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# Clinical and Angiographic Comparison of Matched Patients With Successful Directional Coronary Atherectomy or Stent Implantation for Primary Coronary Artery Lesions

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***Objectives.*** **This study was designed to compare the long-term clinical and angiographic effects of successful directional atherectomy and stent implantation and to examine whether restenosis is related to the mechanism of lumen improvement as well as the extent of lumen gain.**

***Background.*** **Directional atherectomy and coronary stent implantation have been shown to achieve a more optimal immediate result that may lead to a more favorable long-term angiographic outcome and fewer target vessel revascularizations than does angioplasty. However, it remains to be determined whether one of the devices used in these interventions provides consistently better results than the other.**

***Methods.*** **To allow meaningful comparisons, a prospectively collected series of 117 patients successfully treated with atherectomy were individually matched with a prospectively collected series of 117 patients successfully treated with stent implantation. Matching for baseline characteristics identified patients with identical lesion location and lesion severity, and immediate and late angiographic and clinical outcome were compared. To evaluate the possibility of a procedure effect on restenosis, patients were further matched for both immediate angiographic outcome and baseline characteristics, providing 150 matched patients for comparison. As confirmatory analysis, multivariate models were constructed to predict late lumen diameter.**

***Results.*** **Matching resulted in two comparable groups with equivalent baseline clinical and stenosis characteristics (n = 117 pairs). Atherectomy led to a smaller immediate gain than stenting and, because late loss was similar in both groups, stenting resulted in a larger late lumen (1.96 ± 0.51 vs. 1.66 ± 0.55 mm, p < 0.0001). When patients were matched for immediate gain and baseline characteristics (n = 75 pairs), lumen loss was more pronounced after atherectomy, and thus the minimal lumen diameter at follow-up differed significantly between the two groups (1.66 ± 0.53 vs. 1.90 ± 0.47 mm, p = 0.004). This beneficial angiographic effect of stenting was accompanied by a reduced need for repeat interventions. Multivariate analysis confirmed the independent effect of the interventional device used, whereby less loss and greater lumen diameter at follow-up were predicted for stent implantation than for atherectomy.**

***Conclusions.*** **Successful stent implantation provided a more favorable long-term angiographic outcome and lower rates of restenosis and need for target lesion revascularization than did atherectomy. This favorable effect of stenting not only is related to a larger immediate gain, but also seems to attenuate late lumen loss.**

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The importance of optimization of acute interventional results with all treatment devices is now well recognized (1–13). However, it remains to be determined whether the extent of the vessel wall healing process after an intracoronary intervention, and therefore the angiographic outcome, is also influenced by the specific mechanism of an interventional device. An initial exploration of such a relation between device specificity and restenosis, using the loss index as an angiographic correlate of the "proportional injury model" (1,2), did not detect such an independent effect even when the results were corrected for the difference in immediate gain, which has been shown (1,4,5,7,9) to be the most important predictor of restenosis. In contrast, our group has hypothesized that the varying mechanisms of action of interventional devices might induce varying degrees of lumen renarrowing in patients matched for clinical and lesion characteristics (7,8). To try to reconcile these two viewpoints, an automated case-matching method in which patients are matched for baseline *and* procedural characteristics was developed to explore differences in late outcome between patients treated with new devices. An additional advantage of this matching technique is the possibility of assessing long-term results without a colinearity between immediate gain and interventional device.

Recently, directional atherectomy and coronary stenting

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were compared with conventional balloon angioplasty for their ability to reduce restenosis (10–13). Although both techniques achieved a greater lumen gain than did balloon angioplasty, only stenting reduced the restenosis rate significantly (12,13). Whereas these trials showed a comparable lumen gain after atherectomy and stenting, we recognized that the difference in lumen renarrowing after atherectomy and stenting may relate to either the extent or the mechanism (debulking versus scaffolding) of lumen improvement.

In this study we comparatively evaluated successful directional atherectomy and stent implantation in a prospectively collected series of 234 patients by using the previously validated matching methodology. By matching for both immediate angiographic outcome and baseline characteristics, we extended our observations and tested the hypothesis that each interventional device has unique properties with respect to lumen renarrowing that are independent of clinical, angiographic or procedural characteristics.

## Methods

**Atherectomy group.** From September 1989 through March 1994, 208 patients underwent 214 directional atherectomy procedures for native coronary or bypass graft lesions. Of these, 150 consecutive patients (who underwent 157 successful procedures) have had a 6-month follow-up angiographic study (angiographic follow-up rate 90%). For the purpose of this study, the late outcome of atherectomy was compared with that of stenting for consecutive native primary lesions. Therefore, patients with restenotic lesions and patients with a subacute coronary occlusion of <24 h duration were excluded. Of the 150 patients, 3 were treated for a lesion in a venous bypass graft and 13 underwent atherectomy for 18 restenotic lesions after previous angioplasty. Thus, 134 patients who underwent 136 successful atherectomy procedures for native primary coronary artery disease were eligible for matching.

