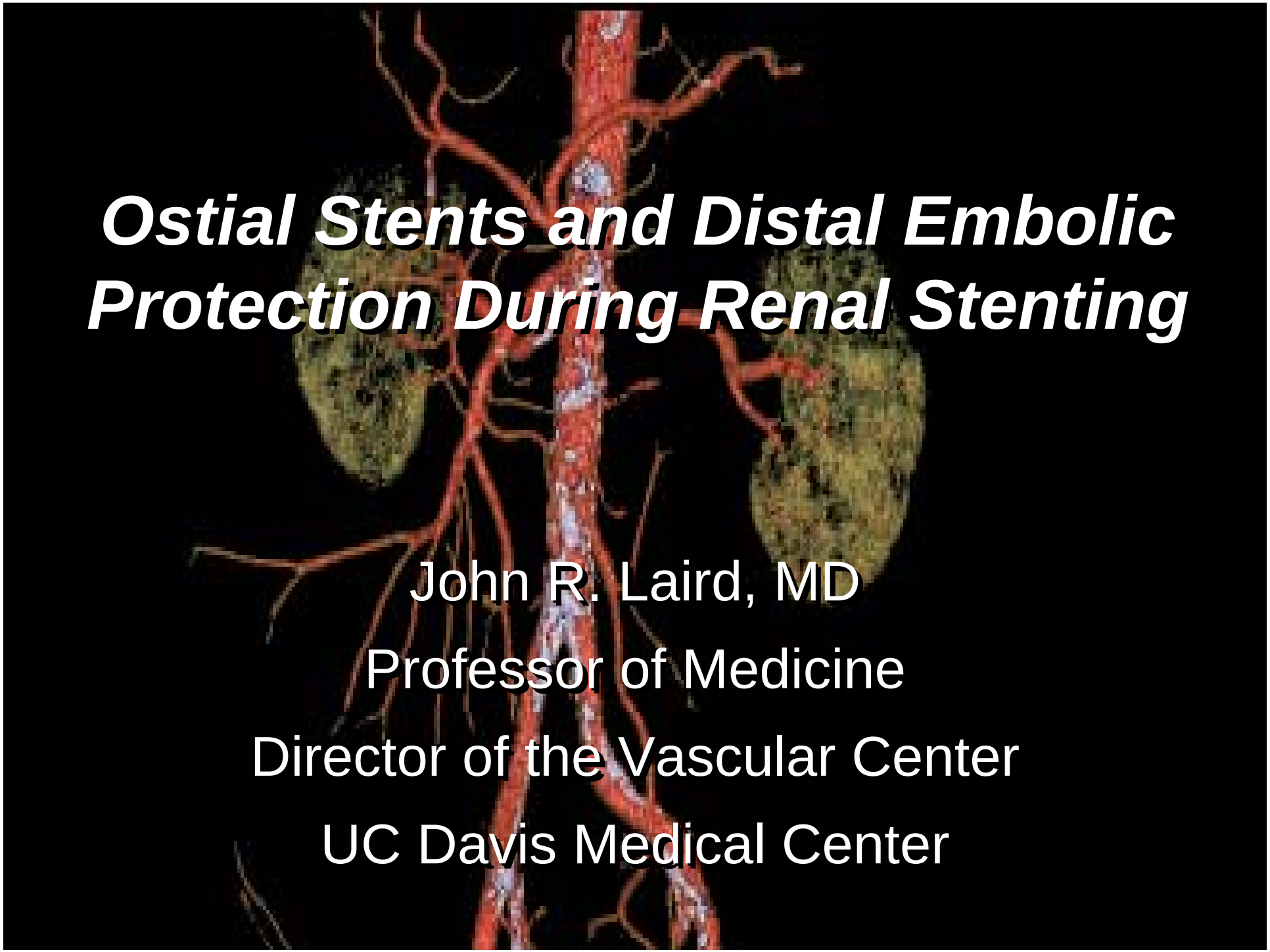

Ostial Stents and Distal Embolic Protection During Renal Stenting

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Professor of Medicine

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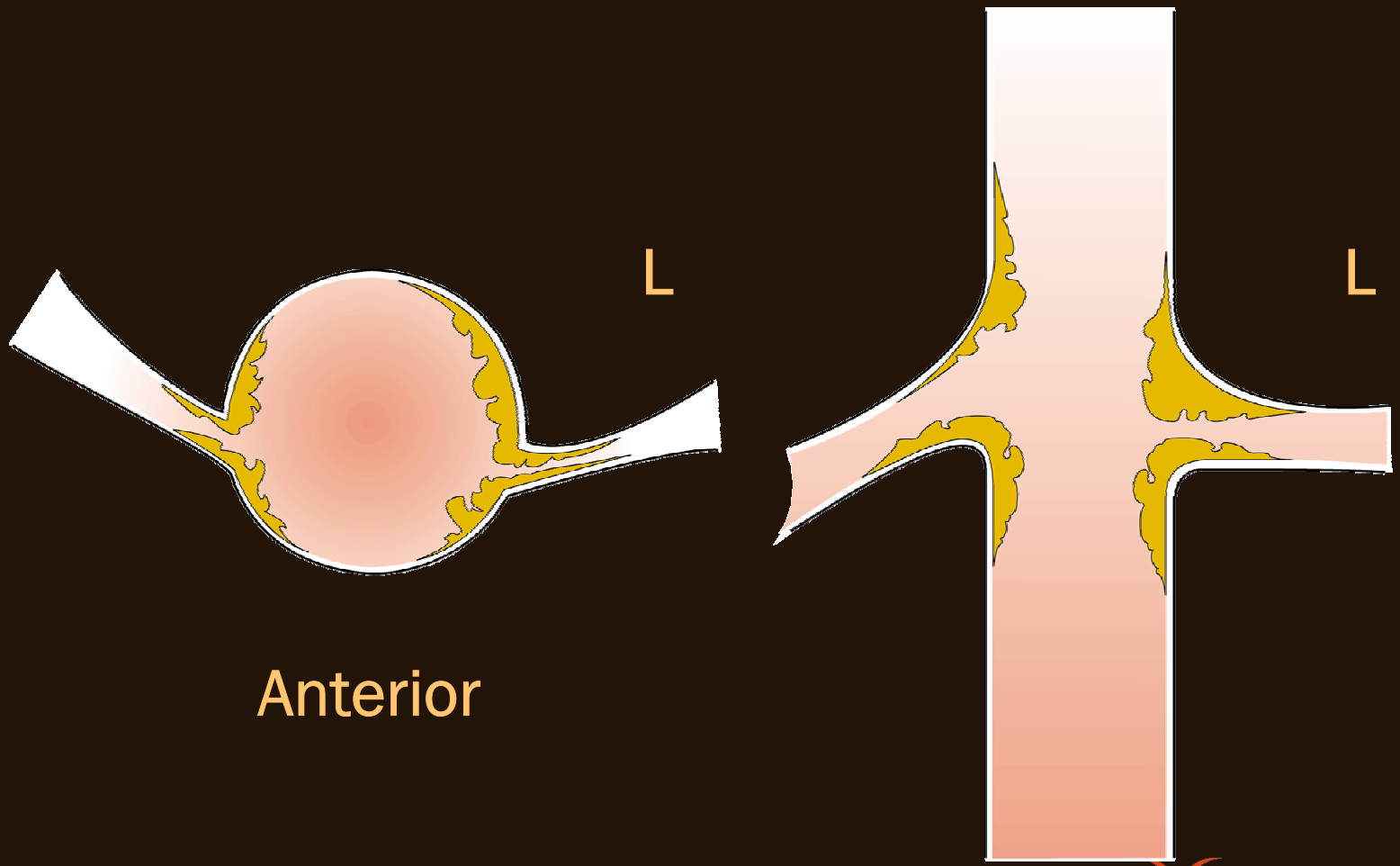
UC Davis Medical Center

Limitations of Current Techniques of Renal Stenting

