In Vivo Assessment of Stent Expansion and Recoil in Normal Porcine Coronary Arteries
Differential Outcome by Stent Design

Joseph P. Carrozza, Jr, MD; Susanne E. Hosley, BS; David J. Cohen MD, MSc; Donald S. Baim, MD

Background—Despite the routine use of high pressure, coronary stents generally fail to achieve a cross-sectional area (CSA) >60% to 80% of the nominal CSA of their dilating balloon. The extent to which incomplete balloon expansion and postdeflation stent recoil contribute to this failure has not been fully evaluated.

Methods and Results—Thirty-two stents (8 Gianturco-Roubin II, 8 Palmaz-Schatz, 8 MultiLink, and 8 NIR) were deployed in nondiseased coronary arteries of 8 Yorkshire pigs. All stents were then expanded according to 1 of 3 balloon strategies: appropriately sized compliant balloons, oversized compliant balloons, or oversized noncompliant balloons. Continuous ultrasound imaging was performed during stepwise balloon inflation and deflation, with an 0.018-in imaging core positioned within the guidewire lumen of the balloon. In these normal arteries, balloon underexpansion relative to the nominal size was not observed. After balloon deflation, however, all stents showed significant recoil from their maximum inflated CSA. Recoil was significantly greater for the coil Gianturco-Roubin II stent (30% CSA) than for the 3 slotted-tube stent designs (15% to 17% CSA).

Conclusions—In normal, compliant coronary arteries, stent recoil is the predominant mechanism by which stents fail to achieve the nominal CSA of their dilating balloon. The magnitude of this in vivo stent recoil is significantly greater than reported from bench testing and varies with stent design (coil versus slotted tube). Postdilatation strategies that result in controlled stent overexpansion are needed to overcome this recoil phenomenon and result in a final stent CSA that approximates the reference artery CSA. (Circulation. 1999;100:756-760.)

Key Words: stents ▪ arteries ▪ balloon ▪ ultrasonics

Multiple registries and randomized trials have demonstrated that favorable short-term and intermediate-term angiographic and clinical outcomes after stenting are contingent on optimal stent expansion. Yet seminal intravascular ultrasound (IVUS) studies in the early 1990s demonstrated that most stents remain underexpanded despite an excellent angiographic appearance. High-pressure stent postdilation improves strut apposition, luminal cross-sectional area (CSA), and concentricity, so that routine adjunctive high-pressure postdilatation has become a standard part of stent implantation.

Although high-pressure dilatation increases the lumen CSA within the stent, final stent CSA still rarely exceeds 60% to 70% of the nominal balloon CSA. This may result from either failure of the balloon to expand fully to its nominal area or recoil of the stent after balloon deflation. The ability to distinguish between these mechanisms (or a combination thereof) has been limited by difficulties in accurately measuring in vivo balloon CSA as a function of pressure and quantifying the amount of stent area recoil that occurs immediately after balloon deflation.

To overcome these limitations, we used an 0.018-in high-frequency ultrasound imaging core positioned within the guidewire lumen of various balloons (both compliant and noncompliant) during stent dilatation. This allowed ultrasonic measurement of balloon CSA as a function of pressure during inflation and immediate quantification of any loss of stent CSA during balloon deflation for different stent designs.

Methods

Animal Preparation
Eight Yorkshire pigs (40 to 60 kg) of either sex were fasted on the day of the procedure. After sedation with ketamine 15 mg/kg IM and endotracheal intubation, general anesthesia was maintained with halothane 2%, with oxygen. An 8F sheath (Cordis Corp) was inserted via cutdown into the right femoral artery. Heparin 5000 U was given intravenously, and additional heparin was administered to maintain an activated clotting time >300 seconds. Arterial blood pressure and the surface ECG were monitored throughout the procedure. An 8F hockey-stick guiding catheter (Boston Scientific Corp) was engaged in the ostium of either the right or left coronary artery. The study was approved by the animal care committee at the Beth Israel–Deaconess Medical Center.

