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Simultaneous Kissing Stents (SKS) Technique for Treating Bifurcation Lesions in Medium-to-Large Size Coronary Arteries

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The treatment of bifurcation lesions (BLs) is associated with high procedural complication and restenosis rates. Two techniques of BL interventions were compared: the simultaneous kissing stents (SKS) technique, involving 2 stents, 1 in the main vessel and 1 in the side branch (n = 100), and the conventional stent strategy (CSS) technique, involving a stent in the main vessel and provisional stenting for the side branch (n = 100). In-hospital and 30-day major adverse cardiac events were greater in the CSS group, with significantly less procedure time with the SKS technique. The incidence of target lesion revascularization was 5% in the SKS group and 18% in the CSS group (p = 0.007). Therefore, the SKS technique seems to be rapid, safe, and effective for the treatment of medium- to large-size BLs, with a trend toward fewer acute complications and promising mid-term results. ©2004 by Excerpta Medica, Inc.

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To overcome various technical issues in the treatment of patients with bifurcation lesions (BLs) in medium- to large-size coronary arteries, we propose a new, simple approach: the simultaneous kissing stents (SKS) technique, which involves the deployment of 2 appropriately sized stents for the main vessel and the side branch, with overlap of the 2 stents in the proximal segment of the main vessel, making a new carina proximally. Therefore, the SKS technique will obviate the need for recrossing the stent struts and prevent stent deformation, with guaranteed coverage of the side branch ostium. We compared the immediate and mid-term results of the SKS technique with those of the conventional stent strategy (CSS) technique of stenting the main vessel, with provisional stenting of the side branch, in BLs of medium- to large-size vessels.

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We analyzed all patients who underwent stenting of true de novo BLs (type D of the Duke classification, with >50% stenosis of the main vessel and the side branch in an inverted Y fashion) from July 2002 to June 2003 at Mount Sinai Hospital, New York, New York. The first 100 consecutive patients with BLs treated with the SKS technique were compared with a control group of 100 patients with BLs treated with the CSS technique, matched with regard to vessel type and side branch size (≥2.5 mm).

The CSS technique included balloon angioplasty, Cutting balloon (Scimed, Boston Scientific, Maple Grove, Minnesota) or Rotablator (Scimed, Boston Scientific) of the side branch with provisional stenting for suboptimal results, followed by angioplasty, Cutting balloon, or Rotablator of the main vessel, and then stenting of the main vessel, leaving behind the jailed wire in the side branch. In case of suboptimal angiographic results of the side branch, it was stented first ("T stent"), or if after the deployment of the main vessel stent, there was side branch compromise, the side branch was recrossed with the wire and repeat balloon angioplasty with or without stenting was done (reverse "T stent"). In these cases, final kissing balloon inflations were routinely performed.

The SKS technique (Figure 1) involves using 2 appropriately sized stents (1:1 stent-to-artery ratio), 1 for the main vessel and 1 for the side branch, with an overlap of the 2 stents in the proximal segment of the main vessel (stent sized 1:1 to the main vessel after the bifurcation). The proximal part of the main vessel should be able to accommodate the 2 stents, and its size should be approximately 2/3 of the aggregate diameter of the 2 stents (e.g., for 2 3.0-mm stents in the left anterior descending artery and the diagonal branch, the proximal main vessel size should be approximately 4 mm). Stent lengths were selected visu-

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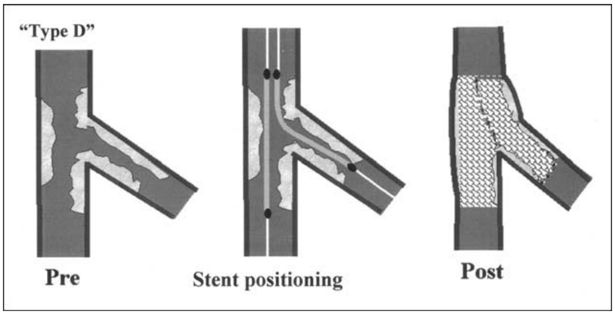

FIGURE 1. The SKS technique.

