



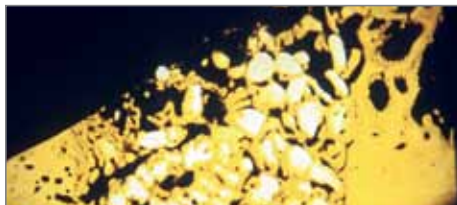
B&B DENTAL
implant company



NOVOCOR[®]
P L U S

HISTOLOGICAL ANALYSIS OF A NOVOCOR PLUS IMPLANT INSERTED IN SHEEP BONE

“FACULTY OF NORMAL HUMAN ANATOMY” of the UNIVERSITY OF MODENA and PARMA (1990)



Micro x-ray of a thick section of NOVOCOR PLUS implanted in a sheep jaw one month previously. The neo-formed bone surrounds almost all the grains. (magnification 4x).



Gomori stained thin section of the NOVOCOR PLUS implant in sheep bone. The cavities containing loose connective tissue also present numerous vessels for the nutrition of the compacting bone. (magnification 12.5x).

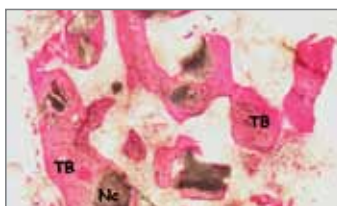


Magnification of a Cajal-Gallego stained section of the NOVOCOR PLUS implant in sheep bone. A row of osteoblasts (red) is laying down new bone (blue) close to two grains of NOVOCOR that were previously inserted in the two cavities. (magnification 100x).

HISTOLOGICAL ANALYSIS PERFORMED ON A NOVOCOR PLUS IMPLANT INSERTED IN A HUMAN MAXILLARY SINUS LIFT

“FACULTY OF MAXILLOFACIAL SURGERY AND ODONTOSTOMATOLOGY” of the UNIVERSITY OF NAPLES “FEDERICO II” (2003)

Sample of coral removed from a patient after 8 months:



New bone mineralisation is evident.



The grains of Novocor and the new trabecular bone have integrated well.



MICRO X-RAY AT A HIGHER MAGNIFICATION: a grain of Novocor (Nc) integrated into the newly formed trabecular bone; the arrows show the erosion of the grains of coral with the substitution of highly mineralised bone.

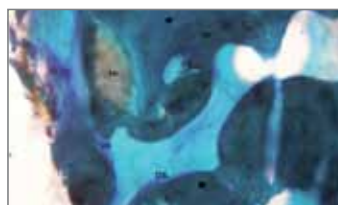


The mineralisation of the bone around the grains of Novocor without the interposition of connective tissue can be clearly seen.

HISTOLOGICAL SAMPLE OF NOVOCOR REMOVED FROM A PATIENT AFTER 18 MONTHS:



The grains of Novocor and the new trabecular bone have integrated well, the empty space has reduced and bone volume has increased with respect to the corresponding histological section at the eighth month.



The image shows the trabecular structures that have become lamellar (sign of a high level of maturation) next to newly-formed trabecular bone structures.



The grains of Novocor (Nc) and the new trabecular bone have integrated well. The grains of Novocor (shown with the arrows) have clearly and significantly absorbed and the presence of bone tissue (OS) shows that the bone is developing.



The micro x-ray reveals the close contact between Novocor and the bone without the interposition of fibrous tissue.

HISTOLOGICAL CONCLUSION:

- Histological samples at 8 months show the good osteoconductive action of Novocor.
- At 18 months, the implants have reached a high level of maturation, as can be seen from: the increased quantity of newly formed bone tissue and the lamellar appearance of the bone structure in certain areas.

The Novocor Plus medical device comprises grains of natural coral with a low surface/volume, ranging from 200 to 500 mm, of natural origin, a material that has been used for some time in bone defects repair, especially in the orthopaedic sector. Madreporic coral, also known as coralline hydroxyapatite, comprises 98% Aragonitic Calcium Carbonate (CaCO₃).

Packaging contains 4 capsule from 500 mg. and little pump.



