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Review

Coatings for biodegradable magnesium-based supports for therapy of vascular disease: A general view

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ABSTRACT

Metal stents are used as base material for fabrication of medical devices to support and improve the quality of life of patients with cardiovascular diseases such as arterial stenoses. Permanently present implants may induce responses that resemble adverse wound healing that compromise tissue function. A similar process namely restenosis, frequently may occur after the use of this kind of implants. However, the use of non-permanent, resorbable stents are a promising option to avoid this problem. The advantage of these implants is that they can degraded upon vascular repair. The most common metal used for this application, is magnesium (Mg) which is an interesting material due its biological properties and because it is an essential element for human life. However, Mg-based resorbable biomaterial have some restrictions in clinical applications because its corrosion resistance, and mechanical properties. As solutions of this problem, the material can be modified in its composition (Mg-based alloys) or by surface treatments. This review shows and discusses recent challenges in the improvement of Mg-based biomaterials to be used to treat vascular disease and novel approaches at design-based biomaterials engineering of the same. Design-based methodologies are introduced and discussed in the context of balancing multi-functional properties against adaptation to the complex extreme in vivo environment. Traditional alloying approaches of Mg-based biomaterials are also discussed in the context of corrosion resistance controlled by surface modification strategies including conversion techniques: physicochemical or electrochemical transformation such as anodization, plasma and electrophoretic deposition.

1. Atherosclerosis and cardiovascular stents

Currently, cardiovascular disease (CVD) is a major problem in public health globally due it is the main cause of death [1]. The incidence of CVD strongly relates to 'improved' welfare of society, in particular the high intake of nutrients rich in sugar and fat, while leading an increasingly sessile life. The societal burden, both in clinical and economic perspective, rises accordingly. In spite of easy-to-take measurements on diet and lifestyle to reduce this burden, the demand for improved diagnostics and treatments for CVD requires large investments. A promising field for treatment is spawned from tissue engineering and regenerative medicine approaches. Much of the CVD relates to pathologies of the large transport conduits i.e. arteries. These pathologies are the consequence of atherosclerosis and may present either as occlusive arterial disease e.g. coronary artery disease (CAD) or peripheral artery disease (PAD) or as dilating arterial disease known as aneurysm. Arterial disease is characterized by intimal (endothelial) dysfunction and by medial dysfunction, in particular compromising the medial smooth muscle cells (SMC). In the case of atherosclerosis and arterial occlusions (stenosis), endothelial dysfunction triggers excessive proliferation of SMCs and arterial stiffening due to excessive secretion of extracellular matrix (ECM) by these SMCs. Current treatment is based on balloon catheterization to open up the artery and placement of a stent to maintain lumen diameter. Stents are expandable tubular medical devices that are wrapped inside catheter in a folded state and unfold after withdrawal of the catheter [2,3]. Stents are vascular

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implants that improve the structural integrity of the arterial wall and the market for this devices is extensive and diverse offering several options with respect to structural design and material formulation [4–8] There are different generation of stents according the materials or technology that they offer. The bare-metal stents (BMS) were the first generation of stent. For these devices conventional materials such as stainless steel, chromo-cobalt alloys, chrome platinum, nickel titanium alloy, among others, have been used [9,10]. Consequently as an improvement of these technology, a second generation known as drug eluting stents (DES) were developed; these devices incorporated drugs and polymeric coatings on the surface with the purpose to decrease the side effects [4,11–13]. Both, first and second generation of stents have been used for decades, however any implanted material that is foreign to the body, will elicit an inflammatory reaction known as the foreign body reaction (FBR). A FBR generally serves to eliminate the implant. The appearance and course of a FBR depends on the type of (bio)material and the tissue in which it is implanted [14,15]. In general, the onset of a FBR is the deposition of serum proteins on the implant, which attract, bind and active the first line of immunological defense: neutrophilic granulocytes. These short lived leukocytes set the stage of influx of monocytes that differentiate to macrophage in situ. Simultaneously, implants are generally surrounded by a fibrous capsule that comprise of a single layer of fibroblasts to thick rigid capsules. From here on, the FBR differs depending on the implanted material. In case of stenting the fibrous capsule is contributed by medial SMCs. Almost half of the patients with implanted arterial stents, respond by progressive thickening of the media. This obviously causes a renewed narrowing, restenosis, of the vascular lumen.

In order to avoid this situation, a new third generation of bioactive materials with resorbable properties have been matured and it is gaining more attention in particular in academic and commercial fields [16–18]. The advantage of bioresorbable materials is the introduction of a temporary, rather than permanent, scaffold to provide the initial necessary mechanical strength that can sustain hemodynamic activity and vascular tissue reconstruction over time while resorbing in the body. In the group of the bioabsorbable materials for stents, it possible to differentiate two groups: polymers where the most common are poly lactic acid (PLA), poly-L-lactic acid (PLLA), poly-lactide-coglycolide (PLGA), polycaprolactone (PCL), poly-D-lactic acid (PDLA), PDLLA, poly-D,L-lactide (PDLA) and poly-glycolic acid (PGA) [16,18–20]; and metals based on iron (Fe), magnesium (Mg) and zinc (Zn) [13,21–24].

The multidisciplinary nature of stent development and clinical applications urged us to bridge clinical science, biological concepts, chemistry, engineering and materials sciences in the prospect of current and future treatment of vascular disease Fig. 1. In this review, we are focused to discuss about current studies of Mg-based materials and methodologies to modify the surface with the purpose to improve the corrosion resistance, mechanical properties and biological behavior.

2. Biomaterials for stent manufacture

Some metal alloys are ubiquitously used to manufacture vascular stents, due to their favorable mechanical properties (e.g. toughness and resilience) and near absent chemical reactivity in the extreme corrosive biological environment. Yet, recurrence of restenosis is a problem, while thrombosis risk is increased too, in particular for degradable BMS [25]. Thus, the use of current conventional BMS, can be considered as a transitory solution because it can lead to future problems once insertion in the lumen of the vessel is completed [26]. This challenge has been recently addressed by introducing the slow-release of surface-loaded drugs on stents [4,27]. This approach improves the biological response of stents, however this solution is at best transient because the drug release is temporary. In addition, there is an increased risk for thrombus formation compared to traditional bare metal stents [4,16,26]. As a consequence of this problem, new designs and formulations of stents have been examined with the purpose to generate a biodegradable material that can heal and repair the tissue and subsequently resorbs without inducing an adverse foreign body response (FBR) [9,19,22,28–30]. Thus, the device needs to be a temporal vascular scaffold which allows radial support while simultaneously avoids vessel recoil. Previous studies have identified Mg as a potentially suitable material for use in cardiovascular applications due to its biological and structural properties, however Mg in its pure state is limited by its highly reactive chemical condition. Obviously, modification of the surface reactivity is an effective mean of preventing adverse tissue responses as will be discussed below.. Important design issues for optimum performance are the efficiency (maintenance of vascular patency) and safety (no release of adverse degradation products) of the device [9]. Stents are class III medical devices, which according with ISO 10993-5(ISO, 2009), ISO 10993-4(ISO, 2006) and ASTM F 756–00 (ASTM, 2000) standard needs to be non-cytotoxic and have excellent hemocompatibility. The cytotoxicity needs to be of grade 0 or grade 1, which means cell viability is higher than 80% and the mean hemolysis < 5%; despite this, some of the materials previously mentioned do not meet these requirements completely and in some cases failures of the stent devices can be associated with material selection [31]. At the same time, the type of material, its surface and overall design of the stent play an important role in the biological response after implantation. In this way, the main goal after the degradation of the stent is the tissue regeneration of the vessel without adverse effects [9].

