WELCOME *To the*

2026 SYMPOSIUM

Initial Clinical results of the Distal staging fistula in catheter dependent ESRD patients

VASA Vascular Access Society of the Americas

Access Excellence.

MAY 20-22, 2026 • HILTON SALT LAKE CITY CENTER • SALT LAKE CITY, UTAH

Disclosure

- Inventor

Background

Vascular Access for Dialysis

Catheter



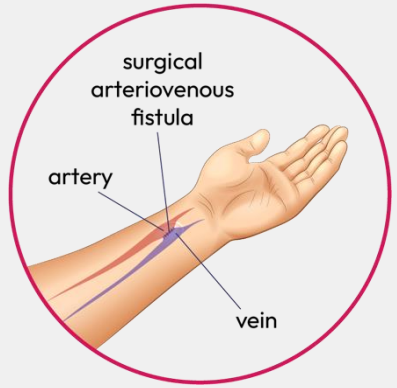
- Associated with a **high rate of complications**, including **infections**, **thrombosis**, high morbidity and high mortality
(white stick of death)

Graft



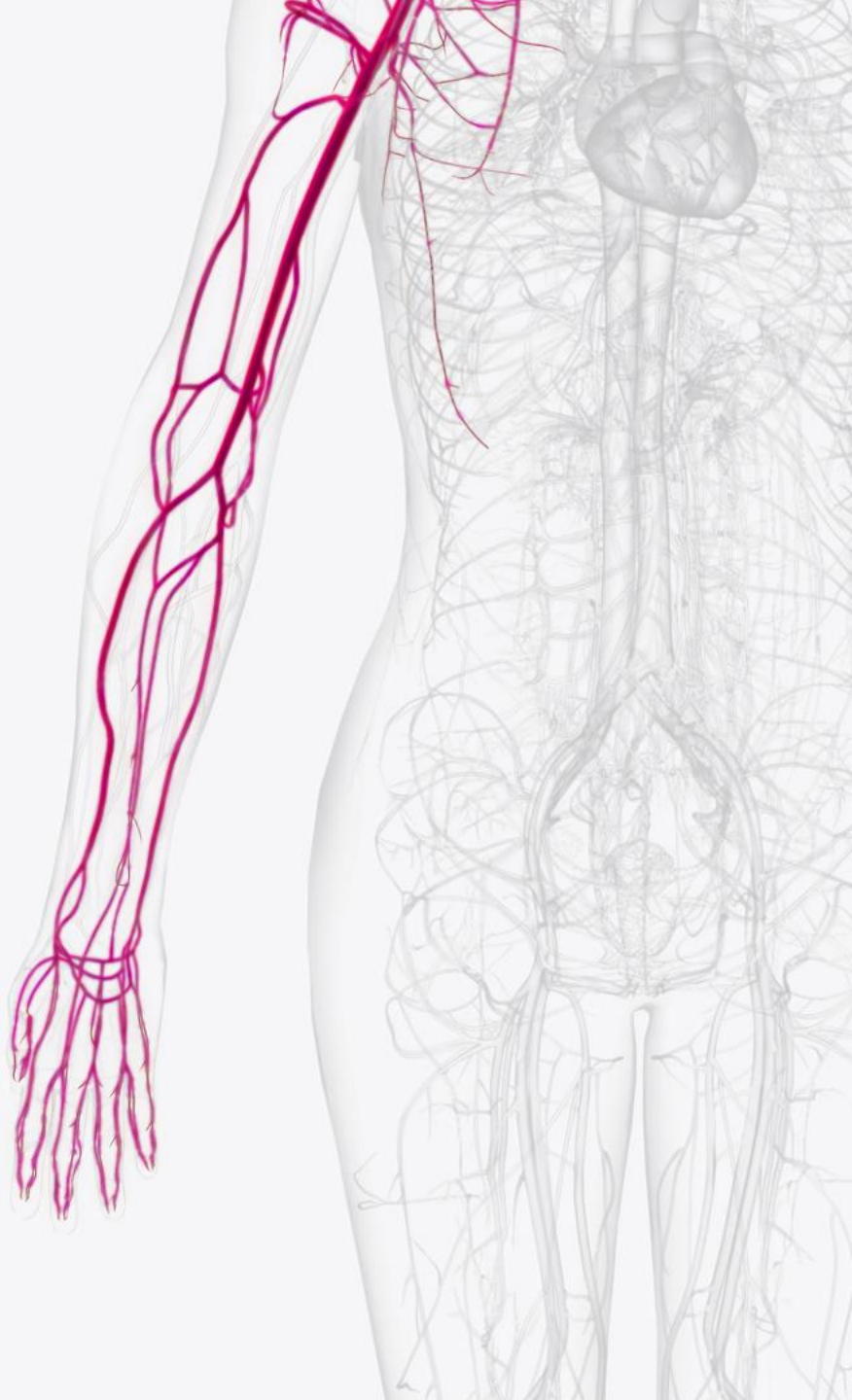
- A synthetic tube surgically implanted to connect an artery and vein.
- **Higher risk of infection** and clotting compared to fistulas.

