Humacyte®

Universally Implantable Regenerative Human Tissue

Disclaimer

These slides and the accompanying oral presentation contain forward-looking statements. All statements, other than statements of historical fact, included in these slides and the accompanying oral presentation are forward-looking statements reflecting management's current beliefs and expectations. In some cases, you can identify forward-looking statements by terminology such as "will," "anticipate," "expect," "believe," "intend" and "should" or the negative of these terms or other comparable terminology. Forward-looking statements in these slides and the accompanying oral presentation include, but are not limited to, statements about our plans and ability to commercialize our bioengineered acellular tissue engineered vessels ("ATEV™s") in the United States under the brand name Symvess™ in vascular trauma repair; the anticipated commercialization of our ATEVs and our ability to manufacture ATEVs and other product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our plans, anticipated timelines and ability to obtain marketing approval from the U.S. Food and Drug Administration ("FDA") and other regulatory authorities, including the European Medicines Agency and Israel, for our ATEVs in other indications and other product candidates; our plans and expectations regarding the results of our clinical trials. Including our V012 Phase 3 clinical trial, and regarding our ongoing or planned clinical trials; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates; the outcome of our ongoing discussions with the FDA concerning the design of our clinical trials; our anticipated growth rate and market opportunities; the potential liquidity and trading of our securities; our ability to raise additional capital in the future; our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates; the anticipated characteristics and performance of our ATEVs; the expected size of the target populations and addressable markets for our product candidates; the anticipated benefits of our ATEVs relative to existing alternatives; our assessment of the competitive landscape; the degree of market acceptance of ATEVs and the availability of third-party coverage and reimbursement; the implementation of our business model and strategic plans for our business; our expectations regarding our strategic partnership with Fresenius Medical Care Holdings, Inc.; the performance of other third parties on which we rely, including our third-party manufacturers, our licensors, our suppliers and the organizations conducting our clinical trials; our ability to obtain and maintain intellectual property protection for our product candidates as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others; our ability to maintain the confidentiality of our trade secrets, particularly with respect to our manufacturing process; our compliance with applicable laws and regulatory requirements, including FDA regulations, healthcare laws and regulations, and anti-corruption laws; our ability to attract, retain and motivate qualified personnel and to manage our growth effectively; our future financial performance and capital requirements; our ability to implement and maintain effective internal controls; and the impact of the overall global economy and increasing interest rates and inflation on our business. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. The potential risks and uncertainties that could cause actual results to differ from the results predicted include, among others, those risks and uncertainties included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K for the year ended December 31, 2025, our quarterly report on Form 10-Q for the quarter ended March 31, 2026, each filed by Humacyte with the Securities and Exchange Commission, and in future filings made with the Securities and Exchange Commission from time to time. Any forward-looking statements contained herein are based on assumptions that we believe to be reasonable as of the date hereof. Except as required by law, we assume no obligation to update these forward-looking statements, even if new information becomes available in the future. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of our securities, in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the reregistration or qualification under the securities laws of any such state or other jurisdiction. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

V012 Interim Results – Study in Women Met Primary Endpoint

- The ATEV met V012's primary endpoint by demonstrating superior catheter-free days compared to arteriovenous fistula (AVF), the standard of care
  - 91 more catheter-free days for ATEV versus AVF
- ATEV patients incurred 17 fewer dialysis access infections than AVF per 100 patient-years, the primary safety measure for the study
- The ATEV was observed to have consistent advantages over AVF in multiple secondary endpoints
- Overall benefit-risk safety profile of ATEV was favorable with no new or unexpected safety concerns identified

Statistically Significant

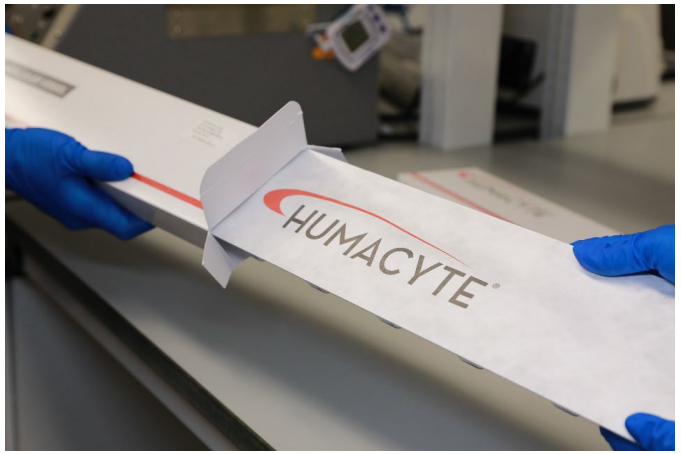
p=0.0007

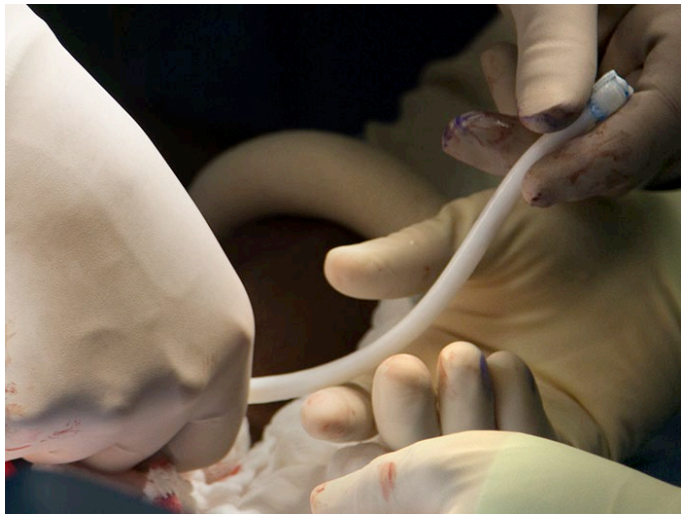
Pre-specified superiority threshold met

Interim analysis: ATEV (N=40) vs AVF (N=40)

Humacyte plans to file a supplemental BLA with the FDA during the second half of 2026 (target indication is in adult patients with end-stage kidney disease (ESKD) who are at increased risk of AV fistula maturation failure)

Humacyte is a Leader the Field of Regenerative Medicine:
Bioengineered Tissues & Organs





- Off-the-shelf, no special preparation required
- Universally implantable with no immuno-suppression
- Regenerate as the patient's own tissue

Category-Defining Innovation that Creates New Tissues

Humacyte Leadership & Board

Leadership Team

Laura E. Niklason, MD, PhD
Founder, President, Chief Executive Officer

Dale Sander
Chief Financial Officer, Chief Corporate Development Officer

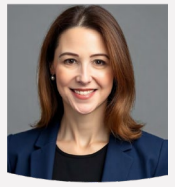
Shamik Parikh, MD
Chief Medical Officer

Heather Connelly
Chief Quality & Regulatory Officer

Jim Mercandante
Chief Commercial Officer

Tood Rasmussen, MD
Chief Surgical Officer

Sabrina Osborne
Chief People Officer



Lisa Molyneux
EVP, Enterprise Planning & Analysis

Board of Directors

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Chair of the Board

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Susan Windham-Bannister, PhD

Prior Experience

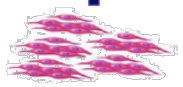
Lilly
AstraZeneca
GSK
Harvard Medical School
Merck
Mayo Clinic
U.S. Department of Heath and Human Services
Duke University School of Medicine
Johnson & Johnson
AVITA Medical
Pfizer
Teleflex
Abbott
Fresenius
Novartis
Yale University School of Medicine

Platform & Manufacturing:
Enable Broad Pipeline of Regenerative Medicine Products

Humacyte®

Bioengineering Platform

1 Cell seeding



Working cell stock

Cells transferred onto polymer mesh

2 Tissue formation

Cells proliferate & build extracellular matrix

Polymer mesh degrades, leaving vascular cells and extracellular matrix

3 Cell removal and packaging

Decellularization solutions clean and remove vascular cells from vessel

Enables creation of universally implantable tissues and organs

Commercial-Scale Manufacturing

Strategically designed with modular capabilities to manufacture products at scale

Vascular tissue constructs (ATEV) ⟷ **Advanced tissue constructs** ⟷ **Advanced organ systems**

Our platform technology enables development of a broad range of product candidates

Symvess Demonstrates Mechanical Strength and Remodeling with Patient's Own Cells

Humacyte®

Mechanical

- **Symvess withstands the forces associated with suturing and the arterial blood flow.[1]**

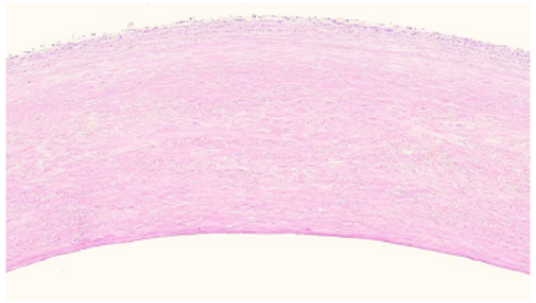
DIFFERENCES OF VESSEL MECHANICAL PROPERTIES[2]

Vessel Type	Suture Strength (g)	Burst Pressure (mmHg)
Symvess	**251**	**3727**
Human Saphenous Vein	196	1599
Human Internal Mammary Artery	138	3196

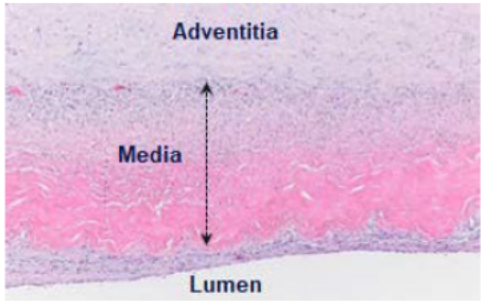
Biological

- **Symvess extracellular matrix can support cell binding and proliferation.[1]**

PRE-IMPLANTATION*



4 WEEKS POST-IMPLANTATION**



Extracellular Matrix Host Cell Infiltration

* H&E-stained cross-section of Symvess pre-implantation

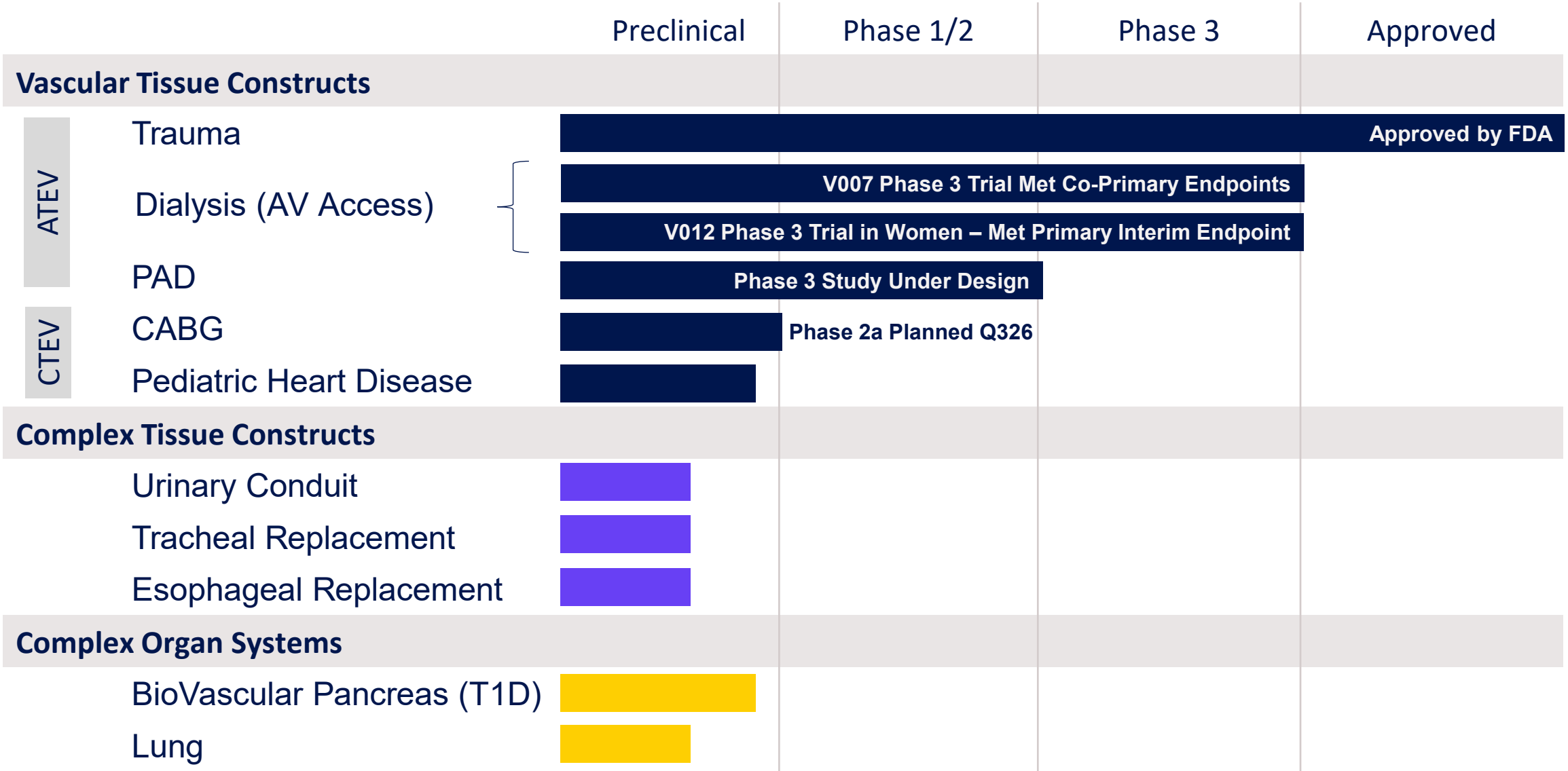
** Observed in porcine preclinical setting of H&E-stained cross-section of Symvess mid-graft tissue explant revealing high density and infiltration depth of host cells.[3]

Once implanted, Symvess integrates with host cells.
The body's host cells recognize the human matrix and populate the vessel in a circumferential manner.

