

A Novel Mechanical Thrombectomy Device for Iliofemoral In-Stent Thrombosis: Retrospective Analysis of Outcomes for Patients with Venous Leg Ulcers

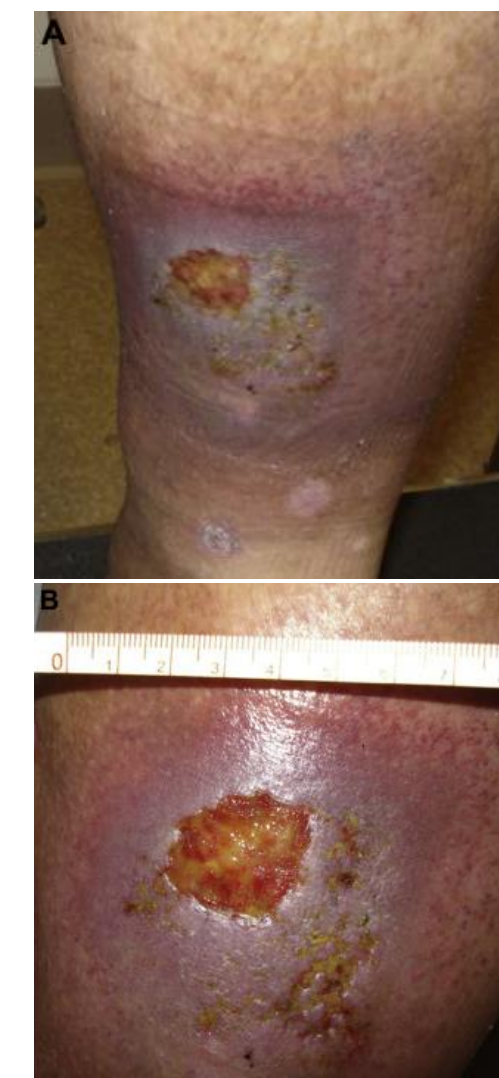
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Background

- Patients with venous **in-stent thrombosis (IST)** often present with lower extremity **postthrombotic syndrome (PTS)**¹
 - In severe cases, PTS can involve the formation of **venous leg ulcers (VLUs)**²
 - Current endovenous therapies for venous IST with ulcerative PTS are generally insufficient³
 - However, an innovative **mechanical thrombectomy (MT)** device designed to treat venous IST is now available
- Promising **PTS improvements** after MT for venous IST have been reported, but there are **no data specific to patients with VLUs**⁴⁻⁶



