

# Six-Month Clinical Follow-Up of the Tryton Side Branch Stent for the Treatment of Bifurcation Lesions: A Two Center Registry Analysis

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**Background:** Treatment of bifurcation lesions with the Tryton Sidebranch stent has been shown to be feasible with an acceptable clinical outcome and low side branch late loss in the first in man trial. **Objective:** To report acute procedural and six month clinical follow-up after the use of the Tryton Sidebranch stent in an “all comer” registry. **Methods:** The first 100 coronary bifurcation lesions assigned for treatment with the Tryton stent were included in a prospective registry. Procedural and angiographic success rates were determined from patient charts and pre- and postprocedural quantitative coronary angiography. **Results:** Totally, 96 patients with 100 lesions were included in the study. Seventy-two percent presented with stable angina, 25% with unstable angina/NSTEMI, and 3% STEMI. The bifurcation was located in the left main in 8%. Two lesions were chronic total occlusions. Sixty-nine percent were true bifurcation lesions. One failure of stent delivery occurred. Acute gain in SB was  $0.76 \pm 0.64$ mm and three patients had residual stenosis of  $>30\%$ . Angiographic success rate was 95%; procedural success rate reached 94%. Peri-procedural MI occurred in two and there was one cardiac death during hospitalization. At a median six months follow-up, TLR rate was 4%, MI 3%, and cardiac death 1%. The percentage MACE-free survival at six months was 94%. No cases of definite stent thrombosis occurred. **Conclusions:** In a real world the use of the Tryton Sidebranch stent is associated with good procedural safety and angiographic success rate and acceptable outcome at six months of follow-up. © 2011 Wiley-Liss, Inc.

**Key words:** bifurcation lesions; percutaneous coronary intervention; procedural success; six month MACE

## INTRODUCTION

Percutaneous coronary intervention (PCI) for bifurcation lesions is considered high risk with increased procedural adverse events as well as inferior long term outcome when compared to non-bifurcation intervention [1]. Several techniques and strategies have been explored, employing one or two conventional tubular stents but the improvement in outcome remains limited. This is primarily reflected in the increased rates of sidebranch restenosis [2]. Dedicated bifurcation stents, specifically designed to allow minimally traumatic implantation in the main vessel and/or sidebranch while providing adequate scaffolding of the sidebranch ostium may offer an advantage over utilisation of conventional stents [3].

The Tryton Side-Branch Stent (Tryton Medical, Inc., Newton, MA) is a dedicated bifurcation stent inspired by the “culotte” stenting technique [4]. This Tryton

Side-Branch stenting strategy showed acceptable clinical outcome with no sidebranch restenosis and low side-branch late loss ( $0.17 \pm 0.35$  mm) at six months in the First-in-Man (FIM) trial that enrolled 30 patients

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with stable coronary artery disease and de novo bifurcation lesions. Being a FIM, the study had restricted inclusion criteria that does not represent routine clinical practice [5].

The present registry analysis was conducted to evaluate the procedural success and to assess clinical outcome of bifurcation stenting with the Tryton Side-Branch Stent<sup>TM</sup> in conjunction with a standard workhorse stent in a "real world," all comer population.

## METHODS

### Patient Population

All patients with ischaemia in a myocardial segment supplied by a coronary artery with a bifurcation lesion with disease in both main vessel and sidebranch that were referred for PCI from December 2006 at two academic tertiary hospitals in the Netherlands (Thoraxcenter, Erasmus MC, Rotterdam) and Poland (University Hospital of Lord's Transfiguration, Poznan) were eligible. Specifically the bifurcation could be located anywhere in the coronary circulation including grafts. The visually estimated reference diameter of the main vessel could be 2.5–5.0mm and that of the sidebranch in the range 2.0–2.75 mm. These dimensions were selected to comply with the available sizes of the Tryton stent. However the decision to treat the bifurcation and employ a Tryton Side Branch Stent remained at the discretion of the treating interventional cardiologist. The first 100 lesions assigned for treatment with the Tryton Sidebranch Stent were included in a collaborative registry between the two institutions.

