

Comparison of Double Kissing Crush Versus Culotte Stenting for Unprotected Distal Left Main Bifurcation Lesions

Results From a Multicenter, Randomized, Prospective DKCRUSH-III Study

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Objectives	The study aimed to investigate the difference in major adverse cardiac event (MACE) at 1-year after double kissing (DK) crush versus Culotte stenting for unprotected left main coronary artery (UPLMCA) distal bifurcation lesions.
Background	DK crush and Culotte stenting were reported to be effective for treatment of coronary bifurcation lesions. However, their comparative performance in UPLMCA bifurcation lesions is not known.
Methods	A total of 419 patients with UPLMCA bifurcation lesions were randomly assigned to DK (n = 210) or Culotte (n = 209) treatment. The primary endpoint was the occurrence of a MACE at 1 year, including cardiac death, myocardial infarction, and target vessel revascularization (TVR). In-stent restenosis (ISR) at 8 months was secondary endpoint, and stent thrombosis (ST) served as a safety endpoint. Patients were stratified by SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) and NERS (New Risk Stratification) scores.
Results	Patients in the Culotte group had significant higher 1-year MACE rate (16.3%), mainly driven by increased TVR (11.0%), compared with the DK group (6.2% and 4.3%, respectively; all p < 0.05). ISR rate in side branch was 12.6% in the Culotte group and 6.8% in the DK group (p = 0.037). Definite ST rate was 1.0% in the Culotte group and 0% in the DK group (p = 0.248). Among patients with bifurcation angle ≥70°, NERS score ≥20, and SYNTAX score ≥23, the 1-year MACE rate in the DK group (3.8%, 9.2%, and 7.1%, respectively) was significantly different to those in the Culotte group (16.5%, 20.4%, and 18.9%, respectively; all p < 0.05).
Conclusions	Culotte stenting for UPLMCA bifurcation lesions was associated with significantly increased MACEs, mainly due to the increased TVR. (Double Kissing [DK] Crush Versus Culotte Stenting for the Treatment of Unprotected Distal Left Main Bifurcation Lesions: DKCRUSH-III, a Multicenter Randomized Study Comparing Double-Stent Techniques; ChiCTR-TRC-00000151) (J Am Coll Cardiol 2013;61:1482-8) © 2013 by the American College of Cardiology Foundation

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Unprotected left main coronary artery (UPLMCA) patients with lower risk scores (1-4) or lesions that are ostial or midshaft (5,6) appear to have comparative outcomes after drug-eluting stent placement to the coronary artery bypass graft (CABG) (1-3). By contrast, distal UPLMCA bifurcation lesions are technically demanding, often requiring double stenting and resulting in less favorable long-term outcomes (3,5-8). Previous studies showed that double kissing (DK) crush and Culotte stenting were effective for coronary artery bifurcation lesions (9-12), but, their durability and safety have never been randomly compared. Thus, we designed this DKCRUSH (DK Crush Versus Culotte Stenting for the Treatment of Unprotected Distal Left Main Bifurcation Lesions)-III study aiming to analyze the difference in the MACE between DK crush versus Culotte stenting for UPLMCA distal bifurcation lesions.

Methods

Patient population and randomization. The DKCRUSH-III study was conducted in 18 centers. The protocol was approved by the ethics committee and institutional research board, and written consent was obtained from all patients.

Inclusion criteria were as follows: age ≥ 18 years, Medina (13) 1,1,1 or 0,1,1 de novo UPLMCA bifurcation lesions, and chronic total occlusion (2) in any parent vessel after successful recanalization. Clinical and angiographic exclusion criteria were demonstrated in Figure 1. Additional exclusion criteria included pregnancy, a platelet count $< 10 \times 10^9/l$ and suspected intolerance to 1 of the study drugs.

The participants were randomly assigned in a 1:1 ratio to either the DK or Culotte group.

Procedure and medications. DK crush and Culotte stenting techniques (Fig. 2) have been described previously (11,14). The candidate stents were Firebird-2 (Microport Co., Shanghai, China) and Xience V (Abbott Vascular, California).

A 300-mg loading dose of clopidogrel was administered before the index procedure. After the intervention, all patients received 100 mg/day aspirin for life and clopidogrel (75 mg/day) for at least 12 months.

Follow-up protocol. Clinical follow-up was performed with office visits or telephone contact at 1, 6, and 12 months. Follow-up coronary angiography was scheduled at 8 months after the index procedure unless clinical reasons indicated earlier.

Serial quantitative coronary analysis was analyzed according to our previous methods (14).

Study endpoints and definitions. The primary endpoint was the occurrence of 1-year major adverse cardiac event (MACE) rate, including myocardial infarction, cardiac death, and/or target vessel revascularization (TVR). Secondary endpoint was in-stent restenosis (ISR). Stent thrombosis (ST) served as a safety endpoint. ST, myocardial infarction, cardiac death, target lesion revascularization (TLR), and TVR were defined according to the Academic Research Consortium definition (15).

