Randomized Comparison of Coronary Bifurcation Stenting With the Crush Versus the Culotte Technique Using Sirolimus Eluting Stents
The Nordic Stent Technique Study

Andrejs Erglis, MD; Indulis Kumsars, MD; Matti Niemelä, MD; Kari Kervinen, MD; Michael Maeng, MD; Jens F. Lassen, MD; Pål Gunnes, MD; Sindre Stavnes, MD; Jan S. Jensen, MD; Anders Galloë, MD; Inga Narbute, MD; Dace Sondore, MD; Timo Mäkikallio, MD; Kari Ylitalo, MD; Evald H. Christiansen, MD; Jan Ravkilde, MD; Terje K. Steigen, MD; Jan Mannsverk, MD; Per Thayssen, MD; Knud Nørgaard Hansen, MD; Mikko Syvännen, MD; Steffen Helqvist, MD; Nikus Kjell, MD; Rune Wiseth, MD; Jens Aarøe, MD; Mikko Puhakka, MD; Leif Thuesen, MD; for the Nordic PCI Study Group

Background—In a number of coronary bifurcation lesions, both the main vessel and the side branch need stent coverage. Using sirolimus eluting stents, we compared 2 dedicated bifurcation stent techniques, the crush and the culotte techniques in a randomized trial with separate clinical and angiographic end-points.

Methods and Results—A total of 424 patients with a bifurcation lesion were randomized to crush (n=209) and culotte (n=215) stenting. The primary end point was major adverse cardiac events; cardiac death, myocardial infarction, target vessel revascularization, or stent thrombosis after 6 months. At 6 months there were no significant differences in major adverse cardiac event rates between the groups; crush 4.3%, culotte 3.7% (P=0.87). Procedure and fluoroscopy times and contrast volumes were similar in the 2 groups. The rates of procedure-related increase in biomarkers of myocardial injury were 15.5% in crush versus 8.8% in culotte group (P=0.08). A total of 324 patients had a quantitative coronary assessment at the index procedure and after 8 months. The angiographic end-points of in-segment and in-stent restenosis of main vessel and/or side branch after 8 months were found in 12.1% versus 6.6% (P=0.10) and in 10.5% versus 4.5% (P=0.046) in the crush and culotte groups, respectively.

Conclusions—Both the crush and the culotte bifurcation stenting techniques were associated with similar and excellent clinical and angiographic results. Angiographically, there was a trend toward less in-segment restenosis and significantly reduced in-stent restenosis following culotte stenting. (Circ Cardiovasc Intervent. 2009;2:27-34.)

Key Words: stents ■ drugs ■ sirolimus ■ restenosis ■ bifurcation

Bifurcation lesions occur in about 15% of percutaneous coronary interventions (PCI). In these lesions, balloon angioplasty without stenting had a high risk of acute vessel closure. Furthermore, implantation of bare metal stents (BMS) was associated with over 30% rate of major adverse cardiac events (MACE) at 1 year in a registry study. Another study found over 30% rate of target lesion revascularization at 6 months follow-up both with 1 and 2 BMS techniques. The use of sirolimus eluting stents (SES) has been reported to reduce restenosis in simple and in complicated coronary lesions. SES implantation in bifurcation lesions has been very promising with low clinical and angiographic event

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From the Latvian Centre of Cardiology (A.E., I.K., I.N., D.S.), Paul Stradins Clinical University Hospital, Riga, Latvia; Division of Cardiology (M.N., M.S., T.M., K.Y.), Department of Internal Medicine, University of Oulu, Finland; Department of Cardiology (M.M., J.F.L., E.H.C., J.R., L.T.), Aarhus University Hospital, Skjebby, Aarhus Denmark; Department of Cardiology (P.G., S.S.), The Feiring Clinic, Feiring, Norway; Department of Cardiology (J.S.J., A.G.), Gentofte University Hospital, Gentofte, Denmark; Department of Cardiology (T.K.S., J.M.), University Hospital of Tromsoe, Tromsø, Norway; Department of Cardiology (P.T., K.N.H.), Odense University Hospital, Denmark; Division of Cardiology (N.K.), Helsinki University Central Hospital, Helsinki, Finland; Department of Cardiology (S.H.), Rigshospitalet, Copenhagen, Denmark; Department of Cardiology (S.V.), Tampere University Hospital, Tampere, Finland; Department of Cardiology (R.W.), Trondheim University Hospital, Trondheim, Norway; Department of Cardiology (J.A.), Aalborg University Hospital, Aalborg, Denmark; and Division of Cardiology (M.P.), Kuopio University Central Hospital, Kuopio, Finland.

