Kardiologia Polska 2018; 76, 2: 464–470; DOI: 10.5603/KP.a2017.0226

ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

First-in-man study of dedicated bifurcation cobalt-chromium sirolimus-eluting stent BiOSS LIM C® — three-month results

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Abstract

Background: The optimal approach to coronary bifurcation treatment by percutaneous coronary intervention (PCI) is still a subject of debate, and dedicated bifurcation stents are one of the proposed solutions.

Aim: The aim of this report was to assess the effectiveness and safety profile of a new dedicated bifurcation stent — sirolimus-eluting BiOSS LIM C® (Balton, Poland) at the first three months of a 12-month registry.

Methods: This is a two-centre registry, which enrolled patients with non-ST elevation acute coronary syndrome (NSTE-ACS) and stable angina. Provisional T-stenting is the obligatory strategy of the treatment. Angiographic control is planned at 12 months. The primary endpoint is the cumulative rate of cardiac death, myocardial infarction (MI), and target lesion revascularisation (TLR) at 12 months.

Results: A total of 48 patients with lesions in coronary bifurcations were enrolled (mean age 67.9 ± 8.9 years, 14.6% female). There were 20.8% of patients with NSTE-ACS, 93.8% with hypertension, 35.4% with diabetes, 52.1% had previous MI, and 47.9% and 14.6% underwent prior PCI and coronary artery bypass grafting, respectively. The device success rate was 100%. The side branch was treated with an additional classical drug-eluting stent implantation in 18.8% of cases. The periprocedural MI (MI type 4a) was observed in two (4.2%) cases. At three months there was one (2.1%) case of TLR. No death, MI, or stent thrombosis were observed in the follow-up period.

Conclusions: Bifurcation treatment with a single dedicated bifurcation stent (BiOSS LIM C®) is feasible and highly successful (100% implantation success rate). The short-term clinical outcomes are very promising, also in distal left main stenosis. The 12-month observations are pending.

Key words: dedicated bifurcation stent, sirolimus-eluting stent, BiOSS LIM C®

Kardiol Pol 2018; 76, 2: 464–470

INTRODUCTION

Coronary bifurcation lesions pose a therapeutic challenge and are linked to higher rates of periprocedural complications as well as higher rates of in-stent restenosis and stent thrombosis [1]. Presently, provisional T-stenting is regarded as the best approach [2, 3]. However, the optimal strategy of coronary bifurcation treatment is still a subject of debate, especially when the side branch is large, not easily accessible, or narrowed by a long lesion [4, 5]. As a result, many dedicated bifurcation stents have been designed. These can be broadly divided into four categories: dedicated main vessel (MV) devices (e.g. Axxess), dedicated MV with side branch (SB) access port (e.g. Xience SBA, Nile Croco), dedicated SB devices (Sideguard, Tryton), and dedicated MV plus SB devices (Medtronic Bifurcation Y-Stent). However, most of these stents do not match optimally MV–main branch (MB) size difference nor take into account vessel angulations [6, 7].

The BiOSS® stent (Balton, Warsaw, Poland) is completely different from the abovementioned systems [8]. The BiOSS® (Bifurcation Optimisation Stent System) Clinical Programme

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Received: 22.08.2017 **Accepted:** 05.10.2017 **Available as AoP:** 24.11.2017

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started in 2008. The first BiOSS® stent was a bare metal one (stainless steel), but shortly after, a paclitaxel-eluting version was introduced into the market — the BiOSS Expert® stent (CE Mark 2010), and in 2012 the sirolimus-eluting BiOSS LIM® stent was developed. The obtained results in registries and clinical trials [8–13] as well as in everyday practice were satisfactory [14–16], but still a means of improvement has been sought. Therefore, a cobalt-chromium sirolimus-eluting version has been developed, i.e. BiOSS LIM C® stent.

The aim of this study was to analyse initial three-month results of the first-in-man BiOSS LIM C® registry.

