



The development of the Siena graft

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The evolution of surgical replacement of the aortic arch has been shaped by advances in surgical techniques and ancillary technologies. From the early pioneering attempts in the 1950s by Ho Ju Lin, Cooley, and DeBakey, which preceded the advent of cardiopulmonary bypass (CPB), the development of perfusion, cerebral protection, and surgical techniques, along with the evolution of prosthetic grafts, has progressively enabled surgeons to address these challenging conditions with greater confidence. Despite these remarkable advancements, aortic arch surgery still remains one of the most technically challenging procedures in cardiac surgery. A major turning point was the introduction of the elephant trunk technique by Borst in 1983. This approach allowed for staged treatment of diffuse aneurysmal disease, including both degenerative and post-dissection cases, and reduced the overall surgical risk across multiple procedures. Initially met with skepticism, the technique has since been universally adopted by centers specializing in aortic pathology. At the same time, numerous modifications to the technique have emerged. Each modification has addressed specific technical challenges or enabled the integration of new technologies. The development of the Siena graft in the early 2000s was driven by the need to harness the growing potential of endovascular devices, which had been evolving since the 1990s, and to address critical technical issues. These included the use of multi-branched prostheses and the introduction of an anastomotic collar to facilitate secure distal anastomoses, even in less-than-ideal anatomical conditions. The design of the Siena graft, now widely adopted by most manufacturers for arch grafts, required close collaboration with industry partners to ensure a reliable product from its inception. Today, the Siena graft remains a highly relevant platform for the treatment of diffuse aneurysmal disease that requires the elephant trunk technique. This paper describes the evolution and design of the graft, the technical approach, including pitfalls and safeguards, and our clinical experience.

Keywords: Aneurysmal disease; aortic arch surgery; elephant trunk technique; collared graft; endovascular surgery; frozen elephant trunk



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Introduction

In the early 2000s, we proposed to a leading vascular graft manufacturer the design of a new graft for arch surgery. By that time, significant progress had already been made in perfusion technology, temperature management, cerebral protection, graft technology (such as gelatin-impregnated grafts, which reduced bleeding and increased biocompatibility), and the evolution of surgical techniques, including the elephant trunk approach (1,2).

The surgical community had learned to selectively perfuse the brain, protect the myocardium, and safely modulate body temperature (3). Furthermore, advancements had improved the reproducibility of thoracic and thoracoabdominal surgery, although the risks and invasiveness of these procedures remained high and were generally considered suitable only for carefully selected patients deemed “fit for surgery” (4).

In Borst’s original conception of the elephant trunk

technique (5,6), the treatment of the aortic arch was thought to prepare patients for subsequent interventions on the descending and thoracoabdominal aorta. However, studies evaluating this approach consistently highlighted a dual challenge. First, although the risk of the initial arch procedure had gradually become increasingly manageable, a significant number of patients were either not eligible for the subsequent surgical step or declined the completion procedure due to the complexity and invasiveness of thoracoabdominal aortic surgery (7-9). Adding to this was the incidence of spinal cord ischemia (10), which has always been a major deterrent for patients considering this critical surgical stage. Depending on the specific case series, a notable percentage of patients either died while waiting, did not proceed with, or were excluded from the treatment pathway.

Moreover, at the turn of the 20th century, we observed an increasing demand for complex aortic procedures. This demand was driven by significant parallel improvements in techniques for circulatory arrest, as well as advancements in the medical and surgical management of acute aortic pathology, which led to associated improvements in survival rates (11).

The goal of repairing the dissected aorta in the acute phase and ensuring the survival of these patients increasingly highlighted the need to address residual dissection pathology. Over time, this residual pathology often resulted in giant aneurysms that required complex treatments. However, these cases had previously lacked standardized solutions, dedicated tools, and a sufficient number of specialized centers capable of managing them.

