Scientific Research Publishing

Materials Sciences and Applications, 2024, 15, 245-252
https://www.scirp.org/journal/msa
ISSN Online: 2153-1188
ISSN Print: 2153-117X

# Degradation Rate Assessment of Biodegradable Magnesium Alloys

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**How to cite this paper:** Cao, B.M., Cao, L.M. and Kallmes, D.F. (2024) Degradation Rate Assessment of Biodegradable Magnesium Alloys. *Materials Sciences and Applications*, **15**, 245-252.
https://doi.org/10.4236/msa.2024.158017

**Received:** May 19, 2024
**Accepted:** August 5, 2024
**Published:** August 8, 2024



## Abstract

Biodegradable magnesium alloys have been widely used in medical implants. But safety concerns were put forward for the high degradation rate of biodegradable magnesium alloy. The optimal biodegradable magnesium alloys that give rise to the desired degradation rate hasn't yet to be defined. Assessing the degradation rate of biodegradable magnesium alloys involves *in vitro* testing, *in vivo* testing, numerical modeling, understanding the factors influencing their degradation in physiological environments, biocompatibility testing, and clinical studies. It is important to standardize analytical tools aimed at assessing the degradation rate of biodegradable magnesium alloys. It is advisable to identify the threshold for safe degradation rate of biodegradable magnesium alloys in biomedical applications.

## Keywords

Magnesium Alloys, Biomedical Application, Biodegradation, Degradation Rate, Biocompatibility

## 1. Introduction

Biodegradable magnesium (Mg) and its alloys have been applied to making bone screws and pins, bone filling, dental implants, and sutures [1]. Compared with other biodegradable implant materials, such as polymers and bioglass, Mg-based alloys show unique advantages, such as their close density with bone, light weight and MRI compatibility [2]. Magnesium alloys do not interfere with magnetic resonance imaging. Due to lower artefact production, Jonathan et al suggested that Mg-based implant material should be promoted for future orthopaedic solutions [3]. Biodegradable (absorbable) magnesium alloys are designed to

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degrade *in vivo* via an electrochemical mechanism (corrosion or degradation) and then metabolized or assimilated by cells and tissue [4]. Assessing the degradation rate of biodegradable magnesium alloys is crucial for understanding their performance in various applications, especially in biomedical implants. Analysis through characterization of the magnesium alloy, including its chemical composition, microstructure, surface morphology, and so on, will provide insights into how the magnesium alloys might degrade over time.

Several factors can influence the degradation rate of magnesium alloy, including the material composition [5], microstructure [6], surface treatment [7], molecular weight [8], sterilization method [9], environmental conditions (such as temperature and pH) [10], and the presence of enzymes or other catalysts [11]. The precise application of magnesium alloys will also play a role in its biodegradability [12].

During biomedical application, magnesium and its alloys were reported to show relatively high degradation rates that can affect human cells and cause infection [13]. The corrosion products, released from magnesium alloys may form a hostile environment. Biocompatibility testing is essential for the safety evaluation of degradation rate of magnesium alloys in biomedical applications. It is advisable to identify the threshold for safe degradation rate of biodegradable magnesium alloys.

Regulatory agencies may require comprehensive evaluation of the degradation properties of biodegradable magnesium alloy as part of the approval process for medical devices. Manufacturers must demonstrate that the magnesium alloys medical device degrades at an appropriate rate, matching the healing timeline of tissues, and does not cause adverse effects.

Understanding the degradation rate of biodegradable magnesium alloy is essential for determining their clinical performance and safety. If the degradation rate is too slow, the magnesium alloy may remain in the body longer than necessary, potentially causing adverse reactions or interfering with tissue healing. If the degradation rate is too fast, it may compromise the mechanical integrity prematurely.

Quality control tests are useful tools for standardized workflows. Practically, when workflows are being developed and optimized, it is beneficial to use multiple quality controls when analyzing samples with standardized protocols. The degradation rate assessment of biodegradable magnesium alloy is critical for ensuring the reliability, safety, and efficacy of these biodegradable magnesium alloys in biomedical applications. Here's a comprehensive approach to evaluating the degradation rate.