### Study Device and PCI strategy

The Tryton Side-Branch Stent is a slotted tube, balloon expandable cobalt chromium BMS with three zones: a distal sidebranch zone, a central transition zone and a proximal main vessel zone. The distal zone has a standard slotted tube workhorse stent design, the central transition zone consists of three panels while the proximal main vessel zone is composed of three fronds that terminate proximally in a circumferential band. The stent is mounted either on a balloon with a uniform diameter of 2.5 mm (straight type) or on a stepped balloon with a diameter of 3.5 mm proximally and 2.5 mm distally (tapered type). The stent delivery system has four markers to delineate the proximal and distal end of the stent as well as the proximal and distal part of the transition zone. Further details of the stent design as well as the standard technique for implantation have been published [4]. In short, the procedure is typically performed via a 6Fr guiding catheter; after optional wiring of both main vessel and sidebranch for predila-

tion, the Tryton stent is advanced over the wire into the sidebranch, and using the two middle markers on the delivery system, the stent is positioned till these markers straddle the carina. Deployment of the stent is followed by retraction of the guidewire from the sidebranch and repositioning it through the fronds of the transition zone into the distal main vessel. A standard stent is then advanced and positioned in the main vessel jailing, the stented sidebranch. Once the main vessel stent is deployed, recrossing into the sidebranch allows final kissing balloon inflation.

### Procedure

Patients were pretreated with aspirin (75 mg) and clopidogrel (300–600 mg) unless they were already taking these antiplatelet agents. Intravenous heparin was administered to maintain an activated clotting time of >250 sec. Glycoprotein IIb/IIIa inhibitor use was left to the treating interventional cardiologist's discretion as was the use of other additional devices such as thrombectomy, excimer laser, rotablator etc. Delivery failures, need for additional overlapping stents to cover the whole lesion, additional ballooning, and procedural angiographic and clinical complications were noted. Aspirin was continued indefinitely and clopidogrel was continued for 12 months after the index procedure.

### Cardiac Enzymes and ECG

Serial cardiac enzymes including creatinine kinase (CK)-MB mass, troponin-T, or troponin-I were measured after the procedure. Preprocedure biomarkers were assessed in all patients with acute coronary syndrome. These patients were included in the biomarker analysis only if preprocedure markers were normal. A 12 lead ECG was obtained before and after procedure as part of routine institutional practices.

### Quantitative Coronary Angiography

Angiographic films were analysed with a dedicated bifurcation software (CAAS 5.5, Maastricht, PIE Medical software, The Netherlands) [6]. Reference vessel diameter, minimal luminal diameter (MLD) and percentage diameter stenosis were obtained for the proximal main vessel (PMV), distal main vessel (DMV), and sidebranch (SB) in the preprocedural angiographic film. Matched views of immediate postprocedural films were then selected for determination of the same parameters. Acute gain was determined from the difference between MLD in each of the three segments (PMV, DMV, SB).

## Follow-Up

Survival data from all patients were obtained from municipal civil registries. A health questionnaire was subsequently sent to all living patients with specific questions on treatment compliance, readmission and major adverse cardiac events. Patients who did not send the filled questionnaire were contacted by phone to obtain the relevant information. Those who reported events had their medical records, discharge summaries and any repeat angiographic films systematically reviewed. Data was carefully verified and adjudicated by cardiologists according to criteria defined below.

## Definitions

Primary device success was defined as successful deployment of the intended stent without system failure or device related complication. Angiographic success was defined as <30% residual stenosis and TIMI 3 flow in both main vessel and sidebranch after the procedure. Procedure success included angiographic success in the absence of in-hospital major adverse cardiac events (MACE). MACE was defined as a composite of cardiac or noncardiac death, Q-wave, or non-Q-wave myocardial infarction (MI) and ischaemia driven target lesion revascularisation (TLR). Non-Q wave MI was defined as clinical signs of myocardial infarction associated with a CK-MB mass or troponin -T/troponin-I increase to more than three times the upper limit of normal in the absence of Q waves and not related to an interventional procedure. Q-wave MI occurred when there was chest pain or symptoms consistent with myocardial ischaemia and new pathological Q waves in two or more contiguous electrocardiograph leads. TLR was defined as any PCI of the index lesion and including the 5 mm persistent segments in either main vessel or sidebranch. Target vessel revascularisation (TVR) was defined as revascularization of any part of the index coronary artery. Stent thrombosis was defined according to the Academic Research Consortium (ARC) [7].

