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Acute Complications of Excimer Laser Coronary Angioplasty: A Detailed Analysis of Multicenter Results

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Objectives. **The aim of this study was to document and analyze the incidence and consequences of complications of excimer laser coronary angioplasty.**

Background. **Excimer laser coronary angioplasty has been reported to be a safe and feasible alternative or adjunct to conventional balloon angioplasty, but serious and unique complications have been observed.**

Methods. **Data on 1,595 interventions of excimer laser coronary angioplasty in 1,521 patients were analyzed, using a merged data base from the U.S. and European Percutaneous Excimer Laser Coronary Angioplasty (PELCA) registries.**

Results. **Procedural success was achieved in 89.3% of interventions. Stand-alone laser angioplasty was performed in 17.8% of interventions. Complications included dissection (22.0%), vasospasm (6.1%), filling defects (4.8%), abrupt reclosure (6.1%), embolization (2.3%), perforation (2.4%), arrhythmia (0.7%) and aneurysm formation (0.3%). Major complications were non-Q wave myocardial infarction (2.3%), Q wave myocardial infarction (1.0%), coronary artery bypass grafting (3.1%) and death (0.7%). Logistic regression analysis revealed correlation between dissections and the use of larger catheter size (p = 0.0005), high energy per pulse levels (p = 0.0001 for native vessels), lesion length >10 mm (p = 0.001) and presence of a side branch (p = 0.01). The incidence of perforations was higher in women (p = 0.004), in treatment of total occlusions (p = 0.02) and in the presence of a side branch (p = 0.03). Fatal complications were correlated with patients with multivessel disease (p < 0.0001), patients with acute myocardial infarction (p = 0.0009) and older patients (>70 years old, p = 0.004). The incidence of major complications decreased after performance of 50 laser angioplasty procedures at one institution (p = 0.02).**

Conclusions. **This analysis defines both the learning curve and the profile of complications for excimer laser angioplasty and provides insight into the selection of appropriate patients and proper performance of the procedure.**

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When excimer laser irradiation is used in the setting of percutaneous transluminal coronary angioplasty, the major advantage of this technique is thought to be ablation of the atherosclerotic plaque, with only minimal thermal and mechanical injury to the adjacent vessel wall structures (1,2). As opposed to the mandatory fissuring and cracking of the plaque and overdistension of the arterial wall using conventional coronary angioplasty (3–5), the new method thus might have the theoretic potential of reducing complications and probably as a result of reduced injury of decreasing the incidence of restenosis (6).

The feasibility and relative safety of excimer laser coronary angioplasty were demonstrated in early clinical trials in a limited number of patients (7–9), and refinements in laser catheter technology resulted in improvement of acute interventional success, comparable to the results of conventional coronary angioplasty (10–12). However, the rate of successful stand-alone procedures was limited by suboptimal reduction of stenosis severity in larger diameter vessels, necessitating additional balloon dilation in most cases (11,12). Furthermore, preliminary results did not show a reduction in the incidence of restenosis (7,12,13).

Recent experimental studies suggest major side effects of excimer laser irradiation. Acoustic damage and rapid vapor bubble expansion are likely to alter adjacent tissue signifi-

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cantly (14–16). In addition to the debate about indications for excimer laser angioplasty (11,12,17–19), ongoing studies of the undesirable effects of laser irradiation (20–22) might elucidate the mechanisms of clinically significant complications.

The primary aim of this analysis was to document the incidence and consequences of acute complications after excimer laser angioplasty using the currently available technology. An attempt was made to identify associations between morphologic and interventional variables and the incidence of complications that might have clinical implications for patient selection and performance of the procedure. Furthermore, the data for clinical results and complications were analyzed according to the number of procedures performed per clinical site to identify the learning curve of excimer laser angioplasty.

