# **6-month** update on **AVeNEW** trial design for outflow stenosis on AV **Fistula** circuits

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# Disclosure

Speaker name: Ta-Wei Su

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☑ I do not have any potential conflict of interest

# AVeNEW Study

**A**rterio**ven**ous (AV) Stent Graft vs. PTA alone in the Treatment of Stenoses in the V**e**nous Outflo**w** of AV Fistula Access Circuits

## Objective

Compare the performance of the COVERA™ Vascular Covered Stent to a concurrent, randomized PTA control for the treatment of stenotic lesions in the upper extremity venous outflow of native AV Fistula

# COVERA™ Vascular Covered Stent



configurations

ePTFE encapsulated nitinol stent
Diameters: **6-10** mm
Lengths: **40**, **60**, **80**, and **100** mm

## Thumbwheel Delivery System

Sheath compatibility: **8-9** F
Working length: 80 & 120 cm
**0.035**” over-the-wire system with atraumatic tip

- **Design**

  Prospective, Multicenter, Concurrently-controlled, Randomized
  - Patient Population: **280** patients
  - **24** International Sites: USA/Europe/Australia/New Zealand

- **Follow Up:** 6 month data presented today-ongoing to **2 years**

- **Independent Analysis:**
  - Clinical Events Committee (CEC): adjudicate serious adverse events
  - Angiographic assessment of lesions (Yale Core Lab)
  - Data Safety Monitoring Board: oversee overall patient safety

# Key Inclusion Criteria

Upper extremity AV fistula (including cephalic arch)

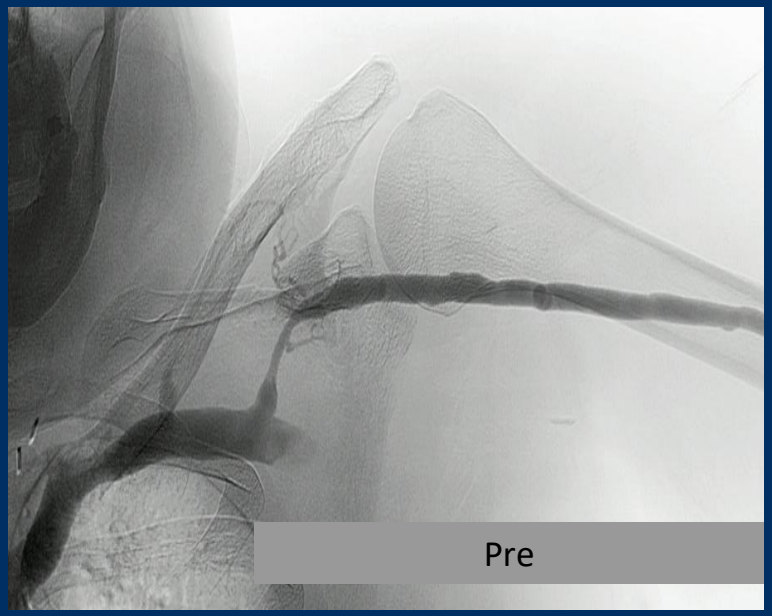
≥ 1 successful dialysis session

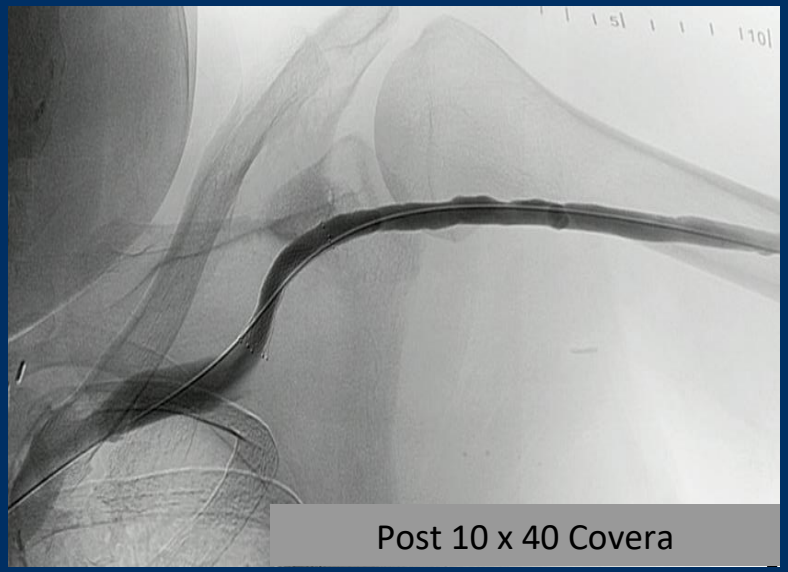
Clinical or hemodynamic fistula dysfunction in the venous outflow