## Statistical Analysis

Continuous data are expressed as mean  $\pm$  SD or as median (interquartile ranges) whereas dichotomous data are summarized as frequencies. The Kaplan-Meier method was used to study the incidence of events over time relative to the number of patients at risk at each time point. Statistical analysis was performed using SPSS software version 17.0 (SPSS, Chicago, USA)

**TABLE I. Baseline Clinical Characteristics**

Characteristics	N = 96
Male	72 (75%)
Age, years (mean $\pm$ SD)	63.9 $\pm$ 8.8
Diabetes mellitus	30 (31%)
Hypertension	58 (60%)
Hypercholesterolaemia	60 (63%)
Family history of coronary artery disease	46 (48%)
Smoker	17 (18%)
Previous myocardial infarction	42 (44%)
Previous PCI	40 (42%)
Previous CABG	8 (8%)
Stable angina	69 (72%)
Unstable angina	24 (25%)
ST elevation myocardial infarction	3 (3%)

Data are presented as numbers (percentages) or mean  $\pm$  SD unless specified. Percentages have been rounded.

## RESULTS

One hundred bifurcation lesions in 96 patients were included between December 2006 and March 2010. Baseline characteristics of patients included are shown in Table I. The mean age of patients was 63.9 years and the majority were male (75%). While most patients presented for PCI with stable angina (72%), three patients were treated for an acute myocardial infarction.

Lesion characteristics are described in Table II. Sixty-six percent of patients had multivessel disease and five patients had two bifurcation lesions that needed revascularization. Most bifurcations targeted for treatment with the Tryton Sidebranch stent were located in the left anterior descending/diagonal junction (72%). Eight stents were implanted in the left main coronary arteries. Two bifurcations involved the anastomosis of a saphenous venous graft with a native coronary artery; in one on the posterior descending and the other on the left anterior descending artery. A left anterior descending/large septal branch bifurcation was also included. Two bifurcations were treated after successful crossing of a chronic total occlusion in two patients. Sixty-nine percent of lesions were true bifurcation lesions (1,0,1 or 1,1,1 or 0,1,1) with involvement of both the main vessel and the sidebranch.

The mean reference diameters for the proximal main branch (PMB), distal main branch (DMB) and side branch (SB) were 2.91, 2.46, and 2.22 mm, respectively. The mean percentage diameter stenosis obtained by including all bifurcations, irrespective of the presence of significant disease in the three segments, were 49%, 41%, and 40% for PMB, DMB, and SB, respectively. The mean angle between the PMB and the SB was 152° while that between the DMB and the SB was 53°. These pre-procedural quantitative coronary angiographic measurements are presented in Table III.

TABLE II. Lesion Characteristics

Lesions	N = 100
<b>Bifurcation location</b>	
Left main	8
Left anterior descending/diagonal	72
Left circumflex/obtuse marginal	11
Posterolateral/posterior descending	5
Saphenous vein graft/native vessel	2
Other	2
<b>Medina classification</b>	
1,0,0	10
1,1,0	11
0,1,0	3
0,0,1	6
1,0,1	13
0,1,1	3
1,1,1	54
<b>ACC classification</b>	
A	0
B1	28
B2	39
C	33
Multivessel disease <sup>a</sup>	62 (66%)
Chronic total occlusion	2

Data represents actual number which is equivalent to the percentage since the number of lesions is 100 unless specified.

<sup>a</sup>62 patients out of 96 had disease in a vessel other than the one with the index bifurcation.

Ninety-nine of the 100 Tryton Sidebranch stents intended for treatment of 100 bifurcation lesions were successfully implanted resulting in a 99% device success rate. A case example is illustrated in Fig. 1 with corresponding optical coherence tomography images (Lightlab Imaging, Westford, MA) in Fig. 2. The tapered balloon delivery system was used in 93% of the procedures. Table IV lists the various types of stents used as the workhorse principal main vessel stent. Two patients received a bare metal stent. Procedural characteristics are shown in Table V. The mean nominal diameter of the main vessel stent was  $3.0 \pm 0.5$  mm with a mean length of  $24 \pm 6$  mm. Additional stents overlapping the Tryton stent in the sidebranch were deployed in 16% while in 19% of lesions further overlapping stents were implanted in the main vessel. Predilation was performed in 90% while final "kissing" ballooning was done in 71%.

Angiographic success was achieved in 95%; one failure of Tryton stent delivery with subsequent dissection in a diagonal sidebranch while four lesions did not meet the predefined angiographic success criterion of 30% residual stenosis. In these four lesions 38–47% residual stenosis on QCA was measured, mainly caused by a disproportionate increase in the distal sidebranch vessel diameter by insertion of an additional stent. Periprocedural PCI-related MI occurred in the same patient who had unsuccessful delivery of the stent.