**Stent group.** From January 1990 through March 1994, 240 patients were successfully treated by Palmaz-Schatz stent implantation at the Thoraxcenter. Of these, 213 patients had a stent electively implanted for a primary coronary lesion without clinical sequelae (i.e., no subacute occlusion). Of these, 179 consecutive patients have had a 6-month follow-up angiographic study and were thus eligible for matching. Patients were selected for directional atherectomy or stent implantation when they presented with a stenosis in a proximal nontortuous coronary artery with a reference diameter >2.5 mm. All patients gave informed consent and were prospectively scheduled for angiography at 6 months, a procedure completed by 90% of the patients. The study was approved by the hospital's Institutional Review Board. All clinical and angiographic data were collected prospectively.

**Atherectomy and stenting procedure.** The atherectomy procedure was performed as described previously (7–9,12). Briefly, the atherectomy device was directed over a guide wire and positioned across the stenosis. The support balloon was then inflated up to 7.5 psi, the cutter was retracted and balloon inflation pressure was increased to maximally 45 psi. The driving motor was activated and the rotating cutter was slowly advanced to cut and collect the protruding atherosclerotic lesion in the collecting chamber located at the tip of the catheter. After every pass the balloon was deflated and either removed or repositioned. A 6F atherectomy device was used in 34% of patients and a 7F device in 66%. Adjunctive balloon dilation was performed in 23%. Although an optimal angiographic result was sought for each lesion treated, the procedure was considered angiographically successful when the residual diameter stenosis was <50% after tissue retrieval. This classic definition of success should be viewed in historical perspective; currently a lumen gain of ≥0.7 mm or a postatherectomy diameter stenosis <20% may be deemed necessary before a procedure is considered successful, as recently observed in retrospective analyses (2) and as defined in the ongoing atherectomy trials (Balloon vs. Optimal Atherectomy Trial [BOAT], Optimal Atherectomy Restenosis Study [OARS], European Carvedilol Restenosis trial [EUROCARE]). Such a result was reached in 22% of cases. Stenting was performed by the femoral approach and the stent was delivered by inflation of the balloon that contained the crimped stent. The following Palmaz-Schatz stents were implanted: 3.0 mm (46%), 3.5 mm (39%) and 4.0 mm (15%). Additional intrastent balloon dilation was performed in 27 patients (23%). Anticoagulation during and after stent implantation was given according to the protocol and contained heparin, dextran, dipyridamole, aspirin and warfarin for 3 months. Patients were monitored as described earlier (7–9,12,13).

**Quantitative coronary angiography.** Quantitative analysis of the coronary segments was performed with the computer-based Coronary Angiography Analysis System (CAAS), which has been previously validated and described in detail (8,12,14,15). In particular, accuracy and precision measurements for in vivo phantom measurements are 0.09 and 0.23 (16). In essence, boundaries of a selected coronary artery segment are detected automatically from optically magnified and video-digitized regions of interest (512 × 512 pixels) of a cine frame. The absolute diameter of the stenosis in mm is determined by using the guiding catheter as a scaling device for calibration. The external diameter of each individual catheter is measured by a precision micrometer with a tolerance of 0.001 mm. Correction for pincushion distortion is performed. Computer estimation of the original dimension of the artery at the site of the obstruction provides an interpolated reference diameter. All other variables (e.g., immediate gain, late loss) are then calculated.

To standardize the method of analysis of the interventional and follow-up angiogram, the following measures were routinely applied. First, the X-ray gantry was exactly repositioned to the settings that were documented at the time of the intervention. Second, all study frames to be analyzed were selected at end-diastole to minimize foreshortening and blurring effects of systolic motion. Third, the user-determined beginning and end point of a segment of a major coronary

artery were identified according to the definitions of the American Heart Association (17). Finally, Polaroid photographs were taken of the video image with the detected contours superimposed to ensure that the analyses were performed on the same coronary segments. Intracoronary isosorbide dinitrate (1 to 3 mg) was given before and after intervention. Administration of intracoronary nitrates was recommended before follow-up angiography.

