Coronary Stents

In Vitro Aspects of an Angiographic and Ultrasound Quantification With In Vivo Correlation

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Background—The validity of quantitative coronary angiography (QCA) after stent placement has been questioned because the optical density of a metallic stent, added to the density of a contrast-filled lumen, could affect border definition.

Methods and Results—We deployed 3.0- and 4.0-mm Palmaz-Schatz, Wiktor, Multilink, NIR, and InStent stents in precision-cast phantoms. Central lumens of 2.0 mm were created. There was no difference between the "true" diameters of any stented lumen by both QCA and quantitative ultrasonic (QCU) measurement poststenting. QCA systematic error (SE) varied from 0.01 for the Wiktor stents to 0.14 mm for the Palmaz-Schatz stents; the random error (RE) was 0.03 to 0.14 mm. QCU SE varied from 0.05 to 0.11 mm, and RE ranged from 0.01 to 0.07 mm. At the next stage, 4.0-mm Wiktor and Palmaz-Schatz stents were deployed into the phantom lumens; 1.5-, 2.0-, 2.5- and 3.0-mm lumens were created inside the stents. QCA and QCU measurements of 1.5- to 2.5-mm residual lumens were overestimated by 0.1 to 0.3 mm. In the 3.0-mm residual lumen within the Wiktor stent, QCA underestimated the luminal size by −0.1 mm. There was no QCA inaccuracy for a 3.0-mm lumen within the Palmaz-Schatz stent. In patients, in 25 stented segments in both the Palmaz-Schatz and Wiktor groups, there was no difference between QCA and QCU diameters.

Conclusions—QCU is sufficiently precise for the assessment of the coronary lumen after stenting. QCA can be used as an accurate method of poststent assessment, except when a very mild recurrence within a highly opaque stent is measured. In that instance, QCA may underestimate the luminal diameter. **(*Circulation*. 1998;98:1495-1503.)**

Key Words: stents ■ angiography ■ ultrasonics

The use of intracoronary stents during the past few years has raised serious doubts regarding the validity of quantitative coronary angiography (QCA) after stent placement. Many authors have been concerned that the optical density of a metallic stent, added to the optical density of the contrast-filled lumen, adversely affects border definition. It is commonly believed that this limitation is more pronounced for the highly opaque Wiktor (Medtronic, tantalum) and moderately opaque Micro (AVE, 316 stainless steel) stents. Moreover, it was reported that determinations made with certain QCA systems on the deployed Palmaz-Schatz (PS) stents in a Plexiglas lumen of known diameter yielded measurements of luminal diameters that were greater than those obtained in the same lumen before stenting.[1] Ozaki et al[2] also reported a significant decrease in QCA accuracy and precision in the presence of metallic stents.[3] Hence, it is unclear to what extent stent opacity interferes with the angiographic quantification of in-stent restenosis. To some degree, these same questions surround intravascular ultrasound (IVUS) interpretation. There are very few validation studies of quantitative[4,5] poststenting ultrasonic measurements (QCU).[2]

To facilitate a combined approach to coronary quantification with both ultrasound and angiography, the present study was designed to address the validity of QCA and QCU for the measurement of phantom lumens stented with different stent models with and without simulated in-stent recurrence. In addition, a clinical comparison between QCA and QCU is reported.

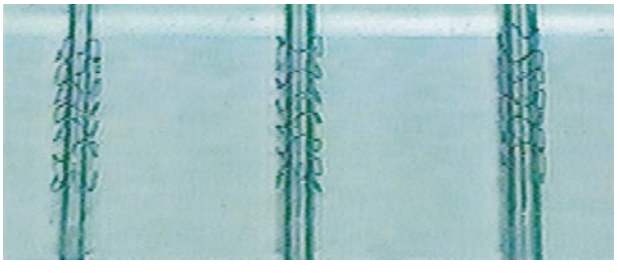

Figure 1. Magnified portion of phantom stage 3. Phantoms were 4.0-mm Wiktor stents with "restenotic" lumen diameter of 2.0, 2.5, and 3.0 mm.