Abbreviations and Acronyms

- CABG** = coronary artery bypass graft
- DK** = double kissing
- ISR** = in-stent restenosis
- MACE** = major adverse cardiac event
- SB** = side branch
- ST** = stent thrombosis
- TLR** = target lesion revascularization
- TVR** = target vessel revascularization
- UPLMCA** = unprotected left main coronary artery

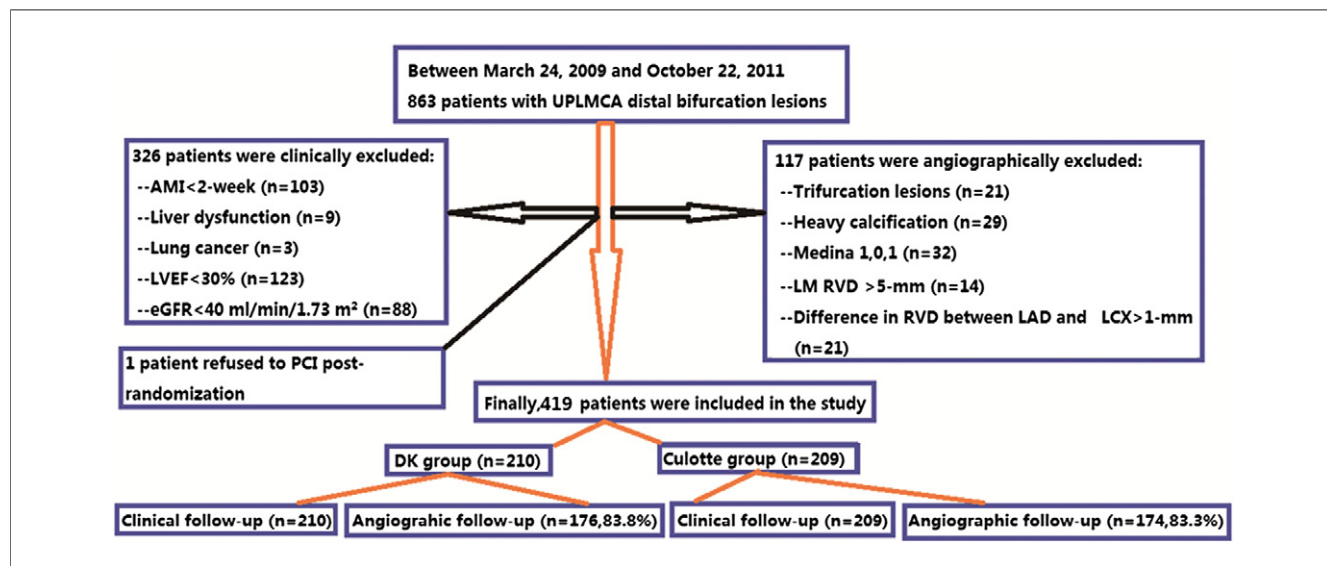


Figure 1 Flowchart of Study Design

AMI = acute myocardial infarction; DK = double kissing; eGFR = estimated glomerular filtration rate; LAD = left anterior descending artery; LCX = left circumflex artery; LM = left main artery; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; RVD = reference vessel diameter; UPLMCA = unprotected left main coronary artery.

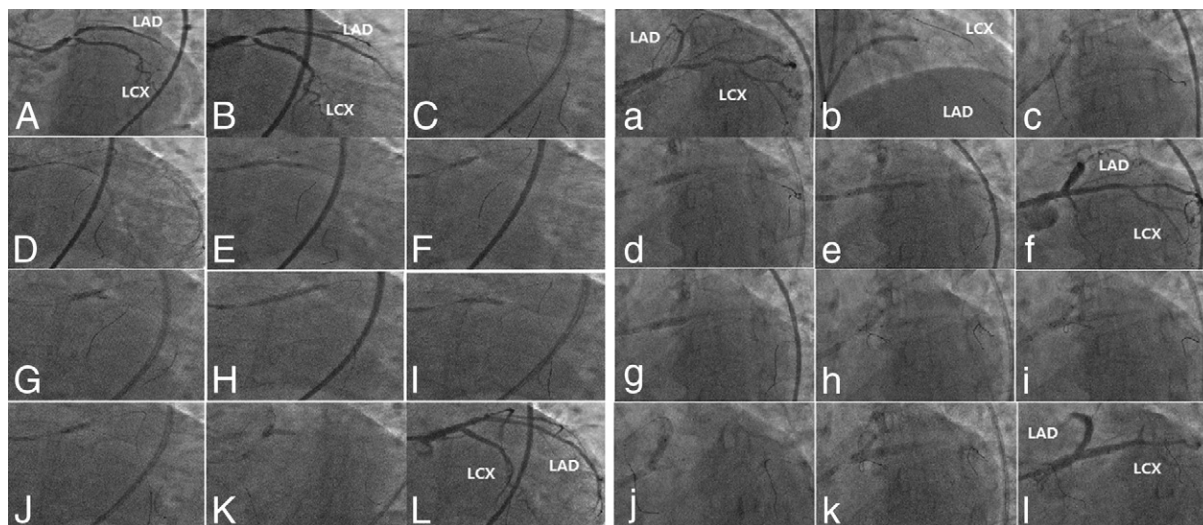


Figure 2 Schematic Description of DK Crush and Culotte Stenting Techniques via a Transfemoral Approach

