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Technical tips and clinical experience with the Cook Triple inner arch branch stent-graft

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1 **Technical tips and clinical experience with the Cook Triple inner arch branch stent-graft**

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Abstract

Open surgical repair remains the gold standard for treatment for aortic arch diseases, but these operations can be associated with wide heterogeneity in outcomes and significant morbidity and mortality, particularly in elderly patients with severe comorbidities or those who had prior arch procedures via median sternotomy. Endovascular repair has been introduced as a less invasive alternative to reduce morbidity and mortality associated with open surgical repair. The technique evolved with new device designs using up to three inner branches for incorporation of the supra-aortic trunks. This manuscript summarizes technical tips and clinical experience with the triple inner arch branch stent graft for total endovascular repair of aortic arch pathologies.

Keywords: A-branch; aortic arch pathologies; total endovascular arch repair; three-inner branches.

Introduction

Since the first thoracic endovascular aortic repair procedure performed by Nikolaos Volodos on March 24, 1987, for the treatment of a post-traumatic thoracic aortic aneurysm(1), endovascular techniques have evolved and disseminated worldwide becoming the first line of treatment for most descending thoracic aortic aneurysms and dissections. This less invasive alternative to open surgical repair allowed treatment of higher risk patients who were previously considered unsuitable candidates.(2, 3) Although several stent-grafts are approved for use in the descending thoracic and abdominal aorta, branch stent-grafts remain mostly investigational. Due to its anatomical and physiological limitations, the aortic arch has been considered one of the last frontiers yet to be conquered by endovascular repair.(4) Technical challenges are many as the device approaches the aortic annulus, including the naturally curved and angulated aortic arch; the variable origin of the supra-aortic trunks and the relative short distance to the coronary ostia and aortic valve. Other factors such as coronary grafts, atherosclerotic debris, mechanical aortic valves, and the presence of kinked ascending grafts or presence of short suitable landing zones may prohibit treatment by endovascular techniques. The natural angulation of the arch curvature may render stents difficult to maneuver, making alignment of branches and fenestrations impossible. Because of hostile hemodynamic forces and respiratory motion, long-term durability requires special stent designs resistant to fatigue, fracture, migration, and kinks.(5)

All the above may explain why open surgical repair remains the gold standard for treatment of aortic arch pathologies in most patients who are deemed low or intermediate risk. Additionally, improvements in cerebral protection with deep hypothermia, retrograde and antegrade cerebral perfusion have lowered the risk of neurological complications associated with open surgical repair.(6) However, despite these improvements, there are significant outcome

1 variations among centers. Open surgical repair is especially challenging among elderly, frail
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3 patients and those with multiple comorbidities or who have undergone prior ascending or arch
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5 procedures via median sternotomy.(7, 8) Concurrently, total endovascular approaches have been
6
7 increasingly utilized to treat aortic arch pathologies, initially as an alternative in higher risk
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9 patients. Increasing experience and refinements in stent-graft design and delivery systems, along
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11 with improved patient selection, have lowered the morbidity and mortality of these procedures,
12
13 rivaling the outcomes of open surgical repair in lower-risk patients.(9, 10) Increasing clinical
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15 experience in the western world with total endovascular aortic arch repair has been gained using
16
17 double or triple inner branch stent-grafts (A-branch, William Cook Europe, Bjaeverskov,
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19 Denmark). Although the first designs included two inner branches, thus requiring a left
20
21 subclavian artery (LSA) debranching, a triple branch device with a preloaded catheter has gained
22
23 wide application. This article summarizes technical tips and clinical experience with the Cook A-
24
25 branch stent-graft with three inner-branches.
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31 **Triple inner branch stent-graft**

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35 The triple inner-branch stent graft or Cook A-branch stent-graft is designed with one or
36
37 two proximal sealing stents and two antegrade and one retrograde inner branches intended to
38
39 incorporate the innominate artery (IA), left common carotid artery (LCCA), and LSA. The IA
40
41 and LCCA o'clock positions are fixed (o'clock position at 12:30 and o'clock position at 11:30,
42
43 respectively), while the LSA o'clock position is variable to fit the patient's anatomy. Each inner
44
45 branch is coupled with a diamond-shaped fenestration to facilitate catheterization. A preloaded
46
47 catheter can be used for access to the retrograde LSA only, LSA/LCCA, or LSA/IA inner branch
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49 via the femoral approach. The pre-loaded catheter is routed primarily into the LSA branch but
50
51 can be allowed to maintain access into the LCCA or IA if a total femoral approach is planned.
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1 The device is self-oriented, so that the diamond-shaped fenestrations and inner branches face the
2
3 outer arch curvature, which is facilitated by a pre-shaped cannula and a four-step release
4
5 mechanism (**Figure 1**). Although the A-branch stent-graft is a custom-made device, the
6
7 predictable location of supra-aortic trunk vessels and the “adaptability” of access to the inner
8
9 branches via diamond-shaped fenestrations can be translated into off-the-shelf concepts.(11)
10
11 Features that facilitate adaptability include the predictable orientation towards the outer
12
13 curvature of the aorta, the tapered middle segment of the arch inner branch stent-graft and wider
14
15 access provided by larger diamond shaped fenestrations. The design requires less precision
16
17 during implantation, while providing continued perfusion to the supra-aortic trunks and
18
19 simplifying catheterization of the inner branches.
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24 **Clinical and anatomical considerations**

