilize

Table 7. *ODI outcomes.*

Outcome	3 Month (n = 46)	6 Month (n = 42)	12 Month (n = 39)	24 Month (n = 17)	36 Month (n = 5)
Clinically significant improvement†, n (%)	22 (47.8%)	27 (64.3%)	26 (66.7%)	12 (70.6%)	4 (80.0%)
Clinically significant improvement‡, n (%)	6 (13.0%)	13 (31.0%)	17 (43.6%)	9 (52.9%)	3 (60.0%)
Mean improvement from 1 M, Mean (SD)	5.3 (4.2)*	7.4 (5.8)*	9.0 (7.7)*	11.0 (10.0)*	14.8 (14.6)§

Notes: †Defined as a 5 point or greater improvement. ‡Defined as a 10 point or greater improvement. *Denotes statistical significance, *P* value < 0.0001. §Denotes statistical significance, *P* value = 0.0137.

Table 8. *ODI categories.*

Category	1 Month (n = 53)	3 Month (n = 46)	6 Month (n = 42)	12 Month (n = 39)	24 Month (n = 17)	36 Month (n = 5)
No disability, n (%)	1 (1.9%)	2 (4.3%)	3 (7.1%)	2 (5.1%)	2 (11.8%)	0 (0%)
Mild disability, n (%)	4 (7.5%)	3 (6.5%)	4 (9.5%)	7 (17.9%)	3 (17.6%)	3 (60.0%)
Moderate disability, n (%)	4 (7.5%)	14 (30.4%)	11 (26.2%)	14 (35.9%)	6 (35.3%)	0 (0%)
Severe disability, n (%)	30 (56.6%)	21 (45.7%)	23 (54.8%)	14 (35.9%)	4 (23.5%)	1 (20.0%)
Complete disability, n (%)	14 (26.4%)	6 (13.0%)	1 (2.4%)	2 (5.1%)	2 (11.8%)	1 (20.0%)

the SIJ, fostering fusion between the ilium and the upper segment of the sacrum. This is achieved through either a lateral or posterolateral approach, where the device is inserted through the ilium towards the sacrum via the SIJ. Initially, MIS devices were primarily intended for lateral approaches (27). Currently, the US Food and Drug Administration (FDA) has approved more than 20 devices for this procedure. According to the FDA's indication statement, these devices are deemed appropriate for patients suffering from chronic SIJ pain or traumatic/degenerative disruption (28).

In a prospective, multi-center, randomized controlled study comparing MIS triangular implants to conservative management for SIJ dysfunction, the group that underwent operative fixation showed notable improvements in pain scores and ODI scores, with statistical significance (18,27). Whang et al (29) carried out a 5-year investigation on the MIS lateral approach using triangular implants, revealing a decrease of 54 points in pain and a 26-point reduction in ODI. Nevertheless, these surgical approaches carry inherent risks and potential complications, with the most frequent being implant breach of the neuroforamen or anterior sacral cortex (30-35). Moreover, the location of the implant most strongly correlated with complications with a rate as high as 11.1% with prolonged recovery of up to six weeks of ambulation with a walker and this may reflect the location of the implant being situated in the superior aspect of the joint (30-35).

In the posterior approach, allograft bone products and/or devices are positioned within the ligamentous portion of the SIJ via a small incision in the skin and soft tissue, followed by dissection through the muscle layers. Typically, a segment of the interosseous SIJ ligament is also excised. The devices commonly employed in this procedure are unclassified allograft bone products sourced from human cells and tissues. As a result, the FDA does not provide a clear indication statement specifically for SIJ fusion (28,36). In contrast to the lateral approach, the postero-inferior path offers a secure passage for implant positioning, beginning from the lower part of the joint, traversing the ilium, crossing the SIJ space, and penetrating the sacrum. This route securely passes through the bony structures of the ilium and sacrum beneath the cartilage (30). Currently, there are two mechanisms for posterior and posterior oblique approach: surgical screw fixation and percutaneous graft placements. For surgical screw fixation, a fluoroscope is set up to capture a sacral outlet view, aiming to pinpoint the posterior sacroiliac spine between the S1 and S2 foramina, where the implants will fit most effectively. The process entails adopting a lateral approach to the posterior sacroiliac spine, targeting the sacral promontory. Subsequently, a pedicle access kit (PAK) needle goes through the ilium, crossing over the SIJ, until it reaches the sacrum. The guidewire is swapped out for the PAK needle, which is then used for drilling. Afterward, a threaded implant is carefully inserted through the prepared pathway, crossing over the SIJ until it sits flush with the ilium. This sequence is repeated as needed, with the surgeon deciding whether to place up to 3 implants. For the percutaneous graft placement, a fluoroscope is tilted at a medial to lateral oblique angle (15°–20°) until the posterior and anterior SIJ lines overlap accurately. Following that, a Steinman pin (or pins) is introduced into the SIJ, offering the option for placing one or 2 allografts. The SIJ is readied by decorticating it with either a joint decorticator or a surgical drill guided

