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ORIGINAL RESEARCH

Degradation Phenomena on “Homemade” Explanted Aortic Textile Endografts

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Objective: In the 1990s, the concept of “homemade” endografts (EGs) using commercially available materials was proposed in clinical practice for endovascular abdominal aortic repair (EVAR). The aim of this study was to analyse the ageing phenomena of these EGs in light of explant analyses.
Methods: The study focused on five explanted homemade EGs collected from 2012 to 2014. The explants were assessed in accordance with the ISO 9001/13485 certified standard protocol, which included naked eye evaluation, organic remnant cleaning, and microscopic and endoscopic examinations and analysis (magnification range from 20% to 200%). The observations report followed a classification based on 12 features assessing the fabric cover, the stitch filament, and the stents.
Results: The reasons for explantation were type 1 endoleak in three cases and aneurysm sac growth in two. The implantation duration ranged from 56 to 202 months. Sixty three per cent of the fabric surface lesions (holes and tears) were related to abrasion between the fabric and the stents. Up to 33% of the knots used to connect adjacent stents were broken on one EG. Other defects including running suture rupture and stent corrosion were also observed. The overall hole cumulated surface ranged from 0.377 mm^2 (56 month of implantation) up to 3.21 mm^2 (78 month of implantation).
Conclusion: In this study, various ageing phenomena on homemade textile EGs were identified and classified. The main damaging mechanisms were related to abrasion stress leading to tears and holes in the fabric, stitch ruptures, and detachment of stent segments responsible for serious EG deformations and further degradation.

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INTRODUCTION

Introduced in the 1990s, endovascular aneurysm repair (EVAR) is a mini-invasive alternative treatment for abdominal aortic aneurysms (AAAs).[1] Commercially available aortic endografts (EGs) have been adopted widely. The European Society for Vascular Surgery (ESVS) 2019 clinical practice guidelines recommends their use “In most patients with suitable anatomy and reasonable life expectancy, …” (Class IIa, Level B). In elective cases, the decision between open or endovascular surgery depends on comorbidities and patient surgical risk, life expectancy, suitable anatomy, preferences, needs, and expectations.[2] But long term performance is strongly related to device durability. Since the start of the EVAR era, some vascular surgeon teams such as La Pitié-Salpétrière Hospital (Paris, France) proposed to develop their own “homemade” EGs (HMEGs) using commercially available textiles and stents.[3—8] One of the arguments for HMEGs was that, at that time, commercially available EGs fitted only 30% of aortic anatomies.[9] The Pitié-Salpétrière team described their specific HMEG and reported their results between 1998 and 2010[3,4,7,8] (Fig. 1). HMEGs aimed to increase the feasibility of endovascular treatment among unselected patients. Another argument was that contrary to commercially available EGs, these HMEGs were morphologically adjusted in order to perfectly match with the patient’s aortic anatomy, with the aim of decreasing endoleak by reducing the dead space around the graft and increasing HMEG longitudinal stability. These devices were manufactured quickly (one to three hours). HMEGs from La Pitié-Salpétrière Hospital were composed of materials adapted and used for conventional surgery. The outer cover was

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made of woven polyethylene terephthalate (PET) fabric (Twillweave; Sulzer Vascutek, Inchinnan, UK) which is thicker (0.6 mm) than the commercially available EG outer cover. This was thought to conduct less *in vivo* textile degradation although the textile surface was not especially designed to resist abrasion. The metallic skeleton was made of stainless steel cylindrical auto-expandable Z stents (Cook, W. Cook Europe, Bjaeverskov, Denmark) connected by sutures/knots inside the fabric with 4/0 knitted polyester sutures (Cardioflon; Peters, Bobigny, France). HMEG devices were designed to fit within the larger part of the aneurysmal aortic lumen allowing the space to be filled. A triple cover running suture was created to adapt the prosthesis shape to the patient's aortic anatomy. In this way, the surgeon realised a triple running suture to adapt the non-waffled textile shape on the stent skeleton and then used a thermal cutter to cut and solder one border to the other. This suture ensured HMEGs structural sealing.

Because of standard EG development and improvement, these HMEGs are not used anymore and studies reporting their outcomes are scarce.[3,4,7,8,10,11]

Nevertheless, despite the currently available wide EG range of choice and the possible end of HMEG use, a retrospective study on their ageing problems remains valuable to understand their performance in complicated vascular lesions.

