ReBOSSIS®: The Only Biosynthetic Scaffold with Electrospun Microfiber Construction

Electrospun PLGA and β-TCP (ReBOSSIS-85) in a Rabbit Model of Posterolateral Fusion

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Introduction

Calcium phosphate materials have been used clinically as bone void fillers for several decades. These materials are usually small, porous granules that can be packed to fill bony defects of various shapes and sizes. ReBOSSIS-85 (RB-85) is a synthetic, bioresorbable bone void filler with handling characteristics similar to those of cotton or glass wool. In this study, we assessed the in vivo performance of RB-85 and of a commercial bone void filler, MASTERGRAFT® Putty (Medtronic). We compared the efficacy of each product when combined with bone marrow aspirate and iliac crest bone graft (ICBG) in an established posterolateral spine fusion rabbit model.

Method

In total, 150 skeletally mature rabbits underwent single-level posterolateral spine fusion. Rabbits were implanted with ICBG, with MASTERGRAFT® Putty plus ICBG, or with RB-85 (0.2, 0.3, 0.45, or 0.6 g) plus ICBG. Plain radiographs were obtained weekly until the animals were euthanized at 4, 8, or 12 weeks postoperatively. After death, rabbits' lumbar spines were tested by manual palpation. Spinal columns in the 12-week group were also subjected to non-destructive flexibility testing. Micro computed tomography and histology were performed after euthanasia in a subset of animals in each implant group.

Results

Radiographic scoring of the fusion sites indicated normal healing responses in all test groups. Fusion rates for all test groups are summarized in Table 1, and Figure 1 depicts fusion masses at 12 weeks. Spine fusion was assessed by manual palpation of the treated motion segments. At 12 weeks, ICBG, MASTERGRAFT® Putty, and RB-85 (volume of 0.6 g) resulted in mechanical fusion in at least 50% of rabbits. All groups demonstrated significantly less range of motion in flexion/extension, lateral bending, and axial rotation compared to unfused controls. In all test groups, histopathological analysis of the fusion masses indicated an expected normal response of mild inflammation with macrophage and multinucleated giant cell response to the graft material at 4 weeks; this resolved by 12 weeks (Fig. 2). Regardless of the product used, new bone formation and graft resorption increased from 4 to 12 weeks postoperatively.

Table 1. Fusion Rates

Implant material	*Fusion rate at time of death*		
	4 weeks	**8 weeks**	**12 weeks**
ICBG alone	0%	43%	50%
MASTERGRAFT® Putty + ICBG	0%	50%	50%
RB-85 + ICBG			
0.20 g RB-85	0%	0%	0%
0.30 g RB-85	0%	13%	25%
0.45 g RB-85	0%	38%	36%
0.60 g RB-85	0%	63%	50%

Abbreviations: ICBG, iliac crest bone graft; RB-85, ReBOSSIS-85.

Figure 1. Micro computed tomography in the sagittal plane demonstrates fusion masses at 12 weeks post-implantation with (A) iliac crest bone graft, (B) MASTERGRAFT® putty (Medtronic), and (C, D, E, F) ReBOSSIS-85 at volumes of 0.2 g, 0.3 g, 0.45 g, and 0.6 g, respectively.

