An Off-the-Shelf Biologic Vascular Graft for Extremity Arterial Trauma:

Combined Long-Term Outcomes from Civilian and Conflict Settings

Presented by Dr. Charles Fox, MD

Director of Vascular Surgery, Univ. of Maryland Capital Region
Attending Surgeon, Shock Trauma & Univ. of Maryland Medical Center
Assoc. Prof. of Surgery, Div. of Vascular Surgery at Univ. of Maryland School of Medicine
U.S. Army: LTC (Ret.)

Oleksandr Sokolov, MD | Ernest E. Moore, MD | Michael A. Curi, MD, MPA | Laura E. Niklason, MD, PhD | Shamik Parikh, MD. | *on behalf of all V005 (NCT03005418) & V017 (NCT05873959) Investigators*

Data cutoff: April 10, 2025

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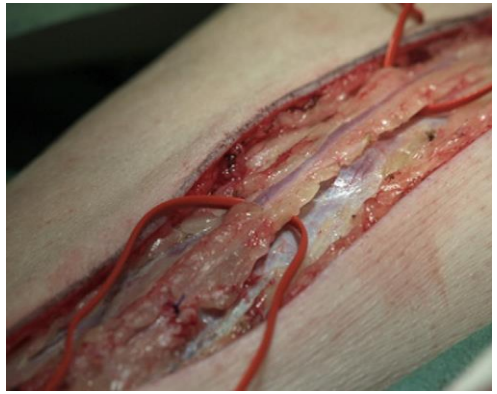
The Unmet Need: Extremity Arterial Trauma in Combat

Why This Matters

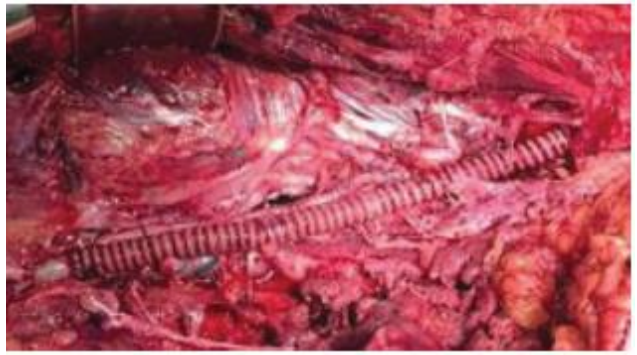
Extremity arterial injury is a leading cause of preventable limb loss in combat

Vascular trauma: ~12% of combat injuries; 79% in the extremities[1]

Current treatment options:



Autologous vein
Gold standard, but harvest is time-intensive, vein may be injured or unavailable



Synthetic grafts (ePTFE/Dacron) Readily available, but high infection risk in contaminated wounds

Contaminated Wounds

Blast, shrapnel, open fractures — high infection risk with synthetic grafts

Autologous Vein Unavailable

Injured vein, prior harvest, urgency, or multiple injuries preclude saphenous harvest

