SynthoGraft®

Pure Phase Beta-Tricalcium Phosphate

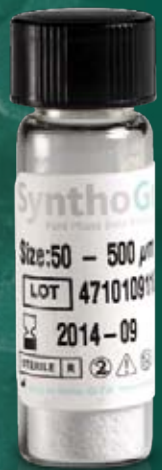
THE NEXT GENERATION OF REGENERATION™

Why SynthoGraft?

SynthoGraft offers a unique structure which provides stability, while its micro-porosity allows for rapid vascularization and subsequent resorption. Although several varieties of beta-tricalcium phosphate are now commercially available, their bone regenerating capabilities are not equal. The differences can affect not only the rate and quality of bone regeneration, but also the rate of resorption and replacement with autogenous bone during the healing process.

SynthoGraft®

Pure Phase Beta-Tricalcium Phosphate



SynthoGraft offers:

- **Increased patient acceptance**
- **Elimination of the inherent risks associated with biologically-derived bone graft materials**
- **Greater surface area compared to other synthetic bone grafting materials**
- **Rapid vascularization and subsequent resorption when mixed with the patient's own blood**
- **Nanometer-scale porosity**
- **Available in two particle sizes: 50–500µm and 500–1000µm**

The Dentist and Patient

SynthoGraft offers clinicians and patients the confidence of knowing that they have a completely synthetic bone graft material. SynthoGraft eliminates the inherent uncertainties and risks associated with bone graft materials that are derived from humans or animals. Patients have benefited from pure phase Beta-Tricalcium Phosphate, SynthoGraft, since 1981.

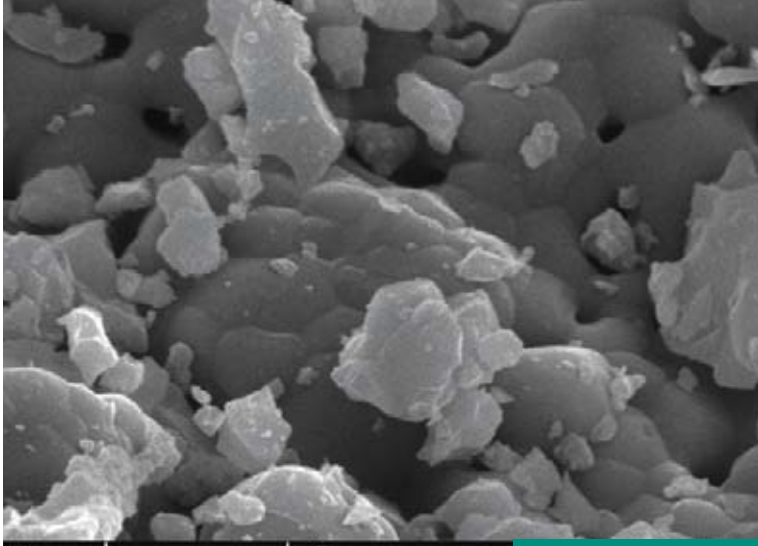


Image courtesy of Paulo G. Coelho, Ph.D., New York University

"Mr. Driskell (inventor of βTCP bone graft materials) has improved the stoichiometric chemistry, the characteristics of this particular tricalcium phosphate compared to the material that we have investigated previously and, by all indications, is a significant improvement for applications in dentistry."

Jack E. Lemons, Ph.D., University of Alabama at Birmingham

"What happens at six to nine months is that the fibrous materials, as well as the grafting materials, are no longer present and the cortical bone is much thicker and much more stabilized. In my opinion, any time after three months it is a very stable site."

Ziedonis Skobe, Ph.D., Forsyth Institute and Harvard University

HISTORY OF SYNTHOGRAFT

The next generation of regeneration.

1968

Tom Driskell begins biomedical research on dental implants and bone structural replacement materials.

1970

Initial research begins on Beta-Tricalcium Phosphate as a possible synthetic bone grafting material.

1971

Tom Driskell was the first to develop calcium phosphate ceramics for use as synthetic bone grafting materials.

1981

Synthetic resorbable bone grafting material (beta phase tricalcium phosphate) introduced and receives FDA clearance.

1982

Tom Driskell received an Industrial Research Magazine IR 100 award for SynthoGraft, one of the "100 most significant technological developments of the year, worldwide."

2005

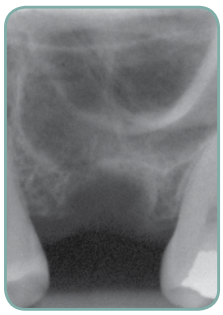
An optimized formulation of SynthoGraft Pure Phase Beta-Tricalcium Phosphate is introduced.

