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Review article

Moving research direction in the field of metallic bioresorbable stents-A mini-review

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ABSTRACT

In contrast to polymer bioresorbable stents (BRS) that exhibited suboptimal performance in clinical trials due to their deficient mechanical properties, metallic BRS with improved mechanical strength have made their way into the clinic and have demonstrated more promising results. In the roadmap of research and development of metallic BRS, magnesium and iron based biodegradable metal stents had been clinically used, and the zinc based biodegradable metal stents had been trailed in Mini-Pigs. In this mini-review paper, we demonstrate the current technology levels and point out the future R&D direction of metallic BRS. Magnesium based BRS should target for decreasing struct thickness meanwhile balancing with enough supporting strength. Iron based BRS should move towards high efficient absorption, conversion, metabolism, elimination of its degradation products. Zn based BRS should strive to improve mechanical stability, creep resistance and biocompatibility. Future R&D directions of metallic BRS should move towards new materials such as Molybdenum, intelligent stent integrated with degradable biosensors, and new stent with multiple biofunctions, such as NO release.

1. Introduction

Permanent metallic drug-eluting stents (DES) are successfully designed to expand the occluded coronary artery lumen and to restore blood flow, unfortunately the permanent presence of a metallic device inside the coronary artery make it susceptible to late stent thrombosis, restenosis, neoatherosclerosis and lack of normal vessel reactivity. Due to these complications associated with permanent DES, there has been a major shift towards clinical research and development of completely bioresorbable stents (BRS). BRS represents the most ambitious emerging stent technology, and aims to mitigate chronic stent thrombosis, restenosis, and inflammation by serving as a mechanical scaffold long enough for the host artery to remodel and heal before 100% completely absorbing within blood vessel.

At the initial stage, polymeric BRS were designed with different polymer degradation periods (ranging from 3 months to >1 year), drug-release kinetics, and strut thickness. Although researchers anticipated a transformative revolution from "vascular reparative therapy" by BRS at the beginning of its development, subsquent randomised trials and meta-analyses evaluating clinical results of BRS, have raised concerns about the safety and efficacy of the polymeric BRS. Abbott Vascular halted to sale the Absorb bioresorbable vascular scaffold (both the Absorb and the Absorb Gt1 Bioresorbable Vascular Scaffold Systems) as of September 14, 2017 to all countries, not only the United States [1]. Long-term follow-up data about Absorb bioresorbable scaffold have raised a concern about the relatively higher incidence of scaffold thrombosis [2,3].

Metallic stents are superior to their polymeric counterparts in terms of mechanical strength. In competition to polymeric BRS, metallic BRS are fabricated with magnesium-, iron- and zinc-based biodegradable metals, with improved mechanical strength and biocompatibility. The performance of the biodegradable metals is highly dependent on various material factors such as the alloying process, processing history, microstructures and their resultant minitube semi-product properties such as the mechanical strength and degradation rate. Among metallic BRS, Mg-based biodegradable metal stents were reported to have relatively

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weaker mechanical properties and rapid degradation rates, Fe-based biodegradable metal stents has good mechanical properties but faces slow degradation with uncertainty over its biocompatibility, and Zn-based biodegradable metal stents suffer from inferior mechanical properties, slow degradation and lower dosage to induce cytotoxicity. Hereafter the status of the various metallic BRS would be briefly reviewed and the technical problems they are facing at present stage, and the future R&D directions in this field would be proposed.

2. Magnesium alloy BRS should target for thinner struct thickness meanwhile keep enough radial supporting strength

In 2007, Erbel et al. [4] reported the multicentre clinical trial of coronary implantations of bare WE43 Mg alloy BRS(10–15 mm in length and 3.0–3.5 mm in diameter). 63 patients in eight centres with single de novo lesions in a native coronary artery were enrolled. Follow-up studies included coronary angiography and intravascular ultrasound at 4 months and clinical assessment at 6 months and 12 months. The primary endpoint was cardiac death, non-fatal myocardial infarction, or clinically driven target lesion revascularization at 4 months. Diameter stenosis was reduced from 61.5 (SD 13.1%) to 12.6 (5.6%) with an acute gain of 1.41 mm (0.46 mm) and in-stent late loss of 1.08 mm (0.49 mm). The ischaemia-driven target lesion revascularization rate was 23.8% after 4 months, and the overall target lesion revascularization rate was 45% after 1 year. No myocardial infarction, subacute or late thrombosis, or death occurred. Only small remnants of the original struts were visible, well embedded into the intima, examined by serial intravascular ultrasound technique. Angiography at 4 months showed an increased diameter stenosis of 48.4 (17.0%). Neointimal growth and negative remodeling were the main operating mechanisms of restenosis.

