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Double-Kissing Culotte Technique for Coronary Bifurcation Stenting - Technical evaluation and comparison with conventional double stenting techniques

Short title: Double-kissing Culotte stenting technique

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Abstract

Aim

To assess, whether Culotte technique could be improved by an additional kissing dilation prior main branch (MB) stenting.

Methods and results

Double-kissing (DK) Culotte was compared to Culotte and DK-Crush techniques *in bench* model (n=24). Results were evaluated for stent apposition, for luminal opening and for flow dynamics.

Total procedure duration of DK-Culotte was 18.3±3.4min, significantly lower than for DK-Crush (24.3±5.7min; p=0.015), however similar to Culotte (21.6±5.9min, p=0.104).

In DK-Culotte overall rate of moderate (200-500μm) and significant (>500μm) malapposition was 2.1±1.9% and 0.4±0.2%; similar as compared to Culotte (3.7±3.8%, p=0.459 and 1.0±1.0%, p=0.517; respectively), and lower as compared to DK-Crush (8.1±2.5%, p<0.001 and 3.7±5.3%, p=0.002; respectively). Lower malapposition rate of DK-Culotte as compared to DK-Crush was due to less moderate and significant malapposition in proximal MB (0.0±0.0% vs. 14.0±7.6%, p<0.001 and 0.0±0.0% vs. 4.2±9.1%, p=0.026, respectively). Micro computed tomography did not show difference in luminal opening at proximal MB, distal MB or SB. There was no difference either in maximum shear rate or in areas of high shear or recirculation.

Conclusion

Bench tests data suggest that DK approach facilitates Culotte technique. Clinical validity and relevance remains to be confirmed in larger in vivo population.

Classification:

Bifurcation; Left main; Drug-eluting stent

Condensed abstract

Present study assessed, whether Culotte technique could be improved by double-kissing approach. It was found that the total procedure duration of DK-Culotte was significantly lower than for DK-Crush, however similar to Culotte. In DK-Culotte overall rate of moderate and significant malapposition was 2.1±1.9% and 0.4±0.2%; similar as compared to Culotte but markedly lower as compared to DK-Crush (8.1±2.5%, p<0.001 and 3.7±5.3%, p=0.002; respectively). Lower malapposition rate of DK-Culotte was due to less moderate and significant malapposition in proximal MB.

Abbreviations:

CFD – computational fluid dynamics; DK – double kissing; GW – guide wire; LAD – left anterior descending; LCx – left circumflex; LM – left main; MB – main branch; OCT – optical coherence tomography; PCI – percutaneous coronary intervention; SB – side branch; μCT – micro computed tomography

Introduction

Coronary bifurcations represent one of the most challenging setting for the interventional cardiologists. This is due to the fact that conventional stents are designed and shaped to restore tubular geometry, while bifurcation anatomy is far more complex with different diameters and non-tubular cross-sections. [1] In addition, despite percutaneous coronary interventions (PCI) have evolved with different techniques using single-, two stents, or dedicated devices, the optimal treatment is still a matter of discussion for each individual case due to the highly complex and specific morphology of each bifurcation lesions. [2]

Provisional T-stenting has been generally considered as the gold standard technique because it is relatively simple and has also demonstrated excellent short- and long-term outcome. [3-4] Nevertheless, its applicability might be limited in more complex coronary anatomies, when intentional double stenting techniques should be considered instead.

A wide variety of two stenting techniques have been described and evaluated, among them recent trials have demonstrated a favorable procedural and long-term outcome associated with Double-kissing Crush (DK-Crush) technique. [5] The specificity of this technique, as compared to the conventional Crush technique, is the performance of an additional kissing-balloon dilation of the side-branch (SB) prior to main-branch (MB) stenting. The advantage of it is that MB stenting should not cause relevant deformation toward the SB, and in the SB stent itself. Therefore, after MB stenting the access to the SB is more predictable and straightforward for the final kissing-balloon dilation.

Single final kissing-balloon dilatation is also foreseen for the Culotte stenting. The aim of the present study is to assess in bench models and human cases, whether Culotte stenting technique could be improved by performing a 'double-kissing approach', i.e. by optimizing the SB result with additional kissing balloon dilation before stenting the MB.

Methods

Tested bifurcation techniques

Reverse double-kissing (DK) culotte was investigated both in a bench model and in patients with amenable stenosis in bifurcations. Results of reverse DK-Culotte were compared to DK-Crush or reverse Culotte as reference techniques.

DK Culotte - Technique differs from conventional reverse Culotte in one additional kissing-balloon dilation, performed after SB stenting, prior MB stenting. The technique has the following steps (**Figure 1**): two guidewires (gw) are used, i.e. the 'MB-gw' and the 'SB-gw'. **(A)** SB-gw was advanced into SB, and **(B)** stent was deployed in the continuity of MB to SB. **(C)** Stent was then proximally optimized in the proximal MB. **(D)** MB-gw is introduced into distal MB, crossing the previously implanted stent at the most distal cell. **(E)** Cell could be first opened with a small balloon. **(F)** Next the *first kissing* dilation was performed using balloons, fitted to the diameter of the distal branches. First the SB balloon was inflated to maintain the stent architecture, followed by MB balloon inflation. Deflation was simultaneous. **(G)** Next, the SB-gw was removed and a stent was deployed in the continuity of proximal to distal MB. **(H)** Stent was then proximally optimized. **(I)** Then SB-gw was introduced to SB, crossing the previously implanted stent at the most distal cell. **(J)** Cell could be first opened with a small balloon. **(K)** Next the *second kissing-balloon* dilation was performed, using balloons, fitted to distal branch diameters. First MB balloon was inflated in order to maintain its architecture, followed by the SB balloon. Deflation was simultaneous. **(L)** As final step proximal optimization was performed.

Reverse Culotte - Procedure was performed as previously described, [6] with additional proximal optimizations after each stenting steps.

DK Crush - Procedure was performed as previously described, [7] with an additional proximal optimization after crushing the SB stent.

For all the three techniques it was aimed to have 3mm protrusion of the SB stent into the true proximal MB beyond the polygon of confluence, so far accurately achievable.

Bench test

A total of 8 tests were performed for each of the 3 techniques (*DK-Culotte, Culotte, and DK-Crush*) in 3D printed, two-side polished, pure saline-filled silicone vessel phantoms. 3D bifurcation models were produced by a polyjet printer, using rubber-like elastomeric material, called TangoPlusTM (Sirris Inc., Brussels, Belgium). Exact parameters are shown in **Supplement Figure 1**. Procedures were performed by operator, having sufficient practical (human- and bench-) experience with both, DK-crush and Culotte techniques. Accordingly, no trend of 'improvement' in procedural times was observed over the bench procedures, which suggests also that cases were performed over the learning curve. Procedural time was defined as the total duration between entering the bench model with the first gw until completing the last step of the procedure, as described above. Rewiring times were defined as the duration between the gw enters the bench model until it reaches an optimal distal position in the aimed branch, through the aimed cell.

