# Does Provider Matter? A Systematic Review of Evidence Supporting Performance of SI Joint Fusion by Surgeons Rather Than Non-Surgeons

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## Abstract

# Introduction

As patient demand for minimally invasive SIJF has increased, non-surgeons (including pain management physicians) have begun to perform a growing number of minimally invasive posterior SIJF procedures, even though these have traditionally been reserved for spine surgeons, whose extensive training renders them experts in spinal instrumentation and biomechanics.

# Objectives

We compare and contrast levels of evidence and data available on minimally invasive SIJF devices in the literature published by both spine surgeons and non-surgeons. In doing so, we hope to provide insight on the role of non-surgeons in managing spinal disease in light of the Position Statement set forth by the AANS and CNS in August 2021.

# Methods

A PubMed search and initial screen yielded 11 studies that were subjected to full text analysis. Using the list of SIJF devices obtained from these studies, additional searches were conducted using the National Institute of Health (NIH) Clinical Trials website and FDA 510(k), among others, yielding 6 unique devices that can currently be used by non-surgeons in the posterior SIJF approach.

# Results

Spine surgeons generally perform lateral or posterolateral MIS SIJF. There are 11 unique FDA-approved devices and a total of 33 SIJF devices overall. 10 of these devices have been described in numerous reports within the peer-reviewed medical literature. For example, Titanium Triangular Implants (lateral) are described in 11 retrospective studies (level 4 evidence), 2 level 2 prospective studies, and 2 level 1 prospective studies. By contrast, non-surgeons have only investigated the use of posterior allograft devices in 2 studies. One of these studies (PainTEQ) is featured on ClinicalTrials.gov and will not be complete until March 2022. The other is a systematic review citing 6 studies on posterior SIJF performed by non-surgeons. However, these are non-peer reviewed conference abstracts – 2 of which are featured on the CornerLoc device website – and therefore cannot be assigned meaningful levels of evidence.

# Conclusion

Instrumentation of the spine requires extensive surgical training such as that completed by spine surgeons. There is an increasing body of evidence in the literature supporting the performance of MIS

SIJF for SI disease by spine surgeons. However, there is no evidence supporting the performance of this procedure by non-surgeons.

# Introduction

Low back pain (LBP) is a commonly encountered clinical entity that places a significant socioeconomic strain on health care systems worldwide.[1] In fact, in developed countries, LBP is the 2nd most common reason patients seek medical care other than cough, and is also the 2nd most common cause of disability among US adults, resulting in the loss of approximately 150 million workdays annually.[2] Although a majority of cases of LBP can be attributed to lumbar spinal pathologies, the sacroiliac (SI) joint is associated with a significant portion (15–30%) of all cases of LBP.[3] A proportion of patients with SI joint-related LBP that is refractory to conservative therapies (oral analgesics, steroids, physical therapy) may become candidates for surgical intervention.[4] In well-selected patients, sacroiliac joint fusion (SIJF) has become a popular surgical treatment over the past decade due largely to improved awareness of SI joint-related LBP, new technologies, as well as the emergence of minimally-invasive surgical (MIS) techniques.[3]

In a recent systematic review[3], Himstead et al. provided the most comprehensive and up to date overview of trends in SIJF and its increased representation – by a factor of 6 with respect to publication number and citations – in the literature over the past decade. This report also categorized and reviewed evidence on new devices for the lateral, posterolateral, and posterior MIS SIJF approaches, including those devices featured in both peer-reviewed, published and non-peer-reviewed sources.[3] Ultimately, it identified a total of 33 unique devices, 24 of which have been FDA or Conformitè Europëene (CE) approved for SIJF.[3]

