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The Double-Kissing Nano-Crush: the ultimate refinement of the crush technique?

Short title: Double-Kissing Nano-Crush

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Brief Summary

In this study, we demonstrate the theory and feasibility of a double-kissing nano-crush technique to treat true bifurcation disease. This technique is a refinement of the mini-crush and DK crush, and provides full lesion coverage, minimal difficulty re-wiring, a short neocarina, minimal protrusion into the MB, and favourable haemodynamics. We demonstrate these points with geometrical modelling, benchtop silicone implantation, micro computed tomography reconstruction, computational fluid dynamics modelling and clinically, with angiographic and intravascular imaging.

Abstract

Background: When possible, a single stent technique to treat coronary bifurcation disease is preferable. However, when two stents are required, there is scope to improve upon existing techniques. The crush technique has already been improved with the introduction of double kissing (DK) and mini-crush. We sought to refine and simplify the mini-crush technique, retaining its advantages whilst avoiding its disadvantages, by developing a DK nano-crush technique.

Methods: The DK nano-crush method allows complete lesion coverage of a bifurcation lesion without excessive metal layers. This is achieved by positioning the SB stent with minimal protrusion into the main branch (MB), implantation of the SB stent with an undeployed balloon in the MB, immediate kissing balloon inflation with formation of a minimal neocarina, stenting the MB, re-crossing the proximal part of the SB without crossing double metal layer, and final kissing. We demonstrate this technique with benchtop implantation, micro computed tomography reconstruction, computational fluid dynamics (CFD) modelling and clinically with angiographic and intravascular imaging.

Results: The DK nano-crush was practically feasible and resulted in full ostial coverage. CFD analysis demonstrated minimally disturbed blood flow. The technique was successfully utilised in nine patients with bifurcation lesions with excellent angiographic outcomes and no adverse events over twelve months.

Conclusions: The DK nano-crush technique may represent the ultimate refinement of the original ‘crush’ with a number of practical and theoretical advantages. It remains to be tested against other bifurcation techniques in prospective trials.

Abbreviations

CFD	Computational Fluid Dynamics
Cx	Circumflex
DK	Double kiss (stent technique)
LAD	Left anterior descending
LMS	Left main stem
MB	Main Branch
SB	Side Branch
TIMI	Thrombolysis in myocardial Infarction

Introduction

Lesions at coronary artery bifurcations are common and challenging to treat with stents. The provisional approach has a strong evidence base (1-3), but many 'true' bifurcation lesions require an up-front two stent strategy (4,5). In recent years, the 'culotte', 'TAP'(6), and improvements in the classic 'crush' technique (7,8) ('mini-crush' and 'DK crush') have translated into more assured procedures with improved clinical outcomes. Yet even the 'mini-crush', according to a European Bifurcation Club consensus document, may give rise to a double metallic layer (9). There is, therefore, scope for refinement with both techniques, notably preserving lesion coverage whilst avoiding procedural complexity and multiple metallic layers at the side branch (SB) ostium. Recently, a very minimal, or 'nano'-crush technique has been described, which aims to minimise protrusion of the SB stent into the main branch (MB) (10). As a further refinement of the nano-crush and DK crush techniques, we have developed a double-kissing nano-crush ('DK nano-crush') technique.

The aims of this study were to demonstrate the deployment, geometry and haemodynamics of the DK nano-crush bifurcation stenting technique in silico, in vitro and in vivo.