Limited Resources

Forward environments lack vascular surgeons and time for complex harvesting

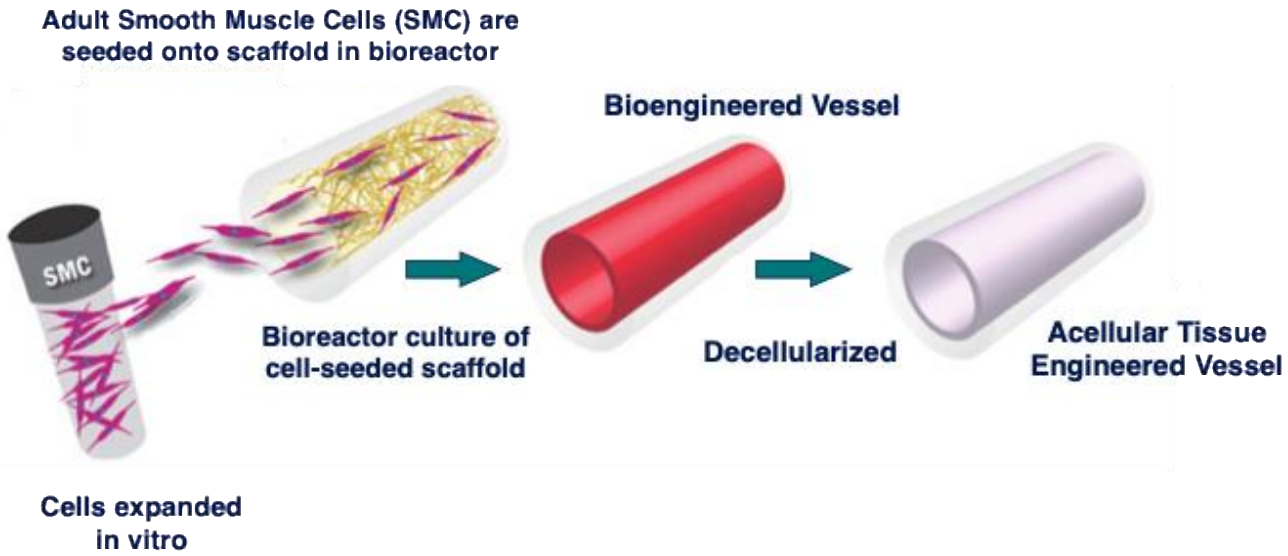
Urgency of Revascularization

Ischemia duration is a key determinant of limb salvage outcomes

1. Katelenets et al. JVS, 2025

Introducing the Acellular Tissue Engineered Vessel (ATEV)

ATEV is a bioengineered human vascular conduit grown from human smooth muscle cells on a degradable polymer scaffold, then **decellularized** to remove immunogenic antigens



Result: A biologic vessel with native-like mechanical properties (compliance, suture strength, burst pressure), no immune rejection risk, and inherent infection resistance versus synthetic grafts

Following implantation, host cells repopulate the conduit, creating living vasculature

Off-the-Shelf

No preparation required — immediate deployment

Refrigerated Storage

2-8 degrees C; 18-month shelf life — standard cold chain

Single Size

6 mm inner diameter x 40 cm usable length

Compact Packaging

~30 x 4 x 1.5 inches — fits in forward medical facilities

No Immune Rejection

Acellular design — no immunosuppression required

Two Complementary Vascular Trauma Trials: Civilian (Prospective) & Wartime

VASCULAR TRAUMA

CLN-PRO-V005 (civilian): N=72

Prospective, multi-center,

19 level 1 trauma centers in USA and Israel

36 Month Follow-up

CLN-PRO-V017 (real-world conflict): N=17

Retrospective study of patients treated under Humanitarian Aid Program, 3 centers in Ukraine

