DOI: 10.1111/jocs.15197

EDITORIAL

JOURNAL OF CARDIAC SURGERY WILEY

Launching the E-vita Open Neo amid COVID—Challenges and strategies

1 | INTRODUCTION

Aortic arch disease commonly involves multiple segments, leading to the needs of multistaged procedures and the intraoperative selective perfusion of arch branches. The total aortic arch replacement with frozen elephant trunk (TAR FET) technique was developed over the past decades. It has become one of the mainstream options with acceptable risk profiles.[1–4] It could offer a single-stage treatment in selected arch aneurysm cases and, more importantly, it facilitates second-stage treatments of descending pathologies with endovascular repair[1,2,5] and open replacement.[1,2,6]

In October 2020, the E-vita Neo Open was introduced in Hong Kong as a third commercially available hybrid arch prosthesis. Introducing a new medical device requires multi-levels of co-ordination to ensure patient's safety and outcome, especially under the challenges of COVID-19 with travel restrictions and social distancing, we would like to report the feasibility and importance of virtual proctorship. The patient involved had an informed consent form signed according to the institutional requirement.

2 | FROZEN ELEPHANT TRUNK—THE USE AND AVAILABILITY IN ASIA

In Asia, before the commercially available hybrid TAR FET device, the "frozen elephant trunk" involved off-label implantation of a conventional thoracic aortic stent graft into the descending thoracic aorta followed by anastomosis with another piece of vascular graft for the arch vessels reimplantation and ascending aortic replacement. This approach was the most widely practiced TAR FET in Asia.[7,8] The problems with this "improvised" approach are long and bulky aortic stent graft system and endovascularly designed deployment mechanism, and the absence of sewing cuff for the anastomosis at the distal arch. These problems led to the improvement of the vascular graft design and the dawn of the hybrid arch device. There are two commercially available hybrid prostheses in Hong Kong: the E-vita Open Plus hybrid stent graft system by JOTEC (Hechingen) and the Thoraflex™ Hybrid by Vascutek (Inchinnan). Similar hybrid prostheses are available worldwide: CRONUS (MicroPort) in China[9] and J Graft Open stent graft (Japan Lifeline)[10] and Frozenix (Japan Lifeline)[11] in Japan. All prostheses have shown acceptable outcomes as proven in a recent meta-analysis.[12,13] In Hong Kong, the number of TAR FET was relatively limited compared to the usage in Europe. In the past 5 years, our institution performed 44 cases of TAR FET and more than 400 aortic cases including root procedure, open descending aortic replacement, and thoracoabdominal aortic replacement.

3 | THE GAP IN THE MARKET UPON DECADES OF FET DEVELOPMENT

The hybrid TAR FET was commercially available in Hong Kong for around 6 years. We observed a gradual adoption of the new devices in various countries in Asia bounded by the local policy of clinical usage in new technology and reimbursement. With CE and FDA approval and clinical trials showing outstanding early and mid-term results, we believe these devices are going to flourish further in Asia.[12–14] In most aortic centers of Asia, individual arch branch anastomosis is preferred during TAR FET procedure, while the first-generation E-vita Open Plus hybrid stent graft system, did not come with individual side branches. The straight graft FET with arch vessels first approach has been reported to allow more flexible supra-aortic branches reconstructions and reducing cerebral, visceral, and myocardial ischemia compared to the commercially available branched hybrid FET prosthesis.[14] The introduction of the E-vita Open Neo with various arch designs could offer additional options and would in turn trigger an increasing adoption of the technique for complex aortic pathology in Asia.

4 | THE E-VITA OPEN NEO—AN UPDATE THAT FILLS THE GAP OF CLINICAL NEED

4.1 | Zone of implantation and the variation of graft designs

Zone of implantation was associated with better survival at Zone 2 with the E-vita Open Plus grafts,[15] that could be related to better exposure of anastomosis and hence shorter circulatory arrest and ischemic time. There are three variations of the E-vita Open Neo at the Dacron graft portion: (I) single tube graft with side branch; (II) arch branched graft for individual selective anastomosis; and (III) the Spielvogel type adopting the "no-arch-touch" principle suturing at Zone 0.[16] These variations allow adaption to individual surgeon for the best exposure, implantation, and supra-aortic anastomosis.

