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Intervention for Lower Extremity PAD: When, why and what?!

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Disclosures

I have no financial disclosures related to this talk

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Objectives

1. Discuss indications for intervention for lower extremity PAD.
2. Identify and become familiar with available endovascular therapy options.
3. Become familiar with some open surgical bypass options.
4. Discuss modes of failure for all interventions for lower extremity PAD
5. Have Fun because that's what vascular is all about.

When to intervene?

Tissue loss

- Ulcers on forefoot or toes
- Non healing surgical wounds on foot or distal leg
- Gangrenous changes on foot
- Mixed venous and arterial ulcers

Rest pain

- Pain occurring in forefoot when leg is in neutral position or elevated and improved with dependent position of leg or ambulation.
- Most noted at night when patient is trying to sleep. Will hang foot off bed, sleep in a chair or wake up and walk around

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When to intervene?

Life-limiting Claudication

- Muscle cramping or fatigue that occurs with exercise and is relieved with short periods of rest.
- Does not occur with prolonged standing
- Should be predictable distance by patient.
- “Life-Limiting” is the area of greatest debate
  - Interferes with ability to work or complete ADLs
  - Interferes with activities important to the patient

When to intervene?

Asymptomatic patient

- No indication for performing an intervention on an asymptomatic patient.

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Why do we Intervene?

Prevent limb loss

Improve quality of life through relief of rest pain

Improve quality of life through increased mobility and function

Non-surgical intervention

Walking regimen

Dietary and life style changes

- Smoking cessation
- Diabetes control
- Hypertension control

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Endovascular Intervention

Treatment of choice for focal stenosis or occlusions

Best results are in more proximal lesions (Iliac and SFA)

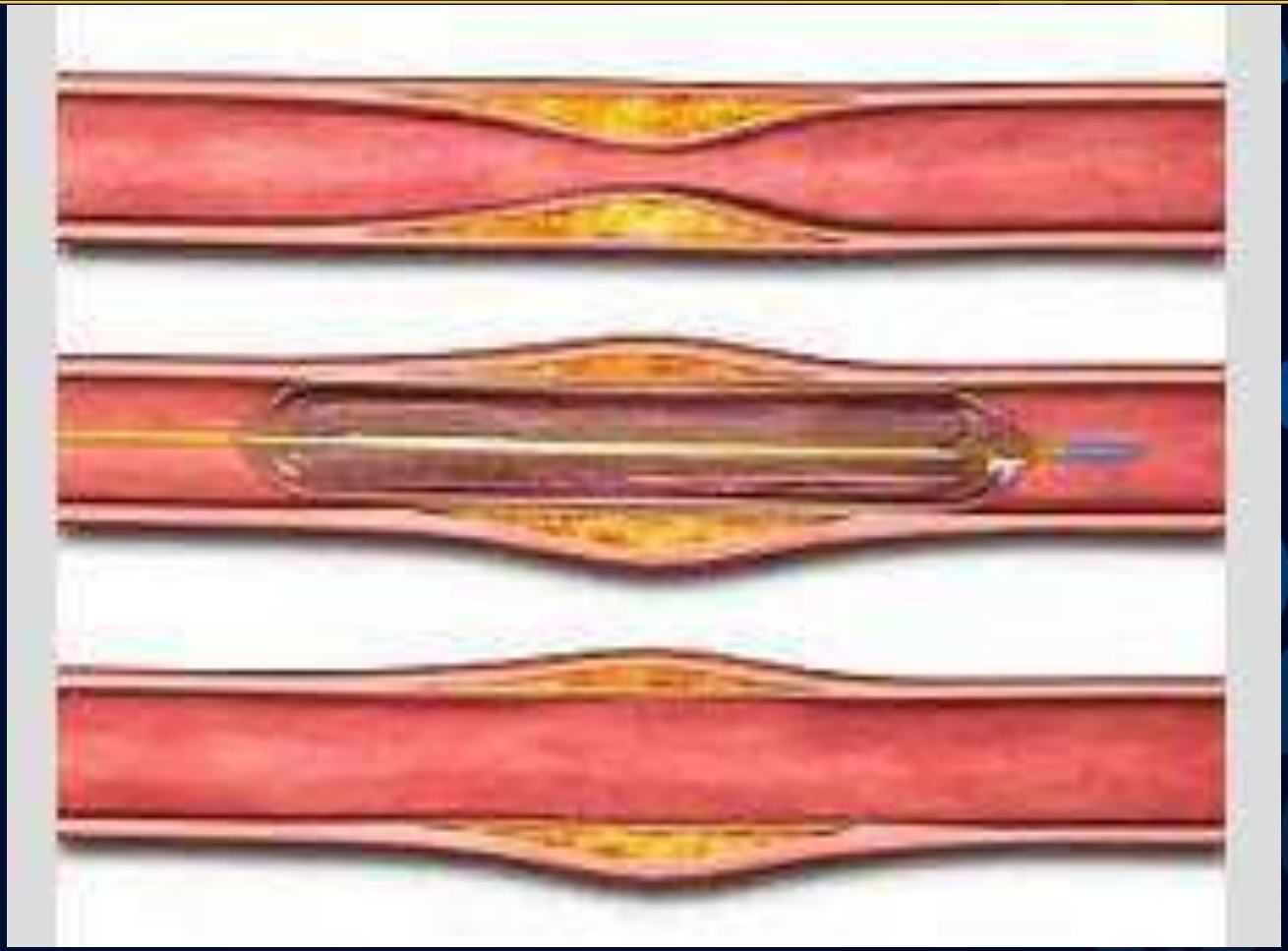
We often have an “Endo First” mentality and will attempt endovascular intervention first if possible regardless of length of lesion

