International Journal of Cardiology 182 (2015) 272–278

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Co-registration of optical coherence tomography and X-ray angiography in percutaneous coronary intervention. The Does Optical Coherence Tomography Optimize Revascularization (DOCTOR) fusion study☆

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ARTICLE INFO

Article history:
Received 1 October 2014
Received in revised form 8 December 2014
Accepted 25 December 2014
Available online 27 December 2014

Keywords:
Optical coherence tomography
Percutaneous coronary intervention
Angiography
Coronary heart disease
Co-registration
Quantitative coronary angiography

ABSTRACT

Background: Intracoronary imaging provides accurate lesion delineation and precise measurements for sizing and positioning of coronary stents. During percutaneous coronary intervention (PCI), it may be challenging to identify corresponding segments between intracoronary imaging and angiography. Computer based online co-registration may aid the target segment identification.
Methods: The DOCTOR fusion study was a prospective, single arm, observational study including patients admitted for elective PCI. Optical coherence tomography (OCT) was acquired pre-stent implantation for sizing of stents. The operator subsequently indicated on the angiogram the target area as identified by OCT. Computer based co-registration was performed on-line immediately after pre-stent acquisition to assess feasibility. The cumulated numerical difference between operator based, and computer based co-registration was assessed as the "Operator Registration Error". The operator implanted the stent blind to the co-registrated angiogram. The difference between the co-registered stent border positions and the actual stent deployment border positions was the "Geographic Miss Distance".
Results: Twenty-two patients were included in the study. Two patients were excluded due to missing pre or post-OCT acquisitions. Online co-registration pre-stenting was successful in all analyzed cases. The mean "Operator Registration Error" was 5.4 ± 3.5 mm. The mean "Geographic Miss Distance" was 5.4 ± 2.6 mm. Without access to the computer-based co-registration, segments of the target lesion indicated on OCT were left uncovered by stent in 14 patients (70%).
Conclusion: Computer based online co-registration of OCT and angiography is feasible. Frequent inaccuracies in operator based registration indicate that computer aided co-registration may reduce errors in corresponding OCT findings to the angiogram.

1. Introduction

Percutaneous coronary intervention (PCI) for atherosclerotic disease has developed over the past decades to a standard treatment with favorable prognosis for most indications. Sizing and positioning of stents may be aided by intracoronary imaging. The use of intracoronary imaging varies from no use, to use in complex procedures and in some centers and countries almost routine use in all cases.

Routine guiding of PCI by intracoronary imaging has potential advantages [1,2] but reduction in major adverse cardiac events by routine use of intravascular ultrasound (IVUS) guidance has not been demonstrated in well powered randomized trials [3–5] though a recent meta-analysis suggested positive effects when including both RCTs and observational studies [6]. Optical coherence tomography (OCT) for guiding PCI is feasible [7] but potential clinical value is unknown.

Incorrect anatomical correspondence of intracoronary imaging and the angiogram during PCI may lead to incorrect assessment of the patho-anatomy and erroneous sizing and positioning of stents. In case of angiographic ambiguity, there is a risk of assessing the wrong location on IVUS or OCT making the wrong diagnosis of the pathology. Likewise, in use of IVUS or OCT for stent positioning, there is a risk that the target area is mismatched to the angiogram e.g.in diffuse atherosclerotic

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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http://dx.doi.org/10.1016/j.ijcard.2014.12.088