Adapted from: Giardina, et al. J Radiol Nurs. 2017;36(3):176-9

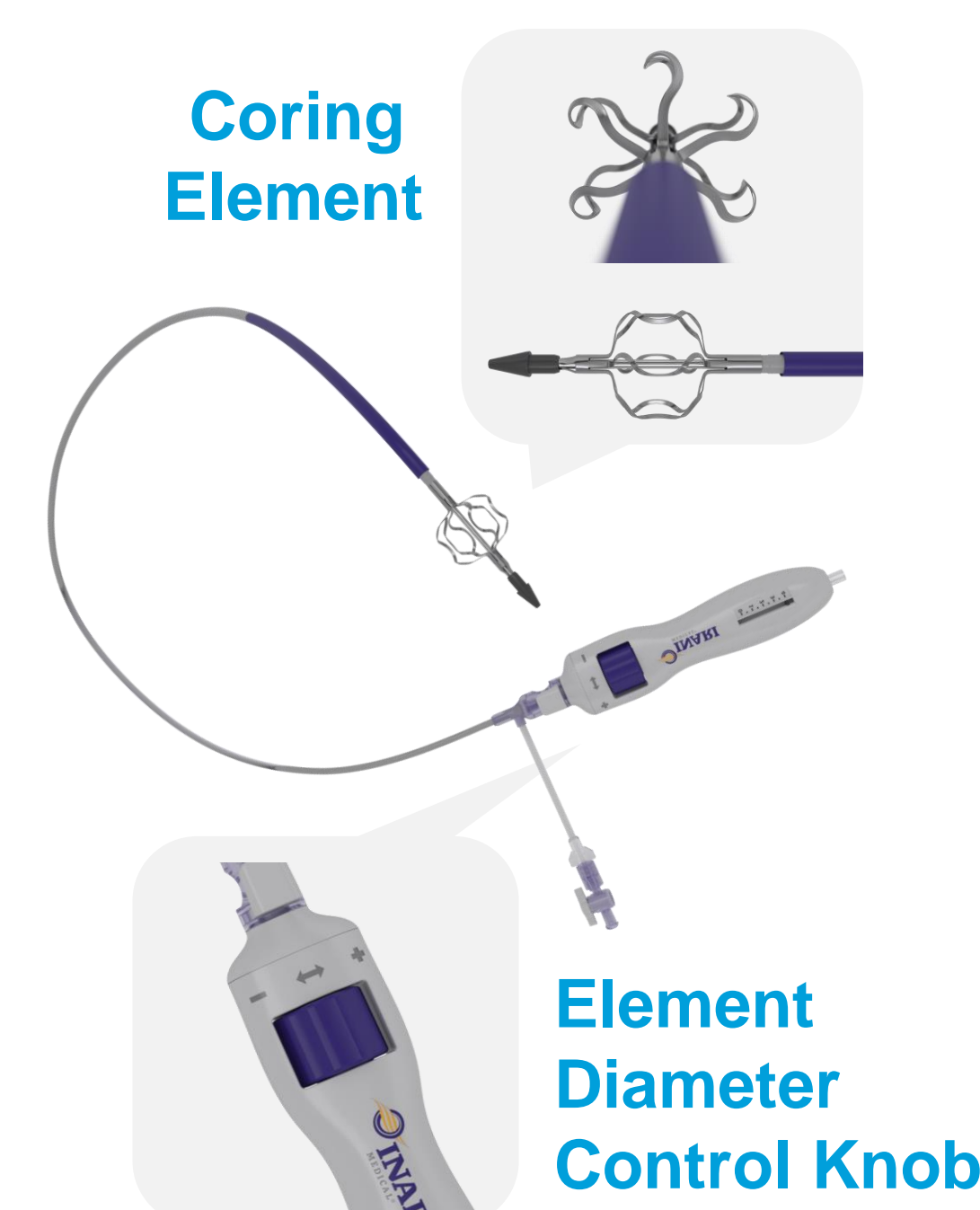
Aim: Assess the safety and effectiveness outcomes of MT for patients suffering from severe PTS with ulceration secondary to venous IST

Methods

Study Device

RevCore Thrombectomy Catheter
Inari Medical

- Over-the-wire device indicated for nonsurgical removal of **acute to chronic thrombi and emboli** from the peripheral vasculature
- Features a wall apposing nitinol coring element that can be manually **expanded up to 20 mm**
- Provides **bidirectional treatment** within the venous stent via manual torquing of catheter
- Liberates material for extraction via compatible aspiration devices



Study Overview

Retrospective, multicenter analysis

Inclusion Criteria

1. Age ≥ 18 years
2. Iliofemoral IST with at least 1 VLU
3. Treated using the study device at 1 of 4 enrolling centers between March 2023 and November of 2023

Endpoints

- **Primary endpoint** – postprocedural effective diameter ≥ 50%
- **Secondary endpoints** – 30-day device-related major adverse events (MAEs):
 - Mortality
 - Vessel perforation
 - Readmission
 - Clinically significant pulmonary embolism

Case Example

• Presentation

- Patient (60/M), 9-year history of IST: inferior vena cava to L common femoral vein
- Presented for **worsening of bilateral VLUs**
- Imaging revealed **stent occlusion** and recent thrombus burden increase

• Procedure

- **MT used to recanalize thrombosed stent**
- **Mobilized thrombus trapped in IVC** using Protrieve sheath (Inari Medical, lower right imaged)
- **No complications** occurred

• Follow-up Outcomes

- At 2-month follow-up, **VLUs had resolved**
- Patient also noted **improved quality of life**



Adapted from: Marino and Lee. Am J Interv Radiol. 2024 (Under review).

Baseline Characteristics

Characteristic (Patient N = 5)	Mean ± SD, n (%), median [IQR]
Age (years)	55.2 ± 18.9
Male	5 (100)
Treated limbs	N = 7
IST symptom duration, years	2.0 [0.8–5.0]
Treated stents	N = 10
Effective diameter, %	16.0 ± 22.7
Inner lumen area, mm ²	0.9 ± 1.3
Treated VLUs	N = 12
VLU area, cm ²	9.9 ± 9.4

Procedural Characteristics

Characteristic (Procedure N = 7)	Median, mean, n (%)
Thrombus removed, %	90.0 [86.3–90.0]
Device time, min	42.0 ± 4.5
Estimated blood loss, mL	75 [45–75]
Single session	7 (100)
Effective diameter ≥ 50%	10 (100)
Inner lumen area, mm ²	140.6 ± 64.6
Stent fractures or migrations	0 (0)