Methods

Patient enrollment. Analysis of complications was performed using a single data base after merging the data sets of the European and the U.S. Percutaneous Excimer Laser Coronary Angioplasty (PELCA) registries. Both registries were designed to evaluate the immediate and long-term success and complications of coronary excimer laser angioplasty. The individual local ethical committees gave approval for the participation in the excimer laser angioplasty trial. All patients were candidates for coronary angioplasty by clinical and angiographic findings, and all patients signed informed consent for the laser procedure. The selection of patients for laser angioplasty was based on the preference and experience of the individual investigator. Patient selection criteria did not change throughout the course of the study. The laser procedure was performed as previously described (7,9,12). Additional interventions were determined by the operator's discretion. After the procedure the patients were monitored according to local practice.

Data base. The data collection forms were completed by the participating investigators and then mailed to the data collection centers, where they were reviewed for completeness, accuracy and consistency. The European PELCA registry contributed data on 247 patients treated at nine clinical sites between September 1990 and July 1992 (see Appendix). The number of patients per center varied from 2 to 123. Quantitative analysis of the intervention angiograms was performed at a central core laboratory (Deutsches Herzzentrum Berlin). The data collection forms and intervention angiogram results were sent to the University of Tübingen and entered into a data base for statistical analysis using the SAS program (SAS 6.04, SAS Inc.). The U.S. PELCA registry contributed the data sets of 1,274 patients treated at 30 clinical sites (see Appendix) between May 1989 and December 1991. The number of patients per site varied from 1 to 142. The intervention angiogram was analyzed by the investigators at the individual sites, and the results were included in the data collection form. The data collection forms were sent to Spectranetics Inc. and entered into a data base for statistical analysis by SAS (SAS 6.04).

In addition to the original data of both data sets, a new variable was created to obtain information about the "learning curve" of the procedure. All interventions were numbered chronologically for each investigational site. In the final analysis three groups were classified: 1) the first 20 interventions at one site, 2) interventions 21 to 50, and 3) all interventions after 50 excimer laser angioplasties at the individual hospital. The definitions of morphologic, procedural and outcome variables used have been described elsewhere (23,24).

The data bases were merged, and a total of 97 variables were accumulated. The analysis was performed at the University of Tübingen.

Laser system. All interventions were performed with a xenon-chloride excimer laser system (CVX 300, Spectranetics), as previously described (12,23,24).

Statistical analysis. Statistical analysis was performed in cooperation with the Institute for Medical Information Processing, University of Tübingen. All tests were carried out with the SAS software Version 6.04.

A stepwise model-building strategy was applied (25). To determine the association of patient-, lesion- and laser-specific factors with each complication, all variables (Table 1) were examined by univariate analysis (chi-square test or Fisher exact test). In a second step, all variables showing a univariate association with the complication were entered in a backward logistic regression analysis for each individual complication. Additionally, variables that were probably correlated to the complication according to theoretic considerations or clinical experience were entered into the model. This second step was performed separately for patient, lesion and interventional variables.

In the third step, all variables that showed a multivariate association with the complication were entered into a model of stepwise logistic regression for each complication. This final model was optimized according to the test of concordance. Thus, the final model showed the variables with independent influence on the incidence of the complication.

Observations with missing data for the specific analysis were treated as "missing values" according to the SAS software algorithms; a p value < 0.05 was considered statistically significant. Data are presented as mean value $\pm$ SD.

Results

Patient population. The data base contained data on 1,595 interventions of excimer laser angioplasty performed in 1,521 patients (mean age 60 ± 12 years). The baseline characteristics are presented in Table 2, showing the incidence of the variable in the available data sets. Symptoms of angina pectoris were classified according to the Canadian Cardiovascular Society functional score (26). Data on the number of diseased vessels were available for 854 patients only, of whom 396 (46%) had multivessel disease. Multives-

Table 1. Variables Used in the Analysis of Complications

Patient variables
CCS class
Unstable angina pectoris
Acute MI
Multivessel disease
Diabetes
Hypercholesterolemia
Smoking
Gender
Age
Target vessel variables
AHA/ACC lesion class
Target vessel
Location
Discrete
Segmental
Eccentric
Calcified
Ulcerated
Occlusion
Bend
Tortuosity
Side branch
Bifurcation
Lesion length
Percent stenosis
Vessel diameter
Interventional variables
Maximal catheter size
Maximal repetition rate
Maximal fluence
Multiple passes

AHA/ACC = American Heart Association/American College of Cardiology; CCS = Canadian Cardiovascular Society functional score; MI = myocardial infarction.

