2017 MID-ATLANTIC
CONFERENCE

7th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

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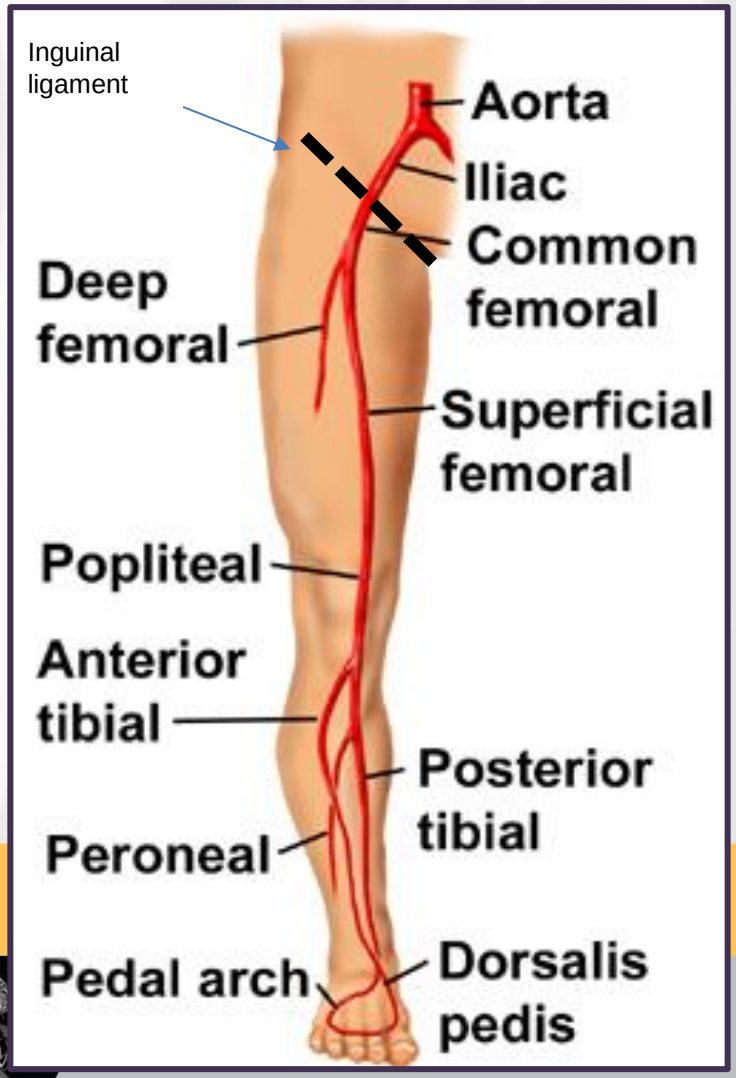
Endovascular Is The Way To Go: Revascularize As Many Vessels As You Can

Background

- Lower extremity anatomy (below the inguinal ligament)
  - Anatomy and disease
  - Multiple collateral pathways
  - 3 vessels to the foot
  - Multilevel disease



How can limb revascularization (salvage) be achieved?

- Different approaches
  1. Treating as many vessels as can be recanalized using catheter-based technology (THE WAY TO GO!)
  2. Treating not all but at least two main below-the-knee vessels
  3. Attempting to provide flow to some collaterals in order to maximize foot perfusion (rare situations)
  4. Bypassing an obstruction by using vein or prosthesis conduit

Endovascular Era

- Endovascular treatment has evolved over the past 50 years…from rigid to flexible/comformable catheters and stents

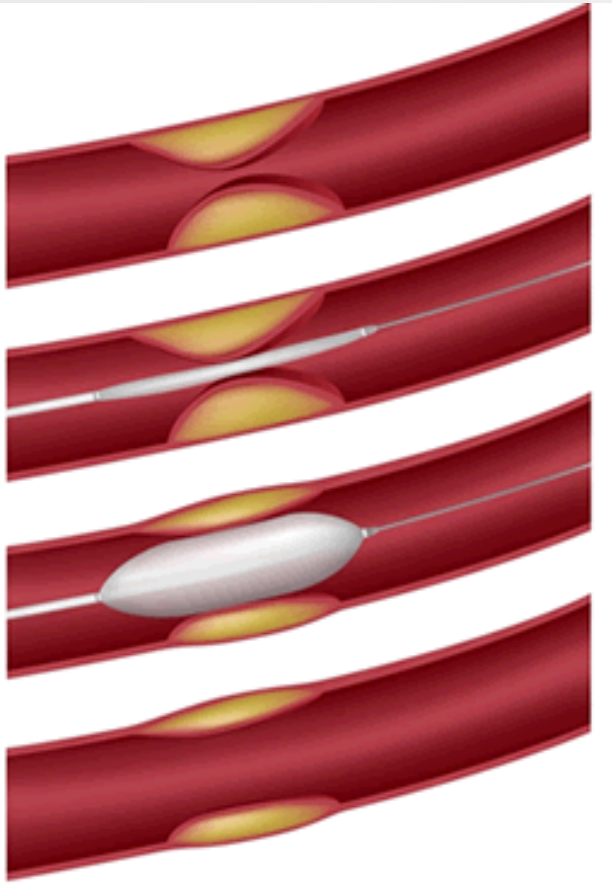
Charles Dotter, M.D.
Leg angioplasty concept, 1964