For the double kissing (DK) crush technique, 2 injections (**A, B**) showed a Medina 1,1,1 distal left main (LM) bifurcation lesions; after pre-dilation using kissing balloon inflation (**C**) through a 6-F guiding catheter, a 2.5×23 mm Firebird-2 (Microport Co., Shanghai, China) stent (**D, E**) was inflated in the left circumflex artery (LCX) (with 1-mm protrusion into LM) and a 3.0×12 mm Sprinter balloon was positioned in the left anterior descending artery (LAD) (**D, E**); balloon crush was performed immediately after stenting LCX (**F**); a 2.5×15 -mm noncompliant balloon inflated by 16 atm was done after rewiring LCX, followed by fist kissing inflation (**G**); a 3.0×28 mm Firebird-2 stent was inflated crossover from LAD to LM (**H**); after rewiring LCX, sequential inflation by at least 16 atm started from LCX (**I**) then LAD (**J**) was performed, followed by final kissing balloon inflation (**K**). The final result was acceptable (**L**). For Culotte stenting, spider-view showed a Medina 1,1,1 distal left main bifurcation lesions (**a**); after pre-dilation, a 2.5×23 mm Xience stent (Abbott Vascular, California) was inflated in the LAD-LM (**b**) (LAD was treated as side branch); rewiring LCX and post-dilation for LAD stent was performed (**c**); opening LAD stent struts (**d**) facilitated the advancement of a 3.0×23 mm Xience stent into LCX (**e**), post-stenting LCX result was good but ostial LAD seemed to be compromised (**f**); alternative inflation at 16 atm using noncompliant balloon started from LCX (**g**) (3.0×12 mm NC Sprinter) then LAD (**h**) (2.5×12 mm NC Sprinter, because a 3.0 mm in diameter noncompliant balloon did not pass through the stent cell) was performed, followed by kissing inflation (**i**); then, a 3.0×12 mm NC Sprinter balloon was positioned in LAD, alternative inflation (**j**) in LAD was followed by final kissing balloon inflation (**k**). Final results were acceptable (**l**).

Sample size calculation and statistical analysis. We hypothesized that the rate of a 1-year MACE rate would be 5% in the DK crush and 15% in the Culotte groups. Accordingly, a total sample size of 358 was needed to detect a power of 0.8 (Type II error = 0.20, $\alpha = .05$, 2-tailed). Because of the considerable uncertainty, the enrollment was extended to 420 patients (15% increment). The treatment-group differences were evaluated with a student *t* test or Wilcoxon rank sum scores for continuous variables when appropriate. The chi-square test or the Fisher exact test was used to analyze categorical variables. Rate-free survival from events were generated by Kaplan-Meier analysis, and they were compared using the log-rank test. Four pre-specified subgroup analyses by Forest plot were planned to be performed. Statistical significance was taken as a *p* value <0.05. All analyses were performed with the statistical program SPSS version 16.0 (SPSS Institute Inc., Chicago, Illinois).

Results

Baseline and procedural characteristics. Baseline clinical (Table 1), lesions (Table 2), and procedural (Table 3) characteristics were well matched between 2 treatment groups. All continuous variables were normally distributed. **Clinical outcomes.** By 12-month follow-up, there were 34 (16.3%) composite MACEs in the Culotte group and 13

(6.2%) in the DK group (*p* = 0.001), mainly because of significantly increased TLR (6.7%) and TVR (11%) in the Culotte group (2.4%, *p* = 0.037) compared with the DK group (4.3%, *p* = 0.016) (Table 4, Figs. 3, 4, and 5). Among patients with distal bifurcation angle $\geq 70^\circ$, NERS (New Risk Stratification) score ≥ 20 and SYNTAX score ≥ 23 , the incidence of the composite MACE in the DK group was significantly lower than that in the Culotte group (Fig. 6).

Stent thrombosis. By 12 months, the incidence of definite ST was 1.0% (*n* = 2) in the Culotte group and 0% in the DK group (*p* = 0.623).

Quantitative coronary analysis. There were 12 (6.8%) ISR at side branch (SB) in the DK group and 22 (12.6%) in the Culotte group (*p* = 0.037), mostly seen at ostial SB (Table 5).

Discussion

The major finding was that Culotte stenting was associated with significantly increased 1-year composite MACE rate, mainly because of the increment of TVR rate.

