

Biodegradable Polymers in Formulation

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ABSTRACT

The field of biodegradable polymers is one that is developing quickly. Their use in pharmaceutical drug delivery systems for therapeutic agents is the main topic of this review. Despite the fact that polymers are frequently utilized in pharmaceutical packaging, this article highlights their function in creating a variety of dosage forms. The creation of biodegradable polymer-based systems offers several benefits, including the ability to deliver pharmaceutical agents systemically or site-specifically without requiring the delivery system to be retrieved later.

Keywords: Biodegradable polymers; Enzymes

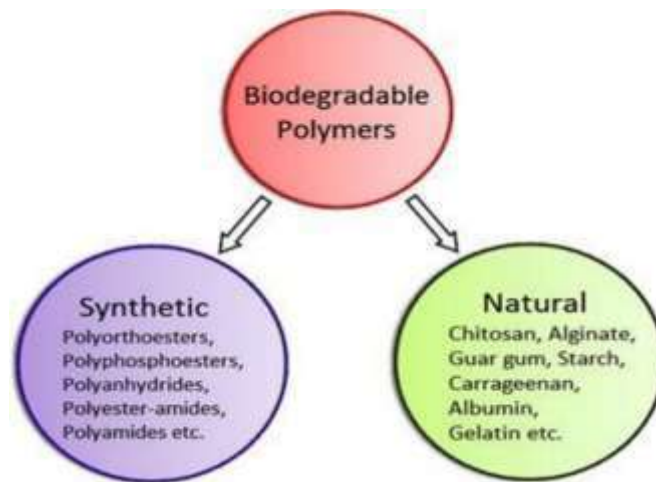
INTRODUCTION

Biodegradable polymers retain their functional properties for a limited duration in vivo and subsequently degrade into byproducts that can either dissolve or be metabolized and safely eliminated from the body. For in vivo applications, the polymers used in such systems must exhibit essential characteristics, including biocompatibility, processability, sterilization stability, and adequate shelf life. For each therapeutic agent and application, it is crucial to evaluate the properties of both the drug whether the formulation is and the delivery method to ascertain optimal for the intended drug delivery purpose [2]. Biodegradation occurs through enzymatic activity and/or chemical processes associated with living organisms. It generally proceeds in two stages. First, polymers are fragmented into lower molecular weight species through abiotic in the second stage, these polymer fragments undergo bio assimilation by microorganisms, ultimately leading to their mineralization. The biodegradability of a polymer is not solely dependent on its three origins but also on the condition of the environment and the composition of its chemicals. Various mechanisms and techniques for estimating polymer biodegradation have been comprehensively reviewed [16]. Biodegradable polymers have wide-ranging applications in the medical field and are primarily classified into drug delivery systems [3,4], wound healing products [5,6],

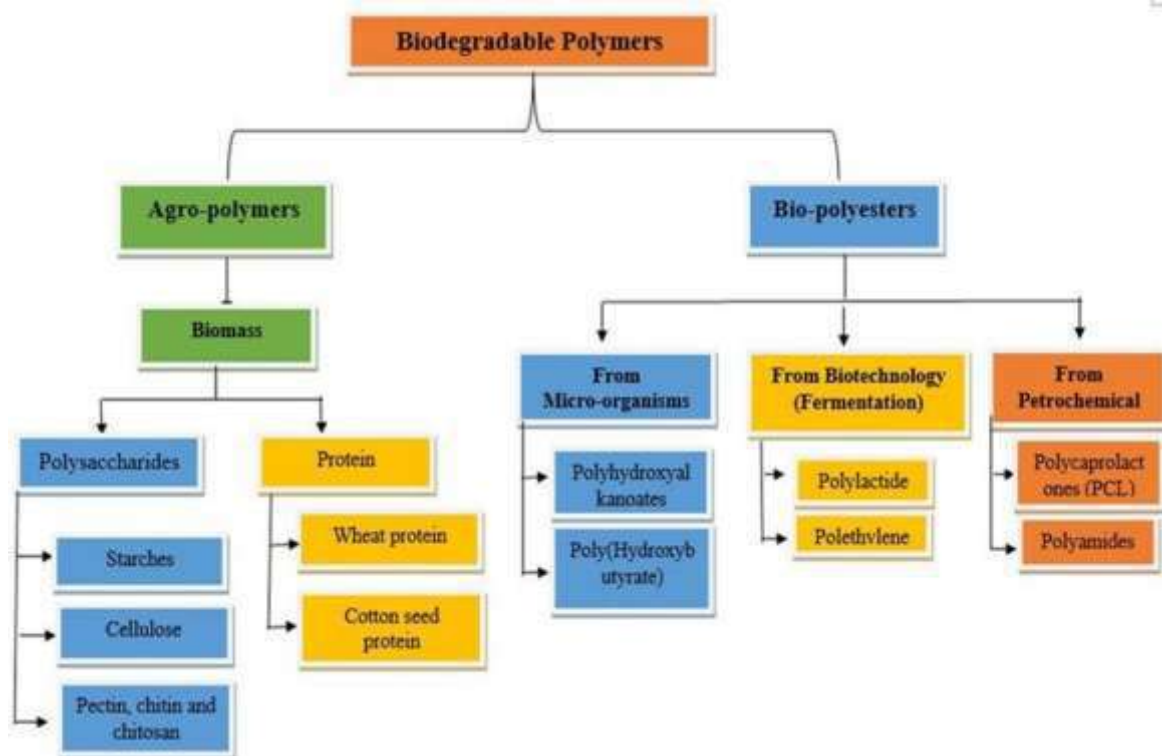
and surgical implant devices [7]. Among these, the development of biopolymeric drug delivery systems has attracted significant attention, particularly for controlled release applications. Drug delivery within the human body can be effectively regulated through biodegradable capsules [18]. Notably, biodegradable polymers are frequently employed in the design of novel formulations, with the buccal mucosa serving as a favorable target due to its high permeability [19]. In this context, drug delivery via biodegradable polymers through the buccal route is considered safe, protective, and fast-Acting. In wound healing, biodegradable polymers are utilized in the production of bioresorbable non-wovens for tissue repair [10], as well as in conventional products such as sutures, staples, and meshes [11]. Likewise, the application of biodegradable scaffolds in tissue engineering has shown great promise [12]. These polymers are not only renewable and cost-effective but are also available in diverse forms [13]. Their bioactive properties make them especially suitable for wound healing, as they can promote cell growth, regeneration, antimicrobial activity, and immunomodulation [14]. Additionally, their high water-absorbing capacity enhances their effectiveness in wound care applications. In recent years, significant progress has been made in engineering biodegradable polymers capable of releasing drugs directly at the site of injury, further improving their potential for healing applications. Moreover, many

