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The Cone Flare Crush Modified-T (CFCT) stenting technique for coronary artery bifurcation lesions

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ABSTRACT

Background: The present study is a prospective observational single arm clinical investigation, with parallel bench test interrogation, aimed at investigating the technical feasibility, safety and clinical outcomes with the cone flare crush modified-T (CFCT) bifurcation stenting technique. Bifurcation percutaneous coronary intervention (PCI) remains an area of ongoing procedural evolution. More widely applicable and reproducible techniques are required.

Methods: From April 2018 until March 2019, 20 consecutive patients underwent bifurcation PCI using the CFCT technique with a Pt-Cr everolimus drug-eluting stent with a bioresorbable polymer. Exercise stress echocardiography was performed at 12-month follow-up. The primary outcome was a composite of cardiac related mortality, myocardial infarction, target lesion/vessel revascularization and stroke. Safety secondary endpoints included bleeding, all-cause mortality and stent thrombosis.

Results: All patients underwent a successful CFCT bifurcation procedure with no complications to 30-day follow-up. One patient met the primary endpoint requiring target lesion revascularization at 9 months for stable angina. There were no other primary or secondary outcome events in the cohort. There were no strokes, deaths, stent thrombosis or myocardial infarction during the follow-up period. The mean CCS score improved from 2.25 to 0.25 ($p < 0.0001$). Optical coherence tomography (OCT) and bench test findings indicated optimal side branch ostial coverage and minimal redundant strut material crowding the neo-carina.

Conclusions: The CFCT technique appears to be a safe, efficacious and feasible strategy for managing coronary artery bifurcation disease. Expanded and randomized datasets with longer term follow-up are required to further explore confirm this feasibility data. (ANZCTR ID: ACTRN12618001145291).

Abbreviations: ACS, Acute coronary syndrome; ACT, Activated clotting time; AHA, American Heart Association; ARC, Academic Research Consortium; BARC, British Academic Research Consortium; CABG, Coronary artery bypass grafting; CCS, Canadian Cardiovascular Society; CFCT, Cone Flare Crush Modified-T; CFI, Cone Flare Inflation; DAPT, Dual antiplatelet therapy; DES, Drug Eluting Stent; DMV, Distal main vessel; DSE, Dobutamine stress echocardiography; ESE, Exercise stress echocardiography; ISKB, Intermediary simultaneous kissing balloon; ISR, In stent restenosis; LAD, Left anterior descending artery; LCx, Left circumflex artery; LMCA, Left main coronary artery; MACCE, Major adverse cardiac and cerebrovascular event; MI, Myocardial infarct; MRA, Mechanical rotational atherectomy; MV, Main Vessel; NSTEMI, Non-ST elevation Myocardial Infarction; NYHA, New York heart association; OCT, Optical coherence tomography; PCI, Percutaneous Coronary Intervention; PMV, Proximal main vessel; POT, Proximal Optimisation Technique; PUKBI, Penultimate kissing balloon inflation; QCA, Quantitative Coronary Angiography; RBP, Rated Burst Pressure; SB, Side Branch; SEM, Standard Error of the mean; ST, Stent thrombosis; STEMI, ST elevation Myocardial Infarction; SYNTAX, Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery; TLR, Target Lesion Revascularisation; TVR, Target Vessel Revascularisation; UAP, Unstable angina pectoris.

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1. Introduction

Bifurcation percutaneous coronary intervention (PCI) remains an area of ongoing procedural evolution and active research [1]. Multiple bifurcation strategies have been studied however bifurcation PCI continues to be heterogeneously managed with approaches that vary between operators, institutions and geographies. Dedicated two-limb pre-fabricated bifurcation stents have not been established to be adequately efficacious and are not widely available commercially [2,3]. Numerous provisional and upfront two-stent approaches have been assessed in registry and clinical trial settings with variable results [4–11]. Clinical outcome data suggests that a single stent provisional side-branch technique, outside of the left main bifurcation setting, should be the preferred approach [12–14]. Countervailing this, an *a priori* two-stent technique is frequently employed because of concern around the risk of irretrievable side-branch loss or the clinical significance of the side branch disease itself [15–18]. The strategy employed varies depending on operator preference, anatomical considerations and relative vessel sizes [8,19]. The cone flare crush modified-T (CFCT) bifurcation technique is a modified double kiss double-crush (DK-Crush) strategy and has been adopted by some operators as a default strategy where an upfront two-stent approach is deemed necessary [20]. The technique offers the potential for greater predictability for side-branch re-access for kissing balloon inflations (with less stent material in the *peri*-bifurcation region) and is potentially applicable to all bifurcation angles.(5) This study is a prospective observational single arm cohort investigation to examine the safety, technical feasibility and clinical outcomes with the implementation of the CFCT technique. The clinical data is complemented by intravascular imaging and bench test findings [21].

2. Methods

2.1. Study population

The CFCT study is a prospective investigator initiated single arm registry of twenty consecutive patients planned to undergo an upfront two-stent bifurcation stenting strategy utilizing a resorbable polymer third generation drug eluting stent (DES) with a platinum-chromium (Pt-Cr) based platform design (SYNERGY, Boston Scientific Inc, Marlborough, MA, USA). The study was approved by the relevant institutional human research and ethics committee (HREC) and all patients provided informed consent in-line with the Declaration of Helsinki and in accordance with the guidelines of the American Physiological Society [22]. The study was registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR ID number, ACTRN12618001145291). Clinical, demographic and procedural data was collected prospectively and entered into a central database as per the study protocol. Data collection was assisted by interrogation of the electronic medical record (EMR) system in place at our institution (Cerner Inc, Kansas, MO, USA). For each patient the Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score was calculated [23]. Angiographic variables assessed included lesion location and bifurcation type (Medina classification), presence of calcification and American Heart Association (AHA) lesion grade [24,25]. Procedural time, contrast load and fluoroscopy doses were collected in addition to the number of stents, stent lengths and diameters.

