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Review

Resorbable bone fixation alloys, forming, and post-fabrication treatments

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ABSTRACT

Metallic alloys have been introduced as biodegradable metals for various biomedical applications over the last decade owing to their gradual corrosion in the body, biocompatibility and superior strength compared to biodegradable polymers. Mg alloys possess advantageous properties that make them the most extensively studied biodegradable metallic material for orthopedic applications such as their low density, modulus of elasticity, close to that of the bone, and resorbability. Early resorption (i.e., <3 months) and relatively inadequate strength are the main challenges that hinder the use of Mg alloys for bone fixation applications. The development of resorbable Mg-based bone fixation hardware with superior mechanical and corrosion performance requires a thorough understanding of the physical and mechanical properties of Mg alloys. This paper discusses the characteristics of successful Mg-based skeletal fixation hardware and the possible ways to improve its properties using different methods such as mechanical and heat treatment processes. We also review the most recent work pertaining to Mg alloys and surface coatings. To this end, this paper covers (i) the properties and development of Mg alloys and coatings with an emphasis on the Mg-Zn-Ca-based alloys; (ii) Mg alloys fabrication techniques; and (iii) strategies towards achieving Mg-based, resorbable, skeletal fixation devices.

Contents

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1. Introduction

From 2004–2005, orthopedic trauma (fractures) accounted for 72% of musculoskeletal injury charges and it was the cause of almost one-half of all the disease or injury-related hospitalizations in the United States [1,2], similar statistics were reported in 2012 with more than $59.5 million in total hospital charges in 2011 [3,4]. For these reported charges, intervention is necessary to reconstruct a damaged skeleton and an effective fixation hardware is needed to support surgically set bones during the healing period. Internal fixation hardware (e.g., plates, screws, nails and wires) is placed over or within bones in order to hold opposing segments of fractured bone still during the healing period, without any deformation at the fracture site [5,6]. In addition to trauma, internal fixation hardware, with or without bone grafts, is essential for skeletal reconstructive surgery [7]. While beneficial, in general, it is not practical to remove fixation hardware after the reconstructed bone has healed. However, the high stiffness of standard of care fixation hardware, relative to the stiffness of the host bone, may subsequently result in detrimental bone stress shielding and/or hardware stress concentrations [8,9]. For children, teenagers and athletes, it is recommended to remove the hardware to avoid future bone fractures caused by unnatural loading patterns [10]. In addition, the fixation hardware may cause irritation in the adjacent soft tissue. Fixation hardware made of a biodegradable material that also offers the required stability during the healing period and subsequently degrades would mitigate stress shielding of the surrounding bone while avoiding any potential complications associated with a second fixation removal surgery [11].

Mg alloys are the most promising biodegradable materials for orthopedic internal fixation hardware [12,13]. The Mg alloys of interest have a low specific density (1.74–2.0) and modulus of elasticity (41–45 GPa) closer to bone (5–23 GPa for cortical bone) [14,15]. Currently used metallic implant materials have a high modulus of elasticity (e.g., 116 GPa for titanium Ti-6Al-4V) [14,16]. The low modulus of elasticity of Mg alloys reduce the possibility of stress shielding associated with the use of stiffer metallic fixation hardware [17–19]. As a biocompatible material, Mg wires were used as a ligature for bleeding vessels >100 years ago [20]. As metallic fixation hardware, an Mg-based skeletal fixation plate was first used by Lambotte [21] in 1907. That work was followed by several investigations of Mg and Mg alloy bone implants. These devices studies showed promising properties in stimulating bone ingrowth and healing. Mg alloys, however, were abandoned for decades due to their undesirable degradation rate and byproducts. The fast degradation rate of pure Mg in a physiological environment results in rapid loss of mechanical integrity and genesis of hydrogen gas [22,23]. The premature loss of mechanical integrity diminishes the fixation's function. The release of hydrogen may also be detrimental to the healing process [24]. Moreover, the strength of pure Mg and the earliest studied alloys was not high enough and much lower when compared to other biocompatible metals such as stainless steel [16,22].

During the last decade, the development of Mg alloys useful for resorbable skeletal fixation has received greater attention as new approaches to providing sufficient mechanical strength and useful corrosion (resorption) rates [25,26]. Post-fabrication treatments of these alloys, such as coatings and mechanical treatments, have also been studied [27,28]. Commercially available Mg alloys (e.g., WE43, AZ91 and AZ31) despite their higher mechanical strength and enhanced corrosion resistance, are generally not considered suitable for biomedical applications due to concerns regarding their biocompatibility [29–32]. In order to achieve better biocompatibility and slower degradation, alloying with elements such as Al, Zn, Zr, Sr, Mn, Ca, and Rare earth (RE) elements (i.e. Gd, Y, La, Ce, Nd, Pr) has been studied [33–40]. Among these alloys, Mg-Zn-Ca alloys have received the greatest interest because of their excellent biocompatibility, and the possibility to tailor the mechanical and corrosion properties by changing the Zn/Ca ratio and/or heat treatments [15,39,41,42].

To achieve practical Mg-based implants, it is possible to apply a protective coating to prevent the biodegradation process until a desired time point. Coating resorption rate and byproduct safety are topics of recent investigations [12,27].

It would be a significant breakthrough if the needed fixation hardware properties and geometry can be tailored/designed to be patient-specific [1,43]. Additive manufacturing (AM) or 3D printing of metals has received significant attention as a fabrication technique to produce highly accurate and complex-shaped structures such as patient-specific fixation hardware [44]. A number of tools can be considered for the improvement of resorbable implants' rendering. Finite element analysis (FEA) has been used in several studies to simulate and evaluate the performance of permanent fixation hardware [45–48]. In Section 3.2, we will discuss different kinds of Mg coating. Also, more in-depth discussion of additive manufacturing of Mg alloys will be the subject of Section 4.5. The primary objective of this paper is to (1) present a crisp review of Mg-based alloys' design considerations for bone fixation applications based on the in vitro and in vivo performances, (2) discuss the emerging trends in the field of Mg fabrication, forming and post-fabrication treatments (e.g. coating and heat treatment) that can help to develop a Mg-based fixation hardware with enhanced biomechanical performance, (3) highlight the current challenges and strategies towards achieving Mg-based, resorbable, skeletal fixation devices.

2. Mg as a resorbable material

Bone implants have historically been made of metallic alloys such as stainless steel (316L SS), surgical grade titanium (Ti-6Al-4V) and CrCoMo due to their high strength, durability and biocompatibility [5]. The modulus of elasticity of these alloys (e.g., 116 GPa for Ti-6Al-4V [16]) is significantly higher than that for bones (5–23 GPa [12]). This mismatch in stiffness leads to the phenomenon known as stress shielding. The higher stiffness of the fixation device compared to bone causes the mechanical load to transfer away from the adjacent bone [49,50]. The absence of mechanical loading leads to a reduction in the shielded bone mass and density and subsequently a loss of bone [8]. Also, in the areas of stress concentration where the stiffer fixation develops high stresses on the bone such as around screws, a bone fracture and subsequent screws pull-out is more likely. In addition to stress shielding, leaving metallic-based fixation inside the body after the healing period, causes other problems such as inflammatory local reactions, possible infection and the inability to adapt to bone growth near the fixation site [11,51]. A new approach to address these issues is based on the use of biodegradable fixation. These materials should provide fixation only during the healing period and thereafter allowing the