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

biopolymers possess excellent film-forming abilities, making them useful for conventional and commodity applications [15].



Classification of Biodegradable Polymers:



Advantages of Biodegradable Polymers:

- 1) They allow drug release at a steady and controlled rate over a recommended period of time, reducing the need for frequent dosing.
- 2) Provide drug release at a steady and controlled rate over a defined period.
- 3) The polymer carrier gradually degrades into non-toxic, absorbable subunits, which are further metabolized.

- 4) The system is biocompatible, preventing dose dumping during the release phase while retaining polymer integrity until drug exhaustion.
- 5) Removes the need for the device to be surgically removed once the drug has run out.
- 6) Degraded materials are transformed into molecules that are acceptable to biology and removed through regular metabolic processes of Biodegradable Polymers:(16)

Disadvantages:

- 1) Sometimes, polymers may exhibit dose dumping at later stages of Implantation.
- 2) A “Burst Effect” Or Rapid Initial Drug Release Is Common In Many Systems.
- 3) Injectable Biodegradable Systems In Particulate Form Are Non-Retrievable, which limits control once administered [17].

Effect of polymer structure:

The body typically breaks down common macromolecules by enzyme activity or hydrolysis. Polymer structure has a significant impact on the rate and method of degradation, including:

Backbone composition (e.g., presence of hydrolysable ester, amide, or anhydride bonds).

Molecular weight – higher molecular weight polymers usually degrade more slowly.

Crystallinity – crystalline regions resist water penetration and enzymatic attack, leading to slower degradation compared to amorphous regions.

Hydrophobicity/Hydrophilicity – hydrophilic polymers absorb more water and degrade faster, while hydrophobic ones show slower degradation.

Crosslinking density – highly crosslinked polymers degrade slowly due to restricted chain mobility and water diffusion.

Copolymer composition – ratio of monomers (e.g., lactic acid:glycolic acid in PLGA) significantly affects the degradation profile.

Hydrolysis followed by oxidation is the main process that breaks down organic frameworks. Since these hydrolyzable linkages—such as amide, enamine, ester, urea, and urethane bonds—can be broken down by microbes and hydrolytic enzymes, the majority of synthetic biodegradable polymers are made with them in their backbone. Because most chemical reactions take place in aqueous media, the balance between hydrophilia and hydrophobicity in synthetic polymers is essential for determining how biodegradable they are. Generally speaking, polymers with both hydrophilic and hydrophobic segments are more biodegradable than polymers made entirely of hydrophilic or hydrophobic segments [19].

Other Factors Includes:

The rate and mechanism of polymer degradation are influenced by several structural, physicochemical, and environmental factors:

1. Polymer-Related Factors:

Presence of unexpected units or chain defects – structural irregularities enhance water penetration and accelerate degradation.

Configuration and stereoregularity – crystalline vs. amorphous arrangements significantly affect hydrolytic accessibility.

