

## THREE-YEAR FOLLOW-UP AFTER IMPLANTATION OF METALLIC CORONARY-ARTERY STENTS

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**Abstract** *Background.* Coronary-artery stents are known to reduce rates of restenosis after coronary angioplasty, but it is uncertain how long this benefit is maintained.

*Methods.* We evaluated clinical and angiographic follow-up information for up to three years after the implantation of Palmaz-Schatz metallic coronary-artery stents in 143 patients with 147 lesions of native coronary arteries.

*Results.* The rate of survival free of myocardial infarction, bypass surgery, and repeated coronary angioplasty for stented lesions was 74.6 percent at three years. After 14 months, revascularization of the stented lesion was necessary in only three patients (2.1 percent). In contrast, coronary angioplasty for a new lesion was required in 11 patients (7.7 percent). Follow-up coronary angiography of 137 lesions at six months, 114 lesions at one year, and 72 lesions at three years revealed

a decrease in minimal luminal diameter from  $2.54 \pm 0.44$  mm immediately after stent implantation to  $1.87 \pm 0.56$  mm at six months, but no further decrease in diameter at one year (in patients with paired angiograms,  $1.95 \pm 0.49$  mm at both six months and one year). Significant late improvement in luminal diameter was observed at three years (in patients with paired angiograms,  $1.94 \pm 0.48$  mm at six months and  $2.09 \pm 0.48$  mm at three years;  $P < 0.001$ ).

*Conclusions.* Clinical and angiographic outcomes up to three years after coronary-artery stenting were favorable, with a low rate of revascularization of the stented lesions. Late improvement in luminal diameter appears to occur between six months and three years. (N Engl J Med 1996;334:561-6.)

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SINCE the initial report by Sigwart et al.<sup>1</sup> of the placement of metallic stents in coronary arteries, coronary-artery stenting has been shown to optimize the geometry of the coronary lumen after balloon angioplasty,<sup>2,3</sup> reducing procedural complications<sup>4,5</sup> and late restenosis.<sup>6-8</sup> Two recent randomized trials (the Stent Restenosis Study [STRESS]<sup>9</sup> and the Benestent study<sup>10</sup>) comparing stenting with standard balloon angioplasty in primary focal lesions clearly demonstrated the efficacy of the Palmaz-Schatz stent in reducing the rate of angiographically detected restenosis. In the Benestent trial, there was both angiographic and clinical benefit, as reflected by a reduction in major clinical end points, especially repeated coronary angioplasty. Colombo et al.<sup>11,12</sup> revolutionized the technique of stent implantation by demonstrating that high-pressure balloon dilatation at the end of the procedure, with confirmation by intravascular ultrasonography of adequate stent expansion and full coverage of the lesion, was associated with a low rate of stent thrombosis without anticoagulant therapy.

Despite these promising observations, one of the uncertainties of coronary stenting concerns the long-term outcome after the permanent placement of metallic prosthetic devices.<sup>13</sup> To address this issue, we evaluated clinical data as well as serial quantitative angiographic information six months, one year, and three years after the placement of single Palmaz-Schatz stents in native coronary arteries.

### METHODS

#### Study Patients

From June 1990 through January 1992, 160 consecutive patients underwent the implantation of a Palmaz-Schatz stent. One patient

had multiple stents, 16 patients had saphenous-vein grafts as their target lesions, and 143 patients underwent the implantation of single Palmaz-Schatz stents in 147 native coronary lesions. All the patients gave informed consent for the procedure and the follow-up treatment, which was approved by the institutional review board.