METHODS

Study population

To evaluate the safety and feasibility of the sirolimus-eluting BiOSS LIM C® stent, patients with stable coronary artery disease or non-ST-elevation acute coronary syndrome (NSTE-ACS) were enrolled into this multicentre registry between August 2016 and June 2017 (consecutive patients meeting exclusion and inclusion criteria). Implantations were performed in two centres in Poland (Warsaw, Olsztyn) by operators with previous experience in BiOSS stent deployment. The main exclusion criteria were ST-elevation acute coronary syndrome (STE-ACS), bifurcations with Medina 0.0.1, serum creatinine level ≥ 2.0 mg/dL, inability to take dual antiplatelet therapy for 12 months, bifurcations a priori qualified to the treatment with a two-stent technique, and lack of informed consent. Written, informed consent was obtained from all patients before cardiac catheterisation. An Institutional Review Board approved the study protocol (No. 84/2016).

Device description

The BiOSS LIM C® is a dedicated bifurcation balloon expandable stent made of cobalt-chromium (strut thickness 70 μm). The stent releases sirolimus (1.4 μg/mm^2) from the surface of a biodegradable coating comprised of a copolymer of lactic and glycolic acids (Fig. 1) [17]. The degradation of the polymer lasts approximately eight weeks [18]. The BiOSS LIM C® stent consists of two main separate parts with different diameters: wider proximally, and distally smaller. The proximal part is always shorter than the distal one (avg. 1 mm). The ratio of the proximal part to the distal one varies between 1.15 and 1.3, ensuring physiological compatibility and optimal flow conditions. In the middle zone both parts are connected by two struts (2.0–2.4 mm in length after the BiOSS® stent implantation).

The stent is crimped on a tapered balloon (Bottle®, Balton, Warsaw, PL). Bottle® balloons are available in a wide range of sizes and lengths allowing the left main (LM) treatment as well. The balloon nominal pressure is 10 atm, whereas the rated burst pressure is 18 atm. The balloon is semi-complaint with an increase in a diameter size of 0.25 mm at 12 atm, both proximally and distally.

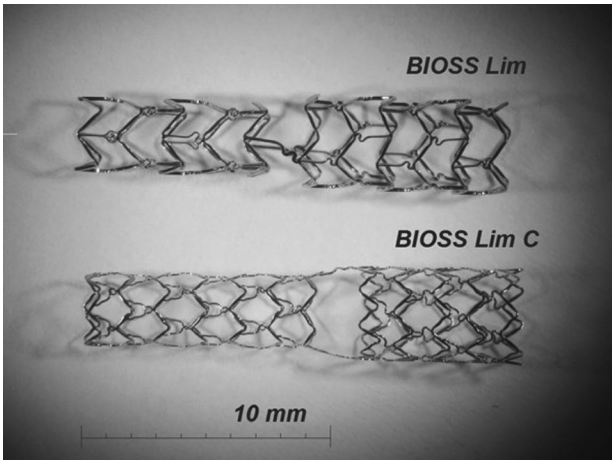

Figure 1. Structure comparison of BIOSS LIM® and BIOSS LIM C® stents

The BiOSS LIM C® stent has a rapid exchange delivery system, which is compatible with 0.014″ guide wires and with 5 Fr (1.63 mm internal diameter) guiding catheters. The BiOSS LIM C® stent is introduced over a single guide wire, which (in contrast to some other dedicated systems guided on two guide wires) eliminates the risk of wire wrap (twisting) or other complications with double guide wire driven systems.

Interventional procedure and concomitant medications

Single stent implantation in the MV–MB across a side branch was the default strategy (provisional T-stenting) in all patients enrolled into our Registry (Fig. 2). Bifurcation lesions were assessed according to the Medina classification using an index of 1 for stenosis greater than 50% and 0 for no stenosis (visual estimation) [19]. There was no restriction regarding the lesion length in patient selection. If required, an additional regular sirolimus-eluting stent was implanted. A stent in a side branch was implanted only if proximal residual stenosis was greater than 70% after balloon dilatation and/or significant flow impairment after MV–MB stenting and/or a flow limiting dissection was present.

