2024 MID-ATLANTIC CONFERENCE

12th ANNUAL CURRENT CONCEPTS IN VASCULAR THERAPIES

2024

Enough is Enough: Time for an Amputation

Samuel N. Steerman, MD FACS
Assistant Professor, Eastern Virginia Medical School

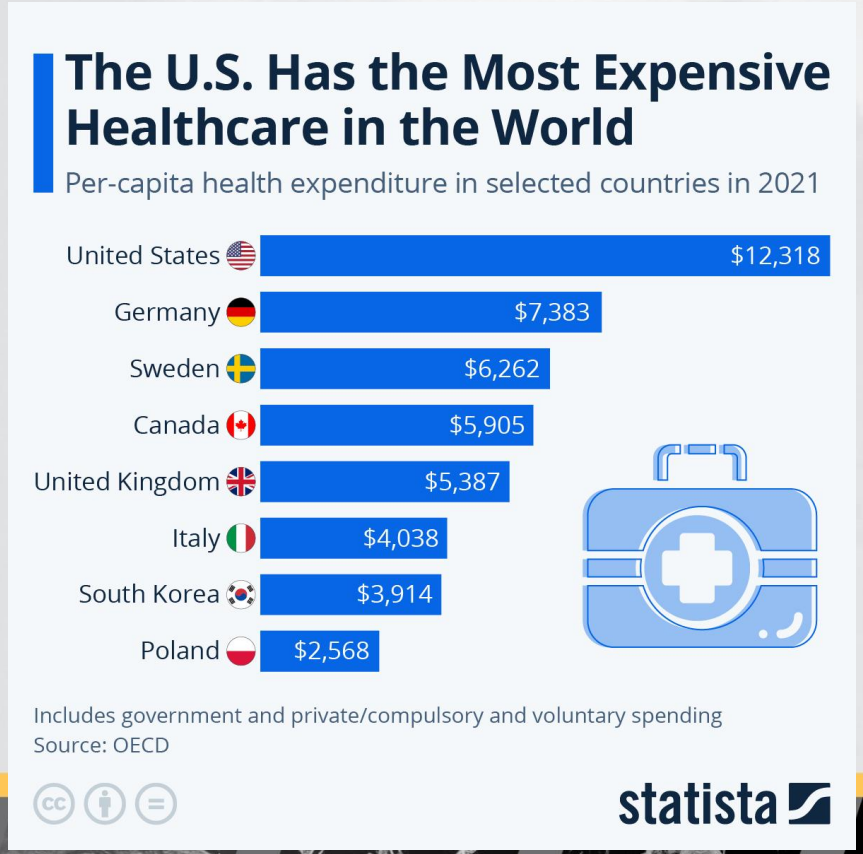
Disclosures

- Speaker
  - Medtronic, Abbott, BD, Endologix
- Consultant
  - Philips

Outline

- Natural History and Distribution of CLI
- Economic Factors
- Introduction to LimFlow
- “Data” on Deep Venous Arterilization
- What life is like after amputation
- Community Response to the technology

Cost of Healthcare



- Last-year-of-life expenses constituted:
  - 22 percent of all medical
  - 26 percent of Medicare
  - 25 percent of Medicaid expenditures.

Hoover DR, Crystal S, Kumar R, Sambamoorthi U, Cantor JC. Medical expenditures during the last year of life: findings from the 1992-1996 Medicare current beneficiary survey. Health Serv Res. 2002 Dec;37(6):1625-42. doi: 10.1111/1475-6773.01113. PMID: 12546289; PMCID: PMC1464043.

