T and small protrusion (TAP) vs Double Kissing Crush technique: insights from *in-vitro* models

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Short title: TAP versus DKC technique

Abbreviations

TAP = T and small protrusion

DKC = Double kissing crush

SB = Side branch

OCT = Optical coherence tomography

PS = Provisional stenting

KBI = Kissing balloon inflation

LM = Left main

MV = Main vessel

POT = Proximal optimization technique

SBO = Side branch obstruction

CSA = Cross-sectional area

EI = Ellipticity index

CFD = Computational fluid dynamics

Structured Abstract

Background

Percutaneous coronary interventions on complex bifurcation lesions may require implantation of two stents to appropriately treat diffuse side-branch (SB) disease. Comparisons among different bifurcation stenting techniques are continuously attempted by various study designs (bench tests, computer simulations, clinical studies). Among different techniques, double kissing crush (DKC) represents the last evolution for "crushing" while T and small Protrusion (TAP) represents the evolution of "T stenting". Both techniques are actually gaining popularity, but head-to-head comparisons are lacking.

Methods and Results

Two last generation drug-eluting stents (Synergy^{TM}, Boston Scientific, MA, USA and Ultimaster^{TM},Terumo Corp., Japan) were implanted in left main bifurcation bench models using TAP (n=6 sets) and DKC (n=6 sets) techniques. A peristaltic pump with fresh porcine blood was used to perfuse the blood through the silicone model at a flow rate of 200ml/min for 4 minutes. Optical coherence tomography (OCT) was used to assess stent struts geometry and thrombus formation. SB cross sectional area as well as SB obstruction did not significantly differ between the two techniques. Numerical (but not statistically significant) differences were found in terms of malapposed struts (fewer with TAP) and floating struts (fewer with DKC). Thrombus formation after blood perfusion was similar between TAP and DKC technique (1.53 ± 1.12 vs. 1.20 ± 1.01 mm^2, p=0.6).

Conclusion

The result of the present in-vitro study shows the absence of significant difference between TAP and DKC in terms of stent struts apposition and acute thrombus formation potential. Despite the completely different technical steps required, both techniques have similar performance according to such articulated pre-clinical evaluation

What is already known about this subject?

Due to its limited complexity, T and Protrusion (TAP) technique is considered the *to-go* technique for bifurcation lesions with good long-term results. Recently, double kissing crush (DKC) technique has been gaining popularity and demonstrated promising results in randomized clinical trials.

What does this study add?

This in-vitro bench test study provides a unique detailed OCT comparison and local hemodynamic environment analysis of the two techniques.

How might this impact on clinical practice?

New insights of acute thrombogenicity and computational flow model simulation may guide percutaneous therapeutic strategies of bifurcation lesions.

1 Introduction

Bifurcation lesions remain one of the most challenging lesions in interventional cardiology. Provisional stenting (PS), i.e. stent in the main vessel eventually followed by side-branch (SB) intervention, represents the gold standard for unselected bifurcated lesions. Yet, one third of PS cases may require crossover to 2-stent approach (1-5) and failures to deliver the second stent may occur (6). Accordingly, both refinements in the PS and double stenting techniques have been developed in the recent years.

The T and Protrusion (TAP) technique represents a modification of the T stenting technique and is able to ensure both full ostium coverage and good stent apposition (7). Initially conceived as a bailout side branch (SB) stenting technique in case of PS failure, TAP technique has gained popularity due to its limited complexity and is now considered by many operators a valuable technique when elective double stenting is required (8). An intrinsic limitation of the TAP technique is the creation of a single layer neocarina at the level of coronary bifurcation flow divider. This metallic neocarina of variable length represents a potential situs for late endothelialisation and act as a focal point for thrombi formation (8).

Among elective double stenting techniques, the crush technique has the value of allow fix the SB, potentially reducing the risk of SB occlusion. The technique evolved over time (step-crush, mini-crush, DK crush) with the aim of limiting the amount of metal struts accumulated in and the difficulty in rewiring. (9) Double kissing crush technique (DKC) has been shown to provide a more reliable final kissing balloon inflation (KBI) and demonstrated to be clinically effective and safe (5). Recently, DKC has shown the most favourable outcome in true distal left main (LM) bifurcation lesions. (10)

High shear gradients and flow recirculation are a known risk factor for platelets activation. (11) Therefore, malapposed and floating struts may increase the chance of stent thrombosis. In vitro bifurcation models have shown not only an increased flow disturbance at high shear regions but also a direct correlation between floating struts at SB ostium and thrombogenicity (12). In this study, we used optical coherence tomography (OCT) and computational flow reconstruction to compare DKC versus TAP strategies to evaluate their different effects in terms of strut apposition and thrombus formation in *in-vitro* models of bifurcation lesions.

2 Methods

2.1 Stent Platforms

Synergy™ (Boston Scientific, United States) is an everolimus-eluting platinum chromium coronary stent with a strut thickness of 74µm. Ultimaster™ (Terumo Corp, Japan) is a sirolimus-eluting cobalt chromium with a strut thickness of 80µm. A total of 24 stents with diameters varying from 2.75mm to 3.5mm were used to deploy 6 sets of TAP and 6 sets of DKC for each stent platform. Each technique received an equal number of Synergy™ and Ultimaster™ stents.

