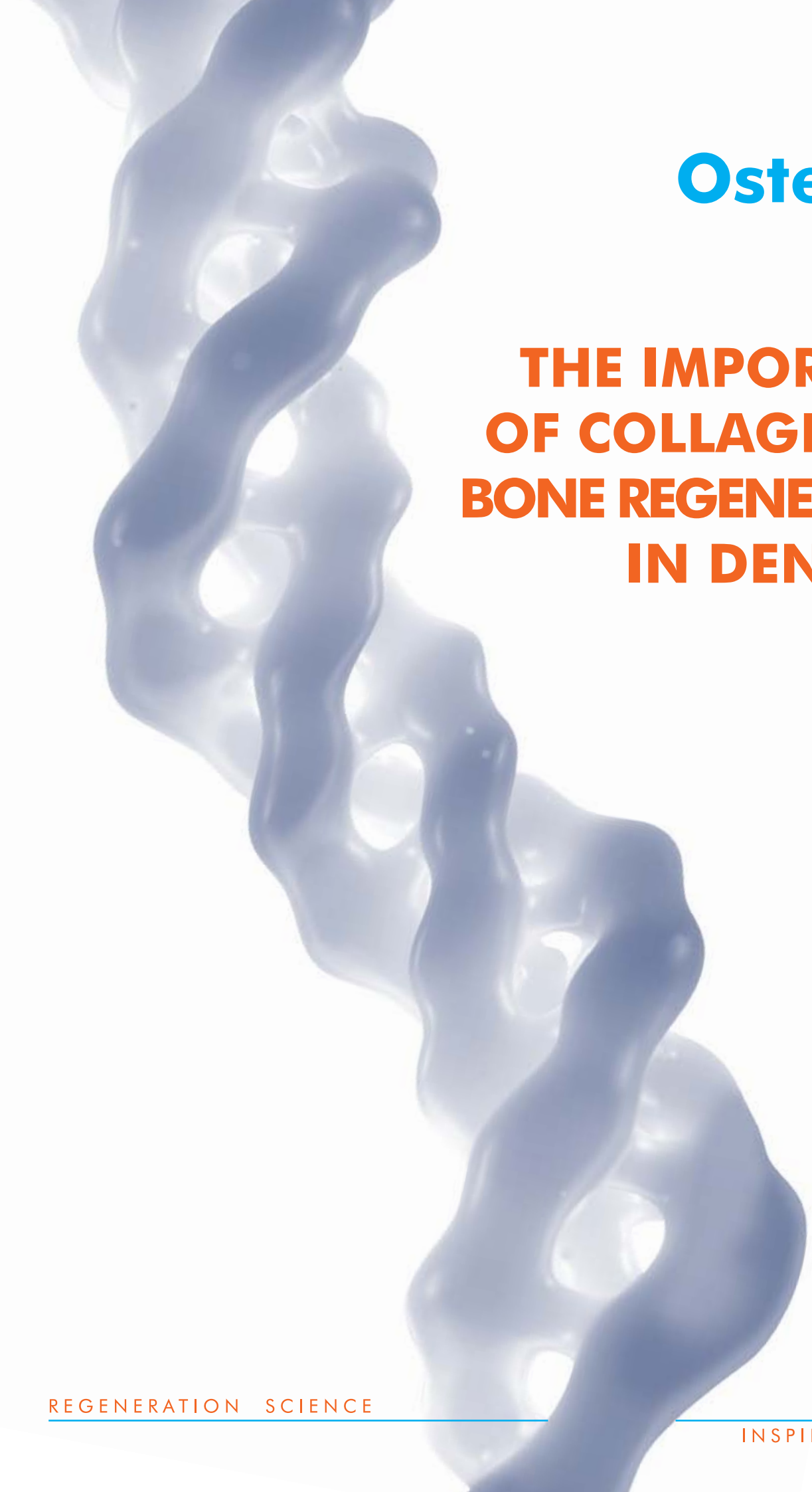
OsteoBiol®
by Tecnoss

THE IMPORTANCE OF COLLAGEN FOR BONE REGENERATION IN DENTISTRY



REGENERATION SCIENCE

INSPIRED BY NATURE

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SIMILARITY WITH NATURAL HUMAN BONE

Human bone is comprised of about 70% minerals (mainly hydroxyapatite, a calcium salt) and 30% organic matter most of which is collagen. A study published in 2010 proved that OsteoBiol® xenogenic collagenated granules are chemically and physically similar to human bone[1]. Other studies, including an inorganic chemical analysis by the University of Essen[2], reconfirmed the OsteoBiol® collagenated matrix to be (22.4%) organic and (73.6%) inorganic. Significantly, a Raman analysis performed by the Polytechnic University of Turin demonstrated the presence of collagen inside OsteoBiol® dual-phase collagenated granules (Fig.1).

THE IMPORTANCE OF COLLAGEN

Collagen is the most abundant protein in the human body and plays a key role in tissue healing. Several studies have demonstrated collagen to be a substrate for platelet aggregation[3], for endothelial cell adhesion and neovascularization[4]. It is also involved in facilitating bone marrow stem cell differentiation[5], and stimulating bone regeneration process[6].

