

Outcomes of Mechanical Thrombectomy for the Treatment of Deep Vein Thrombosis-Associated Venous Leg Ulcers

Nicolas J. Mouawad, MD, MPH, MBA, FSVS, FRCS, FACS, RPVI

Division of Vascular and Endovascular Surgery, Department of Surgery, McLaren Health System – Bay Region



nicolas.mouawad@mcclaren.org

@NickMouawadMD

Background

- Up to one-half of deep vein thrombosis (DVT) patients will develop postthrombotic syndrome (PTS), with ~5% of patients developing a venous leg ulcer (VLU)¹⁻³
- Residual DVT becomes a postthrombotic obstruction (PTO),⁴ contributing to ambulatory venous hypertension and VLU formation
- Most current VLU therapies fail to remove or disrupt PTOs in deep veins, leading to worsening PTS and possible amputation⁵
 - Fibrinolytics cannot dissolve chronic, collagenic PTOs⁴
 - Open techniques have unnecessarily high risks⁶
 - Synechiae and trabeculations in PTOs may render stent placement less effective⁷
- More effective treatments are needed, and mechanical thrombectomy is a promising approach⁸



Vasquez, et al. JVS. 2010;52(5):1387-96.



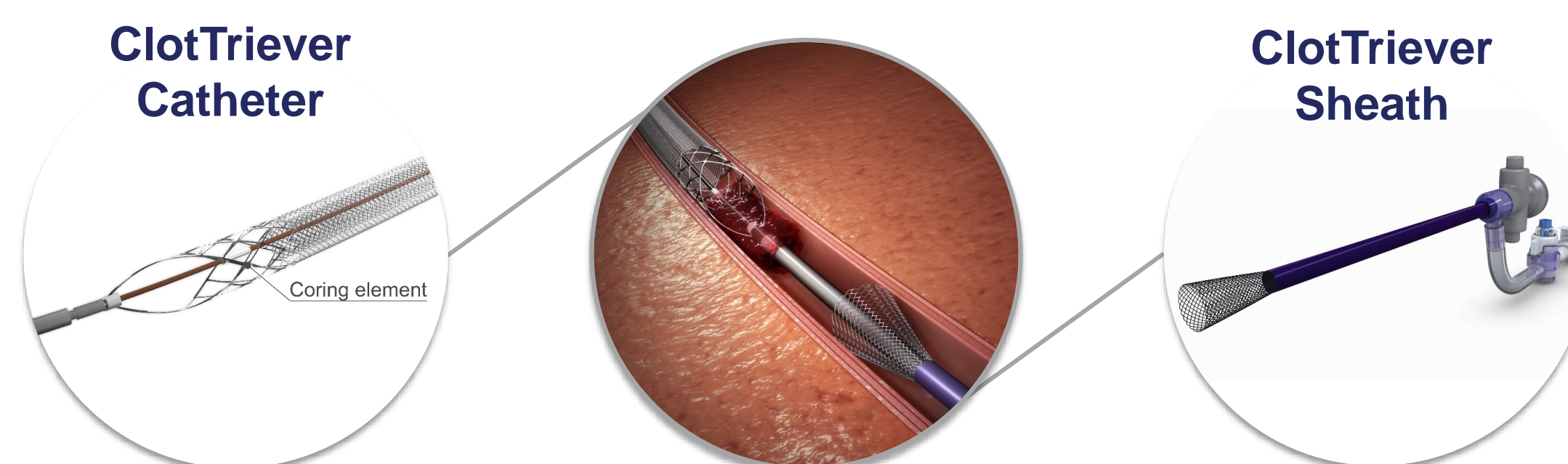
Maleki, et al. Phlebology. 2014;21(3):131-7.

