FLEX™
VESSEL PREP

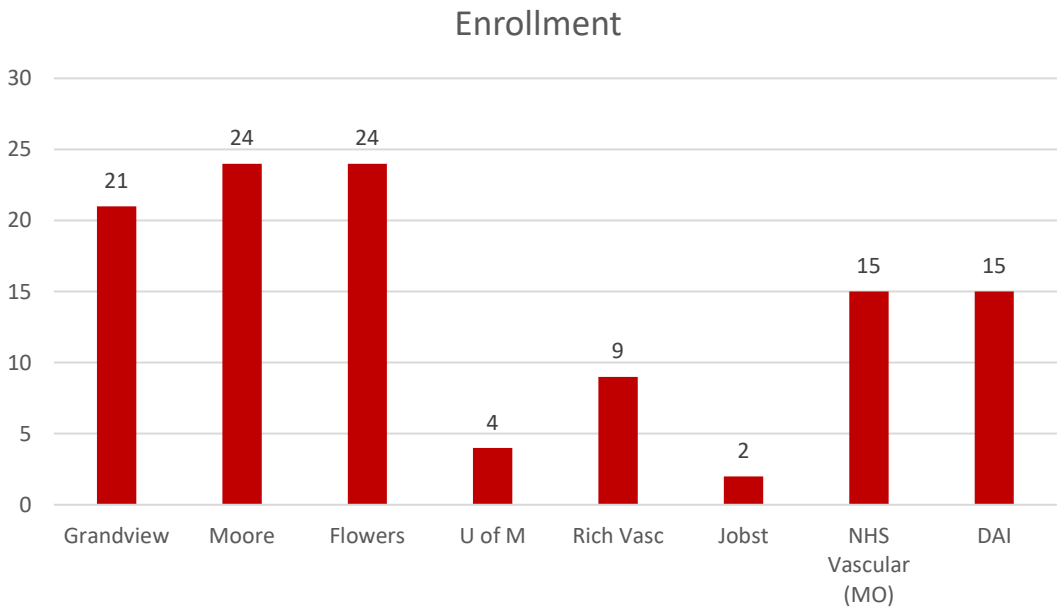
FLEX AV Registry 12-month Results

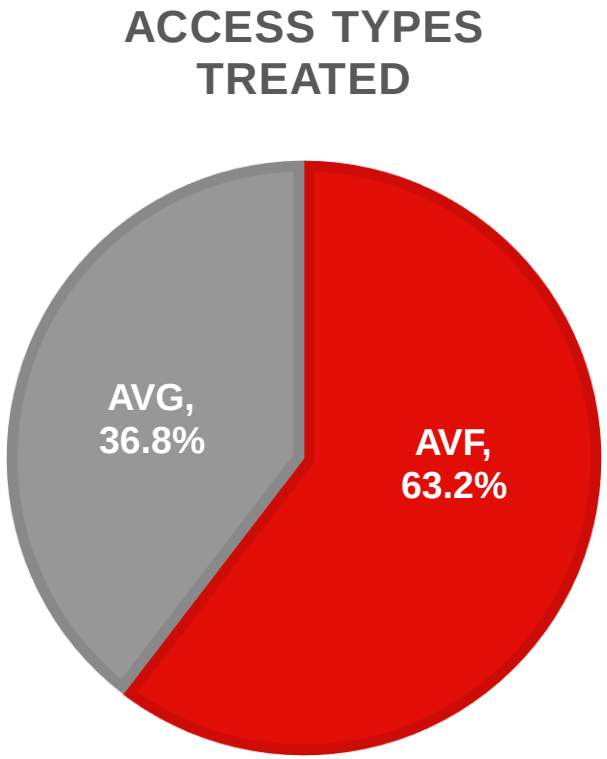
FLEX-AV Registry

- **Study Design:** Multi-Center, Single-Arm, Prospective Study
- **Study Population:** Patients with AVF/AVG stenosis, eligible for FLEX/Angioplasty treatment.
- **Enrollment:** **114**
- **Sites:** **8 Sites**
- **Follow-Up:** Phone call to the patient and/or dialysis center at 6, 9, and 12 months.