2.2 Stent Deployment

The bifurcation model is a silicone-based left main Y-shaped model. The proximal main vessel (MV) has a diameter of 4.5mm which splits into a SB with a diameter of 3.0mm and the distal portion of the main vessel with a diameter of 3.5mm, the angle between the SB and the distal portion of the MV is 90^{o}.

Two stents from the same platform with diameters comparable to the distal MV and SB diameters were chosen for deployment for each bifurcation double stenting procedure and inflated at nominal pressure. Kissing balloon inflation (KBI) was performed with symmetric inflation pressure (12/12 atm) of NC balloons in the MV and SB. Proximal optimization technique (POT) was achieved with a NC compliant balloon 0.5 mm larger than the MV stent deployed at 18 atm. Optical coherence tomography (OCT) C7 system (LightLabs®; St Jude, Minneapolis, MN, USA) was used to obtain pullbacks of MV and SB before and after POT as well as after perfusion.

For TAP, the MV stent was deployed first. Subsequently, a guidewire was advanced into SB (aiming at distal side cell crossing), the SB stent was then advanced and deployed with 1-2mm of the stent protruding into the MV. The protruding SB stent into the MV can be seen in the microscopic image of the stents in the bifurcation model (**Figure 1A**). A final KBI was performed, followed by POT. For DKC, a NC balloon was position into the MV and a stent was advanced into the SB with 1-2mm protruding into the MV to cover the SB ostium and deployed. The MV balloon was then inflated to crush the protruding SB stent (**Figure 1B**). The first KBI was performed, followed by the deployment of the MV stent. A final KBI and POT finalized the procedure, the latter with NC balloons positioned with its distal marker aligned with the carina and across the ostium of SB.

2.3 Flow Perfusion

A peristaltic pump (Minipuls3, Gibson, United States) with fresh porcine blood and 10% anticoagulant (acid-citrate-dextrose) was used to perfuse the blood from a blood reservoir, through the models and back into the reservoir at a constant flow rate of 200ml/min for 4 minutes. The flow rate was selected was based on earlier literature and simulates the peak flow rate in a coronary artery. Blood in the reservoir was heated with a heat plate to 37°C to simulate physiological temperature during flow perfusion. After 4 minutes, perfused models were then flushed with 120ml of Tyrode's solution to remove excess blood before another OCT pullback was performed.

2.4 OCT Analysis

Thrombus area was calculated using the OCT pullback from MV after perfusion. OCT cross sections were analyzed to quantify the thrombus area for each frame of the bifurcation region. The bifurcation regions were divided into the proximal, middle and distal portion. The OCT pullback from MV after POT was used for strut analysis. Bifurcation region was divided in two 180-degree halves towards or opposite SB origin. Malapposed struts were defined as strut protruding into the lumen at a distance greater than the strut thickness. Floating struts were defined as all the struts in the opening angle of the SB. The total number and percentage of malapposed and floating struts were counted for each region. Side branch obstruction (SBO) was calculated on a cross section 0.5 mm before the carina using the OCT pullback from MV after POT. SBO was defined by the ratio of the longest strut-free segment and the estimated SB ostium diameter. Cross-sectional area (CSA), maximum, minimum and mean diameter were calculated at 1mm intervals. Ellipticity Index (EI) was calculated as D_{max}/D_{min} at 1-mm intervals (every 5 frames with a pullback speed of 20 mm /sec) from 5 mm from the SB origin and normalized for the stent length.

2.5 Computational Fluid Dynamics

Flow patterns and shear rate were analyzed using computational fluid dynamics (CFD) to identify segments with higher risk of flow disturbance induced by malapposed and floating struts. 2D longitudinal geometries of the stented models were recreated using the OCT pullbacks. These geometries were then meshed and subsequently simulated with flow conditions similar to experimental conditions using a fluid computational software (Fluent, ANSYS). The area of high shear rate (>1000s^{-1}) was obtained (physiological flow rate in normal human arteries falls within the range of 100-1000 s^{-1}).

2.6 Statistical Analysis

All comparison between two sets of data were done using t test with a 95% confidence interval using GraphPad Prism 6. Any t test with a p value of below 0.05 was deemed statistically significant.

3 Results

3.1 Final stent conformation

Table 1 and 2 compared the two techniques and no significant difference between the two techniques were found in terms of mean diameters of proximal MV, distal MV and SB. SB CSA as well as SBO did not significantly differ between TAP and DKC technique in all the analysed stents (6.6 mm^2 vs 6.8 mm^2, p=0.56 and 52.8% vs 54.5%, p=0.85, respectively). (**Table 1**)

OCT evaluation of total number and percentage of malapposed and floating struts are summarized in **Table 2**. Percentage of malapposed struts in the whole bifurcation region was similar between TAP and DKC techniques while the percentage of floating struts was numerically higher in TAP compared to DKC (34.8 ± 10.5% vs 25.8 ± 9.5, p=0.17). A schematic illustration of the two techniques in terms of average floating, malapposed struts, SBO and ellipticity index (EI) is shown in **Figure 2**. The same trend was observed when region facing and opposite SB were analyzed separately. The prevalence of floating struts were found to be higher in the region facing SB in the TAP group (55.3 ± 16.1% vs 46.3 ± 11.3% p=0.32), compared to DKC. Representative OCT images of main vessel of both techniques (before perfusion) can be seen in **Figure 3**.