Objective: Determine the impact of mechanical thrombectomy on VLUs that formed secondary to DVT in a population of patients referred from an associated wound care clinic

Methods

Mechanical Thrombectomy Intervention

The ClotTriever System (Inari Medical) is a mechanical thrombectomy system designed to remove large thrombi without lytic agents



Intended for use in the peripheral vasculature

Study Overview

Retrospective, single-center analysis

Variables Collected

- Baseline:** age, sex, VLU duration, VLU area
- Procedural:** device passes, adjunctive methods
- Long-term Outcomes:** time to VLU resolution or latest follow-up, VLU area at latest follow-up

Study Population: 11 patients with 15 VLUs secondary to DVT treated using mechanical thrombectomy and followed through VLU resolution or latest follow-up

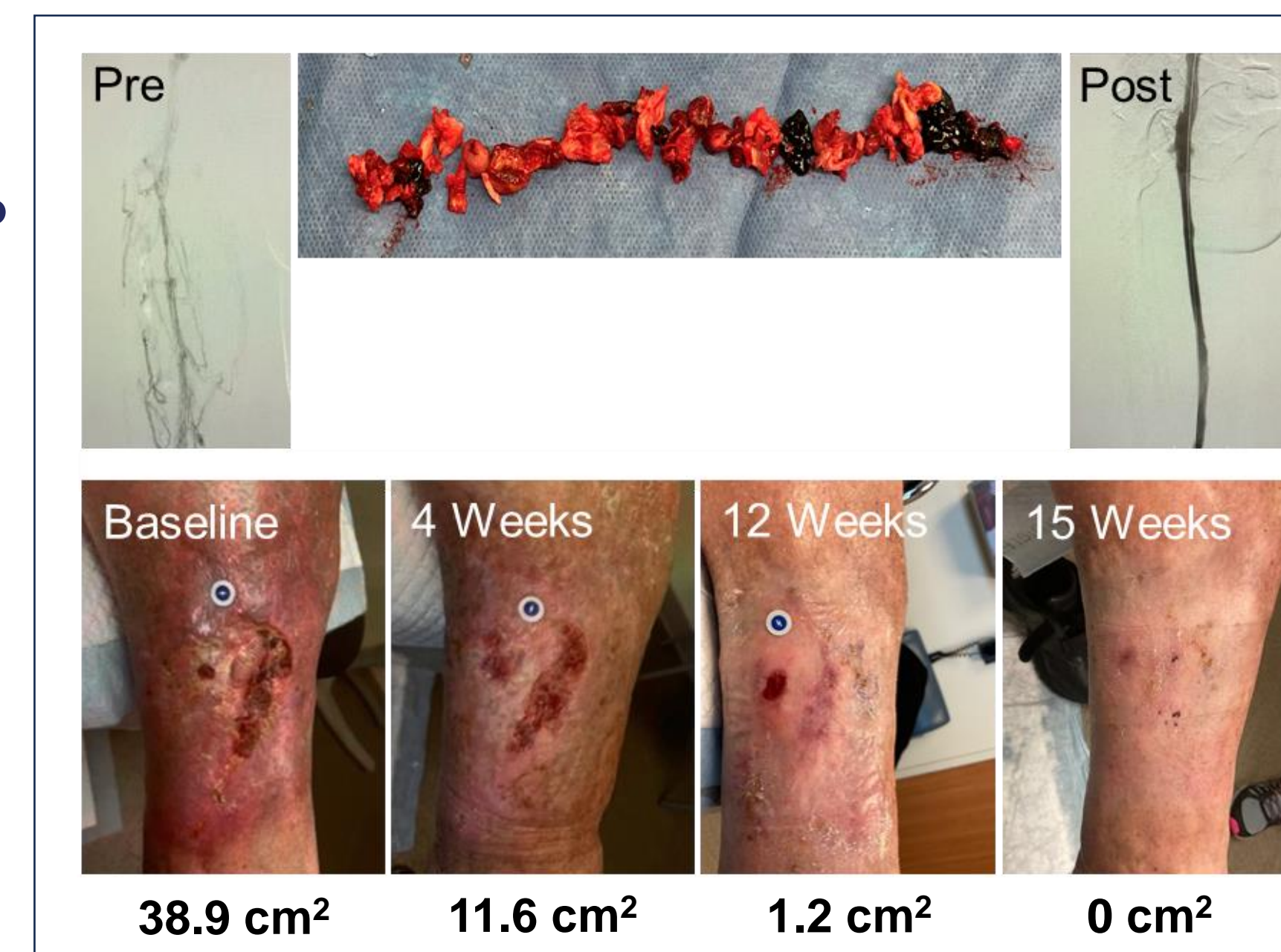
Outcomes

- Technical Success:** ability to cross lesion and deploy device
- Clinical Success:** decrease of ≥ 1 ulcer size category on the revised venous clinical severity score (rVCSS) index (rVCSS_{ulcer diameter})
 - 0 = No ulcer
 - 1 = < 2 cm
 - 2 = 2–6 cm
 - 3 = > 6 cm

