CCC Live Case:
Percutaneous Transmural Arterial Bypass (PTAB) of Recurrent SFA CTO

Division of Endovascular Interventions

The Mount Sinai Hospital

Wednesday, April 24, 2024

Mount Sinai Hospital

History of Presenting Illness

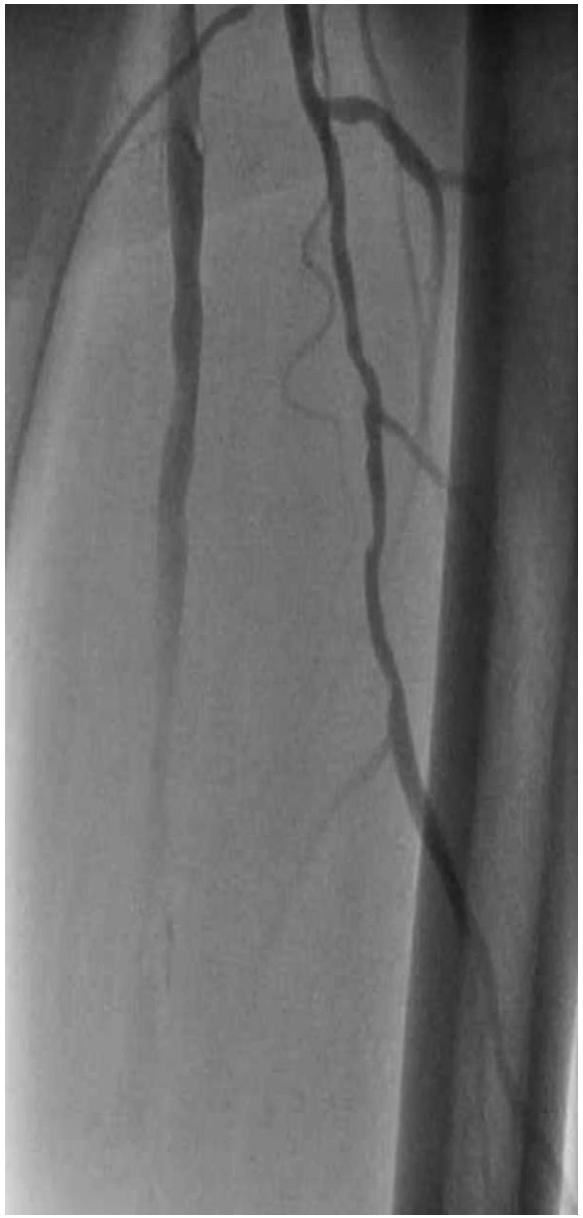
66 year-old gentleman referred for lifestyle-limiting claudication progressive to ischemic rest pain (L>R) with < 1 block of activity (Rutherford Grade II, Category 4). Symptoms began to worsen again 5-6 months ago.

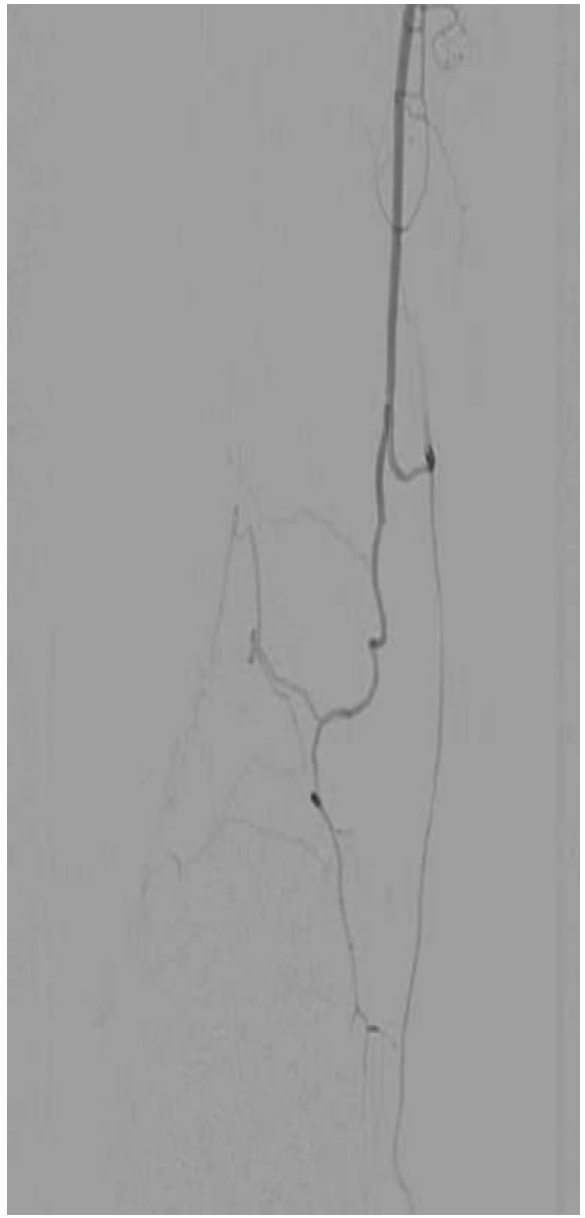
PMHx: PAD s/p multiple interventions (recurrent CTO of left SFA), HTN, HLD, IDDMII

Social Hx: Never smoker

Medications: Aspirin, Plavix, Atorvastatin, Protonix, Losartan, Amlodipine, Insulin

