Bioresorbable Plates and Screws for Clinical Applications: A Review

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ABSTRACT

Bioresorbable implants are being widely used for fracture fixation in orthopaedic surgery and the market is expanding rapidly worldwide. Bioresorbable materials slowly dissolve in the human body, such that a second operation to remove the synthetic material is not needed. Bioresorbable implants have expanded the armamentarium of the surgeon, especially in the field of sports medicine. Interference screws, plates, pins, suture anchors, meniscal repair implants, and simple fracture fixation implants are the most commonly used resorbable implants for anterior cruciate ligament reconstruction, shoulder surgery, meniscal repair, and fracture care. However, many clinicians continue to rely on metal fixation, mainly due to the high mechanical strength and to the complications reported with some of the available resorbable implant materials. The goal of the present paper is to present an overview on the available resorbable materials and their applications with a particular focus on new developments and trends in the field.

Keywords: bioresorbable, internal fixation, plates and screws, calcium phosphates, polymers

1. INTRODUCTION

A key goal of orthopaedic medicine is to restore the structure of damaged or diseased bone tissue to a natural state. Internal fixation implants that are stronger, more acceptable to the body, cheaper and durable have been developed to improve bone fracture osteosynthesis, to attach soft tissues or tissue grafts to bone for more than two decades. Such implants comprise screws, plates, pins, staples and suture anchors which are commonly fabricated of metals such as stainless steel and titanium and its alloys. However, there are intrinsic problems with the use of these metallic implants, such as stress-shielding phenomenon, pain, and local irritation [1–3].

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Retained metallic implants are always at the risk of endogenous infection [4]. In addition, metal plate-screws might lead to destruction and osteoporosis in the surrounding bone tissue [5]. For these reasons, there is need for a second surgery to remove the metallic fixation after the bone has healed [2].

Bioresorbable and biodegradable fracture fixation implants have been considered as an effective fixation system with several advantages over metallic fixation, including no need to remove the implants after osseous healing, radiolucency, no corrosion, no accumulation of metal in tissues, less pain and reduced stress-shielding since the implants bear less load initially and gradually transfer the load as they degrade [6–12]. These devices are most often manufactured from polylactides (polylactic acid, PLA), polyglycolides (polyglycolic acid, PGA) and their co-polymer compositions as they are highly resorbable [13–14]. Commercially available resorbable implants are summarized in Table 1.

Bioresorbable materials allow a newly formed tissue to grow into any surface irregularities [15–17]. Thus, a resorbable implant is free of toxic and mutagenic effects. Nonetheless, there are some problems related to the use of these implants, such as an inflammatory response, rapid loss of initial implant strength, higher refracture rates, inadequate stiffness of the implants, and weakness in comparison to metallic implants [1, 18]. Table 2 summarizes some of the problems observed with the implementations of common bioresorbable materials.

Biodegradable implants are characterized by materials that show disintegration after implantation but with no proof of its elimination from the body [19]. The biodegradation process depends on contact with body fluids, temperature, motion, molecular weight, crystal form and geometry of material, and the tissue that is implanted [20–21]. The ideal biodegradable material provides appropriate strength whilst degrading in a predictable fashion throughout the healing process without causing adverse reactions [22].

The first study on the use of biodegradable implants was published in 1966 by Kulkarni et al. [23], who studied the biocompatibility of poly-L-lactic (PLLA) in animals. The material proved to be non-toxic and gradually degraded. The use of PLLA plates and screws to fix mandibular fractures in dogs was studied by Kulkarni et al. [24]. Another study presented the results of PLLA sutures in mandibular fractures with no serious tissue reactions [25].

A common use of biodegradable interference screws is for the anterior cruciate ligament reconstruction. A recent study showed the potential of these screws as an alternative to titanium screws for the fixation of autologous bone grafts in dental implants [26].

The limitations of biodegradable implants are mainly in their mechanical properties which are lower than those of conventional metal implants, leading to low confidence levels regarding the stability of reduced fractures. Also, the construction of screws and pins for the necessary compression between the implant and the bone is somehow difficult [27–28]. The biocompatibility is another limitation of these materials since they sometimes provoke an adverse tissue response that has the characteristic of an inflammatory, bacterial foreign-body reaction [29–34].

