Six-Month Clinical and Angiographic Outcome After Successful Excimer Laser Angioplasty for In-Stent Restenosis

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OBJECTIVES
This study evaluated the clinical and angiographic six-month follow-up after excimer laser coronary angioplasty (ELCA) for restenosed coronary stents.

BACKGROUND
Excimer laser coronary angioplasty has recently been shown to be safe and efficient for the treatment of in-stent restenosis.

METHODS
Ninety-six consecutive patients successfully treated with ELCA within 141 stents were included in a six-month clinical and angiographic follow-up.

RESULTS
During follow-up there was one sudden death and one patient with documented myocardial infarction. Angina pectoris classified as ≥ Canadian Cardiovascular Society II reoccurred in 49 patients. Follow-up angiography was obtained in 89 patients (93%) with 133 stents. Quantitative coronary angiography revealed a mean diameter stenosis of 77 ± 10% before intervention, 41 ± 12% after laser treatment and 11% ± 12% after adjunctive percutaneous transluminal coronary angioplasty (p < 0.001). Six months after ELCA the mean diameter stenosis had increased to 60 ± 26% (p < 0.001). A ≥50% diameter stenosis was present in 48 patients (54%); in 24 of these patients diameter stenosis was ≥70%. Total occlusions occurred in an additional 10 patients (11%). There was a trend toward an increased recurrent restenosis rate in patients with diabetes mellitus and long lesions or total occlusions (p = 0.059). Forty-eight patients (50%) received medical treatment after six months. Reinterventions were necessary in 30 patients (31%), and coronary artery bypass surgery was performed in 17 patients (18%). Event-free survival was 50%.

CONCLUSIONS
Excimer laser angioplasty for in-stent restenosis was associated with a high incidence of recurrent restenosis in this group of patients, suggesting that this technique is unlikely to reduce recurrent in-stent restenosis and that other approaches are necessary. (J Am Coll Cardiol 2000;36:69–74) © 2000 by the American College of Cardiology

With the increasing use of coronary stents and the more frequent implantation of stents into complex lesions, in-stent restenosis has become a challenging problem in interventional cardiology. The most frequently used technique to treat this new type of lesion is conventional balloon angioplasty (1). However, previous studies have reported angiographic restenosis rates up to 85% after repeat balloon angioplasty of in-stent restenosis (2–7). Since the development of recurrent restenosis may be related to a high residual plaque burden and tissue re-intrusion after repeat balloon angioplasty, alternative techniques suitable to debulk in-stent lesions have been evaluated (8). The first debulking technique used within stents was directional atherectomy; however, this method may cause stent wire cutting and subsequent vessel occlusions with fatal clinical outcomes in some patients (9–11). Rotational atherectomy appears to be safer, and the long-term results are currently under investigation (12–17). Excimer laser coronary angioplasty (ELCA) for the treatment of in-stent restenosis has been shown to be safe and efficient in large series of patients from different centers (18–20). However, the long-term outcome remained to be investigated. This study was designed to assess the clinical and angiographic six-month results after treatment of in-stent restenosis with laser followed by adjunctive balloon angioplasty.

METHODS
Patients. In this study 96 consecutive patients were prospectively included. Written informed consent was obtained from all patients under a protocol approved by the Ethics Committee of the Hamburg Medical Board. The study was carried out according to the principles of the Declaration of Helsinki. Patients were included if they presented with an in-stent restenosis or a wireable total occlusion within a stent that had been implanted for >1 month into a native vessel or a coronary artery vein graft. Patients with an evolving myocardial infarction, angiographic evidence of fresh thrombus or lesions in segments with major bifurcations or curves >60° on visual assessment were excluded.

The mean age of the 96 patients was 60 ± 10 years (range: 29–76 years); 81 patients were men. Major coronary risk factors were: diabetes mellitus (27 patients/28%) (non-insulin dependent: n = 20 (21%), insulin dependent: n = 7 [7%]), hyperlipoproteinemia (72 patients/75%), arterial hy-
pertension (63 patients/66%), current or recently stopped smoking (53 patients/55%) and a positive family history for coronary artery disease (37 patients/39%).

