VIRTUS CLINICAL TRIAL

12-Month Data[1]

Pivotal Cohort 12-Month Primary Safety and Efficacy Results of the VICI Venous Stent™ System

OBJECTIVE:

Assess safety & effectiveness in achieving patency of target venous lesion through 12 months post stent placement, in patients with obstruction of the iliofemoral venous outflow tract

TRIAL DESIGN:

Prospective, multi-center (22 sites in the US and Europe) single arm, non-randomized

KEY INCLUSION CRITERIA:

Unilateral, clinically significant, chronic non-malignant obstruction of the common femoral vein, external iliac vein, common iliac vein, or any combination thereof

- ≥50% reduction in target vessel lumen diameter (venogram)

Clinically significant venous obstruction defined as:
CEAP "C" ≥3 OR VCSS Pain ≥2

BASELINE CHARACTERISTICS:

Patient Demographics	n = 170 subjects
Age (Years)	54.4±16.2
Male/Female	43.5%/56.5%
Thromboembolic Disease	76.5%
History of Smoking	36.5%
Hypertension	40.0%
Coagulation Disorder	13.5%
Peripheral Vascular Disease	17.1%

Clinical Assessment	n = 170 subjects
Chronic Post Thrombotic	75.0%
CEAP Clinical Severity C_5 & C_6	25.3%
VCSS ≥ 8, Severe	65.8%
Lesion Length	111.3±65.8 (range 10-260 mm)
Total Occlusions	31.2%
% Involving entire illofemoral segment	31.8%

EFFICACY RESULTS:

Definition:

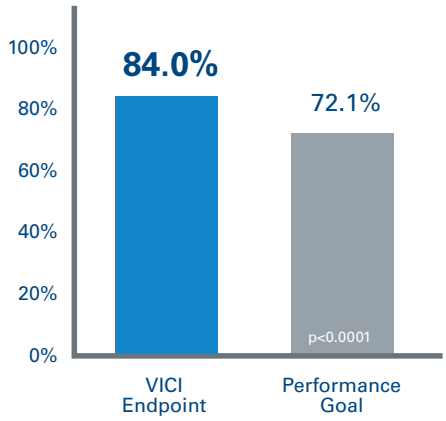
Primary patency rate at 12 months post-intervention

- Freedom from occlusion by thrombosis
- Freedom from surgical or endovascular intervention on target vessel which are found to have re-stenosis or stent occlusion to maintain patency
- Freedom from in-stent stenosis more than 50% by venogram

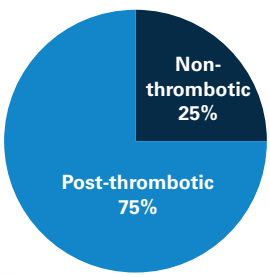
Primary endpoint was met[2]:

Primary patency rate exceeded the performance goal of 72.1% (p<0.0001)[3,4]

12-Month Primary Patency Rate[3]



Etiology



VIRTUS Clinical Trial | 12-month results

Safety Results:

98.8% freedom from MAEs through 30 days

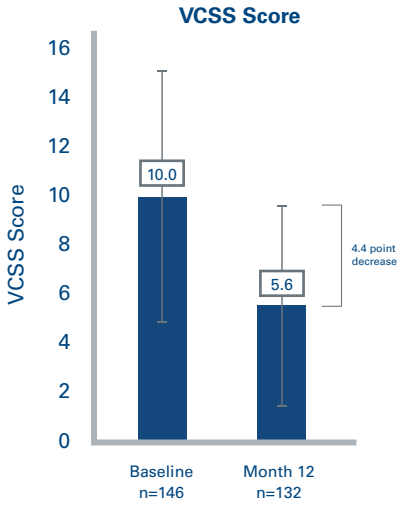
Primary endpoint was met[2]:

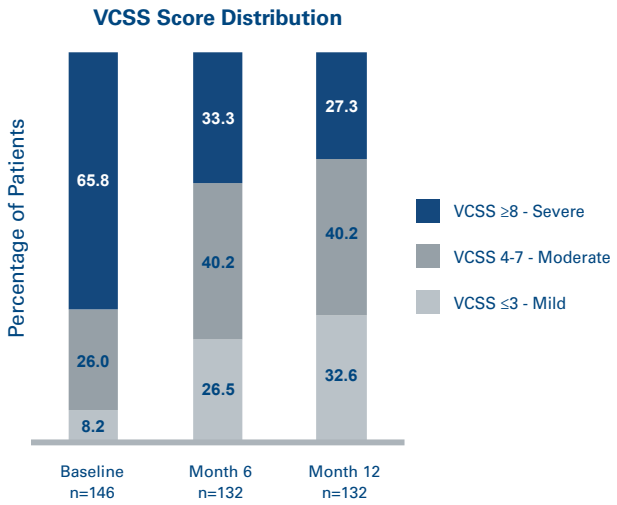
Safety rate exceeded the performance goal of 94%[5]

Major Adverse Events (through 30 days)	n/N
Arterial or venous injury at the target vessel segment and/or target lesion location or at the access site requiring surgical or endovascular intervention	2/169 (1.2%)
Device or procedure-related death	0/169
Bleeding at the target vessel and/or target lession or at the access site requiring surgical or endovascular intervention or blood transfusion	0/169
Acute DVT outside the target vein segment	0/169
Clinically significant pulmonary embolism	0/169
Embolization of the stent	0/169

Patient Outcomes:

- VIRTUS demonstrated a clinically meaningful 4.4 decrease in the VCSS score from baseline out to 12 months.
- Vici shifted patients with a severe VCSS score from almost 66% down to 27%, and increased the patients in the mild VCSS score 4-fold.





Conclusions:

- **VIRTUS primary safety and effectiveness endpoints successfully met:**
  - 84% 12-month primary patency
  - 98.8% freedom from MAE through 30 days
- **Patient sample with challenging characteristics:**
  - 75% of patients with chronic PTS
  - 65.8% VCSS ≥ 8, severe
  - 25% of patients with CEAP Clinical Severity C5 and C6
  - 31% with total occlusions
  - 32% had involvement of the entire iliofemoral segment

1. Presented at LINC 2019 by Mahmood K. Razavi, MD, VIRTUS clinical trial principle investigator
2. The objective performance goal for the primary safety and efficacy endpoints were derived from contemporary literature.
3. For the primary endpoint, patients who did not have venography performed at 12 months had their result imputed by random selection from subjects with a venogram result who had the same etiology and the same DUS outcome (if available).
4. Primary effectiveness analysis based on the combined result from 15 imputations; t-statistic 4.0; p<0.0001
5. Lower confidence limit of 95.8% exceeded the performance goal of 94%

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