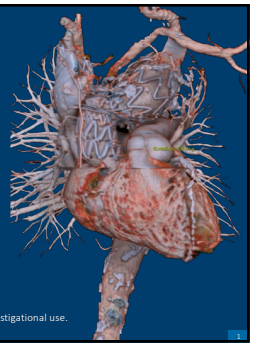
Status And Results From The US TRIOMPHE Trial Of Nexus Endograft (OTS) For Treating Complex Aortic Arch Lesions Including Chronic Dissections



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AT THE FOREFRONT
UChicago Medicine

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1

Disclosures

- *Consultant:* Cydar, CyndRx (equity interest), Endoron, Endospan, Medtronic, Shockwave, Silk Road, ViTAA, and WL Gore

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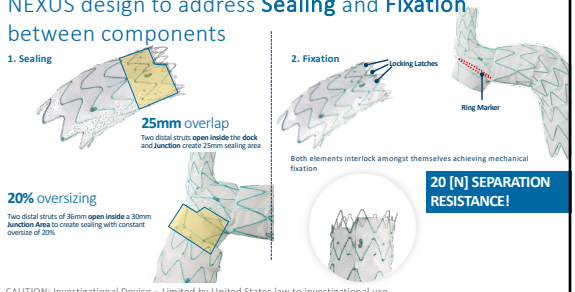
NEXUS design to address **Sealing** and **Fixation** between components



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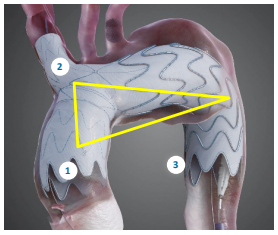
DURABILITY – DESIGNED FOR MIGRATION RESISTANCE



NEXUS Provides three anatomical anchoring points in the arch for secure long-term fixation

1. **Ascending Aorta**
2. **Brachiocephalic Trunk**
3. **Transverse Arch**

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5

NEXUS® DELIVERY SYSTEMS, PRE-SHAPED FOR THE ARCH

Fixation tube with through wire provides tracking for NEXUS®

Designed to reduce device manipulation to position and orient the devices in the arch

20F **Profile**

Pre-curved delivery systems designed to follow the natural curves of the aortic arch

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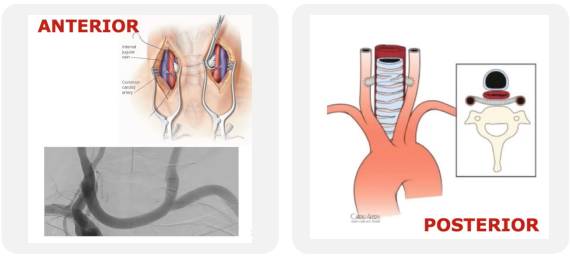
6

CAROTID-CAROTID BYPASS



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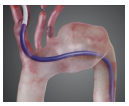
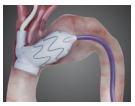
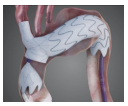
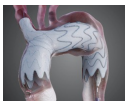
KEY DEPLOYMENT STEPS

Introduction	Arch Stent Graft	Ascending Stent Graft	Completion
			
Passage of Arch Graft delivery system over a through & through guide wire	**Deployment of integrated branch & controlled** positioning of Dock&Lock facing ascending aorta	**Positioning & controlled deployment** with Dock&Lock mechanical fixation	**Modelling balloon across Dock&Lock** to complete the connection

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STUDY DESIGN

Three-Arm, Non-Randomized Study (n=110)

Chronic Dissection	(n=60)
Aneurysms	(n=30)
Penetrating Aortic Ulcer / Intramural Hematoma	(n=20)

Multicenter
Up to 31 centers

30 in US
1 in NZ

5-year follow-up

30 day | 6 months | 1 year | 2 year | 3 year | 4 year | 5 year

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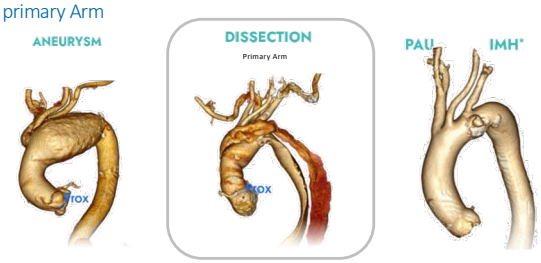
A study design with three arms, DISSECTION being the primary Arm



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TRIOMPHE TWO CO-PRIMARY ENDPOINTS

DEVICE TECHNICAL FAILURE (30D)

- Failure to accurately deliver, track and deploy all required components at the intended implantation site and failure to retrieve
- Device occlusion
- Failed exclusion of primary entry tear
- Additional unanticipated surgical or interventional procedure related to the device or procedure, to prevent life-threatening or permanent disabling event.

