Modern Management of the Diabetic Foot

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Alice Shen PGY2, University of Ottawa

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Presenter Disclosure

Presenter: Alice Shen

- I have no current relationships with commercial entities

What is the Diabetic Foot

Diabetes is on the Rise!

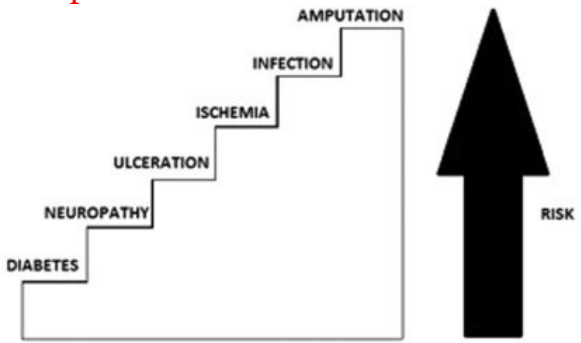
- International Diabetes Federation estimates over 700 million will have diabetes in the world by 2045

World Health Organization definition:

- Diabetic foot as the condition of infection, ulceration, and/or destruction of deep foot tissue associated with neurologic abnormalities and varying degrees of peripheral vascular disease of the lower extremities in a patient with diabetes mellitus

Diabetes is Costly

- 20% will require hospitalization for diabetic foot complications (1)
- 2.5% risk of developing a diabetic foot ulcer annually (1), lifetime risk of 25% (2)
- Those with diabetic foot ulcer are at high risk (85%) of amputation (3)
- 40% of those with major amputation will undergo amputation of contralateral limb within 3 years (4)
- Patients with diabetic foot ulcer have annual mortality rate of 10% → 20% with amputation
- Post-amputation mortality at 27 months with diabetes vs. 47 months (4)



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2) Reiber, G.E., 1996. The epidemiology of diabetic foot problems. Diabetic medicine, 13, pp.S6-S11.
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Diabetic Foot Pathophysiology

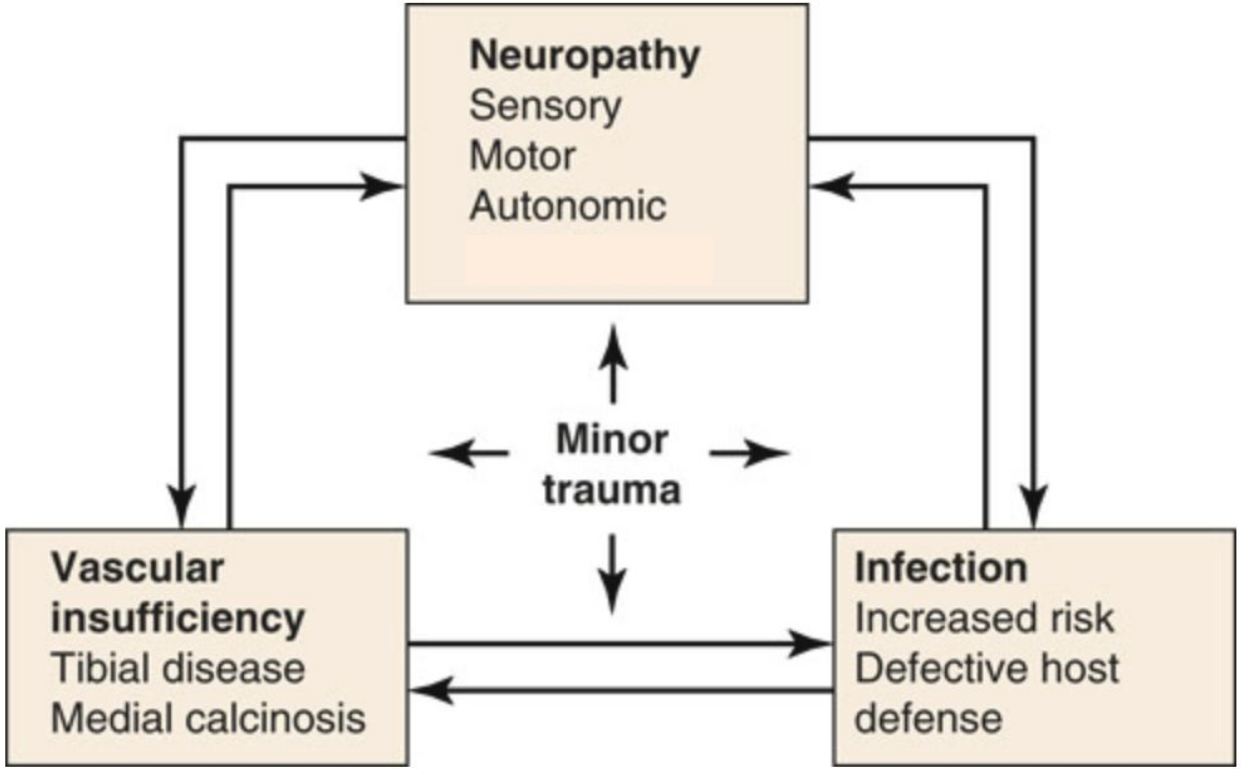


FIGURE 116.1 Multifactorial Etiology of Diabetic Foot Pathology.