The implantation protocol for the bifurcation treatment was based on the recent European Bifurcation Club guidelines as follows [7]:

- wiring of both branches;
- MV predilatation and/or SB predilatation according to the operator's decision;
- stent implantation (inflation for at least 20 s);
- proximal optimisation technique (highly recommended, but at the operator's discretion);
- SB postdilatation/SB stent implantation if necessary;
- final kissing balloon inflation (at the operator's discretion).

In patients with acute coronary syndrome a loading dose of P2Y12 inhibitor was given (clopidogrel 600 mg or ticagrelor

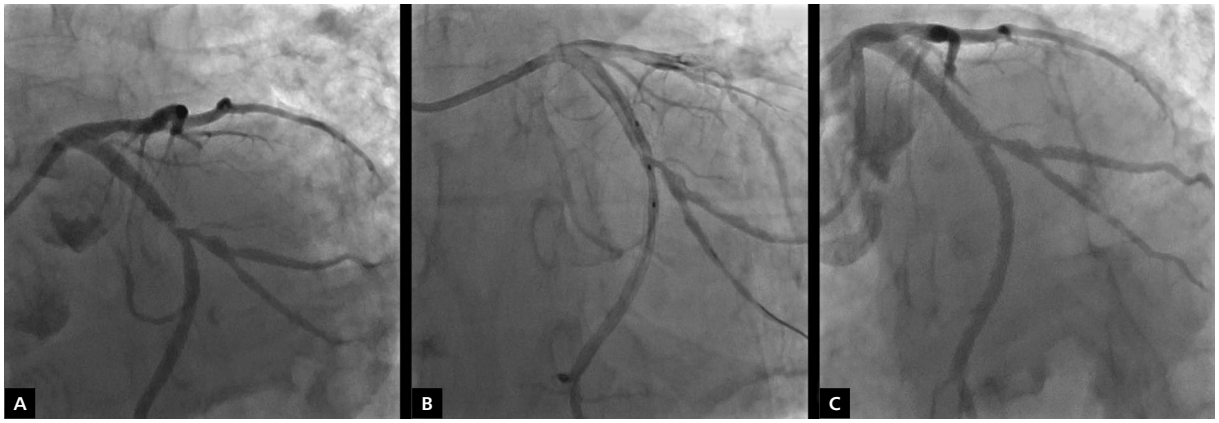

Figure 2. BIOSS LIM C® implantation in the left circumflex artery; **A.** Initial view; **B.** Stent positioning; **C.** Final results

180 mg), and if needed also a loading dose of acetylsalicylic acid (ASA) was administered (300 mg). In planned procedures 72 h before percutaneous coronary intervention each patient received ASA (75 mg/24 h) and clopidogrel (75 mg/24 h) or ticagrelor (90 mg b.i.d). All procedures were performed in a standard way via radial or femoral access using 6 Fr or 7 Fr guiding catheters. After insertion of the arterial sheath each patient received unfractionated heparin (100 IU/kg). Dual antiplatelet therapy was prescribed for 12 months.

All patients had troponin I, creatinine kinase (CK), and CK-MB levels examined before the procedure, and 6 h and 24 h after. Periprocedural myocardial infarction (MI) (type 4a) was assessed according to the third universal definition [20].

Endpoints

The primary endpoint was the cumulative rate of major adverse cardiovascular events (MACE) consisting of cardiac death, MI with or without ST-segment elevation, and target-lesion revascularisation (TLR) within 12 months of the index procedure. The secondary endpoints included rates of death, MI, TLR, target vessel revascularisation (TVR), stent thrombosis (ST), and device, angiographic, and procedure success. Clinically driven TLR was defined as reintervention of the target lesion due to the presence of a symptomatic ≥ 70% diameter stenosis within 12 months of the procedure. Angiographically driven TLR was defined as reintervention due to angiographic detection of significant restenosis (≥ 70%) in a patient who is clinically asymptomatic. TVR was defined as revascularisation of any segment of the index coronary artery. MI was defined according to the third universal definition [20]. All deaths were deemed cardiac unless proven otherwise. Stent thrombosis was defined according to the Academic Research Consortium (ARC) as definitive, probable, or possible.