3. Clinical challenges to resorbable biomaterials for treatment of vascular stenosis

In a recent meta-analysis Katsanos and co-workers showed that for treatment of PAD, DES (drug-eluting stents) are superior to BMS (bare metal stents) or plain BA (balloon angioplasty), yet none of these solutions could fully prevent need of revascularization in all patients [32]. The advent of bioresorbable vascular scaffolds (BVS) i.e. degradable stents in 2011, set off a new era of treatment opportunities for CAD. Some of these have reached phase II clinical trials with moderate success [33,34]. The complexity of the development as well as phenotype of ‘mature’ atherosclerotic vascular pathologies [35], likely warrants the development of specifically acting stents. Drug-eluting stents have the advantage to inhibit excessive media i.e. smooth muscle cell proliferation, yet also inhibit reendothelialization for the same reason. This might correlate with the increased risk for long-term thrombotic events, albeit small [36]. At present, BMS have superior mechanical properties that allow for sufficiently small dimensions (thickness) of the struts. In contrast, polymer-based or Mg -alloy-based BVS require thicker struts that require careful intraluminal placement to avoid short-term or long-term dispositioning i.e. dislocation effects, that might affect thrombogenesis (see also Fig. 2).

4. Magnesium and its role in the body

Elements such as Mg, zinc (Zn), iron (Fe), calcium (Ca) and silicon (Si) are essential for the human body. In the case of Mg, the recommended adult daily dosage is 240–420 mg/day per body, for iron of 8–18 mg/day, for zinc 8–11 mg/day and for silicon 20–50 mg/day [37–39]. After potassium (K^+), magnesium ($Mg2^+$) is the second most abundant cation in the intracellular fluid of the human body. In general, 10% of Mg is in free ionized form while the remaining 90% is bound to proteins (e.g. as co-factor for enzymes), nucleic acids, phospholipids and ATP. In the body, 60% of Mg is accumulated in bone, 39% is in the intracellular space and only 1% remains in the extracellular space. In addition, < 1% of the body's Mg is in the blood. The exogenous administration of Mg is cardio-protective because it reduces mitochondrial production of reactive oxygen species (ROS). Exogenous Mg, prevents also depletion of intracellular pools of Mg, K and Ca, which supports mitochondrial function. Mg ions are important co-factors for several enzymes that require Mg for their activity. These enzymes are

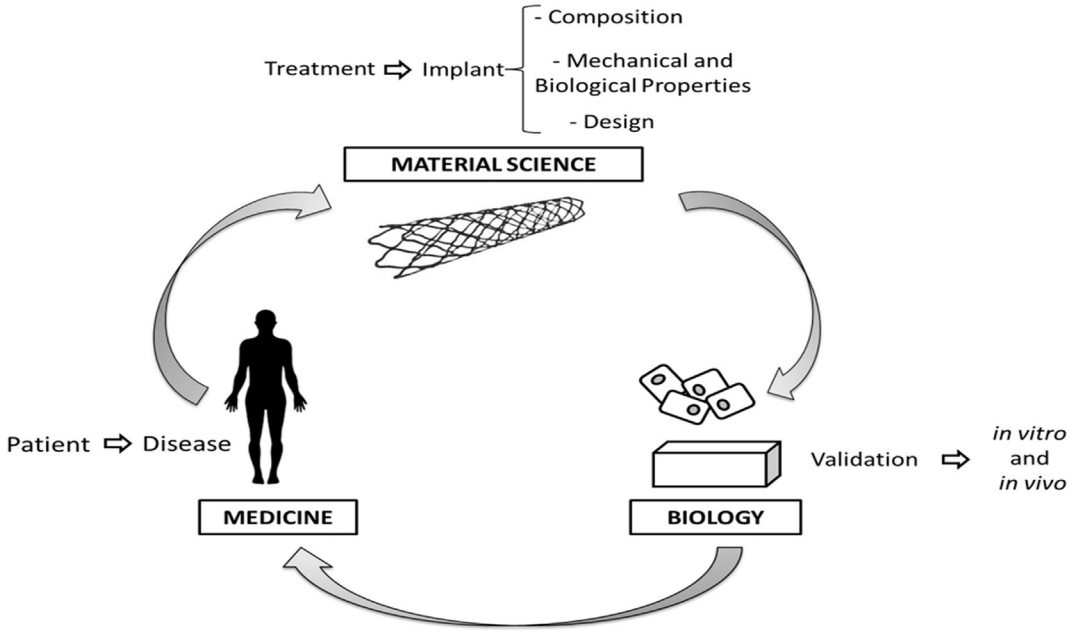

Fig. 1. Novel concepts and technology are emerging in order to find new alternatives for patient that need reliable and fast solutions for a plethora of diseases. Implantable medical devices have frequently used to repair or replace damaged tissues and organs. In this case the interaction of biomaterials with the implant tissue microenvironment will induce specific biological responses. Bioactive interfaces can lead the regeneration or functional recovery of damaged tissue in terms of time, quality and cost. The multidisciplinary understanding of the problem is crucial in the different stages of the process.

e.g. involved in transfer processes of phosphate groups including reactions that require energy production (ATP). Mg also interacts with carbohydrates, fats, proteins and the metabolism of electrolytes [39]. In the transport mechanisms of Mg, Na^{+}/Mg^{2+} antiporter and the Ca^{2+}/Mg^{2+} exchanger both are involved; in this latest case, Mg acts as a natural calcium-channel blocker increasing the levels of prostaglandin E which is both a vasodilator and a platelet inhibitor. In addition, the plasma concentration of Mg directly influence vascular tone [39,40]. Ingested food and supplements are the major source of Mg for the body, the required quantity is absorbed in the intestine by active and passive mechanisms, then transported to different tissues and finally transferred to the cells in the tissues. Excess of Mg is eliminated by the kidneys and expelled in the urine. As was mentioned before, the human body can handle high concentrations of Mg, however, chronic exposure

