Analysis of physician modified endograft utilization using online databases and social media

Rob Tatum, MD; Michael Nooromid, MD; Paul DiMuzio, MD; Dawn Salvatore, MD; Babak Abai, MD

Purpose:
To characterize the present landscape of physician modified endograft (PMEG) utilization and the impact of an institution's investigational device exemption (IDE) status on endograft use by analyzing publication trends and social media coverage.

Methods:
We used social media platform X and three online bibliographic databases to perform a keyword search utilizing the following terms: PMEG; physician-modified endograft; and laser fenestration. Data extracted from X and online articles included authorship, IDE protocol status, pertinent clinical outcome measures, and others. An internet search was performed to determine which institutions offered revascularization with a custom-made device (CMD) within an IDE protocol and which institutions were performing PMEGs without an IDE. Data was compared using standard methods.

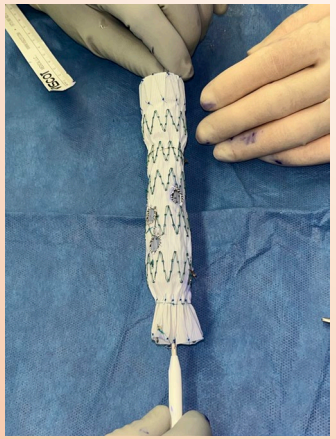
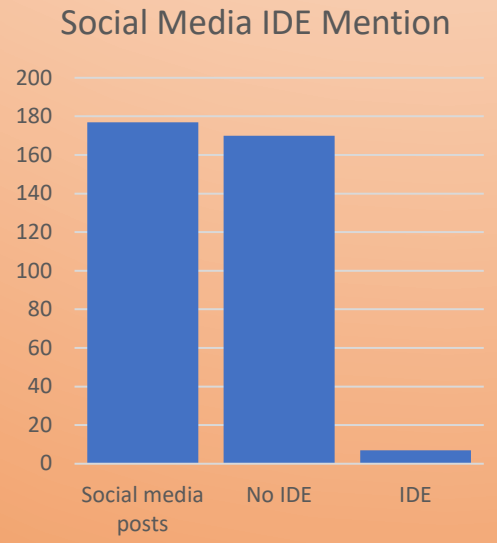


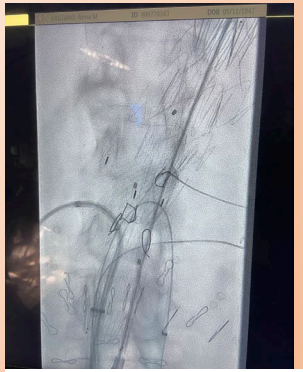
Table I: PMEG Publication Data

Variable	
Number of published articles (2017-2024)	315
Institutions with IDE; without IDE	97 (31%); 218 (69%)
Number of articles documenting commercial device platform	144
Cook; Gore	97 (67%); 47 (33%)
Institution and Clinical Characteristics	
Academic affiliate; Non-academic	236 (75%); 70 (25%)
Urban locale; Rural locale	209 (66%); 106 (34%)
Author training history (total)	274 (87%)
Author training history (U.S; Non-U.S)	238 (87%); 36 (13%)
Author training history (Urban; Rural)	211 (77%); 63 (23%)
Endoleak	249 (79%)
Reintervention	199 (63%%)
Stent Migration	57 (18%)
Aneurysmal Degeneration	41 (13%)



Discussion
Physician modifications of endografts arose shortly after the emergence of early endovascular treatments for TAAD. Since the inception of physician-made graft adaptations, the breadth of modification options and complex array of rules that govern them have made it challenging to effectively regulate this clinical space. One option to address such challenges is to lessen the existing restrictions and provide mechanisms for high-volume institutions and experienced surgeons to gain access to CMDs by regulating themselves and their colleagues. A less restrictive environment that includes mandatory data reporting could reduce some of the existing barriers and ensure accountability and patient safety by entrusting these processes to surgeons.

Although short-term data suggests that PMEG is a safe and effective treatment option when performed by experienced surgeons, more data on long-term outcomes, including survival rates, reintervention rates, and device durability, are needed. There is also a need for standardized protocols for the modification process to ensure consistency and safety across different practitioners and institutions, including the development of best practices for creating fenestrations and branches. Additionally, more comparative studies between PMEGs and commercially available CMDs are needed to determine the relative benefits and risks of each approach, including an evaluation of cost-effectiveness, procedural time, and patient outcomes. Continued innovation in materials and imaging technologies are also necessary to improve the precision and safety of PMEG use. Lastly, research into new materials that are more flexible and durable, as well as advanced imaging techniques for better procedural guidance, are essential to making further advancements.



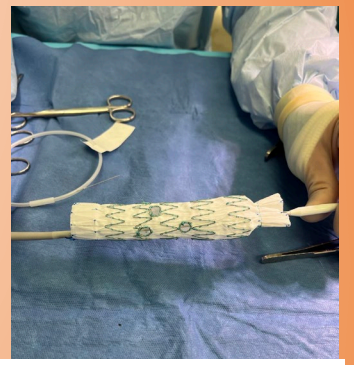


Table II: PMEG X Post Data

X posts (male author)	177 (109 [61%])
Cook	21 (12%)
Gore	12 (7%)
AFX	2 (1%)
IDE; no IDE	7 (4%); 170 (96%)
Thoracoabdominal	119 (67%)
Arch	32 (18%)
Repair not indicated	26 (25%)
Branch graft (total)	74 (42%)
Three-branch	26 (35%)
Four-branch	48 (65%)
Procedural technique	114 (64%)
Meeting Presentation	34 (19%)
Endoleak	8 (5%)
Aneurysmal Degeneration	3 (2%)
Stent Migration	1 (< 1%)

Conclusions:
PMEG has become a broadly utilized treatment option for patients with complex TAAD at non-IDE centers. A less restrictive regulatory environment may expand patient access to CMDs without sacrificing patient safety standards. Collaboration is needed between vascular surgeons, device manufacturers, and lawmakers to achieve this goal.