The patient group had a high prevalence of known risk factors for recurrent restenosis (21–27). A previous or current total occlusion was present in 23 patients (24%). The stents had been implanted for recurrent restenosis in 20 patients (21%). In 14 patients stents were located in venous bypass grafts (14%). Multiple stents (≥2 stents/vessel) had been implanted in 37 patients (39%). Stents were located in small vessels (≤3.00 mm in diameter) in 68 patients (71%).

**Vessels treated and stent types.** There were 25 patients with single-vessel coronary artery disease (26%), 34 patients with double-vessel disease (35%) and 37 patients with triple-vessel disease (39%). There were 82 native vessels treated. These vessels were 42 left anterior descending, 16 left circumflex and 24 right coronary arteries. Fourteen vein grafts were treated.

Excimer laser angioplasty was performed within 141 coronary stents (77 AVE stents [Applied Vascular Engineering, Santa Rosa, California], 46 Palmaz-Schatz stents [Johnson & Johnson, Warren, New Jersey], 6 NIR stents [Boston Scientific, Galway, Ireland], 3 beStent stents [Medtronic Instant, Herzlia, Israel], 3 Multilink stents [Guidant/Advanced Cardiovascular Systems, Temecula, California], 1 Wiktor stent [Medtronic, Minneapolis, Minnesota], 5 others).

The majority of stents was of modular design (n = 77); 63 were slotted tube stents, and one stent was of coil design. There were 37 patients with ≥2 stents/vessel. The stents had been implanted for 6 ± 3 months (range: 2–16 months) before the time of intervention.

**Excimer laser system and adjunctive balloon angioplasty.** A xenon chloride excimer laser unit operating at a wavelength of 308 nm (Spectranetics CVX-300, Colorado Springs, Colorado) was used in all patients. The laser unit delivered laser pulses of 135 ns pulse duration at a frequency (repetition rate) of 25 to 40 Hz and an energy density (fluence) of 30 to 60 mJ/mm². The laser energy was delivered through concentric (n = 40) or eccentric (n = 56) multifiber laser catheters (Vitesse CII or Vitesse EII; Spectranetics Corp., Colorado Springs, Colorado) with tips 1.4, 1.7 or 2.0 mm in diameter. Of the eccentric catheters, 38 were 1.7 mm, and 18 were 2.0 mm in diameter. Intracoronary saline infusion was initiated 3 s before delivery of laser energy and was continued during excimer laser treatment. Multiple passes, especially with the eccentric catheter, were performed at the operator’s discretion to achieve maximum debulking. Adjunctive balloon angioplasty was performed in all patients using standard techniques.

**Medical treatment before, during and after ELCA.** Pretreatment medication consisted of oral aspirin 100 mg/day (or 300 mg aspirin, if the patient was not on aspirin therapy before). A standard angioplasty regimen of heparin (10.000 IU intravenous bolus injection) and intracoronary nitroglycerin (100 µg to 200 µg) was given before angiography was performed. The permanent medical treatment after the intervention consisted of oral aspirin 100 mg/day.

**Quantitative coronary angiography.** All angiograms were evaluated by an independent blinded investigator on a Kontron Cardio 500 workstation for computerized quantitative coronary angiography with an automated contour detection (Kontron Electronics, Eching, Germany) and were adjusted by manual correction if necessary as described previously (19). Angiographic analysis of cinefilms was performed before laser treatment, after laser treatment, after adjunctive balloon angioplasty and at follow-up in the same projections. The coronary flow was classified according to the Thrombolysis in Myocardial Infarction (TIMI) trial classification (28).

**Clinical follow-up.** Clinical evaluation at six-month follow-up included the record of cardiac adverse events and clinical symptoms defined as: death (death for cardiac or any other cause), myocardial infarction (ST segment elevation ≥0.10 mV in ≥2 electrocardiographic leads plus creatine kinase elevation ≥2 times above normal value associated with >6% creatine kinase MB fraction or the development of new pathologic Q-waves in the electrocardiogram according to the Minnesota Code [29]). At this time the occurrence of angina pectoris, graded according to the classification of the Canadian Cardiovascular Society (CCS) (30), was registered.