TABLE III. Quantitative Angiographic Parameters Pre and Postprocedural (n = 100)

Parameter	Preprocedure	Postprocedure
<b>Proximal main branch</b>		
MLD (mm)	$1.49 \pm 0.76$	$3.09 \pm 0.48$
Reference diameter (mm)	$2.91 \pm 0.62$	$3.32 \pm 0.56$
% Diameter stenosis	$49 \pm 24$	$8 \pm 8$
Acute gain (mm)		$1.62 \pm 0.74$
<b>Distal main branch</b>		
MLD (mm)	$1.43 \pm 0.74$	$2.54 \pm 0.44$
Reference diameter (mm)	$2.46 \pm 0.52$	$2.77 \pm 0.44$
% Diameter stenosis	$41 \pm 29$	$8 \pm 8$
Acute gain (mm)		$1.12 \pm 0.77$
<b>Sidebranch</b>		
MLD (mm)	$1.30 \pm 0.56$	$2.04 \pm 0.36$
Reference diameter (mm)	$2.22 \pm 0.40$	$2.31 \pm 0.35$
% Diameter stenosis	$40 \pm 26$	$12 \pm 11$
Acute gain (mm)		$0.76 \pm 0.64$
<b>Bifurcation angles in degrees</b>		
PMB and SB	$151.6 \pm 1.5$	
DMB and SB	$52.5 \pm 0.5$	

Data is expressed in mean  $\pm$  SD. MLD, minimal luminal diameter; PMB, proximal main branch; DMB, distal main branch; SB, sidebranch.

Another patient who presented with acute myocardial infarction with cardiogenic shock and who had a bifurcation treated with good angiographic result died within 48 hours of the procedure. Therefore the procedure success was 94%.

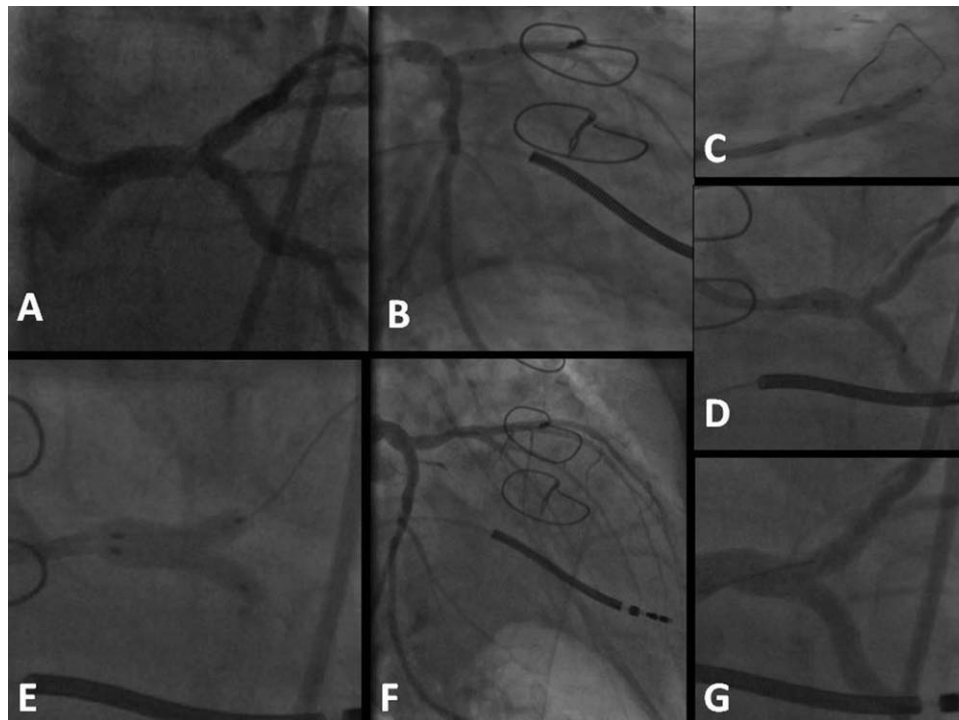
The QCA parameters for the whole cohort pre and post procedure are listed in Table III. The mean acute gain in the sidebranch was  $0.76 \pm 0.64$  mm. On analysis of a subgroup of bifurcations ( $n = 76$ ) with true sidebranch disease (1,0,1; 1,1,1; 0,1,1 and 0,0,1), the mean acute gain was  $0.94 \pm 0.60$  mm.