Endovascular Modalities

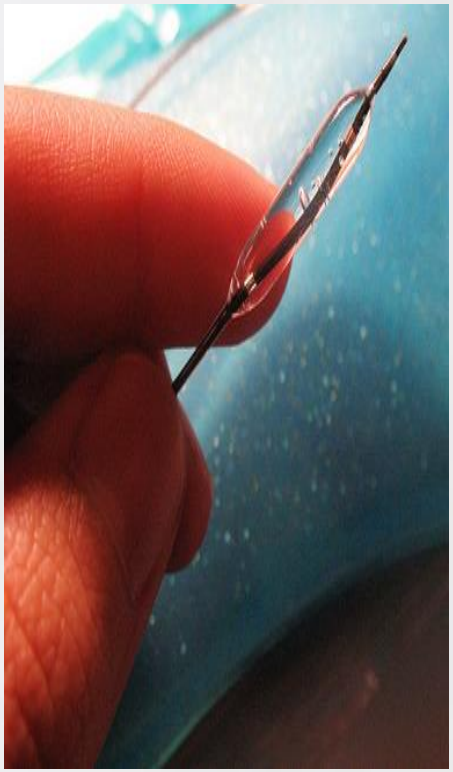
- Balloon angioplasty
  - Regular, not coated
  - Cryo-balloon (“cold” angioplasty)
  - Cutting or scoring balloon
  - Drug coated → Paclitaxel* (anti-rejection med)
- Stenting
  - Bare metal
  - Drug eluted → Sirolimus, Paclitaxel*, and Everolimus
- Atherectomy
  - Laser, rotational, orbital, directional

Balloon Angioplasty

- Arterial stenosis dilated by balloon inflation
- Atherosclerotic plaque remodeling
- Can be repeated if recurrence
- Often, no foreign body left behind
- Can be combined with stents

