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Bioabsorbable Implant Material Review

Peter B. Maurus, MD, and Christopher C. Kaeding, MD

This article reviews the three most common materials used in bioabsorbable implants in orthopaedic surgery: PGA (polyglycolic acid), PLA (polylactic acid), and PDS (polydioxanone). The chemical, material, and resorption properties of the individual polymers as well as their copolymers are reviewed for the orthopaedic clinician. Their clinical indications and use are discussed as well.
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Orthopedic implant design is integral to successful surgical intervention. Ever-changing methods of fixation and materials are studied and used to help attain improved results while limiting adverse outcomes. The development of bioabsorbable implants is an important aspect of this dynamic field of implant design. There are many options available to the surgeon who is interested in using bioabsorbable materials. Although metal implants have shown undoubted success when used for internal fixation of bones or soft tissue, these implants do have some problems. Metal implants are stiff and are permanent in nature. Thus, they tend to unload the tissues by load bearing and may necessitate removal because of the need for future surgery, migration of the implants over time, or irritation of the overlying tissues. Metal implants also interfere with radiologic imaging of the underlying skeleton. Bioabsorbable implants show promise with regards to these points in that they will degrade over time and gradually allow loading of the bone and soft tissues. They do not interfere with future surgery because they have been absorbed or can be drilled through. Furthermore, they do not require removal and are radiolucent on roentgenograms. We are currently seeing an increase in the development of these devices and find them as fixation rods, plates, pins, screws, suture anchors, and sutures. In this article, we will review the history and design of these implants.

There are 3 commonly used polymers for biobsorbable implants. Polyglycolic acid (PGA), polylactic acid (PLA), and polydioxanone (PDS) are the polymers with most clinical applications. These polymers are alpha-polyesters or poly-(alpha-hydroxy) acids. PDS was developed in the early 1980s, but PLA and PGA have been studied for nearly 50 years.[1,2] In the 1960s, Kulkarni and coworkers[3,4] was the first to describe the medical use of PLA as suture and rods for the repair of mandibular fractures in dogs.

These materials are polymers, meaning they are composed of covalently bonded monomers to create macromolecules.[5] Polymers can be made of a repeating single monomer (homopolymer) or a combination of 2 or more types of monomers (copolymer). Moreover, these copolymers can have a random arrangement of its monomers (random copolymer) or they can have long segments of monomers alternating with other segments (block copolymer).[6] Polymer chains can be linear, branched, or cross-linked with other chains. The polymer chains can be organized in either an amorphous or a crystalline state. More typically, these materials are made up of both amorphous and crystalline regions. This "semicrystalline" structure affects the strength and absorption of these implants.[6] A more crystalline structure leads to a stronger construct because of more order within the microstructure and less slippage between neighboring chains. This slippage of the chains is time dependent under load; thus, they are viscoelastic structures. Polymers are also affected by temperature. Above a specific temperature (glass transition temperature [T_g]) the polymers soften and become flexible. It is thus important to have bioabsorbable polymers that have a T_g above body temperature.[5] The molecules' behavior is further governed by orientation, geometric isomerism, conformation, and configuration.[7]

PLA exists as either L-PLA (mostly crystalline) and DL-PLA (mostly amorphous) (Fig. 1). Because of its high crystallinity, L-PLA is highly resistant to hydrolysis, and because of its amorphous nature, DL-PLA is more sensitive to hydrolysis.[8] Therefore, the PLA we use is actually a copolymer of the 2 isomeric monomers.

PGA exists in only 1 form (Fig. 1). Homopolymer PGA has greater strength than PLA. A self-reinforced form of PGA is significantly stiffer than any other form of clinically applicable biopolymer.[9] PGA, however, degrades rapidly. Its acidic breakdown products are responsible for causing inflammation in the surrounding tissues. Most tissue complications

OSU Sports Medicine Center, Columbus, OH.
Address reprint requests to Christopher C. Kaeding, MD, OSU Sports Medicine Center, 2050 Kenny Road, Suite 3300, Columbus, OH 43221-3502. E-mail: kaeding-1@medctr.osu.edu