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28 Multidisciplinary approach involving members of vascular surgery, cardiac surgery,
29
30 interventional cardiology and cardiovascular anesthesia is recommended for treatment of
31
32 complex arch pathology. In order to determine feasibility for a complete endovascular approach,
33
34 certain anatomic criteria need to be met. Most of these patients have prior ascending repair with
35
36 prosthetic graft which serves as proximal landing and sealing zone for an endograft, making it
37
38 crucial that the ascending graft is long and free of kinks to allow a minimum of 2 cm and ideally
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40
41 4cm.
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45 Computed Tomographic Angiography (CTA) remains the most important imaging
46
47 modality for assessment of anatomic feasibility for ascending aortic and arch branched
48
49 endovascular repair. Ideally the study should be gated to eliminate artifact and variations in
50
51 diameter assessment in the ascending aorta. A centerline of flow measurements is used to
52
53 estimate lengths, usually based on the outer aortic curvature instead of the center lumen, which is
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1 typically used for the thoracic and renal-mesenteric aortic segments. Echocardiography is
2
3 obtained to assess adequacy of the aortic valve. While an endovascular approach to arch repair
4
5 may ultimately offer an approach with the least perioperative morbidity, challenges remain in
6
7 device design and implantation to achieve optimal long-term results. Specific concerns for
8
9 endovascular repair include adequate seal, long-term device durability, device alignment, stroke,
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11 aortic valve issues and mortality.
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14 *Seal Zone*

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19 Over the last decade outcomes from endovascular aneurysm repair studies have
20
21 repeatedly demonstrated that an adequate seal zone must be present in order to achieve long-term
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23 device success.(12, 13) In the arch, an adequate seal zone is comprised of neck diameters
24
25 consistent with healthy tissue (< 38mm for native aorta and <42mm for polyester graft), minimal
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27 tapering, a length of >25mm that is free of excess calcification and thrombus, and aortic
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29 angulation < 60°. Although some reports have advocated more liberal use of larger aortic
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31 diameters (40 or 42mm) as sealing zone, these are associated with higher risk of retrograde type
32
33 A dissection. Haulon and colleagues identified that aortic diameter > 38 mm is associated with
34
35 higher mortality and rate of complications, including retrograde type A dissection.(14) Selection
36
37 of patients within proper proximal sealing zones reduces the risk of Type I endoleaks, device
38
39 migration and increases the likelihood of long-term performance. In the case of aortic arch
40
41 treatment, landing the device within a healthy seal zone is challenged by the relatively short
42
43 ascending aorta. Due to the catastrophic consequences that can occur due to loss of device seal
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45 and/or device migration in the aortic arch, maximizing the length of seal beyond the standard
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47 25mm may be warranted to account for aortic growth, remodeling, and potential disease
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49 progression. Sealing zones of > 4cm are ideal in the ascending aorta based on length from the
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1 sino-tubular junction (STJ) to the start of the aneurysm. The minimum requirement using the
2
3 outer curvature of the aortic wall is 25mm. Of specific concern is the high pulsatility of the aortic
4
5 arch, subjecting the stents to more significant fatigue loading conditions. Pulsatility of the
6
7 vessels in this region has been reported to be 2-3 times higher than the pulsatility seen in the
8
9 descending thoracic and abdominal aorta. Additionally, branch vessel motion relative to the aorta
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11 due to cardiac pulsation and respiration will have to be quantified to address long-term
12
13 durability. These motions could lead to device complications such as graft wear, stent fracture,
14
15 and stent kink, all of which could be detrimental to device performance. Although a prosthetic
16
17 graft offers the ideal proximal landing zone and avoids the risk of retrograde dissection, these
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19 grafts must be straight and of enough length to allow at least one full stent apposition and
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21 prevent risk of endoleak. Milne and colleagues reported that 71% of patients with prosthetic
22
23 grafts in the ascending aorta were considered suitable candidates for arch branch devices. In that
24
25 study, the most common exclusion criteria were short graft length (71%), kink (24%, **Figure 2**)
26
27 or diameter >38 mm (5%).(15) Patients with coronary grafts may also have unsuitable landing
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29 zones for endovascular repair.
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36 *Access*

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39 Most aortic arch branched devices require delivery systems with an outer diameter of 22
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41 to 26 French, requiring a 7.5 to 9mm of healthy external iliac artery diameter. In the setting of
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43 severe tortuosity, narrowing, severe calcifications, or prior stents, a planned iliac conduit offers a
44
45 suitable alternative to avoid the risk of inadvertent disruption of the iliac arteries. In addition to
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47 access to the iliac vessels, the brachial and axillary arteries should be assessed for dissection,
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49 narrowing or aneurysmal degeneration that can affect the suitability of stenting into the supra-
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51 aortic trunks.
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Device Alignment

The ability to accurately align and deploy an arch stent graft is essential. Implementing designs with self-aligning features of the inner branches to the target vessels will minimize the need for excessive manipulation of the device in the aortic arch, thus reducing the risk of stroke due to emboli. Due to the length of the delivery systems utilized for transfemoral access, the ability to precisely control the device end of the delivery system is limited, further highlighting the need for “auto” aligning features. Additionally, a controlled release of the stent graft from the delivery system is warranted, with the minimal motion of the device occurring. The motion of the device during release can lead to catastrophic events, including coronary artery coverage and/or misalignment of the inner branches with the great vessels. In this direction, cardiac output reduction has been considered an essential adjunctive to precisely deploy the cook a-branch. Currently, cardiac output reduction with rapid ventricular pacing or partial inflow atrial occlusion with the placement of a semi-compliant balloon in the inferior vena cava have been the most used and most described. Recently, Tsilimparis and colleagues described the use of a modified Valsalva maneuver – Munich Valsalva Implantation Technique – as an alternative for cardiac output reduction.(16)

Aortic Valve

Due to the relative proximity of the aortic valve to the aortic arch and branch vessels, it is of utmost importance to design endovascular devices and delivery systems that will limit valve interaction and be atraumatic to the valve when interactions do occur. While in current TAVI procedures, wire guides, catheters, and sheaths are placed across the valve routinely, these procedures have been associated with stroke and valve damage. Additionally, current EVAR systems are large in diameter, and delivery system tips are relatively stiff, potentially increasing

1 the risk of valve damage, especially in cases where the system must be left across the aortic
2 valve for extended periods of time. Finally, because these procedures are modular and may
3 require crossing the aortic valve multiple times in order to place each component, which will
4 further expose the valve to potential injury. It will be essential to valve health that endovascular
5 repair options limit valve involvement and encompass atraumatic materials such that minimal
6 damage occurs.