Table 1. Commercially available bioresorbable implants

Commercial name	Material	Application	Properties	Advantages/Disadvantages
Biosteon Wedge Interference Screws (Sulzer, Centerpulse)	HA/PLLA (25/75)	ACL reconstruction	Stimulates bone healing, facilitating replacement with bone as the implant is resorbed	<ul style="list-style-type: none"> – Improved implant/bone integration and thereby reduced tunnel widening and risk of graft slippage post-operatively [35] – Increased bone formation and decreased inflammatory cells in vivo, in comparison to a standard polymer [36] – Improved strength retention, bone bonding potential and pH buffering in the graft healing period – Degrades without leaving crystalline remnants – Histological tests show that the bone grows into the tendon within a short time, and that during the degradation, there is no evidence of inflammation in the bone tissue [37]
Sysorb Interference Screw (Sulzer, Centerpulse)	PDLLA	ACL reconstruction	Pull-out strength of 600N	
ProToe™ EndoSorb™ (Merete)	PLGA	Hammertoe Correction	Time of resorption of 12–24 months	During the healing process, the affected bone segments gain strength, while the resorbable screw gradually loses its strength

(Continued)

Table 1. Commercially available bioresorbable implants (Continued)

Commercial name	Material	Application	Properties	Advantages/Disadvantages
Union OTPS™ plates, screws and mesh (Stryker)	n.d.*	Fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization	– Dyed green for better visualisation	– No second surgery required for implant removal, reducing patient trauma and cost – Optimized implant strength/material ratio – Gradually lose most of their strength within 18–36 weeks – Bioresorption takes place within 2–4 years
LactoSorb® SE (Biomet)	PLGA	CMF fixation	n.d.*	– Strength is equal to that of titanium plating – Completely resorbs and is eliminated from the body within 1 year
Sysorb® Synos medical AG (Sulzer Orthopedics)	PLA	ACL reconstruction	n.d.*	Biomechanical studies demonstrated similar fixation strength compared to bone-patellar tendon-bone grafts
BioInterferIX® (ProthAid, Merck Biomaterial)	PLA	n.d.*	n.d.*	n.d.*
Bioscrew® Linvatec (ConMed Linvatec)	PLLA	n.d.*	Long-term absorption rate which ensures secure graft fixation throughout the healing process	n.d.*
Matryx® Interference Screw (ConMed Linvatec)	Self-Reinforced 96L/4D PLA with β -TCP	ACL/PCL graft fixation	n.d.*	– Copolymer provides one of the strongest resorbable implants available – Allows bone in-growth

(Continued)

Table 1. Commercially available bioresorbable implants (Continued)

Commercial name	Material	Application	Properties	Advantages/Disadvantages
Fixsorb® (Takiron)	PLLA/HA	Fracture fixation	n.d.*	Biodegrades as the bone grows
Bio-Phase Suture Anchor; Reunite	PLLA/PLG	Fracture fixation, arthrodesis, suture anchor	n.d.*	n.d.*
Screws, pins, plates; Gentle Threads (Biomet Arthrotek)				
SD Sorb anchors, staples, EZ Tac (Stryker, Howmedica, Osteonics Surgical Dynamics)	PLLG	Suture anchor, meniscus repair	n.d.*	n.d.*
Panaloc RC; BioRoc EZ; Phantom screws (DePuy, Mitek, Ethicon, J&J)	PLLA	Rotator cuff repair, suture anchor	n.d.*	n.d.*
SmartScrew ACL; Duet Suture Anchor; BioCuff; The Wedge (Bionx, Linvatec)	PLLA	Fracture fixation, ACL repair, suture anchor	<ul style="list-style-type: none"> – Torsional strength characteristics unmatched by other resorbable interference screws – A reduction of the stripping and cracking associated with resorbable interference screw insertion 	<ul style="list-style-type: none"> – A standard cannulation for all implant sizes – New larger diameters provide excellent interference fixation in revision surgeries or when larger tunnels are prepared – Pull-out strength comparable to metal anchor – Two times the tensile strength of the braided polyester suture [38]
Bio-Statak (Zimmer)	PLLA	Suture anchor	n.d.*	

*n.d.: not-documented.