up to 19 Month Follow-up

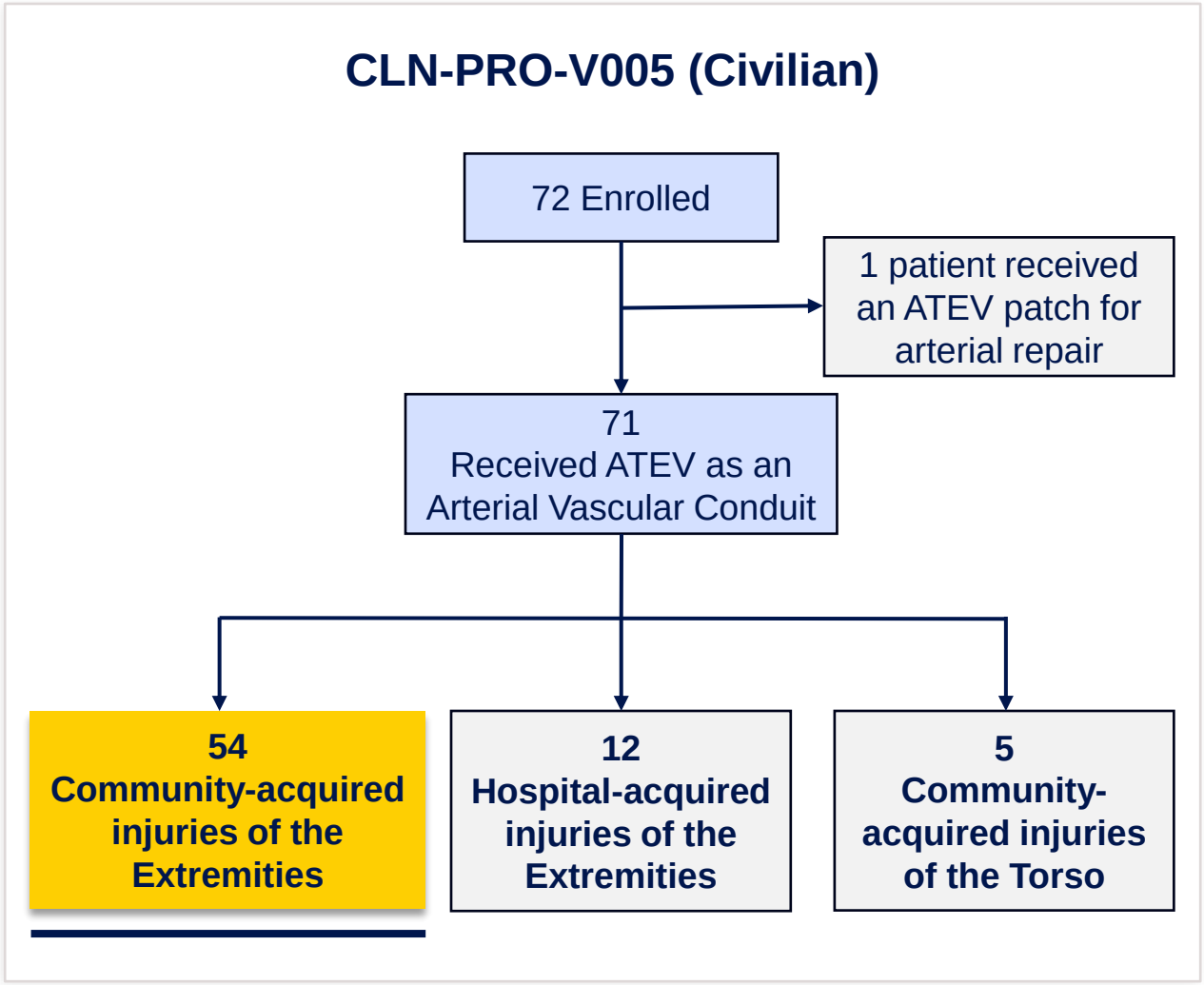
INCLUSION/EXCLUSION CRITERIA

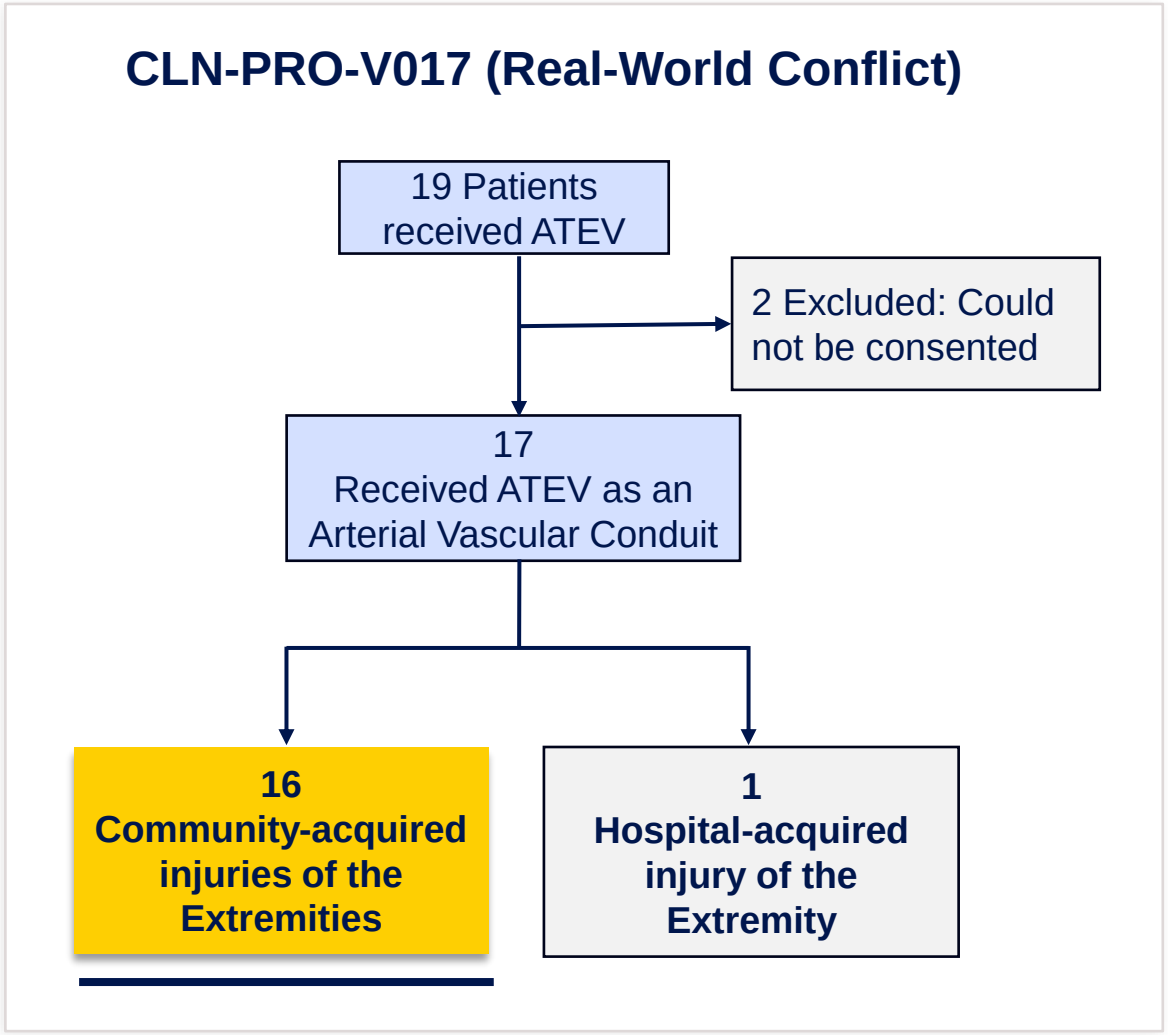
- **KEY INCLUSION CRITERIA**
  - Life- or limb -threatening injury to a vessel in the limb or torso
  - Defect length ≤ 38cm, compatible with 6mm ATEV
  - Autologous vein graft is not suitable in the judgment of the treating surgeon
- **KEY EXCLUSION CRITERIA**
  - Mangled Extremity Severity Score (MESS) of ≥ 7
  - Injury Severity Score (ISS) >60
  - Unable to maintain long-term antiplatelet therapy
  - Circumstances preclude adequate evaluation of the safety and efficacy of the ATEV