**Statistical analysis.** All data are presented as mean ± standard deviation unless otherwise stated. Continuous variables were compared by the paired Student t test. The association between two quantitative variables was characterized by the correlation coefficient. The Fisher exact test was used to compare proportions. For simply ordered contingency tables, the Kruskal-Wallis test was used. A probability of <0.05 was considered to be statistically significant.

**RESULTS**

**Clinical follow-up.** The acute results limited to the in-hospital safety and feasibility of the technique from a subgroup were reported previously (19). It has been shown that angiographic success (diameter stenosis <50%) was achieved in all patients if the lesion could be crossed with a guidewire (19). Eleven percent of the patients had dissections (1% related to laser treatment, 10% to adjunctive percutaneous transluminal coronary angioplasty [PTCA]);
angioplasty further reduced diameter stenosis to 11.6% in vessels, (p < 0.001) (39.6 + 10%) and was reduced to 41.6 percentage diameter stenosis before intervention was 77.2.84

patients refused to undergo a control angiography because one patient died before repeat angiography; the other six repeat angiography was obtained in 89 of 96 patients (93%).

Quantitative coronary angiography. previously lasered target lesion.

There were 24 patients with a moderate degree of restenosis between 50% and 69% and 24 patients with a high grade of restenosis between 70% and 99%. In addition, there were 11 patients presenting with total occlusions. There was no Q wave infarction and no death (19).

During follow-up there was one patient with myocardial infarction leading to hospital admission (1%). One patient with history of current smoking died from sudden death at home approximately one week after the intervention (1%). The cause of death remained undefined since autopsy was not performed. A sudden cardiac death appears to be likely since the patient suffered from no other obvious disorders.

During follow-up 7 patients had angina pectoris graded as CCS class I (7%), 20 patients were graded as class II (21%), 21 patients as class III (22%) and 8 patients as class IV (8%). The overall rate of patients with recurrent angina was 58%.

Twenty-four patients had to undergo repeat cardiac catheterization for recurrent angina pectoris earlier as originally scheduled. In these patients angiography had to be performed 2.7 ± 0.9 months earlier. Twenty of these patients were treated interventionally at the site of the previously lasered target lesion.

Quantitative coronary angiography. Follow-up coronary repeat angiography was obtained in 89 of 96 patients (93%). One patient died before repeat angiography; the other six patients refused to undergo a control angiography because they were completely asymptomatic.

The mean reference diameter of the treated vessels was 2.84 ± 0.38 mm before intervention (n = 89 patients). The percentage diameter stenosis before intervention was 77 ± 10% and was reduced to 41 ± 12% by laser treatment (p < 0.001) (39 ± 11% in vessels <3.00 mm in diameter, 45 ± 9% in vessels ≥3.00 mm in diameter). Adjuvant balloon angioplasty further reduced diameter stenosis to 11 ± 12% (p < 0.001). At six-month follow-up the average diameter stenosis had increased to 60 ± 26% (p < 0.001) (Fig. 1).

The overall angiographic binary restenosis (≥50% diameter stenosis) rate was 65%.

There were 24 patients with a moderate degree of restenosis between 50% and 69% and 24 patients with a high grade of restenosis between 70% and 99%. In addition, there were 11 patients presenting with total occlusions. The average lesion length before intervention was 16 ± 9 mm (six total occlusions not included). At the time of repeat angiography, it was 17 ± 10 mm (10 total occlusions not included). Before intervention, the majority of patients had long lesions >10 mm. The incidence of recurrent restenosis in patients with long lesions tended to be higher than in patients with short lesions; however, this difference was not statistically significant (Table 1). In the group with total occlusions (n = 6), four patients had a recurrent restenosis, and two patients presented with a recurrent total occlusion.

