Are Residual Stenoses After Excimer Laser Angioplasty and Coronary Atherectomy Due to Inefficient or Small Devices? Comparison With Balloon Angioplasty

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Objectives. The purpose of this study was to determine whether residual stenoses after excimer laser angioplasty and atherectomy were due to inefficient tissue ablation/removal or to undersized devices.

Background. Significant residual stenoses are commonly observed after use of laser and atherectomy devices. It is not known whether these residual stenoses are due to inefficient or undersized devices.

Methods. To determine the relative contribution of these factors, the minimal lumen diameter, percent diameter stenosis and normal reference diameter were measured immediately before and after coronary interventions in 696 lesions, including transluminal extraction atherectomy, high speed mechanical rotational atherectomy, excimer laser angioplasty and conventional balloon angioplasty. The ratio of the diameter of the device to the normal reference diameter (D/A, a measure of device sizing) and the ratio of the residual lumen diameter after use of the device to the device diameter (RLD/D, a measure of the efficiency of lumen enlargement) were calculated.

Results. Baseline diameter stenoses were similar for all interventions. The percent diameter stenoses were greater immediately after extraction atherectomy (60 ± 21%), rotational atherectomy (54 ± 23%) and excimer laser angioplasty (61 ± 18%) compared with balloon angioplasty (26 ± 12%, p < 0.001). The D/A ratio was smaller after extraction atherectomy (0.63 ± 0.14), rotational atherectomy (0.59 ± 0.17) and excimer laser angioplasty (0.51 ± 0.11) compared with balloon angioplasty (1.05 ± 0.13, p < 0.001). The RLD/D ratio was similar after extraction atherectomy (0.73 ± 0.24) and balloon angioplasty (0.71 ± 0.11) but was greater after rotational atherectomy (0.92 ± 0.16, p < 0.001) and excimer laser angioplasty (0.85 ± 0.30, p < 0.01) compared with balloon angioplasty.

Conclusions. Residual stenoses after extraction atherectomy, rotational atherectomy and excimer laser angioplasty were more severe than after balloon angioplasty but were due to undersized devices (low D/A ratio), not to inefficient devices (low RLD/D ratio). Rotational atherectomy and excimer laser angioplasty were more efficient (higher RLD/D) than balloon angioplasty, whereas extraction atherectomy and balloon angioplasty were similar.

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Lions Committee of William Beaumont Hospital. The techniques of extraction atherectomy, rotational atherectomy and excimer laser angioplasty have been described elsewhere (2-4).

Angiographic analysis. Quantitative angiographic analysis was performed immediately before and after coronary intervention using the single view that identified the most severe stenosis. Intracoronary nitroglycerin (0.1 to 0.2 mg) was routinely administered before and after intervention. Minimal lumen diameter and reference artery diameter were determined using digital electronic calipers, as previously described in detail (5).

Definitions. The device/artery ratio (D/A) was defined as the ratio of the final diameter (D, in mm) of the device to the normal reference artery diameter (A, in mm) and was a measure of device sizing: D/A = 1 suggested that the diameter of the device was matched to the size of the reference vessel; D/A < 1 suggested that the device was undersized compared with the diameter of the reference segment.

The efficiency of device-mediated lumen enlargement (RLD/D) was defined as the ratio of residual lumen diameter (RLD, in mm) immediately after use of the device to the diameter of the largest device used (D, in mm) and was a measure of the final diameter (after the device) normalized for the size of the device: RLD/D = 1 suggested 100% device efficiency (the minimal diameter achieved after the device was 100% of the device diameter); RLD/D < 1 suggested device efficiency <100%, consistent with elastic recoil.

The diameter of the device was assumed to be that specified by the manufacturer. For rotational atherectomy burrs, excimer laser angioplasty fibers, and conventional angioplasty balloons, the diameter of the device was recorded in mm. For extraction atherectomy, the diameter of the cutter (in mm) was calculated by dividing the size of the device (reported by the manufacturer in F) by 3.

Statistical analysis. All data are reported as mean value ± SD. Comparisons were made using the Student t test for continuous variables and chi-square analysis for categoric variables. Analysis of variance was used for multiple comparisons. A p value < 0.05 was considered significant.