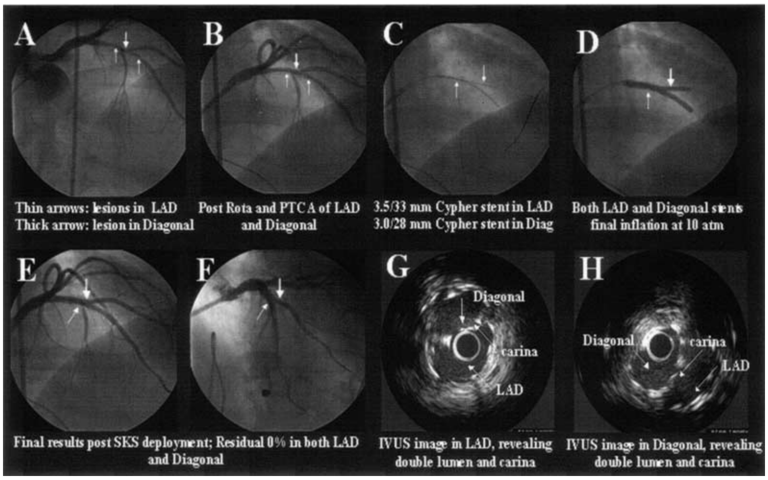

FIGURE 2. SKS technique for a BL involving the left anterior descending artery (LAD) and the diagonal. *(A to F)* Angiographic views; *(G, H)* intravascular ultrasound (IVUS) images revealing double lumen and carina. PTCA = percutaneous transluminal coronary angioplasty.

TABLE 1 Baseline Clinical Characteristics

Variable	CSS Technique (n = 100)	SKS Technique (n = 100)	p Value
Age (yrs)	67 ± 10	66 ± 12	0.42
Men	73	72	0.88
Diabetes mellitus	29	32	0.65
Hypertension	68	74	0.35
Low-density lipoproteins >100 mg/dl	38	36	0.77
Presenting symptom			
Asymptomatic or stable angina pectoris	30	36	0.37
Unstable angina pectoris	58	55	0.67
Acute myocardial infarction	12	9	0.49
Previous myocardial infarction	22	16	0.28
Previous coronary bypass surgery	12	13	0.89
Left ventricular ejection fraction	44 ± 8	46 ± 6	0.23
Multivessel coronary disease	62	68	0.39
Glycoprotein IIb/IIIa inhibitor use	84	83	0.85
Clopidogrel (>6 h before the procedure)	6	5	0.76
Previous statin therapy	68	72	0.54
Previous β-blocker therapy	52	48	0.57
Bifurcation coronary lesion location			
LM/LAD/LCx/right	14/57/13/16	14/57/13/16	

LM = left main; LAD = left anterior descending; LCx = left circumflex.

ally to cover the entire length from the distal end of the side branch and main vessel lesions to the proximal end in the main vessel. A 7Fr or 8Fr guide catheter (internal diameter >0.78 in) was used. The main vessel and the side branch were wired, and debulking using a cutting balloon or Rotablator with or without balloon angioplasty of the main vessel and side branch was performed as clinically indicated. Then, 2 stents were advanced 1 by 1, initially to the side branch followed by 1 to the main vessel. After this step, the 2 stents were pulled simultaneously back to the bifurcation, making a V, and then into the proximal part of the main vessel to configure a Y, with the stem of the Y in the main vessel completely covering the proximal end of the lesion, 1 arm of the the Y in the distal main vessel (covering the distal end of the main vessel lesion) and another arm in the side branch (covering the distal end of the side branch lesions). Once the position of the stents was confirmed and proximal stent markers were overlapped, the stents were deployed with simultaneous inflation and deflation at 10 to 12 atm for 10 to 20 seconds (Figure 2). In case of any stent underexpansion, a second dilation was done at greater pressure to fully expand the stent struts while the other stent balloon remained deflated in the other stent. This was followed by the third (and final) simultaneous inflation and deflation, at 10 to 12 atm. Deflated stent balloons were withdrawn simultaneously. In cases of stent underexpansion, 2 high-pressure balloons of similar length (but possibly of different sizes) were advanced for the simultaneous kissing balloon dilations. Intravascular ultrasound was done in selected patients to understand the mechanisms of luminal enlargement, stent expansion, and new carina formation (Figure 2). Other distal lesions not involving the bifurcation were treated before the SKS technique.

