US clinical trial update on the Gore Excluder iliac branch endoprosthesis (IBE)

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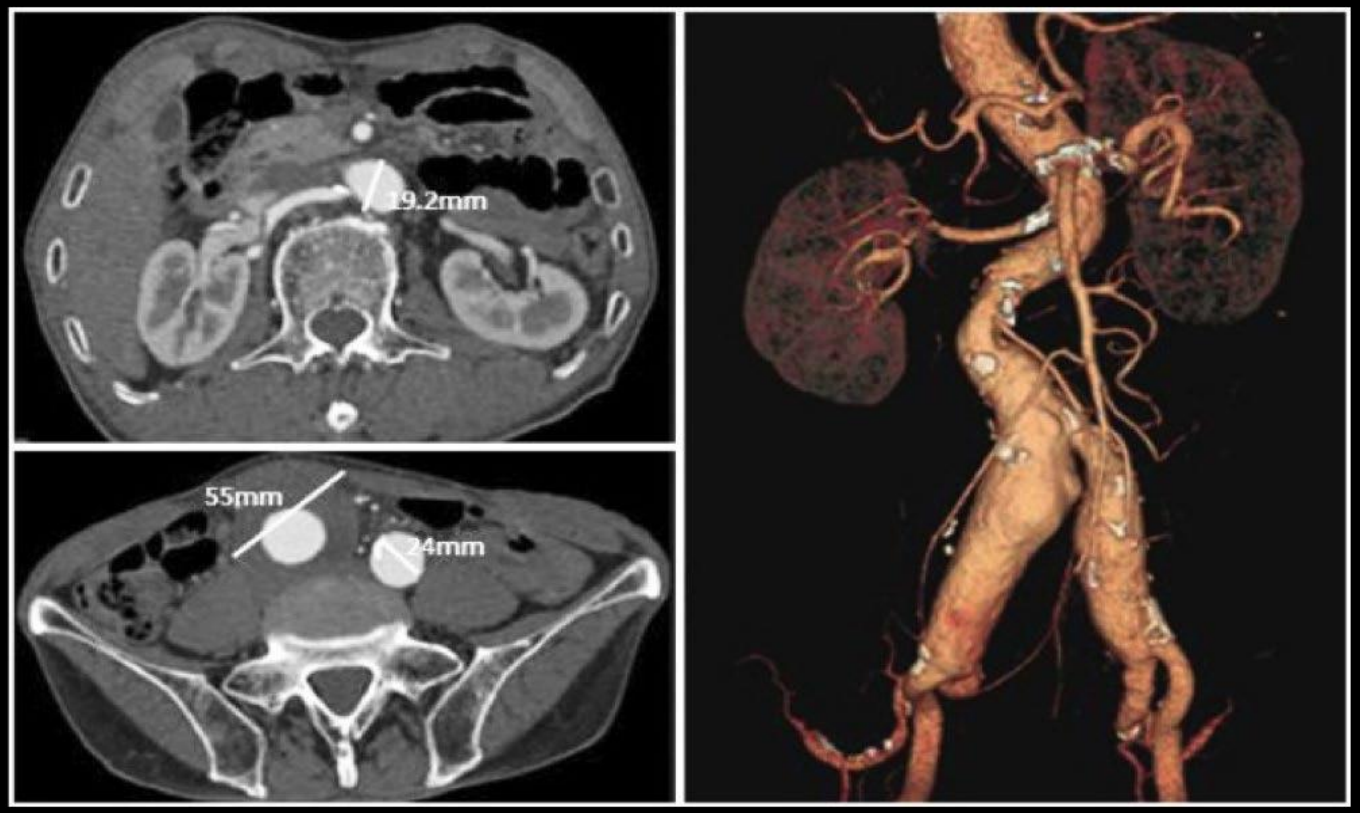


ANEURYSMAL DISEASE

extends into the common iliac arteries

~25% OF ALL AAA CASES

GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

- Currently in clinical testing (U.S. IDE trial enrollment complete and FDA submission) and commercial release (EU)*
- Modular construction
  - Off-the-shelf components
- Durablility
  - EXCLUDER technology
  - Common and Internal Iliac branch components designed for use in the iliacs
- Ease of use
  - Pre-cannulated internal iliac gate
  - Bi-Femoral delivery
  - Low-profile delivery (16Fr)
  - Repositionable (Two-stage Deployment)

GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

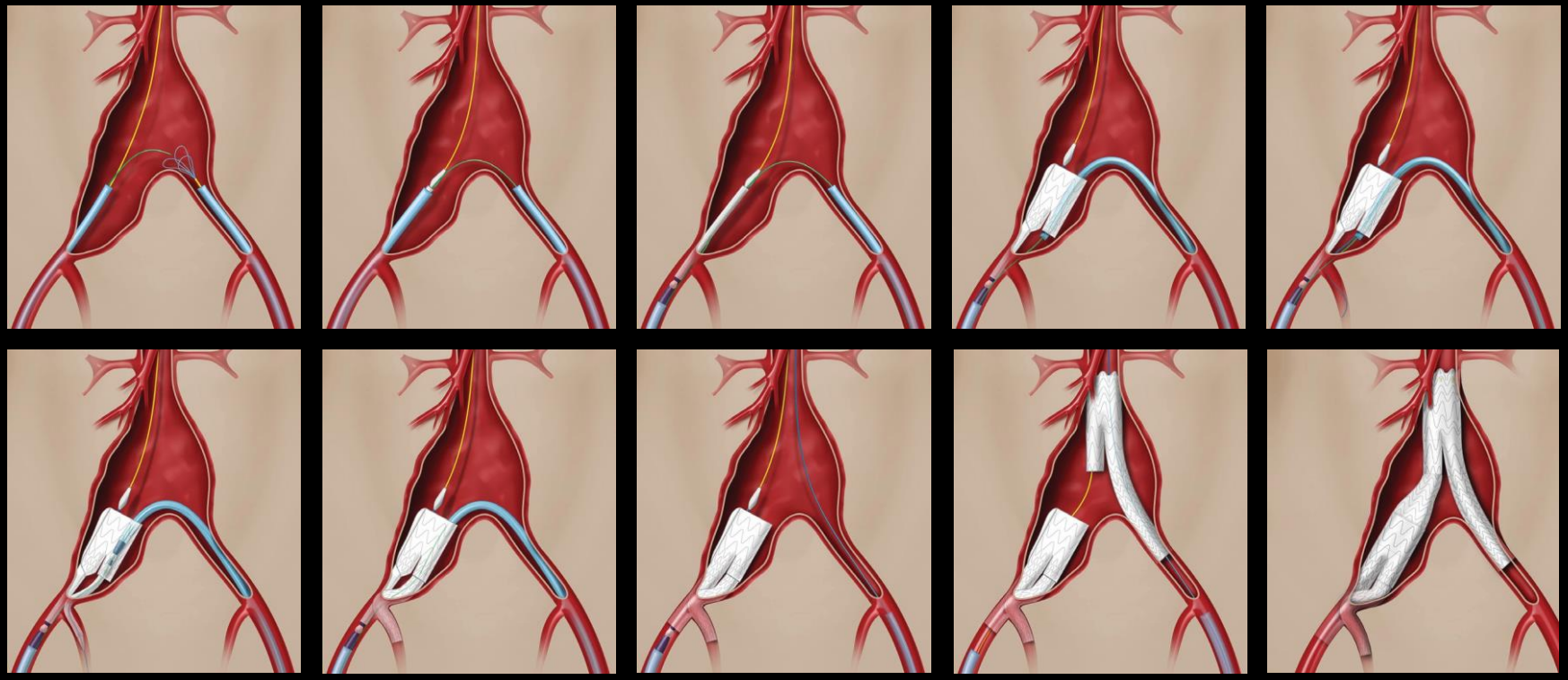
Iliac Branch Component

- 16 Fr compatible
- 6.5 – 25 mm External Iliac treatment range (with EXCLUDER® Iliac Extenders)
- Two-stage deployment
- Repositionable
- Pre-cannulated internal iliac gate

Internal Iliac Component

- 12 Fr compatible (with 0.035” buddy wire)
- 6.5 – 13.5 mm Internal Iliac treatment range
- Deploys Hub-to-Tip