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Correspondence to Andrejs Erglis, Latvian Centre of Cardiology, Pauls Stradins Clinical University Hospital, Pilsrnu 13, Riga, Latvia LV1002. E-mail a.erglis@stradins.lv and Leif Thuesen, Department of Cardiology, Aarhus University Hospital, Skjebby, 8200 Aarhus N, Denmark. E-mail leif.thuesen@ki.au.dk
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rates, both after procedures with stenting of the main vessel (MV) only and in procedures where both MV and side branch (SB) were stented.\(^{5,11,12}\) At present, the general recommended stenting strategy in coronary bifurcation lesions is the provision of SB stenting strategy.\(^{13}\) With this strategy, the MV is stented, whereas the SB is only treated with stent implantation in case of significant residual SB stenosis after stenting of the MV. However, a number of coronary bifurcation lesions need stent treatment of both the SB and the MV. Therefore, to provide stent coverage of the entire bifurcation region, dedicated bifurcation stent techniques have been proposed. Among those, the crush\(^{14}\) and the culotte\(^{15}\) techniques are currently used in clinical practice and have been associated with promising clinical and angiographic outcome.\(^{11,16}\) The present study is the first randomized clinical and angiographic comparison of the crush and the culotte bifurcation stent techniques.

**Methods**

**Patients and Study Design**

This nonblinded randomized multicenter trial was conducted at 13 cardiology centers in Denmark, Finland, Norway, and Latvia. From August 2005 to February 2007 a total of 424 patients were enrolled. On the basis of the total PCI volumes of the participating centers, the number of eligible patients was estimated to 2292 patients. The primary reason for not enrolling in the study was differences in inclusion rates among operators. A flow diagram of the study is shown in Figure 1. Ethics committees in all participating countries approved the protocol, and all participating patients gave written informed consent.

Men and women, aged 18 years or older, with stable or unstable angina pectoris or silent ischemia and a de novo coronary bifurcation lesion were considered eligible for enrolment. A bifurcation lesion was defined according to Lefevre et al\(^{17}\) and could be located in the left anterior descending artery and a diagonal, the circumflex artery and an obtuse marginal, the right coronary artery and posterior descending artery/postero-lateral artery or the left main stem/circumflex artery/left anterior descending artery in a right dominant system. The diameter of MV had to be $\geq 3.0$ mm and of SB $\geq 2.5$ mm by visual estimate. Exclusion criteria were ST-elevation acute myocardial infarction (AMI) within 24 hours, life expectancy less than one year, s-creatinine $\geq 200$ μmol/L and allergy to any of the drugs used (aspirin, clopidogrel, ticlopidine, sirolimus, and paclitaxel).

**Randomization**

Randomization was performed in blocks for each participating hospital, 1:1 by computerized assignment with stratification according to sex, diabetes, age $> 70$ years, use of glycoprotein receptor antagonists, and consent to angiographic follow-up. An automatic telephone randomization/voice-response system was used. Patients were randomized before any balloon dilatation was performed.

**Stent Implantation**

Patients were pretreated with aspirin (75 mg) and clopidogrel (300 mg). Heparin was administrated according to local hospital routine, and ACT control was not mandatory. Glycoprotein receptor antagonists were used at the discretion of the operator. Aspirin was continued indefinitely, clopidogrel for 6 to 12 months according to local practice. Ticlopidine could be used if the patient did not tolerate clopidogrel.

The operator was requested to avoid pretreatment (conventional balloon or cutting balloon) of segments not covered by stent. The SES, “Cypher Select-+” coronary stent (Cordis/Johnson & Johnson, Miami Lakes, Fla) was used in the study.

Main treatment principles of the crush technique are as follows: (1) wiring of MV and SB, (2) optional predilatation of MV and/or SB, (3) stenting of SB with uninflated stent or balloon in MV and with proximal end of SB stent at the center of the MV, (4) SB wire and stent balloon removed, (5) crushing of SB stent with MV balloon or stent, (6) in balloon crush, stenting of MV and rewiring of SB through MV stent, and (7) procedure finalized by kissing balloon dilatation.

Main treatment principles of the culotte technique are as follows: (1) wiring of MV and SB, (2) optional predilatation of MV and/or SB, (3) stenting of MV, (4) rewiring of MV through SB stent, (5) stenting of SB through MV stent, (6) rewiring of MV through SB stent, and (7) procedure finalized by kissing balloon dilatation.

Implantation of additional stents to cover the whole lesion or to cover a dissection was allowed. If the study stent could not be delivered, another drug eluting stent or a BMS was allowed. Different types of drug eluting stents in the same vessel were not allowed. Both operator and patient were aware of the assigned treatment.