Angiographic success was defined as <30% residual diameter stenosis. Clinical success was defined as angiographic success of ≥1 lesion, without any ischemic complication of myocardial infarction (Q-wave or non–Q-wave), urgent revascularization, or death during hospital admission. Non–Q-wave myocardial infarction was defined as an increase in the MB isoenzyme of creatine kinase to >5 times the upper limit of normal in the hospital and >3 times the upper limit of normal after discharge. Major adverse cardiac events at 30 days were defined as death, myocardial infarction, or repeat revascularization of the target lesion. Stent thrombosis was defined as the occurrence of sudden death, clinical symptoms of infarction as-

TABLE 2 Procedural and Angiographic Characteristics

Variable	CSS Technique (n = 100)	SKS Technique (n = 101)	p Value
Main vessel			
Reference vessel size (mm)	3.48 ± 0.42	3.46 ± 0.61	0.24
Minimum luminal diameter (mm)	0.84 ± 0.51	0.81 ± 0.42	0.58
Lesion length (mm)	14.2 ± 6.2	15.4 ± 4.2	0.22
Debulking (%)	38	24	0.04
Rotablator	34	21	—
Cutting balloon	4	3	—
Stenting	100	100	—
Maximal inflation pressure (atm)	18 ± 4	13 ± 3	0.01
Side branch			
Reference vessel size (mm)	2.65 ± 0.32	2.66 ± 0.42	0.22
Minimum luminal diameter (mm)	0.72 ± 0.42	0.68 ± 0.32	0.42
Lesion length (mm)	8.2 ± 4.4	10.1 ± 2.2	0.13
Debulking	44	56	0.09
Rotablator	6	4	—
Cutting balloon	38	52	—
Stenting	32	100	—
Maximal inflation pressure (atm)	15 ± 3	11 ± 2	<0.01
Total number of stents for BL	144	202	—
Drug-eluting stents	34	38	0.55
Total stent length (mm)	26 ± 10	42 ± 8	<0.001
Additional lesion intervention	18	16	0.71
In the same vessel	14	14	1.0
In the remote vessel	4	2	0.41
Total procedure time (min)	62 ± 18	32 ± 12	<0.001

TABLE 3 Procedural, In-hospital, and 30-day Results

Variable	CSS Technique (n = 100; 100 Lesions)	SKS Technique (n = 100; 101 Lesions)	p Value
Procedural success			
Main vessel	100	100	0.98
Side branch	92	99	0.02
Dissections requiring coronary angioplasty only	4	6	0.52
Dissections requiring stent	14	0	<0.001
Coronary perforation	1*	1*	0.98
Postprocedural residual stenosis (%)			
Main vessel: proximal	12 ± 5	0 ± −3	<0.001
Main vessel: distal	8 ± 6	15 ± 5	0.01
Side branch	24 ± 16	8 ± 8	<0.01
Periprocedural myocardial infarction	6	1	0.05
Q-wave	1	0	—
Non–Q-wave	5	1	—
Clinical success	94	98	0.15
In-hospital major adverse cardiac events	6	1	0.05
30-d major adverse cardiac events	9	3	0.07
Stent thrombosis at 30 d	2†	1‡	0.56
Hospital stay (d)	2.2 ± 0.6	1.8 ± 0.6	0.03

*Type II perforations and sealed by prolonged balloon dilation.
†Both in the side branch stent.
‡Involving nonbifurcation stent.

sociated with electrocardiographic changes, or chest pain with an increase of >3 times the normal value of the MB isoenzyme of creatine kinase out of the catheterization laboratory ≤30 days after the procedure. Target lesion revascularization was defined as repeat coronary intervention of the target lesions by repeat percutaneous coronary intervention or coronary artery bypass grafting at follow-up. Coronary dissections were graded as per National Heart, Lung, and Blood Institute classifications: A (intraluminal opacity), B (parallel tracks without stasis), C (parallel tracks with stasis), and D (spiral dissection). Types A and B were considered minor dissections. Perforations were classified as type II (pericardial or myocardial blush without jet extravasation) and type III (frank perforation).