16 *Target vessels*

17 A non-aneurysmal, non-dissected target vessel is required for endovascular repair of
18 aortic arch. There is some variation in maximum required diameter. The innominate artery can
19 be incorporated using a flared stent-graft, usually with diameter up to 20mm. For the left carotid
20 artery and left subclavian arteries, stent-graft diameters range between 8 to 14mm. Some of these
21 limitations can be overcome by surgical debranching of the supra-aortic trunk vessels, such as in
22 the case of patients with dissections that extent into the carotid arteries (**Figure 3**).

32 *Stroke*

33 Neurologic complications remain a major concern with any procedure to treat aortic arch
34 pathology, including open surgical and endovascular repair. Major contributing factors to stroke
35 during these procedures include emboli due to device, delivery system and/or wire manipulation,
36 air emboli released from the delivery system, and coverage of branched vessels. Additionally,
37 special care must be taken to ensure that the systems are entirely void of air upon sheath
38 withdrawal to avoid any potential air emboli. For this purpose, flushing the device with CO₂,
39 followed by flushing of the CO₂ with heparinized saline, has been recommended to decrease the
40 risk of air emboli.(17) Additionally, the use of direct carotid exposure for sequential clamping
41 during catheter manipulations probably decreases the risk of emboli on the ipsilateral side while
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1 providing excellent support for the advancement of the bridging stent grafts. A porcelain aorta
2 with severe calcifications or a thrombus-laden arch is fraught with a formidable risk of stroke
3 and poor apposition of the endograft in the sealing zone, making these contraindications for total
4 endovascular repair (**Figure 4**). The risk of stroke can be related to the etiology of the aortic arch
5 pathology. For example, post-dissection aneurysms may harbor a lower atherosclerotic burden as
6 compared to degenerative aneurysms.
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14 ***Specific device qualifications***

15 The criteria for this device are summarized below:(18, 19)

- 16 1. Ascending aortic length ≥ 50 mm (measured from STJ to origin of innominate artery)
- 17 2. Sealing zone in the ascending aorta ≥ 40 mm in length and ≤ 38 mm diameter for native
18 aorta or ≤ 42 mm for polyester graft
- 19 3. Sealing zone in the innominate artery ≥ 20 mm in length and ≤ 20 mm in diameter
- 20 4. Access able to accommodate 22F or 24F sheaths

21 **Clinical experience**

22 Tenorio and colleagues recently published a global experience with the triple inner
23 branch stent-graft using the A-branched Cook device. The study included a total of 39 patients,
24 with an early mortality rate of 5% and combined major and minor stroke rate of 2.5% each,
25 achieving 100% technical success. The mean diameter at the proximal sealing zone was 34 ± 3
26 mm ($34, 31-36$ mm); the diameter of the proximal sealing zone was larger among patients who
27 had stent-grafts implanted into native aorta compared to surgical grafts (35 ± 3 mm vs. 33 ± 3 mm,
28 $p=.02$). There was no difference in oversizing for stent-grafts implanted in native aorta vs.
29 surgical grafts ($17 \pm 5\%$ vs. $18 \pm 4\%$, $p=.32$). The mean length from STJ to IA was 74 ± 15 mm ($74,$
30 $64-89$ mm). Twenty-three patients (59%) had devices designed with two proximal sealing stents,
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1 and 16 patients (41%) had devices with one proximal sealing stent. The device configuration
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3 with two sealing stents was more common among patients who had the proximal sealing zone
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5 into the native aorta (90% vs. 46%, $p=.01$). The most common axial positions were 12:30
6
7 o'clock for IA branches in 16 patients (42%), 11:30 o'clock for LCCA branches in 12 patients
8
9 (32%) and 12:00 or 12:30 o'clock for LSA branches in 12 patients (32%, **Figure 5**). Chronic
10
11 post-dissection arch aneurysms accounted for 64% of the study population.(20)
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15 Despite the great results regarding early mortality and stroke rates, the authors found high
16
17 rates of secondary procedures been cervical access complications, along with target vessel
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19 endoleaks, were the most common reasons for early secondary interventions. Strategies to reduce
20
21 access-related secondary procedures certainly include meticulous hemostasis and closure, but
22
23 higher intraoperative activated clotting times and a generally lower threshold for hematoma
24
25 decompression in the neck may inevitably predispose these access sites to more frequent
26
27 reinterventions. Therefore, in an attempt to reduce the risk of cervical access issues, the use of
28
29 percutaneous approaches via femoral and axillary access or total femoral access have been
30
31 proposed. The development of steerable sheaths has allowed direct access to the inner branches
32
33 and sequential stenting of the LCCAs and, in some cases, the IA.(21) Experience with
34
35 percutaneous axillary artery for TAAA FB-EVAR has also prompted its use for arch repair.(22,
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37 23) More recently, a report led by Mougin et al described the first three-vessel, totally
38
39 percutaneous aortic arch repairs using inner branches in two patients. Incorporation of all three
40
41 vessels was accomplished from the femoral approach for the LCCA and LSA and the right
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43 axillary artery for the IA, avoiding the need for cervical incisions and its potential complication
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45 risks (**Figure 6**). (24) We have modified this technique to perform a total trans-femoral
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52 percutaneous endovascular aortic arch repair using three-vessel inner branch stent-graft. First, we
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1 proposed a change in the pathway of the preloaded catheter routed from the LSA to IA, instead
2
3 to LCCA (**Figure 7**). Second and most important, we have uses two co-axial systems in parallel
4
5 (6Fr_x90cm Shuttle and 8.5x90cm steerable sheaths) via a 22Fr_x65cm DrySeal sheath to provide
6
7 support and stability in the proximal thoracic aorta. The “push & pull” maneuver allows
8
9 advancement of the sheath without undue stress in the inner branch or risk of stent dislodgement
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11 (**Figure 8**). A total trans-femoral approach can be associated with even less complication since
12
13 the reports from transaxillary percutaneous access have been associated with considerable rates of
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15 open conversion and adjunctive endovascular procedures.(23)
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20 Although none of the patients experienced neurologic deficit despite the lack of
21
22 sequential carotid clamping, the question remains which patients should be selected for total
23
24 percutaneous versus open cervical access techniques and how we can prevent emboli when using
25
26 a percutaneous approach. Currently, it seems prudent to select patients based on underlying
27
28 pathology along with the quality of the arch and supra-aortic trunks, with the ideal candidates
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30 having prior ascending aortic repair and no evidence of any atheromatous disease in the arch.
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32 Other technology, such as filters specific to aortic arch stent-grafts, is under development and
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34 may be used as adjuncts, particularly in these total percutaneous cases.
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38 **Conclusion**

