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SURGERY

FIRST-IN-HUMAN/EARLY REPORTS

Use of a Novel Physician-Modified Frozen Elephant Trunk to Manage an Acute Aortic Arch Aneurysm

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ABSTRACT

BACKGROUND The frozen elephant trunk (FET) technique has become a cornerstone in managing complex aortic arch disease. However, commercial FET systems may be unavailable in emergent situations, necessitating alternative solutions.

FIRST-IN-HUMAN/EARLY REPORTS SUMMARY In a 57-year-old man with an acute arch aneurysm with dissection, we replicated the FET configuration by back-table modification of a standard thoracic stent graft and combining it with a surgical graft. This novel approach, the "C-tag Endograft SanRaffaele Arrangement to Re-create a frozen Elephant trunk" (CESARE), provides a rapid, adaptable solution for emergent aortic arch repair with FET when commercial devices are unavailable.

DISCUSSION The modified device was prepared in 65 minutes and was deployed under moderate hypothermic circulatory arrest, with uneventful recovery and excellent early imaging.

NOVELTY CESARE is a rapid, customizable, and widely accessible alternative to FET.

TAKE-HOME MESSAGE This technique enables effective arch repair when standard FET prostheses are unavailable. (JACC Case Rep. 2025;30:105860) © 2025 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Combining open surgery with endovascular repair, the frozen elephant trunk (FET) technique facilitates complete arch replacement and has become a widely accepted strategy for treating complex aortic arch diseases.[1-3] Encouraging results with this method has led to the development of several FET devices for commercial use, available

TAKE-HOME MESSAGE

- With the reported technique, a standard stent graft was used to re-create the frozen elephant trunk configuration, yielding an effective result in a patient with an acute aortic arch aneurysm after aortic dissection.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

CSBP = carotid-to-subclavian artery bypass

CTA = computed tomography angiography

FET = frozen elephant trunk

SG = stent graft

in both off-the-shelf and custom-made configurations.[1]

However, despite advancements in device technology, commercially manufactured FET systems are not universally accessible and may be unavailable for urgent or emergency use in specific centers. To address these challenges, alternative techniques inspired by the same principles have been described, showing encouraging outcomes but also presenting some drawbacks.[4,5]

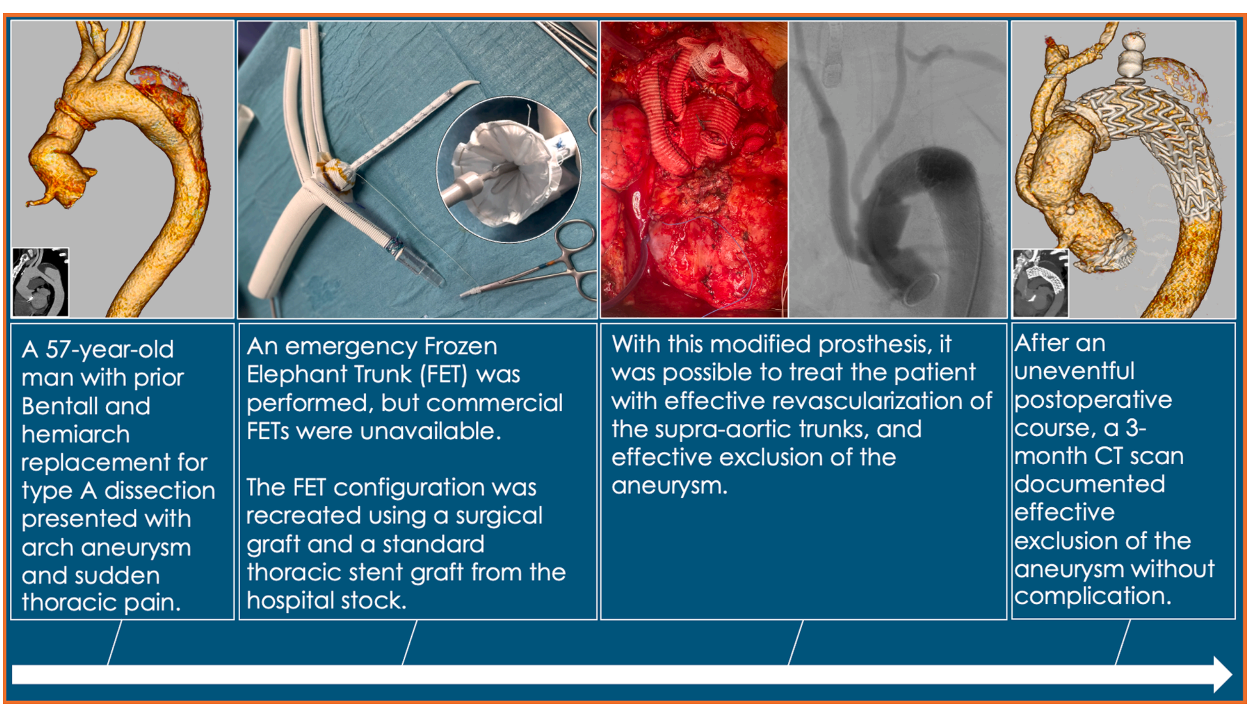
In this report, we describe an innovative method for replicating the FET concept using a standard thoracic stent graft (SG), and we detail the case of a patient successfully managed with this approach. To the best of our knowledge, this is the first reported experience employing this specific approach.

