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Journal

Journal of the American College of Cardiology, 38(6)

ISSN

0735-1097

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Publication Date

2001-11-01

DOI

10.1016/s0735-1097(01)01618-7

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Peer reviewed

Optimizing Stent Expansion With New Stent Delivery Systems

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OBJECTIVES	The purpose of this study was to assess whether the newer stent delivery systems provide a stented lumen cross-sectional area (CSA) that is equal to the delivery balloon nominal dimensions.
BACKGROUND	First generation stents were often not adequately expanded with their delivery system and frequently required higher pressure or a larger balloon after deployment. Newer stents were designed to optimize expansion with noncompliant, high-pressure balloons provided as the delivery systems.
METHODS	Intravascular ultrasound (IVUS) was used to evaluate 38 stents in 32 patients after deployment at 14 to 16 atm with their delivery balloon system. Minimum stent lumen CSA and stent minimum lumen diameter (MLD) were measured by IVUS imaging. The manufacturer's expected stent diameter was defined as the balloon diameter measured by the company at the maximum pressure used. The manufacturer's expected stent area was calculated based on the manufacturer's expected stent diameter.
RESULTS	The MLD (2.5 ± 0.5 mm) and minimum stent CSA (6.0 ± 1.7 mm ²) by IVUS were significantly smaller than the manufacturer's expected stent diameter (3.5 ± 0.4 mm) and area (9.5 ± 1.9 mm ²) ($p < 0.0001$, respectively). The mean MLD by IVUS was $72 \pm 8\%$ of the expected stent diameter, and the mean minimum stent CSA by IVUS was $62 \pm 10\%$ of the expected stent area.
CONCLUSIONS	Despite moderately high-pressure inflations, the mean minimum stent CSA actually achieved was, on average, only 62% of the manufacturer's expected stent area. To optimize stent deployment, these IVUS observations should be considered during coronary artery stenting. (J Am Coll Cardiol 2001;38:1622-7) © 2001 by the American College of Cardiology

Compared with balloon dilation alone, the placement of a coronary stent improves the immediate results as well as the restenosis rate (1,2). Despite these benefits, in-stent restenosis remains a problem in interventional cardiology (3). Stent deployment guided by intravascular ultrasound (IVUS) may reduce the rate of restenosis by optimizing stent expansion (4-7). The initial observations with IVUS showed that first generation stents were not adequately expanded and often required higher pressure or a larger balloon after deployment (8-10). Other authors have suggested that using high-pressure balloon inflation to maximize stent expansion may exacerbate vessel damage and result in increased stent restenosis (11). It has been assumed that the newer generations of stent delivery systems have incorporated this information and, for any given pressure, provide a stented lumen cross-sectional area (CSA) equal to the manufacturer's stated size. The purpose of this study was to assess whether the manufacturer's stated size could be achieved by two of the newer stent delivery systems using moderately high pressures for deployment.

METHODS

Study population. The study population consisted of 32 patients who had Tristar (Guidant Corporation, Temecula, California) or S670 (Medtronic USA Inc., Minneapolis, Minnesota) stents deployed at 14 to 16 atm with their delivery balloon system between August 1999 and October 2000. In addition, patients had to have an IVUS evaluation after stent deployment to be included in this retrospective analysis.

Coronary angiography and stent deployment. Coronary angiography was performed in a routine manner from the femoral artery with a 6F or 8F catheter. Direct stenting was used in eight lesions. Preparation for the stent was performed on 30 lesions with conventional balloon angioplasty alone in 12 cases, one with directional coronary atherectomy, six with rotational coronary atherectomy and eight with cutting balloon angioplasty. In addition, four lesions were treated with an experimental thrombectomy device before stenting (X-SIZER, Endicor Inc., San Clemente, California). Guidant Tristar and AVE/Medtronic S670 stents were deployed at 14 or 16 atm with their delivery balloon system. No patient had additional dilation after stent insertion with another balloon catheter before the IVUS examination.

IVUS. After stent deployment, the IVUS study was performed with a 3.2F monorail system using a 30 MHz

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Manuscript received April 10, 2001; revised manuscript received July 20, 2001, accepted August 15, 2001.

