Percutaneous Excimer Laser Coronary Angioplasty of Lesions Not Ideal for Balloon Angioplasty

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Background. Excimer laser coronary angioplasty is a new, investigational technique for treating coronary artery stenoses. Initial reports have demonstrated acute efficacy and relative safety of this procedure, but have not addressed the effect of lesion type on acute success and complication rates.

Methods and Results. In the first 100 patients undergoing percutaneous excimer laser coronary angioplasty at our institution, acute laser success was obtained in 84% and procedural success was obtained in 94%. There were six acute closures during laser angioplasty and one myocardial infarction. Two patients required emergency coronary bypass surgery. Sixty-five percent of patients had lesions not ideal for balloon angioplasty because of lesion morphology (tubular, diffuse, or chronic total occlusion) or ostial location. There were 10 tubular stenoses, 29 diffuse lesions, 18 chronic total occlusions, and eight ostial lesions, including five aorto-ostial lesions. In this nonideal subgroup, the acute success rate with laser was 86% (72% of chronic total occlusions and 91% of non–totally occluded lesions), and the procedural success rate was 94%. There were three acute occlusions during laser angioplasty but no myocardial infarctions, emergency bypass surgeries, or deaths. One coronary artery perforation occurred without clinical sequelae. Laser angioplasty was successful in four of six lesions (67%) in which balloon angioplasty had failed. Laser success was obtained in 10 of 11 (91%) moderately or heavily calcified stenoses. Eight eccentric lesions and two lesions on bends were successfully treated without dissection or perforation. No side branch occlusions occurred in the 15 patients in whom one or more major branches originated within the lesion treated. Adjunctive balloon angioplasty was performed in 47% of cases, usually to obtain a larger final luminal diameter. Need for adjunctive balloon angioplasty decreased to 36% after a larger (2.0 mm) laser catheter became available. Twenty-eight percent of the 105 lesions treated were American College of Cardiology/American Heart Association classification type A, 47% were type B, and 25% were type C. Laser and procedural successes were obtained in 83% and 97% of type A, 88% and 96% of type B, and 85% and 88% of type C lesions, respectively.

Conclusions. In our initial experience, excimer laser angioplasty was found to be acutely effective and safe therapy for lesions identified as not ideal for balloon angioplasty. This technique may provide a useful adjunct or alternative to balloon angioplasty in selected patients. (Circulation 1991;84:632–643)

When percutaneous transluminal coronary angioplasty (PTCA) was first described, it was believed that this technique would be applicable to a small number of patients with discrete, proximal, and concentric coronary stenoses. During the past decade, improvements in equipment and technique have increased the number of patients who can be treated with balloon angioplasty. Despite these advances, certain types of coronary lesions have been identified as suboptimal for balloon angioplasty. These lesions include complete occlusions, long stenoses, diffusely diseased segments, calcified plaque, and the like.
and aorto-ostial stenoses. Balloon angioplasty of these lesions is associated with lower acute success rates, higher acute closure rates, and/or diminished long-term patency.\textsuperscript{3–9} Although vessel closure may result from spasm\textsuperscript{10} or thrombosis,\textsuperscript{11} it usually is secondary to intimal dissection.\textsuperscript{6} Dissection during balloon angioplasty appears to correlate with the bulk of atherosclerotic material at the site of dilatation.\textsuperscript{12} This limitation of balloon angioplasty has in part stimulated the development of new percutaneous devices capable of removing plaque from coronary arteries.\textsuperscript{13}

See p 939

One such device—the excimer laser—is a pulsed ultraviolet laser recently adapted for medical applications. The excimer differs from longer-wavelength, continuous-wave lasers in that it causes minimal thermal injury to tissue and is capable of ablating calcified plaque.\textsuperscript{14} Our group performed the first successful percutaneous excimer laser coronary angioplasty in 1988.\textsuperscript{15} Initial reports have demonstrated the acute efficacy and relative safety of this procedure in small numbers of patients\textsuperscript{16–19} but have not addressed the effect of lesion type on acute success and complication rates.

The purpose of the present study was to describe the acute outcome of excimer laser coronary angioplasty in lesions known not to be ideal for balloon angioplasty because of morphology, location, or previous unsuccessful PTCA.

