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REVIEW

Explanted Vascular and Endovascular Graft Analysis: Where Do We Stand and What Should We Do?

Anne Lejay [a,b,*], Benjamin Colvard [c], Louis Magnus [a,b], Delphine Dion [a], Yannick Georg [a,b], Julie Papillon [a], Fabien Thaveau [a,b], Bernard Geny [d], Lee Swanström [e], Fréderic Heim [a,e], Nabil Chakfé [a,b]

[a] Groupe Européen de Recherche sur les Prothèses appliquées à la Chirurgie Vasculaire (GEPROVAS), Strasbourg, France
[b] Department of Vascular Surgery and Kidney Transplantation, University of Strasbourg, Strasbourg, France
[c] Division of Vascular Surgery, Department of Surgery, Stanford University, Stanford, CA, USA
[d] Department of Physiology, University of Strasbourg, Strasbourg, France
[e] Laboratoire de Physique et Mécanique Textile, ENSISA, Mulhouse, France

WHAT THIS PAPER ADDS

While the design of vascular and endovascular devices has evolved and improved over the past decades, device failures still occur. A systematic review of explanted grafts and endografts allowed the evaluation of 184 publications, but only 72 publications met the inclusion criteria and only 12 reported sufficient data for structural, histopathological, and epidemiological analysis. This review highlights that there is a clear lack of reporting on explanted grafts or endografts. As a consequence, national vascular bodies should be prompted to having national explants programs. This should be mandatory in order to improve device performance and durability.

Objective/Background: Since the late 1950s, major advances in vascular surgical practice have been closely associated with the introduction of novel vascular implants. These devices have been constructed from a variety of materials and have been designed to be implanted in several different ways. Despite a rigorous regulatory process, regular failures continue to be observed. A systematic review of the literature and of the Geprovas registry was performed in order to improve understanding of the failures.

Methods: A systematic review was performed via a search of the MEDLINE and Embase databases. Full text, English, German, or French language studies without any chronological limit were included. The reference lists of included studies, as well as the first 20 related items, were scanned for other potentially relevant studies.

Results: Data extraction allowed the evaluation of 184 publications; 72 publications met the inclusion criteria. Only 12 publications reported sufficient data for structural, histopathological, and epidemiological analysis. However, explant analysis allowed the understanding of degenerative phenomena: “warp knitted” replaced “weft knitted” polyethylene terephthalate grafts, decreasing the risk of dilatation or rupture; inter-nodal distance was modified in order to improve polytetrafluoroethylene graft incorporation capacities; and index of saturation, endograft fabric/stent interactions, and stent fatigue phenomena have been extensively studied in an attempt to improve endovascular device durability.

Conclusion: A general lack of depth of reporting of explants remains. Dedicated systematic explant analysis programs are the key to improving the performance of future generations of devices.

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INTRODUCTION

Vascular surgery has been marked by the successive introduction of vascular devices, such as vascular grafts, polyethylene terephthalate (PET), expanded polytetrafluoroethylene (ePTFE), and endovascular devices. However, arterial implantation represents an aggressive environment for both vascular and endovascular devices. The haemodynamic

* Corresponding author. Department of Vascular Surgery and Kidney Transplantation, University Hospital of Strasbourg, 1 Place de l’hôpital, BP 426, 67091 Strasbourg Cedex, France.
E-mail address: anne.lejay@chru-strasbourg.fr (Anne Lejay).

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environment is significantly altered at vascular anastomoses and the native endothelium might be exposed to abnormally low or high shear forces. Endovascular devices have to be fatigue resistant as they undergo cyclical loading caused by pulsed cardiac flow (35 million pulsations/year), intraluminal turbulence, high pressure, associated arterial wall deformation, and mechanical forces. As a consequence, the first generations of vascular and endovascular devices demonstrated questionable durability in humans.[1–4]

Explant analysis is probably the key to improving the performance of future generations of devices, as current pre-market bench testing is essential but insufficient to predict the *in vivo* fate of implanted devices. Even if lessons have already been learned from explant analysis, there is still no collective body of information that can provide meaningful information. The purpose of this study was to produce an exhaustive literature review of reports and analyses of grafts explanted for failure in order to summarise the major lessons already learned from explant analysis and to set up how a dedicated explant analysis programme should be run.

METHODS

Major lessons learned from explant analysis have been summarised on the basis of a systematic review of the literature and of the data obtained from a dedicated explant analysis programme.

Systematic review of the literature

A systematic review following the previously published guidelines for the reporting of systematic reviews was performed.[5] No protocol for this systematic review existed or has been published previously.

Eligibility criteria

Studies included were full text English, German, or French language publications without any chronological limit. All primary research studies reporting the analysis of explanted vascular prostheses were included. Reviews, animal studies, studies on autogenous grafts, and those on cardiac or non-vascular grafts were excluded. The main outcomes of interest were the presence of epidemiological data, the presence of structural and mechanical data, and the presence of histopathological data. To these ends, the studies were evaluated for macro- and microscopic structural analysis of the explanted grafts, mechanical testing, chemical analysis, and microscopic histological analysis. Studies that listed patient age, duration of implant, and any other patient specific data were considered to have epidemiological significance. Sufficiency of data reporting for structural analysis was defined as reporting both macroscopic and microscopic structural findings. Histopathological analysis was deemed sufficient if any histological test was done and a test for the presence of bacteria was performed. Epidemiological analysis was deemed sufficient if the patient's age, duration of implant, and any other patient specific data were given.

Table 1. Rough financial estimate of an explanted analysis programme.

Programme requirements	Costs (€)
Investments	
Specific equipment	
Numerical microscope (Keyence VHX600®)	77,000
Scanning electron microscope (Keyence VHX600®)	100,000
Camera (Nikon D5100®)	1000
Laboratory fume hood (Sorbonne 1800 Köttermann®)	13,000
Analytical balance (Mettler Toledo®)	10,000
Stove	5000
Agitators	4000
Website set up	8000
Database set up	10,000
Additional or optional equipment	
Dynamometer (50kN MTS®)	74,000
Fatigue test bench (Bose 400N LM1 TB TA Instrument®)	50,000
Tensile test machine (TTR2 Blockwise®)	53,000
MicroCT	90,000
Permeability column (homemade)	1500
Annual operating costs	
Human resources	
Laboratory manager	60,000
Administrative secretary	30,000
Engineer	45,000
Technician	28,000
Consumables	
ISO certification, laboratory products, devices calibration, explants shipping, communication	10,000
Website	
Management	2000
Database	
Management	2000

Information sources and search strategy

The MEDLINE and Embase databases were searched with a combined strategy using the medical subject heading terms "polytetrafluoroethylene", "polyethylene terephthalates", "vascular grafting", "blood vessels prosthesis", "stents", and "analysis". Two investigators (A.L., N.C.) screened all titles and abstracts collected from the search strategy for relevance. When a relevant article was found, full text articles were retrieved. Studies that did not meet the inclusion criteria were excluded. The reference lists of included studies were searched, and the first 20 related items in MEDLINE were scanned for other potentially relevant studies. The full texts of all potentially relevant articles were obtained and independently reviewed for suitability by both reviewers. No disagreement over study inclusion was noted.

Study records and data items

Two reviewers (B.C., L.M.) independently extracted data using a standardised form. This was done in duplicate to increase accuracy and to reduce measurement bias. No disagreement in data collection was noted. Data extracted included study characteristics (year of publication, number

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