Optical coherence tomography - OCT imaging was done systematically at the end of each procedure for evaluation of apposition. Pullback runs were performed at 20mm/s with Dragonfly Duo OCT catheter and analyzed by a dedicated workstation (C7-XRTM OCT Intravascular Imaging System, Abbott Inc., Illinois, US). Images were recorded at 100 frames per second. Note that OCT pullback was only documentary and not meant to guide PCI. Bifurcations were analyzed in six areas, namely (1) 3mm of the proximal MB; (2) 3mm of the distal MB; (3) 3mm of the SB; (4) polygon of confluence – abostial area; (5) polygon of confluence – roof and (6) polygon of confluence – carina. (**Supplement Figure 1**)

Malapposition of stent struts was calculated as described previously [8], graded as: (1) full apposition (no malapposition can be observed); (2) incomplete apposition (0-200 microns); (3) moderate malapposition (200-500 microns); and (4) significant malapposition (>500 microns). Note, OCT analysis was performed in parallel by two different groups (LDS and DF; VS and GS), blinded to the procedure and to the results of the other group.

Micro computed tomography (μCT) - Final stent deformations were visualized at voxel resolution of 15 microns/voxel. Scanned volumes were segmented using ITK-SNAP [9], smoothed and reconstructed using a finite element meshing technique. Diameter and area stenosis in the proximal MB, in the distal MB and in the SB, as well as angulation between MB- and SB axes were measured. Stenosis was quantified in a planar projection perpendicular to the segments' axis, as accurate following the definition proposed by Ormiston et al. [10], taking the largest circle fitting in the smallest luminal strut-free area as luminal opening. Note, μCT analysis was performed blinded for the performed technique.

Computational fluid dynamics (CFD) analysis - Flow patterns and shear rate were analyzed to identify segments with higher risk of flow disturbance induced. 2-dimensional longitudinal geometries were obtained from OCT, which were subsequently meshed and simulated with flow conditions similar to experimental conditions using fluid computational software (Fluent, ANSYS). Boundary conditions for this simulation were steady flat profile inlet flow velocity, simulating a flow rate of 200 mL/min. Inlet and outlet ends were extended based on respective diameters to allow flow development simulation. The area of high shear rate (>1000 s^{-1}), maximum shear rate and area of flow recirculation were obtained.

Statistical analysis

All analyses were performed with Prism GraphPad 5.0 (GraphPad Software Inc., California, US). Summary descriptive statistics are reported as mean ± SD or n (%), as appropriate. Results of different techniques or models were compared by Mann-Whitney tests or Kruskal-Wallis test and categorical variables were compared with Fisher's exact or chi-square tests, as appropriate. When analyzing the malapposition rates, the average of the two groups' results was taken on procedure and segment level. A probability value of $p<0.05$ was considered as significant.

Results

All procedures with DK-Crush (n=8), Culotte (n=8), and DK-Culotte (n=8) were successfully performed (**Table 1**, **Figure 2**). Total procedure duration of DK-Culotte was 18.3±3.4 minutes, significantly lower than for DK-Crush (24.3±5.7 minutes; p=0.015), however similar to Culotte (21.6±5.9 minutes, p=0.104) (**Figure 3**). Duration of first rewiring through Stent #1 was similar for DK-Culotte and Culotte (20.4±6.8 versus 23.8±9.5 seconds, respectively; p=0.440), with trend for shorter duration as compared to DK-crush (30.5±13.3 sec; p=0.086). There was a trend for shorter duration of second rewiring for DK-Culotte compared to DK-Crush (17.9±10.6 versus 28.1±12.9 sec, respectively; p=0.087), while it was significantly shorter than for Culotte (33.6±15.9 sec; p=0.050).

On average 3.5±0.8 balloons were used per procedure for DK-Culotte, similar to Culotte (3.9±0.8) and DK-Crush (4.0±0.5). Importantly, smaller balloon(s) was needed for opening stent struts towards the jailed branch in 3 out of 8 DK-Culotte, 3 out of 8 Culotte and 7 out of 8 DK-Crush cases. This might be translated into longer procedural durations, as well.

Optical coherence tomography

OCT runs were obtained in all bench models. Image quality in one DK-Crush case was not sufficient for proper assessment, therefore excluded. In total, 1356 OCT frames were analyzed and 12735 struts were identified. (**Table 2**) In DK-Culotte perfect apposition was seen in 69.2±12.2% of the struts, similar to Culotte (69.6±14.5%) and to DK-Crush (66.6±7.0%). Rate of moderate malapposition was 2.1±1.9%, while 0.4±0.2% of the struts were significantly malapposed in DK-Culotte. These rates were found similar as in Culotte (3.7±3.8% and 1.0±1.0%, respectively), and significantly lower as in DK-Crush (8.1±2.5% and 3.7±5.3%, respectively).

In proximal MB DK-Culotte resulted in less moderately and significantly malapposed struts compared to DK-Crush (0.0±0.0% vs. 14.0±7.6%, $p<0.001$ and 0.0±0.0% vs.4.2±9.1%, $p=0.026$, respectively) with no difference compared to Culotte (2.5±6.6%, $p=0.467$ and 0.0±0.0%, $p=1.000$). Moderate and severe malapposition was mainly detected in areas with multiple layers of struts and at their edges where the most inner stent layer 'descends' towards the wall. Note, here multiple layers of stents were identified in 2.7±0.3mm vs. 2.6±0.3mm vs 2.8±0.2mm ($p=0.438$), respectively.

At the roof of polygon of confluence DK-Culotte had less moderate or significant malapposition as compared with DK-Crush and Culotte. At the abostial site of polygon of confluence DK-Crush had highest rate of perfect apposition but the rate of moderate or significant malapposition was similar for all techniques. In distal MB, SB and carina results were comparable for all techniques.

Performance in bifurcations angled 40° versus 60° versus 70° were similar in the terms of moderate and significant malapposition either in Culotte (7±7% vs 3±0% vs 4±4; $p=0.896$), or in DK-Culotte (4±2% vs 2±2 vs 2±0%; $p=0.286$) or in DK-Crush (10±5% vs 19±6% vs 5±5; $p=0.221$).

Micro computed tomography

μCT analysis did not show any difference between the three investigated techniques in terms of luminal opening in proximal MB, in distal MB or in SB (**Figure 4**, **Table 3**). However, DK-Culotte changed the native SB angulation significantly less, as compared to DK-Crush (7±5% vs 15±9%, respectively; $p=0.050$). Compared to Culotte technique the difference was statistically not significant (13±13%; $p=0.463$).