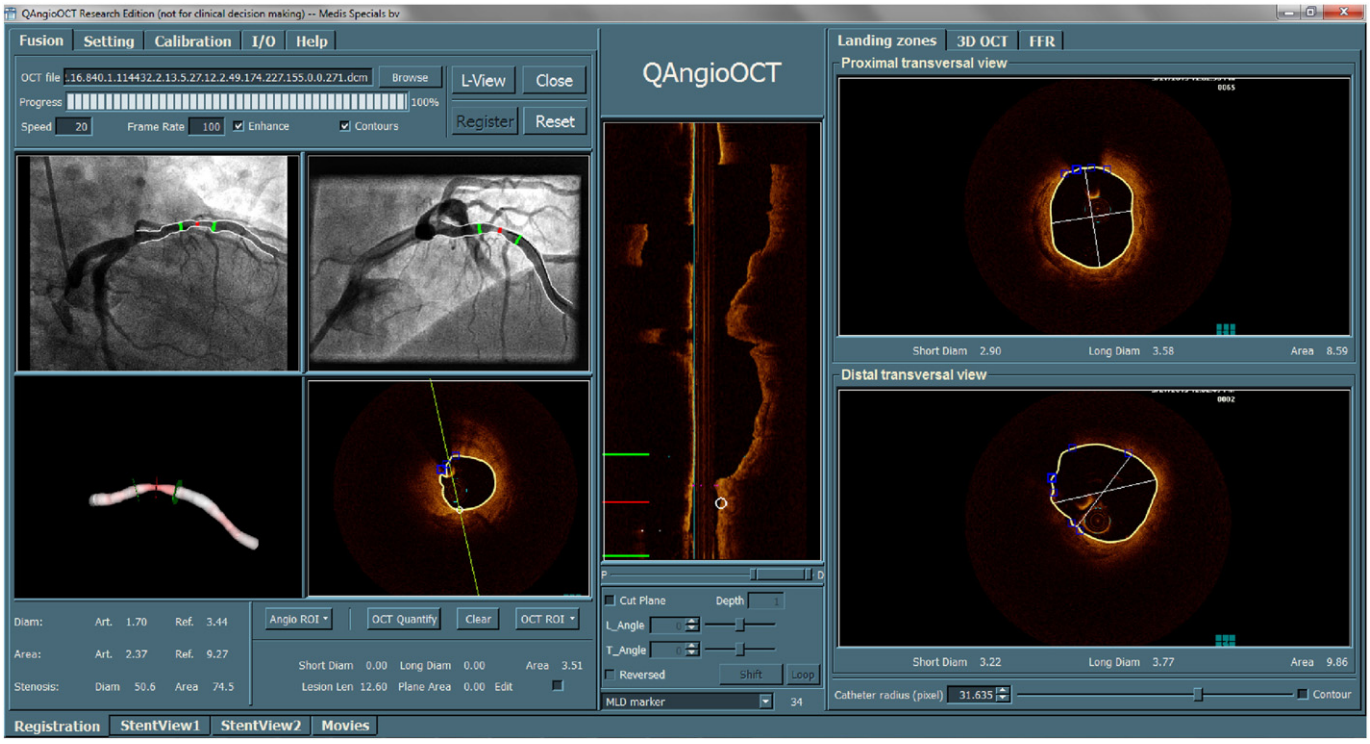


Fig. 1. Co-registration software—working view. User interface of QangioOCT RE (Medis Specials, Leiden, NL). Middle image shows the longitudinal view of the OCT acquisition. Green markers represent the stent boarders and the corresponding cross sections are shown to the right. The lower left quadrant shows the 3D reconstruction of the vessel based on the two angiographic projections shown in the upper two quadrants.

disease. Any of such flaws reduce a potential positive effect of adjunctive imaging and may even be detrimental.

To link intracoronary imaging and angiography during PCI, the operator must identify corresponding structures and segments and thereby mind map the intracoronary scanning images to the angiogram. Computer based co-registration of intracoronary scanning modalities and X-ray angiography may aid correct matching between the two modalities.

Here we present the first clinical evaluation of co-registration of OCT and X-ray angiography. We aimed to evaluate if computer based online