PLA: polylactic acid; PGA: polyglycolic acid.

Table 2. Summary of complications associated with bioresorbable implants

Patients (%)	Follow-up	Material	Implant type	Implant site	Results/ complications	Ref.
1.3	n.d.*	PGA	Pin	Toe	Fluid	[39]
49	2–4 mths	PGA	Pin	Ankle	Discharge/ Osteolysis	[40]
6.3	2–4 mths	PGA	Pin	Ankle	Swelling	[33]
11	5–26 wks	PGA	Screw	Ankle	Swelling	[32]
0	10–44 mths	PGA	Pin	Elbow	none	[41]
5	n.d.*	PGA	Screw	Shoulder	Sinus	[42]
6.8	n.d.*	PGA	Pin	Ankle/Elbow	Discharge	[43]
6.5	n.d.*	PGA/PLA, PGA	Pin	Canc. bone	Fluid	[44]
4	2 mths	PGA	Pin	Osteo-chondral fractures	Swelling	[45]
7.9	2–4 mths	PGA	Pin	Multiple	Swelling	[32]
0	21–59 mths	PLA	Screw	Ankle	none	[46]
100	3.3–5.7 yrs	PLLA	Plates/screws	Zygoma	Swelling	[47]
0	3.5–6.6 yrs	PLLA	Discs	Orbital floor	none	[48]
0	8–37 mths	PLLA	Pin	Multiple	none	[49]
0	6 mths	PLLA	Mini tack	Wrist	none	[50]
16	3.5–18 mths	PLLA	Suture anchor	Bankart	Osteolysis and arthropathy	[51]
47	n.d.*	PLLA	Suture anchor	Stabilization	Asymptomatic	[52]
2	15–23 mths	PLLA	Screw -struction	ACL recon screw fragment	Intra-articular	[53]
31	40–115 mths	PLLA	Screws and rods	Ankle reaction	Foreign-body	[54]
19	8 mths	PLLA/PDLLA	Suture anchor	Stabilization	Arthropathy	[55]
100	n.d.*	PDLLA	Screw	Rotator cuff repair	Osteolysis	[56]
100	n.d.*	PDLLA	Suture anchor	Rotator cuff repair	Disintegration	[57]
4	8 mths	PDLLA (Sysorb)	–	ACL reconstruction	Pretibial cyst	[58]

*n.d.: not documented.

PLA: polylactic acid; PGA: polyglycolic acid.

Several excellent review articles have been published regarding the general topic of bioresorbable implants for internal fixation [6, 18, 59–61]. Instead of replicate these efforts, the goal of the present paper is to present a simple background into the available bioresorbable implants and to identify new developments and tendencies.

2. VARIETY OF BIORESORBABLE MATERIALS

2.1. Ceramics: Calcium Phosphates

Calcium phosphates (CaPs) are found widely in the earth crust and are characterized as white solids unless doped or containing elements that pass in the lattice structure of the respective compound. CaPs are chemical compounds similar to the inorganic part of major normal (bones, teeth and antlers) and pathological calcified tissues of mammals [62–64]. CaPs can be categorized into bioactive and bioresorbable materials [65–66]. A bioactive biomaterial enables establishing direct chemical bonds with bone and surrounding tissues, and could provide good stabilization for materials that are subject to mechanical loading. β -tricalcium phosphate (β -TCP) and hydroxyapatite (HA) are the most commonly used CaPs as ceramics. β -TCP is biodegradable and able to promote osteogenesis and new bone formation. HA is highly crystalline and is the most stable and least soluble CaP in an aqueous solution down to a pH of 4.2 [65]. The resorption of a ceramic HA is believed to be slow (1 to 2% per year), and once implanted into the body, HA may remain integrated into the regenerated bone tissue, while β -TCP is completely reabsorbed [67–68].

