Optimized expansion of the Wallstent compared with the Palmaz-Schatz stent: On-line observations with two- and three-dimensional intracoronary ultrasound after angiographic guidance

Clemens von Birgelen, MD, Robert Gil, MD, Peter Ruygrok, MD, Francesco Prati, MD,
Carlo Di Mario, MD, PhD, Wim J. van der Giessen, MD, PhD, Pim J. de Feyter, MD, PhD, and
Patrick W. Serruys, MD, PhD *Rotterdam, The Netherlands*

Optimized stent expansion by high-pressure inflations of oversized balloons has initially been derived from experience obtained with the Palmaz-Schatz stent, whereas there is little experience with this strategy in the Wallstent. By using this approach with quantitative coronary angiographic guidance, 20 Wallstents and 20 Palmaz-Schatz stents were implanted in 34 patients and consecutively examined by conventional two-dimensional (2D) intracoronary ultrasound (ICUS) and three-dimensional (3D) ICUS on the basis of the application of a pattern recognition algorithm. Ultrasound criteria of adequate stent expansion were defined as a complete apposition of the stent to the vessel wall, a stent symmetry index (SSI = minimum/maximum lumen diameter) ≥0.7, and a stent-reference lumen area ratio (SRR = Minimum intrastent lumen area/Average of proximal and distal reference lumen area) ≥0.8. In all cases a smooth angiographic lumen and a negative diameter stenosis, on the basis of a distal reference, was achieved. For the Wallstents ICUS showed a higher SSI (2D, 0.95 ± 0.04 vs 0.85 ± 0.09; $p < 0.001$; 3D, 0.90 ± 0.09 vs 0.82 ± 0.11, $p < 0.05$) and a lower SRR (2D, 0.66 ± 0.12 vs 0.81 ± 0.13, $p < 0.005$; 3D, 0.63 ± 0.14 vs 0.74 ± 0.15, $p < 0.05$) than for the Palmaz-Schatz stents. Ninety percent of failure in meeting these criteria resulted from a low SRR. The incidence of incomplete stent apposition (one in both stents) or SSI <0.7 was low and generally associated with an SRR <0.8. The Wallstents met the ICUS criteria less often (2D, 2 (10%) vs 10 (50%), $p < 0.01$; 3D, 3 (15%) vs 9 (45%), $p < 0.05$), were significantly longer (35.1 ± 7.7 mm and 14.3 ± 3.3 mm, $p < 0.0001$), and generally demonstrated a larger vessel tapering, measured as proximal minus distal ICUS reference lumen area (1.33 ± 2.91 mm^2 vs 0.44 ± 1.97 mm^2, not significant). Wallstents meeting the ICUS criteria, however, showed less vessel tapering (0.18 ± 1.64 mm^2). Thus optimized stent expansion was followed by excellent angiographic results for both Palmaz-Schatz and Wallstent. Although angiographic results and visual assessment of the ICUS examination suggested a good outcome, few Wallstents met the ICUS criteria in contrast to the Palmaz-Schatz stents. The low value of the SRR in the Wallstents is likely to be caused by vessel tapering, suggesting that this criterion may be unsuitable in assessing the adequacy of the expansion of relatively long stents such as the Wallstent. (Am Heart J 1996;131:1067-75.)

Until recently coronary stenting has in many centers been performed only for acute or threatening vessel occlusion after balloon angioplasty.[1-8] The initial enthusiasm for coronary stenting[9] had been tempered by the high incidence of subacute thrombosis, which now appears to be significantly reduced by many factors, including coating the stent with heparin.[10] Optimization of the results of stenting, first promoted by the Milano group,[11-13] which performed high-pressure inflations of oversized balloons inside stents with intracoronary ultrasound (ICUS) guidance, is an alternative approach to meet the challenge of subacute stent thrombosis. Initial experience suggests[11] that this approach may even reduce the incidence of restenosis after coronary stenting.[14, 15] By changing the technique of coronary stenting from a more restrained to this vigorous approach, the problem of subacute occlusion[16] could be minimized, permitting stenting without anticoagulation and the inherent risk of bleeding.[11] The reduced incidence of subacute thrombosis by optimized stent deployment is achieved at the expense of a small but not insignificant risk of coronary dissection and rupture,[12, 17] emphasizing the necessity of defining certain criteria for safe and effective guidance of the intervention.

From the Thoraxcenter, Division of Cardiology, University Hospital, Erasmus University.

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Reprint requests: Patrick W. Serruys, MD, PhD, Thoraxcenter, Erasmus University Rotterdam, Cardiac Catheterization and Intracoronary Imaging Laboratory, P.O. Box 1738, 3000 DR Rotterdam, The Netherlands.