Our institute adopted an arch branched graft version of E-vita Open Neo. The approach of our TAR FET technique was previously

reported, principally with the distal-proximal-supra-aortic sequence of anastomosis under moderate hypothermic circulatory arrest and selective antegrade cerebral perfusion to all supra-aortic vessels.[17] The distance between the sewing collar and the third (left subclavian artery) side branch of the E-vita Open Neo was 20 mm when compared with that of 5 mm in Thoraflex™ hybrid stent graft, which provides longer anastomosis space to left subclavian artery and lowers the risk of graft kinking.

4.2 | Stent graft design

Higher spinal cord injury when compared with floating elephant trunk has been a concern surrounding the adoption of FET. The growing evidence in balancing between sealing of distal re-entry and spinal cord injury has led to the reduction in length of stent graft. Studies in type I/III aortic dissection patients with the use of intra-operative angioscope were able to identify the position of distal re-entry sites found within 5 cm in 73% of patients distally to the origin of the left subclavian artery and 31% in the 6–10 cm.[15] The design of the 120 mm E-vita stent-graft would be able to seal off most of the re-entry even with a zone 2 anastomosis. Furthermore, the stent-graft portion of the E-vita Open Neo has adopted the traditional endovascular stent design without a distal ring. Follow-up data would allow a reflection of distal stent induced new entry, which has significant implications for second stage operations.[1,2]

5 | ISSUES WITH LAUNCHING NEW PRODUCT IN COVID-19 AND THE OPPORTUNITIES OF VIRTUAL PROCTORING

Improvement in the graft designs and easier-to-handle deployment system, the E-vita Open Neo has expanded its clinical versatility. It was granted with CE-mark in March 2020 and available in Europe. Launching new medical device has been limited by the COVID-19 resultant to travel restrictions and social distancing. The restricted hospital visits by nonessential personnel limited proctoring and skills sharing. This brings hurdles to medical development, however, brings the opportunity of virtual proctoring.

Our first patient with the implantation of E-vita Open Neo was a 60-year-old lady with rapidly expanding Type III aortic dissection and arch aneurysm. Under patient's consent and co-ordination among the multidisciplinary aortic team and local product representative of E-vita Open Neo, a real-time live virtual proctoring was arranged between Hong Kong and Germany. Preoperative online meetings to review clinical and radiological findings, product introduction and discussion of operative strategies; intra-operative real-time on-table discussion and postoperative evaluations were done. Total operative time of 420 min, circulatory arrest at 28°C for 45 min, and selective antegrade cerebral perfusion to all three supra-aortic branches for 137 min. The patient was neurologically intact and discharged 12 days post-operation.

6 | CONCLUSION

Surgical innovation and advancement over the decades have brought outstanding outcomes in aortic arch surgery. The newly available E-vita Open Neo hybrid system offers additional FET options, the use of virtual proctoring allowed its introduction to our patients amid challenging time during COVID-19. Virtual proctoring maintained international collaboration and skills sharing, which could become the "New Normal" in face of global pandemics.

Jacky Y. K. Ho MBChB, FRCS[1]
Mohamad Bashir MD, PhD[2]
Gloria Teh MBA[3]
Heinz Jakob MD, PhD[4]
Randolph H. L. Wong MBChB, FRCS, FCSHK, FCCP, FHKAM[1]

[1]*Department of Surgery, Division of Cardiothoracic Surgery, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong SAR, China*
[2]*Vascular & Endovascular Surgery, Royal Blackburn Teaching Hospital, Blackburn, UK*
[3]*CryoLife, Inc, Asia-Pacific Region, Singapore*
[4]*Department of Thoracic and Cardiovascular Surgery, West German Heart Center Essen, University Hospital Essen, Essen, Germany*

Correspondence
Randolph H. L. Wong, MBChB, FRCS, FCHSK, FCCP, FHKAM, Consultant and Chief, Division of Cardiothoracic Surgery, Department of Surgery, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong, SAR, China.
Email: wonhl1@surgery.cuhk.edu.hk