Results

Angiographic results. Target lesions were located in the left main (6%), left anterior descending (27%), left circumflex (11%) or right coronary (30%) artery or saphenous vein bypass grafts (25%). Using the modifications of the American College of Cardiology/American Heart Association (ACC/AHA) Task Force classification proposed by Ellis et al. (6), lesions were classified as A (10.2%), B1 (21.4%), B2 (51.9%) and C (16.5%).

Baseline angiography revealed smaller minimal lumen diameters in the lesions treated by balloon angioplasty (0.8 ± 0.5 mm) compared with those treated by extraction atherectomy (1.0 ± 0.6 mm, p < 0.01) and rotational atherectomy (1.0 ± 0.5 mm, p < 0.01), but the minimal lumen diameter before excimer laser angioplasty (0.9 ± 0.5 mm, p = NS) was similar to that achieved with balloon angioplasty (Fig. 1). The diameter of the normal reference segment was smaller in vessels treated by balloon angioplasty (2.5 ± 0.7 mm) than in those treated with extraction atherectomy (3.6 ± 0.9 mm, p < 0.0001), rotational atherectomy (3.2 ± 0.8 mm, p < 0.0001) and excimer laser angioplasty (2.9 ± 0.7 mm, p < 0.01) (Fig. 1). However, there were no differences in baseline percent diameter stenosis among the four types of interventions (mean baseline percent diameter stenosis 72 ± 15%) (Fig. 2).

There were significant increases in minimal lumen diameter after each intervention (the minimal lumen diameters

Figure 1. Baseline minimal lumen diameter (MLD) and residual lumen diameter (RLD) after percutaneous coronary interventions in 696 lesions. *p < 0.001, **p < 0.01 and ***p < 0.0001 compared with balloon angioplasty. REF = reference diameter. Balloon angioplasty (solid bars); excimer laser angioplasty (open bars); high speed mechanical rotational atherectomy (hatched bars); transluminal extraction atherectomy (cross-hatched bars).

Figure 2. Percent diameter stenosis before (PRE) and after (POST) percutaneous coronary interventions in 696 lesions. *p < 0.01 compared with balloon angioplasty. Balloon angioplasty (solid bars); excimer laser angioplasty (open bars); high speed mechanical rotational atherectomy (hatched bars); transluminal extraction atherectomy (cross-hatched bars).
were 1.4 ± 0.7 mm after extraction atherectomy and rotational atherectomy, 1.1 ± 0.6 mm after excimer laser angioplasty and 1.9 ± 0.5 mm after balloon angioplasty) (Fig. 1).

The residual percent diameter stenoses after extraction atherectomy (60 ± 21%), rotational atherectomy (54 ± 23%) and excimer laser angioplasty (61 ± 18%) were significantly greater than after balloon angioplasty (26 ± 12%, p < 0.001 for all devices compared with balloon angioplasty) (Fig. 2).

Device size and efficiency. Angioplasty balloons were significantly larger than extraction atherectomy cutters (p < 0.05), Rotablator burrs (p < 0.001) and laser fibers (p < 0.001) (Table 1). Although the residual stenoses after extraction atherectomy, rotational atherectomy and excimer laser angioplasty were significantly greater than after balloon angioplasty (1.05 ± 0.13, p < 0.001) than after extraction atherectomy (0.63 ± 0.14), rotational atherectomy (0.59 ± 0.17) and excimer laser angioplasty (0.51 ± 0.11), suggesting that these three devices were significantly undersized compared with conventional angioplasty balloons (Fig. 3). Furthermore, despite the significantly greater residual stenosis after use of these devices than after balloon angioplasty, the efficiency of lumen enlargement (RLD/D) after these devices was similar to or greater than that achieved with balloon angioplasty. The RLD/D ratios for rotational atherectomy (0.92 ± 0.16, p < 0.001) and excimer laser angioplasty (0.85 ± 0.30, p < 0.01) were significantly greater than for balloon angioplasty (0.71 ± 0.11), and the RLD/D ratio for extraction atherectomy (0.73 ± 0.24, p = NS) was similar to that for balloon angioplasty (Fig. 3).