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Table I. Characteristics of the population and stenting procedures

	Wallstent	*Palmaz-Schatz stent*
Stents	20	20
Patients	18	16
Patients with multiple stents	2 (15%)	4 (25%)
Age (yrs)	60.5 ± 8.8	60.9 ± 8.4
Male sex	13 (72%)	11 (69%)
Vessels		
LAD	3 (15%)	9 (45%)
LCX	0	1 (5%)
RCA	9 (45%)	10 (50%)
SVG	8 (40%)	0
Nominal stent length (mm)	35.1 ± 7.7	14.3 ± 3.3 $p < 0.00001$
Largest balloon (mm)	4.2 ± 0.6	3.6 ± 0.4 $p < 0.005$
Maximum pressure* (atm)	14.7 ± 3.7	15.1 ± 2.6 NS
Balloon:artery ratio	1.4 ± 0.3	1.3 ± 0.2 NS

LAD, Left anterior descending coronary artery; *LCX,* left circumflex coronary artery; *RCA,* right coronary artery; *SVG,* saphenous vein graft.
*Maximum pressure in the largest balloon.

Because the new concept has initially been applied with Palmaz-Schatz stents (Johnson & Johnson, Warren, N.J.), the ICUS criteria for optimized stent deployment[11-13] were primarily made on the basis of this stent with little experience in high-pressure expansion of the Wallstent (Schneider, Bulach, Switzerland), which has a characteristic structural design, length, and clinical application[18-22] that differs considerably from the Palmaz-Schatz stent.[23, 24] This observational study compares the practice and results of the optimized deployment of 20 Wallstents and 20 Palmaz-Schatz stents with quantitative angiography for guiding the procedure and ICUS for assessing the result. Because the potential of two- (2D) and three-dimensional (3D) ICUS in assessing the vessel wall[25-29] and stent[30, 31] geometry and the adequacy of stent deployment[11-13, 32-36] has recently been demonstrated, both conventional 2D and on-line reconstructed 3D ICUS were applied.

METHODS

Study population. The results of implantation of 20 Wallstents and 20 Palmatz-Schatz stents in American College of Cardiology/American Heart Association type B or C lesions[37, 38] without angiographic evidence of major calcification were examined on-line by quantitative coronary angiography and ICUS. The Wallstents were implanted in 18 patients and the Palmaz-Schatz stents in 16 patients aged 60.7 ± 8.5 years (range 46 to 73 years). The Wallstents were significantly longer than the Palmaz-Schatz stents ($p < 0.0001$). Table I gives further details.

Interventional procedure. All patients received 250 mg aspirin and 10,000 U heparin intravenously. During the entire procedure the activated clotting time was measured hourly and intravenous heparin was administered if required to maintain an activated clotting time of >300 seconds. After intracoronary injection of isosorbide dinitrate, the initial on-line quantitative coronary angiography (QCA) was performed. Predilation of the lesion by conventional balloon angioplasty was performed. The interpolated angiographic reference lumen diameter provided by QCA, the lesion length, and the presence of adjacent side branches were taken into account to select an appropriately sized self-expandable Wallstent. The nominal Wallstent diameter chosen was generally 1.5 mm larger than the interpolated reference diameter. A delivery balloon with a diameter corresponding to the interpolated reference lumen diameter was used to implant the Palmaz-Schatz stents.

Additional balloon inflations were performed inside all stents with a low-compliance balloon catheter with at least an 0.25 mm larger diameter than the interpolated angiographic lumen reference and a pressure of at least 14 atm. Progression to larger balloons was permitted to achieve a satisfactory angiographic result. Thus balloons with a maximum size of 4.2 ± 0.6 mm for the Wallstent and 3.6 ± 0.4 mm for the Palmaz-Schatz stent ($p < 0.005$) were inflated with maximum pressures of 14.7 ± 3.7 atm and 15.1 ± 2.6 atm (not significant, NS), respectively (Table I). The balloon/artery ratio was 1.4 ± 0.3 and 1.3 ± 0.2, respectively (NS). In the relatively long Wallstents the largest balloon size and the maximum pressure were frequently applied to only the proximal part of the stented segment. An angiographic appearance of a smooth lumen of the stented segment and a negative distal reference-based diameter stenosis were considered to be the procedural end points on the basis of QCA. After administration of intracoronary nitrates, the stented segment was examined by ICUS.

Quantitative coronary angiography. The computer-based Coronary Angiography Analysis System (CAAS II, Pie Medical Data, Maastricht, The Netherlands), previously described and validated in detail,[39, 40] was used to perform a geometric quantitative analysis. The boundaries of a selected coronary segment were detected by using a weighted sum of the first and second derivative functions of the brightness profile of each vessel scan. The absolute angiographic diameter of the stenosis was determined by using a contrast-free guiding catheter as a scaling device.[39] The measurements were performed on-line after intracoronary nitrates in two orthogonal views. Before stenting, the diameter function was used to determine the minimal lumen diameter, a computer-derived estimation of an interpolated reference diameter at the site of the lesion, and the obstruction length (Fig. 1). The *interpolated diameter stenosis before stenting* was calculated as (Intrastent minimal lumen diameter/Interpolated reference diameter) x 100%.

