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ORIGINAL RESEARCH

Minimally Invasive Posterior SI Joint Fusion with a Novel Cortical Allograft: Real-World, Long-Term, Outcomes from a Large, Multisite US Cohort

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Purpose: Sacroiliac (SI) joint dysfunction accounts for 15% to 30% of reported low back pain. Primary treatments of SI joint dysfunction include medications, bracing, physical therapy, injections, and ablations. When primary non-surgical treatments are unsuccessful, fusion or stabilization may be considered. Here, we report a multicenter study aimed to evaluate real-world outcomes of posterior sacroiliac joint fusion using cortical allograft across six United States clinical sites.

Methods: Patients diagnosed with sacroiliitis through physical examination and diagnostic injection who have failed conservative management that ultimately underwent percutaneous allograft implant with at least 6 months of follow up were included. Data extracted from electronic health records included demographic and clinical characteristics, Numeric Rating Scale (NRS) pain scores, and patient-reported adverse events. Descriptive statistics were utilized to summarize baseline characteristics, and proportion of patients achieving minimally clinically important difference (MCID) was assessed. Paired t-tests were employed to compare pre-operative and post-operative outcomes.

Results: A total of 258 patients were included. Of these, 63.9% were women and 36.1% were men, with a mean age of 69.2 years and an average body mass index of 29.6 kg/m². Average NRS at baseline was 7.61 ± 1.64 and 1.60 ± 1.86 ($p < 0.05$) at last follow-up visit. The mean pain reduction from baseline to the last follow-up (91.2 week mean or 1.75 years) was 6.01 points, exceeding MCID. The safety profile was favorable, with no serious adverse events reported in this cohort.

Conclusion: Our findings affirm that posterior SI joint fusion constitutes an effective and enduring treatment option for patients suffering from SI joint dysfunction unresponsive to conservative care. The results indicate that posterior SI joint fusion is safe and effective at achieving sustained pain relief. Our findings are congruent with previously published studies and provide further evidence of sustained durable pain outcomes.

Plain Language Summary: SI joint dysfunction is a common cause of low back pain with a variety of treatment modalities including posterior access allograft placement in medically refractory patient populations. This approach is relatively new and further studies are needed to fully understand the long term efficacy and adverse events associated with this procedure. This study aims to add to the existing literature to describe efficacy and outcomes for this treatment. The hypothesis of this study is that the posterior approach percutaneous allograft placement for treatment of SI joint dysfunction provides durable relief with minimal risk of associated procedural adverse events.

The study found that the average NRS reduction over the course of follow up in the patient cohort was 6.01 and the MCID was observed from baseline to 1 month follow-up with a 4.07-point reduction, and from baseline to the last follow-up with a 6.01-point reduction. The study results show similar outcomes as noted by previous publications further supporting this posterior approach percutaneous allograft placement for the treatment of medically refractory SI joint dysfunction is a safe procedure that provides durable relief of back pain caused by sacroiliitis.

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Introduction

It is estimated that 20.9% of adults in the United States experience chronic pain, of which with 6.9% experience high impact chronic pain resulting in substantial restrictions on activities of daily living in 2021.[1] The estimated global prevalence of pain in adults greater than 25 years of age is 27.5% with an estimated 7.5% of the global population suffering from low back pain resulting in 64.9 million years lived with disability.[2,3] Of all causes for low back pain, the sacroiliac (SI) joint has been implicated to cause 15–30% of all mechanical chronic low back pain.[4,5] A synovial joint formed between the sacrum and the ilium, the SI joint is the largest synovial joint in the human body. The anterior third of the interface is a true synovial joint, while the posterior two thirds constitutes a fibrous capsule supported by the accessory, posterior sacroiliac, long posterior sacroiliac, sacro-tuberous, and sacrospinous ligaments. The size and morphology of this joint changes with age and contributes to individual variability seen.[4,6]

Sacroiliac joint pain can be generated by intra-articular causes including osteoarthritis and infection or extra articular causes including ligamentous strain or insufficiency fractures.[4] Sacroiliac joint disease secondary to arthropathy is often a diagnosis of physical exam with a sensitivity of 94% and specificity of 78% when patients examine with three out of five positive physical maneuvers including the FABER, thigh thrust, Gaenslen's, distraction, sacral thrust, and compression testing.[7] Imaging modalities including magnetic resonance imaging (MRI) and diagnostic blocks may help confirm the diagnosis treatment varies based on etiology of SI joint pain. Physical therapy, bracing, and medications are often first line treatment. Serola SI joint belt in particular has been found to be particularly effective in not only pain relief but improving dynamic balance as well.[8] Interventions including intra-articular steroid injections and lateral branch radiofrequency ablation being treatment options in patients who fail conservative care. When these measures fail to provide adequate sustained relief, surgical fusion is often a treatment of last resort.

