

30th Annual Trauma Update 2018

BMP/DBM

R. Kumar Kadiyala MD, PhD
Columbia University Medical Center
Dept. Orthopedic Surgery

NewYork-Presbyterian Columbia University DEPARTMENT OF ORTHOPEDIC SURGERY College of Physicians & Surgeons

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Demineralized bone matrix for fracture healing: fact or fiction?

Kinney RC1, Ziran BH, Hirschorn K, Schlatterer D, Ganey T.

Demineralized bone matrix (DBM) has been touted as an excellent grafting material; however, there are no Level I studies that use DBM alone in humans to back up this claim. DBM functions best in a healthy tissue bed but should be expected to have little impact in an anoxic or avascular tissue bed, a situation often encountered in traumatic orthopaedic pathologies. Moreover, there is some evidence of differential potencies of DBM preparations based on donor variability and the manufacturing process. DBM efficacy may also be related to its formulation and the various carriers used. The fact that DBM is an allogeneic material opens up the potential for disease transmission. In addition, DBM activity may be altered by the hormonal status or nicotine use of a patient. In summary, although DBM has proven effective for bone induction in lower form animals, the translation to human clinical use for fracture healing, and the burden of proof, remain

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YODA

These reports were published in June of 2013^{40,41}. Both groups independently performed an analysis that included an aggregate of all individual patient data—an analysis that typically is not performed during the FDA approval process, but that provides increased sensitivity for the identification of rare complications. The analysis of the aggregate individual patient data was compared with a meta-analysis of the published clinical trials, and to a meta-analysis of the confidential clinical trials reports from each of the seventeen Medtronic-sponsored clinical trials that were submitted to the FDA. The aggregate data suggested a higher incidence of complications^{40,41}. The data further showed that while BMP is effective, it does not result in an incidence of spine fusion that is higher than what has been associated with traditional treatment, with use of autologous iliac crest bone graft^{40,41}. The YODA initiative suggests that the original conclusions and the published studies likely overestimated the benefit of BMP. Because this developed into a several billion dollar per year industry, the research was high-stakes, and skepticism developed regarding the integrity of the company and of the involved investigators, many of whom had financial relationships with Medtronic.

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Orthobiologics in Spine

Finally, it is my opinion that the predominant reason for avoiding ICBG is that it is simply more convenient and less work for the surgeon. We surgeons are all occasionally guilty of using new technology in the operating room because of convenience when, in fact, doing so may have no bearing on surgical outcomes.

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Until these questions are answered, surgeons should aim for an optimal healing environment when placing the BMP: reasonable mechanical stability, ample soft tissue coverage, no or minimal infection and reasonable blood supply, McKee said. Surgeons must also inform patients of the involved risks whenever using BMPs off-label, Obremsky said.

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For this reason, "You don't want to use [BMP] indiscriminately," McKee said. "You want to pick who's going to benefit from it. And most of the research that we do is trying to identify how it works, where it works best and when especially to use it.

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