



# Patient Perspectives and Equality

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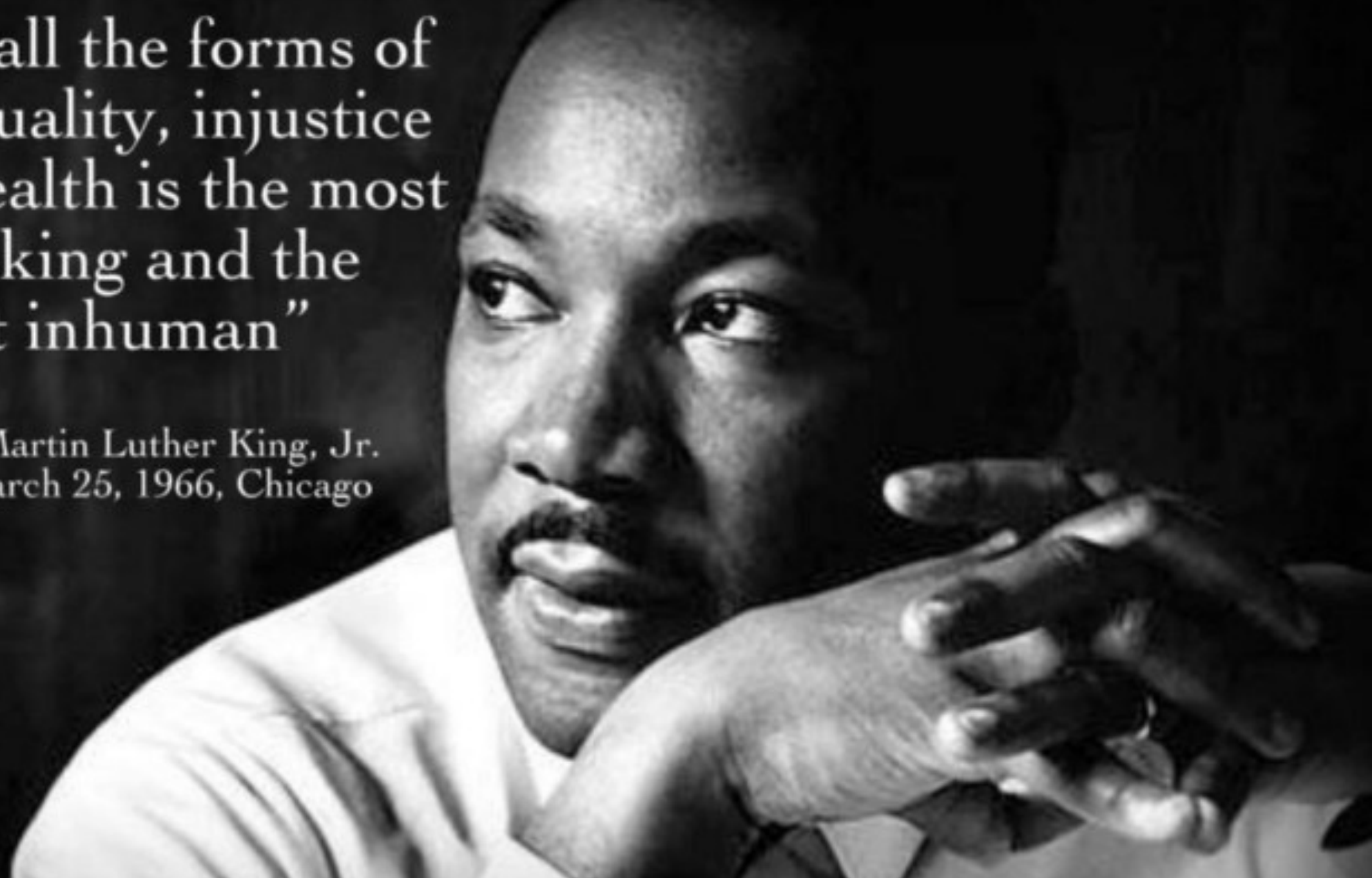
VASA 2022

