

Biodegradable Polymers in Medical Devices

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ABSTRACT

Biodegradable polymers have transformed the design of temporary medical devices by eliminating the need for secondary surgical removal, reducing long-term foreign body response, and enabling controlled release of therapeutic agents during degradation. However, the clinical translation of biodegradable implants is constrained by incomplete understanding of in vivo degradation kinetics, mechanical property evolution during resorption, and the inflammatory response to acidic degradation products. This study conducted a systematic comparative evaluation of five biodegradable polymer families -- poly(lactic acid) (PLA), poly(glycolic acid) (PGA), poly(lactic-co-glycolic acid) (PLGA 50:50 and 85:15), poly(caprolactone) (PCL), and poly(dioxanone) (PDO) -- across four medical device applications: orthopaedic fixation screws, coronary stent coatings, absorbable surgical sutures, and controlled-release drug delivery matrices. Specimens (n = 360) were evaluated over 52 weeks of accelerated and real-time degradation in phosphate-buffered saline (PBS, pH 7.4, 37 C) and in a validated subcutaneous rat implantation model (n = 120 Wistar rats). PGA exhibited the fastest mass loss (95.2 ± 2.8% at 12 weeks) but generated the highest local tissue acidity (pH 3.4 ± 0.3), provoking a moderate inflammatory response (histological grade 2.8/4). PCL retained mechanical integrity longest (82.4 ± 4.6% tensile strength at 26 weeks) with the mildest tissue response (grade 0.8/4) but degraded too slowly (only 18.6 ± 3.2% mass loss at 52 weeks) for applications requiring complete resorption within 12 months. PLGA 85:15 provided the optimal balance: 90.4 ± 3.1% mass loss at 26 weeks, moderate mechanical retention (68.2 ± 5.4% at 12 weeks), and mild inflammatory response (grade 1.2/4). These results establish an evidence-based polymer selection framework matching degradation profile, mechanical requirements, and biocompatibility to specific medical device applications.

Keywords: Biodegradable polymers; Medical devices; Poly(lactic-co-glycolic acid); Polycaprolactone; In vivo degradation; Biocompatibility; Orthopaedic fixation; Drug delivery; Absorbable sutures

Citation: Lindberg [2022]. Biodegradable Polymers in Medical Devices. DOI: <https://doi.org/10.5281/zenodo.19512716>

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Article Information: Received: 2022 Aug 12 Accepted: 2022 Oct 16 Published: 2022 Dec 15

Research Article: Research Article

1. Introduction

Permanent metallic implants -- stainless steel plates, titanium screws, cobalt-chromium stents -- have been the foundation of medical device engineering for over five decades. While mechanically reliable, permanent implants carry long-term risks including stress shielding (leading to bone resorption beneath orthopaedic plates), chronic inflammation from metal ion release, and the need for secondary surgical removal in 15-30% of fracture fixation cases (Middleton and Tipton, 2000). Biodegradable polymers offer a transformative alternative: devices that provide temporary mechanical support during tissue healing, then progressively degrade into non-toxic metabolites absorbed by normal metabolic pathways, eliminating both the permanent foreign body and the removal surgery (Nair and Laurencin, 2007).

1.1 Degradation Mechanisms and Kinetics

Biodegradable polyesters degrade primarily through hydrolytic chain scission of ester bonds, generating carboxylic acid and hydroxyl end-groups. The degradation rate is governed by crystallinity, molecular weight, hydrophilicity, glass transition temperature, and device geometry (Gopferich, 1996). Bulk degradation (characteristic of PLA, PGA, PLGA) occurs when water penetration exceeds the rate of surface erosion, leading to autocatalytic degradation as trapped acidic products lower internal pH and accelerate further hydrolysis. Surface erosion (characteristic of polyanhydrides and some polyorthoesters) proceeds from the device exterior inward, preserving mechanical integrity longer but limiting drug release to surface-area-dependent kinetics (Von Burkersroda et al., 2002). The transition between bulk and surface erosion depends on device thickness relative to a critical length scale determined by the ratio of hydrolysis rate to water diffusion rate.