**Matching process.** The process of matching for clinical and angiographic characteristics (see Appendix) has been previously described (7,8,15). Clinical factors such as gender, diabetes, hypercholesterolemia (18) and nonexertional angina were taken into account. The coronary artery tree was subdivided into 15 segments according to American Heart Association guidelines and the lesions were individually matched according to stenosis location and reference diameter and minimal lumen diameter. The principles of matching by quantitative angiography are threefold: 1) The angiographic dimensions of matched lesions are assumed to be "identical," 2) the observed difference between the two "identical" lesions must be within the range of the reproducibility of the CAAS analysis (0.1 mm [=1 SD]), and 3) the reference diameter of the lesions to be matched is selected within a range of ±0.3 mm (=3 SD) (8,14,16). Clinical factors such as gender, diabetes, hypercholesterolemia and nonexertional angina were taken into account. The automated matching program identified 117 prospectively collected patients with 117 coronary artery lesions treated successfully with atherectomy who could be individually matched with 117 prospectively collected consecutive patients treated successfully with stenting (diameter stenosis <50% on visual inspection). The remaining patients (13%) of the atherectomy cohort could not be matched because no identical patient with stenting was found according to the prespecified matching criteria. The clinical and angiographic details of the two groups are given in Table 1.

To extend our observations and to test the hypothesis that each interventional device has unique properties with respect to lumen renarrowing that are independent of vessel size and lesion severity and lumen gain, matching for immediate procedural result as well as baseline characteristics yielded 150 matched patients.

**Clinical follow-up.** All patients were prospectively seen at the outpatient clinical at regular time intervals during a 7-month follow-up period. The clinical end points were death, myocardial infarction, coronary artery bypass grafting and repeat percutaneous intervention. Death was defined to include all death. Myocardial infarction was defined as the occurrence of a new abnormal Q wave and an increase in creatine kinase more than twice the upper limit of normal. Revascularization of the target lesion was defined as angioplasty or bypass surgery performed because of restenosis of the target lesion in association with angina or objective evidence of myocardial ischemia, or both.

**Statistical analysis.** The unit of analysis reported here is the patient. All values are expressed as mean value ± 1 SD. Comparisons of continuous variables between the two groups were performed by using the paired Student *t* test. Selected angiographic variables were evaluated by univariate regression analysis for their correlation with absolute lumen loss and minimal lumen diameter at follow-up. Multivariate stepwise regression analysis using a commercially available statistical software package (SAS, SAS Institute Inc.) was utilized to take into account the influence of lesion location, preprocedural minimal lumen diameter, acute lumen gain and vessel size in evaluating their contribution to the minimal lumen diameter at follow-up and late lumen loss. Differences between categoric variables were tested with the chi-square and Fisher exact tests as appropriate. Target lesion revascularization was analyzed by means of Kaplan-Meier survival curves, with differences between the two groups compared by Wilcoxon test. Differences were considered statistically significant where the p value was <0.05.

**Table 1.** Clinical and Angiographic Characteristics of the 234 Study Patients

| | Atherectomy (n = 117) | Stent (n = 117) | p Value |
|---|---|---|---|
| Age (yr) | 58 ± 11 | 57 ± 10 | 0.71 |
| Male | 76% | 81% | 0.34 |
| Vessel treated | | | |
| LAD | 77% | 77% | 1.0 |
| LCx | 8% | 8% | 1.0 |
| RCA | 15% | 15% | 1.0 |
| Nonexertional angina | 38 | 48 | 0.11 |
| Previous infarction | 25% | 18% | 0.20 |
| Previous CABG | 0 | 0 | 1.0 |
| Diabetes | 6% | 9% | 0.33 |
| Hypercholesterolemia | 24% | 23% | 0.10 |

Data presented are mean value ± SD or percent of patient group. CABG = coronary artery bypass grafting; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery.

## Results

**Outcome of the matching process (Table 1).** The automated computer matching program provided 117 pairs of patients—117 with successful atherectomy and 117 with successful stenting—with comparable clinical and angiographic characteristics (lesion location and severity). The 234 patients were predominantly male with a mean age ± SD of 57 ± 11 years. Patients were predominantly treated for stable angina according to the American Heart Association classification. By matching design no difference in lesion distribution exists between the atherectomy and stent group: left anterior descending artery (77% vs. 77%), right coronary artery (15% vs. 15%) and left circumflex artery (8% vs. 8%). No differences between groups were found for risk factors for coronary artery disease or preceding cardiovascular events such as myocardial infarction or bypass surgery. By study design, no significant differences between the atherectomy and stent groups were found in baseline quantitative angiographic variables: mean vessel size (3.09 ± 0.45 vs. 3.10 ± 0.44 mm), preprocedural