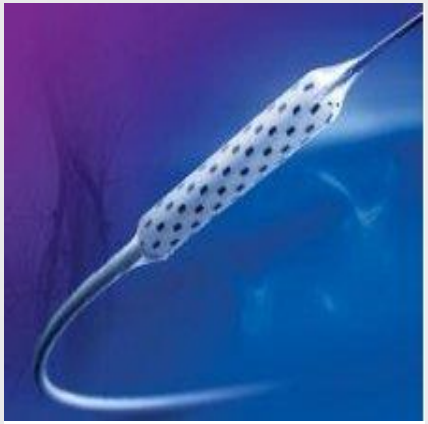


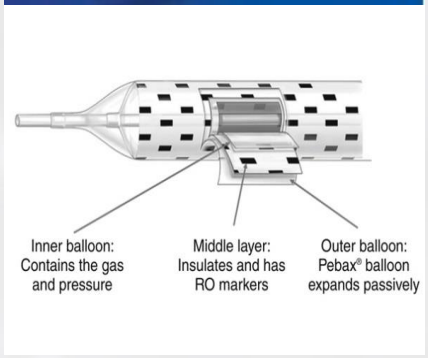
Balloon Angioplasty



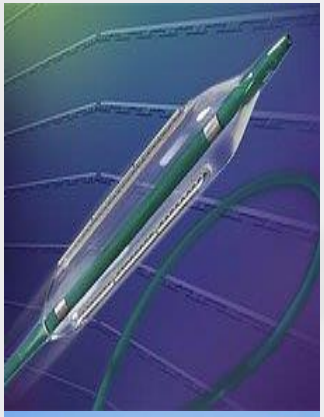
Regular balloon

Drug coated balloon





Cryo-balloon



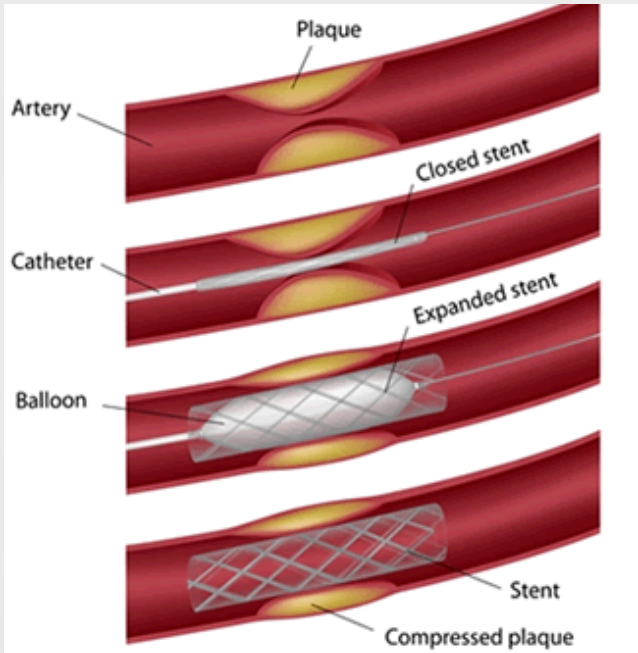
Cutting and scoring balloon

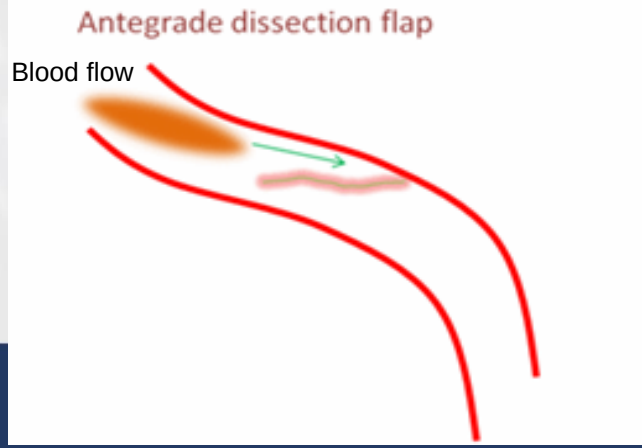
Balloon Angioplasty

77 year-old diabetic female on chronic hemodialysis with left forefoot chronic nonhealing ulcer

Stenting

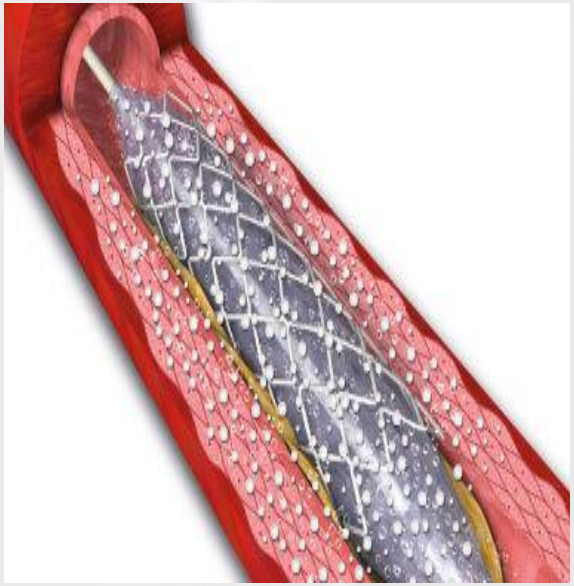
- Scaffold providing support
- Less recoiling
- Can be bare metal or covered
- Can be drug eluted
- No clear superiority compared to balloon angioplasty
- Important when antegrade dissections occur (against the flow





