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Innovations in the Endovascular Treatment of Complex Aortic Pathologies

Habilitationsschrift
für das Fach Gefäßchirurgie

vorgelegt von

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Contents

1. Abbreviations

aSA – Aberrant Subclavian Artery

B-EVAR – Branched Endovascular Aortic Repair

BMJ – British Medical Journal

BTAI – Blunt Traumatic Thoracic Aortic Injury

CI – Confidence Interval

CMD – Custom-Made Device

CPB – Cardiopulmonary Bypass

CSF – Cerebrospinal Fluid

CT – Computed Tomography

dTEVAR – Debranching Thoracic Endovascular Aortic Repair

EACTS – European Association for Cardio-Thoracic Surgery

EJVES – European Journal of Vascular and Endovascular Surgery

ESVS – European Society for Vascular Surgery

EVAR – Endovascular Aortic Repair

fTEVAR – Fenestrated Thoracic Endovascular Aortic Repair

F/B-EVAR – Fenestrated/Branched Endovascular Aortic Repair

HR – Hazard Ratio

I^2 – Heterogeneity Index (I-squared statistic)

IRB – Institutional Review Board

IQR – Interquartile Range

KD – Kommerell's Diverticulum

LMU – Ludwig-Maximilians-Universität (Munich)

LSA – Left Subclavian Artery

MACCE – Major Adverse Cardiovascular and Cerebrovascular Events

MuVIT – Munich Valsalva Implantation Technique

OR – Odds Ratio

PMEG – Physician-Modified Endograft

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT – Randomised Controlled Trial

SCI – Spinal Cord Ischemia

STROBE – Strengthening the Reporting of Observational Studies in Epidemiology

SUMMIT – European multicentre TEVAR registry database

TAAA – Thoracoabdominal Aortic Aneurysm

TEVAR – Thoracic Endovascular Aortic Repair

2. List of publications relevant to this dissertation

2.1. Original articles as first or last author

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   Journal Impact Factor: 1.4

2) **Konstantinou N**, Jakimowicz T, Haulon S, Pichlmaier M, Abisi S, Pedro LM, Khanafer A, Tsilimparis N. Outcomes after Endovascular Arch Repair in Patients with a Mechanical Aortic Valve: Results from a Multicentre Study.
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3) **Konstantinou N**, Tsilimparis N, Stavroulakis K. Intravascular lithotripsy and aortic bare-metal stenting: a low-profile solution for the treatment of heavily calcified aorto-iliac disease
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2.3. Case reports

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Journal Impact Factor: 3.2

Median Impact Factor: 3.2
Citations: 543
H-index: 11

3. Introduction and aims

Aortic disease is a major cause of cardiovascular morbidity and mortality, with aneurysms and dissections together accounting for a substantial proportion of acute vascular emergencies. Population-based studies estimate the incidence of acute aortic dissection at 3–4 per 100,000 person-years, with in-hospital mortality exceeding 25% despite advances in diagnosis and perioperative care (1). Thoracic and thoracoabdominal aortic aneurysms, although often asymptomatic until advanced, carry a cumulative rupture risk of more than 30% at five years once the diameter threshold for repair is exceeded (2, 3). Outcomes after rupture remain poor, with prehospital mortality of up to 50% and operative mortality of 40–50% even in contemporary series (4, 5). Open surgical repair, while the historical standard of care, is associated with perioperative mortality rates of 10–20% and permanent spinal cord injury in up to 7% of thoracoabdominal cases, even in highly specialized and experienced centers (6-8). These figures illustrate the ongoing burden of disease and underscore the need for less invasive strategies that can reduce perioperative risk while providing durable protection.

The introduction of endovascular aneurysm repair (EVAR) in the early 1990s marked a paradigm shift. First applied to infrarenal aneurysms (9), EVAR subsequently proved its value in randomized controlled trials, showing reduced early mortality compared with open repair (10). These successes laid the foundation for thoracic endovascular aortic repair (TEVAR), initially confined to straightforward descending thoracic aneurysms (11). Over the past two decades, however, the scope of (T)EVAR has expanded dramatically, reaching into the aortic arch and thoracoabdominal segment, previously regarded as prohibitive for endovascular techniques. This progress has been facilitated by advances in device design, imaging integration, and perioperative care, as well as increasing operator experience (12).

Despite these advances, major challenges remain. Endovascular repair of the arch is complicated by the proximity of supra-aortic vessels, the risk of stroke from embolization, and the need to achieve secure proximal sealing in anatomically variable landing zones (13). Thoracoabdominal repair is constrained by the risk of spinal cord ischemia (SCI), endoleaks, and branch vessel instability. Bridging stent durability, renal target vessel patency, and long-term outcomes remain active areas of investigation (14). In parallel, the need to manage complex access routes has driven innovation in closure systems and enabling adjuncts such as intravascular lithotripsy and intravascular ultrasound (15-17).

The rationale for ongoing innovation in endovascular aortic repair is therefore twofold: to broaden applicability to anatomies and clinical contexts previously considered untreatable, and to reduce the risk of complications while improving long-term durability. Current European Society for Vascular Surgery (ESVS) guidelines endorse endovascular repair as first-line therapy for many thoracic and abdominal aneurysms, but also highlight unresolved issues regarding device performance, neurological protection, and durability (18, 19).

Against this background, the aim of the present cumulative Habilitation is to synthesize clinical and technical contributions to the field of complex endovascular aortic surgery. The work addresses innovations in aortic arch repair, including fenestrated versus hybrid strategies and the feasibility of repair in patients with mechanical valves; advances in thoracoabdominal repair using both custom-made and off-the-shelf solutions; the durability of bridging stents and renal revascularization techniques; and strategies to mitigate complications such as SCI, endoleaks, and access-related morbidity. Beyond reporting individual study results, the thesis seeks to integrate these findings into the broader trajectory of the field, highlighting their contribution to expanding patient eligibility, reducing perioperative risk, and shaping the future direction of complex endovascular therapy.

4. Methods Across the Portfolio

The studies presented in this thesis employed a range of methodological approaches, tailored to the specific research questions. These included retrospective and prospective single-center analyses, multicenter registries, systematic reviews and meta-analyses, and technical feasibility reports.

Single-center series were used for focused investigations such as bridging stent durability, closure device outcomes, and feasibility of technical refinements in thoracic and thoracoabdominal repair. These analyses provided granular procedural and imaging data, with follow-up performed according to institutional protocols. Multicenter registries, including the SUMMIT database and collaborative datasets on patients undergoing endovascular arch repair with mechanical aortic valves, were employed to capture larger patient populations across multiple institutions. These registries enabled assessment of perioperative neurological outcomes, rare indications, and device-specific safety signals in heterogeneous, real-world cohorts.

Systematic reviews and meta-analyses were conducted for conditions with limited single-center data, including aberrant subclavian artery repair and outcomes after thoracoabdominal branched repair. All reviews were performed in accordance with PRISMA guidelines (20). Quantitative synthesis employed random-effects models (Der Simonian–Laird) to account for between-study heterogeneity. Proportions were stabilized with Freeman–Tukey double arcsine transformation. Heterogeneity was assessed using the I^2 statistic, with thresholds of 25%, 50%, and 75% indicating low, moderate, and high heterogeneity. Where feasible, publication bias was assessed using funnel plots and Egger's regression test.

Technical feasibility reports were used to disseminate novel approaches such as triple-branch fenestrated arch repair under sedo-analgesia and cardiac output reduction with the Munich Valsalva Implantation Technique. These were structured to describe procedural steps, device configuration, intraoperative imaging, and early outcomes, with the goal of providing reproducibility and facilitating translation into clinical practice.

