

CLINICAL PERFORMANCE AND OPTIUM DBM

Background: Use of Demineralized Bone Matrices (DBMs) and Glycerol-Carrier

There is a long history of glycerol-carrier demineralized bone matrices (DBM), such as Grafton® (Osteotech, Inc.) and Optium DBM® (LifeNet Health) used in Orthopaedic procedures. Here, human clinical evidence related to this class of implants is reported.

What does the clinical evidence say?

In a study by Cammisa, et al.¹, “120 patients underwent posterolateral spine fusion with pedicle screw fixation and bone grafting. Iliac crest autograft was implanted on one side of the spine and a [glycerol-carrier DBM]/autograft composite was implanted on the contralateral side.” In this study, “Nearly 70% of patients (81 of 120) provided complete 24-month radiographic studies. The bone graft mass was fused in 42 cases (52%) on the [glycerol-carrier DBM] side and in 44 cases (54%) on the autograft side.” In conclusion, the authors state “**[glycerol-carrier DBM] can extend a smaller quantity of autograft than is normally required to achieve a solid spinal arthrodesis.**”

Kang, et al.² published a randomized, multi-center study that investigated glycerol-carrier DBM in 28 patients and iliac crest bone graft (ICBG) in 13 patients for a single-level instrumented posterior lumbar fusion. After a two year follow-up, the authors found similar fusion rates between the two groups. Furthermore, the authors concluded “**the [glycerol-carrier DBM] group showed slightly better improvement in ODI [Oswestry Disability Index]...consistently higher physical function scores at 24 months...[and] there was a statistically significant greater mean intraoperative blood loss in the ICBG group.**”

In a prospective study, Park, et al.³ treated 31 patients “with ACDF [anterior cervical discectomy and fusion] using the PEEK [polyetheretherketone] cage and DBM [Glycerol-carrier DBM]... at 42 levels,” including 1, 2, and 3 levels. After a 12 month follow-up, the authors noted “**using the Solis cage packed with [glycerol-carrier DBM] demonstrated good clinical and radiologic outcomes... [and] is a safe and effective alternative to the gold standard of autologous iliac bone grafts.**”

In a study reported by Sassard, et al.⁴ “Mineralization and integrity of the bone graft mass were evaluated among patients having posterolateral fusion. Grafting consisted of a composite of [glycerol-carrier DBM] and “local” autologous bone (n=56) or iliac crest autograft alone (n=52). Mineralization was rated radiographically at baseline and at 3, 6, 12, and 24 months. Integrity was judged as fused or not fused. Mineralization ratings did not differ significantly between groups at any postoperative interval (P values

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of .25-1.00). **The percentage of patients fused was similar in both groups** (60% and 56% **for glycerol-carrier DBM and controls**, respectively; P=.83).”

Thalgott, et al.⁵ reported on treating “difficult to fuse patients, such as smokers [and] elderly patients with poor bone quality” who required posterolateral fusion. As an alternative to autogenous fusion, the authors used coralline hydroxapatite in 40 patients along with glycerol-carrier DBM “as a bone graft extender” in 28 of these patients (70%). The authors found an overall fusion rate of 89.3% in the patients that received [glycerol-carrier DBM]. **The high fusion rate is especially significant when the challenging patient population is taken into account.**

Weinzapfel, et al.⁶ performed a study “To compare fusion rates between allograft bone and [glycerol-carrier DBM] following VATS using standard standing lateral spine radiographs.” In studying 40 patients with one or more year follow-up with morselized graft and 28 with [glycerol-carrier DBM], “interbody fusion was assessed on standing lateral radiographs using the Newton et al. 4-level grading scale.” They found “60 of 73 disc spaces (82%) in the Allograft group and 100 of 109 disc spaces (92%) in the [glycerol-carrier DBM] group were rated as radiographically fused” and concluded that “Demineralized bone matrix **([glycerol-carrier DBM]) seem to be an effective bone graft substitute in thoracoscopic surgery for idiopathic scoliosis.**”

Hamadouche et al.⁷ described their technique and preliminary results for “major acetabular reconstruction using the Kerboull acetabular reinforcement device with allograft bone and [glycerol-carrier] DBM.” The authors’ technique is based on the glycerol-carrier DBM, which they describe as “easy to handle and place in [the] acetabular cavity.” In conclusion, the authors state **“that fibre-based [sic] DBM could enhance allograft bone incorporation and remodeling in major acetabular reconstruction.”**

In a study published by Pieske et al.⁸, “twenty patients had ununited diaphyseal fractures of long bones and were treated by ORIF [open reduction and internal fixation] combined either by ICABG [iliac-crest-autologous-bone-grafting] (n = 10) or DBM-augmentation [demineralized-bone-matrix] (n = 10).” After a multi-year follow up, the authors concluded “that the application of [glycerol-carrier] DBM compared to ICABG **led to an advanced outcome in the treatment of non-unions and simultaneously to a decreased quantity of adverse effects.**” Furthermore, **“patients treated with [glycerol-carrier] DBM were more satisfied with the surgical procedure (p = 0.031).”**

Thoradarson and Kuehn⁹ investigated “Sixty-three patients who underwent complex ankle or hindfoot fusion” and were divided into two groups. One group received a glycerol-carrier demineralized bone void filler while the other received a demineralized bone bone void filler, OrthoBlast[®], in a reverse phase medium to stimulate fusion. The authors found similar fusion rates in both groups “compared to historical

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controls [10%]" and **it should be noted these comparable rates of fusion were reached without the donor site morbidity and pain of autografts.**

DBMs using Glycerol as a carrier have extensive, published clinical history and have proven effective in bone void filling applications.

References:

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*The clinical studies reported here used Grafton[®] DBM