Diabetic Foot Pathophysiology

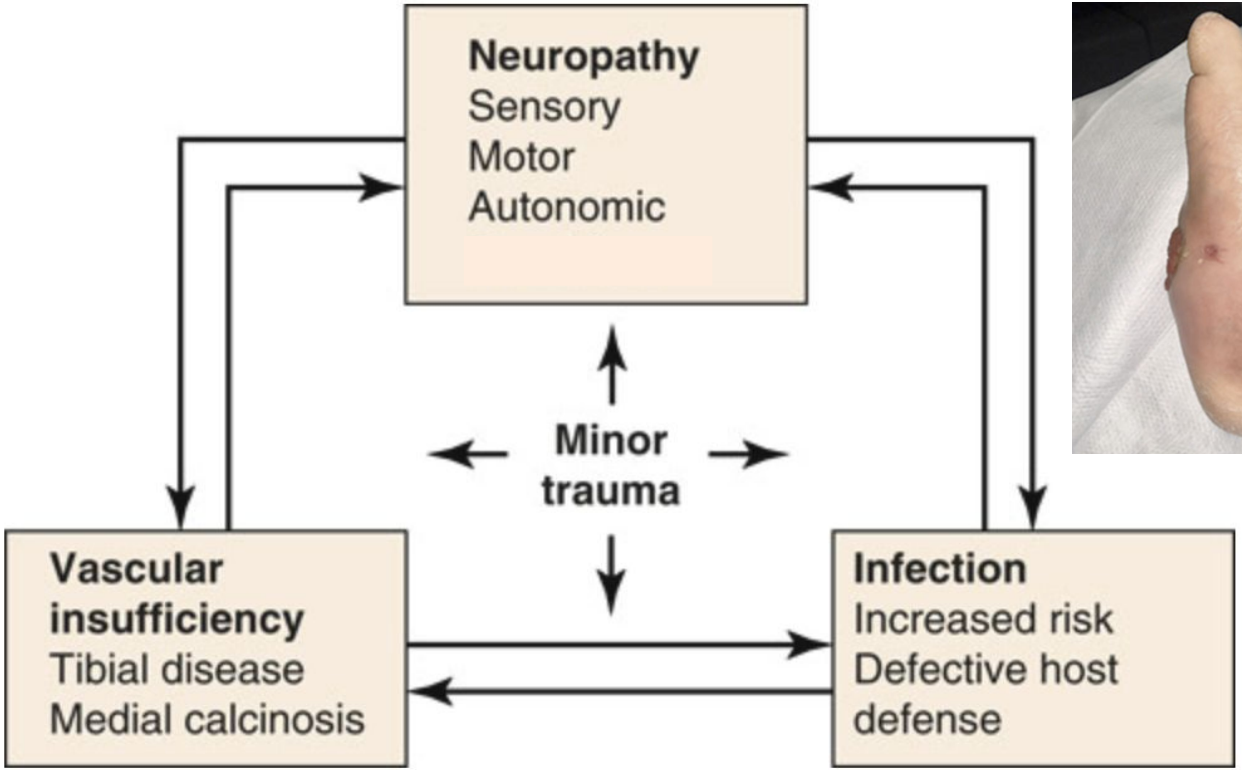


FIGURE 116.1 Multifactorial Etiology of Diabetic Foot Pathology.

Making the Diagnosis

Diagnostic Approach:

Comprehensive Clinical History and Physical Exam

Taking a focused history to assess PVD, wound history, triggering factors, CVS risk factors, and examine the foot for signs of ischemia, palpate the foot pulses.

Performing pedal Doppler waveforms in combination with ankle brachial index (ABI)

Making the Diagnosis

Modern Diagnostic Approach:

Comprehensive Vascular Assessment

Utilizing imaging techniques, such as duplex ultrasound (first line, including toe pressure), CTA, MRA or diagnostic angiography to evaluate the vascular status and identify any obstructions or impaired blood flow.

Neuropathy Evaluation

Bedside exams, such as looking for atrophy, or using a tuning fork/perform the Semmmes-Weinstein monofilament test. Can also employ nerve conduction studies to assess the extent of peripheral neuropathy, a key contributor to diabetic foot complications.

Wound Assessment

Incorporating wound measurement, wound bed evaluation, and wound culture analysis to determine the severity, underlying causes, and presence of infection to guide appropriate treatment strategies for diabetic foot ulcers.

Biomechanical Analysis

Utilizing gait analysis, pressure mapping, and other biomechanical assessments to identify areas of high pressure and altered foot mechanics, which can inform off-loading strategies.

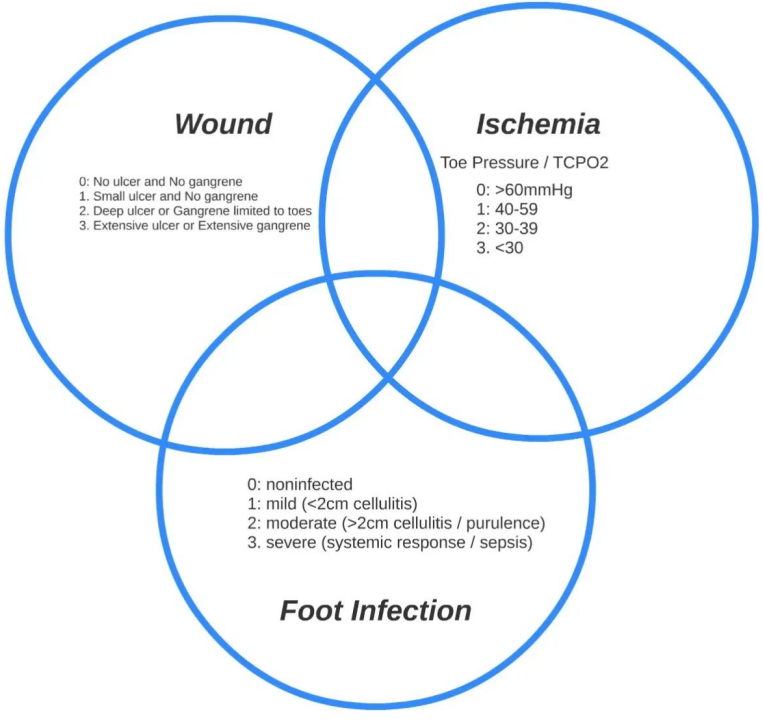
The Hub and Spoke Model

Integrating a system of comprehensive team of specialists, including vascular surgeons, podiatrists, wound care experts, primary care physicians, and rehabilitation professionals, to ensure a holistic assessment and surveillance program in order to catch deteriorations early, expedite investigations and coordinate a tailored treatment plan.

Tools to Assess Diabetic Foot Ulcers

Clinical Classification Tools:

- *Wagner*
- *PEDIS*
- ***WIFi***



a, Estimate risk of amputation at 1 year for each combination

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

b, Estimate likelihood of benefit of/requirement for revascularization (assuming infection can be controlled first)

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	VL	VL	VL	L	L	M	L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M	M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	H	H	H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

fI, foot Infection; I, Ischemia; W, Wound.

Premises:

1. Increase in wound class increases risk of amputation (based on PEDIS, UT, and other wound classification systems)
2. PAD and infection are synergistic (Eurodiale); infected wound + PAD increases likelihood revascularization will be needed to heal wound
3. Infection 3 category (systemic/metabolic instability): moderate to high-risk of amputation regardless of other factors (validated IDSA guidelines)

Four classes: for each box, group combination into one of these four classes

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4
Clinical stage 5 would signify an unsalvageable foot

GUIDELINE RECOMMENDATIONS

Global Vascular Guidelines on Management of CLTI (2019)

5. The Global Limb Anatomic Staging System (GLASS) for CLTI			
5.1	Use an integrated, limb-based anatomic staging system (such as the GLASS) to define complexity of a preferred target artery path (TAP) and to facilitate evidence-based revascularization (EBR) in patients with CLTI.	Good practice statement	
6.6	Use an integrated threatened limb classification system (such as WIfI) to stage all CLTI patients who are candidates for limb salvage.	1 (Strong)	C (Low)

- In average risk patient, if WIFi stage 3 or 4, (or if low WIFi stage but high ischemia grade) → offer revascularization
- In patients with low WIFi stage, and significant wound grade, or if wound fails to heal by 50% reduction in 4 weeks with appropriate wound care → consider revascularization

Guideline Recommendations

Intersocietal Guidelines on PAD in people with diabetes foot ulcer(2023)