#### Stent Placement and Anticoagulant Therapy

All stents were implanted with a commercially available stent-delivery system (Johnson & Johnson) by standard techniques.<sup>6</sup> The mean ( $\pm$ SD) size of the expanded balloon was  $3.48 \pm 0.39$  mm for vessels  $3.12 \pm 0.61$  mm in diameter. The final inflation pressure was  $9.7 \pm 2.1$  atmospheres. Procedural success was defined as the successful deployment of the stent, resulting in stenosis of less than 50 percent as measured by quantitative coronary angiography. Clinical success was defined as procedural success with no major in-hospital complications, such as death, myocardial infarction, or the need for bypass surgery. The conventional regimen of anticoagulant therapy included aspirin, dipyridamole, dextran, heparin, and warfarin and has been described in detail elsewhere.<sup>8</sup>

#### Clinical Follow-up

Clinical follow-up data were obtained by either a review of the hospital records or telephone contact with the patients or their referring physicians. The major clinical events studied were death, myocardial infarction, bypass surgery, revascularization of the target lesion, and coronary angioplasty of nonstented lesions. Death was defined to include death from any cause. Myocardial infarction was defined as an increase in serum creatine kinase activity to more than twice the normal value, in association with new, pathologic Q waves. In the event of "bailout" stenting when there was abrupt closure of the lumen, an elevation in creatine kinase was not considered to constitute a stent-related myocardial infarction if the procedure resulted in the restoration of grade 3 flow according to the criteria of the Thrombolysis in Myocardial Infarction trial.<sup>14</sup> Bypass surgery was defined as any surgical revascularization, even if the stented segment was patent. Revascularization of the target lesion was defined as either bypass surgery or balloon angioplasty involving the stented segments. Clinical follow-up events were studied according to the intention-to-treat principle. In-hospital events were included in the analysis of follow-up events. Repeated balloon angioplasty for subacute stent thrombosis was considered to constitute revascularization of the target lesion.

#### Angiographic Follow-up

According to the study protocol, follow-up angiography was to be performed six months, one year, and three years after the procedure.

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Although many patients in the study cohort actually underwent multiple angiographic procedures within the first six months after follow-up,<sup>8</sup> angiograms obtained less than three months after the procedure were regarded as having been obtained at six months if they revealed restenosis requiring revascularization of the target lesion; similarly, angiography performed between four and nine months after stent implantation was included among the studies done at six months. Although repeated coronary angioplasty performed to treat subacute stent thrombosis was considered revascularization of the target lesion in the analysis of clinical follow-up data, subacute stent thrombosis was not considered to constitute angiographic restenosis, because the underlying mechanisms seemed to be different. Therefore, lesions that underwent successful revascularization for subacute stent thrombosis were considered to be eligible for subsequent angiographic follow-up. The 1-year follow-up studies were defined as those performed between 10 and 18 months, and the 3-year follow-up studies as those performed after 27 months.

Quantitative angiographic analysis was performed with the commercially available Cardiovascular Angiography Analysis System II.<sup>15</sup> The view showing the most stenosis after stent implantation but with no substantial overlapping of the study vessel with other branches and no foreshortening was selected from among multiple projections. Quantitative analysis of the control and follow-up angiograms was performed in nearly identical views, with an intracoronary injection of 2.5 to 5 mg of isosorbide dinitrate administered before each study. Catheters that did not contain contrast medium were used for calibration whenever possible. Proximal and distal reference points were defined by the operator before the intervention, and the length of the lesion, minimal luminal diameter, reference diameter (as derived by interpolation), and percentage of stenosis between those points were calculated by the computer. In the post-intervention and follow-up studies, the same reference points were selected by the operator, and the minimal luminal diameter between the two points was determined by the computer even when the most severe narrowing was outside the stent. Restenosis was defined as stenosis of 50 percent or more observed at follow-up.

To assess intraobserver variability and the reproducibility of the quantitative angiographic analysis, 30 randomly selected pairs of follow-up angiograms obtained at six months and three years were analyzed, with the observer kept unaware of when the angiogram had been obtained. The variations in the readings of minimal luminal diameter were  $0.002 \pm 0.11$  mm for the six-month studies and  $0.003 \pm 0.11$  mm for the three-year studies; the correlation coefficients for repeated measurements were 0.98 at six months and 0.98 at three years ( $P < 0.001$  for both).

### Statistical Analysis

Values are expressed as means  $\pm$ SD. Categorical variables were compared by the chi-square test. Paired numerical data obtained by serial angiography were compared by the paired t-test, and other continuous variables by the unpaired t-test. Linear regression analysis was used to assess the reproducibility of quantitative angiography and predictors of long-term increase in luminal diameter. Rates of event-free survival were studied with Kaplan-Meier analysis.<sup>16</sup> All tests of significance were two-tailed, and P values of less than 0.05 were considered to indicate statistical significance.