Endpoints were defined according to international consensus standards to ensure comparability across studies. Technical success was defined as successful device delivery, deployment, and exclusion of the target lesion with preserved perfusion of intended target vessels. Clinical outcomes included perioperative (30-day) mortality, major adverse cardiovascular and cerebrovascular events (MACCE), and freedom from secondary intervention. Branch-related outcomes included target vessel patency, endoleak, or the requirement for reintervention. Neurological outcomes comprised major and minor strokes, transient ischemic attack, and spinal cord ischemia, graded according to Society for Vascular Surgery standards (21). Access-related endpoints included closure device success, local vascular complications such as bleeding or pseudoaneurysm formation, and need for surgical revision.

Statistical analyses followed established methodology. Continuous variables were reported as means with standard deviation or medians with interquartile ranges. Categorical variables were compared with chi-square or Fisher's exact test; continuous variables with Student's t-test or Mann–Whitney U test, depending on distribution. Time-to-event analyses, including overall survival, target vessel patency, and freedom from reintervention, were performed using Kaplan–Meier estimates and log-rank testing. Independent predictors of outcome were assessed with multivariable Cox proportional hazards regression or logistic regression, with results reported as hazard ratios or odds ratios with 95% confidence intervals.

Ethical approval was obtained for all retrospective and prospective studies from the LMU Munich institutional review board or from the respective participating centers. For prospective data collection, informed consent was obtained. Data integrity in multicenter collaborations was ensured by on-site monitoring and use of harmonized datasets. Reporting adhered to recognized standards, including STROBE for observational studies and PRISMA for meta-analyses (20, 22).

This combination of single-center feasibility, multicenter registry analysis, evidence synthesis, and technical case reporting reflects the methodological breadth of contemporary vascular research. Together, these approaches provided the statistical and clinical framework for evaluating innovation, assessing risk, and translating technical advances into practice.

5. Innovations in the Aortic Arch

The aortic arch has historically represented one of the most technically challenging regions for repair due to the complexity of supra-aortic branch anatomy and the physiological burden of open surgery. Conventional arch replacement with hypothermic circulatory arrest and selective antegrade cerebral perfusion remains a durable benchmark but is associated with substantial perioperative risk, with mortality between 8–15% and stroke rates of 6–8% in contemporary expert series (23, 24). Over the last two decades, thoracic endovascular aortic repair (TEVAR) has progressively extended from the descending thoracic aorta into Ishimaru zone 2, and increasingly into the proximal arch (25). This development has been facilitated by supra-aortic revascularization strategies, fenestrated and branched endografts, and refined imaging and access techniques.

5.1. Zone 2 TEVAR and left subclavian artery management

Achieving an adequate proximal landing zone in the descending thoracic aorta frequently requires coverage of the left subclavian artery (LSA). While technically straightforward, simple coverage has been associated with increased neurologic complications; systematic reviews/meta-analyses report higher stroke risk with LSA coverage and risk reduction when the LSA is revascularized (26, 27). In cohort studies, prophylactic LSA revascularization was linked to substantially lower perioperative stroke: Zamor *et al.* reported 25% stroke rates without revascularization vs 2% with (28), and Bradshaw *et al.* found 14.3% without vs 1.9% with revascularization in zone 2 TEVAR (29). Large-scale registry data from the Vascular Quality Initiative showed LSA coverage without revascularization independently associated with higher spinal cord ischemia (adjusted OR 2.29), while the adjusted stroke difference was not statistically significant (30). Consistent with these data, current ESVS guidelines recommend LSA revascularization whenever feasible for elective zone 2 TEVAR and reserving simple coverage for emergencies (31).

5.2. Cervical debranching and hybrid strategies

Hybrid strategies combining cervical debranching with TEVAR provided one of the first reproducible means of extending repair into the proximal arch [Figure 1]. In a large single-center cohort (201 patients; 211 debranching procedures), 30-day mortality was 7.6%, higher with singlestage hybrid procedures versus staged/isolated debranching (15.0% vs 4.9%), major stroke occurred in 4.3% with no strokes after isolated debranching, and graft durability was excellent (primary patency 98.1%, secondary 100%) (32). Local complications were frequent but mostly minor, including bleeding (11.4%), re-intervention (10.4%), and peripheral nerve injury (9.5%). External series corroborate these results: in a TEVAR-specific carotid–subclavian bypass cohort, 30-day mortality was 4.6%, ipsilateral stroke 3.5%, and permanent paraparesis/paraplegia 0.9% (33). A Vascular Quality Initiative analysis of 837 zone-2 TEVAR cases with LSA revascularization reported 30-day mortality 3.0%, TIA/stroke ~5%, and SCI 3%, with similar outcomes for surgical (bypass/transposition) and endovascular techniques (34). Additional series of carotid–subclavian transposition for zone-2 TEVAR show acceptable risk profiles (operative mortality 5.2%) supporting transposition as a safe alternative (35). Collectively, these data support cervical debranching as a durable adjunct to TEVAR that can expand proximal landing while incurring mainly local, manageable morbidity.

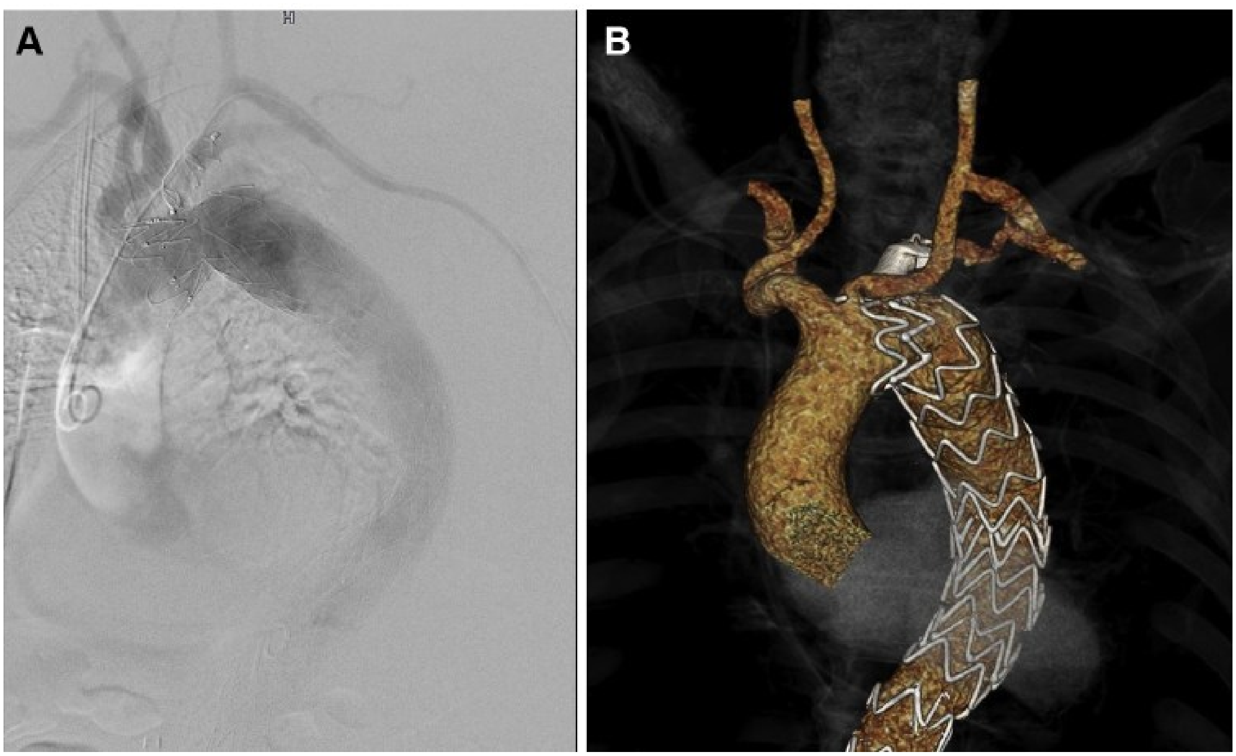

Figure 1: A. Intraoperative completion angiogram after zone 2 thoracic endovascular aortic repair (TEVAR) and previous left carotid subclavian bypass showing a vascular plug in the left subclavian artery (LSA) to avoid the development of a retrograde endoleak. **B.** Three-dimensional reconstruction of the postoperative computed tomography (CT) angiogram