Unfortunately, CaPs have poor mechanical properties that do not allow load-bearing applications. However, advantages are achieved by combining these materials with polymers that are generally bioinert to provide the composite bioactivity, in order to form a composite with optimized properties. The composite implants are able to form a chemical bond with the host tissue, and the fixation of implants is accelerated [69–71]. For example, CaP/poly-DL-lactide-co-glycolide composite biomaterials exhibit good adhesion onto human cells, indicating a high level of biocompatibility [70–71]. Additionally, previous studies with composite materials consisting of PLLA/TCP or PLLA/HA showed a rapid resorption and replacement by newly formed bone tissue [72–74].

The elastic modulus of the composite can also be adjusted to approach that of the human bone by altering the content of ceramic. It is known that the match of elastic modulus between implants and the human bone favours the evasion of stress-shielding and the sequent bone absorption, which is often caused by implants with high elastic modulus [75].

2.2. Polymers

Bioresorbable fixation materials commonly used in orthopaedic applications are PGA, PLA, poly lactide-co-glycolide (PLGA) co-polymers in various ratios, polydioxanone (PDS), propylene (PP), polysulphone (PS), and polycarbonate (PC). Among them, PGA, PLA and their co-polymers have received the most attention, in part because they can be self-reinforced to achieve better strength properties [76]. The mechanical properties of these materials changes over time in a physiologic environment as determined by the molecular weight and degree of crystallinity. Hence, the molecular weight and crystallinity can be altered to optimize mechanical strength of an implant. For example, polymers with a higher degree of crystallinity are stronger and degrade slower than amorphous polymers with the same chemical composition [77].

2.2.1. Polyglycolide - PGA

PGA was the first bioresorbable polymer for reinforcing pins, screws and plates for bone surgery suggested by Schmitt and Polistina in 1969 [78]. PGA is a hard and crystalline polymer with an average molecular weight of 20000 to 145000, a melting point of 224–230°C, and a glass transition temperature of 36°C [79]. It is degraded in hydrolysis, and is broken down by nonspecific esterases and carboxy peptidases. Its mechanical strength is lost in 6 weeks, and it is totally resorbed in a few months depending on the molecular weight, purity, and crystallinity in addition to the size and shape of the implant [80–81]. However, adverse tissue responses to fixation implants made of PGA have been reported [82–85], with the incidence rate varying from 2.0 to 46.7% [60]. The highest incidence has been observed in fractures of the distal radius and the scaphoid bone [86–88]. Another work reported adverse tissue reaction in 5.3% (107 reactions) of operations using self-reinforced-PGA implants [89]. Nevertheless, the frequency of foreign-body reactions significantly decreased when the dye was omitted from the PGA implant material [89–90]. The risk of adverse tissue reactions has deterred the use of PGA implants in favour of PLA, for example, which have lower rate of degradation.

PGA has been used mostly in sutures, rods and screws in fracture fixation of cancellous bone due to the rapid loss of mechanical strength of the implants [32, 34, 91].

2.2.2. Polylactide - PLA

PLA is a semicrystalline polymer with molecular weights of 180000 to 530000, a melting point of about 174°C, and glass transition temperature of 57°C [92]. Depending on the L and D configuration, it can exist in several distinct forms, such as PLLA and poly-D-lactide (PDLA) [93], and it is also degraded via hydrolysis. P(L/D)LA: PLLA is hydrophobic and crystalline and thus resistant to hydrolysis and degradation. By adding D-isomers into an L-isomer based polymerization system, polymer chains widen and cannot be packed as tightly as PLLA polymer chains. This results in a less crystalline and more rapidly degraded material [94].

PLLA interference screws and plates have been used successfully to fixate and heal tissue and bone, for injuries such as ligament damage and skeletal fractures. In the area of high-strength fracture fixation, PLLA is favoured by product specialists because of its slow rate of complete resorption into the body, although it does not have sufficiently high strength characteristics for use in the fixation of larger fractures such as those in the humerus and femur. Much of the referenced PLLA research has focused on veterinary applications using rabbits [95–96]. PDLLA (poly-DL-lactide) also shows characteristics that could be employed in high-strength situations, but PLLA is the preferred material for use in fracture fixation implants due to its higher strength compared with PDLLA [97].

