



## In vitro evaluation of 56 coronary artery stents by 256-slice multi-detector coronary CT

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### ABSTRACT

**Objective:** We sought to investigate stent lumen visibility of 56 coronary stents with the newest 256-multi-slice-CT (256-MDCT) technology for different reconstruction algorithms in an in vitro model.

**Background:** Early identification of in-stent restenosis (ISR) is important to avoid recurrent ischemia and prevent acute myocardial infarction (AMI). Since angiography has the disadvantage of high costs and its invasiveness, MDCT could be a convenient and safe non-invasive alternative for detection of ISR.

**Material and methods:** Percentages of in-stent lumen diameter and in-stent signal attenuation (measured as contrast-to-noise ratio (CNR)) of 56 coronary stents (group A  $\leq 2.5$  mm; group B = 2.75–3.0 mm; group C = 3.5–4.0 mm) were evaluated in a coronary vessel in vitro phantom (iodine-filled plastic tubes) employing four different reconstruction algorithms (XCD, CC, CD, XCB) on a novel 256-MDCT (Philips-iCT, collimation = 128 mm  $\times$  0.625 mm; rotation time = 270 ms; tube current = 800 mA s with 120 kV). Analysis was conducted with the semi-automatic full-width-at-half-maximum (FWHM) method. *P*-values  $< 0.05$  were regarded statistically significant.

**Results:** In-stent lumen diameter  $> 60\%$  for group C stents was significantly larger and CNR was significantly lower (both  $p < 0.05$ ) for sharp kernels (CD; XCD) when compared to groups A/B. The FWHM-method showed significantly smaller in-stent lumen diameter ( $p < 0.05$ ) when compared to the manual method. **Conclusion:** 256-MDCT could potentially be employed for clinical assessment of stent patency in stents  $> 3.0$  mm when analysed with cardio-dedicated sharp kernels, although clinical studies corroborating this claim should be performed. However, stents  $\leq 3.0$  mm reconstructed by soft kernels revealed insufficient in-stent lumen visualisation and should not be used in clinical practice.

Further improvements in spatial and temporal image resolution as well as reductions of radiation exposure and image noise have to be accomplished for the ambitious goal of characterising both CT coronary artery anatomy and in-stent lumen.

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### 1. Introduction

Percutaneous coronary intervention (PCI) is the treatment of choice in (a) patients with acute coronary syndrome (ACS), (b) in symptomatic patients with chronic coronary artery disease (CAD) and symptoms of concomitant myocardial ischemia as well as in (c) acute myocardial infarction (AMI) [1,2]. Stent placement during PCI has become the reference procedure for clinical treatment of these patients rendering former balloon angioplasty a niche procedure. Despite the widespread use of drug eluting stents (DES), in-stent restenosis (ISR) has remained the major limitation of PCI [3]. Since ISR, aside from causing angina, is also associated with significant morbidity and mortality [3], precise diagnosis of potential ISR is of high clinical relevance. Approximately 600,000 stent procedures are annually performed in the US [1] leading

**Abbreviations:** AMI, acute myocardial infarction; BMS, bare metal stent; CAD, coronary artery disease; DES, drug eluting stent; ISR, in-stent restenosis; MDCT, multi-detector CT; PCI, percutaneous coronary intervention.

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to ISR in about 20–30% of bare metal stents (BMS) and ~10% of drug eluting stents (DES) [4]. Therefore, a large number of patients have to be examined by conventional coronary angiography for exclusion of ISR, contributing considerably to health care cost and exposing the patient to the risk of an invasive procedure [5]. Therefore, a non-invasive assessment of ISR would be of great clinical and considerable socio-economic importance [6].

Recently, novel 64-slice multi-detector single- and dual-source CT systems [7–10] (MDCT/DSCT) offered isotropic voxel resolution up to 0.4 mm, 83 ms temporal resolution and cardio-dedicated sharp kernel reconstruction methods [11] which led to considerably improved diagnostic accuracy for the detection of significant CAD [12]. In previously stented patients, there was encouraging evidence from 64-MDCT not only with respect to detecting stent occlusion but also to visualise low attenuation filling defects which are noted as indirect signs of ISR [8,13].

The influence of stent strut design, stent material and lumen diameter on CT image quality is well known from former 16- to 64-MDCT in vitro studies [9,10,14,15]. From these studies there was clear evidence that with increasing CT-detector rows stent lumen visibility would gradually improve.

Hence, this is the first in vitro study with 256-MDCT to investigate lumen visibility of various recent commercially available and experimental coronary artery stents of different types and sizes with state-of-the-art 256-MDCT reconstruction algorithms.

## 2. Materials and methods

Fifty-six coronary artery stents of different manufacturers, materials and strut designs were studied and are summarized in Table 1.

