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Physician-Modified Endografts in the Treatment of Aortic Arch Disease: The Need for Unity and Standardization

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The term Physician-Modified Endovascular Graft (PMEG), used to describe the process of back-table modification of an endograft with fenestrations or branches, was first coined by Starnes in 2012.[1] In retrospect, the first fenestrated endovascular aortic repair, performed in 1996, was in fact physician-modified and be retrospectively considered as a PMEG.[2] Now, nearly 3 decades later, PMEG remains a valuable tool in the armamentarium of vascular surgeons managing complex aortic pathologies, despite the emergence of custom-made (CMD) and off-the-shelf fenestrated and branched devices.[3]

Technological improvements in PMEG techniques have enabled reinforcement of fenestrations, addition of minicuffs, and the incorporation of preloaded guidewires.[4] These advancements have expanded the applicability of PMEGs, extending their use even into complex aortic arch repair. This raises the question of what the current and future roles of PMEG in arch repair comprises, particularly in an era with an increasing availability of custom-made and off-the-shelf endovascular devices.

Is There a Role for PMEG in the Aortic Arch?

Open surgical repair remains the gold standard for aortic arch disease in patients fit for major surgery.[5,6] However, those deemed unfit may benefit from an endovascular alternative. Standard thoracic endovascular aortic repair (TEVAR) with coverage of the left subclavian artery can be performed to extend the sealing zone 2.[7] This approach is not applicable to zones 0 and 1. Moreover, coverage of the left subclavian artery is associated with increased neurologic complications, therefore, maintaining left subclavian artery perfusion is generally preferred.[8]

Hybrid procedures, such as carotid-carotid with carotid-left subclavian bypass, offer another solution. However, this approach is still more invasive than fully endovascular alternatives, carries risks such as phrenic nerve palsy, and would require a sternotomy for zone 0 repairs.[9]

Fenestrated and branched CMD offer an alternative.[10] These devices allow for a fully endovascular approach while maintaining antegrade perfusion. The primary limitation of CMDs is their manufacturing lead time, prohibiting their use in urgent situations. In such cases, PMEG, in situ fenestration, or parallel grafting may be the only viable alternatives.

While acceptable initial technical success with parallel endografts and in situ fenestration can be achieved, there are considerable downsides to these techniques. Parallel grafting has a high risk of type 1 "gutter" endoleak, especially when multiple parallel grafts are used.[11] In situ fenestrations lack reinforcement, which may compromise durability and lead to type 3 endoleak, particularly under the forces exerted by motion in the aortic arch, forces that may, at least theoretically, favor the use of branches over fenestrations.[12–14] In contrast, PMEG best replicates CMD principles. Despite the potential benefits, the adoption of PMEG in arch repair has been limited due to the technical challenge, and lack of high-quality evidence.[15]

Recent studies have reinforced the potential of PMEG in aortic arch repair. The effectiveness of PMEG for zone 0–2 repairs for a wide range of aortic pathologies has been demonstrated in small single center cohorts.[16–19] Bacri et al[20] reported 100% technical success in 74 patients with

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zone 0 PMEG for degenerative aneurysms, post dissection aneurysms and acute type B dissections. The study showed a 5% stroke rate, 1% early mortality, and 9% early reintervention. During a 40.7-month mean follow-up, 1 type 1 endoleak and 4 reinterventions were reported.[20,21] Wen et al[22] confirmed these results in 54 patients across 3 centers. Technical success was 98%, stroke occurred in 7%, early mortality was 4%, and during 12 months median follow-up, 7 patients had type 1/3 endoleak and 10 patients required reintervention.[22] These outcomes are similar to inner-branched CMDs for zone 0 repairs, where 100% technical success, 5% stroke, and 5% early mortality were reported in 39 patients.[23]

The largest series on PMEG in the arch, by Li et al,[24] includes 513 patients from 7 centers. Technical success was 98.6%, with 2.5% early mortality and 2.3% stroke at 30 days. Results were durable after a median 27 months follow-up, with 2.6% requiring reintervention. However, the study's generalizability is limited by the inclusion of a broad range of pathologies and proximal extent of disease (including zone 0–4). It should be noted that the stroke rate is exceptionally low compared with other reports and may not reflect contemporary real-world outcomes.[10]