In 2013, Haude et al. [5] assessed the safety and performance of WE43 Mg alloy based paclitaxel-eluting absorbable metal scaffold (DREAMS) in symptomatic patients (46 patients with 47 lesions) with de-novo coronary lesions at five European centres. Patients were consecutively assigned to angiographic and intravascular ultrasonographic follow-up at 6 months or 12 months. All patients were recommended to take dual antiplatelet therapy for at least 12 months. Overall device and procedural success was 100%. Two of 46 (4%) patients had target lesion failure at 6 months (both clinically driven target lesion revascularizations), which rose to three of 43 (7%) at 12 months. There were no cardiac death or scaffold thrombosis.

In 2016, Haude et al. [6], assessed the safety and performance of the second-generation WE43 Mg alloy based paclitaxel-eluting absorbable metal scaffold (DREAMS 2G) in 123 patients with 123 coronary target lesions (between 2.2 mm and 3.7 mm) at 13 percutaneous coronary intervention centres in Europe. At 6 months, mean in-segment late lumen loss was 0.27 mm (SD 0.37), and angiographically discernible vasomotion was documented in 20 (80%) of 25 patients. Intravascular ultrasound assessments showed a preservation of the scaffold area (mean 6.24 $\pm$ 1.15 mm^2 post-procedure vs 6.21 $\pm$ 1.22 mm^2 at 6 months) with a low mean neointimal area (0.08 $\pm$ 0.09 mm^2), and optical coherence tomography did not detect any intraluminal mass. No definite or probable scaffold thrombosis was observed.

In 2021, Gutiérrez-Barriose et al. [7] valuated the clinical outcomes of 90 patients treated with magnesium-based bioresorbable scaffolds (MgBRS) in the context of acute coronary syndromes (ACS) at long-term follow-up (24 months). The study also aimed to investigate the Mg BRS performance by angiography and the healing and bioresorption pattern by optical coherence tomography (OCT) at 18 months. Clinical follow-up was performed in all patients at 24 months and angiographic and OCT follow-up in 51.5% of patients at 18 months. Serial OCT was available in 33 patients (36.7%). At a 2-year follow-up, 88.8% were free of symptoms, no cardiac death was reported, and the device-oriented composite event (DOCE): consisting of cardiac death, target vessel myocardial infarction, and target lesion revascularization (TLR) was 13.3%. Stent thrombosis and TLR were observed in 2.2 and 11.1%, respectively. Binary restenosis was observed in 21.7% of cases and in-stent late lumen loss was 0.61 $\pm$ 0.75 mm. By serial OCT imaging, the minimal lumen area was significantly reduced greater than 40% (from 6.12 $\pm$ 1.59 to 3.5 $\pm$ 1.55 mm^2, $p < 0.001$). At follow-up, area stenosis was 44.33 $\pm$ 23.07% and half of the patients presented indiscernible struts. The principal observed mechanism of restenosis was scaffold collapse in most of the cases.

On Sept. 20, 2022, BIOTRONIK [8] announced the presentation of new full-cohort 2-year BIOSOLVE-IV data. The PMS registry enrolled 2, 066 patients worldwide with a large amount of complex patient groups including N-STEMI (18.5%) and diabetic (21.6%) patients as well as cases with B2/C lesions (15.2%) and bifurcation lesions (4.6%). In a poster session at the Transcatheter Cardiovascular Therapeutics (TCT) Conference 2022, principal investigator Prof. Dr. Johan Bennett presented the recent findings and highlighted the low TLF rate and the low scaffold thrombosis rate of Magmaris® Resorbable Magnesium Scaffold (RMS). The latest clinical results prove that Magmaris RMS has an excellent safety and efficacy profile up to 24 months with TLF rates comparable to contemporary available drug eluting stents.