Peripheral Diagnostic Angiogram



Left Leg Arterial Evaluation

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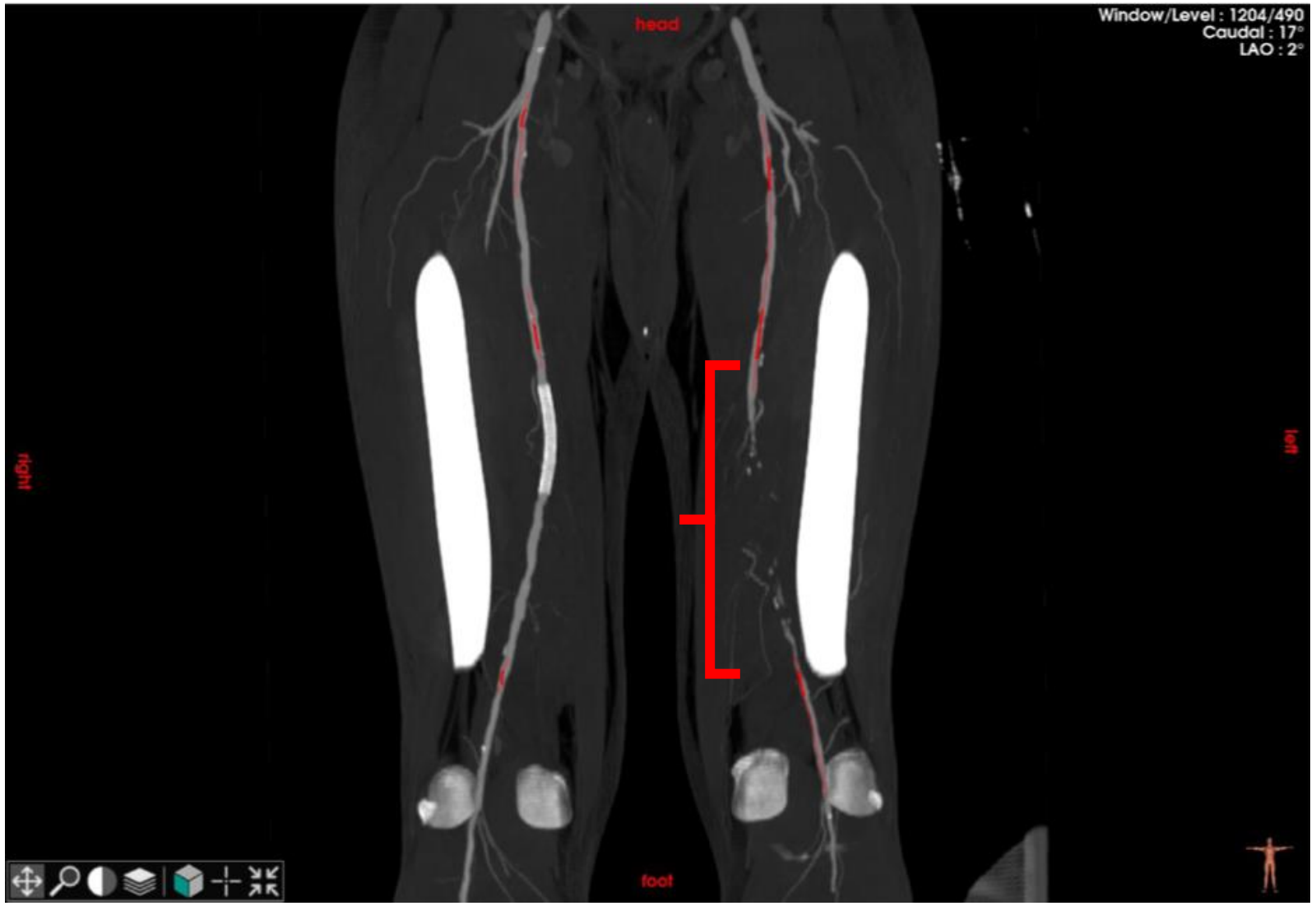
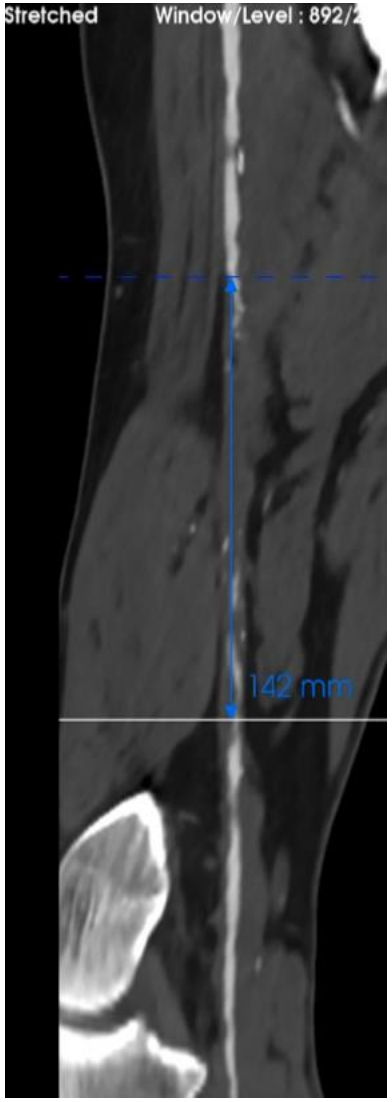
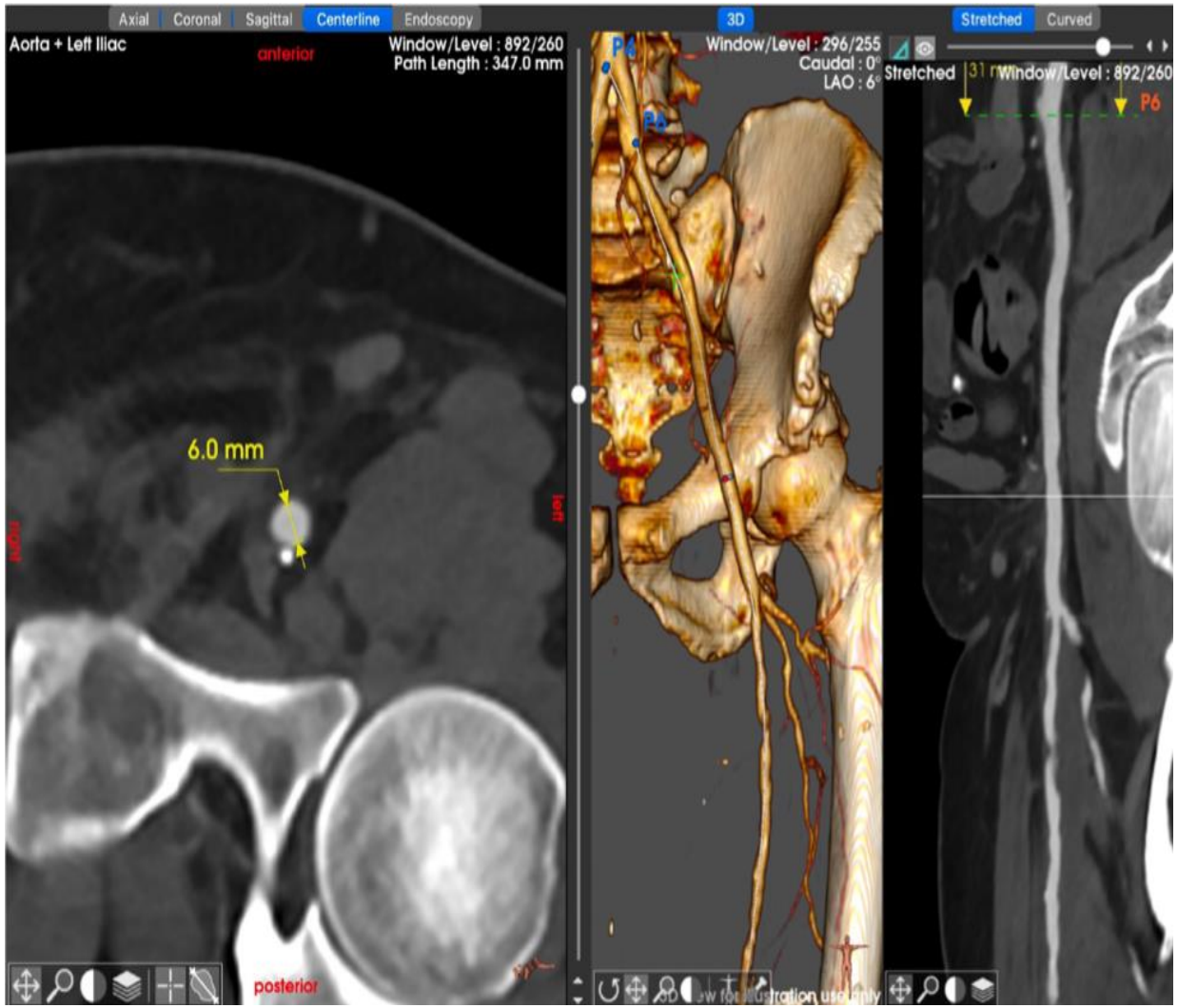
CTA Abdominal Aorta with Bilateral Runoff

