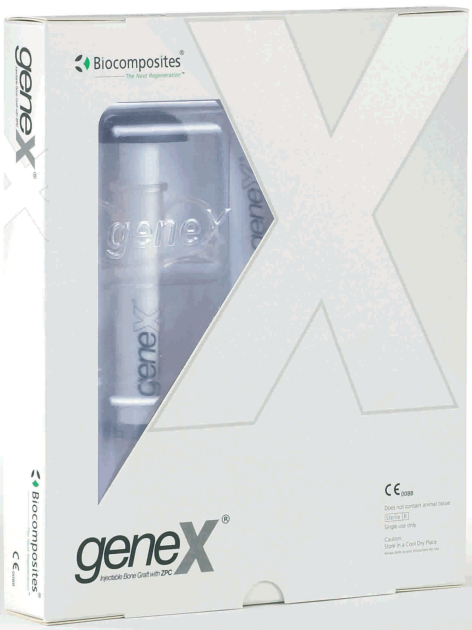
Redefining Bone Repair

Biocomposites®

The Next Regeneration™

geneX

Injectable Bone Graft with ***ZPC***™



The World's First

geneX® represents a new class of synthetic bone graft material. The world's first biomaterial with a controlled surface chemistry designed specifically to accelerate bone healing.

A resorbable, fully synthetic osteoconductive bone graft engineered with the unique feature of ***ZPC***™, Zeta Potential Control.

The result is the first synthetic graft material capable of directing cell activity to produce rapid bone formation.

Biocomposites®

The Next Regeneration™

In a class of it's own

geneX® is a new class of synthetic bone graft material.

Biocomposites has developed a unique patented process ***ZPC***™, Zeta Potential Control.
When applied, this proven process enables the accurate control of material surface properties, to initiate reproducible biological activity and accelerate bone formation without the introduction of single trace elements.

Unlike other synthetic graft alternatives, ***geneX***® is fully resorbed and replaced by bone.

Composed of a biphasic matrix of hydroxyl sulphate and calcium phosphate,
it has a dynamic porosity and optimal resorption.

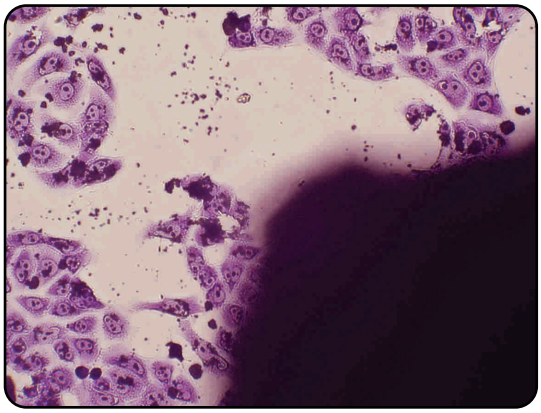
Key Properties

- ***ZPC***™ - Accelerated Bone Growth
- Fully Resorbed - Replaced by bone
- ***Smart****Pores* - Dynamic Porosity
- Compressive Strength
- Sets *in-situ* at body temperature
- Easy to use
- Eliminates the risk of disease transmission

geneX® >>>> BONE

geneX® fully resorbs and is replaced by **bone**

geneX® and ZPC™ The only synthetic graft to trigger bone



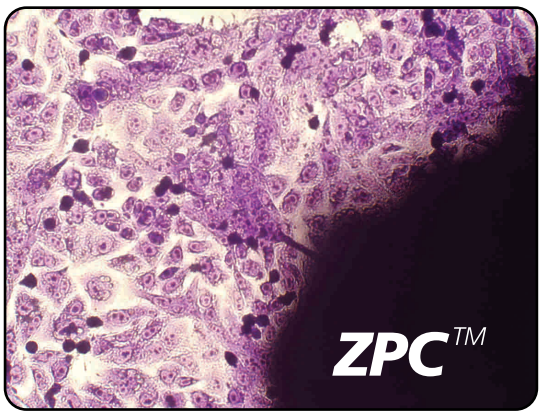
Standard synthetic implant material
Minimal Osteoblast proliferation near implant surface.
(*In-vitro*, 3 days, Toluidine Blue)

geneX® has been engineered with ***ZPC***™, a patented process providing the graft with negative surface charge when placed in apposition to healthy bleeding bone, to produce an enhanced biological response.

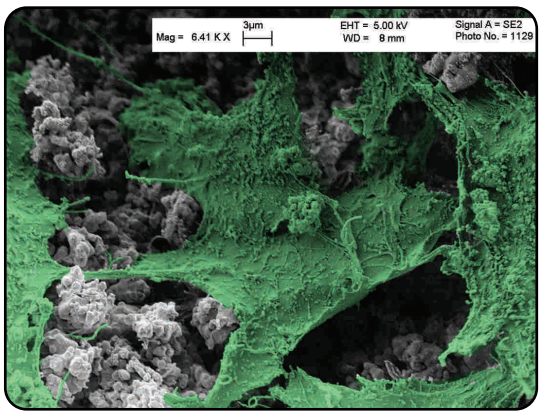
This negative surface charge has a profound influence on the nature of cells harnessed by the graft.