CASE SUMMARY

A 57-year-old man was evaluated in our outpatient clinic. His medical history was notable for an acute type A aortic dissection in 2018, which was managed with a Bentall procedure involving aortic valve replacement using a valved conduit (St Jude 27/30; St Jude Medical), along with hemiarch replacement using a vascular graft (Hemashield Platinum 28 × 10 mm; Maquet Cardiovascular). The patient did not adhere to scheduled follow-up visits, and 81 months after the index procedure, he underwent a thoracic computed tomography angiography (CTA) after a motor vehicle accident. Imaging revealed a 5.9-cm aortic arch aneurysm associated with a residual dissection (Figure 1). Given the initial pathology, the progressive aneurysmal dilation, and the patient's relatively young age, elective aortic arch replacement using the FET technique was indicated.

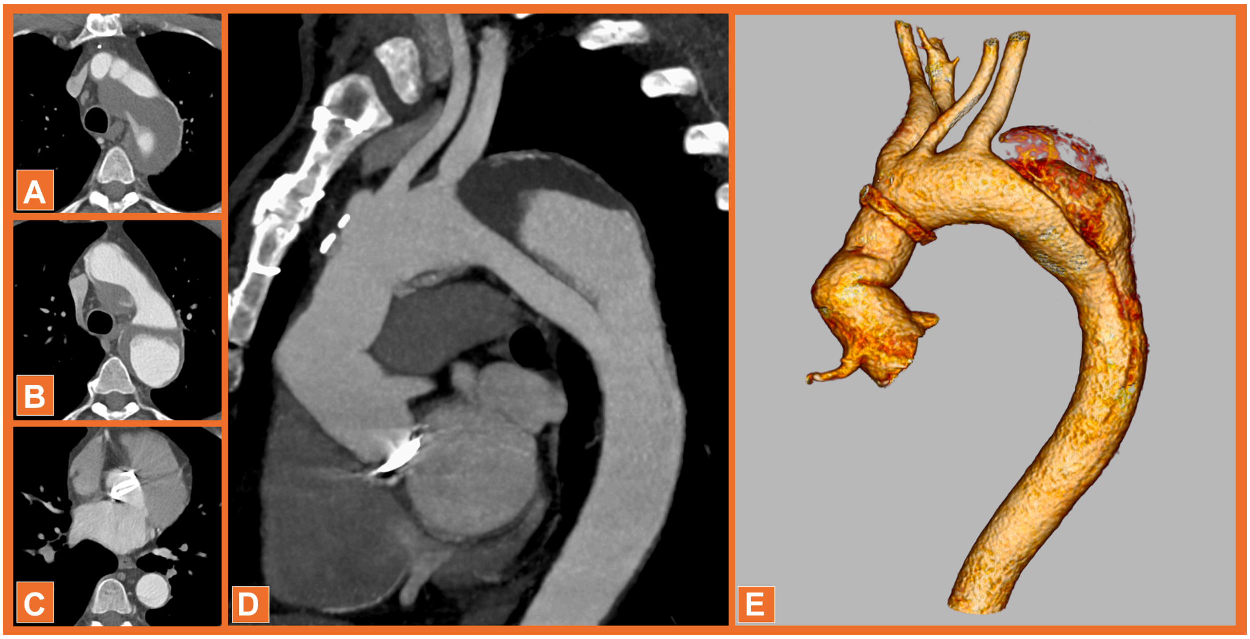
As per institutional protocol, the patient first underwent a left carotid-to-subclavian artery bypass (CSBP), combined with endovascular occlusion of the proximal left subclavian artery, to facilitate extracorporeal circulation and bilateral antegrade cerebral perfusion via bilateral axillary access during the planned FET procedure.[6] The CSBP was performed using a 6-mm ePTFE (expanded polytetrafluoroethylene) graft (W.L. Gore), and the proximal left subclavian artery was occluded using a 16-mm Amplatzer vascular plug II (Abbott Vascular) deployed via a left radial artery approach (Figure 2). The postoperative course was uneventful, and the patient was discharged on postoperative day 4, with aortic arch repair planned after a 15-day interval.

