



Response to letter by Kersten regarding publication by McEntire *et al.*

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Response to: Kersten RFMR, Öner FC, Arts MP, *et al.* Letter to the editor regarding “Two-year results of a double-blind multicenter randomized controlled non-inferiority trial of polyetheretherketone (PEEK) versus silicon nitride spinal fusion cages in patients with symptomatic degenerative lumbar disc disorders”. *J Spine Surg* 2021;7:249-51.

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From time to time, as Editor-in-Chief, I am asked to respond to articles published in Journal. The Journal recently received a letter to the editor with regards to the publication by McEntire *et al.* (1): two-year results of a double-blind multicenter randomized controlled non-inferiority trial of polyetheretherketone (PEEK) versus silicon nitride spinal fusion cages in patients with symptomatic degenerative lumbar disc disorders. Questions regarding statistical analysis and the ‘right to publish’ were raised. Therefore, a review of the publication in question was undertaken.

The article in question was regarding fusion and clinical outcomes following posterior lumbar surgery (2) using PEEK versus Silicon Nitride (SiN) interbody spacers. The material SiN does have a long and fascinating history in the speciality of spine surgery, being the first biomaterial used for Anterior Lumbar fusion surgery with the longest material follow-up to date (3). The submission by McEntire *et al.* was reviewed by three independent reviewers, and based on their assessment of the submitted content, the article was accepted as published (1). As Editor-in-Chief, I stand by the reviewers with their assessment, and the Journal of Spine Surgery will maintain the online access to the article, and in various publicly available platforms.

In order to maintain integrity of the Journal, a thorough review was undertaken. I have read in detail both publications, McEntire *et al.* (1) and Kersten *et al.* (4), and it should be noted that there are no conflicts of interest, nor

coercion financial or otherwise, in my response to the letter to the editor.

My point-by-point response is as follow:

- (I) *Authorization to publish.* Based on review of original correspondence provided to me, the clinical investigators and sponsoring company had agreed to publish the paper; the clinical investigators waived authorship. I have reviewed communication to that effect in the sponsoring company files.
- (II) *Post hoc-analysis.* The sponsors of the study (SINXT) report that the study was underpowered and had greater than expected patient fall-out. This is a common scenario and difficult for any company/investigator team to predict. I understand that there were discussions regarding the observed upper bounds relating to the minimal detectable difference with the potential for the study being underpowered for the non-conservative, non-inferiority margin. I note the following in the article by McEntire *et al.*: “Using the a priori criteria for non-inferiority (i.e., n=50 patients in each cohort, RMDQ standard deviations of ≤ 4.0 , and a one-sided upper confidence interval of 2.5%), the null hypothesis that SiN is non-inferior to PEEK could not be established. ... The confidence interval... exceeds the non-inferiority margin of 2.6 at each follow-up period.” My response here is that readers of either article should read both

publications, and generate their own opinions with regards to study power and stated results. This will provide the reader with a balanced view of the conclusions based on the (different) statistical analysis of both articles.

- (III) *Ethical reporting.* In keeping with good science and statistical practice, the authors McEntire *et al.* evaluated the study both in accordance with the original protocol, and provided a post hoc analyses based on various studies that were available when the original protocol was developed.

As Editor-in-Chief, my role is to remain non-biased and neutral with any assessment regarding questioned academic integrity, to assess the facts, and provide a response. My position within the Journal is non-biased, non-paid and non-financial and this confers neutrality. In conclusion, the readership of the article in question should read *both publications*, from both Kersten and McEntire, and generate their own opinion/s.

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Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *Journal of Spine Surgery*. The article did not undergo external peer review.

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/jss-2021-1>). RJM serves as an unpaid Editor-in-Chief of *Journal of Spine Surgery* from Sep 2015 to Sep 2025. The author has no other conflicts of interest to declare.

Ethical Statement: The author is accountable for all

aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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