Recommendation 10	
In a person with diabetes, peripheral artery disease, and a foot ulcer or gangrene, consider using the Wound/Ischaemia/foot Infection (WIfI) classification system to estimate healing likelihood and amputation risk.	
Grade	Certainty of evidence
Conditional	Low

Guideline Recommendations

Intersocietal Guidelines on PAD in people with diabetes foot ulcer(2023)

Recommendation 19	
In a person with diabetes, peripheral artery disease, and a foot ulcer or gangrene, revascularisation procedures should aim to restore in line blood flow to at least one of the foot arteries.	
Grade	Certainty of evidence
Best Practice Statement	

Guideline Recommendations

Intersocietal Guidelines on PAD in people with diabetes foot ulcer(2023)

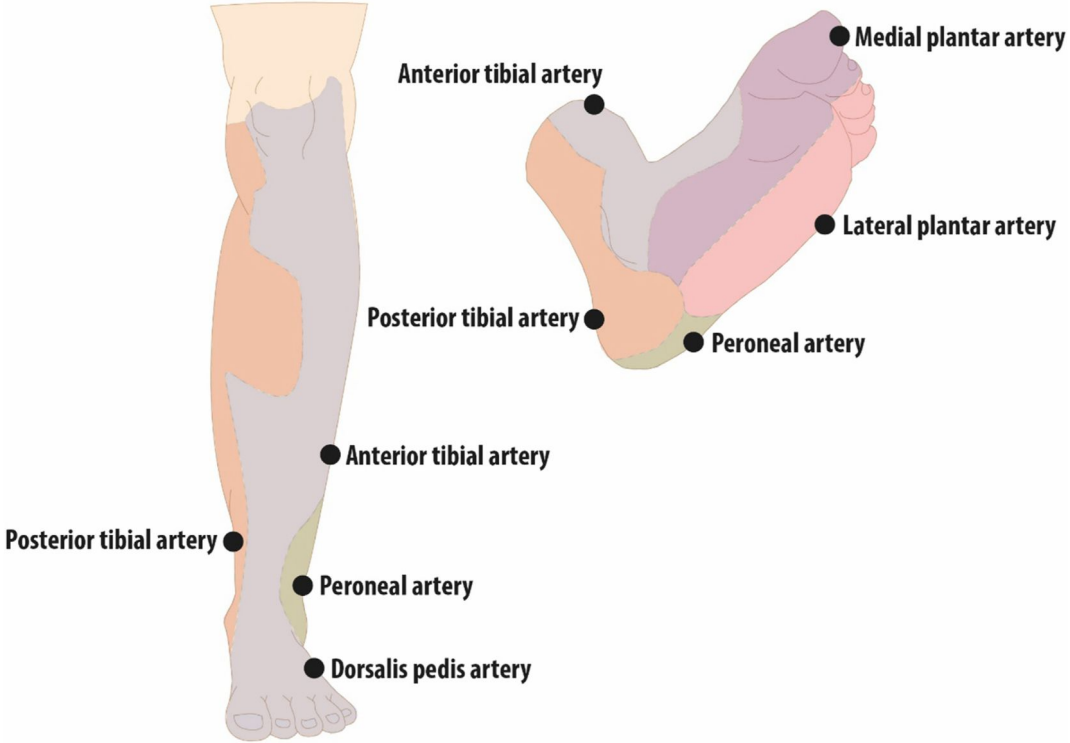


Figure 3. Angiosome distribution in the lower leg and foot.

Management of the Diabetic Foot

Comprehensive Management Approaches:

- Attacking all fronts in a multidisciplinary Continuum

If there is evidence of ischemia, or no improvement after appropriate wound care x 4 weeks, then assess and revascularize to restore blood flow and improve tissue perfusion

Treating for infection

Management of diabetes (HbA1C < 8), LDL cholesterol control, antiplatelet therapy (Clopidogrel)

Optimizing nutrition and vitamin supplementation for wound healing

Comprehensive wound management strategies, including advanced dressings, debridement, and moisture control, to promote healing and prevent complications

Techniques to relieve pressure and redistribute weight, such as offloading footwear or devices, total contact cast and appropriate wearable shoe, to facilitate wound healing and prevent further tissue damage.

Coordination of care involving a team, including surgeons, medical specialists, primary physicians, wound care specialists, allied health workers to provide comprehensive treatment and limb preservation program

Guideline Recommendations

Intersocietal Guidelines on PAD in people with diabetes foot ulcer(2023)

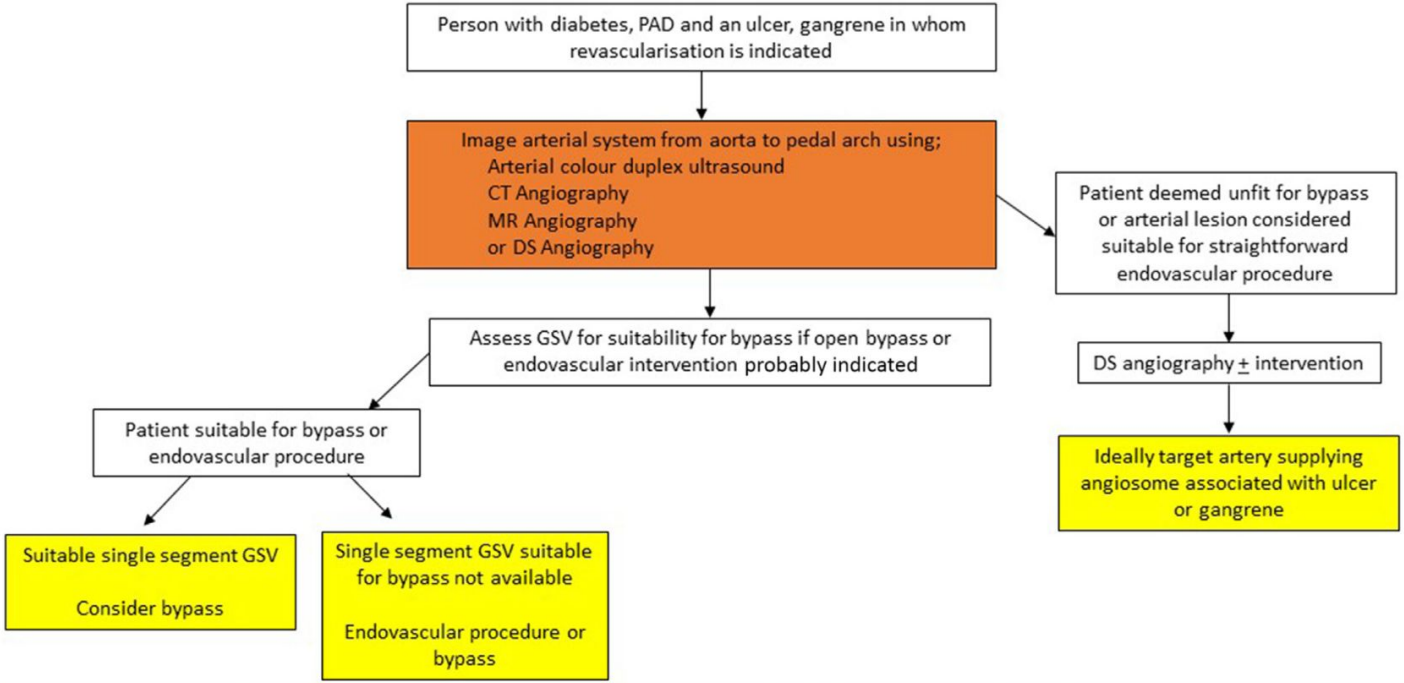
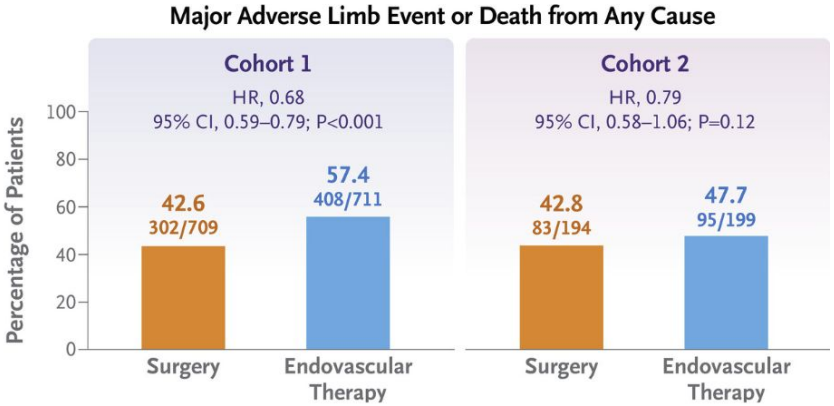


