The STENTYS Self-Apposing® stent

Stylianos A. Pyxaras*, MD, FESC; Thomas Schmitz, MD; Christoph K. Naber, MD, FESC

Contilia Heart and Vascular Center, Elisabeth-Krankenhaus Essen, Essen, Germany

The complete references and the accompanying supplementary data are published online at: http://www.pcronline.com/eurointervention/V_issue/34

Device description

Name and manufacturer: The STENTYS Self-Apposing® stent; Stentys S.A., Paris, France.

Approval status: CE mark in 2010 (for acute coronary syndrome treatment). Sirolimus-eluting version received CE mark in 2014.

Platform: Nitinol.

Strut thickness: 102 microns (0.0040"; small-sized STENTYS) or 133 microns (0.0052"; medium- and large-sized STENTYS).

Coating: Available in three versions: (i) not coated (bare metal stent); (ii) paclitaxel-coated; (iii) sirolimus-coated.

Specific stent design: The STENTYS Self-Apposing stent has a typical "Z-shaped" architecture, which includes disconnectable stent struts called "interconnectors". These latter allow stent disconnection at the level of the coronary bifurcation **(Figure 1, Moving image 1, Moving image 2)**.

Guiding: 6 Fr.

Classification according to MADS: "A" (main branch [MB] stenting across side branch [SB], allowing one-stent [MB stenting + SB balloon; MB stenting + kissing] or two-stent [elective T-stenting; internal crush; culotte; TAP] strategy).

Delivery system: A 6 Fr compatible, rapid exchange delivery system delivers the stent into position over a conventional 0.014" guidewire. The stent is deployed by the withdrawal of a retractable sheath using the delivery system trigger **(Online Figure 1)**.

Stent sizes: There are three different sizes commercially available: (i) small (2.5-3.0 mm); (ii) medium (3.0-3.5 mm); and (iii) large (3.5-4.5 mm).

Stent length: The stent is available in three different lengths: 17, 22 and 27 mm.

Procedural details

The procedure is performed by wiring both MB and SB with standard 0.014" guidewires. MB predilation is recommended. The STENTYS stent is positioned in the main branch across the bifurcation, by advancing the system distal to the desired position by at least 5 mm **(Online Figure 1A)**. Under fluoroscopy guidance, the dedicated trigger is retracted, allowing the withdrawal of the covering sheath **(Online Figure 1B)**. Post-dilatation of the STENTYS stent with an adequately sized balloon is highly recommended. Proximal optimisation or kissing-balloon techniques are not mandatory due to the self-apposing nature of the device. If access or treatment of the side branch is required, a balloon is advanced into the SB after wire re-crossing, and inflated at low pressure, to perform the strut disconnection by a stretch (flexion) and a twist (rotation) motion imparted by the balloon onto the interconnector **(Moving image 1)**. Side branch treatment, e.g., placement of an additional balloon-expandable stent, follows the usual indications and proceedings.

Clinical data

The first-in-man experience with the STENTYS Self-Apposing stent showed encouraging results in terms of procedural results and short- and medium-term efficacy and safety[1,2]. The STENTYS® Coronary Bifurcation Stent System fOr the PErcutaNeous

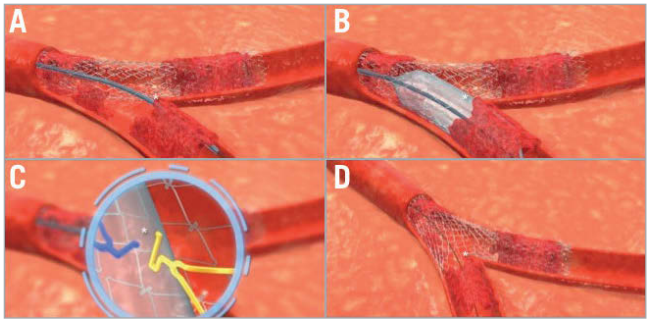


Figure 1. *Sequence of STENTYS strut disconnection in a bifurcation lesion. A) Rewiring of the SB. B) Gentle balloon inflation into the SB. C) Disconnection of the STENTYS interconnectors. D) Wide opening of the STENTYS stent towards the SB. SB: side branch*

**Corresponding author: Contilia Heart and Vascular Center, Elisabeth-Krankenhaus Essen, Klara-Kopp-Weg 1, 45138 Essen, Germany. E-mail: steliospyxaras@gmail.com*

© Europa Digital & Publishing 2015. All rights reserved.