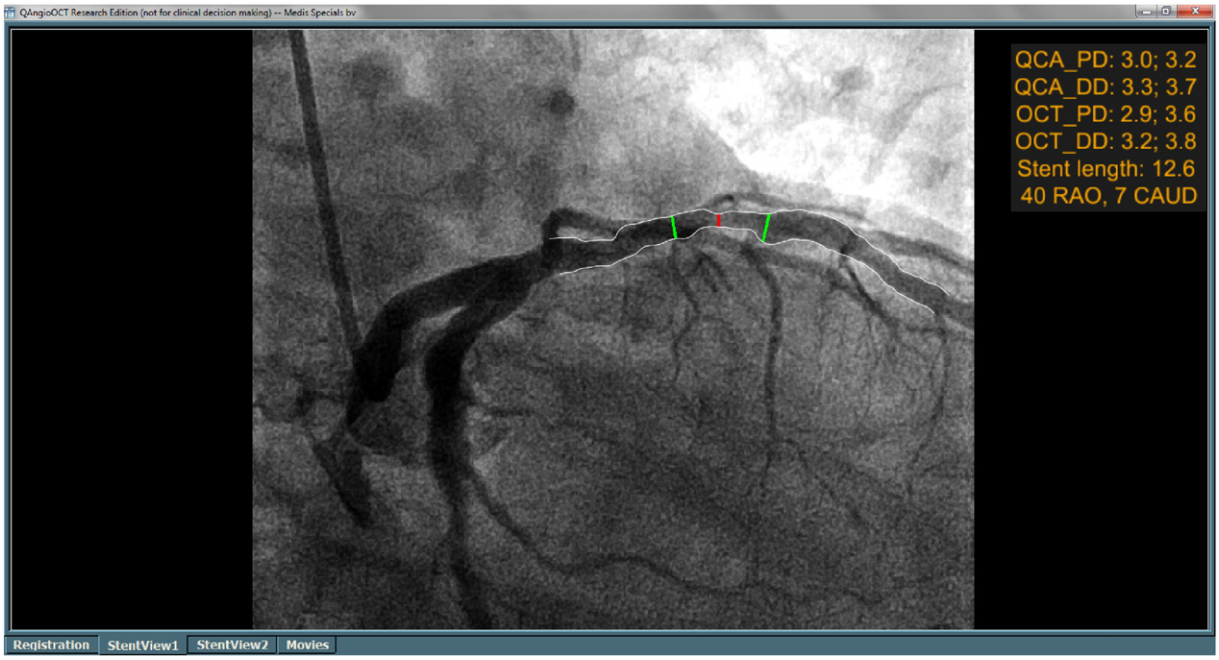


Fig. 2. Co-registrated angiogram. After co-registration and identification of the stent landing zone using OCT, the angiographic working projection is presented with co-registrated stent boarders and corresponding measurements based on OCT and 3D QCA. PD and DD are the proximal and distal diameters, respectively. Optimal projection angle for the least foreshortening and best visibility of the lesion is shown.

co-registration of OCT and angiography was feasible. We examined if co-registration had the potential for improving positioning of stents compared to operator mind mapping of OCT to angiography during PCI.

2. Methods

The DOCTOR fusion study was a prospective, observational, single arm study. Patients admitted for elective or subacute percutaneous coronary intervention were offered inclusion if OCT was not contraindicated. Inclusion criteria were: at least 18 y/o, able to provide written informed consent, maximum 2 lesions requiring treatment, maximum lesion length 40 mm (visually assessed). Exclusion criteria were: life expectancy less than 1 year, pregnancy or possible pregnancy, impaired kidney function (creatinine > 100 μmol/L), ST-elevation myocardial infarction within 7 days, cardiogenic shock, or severely tortuous vessels. The study was conducted according to the Declaration of Helsinki and the study was approved by the Mid Jutland Ethics Committee for Biomedical Research and The Danish Data Protection Agency.

2.1. Study procedure

Percutaneous coronary intervention was performed according to the standard best practice. OCT was acquired before and after stent implantation by protocol. Use of OCT for guiding the intervention pre and post-stenting was allowed at operator's discretion. Co-registration of angiography and OCT was performed immediately after pre-stenting OCT. The co-registered angiogram was not available to the operator.

2.2. Indication of stent landing zone

Upon identifying the angiographic working projection, the operator marked on a print-out paper image of the angiogram the coronary segment he intended to cover by stenting. Based on visual assessment, the operator suggested length and diameter of the stent needed to cover the lesion. OCT pullbacks were recommended to be performed after predilatation to ensure that the image wire would be non-occlusive and to be able to assess extent of dissections inflicted by predilatation. Acquisition of OCT (54 mm, 20 mm/s, Illumien, St. Jude Medical) was evaluated by the operator on a regular OCT acquisition console identifying the landing zone and adjusting stent borders to the nearest, longer available stent length. The operator then marked on the paper image of the angiogram where he believed the stent borders corresponding to the OCT decision should be.

2.3. Lesion segment identification

Angiographic assessments of stent size and position were based on visual assessment using integrated size comparisons, length of opaque wire sections and balloon lengths. Lesion segment identification by OCT was performed by the operator. The aim was to cover segments with minimal luminal area and adjacent segments <2.5 mm^2, areas of dissection and areas of ruptured plaque, and to avoid stenting healthy segments and across side branches if not needed. Partial stent coverage of major lipid plaques in the edge zone was to be avoided.

Table 1
Baseline characteristics.

Baseline clinical characteristics	N (%) or mean ± SD
Male	17 (85%)
Age (yrs)	60.75 ± 10.86
Smoker (1 missing)	
Never	8 (40%)
Current	4 (20%)
Former	7 (35%)
Hypertension	12 (60%)
Hypercholesterolemia	11 (55%)
Diabetes mellitus	2 (10%)
Prior PCI	3 (15%)
Indication	
Stable angina pectoris	13 (65%)
Unstable angina pectoris	0 (0%)
Non-STEMI	7 (35%)

PCI: percutaneous coronary intervention. Non-STEMI: Non-ST-elevations myocardial infarction.