The birth of the Dumbo graft

The Siena graft (12), initially nicknamed the “Dumbo graft” in reference to the Disney cartoon character with large, distinctive ears, drew inspiration from its application in the elephant trunk technique and its anastomotic collar, which resembled Dumbo’s iconic oversized ears. The development of the graft was driven by the need to address key limitations of classical elephant trunk techniques while incorporating targeted improvements to specific aspects of aortic surgery. One of the primary objectives was to refine and streamline the distal anastomosis process. At the time, widely used techniques such as the invagination method facilitated faster anastomosis but prevented the use of multi-branched grafts for independent reimplantation of the supra-aortic trunks. These constraints prompted the development of the collar,

designed not only to enhance the speed and reliability of distal anastomoses—thereby reducing circulatory arrest times—but also to offer versatility in addressing complex anatomical challenges, particularly those related to the size and quality of the distal anastomotic neck.

Moreover, we sought to integrate what was then seen as a significant advancement in aortic surgery: the endovascular approach (13,14). Even in its early stages, it showed potential to revolutionize second-stage treatments by offering a less invasive, lower-risk alternative with greater patient acceptance: a potential that was later profoundly validated by both experience and the rapid evolution of endovascular techniques.

Our first experience with thoracic endovascular aortic repair (TEVAR) dates back to 1997, when we successfully treated a thoracic aortic aneurysm using a Talent stent graft. This case provided early evidence of the feasibility and promise of combining traditional surgical methods with endovascular solutions, paving the way for improved outcomes, and expanded treatment options for complex aortic pathologies.

The introduction of radiopaque markers in key areas of the graft was intended to facilitate the planning and implantation of endovascular grafts. Early sketches shared with the manufacturer illustrated our hypothesis of incorporating a stent graft into the Siena graft. Unfortunately, the technology of the time was not yet available to fully realize this concept.

Significant effort was dedicated to optimizing the spacing and dimensions of the branches to accommodate the wide variety of aortic arch anatomies encountered in clinical practice. In particular, we focused on the perfusion side branch, which was angled for hemodynamic purposes and designed with a caliber sufficient to allow for the antegrade insertion of potential endografts. This feature would later become an integral part of what is now referred to as the “freezing” technique.

A step back: from problem to solution

Reflecting on why we began this journey, it is worth considering the lessons for anyone facing a technical problem and undertaking the task of creating a new design to address it. Today’s complexities, including difficult industry interactions, regulatory hurdles, and financial risks driven by economic factors, make it increasingly challenging to transform an idea into a certified clinical product. Sharing the origins of this process may provide

valuable insights for others in similar situations.

The Siena graft arose from a clinical challenge that evolved into a practical design. Understanding the problem and the steps taken to resolve it offers guidance for those tackling similar advancements in technical and clinical fields.

The issue originated with a failed distal anastomosis on a large aortic neck. An attempted aortic reduction led to postoperative complications, including massive and uncontrollable bleeding. The failure was primarily due to the tension on the anastomosis caused by a significant size mismatch: that's how the ear sprouted on the “Dumbo graft”—a playful nod to the anastomotic collar that became the solution.

As we progressed in our interactions with the project developer, we began to realize the advantages of the “ear” (collar) and its potential for further improvements. The collar made it possible to use a multibranched graft, as it simplified the anastomosis without requiring invagination. Additionally, it opened up new possibilities for facilitating endovascular procedures, further enhancing its versatility and clinical application.

