Tribology International 63 (2013) 265–274

Contents lists available at SciVerse ScienceDirect

Tribology International

journal homepage: www.elsevier.com/locate/triboint

Abrasion behaviour of polymeric textiles for endovascular stent-grafts

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ARTICLE INFO

Article history:
Received 20 October 2011
Received in revised form
3 October 2012
Accepted 1 November 2012
Available online 27 November 2012

Keywords:
Stent-grafts
PET
ePTFE
Abrasion resistance

ABSTRACT

Endovascular aneurysm repair (EVAR) is a type of endovascular surgery used to treat abdominal aortic aneurysms (AAA). The prosthesis used for the purpose, called stent-grafts, are made of polymeric materials reinforced by metallic stents. The polymers used for the graft construction are usually woven PET fibres or extruded ePTFE. After implantation and due to blood flow and to the relative motion between the stent and the graft, abrasion, erosion and fatigue of the graft material can occur, leading to fibre separation/fracture and perforation of the graft. In this paper, abrasion wear tests results are presented for three different materials used in stent–grafts, using the Martindale method. Mass loss as function of wear cycles is presented. Scanning electron microscopy, before and after tests was used to analyse the materials surface. ePTFE specimens presented ruptures between 45,000 and 55,000 cycles and PET specimens at 70,000 cycles. PET-LP (low profile) specimens did not reveal any rupture until 150,000 cycles. These results show an increased life resistance, due to different wear mechanisms of PET-LP fabric, when compared with ePTFE and PET fabric for vascular prosthesis applications.

1. Introduction

Abdominal aortic aneurysm (AAA) disease is a degenerative process, often without symptoms, which can rupture the vessel wall, resulting in profuse internal bleeding and often leading to death. The International Society for Cardiovascular Surgery/Society for Vascular Surgery defines abdominal aortic aneurysm as a focal dilation (widening) of the abdominal aorta where the diameter is at least 50% larger than the expected normal diameter [1].

The rupture of an AAA is a serious medical emergency and is associated with a high mortality rate. Massive bleeding from a ruptured abdominal aortic aneurysm into the abdominal cavity can lead to cardiovascular collapse and shock. A ruptured abdominal aortic aneurysm is an acute medical emergency and must be pre-diagnosed and treated urgently to improve the patient's chances of survival.

Approximately 15,000 people die each year in the United States from ruptured AAA and some researchers estimate that this number may be even higher. In the United Kingdom there are 10,000 deaths from ruptured AAA every year. Up to 15% of people may survive a ruptured aneurysm, but their mortality risk increases since only 50% survive the surgical repair [2].

AAAs were traditionally treated with open surgery involving a large abdominal incision and the placement of a synthetic graft [3]. Population-based studies suggest that the morbidity and mortality rates are significant. Mortality may be as high as 8%, and 10% may suffer cardiac complications [4]. The major risks during open elective repair are perioperative cardiac events (for example, myocardial infarction), but respiratory and renal failure are also common [5].

In 1991, Parodi et al. [6] presented the "endovascular stent placement" as a new technique for the treatment of AAAs. But only in 1999 the first aortic stent grafts for the treatment of AAAs became commercially available to physicians and patients, followed then by numerous devices introduced into the market from diverse manufacturers [3]. Although with some restrictions, endovascular aneurysm repair (EVAR) became very popular due to its numerous advantages over open surgery, including shorter patient recovery and hospitalisation time, minor blood loss, and lower rates of mortality/morbidity.

This minimally invasive technique can be performed under general or regional anaesthesia and involves the placement of a stent-graft inside the aneurysm sac through the common femoral arteries. The stent-graft is a tubular prosthetic vascular graft, constituted by two modules: the graft and the stent. The graft is typically made of polyethylene terephthalate (PET) commercially known as Dacron or expanded polytetrafluoroethylene (ePTFE),

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http://dx.doi.org/10.1016/j.triboint.2012.11.003

which is reinforced by metallic struts (stents). These stents are usually made of nitinol alloy or stainless steel, and its upper ends can be fixed to the arterial wall.

The stent-graft is usually delivered into the aneurysm inside a sheath, manoeuvred into position under X-ray (fluoroscopic) guidance, and deployed by withdrawal of the sheath. Final fixation at the proximal and distal ends of the stent-grafts is usually achieved by inflating a balloon inside the stent-graft to ensure firm attachment to the arterial wall.

These devices must protect the aneurysm sac from arterial pressure and must accomplish this over the natural life of the patient without displacement from sites of attachment or degeneration of components. Furthermore, they should be small enough to fit into a delivery system that can be easily moved through the arterial anatomy [7].