### In-Hospital and Mid-term Clinical Outcome

The clinical events are summarized in Table V. In-hospital MACE rate reached 3%. The only case of death was due to cardiac death in the patient treated for STEMI with cardiogenic shock as mentioned above. Postprocedural elevations of troponins occurred in 11/33 patients treated for stable angina but two met criteria of a PCI related myocardial infarction. The first occurred secondary to dissection of the diagonal branch in which the Tryton stent could not be delivered. The second occurred secondary to transient slow flow in the distal main branch after placement of the main vessel stent. There were no cases of definite/probable stent thrombosis or target vessel revascularization.

Thirty-day follow-up was available in all patients. There were no reported events and therefore the MACE is same as the in-hospital outcome.

Patients were followed up for a median of six months. All patients were compliant with their



**Fig. 1.** Case example of a Tryton Side Branch Stent insertion in the left main (LM) coronary bifurcation. **A:** Diagnostic angiogram of a patient with previous left internal mammary graft to the left anterior descending artery, and persistent ischaemia, showing significant disease at the LM bifurcation. **B:** Positioning of the Tryton stent in the smaller calibre left anterior descending artery, in this case considered the Side Branch. Note the straddling of the carina with the middle two markers.

**C:** Deployment of Tryton by inflation of the stepped balloon. Guide wire retraction and redirection into the dominant larger left circumflex artery (main vessel) was followed by deployment of a standard drug eluting stent with proximal part in LM and distal part in left circumflex (**D**). Wire recross into side branch and fenestration with small balloon allowed final kissing balloon inflation (**E**). Angiographic result at the end of procedure (**F, G**).

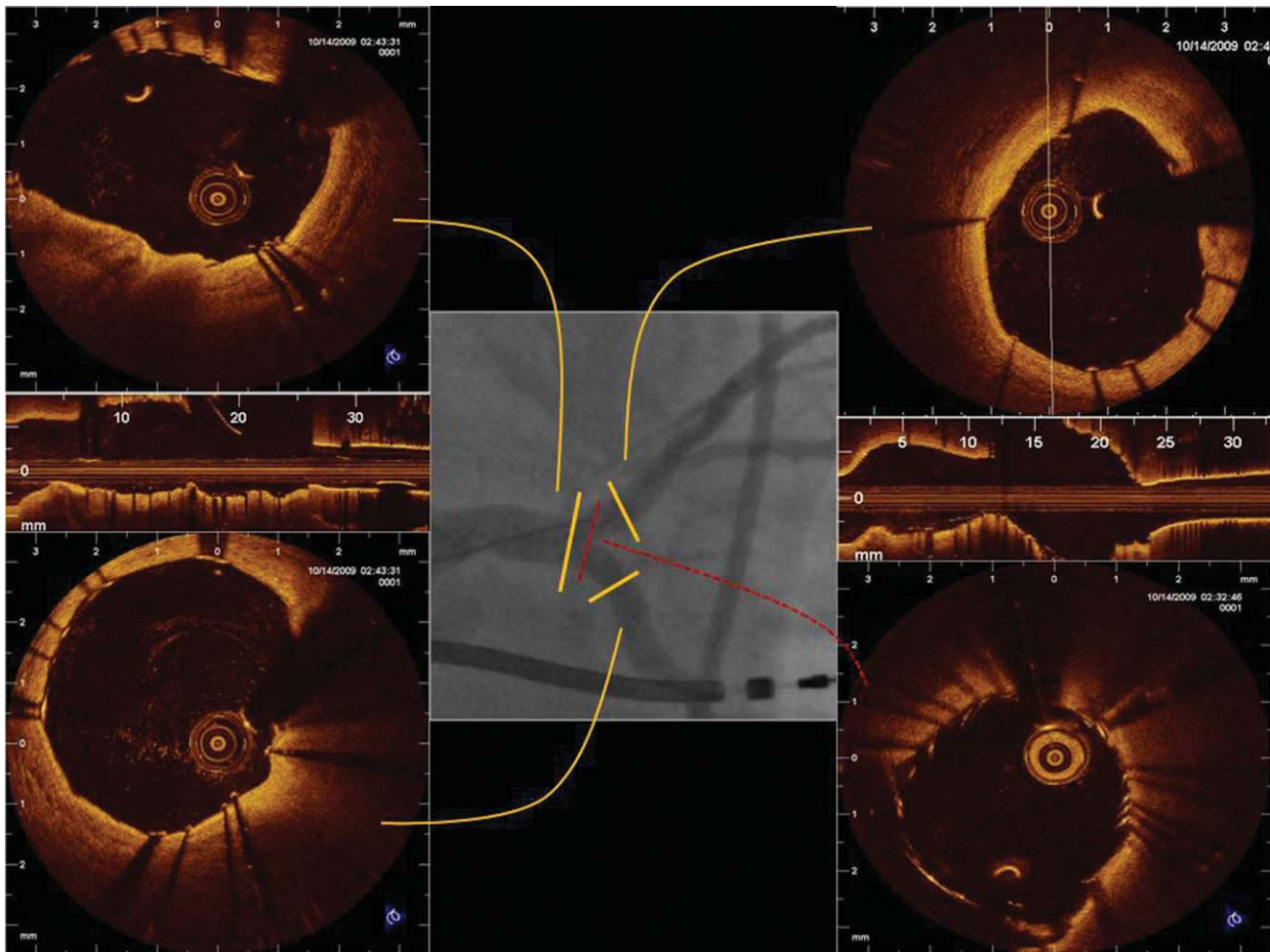
prescribed medications at the time of last contact. Fifty-one patients had at least six months follow-up. Up to this time point, one patient suffered a myocardial infarction due to occlusion of a vessel other than that treated in the index procedure 78 days earlier. The same patient had TLR of SB at 155 days. A second patient had a TLR so that the percentage of survival free of MACE at six months was 94% as shown in the Fig. 3. Two other patients with longer than six months follow-up had ischaemia-driven target lesion revascularization (194 and 292 days). Restenosis occurred in the main vessel in two patients and in the side branch in the other two. No cases of stent thrombosis were reported. Thus the cumulative MACE rate over a median follow-up period of 206 days (IQR: 125-386) at follow up reached 8% as shown in Table V.