The RLD/D ratios were also determined for each size of each device, for new versus restenosis lesions, for native vessels versus saphenous vein bypass grafts and for different lesion morphologies using the modified ACC/AHA criteria proposed by Ellis et al. (6). There were no significant differences in RLD/D ratios for different sized devices within the same device group, for new versus restenosis lesions, or for native vessels versus saphenous vein grafts.

However, there were potentially important differences in the influence of lesion morphology on device efficiency (Table 2). For extraction atherectomy, rotational atherectomy and balloon angioplasty, there were no differences in the efficiency of lumen enlargement when lesion morphology was stratified according to the A, B1, B2 and C classification. However, efficiency of lumen enlargement for excimer laser angioplasty was more clearly influenced by lesion classification (p < 0.05 for A, B1, B2 and C lesions).

Discussion

Many centers are studying the use of lasers, stents and atherectomy devices for patients with coronary artery disease. In fact, the National Heart, Lung, and Blood Institute is sponsoring a multicenter registry to evaluate these new approaches.

Figure 3. Device ratios for percutaneous coronary interventions in 696 lesions. *p < 0.01 and †p < 0.001 compared with balloon angioplasty. D/A = device/artery ratio, RLD/D = residual lumen diameter/device ratio (see text for definitions). Balloon angioplasty (solid bars); excimer laser angioplasty (open bars); high speed mechanical rotational atherectomy (hatched bars); transluminal extraction atherectomy (cross-hatched bars).
After Intervention

Table 2. Influence of Lesion Morphology on Efficiency of Lumen Enlargement (RLD/D ratio)

<table>
<thead>
<tr>
<th>Lesion class</th>
<th>TEC</th>
<th>ROTA</th>
<th>ELCA</th>
<th>Balloon Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>All lesions</td>
<td>0.73 ± 0.24</td>
<td>0.92 ± 0.16*</td>
<td>0.85 ± 0.30²</td>
<td>0.71 ± 0.11</td>
</tr>
<tr>
<td>A (%)</td>
<td>0.65 ± 0.20 (8)</td>
<td>0.92 ± 0.18 (19)</td>
<td>0.93 ± 0.29 (5)</td>
<td>0.70 ± 0.12 (19)</td>
</tr>
<tr>
<td>B1 (%)</td>
<td>0.74 ± 0.24 (20)</td>
<td>0.95 ± 0.16 (31)</td>
<td>0.96 ± 0.28 (20)</td>
<td>0.76 ± 0.11 (17)</td>
</tr>
<tr>
<td>B2 (%)</td>
<td>0.74 ± 0.24 (55)</td>
<td>0.92 ± 0.17 (45)</td>
<td>0.85 ± 0.30 (55)</td>
<td>0.68 ± 0.11 (40)</td>
</tr>
<tr>
<td>C (%)</td>
<td>0.72 ± 0.22 (17)</td>
<td>0.90 ± 0.16 (5)</td>
<td>0.75 ± 0.30 (20)</td>
<td>0.71 ± 0.11 (24)</td>
</tr>
<tr>
<td>p Value</td>
<td>NS</td>
<td>NS</td>
<td>&lt;0.05</td>
<td>NS</td>
</tr>
</tbody>
</table>

* p < 0.001. *p < 0.01 compared with balloon angioplasty. Values presented are mean value ± SD (%). These p values apply to RLD/D ratios for A, B1, B2 and C lesions for each device (analysis of variance). See Ellis et al. (6) for definitions of lesion classification. RLD/D = efficiency of device-mediated lumen enlargement; other abbreviations as in Table 1.

Interventional techniques (7). Some laser, atherectomy and balloon devices result in sufficient lumen enlargement to be considered stand-alone treatments for many lesions (8), but others require adjunctive balloon angioplasty to achieve definitive lumen enlargement (1). Because significant residual stenoses are common immediately after some coronary interventions, it is important to differentiate residual stenoses due to small devices from those due to inefficient devices.