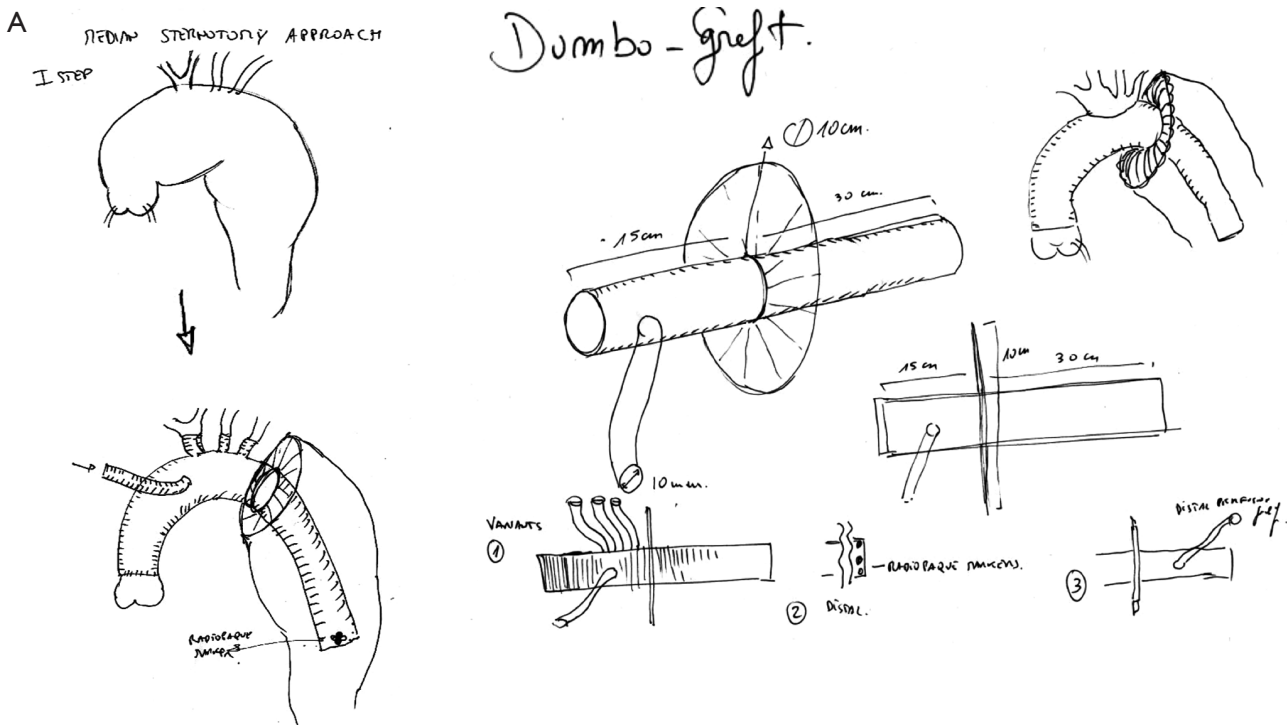
To complement this narrative, I also aim to present a visual story of the design and development process,

supported by select pictures that highlight key moments from concept to realization (*Figure 1A-1C*).

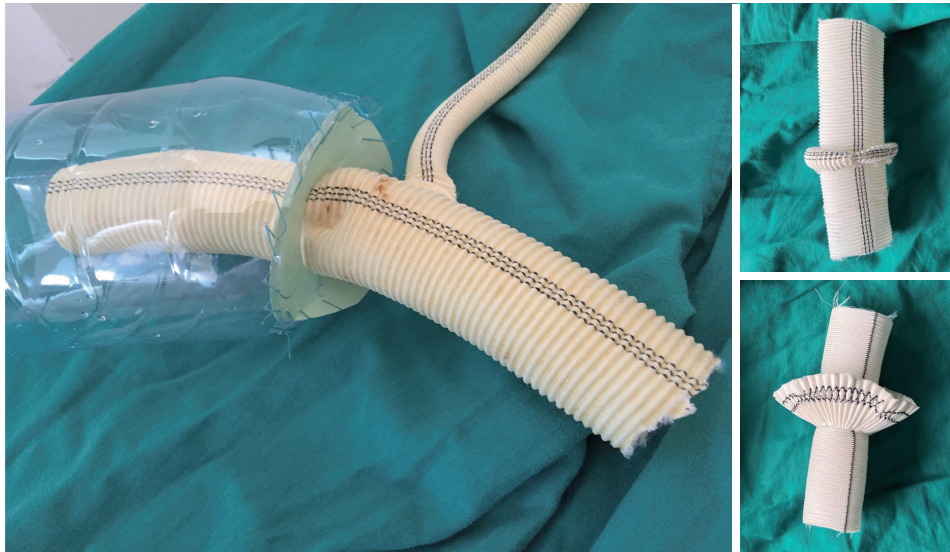
Siena: design and function

The Siena graft represents an evolution and the extension of the elephant trunk concept, providing a robust and flexible platform for treating complex aortic pathologies. Building on the technique first described by Borst *et al.* in 1983 (5), the graft addresses the challenges of multi-stage aortic surgery while incorporating features designed to enhance safety and efficiency.

