Long-Term Vessel Response to a Self-Expanding Coronary Stent: A Serial Volumetric Intravascular Ultrasound Analysis From the ASSURE Trial

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OBJECTIVES

We sought to investigate the in vivo mechanical properties of a new self-expanding coronary stent (RADIUS) and, particularly, the subsequent vessel response over time.

BACKGROUND

Preclinical studies have suggested that self-expanding stents may produce less vessel wall injury at initial deployment, leading to larger follow-up lumens than with balloon-expandable stents. However, the influence of the chronic stimulus from self-expanding stents on the vessel wall remains unknown.

METHODS

Sixty-two patients were randomly assigned to either the RADIUS self-expanding stent group (n = 32) or the Palmaz-Schatz balloon-expandable stent group (n = 30). Intravascular ultrasound was performed after stent deployment and at six-month follow-up.

RESULTS

At follow-up, the RADIUS stents had increased 23.6% in overall volume, while the Palmaz-Schatz stents remained unchanged. Due to the greater mean neointimal area (3.0 ± 1.7 mm² vs. 1.9 ± 1.2 mm², p = 0.02) in the RADIUS group, no significant difference in net late lumen loss was observed between the two groups. On the other hand, analysis at the peristent margins demonstrated that mean late loss was significantly smaller in the RADIUS group than it was in the Palmaz-Schatz group (0.1 ± 2.1 mm² vs. 1.9 ± 2.4 mm², p = 0.02).

CONCLUSIONS

Serial volumetric IVUS revealed that the RADIUS stents continued to enlarge during the follow-up period. In this stent implantation protocol, this expansion was accompanied by a greater amount of neointima than the Palmaz-Schatz stents, resulting in similar late lumen loss in both configurations. In the peristent margins, however, late lumen loss was minimized with the RADIUS stents. (J Am Coll Cardiol 2001;37:1329–34) © 2001 by the American College of Cardiology

Recent studies have shown that coronary stenting reduces restenosis compared with balloon angioplasty. However, restenosis rates of 20% to 30% across a broad range of lesions continue to represent a significant limitation in terms of both clinical and cost effectiveness. The mechanisms of coronary restenosis in nonstented vessel segments involve a combination of neointimal hyperplasia and pathologic remodeling with overall vessel contraction (1,2). Scaffolding a lesion segment with a rigid metal surface prevents contraction but is one of the strongest stimuli for neointimal proliferation (3,4).

Animal studies have suggested that the absolute amount of neointimal proliferation in an arterial segment is proportional to the amount of injury sustained (5–7). For example, as a stent is expanded with high pressure, immediate injury occurs deep in the vessel wall within the stented segment as well as in the unscaffolded peristent margins. Importantly, several stent trials, especially those involving brachytherapy, have drawn new attention to the problem of accelerated lumen loss at stent margins, which accounts for up to one-third of target vessel revascularization in patients treated with balloon-expandable stents (8–10).

The pattern and timing of injury with self-expanding stents, however, may be different from those with conventional balloon-expandable stents. In theory, the ability of the self-expanding stent to grow in volume from baseline to follow-up may allow deployment at lower pressures. Less initial trauma could result in less marked intimal proliferation. On the other hand, the chronic stimulus on the wall from a self-expanding stent may be biologically different from the acute stimulus from a balloon-expandable stent.

The ASSURE (A Stent vs. Stent Ultrasound Remodeling Evaluation) intravascular ultrasound (IVUS) study was conducted as a substudy of the SCORES (Stent COmparative REStenosis) trial—a prospective randomized multicenter study.
trial designed to evaluate the safety and efficacy of the RADIUS self-expanding stent compared with the Palmaz-Schatz balloon-expandable stent. The purpose of the current study was to use serial (postintervention and follow-up) volumetric IVUS to investigate the in vivo mechanical properties of this new self-expanding coronary stent and, particularly, the subsequent vessel response in the entire lesion segment over the follow-up period.

