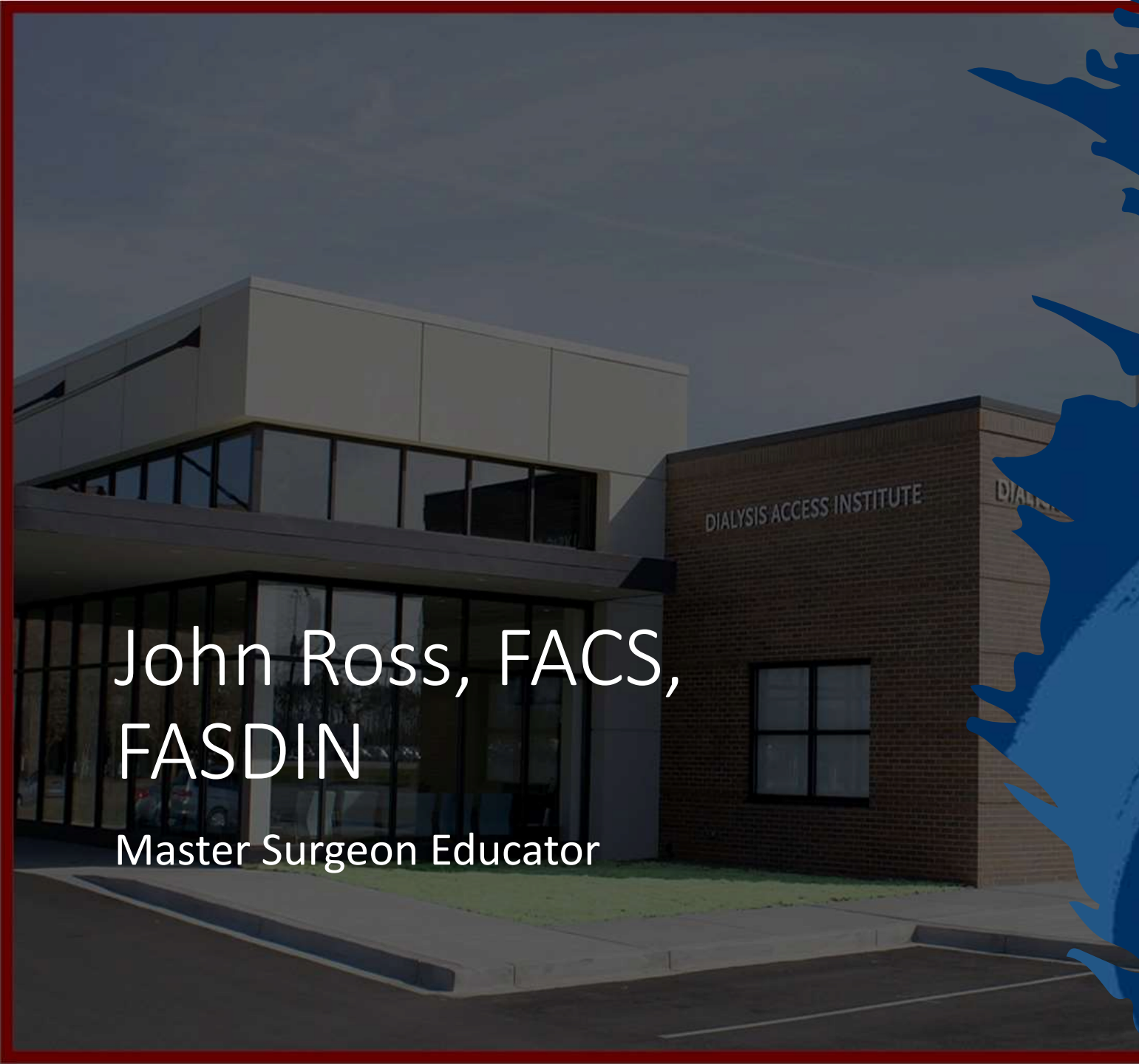


John Ross, FACS, FASDIN

Master Surgeon Educator

LINC

Disclosure

Speaker name: John Ross

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Restoring AV Access: Pilot Study Using a Scoring Balloon in 50 Patients