## 2. Experimental Assessment

### 2.1. *In Vitro* Testing

There are several testing methods. Researchers conduct *in vitro* degradation studies under controlled laboratory conditions to simulate the physiological en-

vironment. Samples are immersed in buffered aqueous solutions at physiological temperature and pH value. According to ASTM G31-72 [14], the degradation process is monitored over time through measurements of mass loss, changes in mechanical properties, and analysis of degradation byproducts. Electrochemical measurements use techniques such as potentiodynamic polarization and electrochemical impedance spectroscopy (EIS) to evaluate corrosion behavior. **Table 1** shows the degradation rate of some magnesium alloys in simulated body fluid (SBF). Surface analyses use scanning electron microscopy (SEM), energy-dispersive X-ray spectroscopy (EDS), and X-ray diffraction (XRD) to analyze surface morphology and composition changes over time. Spectroscopic techniques such as Fourier-transform infrared spectroscopy (FTIR) or nuclear magnetic resonance (NMR) spectroscopy can be used to analyze chemical changes.

**Table 1.** Degradation rate of some Mg alloys in simulated body fluid (SBF).

| Alloy | Immersion Corrosion Rate (mm/yr) | $I_{corr}$ (μA/cm$^2$) | References |
|---|---|---|---|
| Mg-1Zn-2.9Y | 13 | - | [15] |
| Mg-2Zn | 0.4 | - | [16] |
| Mg-Zn-Ca-Mn | - | 6.59 | [17] |

### 2.2. *In Vivo* Testing

In addition to *in vitro* studies, *in vivo* degradation studies involve implanting biodegradable magnesium alloy in animal models or human subjects. Degradation rates obtained via *in vitro* experiments are not necessarily the same as in the *in vivo* case, however, experiments *in vivo* will help define what the degradation rate should be. *In vivo* studies provide insights into how degradation occurs within a biological environment and how it may affect tissue response and long-term outcomes. ASTM F 763-04 [18] can be referenced *in vivo* test. Imaging techniques, such as X-rays, micro-computed tomography (micro-CT), or MRI to monitor the degradation process and structural integrity over time. Histological analysis is conducted to examine tissue samples around the implantation site to assess biocompatibility and inflammatory response.

## 3. Analytical and Computational Modeling

*In vivo* and *in vitro* tests are usually lengthy and costly. Computational modeling can effectively predict the degradation behaviors of medical implants in the living body. Numerical models have been researched to predict the degradation kinetics based on experimental data [19]. Many relevant parameters need to be optimized when analyzing the degradation rate of biodegradable magnesium alloys. The available analytical modeling still needs to be improved.

### 3.1. Degradation Modeling

A useful degradation model should account for the underlying biological envi-

ronment. Empirical models can be developed based on experimental data to predict degradation rates under various conditions. For kinetic models, kinetic equations are used to describe the rate of magnesium dissolution and formation of corrosion products. Finite Element analysis (FEA) can simulate the degradation process to predict how the alloy will degrade over time in different environments.

### 3.2. Machine Learning Models

High-quality data are the precondition for analyzing. Data are first collected from experimental studies, including composition, processing parameters, and degradation rates. Key features influencing degradation are identified, such as alloy composition, microstructure, and environmental factors. Then machine learning algorithms e.g., regression models, are used to develop predictive models of degradation rates. The models should be validated with independent datasets to ensure accuracy and generalization.

## 4. Factors Influencing Degradation Rate

### 4.1. Alloy Composition

Alloying with different elements shows various degradation rates for Mg alloys in biomedical applications [20]. Alloying elements like calcium, zinc, and rare earth elements can influence the degradation rate and mechanical properties. Trace impurities can significantly affect degradation behavior.

### 4.2. Microstructure

Fine-grained structures generally exhibit different degradation rates compared to coarse-grained ones. The degradation of a porous magnesian sample in the biological environment is remarkable as porosity on the sample increases the total surface area and increases the risks of metal ion leaching [21]. In addition, the surface oxides' possible chemical reactions with the physiological fluids significantly influence the applicability of the porous structure. Secondary phases Mg alloys [22] and intermetallic compounds can act as galvanic cells, affecting degradation.

### 4.3. Surface Treatment

Biodegradable coatings or surface modifications can be applied to control degradation rates. Some studies developed coatings and surface treatments to regulate the degradation rate [23] [24]. Anodized layers can provide initial protection but must degrade synchronously with the underlying alloy. **Figure 1** [25] schematically illustrated the coating methods potentially suitable for Mg alloys.