1. Symvess U.S. Prescribing Information. Durham, NC. Humacyte Global, Inc. 2. Nash KM, et al. Evaluation of tissue-engineered human acellular vessels as a Blalock–Taussig–Thomas shunt in a juvenile primate model. JTCVS Open 2023;15:433-45. 3. Kirkton RD, et al. Evaluation of vascular repair by tissue-engineered human acellular vessels or expanded polytetrafluoroethylene grafts in a porcine model of limb ischemia and reperfusion. *J Trauma Acute Care Surg*. 2023;95: 234–241.

acellular tissue engineered vessel-tyod Symvess™

Pipeline with Multiple Potential Commercial Launches




Symvess™
acellular tissue
engineered vessel-tyod
FDA Approved in
Extremity Vascular Trauma
Humacyte®

Symvess is FDA Approved in Extremity Vascular Trauma

Humacyte®

acellular tissue engineered vessel-tyod
Symvess™

- **Repopulates with the patient's cells**[1-2,3]
- **Low susceptibility to infection**[4]
- **No immune response observed**[1-3,5]
- **Off-the-shelf, ready to use**[1,3]
- **Low amputation results**[1]

INDICATION

SYMVESS is an acellular tissue engineered vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

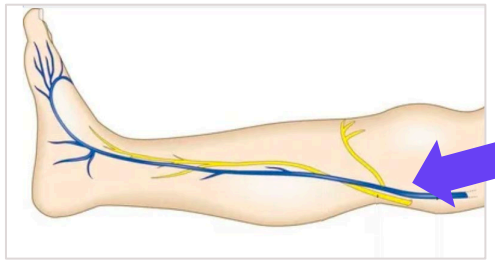
PLEASE SEE ACCOMPANYING FULL PRESCRIBING INFORMATION AT SYMVESS.COM, INCLUDING BOXED WARNING.

REFERENCES: 1. Symvess U.S. Prescribing Information. Durham, NC. Humacyte Global, Inc. **2.** Kirkton RD, et al. Bioengineered human acellular vessels recellularize and evolve into living blood vessels after human implantation. *Sci Transl Med*. 2019;11(485):eaau6934. **3.** Dahl S, et al. Readily available tissue-engineered vascular grafts. *Sci Transl Med*. 2011 Feb 2;3(68):68ra9. **4.** Wang J, et al. Biological mechanisms of infection resistance in tissue engineered blood vessels compared to synthetic expanded polytetrafluoroethylene grafts. *JVS Vasc Sci*. 2023;4:100120. **5.** Moore EE, et al. Bioengineered Human Arteries for the Repair of Vascular Injuries. *JAMA Surg*. 2024 Nov 20:e244893.

Vascular Trauma Injuries – Symvess Value Proposition

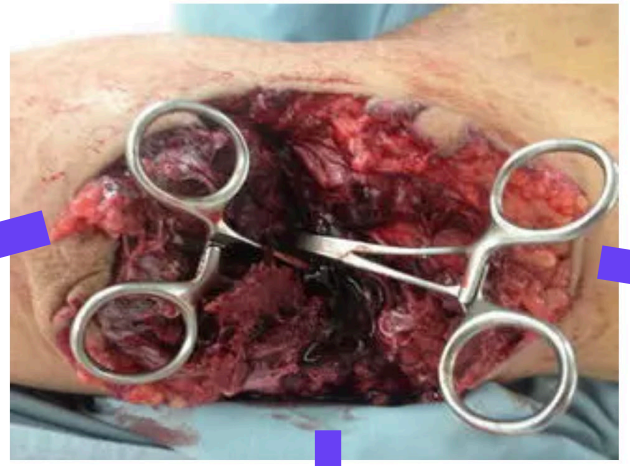
- Common causes of vascular injuries include workplace injuries, car accidents, gunshots and stabbings, and sports injuries
- Symvess addresses major drawbacks of current treatment options:

Symvess is immediately available, off-the-shelf, and does not require further injuring the patient

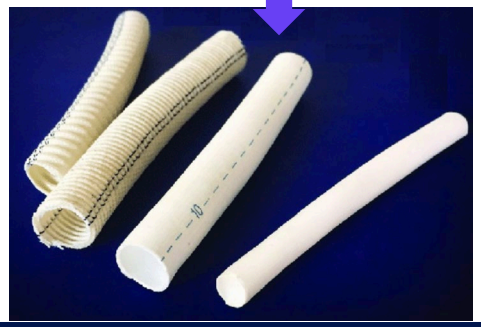


Vein is the standard of care, but takes valuable time, delaying revascularization

Exit wound of a shotgun injury



Amputation



Prosthetic grafts are quick, but have infection risk and high rates of amputation

Two Studies Were Used to Support FDA Approval

First Study: CLN-PRO-V005 Phase 2/3 Pivotal Trial In U.S. and Israel

- Single-arm, open label study
- Conducted at Level 1 trauma centers
- Arteria injury repair
- Extremity injuries at high risk of contamination / infection
- 69 patients enrolled as of data cut off
- As agreed upon with FDA, focus for BLA filing was 51 patients with extremity injuries

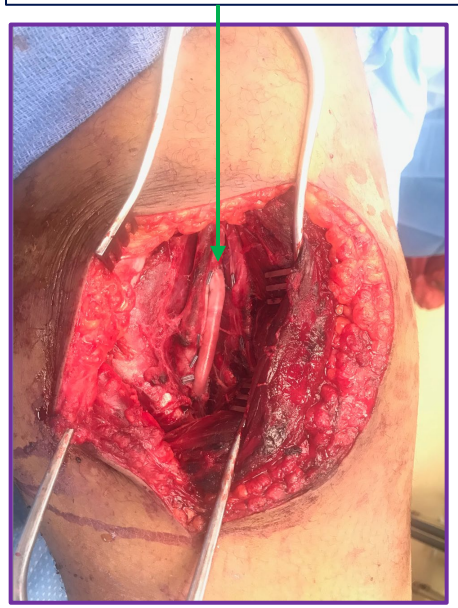
Statistical Analysis Plan

Historical Benchmark Comparator
- > Systematic literature review of synthetic grafts in vascular trauma

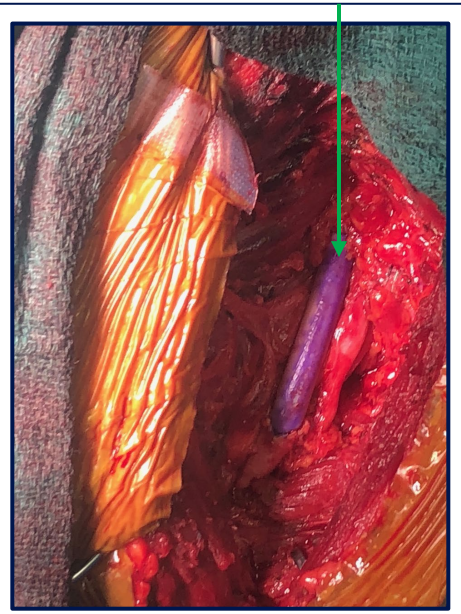
Primary Comparison
- > 30-day endpoint of patency

Secondary Comparisons
- > 30-day infection rate
- > 30-day amputation rate

Examples of Symvess Implants in V005 Study



Gunshot Wound



Industrial Accident

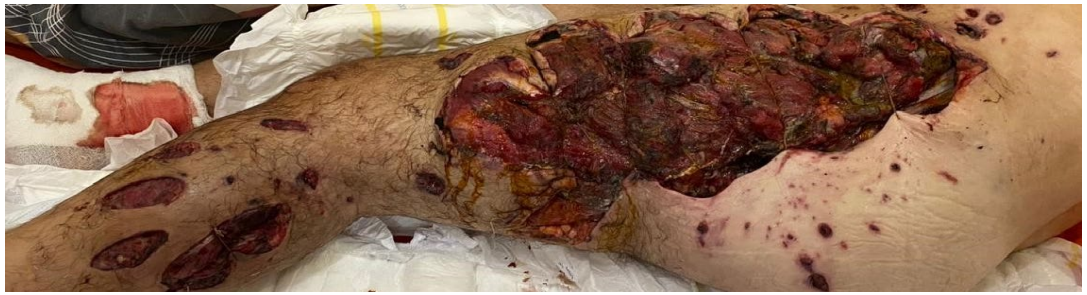
Knee Dislocation

Ukraine Real World Experience in Vascular Repair

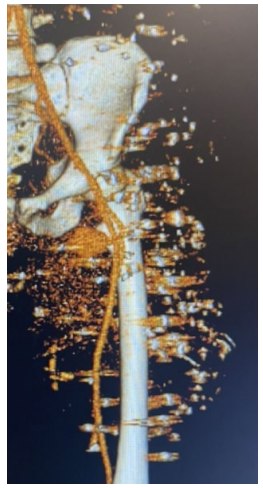
Second Study: V017 Humanitarian Program in Ukraine

- At request of Ukraine surgeons Humacyte supported humanitarian program for patients injured in conflict
- 19 patients received Symvess
- At suggestion of FDA, patients from humanitarian program were included in BLA filing
  - 17 consented for data collection and study participation
  - 16 patients had extremity trauma repair (one patient required Symvess for Iatrogenic trauma repair)

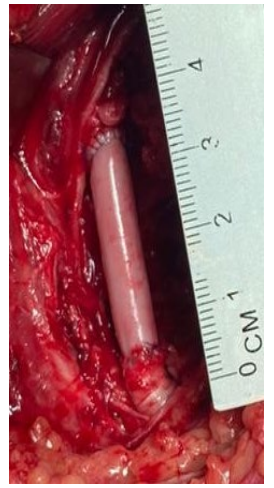
Case Study of Patient Treated in Ukraine Program



Ukraine Patient Blast Injury



Pre-op CT Scan



Symvess repair of Femoral artery

Walking once again (Day 113)

Clinical Improvement with Symvess over Synthetics

acellular tissue engineered vessel-tyod Symvess™

Improved outcomes of Symvess compared to synthetic graft benchmark observed in two studies

Symvess represents a new definitive and durable repair option in patients with extremity arterial injury when a vascular graft is needed and no vein is available.

Symvess was observed to have higher secondary patency and lower amputation and infection rates compared to the synthetic graft benchmark used in the BLA filing.

Outcome Day 30	Combined Symvess V005 and V017 Studies (N=67)	Synthetic Graft Benchmark
Primary Patency	87.1%	78.9%
Secondary Patency	91.5%	78.9%
Conduit Infection rate	0.9%	8.4%
Amputation rate	4.5%	24.3%
Death rate (all cause)	3. 5%	3.4%

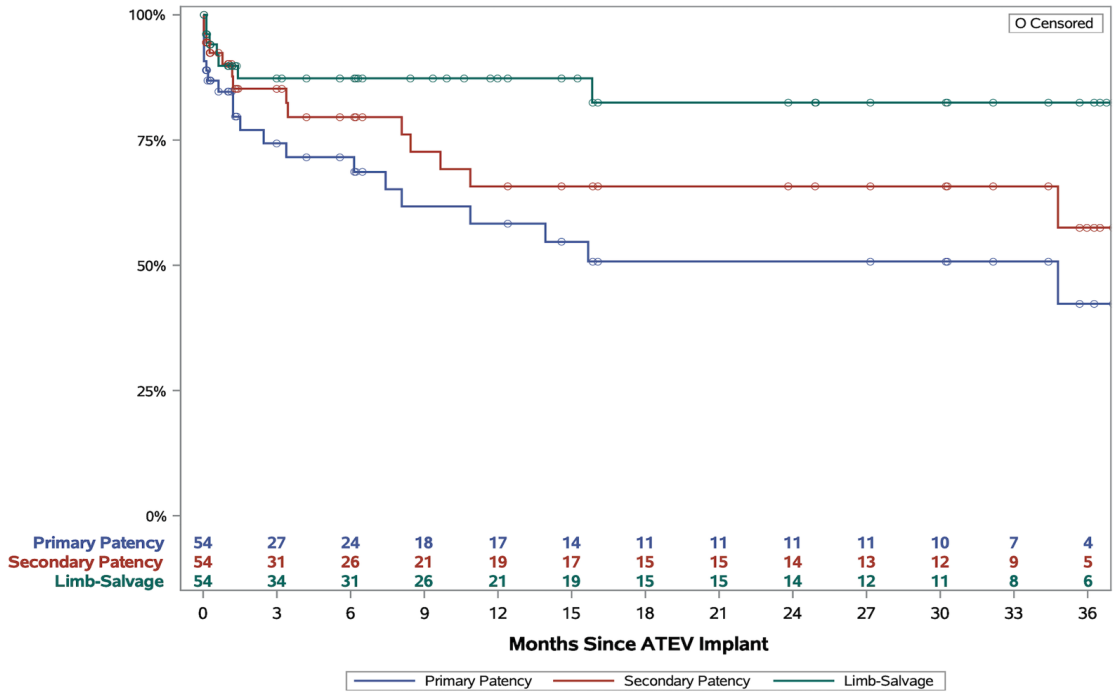
Moore EE, et al. *JAMA Surg*. 2024 Nov 20:e244893. ; Humacyte BLA filed December 11, 2023.