Dr. Ross

Orangeburg Dialysis Access Institute

Orangeburg, South Carolina

AV Access

- By 2008, more than 341,000 patients in the United States were undergoing hemodialysis for the treatment of end-stage renal disease[1]
- Most AV access circuits fail due to neointimal hyperplasia
- Studies have shown 6-month patency (i.e., function AV access) of 50-60% following angioplasty[2,3]
- Scoring balloons may advance the treatment of AV access stenosis

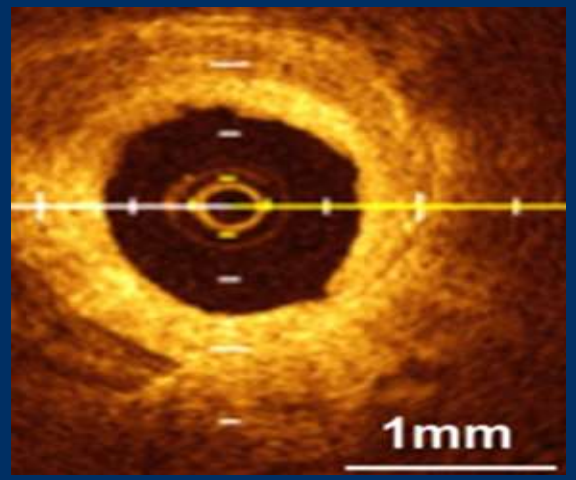
- . Pirozzi N, Garcia-Medina J and Hanoy M. Stenosis complicating vascular access for hemodialysis: indications for treatment. *J Vasc Access* 2014; 15(2): 76–82.
- 2. Bountouris I, Kritikou G, Degermetzoglou N, et al. A review of percutaneous transluminal angioplasty in hemodialysis fistula. *Int J Vasc Med* 2018; 2018: 1420136.
- 3. Davidson CJ, Newman GE, Sheikh KH, et al. Mechanisms of angioplasty in hemodialysis fistula stenoses evaluated by intravascular ultrasound. *Kidney Int* 1991; 40(1): 91–95.

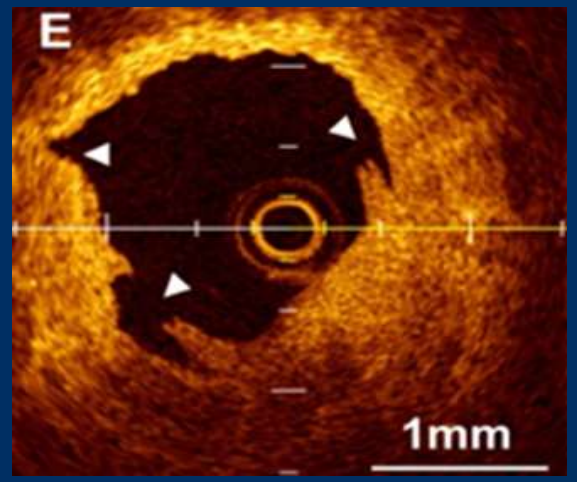
Angiosculpt® PTA Scoring Balloon

Minimizes **Slippage**

Scoring mechanism designed to **reduce** the risk of **flow-limiting dissections**

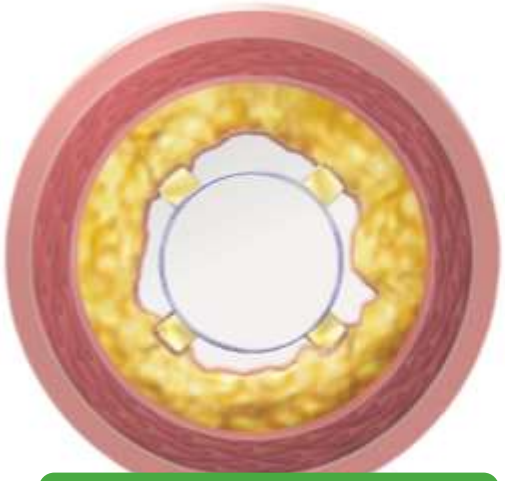
Multiple lesion morphologies including **calcium**