Methods

Patient Entry

Between July 14, 1988, and March 2, 1990, excimer laser coronary angioplasty was attempted in 100 patients at Cedars-Sinai Medical Center, Los Angeles. Patients were considered for this procedure if they had symptomatic coronary artery disease and/or objective evidence of myocardial ischemia sufficient to warrant either balloon angioplasty or coronary artery bypass graft surgery (CABG) and angiographically documented stenoses or occlusions of native coronary arteries or bypass grafts thought to be traversable with angioplasty guide wires. Patients were considered for enrollment into the study based on the preference of the patient or the referring physician. The majority of patients, however, were referred for laser angioplasty because they were considered to be nonideal candidates for PTCA because of lesion morphology or location, previous unsuccessful attempted PTCA, and/or multiple recurrences after PTCA. Patients undergoing an evolving myocardial infarction were not considered for entry into the protocol. This study is part of a nonrandomized multicenter trial. All patients gave informed consent before participating in the study, and the study protocol was approved by the Cedars-Sinai Human Subjects Research Committee and the US Food and Drug Administration.

Excimer Laser Source

We used a magnetically switched, thyratron-driven 308-nm xenon chloride excimer laser (Advanced Interventional Systems, Inc., Irvine, Calif.) specifically designed for intravascular applications. The laser emits as much as 225 mJ/pulse at 5–50 Hz and has a pulse duration of 180 nsec. The electronic specifications of this laser have previously been described.\textsuperscript{20}

Fiberoptic Catheter Delivery Systems

Laser energy was delivered through multifiber catheters 1.3, 1.6, or 2.0 mm in diameter. The 2.0-mm catheters became available in August 1989, and the 1.3-mm catheters became available in October 1989. The silica fibers are concentrically arranged around a central lumen that accepts up to a 0.018-in. guide wire. Early-generation 1.6-mm catheters were constructed of twelve 100-\textmu m fibers with 200-\textmu m fused silica tips.\textsuperscript{21} Currently available catheters have more than 200 individual 50-\textmu m fibers in a concentric array.

Laser Angioplasty Procedure

All patients were treated with 81 mg aspirin twice daily and a calcium channel antagonist starting no later than the day before the procedure. Arterial and venous side arm introducer sheaths were inserted into the femoral vessels using Seldinger's technique. Intravenous heparin boluses were administered (10,000–15,000 units) to increase the activated clotting time to more than 350 seconds and maintain it at this level for the duration of the procedure. Standard angioplasty guide catheters were used: 8F catheters for angioplasty with 1.3- and 1.6-mm laser catheters and 9F for 2.0-mm catheters (Schneider Inc., Minneapolis, Minn.). After selective intracoronary infusion of nitroglycerin (200 \textmu g), simultaneous biplane cineangiography was obtained of each lesion in two or more projections separated by at least 60°. Cineangiography was repeated after laser angioplasty and, when applicable, balloon angioplasty, using the same projections and nitroglycerin protocol.

The lesion was crossed with a 0.016- or 0.018-in. coronary guide wire under fluoroscopic guidance (USCI, Inc., Billerica, Mass., and ACS, Inc., Temecula, Calif.). If the lesion could not be crossed with a guide wire, laser angioplasty was not performed. Major side branches of the treatment artery were not protected with a guide wire.

Laser energy emitted from the catheter tip was calibrated at 35–60 mJ/mm². In early cases, the energy fluence was usually chosen to be 35–42 mJ/mm². Experience showed that higher-energy fluences are often required for successful ablation, particularly with calcified lesions. As a result, most of the later lesions were treated with energy fluences of 45–50 mJ/mm²; even higher fluences were used if the lesion was heavily calcified or attempted laser angioplasty at a lower fluence was unsuccessful.

After calibration of laser tip energy, the laser catheter was advanced over the guide wire until its tip was
immediately proximal to the lesion. Under fluoroscopic control, the laser catheter was advanced slowly across the lesion while laser pulses were delivered at 20 Hz. After each passage through the lesion, the catheter was withdrawn, and angiographic contrast was injected. Multiple (one to five) passes were made through the lesion at the operator’s discretion. The laser catheter was then withdrawn, and biplane cineangiography was performed. If the posttreatment stenosis was visually estimated to be less than 50%, the guide wire was removed, and completion angiograms were performed. If the residual stenosis was more than 50%, adjunctive balloon angioplasty was performed before completion angiography.

After laser angioplasty, patients were transferred to a coronary care unit, where they were monitored by telemetry for at least 24 hours. A 12-lead electrocardiogram was obtained immediately after the procedure and then daily for 2 days. Serial creatine kinase levels were obtained immediately after the procedure and at 8 and 16 hours. Heparin was infused until the next morning, when heparin was discontinued and the sheaths were removed.