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41 Endovascular total arch repair using the a-branch cook device provides a valuable
42
43 alternative option for patients who are poor surgical candidates, and technical success is high
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45 with careful patient selection. However, the rate of early reinterventions is also relatively high,
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47 with the most frequent indications being cervical access site complications and endoleaks.
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49 Learning from current experiences of the multicenter collaborations, the anticipation of these
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1 complications using preemptive strategies such as preparation of target vessel landing zones, and
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4 the use of a total femoral approach can potentially lower reintervention rates in the future.
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1 **Notes**

2
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4 *Conflict of interest*

5
6
7
8 Dr. Gustavo S. Oderich has received consulting fees and grants from Cook Medical, W. L. Gore,
9
10 Centerline Biomedical, and GE Healthcare (all paid to Mayo Clinic and The University of Texas
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12 Health Science at Houston with no personal income). Other co-authors have no conflict of
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14 interest to disclose.

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29 *Authors' contributions*

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31
32 Emanuel R. Tenorio, Andrea Vacirca, Thomas Mesnard, Aidin Baghbani-Oskouei and Titia Sulzer
33
34 worked on manuscript writing. Aleem K. Mirza, Ying Huang and Gustavo S. Oderich worked on
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36 manuscript revision.
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40 All authors read and approved the final version of the manuscript.
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1 **Figure legends**

