Challenging neck anatomy / Stent Design & Performance / Pythagoras IDE study / #01 November 2013

FOREFRONT (

Welcome to Forefront Endovascular News, which has been created by Lombard Medical as part of our commitment to responsible innovation. We are aiming to bring the latest and the most relevant clinical data and publications regarding the use of Aorfix[™] endovascular stent graft, as well as advancements and updates in EVAR, to the attention of EVAR specialists.

For further information on Aorfix[™] Endovascular Stent Graft, please see our website www.lombardmedical.com.

Synopses of third party publications presented in this document are not verified or endorsed by Lombard Medical. Readers are encouraged to refer to full publications to establish the relevance of findings to their own practice.



Challenging neck anatomy leads to early stent graft failures



Adapted from Vascular News International issue 59, Septemer 2013



Many early failures were due to challenging neck anatomy with inadequate seal fixation and infection. Late failures were often due to device failures or aortic disease progression.

Dr Eric J Turney from the Department of Vascular Surgery at the Cleveland Clinic presented important findings at the SVS 2013 meeting*.

The purpose of this study was to evaluate the Cleveland Clinic experience with late conversion between 1999 and 2012 and identify modes of AAA stent graft failures and predictors of outcomes.

It was suggested that the most common indication for graft explant was endoleak, present in 82% of patients, followed by infection with 13% occurrence. In the study endolaeks were Type I in 40% of the patients and type II in 30% of the cases. Some of the other conclusions include:

- Most AAA graft failures occur between years 1 - 5 and are caused by inadequate sealing and endoleaks
- Inadequate sealing is the top reason for stent graft explant
- Reason for Type I endoleaks challenging anatomy with neck outside the IFU
- Early stent graft failures occur due to challenging neck anatomy with inadequate seal, fixation or presence of infection
- Late failures are caused by stent graft structural failures or aortic disease progression.

*For full article details, see Vascular News International, issue 59, Sept 2013

Finite element analysis of the mechanical performances of 8 marketed aortic stent-grafts.

Demanget et al., 2013. J Endovasc Ther. (4):523-35.

This study assesses the flexibility and mechanical stresses undergone by stents and fabric of currently manufactured stent-grafts in tortuous AAA anatomy.

Based on analysis of performance of 8 different stent graft iliac limbs, the study concludes that stent design strongly influences mechanical performances. Spiral and circular stents provide greater flexibility, as well as lower stress values than Z-stents, and can be expected to have better durability.



90° 180°

In comparison of luminal reduction rates at 90° and 180°, Aorfix maintains the most consistent lumen patency and the least variation on lumen reduction across all angles.

Pythagoras IDE study

the largest prospective, controlled and multi-centre study of highly angulated necks (0° - 90°)

This IDE study assess the functionality and effectiveness of the Aorfix[™] endovascular stent.

Study parameters

- Multicenter trial (45 centers)

 no prior practice with Aorfix™ before performing cases
- The US trial enrolled 218 patients on intent to treat, 67 <60°, 151 ≥ 60°

Aorfix[™] patients were significantly older than open surgery cases

Neck angulations in Aorfix[™] patients significantly higher than in OR

CHF patients were very sick

Gender distribution

Due to the nature of this investigation, the patient demographics included several factors previously shown to affect outcomes adversely.

- Age (EVAR 75.6 ± 7.5, vs. 69.1 ± 7.4 years, p=0.001)
- Female (EVAR high angle 35.1% (52/151) vs. 16.7%, p=0.015)
- CHF (EVAR 13.4% vs. 5.4% p=0.029)
- Neck angle (EVAR all 71.4° ± 22.6, EVAR high angle 83° ± 15, vs. Open 48° ± 23 degrees, p<0.001)

35% of Aorfix[™] high angle patients were females vs.

20% in the open group and vs. approximately

10% in other EVAR trials



Findings

Complete Pythagoras data can be compared to competitors' FDA results despite including more challenging anatomy.

Performance is equivalent to or better than competitors despite the more challenging angulated anatomy and sicker patient cohort.

> (Dr Fillinger, SVS presentation, Washington DC June 9, 2012)

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Pythagoras results are encouraging that Aorfix[™] does not exhibit similar degradation in performance, even in high angled necks as previously observed in other competitor studies.

Based on the satisfactory Pythagoras results, the FDA granted approval for the use of Aorfix[™] in angles from 0° to 90°.

Aorfix[™] is the only stent graft approved in angulations up to 90° by the FDA and EU regulatory agencies.

Aorfix[™] (n=218) Talent Endurant Endologix **Aorfix™** Gore Excluder Cook Zenith Cook Zenith (Hi Risk) (n=67) Freedom from SVS MAE (30D) 84.9% 92.5% N/A 96% 89% N/A N/A N/A 1.8% 1.5% 1.8% 0% 1% 1.3% 0.5% 2% 6.9% 4.5% 6.5% 4% 6.8% 7.3% 3.5% 9% (1vr 43.9% 36.7% 33.6% 49.6% 35.7% 14.3% 67.5% 62.9% n 1Yr` 2.3% 7.1% 1.3% 1.6% 1.4% 0% 0% 2% m 1Yr` Type I/III I 1.3% 0% 2.5% 0% 0% 1.3% 1.4% 1.8% Migration (10mm 1yr) 0.7% 2.5% 1.2% 0% 0.8% 0% 2.3% 2.8%

Pythagoras data and competitor data from Summaries of Safety and Effectiveness filed with FDA.

Aorfix[™] performance in challenging anatomy

Comparison of Aorfix[™] results versus competitors



Images Courtesy of Dr Marc Glickman and Dr Jean Panneton, Sentara Heart Hospital, Norfolk, VA

*References Hobo, R. et al J Endovasc Ther 2007; 14(1): 1-11. Choke, E. et al. Cardiovasc Intervent Radiol 2006; 29:975–980. AbuRahma, A. F., et al Vascular. 2010;18(2): 93–101. Torsello, G., et al J Vasc Surg 2011



www.lombardmedical.com

Lombard Medical Limited Lombard Medical House 4 Trident Park, Didcot, Oxon, OX11 7HJ, UK