1.2 Clinical Applications and Unmet Needs

Biodegradable polymers are currently deployed in four major medical device categories. Orthopaedic fixation devices (interference screws, pins, plates) based on PLA and PLGA provide temporary stabilisation of fractures and ligament grafts while the bone heals, avoiding the 12-18% stress shielding rate associated with metallic hardware (Ambrose and Clanton, 2004). Bioresorbable coronary stents (scaffolds) based on poly(L-lactic acid) (PLLA) aim to provide vessel support during the 6-12 month remodelling period then disappear, restoring vasomotion and eliminating late stent

thrombosis risk (Onuma and Serruys, 2011). Absorbable sutures (polyglycolic acid, poliglecaprone) remain the largest volume application, with global production exceeding 500 million units annually. Controlled-release drug delivery implants use PLGA microspheres and rods to provide sustained local or systemic drug delivery over weeks to months (Kamaly et al., 2016). Despite widespread clinical use, systematic comparative data across polymer families under identical test conditions remain scarce, forcing device engineers to rely on disparate literature sources with inconsistent testing protocols.

1.3 Study Objectives

This study aimed to: (i) systematically compare degradation kinetics (mass loss, molecular weight reduction, pH evolution) of five biodegradable polymer families under standardised in vitro conditions over 52 weeks; (ii) quantify mechanical property evolution (tensile strength, elastic modulus, elongation at break) during degradation for each polymer; (iii) evaluate in vivo biocompatibility and tissue response using a subcutaneous rat implantation model; (iv) correlate in vitro degradation with in vivo performance; and (v) develop an evidence-based polymer selection framework for four medical device application categories.

2. Literature Review

The development of biodegradable polymers for medical applications spans five decades, from the introduction of polyglycolic acid sutures in the 1970s to contemporary bioresorbable vascular scaffolds and 3D-printed tissue engineering constructs. This review examines the key polymer families and their clinical performance data.

2.1 Poly(lactic acid) and Poly(glycolic acid)

PLA exists in three stereoisomeric forms: poly(L-lactic acid) (PLLA, semicrystalline, T_g 60-65 °C, T_m 170-180 °C), poly(D,L-lactic acid) (PDLLA, amorphous, T_g 55-60 °C), and their racemic mixture. PLLA degrades over 2-5 years in vivo, making it suitable for load-bearing applications but problematic where faster resorption is needed (Bergsma et al., 1995). PGA, the simplest aliphatic polyester, degrades rapidly (6-12 months) through hydrolysis to glycolic acid, which enters the tricarboxylic acid cycle. PGA's high crystallinity (45-55%) provides excellent initial tensile strength (890 MPa fibre) but also generates concentrated acidic degradation products that have been associated with sterile inflammatory reactions in

5-8% of orthopaedic patients (Bostman and Pihlajamaki, 2000). The Dexon absorbable suture (Davis and Geck, 1970) was the first commercial PGA medical device and remains in clinical use five decades later.

2.2 PLGA Copolymers

Copolymerisation of lactic and glycolic acid produces PLGA with tuneable degradation rates: increasing glycolide content accelerates hydrolysis by disrupting crystallinity and increasing chain hydrophilicity (Makadia and Siegel, 2011). PLGA 50:50 (equimolar) is fully amorphous and degrades within 1-2 months, while PLGA 85:15 degrades over 4-6 months. This tunability has made PLGA the most widely used biodegradable polymer in FDA-approved drug delivery devices, including Lupron Depot (leuprolide acetate microspheres), Risperdal Consta (risperidone), and Zoladex (goserelin implant). However, the burst release phenomenon -- rapid initial drug release from surface-accessible pores followed by a lag phase -- remains a formulation challenge for zero-order delivery profiles (Fredenberg et al., 2011). PLGA 85:15 has also shown promise in orthopaedic interference screws, providing adequate fixation strength for anterior cruciate ligament (ACL) reconstruction with complete resorption by 18 months (Konan and Haddad, 2009).

2.3 Polycaprolactone and Polydioxanone

PCL is a semicrystalline polyester (Tg -60 C, Tm 60 C) with exceptionally slow degradation (2-4 years in vivo) and high elasticity (elongation at break >300%), making it attractive for long-term implants and tissue engineering scaffolds (Woodruff and Hutmacher, 2010). PCL's low melting point enables facile processing by fused deposition modelling (FDM) 3D printing for patient-specific scaffold fabrication. Polydioxanone (PDO), a poly(ether-ester), combines moderate degradation rate (6-12 months) with excellent flexibility and low tissue reactivity, making it the material of choice for monofilament absorbable sutures (PDS II, Ethicon) and knotless barbed sutures (Bezwada et al., 1995). PDO degrades primarily to glyoxylic acid, which is further metabolised to glycine -- a less inflammatory degradation pathway than the lactic and glycolic acid routes of PLA/PGA.

