

## DEBATE: PROS VS CONS

## What Is the Best Option for Non-Infected Proximal Failure After EVAR? Endovascular Repair

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**Abstract:**

Proximal failure after endovascular aneurysm repair (EVAR) remains a major challenge in contemporary aortic surgery. Management requires a meticulous assessment of multiple factors, including patient anatomy, disease progression, aneurysm sac behavior, and endograft characteristics. Many patients facing failed EVAR tend to be older, frail, and often have serious cardiovascular issues, which complicates the decision-making process for clinicians. Open surgical conversion (OSC) is technically challenging due to the need for extensive surgical preparation and the frequent necessity for suprarenal or supraceliac aortic clamping. Consequently, perioperative morbidity and mortality remain considerable, particularly in urgent and emergent settings. Conversely, advanced endovascular techniques like fenestrated, branched, chimney, and physician-modified endografts have shown promising results, offering a lower physiological burden compared to OSC. Although there are ongoing discussions about long-term durability, current literature and our own institutional experience indicate that mid-term outcomes are encouraging. At our institution, we treated 38 patients with advanced endovascular methods for proximal failed EVAR. We achieved a 30-day survival rate of 94.7%, with target-vessel patency at 100% and an 88.1% rate of freedom from reintervention during a median follow-up of 20 months. Importantly, we did not observe any aortic-related deaths or recurrent type Ia endoleaks. These results advocate for an endovascular-first approach for most patients dealing with proximal failed EVAR, particularly through the use of custom-made fenestrated and branched devices. High-volume centers should be able to provide patients with the choice between the two strategies, after a thorough optimization process of patient physiological status, aortic anatomical criteria, surgical risk, patient disposition for long-term postoperative follow-up, and life prognosis.

Endovascular abdominal aortic aneurysm repair (EVAR) is the recommended treatment for infrarenal abdominal aortic aneurysms (AAA) in patients with adequate anatomy, according to the recent European Society of Vascular Surgery (ESVS) Guidelines, due to the lower early morbidity and mortality compared to open surgical repair (OSR).<sup>1,2</sup> However, reinterventions still question the durability of the repair and signify future proximal sealing loss.<sup>3,4</sup> Proximal failed EVAR encompasses a wide range of mechanisms accounting from sealing failure and leading to aneurysm sac pressurization and expansion, with proximal seal loss being the most common and most challenging to treat.<sup>3-5</sup> As EVAR rates continue to rise compared to OSR, so does the incidence of failed EVAR due to endoleak type Ia.<sup>5</sup> Proximal disease progression, EVAR outside instruction for use (IFU), inadequate individualized long-term postoperative surveillance, persistent type II endoleaks with sac expansion and the use of older generation endografts with device fatigue are some of the main reasons behind the increasing rates of proximal failed EVAR.<sup>5-7</sup>

Treatment of proximal failure after EVAR requires meticulous assessment of the underlying etiology, as it rarely represents a single technical event, rather complex dynamic interactions incorporating patient anatomy, disease progression, sac behaviour and endograft performance.<sup>5,7,8</sup>

Patients presenting with failed EVAR frequently represent a highly comorbid vascular population characterized by advanced age, extensive atherosclerotic burden, and substantial cardiopulmonary risk, even more compared to their initial status of primary repair.<sup>9</sup> Male sex, history of smoking, coronary artery disease, chronic kidney disease, chronic obstructive pulmonary disorder and peripheral arterial disease all represent comorbidities consistently represented among patients with proximal failed EVAR.<sup>4</sup> Frailty and diminished physiological reserve, which often guide these patients towards primary AAA repair via endovascular means, is exacerbated during failed EVAR, ultimately affecting treatment selection and postoperative outcomes.<sup>5</sup> The often diminished physiological status of these patients is aggravated during urgent and emergent repairs.

