Flex Vessel Prep System

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Device Overview

The primary intervention to treat peripheral artery stenosis typically involves conventional plain balloon (POBA), drug-coated balloon (DCB), or percutaneous transluminal angioplasty (PTA).[1,2,3] PTA is intended to create luminal gain with or without stent placement.[3] The addition of DCB is to inhibit restenosis and thrombosis.[3] Complications associated with PTA include (but are not limited to) uncontrolled dissections and restenosis.[1,2,4,5] There are a variety of methods utilized for vessel preparation to reduce the number and severity of dissections including prolonged balloon inflation, lower pressure inflation, and scoring or excising plaque.[6,7] PTA is also used to restore patency in vascular access devices (VAD) utilized for hemodialysis.[8] According to the manufacturer, the Flex Vessel Prep System's "precise surgical blades create continuous, circumferential, controlled-depth micro-incisions" and "enables continuous engagement along the entire length of long, complex lesions" (with its retrograde pull-back treatment that self sizes) releasing circumferential tension and improving vessel compliance.[9]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Assess plans for product use and implementation. Include interventional cardiology, vascular surgery, endovascular nursing leadership, and value analysis leaders.

CONSIDER GUIDELINES FOR USE

Understand indications for use and perceived benefits/risks in specific interventions and populations.

UNDERSTAND CONCERNS

Engage a physician champion for peer-to-peer guideline collaboration and questions/concerns.

CONNECT

SEEK CLINICAL IMPACT

Assess current treatment options for target population(s) and potential to impact outcomes. Review available research.

CONDUCT ANALYSIS

In addition to outcomes, compare cost with current techniques. Include reimbursement considerations (available on supplier website).[10]

DETERMINE POPULATION

Work with key stakeholders to determine appropriate patient populations and procedures for use.

COMMUNICATE

EDUCATE AND TRAIN

Share timeline and plan for education, leveraging intraprocedural supplier support during implementation.

PLAN AHEAD

Communicate rationale for initiative with end users increasing buy in and allowing ample time for feedback/questions.

FOLLOW-UP FOR FEEDBACK

Create on-going feedback loop and monitor utilization, outcomes, and physician experiences. Address as needed.

Professional Society Statements & Clinical Practice Guidelines

American Heart Association (AHA) and American College of Cardiology (ACC)

The *2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease* incorporates recommendations for endovascular revascularization including:

"The technique chosen for endovascular treatment is related to lesion characteristics (e.g., anatomic location, lesion length, degree of calcification) and operator experience." Found here.[11]

ACC, AHA, Society for Cardiovascular Angiography and Interventions (SCAI), Society of Interventional Radiology (SIR), and Society for Vascular Medicine (SVM)

In their *Appropriate Use Criteria for Peripheral Artery Intervention,* they initiate and assess criteria for appropriate use for peripheral artery intervention including:

"Lesion characteristics, such as the anatomical location of the lesion, presence of stenosis or occlusion, and length of the lesion, will influence choice." Found here.[12]

Society for Vascular Surgery (SVS)

Their *Clinical Practice Guidelines for the Surgical Placement and Maintenance of Arteriovenous Hemodialysis Access* aimed to "develop practice guidelines in arteriovenous access placement and maintenance with the aim of maximizing the percentage and functionality of autogenous arteriovenous accesses that are placed" and included:

"...a number of observational studies (using historical controls) have shown a substantial reduction in the rate of graft thrombosis after implementing a program of stenosis monitoring or surveillance with preemptive angioplasty."

"When such stenoses are diagnosed later, balloon angioplasty can be performed initially." Found here.[13]

Allow us to connect you with the resources you need. Examples for this category include resources on physician engagement, value analysis, and product trials.

Clinical Evidence

Evidence within this category comparing products and outcomes is limited and primarily-industry sponsored. A sample of the available evidence is provided.