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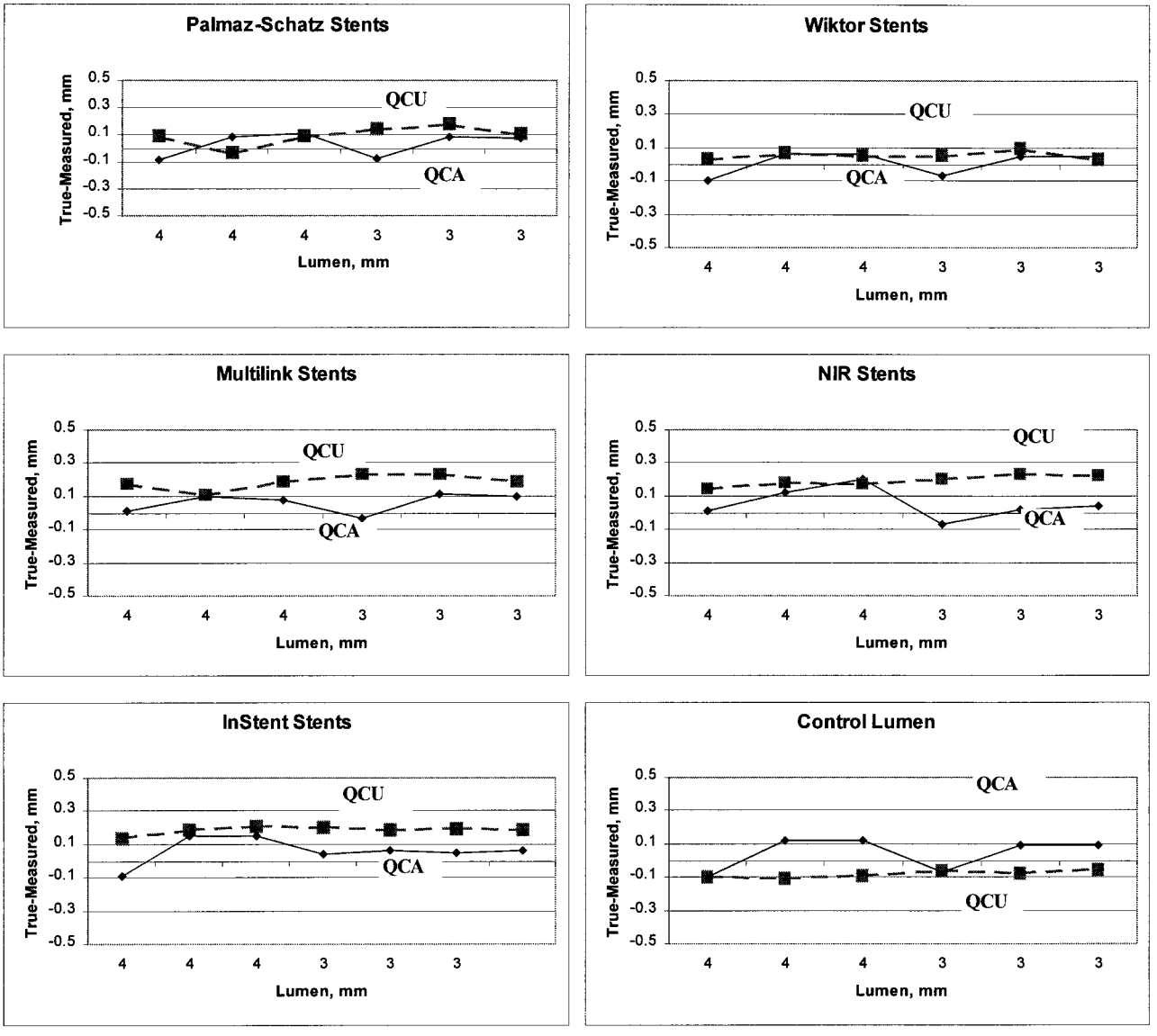

Figure 2. Comparison between QCU and QCA for various stents and control channels (stage 1: immediately after stent deployment).

Methods

Phantom Stage 1: Immediate Poststenting Model

There were 3 stages in the phantom study. In stage 1, 2 phantoms were made from blocks of transparent casting resin that measured 15×6×1.6 cm. Each had a set of 6 lumens cast with high precision over a metal rod of exact dimensions. The diameter of the lumen was 3 mm in phantom 1 and 4 mm in phantom 2.

We deployed 3.0- and 4.0-mm J&J PS, Medtronic Wiktor, ACS Multilink, Boston Scientific NIR, and Medtronic InStent into 5 separate lumens. The sixth lumen was kept unstented to serve as control. Immediately after deployment, inflation to 16 atm was

TABLE 1. QCU and QCA Comparison With Immediate Poststent Model

	Average Lumen, mm*	QCA Average Diameter, mm	QCA Accuracy, mm	QCA Precision, mm	*P* (Control)	QCU Average Diameter, mm	QCU Accuracy, mm	QCU Precision, mm	*P* (Control)	*P* (QCU-QCA)
PS	3.5	3.47	0.03	0.09	0.98	3.41	0.09	0.07	0.62	0.31
Wiktor	3.5	3.49	0.01	0.07	0.92	3.45	0.05	0.02	0.69	0.20
Multilink	3.5	3.44	0.06	0.06	0.95	3.31	0.19	0.05	0.44	0.02
NIR	3.5	3.45	0.05	0.09	0.97	3.31	0.19	0.03	0.43	0.03
InStent	3.5	3.44	0.06	0.09	0.95	3.32	0.18	0.02	0.43	0.01
Control	3.5	3.46	0.04	0.10	0.95	3.58	−0.08	0.02	0.83	0.03

*Average of 3.0- and 4.0-mm lumens.

TABLE 2. QCU and QCA Comparison With Moderate Poststent Restenosis Model

Stent	Average Stent Size, mm	True Lumen, mm*	QCA Average Diameter, mm	QCA Accuracy, mm	QCA Precision, mm	*P* (Control)	QCU Average Diameter, mm	IVUS Accuracy, mm	QCU Precision, mm	*P* (Control)	*P* (QCA-QCU)
PS	3.5	1.78	1.92	−0.14	0.04	0.21	1.88	−0.11	0.04	0.49	0.38
Wiktor	3.5	1.81	1.80	0.01	0.08	0.32	1.87	−0.09	0.04	0.73	0.77
Multilink	3.5	1.82	1.87	−0.05	0.03	0.11	1.86	−0.08	0.01	0.87	0.80
NIR	3.5	1.81	1.82	−0.01	0.08	0.18	1.88	−0.10	0.05	0.62	0.89
InStent	3.5	1.83	1.85	−0.02	0.14	0.23	1.88	−0.11	0.07	0.56	0.17
Control	3.5	1.80	1.86	−0.06	0.05	0.18	1.81	−0.03	0.04	0.63	0.06

*Direct measurement by calibrated rods to 1/100 mm.