At the core of its design is a conventional aortic arch Dacron graft (20–32 mm) combined with a large knitted Gelseal™ collar (up to 100 mm in diameter) (Terumo Aortic, Inchinnan, Glasgow, UK). This collar eliminates the need for graft invagination during distal anastomoses, allowing for a rapid and secure suture even in challenging surgical fields. It also compensates for diameter mismatches between the graft and the distal aorta, reducing tension at the anastomotic site and minimizing the risk of bleeding, rupture, or failure, particularly in cases where the distal neck is dilated or irregular. These features make the Siena graft a reliable solution for addressing anatomical variability



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Figure 1 Developmental evolution of the Siena graft. (A) Sketching the idea—initial drawings capturing the conceptualization of the graft and its potential future developments. These early sketches laid the foundation for the design process, transitioning from theoretical models to practical prototypes. The image illustrates the evolution from raw ideas to structured design concepts, ultimately shaping the first model of what would become the Siena graft. (B) The first naive models of the Siena graft, simulating a challenging large-neck anastomosis. On the right, early attempts at manufacturing the collar using a 10 mm Dacron tube, opened longitudinally and sutured to an aortic graft. (C) The final drawing that marked the beginning of industrial production of a certified graft.

in complex aortic pathologies.

The graft includes a pre-sewn perfusion side branch and up to three additional side branches for individual reimplantation of the supra-aortic trunks. Distal to the side branches, the collar can be trimmed to the desired diameter, offering flexibility to adapt to diverse clinical scenarios.

The Siena graft's hybrid vision is reflected in its thoughtful design, which incorporates radiopaque tantalum markers placed at critical locations. These include the collar level, between the left subclavian and left carotid branches, and along the free-floating portion of the graft (spaced every 2 cm in the relaxed Dacron). These markers guide subsequent endovascular interventions by defining the proximal "landing zone". This ensures precise positioning of stent grafts while preventing inadvertent coverage of the arch vessel branches, further enhancing the graft's utility in hybrid and multi-stage procedures.

Technique, pitfalls, and safeguards

The first stage operation

Preparation

The patient, in supine position, is prepared with central venous access, preferably through the right jugular vein, considering the possibility of needing to divide the innominate venous trunk for a better exposure of the arch. A radial artery pressure line is placed in the left arm, as we prefer direct cannulation of the right axillary artery. Variations in arterial and venous access may be required in cases of re-operations, where specific approaches are necessary for cardiopulmonary bypass (CPB).

Cerebral perfusion is monitored using cerebral oximetry and/or transcranial Doppler. Cerebrospinal fluid drainage has never been used in our practice, as paraplegia has not occurred in our experience.

If endovascular treatment is planned during the initial procedure, the use of a radiologic table with a C-arm or, ideally, a hybrid operating room, should be arranged in advance.

Surgical technique

The aortic arch is exposed through a median sternotomy. CPB is initiated with arterial perfusion via the right axillary artery and single venous drainage using a two-stage cannula in the right atrium. The patient is cooled to a bladder temperature of 25 °C (moderate hypothermia) with passive drift of nasopharyngeal temperature, ensuring perfusion

temperatures remain below 26 °C.

During cooling, the distal ascending aorta is clamped once ventricular fibrillation is induced. Retrograde cold-blood cardioplegia is administered through a coronary sinus cannula and repeated every 20 minutes. The proximal aorta is prepared according to the planned procedure (supra-coronary or root procedures). Once the target temperature is reached, the innominate artery, left common carotid, and left subclavian arteries are clamped, and systemic arrest under brachiocephalic perfusion is initiated. According to our protocol, the infusion rate is reduced to 10–15 mL/kg/min, maintaining mean perfusion pressures below 80 mmHg. The aortic arch is opened, and additional selective perfusion of the left common carotid artery (15) is initiated; the aorta at the site of the distal anastomosis (either in zone 2 or 3) and the supra-aortic trunks are trimmed.

Insertion and sizing of the graft

The Dumbo graft is inserted into the aortic lumen, and the "sewing disk" (collar) is trimmed to match the aortic diameter. In chronic dissection, the graft sizing is based on the true lumen perimeter measured by computed tomography (CT) scan, using the formula: graft diameter = true lumen perimeter/ π , to ensure an accurate fit within the false lumen and prevent graft infolding (*Figure 2A*). If the flap anatomy and visceral vessel origins indicate malperfusion risk, the intimal flap may be fenestrated longitudinally, although this is rarely required. More commonly, the flap anatomy is left intact, and an Amplatz Goose Neck snare device (Medtronic, Minneapolis, MN, USA) is placed in the distal arch during preparation, through a femoral percutaneous access and angiography guide, is used to advance and guide the free-floating portion of the graft into the true lumen (*Figure 2B*).