A 2023 multicenter, prospective, observational registry by Aruny et al. assessed the outcomes of patients who underwent longitudinal, controlled-depth micro-incisions for vessel preparation prior to PTA for treatment of VAD dysfunction. A total of 114 patients (148 lesions) were treated with the FLEX Vessel Prep System (FLEX VP) prior to PTA at eight clinical sites. Endpoints included anastomotic success (<30% stenosis), device technical success, clinical success, target lesion patency, avoidance of revascularization, and circuit primary patency at 6 months. Target lesion primary patency/freedom from revascularization was 63.7% in FLEX VP + PTA (n= 82) and 59.4% in FLEX VP + DCB (n=32). Target lesion revascularization was avoided for 206.7 days for FLEX VP + PTA and 196.1 days for FLEX VP + DCB. Circuit patency at 6 months for all patients was 54.3%.

Systematic search terms: VAD balloon angioplasty, PAD balloon angioplasty, vessel preparation balloon angioplasty, Flex Vessel Prep System
Databases: PubMed, Medline, CINAHL
Timeframe: published from 2019 to 2024.

Complications included one dissection related to the FLEX VP device, three dissections related to PTA, and one balloon burst causing an embolectomy (related to PTA) with no serious adverse events reported. Limitations included not being retrospective, lack of a matched cohort, variety in premorbid conditions and medical histories, sample size and lack of standardization in cohorts, and risk for confirmation bias due to lack of available prospective studies for comparison. Funding for this study was provided by VentureMed Group, Inc.[8]

A 2022 single-center retrospective, single-arm study by Dexpert et al. evaluated the acute and 12-month outcomes in patients who had vessel preparation with longitudinal, controlled-depth micro-incisions (utilizing the Flex Vessel Prep System) prior to PTA. The study included 65 patients with lesions at a median of 90% stenosis, 75.4% mild to severe calcifications, 33.8% rate of occlusion, and median occlusion length of 196 millimeters. Results included low severity dissection or no flow-limiting dissection in 82.1% of patients with a provisional stent rate post-procedure at 16.9% and a median stent length of 60 mm.

Clinical Evidence, continued

Avoidance of target lesion revascularization in at 6 and 12 months was 98.4% and 93.7%, respectively. They concluded that "arterial preparation using longitudinal, concentric micro-incisions to modify obstructive plaque may provide both short- and long-term benefit by improving vessel compliance, and lower the rate and severity of dissections, thereby reducing the need for stenting." Limitations included a discrepancy in matched cohorts between only PTA and PTA with vessel prep and lack of degree and standardization of clinical outcomes.[1]

A 2019 prospective pilot study by Shammas et al. (n=15) evaluated patients (by angiography and intravascular ultrasound) with initial or no-stent femoropopliteal restenosis who received PTA preceded with the Flex Vessel Prep system. Median stenosis severities were 77.0% baseline, 60% post-FLEX, and 34% post-PTA adjunctive therapies respectively (P=0.07 and P<0.001 for baseline vs post-FLEX and post-FLEX vs post PTA, respectively). Lesion length was 63.6 ± 32.5 mm. Peripheral artery calcium scoring system (PACSS) grades 3 and 4 were 6.7% and 40.0%, respectively.

Dissections identified post-FLEX were 14 (ultrasound) and 3 (angiogram) (P=0.35, ratio 4.7 to 1). Dissections after adjunctive angioplasty were 49 (ultrasound) and 6 (angiogram) (P<0.01, ratio 8.2 to 1). There were no flow-limiting dissections or bail-out stents required. Procedural success rate was 86.7%, and no complications were noted. They concluded that dissections noted on angiogram were "grossly under-appreciated" when compared with ultrasound, dissections following use of FLEX with PTA involved the intima < 180-degree width, and that larger trials are necessary to identify the clinical implications of these findings. Limitations included this study being single center, being limited to femoropopliteal lesions, and the need for larger randomized trials. There were no conflicts of interest noted.[5]

Clinical Insights: HealthTrust Physician Advisors

A panel of Interventional Cardiology and Vascular Surgery specialists within our HealthTrust Physician Advisor Network offered the following insights with regard to use of the Flex Vessel Prep System.[14]

Physician Advisor Insights*

- Perceived Benefits when compared to scoring balloons:
  - Ease of use
  - Relatively low profile
  - Potential for more predictable scoring
  - Potential for increased luminal gain
  - Less pressure needed to score vessel
- Perceived Limitations:
  - Concern for embolization (would need to see further studies)
  - Potential for vessel perforation
  - Reimbursement considerations
  - May have limited results in heavily calcified lesions (low pressure)

*Of note, no participants relayed direct experience utilizing Flex Vessel. Feedback based on review of FDA indications for use, product summary, related evidence, and manufacturer website.