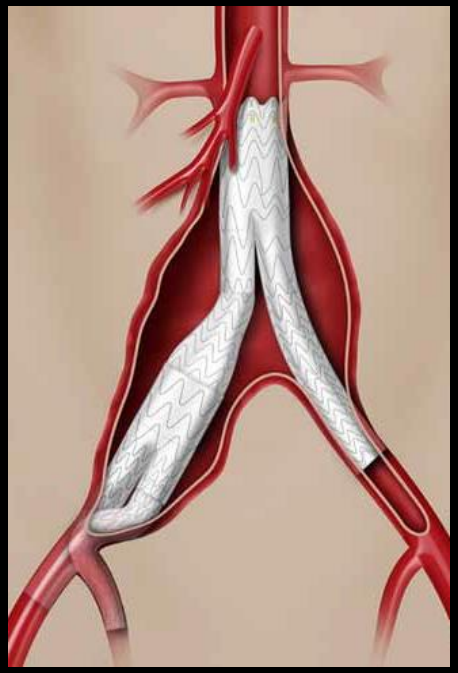
Deployment Steps



ILIAC BRANCH ENDOPROSTHESIS

US Gore IBE 12-04 Trial

- **Patients:**
  - Treatment of subjects with common iliac artery aneurysms (CIAA) or aorto-iliac aneurysms (AIA)
- **Primary Effectiveness Endpoints:**
  - Freedom from patency and/or endoleak related reinterventions
  - Freedom from occlusion of device branches
- **Secondary Effectiveness Endpoint:**
  - Freedom from new-onset buttock claudication
- 50 sites
- 5 year follow-up
- National PI: Dr. Darren Schneider
  New York, NY



Investigative 12-04 Sites US IDE trial

- Athens Medical Center
- Aurora Health Care, Inc.
- Baylor Heart & Vascular Hospital
- Beth Israel Deaconess Medical Center, Inc.
- Cleveland Clinic Foundation
- Coastal Vascular and Interventional, PLLC
- Dartmouth-Hitchcock Medical Center
- Duke University Medical Center
- Essentia Health
- Florida Hospital
- Hatton Institute for Research & Education
- Hawthorne Cardiothoracic & Vascular Surgeons, P.A.
- Health Consultation Center II, USC
- Macon Cardiovascular Institute
- Maimonides Medical Center
- Mayo Clinic, Rochester
- Medical College of Wisconsin
- Medical University of South Carolina
- Minneapolis Heart Institute Foundation – Abbott
- Northwestern University
- Northside Vascular Surgery
- North Central Heart Institute
- Ochsner Health System
- Ohio Health Research Institute
- Oklahoma Heart Hospital
- Oregon Health & Science University
- Robert Wood Johnson Medical School
- Sanford Clinical Vascular Associates
- Sentara Cardiovascular Research Institute
- Spectrum Health System
- Stanford University Medical Center
- St. Anthony's Medical Center
- St. Francis Medical Center – Peoria
- St. Vincent’s Medical Center
- The Vascular Group, Albany
- University of Alabama Medical Center
- University of California-Los Angeles
- University of Chicago Hospital
- University of Iowa Hospitals and Clinics
- University of Maryland
- University of Mississippi Medical Center
- UNC Vascular Surgery Division
- University of Pittsburgh Medical Center
- University of Texas Southwestern Medical Center
- University of Wisconsin Hospital
- Vanderbilt University Medical Center
- Wake Forest Baptist Health
- Weill Cornell Medical Center

Preliminary Data: Demographics

	Primary Enrollment	Continued Access
	N=64	N=29
Sex at Birth		
Male	98.4%	100%
Female	1.6%	0%
Ethnicity		
Not Hispanic or Latino	95.3%	89.3%
Hispanic or Latino	1.6%	10.7%
Unknown	3.1%	0%
Race		
White	92.2%	82.8%
Black	7.8%	13.8%
Age (yrs)		
Mean (Std Dev)	69.6(8.4)	68.4(11.7)
Median	69.5	71.0

Preliminary Data: Medical History

	Primary Enrollment	Continued Access
	N=64	N=29
Hypertension	87.5%	65.5%
Hypercholesterolemia	76.6%	48.3%
Cigarette Smoking	60.9%	44.8%
Peripheral Vascular Disease	42.2%	34.5%
Cardiac Arrhythmia	35.9%	13.8%
Other Concomitant Aneurysm	29.7%	20.7%
Cancer	25.0%	27.6%
Diabetes Mellitus	23.4%	20.7%
Chronic Obstructive Pulmonary Disease	21.9%	13.8%
Myocardial Infarction	23.4%	6.9%
PCI	23.4%	6.9%
Congestive Heart Failure	21.9%	3.4%
Cerebrovascular disease	15.6%	10.3%
Erectile Dysfunction	15.9%	3.6%
Coronary Artery Bypass Graft	14.1%	10.3%
Thromboembolic Event	10.9%	6.9%
Aneurysm Symptomatic	10.9%	0.0%
Renal Insufficiency	6.3%	10.3%
Lower Limb Intervention	6.3%	6.9%

