APATITE/FIBER ABSORBABLE COMPOSITES FOR LOAD-BEARING APPLICATIONS IN BONE FIXATION

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EXECUTIVE SUMMARY

Teleflex Medical OEM, in conjunction with researchers at the University of Connecticut, has developed a tough, high-modulus composite with potential for bone fixation. Fabricated from a unidirectional, fibrous PLLA/apatite, the composite exhibits excellent mechanical properties which correlate to those of natural bone while featuring excellent surface bioactivity. The entire composite is bioabsorbable whereby a device made from the composite will gradually be replaced by natural bone tissue at the implantation site. Early studies indicate integration can occur firmly and permanently with the surrounding tissue. In addition, such prepared composites may have the potential to be used to control the release of growth factors to enhance bone cell stimulation.

BONE FIXATION MATERIAL DEVELOPMENTS IN ORTHOPEDIC SURGERY

Use of metal and ceramic implantation devices

Currently, bone fixation implants such as metal plates, intramedullary rods, and screws are constructed of either titanium or stainless steel. These metals are chosen for their biocompatibility, high mechanical strength, and a bending modulus that is greater than cortical bone. However, because these metals are so stiff, they absorb much of the stress in load-bearing applications (stress shielding), causing any new tissue growth at the implantation site to be relatively weaker. In addition, continued use of these implants may lead to adverse reaction in a patient's body as the metal, though selected for its inert properties, has the potential to leach into the patient's system, thus requiring a second surgery for removal of the implant.

Non-fibrous composites have been prepared using a variety of methods. The combinations of various nonabsorbable and absorbable polymers with calcium-based materials are well accepted by surgeons. For example, polymer composites are very useful in orthopedic surgery while biocompatible polymers and polymer ceramic composites have been used for tissue graft applications. But, most of these non-fibrous composites have relatively poor mechanical properties that cannot meet the strength and toughness demands of many biomedical applications, such as load-bearing skeletal implants.

Research has now turned to the development and introduction of biomaterials into load-bearing fixation procedures. The Teleflex Medical OEM research team has joined the effort in exploring this technology and has identified key parameters in meeting these needs. Ideally, a successful implant device will have:

1) Stiffness and other mechanical properties similar to the natural cortical bone.

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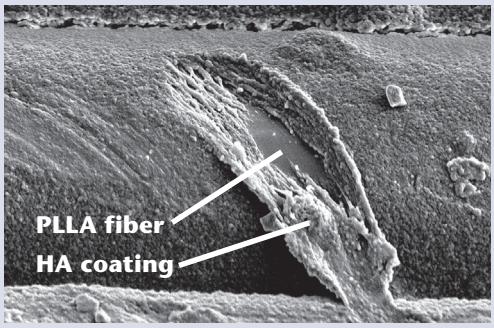
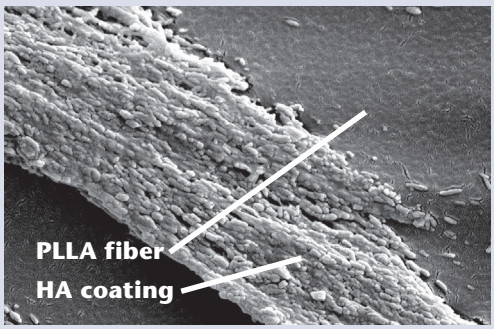




Figures 1 A and B
The alignment of HA on PLLA fibers in a polymer matrix increase the flexural modulus of the composite.

2) The ability to foster new bone growth.

3) The ability to gradually degrade over time with the replacement of the new bone tissue.

Understanding the mechanical properties of cortical bone

Structurally, bone is a composite consisting of inorganic hydroxyapatite crystals (HA) and an organic mix composed of mostly collagen fiber with small amounts of other proteins. A key aspect is that the collagen fibers are aligned in bundles that contain apatite nano-crystals aligned along the fiber axis. This structural alignment is the foundation of the multi-level hierarchial structure of bone and contributes to bone's natural resistance to bending. To be successful, a biocompatible synthetic bone composite must mimic this important orientation of components to achieve the mechanical properties of bone.

TELEFLEX MEDICAL OEM'S BIOCOMPATIBLE COMPOSITE MIMICS NATURAL BONE

Alignment of fibers help achieve desired stiffness

The Teleflex Medical OEM research has been devoted to the fabrication of synthetic implants that support natural bone structurally, mechanically, and biologically. Proper alignment of HA in the polymer matrix has been shown to be essential to gaining the levels of stiffness needed in polymer-matrix composites based on completely degradable polyesters. A successful absorbable bone-fixation device must be as strong as the surrounding bone tissue and it must be able to retain that strength until the bone heals completely.