For UPLMCA bifurcation lesions, single-stent strategy was superior to systematic double-stent (including V-stenting, kissing stenting) techniques (3-6). Actually, Culotte stenting is a reverse T stenting, by which intrapro-

	DK Group (n = 210)	Culotte Group (n = 209)	p Value
Male	162 (77.1)	167 (79.9)	0.552
Age, yrs	64.3 ± 10.3	63.3 ± 9.2	0.296
Body mass index, kg/m ²	24.63 ± 3.46	24.83 ± 3.20	0.314
Hypertension	148 (70.5)	128 (61.2)	0.055
Hyperlipidemia	87 (41.4)	88 (42.1)	0.921
Cholesterol, mmol/l	4.37 ± 1.05	4.36 ± 1.03	0.666
LDL, mmol/l	2.70 ± 0.82	2.69 ± 0.94	0.776
Diabetes	67 (31.9)	63 (30.1)	0.298
Fasting glucose, mmol/l	6.37 ± 3.35	6.31 ± 3.66	0.506
Smoking			0.914
Current smoking	58 (27.6)	54 (25.8)	
Quit smoking	37 (17.6)	37 (17.7)	
>2-week acute MI	18 (8.6)	12 (5.7)	0.344
Previous MI	32 (15.2)	29 (13.9)	0.258
Unstable angina	165 (78.6)	174 (83.3)	0.263
Stable angina	21 (10.0)	20 (9.6)	1.000
Silent ischemia	6 (2.9)	3 (1.4)	0.503
Previous PCI	47 (22.4)	31 (14.8)	0.059
LVEF, %	58.7 ± 11.3	58.8 ± 10.6	0.296
<40%	18 (8.6)	9 (4.3)	0.110
eGFR, ml/min/1.73 m ²	84.97 ± 21.89	83.39 ± 22.09	0.463
<40 ml/min	0 (0)	6 (2.9)	
40-59 ml/min	28 (13.3)	21 (10.0)	

Values are mean ± SD or n (%).

DK = double kissing; eGFR = estimated glomerular filtration rate; LDL = low-density lipoprotein; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.

cedural acute closure of the main vessel after stenting SB is unavoidable (14,16), this rate was 1% in the present study, which might be catastrophic for distal left main, as we showed that 1 patient died soon after LAD closure. In the ISAR-LEFT MAIN study (12), 98% of 384 patients with distal UPLMCA lesions were treated by Culotte stenting, the 1-year MACE (15.8%) and ISR (19.4%) in the cypher group were compared well with the current study (14.4% vs. 12.6%, respectively). Except for the limitation of the cypher stent design (close cell) for bifurcation lesions (17), we might be of great courage to postulate that the ISR rate would become significantly higher if distal bifurcation subgroup was analyzed in that study. Our finding, restenotic lesions are most localized in the SB, is consistent with the previous results (11,12). Thus, we have to say that DK crush is superior to Culotte stenting when bearing in mind that patients in the ISAR-LEFT MAIN study (12) were less at risk compared with the current study. Bench test (17) and intravascular ultrasound findings (18,19) reported that a “napkin” or a gap or a metallic ridge is usually seen at the ostial SB after Culotte stenting, leading to the failure to fully cover the ostial SB and resulting in increased ISR and TLR. In contrast, DK crush introduced 2 times of kissing balloon inflation, allowed the full coverage of ostial SB, resulting in less ISR (4,14).

The sustained durability of DK crush was demonstrated in patients at intermediate- and high-risk strati-

fied by either NERS or SYNTAX score. Furthermore, clinical efficacy of DK crush is also maintained in the patients with distal bifurcation angle ≥70°. The controversy of whether there is a correlation of bifurcation angle with worse outcome has existed for a long time (20). We postulate that the abnormal hemodynamic change of shear stress induced by Culotte stenting might play a central role in the occurrence of ISR.

For bifurcation lesions, a complex stenting approach has been an independent factor for ST (8,16), although there is no convinced data after stenting distal UPLMCA bifurcation lesions. Similar to ST rate (<1%) by the ISAR-LEFT MAIN trial (12), ST rate (1.0%) after Culotte stenting in the present study was slightly lower than the 1.9% reported by Erglis et al. (9) and 1.6% by Adriaenssens et al. (11). It might be plausible that both DK crush and culotte stenting techniques are safe for distal UPLMCA bifurcation lesions, and that optimizing the expansion of the SB stent, as did the DK crush technique, would have put patients at lower risk of ST.