ENDPOINTS

- **Primary Efficacy**: Patency (primary) at Day 30
- **Key Secondary Efficacy**: Patency (secondary), amputation, infection, all at Day 30
- **Other Endpoints at Month 12 and 36 :** Safety, Longer Term Durability and Limb Salvage

Patient Disposition in Vascular Trauma Trials





Combined Evaluation of n=70 Community-acquired Extremity Trauma Injuries

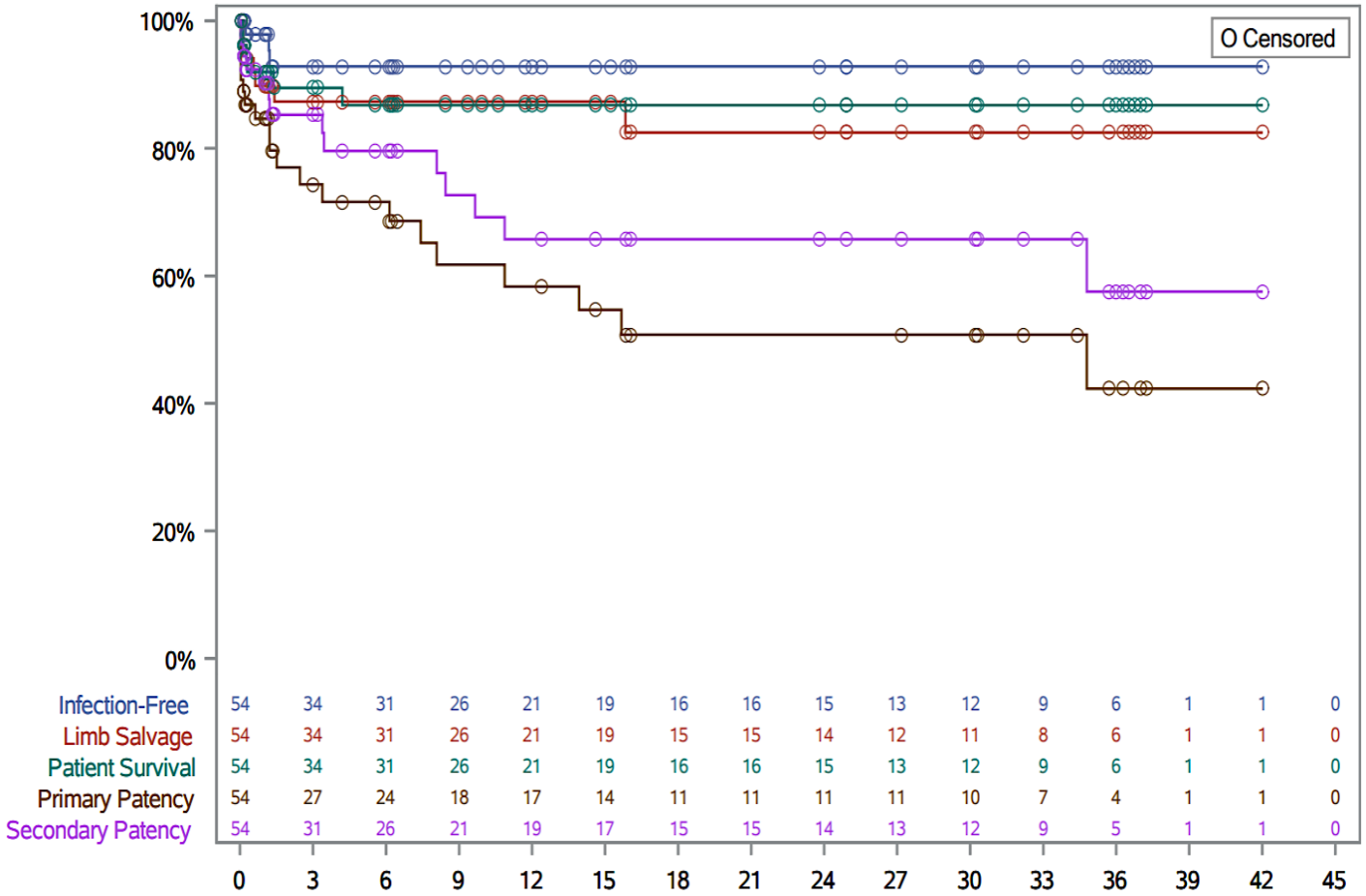
Patient Characteristics in V005 and V017 are Representative of Their Injury Types and Setting