METHODS

Study patients. From December 16, 1996 to April 8, 1997, 66 patients were enrolled in the ASSURE trial and randomly assigned to receive either a RADIUS stent or a Palmaz-Schatz stent. Patients were asked to sign an institution-specific consent form before being entered into the ASSURE protocol. Inclusion criteria consisted of patients aged 18 or more years with single de novo or restenotic native vessel disease less than 30 mm in length and having a reference vessel between 2.75 mm and 4.25 mm in diameter. Patients were not enrolled if they had multivessel disease or if aspirin or ticlopidine was contraindicated.

Stent implantation protocol. Patients in both groups received 325 mg aspirin every day and 250 mg ticlopidine twice a day within 24 h before the procedure. At the beginning of the procedure, 10,000 IU of heparin was administered and supplemented as needed to maintain an activated clotting time greater than or equal to 250 s throughout the procedure.

Palmaz-Schatz stents (15 mm in length) were implanted according to standard protocols as per institutional practice. This included 1:1 stent to artery sizing with low-pressure predilation and high-pressure postdilation deployment techniques. For RADIUS stents, predilation was performed with a balloon 0.5 mm smaller than the reference vessel diameter. Either a 14 or 20 mm length stent was used. Postdeployment dilation was performed in all cases, with balloon selection and inflation pressure at the discretion of the individual operator. All operators were blinded to the IVUS findings after either Palmaz-Schatz or RADIUS stent deployment. Ticlopidine was prescribed for 30 days, beginning of the procedure, 10,000 IU of heparin was administered and supplemented as needed to maintain an activated clotting time greater than or equal to 250 s throughout the procedure.

IVUS imaging protocol. One of two commercially available systems was used for the IVUS studies. The first (Boston Scientific Corporation, San Jose, California) consisted of a single-element 30 MHz transducer within a 2.9 French or a 3.2 French imaging sheath. The second system (Hewlett-Packard, Andover, Minnesota) incorporated a single-element 30 MHz transducer within a 3.5 French imaging sheath.

Intravascular ultrasound imaging was performed after administration of intracoronary nitroglycerin (150 to 200 µg). After stent deployment and at six-month follow-up, a slow pullback was performed from distal to proximal reference sites through the target segment. An automated pullback at a constant speed of 0.5 mm/s was performed in 41 cases (RADIUS: 22, Palmaz-Schatz: 19) after initial deployment and 47 cases (RADIUS: 24, Palmaz-Schatz: 23) at follow-up. Intravascular ultrasound images were recorded on half-inch, high resolution S-VHS videotape for off-line analysis.

Serial two-dimensional IVUS analysis. All ultrasound images were reviewed by an independent core laboratory at Stanford University Medical Center. The images were digitized to perform quantitative analysis with commercially available planimetry software (TapeMeasure, Indec Systems, Inc., Mountain View, California). Quantitative parameters consisted of vessel, lumen and stent cross-sectional areas. Vessel area was defined as the area within the media/adjunct layer border (that is, including lumen, plaque and media). Plaque area was calculated as vessel area minus lumen area. Neointimal area was computed as stent area minus lumen area. Qualitative parameters assessed in the study included: 1) stent apposition (incomplete apposition being defined as one or more struts clearly separated from the vessel wall with evidence of blood speckle behind the strut) and 2) edge tears (defined as disruptions of plaque immediately adjacent to the stent margins where the flap could be clearly differentiated from the underlying plaque). Validation of quantitative and qualitative assessment by IVUS has been reported previously (11–14).

Intravascular ultrasound measurements were performed at the tightest segment within the stent and the proximal and distal reference segments (defined as the location in the native vessel with minimum disease within 5 mm of the proximal and distal stent edges and before the emergence of any major side branches). In cases in which two stents were placed, the stents were treated as a single stented segment for purposes of quantitative analysis (the stents overlapped in all cases). Late lumen area loss was calculated as the minimum stent/lumen area after initial deployment minus the minimum lumen area at follow-up.

