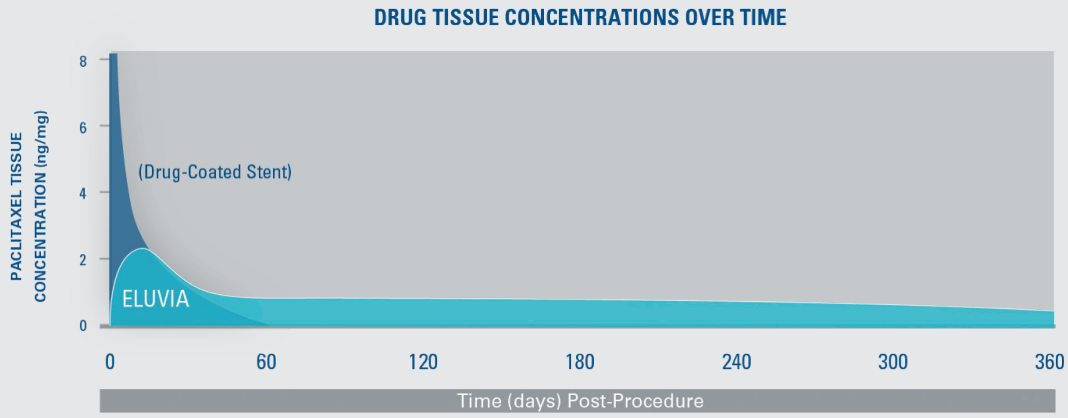
ADVERTORIAL

New data from the IMPERIAL trial reveal Eluvia is more effective in diabetic patients

Patients treated with the ELUVIA drug-eluting vascular stent system (Boston Scientific) demonstrated statistically significant lower rates of target lesion revascularisation (TLR) and stent thrombosis when compared to those treated with the Zilver PTX drug-eluting peripheral stent (Cook Medical), the most recent results of a diabetic subanalysis from the IMPERIAL trial reveal. These conclusions were presented during a first data release session at the Leipzig Interventional Course (LINC; 22–25 January, Leipzig, Germany).

THE IMPERIAL TRIAL is a global, multicentre, randomised controlled trial that included 465 patients with superficial femoral artery (SFA) and proximal popliteal artery (PPA) lesions up to 140mm in length. It is the first head-to-head drug-eluting stent trial in the SFA evaluating both the Eluvia and Zilver PTX stent systems in patients with symptomatic peripheral arterial disease (PAD). Over 400 million people worldwide suffer from diabetes, which raises their risk of heart attacks, stroke and PAD.

Explaining the specific difficulties of treating diabetic patients, coprincipal investigator of the IMPERIAL trial, Stefan Müller-Hülsbeck, (Vascular Center Diako Flensburg; Head of the Department of Diagnostic and Interventional Radiology/Neuroradiology, Academic Hospitals Flensburg, Germany) comments: "Patients with diabetes have an accelerated time course in developing PAD and the lesion characteristics are often challenging. They do particularly poorly if treated with bare technologies (plain transluminal angioplasty or bare metal stent) with a high rate of reintervention."



Subgroup analysis for diabetic patients with PAD

In this IMPERIAL subgroup analysis, diabetic patients in the Eluvia arm of the study experienced more than 70% reduction in TLR (3.7% for Eluvia compared to 13.6% for Zilver PTX), as well as achieved a nine-fold, statistically significant lower rate of stent thrombosis (0.9% for ELUVIA vs. 8.1% for Zilver PTX) at 12 months. All told, 95.4% of patients treated with Eluvia were major adverse event (MAE)-free at one year, compared to 86.4% MAE-free in the Zilver PTX cohort. Those treated with the Eluvia stent also experienced a primary patency rate of 87.4% versus 80.2% for those who received Zilver PTX.