Endovascular options

Percutaneous Transluminal Angioplasty (PTA)

- Balloon catheter is advanced across the lesion and balloon is inflated to fracture plaque and dilate the lumen.
- Cutting balloon has steel blades mounted on balloon to create cuts in the plaque or intimal hyperplasia.
- Drug Eluting Balloon (DEB) has chemotherapeutic chemical imbedded on the balloon which is released into the tissue to decrease rates of recurrence from intimal hyperplasia

PTA



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PTA results

Device	12 month Patency	24 months Patency
Plain Balloon	52%	50%
Drug coated balloon	82%	79%

Atherectomy

Removal or ablation of plaque to restore lumen

Several devices available

- SilverHawk atherectomy
  - Directional blade to excise plaque
- CSI Diamondback
  - Rotating diamond burr to fragment the plaque
- Laser atherectomy
  - Vaporizes plaque
- Jetstream
  - Rotating burr and suction to remove plaque and thrombus

Atherectomy Devices

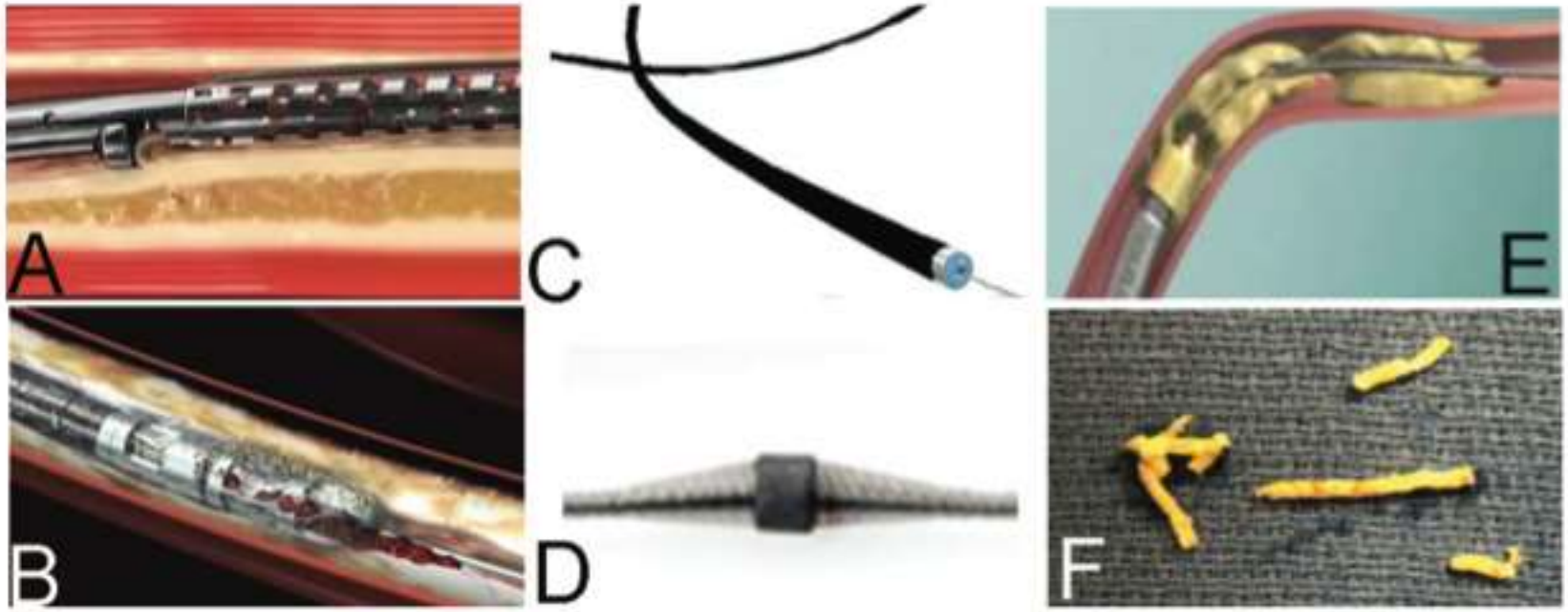

Figure 1. **(A)** *SilverHawk device.* **(B)** *Jetstream Pathway system.* **(C)** *Turbo Elite excimer laser atherectomy device.* **(D)** *Orbital atherectomy burr of the CSI Diamondback 360°.* **(E)** *Phoenix atherectomy device.* **(F)** *Atheroma debris extracted with directional atherectomy.*

Atherectomy devices

TABLE 2. COMPARISON OF PROPERTIES OF DIFFERENT ATHERECTOMY DEVICES

	JETSTREAM™ Atherectomy System (Boston Scientific Corporation)	Peripheral Rotablator™ Rotational Atherectomy System (Boston Scientific Corporation)	Diamondback 360™, Stealth 360™ Atherectomy System (Cardiovascular Systems, Inc.)	SilverHawk™, TurboHawk™ Plaque Excision System (Medtronic)	Turbo-Elite Laser™ Atherectomy Catheter (Spectranetics Corporation)
Front cutting	✔	✔			N/A
Differential cutting	✔	✔	✔		N/A
Active aspiration	✔				
Concentric lumens	✔	✔			
Lesion morphology:					
Calcium	✔	✔	✔	✔ (large vessel only)	✔
Thrombus	✔				✔

Sources: Endovascular Today Buyer's Guide 2014. JETSTREAM System Brochure, Boston Scientific Website, 2014. Peripheral Rotablator product website, Boston Scientific, 2014. Diamondback 360 product website, CSI, 2014. Covidien website, Directional Atherectomy products, 2014. Turbo-Elite Laser Atherectomy Catheter Instructions for Use, May 2014.