## RESULTS

### In-Hospital Outcome

The base-line characteristics of the patients and the coronary lesions are shown in Table 1. Among the 143 patients (with 147 coronary lesions), 139 patients (97.2 percent) and 143 lesions (97.3 percent) underwent successful stent implantation. There was clinical success in 133 patients (93.0 percent). The major complications included death in three patients (2.1 percent), myocardial infarctions with Q waves in seven (4.9 percent), and non-Q-wave myocardial infarctions in three patients

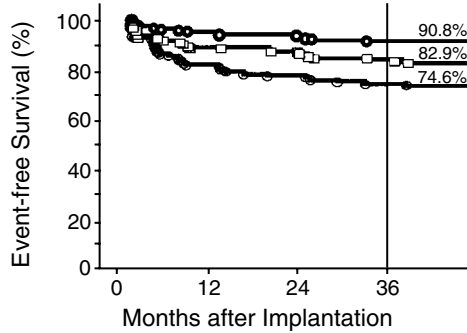
Table 1. Base-Line Characteristics of the Patients and Lesions.

CHARACTERISTIC	VALUE
<b>Patients</b>	
No.	143
Mean ( $\pm$ SD) age — yr	62.6 $\pm$ 9.8
Sex — M/F	112/31
Extent of coronary artery disease — no. (%)	
Single-vessel disease	67 (47)
Multivessel disease	65 (45)
Prior bypass surgery	11 (8)
Prior myocardial infarction — no. (%)	78 (55)
Left ventricular ejection fraction <40% — no. (%)	19 (13)
Class III or IV angina — no. (%)	70 (49)
Diabetes mellitus — no. (%)	33 (23)
Multilesion balloon angioplasty — no. (%)	37 (26)
<b>Lesions</b>	
No.	147
Artery affected — no. (%)	
Left anterior descending coronary	67 (46)
Right coronary	54 (37)
Circumflex coronary	16 (11)
Left main coronary	10 (7)
Restenosis — no. (%)	67 (46)
Calcification — no. (%)	46 (31)
Ulceration — no. (%)	48 (33)
Ostial stenosis — no. (%)	17 (12)
Circumstances of stent placement — no. (%)	
Planned	105 (71)
Unplanned	42 (29)
Suboptimal	22 (15)
To treat abrupt closure	20 (14)

(2.1 percent). Emergency bypass surgery was not needed to treat any patient. Bleeding complications requiring either surgery or blood transfusion were observed in four patients (2.8 percent). Six patients (4.2 percent) had subacute thrombosis of the stent between three and seven days after stent implantation; five of these patients underwent successful revascularization and were discharged with patent stents. Therefore, including those 5 patients, 136 patients (with 140 lesions) who survived to discharge with patent stents were eligible for the six-month angiographic follow-up.

### Clinical Follow-up

The cumulative survival rates were 93.7 percent one year after implantation of the stent, 92.2 percent after two years, and 90.8 percent after three years (Fig. 1). Besides the three patients who died in the hospital, six additional patients died during the first 14 months (Table 2). One patient who had previously had bypass surgery and in whom bailout stenting for the circumflex coronary artery was unsuccessful died of cardiogenic shock due to occlusion of the venous graft to the left anterior descending coronary artery. One patient died of congestive heart failure that was presumably related to restenosis of the stented lesion. Two patients died suddenly, although angiography at six months confirmed that they did not have restenosis. Two other patients died from noncardiac causes (meningitis and an accident). Four additional patients died after 14 months from definite noncardiac causes (renal fail-



EVENT AND NO. AT RISK				
Death (●)	143	132	128	117
Death, myocardial infarction, or bypass (■)	143	124	118	107
Above events or target-lesion revascularization (○)	143	113	106	97

Figure 1. Kaplan–Meier Curves for Event-free Survival in the Study Patients.

The number of patients at risk for each event or combination of events is shown below the graph for each time point. The percentages in the figure are the event-free survival rates at three years (indicated by the vertical line).

ure in one, subarachnoid hemorrhage in one, and cancer in two).