THE DUAL-PHASE BIOMATERIALS TECHNOLOGY

High-temperature production processes denature collagen molecules within the xenogenic bone matrix whilst ceramising the mineral components. The innovative dual-phase production process developed by Tecnoss® preserves collagen (Fig.2) and maintains the natural structure of hydroxyapatite avoiding granule ceramisation. *In vitro* studies[7] and histologies on rabbits[8] and humans[9] have confirmed that OsteoBiol® collagenated biomaterials show chemotactic action on osteogenic cells (Fig.3). Other *in vitro* studies have proven that OsteoBiol® collagenated biomaterials facilitate osteoblasts migration[7], promote cellular differentiation[10] into osteogenic cells, facilitate blood clot formation, and favour neoangiogenesis[4]

CLINICAL EXCELLENCE

Autologous bone is considered the gold standard for bone regeneration but is available in limited quantities and complications can occur at the donor sites. For this reason, biomaterials are used to complement autologous bone or as a preferred alternative. More than twenty years of clinical research[11] have demonstrated that clinical results obtained with OsteoBiol® collagenated biomaterials, in most regenerative protocols, are comparable to autologous bone[11,12,13].

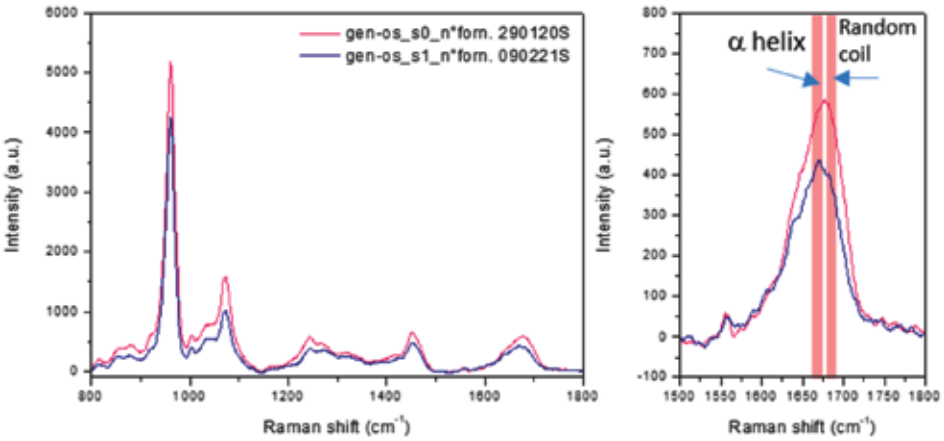

FIG 1

Raman analysis on OsteoBiol® *Gen-Os*®. A helix and random coil prove the presence of collagen whithin OsteoBiol® *Gen-Os*® dual-phase collagenated granules.

Source: Polytechnic University of Turin, PORTHOS Group, DISAT-PoliTo

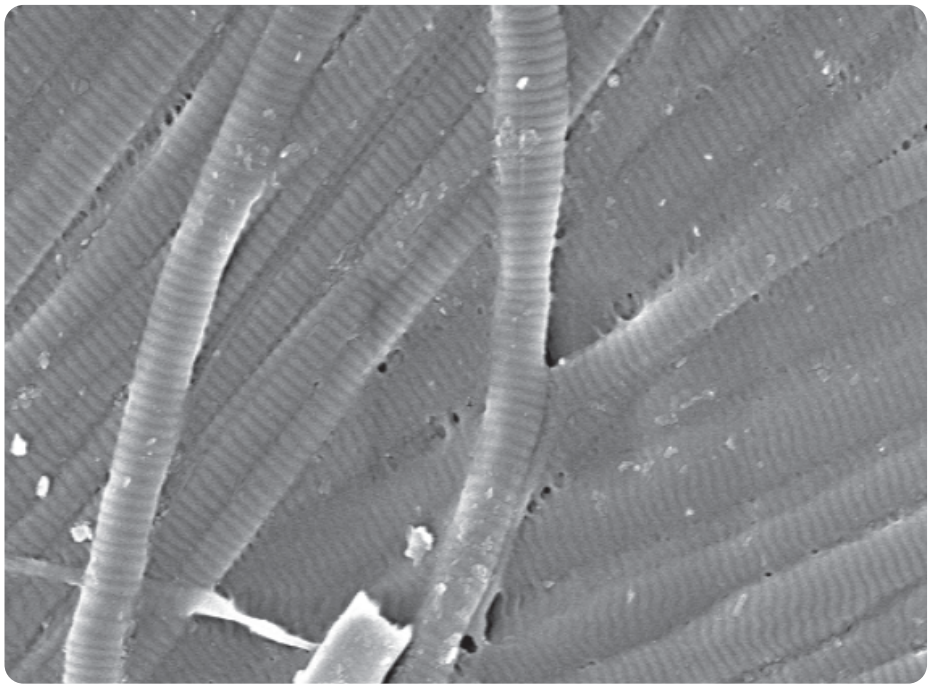

FIG 2

The innovative Tecnoss® production process preserves collagen fibers' structure. In the SEM image, collagen fibers of OsteoBiol® *Gen-Os*® granules are shown.
Magnification x23000

Courtesy of Prof. U. Nannmark, University of Göteborg, Sweden.

