

**MAYO CLINIC**

**NEW CLINICAL RESULTS WITH THE ACCELLULAR TISSUE ENGINEERED VESSEL (ATEV) AS CONDUIT IN CIVILIAN AND MILITARY SETTINGS**

**Todd E. Rasmussen, MD**  
 Professor of Surgery  
 Consultant, Division of Vascular and Endovascular Surgery  
 Director, Mayo Gonda Vascular Center  
 Mayo Clinic  
 Rochester, Minnesota

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**DISCLOSURES**

- Patent(s) in REBOA & vascular shunt technologies (stock options as part of licensing or consulting agreements)
- Mayo Clinic receives funding from Humacyte to support conduct of physician-sponsored IND study of the Human Acellular Vessel (HAV) now the Acellular Tissue-Engineered Vessel (ATEV)
- Publishing and editing royalties relating to educational products from Elsevier and Wolters Kluwer – LLW

**NOVEL BIOLOGIC CONDUIT**

**Surgical Innovation**  
 The Human Acellular Vessel for Vascular Reconstruction or Bypass  
 A Novel Biologic Conduit for Vascular Bypass and Repair

Alexis L. Lauria, MD; Indrani Sen, MBBS; Todd E. Rasmussen, MD  
**JAMA Surgery 2022;175(8):731-32**

**Representation of Human Acellular Vessel Production**

Biodegradable lattice  
 The cells form a strong collagen and extracellular matrix  
 Implementation bypassing a severed or obstructed blood vessel  
 Human vascular smooth muscle cells and endothelial cells are removed to prevent immune response when implanted

**MILITARY RELEVANCE OF CONDUIT**

STATE OF THE SCIENCE

Clinical implementation of the Humacyte human acellular vessel: Implications for military and civilian trauma care

Jonathan J. Morrison, PhD, John McMahon, PhD, Joseph J. DuBose, MD, Thomas M. Scalea, MD, Jeffrey H. Lawson, MD, PhD, and Todd E. Rasmussen, MD, Baltimore, Maryland  
**Journal of Trauma & Acute Care Surgery 2019;87:S44-S47**

- Autologous conduit that may offer efficiency and resistance to infection
- The qualities of an ideal conduit:
  - “Off the shelf” eliminating technical need to harvest and associated wound problems
  - Biologic that is resistant to infection; one that becomes incorporated by host cells
  - Predictable diameter, length and internal contour (i.e. no valves)
  - Handling properties that facilitate technical aspects of reconstruction

**FDA-SUPPORTED MAYO CLINIC IND STUDY**

Outcomes of Arterial Bypass With the Human Acellular Vessel for Chronic Limb-Threatening Ischemia Performed Under the FDA Expanded Access Program

Indrani Sen, MBBS, W. Darrin Clouse, MD, Alexis L. Lauria, MD; Daniel R. Calderon, MD; Peter B. Anderson, MD; Randall R. DeMartino, MD; and Todd E. Rasmussen, MD  
**Mayo Clinic Proceedings 2024;99(1):57-68**

Outcomes of lower extremity arterial bypass using the Human Acellular Vessel in patients with chronic limb-threatening ischemia

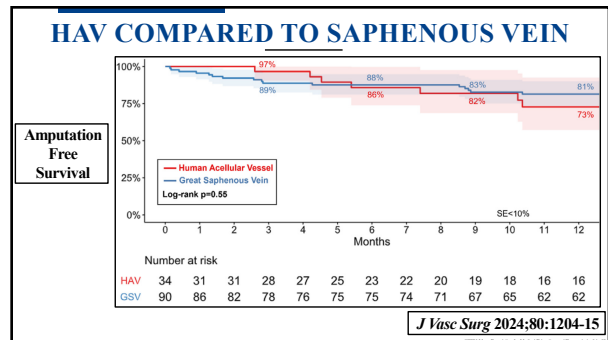
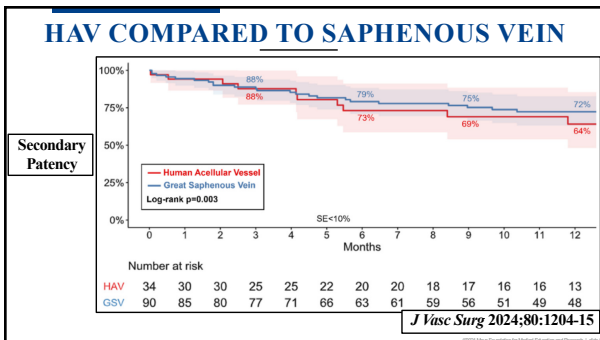
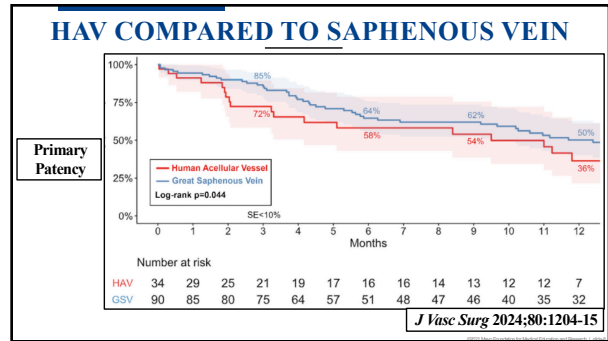
Sebastian Cifuentes, MD,\* Indrani Sen, MBBS,\* Fahad Shuja, MBBS,\* Bernardo C. Mendes, MD,\* Jill J. Colglazier, MD,\* Melinda S. Schaller, MD,\* Manju Kalra, MBBS,\* Jonathan J. Morrison, MB, ChB, PhD,\* Randall R. DeMartino, MD, MS,\* and Todd E. Rasmussen, MD,\* Rochester, MN  
**J Vasc Surg 2024;79(2):348-357**