The rates of survival free of myocardial infarction, bypass surgery, and revascularization of the target lesion were 80.4 percent at one year, 76.8 percent at two years, and 74.6 percent at three years (Fig. 1). Revascularization of the target lesion was performed in 24 patients (16.8 percent). However, when repeated coronary angioplasty related to subacute stent thrombosis was not counted, the rate of revascularization of the target lesion at three years was only 12.6 percent. Revascularization of the target lesion was performed in only three patients (2.1 percent) after 14 months. Two revascularization procedures were related to asymptomatic restenosis at 15 and 37 months, after the 1-year and 3-year angiography, respectively. The other case of revascularization of the target lesion was related to symptomatic restenosis at 27 months. Thus, there was only one case (0.7 percent) in which revascularization of a target lesion was performed because of clinical symptoms after 14 months. In contrast, coronary angioplasty was required for a new lesion in 11 patients (7.7 percent) after 14 months.

**Outcome of Angiographic Follow-up**

Among 136 patients and 140 lesions eligible for the six-month angiographic follow-up, 133 patients and 137 lesions (98 percent) underwent angiography at six months, a mean of 184±34 days after stent implantation. Subsequently, 5 patients died

and 13 patients had revascularization of their target lesions within 12 months, leaving 122 lesions in 118 patients eligible for subsequent angiographic follow-up. One-year angiography was performed in 114 lesions (110 patients, or 93 percent) 375±32 days after implantation, and three-year angiography was performed in 72 lesions (68 patients, or 59 percent) after a mean period of 1071±103 days.

The specific reasons for the failure of patients to undergo angiography after three years were refusal by either the patient or the referring physician (in 36 asymptomatic patients), death (in 3), repeated angioplasty after the one-year angiography (in 3), concomitant medical problems (in 2), and loss to follow-up (in 3). In three other patients, angiography demonstrating the absence of restenosis was actually performed at three years, but the cine films were not available for study. In an effort to compensate for the incomplete three-year data, the characteristics of patients and lesions were compared between the group that had angiography at three years and the group that did not (Table 3). Both base-line characteristics and quantitative angiographic variables at six months of follow-up were similar between these two groups.

The results of immediate and long-term quantitative angiography are shown in Table 4. Minimal luminal diameter was increased from 1.05±0.37 mm to 2.54±0.44 mm immediately after stent implantation, but by six months it had decreased to 1.87±0.56 mm. Angiographic restenosis was documented in 25 lesions (18.2 percent).

In 114 lesions for which there were paired angiograms obtained at six months and one year, there was no further decrease in minimal luminal diameter during the period from six months to one year (diameter at both study times, 1.95±0.49 mm; P=0.73) (Fig. 2A). In 72 lesions for which sequential studies were completed for up to three years, there was significant improvement in minimal luminal diameter at three years (diameter at six months, 1.94±0.48 mm; at three years, 2.09±0.48 mm; P<0.001) (Fig. 3). Among seven patients who had angiographic restenosis at six months, only one still had more than 50 percent stenosis at three years. A case of marked luminal improvement

Table 2. Frequency of Events Studied during Clinical Follow-up.

EVENT	FOLLOW-UP PERIOD				CUMULATIVE FOLLOW-UP
	14 DAYS OR LESS	15 DAYS TO 8 MONTHS	9 TO 14 MONTHS	15 TO 38 MONTHS	
	no. of patients (%)				
Death	3 (2.1)	5 (3.5)	1 (0.7)	4 (2.8)	13 (9.1)
Myocardial infarction	7 (4.9)	0	0	1 (0.7)	8 (5.6)
Coronary-artery bypass grafting	0	4 (2.8)	0	1 (0.7)	5 (3.5)
Target-lesion revascularization	6 (4.2)	12 (8.4)	3 (2.1)	3 (2.1)	24 (16.8)
Coronary angioplasty					
New lesion	0	5 (3.5)	2 (1.4)	11 (7.7)	18 (12.6)
Restenosis of nonstented lesion	0	10 (7.0)	3 (2.1)	0	13 (9.1)

three years after stent implantation is shown in Figure 4. Only two lesions (2.8 percent) were observed to have substantial luminal renarrowing after six months (Fig. 2B).