	DK Group (n = 210)	Culotte Group (n = 209)	p Value
3-vessel disease	149 (71.3)	145 (69.5)	0.130
LAD	64 (30.5)	58 (27.6)	
LCX	36 (17.6)	45 (21.8)	
RCA	58 (27.6)	60 (28.7)	
Left main trunk			
Chronic total occlusion	1 (0.4)	0 (0)	0.653
Ostial	31 (15.2)	42 (20.4)	0.197
Midshaft	71 (34.8)	60 (28.7)	0.102
Whole trunk	45 (21.8)	39 (18.9)	0.159
Distal bifurcation			0.896
Medina 1,1,1	207 (98.7)	198 (94.8)	
Medina 0,1,1	3 (1.3)	11 (5.2)	
LAD*			
Severe tortuous	25 (11.9)	28 (13.4)	0.662
Mild-moderate calcification	30 (14.3)	30 (14.4)	1.000
Thrombus-containing	0 (0)	0 (0)	NS
Chronic total occlusion	10 (4.8)	12 (5.7)	0.209
TIMI flow grade 0-2	23 (10.9)	20 (9.6)	0.320
LCX*			
Severe tortuous	38 (18.1)	45 (21.5)	0.393
Mild-moderate calcification	19 (9.1)	20 (9.6)	0.786
Thrombus-containing	0 (0)	0	NS
Chronic total occlusion	9 (4.3)	12 (5.7)	0.512
TIMI flow grade 0-2	19 (9.1)	22 (10.5)	0.280
IVUS assessment	145 (69.0)	154 (73.7)	0.331
SYNTAX score (points)	30.67 ± 12.89	31.51 ± 15.60	0.254
0-22	69 (32.9)	54 (25.8)	0.462
NERS score (points)	26.03 ± 10.70	26.12 ± 10.55	0.677
<20	55 (26.2)	47 (22.5)	0.241

Values are n (%) or mean ± SD. *Left anterior descending artery (LAD) was treated as main branch in all patients, with exception for 3 in the DK group and 2 in the culotte group, for whom the left circumflex artery (LCX) was considered the main branch.

IVUS = intravascular ultrasound; NERS = New Risk Stratification; RCA = right coronary artery; SYNTAX = Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

Table 3 Procedural Characteristics			
	DK Group (n = 210)	Culotte Group (n = 209)	p Value
Transradial approach	122 (58.1)	123 (58.9)	0.976
IIb/IIIa used	35 (16.7)	39 (18.7)	0.834
Supported device			
IABP	6 (2.9)	7 (3.3)	0.860
Impella	3 (1.4)	3 (1.5)	0.989
Stent types			
Firebird-2	78 (37.1)	75 (35.9)	0.703
Xience V	132 (62.9)	134 (64.1)	
Post-dilation			
Main vessel	205 (97.6)	200 (95.7)	0.693
Side branch	202 (96.2)	200 (95.7)	0.810
FKBI	209 (99.5)	208 (99.5)	1.000
Main vessel stent			
n	1.38 ± 0.45	1.39 ± 0.49	0.556
Diameter, mm	3.40 ± 0.34	3.34 ± 0.40	0.106
Length, mm	33.48 ± 14.01	35.74 ± 15.99	0.124
Side branch stent			
n	1.20 ± 0.39	1.14 ± 0.35	0.159
Diameter, mm	3.04 ± 0.41	3.03 ± 0.41	0.587
Length, mm	25.90 ± 13.83	26.72 ± 11.86	0.519
Angiographic success	204 (97.1)	208 (99.5)	0.122
Complete revascularization	201 (95.7)	201 (96.2)	0.755
Procedural time, min	56.88 ± 33.11	54.87 ± 32.09	0.529
Fluoroscopy time, min	26.57 ± 14.39	27.66 ± 17.53	0.487
Contrast volume, ml	184.40 ± 22.01	170.10 ± 7.22	0.048
Non-left main lesions			
Stent number	1.41 ± 0.73	1.26 ± 0.53	0.410
Stent diameter, mm	2.89 ± 0.42	2.99 ± 0.46	0.468
Stent length, mm	36.86 ± 27.33	32.33 ± 15.34	0.468

Values are n (%) or mean ± SD.
 FKBI = final kissing balloon inflation; IABP = intra-aortic balloon pump; other abbreviations as in Table 1.

Table 4 Clinical Follow-Up			
	DK Group (n = 210)	Culotte Group (n = 209)	p Value
In-hospital			
In-hospital days	6.58 ± 4.31	7.19 ± 3.94	0.134
Composite MACE	7 (3.3)	8 (3.8)	0.800
Cardiac death	1 (0.5)	1 (0.5)	1.000
MI	7 (3.3)	8 (3.8)	0.800
TLR	0 (0)	0 (0)	NS
TVR	0 (0)	0 (0)	NS
CABG	0 (0)	0 (0)	NS
Stent thrombosis	0 (0)	0 (0)	NS
Procedural success	203 (96.7)	201 (96.2)	0.800
At 1 month			
Composite MACE	7 (3.3)	9 (4.3)	0.622
Cardiac death	1 (0.5)	1 (0.5)	1.000
MI	7 (3.3)	9 (4.3)	0.622
TLR	0 (0)	1 (0.5)	0.499
TVR	0 (0)	1 (0.5)	0.499
CABG	0 (0)	0 (0)	NS
Stent thrombosis	0 (0)	1 (0.5)	0.499
Definite	0 (0)	1 (0.5)	0.499
Probable	0 (0)	0 (0)	NS
At 12 months			
Composite MACE	13 (6.2)	34 (16.3)	0.001
Cardiac death	2 (1.0)	2 (1.0)	1.000
MI	7 (3.3)	11 (5.3)	0.377
TLR	5 (2.4)	14 (6.7)	0.037
TVR	9 (4.3)	23 (11.0)	0.016
For LAD	0 (0)	4 (1.9)	0.061
For LCX	1 (0.5)	2 (1.0)	0.623
For left main	9 (4.3)	20 (9.6)	0.036
CABG	2 (1.0)	0 (0)	0.499
Stent thrombosis	1 (0.5)	2 (1.0)	0.623
Definite	0 (0)	2 (1.0)	0.248
Probable	0 (0)	0 (0)	NS
Possible	1 (0.5)	0 (0)	1.000