**Data Collection**

Clinical, angiographic, and laboratory information were recorded during hospitalization on standard forms by a physician and entered into a computerized data bank. Recorded data included age, sex, Canadian Cardiovascular Society functional classification, stress test results, location of treated vessel, history of prior balloon PTCA at the same site, preprocedural and postprocedural percent diameter stenoses, use of adjunctive balloon PTCA and balloon size, laser catheter size, laser energy output, number of laser pulses used, and all complications. Angiographic complications recorded included intimal tear or dissection, perforation, thrombosis, spasm, distal embolization, and acute closure. Clinical complications recorded included myocardial infarction, CABG, and death. Myocardial infarction was defined as creatine kinase elevation of more than 200 IU with an MB fraction of 3% or more.

**Definition of Acute Success and Closure**

Acute laser success was prospectively defined as a more than 20% improvement in the absolute minimal stenotic diameter and a resultant vessel diameter of more than 0.8 mm with the 1.3-mm catheter, more than 1.0 mm with the 1.6-mm catheter, and more than 1.3 mm with the 2.0-mm catheter after excimer laser angioplasty alone. The 20% improvement criterion was the definition of acute angiographic success in the National Heart, Lung, and Blood Institute (NHLBI) Registry. The vessel diameter criterion was based on initial results that showed that laser angioplasty with the 1.6-mm catheter produces, on average, 1.6-mm lumen with an SD of 0.5 mm. Acute procedural success was defined as final diameter stenosis of 50% or less as determined by caliper measurements. Acute closure was defined as angiographic reduction in blood flow in the procedural vessel or clinical or electrocardiographic evidence of myocardial ischemia leading to balloon PTCA, CABG, or myocardial infarction during the same hospitalization as the laser procedure.

**Qualitative Angiographic Review**

Cineangiograms of all patients undergoing laser angioplasty were reviewed by one experienced, unblinded angiographer for the following prospectively defined variables. Lesion morphology was coded using the BARI morphology classification system as one of the following: single discrete (lesion less than 10 mm in length), multiple discrete (more than one discrete lesion in the treatment vessel), diffuse (lesion of 10 mm or more with irregular contour), tubular (lesion of 10 mm or more with hourglass appearance), discrete aneurysmal, diffuse aneurysmal (BARI manual of operations; unpublished material), or complete occlusion. Only arteries with no visible antegrade flow were assigned to the complete occlusion group. “Functionally occluded” arteries were assigned to other groups based on their salient morphological features. Additional angiographic variables recorded were defined as follows.

**Bend point.** A bend point is a 45° angulation of the vessel during diastole involving the lesion or adjacent to the lesion such that a balloon dilating the lesion includes the bend in any angiographic projection in which the vessel is not foreshortened.

**Calcification.** Calcification includes fixed radiographic densities within the lesion; these are subjectively graded as mild (barely visible), moderate (easily visible), or severe (spine density).

**Eccentricity.** Eccentricity is a highly asymmetric appearance of the stenosis in any angiographic projection.

**Unsuccessful balloon angioplasty.** When a lesion is crossed with a guide wire but cannot be crossed with a balloon or there is a residual diameter stenosis of more than 50% after dilatation with an appropriately sized balloon, balloon angioplasty is considered to have been unsuccessful.

**Branch point.** A branch point is one or more branch vessels more than 1.0 mm in diameter originating from a diseased segment receiving laser angioplasty.

**Ostial lesion.** An ostial lesion is a stenosis that involves the origin of the left main coronary artery, right coronary artery, left anterior descending coronary artery, or left circumflex artery or the aortic anastomosis of a saphenous vein graft.

**Quantitative Coronary Angiography**

All angiograms were acquired using isocentric biplane geometry on 35-mm cinefilm at a speed of 30 frames/sec at 30–35 μR/frame using a 7-in. image intensifier field size. Film quality was judged sufficient for quantitative analysis in 98 of 100 patients. Quantitation was performed at baseline, after excimer laser angioplasty, and after balloon PTCA (when applicable) on the projection that most clearly dem-
onstrated the minimal diameter stenosis, using a modification of the method described by Brown et al.22 The reviewer was an experienced angiographer who neither performed the procedure nor knew of the clinical results. Cineangiograms were magnified fivefold (Vanguard Instruments, Inc., Melville, N.Y.) and viewed on a 26-in. rear-projected digitizing screen (LW International, Inc., Woodland Hills, Calif.). The operator hand-traced the edges of the guide catheter with a crosshair cursor to calibrate magnification for each coronary injection. The luminal borders of the stenotic region were traced from a proximal to a distal identifiable branch point on three successive diastolic frames from each projection, and the beginning and end of the lesion were marked. Adequate biplane views were available before and after laser angioplasty in 92 patients. No correction for pin cushion distortion was made because these errors are typically less than 2%. An on-line computer calculated the vessel centerline and then computed the perpendicular diameter at 0.1-mm intervals. The edges were smoothed by a seven-point unweighted average. The parameters calculated by the computer were lesion length, minimal and maximal diameters, and percent diameter stenosis. With this method, mean intraobserver and interobserver variabilities for minimal stenotic diameter in our laboratory are less than 0.15 mm. Total occlusions (lesions with no visible antegrade flow) were assigned a minimal stenotic diameter of 0.0 mm, and subtotal occlusions (no visible column of contrast across a lesion with visible antegrade flow) were assigned a value of 0.15 mm (half the width of the image intensifier point spread function).

