The Role of the Nexus Aortic Stent Graft System in Reducing Neurological Events After Aortic Arch Repair

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on behalf of:

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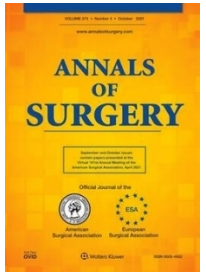
Background

- Historically aortic arch disease was managed with open surgery, but this is associated with significant morbidity and mortality, especially in high-risk patients
- There are a limited range of endovascular solutions for arch repair, and they continue to be associated with relatively high stroke rates
- Recently, the Nexus branched stent-graft has shown promising early and 1-year results* in cases requiring a zone 0 landing solution and this study looks at the 3-results

*Planer D, et al. NEXUS Arch: A Multicenter Study Evaluating the Initial Experience with a Novel Aortic Arch Stent Graft System. Ann Surg. 2021 Mar 4. PMID: 33714965.

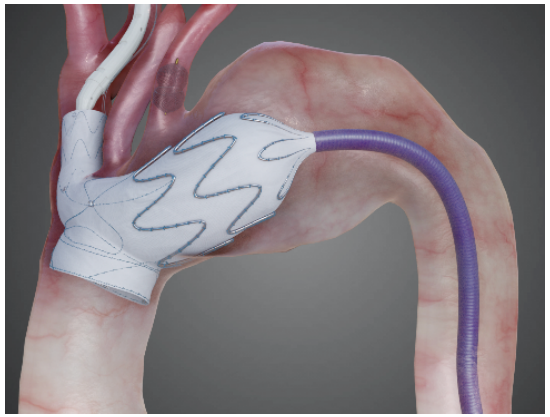


KEY DEPLOYMENT STEPS

Introduction

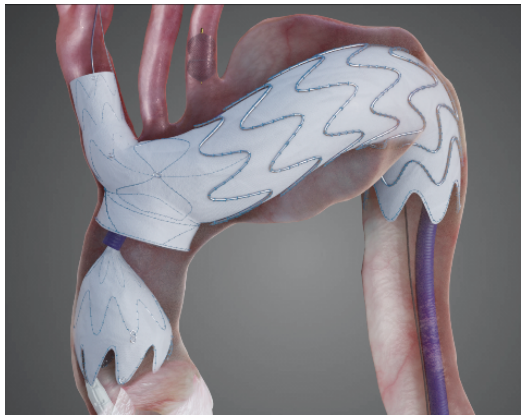
Smooth passage of the pre-shaped arch graft delivery system over a through & through wire

Arch Stent Graft



Deployment of integrated innominate branch & controlled positioning of aortic arch facing section

Ascending Graft



Positioning & controlled deployment of the ascending section which mechanically locks into the arch section

Completion

Modelling balloon across the locking components to ensure durable connection is secured

Study population

- 28 patients
  - Investigational study: 18 (NCT02365454)
  - Compassionate use: 10 (NCT03420066)
- Indications
  - Isolated arch aneurysm: 17 patients (60.7%)
  - Chronic aortic dissection: 6 patients (21.4%)
  - PAU: 1 patient (3.6%)
  - Combined: 4 patients (14.3%)

Baseline demographics

	First in man cohort (n=18)	Compassionate cohort (n=10)	P value
Age (years), mean±SD	71.7±5.9	73.2±6.9	0.55
Male	16 /18 (88.9%)	6/10 (60%)	0.15
BMI kg/m^2, mean±SD	28.6±5.4	27.2±7.2	0.57
Current Smoker	3/18 (16.7%)	1/10 (10%)	1.00
COPD	5/18 (27.8%)	4/10 (40%)	0.68
CAD	7/18 (38.9%)	2/10 (20%)	0.42
Previous Sternotomy	12/18 (66.7%)	3/10 (30%)	0.11
CVA/TIA	1/18 (5.6%)	1/10 (10%)	1.00
ASA risk score ≥ 3	16/17 (94.1%)	9/10 (90%)	0.70

Three year outcomes of NEXUS system

NEW ONSET OF EVENTS	30-days (n=28)	1-year (n=26)	3-year (n=25)
Overall mortality	2 (7.1%)	1 (3.8%)	5 (20%)
Device related mortality	0	0	0
Procedure related mortality	2 (7.1%)	1 (3.8%)	0
Late aneurysm related mortality	N/A	0	0
Strokes - Disabling stroke - Non Disabling stroke	 1 (3.6%) 1 (3.6%)*	0	0
Renal failure (new onset, requiring dialysis)	1 (3.6%)	0	0
Paraplegia	0	0	0
Myocardial infarction	0	0	0
Aortic insufficiency	0	0	0
Aortic-related death/paraplegia/disabling stroke	**2 (7.1%)**	1 (3.8%)	0