FLEX-AV Registry: Enrollment Overview

- 114 patients treated
- Total number of lesions treated, n= 148
- 8 clinical sites





Patient Demographics & Characteristics: Real-World, No "Cherry-picking"

Variable	114 Subjects
Age (years)	63.3 ± 12.7 (114) 31.0-88.0
Gender	
Female	61/114 (53.5%)
Male	53/114 (46.5%)
Race	
American Indian or Alaska Native	2/114 (1.8%)
Asian	1/114 (0.9%)
Black or African American	75/114 (65.8%)
White	36/114 (31.6%)
Smoking History	
Current	17/114 (14.9%)
Never	60/114 (52.6%)
Past	37/114 (32.5%)

114 patients, 8 sites, All-comers Registry	
Prior AV Access Interventions	**4.9 ± 5.8; highest number: 29**
Cephalic Arch %	**22%**
Target Lesion Length (mm)	**21 ± 25**
Maximum PTA Balloon Pressure needed (atms)	**15.2 ± 5.9**
No limitations on Lesion Length	
No limitations on Prior Interventions	

FLEX™ VESSEL PREP

Functional Primary Patency 12 months

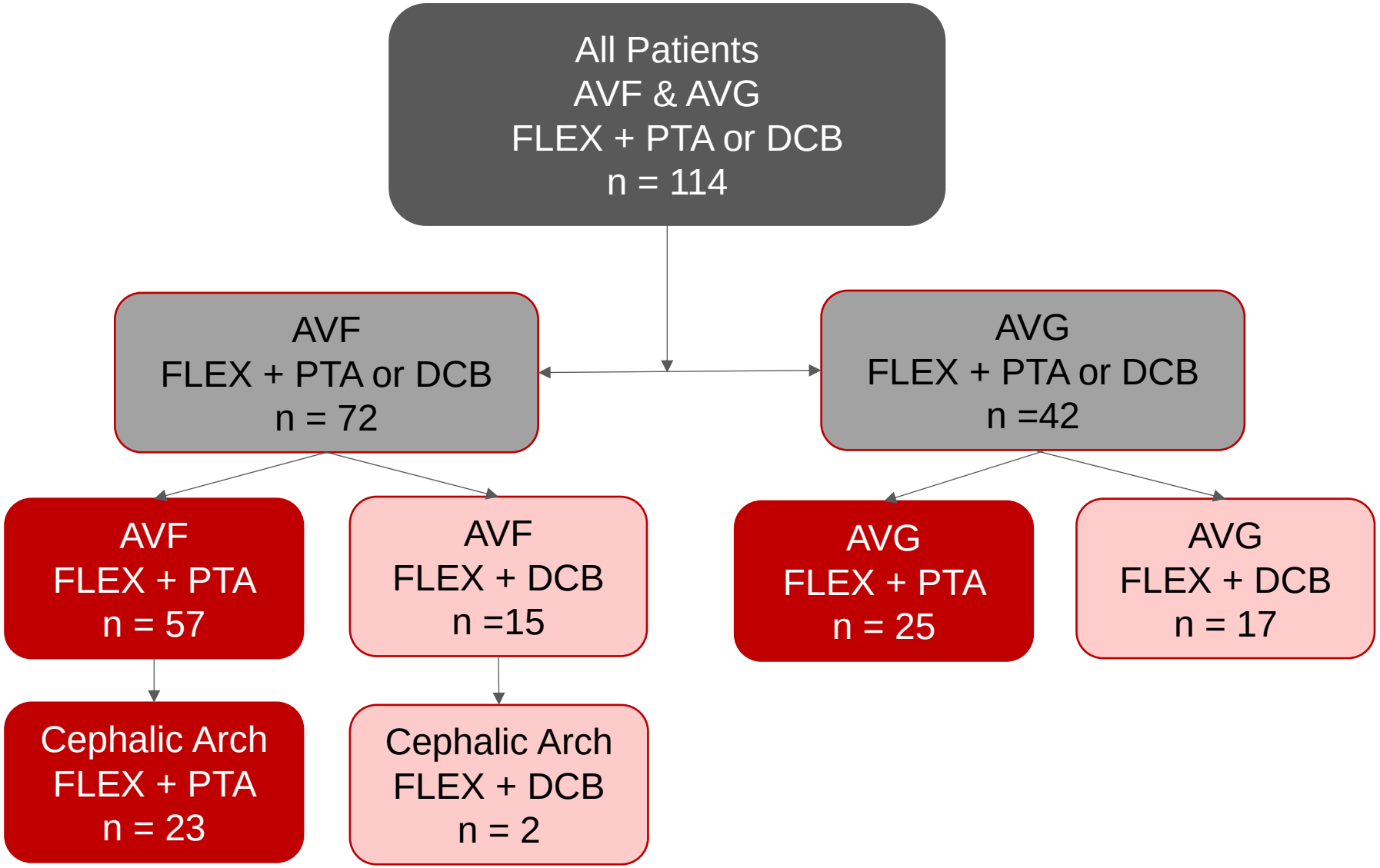
Freedom from Target Lesion Reintervention