Late increases in luminal diameter between six months and three years were significantly correlated with early decreases in luminal diameter during the time from immediately after the procedure to the six-month follow-up ( $r=0.34$ ,  $P=0.004$ ). The index for later increase in diameter, defined as the increase in luminal diameter during the period from six months to three years after stent implantation divided by the decrease in diameter from immediately after the procedure to the six-month follow-up, was  $0.27 \pm 1.27$ . Later increases in luminal diameter at three years were also negatively correlated with minimal luminal diameter at six months ( $r=0.4$ ,  $P<0.001$ ).

The formation of an aneurysm was noted on angiography at six months in one patient; at the three-year follow-up, the aneurysm had nearly the same appearance. No other potentially deleterious vascular effects were observed during the three years of follow-up.

## DISCUSSION

This study was designed to evaluate the long-term safety and efficacy of the placement of metallic stents in

Table 3. Comparison of Patients and Lesions Studied Angiographically at Three Years with Those Not So Studied.

CHARACTERISTIC	ANGIOGRAPHIC STUDIES AT 3 YR*		P VALUE
	YES	NO	
<b>Patients</b>			
No.	68	50	—
Age — yr	61.4±8.7	63.9±9	0.15
Sex — M/F	54/14	38/12	0.66
Multivessel disease — no. (%)	37 (54)	23 (46)	0.51
Prior myocardial infarction — no. (%)	38 (56)	25 (50)	0.53
Left ventricular ejection fraction <40% — no. (%)	8 (12)	5 (10)	0.76
Class III or IV angina — no. (%)	33 (49)	22 (44)	0.63
Diabetes mellitus — no. (%)	14 (21)	11 (22)	0.76
<b>Lesions</b>			
No.	72	50	—
Artery affected — no. (%)			0.36
Left anterior descending coronary	33 (46)	24 (48)	
Right coronary	30 (42)	19 (38)	
Circumflex coronary	8 (11)	3 (6)	
Left main coronary	1 (1)	4 (8)	
Restenosis — no. (%)	31 (43)	25 (50)	0.45
Circumstances of stent placement — no. (%)			
Planned	52 (72)	37 (74)	0.83
Unplanned	20 (28)	13 (26)	
Minimal luminal diameter at 6 mo — mm	1.94±0.48	2.0±0.5	0.58
Percent stenosis at 6 mo	35.3±11.1	34.8±13.1	0.81

\*Plus-minus values are means ±SD.

Table 4. Immediate and Long-Term Results of Quantitative Angiography.\*

VARIABLE	TIME ANGIOGRAPHY PERFORMED				
	BEFORE PROCEDURE	AFTER PROCEDURE	6 MO	1 YR	3 YR
<b>Lesions studied at 6 mo (n = 137)</b>					
Length (mm)	8.02±3.56	—	—	—	—
Reference diameter (mm)	3.12±0.61	3.41±0.51	3.04±0.55	—	—
Minimal luminal diameter (mm)	1.05±0.37	2.54±0.44	1.87±0.56	—	—
Percent stenosis	65.5±12.3	25.3±9.3	38.1±15.1	—	—
Restenosis rate (%)	—	—	18.2	—	—
<b>Lesions studied at 1 yr (n = 114)</b>					
Reference diameter (mm)	3.14±0.61	3.42±0.52	3.03±0.56	3.03±0.56	—
Minimal luminal diameter (mm)	1.05±0.38	2.57±0.44	1.95±0.49	1.95±0.49	—
Percent stenosis	65.7±12.7	24.7±8.7	35.4±12.2	35.6±11.6	—
<b>Lesions studied at 3 yr (n = 72)</b>					
Reference diameter (mm)	3.14±0.58	3.39±0.56	3.02±0.57	3.00±0.54	3.05±0.56
Minimal luminal diameter (mm)	1.00±0.40	2.55±0.46	1.94±0.48	1.95±0.46	2.09±0.48
Percent stenosis	67.6±12.3	24.6±7.8	35.3±11.1	34.8±10.5	30.9±11.2

\*Plus-minus values are means ±SD.

coronary arteries. Quantitative angiographic outcome at three years was analyzed, as well as clinical outcome, to establish late patency of the stent and confirm the absence of deleterious angiographic findings related to stent implantation.

