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Influence of Stent Surface Topography on the Outcomes of Patients Undergoing Coronary Stenting: A Randomized Double-Blind Controlled Trial

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The objective of this study was to examine the relationship between stent surface topography and outcome in patients undergoing implantation of stents with rough and smooth surfaces. Surface topography is considered an important determinant of the bare stent performance. Specifically designed rough surface may increase the drug-storing capacity of stents but its direct impact on the risk of thrombosis and restenosis is not known. A total of 200 patients with significant stenosis in native coronary vessels were randomly assigned in a double-blind way to receive either a rough or a smooth-surface stent. The primary endpoint of the study was late lumen loss. Secondary endpoints included angiographic restenosis and clinical outcomes. The study was designed to test the equivalence of rough-surface stents to smooth-surface stents with respect to late lumen loss based on a noninferiority margin of 0.20 mm. Follow-up angiography was performed in 77% of the patients. Late lumen loss was 1.0 ± 0.7 mm in the rough-surface stent group and 1.2 ± 0.7 mm in the smooth stent surface group with a mean difference of −0.20 mm (95% CI = −0.43 to 0.02) between the two stents ($P < 0.001$ from test for equivalence and $P = 0.08$ from test for superiority). Angiographic restenosis rates were 25% with rough-surface stents and 35% with smooth-surface stents ($P = 0.19$). These results show that a rough stent surface does not increase late lumen loss after stent implantation as compared with a conventional smooth stent surface. © 2005 Wiley-Liss, Inc.

Key words: stent; restenosis; thrombosis

INTRODUCTION

Stent thrombosis and restenosis have limited the success of the stent implantation procedure. To reduce the risk of these complications, investigators, in addition to developing new efficacious adjunctive therapies and optimizing the stent deployment technique, have paid particular attention to the role that stent design and material composition can play on the outcomes of patients undergoing stenting [1–5]. Many experimental and clinical studies have addressed this issue and, based on their results, the importance of several stent characteristics has been identified and recommendations have been given [6–15].

Among other characteristics, surface topography has been attributed an important role in stent performance. A smooth stent surface is believed to reduce platelet activation and aggregation, consequently leading to less thrombus formation and neointimal proliferation. In an earlier study, which used different animal models, stents that underwent electropolishing, a special procedure that results in a smoother surface, caused significantly less neointimal hyperplasia and clot formation than untreated stents [16]. Similarly, peripheral stents with a smoother surface were less thrombogenic in an in vitro model with fresh human blood [17].

Recently, based on data from an in vitro model, Palmaz et al. [18] suggested that a pattern of microscopic parallel grooves on the stent surface may result in a faster endothelialization process than a smooth surface. In more recent study, stents with microscopic parallel grooves placed in porcine carotid arteries were associated with an accelerated endothelialization rate 1 week after implanta-

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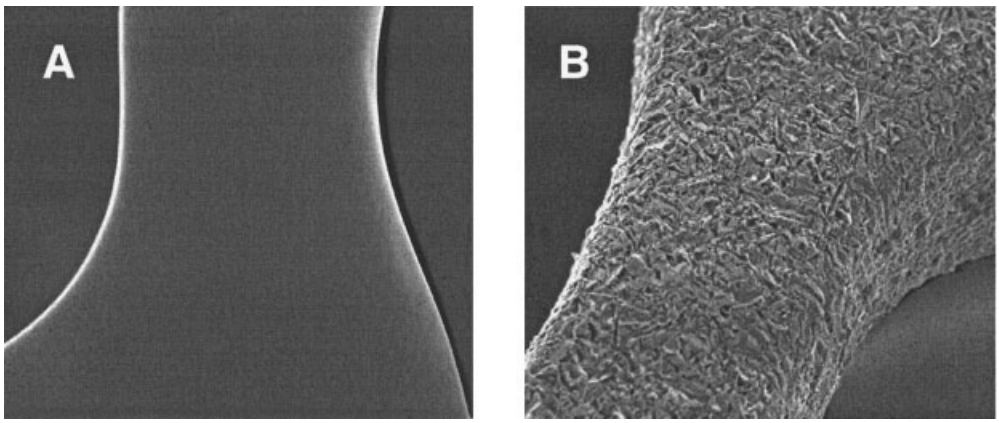

Fig. 1. Comparison of smooth (electro-polished) stent surface (A) and rough (sand-blasted) stent surface (B). Magnification, 500×.

tion when compared to smooth-surface controls [15,19]. An accelerated endothelialization rate has been associated with less thrombus formation as well as decreased neointimal proliferation, while delayed endothelialization has been linked to late side effects after application of intracoroanary radiation therapy [20–24].