CLINICAL FAILURE

Subjects experiencing EARLY MORTALITY or at least one of the following MAE through 30-Day

- Disabling stroke
- Permanent paralysis/paraplegia
- Renal failure
- Aortic rupture
- Development of new dissections in the thoracic aorta or BCT

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MEDICAL HISTORY

	Chronic Dissection Cohort N = 13	Aneurysm Cohort N = 8	PAU/IMH Cohort N = 1	Total N = 22
Age	**65.8 ± 9.55**	71.1 ± 7.00	67.0 (1)	67.8 ± 8.66
Male	**76.9%**	50.0%	0.0%	63.6%
Former/current smoker	**38.5%**	87.5%	100%	59.1%
Hypertension	**100%**	87.5%	100%	95.5%
Coronary artery disease	**30.8%**	50%	0.0%	36.4%
Previous Cerebrovascular accident/TIA	**7.7%**	37.5%	100%	22.7%
Previous Aortic Intervention	**76.9%**	12.5%	0.0%	50.0%
Previous Sternotomy	**76.9%**	0.0%	0.0%	45.5%

Data is from pre-determined data cut in protocol

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PERIOPERATIVE DATA (30D)

	Chronic Dissection Cohort N = 13	Aneurysm Cohort N = 8	PAU/IMH Cohort N = 1	Total N = 22
Early Mortality	**7.6%**	12.5%	0.0%	9.1%
Disabling Stroke	**0.0%**	0.0%	0.0%	0.0%
Renal Failure	**0.0%**	0.0%	0.0%	0.0%
Paraplegia	**0.0%**	0.0%	0.0%	0.0%
Length of ICU Stay (days) Mean ± SD	**3.6 ± 2.3**	3.4 ± 1.7	1.0	3.4 ± 2.06
Length of Hospital Stay (days) Mean ± SD	**9.1 ± 3.7**	14.0 ± 11.8	3.0	10.6 ± 7.9

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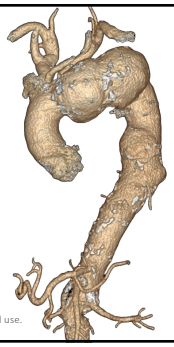
13

Clinical History

- Black, Female, 69
- History: BMI 29.18, Former Smoker (25 ppy), Hypertension, Renal Insufficiency, LVEF 48%
- Asymptomatic greater than 6.5 cm aortic aneurysm



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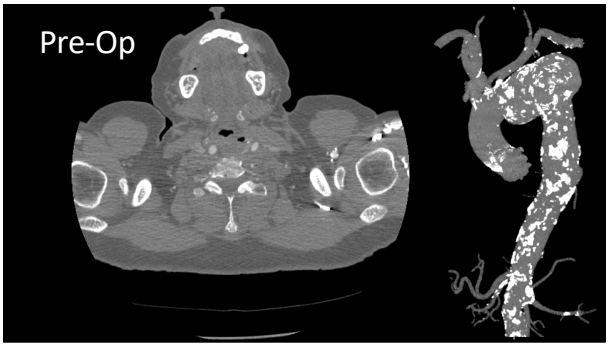
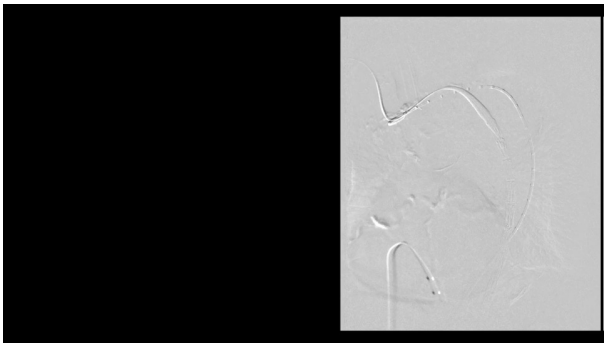
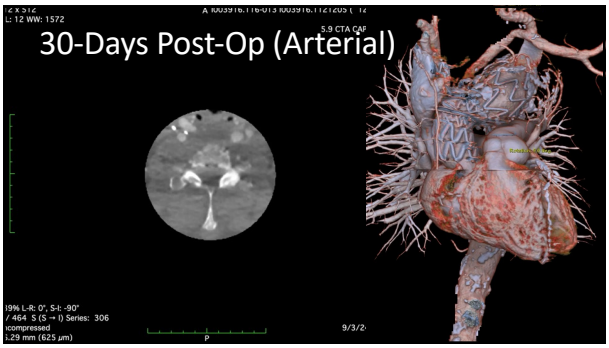
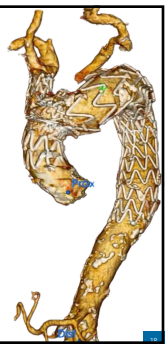






Key Case Take Away

- Technical success with ease of delivery in complex anatomy
- No periprocedural stroke
- Aneurysm regression from 61 to 58mm at 1 Mo, no endoleak



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Thank you

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19