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4 **Figure 1.** Schematic illustration of the plan for total endovascular arch repair showing the route
5 of the preloaded catheter (**A**); Illustration of the device with three inner branches (**B**);
6
7 Photography of the four-step release mechanism of the three inner branches stent-graft (**C**).
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11 **Figure 2.** Illustration showing a severe kink in a previous ascending aortic graft that can
12 preclude the use of endovascular stent-graft (**A**); Examples of ascending aortic grafts without
13 kink with enough landing zone (**B** and **C**).
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19 **Figure 3.** Illustration showing a right carotid-subclavian bypass with stenting as the first stage,
20 creating an adequate landing zone for the right innominate/carotid artery for a total arch
21 endovascular repair.
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26 **Figure 4.** Illustration with a thrombus-laden arch (**A**); Computed tomography angiography
27 (CTA) and 3D reconstruction showing porcelain aorta (**B**); CTA showing a type III arch with
28 thrombus and calcinations (**C**); CTA showing “shaggy aorta” (**D**).
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33 **Figure 5.** Illustration showing o’clock position distribution for the innominate artery (*yellow*
34 *dots*), left common carotid artery (*green dots*) and left subclavian artery (*purple dots*) in the
35 three-vessel inner branch stent-graft with one or two proximal sealing stents. STJ, Sinotubular
36 junction.²⁰
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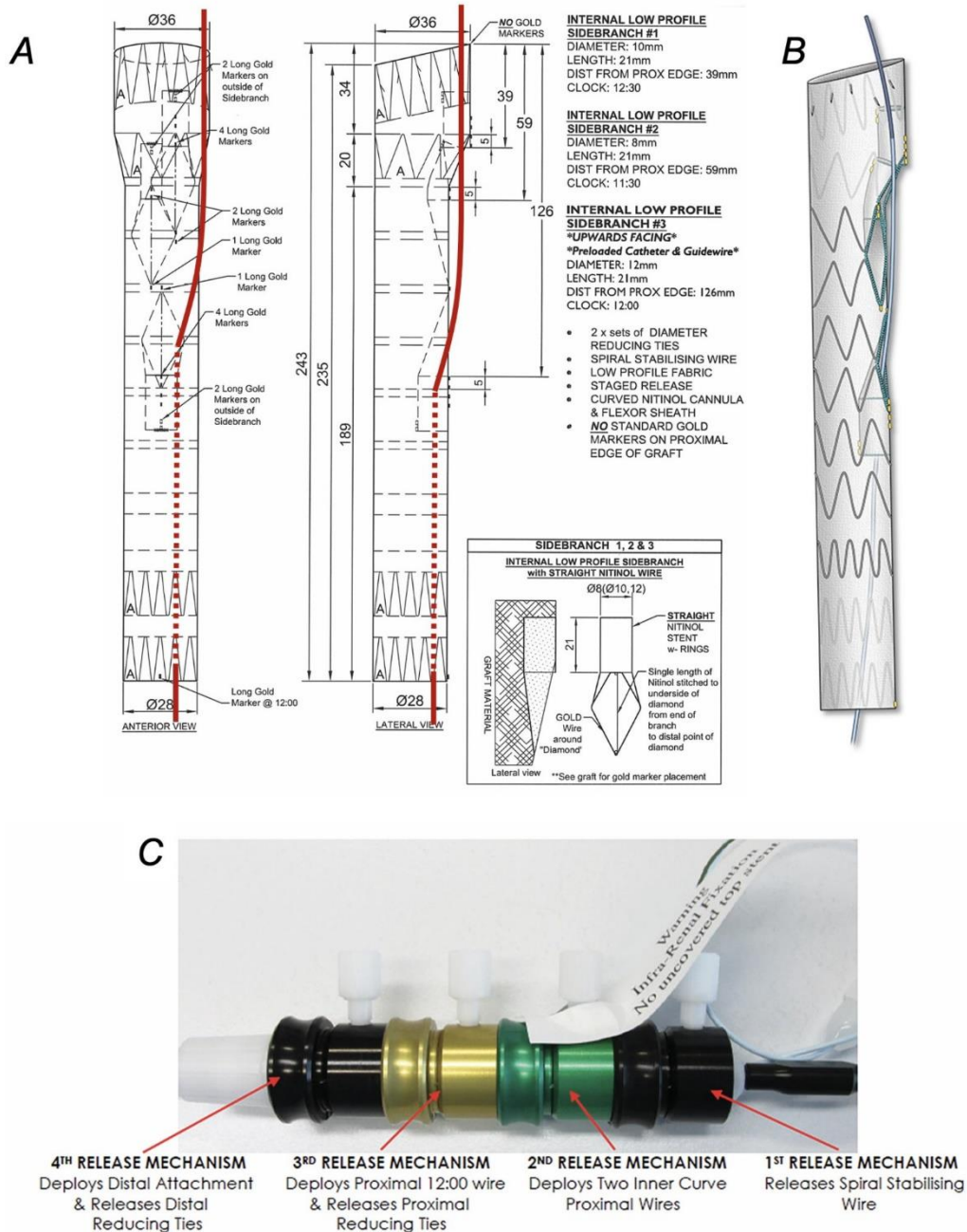
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44 **Figure 6.** Total percutaneous aortic arch repair with three-inner branch stent grafts. The first
45 inner branch intended for the innominate artery was accessed via the percutaneous axillary
46 access (**A-C**). The left common carotid and left subclavian arteries were accessed from the
47 femoral approach (**D-E**). Closure of the axillary access with ProGlide sutures and a short,
48 covered stent graft from the downstream 5Fr brachial access (**F**).
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1 **Figure 7.** Schematic illustrations show the preloaded catheter routes for total percutaneous aortic
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3 arch repair using the total femoral approach (**A**) or axillary plus femoral approach (**B**).
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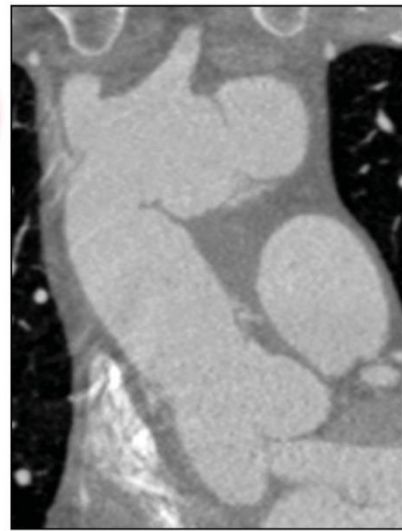