DOI: 10.4244/EIJV11SVA34

treatment of *de novo* lesions in native bifurcated coronary arteries (OPEN I) study showed a six-month major adverse cardiovascular event (MACE) rate of 3.7% for the drug-eluting stent (DES) version of the stent, driven by target lesion revascularisation (TLR). MACE and TLR rates were significantly higher for the BMS version of the stent. Procedural success was 95.2%, while post-stenting disconnection was performed on 90% of the stents implanted. Angiographic follow-up performed in 95% of patients demonstrated late luminal loss of 0.42±0.45 mm and 0.16±0.45 mm in the target main vessel and side branch, respectively. Intravascular ultrasound (IVUS) assessment at six months showed an increase in the mean luminal area (mm^2) observed at baseline and at follow-up (DES: 7.39±1.99 vs. 8.58±2.48; $p>0.05$, and BMS: 7.94±1.39 vs. 8.91±2.54; $p>0.05$)[2]. The recently presented OPEN II observational study enrolled 207 patients and showed a 12-month MACE rate of 13%, mainly driven by TLR. The rate of strut disconnection was 56.0%, while FKBI was performed in only 21.7%. FKBI was not associated with statistically significant differences in MACE observed at six and 12-month follow-up[3].

The STENTYS Self-Apposing stent has also been successfully used in the setting of acute ST-elevation myocardial infarction (STEMI). The APPOSITION I study confirmed safety and feasibility of the STENTYS stent in STEMI patients with no cases of late stent malapposition at six-month follow-up[4]. The randomised APPOSITION II trial showed a lower rate of malapposed stent struts in the STENTYS group compared to the balloon-expandable group at three days after implantation (0.58% vs. 5.46%, $p<0.001$)[5]. The observational APPOSITION III registry data showed a 9.3% MACE rate in patients treated with STENTYS during primary percutaneous coronary intervention (PCI) for STEMI[6]. The randomised APPOSITION IV showed better four-month stent apposition using the sirolimus-eluting version of the STENTYS, as compared to zotarolimus-eluting balloon-expandable stents[7].

Ongoing studies

The APPOSITION V trial randomising STEMI patients to treatment with the bare metal version of STENTYS vs. the MULTI-LINK VISION™ stent system (Abbott Vascular, Santa Clara, CA, USA) was prematurely stopped due to slow enrolment[8,9]. A novel balloon delivery system (BDS) was recently developed for the sirolimus-eluting version of the STENTYS. It consists of inflating a balloon at low pressures to split the covering delivery sheath longitudinally, which releases the self-apposing STENTYS SES. The stent deploys and apposes to the vessel wall whereafter the "jailed" sheath is retracted. This system aims for easy delivery and a highly precise longitudinal placement of the STENTYS SES.

Unique features

The self-apposing nature of the device allows covering different anatomies of bifurcations without manual adaptation of the position, which is sometimes a limitation using other dedicated devices.

Self-apposition is also thought to be of benefit in cases where sizing of a stent is difficult (e.g., aneurysmatic coronary arteries or STEMI patients with heavy thrombotic load).

The "Z-shape" architecture with disruption of the interconnectors allows a facilitated SB access.

Potential improvements

The crossing profile (1.397 mm) is relatively high and can cause failure of the procedure. In general, the current device requires careful predilatation of the lesion to avoid difficulties during positioning. Likewise, the sheath retraction system used for positioning can result in geographical mismatch between the lesion and the positioned STENTYS. The next-generation balloon-expandable device is currently under development.

Acknowledgements

The authors are thankful to Mr David Bouchez and Mr Tom Coles for their help with the iconographic material and the Moving images.

Conflict of interest statement

C. Naber is principal investigator of the OPEN II trial. The other authors have no conflicts of interest to declare.

References

The references can be found in the online version of the paper.

Online data supplement

Online Figure 1. STENTYS Self-Apposing stent implantation under fluoroscopic guidance. A) The STENTYS stent is positioned in the main branch across the bifurcation, by advancing the system distal to the desired position by at least 5 mm. B) The dedicated trigger is retracted, allowing the withdrawal of the covering sheath.

Moving image 1. Graphic representation of the STENTYS Self-Apposing stent implantation.

Moving image 2. Micro-computed tomography of a STENTYS Self-Apposing stent with opening to the side branch.

Online data supplement

References

1. Verheye S, Grube E, Ramcharitar S, Schofer JJ, Witzenbichler B, Kovac J, Hauptmann KE, Agostoni P, Wiemer M, Lefèvre T, Serruys PW, van Geuns RJ. First-in-man (FIM) study of the Stentys bifurcation stent--30 days results. *EuroIntervention.* 2009;4: 566-71.

