Flex Vessel Prep[™] System: Clinical 12 Month Outcomes And Utility In HD Access Practice

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Disclosures

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I have the following potential conflicts of interest to report: Boston Scientific Advisory Board Venture Medical Advisory Merit Medical Investigator Philips Peripheral Vascular Advisor

FLEX Vessel PrepTM System

- 6Fr; .014" or .018" guidewire (OTW)
- 2 working lengths 40cm (AV Access) & 120cm (FemPop)
- Braided shaft design for consistent deliverability
- Atraumatic tip for enhanced trackability & crossing profile



FLEX Vessel Prep[™] System



3 surgical blades mounted on independent skids

- Consistent engagement in stenoses
- Releases

circumferential & fibromuscular tension in resistant stenoses

Subject Demographics & Lesion Characteristics

Variable	114 Subjects				
Age (years)	63.3 ± 12.7 (114)	114 patients, 8 sites, All-comers Registry			
Gender	31.0-88.0	Prior AV Access Interventions	4.9 ± 5.8; highes number: 29		
Male	53/114 (46.5%)	Cephalic Arch %	22%		
Race		Target Lesion Length	21 ± 25		
American Indian or Alaska Native	2/114 (1.8%)	(mm)			
Asian	1/114 (0.9%)				
Black or African American	<mark>75/114 (65.8%)</mark>	Maximum PTA	$\textbf{15.2} \pm \textbf{5.9}$		
White	36/114 (31.6%)	Balloon Pressure			
Smoking History		needed (atms)			
Current	17/114 (14.9%)	No limitations o	n Lesion Length		
Never	60/114 (52.6%)	No limitations on Prior Intervention			
Past	37/114 (32.5%)				

Access Characteristics

Variable	114 Subjects			
Fistula Type				
Arteriovenous Fistula	72/114 (63.2%)			
Arteriovenous Graft	42/114 (36.8%)			
Location				
Forearm	11/114 (9.6%)			
Other	4/114 (3.5%)			
Upper Arm	99/114 (86.8%)			

Access Sites- Detaileds	114 Subjects
Basilic -Cephalic trans fistula	1/114 (0.9%)
Brac-Basil Fistula	<mark>27/114 (23.7%)</mark>
<mark>Brach-Axill Graft</mark>	<mark>36/114 (31.6%)</mark>
Brach-Ceph Fistula	<mark>37/114 (32.5%)</mark>
Brachial-Antecub Graft	3/114 (2.6%)
Left thigh graft	1/114 (0.9%)
Radial Artery-Cephalic Vein Fistula	3/114 (2.6%)
Radial-Ceph Fistula	5/114 (4.4%)
Right Thigh Graft	1/114 (0.9%)

Procedure Characteristics

Variable	114 Subjects		
		Variable	114 Subjects
Target Lesion FLEX	5.1 ± 1.0		
passes (count)	2.0-8.0	PTA / DCB	
Target Lesion Post FLEX Stenosis (%)	53.4 ± 22.1 (114)	DCB	32/114 (28.1%)
	0.0-95.0	ΡΤΑ	82/114 (71.9%)
Number of balloon inflations (count)		Maximum Pressure (atm)	<mark>15.2 ± 5.9</mark> (114
1	67/114 (58.8%)		
2	38/114 (33.3%)	Maximum Effacement	9.5 ± 10.9
3	6/114 (5.3%)	Prossuro (atm)	(114)
4	1/114 (0.9%)	Pressure (atili)	(114)
5	1/114 (0.9%)		
6	1/114 (0.9%)		

AVG-Venous Anastomotic Stenosis



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Cephalic Arch Stenosis

"The Burma Road of Dialysis Access"



Cephalic Arch Stenosis











8 mm PTBA



Patient Cohorts, Anatomic Success





12-month Circuit Primary Patency per Cohort



6 & 12-month Functional Patency FLEX + PTA in AVF



Literature Comparisons 6- & 12- month Functional Patency After PTA – AVF Results

Published Results	FLEX Registry FLEX + PTA	Rajan, et al ¹	Liao, et al ²	Hu, et al ³	Ng, et al ⁴	Phang, et al ⁵
6-month Functional Patency AVF	70.6% (n=57)	55% * (n=53) *ref. Clark et al	55.4%* (n=275) *Only studies for AVFs - reported as event rate of 44.6%	37.5% (n=501) *AVFs only Calculated from table	0%-34%* (n=143) *Only studies for AVFs from table	21.3% (n= 94)
12-month Functional Patency AVF	49.0% (n=34)	26% (n = 53) *ref. Clark et al	31.5% (n= 273) *Only studies for AVFs from table	47.2% (n=341) *AVFs only Calculated from table (not 100% same studies reported at 6 months)	0% - 21.2% (n=143) *Only studies for AVFs from table	N/A* *Not reported

Note: Articles selected that best represented the appropriate population for cohort.