3.2 Effect of POT

Final POT significantly reduced ellipticity index from 1.4 to 1.2 (p=0.05) for DKC. When final POT was performed as last step of TAP, EI decrease from 1.3 to 1.2 (p=0.3), without reaching statistical significance. The decrease of EI by technique is shown in (Table 1).

3.3 Thrombus Formation

From the in vitro perfusion coronary model, no statistical difference in terms of overall thrombus formation were detected between TAP and DKC (1.53 ± 1.12 vs. 1.20 ± 1.01 mm^2, p=0.6, respectively) (**Figure 4A**). There was also no statistical difference in terms of thrombus formation between the two technique according to position (proximal, middle and distal) as shown in **Figure 4B** and the representative OCT images (**Figure 5**).

3.4 CFD simulation

Figure 6A showed the representative flow patterns and maximum shear rate and areas for the two techniques. Flow analysis detected increased flow disturbances in the bifurcation area. Between DKC and TAP, DKC had the same normalized area of high shear rate (>1000s^{-1}) and numerically higher maximum shear rate compared to TAP (5951 ± 853 vs. 5141 ± 1025 s^{-1}) (**Figure 6B**).

4 Discussion

The search for best strategy to implant two stents in complex coronary bifurcations represents a hot topic of contemporary interventional cardiology. TAP and DKC are completely different techniques which have been developed in order to overtake the pitfalls of previous available techniques. The main findings of our study are summarized below:

a) SB CSA and SBO did not significantly differ between the two techniques.
b) Similar rate of floating and malapposed struts were detected at OCT analysis at the bifurcation region when TAP was compared to DKC technique.
c) Final POT significantly decreased the elliptical deformation caused by DKC.
d) No significance difference of thrombus area was found between the two techniques.
e) CFD simulation showed no significant difference in flow disturbances between the two techniques.

Despite recent advances in interventional cardiology, bifurcation coronary artery stenosis (which account for 15-20% of all coronary lesions treated by PCI), remain a challenge for PCI operators with higher rates of failure, in-stent restenosis, stent thrombosis, and recurrent clinical events, when compared to simple non-bifurcation lesions (13-15). Provisional stenting (PS) has been shown to be superior to double elective stenting in most bifurcations and is currently recommended as the most favored approach. However, complex anatomies with large SB and significant ostial lesion may require double stenting strategy from upfront. (16)

In vitro bench testing can provide further information to the anatomical and functional assessment of bifurcation lesions, guiding percutaneous therapeutic strategies. This bench tests report aims to provide insights into bifurcation stenting by evaluating results obtained from two different double stenting techniques. The ease of practice and suitability for both bailout SB stenting and elective two-stent strategy resulted in TAP being a popular technique with reported good long-term results. (17)

On the other hand, DKC is gaining popularity due to increasing scientific data and widespread clinical experience, despite being a more complex technique. In prior multicenter randomized trials, the DKC planned 2-stent technique resulted in lower rates of TLR compared with PS in non-LM coronary bifurcation lesions (5). Recently, a planned DKC strategy resulted in a lower rate of TLF at 1 year than PS approach in true distal LM bifurcation lesions (10). The recent

meta-analysis published by Chen et al. also suggested clinical benefits (lower MACE) of DKC over other two-stent strategies. (18)
Compared to PS, two stent strategies warrant a better scaffolding but at the cost of higher rate of struts left unopposed in the middle of the lumen. Foin et al. reported higher malapposed strut rate detected by micro-computed tomography associated with crush as compared to TAP technique in a bifurcation model. (19) In the present study, we compared the evolved crush technique (DKC) to TAP strategy using OCT analysis. Detailed OCT comparison between the two techniques showed no difference in terms of malapposed and floating strut rates. Different cell size, alloy, strut thickness and number of connectors may influence final malapposition as they may impact on SB rewiring, recoil and other mechanical properties. However, bench model studies have previously shown that stent platform has only a minor impact on SB lumen area in bifurcation stenting. (19) In our report, we confirmed that platform design had no influence on final apposition and final SB lumen area.

A planned two-stent technique should be always finalised with kissing balloon inflation, to ensure optimal stent expansion in both the MV and SB. In addition, POT is mandatory in order to counteract the elliptical deformation caused by KBI and to reduce MV stent malapposition opposite the SB. (20)

Ellipticity index (EI) decrease after POT in both the techniques but with significant difference only in the DKC technique. The main drawback of KBI is the proximal MV distortion induced by stent overstretch. DKC has been conceived to reshape the bifurcation anatomy and leave one layer of metal struts in front of SB ostium. However, the double kissing may severely impact on proximal elliptic deformation of MV stent due to the detrimental effect of proximal balloons juxtaposition. The enhanced benefit of POT in DKC as compared to TAP may be explained by the higher EI values before POT potentially caused by the double KBI.