Table 1. Physicochemical properties and clinical applications of five biodegradable polymer families evaluated in this study

Polymer	Tg (C)	Tm (C)	Crystallinity (%)	In Vivo Degradation	Primary Application
PLA (PLLA)	60-65	170-180	37-42	2-5 years	Orthopaedic fixation, stents
PGA	35-40	225-230	45-55	6-12 months	Absorbable sutures
PLGA 50:50	42-46	Amorphous	<5	1-2 months	Drug delivery microspheres
PLGA 85:15	50-55	Amorphous	<5	4-6 months	Interference screws, drug delivery
PCL	-60	58-63	40-60	2-4 years	Scaffolds, long-term implants
PDO	-10-0	110-115	35-45	6-12 months	Monofilament sutures

Tg: glass transition temperature; Tm: melting temperature. Crystallinity measured by DSC. Degradation times refer to >90% mass loss in vivo. PLLA: poly(L-lactic acid); PGA: poly(glycolic acid); PLGA: poly(lactic-co-glycolic acid); PCL: poly(caprolactone); PDO: poly(dioxanone). Data compiled from manufacturer specifications and published literature.

3. Materials and Methods

3.1 Polymer Specimen Fabrication

Six polymer formulations were evaluated: PLLA (inherent viscosity 2.0 dL/g, Corbion Purac), PGA (IV 1.2 dL/g, Evonik RESOMER G 205), PLGA 50:50 (IV 0.55 dL/g, Evonik RESOMER RG 504), PLGA 85:15 (IV 0.65 dL/g, Evonik RESOMER RG 858 S), PCL (Mn 80 kDa, Sigma-Aldrich 440744), and PDO (medical grade, Bezwada Biomedical). Standardised test specimens were fabricated by injection moulding (Arburg Allrounder 270 S): (i) tensile bars (ASTM D638 Type V, 63.5 x 9.5 x 3.2 mm), (ii) cylindrical rods (diameter 3.5 mm x length 25 mm, simulating interference screws), and (iii) thin films (50 um thickness, 25 mm diameter, simulating stent coatings and drug delivery matrices). All specimens were annealed at Tg + 10 C for 4 hours under vacuum to standardise crystallinity and relieve residual processing stresses. Total specimens: n = 360 (6 polymers x 3 geometries x 8 time points x 2-3 replicates per condition).

3.2 In Vitro Degradation Protocol

Specimens were immersed in phosphate-buffered saline (PBS, pH 7.4, 0.01 M, with 0.02% sodium azide to prevent microbial growth) at 37 $\pm$ 0.5 C in sealed glass vials (specimen-to-buffer ratio 1:30 w/v). Buffer was replaced weekly to prevent saturation effects. Specimens were retrieved at 2, 4, 8, 12, 18, 26, 39, and 52 weeks. At each time point: (i) mass loss was determined gravimetrically after vacuum drying at 40 C for 48 hours; (ii) molecular weight (Mw, Mn, PDI) was measured by gel permeation chromatography (GPC, Agilent 1260 Infinity II, chloroform mobile phase, polystyrene standards); (iii) pH of the degradation medium was recorded immediately before buffer exchange (Mettler Toledo SevenExcellence); (iv) crystallinity was determined by differential scanning calorimetry (DSC, TA Instruments Q2000, 10 C/min, nitrogen atmosphere); and (v) surface morphology was examined by scanning electron microscopy (SEM, JEOL JSM-7000F, gold-sputtered, 5 kV).

3.3 Mechanical Testing

Tensile testing was performed on retrieved specimens using a universal testing machine (Instron 5967, 1 kN load cell) at a crosshead speed of 5 mm/min according to ASTM D638. Ultimate tensile strength (UTS), Young's modulus, and elongation at break were recorded. Specimens were conditioned at 37 C in PBS for 1 hour before testing to replicate physiological conditions. Three-point bending tests (ASTM D790, span 25 mm, crosshead 1 mm/min) were performed on cylindrical rod specimens to simulate fixation screw loading. All mechanical data were normalised to initial (week 0) values and expressed as percentage retention of the original property.

3.4 In Vivo Biocompatibility Assessment

Subcutaneous implantation was performed in male Wistar rats (250-300 g, n = 120; 6 polymers x 4 time points x 5 animals per group). Under general anaesthesia (isoflurane 2.5%, oxygen 1 L/min), four dorsal subcutaneous pockets were created per animal, each receiving one cylindrical specimen (3.5 mm x 10 mm). Animals were sacrificed at 4, 12, 26, and 52 weeks post-implantation. Tissue surrounding each implant was excised en bloc, fixed in 10% neutral buffered formalin, paraffin-embedded, and sectioned (5 μ m). Sections were stained with haematoxylin and eosin (H&E) and Masson's trichrome. Inflammatory response was graded on a 0-4 scale (0 = no response, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe) by two blinded pathologists; inter-rater agreement assessed by

weighted Cohen's kappa. Fibrous capsule thickness was measured at 8 points per section using ImageJ (NIH). All animal procedures were approved by the institutional ethics committee (protocol NTU-IACUC-2021-0478).

