

Bioabsorbable Implants in Orthopaedics: New Developments and Clinical Applications

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Abstract

The use of bioabsorbable implants in orthopaedic surgical procedures is becoming more frequent. Advances in polymer science have allowed the production of implants with the mechanical strength necessary for such procedures. Bioabsorbable materials have been utilized for the fixation of fractures as well as for soft-tissue fixation. These implants offer the advantages of gradual load transfer to the healing tissue, reduced need for hardware removal, and radiolucency, which facilitates postoperative radiographic evaluation. Reported complications with the use of these materials include sterile sinus tract formation, osteolysis, synovitis, and hypertrophic fibrous encapsulation. Further study is required to determine the clinical situations in which these materials are of most benefit.

J Am Acad Orthop Surg 2001;9:280-288

The use of absorbable materials in surgery is not new, as gut suture was described in the writings of Galen in the second century. However, recent improvements in polymer science have led to the development of new orthopaedic implants made of bioabsorbable materials. The chief advantage of these implants is that there is initial stability adequate for healing and then gradual resorption after biologic fixation has been established. In addition, these materials limit stress shielding of bone, gradually apply load as they degrade, obviate hardware removal procedures, and facilitate postoperative radiologic imaging. Polymers made from lactic acid, glycolic acid, and dioxanone, as well as copolymers of these materials, have been studied and are readily available for clinical use as implants for both bone and soft-tissue fixation.

Basic Science of Bioabsorbable Implants

By definition, bioabsorbable implants are degraded in a biologic environment, and their breakdown products are incorporated into normal cellular physiologic and biochemical processes. These materials must also be biocompatible, with degradation products that are well tolerated by the host with no immunogenic or mutagenic tendency. In addition, for musculoskeletal applications, these materials must maintain adequate strength and not degrade too rapidly, so that fixation is not lost before adequate healing can occur.

The perfect bioabsorbable material for orthopaedic use would initially have mechanical characteristics equal to those of standard stainless steel implants. It would degrade with the healing process so that load is gradually transferred to the heal-

ing tissue. The currently available polymers still do not have mechanical characteristics equal to those of metal implants¹⁻³ (Table 1), but improvements continue to be made, particularly with the use of reinforcing techniques.

Polymer Science

Most research on the clinical applications of bioabsorbable materials has focused on the use of polymers known as alpha-polyesters or poly-(alpha-hydroxy) acids. These include polylactic acid (PLA), polyglycolic acid (PGA), and polydioxanone (PDS). Combinations of these materials allow optimization of

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Table 1
Mechanical Properties of Various Bioabsorbable Implant Materials¹⁻³

Implant Material	Diameter, mm	Bending Modulus, GPa	Bending Strength, MPa	Shear Strength, MPa
Stainless steel (for comparison)	...	200	280	...
Self-reinforced polyglycolic acid	2	13	320	240
Injection-molded polyglycolic acid	2	7	218	95
Self-reinforced poly-L-lactic acid	1.3	10	300	220
Injection-molded poly-L-lactic acid	2	3	119	68
Polydioxanone (suture)	48

their biomechanical properties for specific clinical uses.

Polymers are composed of covalently bonded subunits that form large macromolecules.⁴ These repeating subunits are referred to as monomers. A polymer made of a single repeating monomer is a homopolymer. A combination of two or more different monomers results in a copolymer. The various monomeric units in a copolymer may be arranged randomly (random copolymer) or in long regions of one subunit alternating with another (block copolymer). The biomechanical and biochemical properties of a copolymer differ from those of its constituent monomers.⁵

The polymer chains that constitute the implant may be linear, branched, or cross-linked to neighboring chains. The microstructural organization of the chains may be amorphous or crystalline, as determined by the orientation of the polymer chains. The overall crystallinity of a polymer affects its biomechanical and degradation properties. These properties can be influenced by the manufacturing technique, with elevated temperatures and a slow rate of cooling allowing the polymeric chains to align themselves in an ordered solid structure.⁶ Most bioabsorbable implants are made of "semicrystalline" materials containing both amorphous and crystalline

regions, each of which plays a role in strength and absorption rates.^{5,7,8}

Many of the physical properties of a polymer are dependent on the chemical composition, the molecular weight, and the arrangement of the polymer chains. Polymers utilized in orthopaedics are viscoelastic in nature; therefore, their physical properties change with the rate of load application and are time-dependent. Increased molecular weight implies an increased intrinsic viscosity within the polymer, leading to less deformability (i.e., less flow) with an applied load. In general, high- to average-molecular-weight polymers that are highly viscous will undergo slower biodegradation than those of lesser molecular weight and viscosity.

