NEXUS™
AORTIC ARCH STENT GRAFT SYSTEM
BY ENDOSPAN

NEXUS ARCH

A MULTICENTER STUDY EVALUATING THE INITIAL EXPERIENCE WITH A NOVEL AORTIC ARCH STENT GRAFT SYSTEM

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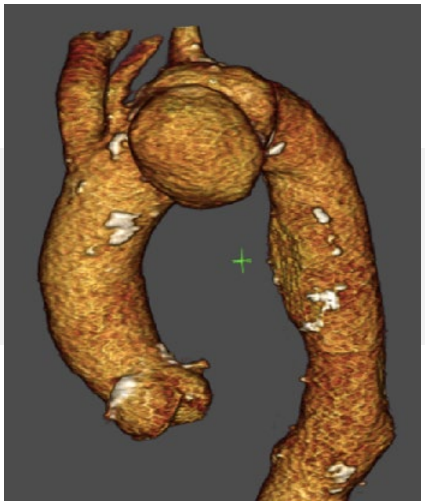
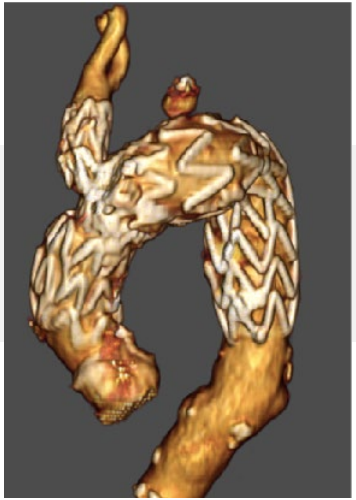
PATIENT TREATED WITH NEXUS™ FOR AORTIC ARCH ANEURYSM*

Baseline



1-Month

12-Months



**Courtesy of Dr Andrew Hill, Auckland New Zealand.*

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STUDY DESIGN

Prospective cohort
28 patients in **5** centers

From first-in-man (FIM n=18) study (NCT02365454) or as **compassionate use** (n=10) with systematic data collection (NCT03420066)

	First-in-human (n=18)	Compassionate use (n=10)
University Hospital Zürich, Switzerland	**14**	**2**
Azienda Complesso Ospedaliero San Filippo Neri, Rome, Italy	**3**	**2**
University Hospital Auckland, New Zealand	**-**	**1**
Toronto General Hospital, Canada	**-**	**5**
University Hospital, Düsseldorf, Germany	**1**	**-**

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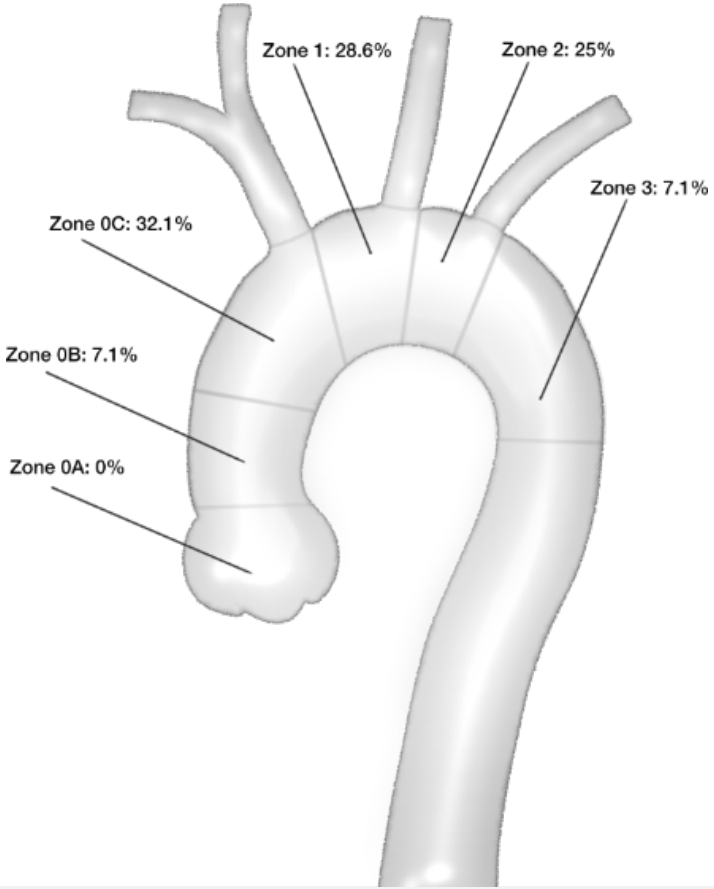
BASELINE CHARACTERISTICS