Angiosculpt® Mechanism of Action

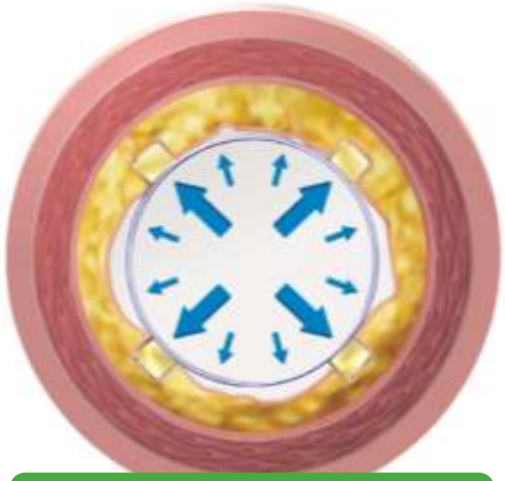
Precision



Minimal Slippage

Rectangular edges “lock” the device into lesion

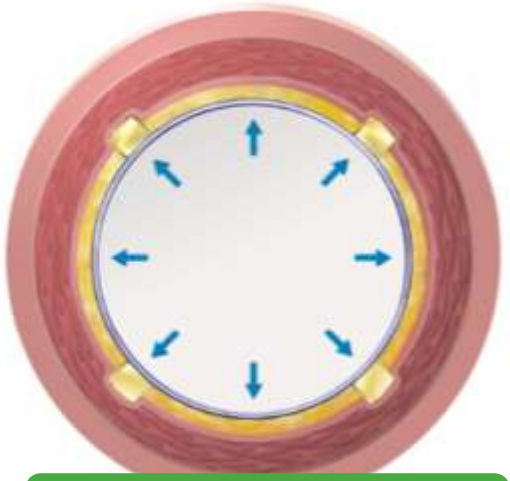
Power



More Dilatation Force

Leading edges drive outward force 15-25 times that of POBA

Safety



Low Dissection Rate

Less flow limiting dissections then POBA

LINC

Angiosculpt® Specifications

Number	Balloon diameter (mm)	Balloon length (mm)	Catheter length (cm)	Guidewire compatibility	Sheath size (F)
2039-2010	2.0	10	137	0.014"	5F
2039-2020	2.0	20	137	0.014"	5F
2155-2040	2.0	40	155	0.014"	5F
2215-20100	2.0	100	137	0.014"	6F
2216-20100	2.0	100	155	0.014"	6F
2039-2520	2.5	20	137	0.014"	5F
2155-2540	2.5	40	155	0.014"	5F
2215-25100	2.5	100	137	0.014"	6F
2216-25100	2.5	100	155	0.014"	6F
2039-3020	3.0	20	137	0.014"	5F
2155-3040	3.0	40	155	0.014"	5F
2215-30100	3.0	100	137	0.014"	6F
2216-30100	3.0	100	155	0.014"	5F
2039-3520	3.5	20	137	0.014"	5F
2155-3540	3.5	40	155	0.014"	5F
2215-35100	3.5	100	137	0.014"	6F
2216-35100	3.5	100	155	0.014"	6F
2076-4020	4.0	20	137	0.018"	6F
2092-4040	4.0	40	90	0.018"	6F
2076-4040	4.0	40	137	0.018"	6F
2290-40100	4.0	100	90	0.014"	6F
2237-40100	4.0	100	137	0.014"	6F
2249-40200	4.0	200	137	0.014"	6F

