

LIFENET HEALTH READIGRAFT® BLX DBM PUTTY VERSUS A DBM WITH A GLYCEROL CARRIER IN A POSTEROLATERAL FUSION STUDY

SILVIA CHEN, PHD; SHERRY TRIPLETT, BS; ANDREW COTTER, BS

Introduction:

A posterolateral fusion study, using athymic rats, was conducted at an independent laboratory under GLP guidelines in order to assess the osteoinductivity of LifeNet Health’s new Readigraft BLX DBM Putty. This study assessed the radiographic and histological performance of BLX Putty, and the results were compared against a predicate control, comprised of DBM in a glycerol carrier, at four and eight weeks.

Materials and Methods:

The graft materials were assessed for bone healing efficacy in the athymic rat posterolateral fusion (PLF) model. This model has been extensively characterized to ensure that there are not instances of spontaneous fusion, and instead that the fusion results from the osteogenic, osteoconductive and/or osteoinductive nature of the graft materials.¹⁻² The transverse processes of the L4 and L5 vertebral body were exposed and decorticated. The defect site was then filled with either BLX Putty or DBM in a glycerol carrier (DBM+Glycerol). The DBM+Glycerol graft material is a commercially available product.

After four and eight weeks post-implantation, the tissue was removed *en bloc* and the soft tissue trimmed prior to placing each spinal segment in 10% neutral buffered formalin. The excised tissues were Faxitron imaged and scored using a five point scale wherein a score of 1-5 represented 1-25%, 26-50%, 51-75%, 76-99%, and 100% fusion, respectively. Each site was then paraffin embedded, sectioned (4 - 5 μm), and stained in hematoxylin and eosin for microscopic evaluation. Microscopic examination of the slides, at magnification ranges of 15X to 400X, was performed to assess bridging and new bone formation.

Results:

Radiographic analysis at four and eight weeks suggests that animals treated with BLX Putty demonstrated more pronounced defect healing than those treated with DBM+Glycerol (Figures 1-2).

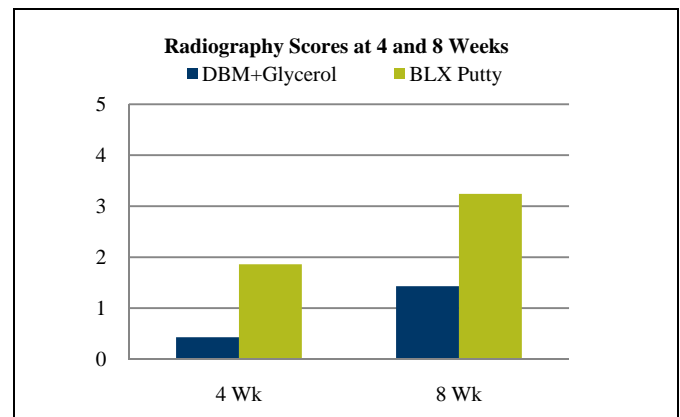


Figure 1: Animals treated with BLX Putty received higher radiography scores after four and eight weeks of implantation than compared to animals treated with DBM+Glycerol.

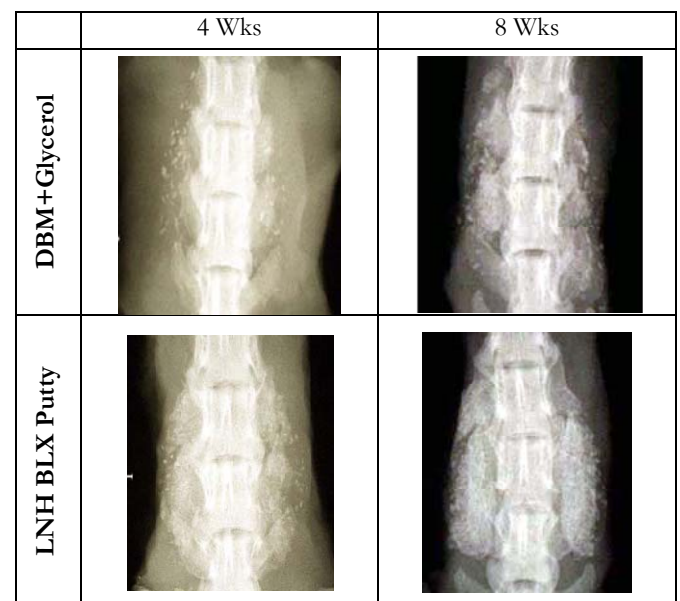


Figure 2: Defect healing is more prominent for BLX Putty than DBM+Glycerol after eight weeks of implantation. Note the consistency of the fusion mass for the BLX Putty at eight weeks.