*carotid-LSCA bypass related

Three year outcomes of NEXUS system

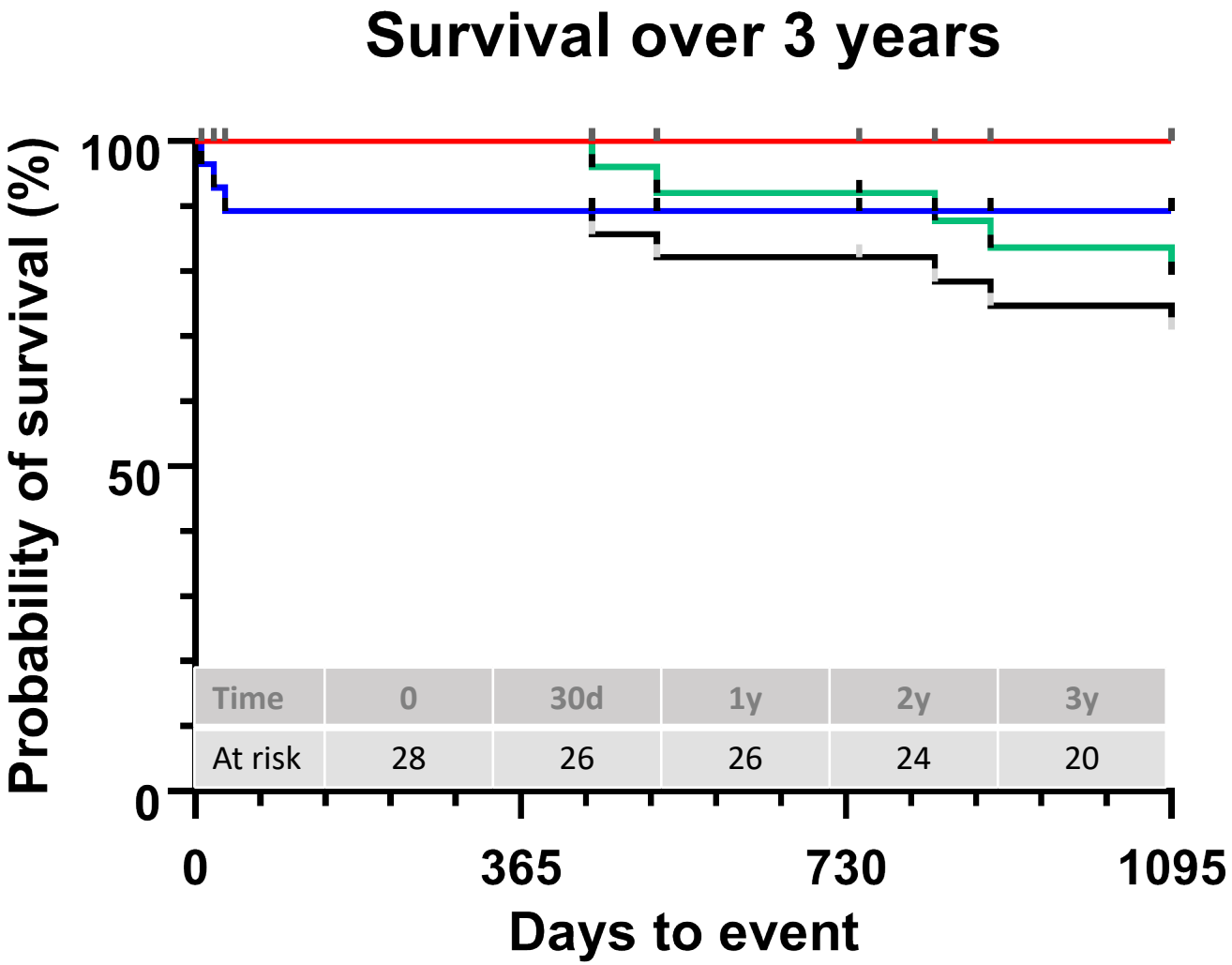
NEW ONSET OF EVENTS	30-days (n=28)	1-year (n=26)	3-year (n=25)
Technical success rate	25/26 (96.1%)*	NA	NA
Aneurysm enlargement >5mm	0	3 (11.5%)	1 (4.0%)
Stent graft migration	0	0	1 (4.0%)
New dissection or extension of existing dissection	0	1 (3.8%)	0
Aneurysm rupture	0	0	0
Occlusion of NEXUS BCT branch	0	0	0
Symptomatic occlusion of cervical bypass	0	0	0
Asymptomatic occlusion of cervical bypass	0	1 (3.8%)	1 (4.0%)

* Successful disease treatment of patients alive at 30-days post-implant

Low endoleak rates over 3 years

	NEW ONSET OF ENDOLEAKS			ENDOLEAKS PRESENT AT FOLLOW UP		
	30-days (n=28)	1-year (n=26)	3-year (n=25)	30-days (n=28)	1-year (n=26)	3-year (n=25)
Type Ia	0	0	0	0	0	0
Type Ib	1 (3.6%)	0	0	1 (3.6%)	1 (3.8%)	1 (4.0%)
Type II	3 (10.7%)	0	0	3 (10.7%)	0	0
Type III	1 (3.6%)	1 (3.8%)	1 (4.0%)	1 (3.6%)	1 (3.8%)	2 (8.0%)
Type IV	0	0	0	0	0	0
Type V	0	0	0	0	0	0
Gutter leak	4 (14.3%)	0	0	4 (14.3%)	2 (7.6%)	1 (4.0%)