- Inaccurate treatment of the renal ostium
- Inadequate lesion coverage
- Excess contrast use during the procedure
- Distal embolization during the procedure – despite a technically successful procedure, 20-30% of patients will have deterioration of renal function

BullsEye

Aorto-ostial Disease



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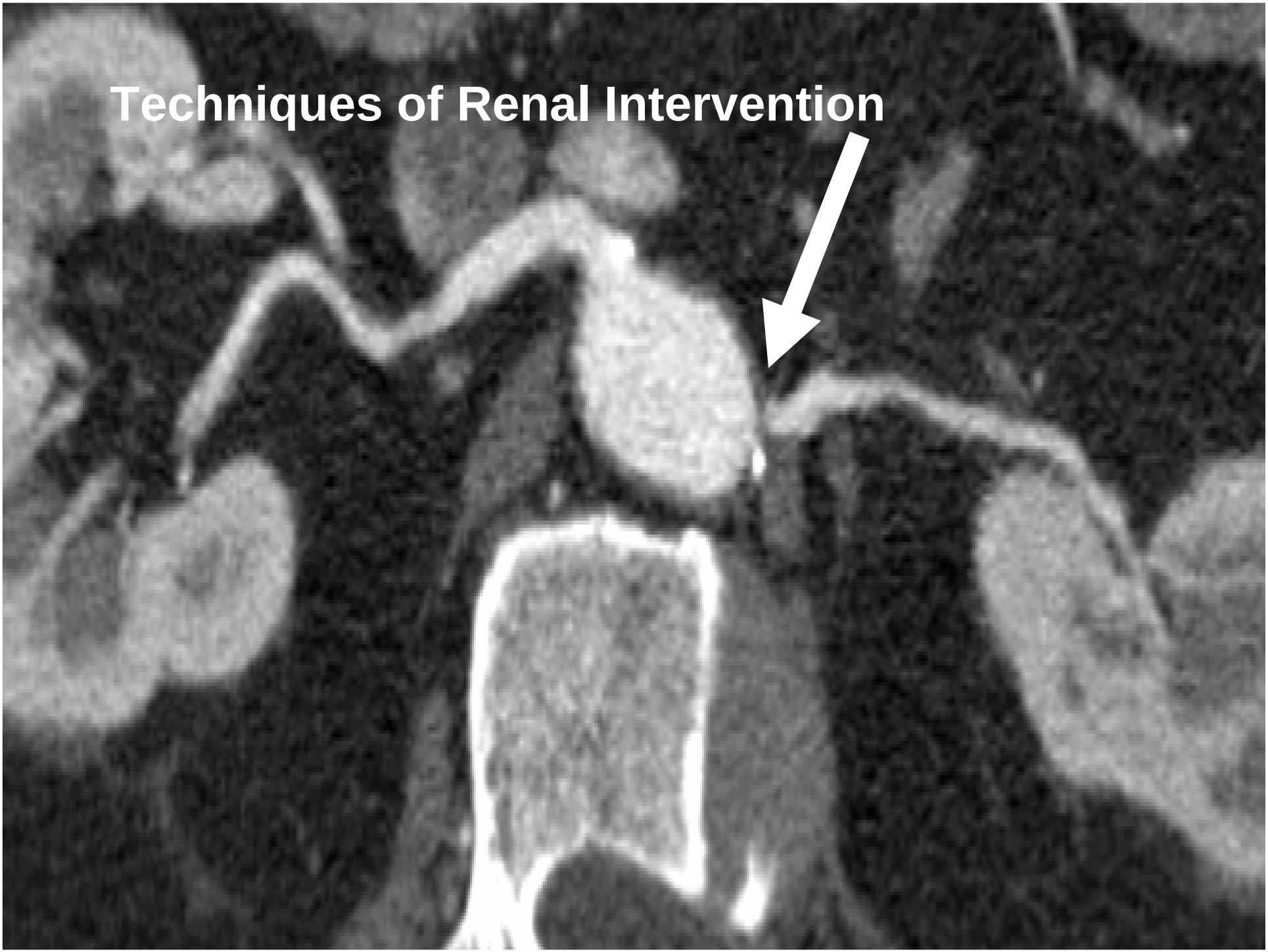

