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Review Article

Biodegradable polymer: basics, approaches to improve biodegradability and its pharmaceutical applications

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Abstract

In recent decades, polymer materials have received more attention as possible biomaterials for a variety of medical purposes. Due to their numerous uses in the environment and the medicinal field, biodegradable polymers have sparked a new area of intense study. Because of their biocompatibility, biodegradability, flexibility, and low side effects, biodegradable polymers have become more popular in biomedical applications. Polymers are resistant to biodegradation because of their hydrophobicity, large molecular weight, chemical, and structural components. The abiotic and biotic mechanisms of degradation, as well as numerous methods that may be used to improve biodegradation, are covered in this study. The primary types of polymers are briefly reviewed in terms of characteristics and biodegradability, as well as recognized degradation mechanisms and their benefits and drawbacks, as well as variables influencing biodegradation. Even we discussed about the applications and role of biodegradable polymers in drug delivery system.

Keywords Biodegradable polymers, chemical structure, classification, pharmaceutical applications.

Introduction

Polymers have gained in popularity and usefulness in a variety of fields in recent years. It is widely utilized in the pharmaceutical and food industries; however, it is non-biodegradable in nature and contributes to worldwide environmental issues. This challenge can be solved by developing environmentally friendly biodegradable polymers (Williams, 2009).

Biodegradable polymers are polymers that break down in the body over a short period and are intended to provide temporary support (Dhaliwal and Dosanjh, 2018). A polymer is a big molecule made up of monomers, which are connected repeating subunits in a chain or ring. Decomposition of polymer by enzymes or chemicals linked with live organisms and their secretory products (Luckachan, 2006).

Categories of biodegradable polymers

Biodegradable polymers are classified into two groups based on the origin of raw ingredients and the manufacturing method (Ul-Islam, Khan, Ullah and Park, 2015) (Fig. 1).

Non-biodegradable polymers

Non-biodegradable polymers are those that cannot be destroyed by enzymes or chemicals found in living organisms or their secretion products. Polyethylene, poly (methyl methacrylate) polyester, polycarbonate, polyamide (nylon), and polyurethane are examples of non-biodegradable polymers.

Factors affecting biodegradation

The various factors affecting the biodegradability of polymers are given below (Amass, Amass and Tighe, 1998; Phale, Agnihotri and Khale 2014).

Chemical structure

The chemical structures of polymers ultimately determine their biodegradability, which has a direct impact on their ability to degrade. Biodegradation capacity of functional groups may be descendant in this order. Aliphatic ester, Peptide bond >Carbamate> Aliphatic ether> Methylene.

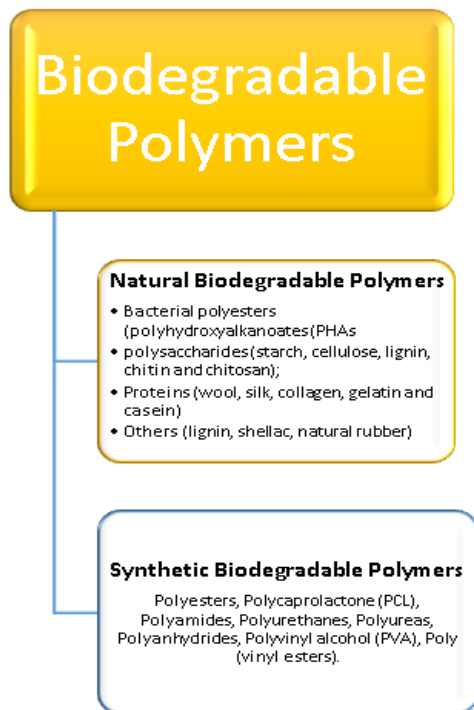


Fig.1 Classification of Biodegradable polymers

Degree and type of branching

The biodegradation is slowed down when the molecular chain branches. Biodegradability is easy for polymers with flexible chains. Branched and cross-linked polymers degrade more slowly than linear polymers.

Molecular size

Due to the presence of fewer end group in the form of unsaturation, hydroperoxide in the polymer structure, high molecular weight polymers are more resistant to biodegradation.

Degree of hydrophilicity

Hydrophilic segments in polymers are more biodegradable than hydrophobic segments in polymers with same molecular weight. Chemical changes can improve a polymer's biodegradability by enhancing its hydrophilicity.

Crystallinity

The rate of degradation is influenced by the difficulty of penetrating crystalline areas of a polymer. Polymers with amorphous regions are simpler to deteriorate than those with crystalline parts.