VISUAL SUMMARY Timeline of Case Presentation and Treatment



CT = computed tomography.

FIGURE 1 **Preoperative CTA**



The patient had previously undergone a Bentall procedure with aortic valve replacement using a valved conduit for acute type A aortic dissection that occurred 7 years ago. Because of loss to follow-up, a new CTA was performed only after a motor vehicle accident. (A to C) Axial images, (D) multiplanar reconstruction, and (E) 3D reconstruction demonstrate progressive enlargement of the residual dissection with a 5.9-cm aortic arch aneurysm. 3D = 3-dimensional; CTA = computed tomography angiography.

Four days postdischarge, the patient presented to the emergency department with acute thoracic pain. A new CTA documented an impending aortic rupture, and an emergent FET procedure was performed to prevent it (Figure 3); in line with local law and institutional practice, the patient was informed and provided consent for physician-modified graft use.

The axillary arteries were bilaterally exposed and cannulated with the interposition of 2 8-mm Dacron grafts (Maquet Cardiovascular) to allow anterograde cerebral perfusion and extracorporeal circulation. Then, through a median sternotomy, the ascending aorta, innominate artery, and left common carotid artery were progressively exposed. According to our standard practice, the common femoral artery was punctured under ultrasound guidance to catheterize the true lumen of the aorta. Then, through a 6-F introducer, a pigtail catheter was advanced over a 0.035-inch guidewire in the ascending aorta under transesophageal echocardiography and fluoroscopy guidance.

At our institution, the E-Vita Open NEO (JOTEC CryoLife/ARTIVION) is the standard device used for FET; however, owing to logistical constraints, this device was not available in stock and had to be ordered. Given the urgency of the clinical situation, we opted to re-create the FET configuration using a standard thoracic SG readily available in our hospital stock. The devices used for this back-table modification were the Gore TAG conformable thoracic aortic graft (CTAG) (34-150 mm; W.L. Gore) and the Hemashield platinum woven aortic branch with 4 branches (30/12/8/8/10 mm; Maquet Cardiovascular), which are routinely stocked at our facility. The modified device was prepared on a back table during the exposure of the ascending aorta and the supra-aortic trunks. The surgical graft with 4 branches (the Hemashield Platinum) was modified to include a Dacron collar to facilitate the distal anastomosis between the FET and the aorta (Figure 4).

The delivery system of the SG was modified to allow the partial release of the distal part of the prosthesis (the CTAG): Briefly, the deployment line access hatch was opened, line n.3 and line n.4 were cut and removed, line n.2 was pulled to remove the inner deployment sleeve, and line n.1 was cut at the access hatch. Then, the surgical graft was inserted onto the SG delivery system, over the SG, and line n.1