**Cardiac Biomarkers and ECG**

CK-MB mass, Troponin-T or Troponin-I were measured at the time of the procedure and after 12 to 18 hours. Troponin-T was used as...
the primary marker, CK-MB mass or Troponin-I only if Troponin-T was not available. To avoid confounding nonprocedure-related marker elevation, patients with unstable angina pectoris were included in the biomarker analysis only if preprocedure and postprocedure markers were normal. Marker elevation of more than or equal to 3 times upper limit of normal was considered significant. A 12 lead ECG was obtained before and 12 to 18 hours after the procedure.

Follow-Up

For safety reasons, total death and MACE were recorded by telephone call after 1 month. There was a clinical follow-up visit after 6 months for primary end-point registration. An 8-month control coronary angiography was scheduled at randomization in patients who consented herein. No patients were lost to clinical follow-up.

Quantitative Coronary Angiography at Eight Months

Coronary angiograms obtained at baseline, at completion of the stenting procedure, and after 8 months, were submitted to 1 of the 2 angiographic core laboratories (Aarhus University Hospital, Skejby, Aarhus, Denmark or Paul Stradins Clinical Hospital, Riga, Latvia) and were analyzed with the use of a computer-based system dedicated to bifurcation analysis (Qangio XA version 7.0, Medis, Leiden, The Netherlands). Quantitative angiographic measurements of the bifurcation lesion were obtained in the following 3 segments: the proximal MV segment, the distal MV segment and the SB. In the MV and the SB segments, measurements were obtained in the stents and in the margins 5-mm proximal and distal to the stents (edge). The analyses were not blinded.

Definitions

Total death; death for any reason. Cardiac death; death was considered cardiac unless other cause documented. Nonprocedure-related MI, a rise of biochemical markers exceeding the decision limit of 0.05 mg/L for CK-MB mass, 0.1 mg/L for Troponin-T, and 0.1 mg/L for Troponin-I only if Troponin-I was not available. A rise of more than or equal to 3 times upper limit of normal was considered significant. Nonprocedure-related MI was regarded as occurring immediately if a rise of any biochemical marker was documented within 72 hours of the procedure or within 30 days for those MI’s documented after the procedure. The primary end-point was death from any cause (total death), cardiac death, nonprocedure-related myocardial infarction, stent thrombosis, or target vessel revascularization by PCI or coronary artery bypass surgery after 6 months. Percent diameter stenosis is calculated as (reference diameter − minimal luminal diameter)/reference diameter. Restenosis is defined according to the ARC criteria.18 Target lesion revascularization is defined as repeated revascularization by PCI or surgery of the target lesion. Target vessel revascularization is defined as repeated revascularization by PCI or surgery of the target vessel. Percent diameter stenosis is calculated as (reference diameter − minimal luminal diameter)/reference diameter×100. Restenosis is defined as >50% diameter stenosis at 8 months angiographic follow-up. Late lumen loss is post procedure minimal luminal diameter − minimal luminal diameter in millimeters at 8 months follow-up. Procedural success is residual stenosis <30% and TIMI flow III in MV and SB after the index procedure.

Study End-Points

The primary end-point of the study was the clinical combined end-point of MACE; cardiac death, nonprocedure-related myocardial infarction, stent thrombosis, or target vessel revascularization by PCI or coronary artery bypass surgery after 6 months.

Secondary end-points were as follows: (1) individual end-points of total death, cardiac death, nonprocedure-related myocardial infarction, target lesion revascularization, and target vessel revascularization; (2) procedure-related biomarker increase (rise of biochemical markers exceeding >3 times the decision limit of myocardial infarction [99th percentile including <10% cardiovascular] of Creatine Kinase-MB (CK-MB) mass, Troponin-T, and/or Troponin-I); (3) the angiographic end-point of significant in-segment and in-stent restenosis (>50% diameter stenosis) of MV and/or SB. The study was monitored by the PCI-Research Unit, Aarhus University Hospital, Skejby. An independent end-point committee, chaired by

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**Table 1. Baseline Clinical Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Crush n=209</th>
<th>Culotte n=215</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>65±10</td>
<td>65±11</td>
<td>0.64</td>
</tr>
<tr>
<td>Male</td>
<td>149 (71%)</td>
<td>154 (72%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Current smoker</td>
<td>42 (20%)</td>
<td>58 (27%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>176 (84%)</td>
<td>159 (74%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Hypertension</td>
<td>130 (62%)</td>
<td>129 (60%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>28 (13%)</td>
<td>31 (15%)</td>
<td>0.78</td>
</tr>
<tr>
<td>Family history</td>
<td>118 (57%)</td>
<td>134 (62%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>84 (40%)</td>
<td>72 (34%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>8 (4%)</td>
<td>11 (5%)</td>
<td>0.64</td>
</tr>
<tr>
<td>Indication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable angina pectoris</td>
<td>162 (78%)</td>
<td>155 (72%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Unstable angina pectoris</td>
<td>43 (21%)</td>
<td>54 (26%)</td>
<td>0.30</td>
</tr>
<tr>
<td>Silent ischemia</td>
<td>4 (2%)</td>
<td>6 (3%)</td>
<td>0.75</td>
</tr>
<tr>
<td>Antiplatelet therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>207 (99.05%)</td>
<td>214 (99.5%)</td>
<td>0.61</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>208 (99.5%)</td>
<td>215 (100%)</td>
<td>0.49</td>
</tr>
<tr>
<td>GP IIb/IIIa inhibitors</td>
<td>106 (51%)</td>
<td>105 (51%)</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Values are mean±1 SD or n (%). Fisher’s exact test or Student’s t test were used.