**HUMAN ACCELLULAR VESSEL (HAV)**

- 37 implants as bypass conduit in patients with CLTI and no vein (6mm diameter x 40 cm length); 100% patient capture median follow-up of 20 months

### HUMAN ACELLULAR VESSEL (HAV)

- HAV to left common femoral, tunneled subcutaneous to anterior tibial and sewn to target with Linton patch using Gortex suture



### HUMANITARIAN PROGRAM IN UKRAINE

- Initiated via requests from Ukrainian surgeons; coordinated with FDA Office of International Programs and Ukraine Ministry of Health; vessels supplied by Humacyte
- Vessels shipped to 5 hospitals
  - Vinnytsya
  - Dnipro
  - Odessa
  - Kyiv
  - Kharkiv
- Virtual and hands-on training with assistance from Polish and U.S. surgeons with experience implanting the ATEV

### HUMANITARIAN PROGRAM IN UKRAINE

Use of bioengineered human acellular vessels to treat traumatic injuries in the Ukraine-Russia conflict

Oleksandr Skoliba,<sup>1</sup> Kostyl Shepurenko,<sup>2</sup> Oleh Stupnyy,<sup>3</sup> Oleksandr Stankiv,<sup>4</sup> Serhiy Yants,<sup>5</sup> Yulija Yurkova,<sup>6</sup> and Laura E. Niklason<sup>7</sup>

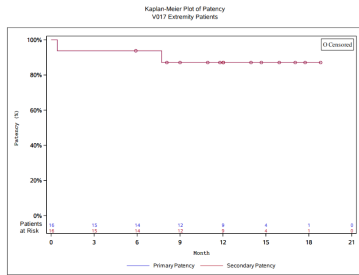
<sup>1</sup>Dnipro State Medical University, Dnipro, Ukraine  
<sup>2</sup>State Institute of Science Research and Practical Center of Preventive and Clinical Medicine, Kyiv, Ukraine  
<sup>3</sup>Vinnytsya Regional Clinical Hospital, Vinnytsya, Ukraine  
<sup>4</sup>Odessa Regional Clinical Hospital, Odessa, Ukraine  
<sup>5</sup>Humacyte Global, Inc., NC, USA

**Lancet Regional Health - Europe 2023;29**

- Enrolled 17 patients with vascular injury and no viable autologous conduit; endpoints of patency, conduit infection, amputation and death
- Majority from blast mechanism (explosive with penetrating element) followed by gunshot (overall 88% penetrating); 56% lower extremity
- 100% technical feasibility with 30-day patency of 94% (most short interposition grafts); no conduit-related infections, amputations or death

### HUMANITARIAN PROGRAM IN UKRAINE

- Mean follow-up 358 days
- KM estimates of 12-month patency of 87.1% (95% CI [42.5, 97.8])
- No conduit infections, amputations limbs or conduit-related deaths
- One conduit thrombosis at six-month follow-up
- No reports of conduit pseudo-aneurysm or structural abnormalities



### SUMMARY OF HAV NOW ATEV

- Mayo IND study shows Acellular Tissue Engineered Vessel to be safe and effective conduit for CLTI patients and no autologous vein; modest patency as long leg bypass in a complex cohort
- ATEV has physical and logistical attributes of a conduit ideal for vascular injury; patency may be better as short interposition grafts more often used for trauma than long-leg bypass
- ATEV shown to be feasible, safe and effective in the wartime setting in its use to manage select patterns of vascular injury in Ukraine in patients with no autologous options