Techniques of Renal Intervention

Unique Challenges with Aorto-Ostial Stenting

Inaccurate Placement

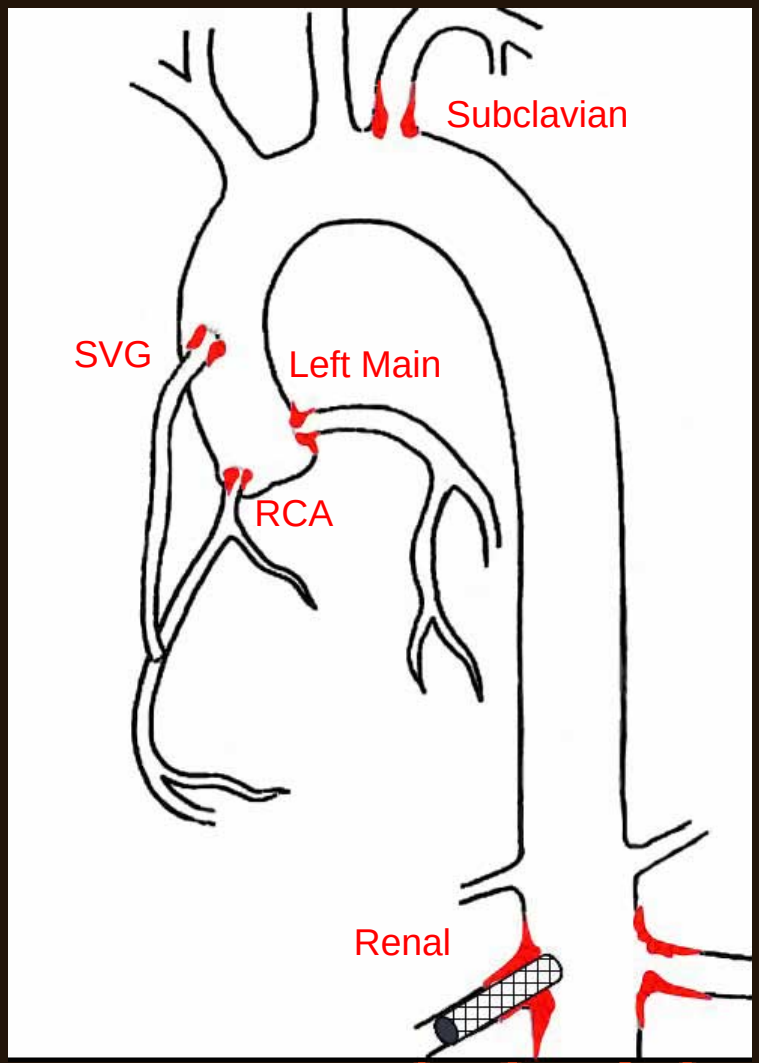
- Not predictable
- Difficult to visualize the ostium

Geometric Mismatch

- Cylindrical stent, funnel shaped anatomy
- Incomplete scaffolding

Re-Cross Difficulties

- Stent damage or migration
- Guidewire entanglement in stent struts

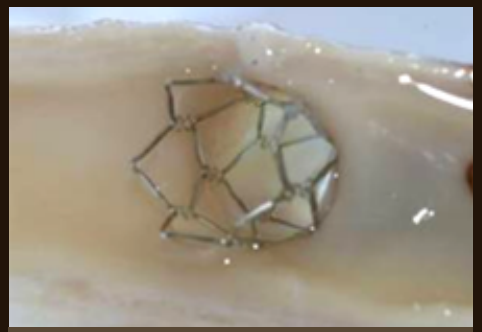


BullsEye Ostial Stent System (SquareOne, Inc.)