Material and Methods

Theory

We developed a DK nano-crush technique, suitable for almost any true coronary bifurcation requiring two stents. The steps are illustrated in Figure 1A. (A) Wires are passed down both MB and SB and the lesions are pre-dilated. (B) A stent is advanced to the SB, and a balloon, slightly smaller than the distal MB, which could be the MB pre-dilatation balloon, is placed, but not inflated, in the MB across the ostium of the SB. The SB stent is withdrawn to the ostium of the SB and carefully positioned under angiography so that the proximal lateral edge of the stent is exactly at, but no further back than, the proximal take-off of the SB. That is the first key step. (C) The SB stent is then deployed. The proximal edge of the SB stent therefore encroaches into the MB a small distance (x). (D) The SB balloon is pulled back half a balloon length and both SB and MB balloons are inflated in 'kissing' formation. The purpose of this manoeuvre is to ensure that there is sufficient space to advance the MB stent whilst keeping the proximal lateral border of the SB stent well opposed at the bifurcation. Both balloons are withdrawn. (E) The MB stent, sized 1:1 to the distal MB, is then positioned and (F) implanted across the bifurcation. The SB wire may then be withdrawn. (G) Proximal optimisation with a short balloon sized 1:1 to the proximal MB may then be performed, care being taken to position the balloon proximal to the carina. (H) The SB is then re-wired through the proximal part of the SB ostium, thereby avoiding the neo-carina. That is the second key step. It is easy to perform, because there is only one layer of stent to cross and the proximal optimisation will have left an angulated entry to the SB. (I) A final kissing inflation is performed with two balloons sized 1:1 with their respective distal vessels. (J) The final result leaves a short neocarina, of two stent layers, slightly angulated between MB and SB. The procedure is compatible with a 6F calibre guide catheter.

Geometry

Please refer to Figure 1B. When the angle between SB and MB is θ degrees, the diameter of the proximal MB is denoted by MBp, the diameter of the distal MB by

MBd, and the diameter of the SB by SB, the length of the expected neocarina (X) may be calculated as:

$$X = SB\ \tan(90-\theta) - \frac{(MB_p - MB_d)}{\sin\theta} \qquad (1)$$

We calculated carinal length for this technique for a 3.5mm MBp leading to three commonly encountered combinations of distal vessel size, all obeying the law of bifurcations as set out by Huo-Kassab, and recommended by Finet et al (3), with MBd/SB 2.9/2.2mm, 2.7/2.5mm and 2.6/2.6mm, at angles of 30, 50 and 70 degrees.

Benchtop demonstration

We implanted pairs of stents (Coroflex Blue™, B-Braun, Melsungen, Germany) in silicone models of bifurcations on the benchtop in the same nine configurations as outlined above (3.5/2.9/2.2mm, 3.5/2.7/2.5mm and 3.5/2.6/2.6mm each at 30, 50 and 70 degrees) under direct vision, with the DK nano-crush technique, using a 3.0 mm stent in MB and a 2.5 mm stent in SB, varying the pressures to achieve 1:1 sizing with the respective downstream vessels. We documented this with photography at each deployment stage. At the end, each stented bifurcation was subjected to micro computed tomography (micro CT, Quantum-FX, PerkinElmer, UK) and 3D image reconstruction.

Computational fluid dynamics

Two stented silicone phantoms, namely the case with vessel size of 3.5/2.6/2.6 mm and angle of 30 degrees and the one with vessel size of 3.5/2.9/2.2 mm and angle of 70 degrees, were selected to perform pulsatile computational fluid dynamics (CFD) simulations, because they represent two extreme scenarios in terms of distal vessel size and bifurcation angle. A 3D reconstruction method (11), initially developed for non-bifurcated geometries and here adapted to bifurcations, was used to create the stented bifurcated geometries for the execution of the simulations. Detailed information about this method is reported in the Supplementary Data. CFD was performed according to a previously described approach (12). A typical human LAD flow waveform was applied at the inlet (13) with an average flow-rate of 50 mL/min (14). A flow-split, which was calculated using the Huo-Kassab scaling law (15) (0.51:0.49 and 0.62:0.38, for the first and second analysed case, respectively), was imposed at the distal MB and SB. The walls were assumed to be rigid with a no-slip wall-boundary condition. The blood was modeled as a non-Newtonian fluid with constant density. For both cases, the flow patterns, regions of disturbed flow and the wall shear stress were analysed.

Clinical feasibility and imaging

We treated nine patients with true bifurcation disease with the ‘DK nano-crush’ technique. We documented acute feasibility, procedural success and one year outcomes.