Stents

Bare metal stents

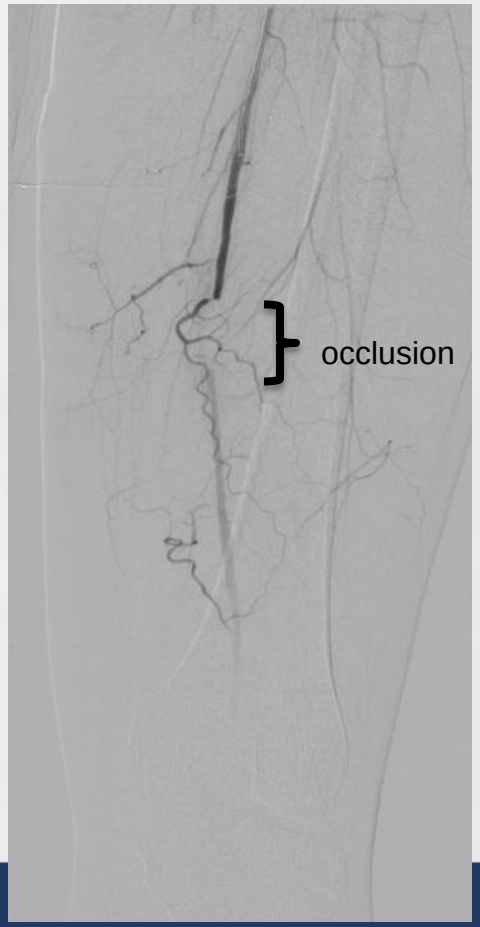


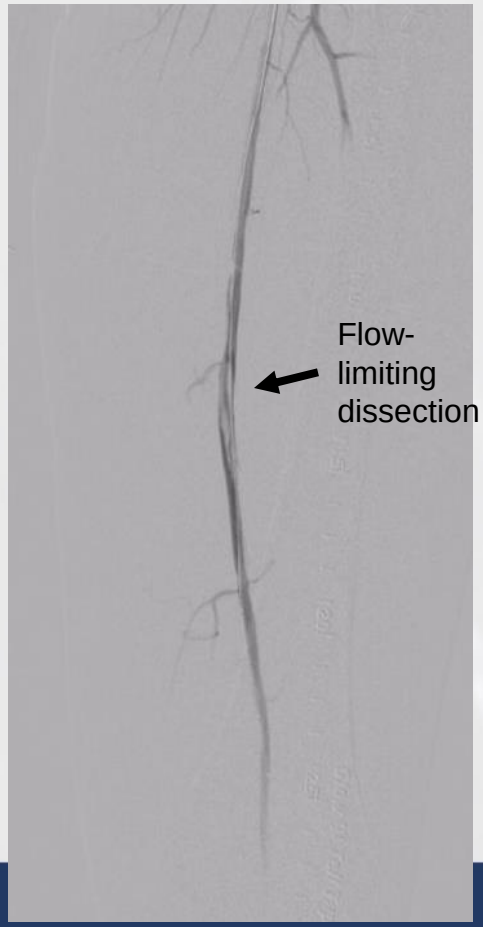
Drug-eluting stents

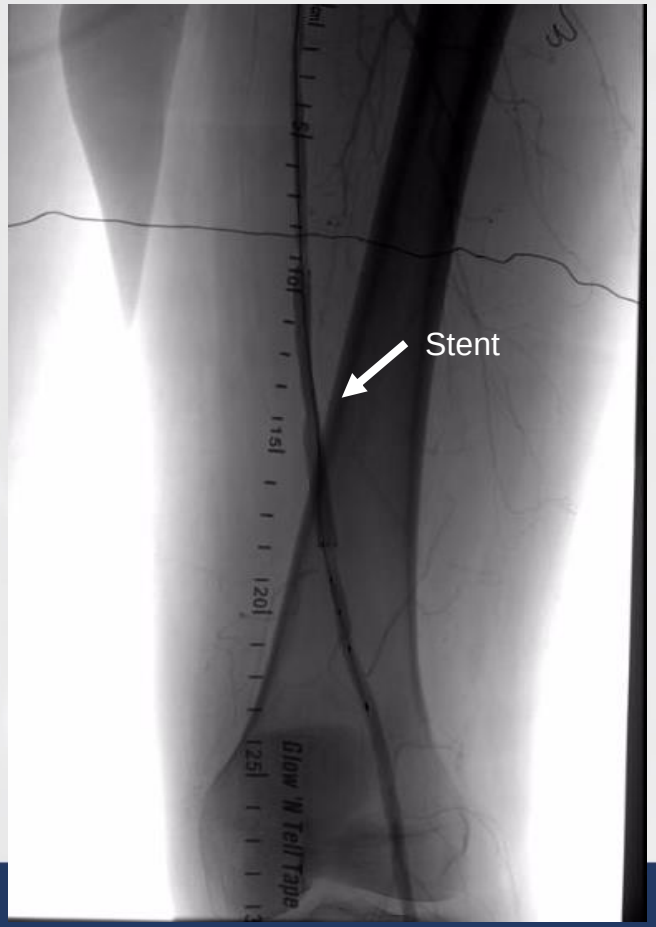
Covered stents

Stenting - Case

- 55yo poorly controlled diabetic, smoker female

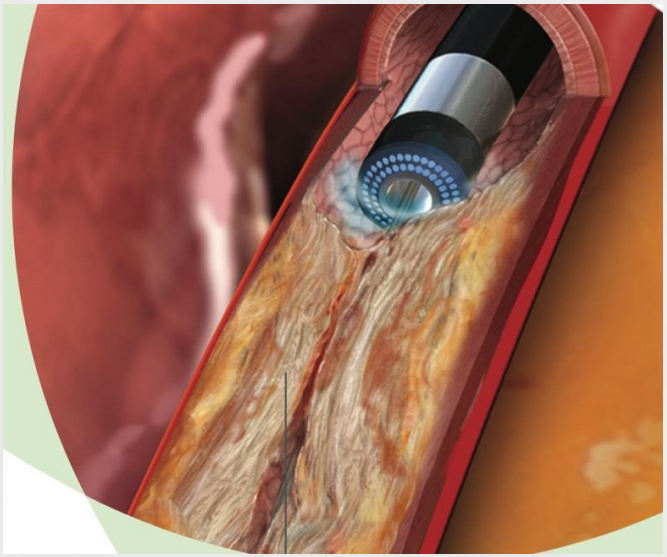


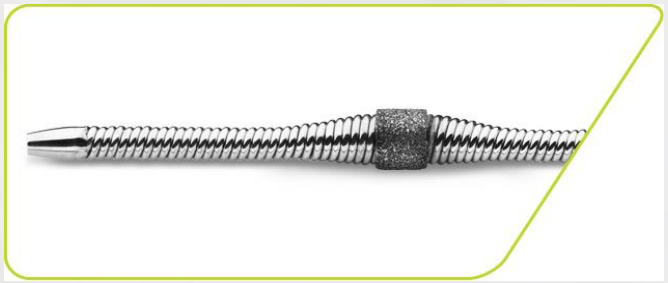




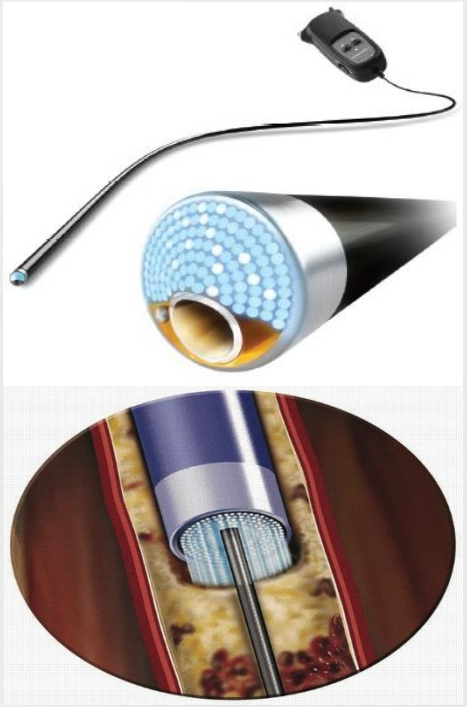
Atherectomy