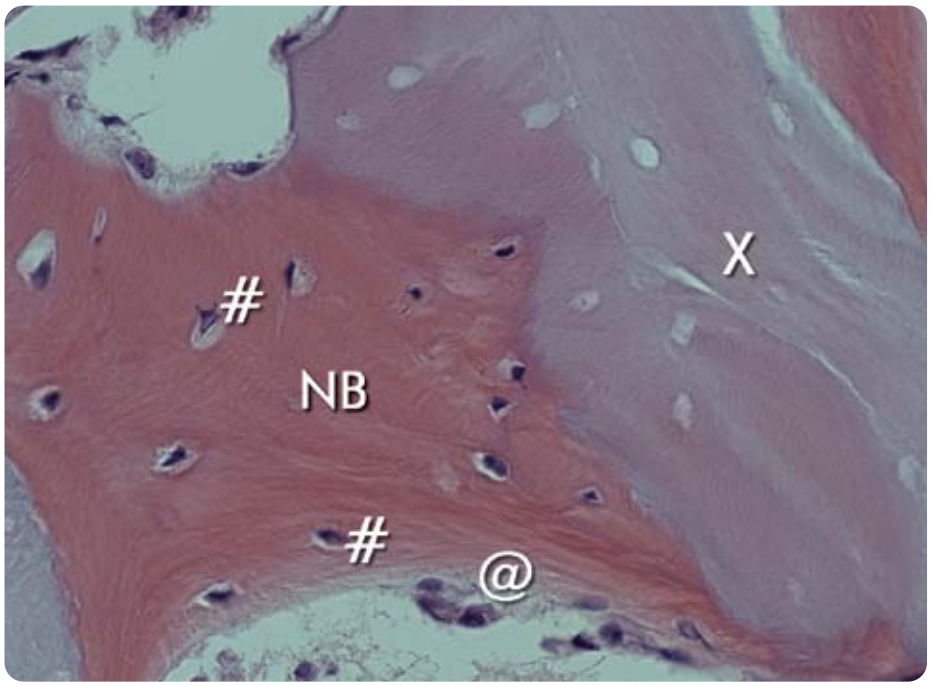

FIG 3

Histology showing new bone deposition (NB) by osteoblasts (@) in close contact with an OsteoBiol® *GTO*® granule (X). Osteocyte (#).

Courtesy of Dr. P Palacci (Marseille, France) and Prof. U. Nannmark, University of Göteborg, Sweden.

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COLLAGEN PROMOTES STEM CELL RECRUITMENT AND DIFFERENTIATION

An experimental study conducted *in vitro* demonstrated that the interaction between collagenated biomaterials and periodontal ligament cells (PDLCs) significantly increased Human Bone Marrow Mesenchymal Stem cell (MSC) proliferation and recruitment[1]. PDLSCs comprise a population of MSCs that can differentiate into osteogenic cells. A team of scientists has investigated the role of collagenated biomaterials during PDLSCs differentiation in osteogenic growth medium[2]. Osteogenic differentiation was evaluated by quantifying collagen expression and calcium deposition at 14 and 21 days. When compared to the control group (growth medium only), PDLSCs in contact with a collagenated biomaterial showed a higher level of collagen expression and calcium deposition (Fig.4).

GRADUAL GRAFT RESORPTION

In an experimental study published in 2008, it was proved that OsteoBiol® collagenated biomaterials are gradually resorbed and replaced by an adequate amount of newly formed bone[3]. Osteoblasts, osteoclasts, and blood vessels were found in close contact with OsteoBiol® granules. 13 years later[4], another experimental study (Fig.5 and 6) demonstrated that in critical size defects in rabbits' femurs (5 mm in diameter by 10 mm in depth) the amount of newly formed bone with OsteoBiol® *mp3*® was equal to 40.93% and 52.49% after 15 and 30 days, respectively.

CLINICAL RESULTS: ADEQUATE AMOUNT OF NEW BONE FORMATION AND VOLUME PRESERVATION

Bone-to-implant-contact (BIC) refers to the amount of vital bone in contact with the implant surface. Lateral sinus grafting was undertaken in twenty-four patients and their sinus floors were augmented with OsteoBiol® *Gen-Os*®. After 6 months, mini-implants were inserted and three months later, sixteen biopsies were taken. New mineralized bone in contact with the implant reached a fraction of 40.9% and 48.5% in the two experimental groups while the remaining xenograft was equal to 12.1% and 15.9%[5]. Finally, a randomized controlled trial (RCT) with twenty-eight patients undergoing socket preservation showed that volume shrinkage after 3 months was significantly lower with collagenated biomaterials than non-collagenated biomaterials (244mm^3 vs 349mm^3, P=0.0140)[6].