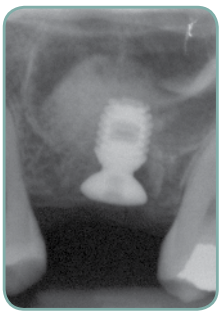
Future

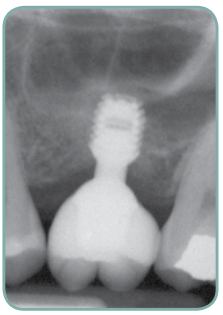
Ongoing research and development continues, using SynthoGraft in various applications.

CLINICAL APPLICATIONS

INTERNAL SINUS LIFT


Pre-Operative


Placement


One Year

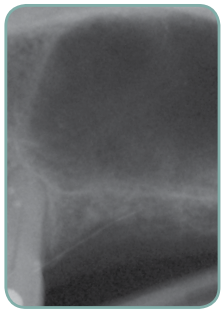
INTERNAL SINUS LIFT


Pre-Operative


Placement


Two Years

INTERNAL SINUS LIFT

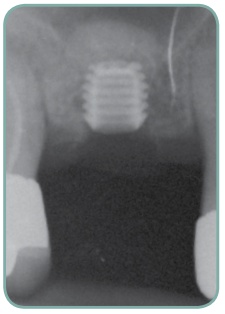

Pre-Operative


Placement


Four Years

INTERNAL SINUS LIFT

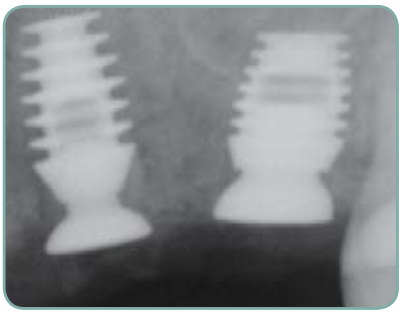

Pre-Operative


Placement


Three Years

CREST AUGMENTATION


Graft In Place


Post Graft

EXTRACTION SITE


Failed Root Canal


Extraction


Post Graft

PERIODONTAL DEFECT


Site Of Defect


Graft In Place

LATERAL SINUS LIFT

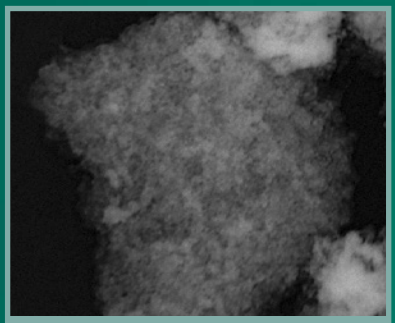

Graft In Place


Post Graft

CLINICAL STUDIES

Extensive human and animal studies have shown the osteoconductive properties of SynthoGraft:

- **Rapid bone regeneration in critical size defects at early implantation times has been observed.**
- **Micro-computed tomographic analysis of retrieved human cores at 3, 6, and 12 months following sinus lift procedures have shown bone-to-grafting material volume ratios ranging from 78 to 98% as early as 3 months.**
- **No foreign body responses were detected.**

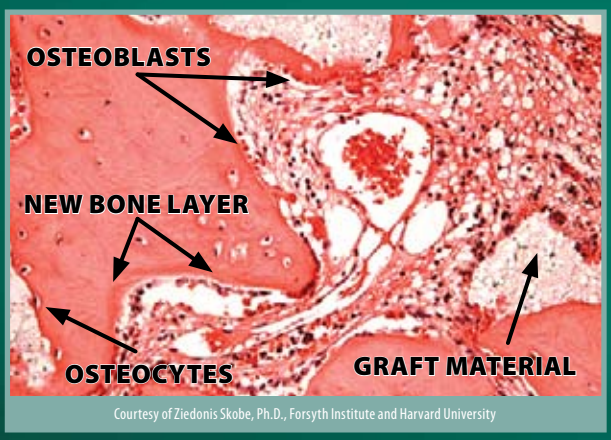


Courtesy of Paulo G. Coelho, Ph.D., New York University

A transmission electron micrograph (TEM) showing the structurally interconnected nanometer size porosity of SynthoGraft.

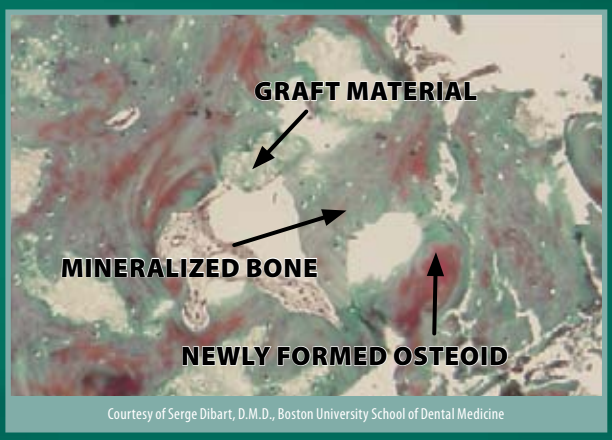
Courtesy of Jack E. Lemons, Ph.D., University of Alabama at Birmingham

Histologic 3D core reconstruction analysis showed significant new bone formation in sinus grafted regions.