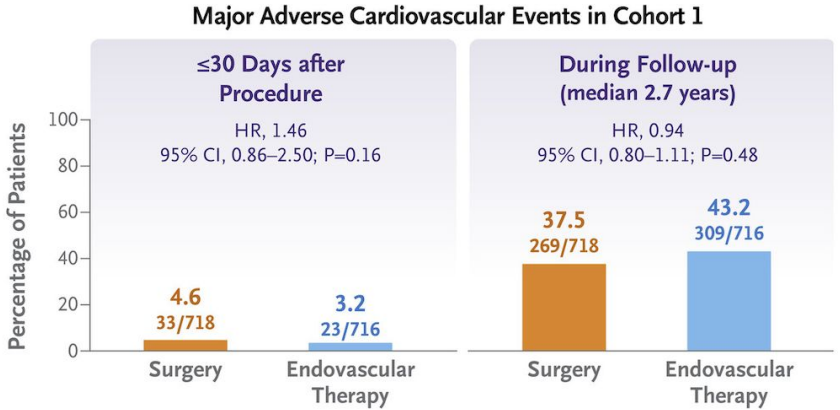
Figure 2. Approach to vascular intervention for a person with diabetes and a foot ulcer or gangrene. Yellow = Conditional Recommendation; gray = Best Practice Recommendation; PAD = peripheral artery disease; CT = computed tomography; GSV = great saphenous vein; MR = magnetic resonance; DS = digital subtraction.

Management of the Diabetic Foot

Surgical vs. Endovascular Revascularization?

- BEST-CLI trial
  - International RCT, n= 1830 followed up to 7 years, median 2.7 years
  - Cohort 1: available single GSV conduit vs. Cohort 2: alternative conduits must be used
    - Best surgical treatment vs. best endovascular treatment in each cohort
  - Primary outcome: MALE (composite of major amputation + re-intervention) & all cause mortality





  - Relevance to diabetic foot:
    - 71.8% of pt in cohort 1 vs. 60% in cohort 2 had diabetes
    - ~66% infra-popliteal disease
    - ~70% had tissue loss
  - Limitations:
    - Local center variation on deciding equipoise, operator bias related to treatment decision and technical success, higher technical failure rate in the endo treatment group…

Surgical vs. Endovascular Revascularization?

- BASIL-2 trial
  - Multicenter European RCT, n = 345 followed for 40 months
  - Compares vein bypass group vs. best endovascular treatment among patients with CLTI requiring treatment of infrapopliteal disease
    - Anticipated life expectancy of 6 months or more

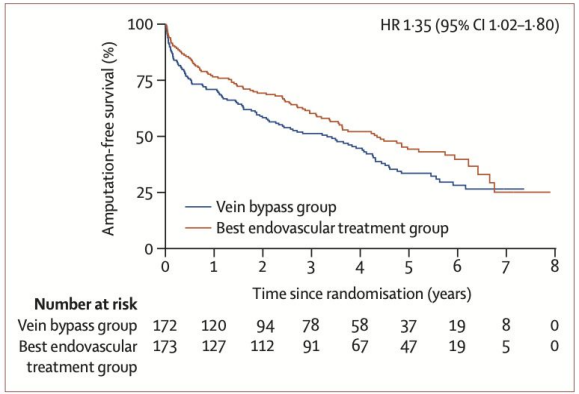


Figure 2: **Amputation-free survival Kaplan-Meier curve**
HR=hazard ratio.

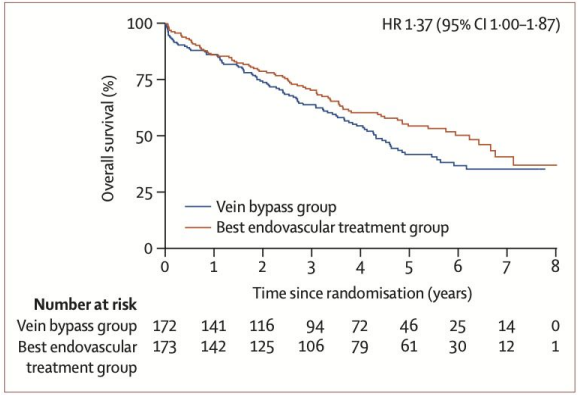


Figure 3: **Overall survival Kaplan-Meier curve**
HR=hazard ratio.

