# AVeVA Study 24-Month Update
## Covered Stent Treatment of Venous Anastomotic Stenosis in AV Grafts

Bart Dolmatch, MD FSIR
(on behalf of the AVeVA Trial Investigators)

# Disclosure

**Bart Dolmatch:**

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I have the following potential conflicts of interest to report:

- [x] 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

# Objective

To assess the Covera™ Vascular Covered Stent for the treatment of stenotic lesions at the graft-vein anastomosis of AV grafts

- **Design:** Prospective, Multicenter, Non-Randomized, Single-Arm
  - 110 patients
  - 14 Study Sites in the United States
- **Follow-up:**
  - 24-month data presented today

# AVeVA Lead Investigators & 14 Study Centers

**Study Sites** 

| Investigator | Site Name | State |
|---|---|---|
| Umar Waheed | Southwest Vascular Center | AZ |
| George Lipkowitz | Renal Transplant Associates of New England | MA |
| Jeffery Hoggard | Capital Nephrology Associates | NC |
| Naveen Atray | Capital Nephrology Access Center | CA |
| Mahmood Razavi | Vascular and Interventional Specialists | CA |
| Gary Saito | AZ Kidney Disease & Hypertension Center | AZ |
| Saravanan Balamuthusamy | Tarrant Vascular Access Center | TX |
| Clifford Sales | The Cardiovascular Care Group | NJ |
| Erin Moore | River City Clinical Research | FL |
| Tim Rogers | Dialysis Vascular Access Center | FL |
| Pablo Pergola | Clinical Advancement Center | TX |
| Jeffrey Packer | AZ Kidney Disease & Hypertension Center | AZ |
| Jonah Licht | Providence Interventional Associates | RI |
| Angelo Makris | Chicago Access Care | IL |

# AVeVA Study Criteria

## Key Inclusion Criteria

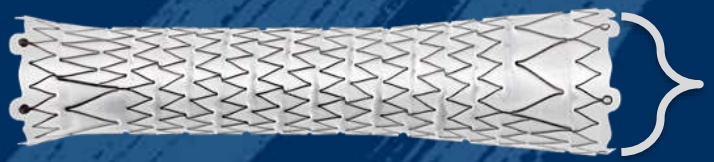
- Synthetic upper extremity AV access graft implanted for ≥ 30 days
- At least one successful dialysis session
- Stenosis ≥ 50% (by visual estimate) at the graft-vein anastomosis with clinical graft dysfunction
- Target lesion(s) ≤ 9 cm in length
- Reference vessel diameter: 5.0 - 9.0mm

## Key Exclusion Criteria

- Placement in an existing stent or stent graft, or across the elbow joint or in the central veins

# Study Device: COVERA™ Vascular Covered Stent

## Covered-Stent Configurations:





- ePTFE encapsulated nitinol stent
- Diameters: 6-10 mm
- Lengths: 40, 60, 80, and 100 mm (30 mm straight only)

## Thumbwheel Delivery System:

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

U.S. Indication (FDA Approved): for use in hemodialysis patients to treat stenoses in the venous outflow of an arterio-venous (AV) fistula and at the venous anastomosis of an ePTFE or other synthetic AV graft.

EU Indication: for the treatment of stenoses in the upper extremity venous outflow of patients dialyzing with an arterio-venous (AV) access graft or fistula.

# Patient Demographics and Risk Factors

| | All-Treated Covered Stent Group |
|---|---|
| Number of Patients (ITT), N | 110 |
| Mean Age, years ± SD | 64.3 ± 14.0 |
| Male/Female, %/% | 45.5/54.5 |
| Mean BMI, kg/m$^2$ ± SD | 28.7 ± 6.6 |
| Mean Time on Dialysis, months ± SD | 19.7 ± 20.0 |
| Clinical Indicators of Access Dysfunction, % (n)* | |
| Pulsatility | 57.3 (63) |
| Decreased Access Blood Flow | 23.6 (26) |
| Elevated Venous Pressure | 23.6 (26) |
| Prolonged Bleeding | 20.9 (23) |
| Diminished or Abnormal Thrill | 18.2 (20) |
| Risk Factor, % (n) | |
| Hypertension | 98.2 (108) |
| Smoker (Current & Former) | 8.2%/30.9% |
| Diabetes (Type 2) | 61.8 (68) |
| Dyslipidemia | 56.4 (62) |