- Reduce plaque burden by shaving, drilling or pulverizing it
- Several devices in the market

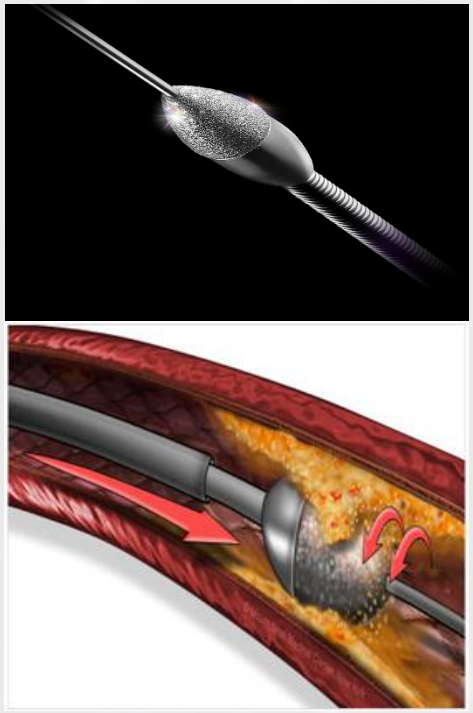




Atherectomy



Laser atherectomy

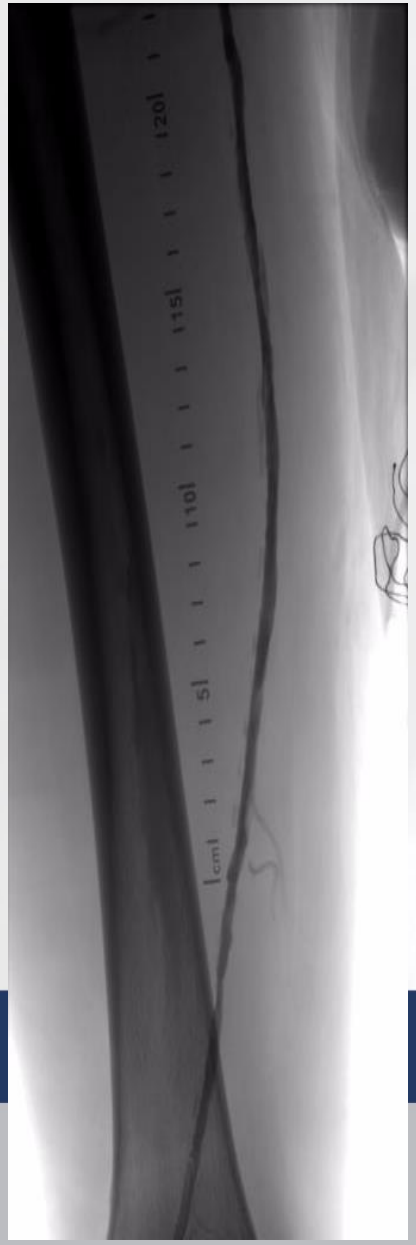


Rotational artherectomy

Directional atherectomy

Atherectomy case

- 74 year-old male smoker with pain at rest



Endovascular Era

- Several endovascular devices to treat lower extremity arterial disease in a minimally invasive way!