5.3. Fenestrated TEVAR as an evolution beyond hybrid strategies

The next step in extending endovascular repair proximally has been the introduction of fenestrated TEVAR (fTEVAR), which allows direct incorporation of supra-aortic branches without surgical bypass [Figure 2]. Initial comparative experience against cervical debranching comes from a single-center series of 36 patients (fTEVAR n=19; debranching n=17): technical success was high in both groups (100% dTEVAR; 95% fTEVAR), there were no 30-day deaths or major strokes, and debranching carried more local access/neck complications, supporting the appeal of fTEVAR for avoiding cervical morbidity (36). Custom-made fenestrated devices, however, generally require manufacturing time and careful planning, which constrains their role in emergencies; contemporary consensus documents recommend hybrid debranching or off-the-shelf solutions when urgent repair is needed (19, 31).

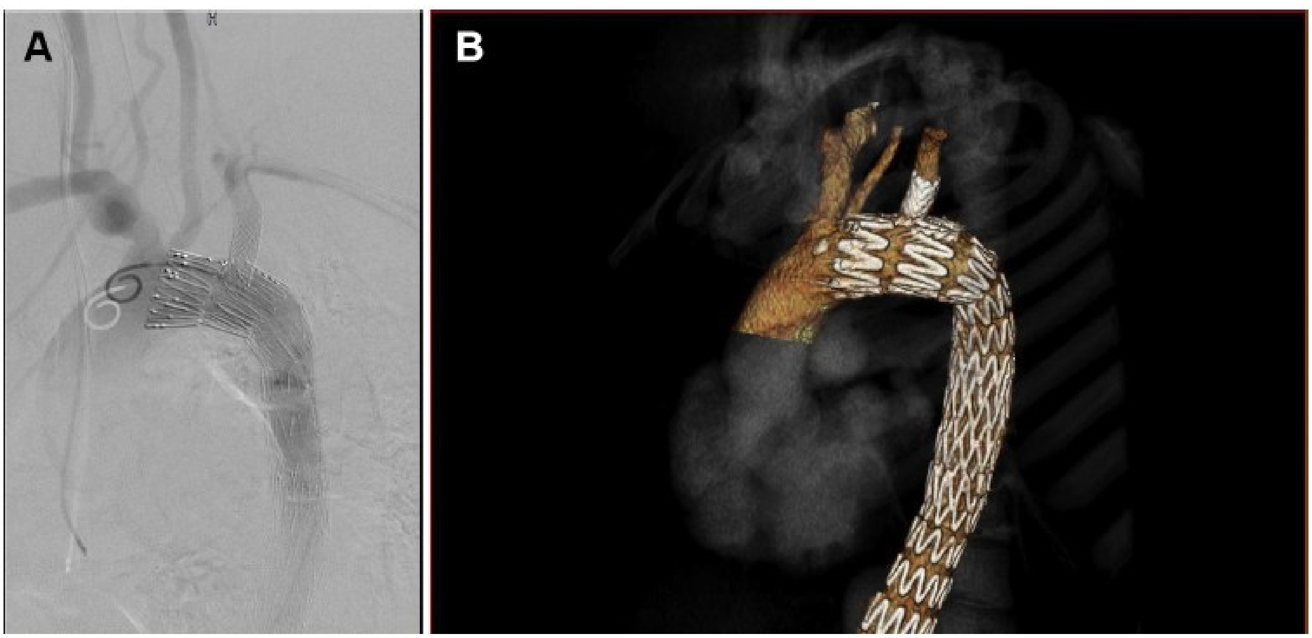

Figure 2: **A.** Intraoperative completion angiogram after implantation of a fenestrated thoracic stent-graft with a 10-mm fenestration for the left subclavian artery (LSA) and a 30- x 12-mm proximal scallop for the left common carotid artery. **B.** Three-dimensional reconstruction of the postoperative computed tomography (CT) angiography.

Beyond early comparisons, multicenter and single-center cohorts have shown durable outcomes with fenestrated technology. In a six-center series of 108 patients treated with a pre-loaded fenestrated thoracic endograft for distal arch disease, technical success was 99%, with 30-day mortality 3.7%, major stroke 5.6%, and spinal cord ischemia 3.7%; three-year survival was 84% and freedom from reintervention 73% (37). For more complex arch repairs, a single-center series of 74 patients undergoing total arch repair with double-fenestrated physician-modified endografts reported technical success 100%, 30-day stroke 5%, one early death, and 4% reintervention over a mean 41-month follow-up, supporting mid-term durability (38). Technical guidance papers detail deployment steps and pitfalls (e.g., wire entanglement, device rotation) specific to pre-loaded fenestrated arch endografts (39).

5.4. Arch repair in patients with mechanical aortic valves

A milestone in this field has been the exploration of TEVAR in patients with mechanical aortic valves, long considered an absolute contraindication. Current international consensus guidelines, including the 2019 EACTS/ESVS recommendations, explicitly advise against endovascular repair in this setting due to the perceived risk of wire entrapment, leaflet damage, acute valve dysfunction, and catastrophic regurgitation (19). For many years, this effectively excluded patients with mechanical prostheses from any endovascular option, leaving them with the high morbidity of redo open arch surgery.

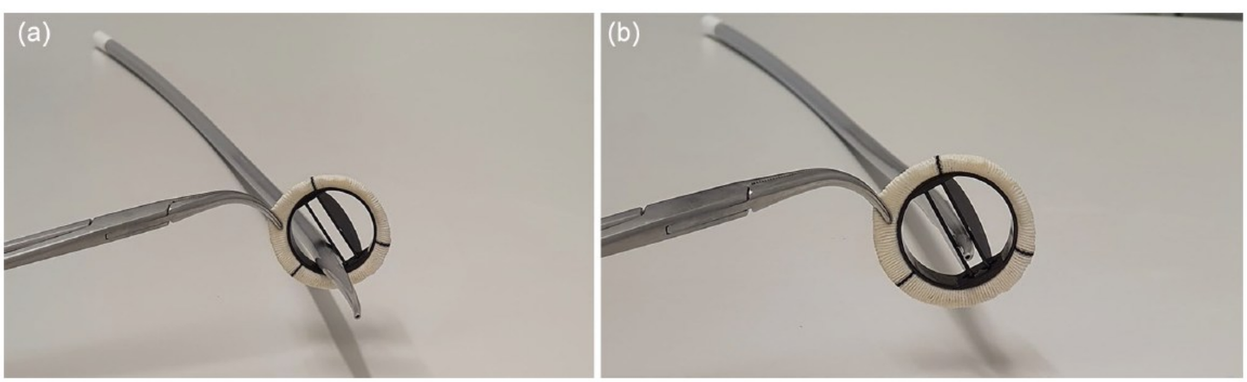

Figure 3: Cannulation of the mechanical aortic valve with an 18-F dilator through the side of the leaflet **(a)** and through the center between the 2 leaflets **(b).**