Thus, experimental studies based on in vitro and animal models have reported conflicting results on the influence that surface topography has on thrombogenicity and neointimal proliferation after stent implantation. In addition, there is no clinical evidence about the impact of surface topography on outcomes of patients undergoing coronary stenting. This issue becomes even more important given the potential of specially prepared rough surfaces, such as a sand-blasted stent surface, to store antirestenotic drugs onto the stent without the requirement of additional polymer coating. Therefore, we designed a randomized double-blind study on the relationship between stent surface topography and outcome in patients undergoing implantation of stents with rough and smooth surfaces.

MATERIALS AND METHODS

Patients

This prospective double-blind randomized trial was performed in two German institutions. A total of 200 patients with symptomatic coronary artery disease and significant angiographic stenosis in native coronary vessels were enrolled. Exclusion criteria were acute myocardial infarction, lesion in left main coronary artery, in-stent restenosis, and contraindications to the antiplatelet drugs (clopidogrel, aspirin).

The study was conducted according to the principles of the Declaration of Helsinki and approved by the institutional ethics committees. All patients had given their informed consent for participation in this trial.

Description of Stent

The stents used in this study were 316 L stainless steel slotted-tube coronary stents produced from a stainless steel tube by laser cutting. All were electrochemically polished. Stents with smooth surface underwent no further treatment. The rough surface was produced by sand blasting (Fig. 1). The roughness of the surface was measured with a Nanofocus white-light interferometer. The surface roughness achieved had a minimum and maximum root mean square roughness value of 0.09 and 0.21 μm, respectively.

Randomization, Stent Placement, and Poststenting Treatment

Immediately after successful passage of the guidewire through the target lesion, the patients were randomly assigned to receive either a rough-surface or smooth-surface stent. Randomization was performed in a double-blind manner with the use of sealed envelopes containing the block randomization sequence for each participating center.

The procedure was considered successful when stent placement was associated with a residual stenosis of $<30\%$ and Thrombolysis in Myocardial Infarction flow grade ≥ 2. All patients received a loading dose of 600 mg clopidogrel at least 2 hr prior to procedure and intravenous aspirin + heparin during the procedure. Part of the patients also received abciximab during the procedure due to either a concurrent randomized trial [5] or at operator's decision. After the intervention, the patients received aspirin (100 mg b.i.d.) indefinitely and clopidogrel 2×75 mg until discharge and 75 mg for at least 1 month.

Angiographic Evaluation

Angiograms recorded before and immediately after the procedure as well as at 6-month follow-up were

TABLE 1. Baseline Clinical Characteristics*

	Rough surface (n = 100)	Smooth surface (n = 100)	*P*
Age, years	67.3 ± 10.3	66.8 ± 10.8	0.76
Women, n	22	29	0.26
Diabetes, n	30	25	0.43
Current smoker, n	16	16	1
Arterial hypertension, n	65	67	0.77
Hypercholesterolemia, n	62	52	0.15
Unstable angina, n	20	20	1
Previous myocardial infarction, n	34	34	1
Previous bypass surgery, n	5	8	0.40

*Data are mean ± SD or number of patients (%).

assessed with the aid of the automated edge-detection system CMS (Medis Medical Imaging System, Nuenen, The Netherlands). Lesions were classified according to the modified American College of Cardiology/American Heart Association grading system. Operators of the core angiographic laboratory who performed the quantitative assessment were blinded to the randomly assigned stent. All measurements were performed on cineangiograms recorded after intracoronary nitroglycerin administration. The same projections were used at all time points. The contrast-filled nontapered catheter tip was used for calibration. Late lumen loss was the difference in the minimal lumen diameter between that immediately after the procedure and that at follow-up. Angiographic restenosis was defined as diameter stenosis $\geq$ 50% at angiographic follow-up at 6 months measured at any point within the stented segment or in the 5 mm proximal or distal segments adjacent to the stent.