That the Eluvia stent performed so well in diabetic patients is "remarkable", and "provides confidence" to clinicians when making treatment decisions, Müller-Hülsbeck says. He elaborates: "Diabetic patients are the most challenging patient group to treat medically and have multiple comorbidities. Their presenting lesion morphology is likely to be more complex and challenging to treat. The results for both safety and efficacy of the Eluvia drug-eluting stent provide confidence that this is an effective primary interventional treatment option for these patients.

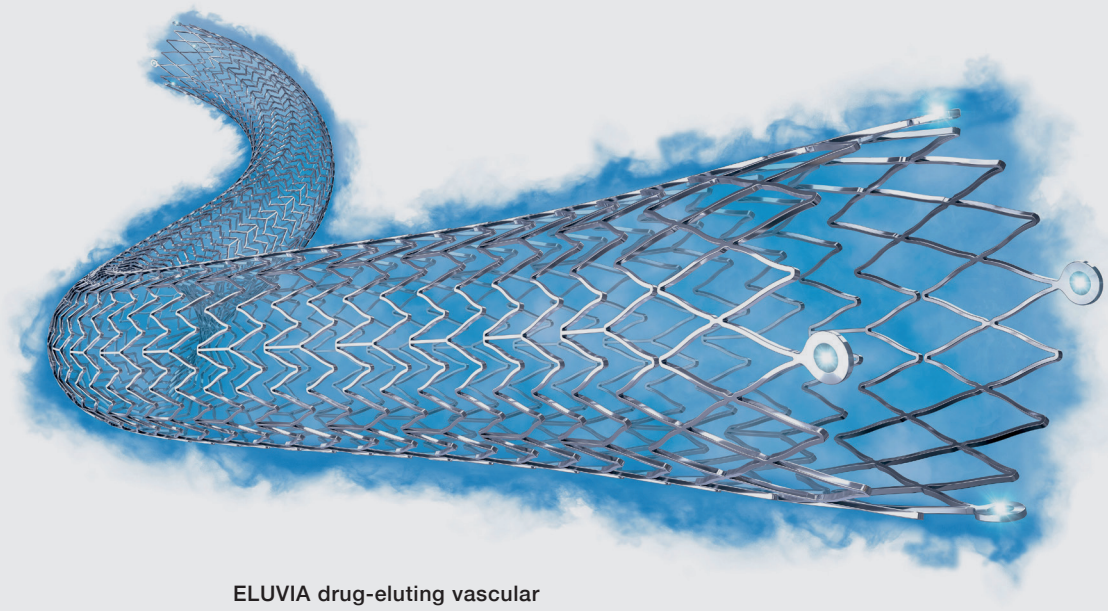
"It is remarkable that the Eluvia drug-eluting stent was able to demonstrate clear advantages over an active drug-coated device. The differentiated polymer-mediated drug release profile must be the responsible factor."

Speaking to *Interventional News*, Müller-Hülsbeck expands on this clinical success: "This study compared two paclitaxel-containing devices, the Zilver PTX drug-coated stent and the low dose Eluvia drug-eluting stent. Diabetic patients treated with Eluvia had an excellent primary patency rate at one year, and there was a statistically significant and clinically relevant reduction in both target lesion revascularisation and stent thrombosis.

"These strong clinical outcomes reinforce what has been demonstrated in the IMPERIAL randomised controlled trial and long-lesion study, in that the Eluvia stent is a viable and effective treatment option for patients who present with some of the most challenging lesion and disease state characteristics."

In historical peripheral vascular disease trials, when patient and lesion complexity increased, efficacy results have decreased. With these latest results from the IMPERIAL trial, ELUVIA continues to demonstrate remarkable, consistent results regardless of patient or lesion complexity.

The Eluvia stent system received FDA approval in September of 2018 and CE mark in February of 2016.



ELUVIA drug-eluting vascular stent system (Boston Scientific)

"Diabetic patients are the most challenging to treat medically and have multiple co-morbidities. Their presenting lesion morphology is likely to be more complex and challenging to treat. The results for both safety and efficacy of the Eluvia drug-eluting stent provide confidence that this is an effective primary interventional treatment option for these patients."

CORP – 609904 – AA Feb 2019