Assessment of efficiency of lumen enlargement. Conventional methods of evaluating interventional devices rely on measurements of percent residual stenosis by using the following formula:

\[
\text{Percent residual stenosis} = 100 - \left( \frac{\text{RLD}}{\text{A}} \right) \times 100. \tag{1}
\]

According to equation 1, the percent residual stenosis is influenced by the residual lumen diameter (RLD) and the size of the reference segment (A). In turn, the residual lumen diameter is dependent on the diameter of the final device and the efficiency of the device to enlarge the lumen:

\[
\text{Residual lumen diameter} = \text{Device diameter} \times \text{Device efficiency}. \tag{2}
\]

By substituting equation 2 into equation 1, percent residual stenosis can be rewritten as follows:

\[
\text{Percent residual stenosis} = 100 - \frac{\left( \text{Device size} \times \text{Device efficiency} \right)}{\text{A}} \times 100 = 100 - \left( \frac{\text{D/A} \times \text{RLD/D}}{\text{D/A}} \right) \times 100. \tag{3}
\]

Therefore, two (device diameter, reference diameter) of the three factors that influence the percent diameter stenosis are unrelated to the efficiency of the device. According to equation 3, the residual stenosis is clearly dependent on the efficiency (RLD/D) and relative size of the device (D/A). Therefore, residual stenosis is a suitable surrogate for device efficiency only if D/A = 1. Direct assessment of the efficiency of lumen enlargement can be achieved using the RLD/D ratio, irrespective of the diameter of the device. Although comparisons using percent diameter stenosis measurements could be possible if similar device sizes are applied to similar sized vessels, such requirements could introduce a significant selection bias toward small vessels. Furthermore, these requirements would not allow meaningful comparisons between small devices (such as those used in rotational atherectomy) and large devices (such as those used in directional atherectomy). Therefore, because of differences in device and vessel size, percent diameter stenosis alone is inadequate for comparing devices, and direct measures of device efficiency are preferable.

The relations among residual stenosis, device efficiency and device size are depicted in Figure 4. As expressed by equation 3, there is an inverse linear relation between device efficiency (RLD/D) and residual stenosis, and the slope of this line is determined by the D/A ratio. Despite the greater efficiency of lumen enlargement with excimer laser angioplasty (Fig. 4, point E, RLD/D = 0.85) and rotational}

![Figure 4. Inverse linear relation between percent residual stenosis, device efficiency (RLD/D) and device size (D/A). See text for definitions. E = excimer laser balloon angioplasty; P = balloon angioplasty; R = high speed mechanical rotational atherectomy with the Rotablator; T = transluminal extraction coronary atherectomy.](image-url)
atherectomy (Fig. 4, point R, RLD/D = 0.92) compared with balloon angioplasty (Fig. 4, point P, RLD/D = 0.71), the residual stenosis after balloon angioplasty was less than that after excimer laser angioplasty and rotational atherectomy because of the availability of larger balloon sizes (D/A = 1.05), not because of better efficiency of lumen enlargement. For devices associated with a D/A ratio of 0.5 to 0.63 (such as in extraction atherectomy, rotational atherectomy and excimer laser angioplasty), the best residual stenosis that can be achieved is 40% to 50%, even if the device is 100% efficient.

Residual stenoses after operation. One of the disappointing features of balloon angioplasty has been the recognition that a fully inflated balloon rarely results in 0% residual stenosis (8-11). The residual stenoses commonly observed after balloon angioplasty are not usually due to undersized balloons (D/A < 1) because most angioplasty operators try to select a balloon to match the diameter of the normal reference segment (D/A = 1). These data are confirmed by the present study, in which a residual stenosis of 26 ± 12% was observed after balloon angioplasty despite a D/A of 1.05. In fact, attempts to improve lumen dimensions and decrease the residual stenosis immediately after balloon angioplasty by using oversized balloons (D/A > 1.1) may result in an unacceptably high incidence of severe dissection and abrupt closure (12).