The mechanical properties of a polymer are further influenced by temperature. The glass-transition temperature (T_g) is the temperature below which the polymer is stiff and hard and above which it is soft and rubbery. The T_g will vary with the chemical composition of the polymer, the molecular weight, and the percentage of the polymer involved in amorphous domains. As a polymeric implant is able to withstand more load at temperatures below its T_g , most polymers utilized clinically have a T_g above body temperature.

Lactic acid is a small, hydrophobic three-carbon molecule that

plays an important role in cellular energy production. Due to the asymmetry of the molecule, it has both a dextrorotatory (D) and a levorotatory (L) configuration. The D-form is readily produced, but the L-isomer is the biologically active form. Polymerized L-lactic acid is referred to as poly-L-lactic acid (PLLA). The copolymer with the D-form (poly-DL-lactic acid) is termed PDLA. The mechanical and degradation properties of these two enantiomers differ markedly, with PLLA being highly crystalline and PDLA being more amorphous.¹ The characteristics of the copolymers are intermediate between those of the two monomers.

Polyglycolic acid is synthesized by ring-opening polymerization from glycolide. It is a hard, tough, crystalline molecule that is more hydrophilic in nature than PLA. Its self-reinforced form is stiffer than other clinically utilized polymers.² Polyglycolic acid has been utilized extensively in orthopaedic implants. This polymer has more rapid degeneration rates than PLA; there have been more synovitic reactions with this material, probably secondary to its rapid degradation.⁹

Polydioxanone was first described in 1981.³ This material is manufactured by polymerizing the monomer para-dioxanone. In its natural state, PDS is a colorless crystalline polymer; its purple hue is obtained with the addition of violet dye. The PDS suture is created by the melt-extrusion of polymer granules through the appropriate dyes. The inherent stiffness of PDS suture has made it invaluable in applications in arthroscopic procedures, as it goes easily through suture passers.

Degradation

The degradation of bioabsorbable implants follows a predictable pattern. The rate of degradation is dependent on the starting molecular weight of the polymer and its crys-

tallinity, the composition and porosity of the implant, and other factors, such as loading conditions and local vascularity. In the degradation process, there is first a loss in molecular weight, followed by loss of strength and finally loss of mass. The early phase of degradation is chemical in nature. Biologic processing and removal of the implant occur later.¹⁰⁻¹² Because of this pattern of degradation, these materials lose functional strength long before they are completely absorbed.

The initial phase of degradation is one of hydrolysis. Water molecules enter the implanted material, causing cleavage of the monomeric molecular bonds. This leads to the scission of long polymer chains into shorter chains, reducing the overall molecular weight. This process is affected by implant porosity.^{13,14} Low porosity enhances autocatalysis of the implant because the slow clearance of degradation products from within the material leads to increased acidity and more rapid molecular scission. The molecular weight plays an important role in the internal friction within the implant, and thus its mechanical properties; hydrolysis of these long chains leads to a loss in mechanical strength. As a result, implants with low porosity may have a shortened functional life.