performed to achieve adequate stent apposition. To assess the results after deployment, the phantoms were filled with Omnipaque 350 mg/mL and imaged on 35-mm cinefilm with a Philips Integris system. Body density was simulated with a copper phantom. A Namic 10-mm area determination grid was placed under the phantom for calibration. QCA was performed off-line using a computerized edge detection program (QCA Plus, Sanders Data System), developed and validated at Stanford.[6–8] QCA measurements included minimum luminal diameter, reference diameter, and average diameter. The same set of measurements

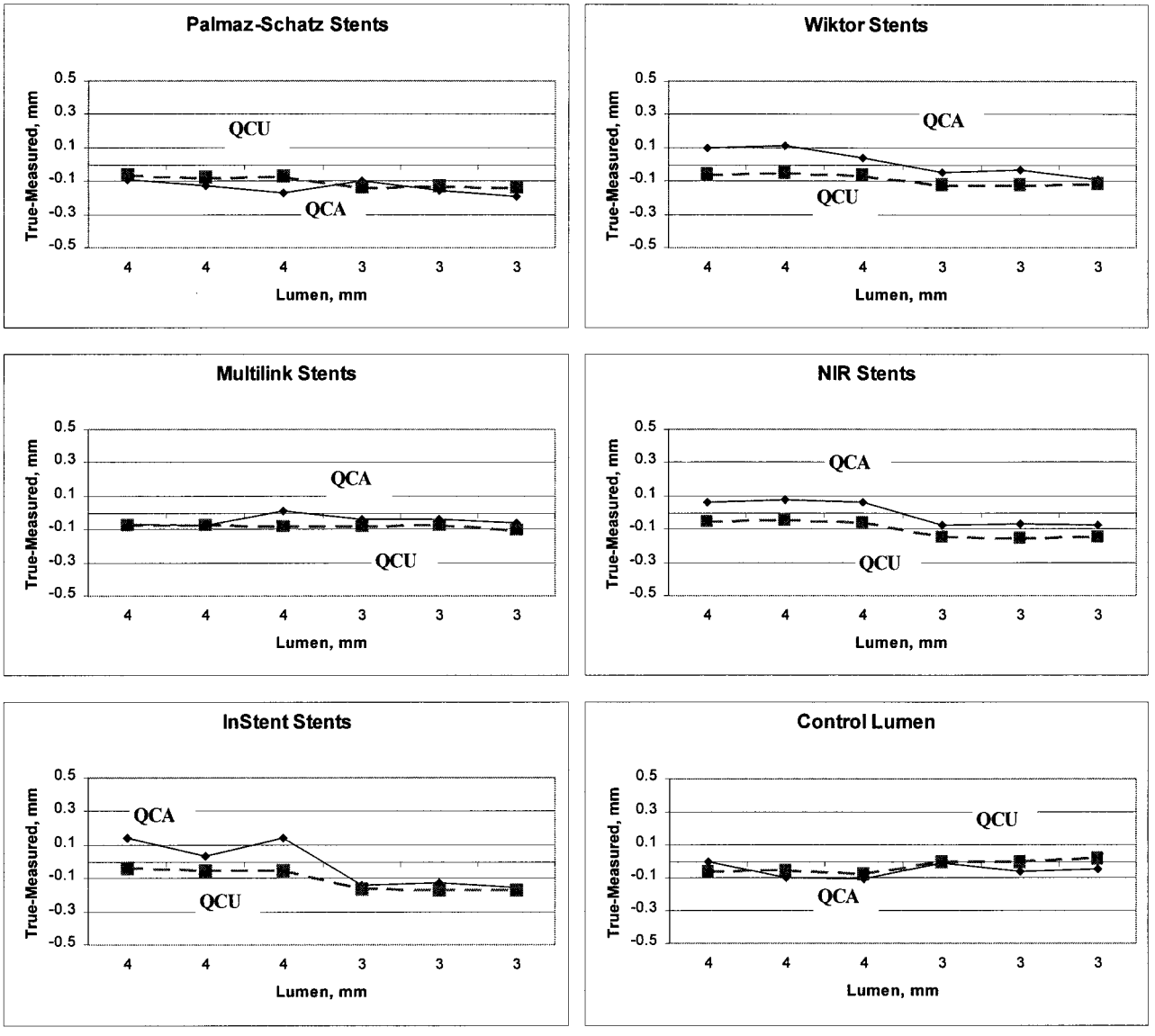

Figure 3. Comparison between QCU and QCA for various stents and control channels (stage 2: model of moderate intrastent restenosis (2.0-mm residual lumen).

TABLE 3. QCA and QCU Comparison for 4.0-mm Wiktor Stents With Model of Variable Amount of Restenosis

"Restenotic" Lumen, mm	QCA Average Diameter, mm	QCA Accuracy, mm	QCA Precision, mm	*P* (Control)	QCU Average Diameter, mm	QCU Accuracy, mm	QCU Precision, mm	*P* (Control)	*P* (QCA-QCU)
1.5	1.61	−0.11			1.58	−0.08			
1.5	1.58	−0.08			1.59	−0.09			
1.5	1.59	−0.09			1.58	−0.08			
2	2.15	−0.15			2.16	−0.16			
2	2.16	−0.16			2.16	−0.16			
2	2.11	−0.11			2.16	−0.16			
2.5	2.62	−0.12			2.57	−0.07			
2.5	2.60	−0.10			2.59	−0.09			
2.5	2.62	−0.12			2.59	−0.09			
3	2.89	0.11			3.01	−0.01			
3	2.93	0.07			3.02	−0.02			
3	3.04	−0.04			3.03	−0.03			
Mean	2.33	−0.08	0.08	0.75	2.34	−0.09	0.05	0.71	0.42

was repeated at a nonstented part of the channel. All measurements were performed in triplicate.