- Similar percentage of patients with diabetes (~70%), ~70% had tissue loss in both groups
- Main differences: all had infra-popliteal disease, average age is older (72 vs. 66), those that randomized to surgery had higher prevalence of prior MI (24% vs. 13% in endo). Higher prior intervention rate ~30% in the index limb. Higher rate of IR performing procedure (80%). Did not include re-intervention rate…

Management of the Diabetic Foot

Surgical vs. Endovascular Revascularization = an Ongoing Debate

1. First line management is center and operator dependent
2. Patient selection is crucial
3. Fem-pedal bypass is a durable option to consider for the right patient
4. Incorporating WIFi classification and GLASS score can help improve comparison in future studies

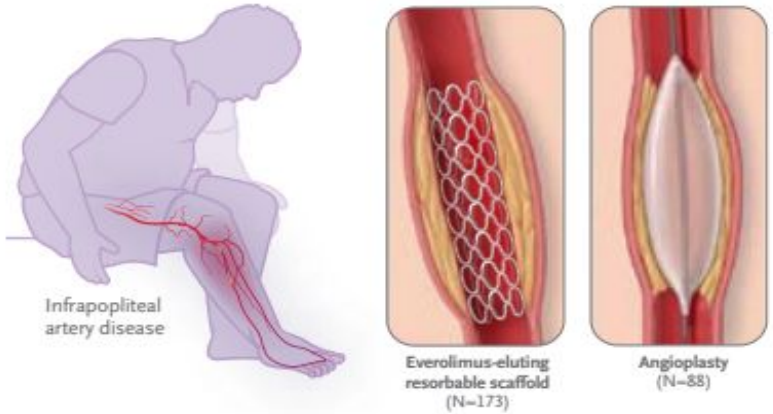
Management of the Diabetic Foot

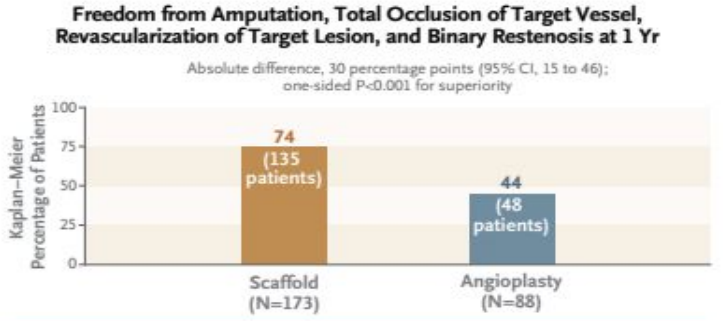
Emerging Endovascular Treatment:

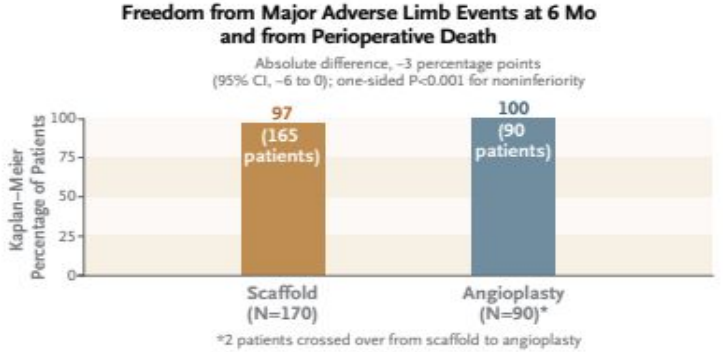
Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease

Varcoe RL et al. DOI: 10.1056/NEJMoa2305637

- LIFE-BTK trial
  - International RCT, n=261 randomized 2:1







Management of the Diabetic Foot

Emerging Endovascular Treatment:

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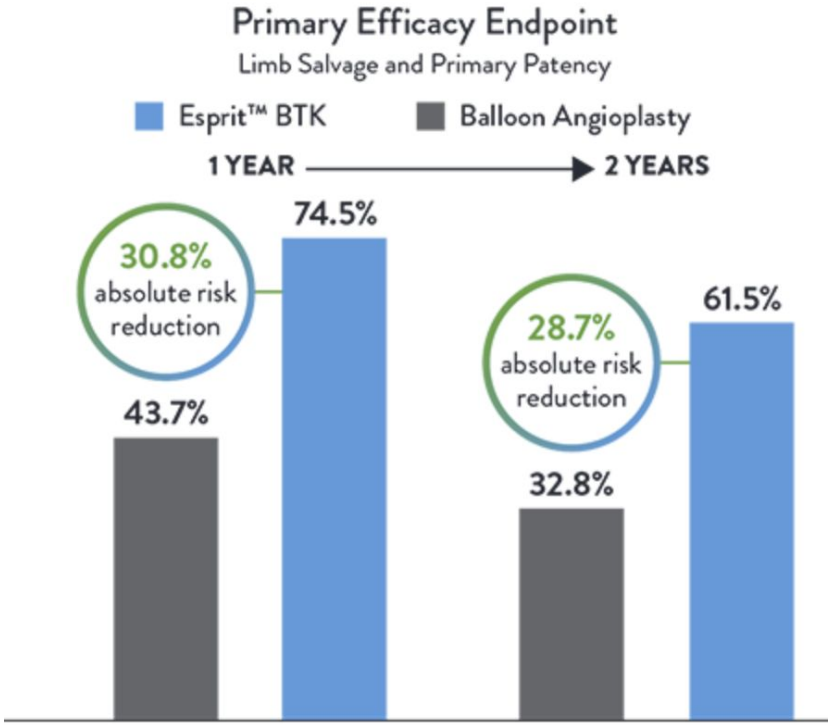
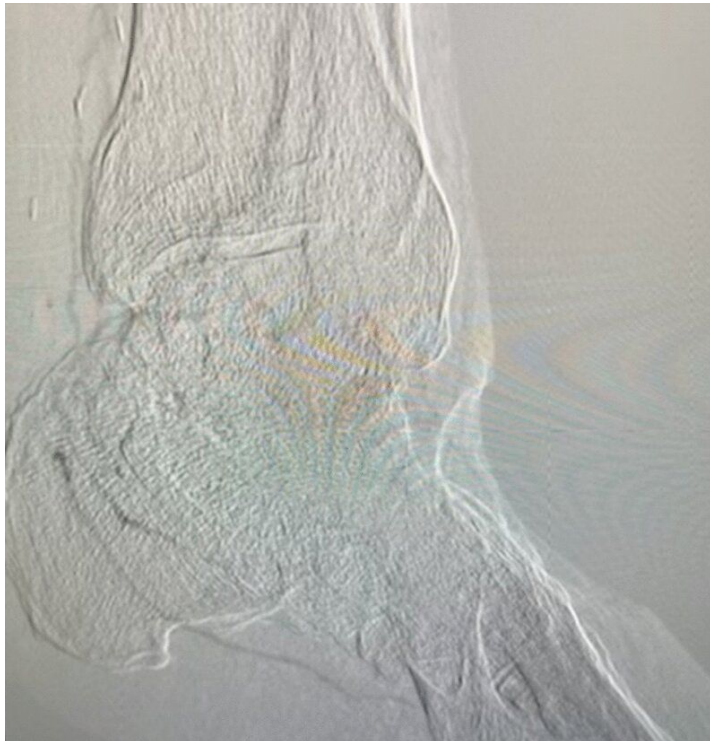
Varcoe RL et al. DOI: 10.1056/NEJMoa2305637

- LIFE-BTK trial
  - International RCT, n=261 randomized 2:1
- Wound healing was observed in 37 of 83 patients (45%) in the scaffold group by 1 year, with a mean time to healing of 196.7±130.1 days. Wound healing was observed in 25 of 45 patients (56%) in the angioplasty group by 1 year, with a mean time to healing of 187.6±122.7 days.