Preliminary Data: Risk Factors

	Primary Enrollment	Continued Access
	N=64	N=29
ASA Classification		
I	6.3%	20.7%
II	25.0%	20.7%
III	57.8%	51.7%
IV	10.9%	0%
V	0%	0%
NYHA Classification		
I	42.2%	17.2%
II	20.3%	13.8%
III	1.6%	0%
IV	0%	0%
No Cardiac Disease	35.9%	62.1%
Iliac Aneurysm Configuration		
Bilateral	39.1%	41.7%
Unilateral	60.9%	58.3%

Preliminary Data: Pre-Treatment Measurements

Aortic Diameter reported as ≥ 50 mm (AAA)	Primary Enrollment	Continued Access
	N=25	N=8
Aortic Neck Length		
mean (SD)	35.8 (10.5)	35.4 (9.2)
median	34.6	35.2
range	(15,60)	(20,50)
Maximum aortic diameter		
mean (SD)	57.2 (5.5)	65.5 (10.6)
median	57.0	64.3
range	(50,67)	(55,83)
Aortic Diameter reported as < 50 mm (non AAA)	N=39	N=20
Aortic Neck Length		
mean (SD)	39.7 (21.5)	50.2 (31.1)
median	30.5	41.5
range	(15,105)	(17,118)
Maximum aortic diameter		
mean (SD)	37.5(7.6)	35.5 (8.5)
median	38.0	36.5
range	(21,49)	(22,49)

Preliminary Data: Pre-Treatment Measurements

	Primary Enrollment	Continued Access
	N=64	N=24
Max common iliac diameter		
mean (SD)	39.1 (10.6)	41.8 (10.2)
median	37.0	42.6
range	(25,72)	(18,65)
Access vessel diameter - IBE side		
mean (SD)	10.7(2.0)	10.5(2.1)
median	10.5	10.0
range	(7,16)	(8,17)
Access vessel diameter - Trunk-Ipsi side		
mean (SD)	10.6(2.0)	10.4(2.3)
median	10.3	10.0
range	(7,15)	(8,19)

Preliminary Data: Treatment

	Primary Enrollment	Continued Access	
	N=63	N=24	N=4
		Unilateral	Bilateral
Endovascular Access Method on IBE Side			
Percutaneous	49.2%	62.5%	75.0%
Cut-down	49.2%	37.5%	25.0%
Cut-down and Conduit	1.6%	0.0%	0.0%
Endovascular Access Method on Non-IBE Side			
Percutaneous	47.6%	62.5%	-
Cut-down	50.8%	37.5%	-
Cut-down and Conduit	1.6%	0.0%	-
Anesthesia Method			
General	87.3%	87.5%	75.0%
Regional	0.0%	0.0%	25.0%
Local	12.7%	4.2%	0.0%

Preliminary Data: Treatment (cont.)

	Primary Enrollment	Continued Access	
	N=63	N=24	N=4
		Unilateral	Bilateral
Procedure Time (minutes)			
Mean (Std Dev)	151.8(47.6)	163.6(59.9)	310.8(116.9)
Median	145	148	261
Range	(68,334)	(85,305)	(236,485)
Blood Loss (mL)			
Mean (Std Dev)	247.6(181.9)	306.8(324.7)	550.0(708.3)
Median	200	200	275
Range	(0,1000)	(0,1400)	(50,1600)
Procedure Survival	100.0%	100.0%	100.0%
Additional Procedures at Treatment	14.3%	33.3%	25.0%
Stent	7.9%	12.5%	0.0%
PTA	0.0%	4.2%	0.0%
Thrombectomy	0.0%	0.0%	0.0%
Embolization	3.2%	4.2%	0.0%
Other	6.3%	12.5%	25.0%