IVUS pullback was performed after that by use of a ClearView Ultra unit (Boston Scientific Corp) with 2.9F MicroView 30-MHz coronary imaging catheter (Cardiovascular Imaging Systems). Images were recorded during slow pullback of the catheter. QCU was performed with TapeMeasure (INDEC Systems, Inc). Luminal area, minimum and maximum diameters, and average diameters were obtained. All measurements were performed in triplicate.

Phantom Stage 2: Moderate Poststent Restenosis Model

In Stage 2, the phantom lumens were rinsed clean, carefully dried, and filled with casting resin. Before the casting resin was solidified, another high-precision rod, 2 mm in diameter, was used to cast another 2.0-mm-diameter lumen in the geometric center of the original lumen to simulate a comparable amount of in-stent intimal proliferation (Figure 1). Angiographic and IVUS imaging was then performed, followed by QCA and QCU. "True" luminal diameter was confirmed by use of calibrated stainless steel rods of increasing size.

Phantom Stage 3: Critical Poststent Restenosis Model

Stage 3 consisted of simulating the different amounts of intrastent proliferation for a highly opaque versus a low-opacity stent. Two phantoms with five 4.0-mm lumens were created. Four 4.0-mm Medtronic Wiktor stents were deployed into these lumens in 1 phantom, and four 4.0-mm J&J PS stents were deployed in the second phantom. The fifth channel was left as control. After deployment, all stented lumens were filled with casting resin, and 1.5-, 2.0-, 2.5-, and 3.0-mm lumens were precision drilled into the geometric center of the original lumens to simulate various amounts of in-stent growth. Angiographic and IVUS imaging were performed, followed by QCA and QCU.

Systematic error (accuracy)[9] of the method was calculated as the average difference between "true" and measured values. Random error (precision) was calculated as the SD of these differences.

Patient Studies

Coronary angiograms in study patients were obtained after the deployment of 25 PS stents and 25 Wiktor stents. Manual IVUS pullbacks were performed to ascertain adequate stent apposition and expansion. To standardize QCA and IVUS measurements, the

TABLE 4. QCA and QCU Comparison for 4.0-mm PS Stents With Model of Variable Amount of Restenosis

"Restenotic" Lumen, mm	QCA Average Diameter, mm	QCA Accuracy, mm	QCA Precision, mm	*P* (Control)	QCU Average Diameter, mm	QCU Accuracy, mm	QCU Precision, mm	*P* (Control)	*P* (QCA-QCU)
1.61	1.90	−0.29			1.83	−0.23			
1.61	1.83	−0.22			1.84	−0.23			
1.61	1.81	−0.20			1.90	−0.30			
1.99	2.15	−0.15			2.14	−0.15			
1.99	2.14	−0.14			2.12	−0.13			
1.99	2.15	−0.15			2.15	−0.16			
2.48	2.60	−0.10			2.60	−0.12			
2.48	2.60	−0.10			2.61	−0.13			
2.48	2.61	−0.11			2.57	−0.09			
2.93	2.98	−0.05			2.95	−0.01			
2.93	2.98	−0.05			2.95	−0.01			
2.93	2.98	−0.05			2.99	−0.05			
Mean	2.39	−0.13	0.08	0.1	2.39	−0.14	0.09	0.5	0.67

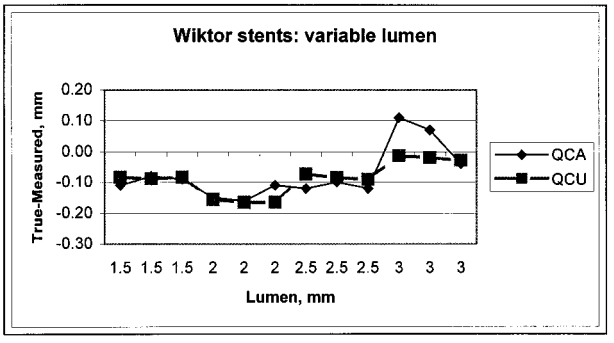

Figure 4. Comparison between QCU and QCA for the model of variable restenosis after 4.0-mm Wiktor stent deployment (phantom stage 3).

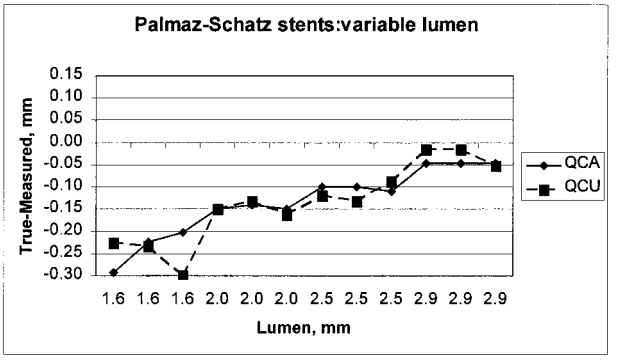

Figure 5. Comparison between QCU and QCA for the model of variable restenosis after 4.0-mm PS stent deployment (phantom stage 3).

angiographic frame selected for QCA with minimal foreshortening of the vessel was captured and printed as a hard copy. During IVUS measurements, this hard copy was used as a road map. The QCU operator (Y.K.) marked the exact position of IVUS cross-sectional measurements on this angiographic image. After QCU, QCA was performed. The method of obtaining QCA measurements was modified specifically for this study: Instead of averaging diameters into mean diameter and extrapolating them into reference diameter, we obtained QCA diameter values in the points at which QCU cross-sectional measurements were made. Four measurements were obtained—2 within the stent, 1 proximal to the stent, and 1 distal to the stent—and used as reference measurements.