* Some patients had multiple clinical indicators of access dysfunction

# Circuit/Lesion Characteristics & Procedural Details

| | Covered Stent Group |
|---|---|
| Lesion Type (Restenotic), % (n) | 71.8 (79) |
| Outflow Vein, % (n) | |
| Axillary | 49.1 (54) |
| Basilic | 40.0 (44) |
| Brachial | 9.1 (10) |
| Mean Lesion Length, mm ± SD | 24.1 ± 15.3 |
| Mean Baseline Target Lesion Stenosis, % ± SD | 71.5 ± 14.8 |
| Thrombosis at Baseline, % (n) | 25.5 (28) |
| Outflow Vein Diameter, mm ± SD | 8.5 ± 2.0 |
| Graft Diameter, mm ± SD | 6.8 ± 0.7 |
| Procedure | |
| Flared/Straight Stent Graft Configuration, %/% | 83.6/16.4 |
| Final Residual Stenosis (post covered stent & post-dilation), % ± SD | 0.9 ± 2.8 |
| Peri-procedural Complications, % (n) | 7.3 (8) |
| Acute Technical Success[1]/Procedural Success[2], %/% | 100/100 |

[1]Successful deployment to the intended location

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

# Primary Endpoint Analyses

## Safety (30 Days): Freedom from a Primary Safety Event

| Primary Safety Endpoint (Proportional Analysis) | ITT Group (N= 110) | [90% CI] p-value |
|---|---|---|
| Freedom from a Primary Safety Event, (n/N) | 96.4% (106/110) | [91.9, 98.7] p=0.002 |

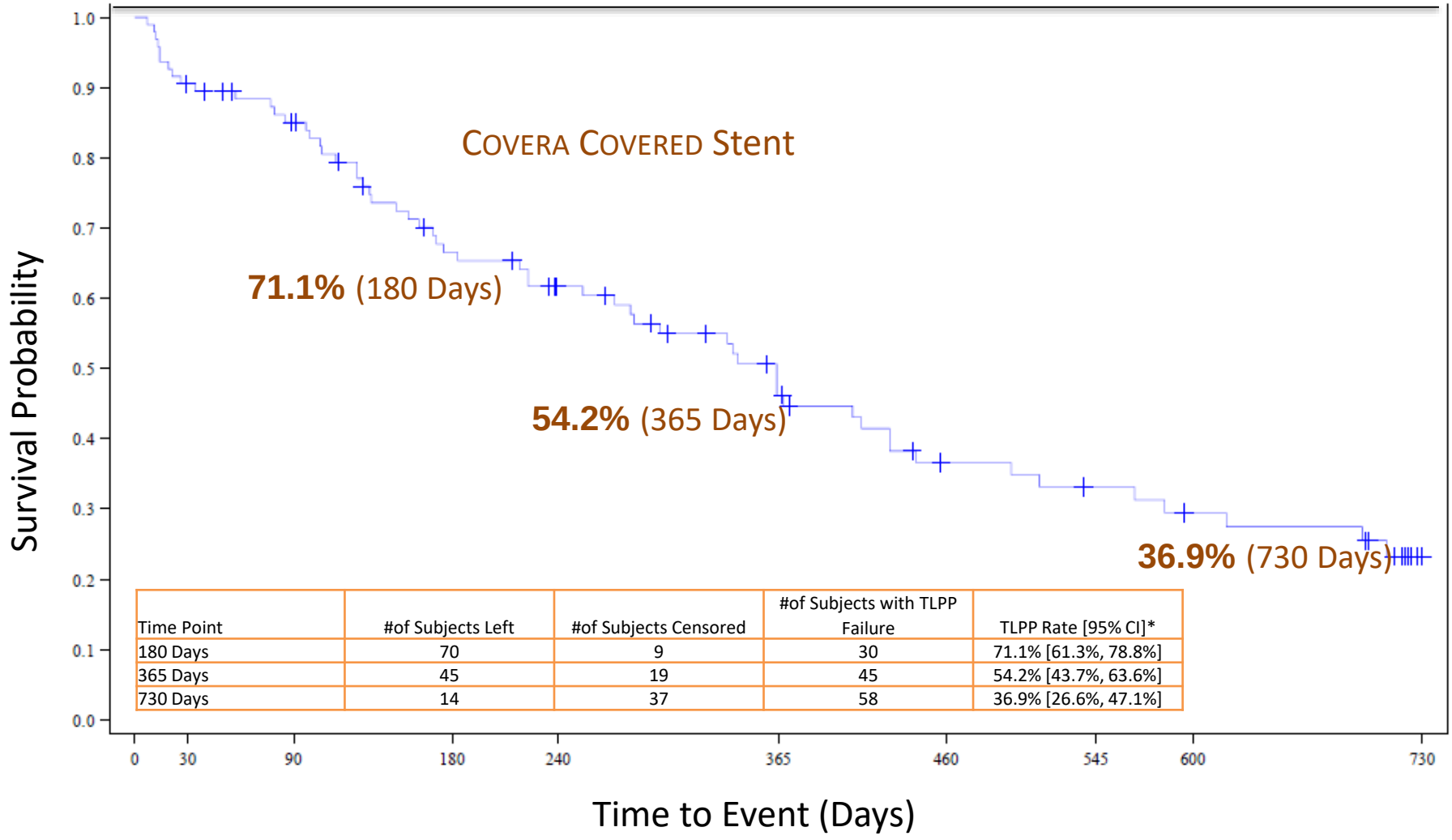
✓ Greater than the PG of 88% (p-value = 0.002)

