INTRODUCTION

An aneurysm is a localized, blood-filled dilation of an artery that, if not treated, may lead to death. It can appear anywhere but it occurs most commonly in the aorta, as well as in arteries located at the base of the brain and in the legs.

Abdominal aortic aneurysms (AAA), Figure 1, are the most frequent arterial aneurysm and, in spite of being relatively indolent, they are one of the causes of sudden death. In fact, in Europe, they represent the 12th cause of death and, in the U.S., the 13th (Wilt et al. 2006), affecting around 12 to 15 per 100,000 persons-year (Ricotta II et al. 2009).

Among the AAA’s risk factors age is an important one and males over 65 years old are predominantly affected by this disease (McPhee et al. 2009). Taking into consideration that, currently, approximately 16% of the European population is aged 65 or over and projections estimate that this value will boom to more than 28% in the year 2050, the disease’s incidence is expected to increase.

Since the early 1950’s, aneurysms’ standard treatment has consisted in an open surgery (done under general anesthesia) and the replacement of the diseased segment of the aorta by a synthetic prosthetic graft (Myers et al. 2001), Figure 2. In spite of its invasiveness and the fact of being limited to fit patients, this treatment is still a current practice and less invasive techniques are being studied to minimize its disadvantages.

ABSTRACT: Aortic aneurysms can be deadly if not treated. Their modern treatment commenced in the early 1950’s, but it was during the 1990’s that was revolutionized by the introduction of endovascular aneurysm repair (EVAR). This minimally invasive procedure is frequently associated with advantages such as shortened hospital stays and the possibility to treat patients unfit for surgery. However, it requires long-term surveillance, which has important implications in the total cost. The development of a smart stent-graft, i.e., a stent-graft with some in-device mechanism to perform a given function and can communicate with an external element, could help mitigate this problem. This paper identifies the main users of a smart stent-graft and presents its key characteristics.
EVAR is a minimally invasive procedure done percutaneously, Figure 3. Typically, a small incision is made in each groin to expose the femoral arteries. Then, with the aid of catheters and guidewires, a stent-graft is guided to the affected artery segment allowing blood to pass without exerting pressure in the aneurysm sac and, thus, preventing wall rupture.

Figure 3: Endovascular aneurysm repair (EVAR), stent-graft deployment sequence.

This surgical procedure is commonly associated with less physiological derangement, lower morbidity and mortality, and early return to full activity. Nonetheless, late complications, such as stent-graft migration, endoleaks or module disconnection, still occur (Katzen et al. 2006), compelling long-term surveillance that is responsible for increased costs and, thus, compromises the cost-benefit relation.

This paper describes the early stages of the development of a smart stent-graft, i.e., a stent-graft with monitoring capabilities. Such device would help to attenuate surveillance costs and improve the patient’s quality of life, since it could regularly send information regarding the patient’s health and the prosthesis performance to the doctor avoiding the dependence of expensive and potentially harmful imaging exams.

This paper is organized as follows. After a brief introduction to the disease and its treatment options, a review of the results of some EVAR cost-benefit analysis will be presented to clarify the need of a new medical device. Following, the potential users of the novel device will be identified and the device’s key characteristics will be indicated. Finally, the conclusions and perspectives of future work will be pointed out.

2 EVAR COST BENEFIT
Comparing EVAR with conventional surgery, the first is preferable due to the fact of being less stressful and reducing significantly systemic complications (Rutherford et al. 2004), as well as having lower costs of inpatient stay and less or no need for intensive care facilities during recovery (Myers et al. 2001; Hayter et al. 2005). While a number of early studies appeared to support this claim, nowadays, data shows otherwise (Rutherford et al. 2004). Shorter stays at both intensive care units and the hospital, reduced use of blood, fewer laboratory studies and fewer resources lead to cost savings, but later, additional cost exist due to surveillance procedures. Currently, EVAR’s surveillance protocol involves imaging at 1, 6, and 12 months after the procedure, and thereafter, on an annual basis (Milner et al. 2006).

The durability of open surgery, established with long-term follow-up studies, is excellent (Rutherford et al. 2004), so good that there is little or no requirement for long-term surveillance.

Hayter (Hayter et al. 2005) compared both hospital and follow-up costs of patients who had undergone EVAR or open surgery and concluded that EVAR costs were higher. One of the justifications presented was the endograft’s high price.

Primary studies describe EVAR as being more economical because the price of the first stent-grafts was lower and excluded surveillance costs. Nowadays, EVAR can be considered cost-effective only for very elderly patients or those with a reduced life expectancy and doubtful for young patients, those who would benefit more from the short hospital stay and early return to full activity.

Considering the longer life expectancies and the rising public expectations for quality of life, EVAR is an attractive treatment. However, its cost-benefit relation can be jeopardized by the requirement of long-term surveillance. In order to reduce and even eliminate these exams, new surveillance technologies are being investigated and the most promising technique identified thus far is remote pressure sensing (Milner et al. 2006).

The authors believe that including sensing capabilities in a stent-graft will benefit EVAR’s future. Yet, that may not be enough. Preliminary results of a recent survey regarding the ideal features of a stent-graft show that attention should be given to the devices adaptability and delivery profile. Another issue that should be considered is the price of the devices: a less expensive stent-graft is desirable.

3 STENT-GRAFT’S USERS
It has been proven that involving users in the medical device development process leads to sundry benefits for manufacturers. Not only they favor product innovation, as they give ideas for new products as well. Knowing the user’s actual requirements and expectations it is possible to reduce development costs by identifying potential
problems in an early stage. Another benefit is the possibility to improve the device’s design, usability and safety (Shah et al. 2007).