Statistical Analysis

Statistical analysis was performed by use of SPSS for Windows (SPSS Inc) with paired and unpaired Student's *t* tests. Continuous variables are expressed as mean±SD. Correlation and linear regression analyses were also performed.

Results

Phantom Stage 1: Immediate Poststenting Model

There was no difference between the control lumen measurements (no stent) and any stented lumen with both QCA and QCU (Table 1) by nonpaired statistics. Systematic error for QCA varied from 0.01 mm for the Wiktor stents to 0.06 mm for the InStent and Multilink stents. Random error was least for the InStent (0.06 mm) and most for the control channel (0.1 mm). QCU systematic error was least for the control channel (−0.08 mm) and most for the Multilink and NIR (0.19 mm) stents. QCU random error was smallest for the Wiktor, InStent, and control channel and highest for the PS stents. There was no difference in accuracy or precision of QCA and QCU of stented versus control lumens. Paired statistics demonstrated significantly smaller lumens for the Multilink, NIR, and InStent stents when measured by IVUS compared with QCA. On the other hand, an estimate of the control channel diameter was higher with QCU. Plots of absolute differences between true and measured values are presented in Figure 2.

Phantom Stage 2: Moderate Poststent Restenosis Model

The simulation of moderate "restenosis" (Table 2) with 1.78- to 1.8-mm lumens within 3.0-mm (40% stenosis) and 4.0-mm (55% stenosis) channels demonstrated no statistically significant differences between the true lumen and its estimates by QCA and QCU. The highest QCA systematic error (−0.14 mm) was obtained for the PS stents; the lowest (0.01 mm), for the Wiktor stents. The highest QCU systematic error value was obtained for the PS and InStent stents (−0.11 mm); the smallest, for the control channel, Wiktor, and Multilink (−0.03, −0.09, and −0.08 mm, respectively). QCA random error was comparable to immediate postdeployment measurements. The highest values were obtained for the InStent and the smallest for the PS and Multilink stents. IVUS random error was also highest for NIR and InStent and smallest for the PS, Wiktor, and Multilink stents. There was no difference in in-stent measurements between QCA and QCU. The plots of absolute differences between the true and measured values (Figure 3) demonstrate the absence of significant differences between the true values and the QCA or QCU estimates. There was no statistically significant difference between QCA and QCU lumen estimates.

Phantom Stage 3: Critical Poststent Restenosis Model

There was no statistically significant difference between the true size of residual lumens and QCA and QCU estimates (Tables 3 and 4) for both Wiktor and PS stents. QCA

TABLE 5. QCA and QCU Measurements: Comparison Between PS and Wiktor Stents in Patients

	Stented Segments					Reference Segments				
Stent Model	n	QCU Average Diameter, mm	QCA Average Diameter, mm	*P* (QCU-QCA)*	*r* (QCU-QCA)	n	QCU Average Diameter, mm	QCA Average Diameter, mm	*P* (QCU-QCA)	*r* (QCU-QCA)
Wiktor	46	3.7±0.5	3.5±0.5	>0.05	0.81	40	3.6±0.7	3.0±0.7	<0.01	0.6
PS	46	3.3±0.1	3.1±0.5	>0.05	0.7	42	3.6±0.6	3.0±0.7	<0.01	0.8
P		<0.001	<0.001				>0.05	>0.05		

*Student's *t* test comparison between QCU and QCA measurements.

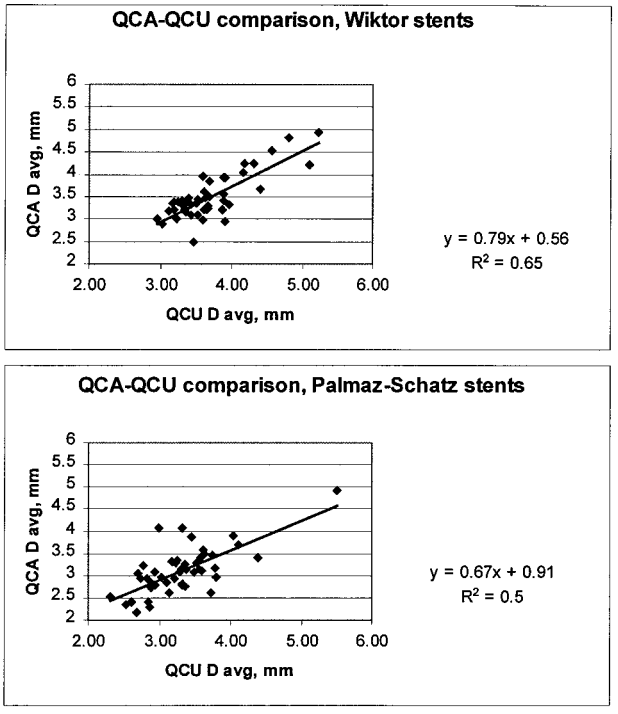

Figure 6. Clinical QCA and QCU comparisons for Wiktor and PS stents. D indicates diameter.

systematic error was −0.08 mm for Wiktor and −0.13 mm for PS stents, whereas QCU systematic error was −0.09 mm for Wiktor and −0.14 mm for PS stents. QCA random error was 0.08 mm for both Wiktor and PS stents. QCU random error was 0.05 mm for Wiktor and 0.09 mm for PS stents. Correlation coefficients between true lumen diameter and QCA or QCU estimate and between QCA and QCU lumen estimates were 0.99 for both stents. The plots of absolute differences between true and measured lumen diameters (Figures 4 and 5) demonstrate close correlation between the 2 methods. QCA and QCU measurements of 1.5- to 2.5-mm residual lumens resulted in some overestimation (0.1 to 0.3 mm) of luminal size.