Graft suturing

The graft suturing technique depends on the quality and texture of the aortic tissue. It is critical to avoid folds or wrinkles in the collar caused by imbalanced suturing or excessive collar material. In cases of good-quality aortic tissue, a 3-0 or 4-0 SH polypropylene (Ethicon, Somerville, NJ, USA) running suture (three semicontinuous sutures) is preferred. For heavily calcified aortas, where suture distortion or breakage may occur, three semicontinuous Ethibond 3-0 (Ethicon) sutures are used.

External Teflon™ (DuPont Pharmaceuticals, Wilmington, DE, USA) reinforcement is often necessary, and an internal

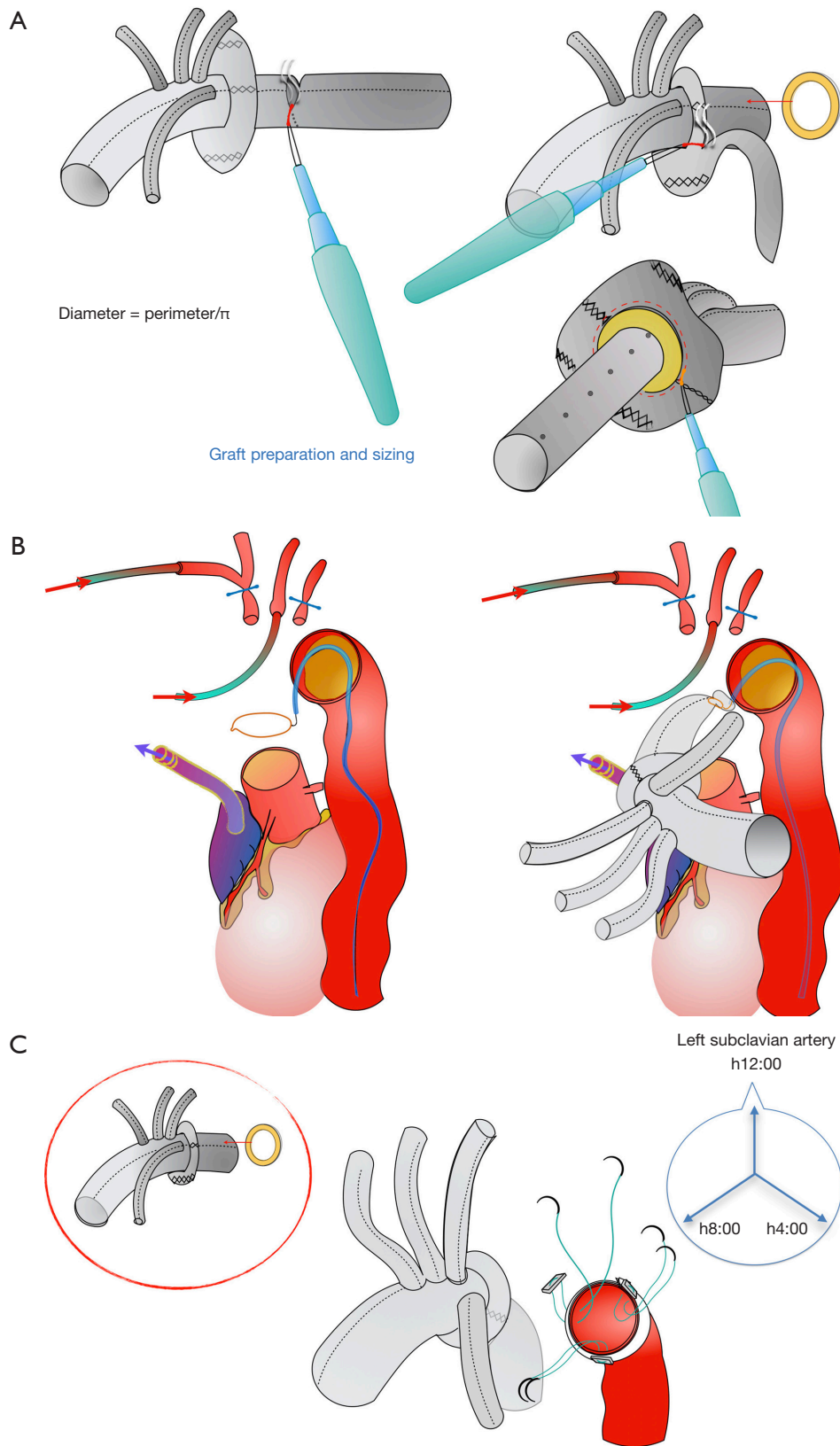


Figure 2 Graft preparation and intraoperative implantation strategy. (A) Graft preparation and sizing. The collar is trimmed to the required

diameter, and a Teflon felt ring is placed on its distal surface to enhance hemostasis and create a secure, blood-tight anastomosis. The appropriate trunk length remains a subject of debate due to concerns about paraplegia and distal embolization. Since blood flow extends the graft by approximately 10%, the graft should be considered in its non-stretched state. Traditionally, the graft is cut at the last radiopaque marker (10 cm); our approach has evolved over time, favoring longer grafts in chronic dissection cases and shorter ones in extensive aneurysms to minimize the risk of thrombosis at the distal end of the elephant trunk. (B) Once the target temperature for circulatory arrest is reached, the aorta is opened, and the anastomotic neck is prepared in zone 2 or zone 3. The graft's elephant trunk is inserted into the aortic lumen using a Gooseneck snare catheter, pre-positioned under angiographic or transesophageal guidance. This step is particularly crucial in dissections, where precise positioning and alignment within the true lumen is essential. The snare catheter has proven highly effective in navigating narrow or angulated aortas, facilitating the use of longer grafts even in small true lumens. This technique is now a standard practice in our cases. (C) To reinforce the anastomosis and improve hemostasis, an external Teflon strip is used in combination with a pre-placed Teflon ring beyond the collar. When the aortic tissue is soft and non-calcified, a single continuous 3-0 Prolene suture is typically sufficient. However, in calcified aortas, three semicontinuous 3-0 Ethibond sutures are preferred to prevent suture imbalance and avoid wrinkles in the collar. These sutures are strategically placed at h12:00, h4:00, and h8:00, with h12:00 corresponding to the divided left subclavian artery. The suture is initiated at h12:00, an area that is particularly challenging to inspect for bleeding, especially after reimplantation of the left subclavian artery.