Clinical Evaluation

Adverse events were monitored throughout the follow-up period: by telephone interview at 30 days, a clinical visit at 6 months, and an additional telephone interview at 12 months after the intervention. If patients reported cardiac symptoms during the telephone interview, at least a clinical and electrocardiographic follow-up visit were performed at the outpatient clinic or by the referring physician. All information available from hospital readmission records, the referring physician, or the outpatient clinic was entered into the study database. Death, myocardial infarction (MI), and target vessel revascularization [TVR; percutaneous transluminal coronary angioplasty (PTCA) or bypass surgery] were considered as major adverse cardiac events. The diagnosis of myocardial infarction was based on the presence of new pathological Q-waves or the rise in creatinine kinase or its MB isoenyzme $>$ 3 times the upper limit of normal. The criteria for TVR included the presence of angiographic restenosis accompanied by symptoms and/or a positive exercise test.

Study Endpoints

The primary endpoint of the study was late lumen loss. Secondary endpoints were angiographic restenosis, need for TVR, and the combined rate of death and MI during 1 year after the procedure.

Statistical Analysis

The study was designed to test the equivalence between the rough- and smooth-surface stents regarding the endpoint of late lumen loss. The noninferiority margin was set to 0.20 mm. The null hypothesis stated that the difference in late lumen loss between rough-surface stent and smooth-surface stent would be $\geq$ 0.20 mm. The alternate hypothesis stated that the difference in late lumen loss between rough-surface stent and smooth-surface stent would be $<$ 0.20 mm. We chose a power of 80% and an α-level of 0.05. For this purpose, 78 patients with follow-up angiography in each group were needed. To accommodate for possible losses to follow-up, we included 100 patients in each group.

The analyses were performed on an intention-to-treat basis. Data are presented as mean ± SD or as proportions (%). The differences between groups were assessed by chi-square test or Fisher's exact test for categorical data and *t*-test for continuous data. All tests were two-sided. Survival parameters were compared using the log-rank test. The relative risk (RR) and its 95% confidence interval (CI) were also calculated. A P value $<$ 0.05 was considered statistically significant.

RESULTS

Baseline Characteristics and Procedural Results

There were no differences between the two study groups with respect to the baseline clinical characteristics (Table I). Mean age was similar among patients in the rough-surface stent group and smooth-surface stent group. Women, diabetics, and current smokers were present in comparable proportions in each study group. Baseline angiographic characteristics, presented in

TABLE II. Baseline Angiographic Characteristics*

	Rough surface (n = 100)	Smooth surface (n = 100)	*P*
Multivessel disease, n	84	81	0.58
Treated vessels, n			0.28
Left anterior descending artery	30	40	
Left circumflex artery	22	26	
Right coronary artery	45	30	
B2/C American College of Cardiology/American Heart Association lesion type, n	74	76	0.74
Chronic occlusions, n	6	6	1
Restenotic lesions, n	4	3	0.70
Lesion length, mm	13.0 ± 6.9	12.8 ± 5.7	0.81
Vessel size, mm	3.0 ± 0.6	3.0 ± 0.5	0.76
Diameter stenosis, %	61.5 ± 16.4	64.2 ± 17.3	0.26
Minimal lumen diameter, mm	1.2 ± 0.6	1.1 ± 0.6	0.34

*Data are mean ± SD or number of patients (%).

TABLE III. Procedural Data*

	Rough surface (n = 100)	Smooth surface (n = 100)	*P*
Administration of abciximab, n	39	41	0.77
Maximal balloon pressure, atm	13.5 ± 2.6	13.9 ± 2.9	0.27
Maximal balloon diameter, mm	3.4 ± 0.5	3.4 ± 0.5	0.89
Balloon-to-vessel ratio	1.2 ± 0.2	1.2 ± 0.1	0.66
Length of stented segment, mm	21.7 ± 9.9	21.5 ± 8.6	0.89
Final minimal lumen diameter, mm	2.9 ± 0.5	3.0 ± 0.5	0.65
Final diameter stenosis, %	5.7 ± 7.3	5.5 ± 8.6	0.89

*Data are mean ± SD or number of patients (%).

