Case Report
Chocolate™ FIM Study

Patient:  15-001
Study Site:   Park Hospital Leipzig
Leipzig, Germany

Principle Investigator:  Professor Dierk Scheinert
Date:   21 April 2011

“The Chocolate™ Balloon may be a viable alternative for the treatment of complex vascular disease above and below the knee. I’m looking forward to trying the drug-eluting version.”

Professor Dierk Scheinert
Developed by:
Quattro Vascular Pte Ltd
ROC REG 201006397R

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Patient Presentation
On 21 April 2011, a 73 year old female with no prior history of lower extremity disease presented with Ischemic Rest Pain consistent with Intermittent Claudication.

Medical History
Patient underwent a recent Coronary Revascularization; suffered a Stroke in 2008; has a documented history of Hypertension, Hyperlipidemia, and Tobacco use.

Angiographic Diagnosis
ATK:
• 99% stenosis in the SFA (Lesion Length = 180mm)
BTK:
• 100% stenosis (occlusion) of proximal/mid Peroneal Artery (Lesion Length = 150 mm)
• 100% stenosis of distal Anterior Tibial Artery

Percutaneous Procedure
ATK Treatment:
Spectranetics Laser Treatment + standard Balloon Angioplasty. See Figure 1 — SFA pre and post treatment (<30% stenosis achieved)

BTK Treatment: Peroneal Artery
• Chocolate™ Balloon (3.0x80 mm)
• 3 inflations (6atm/30sec)
  See Figure 2 — Chocolate™ Balloon inflated in Peroneal Artery

Additional Treatment:
Patient was given Nitro and two additional low pressure (4 atm) inflations with the Chocolate™ PTA Balloon were performed to address a spasm distal to the area treated with Chocolate™. Spasm resolved and no additional devices were used.

Chocolate™ Treatment

Above the Knee Treatment

▲ Figure 1: SFA treated to successfully established in-flow to BTK vessels

▲ Figure 2: Chocolate™ inflated in Peroneal Artery (shows distal to proximal consecutive inflations)
Final Outcomes:
- Blood flow restored to Peroneal Artery (See Figure 3B)
- <50% Diameter Stenosis achieved
- No dissection

Available Follow-Up:
- Duplex Ultrasound Day 1 showed PVR ratio = 1.05
- No Adverse Events have been reported for this patient up to 3 Months post treatment with Chocolate™

Peroneal Artery Before and After Treatment with Chocolate™

Figure 3a: Peroneal Artery before treatment with Chocolate™

Figure 3b: Peroneal Artery after treatment with Chocolate™