

VEITH SYMPOSIUM
Connecting The Vascular Community


Update On The Velocity® Percutaneous AV Fistula (Venova Medical)

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IAD

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Disclosures:

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X Consulting/Teaching: Becton Dickinson, Medtronic, Laminate medical, Bluegrass Vascular, Xeltis, VentureMed

X Speaking: BrosMed medical, Cardionovum

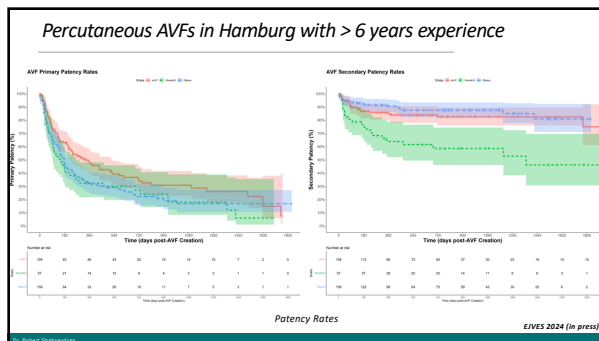
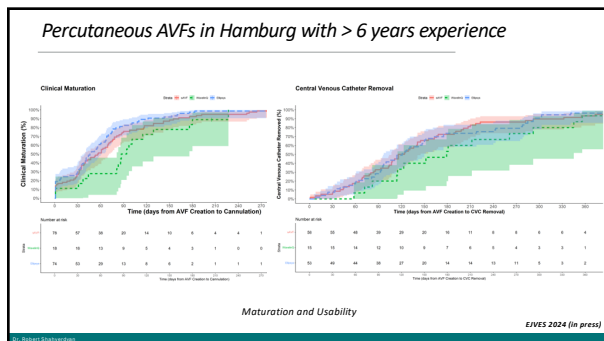
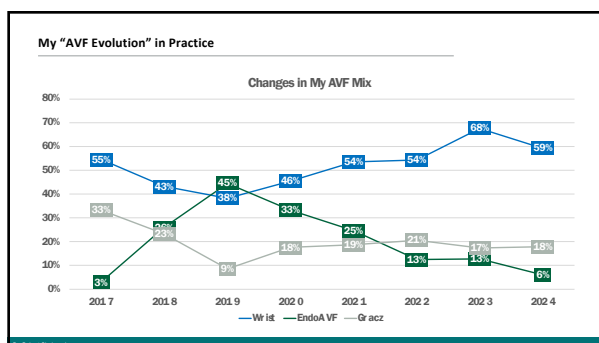
X Advisory Board: Venova medical

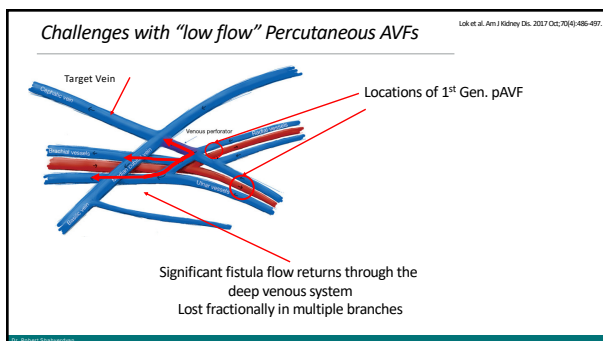
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Percutaneous AVFs

- Were introduced in 2017
- “Create an AVF without incision without trauma”
- 2 FDA and CE (MDR) approved devices available now
 - WavelinQ (BD) and Ellipsys (Medtronic)
- Initial “hype” was high with increasing usage
- „missed” widespread adoption worldwide
 - Decreased usage over the last 2-3 years
- Selected experienced users (WavelinQ, Ellipsys or both) left

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Challenges with Percutaneous AVFs

Cannulation difficulties

High Reintervention rates

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Challenges with Percutaneous AVFs

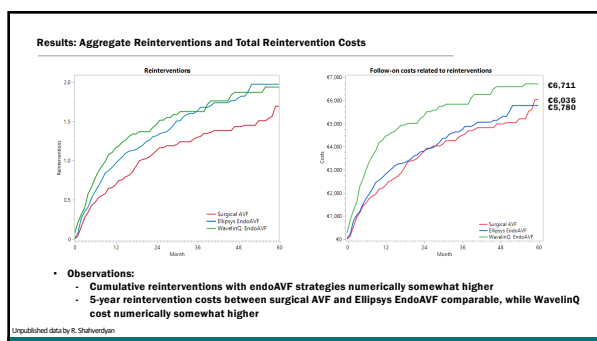
Flow directing procedures to achieve functional maturation (high intervention rates)