BullsEye Visualized with CTA

Flared stent tailored to the unique anatomy of the aorto-ostial junction

- Delivery system enables rapid, precise ostial location

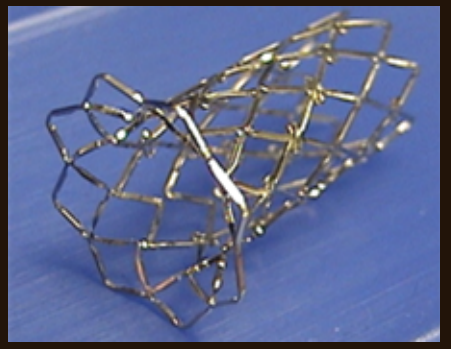


Straight Stent: ~2mm Aortic Protrusion

BullsEye Flare Conformed to Aorta

BullsEye

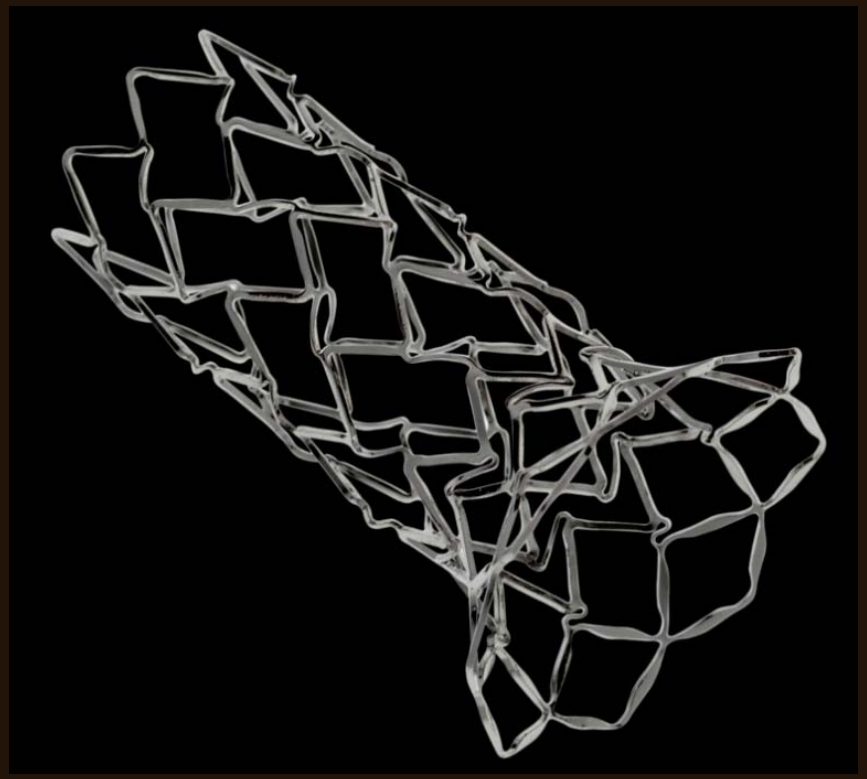
BullsEye Ostial Stent System (SquareOne, Inc.)

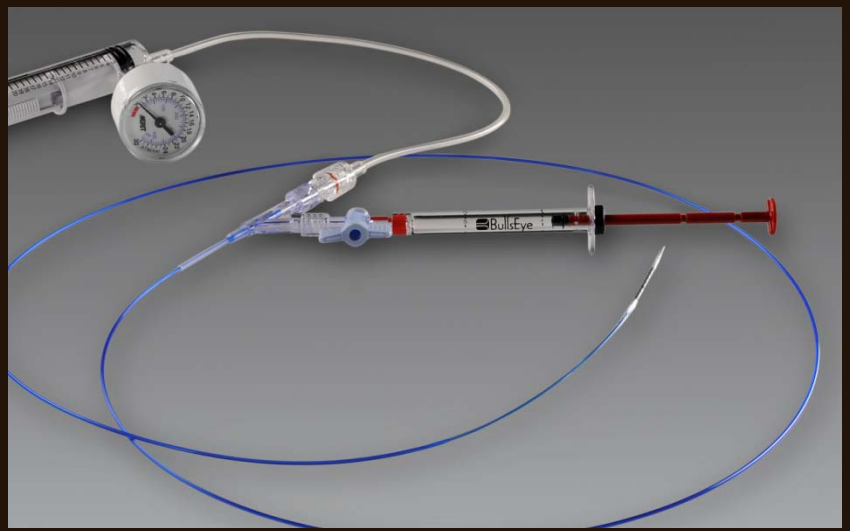
Feature	Ostial Locator Balloon	Conformable Flare
		
Function	**TACTILE POSITIONING** Physically “stops” the stent at the ostium	**OSTIAL CONTOURING** Increased proximal scaffolding
Clinical Benefit	↓ Geographic Miss ↓ Contrast ↓ Procedure Time	↑ Ostial Coverage ↑ Ease of Re-Cross ↓ Stent Damage/Migration

BullsEye

Technology Specifications

Stent	316L BMS
Stent Diameter	5mm, 6mm
Stent Length	15mm
Cell Design	Closed
Dual Balloon Inflation	Locator (Volume) Distal (Pressure)
Guide Compatibility	7F
Usable Length	135cm





BullsEye

BullsEye Stent Procedure

BOSS-1 Study

Purpose	Evaluate deployment and support of BullsEye Ostial Stent System for renal ostial stenoses
Design	Prospective, non-randomized first in man feasibility study
Control	Historic comparison based on literature review
Size	25 patients; 3 EU Centers (Leipzig, Siegburg, Frankfurt)
Primary Endpoint	Acute procedural success: • Angiographic success (residual % DS<30%) • Absence of procedure related (MAE) death, embolic events, TLR

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BOSS-I Demographics & Baseline Characteristics

Patients (n)	25
Female	72% (18/25)
Age	69 ± 10 years
Diabetes	56% (14/25)
Blood Pressure (mm Hg) Systolic Diastolic	 157 ± 22 82 ± 10
Serum Creatinine (µmol/l)	100 ± 43
Kidney Length (cm)	10.0 ± 0.8
Target Lesion Location (per patient) Right Kidney Left Kidney	 44% (11/25) 56% (14/25)
Target Lesion Characteristics (per procedure) Diameter stenosis Target vessel angle Reference vessel diameter	 82% ± 9% 81° ± 9° 6.1mm ± 0.3mm