Table 2. Baseline Characteristics

Male/female (%)	76/24
Mean age (range) (yr)	60 ± 12 (28 to 90)
Symptoms (%)	
Asymptomatic	3.6
CCS class	
1	5.1
2	16.8
3	34.9
4	35.9
Unstable angina	50
Acute MI	1
Clinical history (%)	
Previous MI	47
Smoking	44
Diabetes	20
Hypercholesterolemia	51
Target vessel (%)	
LAD	40.9
Diagonal branch	1.3
LCx	8.7
OMCA	2.8
RCA	24.3
Protected LMCA	1.1
Saphenous vein graft	20.9
Lesion location (%)	
Ostial	7.7
Proximal	46.7
Mid-third	36.9
Distal third	8.7
Vessel bend	36.1
Tortuosity	9.8
Side branch	7.3
Bifurcation	9.3
Lesion morphology (%)	
Single discrete	62.2
Eccentric	50.2
Total occlusion	13.3
Segmental	23.8
Calcified	17.2
Ulcerated	7.6
AHA/ACC classification type (%)	
A	11.5
B1	25.8
B2	29.7
C	32.9

Data presented are percent of patients. CA = coronary artery; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery, LMCA = left main coronary artery; OMCA = obtuse marginal coronary artery; RCA = right coronary artery; other abbreviations as in Table 1.

sel disease was considered present if there was significant stenosis (>50%) in at least two major coronary arteries.

Procedural outcome. Laser success was achieved in 81.1% of all interventions. Procedural success was reported for 89.3% of the interventions. Stand-alone laser angioplasty was performed in 285 interventions (17.8%). Additional procedures performed to resolve complications were coronary angioplasty in 158 cases (9.9%), atherectomy in 1 (0.1%), thrombolysis in 14 (0.9%), bypass operation in 49 (3.1%), intracoronary stenting in 3 (0.2%) and other procedures in 22 (1%).

Overall incidence of complications. The incidence of complications is shown in Table 3. Reclosure was followed by at least one major complication in 38 patients (39.2%) (myocardial infarction in 20.6%, coronary artery bypass grafting in 20.6%, death in 4.1%). Severe (flow-limiting) dissections were followed by major complications in 29 patients (45.3%) (myocardial infarction in 20.3%, coronary artery bypass grafting in 28.1%, no death). Embolization led to myocardial infarction in 16 patients (44.4%). No coronary artery bypass grafting and no death were reported. Perforation was followed by major complications in 15 patients (39.5%) (myocardial infarction in 7.9%, coronary artery bypass grafting in 34.2%, death in 2.6%).

Analysis of energy per pulse. The incidence of minor and severe dissections and perforations of the vessel wall were analyzed according to the maximal energy per pulse used in the procedure. Energy per pulse was calculated from the fluence (mJ/mm^2) and the area of the fibers at the catheter tip. The mean energy per pulse was 21 ± 7 mJ in 340 interventions with dissections and 20 ± 8 mJ in 1,132

Table 3. Incidence of Complications in 1,521 Patients and 1,595 Interventions: Absolute Incidence and Percent of All Interventions

	Overall Incidence		Incidence of Laser-Related Complications	
Complication	No.	%	No.	%
Dissection	351	22.0	230	14.4
Severe dissection	64	4.0		
Vasospasm	97	6.1	78	4.9
Filling defects	76	4.8	61	3.8
Reclosure	97	6.1	75	4.7
Embolization	36	2.3	23	1.4
Perforation	38	2.4	33	2.1
Aneurysm formation	5	0.3	5	0.3
Arrhythmia*	11	0.7	8	0.5
Non-Q wave MI	36	2.3		
Q wave MI	16	1.0		
CABG	49	3.1		
Death	11	0.7		

*Includes three patients with sinus bradycardia after balloon angioplasty, two with atrial fibrillation and six with periprocedural ventricular tachycardia or ventricular fibrillation. CABG = coronary artery bypass grafting; MI = myocardial infarction.

interventions without dissections (p = 0.03). No significant differences were found for severe dissections and perforations. A second analysis was performed for interventions in native target vessels, excluding saphenous vein grafts. Mean energy per pulse was 21 ± 7 mJ in 307 interventions with dissections and 19 ± 7 mJ in 854 interventions without dissections (p = 0.0001). Laser-related dissections were associated with a mean energy per pulse of 20 ± 7 mJ in contrast to 19 ± 8 mJ for interventions without laser-related dissections (p = 0.03). No significant differences in mean energy per pulse were found for severe dissections and perforations.