There is the recent emergence of branched off-the-shelf endografts to consider as an alternative, with potential broad application due to considerable overlap between patient anatomies in the arch.[25] However, this "one-size-fits-most" solution leaves a subset of patients with unsuitable anatomy with less desirable options, like parallel grafting or in situ fenestration, and physicians that are less familiar with these alternatives as a consequence of using off-the-shelf branched option in most patients. In addition, there are some recent concerns about branch occlusion during follow-up. During a median follow-up of 20.0 months, Lemmens et al[26] reported a late stroke rate of 23% in patients treated with an arch branched device, underscoring that the risk of stroke does not end after the procedure. Performing PMEG only in a very select acute group of patients will generally not allow for sufficient number of cases to maintain proficiency of this technically demanding technique. Let alone perform the modifications in a timely and consistent manner under stressful conditions. By maintaining a robust PMEG program, consistent modification times under 25 minutes have been reported.[27] Rather than pushing the envelope with off-the-shelf devices, performing PMEG for patients not amenable to a CMD due to waiting time or financial constraints might overall benefit the largest patient population.

The advantages of PMEG are clear: a patient-specific treatment for different anatomies, that can be achieved timely, significantly reducing the costs compared with CMD, and favorable outcomes in preliminary research compared with in situ fenestration and parallel endograft techniques. It seems that PMEG is here to stay. However, difficulties remain.

Current Issues Regarding PMEG

Despite growing interest and promising short-term to mid-term outcomes, several challenges currently limit the widespread adoption of PMEG in aortic arch repair.

First, PMEG is an umbrella term encompassing a plethora of modification techniques. Variations exist in the materials used to reinforce fenestrations (wire tips, snare loops, coils), the presence or absence of diameter reducing ties (and the technique to add them), the use of preloaded guidewires, and the configuration of fenestration, ranging from multiple small fenestrations for each of the major arch vessels to a large fenestrations for 2 major branches.[20,24,28–32] In addition, there is variation in stenting of 1 or all of the target vessels, and which endograft platform is used. This lack of a standardized technique makes it difficult to generalize results across centers and complicates comparative outcome analysis.

Second, while recent studies have shown durable results up to 3 years postprocedure, there is no guarantee for long-term success.[33] Elucidating long-term outcomes is of particular importance due to questions regarding the structural integrity of endografts after modifications made outside the manufacturer's intended use.

Third, modification of off-the-shelf devices is off-label, placing full responsibility on the surgeon. Ideally, PMEG should be used after approval through an institutional review board or within an investigational device exemption trial.[34,35] The legal and ethical implications of using off-label modifications require careful consideration and informed consent by the patient.

Fourth, the current literature is limited to single center retrospective studies. A larger multicenter retrospective study on this topic was hampered by the heterogeneous population, while each distinct pathology and extent of disease (zone 0–4) will have different technical requirements and outcomes. These positive results all come from high volume centers. Overcoming the learning curve seems crucial in arch repairs to reduce the risk of stroke.[24] Therefore, only limited recommendations can be drawn from the current evidence, prohibiting the uptake of PMEG in treatment guidelines, and requiring careful consideration in light of legal issues.

Where to Go From Here?

Unity is the way forward. Standardization of techniques is the key to establish PMEG as a validated treatment strategy for complex aortic arch pathologies, with reproducible outcomes, cost-benefit analysis, and valid comparisons with alternative treatment strategies. Important questions remain, including which techniques used to modify devices yield the most reliable results, what platform to use, how many procedures are required to maintain proficiency, and what are the long-term outcomes of PMEG. Vascular specialists

should work toward a consensus on the indications, planning, techniques, and platforms used in PMEG. Establishing prospective registries focused on standardized techniques will be key in answering these questions.

Progress is clearly being made, for example, the reporting of PMEG protocols, and the creation of a standardized nitinol ring that mimics the design of a CMD.[31] Collaborative initiatives regarding the treatment of complex abdominal aortic disease provide an example of what is possible.[36] Tsilimparis et al[37] reported positive results for 1274 patients across 19 centers which were retrospectively analyzed, and Piazza et al[38] collected prospective multicenter data of a standardized approach to PMEG for complex AAA, demonstrating excellent technical implantation safety and efficacy. The authors highlight that their efforts can serve as a benchmark for future comparison with other PMEG, off-the-shelf, or custom endografts. Involvement of industry in standardizing PMEG, through dedicated platforms and standardized tools, will further enhance the consistency and reproducibility of PMEG.

Although CMD remains the gold standard for endovascular repair of the arch, they may be unavailable due to time constraints, logistical barriers, and costs. In such cases, PMEG offers a viable alternative. As long as PMEG remains a catch-all term encompassing a broad spectrum of techniques and modifications, its full potential will be difficult to define or compare with regulated alternatives. Unity is the way forward. Standardization is the key to evolve PMEG into an evidence-based, guideline-supported option, and allow for valid comparison between different treatment strategies, or even on-label use of strategies involving modifications of endografts.

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