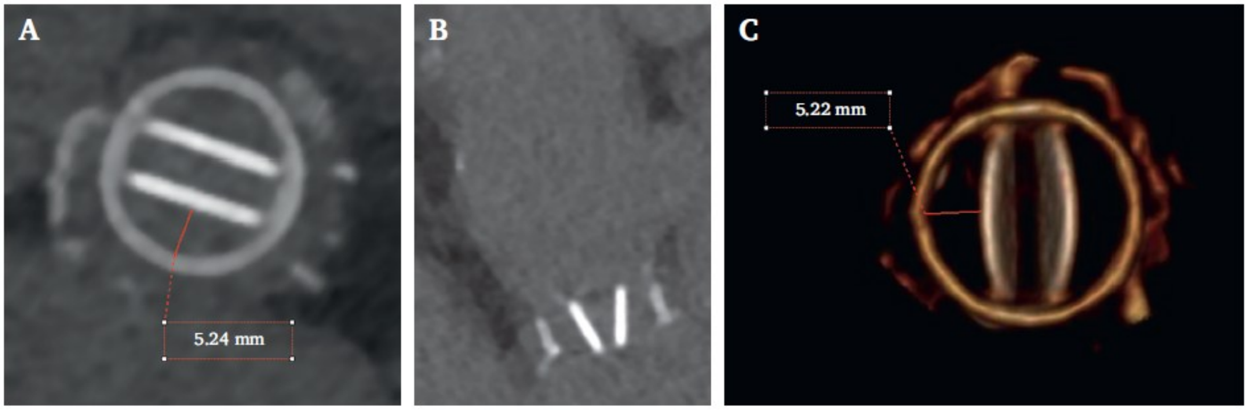

Figure 4: A bileaflet prosthetic aortic valve as shown **(A)** on the pre-operative computed tomography scan after double oblique image reformatting, **(B)** in sagittal oblique view, and **(C)** in a 3D reconstruction.

To address this challenge, we developed a dedicated technique for safe valve cannulation. Mechanical prostheses can be broadly classified as caged-ball valves, tilting-disc monoleaflet valves, and modern bileaflet valves, the latter being by far the most common in contemporary practice (40). Passage through these valves is technically feasible if meticulous attention is paid to anatomical detail. Cannulation is performed along the lateral aspect of the prosthesis, tracking alongside a single leaflet, which allows the contralateral leaflet to remain mobile and prevents complete obstruction [Figures 3, 4]. Central cannulation between the two bileaflets must be strictly avoided, as this risks entrapment, mechanical trauma, and acute severe regurgitation (41). Fluoroscopic imaging at high frame rates is essential for orientation, supported by preoperative three-dimensional reconstructions [Figure 5]. Intraoperative transesophageal echocardiography serves as a valuable adjunct when fluoroscopic visualization is limited, ensuring continuous leaflet mobility and hemodynamic stability (42).

After valve crossing with a hydrophilic guidewire, exchange for a stiff wire is carried out under continuous hemodynamic and imaging control. A short-tipped introducer dilator, usually 35 mm in length, is advanced cautiously through the prosthesis to accommodate the delivery system while reducing the risk of wedging within the leaflets. Following stent-graft deployment, the introducer is promptly withdrawn, and valve competence reassessed [Figure 6]. In the majority of cases, only transient mild regurgitation occurs during cannulation, resolving spontaneously once the delivery system is removed.

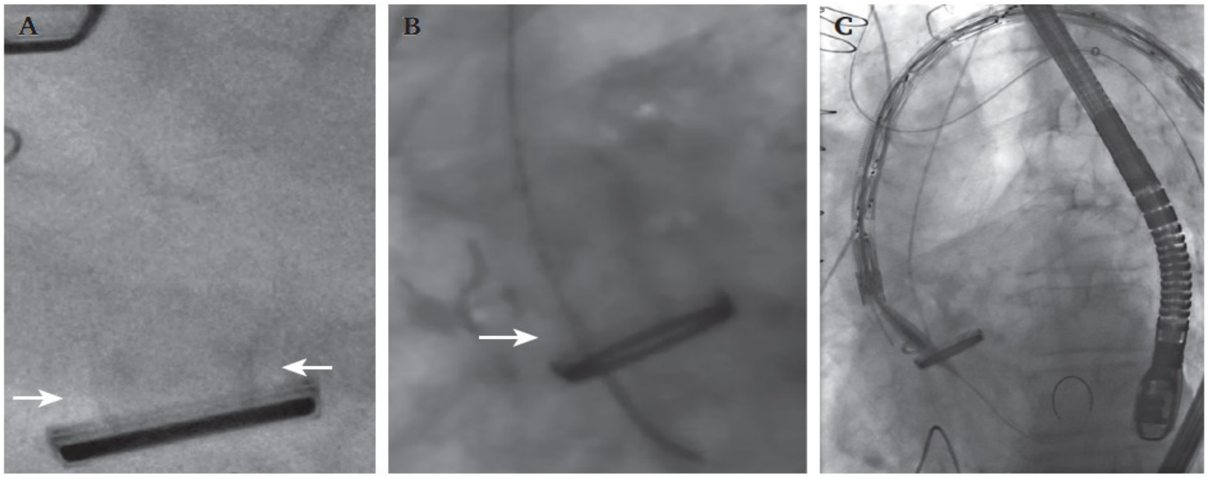

Figure 5: **(A)** The two leaflets of a bileaflet mechanical aortic valve (arrows) visualized on fluoroscopy and **(B)** canulated on the lateral side (arrow), **(C)** which allows the advance of the modified short tip introducer through the valve

Controlled cardiac output reduction, achieved with rapid pacing or techniques such as the Munich Valsalva implantation method, can further enhance stability during deployment (43, 44).

Evidence from a subsequent multicenter registry confirmed the reproducibility of this approach in clinical practice (45). Across 12 patients undergoing TEVAR after mechanical aortic valve replacement, technical success was achieved in all cases. Thirty-day mortality was 17%, attributable to one perioperative stroke and one cardiac arrest, but importantly, no instances of valve dysfunction or structural damage were reported. Minor access-related complications, such as cervical hematomas, occurred in two patients. These results demonstrate that with rigorous adherence to technical principles, TEVAR can be safely performed in patients with mechanical valves, effectively expanding treatment options for a cohort previously excluded from endovascular repair.

5.5. Technical refinements and secondary pathologies

Several technical innovations have aimed to reduce procedural morbidity and broaden the applicability of complex arch endovascular repair. Preloaded fenestrated systems streamline target-vessel cannulation and minimize wire re-navigation, key steps described to mitigate wire entanglement and malrotation risk in the arch, while maintaining high technical success in multicenter series (technical success 99%, 30-day mortality 3.7%, stroke 5.6%, spinal cord ischaemia 3.7% with preloaded f-TEVAR for distal arch pathology) (37, 39).