Molecular weight and distribution – higher molecular weight polymers typically degrade more slowly than low-molecular-weight counterparts.

Processing conditions – thermal and mechanical treatments can induce defects that alter degradation.

Annealing – increases crystallinity, thereby reducing degradation rate.

Sterilization methods (e.g., gamma radiation, ethylene oxide, autoclaving) may cause chain scission or oxidation, altering polymer stability.

Storage history – exposure to humidity, oxygen, or light can cause pre- degradation.

Shape and geometry – surface area-to-volume ratio determines the rate of water diffusion and degradation.

2. Biological and Implantation Factors:

Site of implantation – local enzymatic activity, vascularization, and immune affect degradation rate.

Adsorbed/absorbed compounds – interaction with water, lipids, proteins, or ions influences hydrolytic and enzymatic activity.

3. Physicochemical Factors:

Ion exchange, ionic strength, and pH – acidic or basic environments accelerate hydrolysis of susceptible linkages.

Mechanism of hydrolysis – degradation can be catalyzed by enzymes or occur non-enzymatically in the presence of water.

4. Physical Factors:

Dimensional changes – swelling, shrinkage, or erosion alters degradation dynamics.

Diffusion variations – changes in diffusion coefficients affect transport of water and degradation products.

Mechanical stresses – tension, compression, or shear may accelerate polymer chain scission.

Stress- and solvent-induced cracking – environmental conditions can create microfractures that speed up degradation.

Need for Biodegradable Polymers:

The surgical removal of drug-exhausted delivery systems was found to be challenging, and retaining non-biodegradable foreign materials in the body for an indefinite period often led to toxicity concerns. Although diffusion-controlled release is an effective method for achieving sustained drug delivery, its efficiency is restricted by the polymer's permeability and the drug's physicochemical properties, such as diffusion coefficient.

Biodegradation:

The process of biodegradation has two primary phases. In the first stage, either biotic (microorganism-induced degradation) or abiotic (oxidation, photodegradation, or hydrolysis) processes break down polymers into lower molecular weight species. These polymer fragments go through a second stage where bacteria bioassimilate them and then they mineralize into simpler end products. The chemical structure of the polymer, the degradation environment, and the polymer's point of origin all affect how quickly and how much it degrades. Many studies have been conducted on polymer

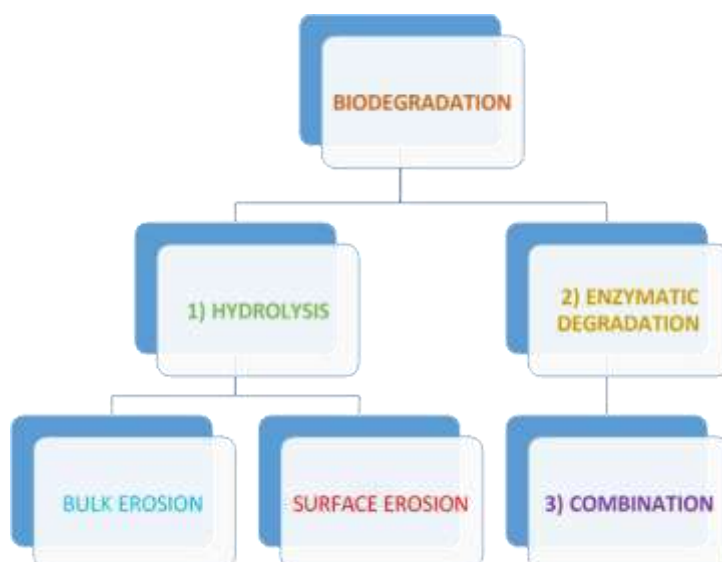
biodegradation mechanisms and assessment methods [20]. The composition, storage, processing, aging, and application circumstances of biodegradable materials, as well as their chemical structure [21,22], all affect their mechanical behavior [23,24]. Biodegradable polymers have been more and more popular as vehicles for the regulated delivery of bioactive proteins and low-molecular-weight medications during the last several decades [25]. These polymers can be used to construct drugs that can be released in a regulated way, keeping the concentration of the medication at the target site within the therapeutic window. Crucially, biodegradable polymers allow for customized medication release rates. In 1970, Yolles and Sartori reported the first use of a synthetic biodegradable polymer for systemic distribution of a medicinal substance. Since then, as research has concentrated on specifically engineered biodegradable systems, a significant body of literature on drug release from bioerodible polymers has been produced.

Mechanism of Degradation:

The term degradation refers to the cleavage of polymer chains, resulting in a reduction of molecular weight. This process leads to the subsequent erosion of the material, which is defined as the mass loss of the polymer. In biodegradable polymers, two main mechanisms of degradation are observed:

Bulk Erosion Surface Erosion

The distinction between these two processes is illustrated in Figure 2.



