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# Novel Device Prior to Balloon Angioplasty for Dysfunctional Arteriovenous Access: Analysis of A Real-World Registry by Race And Sex Cohorts

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## Abstract

### Introduction

Hemodialysis patients often experience arteriovenous (AV) access dysfunction, yet the current standard-of-care, percutaneous transluminal balloon angioplasty (PTA), may introduce risk for vessel damage and long-term complications. Several technologies prepare the stenosed vessel for PTA, however their investigative studies do not consistently represent patient diversity despite inequity of renal care in underrepresented populations such as Blacks and Females. As well, safety concerns and patency limitations are consistently reported among these patient populations. Recently, an all-comers registry reported the safety and effectiveness of vessel preparation by creating longitudinal, controlled-depth micro-incisions prior to PTA in patients with AV access dysfunction. Given the real-world representation of this registry, this sub-analysis assesses clinical outcomes by race and sex.

### Methods

This multicenter, prospective, observational registry (FLEX AV Registry) enrolled hemodialysis patients scheduled to undergo PTA of their AV fistula or graft. Endpoints included anatomic success without adverse event, procedural success, and clinical assessments of target lesion primary patency (TLPP) and freedom from target lesion revascularization (FFTLR) at 6 and 12 months. Data were analyzed by race (Black, Non-Black) and sex (Female, Male) cohorts.

### Results

A total of 114 subjects (65.8% Black; 53.5% Female) were treated at 8 clinical sites with the FLEX Vessel Prep™ System (FLEX VP) prior to PTA. Black (5.4+4.5 vs. Non-Black

3.4+2.4 years) and Female (5.5+6.8 vs Males 3.2+3.7 years) subjects had significantly longer time on hemodialysis. There were no group differences in lesion characteristics. No major complications occurred in any patients, including Blacks and Females. Twelve-month follow-up showed no difference in TLPP and FFTLR. TLPP and FFTLR for Blacks was 44%/267 days and Non-Blacks was 47%/240 days, and for Females 40%/247 days vs. Male 51%/268 days. In patients with cephalic arch lesions, the Black cohort(n=14) maintained high patency at 69% with 292 days FFTLR.

### Conclusion

This cohort analysis of the multi-center, prospective, observational FLEX AV Registry through 12 months reflects real-world populations most impacted by End-stage Kidney Disease (ESKD) incidence. Results reveal equivalent benefit for Blacks and Females, historically underrepresented populations associated with poorer outcomes.

## Introduction

Hemodialysis is a requirement for most patients living with End-Stage Kidney Disease (ESKD). Functional vascular access with an arteriovenous (AV) fistula or graft is essential for effective, life-saving hemodialysis. Unfortunately, AV access dysfunction due to stenotic lesions requires additional interventions with possible hospitalizations

and loss of the access [1]. Restoring patency and minimizing restenosis are critical to maintaining effective hemodialysis.

Percutaneous transluminal balloon angioplasty (PTA) is the standard endovascular technique for treatment of stenoses associated with both native AV fistulas and prosthetic AV grafts [2]. PTA has demonstrated successful immediate results, however, acute procedural complications such as vessel rupture and variable long-term patency rates have encouraged development of vessel preparation techniques to optimize PTA effectiveness. These techniques include modifying the stenotic lesion via high-pressured balloons, cutting balloons, stents, and, recently, longitudinal micro-incisions.

As with any clinical indication, treatment selection for AV access dysfunction should encompass demonstration of effectiveness in the patient populations being treated. ESKD disproportionally affects Black individuals who have a four-fold greater incidence relative to White individuals [3]. As a result, a greater proportion of hemodialysis patients relying on AV access are Black [3]. Black patients with AV access dysfunction have increased odds for primary patency loss after initial PTA intervention. This often requires additional interventions which increase the risk of complications, further compounding inequities [4]. Even though Non-White individuals represent the majority of hemodialysis patients [3]. Their representation in clinical trials for new treatments has not been consistent and equitable, ranging from 2-30% [5-7]. In addition to race, inequities in ESKD care and clinical outcomes have been reported in Females [7-10]. Recently, safety and clinical outcomes following a novel vessel preparation with longitudinal micro-incisions in stenotic lesions prior to PTA have been reported for the FLEX AV Registry [11,12]. This Registry was an all-comers registry intended to represent the real-world population. Enrollment was targeted at community-based centers in regions of the United States with concentration of diverse populations of hemodialysis patients. This approach aligns with the goals of recent FDA guidance for diversity enrollment in clinical trials [13]. The high representations of Black and Female participants enable between-group analyses atypical of medical device studies. The objective of this paper is to assess differences in clinical outcomes between race and sex cohorts through 12 months post-intervention.

