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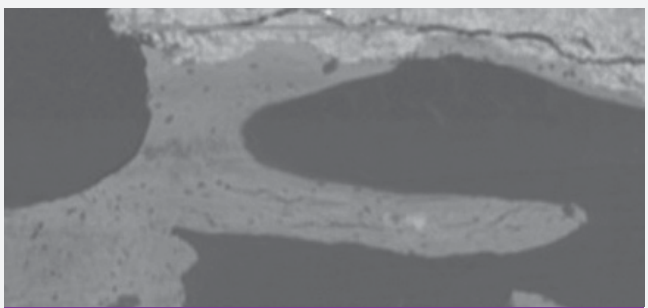
News No. 40 October 2015

Bone Neo-Formation and Mineral Degradation of 4BONE™.



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Bone Neo-Formation and Mineral Degradation of 4BONE™. Part I: Material Characterization and Sem Study in Critical Size Defects in Rabbits.

Jose E. Mate Sanchez de Val[1]; Jose Luis Calvo Guirado[1]; Rafael A. Delgado Ruiz[2]; Gerardo Gomez Moreno[3]; Maria P. Ramirez Fernandez[1]; Georgios E. Romanos[2]

Published in 'Clinical Oral Implants Research', Volume 26, Issue 10, October 2015.

Objectives

This study reports the characterization process and in vivo application of a new highporosity biphasic calcium phosphate (4BONE™ BCH–HA 60%/β-TCP 40%) inserted into the critical size defect of a rabbit tibiae.

Material and methods

Two critical size defects of 6 mm diameter were created in each tibia of 15 New Zealand rabbits, and a total of 60 defects were divided into a test group filled with 4BONE™BCH (n = 30) and a control group (n = 30). The material and the implants were characterized by scanning electron microscope (SEM) fitted with energy-dispersive X-ray spectroscopy (EDX).

Results

The biomaterial's grain size decreased progressively with the graft integration process over the 60-day study period. Element analysis revealed increased percentages of Ca/P (2.86±0.32 vs. 1.97±0.59) in new bone and at the interface ($P < 0.05$). Element mapping showed that Ca and P were concentrated in the medullary and cortical zones in the test group but were concentrated only in cortical zones in the control group.

Conclusions

Critical size defects in a rabbit tibia model can be sealed using this highly porous biphasic calcium phosphate; it supports new bone formation, creates a bridge between defect borders, and facilitates bone in growth.

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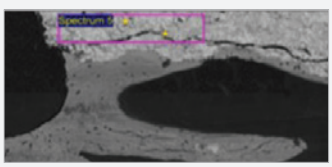
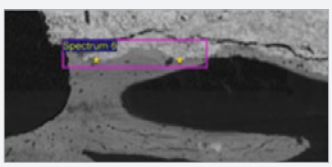
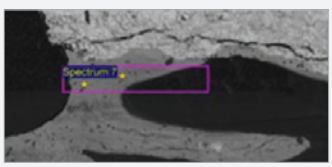
Biomaterial



Interface



New Bone



SEM analysis of samples 60 days after implantation showing biomaterial, interface, and new bone; images show correct integration of the biomaterial and the absence of peripheral gaps surrounding the grafted material. ROI, Region of interest. (*) Element analysis.

Table 1. EDX and Ca/P ratio analysis of biomaterial before implantation and 60 days after implantation. Evaluated as % mean±SD and medians (x). Wilcoxon test was applied to comparison between control and test. P-value established as <0.05 indicating significant difference

	Biomaterial		Interface		New bone	
WT%	Initial	60 days	Initial	60 days	Initial	60 days
Ca	55.32±3.32 (55.32)	58.22±2.68 (58.21)	47.32±1.83 (47.32)	53.43±2.79* (53.42)	61.92±3.01 (61.92)	64.03±1.98* (64.03)
O	19.01±0.93 (19.00)	21.35±1.54 (21.36)	34.67±2.01 (34.67)	19.56±1.30 (19.55)	15.04±1.09 (15.04)	13.59±2.45 (13.58)
P	25.67±1.34 (25.67)	20.43±2.19 (20.43)	18.01±0.68 (18.01)	27.01±1.78 (27.00)	23.04±1.74 (23.04)	22.38±1.43 (22.38)
Ca/P ratio	2.15±0.12 (2.15)	2.84±0.58 (2.83)	2.62±0.13 (2.62)	1.97±0.59 (1.98)	2.68±0.98 (2.68)	2.86±0.32* (2.86)

*Significant difference.

Bone Neo-Formation and Mineral Degradation of 4BONE™. Part II: Histological and Histomorphometric Analysis in Critical Size Defects in Rabbits.

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Published online in 'Clinical Oral Implants Research', Aug. 2014

Objectives

To carry out the histological and histomorphometric plus radiological analysis of biphasic ceramic.

Material and methods

In this study, porous HA/βTCP (4BONE™ BCH) ceramic material was tested for the bone repairing capacity and osteoinductive potential in a New Zealand rabbit model. The ratio of the ceramic's components HA/βTCP was 60/40 (in wt%).

Results

4BONE™ BCH showed significantly more bone formation in the pores and in the periphery of the graft than the control group. Histomorphometric analysis revealed that the ceramic material (66.43%±0.29) produced higher values of bone-to-implant contact (BIC) percentages (higher quality, closer contact); moreover, defect closure was significative higher in relation with control group (64.15%±3.52).

Conclusions

4BONE™ BCH is a biocompatible, partially resorbable and osteoconductive grafting material. Biphasic graft material of HA/βTCP with a porosity of 95% without loading favors new bone formation.

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Table 1. Histomorphometric analysis of new bone ingrowth and defect closure; descriptive measurement of bone-to-implant contact, residual material and resorption rate (%)

	4BONE™ BCH		Control		
	Mean	Median	Mean	Median	*p* Values
BIC (%)	66.43±0.29	66.43	0.00±0.00	0.00	
New bone ingrowth	74.21±2.38*	74.22	32.68±3.97	32.68	0.034
Defect closure	64.15±3.52*	64.15	33.41±2.34	33.42	0.028
Residual biomaterial	35.34±2.75	35.35	0.00±0.00	0.00	
Resorption rate	38.65±3.10	38.65	0.00±0.00	0.00	

*Significant differences $p < 0.05$. Wilcoxon test for related samples. Reported values as mean ±SD and medians (X).

The MIS Quality System complies with International Quality Standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 - Quality Management System and CE Directive for Medical Devices 93/42/EEC. MIS products are cleared for marketing in the USA and CE approved.

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