Abbreviations and Acronyms

- CSA = cross-sectional area
- IVUS = intravascular ultrasound
- MLD = minimum lumen diameter
- QCA = quantitative coronary angiography

transducer-tipped catheter (Ultracross, CVIS/SCIMED Inc, Sunnyvale, California). The IVUS imaging catheter was passed over the guide wire at least 10 mm distal to the stent. The IVUS imaging was performed during motorized pullback (0.5 mm/s) of the catheter. The IVUS images were recorded on S-VHS videotapes for subsequent review and quantitative analysis.

Quantitative coronary angiography (QCA) measurements. Quantitative coronary angiography measurements were performed with an automated computer-based system (CRS-PC+, General Electric Company, Fairfield, Connecticut) by an experienced angiographer. The external diameter of the contrast-filled catheter was used as the calibration standard. Before and after stenting, lesion minimum lumen diameter (MLD) or stent MLD, lesion length and reference diameter were measured. The percent diameter stenosis was calculated automatically as the reference lumen diameter – the MLD divided by the reference diameter. Lesions were characterized according to the modified American College of Cardiology-American Heart Association classification (12). The maximum balloon diameter during stent deployment was measured and compared with the manufacturer's expected values and with the stent lumen diameter measured by QCA.

IVUS measurements. The IVUS images were digitized with a Macintosh G4 computer (Apple Corp., Cupertino, California). Measurements were made with the use of computerized planimetry with public-domain software (NIH image). The digitized IVUS images were reviewed, and the image slice with the minimum stent lumen CSA was chosen for analysis. The minimum stent lumen CSA and stent MLD were measured.

In addition, in 14 lesions from 11 patients, measurements of stent lumen CSA were made every 1-mm along the length of the stent from the distal to the proximal edge of the stent. The minimum stent lumen CSA was selected from each of these 1-mm measurements and was then compared with the minimum stent lumen CSA chosen by the visual scanning method to determine the best method for identifying the minimum IVUS image slice.

A proximal reference site was chosen from the IVUS images at the lumen cross section 3-mm proximal from the stent edge. The MLD at this reference site was measured and was compared with the reference diameter measured by QCA. Reference measurements were not performed if there was a major side branch within 3 mm of the proximal stent edge or if there were two stents placed continuously within 3 mm of each other.

Calculation of expected stent area and diameter. The manufacturer's stated balloon diameter at the inflation pressure written on the package was defined as the expected stent diameter. Based on this expected diameter, the expected stent area was calculated as the square of half of the expected diameter multiplied by π . The expected stent diameter and area were compared with the actual stent diameter and stent area achieved as assessed by IVUS.

Statistical analysis. All values are expressed as mean \pm SD. The paired Student *t* test was used to compare any two measurements made on the same patients. Since different stents within the same patient may not respond independently, the patient was chosen as the unit of analysis. The stent with the largest percent of expected stent area was chosen for data analysis from each patient who had two or more stents. Analysis of variance for repeated measures with a post hoc factorial Bonferroni/Dunn test was used when more than two measurements were compared. A linear regression model was used to assess the relationship of stent lumen CSA between the manufacturer's expected values and the in vivo IVUS measurements and between IVUS measurements and QCA measurements for lumen diameter. The level of significance was set at $p < 0.05$.

RESULTS

Patients characteristics. The mean age of the study patients was 65 ± 11 years, and 69% were men. Acute myocardial infarction was the presenting diagnosis in five cases; six patients had prior myocardial infarction, and four had prior coronary artery bypass surgery.

Systemic arterial hypertension was present in 19 patients (59%), diabetes mellitus in 7 (22%), hypercholesterolemia in 26 (81%), and three patients were currently smoking (9%).

Table 1. Angiographic Characteristics

Vessel	
LAD	16
LCX	9
RCA	10
LM	1
Vein graft	2
Lesion types*	
A	7
B1	6
B2	20
C	5
Quantitative angiography	
Reference diameter (mm)	3.0 \pm 0.7
Lesion length (mm)	11.5 \pm 3.8
MLD (mm)	
Baseline	0.7 \pm 0.6
Post-stent	3.0 \pm 0.6
Percent stenosis (%)	
Baseline	76.1 \pm 18.1
Post-stent	7.0 \pm 6.7

*Modified American Heart Association/American College of Cardiology criteria. Data are expressed as number of lesions or mean \pm SD.