Traditional open SI joint fusion approaches have been replaced with minimally invasive fusion approaches due to the associated risk of neurovascular injury as well as prolonged recovery time. Conventional minimally invasive surgical (MIS) fusion of the SI joint utilized a lateral approach, which has been found to be safe and efficacious.[9] This MIS approach has been found to result in greater pain reduction while minimizing operative time and length of hospital stay for patients compared to open SI joint fusion approaches.[10,11] Recently, advances in procedural technique has resulted in several percutaneous SI joint fusion devices utilizing a lateral or posterior approach. Minimally invasive implants through a lateral approach where three cylindrical or triangular implants are placed through the ilium into the sacrum to promote arthrosis is one such approach. Posterior approach implant can vary in implant placement and technique. One approach utilizes two biologic implants in orthogonal positioning to promote stabilization and fusion, while another utilizes 1–3 cylindrical implants to fixate the SI joint.[12] Another such approach places a cortical bone allograft implant into the SI joint. It has been proven that placing a cadaveric graft into the SIJ can provide a reduction in motion in all planes while changing the center of axis of rotation to the implant promoting graft fusion.[13]

A prospective single arm multi-center study has found that this posterior approach percutaneous single bone allograft implant for SIJ fusion was found to reduce patient VAS by 34.9 and ODI by 17.7 at 6 months and 54.2 and 29.1 at 12 months.[14,15] Smaller case series have supported these findings with sustained NRS improvement over time.[16] However, there exist a need for further evaluation of patient outcomes with this specific implant and procedural approach. To meet that end, here we report the largest multi-center retrospective study of patient outcomes with a posterior approach percutaneous SI joint fusion via bone allograft for the treatment of SI joint dysfunction.

The purpose of this study is to evaluate the efficacy and safety of a posterior percutaneous cortical allograft placement for treatment of SI joint dysfunction to add to the literature that exists regarding this implant and technique. Given the novelty of this approach, there are few large real-world studies published to detail the long-term outcomes of posterior cortical allograft placement for this condition. The intent of this manuscript is to evaluate the outcomes and safety for this particular posterior approach SI joint fusion implant. As there are multiple techniques and products available for sacroiliac fixation, it is critical that outcomes achieved with this product not be applied to other posterior sacroiliac

fusion implants as insert sizing, surgical instrumentation, implant construct, and other variables can and typically do differ across different implants.

Methods

Study Design and Setting

This retrospective, multicenter study was conducted at six clinical sites across the United States to evaluate real-world outcomes of posterior sacroiliac (SI) joint fusion using the LinQ Fusion implant (PainTeq, Tampa, FL) (Figure 1). The study sites included both academic medical and private practice settings, providing a comprehensive representation of diverse clinical environments.

Patient Selection

Participants were included based on a confirmed diagnosis of chronic SI joint dysfunction, determined through a dual-confirmatory diagnostic injection approach comprising clinical and imaging assessments. Initial diagnosis required three out of five positive findings on provocative physical examination maneuvers, including SI joint distraction, thigh thrust, FABER, compression, and Gaenslen's tests. Patients with positive physical examination findings subsequently underwent diagnostic SI joint injections under fluoroscopic guidance, performed without corticosteroids via a posterior approach, to confirm the SI joint as the primary pain generator. A diagnostic injection was considered successful if patients reported a ≥75% reduction in pain within the first four hours post-injection. Diagnostic and therapeutic SI joint injections were performed uniformly by site investigators. Patients who failed conservative management—including active rehabilitation (physical therapy, home exercise, or chiropractic care), medication, bracing, and steroid-based SI joint injections—underwent posterior percutaneous bone allograft SI joint fusion. The study included patients treated between August 2019 and January 2024 with at least 6 month follow up data.