Results

Geometry

The DK nano-crush technique, with full SB coverage, resulted in a length of the neocarina, for all combinations of sizes of two significant branches of a 3.5 mm vessel, from 0.2 mm or nil (SB angle 70 or 90 degrees, respectively) through 1 mm (angle 50 degrees) to 2.7mm (30 degrees) (Figure 1B), without covering the proximal part of the SB ostium with a second metal layer.

Benchtop deployment, micro CT and computed blood flow

The DK nano-crush technique was practically feasible as described when performed under direct vision (Figure 2A). The deployment produced a stented bifurcation as described (Figure 2B). Figure 3A shows the velocity field at peak flow-rate for the bifurcation phantom with vessel size of 3.5/2.6/2.6 mm and angle of 30 degrees and that with vessel size of 3.5/2.9/2.2 mm diameters and angle of 70 degrees. In both cases, blood flow was minimally disturbed by the stent struts without presenting any recirculation at the SB entrance. Only a small stagnation zone was observable at the neocarina of the phantom with 70 degrees bifurcation angle. As illustrated in Figure 3B, the lumen regions with low wall shear stress were located close to the stent struts in both the investigated phantoms. The phantom with 70 degrees bifurcation angle was characterized by a greater percent lumen area exposed to time-averaged wall shear stress <0.4 Pa as compared to the case with 30 degrees (22.9 % vs 15.8 %, respectively). This higher value is related to the larger expansion of the proximal MB that occurred in the phantom with 70 degrees bifurcation angle (Figure 3B, cross-sectional views). The percent area of proximal MB exposed to time-averaged wall shear stress < 0.4 Pa was 32.3 % for the case with 70 degrees bifurcation angle, compared to 20.1 % for the phantom with a 30 degrees bifurcation angle. Conversely, similar values were found by limiting the analysis to the SB and distal MB stented regions (16.5 % versus 12.9 % for the phantoms with bifurcation angle of 70 and 30 degrees, respectively).

Clinical deployment

The DK nano-crush technique was deployed in nine patients with Medina 1,1,1 bifurcation disease. The clinical and procedural details are shown in Table 1. A single dose of peri-procedural heparin was given, and all patients were prescribed dual anti-platelet therapy in accordance with clinical presentation and ESC /National guidelines. The technique was clinically successful in all cases, including one case (Patient 7) who had in-stent restenosis in a previously placed left anterior descending (LAD) stent straddling the diagonal branch. A learning curve was observed with regard to wire-recrossing, so final balloon kissing was not possible in three early cases, but a proximal optimisation technique (POT) was deployed in all. The angiographic results were excellent, TIMI grade 3 flow was achieved in both branches, and there were no adverse outcomes at one year. A representative example, an LAD bifurcation lesion, is shown with the procedure captured in sequence (Patient 3, Figure 4). An example of optical coherence tomography images at the end of the procedure (longitudinal section and cross-section, Patient 7) are shown in Figure 5. Of note, in all cases, is the complete metal coverage and small, unobstructive neocarina.

Discussion

In this study, we have demonstrated the theory and practical feasibility of a DK nano-crush technique to treat true bifurcation coronary artery disease. This technique is a refinement of the mini-crush and DK crush and provides full lesion coverage, minimal difficulty re-wiring, a short neocarina, minimal protrusion into the MB, and favourable haemodynamics.

This technique, which builds upon the most promising recent developments in bifurcation PCI strategy, was pursued because of the continuing need for a simple, effective two-stent strategy to treat bifurcations. It appeared from guidelines that even the ‘mini-crush’ may leave a double metallic layer over the whole SB ostium. We showed, in contrast, that this is not required or, indeed, possible with accurate representation of the distal branch sizes according to the rules of Huo-Kassab (15), as recommended by Finet (16), and meticulous SB stent positioning in the ‘nano-crush’ position. When the best physiological rules are followed (portrayed to exact scale in our Figures), the only double layer forms a short neocarina varying in length from nil (SB angle 70 degrees) to 2.7 mm (SB angle 30 degrees – an unusually extreme case), in a typical bifurcation of a 3.5 mm vessel, whatever the relative calibre of the distal MB and SB. Even large neocarina are promptly covered, so this ultra-short new carina should not be of any concern (17). The size of the neocarina is identical to that of the TAP which is associated with excellent long term outcomes (18). Also, avoidance of a double layer over the proximal SB orifice allows easy wire re-crossing after proximal optimisation, and a high success rate of final kissing, with minimal protrusion into the MB.