Multivariate analysis. The results of the multivariate analysis are presented in Table 4. The first three columns show the results of the separate analysis for patient, lesion and intervention variables together with the results of the final analysis, showing the variables with an association to a higher incidence of the specific complication in the last column. Dissections were seen more frequently in women (risk ratio [RR] 1.5, confidence interval [CI] 1.1 to 1.8, p = 0.03), with the use of catheters >1.4 mm (RR 1.7, CI 1.3 to 2.2, p = 0.01), in the absence of diabetes (RR 1.9, CI 1.5 to 2.3, p = 0.004) and at vessel branch points (RR 2.3, CI 1.8 to 2.8, p = 0.0005). The risk of laser-related perforations was higher in women (RR 2.4, CI 1.7 to 3.1, p = 0.015), at vessel branch points (RR 2.4, CI 1.5 to 3.3, p = 0.05) and in the treatment of total occlusions (RR 3.1, CI 2.3 to 3.8, p = 0.004). Filling defects were correlated to the treatment of ulcerated lesions (RR 3.2, CI 2.5 to 3.8, p = 0.0006). Embolizations were more frequent in the treatment of saphenous vein grafts (RR 11.9, CI 10.9 to 12.9, p = 0.0001) and ulcerated lesions (RR 4.0, CI 3.1 to 5.0, p = 0.003).

A multivariate analysis of the coincidence of complications showed a correlation of abrupt reclosure with the observation of dissections (p = 0.001), vasospasm (p = 0.001) and filling defects (p = 0.001).

Learning curve. The rate of interventions classified as laser success increased from 77% in the first 20 interventions per clinical site to 81% in interventions 21 to 50 and 86% after 50 interventions (chi-square test, p = 0.001). Procedural success increased from 86% to 90% and 92%, respectively (chi-square test, p = 0.004).

Figure 1 shows the incidence of minor complications (occurrence of at least one minor complication, not including severe dissections and perforations), severe dissections, perforations and major complications (infarction, coronary artery bypass grafting, death) in the three groups of the learning curve analysis. There was no significant difference in the occurrence of minor complications and perforations. Severe dissections were more frequent in the first 20 interventions per site (p = 0.03). The incidence of major complications decreased from 8.5% in the first 20 interventions per site to 5.5% in interventions 21 to 50 and 4.5% in the subsequent interventions (p = 0.02). The respective incidences of the individual major complications in the three chronologic patient groups were as follows: myocardial infarction occurred in 5%, 1.9% and 2.3%; coronary artery bypass grafting was necessary in 3.6%, 3.7% and 1.9%; and fatal complications were reported in 0.9%, 0.5% and 0.6%.

Discussion

The results presented in this study demonstrate the pattern of complications of excimer laser angioplasty. The data suggest that specific lesion morphology as well as the operating variables of the laser systems have to be taken into account for patient selection, indication and performance of laser angioplasty to reduce the risk of the intervention.

The baseline variables in our patient population indicate that excimer laser angioplasty was used in a broad spectrum of target lesions and clinical situations. The trend toward treatment of complex lesion morphology not ideal for balloon angioplasty (27) reflects the ongoing discussions about clinical indications for the use of new devices (11,12,23,28). Furthermore, the study documents a shift to the percutaneous treatment of older patients and patients with more severe disease. Consequently, direct comparison of the complication rates presented here with those reported in historic study populations with coronary angioplasty (27,29–33) is not possible.