## DISCUSSION

This registry comprising an “all comer” population with implantations including three for acute myocardial infarctions, eight left main lesions, and two chronic

total occlusions, has shown that the Tryton side branch stent, used in conjunction with a standard workhorse stent for the treatment of complex bifurcation lesions has resulted in a good procedural success rate (94%) and acceptable 8% MACE rate at six months follow-up. More specifically PCI related MI was limited to 2%, the TLR rate at follow up was just 4% and importantly, there were no cases of stent thrombosis.

Bifurcation intervention is historically associated with worse outcome [1,8]. Although stenting has improved the prognosis and DES have further improved it, restenosis and pinching of the side-branch often triggers the need to intervene on the sidebranch. In a bifurcation registry study by Kaplan et al., 80 of 288 (27.8%) bifurcation lesions treated with one stent initially required a second stent due to severe impairment of the SB during the angioplasty procedure [9]. Despite technical improvements in the use of two stent techniques, recent randomized trials failed to show any advantage over the use of one stent technique in terms of clinical outcome. More so, the provisional one stent technique is



**Fig. 2.** Optical coherence tomography performed after treatment of the left main coronary artery bifurcation described in Fig. 1. Pullback from the left anterior descending artery shows good apposition of the Tryton stent (right upper panel). Pullback from the left circumflex artery also shows good standard stent apposition in left circumflex (right lower panel). Left main coronary imaging shows minimal strut overlap (left upper panel). Imaging at the bifurcation also reveals satisfactory strut apposition (right lower panel). [Color figure can be viewed in the online issue, which is available at [wileyonlinelibrary.com](http://wileyonlinelibrary.com).]

**TABLE IV. Main Vessel Stents Implanted**

Stent name	Manufacturer	Drug eluted	Frequency
Xience V	Abbott Vascular, Santa Clara, CA	Everolimus	47
Xience Prime	Abbott Vascular, Santa Clara, CA	Everolimus	17
Taxus Liberté	Boston Scientific, Natick, MA	Paclitaxel	13
ENDEAVOR resolute	Medtronic Vascular, Santa Rosa, CA	Zotarolimus	7
Cypher Select	Cordis Corp, Warren, NJ	Sirolimus	6
Promus	Boston Scientific, Natick, MA	Everolimus	3
Biomatrix	Biosensors International, Singapore	Biolimus A9	1
Coroflex Please	B. Braun, Melsungen, Germany	Paclitaxel	1
Luc - Chopin	Balton, Warsaw, Poland	Paclitaxel	1
Skylor	Invatec, Brescia, Italy	None	1
Vision	Abbott Vascular, Santa Clara, CA	None	1

associated with lower procedural cardiac biomarker release, lower contrast dose used, and less radiation used [10–12].