As illustrated in Fig. 1, the Mg alloy BRS underwent over 10 years clinical studies, and previous products exhibited a large strut thickness (around 150 μm) to provide sufficient radial support. such thick struts impose greater arterial injury upon expansion, create greater surface area for thrombosis, and require larger catheters for delivery, which makes their use challenging in interventional cardiology. As depicted by the research on non-biodegradable DES, thinner struts (less than100 μm) produce less arterial injury, faster re-endothelialization and reduce the risk of restenosis and thrombosis. Because of its fundamental impact on vessel response, reducing strut dimension while maintaining radial mechanical support would be the focus for Mg alloy BRS manufacturers.

3. Iron based BRS should move towards high efficient absorption, conversion, metabolism, elimination of its degradation products

Since 2001 pure iron had been demonstrated safe in vascular microenvironment, but with mechanical strength being inferior to 316L stainless steel, long corrosion period and slow clearance of corrosion products. Electroformed Fe film exhibited good biocompatibility, increased corrosion rates and/or high strength but reduced plasticity. By alloying Fe with other elements, the corrosion rate and material strength of resulting Fe based alloys might be increased, but cytocompatibility might be deteriorated due to toxicity of introduced metallic alloying elements.

As illustrated in Fig. 2, after animal testing with various rabbit and porcine models [9], for different implantation time, even with a follow-up of 53 months, the in vivo biodegradation and biocompatibility of various iron-based BRS had been studied. Recently, metallic BRS with a novel intercalated structure by introducing a nanoscale Zn sacrificial layer between the nitrided Fe platform and the sirolimus-carrying poly (d,L-lactide) drug coating was successfully designed [10]. This new kind of PDLLA-Zn-FeN BRS shows a multistage biodegradation behavior, maintaining mechanical integrity at the initial stage and exhibiting accelerated biodegradation at the subsequent stage in both rabbit abdominal aortas and human coronary arteries, where complete biodegradation was observed about 2 years after implantation. The cunning introduction of the nanoscale Zn sacrificial layer with an adjustable thickness effectively contributes to the tunable biodegradation of BRS and allows the reduction of the metallic strut thickness to 53 μm, but with radial strength as strong as that of the current permanent drug-eluting stents.

For the future study on Fe-based BRS, since in general it corrodes at a slow rate for stenting applications and accumulates a voluminous corrosion product that repels neighboring cells and biological matrix and does not appear to be excreted or metabolized at an appreciable rate, the target should be aimed how to enhance the efficiency of