Computational fluid dynamics (CFD) analysis

CFD analysis did not show any statistical difference between the techniques in terms of overall maximum shear rate, area of high shear or area of recirculation. (**Figure 5**, **Table 4**) However, at the polygon of confluence maximum shear rate was significantly higher for Culotte, as compared to DK-Culotte (3933±57s^{-1} vs. 2590±580 s^{-1}, respectively; p=0.041), while there was just a trend, when compared to DK-Crush (3933±571s^{-1} vs. 2593±293s^{-1}, respectively; p=0.055). Similarly area of high shear rate was also markedly higher for Culotte than for DK-Culotte (0.388±0.009mm^{2} vs. 0.175±0.004mm^{2}, respectively; p=0.050), showing just a trend when compared to DK-Crush (0.388±0.009mm^{2} vs. 0.181±0.004mm^{2}, respectively; p=0.063). (**Figure 6**)

In overall, functional results were better in bifurcations with 70° angulation as compared to bifurcations with less than 70° angulation in terms of maximum shear rate (2731±496s^{-1} vs 4018 ±1804s^{-1}, respectively; p=0.044) and area of high shear (0.33±0.19mm^{2} vs 1.07 ±1.12mm^{2}, respectively; p=0.007) with no difference in area of recirculation (2.36±2.38mm^{2} vs 2.79 ±1.76mm^{2}, respectively; p=0.360).

Discussion

In the present study, we described a modified Culotte technique, the DK-culotte. In the bench tests, DK-Culotte resulted in a markedly lower stent malapposition at least at one location of the bifurcation, as compared to both Culotte- and DK-Crush techniques.

Nearly 10-15% of all PCI procedures are performed in relevant bifurcations. Although provisional T-stenting stands for a good solution in most of the cases, it might not be the right option for the most complex coronary bifurcation anatomies, such as true bifurcations when a large SB is stenosed over a long segment. In these cases, provisional T-stenting does not always provide optimal and predictable result, suggesting that intentional double stenting techniques should be considered instead. [2; 11]

A wide variety of two stenting techniques have been described and evaluated including T-, T-and-Protrusion, Culotte- and Double-kissing Crush (DK-Crush), Single String, Reverse String stenting, etc. Main limitations with these techniques are related to the multiple metallic layers, frequent stent strut malapposition and neocarina formation, incomplete vessel coverage or major deformation of the stent architecture. Still, among all these techniques, recent clinical data support DK-Crush the most. Although triple stent layer in the proximal MB and major deformation of the stent architecture are relevant criticisms against DK-Crush, its major advantage is represented by the minimal neocarina (as compared to T-and-protrusion technique), the perfect SB ostium coverage (as compared to T-stenting technique) and the good stent apposition at the level of the SB, achieved by the first- and maintained by the second kissing dilation. These advantages are reflected by favorable outcome data. [5]

Considering that physiological integrity of the vessel lumen plays a key role in the maintenance of normal flow patterns, during bifurcation PCI emphasis has to be put on avoidance of any disturbance (i.e. ovoid shape, changed angulation, floating struts, massive stent deformation). Accordingly, the more the native tubular anatomy is reconstructed instead of construction of a neo-anatomy, the more physiologic flow patterns can be expected with less turbulence, lower loss in driving pressure, less impaired shear-stress patterns and eventually even less abnormal platelet activation. [12-13] From a structural point of view, Culotte technique might be considered as more 'physiologic', as it ensures full coverage in all the three segments (as compared to T-stenting); there is minimal or no neocarina (as compared to T-and-protrusion); there is no triple layer (as compared to DK-Crush); and stents' tubular architecture is maintained with fractal deformed only (as compared to DK-crush). Still, these structural advantages can be achieved only in case of perfect performance, which might be often limited by certain technical restrains. Namely, while opening the struts of the first stent (i.e. MB stent towards SB in conventional Culotte; SB stent towards MB in reverse Culotte) major deformation is caused in the stent architecture by pulling multiple struts away from the SB and towards its ostium (**Figure 7**; **Video 1**). This causes major malapposition in the SB stent, however it can be probably corrected with the final kissing. But these malapposed struts can even complicate the rewiring process or resulting in false rewiring, which jeopardizes the feasibility and accuracy of the final kissing dilation. The latter can result in major clinical consequences, since lacking final kissing balloon dilatation is one of the major conditions, associated with target lesion failure in long-term in any double-stenting technique. [14]

The present feasibility study aimed to assess, whether the 'double-kissing' approach might be beneficial for the Culotte technique, as well. The rationale behind is that first kissing balloon dilation could already *complete* the SB result, while also preparing the MB access. Then, second kissing-balloon dilation completes the MB result, while just *maintaining* the result in the SB (**Figure 7**; **Video 2**). As suggested by data derived from bench tests, the double-kissing approach for Culotte shows benefits as compared to DK-Crush but also as compared to Culotte: DK-Culotte resulted in markedly lower rate of moderately or significantly malapposed struts. This finding was most pronounced in the proximal MB and in the roof of the polygon of confluence. In the latter location DK-Culotte demonstrated a trend for better result as compared to Culotte. As expected both, DK-Culotte and Culotte showed lower rate of *perfect* apposition at the abostial site of the polygon of confluence (i.e. where stent opening might be limited by other stent), however the rates of either moderate or significant malapposition remained similar. As consequence, even though statistical difference was not reached, the simulated flow patterns are closest to physiologic after DK-Culotte with lowest shear rates. Interestingly, the better structural performance could be achieved within shorter procedure duration despite the additional step of kissing-balloon dilation. This might be explained by the prepared and maintained access to the jailed branches and the simpler rewiring and balloon access, as consequence. We did not find statistical difference in the luminal opening, assessed by μCT, even though there was a numerical trend especially in the proximal MB, favoring DK-Culotte. Interestingly, native bifurcation angle was markedly less influenced by DK-Culotte as compared to DK-Crush, which could have relevance in fluid dynamics, as described above. These findings suggest that post-procedural anatomy after DK-Culotte procedure can be ideally close to the native anatomic structure. Although detailed physiologic evaluation was beyond the scope of this project, one can speculate that a near-normal geometry will translate into near-normal hemodynamics with potential pathophysiological benefits and better long-term outcomes. Still, computational flow dynamic analysis did not reveal any functional differences between the tested techniques.

Limitations

(1) During our bench tests we could not incorporate the impact of different plaque distribution and plaque composition. Even though high-precision 3D printing was used for preparing bench models, the variability between two models was not assessed and therefore cannot be excluded. (2) Due to geometric incoherence (namely the angulation between the plane of the OCT image and the true cross-sectional plane of the SB ostium) the accuracy of OCT in evaluating malapposition is hampered by marked overestimation especially at the level of the carina. Additionally, for one DK-Crush case the OCT had poor image quality, therefore it was excluded for the analysis. (3) Computational flow dynamics allows the assessment in one single longitudinal plane neglecting the 3-dimensional deformation of stent structure during bifurcation PCI.

