Biodegradable Implants in Spine

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ABSTRACT

Biodegradable implants degrade in a biologic environment. The use of bioabsorbable implants in spine surgery is expanding at a rapid pace. Their future as a carrier of biological agents, such as bone morphogenetic proteins and bone graft extenders, their radiolucency, and their eventual resorption make them an ideal implant for use in spinal degenerative disease. For spine fixation, ideally these implants should have mechanical characteristics equal to those of standard metal implants and would degrade with the healing process, so that fixation is not lost before adequate healing and load is gradually transferred to the healing tissue. Several new experimental bioabsorbable devices are in the process of consideration as spinal implants. These include a myriad of posterior lumbar interbody fusion devices, anterior spinal plates, and a variety of screw and mesh designs.

Keywords: Biodegradable implants, Polymer, Polylactic acid, Polyglycolic acid.

INTRODUCTION

Basic Bioabsorbable Implants

Biodegradable implants degrade in a biologic environment. Their breakdown products are incorporated into normal cellular physiologic and biochemical processes with no immunogenic or mutagenic tendency. The use of bioabsorbable implants in spine surgery is expanding at a rapid pace. Biomechanical studies have demonstrated their ability to stabilize effectively a degenerative cervical and lumbar motion segment. Their future as a carrier of biological agents, such as bone morphogenetic proteins and bone graft extenders, their radiolucency, and their eventual resorption make them an ideal implant for use in spinal degenerative disease. For spine fixation, ideally these implants should have mechanical characteristics equal to those of standard metal implants and would degrade with the healing process, so that fixation is not lost before adequate healing and load is gradually transferred to the healing tissue. But, currently available polymers do not have mechanical characteristics equal to those of metal implants.

Flexible and less rigid bioabsorbable implants confer the advantage of stabilizing the motion segments while, over time, allowing a greater transfer of load to the host spine during implant resorption, potentially minimizing junctional degeneration.

Type of Implants

Polyglycolic acid (PGA) and polylactic acid (PLA) implants have been widely used, including rods, screws and plates, are available (Fig. 1). Majority of clinical applications for these new polymers have involved tension band plating in the lumbar and anterior cervical spine, anterior spinal interbody reconstruction, posterior bone graft containment, and bone graft harvest site reconstruction.

Biodegradation

It should degrade with the healing process, so that fixation is not lost before adequate healing and load is gradually transferred to the healing tissue. Degradation occurs by several mechanisms (Table 2), including hydrolysis and enzymatic degradation. Polymer degradation leads to oligomers and monomers which follow the routes mentioned in Table 2. The final products [CO₂ and H₂O products of the tricitic acid cycle (TCA cycle)] are excreted or used by the body. Polylactic acid and polydioxanone (PDS) degradation products can also be excreted by the kidneys. It is also known that PGA degradation is partially performed by enzymes, such as esterase. Enzymes also seem to take part in PLA degradation.

Polymer breakage produces products that lower the regional pH and thus accelerate the procedure. The final degradation of polymer debris is done by macrophages and giant cells followed by mild local tissue reaction around absorbable implants. This leads to production of a thin macrophage layer with incidentally multinucleated giant cells surrounded by a mild connective tissue capsule. That is responsible for many adverse effects.
Biocompatibility

Biodegradable materials should be biocompatible. Not only that it should avoid eliciting inflammatory and immunogenic responses but also its degraded materials should not have any local and the systemic response.8

The biocompatibility of a polymer depends on its chemical structure and the processing method that produces it. During a polymerization process, an initiator, a monomer, and sometimes a catalyst are needed, and these materials often remain in preformed implants even after purification. Toxicity and concentration of residual unreacted monomers or initiators should be considered when assessing biocompatibility. Removal of these potentially toxic components is usually effected by prolonged rinsing in aqueous solution. Biocompatibility of the remaining material is confirmed in vitro by cytotoxicity assays. In vivo observation of the inflammatory response after implantation in animal models is also an important step before clinical application can be considered.

Clinically, significant foreign-body reactions are far more rarely seen with PLA than with PGA. In short-term studies, the biocompatibility has been acceptable with no clinical manifestations of foreign-body reactions.

Processability: Sterility, Reproducibility and Ease of Handling

It should be possible to sterilize biodegradable implants without affecting their chemical or physical properties and to produce and package them on a large scale for practical and economic uses. Factors, such as viscosity, curing time and implant shape, should also be optimized for injectable scaffolds to facilitate their use during complex surgical procedures.5-7

STUDIES

Many of the biomechanical and fusion studies of bioabsorbable implants have been conducted in animal models. In particular, sheep and goats have been most widely used as test subjects for bioabsorbable products in trials to discern their effectiveness and safety. Studies have shown that the biomechanical environment of axial loading of the sheep and goat spine is comparable to that of the human spine.13,15,16,19,20