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Pressure-Area Relations for Different Balloon Types Inflated Within Stented Pig Coronary Arteries

<table>
<thead>
<tr>
<th>Nominal Balloon Diameter/Compliance</th>
<th>Pressure (atm)</th>
<th>3.5 mm/compliant (mm²)</th>
<th>4.0 mm/compliant</th>
<th>4.0 mm/noncompliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 mm/compliant (mm²)</td>
<td>9.6</td>
<td>8.83±0.24</td>
<td>12.6</td>
<td>12.6</td>
</tr>
<tr>
<td>4.0 mm/compliant</td>
<td>12.6</td>
<td>11.2±0.50</td>
<td>12.7±0.63</td>
<td>14.7±0.21</td>
</tr>
<tr>
<td>4.0 mm/noncompliant</td>
<td>12.6</td>
<td>10.9±0.56</td>
<td>11.7±0.27</td>
<td>12.7±0.20</td>
</tr>
</tbody>
</table>

*P<0.001 by ANOVA for comparisons across all pressures.

Stent Procedure
An 0.014-in angioplasty guidewire (Choice PT, Boston Scientific Corp) was advanced into either the distal right or circumflex coronary artery. After the administration of 200 µg nitroglycerin IC, standard IVUS was performed with a 2.9F catheter (UltraCross, CVIS Corp) to assess lumen size. Each stent design (see below) was then deployed at low pressure (<6 atm) with a delivery balloon less than or equal to reference vessel size. Each stent was then assigned randomly to 1 of 3 postdilatation strategies: appropriate-sized compliant balloon (Cobra-18), Boston Scientific Corp with nominal balloon-to-artery ratio ~1.0; oversized compliant balloon (Cobra-18, Boston Scientific Corp) with nominal balloon-to-artery ratio ~1.2; or oversized noncompliant balloon (NC Cobra-18, Boston Scientific Corp) with nominal balloon-to-artery ratio ~1.2.

The postdilating balloon was delivered into the stent over the angioplasty guidewire. The guidewire was then removed and its lumen flushed with heparinized normal saline. An 0.018-in 30-MHz rotating imaging core (Boston Scientific) was inserted into the guidewire lumen of the deflated balloon and positioned just distal to the balloon midmarker. The imaging wire was connected to the rotating motor drive unit, and all images were processed by use of the CVIS ClearView System. The balloon and the inflation device were filled with heparinized saline rather than iodinated contrast medium to avoid changes in density, and thus the speed of sound, in the intervening liquid medium during inflation. Continuous ultrasound imaging was performed as the balloon was gradually inflated in 2-atm steps from 2 to 12 atm. Pressure (and thus balloon volume) was allowed to equilibrate for at least 10 seconds at each pressure level. Ultrasound images were also acquired during slow, progressive balloon deflation. In a subset of stents (n=6), conventional IVUS imaging was performed with the CVIS catheter after balloon deflation and core wire imaging to assess correlation between the 2 imaging modalities.

Stents
Four different stent designs were evaluated: the coil Gianturco-Roubin II stent (Cook Cardiology), the slotted-tube Palmaz-Schatz coronary stent (Cordis Corp), the MultiLink stent (Guidant Corp), and the NIR stent (Medinol). To ensure unbiased distribution of each stent design in a particular location, each stent was implanted in each animal according to a matrix that randomly assigned the stent to vessel location and position (proximal, mid, or distal vessel).

Data Analysis and Statistics
All images were recorded on S-VHS videotape. CSA, minimum lumen diameter (MLD), and maximum lumen diameters were quantified with online, integrated measurement software. Elastic recoil was calculated in the following manner: % area recoil=1−(stent CSA_faluation/balloon CSA_12 atm); % diameter recoil=1−(stent MLD_faluation/balloon MLD_12 atm).

Data are expressed as mean±SEM. Comparisons were made by ANOVA and Student’s t test with correction for multiple comparisons by the Bonferroni method. Correlation between continuous variables was assessed by linear regression. Data were analyzed by JMP software (SAS Institute).

Results
Balloon Expansion
A total of 32 stents (8 of each design) were implanted in 8 animals. Pressure-area relations for 3.5-mm compliant, 4.0-mm compliant, and 4.0-mm noncompliant balloons are shown in the Table. As predicted by the manufacturers’ specifications, all 3 balloon groups demonstrated increases in CSA as a function of pressure. Pressure-area curves for compliant balloons that matched the reference vessel size and oversized noncompliant balloons closely approximated the relationships expected on the basis of these specifications (Figure 1). Compliant balloons that were oversized compared with the reference vessel (balloon-to-artery ratio ~1.2), however, had measured balloon areas that were smaller at high pressure than specified in the manufacturers’ compliance charts.