Conclusion

Bench tests suggest that double-kissing approach can significantly facilitate the performance of Culotte technique: The additional kissing-balloon dilation allows significant reduction in the total procedural duration, while resulting in better optimized overall final strut apposition. At this respect, DK-Culotte may be superior not only to conventional Culotte, but also when compared to DK-Crush technique, which is currently often performed. Clinical validity of present findings remains to be confirmed in a larger in vivo study population.

Impact on daily practice:

Understanding structural benefits of DK-approach during Culotte stenting can facilitate complex bifurcation stenting during everyday practices. In the meanwhile it even sheds new light on potential disadvantages of conventional Culotte stenting, explaining historical clinical differences, when compared to DK-Crush.

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Disclosure

GT receives personal fees from Abbott, Medtronic, Biotronik and Boston Scientific, outside the present work. EB receives speaker's fees from Abbott Vascular, Boston Scientific, GE and Opsens outside the present work. WW has received institutional research grants from MicroPort and Terumo. Other authors have no conflicts of interest to declare.

References

1. Mehmedbegovic ZH, Vukcevic VD, Stankovic GR. Delivering ultimate bifurcation treatment. Minerva Cardioangiol. 2018;66:489-507.

2. Banning AP, Lassen JF, Burzotta F, Lefèvre T, Darremont O, Hildick-Smith D, Louvard Y, Stankovic G. Percutaneous coronary intervention for obstructive bifurcation lesions: the 14th consensus document from the European Bifurcation Club. EuroIntervention. 2019;15:90-98.

3. Hildick-Smith D, Behan MW, Lassen JF, Chieffo A, Lefèvre T, Stankovic G, Burzotta F, Pan M, Ferenc M, Bennett L, Hovasse T, Spence MJ, Oldroyd K, Brunel P, Carrie D, Baumbach A, Maeng M, Skipper N, Louvard Y. The EBC TWO Study (European Bifurcation Coronary TWO): A Randomized Comparison of Provisional T-Stenting Versus a Systematic 2 Stent Culotte Strategy in Large Caliber True Bifurcations. Circ Cardiovasc Interv. 2016;9.pii: e003643.

4. Behan MW, Holm NR, de Belder AJ, Cockburn J, Erglis A, Curzen NP, Niemelä M, Oldroyd KG, Kervinen K, Kumsars I, Gunnes P, Stables RH, Maeng M, Ravkilde J, Jensen JS, Christiansen EH, Cooter N, Steigen TK, Vikman S, Thuesen L, Lassen JF, Hildick-Smith D. Coronary bifurcation lesions treated with simple or complex stenting: 5-year survival from patient-level pooled analysis of the Nordic Bifurcation Study and the British Bifurcation Coronary Study. Eur Heart J. 2016;37:1923-8.

5. Chen SL, Zhang JJ, Han Y, Kan J, Chen L, Qiu C, Jiang T, Tao L, Zeng H, Li L, Xia Y, Gao C, Santoso T, Paiboon C, Wang Y, Kwan TW, Ye F, Tian N, Liu Z, Lin S, Lu C, Wen S, Hong L, Zhang Q, Sheiban I, Xu Y, Wang L, Rab TS, Li Z, Cheng G, Cui L, Leon MB, Stone GW. Double Kissing Crush Versus Provisional Stenting for Left Main Distal Bifurcation Lesions: DKCRUSH-V Randomized Trial. J Am Coll Cardiol. 2017;70:2605-2617.

6. Chevalier B, Glatt B, Royer T, Guyon P. Placement of coronary stents in bifurcation lesions by the "culotte" technique. Am J Cardiol. 1998;82:943-9.

7. Chen S, Zhang J, Ye F, Zhu Z, Lin S, Shan S, Kwan TW. DK crush (double-kissing and double-crush) technique for treatment of true coronary bifurcation lesions: illustration and comparison with classic crush. J Invasive Cardiol. 2007;19:189-93.

8. Räber L, Mintz GS, Koskinas KC, Johnson TW, Holm NR, Onuma Y, Radu MD, Joner M, Yu B, Jia H, Meneveau N, de la Torre Hernandez JM, Escaned J, Hill J, Prati F, Colombo A, Di Mario C, Regar E, Capodanno D, Wijns W, Byrne RA, Guagliumi G. Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary

interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions. EuroIntervention. 2018;14:656-677.

9. Paul A. Yushkevich, Joseph Piven, Heather Cody Hazlett, Rachel Gimpel Smith, Sean Ho, James C. Gee, and Guido Gerig. User-guided 3D active contour segmentation of anatomical structures: Significantly improved efficiency and reliability. Neuroimage 31:1116-28, 2006.

10. Ormiston JA, Webster MW, Webber B, Stewart JT, Ruygrok PN, Hatrick RI. The "crush" technique for coronary artery bifurcation stenting: insights from micro-computed tomographic imaging of bench deployments. J Am Coll Cardiol Intv 2008;1:351–7.

11. Burzotta F, Lassen JF, Banning AP, Lefèvre T, Hildick-Smith D, Chieffo A, Darremont O, Pan M, Chatzizisis YS, Albiero R, Louvard Y, Stankovic G. Percutaneous coronary intervention in left main coronary artery disease: the 13th consensus document from the European Bifurcation Club. EuroIntervention. 2018;14:112-120.

12. Gijsen FJ, Mastik F, Schaar JA, Schuurbiers JC, van der Giessen WJ, de Feyter PJ, Serruys PW, van der Steen AF, Wentzel JJ. High shear stress induces a strain increase in human coronary plaques over a 6-month period. EuroIntervention. 2011;7:121-7.

13. Samady H, Eshtehardi P, McDaniel MC, Suo J, Dhawan SS, Maynard C, Timmins LH, Quyyumi AA, Giddens DP. Coronary artery wall shear stress is associated with progression and transformation of atherosclerotic plaque and arterial remodeling in patients with coronary artery disease. Circulation. 2011;124:779-88.

14. Ge L, Airoldi F, Iakovou I, Cosgrave J, Michev I, Sangiorgi GM, Montorfano M, Chieffo A, Carlino M, Corvaja N, Colombo A. Clinical and angiographic outcome after implantation of drug-eluting stents in bifurcation lesions with the crush stent technique: importance of final kissing balloon post-dilation. J Am Coll Cardiol. 2005;46:613-20

Figure legends:

Figure 1 – Steps of the DK-Culotte technique.

Figure 2 – Final result of the in-bench procedures (n=8 for each technique)

Figure 3 – Duration of the procedure in total and of different rewiring phases: comparison of DK-Crush, Culotte and DK-Culotte techniques.

Figure 4 – Representative cases from the 3D μCT reconstruction of DK-Crush, Culotte and DK-Culotte procedures.

Figure 5 – Representative cases for computational fluid dynamic analysis of DK-Crush, Culotte and DK-Culotte procedures.

Figure 6 – Segmented analysis of computational fluid dynamics in different areas of interest.