Moreover, we further investigated the two strategies assessing acute thrombus formation induced by porcine blood perfusion. Overhanging struts in front of SB ostium are thought to act as a focal point for thrombi formation and consequently possible stent thrombosis. This direct causal effect was recently demonstrated by our group in an in vitro model. (21) Likewise, we have previously shown that stent malapposition has a very direct impact on thrombus formation (22) Similar floating and malapposed struts rates between TAP and DKC in the bifurcation areas may explain similar rate of thrombus formation between the two techniques.

In conclusion we observed no difference in terms of stent struts apposition and acute thrombus formation between TAP and DKC technique in in-vitro models. The results support recent recommendation that additional post dilatation and better apposition of the stent metal could limit prothrombogenic material and risk of late thrombosis in complex bifurcation strategies.

5 Limitations

The statistical power of the study is limited by number of experiments performed (n=12). Further experimental validation with larger sample sizes is required to confirm these findings. The simplified model of left main bifurcation anatomy does not fully reflect the physiological response to stent deployment or the complexity of the other bifurcation anatomies. Moreover, an in-vitro model could not predict the impact of different plaque distribution and plaque composition of in-vivo anatomy. Therefore, the results of our bench test experiments must be carefully interpreted. Lastly, our model is able to detect only acute thrombus formation and do not account for the presence in-vivo of dual antiplatelet therapy. The present observations from an idealized model must be therefore carefully interpreted.

Authors contribution

VP, JN and SL performed the experiment and analysis.

AC,FB,HB,MF and DH reviewed the analysis and manuscript.

HA, NF and PW coordinated the project

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to this study are presented in the article.

Ethics No ethics committee approval was required

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Tables

Table 1. OCT analysis of side branch measurement and effect of POT between the two techniques. (n=6 sets for each technique, total 12 sets)

<table>
<tr><th>Parameters</th><th colspan="3">TAP</th><th colspan="3">DKC</th><th>P-value</th></tr>
<tr><td colspan="8">Main Branch Measurement</td></tr>
<tr><td>Prox. Mean Diameter (mm)</td><td colspan="3">4.4 ± 0.3</td><td colspan="3">4.4 ± 0.3</td><td>1.00</td></tr>
<tr><td>Distal Mean Diameter (mm)</td><td colspan="3">3.6 ± 0.1</td><td colspan="3">3.5 ± 0.1</td><td>0.11</td></tr>
<tr><td colspan="8">Side Branch Measurement</td></tr>
<tr><td>Mean Diameter (mm)</td><td colspan="3">2.9 ± 0.2</td><td colspan="3">3.0 ± 0.1</td><td>0.30</td></tr>
<tr><td>SB CSA (mm^2)</td><td colspan="3">6.6 ± 1.0</td><td colspan="3">6.8 ± 0.8</td><td>0.68</td></tr>
<tr><td>SB Obstruction (%)</td><td colspan="3">52.8 ± 20.0</td><td colspan="3">54.5 ± 6.7</td><td>0.85</td></tr>
<tr><td colspan="8">Effect of POT</td></tr>
<tr><td></td><td>Before</td><td>After</td><td>P value</td><td>Before</td><td>After</td><td colspan="2">P-value</td></tr>
<tr><td>MV Proximal CSA (mm^2)</td><td>15.0 ± 0.7</td><td>15.2 ± 2.2</td><td>0.84</td><td>14.5 ± 0.8</td><td>15.1 ± 1.8</td><td colspan="2">0.47</td></tr>
<tr><td>Ellipticity Index (EI)</td><td>1.3 ± 0.2</td><td>1.2 ± 0.1</td><td>0.30</td><td>1.4 ± 0.2</td><td>1.2 ± 0.1</td><td colspan="2">0.05</td></tr>
</table>

Table 2. OCT strut analysis of percentage of malapposed and floating struts in the whole bifurcation area and in the region facing side branch (SB) and opposite to SB. (n=6 sets for each technique, total 12 sets of analysis)

Parameters	**TAP**	**DKC**	**P-value**
Bifurcation Region			
Number of analysed struts	1498	1282	N.A
% of malapposed	4.0 ± 3.2	4.0 ± 3.8	1.00
% of floating struts	34.8 ± 10.5	25.8 ± 9.5	0.17
Region Facing SB			
Number of analysed struts	946	682	N.A
% of malapposed	4.2 ± 4.8	3.9 ± 4.5	0.92
% of floating struts	55.3 ± 16.1	46.3 ± 11.3	0.32
Region Opposite SB			
Number of analysed struts	552	600	N.A
% of malapposed	3.7 ± 5.1	6.1 ± 9.1	0.59
% of floating struts	N.A	N.A	N.A