Because the segments directly adjacent to the stent are involved in the process of luminal enlargement after opti-

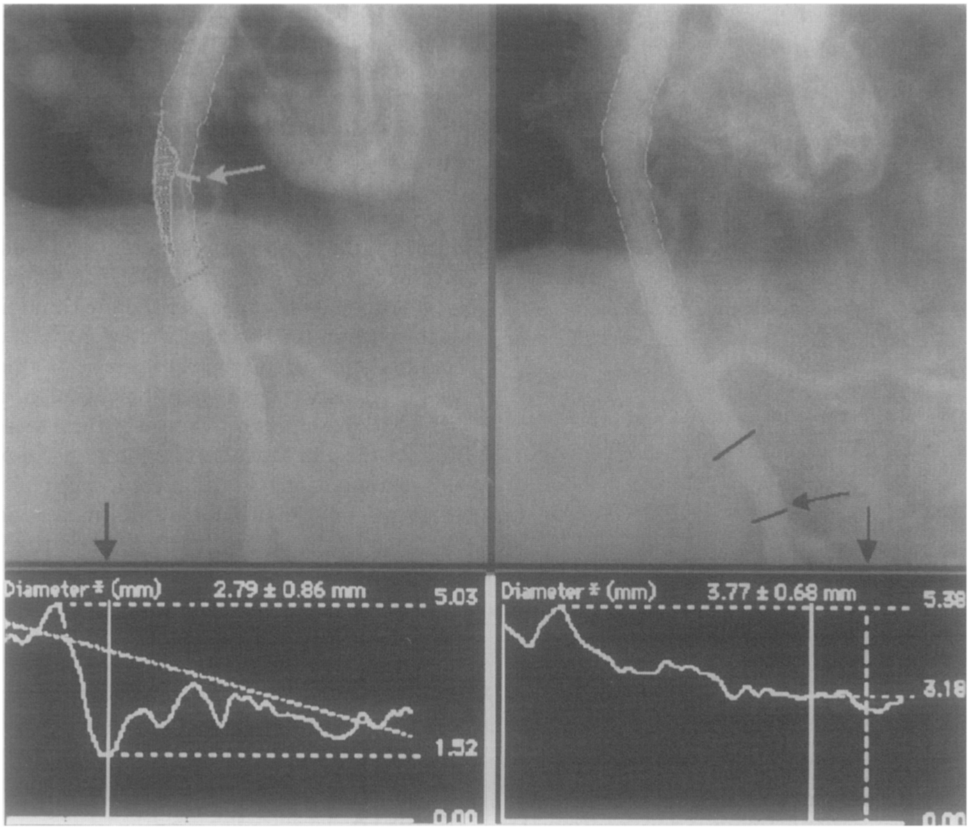


Fig. 1. Quantitative coronary angiography before *(left)* and after implantation of Wallstent *(right)* by CAAS II analysis system. On angiograms site of minimum lumen diameter is indicated by *line. Arrowhead* indicates site of reference measurement. Before stenting *(left)* interpolated reference at site of minimal lumen diameter was used to measure interpolated diameter stenosis. To calculate diameter stenosis after stenting *(right)* angiographically undiseased site up to 1 cm distal to stent was used as reference, showing diameter similar to interpolated reference before stenting.

mized stenting, the interpolated reference diameter was not used to calculate the percent diameter stenosis after stenting but the lumen diameter of an angiographically undiseased reference up to 1 cm distal to the stent without major side branches between the stent and the reference site (Fig. 1). The minimal lumen diameter was measured in the stented segment of the artery and the *distal reference-based diameter stenosis after stenting* was calculated as (Intrastent minimum lumen diameter/Distal reference lumen diameter) × 100%.

Image acquisition of ICUS. A 30-MHz single-element long-monorail ultrasound catheter with a 2.9F echotransparent distal sheath was used (MicroView, CVIS, Sunnyvale, Calif.). The common lumen of the sheath accomodates the imaging core and the guide wire but never both simultaneously. ICUS imaging was performed during a motorized uniform speed (1 mm/sec) pullback of the transducer inside the stationary imaging sheath, which allowed the transducer to move at the same speed as the ICUS handgrip inside the pullback device. The video signal was recorded on a high-resolution super VHS tape for conventional ICUS analysis.