Angiographic stenosis ≥ 50%

Target lesion ≤ 9 cm in length

Vessel diameter 5.0 - 9.0mm



# Key Exclusion Criteria

AV graft or lower extremity

Uncontrolled infection (local or systemic)

Additional stenotic lesions in the venous outflow not successfully treated prior to the study procedure

Aneurysm or pseudoaneurysm in the treatment area

Lesion location: across the elbow joint, cannulation zone, within a stent, or central veins

# Patient Demographics

| | Covered Stent Group | PTA Group | p-value |
|---|---|---|---|
| Number of Patients (ITT), N | 142 | 138 | |
| Mean Age, years ± SD | 63 ± 13.2 | 62 ± 11.5 | 0.70 |
| Male/Female, %/% | 62.7/37.3 | 60.9/39.1 | 0.76 |
| Race, % (n) | | | 0.08 |
| Caucasian | 70.4 (100) | 66.7 (92) | |
| African American | 25.4 (36) | 26.1 (36) | |
| Mean BMI, $kg/m^2$ ± SD | 30.8 ± 6.3 | 28.9 ± 5.8 | 0.01 |
| Risk Factor, % (n) | | | 0.54 |
| Hypertension | 97.9 (139) | 96.4 (133) | |
| Smoker (Current & Former) | 43/7 (62) | 44.9 (62) | |
| Diabetes (Type 2) | 71.1 (101) | 68.1 (94) | |
| Congestive Heart Failure, % (n) | 24.6 (35) | 29.0 (40) | 0.41 |
| Coronary Artery Disease, % (n) | 32.4 (46) | 37.7 (52) | 0.35 |
| Peripheral Artery Disease, % (n) | 16.9 (24) | 21.0 (29) | 0.38 |

# AV Access Circuit & Lesion Characteristics

| | Covered Stent Group | PTA Group |
|---|---|---|
| Upper Arm Access Position, % (n) | 93.0 (132) | 94.2 (130) |
| Brachial Artery Inflow, % (n) | 90.1 (128) | 92.0 (127) |
| Outflow Vein, % (n) | | |
| Cephalic | 73.9 (105) | 68.8 (95) |
| Basilic | 24.6 (35) | 30.4 (42) |
| Months on Dialysis (mean), months ± SD | 28.0 ± 23.2 | 31.5 ± 24.7 |
| Lesion Type (Restenotic), % (n) | 75.4 (107) | 71.0 (98) |
| Lesion Location, % (n) | | |
| Cephalic Arch | 54.9 (78) | 50.7 (70) |
| Cephalic Vein Outflow | 17.6 (25) | 17.4 (24) |
| Basilic Vein Swing Point & Outflow | 20.4 (29) | 23.9 (33) |
| Reference Vessel Diameter, mm ± SD | 8.1 ± 1.4 | 8.0 ± 0.9 |
| Mean Lesion Length, mm ± SD | 28.8 ± 17.4 | 29.7 ± 17.0 |
| Mean Baseline Target Lesion Stenosis, % ± SD | 72.5 ± 12.4 | 72.5 ± 12.7 |

# Procedural & Post-Procedural Observations

| | Covered Stent Group | PTA Group |
|---|---|---|
| Mean Balloon Diameter/Length, mm ± SD/mm ± SD | 8.5 ± 1.0/46.8 ± 14.9 | 8.4 ± 1.1/49.0 ± 16.8 |
| Mean Maximum Inflation Pressure, atm ± SD | 20.6 ± 5.4 | 21.2 ± 5.8 |
| Mean Duration of Inflation, sec ± SD | 43.4 ± 52.8 | 41.2 ± 41.0 |
| Flared/Straight Stent Graft Configuration, %/% | 46.1/53.9 | na |
| Most Used Covered Stent Diameters, % | | |
| 10 mm | 48.2 | na |
| 9 mm | 29.8 | na |
| Most Used Covered Stent Lengths, % | | |
| 40 mm | 41.8 | na |
| 60 mm | 36.9 | na |
| Final Mean Residual Stenosis, % ± SD | 2.2 ± 5.8 | 15.0 ± 18.0 |
| Dialysis Resumed at 30 Days, % (n) | 96.5 (137) | 97.8 (135) |