Consecutive patients over the age of 18 at our institution who were planned to undergo a CFCT bifurcation technique using a Pt-Cr everolimus DES with a bioresorbable polymer in a non-emergent setting were eligible for enrollment. Patients were excluded if they were unable to take dual antiplatelet therapy, were undergoing primary PCI for STEMI (or rescue PCI for failed fibrinolysis), or did not have capacity to provide informed consent.

2.2. Description of the CFCT technique

The original form of the CFCT technique was initially described by Rajdev et al. [20]. The modified version of this technique involves the following steps (and is displayed in Fig. 1):

1. Stenting of the side-branch (SB) is performed first (with predilatation if required) with an *iso*-sized semi-compliant balloon in the main vessel (MV) sized to the vessel distal to the bifurcation.
2. Side-branch (SB) ostial stent placement is positioned so that the proximal end of the stent extends back to the SB-ostium distal vertex only (as shown in Fig. 2) and is deployed at nominal pressure.
3. The stent balloon is then pulled back 50 – 70 per cent of its length and inflated for the 'cone flare' inflation to rated burst pressure (RBP). Following SB balloon deflation, the MV semi-compliant balloon is then inflated to between nominal and RBP, at operator discretion, and an intermediary simultaneous kissing balloon (ISKB) inflation is performed to between 6 and 8 atm.
4. The SB wire and stent balloon are then removed. The MV balloon is then 'jogged' backward and forward to predict ease of MV stent passage with any resistance leading to further MV inflations before MV balloon removal.
5. The MV balloon is then removed and the main vessel stent positioned and deployed at a pressure at operator discretion (usually between nominal and RBP).
6. Murasato optimal proximal optimization technique (POT) is then performed on the MV stent, using an *iso*-sized (to the vessel proximal to the bifurcation) non-compliant balloon, prior to re-wiring of the SB [26]. The SB is re-accessed and a balloon *iso*-sized to the SB stent is positioned across the ostium of the SB. Sequential inflations are then performed in the SB and MV followed by a penultimate kissing balloon inflation (PUKBI) to 6 – 8 atm. A final POT inflation is then performed in the MV.
7. Optical coherence tomography (OCT) is then performed on the MV and SB to document stent expansion and apposition [27].

2.3. Study outcomes

The primary outcome was a composite outcome of cardiac related mortality, non-fatal myocardial infarction (MI), target lesion or target vessel revascularization (TLR/TVR) and stroke at 12 months. Secondary endpoints included the individual components of the primary outcomes in addition to safety outcomes of bleeding (BARC 2–5), all-cause mortality and Academic Research Consortium (ARC) defined stent thrombosis (ST) [28,29]. Periprocedural MI was defined as per contemporary PCI studies but also in accordance with ARC recommendations [29–31]. Symptom data was also recorded using the Canadian Cardiovascular Society (CCS) score for angina at baseline and follow-up reviews [32]. Quantitative coronary angiography (QCA) data was recorded pre and post-PCI. Data was analyzed using descriptive statistics with findings expressed as mean ± standard error of the mean (SEM) unless other specified. Data comparisons were done with Student's T test for continuous variables and Pearson's chi-squared test for categorical variables with SPSS Version 26 (SPSS Institute Inc, Chicago, IL, USA).

