Catheterization and Cardiovascular Interventions 63:332–336 (2004)

Basic Science Review

Drug-Eluting Stents for Coronary Bifurcations: Insights Into the Crush Technique

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Sirolimus-eluting stents appear to reduce substantially restenosis following percutaneous coronary bifurcation intervention. The crush technique was devised to reduce restenosis further by improving stent and drug application to the side-branch ostium. We aimed to investigate the performance of drug-eluting stent (DES) platforms with the crush technique, to identify deployment pitfalls, and to clarify the best deployment strategies. Each stage of the crush technique was photographed in a bifurcation phantom. Simultaneous side- and main-branch dilatation (kissing balloons) fully expanded the stent in the side-branch ostium, widened the gaps between stent struts covering the side branch, and eliminated main-branch distortion. With side branches angled at > 70°, sequential (side- then main-branch) inflations may be needed to achieve best results. Postdilatation of the main branch with a balloon of narrower diameter than the deploying balloon caused main-branch stent distortion. These principles applied to all the bifurcation strategies and stent designs tested. *Catheter Cardiovasc Interv 2004;63:332–336.* © 2004 Wiley-Liss, Inc.

Key words: stents; drugs; restenosis; angioplasty; coronary disease; revascularization

INTRODUCTION

Drug-eluting stents (DESs) have dramatically reduced restenosis and the need for repeat intervention following percutaneous coronary intervention in simple lesions [1–3]. Their use is being extended to more complex anatomy such as bifurcation disease [4]. Bare metal stenting (BMS) of bifurcations is technically challenging and associated with a high restenosis rate, particularly when stenting of both the main vessel and the side branch is required [5]. Preliminary results from the BIFURCATION study [4] with sirolimus-eluting stents are promising, with restenosis rates lower than historically achieved with BMS. When two stents were required, the great majority of restenoses occurred at the ostium of the side branch in the gap between main-branch and side-branch stents where metal coverage and therefore drug application were reduced. In the innovative crush technique (Fig. 1) proposed by Colombo (Transcatheter Therapeutics Meeting, 2002), the two stents are deployed with coverage of the bifurcation including the side-branch ostium, so that drug is delivered without gaps (Fig. 1).

Bench-top testing provides unexpected insights into stenting strategies [6]. With the exponential rise in DES use, there is a growing need to identify appropriate strategies, avoid pitfalls, and correct mistakes. Many operators are unfamiliar with the important subtleties of DES implantation and this may lead to suboptimal stent deployment and adverse outcomes, particularly stent thrombosis. This study reports how different DES platforms perform with the crush technique and clarifies the best ways to deploy these stents.

MATERIALS AND METHODS

Study Stents

Testing was performed on the bare metal Bx Velocity (Cordis, Warren, NJ), Express II (Boston Scientific,

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Grant sponsor: Auckland Heart Group Charitable Trust.

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Received 10 October 2003; Revision accepted 15 April 2004

DOI 10.1002/ccd.20120
Published online in Wiley InterScience (www.interscience.wiley.com).