# Primary Safety Endpoint

## Freedom from a Primary Safety Event (30 days)

- Freedom from an event resulting in additional intervention, hospitalization, or death

| Primary Safety Endpoint (Proportional Analysis) | Covered Stent Group | PTA Group | Difference 90% CI[1] | p-value[2] |
|---|---|---|---|---|
| Proportion Free from a Primary Safety Event | 95.0% (133/140) | 96.4% (132/137) | -1.4% (-7.3%, 4.6%) | 0.002 |

**COVERA was *non-inferior* to PTA**

[1] Confidence interval estimated using Farmington and Manning method)
[2] Farrington Manning non-inferiority test with margin = 10%

# Primary Efficacy Endpoint

## Target Lesion Primary Patency (TLPP) at 6 months

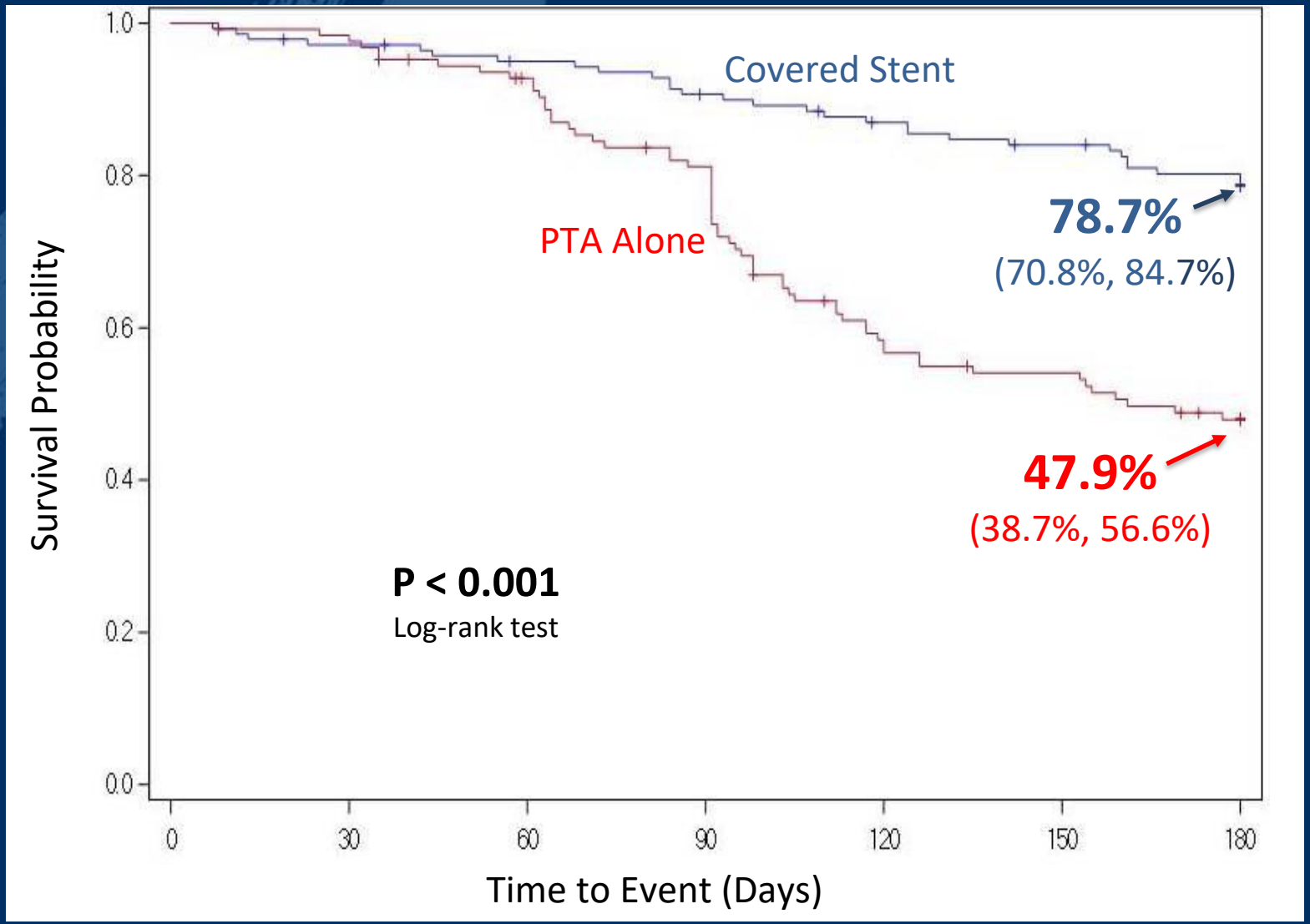
- Time until the next clinically-driven re-intervention at the treatment site or permanent access abandonment