In the Wiktor stent, for a 3.0-mm residual lumen, QCU gave practically perfect luminal estimates, whereas QCA measurements slightly underestimated luminal size (−0.1 mm). There was no statistical difference between QCA or QCU measurements and true lumen size for both stents.

Patient Study

Forty-six measurements of stented segments were performed in both the PS and Wiktor groups (2 measurements per stent). Forty-two and 40 reference segments, respectively, were measured on both sides of stented segments (Table 5). In the ostial or very proximal lesions, only 1 reference segment was measured. There was no difference between QCU and QCA measurements of the reference diameters between the PS and Wiktor groups by nonpaired statistics. QCU and QCA diameters of the stented segment were significantly larger for the Wiktor group. For the reference diameters in both the Wiktor and PS groups, QCU measurements provided larger values than QCA. For the stented segments in both groups, there was no difference between QCA and QCU diameter values. There was also a close linear correlation between QCU and QCA for the PS and Wiktor groups (r=0.81 to 0.7, respectively). Figure 6 demonstrates approximately the same relationships

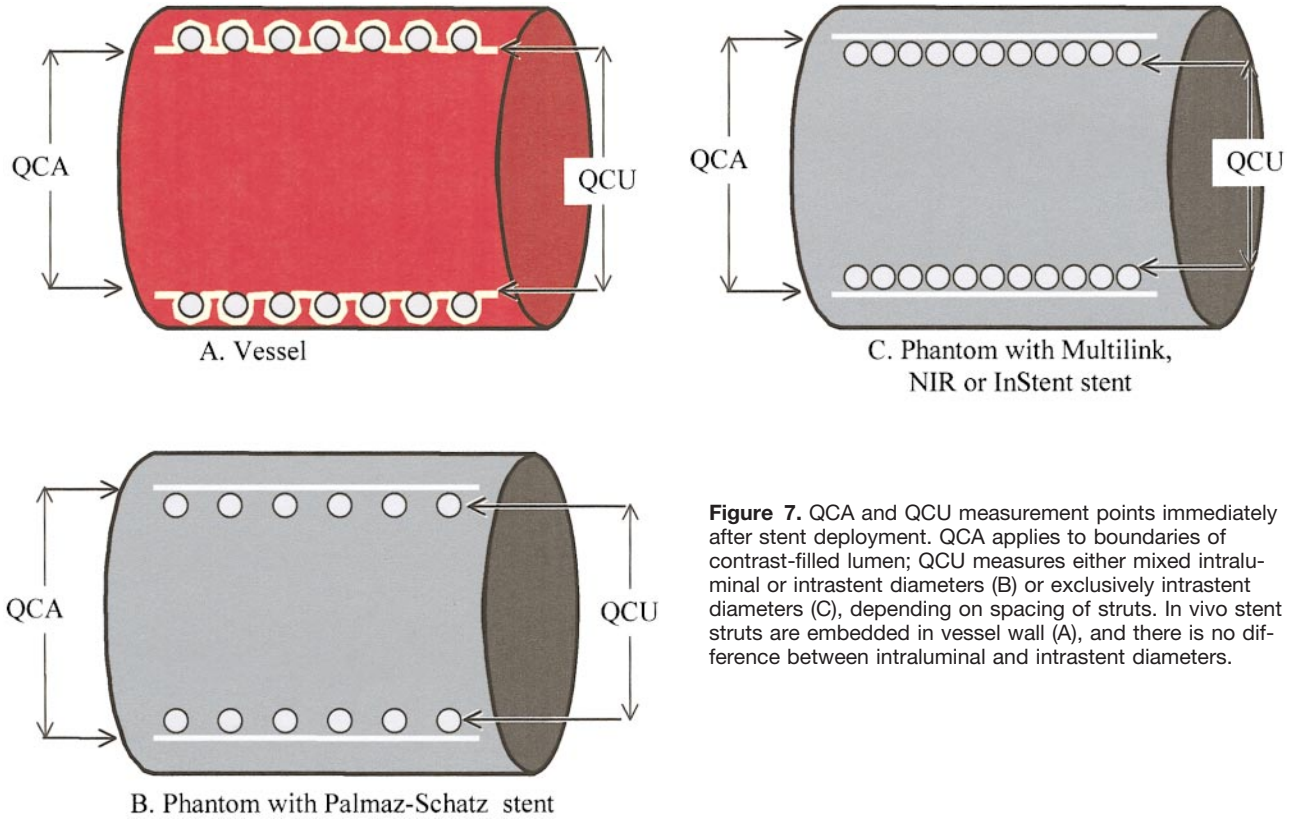

Figure 7. QCA and QCU measurement points immediately after stent deployment. QCA applies to boundaries of contrast-filled lumen; QCU measures either mixed intraluminal or intrastent diameters (B) or exclusively intrastent diameters (C), depending on spacing of struts. In vivo stent struts are embedded in vessel wall (A), and there is no difference between intraluminal and intrastent diameters.