Durability of Symvess in Injury Repair

Long-Term V005 Results[1]

After up to 36 months of follow-up, patients demonstrated:

- High rates of limb salvage
- Low rates of infection
- No unprovoked structural failures



Long-Term V017 Results[2]

- Trauma patients with battlefield injuries in Ukraine were followed for up to 18 months.
- Wartime patients treated with Symvess were observed to have:
  - High rate of patency (87.1%)
  - 100% limb salvage
  - Zero cases of conduit infection
  - Zero deaths

Publications

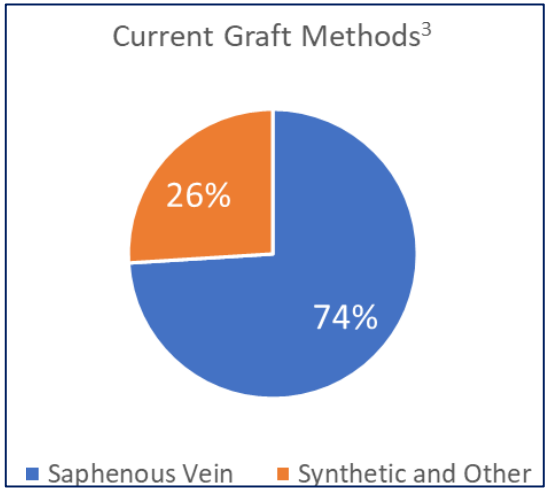
[1]Curi MA, et al. J Vasc Surg Cases Innov Tech. 2025 Nov

[2]Parikh S, et al.. Mil Med. 2025 Sep

U.S. Vascular Trauma Market – Total Addressable Market for Symvess

Total Vascular Trauma Patients (All Injuries)[1]
79,000
Emergent Vascular Trauma – 56,000 Iatrogenic Vascular Trauma – 23,000

Target U.S. TAM for Symvess Based on Hospital Claims Data[2]
26,000
Emergent Vascular Trauma – 18,667 Iatrogenic Vascular Trauma – 7,333



Symvess-Eligible Patients	Exclusions
• Type of repair: Bypass, repair, replacement, supplement, destruction or restriction • Location: Extremity arteries of interest • Iatrogenic: Arterial injuries co-occurring with other surgeries	• Vein injury / repair • Injuries to torso, head, neck, wrist, hand, ankle, foot • Primary repair: Ligation or endovascular repair

[1]Third-party market research based on procedural volumes (2019) and secondary literature search
[2]Based on analysis of Definitive Healthcare (DHC) Claims Database 2022, claims as of November 2023. Adjusted to reflect estimate the database captures approximately 60% of procedures:
Diagnosis (Dx) Codes: Identify Injury type, location
Procedure Codes: ICD-10 PCS or CPT
[3]Based on analysis of Prospective Observational Vascular Injury Trial (PROOVIT) registry

Drivers of U.S. Commercial Launch in Vascular Trauma

Humacyte

Symvess™

acellular tissue engineered vessel-tyod

Concentrated Market

Approximately 200 Level 1 trauma centers in U.S.

Approximately 3,000 vascular surgeons across civilian and military market opportunities

Strong Clinical Results

In the civilian and military clinical studies, Symvess was observed to have high rates of patency and low rates of amputation and infection

The Right Team

Sales team of 12 executives who are experienced in vascular and/or trauma surgery and regenerative therapies

Sales team is complemented by Medical Affairs, market access, and marketing teams

Health Economics

Budget Impact Model projects that the per-patient cost of treating patients with Symvess is estimated to be less than the cost of treating with synthetic grafts and other conduits

Symvess in Extremity Injury: Savings in Hospital Charges

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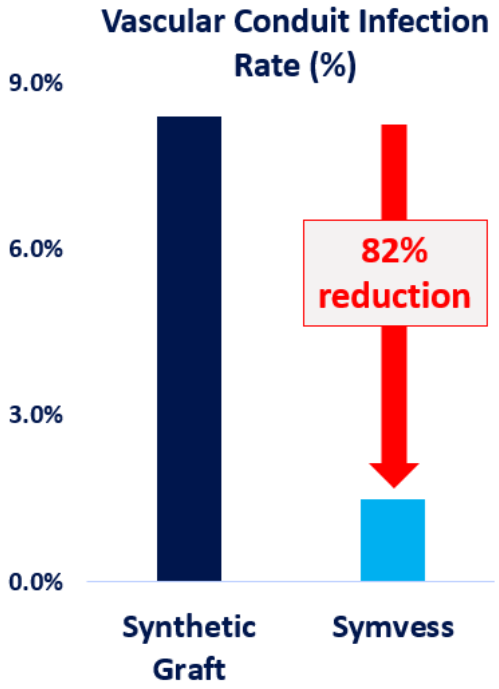
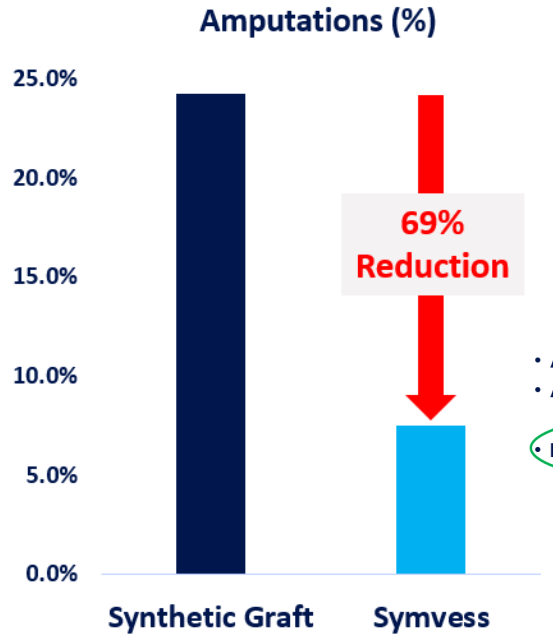
Healthcare Economics

Symvess is associated with meaningful reductions in hospital charges when used in patients lacking feasible saphenous vein



Additional hospital charges associated with each vascular graft infection:
$589,921

- Infection charge per Synthetic graft: $49,553
- Infection charge per Symvess: $8,848
- Potential Savings with EACH SYMVESS: $40,705



Additional hospital charges associated with each amputation:
$492,986

- Amputation cost per Synthetic graft: $119,796
- Amputation cost per Symvess: $36,974
- Potential Savings with EACH SYMVESS: $82,822

1. Velez, F. F., Rajani, R. R., Malone, D. C., et al. Journal of Medical Economics, 28(1), 323–334. **2.** Brouwer E, Velez FF, Tan J. Submitted manuscript undergoing peer review.

Symvess Budget Impact Model (BIM) in Extremity Arterial Injury

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Healthcare Economics

Published in *J Med Econ,* showed use of Symvess in patients without feasible saphenous vein resulted in a net cost reduction[1]

JOURNAL OF MEDICAL ECONOMICS
2025, VOL. 28, NO. 1, 323–334
https://doi.org/10.1080/13696998.2025.2469460
Article /2469460

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ORIGINAL RESEARCH

OPEN ACCESS

Budget impact model of acellular tissue engineered vessel for the repair of extremity arterial trauma when autologous vein is not feasible

Fulton F. Velez[a], Ravi R. Rajani[b], Daniel C. Malone[c], Lucille A. Sun[d], Lisa Bloudek[d], Kai Carter[a], Mary Panaccio[a] and Laura E. Niklason[a]

[a]Humacyte Global, Inc, Durham, NC, USA; [b]Department of Surgery, Emory University, Atlanta, GA, USA; [c]Strategic Therapeutics, LLC, Tucson, AZ, USA; [d]Curta, Inc, Seattle, WA, USA; [e]Independent Consultant, New York City, NY, USA

ABSTRACT

Aims: To predict the budget impact of Symvess (Symvess is a trademark of Humacyte Global, Inc.) (acellular tissue engineered vessel-tyod [ATEV]) for extremity arterial trauma repair when autologous vein repair is not feasible.

Materials and methods: The 3-year budget impact of adding ATEV as a repair option alongside autologous vein, prosthetic graft, and "non-autologous other" grafts was evaluated from the perspectives of a Level I trauma center and third-party commercial payers. Conduit-specific complication rates were obtained from two clinical studies for ATEV and from the published literature and analysis of the PROOVIT registry for other conduits. Costs were compared pre- and post-ATEV availability. Conduit-related costs and complications included conduit infections, amputations, vein harvest site infection, surgical re-interventions, rehabilitation after amputation, and 12-month post-discharge costs. Impact on operating room (OR) time and readmissions was evaluated. A sensitivity analysis was conducted to evaluate parameter uncertainty.

Results: With introduction of ATEV, there was a 29.8% reduction in amputations and a 29.5% reduction in graft infections over 3 years. From a Level I trauma center perspective, seven patients were expected to receive an ATEV over 3 years, with cumulative cost savings of $80,650 (2.3% decrease). OR time would decrease by 8.6 h, and readmission-related costs would be reduced by 16.7% with ATEV availability. From the third-party commercial payer perspective, 35 patients were expected to receive ATEV, with a budget impact showing a savings of −$0.08 per member per month after 3 years. For trauma centers, sensitivity analysis showed that cost drivers were amputation risk associated with "non-autologous other" graft types and market share of autologous vein (short ischemia time).

Limitations: Uncertainty surrounding model parameters.

Conclusions: ATEV was projected to be cost-saving over 3 years for both trauma centers and third-party payers due to reductions in the costs related to amputations and conduit infections.

ARTICLE HISTORY
Received 28 January 2025
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KEYWORDS
Acellular tissue engineered vessel; cryopreserved allograft; bovine xenograft; prosthetic graft; vascular trauma; arterial repair; autologous vein; budget impact; cost

JEL CLASSIFICATION CODES
A12; I10; H51

Introduction

Vascular trauma poses a significant clinical burden in terms of disability and loss of life[1]. The use of autologous vein, typically the greater saphenous vein, remains the gold standard for extremity arterial injury repair due to favorable patency outcomes, infection resistance, low amputation rates, and improved rates of freedom from conduit-related complications[2–4]. Unfortunately, many patients do not possess an adequate vein for autologous injury repair, and the field has seen limited innovations in conduits over the past 60 years[4].

An analysis of patients with lower extremity arterial injuries from the National Trauma Data Bank (NTDB) research dataset ($n = 4,406$) found that the overall mortality was 3.2%, and 11.3% of patients underwent amputation[5]. A recently published analysis of 8,780 patients in the NTDB with extremity arterial trauma found that, compared to repair with autologous vein, use of a prosthetic (i.e. synthetic) conduit was associated with a 2.8-fold higher rate of upper limb amputation and a 1.3-fold higher rate of lower limb amputation[6]. Additionally, reintervention rates were 50% higher with prosthetic conduit compared to autologous vein repairs[6]. Furthermore, recent unpublished analyses of linked hospital chargemaster and claims data have shown the impact of in-hospital and post-discharge complications on costs, which disproportionately affect patients treated with grafts other than autologous vein[2]. Hence, when use of autologous vein is not feasible, the treatment options available to patients and surgeons for repair of extremity arterial injury are suboptimal[4–6].

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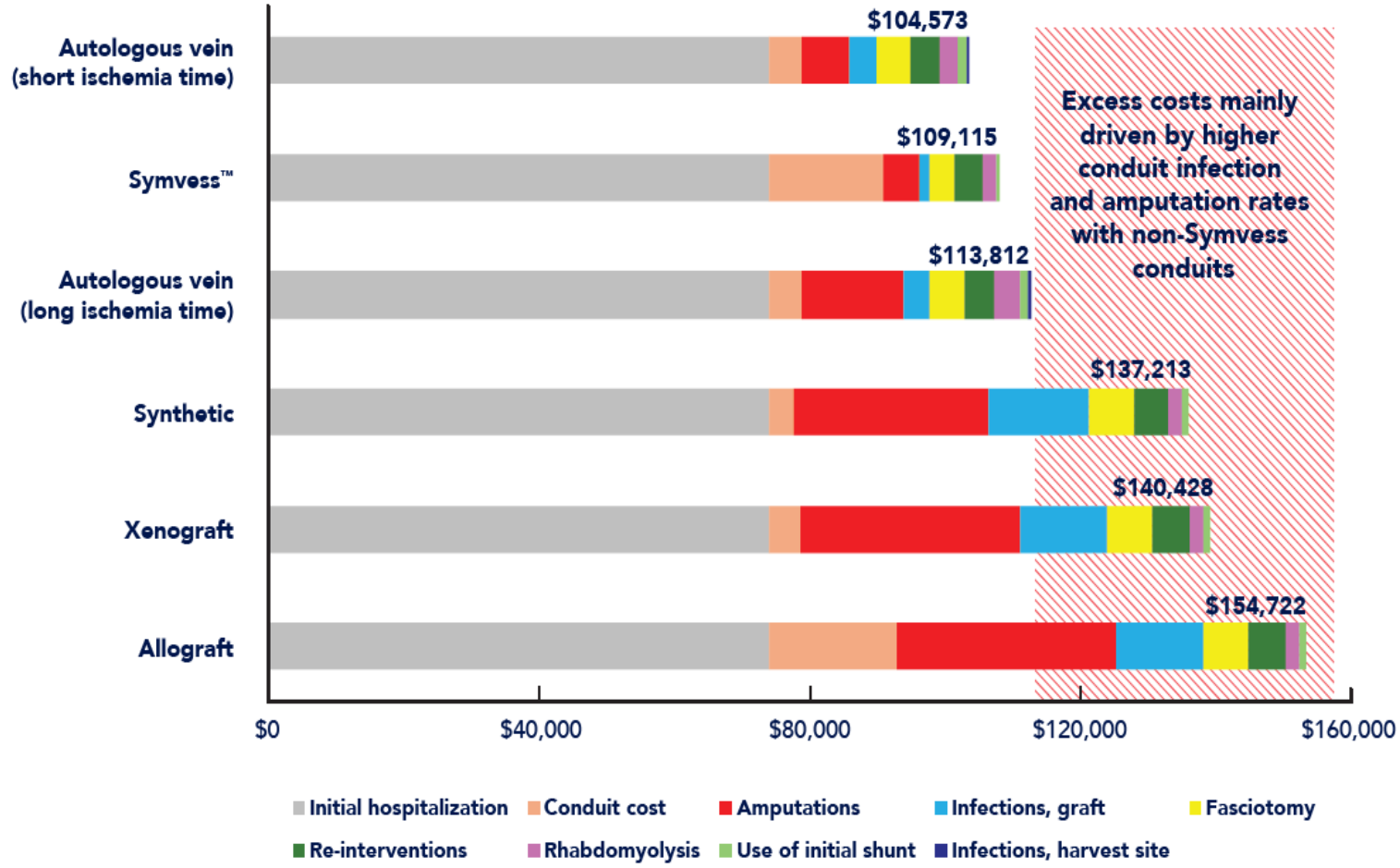
Supplemental data for this article can be accessed online at https://doi.org/10.1080/13696998.2025.2469460.