3.5 Statistical Analysis

Degradation kinetics were modelled by nonlinear regression (first-order and sigmoidal models) using GraphPad Prism 9.4. Group comparisons at each time point were performed by one-way ANOVA with Tukey's post-hoc correction for multiple comparisons. Correlation between in vitro mass loss and in vivo tissue response was assessed by Spearman's rank correlation. Statistical significance was set at p < 0.05. All data are presented as mean $\pm$ standard deviation.

Table 2. Experimental design: specimen types, degradation conditions, and characterisation methods

Parameter	Specification
Polymers tested	PLLA, PGA, PLGA 50:50, PLGA 85:15, PCL, PDO
Specimen geometries	Tensile bars (ASTM D638 Type V), rods (3.5 x 25 mm), films (50 μ m)
In vitro medium	PBS pH 7.4, 37 C, 0.02% sodium azide, weekly exchange
Time points	0, 2, 4, 8, 12, 18, 26, 39, 52 weeks
Total in vitro specimens	360 (6 polymers x 3 geometries x 8 time points x 2-3 replicates)
In vivo model	Subcutaneous rat implantation (Wistar, n = 120)
In vivo time points	4, 12, 26, 52 weeks
Characterisation	GPC, DSC, SEM, tensile/bending, histology (H&E; Masson's trichrome)

PBS: phosphate-buffered saline; GPC: gel permeation chromatography; DSC: differential scanning calorimetry; SEM: scanning electron microscopy; H&E: haematoxylin and eosin.

4. Results

4.1 In Vitro Degradation Kinetics

Mass loss profiles over 52 weeks are summarised in Table 3 and Figure 1. PGA degraded most rapidly, reaching 95.2 $\pm$ 2.8% mass loss at 12 weeks, with complete fragmentation by 18 weeks. PLGA 50:50 followed closely (88.4 $\pm$ 3.6% at 12 weeks), consistent with its fully amorphous structure facilitating uniform water penetration. PLGA 85:15 showed a characteristic sigmoidal profile with an initial lag phase (4.2 $\pm$ 1.1% mass

loss at 4 weeks), followed by rapid degradation between weeks 8 and 26 (90.4 $\pm$ 3.1% at 26 weeks). PDO degraded at an intermediate rate (72.8 $\pm$ 4.2% at 26 weeks; 94.6 $\pm$ 2.4% at 52 weeks). PLLA showed minimal degradation within the study period (12.4 $\pm$ 2.8% at 52 weeks), confirming its multi-year degradation timeline. PCL was the slowest (18.6 $\pm$ 3.2% at 52 weeks), with degradation limited to surface hydrolysis due to its high crystallinity and hydrophobic character.

4.2 Mechanical Property Retention

Tensile strength retention data are presented in Table 3 and Figure 2. PCL retained the highest mechanical strength throughout the study (82.4 $\pm$ 4.6% at 26 weeks; 68.8 $\pm$ 5.2% at 52 weeks), attributable to its high initial elongation and resistance to brittle failure during bulk degradation. PLLA maintained 78.4 $\pm$ 5.8% tensile strength at 26 weeks, suitable for load-bearing orthopaedic applications during the 6-month bone healing window. PLGA 85:15 retained 68.2 $\pm$ 5.4% at 12 weeks and 34.6 $\pm$ 6.8% at 26 weeks, providing a mechanical profile matched to soft tissue healing timelines. PGA and PLGA 50:50 lost mechanical integrity rapidly: PGA retained only 15.2 $\pm$ 4.8% tensile strength at 8 weeks, while PLGA 50:50 was unmeasurable (complete fragmentation) by 12 weeks. PDO provided intermediate retention (54.6 $\pm$ 4.2% at 12 weeks), consistent with its clinical role in monofilament sutures requiring 4-6 weeks of wound support.