As the implant loses integrity and fragments, biologic removal of the implant takes place. The rapid degradation of these implants has been postulated to be the cause of marked foreign-body reactions, synovitis, and even activation of the complement cascade.^{8,15-17} Studies evaluating the tissue response to PGA and PLLA implants have shown foreign-body reactions to the degradation products. The degradation of PLLA has been associated with a foreign-body reaction as late as 143 weeks after implantation.¹² A foreign-body reaction to PGA has been seen as early as 3 to 6 weeks.¹¹ Dif-

ferences in the timing of the cellular response to these materials are probably secondary to the different rates of degradation of PGA and PLLA. Clinically, most symptomatic foreign-body reactions have been associated with the more rapidly degrading PGA,^{9,18} but reactions to PLLA have also been described.¹⁹ The rates of degradation of these materials can be optimized for biologic fixation by changing the copolymer ratios of PGA and PLLA.⁵

The most common soft-tissue complications related to use of these materials are sterile sinus tract formation, hypertrophic fibrous encapsulation, and osteolysis. These inflammatory responses occur in fewer than 10% of patients, but may be severe enough to require surgery for resolution of the reaction.¹⁶

Biochemical Degradative Pathway

Alpha polyesters, such as PLA, PGA, and PDS, primarily degrade by hydrolysis, with the release of their respective monomers. The monomers are then incorporated into normal cellular physiologic processes for further degradation. Lactic acid, glycolic acid, and paradioxanone have well-defined biochemical pathways that lead eventually to their excretion in the form of carbon dioxide and water^{7,20} (Fig. 1).

Lactic acid is produced by the hydrolytic degradation of PLA. Lactic acid is normally produced at the end of the glycolytic pathway from pyruvate when the amount of oxygen is limiting. The oxidation of lactate to form pyruvate is catalyzed by lactate dehydrogenase. In aerobic conditions, pyruvate undergoes oxidative decarboxylation to produce acetyl coenzyme A. This molecule may then enter the citric acid cycle for further oxidation to produce carbon dioxide, water, and adenosine triphosphate by oxidative phosphorylation.

Degradation of PGA and PDS follows nearly the same pathway.

Hydrolysis of PGA produces glycolic acid, which is either excreted directly in the urine or converted to glyoxylate. The PDS degradation products enter the pathway at glyoxylate. The amino acid glycine can be produced from glyoxylate by a transamination reaction. Glycine, a glucogenic amino acid, can be further converted to pyruvate through a serine intermediate. Pyruvate is then converted to acetyl coenzyme A to enter the citric acid cycle, as previously discussed.

Mechanical Properties

The mechanical properties of bioabsorbable orthopaedic implants must be considered both at the time of insertion and throughout degradation. The implants are initially subjected to considerable loads, which gradually decrease with tissue healing. The perfect implant will de-

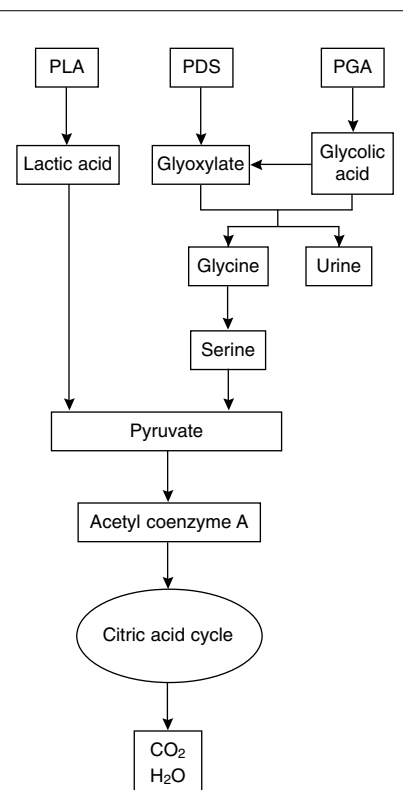


Figure 1 Biochemical degradation pathways for PLA, PDS, and PGA.

grade at a rate that gradually transfers load to healing tissue and does not outpace the healing response. Factors that affect the mechanical properties of an implant include the type of material, its processing, and the local testing environment.²¹ Bioabsorbable polymers differ from common stainless steel implants in that they are more viscoelastic in nature. Therefore, they exhibit enhanced properties of creep and stress relaxation. Claes²¹ exhibited the importance of this property by demonstrating that when used in the form of an interfragmentary screw, bioabsorbable polymers lost 20% of their force 20 minutes after application, due to stress relaxation.