Values are mean ± SD or n (%).
 CABG = coronary artery bypass graft; MACE = major adverse cardiac event; NS = not significant; TLR = target lesion revascularization; TVR = target vessel revascularization; other abbreviations as in Tables 1 and 2.

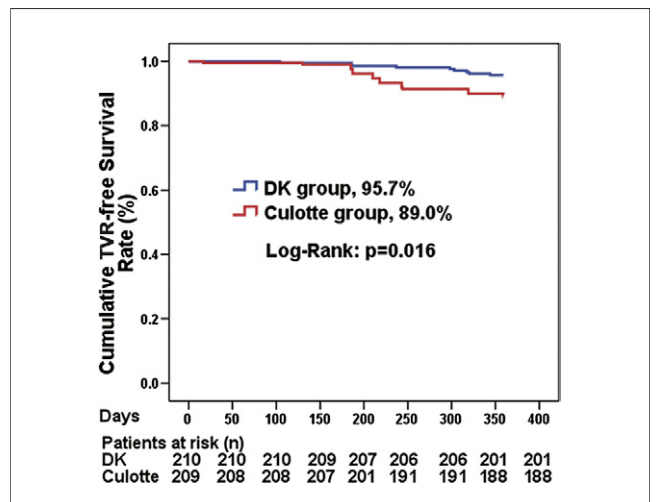
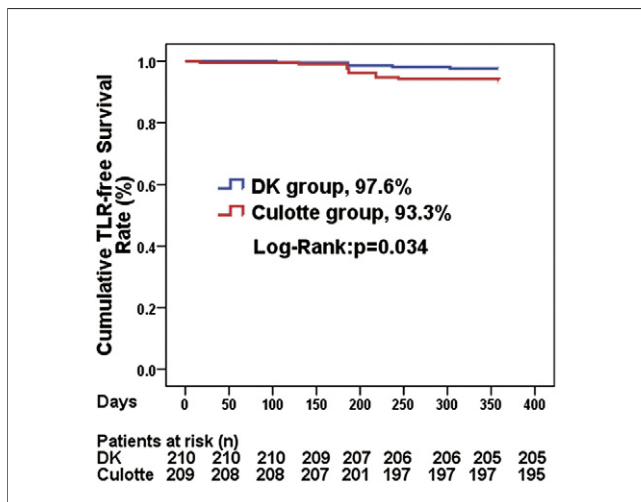


Figure 3 TLR-Free Survival Rate at 12 Months
 Rate was 93.3% in the Culotte group, and 97.6% in the double kissing (DK) group (p = 0.034). TLR = target lesion revascularization.

Figure 4 TVR-Free Survival Rate at 12 Months
 Rate was 89.0% in the Culotte group, and it was 95.7% in the double kissing (DK) group (p = 0.016). TVR = target vessel revascularization.

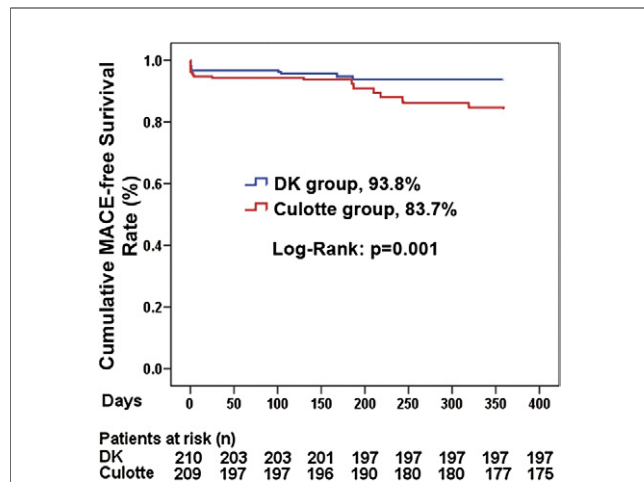


Figure 5 MACE-Free Survival Rate at 12 Months

Rate was 83.7% in the Culotte group, and it was 93.8% in the double kissing (DK) group (p = 0.001). MACE = major adverse cardiac event.

Study limitations. Some kind of angle restriction should have been applied in the design of the study. We did not include a CABG group to contrast with the stenting techniques. However, the promising results achieved by the DK crush technique were comparable with those after CABG. Finally, the results were achieved in very high-volume operators performing these procedures. It remains unclear whether lower volume centers could reproduce these results.

