# BIODEGRADABLE IRON-BASED MATERIALS FOR CARDIAC PURPOSES — WHAT WAS DONE AND WHAT MORE CAN BE DONE?

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**Introduction**

Coronary artery disease (CAD) is characterised by narrowing of the blood vessels that supply oxygenated blood to cardiac muscles: it is responsible for around 20% of all deaths in developed countries [1]. In 1977, for the first time, an angioplasty was performed. This procedure, using a balloon inserted into a narrowed blood vessel and then inflated, enabled the vessel to be restored and prolonged the life of the first 38-year-old patient by 37 years [2]. Balloon angioplasty, however, was limited by unpredictable vessel dissection and recoil and by the high rate of restenosis. Therefore, the next revolution in the treatment of cardiovascular medicine was the introduction of stents, which resulted in both better early results and lower rates of restenosis. At the same time, there were limitations due to stent thrombosis and neointimal hyperplasia resulting in vasoconstriction. In 2007, Mani et al. formulated nine features that an ideal stent should have: (1) good expandability ratio; (2) ability to be crimped on the balloon catheter; (3) sufficient flexibility; (4) sufficient radial hoop strength and negligible recoil; (5) non-toxicity for tissues and all organisms; (6) high thromboresistivity; (7) absence of restenosis after implantation; (8) drug delivery capacity; and (9) adequate radiopacity/magnetic resonance imaging (MRI) compatibility [3]. In the meantime, the idea of biodegradable (or bioresorbable) stents arose. The biggest advantage of biodegradable stents (BDS) is that they disappear when they are no longer needed, which is about six months after the implantation. In this way, all late stent complications, like permanently diminished flow of covered side branches, bleeding problems associated with long term anticoagulation, permanent late fracture abnormal vasomotion and CT/MRI imaging artefacts are omitted. At the same time, BDS provides mechanical support analogous to bare-metal stents. It is also a better solution for still-growing children because it helps avoids a second intervention to remove the implant. This is why the list of features of an ideal stent should include a tenth feature: fully biodegradable.

**Materials used to create bioresorbable stents**

Two types of materials are used to create bioresorbable stents or scaffolds (BRS): polymers and metals. Initially, more attention was paid to polymers, and already in 1998, so over 20 years ago, a scaffold composed of high-molecular-weight poly-l-lactic acid (PLLA) monofilaments) was implanted per Igaki-Tamai into a human coronary artery [4]. The first report, where a total of 25 scaffolds were successfully implanted into 19 lesions of 15 patients, were described and published in 2000. Long-term (>10 years) studies in 50 patients showed that, after three years, no traces of the stent scaffold in the blood vessel could be detected [5]. The results were great, but the device failed to progress as it required a larger guide catheter for implantation than a metal stent, it needed a heated contrast, and it had the lack of a drug coating. However, the proposal to use PLLA in stents was not forgotten, and research is still ongoing. Other biodegradable polymers and copolymers used for research include: poly(ε-caprolactone) (PCL), poly(l-lactide-co-ε-caprolactone) (PLCL), phosphoryl choline (ChoP), etc. Despite very promising results, the polymers also have several disadvantages that limit their use. Compared to metals, polymers have lower values of Young's modulus (0.2–7.0 GPa) than those of metals (54–200 GPa), and generally, have poorer mechanical properties [6]. This makes the spacers in polymer stents thicker than in metal stents, which results in the impossibility of complete expansion as the balloon expands. Therefore, more and more research is being done to create a biodegradable metal stent. Metals degrade in the body through corrosion. Therefore, metals used in first-generation stents, such as stainless steel, nitinol or titanium, which has a high corrosion resistance factor, cannot be used as resorbable materials. From research conducted over the past 20 years, three main metals have emerged that could potentially form biodegradable cardiovascular implants: Fe, Mg and Zn [7-9]. Magnesium BDS are completely biocompatible and have good mechanical properties. However, magnesium has a high corrosion rate, which means it loses integrity when it is still needed. Moreover, it releases hydrogen during degradation that is harmful to cells. Zinc is characterised by good biocompatibility and a corrosion factor adequate to the desired lifetime of the stent. However, its mechanical properties are too weak. It is necessary to introduce modifications to improve the mechanical parameters and, at the same time, not affect the corrosion time. Iron has high strength, ductility, and formability, allowing stents with thinner constructions and struts or fabrication of special shapes, like foils or foams. Unfortunately, in comparison to Zn and Mg, iron has a corrosion rate so low that pure iron can hardly be called "biodegradable". But due to its biocompatibility and excellent mechanical properties, it is worth thinking about modifications that could accelerate corrosion.

In the presentation, the information about the iron properties, its biodegradability and its corrosion test, which can be carried out in immersion mode and during the electrochemical testing will be discussed. Biological properties of iron-based materials, in terms of tissue biocompatibility, cellular biocompatibility, hemocompatibility, and clinical biocompatibility are presented and discussed also. A critical look at the rate of degradation of systems obtained by several different synthesis methods, including: spark plasma sintering, vacuum induction melting, vacuum arc melting, electroforming, powder metallurgy and template-based synthesis of porous materials, as well as by the addition of another phase to the iron, will allow the reader to select methods which are still worth optimizing because they give hope for their use in biomedical applications, and those that they do not provide any chance of obtaining iron-based material as an optimally biodegradable system.

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