Kristian Thygesen, MD, Aarhus University Hospital, Aarhus, Denmark adjudicated the clinical study end-points blindly.

Statistical Analysis

Power calculations of the present study were problematic because there were no available clinical end-point data on culotte stenting and limited data on crush stenting using DES. We based our power calculations on an expected primary end-point event rate of 25% in the culotte group, alpha 5%, power 80%, and using a 2-sided \( \chi^2 \) test. To detect a reduction in primary end-point rate to 13%, 167 patients would be needed in each group. Because of considerable uncertainty in expected end-point rates in drug-eluting stents (DES)-treated bifurcation lesions, it was decided to include 200 patients in each group.3 Differences in categorical variables between the 2 groups were analyzed using the \( \chi^2 \) test or Fisher’s exact test. Continuous variables were analyzed using the Student’s \( t \) test and time to event data using the Kaplan-Meier method and the log-rank test. All probability values were 2-sided. Level of significance was 5%. The analysis was performed on an intention to treat basis. All analyses were performed using SPSS 13.0 (SPSS Inc, Chicago, Ill).

Statement of Responsibility

The authors had full access to the data and take full responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

Baseline Characteristics and Procedural Data

The 2 groups were well balanced regarding baseline clinical characteristics and risk factors with the exception that more patients in the crush group were treated for hypercholesterolemia. In three fourths of the cases, the indication for treatment was stable angina pectoris and in one fourth unstable angina pectoris. In few patients the indication was silent ischemia. The use of aspirin, clopidogrel, and glycoprotein IIb/IIIa inhibitors was similar in the 2 groups (Table 1).

Procedural data are shown in Table 2. The index lesion...
was predilated more often in culotte-stented lesions. A final kissing balloon dilatation was performed in significantly less of the patients in the crush than in the culotte group (Table 2). Cypher Select+ was the study of stent. Few other stents were used; another drug eluting stent was implanted in 3.3% and 2.1% and a BMS in 2.5% and 1.5%, in the MV and in the SB, respectively, with no difference between the study groups.

**Clinical Outcome**

The rate of event free survival for the primary end-point, MACE (cardiac death, MI, target vessel revascularization, stent thrombosis) after 6 months follow-up is shown in Figure 2. There was no significant difference in the 6-month MACE rate between the 6 groups (4.3% in the crush and 3.7% in the culotte group, \( P=0.87 \)). The individual end-points after 6 months are shown in Table 3. The rates of individual end points were low in both groups without significant difference between the groups.

**Procedure-Related Elevation of Biomarkers**

Procedure-related biomarker release could be evaluated in 296 patients (148 patients in both groups). A marker elevation exceeding 3 times the decision limit of myocardial infarction was seen in 15.5% of crush-stented patients and in 8.8% of culotte-stented patients \( (P=0.08) \).

**Quantitative Coronary Angiography Analysis**

At randomization, 373 patients were scheduled for an 8-month follow-up angiography. Complete angiographic evaluation was available in 324 (88%) patients; of these, 160 patients were randomized to crush and 164 patients to culotte