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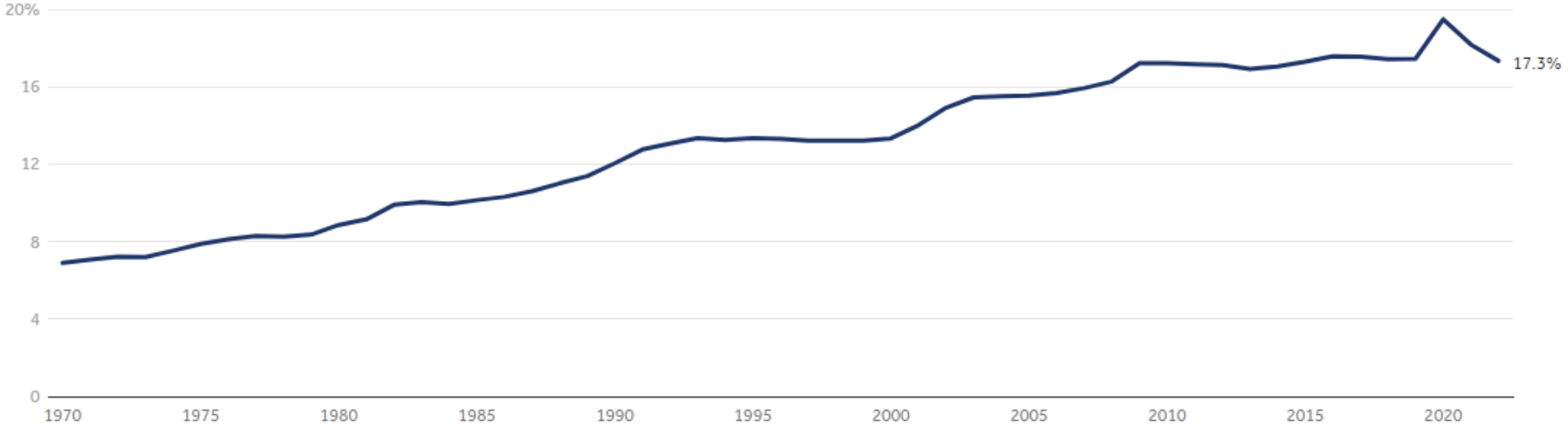
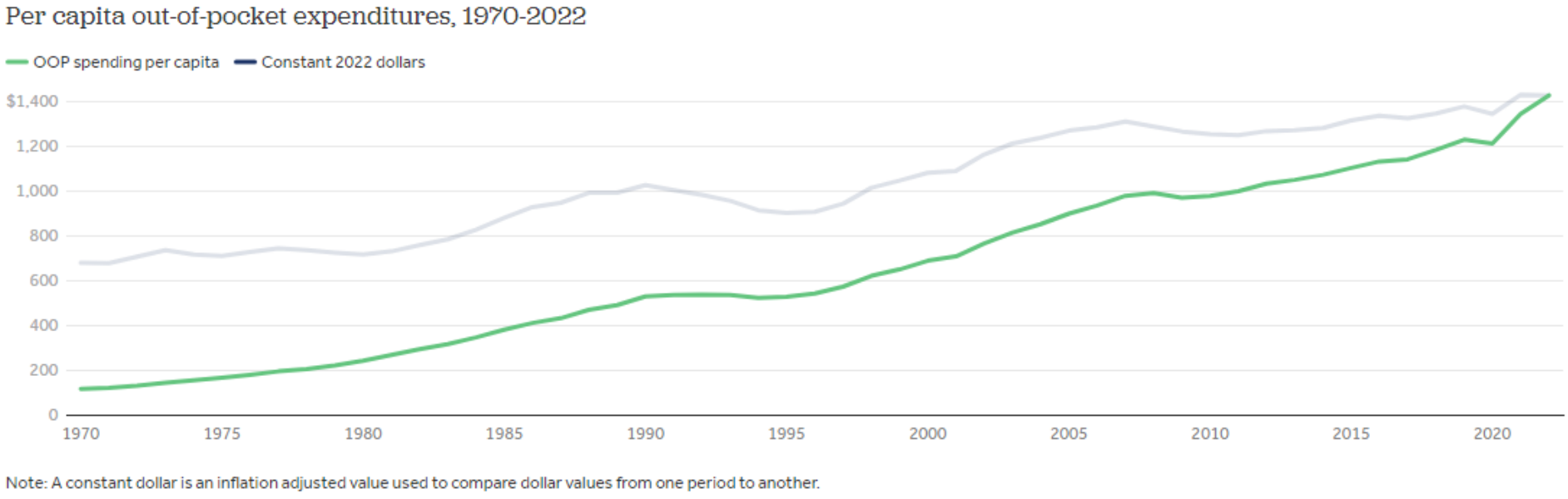
Total national health expenditures as a percent of Gross Domestic Product, 1970-2022



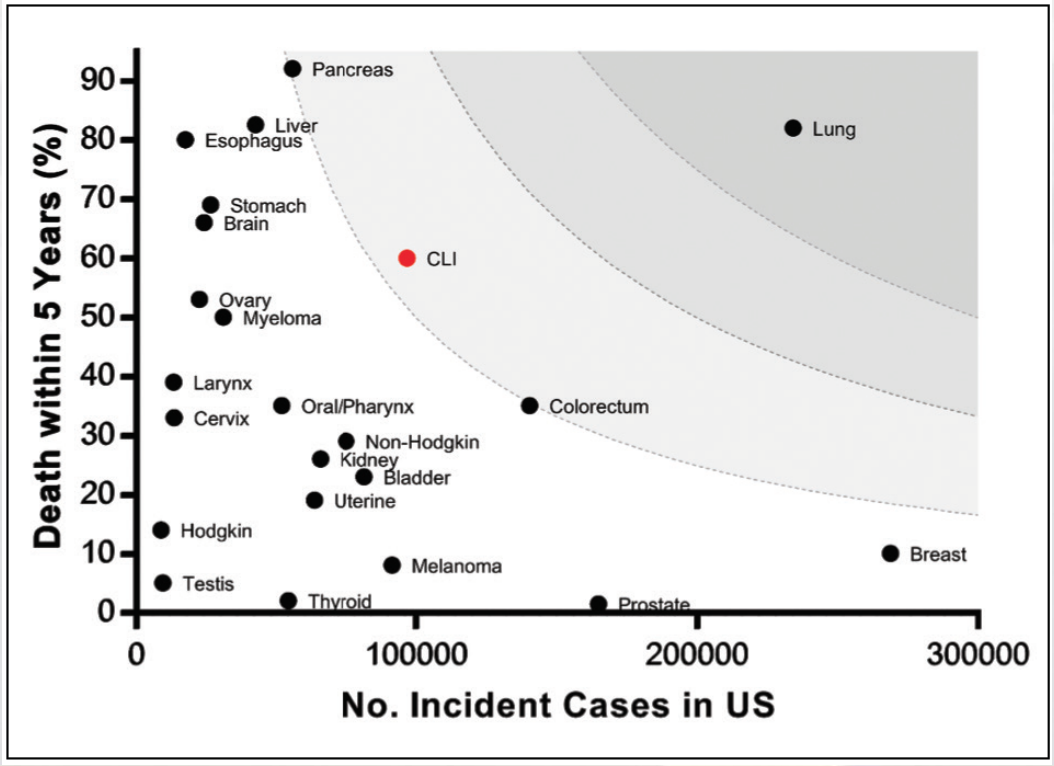
Source: KFF analysis of National Health Expenditure (NHE) data • Get the data • PNG