FDA Approval

The Flex Vessel Prep system received FDA510k approval (K202187) as indicated for the following:

"use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature" Found here.[15]

Summary

1. Collaboration with subject matter experts, supplier engagement in education, and development of criteria for use are important considerations for successful implementation.
2. Available evidence comparing products and outcomes is limited and primarily-industry sponsored. Further follow up may be needed to best determine benefit.
3. As this may be a physician preference item, engaging a physician champion will be beneficial for peer-to-peer collaboration and dialogue.

References

1. Dexpert JB, Hayoz D, Engelberger RP, Krieger C, Meyer MR, Périard D. Arterial Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty of the Superficial Femoral and Popliteal Artery: Acute and 12-Month Results. *J Endovasc Ther*. 2022;29(3):420-426. doi:10.1177/15266028211057089
2. Zeller T, Lopez L, Pigott JP. Acute Outcomes With a Novel Plaque Modification System in Real-World Femoropopliteal Lesions. *J Endovasc Ther*. 2019;26(3):333-341. doi:10.1177/1526602819849955
3. Zeller T, Böhme T, Beschorner U, Noory E. Device profile of the FLEX Vessel Prep System for the treatment of peripheral arterial disease: overview of its safety and efficacy. *Expert Rev Med Devices*. 2022;19(1):25-29. doi:10.1080/17434440.2022.2020092
4. Shammas NW, Torey JT, Shammas WJ, Jones-Miller S, Shammas GA. Intravascular Ultrasound Assessment and Correlation With Angiographic Findings Demonstrating Femoropopliteal Arterial Dissections Post Atherectomy: Results From the iDissection Study. *J Invasive Cardiol*. 2018;30(7):240-244.
5. Shammas NW, Shammas WJ, Jones-Miller S, Radaideh Q, Shammas GA. Femoropopliteal Arterial Dissections Post Flex Vessel Prep and Adjunctive Angioplasty: Results of the Flex iDissection Study. *J Invasive Cardiol*. 2019;31(5):121-126.
6. Katsanos K, Spiliopoulos S, Reppas L, Karnabatidis D. Debulking Atherectomy in the Peripheral Arteries: Is There a Role and What is the Evidence? *Cardiovasc Intervent Radiol*. 2017;40(7):964-977. doi:10.1007/s00270-017-1649-6
7. Afari ME. Atherectomy in Peripheral Artery Disease: A Review. Journal of Invasive Cardiology. 2017;29(4). Accessed November 26, 2024. https://www.hmpgloballearningnetwork.com/site/jic/articles/atherectomy-peripheral-artery-disease-review
8. Aruny J, Hull JE, Yevzlin A, et al. Longitudinal micro-incision creation prior to balloon angioplasty for treatment of arteriovenous access dysfunction in a real-world patient population: 6-month cohort analysis. *Hemodial Int*. 2023;27(4):378-387. doi:10.1111/hdi.13111
9. vmgadmin. SYSTEM - Venture Med Group. Venture Med Group. Published February 7, 2023. Accessed November 17, 2024. https://www.venturemedgroup.com/flex-vp-system/system/
10. vmgmegan. REIMBURSEMENT - Venture Med Group. Venture Med Group. Published April 15, 2024. Accessed November 19, 2024. https://www.venturemedgroup.com/reimbursement/
11. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;135(12). doi:https://doi.org/10.1161/cir.0000000000000470
12. Bailey SR, Beckman JA, Dao TD, et al. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention. *J Am Coll Cardiol*. 2019;73(2):214-237. doi:https://doi.org/10.1016/j.jacc.2018.10.002
13. Sidawy AN, Spergel LM, Besarab A, et al. The Society for Vascular Surgery: Clinical practice guidelines for the surgical placement and maintenance of arteriovenous hemodialysis access. *J Vasc Surg*. 2008;48(5):S2-S25. doi:https://doi.org/10.1016/j.jvs.2008.08.042
14. 2024 HealthTrust Physician Advisor Network: Survey. Collected November 8th through November 22nd, 2024.
15. 510(k) Premarket Notification. Fda.gov. Published 2020. Accessed November 17, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202187