

# LIFENET HEALTH READIGRAFT® BLX DBM PUTTY VERSUS AUTOGRAFT IN A CRITICAL SIZED CALVARIAL DEFECT STUDY

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## 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 an autograft control group at four and eight weeks.

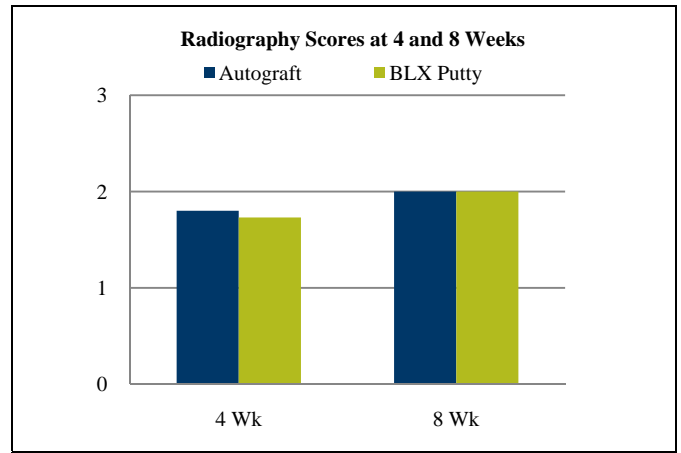
## Materials and Methods:

An 8 mm calvarial defect was created in the athymic rat and filled with either the test article (BLX Putty) or autograft. 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.<sup>1-2</sup> The test article was provided in ready-to-use aliquots, while the autograft control consisted of bone harvested from the calvarial defect, which was finely morselized and implanted back into the defect of origin.

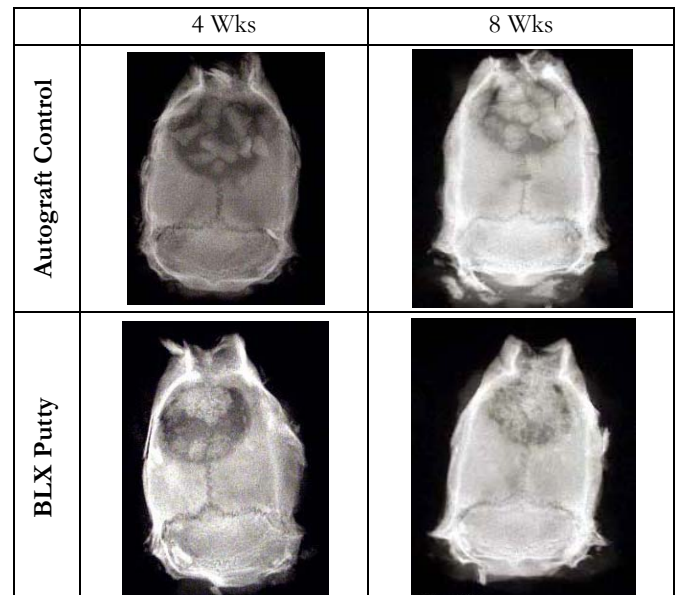
After four and eight weeks post-implantation, the calvaria (including implant material, host bone, surrounding attached tissue, brain tissue, and adhering dura) was harvested from each animal and placed in 10% neutral buffered formalin. The excised tissues were Faxitron imaged and scored for mild, moderate, 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 showed similar defect healing among animals treated with autograft and those treated with BLX Putty (Figures 1-2).

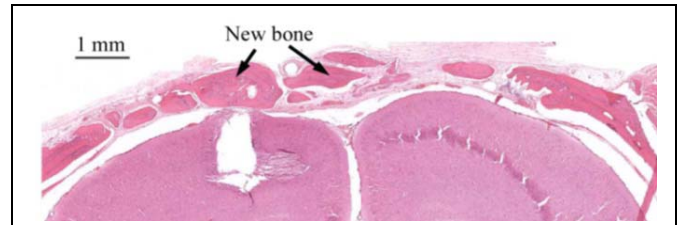


**Figure 1:** Similar radiography scores were achieved between autograft and BLX Putty after four and eight weeks.

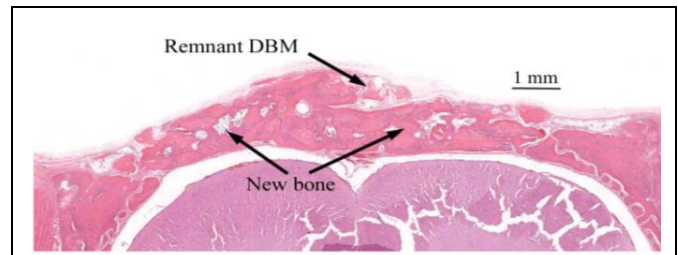


**Figure 2:** Defect healing is proceeding similarly for autograft and BLX Putty after four and eight weeks.

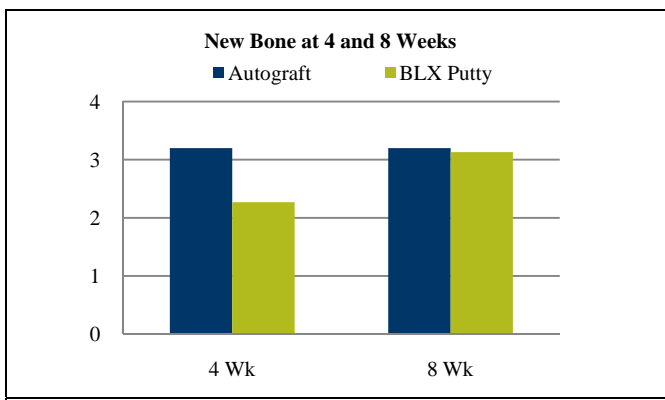
Histological analysis was performed at four and eight weeks, and specimens were evaluated for bridging and new bone formation. Bridging was assessed using a four point scale wherein a score of 1-4 represented 1-25%, 26-50%, 51-99%, and 100% bridging across the defect area, respectively. New bone formation 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 autograft and BLX Putty demonstrated new bone formation and achieved similar levels of 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.<sup>3</sup> Representative histological images are given in Figures 5-6.



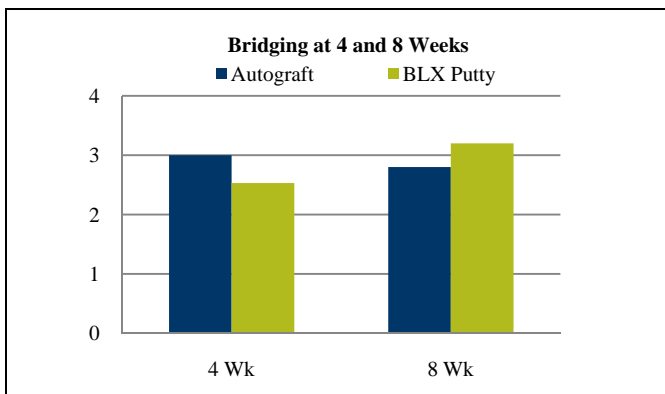
**Figure 5:** Representative histological image of autograft treated animal showing new bone formation consisting of lamellar and woven bone. Note nearly complete bridging.



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



**Figure 3:** Similar histology scores were achieved for new bone formation after eight weeks of implantation.



**Figure 4:** Similar histology scores were achieved for bridging after eight weeks of implantation.

**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 equivalence to autograft after eight weeks of implantation. This was evidenced by similar scores obtained through radiographic and histological assessments.

**References:**

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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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