2. Verheye S, Ramcharitar S, Grube E, Schofer JJ, Witzenbichler B, Kovac J, Hauptmann KE, Agostoni P, Wiemer M, Lefèvre T, Spaargaren R, Serruys PW, Garcia-Garcia HM, van Geuns RJ. Six-month clinical and angiographic results of the STENTYS® self-apposing stent in bifurcation lesions. *EuroIntervention.* 2011;7: 580-7.

3. Naber CK. Self-expanding DES in coronary bifurcation lesions at 12-month follow-up: results from the OPEN II trial and comparison with the British bifurcation coronary trial. EuroPCR 2014, Paris. http://www.pcronline.com/Lectures/2014/Self-expanding-DES-in-coronary-bifurcation-lesions-at-12-month-follow-up-results-from-the-Open-II-trial-and-comparison-with-the-British-bifurcation-coronary-trial.

4. Amoroso G, van Geuns RJ, Spaulding C, Manzo-Silberman S, Hauptmann KE, Spaargaren R, Garcia-Garcia HM, Serruys PW, Verheye S. Assessment of the safety and performance of the STENTYS self-expanding coronary stent in acute myocardial infarction: results from the APPOSITION I study. *EuroIntervention.* 2011;7:428-36.

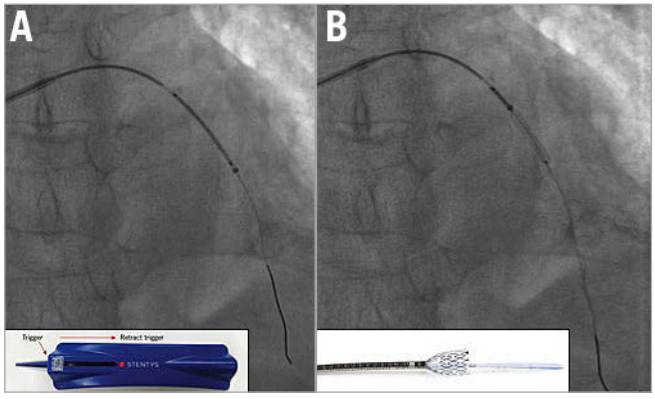
5. van Geuns RJ, Tamburino C, Fajadet J, Vrolix M, Witzenbichler B, Eeckhout E, Spaulding C, Reczuch K, La Manna A, Spaargaren R, Garcia-Garcia HM, Regar E, Capodanno D, Van Langenhove G, Verheye S. Self-expanding versus balloon-expandable stents in acute myocardial infarction: results from the APPOSITION II study: self-expanding stents in ST-segment elevation myocardial infarction. *JACC Cardiovasc Interv.* 2012;5:1209-19.

6. Koch KT, Grundeken MJ, Vos NS, IJsselmuiden A, van Geuns R, Wessely R, Dengler D, Manna A, Silvain J, Montalescot G, Spaargaren R, Tijssen JG, Amoroso G. One-year clinical outcomes of the STENTYS Self-Apposing® coronary stent in patients presenting with ST-segment elevation myocardial infarction: results from the APPOSITION III registry. *EuroIntervention.* 2015 Feb 19. [Epub ahead of print].

7. van Geuns RJ. Randomised comparison between a self-apposing sirolimus-eluting coronary stent and a balloon-expandable stent in acute myocardial infarction. EuroPCR 2014, Paris. http://www.pcronline.com/Lectures/2014/Randomised-comparison-between-a-self-apposing-sirolimus-eluting-coronary-stent-and-a-balloon-expandable-stent-in-acute-myocardial-infarction.

8. Grundeken MJ, Lu H, Mehran R, Cutlip DE, Leon MB, Yeung A, Koch KT, Montalescot G, van Geuns RJ, Spaargaren R, Buchbinder M. APPOSITION V: STENTYS coronary stent system clinical trial in subjects with ST-segment elevation myocardial infarction--rationale and design. *Am Heart J.* 2014;168:652-60.

9. http://www.stentys.com/file_bdd/documents/1406788318_2014_07_31_STENTYS_reallocates_Resources_on_DES.pdf



Online Figure 1. *STENTYS Self-Apposing stent implantation under fluoroscopic guidance. A) The STENTYS stent is positioned in the main branch across the bifurcation, by advancing the system distal to the desired position by at least 5 mm. B) The dedicated trigger is retracted, allowing the withdrawal of the covering sheath.*