Results

Case Example

- Presentation**
 - 66-year-old male
 - Severe PTS s/p DVT 42 years ago
- Referred for amputation**
- Procedure**
 - Mechanical thrombectomy extirpated and disrupted PTOs and thrombus
 - Single session
 - No postprocedural hospital stay
- Clinical outcomes**
 - Immediate flow improvement
 - Resolution of VLU by 15 weeks



Mouawad, J Vasc Surg Cases Innov Tech. 2022;8:196-200.

Baseline and Procedural Characteristics

Patient-level characteristic	Mean \pm SD, n (%)
Age (years)	59.7 \pm 11.8
Female sex	4 (36.4)

VLU-level characteristic	Median [IQR], mean \pm SD
VLU duration (months)	11.0 [6.0–17.0]
VLU area (cm ²)	13.6 \pm 9.0
rVCSS _{ulcer diameter}	2 [2–2]

Procedural and Discharge Characteristics

Limb-level characteristic	Median [IQR], n (%)
Devices passes	5 [4–6]
Stent placed	10 (71.4)
Technical success*	14 (100)

*Ability to successfully cross lesion and deploy device

Patient-level characteristic	n (%)
Single session	11 (100)
Procedure-related stay	0 (0)

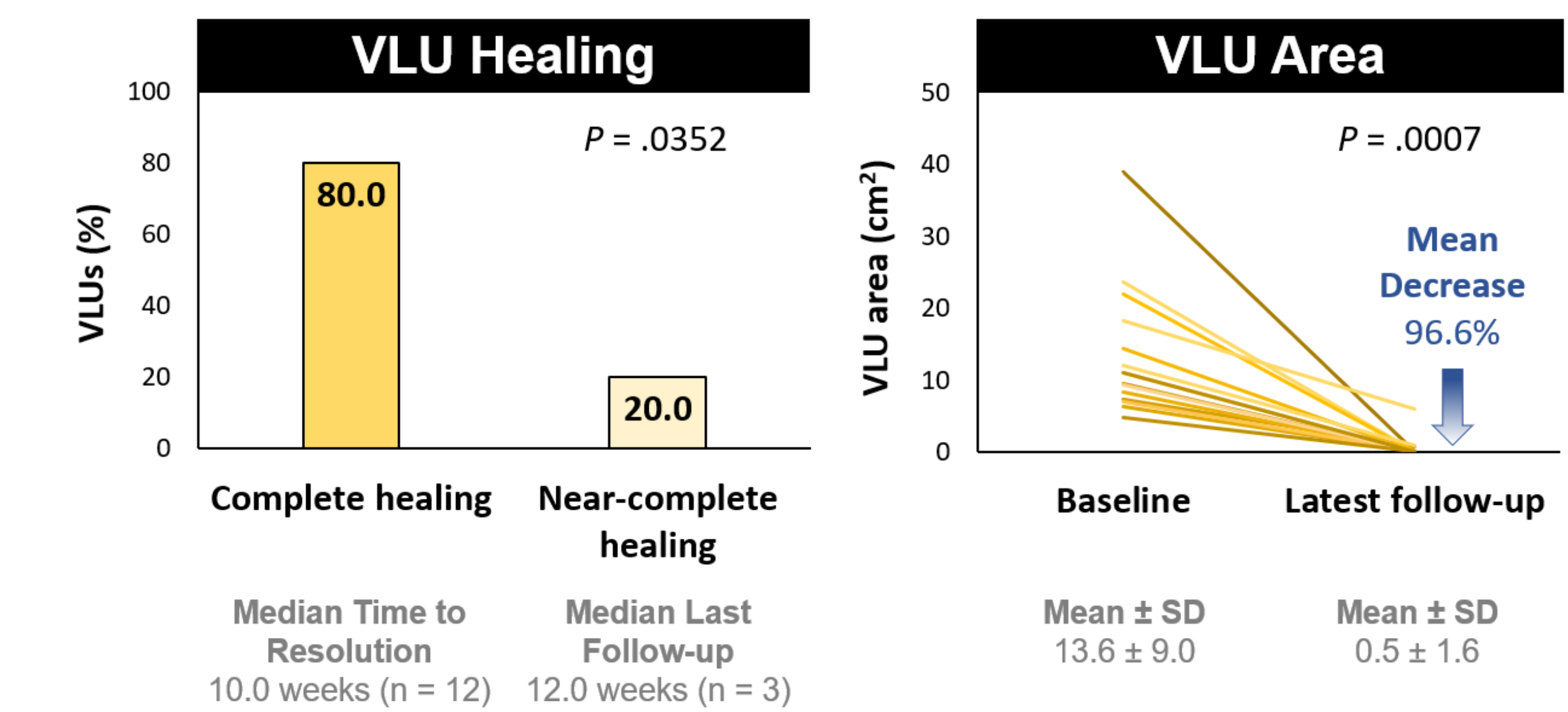
Safety Outcomes

Outcome	n (%)
All-cause mortality	0 (0)
Amputation	0 (0)
Bleeding	0 (0)
Pulmonary embolism	0 (0)
Acute kidney injury	0 (0)
Vessel / valve damage	0 (0)

Clinical Outcomes

Outcome	Median [IQR], n (%)
VLU area (cm ²)	0.5 \pm 1.6
Latest follow-up (weeks)	12.8 \pm 10.5
rVCSS _{ulcer diameter}	0 [0–0]
Clinical success*	15 (100)