Laser atherectomy results

Table 4. Laser atherectomy studies.

Study	Patients			Lesion Length (cm)	Inter	Adjunctive Therapy		Results at 12 Months			MAE at 12 Months	
	Age (y)	No.	Stage (R)			PTA	Stent	Endpoint	PP	TLR	Amp	Death
PATENT[39,b]	69.5	90	2-5	12.3	LA+PTA	NA	2.2%	MAE, PP	43%	27%	0%	5.5%
CELLO[37,a]	68±10	65	1-3	5.6±4, 61.5% moderate to severe calcium, 20% occlusions	CliRpath	64%	23%	decrease in diameter stenosis	54%	23%	0%	0%
SALVAGE[38,a]	70±10	27	2-5	20±10	LA+ PTA + Endoprosthesis	No	PP MAE	48%	17%	TBA	TBA	TBA
LACI[41,a]	72±10	145	4-6	11	LA+ PTA with provisional stent	NA	45%	limb salvage	NA	8%	6%	10%
Stoner et al[42,b]	62±8	40	3-5	NA	LA ± PTA/ stent	75%	13%	limb salvage	44%	23%	27%	NA
Shutze et al[40,43,c]	≥18	200	4-6	TBA	LA vs PTA with provisional stent	TBA	TBA	PP	TBA	TBA	TBA	TBA

[a]Prospective multicenter; [b]Registry; [c]Prospective, single-center, randomized study. MAE = major adverse events at 12 months (except for LACI, which reported data at 6 months); LA = laser atherectomy system; NA = none applicable or found in the study publication; TBA = data not released for publication or study under current enrollment; PATENT = photoablation using the TURBO-Booster and Excimer Laser for In-stent Restenosis Treatment; CELLO = CliRpath Excimer Laser System to Enlarge Lumen Openings; SALVAGE = See reference 38; LACI = Limb Salvage Following Laser-Assisted Angioplasty for Critical Limb Ischemia. Other abbreviations as in Table 3.

Atherectomy and Drug coated balloon

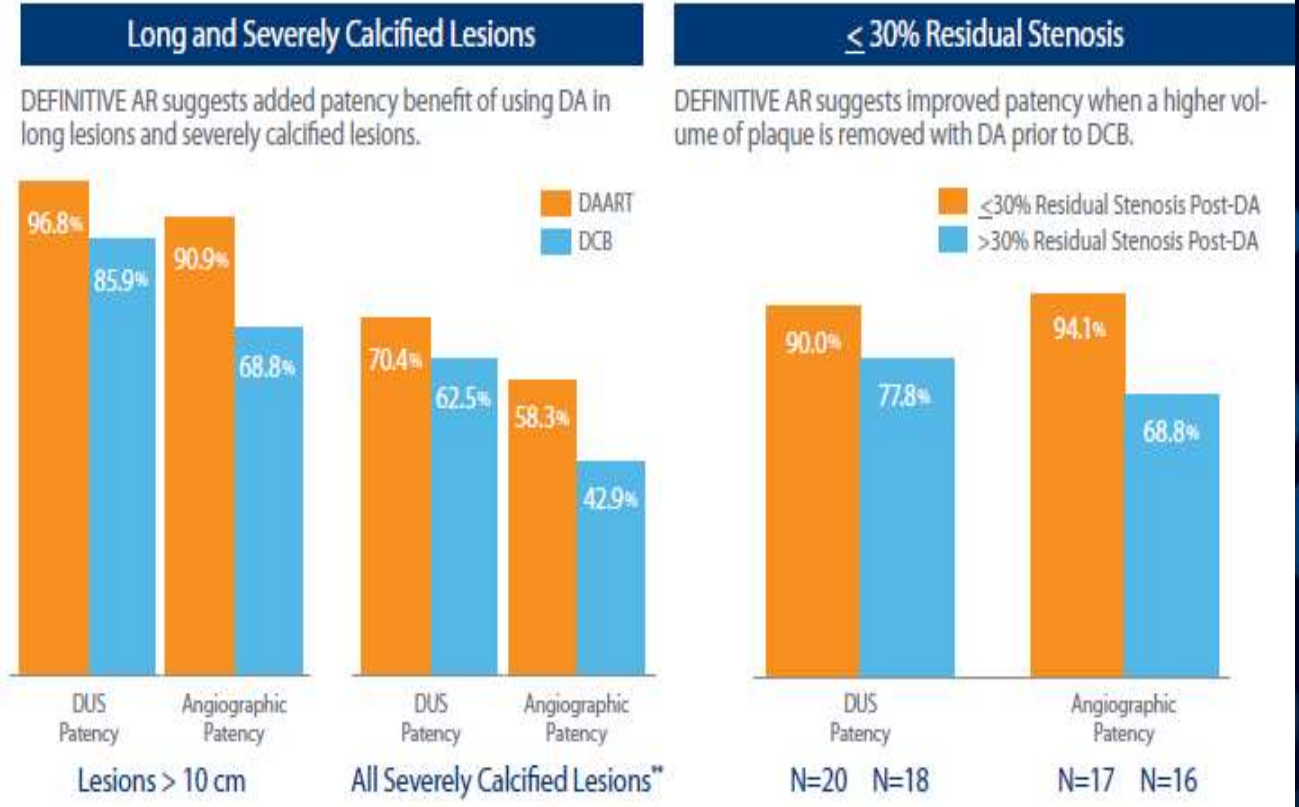

Figure 2. Twelve-month patency outcomes in patients who received directional atherectomy followed by a DCB versus patients who received DCB only.