Assessment by ICUS. After the pullback of the ultrasound catheter was completed, the videotape was used to obtain lumen area measurements of the ICUS references that were by definition 3 to 5 mm proximal and distal to the stented segment. Stent apposition to the vessel wall was reviewed over the entire stented segment. The ICUS image with the minimal intrastent lumen area was found by scrolling the videotape back and forth. On this cross-section, the lumen area was manually traced and the stent symmetry was assessed by measuring the minimum and maximum lumen diameter.

3D reconstruction of ICUS. Simultaneously with the video recording on s-VHS tape, video signals were also transferred to a 3D ICUS system (EchoQuant, Indec Systems Inc., Capitola, Calif.) that automatically acquires 8.5 images per second so that contiguous tomographic ICUS image slices, 118 µm apart, could be reconstructed on-line. The memory capacity of the 3D system operated by a second analyst allowed the acquisition and processing of a maximum of 255 images within 2 minutes; thus segments up to 30 mm long could be reconstructed. If Wallstents were longer than 30 mm, ICUS images recorded on videotape were used to reconstruct the proximal part of these stents.

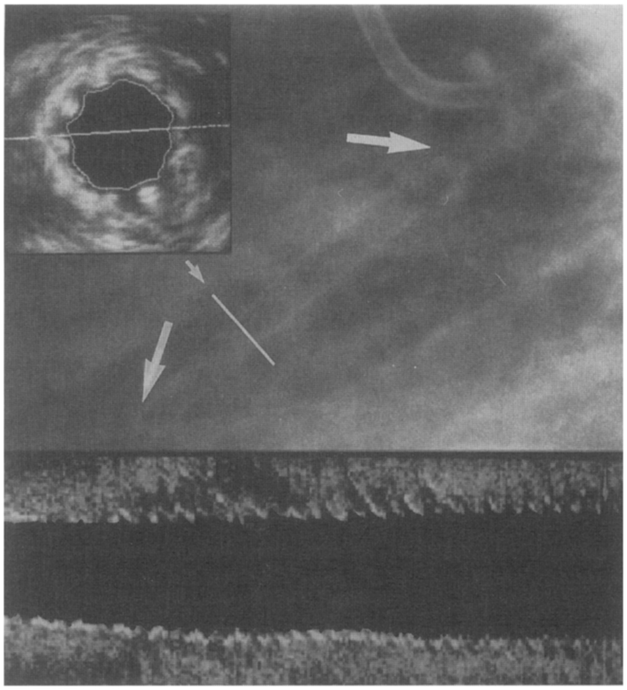


Fig. 2. Wallstent after implantation in left anterior descending coronary artery. *Arrowheads* indicate proximal and distal ends of stent on radiographic image *(upper panel)*. Location of 2D ICUS image *(insert)* is indicated by *small arrowhead*. Cross-sectional image is derived from 3D analysis system, performing semiautomated detection of blood pool on basis of application of pattern recognition algorithm. Longitudinal view *(lower panel)* is reconstructed, showing smooth tapering of luminal dimensions from proximal *(right)* to distal *(left)*. Besides 3D, conventional 2D analysis was performed in this study on basis of review of videotape and manual contour tracing.

Assessment by 3D ICUS. The 3D system provided a longitudinally reconstructed view (Fig. 2) that could be rotated around the longitudinal axis of the vessel segment. Furthermore, a cylindrical format was displayed cut open lengthwise and tilted back. The cylindrical view and more frequently the longitudinal display were used to evaluate the adequacy of stent strut apposition to the vessel wall. Automated image segmentation, on the basis of a pattern recognition algorithm (Acoustic Quantification)[25] that has previously been validated,[41] provided on the cross-sectional ICUS images of the entire reconstructed segment the measurement of the lumen area and the minimum and maximum diameters. The detected contour, indicating the lumen-intima boundary, was rapidly checked and manual correction could be performed on individual ICUS cross-sections. A display of the lumen area and corresponding diameter measurements facilitated the assessment. The minimum lumen area and the minimum and maximum lumen diameters were measured.

Adequate stent expansion by ICUS. During the ultrasound examination of the entire segment, criteria on the basis of our previous experience and slightly modified criteria of the Italian group[11] were applied to define adequate stent deployment. First, good *apposition to the vessel wall* had to be found at all sites of the stented segment. Moreover, the *stent symmetry index* (SSI), defined as ratio of minimal divided by maximal intrastent diameter, had to be ≥0.7 at the site of the minimal intrastent lumen area. The adequacy of the intrastent lumen area finally achieved was assessed by the *stent-reference lumen area ratio* (SRR), a ratio of the minimum intrastent divided by reference lumen area, which had to be ≥0.8. The reference lumen area was defined as the mean of the proximal and distal reference measurements; however, if only a single reference could be measured (e.g., ostial lesion), this measurement was used alone to calculate the SRR. During both 2D and 3D ICUS examinations, these criteria were applied to define an adequate result after the stenting procedure. After this examination was completed, each operator was free to perform additional balloon inflations inside the stent on the basis of the clinical situation and the angiographic or ICUS findings.