Biodegradable polymers typically possess a hydrolysable backbone, making them susceptible to hydrolysis or enzymatic attack in physiological environments. Bulk erosion occurs throughout the cross-section of the polymer. Water penetrates the polymer matrix, causing slow cleavage of long polymer chains. This leads to a gradual weakening and mass loss. Surface erosion, on the other hand, only impacts the outermost layers. The rate of erosion is according to how much surface area is in contact with the hydrolytic environment. The primary determinants of bulk erosion rate are the crystallinity and porosity of the polymer matrix, whereas the geometry and surface of the polymer affect surface erosion characteristics. Drug Release Pattern from Biodegradable Polymers The release of drugs encapsulated in microspheres or implants generally follows a three-step process:

Initial burst release – caused by dissolution of drug molecules present on or near the polymer surface.

Sustained release – governed by degradation-dependent relaxation of the polymer network, which generates free volume for drug diffusion.

Accelerated release – triggered by the autocatalytic effect of acidic by products (e.g., lactic and glycolic acids) that accumulate within the polymer microenvironment, accelerating further degradation.

Numerous factors influence the overall drug release profile, such as: the drug's physicochemical makeup, rate of polymer degradation water permeability, and drug-polymer matrix interactions. Upon complete degradation, the resulting soluble monomers or oligomers (such as lactic acid and glycolic acid) are excreted via the kidneys and further metabolized into carbon dioxide and water through the tricarboxylic acid (Krebs) cycle. Analytical Techniques for Studying Polymer Degradation Various advanced analytical methods are used to investigate degradation mechanisms. Common approaches include:

Gravimetric analysis: monitoring polymer mass loss during degradation.

Molecular weight determination: using gel permeation chromatography (GPC) or intrinsic viscosity measurements.

Morphological analysis: using scanning electron microscopy (SEM) or atomic force microscopy (AFM) to study surface and internal changes.

Thermal analysis: evaluating transitions and phase changes in the polymer during degradation.

Other parameters: changes in crystallinity, pH variation, and thermal stability are also useful indicators of degradation progress.

Applications:

1. Dental medicine

Chitin and chitosan are known to speed up wound healing, improve skin recovery for a natural appearance, and reduce scar formation. In dentistry, they are used as dressings for oral mucosal wounds and as tampons after surgical treatment of the maxillary sinus. They are also being studied as absorbable membranes for periodontal surgery.

2. Oral drug delivery – film dosage form

Chitosan has the ability to form thin films, which makes it useful for drug delivery. A study tested chitosan films containing diazepam in rabbits. The results showed that a 1:0.5 drug-to-chitosan ratio worked as effectively as commercial tablets.

3. Polymethacrylates in pharmaceuticals

Neutral poly(meth)acrylates are inactive in the body but are very compatible with skin and mucous membranes, making them useful in sprays and ointment bases.

4. General pharmaceutical applications

Polymers are widely used in many dosage forms because they are biocompatible and non-toxic. They serve as excipients in conventional formulations and play vital roles in newer drug delivery systems.

5. Polymers with pharmacological effects & blood substitutes

Some polymers are therapeutic in and of themselves. As an illustration, DIVEMA (a copolymer of maleic anhydride and divinyl ether) possesses antiviral and antitumor qualities by promoting the synthesis of

glycoproteins, which inhibits tumor cell growth and viral RNA activity.

6. Macromolecular prodrugs

A prodrug is a chemically modified drug that becomes active only after metabolism in the body. Macromolecular prodrugs are especially useful in cancer treatment. For example, 5-fluorouracil can be delivered orally or locally to treat cancers of the gastrointestinal tract, bladder, and prostate.

7. Prolonged-release drug formulations

Polymers are key materials in sustained- or delayed-release dosage forms.

CONCLUSION:

A wide range of bioactive substances can be delivered using biodegradable polymers, which have shown great promise in the creation of sophisticated and effective drug delivery systems. Development of innovative drug delivery systems (NDDS) has advanced quickly as patient compliance has become more and more important. The use of natural polymers, especially microspheres, is essential for site-specific targeting and controlled drug release. The interactions of polymeric particles with biological systems, including phagocytic cells, blood components, and particular receptors, require further investigation. In the past few decades, biodegradable polymers have drawn more interest for their potential benefits to human health and the environment in addition to their medicinal uses. Additionally, to enhance their qualities, methods like random and In order to improve the finished products' mechanical strength and biodegradation rates, block copolymerization or blending has been created.

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HOW TO CITE: Borse Komal*, Deore Ruchika, Pagar Sarla, Nikam Sakshi, Dode Raj, Bairagi Vinod, Biodegradable Polymers in Formulation, *Int. J. Sci. R. Tech.*, 2025, 2 (11), 477-483. <https://doi.org/10.5281/zenodo.17638267>