*Decrease of ≥ 1 ulcer size severity category on the rVCSS index



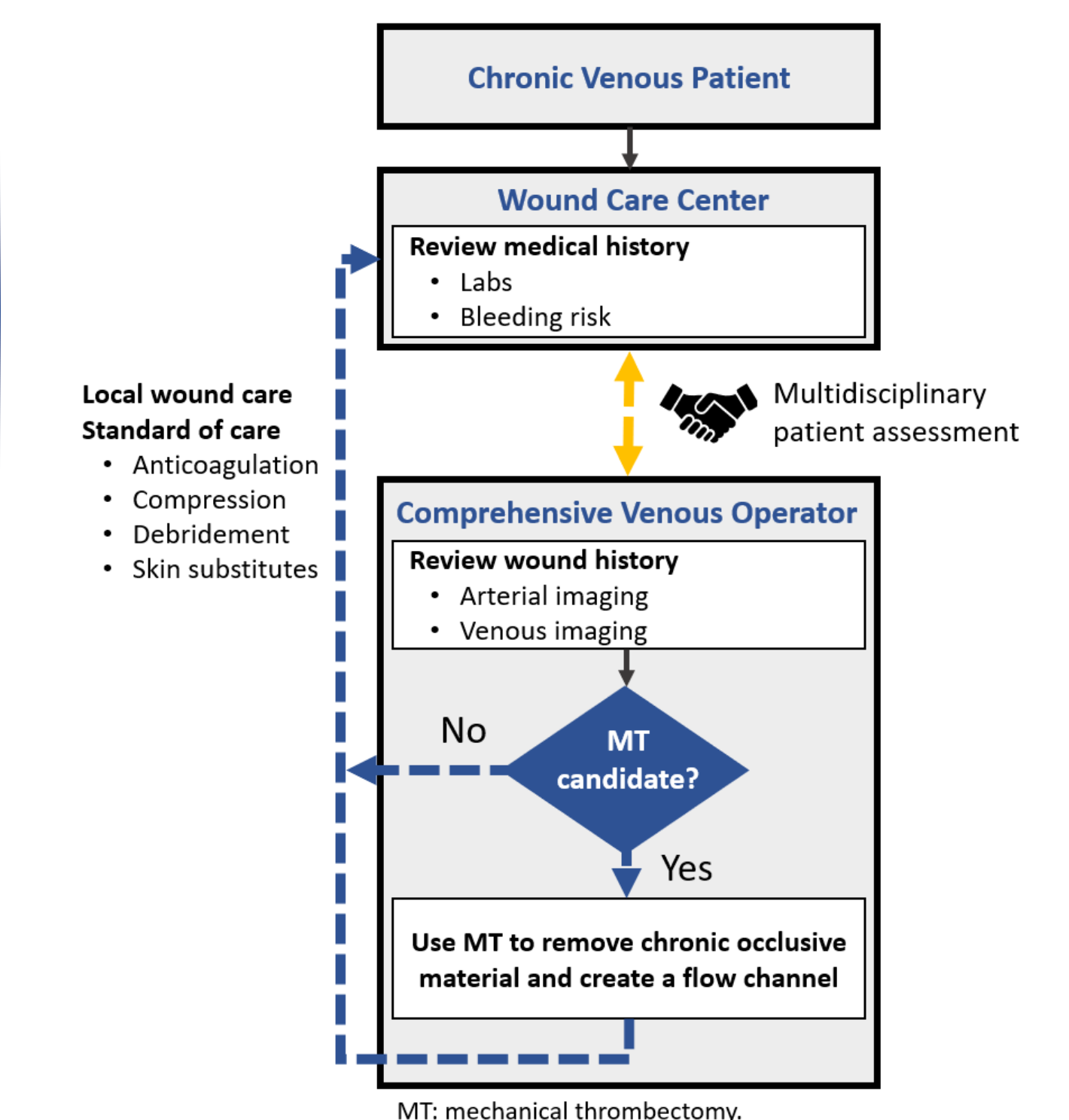
Conclusions

Mechanical thrombectomy appears safe and effective for VLUs, but...

- No adverse events
- 100% clinical success, with 97% mean reduction in VLU area
- No procedure-related hospital stays

Partnering with wound care providers to identify chronic venous patients may improve successful VLU treatment rates

...more patients must be identified and referred for evaluation.



References

- Kahn SR, Comerota AJ, Cushman M, et al. The postthrombotic syndrome: evidence-based prevention, diagnosis, and treatment strategies: a scientific statement from the American Heart Association. *Circulation*. Oct 28 2014;130(18):1636-61. doi:10.1161/CIR.0000000000000130
- Schulman S, Lindmarker P, Holmstrom M, et al. Post-thrombotic syndrome, recurrence, and death 10 years after the first episode of venous thromboembolism treated with warfarin for 6 weeks or 6 months. *J Thromb Haemost*. 2006;4:734-42. doi:10.1111/j.1538-7836.2006.01795.x
- Ashrani AA, Heit JA. Incidence and cost burden of post-thrombotic syndrome. *J Thromb Thrombolysis*. Nov 2009;28(4):465-76. doi:10.1007/s11239-009-0309-3