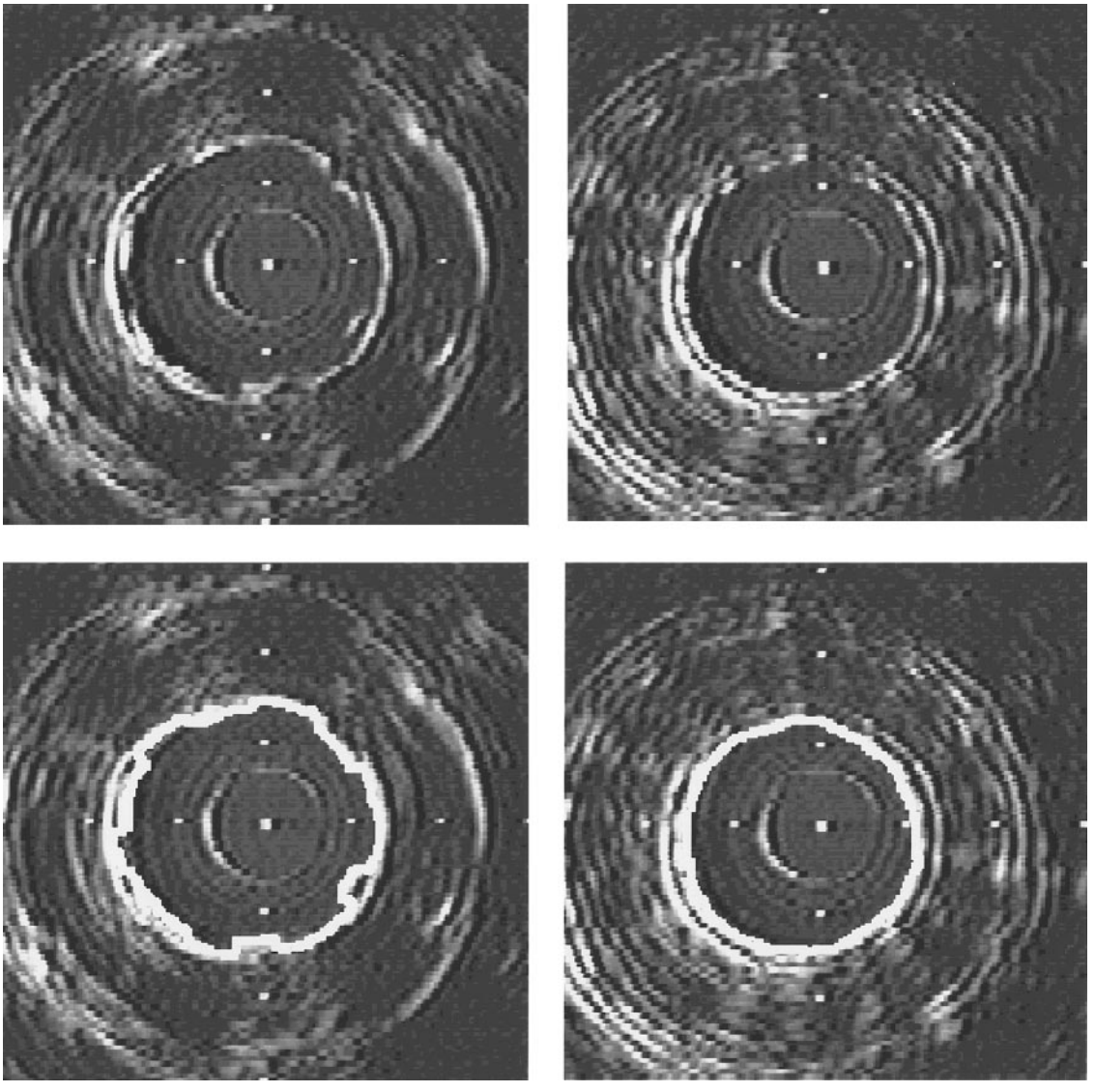

Figure 8. IVUS images of different stents. Top left photograph was taken immediately after deployment of PS stent (stage 1), with superimposed tracing of vessel lumen (bottom left). Because of the wide spacing of struts, portions of luminal wall also are traced. Close spacing of the NIR struts (right top and bottom) prevents operator from tracing actual lumen.

between QCA and QCU for both groups.

Discussion

Immediate postdeployment measurements in vitro (phantom stage 1) demonstrated that there was no difference between the measurement of control or any stented lumen by either QCA or QCU. For QCA, this means that even the addition of the highly opaque Wiktor stent did not influence border definition. Previously reported poststenting "increase" in the lumen of a similar phantom[1] can be related to a difference in the border detection algorithm. Both systematic and random error values for QCA and QCU are excellent, and the detected variations are minor. There was significantly smaller lumen for the Multilink, NIR, and InStent stents when measured by IVUS compared with QCA. An estimate of the control channel diameter was higher with QCU. We believe that the differences between QCU and QCA measurements of the stented lumen immediately after stent deployment reflect the fact that QCA measures the outer boundaries of the contrast-filled channel (Figure 7), whereas QCU traces the inner surface of the stent. In vivo, stent struts are ideally embedded into the vessel wall, causing intrastent lumen to equal vessel lumen. In the rigid phantom channel, the stent lies within the lumen; therefore, QCU cross-sectional measurements of the stented lumen are somewhat smaller than the actual lumen diameter of the cast model. In PS and Wiktor stents, widely spaced struts allowed QCU tracing of portions of the channel wall as well as metal, while in Multilink, NIR, and InStent stents, the closely spaced struts prevented wall tracing, thus creating a significant difference in the luminal diameter between QCU and QCA (Figures 7 and 8). Of course, this difference between stent models could disappear if the operator measures only the distance between opposing leading stent edges. However, this is not possible because of variance in strut spacing and the nature of computerized planimetry.