Fistula



- Created by connecting an artery to a vein.
- Associated with fewer complications and better blood flow rates.
- **Best long-term solution for dialysis.**

What Problem Are We Solving?



The Problem

Dialysis Access Is a Catastrophe

No other surgical field tolerates a 50% failure rate.

50%
of fistulas fail to mature

~40%
of patients excluded (small veins)

80%
start dialysis on a catheter

50%
require reintervention in yr 1

400,000+ US patients | 2.5M+ globally | $90K/patient/year Medicare cost

Distal Solution

Enlarge veins before fistula surgery. Convert ineligible patients into candidates.

Stage 1: DisTal Procedure

Percutaneous wrist-based procedure creates a staging fistula between the distal radial artery and radial vein.

Arterial blood enters the venous system, triggering hemodynamic remodeling.

Vein Remodeling

Over 5-30 days, increased flow and pressure enlarge the cephalic vein through perforating veins.

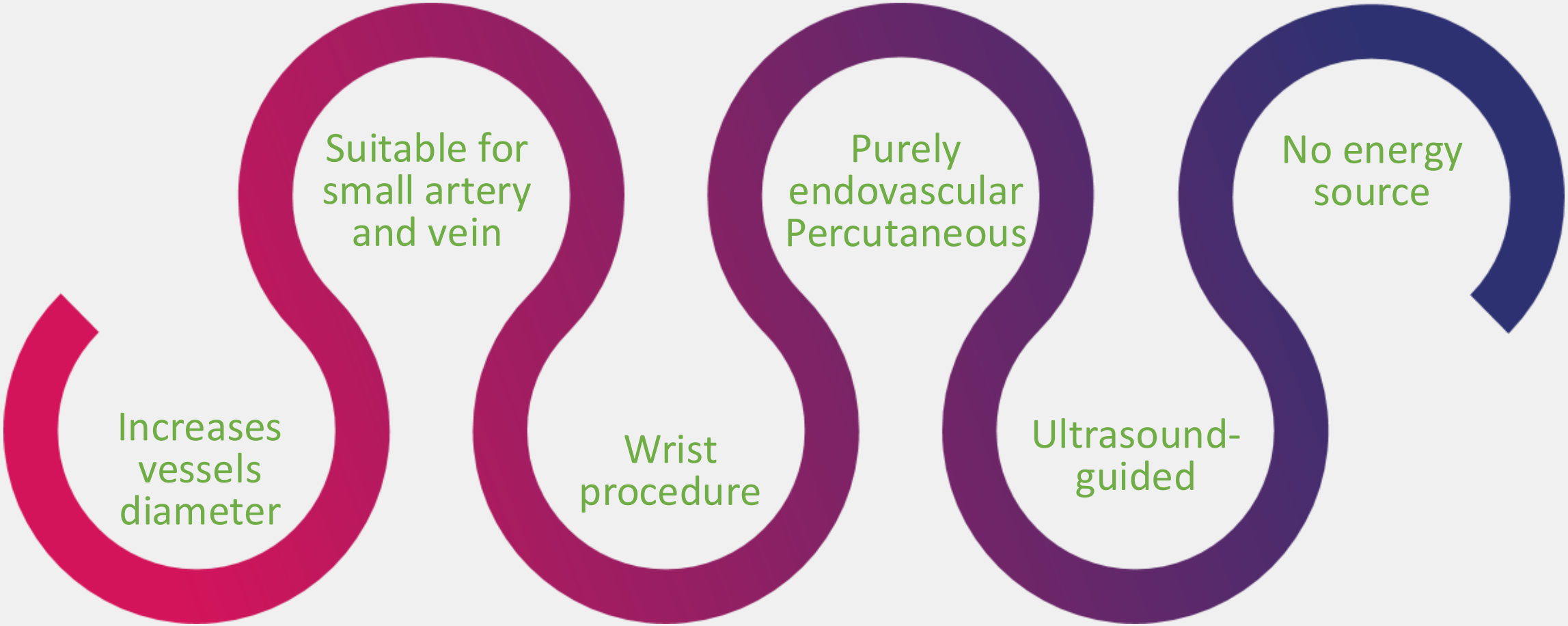
Stage 2: Surgical AVF

Over ~30 days, and once vein reaches surgical threshold (≥2.0 mm), a standard surgical AVF is created with dramatically improved maturation.

Larger Vessels = more eligible patients for fistula creation, better maturation and reduced complications

Ref. Link 1; Ref. Link 2

The Solution- Distal Genesis Fistula



Clinical Results



Clinical Results

Patient #110		
Vessel [position]	**4-Dec-2024** Diameter [mm]	**6-Dec-2024** Diameter [mm]
Brachial A [3]	2.8	5.3
Basilic V [3]	2	3.7
Brachial V [3]	1.7	4.8
Cephalic V [1]	1.4	2.8
Cephalic V [2]	1.9	3.8
Cephalic V [3]	1.1	2
Cephalic V [4]	0.9	1.8



Cephalic V [1]	1.4 →	2.8
Cephalic V [2]	1.9 →	3.8
Cephalic V [3]	1.1 →	2
Cephalic V [4]	0.9 →	1.8

The Procedure



How the Distal procedure works



Access at the wrist

1. Percutaneous access at the distal radial artery and adjacent radial vein under ultrasound guidance. No surgical incision.