Because angioplasty balloons are available in inflated diameters ranging from 1.5 to 6.0 mm, balloon angioplasty is rarely limited by the size of the balloon or by the diameter of the reference segment (in other words, it is possible to achieve D/A = 1 for virtually all target vessels). In contrast, such wide variety of sizes is not generally available for many new laser and atherectomy devices, and the residual stenoses after these devices may be influenced more by the size of the device and the diameter of the reference segment (D/A < 1) compared with balloon angioplasty. The D/A ratios of 0.51 to 0.63 in this study confirm that extraction atherectomy cutters, Rotablator burrs and excimer laser fibers were clearly undersized compared with the diameter of the vessel. The residual stenoses of 54% to 62% were significantly higher than the residual stenosis of 26% after balloon angioplasty and were similar to the residual stenoses reported by other investigators of these devices (2-4,13). However, the RLD/D ratios of 0.92 for rotational atherectomy and 0.85 for excimer laser angioplasty suggest that these devices are actually more efficient than balloon angioplasty, whereas the RLD/D ratio of 0.73 for extraction atherectomy was similar to that for balloon angioplasty.

There are several reasons why it may be important to distinguish suboptimal lumen enlargement due to inefficient devices from that due to small devices. 1) As suggested by Figure 4, large, inefficient devices may achieve residual stenoses similar to those achieved with small, efficient devices. From a cost-containment standpoint, it seems reasonable to pursue development of the most efficient device in the widest variety of sizes, provided that it meets acceptable safety standards. However, there may be a practical limit to the size of a device that can be safely applied to a coronary artery. 2) Large, inefficient devices may require large guiding catheters, which could increase the potential for coronary and femoral vascular injury and could increase requirements for radiographic contrast agents. 3) An inefficient device may have basic design flaws that limit its application regardless of device size, whereas small but efficient devices could potentially achieve better lumen enlargement if larger sizes could be developed. Finally, from a scientific standpoint it is important to understand all of the limitations of new technologies, whether they are due to basic flaws in design or to small size, or both.

Device efficiency after intervention. Although RLD/D ratios have not been reported by other investigators, these data can be calculated from previous studies of balloon angioplasty and other devices (12,14). Roubin et al. (12) performed balloon angioplasty in larger vessels than in our study, but the D/A ratio of 1.03 and the RLD/D ratio of 0.70 they reported were remarkably similar to the D/A ratio of 1.05 and RLD/D ratio of 0.71 in our study. In addition, Zacca et al. (14) reported their quantitative angiographic results with single, large Rotablator burrs (2.25 to 2.75 mm) in 81 coronary stenoses (these larger burrs were not available to us at the time of our study). Although the D/A ratio of 0.7 in their study was larger than the D/A ratio of 0.59 in ours, their RLD/D ratio of 0.93 was similar to our RLD/D ratio of 0.92. Other studies of laser balloon angioplasty (RLD/D = 0.8) and balloon-expandable stents (RLD/D = 1) suggest that these devices also may be more efficient than balloon angioplasty (8).

The explanation for why devices are <100% efficient is not known. This study and others (8-11) suggest that there is an approximately 25% loss of diameter immediately after balloon angioplasty (RLD/D = 0.71), which is usually ascribed to varying degrees of elastic recoil and vasospasm. However, as indicated by data in our study, device sizing (D/A) must also be considered when using percent diameter stenosis measurements. However, even when using a direct measure of device efficiency (RLD/D), it is apparent that none of the devices in this study were 100% efficient at lumen enlargement. Although some rotational atherectomy investigators suggest that the "wobble effect" may result in lumen dimensions greater than the burr diameter (i.e., RLD/D > 1), this was not uniformly observed in our study. However, there was only 8% loss in diameter immediately after rotational atherectomy (RLD/D = 0.92) and 15% loss in diameter immediately after excimer laser angioplasty (RLD/D = 0.85), suggesting less elastic recoil after use of these devices than after balloon angioplasty. After extraction atherectomy, there was a 27% immediate loss in diameter (RLD/D = 0.73), which was similar to that after balloon angioplasty. However, extraction atherectomy may have other important uses, such as aspiration of thrombus, and should not necessarily be considered comparable to balloon angioplasty.
There were several interesting observations with regard to factors that may influence device-mediated efficiency of lumen enlargement. 1) The target lesion location (native vs. saphenous vein graft), the type of lesion (new vs. restenosis lesion) and the diameter of the device had no impact on device efficiency. 2) For extraction atherectomy, rotational atherectomy and balloon angioplasty, the presence of A, B1, B2 or C lesion classification did not influence device efficiency. In contrast, efficiency of lumen enlargement for excimer laser angioplasty was significantly influenced by lesion classification, in that lower RLD/D ratios were achieved for more complex lesion morphology (Table 2). Although rotational atherectomy and excimer laser angioplasty demonstrated high efficiency for lumen enlargement in less complex (A and B1) lesions, the efficiency of excimer laser angioplasty decreased significantly in more complex (B2 and C) lesions. For excimer laser angioplasty (and other ablative laser technologies) the ideal peak power density and pulse repetition rate may vary with plaque composition, and because the threshold for tissue ablation is dependent on these factors, it is possible that the peak power density and pulse repetition rate in this study were inadequate for more complex lesions. However, measures of device efficiency are well suited for studying the effect of these variables on improving lumen dimensions.

