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# Assessment of coronary stent deployment using computer enhanced xray images- validation against intravascular ultrasound and best practice recommendations

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Short title: Assessing stents with StentBoost

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#### ABSTRACT

Objective: Investigate the accuracy of stent measurements using coronary xray angiograms with a computer based stent enhancement algorithm applied (StentBoost, SB). To derive recommendations for best practice when using such systems.

Background: Computer enhancement algorithms allow better visualisation of intra-coronary stents to assist in ensuring adequate stent deployment. Factors that affect the accuracy of measurements taken on such systems are yet to be fully understood.

Methods: We analysed stent deployment of 43 stents in 33 patients measuring minimum stent diameter and cross sectional area (CSA) using intravascular ultrasound (IVUS), SB enhanced x-ray images, and quantitative coronary angiography (QCA). We investigated if the use of two projections and method of calibration influenced correlation between IVUS and SB measurements.

Results: Using two views and performing calibration via the guide catheter improved agreement between SB and IVUS measurements. E.g. minimum stent diameter assessed with SB using one view and balloon markers for calibration produced a correlation coefficient, r, of 0.21, whereas using two views and the guide catheter for calibration increased improved agreement to r=0.62. Relative measures of stent deployment, such as the ratio of minimum to maximum CSA, produced good correlation between IVUS and SB (r=0.74).

Conclusions: When using the SB system, two projection angles should be used to image the stent. For absolute measurements, the guide catheter should be used for calibration purposes. Relative measures of stent size, which are probably sufficient for assessment of deployment, also give good agreement with similar measures on IVUS, and require no calibration.

#### INTRODUCTION

Under deployed intra coronary stents are associated with poorer patient outcomes. One of the limitations in visualising stents on conventional coronary angiography is related to the low x-ray subject contrast due to the thinner struts of modern stents, despite the use of highly radio-opaque materials in stent construction. Motion of the stent within an imaging sequence further reduces stent visibility. In larger patients increased scatter to primary ratio and the higher x-ray tube voltages typically used when imaging these patients, reduce radiographic contrast of the stent compared to thinner patients, making the visualisation of stents particularly challenging in these patients. Intravascular ultrasound (IVUS) is superior to conventional angiography for the detection of stent under-deployment and strut malapposition, and its routine use to optimise stent deployment may reduce the rate of subsequent need for target lesion/vessel revascularisation [1-3]. However, routine IVUS adds cost, time and increases the risk procedural complications, with little or no effect on rates of subsequent death or myocardial infarction (MI) [4]. IVUS is therefore unlikely to be cost-effective [5]. Quicker, cost effective and less invasive means of improving recognition of stent under-deployment is therefore desirable.

Recently, computer enhancement algorithms for enhancing stent visibility in xray angiograms have been described [6-8]. This study used a commercial stent enhancement algorithm called StentBoost (Philips Healthcare, The Netherlands). The StentBoost (SB) system combines information from a sequence of image frames to form a composite image, with the intention of

improving the visibility of a stent. The system has been described as being used to assist with the deployment of stents [9-12], in assessing if a stent is correctly deployed, or for assessing other complications such as stent fracture [13-15]. To utilise the SB system, a digital cine run is acquired immediately after stent deployment with the balloon deflated before it was withdrawn from the vessel (figure 1a). The SB algorithm fixes the stent in space throughout the cardiac cycle by aligning and registering the radio opaque markers of the deployment balloon at the same location throughout the acquisition sequence. The sequence is then temporally averaged to obtain a single composite image (figure 1b). In this study, the software was used retrospectively for quantitative assessment of the stent diameter and length.

Two recent studies have compared quantitative measurements taken with SB to measurements taken using IVUS [16,17], although both are single centre small studies, the latter having a particularly small number of stents studied (n = 19). Both studies found good correlation between minimum stent diameter measured via SB and IVUS (r = 0.79 [16] and 0.80 [17]), although there are important differences in the methodologies used. It is standard angiographic practice to image a vessel (and deployed stent) from two or more projection angles to ensure adequate depiction of the vessel shape given the projection nature of the angiographic imaging technique. Mishell at al [16] only employed assessment of stents via a single angiographic sequence, i.e. the stent was examined at one projection angle only, whereas Cordova et al [17] utilised two views although how data were combined from the two views is not explicitly

stated. The question as to whether two views of a stent are required for adequate assessment of stent deployment remains unanswered.

