IF YOU WERE A PAD PATIENT: **FAVOR**

What is the minimum efficacy threshold you would accept for an invasive treatment strategy for life-style limiting claudication?

1. >50% likelihood of improvement for at least one year
2. >50% likelihood of improvement for at least two years
3. >50% likelihood of improvement for at least three years

**Restenosis: The Continuing Challenge for Peripheral Vascular Intervention**

- Most severe in the infrainguinal vessels
- Limited Current Strategies
  - Cutting balloons
  - Covered stents
  - Brachytherapy
  - Atherectomy
  - Drug-eluting stents, balloons
    - Promising data in early studies
  - Gene and cell-based therapies
- Remains the greatest unmet need in Vascular Intervention

**Disclosures**

• NONE
**Risk Factors for Restenosis**

- Female gender
- Long-segment disease (>15 cm)
- Small caliber artery (≤5 mm)
- Extensive calcification
- Stent fracture
- Poor runoff
- Systemic inflammation (e.g. elevated hsCRP)
- Diabetes (?)

**Strongest Predictors of Endovascular Treatment Failure in PAD**

- POOR SELECTION
- OVERUTILIZATION OF INTERVENTIONS- ESPECIALLY IN CLAUDICATION

**Improving Technology for PVI**

- Needed to address current limitations
  - Atherosclerotic burden, calcification
  - High rates of restenosis
  - High prevalence of permanent implants; challenges of ISR
- Evolution of Balloon Angioplasty for PVI
  - Improve lumen gain
  - Reduce dissection
  - Reduce Restenosis rates
- Improvements in stents for femoropopliteal disease
  - Drug elution to reduce restenosis
  - Woven nitinol design to increase flexibility and reduce fracture in highly mobile vessels
Improving Technology for SFA Disease

Options for TASC C/D SFA Disease

In-Stent Restenosis: The Ongoing Challenge for Vascular Intervention

**Fig. 2.** Rates of Restenosis by ISR Classification. Overall restenosis rates were high. Type III (total occlusion of the stent) ISR was associated with higher rates of recurrent restenosis than type I or type II ISR.

**Proportion of all LEB (N=3,504) performed as secondary procedures, By indication and year**

RESTENOSIS IS THE NEW VASCULAR EPIDEMIC

Impact of Treatment Failure on Surgical Options in PAD

- Many advocate “endovascular first” treatment strategies
  - Presumed harmless as long as bypass targets remain intact
  - Stakes may increase with each PVI
- However, prior work has suggested that bypass following a failed prior peripheral endovascular intervention (PVI) is associated with poorer outcomes

Growing impact of restenosis on the surgical treatment of peripheral arterial disease. Jones D et al; JAH A 2013

Propensity score adjustment included approximately 20 patient-level, anatomic and surgical variables

The difference in outcomes is increasing with observation time
What are the potential explanations for inferior bypass outcomes after PVI failure?

- Systemic Factors (i.e. Bad Patient)
- Being a poor surgical candidate associates with "pushing the envelope" in PVI
- Change in DANA to more distal target
- Embolization of runoff vessels in calf and foot
- Target artery inflammation/injury from catheter and wire manipulations
- Delay in effective revascularization for CLI—further tissue loss, infection worsens limb stage

Fem-tib for limb salvage after failed full metal jacket for claudication (fortunately, did OK)

Was a “bridge burned”? Would 100 of these bypass grafts do as well as 100 fem-pop BPGs?

Is treatment failure worse than the natural progression of disease?

Everything we do has the potential for negative, unintended consequences

Those who don’t manage those consequences may lack full perspective
In treating lifestyle limiting claudication, shared decision-making should include honest discussions about the durability of the intervention and the likelihood of sustained functional improvement, as well as the possible negative sequelae of treatment failure.

Evidence-Based Practice in PAD?

We are going to have to become MORE SELECTIVE about who we treat, and how we treat them, to demonstrate EFFECTIVENESS and VALUE.

[Fewer Procedures, Better Outcomes]