In this study, the patients' rate of survival free of myocardial infarction, bypass surgery, and revascularization of the target lesion was 80.4 percent at one year, a figure similar to the values of 80.5 percent in the stent group studied in the STRESS<sup>9</sup> trial at eight months and 79.9 percent in the corresponding group in the Benestent<sup>10</sup> trial at seven months; apparently, this was a higher rate than has been attained with other interventional devices. Detre et al.<sup>17</sup> reported an event-free survival rate of 66 percent one year after standard balloon angioplasty; in the Coronary Angioplasty versus Excisional Atherectomy Trial,<sup>18</sup> this rate was 66.1 percent one year after balloon angioplasty and 63.5 percent after directional coronary atherectomy. The favorable clinical outcome noted at one year in the present study remained at three years (74.6 percent event-free survival). Schömig et al. reported a similarly slow decline in event-free survival during the period from one to two years after Palmaz-Schatz coronary stenting.<sup>5</sup> The low rate of events beyond one year associated with coronary stenting compared well with that reported for balloon coronary angioplasty.<sup>17,19</sup> In accordance with the favorable long-term clinical outcome, serial quantitative coronary angiography performed for up to three years demonstrated no further decline in minimal luminal diameter during the period six months after coronary stenting, a finding similar to those of previous studies with follow-up periods of up to one year.<sup>20,21</sup> The length of this period free of restenosis compared well with those we observed with balloon coronary angioplasty.<sup>22</sup> Thus, it is unlikely that coronary stenting simply delayed clinical restenosis instead of preventing it. Although we noticed the formation of an aneurysm in one patient, we did not observe any

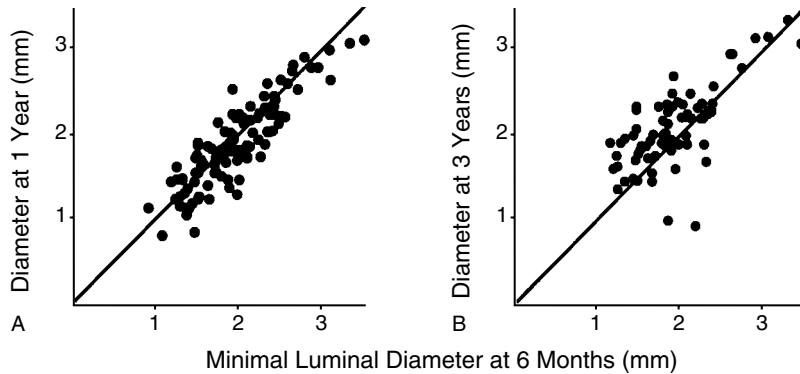


Figure 2. Minimal Luminal Diameters of the Study Vessels Six Months after Stent Implantation, as Compared with the Diameters Measured at One Year (Panel A) and Three Years (Panel B).

At the one-year follow-up, the values for all the lesions, including those that later underwent revascularization, were clustered along the line of identity, indicating little change from the six-month values. The mean ( $\pm$ SD) change in minimal luminal diameter during this period was a decrease of  $0.002 \pm 0.24$  mm. Mean minimal luminal diameter at three years was increased by  $0.15 \pm 0.36$  mm from the diameter measured at six months. Only two lesions decreased substantially in minimal luminal diameter during this interval.

other potentially deleterious angiographic findings suggestive of late migration of stents, metal fatigue, or endarteritis.

This study demonstrated late regression of lesions more than six months after coronary stenting, as detected by well-validated quantitative coronary angiography. Restenosis inside the stent has been reported to be due to neointimal hyperplasia in studies in animals<sup>23,24</sup> and also in the autopsy report of a human<sup>25</sup> and in a study using intravascular ultrasonography.<sup>25</sup> Schatz et al.<sup>23</sup> demonstrated regression of intimal hyperplasia inside the stent over time in a study in animals. In a study of disease in humans, we showed a decrease in the extracellular matrix of the newly proliferating intima and subsequent fibrotic change during the first two to three years after balloon angioplasty.<sup>26</sup> Therefore, fibrotic maturation of the intimal hyperplasia inside the stent may be one of the mechanisms of the observed improvement in the lumen at three years.