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**Table 2. Procedural Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Crush n=209</th>
<th>Culotte n=215</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF (%)</td>
<td>57±11</td>
<td>57±12</td>
<td>1.00</td>
</tr>
<tr>
<td>Lesion location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left anterior descending artery</td>
<td>132 (63%)</td>
<td>142 (66%)</td>
<td>0.54</td>
</tr>
<tr>
<td>Circumflex artery</td>
<td>42 (20%)</td>
<td>43 (20%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Right coronary artery</td>
<td>15 (7%)</td>
<td>9 (4%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Left main stem</td>
<td>20 (10%)</td>
<td>21 (10%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Mean lesion length,* mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main vessel</td>
<td>17.4±10.3</td>
<td>17.4±10.1</td>
<td>0.93</td>
</tr>
<tr>
<td>Side branch</td>
<td>7.3±5.8</td>
<td>7.5±6.0</td>
<td>0.76</td>
</tr>
<tr>
<td>Mean stent length,* mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main vessel</td>
<td>23.5±9.3</td>
<td>23.6±9.2</td>
<td>0.93</td>
</tr>
<tr>
<td>Side branch</td>
<td>10.6±5.6</td>
<td>10.6±5.8</td>
<td>0.96</td>
</tr>
<tr>
<td>Proximal reference diameter,* mm</td>
<td>3.38±0.38</td>
<td>3.32±0.33</td>
<td>0.07</td>
</tr>
<tr>
<td>Main vessel</td>
<td>3.28±0.33</td>
<td>3.27±0.33</td>
<td>0.77</td>
</tr>
<tr>
<td>Side branch</td>
<td>209 (100%)</td>
<td>213 (99.1%)</td>
<td>0.50</td>
</tr>
<tr>
<td>Side branch stented</td>
<td>207 (99.0%)</td>
<td>210 (97.7%)</td>
<td>0.45</td>
</tr>
<tr>
<td>No. stents, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main vessel</td>
<td>1.23±0.44</td>
<td>1.20±0.47</td>
<td>0.50</td>
</tr>
<tr>
<td>Side branch</td>
<td>1.03±0.24</td>
<td>1.04±0.28</td>
<td>0.61</td>
</tr>
</tbody>
</table>

**Table 3. Individual End Points After 6 Months**

<table>
<thead>
<tr>
<th></th>
<th>Crush n=209</th>
<th>Culotte n=215</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target lesion revascularization</td>
<td>5 (2.4%)</td>
<td>6 (2.8%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>3 (1.4%)</td>
<td>4 (1.9%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4 (1.9%)</td>
<td>3 (1.4%)</td>
<td>0.72</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>2 (1.0%)</td>
<td>1 (0.5%)</td>
<td>0.62</td>
</tr>
<tr>
<td>Total death</td>
<td>2 (1.0%)</td>
<td>1 (0.5%)</td>
<td>0.62</td>
</tr>
</tbody>
</table>

Values are n (%). Fisher’s exact test was used.
stenting. A major reason for not having 8 months angiographic follow-up was the extremely long distances to interventional centers in the northern part of Scandinavia. In-segment and in-stent QCA data (reference diameter, minimal luminal diameter, percentual stenosis, and late loss) were similar in the 2 groups (Table 4). There was a trend to less in-segment restenosis at 8-month follow-up (Figure 3) because of significantly reduced SB in-stent restenosis in culotte-treated patients (Table 4). In-stent restenosis of MV and/or SB after 8 months was found in 10.5% versus 4.5% (P=0.046) in the crush and culotte groups, respectively.

**Discussion**

In this first randomized comparison of the crush and the culotte bifurcation stenting techniques using SES, we found low and similar 6-month clinical event rates in both study groups. At 8-month angiographic follow-up, rates of in-lesion restenosis were low in both groups. There was a trend toward less restenosis of the entire bifurcation lesion because of significantly reduced SB in-stent restenosis in patients treated with the culotte technique.

In PCI, bifurcation lesion treatment without stenting or with BMS used to be associated with high risk of complications and restenosis.1–4 The use of drug eluting stents and introduction of different bifurcations stenting strategies and techniques resulted in marked improvements.5,6,12 Thus, the recently published ARTS II study20 had similar event rates in bifurcation and nonbifurcation lesions. At present, a strategy of optional SB stenting, where the SB is stented only in case of severe stenosis or flow problems after MV stenting, has been found to be safe and efficient in registries and randomized clinical and angiographic trials.5,11,12,21 However, it is still an open question if the strategy of optional SB stenting

