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Bioabsorbable Implants: Review of Clinical Experience in Orthopedic Surgery

CATHERINE G. AMBROSE and THOMAS OSCAR CLANTON

Department of Orthopedic Surgery, The University of Texas Health Science Center at Houston, TX

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Abstract—Bioabsorbable implants are widely used in orthopedic surgery today and the worldwide market is expanding rapidly. Despite the popularity of these implants, reports of complications continue to appear in the literature. Although the complications rarely have an adverse affect on long-term outcomes, the reports are too numerous to be mere isolated incidents related to one specific implant. Complications have been reported with most of the commercially available implant materials with varying incidence rates and severities of reactions to the implants. The purpose of this review is to summarize the adverse events that have been reported in clinical trials of bioabsorbable implants in orthopedic surgery.

Keywords—Polylactic acid, Polyglycolic acid, Polyglyconate, Bioresorbable, Biodegradable.

NOMENCLATURE

LPLA	Poly(L-lactide)
DLPLA	Poly(DL-lactide)
LDLPLA	Poly(DL-lactide-*co*-L-lactide)
LPLA-HA	Poly(L-lactide) with hydroxylapatite
PGA	Poly(glycolide)
PGA-TMC	Poly(glycolide-*co*-trimethylene carbonate) or polyglyconate
PDO	Poly(dioxanone)
LPLG	Poly(L-lactide-*co*-glycolide)
DLPLG	Poly(DL-lactide-*co*-glycolide)

INTRODUCTION

Bioabsorbable polymers are becoming more popular as implant materials in orthopedics. These implants have several advantages over the traditional metallic implants including reduced stress shielding since the implants bear less load initially and gradually transfer the load as they degrade. Although there have been reported cases where bioabsorbable implants have had to be removed,[13,17,36] the incidence of a required second surgery to remove the implants is much lower than with metallic implants.[10] Finally, the polymers can be engineered to provide the optimum degradation profile for a specific application.

In the late 1960s and early 1970s, animal studies reporting the use of bioabsorbable polymers began to appear in the literature. In 1966, Kulkarni and coauthors[32] published a report on the biocompatibility of LPLA in animals. The polymer was implanted in powder form in both guinea pigs and rats. Both the histological response and the degradation of the polymer were studied over the course of 2 months. It was found that the polymer was nontoxic, nontissue reactive, and degraded slowly. In 1971, Kulkarni and coauthors[31] presented the results of using LPLA plates and screws to fix mandibular fractures. In the same year, Cutright and colleagues[18] presented their work on using LPLA suture to fix mandibular fractures. Both studies demonstrated that the material did not cause detrimental inflammatory or foreign body reactions, although the material had not completely degraded by the end of the study.

Today, nearly every orthopedic manufacturer has an extensive line of bioabsorbable devices to offer.[4] Samples of the types of implants available are presented in Table 1. These devices are manufactured in the form of pins, screws, plates, rods, tacks, and suture anchors and are most often manufactured from LPLA, PGA, PDO, or a copolymer of PLA or PGA. In 1995, the market for orthopedic fixation devices (pins, screws, rods, etc.) was estimated to be $15 million in the United States.[39] In a recent report by DataMonitor Corporation,[19] the worldwide market value had jumped to over $60 million in 2000 and was projected to reach nearly $90 million by the year 2006.

Bioabsorbable implants have three main disadvantages: lower strength, higher cost, and, in some cases, undesired biological response. Many studies have shown that bioabsorbable devices can provide the necessary initial strength for orthopedic applications[29,35,46,47,57,58] as long as the application is chosen with care, and other studies have shown that the strength reduction during degradation is slow enough to allow tissue healing.[29,49,58] In addition, the

Address correspondence to Dr. Catherine G. Ambrose, Department of Orthopedic Surgery, The University of Texas Health Science Center at Houston, 6431 Fannin, Room 6.148, Houston, Texas 77030. Electronic mail: catherine.g.ambrose@uth.tmc.edu

TABLE 1. Commercially available resorbable orthopedic implants.