Reinforcing techniques have been developed to improve the mechanical characteristics of bioabsorbable implants. Self-reinforced absorbable components are polymeric materials in which the reinforcing elements and matrix material have the same chemical composition. The most effective way to manufacture the self-reinforced structure into the polymer is by the mechanical deformation of the nonreinforced material.⁷ This deformation process leads to the formation of oriented polymeric chains, the self-reinforcing structures.

The reported properties of these implants vary, due mostly to differences in processing and testing conditions. Overall, the self-reinforced materials show an improvement in their initial mechanical values compared with the nonreinforced polymers (Table 1). The initial bending strength of self-reinforced PGA exceeds that of stainless steel; however, with rapid rates of degradation, this strength is not maintained. In general, the mechanical properties of these polymeric implants do not approach those of standard stainless steel implants. While rapid loss of the mechanical properties might be expected to allow excessive motion between fracture fragments, these

materials have been used successfully in specific clinical situations.

Mechanical degradation studies have been performed in both *in vivo* and *in vitro* conditions. The most important determinant of the rate of degradation is the material itself, but the environment surrounding the implantation site can also be an influence. There is evidence that degradation rates are more rapid with *in vivo* testing secondary to enzymatic contributions.¹ Areas of high tissue metabolism and blood flow facilitate material degradation. Furthermore, implants under load tend to degrade faster, possibly secondary to microfracture.

The mechanical degradation rate of PDS suture has been studied by Ray et al.³ The breaking strength of PDS suture was tested after being implanted in the subcutaneous tissue of rats. The PDS suture retained 74% of its nonimplanted strength at 2 weeks, but by 6 and 8 weeks that value had dropped to 41% and 14%, respectively. The authors also determined, with the use of radioactive labeling, that the material absorption was complete by 182 days after implantation. Likewise, PGA materials lose their mechanical strength by 6 to 8 weeks. The loss of the mechanical properties of this material occurs at varying rates, with the loss of shear strength being slower than loss of bending strength. In self-reinforced materials, the matrix material loses its strength more rapidly than the reinforcing elements. Therefore, these materials may be more suited for the fixation of fractures involving periarticular cancellous bone, where high shear loads are common.

Clinical Applications

The use of bioabsorbable fixation for the attachment of soft tissue to bone is being increasingly utilized by orthopaedic surgeons, especially in

the treatment of soft-tissue lesions in the shoulder. These implants have facilitated the repair and reconstruction of labral and rotator cuff lesions. The development of bioabsorbable tacks, suture anchors, and screw-and-washer implants has given surgeons more treatment alternatives (Fig. 2).

Bioabsorbable suture anchors are useful as an alternative to metal staples and screws, which may have a high profile. They also eliminate the need for passing sutures through bone tunnels. Pullout strengths for bioabsorbable suture anchors are comparable to those of their metallic counterparts.²² These implants have sufficient strength that the point of failure is the suture-soft-tissue interface.²³

The complications observed with the use of bioabsorbable suture anchors are similar to those seen with metallic anchors. Improper insertion of the anchor too deep in the bone can cause suture fraying or failure. Superficial insertion of the anchor can lead to cartilage wear on the opposing articular surface. The anchor can also fail by pullout from bone and become an intra-articular loose body. As these implants are radiolucent, this diagnosis can be difficult to make postoperatively in a persistently painful joint. Unique to bioabsorbable anchors is the potential for eyelet failure with secondary suture cutout.