LAD = left anterior descending artery; LCX = left circumflex artery; LM = left main; MLD = minimum lumen diameter; RCA = right coronary artery.

Table 2. Intravascular Ultrasound Measurements

MLD (mm)	2.5 ± 0.5
% of the manufacturer's expected stent diameter	72 ± 8
Minimum CSA (mm ²)	6.0 ± 1.7
% of the manufacturer's expected stent area	62 ± 10

Data are expressed as mean ± SD.
CSA = cross sectional area; MLD = minimum lumen diameter.

Angiographic results. Angiographic characteristics are summarized in Table 1. A total of 38 stents were deployed in 32 patients. There were 28 de novo lesions. Stent deployment was successfully completed in all cases, and no major complication occurred during these procedures. Balloon inflation was performed using 16 atm during stent deployment in 31 lesions, and 14 atm pressure was used in seven cases. No lesion received a postdeployment second dilation before the IVUS examination.

Comparison of two methods for determining the smallest stent CSA by IVUS. The selection of the image that was used to measure the minimum stent lumen CSA was determined by comparing two methods. In 14 lesions from 11 patients, the minimum lumen CSA (5.9 ± 1.4 mm²), selected by visually scanning the entire IVUS pullback run, was significantly smaller than the minimum lumen CSA selected by measuring each 1-mm section of the stent (6.3 ± 1.5 mm², p < 0.005). However, the MLD was not significantly different between these two methods (2.5 ± 0.4 mm, 2.6 ± 0.3 mm, respectively). The difference between visually scanning the IVUS tape and measuring frames at 1-mm intervals suggests that the human eye is

capable of picking up the minimal CSA when scanning at 30 frames per second. By measuring a coronary artery segment at the predetermined 1-mm interval, the smallest CSA within each 1-mm distance would be overestimated. Based on the sample observation, the visual scanning method was used to search for the minimum stent lumen CSA by IVUS in all cases.

IVUS results. The IVUS imaging was successfully completed in all stents. As shown in Table 2, the mean stent MLD was 2.5 ± 0.5 mm, and the mean minimum stent CSA was 6.0 ± 1.7 mm².

Comparison of measurements with IVUS and QCA. The MLD measured by IVUS was significantly smaller than that measured by QCA both within the stent (2.5 ± 0.5 mm by IVUS vs. 2.9 ± 0.6 mm by QCA, p < 0.0001) and at the reference site (2.7 ± 0.7 mm by IVUS vs. 3.1 ± 0.6 mm by QCA, p < 0.02). The lumen diameters measured by IVUS correlated closely with those measured by QCA but were consistently smaller (y = 0.5x + 1.7, r = 0.5, p < 0.0001).

Comparison of expected stent diameter and area. The MLD measured either by IVUS (2.5 ± 0.5 mm) or QCA (3.0 ± 0.4 mm) was significantly smaller than the manufacturer's stated mean balloon diameter (3.5 ± 0.4 mm) at 32 stent sites from 32 patients (Fig. 1). The minimum lumen CSA measured by IVUS (6.0 ± 1.7 mm²) was also significantly less compared with the manufacturer's expected stent balloon area (calculated based on the balloon diameter at 9.5 ± 1.9 mm², p < 0.0001) (Fig. 2). There was no