Peterson-KFF
Health System Tracker

Cost of Healthcare



Mortality of Critical Limb Ischemia



LimFlow procedure

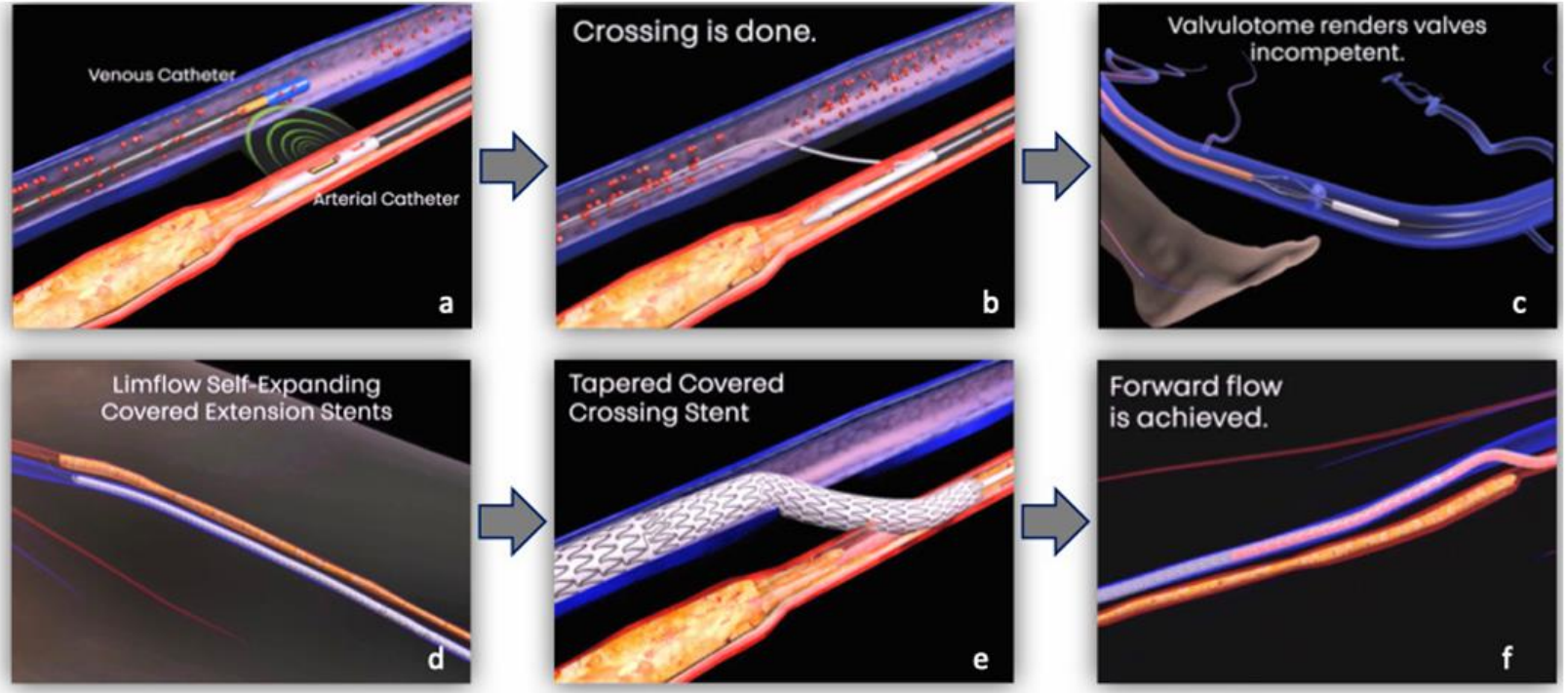


Figure 4. LimFlow Procedure overview: a) Artery to vein alignment with LimFlow ultrasound kit; b) artery to vein crossing with LimFlow crossing catheter; c) valvulysis with LimFlow push valvulotome; d) self-expanding extension stent-graft deployment; e) self-expanding tapered crossing stent-graft deployment; f) forward flow into foot achieved.

What's old is new, again

Arterialization of the Distal Venous System Alone or Combined With Bypasses to Limited Outflow Tracts: A Last Resort for the "Unsalvageable Leg"?