Stents

Balloon Expandable Stents

- Mostly used in Common Iliac artery due to high radial force and lack of vessel mobility
- Mounted on a balloon and is deployed by inflation and deflation of balloon

Self expanding stents

- Most common for external iliac, SFA and popliteal lesions
- Nitinol cage that expands to premade size when exposed to body temperature
- May be drug coated to decrease restenosis

Bare Metal Stents

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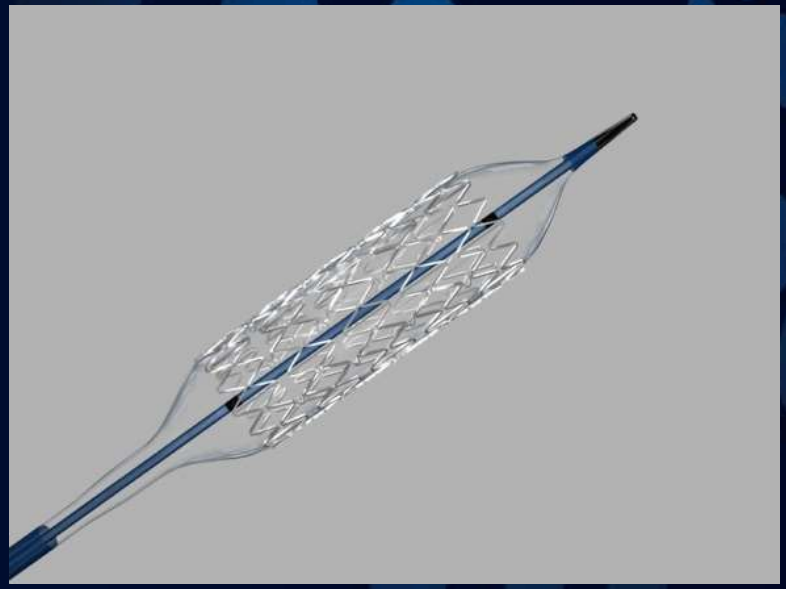
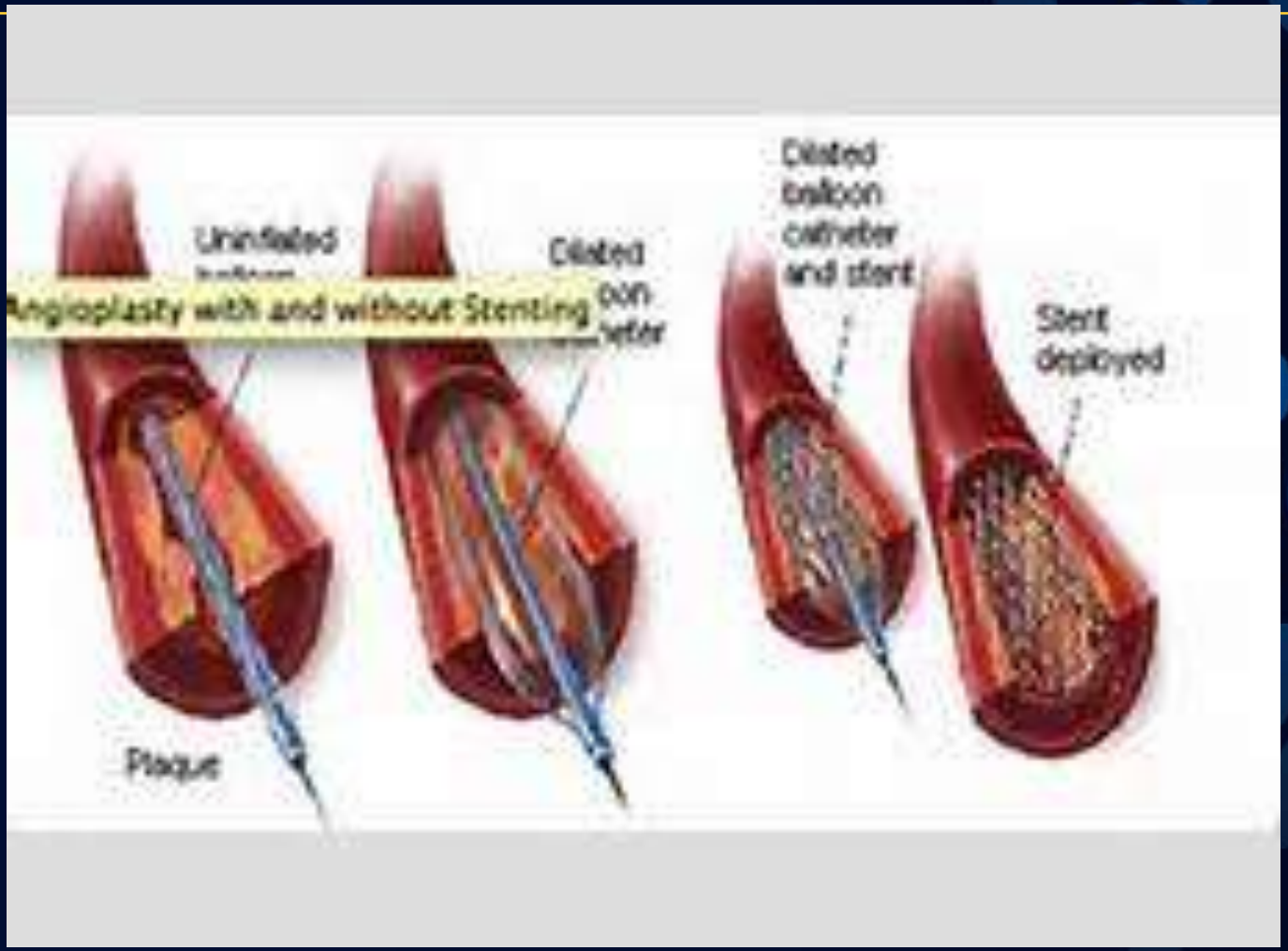
Self-expanding

