JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 8, NO. 7, 2015

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2015.01.037

Single String Technique for Coronary Bifurcation Stenting

Detailed Technical Evaluation and Feasibility Analysis

Gabor G. Toth, MD,*† Stylianos Pyxaras, MD,* Peter Mortier, MS, PhD,‡§ Frederic De Vroey, MD,* Giuseppe Di Gioia, MD,*‖ Julien Adjedj, MD,* Mariano Pellicano, MD,* Angela Ferrara, MD,* Thomas De Schryver, MS,¶ Luc Van Hoorebeke, MS,¶ Benedict Verhegghe, MS, PhD,‡§ Emanuele Barbato, MD, PhD,*‖ Bernard De Bruyne, MD, PhD,* Matthieu De Beule, MS, PhD,‡§ William Wijns, MD, PhD*

ABSTRACT

OBJECTIVES The study aimed to evaluate the adequacy and feasibility of the single string bifurcation stenting technique.

BACKGROUND Double-stent techniques may be required for complex bifurcations. Currently applied methods all have their morphological or structural limitations with respect to wall coverage, multiple strut layers, and apposition rate.

METHODS Single string is a novel method in which, first, the side branch (SB) stent is deployed with a single stent cell protruding into the main branch (MB). Second, the MB stent is deployed across this protruding stent cell. The procedure is completed by final kissing balloon dilation. The single string technique was first tested in vitro (n = 20) and next applied in patients (n = 11) with complex bifurcation stenoses.

RESULTS All procedures were performed successfully, crossing a single stent cell in 100%. Procedure duration was 23.0 ± 7.9 min, and the fluoroscopy time was 9.4 ± 3.5 min. The results were evaluated by optical coherence tomography, showing fully apposed struts in 83.0 ± 9.2% in the bifurcation area. Residual area obstruction in the MB was 6.4 ± 5.6% and 25.0 ± 16.9% in the SB, as evaluated by micro computed tomography. All the human cases were performed successfully with excellent angiographic results: the residual area stenosis was 27 ± 8% and 29 ± 10% in the MB and in the SB, respectively, by 3-dimensional quantitative coronary angiography. No relevant periprocedural enzyme increase was observed. During follow-up (6 ± 4 months), no adverse clinical events (death, myocardial infarction, target vessel revascularization) were noted.

CONCLUSIONS The single string technique for complex bifurcation dilation was shown to be adequate in vitro and feasible in humans, with favorable results in terms of stent overlap, malapposition rate, and low residual obstruction in both the MB and SB. (J Am Coll Cardiol Intv 2015;8:949–59) © 2015 by the American College of Cardiology Foundation.

From the *Cardiovascular Research Centre Aalst, OLV Clinic, Aalst, Belgium; †University Heart Centre Graz, Medical University of Graz, Graz, Austria; ‡FEops Besloten Vennootschap met Beperkte Aansprakelijkheid, Ghent, Belgium; §IBiTech-bioMMeda, IMinds Medical IT, Ghent University, Ghent, Belgium; ‖Division of Cardiology, Department of Advanced Biomedical Sciences, Federico II University, Naples, Italy; and the ¶UGCT, Ghent University, Ghent, Belgium. Testing equipment, including guidewires, stents, and balloon catheters were provided by Abbott Laboratories Inc. (Abbott Park, Illinois), Biosensors Interventional Technologies Ltd. (Singapore), Biotronik SE & Co. (Berlin, Germany), Boston Scientific Inc. (Natick, Massachusetts), and Medtronic Inc. (Minneapolis, Minnesota) without financial involvement or intellectual restriction. Drs. Verhegghe and Mortier are cofounders of FEops. Dr. Adjedj is supported by a grant from Federation Française de Cardiologie. Dr. De Bruyne has received institutional grant support and consulting fees from St. Jude Medical. Dr. De Beule is a shareholder in FEops. Dr. Wijns has received institutional grants from Abbott Vascular, Biosensors Interventional Technology, Biotronik, Boston Scientific, and Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received September 29, 2014; revised manuscript received January 20, 2015, accepted January 29, 2015.

ABBREVIATIONS AND ACRONYMS

GW = guidewire

MB = main branch

mCT = micro computed tomography

OCT = optical coherence tomography

PCI = percutaneous coronary intervention

QCA = quantitative coronary angiography

SB = side branch

The basic concept of conventional stent systems relies on restoration of the native tubular geometry and expected luminal area of epicardial coronary arteries. Therefore, percutaneous coronary intervention (PCI) of complex bifurcation stenosis remains a challenge for interventional cardiologists. The evolution of bifurcation PCI resulted in several techniques, using either single- and double-stent techniques (1) or a number of dedicated devices (2-5). Yet the universally optimal solution is still lacking, mainly due to the highly complex morphology with large variation of bifurcations stenoses.

