VDM Vascular Disease Management

INTERVIEW

# Current Studies of the MicroStent System for Treating PAD and CLI

*An Interview With Robert E. Beasley, MD, FSIR, FSCAI*

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**Keywords** Peripheral Arterial Disease
Critical Limb Ischemia

January 2024
ISSN 2152-4343



VASCULAR DISEASE MANAGEMENT 2024;21(1):E4-E5

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At the 2023 VEITH Symposium in New York City, Robert E. Beasley, MD, FSIR, FSCAI, a vascular interventionalist from Miami, Florida, presented several sessions, including "Updated Results With a 3-French Compatible MicroStent (From Micro Medical) for Antegrade or Retrograde Insertion to Treat Tibial Artery Lesions: From the STAND Randomized Control Trial and the HEAL Registry." *Vascular Disease Management* spoke with Dr. Beasley, who is the National Principal Investigator for the STAND Trial, to discuss these 2 current clinical studies in patients with chronic limb-threatening ischemia (CLTI). The STAND randomized controlled trial examines the clinical evaluation of the MicroSTent PeripherAl Vascular SteNt in Subjects with Arterial Disease Below the Knee. The HEAL Registry is an All-Comers Observational Study of the MicroStent Peripheral Vascular Stent System in Subjects With Peripheral Arterial Disease (PAD) and CLTI.

***Can you describe the MicroStent system?***

The MicroStent system has a tightly woven nitinol design. It has a platinum core, which makes it very easily visualized under intravascular ultrasound (IVUS), duplex ultrasound, and angiography. It has a strong radial force that prevents crushing, keeping it open during any type of external compression. It's available in 5 different lengths up to 6 cm and 5 different diameters.

***What is the status of the current clinical studies of the MicroStent system for patients with PAD and CLTI? What has the data shown?***

There are 2 ongoing studies. One is an investigational device exemption study here in the United States called the STAND Trial. It's a randomized controlled trial placing MicroStent 2 to 1 against percutaneous transluminal angioplasty, and it's almost complete. The primary efficacy endpoint of the STAND trial is freedom from target lesion occlusion with no clinically driven target lesion revascularization (CD-TLR) or major amputation at 6 months post index procedure. The STAND Trial is limited to enrolling patients with Rutherford classifications 4 and 5.

The HEAL Registry is ongoing in Europe, and Dr. Marco Manzi is the Principal Investigator. Its primary effectiveness endpoint is freedom from target lesion occlusion and no CD-TLR at 6 months. So far, 170 out of 300 patients have been enrolled. The HEAL Registry is enrolling patients with Rutherford classifications 3 through 6. The calculated primary patency of the HEAL study, which is freedom from occlusion or freedom from CD-TLR at 6 months, is 80.4%. There are also 2 cohorts in the HEAL Registry: one is primary treatment of the target lesion, and the other is bailout from another treatment. The breakdown is about 50/50 for all HEAL patients, again showing very good results for primary patency and freedom from CD-TLR.

There is also a safety component in both trials. In the HEAL Registry, freedom from perioperative death at 3 months is 100% and freedom from major adverse limb events at 6 months is 94%.

***What are the next steps for these studies?***

For the STAND Trial, 2 more patients are needed before the enrollment is complete. At that point, data analysis will begin, ultimately culminating in premarket application later next year.  For the HEAL Study Real World Registry, enrollment will continue until 300 patients have been accrued.

***What is the takeaway that you wanted the audience to get from your presentation at VEITH?***

That the MicroStent is an excellent, below-the-knee scaffold for treatment of patients with CLTI. It deserves a place alongside atherectomy and drug-coated balloon technology for the treatment of tibial vessel disease. ■