Doctors, nurses and patients can be quoted as only few within the myriad of medical devices’ possible users. Besides the variety, each group has a distinctive perspective given the fact the device is used differently and with dissimilar expectations by each of them. Nonetheless, all perspectives are important for the medical device’s success, even if they are competing.

In Shah (Shah et al. 2008) a definition and a classification for medical device’s users are proposed. The authors distinguish medical device user from end-user. The first refers to ‘a person who uses a medical device for the treatment and/or care of him-/her-self or someone else’, while the second refers to ‘a person who is the ultimate beneficiary of the usage of a medical device and who can also be the user of a medical device if using the medical device for him-/her-self’.

In the case of stent-grafts, the medical device user is different from the end-user. While the first are the doctors involved in the treatment and the follow-up of the aortic diseases, the later are the patients that suffer from them.

With stent-graft’s current design, patients only benefit from the protection against the blood pressure. However, if sensing capabilities are added, patients could also gain from less invasive follow-up protocols since imaging exams, and the consequent use of radiation and nephrotoxic contrast agents, would only be performed to confirm an alarm issued by the device. Reduction of costs is also expectable since patients would perform fewer imaging exams and reduce the number of doctor’s appointments to verify the state of the stent-graft. A decrease in the number of visits to the doctor, would eliminate the inherent cost of the appointment, and would also contribute to the reduction of work hours lost by the patient and the person that eventually accompanies him. Ultimately, such device could lead to an improvement of the quality of life since patients would be constantly monitored and a health professional would be warned if a problem occurred.

Stent-grafts are prostheses that are used inside the human body. As most patients are laymen concerning diseases of the aorta, they trust their surgeon to decide which device is best. A stent-graft with sensing capabilities will do more than just protect the artery, it will also transmit data which may make patients feel uncomfortable and ask doctors not to use such a device. Even if a smart stent-graft is cheaper, more efficient and pleases doctor’s, it will only be successful if patients are willing to use it.

Doctors use stent-grafts to treat aortic diseases and, after the endovascular procedure, they have to perform imaging exams to verify both the health of the patient and the performance of the device. If sensing capabilities are added, doctors can learn about the aneurysm behavior after the introduction of a stent-graft. The information gathered could also alert doctors to problems that currently are difficult or impossible to detect, namely graft wear.

Doctors’ involvement is essential for the development of a (smart) stent-graft because they not only know the disease, as well as they can identify potential complications and difficulties with current state-of-the-art treatment solutions.

4 SMART STENT-GRAFT CHARACTERISTICS

A smart stent-graft can be defined as a stent-graft with some in-device mechanism to perform a given function and can communicate with an external element.

Although there is still no commercial device available, it could be decomposed in three elements: a stent-graft, a sensing element and a display, Figure 4. The stent-graft, besides protecting the aneurysm from the blood pressure, has built-in sensing elements that are able to gather information concerning the patient’s health and/or the prosthesis performance. The information gathered is then sent to an external element - a display - and can be used in the patient’s diagnose or in the comprehension of the aneurysm’s sac behavior after the implementation of the stent-graft.

Figure 4: Decomposition of a smart stent-graft.

Like a conventional stent-graft, the novel device will be classified as a class III medical device and, as such, will have to be biocompatible, biostable, non-toxic, non-allergic and non-carcinogenic. Furthermore, it will have to be tolerated by the human body not causing a foreign body reaction or an inflammatory reaction.

Regarding the mechanical requisites, the device should be durable, flexible, tough and yet ductile. Its components should also present resistance to both wear and tear, as well as excellent corrosion resistance.

For a successful protection of the blood vessel, the device should have a design as less invasive as possible in order to minimize flow resistance and pressure drops. Radial force is another relevant feature, not only for stents to stay open without being crushed with muscular activity, but also to provide a good seal and to ensure fixation.

The deployment of the device is a critical step for the procedure’s success, thus, the stent-graft should have a low profile to facilitate the deployment and
minimize lesions in the access arteries. At this stage, radiopacity is also crucial to ensure the correct positioning of the prosthesis.

From the commercial point of view, the device must be capable of being adequately sterilized and stored as an "off-the-shelf" product. A broad range of sizes is desirable since it allows the treatment of a wider array of anatomies.

One of the key questions in the design of a smart stent-graft regards the instrumentation capabilities required. Ideally, the device should be able to monitor its material degradation, detect migration and leakages.

Regarding the transmission of the measured data, the device must be able to transmit the data without any internal power. Moreover, the data cannot interfere with other implants nor be influenced by other electronic signals.

To assure patient’s comfort and even reduce costs, the measurement protocol should be done during the doctor's appointment or at home and the results transmitted to the doctor’s office. Regardless where measurements are taken, the procedure should be quick, the least invasive as possible and avoid any kind of pain or even discomfort.

5 CONCLUSIONS AND FUTURE WORK

A stent-graft with sensing capabilities could help to alleviate the costs associated to EVAR follow-up protocols. Even so, it will not be surprising if, initially, the procedure costs increase since the introduction of new functions usually results in more expensive devices.

The success of the new endoprosthesis will depend on the ability to develop a stent-graft with an excellent performance and a lower price than the existent devices. Another factor that will surely influence the device’s success is its adoption by the medical community. Thus, to effectively address the doctor’s needs, the device must be developed jointly with them.

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7 REFERENCES