**Table 4. Results of Quantitative Angiography in the Three Bifurcation Segments**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Proximal MV Segment</th>
<th>Distal MV Segment</th>
<th>Side Branch</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crush n=160</td>
<td>Culotte n=164</td>
<td>P</td>
</tr>
<tr>
<td>In-stent* minimal luminal diameter, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>1.91±0.77</td>
<td>1.81±0.79</td>
<td>0.27</td>
</tr>
<tr>
<td>After</td>
<td>3.18±0.54</td>
<td>3.14±0.55</td>
<td>0.44</td>
</tr>
<tr>
<td>Follow-up</td>
<td>3.02±0.55</td>
<td>3.02±0.55</td>
<td>0.96</td>
</tr>
<tr>
<td>In-stent* reference diameter, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>3.04±0.66</td>
<td>3.01±0.65</td>
<td>0.68</td>
</tr>
<tr>
<td>After</td>
<td>3.51±0.55</td>
<td>3.44±0.52</td>
<td>0.23</td>
</tr>
<tr>
<td>Follow-up</td>
<td>3.41±0.51</td>
<td>3.35±0.51</td>
<td>0.27</td>
</tr>
<tr>
<td>In-stent* diameter stenosis, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>36.33±22.51</td>
<td>39.60±23.31</td>
<td>0.21</td>
</tr>
<tr>
<td>After</td>
<td>9.16±8.22</td>
<td>8.54±10.21</td>
<td>0.56</td>
</tr>
<tr>
<td>Follow-up</td>
<td>11.50±9.18</td>
<td>9.60±10.89</td>
<td>0.10</td>
</tr>
<tr>
<td>Edge minimal luminal diameter (mm)</td>
<td>0.17±0.50</td>
<td>0.12±0.42</td>
<td>0.36</td>
</tr>
<tr>
<td>Edge minimal luminal diameter (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent* late lumen loss, mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>3.14±0.65</td>
<td>3.08±0.62</td>
<td>0.41</td>
</tr>
<tr>
<td>After</td>
<td>3.00±0.64</td>
<td>3.04±0.64</td>
<td>0.50</td>
</tr>
<tr>
<td>Follow-up</td>
<td>3.00±0.64</td>
<td>3.04±0.64</td>
<td>0.50</td>
</tr>
<tr>
<td>Restenosis, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-stent*</td>
<td>0</td>
<td>0</td>
<td>…</td>
</tr>
<tr>
<td>Edge</td>
<td>3 (2.0)</td>
<td>0 (0)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

*p<0.10, p<0.19, p<0.01 (Fisher’s exact test or Student’s t test were used.

SB indicates side branch; MV, main vessel.

**Figure 3. Rates of in-segment restenosis in crush vs culotte-treated bifurcation lesions. Restenosis, ≥50% diameter stenosis at 8 months follow-up. MV+SB, main vessel and/or side branch; MV, main vessel; SB, side branch. Fisher’s exact test was used.**
should be the preferred treatment in all bifurcation lesions, especially if the bifurcation lesion encompasses a large SB or there is a long lesion of the SB.

We selected crush and the culotte bifurcation techniques for the present evaluation. These techniques are dedicated bifurcation techniques aiming at full stent coverage of the bifurcation lesion, based on extensive documentation of low in-stent restenosis rates in DES-treated lesions.18

The culotte technique was described by Chevalier et al15 using BMS. Originally, they recommended to stent the branch with the sharpest angle first, usually the SB, and then stent the other vessel through the first stent. This resulted in 2 layers of stent proximal to the bifurcation, full coverage of the bifurcation region and of both branches distal to the bifurcation. Because of technical complexity, high rates of procedural events, and restenosis in the BMS era, the technique was infrequently used. In the DES era, the technique was reintroduced with promising results in observational studies16 and in the Nordic Bifurcation Study.11 The present study recommended stenting of the MV first to avoid acute closure of the MV and showed that culotte stenting could be performed with excellent short- and medium-term results.

The crush technique, introduced by Colombo et al14 also ensures complete lesion coverage at the SB ostium. As a modified T-stenting technique, the SB stent is deployed 2 to 3 mm proximal to the bifurcation within the MV and thereafter crushed by a stent or a balloon in the MV. The crush technique ensures flow in both MV and SB, but the 3 layers of stent proximal to the SB ostium has been a concern. Therefore, in the present study we recommended positioning of the SB stent with its proximal end in the middle of the MV to avoid extensive areas with multiple stent layers. In registries and a randomized trial, restenosis rates of 12% to 28% have been reported after crush stenting.5,19 Our in-segment restenosis rate of 12.1% compares favorably with these results, possibly because there was a per protocol kissing balloon postdilatation. A final kissing balloon dilatation has been related to low restenosis rates in bifurcation lesions using crush and other bifurcation stenting techniques.22

Crush Versus Culotte Bifurcation Technique

It is noteworthy that both techniques were associated with excellent clinical and angiographic results. Procedure complexity as assessed by procedure time, fluoroscopy time, and contrast use was similar in the 2 groups. There was a higher success rate of final kissing balloon dilatation in culotte-treated patients, probably because rewiring and balloon insertion through stent struts are more difficult in the crush technique, where 3 layers of stent have to be crossed versus only 1 layer in the culotte technique. This might be an explanation for the higher rate of angiographic SB in-stent restenosis in the crush group. Both techniques had a very high procedural success rate without any difference between groups. This suggests that the 2 procedures are technically equally demanding and probably also reflects high operator skill and dedication. Interestingly, SB predilatation was used significantly more often in the culotte group. This may reflect that there were more SBs with significant preprocedure stenosis, or that operators were more prone to perform a proper dilatation of the SB in culotte lesions to facilitate crossing with the SB stents.