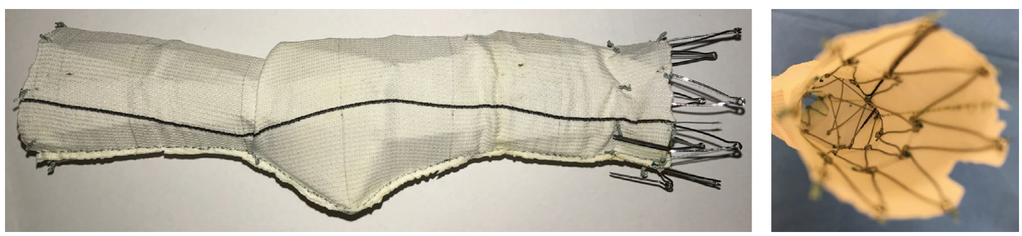
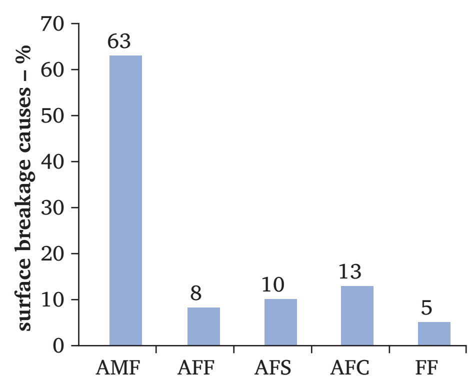


Figure 1. Photographs of one specimen of explanted homemade endograft with a global and an inner view.

A

Implantation time (months)	Explantation reason
56	Type 1 endoleak
78	Aneurysm growth
145	Type 1 endoleak
161	Type 1 endoleak
202	Prosthetic migration + aneurysm growth

B



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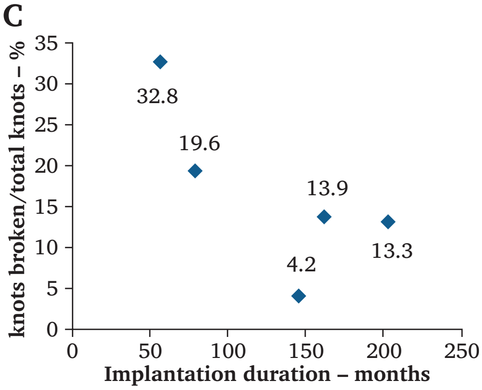

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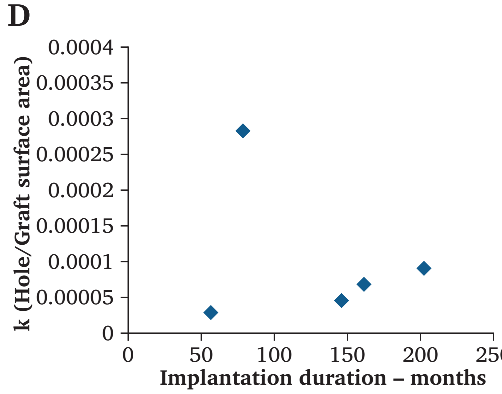

Figure 2. Information and degradation phenomena on five HMEGs. (A) Information of five HMEGs. (B) Percentage of causes concerning holes and cuts on the fabric surface. C) Ratio of broken knots/total knots used to connect adjacent stent rings inside HMEGs. (D) Correlation of implantation duration and *k* value. AFS = abrasion fabric stitch; AFF = abrasion fabric/fabric; AMF = abrasion fabric/metal; AFC = abrasion fabric/calcification; FF = fabric fatigue.