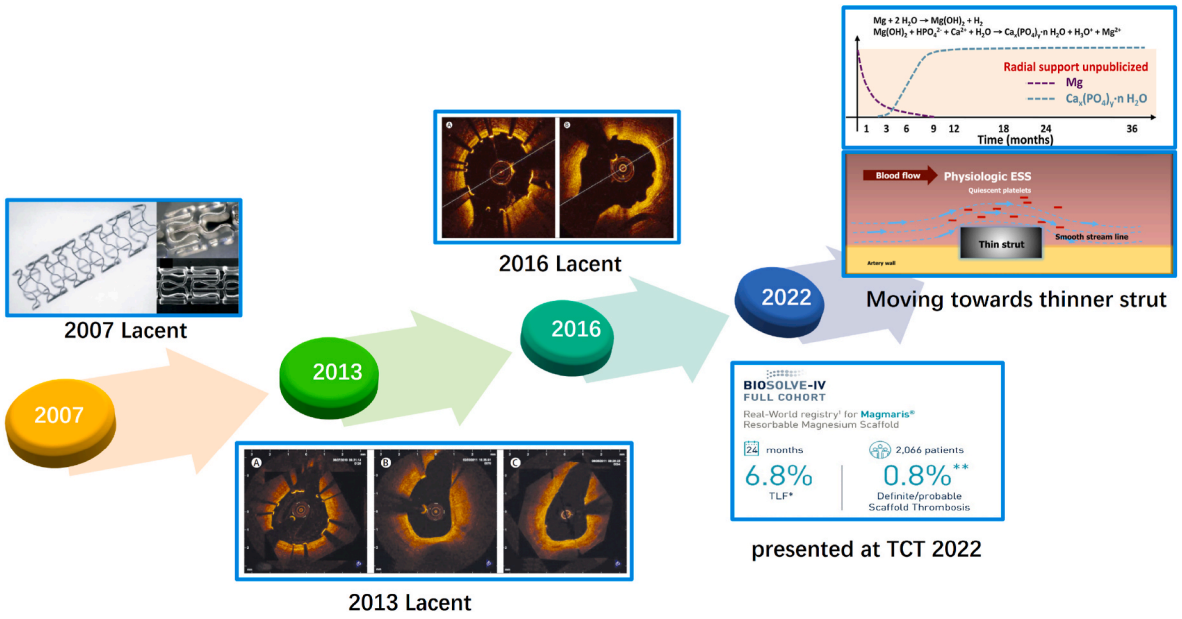

Fig. 1. Moving direction of magnesium alloy BRS.

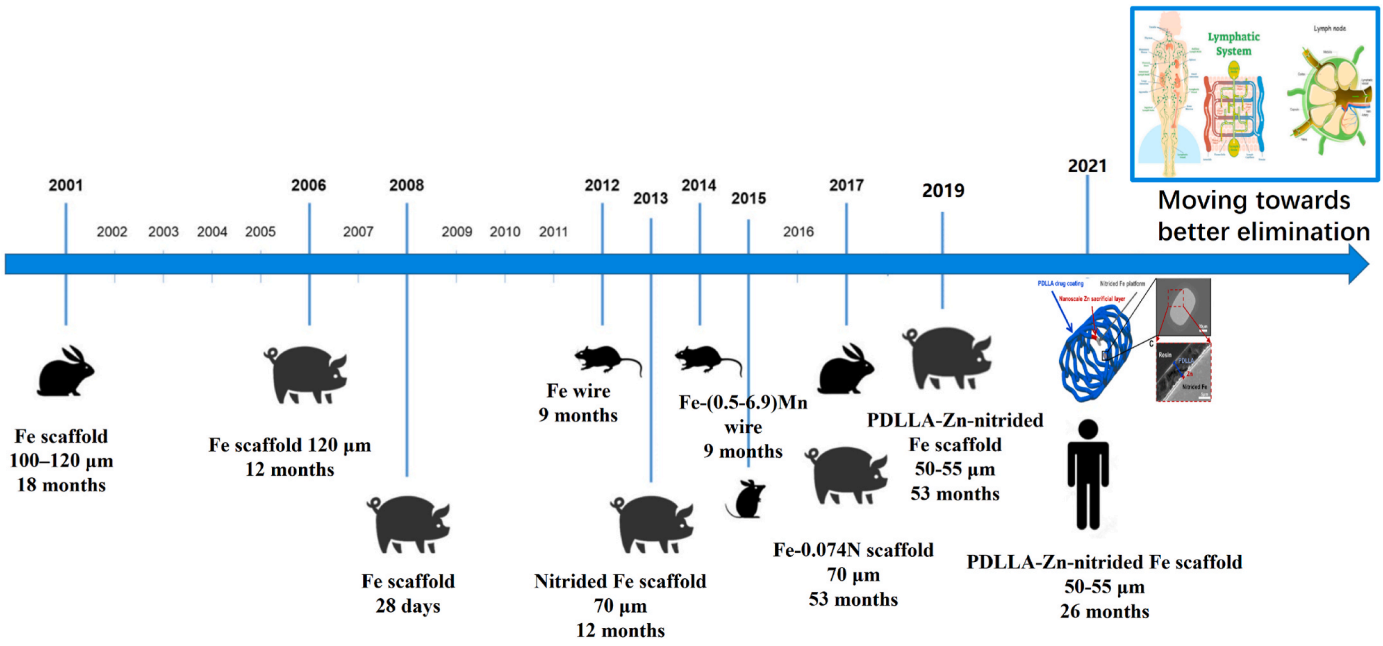

Fig. 2. Moving direction of Fe based BRS.

absorption, conversion, metabolism, elimination of the degradation products of Fe-based BRS. Further study on the lymphatic transport of iron-based particles by macrophages from the implantation site to para-aortic lymphatic nodes are expected, since it would be profoundly important in long-term degradation of bioresorbable iron-based stents and better understanding chronic inflammation [11].