<table>
<thead>
<tr>
<th>Implant material</th>
<th>Diameter (mm)</th>
<th>Bending modulus (GPa)</th>
<th>Bending strength (MPa)</th>
<th>Shear strength (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless steel (for comparison)</td>
<td>—</td>
<td>200</td>
<td>280</td>
<td>—</td>
</tr>
<tr>
<td>Self-reinforced polyglycolic acid</td>
<td>2</td>
<td>13</td>
<td>320</td>
<td>240</td>
</tr>
<tr>
<td>Injection-molded polyglycolic acid</td>
<td>2</td>
<td>7</td>
<td>218</td>
<td>95</td>
</tr>
<tr>
<td>Self-reinforced poly-L-lactic acid</td>
<td>1.3</td>
<td>10</td>
<td>300</td>
<td>220</td>
</tr>
<tr>
<td>Injection-molded poly-L-lactic acid</td>
<td>2</td>
<td>3</td>
<td>119</td>
<td>68</td>
</tr>
<tr>
<td>Polydioxanone (suture)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>48</td>
</tr>
</tbody>
</table>

**Table 1:** Mechanical properties of various bioabsorbable implant materials1-3

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**Table 2:** Degradation of implants by various mean

- Poly (p-dioxanone) → Glyoxalic acid
- Polyglycolic acid → Glycolic acid
- Poly(L-lactic acid) → Lactic acid
- Poly (β-hydroxybutyrate) → β-hydroxybutyric acid
- Oxalic acid → Glycine
- Glycine → Sorine
- Sorine → Pyruvic acid
- Pyruvic acid → Acetoacetoone
- Acetoacetoone → Acetyl-CoA
- Acetyl-CoA → TCA cycle
- TCA cycle → CO₂ + H₂O

**Fig. 1:** Various biodegradable implants in spine
Van Dijk et al\(^8\) evaluated the compression strength and mechanical properties of titanium lumbar interbody cages compared with resorbable poly-L-lactic acid (PLLA) cages over 21 goats and postulated that bioabsorbable implants had a potential advantage over metallic implants because their modulus of elasticity is closer to that of vertebral bone.

Study of DiAngelo et al\(^4\) over human cadavers evaluated the use of a bioabsorbable anterior lumbar plate combined with a traditional metallic cage in anterior lumbar interbody fusions and suggested that the increased stability afforded by the addition of an anterior absorbable plate increased the fusion rate over nonplate treated cage fusions.

Cahill et al\(^1\) evaluated the efficacy of a bioabsorbable anterior cervical cage compared with ABG for anterior cervical fusion in goats after anterior cervical disectomy and fusion. Of the 12, eight underwent fusion with an 85:15 polylactide/polyglycolide bioabsorbable cage packed with ABG, and the remaining four underwent fusions with autologous bone grafting alone. Stable interbody fusions were obtained in only three (19%) of 16 in the group treated with the bioabsorbable device, and in one (14%) of seven in the group treated with ABG.

Toth et al\(^1\) evaluated the combination of 70% L-lactide and 30% D,L-lactide copolymer as an interbody fusion cage in a sheep model.

Austin et al\(^1\) evaluated the use of a bioabsorbable interbody spacer in the treatment of lumbar degenerative disease and deformity in 12 patients after multilevel posterior lumbar interbody fusion with bilaterally placed bioabsorbable spacers augmented with pedicle screw fixation. At the 1 year follow-up visit, all patients were found to have attained a successful clinical outcome with radiographically confirmed fusion.

**Advantage**

Biodegradable implants provide the advantages of gradual load transfer to the healing tissue; hence, less bone resorption, reduced or no need for implant removal, and radiolucency, which facilitates postoperative radiographic evaluation and no hindrance or complication in 2nd surgery, leading to reduced trauma to soft tissue hence reduced total cost of surgery and cross infection. They can be engineered to alter their degradation characteristics and material properties. These biodegradable implants are safe as they are biocompatible hence less risk of metal allergic reactions.

As compared to metallic implants, there is no long-term implant palpability hence patient compliance. There is no implant temperature sensitivity so short-wave diathermy and microwave diathermy can be used after a period of time so these overall lead to increased patient satisfaction.

Due to characteristic nature of these biodegradable implants, there is no growth disturbances in children after surgery as biodegradable screws or rods can also be used for treating epiphyseal fractures.\(^9,10\) It facilitates fracture healing by allowing micromovements at fracture site. It can be used to control the release of bioactive molecules to accelerate the healing process. The fixation does not disturb the anatomy as depicted on radiographs as there is reduced radiographic scatter or obstruction and is compatible with magnetic resonance imaging if further evaluation of the affected joint postoperatively is necessary. There is minimized risk of obstruction during any follow-up surgery.

**Disadvantage**

More expensive, and have less strength than metals.

Complications include tissue reactions, like mild fluid accumulation, painful erythematous fluctuating papule over the implant track, if left untreated, bursts forming sinuses leading to sterile sinus tract formation, osteolysis around the implants and hypertrophic fibrous encapsulation.

Adverse effect includes migration of implant, growth disturbance, rigidity, infection, effects on cellular level and implant removal operations.\(^4\) Due to its radiolucent nature, diagnosis can be difficult to make postoperatively in a persistently painful condition.

**DISCUSSION**

Clearly, future work in the area of orthopedic biomaterials should be focused on the reduction of the foreign-body response. Reducing the crystallinity of the polymer or controlling the pH in the degrading implants may help to reduce the incidence of the foreign-body response. Several new experimental bioabsorbable devices are in the process of consideration as spinal implants. These include a myriad of posterior lumbar interbody fusion devices, anterior spinal plates, and a variety of screw and mesh designs.

**REFERENCES**