Create the anastomosis

2. Creating a side-to-side AVF at the distal forearm.

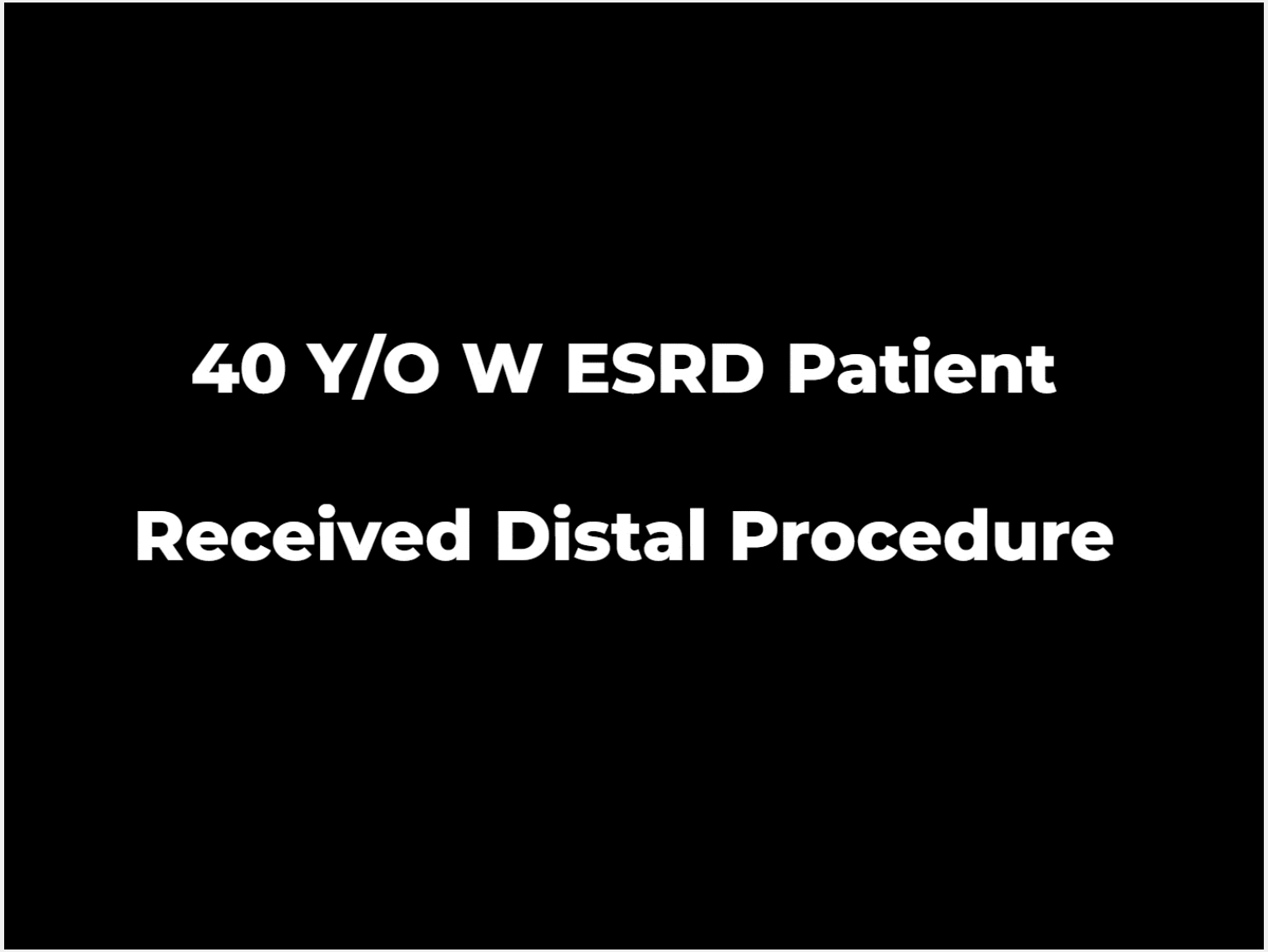
Redirect flow through the perforator

3. Arterial flow is directed from the deep system through the perforating (communicating) vein into the superficial cephalic vein.

Vein remodeling and maturation

4. The cephalic vein dilates, remodels, and matures under the influence of arterial flow.

1.2mm Cephalic



Clinical Results



Clinical Evidence: Feasibility Study

80+ procedures | 12 US physicians | Dominican Republic

0

Adverse Events

Zero complications across all procedures

74%

Vein Enlargement

Mean cephalic vein diameter increase at wrist

5.2x

Eligibility Conversion

13% → 67% now eligible for surgical AVF

67%

Functional Fistula

Of patients who received surgical AVF

80+

Patients

Mean age 50±13.1

Males – 72;

Females - 13

Procedure time: 4–12 min | ~95% target vein enlargement

Procedural Profile

Procedure Time

4–12 minutes

Performed by multiple physicians

Anesthesia

Local only

Guidance

Ultrasound (no fluoroscopy)