Manufacturer	Trade name	Material	Purpose
Arthrex	Bio-Corkscrew; TissueTak II; Bio-FASTak; Bio-Anchor	LDLPLA	Rotator cuff repair, SLAP and Bankart repair, suture anchor
	BioTenodesis Screw; Bio-TransFix; Bi-Cortical Bio-Post; TissueButton	LPLA	Fracture fixation, suture anchor
Biomet, Arthrotek	Bio-Phase Suture Anchor; Reunite Screws, pins, plates; Gentle Threads	LPLG	Fracture fixation, arthrodesis, suture anchor
Bionx, Linvatec	Smartscrew ACL; Duet Suture Anchor; BioCuff; The Wedge	DLPLA	Fracture fixation, ACL repair, suture anchor
	Contour Meniscus Arrow	LDLPLA	Meniscus repair
	SmartScrew; SmartPin; Bankart Tack; BioStinger; BioScrew	LPLA	Bankart lesion repair, meniscus repair
	SmartPin	LPLG	Fracture fixation
DePuy, Mitek, Ethicon, J&J	Panaloc RC; BioRoc EZ; Phantom screws;	LPLA	Rotator cuff repair, suture anchor
	PDS/PGA staple	PDO coated PGA	Scaffold fixation (grafting)
	Orthosorb Pins	PDO	Fracture fixation, arthroscopic knee
Smith&Nephew, Acufex, Instrument Makar	Biologically Quiet Screw	DLPLG	ACL reconstruction
	RotorloC; BioRCl; Endo-Fix L; TwinFix	LPLA	Suture anchor, ACL reconstruction
	TAG; Endo-Fix; Suretac	PLG-TMC	Suture anchor, ACL reconstruction
	BioRCl-HA	LPLA-HA	ACL reconstruction
Stryker, Howmedica, Osteonics Surgical Dynamics	SD Sorb anchors, staples, EZ Tac	LPLG	Suture anchor, meniscus repair, rotator cuff repair
	Biosteon Wedge	LPLA-HA	ACL reconstruction
Sulzer, Centerpulse	Sysorb Interference Screw	DLPLA	ACL reconstruction
Zimmer	Bio-Statak	LPLA	Suture anchor

high initial cost of the implant, when compared to metallic implants, can be offset when one considers the added expense for a second surgery to remove a nonresorbable implant. In a recent study, Bostman[10] estimated that if the removal rate for metallic implants is above 19–54% (depending on the fracture type), resorbable implants would be cost-effective. Thus the primary drawback for resorbable implants is foreign-body reaction. Although the incidence of this reaction varies widely, it has been reported with most of the currently available materials.

Biological reaction to resorbable implants presents in varying levels of severity from mild fluid accumulation to discharging sinus formation to irreversible tissue damage. In many clinical studies the reported incidence of inflammatory reactions has been small and the reactions themselves mild enough to have no effect on the long-term outcome. However, in a few studies, the reactions have been moderate to severe and have necessitated second surgeries. Even with these varying clinical presentations, the histologic picture is remarkably consistent: sterile, nonspecific inflammatory response with multinucleated foreign body giant cells present. Polymeric debris is usually visible—both extracellularly and intracellularly—and osteolytic lesions are often found.

Many factors affect the degradation of the polymer and the resulting reaction of the body to the polymer including implant material, implant geometry, site of implantation, and method of sterilization. The crystallinity of the implant is dependent upon the exact material used,[30] and the crystallinity can affect the biocompatibility of the implant.[8] Although these varying factors make it difficult to make generalizations, the results of the many published clinical trials demonstrate some common complications resulting from the widespread use of resorbable implants. In the following sections the results of these clinical trials are presented grouped by implant material. Although there are many publications that report no complications from the use of resorbable implants, this review is limited to the studies that have reported complications.

POLY(GLYCOLIDE)

In 1989, Hirvensalo[21] reported on his experience using PGA rods (Biofix C, Bioscience, Tampere, Finland) to treat ankle fractures. Forty-one cases were included in his study and these patients were followed for an average of 16 months. This series was one of the first to report the transient sterile fluid accumulation that occurs in some patients at the end of the polymer degradation. Six of the patients (15%) developed the fluid accumulation at an average time of 3 months after insertion of the rods. In half of these the fluid accumulation was asymptomatic; in one case a sinus formed and in two cases fluid was evacuated through an incision.

Also in 1989, Bostman[11] reported on a larger series of ankle fractures fixed with either PGA or LPLG implants. In this series, 6 out of 102 (6%) of the patients presented with spontaneously draining sinuses. Under local anesthesia, the remnants of the degrading polymer were removed from the sinuses.

TABLE 2. Clinical studies reporting adverse events with PGA implants.