In the short time since we reported on SIJF devices and levels of evidence for MIS SIJF performed by spine surgeons in our comprehensive review[3], the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves released (in August 2021) a Position Statement on fusion (arthrodesis) of the spine by the non-surgeon.[5] This statement highlights the increasing frequency with which *posterior* MIS SI joint arthrodesis/fusion (in addition to facet and lumbar interspinous process fusion) is performed by non-surgeons such as physiatrists and pain management anesthesiologists in the outpatient and office clinic setting (note that *lateral* approaches are generally performed by surgeons).[6] Given the rise of patient demand for MIS procedures that can treat LBP and emergence of spinal fusions performed by non-surgeons, we now seek to build off the prior report by Himstead et al. reviewing the range of approaches and devices used in posterior MIS (percutaneous) SIJF, the procedure non-surgeons are currently using to treat pain associated with SI disease. Additionally, we will compare and contrast levels of evidence and data available on MIS SIJF in the literature published by both spine surgeons and non-surgeons. In doing so, we hope to shed light on optimal SI-related LBP patient care algorithms and help characterize the ongoing relationship among SIJF, spine surgeons, and pain management physicians.

# Methods

In order to identify studies reporting on devices used in MIS posterior SIJF, we queried the PubMed, Google Scholar, and Web of Science databases from 2010 to present using the following Boolean search term: (sacroiliac joint) AND (posterior) AND (fusion OR arthrodesis) AND (minimally invasive OR percutaneous). Our search yielded 35 results which were screened by title and abstract according to the following inclusion criteria: 1) studies reporting on MIS sacroiliac joint fusion performed using the posterior approach in human subjects and 2) investigating patient-reported outcome measures (PROMs). We excluded studies that were 1) not available in English 2) not available in full text and/or 3) reporting on open SIJF. Following our initial screen 11 studies remained and were subject to full text analysis, from which devices used in MIS posterior SIJF were identified and used to generate a formal list. Next, using this list, additional searches were conducted using the National Institute of Health (NIH) Clinical Trials website, FDA 510(k), Google, LinkedIn, and premarket approval and de novo databases using the terms “SI Joint”, “Sacroiliac joint”, “Sacroiliac joint fusion”, and “SI joint fusion”. Collectively, these searches yielded 6 unique devices used in MIS posterior SIJF (**Table 1**). Finally, we referenced medical device websites and FDA 510(k) approval documentation in order to gather further information regarding each device, such as composition and FDA-approved indications.

# Results

Our literature and database review identified 6 unique devices that can be used by spine surgeons and pain management physicians for MIS (percutaneous) posterior SIJF (**Table 1**). Although it is becoming increasingly[5] common for pain management physicians and physiatrists to perform percutaneous SIJF at the bedside using a posterior approach, our search yielded only 2 studies (one meta-analysis and one clinical trial) pertaining to performance of this procedure by non-surgeons. Additionally, because spine surgeons most commonly use other approaches, there is only one study describing the implementation of the posterior allograft approach by surgeons.[7]

This is in contrast to the performance of other MIS SIJF techniques by spine surgeons, who often employ lateral (most common), posterolateral, and combined approaches by using a 11 unique FDA approved SIJF devices and a total of 33 devices overall (including those not featured in the peer-reviewed, published literature)[3]. In contrast to devices used in the posterior allograft approach, which have only been described in the 3 aforementioned studies, over 10 unique devices used in the lateral and posterolateral MIS SIJF approaches by spine surgeons have been described in numerous reports throughout the literature. For example, Titanium Triangular Implants manufactured by SI-Bone are used by spine surgeons in MIS lateral SIJF and have been described in 11[8–18] retrospective case series (level 4 evidence), 2[19, 20] prospective cohort studies (level 2 evidence), 2[21, 22] additional prospective studies (level 1 evidence) and 2 safety analyses.[3] Overall, the lateral approach is performed only by spine surgeons and encompasses the strongest body of evidence and largest number of devices[3] relative to any other approach. Other studies[23–25] describing the utility of MIS lateral SIJF using devices such as SImmetry include 2 case series (level 4 evidence) and one prospective cohort study (level 2 evidence). Furthermore, studies describing these lateral approaches report notable improvements in ODI, decreased opioid usage,

and improved functionality with minimal complications following MIS lateral SIJF.[25–27] MIS SIJF performed by spine surgeons using posterolateral devices has also been associated with favorable, albeit less robust, outcomes. For example, a retrospective study (n = 24) describing MIS placement of Medtronic's posterolateral fusion device reported statistically significant reduction in low back pain and leg pain scores postoperatively.[28] Overall, the lateral and posterolateral approaches to MIS SIJF have become increasingly popular over the last decade and can provide pain relief for patients with SI-related LBP when conservative management fails.[3]