# The Time is NOW for Studies to be INCLUSIVE

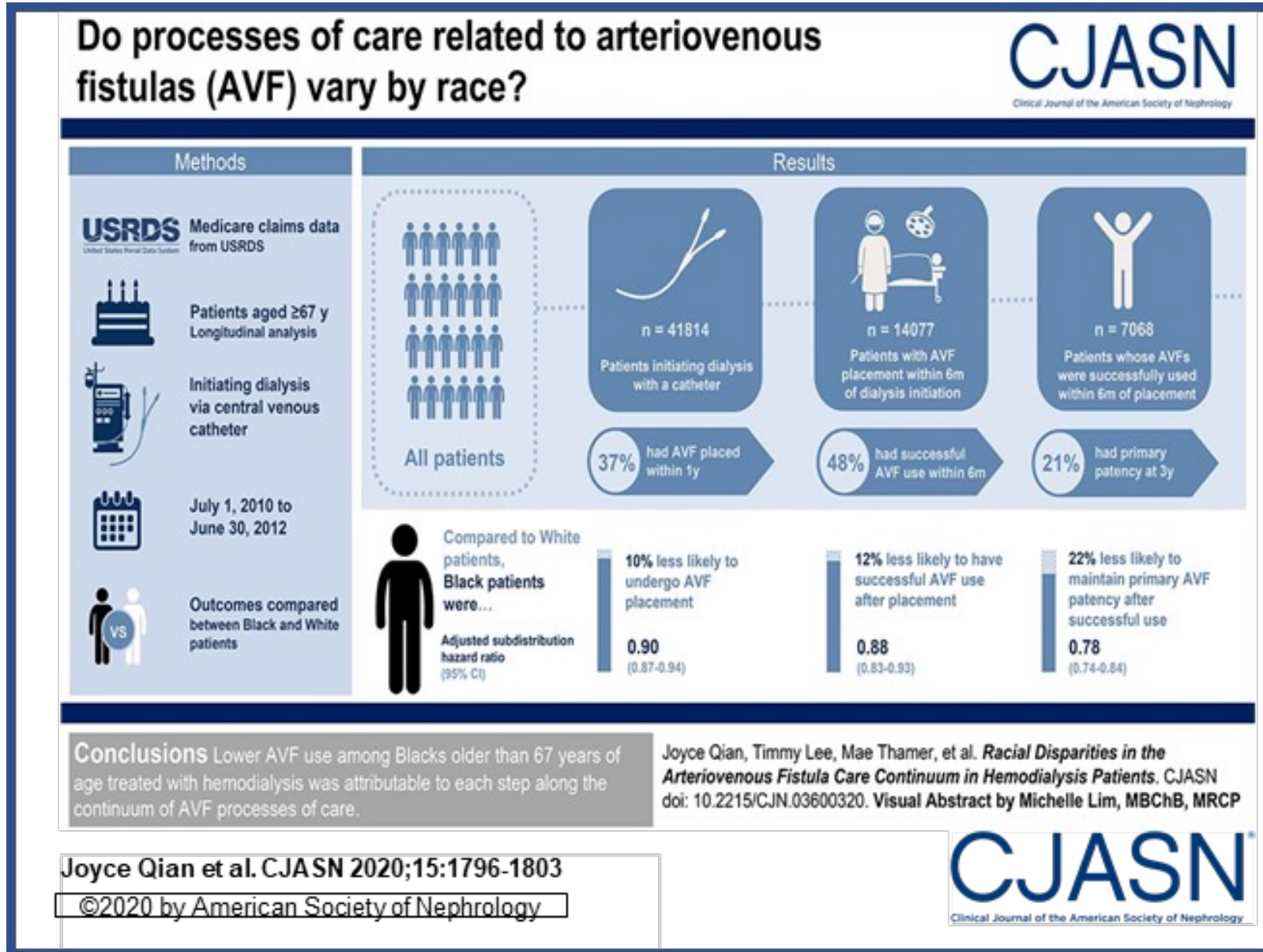
- ESRD is a disease of color—African Americans have 3.7 times greater incidence; 1.4 times greater in Native Americans and 1.5 times greater in Asian Americans compared to Whites
- Patients of color with CKD have 4 times greater likelihood to progress to dialysis
- A black female starting dialysis is 5 times more likely to start dialysis with a catheter than white patients despite being younger and having fewer comorbidities
- Studies in dialysis access are not representative of the patient population
- One pivotal trial of a novel device had NO black patients enrolled