Clinical Implications

According to our results and those of others,5,6,11 PCI with implantation of SES seems to be the treatment of choice in bifurcation lesions. SES in these lesions have reduced complication rates and rates of clinical and angiographic restenosis to the same level as in less complex coronary artery lesion subsets.20

Several authors have advocated the simple strategy in percutaneous bifurcation treatment with stenting of MV and provisional SB stenting.13 Our results do not contradict these recommendations, but show that dedicated 2-stent techniques can be used by experienced operators with excellent results. Therefore, 2-stent strategies may be considered when SB restenosis should be avoided, ie, in large SBs, where restenosis is likely to result in clinical problems.

Both the crush and the culotte bifurcation strategy were associated with excellent clinical and angiographic results. On the basis of the present study results, 1 of the 2 techniques studied cannot be claimed superior to the other. This choice should be based on operator experience and the lesion characteristics.

Study Limitations

This study had an open design with operators and patients being aware of the technique used. MACE, however, was adjudicated by a blinded event committee and should not be influenced by the open design of the study. The study was considerably underpowered given the observed MACE rate. A properly powered study would include >15 000 patients. An inclusion of this order of magnitude would not be feasible in the complex lesion subset of the present study. The patients studied were operator selected, and there was a large center difference in inclusion of patients, from less than 5% to more than 50% of eligible patients. Also, it is likely that patient selection included feasibility for both treatment modalities. Therefore, the overall recommendation from the study may not be valid for all bifurcation lesions and operators. Furthermore, although the rates of MACE and significant angiographic stenosis were low after 6 months clinical and 8 months angiographic follow-up, the durability of these results on a long-term basis is not known.

Conclusions

In conclusion, excellent 6 months clinical and 8 months angiographic results can be obtained with the crush and culotte stenting of de novo coronary artery bifurcation lesions using SES. Culotte-stented lesions tended to have lower angiographic restenosis rates making this technique an attractive bifurcation stenting technique in feasible bifurcation lesion anatomies.

The 6 months clinical results and the 8 months quantitative coronary angiography results of the trial were presented as late breaking clinical trials at the Transcatheter Cardiovascular Therapeutics meeting, October 2007 and at the annual meeting of the American College of Cardiology in Chicago, March 2008.
Appendix

The Nordic-Baltic PCI Study Group: The purpose of the Nordic PCI Study Group is to conduct academic randomized clinical trials and to optimize PCI treatment in the Nordic and Baltic countries. Steering committee members are as follows: Leif Thuesen, Aarhus University Hospital, Skejby, Aarhus, Denmark; Jens Flensted Larsen, Aarhus University Hospital, Skejby, Aarhus, Denmark; Jens Aaroe, Aalborg University Hospital, Aalborg, Denmark; Per Thayssen, Odense University Hospital, Odense, Denmark; Steffen Helqvist, Rigshospitalet, Copenhagen, Denmark; Jan Skov Jensen, Gentofte University Hospital, Gentofte, Denmark; Anders Gallae, Gentofte University Hospital, Gentofte, Denmark; Stefan James, Uppsala University Hospital, Uppsala, Sweden; Ivar Sjögren, Falun Hospital, Falun, Sweden; Terje Steigen, University Hospital of Tromsø, Tromsø, Norway; Jan Mannsverk, University Hospital of Tromsø, Tromsø, Norway; Oliver Meyerdieks, Ullevaal University Hospital, Oslo, Norway; Pål Gunnnes, The Feiring Clinic, Feiring, Norway; Svein Rotevatn, Haukeland University Hospital, Bergen, Norway; Rune Wiseth, St. Olav Hospital, Trondheim, Norway; Kjell Nikus, Tampere University Hospital, Tampere, Finland; Sahl Vikman, Tampere University Hospital, Tampere, Finland; Juha Hartikainen, Kuopio University Central Hospital, Kuopio, Finland; Matti Niemelä, Department of Internal Medicine, University of Oulu, Oulu, Finland; Kari Kervinen, Department of Internal Medicine, University of Oulu, Oulu, Finland; Kari Virtanen, Helsinki University Central Hospital, Helsinki, Finland; Juhan Airaksinen, Turku University Central Hospital, Turku, Finland; Antti Ylitalo, Satakunta Central Hospital, Pori, Finland; Andreas Erqlis, Paul Stradins Clinical Hospital, Riga, Latvia; Indulis Kumsars, Paul Stradins Clinical Hospital, Riga, Latvia.

Quantitative Coronary Angiography Core Laboratories: Aarhus University Hospital, Skejby, Aarhus, Denmark; Michael Maeng and Helle Hoejedahl. Paul Stradins Clinical Hospital, Riga, Latvia; Inga Narbute.