Balloon expandable



Balloon Expandable Stent



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Stenting Results

Device	12 month patency	24 month patency	60 month patency
Plain Stent	73%	61%	19%
Drug coated	90%	83%	65%

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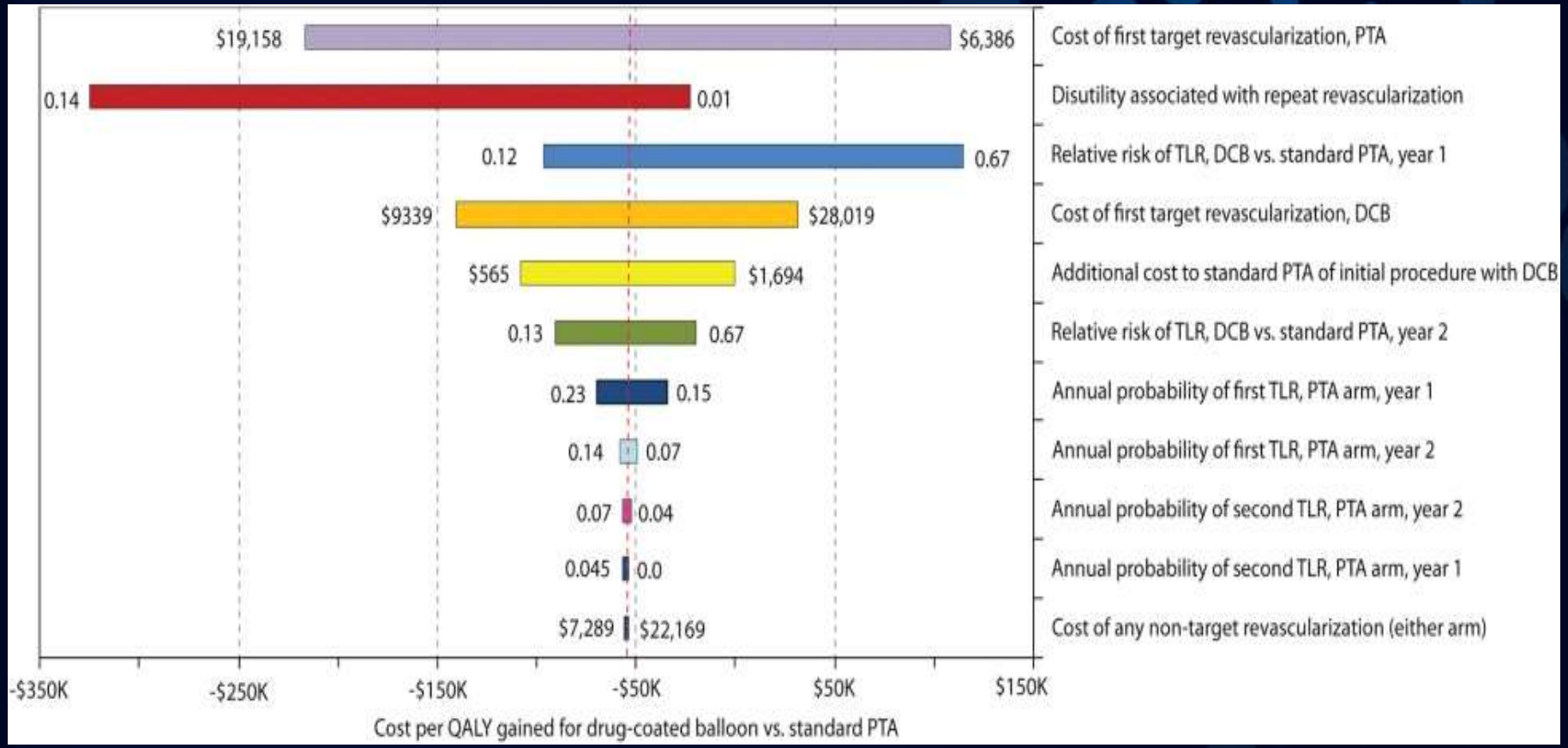
Costs of stenting