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BOSS-I Acute Results

Technical Success	100% (25/25)
Acute Procedural Success	100% (25/25)
Procedural Complications (dissection, thrombosis, perforation)	0% (0/25)
Major Adverse Events (death, target lesion revascularizations, embolic events)	0% (0/25)
Procedure time (mean)	26 minutes
Successful stent positioning & deployment (angiographic confirmation)	100% (25/25)
Successful re-cross of lesion/stent	100% (25/25)

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BOSS-I 12M Results

MAE (%)	8.0 (2/25)	
Death	0% (0/25)	
TLR (189 and 257 days post treatment)	8.0% (2/25)	
Embolic Events	0% (0/25)	
Blood Pressure (mm Hg)	Baseline	12 Months
Systolic	157 ± 22	141 ± 18
Diastolic	82 ± 10	83 ± 8
Antihypertensive Medications	3.0 ± 1.6	2.5 ± 1.4
Serum Creatinine (µmol/l)	100 ± 43	103 ± 34

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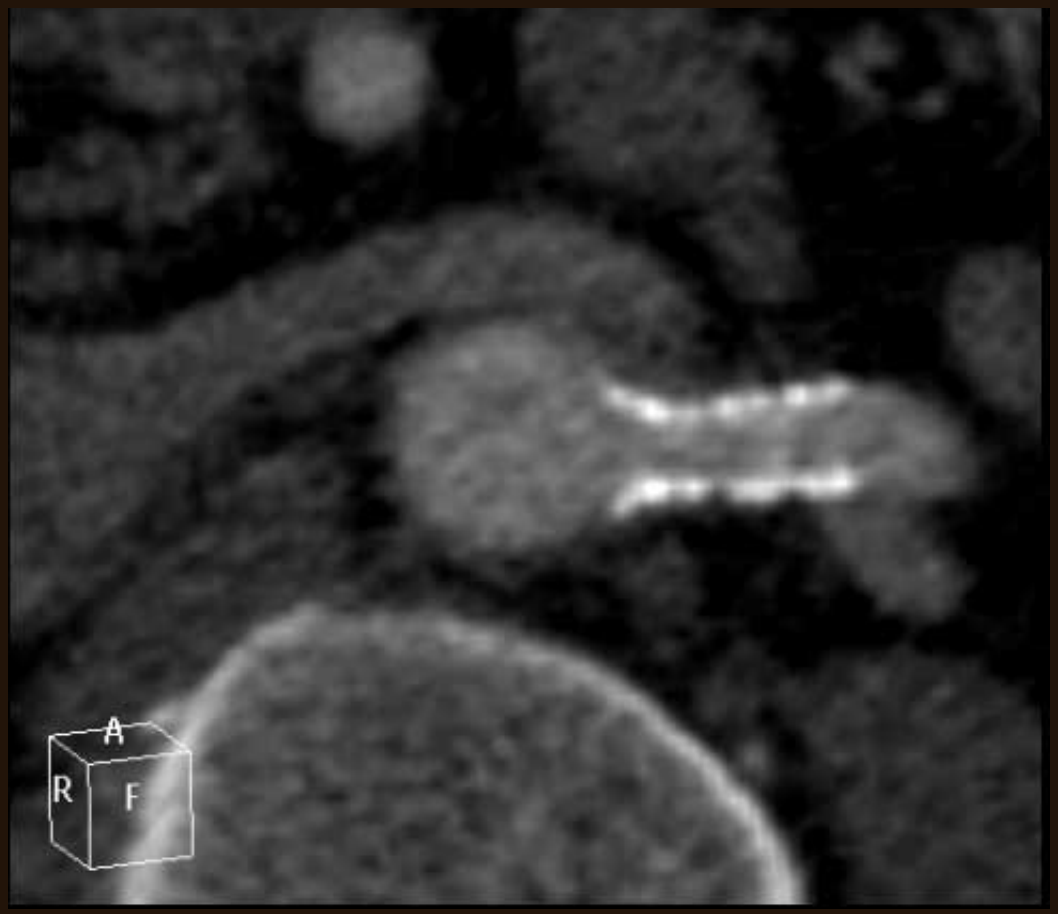
Post Procedure Result

Post Procedure Result



Summary

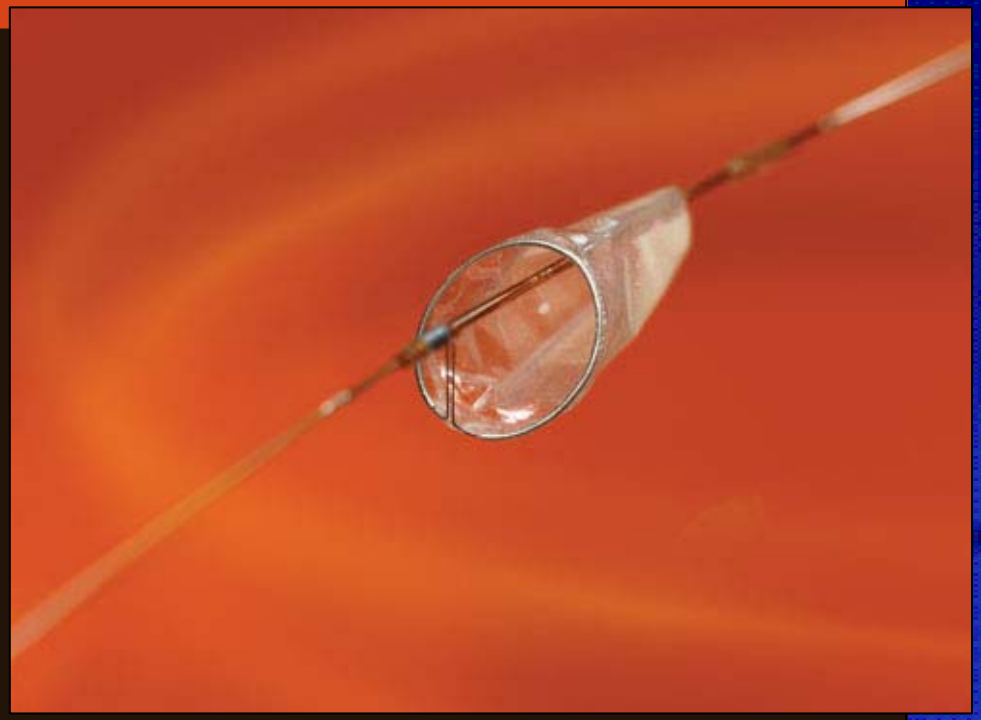
Primary endpoint of Acute Procedural Success met in 100% of cases (24/24)