The culotte technique seems to be the safest, most effective, offering the best long term outcome of the two stent techniques [9,13–15]. Table VI lists the

**TABLE V. Procedural and Clinical Outcome**

Predilation	
Side branch	69 (70%)
Main vessel	83 (84%)
Separate postdilation	71 (72%)
Final kissing	70 (71%)
Additional overlapping stent implantation <sup>a</sup>	
Side branch	15 (16%)
Main vessel	19 (20%)
Total stents implanted	275
Stents per bifurcation	2.4 ± 0.7
Stents per patient	2.9 ± 1.3
Multivessel stenting in index procedure	26 (26%)
<b>Acute procedural outcome</b>	<i>N</i> = 100
Device success	99
Angiographic success	95
PCI related biomarker elevation	11/33 (33%)
PCI related MI	2
Procedural success	94
<b>In-hospital outcome<sup>b</sup></b>	<i>N</i> = 96
Cardiac death	1
Myocardial infarction	2
CABG	0
Target lesion revascularization	0
Target vessel revascularization	0
Definite/probable stent thrombosis	0
Cardiac death or MI	2
MACE (cardiac death, MI, CABG or TLR)	2
<b>Median six month outcome (cumulative)<sup>b</sup></b>	<i>N</i> = 96
Cardiac death	1
Myocardial infarction	3
CABG	0
Target lesion revascularization	4
Target vessel revascularization	4
Definite/probable stent thrombosis	0
Cardiac death or MI	3
MACE (cardiac death, MI, CABG or TLR)	8
Device/PCI strategy-related MACE <sup>c</sup>	8

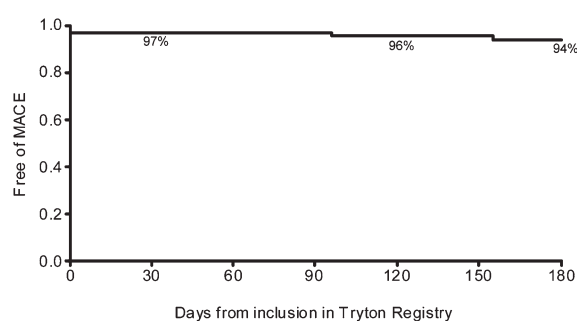
Data are expressed in numbers and percentages. MI, myocardial infarction; CABG, coronary artery bypass grafting; TLR, target lesion revascularisation.

<sup>a</sup>Refers to number of lesions requiring extra stent apart from the Tryton stent and the main vessel stent.

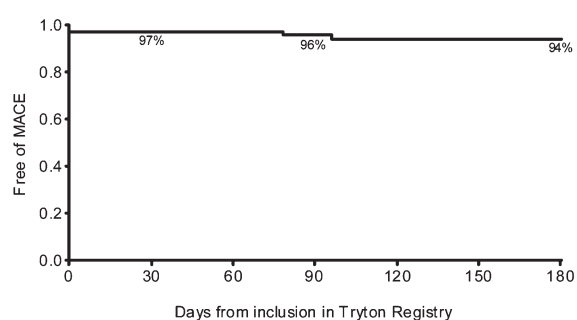
<sup>b</sup>Data expressed in actual numbers which is also equivalent to percentages.

<sup>c</sup>Excludes one patient with a MI at follow up in a territory other than that supplied by treated vessel and another who died of cardiogenic shock that commenced prior to index intervention.

studies that employed the culotte technique in the DES era. A recent randomized study comparing the culotte technique (*n* = 215) and the crush technique (*n* = 209) found significant differences in biomarker release (8.8 % vs. 15.5%) peri-procedurally favoring the culotte technique though the incidence of major adverse cardiac events including stent thrombosis at six months was similar between the two groups. By eliminating the need for crushing the side branch stent, theoretically trauma to the bifurcation vessel walls is reduced as may be the procedural complications. In the same

**A Device MACE**

No. At Risk 96 88 86 82 74 57 51

**B Over all MACE**

No. At Risk 96 88 86 81 73 56 51

**Fig. 3. Kaplan Meier curves for cumulative MACE. A: Composite of index bifurcation treatment-related cardiac death, myocardial infarction, and target lesion revascularization. B: Composite endpoint of all cause mortality, cardiac death, any myocardial infarction, or target vessel revascularization.**

study, at eight months, angiographic follow-up revealed a significantly higher in-stent restenosis in the “crush” group (10.5% vs. 4.5%). This can be explained by the better scaffolding of the sidebranch ostium. Also recross into the sidebranch is theoretically easier in the culotte group with the guide wire having to cross less layers of struts so that final kissing balloon is more likely to be feasible. This last together with the fewer overlapping layers of metal is thought to reduce the chance of incomplete stent apposition which can then lead to complications such as stent thrombosis and restenosis.