Teflon ring (matching the graft diameter and collar size) is added to prevent oozing (*Figure 2A-2C*). These safeguards ensure a secure anastomosis, particularly in challenging anatomical scenarios.

Perfusion and monitoring

Once the anastomosis is complete, a second arterial line is connected to the perfusion branch of the graft. After careful de-airing of the aorta and graft, systemic distal perfusion is resumed by clamping proximal to the side branch. Intraoperative transesophageal echocardiography (TEE) provides critical information on the positioning and flow of the elephant trunk graft within the true lumen, while trans-pericardial color-Doppler ultrasound is used to assess visceral perfusion. Any bleeding from the anastomosis or reimplanted supra-aortic branches is meticulously checked and controlled.

Following the completion of the distal anastomosis, the proximal graft anastomosis is performed to minimize aortic cross-clamp time. Once the clamp is removed, the heart is defibrillated during rewarming, and the supra-aortic branches are reimplanted individually. Brachiocephalic perfusion is subsequently stopped, and total arterial blood return is redirected to the side-branch cannula. The patient is then gradually weaned from CPB.

Second-stage completion: surgical and endovascular approaches

The second stage of repair, whether surgical or endovascular, has been previously described and reflects current best

practices in managing complex aortic pathologies (16).

The surgical approach follows standard thoracic or thoracoabdominal aneurysm repair techniques. After adequate recovery from the index operation, the second-stage procedure is scheduled; based on the required extent of the repair, the descending aorta is exposed through a thoracic or thoracoabdominal incision. The repair is performed using partial or full CPB, with or without circulatory arrest, as dictated by the specific case. The aorta, containing the elephant graft from the first stage, is clamped, and the aneurysm is opened. The graft is then clamped, and a new graft is anastomosed proximally to the first-stage graft and distally beyond the aneurysm. Intercostal and visceral arteries are reimplanted as necessary.

