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Evolving Role For Physician Modified Endografts (PMEGs) For Complex AAA Repair: Why Are Poor Results Underreported And When Are They Justified

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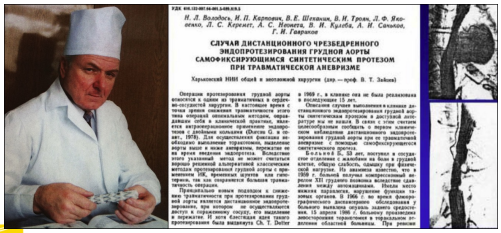
Disclosures

- Advisory Board/Consultant for Gore, Cook, Terumo, Endologix
- Educational/Speaker: Cook, Gore, Terumo

First PMEG – 1987 - TEVAR



СЛУЧАЙ ДИСТАНЦИОННОГО ЧРЕСБЕДРЕННОГО ЭНДОПРОТЕЗИРОВАНИЯ ГРУДНОЙ АОРТЫ САМОФИКСИРУЮЩИМСЯ СИНТЕТИЧЕСКИМ ПРОТЕЗОМ ПРИ ТРАВМАТИЧЕСКОЙ АНЕВРИЗМЕ

First EVAR 1990

Case Reports > Ann Vasc Surg. 1991 Nov;5(6):491-3. doi: 10.1007/BF02015271.

Transfemoral intraluminal graft implantation for abdominal aortic aneurysms

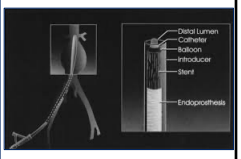
J C Parodi [1], J C Palmaz, H D Barone

Affiliations + expand

PMID: 1837729 DOI: 10.1007/BF02015271

Abstract

This study reports on animal experimentation and initial clinical trials exploring the feasibility of exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia. Experiments showed that when a balloon-expandable stent was sutured to the partially overlapping ends of a tubular, knitted Dacron graft, friction seals were created which fixed the ends of the graft to the vessel wall. This excludes the aneurysm from circulation and allows normal flow through the graft lumen. Initial treatment in five patients with serious co-morbidities is described. Each patient had an individually tailored balloon diameter and diameter and length of their Dacron graft. Standard stents were used and the diameter of the stent-graft was determined by sonography, computed tomography, and arteriography. In three of them a cephalic stent was used without a distal stent. In two other patients both ends of the Dacron tubular stent were attached to stents using a one-third stent overlap. In those latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution. The catheter was gently removed caudally towards the arterial entry site in the groin to keep tension on the graft, and the second balloon inflated so as to deploy the second stent. Four of the five patients had heparin reversal at the end of the procedure. We are encouraged by this early experience, but believe that further developments and more clinical trials are needed before this technique becomes widely used.



Home-made Fenestrated Endograft 1999

ENDOVASCULAR AND SURGICAL TECHNIQUES

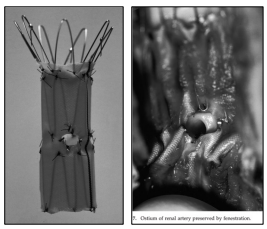
A Fenestrated Covered Suprarenal Aortic Stent

T. F. Browne*[1], D. Hartley[2], S. Purchas[2], M. Rosenberg[1], G. Van Schie[1] and M. Lawrence-Brown[2]

[1]Department of Surgery, Broomfield Hospital, Chelmsford, Essex, U.K.; [2]Department of Vascular Surgery and [2]Department of Radiology, Royal Perth Hospital, Western Australia

Objective: to address the clinical problem of inadequate neck length of abdominal aortic aneurysms in endoluminal surgery.
Design: a covered suprarenal aortic stent was designed with a fenestration to preserve blood flow in a targeted renal artery.
Method and material: a Dacron-covered stent was accurately cut to size with a fenestration according to pre-imaging studies.
Results: the stent was successfully deployed in canine models, preserving the visceral and renal artery of interest.
Conclusion: by accurately placing a covered stent in the aorta and preserving the blood flow to its branches, it may be possible to extend the indications for endoluminal aortic aneurysm grafting.

