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Development of a new niobium-based alloy for vascular stent applications

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ABSTRACT

This study was performed in order to develop a new stent material that would provide reduced MR image artifact compared to current stent materials. Alloy design rationale is initially presented and following this the development of a Nb–28Ta–3.5W–1.3Zr alloy is described, including the manufacture of stent tubing. Tensile testing of this new alloy showed that it had approximately twice the yield strength of current Nb–1Zr material with a 25% higher elastic modulus. The new alloy was also confirmed to have suitably low magnetic susceptibility. Mechanical testing of demonstration coronary stents made from the new alloy were shown to have acceptable compression strength and elastic recoil performance. It is concluded that this new Nb–28Ta–3.5W–1.3Zr alloy is a practical candidate stent material for both coronary applications and peripheral uses such as carotid or intracranial stenting, where reduced MR image artifact would be beneficial.

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1. Introduction

The use of metallic stents for the treatment of coronary and peripheral vascular disease is now a standard practice. Successive iterations of coronary stents have seen restenosis levels reduced to below 10%, particularly with the relatively recent introduction of drug eluting stents (Ong and Serruys, 2005). The majority of the commercially successful coronary stents are made from materials such as 316L stainless steel or cobalt–chromium-based alloys such as L605 and MP35N (Mani et al., 2007). Selection of these materials has been primarily driven by mechanical performance requirements and to a lesser extent by the availability of fabrication technologies. Whilst biocompatibility was a significant factor, prior implant experience in orthopaedic applications contributed to what is now widespread acceptance of these materials.

It was however somewhat fortunate that these materials had reasonable compatibility with the imaging tools most widely used during stent implantation. During implantation, the location and deployment of the stent is typically monitored by x-ray fluoroscopy. The attenuation of x-rays by the stent material allows the device to be imaged, with sufficient accuracy to ensure proper placement and deployment against the vessel wall. A number of approaches have been used to more finely tune radiopacity, such as coatings (Reifart et al., 2004) or marker bands made from dense noble metals (Wiskirchen et al., 2004). These have had varying degrees of success but overall, the use of stainless

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steel and cobalt–chromium alloys has been acceptable from an x-ray fluoroscopy perspective. Material such as nitinol has been more challenging and the wide use of this material in peripheral stenting applications is dependent on radiopacity enhancement through markers or coatings (Stoeckel et al., 2004).

Similarly, during follow-up angiography to assess for patency, stents made from stainless steel or cobalt–chromium perform well under x-ray fluoroscopy, allowing detection of restenotic tissue or thrombus within the stent lumen. However recent years has seen a rapid development in new imaging modalities such as computed tomography (CT) and magnetic resonance imaging (MRI). While x-ray fluoroscopy will continue to be the preferred imaging technique during interventional procedures, these new methods are increasingly being used for screening and follow-up procedures. CT angiography can provide significantly more information on the configuration and condition of the vessel and stent due to the three-dimensional nature of the data collected. This has resulted in rapid take up of CT for non-interventional imaging, particularly for coronary vessels (Schoenhagen et al., 2004; Ehara et al., 2006). In addition, MR offers advantages in terms of eliminating both ionizing-radiation- and iodine-based contrast agents as well as being non-invasive for some procedures. MR angiography for the coronary vessels is challenging due to insufficient resolution and relatively slow image capture combined with vessel motion artifacts (Woodward et al., 2000). These issues are being addressed with on-going developments by the large imaging companies. However, MR is already seeing increased use for peripheral angiography where these aspects are less of an issue (Rofsky and Adelman, 2000).

However, challenges arise when it is desired to use MR angiography for a stent follow-up procedure, or for a screening procedure on a vessel with a previously implanted stent. The paramagnetic nature of austenitic stainless steel and cobalt–chromium stents causes a localized distortion of the magnetic fields resulting in loss of signal which ultimately shows as an artifact on the collected image. In the case of these paramagnetic materials the artifact usually obscures the stent lumen and most often extends well beyond the boundary of the device itself (Hug et al., 2000; Nitatori et al., 1999). This can prevent full or proper interpretation of the data. This artifact problem is more critical on coronary stents than peripheral sizes and furthermore, many peripheral stents are made from nitinol which has lower paramagnetism and therefore less artifact (Lenhart et al., 2000). However in summary, magnetic induced artifact is a problem for MR imaging of both peripheral and coronary devices and while imaging of peripheral devices is feasible to some extent, imaging of coronary stents is not practical. A need therefore exists to provide a stent material which meets all the regular requirements for stent performance, but which will also provide reduced image artifact during MR angiography or during any other MR imaging procedure. This ideal material does not exist and the study reported here aimed to develop and evaluate a niobium-based alloy for this purpose.

Table 1 – Bulk magnetic susceptibility values for selected metals and alloys

Material	Magnetic susceptibility, χ
Ti	182×10^{-6}
Ta	178×10^{-6}
Nb	237×10^{-6}
W	77.2×10^{-6}
Zr	109×10^{-6}
Mo	123×10^{-6}
Cr	320×10^{-6}
Nitinol	245×10^{-6}
Stainless Steel (austenitic)	$3520–6700 \times 10^{-6}$
Ni	600
Co	250
Fe	200,000

2. Alloy design rationale

One of the first selection criteria was to consider only compositional elements which have low bulk magnetic susceptibility but which also have appropriate mechanical characteristics. Magnetic susceptibility is a measure of the extent to which a material becomes magnetized in a magnetic field. Table 1 lists the magnetic susceptibility (χ) for some of the relevant elements and alloys as originally described by Schenck (1996). Units shown are in the SI system, which are dimensionless.

Niobium, tantalum and titanium are all immediate candidates due to their low magnetic susceptibility and useful mechanical properties. Table 2 shows some basic mechanical property data for these elements as well as for some related commercially available alloys. All data refer to the material in the annealed condition, which is normally desirable from a stent durability perspective.

Pure titanium and commercially available Ti alloys were ruled out due to having relatively low elastic modulus and only moderate ductility, in comparison to stainless steel. These are important characteristics when considering the expansion behaviour and durability of balloon expandable stents. Stent materials need to have a balance of relatively high elastic modulus combined with a significant plastic deformation capability to ensure good expansion and durability without risk of elastic recoil or strut fractures. It is worth noting that while there are many other well-known titanium alloys being developed for orthopaedic implant applications, the mechanical property requirement is significantly different. Specifically, the desire in these applications is to decrease the elastic modulus so that it more closely matches the behaviour of bone (Niinomi, 2008). Even when titanium is alloyed with relatively high elastic modulus constituents, the additions invariably result in a decrease in modulus, as demonstrated in the case of tantalum additions to titanium (Zhou et al., 2004).

Tantalum has been used in the past with some degree of success for both the Wiktor coronary stent (Vaishnav et al., 1994) and the Strecker peripheral stent (Long et al., 1995). However, the possibility of Ta alloy development was ruled out as it was considered that the high density of the material would result in excessive radiopacity when imaged

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