Environmental factors

The biodegradation process requires temperature, moisture, salts, pH, and oxygen. Water is required for microbes to grow. Biodegradation of polymeric materials is limited by humidity, and temp has a twofold influence on biodegradation. High temperature speeds up microbial metabolic activities and

induces robust development, which is beneficial to degradation in a specific range. The biological activities of proteins and enzymes, on the other hand, are more affected by temperature. As a result, each type of microbe has a certain temperature range for development and reproduction. The pH level has a significant impact on microbial development. Optimal pH promotes microbial metabolism and, as a result, accelerates the pace of disintegration.

Polymer degradation

In the natural environment, polymer breakdown happens in two phases. The first stage is predominantly abiotic, whereas the second is entirely biotic (Kolybaba1 et al., 2003; Joshi and Patel, 2012).

- A. Abiotic degradation
- B. Biotic degradation

A. Abiotic Degradation

Mechanical characteristics of the polymer are lost as a result of alteration. The polyethylene, chemical pro-oxidant, photo-initiators, or both employed in film production create free radicals on the polyethylene chain, causing the chain to lose its physical characteristics and making it more susceptible to microbial deterioration.

Thermal degradation, photo-oxidative degradation, Hydrolytic Deterioration or Bioerosion, Degradation because of Environmental Stress Cracking (ESC), Chemical Degradation, Mechano-chemical Degradation, as well as Weathering are examples of environmental variables that cause chemical degradation of polymers.

B. Biotic Degradation

Enzymes generated by live microbial organisms break down molecules into smaller compounds in this process. Microorganisms eat the low molecular weight compounds generated by abiotic degradation, leaving CO₂, water, and other innocuous chemicals at the conclusion of the metabolic process.

Approaches to improve biodegradability of polymers

Biodegradable polymers are a form of polymer that degrades naturally after serving its purpose, yielding gases, water, biomass, and inorganic salts. Polymers having solely carbon-carbon bonds in their main chain (with the exception of those with a significant number of polar groups on the main chain) are resistant to enzyme-catalysed breakdown processes. Various methods have been used to alter polymers by inserting weak links into their backbones to allow for the controlled breakdown of a high molecular weight polymer into a low molecular weight oligomer that may be utilised and eaten by microorganisms through the biodegradation process. The different methods for determining polymer biodegradability are mentioned here (Luckachan, 2006).

Types of modifications

I. Insertion of weak links into polymers

To generate biodegradable polymers from synthetic polymers, this method primarily employs two forms of polymer modification (Luckachan, 2006).

1.1. The introduction of functional groups into the main chain that can be broken down by chemical hydrolysis (especially ester groups).

1.2. Insertion of functional groups in the main chain which can be broken by photochemical reactions (especially carbonyl groups)

- Insertion of ester groups
- Insertion of carbonyl groups
- Photodegradation of carbonyl linkages

II. Compounding of polymer with pro-oxidants and photosensitizer

The use of pro-oxidant additives might improve the thermal and/or photolytic pre-biotic treatment, which is the main pathway for boosting polyethylene biodegradation. Divalent transition metal salts of higher aliphatic acids like stearic acid, unsaturated elastomers as auto-oxidizable compounds, and transition metal complexes like dithiocarbonates as photosensitizers or photoinitiators are the most often utilized pro-oxidants for this purpose.

III. Blends of biodegradable and non-biodegradable polymers

The insertion of pro-degradant additives like starch and cellulose into synthetic polymers is the most widely used method to polymer degradability design. When these mixes are released into the environment, the biodegradable component is consumed by a variety of microbes.

IV. Modified natural polymers

By co-blending polysaccharide polymers that are readily biodegradable in nature, such as starch, cellulose, cellulose, chitosan, and chitin, novel biodegradable polymers can be created. The biodegradable films have better mechanical properties, reduced water vapor permeability, and are more soluble.

V. Chemically synthesized polymers

These polymers are created chemically and have chemical structures that are comparable to natural polymers. These polymeric chains with ester, amide, and peptide linkages can biodegrade quickly. Luo et al. reported synthesizing a biodegradable polymer (poly (lactic acid-co-glycerol) utilizing L-lactic acid and glycerol as starting ingredients under ideal synthetic circumstances.

VI. Microbiologically Synthesized Polymers

Organisms may make a variety of complex polymeric compounds utilizing organic matter as a food supply, such as glucose or starch. Silk, polysaccharides, polyesters, and other materials are found in these polymers. Due to their comparable chemical characteristics, separating these products is challenging. Bacterially produced polyhydroxyalkanoates (PHA) have garnered a lot of attention as extremely biocompatible and biodegradable polymers that may be made from a variety of renewable resources.

