LIFENET HEALTH READIGRAFT® BLX DBM PUTTY VERSUS AUTOGRAFT IN A POSTEROLATERAL FUSION STUDY

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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 to an autograft control group 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 the test article (BLX Putty) or autograft. Due to the size of the defect and the similarities among the strain of athymic rats, the iliac crest from multiple donor rats were morselized and placed into the defect to represent an autograft control.

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 decalcified, 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 showed similar defect healing among animals treated with autograft and those treated with BLX Putty (Figures 1-2).

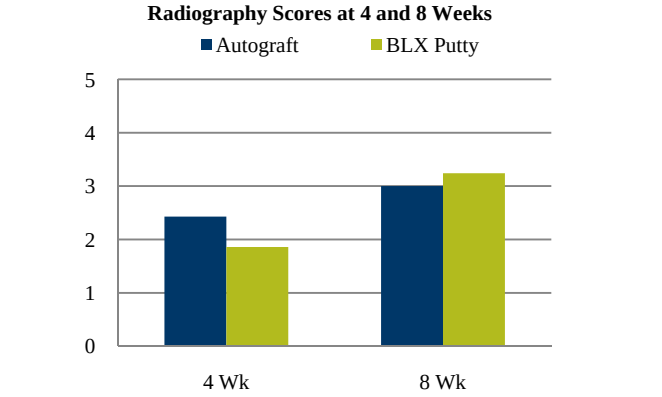

Figure 1: Similar radiography scores between autograft and BLX Putty were achieved after four and eight weeks of implantation.

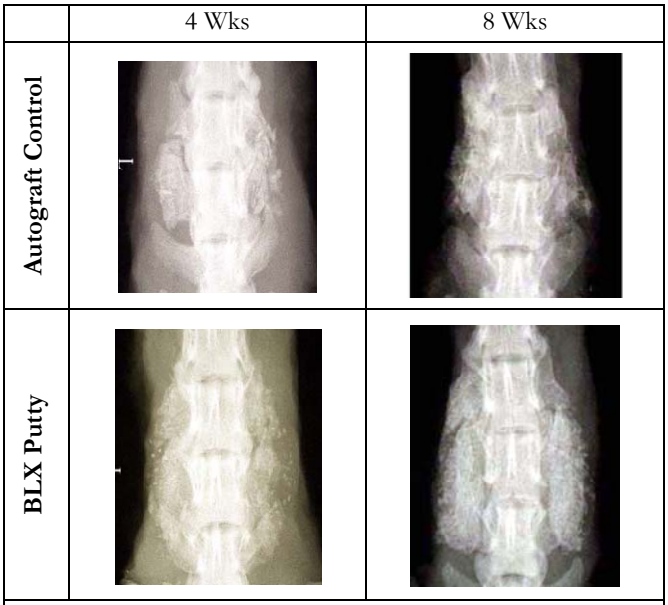

Figure 2: Defect healing is proceeding similarly for autograft and BLX Putty after four and eight weeks.

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 four and eight weeks of implantation (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.

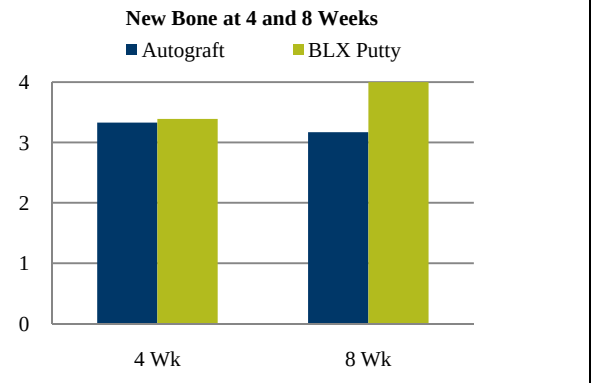

Figure 3: Similar histology scores were achieved for new bone formation after four and eight weeks of implantation.

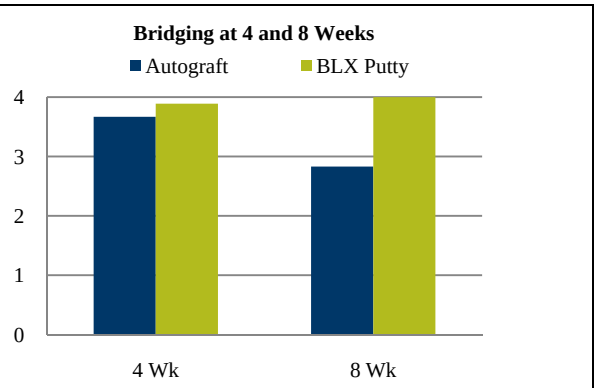

Figure 4: Similar histology scores were achieved for bridging after four and eight weeks of implantation.

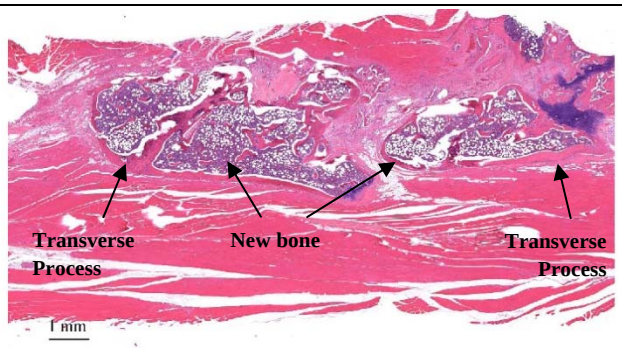

Figure 5: Representative histological image of an autograft treated animal showing new bone formation consisting predominantly of bone marrow. Note the nearly complete bridging.

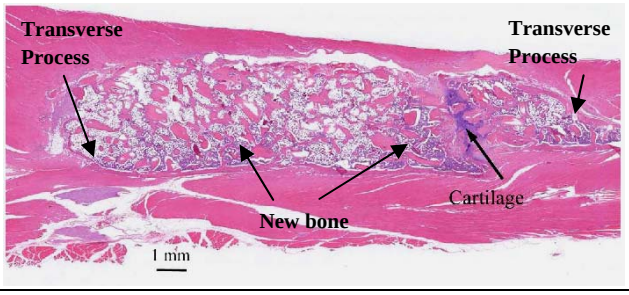

Figure 6: Representative histological image of a BLX Putty treated animal showing new bone formation consisting predominantly of bone marrow; an area of cartilage is also present. Note the complete bridging.

Conclusion:

LifeNet Health's Readigraft 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 equivalence to autograft after four and eight weeks of implantation. This was evidenced by similar scores obtained through radiographic and histological assessments.

References:

1. Grauer JN, Bomback DA, Lugo R, et al. Posterolateral lumbar fusions in athymic rats: characterization of a model. The Spine Journal. 2004; 4(3): 281-286.

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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