Management of the Diabetic Foot

The Desert Foot:



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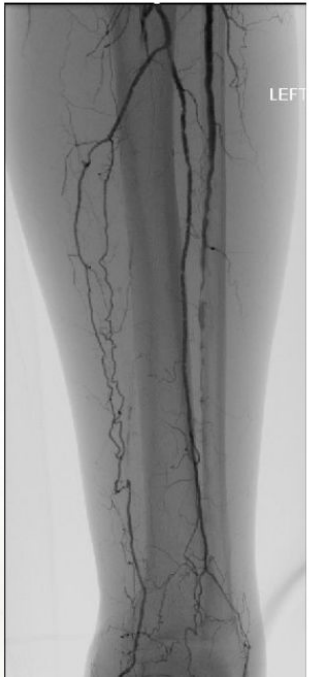
The Desert Foot:

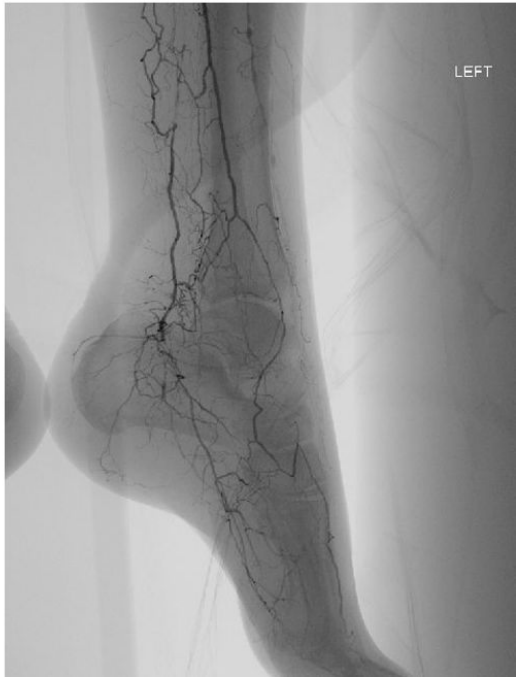
- 68M with 6-week history of worsening diabetic foot ulcer (L) after doing a lot of walking on vacation.
- Past history is significant for T2DM, HTN, DLD. Non-smoker. No ischemic heart disease or stroke.
- On exam, he has bilateral palpable femoral and popliteal pulses. No Pedal pulses. Monophasic signals of DP & PT.

- Left ABI 0.6, likely falsely elevated, TBI not obtainable
  - Iliacs, CFA, SFA and PFA are calcified but no hemodynamically significant disease identified
  - PTA occluded from origin to distal calf with reconstitution via collaterals
  - ATA and PerA are patent

Management of the Diabetic Foot

The Desert Foot:

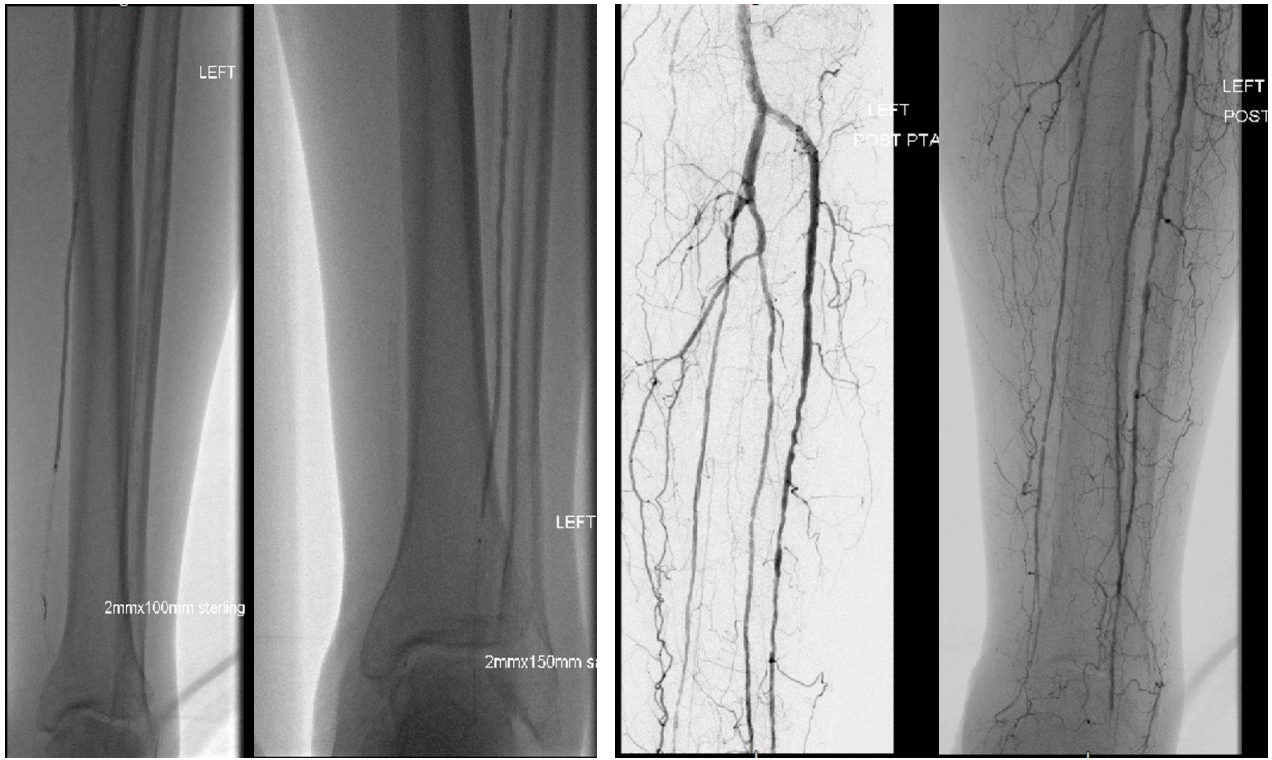




Management of the Diabetic Foot

How would you treat now?