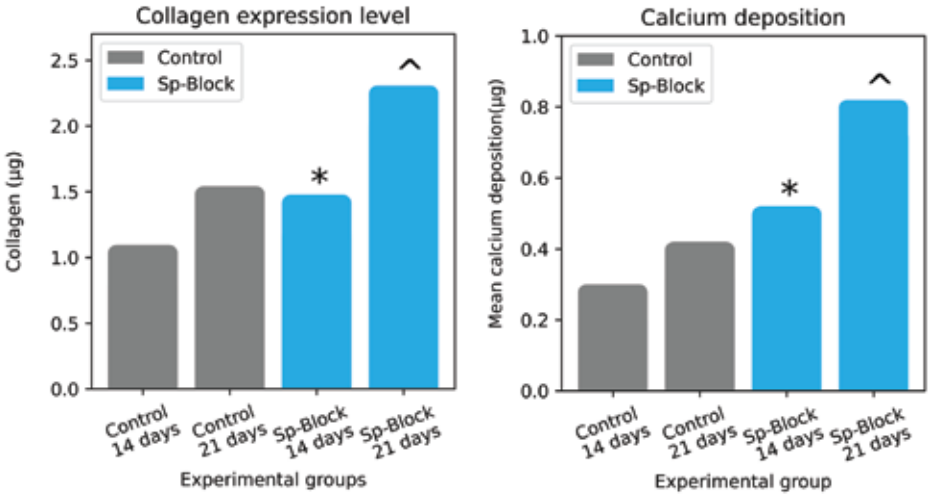

FIG 4

Collagen expression (left) and calcium deposition (right) of PDLSCs cultured into a differentiation medium (Control) or seeded onto an OsteoBiol® cancellous block (*Sp-Block*) and placed into a differentiation medium. *, ^ statistically significant comparison to 14 and 21 days, respectively.

Graphically adapted from Fig. 1 and Fig. 3. Alqutub Monaster N, Mukhtar Areej H. , Alali Yasser, Vohra Fahim, Abduljabbar Ttariq. **Osteogenic Differentiation of Periodontal Ligament Stem Cells Seeded on Equine-Derived Xenograft in Osteogenic Growth Media.** Medicina. 2022; 58(11):1518. CC BY license.

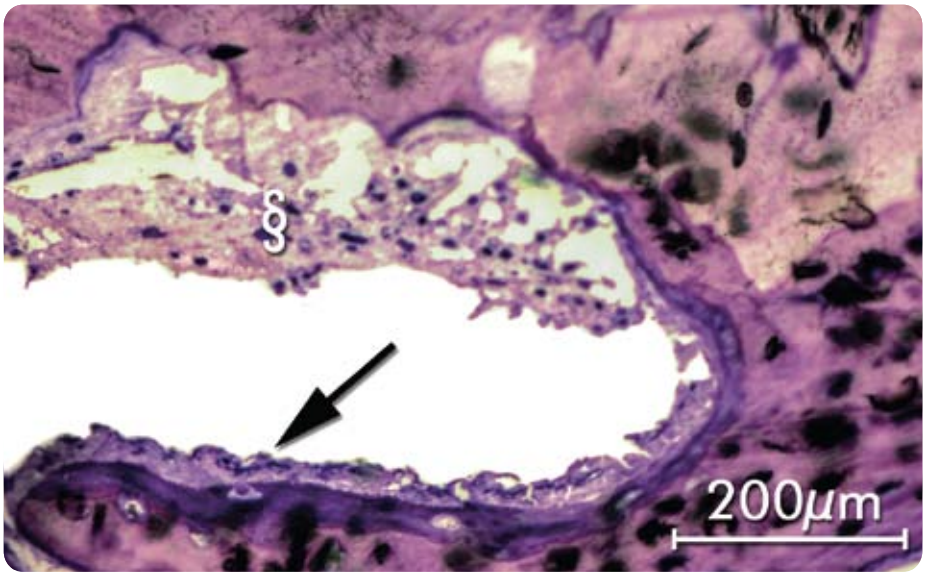

FIG 5

Histological image of the defect treated with OsteoBiol® *Gen-Os*® at 30 days. Osteoclastic (§) bone particle resorption and osteoblastic activity was in evidence. The black arrow indicates the presence of osteoblast and osteoid.

Adapted from Fig.3, Falacho Rui I, Palma Paulo J, Marques Jaona A, Figueiredo Maria H, Caramelo Francisco, Dias Isabel, Viegas Carlos, Guerra Fernando. **Collagenated Porcine Heterologous Bone Grafts: Histomorphometric Evaluation of Bone Formation Using Different Physical Forms in a Rabbit Cancellous Bone Model.** Molecules. 2021 Mar 2;26(5):1339. CC BY license.