VentureMed®

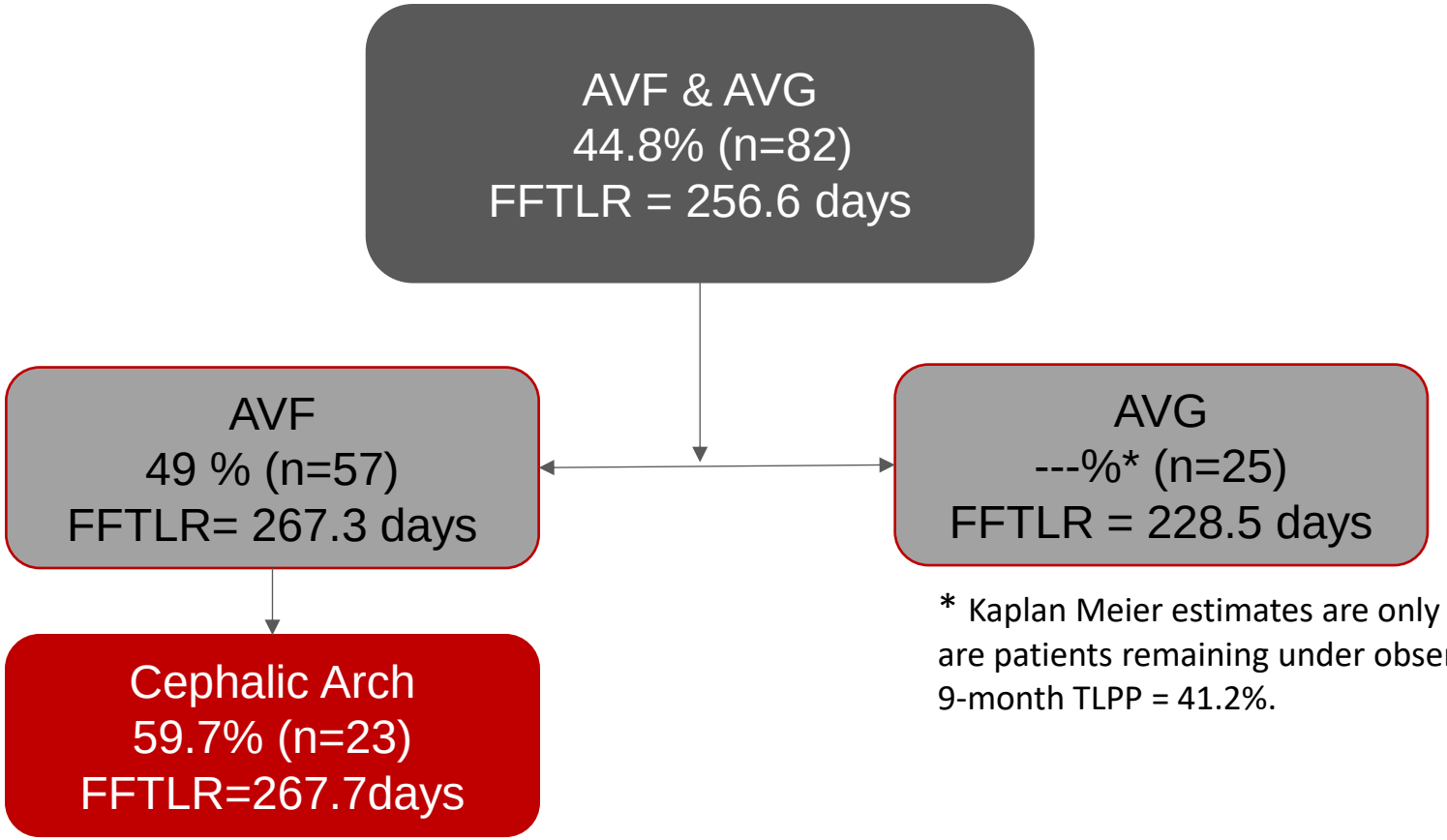
12-month Target Lesion Primary Patency Analysis

