

# Micro-Structured Stent Surfaces: Randomized Study

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**Original Title:**

Influence of Stent Surface Topography on the Outcomes of Patients Undergoing Coronary Stenting

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**STUDY DESIGN:**

A randomized double blind study designed on the relationship between the stent surface topography and outcome of patients undergoing implantation of stents with rough and smooth surface. A total of 200 patients with significant stenosis in native coronary vessels, excluding the left main trunk, acute myocardial infarction and in-stent restenosis, were randomized to receive either a rough (n=100) or a smooth-surface stent (n=100).

**Baseline demographic and clinical characteristics of the study patients**

Characteristic	Rough surface (n=100)	Smooth surface (n=100)	P
Age (yrs)	67,3±10,3	66,8±10,8	0,76
Women, n	22	29	0,26
Diabetes mellitus, 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
Prior MI, n	34	34	1
Prior CABG, n	5	8	0,40

**Baseline angiographic characteristics of the study patients**

Characteristic	Rough surface (n=100)	Smooth surface (n=100)	P
Vessel size, mm	3,0±0,6	3,0±0,5	0,76
Lesion length, mm	13,0±6,9	12,8±5,7	0,81
Minimal lumen diameter before procedure, mm	1,2±0,6	1,1±0,6	0,34
Diameter stenosis before procedure, %	61,5±16,4	64,2±17,3	0,26

**STUDY ENDPOINTS:**

The primary endpoint of the study was late lumen loss at 6 months follow-up angiography. Secondary endpoints were angiographic restenosis and clinical outcomes (TVR, combined rate of death or MI) during one-year follow-up.

## RESULTS:

### Angiographic outcomes:

Follow-up angiography was performed in 76 (76%) patients in the rough-surface group and in 78 (78%) patients in the smooth-surface group (P=0,74). With respect to primary end point analysis late lumen loss was 1,0±0,7 mm in the rough-surface group and 1,2±0,7 in the smooth-surface group with the mean difference of -0,20 mm (95% CI = -0,43 to 0,02) between two stent types (P<0,001 from test for equivalence and P = 0,08 from test for superiority). Angiographic restenosis was found in 19 (25%) of the patients in the rough-surface group and in 27 (35%) of patients in smooth-surface stent group (P=0,19).

### Angiographic data at follow-up

Characteristic	Rough surface (n=76)	Smooth surface (n=78)	P
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
Angiographic restenosis, n (%)	19 (25)	27 (35)	0,19

### Clinical outcomes:

#### During the first 30 days after randomization

Result	Rough surface (n=100)	Smooth surface (n=100)	P
Thrombotic stent occlusion, %	0	0	1
Death of myocardial infarction, %	5	3	0,47

#### During 1 year after randomization

Result	Rough surface (n=100)	Smooth surface (n=100)	P
Death + myocardial infarction, %	9	7	0,60
Target lesion revascularization, %	21	23	0,86
Repeat PTCA, %	21	21	1
Aortocoronary bypass surgery, %	1	1	1

## CONCLUSION:

The results of this study showed that the rough and smooth-surface stents were equivalent with respect to the late lumen loss. There was also a trend toward a reduced rate of angiographic restenosis with rough-surface stent. Both stent types were associated with similar rates of thrombosis-related events indicating that rough-surface stent was as safe as stent with a smooth surface. These data are important as a specially elaborated rough surface may increase the drug storage capacity of the stent, which may obviate the need for polymer coating.