Preliminary Data: Technical Success

	Primary Enrollment	Continued Access
	N=63	N=28
Technical Success	95.2%	96.4%
Successful access	100.0%	100.0%
Successful deployment of IBE and EXCLUDER components	98.4%[1]	100.0%
Patent IBE and EXCLUDER components	100.0%	100.0%
Absence of Type I and III endoleaks	96.8%[2]	96.4%[3]
Successful removal of IBE delivery catheters	100.0%	100.0%
Successful access site closure	100.0%	100.0%

1. Site had difficulty advancing IIC into the internal iliac artery, withdrew component before deploying, and, thinking they had no additional IICs, elected to implant an Iliac Extender.
2. One small Type III endoleak (between components) noted on final angiography. Physician re-ballooned the overlap of the components but elected not to do another angiogram. Endoleak absent on 30-day follow-up. One small Type IB on IBE treatment side. Core lab identified only Type II endoleak at 1 month FU.
3. One procedural Type Ia endoleak, site decided to not treat due to accessory renal

Preliminary Data: Hospitalization

	Primary Enrollment	Continued Access
	N=63	N=28
Intubation	85.7%	75%
Ventilator Days		
Mean (Std Dev)	0.8 (0.4)	0.6(0.5)
Median	1.0	1.0
Range	(0, 1)	(0,1)
ICU Stay	22.2%	3.6%
ICU Days		
Mean (Std Dev)	1.4 (0.8)	1
Median	1.1	0.8
Range	(1, 3)	0.8
		(1,1)
Hospitalization Duration (days)		
Mean (Std Dev)	2.0 (1.8)	1.7(1.4)
Median	1.0	1.0
Range	(1, 11)	(1,6)
Return to Normal Activities (days)		
Mean (Std Dev)	32.5(41.0)	21.3(16.2)
Median	27.0	21.0
Range	(1, 205)	(1,60)

Preliminary Data: Device Usage

	Primary Enrollment	Continued Access	
Number of Subjects with Device Data	N=63	N=23	N=4
		Unilateral	Bilateral
Subjects with Iliac Branch Components (IBC) Implanted	100%	100%	100%
Subjects with Internal Iliac Components (IIC) Implanted	98.4%	100%	100%
Subjects with Trunks Implanted	100%	100%	100%
Subjects with Contralateral Legs Implanted	100%	100%	100%
Subjects with Aortic Extenders Implanted	9.5%	8.7%	25%
Subjects with Iliac Extenders Implanted	17.5%	13.0%	0%
Number of Devices Per Subject			
Total number of devices	341	119	29
Mean (Std Dev)	5.4 (0.8)	5.2(0.7)	7.3(0.5)
Median	5.0	5.0	7.0
Range	(4, 9)	(4,7)	(7,8)

Preliminary Site Reported Data (n=88)

1 month follow up, N=86

- 0 migrations
- 0 claudication on IBE treatment side
- 1 procedural Type II endoleak that required embolization
- 1 reintervention – IBE side: placement of a stent to treat a left external iliac artery dissection (POD 26) distal to a bare metal stent
- *5 site reported occlusions of the IIC* (asymptomatic, no treatment)
- 1 site reported occlusions on the non-IBE side POD 1, thrombectomy
- 1 bilateral external iliac artery occlusion, IIC remained patent and not thrombosed, thrombosis in native external iliac arteries.

Preliminary Site Reported Data (n=88)

6 month follow up, N=70

- 0 migrations
- 1 claudication (location not reported by site)
- 1 reintervention (embolized Type II endoleak)

1 year follow up, N=53

No reinterventions, migrations, claudications, new occlusions or endoleaks (Type I or III)

GORE® EXCLUDER® IBE Summary

- *Complete iliac branch device system*
  Gore designed iliac branch and internal iliac component

- *Highest patient inclusion* per IFU in clinical practice as compared to other off-the-shelf iliac branch device

- Largest internal and external iliac diameter treatment ranges 6.5- 3.5mm iliacs

- Lowest profile iliac branch component…..16 Fr

- The GORE® EXCLUDER® Iliac Branch Endoprosthesis can be positioned *above the aortic bifurcation* - does not require deployment fully within common iliac artery

US IDE trial update (after 6-12 month)

- *Safe and Effective* : 95% procedural success
- Internal Branch Limb : 95% patency
- Claudication: None
- Sexual Dysfunction: None
- Bowel Ischemia: None

Thank you!

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