VII. Enzymatic synthesis

Enzymatic synthesis is a novel technique for making biodegradable polymeric materials. Due to the great specificity of the enzymes, this type of polymerization method may not create any by-products, making product separation simple. In addition, the enzyme may be recycled, and the moderate catalytic reaction conditions (usually at ambient temperature and air pressure) considerably lower the process cost. Fully biodegradable polymers such as polyester, polysaccharide, polyamide, and others can also be made using enzymatic synthesis.

VIII. Chemo-enzymatic synthesis

The chemo-enzymatic synthesis method combines traditional polymerization with a very efficient and region-specific enzymatic approach to produce high molecular weight biodegradable polymers, making it a particularly appealing option. Cai et al. developed several optically active polymeric prodrugs for non-steroidal anti-inflammatory drugs with a high molecular weight using an effective chemo-enzymatic method.

Biodegradable polymers in pharmaceutical applications

Although biodegradable polymer-based composite materials are now being employed in the creation of artificial blood arteries, artificial human parts, and a variety of other novel applications, our focus here is on their role in drug delivery systems. Various technologies have been developed (based on biodegradable materials) that allow for the safe as well as targeted administration of particular medicines (Ul-Islam, Khan, Ullah and Park, 2015).

Biodegradable polymers in drug delivery

Controlled drug-delivery systems have been quickly created and enhanced in tandem with developments in polymer science and engineering. To overcome the limits of conventional drug delivery methods, sustained and pulsatile release systems, as well as polymer-drug conjugates, were created. This allowed for the controlled release of numerous medicines (Hayashi, 1994). The programmability and site-specific release of therapeutic medicines have been made possible because to advances in strategy and smart polymer systems. Furthermore, multidisciplinary research has

Table 1. Difference between Non-biodegradable Polymers & Biodegradable Polymers

Non-biodegradable Polymers	Biodegradable Polymers
Degradation process is very slow.	Degradation process is slow.
Rate of biodegradation is very low.	Rate of biodegradation is very high.
They cannot decompose by the living organisms.	They decompose by the living organisms.
Costly chemicals used for decomposition.	Cost free decomposition.
They cannot be recycled naturally.	They can be recycled naturally.
They cannot be broken down into harmless substance by any biological processes.	They can be broken down into harmless substance by the action of microorganisms like bacteria.
They can pollute the environment.	They cannot pollute the environment.
They remain unchanged over a long period of time.	They change their form and structure over time.

Table 2. Applications of Biodegradable Polymers in Medical devices

Application	Polymer used
Sutures	PLA (8%)-co-PGA (92%) (Tritle, Haller and Gray, 2001).
Suture Anchor	LPLA, SR-LPLA, SR-LPLA L, R-LPLA. (Middleton and Tipton, 2000; Kerimoglu and Alarçin, 2012)
Angio plastic plug	PGA-DLPLA (Middleton and Tipton, 2000)
Guided Tissue	LPLA-DLPLA, LPLA, PGA-DLPLA (Middleton and Tipton, 2000)

Table 3. Applications of Biodegradable Polymers in Pharmaceuticals

Drug Delivery System	Polymer used	Drug	Advantages
Nanoparticles	Albumin	Doxorubicin-Loaded Trastuzumab	Site Specificity (Anhorn, Wagner, Kreuter, Langer and Von Briesen, 2008)
polymeric nanoparticles	Chitosan-graft-mPEG	5-fluorouracil	Tumor Targeting (Antoniraj et al., 2018)
Solid lipid Nanoparticles	Pluronic®F68	Hydrochlorothiazide, Cyclodextrin	Sustained Release of drug (Cirri et al., 2017)
Hydrogels	Guar gum	dexamethasone	Controlled delivery of drug (Das and Subuddhi, 2015)
Lyophilized muco-adhesive wafers	Carrageenan and Pluronic acid	Paracetamol and ibuprofen	Gradual release of drugs (Farnoosh, Antonijevic, Chowdhry and Boateng, 2013)
Nanoparticles	Chitosan	siRNA	targeted delivery across the blood-brain barrier (Gu, Bayati, and Ho, 2017)
Micelles	PEG	Protein	Protein Delivery (Jiang et al., 2016)

developed highly integrated as well as sophisticated polymer systems for achieving multifunctionality of a single drug carrier in addition to maximizing therapeutic efficacy (Kim, Kim, Jeon, Kwon and Park, 2009). However, there have been significant issues with drug-delivery system licensing and clinical studies. The main problem is one of safety, which must be taken into account while designing a medication delivery system. As a result, much effort has gone into creating safe and mass-producible drug delivery methods. Biodegradable polymers have now gotten a lot of press as a regulated medication delivery method. A biodegradable polymer is one that can be broken down in the body, either enzymatically or nonenzymatically, to generate biocompatible or harmless by-products (Rezwan, Chen, Blaker and Boccaccini, 2006). A biodegradable polymer can also be digested and eliminated via regular physiological processes.