Characteristic	V005 (n=54) Civilian / Prospective	V017 (n=16) Real-World / Retrospective	V005+V017 (n=70) Combined
Setting	US / Israel (L1 trauma centers)	Ukraine (conflict zone)	**Civilian + Military**
Sex	74% Male	100% Male	**80% Male**
Race	43% White	100% White	**56% White**
Age (years), mean	33.4	34.2	**33.5**
Injury Severity Score (ISS), mean	21.1	20.6	**21.0**
Mechanism of Injury	57% Penetrating 43% Blunt	88% Penetrating (blast/shrapnel/GSW) 12% Blunt	**Predominantly penetrating**
Median Implanted Graft Length	7.0 cm	13.5 cm	**7.0 cm**
Autologous Vein	Not feasible in all patients	Not feasible in all patients	**Not feasible in all patients**

1. Curi et al. JVS-CIT, 2026, 2. Parikh et al. Mil Med, 2025

V005: 36-Month Outcomes – Civilian Prospective Trial (n=54)

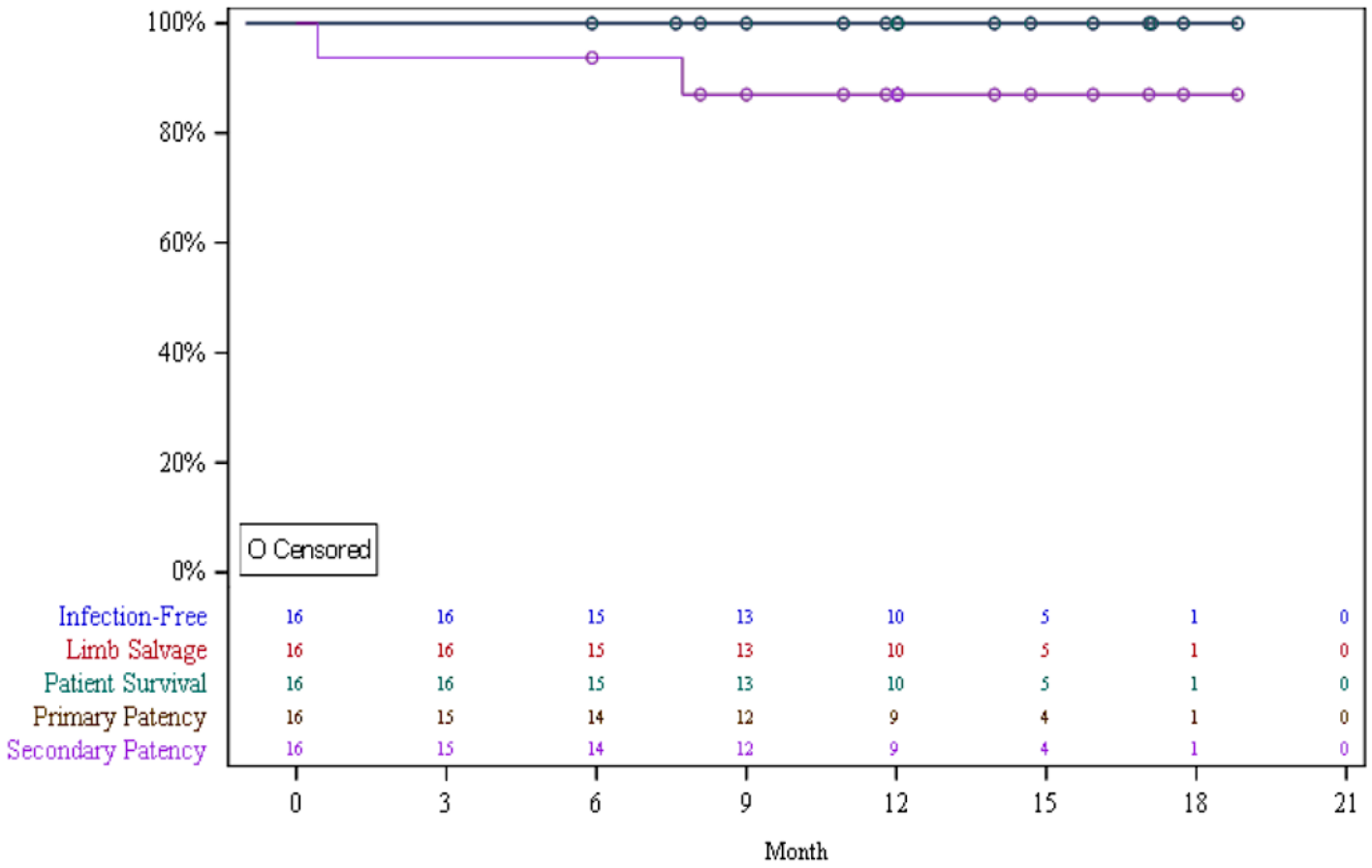
OUTCOMES
Total follow up 60 patient years
Infection-free rates remained at **93%** from months 3 through 36
Limb salvage was **87%** at month 12 and **83 %** at month 24 – 36
Patient survival rate remained at **87%** from months 6 through 36
Primary patency was **58%** at 12M, **51%** at 24M, **42%** at 36M
Secondary patency was **66%** from months 12 – 24, and **58%** at 36M