Stents were expanded at the nominal pressure of their respective stent delivery systems in a coronary vessel phantom which was made of a plastic tube with a wall thickness of 0.5 mm. Stents with a diameter up to 3 mm were implanted into tubes with an inner diameter of 3 mm. Larger stents were positioned in tubes with an inner diameter of 4 mm.

As previously published [9], after stent deployment the tube lumen was filled with contrast media (Ultravist 370, Schering AG, Berlin, Germany) and diluted to a radio-density of approximately 250 HU (Hounsfield units).

Tubes were sealed at both ends and positioned in a plastic container filled with vegetable oil with an adjusted radio-density of approximately –70 HU by adding iodine, simulating epicardial fat tissue. Stents were placed parallel to the z-axis of the scanner.

Imaging was performed in a 256-slice CT-scanner (Brilliance iCT, Philips Healthcare, Cleveland, OH, USA) with the following parameters: helical scan mode, collimation = 128 mm × 0.625 mm, pitch = 0.18, tube rotation time = 270 ms, effective tube current = 800 mAs, tube voltage = 120 kV, field-of-view = 180 mm, matrix = 512 × 512, slice thickness = 0.67 mm, artificial ECG-gating (60/min) with retrospective reconstruction at 75%.

Images were reconstructed with four different convolution kernels: (a) Xres detailed stent (XCD), (b) cardiac sharp (CC), (c) cardiac detailed stent (CD) and (d) Xres standard (XCB) on a dedicated CT workstation (Extended Brilliance Workspace V 3.5.3.1020, Philips Healthcare, Cleveland, OH, USA) with a window setting of 300/1200 HU as previously described [9]. While XCB is usually employed for assessment of coronary artery disease, XCD and CD are dedicated stent kernels.

Stent lumen diameters were evaluated with two methods: (a) by subjectively drawing the estimated lumen diameter with an electronic caliper (manual method) and (b) semi-quantitatively by application of the full-width-at-half-maximum method (FWHM-

method) which has been validated previously [9]. In either method lumen diameters were assessed in axial orientation at proximal, middle and distal parts of the stent and mean values were employed for statistical analysis.

To test the influence of different stent diameters on CT lumen visibility, all coronary stents were assorted into three groups of incremental diameter size: group A = 2.25–2.5 mm, group B = 2.75–3.0 mm and group C = 3.5–4.0 mm.

### 2.1. Lumen attenuation

Signal densities inside a deployed stent lumen are most often increased or rarely decreased due to beam hardening and partial volume effects, both described as attenuation [9,10]. To quantify this effect, two types of attenuation were defined: (a) tube lumen attenuation (TLA) inside the tube and (b) stent lumen attenuation (SLA) inside the deployed stent, both filled with contrast media (~250 HU). Values for TLA and SLA were measured in a coronary view by a region of interest (ROI) technique. For TLA, two ROIs were positioned outside the stent inside the tube lumen and a weighted mean value was calculated. For SLA, a third ROI was placed inside the stent lumen omitting strut artifacts.

### 2.2. Contrast- and signal-to-noise ratio (CNR and SNR)

Contrast-to-noise ratio (CNR) was defined as the difference between the values of SLA minus TLA, divided by the image noise. Image noise was defined as the mean value of the standard deviations of three axial ROIs in the surrounding oily fluid outside the tube lumen.

$$\text{CNR} = (\text{SLA} - \text{TLA}) / \text{Std}_{\text{noise}}.$$

Furthermore, coronary stents were subdivided into three types according to previously suggested thresholds [10] for the assessment of stent lumen visibility: type I = good visualisation with measured stent diameter > 60% of nominal diameter, type II = moderate visualisation between 50% and 60% and type III = insufficient visualisation with less than 50%.

### 2.3. Statistics

Data were expressed as mean ± 1 standard deviation. Differences between any two groups were compared by Student's *t*-test for continuous variables. Continuous variables among more than two groups were compared by one-way ANOVA with post hoc analysis with Bonferroni adjustment for multiple comparisons.

For all analyses,  $p < 0.05$  was regarded statistically significant. All statistical analyses were carried out using MedCalc 9.4.1.0 (MedCalc Statistical Software bvba, Belgium).

## 3. Results

All 56 coronary stents were reconstructed using the aforementioned four convolution kernels. Fig. 1 shows longitudinal through-plane 0.67 mm thick reformations of all stents using the XCD kernel.

### 3.1. Percent lumen diameter of the FWHM and the manual measurements

Mean lumen diameters for the FWHM and manual method for the four different kernels are given in Fig. 2. In general, the FWHM method showed significantly smaller percentages of lumen diameter for three of the four kernels (XCD, CC, XCB,  $p < 0.05$ ), when

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