4. Zn based BRS should strive to improve mechanical stability, creep resistance and biocompatibility

Starting from 2017, the feasibility of zinc and its alloys for cardiovascular applications had been studied by animal implantations, such as Pure Zn [12], Zn-0.8Cu [13], Zn-3Ag [14] and Zn-0.02Mg-0.02Cu [15], as illustrated in Fig. 3. The present results revealed that there were no cases of scaffold thrombosis and similar endothelialization properties to Fe and Mg stents in preclinical models, and promising degrees of SMC neointimal hyperplasia and inflammation were also observed.

Looking ahead, some high-strength (ultimate tensile strength >500 MPa) Zn based BMs have already been developed through alloying and plastic working, making their usage in load-bearing environments becomes a reality [16], in which the Zn-0.8Li-0.1Mn alloy exhibited the fracture elongation over 100%, meanwhile had the ultimate tensile strength over 500 MPa, well qualified as stent materials. However, different from Mg and Fe based BMs, Zn based BMs exposed significant "strain-softening" effect that leads to limited uniform deformation. This kind of non-uniform deformation is detrimental to Zn based devices or implants, which will possibly lead to unexpected failure. According to Huang et al. [17], Zn based BMs can be divided into three categories on

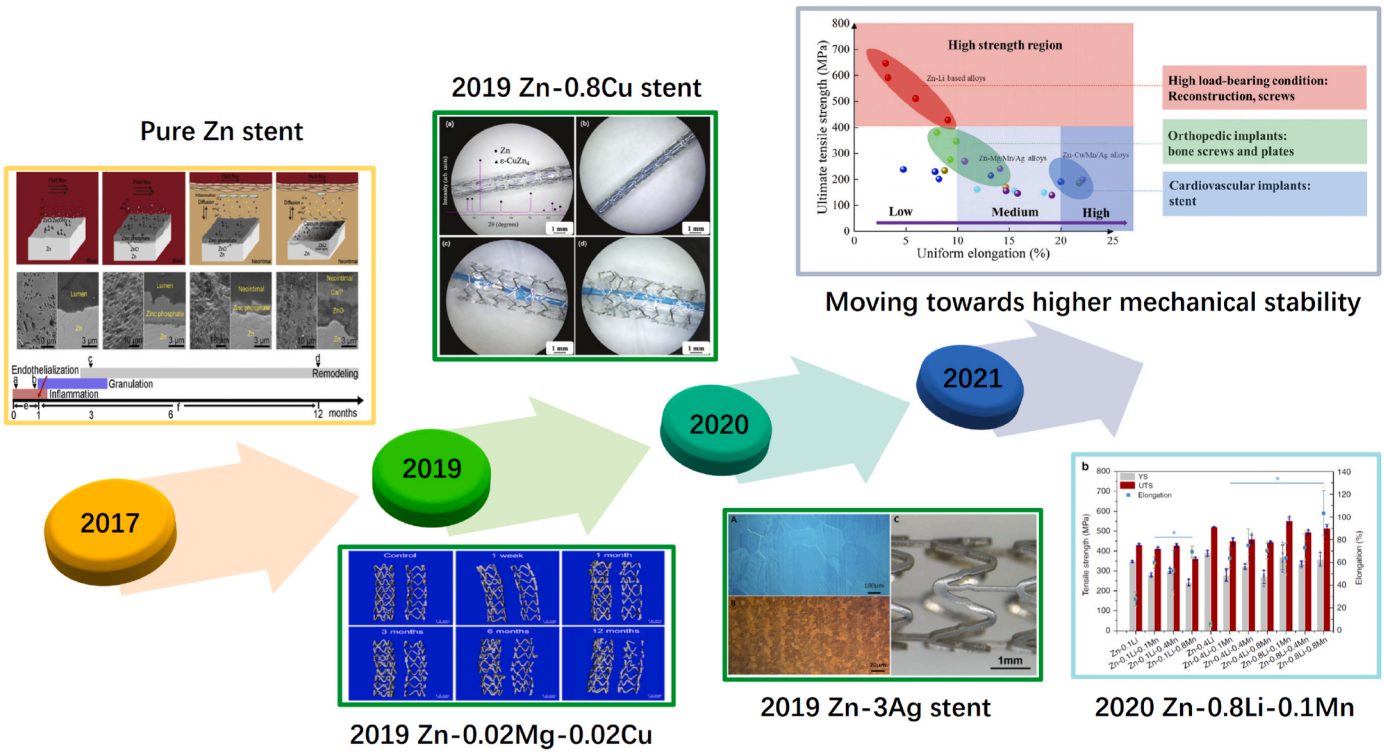

Fig. 3. Moving direction of zinc based stent design.