- Five of the 7 limb loss cases occurred before day 30 post-implant. Additional limb losses cases occurred on day 43, and on day 482
- Three conduit infections occurred in 3 patients (5.6%) over 3-year period, all prior to day 40

1. Curi et al. JVS-CIT, 2026

V017: 18-Month Outcomes – Real-World Combat Setting, Ukraine (n=16)



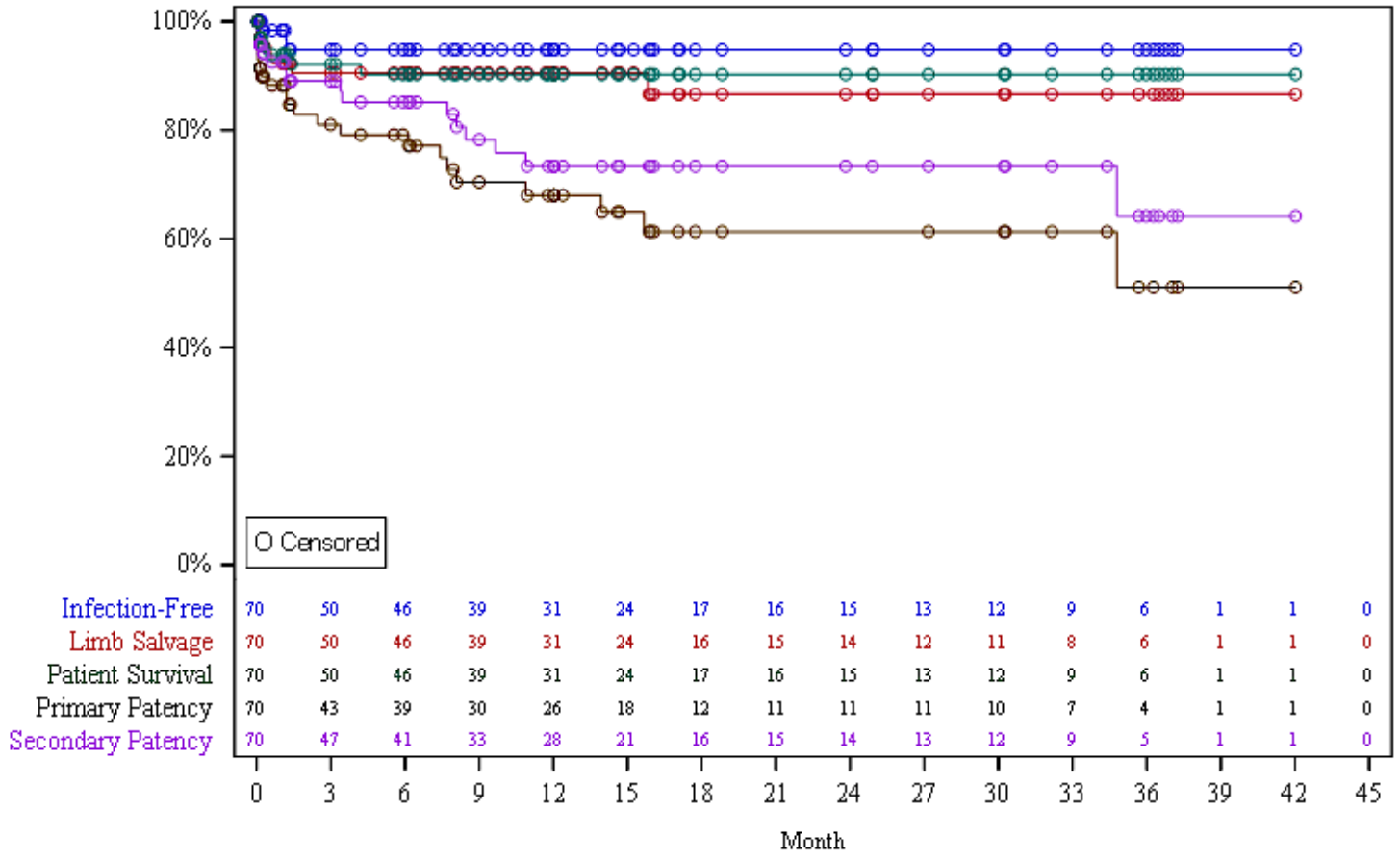
OUTCOMES
Total follow up 16 patient years
Infection-free rates remained at **100%** through 18 months
Limb salvage was **100%** through 18 months
Patient survival rate was **100%** through 18 months
Primary patency and **Secondary patency** were both **87%** from months 8 – 18*
*Two subjects lost ATEV patency: one related to graft rupture and subsequent bleeding events (day 13) associated with retained shrapnel fragments at implantation; and one due to occlusive thrombosis at month 6 with graft abandonment at month 8.