This article was originally published with errors, which have now been corrected in the online version. Please see Correction (https://doi.org/10.1080/13696998.2025.2477875).

www.tandfonline.com/ijme

At its current price point of $17,000, Symvess was shown to be the second-most economical arterial graft, after saphenous vein[1]



1. Velez, F. F., Rajani, R. R., Malone, D. C., et al. Journal of Medical Economics, 28(1), 323–334. **2.** Brouwer E, Velez FF, Tan J. Submitted manuscript undergoing peer review.

Department of Defense Support

acellular tissue engineered vessel-tyod Symvess™

The Department of Defense (DoD) invested in Symvess in recognition of its benefit in battlefield injuries for warfighters

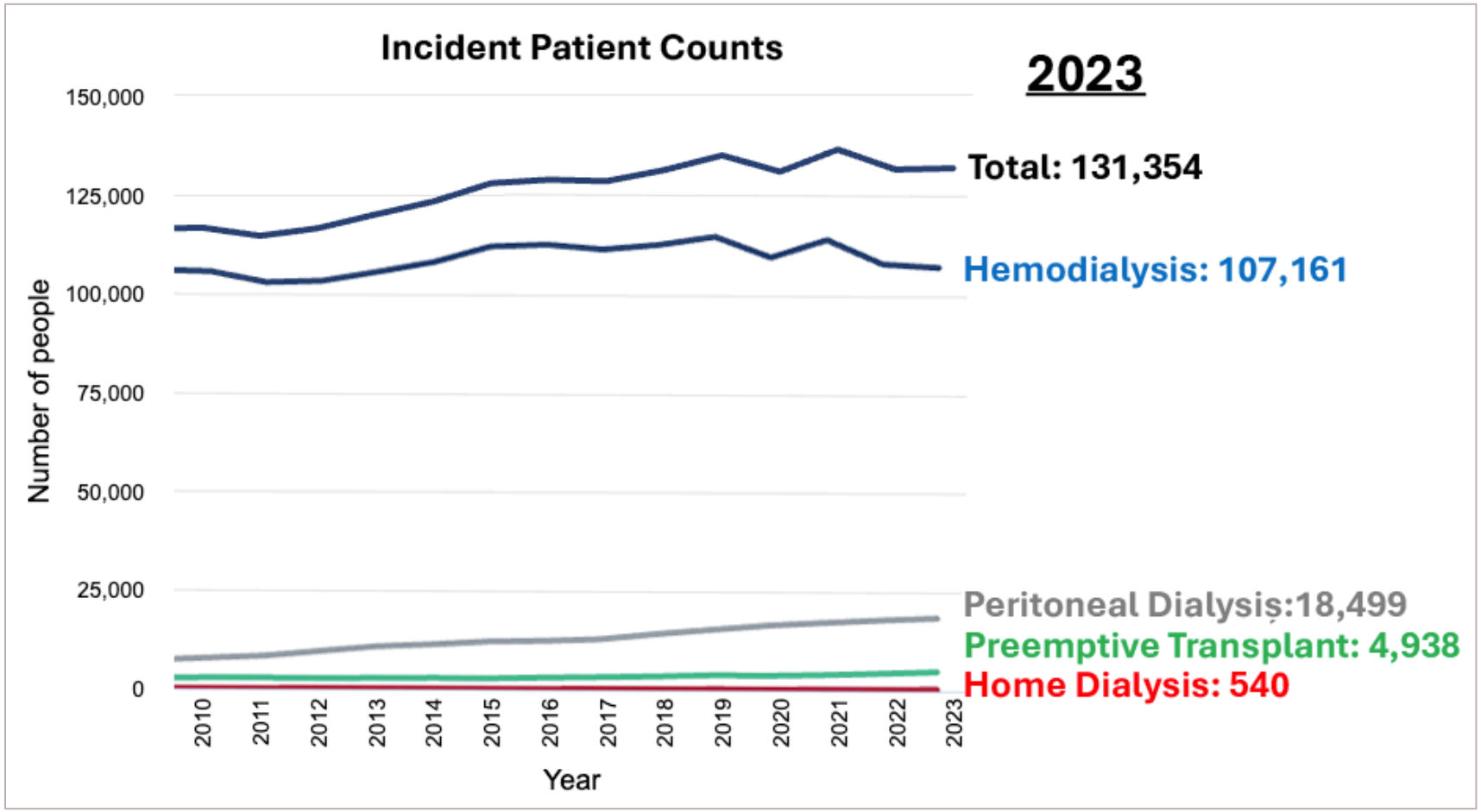
DEPARTMENT OF DEFENSE SUPPORT
Symvess (ATEV) for Vascular Trauma designated as a **"Priority Product"** by DoD • designation created by Public Law 115-92 to expedite the development and FDA review of DoD priority technologies
V005 Phase 3 clinical trial was partially funded by the DoD
Symvess successfully treated Ukrainian warfighters, resulting in 100% limb salvage
FY 2026 DoD Appropriations Act includes funding for the evaluation and incorporation of biologic vascular repair technologies for warfighters

In civilian mass-casualty situations, having Symvess on the shelf can also help with response to terrorism/other threats, since surgeons can operate more quickly and treat more patients, not having to take time to harvest vein

Pipeline: AV Access for Dialysis

Humacyte®

Incident Patients With End-Stage Kidney Disease



Every year, more than 100,000 people start hemodialysis.
Most patients start hemodialysis on a catheter.

USRDS 2025: Chapter 1, Figures 1.1 and 1.3

AV Access for Hemodialysis Has Limitations

Estimate of Permanent Access Procedures Performed in U.S.

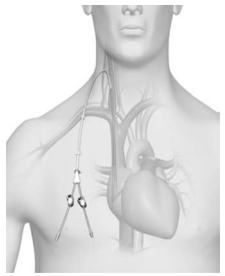
~60% AV fistulas

Primary/AV Fistula (Autogenous)

Market targeted by V007 and V012 Phase 3 Trials

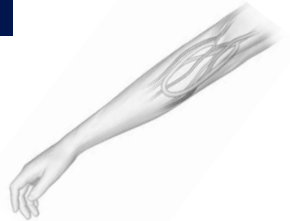
~20% Catheters

Venous / Temporary Catheter

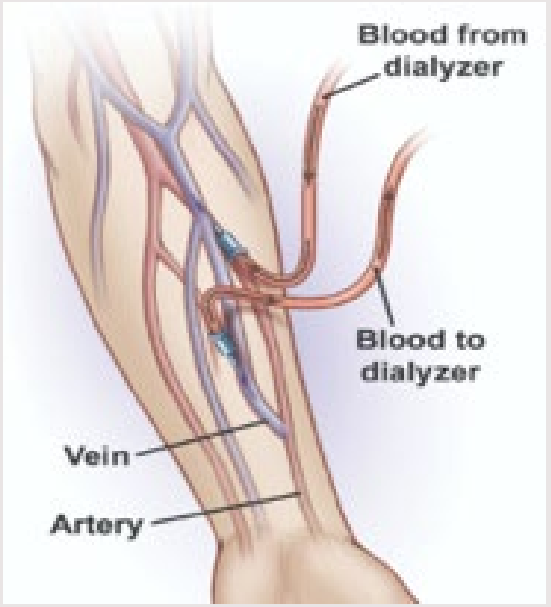


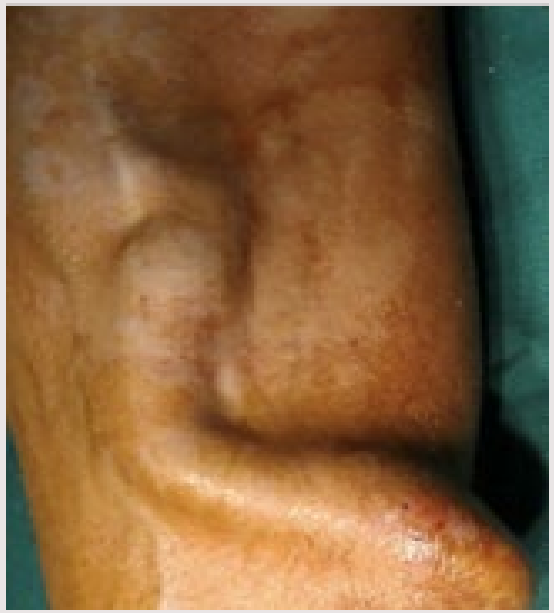
~20% Grafts

Secondary / Graft



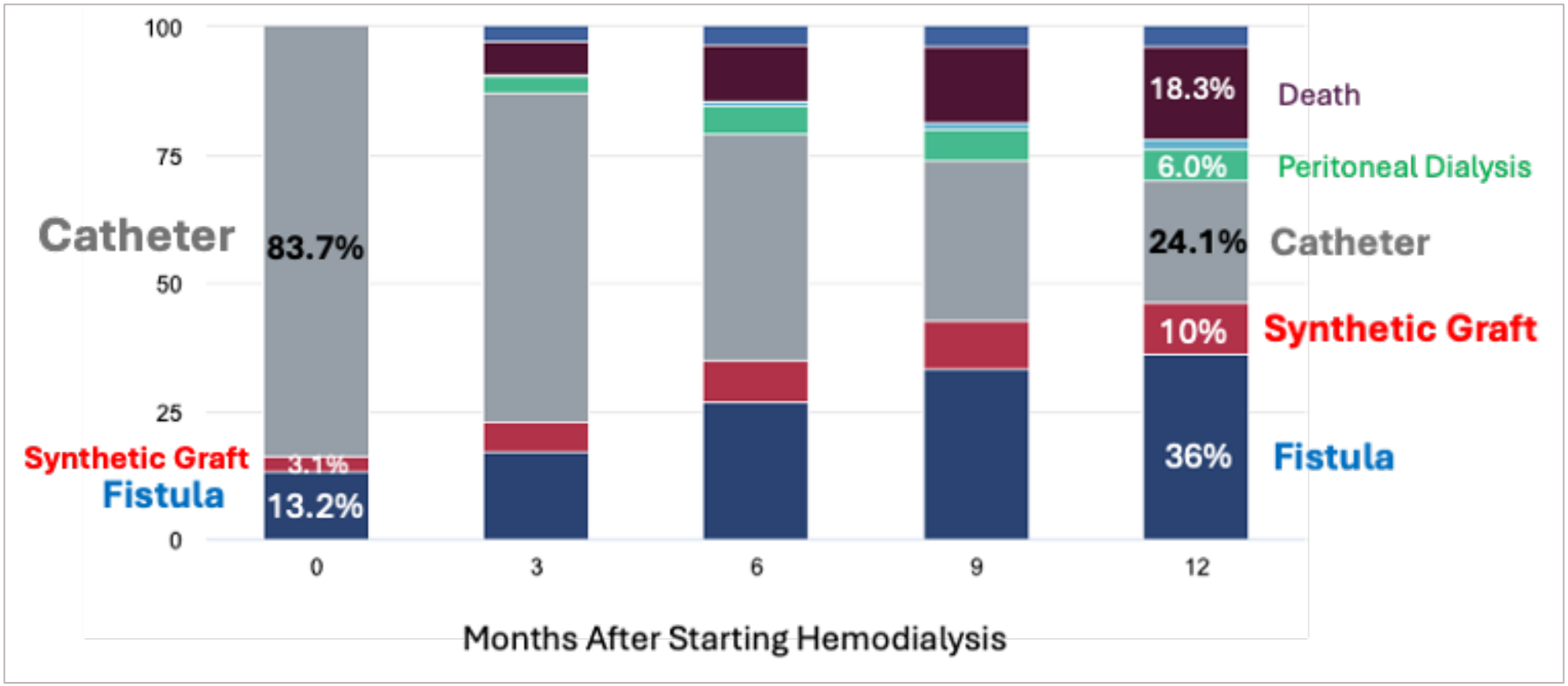
Limitations of AV Fistulas (Current Standard of Care)





- ~40% of fistulas fail to mature
- Even the fistulas that do mature take 3-6 months to become usable for dialysis
  - Catheter infection rates are up to 200% per patient-year

Access During the First Year: Too Many Catheters!