Figure 7 – **Panel A and B:** SB stent deformation during MB opening and MB stenting in the Culotte technique, resulting in difficult SB access for final kissing dilation. **Panel C:** DK-Culotte allows the maintenance of SB result during MB preparation and stenting, resulting in a favorable SB access for final kissing dilation.

Table 1.

	DK-Culotte n=8	Culotte n=8	DK-Crush n=8	p for trend	p versus Culotte	p versus DK-Crush
Total procedural duration (minutes)	18.3±3.4	21.6±5.9	24.3±5.7	**0.039**	0.104	**0.015**
First rewiring through Stent #1 (seconds)	20.4±6.8	23.8±9.5	30.5±13.3	0.180	0.440	0.086
Second rewiring through Stent #2 (seconds)	17.9±10.6	33.6±15.9	28.1±12.9	0.087	**0.050**	0.123

Table 1 – Duration of the procedure in total and of different rewiring phases: comparison of DK-Culotte to conventional Culotte and DK-Crush techniques.

Table 2.

	DK-Culotte n=8	**Culotte** n=8	**DK-Crush** n=7	**p for trend**	**p versus Culotte**	**p versus DK-Crush**
Overall						
Struts in total	570±115	530±69	562±109	0.701	0.433	0.999
Well apposed;%	69.2±12.2	69.6±14.5	66.6±7.0	0.763	0.999	0.520
Moderately malapposed;%	2.1±1.9	3.7±3.8	8.1±2.5	**0.043**	0.459	**<0.001**
Significantly malapposed;%	0.4±0.2	1.0±1.1	3.7±5.3	**0.023**	0.517	**0.002**
Proximal main branch						
Well apposed;%	66.8±16.1	66.4±25.0	51.8±8.5	**0.033**	0.854	**0.029**
Moderately malapposed;%	0.0±0.0	2.5±6.6	14.0±7.6	**<0.001**	0.467	**<0.001**
Significantly malapposed;%	0.0±0.0	0.0±0.0	4.2±9.1	**0.005**	1.000	**0.026**
Side branch						
Well apposed;%	81.6±12.1	87.0±7.8	86.6±14.9	0.465	0.375	0.332
Moderately malapposed;%	0.5±1.2	0.8±1.4	1.0±1.7	0.864	0.765	0.648
Significantly malapposed;%	0.0±0.0	0.2±0.4	0.1±0.4	0.373	0.467	0.467
Distal main branch						
Well apposed;%	84.9±14.6	86.8±9.2	82.0±9.1	0.494	0.854	0.295
Moderately malapposed;%	0.1±0.3	0.1±0.3	0.6±1.1	0.408	0.999	0.347
Significantly malapposed;%	0.0±0.0	0.1±0.2	0.0±0.0	0.392	0.999	0.999
Polygon of confluence - carina						
Well apposed;%	35.6±10.4	33.5±22.6	33.6±13.3	0.840	0.629	0.752
Moderately malapposed;%	11.5±7.5	19.1±10.8	18.1±9.3	0.233	0.130	0.230
Significantly malapposed;%	4.6±2.8	5.3±5.8	15.7±16.3	0.218	0.973	0.126
Polygon of confluence - roof						
Well apposed;%	56.0±13.5	40.6±31.0	33.8±8.0	**0.072**	0.375	**0.006**
Moderately malapposed;%	4.0±6.4	7.6±8.0	19.0±12.4	**0.043**	0.323	**0.020**
Significantly malapposed;%	0.0±0.0	2.0±2.5	9.8±18.2	**0.045**	**0.077**	**0.026**
Polygon of confluence - abostial						
Well apposed;%	57.2±20.9	57.7±23.1	78.4±14.1	**0.076**	0.999	**0.040**
Moderately malapposed;%	3.6±7.1	5.3±11.6	4.2±7.4	0.888	0.706	0.843
Significantly malapposed;%	0.1±0.3	1.5±3.9	3.0±7.3	0.551	0.446	0.323

Table 2 – Malapposition rates overall and in different subspecified locations: comparison of DK-Culotte to conventional Culotte and DK-Crush techniques.

Table 3.

	DK-culotte n=6	Culotte n=6	DK-Crush n=6	p for trend	p vs Culotte	p vs DK-Crush
Proximal MB minimal diameter	3.2 ±0.3	3.0 ±0.3	3.1 ±0.2			
Diameter stenosis (%)	22±7	27±8	25±5	0.634	0.474	0.423
Area stenosis (%)	28±8	34±11	31±7	0.537	0.305	0.474
Distal MB minimal diameter	2.6 ±0.1	2.5 ±0.2	2.6 ±0.2			
Diameter stenosis (%)	15±4	17±8	14±7	0.812	0.788	1.000
Area stenosis (%)	11±10	13±13	10±12	0.876	0.738	0.939
SB minimal diameter	2.3 ±0.3	2.3 ±0.4	2.3 ±0.3			
Diameter stenosis (%)	23±10	24±13	23±9	0.981	1.000	1.000
Area stenosis (%)	28±11	31±15	30±10	0.938	1.000	0.675
Delta angulation						
Absolute (°)	3±2°	6±5°	8±4°	0.159	0.323	**0.074**
Relative (%)	7±5	13±13	15±9	0.188	0.463	**0.050**

Table 3 – Results of the μCT analysis: comparison of DK-Culotte to conventional Culotte and DK-Crush techniques.

Table 4.

	DK-Culotte n=8	**Culotte** n=8	**DK-Crush** n=8	**p for trend**	**p versus Culotte**	**p versus DK-Crush**
Maximum Shear Rate (s^{-1})	3054±1348	3968±1558	3672±1916	0.196	0.104	0.323
Area of High Shear (mm^2)	0.46±0.29	1.25±1.50	0.63±0.55	0.172	**0.065**	0.560
Area of Recirculation (mm^2)	2.41±1.54	3.40±2.57	2.08±1.56	0.415	0.560	0.595