Both Mishell et al and Cordova et al used SB measurements of minimal stent diameter were compared to minimal stent diameter measured on IVUS. This has two disadvantages. Firstly IVUS is a cross sectional imaging device, allowing cross sectional area (CSA) to be assessed, and it is minimum CSA, not minimum diameter, that is key to flow limitation. Secondly, assessment of minimum stent diameter requires an absolute measurement of an object within the image. One of the biggest limitations to any absolute measurement of an object size in any projection x-ray image, is the requirement to calibrate measurements via an object of known size located in the same plane as the object to be measured. In cardiac images calibration is typically performed using the guide catheter. This may require a larger field of view than necessary just to visualise the stent in a SB sequence resulting in a larger radiation dose to the patient, lower image quality due to increased scatter, adds an additional stage to the image analysis, and may be cumbersome to achieve in clinical practice. An alternative object to calibrate measurements to with SB is the markers for the balloon inflation device, which have the advantage that they are always within the field of view, but may be subjected to a degree of foreshortening, making absolute measurements less accurate. Using a ratio of measurements from the same image sequence would remove the requirement for calibration, and if a relative measure can be used to assess stent deployment instead of an absolute measure of stent dimension,

quantitative measurements with SB would be simpler to achieve in clinical practice, and require fewer steps in the calculation process.

In this prospective study, we set out to investigate:

- a) whether or not the accuracy of stent assessment improves when the stent is imaged from two near-orthogonal projection angles rather than using a single view
- b) if the use of the balloon markers can be used for size calibration without loss of accuracy compared to when using the guide catheter
- c) if a relative measure of stent deformity can be used to assess stent deployment avoiding the need for absolute calibrated measurements, and
- d) if stent measurements obtained with SB provide additional information to that available with Quantitative Coronary Angiography (QCA) in assessing stent deployment.

The overall aim of the study was to provide indicators of best practice to users and potential users of the SB system.

#### MATERIALS AND METHODS

This study was approved by the local research ethics committee and all data were independently assessed. Only patients who had previous interventions to the same arterial segment of interest and patients in whom two orthogonal angiographic views of the stented segment could not be performed were excluded. The computer enhancement algorithm used in this study was available commercially - "StentBoost®" Version 1.0 (Philips Medical Systems Nederland BV, Best, The Netherlands).

#### **Data Acquisition**

In 33 patients undergoing PCI and stent procedures at our centre, we studied 43 stent deployments. Immediately following stent deployment, SB images were obtained in two projections as orthogonal to each other as practicable, with minimal foreshortening of the stented segment chosen by the interventionalist. The first of the two views was acquired using the projection found in the diagnostic angiograms performed earlier in the procedure to provide the clearest view of the stenosis. All data were acquired following a bolus of intracoronary nitroglycerin. The heart was not isocentered prior to the image acquisition.

A specific digital cine acquisition mode was selected on our x-ray system (Philips Allura Xper FD10, Philips Medical Systems Nederland B.V., Best, The Netherlands) in order to acquire a SB stent sequence. This acquisition was performed without any contrast injection and with arrested respiration. The

image data were automatically transferred to a dedicated computer workstation within the catheter lab for processing by the SB system.

Although the enhanced (stent) images from the SB system can be analysed rapidly for use 'on-line' within the catheterisation laboratory, for the purposes of this study the data were analysed 'off-line' some time following the completion of the cases.

Immediately following the SB data acquisition, and prior to any further postdilatation, IVUS was performed using the Galaxy II system (Boston Scientific, Maple Grove, MN, USA) and IVUS Atlantis SR Pro catheters (Boston Scientific, Maple Grove, MN, USA), producing 2D cross-sectional images at a rate of 30 frames per second. An automated pullback device was used for all IVUS data acquisition running at a speed of 0.5 mm per second. The IVUS images were made available to the operator to further optimise stent deployment if required, although as all quantitative analysis was performed after the cases had been completed measurements from IVUS and SB were not used to guide the procedure.

#### Data Analysis

All quantitative measurements for the purpose of this study were performed 'off-line' using the following procedure. Measurements from each modality were made independently without reference to the other data. SB and IVUS images were analysed by the same observers, but this analysis was

performed some months apart to minimise bias due to familiarity with the cases. QCA analysis was performed by different observers.

IVUS measurements of intra-luminal CSA and minimum and maximum diameters were taken at the distal end of the stent and following every 60 frames (equivalent to 1 mm pullback) until the proximal end of the stent was visualised. In-stent CSA was defined as the area bound by the visible stent struts, measured by interactive planimetry. The distal and proximal ends of the stent were defined as the first and last frames (respectively) in which at least 75% of the circumference of the image had visible stent struts. In addition we obtained measurements of CSA and minimum and maximum diameters at reference points within the native vessel lumen and within 3 mm of the ends of the stent of the native vessel when the anatomy permitted.