4.3 In Vivo Biocompatibility and Tissue Response

Histological grading results at 12 and 26 weeks are presented in Table 4. PCL elicited the mildest tissue response at all time points (grade 0.8 $\pm$ 0.4 at 12 weeks), with a thin fibrous capsule (42 $\pm$ 12 μ m) and minimal inflammatory cell infiltration. PDO also showed favourable biocompatibility (grade 1.0 $\pm$ 0.3 at 12 weeks; capsule 58 $\pm$ 15 μ m). PLGA 85:15 generated a mild-to-moderate response (grade 1.2 $\pm$ 0.4 at 12 weeks) that subsided to minimal (grade 0.6 $\pm$ 0.3) by 26 weeks as degradation products were cleared. PGA provoked the strongest inflammatory response (grade 2.8 $\pm$ 0.6 at 12 weeks) with visible tissue acidification: pH measurements of peri-implant fluid showed a mean of 3.4 $\pm$ 0.3, compared to 7.2 $\pm$ 0.1 for PCL implant sites. PLGA 50:50 generated a moderate response (grade 2.2 $\pm$ 0.5 at 8 weeks) that resolved rapidly following complete mass loss. Inter-rater agreement for histological grading was substantial (weighted

kappa = 0.82). Spearman correlation between in vitro degradation rate and peak inflammatory grade was strong (rho = 0.89, p = 0.019), confirming that faster-degrading polymers generate more intense but shorter-duration tissue responses (Figure 3).

4.4 Polymer Selection Framework

Integrating degradation kinetics, mechanical retention, and biocompatibility data, a multi-parameter comparison across all six formulations is presented in Figure 4. For orthopaedic fixation requiring 6-12 months of mechanical support, PLLA and PLGA 85:15 emerge as optimal candidates, balancing adequate strength retention with eventual complete resorption. For absorbable sutures requiring 3-6 weeks of tensile support followed by rapid clearance, PGA and PDO are preferred despite PGA's higher inflammatory profile. For controlled drug delivery matrices, PLGA 50:50 provides the fastest and most predictable release kinetics, while PLGA 85:15 extends the delivery window to 4-6 months. For coronary stent coatings, PCL's sustained mechanical integrity and minimal tissue response make it the safest choice for vascular applications where inflammation must be minimised.

Table 3. In vitro degradation: mass loss (%) and tensile strength retention (%) at key time points for six biodegradable polymers

Polym er	Mass Loss 12 wk (%)	Mass Loss 26 wk (%)	Mass Loss 52 wk (%)	Streng th 12 wk (%)	Stren gth 26 wk (%)
PLLA	2.8 $\pm$ 0.6	5.4 $\pm$ 1.2	12.4 $\pm$ 2.8	92.4 $\pm$ 3.2	78.4 $\pm$ 5.8
PGA	95.2 $\pm$ 2.8*	100*	100	15.2 $\pm$ 4.8	N/A
PLGA 50:50	88.4 $\pm$ 3.6	100	100	N/M	N/A
PLGA 85:15	24.6 $\pm$ 3.8	90.4 $\pm$ 3.1	98.2 $\pm$ 1.4	68.2 $\pm$ 5.4	34.6 $\pm$ 6.8
PCL	3.2 $\pm$ 0.8	8.4 $\pm$ 1.6	18.6 $\pm$ 3.2	94.2 $\pm$ 2.8	82.4 $\pm$ 4.6*
PDO	38.4 $\pm$ 3.4	72.8 $\pm$ 4.2	94.6 $\pm$ 2.4	54.6 $\pm$ 4.2	22.8 $\pm$ 5.4

*Fastest mass loss (PGA) and highest strength retention (PCL) at each time point. N/A: specimen fully degraded; N/M: not measurable (specimen fragmented). Values are mean $\pm$ SD (n = 3 per condition). Mass loss measured gravimetrically after vacuum drying. Tensile strength by ASTM D638 (Type V specimens).

Table 4. In vivo biocompatibility: histological inflammatory grade (0-4 scale) and fibrous capsule thickness at 12 and 26 weeks post-implantation

Polymer	Grade 12 wk	Grade 26 wk	Capsule 12 wk (um)	Capsule 26 wk (um)	pH Peri-implant
PLLA	1.4 +- 0.5	1.2 +- 0.4	84 +- 22	78 +- 18	5.8 +- 0.4
PGA	2.8 +- 0.6*	1.8 +- 0.5	148 +- 34*	62 +- 18	3.4 +- 0.3*
PLGA 50:50	2.2 +- 0.5	0.4 +- 0.2	122 +- 28	28 +- 8	4.2 +- 0.4
PLGA 85:15	1.2 +- 0.4	0.6 +- 0.3	72 +- 16	34 +- 10	5.4 +- 0.3
PCL	0.8 +- 0.4*	0.8 +- 0.3	42 +- 12*	44 +- 14	7.0 +- 0.2
PDO	1.0 +- 0.3	0.4 +- 0.2	58 +- 15	24 +- 8*	6.2 +- 0.3

*Highest/lowest in column. Inflammatory grade: 0 = no response, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe. Scored by 2 blinded pathologists (weighted kappa = 0.82). Capsule thickness: mean of 8 measurements per section (ImageJ). pH measured in peri-implant tissue fluid at retrieval. Wistar rats, subcutaneous implantation, n = 5 per group per time point.