2.4. Co-registration

Immediately after obtaining the working projection and a projection at least 25° apart, DICOM runs were exported to an imaging workstation. After correction for system distortion, a 3D angiographic reconstruction of the target vessel was rendered from vessel contours detected automatically on the two corresponding projections using a validated software (QAngio XA 3D straight, Medis Special, Leiden, NL) [8–10]. The pre-stenting OCT pullback was transferred to the imaging workstation containing the stent borders as indicated by the operator on the OCT console. Co-registration was performed by indicating a common landmark e.g. the same side branch on the angiogram and on the OCT pullback (Fig. 1). To evaluate if co-registration was correct, correspondence of another, preferably distant landmark was evaluated. The angiogram in working projection with co-registered landing zone and size measurements was then available (Fig. 2). Co-registration was performed using a validated software (QAngioOCT RE, Medis Specials, Leiden, NL) [8,11].

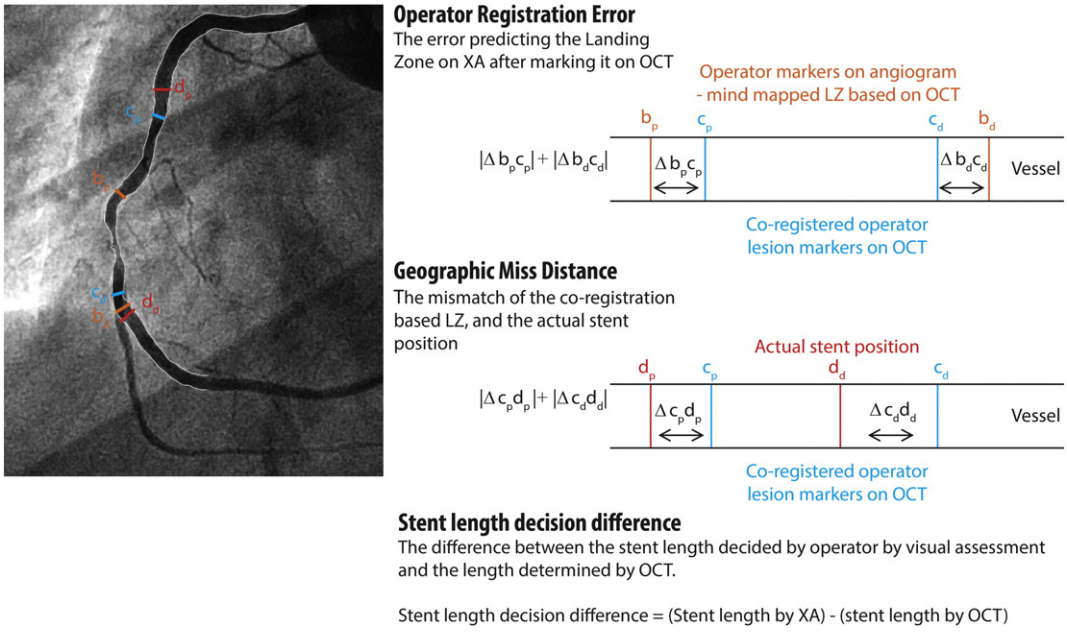


Fig. 3. Definitions. Definitions used in the analysis. Operator Registration Error measures operators' error in predicting the landing zone (LZ) on angiography (XA) after marking it using the regular OCT console. Geographical Miss Distance is the mismatch of the co-registration based LZ and the actual stent edge position. Operator Stent Length Decision Difference is the difference between visual determined stent length determined by angiography versus by OCT. Letter b: Operator markers on angiogram based on OCT without co-registration (yellow), c: Operator lesion markers on OCT, co-registrated (blue), d: Actual stent position (red). Subscripts p and d represent proximal and distal markers respectively.

Table 2
Procedural characteristics.

