opportunity to react on a subject that is, in our opinion, of important interest for all researchers in this field.

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Reference


To the Editor:


Kleeman et al concluded that recombinant human bone morphogenetic protein-2 (rhBMP-2) can be used safely and effectively as an alternative to autogenous bone graft. No adverse effects were identified in 8 male and 14 female patients who underwent laparoscopic anterior lumbar interbody fusion assisted with rhBMP-2. Contiguous ossification was seen in all patients at 6-month follow-up without evidence of motion or lucent zones at the implant–bone interface in the study conducted under a Food and Drug Administration (FDA) approved device exemption (IDE). The favorable results of the study were included in the original FDA approval for rhBMP-2.2

Recently, Toth et al3 mentioned in their response that there were instances of resorption in the series of patients with the titanium trapezoidal fusion cages used to gain the original FDA approval. Additionally, Sasso et al4 mentioned in their response that laparoscopic technique additionally increases the risk of retrograde ejaculations, a complication which occurred in 6.4% of male patients receiving rhBMP-2 during open anterior lumbar interbody fusion in another of 3 IDE trials included in the FDA premarket approval.2

What concerns us is how Kleeman et al are able to comment that none of the mentioned adverse effects was observed among their patients. We are aware that the clinically significant adverse effects, whose occurrence in the IDE trials were confirmed by Toth et al3 and Sasso et al,4 could have occurred only in patients operated at other sites of the nonrandomized, multicenter arm of the IDE study, the data for which remain unpublished. If so, was that the reason why only the data from these centers have not been published yet? Finally, we would appreciate the authors’ opinion as to why there was no mention of the resorptions in the FDA premarket approval?2 It should be emphasized that the incidence of implant displacement/loosening and subsidence (clinical consequences of the resorptions) were greater in the rhBMP-2 group compared to the control group.2

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References


The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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