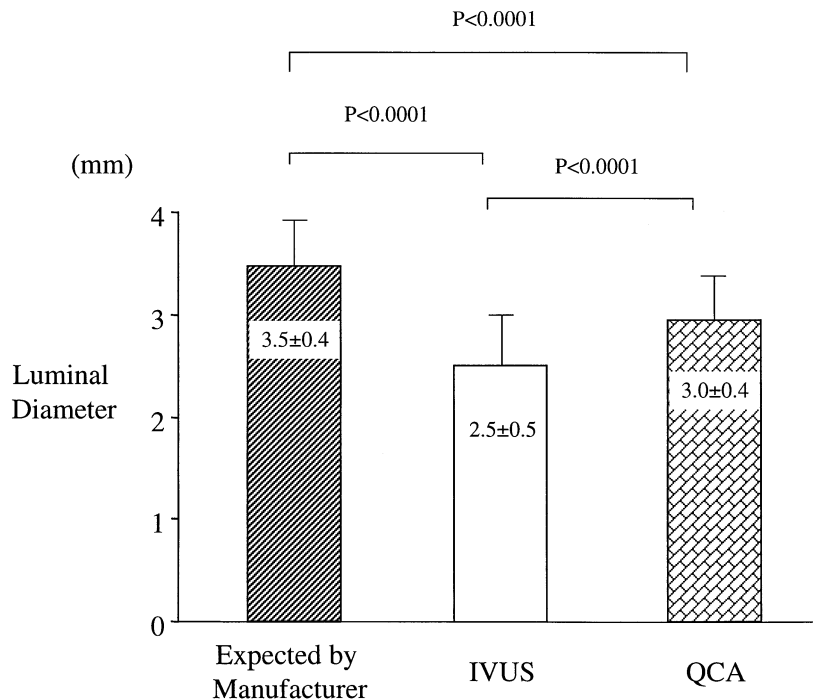


Figure 1. Minimum lumen diameter (MLD) predicted by the manufacturer at the pressure used compared with intravascular ultrasound (IVUS) and quantitative coronary angiography (QCA) measurements within the stent. The MLD measured by either IVUS or QCA was significantly smaller than the manufacturer's expected values.

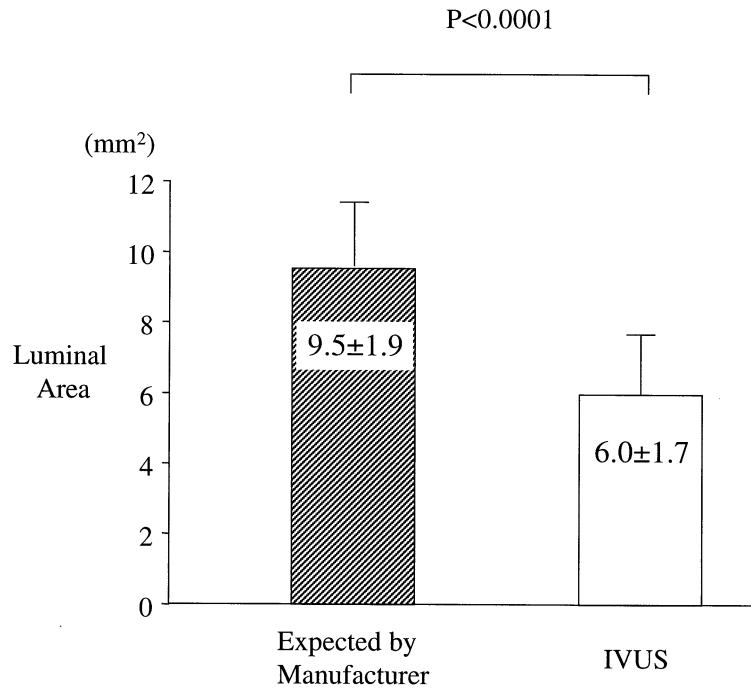


Figure 2. Minimum stent lumen cross-sectional area (CSA) predicted by the manufacturer and measured directly by intravascular ultrasound (IVUS). The measurement of minimum stent CSA by IVUS was significantly smaller than the manufacturer's expected stent CSA.

difference in these results between the two types of stent. The stent lumen CSA measured by IVUS correlated with the manufacturer's expected stent area ($r = 0.85$, $p < 0.0001$) (Fig. 3). The mean MLD of the stents measured by IVUS was $72 \pm 8\%$ of the expected stent diameter, and the mean minimum CSA of the stents was $62 \pm 10\%$ of the expected stent area (Table 2, Fig. 4).

Comparison of balloon diameter during inflation with stent lumen diameter. The maximal balloon diameter achieved during stent deployment (3.1 ± 0.4 mm) was significantly smaller than the manufacturer's expected mean balloon diameter ($p = 0.005$) but was not significantly different from the post-stent angiographic MLD measured by QCA.