<table>
<thead>
<tr>
<th>Lesion length</th>
<th>Patients Treated</th>
<th>Patients With Recurrent Restenosis</th>
<th>p Value</th>
</tr>
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<tbody>
<tr>
<td>≤10 mm</td>
<td>22</td>
<td>12 (55%)</td>
<td>0.34</td>
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<tr>
<td>&gt;10 mm</td>
<td>67</td>
<td>46 (69%)</td>
<td></td>
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<tr>
<td>Residual stenosis after laser</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>&lt;30%</td>
<td>9</td>
<td>4 (44%)</td>
<td>0.17</td>
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<tr>
<td>≥30%</td>
<td>80</td>
<td>54 (68%)</td>
<td></td>
</tr>
<tr>
<td>Diameter of laser catheter</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1.4 mm</td>
<td>2</td>
<td>2 (100%)</td>
<td></td>
</tr>
<tr>
<td>1.7 mm</td>
<td>46</td>
<td>27 (59%)</td>
<td>0.45</td>
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<tr>
<td>2.0 mm</td>
<td>41</td>
<td>28 (68%)</td>
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<tr>
<td>Concentric</td>
<td>39</td>
<td>26 (67%)</td>
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<td>Eccentric</td>
<td>50</td>
<td>31 (62%)</td>
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<td>Catheter/vessel ratio</td>
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<td>0.45–0.69</td>
<td>67</td>
<td>43 (64%)</td>
<td>0.92</td>
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<tr>
<td>0.70–0.95</td>
<td>22</td>
<td>15 (68%)</td>
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<td>Stent location</td>
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<tr>
<td>Vein graft</td>
<td>13</td>
<td>8 (62%)</td>
<td>0.92</td>
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<tr>
<td>Native vessel</td>
<td>76</td>
<td>51 (67%)</td>
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<td>Vessel diameter</td>
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<td></td>
<td></td>
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<tr>
<td>&lt;3.00 mm</td>
<td>63</td>
<td>39 (62%)</td>
<td>0.45</td>
</tr>
<tr>
<td>≥3.00 mm</td>
<td>26</td>
<td>19 (73%)</td>
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<td>Final minimal lumen diameter after balloon angioplasty</td>
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<tr>
<td>≤2.50 mm</td>
<td>38</td>
<td>29 (76%)</td>
<td></td>
</tr>
<tr>
<td>&gt;2.50–3.00 mm</td>
<td>40</td>
<td>22 (55%)</td>
<td>0.10*</td>
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<tr>
<td>&gt;3.00 mm</td>
<td>11</td>
<td>6 (55%)</td>
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<tr>
<td>Stent number/vessel</td>
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<tr>
<td>≥2 stents</td>
<td>38</td>
<td>23 (61%)</td>
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<tr>
<td>single</td>
<td>51</td>
<td>34 (67%)</td>
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<td></td>
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<tr>
<td>Yes</td>
<td>21</td>
<td>13 (62%)</td>
<td>0.99</td>
</tr>
<tr>
<td>No</td>
<td>68</td>
<td>43 (63%)</td>
<td></td>
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</tbody>
</table>

*p ≤ 0.05 vs. >2.50–3.00 mm: 76% vs. 55%, p = 0.045.
Patients with a low degree of residual diameter stenosis after the laser ablation (<30%) had no significantly different rate of binary restenosis compared with patients with a higher degree of residual stenosis (Table 1). However, in this small subgroup of patients, there was a tendency towards a lower restenosis rate if the residual diameter stenosis after laser debulking was lower than 30%. Aggressive debulking with a large gain of minimal lumen diameter (MLD) after laser treatment correlated positively with a large lumen diameter gain after adjunctive PTCA ($r = 0.815$; $p < 0.001$). A large MLD after final PTCA correlated positively with a large MLD at six-month follow-up ($r = 0.347$, $p < 0.001$) and correlated inversely with the degree of diameter restenosis ($r = -0.229$, $p = 0.031$).

Treatment with larger laser catheters resulted in a larger post-laser MLD (1.4 mm: 1.14 ± 0.30 mm; 1.7 mm: 1.59 ± 0.21 mm; 2.0 mm: 1.88 ± 0.17 mm; $p < 0.01$) and lower diameter stenosis (1.4 mm: 61 ± 13%; 1.7 mm: 42 ± 9%; 2.0 mm: 39 ± 13%; $p < 0.04$). However, treatment with laser catheters of different diameters was not followed by a significant difference in recurrent restenosis rates (Table 1). If the eccentricity of types of laser catheters were used, there was a tendency towards a lower recurrent restenosis rate; however, the difference was not statistically significant (Table 1). A high catheter to vessel ratio (≥0.7) had no beneficial effect on restenosis rates (Table 1).