Figure Legend

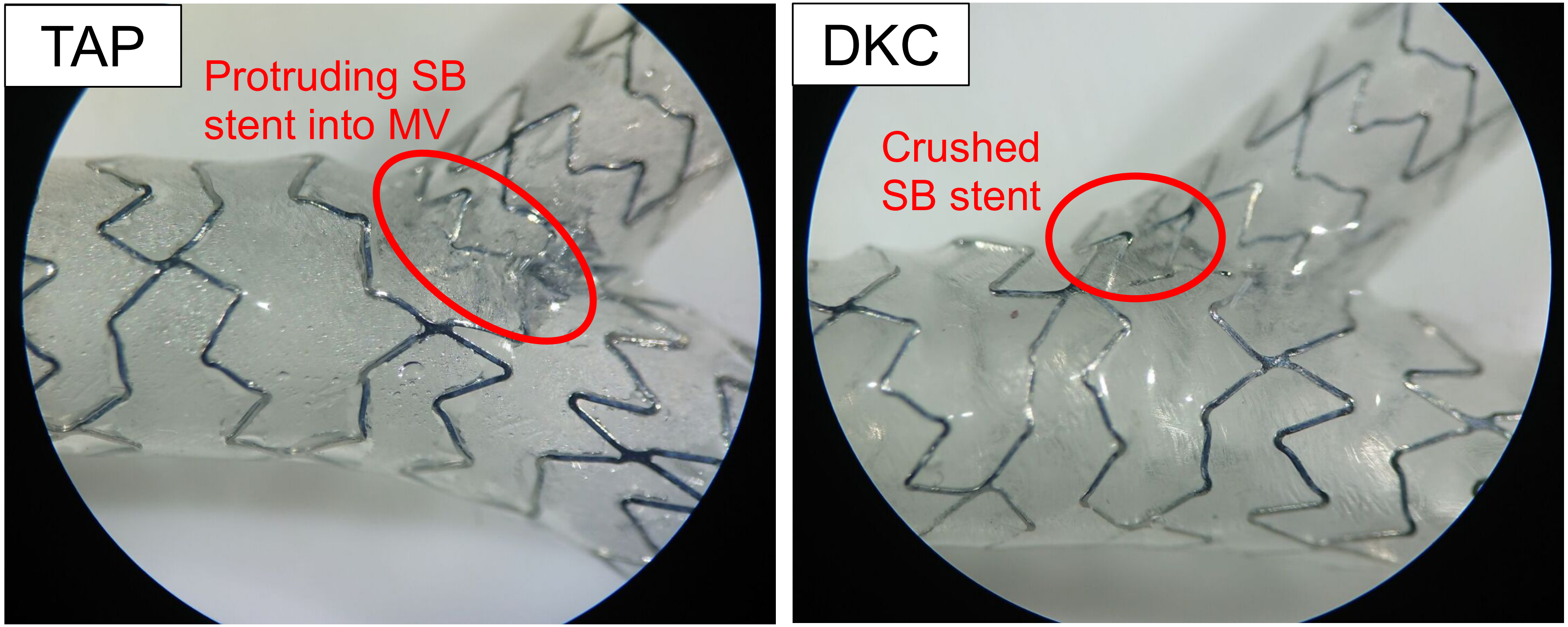

Figure 1. Optical microscopic images of the TAP and DKC technique after stent deployment. For the TAP technique, the side branch (SB) stent can be seen protruding into the main vessel (A) and the crushed SB stent in the DKC technique is highlighted in the image (B).