On a technical note, OSR of failed EVAR remains one of the most challenging and technically demanding procedures in contemporary vascular surgery.<sup>3</sup> Suprarenal fixation struts, prior endograft incorporation as well as the need for extensive aortic and visceral dissection often required for proximal aortic clamping, substantially increase procedural complexity compared to primary OSR.<sup>10</sup> The effect of suprarenal or even supraceliac aortic cross clamping is detrimental for patient physiology and is frequently necessitated, while being asso-

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ciated with significant risk for mesenteric and renal ischemia, cardiac complications and major blood loss.<sup>9</sup> The mismatch between procedural complexity and patients' physiological reserve is obvious in the high morbidity and mortality rates depicted in open surgical conversion of failed EVAR.<sup>5,9</sup> These outcomes are even more aggravated in urgent/emergent cases with aortic ruptures, presence of symptoms.<sup>5</sup> Even with the implementation of less aggressive strategies, including "semi-conversion" techniques with partial graft explantation, aiming towards the reduction of ischemia duration and operative trauma, as well as the advances in perioperative care and aortic reconstruction techniques, OSR of failed EVAR carries significant risk of perioperative morbidity and mortality for this quite frail patient cohort.<sup>5</sup> In any case an OSR approach requires the admission of the patient to Intensive Care Unit (CU) for at least the day of surgery, which carries a significant risk of infection if his/her stay needs to be prolonged. Admittedly, the perioperative management, from an anaesthesiologist's and intensivist's standpoint, and the postoperative care of patients treated via open surgical repair, even for standard infrarenal AAA, is significantly more meticulous and tiresome compared to patients undergoing endovascular repair. The extensive implementation of endovascular strategies, both for standard and complex endovascular repair, has reduced the experience of all associated healthcare personnel with patients treated via open surgery ('de-skilling' phenomenon), inadvertently affecting outcomes.<sup>11</sup>

The treatment of proximal failed EVAR has shifted towards the implementation of complex endovascular reconstruction, focusing on, but not contained to, more proximal sealing zones alongside the incorporation of target vessels via fenestrated (FEVAR) or branched (BEVAR) endografts.<sup>7,12</sup> Elective repair of failed EVAR is mainly managed through patient-specific custom-made devices (CMD), offering a wide range of solutions via fenestrations, branches, either in an inner or outer configuration, while more recently the semi-branch and bidirectional branch technologies have been successfully applied in anatomically challenging cases.<sup>13,14</sup> Urgent and emergent repair is rendered feasible through "off-the-shelf" multibranched endografts, physician-modified endografts (PMEG) or the use of parallel endografts (Chimneys). The immediate availability of "off-the-shelf" endografts is counterbalanced via their extensive proximal coverage of thoracic aorta, increasing the risk of spinal cord ischemia.

F/BEVAR offers less invasive repair, avoiding laparotomy and aortic cross clamping, while preserving end-organ perfusion. Several technical challenges arise, including access vessels, aortic angulation, presence of suprarenal struts in front of target vessel orifices, endograft alignment through the previous endograft, but also the usually short existing distance between lowest renal artery and previous endograft bifurcation.<sup>5,7</sup> F/BEVAR following proximal failed EVAR requires standardized preoperative imaging protocols in dedicated software, expertise in complex aortic endovascular repair and optimized patient management for ideal outcomes. Perioperative outcomes are most consistent in high-volume, specialized centres, including technical success, survival and reintervention rates.<sup>15</sup>

Esposito et al. provide data on lower perioperative complications in endovascular repair of failed EVAR when compared to OSR, especially in elderly or frail patients, deemed unfit or high-risk for OSR.<sup>5</sup> Contemporary series have demonstrated excellent perioperative results, with very high technical success and comparable morbidity and mortality to primary elective F/BEVAR while when compared to OSR, the major systemic complications remained relatively low (15.7% vs. 21.3%).<sup>5</sup> Contemporary data on urgent and emergent cases treated via PMEGs demonstrated technical success rates consistently exceeding 90%, with acceptable target-vessel durability and sac stability during mid-term surveillance, supporting their role when CMDs are either unavailable or time-prohibitive.<sup>12</sup> Similarly, "off-the-shelf" branched endografts have shown excellent perioperative outcomes, with high-technical success rates, albeit being associated with higher mortality rates, especially in symptomatic patients.<sup>13</sup> The use of parallel/Chimney (ChEVAR) endovascular repair in urgent and emergent failed EVAR cases is also feasible.<sup>16</sup> In the Parallel Endografting And Chimney Endovascular (PEACE) registry, 18% of patients were treated with ChEVAR for either emergent or ruptured failed EVAR. Perioperative technical success (90.6%) and mortality (17.7%) appear to be acceptable for emergent and urgent cases, while low mid-term survival rates ( $45 \pm 6\%$ ) are expected given the profile of treated patients.<sup>16</sup> The increased risk for perioperative complications related to OSR of failed EVAR commonly guides treatment towards endovascular strategies, rather than long-term durability alone.<sup>5,7</sup> Nevertheless, sac dynamics and regression is crucial for long-term durable outcomes. Sac stabilization or even regression should be the aim of complex endovascular salvage of failed EVAR, as it has been associated with lower future reintervention rates and adverse aortic events.<sup>11</sup> Sac dynamics are of particular importance, as data suggests that sac stabilization or regression is associated with better overall long-term outcomes.<sup>12</sup> Sac expansion is indicative of accumulating reintervention burden, associated with poor outcomes.<sup>15</sup>