Device success was defined as successful deployment of the intended stent in site without system failure (i.e. stent slipping from the balloon catheter, fracture of the balloon catheter shaft). Angiographic success was assessed as end-procedural MB diameter stenosis less than 20% and SB ostial stenosis less than 70% without significant dissection and flow impairment. Procedure success included angiographic success in the absence of in-hospital MACE.

Statistical analysis

Continuous variables were presented as mean ± standard deviation. Categorical data were presented as numbers (%). Statistical analyses were performed using SPSS13.0 for Windows (SPSS Inc., Chicago, USA).

RESULTS

A total of 48 patients were enrolled. The mean age was 67.9 ± 8.9 years, and women accounted for 14.6.3% of the study population. Patients represented a diseased population, with hypertension (93.8%) and dyslipidaemia (85.4%) as the most common risk factors (Table 1). In most patients, the target lesion was located in the LM (52.1%), and true bifurcations were present in 50% (Table 2).

The main procedural aspects are presented in Table 3. The device and angiographic success rates were 100%, whereas the procedure success rate was 95.8%. The MB was predilated in most cases (87.5%). The rate of proximal optimisation technique was 54.2%, whereas the final kissing balloon inflation was performed in 12 (25%) patients, reflecting a good outcome in the SB after stenting. However, the SB required additional balloon dilatation in almost half of the lesions (41.7%), and in nine (18.8%) cases a second stent (classical drug-eluting stent [DES]) was deployed.

Three-month follow-up was available in all patients (Table 4). Periprocedural MI (type 4a) was observed in two (4.2%) patients and was associated with transient SB occlusion. In the first case, true bifurcation was treated (1.1.1) with severe ostial/proximal lesion in the SB. And despite prior SB predilatation, after stent implantation transient SB occlusion

Table 1. Baseline clinical characteristics

Parameter	N = 48
Age [years]	67.9 ± 8.9
Women	7 (14.6%)
Arterial hypertension	45 (93.8%)
Hypercholesterolaemia	41 (85.4%)
Diabetes type 2	17 (35.4%)
Prior MI	25 (52.1%)
Prior PCI	23 (47.9%)
CABG	7 (14.6%)
Peripheral artery disease	2 (4.2%)
Chronic kidney disease	10 (20.8%)
History of smoking	6 (12.5%)
Clinical indication for PCI:	
Planned PCI	38 (79.2%)
UA	6 (12.5%)
NSTEMI	4 (8.3%)

Data are presented as mean ± standard deviation or number (percentage). CABG — coronary artery bypass graft; MI — myocardial infarction; NSTEMI — non-ST elevation myocardial infarction; PCI — percutaneous coronary intervention; UA — unstable angina

Table 2. Baseline angiographic characteristics

Parameter	N = 48
Lesion location:	
LM	25 (52.1%)
LAD	13 (27.1%)
LCx	7 (14.6%)
RCA	3 (6.3%)
Medina classification:	
1.1.1.	11 (22.9%)
1.0.1.	4 (8.3%)
0.1.1.	9 (18.8%)
1.0.0.	7 (14.6%)
0.1.0.	5 (10.4%)
1.1.0.	12 (25%)

Data are presented as number (percentage). LM — left main; LAD — left anterior descending artery; LCx — left circumflex artery; RCA — right coronary artery

Table 3. Procedural characteristics

Parameter	N = 48
Main vessel predilatation	42 (87.5%)
Side branch predilatation	18 (37.5%)
Both branches predilatation	12 (25%)
Nominal stent diameter in main vessel [mm]	3.82 ± 0.42
Nominal stent diameter in main branch [mm]	3.11 ± 0.40
Nominal stent length [mm]	19.29 ± 3.43
Side branch postdilatation	20 (41.7%)
Proximal optimisation technique	26 (54.2%)
Final kissing balloon	12 (25%)
Additional stent in side branch	9 (18.8%)
Dissection requiring an additional stent in main vessel — main branch	2 (4.2%)
Fluoroscopy time [min]	18.9 ± 12.5
Contrast volume [mL]	203.3 ± 70.3
Vascular access: femoral/radial [%]	8.3%/91.7%
Guiding catheter: 6 F/7 F [%]	93.8%/6.3%