PRODUCT CHARACTERISTICS:

Natural coral is one of the best osteoconductive materials for new bone growth in cases of low tissue metabolism. The high level of reactivity of madreporic coral achieves results in bone defect repair by means of:

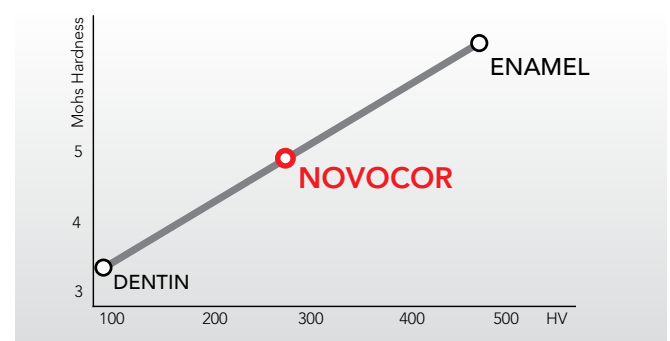


- The release of Calcium ions by macrophages or biological fluids inducing the activation of bone neodeposition (first months).
- Absorption of coral grains with their osteointegration and growth of interwoven-fibre bone tissue (6 - 12 months).
- Subsequent substitution of interwoven-fibre bone and coral grains with lamellar bone (12-24 months).

TECHNICAL SPECIFICATIONS AND CHEMICAL-PHYSICAL CHARACTERISTICS

- X-Ray Microanalysis (E.D.5)
- Inductively Coupled Plasma Emission Spectrometre Analysis

• Ca	39.2 ± 0.1 %
• Sr	0,28 %
• S	0,07 %
• Na	0,17 %
• Mg	0,13 %
• K	0,04 %
• Fe	2,1 mg/g
• Mn	0,73 mg/g
• Zn	1,0 mg/g
• Cd	tracce
• Cr	tracce
• Cu	tracce
• Pb	tracce
• Proteins	0,16%
• Amino acids	7 mg / 100 gr



- X-ray microanalysis of the composition of Novocor reveals that the device mainly comprises calcium together with traces of other elements (carbon is not measured with this analytical method). Small quantities of Strontium and Sulphur are also present.
- Analysis of the composition of Novocor according to the three indicated methods.

- Graph showing the Vickers microhardness values of Novocor, dentin enamel and various minerals with a known Mohs hardness value. It can be seen that Novocor is harder than dentin but softer than enamel.

METHOD



Blister opening



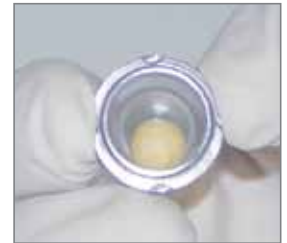
Novocor plus capsule opening



1 or 2 drops of sterile physiological saline are poured into the cup



Powder and liquid are mixed for 2 minutes inside the amalgamator



...until a hard but malleable compound is obtained, that is easy to model when there is a lack of bone tissue, but capable of resisting the solvent action of the blood during application

USE

The Novocor medical device is used as a filler in odontostomatology following the insertion of dental implants. It sets out to create a suitable environment optimising the biological potential for the regeneration of the periodontal ligament and the bone. More generally,

the physical characteristics of the material make it particularly suitable for the repair of metabolically slow bone defects (maxilla, mandible), parodontal defects in general, vertical bone defects, large parodontal pockets, implant stabilisation, maxillary sinus lift.

REPAIR OF BONE DEFECTS

FIRST CASE



Implant stabilization in the defect



Filling with NOVOCOR PLUS



Filling with NOVOCOR PLUS



Suture

SECOND CASE



Parodontal defect



Insertion of NOVOCOR PLUS



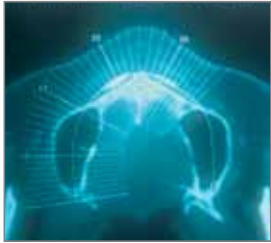
Titan membrane



Suture



CREST THICKENING



Initial x-ray.



Opening the flap. The thinness of the maxillary crest can be clearly seen.



Initial insertion of Novocor on the vestibular surface of the crest.



Final filling.



Suture.



Surgical reopening at one year.



Excellent thickening of the left-hand sector with insertion of the titanium implants.



Satisfactory thickening of the right-hand sector with insertion of the titanium implants.



Filling of the residual defect in the right-hand sector.



The X-ray shows excellent long-term thickening.

MAXILLARY SINUS LIFT



Initial x-ray.



Cutting the flap.



Opening the flap.



Opening the bone window.



Lifting the window.



Positioning the membrane.



Initial insertion of the NOVOCOR.



Final filling.



Suture.



Final x-ray at 8 months.

Analysis of the results of a product implant, first in the mandible of a sheep and subsequently in that of an adult male subjected to a post-extractive implant.



B&B DENTAL
implant company

Via San Benedetto, 1837 - 40018 San Pietro in Casale (BO) Italy
Tel. +39 (0) 51.81.13.75 - Fax +39 (0) 51.666.94.00
info@bebdental.it - www.bebdental.it



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