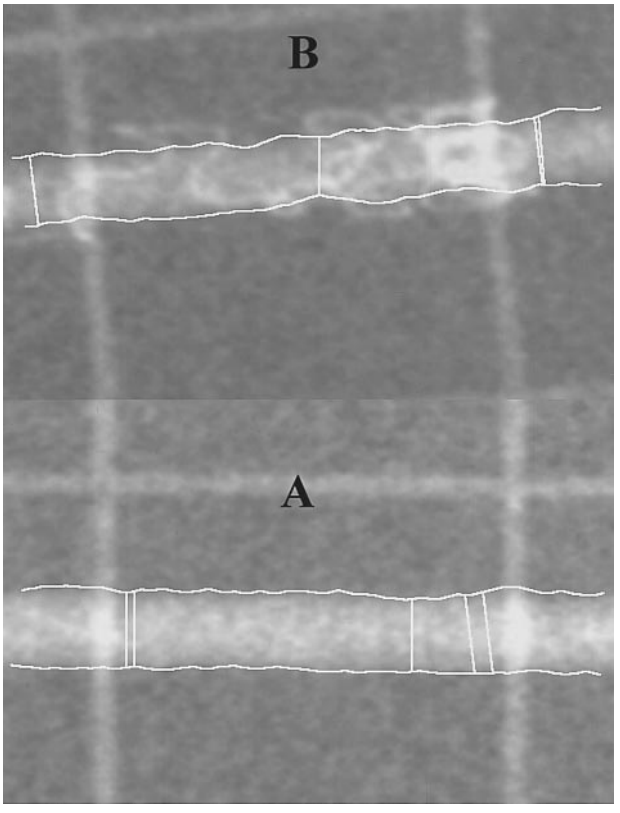

Figure 9. Examples of edge detection (phantom stage 2). A, Control lumen; B, phantom model of moderate restenosis within Wiktor stent.

The fact that QCU diameter of control lumens was slightly larger than that of QCA and larger than the "true" lumen is probably related to the fact that IVUS was not designed to image lumens in a block of casting resin. The properties of casting resin differ considerably from the blood vessels. It is important that immediately after deployment, QCA and QCU accuracy and precision did not differ between control and any stented lumen.

The moderate poststent restenosis models (phantom stage 2) were more complex than phantom stage 1 models. Except for PS stents, systematic and random QCA errors were the same for these models. QCU systematic error was somewhat smaller for the control lumen. Nevertheless, overall systematic and random error values for QCU and QCA were acceptable, ie, comparable to that reported for other nonstent QCA and QCU validation studies.[10–13] The QCA Plus system used at Stanford allows the operator to specify the search path along both sides of the vessel before the automatic edge detection algorithm is applied. Consequently, compared with path-line[14] systems like CAAS[15] or CMS,[16] QCA Plus provides better poststent edge definition (Figure 9). The results of the phantom validation of the newer and promising gradient field transform function for the poststent coronary analysis have not been published yet.[16] The fact that there was no difference between QCA and QCU diameters supports our explanation for the stage 1 discordance.

The critical poststent restenosis models (phantom stage 3) with both the highly opaque Wiktor stent and the minimally opaque PS stent, along with decreasing diameter of residual lumen, demonstrated excellent reproducibility between QCA and QCU and acceptable levels of systematic and random errors. There was no difference between QCA or QCU and true diameter estimates. Figure 4 shows the close agreement between QCU and QCA, except in the last channel with a residual lumen of 3.0 mm. This last channel represented the smallest difference between the stent and the lumen, ie, very mild recurrence. In these 3 measurements, QCA tended to underestimate channel diameter. This finding is probably related to the short distance between the metal stent and its lumen ($<$0.5 mm). We conclude therefore that the only instance in which QCA measurements can be misleading occurs when there is mild in-stent restenosis. This observation is applicable only for the highly opaque Wiktor stent. With PS stents, there was no QCA underestimation for the 3.0-mm phantom lumen. This observation is similar to that reported by Ozaki et al,[2] implying that in the poststenting QCA measurement, the reference diameter should never be selected within a stented region. The systematic error values were slightly higher for the PS than Wiktor stents. We do not have an explanation for this result, but it suggests that factors other than radiopacity could be involved.

The patient study part of our study confirms that immediately after stenting in vivo, there is no difference between QCA and QCU intrastent lumen estimates, despite the difference in x-ray opacity. The absence of difference was substantiated with the nonpaired *t* test. With paired *t* test applied, however, the difference between QCU and QCA measurements of both PS and Wiktor was significant ($P<0.01$). We believe, however, that the paired statistic is not applicable here because of the remaining differences in the location of the QCA and QCU determinations and in measurements during different phases of the cardiac cycle.

We also observed a close linear relationship between QCA and QCU measurements. The significant difference in the reference lumen size (QCU estimate is larger; QCA is smaller) probably results from the presence of angiographically undetected eccentric disease of the reference segment. Stenting usually results in a concentric residual lumen, thus eliminating the differences between QCU and QCA estimates. This study demonstrated that the accuracy and precision of QCA and QCU in vitro are not related to the amount of stent x-ray opacity or to stent design either immediately after deployment or with simulated in-stent restenosis. In vivo, QCA and QCU of stented segments produce nearly identical quantitative measurements.

Study Limitations

A main limitation of this study is the predominantly in vitro character of the data, with limited in vivo validation represented only by acute poststent imaging. The absence of the perfect method to quantify the extent of in-stent growth with absolute precision is the cause of this criticism. Our in vivo validation was undertaken chiefly to compare the lumen quantification within the most visible (Wiktor) and least visible (PS) stents.

Conclusions

QCU lumen measurements remain quantitatively robust for the assessment of the coronary lumen after stenting. QCA can

be used as a sensitive and accurate method of poststent lumen assessment, except when a very mild recurrence is measured within a highly opaque stent. In that instance, QCA may underestimate luminal diameter.

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Coronary Stents: In Vitro Aspects of an Angiographic and Ultrasound Quantification With In Vivo Correlation

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