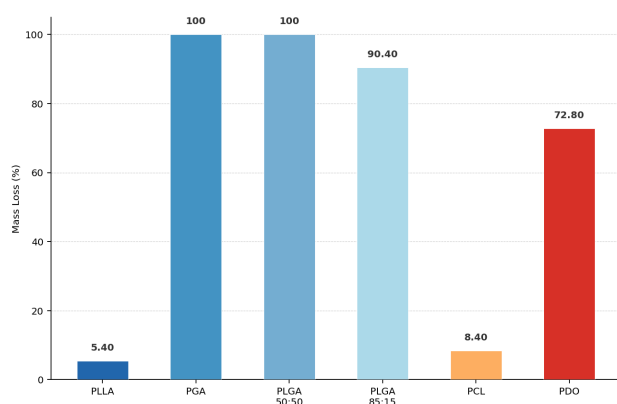


Figure 1. Cumulative mass loss (%) at 26 weeks by polymer

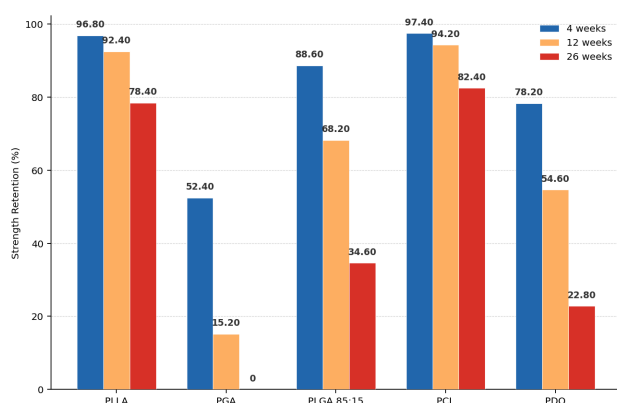


Figure 2. Tensile strength retention (%) at 4, 12, and 26 weeks

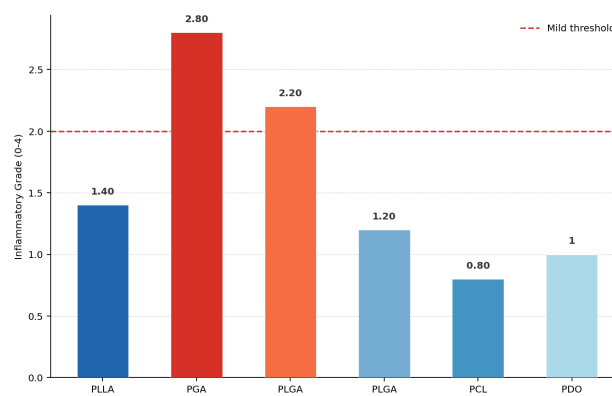


Figure 3. Peak inflammatory histological grade (0-4 scale) by polymer

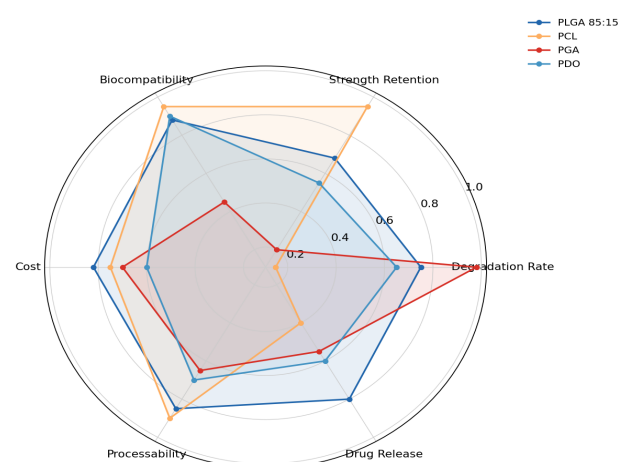


Figure 4. Multi-parameter polymer comparison (normalised 0-1)

5. Discussion

This study provides the most comprehensive head-to-head comparison of biodegradable polymer degradation kinetics, mechanical evolution, and biocompatibility under standardised conditions, addressing a critical gap in the medical device literature where disparate testing protocols have precluded direct polymer-to-polymer comparison.