ENRICO ASCER, M.D., and FRANK J. VEITH, M.D.

Perspectives in Vascular Surgery and Endovascular Therapy. 1993

- 11 patients over 5 years resulted in only 4 durable limb salvage cases
- Two patients developed CKD and one had idiopathic systemic capillary leak syndrome, all requiring ligation of the bypass
- 7/11 cases underwent a major amputation within 2 months of the procedure.

Ascer E, Veith FJ. Arterialization of the Distal Venous System Alone or Combined With Bypasses to Limited Outflow Tracts: A Last Resort for the "Unsalvageable Leg"? Perspectives in Vascular Surgery and Endovascular Therapy. 1993;6(1):67-83. doi:10.1177/153100359300600109

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Transcatheter Arterialization of Deep Veins in Chronic Limb-Threatening Ischemia

Shishehbor MH et al. DOI: 10.1056/NEJMoa2212754

Major amputation	23/102 patients
Death	12/102 patients

CONCLUSIONS

Among patients with chronic limb-threatening ischemia and no option for revascularization who underwent transcatheter arterialization of the deep veins, nearly two thirds were alive and free of above-ankle amputation at the 6-month follow-up, with no unanticipated safety concerns.

LIMITATIONS AND REMAINING QUESTIONS

- The study lacked a control group, although randomization of patients at high risk for amputation was not ethically feasible.
- The procedure may not be available outside specialist centers.
- Follow-up was relatively short-term.

Successful case?

- Wound progression from G) baseline to H) 6-months, and I) 9-months
- At 9 months, the Limflow occluded requiring endovascular intervention

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Published Success?

Figure	Months to Heal
A	7
B	6
C	12
D	8
E	8

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Secondary Endpoints

- Primary Patency at 6 month – 26%
- Complete wound healing at 6months – 25%
- Procedure time: 199 minutes (interquartile range 151, 260)
- Subjects with 1 or more serious adverse events: 93%
- Total Number of Serious Adverse events: 350 (of 105 patients in the study!)

LimNo!

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Eur J Vasc Endovasc Surg (2017) 53, 387–402

REVIEW

Venous Arterialisation for Salvage of Critically Ischaemic Limbs: A Systematic Review and Meta-Analysis

M.A. Schreve [a,*], C.G. Vos [a], A.C. Vahl [b], J.P.P.M. de Vries [c], S. Kum [d], G.J. de Borst [e], Ç. Ünlü [a]

[a] Department of Surgery, Noordwest Ziekenhuisgroep, Alkmaar, The Netherlands
[b] Department of Surgery, OLVG, Amsterdam, The Netherlands
[c] Department of Vascular Surgery, St. Antonius Hospital, Nieuwegein, The Netherlands
[d] Department of Surgery, Changi General Hospital, Singapore
[e] Department of Surgery, UMCU, Utrecht, The Netherlands

esvs Journal
European Journal of Vascular & Endovascular Surgery

- Meta-Analysis of papers published between January 1966 and January 2016. Results: 15 articles, 768 patients. Methodological quality was moderate to poor.
- The estimated pooled limb salvage rate at one year was 75%
- Conclusion: In this systematic review on venous arterialisation in patients with non-reconstructable critical limb ischaemia, the pooled proportion of limb salvage at 12 months was 75%. Venous arterialisation could be a valuable treatment option in patients facing amputation of the affected limb; however**, the current evidence is of low quality.**