Additionally, in 2008, Wise[7] and Dall contributed to the limited body of evidence regarding the posterior allograft approach with a prospective study of 13 patients. They reported no significant complications, an 89% fusion rate at 6 month follow-up, and a statistically significant reduction in LBP visual analog scale (VAS) scores.[3, 7] Despite these results, there is currently no FDA approved device for posterior allograft SIJF on the market.[3]

As such, when interventional pain management specialists or physiatrists perform posterior percutaneous SIJF, they are doing so with devices that are not yet FDA approved. Despite this fact, one advantage of the posterior approach for non-surgeons is that it avoids critical neurovascular structures that are otherwise encountered in the lateral and oblique approaches.[29] In the first peer-reviewed, published review on the performance of MIS SIJF by non-surgeons, which appeared in the *International Journal of Spine Surgery* in June 2021, Lee et al.[29] conducted a systematic review that identified 10 studies on MIS posterior SIJF. However, this study does not include any evidence that would help delineate a clear-cut stance on the role of pain management physicians in performing MIS SIJF for refractory SI disease and/or LBP. In fact, one of the studies included in Lee et al.'s review is that published in 2008 by Wise and Dall, a study which describes 13 patients undergoing posterior allograft SIJF performed by spine surgeons.[3, 7, 29] Additionally, 3 other studies included in Lee et al.'s review describe posterolateral (or other) approaches performed by spine surgeons.[30–32] The 2 studies describing posterolateral devices were featured in the prior systematic review by Himstead et al., while the 3rd was not included in that prior review because it described an atypical distraction-arthrodesis technique (as opposed to typical fusion or arthrodesis).[3] However, the remaining 6 studies included by Lee et al.[29], which feature reports on the performance of MIS posterior SIJF by pain management physicians, are each non-peer reviewed abstracts that were presented at pain management conference meetings. For example, Patterson and colleagues presented their case series at the California Society of Interventional Pain Physicians (CASIPP) annual meeting, held in November 2018, while Mann et al. presented on MIS posterior SIJF at The American Society of Pain and Neuroscience (ASPN) annual meeting in July 2019. Altogether, because each of the 6 studies cited by Lee et al.[29] are conference abstracts as opposed to peer-reviewed publications, they cannot be used to inform guidelines on the role of non-surgeons in the MIS SIJF treatment algorithm for patients with SI joint disease.

Aside from this study, the only other study investigating the role of pain management physicians in performing MIS SIJF for SI joint disease is a clinical trial featured on ClinicalTrials.gov, termed the

PainTEQ study. Led by a pain management physician principal investigator, the PainTEQ study is a prospective, multi-site, single arm study designed to collect patient reported outcomes data following the MIS posterior SIJF procedure in 100 patients with SI disease.[33] The study began enrolling patients in early 2020 and is expected to reach completion by March 2022.[33] Until data from this study is subject to peer-review and ultimately published, there is no peer-reviewed evidence available within the medical literature on conduct of MIS SIJF by non-surgeons and therefore no way to assign levels of evidence for the purpose of formulating recommendations on the role of non-surgeons in performing MIS posterior SIJF. By contrast, there are multiple MIS SIJF approaches performed by spine surgeons – as well as multiple studies investigating each approach – which have been assigned varying levels of evidence (highlighted in the present review) that have factored into recommendations made regarding the indications for MIS SIJF performed by spine surgeons.