FIGURE 2 Left CSBP and Proximal LSA Occlusion

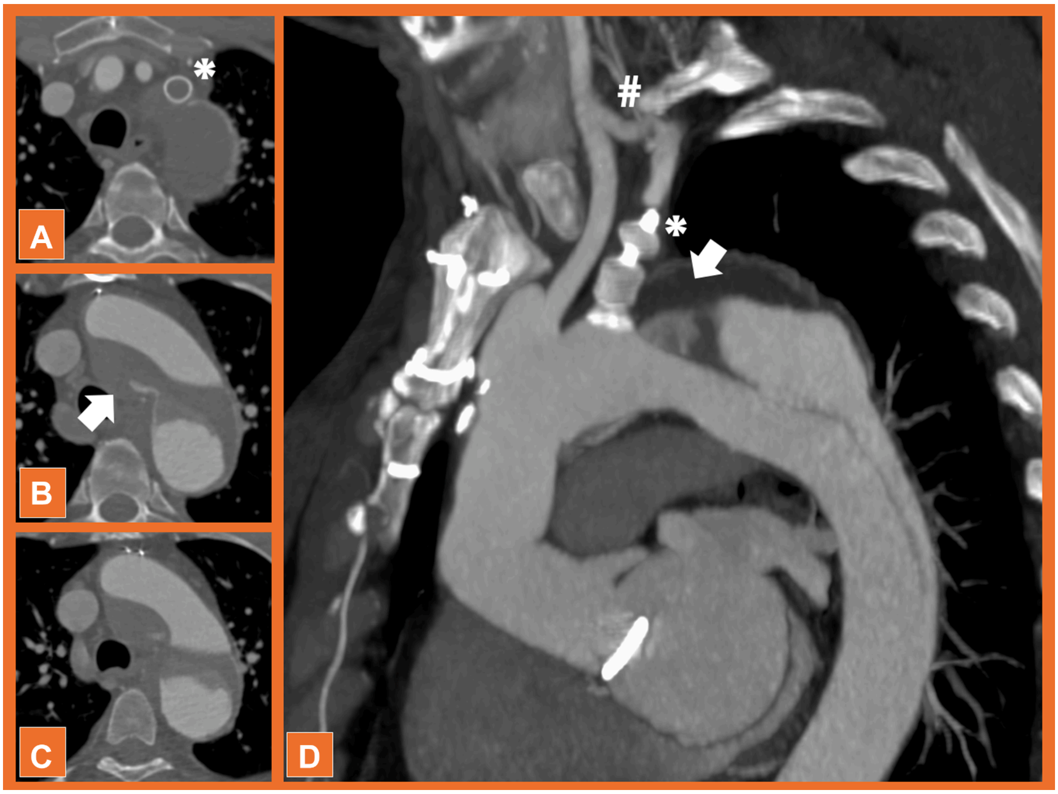
According to institutional protocol, patients undergoing FET repair first receive a CSBP to facilitate bilateral antegrade cerebral perfusion via bilateral axillary access. When feasible, the LSA is endovascularly occluded to prevent back-bleeding during and after FET. In this case, after CSBP, the proximal LSA was occluded with a 16-mm Amplatzer vascular plug II (Abbott Vascular) deployed via a left radial approach. (A) Angiography before complete device release shows patency of the left vertebral artery (°), CSBP patency (* and dotted lines), and partial retrograde opacification of the LCCA (#). (B) Final angiography after complete Amplatzer vascular plug II deployment in the prevertebral LSA (dotted circle). CSBP = carotid-to-subclavian artery bypass; FET = frozen elephant trunk; LCCA = left common carotid artery; LSA = left subclavian artery.

was proximally retrieved at the level of the SG to allow for an independent release and to remove line n.1 from the subsequent anastomosis between the SG and the surgical graft. Then, the distal part of the deployment sleeves was cut, and the distal part of the SG was manually opened (Figure 5); the modified surgical graft and the SG were then sewn together using a CV-4 Gore-Tex suture (W.L. Gore), re-creating an FET (Figure 6). The entire modification process lasted 65 minutes.

Once the patient was cooled to 28 °C, the previous aortic tube was clamped, and anterograde cardioplegia with Custodiol was administered. Then, while bilateral axillary perfusion was maintained, the previous tube-graft was circumferentially transected and prepared for the proximal anastomosis. Next, the distal perfusion was stopped, the clamp was removed, and the distal aortic neck was prepared in zone 0 using a 2/0 Prolene running suture and Teflon felt. A stiff 0.035-inch guidewire was introduced from the common femoral artery over the pigtail catheter. The modified graft was introduced in an over-the-wire manner, and the SG was released by pulling the independent line n.1. To ensure immediate and adequate expansion of the SG, an over-the-wire ballooning procedure with a 32-mm compliant balloon was also performed. The sewing collar of the graft was anastomosed to the previously prepared distal aortic neck with a 2/0 Prolene running suture. Once the anastomosis was completed, the surgical graft was clamped above the reperfusion branch, and distal perfusion was restarted; the total time of circulatory arrest was 21 minutes.

While the patient was being progressively rewarmed, the proximal end of the graft was anastomosed to the previous ascending graft. The innominate artery was proximally ligated, transversally transected, and reattached to the 12-mm branch; the left common carotid artery was reattached using the distal 8-mm branch in the same fashion, while the middle branch (8 mm) was ligated (Figure 7). At 36 °C, the cardiopulmonary bypass was weaned and stopped, cannulas were removed, and axillary branches were ligated. An aortography was performed at the end of the procedure to assess the patency of the supra-aortic trunks and the correct expansion of the SG (Figure 8).

FIGURE 3 CTA Performed in the Emergency Department



(A to C) Axial images and (D) multiplanar reconstruction, when compared with the previous CTA, demonstrated a progressive enlargement of the aortic arch aneurysm (3 mm; new total aortic diameter 6.2 mm) and an increased perfusion of the false lumen in the posterior part of the aortic arch (white arrows in B and D). In this new CTA, it is also possible to observe the Amplatzer vascular plug II in the LSA (* in A and D) and the patent left CSBP (# in D). Owing to these radiological aspects and to the presence of acute and severe thoracic pain, only partially responsive to medications, the patient was urgently treated to prevent impending aortic rupture. CSBP = carotid-to-subclavian artery bypass; CTA = computed tomography angiography; LSA = left subclavian artery.