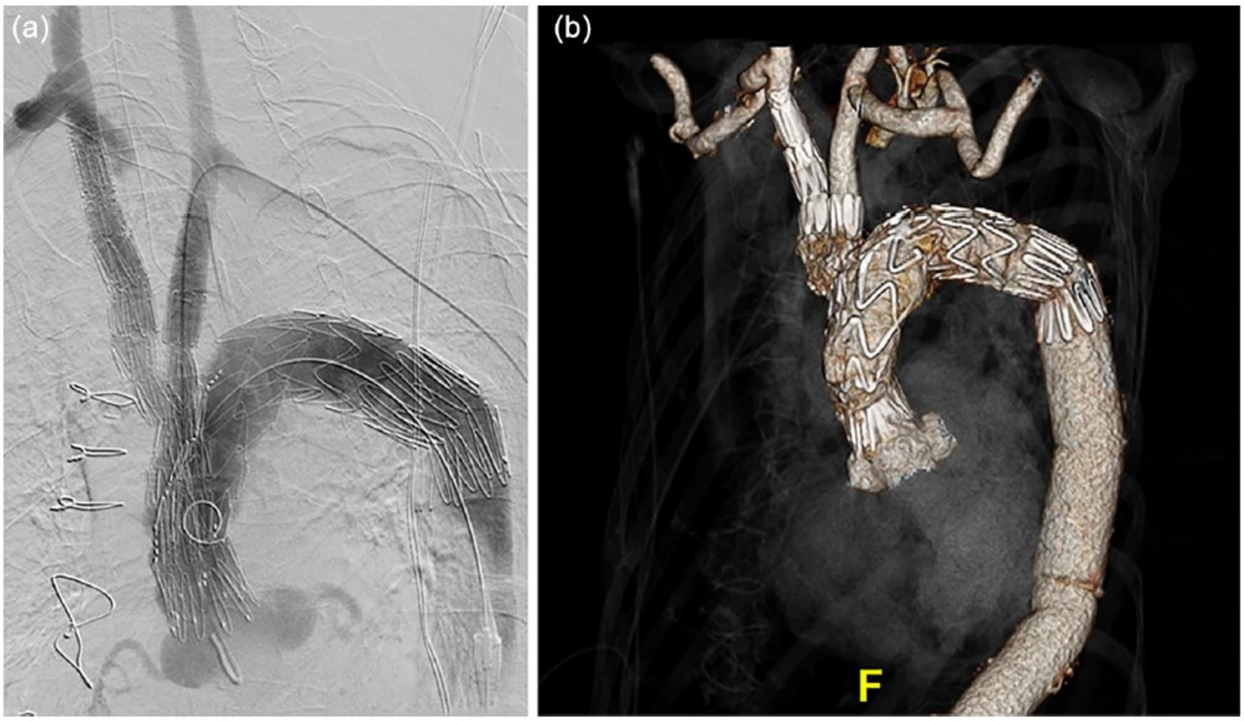

Figure 6: Final intraoperative angiogram **(a)** and 3-D reconstruction of the postoperative computed tomography angiography **(b)** in a patient with a mechanical aortic valve that underwent branched endovascular aortic arch repair.

A further refinement is performing complex arch repair under sedo-analgesia. A prospective study of total arch repair using a double-fenestrated physician-modified endograft under local anesthesia with sedation reported feasibility without conversions to general anesthesia (38). A contemporary case report similarly demonstrated successful triple-branch arch TEVAR under monitored anesthesia care in an elderly patient, with an uncomplicated recovery (46).

Endovascular treatment of secondary arch pathologies after prior ascending or arch replacement is increasingly reported as an alternative to redo sternotomy. In a single-center case series of patients with distal anastomotic aneurysms after previous open repair, custom double- or triple-branched arch endografts achieved 90% technical success; all elective patients survived 30 days, two urgent contained ruptures were fatal, and no early endograft-related reinterventions were required at a median 20-month follow-up (47). Earlier series of branched endografts after prior DeBakey I repair also showed feasibility with low 30-day stroke (5%) and mortality (5%) (48).

5.6. Management of the Unusual: Anatomical Variants and Traumatic Injuries

Anatomical variants at the arch and isthmus, particularly aberrant subclavian artery (aSA) with or without Kommerell's diverticulum (KD), and non-degenerative acute pathologies such as blunt traumatic thoracic aortic injury (BTAI), are less frequent but clinically decisive scenarios in which the endovascular playbook must adapt without compromising neurological protection or durability. A comprehensive systematic review and proportion meta-analysis synthesizing 314 studies and 732 patients with aSA/KD reported that aRSA in a left-sided arch accounted for 71.4% of cases, KD was present in 50.1%, and 68% were symptomatic at presentation, most commonly dysphagia (49.6%), followed by chest/back pain (36.1%) and dyspnea/cough (19.7%) (49). Techniques were broadly dichotomized into open/invasive hybrid (sternotomy/thoracotomy, 61.9%) versus minimally invasive hybrid/endovascular (38.1%). In studies with ≥5 cases, pooled early mortality was 1.62% (95% CI 0.05–4.53) for open/invasive hybrid and 1.96% (95% CI 0–6.34) for minimally invasive hybrid/endovascular, while symptom relief pooled 99.5% and 95.8%, respectively (49). When examined by dominant strategies, outcomes were concordant: after open aortic replacement with CPB/left-heart bypass (n=377), early death 5.3%, major stroke 3.7%, SCI 1.6%, and after TEVAR with cervical debranching (n=146), early death 4.8%, stroke 3.4%, SCI 1.4%, with respiratory failure occurring in 9.0% vs 4.1%, respectively. These data substantiate a zone-2 endovascular-first paradigm, with planned revascularization when coverage is required, as a credible alternative to more invasive reconstructions for aSA/KD, achieving near-universal symptom relief while maintaining low early risk, provided meticulous planning of landing zones and vertebral dominance is undertaken.

Non-elective pathology at the isthmus displays a parallel trajectory. In a retrospective 20-year cohort of 46 BTAI patients (median age 42.4 years, 71.7% male), urgent repair was performed in 73.8%, with TEVAR used in 87% and open repair in 10.9% (50). Technical success was 92.1% for TEVAR (overall 82.6%) and 79% for open repair. In-hospital mortality reached 19.5% overall, 17.5% after TEVAR versus 40% after open surgery, with aortic-related mortality 6.5% (5% TEVAR, 20% open). Early reintervention occurred in 15.2%, predominantly access- or LSA-related, and among TEVAR cases with primary zone-2 coverage without prophylactic LSA revascularization, 9.1% required delayed carotid–subclavian bypass for arm ischaemia (50). Device usage reflected the trauma era's constraints (straight thoracic grafts 22–36 mm, mean proximal oversizing ~11.5%), and mid-term durability was favorable: median follow-up 34 months, only one late vascular reintervention (acute graft thrombosis) and no aortic-related deaths among survivors (50). Taken together with the aSA/KD meta-analysis, these data argue that standard arch/zone-2 endovascular concepts, secure sealing zones, planned LSA strategies, and vigilant access management, scale effectively to anatomically unusual or high-energy scenarios when procedural discipline is maintained.

5.7. Neurological outcomes and risk factors

Neurological injury, primarily stroke, remains the principal limitation in arch endovascular repair. Analysis of 594 patients in the SUMMIT registry revealed early stroke in 3.5%, paraplegia in 1.3%, and paraparesis in 2.5% (51). Acute type B dissection, coverage of the left subclavian artery without revascularization, and extended procedural duration were identified as independent predictors in multivariable regression (adjusted OR for LSA coverage without bypass ~2.4, 95% CI 1.3–4.5).

Given that embolic phenomena during device introduction and branch cannulation contribute significantly to stroke risk, procedural techniques for reducing air and particulate emboli have been explored. CO_2 flushing of thoracic stent-grafts is one such measure that showed some promise in bench/experimental work (52), but no completed randomized outcome trial yet exists; a multicenter pilot RCT protocol (INTERCEPTevar) has been published (53).

Other modifiable/procedural factors associated with stroke include longer procedure duration (also observed in SUMMIT) and increased complexity of arch manipulation/branch incorporation; in VQI data for elective degenerative aneurysms, endovascular supra-aortic trunk revascularization was associated with higher stroke risk (RR ~2.66) and more proximal zones (0–1) carried greater risk than zone 2 (54). These insights underscore mitigation via efficient workflows, careful LSA strategy, and minimizing manipulations during branch cannulation.

6. Innovations in the Thoracoabdominal Aorta

Thoracoabdominal aortic aneurysms (TAAA) remain among the most demanding pathologies in vascular surgery. Natural-history data show that descending thoracic/thoracoabdominal aneurysms ≥6.0 cm carry an ~19% yearly risk of rupture, dissection, or death, and high-risk patients deemed unfit for intervention experience substantial aneurysm-related mortality on short-term follow-up (55, 56).

Open repair with advancements in surgical technique can produce durable outcomes in experienced centers (7) but, especially in high-risk patient populations, mortality and morbidity can be prohibitively high (57).