No immune rejection | No ATEV-attributed adverse events

1. Parikh et al. Mil Med, 2025

Combined 36-Month Kaplan-Meier Estimates: V005 + V017 (n=70)

OUTCOMES
Average follow-up duration 13.2 months
Infection-free rates remained at **95%** from months 3 through 36
Limb salvage was **91%** from months 3 – 12 and **87%** from months 24 – 36
Patient survival rate remained at **90%** from months 6 through 36
Primary patency was **66%** at 12M, **60%** at 24M, **50%** at 36M
Secondary patency was **72%** from months 12 – 24, and **63%** at 36M



Overall positive infection resistance & good limb salvage

Patency loss driven predominantly by early thrombosis

Safety Summary: Combined Cohort Through 36 Months

	First 30 Days n (%), Events		Up to 36 Months n (%), Events	
	V005 (n=54)	V017 (n=16)	V005 (n=54)	V017 (n=16)
Any AESI	8 (15%), 13	1 (6.3%), 3	18 (33%), 35	2 (13%), 4
Any Infections	20 (37%), 35	3 (19%), 3	26 (48%), 60	4 (25%), 5
ATEV Infections	1 (1.9%), 1	0	3 (5.6%), 3	0
ATEV Rupture or Anastomotic Failure	2 (3.7%), 2	1 (6.3%), 1	4 (7.4%), 4	1 (6.3%), 1
ATEV Occlusion/Thrombosis	7 (13%), 9	0	17 (32%), 24	1 (6.3%), 1
Pseudoaneurysm	1 (1.9%), 1	0	2 (3.7%), 2	0
Aneurysm	0	0	1 (1.9%), 1	0
Limb Loss	5 (9.3%), 5	0	7 (13%), 7	0
Other*	0	1 (6.3%), 2	1 (1.9%), 1	1 (6.3%), 2

*Bleeding from a previous ATEV repair site

- Most adverse events in Year 1; no late safety signals
- Patency loss largely driven by early thrombosis events
- No graft rupture, limb loss, or death was attributed to ATEV
- Adequate tissue coverage is essential — all ruptures occurred in failing wounds

1. Curi et al. JVS-CIT, 2026, 2. Parikh et al. Mil Med, 2025

ATEV for Military & Conflict Environments

Immediate Availability

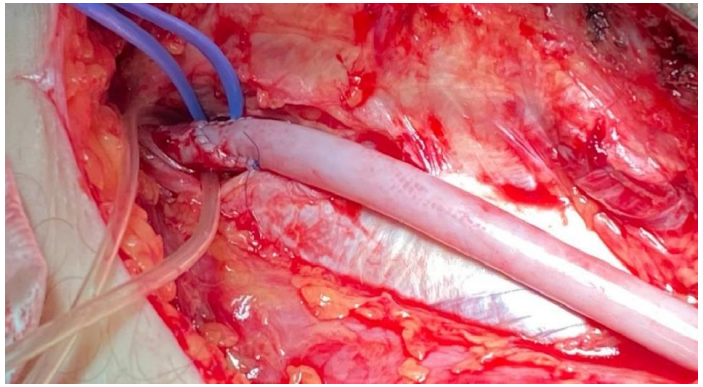
No preparation required. No vein harvest. Available when and where needed.