Statistics. Measurements of continuous parameters are given as mean ± 1 SD. The two-tailed student's t test for unpaired data analysis was used to compare the Wallstent group with the Palmaz-Schatz stent group, and a p value of <0.05 was considered statistically significant. Categorical variables were assessed using chi-square statistics.

RESULTS

Initial QCA. In the Wallstent and Palmaz-Schatz stent groups the minimal lumen diameter was 1.26 ± 0.48 mm and 1.04 ± 0.23 mm (NS) before stenting, and the obstruction length was 12.24 ± 4.25 mm and 8.18 ± 3.21 mm ($p < 0.005$), respectively. The interpolated reference diameter was 3.04 ± 0.76 mm and 2.86 ± 0.55 mm (NS), and the interpolated diameter stenosis was 58.1% ± 12.6% and 60.9% ± 9.2% (NS), respectively.

Angiographic results and clinical outcome. After stenting, a smooth lumen of the stented segment was obtained in all angiographic views and the QCA analysis revealed a negative distal reference-based diameter stenosis in all Wallstents and Palmaz-Schatz stents. The QCA results after the Wallstent and Palmaz-Schatz stent implantation did not differ significantly. In both the Wallstent and Palmaz-Schatz stent groups, a significant increase in the minimal lumen diameter and reduction of the percent diameter stenosis (Fig. 3) was observed ($p < 0.0001$ for both). The minimal lumen diameter after stenting was 2.95 ± 0.39 mm for the Wallstent and 3.19 ± 0.51 mm for the Palmaz-Schatz stent (NS), and the distal reference-based diameter stenosis was −18.0% ± 11.2% and −17.3% ± 10.0% (NS), respectively. The interpolated reference diameter obtained before stenting and the distal reference diameter after stenting (2.84 ± 0.39 mm and 2.95 ± 0.45 mm

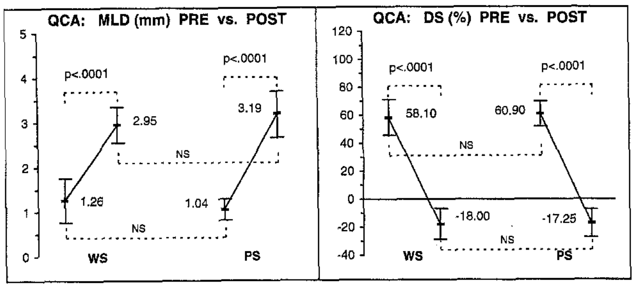


Fig. 3. QCA measurements before (PRE) and after (POST) implantation of Wallstent (WS) or Palmaz-Schatz stent (PS). In both stent groups minimal lumen diameter (MLD) increased significantly after stenting *(left panel)*. Diameter stenosis (DS), derived from interpolated reference before and distal reference measurement after stenting, was significantly reduced by intervention. Between Wallstents and Palmatz-Schatz stents no significant difference was observed.

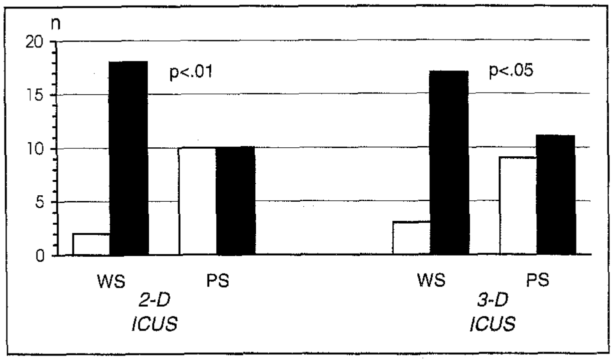


Fig. 4. ICUS criteria of adequate stent expansion met *(white bars)* or not met *(black bars)*. Both conventional 2D and 3D analysis of ICUS images demonstrated that Wallstents *(WS)* met ICUS criteria less frequently than the Palmaz-Schatz stents *(PS)*.

(NS) for the Wallstent group and Palmaz-Schatz stent group, respectively) did not differ significantly.

On the basis of QCA criteria of a smooth stented segment lumen and the realization of a negative percent diameter stenosis, all Wallstents and Palmaz-Schatz stents were successfully implanted. Anticoagulation was performed with aspirin and coumadine or ticlopidine at the operator's discretion. No procedural or post-procedural complications were encountered in either group before discharge.