**Table 2.** Comparison of Quantitative Angiographic Data of 234 Matched Patients Who Underwent Atherectomy or Stent Implantation for Similar Lesion Severity

| | Atherectomy (n = 117) | Stenting (n = 117) | p Value |
|---|---|---|---|
| Reference diameter pre (mm) | 3.09 ± 0.45 | 3.10 ± 0.44 | 0.92 |
| Minimal lumen diameter (mm) | | | |
| Pre | 1.12 ± 0.29 | 1.12 ± 0.27 | 0.97 |
| Post | 2.32 ± 0.41 | 2.53 ± 0.37 | 0.001 |
| Follow-up | 1.66 ± 0.55 | 1.96 ± 0.51 | 0.0001 |
| Diameter stenosis (%) | | | |
| Pre | 64 ± 8 | 64 ± 8 | 0.0001 |
| Post | 28 ± 10 | 21 ± 7 | 0.0001 |
| Follow-up | 44 ± 17 | 35 ± 13 | 0.0001 |
| Lumen loss (mm) | | | |
| Absolute | 0.66 ± 0.58 | 0.57 ± 0.47 | 0.22 |
| Relative | 0.22 ± 0.19 | 0.19 ± 0.15 | 0.18 |
| Restenosis rate (%) | 36 | 14 | 0.005 |
| Lesion length (mm) | 6.83 ± 2.54 | 7.23 ± 2.05 | 0.82 |
| Curvature value pre | 14.5 ± 6.3 | 14.7 ± 5.9 | 0.91 |
| Symmetry index pre | 0.45 ± 0.25 | 0.37 ± 0.25 | 0.79 |
| Area plaque pre ($mm^2$) | 9.53 ± 4.64 | 9.46 ± 4.00 | 0.87 |

Data presented are mean value ± SD. Post = after intervention; pre = before intervention.

minimal lumen diameter (1.12 ± 0.29 mm vs. 1.12 ± 0.27 mm) and percent diameter stenosis (64 ± 8% vs. 64 ± 8%), respectively.

**Immediate and late outcome after matching for baseline characteristics (Tables 2 and 3, Fig. 1).** The reference diameters were not significantly different after atherectomy or stenting (3.23 ± 0.46 vs. 3.22 ± 0.41 mm, p = 0.83). Directional atherectomy resulted in a smaller immediate gain in minimal lumen diameter than did coronary stenting (1.20 ± 0.46 vs. 1.41 ± 0.39 mm, p = 0.002) with a consequently lower postprocedural minimal lumen diameter (2.32 ± 0.41 mm vs. 2.53 ± 0.37 mm, p < 0.001) and concomitantly higher percent diameter stenosis (28 ± 10% vs. 21 ± 7%, p < 0.001). Because absolute loss during follow-up did not differ significantly between the atherectomy and stent groups (0.66 ± 0.58 vs. 0.57 ± 0.53 mm, p = 0.22), the initial favorable immediate result after stenting was maintained during follow-up. Thus, the minimal lumen diameter at follow-up after atherectomy was significantly lower than after stenting (1.66 ± 0.55 vs. 1.96 ± 0.51 mm, p < 0.0001). Accordingly, atherectomy

**Table 3.** Long-Term Clinical Outcome After Successful Atherectomy and Stent Implantation in Matched Patients

| | Atherectomy (n = 117) | Stenting (n = 117) | p Value |
|---|---|---|---|
| Death | 0 | 0 | 1.0 |
| Myocardial infarction | 3% | 3% | 1.0 |
| Coronary artery bypass surgery | 3% | 2% | 0.68 |
| Repeat PTCA | 20% | 10% | 0.07 |

Data presented are percent of patient group. PTCA = percutaneous transluminal coronary angioplasty.

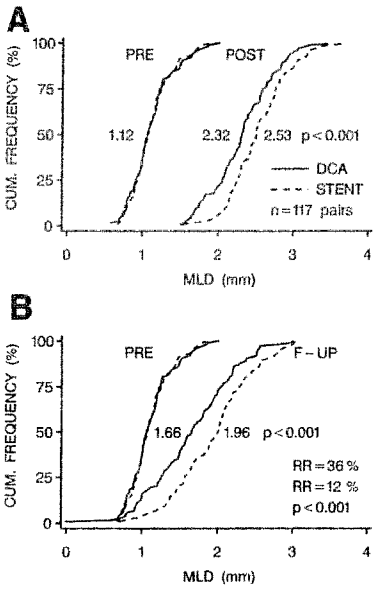


**Figure 1.** Cumulative (CUM.) frequency curves illustrate the immediate (**A**) and follow-up (F-UP) (**B**) effects on minimal lumen diameter (MLD) of directional coronary atherectomy (DCA) and stent implantation in patients matched for lesion location and severity (n = 117 pairs). As shown, the matching process was adequate, with superimposition of the distribution frequency curves of the minimal lumen diameter before atherectomy and stenting indicating similar preprocedural stenosis severity. POST = after the procedure; PRE = before the procedure; RR = restenosis rate (diameter stenosis at follow-up <50%).