Uses for the RLD/D ratio. There are several potential uses for the RLD/D ratio. 1) This ratio can be used to anticipate the minimal lumen diameter and to plan revascularization strategy (Fig. 4). For example, a residual lumen diameter of 1.8 mm should be expected for a 2-mm device with RLD/D = 0.9. If the reference diameter of the target vessel is 4.0 mm (D/A = 0.5), the operator can expect a residual stenosis of 55%, and adjunctive balloon angioplasty may be reasonable to further enlarge the lumen. 2) The RLD/D ratio is useful for comparing devices with different mechanisms of lumen enlargement, independent of device size, as suggested by the data in this study. 3) The RLD/D ratio may provide insight into the extent of elastic recoil immediately after intervention. However, it is not useful for distinguishing tissue ablation or removal from "Dotter" effect or for distinguishing elastic recoil, spasm or laminated thrombus as factors contributing to a residual stenosis. 4) The RLD/D ratio may be useful for assessing the efficiency of new devices and their subsequent modifications. For example, it may be reasonable to pursue development of devices with RLD/D = 0.7 to 1.0, whereas devices with RLD/D < 0.7 would have to demonstrate some other utility besides lumen enlargement (e.g., aspiration of thrombus, sealing dissections) to be as clinically useful as balloon angioplasty.

Limitations of the study. There are several important limitations of this study. 1) It is a retrospective, nonrandomized observational study that should be considered in the context of evaluating first-generation laser and atherectomy devices. It is possible that modifications of the design and size of these devices, as well as greater operator experience, could have a significant impact on improving these short-term results. 2) The indications for lasers, atherectomy devices and balloon angioplasty are in evolution, and it is likely that the morphology of lesions selected for laser angioplasty and atherectomy will be quite different from those selected for balloon angioplasty. 3) Lumen enlargement itself should not be the only criterion on which the utility of a device is measured. For example, despite the fact that extraction atherectomy and balloon angioplasty share a similar efficiency of lumen enlargement (RLD/D), extraction atherectomy may have unique advantages based on its ability to remove tissue and aspirate thrombus. 4) There was no attempt to measure the diameter of the inflated balloon or the devices. It is possible that the actual size of the balloon or device differed from the nominal size, due to either variances in manufacturing or to differences in balloon compliance. However, previous studies using both compliant and noncompliant balloon materials suggest that even though the diameter of the inflated balloon is not uniform, the D/A ratio using the maximal measured balloon diameter was similar to the D/A ratio using the nominal size of the inflated balloon (15). Therefore, nominal balloon size is reasonable for calculating the maximal D/A ratio, as described in this study. 5) Quantitative angiography with digital calipers has several limitations, and these studies should be validated using other methods, such as intravascular ultrasound, if possible. Finally, the purpose of this study was to evaluate the short-term efficiency of lumen enlargement for three new devices compared with balloon angioplasty, and it was not intended as an evaluation of the safety or long-term efficacy of these new devices.

Conclusions. Significant residual stenoses commonly occur after coronary atherectomy and excimer laser angioplasty and are due to undersized devices (low D/A ratio) rather than to inefficient devices (low RLD/D ratio). High speed mechanical rotational atherectomy and excimer laser angioplasty achieve more efficient lumen enlargement than does balloon angioplasty, whereas the efficiency of lumen enlargement with extraction atherectomy and balloon angioplasty are similar.

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References