American College of Cardiology/American Heart Association Lesion Classification

Lesions were classified using guidelines established by the joint American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures as type A, B, or C.23 Categorization based on lesion length was performed using lengths derived from quantitative angiography. Other type B and C attributes were assigned as described under qualitative angiographic review. Total occlusions were assigned to type B, except when the occlusion was known from a prior angiogram to be more than 3 months old or had other type C attributes. The BARI and ACC/AHA Task Force lesion classifications of individual lesions were different in some instances because of differing definitions of lesion morphology. For example, tubular and diffuse lesions are defined in the BARI system by both length and morphology but in the ACC/AHA system by length alone.

Statistical Analysis

For comparative purposes, a “nonideal lesion” subgroup was defined as treated lesions that were not favorable for balloon PTCA because of morphology

<table>
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<th>Characteristic</th>
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<td>Canadian Cardiovascular Society</td>
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<td>functional class (n)</td>
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<td>9</td>
<td></td>
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<tr>
<td>II</td>
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<td>III</td>
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<td>IV</td>
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<td>Two</td>
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<td>Three</td>
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<td>Four or more</td>
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(tubular, diffuse, or totally occluded) or ostial location. Biplane quantitative coronary angiography data were analyzed as the geometric mean of the derived parameters from the two projections. Mean diameter \(d\) was calculated as the square root of the product of \(d_1 \times d_2\). Results are presented as the mean±SEM value. Comparison of proportions was performed with the \(\chi^2\) test unless the number of patients in a subgroup was small, in which case Fisher’s exact test was used. Quantitative coronary angiography data were compared using the paired \(t\) test adjusted for multiple comparisons. A difference between groups was said to achieve statistical significance if the probability value was 0.05 or less.

Results

Overall Results

Demographic and clinical characteristics of the first 100 patients undergoing eximer laser coronary angioplasty at our institution are shown in Table 1. Seventy-nine percent were men, and mean patient age was 62.2 years. Seventy-four percent of patients had Canadian Cardiovascular Society functional class III or IV anginal symptoms. Forty-two percent of patients had undergone one or more prior balloon angioplasties of the lesion that received laser angioplasty. One patient had undergone six PTCA proce-

<table>
<thead>
<tr>
<th>Location</th>
<th>Laser successes (n)</th>
<th>Laser successes (%)</th>
<th>Procedural successes (n)</th>
<th>Procedural successes (%)</th>
</tr>
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<tr>
<td>LAD</td>
<td>42</td>
<td>35 (83)</td>
<td>40 (95)</td>
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<tr>
<td>LCx</td>
<td>15</td>
<td>13 (87)</td>
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<td>RCA</td>
<td>30</td>
<td>23 (77)</td>
<td>27 (90)</td>
<td></td>
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<tr>
<td>SVG</td>
<td>13</td>
<td>13 (100)</td>
<td>13 (100)</td>
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<tr>
<td>Total</td>
<td>100</td>
<td>84 (84)</td>
<td>94 (94)</td>
<td></td>
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</table>

LAD, left anterior descending artery; LCx, left circumflex artery; RCA, right coronary artery; SVG, saphenous vein graft.
Surgeries, stent placement, and two directional atherectomy procedures to a saphenous vein graft to an obtuse marginal. Distribution of vessels treated is shown in Table 2.

Acute success was obtained with laser angioplasty in 84% of the 100 patients in this initial cohort, and procedural success was obtained in 94% of patients. The laser and procedural success rates by lesion location are shown in Table 2. The lower laser success rate with right coronary lesions, although not statistically significant, may reflect a higher proportion of total occlusions treated in the right coronary artery compared with other locations (36% versus 13%, p=0.04). Laser success rates in nonoccluded arteries by location were similar. Reasons for laser failure were inability to cross the lesion with guide wire (three patients), inability to advance the laser catheter through tortuosity proximal to the lesion (two patients), inability to completely cross the lesion with laser catheter (four patients), acute closure of lesion (six patients), and severe dissection of the artery (one patient). In all cases of failed laser angioplasty except the three failures to cross with a guide wire and one of the acute closures, adjunctive balloon angioplasty was performed. Two patients required emergency CABG—one for an acute occlusion after laser angioplasty and one for a severe dissection that worsened after PTCA. One of these patients suffered a myocardial infarction; there were no other myocardial infarctions. One patient had a localized perforation with no acute clinical sequelae. No evidence of distal embolization was observed, and there were no deaths.