yielded a lower net gain (0.54 ± 0.58 vs. 0.84 ± 0.53, p < 0.0001) and a higher percent diameter stenosis at follow-up (44 ± 16% vs. 35 ± 13%, p < 0.0001). The restenosis rate (diameter stenosis at follow-up >50%) after stenting was significantly lower than after atherectomy (14% vs. 36%, p = 0.0053). These results were also found in the subgroup analysis for *optimally* treated patients (minimal lumen diameter >2.75 mm, n = 18 pairs). Although there was a trend for a higher postprocedural minimal lumen diameter after atherectomy than after stenting (2.96 ± 0.17 vs. 2.74 ± 0.35 mm, p = 0.03) in these patients, late loss was nearly two times higher in the atherectomy group (1.03 ± 0.59 vs. 0.58 ± 0.63 mm, p = 0.04), yielding a lower, but not significantly different, final minimal lumen diameter in the patients with atherectomy than in those with stenting (1.93 ± 0.55 vs. 2.16 ± 0.53 mm, p = 0.22).

The late clinical follow-up was also more favorable for patients with stenting and showed a reduced need for repeat revascularization. Clinical follow-up data were available in 100% of the patients. No deaths were observed and significantly fewer patients with stenting than patients with atherectomy required target lesion revascularization (12% vs. 23%, p = 0.05) (Fig. 2). In multivariate analysis, lesion location, vessel size, minimal lumen diameter before intervention, absolute gain and type of interventional device were identified as independent predictors of the absolute lumen loss and minimal

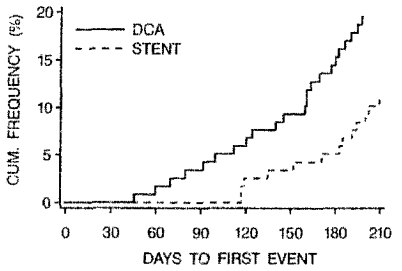


**Figure 2.** Cumulative curves for target lesion revascularization (repeat angioplasty or coronary artery bypass surgery). Fewer patients in the stent group than in the atherectomy group needed revascularization of the target artery (p = 0.05). Abbreviations as in Figure 1.

lumen diameter at follow-up. Both models can be described by the following equations:

$$\text{Absolute loss} = -0.35 - 0.24\,\text{vessel size} + 0.63\,\text{gain} + 0.58\,\text{MLD pre} + 0.16\,\text{LAD} + 0.22\,\text{device}. \quad [1]$$

$$\text{Minimal lumen diameter at follow-up} = 0.35 + 0.24\,\text{vessel size} + 0.37\,\text{gain} + 0.42\,\text{MLD pre} - 0.16\,\text{LAD} - 0.22\,\text{device}, \quad [2]$$

where LAD = left anterior descending coronary artery lesion, MLD pre = minimal lumen diameter before the procedure; atherectomy = 1 and stenting = 0, LAD lesion = 1, non-LAD lesion = 0.

A linear relation was observed between immediate gain and late loss in the two groups, with a steeper gain/loss regression line slope in the atherectomy group (0.50) than in the stent group (0.30) (p = NS).

**Immediate and late outcome after matching for both procedural outcome and baseline characteristics (Table 4, Fig. 3).** Matching for procedural outcome as well as lesion location and vessel size and lesion severity and procedural outcome identified 75 pairs of matched patients with successful atherectomy or stenting. By virtue of this matching protocol, vessel size and minimal lumen diameter before *and* after the procedure in the atherectomy and stent groups were similar (3.06 ± 0.43 vs. 3.05 ± 0.42 mm, p = 0.93; 1.09 ± 0.25 vs. 1.08 ± 0.24 mm, p = 0.98; and 2.41 ± 0.29 vs. 2.42 ± 0.28 mm, p = 0.84), respectively. Therefore, the values for immediate lumen gain achieved with atherectomy and stenting were comparable (1.33 ± 0.37 vs. 1.34 ± 0.34 mm, p = 0.86). Patients in the atherectomy group had a significantly greater late loss during follow-up (0.75 ± 0.57 vs. 0.52 ± 0.44 mm, p < 0.006) so that the residual minimal lumen diameter at follow-up was significantly smaller after atherectomy than after stenting (1.66 ± 0.53 vs. 1.90 ± 0.47 mm, p < 0.004). Likewise, atherectomy yielded a higher percent diameter stenosis at follow-up (43 ± 17% vs. 36 ± 12%, p < 0.004). Additionally, the restenosis rate (diameter stenosis at follow-up >50%) after stenting was significantly lower than after atherectomy (12% vs. 32%, p = 0.00026).