Serial volumetric IVUS analysis. To further investigate the in vivo mechanical behavior of the self-expanding stent and the vessel response in the entire lesion segment, serial volumetric analysis was performed immediately after stent
deployment and at follow-up within the stent and in the peristent margins (5 mm distal and proximal to the stent edge) in those cases in which the same IVUS system (Boston Scientific Corporation) with an automated pullback was used. Margins were excluded if complete visualization of the vessel boundary was not achieved along the entire peristent margin or if a major side branch emerged from the margin. Measurements of vessel, lumen and stent areas were made at 1 mm axial intervals, and vessel, stent, lumen, plaque and neointimal volumes were calculated using Simpson’s rule (10,15,16). For comparison between the two stent configurations, mean stent, lumen and neointimal areas were computed as the volume divided by the stent length (mean period: 6.8 ± 2.0 months). In the 51 (RADIUS: 25, Palmaz-Schatz: 26) patients with interpretable follow-up IVUS images, 47 (RADIUS: 24, Palmaz-Schatz: 23) had an automated pullback at follow-up. Reasons for failure to perform follow-up IVUS for the complete initial cohort (n = 66) were as follows: 1) patient refusal in six cases (RADIUS: 4, Palmaz-Schatz: 2); 2) acute myocardial infarction in one (RADIUS); 3) unstable angina in one (Palmaz-Schatz); 4) near total occlusion in two (RADIUS: 1, Palmaz-Schatz: 1) and 5) lost records in two (RADIUS: 2).

**Statistics.** Quantitative data are presented as mean value ± SD, and qualitative data are presented as frequencies. Statistical analysis was performed with StatView 4.5 software (Abacus Concepts, Berkeley, California). Continuous variables were compared using paired t or unpaired t tests. A two-way repeated measures one-way analysis of variance was used to test for group (RADIUS, Palmaz-Schatz) and time (baseline/follow-up) effect and their interactions. Categorical variables were compared using chi-square test or Fisher exact test. Significance was assumed at a value of p < 0.05.

**RESULTS**

**Patient characteristics.** Sixty-six patients were enrolled in the ASSURE trial. Due to incomplete image acquisition or inadequate image quality, four patients were voided. Thirty-two patients were randomly assigned to the RADIUS group and 30 to the Palmaz-Schatz group. The demographic information for these 62 patients is shown in Table 1. No significant differences were observed between the two groups with respect to the baseline characteristics.

Fifty-four patients returned for follow-up IVUS examination (mean period: 6.8 ± 2.0 months). In the 51 (RADIUS: 25, Palmaz-Schatz: 26) patients with interpretable follow-up IVUS images, 47 (RADIUS: 24, Palmaz-Schatz: 23) had an automated pullback at follow-up. Reasons for failure to perform follow-up IVUS for the complete initial cohort (n = 66) were as follows: 1) patient refusal in six cases (RADIUS: 4, Palmaz-Schatz: 2); 2) acute myocardial infarction in one (RADIUS); 3) unstable angina in one (Palmaz-Schatz); 4) near total occlusion in two (RADIUS: 1, Palmaz-Schatz: 1) and 5) lost records in two (RADIUS: 2).

**Procedural and angiographic results.** As expected, the stent length was significantly greater in the RADIUS group compared with the Palmaz-Schatz group. While the final balloon sizes were similar in both groups, the maximum inflation pressure was significantly lower in the RADIUS group (11.7 ± 3.6 atm) than it was in the Palmaz-Schatz group (15.6 ± 2.9 atm). There was no significant difference in the baseline reference diameter in the two groups (RADIUS: 3.2 ± 0.5 mm, Palmaz-Schatz: 3.1 ± 0.6 mm).

**Serial two-dimensional IVUS results.** Initially, there were no significant differences between the two groups, including the average reference lumen area (the average of distal and proximal reference lumen areas), the minimum stent area and the incidence of incomplete stent apposition (Table 2). There was a trend toward a lower incidence of edge tears in the RADIUS group (6% vs. 23%, p = 0.06).