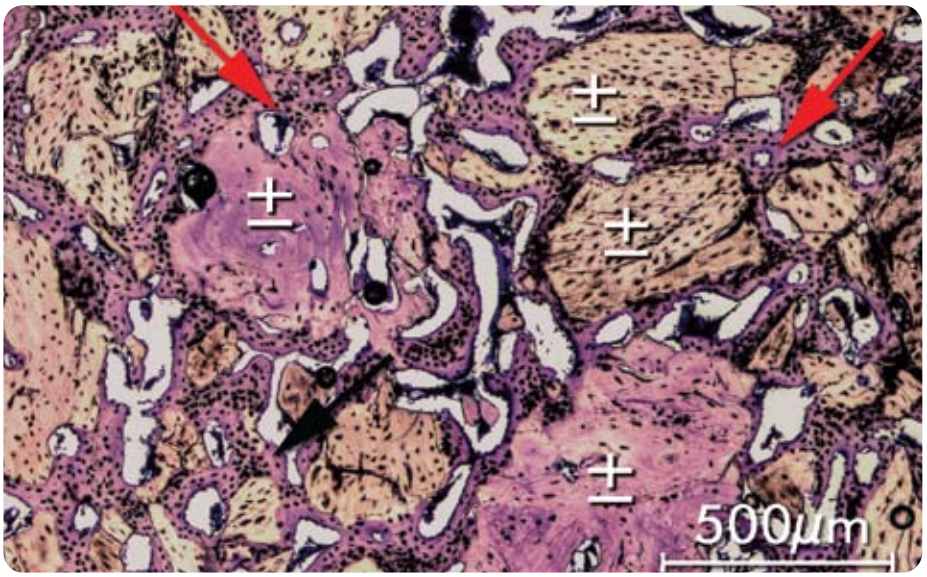

FIG 6

Histology of the group treated with OsteoBiol® *mp3*® at 30 days. Red arrows show newly formed bone trabeculae.
± indicates OsteoBiol® *mp3*® bone granules.

Adapted from Fig.4, Falacho Rui I, Palma Paulo J, Marques Jaona A, Figueiredo Maria H, Caramelo Francisco, Dias Isabel, Viegas Carlos, Guerra Fernando. **Collagenated Porcine Heterologous Bone Grafts: Histomorphometric Evaluation of Bone Formation Using Different Physical Forms in a Rabbit Cancellous Bone Model.** Molecules. 2021 Mar 2;26(5):1339. CC BY license.

ANGIOGENESIS AND VEGF

The main function of blood vessels is to supply cells with oxygen and nutrients[1]. Neo-angiogenesis is the physiological process whereby new blood vessels are formed from pre-existing ones. Among proteins that regulate neo-angiogenesis, the Vascular Endothelial Growth Factor (VEGF) plays a key role. Mice with a reduced expression of VEGF show abnormal blood vessel development[2,3].

THE LINK BETWEEN ANGIOGENESIS AND NEW BONE FORMATION

It has been found that VEGF improves bone formation and bone healing through the modulation of angiogenesis. Using a mouse model and performing histologic and radiographic analysis, scientists have demonstrated that VEGF acts in synergy with the Bone Morphogenetic Protein 2 (BMP2), a key protein for bone regeneration, and VEGF inhibition reduces bone formation[4].

THE IMPORTANCE OF COLLAGEN FOR ANGIOGENESIS

Collagenated dual-phase biomaterials have proven to have an angiogenic potential when placed in contact with periodontal ligament (PDL) cells[5] that remain exposed after tooth extraction. It has been found that the secretion of VEGF from PDL cells in contact with OsteoBiol® *Gen-Os*® is three times higher than the control and over 50% higher than the anorganic bovine bone (ABB) (Fig.7). An increase in the endothelial cell proliferation rate is likely to be related to an augmented VEGF secretion (Fig.8). It was also found that the perimeter of newly formed capillaries is more than three times larger with OsteoBiol® *Gen-Os*® than with ABB (Fig. 9). Those data were reconfirmed by a team of French scientists who found a positive correlation between collagen content and the angiogenic potential of a biomaterial for bone regeneration. Data revealed that in OsteoBiol® *GTO*® the collagen content is significantly higher than in OsteoBiol® *Gen-Os*® and ABB, thus leading to a higher angiogenic potential[6].

THE IMPORTANCE OF ANGIOGENESIS

Histology performed on rabbits showed new blood vessels in close contact with collagenated biomaterial granules[7]. When performing ridge preservation on twenty-one patients with collagenated biomaterial, the researchers found new blood vessels in close contact with biomaterials granules and adequate amount of newly formed bone at three, six, and twelve months after surgery[8].

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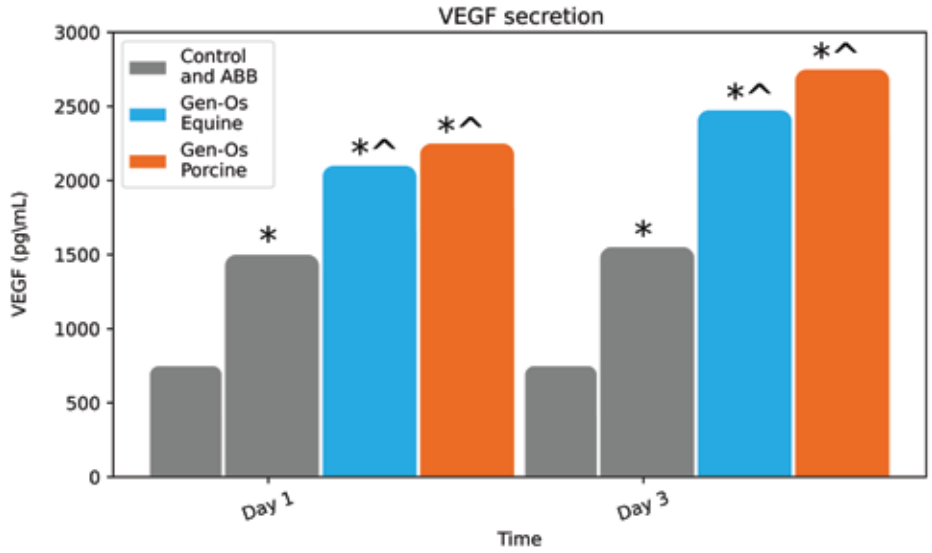

FIG 7

y-axis = secretion level of VEGF; x-axis =experimental groups. Cyan and orange = VEGF expression OsteoBiol® Gen-Os group; grey = VEGF expression with ABB and control group; * = statistically significant difference vs control; ^ = statistically significant difference and vs control vs ABB.