Complications. Dissection was the most frequently observed overall and laser-related complication. Because of the mechanism of the procedure, dissection is an almost inevitable consequence of balloon dilation (4,5,34), although angiography reveals dissections after coronary angioplasty in only 14% to 32% of patients (35,36). This rate is comparable to that found in our study. Initial expectations based on the different mechanism of stenosis reduction by excimer

Table 4. Multivariate Analysis of Complications: Variables With Significant Correlation to the Complication

	Patient		Target Vessel		Intervention		Final Model				
Complication	Variable	p Value	Variable	p Value	Variable	p Value	Variable	p Value	Beta Coeff	RR	CI
							n = 1,204				
Dissection	No Diabetes	0.031	Side branch	0.048	Cath >1.4 mm	0.0008	Side branch	0.01	0.6	2.0	1.4–2.5
	No Hyperchol	0.035	Length ≥10 mm	0.007	Energy ≥50 mJ/mm²	0.015	Length ≥10 mm	0.001	0.5	1.6	1.4–2.0
	Acute MI	0.005*					Cath >1.4 mm	0.0005	0.8	2.3	1.9–2.8
							Energy ≥50 mJ/mm²	0.016	0.4	1.5	1.2–1.9
							n = 1,424				
Severe dissection	Age	0.0002	—		Cath >1.4 mm	0.02	Age	0.0002	0.03	0.97	0.95–0.98
	Female	0.0017			Multiple passes	0.011	Female	0.002	0.9	2.5	1.9–3.0
	No diabetes	0.025					No diabetes	0.02	1.1	3.0	2.1–4.0
	Pts 1–20	0.017					Pts 1–20	0.03	0.6	1.8	1.3–2.4
							Cath >1.4 mm	0.03	1.1	3.0	1.9–4.0
							n = 1,311				
Vasospasm	Smoking	0.003	Stenosis ≤90%	0.02	—		Smoking	0.002	0.7	2.1	1.6–2.5
	No diabetes	0.018					No diabetes	0.036	0.8	2.2	1.5–3.0
							Stenosis ≤90%	0.05	0.5	1.6	1.1–2.1
							n = 1,264				
Filling defects	—		Ulcerated lesion	0.0006	Energy ≥50 mJ/mm²	0.034	Ulcerated lesion	0.0006	1.1	3.1	2.4–3.7
			No bend	0.029			No bend	0.028	0.6	1.9	1.3–2.4
Abrupt closure	—		—		—		—				
							n = 1,504				
Embolization	Male	0.05	Graft	0.019	Cath 2.0 mm	0.0035	Male	0.029	1.3	3.8	2.6–5.0
	Pts 1–20	0.05					Graft	0.0001	1.8	6.6	5.8–7.3
							Cath 2.0 mm	0.042	0.8	2.1	1.4–2.8
							n = 1,504				
Perforation	Female	0.01	Occlusion	0.02	—		Female	0.004	1.0	2.6	2.0–3.3
	Multi-VD	0.02	Side branch	0.05			Occlusion	0.016	0.9	2.5	1.7–3.2
							Side branch	0.03	0.9	2.5	1.7–3.4
							n = 1,487				
Non-Q wave infarction	—		Side branch	0.001	Energy <50 mJ/mm²	0.014*	Side branch	0.01	1.2	3.2	2.3–4.1
			Stenosis ≤90%	0.011			Stenosis ≤90%	0.003	1.4	3.9	3.0–4.8
							n = 1,525				
Q wave infarction	Acute MI	0.022	Graft	0.01	Energy <50 mJ/mm²	0.043	Pts 1–20	0.004	3.0	20	18–22.1
	Pts 1–20	0.005					Acute MI	0.05	2.1	8.0	5.8–10.2
							Graft	0.03	1.1	3.1	2.1–4.1
							n = 1,550				
All infarctions	Multi-VD	0.025	Side branch	0.0006	Energy <50 mJ/mm²	0.004*	Pts 1–20	0.0005	1.0	2.8	2.2–3.4
	Pts 1–20	0.011	Stenosis ≤90%	0.03			Side branch	0.0008	1.3	3.7	3.0–4.5
							Stenosis ≤90%	0.0016	1.1	3.0	2.3–3.7
							n = 1,251				
CABG	Female	0.025	Length <10 mm	0.011	—		Female	0.038	0.7	2.0	1.4–2.6
			Diameter <3 mm	0.031			V diameter <3 mm	0.03	0.7	2.1	1.4–2.7
							LAD	0.05	0.6	1.9	1.2–2.5
							n = 868				
Death	Age ≥70 yr	0.012	—		—		Age >70 yr	0.004	2.1	8.5	7.0–10
	Acute MI	0.001					Multi-VD	< 0.0001	28.0	2×10^{12}	
	Multi-VD	< 0.0001					Acute MI	0.0009	3.4	31.0	28–33