## Methods

This multicenter, prospective, observational registry (FLEX AV Registry) has been previously described [11,12]. In brief, patients scheduled to undergo PTA of their arteriovenous fistula or graft due to clinical or hemodynamic abnormalities were enrolled. This study was approved by an Institutional Review Board responsible for each site. The primary objective of the FLEX AV Registry is to document the endovascular intervention approaches and outcomes when the FLEX VP™ system is utilized in a clinical setting per the institution's standard practice and following treatment. Once enrolled, the patient demographics, medical history, chronological access history and the following treatment details were collected: access location, target vessel reference diameter, number of lesions, pre-dilation % stenosis, number of device passes, maximum balloon inflation pressure, lesion location and lesion length. Procedural complications were also recorded.

### Study device and PTA

This Registry was performed with marketed devices within the defined indications for use. There were no additional treatments or examinations that were required. The only differences to routine care were collection and analysis of patient data, informed consent, and the option of performing follow-up visits via telephone as this Registry took place during the COVID-19 pandemic.

The FLEX Vessel Prep™ System provides vessel preparation prior to PTA for AV access dysfunction. The FLEX VP device is an endovascular, over-the-wire, sheathed catheter with a 3- strut treatment element at the distal tip. The struts are radially opposed, and the proximal portion of each strut includes a 0.010" depth micro-surgical blade. When deployed, the device's struts independently engage with neointimal hyperplastic stenoses occluding an arteriovenous fistula or graft used for hemodialysis. As the device is pulled back though the lesion, the blades create three continuous, parallel micro-incisions approximately 250 microns in depth along the lesion's entire length. This is a non-balloon-based device. The device's struts exert a consistent force of approximately one

atmosphere on the vessel wall. Additional micro-incisions may be created by using several passes of the device, rotating it within the vessel 30 to 90 degrees each time. The micro-incisions improve acute luminal gain and vessel compliance by releasing circumferential tension in the lesion.

The target lesion was defined by the treating physician as the most severely stenosed lesion in the setting of multiple lesions. The lesions were treated by creating longitudinal micro-incisions with the FLEX Vessel Prep™ System and then followed with standard PTA during the baseline procedure. The endovascular treatment decisions, including the type of PTA used, were at the discretion of the physician. Balloon diameters were chosen by the treating physician. The balloon was inflated until the walls were parallel.

### Outcomes

As described previously, [11-12] follow-up was conducted by telephone at 6, 9, and 12 months post-operatively to both the subject and/or patient's dialysis clinic to determine target lesion primary patency (TLPP) and freedom from target lesion revascularization (FFTLR). Site physicians and dialysis centers followed their institutional procedures for hemodialysis access surveillance. Each site reported on all reinterventions required during the follow-up period, specifically identifying when the target lesion required reintervention.

### Data analysis

Patient, procedure, and lesion characteristics assessed at baseline were analyzed with descriptive statistics, including mean and standard deviation for continuous variables and frequency counts and percentages for categorical variables. For comparison of baseline characteristics between groups, a t-test or Fisher's exact test was performed when comparing two groups or ANOVA or chi-square tests when comparing more than two groups, as appropriate. Time to first target lesion re-intervention was analyzed using the Kaplan-Meier method to estimate the proportion of subjects free from target lesion re-intervention at 6 months. Follow-up was censored at the earlier of last contact or 187 (6 month) and 372 (12 month) days post-procedure. Kaplan-Meier curves were compared between groups using log-rank tests. Analyses were completed by a biostatistician (NAMSA; Minneapolis, MN).