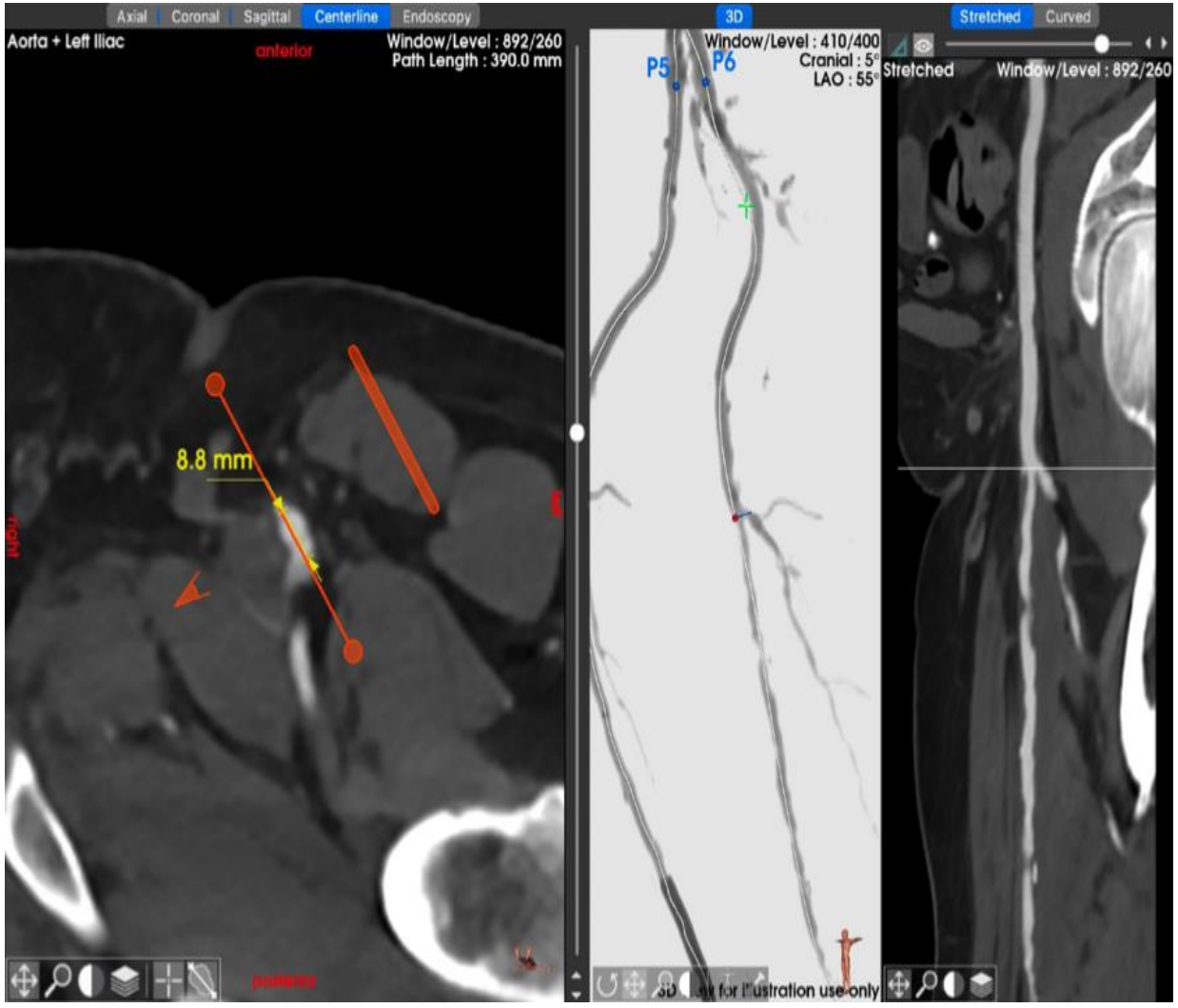




CTA Abdominal Aorta with Bilateral Runoff

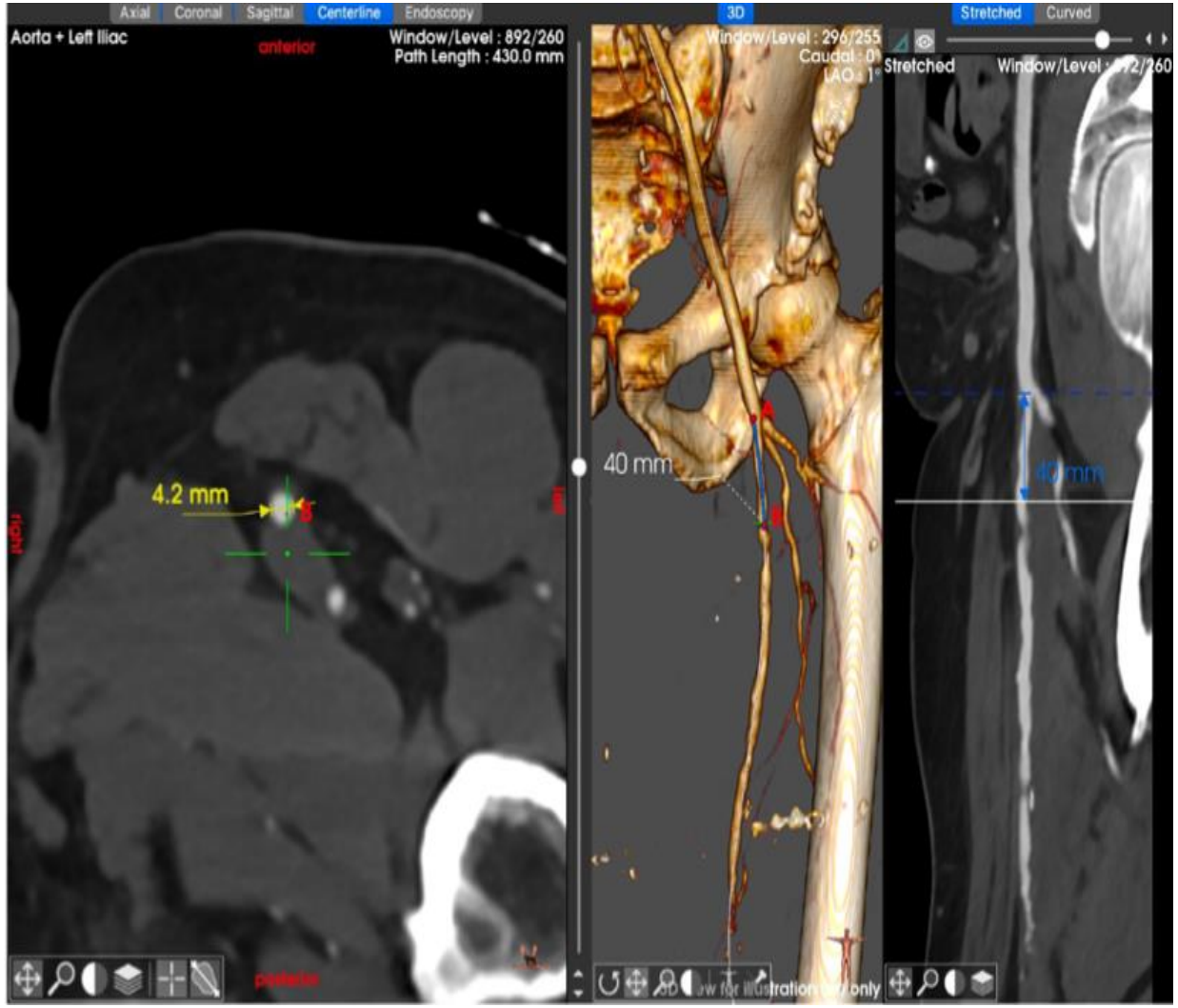


Left CFA Dimensions

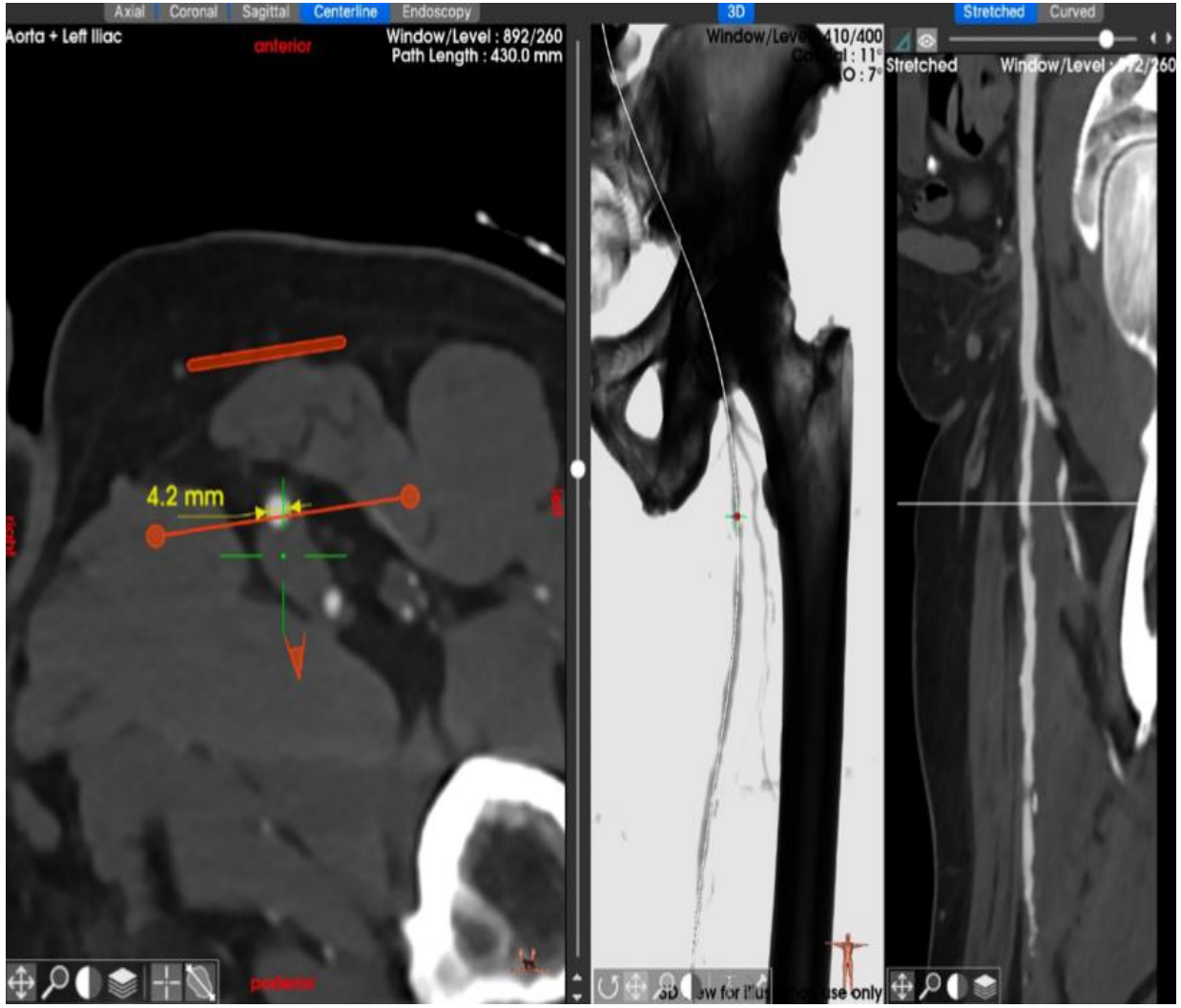


Left PFA/CFA Bifurcation Angle

CTA Abdominal Aorta with Bilateral Runoff

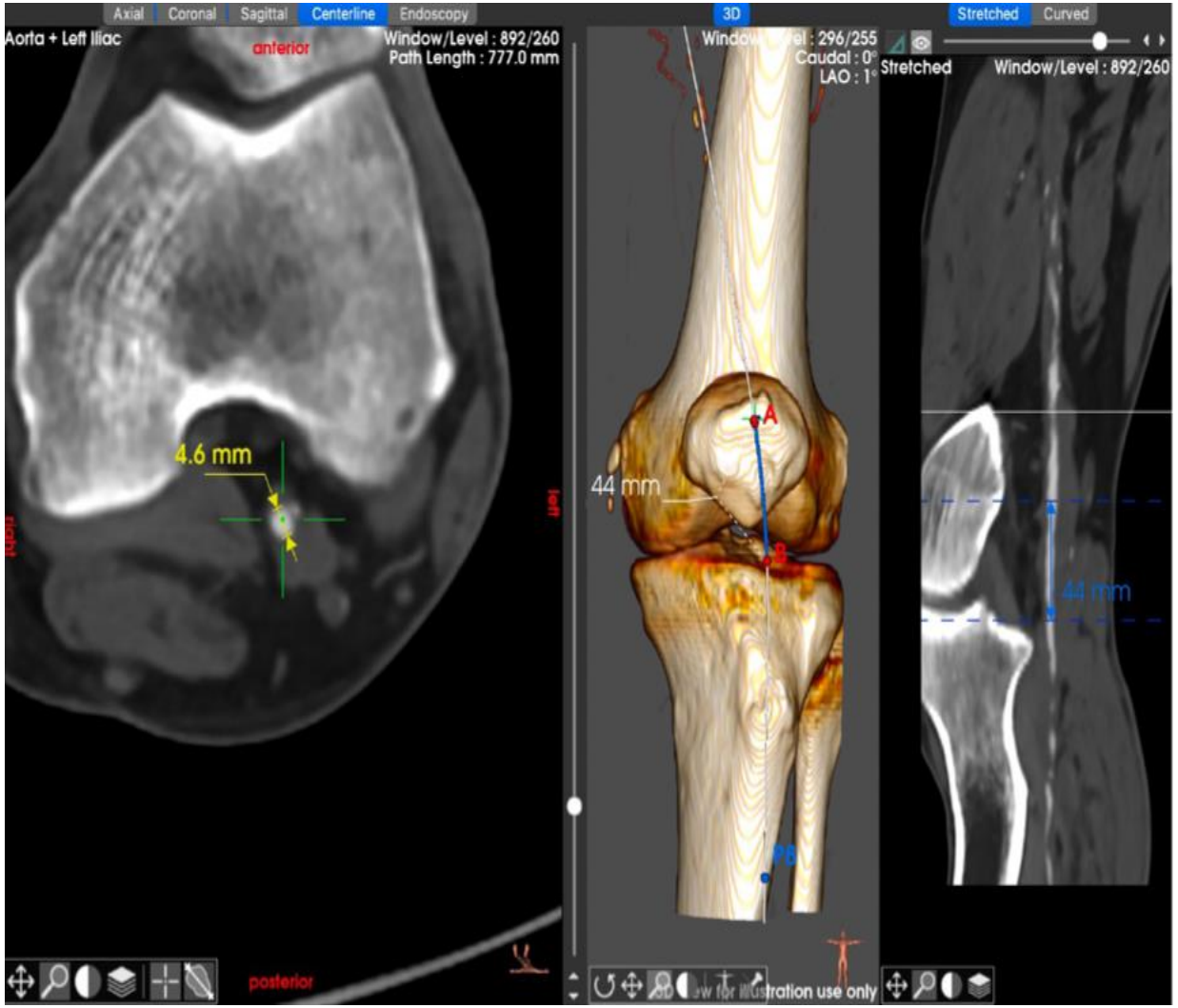


Left Proximal Landing Zone