References	Implant/indication	Adverse event/incidence	Timing of event
Bostman, 1989[11]	Rods made form Dexon Suture (Bioscience, Tampere, Finland)	Sinus formation: 6/102 (6%)	2–4 months
Hirvensalo, 1989[21]	Biofix (Bioscience, Tampere, Finland)/ankle fracture fixation	Fluid accumulation: 6/41 (15%)	3 months
Casteleyn, 1992[16]	Biofix (Cyanamid, Fareham, England)/wrist fracture fixation	Fluid accumulation: 7/15 (47%) Sinus formation: 6/15 (40%) Osteolysis: 9/15 (60%)	8–18 weeks 3–6 months
Hoffman, 1992[22]	Biofix (Bioscience, Tampere, Finland)/trauma	Sinus formation: 3/101 (3%)	Not reported
Hovis, 1997[23]	Biofix (Bioscience, Tampere, Finland)/ankle fracture fixation	Fluid accumulation: 8/16 (50%) Sinus formation: 1/16 (6%)	3–4 months 4 months
Pelto-Vasnenius, 1997[44]	Biofix (Bioscience, Tempere, Finland)/chevron osteotomy in metatarsal	Fluid accumulation: 6/94 (6%) Osteolysis: 21/94 (22%)	8–11 weeks 3–6 months
Kankare, 1998[28]	Biofix (Bioscience, Tampere, Finland)/calcaneal fracture fixation	Fluid accumulation: 3/25 (12%)	Not reported
Bostman, 2000[12]	Biofix (Bioscience, Tampere, Finland)/fracture fixation	Fluid accumulation: 107/2037 (5%)	1–4 months
Tuompo, 2001[53]	PGA (manufacturer not reported)/multiple indications	Fluid accumulation: 90/1879 (5%) Sinus formation: 60/1879 (3%)	63–517 days 34–137 days

Since then, many authors have reported similar complications with PGA implants as summarized in Table 2. The incidence of complications ranged from 3% for general trauma to 60% in wrist fractures. The timing of the foreign-body response ranged from 1 to 6 months and is consistent with the theory that the reaction is related to the final stages of polymer degradation. In most cases, the foreign-body reaction did not affect the long-term results of the surgery. However, in some cases, the reaction was severe enough to require revision surgery or arthrodesis.

POLY(GLYCOLIDE-*CO*-TRIMETHYLENE CARBONATE) OR POLYGLYCONATE

There have been fewer studies reporting complications resulting from the use of implants made from PGA-TMC than from PGA implants, probably due to the limited number of implants made from this material. As can be seen from Table 3, the complication rates ranged from 2 to 30% and the timing of the reaction ranged from 2 weeks to 6 months.

In 2000, Benedetto and coauthors[7] reported on a prospective study evaluating a polyglyconate screw (PGA-TMC) (Endo-Fix, Smith & Nephew, Andover, MA) compared to a metal screw for anterior cruciate ligament (ACL) reconstruction. One-hundred and thirteen patients (62 PGA-TMC, and 52 controls) were available for a 1-year follow-up. Radiographic assessment was only reported for the 1-year follow-up, and the groups were not significantly different at 1 year. Three PGA-TMC patients (5%) developed effusions and one patient (2%) developed a cyst, which was thought to be related to resorption of the screw at 6 months.

In 2000, Burkart[15] reported on four cases of foreign-body reaction of patients to a PGA-TMC tack (Suretac, Acufex, Mansfield, MA). In this series, 3 of 18 (22%) of patients treated for SLAP lesions and 1 patient with a Bankart lesion demonstrated a foreign-body reaction to the device. These patients complained of pain starting from as early as 2 weeks postoperatively.

POLY(DL-LACTIDE-*CO*-GLYCOLIDE)

In 1999, Lajtai and coauthors[33] reported on their series of patients where bioabsorbable interference screws (Biologically Quiet, Instrument Makar, Okemos, MI) were used for ACL reconstruction. Thirty-two patients were followed for 2.5 years. Magnetic resonance imaging showed that the screws were completely resorbed by 6 months. Effusions were present in 17 (53%) of the cases, although the effusions

TABLE 3. Clinical studies reporting adverse events with PGA–TMC implants.

References	Implant/indication	Adverse event/incidence	Timing of event
Benedetto, 2000[7]	EndoFix (Smith&Nephew, Andover, MA) ACL reconstruction	Fluid accumulation: 3/62 (5%) Cyst formation: 1/62 (2%)	6 months
Burkart, 2000[15]	Suretac (Acufex, Mansfield, MA) SLAP repair	Synovitis: 3/18 (22%)	2–5 weeks
Bach, 2002[2]	EndoFix (Smith&Nephew, Andover, MA) ACL reconstruction	Fluid accumulation: 6/20 (30%)	6 months

did not adversely affect the final outcome. The timing of these effusions was not reported.