- Fistula flow is the best predictor of maturation and unassisted cannulation
- Embolization of deep venous outflow

(Juxta)Anastomotic stenosis (high intervention rates)

- Combination of "energy" injury ± angioplasty and turbulent hemodynamics

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What to expect from next generation endoAVF devices?

We need cheaper devices (index procedure cheaper)

We need less interventions after endoAVF creation (follow-up costs lower)

Additionally: fast and technically successful

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Generation 2.0 pAVF: Velocity
A pAVF that replicates surgical AVF anatomy

- ✓ **Optimal geometry for ideal flow conditions to support fast maturation**
 - Single outflow
 - No need for flow diversion or embolization
- ✓ **Lowest incidence of anastomotic stenosis**
 - Absent inflammation or thermal injury
 - Endothelium shielded from turbulence
 - No angioplasty
- ✓ **Ease of use + Accessibility**
 - Local anesthesia / block only
 - Ultrasound

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VENOS - 1 Trial (FIH) with latest design

Prospective, single-arm, single-center, open-label study Clinicaltrials.gov NCT 05757726

10 subjects have completed the final study one year follow up visit

Number Enrolled	10
Age	47 (27 - 62)
Male gender	8/10 (80%)
BMI	26.7 (20.0 - 38.1)
Diabetes	6/10 (60%)
Hypertension	10/10 (100%)
Etiology of Kidney Failure	
Hypertension	4/10 (52%)
Diabetes	6/10 (30%)

Radial artery diameter	3.0 (2.3 - 3.7)
CPV diameter	3.9 (3.6 - 4.9)
Upper arm venous outflow	
Cephalic + Basilic	7/10 (70%)
Cephalic	3/10 (30%)

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Velocity pAVF Sizing

2 sizes to address expected anatomies

6 large / 4 small used in VENOS-1

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Diagnostic Angiogram - Patient #1

Effectiveness

- 100% technical success
- All procedures performed exclusively with ultrasound
- Regional anesthesia

Safety

- No AE/SAE @ 6 weeks
- No hand ischemia in any patient

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Single Outflow Bypassing Deep Veins

1:1 relationship between arterial flow and superficial venous flow

Brachial artery 982 ml/min **Cephalic vein 955 ml/min**

No re-interventions Unassisted Cannulation @ 6 weeks Uninterrupted Clinical Use x 9 months

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Physiologic Maturation

Definition

Arterial flow > 500 ml/min + Cephalic vein dia. > 5.0 mm

100% met criteria within 6 weeks

Ave 18 days to reach endpoint

No Reinterventions Needed to Reach Endpoint

J Am Soc Nephrol. 2018 Nov;29(11):2735-2744.

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Primary Patency

80% Primary Patency at 1 year

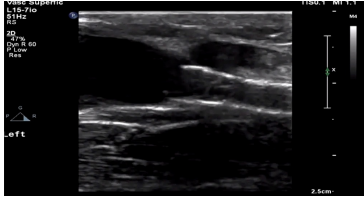
Single angioplasty for JA stenosis @ day 242

2 reinterventions for the entire cohort in first year

0.2 reinterventions / patient year

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Durability – 1 Year Ultrasound



Direction of Flow


Single angioplasty for JA stenosis @ day 242

No evidence of implant stenosis in any other subject on 1 year ultrasounds

Velocity pAVF is the least inflammatory way of creating an AVF
The implant shields juxta-anastomotic segment from sensing turbulence and developing stenosis

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US Early Feasibility Study The VENOS-2 Trial



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Generation 2 pAVF Velocity System

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Summary

- FIH experience with Velocity System demonstrates **implant advantages and anticipates**
 - Ideal flow into superficial venous system optimizes time to maturation
 - Maturation without needing adjunctive procedures such as embolization or PTA
 - Single outflow preserves inline cannulation in upper arm
 - Reduction in CVC duration time
 - Reduction in reintervention and costs

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THANK YOU!!!!

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