## Results

### Subjects and lesion characteristics

**Table 1.** Patient demographics by group (NS = non-significant; p>0.05).

| Variable | Black (N=75) | Non-Black (N=39) | p-value | Female (N=61) | Male (N=53) | p-value |
|---|---|---|---|---|---|---|
| Age (years) | 62.1 ± 13.3 | 65.6 ± 11.5 | NS | 64.3 ± 11.8 | 62.2 ± 13.8 | NS |
| | 31.0-87.0 | 38.0-88.0 | | 31.0-87.0 | 32.0-88.0 | |
| Sex | | | NS | | | |
| Female | 44 (58.7%) | 17 (43.6%) | | | | |
| Male | 31 (41.3%) | 22 (56.4%) | | | | |
| Race | | | | | | |
| Black or African American | | | | 44 (72.1%) | 31 (58.5%) | |
| Non-Black or African American | | | | 17 (27.9%) | 19 (35.8%) | |
| Smoking History | | | <0.05 | | | NS |
| Current | 10 (13.3%) | 7 (17.9%) | | 8 (13.1%) | 9 (17.0%) | |
| Never | 46 (61.3%) | 14 (35.9%) | | 34 (55.7%) | 26 (49.1%) | |
| Past | 19 (25.3%) | 18 (46.2%) | | 19 (31.1%) | 18 (34.0%) | |
| Medical History | | | | | | |
| Diabetes | 44 (58.7%) | 27 (69.2%) | NS | 35 (57.4%) | 36 (67.9%) | NS |
| Hypertension | 69 (92.0%) | 36 (92.3%) | NS | 58 (95.1%) | 47 (88.7%) | |
| Congestive Heart Failure | 33 (44.0%) | 11 (28.2%) | NS | 27 (44.3%) | 17 (32.1%) | NS |
| Prior AV Access Interventions (count) | 4.6 ± 6.3<br>0.0-29.0 | 4.2 ± 4.3<br>0.0-18.0 | NS | 5.5 ± 6.8<br>0.0-29.0 | 3.2 ± 3.7<br>0.0-18.0 | <0.05 |
| Years since AV Access Creation (years) | 3.2 ± 2.8<br>0.2-13.9 | 3.0 ± 2.2<br>0.1-9.0 | NS | 3.7 ± 3.0<br>0.1-13.9 | 2.4 ± 1.7<br>0.2-8.5 | <0.01 |
| Years since Started Hemodialysis (years) | 5.4 ± 4.5<br>0.5-19.3 | 3.4 ± 2.4<br>0.1-9.0 | <0.01 | 5.6 ± 4.5<br>0.1-19.3 | 3.7 ± 3.1<br>0.4-15.1 | <0.01 |
| Days since last dialysis (days) | 1.3 ± 1.0 (74)<br>0.0-6.0 | 4.3 ± 18.9<br>0.0-119.0 | NS | 1.1 ± 0.6<br>0.0-4.0 | 3.7 ± 16.3<br>0.0-119.0 | NS |

As previously reported, the FLEX AV Registry enrolled a total of 114 patients with 148 lesions at 8 clinical sites with mean subject age of 63.3±12.7 years (range 31–88 years), 65.8% Black and 53.5% Females. [11,12] Table 1 presents the demographics and clinical characteristics for all participants and by group. The Black cohort represented 65.8% (n=75) of enrolled participants. The demographics and clinical characteristics of the cohorts are presented in Table 3. The Black cohort had a significantly lower proportion of smoking history (38.7% vs 64.1%; p<0.05). The groups were similar in the period since AV access creation (Black 3.2+2.8 years vs Non-Black 3.0+2.2 years; p>0.05) and number of prior AV access interventions (Black 4.6+6.3 vs Non-Black 4.2+4.3 years; p>0.05). However, the Black cohort was on hemodialysis longer than the Non-Black cohort (Black 5.4+4.5 years vs Non-Black 3.4+2.4 years; p<0.01). Females did not differ from Males in smoking history or medical history. However, Females had a higher number of prior AV access interventions (5.5+6.8 vs 3.2+3.7, p<0.05), a longer period since AV access creation (3.7+3.0 vs 2.4+1.7 years, p<0.01) and a longer period on hemodialysis 5.6+4.5 vs 3.7+3.1 years, p<0.01) relative to Males.