At follow-up, there were no significant differences in the two-dimensional IVUS parameters between the two groups, including the average reference lumen area, the minimum lumen area and late lumen area loss.
Serial volumetric IVUS results. Forty-one cases (RADIUS: 22, Palmaz-Schatz: 19) with an automated pullback both initially and at follow-up were entered into serial volumetric analysis. This subset of patients had comparable baseline characteristics as the overall enrolled patients with no significant differences between the two stent groups. The mean neointimal area at follow-up was significantly greater in the RADIUS group than it was in the Palmaz-Schatz group (3.0 ± 1.7 mm² vs. 1.9 ± 1.2 mm², p = 0.02, Figure 1). For stent volume, the time effect of the RADIUS and Palmaz-Schatz groups showed significant differences, comparing baseline and follow-up (p < 0.0001). Between the two stent groups, there was a significant interaction effect (p < 0.0001) indicating that the patterns of changes in stent volume over time differed by the stent types. The RADIUS stents increased 23.6% in overall stent volume (140.4 ± 49.3 mm³ to 136.8 ± 45.3 mm³, p = 0.17) or mean stent area (8.7 ± 2.2 mm² to 8.5 ± 2.2 mm², p = 0.23). As a result, mean late lumen area loss trended smaller in the RADIUS group (1.1 ± 2.0 mm² vs. 2.1 ± 1.3 mm²), but this difference did not reach statistical significance (p = 0.09). Persistent margins. Twenty-one margins (distal: 10, proximal: 11) from 16 patients for the RADIUS group and 16 margins (distal: 9, proximal: 7) from 11 patients for the Palmaz-Schatz group were acceptable for serial volumetric analysis. During the follow-up period, the increase in mean plaque area in the persistent margins was similar in the two stent groups (0.7 ± 1.3 mm² vs. 0.9 ± 1.3 mm², p = 0.71) (Table 3, Fig. 3). For vessel volume or mean vessel area, significant stent type-by-time interaction was observed (p < 0.01). Vessel volume or mean vessel area in the persistent margins tended to increase in the RADIUS group (0.8 ± 2.4 mm², p = 0.13) but was significantly decreased in the Palmaz-Schatz group (−1.1 ± 1.8 mm², p = 0.03) Consequently, mean lumen area in the persistent margins did not change significantly in the RADIUS group but decreased significantly in the Palmaz-Schatz group; mean late lumen area loss was significantly smaller in the RADIUS group compared with the Palmaz-Schatz group (0.1 ± 2.1 mm² vs. 1.9 ± 2.4 mm², p = 0.02).

DISCUSSION

This is the first report comparing the RADIUS stent to the Palmaz-Schatz stent by serial IVUS examination in a clinical setting. The major findings of this study were as follows: 1) the RADIUS stent achieved the same acute minimum stent area as the Palmaz-Schatz stent using lower maximum inflation pressures, with a trend toward lower incidence of edge tears; 2) the RADIUS stent increased

Table 2. Serial Two-dimensional Ultrasound Results

<table>
<thead>
<tr>
<th></th>
<th>Balloon-Expandable</th>
<th>Self-Expanding</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial (after stenting) (n = 30)</td>
<td>(n = 32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avg. reference, area, mm²</td>
<td>8.3 ± 3.2</td>
<td>8.5 ± 2.5</td>
<td>NS</td>
</tr>
<tr>
<td>Minimum stent area, mm²</td>
<td>6.8 ± 2.0</td>
<td>6.4 ± 2.0</td>
<td>NS</td>
</tr>
<tr>
<td>Incomplete apposition, n (%)</td>
<td>5 (17%)</td>
<td>5 (16%)</td>
<td>NS</td>
</tr>
<tr>
<td>Edge tears, n (%)</td>
<td>7 (23%)</td>
<td>2 (6%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Follow-up (n = 26)</td>
<td>(n = 25)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avg. reference area, mm²</td>
<td>8.0 ± 2.9</td>
<td>8.1 ± 3.2</td>
<td>NS</td>
</tr>
<tr>
<td>Minimum lumen area, mm²</td>
<td>4.5 ± 1.6</td>
<td>4.6 ± 2.2</td>
<td>NS</td>
</tr>
<tr>
<td>Late lumen area loss, mm²</td>
<td>2.7 ± 2.0</td>
<td>2.0 ± 1.8</td>
<td>NS</td>
</tr>
</tbody>
</table>

Avg. = average.