Table 4 – Computational fluid dynamics

Figure 1

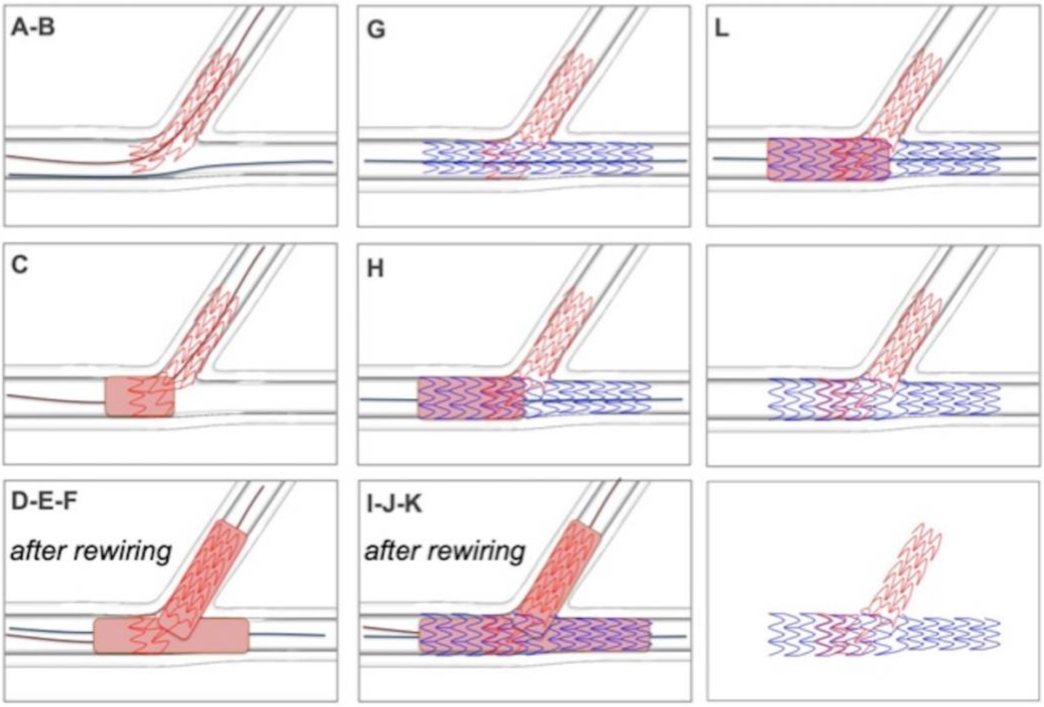


Figure 2

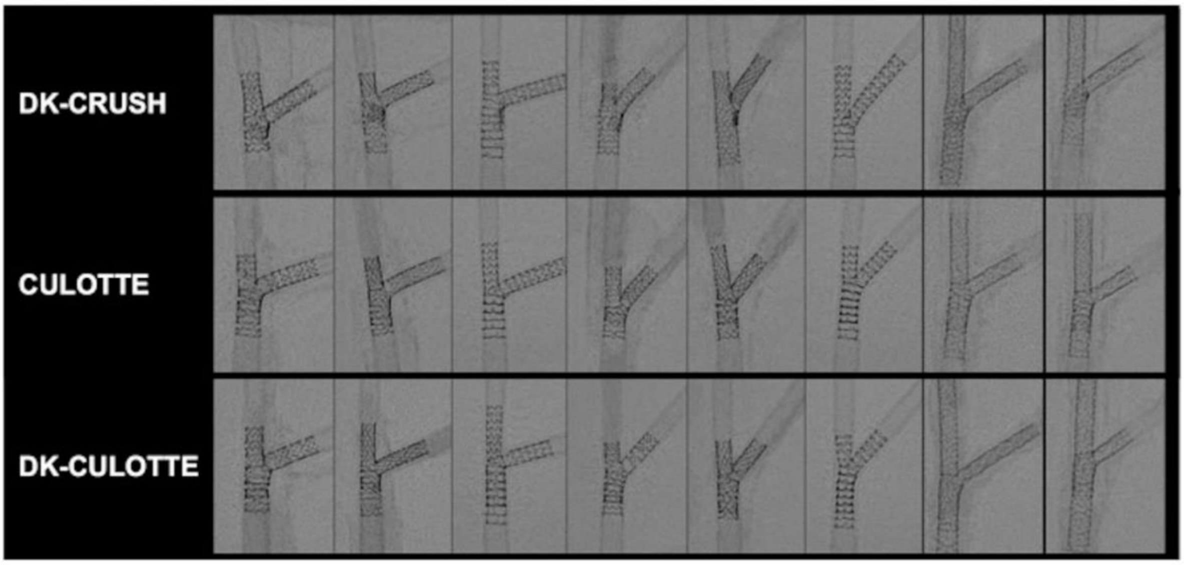


Figure 3

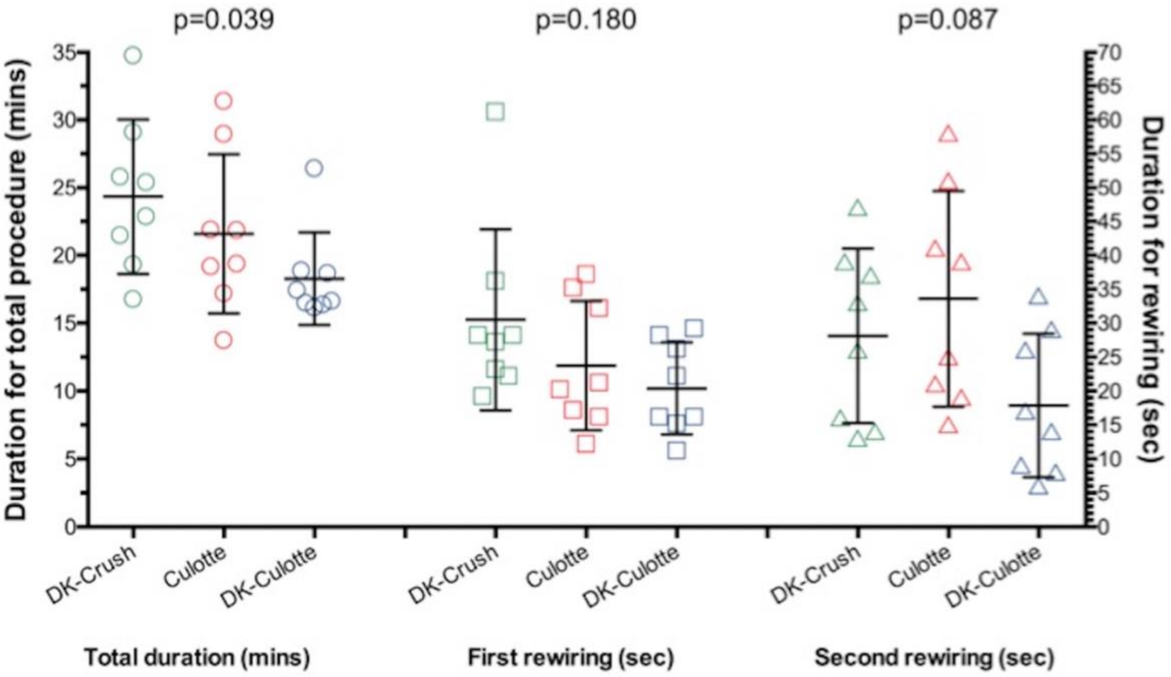
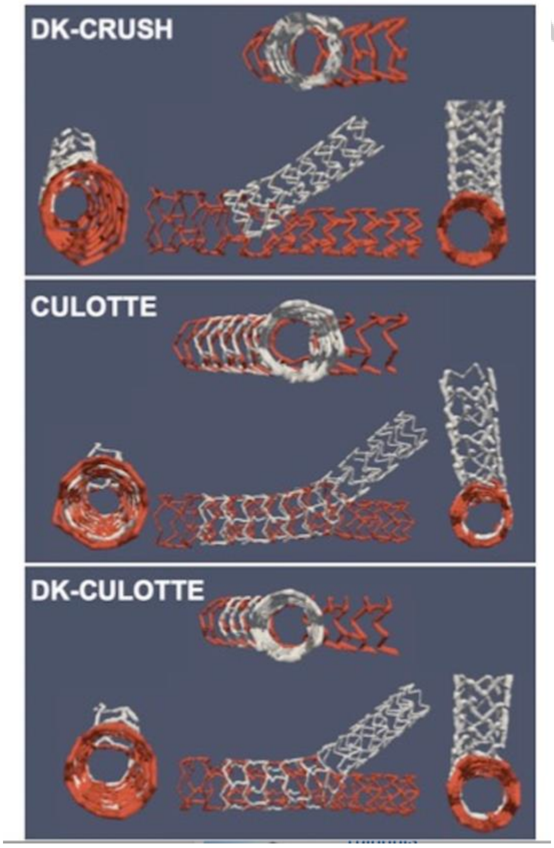