*Concordance of the model <50%. Cath = maximal catheter size used; CI = confidence interval; Coeff = coefficient; Hyperchol = hypercholesterolemia; MI = myocardial infarction; Pts = patients; RR = risk ratio; V = vessel; VD = vessel disease; other abbreviations as in Table 1.

laser irradiation suggested a reduced vessel injury. However, our findings indicate that experimental observations of expanding vapor bubbles (15,20) and pressure waves resulting in barotrauma of the vessel wall layers (14,16) may indeed be important in the clinical setting. In the multivariate analysis, the incidence of dissections was associated with

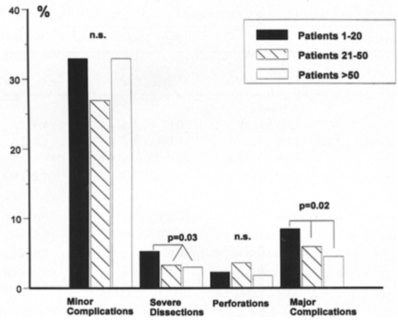

Figure 1. Incidence of complications with growing operator experience.

the use of catheters with a diameter >1.4 mm and a fluence ≥50 mJ/mm^2. Additional analysis showed an association of higher energy per pulse levels with an increased incidence of dissections, especially in native coronary arteries. These findings are consistent with the results of other studies (37). However, the results might also reflect a subset of lesions where a second pass with higher energy densities was required after an initially failed laser approach. The information in the data set does not allow further analysis of this potentially confounding factor. The influence of arterial wall morphology on the occurrence of dissections is substantiated by the finding that severe dissections were more frequently observed in younger patients, women and patients without diabetes.

The overall incidence of vasospasm was low and is comparable to conventional coronary angioplasty. Differences in the reported incidence of vasospasm after laser angioplasty are probably the result of different procedural protocols. If additional balloon angioplasty is performed immediately after laser ablation, the interpretation of complications is restricted to the combined procedure. This limitation accounts not only for the observation of vasospasm but for the total scope of laser-related complications. Protocols that allow additional procedures like coronary angioplasty only after a period of 20 to 30 min detect higher incidences of complications as a direct consequence of laser irradiation and laser-induced injury (7,13).

The mechanism of thrombus formation after laser irradiation is largely unknown and may include laser-independent consequences of deep vessel wall injury (38,39) and laser-specific processes. In the current clinical experience, the finding of intraluminal filling defects was rare but was frequently associated with vessel reclosure. Therefore, sufficient anticoagulant and antiaggregant treatment is mandatory in excimer laser angioplasty.

Abrupt vessel closure at the intervention site complicating the course of angioplasty is a common phenomenon in conventional balloon dilation (35,40–42), with an incidence of 4.6% to 6.8% (35,40). In this report, vessel closure after laser angioplasty was seen in 6.1%, and in 4.7% the operators classified the vessel closure as laser related. There was no baseline variable associated with abrupt vessel reclosure. However, filling defects, vasospasm and dissections were associated with vessel closure in the multivariate analysis, which corresponds to the mechanisms of vessel closure after conventional coronary angioplasty (41–44).