Variable	First in Man Cohort (n = 18)	Compassionate Cohort (n = 10)	Entire Cohort (n = 28)	P-value
Age (years), mean ± SD	**71.7 ± 5.9**	**73.2 ± 6.9**	**72.2 ± 6.2**	**0.55**
NEXUS procedure time (min)[†]	**16/18 (88.9%)**	**6/10 (60%)**	**22/28 (78.6%)**	**0.15**
BMI kg/m^2, mean ± SD	**28.6 ± 5.4**	**27.2 ± 7.2**	**28.1 ± 6.0**	**0.57**
DM	**2/18 (11.1%)**	**0/10**	**2/28 (7.1%)**	**0.52**
HTN	**18/18 (100%)**	**9/10 (90%)**	**27/28 (96.4%)**	**0.36**
DLP	**6/18 (33.3%)**	**5/9 (55.5%)**	**11/27 (40.7%)**	**0.41**
Current smoker	**3/18 (16.7%)**	**1/10 (10%)**	**4/28 (14.3%)**	**1.00**
COPD	**5/18 (27.8%)**	**4/10 (40%)**	**9/28 (32.1%)**	**0.68**
CAD	**7/18 (38.9%)**	**2/10 (20%)**	**9/28 (32.1%)**	**0.42**
Arrhythmia	**6/18 (33.3%)**	**1/10 (10%)**	**7/28 (25%)**	**0.36**
Previous sternotomy	**12/18 (27.8%)**	**3/10 (30%)**	**15/28 (53.6%)**	**0.11**
CVA/TIA	**1/18 (5.6%)**	**1/10 (10%)**	**2/28 (7.1%)**	**1.00**
CHF (NYHA III/IV)	**0**	**2/10 (20%)**	**2/28 (7.1%)**	**0.12**
PVD	**2/18 (11.1%)**	**1/10 (10%)**	**3/28 (10.7%)**	**1.00**
CKD (Creatine > 2.0)	**2/18 (11.1%)**	**0**	**2/28 (7.1%)**	**0.52**
Anemia	**7/18 (38.9%)**	**2/10 (20%)**	**9/18 (32.1%)**	**0.42**
ASA risk score ≥ 3	**16/17 (94.1%)**	**9/10 (90%)**	**25/27 (92.5%)**	**0.70**

ASA indicates American Society of Anesthesiology; CAD, coronary artery disease; CHF, congestive heart failure; CKD, chronic kidney disease; COPD, chronic obstructive lung disease; CVA, cerebrovascular accident; DLP, dyslipidemia; DM, diabetes mellitus; HTN, hypertension; IQR, interquartile range; NYHA, New York Heart Association; PVD, peripheral vascular disease; TIA, Transient ischemic attack.

TREATED AORTIC ARCH ACCORDING TO MOST PROXIMAL PATHOLOGY*



*Roselli et al. Zone zero thoracic endovascular aortic repair: A proposed modification to the classification of landing zones. J Thorac Cardiovasc Surg. 2018;155(4):1381-9

PROCEDURAL CHARACTERISTICS

Variable	Median [IQR]
Total procedure time (min)*	**185 [148–254]**
NEXUS procedure time (min)†	**80 [46.5–113]**
Fluoroscopy time (min)‡	**48 [37.5–54]**
Contrast volume (mL)§	**122.5 [102.5–187.5]**
Length of hospitalization following procedure (d)	**8.5 [7.0–14.7]**
Number of patients admitted to ICU	**16/28 (57.1%)**
Length of ICU stay (d)	**1.0 [1.0–3.0]**
Complete percutaneous access	**19/28 (67.9%)**