Key Words: Abdominal Aortic Aneurysm; Endovascular deployment; Fenestrated suprarenal covered stent.



1st Branched EVAR in US 2001

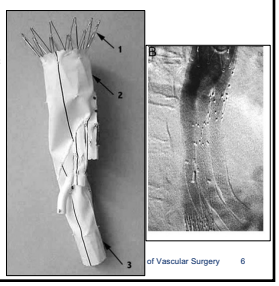
An Endovascular System for Thoracoabdominal Aortic Aneurysm Repair

Timothy A.M. Chuter, MD; Roy L. Gordon, MD*; Linda M. Reilly, MD; Jay D. Goodman, MD*; and Louis M. Messina, MD

Departments of Surgery and *Radiology, University of California San Francisco, California, USA

Purpose: To describe a stent-graft system for endovascular repair of thoracoabdominal aortic aneurysm (TAAA) that preserves side branch perfusion.
Technique: The modular endograft system includes 3 components. The *primary stent-graft* is custom-made from conventional graft fabric and Gianturco Z-stents. Covered nitinol Smart Stents are used for the *visceral and renal extensions*, and the *distal extension* is made from a modified Zenith system. With the supine patient under general anesthesia, the components are delivered sequentially through surgically exposed femoral and right brachial arteries in an operation that requires prolonged periods of magnified high-resolution imaging.
This system was first used in a 76-year-old man with a contained rupture of a supraceliac ulcer and a large abdominal aortic aneurysm ending proximally at the celiac artery. The endograft was implanted successfully, but the patient developed paraplegia on day 2; imaging documented an excluded aneurysm and excellent flow through the endograft and all prosthetic branches.
Discussion: Endovascular repair of TAAA appears to be feasible. If there are no serious, specific, unavoidable complications, the potential advantages are enormous.
J Endovasc Ther 2001;8:25–33

Key words: stent-graft, Zenith, Gianturco Z-stent, visceral vessels, paraplegia



First PS-IDE - 2001

- Greenberg introduced FEVAR/BEVAR
- Evolution of device design and concept of CMDs

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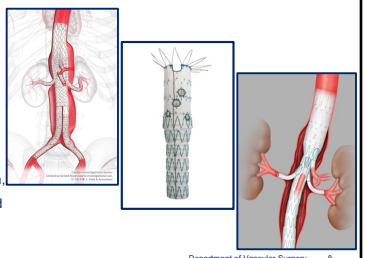
The Need for Physician Modified Endografts

- 20-40% are complex AAA
- Lack of commercially available devices
- TAMBE
- Clinical trials ongoing
  - Fen plus / T-branch
- CMD seems to be the ideal solution, but very limited access and delayed availability



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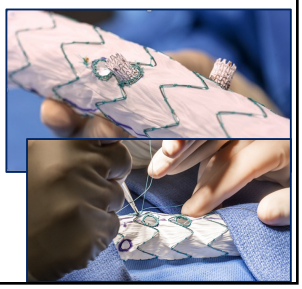
Role of Physician Modified Endografts

- Immediately available
  - Symptomatic / ruptures
  - Rapidly enlarging / large aneurysms
- Complex aortic aneurysms
- Customizable to anatomic constraints



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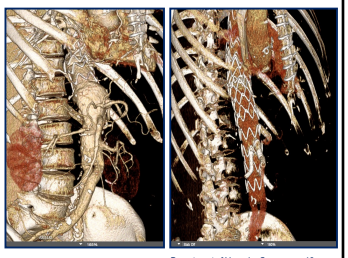
Failed Open Repair

- 81M presents with an extent II TAAA, contained rupture of a 9cm pseudoaneurysm at the level of the visceral aorta
- Hx of prior infrarenal open repair
- Hx of prior TEVAR
- CAD and CHF, on Plavix



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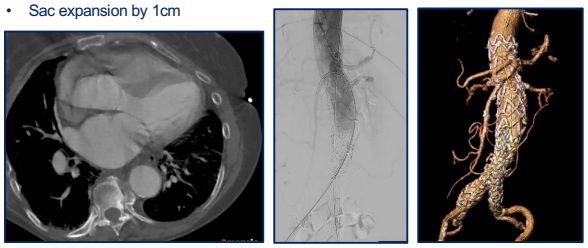
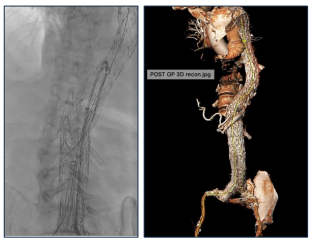
Failed EVAR for 1A Endoleak