Number	Balloon diameter (mm)	Balloon length (mm)	Catheter length (cm)	Guidewire compatibility	Sheath size (F)
2249-40200	4.0	200	137	0.014"	6F
2076-5020	5.0	20	137	0.018"	6F
2092-5040	5.0	40	90	0.018"	6F
2076-5040	5.0	40	137	0.018"	6F
2290-50100	5.0	100	90	0.014"	6F
2237-50100	5.0	100	137	0.014"	6F
2249-50200	5.0	200	137	0.014"	6F
2105-6020	6.0	20	50	0.018"	6F
2092-6020	6.0	20	90	0.018"	6F
2076-6020	6.0	20	137	0.018"	6F
2105-6040	6.0	40	50	0.018"	6F
2092-6040	6.0	40	90	0.018"	6F
2076-6040	6.0	40	137	0.018"	6F
2290-60100	6.0	100	90	0.014"	6F
2237-60100	6.0	100	137	0.014"	6F
2249-60200	6.0	200	137	0.014"	6F
2332-7040	7.0	40	50	0.018"	6F
2333-7040	7.0	40	90	0.018"	6F
2334-7040	7.0	40	137	0.018"	6F
2332-8040	8.0	40	50	0.018"	6F
2333-8040	8.0	40	90	0.018"	6F
2334-8040	8.0	40	137	0.018"	6F

Angiosculpt® Indications

- The AngioSculpt® PTA scoring balloon catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae

- Not for use in the coronary or neuro-vasculature

Study Design

- Objective: To determine safety and efficacy of the Angiosculpt PTA balloon in restoring AV fistula/graft access
- Prospective, single-arm, pilot study including 50 patients
- Primary endpoint: target lesion primary patency (i.e., functional AV access) at 2 and 6 months defined as freedom from re-intervention
- Safety endpoint: freedom from major device, procedure, and treatment site-related adverse events through 30 days post-procedure

Patient and Lesion Characteristics

Table 1. Patient and lesion characteristics.

Patient and lesion characteristics	All	Male	Female	*p* value
Numbers	50	23	27	
Age (years)	61.08 ± 10.62	57.74 ± 10.53	65 ± 9.496	$p=0.013^a$
Hypertension	96.00%	95.70%	96.30%	n.s.[b]
Hyperlipidemia	59.57%	60.90%	58.30%	n.s.[b]
Diabetes mellitus	52.08%	56.50%	48.00%	n.s.[b]
Coronary artery disease	28.57%	26.09%	30.77%	
Ethnicity				
African American	85.71%	81.82%	88.89%	n.s.[b]
Caucasian	12.25%	13.64%	11.11%	
Asian	2.04%	4.55%	0%	
Previous interventions				
None	24.00%	13.04%	33.33%	n.s.[b]
1	24.00%	30.43%	18.52%	
2–5	22.00%	26.09%	18.52%	
More than 5	20.00%	17.39%	22.22%	
Unknown	10.00%	13.04%	7.41%	
Stenosed graft	28.00%			
Stenosed AV fistula	72.00%			
Lesion locations				
Outflow stenosis	*42.00%*			
Cephalic arch stenosis	*24.00%*			
Intrafistular stenosis	*10.00%*			
Edge/intra-stent stenosis	*10.00%*			
Swing segment stenosis	*6.00%*			
Inflow stenosis	*4.00%*			
Intragraft stenosis	*2.00%*			
Anastomotic stenosis	*2.00%*			
Fistula age (years)	2.512 ± 2.1	2.824 ± 2.7	2.292 ± 1.6	n.s.[a]
Lesion length (mm)	4.56 ± 1.005	2.391 ± 1.076	6.4 ± 0.957	n.s.[a]

[a]Mann–Whitney.
[b]Fisher's exact test.
The shading and italics are for visualization purposes only.