Adjunctive balloon angioplasty was performed in 47% of all patients. This proportion decreased to 36% in the 69 patients treated after the 2.0-mm laser catheter became available (p=0.003). In 35 patients, adjunctive PTCA was performed to obtain a larger final lumen. In the remainder, adjunctive PTCA was performed because of an inability to advance the laser catheter to the lesion (two patients), inability to completely cross the lesion with the laser catheter (four patients), acute closure of the artery (five patients), and severe dissection of the vessel (one patient).

Laser Angioplasty of Nonideal PTCA Lesions

Sixty-five percent of lesions treated were identified as not ideal for PTCA because of morphology (tubular, diffuse, or total occlusion) or ostial location (Tables 3 and 4). The overall laser success rate in this group was 86% and 91% in patients with nonoccluded arteries. The procedural success rate was 94%. Laser and procedural success rates did not differ significantly between patients with favorable lesions (discrete and multiple discrete lesions) and those with nonideal lesions. Adjunctive PTCA was performed in 46% of patients with favorable lesions and 47% of patients with nonideal lesions (p=NS). In the nonideal subgroup, there were three acute closures (4.6%), no emergency bypass surgeries, one perforation (see below), and no deaths (p=NS compared with favorable lesions for total complications).

Laser angioplasty of a diffuse lesion is shown in Figure 1. Laser angioplasty was successful in 90% of tubular and diffuse lesions, with procedural success obtained in 97%. In the total patient population, laser and procedural success rates declined with increasing lesion length, although not significantly (Figure 2, top panel). This decline resulted from lower success rates with long total occlusions. Laser and procedural success rates for occlusions of 10 mm or more were 67% and 78%, respectively, compared with 78% and 87% in occlusions less than 10 mm (p=NS). In nonoccluded lesions, laser and procedural success rates did not decrease with increasing lesion length (Figure 2, bottom panel).

Laser angioplasty of an aorto-ostial lesion is shown in Figure 3. Laser success was obtained in all eight ostial lesions (100%), with adjunctive balloon PTCA performed in no cases (Table 4). A localized perforation was created in one aorto-ostial lesion without clinical sequelae.

<table>
<thead>
<tr>
<th>Lesion type</th>
<th>Patient (n)</th>
<th>Laser successes (n) (%)</th>
<th>Procedural successes (n) (%)</th>
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<tr>
<td>Discrete</td>
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<tr>
<td>Multiple discrete</td>
<td>5</td>
<td>3 (60)</td>
<td>4 (80)</td>
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<tr>
<td>Tubular lesion</td>
<td>10</td>
<td>10 (100)</td>
<td>10 (100)</td>
</tr>
<tr>
<td>Diffuse disease</td>
<td>29</td>
<td>25 (86)</td>
<td>28 (97)</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>18</td>
<td>13 (72)</td>
<td>15 (83)</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>84 (84)</td>
<td>94 (94)</td>
</tr>
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Table 4. Excimer Laser Angioplasty of Ostial Stenoses

<table>
<thead>
<tr>
<th>Location</th>
<th>Patients (n)</th>
<th>Laser successes (n) (%)</th>
<th>Procedural successes (n) (%)</th>
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<tbody>
<tr>
<td>LAD</td>
<td>2</td>
<td>2</td>
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</tr>
<tr>
<td>LCx</td>
<td>1</td>
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</tr>
<tr>
<td>RCA</td>
<td>2</td>
<td>2</td>
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</tr>
<tr>
<td>SVG</td>
<td>3</td>
<td>3</td>
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</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>8 (100)</td>
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</table>

LAD, left anterior descending artery; LCx, left circumflex artery; RCA, right coronary artery; SVG, saphenous vein graft.
FIGURE 1. Angiogram of an excimer laser angioplasty of a diffuse lesion of proximal left anterior descending artery (arrow). Anteroposterior cranial views are shown before treatment (top panel) and after laser ablation (bottom panel). Three hundred sixty pulses of laser energy were delivered through a 1.6-mm laser catheter with an energy density of 43 mJ/mm². Adjunctive balloon angioplasty was not performed.
Balloon PTCA
Excimer Laser

Table 5 shows unsuccessful attempted favorable group. The nonideal subgroups. The nonideal group had a significantly greater baseline stenosis severity, smaller baseline stenotic diameter, and longer average length than the favorable group. The percent stenosis and stenotic diameter, however, did not differ significantly between groups after laser angioplasty and (when applicable) balloon angioplasty.