ICUS assessment after stenting. The stent symmetry index (SSI) was significantly higher in the Wallstent than Palmaz-Schatz stent group (Table II). This difference was even more pronounced in the 2D ($p < 0.001$) than the 3D ICUS results ($p < 0.05$), demonstrating an SSI of 0.95 ± 0.04 and 0.90 ± 0.09 for the Wallstent group and 0.85 ± 0.09 and 0.82 ± 0.11 for the Palmaz-Schatz stent group, respectively. A significantly lower value of the stent-reference lumen area ratio (SRR) was measured in the Wallstent group compared with the Palmaz-Schatz stent group with both 2D (0.66 ± 0.12 vs 0.81 ± 0.13, $p < 0.005$) and 3D ICUS (0.63 ± 0.14 vs 0.74 ± 0.15, $p < 0.05$). The minimal lumen area of the Wallstents was slightly lower (NS) than the minimal lumen area of the Palmaz-Schatz stents (7.65 ± 2.05 mm^2 vs 8.98 ± 2.78 mm^2 by 2D ICUS and 7.62 ± 2.01 mm^2 vs 8.49 ± 3.18 mm^2 by 3D ICUS). No significant difference between the results of 2D and 3D ICUS measurements for the different parameters was found (Table II).

Two (10%) Wallstents and 10 (50%) Palmaz-Schatz stents ($p < 0.01$) met the ICUS criteria of adequate stenting by 2D ICUS (Fig. 4). By using 3D ICUS, 3 (15%) Wallstents and 9 (45%) Palmaz-Schatz stents were found to meet the ICUS criteria of adequate stent expansion ($p < 0.05$). A low SRR was the main reason for >90% of the failures in meeting the criteria. The incidence of an incomplete stent apposition to the vessel wall or an SSI <0.7 was low and mostly associated with a low SRR (Table III). The average ICUS reference lumen area was 12.50 ± 3.41 mm^2 proximally and 11.17 ± 3.07 mm^2 distally for the Wallstent group and 11.34 ± 2.68 mm^2 proximally and 10.89 ± 3.13 mm^2 distally for the Palmaz-Schatz stent group. Consequently, the tapering of the lumen area along the entire stented segment was higher (NS) in the Wallstent group (1.33 ± 2.91 mm^2) compared with the Palmaz-Schatz stent group (0.44 ± 1.97 mm^2). The Wallstents, which met the ultrasound criteria by 2D or 3D ICUS, had an average tapering of the lumen area of 0.18 ± 1.64 mm^2, and all but one were implanted in bypass grafts.

DISCUSSION

Procedure and angiographic assessment. On the initial angiogram the minimal stenosis lumen diameter, the reference lumen diameter, and the balloon-artery ratio were slightly higher for the Wallstent group, whereas the diameter of the maximum size balloon was significantly higher for these cases when compared with the Palmaz-Schatz stent group. This finding may reflect the fact that 40% of Wallstents were implanted in saphenous vein grafts, which usually show larger luminal dimensions than native coronary arteries. Indeed, the relatively long Wallstent is frequently implanted in vein grafts[18, 19] or mid–right coronary arteries without concern for side branches.

Recently, the effect of "conventional" nonopti-

Table II. 2D and 3D ICUS parameters after stenting

	Wallstent	*Palmaz-Schatz stent*	*p*
2D SSI	0.95 ± 0.04	0.85 ± 0.09	<0.001
3D SSI	0.90 ± 0.09	0.82 ± 0.11*	<0.05
2D MLA (mm^2)	7.65 ± 2.05	8.98 ± 2.78	NS
3D MLA (mm^2)	7.62 ± 2.01	8.49 ± 3.18*	NS
2D SRR	0.66 ± 0.12	0.81 ± 0.13	<0.005
3D SRR	0.63 ± 0.14	0.74 ± 0.15*	<0.05

MLA, Minimum lumen area.
*No significant difference between measurements by 2D and 3D intracoronary ultrasound.

Table III. Adequacy of stent expansion by ICUS

	Wallstent	*Palmaz-Schatz stent*
2D ICUS		
ICUS criteria fulfilled	2 (10%)	10 (50%)
ICUS criteria not fulfilled	18 (90%)	10 (50%)
SRR <80%	18	9
SSI <0.7 or incomplete apposition	0	1
SRR <80% and SSI <0.7	0	0
3D ICUS		
ICUS criteria fulfilled	3 (15%)	9 (45%)
ICUS criteria not fulfilled	17 (85%)	11 (55%)
SRR <80%	16	9
SSI <0.7 or incomplete apposition	0	0
SRR <80% and SSI <0.7	1	2

mized deployment of self-expandable and balloon-expandable stents on the stenosis geometry have been examined by our group on the basis of QCA, which demonstrated a similar improvement in stenosis geometry despite major differences in design and mechanical characteristics of the two stent types.[42] Also after angiographic optimization of the Palmaz-Schatz and Wallstent expansion in this study, the residual minimal lumen diameter did not show a statistically significant difference, although the minimal lumen diameter was slightly higher in the Palmaz-Schatz stent group. Nevertheless a smooth lumen contour with a negative distal reference-based diameter stenosis was observed in all stents. Thus no difference between the Palmaz-Schatz and Wallstents was observed in accomplishing an angiographic success.