Data are presented as mean ± standard deviation or number (percentage)

was observed. In the second case (also true bifurcation 1.1.1) the BiOSS LIM C® stent was implanted too proximally and there was a significant plaque and carina shift, which caused SB occlusion. In the three-month follow-up the rate of MACE was 6.3% (n = 3). It was caused by two cases of periprocedural MI and by one case of TLR (2.5 months) successfully treated with regular DES. The focal restenosis was located in the distal part of the stent (in the MB). There were no deaths, MI, or stent thromboses in the follow-up period.

DISCUSSION

The BiOSS LIM C® stent is a dedicated bifurcation stent for treating the MV and ensuring SB access (type A stent) [21]. The immediate and short-term outcomes of BiOSS LIM C® implementation are encouraging. The device was successfully implanted in 100% of cases without significant difficulties, even in cases with direct stenting. Two cases of transient SB occlusion were registered [22].

BiOSS LIM C® is the next version of BiOSS® stent. The previous ones (BiOSS Expert® and BiOSS LIM®) were made of stainless steel (the same design), and the first one eluted paclitaxel, whereas the second one — sirolimus. The immediate and short-term outcomes for the three stents were comparable, with a numerically higher rate of periprocedural MI in the case of the BiOSS Expert® [8, 23]. However, there is one huge difference between the newest stent and previous BIOSS versions, namely the smaller strut thickness in the BiOSS LIM C® (70 μm vs. 140 μm), and this fact gives hope for better results.

As mentioned above, the BiOSS Expert® and BiOSS LIM C® stents are made of stainless steel and therefore they have relatively thick struts (in total ~140 μm). This might predispose to excessive neointimal proliferation. In accordance with results of the "ISAR Stereo" study, stents with thinner struts may provoke less arterial wall injury and consequently may yield lower restenosis rates. Also, thinner struts may facilitate endotheli-

Table 4. Three-month follow-up

	BiOSS LIM C® Registry (n = 48)	BiOSS LIM® Registry (n = 60)	BiOSS Expert® Registry (n = 63)
MACE	3 (6.3%)	0 (0%)	6 (9.5%)
Death	0 (0%)	0 (0%)	0 (0%)
Cardiac death	0 (0%)	0 (0%)	0 (0%)
Periprocedural MI (type 4a)	2 (4.2%)	0 (0%)	6 (9.5%)
MI	0 (0%)	0 (0%)	0 (0%)
Target lesion revascularisation	1 (2.1%)	0 (0%)	0 (0%)
Stent thrombosis	0 (0%)	0 (0%)	0 (0%)

Data are presented as number (percentage). MACE — major adverse cardiovascular event; MI — myocardial infarction

alisation [24, 25]. In other words, the cobalt-chromium alloy enables stent construction with thinner struts, lower profile, and higher radial strength, with preserved maximal elasticity.

In the BiOSS Expert® paclitaxel was used at a concentration of 1 $\mu g/mm^2$. In the next version of the stent BiOSS LIM® sirolimus was applied because it was shown that sirolimus decreased the rates of MACE and TLR [26]. Initially, the sirolimus in the BiOSS LIM® stent was used at a concentration of 1.0 $\mu g/mm^2$, but later it was increased to the final concentration of 1.4 $\mu g/mm^2$. Also, a similar concentration of sirolimus in BiOSS LIM C® (1.4 $\mu g/mm^2$) was used; it was comparable with Cypher® stent (1.4 $\mu g/mm^2$) as well as with most DES currently available on the market (Alex® stent: 1.4 $\mu g/mm^2$, Orsiro®: 1.4 $\mu g/ mm^2$, Excel® stent: 1.4 $\mu g/mm^2$, or Nevo® stent: 1.25 $\mu g/mm^2$ [27]). In the BiOSS® stent biodegradable polymer is applied, so the crucial matter is its stability and time of degradation. However, in other reports it was shown that the type of the polymer (biodegradable vs. durable) did not play a significant role in coronary bifurcation treatment [28].