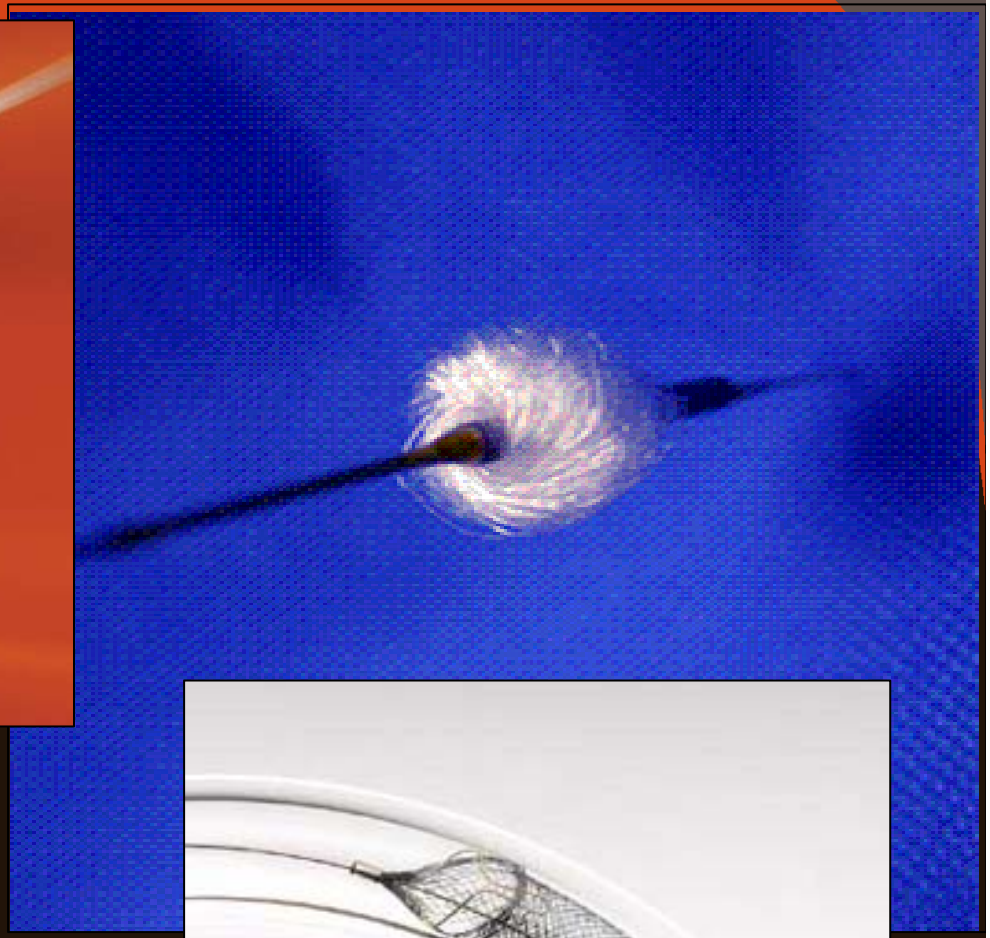
No observations of geographic miss or stent protrusion into aorta