Graphically adapted from Fig.6, Rombouts Charlotte, Jeanneau Charlotte, Camilleri Josette, Laurent Patrick, About Imad. **Characterization and angiogenic potential of xenogeneic bone grafting materials: Role of periodontal ligament cells.** Dent Mater J. 2016 Dec 1;35(6):900-907 ^

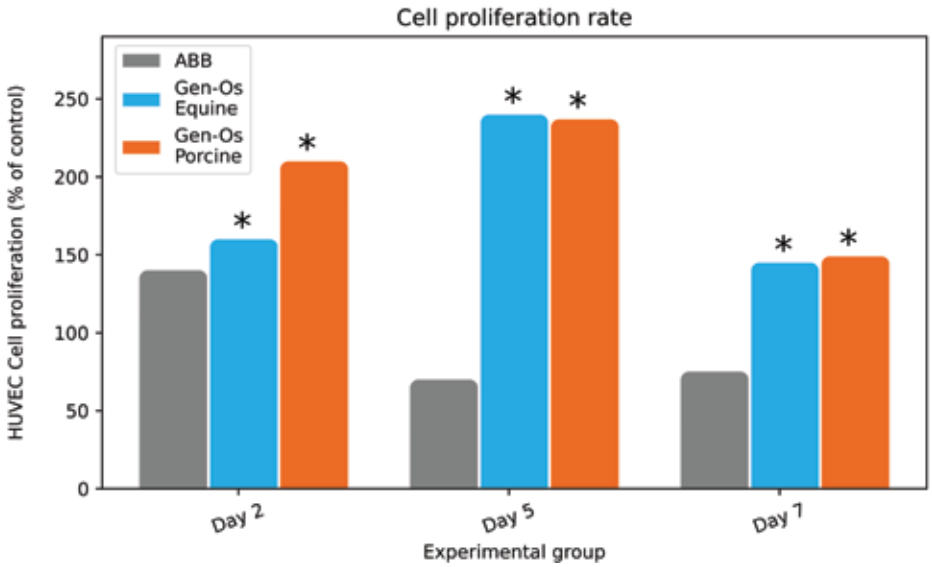

FIG 8

Y-axis = Human Umbilical Vein Endothelial Cells proliferation rate expressed as a % of the control group (PDL cells in serum-free EBM-2 medium for three days). Cyan and orange = OsteoBiol® Gen-Os group; grey = ABB group; * = statistically significant differences between ABB and OsteoBiol® *Gen-Os®*.

Graphically adapted from Fig.7, Rombouts Charlotte, Jeanneau Charlotte, Camilleri Josette, Laurent Patrick, About Imad. **Characterization and angiogenic potential of xenogeneic bone grafting materials: Role of periodontal ligament cells.** Dent Mater J. 2016 Dec 1;35(6):900-907 ^

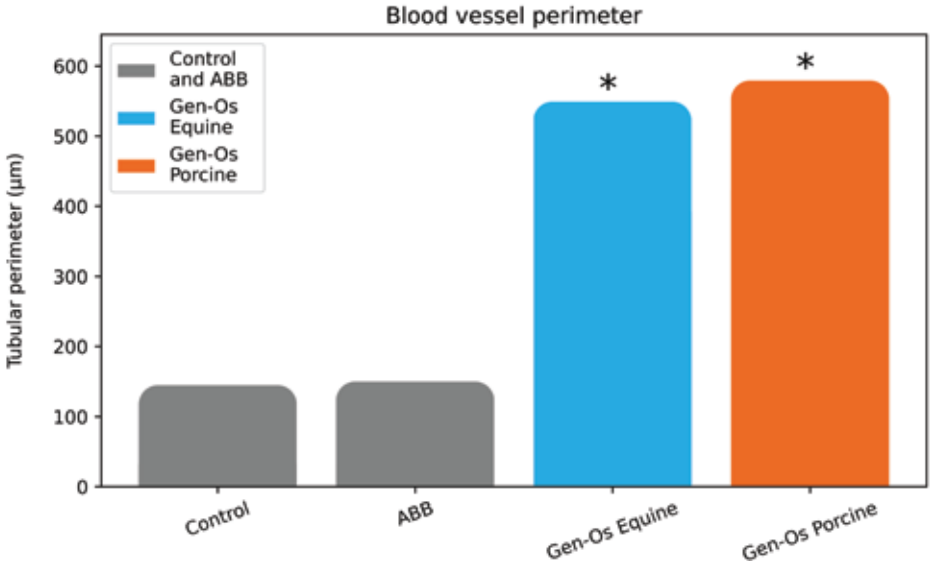

FIG 9

Y-axis = blood vessels perimeter (µm), control = conditioned medium from PDL cells exposed to serum-free EBM-2 medium for three days. Cyan and orange = Blood vessel perimeter of cells - OsteoBiol® Gen-Os group; grey = Blood vessel perimeter of cells exposed to ABB and control group. * = statistically significant difference vs control and ABB.