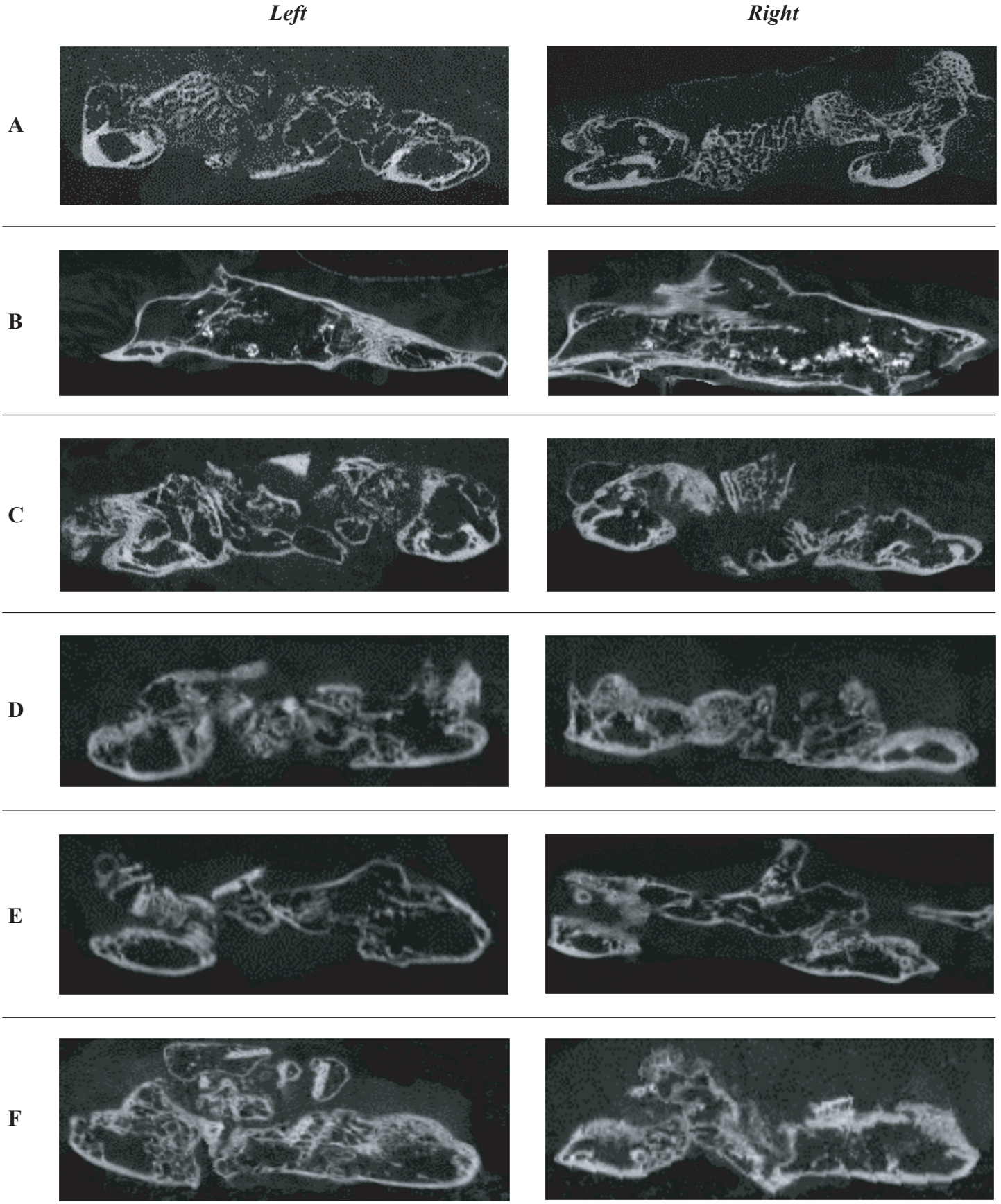


Figure 2. Hematoxylin and eosin staining show histopathological analysis at 12 weeks post-implantation with (A) iliac crest bone graft, (B) MASTERGRAFT® putty (Medtronic), and (C, D, E, F) ReBOSSIS-85 at volumes of 0.2 g, 0.3 g, 0.45 g, and 0.6 g, respectively.