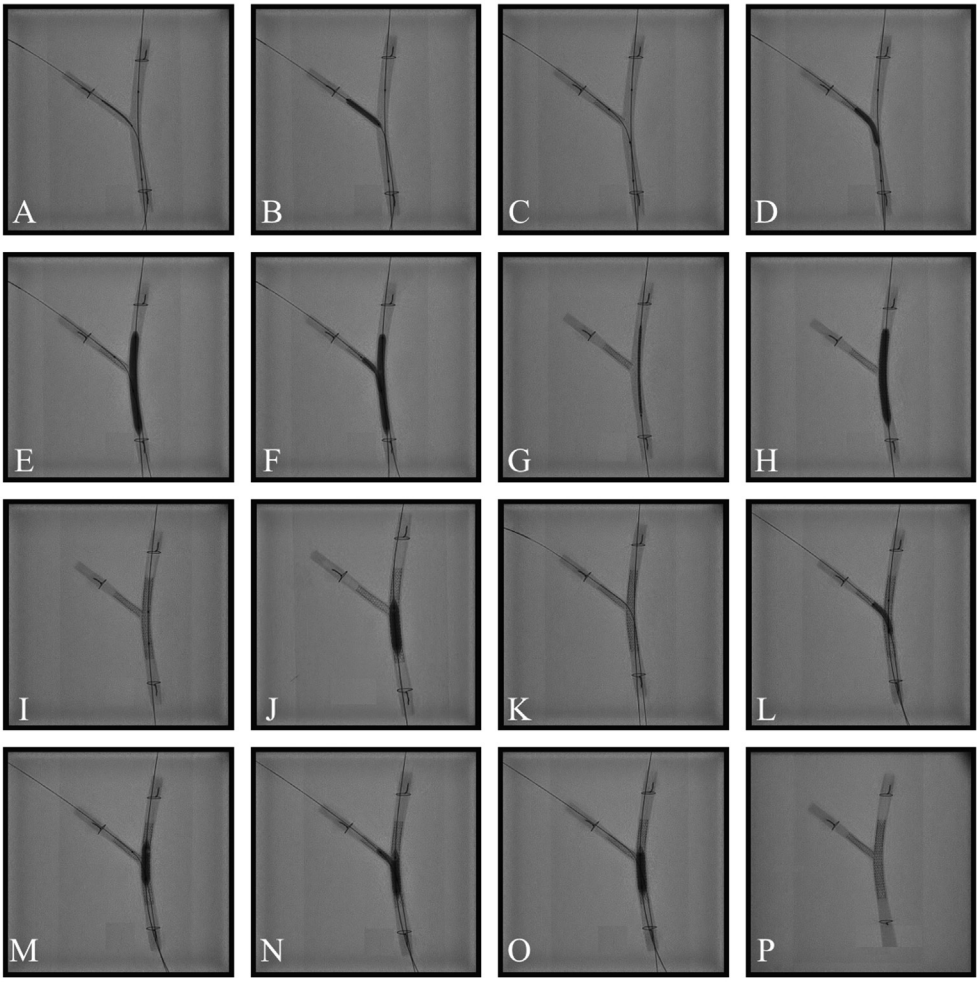

Fig. 1. (A) Optimal SB stent positioning. (B) SB stent deployment. (C) Balloon retracted for flare. (D) Flare inflation. (E) Crush inflation. (F) First KB inflation. (G) MV stent positioning with side branch wire removed. (H) MV stent deployment. (I) Murasato POT positioning. (J) Initial POT. (K) SB rewired. (L) Post-dilatation of SB. (M) Post dilatation of MV. (N) Penultimate KB inflation. (O) Final POT. (P) Final result.

2.4. Follow up

Follow-up data was obtained during outpatient clinic visits (in person or via telehealth link) at 1, 6 and 12 months. All patients underwent an exercise stress echocardiogram (ESE) at 12-month follow-up on guideline mandated medical therapy including beta-blockade with invasive coronary angiography for all patients who had a result suggestive of inducible ischemia (but not for sub-maximal or equivocal studies without definite ischaemic features). Patients who could not exercise due to mobility or other issues underwent a dobutamine stress echocardiogram (DSE).

2.5. Bench testing Methods

Bench testing was performed employing consensus principles [33]. Two pre-fabricated separate bifurcation models representing narrow and wide bifurcation angles (30° and 70° respectively) were used (Terumo Inc, Tokyo, Japan). They both consisted of clear polyurethane tubing affixed to a transparent Perspex™ plate via stainless-steel ties. The 30° model had 4.0 mm proximal MV (PMV), 3.0 mm distal MV (DMV) and 3.0 mm SB lumens. The 70° model had 3.5 mm PMV and DMV lumen with a 2.5 mm SB lumen.

The models were bathed in water on our catheter laboratory table and fluoroscopic images were taken with a Philips Allura Clarity imaging system (Koninklijke Philips NV, Amsterdam,

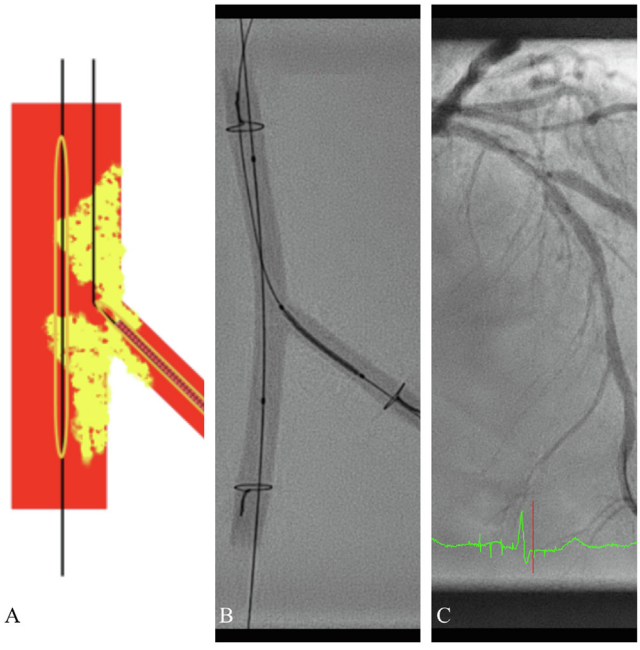

Fig. 2. (A) Illustration. (B) Bench test. (C) Angiographic appearance.

Table 1
Baseline clinical characteristics of study participants.

Clinical characteristics	
Number of patients	20
Mean age (years)	64.85 (±2.23)
Mean BMI (kg/m2)	28.5 (±1)
Male	15 (75%)
Diabetic	6 (30%)
Smoker	19 (95%)
Hypertension	12 (60%)
Dyslipidemia	12 (60%)
Previous PCI	2 (10%)
Cr Clearance (ml/min)	67.5 ± 10.8
Periprocedural LVEF (%)	54% ± 1.9
Baseline CCS	2.25 ± 0.38
Baseline NYHA	1.2 ± 0.52
Indication	
NSTEMI	8 (40%)
Unstable Angina	1 (5%)
Stable Angina	11 (55%)
Medications	
DOAC/VKA	4 (20%)
Aspirin	18 (90%)
Clopidogrel	16 (80%)
Prasugrel	4 (20%)
ACE Inhibitor/ARB	16 (80%)
Statin	20 (100%)
Beta blocker	14 (70%)

Abbreviations: BMI, body mass index; Cr, creatinine; PCI, percutaneous Coronary Intervention; CCS, Canadian Cardiovascular Society angina grade; NYHA, New York Heart Association functional score; DOAC, direct oral anticoagulant; LVEF, left ventricular ejection fraction; NSTEMI, Non ST segment elevation myocardial infarction; VKA, Vitamin K antagonist; ACE, Angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker. Data are shown as mean ± standard error of the mean or as n (%).

Netherlands). A Balance Middle Weight 0.014″ Elite wire (Abbott, Chicago, IL, USA) was used in the MV and a PT2 Light Support 0.014″ wire (Boston Scientific Corporation, Marlborough, MA, USA) in the SB. CFCT was performed in the sequence described above. The testing was performed with a 4.0 × 38 mm SYNERGY DES for the MV and a 2.5 × 12 mm SYNERGY DES in SB for both models. The stepwise sequence of the bench model is shown in the image panel in Fig. 1.