Participating centers, primary investigators, and inclusions per center: Denmark: Aarhus University Hospital, Skejby, Aarhus, Primary investigator: Leif Thuesen (83 pts); Gentofte University Hospital, Primary investigator: Jan Skov Jensen (44 pts); Aalborg University Hospital, Primary investigator: Jens Aaroe (3 pts); Rigshospitalet, Copenhagen, Primary investigator: Steffen Helqvist (11 pts); Odense University Hospital, Primary investigator: Per Thayssen (14 pts). Norway: Tromsø University Hospital, Primary investigator: Terje Steigen (15 pts); The Feiring Clinic, Oslo, Primary investigator: Pål Gunnnes (50 pts); Trondheim University Hospital, Primary investigator: Rune Wiseth (4 pts). Finland: Oulu University Hospital, Primary investigator: Matti Niemelä (87 pts); Tampere University Hospital, Primary investigator: Sahl Vikman (8 pts); Helsinki University Central Hospital, Primary investigator: Kari Virtanen (11 pts); Kuopio University Hospital, Primary investigator: Mikko Puhakka (2 pts). Latvia: Paul Stradins Clinical Hospital, Riga, Primary investigator: Andreas Erqsli (92 pts).

Coordination and data entry: Hanne Rask Hansen, study secretary, Helle Bargsteen, study secretary, Dorte Fredysberg, study nurse, Marianne Esbjerg, study nurse. Data monitoring and safety: Members of the steering committee. Statistical support: Leif Spange Mortensen, MSc, UNI-C, Danish Information Technology Centre for Education and Research. Clinical end-point committee: Kristian Thygesen, MD, Aarhus University Hospital, Aarhus, Denmark. Kjell Nikus, MD, Department of Cardiology, Tampere University Hospital, Finland.

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Disclosures

None.


Randomized Comparison of Coronary Bifurcation Stenting With the Crush Versus the Culotte Technique Using Sirolimus Eluting Stents: The Nordic Stent Technique Study


for the Nordic PCI Study Group

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Supplemental Material

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Steering committee:

Leif Thuesen, Aarhus University Hospital, Skejby, Aarhus, Denmark
Jens Flensted Lassen, Aarhus University Hospital, Skejby, Aarhus, Denmark
Jens Aarøe, Aalborg University Hospital, Aalborg, Denmark
Per Thayssen, Odense University Hospital, Odense, Denmark
Steffen Helqvist, Rigshospitalet, Copenhagen, Denmark
Jan Skov Jensen, Gentofte University Hospital, Gentofte, Denmark
Anders Galløe, Gentofte University Hospital, Gentofte, Denmark
Stefan James, Uppsala University Hospital, Uppsala, Sweden
Iwar Sjögren, Falun Hospital, Falun, Sweden
Terje Steigen, University Hospital of Tromsoe, Tromsoe, Norway
Jan Mannsverk, University Hospital of Tromsoe, Tromsoe, Norway
Oliver Meyerdierks, Ullevaal University Hospital, Oslo, Norway
Pål Gunnes, The Feiring Clinic, Feiring, Norway
Svein Rotevatn, Haukeland University Hospital, Bergen, Norway
Rune Wiseth, St. Olav Hospital, Trondheim, Norway
Kjell Nikus, Tampere University Hospital, Tampere, Finland
Saila Vikman, Tampere University Hospital, Tampere, Finland

Juha Hartikainen, Kuopio University Central Hospital, Kuopio, Finland

Matti Niemelä, Department of Internal Medicine, University of Oulu, Oulu, Finland

Kari Kervinen, Department of Internal Medicine, University of Oulu, Oulu, Finland

Kari Virtanen, Helsinki University Central Hospital, Helsinki, Finland

Juhani Airaksinen, Turku University Central Hospital, Turku, Finland

Antti Ylitalo, Satakunta Central Hospital, Pori, Finland

Andrejs Erglis, Paul Stradins Clinical Hospital, Riga, Latvia

Indulis Kumsars, Paul Stradins Clinical Hospital, Riga, Latvia
Quantitative Coronary Angiography Core Laboratories:

Aarhus University Hospital, Skejby, Aarhus, Denmark: Michael Maeng and Helle Hoej Dahl.

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Primary investigator: Jens Aarøe (3 pts.)

Rigshospitalet, Copenhagen
Primary investigator: Steffen Helqvist (11 pts.)

Odense University Hospital
Primary investigator: Per Thayssen (14 pts.)

Norway
Tromsoe University Hospital
Primary investigator: Terje Steigen (15 pts.)

The Feiring Clinic, Oslo
Primary investigator: Pål Gunnes (50 pts.)

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Primary investigator: Rune Wiseth (4 pts.)

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