Against this backdrop, fenestrated/branched endovascular repair (F/B-EVAR) has expanded eligibility and can achieve favorable early outcomes. A meta-analysis comparing endovascular versus open repair found similar perioperative mortality but differing complication profiles (58). Importantly, a large prospective multicenter cohort showed low aortic-related mortality (5-year cumulative incidence ~3.8%) and low rupture rates (~2.7%) after F/B-EVAR, albeit with substantial reintervention (5-year ~40%) (59).

6.1. Custom-made, off-the-shelf and physician-modified grafts

Endograft advancements for thoracoabdominal aortic aneurysms has produced a spectrum of strategies ranging from bespoke custom-made devices (CMDs) to off-the-shelf multibranched platforms and, in selected urgent situations, physician-modified endografts (PMEGs). CMDs permit precise tailoring to patient-specific anatomy, accommodating short visceral segments, accessory vessels, and marked angulation, thereby optimizing branch orientation and sealing and reducing the risk of type I endoleak in elective settings (60, 61). Their limitation is production delay, typically 4 to 8 weeks, rendering them unsuitable for acute or symptomatic cases (62). The off-the-shelf t-Branch graft was introduced to overcome this limitation and has become the standard for urgent and ruptured TAAA. In a recent post-market and meta-analytic experience, including substantial proportions of urgent/emergent cases, technical success was at 93–97%, perioperative mortality 6–8% [Figure 7], stroke 3–4%, and mid-term reintervention 10–15% (63, 64).

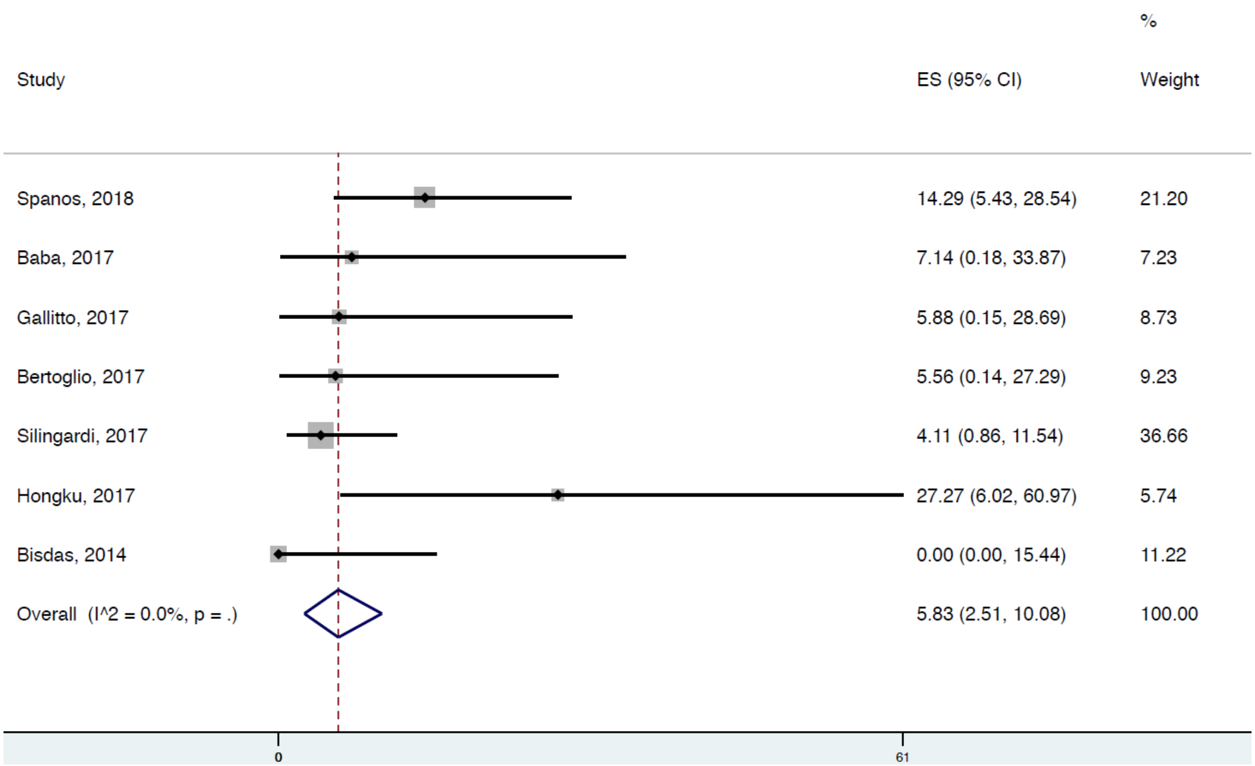

Figure 7: Forest plot presenting the meta-analysis of technical success based on event rates for included studies. Event rates in the individual studies are presented as squares, with 95% confidence intervals (CIs) presented as extending lines. The pooled event rate with its 95% CI is depicted as a diamond. ES, Effect size.

Additional series have confirmed high branch patency (>90%) and freedom from reintervention exceeding 80% at two years (65). CMDs therefore remain preferable for elective repair, while the availability of t-Branch has ensured a reliable solution in emergencies when CMD production time is prohibitive.

When neither CMDs nor t-Branch are suitable, particularly in anatomies outside the design envelope of off-the-shelf solutions, physician-modified endografts (PMEGs) provide an important alternative. Originally developed for complex abdominal aortic aneurysms, PMEGs have increasingly been extended into thoracoabdominal repair in urgent settings where bespoke devices are not available in time. Reported technical success rates exceed 90%, with mid-term branch patency >85% and reintervention rates of 10–15%, mostly treatable endovascularly, and pooled short-term outcomes from systematic review support feasibility and acceptable safety in selected patients (66-68). Thirty-day mortality in multicenter registries approximates single digits with permanent paraplegia generally low in contemporary cohorts, outcomes broadly comparable to dedicated devices in similar high-risk settings (69). Although heterogeneity of technique and absence of regulatory approval have constrained wider adoption, PMEGs remain indispensable in selected emergencies, extending therapeutic reach where no other option is available.

Together, these three approaches, CMDs, t-Branch, and PMEGs, constitute a growing endovascular armamentarium for thoracoabdominal disease, allowing repair across the spectrum from elective anatomic precision to emergent life-saving intervention.

6.2. Durability of bridging stents and branch stability

Durability of bridging stents is central to the long-term performance of F/B-EVAR [Figure 8]. Early experience noted stent-related problems (kinking, fracture, component separation) and non-trivial branch events; for example, a series of 523 target vessels found bridging stent-graft occlusion 2% and reintervention 4% at a median 14 months (70). Balloon-expandable covered platforms were then adopted to improve radial strength and deployment precision; a multicenter analysis of balloon-expandable stent-grafts reported high technical success and encouraging short-term durability (71). In a high-volume single-center series (113 patients; 440 reno-visceral vessels) using BeGraft (Bentley Innomed, Hechingen, Germany) for 361 targets, technical success was 99.4%, with target-vessel instability between 0.27% and 0.8% at 20-month follow-up and 30-day mortality 0.9% (72). These findings align with prior BeGraft cohorts showing 98% and 97% target-vessel patency at 1 and 2 years, respectively, and 96% freedom from secondary procedures at 2 years (73), as well as earlier one-year data in 101 BeGraft bridging-stents with 98% fenestration patency (74). While comparative data often favor balloon-expandable stents for radial force and precise alignment, self-expanding devices retain value, particularly in directional branches and tortuous renovisceral anatomy, where registry analyses have shown lower rates of target-artery endoleak and reintervention with self-expanding than some balloon-expandable stent-grafts without patency penalties (75). Contemporary platforms and selection strategies have thus reduced branch-related failures substantially, addressing the earlier perception that bridging stents were the “weak link” of complex endovascular repair.