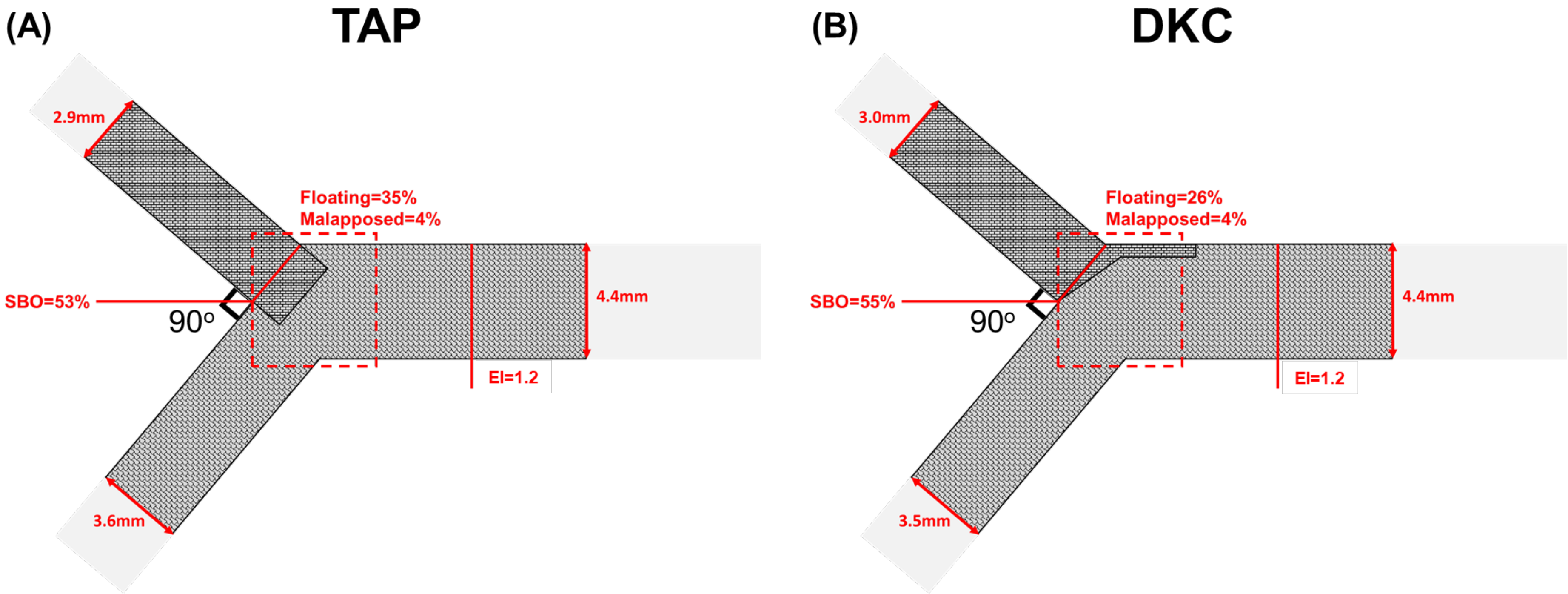

Figure 2. Schematic illustration of the average side branch obstruction, ellipticity index, % of floating and malapposed struts after TAP (A) and DKC (B) technique in the bifurcation model. (Vessel model is fabricated from Shore 40A Silicone, Main Vessel Diameter: 4.5mm, Side Branch Diameter: 3.0mm)

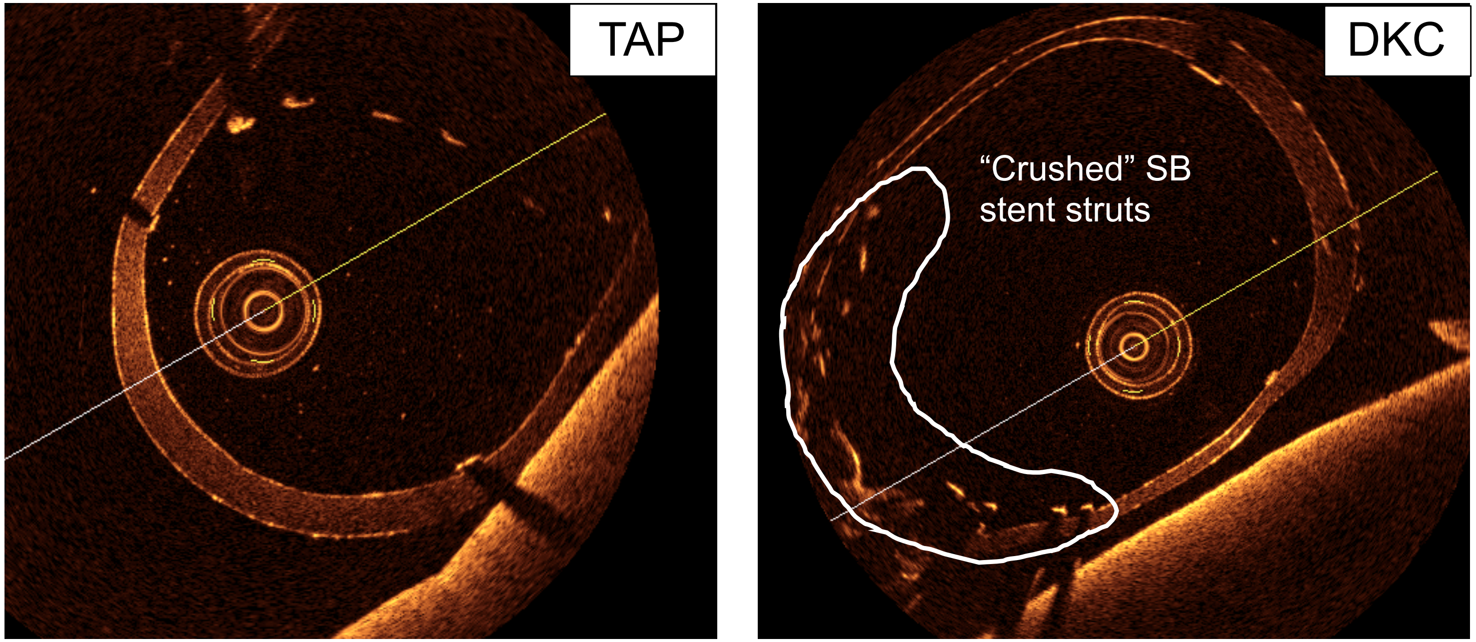

Figure 3. Representative main vessel OCT images of stent struts at proximal of side branch ostia with TAP (A) and DKC (B) technique. The “crushed” side branch stent struts can be observed in the DKC technique as highlighted.