Limitations of conventional drug-delivery systems

Over time, the use of traditional drug-delivery systems led to the discovery that not only was surgical removal of a drug-depleted delivery system difficult, but that keeping non-biodegradable foreign materials in the body for an extended period of time might induce toxicity (Joshi and Patel, 2012). Similarly, polymer permeability limits a diffusion-controlled release mechanism, and when a drug's properties improve, its diffusion coefficient decreases. Furthermore, with most traditional delivery methods, the issue of significant "dose-dumping" arises at some time after implantation (Hatefi and Amsden, 2002). A "burst effect," or a large initial drug release immediately after injection, is another common drawback linked with most systems. Degradable systems that are injected in a particulate state are also non-recoverable.

Advantages of using biodegradable polymers in drug delivery

Biodegradable polymers have sparked a lot of attention in recent years, and they've been frequently employed in medication administration due to their well-known biocompatibility and biodegradability. When employed in a regulated and sustained medication delivery system, biodegradable polymers provide potential benefits. Over a certain length of time, a medication is released at a particular and consistent pace (Shaker and Younes, 2010). Because it is broken into harmless, absorbable subunits that are then metabolized, a biodegradable polymer does not damage live tissues or cells at target locations. Furthermore, a biodegradable and biocompatible polymer system does not display dose-dumping at any point throughout the process, and the polymer keeps its characteristics until the drug is depleted. After drug depletion, this method eliminates the need for surgical removal of implanted devices, as the polymer is released through natural metabolic routes shortly after breakdown. Furthermore, the medicines contained in these polymers can be delivered in a regulated manner. The necessary dosage may be easily maintained by keeping the drug concentration at the target location within the

therapeutic window and controlling the rates of drug release from biodegradable polymers.

Role of Biodegradable Polymers in Drug Delivery System

Immediate drug release dosage form tablets: Polymers such as polyvinyl pyrrolidone and hydroxy propyl methyl cellulose (HPMC) have been shown to be effective binders for improving the flow as well as compaction properties of tablet formulations before tableting.

Capsules

Many of the polymeric additives utilised "bulk out" capsule fillings are also found in intermediate release tablets. For both hard and soft shells, gelatin is commonly utilized (Heller, 1984). HPMC has recently gained acceptance as a substitute material for hard and soft capsules as a result of recent advancements.

Modified drug release dosage forms

Polymers have been investigated, with little success so far, for their potential to increase gastric residence duration by attaching to the mucus lining of the stomach and floating on top of the gastric contents in order to achieve mucoadhesive and low-density gastro retention (Rao, 1998; Roy et al., 2010).

Extended-release dosage forms

Extended and sustained release dosage forms extend the period that systemic drug levels are within therapeutic range, reducing the number of doses a patient must take to maintain a therapeutic effect and therefore improving compliance (Charman, Chan, Finnin and Charman, 1999; Roy, Panda, Parida and Biswal, 2013). The ammonium methacrylate copolymers cellulose derivatives ethyl cellulose and cellulose acetate, and polyvinyl derivative polyvinyl acetate are the most widely utilized water insoluble polymers for extended-release applications (Malafaya, Silva and Reis, 2007; Bhanja, Sudhakar, Neelima, Panigrahi and Roy, 2013).

Gastro retentive dosage forms

Gastro retentive dosage forms provide an alternate method for achieving an extended-release profile by remaining in the stomach for lengthy periods of time, releasing the medication in-situ, which will subsequently dissolve in the liquid contents and slowly move into the small intestine.