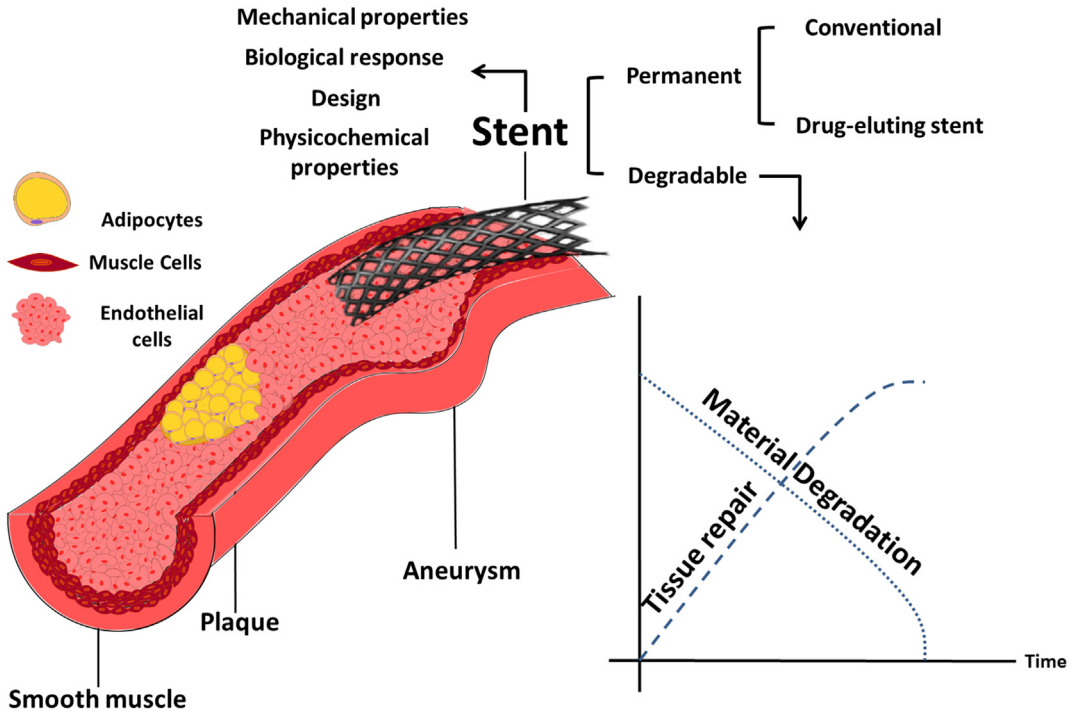

Fig. 2. There are multiple options for cardiovascular stents including permanent and degradable materials. For the last option an adequate bioresorbable stent with optimal mechanical strength and support of the healing of the vascular lesion without medial hyperplasia, is needed. In this therapy a progressive degradation and turnover of the stent material should be synchrony with the progress of the tissue healing.

to serum levels above 1.2 mmol/L is toxic and a health risk. The corresponding disorder, hypermagnesemia and is associated with reduced clearance of Mg due to renal dysfunction. Patients with this complication present delays in the formation or thrombin and platelet aggregation; also high risk to contract other problems as neuromuscular toxicity, hypothyroidism and diabetes. On the other hand, a deficiency of Mg or reduction in its dietary intake may increase the risk for diabetes, thrombosis, arthrosclerosis, ischemia, myocardium infarction, hypertension and cardiac arrhythmias [18,39,41]. That is how, by the increasing of Mg doses, the endothelial function and vascular smooth muscle cells contraction can be modulated which decrease the risk for cerebrovascular accidents (CVA) or CVD such as cardiac arrhythmias and hypertension. Mg stimulates the production of vasodilators by endothelium such as prostacyclin and nitric oxide and suppress the inhibitory activity of the sodium-potassium ATPase pump which prevents negative changes in the vascular tone and dysfunctional coagulation [38,39].

5. Magnesium as material

In its metallic form, Mg has several material advantages such as high strength, excellent thermal conductivity, dimensional stability and damping characteristics. In addition, Mg also has a low density and good electromagnetic shielding properties and it is easy to mechanize and recycle [42]. Mg is the lightest of all structural metals, its density is 1.738 g/cm^3 which is similar to cortical bone which is 1.75–2.1 g/cm^3 [18]. Mg has a great capacity to absorb kinetic energy while its elongation is limited to 2–10% [18] and it has a Young's modulus of 45 GPa. Its modulus of rigidity, is about 16 GPa which is relatively low when compared to other biomaterials such as titanium (Ti), Ti alloys or steel about 110.3, between 105 and 120 and 200 GPa respectively. However this is still far from the modulus of tissues such as for the human carotid artery which is around 300 kPa (this value change for diastole and systolic pressure and also can change in case of vascular diseases) [43,44]. Nevertheless, Mg is an interesting material for biomedical applications because it reduces the probability of having stress shielding in the material-tissue interface. An example of this is in bone replacement in which Mg has showed a good mechanical behavior because osseous tissue has an elastic modulus of 20 GPa which is relatively close to the elastic modulus of Mg [18,45]; additionally, Mg is easy to machine with high dimensional stability, which facilitates the manufacture of complex shaped parts [18]. With respect to biological properties, Mg is considered biocompatible, non-toxic, and it is actively involved in the deposition process of biological apatite and consequently in the formation of bone [18]. As was mentioned before Mg is an important element for the body and daily doses are needed, rendering Mg a promising material for cardiovascular applications. This relates to its proper mechanical behavior and biological properties. As an alkaline earth metal its surface properties are uniquely suitable for modification and surface chemistry control. The corrosion rate of Mg is about 2.89 mm/year in 0.9% NaCl in which hydrogen evolution reaction is involved. However, a major challenge for application of Mg as biomaterial is its corrosion properties and the improvement of its mechanical properties for its use as biomedical device. Diverse studies in the field have been studied the improvement of the mechanical performance of Mg by using different alternatives of extrusion at the moment of the fabrication of implants [46–48]. This strategy allows improving the performance of the material by grain refinement and producing a more homogeneous microstructure [46]. On the other hand, same authors have proposed the use of a coating such as APTES/PLA [49], hydroxyapatite [50] and MgF_2/polydopamine [51] which not only improve the mechanical properties of the Mg but also increase the corrosion resistance of the material.

6. Magnesium with high properties for vascular stents

Mg was discovered in 1755 by Joseph Black and already within years after the discovery, researchers explored the use of Mg as biodegradable material in implants such as staples or screws. The characteristics of this material makes it an interesting option for orthopedic replacements of bone and for cardiovascular applications [18]. For this last field, the pioneer was the physician Edward C. Huse who in 1878 used Mg wires in humans to bind blood vessels obtaining successful results [52–54]. Prior to that, the famous physician/surgeon, Erwin Payr, used Mg implants to make not only wires but also tubes, pins, plates, cramps and nails, which were used in his clinical interventions in particular transplantations [53,55]. In all these previous cases, Mg was successfully used in its pure metallic form (c.p Mg), where the element of Mg was in approximately 99.9% and the rest small quantity of impurities, but progress was hampered due to its fast degradation and concurrent release of hydrogen.