Endovascular	Bypass
A puncture	At least two incisions
Same-day procedure	A few nights in the hospital
Local anesthesia/sedation	General or regional anesthesia
Flexible scheduling (“cath lab”)	Operating room availability
One procedure can tackle several arteries – less hassle, more flow to the foot!	One target vessel that can signify one vessel to the foot

Literature Review

- Claudicants

Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication

Society for Vascular Surgery Lower Extremity Guidelines Writing Group: Michael S. Conte, MD, (Co-Chair),[a] Frank B. Pomposelli, MD, (Co-Chair),[b] Daniel G. Clair, MD,[c] Patrick J. Geraghty, MD,[d] James F. McKinsey, MD,[e] Joseph L. Mills, MD,[f] Gregory L. Moneta, MD,[g] M. Hassan Murad, MD,[h] Richard J. Powell, MD,[i] Amy B. Reed, MD,[j] Andres Schanzer, MD,[k] and Anton N. Sidawy, MD, MPH,[l] San Francisco, Calif; Boston and Worcester, Mass; Cleveland, Ohio; St. Louis, Mo; New York, NY; Tucson, Ariz; Portland, Ore; Rochester, Minn; Lebanon, NH; Hershey, Pa; and Washington, D.C.

J Vasc Surg. 2015 Mar;61(3 Suppl):2S-41S.

Literature Review

- Claudicants (aortoiliac disease)

Clinical question	Data source	Finding	Quality of evidence
The effect of endovascular vs open surgery for AIOD on the outcomes of mortality, complications, and patency	Meta-analyses of mostly nonrandomized series (AIOD, not all IC)[139]	The open bypass group experienced more complications and greater 30-day mortality. At 1, 3, and 5 years, primary patency rates were greater in the open bypass group	B-C
The effect of PTA vs stent placement for AIOD on the outcomes of mortality, complications, and patency	Meta-analyses of mostly nonrandomized series (AIOD, data provided for IC).[137] Meta-analyses of mostly nonrandomized series (class C and D aortoiliac lesions)[138]	Complication and mortality rates were similar. Immediate technical success rate (PTA group, 91%; stent group, 96%); 4-year primary patency rates for PTA (65% for stenosis, 54% for occlusions) and for stents (77% for stenoses, 61% for occlusions)	B-C
The effect of endovascular vs open surgery for extensive AIOD on the outcomes of mortality, complications, and patency	Meta-analyses of nonrandomized series of EVT for extensive AIOD[188]	With endovascular approach, mortality ranged 1.2%-6.7% and complications ranged 3%-45%. Clinical symptoms improved in 83% to 100%. Technical success was achieved in 86% to 100% of the patients. The 4-year or 5-year primary and secondary patency rates were 60% to 86% and 80% to 98%, respectively	B-C

Literature Review

- Claudicants (femoropopliteal disease)

Clinical question	Data source	Funding	Quality of evidence
Endovascular vs surgical reconstruction	Four RCTs and six observational studies reporting on 2817 patients with FP arterial disease[233]	EVT was associated with lower 30-day morbidity (OR, 2.93; 95% CI, 1.34-6.41) and higher technical failure (OR, 0.10; 95% CI, 0.05-0.22) than bypass surgery. No difference in 30-day mortality (OR, 0.92; 95% CI, 0.55-1.51). Higher primary patency in the surgical treatment arm was found at 1 (OR, 2.42; 95% CI, 1.37-4.28), 2 (OR, 2.03; 95% CI, 1.20-3.45), and 3 (OR, 1.48; 95% CI, 1.12-1.97) years after intervention. Progression to amputation occurred more commonly in the endovascular group at the end of the second (OR, 0.60; 95% CI, 0.42-0.86) and third (OR, 0.55; 95% CI, 0.39-0.77) year of intervention. The bypass group had higher amputation-free (OR, 1.31; 95% CI, 1.07-1.61) and overall survival (OR, 1.29; 95% CI, 1.04-1.61) rates at 4 years	C (risk of bias, indirectness because most trials enrolled CLI patients)

Literature Review

- Claudicants (femoropopliteal disease)

The effect of stenting vs no stenting in patients with IC on morbidity, mortality and patency	Meta-analysis of 8 RCTs (968 patients with IC or CLI and SFA disease)[189]	Primary patency better with stenting at 6 months but not 12 months	C (indirectness due to CLI patients included and imprecision of long-term outcome)
Balloon angioplasty with optional stenting vs routine stenting with nitinol stents	Meta-analysis of 4 RCTs (627 patients with IC or CLI and SFA disease)[234]	Mortality was similar in both groups (OR, 0.83; 95% CI, 0.39-1.77). Technical success was significantly higher in the stenting group (96% vs 64%; OR, 0.31; 95% CI, 0.09-0.92) The 12-month binary restenosis rate was significantly lower in the primary stenting group (OR, 3.02; 95% CI, 1.3-6.71)[7]	C (indirectness due to CLI patients included and imprecision)
Comparison of various stents	Network meta-analysis of 16 RCTs (2532 patients with IC or CLI and FP arterial disease)[235]	Technical success was highest with covered stents. Vascular restenosis was lowest with paclitaxel DES and with paclitaxel-coated balloons. Major amputations were rare in all treatment and control groups (pooled amputation rate of 0.7 events/100 person-years)	C (indirect comparisons, CLI patients included, imprecision)