Energy Source

None — purely mechanical

Min Vessel Size

Artery ≥1.8 mm, Vein ≥1.5 mm

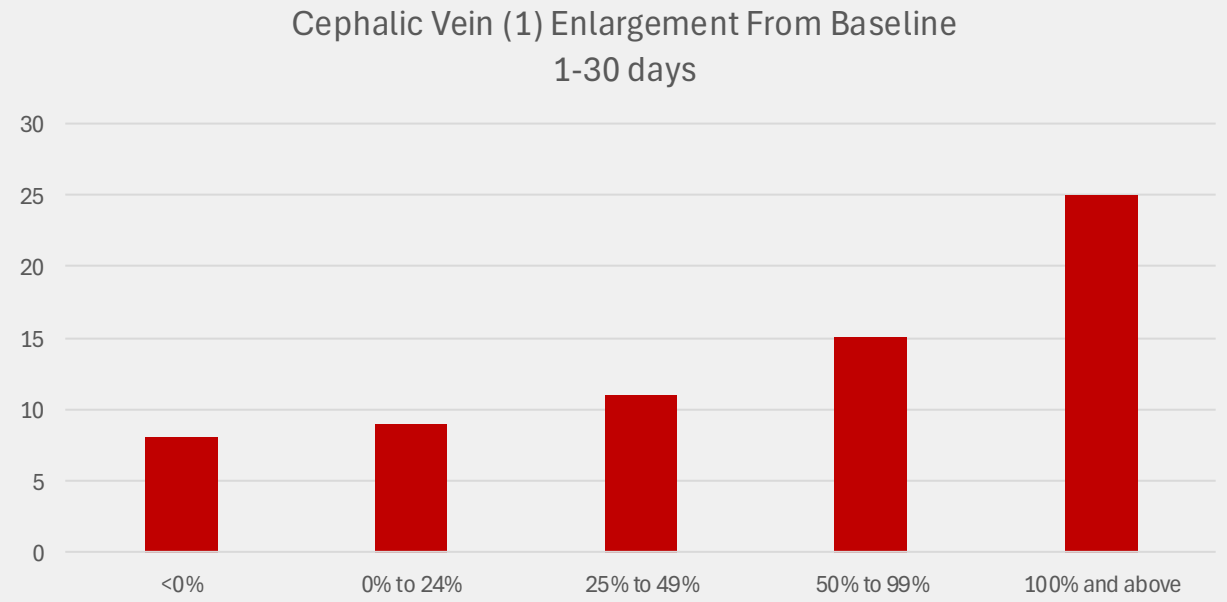
Complications

Zero adverse events (80+ procedures)

Cephalic Vein Enlargement at the Wrist

Average increase of **73.5%** observed in **88.2%** of patients; from 1.3 mm to 2.1 mm at 1–30 day follow-up.

Cephalic vein Diameter at the Wrist	Baseline	Follow-up	Change from Baseline	% Change
1-30 days, n	68	68	68	68
Mean ± SD [mm]	1.25±0.44	2.07 ±0.84	0.82	73.5%