Bioabsorbable suture anchor fixation has several advantages. The anchor undergoes reabsorption and therefore reduces the need for removal of a prominent implant. Resorption also makes revision surgery less complicated, as hardware removal is not necessary. The fixation does not obscure the anatomy as depicted on radiographs and is compatible with magnetic resonance imaging if further evaluation of the affected joint is necessary. Improperly placed anchors may simply be drilled out rather than

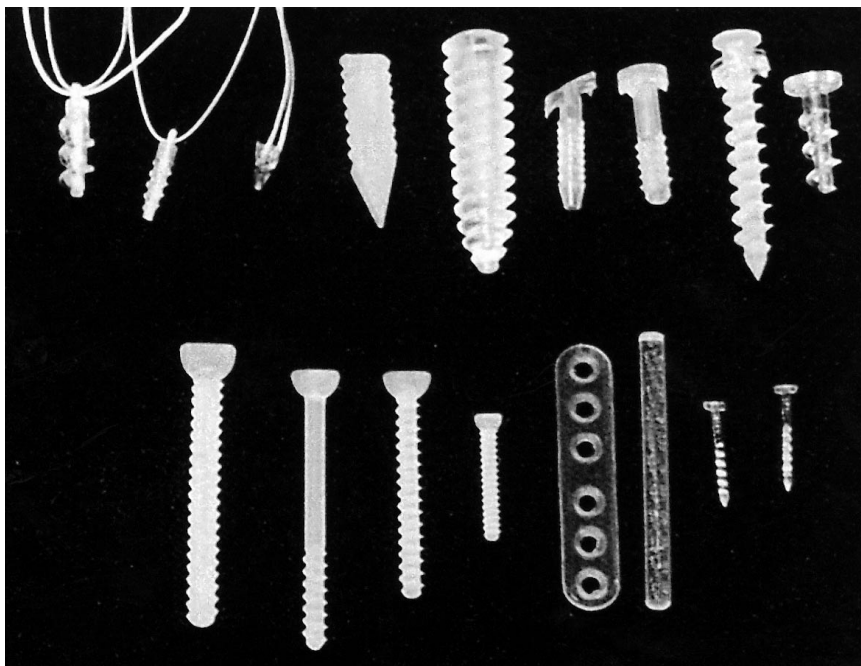


Figure 2 Currently available bioabsorbable implants for fracture fixation, interference fixation, and meniscal repair.

unscrewed or pushed through, as is necessary with metallic anchors. Finally, stress is gradually transferred to the healing soft tissue as the anchor degrades.

Repair of Shoulder Lesions

The effectiveness of bioabsorbable anchors for use in Bankart repairs, as well as in treatment of rotator cuff tears and “SLAP” lesions (i.e., anterior-to-posterior lesions of the superior labrum), is currently under investigation. Warne et al²⁴ compared the usefulness of bioabsorbable and nonabsorbable suture anchors in a prospective randomized study of open Bankart repairs. At an average follow-up interval of 25 months, there was one failure in the 18 patients treated with nonabsorbable anchors, compared with two failures in 20 patients treated with absorbable anchors. Radiographs obtained at the 2-year follow-up in the absorbable group demonstrated near-complete implant degradation

and osseous replacement. At 6 months, the anchor holes used for nonabsorbable implants demonstrated a sclerotic rim but no increase in size from the measurements on the initial postoperative radiographs. There was no subsequent radiographic change after that. It must be noted that no reports of complications attributable to the bioabsorbable nature of these suture anchors have been published.

The use of bioabsorbable tacks for the repair of labral lesions has made arthroscopic management of these injuries technically less complicated. The development of labral tacks, such as Suretac (Smith&Nephew, Andover, Mass), TissueTack (Arthrex, Naples, Fla), ConTack (Mitek, Westwood, Mass), and the Contour Labral Nail (Bionx Implants, Blue Bell, Pa), has led to the ability to treat more patients with Bankart and SLAP injuries arthroscopically. These tacks are cannulated for ease of insertion and allow the labrum to be

reattached to the glenoid in an anatomic position. These devices eliminate the risks of metal around joint surfaces, do not require transglenoid drilling or an accessory posterior incision, and avoid technically difficult arthroscopic knot tying.

The first absorbable tack was constructed of PGA, which rapidly loses strength over the first 4 to 6 weeks. Complete reabsorption occurs in approximately 6 months. This implant has been implicated in several cases of aseptic synovitis secondary to a histiocytic or phagocytic reaction to the rapidly degrading polymer.⁹ Currently, most tacks are composed of longer-absorbing materials such as PDLA, PLLA, or composites, which may reduce the rate of synovitis.