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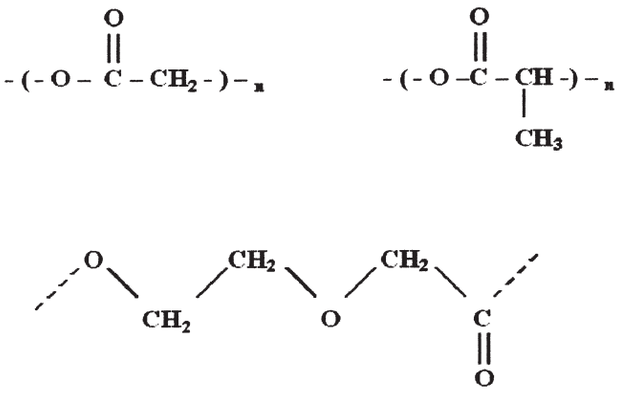

Figure 1 Structural formulas for PGA, PLA, and PDS.

with bioabsorbable implants are caused by PGA polymers. Furthermore PLA-PGA copolymers exist. For example, the commonly used suture material Vicryl (Ethicon, Somerville, NJ) is 90:10 PGA:PLA. The ratios of PGA to PLA alter the degradation rates and mechanical characteristics of these materials.[5] Thus, a PGA-PLA copolymer is beneficial in that it degrades more quickly that L-PLA but does not have the rapid degradation and release of acidic breakdown products that pure PGA would have.

PDS is a colorless, crystalline polymer (Fig. 1). A purple hue is added for handling by introduction of an inert dye. PDS is produced through melt extrusion of granules through a dye and then completed by heat treating the polymer.[1]

Inherent in the name, bioabsorbable implants should effectively degrade and eventually be resorbed or excreted. This occurs first through a loss of molecular weight, loss of strength, and then a loss of material over time. Degradation of these copolymers occurs through a nonspecific scission of their ester bonds. PGA is broken down into glycine. Glycine is either excreted in the urine or converted into carbon dioxide and water through the citric acid cycle. Lactic acid, a normal human metabolic byproduct, is the breakdown product of PLA and it also is converted to water and carbon dioxide in the citric acid cycle. PDS is either broken down into glycoxylate and excreted in the urine or converted into glycine then carbon dioxide and water through the same mechanism as PGA. The time it takes for degradation to occur is related to the copolymer's porosity, crystallinity, and molecular weight[10] (Fig. 2).

The process of hydrolysis occurs immediately on implantation of the implant by scission of the long polymer chains as described earlier. This leads to a loss of molecular weight of the implant.[11,12] Pitt and coworkers[13] showed that loss of molecular weight occurs before any material loss is observed, and Li and coworkers[14] showed that the material weight of PLLA does not decrease until after 5 weeks of submersion in an unbuffered saline solution. Water enters the material through pores in its surface. For this reason, porosity and surface area play a major role in the degradation of these implants. Athanasiou and coworkers[12] showed that materials that are less porous tend to hold in the acidic breakdown products, leading to an acceleration of the hydrolytic process. Low porosity implants, thus, have a lower functional lifespan. Similarly, acidic environments can hasten the degradation process. If the host tissue is unable to effectively remove the acidic breakdown products, the pH will decrease, leading to an acceleration of degradation and possibly a local tissue reaction. This has led to an interest in incorporating buffering agents into these devices.[15]

The amount of exposed implant surface also enhances hydrolysis because it increases the surface area available for reaction. Implants placed in areas of greater stress degrade at a faster rate.[16,17] This is thought to be caused by microstructural cracks, which lead to an increase in exposed surface area. Cracks also lead to an overall loss of mechanical strength, regardless of chemical reactions.

Except for L-PLA, which degrades very slowly over time, most other bioabsorbable polymers see a loss of strength over approximately 5 to 8 weeks and a complete loss of mass over 6 to 12 months.[5,18] In vivo testing of L-PLA showed no loss of strength after 5 months, and it is unknown whether or not L-PLA ever completely degrades. The addition of D-PLA increases the rate of degradation. A 50:50 mixture of L-PLA:D-PLA degrades over about 60 days and loses almost 70% of its strength in 1 month.[19] Vert and coworkers[19] concluded that L-PLA alone was "too biostable for bone surgery," but that a polymer with more than 16% D-PLA would degrade too rapidly for effective orthopedic use. PGA and PDS degrade over approximately 60 days and have a complete loss of mass over 9 to 12 months[5] (Table 1).