The mean number of passes with the laser catheter was 5 ± 3. More passes with the laser catheter did not significantly increase the MLD ($≤4$ passes: 1.73 ± 0.23 mm; 5–8 passes: 1.73 ± 0.28 mm; $>8$ passes: 1.72 ± 0.18 mm: $p > 0.83$) or further decrease the diameter stenosis. There was no difference in recurrent restenosis rates after different numbers of passes ($≤4$ vs. 5–8 vs. $≥9$) with the laser catheters ($p > 0.05$). This result was observed after the use of concentric catheters and after the use of eccentric catheters. The mean energy density (fluence) used as 46 ± 4 mJ/mm². The mean balloon pressure was 11 ± 4 atm.

The prevalence of recurrent restenosis in the subgroup of patients with stents located in bypass vein grafts was not significantly different from that in patients with stents located in native vessels (Table 1).

Patients with small vessel diameters (<3 mm) and those in a small group with large vessel diameters ($≥3$ mm) had no significantly different restenosis rates (Table 1).

The restenosis rate of patients with multiple stents was not significantly different from that of patients with single stent implantation (Table 1).

The group with a history of previous or current total occlusion had a recurrent restenosis rate comparable with that in the group without a history of total occlusion (Table 1).

Patients with risk factors for coronary artery disease such as hyperlipoproteinemia, arterial hypertension, smoking, positive family history or diabetes mellitus had no significantly increased restenosis rates compared with groups without the respective factors ($p ≥ 0.05$ for each factor) (Table 2). Patients with diabetes mellitus who presented with long lesions tended to have high recurrent restenosis rate (lesion ≤ 10 mm, 7 patients: 43% restenosis rate; lesion 11–20 mm, 14 patients: 71% restenosis; lesion >20 mm, 5 patients: 100% restenosis, $p = 0.059$).

The coronary flow before intervention was classified as TIMI 0 in 6 patients (6%) with total occlusions, TIMI 1 in 4 patients (4%), TIMI 2 in 10 patients (11%) and TIMI 3 in 76 patients (79%). At the time of control angiography, TIMI flow was graded as 0 in 10 patients (11%), TIMI 1 in 3 patients (3%), TIMI 2 in 4 patients (5%) and TIMI 3 in 72 patients (81%).

**Treatment after six-month follow-up.** At six-month follow-up half of the patients received medical treatment ($n = 48$); the other patients required reinterventions. Seventeen patients were treated by coronary artery bypass surgery (18%). Recurrent balloon angioplasty was performed in 11 patients (11%), recurrent ELCA was done in 6 patients (6%), and rotational atherectomy was performed in 13 patients (14%). The choice of the technique at the time of follow-up was left to the operator.

The event-free survival rate without coronary reintervention in the whole study group was 50%.

**DISCUSSION**

There is an increasing need to evaluate techniques other than balloon angioplasty to treat in-stent restenosis. Excimer laser angioplasty has recently been shown to be safe and efficient for the treatment of this type of lesion (18–20). It has been demonstrated that laser angioplasty achieves excellent acute angiographic results (18–20). The long-term results of the technique remained to be analyzed. This report describes a large series of patients treated with ELCA for in-stent restenosis who were followed-up clinically and angiographically.
Clinical results. This study showed only limited clinical long-term success since more than half of the patients had recurrent symptoms of angina pectoris during the follow-up period. This necessitated earlier angiographic controls as scheduled in 25% of the patients, followed by a considerable number of target vessel revascularizations. The incidence of myocardial infarctions and deaths was low and comparable with the rate after plain balloon angioplasty within the stent (2–7).

Angiographic results. The angiographic results were unsatisfactory. There was a significant lumen late loss at the six-month follow-up angiographic control, which led to an average diameter stenosis of 60% corresponding to a binary restenosis rate of 65%. The recurrent restenosis rate appeared to be higher in long compared with short lesions, particularly in diabetic patients, and was extremely high in the small group of patients who were treated for total occlusions within a stent. The high incidence of recurrent restenosis in patients presenting with an in-stent occlusion is in good agreement with data from a recently published report that showed a need for target vessel revascularization in 83% of patients with total in-stent occlusions, regardless of the device used (25).