One hundred fourteen target lesions were treated with FLEX VP. The mean age of all AV access was 3.1+2.6 years (range 0.1-13.9). One hundred four subjects (91.2%) had experienced prior interventions. The mean number of prior interventions was 4.9+5.8 (range 0-29) [11,12]. The lesion location and characteristics by race and sex are shown in Table 2. Thirty-two of 114 subjects (28.1%) had secondary lesions. For target lesions, mean lesion length was 21+25mm (1- 200 mm) with a mean pre-procedure stenosis of 75.2%+14.7%. For all lesions, mean lesion length was 20+25 mm (1-200 mm) with a mean pre-procedure stenosis of 72.4%+15.7%. Groups did not differ in number of lesions, secondary lesions, target lesion length, and pre-procedure stenosis.

## Procedure performance

**Table 2.** Lesion characteristics by cohort (NS = non-significant; p>0.05).

| Variable | All (N=114) | Black (N=75) | Non-Black (N=39) | p-value | Female (N=61) | Male (N=53) | p-value |
|---|---|---|---|---|---|---|---|
| Type of Access | | | | NS | | | NS |
| Arteriovenous Fistula | 72 (63.2%) | 46 (61.3%) | 26 (66.7%) | | 34 (55.7%) | 38 (71.7%) | |
| Arteriovenous Graft | 42 (36.8%) | 29 (38.7%) | 13 (33.3%) | | 27 (44.3%) | 15 (28.3%) | |
| Location | | | | NS | | | NS |
| Forearm | 11/114(9.6%) | 5 (6.7%) | 6 (15.4%) | | 5 (8.2%) | 6 (11.3%) | |
| Other | 4/114(3.5%) | 2 (2.7%) | 2 (5.1%) | | 3 (4.9%) | 1 (1.9%) | |
| Upper Arm | 99/114(86.8%) | 68(90.7%) | 31 (79.5%) | | 53 (86.9%) | 46 (86.8%) | |
| Target Vessel Diameter (mm) | | 7.8 ± 1.9 4.7-14.0 | 7.9 ± 2.7 4.0-18.8 | NS | 7.6 ± 2.2 4.7-18.8 | 8.1 ± 2.1 4.0-14.0 | NS |
| Number of Lesions | | | | NS | | | NS |
| Single Lesion | 82/114(71.9%) | 53 (70.7%) | 29 (74.4%) | | 42 (68.9%) | 40 (75.5%) | |
| Multiple Lesions | 32 (28.1%) | 22 (29.3%) | 10 (25.6%) | NS | 19 (31.1%) | 13 (24.5%) | NS |
| Target Lesion Length (cm) | 2.1 ± 2.5 (113) 0.0-20.0 | 1.9 ± 1.7 (74) 0.0-7.0 | 2.3 ± 3.5 0.0-20.0 | NS | 2.0 ± 1.8 (60) 0.0-7.0 | 2.1 ± 3.1 0.0-20.0 | NS |
| Target Lesion Pre Procedure Stenosis (%) | 75.2 ± 14.7 | 74.2 ± 14.7 45.0-100.0 | 77.3 ± 14.6 50.0-100.0 | NS | 75.7 ± 15.5 50.0-100.0 | 74.7 ±13.8 45.0-100.0 | NS |