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ADVANTAGES OF PORCINE XENOGRAFT OVER AUTOGRAFT IN SINUS LIFT

Autologous bone is considered the gold standard for bone regeneration; however, it has limitations such as reduced availability, risk of morbidity, and postoperative pain. In a randomized split-mouth clinical trial, a group of researchers compared the clinical, radiological, histological, and histomorphometric outcomes of autologous bone to OsteoBiol® collagenated dual-phase granules in lateral access sinus lift[1]. Twelve patients were treated in a split-mouth RCT and a total of twenty-four sinuses have been augmented either with autologous bone or OsteoBiol® *mp3*®. The antrostomy were covered with an OsteoBiol® *Evolution* collagen membrane.

OUTCOMES

For radiological evaluation, CT scans were performed before and six months after the surgery. Data analysis revealed a statistically significant increase in bone height for both groups while inter-group comparison did not show a significant difference. (Fig.10). The bone gain allowed the insertion of thirty-nine implants from 9 mm to 11 mm in length. Biopsies taken six months after surgery have shown autologous bone and collagenated OsteoBiol® *mp3*® granules surrounded by newly formed bone. Histology has detected both osteoclasts and osteoblasts in close proximity to bone granules, highlighting progressive biomaterial resorption and new bone formation (Fig.11). Total hard and soft tissue volume has been similar for both groups (Fig 12).

FOLLOW–UP

After 1-year follow-up, the marginal bone loss around the implants, and the implant survival rate has been evaluated[2]. Radiographic analysis showed a minimal marginal bone loss for autologous bone and for OsteoBiol® *mp3*®. The difference was not statistically significant. Implant survival rate was equal to 100% in patients treated with autologous bone, whilst in the group treated with OsteoBiol® *mp3*® only one implant out of nineteen implants placed did not osseointegrate. Comparable results between the two experimental groups were reported after 3-year follow-up[3].

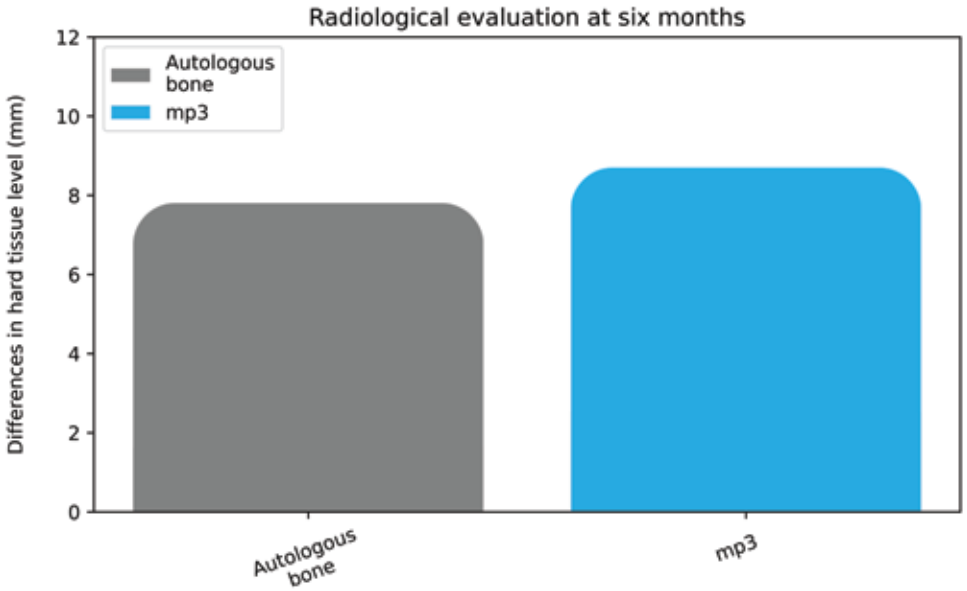

FIG 10

Hard tissue level gain (6 months - baseline, mm).
Comparison experimental groups (autologous bone and OsteoBiol® mp3) did not reach statistical significance.