ICUS assessment. For almost 2 decades angiography has been the standard method of examining the adequacy of coronary interventions.[39] However, it displays only the opacified luminal silhouette of the vessel. ICUS imaging visualizes the lumen and vessel wall[43-45] and depicts the stent architecture, permitting careful examination of its dimensions and apposition to the vessel wall.[11-13, 32-35, 46-48] The comprehensive insight into vessel and stent geometry provided by ICUS has played an important educational role in triggering and developing the concept of optimized stent deployment.[11-13] In this study the minimal lumen area of the Wallstent group and Palmaz-Schatz stent group did not differ significantly after stent implantation; however, a tendency towards a smaller minimal luminal dimension was found for the Wallstent group in accord with the angiographic findings.

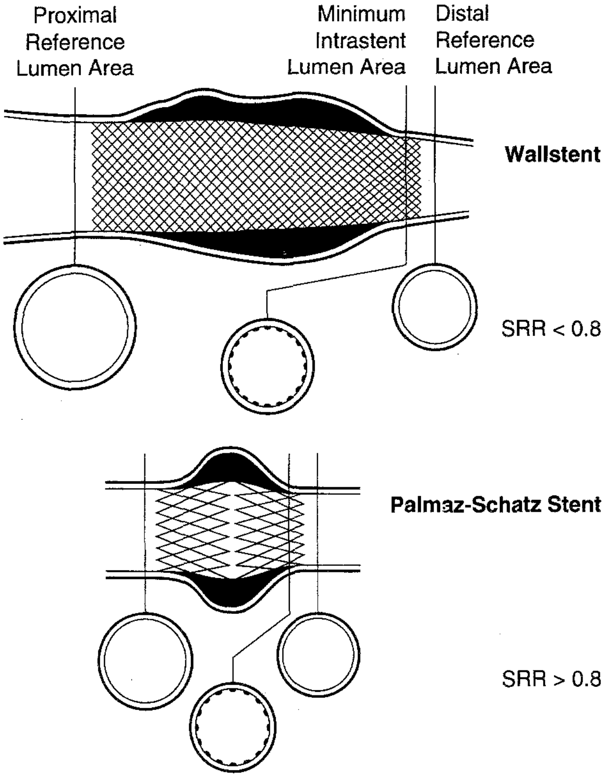
Adequacy of stent expansion by ICUS. The ICUS criteria for safe and effective guidance to optimize stent expansion were developed on the basis of experience with Palmaz-Schatz stents,[11-13] although there has been little experience with the Wallstent with its characteristic design, length, and application.[18-22] In this study ICUS criteria employed in our center, derived from the experience with Palmaz-Schatz stents, were applied to both Palmaz-Schatz stents and Wallstents to help assess the criteria's value in evaluating optimized Wallstent expansion and to compare the application in the two different types of stents.

No difference in stent apposition to the vessel wall was observed between Palmaz-Schatz stents and Wallstents, but the SSI of both groups differed significantly and demonstrated a more symmetrical lumen shape in the Wallstent. Differences in stent design and mechanical properties between the tubular-slotted Palmaz-Schatz stent and the self-expandable wire-mesh Wallstent, which continues to exert active radial force on the vessel wall after deployment, may explain this finding.

A result that fulfilled the criteria for optimized stenting was achieved in 10% to 15% of the Wallstents compared with 45% to 50% of the Palmaz-Schatz stents. Incomplete stent apposition or an SSI <0.7 were infrequently observed and not significantly different between the Palmaz-Schatz and Wallstent groups. However, an SRR <0.8 despite an optimal angiographic result was responsible for the frequent ICUS-based judgment of inadequate stent deployment and accounted for the differences in fulfillment of the criteria of adequate stent expansion between Palmaz-Schatz stents and Wallstents.

The extent of vessel tapering[49] along the stented segment appears to be crucial for the SRR and may explain the significant difference between the SRR of Palmaz-Schatz and Wallstents despite good results by angiography and visual assessment of the ICUS images for both stent types (Fig. 5). In this study, segments treated by Wallstents, which were significantly longer than Palmaz-Schatz stents, showed relatively more pronounced vessel tapering, demonstrated by the difference between the ICUS-measured proximal and distal reference lumen area that for the Wallstent was almost threefold greater than for the Palmaz-Schatz stent. Indeed, it is evident that a minimal lumen area at the distal end of a tapering stent may not meet the criterion of an SRR ≥ 0.8 if the difference between the distal and proximal reference lumen area is great, resulting in a relatively large mean reference lumen area. This is supported by the finding that the difference between proximal and distal reference lumen area of the Wallstents that met the SRR criterion was particularly low. The ICUS adequacy of the Palmaz-Schatz stent group supports previous observations reporting a 40% incidence of inadequate results after angiographically optimized stent expansion,[11] but data for the Wallstent have yet to be reported.

