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Non-invasive imaging of bioresorbable coronary scaffolds using CT and MRI: First in vitro experience☆,☆☆

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ABSTRACT

Background: Accurate assessment of coronary stents after PCI using non-invasive imaging remains challenging despite technological improvements. New bioresorbable vascular scaffolds (BVS) have recently become available promising improved non-invasive imaging properties, which however have not be examined specifically yet. Therefore we investigated CT and MRI visualization properties of the only two CE-marked coronary BVSs.
Methods: The Abbott Absorb and the Elixir DESolve BVS were placed in plastic tubes filled with contrast agent and scanned with a latest generation CT respectively MR system. For CT image quality was assessed by two blinded, independent readers and in-scaffold diameter difference as well as in-scaffold attenuation difference were measured. For MRI in-scaffold signal intensity, in-scaffold lumen visibility and in-scaffold signal homogeneity were measured.
Results: In CTA both BVSs showed no significant difference to nominal tube diameter (DESolve 101%, Absorb 100%) and to nominal tube attenuation (DESolve 96%, Absorb 98%) and were both rated with the highest score for unrestricted lumen visualization.
In MRA both BVSs showed unimpaired signal intensity (DESolve 103%, Absorb 100%), lumen visibility (DESolve 92%, Absorb 89%) and lumen homogeneity (DESolve SD 7.1%, Absorb SD 9.5%) when compared to the unstented tube. There was no significant difference between CTA and MRA results of both BVSs.
Conclusions: Coronary BVSs show no relevant impairment for subjective and objective measures of in-stent lumen visualization by CT and MRI and will therefore allow reliable non-invasive assessment of coronary artery patency after PCI with deployment of a BVS, which is an (additional) advantage when compared to conventional stents.

1. Introduction

Coronary artery disease (CAD) is still one of the leading causes of death and disability in the developed countries [1]. Therefore percutaneous coronary intervention (PCI) has become one of the most frequently performed therapeutic procedures in medicine [2]. The main complication after coronary stent implantation is the occurrence of in-stent restenosis (ISR). Its clinical incidence, however, has been significantly lowered with the usage of drug eluting stents (DES) compared to the former bare metal stents (BMS). Nevertheless, ISR still occurs in about 5% of all cases [3]. Therefore accurate assessment of the patency of coronary stents after PCI is a common and relevant task usually completed by conventional coronary angiography (CCA) [4]. This procedure, however, represents an additional risk for complications and patient discomfort.

For the primary evaluation of patients with a low-to-moderate pretest-probability of suspected CAD non-invasive imaging by computed tomography (CT) and (in certain conditions) stress magnetic resonance imaging (MRI) have already evolved as recommended diagnostic procedures in international guidelines [5,6]. Nevertheless, non-invasive imaging after coronary stent implantation by CT as well as by MRI still is not an established diagnostic procedure [4] because of persistently relevant numbers of non-diagnostic examinations, which are mainly due to stent artifacts [7–9] despite distinct technical improvements and promising research results in the last decades [10–13].

Aside from the advancements in imaging technique, the field of the coronary stents itself is also progressing and the use of new stent materials implicated also further artifact reductions [14,15]. Lately a new generation of coronary intervention devices, the bioresorbable vascular scaffolds (BVSs), has become available for the mass market which

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consist of bioresorbable poly-L-lactic acid (PLLA) polymers. BVSs showed encouraging clinical results in first short- to midterm studies and promise improved non-invasive imaging properties without relevant artifacts [16–21]. Nevertheless, the genuine imaging characteristics of these BVSs have not been systematically examined yet.

Therefore, the present study aims to investigate CT and MRI visualization properties of the only two CE-marked and most commonly deployed coronary BVSs [22] in a well established in vitro setting [14, 23–37].

2. Methods

2.1. Evaluated BVSs and experimental setup

The only two CE-marked coronary BVSs (see Table 1) were studied in a previously established in-vitro setup [37]. Prior to imaging, each scaffold was placed into a plastic tube with an inner diameter of 3 mm, simulating a coronary artery. The plastic material had a thickness <0.3 mm with its CT number being comparable with that of a vessel wall (35 HU).

For CT imaging, the tube was filled with Iohexol (300 mg Iohexol/mL; Accupaque 300; GE Healthcare, Braunschweig, Germany), which was diluted with saline solution to a CT number of 320 HU at 100 kVp, and sealed at both ends. The tube finally was placed in a plastic container (36 × 24 cm) filled with vegetable oil to simulate epicardial fat. The density of the oil was calibrated to measure −95 HU at 100 kVp. Fig. 1 illustrates the phantom setup. The phantom was then positioned on the CT scanner table in the gantry parallel to the z-axis of the scanner.

