First clinical evaluation of a new angiographic enhanced stent imaging technology.

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Background:

- Coronary angiography has limitations in the assessment of stent expansion. Intravascular ultrasound (IVUS) can evaluate more accurately struts apposition and underexpansion but adds time and cost to a percutaneous coronary intervention (PCI).
- Stent underexpansion during PCI is the main cause of stent thrombosis and restenosis. Enhanced stent imaging techniques (ESI) permit a detailed visualization of stent architecture, position and deployment.

Objectives:

- The aim of this study was to compare a novel vendor independent ESI technique, StentEnhancer® (Pie Medical Imaging; Maastricht, The Netherlands) to the earliest described StentBoost® (Philips Medical Systems; Eindhoven, The Netherlands) which can only be used with Philips angiograms.

Methods:

- The StentEnhancer algorithm computes a single image in which the visibility of a deployed stent is improved using an algorithm that automatically detects the balloon markers of the stent or post-dilatation balloon. After background subtraction all frames are transformed to a common reference frame. Weighted averaging is used to combine the resulting images into a single image. After image sharpening and contrast adjustment, the enhanced stent image is generated.

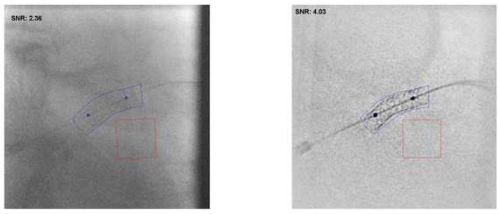

Figure 1: Original angiographic frame (left) and Enhanced stent image

	Observer 1		Observer 2	
	SE	SB	SE	SB
Stent struts visibility	74%	63%	59%	62%
Stent outline visibility	94%	86%	82%	76%
Proximal edge visibility	77%	66%	79%	85%
Distal edge visibility	66%	69%	68%	70%
Global ESI quality (0-4)	3.06 (76.5%)	2.83 (71%)	2.88 (72%)	2.94 (73.5%)

Table 1 : Evaluation of the features of StentEnhancer (SE) and StentBoost (SB)

- We analyzed a total of 53 coronary stents implanted in 53 patients between September 2015 and May 2016. Two different operators, blinded to each other, compared the features of the enhanced stent images obtained by each technique, StentEnhancer and StentBoost. Images quality evaluation was based on four criteria: 1) Stent struts visibility 2) Proximal edge visibility 3) Distal edge visibility and 4) Stent outline visibility.
- Signal-to-Noise Ratio (SNR) was compared from the original image, and in the StentEnhancer and StentBoost images. The Signal-to-Noise Ratio of an image is defined as the ratio of the average signal value μ_{sig} to the standard deviation σ_{bg} of the background. The signal value was defined as an area including the stent and stent boundaries (blue area in figures 1 & 2). The background was calculated in an uniform area where no/minimal background structures were present (red area in figures 1). Two average signal values μ_{sig} were computed: for all stent, and for struts only.

Results:

- Mean age was 67±13 years and 34% (n=18) of our patients were females. PCI was performed on the LAD in 38% of cases (n=20), the RCA in 36% (n=19), the LCx in 23% (n=12) and the LMCA in 3% (n=2). Important calcifications were present in 45% of cases (n=24), stitches in 8% (n=4). Long stents (>30 mm) were used in 38% of PCIs (n=20) and in 28% (n=15) of cases we used two or more guidewires.
- Global StentEnhancer quality was 76.5% (observer 1) versus 72% (observer 2) and compared favorably to StentBoost: 71% (obs 1) versus 73.5% (obs 2). Stents length, calcifications, number of guidewires or presence of stitches did not significantly interfere with enhanced image quality. However StentEnhancer appears more robust in frames with multiple wires/balloons, as illustrated in figure 3.

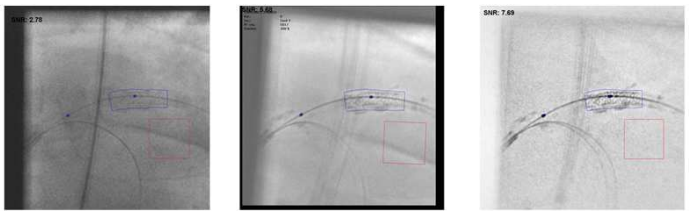

Figure 2: Original frame and StentBoost (middle) and StentEnhancer results where underexpansion can be detected from the important calcifications outside of the stent. SNR in original image 2.8, and respectively 5.7 and 7.7 on the StentBoost and StentEnhancer images (in area around stent).

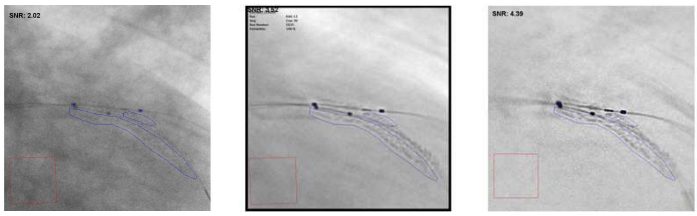

Figure 3: Challenging original frame with two balloons in a treated bifurcation. StentBoost (middle) and StentEnhancer results with SNR calculated with method 2, with the blue area drawn around only struts. In original image SNR=2.0, and respectively 3.5 and 4.4 on the StentBoost and StentEnhancer images.

Conclusion:

- StentEnhancer allows an adequate stent visualization and improve the angiographic guidance of stent deployment similar to a reference method. On average, the SNR of the original frames was 2.2±0.3 and was significantly higher with StentBoost (3.2±1.0) and StentEnhancer (4.3±1.5, p<0.01 vs SB)
- The main advantages of StentEnhancer are to be fully independent of the vendor's angiography system and to be used off-line in a corelab setting.

1. Topol EJ, Nissen SE. Our Preoccupation With Coronary Luminology The Dissociation Between Clinical and Angiographic Findings in Ischemic Heart Disease. Circulation. 15 oct 1995;92(8):2333-42.
2. Fujii K, Mintz GS, Kobayashi Y, Carlier SG, Takebayashi H, Yasuda T, Moussa I, Dangas G, Mehran R, Lansky AJ, Reyes A, Kreps E, Collins M, Colombo A, Stone GW, Teirstein PS, Leon MB, Moses JW. Contribution of Stent Underexpansion to Recurrence After Sirolimus-Eluting Stent Implantation for In-Stent Restenosis. Circulation. 2004;109:1085–1088.
3. Fujii K, Carlier SG, Mintz GS, Yang Y, Moussa I, Weisz G, Dangas G, Mehran R, Lansky AJ, Kreps EM, Collins M, Stone GW, Moses JW, Leon MB. Stent underexpansion and residual reference segment stenosis are related to stent thrombosis after sirolimus-eluting stent implantation: An intravascular ultrasound study. J Am Coll Cardiol. 2005;45:995–998.
4. Takebayashi H, Kobayashi Y, Mintz GS, Carlier SG, Fujii K, Yasuda T, Moussa I, Mehran R, Dangas GD, Collins MB, Kreps E, Lansky AJ, Stone GW, Leon MB, Moses JW. Intravascular ultrasound assessment of lesions with target vessel failure after sirolimus-eluting stent implantation. Am J Cardiol. 2005;95:498–502.
5. Gavit L, Carlier S, Hayase M, Burkhoff D, Leon MB. The Evolving Role of Coronary Angiography and Fluoroscopy in Cardiac Diagnosis and Intervention. Eur J Interv, 2007; (2): 526-532.