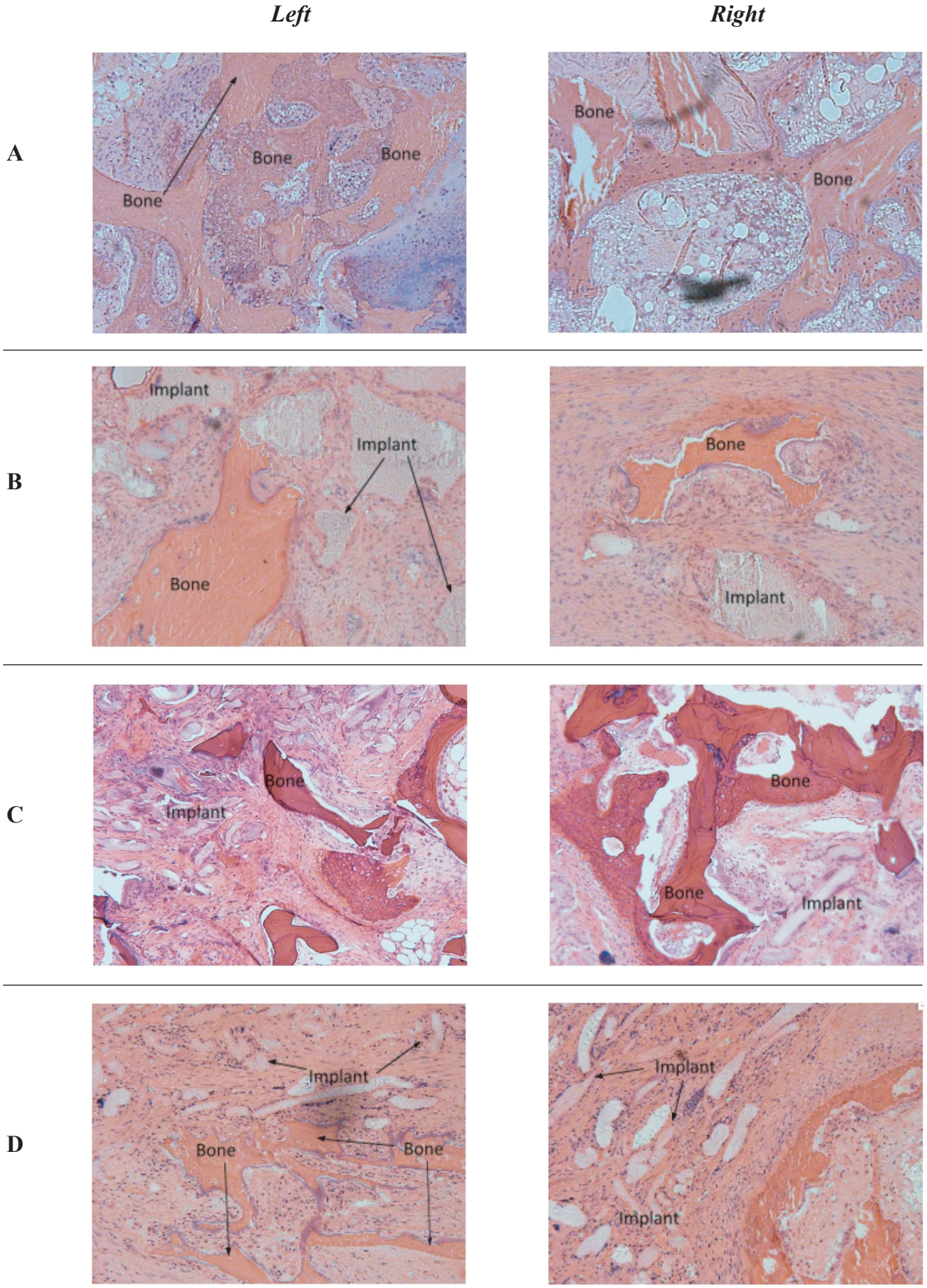
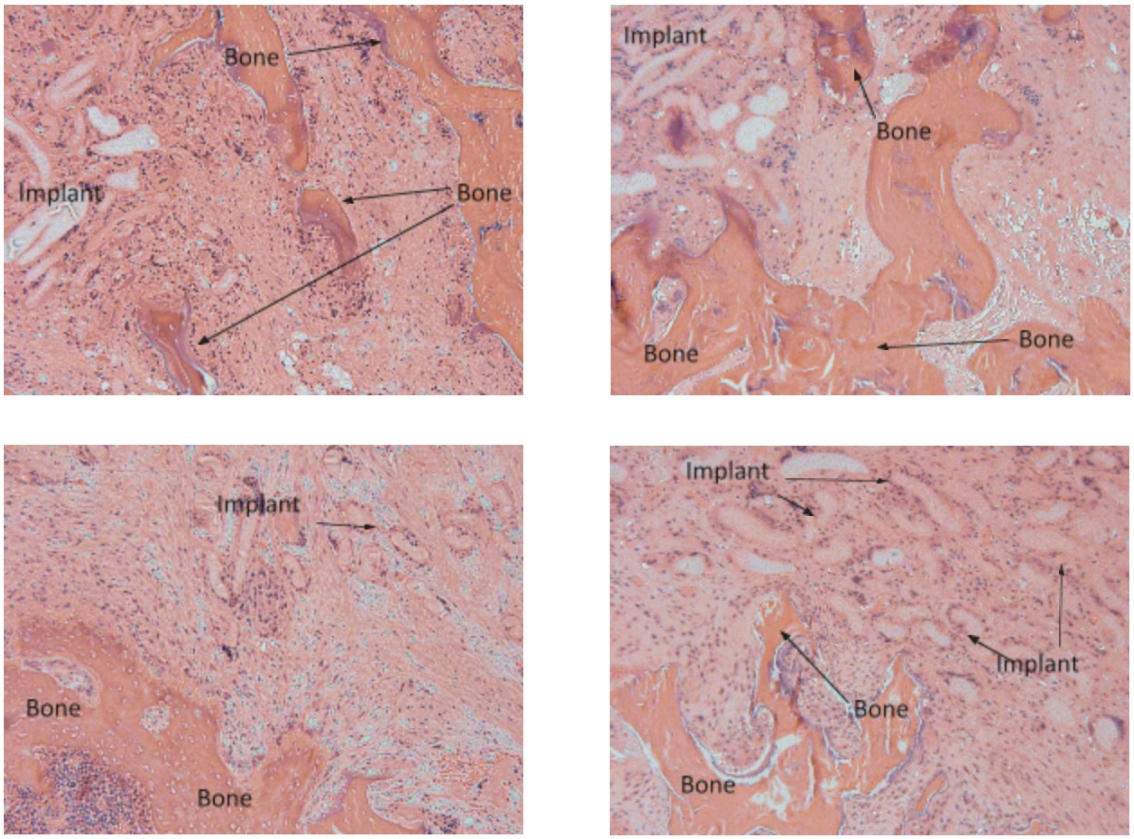


Figure 2. Continued



Conclusions

This animal study demonstrates the biocompatibility and normal healing features associated with the ReBOSSIS-85 bone graft when combined with autograft as an extender. ReBOSSIS-85 was more effective in larger volumes (ie, 0.6 g) than in smaller volumes.

Clinical Relevance

ReBOSSIS-85 can be used as an extender in repairing bony defects, negating the need for large amounts of local or iliac crest bone in posterolateral spine fusion procedures.

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