- 112/114 target lesions were considered for the Kaplan-Meier estimate
  - 2 subjects did not contribute to any follow-up analysis
- Patients analyzed in following cohorts
  - AVF with PTA alone
  - AVG with PTA alone
  - Cephalic Arch target lesions with PTA alone
- Statistical Analysis
  - ✓Functional Patency estimation via Kaplan-Meier analysis at the close of the 6-month FU visit
  - ✓Freedom from TLR (time) was determined using restricted mean survival time analysis (RMST) restricted to 270 days

Patient Cohorts



12-month Target Lesion Primary Patency
FLEX + PTA



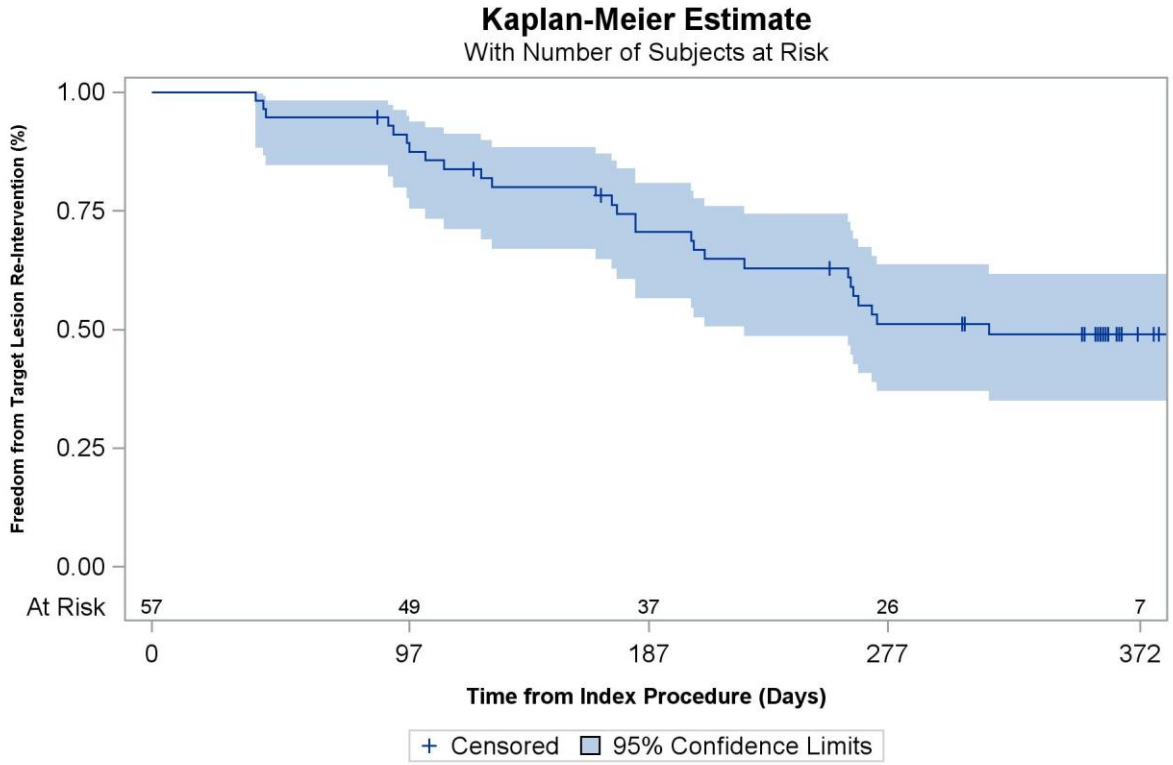
* Kaplan Meier estimates are only provided when there are patients remaining under observation at 372days. The 9-month TLPP = 41.2%.