Furthermore, this contrast in available levels of evidence may be interpreted in light of the Position Statement offered by the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) on “arthrodesis of the spine by the non-spine surgeon”.[5] This Position Statement, set forth by the Joint Section on Disorders of the Spine and Peripheral Nerves in August 2021, emphasizes the fact that neurosurgeons and orthopaedic spine surgeons have completed extensive surgical training, rendering them experts in the diagnosis and treatment of disorders requiring instrumentation of the spine or changes to its biomechanics.[5] Furthermore, it stipulates that “non-surgeon spine practitioners…are valuable members of the spine care team” who can play an instrumental role in the diagnosis and treatment of various spinal pathologies, but who should not engage in operative measures (such as SIJF) that alter the biomechanics of the spine. In summation, the Position Statement maintains that pain management physicians and physiatrists have not undergone the training necessary to properly handle complications associated with spinal instrumentation or to perform the calculated decision-making necessary to achieve optimal surgical stabilization of the spine.[5] Above all, the AANS and CNS emphasize the prioritization of best care practices and patient safety in situations where clinicians must manage surgical diseases of the spine.

# Conclusion

Spine surgeons generally perform lateral or posterolateral MIS SIJF. There are 11 unique FDA approved devices and a total of 33 SIJF devices that are available for MIS SIJF. 10 of these devices have been described in numerous reports. For example, most commonly used by spine surgeons are the Titanium Triangular Implants in the lateral approach, and these have been associated with multiple studies containing level 1, 2, and 4 evidence. By contrast, non-surgeons have only investigated the use of posterior allograft devices in 2 studies, one of which is an incomplete clinical trial and the other of which cites non-peer reviewed abstracts. Ultimately, in line with the AANS/CNS Position Statement that instrumentation of the spine requires extensive surgical training such as that completed by spine surgeons, there is an increasing body of evidence in the literature supporting the performance of MIS SIJF

for SI disease by spine surgeons. However, there is currently no evidence supporting the performance of this procedure by non-surgeons.

## Declarations

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## References

1. Agarwal, N., *Neurosurgery fundamentals*. 2019, Thieme,: New York. p. 1 online resource.
2. Hoy, D., et al., *The global burden of low back pain: estimates from the Global Burden of Disease 2010 study*. Ann Rheum Dis, 2014. **73**(6): p. 968–74.
3. Himstead, A.S., et al., *Trends in Diagnosis and Treatment of Sacroiliac Joint Pathology Over the Past 10 Years: Review of Scientific Evidence for New Devices for Sacroiliac Joint Fusion*. Cureus, 2021. **13**(6): p. e15415.
4. Finley, C.R., et al., *What are the most common conditions in primary care? Systematic review*. Can Fam Physician, 2018. **64**(11): p. 832–840.
5. American Association of Neurological Surgeons, C.o.N.S., *AANS/CNS Position Statement on Arthrodesis of the Spine 8.21.21.* 2021.
6. Falowski, S., et al., *A Review and Algorithm in the Diagnosis and Treatment of Sacroiliac Joint Pain*. J Pain Res, 2020. **13**: p. 3337–3348.
7. Wise, C.L. and B.E. Dall, *Minimally invasive sacroiliac arthrodesis: outcomes of a new technique*. J Spinal Disord Tech, 2008. **21**(8): p. 579–84.
8. Cummings, J., Jr. and R.A. Capobianco, *Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients*. Ann Surg Innov Res, 2013. **7**(1): p. 12.
9. Gaetani, P., et al., *Percutaneous arthrodesis of sacro-iliac joint: a pilot study*. J Neurosurg Sci, 2013. **57**(4): p. 297–301.
10. Kancherla, V.K., et al., *Patient Reported Outcomes from Sacroiliac Joint Fusion*. Asian Spine J, 2017. **11**(1): p. 120–126.
11. Rudolf, L., *Sacroiliac Joint Arthrodesis-MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes*. Open Orthop J, 2012. **6**: p. 495–502.
12. Rudolf, L., *MIS Fusion of the SI Joint: Does Prior Lumbar Spinal Fusion Affect Patient Outcomes?* Open Orthop J, 2013. **7**: p. 163–8.
13. Rudolf, L. and R. Capobianco, *Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants*. Open Orthop J, 2014. **8**: p. 375–83.
14. Sachs, D. and R. Capobianco, *One year successful outcomes for novel sacroiliac joint arthrodesis system*. Ann Surg Innov Res, 2012. **6**(1): p. 13.