the basis of tensile strength and uniform elongation terms, i.e. Zn–Li based alloys with high strength and low uniform elongation, Zn–Mg based alloys with medium strength and uniform elongation, and Zn–Cu, Zn–Mn, Zn–Ag based alloys with low strength and high uniform elongation. As for Zn alloys with high uniform elongation (>20%), the considerable uniform elongation is favorable for stent applications.

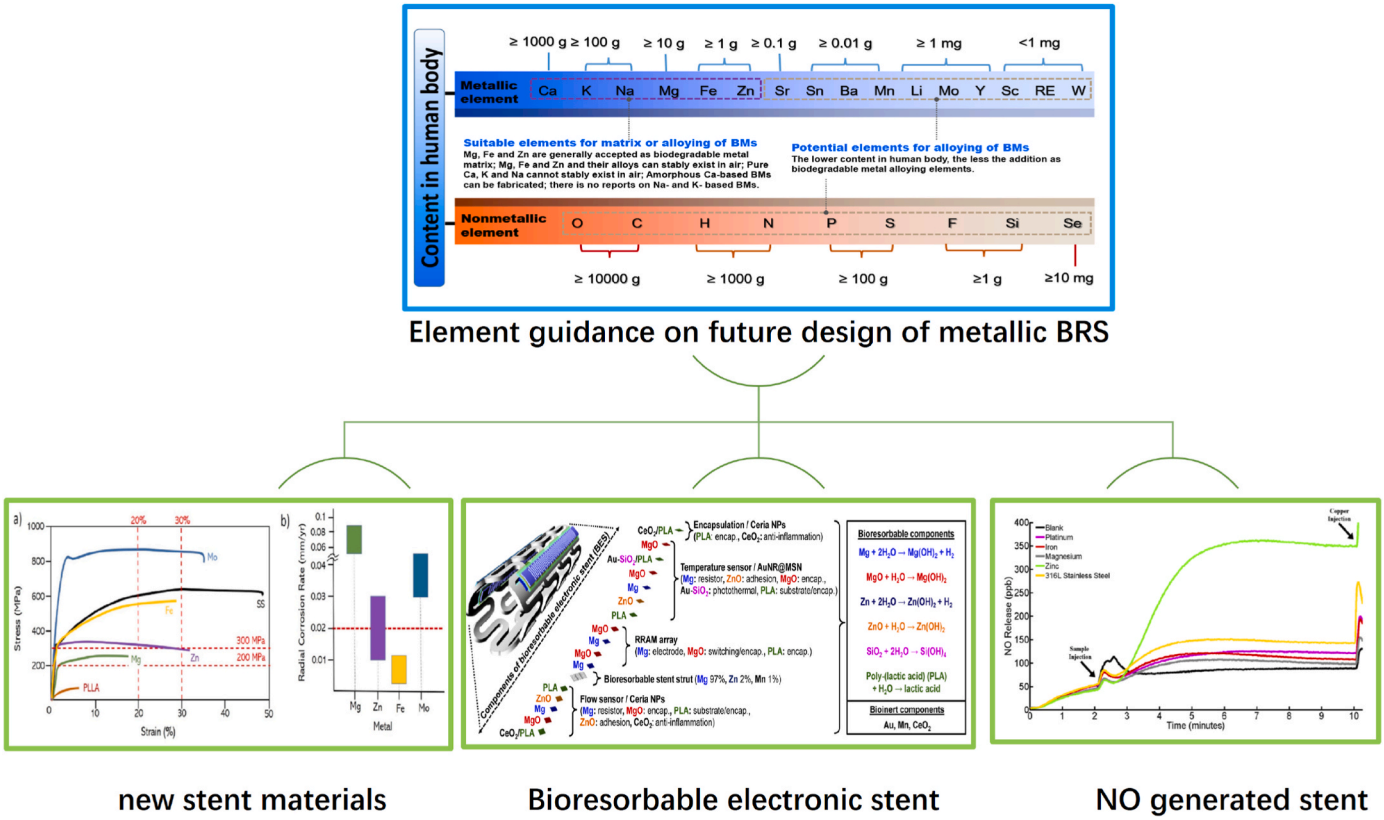

Fig. 4. Future R&D directions of metallic BRS.