Microparticles

Polymer particles like microspheres, microcapsules, and nanoparticles are frequently employed in biodegradable polymer systems for drug delivery. Because they may be injected into numerous places in vivo using a syringe needle, these particles are widely helpful (Berkland, King, Cox, Kim and Pack, 2002). Polyesters, polyanhydrides, Polyorthoesters, Polyphosphazenes, and polysaccharides are some examples

of biodegradable polymers that have been utilized in the production of microparticles (Kipper, Shen, Determan, and Narasimhan, 2002). Such microspheres can be easily transported to the action location, however there are certain restrictions Fig.2

Emulsions

Emulsions are made by combining medicines with liquid polymers and then delivering the emulsion to the desired location. Emulsions are widely employed in parenteral medicines, although they are usually not suitable for long-acting formulations due to their low dosage form stability (Yim, Zupon, and Chaudry, 1989).

Liposomes

Using liposomes to deliver medicines to a specific location is a successful strategy. When compared to free medicines, liposome-delivered pharmaceuticals can be kept at the location for much longer periods of time (Moghimi, 1998).

Micelles

Despite the fact that micelles have been widely utilized as a drug delivery system to treat a variety of illnesses, the system's efficacy has been hampered by a number of issues. Most significantly, micelles are prone to migrating, and a variety of regulating variables influence their characteristics.

Injectables

Injectables are biodegradable materials that are injected into the body through a syringe and solidify to create a semisolid depot once within the body (Lambert and Peck, 1995). Several types of biodegradable depots have been created using diverse approaches, and these may be divided into four categories according on how solidification occurs in vivo: (a) thermoplastic pastes, (b) in-situ crosslinked systems, (c) in-situ precipitations, and (d) in-situ solidifying organogels (Hatefi and Amsden, 2002).

Elastomers

Because they provide numerous benefits over traditional manufactured materials, elastomers have lately garnered a lot of interest in the development of controlled drug delivery systems (Shaker and Younes, 2010). Elastomers have also been shown to be successful as biomaterials for the delivery of protein drugs.

Hydrogels

Hydrogels are polymeric networks that have a high capacity for absorbing water without being dissolved in it, causing the hydrogel substance to expand. The porous structure has been utilized as a wicking agent to reduce polymer disintegration time, such as in the creation of fast-disintegrating tablets (Kabanov et al., 2005).

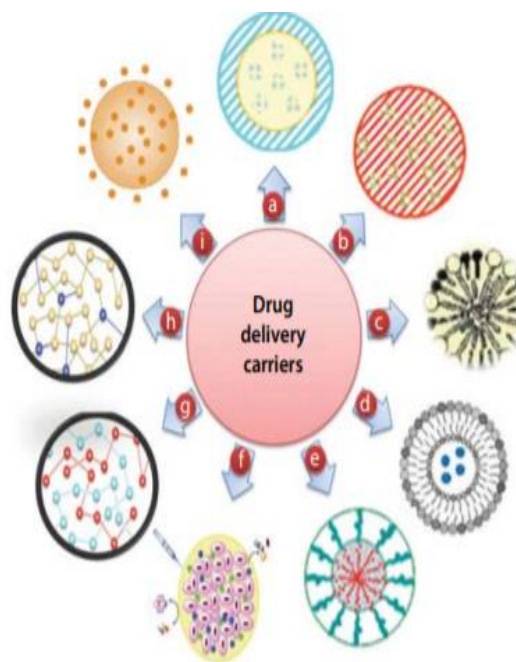


Fig.2 Application of Biodegradable polymers in DDS (a)Microspheres, (b) Nanospheres, (c) Emulsions, (d)Liposomes, (e) Micelles, (f) Injectables, (g) Thermoplastic Elastomers, (h) Thermoset Elastomers, (i) Hydrogels

Conclusion and future perspective

Because of their potential uses in medicine, agriculture, cosmetics, packaging, environmental protection, and physical health maintenance, biodegradable polymers have gotten a lot of attention in recent decades. There has been a surge in interest in biodegradable polymers in recent years. Biopolymer's materials have a bright future ahead of them in terms of development. Biodegradable polymers have had a variety of constraints in terms of strength and dimensional stability until recently. The majority of them have processing issues and are also rather costly. Polymers are significant because of their inherent biodegradability, biocompatibility, and ease of availability, according to recent advancements in biodegradable polymers. Many approaches have been developed to enhance the characteristics of biodegradable polymers. These techniques increase the finished product's biodegradation rate as well as its mechanical characteristics. More and more novel preparation techniques will be investigated as smart design advances, and better biodegradable polymers will be produced.

Abbreviations

ESC-Environmental Stress Cracking; PHA- Polyhydroxyalkanoates; HPMC- Hydroxy Propyl Methyl Cellulose; PLA- Polylactic Acid; PGA-Polyglycolide or poly (glycolic acid); LPLA- L-Polylactic Acid.

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