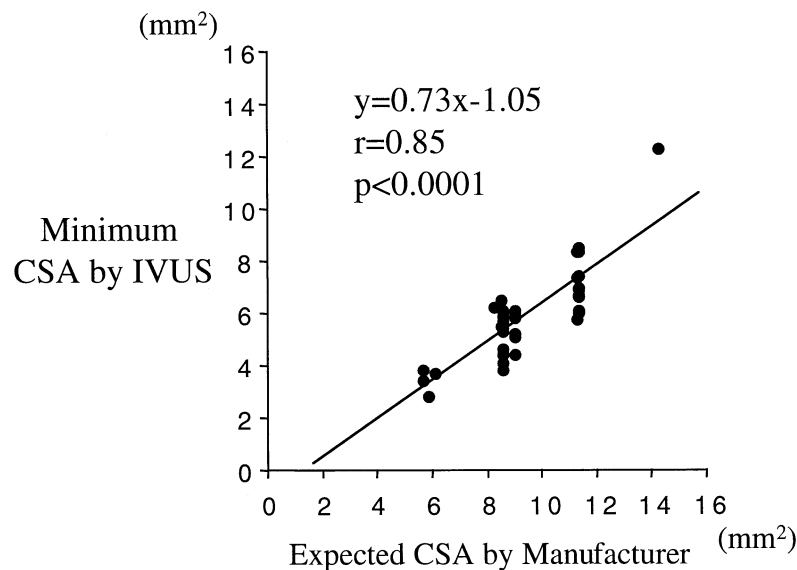


Figure 3. Relationship of stent lumen cross-sectional area (CSA) between manufacturer's stated values and in vivo intravascular ultrasound (IVUS) measurements. The manufacturer's expected areas were determined from a combination of two kinds of stents (Guidant/Tristar or AVE-Medtronic/S670), four stent sizes (2.5 mm, 3.0 mm, 3.5 mm or 4.0 mm) and two inflation pressures (14 or 16 atm).

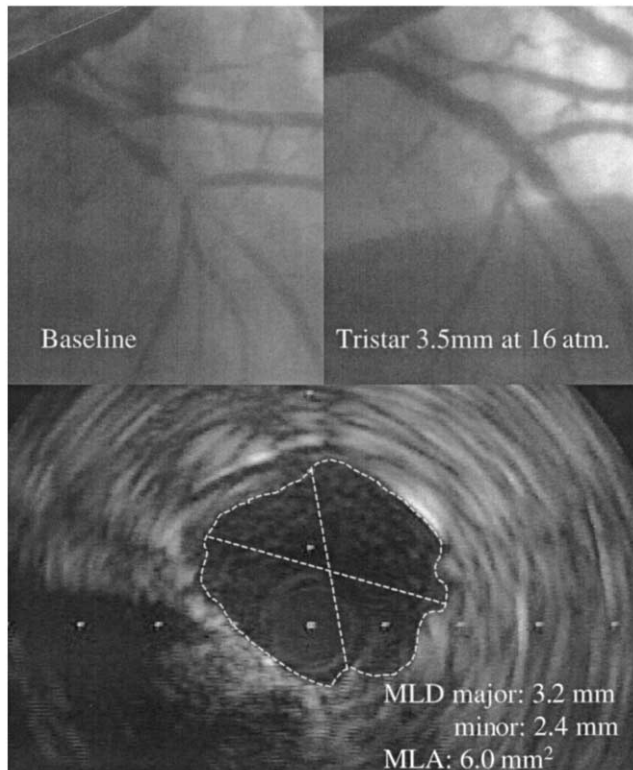


Figure 4. Stenting a left anterior descending coronary artery lesion. **Upper left panel:** Baseline angiogram shows a severe stenosis at the trifurcation of a diagonal and large septal branch. **Upper right panel:** After rotational atherectomy and cutting balloon dilation, a 3.5-mm Tristar stent was deployed at 16 atm. There is no residual stenosis, but the minimum stent diameter was 2.8 mm by quantitative coronary angiography. **Lower panel:** Intravascular ultrasound (IVUS) imaging just after stenting. Intravascular ultrasound revealed a major and minor diameter of 3.2 mm by 2.4 mm, which was 63% of the manufacturer's expected stent diameter. The predicted stent area at 16 atm was 11.4 mm². The actual minimum stent cross-sectional area measured by IVUS was 6.0 mm², which was 53% of the manufacturer's expected stent area. MLA = minimum lumen area; MLD = minimum lumen diameter.