Literature Review - CLI

- BASIL trial (Bypass versus Angioplasty in Severe Ischemia of the Leg)
  - Sponsored by the United Kingdom National Institute of Health Research Technology Assessment Program
  - Started in 1996, the trial enrolled 452 patients over a 5-year period
  - There was no difference in amputation-free survival between both the arms (57% for Bypass and 52% for percutaneous transluminal angioplasty at 3 years)
  - Questionable endovascular strategy (excluded stenting) and surveillance methods (no hemodynamic studies)

(J Vasc Surg. 2010 May;51(5 Suppl):5S-17)

Literature Review - CLI

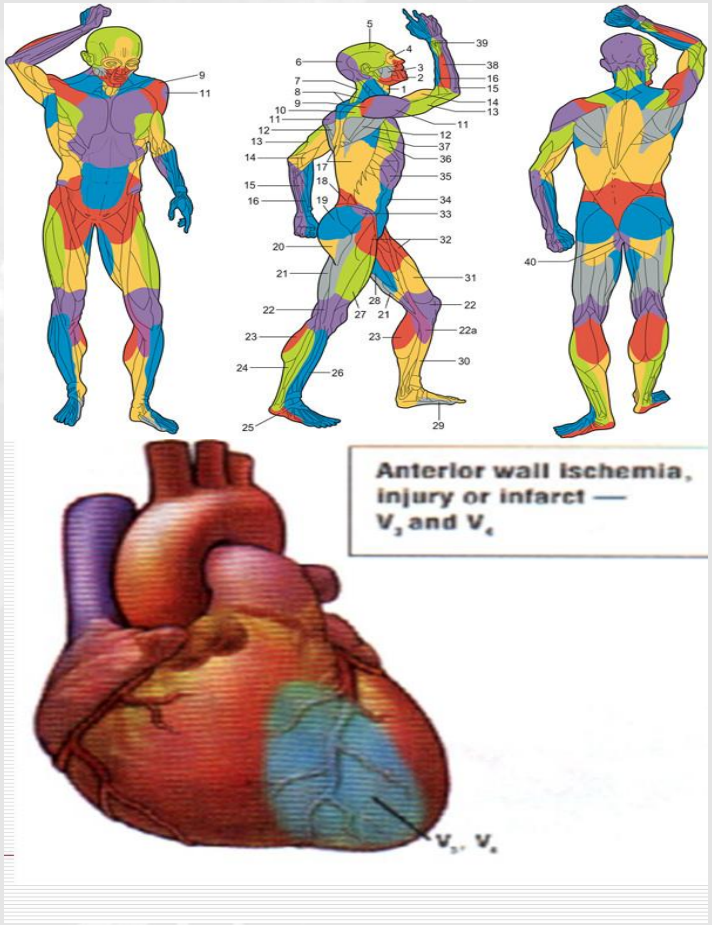
- BEST-CLI (Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia)
  - Ongoing trial funded by the National Lung Heart and Blood Institute of the National Institutes of Health
  - Randomization of patients with either pain at rest or tissue loss (ulcers, wounds) into endo or open
  - No restriction regarding endovascular modality
  - Aim: to enroll 2100 patients at 120 sites in North America over the course of 4 years (~900 patients)

Where is the evidence?

- Currently, there is no strong data showing superiority of one type of endovascular method over the others despite recent “network” meta-analysis (J Vasc Surg. 2017 Jan;65(1):234-245)
- Several trials sponsored by companies involved in developing new technology
- Lack of high-quality publications (with no conflict of interest) comparing surgery versus endovascular treatment (BEST-CLI under way)

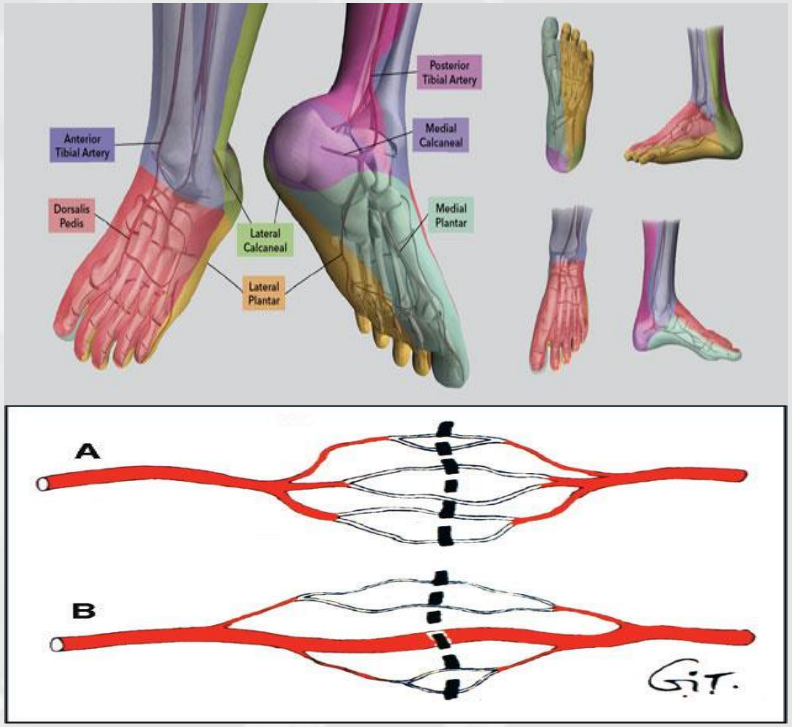
The Angiosome concept

- Derived from plastics and cardiac surgery
- 40 angiosomes in the body → 6 of them in the foot!
- Acute versus chronic presentation
- Muscle ischemia conditioning