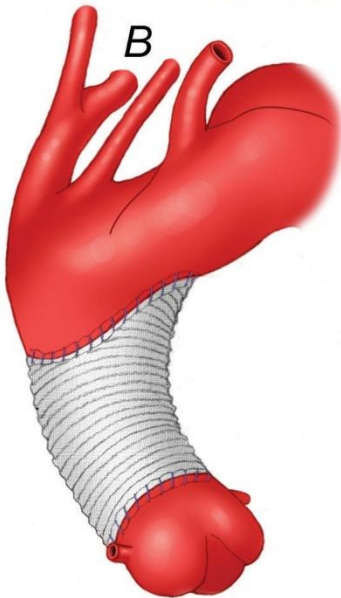
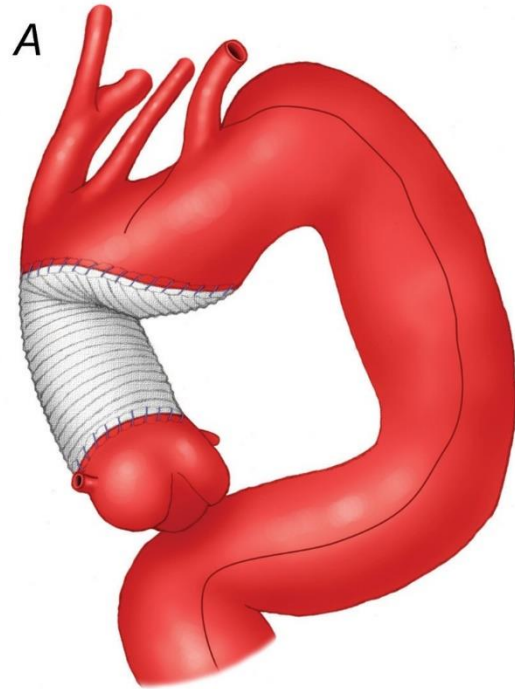
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7 **Figure 8.** Total trans-femoral percutaneous endovascular aortic arch repair using three-vessel
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9 inner branch stent graft. The stent graft was introduced via the right femoral access over the
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11 Lundquist wire and positioned in the ascending aorta. Using temporary rapid ventricular pacing,
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13 the three-vessel inner branch stent graft was deployed precisely distal to the sinotubular junction
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15 (**A-B**). A 6Frx110cm shuttle sheath was advanced into the innominate artery (IA) branch. Using
16
17 a VS1 catheter, a 0.014 wire was advanced and snared via the same right femoral sheath,
18
19 establishing through-and-through right femoral access via the IA branch. The 6Fr shuttle sheath
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21 was advanced via the IA branch and married into the dilator of a with an 8.5Frx90cm steerable
22
23 sheath. Using a “push & pull” maneuver, the 8.5Frx90cm steerable sheath was advanced and
24
25 positioned inside the IA branch (**C-D**). The repair was extended into the right common carotid
26
27 artery (RCCA) using two 8Lx79 mm balloon-expandable stent grafts, which were post-dilated
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29 proximally to 14 mm. The same steps were repeated for the left common carotid artery (LCCA)
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31 with the placement of 8Lx79 mm balloon-expandable stent graft in the LCCA, which was post-
32
33 dilated proximally to 14 mm (**E**). Finally, the left subclavian artery (LSA) was selectively
34
35 catheterized with a Glidewire and Kumpe catheter, which was exchanged for Amplatz wire.
36
37 Stenting from the retrograde LSA branch to the proximal LSA was performed using two 13x50
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39 mm overlapping self-expandable stent-graft (**F**). The repair was extended distally into Zone 5 in
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41 the thoracic aorta using a 30-30-200-mm Alpha thoracic stent-graft (**G**)
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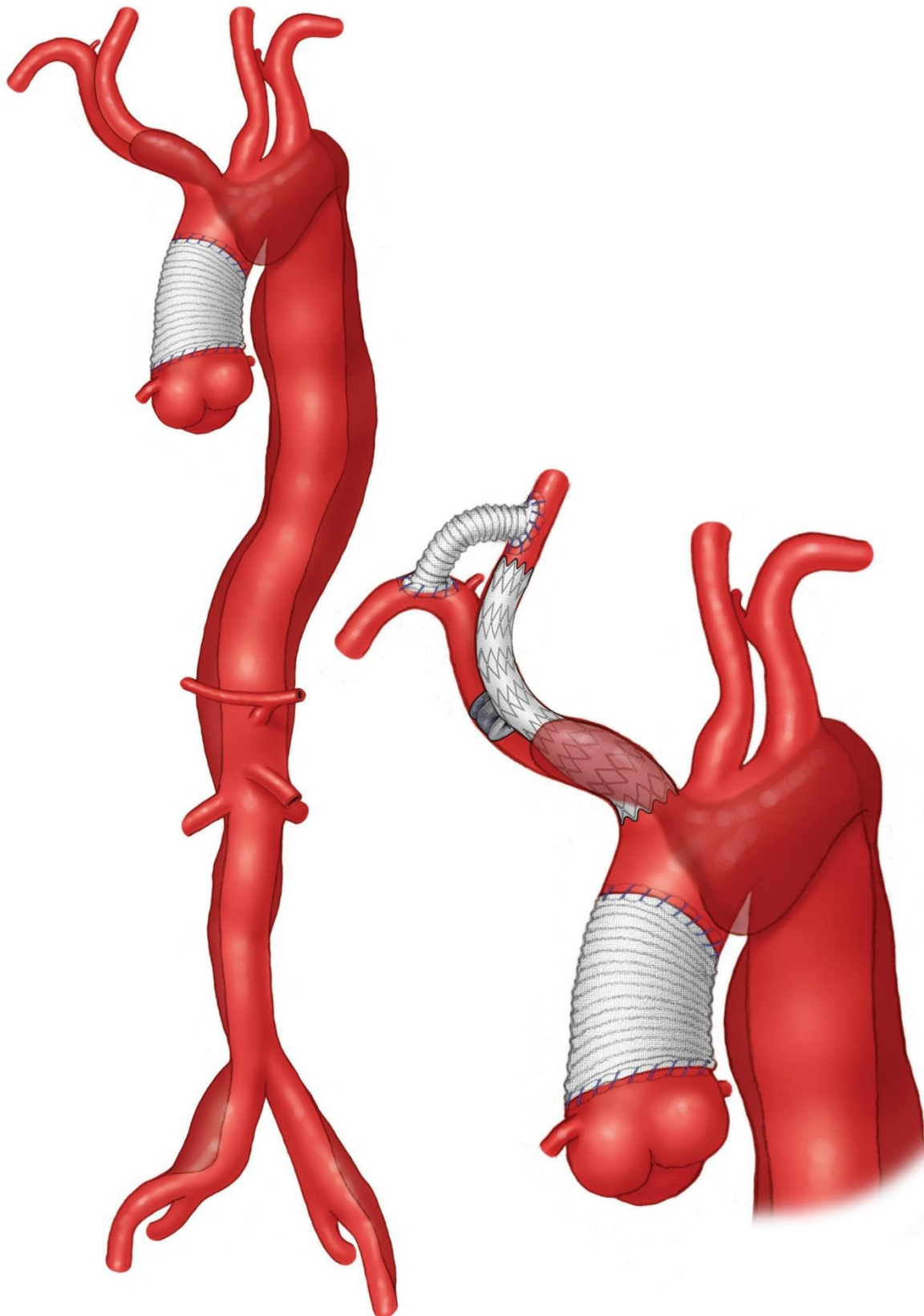
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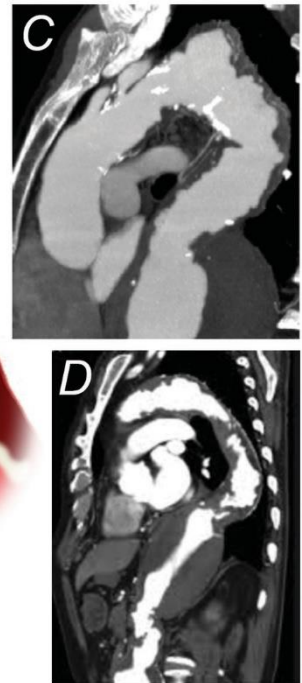
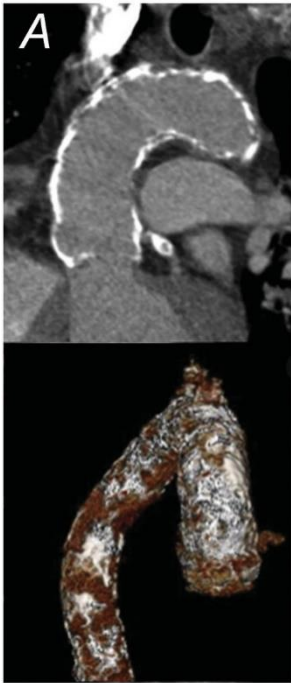
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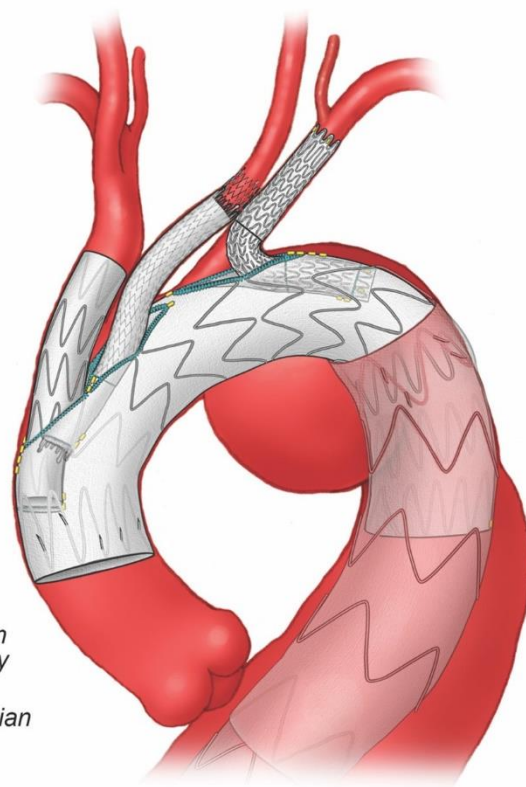