12-month Target Lesion Primary Patency FLEX+PTA in AVF

AVF's
FLEX + PTA
N=57

12 Month
49.0%

Avg. time FFTLR
***267.3** days*



12-month TLPP Literature Comparisons PTA in AVF Results

Published Results	FLEX Registry FLEX + PTA	Liao, et al[1]	Rajan, et al[2]	Ng, et al[3]	Hu, et al[4]
12-month TLPP AVF	**49.0% (n=34)**	31.5% (n= 273)*	26% (n = 53)	0% - 21.2% (n=143)*	47.2% (n=341)*

*restricted to AVF studies only

[1]Liao M-T, Chen M-K, Hsieh M-Y, Yeh N-L, Chien K-L, Lin C-C, et al. Drug-coated balloon versus conventional balloon angioplasty of hemodialysis arteriovenous fistula or graft: A systematic review and meta-analysis of randomized controlled trials. PLOS One; 2020 15(4).

[2] Rajan D., et al., Dysfunctional Autogenous Hemodialysis Fistulas: Outcomes after Angioplasty – Are There Clinical Predictors of Patency? Radiology. Sept 2004.

[3] Ng B, Fugger M, Onakpoya IJ, et al. Covered stents versus balloon angioplasty for failure of arteriovenous access: a systematic review and meta-analysis. BMJ Open 2021;11

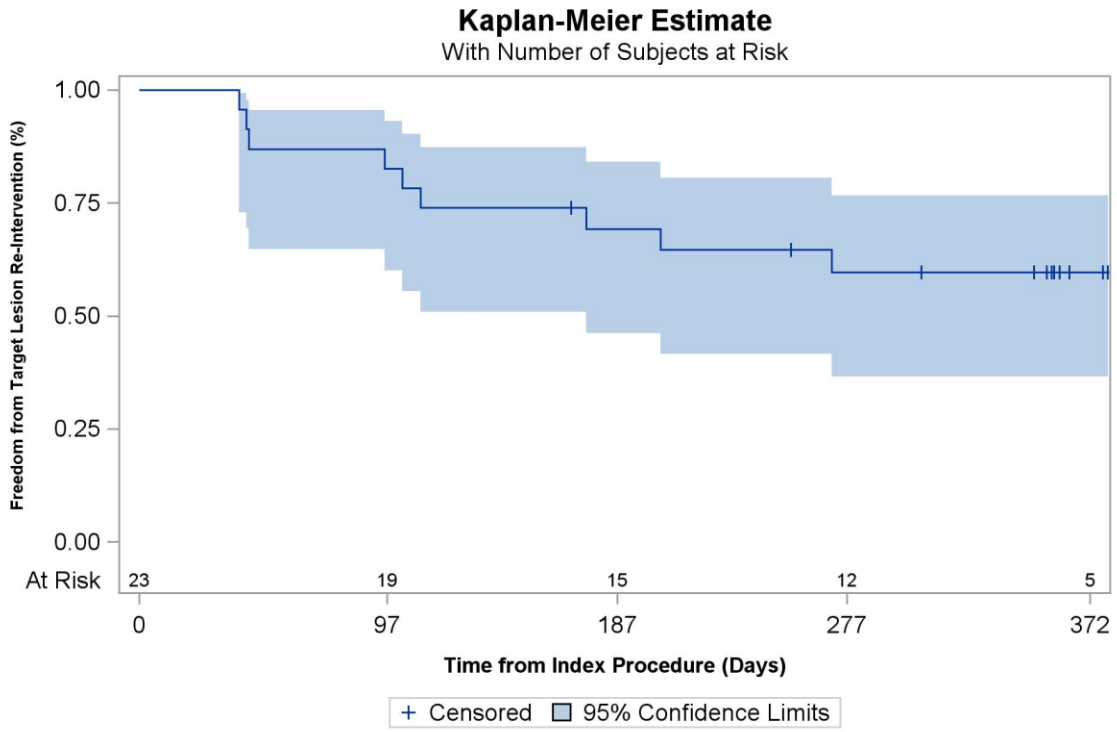
[4] Hu H, Tan Q, Wang J, Liu Y, Yang Y, Zhao J. Drug-coated balloon angioplasty for failing haemodialysis access: meta-analysis of randomized clinical trials. Br J Surg. 2021 Nov 11;108(11):1293-1303.