Procedure

The cortical allograft implant was placed via a posterior percutaneous approach under fluoroscopic guidance, employing a standardized technique as previously described in the literature.[16] The procedure involved the placement of a windowed bone allograft with a drill-less system to achieve stabilization of the SI joint (Figures 2 and 3) after a channel is created and a decortication tool is used. All procedures were performed by experienced physicians at their respective study sites. A detailed review of the technical aspects of the procedure is beyond the scope of this study.

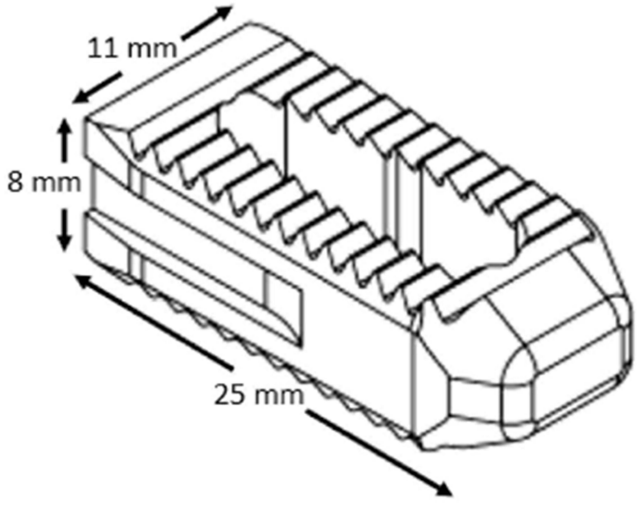

Figure 1 Diagram of cortical allograft implant.

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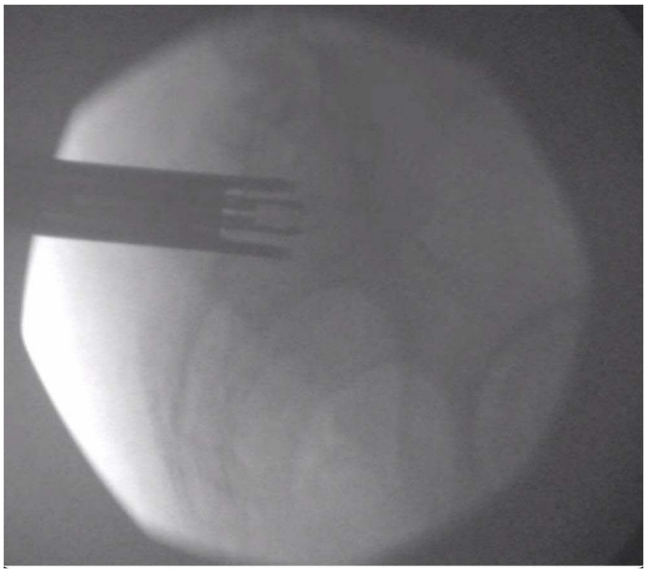

Figure 2 Lateral intraoperative fluoroscopic image of percutaneous SI fusion with cortical allograft placement.

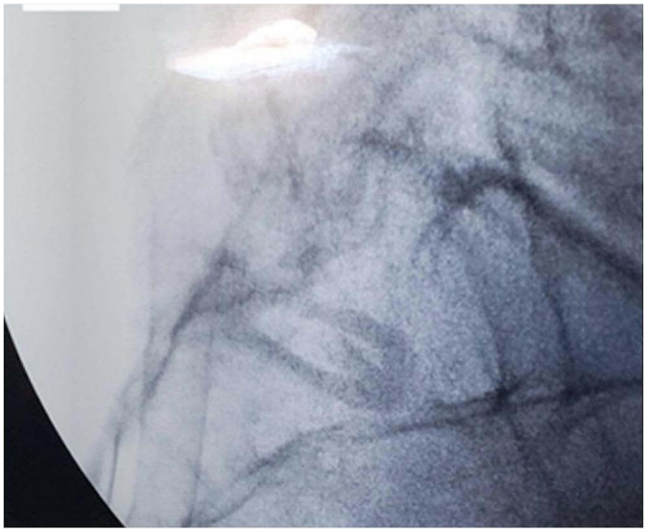

Figure 3 A lateral intraoperative fluoroscopic image of cortical allograft in the SI joint after implant deployment.