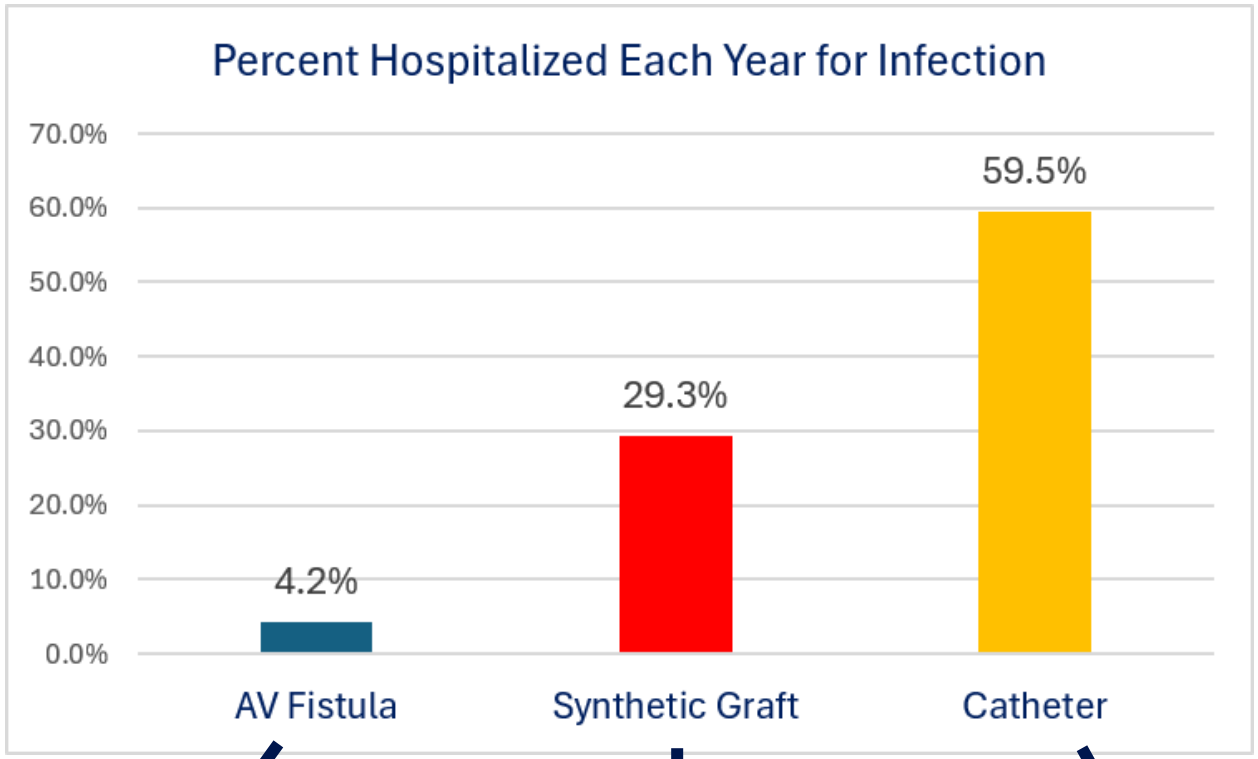


More than 80% of patients begin dialysis with a catheter.
After 12 Months, many patients are ***still on a catheter –***
Fistulas and Synthetic Grafts Are Not Working for These Patients.

USRDS 2025: Figure 4.8a, Chapter 4

Hospitalizations From Access Infections Each Year

Annual Hospitalized Percentage for Each Access Type



11,335 Patients hospitalized per year

22,671 Patients hospitalized per year

73,680 Patients hospitalized per year

Though less than half of accesses one year after starting dialysis, Catheters and Synthetic Grafts ***together account for ≈90% of infections***.

USRDS 2025: Figures 4.5a and 4.6, Chapter 4
Prevalent patients from Figure 1.12, Chapter 1
Assumes no more than 1 hospitalization per month per patient.

> 100,000 Hospitalizations Per Year for Hemodialysis Access Infections: A Multi-Billion Dollar Problem for Insurers

Hemodialysis Catheter Infections [1.3]

Hospitalization rate ~ 60%/patient-year
> 70,000 hospitalizations per year
Average hospitalization 4-5 days

Metastatic infections to heart, bones, joints, lungs, etc.

Can be debilitating and/or fatal.

COST PER Hospitalization: $29,175
COST TOTAL: $2.15 billion/yr

Synthetic Graft Infections [2,3]

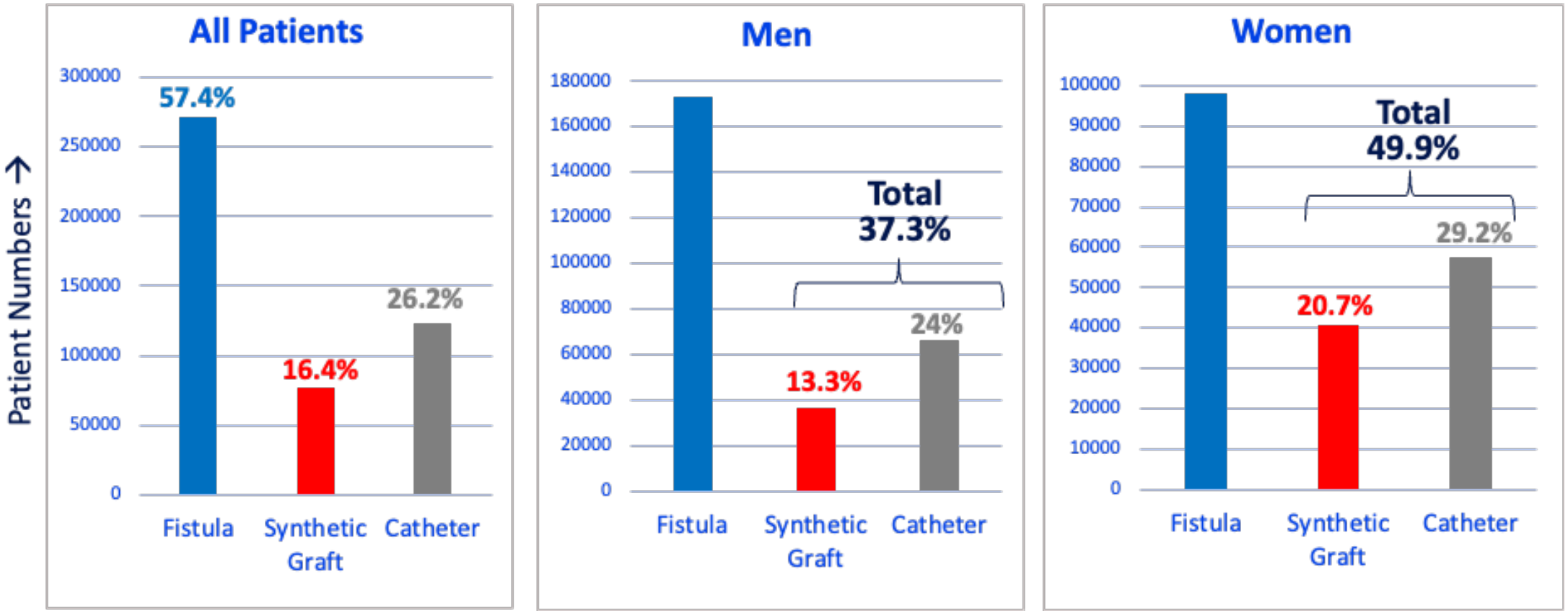
Hospitalization rate ~ 27%/patient-year
> 20,000 hospitalizations per year
Average hospitalization 8 ± 6 days

Half of patients still on catheter after 1 year, for fear of surgical access re-infection.

COST PER Hospitalization: $29,175
COST TOTAL: $0.62 billion/yr

1: Farrington, C.A. et al, Am J Nephrol 2019; 50: 126-132.
2: Cheng, T.W. et al, J Vasc Surg 2019; 70: 193-198.
3: Mohapatra, A., et al, J Vasc Surg 2021; 73: 581-587

Women are Burdened with Infection-Prone Accesses



49.9% of women use an infection-prone access – ***half of all women on dialysis***.
Catheters cause more bloodstream infections; episodes of sepsis; metastatic infections;
and hospitalizations. **Catheters and infections substantially increase costs.**

USRDS 2025: Table 1.6, Chapter 1
USRDS 2025: Figure 4.7, Chapter 4

ATEV is Designed to Address Failures in AV Access

ATEV provides potential for improved patient outcomes

- ATEV usable for dialysis after only four weeks
- ATEV reduces catheter contact time, thereby reducing risk of catheter infection
- > 80% of ATEVs functional for dialysis at 6 months
- ATEV infection rate is comparable to AVF
- Opportunity to reduce cost of access failures and other complications:
  - Access failures and complications
  - Dialysis complications
  - Infections

FRESENIUS MEDICAL CARE

Strategic collaboration with FMC, the largest provider of renal care services

RMAT

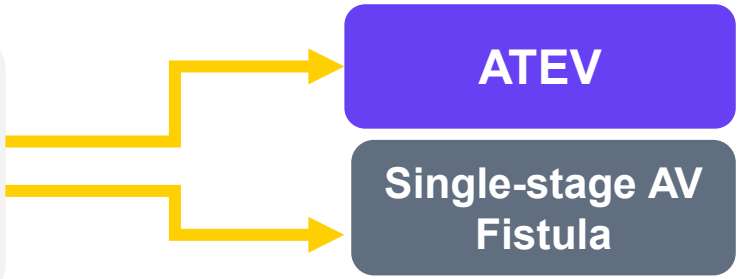
RMAT designation granted by FDA

V007 Phase 3 Results in Dialysis Access

Humacyte®

V007 Top-Line Results – ATEV Met Co-Primary Endpoints

- Subjects with end-stage renal disease in need of dialysis
- Enrollment completed April 2023, 242 total subjects



ATEV was observed to have superior function and patency at six and 12 months (co-primary endpoints) compared to autogenous fistula, the current standard of care for hemodialysis

Co-Primary Endpoints	ATEV (N=123)	AVF (N=119)	p-value
Functional Patency at Month 6	81.3%	66.4%	0.0071
Secondary Patency at Month 12	68.3%	62.2%	

- More adverse events were reported in patients on the ATEV treatment arm than those on the AV fistula treatment arm:
  - More thromboses in the ATEV group, but virtually all were resolved
  - A number of serious events occurred more frequently in the AVF arm:
    - Two ruptures of AVF (a potentially fatal event), none for ATEV
    - Substantially more "steal" (ischemia of the hand), surgical revisions, and balloon-assisted maturation in the AVF group compared to the ATEV group

V007 Superior Subgroup Results

ATEV showed superior function and patency in subgroups with historically poor outcomes

Females	ATEV (N=37)	AVF (N=33)	p-value	
Functional Patency at Month 6	89.2%	54.5%	<0.0001	
Secondary Patency at Month 12	81.1%	48.5%		
			Difference	p-value
Duration of Use Over First 12 Months	8.3 months	5.0 months	3.3 months	0.0011

Females, and males with BMI ≥ 30 and diabetes	ATEV (N=56)	AVF (N=54)	p-value	
Functional Patency at Month 6	85.7%	51.9%	<0.0001	
Secondary Patency at Month 12	76.8%	46.3%		
			Difference	p-value
Duration of Use Over First 12 Months	8.0 months	4.5 months	3.5 months	0.0002

V007 Safety Results in Key Subgroup

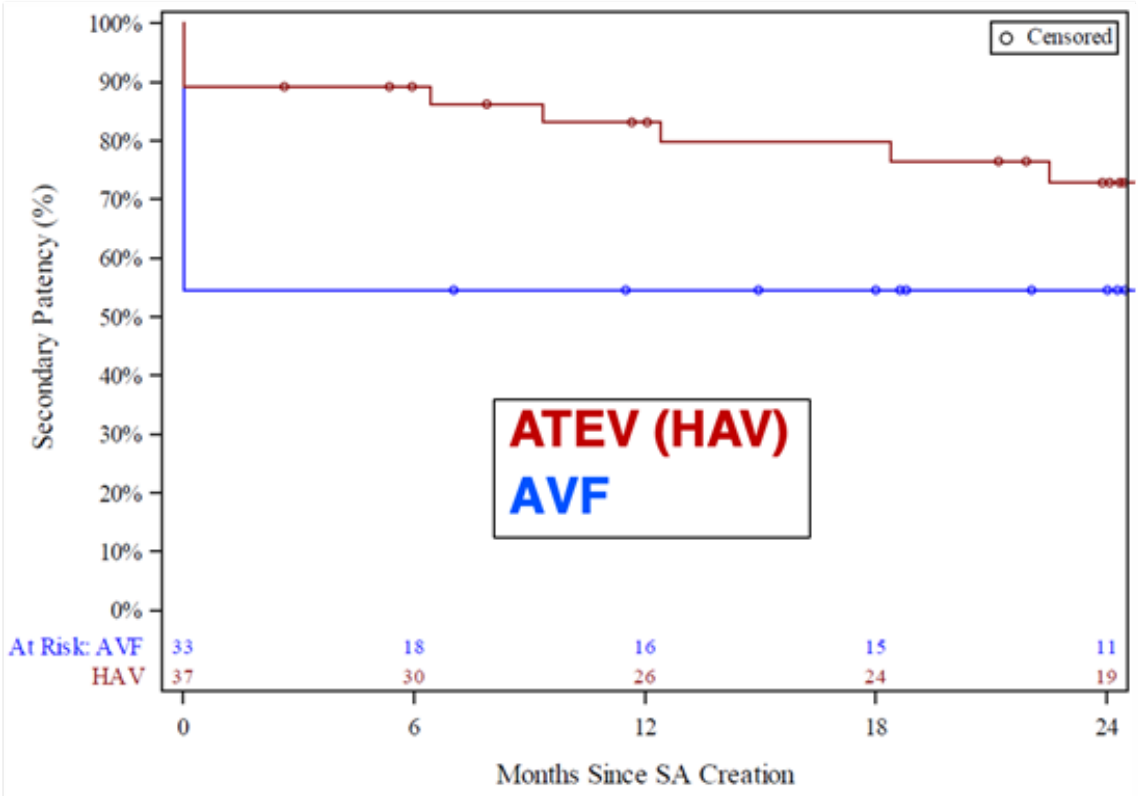
ATEV has shown no increased safety events per year of usability in all females and males with BMI ≥ 30 kg/m2 and diabetes

12-Month Safety Summary	ATEV		AVF	
	Subjects (%) n=54	Events per Patient Year	Subjects (%) n=56	Events per Patient Year
Treatment Emergent Adverse Events	96.3%	14.8	98.2%	21.8
Serious Adverse Events	77.8%	4.2	67.9%	6.1
Adverse Events of Special Interest:				
CEC SA-related infections	7.4%	0.1	5.5%	0.1
Thrombosis	51.9%	1.2	12.5%	0.3
Stenosis	64.8%	3.0	51.8%	2.9
Clinically significant Steal Syndrome	1.9%	0.0	3.6%	0.1
Rupture of SA	0.0%	0.0	3.6%	0.1
Leading to SA revision or ligation	11.1%	0.2	28.6%	1.2
Leading to SA excision	5.6%	0.2	3.6%	0.1

V007 Two-Year Results in Female Patients

ATEV has shown superior long-term patency at 24 months in females, and in all females and males with BMI ≥ 30 kg/m2 and diabetes

Higher 2-Yr Secondary Patency with ATEV in Females



V012 Top-Line Interim Results

ATEV for Dialysis Access in Women

CLN-PRO-V012:
Phase 3 Study Designed to Address the Unmet Need in Women

STUDY DESIGN

Prospective · Multicenter · Open-Label · Randomized

150 patient enrollment target

Female ESKD patients on HD

1:1

- **ATEV**
- **AVF**

24-month follow-up · All patients with study access

PRE-SPECIFIED INTERIM ANALYSIS

Follow-up Period

0 — 6 — **12** — 18 — 24 Months

n=80 patients enrolled

Interim Analysis Trigger
Superiority Analysis

PRIMARY ENDPOINT

Catheter-free days at 12 months

OTHER ENDPOINTS AT 12 MONTHS

Dialysis Access Infection Rate & Severity · Catheter-free Days at 6 months · Functional Patency at 12 months · Secondary Patency at 6 & 12 months · Study Access Survival (from maturation to abandonment) · AESIs

NCT05908084 | ClinicalTrials.gov | CLN-PRO-V012

V012 - Two Arms are Balanced in Baseline Characteristics

Characteristic	ATEV (N=40)	AVF (N=40)
Age (Y), Mean (SD)	53.9 (16.6)	52.6 (16.9)
Age > 65 years, N (%)	10 (25.0%)	11 (27.5%)
Obese (BMI ≥ 30), N (%)	20 (50.0%)	19 (47.5%)
Diabetes, N (%)	21 (52.5%)	20 (50.0%)

Subject counts (N) are intent-to-treat population

Stratification: By location of the vascular access (**forearm versus upper arm**) and by type of AVF creation procedure planned by the surgeon at randomization (**1-stage AVF versus 2-stage AVF**).