Procedural characteristics	
Study lesion location	
RCA	9 (45%)
LMA	1 (5%)
Cx	2 (10%)
LAD	8 (40%)
Diameter stenosis % (visual assessment)	85.2 ± 10.4
Calcified lesion	4 (20%)
Predilatation before OCT	17 (85%)
Entire lesion obtained by OCT pullback	18 (90%)
Successful co-registration (feasibility)	20 (100%)
Correct co-registration in first attempt (procedural)	19 (95%)
Stent type	
Nobori	8 (40%)
Osiro	7 (35%)
Other	5 (25%)
Number of stents	1.10 ± 0.31
Final OCT	20 (100%)
Procedural success	100%
Contrast use, including OCT acquisition (mL)	131.75 ± 43
Fluoro time (minutes)	8.65 ± 3.87
Procedure time (minutes)	39.65 ± 9.82
Operator overruled OCT assessment	2 (10%)

2.5. Treatment

Actual treatment was performed as normal best practice and as such not altered by the study. Use of pre-stenting OCT measurements for actual treatment was performed at the discretion of the operator and was noted. The angiogram with co-registered stent borders was not available to the operator. Post-stenting OCT acquisitions were available for evaluation of final result at operator's discretion.

2.6. Endpoint definitions

Feasibility was achieved when the correct co-registered angiogram in the working projection including the stent borders was shown during the procedure.

"Operator Registration Error" was the cumulated numerical difference in positions of the operator's mind mapped landing zone on the angiogram as corresponding to the stent borders indicated on OCT, compared to the computer based co-registration results. See Fig. 3.

"Geographic Miss Distance" was the cumulated numerical difference between the co-registrated OCT based landing zone and the actual stent landing position assessed by co-registrated post-stent OCT.

"Operator Stent Length Decision Difference" was the difference between operator determined stent length by angiography versus by OCT.

"Operator Stent Diameter Decision Difference" was the difference between the nominal stent diameter determined by the operator based on angiography versus by OCT.

Procedural success: TIMI flow III and <30% residual stenosis by visual assessment.

Core lab analysis was performed using QAngioOCT RE, QAngio XA 3D RE (Medis Specials, Leiden, NL) and OPTIS ORW (St. Jude, St. Paul, MN, USA).

3. Results

A total of 22 patients were included in the study. Two patients were excluded from analysis, one due to missing pre-stent OCT and one due to missing post-stent OCT. Pre-stent co-registration was successful in the latter patient but final OCT was not acquired due to severe coronary spasms. Baseline clinical characteristics are shown in Table 1. One third of procedures were indicated by stabilized myocardial infarction (non-STEMI) and the remaining had stable angina pectoris. Pre-stent OCT was performed after predilatation in 85% of cases and the OCT pullback did not cover the entire lesion in 5% of cases. Mean 1.1 ± 0.3 stent was implanted (Table 2).

3.1. Feasibility

In the 20 patients entering analysis, full co-registration was achieved during the procedure. Incorrect registration by non-matching landmarks occurred in one case and was immediately identified by the second landmark check and corrected. Co-registration and matching of one post intervention OCT pullback was not possible due to a cardiac motion artifact causing 10 mm of the same vessel segment to appear twice in the OCT acquisition. There were no procedural clinical events.

3.2. Stent length and position

Fig. 4 shows schematic the segments to be covered by stent as determined 1) by OCT after computer co-registration, 2) by OCT after operator co-registration, 3) by visual assessment, and 4) shows the actual stent position. Operator Registration Error was 5.4 ± 3.4 [0.8; 14] mm [absolute range], Geographic Miss Distance was 5.3 ± 2.6 [1.6; 10.8] mm. In 14 out of the 20 analyzed patients, one or more lesion segment areas marked on OCT were uncovered by stent. Uncovered OCT determined lesion area longer than 2 mm was detected in 6 patients. The stent diameter by angiographic decision compared to OCT guiding was equal in 75% of cases 0.5 mm smaller in 5%, and 0.5 mm larger in 20% of cases. Mean stent length when decided by visual assessment of angiographic images was 22.5 ± 8.5 mm, by OCT 22.3 ± 8.7 mm and actual implanted stent length was 22.4 ± 5.7 mm (Table 3).

4. Discussion

This is the first systematic clinical evaluation of online co-registration of angiography and OCT. We found that co-registration of pre-stent OCT and angiography was feasible during PCI using the investigated approach. Landing zones identified using OCT and transferred to the angiogram by the operator, differed 5.4 ± 2.6 mm in cumulated position length difference compared to computer based co-registration. Without access to the co-registrated landing zone, parts of the OCT-identified lesion area to be covered by stent, were left uncovered in 70% of the investigated lesions.