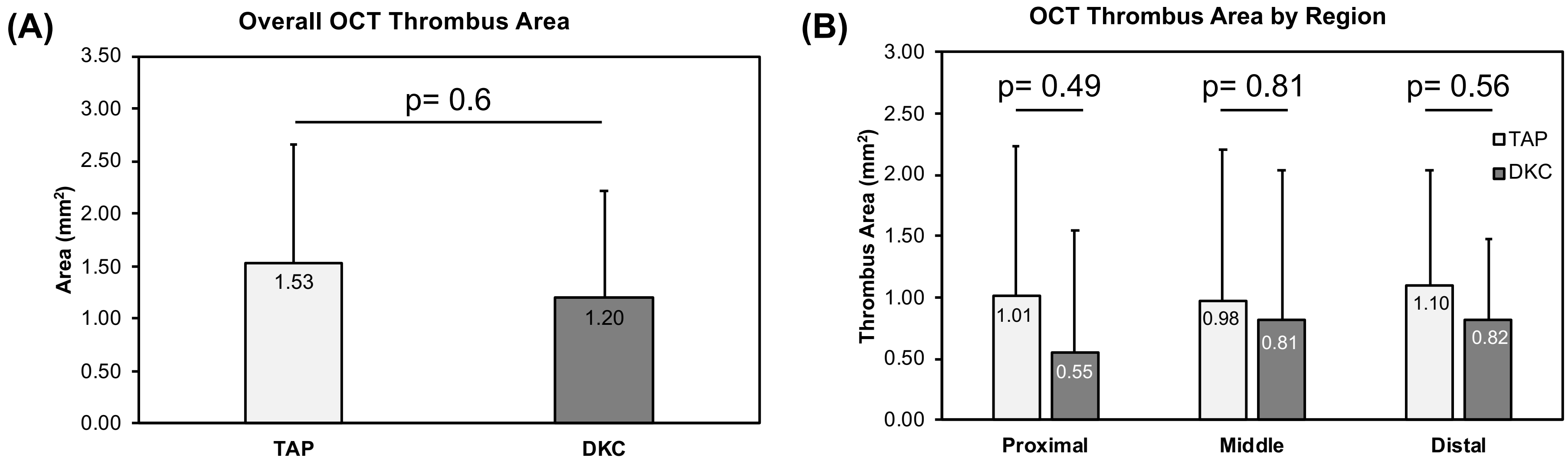

Figure 4. Thrombus formation comparison between the two techniques in the whole bifurcation area and according to positions (proximal, middle and distal) based on OCT analysis. (n=6 for each technique, total=12 sets of analysis) TAP technique exhibited numerically higher thrombus area at the side branch ostium at 4 minutes than DKC (A). No significant difference observed between the two techniques in terms of thrombus formation at the proximal, middle and distal position. (B)