Table II, were also comparable between patients in the respective groups. The two study groups did not differ with respect to procedural data with almost identical final lumen diameter and final diameter stenosis (Table III).

Thirty-Day Outcome

No cases of stent thrombosis and death occurred in the two study groups. A myocardial infarction occurred in five patients in the rough-surface stent group and in three patients in the smooth-surface stent group ($P = 0.47$). No emergency bypass operation was performed in any of the study groups, while one patient in the smooth-surface group underwent urgent target vessel balloon angioplasty.

Angiographic Follow-Up

Follow-up coronary angiography was performed in 76 (76%) patients in the rough-surface group and 78 (78%) patients in the smooth-surface group ($P = 0.74$). The results of the quantitative measurements of coronary angiograms are reported in Table IV. Late lumen loss, the primary endpoint of the study, was 1.0 ± 0.7 mm in the rough-surface stent group and 1.2 ± 0.7 mm in the smooth stent surface group with a mean difference of −0.20 mm (95% CI = −0.43 to 0.02) between the two stent types ($P < 0.001$ from test for equivalence and $P = 0.08$ from test for superiority). Angiographic restenosis was found in 25% (19/76) of the patients in the rough-surface stent group and 35% (27/78) of the patients in the smooth-surface stent group (RR = 0.72; 95% CI = 0.44–1.18; $P = 0.19$; Fig. 2). Likewise, other quantitative measurements did not significantly differed between the two groups of patients, although, similar to the observed rates of angiographic restenosis, there was a trend in favor of the group of rough-surface stent.

One-Year Outcome

One-year follow-up data are presented in Table V. There were four deaths in the smooth-surface stent group and five deaths in the rough-surface stent group ($P = 0.73$). Myocardial infarction rates were also not different between the two study groups ($P = 0.47$). A TVR was performed in 21% of the patients in the rough-surface stent groups versus 23% of the patients in the smooth-surface stent group ($P = 0.86$). There were no differences between patients in the rough- and smooth-surface stent groups with respect to the rates of repeat PTCA and bypass surgery.

TABLE IV. Angiographic Data at Follow-Up*

	Rough surface (n = 76)	Smooth surface (n = 78)	P^a
Minimal lumen diameter, mm	2.0 ± 0.8	1.8 ± 0.8	0.18
Diameter stenosis, %	34.5 ± 3.7	40.5 ± 23.5	0.12
Late lumen loss, mm	1.0 ± 0.7	1.2 ± 0.7	0.08
Restenosis, n (%)	19 (25)	27 (35)	0.19

*Data are mean ± SD or number of patients (%).
[a]*P* values are generated from the superiority test.

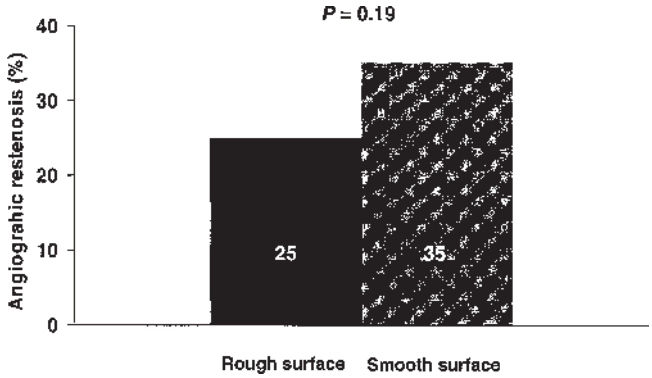

Fig. 2. The incidence of angiographic restenosis among patients in the rough- and smooth-surface stent groups.

DISCUSSION

Surface topography is considered to have an important influence on stent performance. While earlier experimental studies have suggested that stents with a smooth surface reduce thrombogenicity and neointimal proliferation, more recent data show that specially treated rough surfaces may accelerate stent endothelialization, a process that has been associated with less clot formation and neointimal growth after stent implantation. In a double-blind randomized trial, we compared for the first time a stent with rough surface with a stent with smooth surface. We found that the two studied stents were equivalent with respect to the late lumen loss. However, it should be noted that the observed difference favored the rough-surface stent. There was also a trend toward a reduced rate of angiographic restenosis with this stent. Both types of stents were associated with similar rates of thrombosis-related events. These data are important as a specially elaborated rough surface may increase the drug storage capacity of the stent.