Table 1 resumes the devices currently in the market. The third column indicates the materials currently used as grafts and its position related to the stent frame.

Despite the advances regarding materials development and design of endovascular prosthesis, during the two past decades some problems have been reported with endovascular after implantation [8–11], such as: inflammatory process, endovascular stent-graft leaks, kinking, abrasion (due to the relative motion between the stent and the graft) and fatigue (due to changes in blood pressures - systolic to diastolic).

Endovascular graft leak constitutes the major complication associated with EVAR [12–14]. Classification includes:

- Type I: leak around the proximal and distal attachment site;
- Type II: leak inside the aneurysm by a feeder vessel circuit;
- Type III: leak due to graft fabric tear or disconnection;
- Type IV: leak through the graft itself.

Most of the early stent-grafts were relatively porous. High porosity was thought to be essential to long-term patency based on experience with surgical grafts, and no limit on stent-graft porosity was imposed. However, some problems have been reported [15] with some prosthesis, such as low rates of aneurysm shrinkage or enlargement, suggesting that the aneurysm remains pressurised. Hence porosity has been diminished and it is an important parameter to analyse and control over time.

The stents may be tightly sutured to the fabric in an attempt to simulate a composite structure or may allow, to some degree, motion between the metal and the fabric. This relative motion between materials and the blood flow over time produces abrasion, erosion and fatigue on the graft material, which can lead to fibre separation and perforation of the graft [16–19].

Although patients with aneurism related diseases are usually of advanced age, nowadays aneurisms are increasingly being reported at younger ages and population life expectancy is becoming higher. Despite these facts, tests made for approving devices are conducted simulating only 10 years life for which they must keep their properties. After 10 years of device implantation there are reports of 21% fails in implants, increasing to 30% after fifteen years and 44% after 20 years [20]. The new generation of stent grafts with fixation barbs skirted the problem of graft migration after the implantation, but possesses a serious problem if late graft fail occurs and graft replacement is necessary, due to tremendous injury made to the artery wall. However, small quantity of information regarding grafts properties after 10 years has been published, with just qualitative analyses like "fair", "good" or "excellent" being reported. This lack of quantitative information makes difficult to predict materials life behaviour. Due to this fact, it is important to understand wear mechanisms in polymeric materials used to produce grafts to help researchers to develop materials with safer life times and to produce materials with longer life expectation.

Abrasion is one of the most frequent wear mechanisms on materials surface. It is defined as material pull-out caused by the action of hard particles spread on the material surface which is subjected to the abrasive wear due to the relative movement between two surfaces [21].

The measurement of the abrasion wear resistance of any type of material is very complex. In this case, the abrasion resistance of a fabric is affected by many factors such as the inherent mechanical properties of the fibres, its dimensions, the structure of the yarns, the construction of the fabrics and the type, kind and amount of finishing material added to yarns or fabrics, beyond the softening point of the fibre material. These observations are applied to all kind of fabrics, including woven, nonwoven and knitted fabrics [22].

The evaluation of the abrasion resistance of fabrics is possible through various types of abrasion testing machines, testing procedures and methods of evaluation [22]. In this study, the Martindale abrasion test method is used, according to ISO standard 12947-3, with determination of mass loss [23] and the observation of the abraded surfaces by microscopy.

2. Materials under study

Three different materials, currently used by manufacturers in EVAR prosthesis, were analysed in terms of wear: ePTFE, PET and PET-LP (low profile).

Square textile samples were cut from the tubular prosthesis, for material characterisation prior to the experimentation regarding wear behaviour.

ePTFE is a porous polymeric membrane usually produced in a continuous form by a process that includes extrusion, rolling,

Table 1
Devices and materials for endovascular prosthesis, currently in the market.

Name	Manufacturer	Graft material/positioning	Stent construction
AneuRx	Medtronic Inc, USA	PET/inside	Nitinol
Talent	Medtronic Inc, USA	PET/both	Nitinol
Excluder	WL Gore, USA	ePTFE/inside	Nitinol
Zenith	Cook Inc, USA	PET/both	Stainless steel
Powerlink	Endologix, USA	ePTFE/outside	Co–Cr alloy
Aorfix	Lombard Medical, UK	PET/inside	Nitinol
Anaconda	Vascutek Ltd, UK	PET/both	Nitinol
Lifepath	Edwards Lifesciences, USA	PET/outside	Elgiloy and stainless steel
Aptus	Aptus Endosystems, USA	PET/both	Elgiloy and stainless steel
Cordis Fortron	Cordis Corporation, USA	PET/outside	Nitinol
Endurant	Medtronic Vacular, USA	PET/inside	Nitinol