**Table 3.** Procedure characteristics by cohort (NS = non-significant; p>0.05).

| Variable | Black (N=75) | Non-Black (N=39) | p-value | Female (N=61) | Male (N=53) | p-value |
|---|---|---|---|---|---|---|
| Target Lesion FLEX passes (count) | 5.2 ± 1.1 2.0-8.0 | 5.1 ± 0.9 3.0-7.0 | NS | 5.3 ± 1.1 3.0-8.0 | 4.9 ± 0.9 2.0-7.0 | < 0.05 |
| Target Lesion Post FLEX Stenosis (%) | 53.9 ± 21.2 0.0-90.0 | 52.5 ± 24.1 0.0-95.0 | NS | 51.9 ± 22.1 0.0-89.0 | 55.2 ± 22.3 9.0-95.0 | NS |
| Largest PTA Diameter (mm) | 8.4 ± 1.5 5.0-14.0 | 8.1 ± 1.3 5.0-12.0 | NS | 8.0 ± 1.3 5.0-14.0 | 8.6 ± 1.6 5.0-14.0 | NS |
| Longest PTA Length (mm) | 53.1 ± 19.4 6.0-100.0 | 50.9 ± 18.4 6.0-100.0 | NS | 53.8 ± 19.2 40.0-100.0 | 50.8 ± 18.9 6.0-100.0 | NS |
| Maximum Pressure (atm) | 15.5 ± 5.7 4.0-30.0 | 14.5 ± 6.5 4.0-32.0 | NS | 14.2 ± 5.6 4.0-30.0 | 16.3 ± 6.2 4.0-32.0 | NS |
| Stent Used | 4 (5.3%) | 3 (7.7%) | NS | 4 (6.6%) | 3 (5.7%) | NS |

**Table 4.** Clinical outcomes by race TLPP = target lesion primary patency; FFTLR = freedom from target lesion revascularization.

| | BLACK n | TLPP | FFTLR (average days) | Non -BLACK n | TLPP | FFTLR (average days) | % FFTLR log rank p-value |
|---|---|---|---|---|---|---|---|
| **6 months** | | | | | | | |
| **All Subjects (n=112)** | 74 | 63.70% | 207.8 | 38 | 58.80% | 192.2 | 0.451 |
| Subjects Treated with PTA | 51 | 68.30% | 218.3 | 30 | 55.70% | 186.9 | |
| Cephalic Arch Subjects with PTA | 14 | 76.90% | 226.2 | 10 | 58.30% | 189.4 | |
| **12 months** | | | | | | | |
| **All Subjects (n=112)** | 74 | 45.90% | 257.8 | 38 | 45.70% | 237.4 | 0.593 |
| Subjects Treated with PTA | 51 | 43.80% | 266.5 | 30 | 46.90% | 239.9 | |
| Cephalic Arch Subjects with PTA | 14 | 69.20% | 292.1 | 10 | N/A* | 233.8 | |

*Kaplan-Meier estimates were provided at day 372. No patients remained under observation.

**Table 5.** Clinical outcomes by sex TLPP = target lesion primary patency; FFTLR = freedom from target lesion revascularization.

| | FEMALE | | | MALE | | | % FFTLR Log rank p-value |
|---|---|---|---|---|---|---|---|
| | n | TLPP | FFTLR c (average days) | n | TLPP | FFTLR (average days) | |
| **6 months** | | | | | | | |
| All Subjects (n=112) | 60 | 56.90% | 197.5 | 52 | 68.30% | 208.7 | 0.336 |
| Subjects Treated with PTA | 46 | 55.10% | 197.2 | 35 | 74.20% | 218.4 | |
| Cephalic Arch Subjects with PTA | 11 | 63.60% | 209.7 | 13 | 76.90% | 216.7 | |
| **12 months** | | | | | | | |
| **All Subjects (n=112)** | 60 | 42.20% | 245.7 | 52 | 49.50% | 256.4 | 0.562 |
| Subjects Treated with PTA | 46 | 40.00% | 247 | 35 | 50.70% | 268.2 | |
| Cephalic Arch Subjects with PTA | 11 | 50.00% | 251.3 | 13 | 68.40% | 281.7 | |

Procedural characteristics by race and sex are presented in Table 3, respectively. Vessel preparation was performed with a mean 5.1+1.0 passes (range 2.0-8.0). Vessel preparation was followed by PTA in 82/114 (71.9%) of subjects and PTA-DCB in 32/114 (28.1%) of the subjects. Patients receiving PTA -DCB were excluded from clinical outcome analysis to maintain homogeneity of the comparisons. Maximum PTA pressure was 15.2+5.9 atm (range 4.0-32.0).

Vessel preparation was performed with a mean 5.1+1.0 passes (range 2.0-8.0) with a significantly higher number of passes performed in target lesions of Females (5.3+1.1) relative to Males (4.9+0.9) ($p<0.05$). Post-FLEX VP stenosis did not differ by race or sex. PTA maximum diameter and maximum pressure did not differ by race or sexual cohort.