These 3 copolymers can have a variety of mechanical properties based on their crystallinity, viscosity, and molecular weight. The manufacturing process affects these mechanical

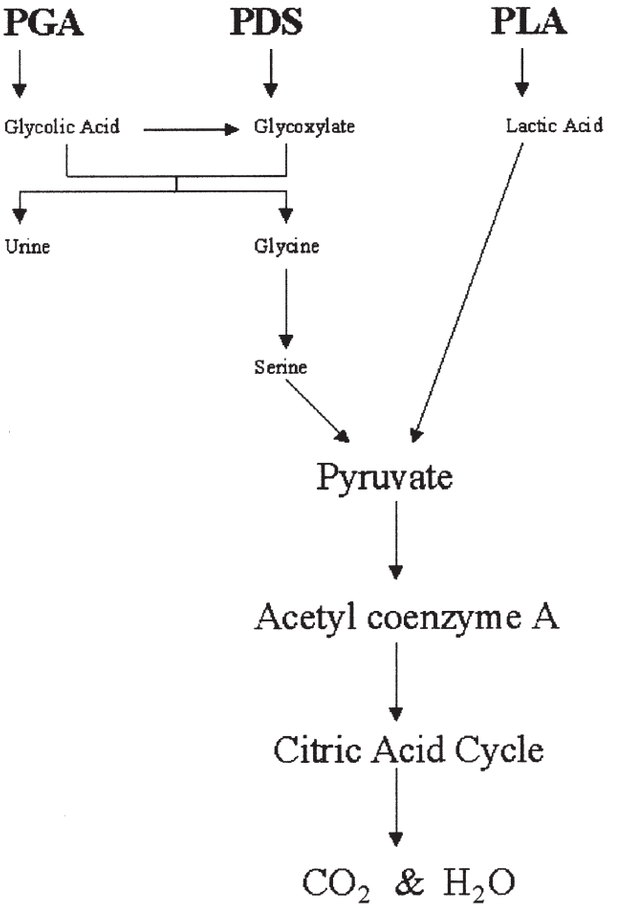

Figure 2 The breakdown of bioabsorbable polymers.

Table 1 Properties of Common Bioabsorbable Materials

Polymer	Melting Point (°C)	Glass-Transition Temp (°C)	Modulus (Gpa)	Loss of Strength (months)	Loss of Mass (months)
PGA	225-230	035-40	12.8	1-2	6 to 12
LPLA	173-178	60-65	4.8	6	?
DLPLA	Amorphous	55-60	1.9	1-2	12 to 16
PDS	NA	(−10)-0	1.5	1-2	6 to 12

Abbreviation: NA, not applicable.

properties. The flexural strength, tensile strength, and tensile modulus have been tested on all of the available materials. Compared with stainless steel, these properties are poor. To improve the mechanical properties of bioabsorbable implants, fiber-reinforced implants have been designed. These materials have much higher tensile strength because of the orientation of fiber molecules. And, when the fibers are combined with a matrix of the same polymer (self-reinforcement), the mechanical properties improve substantially. In fact, initially, the bending strength of self-reinforced PGA is stronger than stainless steel but quickly decreases with degradation.[18] Also, because of the viscoelasticity of these materials, they lose a significant amount of their screw force immediately after application. For example, both L-PLA and copolymer D-PLA/L-PLA screws lost approximately 20% of their force within 20 minutes. In distilled water, this effect was even more pronounced, with a loss of 30% and 45% of the initial force of these screws.[18]

Clinical Applications

The use of bioabsorbable materials has become commonplace in orthopedic surgery. These devices have expanded the armamentarium of the surgeon, especially in the field of sports medicine. Interference screws, suture anchors, meniscal repair devices, and simple fracture fixation devices are the most commonly used biabsorbable implants for anterior cruciate ligament reconstruction, shoulder surgery, meniscal repair, and fracture care.

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