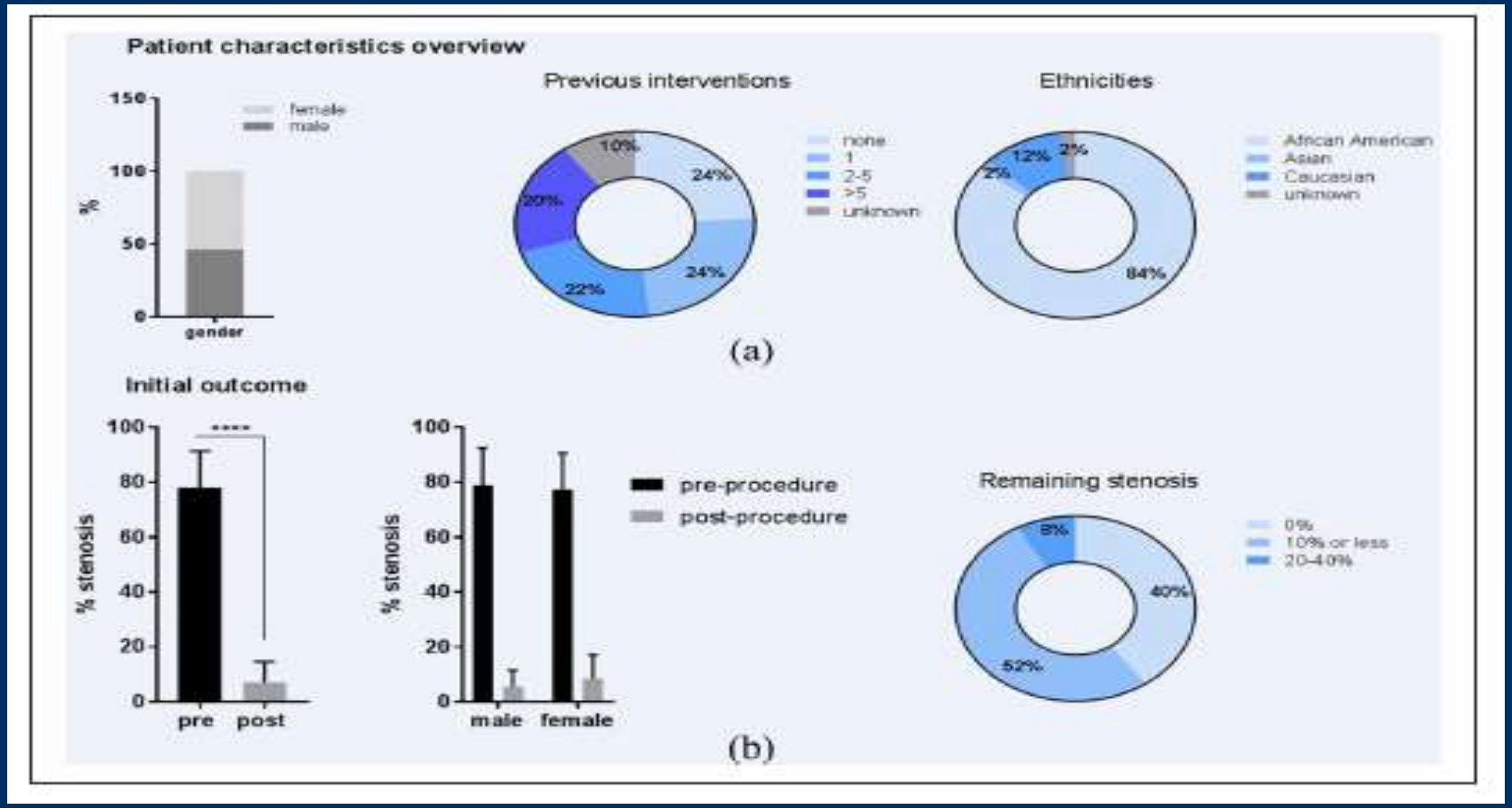
Procedural Characteristics

Table 2. Procedural characteristics.