- 84F with EVAR in a wide neck who developed 1A endoleak at 1 year
- Sac expansion by 1cm



Failed Chimney Graft

- 79F with 3v chimney in 2013 presented with a ruptured extent II TAAA



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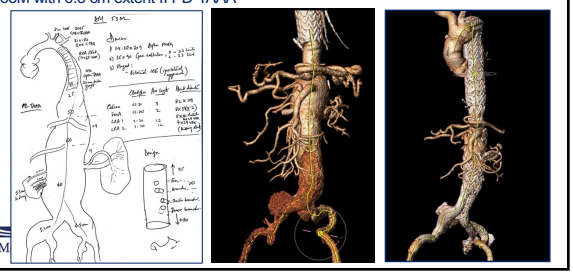
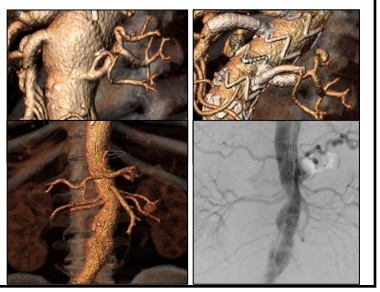
F/BEVAR PMEG in Post-Dissection TAAA

53M with 6.3 cm extent II PD-TAAA



Challenging Anatomy

- Immediate renal bifurcation
- Multiple target vessels (5 or 6 fens or branches)
- Other anatomic constraints



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Investigational Device Exemption (IDE)

- Best when done under the purview of Investigational Device Exemption
- Prospective data collection
- Ability to publish the experience and outcomes
- **Adequate oversight and quality control**
- Ideally at aortic centers with experience for optimal outcomes

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Current Active PMEG IDEs

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PMEG IDEs = 11

PMEG Data

Significant aortic neck dilation occurs aneurysms with fenestrated endovasc

Systematic Review and Meta-analysis of Physician Modified Endografts for Treatment of Thoraco-Abdominal and Complex Abdominal Aortic Aneurysms

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PMEG PS-IDE Outcomes (n= 135)

- Technical success = 99%
- 30-day mortality = 1.8%
- Freedom from aortic related mortality = 99%
- Target vessel patency at last follow-up 98%
- Median ICU stay is 2 days (1,3 IQR)
- Median overall hospital LOS is 2 days (1,5 IQR)
- 1-year overall survival = 95%
- 1-year freedom from target artery reintervention = 94%

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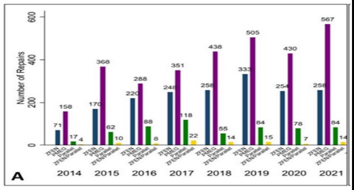
National Trends in Use of Surgeon-Modified Grafts for Complex Aortic Aneurysms - VQI

- 2014-2022
- 5826 complex aortic repairs
- 3241 PMEG repairs
- Only 29% JRAA were 4v repairs
- Volume per center: 1-2/yr to 18/yr (100+ centers)



Thomas O'Donnell, et al

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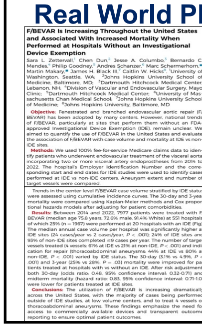
Real World PMEG Data


F/BEVAR Is Increasing Throughout the United States and Associated With Increased Mortality When Performed at Hospitals Without an Investigational Device Exemption