Table 9. *Post-operative opioid and NSAID Reliance at 6 months (n = 42).*

Category	Opioid Analgesics, n (%)	Prescription NSAIDs, n (%)
No disability (n = 3)	1 (33.3%)	2 (66.7%)
Mild disability (n = 4)	1 (25.0%)	2 (50.0%)
Moderate disability (n = 11)	2 (18.2%)	8 (72.7%)
Severe disability (n = 23)	6 (26.1%)	13 (56.5%)
Complete disability (n = 1)	1 (100%)	1 (100%)

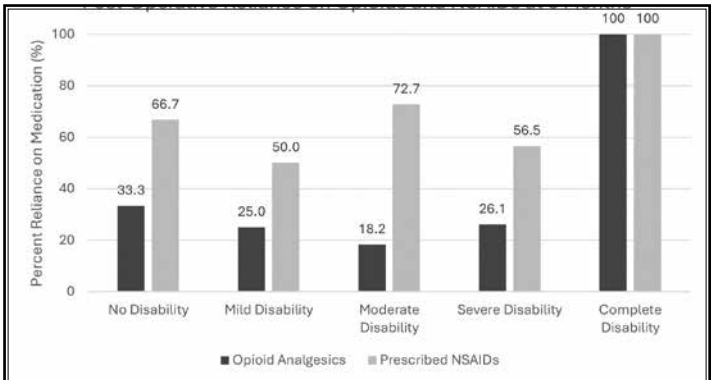

Fig. 5. *Bar graph of opioid and prescription NSAID reliance at 6 months post-operative. Amongst the 5 disability groups recognized by the ODI, Blue bars depict opioid reliance, and orange bars depict prescription NSAID reliance. The number above each bar represents the percentage of individuals that rely on the specified medication.*

through the retraction tube. Following this, demineralized bone matrix (DBM) and the cortical allograft(s) are introduced into the SIJ (Fig. 3) (11).

Currently, there are a variety of devices utilized for the posterolateral transiliac (PLTI) approach and posterior interpositional or intraarticular (PI) approach. Some examples of devices cleared by the FDA for PLTI procedures are Transloc (Foundation Fusions Systems), RIALTO (Medtronic), SI-LOK (Globus Medical), and Sacrofuse (Sacrix). Since these procedures entail inserting devices through the ilium, crossing over the SIJ, and reaching the sacrum, they're seen as a type of transiliac procedure outlined in CPT 27279. The PLTI technique initiates from a more posterior position and proceeds along an angled trajectory across the SIJ. Its purpose is to minimize the risk of injury or irritation to the S1 and S2 nerves within the foramina, along with the branches of the superior gluteal artery. Another method involves inserting implants (such as structural bone allografts or metallic devices) directly into the SIJ from a posterior angle, without penetrating the joint itself. This technique is known as a PI approach. Devices used for this approach include DIANA (SIGNUS) and NADIA (Ilion Medical). Aside from this, other devices are positioned in a posterior procedure, featuring elements that bridge or span the SIJ and interact with both the medial ilium and the lateral sacrum. Examples of these devices include Transfix (Aurora) and Catamaran (Tenon) (37). Considering the breadth of this paper, our attention will be directed towards PsiF™ Sacroiliac Joint Fusion System (Omnia Medical, Morgantown, WV, USA) and LinQ device (PainTEQ, Tampa, FL, USA).

The LinQ posterior sacroiliac fusion system has received FDA approval and is utilized for stabilizing patients experiencing SIJ dysfunction through transfixation. This system stands out from other devices by integrating a patented cortical allograft and a unique drill-free method for posterior sacroiliac fusion (38). In recent years, there has been an increase in studies supporting the effectiveness of posterior MIS SIJ fusion. In a retrospective case series conducted by Deer et al., researchers employed an innovative fusion system comprising a single ridged allograft with a DBM-filled window (PainTEQ, Tampa, Florida). The study enrolled 111 patients who had posterior SIJ fusion for chronic SIJ-related pain after treatments like spinal cord stimulation, interspinous spacer, intrathecal drug delivery, and/or minimally invasive lumbar decompression. On average, patients experienced a 67.6% reduction in reported pain after the fusion. For those with a history of failed back surgery syndrome, the relief was even better, with an average reduction of 76.5% (39).