- Angioplasty of the left PTA and ATA → follow up after 3-4 weeks



Management of the Diabetic Foot

Afterwards…

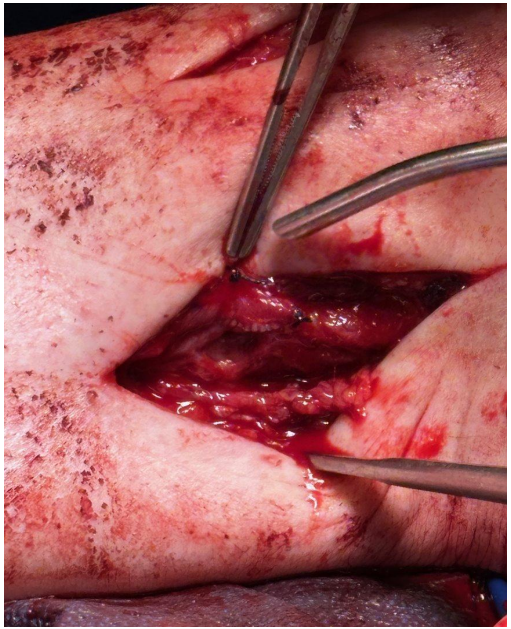
- Hyperbaric Oxygen therapy for 6 weeks ?some improvement
- Deteriorated again at follow up → duplex shows TBI 0.2 (PTA occlusion) → WiFI stage 4 (W2I3Fi1)

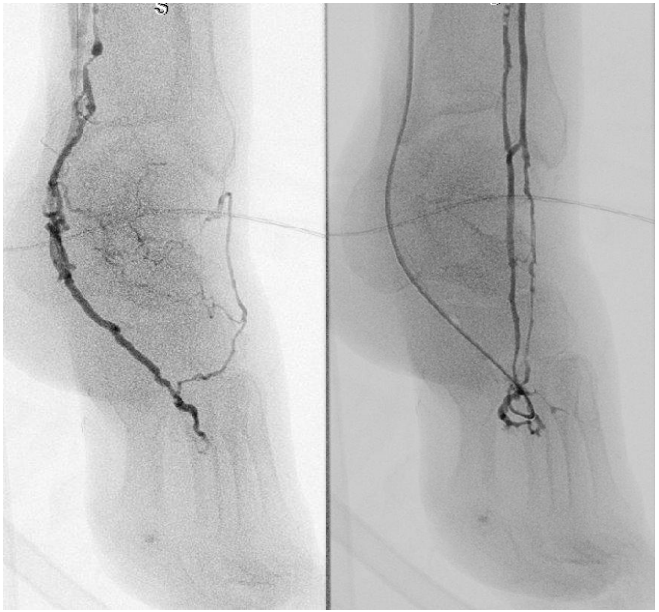
What now?

Management of the Diabetic Foot

What now?

- Deep venous arterialization





Management of the Diabetic Foot

PROMISE I trial

- Feasibility study of LimFlow system for no-option CLI

Efficacy and Durability of Percutaneous Deep Vein Arterialization: A Systematic Review

Samuel E. So, Yiu Che Chan, Stephen W. Cheng

Management of the Diabetic Foot

How much flow is enough?

- ABI – calcified vessels, severe edema
- TBI – necrotic toes, amputated toes
- PAT (pedal acceleration testing) – good alternative
  - A few cross-sectional studies with small sample sizes correlated PAT with ABI to determine what corresponded to each class of ischemia (mostly using dorsalis pedis or lateral plantar artery)
  - Low levels of evidence and small studies

Management of the Diabetic Foot

Other adjuncts:

- Hyperbaric Oxygen Therapy vs. Topical Oxygen Therapy

Wound Management:

- Ultrasound Assisted Debridement (UAD)
  - Systematic review and meta-analysis showing UAD had higher healing rates, a greater percentage of wound area reduction, and similar healing times when compared with placebo (sham device) and standard of care in patients with DFUs (1)
- NPWT with automated instillation
  - facilitating wound cleansing, debris removal, and promotion of granulation tissue formation (2)
- Advanced wound care:
  - Proper wound cleansing
    - Hypochlorous acid cleansing solution in adjunct to UAD for complex wounds
  - Various biological collagen dressing
  - Some evidence of improved wound healing with:
    - Topical Fibrin and Leukocyte Platelet Patch
    - Topical Sucrose Octasulfate– Impregnated Dressings
    - Cryopreserved amniotic membrane allograft
- Wound closure: skin graft or flap

References:
1) Flores-Escobar, S., Álvaro-Afonso, F.J., García-Álvarez, Y., López-Moral, M., Lázaro-Martínez, J.L. and García-Morales, E., 2022. Ultrasound-Assisted Wound (UAW) debridement in the treatment of diabetic foot ulcer: a systematic review and meta-analysis. Journal of Clinical Medicine, 11(7), p.1911.
2) Dalla Paola, L., 2013. Diabetic foot wounds: the value of negative pressure wound therapy with instillation. International wound journal, 10(s1), pp.25-31.

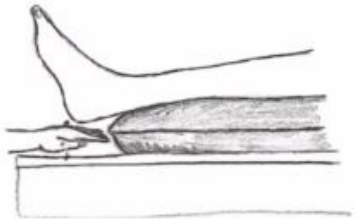
Management of the Diabetic Foot

Wound Management:

- Prevention > Treatment
- Don't forget the contralateral limb!

OFFLOAD all at risk patients***

- Pillow



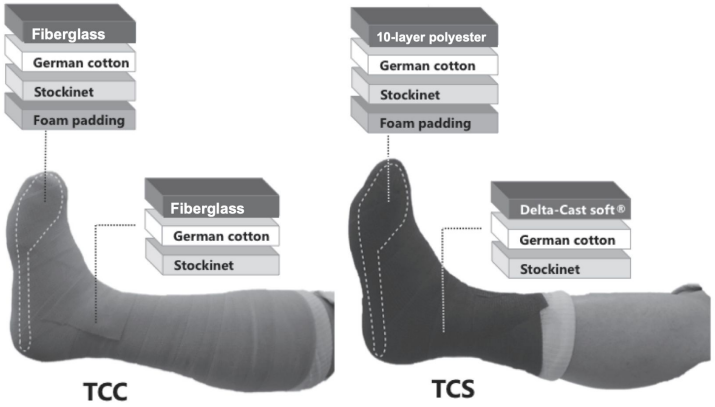
low air loss mattress: modality that helps disperse focal pressure under bony prominences in bedridden and immobile patients.