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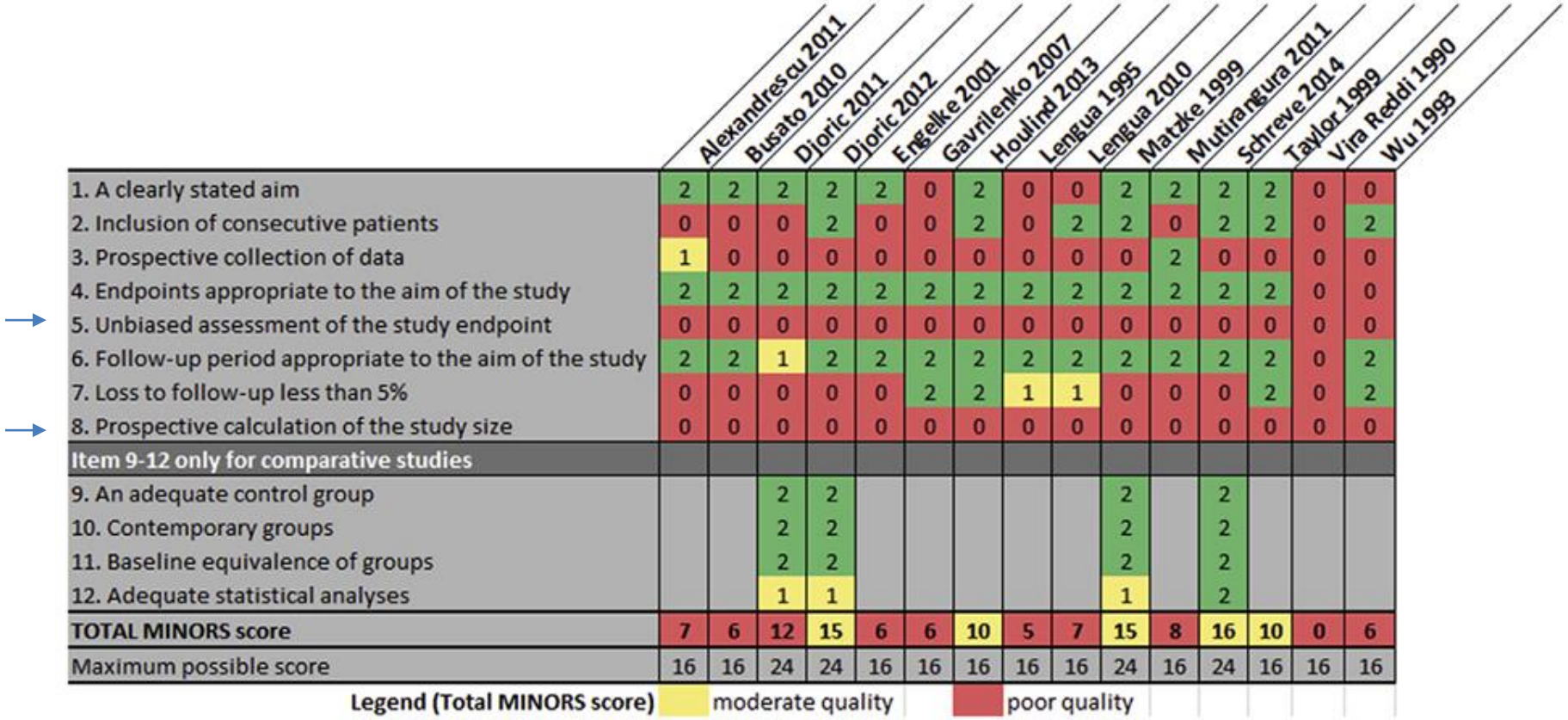


	Alexandrescu 2011	Busato 2010	Djoric 2011	Djoric 2012	Engelke 2001	Gavrilenko 2007	Houlind 2013	Lengua 1995	Lengua 2010	Matzke 1999	Mutiranguira 2011	Schreve 2014	Taylor 1999	Vira Reddi 1990	Wu 1993
1. A clearly stated aim	2	2	2	2	2	0	2	0	0	2	2	2	2	0	0
2. Inclusion of consecutive patients	0	0	0	2	0	0	2	0	2	2	0	2	2	0	2
3. Prospective collection of data	1	0	0	0	0	0	0	0	0	0	2	0	0	0	0
4. Endpoints appropriate to the aim of the study	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0
5. Unbiased assessment of the study endpoint	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6. Follow-up period appropriate to the aim of the study	2	2	1	2	2	2	2	2	2	2	2	2	2	0	2
7. Loss to follow-up less than 5%	0	0	0	0	0	2	2	1	1	0	0	0	2	0	2
8. Prospective calculation of the study size	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Item 9-12 only for comparative studies															
9. An adequate control group			2	2						2		2			
10. Contemporary groups			2	2						2		2			
11. Baseline equivalence of groups			2	2						2		2			
12. Adequate statistical analyses			1	1						1		2			
TOTAL MINORS score	**7**	**6**	**12**	**15**	**6**	**6**	**10**	**5**	**7**	**15**	**8**	**16**	**10**	**0**	**6**
Maximum possible score	16	16	24	24	16	16	16	16	16	24	16	24	16	16	16

Legend (Total MINORS score) moderate quality poor quality

Figure 2. Study quality assessment (MINORS score).

What is the community saying?

- Interesting how fads recycle. Venous arterialization was "hot" 40 years ago and faded into obscurity because in the end it was not successful at limb salvage. I guess we have to spend another 5 years and millions of dollars to confirm something we already know. It will be interesting to watch the cycle repeat itself until it burns out.

  -Professor, Vascular Surgeon, WI

- I recently had two of my wound care patients need open vascular reconstruction. No endo options left. Both underwent DVA procedures.
- One occluded within 30 days and underwent an AKA. The other (the first patient who underwent DVA) healed her foot wound but now lost to f/u.
- Just my limited experience with this limb salvage procedure.