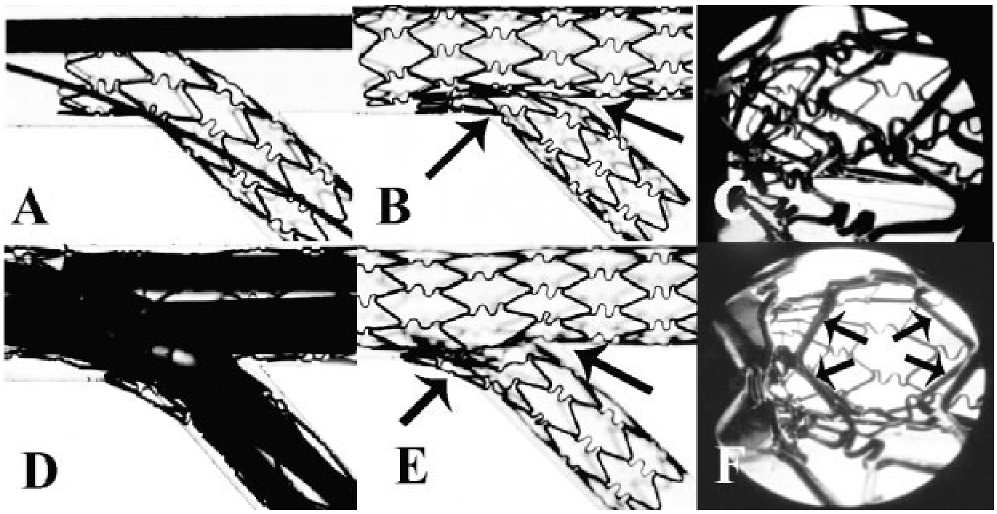

Fig. 1. The crush technique involves deployment of the side-branch stent (A), then the main-branch stent (B) so that the portion of side-branch stent within the main branch is crushed. The suboptimally expanded side-branch stent struts (B, arrows) after kissing balloon inflation. D become fully expanded (E, arrows). An endoscopic view from the side branch before (C) and after (F) kissing balloon inflation shows that postdilatation widens the gaps between the two layers of struts separating the side branch from the main branch (F, arrows), partially releasing the side branch from jail and improving subsequent access.

Natick, MA), and the Driver (Medtronic AVE, Minneapolis, MN), which are the delivery platforms of the Cypher sirolimus-eluting, the Taxus Express paclitaxel-eluting, and Driver ABT 578-eluting systems, respectively.

Technique

Stents were deployed in our previously described phantom [6], which incorporated side branches angled at 45° and 80° from the main branch. The exteriors of the stents were photographed at each stage of each strategy. In addition, the interiors of the stents were photographed through a pediatric endoscope during stages of deployment.

RESULTS

When stents were deployed using the crush technique in a bifurcation phantom with the side branch angled at 45° (Fig. 1), the suboptimally expanded stent at the side-branch ostium was fully expanded by kissing balloon inflations with appropriately sized balloons (Fig. 1). When deployment was in the bifurcation with an 80° angled side branch, underexpansion at the side-branch ostium was more marked and not always corrected by kissing balloon inflation (Fig. 2), especially if the side-branch balloon remained bent and not fully expanded at the ostium (Fig. 2). Full expansion at the ostium was achieved with sequential (side-branch then main-branch) inflations if the side-branch balloon extended only several millimeters into the main branch to allow it to inflate fully. The side-branch balloon needed to be of the same diameter or larger than the deploying balloon to expand fully the side-branch stent at the ostium. With simultaneous (kissing) or sequential inflations in the bifurcation branches after crush deployment, the gaps in the two layers of stent lying across the side-branch ostium were enlarged (Fig. 1), thus improving side-branch access.

Stent distortion occurred with kissing balloon inflations if the main-vessel balloon was smaller in diameter than the delivery balloon (Fig. 3). The distortion occurred with all three stent designs tested and with all bifurcation strategies tested (crush, culotte [5], and single stent). The distortion was corrected by redilating the main vessel with an appropriately sized balloon either with (Fig. 3D and E) or without simultaneous side-branch dilatation.

DISCUSSION

Stenoses at bifurcations remain one of the most challenging lesion subsets for percutaneous coronary intervention [6]. Preliminary results from the BIFURCATION study [4] with sirolimus-eluting stents showed that DESs have considerable potential for these lesions, but found that deployment strategies need further improvement. While patients who received a single DES had a lower restenoses rate than those who received two DESs, half of those randomized to receive a single stent crossed over to receive two DESs. When a T-stent strategy [4,7] was employed and there was a narrow angle between the