12-month Target Lesion Primary Patency
FLEX + PTA in Cephalic Arch

Cephalic Arch Lesions
FLEX + PTA
N=23

12 Month
59.7%

Avg. time FF-TLR
267.7 days



12-month TLPP Literature Comparisons PTA in Cephalic Arch Results

Published Results	**FLEX Registry FLEX + PTA**	D'Cruz, et al[1,5]	Tng et al.[2]	Vasanthamohanm, et al.[3]	Miller, et al.[4]
12-month Functional Patency Cephalic Arch	**59.7% (n=14)**	9.5%* (n=146) *Pooled multi-studies (0-39.6%)	33.9% (n=59)	0%-23% (n= 13-24) * multi-studies small sample sizes	11% (N=50)* * Historical controls

[1] D'Cruz RT, Leong SW, Syn N, et al. Endovascular treatment of cephalic arch stenosis in brachiocephalic arteriovenous fistulas: a systematic review and meta-analysis. J Vasc Access 2019; 20: 345.
[2]Tng RK, et al., Treatment of cephalic arch stenosis in dysfunctional arteriovenous fistulas with paclitaxel-coated versus conventional balloon angioplasty, CVIR Endovascular, (2021) f:80.
[3] Vasanthamohanm, L., et al. The Management of Cephalic Arch Stenosis in Arteriovenous Fistulas for Hemodialysis: A Systematic ReviewCardiovasc Intervent Radiol (2015) 38:1179–1185
[4] Miller GA, Preddie DC, Savransky Y, Spergel LM. Use of the Viabahn stent graft for the treatment of recurrent cephalic arch stenosis in hemodialysis accesses. J Vasc Surg. 2018.
[5] Beathard et al., End Points for Interventional Studies for AV Access,Clin J Am Soc Nephrol 13: 501–512, March 2018.

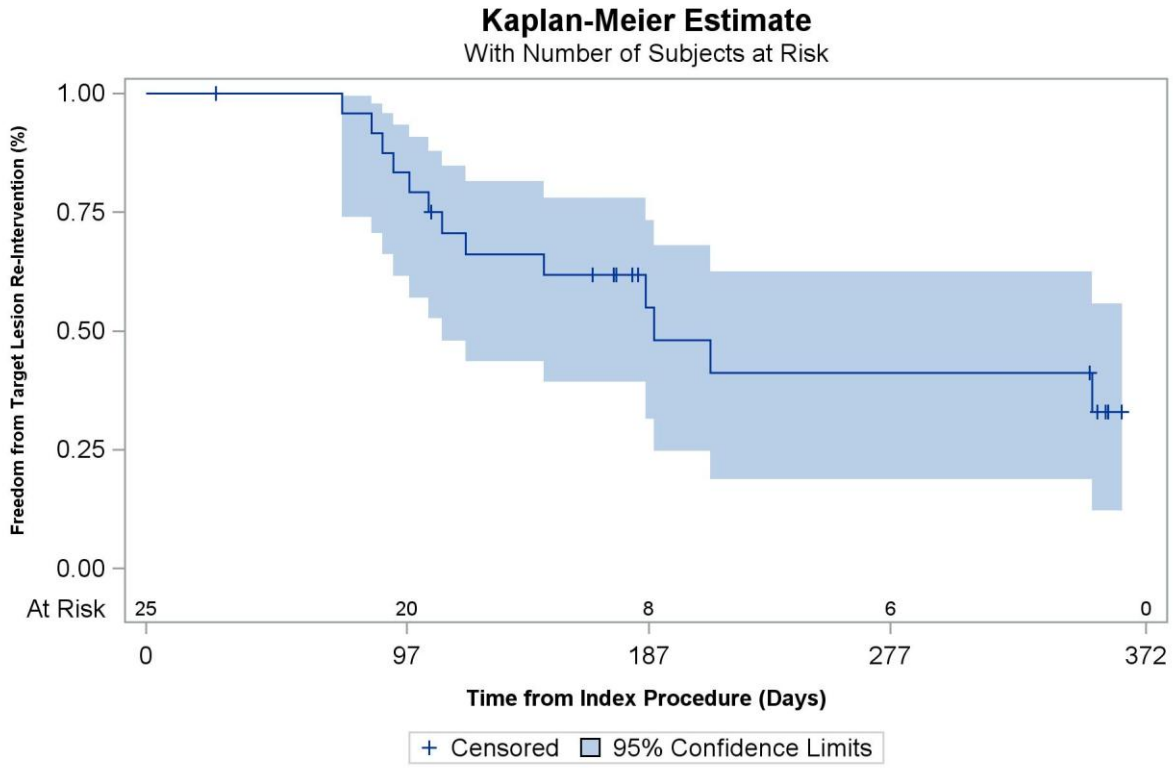
12-Month Functional Patency
FLEX + PTA in AVG