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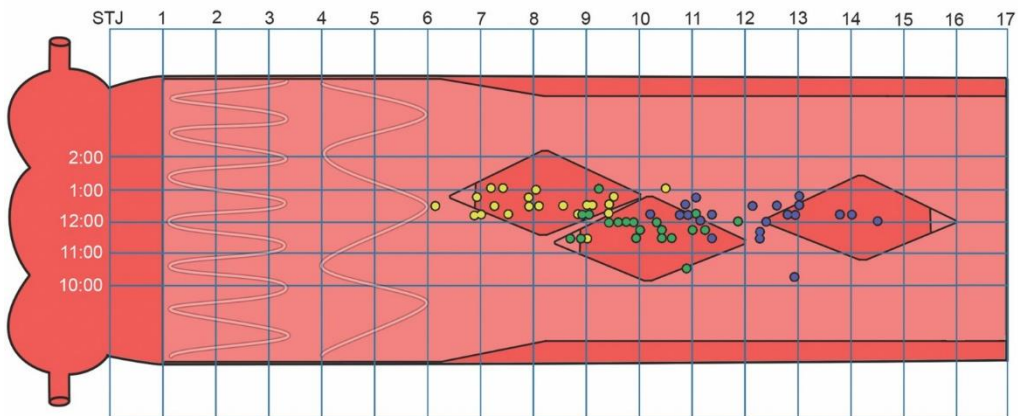
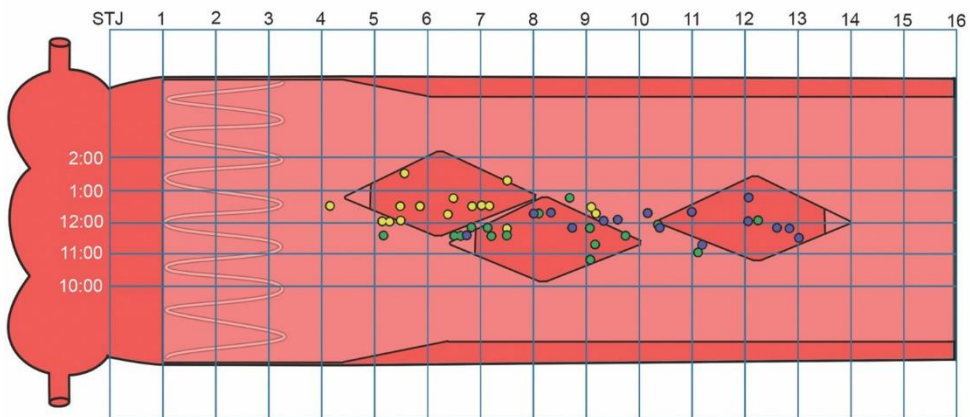
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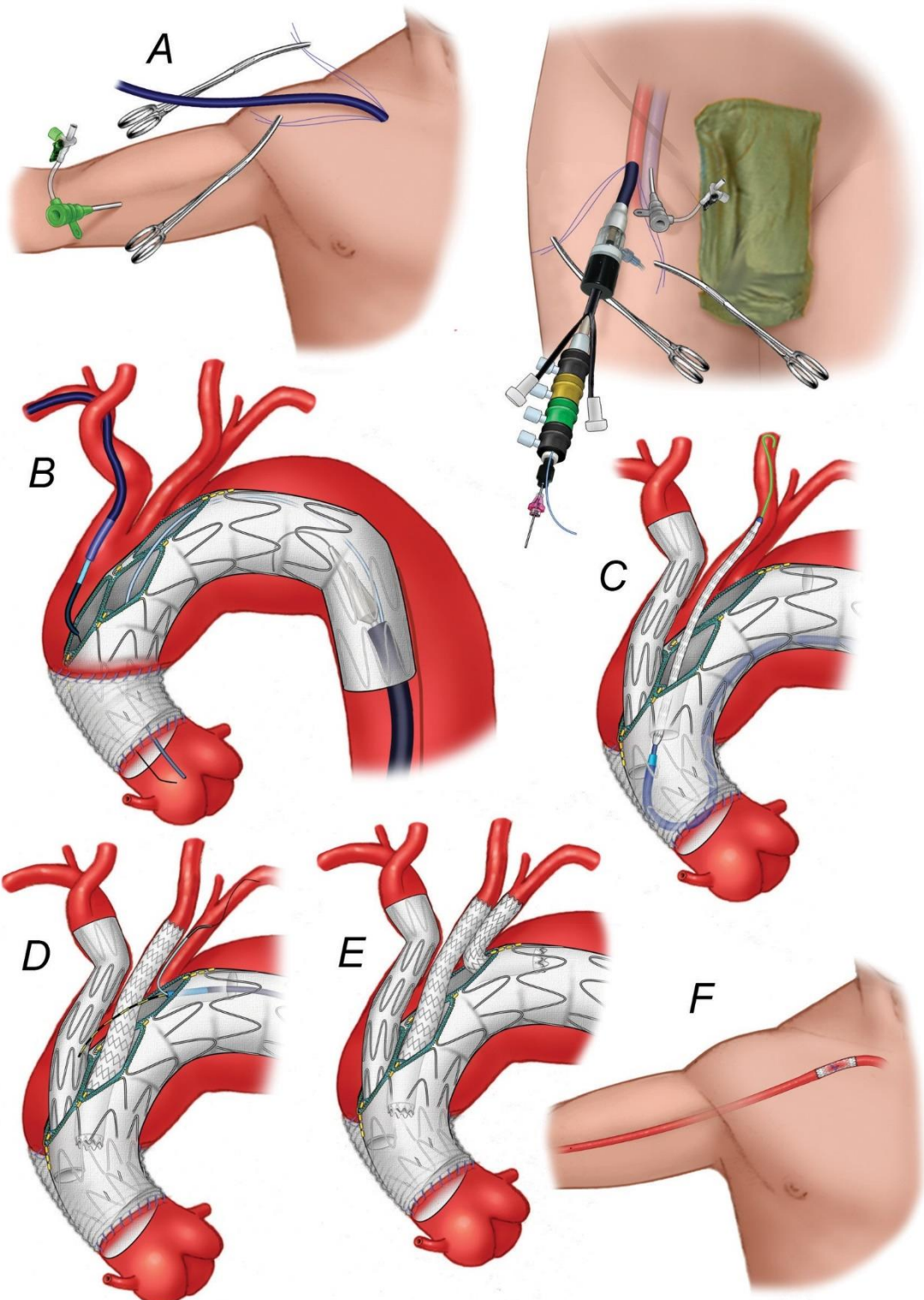