The SB images were analysed in much the same manner as the IVUS images. Stent diameter was measured every 1 mm throughout the length of the stent. Calibration of distance within the SB images was performed using two objects- the balloon markers and the guide catheter end where possible. Following an interactive manual tracing of the edges of the stent, the SB software can calculate the diameter at any point along the length of the stent. Measurements of stent diameter were taken in each view at proximal and distal ends of the stent and at 1 mm intervals along the length of the stent. We assumed that the final dimensions of the deployed stent length approximated to the stated manufacturers' specification - we therefore did not take into account any 'shortening' of the stent which may have resulted at the time of

deployment. Quantitative measurements using the distance between the balloon markers as a reference was possible for all deployments in both views, while quantitative measurement using catheter dimensions as reference was only feasible when the guide catheter was clearly visible.

Quantitative Coronary Angiography analysis was performed using a commercially available interactive semi-automated software of the angiographic system (Philips Allura Xper-FD 10, Philips Medical Systems Nederland B.V., Best, The Netherlands). Contrast filled guide catheter was used for the calibration, and fully opacified segments of the related vessel which provided optimal visualisation without foreshortening of the stent/treated lesion was assessed. Minimum luminal diameter was recorded within the vessel region where the stent was placed.

The following comparisons were made: minimum diameters  $(d_{min})$  on IVUS to SB and QCA, minimum cross sectional area (CSA<sub>min</sub>) on IVUS to a corresponding estimate on SB and QCA (PI x  $(d_{min}/2)^2$ ), and the ratio of the minimum to maximum CSA on IVUS to the square of the ratio of minimum and maximum stent diameters on SB.

For all SB and QCA measurements, measurements were made using two views. The first view was the view chosen as the primary view used during the intervention; the second was selected to be as close to orthogonal to the primary view with minimal foreshortening of the segment. Results are presented from the primary view alone, and for a combined measurement

from the two views, which was calculated by taking the "worst case" measurement (e.g. lowest  $d_{min}$ , or lowest ratio of minimum to maxiumum diameter) from the two views.

## **Statistical Analysis**

For each comparison the correlation co-efficient (*r*) between the reference IVUS measurement and the corresponding SB or IVUS measurement was calculated and Bland-Altman analysis was performed. All analysis was performed using software written in MATLAB R2009b (Mathworks Inc, Natick MA).

#### RESULTS

The stents used in this study included; Tecnic (Sorin Biomedica, Via Crescentino, Italy) 11, Driver (Medtronic, Minneapolis, MN, USA) 26, Cypher (Cordis UK, Ascot, Berks, UK) 6. Stent lengths ranged from 12 mm to 33 mm per deployment (mean 18 mm). The mean angle subtended between the two projections used for the SB views was  $59^{\circ}$  (sd=24°).

Correlation coefficients, r, and associated p values for all comparisons are given in Table 1. In all cases, for SB and QCA comparisons, using two views gave better correlations to IVUS measurements than using a single view. This effect was smaller for QCA data. For example, comparing  $d_{min}$  measurements using catheter calibration, *r* for SB correlation with IVUS was 0.46 and 0.62 using a single view and two views respectively. For the same comparison QCA resulted in *r* values of 0.47 and 0.51 for one and two views respectively.

In all cases using catheter calibration improved the correlation of stentboost measurements with IVUS over using the balloon markers. For example, assessing minimum CSA with SB using two views, comparing to IVUS, produced r=0.63 and r=0.9 for the balloon and catheter calibrations respectively.

In all cases SB provided comparable or occasionally better agreement with IVUS than QCA.

The relative measurement of  $CSA_{min/max}$  provided good agreement between SB and IVUS (r = 0.74 for two views). Selected Bland-Altman and scatter diagrams are given in figures 2 - 4.

#### DISCUSSION

There are many factors implicated in the development of restenosis, these include clinical ones such as diabetes, smoking etc, procedural parameters such as stent length, number of stents, deployment balloon size and pressure, post-procedure minimum lumen diameter and cross-sectional area and anatomical features like small vessels, long lesions, chronic total occlusions, ostial lesions, vein grafts, calcified lesions etc. to name a few. Although many studies have analysed the stent dimensions at the conclusion of the procedure, they have suggested different absolute 'cut-off' values for postprocedural CSA by IVUS and subsequent risk of restenosis (e.g. CSA 6.0 -7.0 mm<sup>2</sup>) [18,19]. It is also known that there are discrepancies in measuring luminal diameters using IVUS and QCA and that the magnitude of error varies according to disease extent [20] and vessel size [21]. It has been supposed that differences between QCA measurements and IVUS measurement were due in part to the fact that in some cases the vessel was highly eccentric, leading to large errors in the QCA measurement due to the fact that it was obtained from a single projection. In such cases the use of two views over a single view is likely to improve the assessment of the minimum diameter of the vessel in the case of eccentric lesions. IVUS, which is a cross sectional imaging modality, is capable of describing highly eccentric vessels. Our results, which demonstrated improved measurement correlation with IVUS when two views are obtained in QCA and SB support this proposition. There will be inaccuracies in IVUS diameter measurements, however, when the IVUS catheter is not parallel to the vessel wall.