DISCUSSION

The new generation of stents have several desirable features such as easy deliverability, low profile, improved flexibility and enhanced balloon technology to diminish edge dissections during stent deployment. In addition, the manufacturers are aware that subacute stent thrombosis and restenosis are decreased by maximizing the stent lumen CSA. The balloon composition and deployment characteristics are developed to ensure that the operator is able to attain the desired stent lumen diameter. The manufacturers rigorously test their stent deployment systems and generate a table of expected stent diameters for a series of inflation pressures. However, these tests are performed in vitro and in air without any opposing resistance. Based on our experience with IVUS measurements of prior stent systems, we hypothesized that the actual stent lumen area achieved might be less than predicted due to the inherent resistance of dilating a stent within an atherosclerotic artery. The purpose of this study was to assess whether the newer stent delivery

systems provide adequate expansion and meet the manufacturer's expected values so that the interventional operator can reliably depend on the package insert tables.

The manufacturer's expected stent diameter and area. The results of this study demonstrate that there is a significant discrepancy between the manufacturer's estimation of the stented lumen dimensions and those that are actually obtained. As measured by IVUS imaging, the minimum stent lumen CSA was only 62% of the manufacturer's expected stent area. The observed stent MLD was only 72% of the expected stent diameter. These results were obtained despite the use of moderately high pressures to deploy the stents (14 or 16 atm during balloon inflation). If a lower pressure had been used, such as the recommended nominal balloon inflation pressure, then a smaller diameter and CSA would have been achieved (9,13,14). Since a strong predictor of restenosis is minimum stent lumen CSA, a smaller than expected lumen would predictably increase the chance for developing restenosis (15). Based on the IVUS results, 14 lesions (37%) were redilated with larger balloons or higher pressures.

Manufacturers provide stent dimensions that are obtained by balloon inflation in air. The difference between expanding a stent in air versus an artery with resistance might explain the mismatch between the measured and predicted stent dimensions. In the seven lesions with the lowest stent expansion, extensive calcium was present with an arc of 270 to 360°. Four of these seven lesions had rotational atherectomy performed before stenting. The maximum balloon diameter during stent deployment was not significantly different from the stented lumen diameter measured by QCA. This suggests that stent recoil does not play a role in inadequate stent expansion.

Comparison with previous studies of first generation stents. The initial observations of coronary artery stenting with IVUS imaging demonstrated that the recommended pressures for deployment using the balloons available at that time resulted in smaller lumen diameters than expected by the balloon size or the measurements obtained by angiographic QCA (8,10,16). Bermejo et al. (17) reported that the final acute luminal gain achieved with the first generation stents (Palmaz-Schatz and Wiktor) at an average of 14 atm inflation pressure was only 55% of the theoretical value. Because these observations have been generally accepted by the interventional cardiology community, it has been assumed that the current state of technology has advanced such that the balloon size predicted by the manufacturer's in vitro testing will be achieved at the time of actual stent deployment in vivo. This study indicates that this assumption is incorrect and that a "look up" table is necessary to interpret the expected stent deployment results provided by the manufacturers.

The differences in measurements of MLD between IVUS and QCA. In this study, the MLD measured by IVUS was significantly smaller than the MLD measured by QCA at both the in-stent and reference sites. The correlation be-

tween these measurements was weak ($r = 0.5$) but consistent with previous studies (18–20). These results may have been caused by the two measurements not being performed at exactly the same cross section. In addition, the lumen may not be circular; thus, the minimal diameter chosen by IVUS may be less than QCA, even at the same site.

Study limitations. This study is limited because preintervention IVUS imaging was not performed routinely. Thus, tissue characterization of the underlying atherosclerotic plaque was not assessed in all lesions. Hard calcified plaque would be expected to yield less expansion than softer plaque. However, if plaque characterization were taken into account, it is likely that the manufacturer's expected stent area and diameter would be even less when calcified plaque is present. In addition, in patients who received directional atherectomy, the resistance to stent expansion might be reduced due to removal of plaque bulk. However, this series of patients was nonselected by lesion type and is representative of our patient population.

Conclusions. Despite moderately high inflation pressure, the mean minimum stent CSA was only 62% of the manufacturer's expected stent area. To optimize stent deployment, even with the newer generation of flexible, low-profile stents, these IVUS observations should be considered during coronary artery stenting, especially if lower pressures are used during deployment.

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