BioComposite Interference Screws for ACL and PCL Reconstruction

Introduction

Arthrex has developed a new absorbable composite interosseous screw for graft fixation in ACL and PCL reconstruction procedures, combining the inherent degradation characteristics of a bioceramic material with the biocompatibility of a biopolymer. The BioComposite Interference Screw is a composite screw made from polylactide (PLDLA) and 30% biphasic calcium phosphate (BCP).

Material Composition

Bioceramic polymeric materials such as polylactide (PLA) and polyglycolide (PGA) have been used in orthopedic applications since the 1970s, when sutures made from these materials were approved for use by the FDA. Both compounds have a Ca/P ratio lower than 1.67, which is considered “optimal.” Calcium-deficient BCP has a Ca/P ratio lower than 1.67. This ratio is controlled by the amount of HA to ß-TCP in the bone matrix after aining at a high temperature to convert to a mixture of the two ceramics. It has been demonstrated that using a stoichiometric calcium-deficient HA powder to form BCP as opposed to physically combining separate HA and ß-TCP powders results in higher compressive strength and less degradation rate in vivo [8]. Physically combining the powder might result in the final material, lacking the porosity and strength and making for poor bone formation much better than HA or ß-TCP alone, since studies have shown new bone formation with a fibrous tissue layer at earlier timepoints with BCP alone compared to pure HA [10] and shows excellent bioactivity without a fibrous interface in a rat calvarial defect model [11]. An osteoconductive material supports bone formation, growth, and provides stable mechanical strength when the right cells, growth factors, and other agents are in the vicinity. A well-combining PLDLA and PDLC-ß-TCP interference screws to titanium interference screws found that the composite screws had higher pullout strength and stiffness compared to the metallic screws [12]. Combining HA and ß-TCP ceramics to PLA-matrix materials also results in higher dynamic modulus [13]. As BCP content increases in PLDLA materials, ultimate tensile strength decreases, but it is within range for bone fixation materials [14]. A 70:30 PLDLA-ß-TCP screw, containing BCP particles in the screw thread sections, showed new bone formation and remodeling in the bone after 4 months [15], further proof what studies using those materials separately have found. If the optimal properties of PLDLA and BCP can be combined in a spiral appliance, as shown above, similar results can be observed in ACL and PCL reconstruction.

References

Introduction

Arthrex has developed a new absorbable composite interference screw for graft fixation in ACL and PCL reconstruction procedures, combining the inherent degradation characteristics of two distinct ceramics with the biocompatibility of a synthetic polymer. This BioComposite Interference Screw is a composite of poly(L-lactide-co-D,L-lactide) (PLDLA) and biphasic calcium phosphate (BCP).

Material Composition

Biocompatible polymeric materials such as polylactides (PLA) and polylactic acid (PLLA) have been used in orthopedic applications since the 1970s, when initial tests were made from these materials were approved for use by the FDA. Both PLA and PLLA are derived from corn starch and results much flatter. PLA and PLLA materials can be combined in different ratios to produce poly(L-lactide-co-glycolide) (PLGA) polymers with variable degradation rates. PLA units are in two stereomeric forms, L-lactide and D-lactide. L-lactide is more commonly found and semi-crystalline, while D-lactide is mostly amorphous and amorphous. Even combining just these PLA monomers alone can alter degradation time and mechanical strength. The 70:30 L/D ratio in the PLDLA material in our BioComposite Interference Screw results in retention of ½ of its tensile strength after 24 weeks and ultimate retention of ½ of its tensile strength after 32 weeks.

Screw design: from 70% biocomposite to titanium interference screws

An osteoconductive material supports bone formation, and provides bioactive elements needed when the right cells, growth factors, and other signals are in the tissues. A well-combining PLDLA and PLGA and PLDLA-ß-TCP interference screws to titanium interference screws found that the composite screws had higher pull-out strength and stiffness compared to the metallic screws [12]. Combining HA and ß-TCP ceramics in PLA-polymer materials also results in higher dynamic modulus [13]. As cortical bone contains in PLDLA materials, ultimate tensile strength increases, but is still within range for bone fixation materials [14]. A 70:30 PLDLA-TCP spiral screw, combining BCP particles in the core of the screw, showed new bone formation and bone-like collagen fibers on the bone after 4 to 6 weeks [15], and what studies using those materials separately have found. If the optimal properties of PLDLA and BCP can be combined in a spiral apparatus, as shown above, similar results can be achieved in ACL and PCL reconstructions.