AVG's
FLEX + PTA
(n=25)

9 Month
41.2%

12 Month
--%*

Avg. time FF-TLR
228.5 days



*Kaplan-Meier estimates are only provided when there are patients remaining under observation at 372

12-month TLPP Literature Comparisons
PTA in AVG Results

Published Results for PTA of AVGs	**FLEX Registry FLEX + PTA**	Yang, et al[1]	Liao, et al.[2]	Ng, et al.[3]
12-month Functional Patency AVG	**--%* (n=25)**	7.8% (N=49)	9% (n=22)	0% - 24.8% (n=339) *Meta-analysis of RCTs of covered stents – AVGs

9 Month
41.2% (n=18)

*Kaplan-Meier estimates are only provided when there are patients remaining under observation at 372

[1] Yang HT, Yu SY, Su TW, Kao TC, Hsieh HC, Ko PJ. A prospective randomized study of stent graft placement after balloon angioplasty versus balloon angioplasty alone for the treatment of hemodialysis patients with prosthetic graft outflow stenosis. J Vasc Surg. 2018 Aug;68(2):546-553.

[2] Liao M-T, Chen M-K, Hsieh M-Y, Yeh N-L, Chien K-L, Lin C-C, et al. Drug-coated balloon versus conventional balloon angioplasty of hemodialysis arteriovenous fistula or graft: A systematic review and meta-analysis of randomized controlled trials. PLOS One; 2020 15(4).

[3] Ng B, Fugger M, Onakpoya IJ, *et al*. Covered stents versus balloon angioplasty for failure of arteriovenous access: a systematic review and meta-analysis. *BMJ Open* 2021;11