The postoperative course was uneventful, and the patient was discharged 7 days after the procedure. CTA performed 3 months after the intervention documented good postoperative results (Figure 9). Six months after the procedure, the patient was in good general condition; no late complications have been reported.

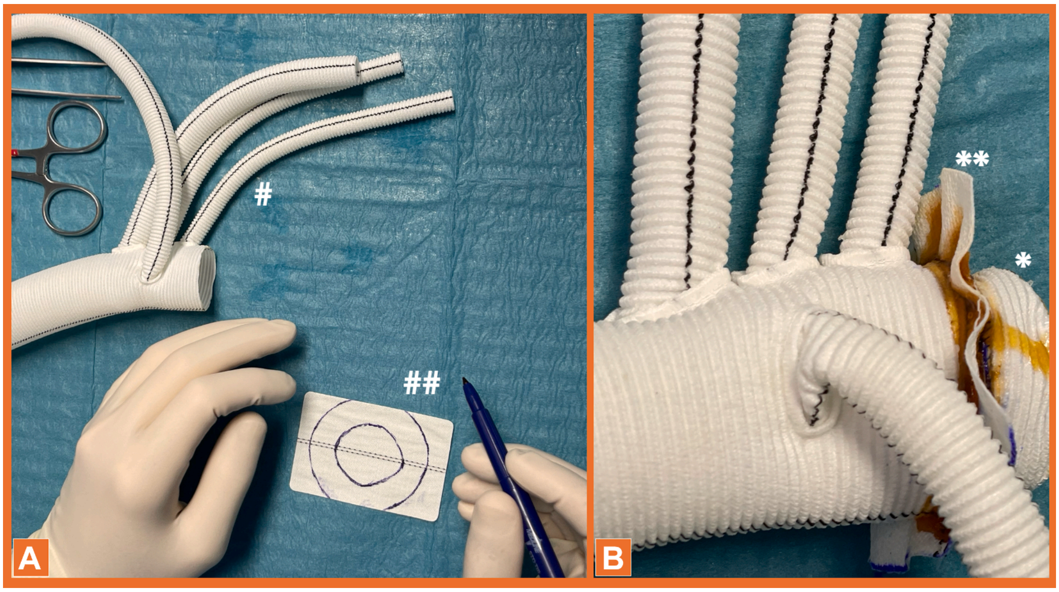
NOVELTY OF THE SUBMISSION

The FET technique has emerged as a significant technical advancement in the management of complex aortic pathologies, with encouraging outcomes supporting its increasingly widespread use, including in urgent and emergent settings.[1,7,8] Nonetheless, despite the increasing availability of commercially produced FET devices, their use is not universally feasible, and alternative approaches have been described to re-create the FET.[4,5,9] However, these techniques may require longer circulatory arrest times, may be more limited by anatomical characteristics, and may be more technically challenging to perform compared with the standard FET.

We describe a novel technique used for replicating the FET configuration using a commercially available thoracic SG. This technique was named "C-tag Endograft San Raffaele Arrangement to Re-create a Frozen Elephant Trunk" (CESARE). The key strengths of this modified device are several; among them, it is entirely customizable, it is easy and fast to create, and in addition, the device selected for this modification is likely among the most widely distributed and readily available SG in hospital inventories worldwide.[10]

