“IN VIVO” ASSESSMENT OF A NEW BIOMATERIAL DEVELOPED IN THE FRAMEWORK OF NANOBIOCOM PROJECT.

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INTRODUCTION

The objective of NANOBIOCOM project was the development of a new porous nanostructured biomaterial for the treatment of critical bone defects, and its in vitro and in vivo evaluation. The experimental model selected was the critical bone defect of radii in rabbits. Three different treatments were selected: autologous implant (as a control), and scaffolds with and without rhBMP-2. Bone defect healing was analysed at 8 and 16 weeks after implantation. Biomechanical, densitometric and histomorphometrical studies were performed.

METHODS

After the implantation time, regenerated bone samples were tested by a non-destructive four-point bending test, and a destructive torsion test. CT analysis was performed in all implanted and intact radii. A 3D morphometry analysis and a densitometric study were carried out. Also, 5-µm sections of undecalcified bone samples were collected to perform histomorphometrical analysis.

RESULTS AND DISCUSSION

Mechanical tests: NANOBIOCOM scaffolds with or without rhBMP-2 were able to regenerate bone in rabbit radius with comparable mechanical strength to autograft-filled defects. Results showed the restoration of bone strength and stiffness in a significantly short time compared with data in the literature. Addition of rhBMP-2 did not clearly improve bone regeneration as some authors stated previously

Densitometry: All groups show higher bone volume values than intact bone at the three analysed zones and it could imply that bone remodelling has not finished even at sixteen weeks. Nanocomposite has allowed a bone formation with similar bone density to the intact bone even at eight weeks. Based on 3D CT reconstructions in nearly all cases a total bone formation was achieved at sixteen weeks and in many cases, good 3D reconstruction is observed at eight weeks.

Histology: Autograft samples show the highest percentage of regenerated bone. However, there is no difference between scaffolds with or without rhBMP-2.

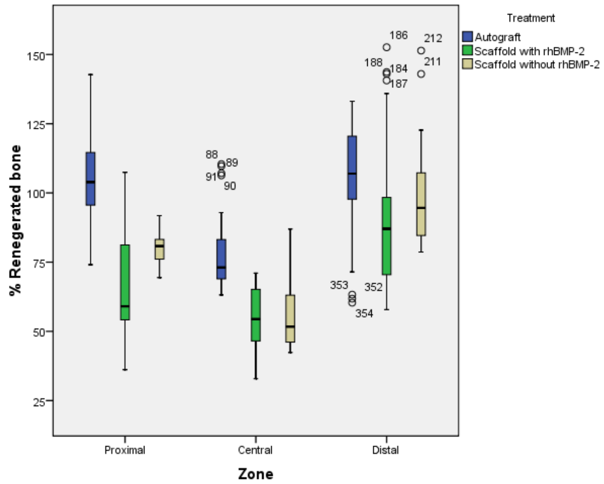

Figure 1: Regenerated bone (%) for each treatment, zone and experimental periods at 8 weeks.

CONCLUSIONS

Mechanical and densitometric behaviour of the new biomaterial is quite similar to autologous implant. However, histomorphometrical data showed a significant difference between scaffolds and autologous implant.

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		Autograft		Scaffold with rhBMP-2		Scaffold without rhBMP-2
		8 Weeks	16 Weeks	8 Weeks	16 Weeks	8 Weeks
Mechanical test	Torque (%)	99,91 ± 25,89	90,65 ± 16,03	80,54 ± 29,92	85,05 ± 18,16	71,01 ± 19,26
	Torsional Stiffness (%)	115,15 ± 36,87	98,85 ± 21,34	69,78 ± 34,92	96,33 ± 23,18	100,47 ± 32,95
	Tenacidad (%)	99,16 ± 33,11	91,19 ± 21,93	109,00 ± 44,92	79,09 ± 23,21	78,15 ± 27,01
Densitometric analysis	Regenerated bone volume at hole defect (%)	146,68 ± 21,66	125,02 ± 7,57	126,44 ± 22,20	119,41 ± 13.01	130,43 ± 18,74
	Average density (mg/mm^3)	1972 ± 82	1951 ± 87	1975 ± 66	1994 ± 64	1958 ± 53
Histomorphometric analysis	Regenerated bone at central zone (%)	84,82 ± 15,42	70,31 ± 7,62	58,51 ± 15,81	51,59 ± 20,60	56,45 ± 24,85

Table 1: Mechanical, densitometric and histomorphometrical parameters