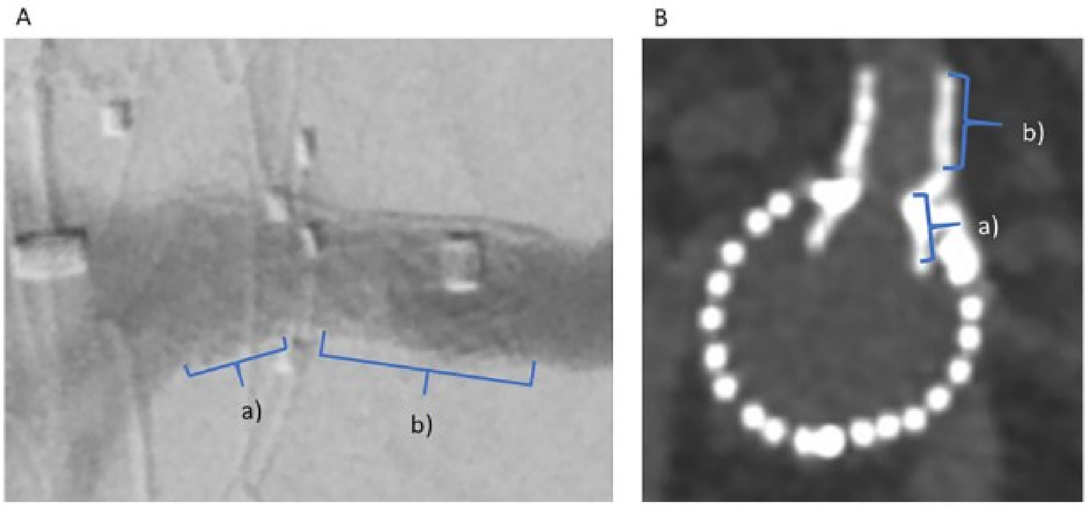

Figure 8: Bridging stent: (A) intra-operative angiography; (B) post-operative CTA scan: (a) protrusion in stent-graft; (b) sealing zone in target vessel. CTA, computed tomography angiography.

6.3. Renal stent occlusion and salvage revascularization

Renal target vessel loss remains infrequent but clinically consequential given its association with renal function decline, dialysis dependence, and late mortality. Chronic kidney disease independently predicts adverse outcomes after complex EVAR, and dialysis dependence confers poor prognosis (76). A multicenter analysis of renal stent-graft occlusions after F/B-EVAR (38 patients, 46 target vessels; eight bilateral occlusions; 15.8% solitary kidneys) demonstrated that endovascular revascularization was feasible in 95.7% (44/46), despite prolonged median renal ischemia time of 27.5 hours (IQR 4–36; range 4–720), with 94.4% treated beyond six hours and 55.6% beyond 24 hours; in-hospital mortality was 2.6% (77). Techniques included aspiration thrombectomy alone (5.3%), aspiration plus relining (52.6%), and relining alone (36.8%). Post-intervention, 36.8% of patients showed improvement in renal function. Among those with bilateral occlusion or a solitary kidney (n=14), nine recovered sufficient function to avoid chronic hemodialysis, whereas 10 patients overall (26.3%) were discharged on permanent hemodialysis. The cause of occlusion was indeterminate in 50% of target vessels and attributed to significant stenosis or kinking in 41.3%, underscoring the importance of meticulous bridging stent geometry. These results rebut the assumption that renal stent occlusion is inevitably terminal and instead support a strategy of vigilant surveillance and early endovascular salvage to preserve renal function.

6.4. Spinal cord ischemia

Spinal Spinal cord ischemia (SCI) remains the most feared neurological complication in thoracoabdominal repair. Across F/B-EVAR series, overall SCI incidence is typically 6–10%, with permanent paraplegia in 3–5%, but risk varies according to coverage length, urgency, hemodynamics, and prior aortic interventions (78, 79).

In a 243-patient cohort of complex aneurysms undergoing F/B-EVAR, SCI occurred in 17.7% (43/243), comprising paraplegia in 4% (10/243) and paraparesis in 13.7% (33/243); 72% of events manifested immediately postoperatively. Multivariable analysis identified preoperative renal dysfunction (eGFR <60 mL/min/1.73 m²; odds ratio ~2.4) and increased vertebral segment coverage as independent predictors, while preoperative CSF drainage was associated with reduced SCI (12% with drainage vs 24% without, p=0.018); 30-day mortality was 9% (80).

6.5. Access and closure devices

Transition from surgical cutdown to fully percutaneous transfemoral access has reduced access-site morbidity and shortened recovery while maintaining high technical success rates in complex aortic repair. Nevertheless, outcomes hinge on the quality and diameter of the femoral and iliac access vessels. In a prospective single-center comparison of suture-mediated closure systems (ProGlide versus ProStyle) for large-bore access, overall technical success exceeded 90%; in severely calcified femoral arteries, success fell to approximately 80% compared with >95% in less diseased vessels, and major access complications occurred in 8%, including bleeding necessitating surgical revision and femoral occlusion. Complication risk rose with sheath size [Figure 9].

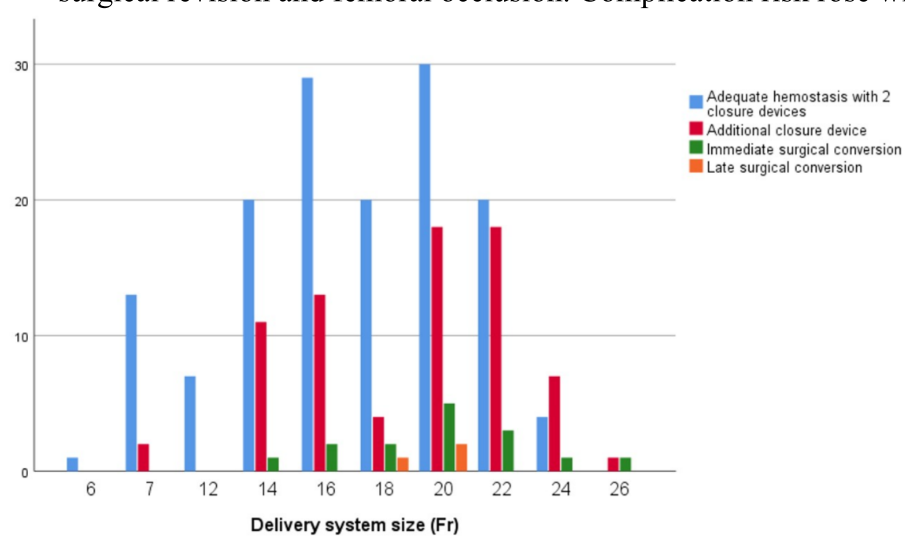

Figure 9: Distribution of type of closure device used (amount on the y axis) among different sheath sizes (French size on the x axis).

These findings, consistent with registry observations, support routine use of preoperative CT planning, ultrasound-guided puncture, consideration of adjuncts for hostile access, and readiness for immediate surgical conversion in the minority where percutaneous closure fails (81).

7. Discussion

Over the past two decades, endovascular technology has transformed the management of thoracic and thoracoabdominal aortic disease. Initially restricted to infrarenal and straightforward descending thoracic aneurysms, the indications for thoracic endovascular aortic repair (TEVAR) have progressively expanded proximally into the aortic arch and into the thoracoabdominal aorta. This evolution has been enabled by advances in device technology, procedural techniques, and complication mitigation. The cumulative work presented in this thesis reflects these developments across three domains: extension of endovascular repair into the aortic arch, refinement of thoracoabdominal repair using custom-made and off-the-shelf platforms, and strategies to reduce and manage complications.