2.6. Funding source and role of sponsor

The CFCT study is an investigator-initiated prospective registry. An institutional grant to cover registry costs was provided by Boston Scientific Corporation (Marlborough, MA, USA). Terumo Corporation (Tokyo, Japan) provided pre-fabricated bench-testing models. The study structure, design and subsequent manuscript were prepared by the listed investigators. The study sponsor was given the opportunity to review the completed manuscript. All final decisions about manuscript content were made by the authors.

3. Results

3.1. Baseline characteristics

The baseline characteristics are reported in Table 1. The mean age was 64.84 ± 2.23 years with 25% of female gender. Cardiac risk factors included hypertension and dyslipidemia in 12 patients (60%) and diabetes in 6 (30%). 14 patients had a history of current or prior smoking. Remote prior MI had occurred in 5 (25%) patients with 2 (10%) having undergone remote prior PCI. PCI was performed for acute coronary syndrome (ACS) in 45% of patients (NSTEMI n = 8, UAP n = 1). Most patients were taking statin therapy prior to PCI (90%) and all were loaded with DAPT prior to the PCI procedure.

3.2. Procedural characteristics

Procedural characteristics are shown in Table 2. The mean fluoroscopy time was 35 min. The median SYNTAX score was 27.9 ± 2.73. Medina 1,1,1 bifurcation disease made up 70% (n = 14) of the cohort. LAD/diagonal bifurcation disease accounted for 70% of cases (n = 14) while 10% were located in the distal LMCA (n = 2). Mechanical rotational atherectomy (MRA) was performed in 15% (n = 3) patients. The average number of stents was 2.35 ± 0.1. Penultimate kissing balloon inflations (PUKBI) were achieved in all patients (with a final POT inflation following this in all cases). Figs. 3 and 4 are panels that display the pre and post-PCI angiographic appearances for all patients. OCT was performed at the conclusion of all cases to confirm adequate stent apposition and expansion (Figs. 5 and 6 display representative OCT findings). All procedures were performed with intraprocedural unfractionated heparin (target ACT 250 – 300) with no use of glycoprotein IIb-IIIa inhibitors or bivalirudin. QCA data is presented in Table 3.

3.3. Clinical outcomes

Complete follow-up data for all patients was available to 12 months with no loss to follow-up. One patient engaged in clin-

Table 2
Procedural and lesion characteristics of study participants.

SYNTAX score	
Mean Baseline SYNTAX score	27.87 ± 2.73
SYNTAX 0–22	7 (35%)
SYNTAX 22–32	7 (35%)
SYNTAX > 32	6 (30%)
Location of Bifurcation	
Left Main	4 (20%)
LAD	13 (65%)
LCx	3 (15%)
Medina	
1,1,1	15 (75%)
1,0,1	1 (5%)
0,1,1	4 (20%)
Calcified vessel	10 (50%)
TIMI Flow Grade	
TIMI 1	0
TIMI 2	0
TIMI 3	20 (100%)
Procedure Characteristics	
Radial Access	14 (70%)
Rotablation	5 (25%)
7F guide	18 (90%)
6F guide	2 (10%)
Multivessel PCI	2 (10%)
Procedural time (mins)	102.8 (±7.23)
Fluroscopy time (mins)	35 ± 1.97
Contrast volume (mls)	335.6 ± 22.11
Mean number of stents	2.35 ± 0.1
Penultimate kissing balloon inflation	20 (100%)
Murasato final POT	20 (100%)
Main Vessel	
Mean stent length	29.4 ± 1.94
Mean stent diameter	3.4 ± 0.09
Side Branch	
Mean stent length	17.9 ± 2.22
Mean stent diameter	2.9 ± 0.13

Abbreviations: SYNTAX, SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery; LAD, left anterior descending artery; LCx, left circumflex artery; F, French size; PCI, percutaneous coronary intervention; POT, Proximal optimisation technique; TIMI, Thrombolysis in Myocardial Infarction. Data are shown as mean ± standard error of the mean or as n (%).