-FACS Vascular Surgeon, NY

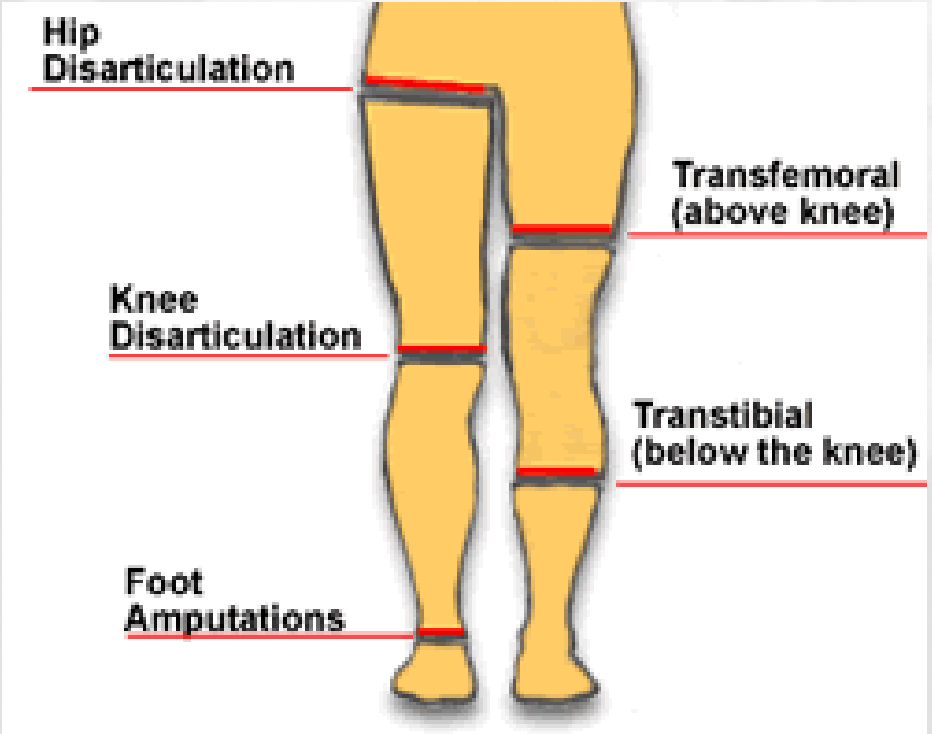
Is this data?

- 1 patient – In my experience
- 2 patients – In my case series
- 3 patients – In case, after case after case

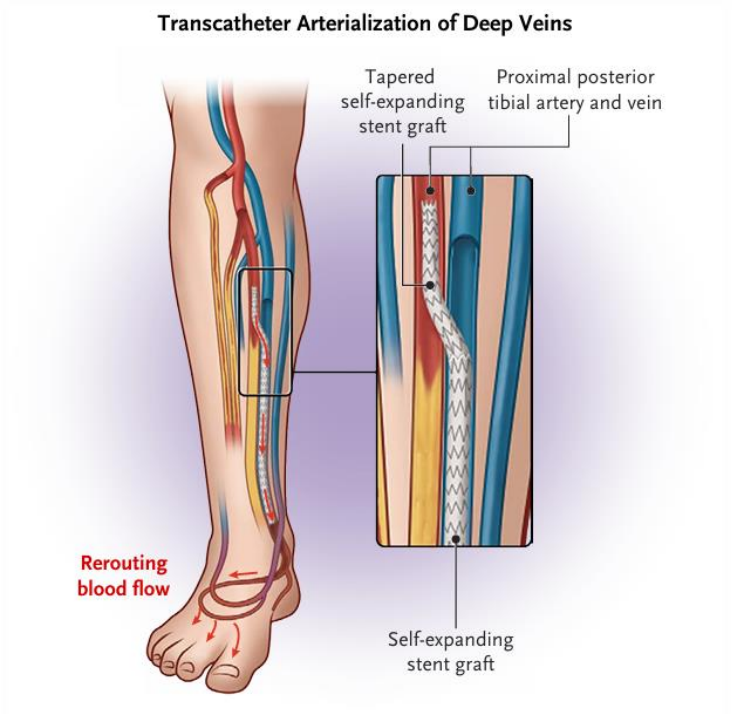
Limflow vs what?

- Hip Disarticulation?
- Above the knee amputation?

- Trans metatarsal amputation?
- Toe amputation?