Sara L. Zettervall,[1] Chen Dun,[2] Jesse A. Columbo,[3] Bernardo C. Mendes,[4] Philip Goodney,[5] Andres Schanzer,[6] Marc Schermerhorn, Martin Makary, James H. Black III,[7] Caitlin W. Hicks[8]. [1]University of Washington, Seattle, WA; [2]Johns Hopkins University School of Medicine, Baltimore, MD; [3]Dartmouth Hitchcock Medical Center, Lebanon, NH; [4]Division of Vascular and Endovascular Surgery, Mayo Clinic; [5]Dartmouth Hitchcock Medical Center; [6]University of Massachusetts Chan Medical School; [7]Johns Hopkins University School of Medicine; [8]Johns Hopkins University, Baltimore, MD

Objective: Fenestrated and branched endovascular aortic repair (F/BEVAR) has been adopted by many centers. However, national trends of F/BEVAR, particularly at sites that perform them without an FDA-approved Investigational Device Exemption (IDE), remain unclear. We aimed to quantify the use of F/BEVAR in the United States and evaluate the association of F/BEVAR with case volume and mortality at IDE vs non-IDE sites.

Methods: We used 100% fee-for-service Medicare claims data to identify patients who underwent endovascular treatment of the visceral aorta incorporating two or more visceral artery endoprostheses from 2014 to 2022. The hospital's Employer Identification Number and the corresponding start and end dates for IDE studies were used to identify cases performed at IDE vs non-IDE centers. Aneurysm extent and number of target vessels were compared.

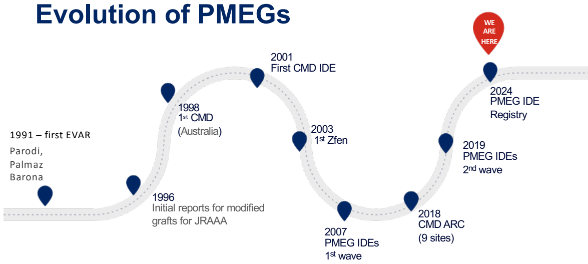
Trends in the center-level F/BEVAR case volume stratified by IDE status were assessed using cumulative incidence curves. The 30-day and 3-year mortality were compared using Kaplan-Meier methods and Cox proportional hazards models after adjusting for patient comorbidities.

Results: Between 2014 and 2022, 7977 patients were treated with F/BEVAR (median age 75.8 years, 72.6% male, 91.4% White) at 551 hospitals, of which 25% (n = 1967) were performed at 20 hospitals with an IDE (Fig). The median annual case volume per hospital was significantly higher at IDE sites (24 cases/year vs 2 cases/year, $P < .001$); 24% of IDE sites and 93% of non-IDE sites completed ≤9 cases per year. The number of target vessels treated (4 vessels: 61% at IDE vs 21% at non-IDE, $P < .001$) and indication for repair (thoracoabdominal aneurysms: 44% at IDE vs 80% at non-IDE, $P < .001$) varied by IDE status. The 30-day (3.1% vs 4.9%, $P < .001$) and 3-year (25% vs 28%, $P = .03$) mortality were improved for patients treated at hospitals with vs without an IDE. After risk adjustment, both 30-day (odds ratio: 0.48, 95% confidence interval: 0.32-0.71) and midterm mortality (hazard ratio: 0.83, 95% confidence interval: 0.71-1.0) were lower for patients treated at IDE sites.

Conclusions: The utilization of F/BEVAR is increasing dramatically across the United States, with the majority of cases being performed outside of IDE studies, at low volume centers, and to treat 4 vessels or thoracoabdominal aneurysms. These findings emphasize the need for access to commercially available devices and transparent outcome reporting to ensure optimal patient outcomes.

- Under-reporting of PMEGs – voluntary quality initiative
- No standardization of construct
- Several surgeon and patient specific factors
- Differential reporting standards
- IDE investigators results are not included in the VQI
- Limited follow-up so no information on reinterventions and outcomes beyond the peri-op/early post-op

Evolution of PMEGs



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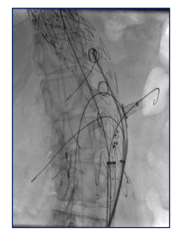
Summary

- PMEG for has evolved from its occasional use to widespread use today
- It is feasible, effective and durable treatment strategy
- Ideally done under PS-IDE for quality control
- Patient outcomes are critical for success
- There is need for commercially available devices
- PMEG is here to stay! Focus should be on optimization



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Questions?

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