Distal embolization was associated with myocardial infarction in 16 (44%) of 36 patients. Embolization was more frequently observed in the treatment of saphenous vein grafts. The incidence of distal embolization has also been found to be increased in target lesions containing thrombus (22). These data suggest that embolization of plaque material is bound to target lesion morphology, not to laser irradiation. The passage of the laser catheter is associated with shear stress at the outer surface. Thus, embolization might occur in lesions susceptible to detachment of material. Advancement of the catheter tip into the lesion without efficient ablation might increase the risk of mechanical alteration of the plaque because tissue ablation is dependent on contact of the laser probe with the target, the etch rate of laser ablation is low (1,45), and the steerability of the catheters is limited (7,12). As a consequence, the approach to friable lesions, especially in saphenous vein grafts, should be cautious, and advancement of the catheter should be strictly limited to the experimentally defined etch rates.

Perforation was associated with a major clinical event in 15 patients and led to emergency operation in 13. Baseline variables with an independent correlation to a higher incidence of this complication were female gender, treatment of total occlusions and lesions at a vessel branch point. This is consistent with a recently published study on the first 764 patients of the U.S. PELCA registry (23), which found a higher overall incidence of complications correlated with the treatment of lesions at an arterial bifurcation. Analysis of the individual complications was not performed in this study. The higher incidence of perforations in occlusions and branch points may be due to an increased risk of laser irradiation in the deeper vessel wall layers because the potential for misalignment is higher under these conditions. Although acoustic side effects (14) and vapor bubble expansion (15) in the deeper wall layers remain to be investigated, tissue disruption is likely to occur. Thus, whether extravasation of contrast media after laser irradiation represents an oblique direct channel or a complex dissection with scattering of medial and adventitial tissue remains open to question. However, what is important is that balloon angioplasty can resolve the extravasation in many cases (13,46,47), probably by simply compressing the vessel wall. A recently published study (48) shows a relation between the catheter/vessel diameter ratio and perforations and suggests a safety margin of 1 mm between catheter size and vessel diameter. Therefore, attempts to reduce the risk of perforation should include 1) careful target lesion selection, 2) a cautious approach to total occlusions and lesions at vessel branch points, 3) choice of laser catheter size in relation to vessel diameter, and 4) restriction of laser irradiation to situations with coaxial catheter alignment.

The incidence of major complications was low and is comparable to that of conventional coronary angioplasty (29,35,49,50). In the small number of patients treated for acute myocardial infarction in the European PELCA registry, the incidence of Q wave infarction was increased, which is concordant with the experience in the treatment of acute ischemic episodes with balloon dilation (43). Excluding these patients treated for acute myocardial infarction from the analysis results in an incidence of Q wave infarction of 0.9% and a reduction of incidence of fatal complications to 0.6%. Fatal complications were associated with patients who had a high risk for percutaneous interventions. No target lesion and no interventional variables were associated with a higher incidence of fatal complications. These findings suggest that fatal outcome is more related to the individual clinical situation than to the laser angioplasty procedure. However, unless there is evidence for benefit of laser angioplasty compared with conventional balloon angioplasty for specific target lesions, patients at high risk should be excluded from excimer laser angioplasty trials.

Learning curve. As previously reported (35,49,51,52), our data suggest a learning curve for excimer laser angioplasty. Whereas there was no change in the incidence of minor complications, a significant reduction in major complications with growing operator experience was observed. This reduction is predominantly due to a decrease in the incidence of myocardial infarction and coronary artery bypass grafting. The low incidence of fatal complications does not allow further interpretation. The success rates showed a significant increase after performance of 20 and 50 excimer laser angioplasty procedures per institution. Thus, probably as a result of a variation in patient selection and operator skill, the clinical results of excimer laser angioplasty improved with growing operator experience.

Study limitations. The study population was heterogenous in terms of patient and lesion selection as well as interventional strategies. The data are the combined results of two registries. However, although detailed analysis of failure and procedural success revealed differences for specific target lesions, there was no substantial difference in the overall results and complication rates of both registries (23,24). This was not a randomized trial, and the data presented are purely observational. In addition, because of the nature of multicenter trials, the report of complications is based on the interpretation of different investigators. However, the analysis represents the results of excimer laser angioplasty performed in multiple centers in Europe and the United States. The analysis of the influence of multivessel disease is limited by the late inclusion of this variable in the U.S. registry, leaving missing values in 44% of patients. A major drawback of both registries is the almost routine use of additional balloon angioplasty after laser irradiation. Because of this procedural strategy, identification of the acute and subacute consequences of stand-alone laser angioplasty on the angiographic appearance of the target vessel was not possible.