Excimer Laser Angioplasty After Failed Balloon PTCA

Six patients had excimer laser angioplasty after an unsuccessful attempted balloon PTCA. Reasons for PTCA failure were inability to cross the lesion with a balloon catheter (two patients), elastic recoil in an aorto-ostial stenosis (two patients), and severe dissection with an inadequate residual lumen (two patients). Excimer angioplasty was successful in four cases (67%). One failure occurred in a chronic total occlusion that could not be crossed with a guide wire; the other was in a lesion that had developed a severe dissection during a recent angioplasty attempt. This vessel developed an acute closure during laser angioplasty, and emergency CABG was required.

Effect of Other Angiographic Variables on Laser Success and Complications

Other angiographic variables previously shown to adversely affect acute success and complication rates of PTCA are calcification, eccentricity, presence of a bend point, and side branches originating from within a lesion. Eleven stenoses were moderately or heavily calcified on cinefluoroscopy; 10 (91%) were treated successfully with laser angioplasty. The 11th could not be crossed over its entire length with the laser catheter at 42 mJ/mm². Its

Quantitative Coronary Angiography

Figure 4 shows the frequency distribution of percent diameter stenosis and minimal stenotic diameter at baseline, after laser angioplasty, and at the end of the procedure with or without adjunctive PTCA in 98 of 100 patients. On average, laser angioplasty produced a significant decrease in percent diameter stenosis (p<0.05) and a significant (more than threefold) increase in minimal stenotic diameter (p<0.05). Adjunctive PTCA produced further involvement. Table 5 shows quantitative angiography parameters for the favorable and nonideal lesion subgroups. The nonideal group had a significantly greater baseline stenosis severity, smaller baseline stenotic diameter, and longer average length than the favorable group. The percent stenosis and stenotic diameter, however, did not differ significantly between groups after laser angioplasty and (when applicable) balloon angioplasty.

Figure 2. Bar graphs of laser and procedural success rates for lesions less than 10 mm, 10–20 mm, and more than 20 mm in length. Top panel: Results for all lesions (stenoses and total occlusions). Bottom panel: Results for nonoccluded lesions (stenoses only). p=NS between groups.
FIGURE 3. Angiogram of an excimer laser angioplasty of a discrete, aorto-ostial stenosis of a saphenous vein graft to an obtuse marginal (arrow). Right anterior oblique views are shown before treatment (top panel) and after laser ablation (bottom panel). Five hundred fifty pulses of laser energy were delivered through 1.6- and 2.0-mm catheters with an energy density of 35 mJ/mm². Adjunctive balloon angioplasty was not performed.
4. Plots showing frequency distributions of percent diameter stenosis (top panel) and minimal stenotic diameter (bottom panel) at baseline, after laser angioplasty, and at the end of the procedure with or without adjunctive percutaneous transluminal coronary angioplasty (n=98). ELCA, excimer laser coronary angioplasty.

American College of Cardiology/American Heart Association Classification of Lesions Treated

Of 105 lesions treated, 28% were ACC/AHA type A, 47% were type B, and 25% were type C. Acute laser success for each type was type A, 83%; type B, 88%; and type C, 85%. Procedural success for each type was type A, 97%; type B, 96%; and type C, 88% (Figure 5). Three acute closures occurred in type A lesions, three in type B lesions, and none in type C lesions. Major ischemic events (myocardial infarction, emergency CABG, or death) occurred with one type A lesion (3%), one type B lesion (2%), and no type C lesions (0%).

Discussion

Excimer laser angioplasty was successful in producing a reduction of at least 20% diameter stenosis in 84% of patients treated. This result is comparable to the 88% angiographic success rate obtained in the 1985–1986 NHLBI PTCA Registry, using the same definition of success. In patients undergoing laser angioplasty, acute closure occurred in 6%, nonfatal myocardial infarction in 1%, emergency CABG in 2%, and death in 0%. In the 1985–1986 NHLBI Registry, rates were 4.9% for acute closure, 4.3% for nonfatal myocardial infarction, 3.5% for emergency CABG, and 1.0% for mortality. Death, myocardial infarction, or emergency CABG occurred in 2% of patients in our study compared with 7.2% in the NHLBI Registry. The lower incidence of myocardial infarction and emergency CABG in our study, despite a similar acute closure rate, reflects successful reopening of acutely closed arteries in most cases with balloon angioplasty. The patient populations in these two studies, however, differ in several important aspects. Many of the patients in our study had restenotic lesions, which are generally easier to dilate than de novo stenoses. Conversely, a larger proportion of patients in our study had unfavorable lesion morphologies.