Data Collection and Outcome Measurements

Data were retrospectively extracted from electronic health records, not direct patient interviews, at each participating site and included demographics (age, sex, and body mass index - BMI), preoperative and postoperative Numeric Rating Scale (NRS) pain scores, follow-up intervals, and patient-reported adverse events. Primary outcomes included changes in NRS pain scores from baseline visit, immediate post operative follow-up, and last follow-up provided by patients. Secondary outcomes included patient-reported complications and adverse events.

Statistical Analysis

Descriptive statistics were used to summarize demographic and baseline clinical characteristics. Continuous variables were reported as means ± standard deviations (SD). Changes in NRS scores from baseline to follow-up were analyzed using paired t-tests, with statistical significance set at $p < 0.05$. The proportion of patients achieving clinically meaningful pain relief (≥50% and ≥80%) was calculated at each follow-up interval. The minimally clinically important difference (MCID) was also assessed, defined as a reduction of ≥2.00 in patients with chronic back pain coinciding with the commonly adopted metric of MCID in prior SI joint fusion studies.[17–20]

Table 1 Patient Demographic and Procedural Data

Age	69.2 ± 11.0 years
Gender	93 male (36.1%)
	165 female (63.9%)
BMI	29.6 ± 5.9
Average duration of implant at follow up	91.2 ± 55.1 weeks
Serious Adverse Events	0/258
Implant related perioperative transfusions	0/258
Required post operative overnight hospitalizations	0/258

Ethical Considerations

This study was conducted in compliance with the Declaration of Helsinki and applicable ethical standards. The University of Kansas Medical Center Institutional Review Board (IRB) approval was obtained (#00160245) and informed consent waiver was granted due to the retrospective nature of the study for the academic center study site. The WCG IRB provided approval (#20232571), and informed consent waiver was granted due to the retrospective nature of the study for the other 5 private practice sites. Standard protocols were utilized at all institutions to ensure patient confidentiality and ensure the data were deidentified for this study.

Results

A total of 258 patients underwent posterior SI joint fusion among all sites with complete NRS data available at baseline and follow-up of at least 6 months. The majority were women (63.9%), with men comprising 36.1%. The mean age at the time of surgery was 69.2 years, and the average BMI was 29.6 kg/m² (Table 1). The average duration of implant at the time of follow up was 91.2 ± 55.1 weeks, approximately 1.7 years. NRS scores demonstrated a significant and sustained reduction in pain following posterior SI joint fusion. Baseline mean NRS scores of the cohort were 7.61 ± 1.64. Immediate 2 week follow up mean NRS was found to be 3.54 ± 2.45 with mean NRS at last follow-up (last FU) of 1.60 ± 1.86 (Figure 4). The mean improvement in pain at immediate postoperative follow-up (4.07-points) and from baseline to the last follow-up (6.01-points)

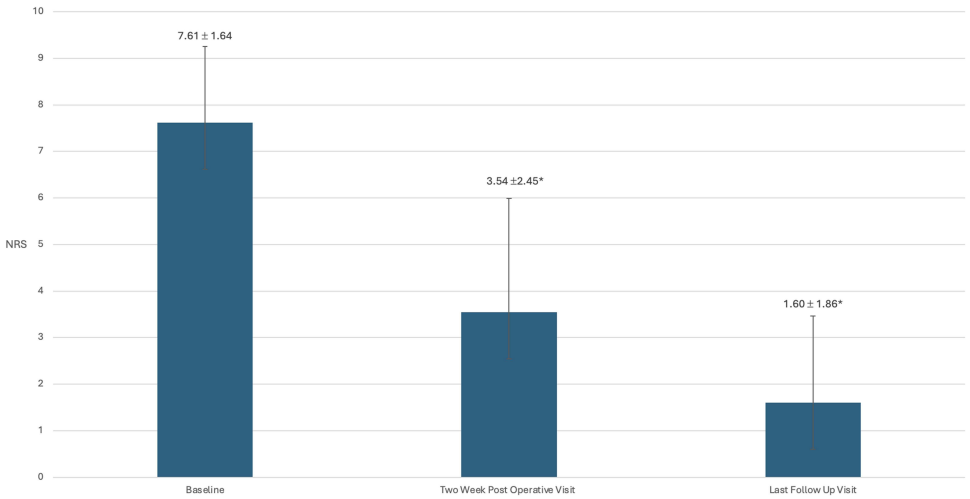

Figure 4 Trends in numeric rating score (NRS) from baseline, immediate post op and last follow up visit. Numeric values are listed above the figure (Mean ± SD). *indicates statistically significant finding ($p \leq 0.05$).