2D and 3D ICUS. Similar results for the various parameters were obtained by 2D and 3D ICUS. Measurements of the minimal lumen area by 3D ICUS were almost identical to those of 2D ICUS for the Wallstents. For the Palmaz-Schatz stents, a nonsignificant overestimation by the 2D ICUS was observed, but it remains unclear why this slight difference between 2D and 3D measurements was only observed in the relatively shorter Palmaz-Schatz stents and not in Wallstents. An overestimation of the minimal lumen area measurements by 2D ICUS may be expected because some sites of the vessel segment may be missed by visual examination and conventional 2D assessment. The differences between 2D and 3D measurements in this study may be small for two reasons. First, a motorized pullback of the ICUS transducer was performed, ensuring that 2D ICUS images of all sites of the entire vascular segment were equally displayed. This view may not always be guaranteed if the ICUS catheter is manipulated by hand. Second, the experience of the analysts who had previously performed more than 100 3D ICUS examinations enabled them to mentally obtain an approximate spatial picture of the vessel segment by 2D ICUS information.



$$SRR = \frac{\text{Minimum Intrastent Lumen Area}}{\text{Average of Proximal and Distal Reference Lumen Area}}$$

Fig. 5. Possible explanation for difficulty in achieving SRR ≥ 0.8 after Wallstent implantation. In this scheme Wallstent clearly tapers and does not fulfill SRR criterion because minimal lumen area is located near distal reference site, with lumen dimensions significantly smaller than proximal reference. Example of Palmaz-Schatz stent, however, shows little vessel tapering and is much more likely to fulfill SRR criterion.

Limitations. This study provides an insight into the clinical practice of the optimized expansion of the Palmaz-Schatz stent and Wallstent. The patient population was unselected and included a number of Wallstents in vein grafts. Because vein grafts show less vessel tapering than native coronary arteries and most Wallstents with adequate stent expansion by ICUS were placed in bypass grafts, differences between the ICUS findings of Palmaz-Schatz and Wallstents observed in this study are likely to be even more pronounced in a series of native coronary arteries. Further trials should try to address the issues raised by this study in homogeneous populations of either native coronary arteries or venous bypass grafts. Coronary angiography displays only the silhouette of the opacified lumen and provides no direct information on the apposition of the stent to the vessel wall. In clinical practice quantitative angiography[39] is further limited by foreshortening and overlapping vessels. The use of a distal reference diameter to calculate the percent diameter stenosis after stenting introduces certain subjectivity; however, this on-line QCA approach is feasible for the analysis after optimized stent deployment and takes the frequently fusiform angiographic shape of the stented vessel into account.

ICUS consistently yields larger values of the luminal dimensions compared with quantitative angiography[50] and has some inherent limitations, such as the dependence on the angle of incidence of the ultrasound beam and the relatively high variability of measurements on the basis of manual tracing.[51] The variability of measurements can be minimized by semiautomated boundary detection in 3D reconstructed ICUS.[25, 29, 41, 52-54] In this 3D ICUS study, the automated lumen detection was sometimes impaired by the echo shade behind larger deposits of calcium, and the quality of the 3D reconstruction was occasionally limited by artifacts resulting from the cyclic movement of the ICUS catheter and systolic-diastolic changes of the lumen dimensions.[25, 27, 29] The latter problem will be solved in the future by ECG-gated 3D reconstruction.[29] Because the 3D reconstructed view does not depict the true spatial orientation of the vessel segment,[29] careful interpretation by an experienced investigator was required.

Conclusions. Optimized stent expansion by high-pressure inflations of oversized balloons provided excellent angiographic results for both Palmaz-Schatz stents and Wallstents. 2D and 3D ICUS provided on-line valuable additional information without significant differences between the two approaches. The ultrasound criteria for adequate stent expansion, which evolved from the use of ICUS in Palmaz-Schatz stents, indicated a good result in half of the Palmaz-Schatz stents but few Wallstents, although the angiographic findings and visual assessment of the ICUS images suggested a good outcome. Stent symmetry index and apposition to the vessel wall could be well examined in the Wallstents, whereas the stent-reference lumen area ratio (SRR) infrequently fulfilled the ICUS criteria for adequate stent expansion. We suggest that this is likely caused by vessel tapering and differences between the proximal and distal reference lumen dimensions. Thus the standard SRR criterion appears to be unsuitable in assessing relatively long stents such as the Wallstent.

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