References:

Interference Screw show that molecular weight (MW) is critical to degrade completely, as seen in the BioComposite Interference Screw (Figure 5a) and the Milagro screw (Figure 5b) in an ovine ACL reconstruction model. The degradation behavior of the BioComposite Interference Screw appears to be quite similar to a fracture callus. However, inflammatory response is not complete at 2 years. Some new bone is evident, with tissues heading toward a fibrous, cartilage-like, or bone lineage, as well as less bone than what is seen in the tibial site. This histological response was also seen at the femoral site. Figure 10c shows only some collagen surrounding the screw void in the BioComposite Interference Screw. At 104 weeks, there is no sign of the screw at all. Therefore, the screw degradation occurred between 52 and 108 weeks in this model. The results showed that some inflammatory response, without a significant inflammatory response, and some bone degradation. The Milagro screw produced some bone, as well as fibrous tissue and an inflammatory response. If Milagro produces fibrous tissue without much bone, this would be to have a more productive response with the BioComposite Interference Screw.

**Conclusion**

This 2-year in vivo animal study showed the degradation profile of the BioComposite Interference Screw in a deep model, as well as the screw’s ability to support new tissue formation on the bone. The BioComposite Interference Screw produced some bone, fibrous tissue, and an inflammatory response, and some bone degradation. The Milagro screw produced some bone, as well as fibrous tissue and an inflammatory response. The Milagro screw produces fibrous tissue without much bone, as it would be to have a more productive response with the BioComposite Interference Screw.
Controlled Solubility

Studies of the material properties of the BioComposite Interference Screw show that the inclusion of hydroxyapatite (HA) and inherent viscosity (IV) Figure 1b) drop slowly and uniformly from time 0 up to 12 weeks; however, the mechanical strength at both timepoints is equivalent.

Arthrex vs. Our Competitors’ Composite Screws

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<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name</th>
<th>Material Composition</th>
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<tbody>
<tr>
<td>ArthroCare BiLok</td>
<td>75% PLLA and 25% ß-TCP</td>
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<tr>
<td>96/4 PLDLA and 25% ß-TCP</td>
<td></td>
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<tr>
<td>ConMed Linvatec Matryx</td>
<td>75% self-reinforced (SR)</td>
<td></td>
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<tr>
<td>DePuy Mitek Milagro</td>
<td>70% PLGA &amp; 30% ß-TCP</td>
<td></td>
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<tr>
<td>BCP - 60 HA/40 ß-TCP</td>
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<td></td>
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<tr>
<td>Interference Screw</td>
<td>PLDLA - 70 PLLA/30 PLDA</td>
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Mechanical Testing

Torsion testing found that 10 mm BioComposite Delta Screws showed a consistent, low cycle peak torque at 24 hours. In contrast, the biomechanical properties were constant, with the BioComposite Interference Screw, where the primary difference is the absence of a screw inclusion material. This material behavior. Either lowering or raising the amount of material should be optimized for mechanical strength and material behavior. Either lowering or raising the amount of polymer and/or cement material can affect stiffness of the interface by making the screw brittle or pliable, or possibly induce additional stress. The shape of the screw that occurs too quickly can lead to a pH drop, therefore increasing the screw diameter and thickness in the screw, resulting in a change in the screw’s behavior.

Animal Testing - 2 Weeks

CT data at 52 weeks show a minimal inflammatory response, similar to the tibial site. Again, there is quite a significant inflammatory response at the femoral site, with tissues heading toward a fibrous, cartilaginous response. At 52 weeks, bone formation is evident, with new bone always surrounding the screw, with new bone always surrounding the screw.

Animal Testing - 12 Weeks

Compared to the BioComposite Interference Screw in the tibial insertion site, the BioComposite Interference Screw keeps its shape and is well-integrated into cortical bone (Figure 8), with some evidences bone apposition. The Milagro Screw (Figure 8) shows a minimal inflammatory response in its surrounding bone. Histology at the tibial insertion site shows that the BioComposite Interference Screw has bone (black arrow) (Figure 9), with some evidence of bone apposition. The Milagro Screw (Figure 8) shows a thin tract of new bone (black arrow), along with some fibrous tissue in the screw site, in the femoral tunnel site, the BioComposite Interference Screw (Figure 9) shows that the void is filled with a layer of fibrous tissue at the screw-tissue interface.

Animal Testing - 26 Weeks

The BioComposite Interference Screw shows a mixture of bone and fibrous tissue surrounding the screw void, which is seen in the CT and histology images. The PLDLA screws show a mixture of bone and fibrous tissue, with some areas showing inflammation. The PLDLA screws have some areas showing inflammation, and the bioComposite Interference Screw is still well- integrated into cortical bone.