Summary. This study documented the relative safety of excimer laser coronary angioplasty in selected patients and a learning curve resulting in increasing success rates and reduction of major complications with growing operator experience. Risk groups for individual complications were identified in this analysis that have direct implications for patient selection and interventional technique. The influence of catheter size and energy per pulse on the incidence of dissections was documented, suggesting clinical relevance of acoustic side effects and vapor bubble formation after laser irradiation of tissue and blood. Fatal complications were more frequent in patients at high risk for percutaneous interventions, including patients with acute ischemic syndromes.

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Appendix

Percutaneous Excimer Laser Coronary Angioplasty Registry (PELCA) Participating Centers and Principal Investigators

U.S. PELCA Registry

Alabama Heart Institute, Birmingham, Alabama, E. Cohen; *Brigham and Women's Hospital, Boston, Massachusetts,* J. Bittl; *Charleston Area Medical Center, Charleston, West Virginia,* S. Warren; *Duke University Medical Center, Durham, North Carolina,* J. Tcheng; *Emory-Crawford Long Hospital, Atlanta, Georgia,* D. Morris; *George Washington University Medical Center, Washington, D.C.,* J. Segal; *Gundersen Clinic, LaCrosse, Wisconsin,* R. Green; *Humana Hospital, Phoenix, Arizona,* R. Siegel; *Johns Hopkins University, Baltimore, Maryland,* J. Brinker; *Memorial Hospital, Colorado Springs, Colorado,* C. Kucinski, R. Blonder; *Methodist Hospital, Lubbock, Texas,* P. Walter, P. Overlie; *Mount Sinai Medical Center, Miami, Florida,* P. Swaye, P. Vignola; *New England Deaconess Hospital, Boston, Massachusetts,* G. Abela; *New York Hospital, New York, New York,* T. Sanborn; *Northwestern Memorial Hospital, Chicago, Illinois,* C. Tomasso; *Penrose-St. Francis, Colorado Springs, Colorado,* J. Kleiner, R. Moothart; *Sacred Heart General Hospital, Eugene, Oregon,* F. Keene, P. Bergin; *Scott and White Clinic, Temple, Texas,* L. Watson; *St. Anthony's Hospital, Rockford, Illinois,* D. Yardley; *St. Elizabeth's Hospital, Boston, Massachusetts,* J. Isner, K. Rosenfield; *St. Francis Hospital, Memphis, Tennessee,* B. Harris; *St. Francis Medical Center, Pittsburgh, Pennsylvania,* J. Power; *Southeast Missouri Hospital, Cape Girardeau, Missouri,* C.R. Talbert, M. Canedo; *Tampa General Hospital, Tampa, Florida,* S. Chokshi, J. Chapman; *University of California, San Diego, California,* M. Buchbinder; *University of California, Irvine, California,* J. Tobis; *University Hospital, Denver, Colorado,* R. Ginsburg; *University of Iowa, Iowa City, Iowa,* M. Winniford; *University of Minnesota, Minneapolis, Minnesota,* S. Zimmer, R. Wilson; *University of Michigan, Ann Arbor, Michigan,* S. Ellis.

European PELCA Registry

Belgium: *Middleheim Hospital, Antwerpen,* v.d. Heuvel.

Germany: *Deutsches Herzzentrum, Berlin,* E. Fleck; *Rotes-Kreuz-*

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Krankenhaus, Frankfurt, N. Reifart; *Medizinische Universitätsklinik Homburg*, C. Özbek; *Medizinische Universitätsklinik Köln*, H.W. Höpp; *Medizinische Universitätsklinik Tübingen*, K.R. Karsch.

Italy: *Ospedale PDGIF, Faenza*, A. Maresta.

France: *Hopital H Mondor, Créteil*, H. Geschwind; *Clairval, Marseille*, H. Escojido.

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