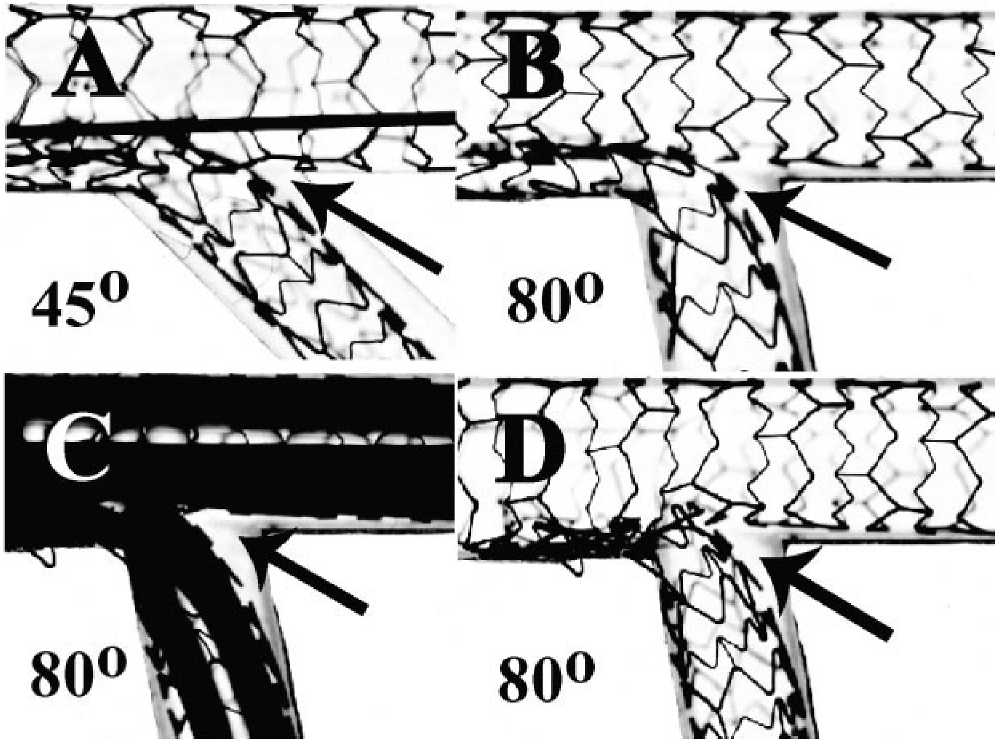

Fig. 2. When the crush technique was carried out in a phantom with a steeply angled side branch (80°), there is marked underexpansion of the stent at the ostium of the side branch (B) compared with deployment in a phantom with a 45° side branch (A). This may not be corrected by kissing balloon inflations (C and D), but can be corrected by sequential side-branch and then main-branch postdilatation if the side-branch postdilating balloon is not bent on itself as it is in C and is able to expand fully.

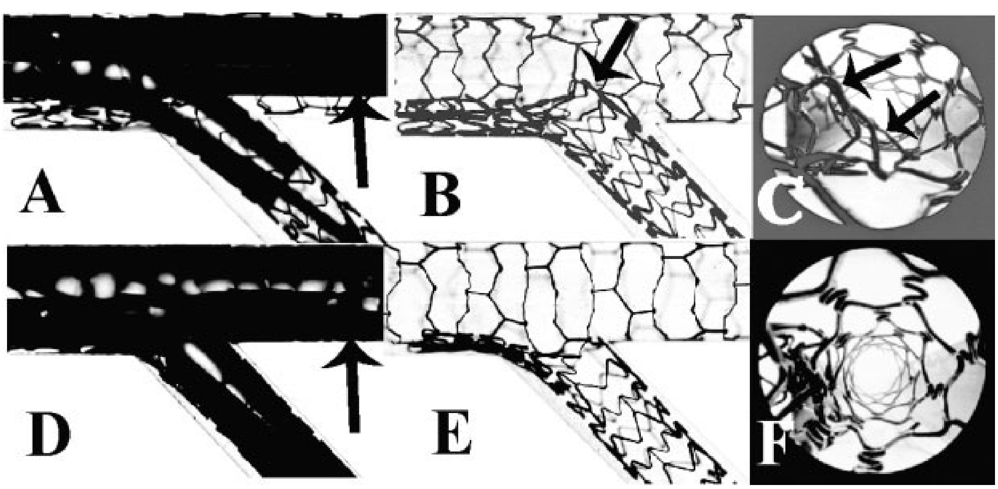

Fig. 3. In A, the crush technique stents (Express II) were postdilated with a main-vessel kissing balloon (A, arrow) that was smaller in diameter than the delivery balloon. This undersized main-vessel postdilating balloon caused distortion of the main-branch stent (B, arrow), which, following kissing balloon inflations (D) with an appropriately sized main-branch balloon, was corrected (E). C is an endoscopic view of the main branch (Bx Velocity stent) showing distortion (arrows) caused by an undersized main-vessel kissing balloon. In F, an undistorted main-vessel stent following crush deployment is shown.