In experimental studies, the biocompatibility of PLA has been well tolerated by the host tissue [98–101]. PDLLA and PLLA were well-tolerated and the tissue response inside muscle was similar to that of stainless steel [102]. A good biocompatibility has also been observed with PDLLA implants in craniomaxillofacial surgery [103]. PDLLA

pins were compared with PDLA (70:30) with β -TCP (10%) and no different reaction in synovial membrane, lymph nodes, or bone formation was observed with either polymer [104]. Complete degradation of both materials occurred within 36 months. The implant channel was filled with cancellous bone or scar tissue.

However, some problems related to foreign-body reactions were reported although they should not be generalized to all PLLA materials. Eitenmüller et al. [105] used PLLA plates for fixation of ankle fractures, and observed that 52% of the patients demonstrated an aseptic soft tissue problem caused by delayed clearance of the degrading PLA particles. In a second protocol, smaller plates and screws did not cause any soft tissue reactions. Bergsma et al. [47] reported a late tissue response to PLLA bone plates and screws used in the fixation of ten zygomatic fractures in humans. Intraosseally implanted self-reinforced-PLLA screws and pins have been shown to cause similar, mild foreign-body reactions as corresponding metallic devices, without signs of inflammatory reactions during follow-up of 48 weeks [98, 106].

The total resorption time of PLA is considerably longer than PGA [102]. PGA screws have been shown to completely disappear within 6 months while PLLA has a very long degradation time and has been shown to persist in tissues for as long as five years post implantation [60]. Therefore, many resorbable orthopaedic implants are currently manufactured from PLLA. Toxicity is then minimized and biocompatibility is exceptional [13, 107]. The incidence of adverse tissue reaction with PLA-based implants is lower from 0 to 1% [89].

PGA also differs from PLA in that PGA is a stronger acid and behaves more hydrophilically than PLA which is more hydrophobic because of its methyl groups. The decrease of pH values in the tissues adjacent to degrading biodegradable polymers may contribute to adverse effects, an issue that could be addressed by the incorporation of basic salts within the polymer [108].

2.2.3. *Co-polymers*

PGA and PLA can be combined to form a full range of PLGA polymers. Both L- and DL-lactides have been used for co-polymerization. Properties can be controlled by varying the ratio of glycolide to lactide for different compositions [109]. The rates of hydration and hydrolysis can be increased when the crystalline PGA is co-polymerized with PLA.

The degradation time of the co-polymer depends on the ratio of monomers used in synthesis. In general, the higher content of glycolide, the faster is the rate of degradation. For example, the degradation time is 5 months for a 85:15 PDLA:PGA co-polymer [110]. However, an exception to this rule is the 50:50 ratio of PGA:PLA, which exhibits the fastest degradation [111].

There are some concerns about the potential aseptic inflammatory wear debris generated during implant resorption. Caminear et al. [112] used 82:18 PLLA:PGA copolymer implants to fix distal chevron osteotomies in 15 patients and only one patient developed postoperatively a giant cell granuloma needing debridement. Andrews and

Veznedaroglu evaluated the incidences of infection in a group of 296 patients in which 146 received craniotomy fixation with titanium implants and 150 received craniotomy fixation with a PDLLA co/polymer [113]. 43 patients in the titanium group and 37 patients in the polymer group also received postoperative irradiation. The incidence rate of infection was 4.6% for the titanium group and 4.0% for the resorbable polymer group.

Some resorbable membranes made of PLA:PGA have been used for guided bone regeneration (GBR) procedure [114–115]. These membranes generally start to resorb after 4 to 6 weeks. However, their stiffness and duration are questionable. Sandberg et al. [116] noted that some resorbable membranes used in their study demonstrated a lack of stiffness, resulting in collapse of the membrane into the defect area, causing the newly formed bone to take on an hourglass shape.

3. CLINICAL EMPLOYMENTS OF BIORESORBABLE IMPLANTS

The main applications of bioresorbable implants are to stabilize fractures, osteotomies, bone grafts and fusions mostly in trabecular bones, as well as to reattach ligaments, tendons, meniscal tears and other soft tissue structures [117–118]. The midfacial skeleton would seem to be an acceptable location for the use of bioresorbable implants, given the relatively easy access to fractures of this region and the low biomechanical stresses to which they would be exposed to. Andrews and Veznedaroglu studied the incidence of infection in patients after receiving craniotomy fixation with titanium and resorbable PDLA implants [113].