The TAP has become a popular strategy because it produces a good final result in most cases, comprises relatively few, uncomplicated steps and is feasible via a 6F guiding catheter. However, the TAP is a provisional technique (A in the EBC ‘MADS’ classification); the MB is treated first and the SB is rescued, post hoc, if needed. This has a strong evidence base and is appropriate for many cases. However, there are some cases which require the SB to be secured before the MB is treated. Current ‘upfront’ two stent techniques include crush (DK and mini), culotte, SKS and V.

These techniques are either more complicated and /or are beset with potential limitations. This is where the DK nano-crush is effective because it is appropriate in cases where securing the SB is a priority (S in the MADS classification) but with key advantages of the TAP. Key procedural, tehnical and clinical characteristic of bifurcation stent techniqies are compared in Table 2.

In contrast, DK nano-crush is an upfront two-stent bifurcation strategy. It is well suited to cases where the priority is to secure the SB. There is no need to lose access to the MB at any point and SB re-wiring is improved by only needing to cross one layer of stent and is facilitated by the first kiss. The key technical challenge is positioning the SB stent prior to deployment. Careful angiography and optimal visualisation of the bifurcation is required so that the SB stent is positioned at the ostium ensuring full proximal ostial coverage with minimal MB protrusion. Similar to other bifurcation stent strategies, it is vital that the POT step is also performed adequately to high pressure, sized 1:1 to the proximal vessel, covering the proximal portion of the SB ostium.

Good 30 day and one year clinical results were achieved with this technique in an unselected series of nine ‘all-comer’ patients with true bifurcation disease, although the final kissing SB balloon could not be advanced in one case with heavy calcification. Prior to widescale adoption, it will be important to ascertain the long-term outcomes in a large, adequately-powered cohort and to generate prospectively collected, randomised comparative data versus other two stent techniques.

Conclusion

The DK nano-crush technique may offer all the advantages of mini-crush and DK crush without the disadvantages. It is reasonably easy and quick to perform, and has the advantages of full lesion coverage, easier SB re-cross and minimised carinal protrusion and doubled metallic layers. As with all two stent techniques, heavily calcified lesions require comprehensive preparation. Long term results are awaited.

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Disclosures

The authors have no conflicts of interest to declare.

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Tables

Table 1: Clinical and procedural details of patients who underwent the DK nano-crush technique.

Patient	Sex	Age	Present-ation	Lesion	Stents	Wire re-cross	POT	Final kiss	Angio success	TIMI flow	12 month events
1	M	66	NSTEACS	LAD/D	3.5/2.75	N	Y	N	Y	3	N
2	M	76	STEMI	LAD/D	3.5/2.75	N	Y	N	Y	3	N
3	M	56	Stable	LAD/D	3/2.5	Y	Y	Y	Y	3	N
4	M	48	NSTEACS	LAD/D	3/2.5	Y	Y	Y	Y	3	N
5	F	69	Stable	LAD/D	3/2.5	Y	Y	Y	Y	3	N
6	M	66	Stable	LAD/D	2.75/2.5	Y	Y	N	Y	3	N
7	M	59	Stable	LMS/Cx	4.5/3	Y	Y	Y	Y	3	N
8	F	50	NSTEACS	LMS/Cx	4/3	Y	Y	Y	Y	3	N
9	M	58	Stable	LAD/D	3.5/2.5	Y	Y	Y	Y	3	N

NSTE-ACS = Non-ST Elevation Acute Coronary Syndrome, LAD = Left anterior descending, D = diagonal, LMS = Left main stem, Cx = Circumflex.