Stent results based on Lesion length

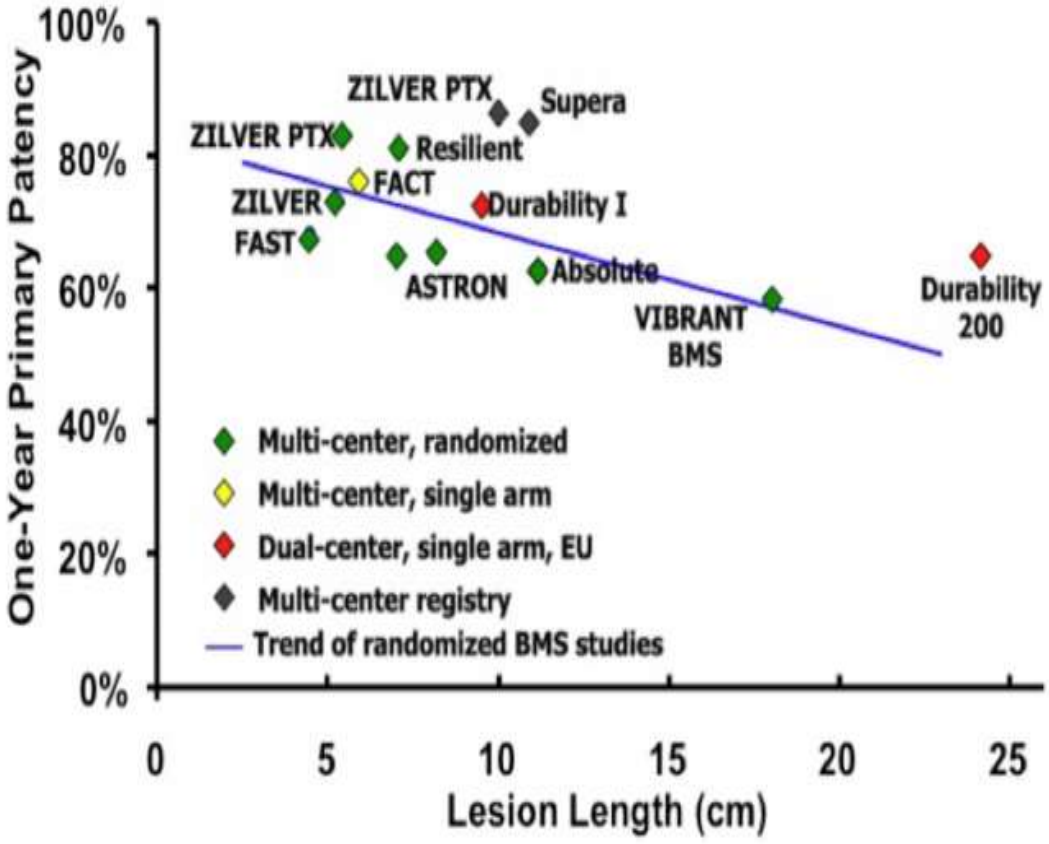
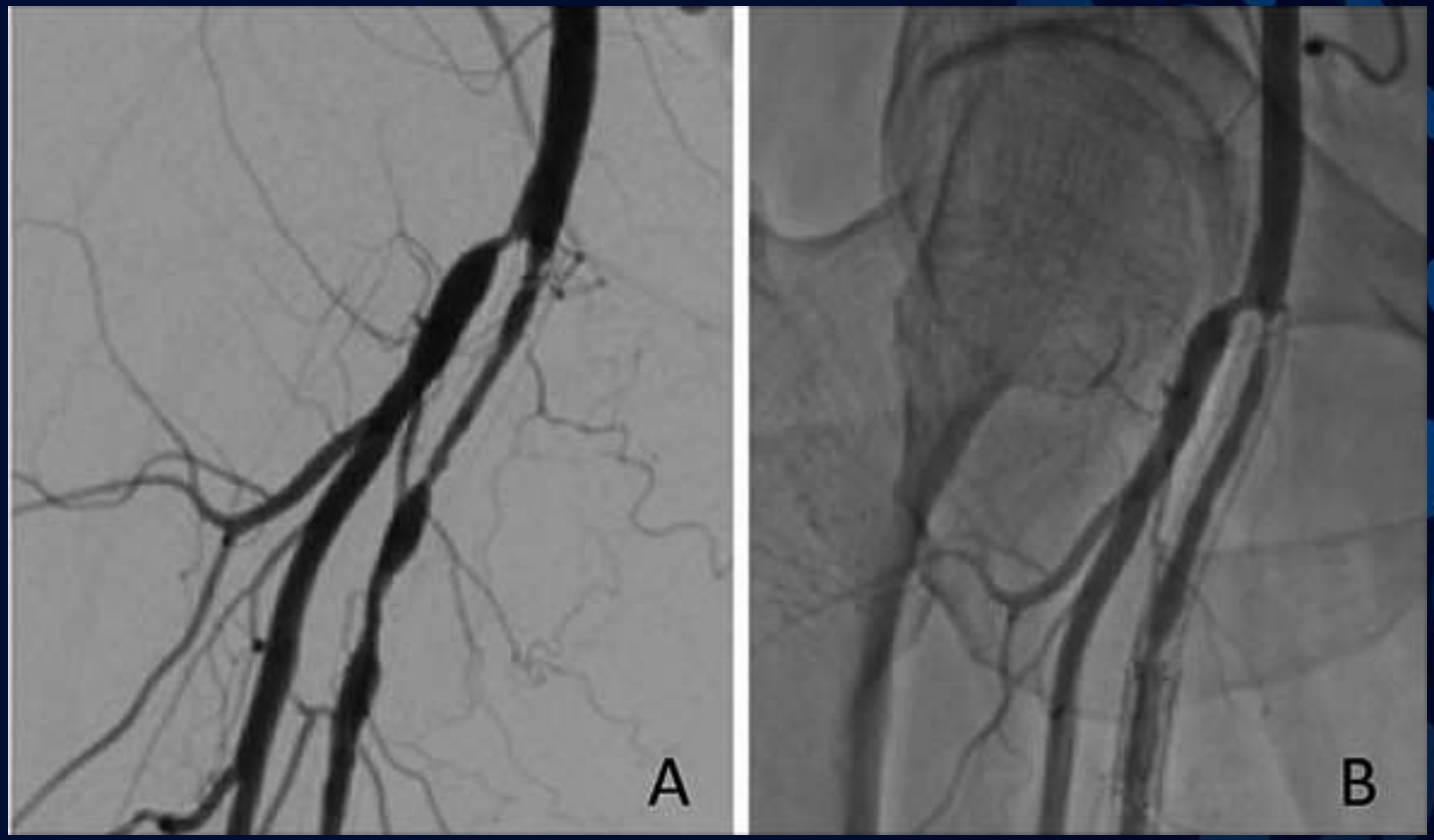


Figure 1. Primary patency in superficial femoral artery stenting.