The result found in the porcine model with a BiOSS LIM C® stent seemed to confirm our hope [29]. A total of seven BiOSS LIM C® stents were implanted in normal non-atherosclerotic straight porcine coronary arteries using a 1.2 stent-to-artery ratio. In quantitative coronary angiography (QCA) at 28 days the late lumen loss was 0.25 ± 0.18 mm. In optical coherence tomography (OCT) analysis the mean neointimal thickness was 0.36 ± 0.086 mm and 92% ± 15% of struts were embedded. Histomorphometry showed that the area stenosis at 28 days was 16 ± 6.5% and mean intimal thickness was 0.11 ± 0.03 mm. The injury and inflammation scores (0.33) were also low. The obtained values were significantly lower when compared with the BiOSS LIM® stent. In the same study the new generation DES Orsiro® stent (Biotronik) was also evaluated. No statistically significant differences were noted in the abovementioned parameters between the BiOSS LIM C® and Orsiro® stents, i.e. the Orsiro

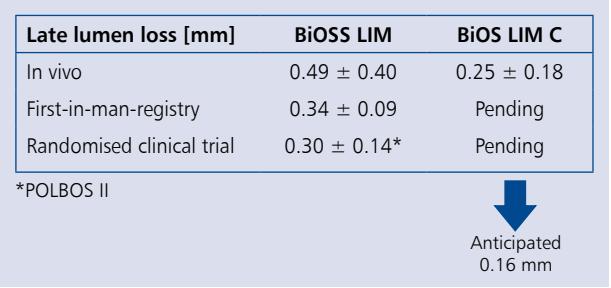

Figure 3. BiOSS LIM C® late lumen loss anticipation

late lumen loss was 0.31 ± 0.10 mm (p = 0.47), Orsiro OCT mean neointimal thickness was 0.27 ± 0.051 mm (p = 0.17), percentage of embedded struts was 93 ± 7.7% (p = 0.54), in histomorphometry the Orsiro area stenosis was 15.2 ± 2.6% (p = 0.68), and the inflammation score was 0.39.

Presently, the BiOSS LIM C® first-in-man registry is ongoing. Based on the results of *in vivo* studies, one might speculate the late lumen loss in clinical trials. This is very encouraging because based on these calculations late lumen loss of 0.16 mm is to be expected [17], which is significantly lower compared to previous types of BiOSS stent (Fig. 3). Therefore, the expectation of better long-term clinical results is rational.

When analysing the results a high rate of predilatation can be observed (87.5%). This can be caused by a moderately high rate of true bifurcation (50%). Also, the relatively low rate of cases with proximal optimisation technique (POT) might be a little bit surprising. However, one should remember about the POT-like effect associated with the stent structure. When sizing the BiOSS stent (visual or on-line QCA) the operator commonly overestimates the MW diameter and therefore is convinced that a POT-like effect has been obtained. In our registry the balloon: artery ratio was 1.09 for cases without POT and 1.14 for cases with POT (p = 0.065).

Limitations of the study

This study also has some limitations. The number of treated patients was small. Bifurcations lesions *a priori* qualified to the treatment with a two-stent technique were excluded. Also, no uniform implant technique was used; however, procedures were performed by operators experienced in BiOSS stent implantation. Additionally, no control group was introduced to compare the use of this dedicated bifurcation stent and stenting with other devices and techniques.

CONCLUSIONS

Bifurcation treatment with a single dedicated bifurcation stent (BiOSS LIM C®) is feasible and highly successful (100% implantation rate). The short-term clinical outcomes are very promising, also in distal LM stenosis, and long-term observations are pending.

Conflict of interest: *Robert J. Gil — Balton consultant*

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Cite this article as: Gil RJ, Bil J, Kern A, et al. First-in-man study of dedicated bifurcation cobalt-chromium sirolimus-eluting stent BiOSS LIM C® — three-month results. Kardiol Pol. 2018; 76(2): 464–470, doi: 10.5603/KP.a2017.0226.