All patients were monitored for any postprocedural events of chest pain, heart failure, bleeding, or any ischemic events. The MB isoenzyme of creatine kinase and troponin I were measured at 6 to 8 and 12 to 24 hours after the procedure. All patients received aspirin 325 mg/day orally for 1 month, which was then reduced to 81 mg/day orally, and a clopidogrel 300 mg loading dose followed by 75 mg/day orally for 9 to 12 months.

All patients were contacted at 1, 3, 6, and 12 months after the procedure, and clinical events of death, myocardial infarction, and target lesion revascularization were recorded. All patients had a minimum clinical follow-up of 6 months. Repeat coronary angiography was encouraged at follow-up and analyzed for any angiographic restenosis (34% in the CSS group and 44% in the SKS group had clinically indicated follow-up angiograms 3 to 12 months after intervention).

The data were entered in a spreadsheet program (Excel, Microsoft, Redmond, Washington) and transferred to a statistical program for analysis. Data are presented as numbers or percentages for categorical variables and means ± SDs for continuous variables. Groups were compared using the chi-square test or Fisher's exact test for categorical variables and Student's *t* test for continuous variables. Important univariate variables with p values <0.1 were used for multivariate regression analysis to evaluate the independent predictors of target lesion revascularization, and values were expressed as odds ratios (ORs) and 95% confidence intervals (CIs). A p value <0.05 was considered significant.

TABLE 4 Midterm Follow-up Results (Minimum >6 months after intervention)

Variable	CSS Technique (n = 100)	SKS Technique (n = 100)	p Value
Follow-up duration (mo)	9.4 ± 3.2	8.8 ± 2.6	—
Death	2	2	1.0
Myocardial infarction	10	4	0.09
Q-wave	2	1	—
Non–Q-wave	8	3	—
Late stent thrombosis >1 mo	0	0	—
On dual-antiplatelet therapy	88	92	0.35
Target lesion revascularization	18	5*	0.004
Main vessel only	2	0	—
Side branch only	10	2	—
Both	6	2	—
Coronary artery bypass surgery	5	1	0.09
Freedom from major adverse cardiac events	78	90	0.02

*No restenosis in drug-eluting stents.

We analyzed 100 consecutive patients who underwent the SKS technique for 101 BLs and compared them with a lesion-matched control group of 100 patients with 100 BLs who underwent CSS treatment. Baseline clinical and angiographic data are listed in Table 1. Abciximab was used in 80% of cases. Procedural characteristics of the study are listed in Table 2. The incidence of debulking was greater for the main vessel with the CSS technique (rotational atherectomy) and greater for the side branch with the SKS technique (cutting balloon). The use of drug-eluting stents (in approximately 36%) was not different between the 2 groups. Procedural success was greater for the side branch with the SKS technique than with the CSS technique ($p = 0.02$) (Table 3). Final kissing balloon dilations were performed in 88% of the CSS group, and additional kissing balloon dilation after the SKS technique was required in 3 patients. There were no urgent bypass surgeries or deaths. In-hospital and 30-day major adverse cardiac events were greater in the CSS group than in the SKS group, largely because of more non–Q-wave myocardial infarctions. At follow-up of approximately 9 months (Table 4), the incidence of additional myocardial infarctions and death was similar in the 2 groups, with significantly less target lesion revascularization (5% vs 18%, $p = 0.004$) and greater event-free survival (90% vs 78%, $p = 0.02$) in the SKS group than in the CSS group, respectively. Further analysis of patients with BLs who received drug-eluting stents revealed target lesion revascularization of 6% in the CSS group and none in the SKS group ($p = 0.04$). In the SKS group, there were no cases of stent thrombosis, subacute or late, despite the discontinuation of clopidogrel in 8 patients 2 to 16 weeks after stent deployment. Multivariate predictors of target lesion revascularization were diabetes mellitus (OR 2.3, 95% CI 1.5 to 2.9), CSS technique (OR 3.2, 95% CI 1.4 to 5.1), and the use of non–drug-eluting stents (OR 4.5, 95% CI 2.2 to 6.6).