### Clinical outcomes

One hundred twelve subjects were evaluated through 12 months. Two subjects (1.7%) did not complete follow-up analysis. As previously reported [11, 12]. No adverse events or major complications occurred during the study procedures nor follow-up. Clinical outcomes by race and sex cohorts are presented in Table 4 and Table 5 for both 6 months and 12 months follow- up. No significant difference in TLPP or FFTLR was observed in Blacks (43.8%, 266.5 days) at 12 months relative to Non-Blacks (46.9%, 239.9 days). Furthermore, no statistical difference was found in TLPP or FFTLR in Females (40%, 247 days) relative to Males (50.7%, 268.2 days). TLPP for Cephalic arch lesions for the Black cohort was notably sustained at 69.2% with FFTLR of 292.1days.

## Discussion

The FLEX VP has been reported to be a safe and effective device in patients with AV access dysfunction [11, 12]. As noted in the article, there were no major complications in the study. Published data reports that about 12% of angioplasty procedures performed in Black patients result in major complications [5-14]. This is a substantial improvement over

standard PTA for Black patients. Additionally, this sub-analysis extends the previous findings by highlighting similar patency and safety outcomes across race and sex cohorts following vessel preparation with FLEX VP [11,12]. Furthermore, Black patients with cephalic arch lesions had a higher rate of freedom from target vessel reintervention at 6- and 12-months relative to the Non-Black cohort. These findings are notable given reports of inequities for these patient populations. End-stage kidney disease impacts Non-White populations 1.5 to 4.0 times the rate of White patients and is accompanied by disparities in vascular access and renal care [15-17]. In this FLEX AV Registry, Black and Female patients had undergone hemodialysis significantly longer, and Female patients demonstrated a higher number of AV access interventions. Yet freedom from target lesion revascularization and target lesion primary patency did not differ across cohorts, suggesting potential contribution of FLEX VP in normalizing clinical outcomes following AV access dysfunction in broad patient populations with a history of health inequities. The rationale to evaluate clinical outcomes in sub-populations was driven by the atypically high proportion of Black and Female patients enrolled in this Registry. This contrasts to the low historic representation of Non-White and Female participants in ESKD clinical trials (2-30%) [5-6]. This all-comers registry focused on enrollment from smaller community hospitals and clinics. These facilities care for a majority of end-stage renal disease patients, thus representing the real-world environment [3]. Furthermore, enrollment prioritized locations in the southern United States, a region with high rates of ESKD and diverse patient populations. This diverse enrollment profile is noteworthy given historic inequities in clinical trial enrollment [3-17]. Such enrollment follows recent FDA guidelines for industry to ensure diversity in patient populations represented in clinical trials of innovative products [12]. In addition, this study represents a collective call to action to "directly engage with communities most impacted with inequities in care" [17]. The limitations of this FLEX AV Registry have been previously described. [11,12] However, despite that the all-comers design of this protocol enrolls participants with a large variability in pre-existing conditions, the reported results are comparable to those reported in more controlled studies with stricter inclusion criteria.

In conclusion, this cohort analysis of the multi-center, prospective, observational FLEX AV Registry reflects real-world populations most impacted by dysfunctional AV Access. Results reveal equivalent benefit to Blacks and Females, historically underrepresented populations associated with poorer outcomes. These results provide rationale of substantial benefit for adding FLEX VP prior to PTA in broad clinical practice across providers. Healthcare equity is an important imperative in kidney care and the inclusion of minority populations in all related studies should be a priority. Bridging inequalities in dialysis access outcomes will benefit from clinical studies such as this with FLEX VP. In addition, we must all continue to enroll diverse populations in ESKD studies to ensure new devices and technologies demonstrate benefit to all patients.

### Declaration of conflicting interests

OD is a consultant physician trainer for Medtronic and Bard. ACA is a grant recipient from BD, a consultant for Inari, and a speaker for BD, Inari, and Medtronic. TFL is a patient advocate and consultant for VentureMed Group, Inc. JH has no conflicts to disclose.

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