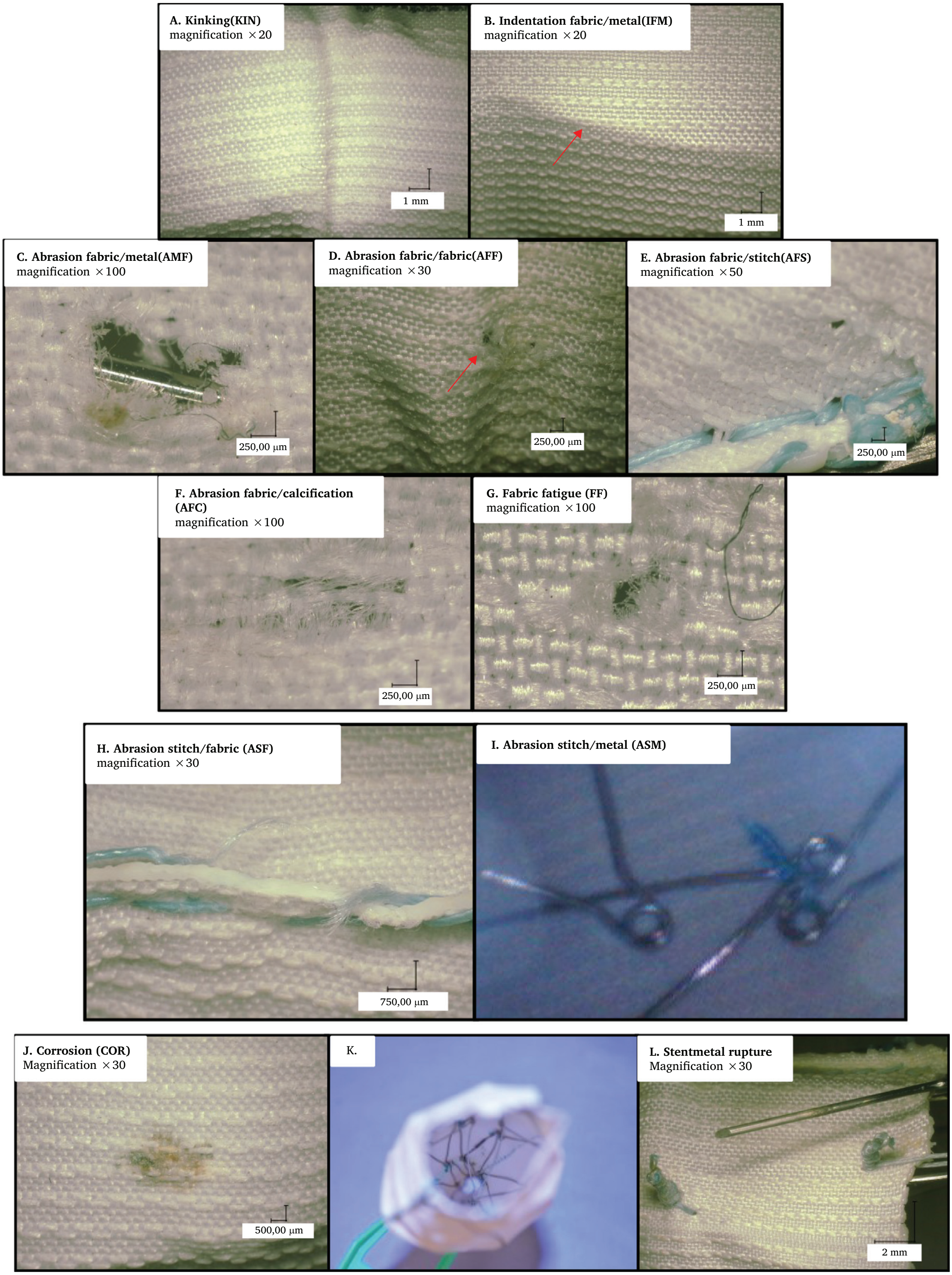

Figure 3. Classification of fabric, stitch, and stent degradation. Classification of fabric degradation. (A) Compression: kinking (KIN). The compression in the sheath leads to permanent kinks. (B) Indentation fabric metal (IFM). A mark (red arrow) is seen where the internal stent pressed hard into the fabric. (C) Abrasion. Abrasion fabric/metal (AFM). The stent rubs against the fabric and causes lesions.

In the early 1990s, the European Collaborative Retrieval Program GEPROVAS (ECRP) was set up in order to analyse the degenerative phenomena occurring in explanted vascular devices. Different studies[12–16] have been carried out at GEPROVAS on both first and second generation EGs focusing on ageing phenomena. A classification of degradation mechanisms has been established.[13] However, up to now there are no available data about the HMEG ageing curve.

The aim of this study was to identify the degradation mechanisms within the textile structure of five human explanted HMEGs.

MATERIALS AND METHODS

Explanted endografts

Five explanted HMEGs from 876 implanted at the department of La Pitié Salpétrière were studied; they were collected between 2012 and 2014. They were implanted to treat aorto-iliac aneurysms. Implantation duration ranged from 56 to 202 months. Reasons for explantation and implantation duration are shown in Fig. 2A. None of these explants presented with a type 4 endoleak.