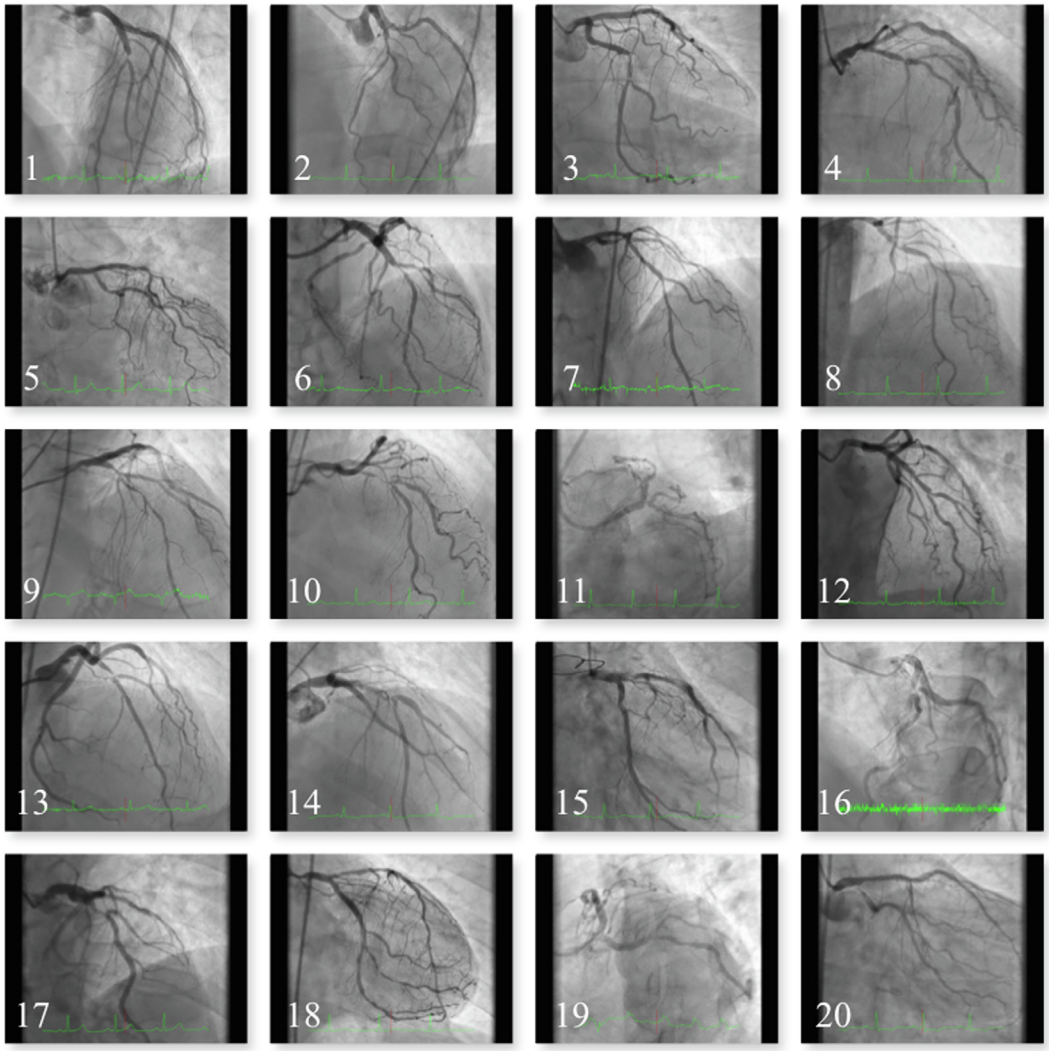

Fig. 3. Study subjects labelled 1 through to 20.

ical follow-up but declined to undergo a 12-month ESE owing to living in a regional area without easy access to testing facilities but was well (CCS 0/NYHA I) with no symptoms suggestive of myocardial ischemia. Clinical data is shown in Table 2. One patient met the primary endpoint requiring TLR at 9 months (patient 15 in the image panel shown in Figs. 3 and 4). The patient had undergone distal LMCA into LAD and Cx MRA facilitated bifurcation CFCT PCI after having been turned down for CABG owing to significant comorbidities. Owing to bulky calcium, his initial procedure was performed with a 2.0 Rotablator burr (Boston Scientific, Marlborough, MA, USA) for preparation of the LMCA, LAD and LCx. This patient re-presented with recurrent angina and an abnormal ESE with repeat angiography showing severe ISR of the left circumflex artery ostium and moderate ISR of the LMCA. The patient was treated with repeat bifurcation stenting utilizing the CFCT technique. There were no other primary or secondary outcome events in the study cohort. There were no strokes and no deaths during the follow-up period. The mean CCS score improved from 2.25 to 0.25 (p=<0.0001). QCA also demonstrated satisfactory findings with significant reductions in percentage stenosis for both the SB and MV (see Table 3). An additional patient presented more than 12 months post PCI with indeterminate symptoms and underwent coronary angiography that demonstrated moderate to severe stenosis in the proximal to ostial portion of the side-branch stent and was managed medically given satisfactory symptomatic control on medical therapy. There were no cases of possible, probable or definite stent thrombosis.

3.4. Bench testing findings

The bench test demonstrated satisfactory ostial morphology on fluoroscopic and photographic assessment. Stent coverage was satisfactory without *peri*-bifurcation metallic crowding and no evidence of geographic miss around the carina (Figs. 1 and 7). End-on fluoroscopy demonstrated circular expansion of the SB ostium (Fig. 8).

4. Discussion

4.1. General discussion

The data presented demonstrates the potential role for the CFCT technique in the treatment of coronary bifurcation disease. Bifurcation management represents an ongoing area of evolution and debate owing to sub-optimal outcomes when compared with the