The overall reaction of the Mg is described by Eq. (1). The anodic and cathodic reaction are show in Eq. (2) and Eq. (3) respectively.

$$Mg_{(s)} + 2H_2O \rightarrow Mg^{2+}_{(aq)} + 2OH^{-}_{(aq)} + H_{2(g)}$$

$$Mg^{2+}_{(aq)} + 2OH^{-}_{(aq)} \leftrightarrow Mg(OH)_{2(s)} \text{ (Overall reaction of Mg)} \quad (1)$$

$$Mg_{(s)} \rightarrow Mg^{2+}_{(aq)} + 2e^{-} \text{ (Anodic reaction)} \quad (2)$$

$$2H_2O + 2e^{-} \rightarrow H_{2(g)} + 2OH^{-}_{(aq)} \text{ (cathodic reaction)} \quad (3)$$

According whit this, per each atom of corroded Mg, one molecule of H_2 is produced (Eq. (3)) and although this gas is not toxic, it's accumulation in cavities might be. Previous studies shown that formation of gas pockets, may also cause separation between the implant and tissue, delaying the healing process and in some cases inducing necrosis in the surrounding area [45,56]. However, the effect of H_2 production can be more critical for bone applications in comparison with cardiovascular devices as the latter are usually part of a dynamic system were blood flow can remove and control the gas evolution by mass transport. On the other hand, blood clotting may increase with gas hydrogen production. Notwithstanding, if the H_2 production is so high and depending of the anatomical location of the stent, the production of gas bubbles could mostly or completely block blood flow causing death however most due to the dissolution of the hydrogen in blood is fast, this risk is low [52,57,58]. In addition, previous studies of composition of gas cavities in tissue produced after degradation of Mg, show that also N_2, O_2 and CO_2 are involved in this process were H_2 is quickly exchanged for these other gases and consequently the problem associated with H_2 evolution in Mg implants might not be so hard to solve [59]. On the other hand, during the exposure of Mg in its pure form to an aqueous system (blood or culture medium), a process of fast alkalization occurs in the surrounding environment [60]. The increment of the local pH, as a consequence of the $Mg(OH)_2$ (Eq. (1)) may affect the biological response of the cell in terms of adhesion and may induce apoptosis [17]. In any case, as a consequence of those situations, Mg was severely restricted to use as implant and at the same time the use of other materials such as stainless steel and then Ti as biomaterial were increasing with time [18]. A summary of Mg based materials used in cardiovascular applications is shown in Table 1. In summary, until now, the use of c.p Mg does not provide the best mechanical properties and corrosion resistance required to be used in implants; however alternative solutions such as the use of alloys or the production of an insulating barrier between the bare material and cells may improve the material performance Fig. 3 [18,42].

In its chemically pure form, (metallic) Mg has limitations due to its corrosion. However, this process can be controlled by addition of alloying elements into the matrix which not only influence the corrosion resistance but also the mechanical properties. As mentioned earlier, the first use of alloyed Mg was in the industrial sector where it was mixed

Table 1
in vivo experiments using based magnesium implants.

Material	Model	Place of implantation	Time	Results	Ref.
c.p Mg, WZ21 and AZ91	Rats	Muscle pocket-subcutaneous	1and 2 months	Good tissue response for all samples. AZ91 showed a fast corrosion process after being compared with WZ21 and c.p samples. All samples formed gas pockets except for WZ21.	[130]
c.p Mg	Rats	abdominal aorta	5–32 days	Process of corrosion was observed in vivo after the 7 day. Degradation process was completed between 21 and 29 days. An in vitro and in vivo correlation was developed.	[131]
WE43	Pig	Coronary arteries	~1 Month	Long time inflammatory response as a consequence of permanent implants was avoided due to the absorbable conditions of Magnesium. Biocompatibility of the implant was observed.	[13]
WE43	Human	Different places. Treatment for critical lower limb ischemia		No allergic or toxic reactions were observed after the implantation of the stents. Some implants showed calcification	[13]
Mg alloy	Human	Left pulmonary artery	5 month	Increment in the diameter of the lumen was reported. The stent was completely degraded without any damage in the arterial wall.	[132]
AZ31	Rabbit	Thighbone	2 Months	No inflammation process were observed. Precipitation of apatite was founded. Non-presence of gas hydrogen pockets. After the maximal time, samples showed a starting process of degradation but in a slowly way after be compared with naked samples.	[133]
WE43	Miniature pigs	Frontal bone	3 and 6 months	Proper wound healing process. Gas pocket formation was founded in samples without coating after the 4th week. At the final time samples were not diluted in totality however the rate of corrosion was lower in the coated sample avoiding the presence of hydrogen gas between the tissue and the implant	[134]
WE43	Pigs and minipigs	Coronary arteries	3 days, 28 days, 3 months	The implant was consider as safe. Less neointima formation was observed. The process of degradation was appreciated in samples of 28 days and 3 months	[135]
AE21	Pigs	Left anterior descending artery, the circumflex artery and right coronary artery	10 days, 1 month and 2 months	Neointimal formation was observed. Good hemocompatibility. Material with signals of degradation but not completely disappear after 2 months.	[136]
WE43	Human	Proximal left anterior descending artery (stenosis)	15 months	New neo intimal layer was observed in the place of implantation. Biocompatible material	[137]

with other elements with the purpose of having a more resistant and light material for different applications such as in automotive and aerospace sectors, electronic devices, among others. With the pass of time, these same materials were tested for biomedical applications and as improvement of them new formulations were developed. For this application, one of the most crucial criteria for the choice of elements in a Mg-alloy is related with its toxicity and dissolution. For this reason, the added elements and its concentration need to be selected carefully taking care not to exceed the permissible values for the body in the toxic range and the easy distribution or elimination by excretions ways [45]. According with this, elements such as Ca, Mn, Zn, Sn are present throughout the human body and are a good option for bioabsorbable implants. In contrast, alloys that contain elements such Be, Ba, Pb, Cd and Th are toxic and require caution for biomedical use. Other elements such as Al, Bi, Li, Ag, Sr, Zr can only be used in low doses [45]. Allergic responses or hepatotoxicity have been attributed to alloys containing Al, V, Cr, Co, Ni, Cu, La, Ce, Pr [45]. Table 2 summarizes the most commonly used alloys, composition, applications and results found.

The solubility of alloying elements depends mainly on their atomic size with relation to Mg and also on its valence as in the case of Al, Zn, Ca, Ag, Ce, Ni, Cu and Th. The addition of alloying elements also induce grain refinement and/or plastic deformation due to induction of a high density of dislocations and stacking faults in the microstructure [61–64]. Alloys of Mg—Al, Mg—Zn, and Mg–rare earths present a precipitation hardening due to the high solubility of the secondary element in Mg [65], otherwise occurs with Mg—Ca and Mg—Si alloys which are unable to do it without being reinforced by thermic treatment which can improve properties such as corrosion resistant of the alloys [66,67]. Moreover, some of the most common alloy elements incorporated to Mg are Al, Zn, Mn and Ca and rare earths. However, the use of elements such as rare earths and Al is highly controversial because of considerable health risks if the permissible concentrations are exceeded e.g. locally during degradation [32,68].