Key proteins are harnessed at the surface, directing bone cell adhesion and proliferation for rapid osteogenesis and healing.

The development of ***ZPC***™ heralds the arrival of a new generation of biomaterials.



ZPC™ Negative Surface Charge
Enhanced Osteoblast adhesion and proliferation on implant surface.
(*In-vitro*, 3 days, Toluidine Blue)



Primary human osteoblast adhesion and proliferation on the surface of ***geneX***® at 3 days.
(*In-vitro*, scanning electron microscopy)

healing and control bone cell activity

"The higher the negative **surface charge**, the greater the mass of new bone induced, and the higher the degree of mineralization..."

Eriksson C, Jones S,Clin Ortho Rel Res. 1977 Oct; (128): 351-3

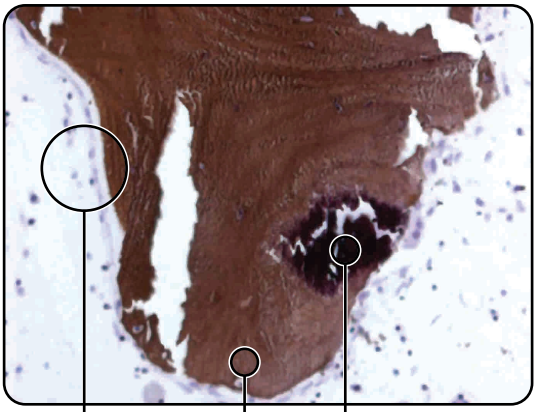
"...**zeta potential analysis** is an effective predictor of biomaterial attraction to osteoblasts and bone, providing a useful *in vitro* method for predicting such interactions."

Smith IO, et al. J Biomed Mater Res A, 2004 Sept 1; 70(3):436-41 "Electrostatic interactions as a predictor for osteoblast attachment to biomaterials."

"...(results) showed more active osteobonding ability with a **negatively charged surface** than with a positively charged surface and a non-polarized (surface)...
The superior osteobonding activity of the negatively charged surfaces was statistically proven."

Nakamura S, Kobayashi T, Yamashita K, J Biomed Mater Res A. 2004 Jan 1; 68(1): 90-4

Human Biopsy Histology
Sample obtained 8 months post implantation indicating prolific bone formation*.



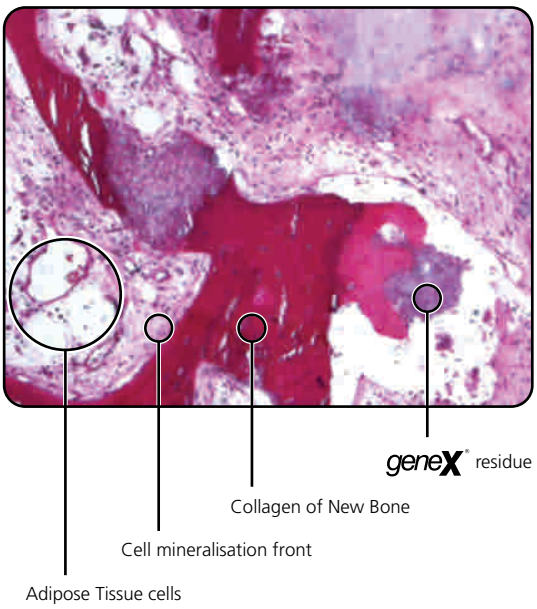
Gene expression by RT-PCR

Relative gene expression for 5 key proteins associated with bone formation

Protein	ß-TCP Scaffold	geneX
Alkaline Phosphatase	++	++
Osteocalcin	o	++
Osteopontin	++	+++
CBFA1	- -	++
Collagen Type 1	-	+

The use of '+' and '-' indicated the relative quantities of protein that each of the materials harnessed

Primary human osteoblasts cultured for 14 days on both ***geneX***® and a standard calcium phosphate



* Full study details on file. Available from Biocomposites

Fully Resorbed - Replaced by bone

Unlike other synthetic graft alternatives, ***geneX***® has been designed with a resorption profile complimentary to the rate of new bone growth.

Complete resorption of the graft material is achieved in 12 months.