Infection Resistance

95% infection-free at 36 months combined civilian & military; biologic - no synthetic foreign material

Durable Limb Salvage

87% limb salvage at 36 months in high-severity combined cohort



Example of ATEV popliteal artery repair

29 y/o male, blast shrapnel injuries of the left hip; ATEV repair of CFA; Patient WALKING at Day 113

ATEV for Military & Conflict Environments

Forward Compatible Logistics

Refrigerated 2-8 deg C; 18-month shelf life; ~30x4x1.5 inch packaging

Proven in Combat

Ukraine: 100% infection-free, 100% limb salvage, 87% patency at 18 months

No Immune Rejection

Acellular design – no immunosuppression required; no rejection in >500 patients implanted

ATEV deployed to 5 Ukrainian hospitals under Humanitarian Aide Program

Conclusions

1. ATEV provides military surgeons with a portable, refrigerated, immediately deployable biologic conduit requiring no preparation and compatible with forward logistics

2. Combined 36-month KM estimates (n=70): 87% limb salvage, 95% infection-free — durable long-term performance in high-severity trauma

3. Performance consistent across settings: V005 (civilian, prospective, 36 mo) and V017 (Ukraine combat, 18 mo) both show low infection rates and acceptable limb salvage

4. Most adverse events occurred early, associated with initial injury severity; no late safety signals and no outcomes attributable to ATEV

5. ATEV represents a practical solution for arterial reconstruction in austere and conflict environments when autologous vein is not feasible

V005: NCT03005418 | V017: NCT05873959 | Data cutoff: April 10, 2025

1. Curi et al. JVS-CIT, 2026, 2. Parikh et al. Mil Med, 2025

ATEV Available on ECAT as Symvess™

- Electronic Catalog (ECAT) listing approval makes Symvess available to healthcare professionals at U.S. Department of Defense and U.S. Department of Veterans Affairs facilities
- Makes Symvess available to military service members, veterans, and other patients receiving care at these facilities

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PI	Institution	Site	Institution
Dr. Moore	Ernest E Moore Shock Trauma Center at Denver Health	Dr. Seamon	Upenn
Dr. Fox	Ernest E Moore Shock Trauma Center at Denver Health	Dr. Skarupa	University of Florida Jacksonville
Dr. Kundi	R Adams Cowley Shock Trauma Center	Dr. Malas	University of California San Diego UCSD
Dr. Morrison	R Adams Cowley Shock Trauma Center	Dr. Greenberg	Soroka (Israel)
Dr. Lum	Johns Hopkins Bayview Medical Center/ Johns Hopkins Hospital	Dr. Oresanya	Temple University
Dr. Shores	Johns Hopkins Bayview Medical Center/ Johns Hopkins Hospital	Dr. Sjoholm	Temple University
Dr. Curi	Rutgers New Jersey Medical School	Dr. Clouse	University of Virginia (UVA)
Dr. Namias	Ryder Trauma Center/ Jackson Memorial	Dr. Schreiber	Oregon Health & Science University (OHSU)
Dr. Rajani	Grady Memorial Hospital	Dr. Rasmussen	Mayo Clinic
Dr. Southerland	Duke University	Dr. Hurie	Atrium Health Wake Forest Baptist Medical Center
Dr. Goldin	Shaare Zedek (Israel)	Dr. Karram	Rambam HCC (Israel)
Dr. Naslund	Vanderbilt	Dr. Halak	Sheba Medical (Israel)
Dr. Batista	Cooper University	Dr. Sokolov	Dnipro State Medical University, Dnipro (Ukraine)
Dr. Magee	University of Southern California (LA)	Dr. Shaprynskyi	State Institution of Science Research and Practical Center of Preventive and Clinical Medicine, Kyiv (Ukraine)
Dr. Calero	University of South Florida	Dr. Skupyy	Vinnytsya Regional Clinical Hospital, Vinnytsya, Ukraine
Dr. Freeman	St. Louis University	Dr. Yurets	Vinnytsya Regional Clinical Hospital, Vinnytsya, Ukraine
Dr. Fujitani	UC Irvine Medical Center	Dr. Stanko	Odessa Regional Clinical Hospital, Odessa, Ukraine

Thank you,
Questions?