4.1. Potential clinical implications of co-registration

Clinical co-registration of angiography and intracoronary imaging may be an important tool to reduce the risk of incorrect correspondence with potential serious consequences but also to fully exploit the benefits of the various intra coronary scanning modalities. The registration is important in both directions enabling 1) correct intracoronary diagnosis of ambiguous segments identified on the angiogram and 2) correct transfer to the angiogram of delimited lesion segments and other features identified by intracoronary modalities. Despite the simple lesions assessed in our study, a high rate of incorrect operator matching resulted in uncovered lesion area in 70% of cases. Although the magnitude of clinical impact of uncovered lesion area cannot be assessed by this material it is an indication that even in simple lesions the transfer of intracoronary imaging information may be challenging.

4.2. Lesion area identification by OCT

Guiding of PCI by IVUS or OCT has shown promising, but not confirmatory results in studies flawed by unclear treatment criteria, mix of high- and low-risk populations and lack of randomization in most positive studies [12–17]. Specific high-risk lesion groups as left main lesions may benefit from routine use of intracoronary imaging as also recommended in European and US guidelines [18–22]. The OCT criteria for sizing and positioning the stent in non-left main vessels applied in the present study lack validation but were proposed by synthesis of evidence [23–27] and clinical experience. In 10% of the study procedures, the operators expressed disbelief in the size and position of the segment to be treated as assessed by OCT. Longer stents were implanted at operator's discretion in those cases. Still the mean stent length as suggested by visual assessment, by OCT and the actual implanted stent was numerically similar. Thus guiding by OCT did not increase stent length in this study. Co-registrated OCT might also help reducing the number of stents implanted owing to improved sizing and positioning.

Patient no. 1
Operator Registration Error (OPE)
2.6mm + 0.2mm = **2.8mm**
Geographical Miss Distance (GMD)
2.6mm + 2.8mm = **5.4mm**