Stent Recoil
In the subset of stents in which conventional IVUS imaging was performed after balloon deflation and imaging wire assessment, there was excellent correlation of stent CSA as measured by IVUS and the imaging core (Figure 2). The magnitude of acute stent recoil (from maximum expansion to postdeflation) ranged from 15% to 30% CSA and differed among the 4 stent types (Figure 3). Area recoil was significantly greater for the coil design (Gianturco-Roubin II stent) than for any of the slotted-tube configurations (Figure 4). The corresponding diameter recoil (17.8% versus 10.4%, P<0.01) was also significantly greater for the Gianturco-Roubin stent than for the reference Palmaz-Schatz coronary stent. As a result of these differences in stent recoil, the ratio of final stent to reference vessel area was significantly smaller for the coil than for the slotted-tube stents (0.94±0.06 versus 1.11±0.04; P=0.022) despite similar ratios of maximum measured balloon size to reference vessel CSA across all 4
stent designs (Figure 5). This greater recoil of the coil stent design is reflected graphically by a downward shift in the final stent–maximum balloon expansion curve when normalized by vessel size (Figure 6). To overcome this recoil effect in a coil design would require substantially greater overexpansion (to a balloon-to-artery area ratio of 1.4 by area [diameter ratio 1.2]) than in a slotted-tube design (area ratio 1.2 [diameter ratio 1.1]).

Discussion

During the past several years, stenting has emerged as the predominant modality for percutaneous coronary revascularization, and it is now used in >50% of all interventions. The favorable short- and long-term outcomes after stenting relate to the ability of these metallic endovascular prostheses to seal dissection planes and resist elastic recoil, thereby achieving a large final lumen. Numerous studies have documented that more complete stent expansion is associated with reductions in subacute thrombosis and late restenosis.1–6 Although there has been a lack of consensus regarding what constitutes optimal stent expansion, angiographic and IVUS definitions usually stipulate that a ratio of stent to reference lumen CSA of 0.9 to 1.0 should be achieved.9–11

Nakamura et al7 demonstrated that despite excellent angiographic appearance, the majority of stents deployed at low pressure remain suboptimally expanded by IVUS criteria. Use of high-pressure postdilatation increased stent CSA and improved stent geometry, so that routine high-pressure postdilatation is now a universally accepted practice. Even so, final stent CSA rarely exceeds 60% to 80% of the nominal balloon CSA. Potential explanations for this persistent stent undersizing include balloon underexpansion (despite high inflation pressures), acute stent recoil, or a combination of the 2 mechanisms.

Haude et al12 reported that compared with conventional balloon dilatation, the slotted-tube Palmaz-Schatz coronary stent reduced diameter (3.5%) and area (5.1%) recoil. These findings have been interpreted to mean that stenting largely eliminates acute elastic recoil after coronary intervention. In that study, however, high-pressure dilatation was not performed uniformly, and recoil was calculated by use of geometric assumptions derived from angiographic variables. Lumen CSA was thus calculated from a single, measured diameter assuming a uniform, elliptical geometry. In addition, expansion was assumed to be uniform along the entire length of the balloon. Because the maximum balloon diameter was measured and equivalent was assumed in the diseased noncompliant segment of the artery, balloon size may have been significantly underestimated. More recently, Bermejo and colleagues13 used a combination of quantitative angiography and IVUS to assess the relative contribution of balloon underexpansion and stent recoil to the residual lumen stenosis after high-pressure dilatation. They measured minimum and maximum balloon diameters by quantitative coronary angiography and demonstrated a failure to reach nominal diameter as well as nonuniformity of balloon expansion within the diseased segments. By then performing IVUS in the same stented segments after high-pressure dilatation, they calculated area recoil of 15% for the Palmaz-Schatz stent and 26% for the coil Wiktor stent relative to the inflated balloon area.

In the present study, online IVUS was performed with a 0.018-in imaging core positioned in the guidewire lumen of the balloon to allow accurate assessment of both the balloon expansion during progressively higher-pressure inflation and acute stent recoil during balloon deflation. Balloon diameters and CSAs were thus measured directly, rather than being calculated from geometric assumptions and disparate imaging methodologies. In these normal (nondiseased) porcine arteries, balloon CSA closely matched that expected from the manufacturers’ compliance charts. The only exception to this finding was for oversized (balloon-to-artery ratio >1.15) compliant balloons, for which some balloon underexpansion relative to specifications was seen at the highest pressures (12 atm).

The surprising finding, however, was the magnitude of stent recoil during balloon deflations. Acute stent recoil

Figure 2. Correlation of stent CSA by IVUS (x axis) and imaging wire (y axis). Regression equation: $y = 1.028x + 0.445$.