*Total procedure time: skin-to-skin; data was collected for 26 patients

†NEXUS procedure time: time from access with the arch stent graft delivery system until retrieval of the ascending stent graft delivery system; data was collected for 17 patients

‡Fluoroscopy time data was collected for 25 patients

§Contrast volume data was collected for 24 patients

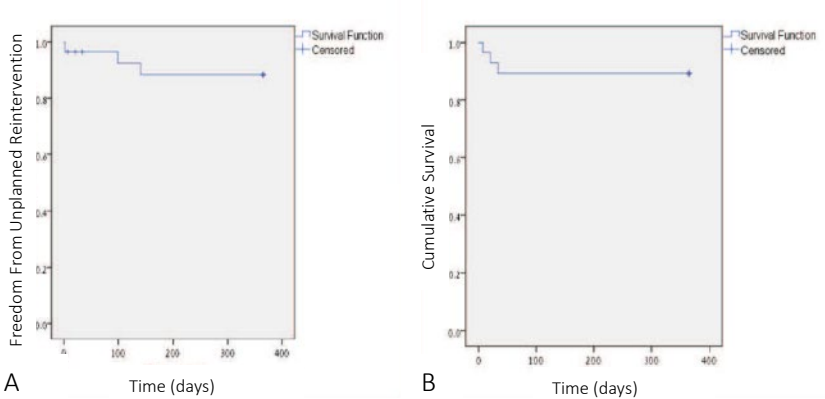
ICU indicates intensive care unit

MORTALITY & STROKE RATE

	30 Days	1 Year
Mortality Rate	**7.1%**	**10.7%[1]**
Stroke		
Disabling	**0.0%**	**0.0%**
Non-Disabling	**3.6%**	**7.1%[2]**

1. Not device or aneurysm-related death per CEC Adjudication

2. Reported Stroke or TIA that completely recovered



Kaplan-Meier survival curves

A: Freedom from device-related unplanned reinterventions

B: Overall survival

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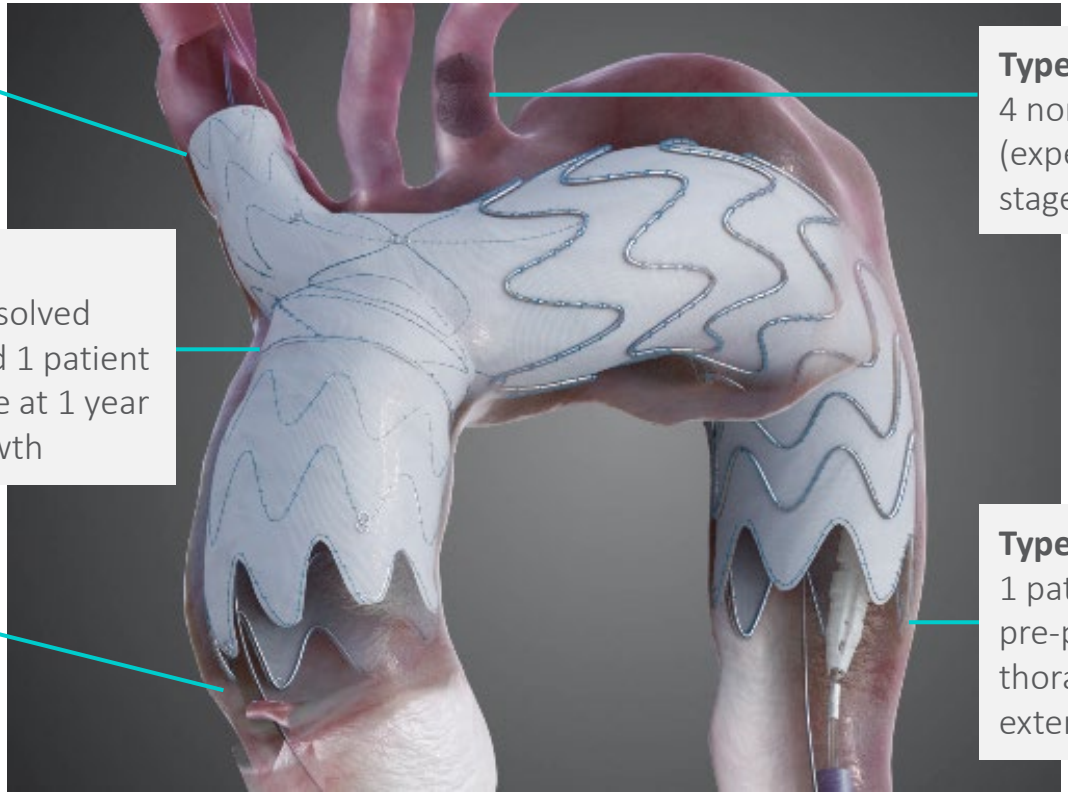
ENDOLEAKS WITHOUT CLINICAL SEQUELAE

