Desired features for a novel stent-graft

Isa C.T. Santos[1,a], Luís A. Rocha[2,b,] and João Manuel R.S. Taveres[1,c]

[1] Instituto de Engenharia Mecânica e Gestão Industrial, Faculdade de Engenharia, Universidade do Porto, Rua Dr. Roberto Frias, s/n 4200-465 Porto, Portugal

[2] Instituto de Polímeros e Compósitos, I3N, Universidade do Minho, Guimarães, Portugal

[a] isa.santos@fe.up.pt, [b] lrocha@dei.uminho.pt, [c] tavares@fe.up.pt

Keywords: Aortic aneurysm, Stent-graft, Artificial organ, Medical device, Product development.

Abstract. Abdominal aortic aneurysms are indolent but deadly. Among the current treatments is endovascular aneurysm repair, a minimally invasive procedure that resorts to a stent-graft to shield the aortic wall from blood pressure. Although this procedure allowed more patients to be treated and offers several other advantages, complications still occur and there is a need for a more efficient stent-graft. Here, the early steps performed in the development of a novel stent-graft are described, and desired features for an 'ideal' device are pointed out. The implementation of these characteristics will lead to a more efficient medical device.

1. Introduction

In 1948, Albert Einstein was diagnosed with an abdominal aortic aneurysm (AAA or triple A), i.e., his aorta had a permanent and irreversible localized dilatation having at least a 50% increase in diameter compared with the normal one [1]. Like him, currently, it is estimated that more than 12 per 100 000 persons-year [2] are affected by this relatively indolent but serious condition.

In an attempt to reinforce the aortic wall and delay the inevitable rupture that took Einstein's life in 1955, Dr. Rudolph Nissen wrapped the visible anterior portion of the aneurysm with polyethene cellophane. Nowadays, more effective treatments are offered, namely open surgery, laparoscopy or assisted laparoscopy, and endovascular aneurysm repair (EVAR). The treatment is selected considering the technology available in the medical center, the anatomy of the aneurysm, the operative risk of repair and the patients' life expectancy.

Open surgery is an invasive procedure in which the diseased segment of the aorta is replaced by a synthetic graft. Total laparoscopy and assisted laparoscopy are two recent minimally invasive procedures with similar purposes to those of open surgery [3].

EVAR was introduced in the early 1990s and is a minimally invasive procedure in which an endoprosthesis, known as stent-graft, is guided from the femoral artery to the affected artery segment. The objective of this procedure is to shield the aneurysm sac from the blood pressure, thus preventing the rupture of the artery wall. Although this technique is associated with advantages such as shortened hospital stays, accelerated recovery and early return to full activity, complications still occur (Table 1), requiring life-long surveillance of patients [4]. The current surveillance protocol involves imaging exams, namely ultrasound and computed tomography angiography (CTA), at 1, 6, and 12 months after the procedure, and thereafter, on an annual basis [3].

The introduction of EVAR revolutionized the treatment of aortic aneurysms by allowing more patients to be treated. However, after 20 years of use, questions are being raised regarding the follow-up costs [5]. Thus, in order to reduce EVAR's follow-up costs that are mainly driven by imaging exams, it was suggested the development of a smart stent-graft, i.e., a stent-graft with some in-device mechanism to perform a given function with communication capabilities to an external

element. Here, the methodology adopted to develop the new device is introduced along with the results obtained during first steps.

Table 1. Usual complications involving stent-grafts (adapted from [4]).

Early complications	Late complications
Graft kink Endoleaks Graft explantation Structural failure Graft infection	Graft migration Neck dilatation Endoleaks Structural failure: component separation, fabric tears, hook fractures

2. Planning the development of a novel stent-graft

The planning of the development of the novel stent-graft followed the product development methodology described by Ulrich et al. [6]. The activities that should be carried out are summarized in Fig. 1.

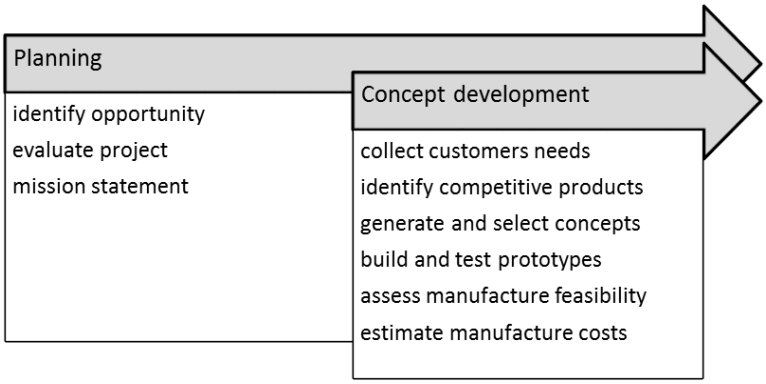

Fig. 1. Planning of the development of the smart stent-graft.

The opportunity had been identified earlier, and it was to reduce EVAR's follow-up costs. Taking into account the incidence rate of AAA and the number of EVARs performed annually, the project was considered attractive. The project's mission statement is presented in Table 2.

Table 2. Mission statement regarding the development of the smart stent-graft.