Management of the Diabetic Foot

Emerging Evidence on Off-loading:

- Five categories of surgical offloading are used in recalcitrant ulcers:
  1. Lesser toe tenotomies
  2. Metatarsal head resection ± Achilles tendon release
  3. Hallux procedures
  4. Bony off-loading procedures in the form of exostectomy
  5. Complex surgical foot reconstruction

- Total Contact Cast



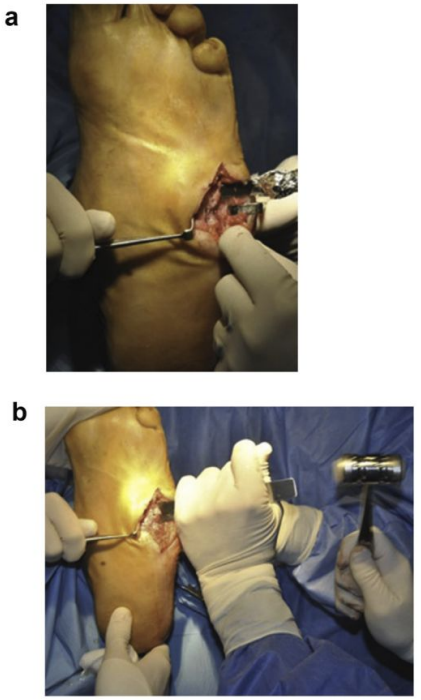
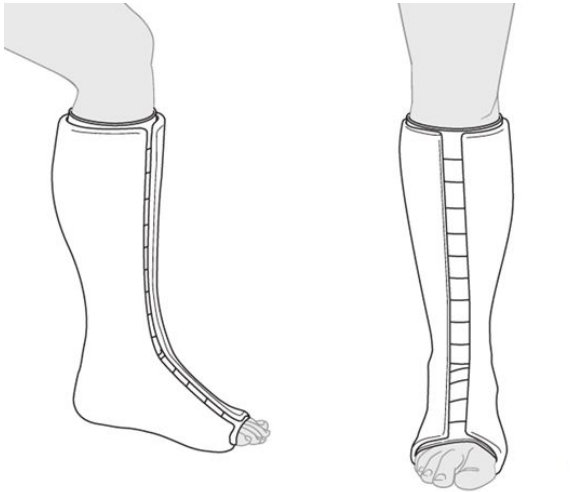


Figure 2 – Exostectomy undertaken for lateral pressure area, following cuboid subluxation and use of osteotomies for pressure relief to manage re-ulceration. Excision of the ulcer (2a), followed by bone excision (2b) and possible wound closure.

Management of the Diabetic Foot

Local Limb Preservation Techniques:

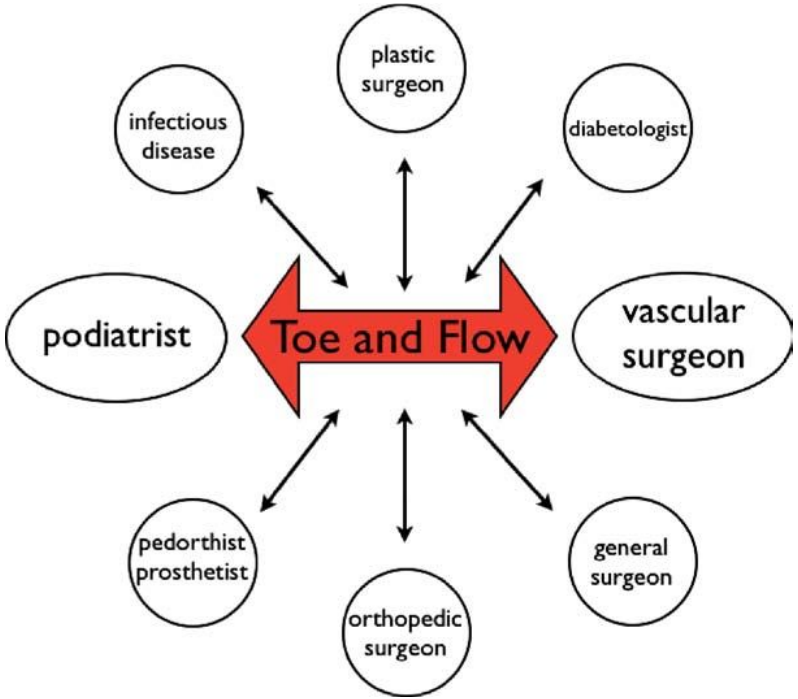
- Split Foot Cast
  - Allows for daily dressing changes and wound assessment
- VAC Veraflo instilled with hypochlorous solution
- Serial ultrasound debridement with in-clinic skin grafting

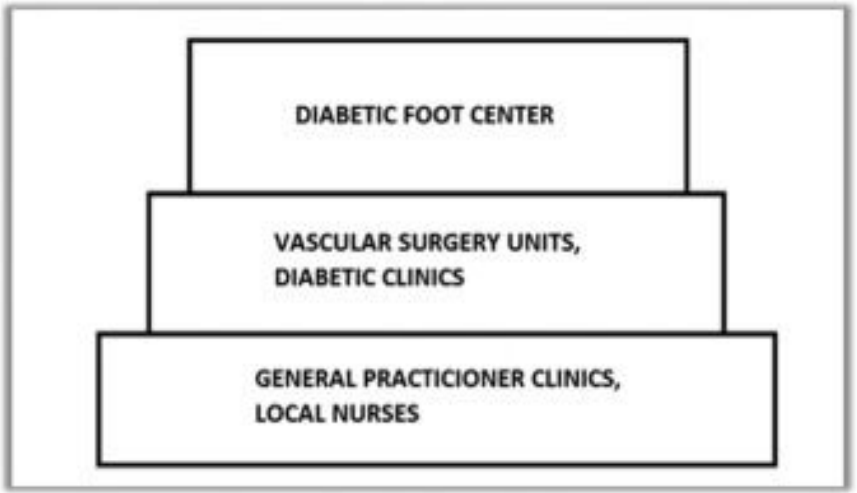


Limb Preservation Programs for Diabetic Foot

Multidisciplinary Management System:

- Early cost analysis shows a higher up-front cost with the “hub and spoke” and the “toe and flow” programs, however, this ultimately reduces the cost of recurrent hospital admissions and major amputation.





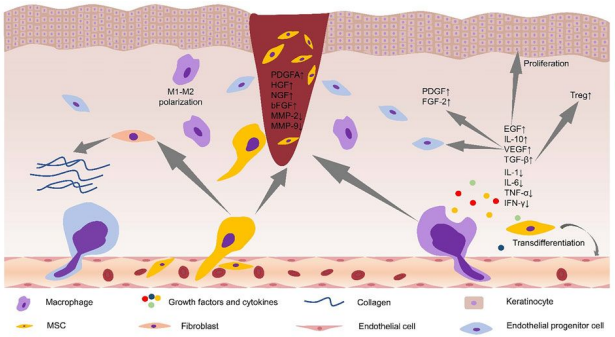
Technological Advancements

Wearable Sensors

Continuous monitoring of foot health and early detection of complications

Artificial Intelligence

Automated analysis of diagnostic data to optimize treatment decisions



Regenerative Therapies

Stem cell and gene therapies to promote tissue regeneration and wound healing

Digital Health Solutions

Telemedicine and mobile apps for remote patient monitoring and care delivery

Conclusion

The diabetic foot is multifactorial and an evolving topic in vascular surgery.

The “modern approach” is multidisciplinary involving various health specialists, and care providers in order to assess and treat diabetic foot wounds to prevent limb loss.

Conclusion

Thank you for your time and attention!