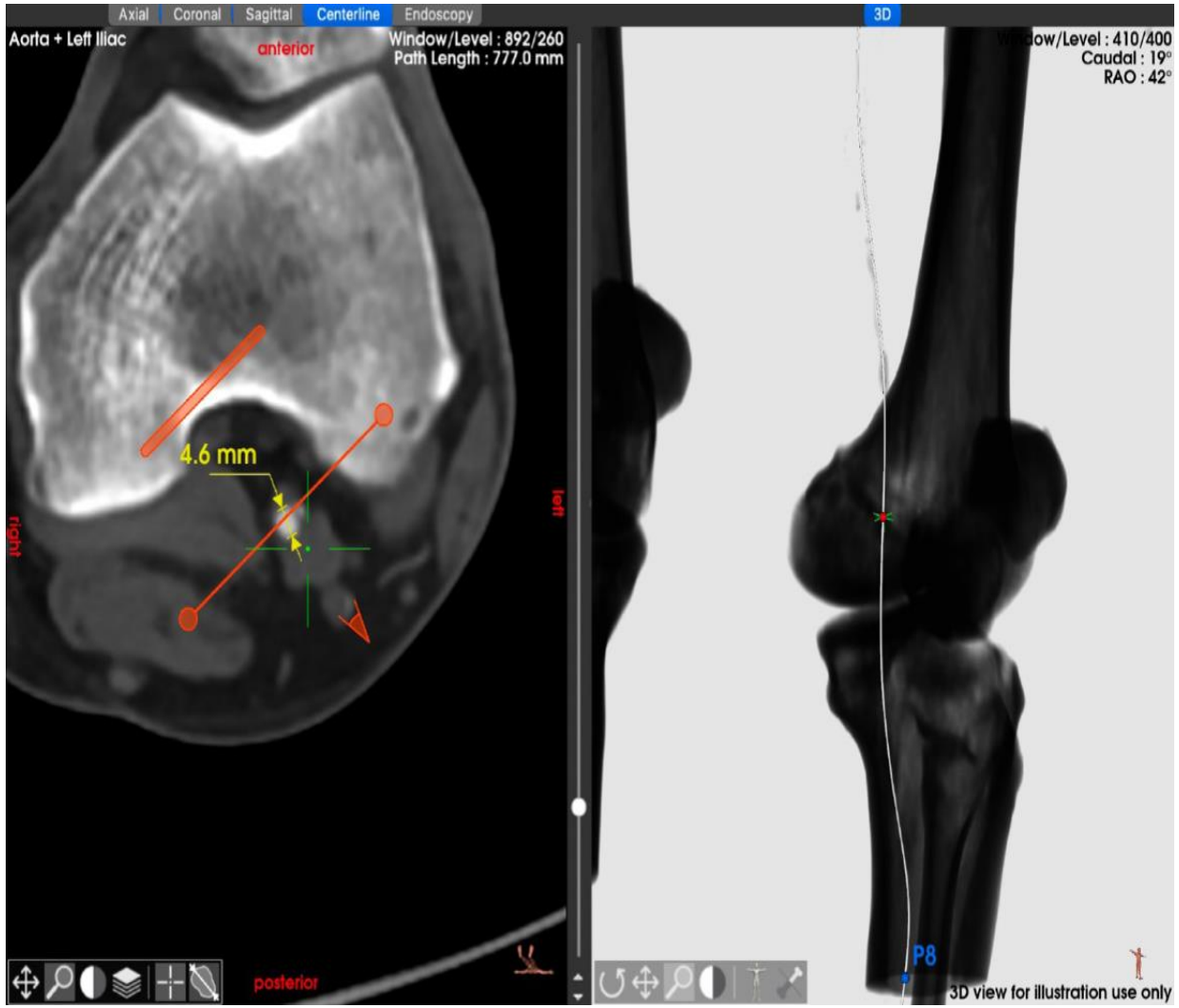


Left Proximal Anastomosis Angle

CTA Abdominal Aorta with Bilateral Runoff



Left Distal Landing Zone



Left Distal Anastomosis Angle

Left Leg Venous Evaluation

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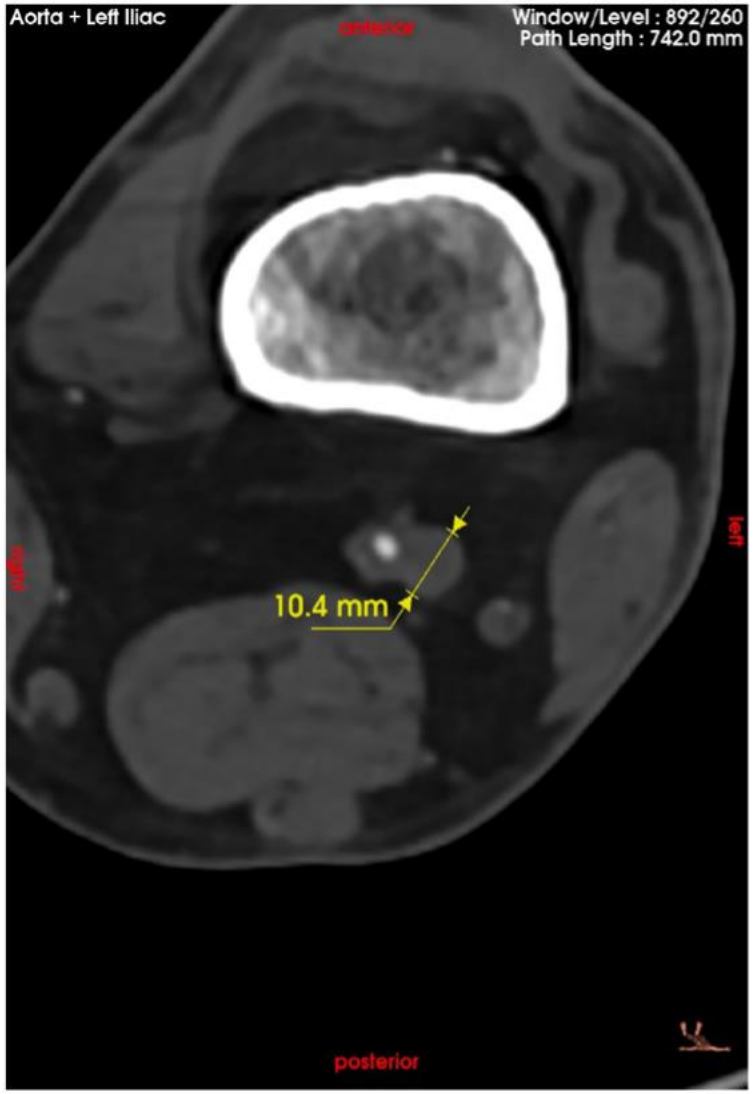
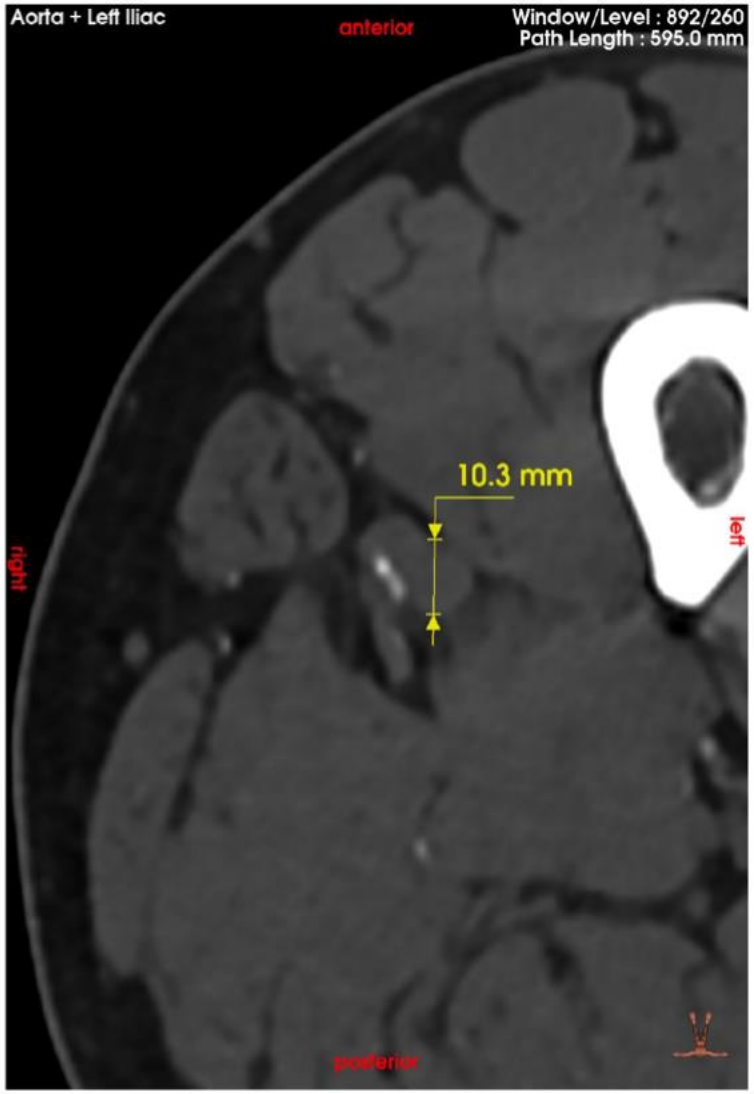
Left Femoral Vein Measurements





