Endologix

DELIVERING HEALTHCARE INNOVATION

Improving the lives of patients with vascular disease

Percutaneous Femoral-Popliteal Bypass with Conduit through Femoral Vein

ICD-10-PCS C&M Meeting

March 2023

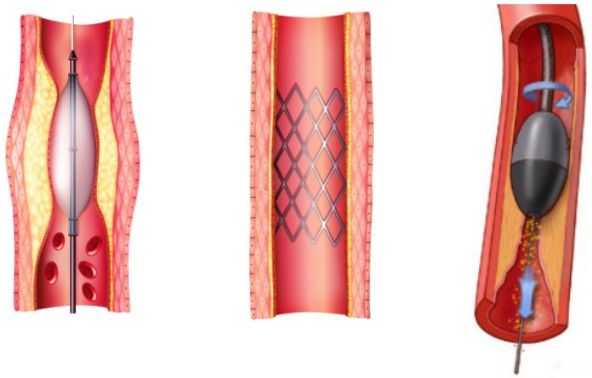
Background

- Peripheral Artery Disease (PAD) affects ~8-12 million Americans
- Prevalence of PAD increases with age. More than 10% of people with PAD are in their 60s and 70s.
- Severity of disease varies from asymptomatic, symptomatic, CLTI (Critical Limb Threatening Ischemia) and CLI (Critical Limb Ischemia)
- Patients with PAD have a poor quality of life and have comorbidities such as heart disease, diabetes, and increased mortality
- There are several therapies to treat PAD, including risk factor modification, medical therapy, surgical, and endovascular interventions

Conventional Treatments

Percutaneous Interventions

- Angioplasty
  (POBA, drug coated)
- Placement of stents
  (bare metal, drug-eluting)
- Atherectomy

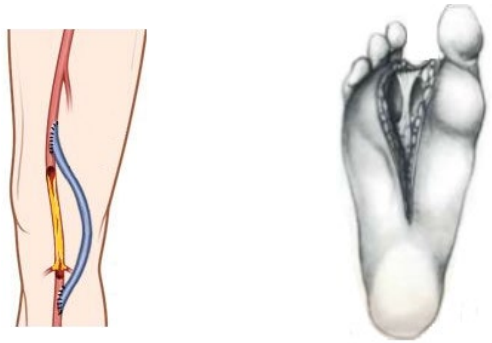


Shortcomings

- Certain lesions are not amenable to percutaneous interventions, e.g. long or calcified lesions, CTO, long procedure times
- Resource intensive
- Lack of durable (effective) long-term clinical outcomes

Open Surgical Procedures

- Open surgical bypass
- Amputation



Shortcomings

- Invasive procedure
- Post-op AMI
- Surgical site infections
- Need for transfusions
- Unplanned return to the OR
- Long length of stay (4-7 days) inpatient rehabilitation services

LE Bypass Procedures

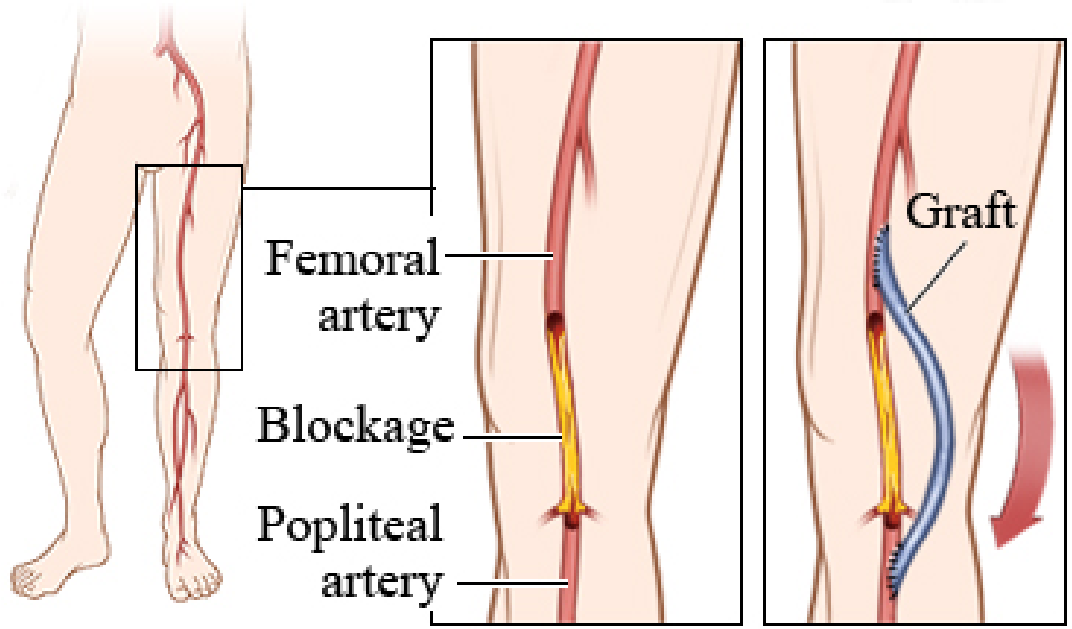
- After surgical exposure, the inflow artery (from) is connected to the inflow artery (to), rerouting blood flow around the diseased segment