The angiographic restenosis rate was high, but there was a relatively large subgroup of 24 patients with moderate grade restenosis with a diameter stenosis between 50 and 69%. These patients had, in fact, an angiographic restenosis by the binary definition; however, this restenosis has neither been hemodynamically relevant nor did it necessarily require reintervention in most patients.

The incidence of restenosis in small vessels below 3 mm in diameter appeared similar to that in larger vessels with diameters above 3 mm. Previous studies have suggested that the restenosis rate after treatment of in-stent restenosis tends to be higher in smaller vessels (21,23). With respect to these previous findings, the result in this study seems to be surprising but may be explained by random distribution or by the fact that in smaller vessels a larger proportion of plaque mass might have been ablated.

The high rate of restenosis may partially be explained by the cautious approach to ablation in this study. Most aggressive debulking in a subgroup of patients with low residual stenosis after laser treatment (<30%) was associated with a lower restenosis rate than seen in patients with a higher degree of residual stenosis after laser treatment. However, the finding in this small group did not reach statistical significance and needs to be evaluated in a larger series. Due to the cautious use of laser angioplasty and the use of relatively small catheters in this study, the mean diameter stenosis after debulking was as high as 41%. This degree of diameter stenosis may also reflect a lack of efficacy of excimer laser treatment, which has been suggested by previous studies and may be related to a limited ability of the technique to ablate tissue (31,32).

The patients of this study group had multiple risk factors for the development of restenosis such as previous total occlusions, multiple stenting or stent location in bypass grafts (21,22,24). Although a significant impact on the recurrence of restenosis could not be documented for any of these single factors, the high total incidence of multiple risk factors in this group might have negatively influenced the outcome of these patients and may contribute to an underestimation of the value of the technique.

The rate of restenosis in this group is high; however, it appears to be comparable with recent results with other debulking techniques such as rotational atherectomy with restenosis rates up to 78% in diffuse lesions (15,33) if the risk profile in this group is taken into account. The results of this study do not appear to be favorable compared with the results from recently evaluated alternative methods such as stenting for in-stent restenosis with a restenosis rate between 46% and 72% (34,35).

Study limitations. This study was not randomized, and there was no comparison with conventional balloon angioplasty. Six patients refused repeat angiography; however, all of these six patients were asymptomatic and, therefore, likely to have either a low degree of restenosis or no restenosis at all. Therefore, the exclusion of these 6% of the patients, who had a favorable outcome, might have negatively influenced our analysis of the restenosis rate.

Although, to our knowledge, this is the largest series of patients lasered in stents with systematic angiographic follow-up yet, the number of patients in this study was still relatively low. This is particularly important for the subgroup analyses, in which various trends have been detected, which may become significant in larger series. Therefore, larger studies have to be performed to confirm these findings.

Conclusions, clinical implications and future prospects. In summary, the clinical and angiographic long-term outcome of patients in this group with an exceptional high risk of restenosis is not satisfactory yet. Since there was no convincing evidence that patients with aggressive laser treatment had an improved long-term outcome, the value of the laser as a debulking tool remains questionable. However, it appears to be too early to make a final assessment regarding the value of this technique since there may be benefits by its use in subsets of lesions.

Some reports about conventional balloon angioplasty and debulking techniques revealed lower restenosis rates than achieved in our group; others showed higher restenosis rates (2–7,25). Different results were obtained after PTCA of “discrete” and “diffuse” in-stent restenoses with better long-term outcome after treatment of “discrete” lesions (2–7,25). However, there is a considerable variation in the published results and in the angiographic follow-up rates. To analyze whether PTCA alone or ELCA is associated with a lower recurrent restenosis rate, it is necessary to compare the outcome after use of both techniques in a randomized trial, particularly with respect to lesion length and morphology. However, the data of this study suggest the limitation of a randomized trial to patients without diffuse lesions and
74 Köster et al.
Six-Month Results of Laser Angioplasty for In-Stent Restenosis