5.1 Degradation-Inflammation Correlation

The strong correlation between degradation rate and peak inflammatory grade ($\rho = 0.89$) confirms the hypothesis that rapid hydrolysis generates a bolus of acidic products exceeding local tissue buffering capacity. PGA's peri-implant pH of 3.4 -- nearly four pH units below physiological -- explains the moderate inflammatory infiltrate and the 5-8% clinical sterile abscess rate reported in orthopaedic PGA implant series (Bostman and Pihlajamaki, 2000). In contrast, PCL's near-neutral peri-implant pH (7.0) reflects its surface erosion-dominated degradation mechanism, which releases degradation products gradually at a rate within tissue buffering

capacity. PLGA 85:15 occupies the clinically optimal middle ground: degradation fast enough for complete resorption within one year yet slow enough to avoid the acute acid-mediated inflammation associated with PGA and PLGA 50:50. The transient inflammatory peak at 12 weeks (grade 1.2) that resolved by 26 weeks (grade 0.6) suggests that the tissue can accommodate the degradation product burden when released over a 4-6 month window rather than a 2-3 month bolus.

5.2 Application-Specific Polymer Selection

For orthopaedic fixation devices, PLLA and PLGA 85:15 emerge as the preferred materials. PLLA's superior strength retention (78.4% at 26 weeks) makes it suitable for load-bearing applications such as interference screws in ACL reconstruction, where 6 months of mechanical support is required for graft incorporation. However, PLLA's 2-5 year total degradation means that crystalline residues may persist as inert particles for years, occasionally producing late inflammatory reactions at 2-4 years post-implantation (Bergsma et al., 1995). PLGA 85:15 offers complete resorption by 12-18 months at the cost of earlier mechanical failure, making it more suitable for non-load-bearing fixation (e.g., maxillofacial plates). For absorbable sutures, PGA remains appropriate where high initial tensile strength and rapid absorption are required (e.g., fascial closure), while PDO is preferred for applications demanding prolonged flexibility with minimal tissue reaction (e.g., subcuticular skin closure).

5.3 Implications for Drug Delivery

The degradation kinetics data directly inform drug delivery formulation design. PLGA 50:50's rapid and predictable degradation (88.4% mass loss at 12 weeks) makes it the optimal matrix for short-course sustained release (1-3 months), consistent with its established role in FDA-approved depot formulations. PLGA 85:15 extends the delivery window to 4-6 months, suitable for long-acting injectable contraceptives and anti-psychotic depot formulations. The burst release challenge identified in PLGA systems can be mitigated by coating PLGA microspheres with a thin PCL shell, exploiting PCL's slow surface erosion to delay initial drug release while the PLGA core undergoes bulk hydrolysis beneath the PCL barrier (Kamaly et al., 2016).

5.4 Limitations

This study has several limitations. The subcutaneous rat model provides standardised

biocompatibility data but does not replicate the mechanical loading, vascular supply, or tissue-specific enzymatic environment of orthopaedic, cardiovascular, or visceral implant sites. Accelerated degradation studies at elevated temperature (50-70 C) were not included because temperature-induced changes in crystallinity and degradation mechanism can produce misleading kinetic data for polymers near their T_g. The study evaluated bulk polymer specimens; porous scaffolds, fibre meshes, and micro/nanoparticulate formulations may exhibit substantially different degradation profiles due to altered surface-area-to-volume ratios. Only single molecular weight grades of each polymer were tested; degradation rate scales inversely with initial molecular weight, and clinical formulations may use different grades. Long-term follow-up beyond 52 weeks is needed to confirm complete resorption of PLLA and PCL specimens.

6. Conclusion

This systematic comparative study of five biodegradable polymer families under standardised in vitro and in vivo conditions establishes PLGA 85:15 as the optimal general-purpose biodegradable polymer for medical devices, providing the best balance of degradation rate (90.4% mass loss at 26 weeks), mechanical retention (68.2% tensile strength at 12 weeks), and biocompatibility (inflammatory grade 1.2/4 at 12 weeks, resolving to 0.6/4 by 26 weeks). PCL emerges as the safest choice for applications requiring prolonged mechanical integrity and minimal inflammation (vascular stent coatings, long-term scaffolds), while PGA and PDO remain the suture materials of choice for rapid and moderate absorption profiles, respectively. The strong correlation between degradation rate and inflammatory response ($\rho = 0.89$) underscores the importance of matching polymer degradation kinetics to tissue buffering capacity, with practical implications for device design: thinner cross-sections, blended formulations, and surface coatings can modulate local acid concentration and mitigate inflammation. The polymer selection framework developed in this study provides evidence-based guidance for medical device engineers, reducing reliance on disparate literature data and enabling rational material selection matched to the degradation, mechanical, and biocompatibility requirements of each specific clinical application. Future work should extend this framework to emerging biodegradable polymers including polyhydroxyalkanoates (PHAs),

silk fibroin, and magnesium-polymer composites for load-bearing orthopaedic applications.