Mg is a highly reactive material and the corrosion process can be induced by exposure to chloride ions in a non-oxidizing medium. The corrosion mechanism for c.p Mg is typically localized, the surface appearance change after some time to a dark color and some cavities or pitting is produced in the surface [69]. On the other hand, due to the presence of elements and phases with different electrochemical potentials, galvanic corrosion is the prevalent mechanism for the degradation of Mg alloys where some phases act as anodes and others as cathodes inducing the occurrence of reduction oxidation processes. This behavior can be produced also in c.p Mg in a minor extent due to the presence of impurities. Factors such as grain size, heat treatment and the environment to which it is exposed can influence the rate of degradation of the material [70,71]. In terms of corrosion resistance, corrosion resistance of Mg can be improved by the addition of elements that have electrochemical potentials close to that of Mg, about −2.37 V, decreasing the probability of galvanic corrosion processes these, elements are Y: −2.37 V; Nd: −2.43 V; and Ce: −2.48 V [45]. As H_2 evolution is a critical by product for Mg materials used in biological systems, some alloys have been developed to decrease this rate; that is the case of Mg alloys containing Zn, Al and Mn, where H_2 liberation was in the order of 0.01 mL/cm^2/day according with results obtained through in vitro techniques [18].

Mg is a promising material to be used as degradable implant; however, concerns have been raised about its rapid and non-homogeneous degradation under physiological conditions, fast release of degradation products and premature loosening of mechanical stability of the implant during this process, considering that, the disappearance of the material should be synchronized with the recovering of the tissue. At the cardiovascular context, stents are subject to mechanical loadings that start at the moment when the implant is placed in the vessel. After that, tensile and shear stress induced by the blood and the contraction and relaxation of the tissue by the heartbeats affect directly the degradation and stability of the implant. On the other hand, health

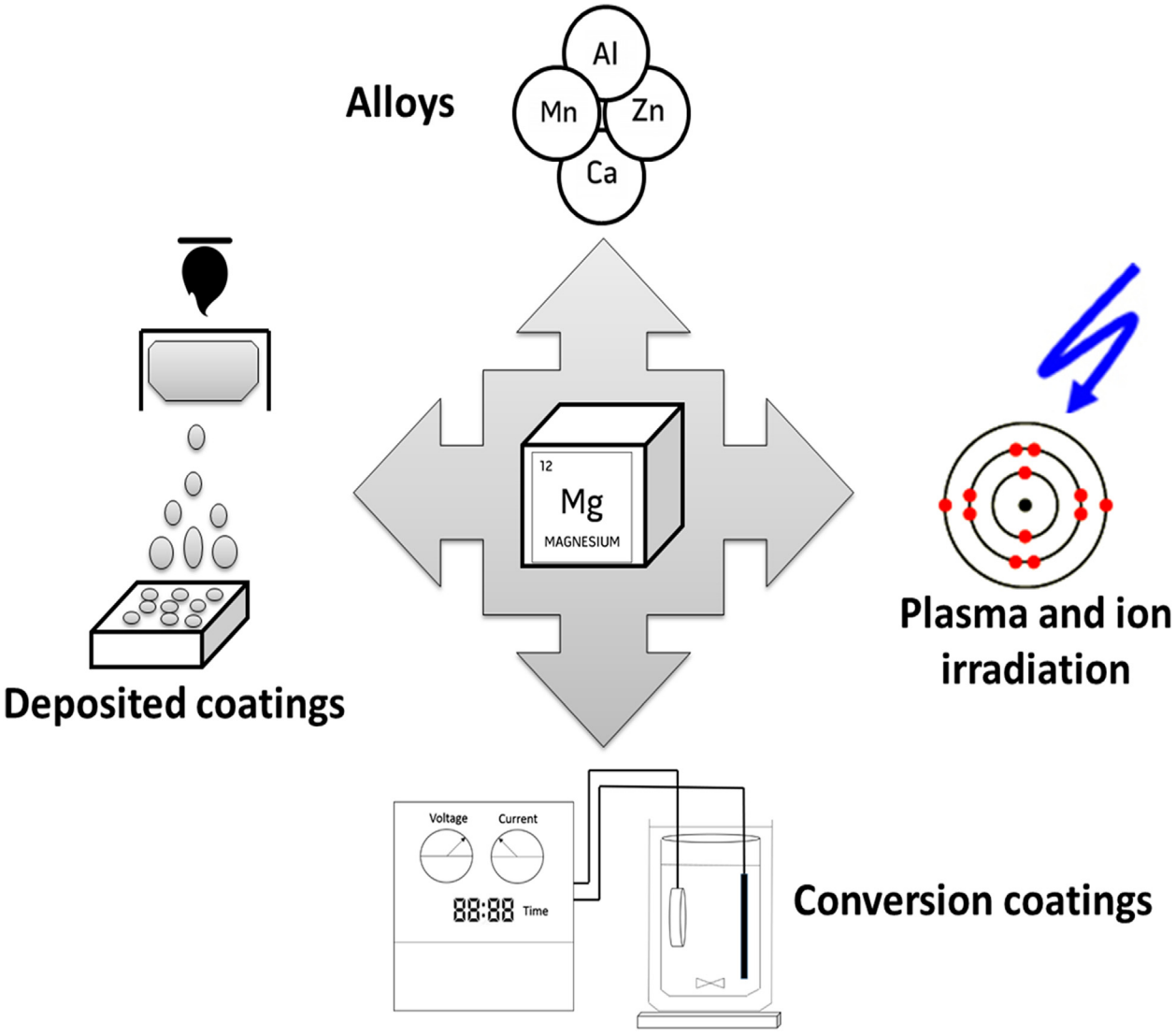

Fig. 3. Performance of c.p Mg can be improved by the addition of other elements (Magnesium based Alloys or by coating the material through different techniques.

condition of the patient may influence the performance and speed degradation of the implant where high pressure, coagulation factors and general stage of the tissue play an important role [72,73].

Under this context, the use of alloying element contributes to improve the mechanical and biological performance of Mg. The final performance of the implant will depend of its composition, surface modification, design of microstructure, precipitation distribution of elements inside of the main Mg matrix and the material fabrication and processing. Pitting corrosion is other limitation related with the Mg-alloy degradation process. Mg is susceptible to react with ions present in the surrounding physiological environment, meanly chloride and sulphate ions, producing a non-uniform and fast corrosion process where the integrity of the implant can be affected. In order to solve this problem, some studies have shown that the use of Zn, Zr, Ca, Nd as allowing elements can improve the degradation process of Mg. For instance, Mao et al. used Mg alloys containing Nd, Zn and Zr showing a uniform corrosion of the material and conserving the mechanical integrity of the implant for longer time [74–76].

7. Clinical application of biodegradable Mg-based stents

Degradable stents are a relatively new generation of implants. In comparison with other biodegradables technologies as polymeric implants, Mg-based stents has been showed better mechanical performances and less frequent late thrombosis [77]. Additionally during the elimination process of the material, low vessel wall inflammation has been reported. In addition, in the clinical practice, Mg implants can be easily followed by imagining techniques providing an adequate follow-up of the implant and information about its interaction with the target vessel. So far, at commercial level and under clinical trials, Biotronik (Germany) is the company with more experience in Mg-based stent. This company developed different products using the WE43 Mg-alloy. The first generation of implants called AMS (as abbreviation of absorbable metal scaffold) consisted of a tubular, processed by laser cutting system, balloon-expandable implant without drug-elution. This device was evaluated in patients under the clinical trial PROGRESS-AMS. The study focused in demonstrate the safety and feasibility of the AMS technology. However some issues related with the fast degradation of the implant after four months were detected accompanied of some cases of target lesion revascularization (TLR), 23.8% at 4 months and 45% at 12 months [78]. Consequently, a new version called DREAMS-1G (Drug-eluting absorbable metal scaffold) was evaluated in the clinical study BIOSOLVE-I. For this new generation of stent, the improvement included the addition of Paclitaxel on the surface of the implant, slower desorption of the material by the addition of a coating of PLA, higher collapse pressure and some changes in the design

Table 2
Most used alloys elements added to Mg for biomedical applications.