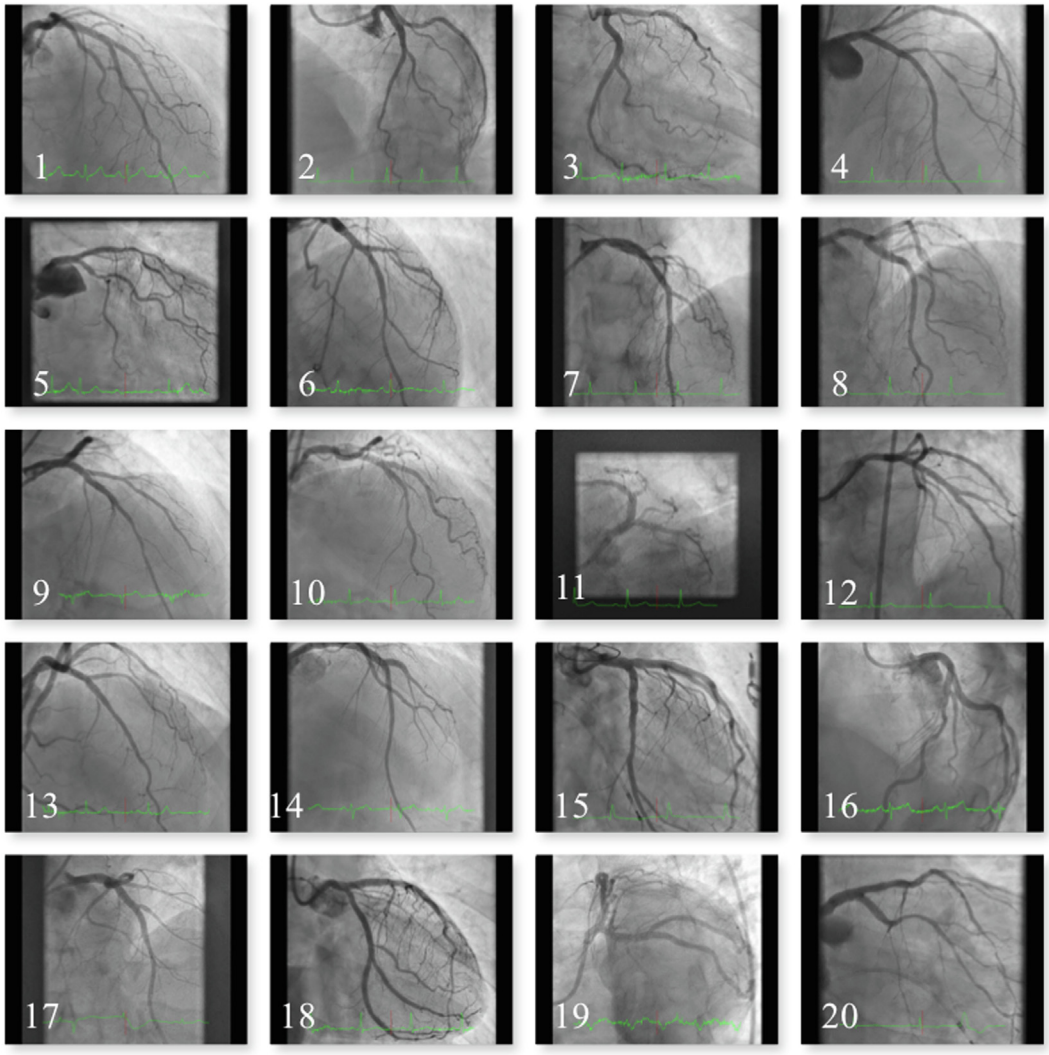

Fig. 4. Study subjects labelled 1 through to 20.

management of non-bifurcation disease and as a result has no universally accepted single technical solution [1]. The data from this cohort suggests that the CFCT strategy is a potentially reproducible method that minimizes strut material in the *peri*-bifurcation region and maximizes the ability for SB re-entry to facilitate a penultimate kissing balloon inflation (PUKBI). Bench testing and OCT findings indicate that the CFCT technique results in satisfactory coverage of the side-branch ostium. The technique emphasizes the role of optimal POT balloon inflation to cause carinal modification and to utilize extrusion of the *peri*-SB-ostial MV strut to facilitate proximal SB ostial coverage [26].

The CFCT technique appears to be a safe strategy and potentially holds promise as an additional tool in the armamentarium of contemporary bifurcation techniques. The findings also indicate the technical feasibility and suitability of this approach when using an everolimus-eluting bioresorbable polymer abluminal coated Pt-Cr DES (SYNERGY, Boston Scientific, Marlborough, MA, USA). The clinical data is supported by the above described bench testing findings with this platform. The complete resorption of polymer (poly-DL-lactide-coglycolide {PLGA]) with this platform within approximately 16 weeks and reduced levels of vessel inflammation may be particularly well suited to the bifurcation setting [34].

The twelve-month major adverse cardiac and cerebrovascular event (MACCE) rate in the present study was 5% owing to a single patient with symptom driven TLR for TLF. The DKCRUSH III study reported a 12-month MACCE of 6.2% in the DK-crush arm and 16.3% in the culotte arm with TLR of 2.4% and 6.7% respectively [4]. The findings are also comparable to the DKCRUSH V study where TLR was 5% in the DK-crush arm [35]. The current study findings appear to be in keeping with the original work on the initial iteration of the CFCT technique presented by Radjev et al. [20]. There were no instances of stent thrombosis, procedure related mortality or 12 mortality in the present study.

The technique is reproducible with potentially greater predictability for SB re-crossing and PUKBI (prior to final POT inflation) than other techniques [26]. It is postulated that SB re-access for the PUKBI is enhanced by the cone-flare inflation (CFI) prior to the intermediary KB step. The CFI step also serves to ensure apposition of the side branch stent to the ostium and acts as a high-pressure post inflation in the event that it is not possible to deliver a non-compliant balloon through the jailed stent. In the present cohort PUKBI was achieved in all patients and compares favorably with reported rates of 75 – 90% of patients in the DK Crush literature [12,36]. Utilization the initial iteration of the technique Rajdev et al also found a higher success rate re-crossing side branches with shorter time taken compared with conventional crush stenting [20]. Sixty to seventy per cent of in-stent restenosis in bifurcation stent strategies is reported to occur at the neo-carina