Inclusion criteria- Women on Hemodialysis needing AV access with suitable anatomy for creation of a forearm or upper arm AVF and for implantation of straight, curved, or looped ATEV in either the forearm or upper arm.

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V012 Met Primary Endpoint: 12-Month Catheter-Free Days

PRE-SPECIFIED PRIMARY ENDPOINT • 12-MONTH CATHETER-FREE DAYS

Statistically Significant

p=0.00070

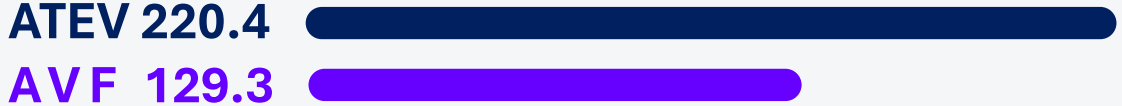
Pre-specified superiority threshold met

Interim analysis: ATEV (N=40) vs AVF (N=40)

TREATMENT DIFFERENCE

91 More Catheter-Free Days in Year 1

95% CI: 39.8 – 142.4



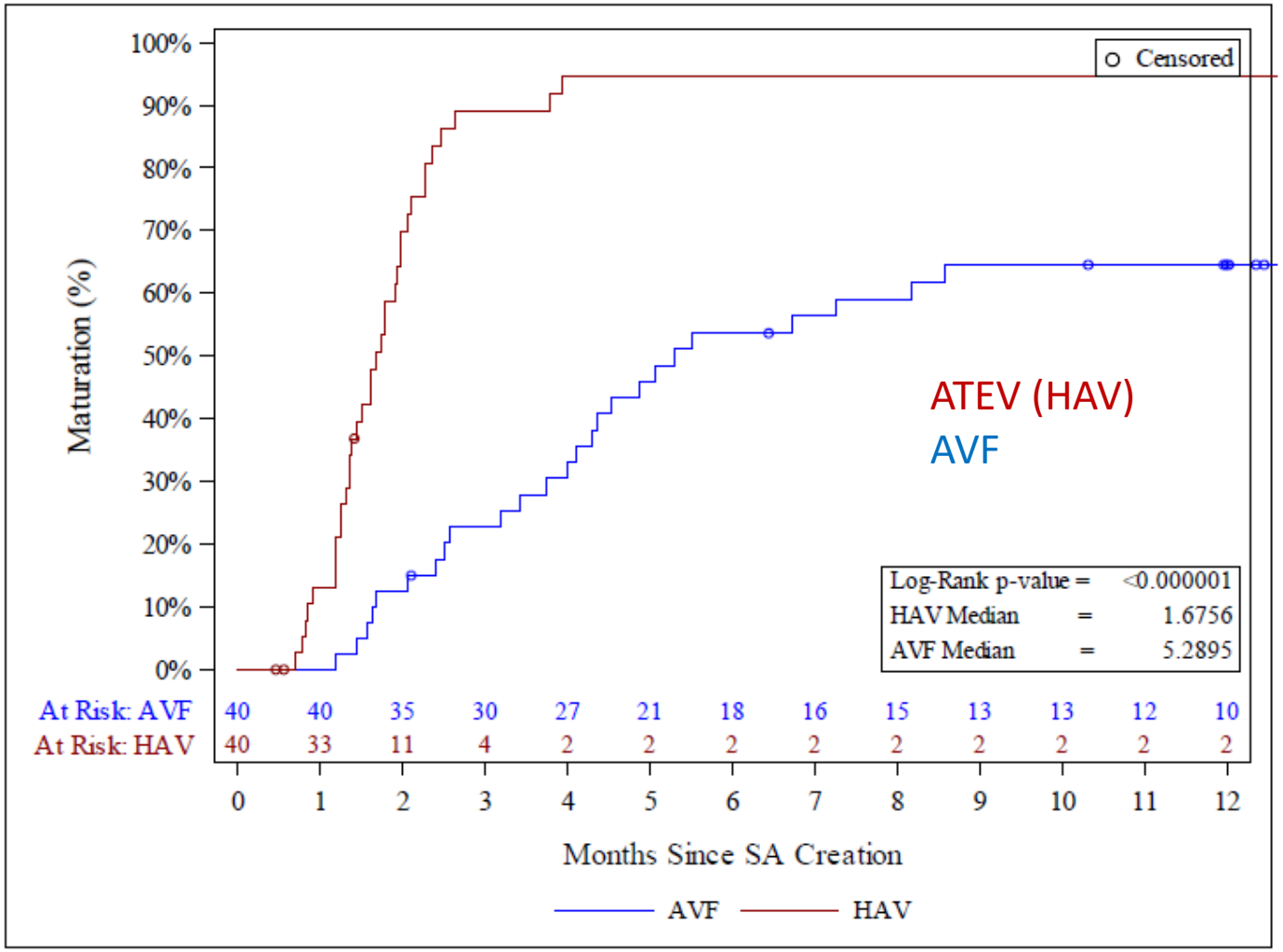
WHAT IT MEANS

ATEV patients spent ~3 additional months off a catheter vs. AVF in the first year.

CLN-PRO-V012 · Pre-specified interim analysis · ITT population · NCT05908084

V012 – ATEV Superior Rate of Maturation

The ATEV matured faster and a higher rate than AVF



Earlier and more consistent maturation means less time on catheter

V012 Primary Safety – Fewer Access Infections

ATEV Observed to Have Reduced Dialysis Infection Rates

17 Less Dialysis Access Infections per 100 Patient-Years

No hypothesis was pre-specified

ATEV: 2 subjects (5.1%)
AVF: 6 subjects (15.0%)

V012 Secondary Efficacy Analyses

ATEV was observed to have consistent advantages over AVF

Secondary Analyses	ATEV (N=40)	AVF (N=40)	p-value
1. Six-Month Catheter-Free Days	**88.4** days	**32.3** days	**0.00009**
2. 12-Month Functional Patency	**250.1** days	**151.7** days	**0.00057**
3. Six-Month Secondary Patency	**87.5%**	**65.0%**	**0.0013**
4. 12-Month Secondary Patency	**77.5%**	**62.5%**	**0.16**

V012 Interim Safety Results

Overall benefit-risk safety profile of ATEV is favorable with no new or unexpected safety concerns identified

12-Month Safety Summary	ATEV (n=39)(PYU[1]=26.6)			AVF (n=40)(PYU=15.7)		
	% of Subjects	Events	Events per Patient Year of Use (ETUY[2])	% of Subjects	Events	Events per Patient Year of Use (ETUY)
Treatment Emergent Adverse Events	94.9%	235	8.84	92.5%	287	18.26
Serious Adverse Events	51.3%	46	1.73	60.0%	75	4.77
Adverse Events of Special Interest:						
Study access infections	0.0%	0	0.00	7.5%	3	0.19
Thrombosis*	35.9%	20	0.75	17.5%	8	0.51
Stenosis	66.7%	43	1.62	40.0%	36	2.29
Clinically significant Steal Syndrome	7.7%	3	0.11	7.5%	3	0.19
Rupture of SA	0.0%	0	0.00	0.0%	0	0.00
Iatrogenic injury of SA	2.6%	1	0.04	0.0%	0	0.00
AE leading to Abandonment	7.7%	3	0.11	20.0%	9	0.57

***75% of the ATEV thrombosis cases were successfully resolved compared to 37.5% of AVF cases**

[1]PYU (patient years of usage) = sum of patient's time of SA usage expressed in years
[2]ETUY (event to usage years ratio) = number of events in 12 months/PYU

V012 Interim Results Summary

- The ATEV met V012's primary endpoint by demonstrating superior catheter-free days compared to AVF, the current standard of care
  - 91 more catheter-free days than AVF (p=0.0007)
- ATEV patients incurred 17 fewer dialysis access infections than AVF per 100 patient years, the primary safety measure for the study
- The ATEV was observed to demonstrate consistent advantages over AVF in multiple secondary endpoints
- Overall benefit-risk safety profile of ATEV is favorable with no new or unexpected safety concerns identified

In accordance with the study protocol, as a result of meeting the primary endpoint, study enrollment has terminated. Humacyte plans to file a supplemental BLA with the FDA during the second half of 2026 (target indication is in adult patients with ESKD who are at increased risk of AV fistula maturation failure).

Pipeline: Peripheral Arterial Disease (PAD)

Humacyte®

Peripheral Artery Disease (PAD)

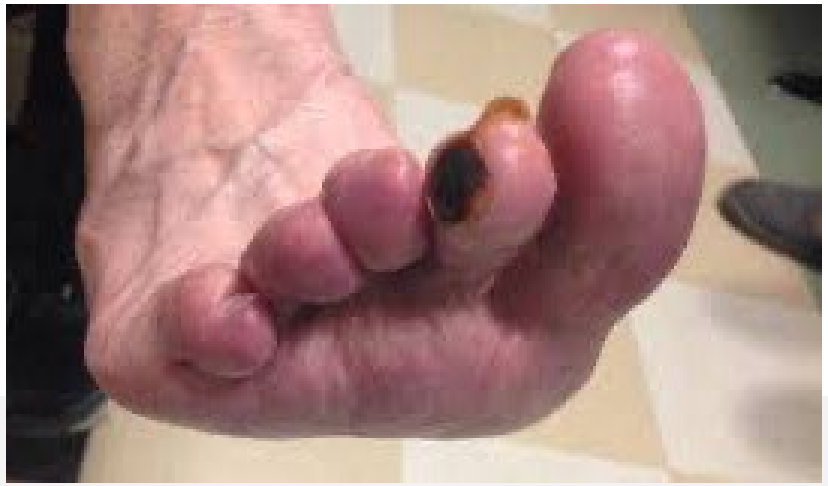
Can progress to multiple leg arteries, further reducing circulation

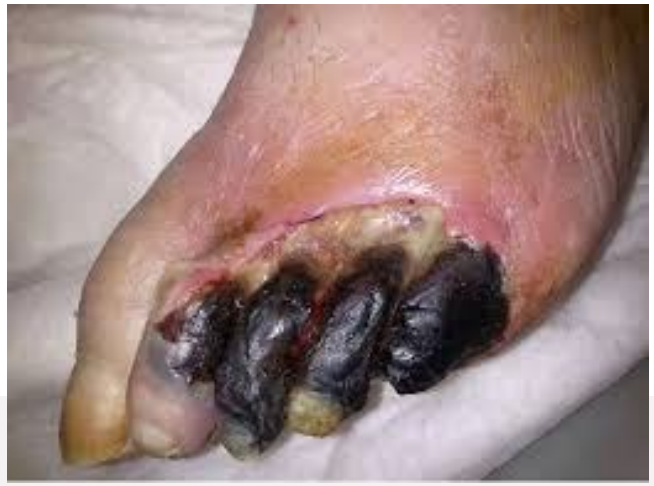
Critical Limb Threatening Ischemia

- Tissue does not receive enough blood flow to survive
- If untreated, leads to tissue loss, gangrene, and ultimately amputation

Treatment Requires Restoration of Blood Flow

- Non-surgical, catheter-based intervention
- Surgical bypass





For the 40% of PAD patients who do not have an ipsilateral saphenous vein for arterial bypass, ATEV may represent a promising means of revascularization and limb salvage

Humacyte®

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Current Clinical Experience with ATEV in Peripheral Arterial Disease

Phase 2 Trials

- V002 – 20 patients (EU)
- V004 – 15 patients (US)

EA

Over 20 U.S. patients with critical limb ischemia treated under FDA Expanded Access program

Mayo IND

Investigator-sponsored IND

- 29 patients with severe PAD at risk of limb loss
- Patients did no have saphenous vein available

- Six-year results from V002 published in *Journal of Vascular Surgery – Vascular Science*[1]
- Publication of First Eight Expanded Access Cases in *Annals of Vascular Surgery*[2]
- Outcomes published in *Midwestern Vascular Surgical Society* showing 86% limb salvage rate

[1]Piotr Gutowski, et al, 6-Year Outcomes of a Phase 2 Study of Human-Tissue Engineered Blood Vessels for Peripheral Arterial Bypass, JVS: Vascular Science (2023)

[2]Lauria A, Kersey A, Propper B, et al. *Annals of Vascular Surgery*. 2022 Apr 6:S0890-5096(22)00180-7