Alloying element	Mg alloy composition	Observations	Ref.
Aluminum (Al)	**AZ31:** Mg(96%), Al(2.5–3.5%), Zn(1.3%), Si (0.05%), Mn(0.2%) **AZ61:** Mg(93%), Al(6%), Zn(0.5), Si(0.04%), Mn (0.15%), Cu(0.003%), Fe(0.007%) **AZ91:** Mg(90.8%), Al(8.25%), Zn(0.63%), Si (0.035%), Mn(0.22%), Cu(0.003), Fe (0.014%), Be(0.002%) **AM60:** Mg(93.5%), Al(6%), Zn(0.1%), Mn(0.35%)	- Improvement in mechanical properties such as castability, hardness, tensile strength, ductility and elongation - Al shows a limited biocompatibility when the permissible concentration is exceeded - Presence of Al in the corrosion products after in vivo assays has been reported - Some studies show precipitation of apatite on the material after its immersion in SBF which make this a good option for bone implants - The wettability and bioactivity of the material depends on the microstructure, amount and distribution of the intermetallic phases and grain size. - Fast galvanic corrosion by the action of cathodic activation after the exposition of the material with chloride species in the medium. However in presence of more aluminum more uniform corrosion can be produced	[22,61,138–152]
Zinc (Zn)	**ZK30:** Mg(96.4%), Zn(3%), Zr(0.6%) **ZK60:** Mg(93%), Zn(6%), Zr(1%)	- Zn is essential for the human body - High solubility in Mg (6.2%) - Improvement of mechanical properties such as tensile strength and elongation - Aging strengthening effect - Grain refined - Used in bone implant for induction of apatite precipitation.	[62,144,153–156]
Rare earth (RE)	**WE43:** Mg(93.6%), Y(4%), Nd(2.25%), Zr(0.15%) **LAE442:** Mg (90), Li (4%), Al (4%), RE (2%)	- Some rare earths such as Y, Gd, Tb, Dy, Ho, Er, Tm Yb, Lu among others are commonly used - Improvement of high temperature strength and creep resistance of Mg - Solubility in Mg is a critical factor to be considered - Influence on the degradation rate	[157–165]
Others elements added		- Ca, Sr, Zr, Si, Sn can beaded to tailor a specific microstructure. - Grain refiner and improvement of the strength and other mechanical properties of magnesium such as ductility and damping capacity - Slow down the corrosion rate of the alloy	[22,63,144,156,166–169]

(shape and strut thickness). Results showed a decrease in the target lesion failure rate of 7.0% at up to 12-month follow-up and an improvement in the speed degradation of the material [79]. A second generation of this technology was presented as DREAMS-2G or Magmaris and tested under the study BIOSOLVE-II. The novelty of the product was the use of Sirolimus on the surface of the material and improvements in the design [33,80]. An extension of this information is shown in the Table 3.

8. Improvement of the corrosion resistance of Mg by surface modification

Changes in the surface of the Mg is another effective way to improve the corrosion resistance. The design of the surfaces can not only reduce the rate of degradation of the material, but also the biological response and the mechanical fixation of the implant [42]. In addition, the new surface needs to respond to physicochemical and mechanical characteristics for the application required and also meet the required requirements for biocompatibility and hemocompatibility [81]. Moreover, the biomaterial interface can be quite sensitive to its bioactive environment and surface properties not only have intrinsic features but these can be dynamic and transform during exposure to complex, extreme bioactive environments [82]. The ability to design bioactive materials that can respond favorably with enhanced surface properties yet maintaining effective bulk properties has opened opportunities for new biomaterials surface modification approaches that can with a high degree of selectivity and control result in optimal bioresorbable materials and in particular Mg-based materials for the regeneration of damaged blood vessels [18,83].

Below, some superficial modification techniques for Mg are described with the purpose to offer an overview of the current stage in the topic. In addition in Table 4 this information is summarized. The geometry of the implant is an important criteria to take into consideration when selecting a technique to modify a surface. A homogenous treatment needs to be guaranteed avoiding defects than can accelerate the corrosion process or be sources of failure via fatigue, creep or fracture.

8.1. Conversion coatings

Conversion coating of Mg, or any metallic material, is feasible by in situ growing of an oxide layer from the surface. This process is commonly used in some metals like Al, Ti and Mg, however the specific process conditions and resulting material characteristics are variable. Passivation is one of this methods, in this, the material protects itself from further oxidation by the growing of an oxide layer in a natural way (without any external source) after the contact with aqueous solution or the air. For Mg this layer consists of an oxide-hydroxide layer, normally with higher oxide (MgO) than hydroxide ($Mg(OH)_2$) and may also contain other elements present in the used solution. However, this kind of treatment produce generally a weak layer with only few nanometers of thickness which may not be protective enough.

Another widely used technique in the same context, is anodization, in which the material to be modified, in this case Mg, is set up as anode in an electrolytic cell and submerged in a supporting electrolyte where through a voltage source an electrical current is induced. Then, an anodic layer from the material is produced controlled. In the formation of a new protective coating, a chain of reactions are involved: dissolutions, depositions and formation of new phases and compounds. Moreover, as a modification of conventional anodization method, a technique called plasma electrolytic oxidation (PEO) or micro arc oxidation (MAO) or anodic spark deposition (ASD) has emerged. In this method, high voltages (in the order of 300 V, 400 V and inclusive 500 V) are used to achieve the breakdown potential and the energy concentrated at specific points which offer less resistance, results in the formation of fine spark discharges which have an important influence on the morphology of the film. Typically, the final coating consists of two structures; first a barrier layer which acts like a protective film and on top of this, an irregular film that usually is a porous layer with structures that look like craters as a consequence of the multiples process of melting, solidification, crystallization, partial sintering and

Table 3
Mg-based stents in clinical application.

	Stent characteristics	Dimensions	Mechanical characteristics	Coating and drug	Clinical trial	Type	Number of cases	Time of evaluation post-implant	Observation	Ref
AMS	Tubular Laser cutBallon-expandible WE43 alloy Strut thickness 165 μm	Length 10 and 15 mm Diameter: 3 and 3.5 mm	Sufficient collapse pressure (0.8 bar) Low elastic recoil (< 8%) Lesser acute recoil: 5.22% ± 0.38%	–	PROGRESS-AMS	Multicenter non-randomized prospective single-arm study	n = 63	4 months	Cases of TLR Full degradation after 4 months Mechanical collapse of the implant previous to tissue repair	[78]
DREAMS-1G	Ballon-expandible WE43 alloy Six crown3-link design Strut thickness 120 μm	Length 16 mm Diameter: 3.25 and 3.5 mm	Collapse pressure (1.5 bar) Lesser acute recoil: 9.42% ± 0.21%	1 μm PLGA +0.07 μg/mm^2	BIOSOLVE-1	Multicenter, Non-randomized	n = 46	6 and 12 months	Improvement in degradation time	[79]
DREAMS-2G	Ballon-expandible WE43 alloy Six crown2-link design Strut thickness 150 μm Radiopaque tantalium marker	Length 20 and 25 mm Diameter: 2.5, 3 and 3.5 mm	Lesser acute recoil: 4.94% ± 0.31%	7 μm PLGA +1.4 μg/mm^2 Sirolimus	BIOSOLVE-2	Multicentered Non randomized	n = 123	1, 6, 12 and 36 months	Improvement device performance, efficacy and safety	[33,80]

Table 4
Techniques to modify the c.p magnesium to improve its corrosion resistance.