Bioresorbable fixation implants have also been used for the fixation of facial bones in orthognathic surgery, offering clinical advantages over titanium plates by eliminating the possible need for a second operation for their removal [119]. Fedorowicz et al. [119] evaluated the effectiveness of bioresorbable implants used in orthognathic surgery. Adverse effects were observed in two plate exposures between the third and ninth months, and occurred mainly in the posterior maxillary region. Known causes of infection were associated with loosened screws and wound dehiscence [119].

Bioresorbable implants have been also employed for management of foot and ankle fractures [7, 30–31, 34, 105, 120]. Eitenmuller et al. [105] investigated the suitability of PLLA screws and plates for the treatment of ankle fractures. Fractures healed within 6 weeks, but 52% of the patients experienced an aseptic soft tissue problem caused by delayed clearance of the degrading PLA particles. Prompted by these problems, the authors treated 7 patients with volume reduced plates and screws with flat heads, and none of the patients experienced any soft tissue reactions. The authors concluded that the use of PLLA screws and plates is acceptable for the fixation of ankle fractures, and soft tissue inflammatory reactions can be avoided by using implants with reduced volume of biodegradable material.

Bioresorbable implants have also been used in treating knee [121], wrist [122] and hand [1] injuries. Soft tissue reconstruction in complex knee injuries were performed by using meniscal tacks and biodegradable suture anchors [121]. Bioresorbable implants were successfully applied in the repair and reconstruction of many intra-

articular and extra-articular abnormalities in the shoulder, such as shoulder instability, rotator cuff tears, and biceps lesions or biceps tendon tenodesis [123].

Applications of bioresorbable implants in spinal reconstructive surgery have been reported [59, 124–127]. For example, PLA screws were used for anterior cervical decompression and fusion procedures [125, 128]. Deguchi et al. [126] evaluated the biomechanical stability of PLLA pins in the posterior lumbar spine in comparison with other spinal implants, and showed that the PLLA pin construct provided improved stability to the spine, although it was not as stiff as the screw construct due to the sliding motion of the pins during testing.

Bioresorbable materials are also used in paediatric orthopaedics [45, 129–133]. Svensson et al. [45] reported the use of biodegradable osteosynthetic materials in 50 children with transphyseal or osteochondral fractures. Two patients had non-union of articular radial head fractures, possibly related to a foreign-body reaction. Illi et al. [132] evaluated the efficiency of PLLA implants in 32 children, aged 11 months to 17 years, with 15 cases of craniofacial malformations, 16 cases of neurotraumatological lesions and 1 case of refixation of an osteochondral flake of the patella. The follow-up time ranged from 3 months to 5.6 years, with an average of 3 years. The stability achieved was comparable to that of metal implants. No foreign-body reaction or local infections were observed, and it was not necessary to remove any of the resorbable implants. Furthermore, there was no interference with skull growth. In a study by Eppley et al. [133], where resorbable PLLA-PGA (LactoSorb) plate and screw fixation for craniofacial surgery was applied in 1883 infants and young children, it was observed that device-related complications requiring reoperation occurred in less than 0.5% of the implanted patients, which is less frequent than that reported for metallic bone fixation. Significant infectious complications occurred in 0.2%, device instability primarily resulting from postoperative trauma occurred in 0.3%, and self-limiting local foreign-body reactions occurred in 0.7% of the treated patients. The overall reoperation rate attributable to identifiable device-related problems was 0.3%.

Bioresorbable membranes are used in several oral surgical procedures, such as sinus lifts [134–135] and GBR for the treatment of periodontal intraosseous defects [136–137].

4. CONCLUSIONS

Bioresorbable fracture implants are effective fixation devices offering significant advantages over the traditional metal implants. They retain their strength long enough to support healing of bone, and then gradually and harmlessly disintegrate in the patient's body. These implants can also be engineered to alter their material properties and degradation characteristics. Future developments of these materials as orthopaedic implants should be focused on the reduction of the foreign-body reaction and enhancement of the mechanical strength.

CONFLICT OF INTEREST

The authors indicated no potential conflicts of interest.

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