“Of all the forms of  
inequality, injustice  
in health is the most  
shocking and the  
most inhuman”

- Dr. Martin Luther King, Jr.  
March 25, 1966, Chicago



# AVF Hemodialysis and African-Americans



- By every measure Blacks do worse than Whites in AVF use
- Nearly 1 in 4 Blacks lose AVF patency sooner than Whites

# Patient Perspectives on FLEX Vessel Prep

- Anecdotes from RMC about pain
- Patient input sought for recently completed trial
- Comments included less pain and seemed faster
- Enrollment in the FLEX AV registry and the trial reflected typical patient with ESRD – real world patients (minorities, females and older patients)



# AV Registry Data

African American Population Outcomes





# African American Population

## Demographics and Medical History

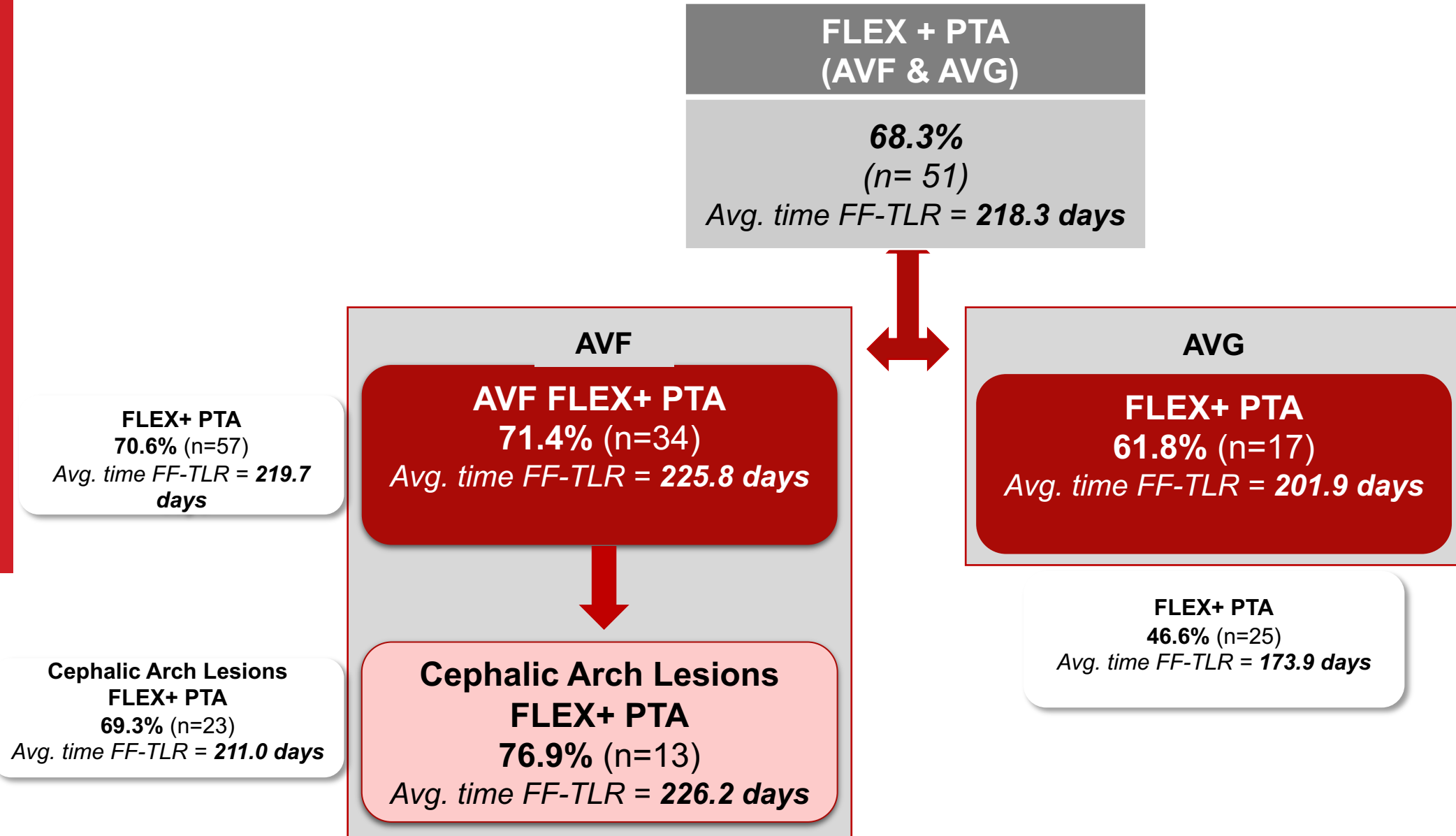
Demographics	75 Subjects
Age (years)	62.1 ± 13.3 (75) 31.0-87.0
Gender	
Female	44/75 (58.7%)
Male	31/75 (41.3%)
Smoking History	
Current	10/75 (13.3%)
Never	46/75 (61.3%)
Past	19/75 (25.3%)
Days since last dialysis (days)	1.3 ± 1.0 (74) 0.0-6.0