### 4.4. Environmental Factors

Varying pH levels and ion concentrations in the physiological environment can accelerate or decelerate degradation rate. Cyclic loading and mechanical stress

can influence degradation rate through mechanisms like stress corrosion cracking and fatigue. Inorganic ions and cyclic loading may accelerate the degradation rate of magnesium alloys. While organic substances could decrease the degradation rate of Mg alloys [26].

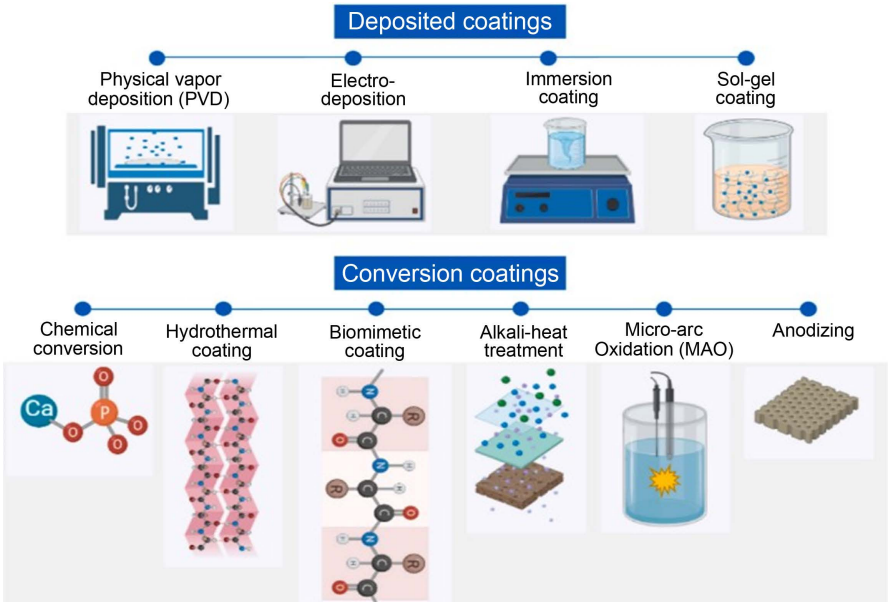


**Figure 1.** Coating methods applicable for Mg alloys [25].

## 5. Biocompatibility and Clinical Considerations

The degradation rate of Mg-based alloys is often required to match the level of tissue-healing progress in order to maintain biological stability surrounding the implant. Through biocompatibility assays and clinical studies, the threshold for safe degradation rate of biodegradable magnesium alloys in biomedical applications may be identified.

### 5.1. Biocompatibility Testing

Cytotoxicity tests are useful steps to determine the potential toxicity of a test substance. Cytotoxicity assays can be developed according to ISO 10993-5 [27] to assess the toxicity of biomedical Mg-alloys degradation products on cell cultures.

Referring to ISO 10993-6 [28], histological analysis can examine tissue responses to implanted materials, including inflammation and fibrosis. And it is used to monitor the degradation products *in vivo* that dissolved into the surrounding tissue.

### 5.2. Clinical Translation

Clinical translation should ensure compliance with regulatory standards for biomedical implants. The degradation behavior of magnesium alloys should be continuously monitored over extended periods to capture any unexpected phe-

nomena or late-stage degradation mechanisms. Artefact production may be used as an alternative approach for degradation tracking to determine the degradation rates of Mg alloys implants [3]. Long-term *in vivo* studies can be conducted to assess the performance and safety of the magnesium alloys over the intended lifespan of the medical implants.

## 6. Conclusion

Combining experimental methods with advanced modeling techniques, including AI and machine learning, provides a robust framework for assessing the degradation rate of biodegradable magnesium alloys. This integrated approach enables the development of reliable and safe biodegradable implants for medical applications. Precise tests and qualitative data analysis should be established as a powerful tool for quality control and then facilitating the implementation of cost-effective and standardized analytical workflows into clinical practice. It is advisable to identify the threshold for safe degradation rate of biodegradable magnesium alloys in biomedical applications.

## Acknowledgements

The authors would like to thank the involved organizations for providing the platform for this research to take place.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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