Endovascular completion may be staged or performed during the initial operation under fluoroscopy, using the perfusion side branch of the collared graft for access. Planning is guided by recent CT angiography. In chronic dissections, stent grafts are deployed in the true lumen when anatomical conditions are favorable, or distal re-entry tears are sealed to partially thrombose the false lumen. For more complex cases, extended longitudinal fenestration converts the double-lumen aorta into a single lumen, allowing for safe deployment of branched stent grafts. This technique uses a “body floss” wire or radio-frequency device to penetrate organized dissection membranes, ensuring full graft expansion and adequate visceral perfusion (17,18).

Endovascular repairs for aneurysms are tailored to anatomical extension. Straight or tapered endografts are used for descending aortic lesions, while branched devices are employed for thoracoabdominal involvement. The

surgical elephant trunk neck serves as the proximal landing zone with at least 2 cm overlap. In urgent situations, off-the-shelf devices or parallel grafts (chimneys) are utilized, while elective cases may rely on custom-made stent grafts to optimize outcomes (19–21).

Pitfalls and safeguards

One of the key considerations when using the Siena graft is the proper sizing and trimming of the collar. Wrinkles or folds in the collar must be carefully avoided, as they can lead to leaks, suture failure, or excessive tension on the anastomosis. To address this, suturing techniques and reinforcement materials must be adapted based on the quality of the aortic tissue. In heavily calcified tissues, for example, the use of external Teflon reinforcement combined with an internal Teflon ring helps prevent oozing and adds structural stability to the anastomosis (*Figure 2A*). A thorough inspection of the collar suture area before proceeding with the subsequent phases of the procedure is essential to detect and address any potential sources of postoperative bleeding. Such bleeding, if not corrected at this stage, can be extremely difficult to repair once the supra-aortic trunk anastomoses have been completed.

Proper graft diameter selection is equally critical, especially in cases of chronic dissection. Ensuring the correct size helps prevent invagination or diameter mismatch, which could compromise the integrity and functionality of the graft. For these cases, a Gooseneck catheter is a valuable tool (*Figure 2B*). It allows for precise guidance of the free-floating portion of the graft into the true lumen, ensuring optimal placement and proper expansion of the graft within the intended anatomical space.

In patients with dissection, assessing the perfusion of visceral arteries is a crucial step. We routinely use transpericardial Doppler echography to evaluate blood flow in the visceral branches (22). This approach ensures that perfusion is adequate and helps identify any potential malperfusion issues during the procedure, adding an extra layer of safety to the operation.

Our experience

Between February 2002 and June 2024, we performed 202 aortic arch replacement procedures using the Siena graft. Of these patients, 81 were women (40.1%), with a median age of 70.8 [interquartile range (IQR), 61.2–76.5] years. Seventy-six (37.6%) had acute/chronic dissection with false

lumen aneurysmal dilatation, 126 (62.4%) had degenerative aneurysms, 58 (28.7%) underwent redo operations, and 22 (10.9%) had connective tissue disease.

First-stage outcomes included a 30-day mortality of 8.9% (n=18), stroke in 5.0% (n=10); 6 disabling (including 3 fatalities), 4 non-disabling, and paraplegia in 0.5% (n=1). Of the 162 second-stage procedures (80.2%), 139 (68.8%) were endovascular and 20 (9.9%) were surgical, with a 30-day mortality of 7.4%, no strokes, and paraplegia/paraparesis in 12 patients (2 after open surgical repair, 10 after TEVAR).

The median survival was 16.6 (IQR, 15.1–16.8) years, with no significant difference between patients with aneurysms and those with dissections (*Figure 3A*). The median time to further treatment was 0.5 (IQR, 0.4–0.7) years. Median time free from final completion procedure was 0.7 (IQR, 0.5–1.6) years in dissections and 0.4 (IQR, 0.2–0.5) years in aneurysms, a significant difference was observed between the groups ($P=0.0026$) (*Figure 3B*). There were no significant differences in overall survival among the three completion strategies—endovascular, surgical, and the unstented (“soft”) approach—as confirmed by the log-rank test (*Figure 3C*).