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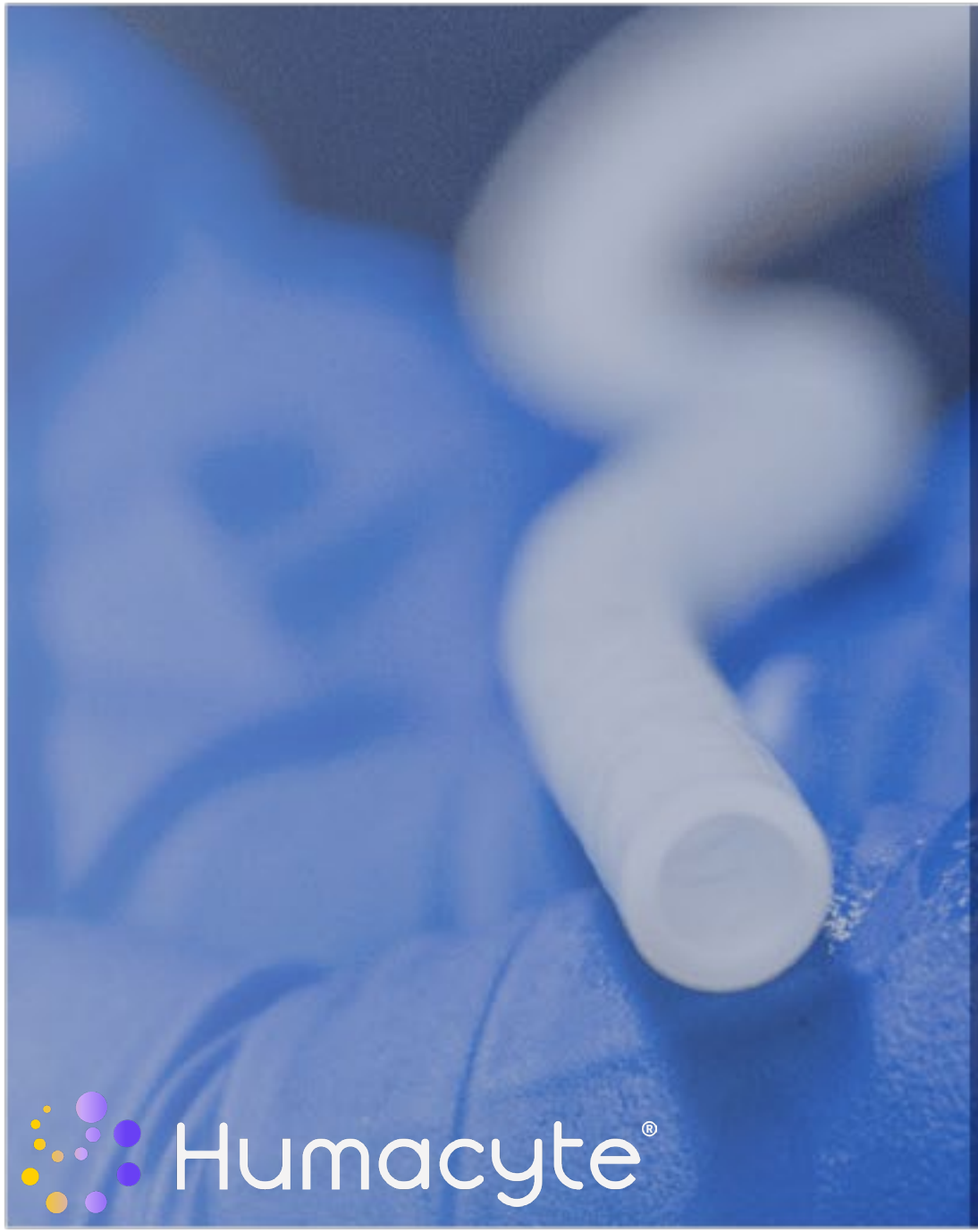
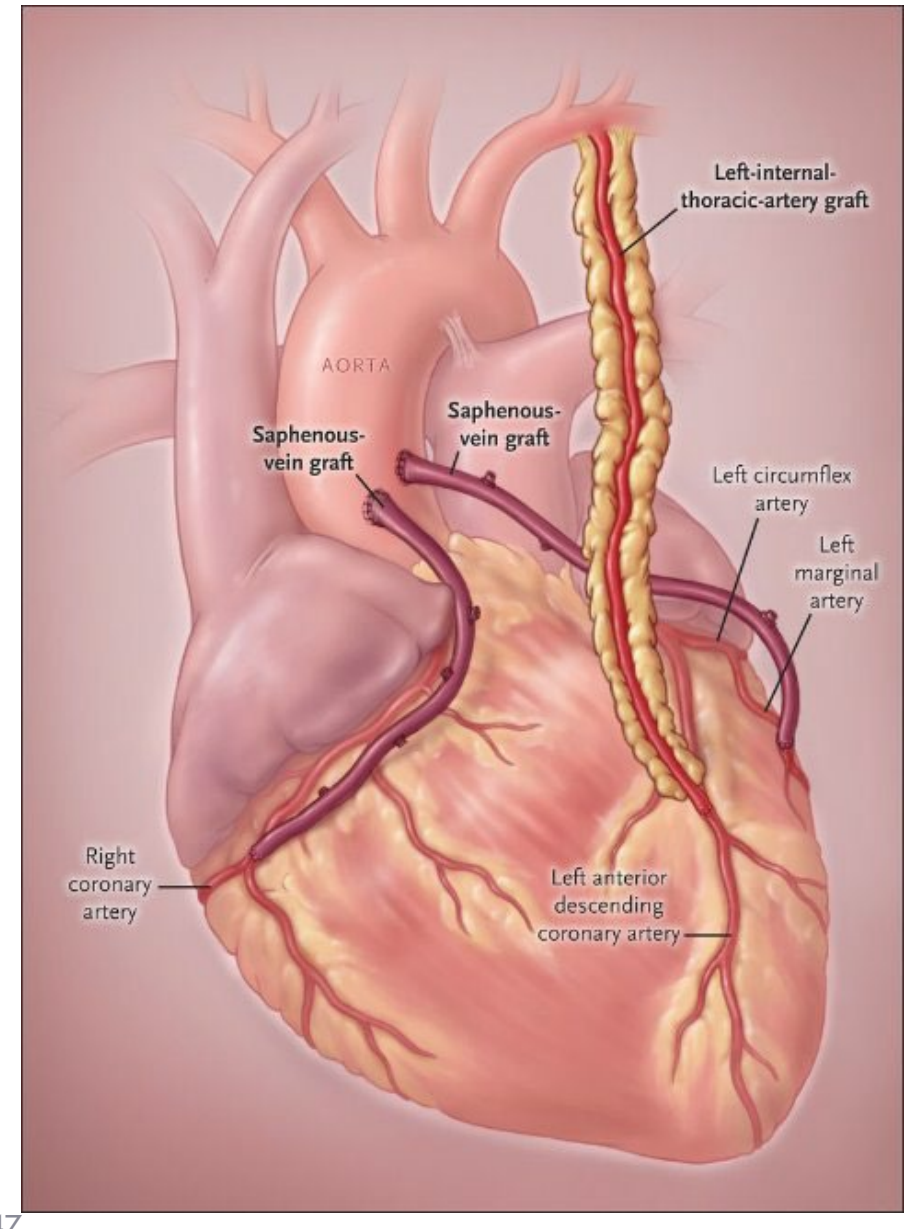


Pipeline: CTEV for Coronary Bypass Graft Surgery

Humacyte®

Coronary Artery Bypass Grafting (CABG)



Introduction

- The most commonly performed cardiac surgical procedure in the U.S. (approx. 300,000 per year)
- In the United States, 79 people per 100,000 have triple bypass surgery each year.
- CABG is generally recommended when there are high-grade blockages in any of the major coronary arteries and/or percutaneous coronary intervention (PCI) has failed to clear the blockages

Most commonly used autologous grafts

- **Left internal mammary artery (LIMA)**
  - Most often used to bypass Left Anterior Descending (LAD) Artery
  - >90% patency at 10 years
- **Saphenous vein graft (SVG)**
  - Often used to bypass Right Coronary Artery (RCA) or Left Circumflex Artery
  - SVGs used in 80-90% of CABG procedures
  - 10%-25% failure rate at 1 year, 40%-50% failure rate at 10 years
- Radial artery and other arm veins

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Concerns with Saphenous Vein Grafts

Vein Quality Issues

- Varicosities (20-30% of patients)
- Previous vein stripping or ablation
- Small diameter (<3mm)
- Sclerotic or diseased veins
- Peripheral vascular disease effects

Harvest-Related Morbidity

- Wound complications (5-10%)
- Leg edema and pain
- Infection risk
- Nerve injury (saphenous nerve)
- Prolonged recovery time

Medical Co-morbidities

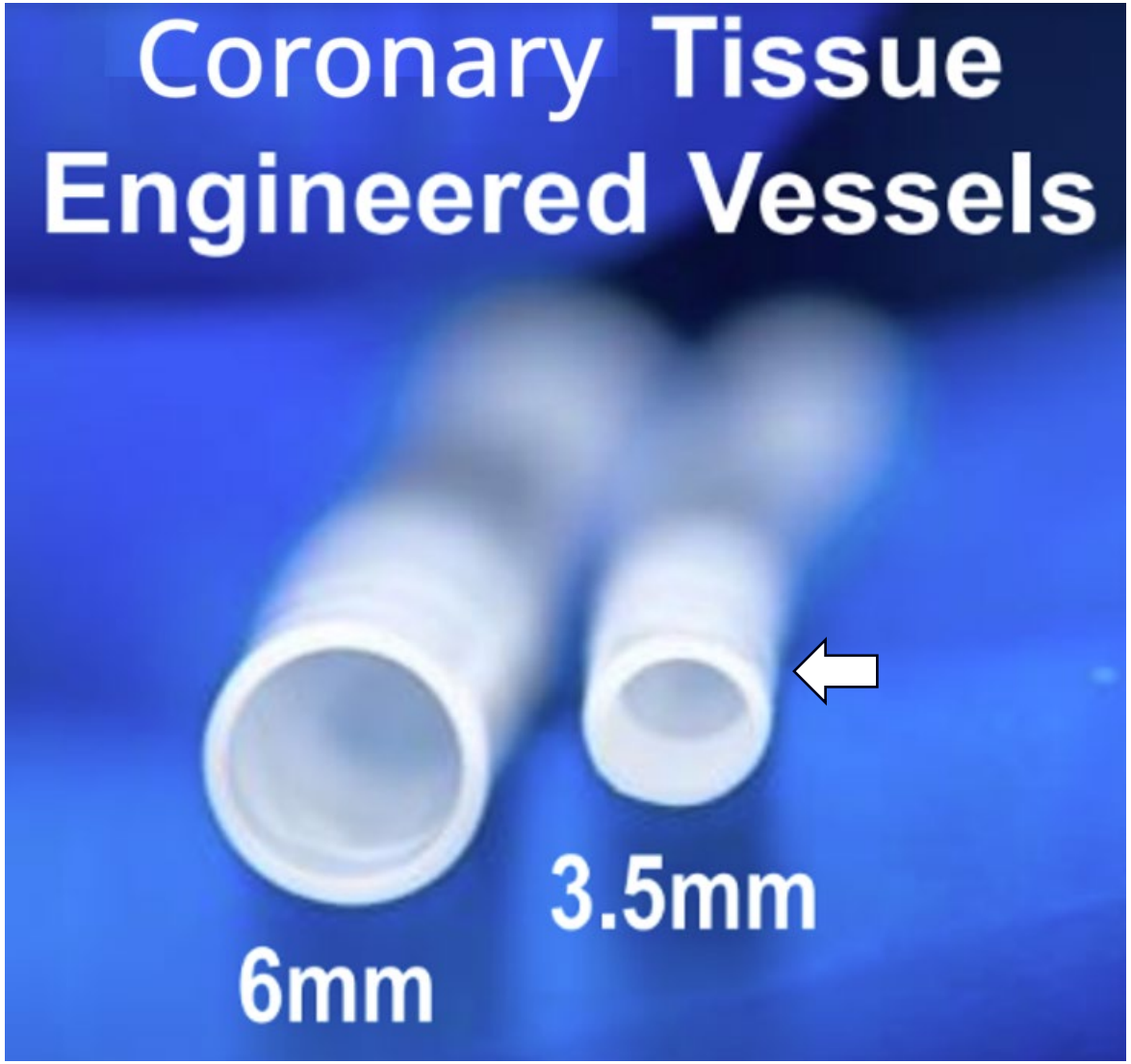
- Bilateral leg amputations
- Need to preserve vein for future peripheral bypass
- Prior vein harvest for CABG or peripheral surgery
- Obesity (difficult harvest)
- Patients with diabetes (higher failure rates)

Long-Term Clinical Impact

- Need for repeat revascularization
- Recurrent angina (20-30% at 5 years)
- Risk of graft atherosclerosis
- Reduced event-free survival
- Higher healthcare costs

- Zenati MA et al. N Engl J Med. 2019;380:2069-77
- Hess CN et al. Circulation. 2014;130:815-27
- Lopes RD et al. JAMA. 2012;307:265-74

Coronary Tissue Engineered Vessel (CTEV): Addressing an Unmet Need in Multivessel CABG



- The CTEV is designed to be a first-of-its-kind, sterile, off-the-shelf human-derived vessel that requires no preparation, is non-immunogenic, and resist infection.
- The CTEV has an inner diameter of 3.5 mm and is approximately 23 cm in length.
- Designed to address unmet conduit needs in CABG patients lacking autologous options, potentially offering patency and durability comparable to or better than saphenous vein without the need for harvesting.
- First human study of CTEV planned for 2nd Half 2026.