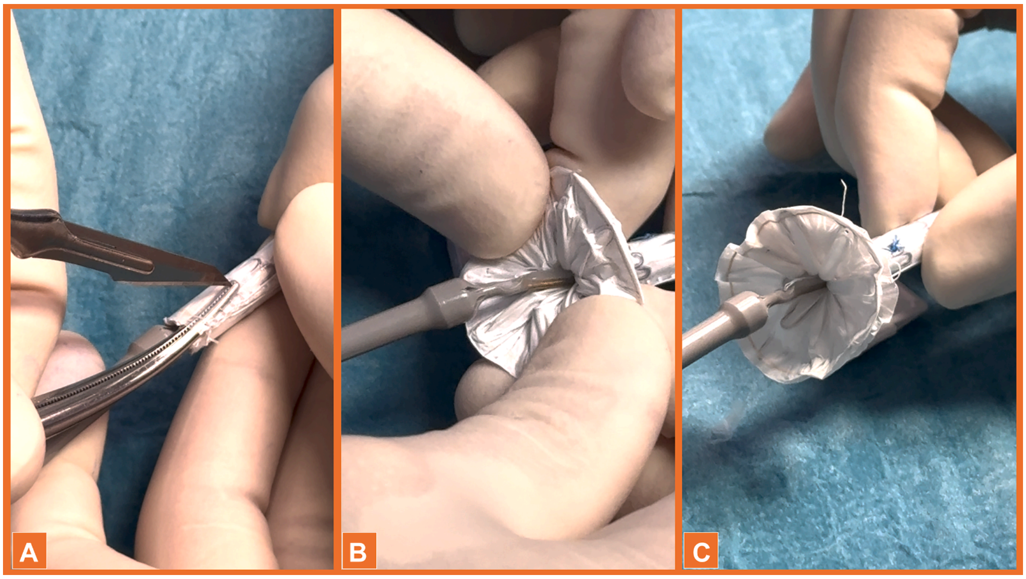
This report is the first application of the CESARE in a human patient. This modification had been

FIGURE 4 **Back-Table Modification of the Surgical Graft With a Dacron Collar**



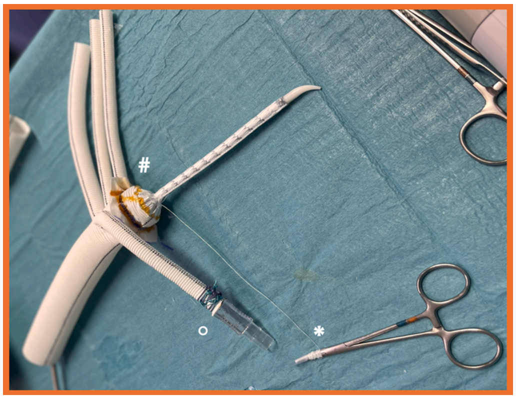
(A) The Hemashield graft was transected near the LSA branch (#). A Dacron patch was prepared into a 10- to 15-mm collar by cutting concentric inner and outer circles matching the graft diameter (##). (B) A short 10 to 12-mm tube segment (*) from the Hemashield was combined with the main graft and the Dacron collar (**) using a continuous 4-0 Prolene suture, then sealed with surgical glue. This configuration separated the anastomosis between the graft and collar from that between the graft and the stent graft. LSA = left subclavian artery.

FIGURE 5 **Back-Table Modification of the Stent Graft**



Delivery system control lines (n.1-n.4) were selectively cut or pulled from the access hatch to enable partial deployment and removal of the distal sleeve. (A) The stent graft was separated from the sleeves with a curved mosquito forceps, and the sleeves were excised circumferentially using a scalpel, without damaging line n.1. (B) The distal stent graft segment was manually opened after the sleeves were removed. (C) Detailed view of the completely opened distal stent graft.

FIGURE 6 Assembly of the Modified Surgical Graft and Stent Graft



The Hemashield and the stent graft were anastomosed with a CV-4 Gore-Tex running suture, re-creating the FET configuration (#). Line n.1 was routed over a mosquito forceps to allow independent stent graft release (*). A 12/8 mm tube connector was inserted into the distal perfusion branch (°) for rapid reconnection after completion of the distal anastomosis. FET = frozen elephant trunk.

previously extensively tested by us using bench tests with demonstration stent grafts to assess the adequate safety of the release despite the modifications to the delivery system.

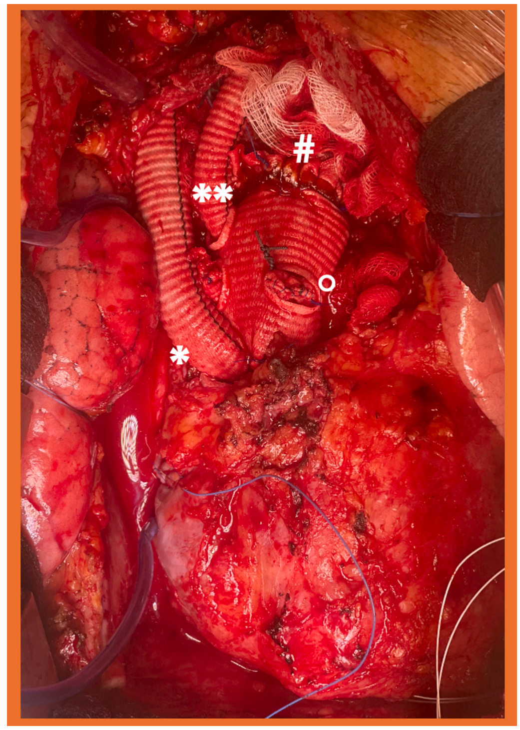
FUTURE DIRECTIONS

Although this technique was not developed to replace commercially available devices, its application may be of interest and is potentially lifesaving, particularly in emergency settings where standard FET prostheses are unavailable.