Currently some material process technologies, such as equal channel angular pressing, are trying to solve the strain-softening problem.

5. Concluding remarks on future R&D direction of metallic BRS

Metallic BRS should provide spatial and temporal mechanical stability with a degradation rate similar to that of regenerating blood vessel tissue. Corrosion products of the metallic BRS should be biocompatible and promote specific biological effects, such as anti-inflammation, anti-platelet activation, and anti-smooth muscle cell hyperplasia. Therefore future BRS stents require further improvement and validation in terms of (i) mechanical properties; (ii) strut thickness; (iii) biodegradation rate; (iv) inflammatory responses; (v) the rate of device thrombosis; (vi) in-stent restenosis; (vii) the rate of drug-eluting.

The moving directions of R&D of the future metallic BRS are proposed in the following:

(1) New material candidate; In 2019, the present authors [18] proposed the fundamental theory applicable for biodegradable metals, and the metal elements in the periodic table suitable for biodegradable metals include Na, K, Ca, Mg, Fe, Zn, Sr, Sn, Ba, Mn, Li, Mo, Y, Sc, RE and W, as illustrated in Fig. 4 (top). In 2022, Sikora-Jasinska et al. [19] evaluated the mechanical performance of metallic Mo in vitro and the biodegradation properties in vivo, as a potential novel biodegradable material for stent manufacturing. The results demonstrated favorable mechanical behavior and a uniform degradation profile as desired for a new generation ultra-thin degradable endovascular stent material. Moreover, Mo implants in mouse arteries avoided the typical cellular response that contributes to restenosis. There was minimal neointimal hyperplasia over 6 months, an absence of excessive smooth muscle cell proliferation or inflammation near the implant, and avoidance of significant harm to regenerating endothelial cells. Qualitative inspection of kidney sections showed a potentially pathological remodeling of kidney Bowman's capsule and glomeruli, indicative of impaired filtering function and development of kidney disease, although quantifications of these morphological changes were not statistically significant. While promising [20], the in vivo biocompatibility of this new bulk material remains to be evaluated, as molybdenum exists in trace concentrations within the body, possibly hinting at its lower toxicity threshold when compared to Mg, Fe, and Zn based biodegradable metals.

(2) Smart/intelligent metallic BRS integrated with degradable biosensors; Implantable endovascular devices such as bare metal, drug eluting, and bioresorbable stents have transformed interventional care by providing continuous structural and mechanical support to many peripheral, neural, and coronary arteries affected by blockage. Although effective in achieving immediate restoration of blood flow, the long-term re-endothelialization and inflammation induced by mechanical stents are difficult to diagnose or treat. As shown in Fig. 4, Son et al. [21], presented nanomaterial designs and integration strategies for the bioresorbable electronic stent with drug-infused functionalized nanoparticles to enable flow sensing, temperature monitoring, data storage, wireless power/data transmission, inflammation suppression, localized drug delivery, and hyperthermia therapy.

(3) Multi-biofunctional BRS; Recently, Drelich et al. [11] proposed a new paradigm, wherein the appropriate degradation by-products should be envisioned as therapeutic agents, similar to the synthetic drugs impregnated into modern-day DES yet naturally found in the body and therefore less likely to produce toxic effects. One potentially useful application of these metal ions capable of generating NO from endogenous S-nitrosothiols is their use in the fabrication of biodegradable metallic stents capable of generating NO at the stent-blood interface, thereby reducing stent-related thrombosis and restenosis [22].

In summary, there is a bright future for metallic BRS. With more interdisciplinary research works on material design and surface coating engineering technology, there will be more biocompatible, intelligent and vital metallic BRS being developed.

Ethics approval and consent to participate

Not applicable.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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