Animal Testing - 52 Weeks

CT data at 52 weeks show a minimal inflammatory response, similar to the tibial site. Again, there is quite a significant inflammatory response. With a high resolution image with micro CT, the bioComposite Interference Screw produces new bone, little to no inflammatory response, and some bone degradation. The Milagro screws produced new bone, as well as inflammatory response and some bone degradation. This model shows a lot of fibrous tissue and not much bone formation.
The green fluorescent stain shows uniform dispersion of the ceramic material with mechanical strength at both timepoints is equivalent.

The activity of osteoclasts [16] to resorb tissue and screw increase resorption via acidosis. Polymer degradation that interface by making the screw brittle or pliable, or possibly material behavior. Either lowering or raising the amount of material should be optimized for mechanical strength and material behavior. Either lowering or raising the amount of polymer takes about 5-6 months to degrade completely.

Table 1

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<td>ConMed Linvatec</td>
<td>Matryx 75% self-reinforced (SR)</td>
<td>95% PLLA &amp; 5% HA</td>
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<tr>
<td>Smith &amp; Nephew</td>
<td>BioRCI-HA</td>
<td>95% PLLA &amp; 5% HA</td>
</tr>
<tr>
<td>Interference Screw</td>
<td>PLDLA - 70 PLLA/30 PLDA</td>
<td>Interference Screws.</td>
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In vitro studies of the material properties of the BioComposite Interference Screw show that the material, at 12 weeks, has some minimal new bone within the tibial screw site. The Milagro screws also show a thin tract of new bone (black arrow), along with some fibrous tissue within the tibial site. The BioComposite Interference Screw always has a rim of bone completely surrounding the screw void as seen with CT (white arrow), with good bone apposition within the screw void. Some isolated bone pieces and marrow is seen in the screw void. The BioComposite Interference Screw always has a rim of bone completely surrounding the tibial site. Again, there is quite a significant inflammatory response here, with tissues heading toward a fibrous, cartilaginous, or bone lineage, as well as less bone than what is seen in the tibial site.
Beta-TCP is amorphous and resorbs quickly, not leaving enough bone ingrowth to the site of operation. Polymers and ceramics, such as hydroxyapatite (HA) and Beta-tricalcium phosphate (ß-TCP), have been used in orthopedic applications since the 1970s, when natives made from these materials were approved for use by the FDA. Both of these materials are biocompatible, biodegradable, and resorbable.HA is crystalline and contains all of the elements that make up bone tissue. β-TCP, on the other hand, is a ceramic and results from a mixture of materials. Poly-l-lactide (PLLA) and poly-D-lactide (PDLA) are both resorbable in the body, but PLLA resorbs much faster. PLGA is a polymer that can be combined with different ratios of lactide and glycolide to produce PLDLA, which has variable degradation rates. PLDLA with a 70:30 L:D ratio is very similar in mineral content to natural bone. However, as with polymers, these materials have resorbability issues. Therefore, researchers have developed a range of materials to achieve the ideal properties of bone: mechanical strength, bioactivity, and resorbability. In order to achieve the best balance of these properties, composite materials combining the resorption rates of HA and ß-TCP would be ideal. A new class of ceramic materials, biphasic calcium phosphate (BCP), can be created by combining HA and ß-TCP in different ratios, resulting in a range of controllable resorption profiles. Typical commercial BCP formulations can vary in HAp:TCP ratios from 80:20 to 20:80. The BioComposite Interference Screw is formed from PLDLA (70:30 L:D) and BCP, which results in a combination of mechanical strength and bioactivity.

Ceramics such as hydroxyapatite (HA) and Beta-tricalcium phosphate (ß-TCP) are osteoconductive materials that support bone formation. The BioComposite Interference Screw is a combination of a biocompatible polymer with the bioactivity of a ceramic. This allows for new bone to replace the material in the defect site. Combining the resorption rates of HA and ß-TCP would be ideal. A new class of ceramic materials, biphasic calcium phosphate (BCP) [7], can be created by combining HA and ß-TCP in different ratios, resulting in a range of controllable resorption profiles. Typical commercial BCP formulations can vary in HAp:TCP ratios from 80:20 to 20:80. The BioComposite Interference Screw is formed from PLDLA (70:30 L:D) and BCP, which results in a combination of mechanical strength and bioactivity.

The BioComposite Interference Screw is a combination of a biocompatible polymer with the bioactivity of a ceramic. This allows for new bone to replace the material in the defect site. Combining the resorption rates of HA and ß-TCP would be ideal. A new class of ceramic materials, biphasic calcium phosphate (BCP) [7], can be created by combining HA and ß-TCP in different ratios, resulting in a range of controllable resorption profiles. Typical commercial BCP formulations can vary in HAp:TCP ratios from 80:20 to 20:80. The BioComposite Interference Screw is formed from PLDLA (70:30 L:D) and BCP, which results in a combination of mechanical strength and bioactivity.

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