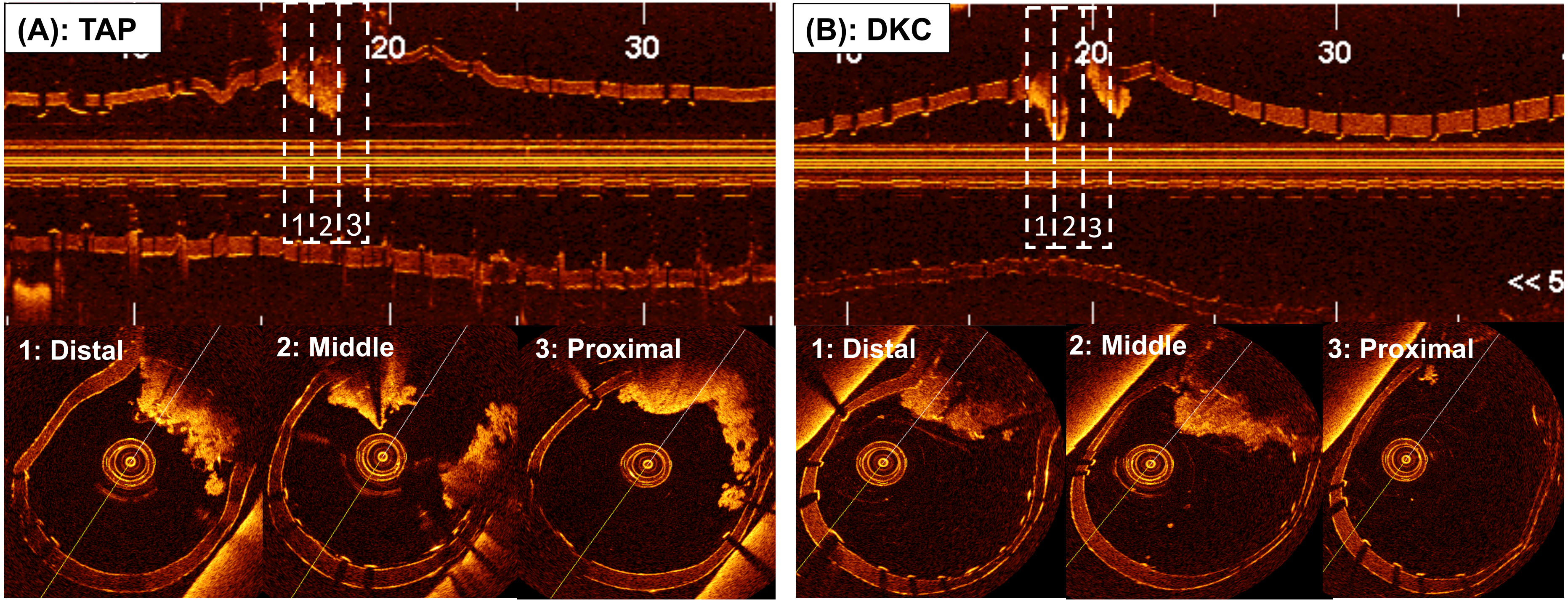

Figure 5. Representative OCT images of thrombus formation with TAP (A) and DKC (B) technique. Upper panel represents the OCT longitudinal section of the bifurcation region; Lower panel represents OCT cross sections of the proximal, middle and distal segments of the bifurcation region.

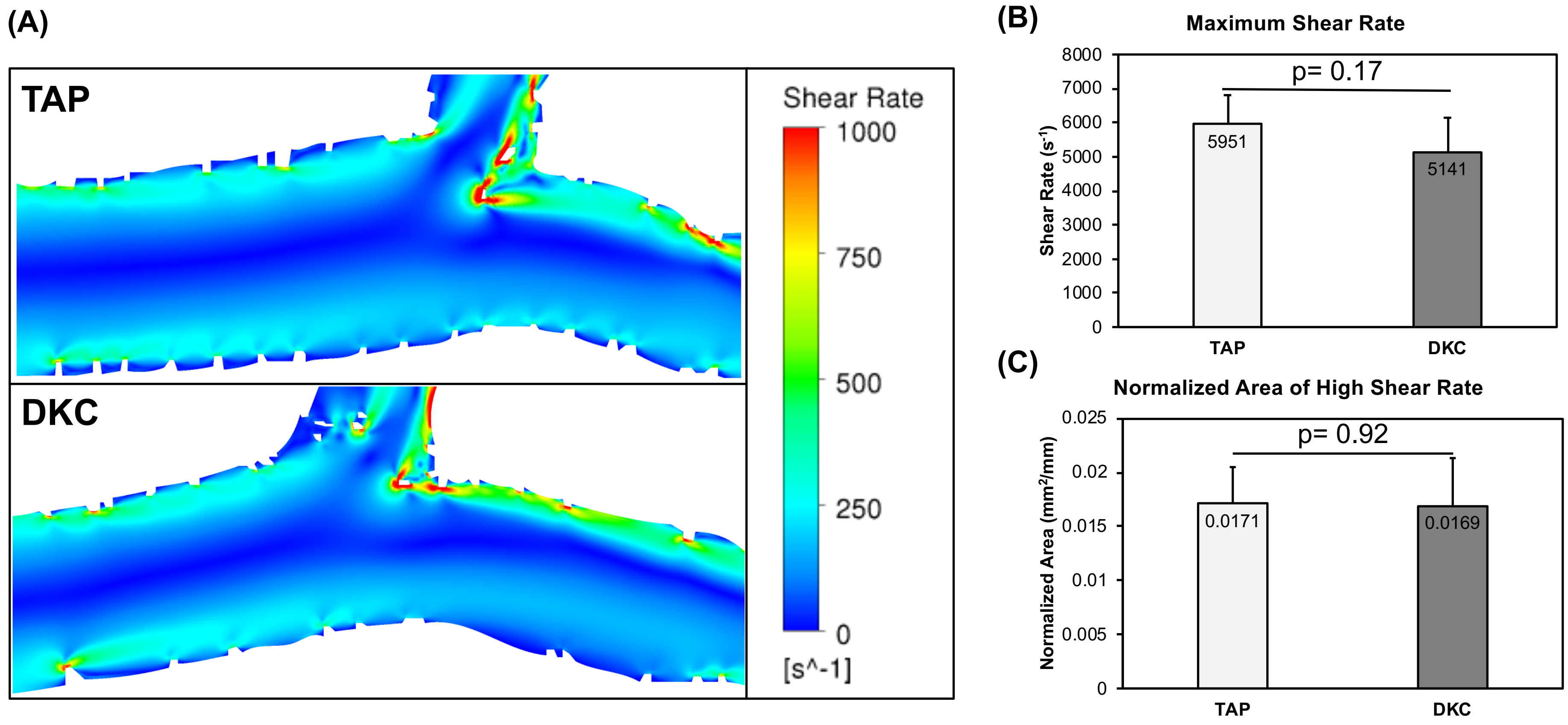

Figure 6. Simulation illustrating the effect of TAP and DKC on flow patterns. Representative shear rate plot of bifurcations with TAP and DKC (A). Quantification of maximum shear rate (B) and normalized regions of high shear (>1000s-1) based on length (C). (n = 6 simulation runs for each technique, total = 12 sets of simulations)