Medical Devices: Evidence and Research

Dovepress

open access to scientific and medical research

Open Access Full Text Article

RESPONSE TO LETTER

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

Andy Kranenburg[1], Gabriel Garcia-Diaz[2], Judson H Cook[3], Michael Thambuswamy[4], Whitney James[5], David Stevens[6], Adam Bruggeman[7], Ying Chen[8], Robyn Capobianco[9], W Carlton Reckling[9], Joel D Siegal[10]

[1]Southern Oregon Orthopedics, Medford, OR, USA; [2]OrthoSpine Advance Health, Inc, Merced, CA, USA; [3]Central Texas Brain and Spine, Austin, TX, USA; [4]Oklahoma Spine & Brain Institute, Tulsa, OK, USA; [5]James Marco Health, Prescott, AZ, USA; [6]Utah Spine Specialists, Bountiful, UT, USA; [7]Texas Spine Care Center, San Antonio, TX, USA; [8]OrthoNeuro Inc, New Albany, OH, USA; [9]SI-BONE Inc, Santa Clara, CA, USA; [10]Key Clinics LLC, Mayfield Heights, OH, USA

Correspondence: Andy Kranenburg, Tel +1 541-864-0263, Email andy.kranenburg@gmail.com

Dear editor

We thank Deer et al for their letter on our manuscript that describes a 37 patient case series of failed SI joint fusion using dorsally placed structural allograft, revised with lateral transfixing devices. While we appreciate the interest in our manuscript, the letter is not a scholarly critique of our work and is unsupported by any literature or regulatory guidance. We disagree with Dr. Deer on several items.

We disagree with Deer's comment that our manuscript presumes that the lateral approach is more effective. Our manuscript did not address this point.

Deer noted that posterior fusion procedures have "similar efficacy" and therefore should be first-line treatments. The authors cite the SECURE study (https://clinicaltrials.gov/ct2/show/NCT04423120) to support this claim of similar efficacy. First, SECURE had different enrollment criteria from the iFuse studies to which it claims equivalence. Second, the SECURE study publication is an unplanned interim analysis, drawing into question any statistical claims related to unadjusted multiplicity. Third, while the SECURE publication claimed non-inferior efficacy results compared to lateral transiliac SI joint fusion, the published SECURE study protocol[1] (available on clinicaltrials.gov) did not include a description of a non-inferiority comparison, and the study publication did not include a typical non-inferiority calculation. A careful read of results shows that efficacy for structural allografts is actually statistically inferior to that for lateral transiliac SI joint fusion (see calculations in Appendix). While a treatment with inferior efficacy results could have a favorable benefit-risk profile, neither the publication nor the Deer letter to the editor has proven such. Finally, the SECURE study protocol does not include any imaging component. The paper by Calodney et al shows a single image slice from a CT scan, one of which shows lucency around the implant. It is unclear if the two images are from the same patient as no imaging results are presented.

Deer et al do not address one of our manuscript's primary concerns, namely the intraarticular placement rate for structural allografts. Many patients in our case series had allografts placed outside of the joint. It is unclear how joint stabilization and fusion could occur when an implant is outside the joint. Our case series raises an important unanswered question (how often does extraarticular placement occur?) that has not been addressed by any structural allograft publication, including the SECURE study. Further, authors claim that placement of structural allografts result in fusion. The SECURE study protocol does not include imaging requirements; thus, it is unclear as to how fusion will be proven.

Received: 2 September 2022
Accepted: 22 September 2022
Published: 18 October 2022

Deer notes a large number (16,250) of cases recorded in the Centers for Medicare and Medicaid Services (CMS) database. The Current Procedural Terminology (CPT) code 27279 is used in the US healthcare system to describe and track minimally invasive SI joint fusion procedures. The code does not currently distinguish between metallic implants and structural allografts, though it requires that devices must "transfix" the joint by passing through the ilium, across the SI joint, and into the sacrum. Recently, the American Medical Association CPT Editorial panel decided that procedures to place intraarticular bone allograft within the SI joint are different from standard lateral transiliac SI joint fusion procedures and should be coded differently. This decision acknowledges inherent differences between the two approaches. Many of the 16,000+ cases were likely lateral transiliac SI joint fusion with metallic devices. Any subsequent calculation based on this figure is inaccurate.

Deer et al compare adverse events from an interim analysis of the SECURE study (60 patient interim study with 6 months of follow up) to complaints in the FDA MAUDE (Manufacturer and User Facility Device Experience) database. Deer et al note that the number of adverse events reported in the SECURE study points to a lower rate than that implied by an analysis of FDA's MAUDE database. This statement is misleading for several reasons. First, our study reports structural allograft events in the experience of a handful of surgeons, whereas MAUDE represents nationwide experience. Second, because structural allografts are marketed as human cell and tissue products (HCT/Ps), and not as medical devices, they are not subject to MAUDE reporting except in unusual circumstances. Third, the authors' use of MAUDE to compare adverse event rates across devices is specifically discouraged by US FDA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm).

Deer et al criticize our statement that allografts are being promoted for SI joint fusion against FDA regulations. Manufacturers of structural allografts commercialize their implants through a regulatory pathway known as human cell and tissue products (HCT/Ps). This pathway is reserved for minimally manipulated tissue that serves basic functions as outlined in an FDA guidance document (https://www.fda.gov/media/109176/download). This pathway allows manufacturers to claim only "homologous" use for their products, ie, use in the

> repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. (https://www.fda.gov/media/109176/download)

This approach is based on the assumption that generic (homologous) use leads to predictable product behavior and does not increase safety and effectiveness concerns. Instead, several manufacturers of structural allografts used for SI joint fusion promote their implants specifically for SI joint fusion. This specific use (joint fusion), as well as the proposed mechanism of action (distraction arthrodesis) is non-homologous. These claims require review by FDA, either as a drug, biologic, or medical device.

Finally, Deer et al criticize our statement regarding the need for properly performed randomized trials by citing results from the interim analysis of the SECURE study. This statement is not supported by any regulatory or society guidelines. We stand by the idea that new medical/surgical interventions need to be confirmed with high-quality clinical science, including long-term follow-up and imaging components. Given the minimally invasive nature of the allograft procedure as well as the subjective nature of pain responses, we believe a sham-controlled trial is needed. Any claim that structural allografts are somehow exempt from standard scientific inquiry is indefensible.

Disclosure

AK reports consulting fees and royalties from a non-study device from SI-BONE, GD reports teaching honoraria from SI-BONE, Inc., JC has nothing to disclose, MT reports consulting fees from CoreLink, WJ reports consulting fees from Abbott Labs and Boston Scientific, DS has nothing to disclose, AB has a contract for teaching or speaking engagements on behalf of SI-BONE, JS reports consulting fees from SI-BONE. RC and WR are employees of a device manufacturer. The authors report no other conflicts of interest in this communication.

Reference

1. 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 Device*. 2022;19:451–461. doi:10.1080/17434440.2022.2090244