Flared stent enabled immediate re-cross in all cases

Promising response at 12 months with regards to restenosis and BP response

Distal Embolic Protection in RAS



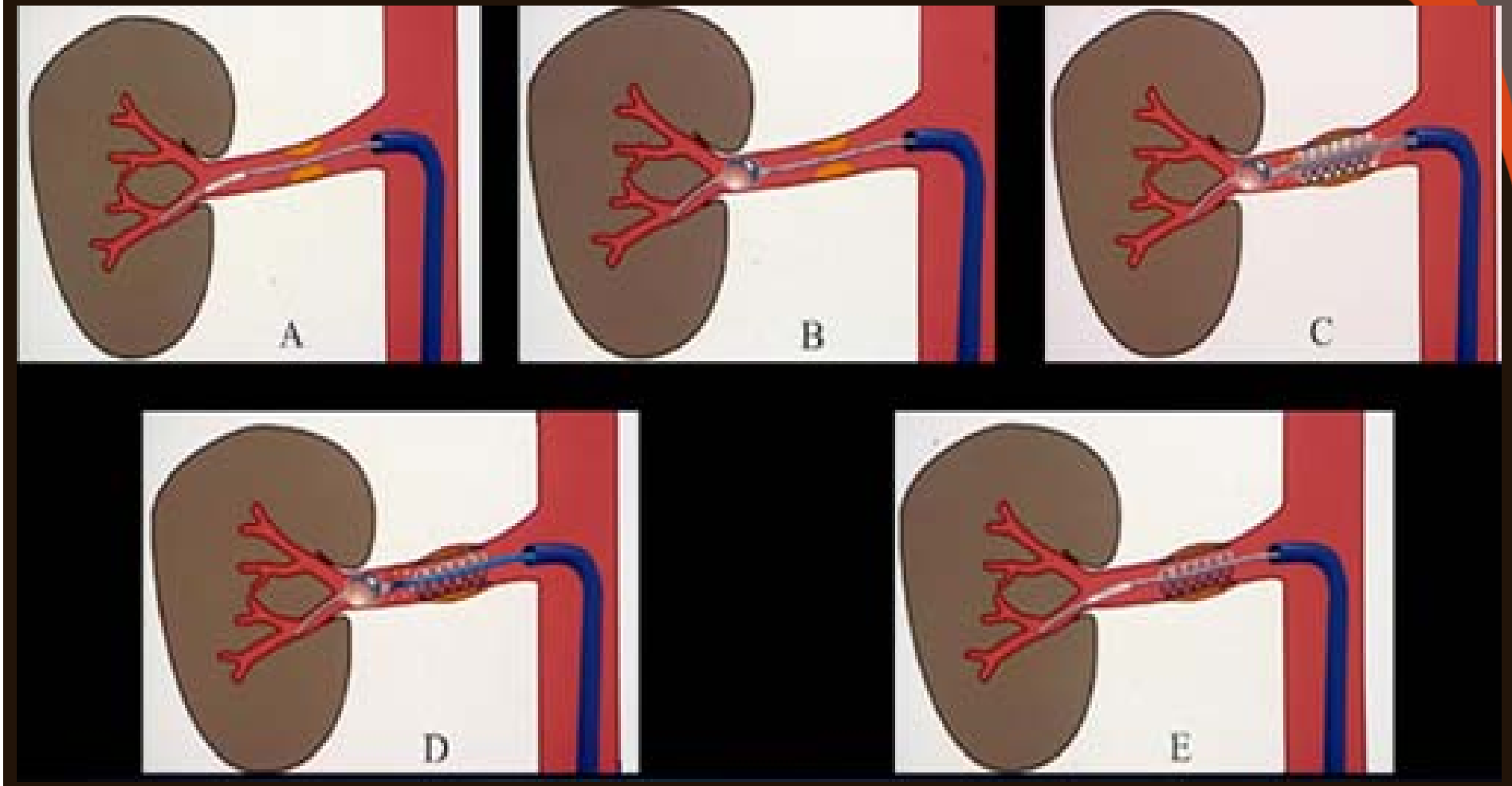


Current Challenges

- No device specifically designed for renal embolic protection
- Anatomic challenges
  - Early renal artery bifurcation
  - Large diameter renal artery
  - Short length of main renal artery
- Increased procedural complexity

BullsEye

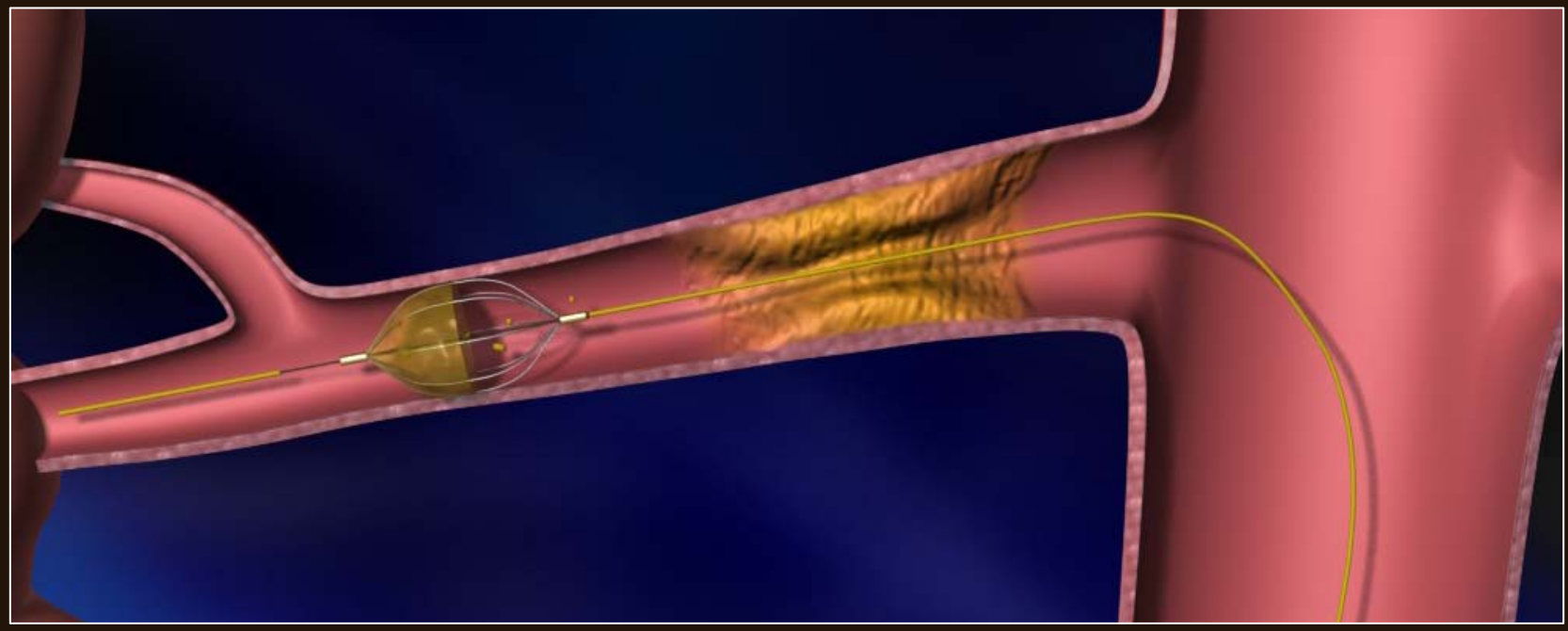
Optimal Renal EPD?