The research team has fabricated a uniaxial fibrous/HA composite that successfully mimics natural cortical bone in mechanical strength, promotes bone growth, and biodegrades over time. The research team's approach has been to coat poly-L-lactic acid (PLLA) fibers with oriented HA *(figures 1 A and B)* in order to increase the flexural (bending) modulus and bind the apatite-coated fibers together in a bioabsorbable polyester resin. The researchers determined that proper alignment of HA in the polymer matrix is essential for gaining the levels of stiffness needed in polymer-matrix composites based on completely degradable polyesters.

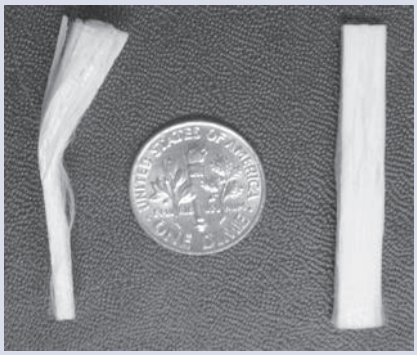
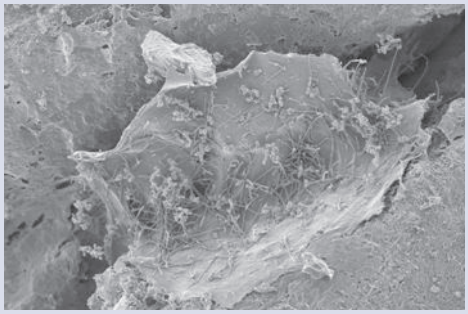
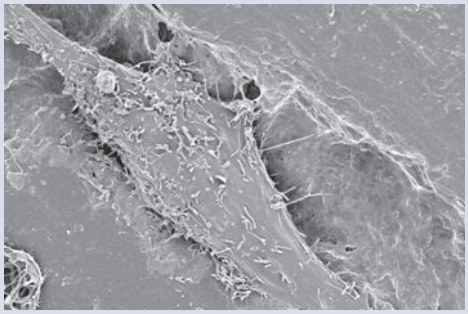


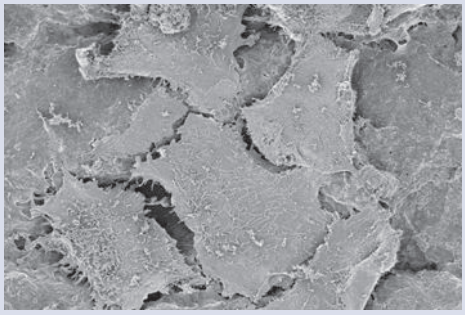
Figure 2
Novel bone composite provides flexibility and strength to surrounding tissue.

The flexural modulus of the resulting composite reached approximately 8 GPa, which falls within the flexural modulus for cortical bone (6.5 to 30 GPa). These composites exhibit very good toughness. They do not fracture when bent at 90° *(figure 2)*, proving that it is possible to prepare an implant that is flexible enough to avoid stress shielding and strong enough to provide mechanical support to the body.

In addition, these dense composites may feature a porous bioactive layer that facilitates cell attachment and promotes healthy bone ingrowth that will eventually replace the bioabsorbable fiber *(figures 3 A, B and C).*







Figures 3 A, B and C
Scanning electron micrographs of successful osteoblast growth on HA-coated PLLA fibers.

PARTNER WITH TELEFLEX MEDICAL OEM TO EXPLORE POTENTIAL APPLICATIONS OF THE NOVEL BONE COMPOSITE

The hydroxyapatite bone composite material, available through Teleflex Medical OEM, has the potential to present an important advancement in the field of biocompatible materials for the health care industry. The material's unique structural and mechanical properties give it tremendous potential for a variety of applications as bioabsorbable orthopedic devices, which could include pins, screws, plates, and suture anchors. Initially, the composite material will be available in plate form *(figure 2)*. Rod production is within the scope of future research activities.

With the novel composite material, Teleflex Medical OEM intends to enhance its position as a major innovator and manufacturer of custom medical devices and products for the orthopedic industry. By concentrating on strategic collaborations, Teleflex Medical OEM will build a diverse portfolio of biocompatible orthopedic products. Teleflex Medical OEM welcomes inquiries from health care companies interested in customized applications of the composite material.

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