We could not address the issue of changes in the diameter of the stent over time as evidence of the compression or expansion of the stent itself, because the extremely radiolucent nature of the Palmaz-Schatz stent precluded accurate angiographic quantitation of stent diameter in most patients. However, a recent serial study using intravascular ultrasonography revealed no significant change in the cross-sectional area of the metallic slotted-tube stent during four months of follow-up after implantation.<sup>27</sup> It is unlikely, therefore, that changes in the diameter of a stent play an important part in either restenosis or late regression of the lesion.

In this study, late increases in luminal diameter (during the period from six months to three years after implantation) were significantly correlated with early de-

creases in diameter (during the period from immediately after the procedure to the six-month follow-up), suggesting that the earlier intimal hyperplasia occurs, the greater the potential for late regression. These data imply that when a relatively small lumen is found six months after coronary stenting, it may safely be observed, without repeated coronary intervention, unless the patient is highly symptomatic. Asymptomatic restenosis has been reported to occur frequently, with a good prognosis, in patients with negative exercise tests after balloon angioplasty,<sup>28</sup> directional coronary atherectomy, or Palmaz-Schatz coronary-artery stenting.<sup>29</sup> Given the low incidence of angiographically detected restenosis, the need for angiographic follow-up after each implantation of a single stent in a native

coronary artery must be seriously questioned in clinical practice.

This study has several important limitations. This series of patients represented our very early experience with stent implantation, and current modifications of the technique (with high-pressure dilatation at the end of the procedure) and the regimen of anticoagulant therapy (with the use of more potent antiplatelet agents) would probably improve the clinical outcome. On the other hand, extending the application of coronary-artery stenting to longer lesions, smaller arteries, or both might produce a different clinical and angiographic outcome. Our study did not include a comparison group of patients who underwent standard balloon

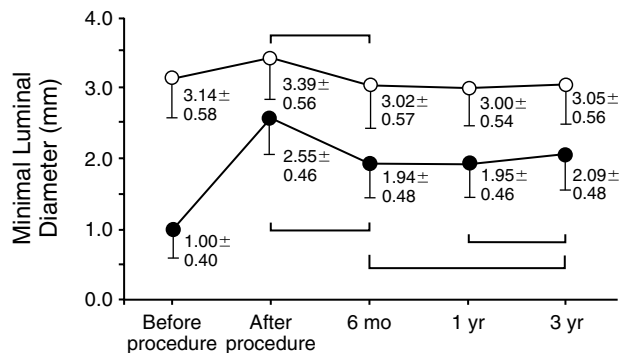


Figure 3. Serial Changes in the Mean ( $\pm$ SD) Minimal Luminal Diameter of 72 Lesions for Which Sequential Studies over a Three-Year Period, Were Completed ( $\bullet$ ), as Compared with a Reference Diameter ( $\circ$ ).

There was significant improvement in minimal luminal diameter during the period from one year to three years after implantation of the stent.  $P < 0.001$  for the comparison between the points linked by brackets.



Figure 4. Angiograms Showing Marked Luminal Improvement in a Patient after Three Years.

Coronary-stent implantation was performed electively in this patient for a primary lesion of the left anterior descending coronary artery. The minimal luminal diameter of the vessel improved from 0.68 mm before the intervention (upper left) to 2.63 mm immediately after the implantation of the stent (upper right). At six months (lower left), the diameter had decreased to 1.49 mm, but at three years (lower right), it had increased to 2.31 mm.

angioplasty without stenting. In comparing our follow-up data with those of studies using historical controls to evaluate other interventions, one must keep in mind the differences in base-line characteristics. Also, although a well-validated system of quantitative coronary angiography was used, the analysis was not done in a core laboratory. Finally, although not all the patients returned for study after three years, base-line characteristics and quantitative angiographic variables measured after six months were similar between the group that had angiography at three years and the group that did not. Despite these limitations of the study, the safety and efficacy of the implantation of a single stent in a native coronary artery appeared to persist for at least three years.

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