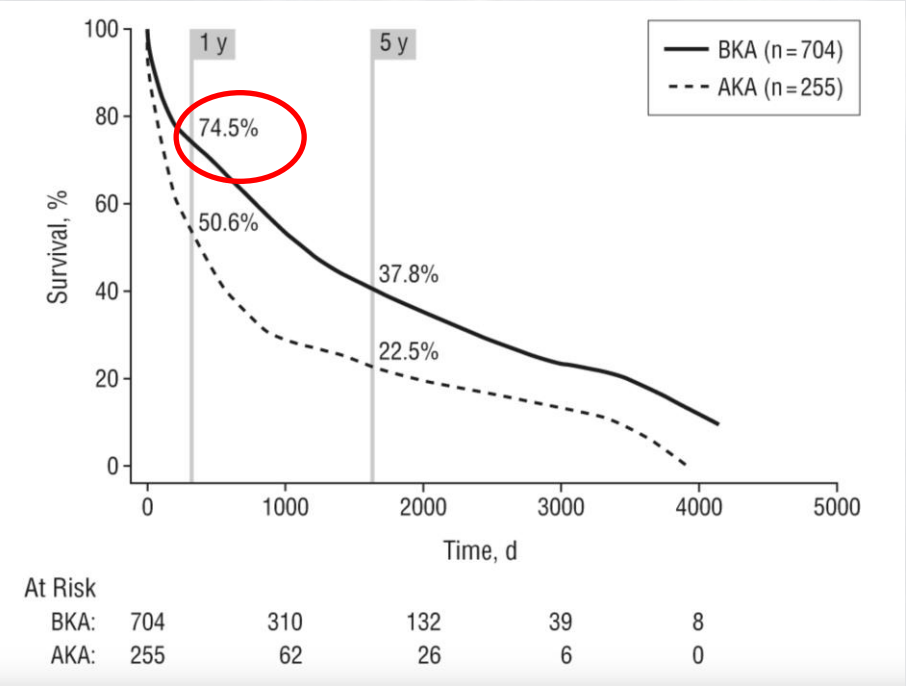


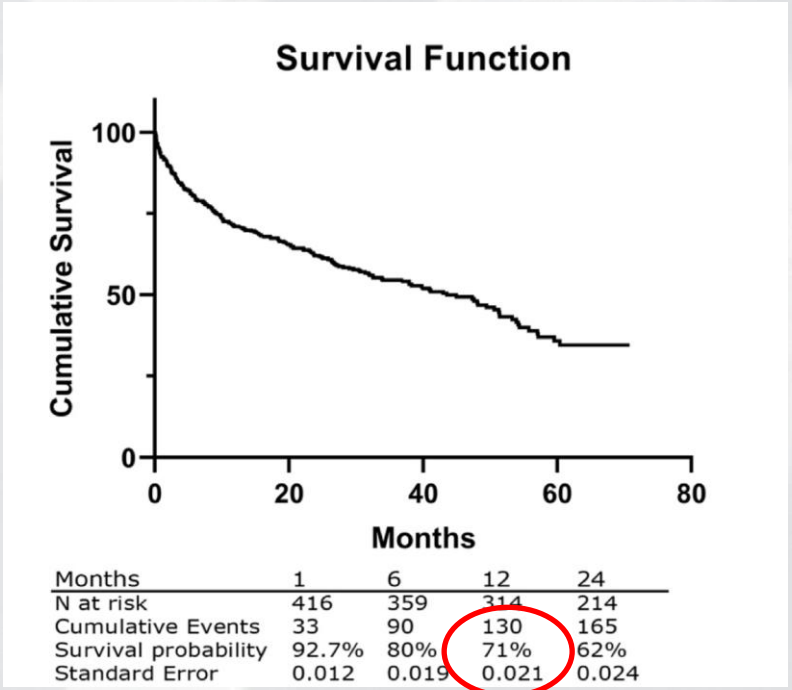
Limflow vs what?



Below the knee amputation

Mortality outcomes





Aulivola B, Hile CN, Hamdan AD, et al. Major Lower Extremity Amputation: Outcome of a Modern Series. *Arch Surg.* 2004;139(4):395–399. doi:10.1001/archsurg.139.4.395

A mortality prediction model for elderly patients with critical limb ischemia

Check for updates

Joost P. Roijers, MD,[a] Yannick S. Rakké, MD,[a] Cornelis J. Hopmans, MD, PhD,[a] Mathijs G. Buimer, MD,[a] Gwan H. Ho, MD, PhD,[a] Hans G. W. de Groot, MD,[a] Eelco J. Veen, MD, PhD,[a] Paul G. H. Mulder, PhD,[a] *and* Lijckle van der Laan, MD,[a,b] *Breda, The Netherlands; and Leuven, Belgium*

Journal of Vascular Surgery, Volume 71, Issue 6, 2020

Predictors of Postoperative Complications in Patients Undergoing Below Knee Amputation

Maxwell J. Grant, Samuel Steerman, Andrew McChesney, Fanny Alie-Cusson, Justin Milligan, Animesh Rathore, Jean M. Panneton. Eastern Virginia Medical School, Norfolk, Virg

Journal of Vascular Surgery
July 2020

- 155 BKAs identified in 129 patients. Mean follow-up was 836 days after index amputation
- If a patient experienced a complication after any LSA (postoperative DVT, Clostridium difficile, community-acquired infection, need for postoperative transfusion, acute cardiopulmonary event, or need for unplanned surgical reintervention within 24 hours), their risk for developing wound complications after BKA more than doubled (45.6% vs 22.0%; P 1⁄4 .003). Patients admitted more than 17 cumulative days after LSAs were more likely to experience a BKA complication (38.1% vs 22.0%; P 1⁄4 .030). Patients who underwent two or more prior revascularizations experienced a higher rate of BKA complications (36.7% vs 21.0%; P 1⁄4 .032).
- Conclusions: Risk factors for wound complications after BKA include … longer total admissions for LSA, and multiple revascularizations before amputation. Greater scrutiny regarding the usefulness of multiple LSAs may decrease rates of wound complications after BKA.