The multivariate models to predict late loss and residual diameter at follow-up were found to be

**Table 4.** Comparison of Quantitative Angiographic Data of 150 Matched Patients Who Underwent Atherectomy or Stent Implantation for Similar Lesion Severity and Procedural Outcome

| | Atherectomy (n = 75) | Stenting (n = 75) | p Value |
|---|---|---|---|
| Reference diameter pre (mm) | 3.06 ± 0.43 | 3.05 ± 0.42 | 0.93 |
| Minimal lumen diameter (mm) | | | |
| Pre | 1.09 ± 0.25 | 1.08 ± 0.24 | 0.98 |
| Post | 2.41 ± 0.29 | 2.42 ± 0.28 | 0.84 |
| Follow-up | 1.66 ± 0.53 | 1.90 ± 0.47 | 0.0035 |
| Diameter stenosis (%) | | | |
| Pre | 64 ± 8 | 64 ± 7 | 0.94 |
| Post | 25 ± 7 | 22 ± 7 | 0.0064 |
| Follow-up | 43 ± 17 | 36 ± 12 | 0.0035 |
| Lumen loss (mm) | | | |
| Absolute | 0.75 ± 0.57 | 0.52 ± 0.44 | 0.0056 |
| Relative | 0.25 ± 0.18 | 0.18 ± 0.14 | 0.0082 |
| Restenosis rate (%) | 32 | 12 | 0.0003 |
| Lesion length (mm) | 6.88 ± 2.34 | 7.40 ± 2.24 | 0.71 |
| Curvature value pre | 16.5 ± 6.4 | 15.7 ± 5.7 | 0.83 |
| Symmetry index pre | 0.41 ± 0.25 | 0.36 ± 0.23 | 0.82 |
| Area plaque pre ($mm^2$) | 9.63 ± 4.62 | 9.70 ± 4.24 | 0.75 |

Data presented are mean value ± SD. Abbreviations as in Table 2.

$$\text{Absolute loss} = -0.74 - 0.18\,\text{vessel size} + 0.68\,\text{gain} + 0.76\,\text{MLD pre} + 0.13\,\text{LAD} + 0.24\,\text{device}. \quad [3]$$

$$\text{Minimal lumen diameter at follow-up} = 0.75 + 0.17\,\text{vessel size} + 0.32\,\text{gain} + 0.27\,\text{MLD pre} - 0.13\,\text{LAD} - 0.24\,\text{device}, \quad [4]$$

where MLD pre = minimal lumen diameter before the procedure, LAD = left anterior descending coronary artery lesion, atherectomy = 1 and stenting = 0, LAD lesion = 1, non-LAD lesion = 0.

After matching for procedural outcome, the greater loss observed after directional atherectomy is reflected by the finding in multivariate analysis of a significant independent effect of the procedure used, whereby less late loss and greater minimal lumen diameter at follow-up is predicted for stent implantation.

## Discussion

In this study, we compared the immediate and long-term clinical and angiographic effects of successful directional atherectomy and stent implantation for primary coronary artery lesions. The major findings of this study are threefold: 1) In matched patients with similar lesion severity and location, stenting is associated with a significantly larger immediate lumen, which is preserved during follow-up and is reflected by a concomitant reduced need for target lesion revascularizations during the 1st 6 months; 2) when the procedural result and baseline characteristics are matched, stent implantation is found to provide a superior late angiographic outcome due to significant less lumen renarrowing than after atherectomy; and 3) these findings may reflect a device-specific effect on lumen

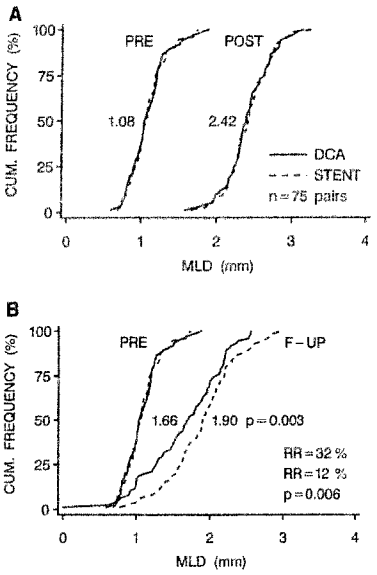


**Figure 3.** Graphic display of the immediate (**A**) and late (**B**) results after atherectomy and stenting in patients who were matched for lesion location and severity and immediate gain (n = 75 pairs). As displayed, the matching process was adequate, with superimposition of the distribution frequency curves of the minimal lumen diameter before and after atherectomy and stenting indicating similar pre- and postprocedural stenosis severity irrespective of the device deployed. Abbreviations as in Figure 1.

renarrowing, independent of baseline characteristics or immediate procedural result.