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both exceeded the study's 2.00 threshold. These findings indicate a statistically ($p < 0.05$) and clinically significant reduction in pain in this cohort.

This study suggests the possible favorable safety profile of posterior SI joint fusion as no serious adverse events defined as death, spinal nerve injury, or major vascular injuries were reported, supporting the existing prospective studies on the significant decrease risk of major adverse events with this surgical procedure.[15] No transfusions and no overnight hospital stays were required for any of the performed implants. These results underscore the importance of considering posterior SI joint fusion as a viable treatment option for patients with chronic SI joint pain unresponsive to conservative management.

Discussion

Our findings align with the evolving literature supporting posterior SI joint fusion as an effective intervention for managing chronic SI joint pain refractory to conservative treatment. Sacroiliac joint fusion is typically recommended after patients fail to achieve satisfactory results following at least six months of conservative management. At present, no robust evidence exists to suggest the superiority of one technique over another.[21,22] Minimally invasive techniques for SI joint fixation primarily include posterior and lateral approaches with a potentially lower rate of adverse events associated with the posterior approach.[12,15] Posterior approaches may involve the use of one or two allografts or titanium-based constructs, depending on the specific procedural strategy. Traditionally, the posterior approach utilizes an intra-articular implant where the implant itself is placed inside the joint line. Comparatively, the lateral fusion technique utilizes 1–3 titanium screws to traverse the ilium into the sacrum to promote fusion.

Our multicenter retrospective study of 258 patients demonstrated a longitudinal sustained improvement in pain scores with an average follow up time of 91.2 weeks. Baseline NRS scores were 7.61 ± 1.64, and at last follow-up revealed a statistically significant decrease in pain to 1.60 ± 1.86. The mean pain reduction from baseline to the last follow-up was 6.01 points, which exceeded the MCID. These findings demonstrated clinically meaningful and statistically significant improvement in pain and safety profile beyond 1 year. Interestingly, there was notable pain reduction even after 2 weeks from implant date. It should be noted that though placebo effects may last for weeks to a few months, it is typically a temporary effect. Though fusion is likely not achieved at this time point, it does reinforce previous published biomechanic findings where allograft placement placed by this approach resulted in instant reduction in SI joint movement.[13] The immediate analgesic effect may reflect one of the proposed mechanisms of action for posterior cortical allograft placement, namely decreased joint mobility via distraction of the joint. Furthermore, the safety profile was favorable, with no serious adverse events occurring to any patients in this cohort.

The present study expands the literature on posterior percutaneous cortical allograft implants reporting further data from multiple centers across the US and builds upon earlier studies emphasizing the procedure's efficacy and safety. Sayed et al conducted a retrospective evaluation involving 50 patients. Over 12 months of follow-up, the mean NRS score declined from 6.98 pre-procedure to 3.06, with no adverse events or complications reported.[16] Similarly, Deer et al analyzed outcomes in 111 patients who underwent posterior SIJ fixation as a salvage therapy following unsuccessful spinal interventions including failed spinal cord stimulation, interspinous spacers, intrathecal drug delivery systems and minimally invasive lumbar decompression. These patients achieved a mean pain reduction of 67.6%, with those presenting a history of failed back surgery syndrome experiencing an even greater reduction of 76.5% suggesting a possible cause of back pain may not be due to failed back syndrome alone but undiagnosed SI joint dysfunction as well.[23] Moreover, the SECURE study provided prospective data showing a mean pain score reduction of 34.9 points and a functional improvement of 17.7 points on Oswestry Disability Index at six months post-procedure.[14] Similarly, Kaye et al retrospective analysis on the SI joint fusion posterior approach demonstrated equivalent sustained efficacy, minimal adverse events, and significant improvements in disability over a three-year follow-up period.[24] Recent 12-month data on posterior SI joint fusion involving 159 participants across 16 investigational sites demonstrated a stable response rate at 66.0%, 74.4%, and 73.5% at the 3-, 6-, and 12-month follow-up visits, respectively, with statistically significant reduction in pain and disability scores, as well as within all domains of PROMIS-29 denoting marked improvement in quality of life. These results suggest that the posterior SIJ fusion approach is both a safe and effective treatment and outcomes at the 12-month mark are favorable when compared to the lateral approach with triangular titanium bars.[15]