ORCID
Jacky Y. K. Ho http://orcid.org/0000-0003-2339-0454
Mohamad Bashir http://orcid.org/0000-0002-2605-538X
Heinz Jakob http://orcid.org/0000-0001-8963-0102
Randolph H. L. Wong https://orcid.org/0000-0003-0027-459X

REFERENCES

1. Leone A, Beckmann E, Aandreas M, et al. Total aortic arch replacement with frozen elephant trunk technique: results from two European institutes. *J Thorac Cardiovasc Surg*. 2020;159(4):1201-1211.
2. Berger T, Weiss G, Voetsch A, et al. Multicentre experience with two frozen elephant trunk prostheses in the treatment of acute aortic dissection. *Eur J Cardiothorac Surg*. 2019;56(3):572-578.
3. Borst H, Walterbusch G, Schaps D. Extensive aortic replacement using 'elephant trunk' prosthesis. *J Thorac Cardiovasc Surg*. 1983;31:37-40.
4. Shrestha M, Bachet J, Bavaria J, et al. Current status and recommendations for use of the frozen elephant trunk technique: a position paper by the vascular domain of EACTS. *Eur J Cardiothorac Surg*. 2015;47(5):759-769.
5. Wong RHL, Yu PSY, Kwok MWT, et al. Endovascular fenestration for distal aortic sealing after frozen elephant trunk with Thoraflex. *Ann Thorac Surg*. 2017;103(6):e479-e482.
6. Fujikawa T, Ho JYK, Wong HMK, Wong RHL. Open descending aortic replacement after Thoraflex™ hybrid graft implantation. *Eur J Cardiothorac Surg*. 2019;56(3):612-614.

7. Usui A, Fujimoto K, Ishiguchi T, Yoshikawa M, Akita T, Ueda Y. Cerebral dysfunction after endovascular stent-grafting via a median sternotomy: the frozen elephant trunk procedure. *Ann Thorac Surg*. 2002;74(5):S1821-S1824.
8. Uchida N, Katayama A, Tamura K, et al. Long-term results of the frozen elephant trunk technique for extended aortic arch disease. *Eur J Cardiothorac Surg*. 2010;37(6):1338-1345.
9. Liu ZG, Sun LZ, Chang Q, et al. Should the "elephant trunk" be skeletonized? Total arch replacement combined with stented elephant trunk implantation for Stanford type A aortic dissection. *J Thorac Cardiovasc Surg*. 2006;131:107-113.
10. Kato M, Kuratani T, Kaneko M, Kyo S, Ohnishi K. The results of total arch graft implantation with open stent-graft placement for type A aortic dissection. *J Thorac Cardiovasc Surg*. 2002;124:531-540.
11. Okita Y. Frozen elephant trunk with Frozenix prosthesis. *Ann Cardiothorac Surg*. 2020;9(3):152-163.
12. Harky A, Fok M, Bashir M. Which is the optimal frozen elephant trunk? A systematic review and meta-analysis of outcomes in 2161 patients undergoing thoracic aortic aneurysm surgery using E-vita Open Plus Hybrid Stent Graft versus Thoraflex™ hybrid prosthesis. *Braz J Cardiovasc Surg*. 2020;35(4):427-436.
13. Tian DH, Wan B, Di Eusanio M, Black D, Yan TD. A systematic review and meta-analysis on the safety and efficacy of the frozen elephant trunk technique in aortic arch surgery. *Ann Cardiothorac Surg*. 2013;2:581-591.
14. Di Bartolomeo R, Murana G, Di Marco L, et al. Frozen versus conventional elephant trunk technique: application in clinical practice. *Eur J Cardiothorac Surg*. 2017;51:i20-i28.
15. Tsagakis K, Jakob H. Which frozen elephant trunk offers the optimal solution? Reflections from Essen Group. *Semin Thorac Cardiovasc Surg*. 2019;31:679-685.
16. Jakob H, Idhrees M, Bashir M. Frozen elephant trunk with straight vascular prosthesis. *Ann Cardiothorac Surg*. 2020;9(3):164-169.
17. Wong RH, Ho JY, Underwood MJ. Multimodality imaging assessment for Thoraflex hybrid total arch replacement. *Asian Cardiovasc Thorac Ann*. 2016;24(5):496-501.