Poor Long-term Stability of the Corvita Abdominal Stentgraft

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INTRODUCTION

The endovascular treatment of abdominal aortic aneurysms (AAA) was introduced in the early 1990s, with different generations of devices using various options for either the stent skeleton or the membrane. The majority of the first generation devices were associated with a skeleton made of nitinol Z-shaped rings attached together to a woven polyester membrane using ligatures. Failures related to either stent corrosion or fabric instability have been reported. The Corvita stentgraft (CSG) (Corvita Corporation, Miami, FL, USA) has been proposed as another concept. This stentgraft comprises a proximal aortic trunk divided into two distinct sockets to receive two smaller diameter leg (iliac) components. All components comprise self-expanding braided wire stents integrally attached to porous spun polycarbonate urethane (PCU) liners (Corethane). One of the potential weaknesses of the concept was the uncertain in vivo long-term stability of the PCU membrane. This device has been retrieved from the market; however, there is no scientific evidence available concerning the long-term stability of this instrument. In this report, we describe the first structural investigation of an explanted CEG.

CASE REPORT

A 75-year-old man was admitted to the Department of Vascular Surgery of the University Hospital of Nancy for the complete reperfusion after 13 years, demonstrating major degradation of the polyurethane membrane. The patient underwent open surgical conversion, exhibiting a fully pulsatile aneurysm. After temporary supra-renal clamping the aneurysmal sac was opened, exhibiting the stentgraft with major lesions on the membrane. The stentgraft was explanted, and the operation was completed using prosthetic aorto-bi-iliac revascularisation. The patient recovered well without any morbidity. The explant was sent to the GEPROVAS laboratory as a part of a European retrieval explant programme and was submitted to a standardised protocol for evaluation. Naked-eye examinations followed by images investigating the body and both limbs of the stentgraft were performed. The bifurcated body measured 9 cm in length and included two channels of 3 cm length and 9 mm in diameter for limb insertion. Both extremities of the body were slightly conic, respectively, measuring 4 × 3.5 cm and 3 × 2.2 cm (Fig. 2).

The three components of the stentgraft were subjected to a slow cleaning process. Images of the samples were captured after each change to exclude the occurrence of any damage associated with the cleaning process. After cleaning, the stentgraft was extensively evaluated, and the images of all of the primary points of interest were captured using a camera (Nikon D5100) and a digital microscope (Keyence VHX-600).

We observed the fragmentation of the PCU membrane primarily at the extremities of each of the three components. This membrane comprises layers of PCU filaments with a helicoidal orientation of approximately 55°. We observed two modes of degradation of the PCU membrane (Fig. 3):

- Degradation initiated at the middle of each cell, as defined by the braided stent structure, and extending to the edges (Fig. 3A, B, C).
The detachment of PCU membrane fragments, initiating at the periphery of the cells (Fig. 3D).

Filament fractures of the braided stent structures were observed at the conical extremity of the bifurcated segment (Fig. 4).

**DISCUSSION**

The CSG was one of the first generation stentgraft models proposed in the 1990s for the treatment of AAA. The first generation stentgrafts were disappointing in terms of stability and have subsequently been retrieved from the market. Therefore, it might be important to report this case for the following reasons. First, although this device has been retrieved from the market, there is no available information concerning the reasons for retrieval. The CSG has been used for the treatment of peripheral aneurysms, and cases of “cigar-shape” deformation have been reported after a few months of implantation.

The only clinical evaluation reported in the literature offered encouraging medium-term results. However, no evidence of the durability of this device has been reported, and to the best of our knowledge, this case is the first instance of explant analysis reported since the extensive analysis of explants using other first generation devices retrieved from the market. The second reason is the specificity of the fabric that has been used in this device. The first-generation devices extensively used polyethylene terephthalate (PET) woven fabrics; thus, in the present study, we used porous spun PCU liners. The choice of polyurethane was questionable because of the lack of data concerning the long-term stability of this material in vivo. The same membrane was used to construct a vascular graft, but a PET external mesh was added to reinforce this structure. This prosthesis has been studied in animal models, demonstrating the degradation of the melted adhesive between the external PET mesh and the underlying PCU membrane after 6 months. Another animal model study of the PCU vascular graft showed adequate biostability with only minor hydrolysis after 3 years.

In conclusion, this study aimed to provide data to the medical community regarding the long-term durability of a particular model of the vascular device. Although this...
device is no longer available on the market, the knowledge of this report provides evidence for the control of the stentgraft in patients potentially lost to follow-up and should be helpful for designing future devices. One of the biases of such a retrieval programme is that we only analysed devices presenting complications and requiring open reintervention, and we are aware that we cannot firmly confirm the obligatory degradation of all devices or sporadic cases of degradation in this particular case.

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CONFLICT OF INTEREST
None.

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REFERENCES