Absolute measurements (d<sub>min</sub> and CSA<sub>min</sub>) improved in accuracy with reference to similar results taken on IVUS when the guide catheter was used to calibrate the measurements compared to using the balloon markers for callibration. Calibration with the balloon markers is likely to be affected by foreshortening along the longitudinal axis of the vessel; measurements made in the orthogonal direction (i.e. vessel or stent diameter) are unlikely to be subjected to the same degree of foreshortening; when there is foreshortening of the balloon markers, calibration using these points will be incorrect, and not necessarily proportional to errors in the stent diameter; increasing the foreshortening of a vessel will decrease its projected length, but may not alter the projected width (diameter). Calibration via the guide catheter is not subjected to this problem, although it is clearly important that the catheter is in the same plane as the vessel for accurate calibration. If the source to object distances for the catheter and vessel are not the same, there will be a scaling error in any measurements taken. For example, this will occur in the RAO projection in the distal left circumflex artery- in this case stent measurements will be underestimated.

The use of a relative measurement, such as minimal luminal diameter with respect to either the maximum luminal diameter within the stent or the reference vessel, is a more convenient method of assessing stent deployment in SB or QCA images as a calibration procedure is not required. A similar relative measure has been proposed for IVUS as a predictor of restenosis [21,22]. Our results indicate that a relative measure of the ratio of minimum to maximum stent measurement demonstrates good correlation between SB and

IVUS. This comparison was not performed with QCA, as it was difficult to identify the exact proximal and distal ends of the stent in the QCA sequences to ensure that the measurements were taken within the stent. We note that later revisions of the SB software allow the enhanced stent to be super-imposed upon the vessel allowing stent diameter to be assessed in the context of the size of the surrounding vessel, in addition to the intra-stent diameters.

Another advantage of using a relative measure for assessing stent deployment is that it is not necessary to ensure the guide catheter is visible within the imaged segment. This allows the x-ray beam collimators to be used to more tightly delimit the image area around the stent. The smaller field of view will result in lower doses of radiation to the patient and staff per SB run. Moreover the smaller irradiated area of the patient will produce fewer scattered x-ray photons, improving the image quality via a lower scatter to primary ratio.

It is likely that the findings of this study are not limited to the SB product, but would apply to any stent enhancement software that works in a similar manner, i.e. combines information from a sequence of images taken in the same projection. For all these systems more than one projection of the stent should be imaged.

The operators in this study were instructed to obtain two views of a stent at projection angles as close to orthogonal as practicable. Our results indicate

that the angles chosen in this study were somewhat less than orthogonal in most cases, probably due in part to the need to find projections that do not overlap the stent with other objects (diaphragm, surgical clips, etc.), have an acceptable degree of foreshortening, and acceptable radiation dose to the patient and staff. It is likely that the error in assessing stent diameter will increase with more eccentric vessels and smaller angular differences between projections. Nevertheless our results indicate that with simple instruction, and suitable clinical experience, our operators could obtain better results from the SB system by using two projections. Figure 5 demonstrates the value of using two projections, showing an under-deployed stent imaged from the two angles chosen by the operator in this study. The stent appears reasonably deployed in one view (5a), yet there is clear under-deployment in the other view (5b). There was an 85° angle between the two projections in this case.

#### CONCLUSIONS

As new technological developments, such as SB, are integrated into clinical routine, it is important that evidence is gathered to guide good practice when using the new technology. To this end, our results indicate that when using SB to assess stent deployment, two views as close to orthogonal as practicable, of the stent should be acquired, and that a relative measure of stent diameter (i.e. the ratio of the minimum to maximum diameter) correlate well to measurements taken on IVUS. The radiation field should be collimated tightly around the stent in order to minimise radiation dose and improve image quality.

If absolute measurements of stent size are desired, SB can provide accurate assessment of a deployed stent. In such cases, it is important to ensure that the guide catheter is visible within the image for calibration purposes, and that two orthogonal projections are taken of the stent.

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## FIGURE LEGENDS

Figure 1: Image enhancement algorithm in practise; (a) positioning the balloon markers just outside the stent, and (b) the enhanced image.



Figure 2: Bland-Altman plots of minimum diameter measured on IVUS and SB. a) balloon calibration, single view. b) balloon calibration, two views. c) catheter calibration, single view. d) catheter calibration, two views.



Figure 3: Bland-Altman plots of minimum CSA on IVUS and estimated from SB. a) balloon calibration, single view. b) balloon calibration, two views. c) catheter calibration, single view. d) catheter calibration, two views.





Figure 4: Bland-Altman and scatter plots of CSA minimum to maximum ratio measured on IVUS and estimated on SB. a) & c) single view, b) & d) two views.

Figure 5: StenBoost enhanced image from two projections a) 29° RAO 19° Caudal, and b) 44° LAO, 28° Cranial.