Safety Outcomes

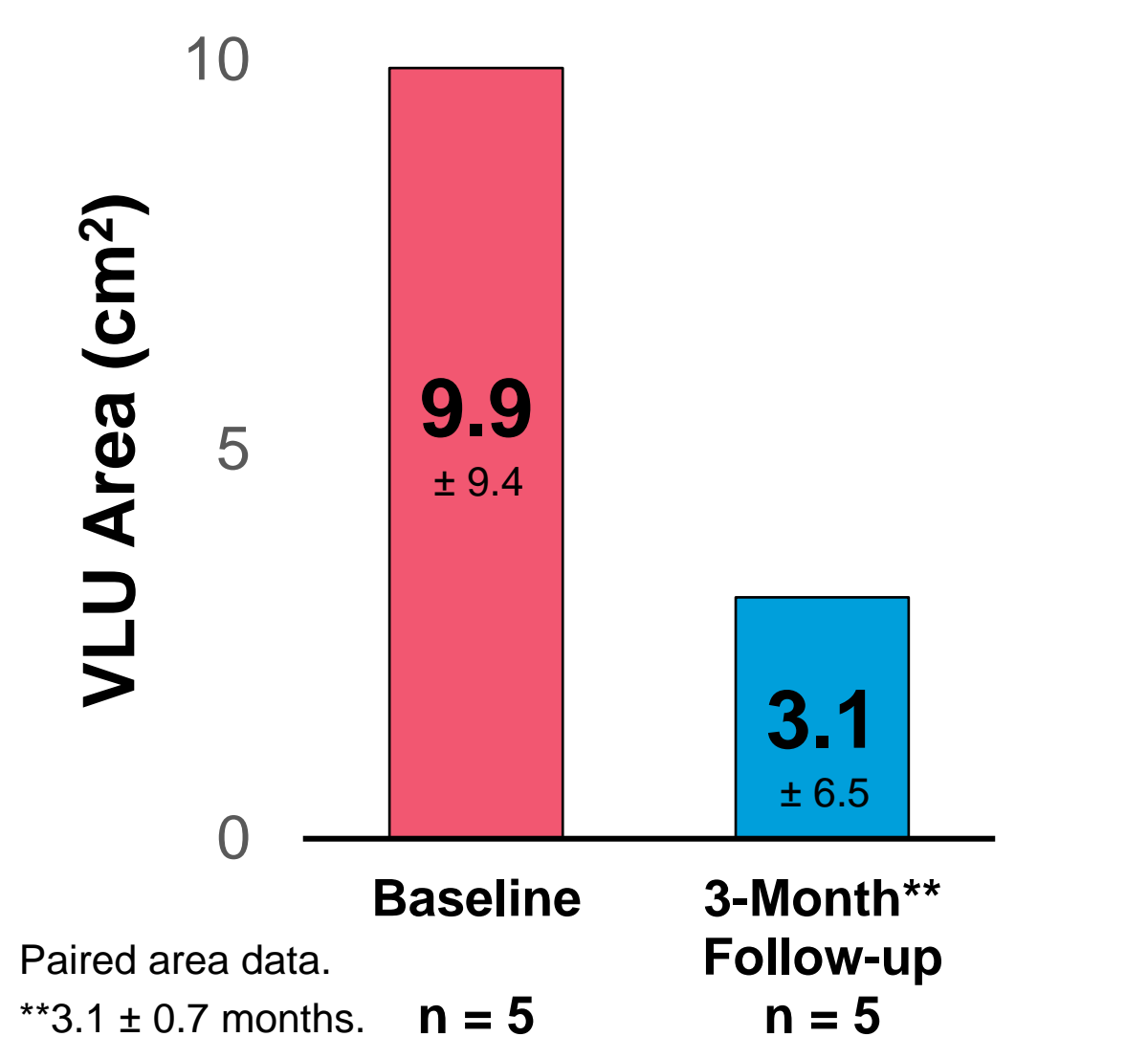
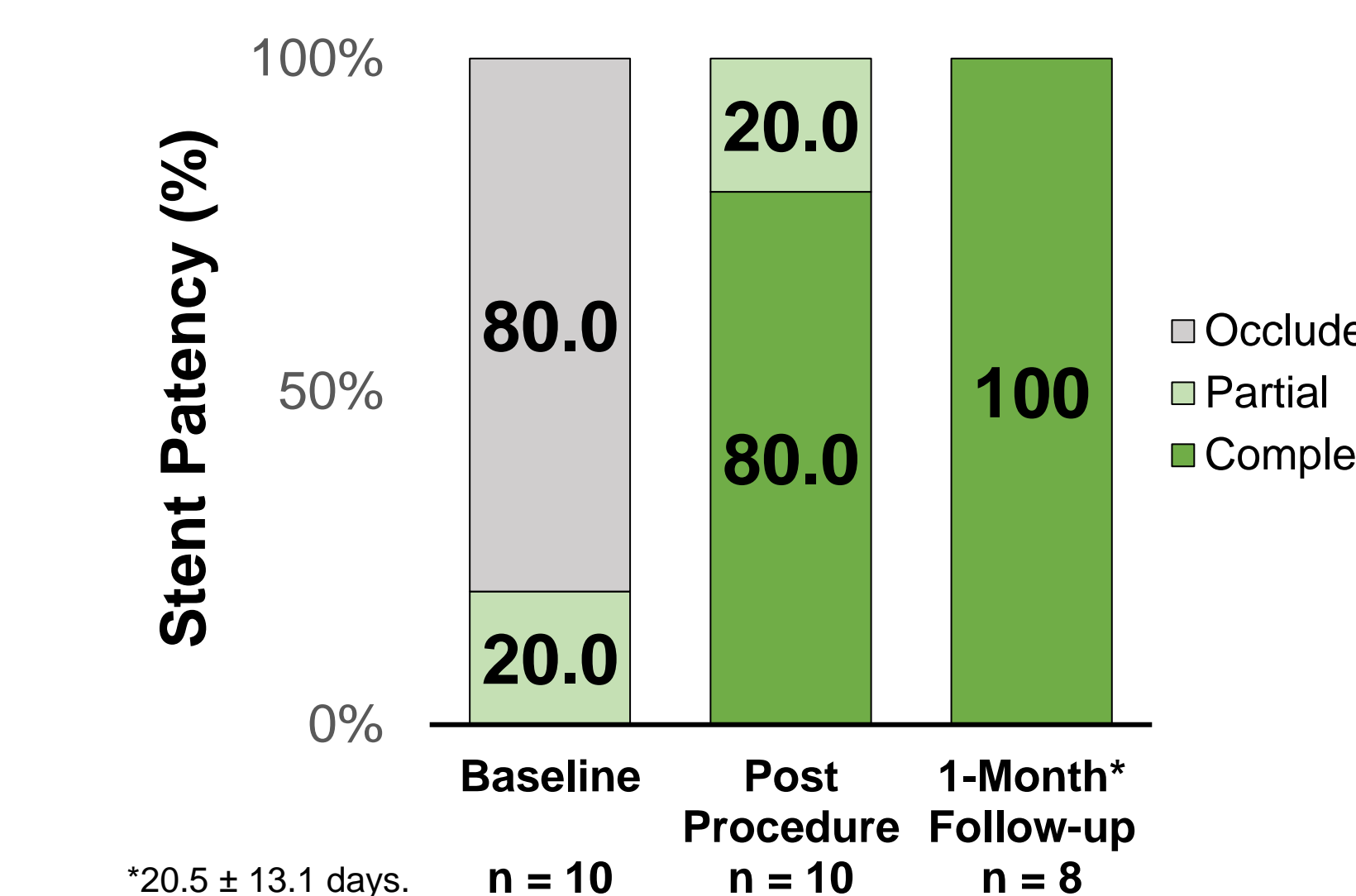
30-Day Outcome	n (%)
Mortality	0 (0)
Readmission	0 (0)
Vessel perforation	0 (0)
Pulmonary embolism	0 (0)

Results

Outcomes and Additional Case Images

Outcome	Mean ± SD, n (%)
Last follow-up, months	3.1 ± 0.7
VLU healing	11 (100)
VLU resolved	4 (36.4)
VLU area, cm ²	3.1 ± 6.5

Available VLU Data N = 11



Conclusions

- In this analysis, **all (100%) treated stents showed postprocedural patency with effective diameter ≥ 50% after debulking with MT**, indicating that the study device is highly effective for venous IST
- The MT device appears safe for treating patients with venous IST as there were **no (0%) 30-day device-related MAEs**, including no mortality, readmission, vessel perforation, or pulmonary embolism
- For patients seen at a follow-up visit, **100% demonstrated improvement of PTS symptoms**
- By approximately 3-month follow-up, all VLUs with available data (92%) showed signs of healing, and **over one-third of VLUs had completely resolved**

References

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