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Seeking for the ideal stent graft

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Abstract

Aortic aneurysms are localized dilatations of the aorta that if not treated may lead to death. One of the current treatments is endovascular repair, a minimal invasive procedure in which a stent graft is placed transluminally to prevent wall rupture shielding the aneurysm from blood pressure.

Stent grafts are classified as class III medical devices. They are composed of a metallic scaffold covered by a polymeric membrane. While early devices were custom designed by the operating surgeon, nowadays several commercially devices are available.

The introduction of new devices helped solving several complications, however other problems, like fatigue, still persist. Furthermore, innovative functions, namely measurement of the intrasac pressure, are demanded to improve patient’s quality of life.

Based on an acutely literature review, this article classifies stent grafts according to different characteristics and points out the

guidelines for an ideal stent graft. Finally, it proposes new features to be included in the next generation of stent grafts.

Keywords

Biomedical devices, design, review, sensing devices, guidelines

1 Introduction

Aortic aneurysms, Figure 1, are localized dilatations of the aorta that if not treated may lead to death. They occur most commonly in arteries located at the base of the brain, as well as in the legs and in the aorta. If left untreated, they may burst or rupture causing a stroke – in the case of brain aneurysms – or, if located in the aorta, shock, and even death, due to massive blood loss. It is estimated that thoracic aortic aneurysms affect 10.4 per 100,000 persons-year [1], while abdominal concern about 12 per 100,000 persons-year [2].

Since the early 1950’s, the standard treatment of aortic aneurysms has consisted in an open surgery and the replacement of the diseased segment of the aorta by a synthetic prosthetic graft [3]. By the 1990’s, Parodi [4] and Dake [5] presented an alternative to open surgery demonstrating that endovascular repair was a

safe and feasible procedure. Currently, published data show that the treatment of both abdominal and thoracic aortic aneurysms is also viable with total laparoscopy or assisted laparoscopy [6].



Figure 1. Representation of fusiform (on the left), and saccular (on the right) aneurysms

Endovascular repair, or EVAR, is a minimally invasive surgery in which a stent graft is guided from the femoral artery to the affected segment in order to prevent wall rupture by shielding the aneurysm from the blood pressure [7]. The first procedures resulted in several complications, some due to the learning process inherent to it while others due to the devices' inefficiency. With time, many of the problems have been solved due to the accumulation of experience and the introduction of better devices but, nevertheless, some problems still occur and improvements are still possible in the design and fabrication of stent grafts.

The major purpose of this paper is to point out the main challenges that a stent graft must address. Thus, after presenting a classification of current endoprosthesis, the "ideal" stent graft is described, followed by a reflection on possible enhancements for the next generation of stent grafts.

2 Stent graft classification

Stent grafts are endoprosthesis classified as class III medical devices both in Europe and the USA. They are composed of a metallic scaffold with a polymeric covering membrane. If early stent grafts were custom designed for

each patient by the operating surgeons assembling off-the-shelf components [8], nowadays several commercially devices are available [9-11]. These devices have distinct designs and can be classified based on different characteristics, Table 1.

Table 1. Stent graft main attributes.

Location	- Thoracic - Abdominal
Shape	- Tubular - Tapered - Bifurcated
Number of components	- Single-piece - Modular
Deployment technique	- Self-expanding - Balloon inflated
Fixation	- Radial force - Hooks
Stent material	- Stainless steel - Nitinol - Elgiloy
Shape of the stent	- Sinusoidal - Diamond - Multiple rings
Graft material	- PET (Dacron) - ePTFE - Polyurethane

3 "Ideal" stent graft

Throughout the past two decades, many stent graft's designs have been presented. At present, it is possible to identify a more or less consensual definition of what an ideal stent graft should be like.

Biocompatibility is of decisive importance since the stent graft will be placed inside of the human body in direct contact with blood. The materials chosen, besides being biostable, cannot be toxic and carcinogenic; they also cannot cause thrombosis and hemolysis, and the human body must tolerate them so as not to cause a foreign body reaction or an inflammatory reaction.

The ideal stent graft should have and maintain the same compliance as a normal aorta without interfering with the surrounding anatomical structures. For that, porosity plays an important role since the rate of tissue ingrowth depends

on the graft porosity [12].

The design of the stent graft ought to be the least invasive as possible in order to minimize flow resistance and pressure drops maintaining the blood flow (permeability).

Stent grafts should also mimic the aorta's mechanical properties. Besides durable, they should be flexible so that the contour can be maintained without kinking and bending avoiding partial or full occlusion. They should be tough and yet ductile in order to avoid stent fracture and later complications. Furthermore, to withstand the continuous pulsatile blood flow, they should resist fatigue and have a stable configuration, i.e., they cannot allow overexpansion or bursting.

Fabric erosion occurs since the endograft is a moving prosthesis composed of metal stents and soft fabric [13]. To prevent such a problem, and consequent endoleaks, fabrics should be resistant to both wear and tear, especially near the holes made by sewing the stent to the graft. Moreover, stents must exhibit excellent corrosion resistance.

Another relevant feature is radial force. It is important, not only for stents to stay open without being crushed with muscular activity, but also to provide a good seal and to ensure fixation thus preventing endoleaks and migration.

Radiopacity is an essential trait given that it will allow precise deployment of stent grafts and follow the evolution of the device within the patient's arteries.

Stent grafts should have a low profile to facilitate the deployment and minimize lesions in the access arteries.

From the handling point of view, is useful a wide range of stent grafts sizes. Predictable and convenient sizing of stent grafts is also necessary for physicians to place the device correctly and make sure that the injured portion of the artery is covered.

4 Additional features

After an EVAR, patients are regularly submitted to imaging exams to evaluate the size of the aneurysm sac and detect complications, such as endoleaks, endograft migration and module disconnection. To avoid

these expensive and potentially harmful exams, the ideal stent graft should provide this kind of information. At best, the device should be able to monitor its material degradation (type III endoleaks), detect migration and leakages. While the first may require the use of conductive wires woven within the graft material [14], pressure sensing within the aneurysm sac promises to be a good candidate for leakage detection and even migration.

The transmission of the measure data is another important design parameter. The ideal stent graft must be able to transmit the data without any internal power supply. Moreover, the data cannot interfere with other implants nor be influenced by other electronic signals.

To assure patient's comfort, the measurement protocol should be achievable at home and the results transmitted to the medical office, if no, the exam at the medical office should be quick and the least invasive as possible. Nonetheless, the measurement procedure should avoid any kind of pain or even discomfort.

If pressure measurements within the aneurysm sac are considered for migration and leakages detection, the knowledge of the values and the exact location where the pressure is being measured is of the outmost importance. There are already solutions [15-16] able to measure one single pressure point, but, idyllically, the sensor would allow drawing the pressure profile within the aneurysm sac indicating the maximum and minimum pressure. This feature would not only help to diagnose complications but also to learn the behavior of the aneurysm sac after the implementation of stent grafts.

5 Conclusions and future work

Since the introduction of EVAR, several stent grafts became available. Currently, an ideal stent graft can be described as being biocompatible, non-toxic and non-carcinogenic. Besides having good mechanical properties and a minimally invasive design, it should also provide information regarding the device's performance and the patient's condition to the medical doctors.

The next step in this work involves the study of the technologies available to implement the features described.

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