POLY(DL-LACTIDE)

In 1999, Martinek and coauthors[37] reported one case of a cyst formation after ACL reconstruction using a DLPLA interference screw. The cyst was accompanied by osteolysis of the tibial tunnel but did not penetrate into the knee joint. The cyst appeared 8 months after surgery, and open debridement found that this timing was indeed coincident with the final stages of screw degradation: part of the head of the screw was located along with a "gelatin-like mass." After debridement of the cyst, the patient recovered uneventfully.

Since that report, there have been other reported reactions to DLPLA devices as shown in Table 4. The incidence of complications ranged from 1 to 47% and the timing of these reactions has been from as early as 2 weeks to as late as 1 year.

POLY(DL-LACTIDE-*CO*-L-LACTIDE)

In 2002, Cummings and coauthors[17] reported their clinical outcomes for rotator cuff repairs using metal suture anchors (RC Suture Anchor, Mitek) versus bioabsorbable screws (BioCorkscrew, Arthrex). Eighteen patients had metal suture anchors while nine had bioabsorbable screw fixation. The bioabsorbable group had a higher pain score after 3 months and lower shoulder function scores at 1 year. Three of the nine patients (33%) subsequently underwent a revision rotator cuff repair, while no patients in the metal group underwent revision repair. In the first revision surgery (3 months after the primary surgery), histological specimens obtained demonstrated a focal foreign-body giant cell reaction to the screw material. In the second revision surgery (6 months after the primary surgery) the screw was found to be loose in the subacromial space. In the third revision surgery (15 months after the primary surgery), the screw was not visible. A fourth patient underwent a surgery for suspected infection 25 days after the primary surgery but all cultures were negative and the screw was intact. After thorough irrigation, the patient improved.

POLY(L-LACTIDE)

The LPLA implants clearly take the longest to degrade *in vivo*[26] and any adverse reactions due to the final stages of degradation cannot be expected to occur within the first 3 years of implantation. Probably because of this, there have not been many large clinical studies reporting foreign-body reactions to these devices. In fact many publications have reported that there are no complications with these devices[3–5,9,24,55] but the follow-up time on these studies has been too short to accurately determine the complication rate. In the articles that have demonstrated complications, these have arisen as late as 9.5 years after implantation. As shown in Table 5, except for the reports of implant failure (intra-articular screw fragment, etc . . .), all of the complications have occurred more than 1 year after implantation of the device.

In 1994, Bucholz and coauthors[14] reported on a series of 83 patients where bioabsorbable screws had been used to fix fractures in the ankle. Follow-up times ranged from 21 to 59 months, with an average of 37 months. In one patient (1%) a cyst was removed 15 months after implantation of two screws to fix a medial malleolar fracture. Histological examination demonstrated fragmented PLA, fibrous tissue, granulation material, and abundant macrophages.

In 1995, Bergsma and coauthors[8] reported on their experience with LPLA plates and screws to treat zygomatic fractures. Three years after implantation four out of nine (44%) patients returned spontaneously to the clinic with swelling at the site of implantation. The remaining five patients were called in for follow-up and all of them presented with swelling. Seven patients agreed to have exploratory surgery. Histological examination of the biopsied tissue demonstrated needle-like particles of LPLA as well as macrophages and foreign body giant cells. At the longest time (5.7 years), LPLA material was still visible, leading the authors to conclude that "substantial mass loss or total resorption had not taken place up to 5.7 years." They also postulated that the swelling might be due to the LPLA particles and was not unlike the biological reaction seen with polyethylene particles after total joint replacement.

TABLE 4. Clinical studies reporting adverse events with DLPLA implants.

References	Implant/indication	Adverse event/incidence	Timing of event
Martinek, 1999[37]	Sysorb (Sulzer, Baar, Switzerland) ACL reconstruction	Pretibial cyst: 1/25 (4%)	8 months
Ellerman, 2002[20]	Meniscus Arrow (Bionx, Blue Bell, PA) meniscus repair	Fluid accumulation: 41/105 (39%)	not reported
		Cartilage damage: 2/105 (2%)	not reported
		Migrating arrowhead 1/105 (1%)	2 weeks
Muller, 2002[41]	suture anchor (AO ASIF, Davos Switzerland) shoulder capsule	Osteolysis: 7/15 (47%)	16 weeks
Jones, 2002[25]	Meniscus Arrow (Bionx, Malvern, PA) meniscus repair	Pain, swelling: 12/38 (32%)	3–12 months
Landes, 2003[34]	Macrosorb (Macropore, San Diego, CA) PolyMax (Synthes, Oberdorf, Switzerland) Mandibular Fractures	Foreign body reaction: 5/24 (21%)	up to 1 year

TABLE 5. Clinical studies reporting adverse events with LPLA implants.

