

# 6-year results of BiOSS stents in coronary bifurcation treatment.

Robert J. Gil, Adam Kern, Radoslaw Formuszewicz, Luis A. Iñigo Garcia, Slawomir Dobrzycki, Dobrin Vassilev, Jacek Bil

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## Background

The wide variation in bifurcation anatomy has generated an ongoing search for **stents explicitly designed for coronary bifurcations**, and to date, results have been underachieved.

## Methods

The POLBOS I and POLBOS II were international, multicentre, randomized, open-label, controlled trials. Patients were randomly assigned to BiOSS Expert (in POLBOS I, biodegradable polymer eluting paclitaxel)/BiOSS LIM (in POLBOS II, biodegradable polymer eluting sirolimus) stent implantation or regular drug-eluting stent (rDES) deployment. A provisional T-stenting strategy was the default treatment option. The primary endpoint of this pooled data study was the cumulative rate of major adverse cardiovascular events (MACE) consisting of cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR). Telephone follow-up was performed annually up to 72 months. (ClinicalTrials.gov Identifier: POLBOS I—NCT02192840, POLBOS II—NCT02198300).

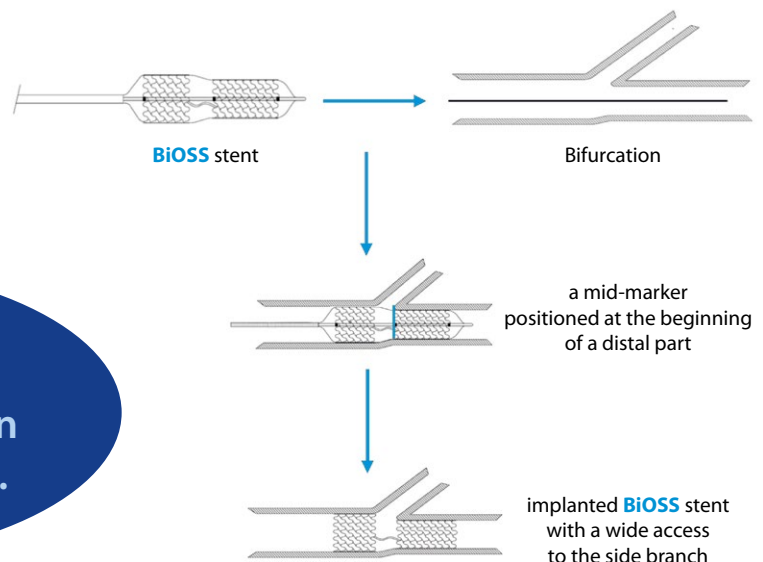
## Results

The total study population consisted of 445 patients, 222 patients in the BiOSS group and 223 patients in the rDES group. The follow-up rate was 93.7% in the BiOSS group and 91.9% in the rDES group. At 72 months, there was no significant difference between BiOSS and rDES groups regarding MACE (25.7% vs 25.1%, HR 1.06, 95% CI 0.73-1.52), cardiac death (3.1% vs 4.0%, HR 0.94, 95% CI 0.43-2.34), MI (3.6% vs 4.9%, HR 0.76, 95% CI 0.32-2.89), TLR (18.9% vs 16.1%, HR 1.17, 95% CI 0.75-1.83) and stent thrombosis rates (0.9% vs 0.5%, HR 1.21, 95CI 0.75-2.09).

## Conclusions

At the 6-year follow-up, clinically significant clinical events **did not differ between BiOSS stents and rDES**.

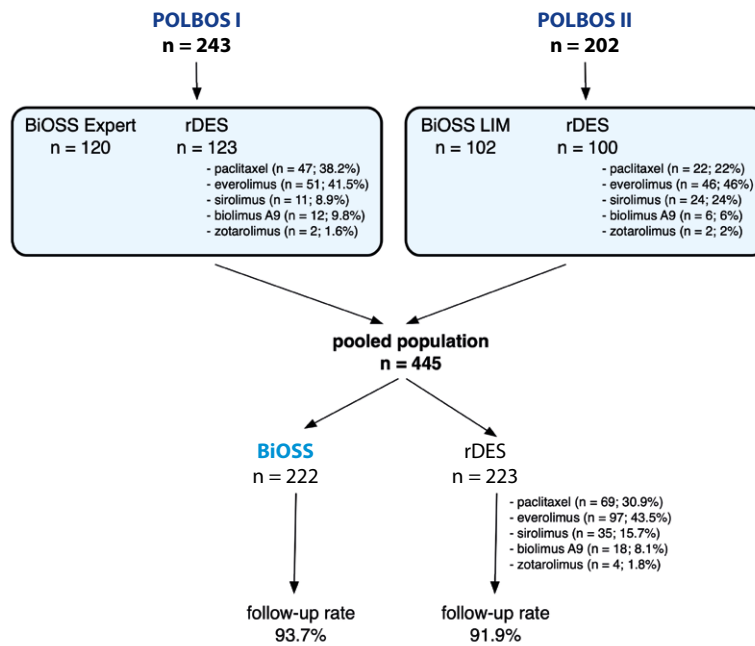
**Optimal choice for patients with the distal left main stenosis and diabetes.**



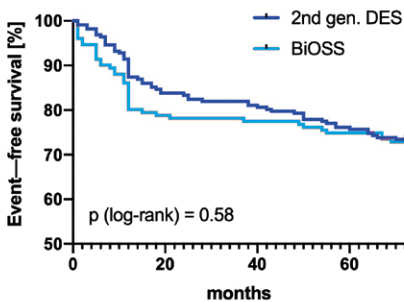
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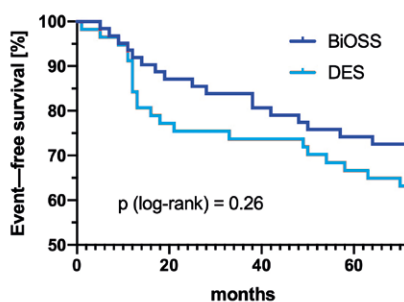
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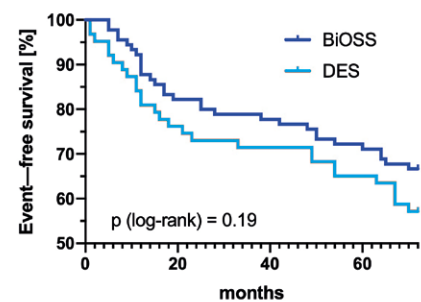
MACE-free survival at 72 months



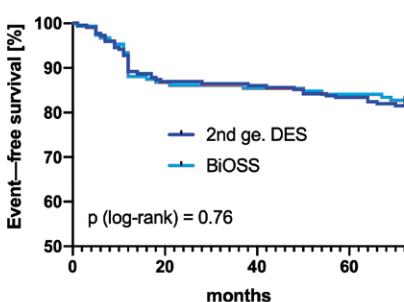
MACE at 72 months: LM subgroup



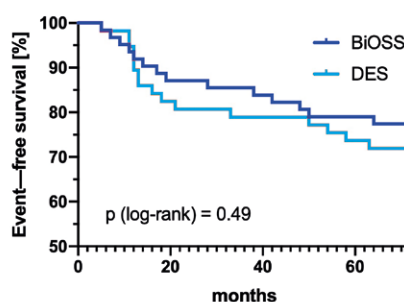
MACE at 72 months: DM subgroup



TLR-free survival at 72 months



TLR at 72 months: LM subgroup



TLR at 72 months: DM subgroup