**Matching.** To overcome the limitations in design of previous comparative interventional studies, we applied the previously validated concept of matching (7,8,15,19,20) to the atherectomy and stent groups to evaluate and compare the effect of the interventional devices used on long-term angiographic and clinical outcome. In particular, the confounding effects of unequal vessel size and immediate lumen gain, which have been shown to be independent predictors of restenosis (4,5,9) and which have not been controlled in such studies, are avoided by this matching technique. Matching for the immediate result of intervention provides the possibility to objectively evaluate for a specific device effect, which was not possible in randomized trials, because the postprocedural results in the treatment groups were significantly different. Furthermore, matching a study group with a reference patient group of similar characteristics can compensate for some of the limitations of nonrandomized studies such as population heterogeneity (21). However, prospective randomized trials are traditionally regarded as the method of choice for comparing long-term outcome of different interventional procedures because case selection is potentially limited in such trials. Despite a potential patient selection bias in matching studies, our atherectomy and stent patient groups had angiographic characteristics and an immediate outcome comparable to those of patients in several reported studies (Coronary Angioplasty Versus Excisional Atherectomy Trial [CAVEAT], Canadian Coronary Atherectomy Trial [CCAT], BElgian NEtherlands STENT study [BENESTENT] and STent REStenosis Study [STRESS]) (10–13). Thus, the findings in our comparative study may be applicable to patients selected for stenting or atherectomy and may be useful in planning future trials.

**Determinants of a favorable long-term outcome.** When our group (7,8,22) first studied the differences between restenosis after atherectomy and balloon angioplasty in a matched series, we not only observed a linear relation between immediate gain and late loss but also recognized that the slope of this regression line may represent an index of lumen renarrowing specific for each treatment modality. In a subsequent matching study (20), we further extended this observation and could indeed demonstrate that the process of lumen renarrowing was dependent not only on the extent but also on the mechanism of lumen improvement. These observations may implicate that a beneficial late outcome can be achieved by using a device that can associate a large immediate gain with a favorable relation between the degree of vessel wall injury and vessel wall response. In the present study, we compared the two available interventional devices that can consistently achieve a large immediate gain and found that the long-term outcome after stent implantation is significantly superior to that after atherectomy. A superior immediate gain achieved by stenting in patients matched only for baseline characteristics indicates that the improved angiographic outcome of stenting may be due to the combination of the extent and possibly the mechanism of lumen increase.

**Why might stenting be superior to atherectomy?** The comprehensive analysis of long-term outcome of stent implantation and atherectomy suggests that the scaffolding effect of stenting may lead to less lumen loss and a larger late lumen at follow-up than are achieved with the debulking mechanism of directional atherectomy in matched patients. Multivariate analysis confirmed the significant independent influence of the device used whereby less late loss and a larger lumen diameter at follow-up was predicted for stent implantation compared with directional atherectomy. In a well-controlled serial IVUS study, Mintz et al. (23) found a significant difference in the ultrasound aspect of lumen renarrowing after different transcatheter treatment strategies. In particular, stented lesions exhibited virtually no geometric remodeling but restenosis consisted predominantly of intimal hyperplasia, whereas remodeling appeared to be the main mechanism of restenosis in nonstented lesions. In fact, their study suggests a device-specific effect on restenosis with less arterial recoil after stenting than after other interventions. Kimura et al. (personal communication) subsequently documented the time course after stenting and atherectomy by using serial ultrasound measurements. They also found a different interrelation between remodeling and hyperplasia in that stenting was not associated with immediate or late recoil whereas patients with atherectomy exhibited a geometric remodeling process (decrease in external elastic membrane) that was already present at 1 month of follow-up and ongoing at 6 months. These ultrasound observations support our data and suggest that a

lower restenosis rate after stenting may be the result of less vascular recoil. Indeed, earlier observational angiographic studies have demonstrated that this beneficial effect may be secondary to less elastic recoil (24) or to the restoration of the "Glagovian balance" between plaque and lumen area (25). Furthermore, by using coronary angioscopy and ultrasound techniques, Baptista et al. (26) demonstrated that, compared with atherectomy, stenting reduces the amount of trauma to the vessel wall, which ultimately may lead to a reduced vessel wall healing response (i.e., renarrowing).

