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Revision of Failed Sacroiliac Joint Posterior Interpositional Structural Allograft Stabilization with Lateral Porous Titanium Implants: A Multicenter Case Series [Letter]

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Dear editor

We recently read "Revision of Failed Sacroiliac Joint Posterior Interpositional Structural Allograft Stabilization with Lateral Porous Titanium Implants: A Multicenter Case Series", by Kranenburg et al. This small retrospective case series by nine surgeons, with five having conflicts of interest representing the salvage technique manufacturer, and two employees of the same manufacturer, presents a small number of posterior SI fusions that required revision. Although this article provides insights for revision technique, unfortunately there are misleading statements that need clarification, specifically, the presumption that a more invasive lateral approach may be a more effective method of SI joint fusion than a posterior approach. This article does not make this case and an additional perspective is required, given that failures occur with any SI joint fusion method.

This series on SI joint fusion revision presents 37 patients.¹ Based on the CMS database the number of posterior SI joint fusions totals up to 16,250 cases performed in the US by 2020. These 37 revision cases would only represent 0.22% of patients undergoing posterior fusion. This small number is consistent with the adverse events (SAEs) of posterior fusion reported in the SECURE study.² In comparison, the Maude database of SI joint fusion of FDA-cleared devices has 1538 SAEs (2012–2021), nearly all involving the device used to revise the posterior approach in the previously mentioned manuscript. There were three patient deaths, 50% of the SAEs were malposition implants, 58% had nerve root injury, 92% required revision surgery, and more than 50 reported cases of hemorrhages, pelvic fractures, intra-abdominal violations, and non-unions.³ The revision rate for this triangular titanium device has been reported as high as 5.7%.⁴

We were surprised by the authors' reported average pain relief of 89%, well beyond any published data for lateral porous titanium implants⁵ referenced by the authors, with the average pain relief of 64%.⁵

Biomechanical evidence suggests that the posterior approach allows for bony fusion, and distraction alone is not the only mechanism of action.

Finally, in the conclusion section of the article the authors make two unsupported claims. First, they state that structural allograft is being promoted for SI joint fusion against FDA regulations, which is false and not consistent with guidance from the FDA. Secondly, against published evidence regarding the safety and efficacy of SI joint fusion,² they recommend an RCT with a sham arm that is against study design recommendations.

Given the small revision and complication rate with posterior fusion as compared to the lateral method, and similar efficacy, should safer methods be first-line? We would suggest, based on prospective data such as the SECURE study by Calodney et al, that the risk-benefit profile favors a posterior approach.² Further long-term studies are needed, but clearly less invasive methods may reduce cost and complications, making posterior SI fusion not only viable but preferred.

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Disclosure

Dr Timothy R Deer reports personal fees for consulting from Painteq and Cornerloc, outside the submitted work. He also owns stock options from these companies. Dr Douglas P Beall is consultant for Medtronic and Companion Spine, and he reports grants from Genesys, during the conduct of the study. Dr Steven M Falowski reports personal fees for consulting from CornerLoc, Aurora, Abbott, Saluda, Vertiflex, Vertos, Surgentec, Mainstay, Relievant, and Medtronic. He also owns stock from PainTeq, outside the submitted work. The authors report no other conflicts of interest in this communication.

References

- 1. Kranenburg A, Garcia-Diaz G, Cook JH, et al. Revision of failed sacroiliac joint posterior interpositional structural allograft stabilization with lateral porous titanium implants: a multicenter case series. *Med Devices*. 2022;15:229–239. doi:10.2147/MDER.S369808
- Calodney AK, Azeem N, Buchanan P, et al. Six month interim outcomes from SECURE: a single arm, multicenter, prospective, clinical study on a novel minimally invasive posterior sacroiliac fusion device. *Expert Rev Med Devices*. 2022;19(5):451–461. doi:10.1080/17434440.2022.2090244
 Rahl MD, Weistroffer J, Dall BE. Analysis of complications in sacroiliac joint fusions using FDA 510(k) cleared devices. *Clin Spine Surg*. 2022;35 (3):E363–367(5). doi:10.1097/BSD.00000000001264
- 4. Spain K, Holt T. Surgical revision after sacroiliac joint fixation or fusion. Int J Spine Surg. 2017;11:5. doi:10.14444/4005
- Polly DW, Cher DJ, Wine KD, et al.; INSITE Study Group. Randomized controlled trial of minimally invasive sacroiliac joint fusion using triangular titanium implants vs nonsurgical management for sacroiliac joint dysfunction: 12-month outcomes. *Neurosurgery*. 2015;77(5):674–90;discussion 690–1. doi:10.1227/NEU.00000000000088

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