Energy Expenditure (compared with control) after lower extremity amputation

Level of Amputation	Increase in Energy Expenditure (%)
Unilateral BKA	9-25
Bilateral BKA	41
Unilateral AKA	25-100
Bilateral AKA	280

Ambulation after BKA

ELSEVIER

Annals of Vascular Surgery

Volume 71, February 2021, Pages 331-337

Clinical Research

Ambulatory Status following Major Lower Extremity Amputation

Katherine P. MacCallum [1], Patricia Yau [1], John Phair [2], Evan C. Lipsitz [1], Larry A. Scher [1], Karan Garg [3]

- 811 patients who underwent BKA or AKA between January 2009 and December 2014
- 83.1% of BKA patients were ambulatory
- Of those: 182/246 (73.9%) of BKA and 32/51 (62.7%) of AKA remained so post-amputation

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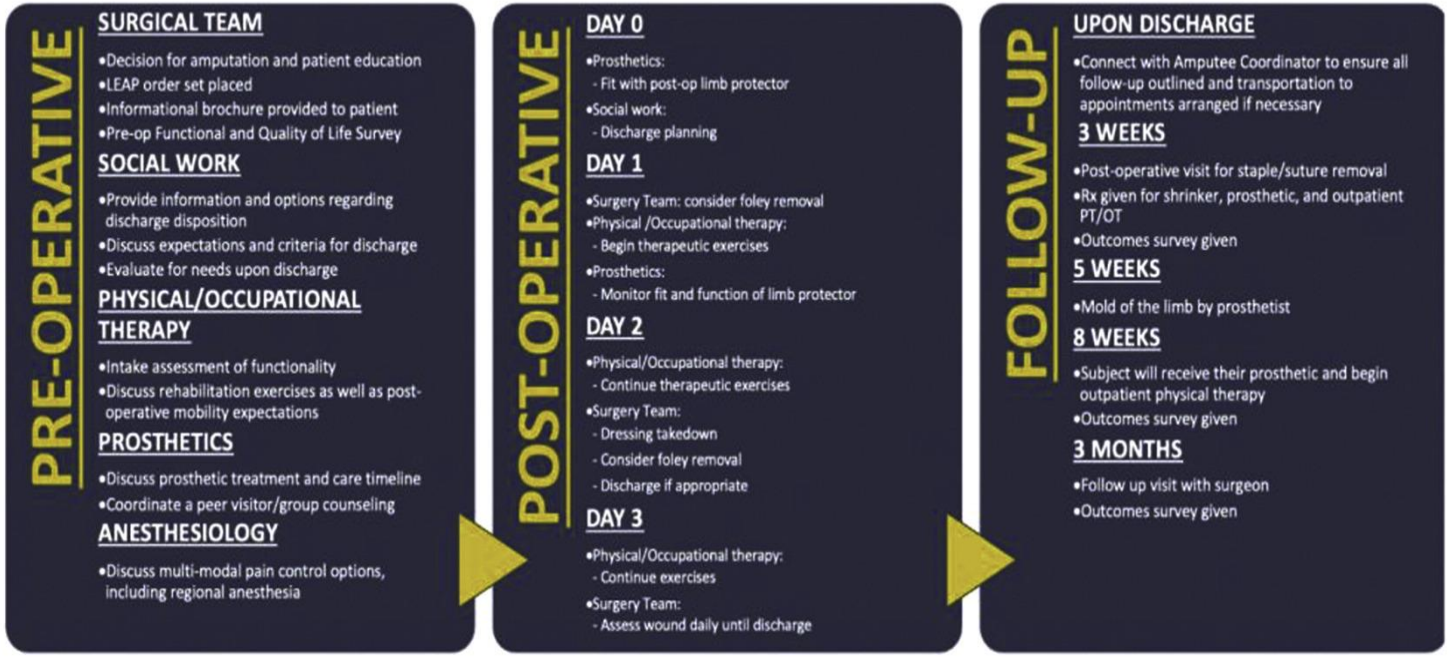
Lower Extremity Amputation Protocol (LEAP)



Journal of Vascular Surgery 2021 74DOI: (10.1016/j.jvs.2021.06.412)

LEAP has been found to significantly decreases postoperative length of stay and expedites time to independent ambulation with a prosthetic in vascular patients undergoing major amputation

Post amputation management

- Surgeon
- Physical Therapists specialty trained in amputation management
- Prosthetists
- Social Worker

Amputation Clinic

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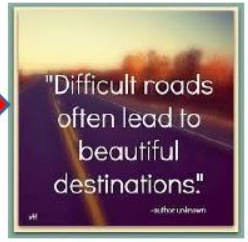
Support for amputees

2016 - THE ROAD TO A NEW BEGINNING



If you are an amputee or caregiver, please plan to be a part of the Hampton Roads Amputee Support Group. This group will discuss information needed to ASSIST AND SUPPORT amputees and their families. The group meets the second Wednesday of each month at four o'clock p.m. in the first floor conference room of Sentara Heart Hospital in Norfolk.

2016 Meeting Dates

January 13, 2016	May 11, 2016	September 14, 2016
February 10, 2016	June 8, 2016	October 12, 2016
March 9, 2016	July 13, 2016	November 9, 2016
April 13, 2016	August 10, 2016	December 14, 2016

If you are interested, please contact one of the following people:

Belinda - **LCSW** (757) 395-1672	Connie - **BKA** (757) 334-5707	Joe - **BKA/TMA** (757) 272-8144	Lauri - **AKA** (864) 430-6946

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Conclusions

- Below the knee amputation has an acceptable mortality and morbidity
- Expensive, poor outcome procedures should not be avoided for minimal benefit
- Data is necessary to offer new procedures, particularly to patients desperate for a miracle