# LifeNet Health Readigraft® BLX DBM Putty Versus a DBM with a Glycerol Carrier in a Critical Sized Calvarial Defect Study

Silvia Chen, PhD; Ashley Bowman, BS; Andrew Cotter, BS

**Introduction:**

A critical sized calvarial defect 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:**

An 8 mm calvarial defect was created in the athymic rat and filled with either BLX Putty or DBM+Glycerol. This model is a well-established and validated model for testing the osteoregenerative capacity of bone substitutes wherein an 8 mm defect in the rat calvaria will not spontaneously heal without treatment.[1-2] The defect site was then filled with either BLX Putty or DBM in a glycerol carrier (DBM+Glycerol).

After four and eight weeks post-implantation, the calvaria (including implant material, host bone, surrounding attached tissue, brain tissue, and adhering dura) was harvested from each animal and placed in 10% neutral buffered formalin. The excised tissues were Faxitron imaged and scored for mild, moderate, or complete defect healing which was represented by a three point scale. After imaging, each explant was bisected coronally at the midline. The posterior half of the explant was decalcified and embedded in paraffin. One thin (4-5 µm) cross-section was taken from each explant block and stained with hematoxylin and eosin (H&E). 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 the DBM+Glycerol (Figures 1-2).

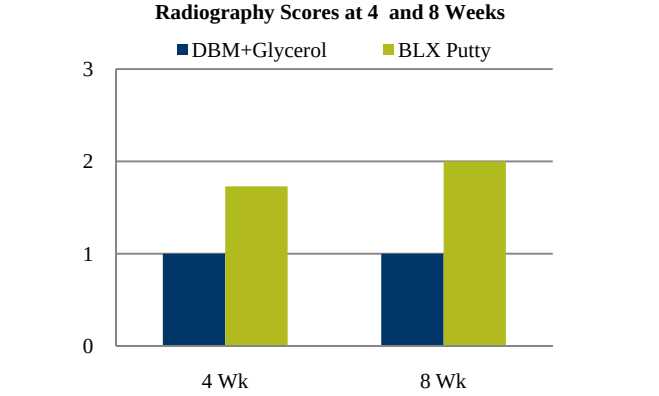


**Figure 1:** BLX Putty received higher radiography scores after four and eight weeks of implantation compared to the DBM+Glycerol.

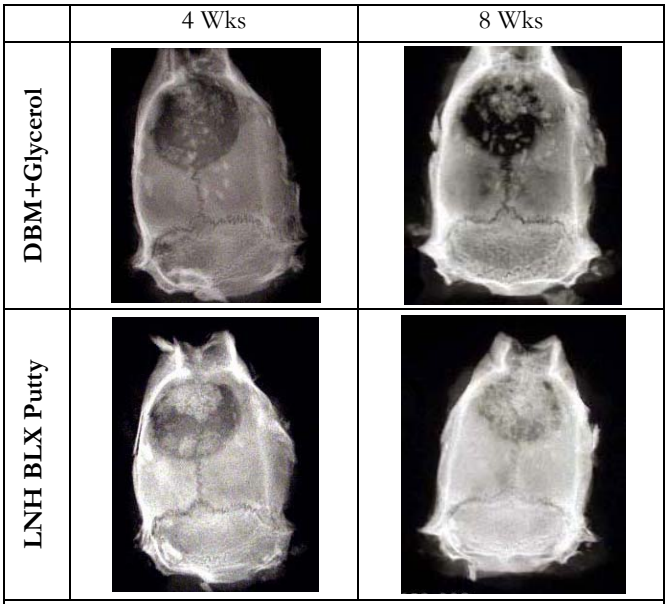


**Figure 2:** Defect healing is more prominent for BLX Putty than DBM+Glycerol after eight weeks of implantation.

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 the DBM+Glycerol demonstrated new bone formation, but the BLX Putty achieved greater levels of new bone formation and bridging after eight weeks of implantation (Figures 3-4). The new bone was identified as predominately lamellar and woven bone and occasionally contained areas of bone marrow. The predominance of lamellar and woven bone is consistent with the literature, which suggests that calvaria bone forms through intramembranous ossification.[3] Representative histological images are given in Figures 5-6.