For MR imaging, the tube was filled with gadoteric acid (Dotarem, Guerbet GmbH, Sulzbach, Germany) which was diluted with saline solution to a concentration of 25 mmol/L (1:20 dilution of the standard preparation), and sealed at both ends. The tube was then placed in a plastic container (36 × 24 cm) filled with water. The phantom was then positioned in the center of the magnet with an orientation parallel to the z-axis of the scanner.

2.2. CT acquisition parameters

CT data were acquired on a latest-generation 256-section CT machine (iCT; Philips Healthcare, Best, The Netherlands) with a simulated electrocardiogram (ECG) signal at a heart rate of 60 beats/min for prospectively ECG-triggered data acquisition. Clinical routine cardiac scanning parameters were used for all scans without specific optimization (compare to [38, 39]). Scanning parameters were identical for all scans: slice collimation: 128 × 0.625 mm, rotation time: 0.27 s, tube current-time product: 125 mAs, and tube potential: 100 kV. The reconstructed field of view was set to 250 mm with a pixel matrix of 512 × 512.

All raw data were reconstructed on an offline workstation by using a slice thickness of 0.67 mm and an increment of 0.35 mm with the use of filtered back projection (FBP) and a dedicated cardiac convolution kernel (CB).

All quantitative analyses were performed with a fixed window width of 1500 HU and a window center of 300 HU as previously recommended [14,31,32].

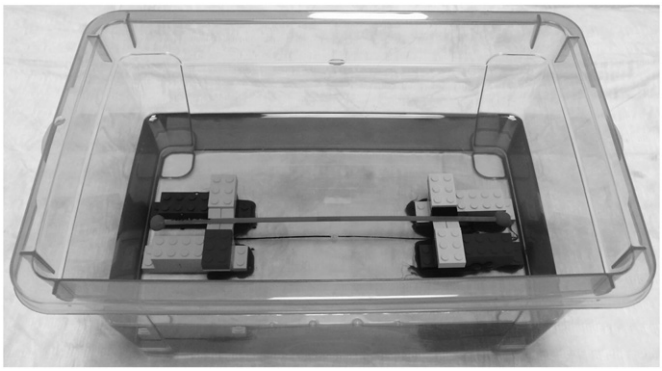

Fig. 1. Photograph of the phantom setup. The tube with the scaffold is filled with contrast medium and positioned in a plastic container with surrounding liquid.

2.3. CT data analysis

For readout, multiplanar reformats (MPR) longitudinal and perpendicular to the scaffold axis were reconstructed on the scanner's standard workstation (IntelliSpace Portal; Philips Healthcare, Best, The Netherlands) with a thickness equal to that of the underlying slice stack (Fig. 2).

CT blooming artifacts mainly affect the evaluation of stent/scaffold patency by altered luminal attenuation values and by artificial lumen narrowing. Additionally to the assessment of these objective parameters a subjective qualitative readout was performed using a 3-point Likert scale.

In-scaffold diameter difference was determined as follows: first, the in-scaffold diameter was measured in the center of the scaffold on the longitudinal reformats using an electronic caliper tool (average of 4 measurements). Then the difference between the measured and the true plastic tube diameter was calculated as percentage.

Luminal attenuation difference across the scaffold was determined as follows: first, the CT number inside the scaffold lumen was measured using the longitudinal reformats (average of 2 measurements). The regions of interest (ROIs) for these measurements were chosen as large as possible and placed in the center of the scaffold lumen, carefully avoiding the inclusion of scaffold struts or blooming artifacts of the radio-opaque markers at each end. Then, the CT number in the vessel lumen outside the scaffold was measured (average of 2 measurements: proximal and distal to the scaffold). The difference in attenuation as percentage across the scaffold was calculated as follows: attenuation difference = in-scaffold CT number divided by CT number outside the scaffold.

Qualitative readout was performed by two blinded and independent readers (R1 and R2) on images that were displayed separately and magnified by a zoom factor of 5 without interpolation. The visibility of the in-scaffold lumen was evaluated on a 3-point Likert scale as follows: 1 = in-scaffold lumen not delineated due to severe artifacts; 2 = partially delineated but of moderate quality; 3 = delineated with good quality.

Table 1
Summary of types, manufactures, materials, dimension and attributes of scaffolds that were used in the coronary artery phantom.

Coronary BVSs used in this study						
Name	Manufacturer	Material/drug	Diameter	Length	Strut thickness	Radio-opaque markers
DESolve	Elixir Medical	PLLA/novolimus	3 mm	14 mm	150 μm	2 at each end
Absorb	Abbott	PLLA/everolimus	3 mm	12 mm	150 μm	2 at each end