In this all comer study, we have noticed similar rates of procedural success as in the FIM trial reported by our group [5]. The 94% rate in this study was slightly lower than that reported in a culotte versus T stenting study [9]. One explanation could be the difference in scaffolding and recoil properties between the transition zone part of the Tryton stent and a standard stent utilised in the conventional culotte technique. In fact the three patients with residual diameter stenosis (%DS) of >30% after successful Tryton stent implantation, had their MLD located at the sidebranch ostium. The

TABLE VI. Studies With "Culotte" Technique for Bifurcation Lesions in the Drug Eluting Stent Era

	Culotte-treated patient	Stent used	Kissing %	Follow-up in months	TLR	Binary restenosis rate <sup>a</sup>	Late loss (mm) MV <sup>a</sup>	Late loss (mm) SB	ST	MACE
Hoye et al.	23	SES, PES	74%	8	5%	18.8%; 12.5%	0.48 ± 0.56	0.53 ± 0.33	0%	15.4%
Kaplan et al.	45	SES, PES	84.4%	9	8.9%	6.6%; 4.4%	0.23 ± 0.52; 0.42 ± 0.61	0.28 ± 0.45	2.2%	13.3%
Adriaenssens et al.	134	SES, PES	62%	12	21%	9.1%; 16%	0.10 (−0.04–0.38); 0.34 (−0.03–0.66)	0.30 (−0.01–0.72)	1.5%	26%
Erglis et al.	215	SES, PES	92%	6	2.8%	6.6%; 4.5%	0.12 ± 0.42; 0.19 ± 0.49	0.20 ± 0.48	1.9%	3.7%
Onuma et al.	30	Tryton + SES, PES, EES	100%	6	0%	0%	0.25 ± 0.43; 0.00 ± 0.31	0.17 ± 0.35	0%	9.9%

MV, main vessel; SB, side branch; ST, stent thrombosis; MACE, major adverse cardiac events; SES, sirolimus eluting stents; PES, paclitaxel eluting stents; EES, everolimus eluting stents

<sup>a</sup>First figures indicate value for proximal MV and second figures indicate value for distal MV.

clinical importance of this is however uncertain as there was still a significant acute gain in the side branch and none of these patients had a TLR during follow-up. Moreover as Koo et al. demonstrated, QCA is unreliable to assess the functional significance of sidebranch jailing when compared to fractional flow reserve [16]. Of the four cases of TLR, two occurred in the SB covered by the BMS. While we know that the late lumen loss in side branch at six months averaged 0.17 mm in the FIM, being even better than that reported for DES (0.34–0.53 mm) the TLR rate is less than that reported for two stent techniques. Studies report TLR rates of 24–43% the when two BMS stents are employed and 5.1–28% when two DES are used.[1,9-15,17]

Importantly, we did not observe any stent thrombosis in our cohort at six months follow-up which compares well with previous studies that employed the culotte technique. Adriaenssens et al. reports a 1.5% ST rate at 12 months follow-up in a study with 134 lesions in 132 patients. The high rate of final kissing that aims to ensure adequate strut apposition may be a contributing factor.

Although general evidence supports the use of simple, single stenting with conventional stents, the use of dedicated bifurcation stents especially in cases with significantly narrowed true bifurcations where double stenting is highly likely to be performed is probably justified. More data is therefore needed from the registries and randomized trials of the use of dedicated bifurcation stents in this high risk patient/lesion subset.

### Study Limitations

This study has the intrinsic limitations of a registry. Selection bias could have occurred in treatment of bifurcation lesions with the study stent. No control group was used to compare the use of this dedicated

bifurcation stent and stenting strategy with other devices and techniques. The registry was confined to two academic referral centers and the study lesions were limited to 100. Also, the patients enrolled had no angiographic or other invasive imaging follow-up. However the study still very likely represents the utilization of the Tryton sidebranch stent and its performance in the "real world" everyday practice.

### CONCLUSIONS

In a real world, two centre registry, the use of the Tryton Sidebranch stent is associated with good procedural safety and angiographic success rate and acceptable outcome at six months of follow-up.

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