downstream vessels, restenosis largely occurred at the ostium of the side branch where there were gaps in metal coverage and drug application. Concordant data have been reported from a study of nonbifurcation lesions where restenosis after DES occurred where there was stent discontinuity [8]. The crush technique ensures complete vessel scaffolding without gaps in drug delivery at the bifurcation. The crush technique is a safe, simple, and quick strategy. However, postdilatation, which may not be easy, is needed to expand the stent fully in the side-branch ostium (Fig. 1), to widen gaps between the two layers of stent covering the side branch facilitating access (Fig. 1), and to prevent or repair main-branch distortion (Fig. 3). With side branches angled at $\leq 70°$, kissing balloon inflations can produce these outcomes (Figs. 1 and 3). In contrast, with side branches angled at $> 70°$, kissing balloon inflations may not expand the side-branch stent at the ostium (Fig. 2). To expand the stent fully when the branch is angled at $> 70°$, it may be necessary first to postdilate the side branch with a balloon that protrudes only a few millimeters into the main branch. After deflation of this balloon, the main branch should be dilated with an appropriately sized balloon to repair any main-branch distortion. This does not result in recurrence of side-branch ostial stenosis.

The crush technique has a high degree of safety because wire access is maintained in the main vessel throughout and is maintained in the side branch until that stent is deployed and crushed. It is a quick procedure that limits ischemic time, which is particularly important in situations such as left main coronary artery stenting.

However, this study demonstrates that it is important to postdilate both stents with appropriately sized balloons. If side-branch postdilatation is performed without a simultaneous or subsequent main-vessel postdilatation or is performed with an undersized main-vessel balloon, the main-vessel stent will be deformed and potentially unapposed to the vessel wall (Fig. 3). This may predispose to restenosis or stent thrombosis [9]. Distortion occurred with all stent designs and all strategies tested. It can be remedied with postdilatation of the main vessel with a balloon that has the same or greater diameter than the deployment balloon (Fig. 3). The side-branch postdilating balloon should be deflated at the same time or before the main-vessel balloon to avoid recurrence of deformation. The final act in the crush technique should be inflation of an appropriately sized balloon in the main branch, either as part of a kissing balloon inflation or alone, to ensure there is full expansion and no deformity of the main-vessel stent.

If there are concerns that kissing balloon inflations might overdilate the vessel proximal to the side-branch [6], then sequential inflations (side branch then main branch) may be performed. The dangers of using undersized postdilating balloons are that the main-branch stent will be distorted or in the case of an undersized side-branch balloon, the side-branch stent will not be fully expanded at the ostium.

Although with the crush technique, there are three layers of stent applied to the main-vessel wall immediately upstream from the ostium, it is unlikely that three times the usual dose of drug will be delivered because the outer layer partially separates the inner layers from the vessel wall. The operator can limit the length of stent that is crushed, thus limiting the length of the triple layers. The clinical impact of this potentially increased dose to the wall is unknown and may vary between drugs.

There is a growing consensus that to limit restenosis, DES should fully cover the length of a lesion from normal vessel to normal vessel [10]. Pre- and postdilatation should be confined to the region of artery to be stented or already stented, thereby confining arterial damage to the stented region and avoiding geographic miss. While aggressive postdilatation may not be as important with DES as with BMS, it is still essential to expand the stent fully to ensure that the drug is in contact with the vessel wall.

The crush technique was designed for DES. It may not be an appropriate technique for BMS because multiple BMS deployment is associated with a high restenosis rate [5]. In the future, there are likely to be dedicated bifurcation stents that are drug-eluting. These are likely to improve in profile and flexibility so that deliverability will be improved.

Study Limitations

Any bench-top testing is intrinsically limited because it can never precisely reproduce in vivo conditions.

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