Histological analysis was performed at four and eight weeks, and specimens were evaluated for bridging and new bone formation. Bridging was assessed using a four point scale wherein a score of 1-4 represented 1-25%, 26-50%, 51-99%, and 100% bridging across the defect area, respectively. New bone formation was also assessed using a four point scale wherein a score of 1-4 represented 1-25%, 26-50%, 51-75%, and 76-100% new bone within the defect area, respectively. Both BLX Putty and DBM+Glycerol demonstrated new bone formation, but the BLX Putty remodeled more quickly, and achieved greater levels of new bone formation and bridging after four and eight weeks (Figures 3-4). In fact, all animals treated with BLX Putty achieved complete histological bridging by eight weeks. The new bone was identified as predominantly bone marrow with areas of lamellar bone, woven bone, and cartilage. The presence of cartilage among the new bone elements suggests that the new bone was formed through endochondral ossification.³ Representative histological images are given in Figures 5-6.

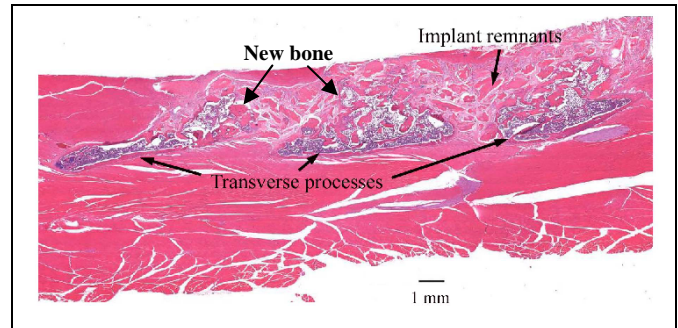


Figure 5: Representative histological image of a DBM+Glycerol treated animal showing a small amount of new bone formation consisting predominantly of bone marrow. Note the incomplete bridging and presence of implant remnants between transverse processes.

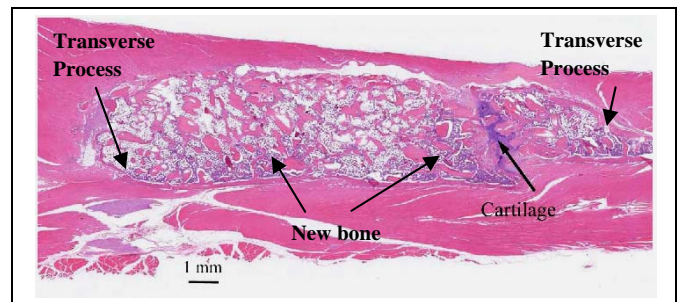


Figure 6: Representative histological image of a BLX Putty treated animal showing new bone formation consisting predominantly of bone marrow; an area of cartilage is also present. Note the complete bridging.

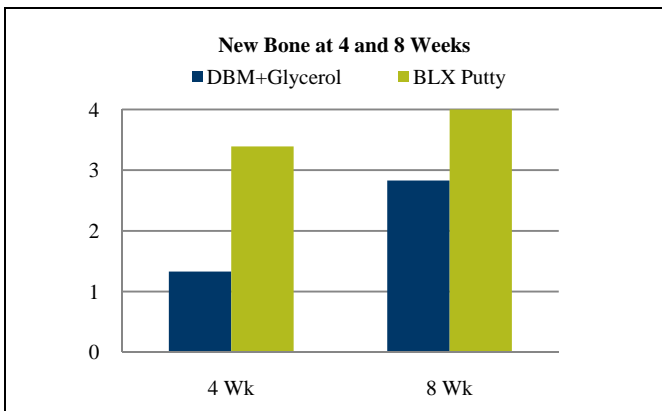


Figure 3: BLX Putty achieved greater histological scores for new bone formation after four and eight weeks.

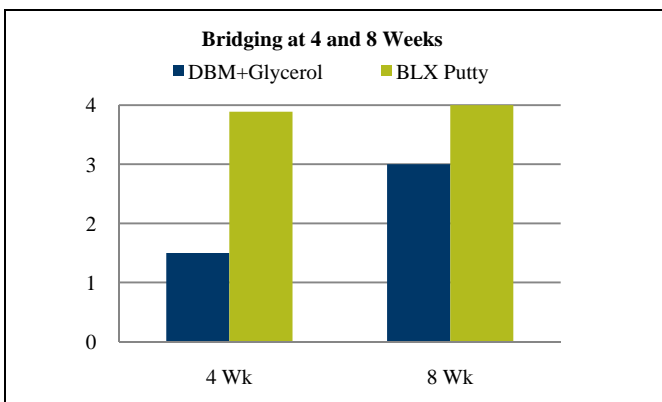


Figure 4: BLX Putty achieved greater histological scores for bridging after four and eight weeks.

Conclusion:

LifeNet Health’s Readigrift BLX DBM Putty demonstrated efficacious performance in the well-established and validated posterolateral fusion model. The BLX Putty treated animals achieved complete histological bridging by eight weeks, and demonstrated more pronounced defect healing than the DBM+Glycerol treated animals after four and eight weeks of implantation. This was evidenced by greater scores obtained through radiographic and histological assessments.

References:

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2. Wang JC, Alanay A, Mark D, et al. A comparison of commercially available demineralized bone matrix for spinal fusion. *European Spine Journal*. 2007; 16(8): 1233-1240.
3. Lu SS, Zhang X, Soo C, et al. The osteoinductive properties of Nell-1 in a rat spinal fusion model. *The Spine Journal*. 2007; 7(1): 50-60.

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