Explant processing and analysis

The HMEGs were assessed in accordance with the ISO 9001/13485 certified standard protocol. The different steps were (1) naked eye examination followed by digital image capture (Nikon D5100, Nikon France, Champigny sur Marne, France); (2) cleaning with a 0.26% aqueous solution of sodium hypochlorite followed by rinsing using fully de-ionised water and stopping all reactions using a highly diluted hydrogen peroxide solution; (3) microscopic examination and analysis by two different investigators using a Keyence VHX-600 digital microscope (Keyence France, Courbevoie, France); and (4) a VOLTCRAFT BS-1000T Endoscope (Conrad, Germany).

Degradation mechanisms assessment criteria

The assessment was systematised according to the classification of degradation mechanisms described previously.[13] This classification distinctly considers the textile outer cover, the stent struts, the stitches between stents and the stitches between cover and stents, and finally the cover running suture. The fabric defects were identified in accordance with damage patterns published previously.[17] The different mechanisms observed were abrasion between metal stent and fabric, abrasion between fabric and fabric, abrasion between fabric and stitching filament, abrasion between fabric and aortic calcifications, textile fatigue (TF), and kinking phenomena (KIN). Two investigators referenced all the damages. Regarding the stitches between stents, the number of damaged knots was given as a percentage (%) considering the total number of knots on the corresponding explant.

Hole surface characterisation

On each HMEG, both investigators referenced the hole number, position, and size observed through the microscope. To compare the different HMEGs, the hole surface area was normalised to the textile surface area by giving a k value. The k value indicated the amount and size of defects per area: k = defect area/HMEG superficial area.

Statistical analysis

The different HMEGs were compared thanks to quantitative data reported as a percentage relative to the total surface area or the total number of knots.

RESULTS

Degradation mechanisms identified

Fig. 3 shows all the degradation mechanisms observed in the fabric, the stitches, and the stent segments.

Fig. 2B shows the percentage of the different causes of holes and cuts on the fabric surface among the cohort.

Every specimen suffered from different degradation mechanisms. Abrasion was observed between metal stent and fabric and kinking phenomena on each HMEG. TF was observed in the two oldest HMEGs (161 and 202 months). In this small number of explants, no link was found between implantation duration and the other degradation mechanisms.

Defects identified on the fabric. Sixty-three per cent of the fabric surface lesions (holes and cuts) were related to abrasion between metal stent and fabric (Fig. 2B, Fig. 3C, 24 cases). At the same time, a total of 24 KIN (Fig. 3A) were found, which led to multiple areas of weakness. Fourteen of 32 surface lesions (44%) were identified near or on these kinks (excluding abrasion between fabric and aortic calcifications). The kinking phenomena promoted the appearance of surface breakages due to cyclic friction between stents and fabrics and between fabrics (AFF, Fig. 3D, three cases) and due to cyclical flexion of fabrics leading to TF (Fig. 3G, two cases).

The other lesions occurring on the fabric surface that led to damage were mainly related to abrasion between fabric

(D) Abrasion fabric/fabric (AFF). Depending on the position of the graft in the artery, abrasion between two areas can occur (red arrow). (E) Abrasion fabric/stitch (AFS). The filaments of the stiches move against the fabric and cause abrasion. (F) Abrasion fabric/calcification (AFC). Hard particles in the environment of the graft damage the fabric. (G) Fabric fatigue (FF). Cyclical movement causes tears in the fabric. The characteristic pointing geometry of the cut filaments is visible. Classification of stitch degradation. (H) Abrasion stitch/fabric (SF). Depending on the position of the graft, a cyclical movement can cause abrasion of the stitching touching the fabric. (I) Abrasion stitch metal (ASM). The abrasion starts under the knot, where it is in contact with the metal. Classification of stent segment degradation. (J) Corrosion (COR). (K) Rupture of the fixing knots led to the detachment of the adjacent struts from the circumferential rings. (L) Rupture of the stent metal.

and stitching filament (Fig. 3E) or abrasion between fabric and aortic calcifications (Fig. 3F). Four cases of abrasions were observed between fabric and stitching filament, on two HMEGs at 56 and 202 months of implantation duration. Five cases of abrasions were observed between fabric and aortic calcifications, on two HMEGs, at 56 and 78 months of implantation duration. As described previously,[13] the damage is explained by the cyclical moving contact between aortic wall calcifications and the HMEG.

Defects identified on the stitches. The defects identified on the stitches were separated into two categories: the cover running suture and knot rupture.