## Efficacy (6 Months): Target Lesion Primary Patency (TLPP)

| Primary Efficacy Endpoint (Proportional Analysis) | Group | [90% CI] p-value |
|---|---|---|
| Target Lesion Primary Patency, (n/N) | 70.3% (71/101) | [61.9, 77.7] P<0.0001 |

✓ Greater than the PG of 40% (p-value <0.0001)

# Freedom from Loss of TLPP




| Time Point | #of Subjects Left | #of Subjects Censored | #of Subjects with TLPP Failure | TLPP Rate [95% CI]* |
|---|---|---|---|---|
| 180 Days | 70 | 9 | 30 | 71.1% [61.3%, 78.8%] |
| 365 Days | 45 | 19 | 45 | 54.2% [43.7%, 63.6%] |
| 730 Days | 14 | 37 | 58 | 36.9% [26.6%, 47.1%] |

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

# Secondary Outcomes Through 24 Months

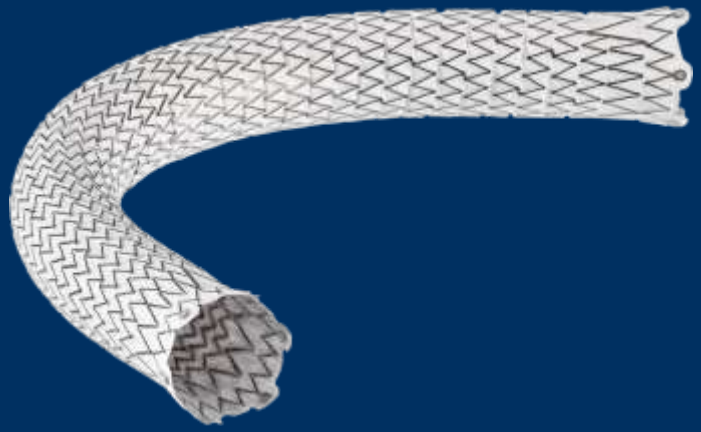
| Outcomes | 6 Months | 12 Months | 24 Months |
|---|---|---|---|
| Access Circuit Primary Patency[+] (Kaplan-Meier Survival Estimate) | 40.4% [30.9%, 49.8%][^] | 16.7% [9.8%, 25.1%] | 7.8% [3.1%, 15.3%] |
| | | | |
| Secondary Patency | 92.1% | 85.4% | 73.6% |

Follow-up at 24 Months: 68.2% (75/110 patients)
24.5% died during the study

[+] Survival estimate based on the Kaplan-Meier analysis
[^] 95% confidence intervals are estimated using Greenwood's formula

# AVeVA Summary

**This first-in-man study of the Covera™ vascular covered stent compared outcomes to predicted goals from prior similar studies.**



**Results met or exceeded predicted safety and efficacy goals at 6 months.**

**At 24 months, target lesion patency was 37% and assisted circuit patency 74%.**

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