Medical History	75 Subjects
Diabetes	44/75 (58.7%)
Hypertension	69/75 (92.0%)
Congestive Heart Failure	33/75 (44.0%)
Prior AV Access Interventions (count)	4.6 ± 6.3 (75) 0.0-29.0
Years since AV Access Creation (years)	3.2 ± 2.8 (75) 0.2-13.9
Years since Started Hemodialysis (years)	5.4 ± 4.5 (75) 0.5-19.3

51 of 75 African American patients were FLEX + PTA in the FLEX+PTA Arm

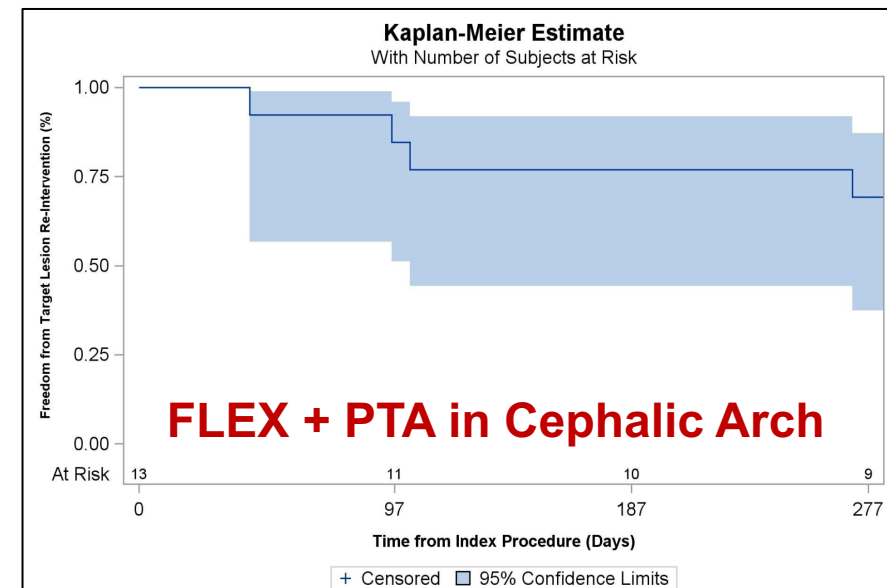
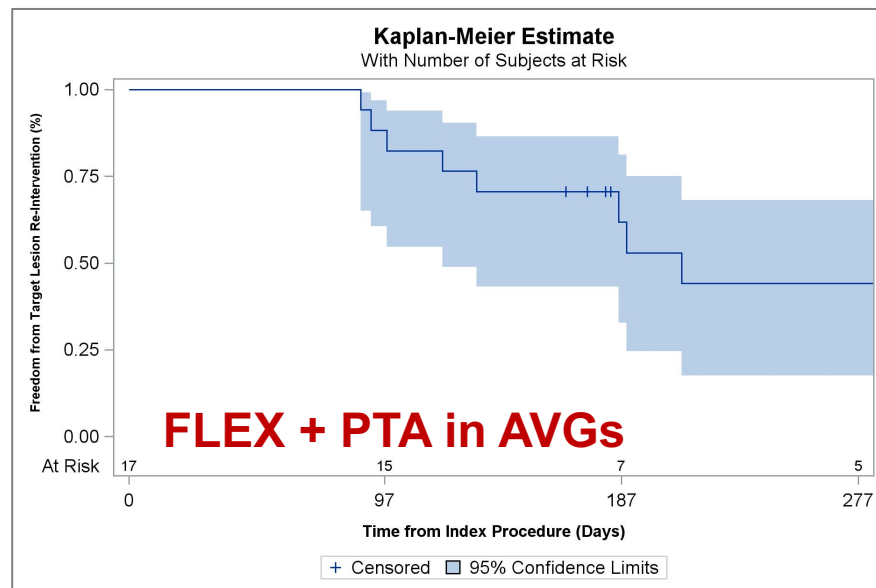
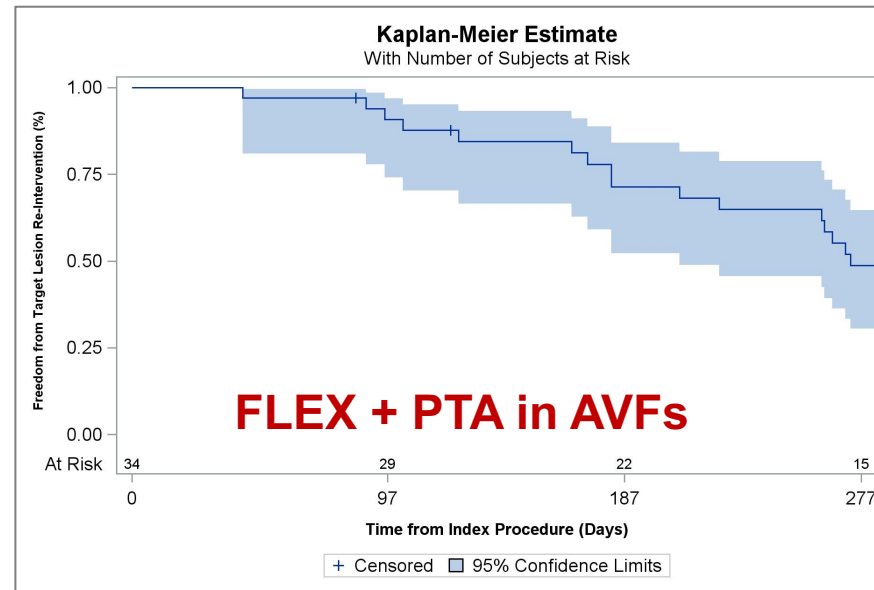
# 6-month Functional Patency

## African American Population – 51 patients (FLEX + PTA)





# African American Patients in Flex AV Registry (n=75) Functional Patency



# 6-month Functional Patency African American Population

- FLEX extends time vs stand-alone PTA in AVF's
- FLEX extends time vs stand-alone PTA in AVG's
- FLEX extends time vs stand-alone PTA in Cephalic Arch Interventions

	AVF's	AVG's	Cephalic Arch
All Patients (n= 114)	71%	47%	69%
African-American patients (n=75)	71%	62%	77%