Case Plan

Pre-Procedure

- Verify Runoff
- Assess aortic bifurcation and iliacs bilaterally
- CTA indicates at least 2V runoff to foot, confirm with angiogram
- Assess femoral vein with venogram CT shows adequate FV
- Consider use of long 6 Fr venous sheath 23 cm or 25 cm

TORUS Configuration (Distal to Proximal)

- 5.5 x 200 – *Verify with angiogram, potential to use 6.0 mm*
- 6.0 x 200 – *Use 6.7 x 200 if 6.0 x 200 is used distal*
- 6.7 x 200 – *Verify with marking tape, 150mm will be available if needed*

- ≥6 cm of overlap distally

Landmark for Proximal Crossing: 3-4 cm below SFA/Profunda bifurcation base of the ischium
Distal Crossing landmark: Just above or at level of the top of the patella
Landing zone landmark: 1-2 mm proximal to the knee joint space

Procedure Consideration/Watchouts:

- L SFA pre dilate 5x4 balloon

Torus Stent Size	Quantity Needed
5.5 x 200	1
6.0 X 100	
6.0 X 150	2
6.0 x 200	2
6.7 x 100	1
6.7 x 150	2
6.7 x 200	2

ENDOCROSS	Quantity Needed
ENDOCROSS	2

Device	Suggested Devices	Qty.	Purpose
Access (Micropuncture) Kit	Echogenic Tip	1	Venous/Arterial Access
Ultrasound/Sterile Tornquet		1	Venous Access
4-6 Fr Introducer Sheath	Suggested: 10 cm - 23 cm	1	Venous Access
8 Fr Contralateral Introducer Sheath	Suggested: 45 cm, 65 cm, 71 cm Example: Ansel, Destination, Destino (8.5 Fr)	1	Arterial Access
0.035" x 180 cm Glidewire or Stiff Glidewire	Example: Advantage	1	Venous Snare Delivery
0.035" x 180 cm Stiff Wire	Example: Amplatz Superstiff	1	Arterial Contralateral Sheath Delivery
0.014" x 190 cm Support Guidewire*	Example: Spartacore, Thruway	1	ENDOCROSS™ Device Delivery
0.014" x 300 cm Support Guidewire	Suggested: Hydrophobic Guide Wires Example: Nitrex Wire, Ironman, Grandslam, Thruway, Spartacore	2	Anastomosis Creation
0.035" x 300 cm Support Guidewire	Example: Supra Core, VersaCore	1	TORUS™ Stent Graft Delivery
PTA Balloon Catheter	Suggested: 4 mm x 40 mm, 5 mm x 40 mm Example: Armada 14, Coyote	2	Anastomosis Dilatation Pre-dilate SFA, if needed
PTA Balloon Catheter	Suggested: 6 mm & 7 mm x 100 mm	2	Stent Graft Dilatation
Inflation Device		1	Balloon Inflation
Exchange Catheter	Suggested: 0.014" (150 cm) and 0.035" (135 cm) Example: CXI, Trailblazer, Quickcross	2	Guidewire Exchange
Sizing/Measuring Catheter/ Adhesive Radiopaque Measuring Tape		1	Graft Length/Overlap
Snare	Example: EnSnare 9 - 15 mm, 12 - 20 mm Gooseneck 10 mm or 15 mm	1	Guidewire Externalization

Endologix

DETOUR System

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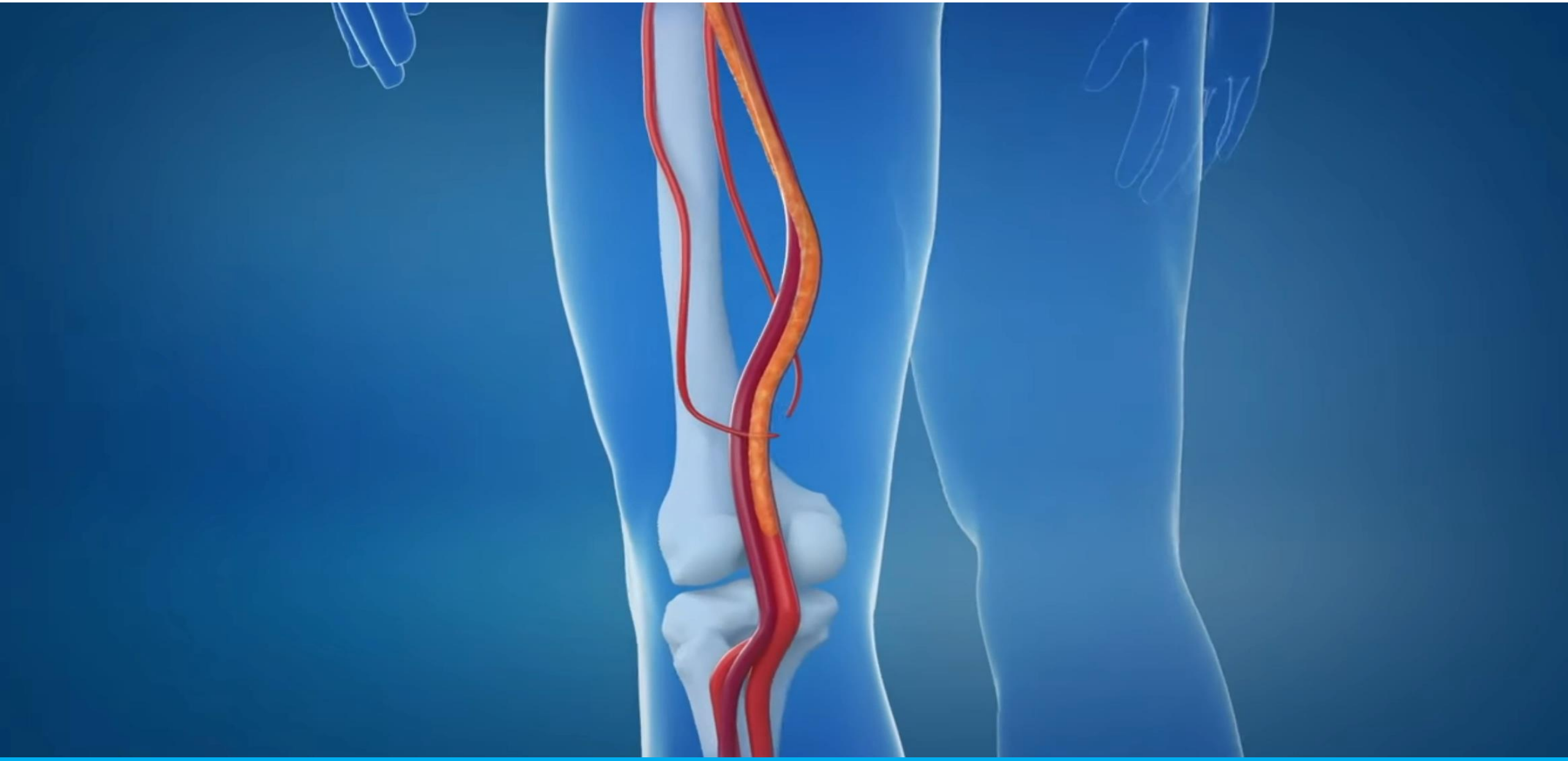
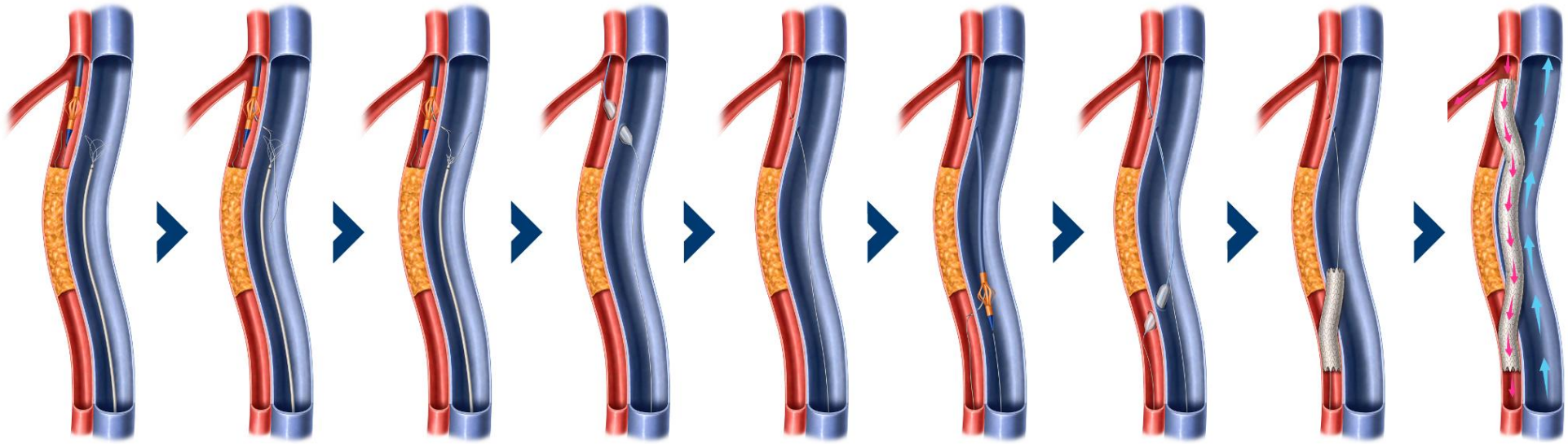
DETOUR System