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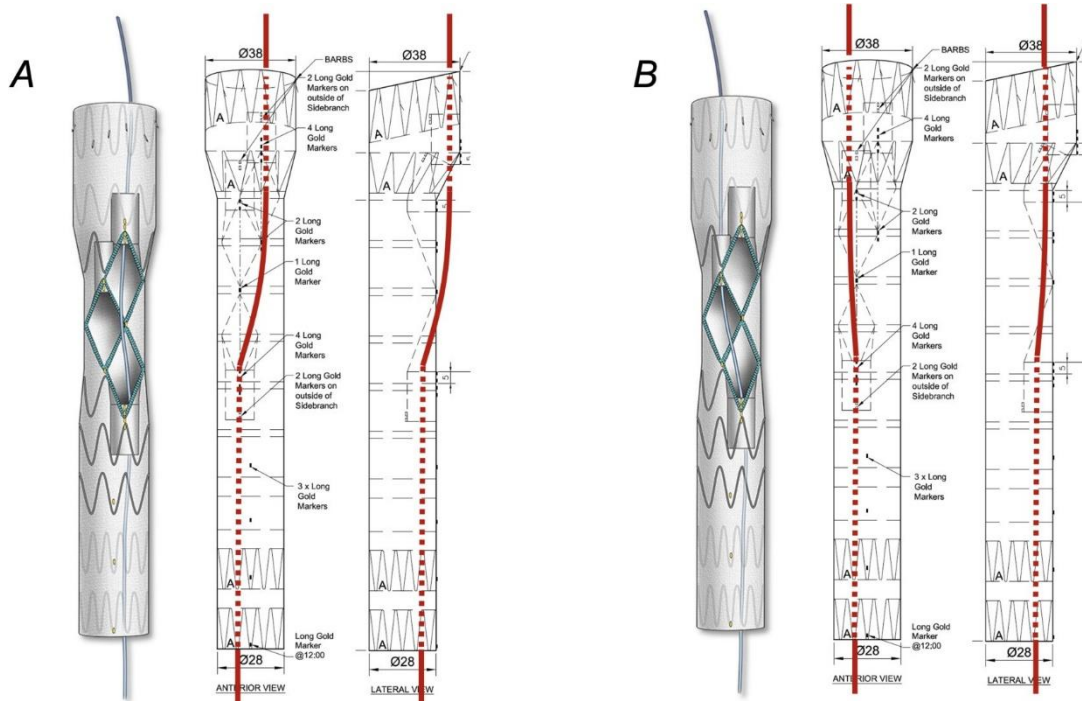
- *Innominate artery*
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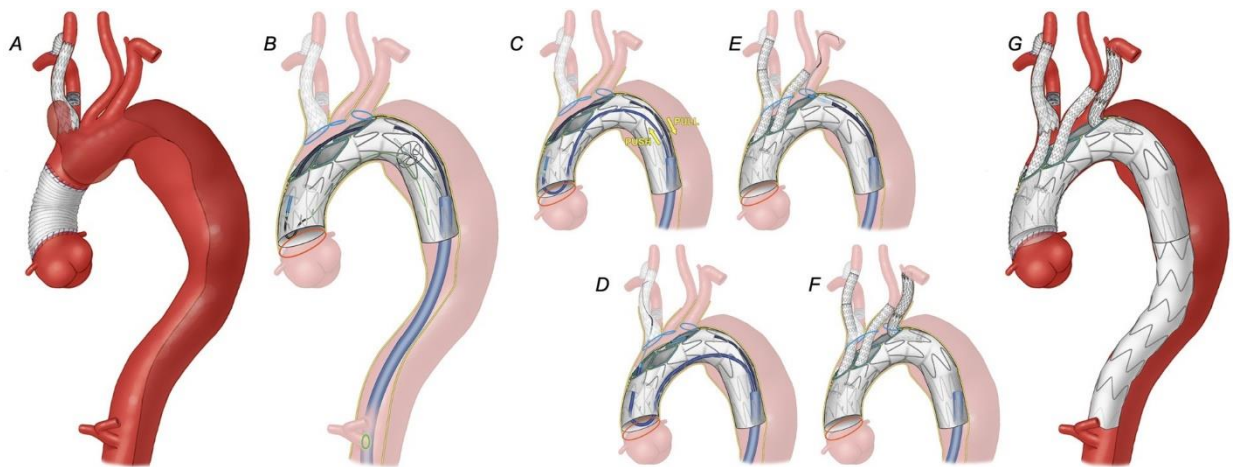


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