What Presently Defines A No Option Or Desert Foot Before Or After Failed Endo Or Open Treatments:

Under What Conditions Are Further Extreme Limb Salvage Procedures Possible

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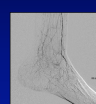
Peter A. Schneider Disclosures

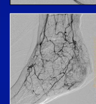
Consulting:
Surmodics, Medtronic, Boston Scientific, Phillips, Cagent, Acotec, Abbott, Endologix, Shockwave, Silk Road, Healthcare Inroads, Inari, BD

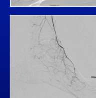
Site PI and enroller for Promise Early Feasibility Study, Promise I Trial, Promise II Trial, Promise III Trial

No Option for Traditional Revascularization

Type	Category	Description
Type I: “Desert foot” pedal anatomy	Anatomic	No patent pedal vessels or “desert foot” anatomy. Should be staged with the WIfI and GLASS staging classifications (including pedal modifier)
Type II: Inadequate venous conduit	Anatomic	Patent pedal target without adequate venous conduit for bypass No endovascular options
Type III: Extensive tissue loss	Anatomic	Tissue loss with exposure of vital structures precluding limb salvage of a functional foot
Type IV: Prohibitive risk for procedure	Medical-comorbid	Excessive or prohibitive risk for revascularization due to advanced medical comorbid conditions
Type V: Nonfunctional limb	Medical-comorbid	Nonfunctional limb due to conditions such as contractures, paralysis, or chronic non-ambulatory status







Kim et al. J Endovasc Ther 2020

Type I No Option: Desert Foot Anatomy

Prevalence of Type I No Option: 8-20% of CLTI

Study	N	Event-free survivors (n)	Observed AFS Rate	Included Rutherford Categories	Observed Proportion R4	Observed Proportion R 5/6	Imputed Proportion R 5/6	Adjusted AFS Rate
Marston et al. 2006	142	105	73.9%	4, 5, 6	NR	NR	60.3%	50.3%
Nikol et al. 2008	56	27	48.2%	4, 5, 6	NR	NR	60.3%	32.8%
Belch et al. 2011	259	173	66.8%	4, 5, 6	NR	NR	60.3%	45.5%
Losordo et al. 2012	12	6	50.0%	4,5	41.7%	58.3%	NA	33.5%
Teraa et al. 2015	79	53	67.1%	3, 4, 5, 6	31.6%	63.3%	NA	46.8%
Raval et al. 2014	3	1	33.3%	4, 5, 6	NR	NR	60.3%	22.7%
Powell et al. 2012	24	16	66.7%	4, 5, 6	NR	NR	60.3%	45.4%
Benoit et al. 2011	14	9	64.3%	4,5	50.0%	50.0%	NA	40.4%
Kibbe et al. 2016	11	9	81.8%	4, 5	63.6%	36.4%	NA	46.7%
Idei et al. 2011	30	0	0.0%	4, 5, 6	27.0%	73.0%	NA	0.0%
Szabo et al 2013	10	4	40.0%	4, 5, 6	NR	NR	60.3%	27.2%
Pignon et al. 2017	19	14	73.7%	4, 5	35.0%	65.0%	NA	52.1%
Wang et al. 2018	36	25	69.4%	4,5	66.7%	33.3%	NA%	38.8%
Faglia et al. 2010	27	1	3.7%	4,5,6	37.0%	63.0%	NA	2.6%
Dalla Paola et al. 2019	84	29	34.5%	4,5,6	NR	NR	60.3%	23.5%
Dubsky et al. 2019	44	23	52.3%	4,5,6	NR	NR	60.3%	35.6%
Faglia et al. 2012	12	3	25.0%	5.6	0.0%	100.0%	NA	25.0%

Simple Average	50.0%	**Simple Average**	33.5%
Weighted Average	57.8%	**Weighted Average**	39.1%
Meta-Analytic Average	50.3%	Meta-Analytic Average	33.3%
Min	0.0%	**Min**	0.0%
Max	81.8%	**Max**	52.1%
SD	24.3%	**SD**	15.3%

One-year amputation free survival: 33%

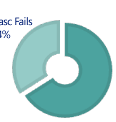
23% of those undergoing major amputation for CLTI are DVA candidates

Satam et al. Ann Vasc Surg 2022;86:260

Schreve et al. Ann Vasc Surg. 2014 Jul;28(5):1123-7.
Yost SAGE Group, CLI Supplement 2016
https://www.marketwatch.com/press-release/according-to-the-sage-group-1-million-or-more-japanese-citizens-suffer-from-critical-limb-ischemia-cli-2017-05-22
Ghare et al. Journal of Critical Limb Ischemia, 2021.

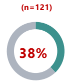
CLariTI 6-Month Results: Natural History of Desert Foot

Median Age (range)	**70 (60-78)**
Male	120 (**66.6%**)
Race	
Caucasian	99 (55.0%)
Black or African Descent	65 (**36.1%**)
Asian	4 (2.2%)
Unknown/Declined to State	11 (6.1%)
Ethnicity	
Not Hispanic or Latino	156 (86.7%)
Hispanic or Latino	19 (**10.6%**)

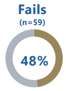


AFS Rate

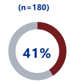
No-Option/Desert Foot (n=121)



Multiple Revasc Fails (n=59)

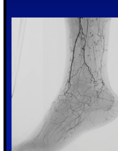


Full Cohort (n=180)

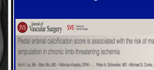


Presented by: Dr. A. Dua

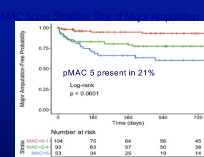
Pedal Medial Arterial Calcification Score pMAC-Ferraresi