Courtesy of Ziedonis Skobe, Ph.D., Forsyth Institute and Harvard University

3 month histology



Courtesy of Serge Dibart, D.M.D., Boston University School of Dental Medicine

6 month histology

Retrieval of sinus elevations after 3 and 6 months showed progressive resorption of SynthoGraft particles and increasing bone regeneration.

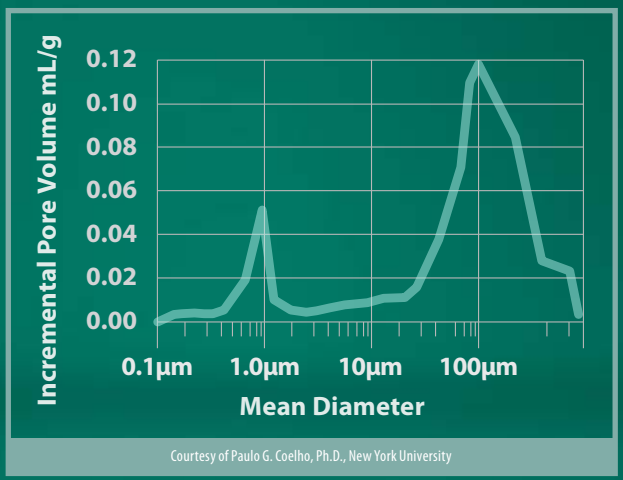
Selected Research:

- Coelho, P.G., Coimbra, M.E., Ribeiro, C., Francio, E., Higa, O., Suzuki, M., Marincola, M., *Physico/Chemical Characterization and Preliminary Human Histology Assessment of a B-TCP Particulate Material for Bone Augmentation*, Materials Science and Engineering C. 2009 29:2085-2091.
- Coimbra, M., Salles, M., Yoshimoto, M., Allegrini, S. Jr., Fancio, E., Higa, O., Suzuki, M., Coelho P., *Physico/Chemical Characterization, In Vitro, and In Vivo Evaluation of Hydroxyapatite/PLGA Composite and Tricalcium Phosphate Particulate Grafting Materials*, TITANIUM: The International Journal of Dental Implants & Biomaterials, 2009 1(1): 16-28.
- Chopra P.M., Johnson M., Nagy T., and Lemons J.E., *Micro-Computed Tomographic Analysis of Bone Healing Subsequent to Graft Placement*, Journal of Biomedical Materials Research. Part B, Applied Biomaterials, October 2008.
- Schulze-Späte1 U., Dietrich T., Dobeck J., Kayal R., Time A., Skobe Z., Dibart S., *Sinus Augmentation Procedure Using Beta-Tricalcium-Phosphate: Histological Analysis of Grafted Bone at Time of Implant Placement*, AAP 94th Annual Meeting, Seattle, Washington, September 2008.
- Chopra P.M., Johnson M., Beck P., Nagy T., Marincola M., and Lemons J.E., *Investigation of Maxillary Sinus Bone Graft Healing by MicroCT*, IADR General Session, New Orleans, Louisiana, March 2007.
- Coelho P.G., Dobeck J., Skobe Z., and Bottino M.C., *Characterization of a Beta Tricalcium Phosphate Powder for Bone Grafting*, AADR General Session, Orlando, Florida, March 2006.

SCIENTIFIC STUDIES

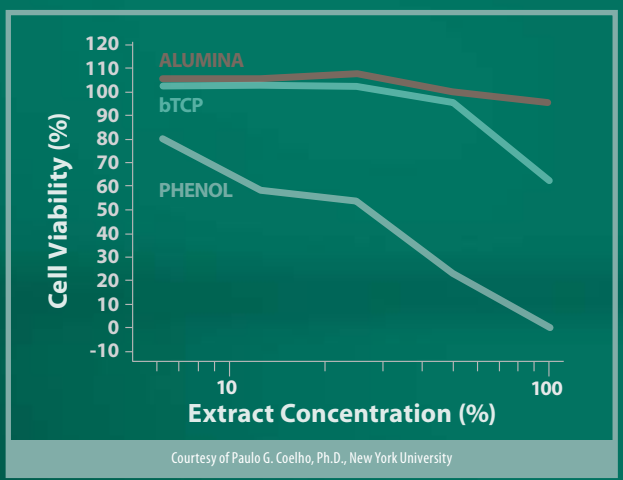
Extensive laboratory studies have demonstrated the unique physical properties of SynthoGraft:

- Nanometer-scale porosity
- Pure, synthetic material
- Cellular-level biocompatibility



Courtesy of Paulo G. Coelho, Ph.D., New York University

Micrometer and nanometer pore size for optimized material dissolution and bone regeneration rates.



Courtesy of Paulo G. Coelho, Ph.D., New York University

In vitro cytotoxicity assays confirmed the cellular-level biocompatibility of SynthoGraft.

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