EDITORIAL

Physician-Modified Endografts (PMEGs): Innovation Born of Necessity or a Challenge to Regulatory Order?

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Complex aortic aneurysms—including juxtarenal, pararenal, and thoracoabdominal aneurysms—represent a significant challenge in contemporary vascular surgery. These aneurysms frequently involve critical visceral and renal branches, precluding the use of conventional endovascular aneurysm repair (EVAR) due to inadequate proximal landing zones or branch vessel involvement. While fenestrated and branched endovascular aneurysm repair (FEVAR and BEVAR) have expanded treatment options, limitations relayed to device availability, manufacturing timelines, regulatory approval, and cost continue to restrict their universal application. In this context, physician-modified endografts (PMEGs) have evolved as a realistic alternative, allowing experienced operators to adapt standard stent grafts to complex anatomies through intraoperative modifications. Although controversial in principle, PMEGs have gained substantial traction in select centers worldwide, driven by increasing evidence supporting their feasibility and intermediate-term outcomes. However, their continued role raises important questions regarding safety, reproducibility, training, and ethical governance.

The fundamental clinical impetus for PMEG development lies in the mismatch between the urgency of certain aneurysm presentations and the logistical constraints of custom-made devices. Custom fenestrated and branched endografts typically require 4 to 12 weeks for design, manufacturing, and delivery. For patients presenting with symptomatic aneurysms, rapid aneurysm expansion, impending rupture, contained or active rupture, these timelines are incompatible with clinical reality. Moreover, access to custom devices may be limited by regional regulatory restrictions, lack of institutional infrastructure, financial constraints, and restricted availability in low- and middle-income health systems. PMEGs therefore represent a time-critical solution, allowing clinicians to proceed with endovascular repair using immediately available devices, modified to accommodate patient-specific anatomy. While this approach may have originated as an emergency measure, its scope has expanded to include elective cases in regions where approved fenestrated devices are not readily accessible or when patient-specific constraints preclude waiting.

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Physician modification of standard endografts involves precise back-table alterations to create fenestrations or directional branches that align with visceral vessels. The modification process typically includes careful unsheathing of a commercially available endograft under sterile conditions, creating fenestrations using electrocautery or thermal devices based on preoperative computed tomography angiography (CTA) planning, reinforcing fenestrations with suture rings or radiopaque markers to prevent fabric tearing and improve intraoperative visualization and re-sheathing the device prior to endovascular deployment. The process requires detailed understanding of aortic anatomy and three-dimensional vascular geometry, familiarity with stent graft design and structural behavior, and high technical precision to prevent damage to supporting stent structures. Errors in fenestration positioning, reinforcement, or structural integrity may lead to catastrophic complications including malperfusion, type I or III endoleaks, device migration, and branch occlusion. Therefore, PMEG application necessitates not only advanced endovascular skill but also meticulous preoperative planning and intraoperative imaging guidance.

Over the past decade, a body of literature has emerged describing outcomes following PMEG deployment for complex aortic aneurysm repair. While most evidence derives from single-center and multicenter retrospective series, the growing sample size and consistency of findings warrant careful consideration. Across high-volume centers, reported outcomes generally demonstrate technical success rates exceeding 85-95%, visceral vessel patency rates >90% at mid-term follow-up, acceptable 30-day mortality, comparable to FEVAR (often between 2-6%), sustained aneurysm sac regression in the majority of patients, and relatively low rates of type I and type III endoleaks. Several large series have demonstrated freedom from aneurysm-related mortality exceeding 85-90% at mid-term follow-up (3-5 years), with reintervention rates comparable to custom fenestrated devices. Importantly, most favorable outcomes have been reported by highly specialized centers with extensive experience in complex endovascular aortic repair. This raises important questions regarding external validity and generalizability of results.

While both PMEGs and custom-manufactured FEVAR/

BEVAR devices address the same anatomical challenges, they differ fundamentally in design, regulation, and reproducibility. Custom devices offer industrial-quality precision, consistency of manufacturing, regulatory oversight, and standardized testing and quality assurance. However, they remain limited by production delay, high cost, limited global availability, and reduced applicability in emergency settings. PMEGs provide immediate availability, reduced cost, adaptability to urgent or atypical anatomy and greater procedural flexibility. Yet they lack the same level of standardization, bench testing, and regulatory validation as commercial products. In many respects, PMEGs represent an interim solution addressing current logistical and technological gaps. Rather than viewing these approaches as competitors, it may be more constructive to consider them complementary within a tiered decision-making framework depending on clinical urgency, anatomical complexity, and institutional capability.

The ethical justification for PMEG use rests largely on the principle of beneficence when no approved or timely alternative exists. However, several important concerns persist:

- device Liability and Manufacturer Responsibility. Since the graft is physically altered, responsibility for device performance shifts entirely to the modifying physician and institution.
- Informed Consent. Patients must be fully counseled regarding the off-label and modified nature of the intervention, including unknown long-term durability and regulatory status.
- Standardization and Oversight. There remains no universal protocol or governing framework regarding which patients should be eligible or how modifications should be performed.

From a regulatory perspective, PMEGs exist in a grey zone between innovation and deviation. While off-label use is a long-standing element of medical practice, the physical modification of regulated devices introduces unique challenges that may warrant new frameworks for oversight, documentation, and post-market surveillance.

The safe implementation of PMEG techniques is heavily dependent on institutional expertise and procedural volume. Centers performing PMEG repairs should ideally possess high volumes of complex aortic interventions, integrated hybrid operating environments, expertise in advanced imaging and 3D reconstruction, multidisciplinary endovascular teams and structured post-procedural surveillance systems. Furthermore, operator experience significantly influences outcomes. Institutions adopting PMEG strategies must commit to structured training, proctoring, and careful patient selection during the learning phase. Without these safeguards, expanded use risks inconsistent outcomes and potential erosion of confidence in the technique.

Although mid-term results are encouraging, long-term durability of PMEGs remains a critical area for continued evaluation. Concerns include progressive fabric fatigue around fenestrations, stent structural failure from modification, late endoleak development, branch instability over time, and altered hemodynamics due to manual fenestration geometry. Longitudinal registries and standardized reporting of outcomes will be essential to determine whether PMEGs can be considered durable solutions or remain primarily bridging therapies.

The evolution of PMEGs reflects broader trends in vascular surgery: a shift toward greater individualization, procedural flexibility, and integration of physician-led design. Future developments may include semi-custom modular devices, faster manufacturer customization pipelines, industry-physician collaboration to formalize PMEG methodologies, integration of 3D printing to pre-plan and templating modifications, and regulatory frameworks recognizing physician-device co-creation models. Rather than being viewed as an aberration, PMEGs may represent a transitional phase in a future where customized endovascular solutions become mainstream.

In conclusion, physician-modified endografts represent a compelling example of necessity-driven innovation in vascular surgery. They have extended endovascular treatment to patients who would otherwise face prohibitive surgical risk or delayed care. While they raise legitimate concerns surrounding safety, reproducibility, and regulation, current evidence suggests that in experienced hands and appropriate settings, PMEGs represent a viable and often life-saving strategy for complex aortic aneurysm repair. Moving forward, the challenge lies not in eliminating PMEGs, but in integrating them responsibly—through structured training, registry-based outcome tracking, and evolving regulatory engagement—ensuring that innovation remains aligned with patient safety and scientific rigor.