| Target Lesion Primary Patency (TLPP) (Kaplan-Meier Analysis) | Covered Stent Group (95% CI)[2] | PTA Group (95% CI) | Hazard Ratio[3] (95% CI) | p-value[4] |
|---|---|---|---|---|
| Estimated Survival (TLPP) at 6 months[1] | 78.7% (70.8%, 84.7%) | 47.9% (38.7%, 56.6%) | 0.322[5] (0.213, 0.519) | <0.001 |

**COVERA was *superior* to PTA**

[1] Rates are estimated using the Kaplan-Meier method
[2] 95% confidence intervals are estimated using Greenwood's formula
[3] Hazard ratio calculated using the COX regression with treatment in the model
[4] One-sided p-value calculated using the log-rank test

# Freedom from Loss of TLPP (K-M Curve*)




*The rates are estimated using the Kaplan-Meier method, and the 95% confidence intervals are estimated using Greenwood's formula

# Secondary Outcomes

| 6-Month Outcomes | Covered Stent Group | PTA Group | Difference 95% CI |
|---|---|---|---|
| Acute Technical Success[1] | 100% | na | -- |
| Acute Procedural Success[2] | 98.6% | 98.4% | -- |
| | | | Difference μ ± SD |
| Index of Patency Function (IPF), μ (days) ± SD[3] | 126.1 ± 54.4 | 116.1 ± 53.2 | 10.0 ± 6.8 |
| Target Lesion IPF, μ (days) ± SD[3] | 156.3 ± 43.7 | 121.8 ± 51.9 | 34.6 ± 6.1 |
| # of Target Lesion Reinterventions, μ ± SD | 0.3 ± 0.6 | 0.8 ± 0.9 | -0.5 ± 0.1 |
| # of Access Circuit Reinterventions, μ ± SD | 0.8 ± 0.9 | 0.9 ± 1.0 | -0.1 ± 0.1 |

[1]Successful deployment to the intended location

[2]Anatomic success (residual stenosis ≤ 30%), and resolution of the pre-procedure clinical indicators of stenosis

[3]The IPF is representative of the approximate number of days between interventions to maintain access circuit patency

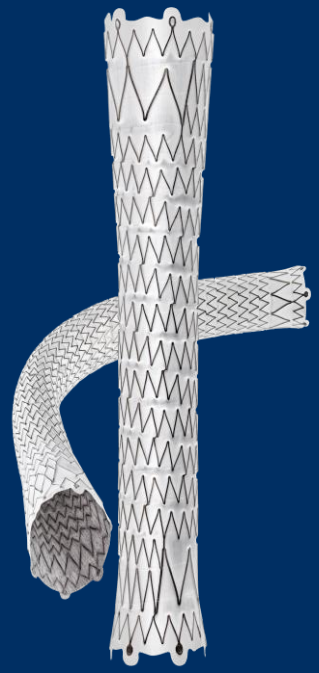
# AVeNEW 6-Month Summary

Freedom from a Primary Safety Event (30 days):**95.0% non-inferior to PTA**

Target Lesion Primary Patency (6 months): **78.7% superior to PTA**

COVERA™ Vascular Covered Stent demonstrated a primary patency benefit compared to PTA (6 months) while showing equivalent safety (30 days) when used to treat venous outflow stenosis in AV Fistula patients

Follow-up is ongoing out to 2 years

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