Distal Filtration

Enables maintenance of flow throughout the procedure

May allow small but important particles through



Renal Artery Stenting with EP in Patients with Ischemic Nephropathy

83 arteries treated in 63 consecutive patients from May 2002 to February 2005

All patients had baseline CRI with a documented decline in renal function over the preceding 6 months

CE-MRA used in the work-up in all patients

All patients had an identical “primary filter passage” technique and stenting

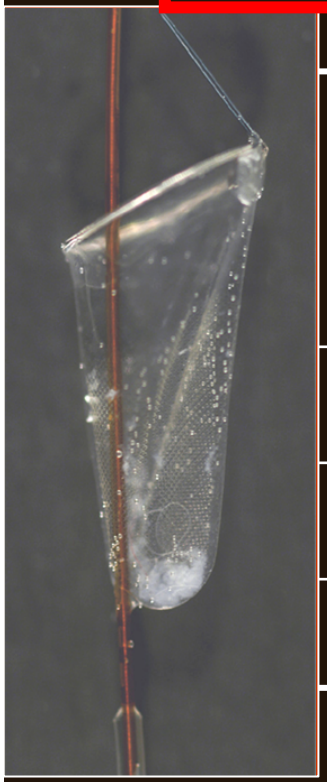
All patients had a minimum 6 months follow up

Holden, et al. Kidney International, 2006

Filter Contents

(in pts that did not deteriorate)

Macroscopic emboli present in 38/63 filters (60%)



Filter contents	Improved	Stabilized or Unchanged Decline	Total (%)
Positive	20	18	38 (60%)
Negative	5	20	25 (40%)
Total	25	38	63 (100%)

Even Patients with positive filter contents had significantly improved outcome (p= 0.01)

Holden, et al. Kidney International, 2006

Renal Artery Stenting with EP in Patients with Ischemic Nephropathy

Level of pre-intervention CRI

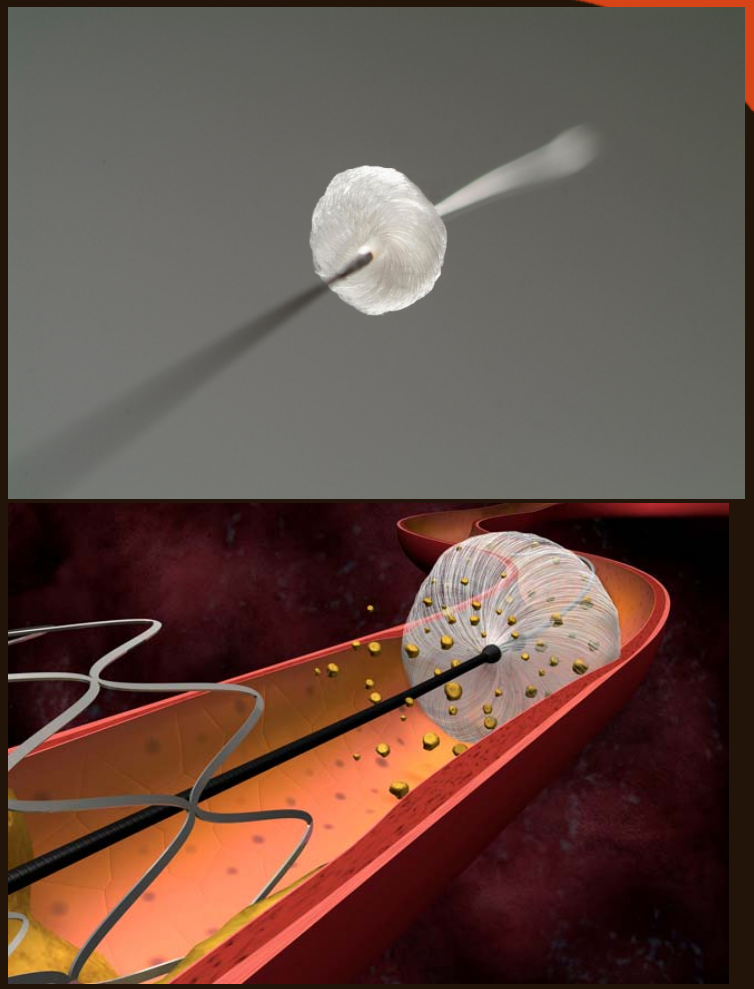
	Mild	Moderate	Severe	Total
Improved	12(52%)	8(32%)	5(33%)	25(40%)
Stabilized	11(48%)	15(60%)	10(67%)	36(57%)
Unchanged decline	0(0%)	2(8%)	0(0%)	2(3%)
Total	23	25	15	63

97% of patients had improved or stabilized renal function at 6months

Holden, et al. Kidney International, 2006

Fibernet-Lumen Biomedical

- Fiber based filter
- Low crossing profile
- 100 micron
- Vessel conformable
- Aspiration and retrieval required
- EPIC- US pivotal trial
- RETRIEVE-US IDE



The FORTRESS Trial

- 20 patient feasibility trial
- 5 US sites
- Trial Sponsor: VIVA Physicians

Conclusions

The Bullseye ostial stent system has the ability to improve the results of renal stenting by increasing the accuracy stent placement, reducing contrast use, and improving ostial coverage

Embolic protection has the potential to increase the safety of the procedure and better protect the kidney against the consequences of distal embolization