Figure 3. Top, Acute area and bottom, diameter recoil for 4 different stents. GR II indicates Gianturco-Roubin II.
ranged from 15% to 17% area for the slotted-tube stents and 30% area for the coil stents. This corresponds to diameter recoil of 6.9% to 10.4% for slotted-tube stents, versus 17.8% for the coil stent. This 2-fold greater elastic recoil observed for the Gianturco-Roubin coil was similar to what Bermejo et al.13 and Werner et al.14 observed for the Wiktor coil stent compared with the Palmaz-Schatz slotted-tube design. These recoil data may explain the greater residual stenosis observed clinically after coil stent compared with slotted-tube place-

Figure 4. IVUS imaging with 30-MHz transducer positioned in guidewire lumen of balloon at 12 atm (top) and immediately after balloon deflations (bottom). Images were obtained during expansion of Palmaz-Schatz stent (left) and for Gianturco-Roubin II (GR II) (right). NC indicates noncompliant.

Figure 5. Stent expansion and recoil maximum balloon-to-artery CSA represented as top of stacked bar graph. Final stent-to-artery CSA ratio represented by top of each black bar. Difference between tops of white and black bars thus represents acute recoil as a percentage of balloon/artery CSA.

Figure 6. Regression lines relating balloon expansion and final stent-to-artery ratios for slotted-tube (○; solid line) and coil (□; dashed line) stents. \( y = 0.73 \) (slotted tube) + 0.14; \( r^2 = 0.69 \), \( P < 0.001 \). \( y = 0.83 \) (coil) – 0.17; \( r^2 = 0.74 \), \( P = 0.003 \). Coil stents require 41% area overexpansion (17% diameter overexpansion), whereas slotted-tube stents require only 17% area overexpansion (9% diameter overexpansion) to achieve a final CSA equivalent to reference CSA.
ment. Despite similar maximum balloon-to-artery ratios with all 4 stent designs, the greater magnitude of recoil observed for the Gianturco-Roubin stent led to a significantly lower final ratio of stent to reference artery CSA than in the slotted-tube designs (0.9 versus 1.1, P = 0.02). To achieve a final stent-to-artery ratio of 1.0, the coil stents would require overexpansion to a balloon-to-artery area ratio of 1.4 (diameter ratio 1.2), whereas slotted-tube stents would require overexpansion only to an area ratio of 1.2 (diameter ratio 1.1).

With the exception of oversized compliant balloons, balloon underexpansion was not observed in this study. This is in contradistinction to the findings of Bermejo et al, which documented up to a 33% balloon underexpansion in diseased human coronary arteries. The discrepancy between these studies may be due to different methodologies (quantitative coronary angiography versus IVUS balloon sizing) or because balloon underexpansion is more likely in diseased vessels, which are less compliant and often contain bulky fibrocalcific plaque (which physically limits balloon expansion), than in normal arteries as evaluated in the present study. It must be noted, however, that the magnitude of elastic stent recoil (20% to 30% of stent area) seen in this study is comparable to that seen by Bermejo et al and would alone be sufficient to explain the degree of final stent undersizing seen clinically. To compensate for this elastic stent recoil and achieve the optimal stent result (final stent-to-artery ratio of 1.0), stents must then be overexpanded by 10% to 20% diameter relative to the reference vessel diameter. This may be done by use of either an oversized noncompliant balloon or a correctly sized compliant balloon relative to the reference lumen that is inflated to high pressure. As long as the desired degree of balloon oversizing is achieved, however, inflation to high pressure is not per se a requirement for optimal stent results. This principle may explain the recent trend toward lower (~12 atm) inflation pressures with balloons slightly oversized relative to the desired reference lumen diameter (including balloons sized to approach the diameter of the external elastic lamina measured by IVUS). In heavily diseased arteries, however, this calculation may increase the risk of edge dissection or frank vessel rupture, as was observed in the early experience of Colombo et al.

Limitations

This study has several important limitations. First, all stents were expanded in nondiseased, compliant arteries. The forces resisting balloon expansion are clearly less in this model than in atherosclerotic vessels. The contribution of balloon undersizing to final stent underexpansion may thus have been underestimated significantly compared with that which occurs in diseased human arteries. Second, the degree of stent recoil may be even higher in diseased arteries, which may exert greater recoil force. Even so, the 15% area recoil observed for slotted-tube stents and 30% area recoil observed for coil stents in this study represent a “best-case scenario” for these devices and mandate intentional stent overexpansion to achieve the desired final stent luminal CSA.

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References

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