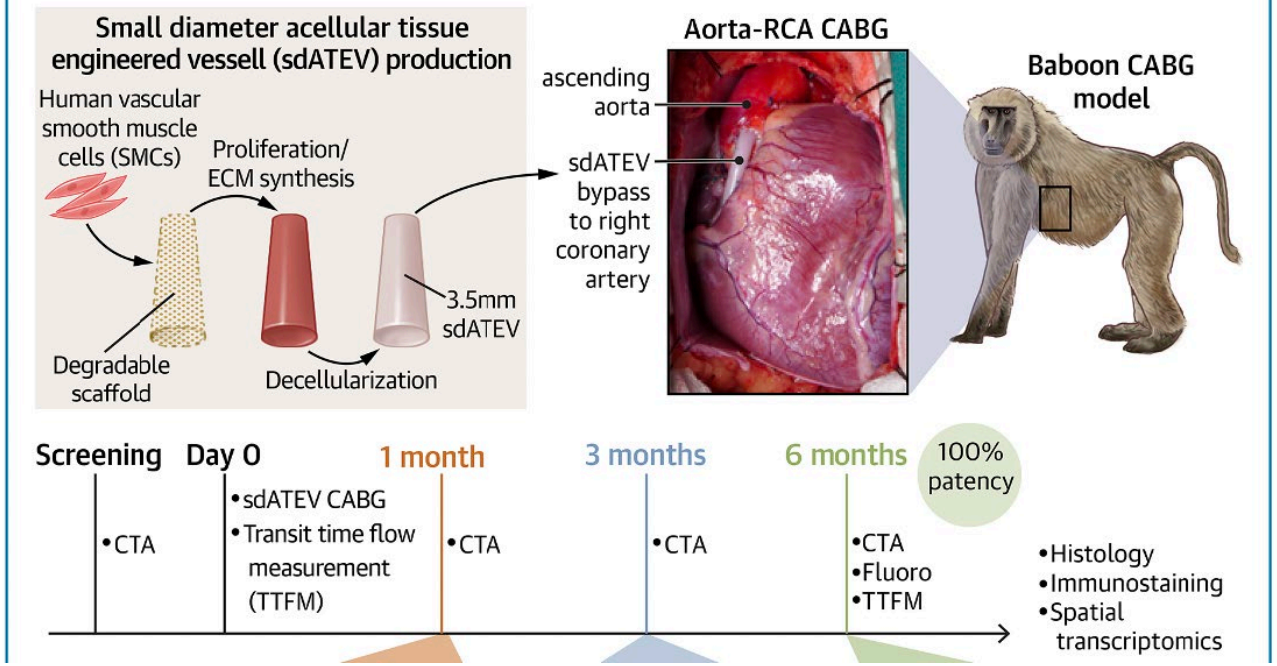
Humacyte®

Non-Human Primate CABG Out To 6 Months

Acellular Tissue Engineered Vessels as Coronary Artery Bypass Grafts

Adam R. Williams, MD,[a,*] Kevin M. Nash, PhD, DABT,[b,*] Robert D. Kirkton, PhD,[b] Garyn S. Levitan, BS,[b] Melissa A. Daubert, MD,[c] Susan A. Whitney, MBA, BSRT(R)(N)(CT),[c] Kaleb M. Naegeli, PhD,[b] Abigail R. Benkert, MD,[a] Sharon L. McCartney, MD,[d] Heather L. Prichard, PhD,[b] Laura E. Niklason, MD, PhD,[b] Alan P. Kypson, MD[b,e]

VISUAL ABSTRACT

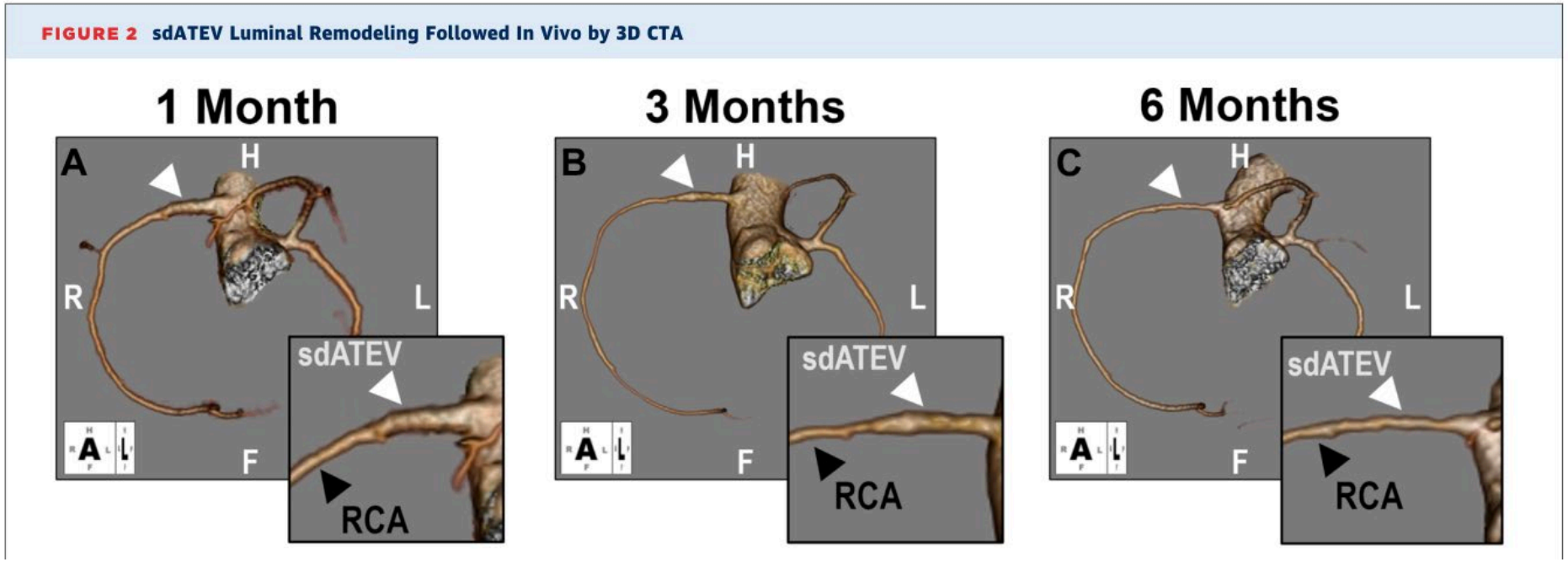


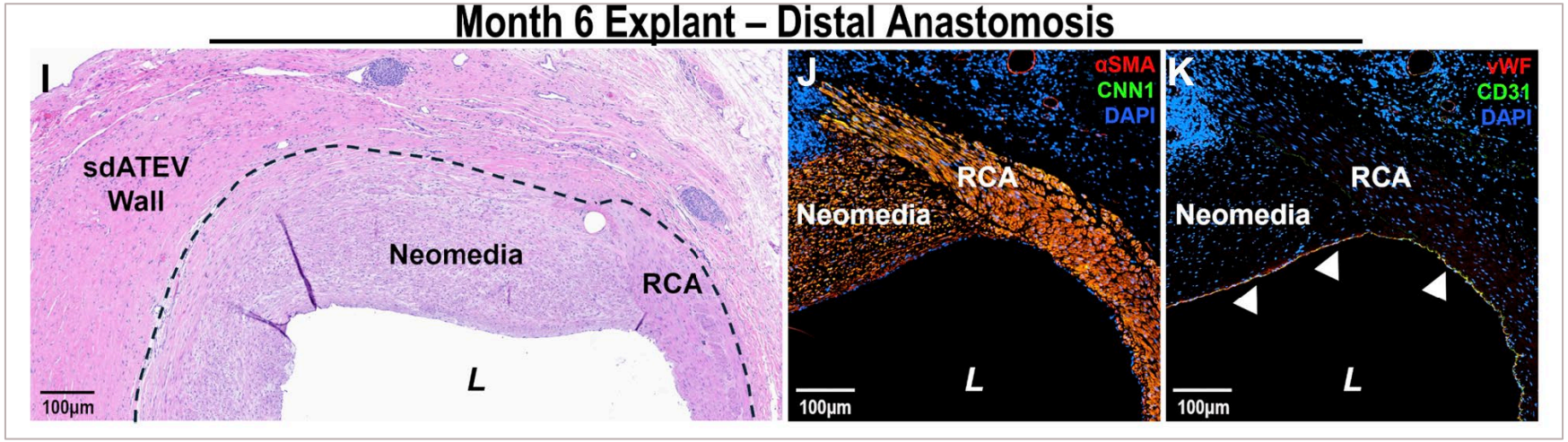
HIGHLIGHTS

- Over the past 50 years, no novel CABG conduits have gained routine clinical use despite attempts with synthetics and xenografts.
- The sdATEV (3.5 mm) remained patent as an RCA CABG conduit through 6 months in a baboon surgical model.
- CTA revealed that adaptive host remodeling led to gradual tapering of the sdATEV to size-match the smaller baboon RCA.
- Quiescent host cells derived from the bypassed RCA media lined the sdATEV lumen and expressed vascular SMC and EC markers at 6 months.

50

Remodeling of CABG Conduit in Non-Human Primates





Pipeline:
BioVascular Pancreas

Humacyte®

The BioVascular Pancreas (BVP)

The BVP is an innovative implantable device designed to deliver pancreatic islets, for treating Type 1 Diabetes (T1D)

- Core Components: Combines Humacyte's FDA-approved Acellular Tissue-Engineered Vessel (ATEV) with a fibrin-based hydrogel "sleeve" populated with islets.

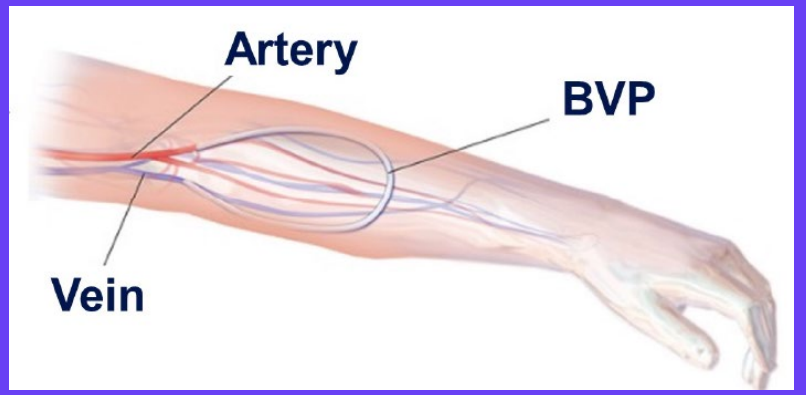
- Mechanism: The ATEV hydrogel coating allows islets access to oxygen from arterial blood through the vessel wall without direct blood contact, reducing hypoxia and inflammation.

- Implantation: Deployed as a vascular graft – i.e. as an arteriovenous graft in the arm. After implantation BVP promotes neovascularization and long-term islet survival and function.

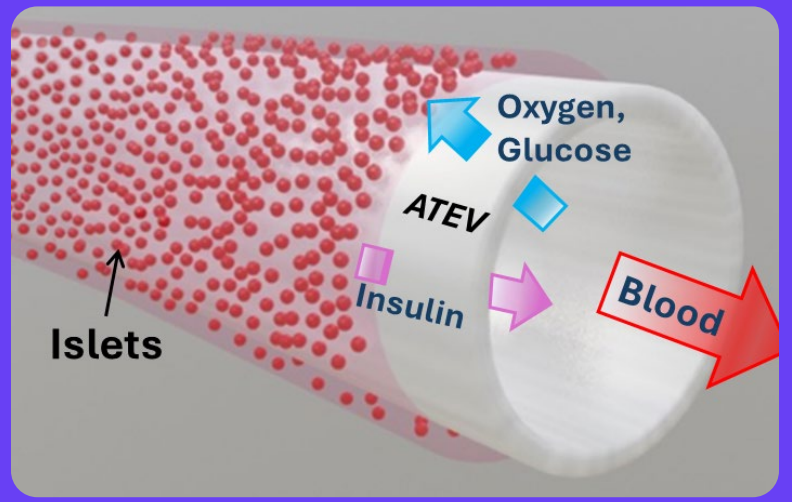
- Development Status: Non-human primate dose range finding studies planned 2026. First in human study planned 2027.

Developed in collaboration with Breakthrough T1D™

Acellular Tissue Engineered Vessel (ATEV) is implanted in the arm



BioVascular Pancreas (BVP)



Milestones

Humacyte®

Commercial Manufacturing Scale – LUNA200 System

Bioreactor bag

Each bioreactor bag contains a single polymer mesh scaffold, seeded with banked human cells

Growth drawer

10 bioreactor bags per growth drawer; tubing connects to shared nutritive media

LUNA200 System

Each LUNA200 can produce 200 ATEVs per batch (or ~1,000 ATEVs annually)

Commercial 83,000 sq ft Bioprocessing Facility

- Currently operating 8 LUNA200 systems
- Annual capacity expected to exceed 40,000 ATEVs
- Functionally closed system with state-of-the-art process automation

Humacyte®

Anticipated 2026 Milestones

Completed in 2025

Vascular Trauma - Symvess:

- *U.S. commercial launch* ✓
- *Long-term results showing durability of Symvess* ✓

V007 dialysis positive Phase 3 ATEV two-year results ✓

Cardiac Bypass Graft Surgery (CABG) CTEV preclinical results from large-animal studies ✓

Preclinical BVP results showing survival and function of islets in large animals ✓

Planned for 2026

Vascular Trauma (Symvess):

- U.S. commercial launch growth
- Expansion into international markets

Dialysis (ATEV):

- Publication of V007 Phase 3 results
- Interim results from V012 Phase 3 trial in female patients ✓
- Supplemental BLA filing with FDA

CABG (CTEV):

- Commencement of first-in-human study
- First patient results

BioVascular Pancreas (BVP) for type-1 diabetes:

- Preparation for first human study

Publications & Presentations
(Multiple other clinical and preclinical publications and presentations expected for 2026)

All milestone dates are only management estimates

Humacyte®

Universally Implantable Regenerative Human Tissue

Thank You