SEE PAGE 960

The single-stent technique, namely, provisional T-stenting, is associated with excellent short- and long-term outcomes in the vast majority of cases (6-8) and is currently recommended as the default approach to bifurcation PCI with or without involvement of the side branch (SB) (9). For more complex pathologies, in which an important SB is involved or stenosed over a longer segment (more than 5 mm, starting at its ostium), the single stent strategy may not provide optimal results with adequate downstream flow in both territories. For such pathologies, double stent techniques or the use of dedicated devices may be recommended. A wide variety of techniques using 2 regular stents has been described and evaluated including T-, culotte, crush, minicrush, T- and protrusion stenting, but the best choice remains unclear. The main limitations of each of these techniques are due to superimposition of multiple metal layers and frequent stent strut malapposition. The introduction of novel dedicated SB stents aimed at eliminating these limitations (10). However, dedicated devices lack the anatomic conformability and flexibility of regular stents and may not be available as drug-eluting devices.

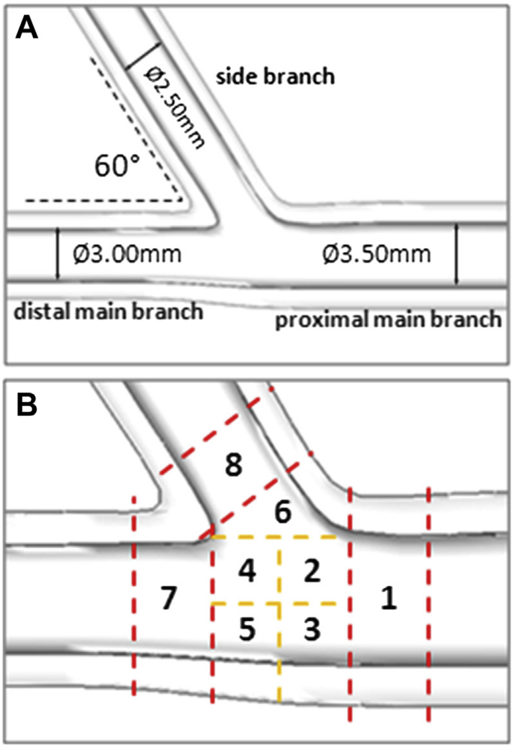
With the purpose of optimization of the pros and cons of conventional double-stent techniques, Kawasaki et al. (11) reported a modification of culotte technique that we propose to describe as the single string bifurcation stenting technique. The aim of the present study was the in vitro assessment of performance and feasibility of the single string technique by extensive technical and mechanical evaluation, using optical coherence tomography (OCT) and micro computed tomography (mCT). Additionally, we report here the experience in humans with a prospective pilot registry using the single string technique in 11 patients undergoing PCI for complex bifurcation stenosis involving a large SB.

METHODS

IN VITRO TESTING. Bifurcation models. The single string technique was first extensively tested in vitro. Tests were performed in uniform silicone phantoms, manufactured using a rapid prototyping technique. Technical parameters are shown in Figure 1A.

SINGLE STRING STENTING PROCEDURE. Single string stenting procedures were performed with uniform materials using a standardized technique and predefined steps. Biomatrix and Biomatrix Flex drug-eluting stents (Biosensors Interventional Technologies Ltd, Singapore) were 2.5 mm and 3.0 mm in size. Both types of stents use the same platform in both sizes. Stents have a 120-µm strut thickness and

FIGURE 1 Silicone Phantoms Used for In Vitro Testing



(A) For the in vitro experiments, silicone phantoms were used with uniformed geometrical parameters. **(B)** For optical coherence tomography analysis, the bifurcation was divided into 8 sectors: proximal main branch (**1**, every third frame along 1.6 mm), proximal bifurcation ostial half (**2**, frame by frame), proximal bifurcation abostial half (**3**, frame by frame), distal bifurcation ostial half (**4**, frame by frame), distal bifurcation abostial half (**5**, frame by frame), bifurcation side branch abostial half (**6**, frame by frame), distal main branch (**7**, every third frame along 2.4 mm), and side branch (**8**, every third frame along 1.6 mm).