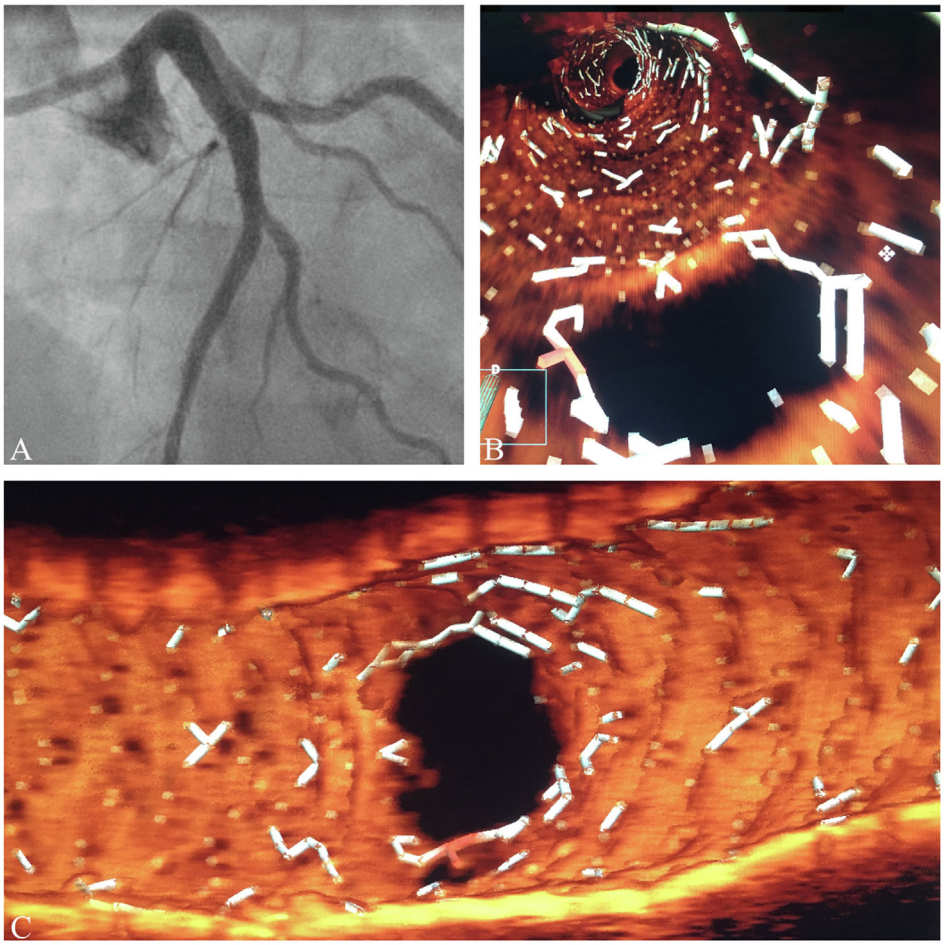

Fig. 5. (A) Angiographic appearance. (B) St Jude OPTIS OCT 3D Flythrough image. (C) St Jude OPTIS OCT Carina View.

[4,37]. The CFCT technique minimizes stent struts at the carina through precise positioning of the proximal edge of the SB stent level with, but not beyond, the distal vertex of the SB ostium. The CFCT technique then relies on the Murasato POT to push main vessel stent struts into the proximal vertex of the SB-ostium rather than having two or three layers of stent struts with significant strut deformation in this region (see Figs. 1–3) [26,38]. Accurate positioning of the ostial SB stent is therefore a crucial part of the CFCT technique. Precise positioning of the stent so that the distal vertex of the SB ostium is level but not beyond will result in adequate final SB ostial coverage at the proximal vertex following Murasato optimal POT and PUKBI (Fig. 1). The dichotomy of either complete ostial coverage with DK-crush or culotte versus none with provisional SB management may be better addressed by the middle ground that the CFCT strategy represents.

4.2. Study limitations

The present study has several limitations. The first is the observational (albeit prospective) nature of the study with a relatively small sample size. The small sample size itself is in keeping with other technical feasibility studies in the bifurcation field [39,40]. The purpose of this was to attain data and outcomes in an organized, systematic, prospective way regarding current practice of a technique with limited published findings, but with growing adoption. The study is also limited by the absence of a randomized study design with a comparator arm. Furthermore, the procedures were performed by relatively high-volume individual PCI operators (150–200+ PCI cases per year) and this may limit applicability to lower volume operators. Countervailing this, a strength of the CFCT technique is its relative predictability and safety. The study would also have been enhanced by routine angiography with intravascular imaging at 12 months on all patients (rather than clinically driven) but this would not have been appropriate given the observational nature of the registry and that routine angiography is not used to check stent patency.

4.3. Conclusion

The CFCT technique for bifurcation coronary artery stenosis appears to be safe and feasible with satisfactory clinical outcomes at 12 months in this prospective cohort. Expanded datasets to confirm this feasibility data will include angiographic and OCT follow-up, and subsequent randomized controlled data.

Declaration of Competing Interest

The cost of the registry was funded by an institutional grant from Boston Scientific Incorporated. ACC is a clinical proctor for