Figure 1. Mean stent, neointimal and lumen area changes within the stented segment during the follow-up period. Notably, the RADIUS stents increased by 1.9 ± 1.0 mm² in mean stent area while the Palmaz-Schatz stents showed no significant changes. On the other hand, the RADIUS stents had a greater amount of neointimal proliferation than the Palmaz-Schatz stents. Values are expressed as mean ± SD. Open box = Palmaz-Schatz; solid box = RADIUS.
Late lumen loss in peristent margins. Recently, several stent trials with balloon-expandable stents have focused attention on the accelerated restenosis observed at the stent margins. These sites have an abrupt transition between the rigid metal edge of the stent and the adjacent, more compliant vessel wall. Because the balloon length often exceeds the stent edge, injury with high-pressure inflations can occur in the peristent margins several millimeters proximal and distal to the stent edges. In ASSURE, late loss in the peristent margins of the Palmaz-Schatz stent resulted from a combination of neointimal proliferation and vessel contraction, which is consistent with previous studies (10,27). In contrast, the gradually expanding stent edge of the RADIUS stent minimized vessel contraction at the margins, leading to less net lumen loss at six-month follow-up.

The clinical data from the ASSURE trial demonstrate that chronic expansive force does, in fact, promote a greater amount of neointimal proliferation in the RADIUS stents. One potential explanation for this difference in the animal and clinical data is that the amount, type and distribution of underlying plaque burden before stent placement can markedly alter the amount of subsequent neointimal proliferation. Several studies have shown that plaque burden alone constitutes a strong predictor for restenosis (22,23). Moreover, recent studies have revealed that the plaque burden behind the stent is strongly correlated with the pattern of neointimal development (24–26). It is, therefore, reasonable to assume that chronic expansive force and the underlying plaque burden may interact in determining the degree of intimal proliferation. Chronic dilation of a large plaque burden might be a strong stimulus for intimal growth although this potential effect did not translate into clinical disadvantage in this study because of the offset by continued stent expansion. Considering these properties of self-expanding stents, unnecessary postdeployment dilation with high pressures should be avoided in order to minimize vessel wall injury and subsequent neointimal proliferation. Further investigation will be needed to determine the appropriate vessel or lesion subset as well as optimal implantation technique for this particular type of stents.

Table 3. Serial Volumetric Ultrasound Results in the Peristent Margins

<table>
<thead>
<tr>
<th></th>
<th>Balloon-expandable (n = 16)</th>
<th>Self-expanding (n = 21)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessel volume, mm³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>89.6 ± 34.7</td>
<td>76.2 ± 28.3</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>83.9 ± 31.4</td>
<td>80.3 ± 33.8</td>
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<tr>
<td>Intimal plaque</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>volume, mm³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>41.6 ± 20.0</td>
<td>33.5 ± 18.4</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>45.3 ± 23.9†</td>
<td>38.0 ± 20.0‡</td>
<td>NS</td>
</tr>
<tr>
<td>ΔPlaque volume, mm³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumen volume, mm³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>48.0 ± 22.8</td>
<td>42.7 ± 14.8</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>38.7 ± 18.6§</td>
<td>42.3 ± 21.1</td>
<td>NS</td>
</tr>
<tr>
<td>Late lumen volume</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>loss, mm³</td>
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<td></td>
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<tr>
<td>Initial</td>
<td>9.3 ± 12.1</td>
<td>0.4 ± 10.6</td>
<td>0.02</td>
</tr>
<tr>
<td>Follow-up</td>
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<tr>
<td>Mean lumen area, mm²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>9.6 ± 4.6</td>
<td>8.5 ± 3.0</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>7.7 ± 3.7†</td>
<td>8.5 ± 4.2</td>
<td>NS</td>
</tr>
<tr>
<td>Mean late lumen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>area loss, mm²</td>
<td></td>
<td></td>
<td>0.02</td>
</tr>
</tbody>
</table>

* p = 0.03; † p = 0.04; ‡ p = 0.004; § p = 0.02 vs. initial volumes; † p = 0.008 vs. initial mean lumen area.

23.6% in overall volume by six-month follow-up; 3) the RADIUS stent had a greater amount of intimal proliferation than the Palmaz-Schatz stent; 4) the net effect was similar late loss of lumen area in the stented segment between the two groups at follow-up; and 5) late lumen loss in the peristent margins was smaller in the RADIUS group than it was in the Palmaz-Schatz group.