- Czaplicki C, Albadawi H, Partovi S, et al. Can thrombus age guide thrombolytic therapy? *Cardiovasc Diagn Ther*. Dec 2017;7(Suppl 3):S186-S196. doi:10.21037/cdt.2017.11.05
- Saha P, Black S, Breen K, Patel A, Modaral B, Smith A. Contemporary management of acute and chronic deep venous thrombosis. *Br Med Bull*. Mar 2016;117(1):107-20. doi:10.1093/bmb/ldw006
- Schleimer K, Barbati ME, Grommes J, et al. Update on diagnosis and treatment strategies in patients with post-thrombotic syndrome due to chronic venous obstruction and role of endovenous recanalization. *J Vasc Surg Venous Lymphat Disord*. 2019;7(4):592-600. doi:10.1016/j.jvs.2019.01.062
- Seager MJ, Busuttill A, Dharmarajah B, Davies AH. Editor's Choice-- A Systematic Review of Endovenous Stenting in Chronic Venous Disease Secondary to Iliac Vein Obstruction. *Eur J Vasc Endovasc Surg*. Jan 2016;51(1):100-20. doi:10.1016/j.ejvs.2015.09.002
- Mouawad NJ. Chronic Venous Ulcer Resolution and Post-Thrombotic Syndrome Improvement After Percutaneous Mechanical Thrombectomy of a Forty-Two-Year-Old DVT. *Journal of Vascular Surgery Cases, Innovations and Techniques*. 2022;doi:10.1016/j.jvsct.2022.03.001