A central finding of the presented portfolio is that endovascular arch repair has matured into a safe and effective alternative to open and hybrid strategies in selected patients. Across contemporary multicentre series and systematic reviews, technical success typically exceeds 90%, with 30-day mortality ~3–7% and stroke ~5–10%, particularly in elective settings using dedicated fenestrated/branched platforms (e.g., preloaded fenestrated TEVAR multicentre series: technical success 99%, 30-day mortality 3.7%, stroke 5.6%; systematic review of manufactured arch F/B-TEVAR: pooled technical success 95.9%, 30-day mortality 6.7%; early outcomes from thoracic branched endoprosthesis programs report stroke ~5–8% and no permanent paraplegia in initial cohorts) (82-84). The comparative analysis of fenestrated TEVAR (fTEVAR) versus debranching TEVAR (dTEVAR) provides important nuance. Both approaches achieve high technical success with low rates of permanent neurological injury; however, dTEVAR carries risks inherent to open cervical revascularisation (e.g., neck hematoma and nerve injuries) that are not observed after purely endovascular fTEVAR, whereas fenestrated devices require weeks of planning/production that limit their use in acute presentations (36) . This trade-off between anatomic precision and temporal availability illustrates the central challenge of complex aortic repair: balancing durability with the need for timely intervention.

Another important contribution has been the demonstration that endovascular arch repair is feasible in patients with mechanical aortic valves, a cohort historically cautioned against in international consensus documents because of concerns about leaflet damage, acute regurgitation, and wire entrapment (19). In an international multicentre observational study (n=12), endovascular arch repair requiring mechanical-valve crossing achieved 100% technical success with no valve damage; 30-day mortality was 17% (one major stroke, one cardiac arrest) (45). These findings suggest that when strict technical principles are applied in experienced centres, a mechanical aortic valve need not represent an absolute contraindication, though careful case selection and team expertise remain critical.

In the thoracoabdominal domain, the studies in this thesis document how off-the-shelf multibranched devices, such as the t-Branch, have broadened the availability of F/B-EVAR to patients presenting with urgent or ruptured pathology. In contemporary multicenter and national series, technical success typically ranges 90–97% and 30-day mortality 6–12% overall (lower in elective cases, higher in symptomatic/ruptured cohorts); stroke is 2–4%, and permanent spinal cord ischemia varies by extent and era, with permanent deficits ~4% in a large two-center experience and higher in some national real-world cohorts (64, 85). These results compare favorably with open surgical series, where large single-center benchmarks report 7–16% early mortality and permanent SCI ~5% overall (higher with more extensive repairs) (7). Together, they support the role of off-the-shelf solutions for time-sensitive presentations, while custom-made devices remain preferable for elective cases given the superior anatomic fit and the manufacturing delay of several weeks.

Durability of target vessel incorporation has been another important aspect of this work. Early concerns that bridging stents might be the “weak link” have been tempered by mid-term data showing high patency and low reintervention with contemporary balloon-expandable platforms. For example, BeGraft bridging stents have shown 1- and 2-year target-vessel patency of 98% and 97% with 96% freedom from secondary procedures at 2 years in multicenter series (72).

Importantly, when target vessel failure does occur, salvage can be effective. Our multicenter study on revascularization of renal bridging stent occlusions after complex EVAR reported 95.7% technical success; among patients with a solitary kidney or bilateral occlusions, most avoided permanent dialysis after successful recanalization (77). These findings support structured surveillance and prompt reintervention when loss of a renal target vessel is detected.

Complication mitigation has been a unifying theme across all studies. Protocolized strategies, prophylactic LSA revascularization when zone-2 coverage is required, selective cerebrospinal fluid drainage in high-risk cases, staged repair to limit single-procedure coverage, permissive hypertension, and perioperative hemoglobin optimization are associated with lower SCI risk in contemporary series and systematic reviews (86). Endoleaks and branch instability remain non-trivial but are increasingly amenable to secondary endovascular treatments, as reflected by the low mid-term reintervention needs in recent F/B-EVAR cohorts (73, 87).

Taken together, the cumulative body of work presented in this thesis provides a coherent picture of how endovascular aortic surgery has progressed. In the arch, endovascular repair has become a viable alternative to open replacement, with outcomes approaching those of descending TEVAR in selected patients. In the thoracoabdominal aorta, off-the-shelf solutions and durable bridging stents have increased access and reliability, while salvage strategies have preserved organ function when complications occurred. Across both domains, systematic complication mitigation has reduced the incidence of catastrophic outcomes such as stroke, SCI, and dialysis dependence to historically low levels.

The broader significance of these findings lies in their contribution to shifting the threshold of treatability in aortic disease. Where once only open repair or palliation were options, patients with arch or thoracoabdominal pathology, including those with symptomatic or ruptured aneurysms or hostile access, can now undergo minimally invasive endovascular repair with acceptable risk. This transformation has been driven by incremental innovations: refinement of fenestrated and branched platforms, optimization of bridging-stent technology, systematic preventive protocols, and collaborative multicenter research, each reflected across the studies in this dissertation.

8. Limitations and Future Directions

Despite significant advances, important limitations persist in the current evidence base for endovascular aortic repair. Much of the available literature, including several studies synthesized in this thesis, is retrospective in nature and therefore subject to inherent biases such as selective patient inclusion, center-dependent protocols, and non-standardized follow-up. Prospective trials would provide greater robustness, but such studies are challenging to conduct due to the heterogeneity of aortic anatomies, the urgency of many presentations, and ethical barriers to randomization in the setting of life-threatening disease.

Sample sizes in specific subgroups remain small. For example, reports on endovascular arch repair in patients with mechanical valves are necessarily limited given the rarity of this condition, constraining the strength of conclusions and precluding robust subgroup analysis. Similarly, while off-the-shelf multibranched devices have expanded applicability, their use outside dedicated centers remains underrepresented in the literature. A further limitation lies in follow-up duration, robust long-term data beyond five years remain scarce, particularly with regard to bridging stent durability and late branch patency. The majority of studies originate from high-volume centers with specialist expertise, raising questions about generalizability to lower-volume institutions. Harmonization of reporting standards and independent registry audits are needed to address these concerns.

Future research should prioritize several areas. First, the development of next-generation off-the-shelf devices with greater anatomical adaptability is required to reduce reliance on custom manufacture and to provide reliable options in emergencies. Modular designs and extended size ranges are already under investigation and should be evaluated in prospective registries. Second, the prevention of neurological complications remains paramount. Stroke continues to be one of the limiting factors in arch repair, while spinal cord ischemia remains a challenge in extensive thoracoabdominal reconstructions. Adjuncts such as cerebral protection devices, refined staging protocols, and optimized spinal cord perfusion strategies warrant systematic evaluation in prospective multicenter fashion. Third, bridging stent durability must be assessed through international registries with long-term imaging surveillance and standardized endpoints. Collaboration across centers will be crucial to capture sufficient numbers and follow-up duration.

In summary, the innovations synthesized in this thesis demonstrate how endovascular aortic repair has expanded from selected descending thoracic aneurysms into the arch and thoracoabdominal aorta, encompassing anatomies and patient populations once considered untreatable. The next decade will need to focus on refining device technology, optimizing complication prevention, and generating long-term durability data. Through collaborative registries, harmonized standards, and rigorous evaluation of novel adjuncts, the goal is to consolidate the gains of endovascular innovation while ensuring sustainable, reproducible outcomes across diverse patient populations and practice environments.

Looking forward, the trajectory of progress leaves little doubt that the future of complex aortic surgery will be increasingly endovascular. Continued advances in device platforms, imaging, and perioperative management promise to further reduce morbidity, broaden applicability, and ultimately redefine the standard of care. What was once experimental and restricted to a handful of centers is rapidly becoming mainstream therapy, and with ongoing innovation, endovascular repair is poised to become the dominant paradigm for the treatment of complex thoracic and thoracoabdominal aortic disease.

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