Conclusions

The rapid advancements in endovascular devices and ancillary techniques have significantly expanded the role of elephant trunk procedures within broader strategies for complex aortic treatment. The Siena graft represents a major evolution in the design of grafts for aortic arch surgery and continues to be a reliable tool for managing complex aortic pathologies. It serves as an effective platform for both the classic elephant trunk technique and for facilitating endovascular completion. Its versatility offers certain advantages over hybrid devices, providing comprehensive solutions for both surgeons and patients.

The journey from concept to a globally available clinical product underscores the critical interplay between innovation, persistence, and collaboration. Transforming an idea into a practical solution requires not only identifying an unmet clinical need but also engaging with industry partners, navigating regulatory challenges, and refining the design through continuous feedback.

The Siena graft’s success highlights the importance of adaptability and forward-thinking design, ensuring that surgical innovations remain relevant as technology and clinical strategies evolve. For those striving to bring a new

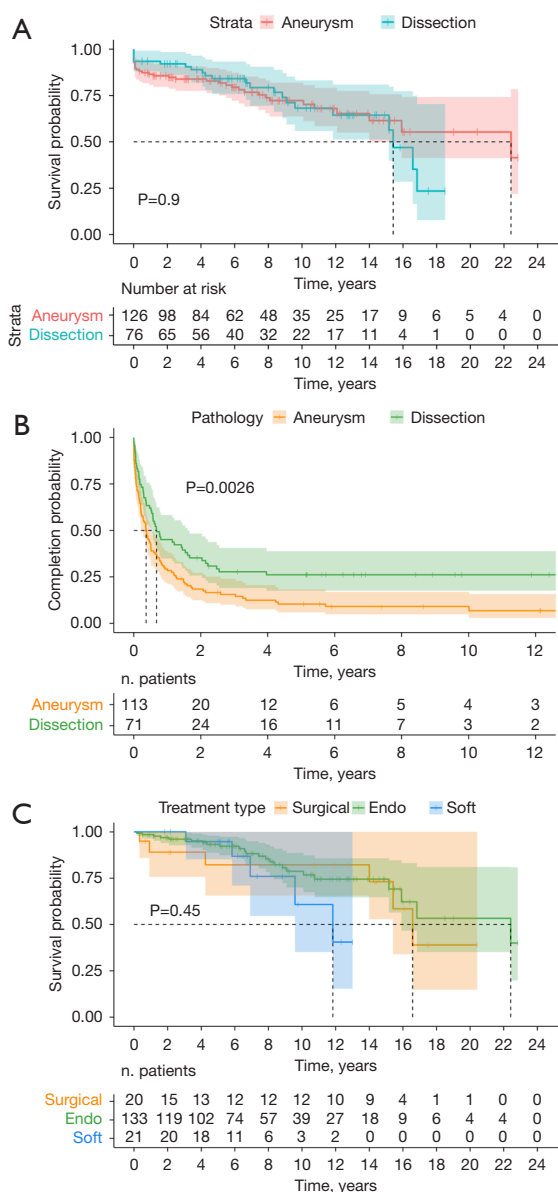


Figure 3 Outcomes following the Siena graft procedure. Results of elephant trunk procedures and subsequent treatments according to our institutional approach to complex aortic pathology. (A) Survival rates were assessed in relation to the underlying pathology (aneurysm *vs.* dissection). The comparison of survival between the groups, performed using the log-rank test, did not reveal a statistically significant difference. (B) Kaplan-Meier estimates for freedom from further treatment following the elephant trunk procedure. (C) Kaplan-Meier estimates for overall survival following the elephant trunk procedure. This figure compares overall survival across three techniques: endovascular, surgical, and the unstented (“soft”) approach. In the “soft” technique, the elephant trunk is left unstented within the true lumen, a strategy predominantly applied to patients with dissection. The log-rank test did not reveal a statistically significant difference. Endo, endovascular.

idea to reality, the key lesson is that true progress lies at the intersection of vision, technical rigor, and the ability to anticipate future needs—always designing with both present and future applications in mind.

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Footnote

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Conflicts of Interest: The author has no conflicts of interest to declare.

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