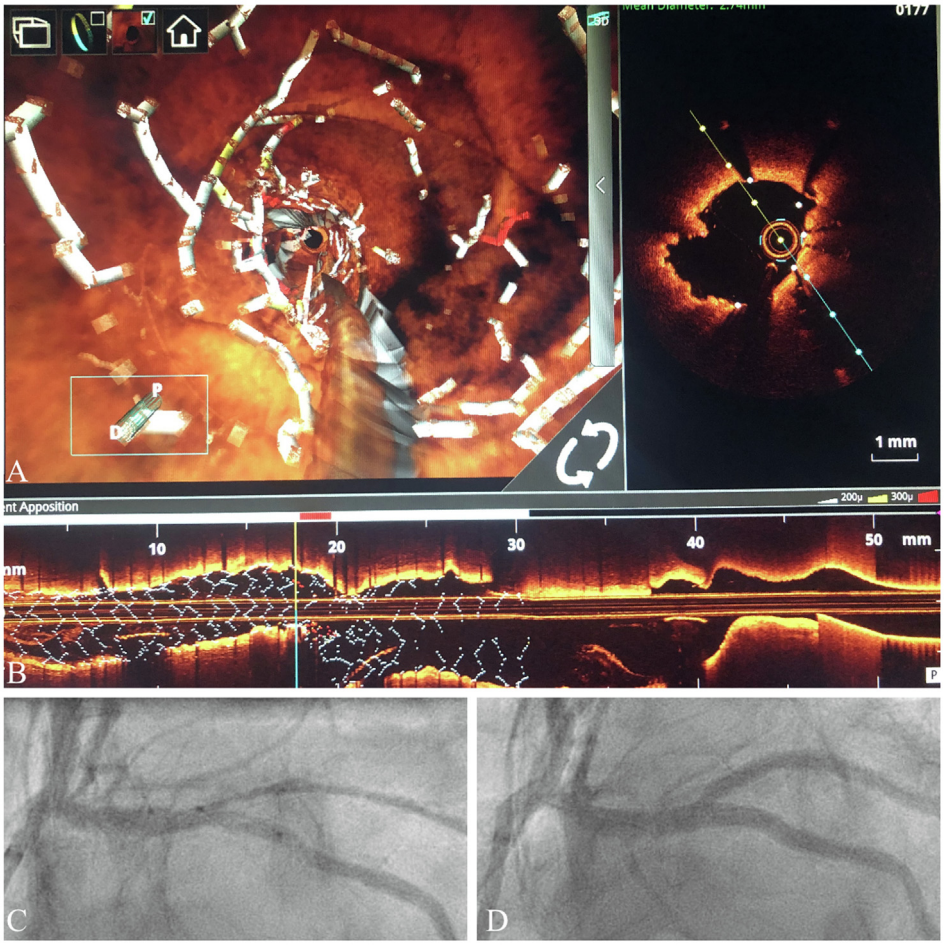

Fig. 6. (A) St Jude OPTIS OCT 3D Flythrough image of main vessel stent showing minimal disruption at neo-carina. (B) St Jude OPTIS OCT Rendered Stent demonstrating main vessel struts covering proximal carina after final POT. (C) Angiographic image of vessel pre-PCI. (D) Angiographic image of vessel post-PCI.

Table 3
Quantitative coronary angiography findings.

Proximal MV	Baseline	Post PCI	p value
Reference diameter (mm)	3.75 ± 0.8	4.40 ± 0.64	<0.0001
Minimal luminal diameter (mm)	1.22 ± 0.8	3.38 ± 0.70	<0.0001
Diameter stenosis (%)	63 ± 24	19 ± 8	<0.0001
Distal MV			
Reference diameter (mm)	3.17 ± 0.70	3.69 ± 0.51	0.001
Minimal luminal diameter (mm)	1.25 ± 0.83	2.94 ± 0.53	<0.0001
Diameter stenosis (%)	62 ± 24	17 ± 5	<0.0001
SB			
Reference diameter (mm)	2.73 ± 0.51	3.02 ± 0.62	0.15
Minimal luminal diameter (mm)	1.08 ± 0.64	2.4 ± 0.51	<0.0001
Diameter stenosis (%)	57 ± 25	15 ± 6	<0.0001
Bifurcation angle (degrees)	54 ± 20		

Abbreviations: MV, main vessel; SB, side-branch; PCI, Percutaneous coronary intervention. Data are shown as mean ± standard error of the mean.

Abbott and Edwards Lifesciences and has received advisory board and or consulting fees from Boston Scientific, Medtronic and Abbott. SGW is a clinical proctor for Abbott and Edwards Lifesciences and has received research grant support from Abbott and Biotronik. AI is a clinical proctor for Edwards Lifesciences. SVC is a clinical proctor for Abbott. The remaining authors have nothing to disclose.

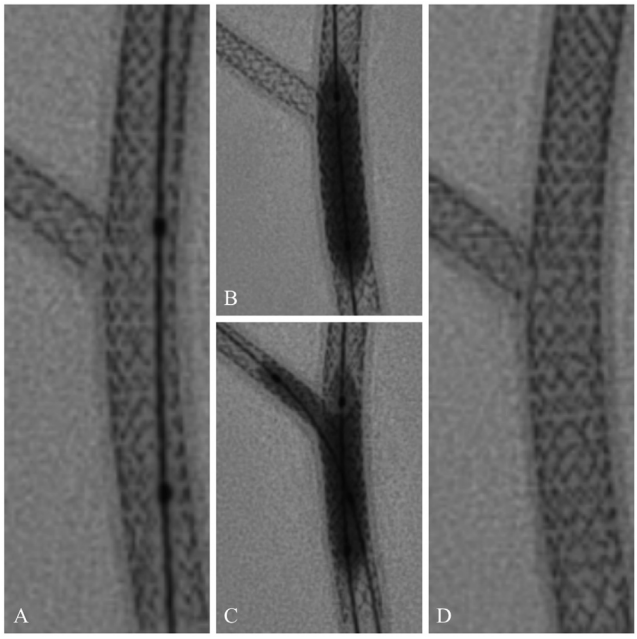

Fig. 7. (A) Bench test revealing naked proximal carina and optimal positioning of POT balloon. (B) POT inflation. (C) Kissing inflation. (D) Final result (following further final POT inflation).

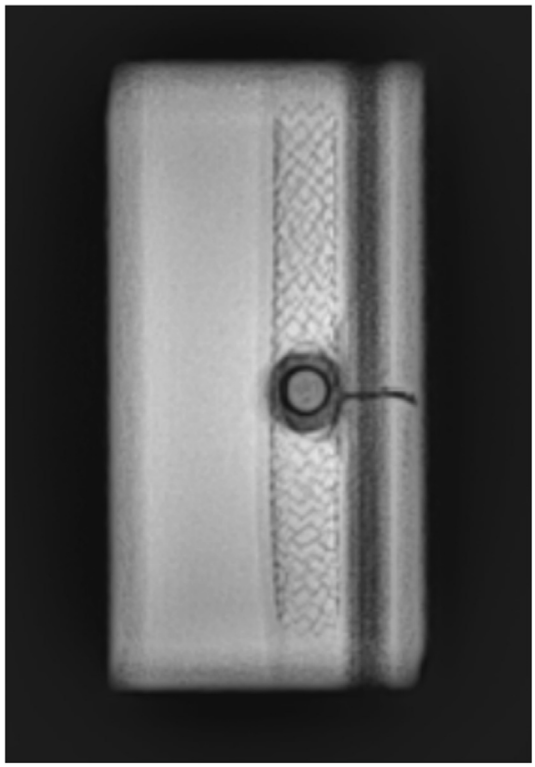

Fig. 8. End-on fluroscopic view coaxial with the long access of the side-branch stent demonstrating unobstructed circular ostium and absence of stent-strut crowding or deformation.

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