Graphically adapted from Table 1, Correia Francisco, Pozza Daniel Humberto, Gouveia Sonia, Felino Antonio Campos, Faria-Almeida Ricardo.
Advantages of Porcine Xenograft over Autograft in Sinus Lift: A Randomised Clinical Trial.
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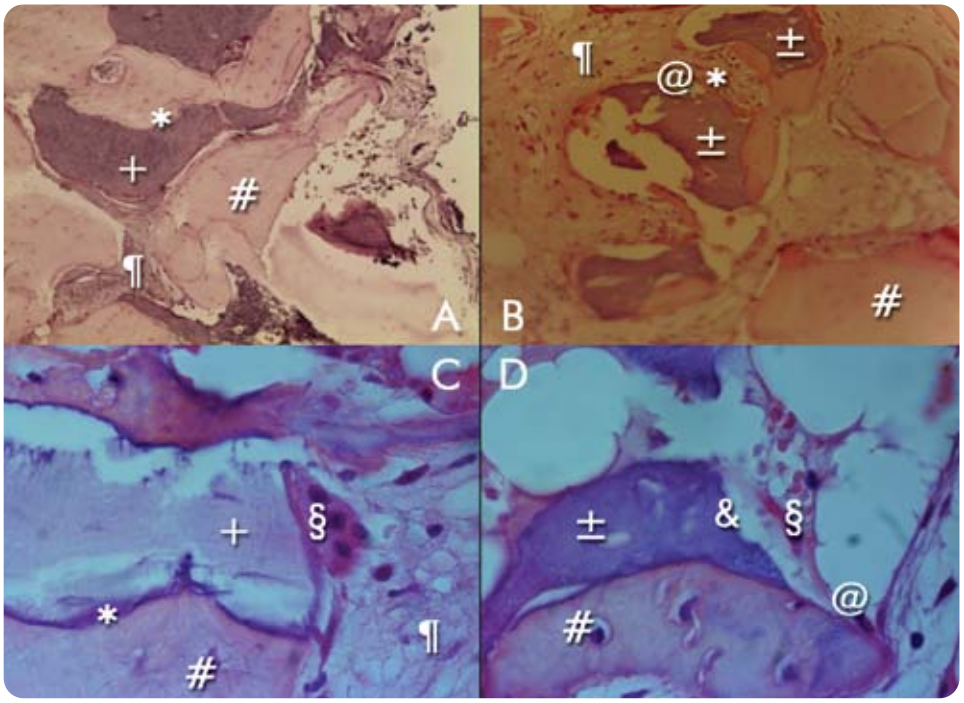

FIG 11

Histologies stained with hematoxylin and eosin. (A - C) Autologous bone graft (200×, 400x). (B-D) OsteoBiol® *mp3*® (200×, 400x). Legend:
* immature bone, + autologous bone graft, # osteocyte, ± OsteoBiol® *mp3*® granules; ¶ soft tissue, @ osteoblast, § osteoclast, & Howship lacunae.

Adapted from Fig.3 Correia Francisco, Pozza Daniel Humberto, Gouveia Sonia, Felino Antonio Campos, Faria-Almeida Ricardo.
Advantages of Porcine Xenograft over Autograft in Sinus Lift: A Randomised Clinical Trial.
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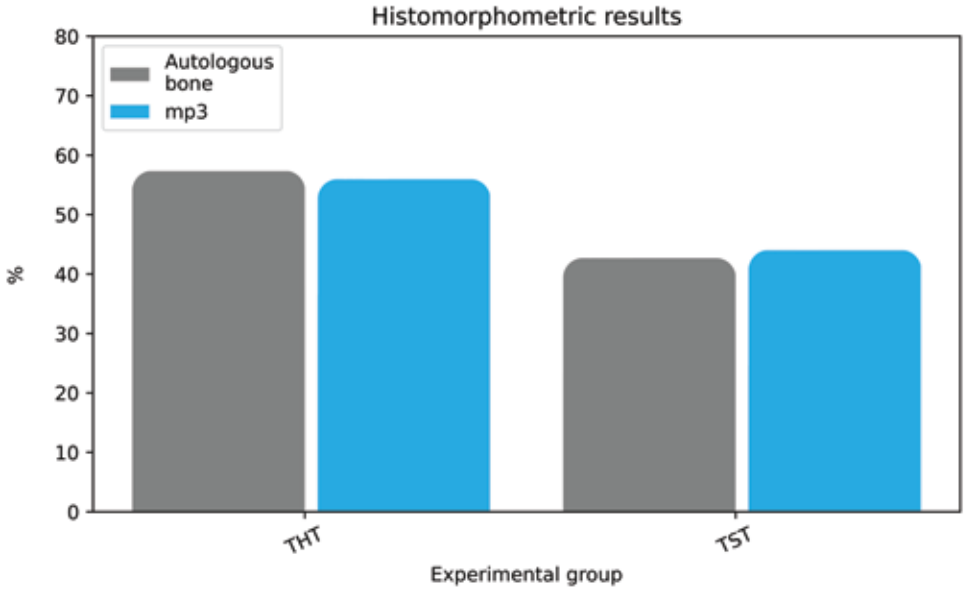

FIG 12

Histomorphometric results at 6 months. Results have been similar for both groups and did not reach statistical significance. THT= total hard tissue volume; TST= total soft tissue volume.

Graphically adapted from Table 2, Correia Francisco, Pozza Daniel Humberto, Gouveia Sonia, Felino Antonio Campos, Faria-Almeida Ricardo
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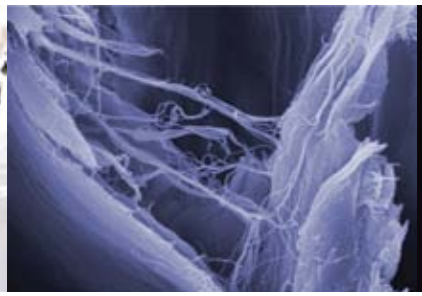

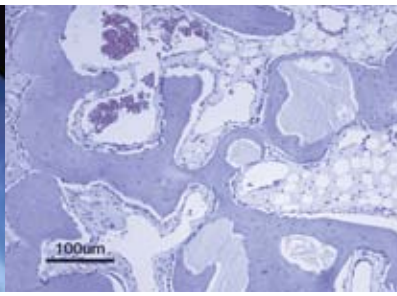

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