Type of Modification	Technique	Advantages	Disadvantages	Ref.
Electrochemical	Electro-Deposition	Easy to work out, cost less, the surface topography uniform, and very reproducible	High reactivity of Magnesium. Production of a (MgO)/Mg(OH) on surface previous to the treatment altering the final product. Non thick coatings	[147,170–173]
	Conventional Anodization	Excellent adhesion and bonding. Really protective coatings. Simple and cheap mechanism. Good in different implant shapes	Only basic solutions due to the high reactivity of Mg. Lower wear resistance	[174,175]
	Microarc oxidation (MAO) or Plasma electrolytic oxidation (PEO)	Surface parameters and topography can be controlled. Non expensive	In some cases non-homogenous surfaces. Susceptible to early pitting corrosion. High temperatures can be reached.	[84,85,138,176]
Chemical	*Chemical vapor deposition* (*CVD*)	Non-energy consuming and non-toxic for environment	Complexity of growth reactions, high temperatures required, formation of undesired layers	[177–180]
	Chemical Conversion Coating	Good adhesion of the coating to the substrate. Sometimes used as pretreatment previously to other techniques	Toxicity of some elements used in the treatment solutions usually based in chromium compounds. Non uniform surface composition	[181–184]
Physical	Ion Implantation	Usually in vacuum systems avoiding pre passivation of the substrate. Control in temperature of operation. Physical, chemical and electrical properties can be modified	Expensive technique. Restricted to complex shapes	[146,153,158,185–187]
	Physical vapor deposition (PVD)	Hard coatings with convenient tribological properties	Thin layers. Non uniform layers, formation of pinholes	[188–190]
	Sputtering	Good control and flexibility over control, structure and stoichiometry. Smooth, and uniform film.	Ultra-high vacuum is required leading possible contamination with residual gas	[149,166]
Physiochemical	Passivation	Natural process accelerated with nontoxic and common reagents. Cheap and fast technique	Thin layers sometimes non enough protective	[191–193]
	Organic or Biomimetic Coating	Spontaneous process in which no heat process are involved	Adhesion or stability problems, thickness	[194–198]
	Organic/Polymer Coatings	Performed at low temperatures. Organic product such as polymers and proteins can be used. Improvement in the biological action in a direct way.	Non strong adhesion	[127,133]
	Self-Assembled Monolayer	Thickness of the layer can be controlled. Room temperatures. Organic coating can be used. High chemical stability	Expensive equipment. Not enough strong adhesion coating-substrate. Reactivity of Mg with some acid components needed	[128,145,199–202]

densification [84–87].

In all these techniques, parameters such as type and concentration of electrolyte, temperature, time, current density and applied voltage determine the final morphology, composition, thickness and adherence of the coating [34]. Those parameters may play a crucial role in the biological behavior as cells response to interfacial features of the implant [42,82]. Coatings formed by conversion have the advantage that the film will tightly adhere, because it grows from the material, subsequently the wear resistance and hardness of anodized layers improve the substrate performance. However as the produced layer is a ceramic material it may not have the desired mechanical characteristics [42]. Usually, coatings on Mg are formed in basic aqueous electrolytes because under acidic solutions Mg is highly reactive and it can easily degraded. Solutions based in NaOH and KOH area widely used for anodizing of Mg [60,88], some studies incorporate other elements such as calcium, silicates, aluminates, borates and phosphates [89–94].

Usually the thickness obtained by anodization depends on the voltage applied and can vary from 5 to 200 μm. In addition, other characteristics such the electric conductivity of the modified Mg resulting material are highly influenced by the electrolyte composition due to incorporation of some species into the anodic layer. For this reason, it is necessary to determine the ratio of the elementary cell volume of the formed oxide respect to that of the metal (relation of Pilling-Bedworth) to evaluate if the formed oxide is protective or not [95].

8.2. Deposited coatings

Another alternative for surface modification is the deposition of a metallic, polymer, ceramic or a compound material on the primary metallic substrate. Sol-gel, plasma spraying and electrophoresis are some of the most used techniques in this context. With respect to the material to be used as a coating, it is important to consider certain points, for instance, the deposition of metallic layer on another metallic surface may cause a galvanic corrosion and changes in the interface substrate/coating. Additionally, stress shielding can induce large differences in Young's modulus between the scaffold material and the tissue. For example, in a practical situation for an endoluminal vascular stent, at the interfaces between the coating and material substrate, additional shear forces induced from the pulsating hemodynamic environment could result in detachment of the film. In addition, metal films must be biocompatible, which reduces the number of options between the metallic materials commonly used as coatings. In contrast, polymers and ceramics can be a better options. Ceramics are a highly stable materials but at the same time they are fragile. This kind of materials are the most common used as coatings for bone implants due to their inherent bioactive properties to precipitate biological apatite and thus to improve the direct link with osseous-tissue. On the other hand, polymers such as polylactic acid (PLGA), polycaprolactone (PCL), polylactic acid (PLA), chitosan, among others have been used to coated Mg; [26,96–101]. Other organic compounds i.e. peptides, proteins, drugs and among others, can be also deposited or immobilized on Mg, however it is important to consider that the operating temperatures and the general procedure should not cause changes in the composition and structure of the coating. In this situation the immersion techniques are a good option through the use of solutions, suspensions, colloids or precursors. Techniques such as cathodic electrodeposition and sol-gel are some of the most used for this kind of coatings. In the cathodic electrodeposition, particles with a specific charge suspended in the working medium are able to migrate to the material after to apply an electric field in the system. The variety of materials used in this application are diverse and includes metals, ceramic, polymers among others. This technique is simple and economical, however problems to control the purity of the coatings and the presence of unexpected phases can affect the stability for the coating [81,102]. On the other hand sol-gel is a process that also involves colloidal solution. In this, the sol (colloidal solution) is a precursor for a gel network that allow the deposition of films with a specific distribution, thickness and composition. The advantage of this techniques is that is very useful to deposit inorganic and organic material due to its low temperature operation. However, in the case of Mg, the material can react with the immersion media resulting in limited coating thickness; despite organic coatings can be used to protect the metal from corrosion by temporal isolation of the media during the treatment.