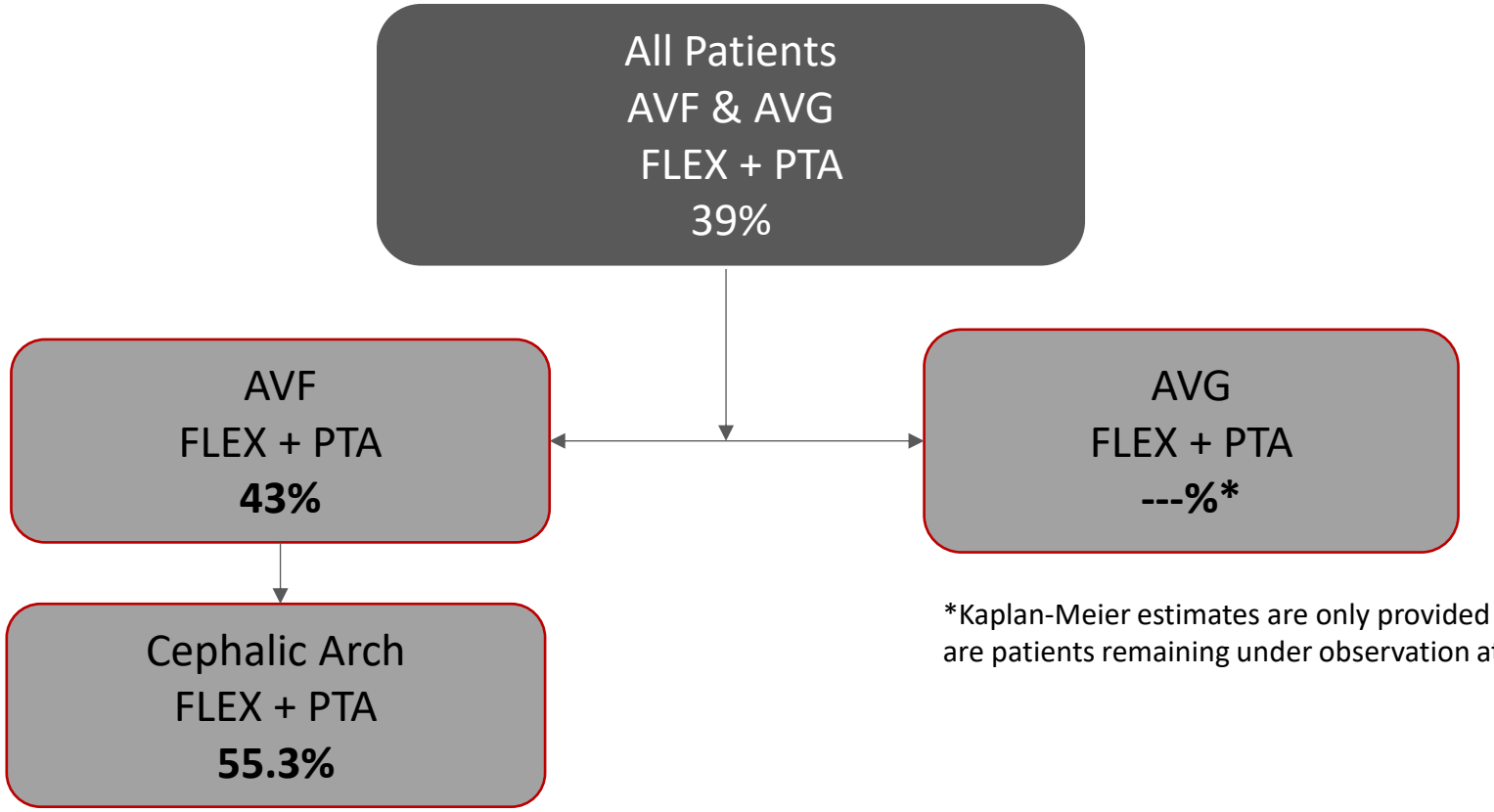
Procedure Complications Reported

- **No Serious Adverse Events**
- 4.3% Procedure complications reported during the study

Classification	Reported Complication	Number	Reported Cause	Treatment	FLEX %	JVIR Quality Improvement Guideline[1] Thresholds
Major	None	0	N/A	N/A	**0%**	2% (AVF) 7% (AVG)
Minor	Dissection, Grade B,C	4	Angioplasty	1 – No treatment 3 – Balloon inflation	**4.3%**	8% (AVF) 4% (AVG)
	Balloon burst	1	Balloon Rupture	Embolectomy		

[1] Daruiushnia, S. et al. Quality Improvement Guidelines for Percutaneous Image-Guided Management of the Thrombosed or Dysfunctional Dialysis Circuit, J VascInterv Radiol 2016;27:1518–1530

Access Circuit Primary Patency at 12 months



*Kaplan-Meier estimates are only provided when there are patients remaining under observation at 372

Comparison ACPP

Published Results for ACPP	FLEX Registry FLEX + PTA	Dolmatch 2023[1]	Holden 2022[2]	Fong 2021[3]	Haskel 2016[4]
12-month ACPP in AVF	**43%**	17.7% (n=138)	32.4% (n=160)	29.8% (n=424)	n/a
12-month ACPP in AVG	**---%***	n/a	n/a		11% (n=132)

Conclusions

- The FLEX AV Registry 12-month outcomes demonstrate sustained patency across most subjects and impressive results specifically in the Cephalic Arch.
- Result highlights for FLEX + PTA:
  - 49% patency at 12 months
  - 60% patency at 12 months
  - 41.2% patency for all AVG patients at 9 months
  - AVG Days, Freedom from TLR
    - All (AVF & AVGs) Flex + PTA ***256.6*** *(8.5 months)*
    - All AVF, FLEX + PTA ***267.3*** *(8.9 months)*
    - All CA + PTA ***267.7*** *(8.9 months)*
    - All AVG, Flex + PTA **228.5** *(7.6 months)*
  - Lower PTA max inflation pressures 15.2 ATM
  - No observed SAEs