15. Sachs, D. and R. Capobianco, *Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients.* Adv Orthop, 2013. **2013**: p. 536128.
16. Sachs, D., et al., *Durable intermediate-to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants*. Med Devices (Auckl), 2016. **9**: p. 213–22.
17. Schroeder, J.E., et al., *Early results of sacro-iliac joint fixation following long fusion to the sacrum in adult spine deformity*. HSS J, 2014. **10**(1): p. 30–5.
18. Vanaclocha-Vanaclocha V, V.-L.F., Sánchez-Pardo M, et al, *Minimally invasive sacroiliac joint arthrodesis: experience in a prospective series with 24 patients*. Journal of Spine, 2014. **3**(5).
19. Darr, E., et al., *Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants*. Med Devices (Auckl), 2018. **11**: p. 113–121.
20. Duhon, B.S., et al., *Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study*. Global Spine J, 2016. **6**(3): p. 257–69.
21. Dengler, J.D., et al., *1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain*. Pain Physician, 2017. **20**(6): p. 537–550.
22. Polly, D.W., et al., *Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction*. Int J Spine Surg, 2016. **10**: p. 28.
23. Araghi, A., et al., *Pain and Opioid use Outcomes Following Minimally Invasive Sacroiliac Joint Fusion with Decortication and Bone Grafting: The Evolusion Clinical Trial*. Open Orthop J, 2017. **11**: p. 1440–1448.
24. Cross, W.W., et al., *Minimally Invasive Sacroiliac Joint Fusion: 2-Year Radiographic and Clinical Outcomes with a Principles-Based SIJ Fusion System*. Open Orthop J, 2018. **12**: p. 7–16.
25. Kube, R.A. and J.M. Muir, *Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery*. Open Orthop J, 2016. **10**: p. 679–689.
26. Cher, D., et al., *Postmarket surveillance of 3D-printed implants for sacroiliac joint fusion*. Med Devices (Auckl), 2018. **11**: p. 337–343.
27. Miller, L.E., W.C. Reckling, and J.E. Block, *Analysis of postmarket complaints database for the iFuse SI Joint Fusion System(R): a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption*. Med Devices (Auckl), 2013. **6**: p. 77–84.
28. Claus, C.F., et al., *Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium versus Cylindrical Threaded Implants: A Comparison of Patient-Reported Outcomes*. World Neurosurg, 2020. **133**: p. e745-e750.
29. Lee, D.W., D.G. Patterson, and D. Sayed, *Review of Current Evidence for Minimally Invasive Posterior Sacroiliac Joint Fusion*. Int J Spine Surg, 2021. **15**(3): p. 514–524.
30. Rajpal, S. and S. Burneikiene, *Minimally Invasive Sacroiliac Joint Fusion with Cylindrical Threaded Implants Using Intraoperative Stereotactic Navigation*. World Neurosurg, 2019. **122**: p. e1588-e1591.

31. Endres, S. and E. Ludwig, *Outcome of distraction interference arthrodesis of the sacroiliac joint for sacroiliac arthritis*. Indian J Orthop, 2013. **47**(5): p. 437–42.
32. Fuchs, V. and B. Ruhl, *Distraction arthrodesis of the sacroiliac joint: 2-year results of a descriptive prospective multi-center cohort study in 171 patients*. Eur Spine J, 2018. **27**(1): p. 194–204.
33. Pope, J., Evolve Restorative Center, *Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device.* 2020, March 13–2022, March 21

# Table 1

| Device Name | Manufacturer | Approach | Device Composition | Graft Compatibility |
|---|---|---|---|---|
| **Catamaran** | Tenon Medical | Posterior allograft | Double-Barreled Hollow Metal Allograft | Yes |
| **CornerLoc** | Fusion Foundation Solutions | Posterior allograft | Bone Allograft | No |
| **LinQ** | PainTEQ | Posterior allograft | Bone Allograft | No |
| **Posterior Si Fusion System** | Omnia Medical | Posterior allograft | Bone Allograft | No |
| **SIFix System** | Nu Tech | Posterior allograft | Bone Allograft | No |
| **TransFasten** | Captiva Spine | Posterior allograft | Bone Allograft | No |

**Table 1.** Overview of devices used by spine surgeons or pain management physicians in minimally invasive posterior SIJF.