While the lateral approach to SIJ fusion has a more extensive evidence base due to its earlier adoption, current data suggest that the posterior approach offers equivalent efficacy with fewer safety concerns.[15,21,25,26] Comparative analyses of complication rates across techniques are limited, but minimally invasive lateral fusion has been associated with a complication rate of approximately 11.11%.[27] Currently, percutaneous posterior allograft SI joint fusion has not been linked to any serious procedural complications in the most recent existing literature.[15] This may reflect the approaches avoidance of critical neurovascular structures that may be encountered with lateral or posterolateral approaches. These findings indicate that the posterior approach may be safe and effective and demonstrates outcomes that compare favorably to those with the lateral approach.[15,24]

Our findings add to the growing body of evidence supporting the posterior approach to SI joint fusion as a viable and highly effective treatment option for chronic SI joint pain. The significant and sustained improvements in pain relief, coupled with a favorable safety profile, reinforce the value of this method. These results, when contrasted with the current literature, underscore the posterior approach as a potential option for treatment of SI joint dysfunction with similar rates of efficacy and safety profile in the management of SI joint pain refractory to conservative management. Further randomized controlled studies evaluating successful fusion with imaging confirmation and functional outcomes are needed to fully study the efficacy of this implant and approach for treatment of SI joint dysfunction. In the absence of comparative evidence, future research should focus on direct comparative trials evaluating distinctive approaches and their clinical outcomes and safety profile. Such studies would provide critical insights into the relative advantages of each method to eventually expand to cost-effectiveness and long-term durability analysis. Previous studies have shown that minimally invasive SI joint fusion is cost effective for the treatment of sacroiliitis where SI joint fusion was associated with a 0.74 quality adjusted life years gained where cost savings are achieved at 13 years post intervention compared to non-surgical treatments.[28] Similar studies are needed to assess the cost savings associated with this approach for the treatment of SI joint dysfunction.

Limitations

Our study provides valuable insights but also presents several limitations that should be considered when interpreting the results. Firstly, the study's retrospective design poses inherent limitations. Since the data were collected from existing records rather than through prospectively planned data collection, there is a risk of bias. Due to the nature of the retrospective review, we do not have follow up CT imaging and Modified Bridwell assessments to evaluate for and confirm bony fusion (Figure 5). Thus, evaluation for rate of and success of SIJ fusion is outside the scope of this manuscript. Further, we do not have imaging to confirm intra-articular versus periarticular device placement and thus assessing the rates of intra-articular placement is also outside the scope of this manuscript. The absence of a control group restricts the ability to draw definitive conclusions. Without a control group, it is difficult to clearly attribute clinical improvement to the procedure alone, although the data does reflect statistical and clinical improvement surpassing MCID from baseline after treatment. It is difficult to gleam how this technique and treatment compares to conservative treatments or alterative surgical techniques without a comparator group though previous controlled trials on similar

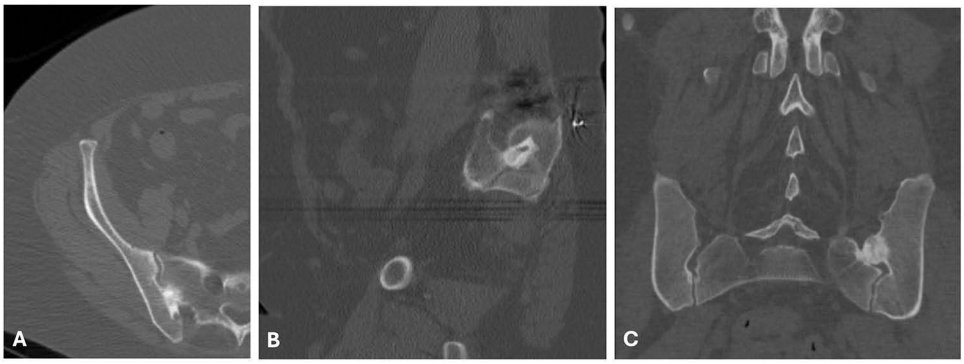

Figure 5 12 Month CT imaging of SIJ fusion with cortical allograft insert. (**A**) Axial view. (**B**) Sagittal view. (**C**) Coronal view.