Our initial experience suggests that excimer laser coronary angioplasty is an effective acute therapy for lesions not ideal for PTCA, including tubular and diffuse lesions, calcified plaque, and ostial lesions. Excimer laser angioplasty was successful in 90% of long lesions (BARI tubular or diffuse), with proce-

| TABLE 5. Quantitative Coronary Angiography of Lesions Undergoing Excimer Laser Angioplasty in 98 Patients |
|----------------------------------|----------------|----------------|----------------|----------------|
| Stenosis (%)                     | Baseline       | After ELCA     | After PTCA     | Final          |
| Favorable lesions (6±6 mm)       | 80±13          | 52±18          | 44±10          | 44±14          |
| Nonideal lesions (15±11 mm)*     | 88±11†         | 54±19          | 41±19          | 46±20          |
| Stenotic diameter (mm)           |                |                |                |                |
| Favorable lesions                | 0.5±0.1        | 1.3±0.7        | 1.6±0.4        | 1.5±0.5        |
| Nonideal lesions                 | 0.3±0.3†       | 1.3±0.6        | 1.7±0.6        | 1.5±0.6        |

Values are mean±SEM.
ELCA, excimer laser coronary angioplasty; PTCA, percutaneous transluminal coronary angioplasty (balloon angioplasty).

*p<0.01, †p<0.05.
dural success obtained in 97% of cases (Figure 3). Lesion length has been shown to increase acute closure and restenosis rates after balloon angioplasty, but there are little published data on the effect of lesion length on acute procedural success rates. Our data suggest that in these lesions, excimer laser may be useful as either definitive therapy or to “debulk” a lesion before PTCA.

Recently, the ACC/AHA Task Force published guidelines for the performance of balloon PTCA.23 These guidelines included a system for classification of lesions and expected success rates. Lesions were divided into type A (expected success, 85% or more; low risk), type B (expected success, 60–85%; moderate risk), and type C (expected success, 60% or less; high risk). Ellis and coworkers30 recently reported acute procedural success and complication rates obtained during PTCA for multivessel coronary artery disease. Acute success was obtained in 92% of type A lesions, 81% of type B lesions, and 61% of type C lesions. Major ischemic complications (death, myocardial infarction, or emergency CABG) occurred in 2% of type A, 6% of type B, and 21% of type C lesions.

In the present study, 72% of lesions treated with excimer laser angioplasty were type B or C. Acute laser and procedural successes were obtained in 83% and 97% of type A lesions, 88% and 96% of type B lesions, and 85% and 88% of type C lesions, respectively. Major ischemic complications occurred in 3% of type A lesions, 2% of type B lesions, and 0% of type C lesions. Success and complication rates for type B and C lesions treated with laser angioplasty did not differ significantly from rates with type A lesions and exceeded ACC/AHA standards for expected outcomes.

The ACC/AHA classification system does not address the effect of multiple type B or C factors on success rates and risk. The effect of these risk factors is cumulative.7 Ellis et al30 compared their results with balloon angioplasty for type B lesions with one type B characteristic (B1 lesions) and with two or more type B characteristics (B2 lesions). Acute procedural success was obtained in 84% and 76% of type B1 and B2 lesions, respectively. Major ischemic complications occurred in 4% and 10% of type B1 and B2 lesions, respectively. In our study, acute laser and procedural successes were obtained in 86% and 93% of type B1 lesions and 85% and 100% of type B2 lesions, respectively. Major ischemic complications occurred in 3% of B1 lesions and 0% of B2 lesions. A recent report by the ACP/ACC/AHA Task Force on Clinical Privileges in Cardiology established diffuse disease as an absolute contraindication and presence of other type C characteristics as a relative contraindication for the performance of balloon angioplasty.31 Our data suggest that excimer laser angioplasty may be a useful therapy in type B and C lesions.

Of all lesion types undergoing balloon angioplasty, complete occlusions continue to have the lowest success rates because of difficulty crossing these lesions with a guide wire. As an over-the-wire system, the excimer laser catheters used in this study have the same limitation. Excimer laser may, however, be useful in treating longer occlusions. In this study, half of the total occlusions were 10 mm or longer in length. Although the laser and procedural success rates were lower in longer occlusions than in discrete occlusions, overall results with longer occlusions suggest a possible role for excimer laser in this situation.