Causes of mortality during follow up

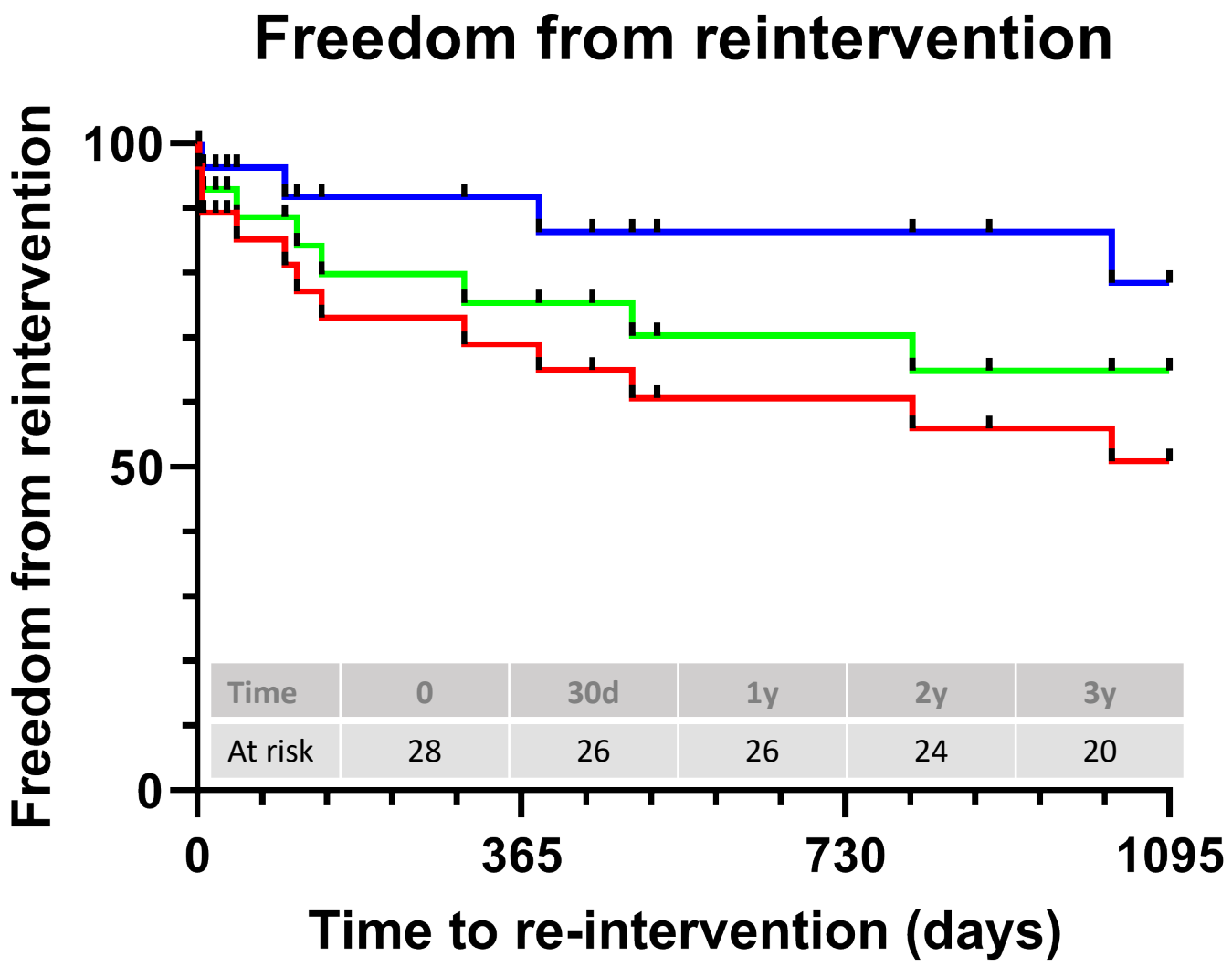


- Device related death
- Procedure-related death
- Non-aortic related death
- All cause death

Late mortalities

- 15mo sepsis
- 17mo AF-related stroke
- 24mo cardiac failure
- 29mo COPD
- 36mo COVID

Causes of re-intervention during follow up



Surgical reintervention

Endovascular reintervention

Any reintervention

Re-interventions (n=13)

- 9/13 endovascular
  - 6 related to chimney use
  - 2 TEVARs
  - 1 coiling perforation
- 4/13 open surgery
  - 3 peripheral graft ops
  - 1 ascending haematoma

Conclusions

- In a cohort containing a number of high risk and compassionate cases, use of the NEXUS Aortic Arch Stent Graft System resulted in a excellent combined aortic-death/paraplegia/disabling stroke rate of only 7.1% at 30 days

- Despite all cases having a proximal landing site in zone 0, the medium term outcomes were very good with few reinterventions

- The NEXUS system has great potential to expand the use of endovascular therapy for those with aortic arch disease, and results in low morbidity and mortality rates