DETOUR System

PTAB with the DETOUR System utilizes the femoral vein to bypass long lesions in the SFA.



Under fluoroscopic guidance, the DETOUR System creates a femoropopliteal bypass routed through the femoral vein, delivering unobstructed flow from the superficial femoral artery to the popliteal artery.

DETOUR 2 Clinical Data

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DETOUR 2

Objective: Prospective, single-arm, multi-center clinical evaluation of the DETOUR™ System and Procedure for a percutaneous Fem-Pop bypass	
N Patients	202
N Sites	36
Regions	US and Europe
Enrollment Period	Dec 13, 2017 -Oct. 5, 2020
Follow Up	30 Days, 6M, 12M, 24M, 36M
Duplex Core Lab	✓
Angiographic Core Lab	✓
Clinical Events Committee	✓
Data Safety Monitoring Board	✓
Primary Safety Endpoint	MAE at 30D (Death, CDTLR, Amputation, DVT, PE, Major Bleeding)
Primary Efficacy Endpoint	Patency at 12M (defined as the absence of CD-TLR and PSVR of >2.5 within the stent
	Additional economic sub study

DETOUR 2

Inclusion Criteria (partial list)

- Rutherford Classification of 3-5
- Symptomatic femoropopliteal lesions ≥ 20 cm in length considered to be:
  - Chronic total occlusion (100% stenosis)
  - Diffuse stenosis (> 50% stenosis)
  - In-stent restenosis
- Reference vessel diameter (RVD) ≥ 4.5 mm and ≤ 6.7 mm
- Accessible SFA at origin
- Patent popliteal artery (< 50% stenosis) distal to the landing zone
- At least 1 patent tibial artery extending to the foot
- Patent femoral vein ≥ 10 mm in diameter or duplicate femoral vein

DETOUR 2 – Patient Characteristics and Lesion Characteristics

Demographics	All Subjects N=202
Age	68.9 ± 9.38 (202) 69.0 (47, 88)
Gender (Male)	73.8% (149/202)
Rutherford Classification Category	
3	77.7% (157/202)
4	17.8% (36/202)
5	4.5% (9/202)
Hypertension	87.6% (177/202)
Hyperlipidemia	69.3% (140/202)
Diabetes	34.7% (70/202)
CAD	87.6% (177/202)
Prior History of Smoking	91.1% (184/202)
Renal Insufficiency	10.9% (22/202)
Previous PAD Intervention	59.9% (121/202)
Previous PAD Surgery	16.8% (34/202)
History of Venous Disease	0.0% (0/202)

Lesion Characteristics	All Subjects N=202
Total Occlusion (100% stenosis)	96.0% (194/202)
Diffuse Stenosis (> 70% stenosis)	97.0% (196/202)
In-stent Restenosis	17.3% (35/202)
Lesion Length (Normal to Normal, mm)	327.14 ± 61.376 (196) 328.15 (194.6, 520.3)
Calcified Length (mm)	64.12 ± 77.496 (178) 41.10 (0.0, 415.7)
CTO length (mm)	217.35 ± 85.999 (191) 232.50 (0.0, 436.1)
Definitive Ca++	
None/Mild	29.1% (52/179)
Moderate	0.6% (1/179)
Severe	70.4% (126/179)
Pre-DETOUR PTA performed	76.1% (153/201)

DETOUR 2 – Procedural Outcomes

	All Subjects
Technical Success (Through Procedure)	100.0% (200/200) [98.2%, 100.0%]

Technical Success defined as successful delivery of the investigational devices to the identified area and removal of delivery system
Data presented as % (n/N) [95% CI] where N is the number of subjects with available data.

	All Subjects
Procedural Success (Through Discharge)	98.5% (197/200) [95.7%, 99.7%]

Procedural Success defined as successful delivery of the investigational devices to the identified area and removal of delivery system in the absence of in-hospital MAEs
Data presented as % (n/N) [95% CI] where N is the number of subjects with available data.

	All Subjects
Length of Stay (Through Discharge)	1.1 ± 1.83 days (200)

Data presented as mean ± SD (N) median where N is the number of subjects with available data.

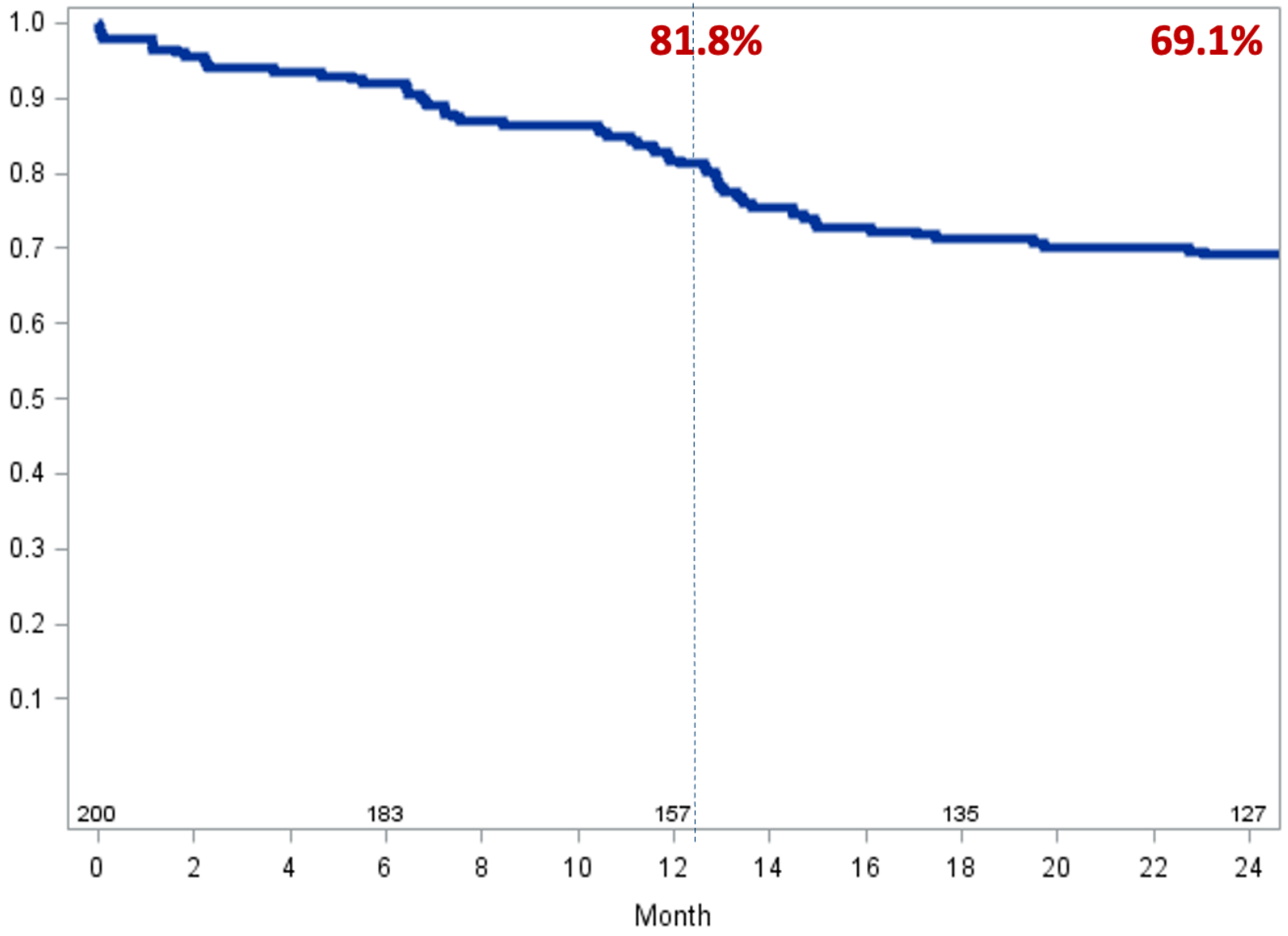
	All Subjects
Major Procedure-Related Infections within 30 Days	0.5% (1/199) [0.0%, 2.8%]