In stent stenosis



Covered Stents

Metal stent frame is covered by a lining over the stent.

No intersticies in mid portion of stent

Often used for aneurysm disease, perforation or vessels with thrombus or heavily calcified

Eliminates in stent stenosis as intimal hyperplasia cannot grow through lining

Covered Stent (graft)

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Self-Expanding

Balloon Expandable

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Covered Stent Patency

Viabahn Self expanding in SFA

- 1 year patency of 79%
- 4 year patency of 55%

Edge stenosis

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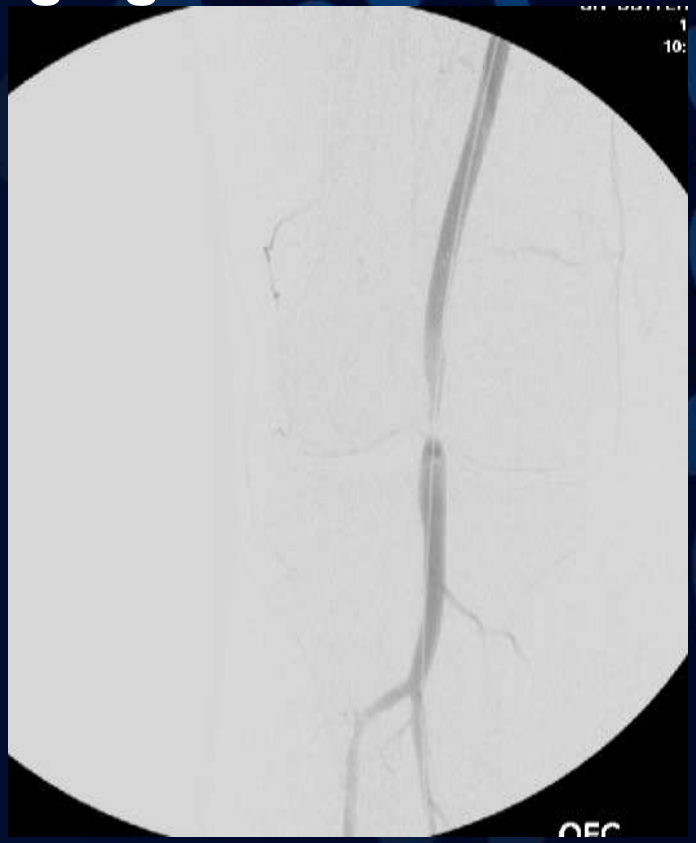
Ultrasound

Angiogram



SFA Surgical Bypass

Can be performed with autologous vein, PTFE, Dacron, Cryopreserved artery or vein

Best results are for autologous vein to above knee popliteal segment

Vein Bypass

Single segment autologous GSV with > 2.5- 3mm diameter is best for conduit

Graft Orientation may be:

- Reversed
- In-situ
- Transposed, non-reversed

Tunneling

- Anatomic
- Extra-anatomic

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Endoscopic Vein Harvest

RGSV Bypass

GSV is removed entirely from bed and turned around. SFJ is sewn to distal anastamosis

- Advantages:
  - Valves open with flow and therefore less potential damage
  - Faster
- Disadvantages
  - Size mismatch at each anastamosis may lead to velocity elevations on follow-up duplex

In-Situ

GSV is left in its anatomic bed with minimal mobilization except for proximal and distal ends to allow for anastamosis

- Advantages:
  - Vein is left in native tissue so lower chance of ischemia and stenosis
  - Size match is more anatomically correct
  - Graft lies in GSV plane so easy to follow with duplex
- Disadvantages:
  - Management of side branches
  - Need to lyse the valves

Transposed, Non-reversed

GSV is removed from its bed and prepped then tunneled with SFJ at proximal end

- Advantages
  - Better size match at anastamosis
  - Able to easily ligate side branches
- Disadvantages
  - Need to lyse valves
  - Increased risk of vein ischemia as it is removed from native bed

Tunneling

Anatomic: Graft is passed under the sartorious muscle in the normal path of the SFA

- Advantages:
  - Graft is protected by muscle and away from skin
  - Straighter path so less likely to have elevated velocities due to change in path
- Disadvantages:
  - May traverse muscle which can lead to failure
  - Scar tissue from prior intervention on SFA may impinge graft
  - Need to pass tunneler along SFA/SFV

Tunneling

Extra-Anatomic: Graft is passed in plane other than along native vessels (usually superficial)

- Advantages:
  - Less risk of vessel injury or impingement from scar tissue
  - Easier to follow postoperatively as it is superficial
- Disadvantages:
  - Closer to skin and may have higher likelihood of infection/injury if wound dehiscence
  - Graft has to dive through muscle layer to reach artery for anastamosis

Vein graft failure

Early: Technical issue with anastamosis or vein tunneling

- Twist or kink in vein graft, dissection at anastomosis , clamp injury to native vessel above or below graft, incomplete valve lysis

Late: Intimal hyperplasia within the graft or at anastamosis

Very late: Progression of atherosclerosis in native vessels

Prosthetic Bypass

Synthetic graft used as conduit for bypass

Dacron or PTFE

Advantages:

- readily available
- faster surgery with less incisions than vein bypass

Disadvantages:

- Patency rates are not as good, especially below the knee
- Higher risk of infection if wound complication occurs