Conclusions

Compared to the DK crush technique, Culotte stenting is associated with significantly increased MACEs in patients with UPLMCA bifurcation lesions.

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Table 5 Quantitative Coronary Analysis for Main Vessel and Side Branch			
	DK Group (n = 176)	Culotte Group (n = 174)	p Value
Days from indexed procedure	223.0 ± 15.3	211.9 ± 14.1	0.109
Left main trunk			
Lesion length, mm	6.36 ± 3.69	6.97 ± 3.86	0.100
Minimal lumen diameter, mm			
Prior stenting	1.47 ± 0.43	1.49 ± 0.42	0.719
Acute gain	2.34 ± 0.47	2.34 ± 0.49	0.980
Late loss	0.18 ± 0.29	0.23 ± 0.34	0.378
Diameter stenosis			
Prior stenting	59.84 ± 9.35	59.18 ± 8.47	0.772
Follow-up	11.08 ± 7.24	11.81 ± 6.83	0.401
Restenosis	0	0	NS
LAD*			
Lesion length, mm	16.67 ± 9.23	18.65 ± 12.26	0.067
Minimal lumen diameter, mm			
Prior stenting	1.09 ± 0.42	1.07 ± 0.44	0.984
Acute gain	1.79 ± 0.41	1.79 ± 0.42	0.988
Late loss	0.19 ± 0.32	0.20 ± 0.33	0.938
Diameter stenosis			
Prior stenting	64.62 ± 5.66	65.69 ± 6.46	0.414
Follow-up	16.15 ± 8.33	15.41 ± 7.10	0.622
Restenosis	2 (1.14)	1 (0.57)	1.000
LCX*			
Lesion length, mm	16.48 ± 11.09	16.97 ± 13.01	0.804
Minimal lumen diameter, mm			
Prior stenting	1.01 ± 0.43	1.07 ± 0.49	0.990
Acute gain	1.58 ± 0.43	1.58 ± 0.49	
Late loss			
In-stent	0.20 ± 0.30	0.39 ± 0.36	0.001
In-segment	0.09 ± 0.21	0.21 ± 0.30	0.048
Diameter stenosis			
Prior stenting	65.29 ± 7.34	63.36 ± 7.75	0.640
Follow-up	16.39 ± 7.45	25.50 ± 7.36	0.001
Restenosis	12 (6.82)	22 (12.64)	0.037
In-segment	4 (2.27)	6 (3.45)	0.540
In-stent	9 (5.11)	19 (10.92)	0.034
Ostial	9 (5.11)	16 (9.19)	0.045

Values are mean ± SD or n (%). *LAD was treated as main vessel in all patients, with exception for 2 in the DK group and 1 in the Culotte group, for whom LCX was considered as main vessel. Abbreviations as in Tables 1 and 2.

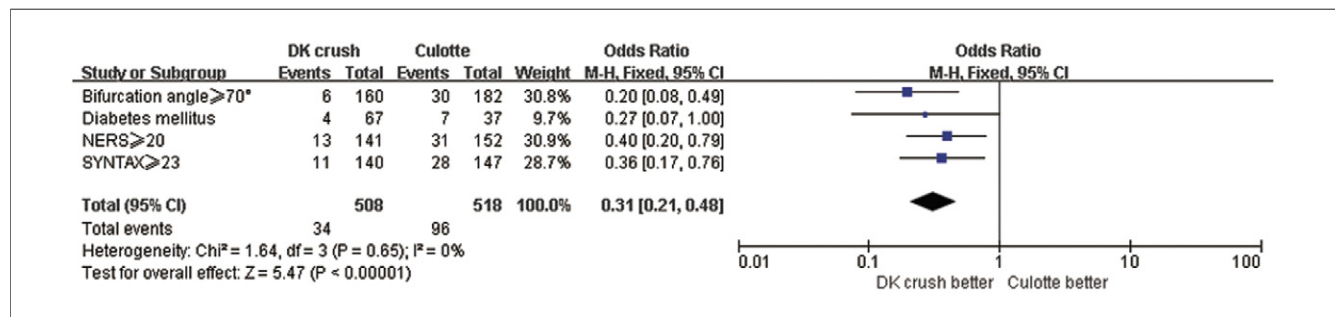


Figure 6 Forest Plots of 1-Year MACE Rate in Pre-Specified Subgroups

Among patients with distal bifurcation angle ≥70°, NERS (New Risk Stratification) score ≥20, and SYNTAX (Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) ≥23, the incidence of the composite major adverse cardiac events (MACE) (3.8%, 9.2%, and 7.1%) in the double kissing (DK) group was significantly different to 16.5% (p < 0.001), 20.4% (p = 0.014), and 18.9% (p = 0.006) in the Culotte group, respectively. CI = confidence interval; M-H = Mantel-Haenszel.