Data presented as % (n/N) [95% CI] where N is the number of subjects with available data.

	30 Days	6 Months	12 Months	24 Months
Clinical Success	92.9% (182/196) [88.3%, 96.0%]	94.8% (182/192) [90.6%, 97.5%]	97.2% (173/178) [93.6%, 99.1%]	95.9% (142/148) [91.4%,98.5%]

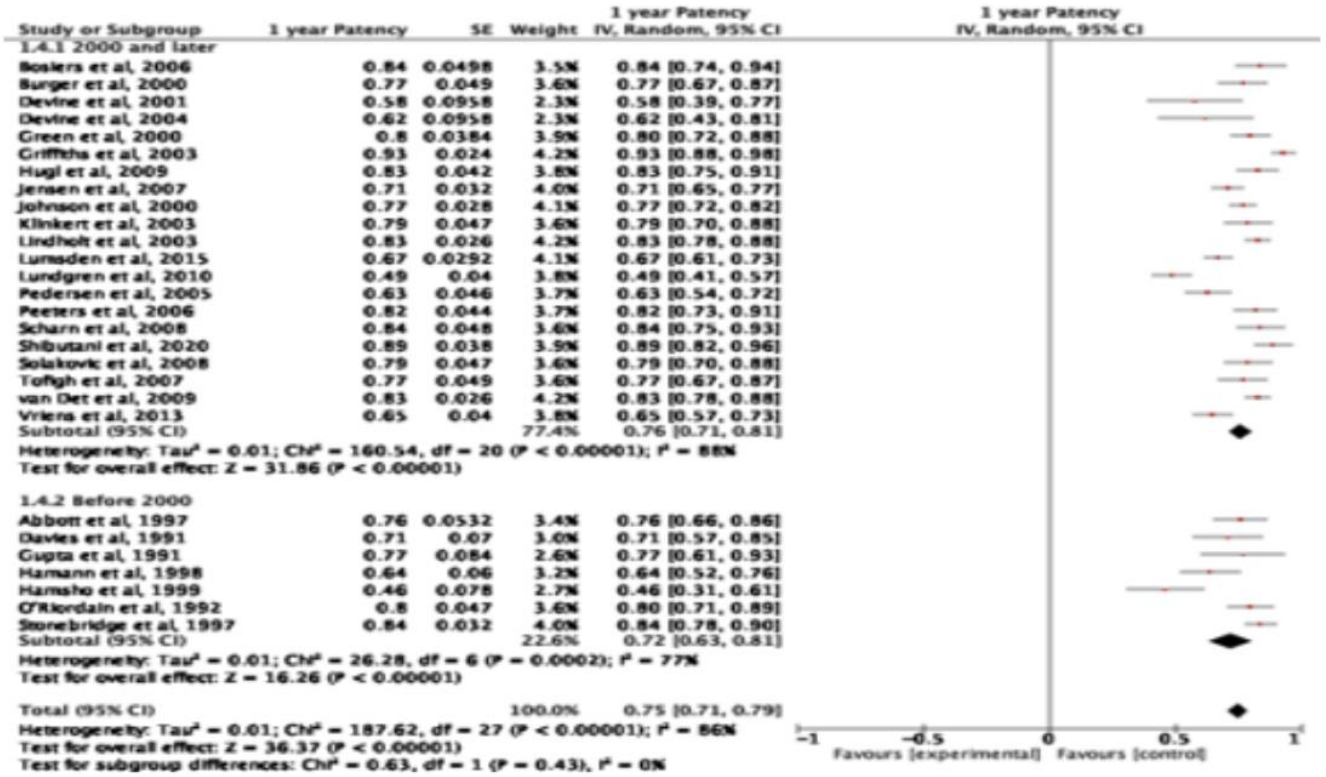
Clinical Success defined as limb ischemia improvement as assessed by Rutherford Clinical Classification (improvement in scale by ≥1) at 30 days and 6, 12, 24 and 36 months
Data presented as % (n/N) [95% CI] where N is the number of subjects with available data.

DETOUR 2 – Primary Patency Up To 2 Years



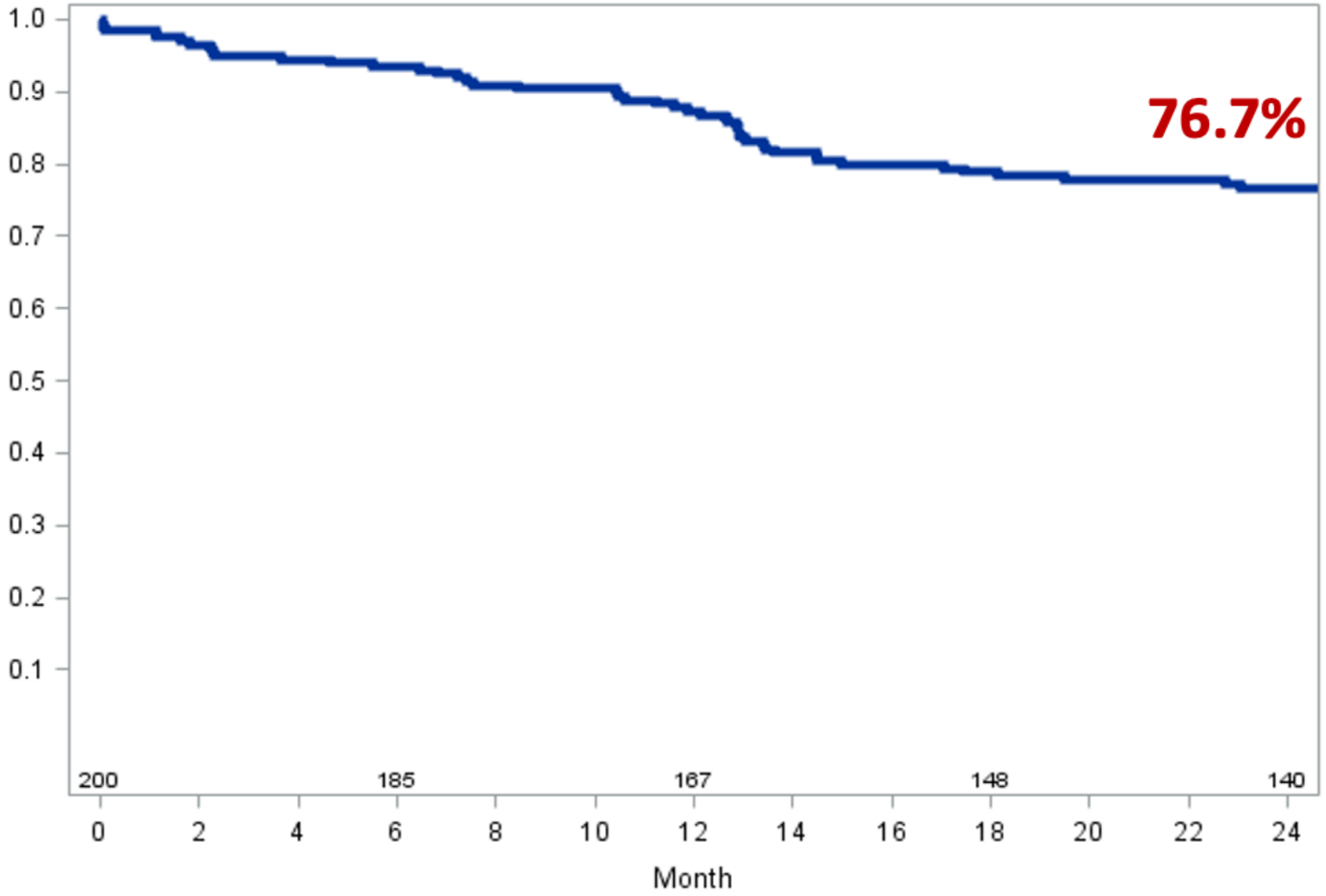
DETOUR 2 – Historical Patency of Surgical PTFE