This is the first clinical study specifically designed to evaluate the influence of stent surface topography on the outcomes of patients undergoing coronary stenting. Previous data on the relationship between surface topography and stent performance have been provided from experimental studies carried out in in vitro or animal models. Thus, de Scheerder et al. [16] found that stents with a smoothed surface by electrochemical polishing caused less clot formation compared to non-polished stents after implantation in a rat carotid arteriovenous shunt model. In the same study, when the two stent types were implanted in the right coronary arteries of healthy pigs, mural thrombi at 7 days were less frequently found among smooth-surface stents. In addition, at 6 weeks after implantation, neointimal hyperplasia decreased by 40% in smooth-surface stents compared to stents with a rougher surface [16]. More recently, in an in vitro model with fresh human whole blood, Tepe et al. [17] evaluated the thrombogenicity of different peripheral stent types. They reported that smoothing the stent surface clearly reduced their thrombogenicity [17]. Based on these data and some other experimental study, it has been suggested that a smooth surface can help prevent the activation and aggregation of platelets that lead to thrombus formation, reduce the local concentration of macrophages, and decrease neointimal hyperplasia of coronary stents [25–27]. These have constituted the rationale for recommending the use of stents with smooth surface to improve patients' outcomes.

Recent work, however, suggests that a rough surface may be associated with a more favorable timing of stent endothelialization. Thus, in an in vitro model, investigators found that creating surfaces with parallel microgrooves accelerated the migration rate of endothelial cells compared to smooth controls, suggesting a potential effect of grooved endovascular stent surfaces on faster endothelialization times [18]. This was confirmed in a more recent study in which stents with microscopic parallel grooves were placed in carotid arteries of pigs. The authors of this study reported that at 1 week after implantation, stents with grooved surfaces had a faster endothelialization rate than stents with smooth surfaces [19]. Rapid stent endothelialization has been shown to reduce in-stent thrombus and obstruction due to intimal thickening [21,22] Furthermore, delayed endothelialization has been associated with late adverse events among patients treated with different antiproliferative therapies [24,28,29].

The results of our study showed that a stent with a rough surface was as safe as a stent with a smooth sur-

TABLE V. Major Adverse Cardiac Events at 12-Month Follow-Up

	Rough surface (n = 100)	Smooth surface (n = 100)	*P*
Death, n	5	4	0.73
Myocardial infarction, n	5	3	0.47
Death or myocardial infarction, n	9	7	0.60
Target vessel revascularization	21	23	0.86
Repeat Percutaneous transluminal coronary angioplasty	21	22	1
Aortocoronary bypass surgery	1	1	1

face. Interestingly, there was even a difference, although not statistically significant, that favored the rough-surface stent with respect to angiographic restenosis. This finding could well be a play of chance. It may be, however, the product of the more favorable pattern of endothelialization with grooved-surface stents. In fact, while the postprocedural minimal lumen diameters were identical in the two stent groups in our study, late lumen loss was smaller among patients in the rough-surface stent group. It has been shown that microrough surfaces of metallic biomaterials result in a thinner tissue reaction layer, with less or absent inflammatory cells in comparison to smooth surfaces [30]. A recent study also found that stents with a rough ceramic-like iridium oxide coating had a significant reduction in neointimal thickening compared to smooth-surface stents in porcine coronary arteries [31].

In the era of drug-eluting stents, the data reported in this study are of particular interest because, while favorably influencing the endothelialization process, a rough surface may also increase the capacity of antirestenotic drug storage of the stent, which may obviate the need for polymer coating. The latter may often be associated with an inflammatory response [32].

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A. Schömig and A. Kastrati designed the study and contributed to the analysis and interpretation of the data. A. Dibra contributed to the analysis and interpretation of the data as well as wrote the first draft of the manuscript. J. Mehilli, J. Pache, R. von Oepen, and J. Dirschinger contributed to the analysis and interpretation of the data. All authors critically reviewed the manuscript for important intellectual content and approved its final version for submission.

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