Figure 4



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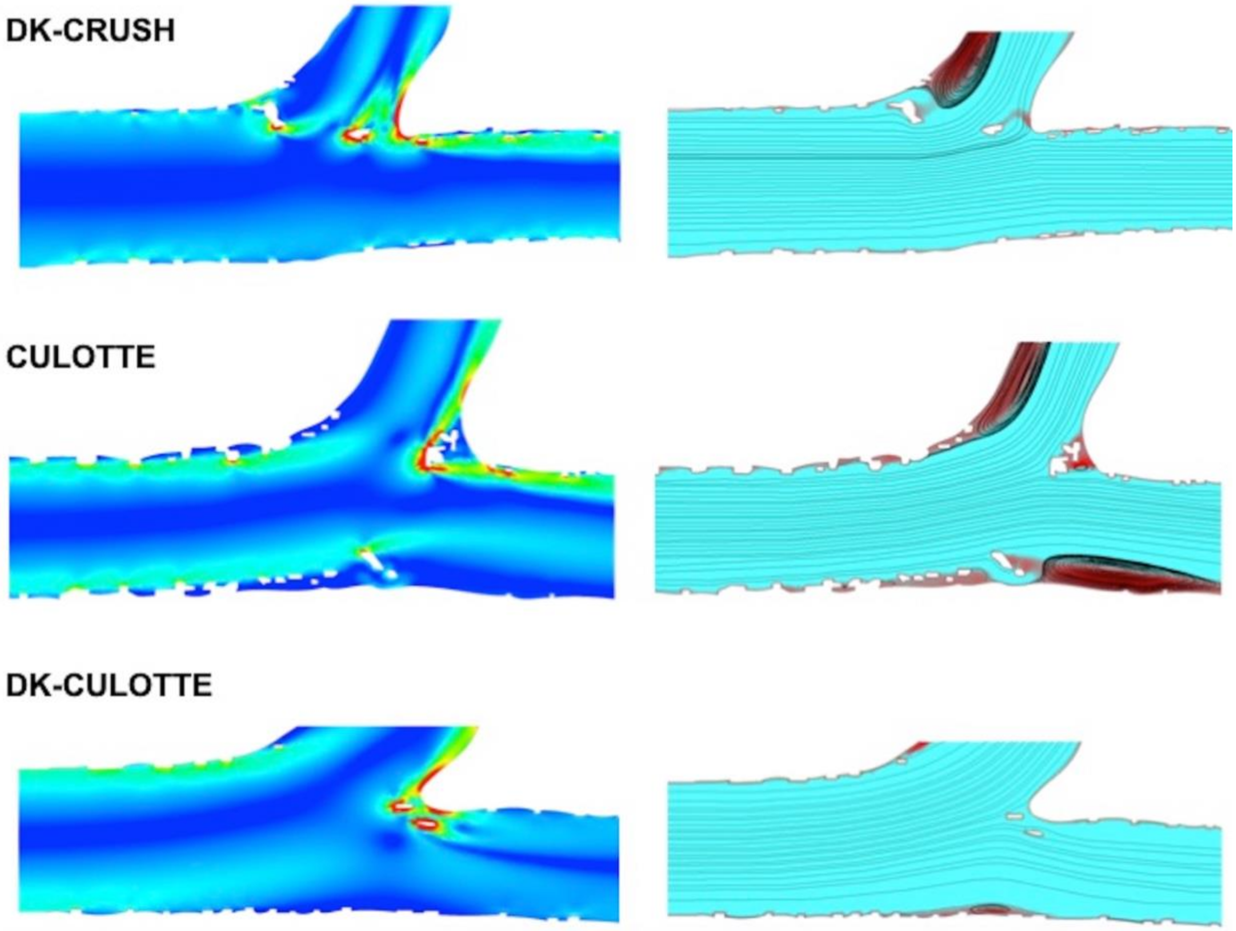