Primary Patency: Open Lower Extremity Bypass Interventions (Non autologous graft)

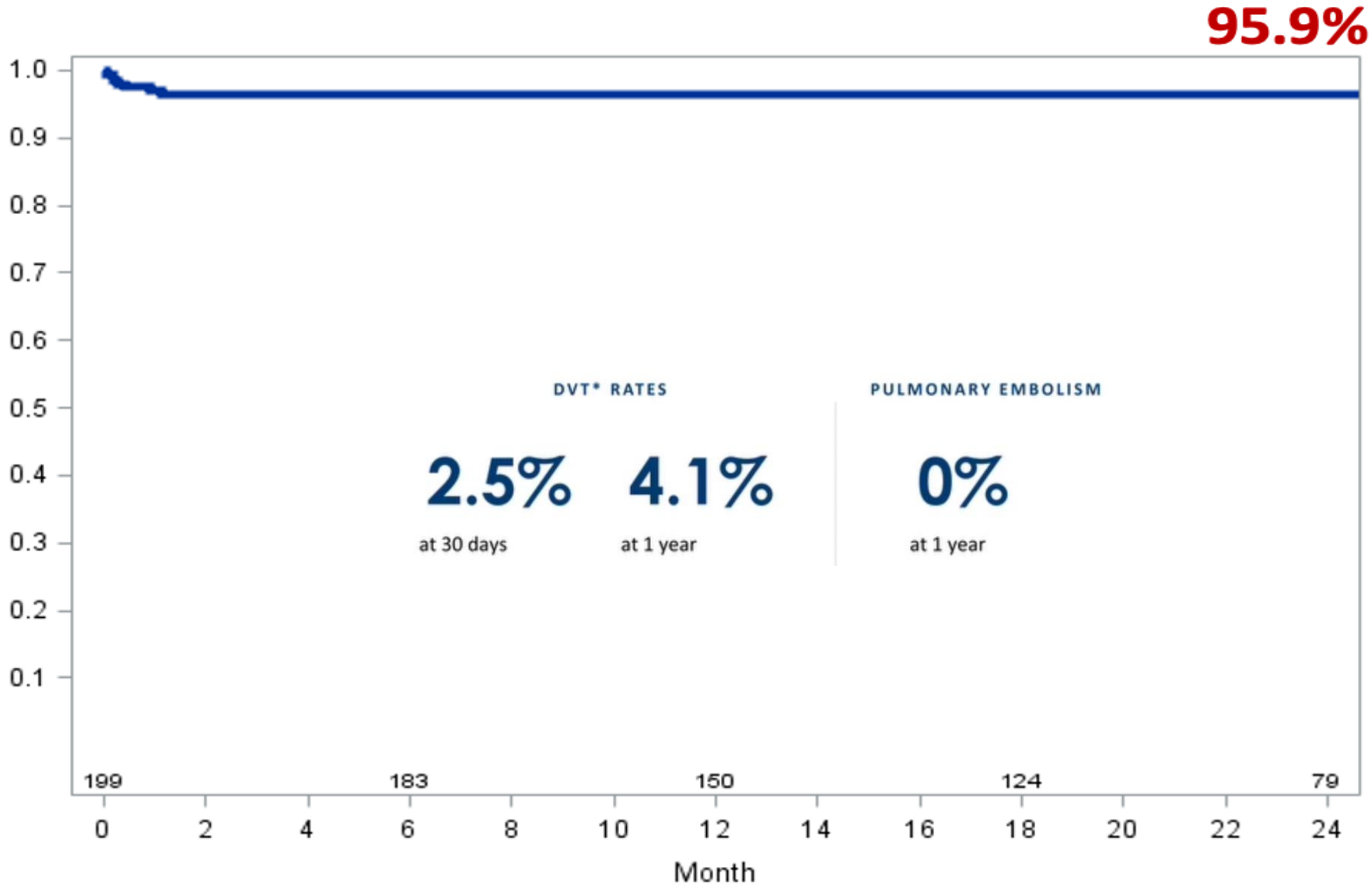


Pooled primary patency through 1 year: **75%** (95% CI [0.71, 0.79])

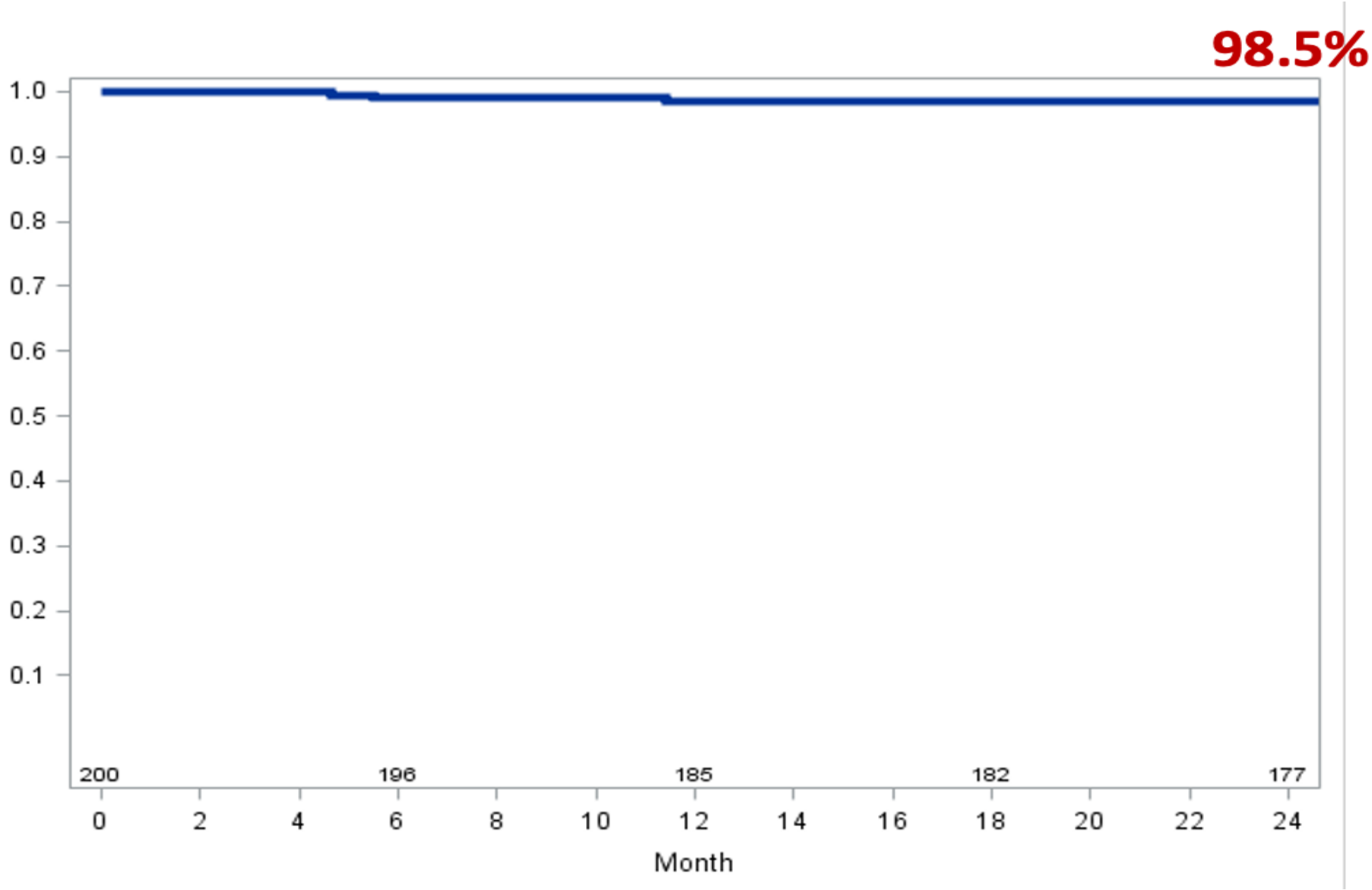
DETOUR 2 – Freedom From TLR Up To 2 Years



DETOUR 2 – Safety: Freedom From Symptomatic DVT Up To 2 Years



DETOUR 2 – Safety: Freedom From Major Amputations Up To 2 Years



DETOUR 2 - Conclusions

- PTAB using the DETOUR System creates a percutaneous femoropopliteal bypass for long and complex SFA lesions with high procedural success

- Primary safety and efficacy endpoints were achieved in the DETOUR 2 Study

- DETOUR 2 reports low long-term venous events which further demonstrates the safety of this novel technique

- DETOUR 2 had comparable efficacy to open surgical bypass with 69.1% primary patency and 76.7% freedom from TLR up to 2 years without the risks of general anesthesia, surgical complications, or extended LOS

- The DETOUR System provides a standardized, durable, and safe endovascular technique for complex SFA lesions > 200 mm in length

Discussion Points

- How does PTAB fit into your endovascular algorithm?

- Is pre-procedural case planning with axial imaging and venous imaging a necessity?

- What will your surveillance protocol post-procedure be? Any differences from your routine protocol?

- What will your antiplatelet or anticoagulation regimen be? Any differences from your routine protocol?

Thank You/Any Questions?

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