Type Ic
None

Type III
1 patient at 30d (resolved spontaneously) and 1 patient at 6 months – stable at 1 year – no aneurysm growth

Type Ia
None



Type II
4 non occluded LSA (expected) – successful staged embolization

Type Ib
1 patient – expected – pre-planned distal thoracic stent graft extension

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OTHER OUTCOMES

A 1-year follow-up CTA

No graft migration, stent graft separation, branch occlusion, stent fracture, graft infoldings or collapse.

1 report of asymptomatic surgical graft occlusion (LCC artery to LSA)

No reports of periscope occlusion

Periscope stent grafts in 10 patients

Unplanned periscope interventions:
1 at 30 days and **2 at 12 months**
(Aneurysm enlargements >5mm)

Planned device related interventions: (periscope):
1 at 12 months

No stent migration

CONCLUSION

1. **In patients with aortic arch pathologies that require landing** in the ascending aorta, endovascular repair with the NEXUS Aortic Arch Stent Graft System can be performed with high success rate and promising results at 1 year.

2. **Further follow-up is required to establish** the long-term safety and effectiveness of this device.

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28 Patients with 1 year FU
KEY OUTCOMES

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100% procedural success.

At one month, the vascular pathology was excluded in **25 of 26** alive patients **(96.1%)**. One year mortality was **10.7%**, without device or aneurysm related death.

Two patients (7.1%) reported non-disabling stroke or TIA at one year that recovered completely.

Three patients (10.7%) had device related unplanned reinterventions through one year.

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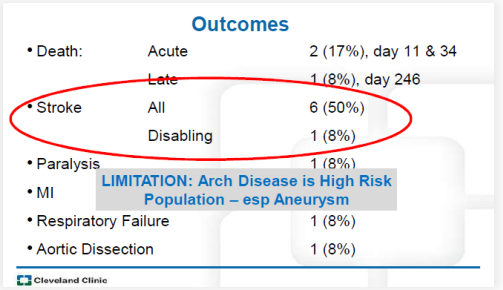
NEXUS™ VS TERUMO

	NEXUS™: OUS (n=28)[1,2]	NEXUS™: US IDE (n=10)[1,3]	TERUMO (n=12)
Early Mortality	2/28 (7.1%)	1/10 (10%)	2/12 (17%)
Stroke	1/28 (3.6%)	0/10 (0%)	**6/12 (50%)**
Paralysis	0/28 (o%)	0/10 (0%)	1/12 (8%)
Respiratory Failure	1/28 (3.6%)	0/10 (0%)	1/12 (8%)



Presented by Dr. Roselli
from the Cleveland Clinic at VEITH in 2019

[1] Results includes Bypass and NEXUS Implant
[2] NCT02365454; NCT03420066
[3] NCT04471909

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