CONCLUSIONS

The CESARE technique is a feasible approach to re-create a FET. This approach should be reserved for select cases where commercial devices are not available. Additional prospective research is necessary to better assess the safety and efficacy of this approach.

FIGURE 7 Final Intraoperative Result



The distal anastomosis was performed using the Dacron collar (#). The innominate artery was reattached to the 12-mm branch with a continuous 4-0 Prolene suture (*); because of better prosthesis orientation, the middle 8-mm branch was ligated, and the left common carotid artery was reattached to the distal 8-mm branch with a 5-0 Prolene suture (**). After cardiopulmonary bypass weaning, cannulas were removed, and the distal perfusion branch was ligated proximally (°).

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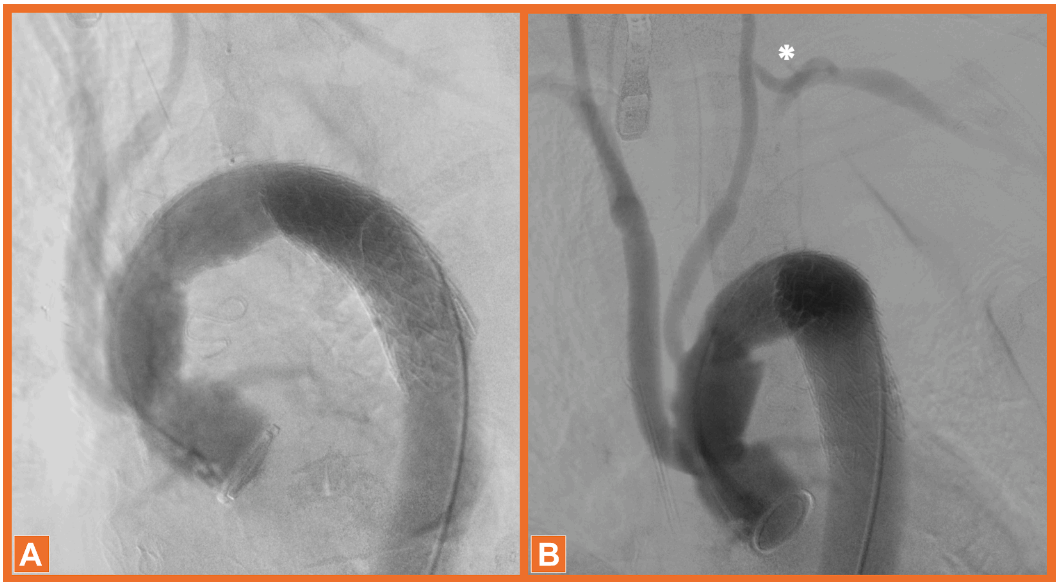
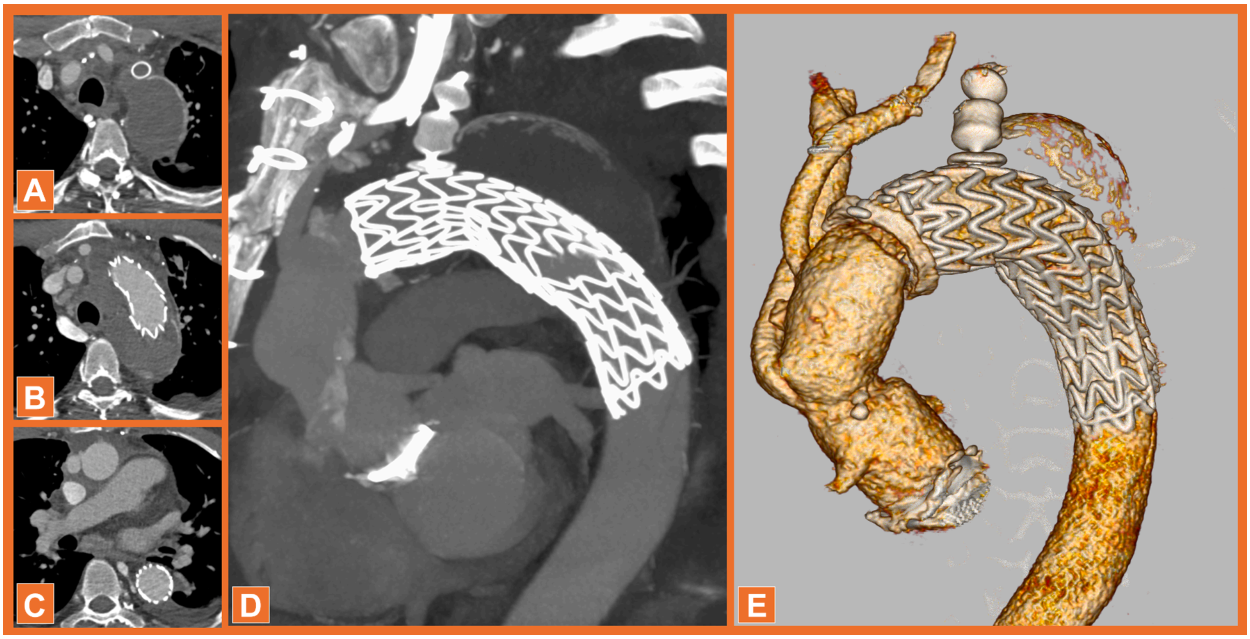
FIGURE 8 **Completion Angiography**