The triple cover running suture degradation was far less important than the degradation level of fabric materials or knot rupture. There were only two cases of cover running suture ruptures (Fig. 3H) caused by multiple frictions of the implanting environment and the stitched fabrics. Despite these ruptures, openings were not observed between the two textile parts.

However, serious knot ruptures (Fig. 3I), used to connect adjacent stent rings together to form the whole stent body, were observed inside all five HMEGs. Up to 33% of knots were broken on one HMEG (Fig. 2C). The knot ruptures ranged from 4% to 33% (mean: 17%). These phenomena caused detached stent segment dislocation leading to serious HMEG contour deformation. The knot ruptures could be related to the friction brought by the metal stent as well as to the blood flow.

A 3D reconstruction of a computed tomography (CT) scan performed one year before explantation of one HMEG was reviewed. The classic 3D map of the CT scan found two stent detachments, but the quality of this CT scan did not allow other knot ruptures to be observed. The 3D reconstruction allowed observation of seven other zones with possible stent detachment or suture enlargement. When this 3D reconstruction was compared with the explant evaluation, five of the nine possible detachment zones were indeed knot rupture zones (Fig. 3) but also four possible detachment zones were not knot rupture zones.

Lesions identified on the stent. Stent degradation consisted of two kinds of ageing phenomena, corrosion (Fig. 3J) and strut detachment from the circumferential stent rings (Fig. 3K), in all specimens. There was only one case of broken stent (Fig. 3L). The strut detachment, as mentioned above, was due to rupture of the fixing knots, which led to strut dislocation.

Characterisation of hole surface area. Fig. 2D shows the correlation between k value and implantation duration. No correlation was found between the hole surface area and the HMEG total surface area. The hole surface area varied from 0.38 to 3.21 mm^2. The k value varied from 2.88×10^{-5} to 2.83×10^{-4}. The higher k value was approximately three to 10 times higher than the four other k values. Except this higher k value, the others ranged from 2.88×10^{-5} to 9.04×10^{-5}. The higher k value represented a hole surface of 3.21 mm^2 on an HMEG explanted because of aneurysm sac growth at 78 months. Except for this higher k value, there is a tendency for k values to increase with time.

DISCUSSION

The main degradation mechanisms observed on these HMEGs were abrasion due to an association between the stent metal and fabric, KIN, and knot rupture, which were related to each other and to their creation technique. The study shows that despite no compromise with the choice of material, fatigue and wear could appear with time. Thus, the new generations of EGs have to take into account these fatigue and corrosion phenomena.

To be compatible with a reasonable delivery system size, the first commercial generation of EGs had to use thinner textiles than classical surgical textiles. This was responsible for higher rates of holes and tears, and they were incriminated in higher rupture risk.[15] At the beginning, with off the shelf devices provided by industry, the feasibility rate remained relatively low among unselected patients and feasibility depended on aneurysm morphology.[9] Currently, many modules are available and have to be intubated one into each other to fit the aneurysm anatomy, which is exposed to type III endoleaks. HMEGs were built with only one piece and were morphologically adjusted to fit with each anatomy. Even with such a device the study shows that the relative movements of the metallic skeleton and the fabric can generate material friction and abrasion.

Other teams also developed HMEGs but some technical differences in conception have been described. Kawagushi et al., reported the use of HMEGs with some common points but different conception.[18] The stent skeleton was created with self expanding Z stent and the cover was from vascular prosthesis material too (PET fabric or an expanded polytetrafluoroethylene film). The main difference was their tubular shape. Their HMEGs did not fit the aorta anatomy. At this time, for all commercially available EGs, tightness and migration prevention were ensured by proximal and distal fixation. Therefore, adapting the EG shape to the patient's aortic anatomy with the objective of decreasing endoleak, by reducing the dead space around the graft and increasing EG longitudinal stability, was a new and promising concept. There were similarities between this concept and the endovascular aortic sealing concept published a few years later.[19]

Another technique to improve the proximal stability of the EG was the addition of a suprarenal uncovered stent. Malina et al. reported their use in 1997.[5] Koskas et al. used it since 1998. An uncovered proximal stent is currently present in different commercially available EGs. It is a reminder that the technique has evolved and results have improved partly thanks to precursor surgeon teams. Even if these HMEGs are no longer used, this first evaluation of the Koskas et al. HMEG ageing phenomena remains valuable because it enables understanding of the performance of these precursor techniques.