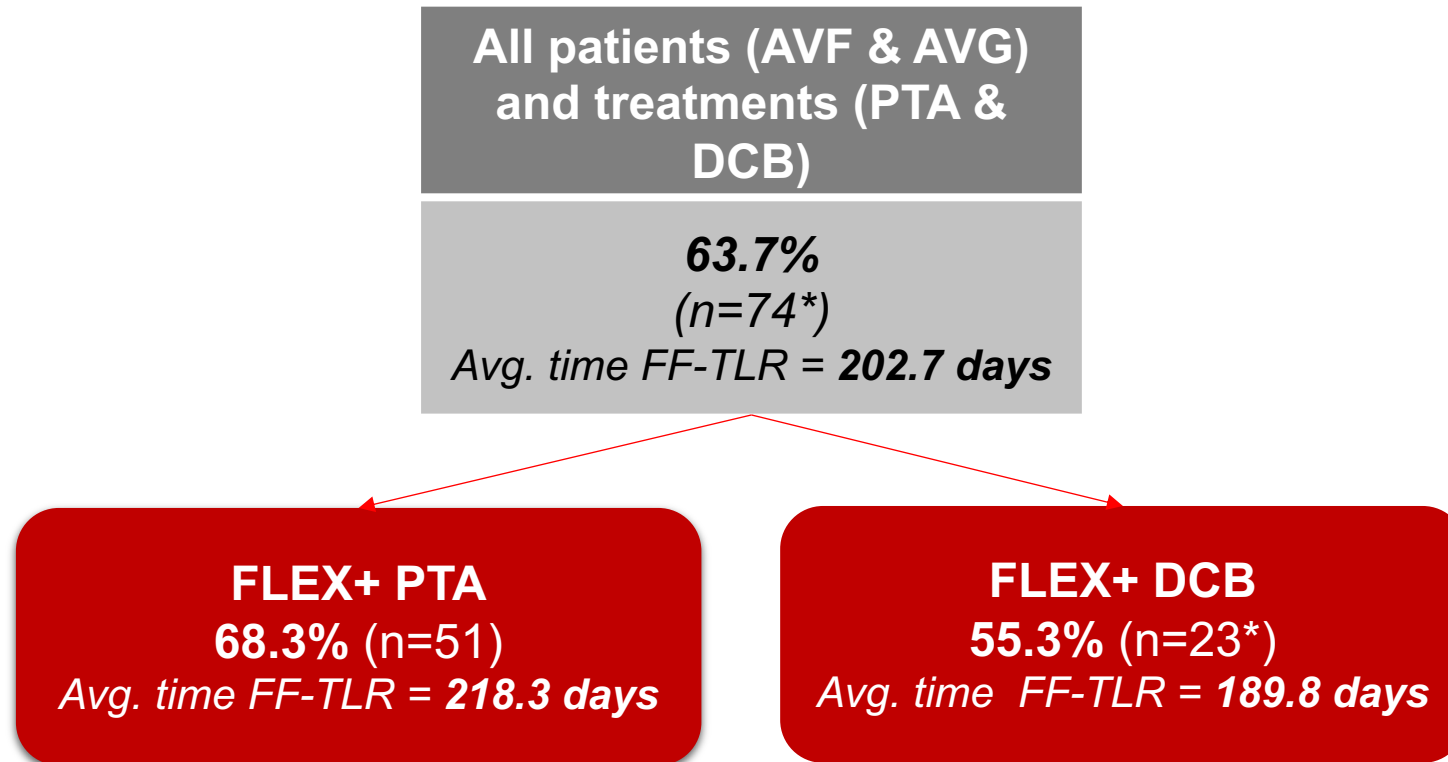
**FLEX excelled in challenging AVG's and Cephalic Arch lesions in African-American patients**

# Conclusion & Call to Action

- FLEX AV Registry included real world patients
- FLEX Vessel Prep demonstrated real world benefit for real world patients
- Device makers are encouraged to include your trials real world patient populations
- Providers - Help industry design real world clinical studies
- It is time to debunk the myths associated with gender and race related to Vascular Access
- The time is NOW

- Back up DCB slide

# 6-month Functional Patency African American Population



\* One patient did not contribute to follow-up so not included in Kaplan-Meier Analysis.