Ferraresi et al., J Endovasc Ther. 2020
Liu et al., J Vasc Surg. 2021

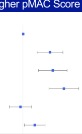

Journal of Vascular Surgery SVS
Pedal arterial calcification score is associated with the risk of major amputation in chronic limb-threatening ischemia
Iris H. Liu, BA • Bian Wu, MD • Viktoriya Krepkiy, DPM • ... Peter A. Schneider, MD • Michael S. Conte, MD • Shant M. Vartanian, MD • Show all authors

pMAC Score Stratifies Risk of Major Amputation



Factors Associated with Higher pMAC Score

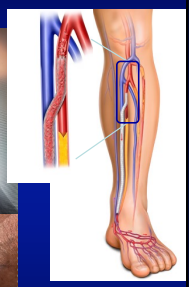
Covariate	OR (95% CI)	p-value
Age	1.01 (0.99-1.04)	p=0.20
Male	3.3 (1.9-5.7)	p<0.0001
Diabetes Mellitus	3.7 (2.0-6.8)	p<0.0001
ESRD	6.0 (3.1-11.4)	p<0.0001
WIfI Stage 4	0.9 (0.6-1.5)	p=0.67
GLASS Pedal Score	1.7 (1.1-2.6)	p=0.02



TADV-Transcatheter Arterialization of the Deep Veins

65 y/o Diabetes, CKD, smoking, and hyperlipidemia.

Nonhealing wound at location of 5th toe amputation.



Patient Selection

- Type I "No option" by angiogram-desert foot
- Wounds
  - Stable enough to last the 4-6 weeks of fistula maturation
  - Minimal or no infection
- Patients with motivation, social support
- Adequate inflow and appropriate donor vessel
- Interrogate pedal veins with ultrasound to evaluate for thrombosed or diseased vessels

Wound Evaluation

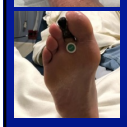
Proceed, Proceed With Caution, Not Recommended

Green - Involving the forefoot and little to no overlap to the metatarsal region

Yellow – Metatarsal Region – assess how much tissue is salvageable

Red – Heel and/ or ankle wound involvement. Risk/reward for limb and patient's ambulatory future

Wound Evaluation



Ideal TADV wound:

- Forefoot wound
- Stable – could wait a few weeks for foot surgery

Wound Evaluation

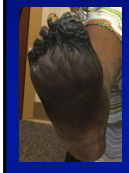
Proceed with Caution-Higher Risk

Marginal wound for DVA:

- Wound encroached metatarsal area
- Infection
- Closed wound site
- Progressing

Wound Evaluation

Prohibitive risk

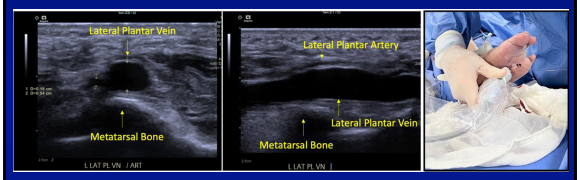


Poor wound for DVA

- Extensive tissue damage
- Proximal to TMA site
- Located on the heel
- Infection

Pedal Vein Puncture Site

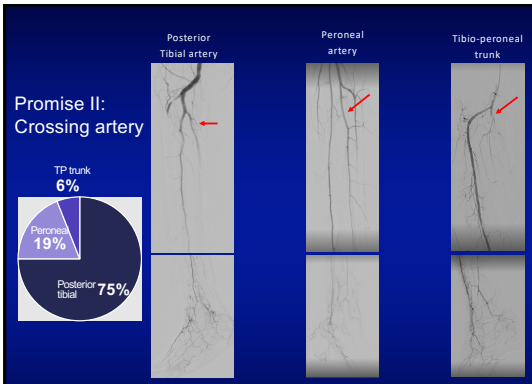
Transverse Longitudinal



Puncture as distal on the foot as possible
Evaluate in both transverse and longitudinal
Avoid valve site

Montero-Baker et al. J Vasc Surg Cases Innov Tech 2023;9:101160

Promise II: Crossing artery



Technical Success 99%

If remnant flow to the foot is based upon the posterior tibial artery

Consider hybrid superficial venous arterialization

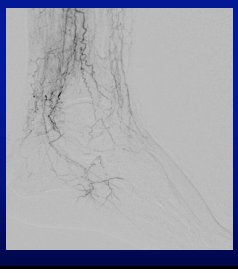
Montero-Baker et al. J Vasc Surg Cases Innov Tech 2023;9:101160

Rescue from Recurrent CLTI

Recurrent forefoot CLTI in a Diabetic

Successful healing of 1st digit gangrene:
s/p pop-peroneal bypass years ago – now failed

No targets and no conduit



Courtesy: S. Vartanian

Rescue from Recurrent CLTI

When to re-open and when to abandon the DVA?

Now 22 months post DVA

TMA fully healed and patient ambulatory with no episodes of breakdown or ulceration

DVA occluded 6 mo post op salvaged with thrombolysis + venous outflow PTA

Thrombosed again 2 mo later and abandoned

What Presently Defines A No Option Or Desert Foot?

Conclusions

- Transcatheter Arterialization of Deep Veins is safe and technically feasible.
- Limb salvage in “desert foot” anatomy is achievable in majority of patients.
- Increasing prevalence of small artery disease and “desert foot”.
  - Many patients receive traditional revascularization without hemodynamic benefit.
- Pedal artery occlusive disease driven by increased prevalence of diabetes and chronic renal failure: one-year limb salvage 0-34%.
- Continued development: patient selection, techniques, technology, methods to improve outcomes, address specific subgroups such as dialysis, understand mechanism of action.

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