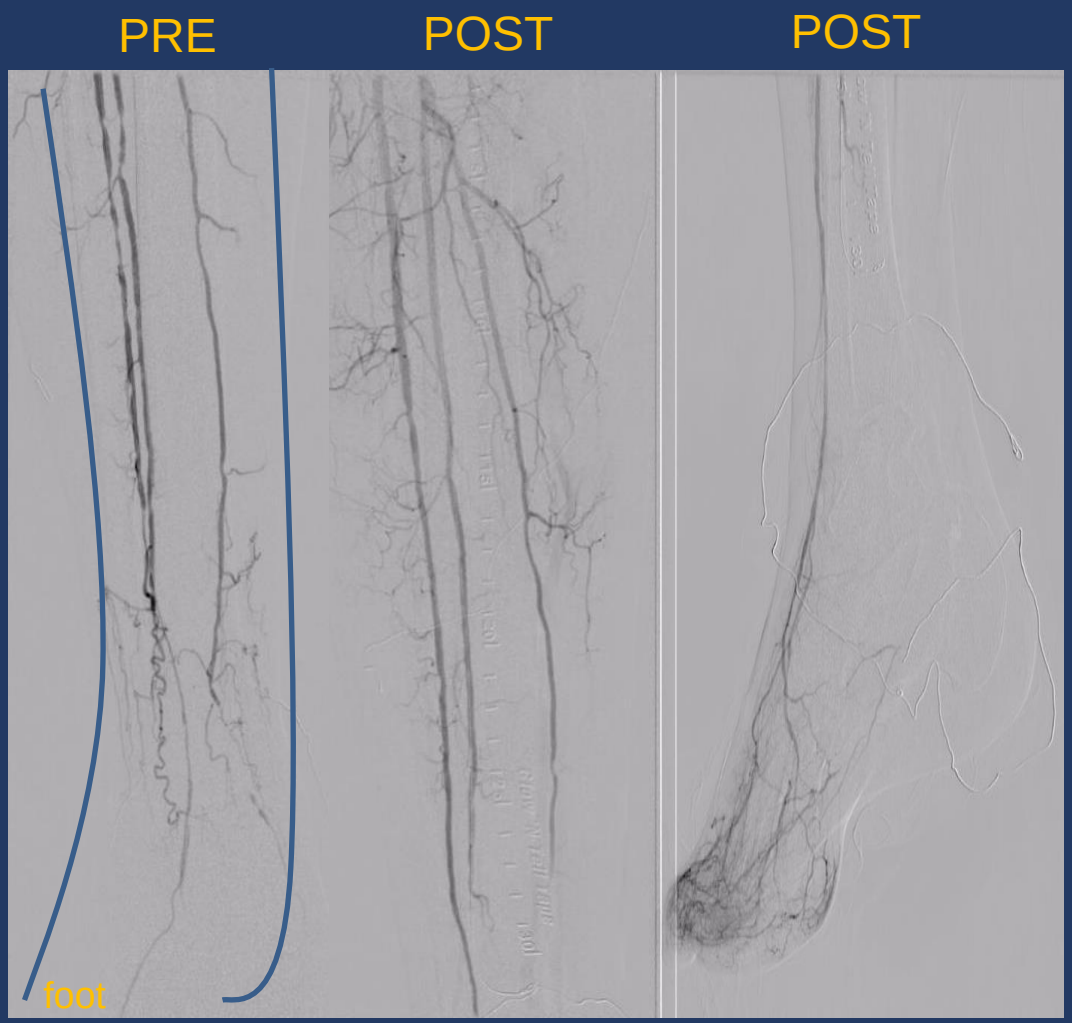
The Angiosome concept

- Peripheral vascular issues with the theory
  - Interangiosome connections for perfusion
  - Perfusion is a matter of flow/pressure to the target area
    - "Choke vessels": reduced-caliber anastomosing vessels. Normally the barrier in the vasculature



Case Presentation

- 60yo M (non smoker)
  - Type II diabetes
  - 3-month hx of second toe non-healing wound
  - Treated unsuccessfully with wound care + hyperbaric oxygen therapy



What is the best option out there for limb salvage?

- Patient selection is key…not everyone is a candidate (very long segment occlusions)
- Start minimally invasive…less is more.
- Open as many vessels as possible to give the leg the best chance to heal…go big or go home!

↓

Endovascular is the way to go!

Thank you