Patient no. 2
ORE: 2mm + 7.8mm = 9.8**mm**
GMD: 3.2mm + 7mm = 10.2**mm**

Patient no. 3
ORE: 2.4mm + 1.2mm = 3.6**mm**
GMD: 5.6mm + 1.6mm = 7.2**mm**

Patient no. 5
ORE: 5.8mm + 2.6mm = **8.4mm**
GMD: 1.8mm + 0.4mm = **2.2mm**

Patient no. 6
ORE: 1mm + 3.4mm = **4.4mm**
GMD: 0.7mm + 2.7mm = **3.4mm**

Patient no. 7
ORE: 1.8mm + 0.6mm = **2.4mm**
GMD: 3.8mm + 2.4mm = **6.2mm**

Patient no. 8
ORE: 0.8mm + 0mm = **0.8mm**
GMD: 2.6mm + 1.4mm = **4mm**

Patient no. 9
ORE: 2mm + 0.6mm = **0.6mm**
GMD: 0.8mm + 17mm = **17.8mm**

Patient no. 10
ORE: 7.8mm + 1.2mm = **9mm**
GMD: 1.6mm + 0mm = **1.6mm**

Patient no. 11
ORE: 0.4mm + 0.6mm = **1mm**
OPE: 2.6mm + 4.2mm = **6.8mm**

Patient no. 12
ORE: 2.6mm + 1.2mm = **3.8mm**
GMD: 4.2mm + 0.2mm = **4.4mm**

Patient no. 13
ORE: 2.4mm + 3.0mm = **5.4mm**
GMD: 2.2mm + 1.2mm = **3.4mm**

Patient no. 14
ORE: 5.4mm + 5mm = **10.4mm**
GMD: 6.6mm + 4.2mm = **10.8mm**

Patient no. 15
ORE: 4.8mm + 0.2mm = **5mm**
GMD: 1mm + 3.8mm = **4.8mm**

Patient no. 16
ORE: 0.2mm + 6mm = **6.2mm**
GMD: 1.4mm + 2.6mm = **4mm**

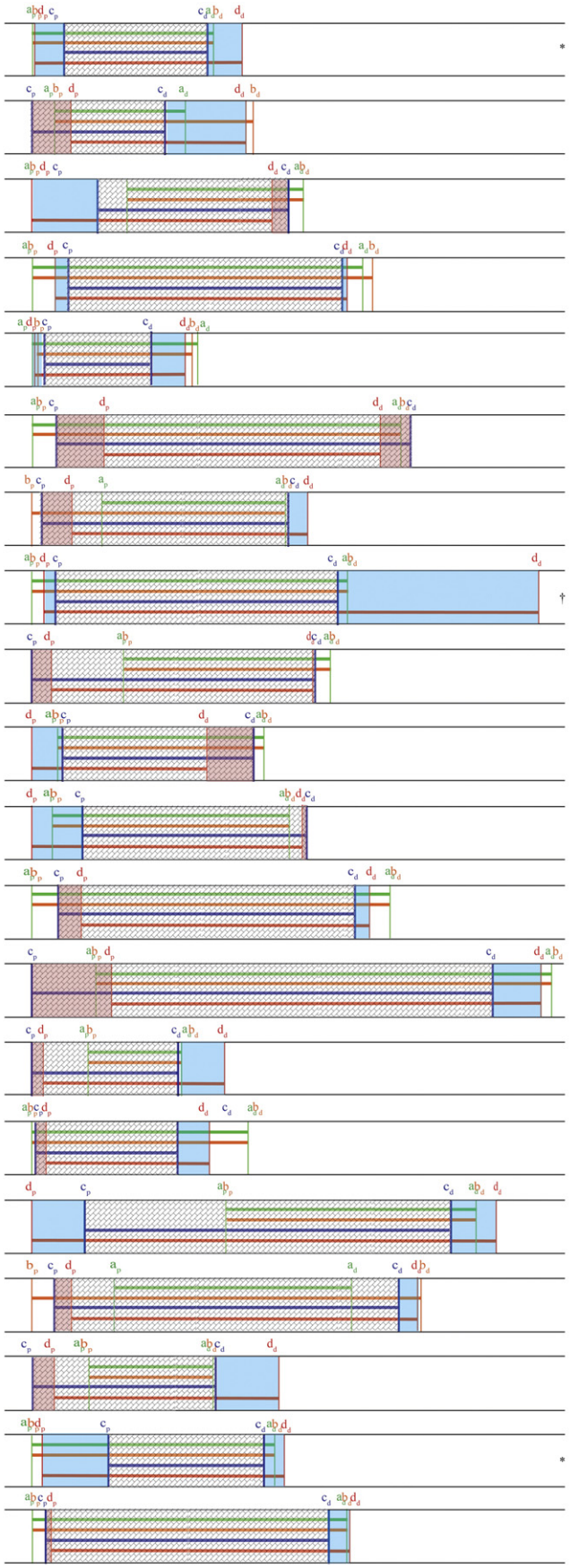
Patient no. 17
ORE: 12mm + 2mm = 14**mm**
GMD: 4.4mm + 3.6mm = 8**mm**

Patient no. 19
ORE: 1.8mm + 2mm = **3.8mm**
GMD: 1.4mm + 1.8mm = **3.2mm**

Patient no. 20
ORE: 5mm + 0mm = **5mm**
GMD: 2mm + 5.2mm = **7.2mm**

Patient no. 21
ORE: 6.6mm + 1mm = **7.6mm**
GMD: 5.4mm + 1.4mm = **6.8mm**

Patient no. 22
ORE: 0.8mm + 1.6mm = **2.4mm**
GMD: 0.2mm + 1.8mm = **2mm**



Schematic depiction of patient 1 lesion

a: Operator markers on angiogram - predicted LZ based on XA

b: Operator markers on angiogram - predicted LZ based on OCT - No co-registration

c: Operator lesion markers on OCT - Co-registered

d: Actual stent position

Grid indicates lesion area as marked on OCT

Blue shade indicates healthy area covered by stent

Red shade indicates uncovered lesion area

Table 3
Stent sizing.

	Lesion by visual assessment	Stent size by visual assessment	Stent size by OCT assessment	Implanted stent, nominal	Implanted stent, actual[b]
Diameter	3.47 ± 0.49[a]	3.31 ± 0.53	3.24 ± 0.46	3.24 ± 0.45	3.58 ± 0.45
Length	21.4 ± 7.76	22.45 ± 8.48	22.30 ± 8.70	22.35 ± 5.65	–

Mean sizes based on visual assessment of X-ray angiography, stent sizes by OCT assessment and implanted stent sizes. The length is assumed to be equal to the nominal size of the implanted stent.
[a] Reference size.
[b] Diameter according to balloon pressure.

In the present study including only simple lesions we did not expect major differences between guiding methods but still found differences between modalities as shown by the mean cumulated numerical difference in lesion position of 3.5 mm ranging up 11 mm. For less experienced operators and in complex lesion subsets including long diffuse lesions the difference between guiding methods may be even larger.