Ostial stenoses are often difficult to dilate. High inflation pressure is often required, which increases the risk of intimal dissection.8 Aorto-ostial stenoses, in particular, are difficult to treat with balloon PTCA. These lesions can be heavily calcified with involvement of surrounding aortic tissue. Obtaining adequate guide catheter support to cross high-grade aorto-ostial stenoses with a balloon catheter is often difficult.8,32 Techniques that remove tissue, such as mechanical atherectomy or ablative laser, may be better suited to these lesions. The reported success rate with one type of atherectomy device in aorto-ostial lesions, however, has been less than 50%.33 In
this study, all eight ostial lesions, including five aorto-ostial, were treated successfully without adjunctive PTCA (Table 4). In this experience with aorto-ostial stenoses, guide catheter support was not critical: Most of these procedures were performed with the guide catheter disengaged from the ostium. We found that care must be taken to keep the tip of the laser catheter coaxial with the vessel. The one perforation in the 100-patient cohort occurred in an aorto-ostial lesion when the laser catheter entered the vessel at an angle while the guide catheter was disengaged from the ostium.

Six patients had prior unsuccessful attempted balloon PTCA. Laser angioplasty was successful in four of these cases. One laser failure occurred in a chronic occlusion that could not be crossed with a guide wire. In the other failure, a stenosis that had been severely dissected during a recent attempted PTCA was further complicated by laser angioplasty, resulting in acute closure of the vessel and emergency CABG. We now consider acute disruption of an artery secondary to recent balloon dilation to be a contraindication to excimer angioplasty.

In this study, 11 lesions had moderate or heavy calcification, and 10 (91%) were successfully treated. Our recent experience has shown that higher-than-usual energy densities (50–60 mJ/mm²) are often required to ablate calcified plaque.

We treated only eight highly eccentric lesions and two lesions on bends of more than 45°. In part, this reflects a selection bias away from these types of lesions to minimize the risk of perforation. All of these lesions were successfully treated without complications, which suggests that in selected cases, excimer laser may be useful for these types of lesions.

Side branch closure resulting from plaque displacement is a recognized complication of balloon PTCA.⁴ This complication has led to the development of dual-wire or balloon techniques to protect major side branches, which can add complexity and risk to an angioplasty procedure.⁴ In some instances, such as in diffusely diseased or occluded arteries, it may be impossible to protect side branches. In this series, 15 lesions in which one or more major side branches originated were treated by excimer laser angioplasty. No closures were observed.

Karsh and colleagues¹⁸ recently reported their initial experience with excimer laser angioplasty of coronary stenoses. By the criteria used in the present study, they reported a 70% laser success rate, an 88% procedural success rate, and an 18% acute closure rate. In addition to differences in the laser energy source and catheter configuration, the techniques used in the present study differed in several respects. In the Karsh et al study, the mean energy density used was 30 mJ/mm² and less than 35 mJ/mm² in 92% of procedures. During the laser procedure, the energy density decreased to 16 mJ/mm² and less than 15 mJ/mm² in at least 35% of procedures. In the present study, the minimum energy density was 35 mJ/mm² in all procedures. Energy density typically varied less than ±10% during the procedure. We believe that the lower acute laser success rate and higher complication rate in the Karsh et al study are largely results of the use of technology in which laser angioplasty was attempted with subthreshold energy densities.

Limitations of Study

Excimer laser coronary angioplasty is a new, investigational technique, and its appropriate applications remain to be determined. A major limitation of this study is its lack of randomization. Most of the patients in this study, including those with favorable balloon lesions, were referred for laser angioplasty because they were felt to be nonideal candidates for PTCA because of lesion morphology or location, failed prior PTCA, or multiple recurrences after PTCA. Patients selected to undergo this procedure were those in whom the operator thought there was a reasonable chance of procedural success based on previous experience with PTCA and excimer laser angioplasty. As a result, there is selection bias in the study. Another limitation is that we are presenting only data on acute efficacy and safety. Follow-up of this patient cohort is ongoing. Preliminary data from the larger multicenter trial, however, indicate a restenosis rate similar to that of PTCA (F. Litvack, J.R. Margolis; personal communication). Finally, even though the criteria for analyzing lesion morphology used in this report were originally developed for PTCA, there are little published data on PTCA success and/or complication rates for many of these lesion types. These limitations suggest that definitive comparison of excimer laser and PTCA in these lesion types will require a randomized trial. The proposed multicenter registry of new devices for coronary intervention should also play an important role in determining the relative benefits of these devices in unfavorable balloon angioplasty lesions.³⁵

Summary

Our initial experience with excimer laser angioplasty suggests that it can be used either as a stand-alone technique or as an adjunct to balloon angioplasty. Excimer angioplasty may be particularly well suited to long and diffuse disease, calcified lesions, ostial stenoses, lesions that involve major side branches, and stenoses that cannot be crossed or dilated with a balloon. We do not, however, presently perceive any advantage of excimer laser angioplasty over balloon angioplasty in the treatment of discrete coronary stenoses without complicating features.

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References


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S L Cook, N L Eigler, A Shefer, T Goldenberg, J S Forrester and F Litvack

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