In an initial multi-center, retrospective study, researchers investigated the clinical results of MI SIF for treating chronic pain caused by SIJ dysfunction. In this study, 50 patients were studied, with observations made over an average follow-up period of 612.2 days. Throughout this assessment, there was an average reduction of 3.9 points in the numeric rating scale scores, dropping from 7.0 to 3.1. Moreover, there were no major adverse events or complications reported among any of the patients (27,38). In a recent study by Calodney et al (27), a multicenter, prospective, single-arm study was conducted following patient identification and treatment using the innovative posterior fusion, single-point transfixation system, and monitoring them for 24 months. 6 months ago, preliminary results were published. In this study, 69 patients were enrolled in this trial. They revealed that 68.1% of patients (47 out of 69) responded positively to the therapy. This response was determined by meeting the composite criteria for the primary endpoint, which included achieving a > 20 mm reduction in VAS from baseline to 6 months without encountering SAE, neurological deterioration, or requiring additional interventions. The VAS score decreased by an average of 34.9 mm from the baseline value of 74.6 mm. Moreover, 52.2% of patients (36 out of 69) experienced significant pain relief, surpassing 50%. Additionally, there was an amelioration in pain-related disability, as reflected by a mean improvement of 17.7 points on the ODI among patients. A clinically significant improvement, defined as a score increase of 15 points or more, was observed in over half of all patients (39 out of 69; 56.5%) (27,38). At 12 months, the number of patients achieving this endpoint rose to 73.5% (61 out of 83), accompanied by an increase in the overall mean improvement in VAS score for SIJ pain. Specifically, there was a shift from a 34.9-point improvement at 6 months to a 43.3-point improvement at 12 months. Regarding clinically significant improvements, 61.4% (51 out of 83) of patients saw a 50% or greater improvement in VAS score for SIJ pain, and 68.7% (57 out of 83) achieved a 15-point or greater enhancement in ODI scores at 12 months (27).

In contrast, the Omnia approach utilizes an inferior, intraarticular surgical approach. By bypassing the challenge of dealing with the PSIS during surgery, this system positions the allograft bone implant below and toward the front of the PSIS, within the purely articular part of the joint, positioned almost perpendicular to

the S1 endplate. This process involves preparing the bone surface by decorticating and using a drill and broach to carve out a distinct "channel" within the underlying subchondral bone. This facilitates the secure intra-articular placement of the structural allograft along the joint line in a robust mortise and tenon fashion. This theoretically offers the advantage of stabilizing the joint. Furthermore, positioning the implant below the PSIS and close to the sacral axis of rotation may enhance stabilization and decrease biomechanical forces acting on the implant, especially those associated with sacral rotation and flexion-extension. In a study by Lynch et al (39), researchers collected observational data from 57 patients (mean age: 63 ± 15 years), who were followed up at 6 months. This study was part of a multi-center registry examining individuals undergoing intraarticular SIJ fusion with decortication and allograft bone implantation. There were improvements in all clinical measures compared to preoperative levels (mean ± SD). Back pain severity decreased by 44% (from 6.8 ± 2 to 3.8 ± 3), pain-tolerant standing time improved by 183% (from 29 ± 53 minutes to 82 ± 36 minutes), and pain-tolerant walking distance improved by 55% (from 87 ± 267 steps to 135 ± 374 steps). Statistically significant improvements were observed in all measures ($P < 0.001$ for all comparisons) (40). Compared to LinQ (PainTEQ, Tampa, FL, USA), there are only a limited number of studies supporting the use PsiF™ Sacroiliac Joint Fusion System (Omnia Medical, Morgantown, WV, USA) (40,41).

Overall, posterior minimally invasive SIJ fusion (MI-SIF) offers advantages in terms of reduced invasiveness, decreased surgical dissection and duration, reduced recovery time, and minimized bone damage. Although our patients were provided general anesthesia intraoperatively, the posterior approach can be performed with intravenous sedation, allowing patients to leave the post-anesthesia care unit typically within one hour (28). All the patients in our study were discharged from the post-anesthesia care unit within one hour without any of them returning for complications. All of them were administered injectable 1.3% liposomal bupivacaine (Exparel) along the SIJ fusion with a short prescription of an opioid for postoperative pain management.

Limitations

There were a few limitations to this study. First, many of the patients had additional spine pathology that could have contributed to lower back pain, making it a confounding variable when assessing pain relief from the SIJ fusion. Some of these documented additional comorbidities included lumbar facet arthritis, lumbar disc disease, obesity, osteoarthritis, and rheumatologic diseases. Other limitations of the study were that this was a retrospective study, 26% of the patients were lost to follow up, and 54% completed one-year follow-up.

Conclusion

In summary, the results of the present investigation demonstrate strong efficacy with significant reduction in pain score and improvement in disability scores after posterior SIJ fusion without any significant adverse effects postoperatively. This is the longest study to date in world literature measuring efficacy and adverse effects over a three-year period post SIJ fusion and the results demonstrate that a significant number of patients continued to have reduction in pain score, improvement in disability without adverse effects. Overall, patients had a low incidence of opioid, NSAID, or analgesic use after SIJ fusion. In summary, the present investigation demonstrates strong efficacy without minimal adverse side effects for SIJ fusion via a posterior approach.

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