Table 2. Comparing DK nano-crush with other 2-stent bifurcation strategies.

	Prov T	TAP	Culotte	V /SKS	DK /mini-crush	DK nano-crush
Guide catheter	5-6F	6F	6F	7F	7F	6F
MB de-wired	No	No	Yes	No	No	No
Provisional	Yes	Yes	Possible	No	No	No
Full coverage	Possible	Yes	Yes	Yes	Yes	Yes
SB rewiring	Yes	Yes	Yes (multiple)	No	Yes (through multiple layers)	Yes
Steps*	8	8	9	4	10, 13 if DK	8
Shallow angle	Suitable	Not ideal	Suitable	Not ideal	Suitable	Suitable
Wide angle	Ideal	Suitable	Not ideal	Not ideal	Not >60	Suitable
Small SB	Ideal	Suitable	Not ideal	Not ideal	Suitable	Suitable
Potential limitations	Gap at ostium	Careful SB stent positioning	Multiple re-wiring	Large neocarina, difficult re-intervention	Multiple crushed stent layers, difficulties re-wiring and delivering balloons to SB	Careful SB stent positioning

Prov T; provisional T, TAP; T and protrusion, SKS; simultaneous kissing stents, DK; double kissing, MB; main branch, SB; side branch, * including initial wiring, pre-dilatation and proximal optimisation steps. Adapted from Foin et al (19).

Figure Legends

Figure 1

The DK nano-crush technique. A) The procedure. For commentary, see ‘Theory’ in Methods. B) Geometrical analysis, showing the length and position of the neocarina for three combinations of branch size and angle.

Figure 2

A) Photographs of the key stages of the DK nano-crush technique in a silicone bifurcation. B) Micro CT images of the deployments in silicone bifurcations deployments at 30, 50 and 70 degrees.

Figure 3

Computational fluid dynamics results of the stented silicone phantoms with vessel size of 3.5/2.6/2.6 mm and angle of 30 degrees (left), and vessel size of 3.5/2.9/2.2 mm and angle of 70 degrees (right). A) Velocity contours in the middle plane at peak flow-rate. The panels show a magnified image of the velocity field with in-plane velocity vectors at the bifurcation region. B) Contour maps of time-averaged wall shear stress (WSS). A cross-sectional view at the proximal main branch with the lumen border coloured with the time-averaged WSS is also displayed for each case.

Figure 4

An example of the DK nano-crush technique in a 66 year old patient with severe disease at the LAD/D1 bifurcation (A). Both vessels were wired and then predilated (B,C,D). A 2.5x20mm Promus Premier™ (Boston Scientific) stent was positioned in D1 with a 2.5mm balloon (the one used to predilate the LAD) in the MB. Care was taken to ensure that the proximal end of the SB stent was precisely positioned at the take-off of the SB (E). The SB stent was deployed (F). The MB balloon was inflated (G, H) and the SB balloon was pulled back and a kissing inflation was performed. Angiography demonstrated patency of both vessels (I). A 3x48mm Xience™ (Abbott) stent was positioned (J) and deployed in the MB (K). Proximal optimisation was performed with a 3.5x12mm balloon (L) with a good angiographic result (M). The SB was rewired through the proximal part of the SB ostium and a final kissing inflation was performed with 3.0 and 2.5mm balloons (N) with and excellent angiographic result (O) and a short neocarina (P).

Figure 5

Optical coherence tomography of Case 7 after 'DK nano-crush' stent deployment to the LAD and diagonal. A) Longitudinal section through LAD showing origin of stented diagonal branch. 'X' indicates the neocarina; the black arrow indicates the position of cross-section shown in B. 'S1' and 'S2' are the original and new MB stents respectively. B) Cross-section at the level of the neo-carina (x). This example was originally a severe case of 1,1,1 bifurcation in-stent restenosis in a stent placed using a 'provisional' technique across the diagonal branch which explains the double strut layer in the LAD.