patient populations, which have exhibited the therapeutic value of conservative and control groups.[22] This necessitates real world registry based studies to capture additional data to validate this therapy in the future.

Another limitation is the potential for selection bias. Although patients were included based on a dual-confirmatory diagnostic approach and a history of failed conservative management, the study population may not be fully representative of the broader population. We tried to minimize this selection bias by conducting the study across six clinical sites and included factors such as geographic location, differences in healthcare access, and institutional practices (academic and private practices) to highlight the generalizability and applicability of the results to other settings or populations. The combination of this has resulted in limited statistics to be able to be performed on the data, which also limits the evaluation of and applicability of these findings. Further, this study evaluated patients with available data of at least 6 months follow up. Due to this, it is difficult to ascertain true bias with available versus non-available data as it may reflect failure of therapy or loss to follow up unrelated to therapy results.

The study also relied on self-reported outcomes and adverse events, which are subjective and may be influenced by factors such as the patient's expectations, psychological state, or the clinical environment. In an ideal situation, more formalized metrics in addition to patient reported pain scores such as functional metrics including the Oswestry disability index would provide greater insight on the full clinical effect of the procedure. With the retrospective multisite nature of the study, it was difficult to obtain consistent reported measures across all sites to assess for other factors aside from pain improvement, which may affect the generalizability of the findings within to quality of life or functional improvements seen in these patients. Similarly, imaging was not available to assess for the rates of joint arthrodesis and the evaluation of this is thus outside the scope of this study but does warrant future investigation. While, our study supports the safety and efficacy of posterior SI joint fusion, the limitations outlined above suggest that caution should be exercised when generalizing these results. Future studies, particularly randomized controlled trials with larger, more diverse populations, longer follow-up periods with consistent data across all sites, and detailed adverse event reporting, would be beneficial in strengthening the evidence for posterior SI joint fusion.

Conclusion

In this retrospective study, the average NRS reduction over course of follow up in the patient cohort was 6.01 and the MCID was observed from baseline to 1 month follow-up with a 4.07-point reduction, and from baseline to the last follow-up with a 6.01-point reduction. The data presented in this study hopes to add to the growing literature validating the safety and efficacy for a percutaneous posterior approach for SI joint fusion with a cortical allograft implant for the treatment of medically refractory SI joint dysfunction.

Data Sharing Statement

The dataset generated during and/or analyzed during this study are available from the corresponding authors on reasonable request.

Ethical Approval

This study was conducted in compliance with the Declaration of Helsinki and applicable ethical standards. The University of Kansas Medical Center Institutional Review Board (IRB) approval was obtained (#00160245) and informed consent waiver was granted due to the retrospective nature of the study for the academic center study site. The WCG IRB provided approval (#20232571), and informed consent waiver was granted due to the retrospective nature of the study for the other 5 private practice sites.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Dawood Sayed, Chris Bovinet, Pankaj Mehta, Nomen Azeem, and Ajay Antony are consultants for PainTeq. Dr Ajay Antony reports personal fees from PainTeq, during the conduct of the study; grants, personal fees from Boston Scientific, personal fees from Abbott, personal fees from Mainstay Medical, personal fees from Saluda Medical, personal fees from Stryker, grants from Vivex, outside the submitted work. Dr Richard Epter reports personal fees from Nevro, personal fees from PainTeq, outside the submitted work. Dr Vinicius Tieppo Francio reports Consultant from Mainstay Medical, outside the submitted work. Dr Dawood Sayed reports personal fees, options from PainTeq, personal fees, options from Surgentec, personal fees from Saluda, personal fees from Abbott, outside the submitted work. The authors report no other conflicts of interest in this work.

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