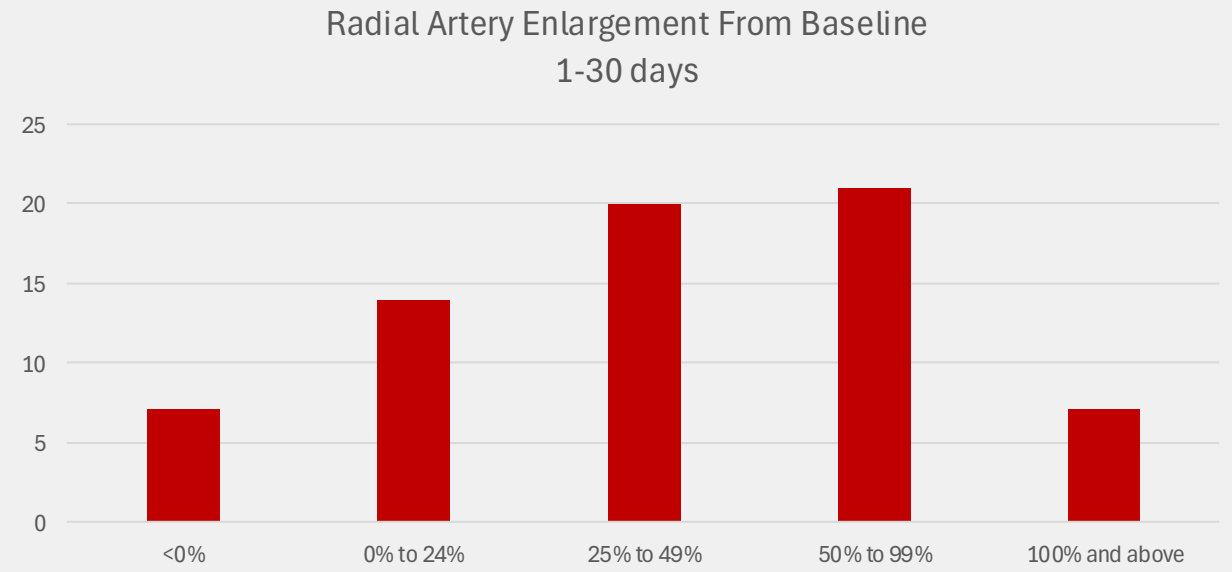


Radial Artery Enlargement at the Wrist

Average increase of **47.0%** observed in **89.9%** of patients;

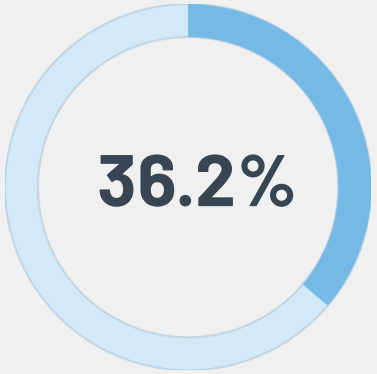
from 2.26 mm to 3.23 mm at 1–30 day follow-up.

Radial Artery Diameter at the Wrist	Baseline	Follow-up	Change from Baseline	% Change
1-30 days, n	69	69	69	69
Mean ± SD	2.26±0.41	3.23±0.78	0.97	47.0%



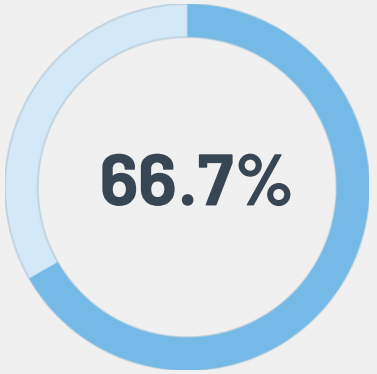
6-Month Follow-Up Results

n=58 catheter-dependent ESRD subjects — **no supplementary procedures** to create or maintain fistula



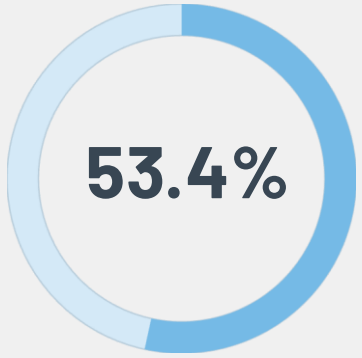
Surgical Fistula/Graft

21/58 patients underwent surgical creation post-staging



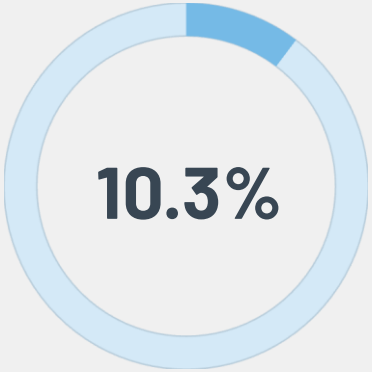
Functional Fistula

14/21 of those patients have a functional surgical fistula



Awaiting Surgery

31/58 with successful staging waiting for surgical AVF creation



Left Study

6/58 due to staging fistula occlusion

Win for Everyone

- Win- **Patients** will have preferred AV access. Less complications.
- Win- **Surgeons** will have more optimal vessels for fistula creation procedures.
- Win- **Hospitals** will have fewer hospitalizations for catheter-related complications.
- Win- **The dialysis centers** will have more patients on dialysis using preferred access.
- Win- **Interventional Radiologists and Nephrologists** will be integral part of creation the preferred access with the surgeon.



Thank you

For more information please contact:

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