Therefore, the favorable stent effect found in our study concurs with preliminary angioscopic (27,28) and ultrasound (26,29) observations and suggests a favorable relation between vessel wall injury (smooth circular wall configuration) and vessel wall healing response (reduced geometric remodeling) and suggests the importance of the scaffolding action of stenting. If larger studies confirm this observation, the clinical importance is that trials of restenosis prevention attempting to prevent the formation of intimal hyperplasia may particularly affect patients with stenting because intimal hyperplasia may be the dominant mechanism of restenosis. It seems unlikely that this favorable effect of stenting is attributable to a difference in treatment strategy (optimal stenting versus less optimal atherectomy) because this effect is avoided by matching for both baseline characteristics and outcome. The postatherectomy lumen diameter found in our series is comparable to that observed in the CCAT and CAVEAT trials (10,11) although smaller than in the series of Kuntz et al. (1,6), whereas our stent results are comparable to those reported in the BENESTENT, STRESS and Palmaz-Schatz Stent Study trials (12,13,30). Such an observation does not influence the conclusions of the present study because the linear relation between immediate gain and late loss is maintained at all levels of gain, showing a favorable effect (lower slope value) for stenting when compared with atherectomy.

**Clinical implications.** The favorable angiographic outcome of stenting is further underlined by a significant reduction in the clinical need for target vessel revascularization. In accordance with Baim and Kuntz (31), we have refrained from using the composite "any event" clinical end point criteria to compare stenting with atherectomy to avoid potentially confounding factors induced by cardiac events not related to the type of interventional device used. By using such "filtered clinical end points" (31), we found an agreement between quantitative angiographic follow-up and the late clinical course, emphasizing the need for a dual approach (angiographic and clinical follow-up) in that quantitative angiography demonstrates the mechanistic explanation of the favorable stent results, whereas clinical follow-up provides the clinical implications of this finding. The 14% restenosis rate after successful stenting found in this study is identical to the 14% restenosis rate of patients with successfully stenting in the BENESTENT study (i.e., successful stent implantation without subacute occlusion) and comparable to the findings of the BENESTENT II pilot phase (32).

**Summary and conclusions.** In matched patients, successful stent implantation provides a more favorable long-term angiographic outcome with a reduction in restenosis rate and in need for subsequent revascularization compared with directional atherectomy. This favorable effect is related not only to a larger immediate gain but also to a device-specific effect, whereby less renarrowing is provoked by stent implantation for a given degree of immediate gain.

**Limitations of the study.** Matching of prospectively collected patients is retrospective in nature and may have led to a selection bias such as the selection of larger vessels. Inherent to the purpose of this study, only patients who underwent a successful procedure were matched and included in this study, and we acknowledge that the results apply to a restricted group of patients who had a successful procedural outcome after undergoing atherectomy or stenting.

Whether the favorable stent effect observed in this study is due only to a scaffolding effect or could also be due to a difference in anticoagulant therapy, acute recoil or postprocedural vessel wall configuration is beyond the scope of this study. However, various reports (33–35) have ruled out an effect of anticoagulation, whereas in this study the effect of acute recoil was minimized by the use of a meticulous approach, as described earlier (7,20). Criticism of the "suboptimal result" in the atherectomy group may be valid in view of the very latest opinions that a postprocedural stenosis <20% must be achieved. However, such criticism applies equally to the stent group, and we believe it does not detract from the findings of a device-specific effect of stenting in the context of similar immediate results. Confirmation of these findings in the future among optimally treated lesions may be required. In fact, our data underscore the need for optimal results, especially for atherectomy, to accommodate late lumen renarrowing.

# Appendix

## *Process of Automated Matching for Angiographic and Clinical Characteristics*

To compare the results of successful atherectomy and successful stent implantation, all consecutive patients from the atherectomy and stent data sets were matched, creating pairs with a patient from each data set. The variables and criteria for matching are described in Methods, under "Matching process." Technically, the creation of matched pairs is as follows. First, a Cartesian product of the two data sets is made, from which all pairs are determined that fulfill to the matching criteria. The result of this is the "set of eligible pairs." On the basis of the matching criteria a matching score for each pair is calculated, which is an indication of the degree of similarity. As it is possible for the patients of one data set to be coupled to many members of the other data set, the process then goes in an iterative way: first, the best matching score is determined and put into the final data set, the "set of elected pairs." All the other pairs in which the patients of the selected pair participate are then discarded from the set of eligible pairs. This process is repeated for the remaining patients: The pair with the best matching score is determined and transferred to the set

of elected pairs, until eventually there are no eligible pairs remaining so that all patients are matched according to the aforementioned matching criteria.

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