Combination Of Atherectomy (With Stealth 360 Device From CSI) And DCB For Treating Calcified Lesions In BTK Arteries: How The Device Works And Preliminary Results

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Limitation of Drug Coated Balloons in Calcified Lesions

- As circumferential calcium increases, the effectiveness of DCBs decreases
- Late lumen loss increased & primary patency decreased with calcium severity
- As calcium severity increases, late lumen loss at 6 months increases
- Severity of lesion calcification was a single independent predictor of late lumen loss outcome after DCB treatment

Below the Knee DCB Studies

Single-center studies suggest DCBs may lower amputation rates; however, results of RCTs have been mixed.

STEALTH 360® Peripheral Orbital Atherectomy System

- Sleek Electric-Powered Handle
- Single frequency setting
- Optimized crown radius to the shaft and crown
- Short overall treatment time

CSI’s Unique MOA: Changing Compliance using Centrifugal Force

- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit

Disclosure

Speaker name: Marianne Brodmann, MD

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

*Results vary based upon plaque morphology, calcification, and anatomy
*In a phantom non-diseased popliteal artery
**Results vary based upon plaque morphology, calcification, and anatomy

Company Name: CSI’s Unique MOA

- Changing Compliance using Centrifugal Force

- Differential Sanding
- Pulsatile Forces
Calcified Plaque Modification Alters Local Drug Delivery in the Treatment of Peripheral Atherosclerosis


These data illustrate that calcified plaque limited intravascular drug delivery, and controlled OAS treatment of calcific plaques trended in greater drug permeability and improved adjunct drug delivery to diseased arteries.

OPTIMIZE-BTK: Inclusion/Exclusion Criteria

Notable Inclusion Criteria:
- Rutherford Clinical Category 3 – 5
- Lesion (except in-stent restenosis [ISR]) of the distal POP (POP segment below the anatomical knee joint), AT, PT, TPT, and PR arteries with ≥ 70% DS by angiography
- Presence of clearly visible distribution of calcium in two views (both sides of vessel at the same segment assessed angiographically)
- Length of calcification ≥ 25% of total lesion length or ≥ 2 cm total length
- Target lesion length up to 20 cm

Notable Exclusion Criteria:
- Presence of inflow lesion (≥ 50 % DS) or inflow not successfully treated (≥ 50 % DS and/or unresolved significant angiographic complication)
- Compromised runoff: lesion located at the target lesion (≥ 70 % DS) or presence of lesion(s) or occlusion(s) located from 5 cm above the ankle to below the ankle joint space
- Subject has more than 2 target vessels requiring intervention
- Presence of ≥ 70% DS lesion(s) or occlusion(s) not meeting the study criteria which were not successfully treated during the index procedure (≥ 50 % DS and/or significant angiographic complication)
- Subject has planned amputation (including minor) of the index limb or previous major amputation of the contralateral limb
- Presence of clearly visible calcification in two views (both sides of vessel at the same segment assessed angiographically)
- Length of calcium ≥ 25% of total lesion length or ≥ 2 cm total length

OPTIMIZE-BTK: Primary Outcome Measures

- LLL of the target lesion by QVA at 6 months post-procedure or at the time of TLR
- Patency of the target lesion by DUS at 6 mo and 12 mo post-procedure
- Freedom from Major Adverse Events at 30 days, 3, 6, 12, and 24 months post-procedure
  - MAEs include: clinically-driven TLR; unplanned, unavoidable major amputation of the index limb; and death within 30 days of the index procedure
- Freedom from clinically driven TLR at follow up (core lab adjudicated)
- Freedom from unplanned, unavoidable major amputation of the index limb follow up

OPTIMIZE-BTK: Study Update

Enrollment completed May 2018

Active Sites:
- Austria (Prof. Brandmann/Deutschmann & Dr. Werner)
- Germany (Prof. Zeller, Prof. Tepe, Prof. Andrassy, Prof. Blessing, Prof. Scheinert)

Conclusions

- Calcified lesions may reduce the efficacy of DCBs by blocking uptake of drug into vessel wall
- Preclinical data suggest OAS treatment of calcific plaques trended in greater drug permeability and improved adjunct drug delivery to diseased arteries
- OPTIMIZE-BTK trial is designed to test the hypothesis that pre-treatment with OAS for calcified BTK arteries followed with DCB will provide incremental benefits versus DCB angioplasty alone