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REFERENCES

1. Morice MC, Feldman TE, Mack MJ, et al. Angiographic outcomes following stenting or coronary artery bypass surgery of the left main coronary artery: fifteen-month outcomes from the synergy between PCI with TAXUS express and cardiac surgery left main angiographic substudy (SYNTAX-LE MANS). *EuroIntervention* 2011;7:670-9.
2. Serruys PW, Morice MC, Kappetein P, et al., for the SYNTAX Investigators. Percutaneous coronary intervention versus coronary artery bypass grafting for severe coronary artery disease. *N Engl J Med* 2009;360:961-72.
3. Salvatella N, Morice MC, Darremont O, et al. Unprotected left main stenting with a second-generation drug-eluting stent: one-year outcomes of the LEMAX Pilot study. *EuroIntervention* 2011;7:689-96.
4. Chen SL, Chen JP, Mintz G, et al. Comparison between the NERS (New Risk Stratification) score and the SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score in outcome prediction for unprotected left main stenting. *J Am Coll Cardiol Intv* 2010;3:632-41.
5. Chieffo A, Park SJ, Valgimigli M, et al. Favorable long-term outcome after drug-eluting stent implantation in nonbifurcation lesions that involve unprotected left main coronary artery: a multicenter registry. *Circulation* 2007;116:158-62.
6. Palmerini T, Sangiorgi D, Marzocchi A, et al. Ostial and midshaft lesions vs. bifurcation lesions in 1111 patients with unprotected left main coronary artery stenosis treated with drug-eluting stents: results of the survey from the Italian Society of Invasive Cardiology. *Eur Heart J* 2009;30:2087-94.
7. Carrie D, Eltchaninoff H, Lefevre T, et al. Early and long-term results of unprotected left main coronary artery stenosis with paclitaxel-eluting stents: the FRIEND (French multiventre registry for stenting of unprotected LMCA stenosis) registry. *EuroIntervention* 2011;7:680-8.
8. Lee MS, Kapoor N, Jamal F, et al. Comparison of coronary artery bypass surgery with percutaneous coronary intervention with drug-eluting stents for unprotected left main coronary artery disease. *J Am Coll Cardiol* 2006;47:864-70.
9. Erglis A, Kumsars I, Niemela M, et al. Randomized comparison of coronary bifurcation stenting with the crush versus the culotte technique using sirolimus eluting stents: the Nordic stent technique study. *Circ Cardiovasc Interv* 2009;2:27-34.
10. Chen SL, Zhang JJ, Ye F, et al. Study comparing the double kissing (DK) crush with classical crush for the treatment of coronary bifurcation lesions: the DKCRUSH-1 Bifurcation Study with drug-eluting stents. *Eur J Clin Invest* 2008;38:361-71.
11. Adriaenssens T, Byrne RA, Dibra A, et al. Culotte stenting technique in coronary bifurcation disease: angiographic follow-up using dedicated quantitative coronary angiographic analysis and 12-month clinical outcomes. *Eur Heart J* 2008;29:2868-76.
12. Mehilli J, Kastrati A, Byrne RA, et al. Paclitaxel- versus sirolimus-eluting stents for unprotected left main coronary artery disease. *J Am Coll Cardiol* 2009;53:1760-8.
13. Medina A, Surez de Lezo J, Pan M. A new classification of coronary bifurcation lesions. *Rev Esp Cardiol* 2006;2:183-4.
14. Chen SL, Santoso T, Zhang JJ, et al. A randomized clinical study comparing double kissing crush with provisional stenting for treatment of coronary bifurcation lesions: results from the DKCRUSH-II (Double Kissing Crush versus Provisional Stenting Technique for Treatment of Coronary Bifurcation Lesions) trial. *J Am Coll Cardiol* 2011;57:914-20.
15. Mauri L, Hsieh WH, Massaro JM, et al. Stent thrombosis in randomized clinical trials of drug-eluting stents. *N Engl J Med* 2007;356:1020-9.
16. Colombo A, Bramucci E, Saccà S, et al. Randomized study of the crush technique versus provisional side-branch stenting in true coronary bifurcations: the CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) study. *Circulation* 2009;119:71-8.
17. Murasato Y, Hikichi Y, Horiuchi M. Examination of stent deformation and gap formation after complex stenting of left main coronary artery bifurcations using microfocus computed tomography. *J Interv Cardiol* 2009;22:135-44.
18. Mezzapelle G, Baldari D, Baglini R. Culotte bifurcation stenting with paclitaxel drug-eluting stent. *Cardiovasc Revasc Med* 2007;8:63-6.
19. Fitzgerald PJ, Oshima A, Hayase M, et al. Final results of the can ultrasound influences stent expansion (CRUISE) study. *Circulation* 2000;102:523-30.
20. Girasis C, Serruys PW, Onuma, et al. 3-Dimensional bifurcation angle analysis in patients with left main disease: a substudy of the SYNTAX Trial (SYNergy Between Percutaneous Coronary Intervention With TAXus and Cardiac Surgery). *J Am Coll Cardiol Intv* 2010;3:41-8.

Key Words: bifurcation lesions ■ culotte stenting ■ double kissing crush ■ major adverse cardiac event ■ unprotected left main coronary artery.