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With BMS-type safety . . .

New polymer-free DES, with 60% less drug, effective in patients

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MIV Therapeutics (MIVT; Atlanta) reported promising results from a trial of its polymer-free VESTAync drug-eluting stent (DES) at this year's **American College of Cardiology** (Washing-

ton) annual meeting in Chicago, saying that it has the potential to deliver DES-type efficacy with bare

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metal stent (BMS) safety, and short-term anticoagulant therapy.

The data also suggest that the stent may allow for the delivery of 60% less drug than most DES devices.

"It has been well-documented by experts in the field that polymers cause some form of delay in healing," Mark Landy, MD, president/CEO of MIVT told *Medical Device Daily*. "When you put a bare metal stent in an artery, it heals naturally and quickly. The stent becomes cocooned in a nice layer of tissue.

"Polymers by themselves are relatively inflammatory . . . so you have to treat the inflammation and you can cause more harm than good with respect to healing," he told *MDD*. "You maintain a nice lumen with the drug eluting stents, but the opportunity to thrombose because it's not really healed is there. That's what led us to look at polymer-free systems."

Jose Costa, MD, of **Institute Dante Pazzanese of Cardiology** (Sao Paulo, Brazil) discussed the data at the ACC meeting in a presentation titled, "Preliminary Results of the Hydroxyapatite Non-Polymer-Based Sirolimus-Eluting Stent for the Treatment of Single *de novo* Coronary Lesions: A First-in-Human Analysis of a Third-Generation Drug-Eluting Stent System." Researchers concluded that the polymer-free, nanoscale microporous hydroxyapatite stent demonstrates excellent efficacy and safety.

Costa presented nine-month follow-up intravascular ultrasound (IVUS) data for 11 patients who demonstrated a volumetric obstruction of 3.8% (+/- 2.3%) vs. 2.8% (+/- 2.2%) at four months.

This was a first-in-man trial of MIV's VESTA^{sync} drug-eluting stent.

Quantitative coronary angiography (QCA) of 12 patients at nine months found a late-lumen loss of 0.37 mm (+/- 0.24) vs. 0.31mm (+/- 0.26) at four months.

The study concluded that there was no significant difference between the four- and nine-month results, and that the observed degradation was uniform across all patients, with no outliers. No late-acquired incomplete stent apposition, stent thrombosis or major adverse coronary events were reported.

The nanoscale microporous hydroxyapatite stent has a coating that is 600 nm thick or 0.6 micron, and the pore sizes into which the drugs are loaded vary between nanoscale and micron-scale size. "We are orders of magnitude thinner than other stents," Landy said. "And it provides more flexibility and better healing."

Landy said he is "fairly sure" that there are no CE-mark-approved, polymer-free DES devices on the market.

"We are familiar with three or four other companies working on this type of stent, but I believe we are the furthest along. The ultimate goal is to allow us to shorten the term of antiplatelet therapy for patients. It will be a huge differentiator for our product," he said.

Researchers will follow patients in the current VESTA^{sync} study for 24 more months, but the trial is essentially over and a larger trial is in the works.