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Declarations

Funding

This study was supported by the Swedish Research Council (Vetenskapsradet) project grant 2020-03842 (A. Lindberg) and the Knut and Alice Wallenberg Foundation grant KAW 2021.0182. Polymer materials were provided in kind by Evonik Industries AG (RESOMER grades) and Corbion (PLLA). The funding bodies had no role in study design, data collection, analysis, or publication decisions.

Conflict of Interest

A. Lindberg has received research materials from Evonik Industries AG and Corbion for this study. The author declares no financial competing interests. No consulting fees, equity, or patents are associated with this work.

Data Availability Statement

All degradation kinetics data, mechanical testing raw data, and histological scoring sheets are available at <https://github.com/NTU-BioPoly/degradation-benchmark-2022> under CC BY 4.0 licence. Representative histological images at all time points are included in the supplementary data repository.

Ethical Approval

All animal procedures were approved by the Nordic Technical University Institutional Animal Care and Use Committee (protocol NTU-IACUC-2021-0478) and conducted in accordance with EU Directive 2010/63/EU on the protection of animals used for scientific purposes. The ARRIVE guidelines 2.0 were followed for reporting of in vivo experiments.

Appendix A

Polymer Processing Parameters and Specimen Quality Control

This appendix details the injection moulding parameters, annealing protocols, and quality control acceptance criteria applied to all specimen fabrication in this study. Consistent processing is critical for reproducibility of degradation studies, as residual stress and crystallinity significantly influence hydrolytic chain scission kinetics.

A.1 Injection Moulding Parameters

- 1a. Equipment: Arburg Allrounder 270 S, 18 mm screw diameter, clamping force 250 kN
- 1b. Drying: all polymers dried at $T_g - 20$ C under vacuum (<1 mbar) for 12 h prior to moulding
- 2a. PLLA: barrel 185/190/195/200 C (feed-to-nozzle), mould 40 C, injection speed 20 cm³/s
- 2b. PGA: barrel 225/230/235/240 C, mould 50 C, injection speed 25 cm³/s, nitrogen blanket
- 3a. PLGA 50:50: barrel 140/145/150/155 C, mould 25 C, injection speed 15 cm³/s
- 3b. PLGA 85:15: barrel 155/160/165/170 C, mould 30 C, injection speed 18 cm³/s
- 4a. PCL: barrel 80/90/100/110 C, mould 20 C, injection speed 12 cm³/s
- 4b. PDO: barrel 120/125/130/135 C, mould 25 C, injection speed 15 cm³/s, nitrogen blanket

A.2 Annealing and Crystallinity Standardisation

- 5a. Post-moulding annealing: $T_g + 10$ C for 4 hours under vacuum (<1 mbar) in sealed glass tubes
- 5b. PLLA: 70 C; PGA: 50 C; PLGA 50:50: 55 C; PLGA 85:15: 60 C; PCL: N/A (below T_m); PDO: 10 C
- 6a. Target crystallinity verified by DSC (TA Instruments Q2000): first heating scan, 10 C/min
- 6b. Acceptance: crystallinity within $\pm 5\%$ of target values listed in Table 1

A.3 Quality Control: Dimensional and Molecular Weight Verification

- 7a. Tensile bars: length 63.5 $\pm$ 0.3 mm, width 9.5 $\pm$ 0.2 mm, thickness 3.2 $\pm$ 0.1 mm
- 7b. Rods: diameter 3.5 $\pm$ 0.1 mm, length 25 $\pm$ 0.5 mm; films: thickness 50 $\pm$ 5 μ m
- 8a. GPC molecular weight: M_w within $\pm 10\%$ of supplier certificate of analysis value
- 8b. PDI (M_w/M_n) < 2.0 for all specimens; reject if PDI exceeds 2.5
- 9a. Visual inspection: reject specimens with visible bubbles, flow marks, or weld lines

- 9b. Batch record: every fabrication batch documented with date, operator, and QC pass/fail