Indeed, compared with the currently commercially available EGs, the stent struts were not fixed to the textile cover. The fixation technique consisted of connecting adjacent stents to each other by knots and connecting them to the textile only at the proximal and distal HMEG extremities. The stent skeleton was free from textile connection except at its extremities. The stents formed a connected stent skeleton due to the absence of free space between two stent levels and thanks to knots connecting adjacent stents as in the first generation of Stentor (MinTec Ltd, Freeport, Bahamas). Moreover, the shape of these HMEGs was ensured by the stent skeleton position, which was on the inside of the textile cover. The stent skeleton pushed out the textile, which was cut and sutured in order to fit the patient's aortic anatomy and both (stent skeleton and textile deformation resistance) ensured the HMEG shape.

The lack of free space between stents, the lack of connection between "middle" stent and textile, and the inside position of the stents were responsible for significant friction between stents and textile when exposed to aortic movements. Concerning the corrosion observed on the stent surface, the corrosion process can be expected to be the result of fretting ue to stent to stent contact but the corrosion mechanisms were not explored in more detail.[20]

For knot rupture, the stent wire could move freely. These free movements could be responsible for an increase in the friction between stent and textile cover by means of serious deformation and KIN on the textile cover. They were responsible for one stent fracture. Furthermore, the stent wire could invaginate into the lumen and no longer guarantee the EG shape. The stent wire could also penetrate a textile hole and increase its size.

The cyclical movement of the HMEG in the aorta and the friction between two metal stents were responsible for 4%—33% of knot ruptures. Almost half of the surface breakages were close to KIN and 63% of surface breakages were due to metal against fabric abrasion. It is thought that indirectly the absence of free space between two stents and the absence of stent and textile connection associated with the inside position of the stent skeleton increased the number of surface breakages. These different mechanisms could lead to secondary graft failure. However, the HMEG, which had 33% of broken knots, was not the one with the higher *k* value and was explanted for type 1 endoleak.

In 2017, Bussmann et al. reported the analysis of textile ageing characteristics on a new generation of explanted commercial EGs.[13] They reported a ratio of hole to graft surface area with respect to implantation duration (the same presented as the *k* value in the study) for 41 explanted EGs. The results here seem comparable and are even in the low range of theirs. For example, a *k* value of 0.00009 was found after 202 months of implantation duration (16.8 years) when their time curve reached 0.0003 at 84 months (seven years). The textile cover used to create the HMEGs may explain these results. Koskas et al. used a commercially available vascular prosthesis material composed of standard woven PET to cover the stent skeleton.[3,4] It was reported that the textile structure could have an influence on EG degradation.[12] This cover was thicker than those used for the new generation of commercial EGs. Thus, concerning the surface breakage, the Koskas HMEGs presented satisfactory results compared with commercially available EGs. However, the surface of such a cover was not genuinely designed to resist abrasion. Indeed, efforts were made by the industry for the later generation EGs to reduce the friction coefficient of the cover surface. Finally, as reported by Bussmann et al., the results highlight once again that degradation increases with time, questioning the sealing maintenance with implantation duration.[13] And it also serves as a reminder to never stop closely overseeing and assessing every new concept and material in vascular and endovascular surgery.[21,22]

The study has limitations which require cautious interpretation. Firstly, only five HMEGs were explored. By definition, these HMEGs were explanted, thus they could have suffered damage such as knot rupture, increased size of holes, or stent/suture line fractures due to surgical manipulations at the time of explantation. Regarding knot rupture and stent position, a previous 3D CT scan reconstruction could be one helpful way to compare EG morphology before and after explantation, but it could not help to appreciate the microscopic lesions. Autopsy samples could be another way to limit the errors but could not be adapted to clinic activity. Moreover, the damage could have been over represented in these five specimens due to their EG secondary failure.

CONCLUSION

In this work, various ageing phenomena on five HMEGs were identified and classified. The main damaging mechanisms were related to abrasion stress leading to tears and holes in the fabric and stitch rupture and detachment of stent segments causing serious HMEG deformation and further degradation. The technical details could partly explain those mechanisms and further evaluation on a larger number of HMEGs could be valuable to more extensively explore them. However, these HMEGs were an interesting concept and some of their technical innovations have been used later in commercial EGs. In this work, these HMEGs do not seem to have more structural degradation than the second generation of EGs.

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CONFLICT OF INTEREST

None.

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