(A) Left lateral projection shows stent graft expansion with complete exclusion of the aneurysm. (B) Right lateral projection confirms aneurysm exclusion, patency of the supra-aortic trunks, and integrity of the anastomoses. The CSBP with LSA perfusion through the bypass is also visualized (*). CSBP = carotid-to-subclavian artery bypass; LSA = left subclavian artery.

FIGURE 9 **Three-Month Follow-Up CTA**



(A to C) Axial images, (D) multiplanar reconstruction, and (E) 3D reconstruction demonstrate durable aneurysm exclusion, complete thrombosis of the false lumen, and absence of endoleak. 3D = three-dimensional; CTA = computed tomography angiography.

REFERENCES

1. Hussain M, Jubouri YF, Hammad A, et al. The frozen elephant trunk: an overview of hybrid prostheses. *Expert Rev Med Devices*. 2025;22(3):193–208. https://doi.org/10.1080/17434440.2025.2471455

2. Karangelis D, Stougiannou TM, Christodoulou KC, et al. Hybrid aortic arch replacement with Frozen Elephant Trunk (FET) technique: surgical considerations, pearls, and pitfalls. *J Clin Med*. 2024;13(23):7075. https://doi.org/10.3390/jcm13237075

3. Coselli JS, Roselli EE, Preventza O, et al. Total aortic arch replacement using a frozen elephant trunk device: results of a 1-year US multicenter trial. *J Thorac Cardiovasc Surg*. 2024;167(5):1680–1692.e2. https://doi.org/10.1016/j.jtcvs.2022.08.029

4. Desai ND, Hoedt A, Wang G, et al. Simplifying aortic arch surgery: open zone 2 arch with single branched thoracic endovascular aortic repair completion. *Ann Cardiothorac Surg*. 2018;7(3):351–356. https://doi.org/10.21037/acs.2018.05.08

5. Gallingani A, Venturini A, Scarpanti M, Mangino D, Formica F. Frozen Elephant trunk: technical overview and our experience with a patient-tailored approach. *J Clin Med*. 2022;11(4):1120. https://doi.org/10.3390/jcm11041120

6. Bertoglio L, Fittipaldi A, Giambuzzi I, et al. Preliminary results of debranch-first technique in frozen elephant trunk procedures. *Ann Thorac Surg*. 2019;108(5):1345–1353. https://doi.org/10.1016/j.athoracsur.2019.04.010

7. Murana G, Campanini F, Orioli V, et al. Frozen elephant trunk in acute aortic dissection: a literature review. *Indian J Thorac Cardiovasc Surg*. 2023;39(Suppl 2):315–324. https://doi.org/10.1007/s12055-023-01624-2

8. Okita Y. Frozen elephant trunk usage in acute aortic dissection. *Asian Cardiovasc Thorac Ann*. 2021;29(7):612–618. https://doi.org/10.1177/0218492320951304

9. Chivasso P, Masiello P, Miele M, et al. The need for custom made frozen elephant trunk: when and where. *Cardiovasc Diagn Ther*. 2022;12(4):516–520. https://doi.org/10.21037/cdt-22-191

10. Skrypnik D, Bischoff MS, Meisenbacher K, Kronsteiner DB, Böckler D. A 10-Year single-center experience with the GORE TAG conformable thoracic stent graft in the treatment of thoracic aortic disease. *J Endovasc Ther*. 2022;29(3):370–380. https://doi.org/10.1177/15266028211049340

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