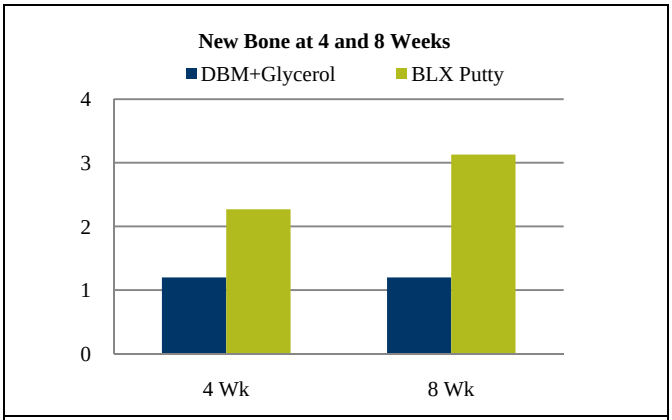


**Figure 3:** BLX Putty achieved greater histological scores for new bone formation after eight weeks of implantation.

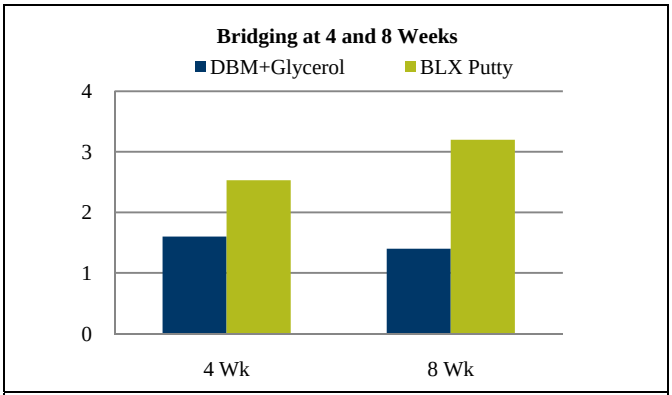


**Figure 4:** BLX Putty achieved greater histological scores for bridging after eight weeks of implantation.

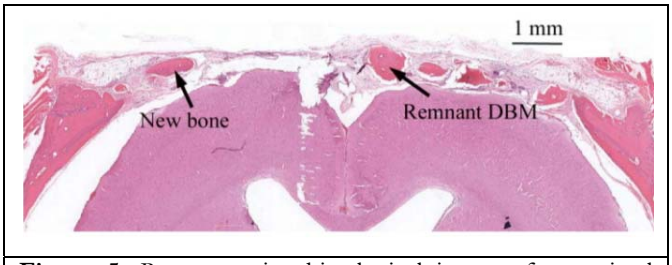


**Figure 5:** Representative histological image of an animal treated with DBM+Glycerol showing a small amount of new bone formation consisting of lamellar and woven bone. A small amount of remnant DBM is also present. Note the incomplete bridging.

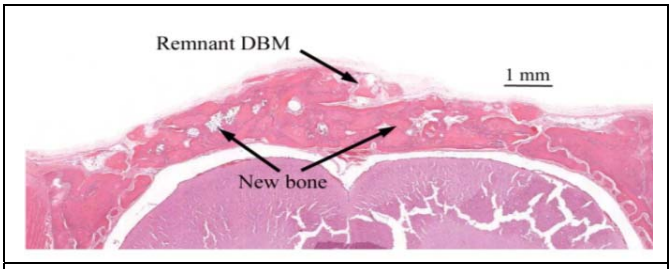


**Figure 6:** Representative image of an animal treated with BLX Putty showing new bone formation consisting of lamellar and woven bone. A small amount of remnant DBM is also present. Note the complete bridging.

## Conclusion:

LifeNet Health's Readigraft BLX DBM Putty demonstrated efficacious performance in the well-established and validated calvarial defect model. The BLX Putty produced predominately lamellar and woven bone and demonstrated more pronounced defect healing than the DBM+Glycerol after eight weeks of implantation. This was evidenced by greater scores obtained through radiographic and histological assessments.

## References:


1. Acarturk TO, Hollinger JO. Commercially available demineralized bone matrix compositions to regenerate calvarial critical-sized bone defects. Plastic and Reconstructive Surgery. 2006; 118(4): 862-873.

2. Hollinger JO, Kleinschmidt J. The critical size defect as an experimental model to test bone repair materials. Journal of Craniofacial Surgery. 1990; 1(1): 60-68.

3. Glatt V, Kwong FN, Park K, et al. Ability of recombinant human bone morphogenetic protein 2 to enhance bone healing in the presence of tobramycin: evaluation in a rat segmental defect model. Journal of Orthopaedic Trauma. 2009 Nov-Dec;23(10):693-701.


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