4.3. Feasibility

For optimal end-user experience co-registration must be precise, simple, fast, and feasible in almost all cases. Different technical approaches to co-registration all have trade-offs in terms of these criteria. Clinical acceptable accuracy have been reported for a number of systems [11,28–30] but no other co-registration system have been systematically clinically evaluated for online use limiting the knowledge of achieved feasibility. The evaluated system is based on a three-dimensional quantitative coronary angiography (3D QCA) reconstruction of two angiographic projections. Measurements derived automatically by the 3D QCA are co-presented along the OCT data to aid stent sizing in the evaluated solution. This approach also provides automatic calculation of optimal projection angle, detection of overlap for optional projections, and sizing according to 3D QCA measurements if OCT is not acquired. Methods using one or two point co-registration between 2D angiography and OCT may be fast but may also be limited in accuracy due to foreshortening in the angiogram [31]. Methods requiring continuous angiographic detection of a moving marker on the imaging wire [29] may provide fast co-registration with limited user interaction. In co-registration of IVUS the marker to detect moves at up to 1 mm/s whereas for OCT, reliable detection of a marker moving at up to 40 mm/s on the angiogram during flushing with contrast may require high angiographic frame rates and might be sensitive to overlapping vessels. Feasibility of such approach for OCT remains to be evaluated.

4.4. Requirements of scanning modalities

We studied only short and simple lesions making the OCT pullback length of 54 mm sufficient in all but one case. Co-registration may be even more important in long diffuse lesions without clear landmarks where longer OCT pullbacks are needed. One-point registration may be sensitive to cardiac motion artifacts and wire tension movements that vary in size and may be considerable. The use of multiple landmarks might improve the accuracy in the co-registration at an expense of more user interaction. Optional two-point registration has been added to the tested solution after finalizing the study. Despite potential advantages, the present cost of imaging catheters prevents routine use in most health care systems [32].

4.5. Universal co-registration

The overall feasibility of co-registration may be increased by full integration of a universal platform in angiographic equipment. Such common platform should enable registration to any modality with longitudinal information relevant to the interpretation of the angiogram. Intracoronary imaging modalities but also motorized FFR pullback and non-invasive imaging modalities should be connectable. The application tested featured registration to IVUS [11], near infrared scans (NIRS) and constant speed FFR pullbacks [33] though only the feasibility of OCT registration was evaluated.

5. Limitations

The study was an explorative study with a small sample size limiting the information on the utility in various lesion subsets. The observational design did not provide confirmatory data on feasibility of OCT guided PCI. Randomized trials are needed to assess clinical impact of co-registration, though such comparison may be obsolete if fully integrated, feasible, fast and user-friendly co-registration becomes available. Carefully designed randomized trials of co-registrated OCT versus angiography for guiding treatment of complex lesions may however be appropriate as the optimized co-registrated use of OCT may be necessary for showing clinical benefit in routine guiding. The applied co-registration software was a research version with a pre-clinical user interface operated by research fellows. The feasibility of such approach applies to labs staffed with technicians. This emphasizes the need for integration and user interface optimization before entering routine clinical practice.

6. Conclusion

Computer based online co-registration of OCT and angiography is feasible. High rate of inaccuracy in corresponding OCT findings to the angiogram was detected indicating that computer based co-registration may improve the utility of intracoronary imaging.

Conflict of interest

The authors report the following relationships that could be construed as a conflict of interest. Lasse Hebsgaard: Travel grant from St. Jude Medical and Terumo, Troels Munck Nielsen: Travel grant from Terumo, Shengxian Tu, Employment by Medis medical imaging systems bv and research appointment at Leiden University Medical Center (LUMC), Lars Romer Krusell: None, Michael Maeng: None, Karsten Tange Veien: None, Bent Raungaard: None, Christian Juhl Terkelsen: None, Anne Kaltoft: None, Johan H.C. Reiber, CEO of Medis medical imaging systems bv and research appointment at LUMC, Jens Flensted Lassen: Research grants from Terumo and St. Jude Medical, Evald Høj Christiansen: Speakers fees and research grants from St. Jude Medical, research grants from Terumo, Niels Ramsing Holm: Speakers fees and research grants from St. Jude Medical and Terumo.

Fig. 4. Schematic lesion level results.Longitudinal results for all included patients. Green lines indicate the lesion area based on angiography alone. Orange lines indicate the operators' predicted stent landing zone (LZ) based on OCT, without using co-registration. Gridded area (and blue lines) indicates the lesion area as marked by the operator on OCT applying co-registration. The red lines indicate the actual stent position. *marks operator overruling OCT stent sizes. † Post-PCI pullback had a major cardiac motion, or catheter movement artifact thereby increasing the apparent length of the 24 mm stent to 42 mm. Measurements of actual stent position from this patient were excluded from further analysis.

Funding sources

The study was funded byAarhus University Hospital and the research group.

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