Warner et al²⁵ reported on a cohort of 15 patients who underwent “second look” arthroscopy for a failed arthroscopic Bankart repair performed with the Suretac device. These patients were a subgroup of 96 patients initially treated for posttraumatic recurrent anterior dislocation or subluxation. The repeat procedure was necessitated by recurrent instability in 7 patients, pain in 6, and pain with stiffness in 2. When reevaluated, the failure in the patients with instability was considered to be secondary to inadequate reconstruction of either the anterior glenohumeral ligaments or the anterior labral complex. The cause of failure in the 8 patients with either pain or pain and stiffness was less clear, although an indolent inflammatory response to the PGA polymer was found in several. Six of the patients eventually had complete or partial pain relief after a second arthroscopy and subacromial decompression, biceps tenodesis, or a capsular release or manipulation.

Bioabsorbable fixation devices are now also being used for the repair of rotator cuff tears. These procedures were initially performed with suture anchors, but more re-

cently screw-and-washer-type devices have become available. The rationale behind the use of these soft-tissue screws is to repair the tendon to bone without a suture, reducing the incidence of complications at the tendon-suture interface and increasing the surface area of tendon contact with bone. These devices (Bio-Headed Corkscrew, Arthrex; Biocuff Screw, Bionx; Bio-twist, Linvatec, Naples, Fla) all employ a screw-in device with a large head for soft-tissue compression. The Biocuff screw has an independent spiked washer to prevent tendon damage and reduce pressure necrosis. No clinical studies on the use of these devices are yet available.

Meniscal Repair

The "all inside" technique of meniscal repair described by Morgan was developed to safely repair the posterior and central peripheral portions of the meniscus, a location difficult to reach with traditional arthroscopic techniques because of the risk of neurovascular injury. The use of bioabsorbable implants for use in all-inside meniscal repair has now been described.²⁶ These devices eliminate the need for a posterior incision, reduce the risk of neurovascular injury, and simplify the fixation procedure.

The Bionx Meniscal Arrow is a well-characterized bioabsorbable implant that has been approved by the US Food and Drug Administration for meniscal repair. It is a T-shaped device composed of self-reinforced PLLA with a 1.1-mm-diameter barbed stem. The stem penetrates the meniscus and capsule, and the bar portion approximates the torn meniscal leaf to the periphery. The arrows remain in the joint for approximately 1 year and are gradually absorbed through hydrolysis to carbon dioxide and water.

Biomechanical data reported by Boenisch et al²⁷ compared the pullout strength and linear stiffness of

meniscal repair performed with bioabsorbable arrows and vertical and horizontal looped sutures in bovine menisci. The pullout strengths in both suture groups were significantly ($P < 0.05$) higher than those in the arrow-fixation group. Further, vertical-suture fixation was significantly stiffer than fixation with either horizontal sutures or arrows. However, more recent data from another bovine study²⁸ demonstrated no difference between the pullout strength of the arrow and that of a vertical PDS suture when the arrow was inserted with a mechanical "gun." In fact, significantly greater pullout strength for arrow fixation was noted at 12 and 24 weeks compared with PDS-based implants. Technical considerations of insertion, such as keeping the arrow parallel to the joint surface and maximizing the number of barbs engaging beyond the tear, have been demonstrated to be essential to the integrity of the repair.

Albrecht-Olsen et al²⁹ performed a randomized prospective study comparing meniscal repair utilizing the bioabsorbable meniscal arrow implant to inside-out repair with horizontal meniscal sutures. Sixty-eight patients were divided evenly between the two groups. Repairs were performed only in red-red or red-white zones, and rehabilitation protocols were standardized. In all, 65 patients (96%) underwent repeat arthroscopy at 3 to 4 months. A healed meniscus was observed in 91% of the arrow repair group but in only 75% of those in the suture group. There were no complications reported in the group with bioabsorbable fixation. The operative time for the procedures averaged 30 minutes for repair with the arrow and 60 minutes for suture repair. The advantages of decreased operative time, ease of insertion, and improved meniscal healing with an all-inside meniscal repair with a bioabsorbable implant were confirmed by this study.