PTFE bypass

End-to-side anastamosis

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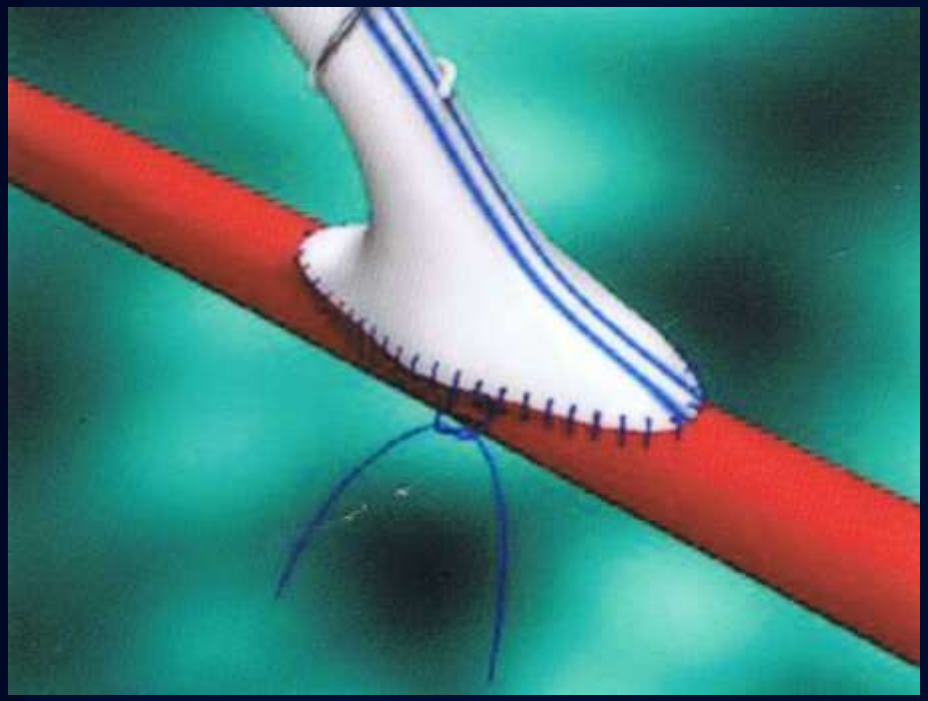
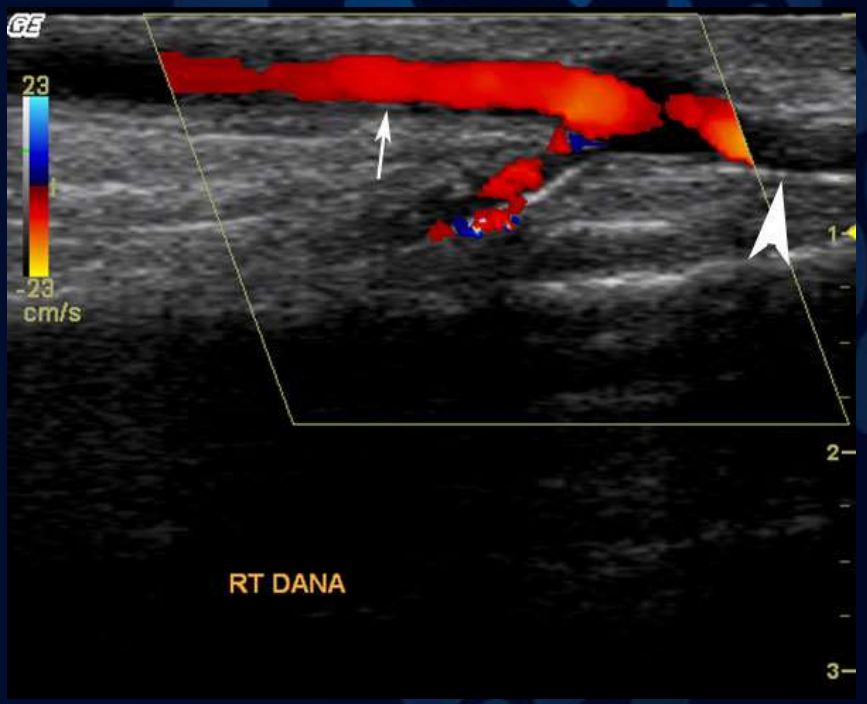
End-to-side Anastmaosis



Ultrasound of end-to-side



Prosthetic Graft failure

Early: clamp injury, technical failure

Late: Intimal hyperplasia at anastamoses

Most likely at the distal anastamosis

When do I choose Surgical Bypass?

For femoral disease

- Treatment of choice if significant CFA disease in conjunction with SFA occlusion
- After failed endovascular intervention
- Long segment SFA disease with heavily calcified plaque

Results of Fem-AK Pop Surgical Bypass

	4 year (Primary)	5 year (secondary)
PTFE	47%	84%, 79%
Vein	73%	70%, 88%

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Ultrasound Cheat Sheet

Device/Procedure	Examples	Failure Location	Comments
PTA	Plain balloon, Cutting balloon, DCB	Site of PTA	Dissection, rebound stenosis, intimal hyperplasia
Bare metal Stent	Balloon expandable, self expanding, drug eluting	In-stent stenosis	Intimal hyperplasia in hourglass configuration
Atherectomy	Silverhawk, CSI, Laser	Anywhere along the treated area	Intimal hyperplasia
Covered Stents	Icast, Viabahn, Gore VBX	At the ends of the stent	“Sausage” link
Vein Bypass	Reversed GSV, In-situ, transposed, cadaveric	Anywhere along the the vein graft	Short areas of intimal hyperplasia or valve leaflet
Prosthetic Bypass	Dacron, PTFE	At the anastamoses	Intimal hyperplasia

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Questions/ Comments

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I would like to thank the program committee of the Michigan Sonographers Society for the opportunity to be part of your meeting today.