Clinical Study

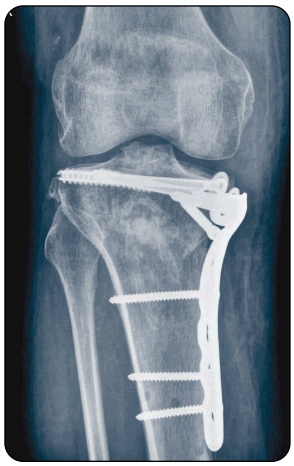
A 45 year old male presented with severe comminution of the distal tibial condyle, with osseous avulsion of the cruciate ligament, following a motorcycle accident.
The fracture was classified as Schatzker Type IV.

The fracture was reduced with a low contact plate (LCP) and cannulated 7.3 AO Screws, in conjunction with ***geneX***® to reduce the compression.

Immediately post-op

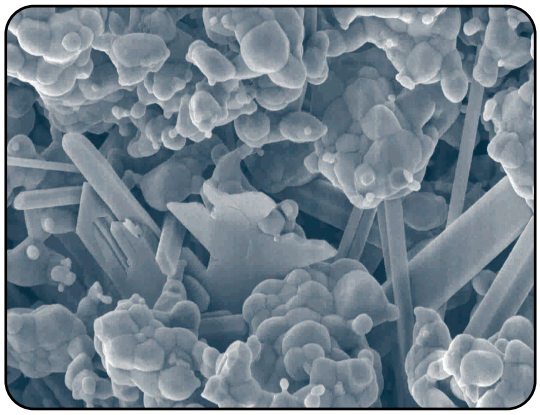
4 weeks post-op

12 weeks post-op



6 months post-op

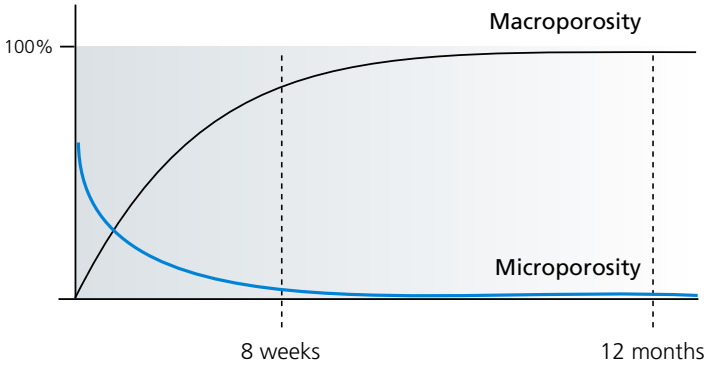
Smart*Pores* Optimised Porosity Development



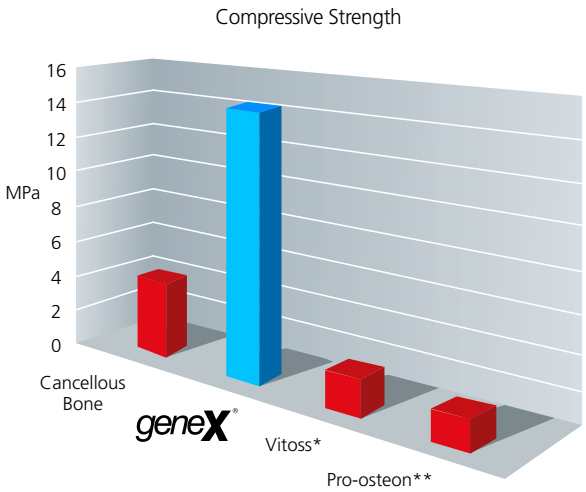
Scanning electron micrograph (SEM) image of ***geneX***®.
This shows the inherent microporosity.
The 2 separate crystalline components are clearly identified.

geneX® has been engineered with ***Smart****Pores*, a dynamic porosity designed to evolve with the bone healing cascade, with complete resorption of the graft material in 12 months.

geneX® is a biphasic matrix of hydroxyl sulphate and porous calcium phosphate.
The porosity development in the graft material is the direct result of carefully controlled composition.



Dynamic porosity development in ***geneX***®



Compressive Strength when set at implantation
Time = 0

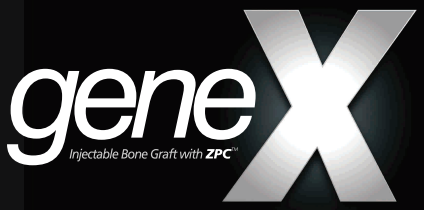
* Vitoss is a trademark of Orthovita Inc.
** Pro-osteon is a trademark of Interpore-Cross Inc.

Stronger than bone

geneX® has been shown to have a compressive strength more than 3 times that of cancellous bone on setting.

The material can be drilled through and allows early fixation of metallic implants at the surgical site.

The compressive strength then reduces as the ***geneX***® is resorbed and load is transferred to the new bone at the site.



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To place an order or for more information please call

Keele Science Park, Keele, Staffordshire
England. ST5 5NL
Telephone: **+44 (0)1782 338580**
Facsimile: **+44 (0)1782 338599**
E-Mail: info@biocomposites.co

www.biocomposites.com