¹Rajan D., et al., Dysfunctional Autogenous Hemodialysis Fistulas: Outcomes after Angioplasty – Are There Clinical Predictors of Patency? Radiology. Sept 2004. ²Liao 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 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.

⁴ 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 ⁵ Phang, C., et. Al, Paclitaxel-coated balloon in the treatment of recurrent dysfunctional arteriovenous access, real-world experience and longitudinal follow up, Nephology, 24 (2019) 1290-1295.

6 & 12- month Functional Patency FLEX + PTA in Cephalic Arch

Literature Comparisons 6-month Functional Patency after PTA – 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
6-month Functional Patency Cephalic Arch	69.3% (n=23) Avg time to TLR = 211	23%* (n=224) *Pooled multi- studies (0-70.8%)	51.6% (n=62)	8%-42%* (n=11-25) * multi-studies small sample sizes	27% (n=50)* * Historical controls
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

Note: Articles selected that best represented the appropriate population for cohort.

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. ²Tng 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.

6 & 12- month Functional Patency FLEX + PTA in AVG

Literature Comparisons 6-month Functional Patency after PTA – AVG Results

Published Results for PTA in AVGs	FLEX Registry FLEX + PTA in AVGs	Vesely, et al ¹	Haskel, et al ²	Yang, et al ³	Liao, et al. ⁴	Ng, et al. ⁵	Phang, et al. ⁶
6-month Patency AVG	46.6% (n=18)	34% (n=148)	23% (n=86)	28% (n=49)	9% (n=22)	8% – 34.2%* (N=293) *Meta-analysis of RCTs of covered stents – AVGs	5.7% (n=53)
12-month Patency AVG	0% (n=13) 9 Month	N/A* *Not reported	N/A* *Not reported	7.8% (N=49)	9% (n=22)	0% - 24.8% (n=339) *Meta-analysis of RCTs of covered stents – AVGs	N/A* *Not reported

Note: Articles selected that best represented the appropriate population for cohort.

¹ Vesely T, DaVanzo W, Behrend T, et al. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. J Vasc Surg. 2016;64:1400-1410.e1.4 ² Haskel, Z., et al. Stent Graft versus Balloon Angioplasty for Failing Dialysis-Access Grafts N Engl J Med 2010;362:494-503.

³ 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.

⁴ 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).

⁵Ng 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 ⁶ Phang, C., et al., Paclitaxel-coated balloon in the treatment of recurrent dysfunctional arteriovenous access, real-world experience and longitudinal follow up, Nephology, 24 (2019) 1290-1295.

Procedure Complications Reported

No Serious Adverse Events

• 4.3% Minor Procedure Complications

Classification	Reported Complication	Number	Reported Cause	Treatment	%	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

Conclusions

- The FLEX AV Registry 12-month outcomes demonstrate sustained patency across most patients and superior results specifically in the Cephalic Arch.
- Result highlights PTBA only:
 - 49% patency for all AVF patients
 - 59.7% patency for Cephalic arch lesions
 - AVGs had Avg Time to TLR of 228 days (41.2% patency at 9 months)
 - No observed SAEs (only acute observations)

Implications from FLEX AV Registry Results

The FLEX Vessel Prep System may :

- Maximize PTA outcome
 - Offer superior solution to AVF and AVG treated with stand alone HP PTA
- Offer an attractive alternative to DCB for AV access repair
 - FLEX + PTA exhibits similar patency as PTA + DCB
 - Likely impressive implication of product cost and access center throughput
- Offer safer procedure than stand alone HP-PTA (n=114 lesion treatment with no adverse events)
- Introduce a better solution to treat cephalic arches
- In AVG FLEX + HP-PTA yields better results than historic HP-PTA alone