Complications with the Bionx Arrow have been published in several case reports.³⁰⁻³⁴ These include hematoma formation, subcutaneous migration, foreign-body reaction, and loss of fixation. The use of these newly developed implants appears to be simple. However, attention to technical detail in terms of placement, choice of length, and orientation is required to avoid complications and ensure optimal fixation.

Anterior Cruciate Ligament Reconstruction

Graft fixation devices for anterior cruciate ligament reconstruction have been manufactured in the past from nonabsorbable materials such as metal and plastic. These devices are often difficult to remove or avoid if revision anterior cruciate ligament reconstruction is required. Furthermore, the evaluation of soft-tissue lesions with MR imaging after the use of metal fixation is difficult. Additionally, aperture fixation (soft-tissue fixation at the joint line), which provides a stiffer construct, is hampered by concerns about graft severance by metal interference screws. Use of bioabsorbable fixation devices, such as interference screws, can potentially eliminate some of these problems.

Several different types of screws, which vary in polymeric composition, are currently available. Graft fixation strength in anterior cruciate ligament reconstruction is critical in the period from initial fixation to osseous integration of the graft. This period ranges from 6 weeks for bone-patellar tendon-bone fixation to approximately 12 to 16 weeks for hamstring fixation. Therefore, the bioabsorbable interference screw must maintain virtually all of its structural integrity during that entire interval. The initial pullout strengths of these implants should exceed the estimated 500-N load for activities of daily living. For this

reason, most screws on the market are manufactured from PLLA or a variant copolymer with a longer half-life (Fig. 3). This composition can lead to delayed osseous integration, thus negating the main benefit of the bioabsorbable fixation.

No consensus is supported by the results of recent biomechanical studies. Pena et al³⁵ published data on the insertion torques and fixation strengths of bone–patellar tendon–bone grafts fixed with PLA interference screws (Bioscrew, Linvatec, Key Largo, Fla) and compared them with metal interference screws in cadaveric specimens from young and middle-aged individuals. With use of a correction factor for bone-mineral density, the pullout forces were 730 N for the metal screws and 668 N for the PLA screws. The insertion torque was 1.52 N for the metal screws and 0.30 N for the bioabsorbable screws. Both pullout force and insertion torque were significantly ($P>0.05$) higher for metal interference fixation. The authors noted that loss of tensile strength of bioabsorbable screws is possible with excessive time in storage due to hydrolysis or wetting the implant before insertion.

Caborn et al³⁶ have published the results of a biomechanical comparison of metal and bioabsorbable interference screw fixation of quadrupled semitendinosus-gracilis grafts. No statistically significant difference was found in the maximum load at pullout, nor did the screw insertional torques correlate with the maximum load at pullout. However, a follow-up study in which the bone tunnels were specifically sized within 5 mm of the graft diameter showed that the bioabsorbable screw-insertion torque correlated directly with ultimate graft failure strength.³⁷ Therefore, it appears that bioabsorbable interference screw fixation is not appropriate for all patients, especially those with poor bone quality. Careful graft preparation and sizing can,

however, result in interference fixation capable of withstanding the forces of accelerated rehabilitation.

A recent prospective, randomized study by McGuire et al³⁸ compared the Linvatec Bioscrew with metal interference screws in 204 patients. A variety of graft sources were used, including autogenous and allograft bone and patellar tendon and allograft Achilles tendon. The average follow-up interval was 2.4 years, and the mean age of patients was 30 years. A standardized rehabilitation protocol was used. No statistically significant difference was noted in the Lysholm or Tegner score, pain, thigh size, Lachman test result, pivot shift, patellofemoral crepitus, or joint effusion. There was no statistically significant difference in mean maximum manual side-to-side KT-1000 rating between the 1.8-mm bioabsorbable screw and the 1.6-mm metal screw. Twelve PLLA screws broke during insertion without adverse effects. There were no reported complications related to loss of fixation, toxicity, allergenicity, or osteolysis.