Examples

- Femoral-popliteal
- Femoral-posterior-tibial
- Peroneal-tibial

- The material for a harvested conduit may be a harvested vein, harvested artery, or synthetic graft

- From the time of the procedure to 30-day follow up, about 37% of open bypass patients experience a complication



DETOUR® System (formally PQ Bypass System)

TORUS Stent Graft Delivery System

- 8 Fr compatible
- 0.035” wire compatible
- 135 cm working length
- Tri-axial shaft design
- Ergonomic handle

TORUS Stent Graft

- Self-Expanding endoprosthesis made of nitinol wire frame
- Encapsulated in an expanded polytetrafluorethylene (ePTFE) film

ENDOCROSS Device

- Spring-loaded dual guidewire delivery tool
- 0.025” Nitinol needle with a 15 mm throw
- Dual 0.014” guidewire ports

Procedural Steps

Pre-procedure imaging

- Pre-procedural angiogram or CTA is performed to verify anatomic inclusion criteria are met. The angiogram is also used to assist with procedural planning and provide reference images for comparison with post-procedural results.

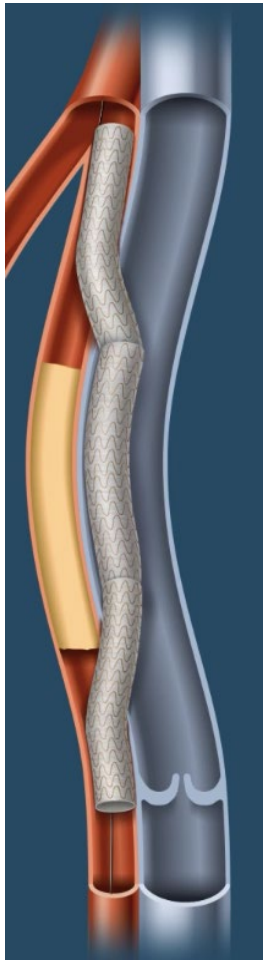
Access

- Contra-lateral common femoral arterial access is obtained, and sheath is placed.
- Ipsilateral distal venous access is obtained, sheath is placed, and the snare is advanced to the proximal femoral vein.

Anastomoses Creation

- The Crossing Device is advanced 3-4cm into the superficial femoral artery, and the needle is fired to create the proximal anastomosis from the superficial femoral artery into the snare in the proximal femoral vein. The Crossing Device is then removed for flushing.
- The Crossing Device is then advanced from the artery through proximal anastomosis into the vein and positioned distally to create the distal anastomosis by firing through the wall of the distal femoral vein or proximal popliteal vein and into the distal SFA or popliteal artery.
- A .014” wire is then advanced through the popliteal artery into one of the tibial arteries for stability, in preparation for stent graft deployment.

Procedural Steps (cont.)



TORUS Graft Deployment

- The proximal and distal anastomosis sites are dilated to facilitate movement of the stent graft delivery system.
- The .014” wire is then exchanged for a .035” wire for the stent graft delivery system.
- The distal TORUS Stent Graft is placed in popliteal artery or distal superficial femoral artery (SFA) and bridges across the distal anastomosis into the femoral vein.
- Additional TORUS Stent Grafts are placed extending up to the level of the SFA/Profunda bifurcation to complete the bypass.
- The stent grafts are then dilated along the entire bypass to ensure maximum diameter, expansion across the anastomoses, and apposition of the graft in the proximal SFA and the distal SFA or proximal popliteal.

Post-procedure imaging and monitoring

- The final venogram runoff is obtained for assessment of flow in the femoral vein throughout the course of the bypass.
- The final arteriogram runoff is obtained for assessment of the flow through the bypass.

Medical Record Documentation and Regulatory Status

- The DETOUR® System received Breakthrough Device Designation from the FDA (Q201151) on August 21, 2020
- FDA approval is anticipated in 1H 2023
- Documentation of the DETOUR® System will be included in the operative report and may be referred to as:
  - DETOUR® System
  - PQ Bypass System
  - Percutaneous bypass
  - Percutaneous fem-pop bypass

Thank you