8.3. Modification of surfaces by plasma and ion irradiation

An alternative and in some cases a complementary surface-modification technique is the use of plasma-irradiation driven treatments to modify the biomaterial surface. Plasma modification can provide a high fidelity and refined method to control the surface properties at physical scales that can dominate protein adhesion and cell proliferation [82]. With these alternatives, an effective and viable set of surface modification methodologies could be envisioned for Mg-based biomaterials expanding its use for biomedical applications as in the case of cardiovascular diseases. The interaction of highly energetic ions from plasma sources exposed to biomaterial surfaces can be quite complex due to the inherent coupling between them and the complexity of both the plasma (e.g. ionized gas) and hemodynamic environment. The interaction is a multi-scale phenomenon that involves complex temporal and physical scales. Ion beam irradiation refers to the acceleration of charged species that implants energy onto a surface [103,104]. The charged species can be either single ions (monomeric beam), or ion clusters (cluster beam) [105–107]. In addition, the ions can either be chemically inert, which means they do not interact with the surface being bombarded, or chemically reactive, in which case there is a chemical reaction that occurs upon the interaction between the irradiating species and the surface being bombarded. In some cases, either inert or chemically reactive irradiating species when combined can effectively impart energy to a surface inducing metastable phase formation. These metastable phases can introduce surface topography and surface chemistry that fine tune the physical and chemical properties of the material. New vascular therapeutic technology has recently focused on the ability to controlled engineering of tissues and in particular tissue-engineering blood vessels which could shed light on endovascular regeneration from acute or chronic injury [108]. The need for inherent multi-functional properties of a stent surface derive from the complexity in early angiogenesis steps and the management of cell recruitment to the injured site involving complex cascade of immune mediators, soluble signaling molecules, and cell-to-cell interactions [108,109]. In particular, topographical cues are known to influence both recruitment and migration of cells [110]. Furthermore, mounting evidence exists for the importance of mesoscale and nanoscale structure that can alter cell morphology, adhesion, motility, proliferation, endocytosis activity, protein abundance, and gene regulation [111] Therefore, techniques that can modify and vary surface structure and morphology over different spatial scales are attractive towards establishing a strategy to design novel “smart” biomaterials.

Besides situations in which the purpose is film deposition on substrates [112], ion implantation is another way in which surface properties can be modified towards a specific desired characteristic [113–115]. In this context, the chemical nature of the ions used, as well as the energy of the ion beam, the charge and energy are all characteristics that have significant influence on the outcome of the ion irradiation procedure. Among these, however, the dominant parameter is the energy of ion irradiation. At low ion energies, of below 100 eV, desorption and/or adsorption are phenomena that are dominant, as well as migration leading to island formation. Ion irradiation has been used for surface engineering to induce characteristics such as cleaning, smoothing, film growth or etching [116–118]. The characteristic that stands out from the current project's point of view is the fact that irradiation of a material's surface can induce changes to its wettability [119,120]. More importantly, for the purpose of surface properties

control and bioactivity enhancement in biomaterials, the wettability can be either enhanced or reduced by manipulating the characteristics of the ion beam. The advantages that this brings for improving the biocompatibility of medical devices, especially vascular stents are obvious: by manipulating the ion beam composition, energy, or flux, we can potentially be able to set [121] up criteria for optimum surface wettability in vascular grafts with consequences in refining our capacity to control thrombogenicity and tissue integration of these implants.

9. Problems and future challenges

An appropriate material to be candidate for biodegradable cardiovascular stents must meet some essential requirement. For instance, from the mechanical point of view, the material should resist the strength and ductility required for the system, the degradation should be uniform and generalized and the corrosion products must be non toxic. In order to encourage the biological and mechanical performance of the Mg implants, different approaches has been explored which include the use of micro alloying, thermal treatments, control of microstructure, modification of surfaces o addition of coatings. With all these strategies the purpose is to slow down the degradation speed and promote a uniform degradation. In addition, during the degradation process, the corrosion products should be eliminated without any adverse effect and avoiding drastically host responses that may cause damage or inflammatory reactions either locally or systematically. Also materials with low thrombogenic effect should be considered and use of an antiproliferative drug to slows down the neointimal tissue (atherosclerotic) around the lesion. The design and geometry of the stent is also a key point that affects the biomechanics, of the system. By using designing and simulation tools, flow disturbances, strut fractures can be predicted and controlled.

The non-homogenous degradation of Mg is a challenge for its biomedical applications. This heterogeneity in most of the cases is due to the presence of impurities, secondary phases or contact with materials of other nature that may induce a localized corrosion of galvanic type. As a consequence of this, small cracks and spots of failure may start to appear that accelerate the degradation at these nano and micro niches, while simultaneously the production of hydrogen gas may locally accumulate as a degradation product. Low quantities of hydrogen gas are absorbed by the body but too high amounts cause necrosis and other damage of the tissue that surrounds the Mg implant. The ideal situation is having a protective coating on the Mg that degrades in a controlled way [122,123]. In addition, as a passive layer of Mg is highly sensible to chloride ions (Cl-) present in physiologic fluids and culture media, this is not considered an efficient alternative for biomedical applications, however it can be used in combination with others treatments such as coating with polymers or immobilization of drugs [124].

Corrosion phenomena can be readily investigated in vitro, e.g. through electrochemical testing potential-dynamic polarization using simulated body fluid (SBF) or NaCl as immersion solution. To date, this is the method of choice to determine the corrosion rate of a material. With the obtained data, it is possible to evaluate the efficiency of corrosion protection of the coating. However, the most critical tests are preclinical in vivo experiments in rodents of large animals such as pigs, where the material is exposed to a complete organism, with real-life variables and where elimination methods and homeostatic controls are carried out. Several studies show that results from in vitro and in vivo tests are frequently disparate for reasons that are unclear. Nevertheless, in vitro assessment of corrosion and biological properties of surface-modified Mg, still is an excellent and pivotal way to bridge between physicochemical studies and preclinical evaluation. The challenge is to find a model closer between in vivo and in vitro tests, so it could be easier to predict the future behavior of a material or based-Mg formulation previous to the implant [125–129]. Another important consideration about based-Mg implants is to reach a proper solution ensuring the right balance between degradation of the material and formation of a new tissue and keeping the adequate elimination of the material. Other characteristics such morphology and interface interactions need to be improved.

10. Conclusions

Stents for the treatment of cardiovascular diseases are usually made of non-degradable metallic materials such as Ni−Ti alloy or Cr−Co alloy. Their permanent implantation, however, increases the risk for long-term restenosis. Biodegradable materials are a novel option to solve this problem. Mg is a promising yet challenging material and although has been used as biodegradable implant in different applications such as orthopedic and cardiovascular research. Mg has interesting mechanical properties and good absorption in the body without causing adverse side effects, while it is a natural constituent of the body and essential for physiology. The disadvantage of Mg is its high reactivity and fast dissolution in physiologic fluids. However, this can be controlled for different techniques as incorporation of alloying elements or with the surface modification of the material by coatings. In this context, base Mg-alloys have been used more frequently and new formulations including elements to improve mechanical and biological properties are currently more employed. However, the answer about why not using c.p Mg is still not resolved. This work collects some information around Mg and its alloys offering an overview about what points can be studied in detail in order to made contributions around this topic.

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