Figure 6

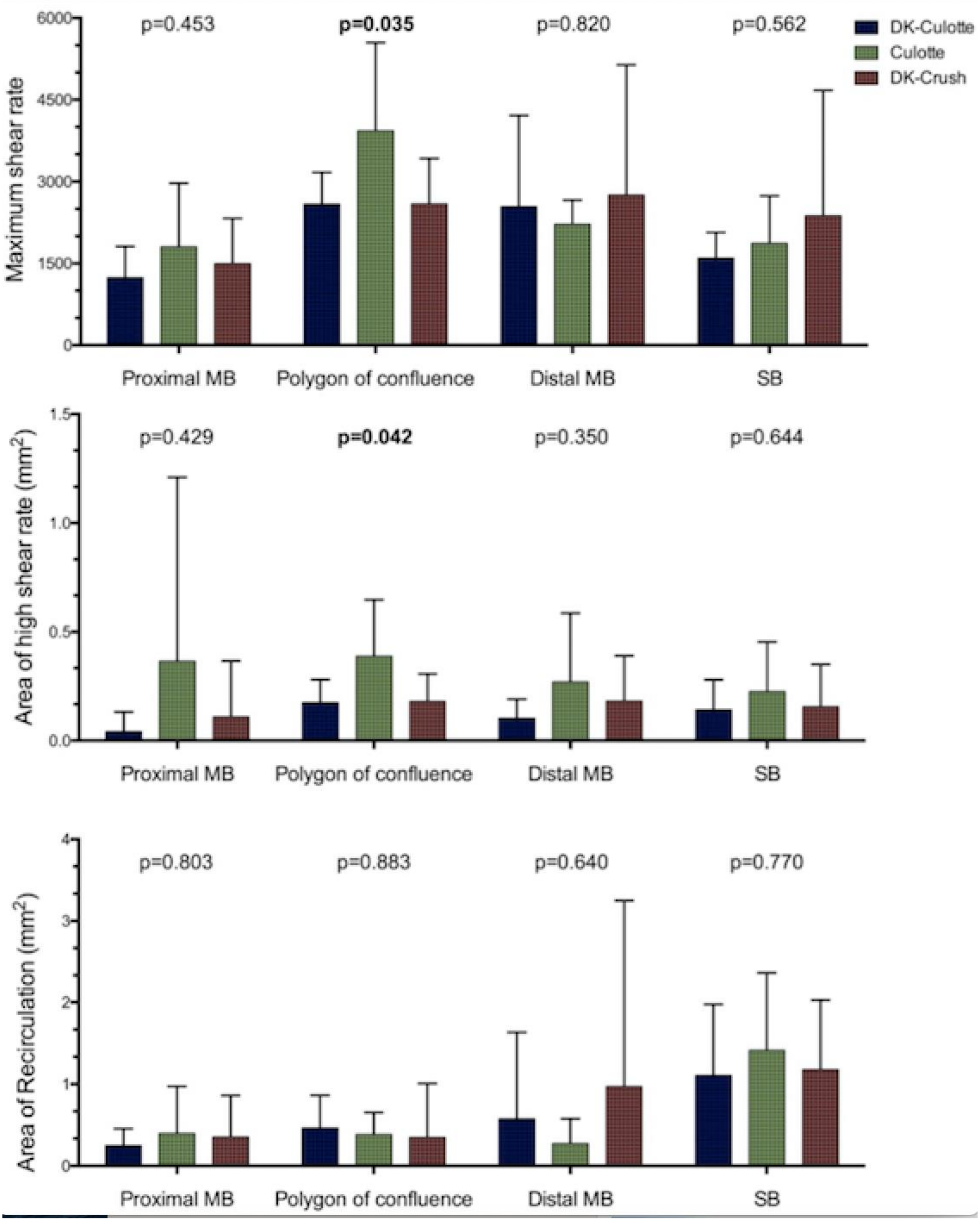
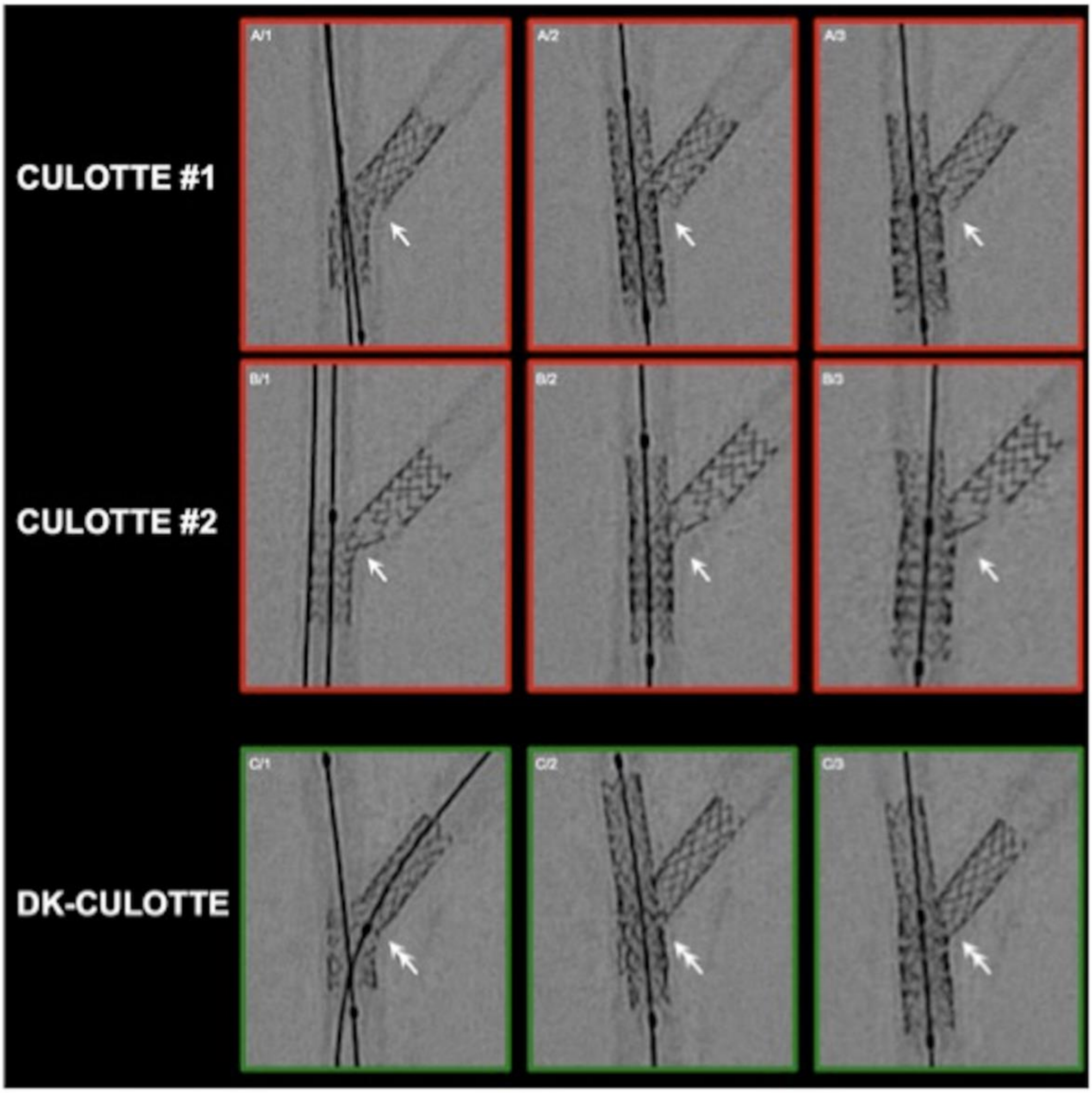

Maximum shear rate
0
1500
3000
4500
6000
p=0.453
p=0.035
p=0.820
p=0.562
DK-Culotte
Culotte
DK-Crush
Proximal MB
Polygon of confluence
Distal MB
SB
Area of high shear rate (mm²)
0.0
0.5
1.0
1.5
p=0.429
p=0.042
p=0.350
p=0.644
Proximal MB
Polygon of confluence
Distal MB
SB
Area of Recirculation (mm²)
0
1
2
3
4
p=0.803
p=0.883
p=0.640
p=0.770
Proximal MB
Polygon of confluence
Distal MB
SB

Figure 7



Supplementary figure legends:

Supplementary Figure 1 – Parameters of the bifurcation bench models with 40° (n=3 per technique); with 70° (n=3 per technique) and with 60° (n=3 per technique) angulation, including the areas of focus for OCT analysis.

Supplementary Video 1 – SB stent deformation during MB opening and MB stenting in the Culotte technique, resulting in difficult SB access for final kissing dilation.

Supplementary Video 2 – DK-Culotte allows the maintenance of SB result during MB preparation and stenting, resulting in a favorable SB access for final kissing dilation.

Supplementary Figure 1