Chronic injury. The stimulus on the vessel wall from self-expanding nitinol stent implantation is theoretically different from the stimulus provoked by balloon-expandable stents. Several animal studies have provided a histological framework assessing the vessel response to chronic deep vessel wall injury caused by self-expanding stents. However, interpretations vary as to whether gradual stent expansion is associated with an increase in subsequent neointimal proliferation (17–20). Some animal models with different types of self-expanding stents have shown that these stents provoked cellular proliferation that reached its maximum in three to six months, compared with the earlier peak at one to three months in the balloon-expandable stent (18,21). These animal studies indicate that gradual stent expansion may prolong neointimal proliferation to a variable degree even beyond three months. On the other hand, there have been several animal studies (18–20) that indicated no difference with respect to neointimal proliferation between the two stent types over time.

The clinical data from the ASSURE trial demonstrate that chronic expansive force does, in fact, promote a greater amount of neointimal proliferation in the RADIUS stents. One potential explanation for this difference in the animal and clinical data is that the amount, type and distribution of underlying plaque burden before stent placement can markedly alter the amount of subsequent neointimal proliferation. Several studies have shown that plaque burden alone constitutes a strong predictor for restenosis (22,23). Moreover, recent studies have revealed that the plaque burden behind the stent is strongly correlated with the pattern of neointimal development (24–26). It is, therefore, reasonable to assume that chronic expansive force and the underlying plaque burden may interact in determining the degree of intimal proliferation. Chronic dilation of a large plaque burden might be a strong stimulus for intimal growth although this potential effect did not translate into clinical disadvantage in this study because of the offset by continued stent expansion. Considering these properties of self-expanding stents, unnecessary postdeployment dilation with high pressures should be avoided in order to minimize vessel wall injury and subsequent neointimal proliferation. Further investigation will be needed to determine the appropriate vessel or lesion subset as well as optimal implantation technique for this particular type of stents.

Figure 3. Mean vessel, plaque and lumen area changes in the peristent margins (adjacent reference segments) during the follow-up period. The RADIUS stents minimized vessel contraction resulting in significantly less net late lumen loss compared with the Palmaz-Schatz stents (0.1 ± 2.1 mm² vs. 1.9 ± 2.4 mm², p = 0.02). Open box = Palmaz-Schatz; solid box = RADIUS.
Study limitations. Several significant issues should be noted. First, the sample size is relatively small, which limited our ability to determine significance. However, the SCORES trial consisting of 1,096 patients showed similar results with respect to the late loss assessed by angiography. Second, due to the need to pass the IVUS catheter through the lesion site in order to observe measurement data, only cases with sufficient lumens to allow for catheter passage can be analyzed. This might create a study bias toward patients with larger lumens at follow-up. Third, long-term observations beyond six months are lacking. However, according to nonradiation studies with other self-expanding stents and balloon-expandable stents, neointimal proliferation peaks by six months without further progression (20,21,28). Fourth, volumetric measurements in the persistent margins were limited to the segments in which the vessel boundary could be clearly visualized throughout the length. Thus, the current results may not be applicable to severely fibrotic or calcified lesions. Finally, there remains a possibility that nitinol itself might have been responsible for the greater neointimal formation in the RADIUS group. Recently, hypersensitivity to stent materials has been proposed as a possible risk factor for stimulation of neointimal hyperplasia. In the general population, however, titanium hypersensitivity is not as common as nickel or stainless steel allergy.

Conclusions. RADIUS stents achieved comparable initial minimum stent area as Palmaz-Schatz stents at lower deployment pressures, with a trend toward less stent edge injury patterns. At follow-up, unlike the Palmaz-Schatz stent, the overall vessel volume within the RADIUS stent was significantly increased. However, greater neointimal proliferation was observed within the RADIUS stent. These observed differences resulted in similar net late lumen loss for both stent groups. The margins of the RADIUS stent, however, showed significantly less late lumen loss than the margins of the Palmaz-Schatz stent.

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