Excellent clinical results are possible with bioabsorbable interference screws, although there is no consensus opinion as to whether biomechanical strength is the same between metal and bioabsorbable screw fixation. Disadvantages of bioabsorbable interference screws include concerns about sterile drainage, cyst formation, lack of complete osseous ingrowth into the defect, early loss of pullout strength secondary to hydrolysis, and intraoperative breakage of the device. The reported rate of these clinical complications is low and has not resulted in a clinically significant difference in outcome studies published to date.

Fracture Fixation

Although bioabsorbable fracture-fixation devices appear to have obvious advantages over metal implants,

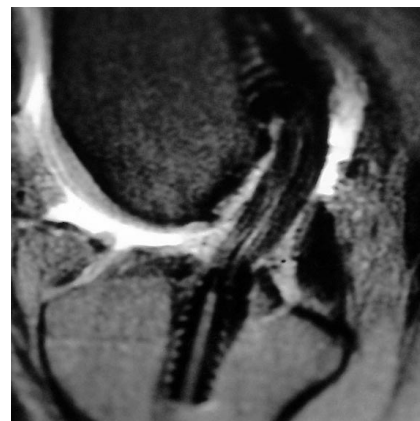


Figure 3 MR image obtained 24 months after interference fixation of hamstring autografts with bioabsorbable PLLA screws shows minimal degradation.

concerns about the initial fixation strength of these materials have limited their widespread acceptance. These materials must have the initial fixation strength necessary to maintain the reduction of bone fragments during the healing process. Manufacturing techniques are critical, as melt-molded polymers do not possess the strength necessary for reliable fixation, whereas self-reinforced materials have the mechanical characteristics more suitable for this use.

In a review of more than 2,500 fracture-fixation cases in which bioabsorbable implants were used, Rokkanen et al³⁹ reported that the incidence of bacterial wound infection was 3.6%; nonspecific foreign-body reaction, 2.3%; and failure of fixation, 3.7%. Compared with metallic fixation, absorbable fixation has shown a lower incidence of infection.⁴⁰

Bucholz et al⁴¹ performed a prospective randomized trial comparing PLA screws with stainless steel screws for fixation of displaced medial malleolar fractures. They found no statistically significant difference in operative or postoperative complications between the two groups.

Foreign-body reactions to PGA have been described,^{9,18,39} but neither Rokannen et al³⁹ nor Bucholz et al⁴¹ reported late reactions to PLA screws. However, a recent case report described an osteolytic reaction to an intraosseous PLA screw 52 months after the operative procedure.¹⁹ Longer-term follow-up may be necessary to determine the actual clinical biocompatibility of intraosseous PLA.

The use of bioabsorbable implants for pediatric fracture fixation is particularly appealing because it obviates implant removal. In experimental studies, the presence of an absorbable implant does not seem to interfere with the growth plate any more than an empty drill hole does.⁴² Biodegradable implants have shown satisfactory results,

especially in the treatment of distal humeral physeal fractures.⁴³⁻⁴⁵

Böstman et al⁴³ evaluated the use of absorbable self-reinforced PGA pins in the treatment of 71 physeal and nonphyseal fractures in skeletally immature patients, with a mean follow-up interval of 15.8 months. Anatomic reduction was maintained until union in 87% of the fractures, but in only 8 of 14 supracondylar humerus fractures. The authors felt that the displacement forces encountered in supracondylar fractures overwhelmed the mechanical properties of the absorbable pins, resulting in displacement. They concluded that the preliminary results of fracture treatment with self-reinforced PGA were satisfactory except for supracondylar humerus fractures. Long-term clinical studies are still

required to determine the effects of these implants on the growth plate.

Summary

The use of bioabsorbable implants in musculoskeletal procedures is gaining acceptance. While most commonly utilized in the field of sports medicine for soft-tissue fixation, these implants may have applications in other aspects of orthopaedics. Complications associated with the use of these materials have diminished with the development of newer, self-reinforced polymers. Until more long-term, peer-reviewed research becomes available, the appropriate clinical usage of these implants remains a concern for the practicing orthopaedist.

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