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The present study of SKS deployment describes a simple technique for the treatment of patients with true BLs in medium- to large-size vessels involving the creation of a new carina and the maintenance of the normal geometry of bifurcation and full stent coverage of the BLs (including the side branch ostium), without any stent crushing or deformation. The SKS technique, compared with the standard technique for BLs of stenting the main vessel with provisional stenting of the side branch, was associated with a trend toward fewer in-hospital major adverse cardiac events and less restenosis. The SKS technique was associated with greater procedural success of the side branch, with less postprocedural residual stenosis and with less procedure time, largely by obviating the need for recrossing the stent and additional kissing balloon dilation. Traditionally, the CSS technique (a stent in the main vessel with provisional stenting of the side branch) has been shown to have the best acute results and a lower restenosis rate in treatment of patients with BLs compared with the use of 2 stents (1 in the main vessel and 1 in the side branch), even with drug-eluting stents.[1–10] Among various newer BL intervention techniques (dedicated bifurcation, "culotte," "crush T stent," or SKS techniques), preliminary results are most encouraging with the SKS technique.[11–14]

Although the SKS technique has obvious advantages, the main limitation of the present study is the lack of routine angiographic follow-up, but all patients were followed clinically in groups, and follow-up angiograms >3 months after the procedure were available in approximately 40% of cases. Another limitation is the study's retrospective nature and matching process, based on vessel type, side branch size, and the use of drug-eluting stents in only 1/3 of cases (because of their availability only since April 2003), although there was no statistically significant difference between the 2 groups. Recrossing the carina using a J-tip guidewire can easily be performed, and devices such as balloons or stents can be advanced distally. In this study, recrossing the carina at a later date for restenosis treatment did not pose any problem. Although these results seem encouraging, long-term data are needed to address the issues of thrombosis and the feasibility of recrossing the carina at a later date, in case restenosis occurs or new lesions develop distally to the bifurcation. The chances of coronary perforation or proximal dissection can be significantly reduced by avoiding high-pressure inflations and using appropriate debulking techniques in calcified lesions. If any of these still occur, prolonged dilation with 2 balloons proximally and/or 2 stents extending the proximal carina in the main vessel is recommended.

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Comparison of Acute and Long-Term Results and Underlying Mechanisms from Sirolimus-Eluting Stent Implantation for the Treatment of In-Stent Restenosis and Recurrent In-Stent Restenosis in Patients in Whom Intracoronary Radiation Failed as Assessed by Intravascular Ultrasound

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In-stent restenosis (ISR), especially after vascular brachytherapy, is a therapeutic challenge. Sirolimus-eluting stent implantation is a promising new option for the treatment of patients with ISR. The efficacy of sirolimus-eluting stent implantation for the treatment of patients with their first episodes of ISR and with recurrent ISR due to the failure of vascular brachytherapy was compared using intravascular ultrasound imaging. ©2004 by Excerpta Medica, Inc.

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Despite significant progress in its prevention and treatment, in-stent restenosis (ISR) remains a challenge for interventional cardiologists. Various interventional techniques have not yielded satisfactory long-term outcomes.[1–5] To date, only vascular brachytherapy (VB) has convincingly been shown to reduce the incidence of repeat restenosis and major adverse cardiovascular events by approximately 50% and therefore has emerged as the gold standard for the treatment of patients with ISR.[6–9] However, VB is not without failure. Depending on lesion complexity and the clinical situation, approximately 20% of patients again require target vessel revascularization. Repeat irradiation has been proposed as a treatment option, but again, recurrent revascularization has been necessary in about 25% of patients.[10] The use of sirolimus-eluting stents might be a valuable alternative. Their potential to reduce neointima formation in de novo lesions has been demonstrated in randomized clinical trials.[11–14] For the treatment of patients with ISR, preliminary data are promising. Two pilot trials using sirolimus-eluting stents showed very favorable results.[15,16] However, no data exist regarding the efficacy of sirolimus-eluting stents for recurrent ISR due to VB failure. Thus, the aim of our study was to compare, using intravascular ultrasound (IVUS), the acute and long-term changes in vessel morphology after sirolimus-eluting stent implantation for the treatment of patients with their first episodes of ISR and patients with recurrent ISR due to the failure of VB.

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