While long-term data is missing, mid-term outcomes of F/BEVAR for failed EVAR could be considered acceptable, taking into account patients' frailty, physiological reserve and ultimately, prognosis. Mid-term survival following endovascular salvage remains satisfactory but inferior to open conversion in several comparative analyses.<sup>5,17</sup> Esposito et al. demonstrated an overall survival of 81.6% at approximately 18 months after F/BEVAR for failed EVAR.<sup>5</sup> Importantly, this reduced survival likely reflects baseline patient frailty and comorbidity burden rather than procedural inadequacy alone.<sup>5,19</sup> However, reinterventions still are the Achilles's heel for durable, long-term outcomes. Reintervention remains the principal limitation of secondary endovascular repair. The same meta-analysis demonstrated a pooled mid-term reintervention rate of 26% after F/BEVAR, significantly higher than after elective open conversion (4.5%).<sup>5</sup> Reinterventions following F/BEVAR for failed EVAR are most commonly related to target vessel instability.<sup>17,18</sup> The European Multicentric Experience with Fenestrated-Branched ENDovascular Stent-grafting after Previous FAILED Infrarenal Aortic Repair (EU-FBENDO-FAIL) registry,

depicts that F/BEVAR is feasible in both failed EVAR and failed OSR, with excellent primary patency rates even in this complex patient cohort.<sup>20</sup> Hostalrich et al. in their recent propensity score matching analysis showed comparable midterm survival between patients treated with OSR ( $88 \pm 4\%$ ) and FEVAR ( $94 \pm 3\%$ ) for failed EVAR.<sup>21</sup> However, comparison between the OSR and F/BEVAR for failed EVAR should be done carefully, as patients often selected for OSR are more fit, with less physiological burden.<sup>2</sup>

In our department, during an 8-year time period (2018-2026), a total of 38 patients (all male, median age 78 years old) have been treated for failed EVAR, applying a combination of F/BEVAR, as well as the parallel graft technique. Twenty-five (65.8%) of patients were treated electively, while 13 patients (34.2%) were treated urgently, with four ruptures. A total of 24 branched (63.1%), five fenestrated (13.1%) and nine chimney graft (23.6%) repairs were executed, based on urgency of repair and aortic anatomy. Eight patients (21%) were treated with an “off-the-shelf” branched endograft, requiring extensive proximal aortic coverage. One case of spinal cord ischemia was observed, in a patient treated with an “off-the-shelf” branched endograft for a rupture. The 30-day survival and major adverse events rates were 94.7% and 18.4%, respectively. The target-vessel patency was 100%. Only one reintervention related to vascular access was required. During a median follow-up of 20 months (Q1: 1, Q3: 80), the estimated survival was 72.5% (SE: 9%), without aortic-related deaths and the estimated freedom from reintervention was 88.1% (SE: 8%). No type Ia endoleak was recorded while two type IIIc endoleaks were managed with relining. Our accumulative experience and patient outcomes have led us towards an endovascular first approach for failed EVAR cases, implementing the use of CMDs, while confining the use of “off-the-shelf” branched endografts and the chimney graft technique only in urgent and emergent cases.

Endovascular and open surgical repair of failed EVAR should not be considered as counterparts but rather as both equally important weapons in modern vascular surgery. High-volume centres should be able to provide patients with the choice between the two strategies, after a thorough optimization process of patient physiological status, aortic anatomical criteria, surgical risk, patient disposition for long-term postoperative follow-up, and life prognosis.

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