References	Implant/indication	Adverse event/incidence	Timing of event
Bucholz, 1994[14]	Screws (manufacturer not reported)/ankle fracture	Cyst: 1/83 (1.2%)	15 months
Bergsma, 1995[8]	Plates, screws (manufacturer not reported)/ zygomatic fractures	Swelling: 9/9 (100%)	3.3–5.7 years
Takizawa, 1998[52]	Screws (manufacturer not reported)/distal femur fracture	Screw fragment–effusion:	5 months
Bottoni, 2000[13]	Bio-Interference (Arthrex, Naples, FL)/ACL reconstruction	Intra-articular screws: case report	7 months
Bostman, 2000[12]	LPLA implants (Bioscience, Tampere, Finland)/ multiple indications	Foreign-body reaction: 1/491(0.2%)	4.3 years
Werner, 2002[59]	Bio-Interference (Arthrex, Naples, FL)/ ACL reconstruction	Intra-articular screw fragment, tunnel enlargement: case report	5 months
Mosier-LaClair, 2001[40]	Biofix (Bioscience, Tampere, Finland)/ tarsometatarsal fracture	Sinus: case report	30 months
Voutilainen, 2002[54]	LPLA screws, rods (Bioscience, Tampere, Finland) ankle fracture	Foreign-body reaction: 5/16 (31%)	40–115 months
Juutilainen, 2002[27]	LPLA (manufacturer not reported)/multiple indications	Fluid accumulation: 3/1043 (0.3%)	22 months
Shafer, 2002[48]	LPLA screw (Linvatec, Largo, FL)/ACL reconstruction	Intra-articular screw fragment 2 case reports	15, 23 months
MacDonald, 2003[36]	LPLA screw (manufacturer not reported)/ACL reconstruction	Intra-articular screw fragment case report	11 months

DISCUSSION

The type of implant, method of manufacture, method of sterilization, and site of implantation all affect the degradation of the implant and the resulting biological response, making it difficult to make generalizations on the cause and possible solution for the foreign body response. Most of the clinical studies presented in this paper were unable to clearly identify risk factors for this reaction. However, one study[12] did present a large enough number of patients to establish risk factors for the inflammatory response. The presence of quinone dye, an implant with a large surface area such as screw, and implant sites with low vascularity such as the scaphoid were all found to be related to a higher incidence of adverse tissue response.

Resorption of polymers generally occurs in two phases.[30] In the first phase, the polymer chains are broken down through hydrolysis. In this phase, the molecular weight drops first, followed by mechanical strength loss, and finally by a loss of mass.[45] In the second phase, the implant loses its form and breaks physically into particles, which are attacked by macrophages. Depending on the size of the particulates, they are phagocytosed and the byproducts are excreted by the kidneys and lungs. The corresponding biological response to the degrading polymer is thought to happen as a result of either a build up of acidic degradation products or as a response to the particulates of the polymer.[8]

The timing of the foreign-body response is thought to be related to the final stage of polymer degradation and the clinical trials reviewed in this paper lend credence to this theory. Animal studies have shown that the *in vivo* degradation of PGA implants is usually complete by 3–9 months[42,43] depending on the implant geometry and animal model. The clinical results summarized in Table 2 show that the average time of foreign-body response was 3 months. Animal studies have demonstrated the degradation time of PGA-TMC implants to be at least 3 months.[49] In the clinical trials summarized in Table 3, the timing of the adverse events ranged from 2 weeks to 6 months. One human trial used MR imaging to monitor the *in vivo* degradation of DLPLG.[33] In this study the implant was fully resorbed by 6 months. The *in vivo* degradation of DLPLA has been shown in one animal study to be approximately 24 months,[56] although there is a case report that indicates the degradation time is shorter (less than 10 months) in humans.[50] The clinical trials summarized in this review reported a range of times from 2 weeks to 1 year for reaction to DLPLA implants to present. Animal studies using LPLA implants have demonstrated degradation time to be at least 3 years.[26,51] One human study reported the presence (visible on MR image) of a LPLA interference screw 68 months after surgery.[38] In the studies reviewed here, the reactions presented as late as 9.5 years, and no cases of reactions earlier than 1 year (except screw breakage reports) were reported.

It is important to note that although the incidence of undesirable responses could be as high as 100%,[8] most of the reactions were not accompanied by adverse clinical symptoms and did not affect the final outcome. However, these reports clearly indicate that reaction to bioresorbable implants occurs to some degree with most of the currently available materials. One of the main advantages of these polymers as orthopedic implant materials is that they can be engineered to alter their material properties and degradation characteristics. 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[1] may help reduce the incidence of the foreign-body response.

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