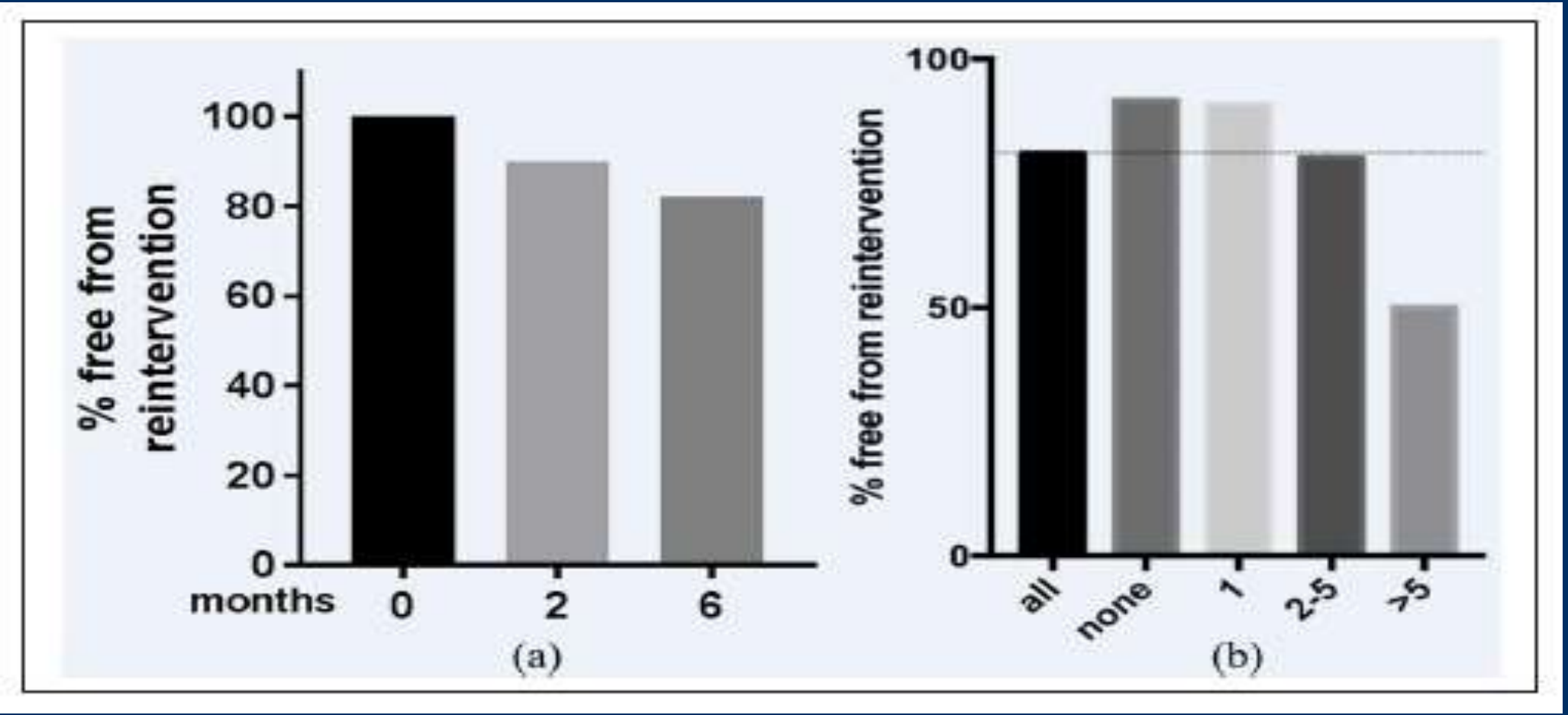
Procedural characteristics	Average	p value
Average inflation pressure (atm)	11.4 ± 1.6	
Post-scoring high-pressure balloon (%)	9 (18%)	
Pre-procedure stenosis	78 ± 13.4	$p < 0.0001$[a]
Post-procedure stenosis	7.2 ± 7.6	
Dissections (%)	0 (0%)	
Slippage (%)	0 (0%)	

[a]Wilcoxon's matched-pairs signed rank.
The shading is for visualization purposes only.

Patient Characteristics and Initial Outcomes



Percentage of Patients Free from Re-intervention of Total Enrolled (N = 50)



Conclusions

- Results from this single-center pilot study suggest that the AngioSculpt® scoring balloon may be a viable treatment option for stenosed AV fistula/graft access
  - Patency (functional AV access) 6-months: 80.9%
  - No device or procedure-related complications through 30 days post-procedure
- Further research from well-controlled, randomized trials is needed