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Pathology of graft and stent-graft infections: Lessons learned from examination of explant materials

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ABSTRACT

Due to the aging population, the number of patients treated with aortic grafts or endografts continues to increase. Although infection after these procedures is uncommon, aortic graft infection is a life-threatening condition, and refinement of management guidelines based on implant pathophysiology is appropriate. In the early 1990s, our European collaborative retrieval program, European Group for Research on Prostheses Applied for Vascular Surgery (GEPROVAS) was commissioned to analyze the degenerative phenomenon occurring on explanted grafts or endografts. In this review, our observations from the examination of explanted aortic grafts and endografts found that both fabric and structural degradation is present and is greater in the setting of inflammation produced by infection.

1. Introduction

Seventy years of clinical experience with aorta replacement with prosthetic grafts has led to the selection of the following materials: polyester textile, polyethylene terephthalate, and expanded polytetrafluoroethylene (ePTFE) grafts. Endovascular stent graft of aorta pathology, introduced in the early 1990s, has evolved with different generations of devices manufactured using various options for both the stent skeleton and graft membrane. The endovascular devices differ in the combination of cover material (woven polyester textile or ePTFE fabrics) and stent material (Nitinol, Elgiloy, or stainless steel).

The aorta is a challenging environment for life-long implantation of prosthetic grafts or endografts, with approximately 35 million pulsations per year, intraluminal pulse pressure deformations contribute to device structure fatigue. Additionally, blood cells and the components of the surrounding tissue can biochemically degenerate most foreign material through inflammation [1,2]. In the early 1990s, our European collaborative retrieval program, European Group for Research on Prostheses Applied for Vascular Surgery (GEPROVAS), was set up to analyze the degenerative phenomenon occurring on explanted grafts or endografts. The main interest of our retrieval program of explanted materials was to allow the analysis of a significant number of devices in order

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to describe the characteristics of aging of the different models of devices, and also to learn about the concept itself.

With the growing number of patients treated with aortic grafts or endografts and the aging population, the number of patients with aortic grafts or endografts infection is expected to increase. Aortic device infection is a rare but life-threatening condition, and there is a need for physical and pathologic evidence to guide management. Without device removal, aortic infection is uniformly fatal due to sepsis and aorta-wall breakdown leading to rupture. In this report, we detail our experience from examination of explanted aortic grafts and endovascular stent grafts. These devices were implanted with the intent of life-long function by healing with the aorta and surrounding tissues.

2. Explant graft analysis

The European collaborative retrieval program, GEPROVAS, located in Strasbourg, France, provided the facilities for analyzing the explanted grafts or endografts [3]. All specimens were studied according to the ISO 9001 certified standard protocol based on the following steps:

1. Graft specimens shipped and stored under controlled conditions,
2. Clinical data collected as an anonymous inclusion in a specific database, and
3. Naked-eye examination of graft, followed by specimen photography using a Nikon D5100 camera (Nikon France, Champigny sur Marne, France).

Because the explants are surrounded by tissue, the larger tissue pieces are carefully removed using forceps before beginning the cleaning procedure. The cleaning procedure is performed using a 0.26% aqueous solution of sodium hypochlorite and photographs of the samples are captured after each change of the cleaning solution in order to exclude occurrence of any damage associated with the cleaning process. Samples are rinsed with fully deionized water and all reactions are stopped using a highly diluted solution of hydrogen peroxide. Finally, microscopic examination using a Keyence VHX-600 digital microscope (Keyence France, Courbevoie, France) was performed with magnification between 20 and 200 times to observe damaged zones.

3. Lessons learned from explanted graft examination

Long-term degradation is a complication of vascular grafts that can lead to dilation or prosthetic ruptures [4–8]. Degradation is related to multiple factors, such as the design of the textile structure, alterations of the grafts during the manufacturing process or during the implantation by handling or application of clamps, and secondary physicochemical alterations when the graft is exposed to chronic foreign-body inflammatory or infectious reaction and to the systole-diastolic arterial stress [9,10]. The first cases of ruptures of textile polyester vascular grafts occurred on weft-knitted structures [11–14]. A weft knit is the simplest form of knitting because a single yarn travels in the weft direction, forming each row of stitches. A second yarn, traveling with the body yarn, can be used to form velour loops perpendicular to the surface. These ruptures consisted of holes and transversal longitudinal tears. Consequently, weft-knit structures have been discarded because of their poor long-term stability and have been replaced with warp-knitted structures. Warp-knitted structures are more complex because yarns are assembled in the warp, or machine, direction, similar to threading a weaving loom. A series of needles interact with these yarns to form the stitches. Warp-knitted structures demonstrated good mechanical performances in terms of long-term stability. However, sporadic cases of ruptures of warp-knitted structures have been reported and are probably related to changes in the manufacturing process in which trilobar filaments were substituted for cylindrical filaments in the velour yarn in an attempt to produce velour of superior quality [15]. This modification was discontinued in the early 1980s, when degradation tests demonstrated that cylindrical filaments were more durable [10,15].

Our collaborative program enabled us to characterize a peculiar kind of degeneration of polyester warp-knitted grafts, that is, longitudinal ruptures. These longitudinal ruptures occurred on two areas of the grafts: the guide line and the remeshing line. The remeshing line is created with a knitting technique. Two bands are simultaneously knitted and joined to create a tube. These two lines may be considered as areas of weakness because the ruptures resembled a complete disruption of the textile and occurred on a textile structure that did not seem to be degraded]10]. The analysis of the explanted grafts with scanning electron microscopy demonstrated that the trilobar filaments constituting the velour structure were highly damaged because they were completely broken with transversal fractures. This aspect was observed in particular on the external surface of the grafts, where the velour sometimes disappeared completely. The mechanisms of damage to the yarns can create heterogeneity of the behavior of the filaments inside the yarns and this damage is probably related to significant stresses applied to the yarns in this specific area. On the other hand, the guide line has the same structure of knitting as the standard knit, except for the incorporation of a dyed yarn in this area. The examination of the areas of rupture found complete rupture of all of the trilobar filaments of the velour. The flat filaments were transversely broken with an aspect of incomplete and gradual rupture. This might be explained by a weakening of the dyed yarn by the process of dyeing itself, which can modify the macromolecular structure of the polymer [10]. The mechanisms of rupture are probably underestimated and related to the knitting technique for the remeshing line and to the dyed yarns for the guide line [16].

In the setting of infection, two important factors have to be considered: the biomaterial must have low propensity for infection and good stability when infected [16–20]. We specifically studied 93 vascular grafts surgically excised for overt infection: 23 human umbilical vein, 51 polyethylene terephthalate grafts, and 19 ePTFE grafts [17]. Techniques used for examinations were gross morphology, histopathology, and scanning electron microscopy evaluation. The human