

An Update on the Cook Venous Valve Project

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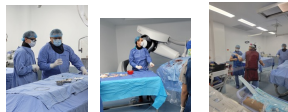
Disclosures

- Consultant for Cook Medical

Venous Valve Clinical Study Update

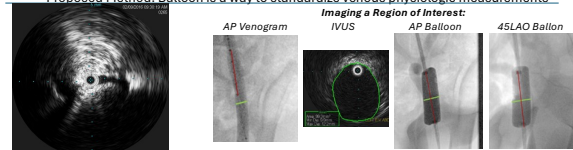


- Enrollment stopped in Cook Venous Valve clinical trial
- Early results from trial: the clinical benefit observed was not directly attributable to valve function
- Complexity of venous disease - lessons learned applied to other clinical needs



Lesson Learned - Need for Standardized Physiologic Measurement

- During early planning of study knew implant site evaluation would be critical
- Developed a protocol to be able to size and visualize the vein
- Current Method: Dynamic IVUS / Venogram used to provide dynamic measurements (respiration, Valsalva)
- Proposed Method: Balloon is a way to standardize venous physiologic measurements



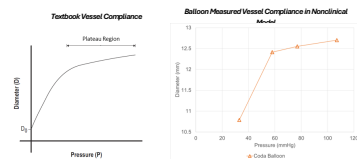
Clinical Challenge – Stent Migration

- Venous stent migration occurs at a rate as high as 6.25%¹
- Migration likely more common than reported, in part due to common asymptomatic presentations
- Need for more accurate evaluations of target implant region to guide stent selection

¹Li J, Guo H, Chen L, et al. Ann Vasc Surg. (2014) 38(2): 456-754.

Standardizing Physiologic Measurement with Balloon

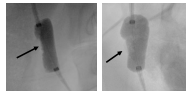
- Vein diameter increases rapidly with increased pressure up to a plateau region
- Extent of vein distention not known during sizing with conventional techniques
- Need to understand pressure conditions when sizing measurement is taken
- Dilating the vessel w/ a controlled balloon pressure => sizing under known conditions



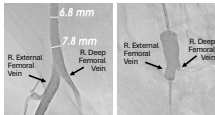
Other Clinical Benefits

- Venogram without circulating contrast:
 - Visualization of focal stenosis
 - Visualization of confluences and tributary vessels

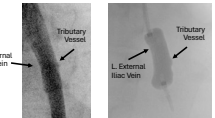
Multiplanar Visualization of External Iliac Focal Stenosis with Balloon in a nonclinical model



Confluence Vessel Visualization Venogram AP (left) and Balloon AP (right) in a nonclinical model

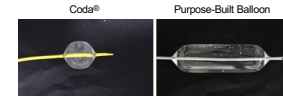
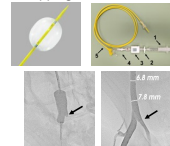


Tributary Vessel Visualization Venogram AP (left) and Balloon 45 RAO (right) in a nonclinical model



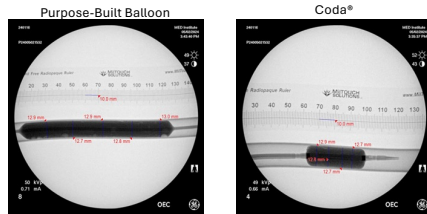
Purpose-Built Balloon

- Concept value for vessel mapping (e.g., sizing, branch identification, stenosis characterization) demonstrated with Coda® Balloon
- Prompted development of a purpose-built vessel mapping balloon
- Planned clinical evaluation comparing balloon-assisted, precision sizing and vessel mapping to state-of-the-art methods



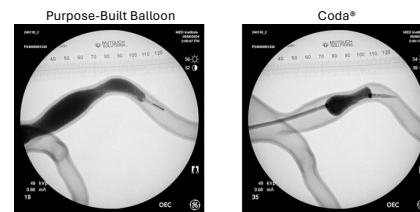
Comparing Purpose-Built Balloon and Coda® in Nonclinical Model

Straight Vessel Segment (12.8 mm nominal diameter)



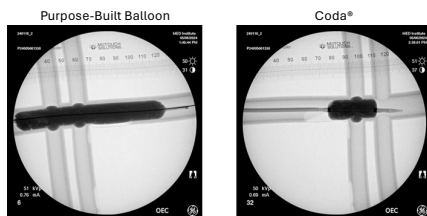
Comparing Purpose-Built Balloon and Coda® in Nonclinical Model

Flexible Model with Tortuous and Variable Geometry

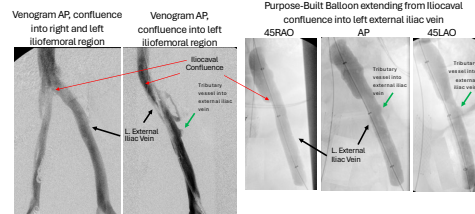


Comparing Purpose-Built Balloon and Coda® in Nonclinical Model

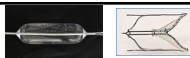
Straight Vessel Segment (12.8 mm nominal diameter) with Branches



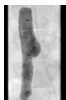
Comparing Venogram and Purpose-Built Balloon in Nonclinical Model



Conclusion

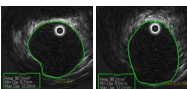


- Study update: Enrolled four patients, the clinical benefit observed was not directly attributable to valve function
- Treating venous disease remains challenging – standardizing venous physiologic measurements is the next step
- Clinical validation needed to test purpose built balloon for standardization on Measurements



Methods for Visualizing a Vein.

AP and Lateral Venogram with and without Valsalva



AP and Lateral Balloon Inflated to known Pressure