Product description	A stent-graft with a sensing mechanism to perform a given function (e.g., measure intraluminal pressure) with communication capabilities to an external element
Key business goals	Develop a proof of concept
Assumptions and constrains	Improve the performance of the current stent-grafts applying different materials Apply a flexible sensing technology
Stakeholders	Vascular surgeons and physicians Patients with aortic aneurysms

3. Concept development of a novel stent-graft

With the definition of the mission statement, the concept development stage began. The medical condition (aortic aneurysms) was studied, and the existing stent-grafts and their materials were identified and analyzed [7]. To identify new stent-grafts designs, patents and scientific journals were reviewed.

The requirements for the new device were gathered by reviewing the literature and conducting surveys and interviews. The literature provided information about the disease and its incidence as well as the most common causes of failure in current devices and suggestions for future research. The surveys were administered to patients and healthcare professionals and aimed to identify the stent-graft's characteristics and the customer's willingness to adopt a smart device.

The questionnaire to healthcare professionals was prepared in English and Portuguese and was accessible through the web. Between June 2010 and February 2011, links to the surveys were available in a blog specifically created to divulge the project but no answers were obtained. The link was then sent by email to several vascular surgeons and physicians, and 65 answers were gathered.

The answers came from Europe, North America and Africa, and the majority of the respondents (77%) was never involved in the development of a medical device. The factors considered in the selection of a stent-graft and their relevance are displayed in Fig. 2.

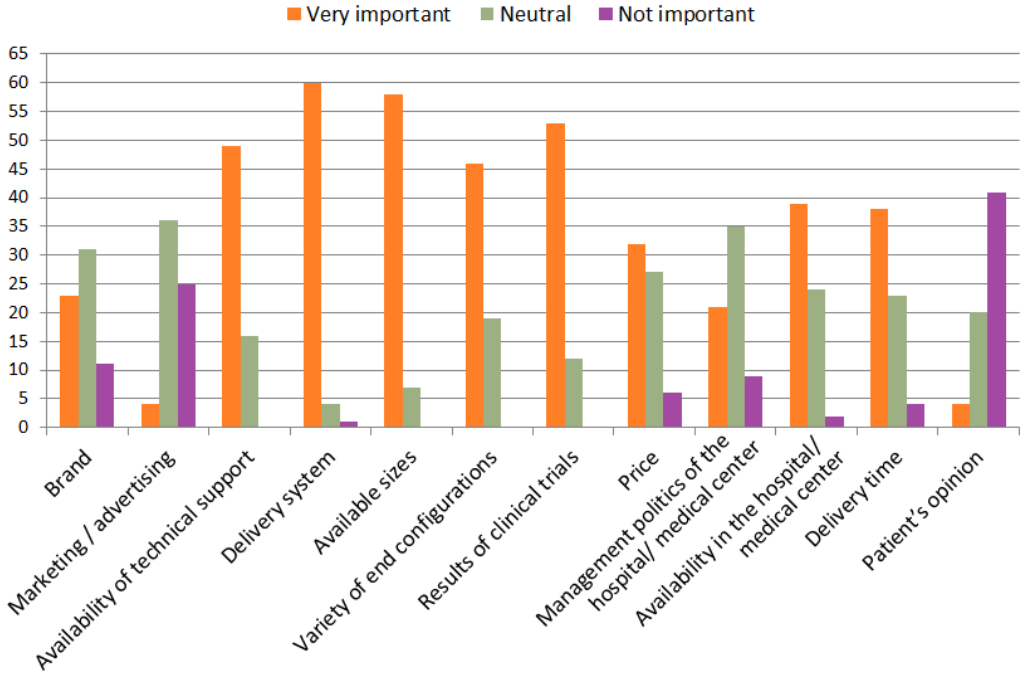

Fig. 2.Criteria considered during the selection of a stent-graft and their relevance.
(Question: When selecting a stent-graft, what is the relevance of the following factors?; Total answers: 65)

To the question "What do you value in a stent-graft?", the respondents answered that they value most flexibility, fixation and the delivery profile (Fig. 3). These answers were consistent with the ones given to the open question "What changes would you introduce in the stent-grafts that you use?".

The respondents of this survey do not follow the current surveillance protocol; they adopted one with different exam periodicities and even diagnostic tools. However, they consider the exam process that they follow effective, reliable and practical (Fig. 4).

As far as the identification of complications is concerned, the results do not indicate a trend (Fig. 5) but the majority of the respondents (83%) considers the use of a smart stent-graft advantageous and would like to obtain information about the stent-graft migration (Fig. 6).

Like the questionnaire to the healthcare professionals, the survey to patients was also prepared in English and Portuguese and was available through the web. The links were also available in the blog, but again no answers were obtained. Thus, three Portuguese hospitals with vascular surgery (H.S. João in Porto, H.U.C. in Coimbra and H.S. Marta in Lisbon) were contacted to administer the survey to their patients. To interact with patients, the three hospitals required that the questionnaire was approved by the Ethics Committee (a process that took about a year to conclude). Upon approval, the patients of H.S. João and HUC were interviewed while waiting for their appointment. In the latter, some surveys were filled during the appointment with a doctor. At H.S. Marta, the surveys were distributed during the appointments by the doctor and the answers returned by postal mail.

From the 87 patients questioned, only 21 had an aneurism in the aorta (either thoracic or abdominal). Every patient said that the surgeon decided the treatment and which stent-graft should be used. Although the majority (86%) was not afraid of performing imaging exams, they feel

uncomfortable while doing them (76%). 95% of the respondents would ask his doctor for a smart stent-graft.

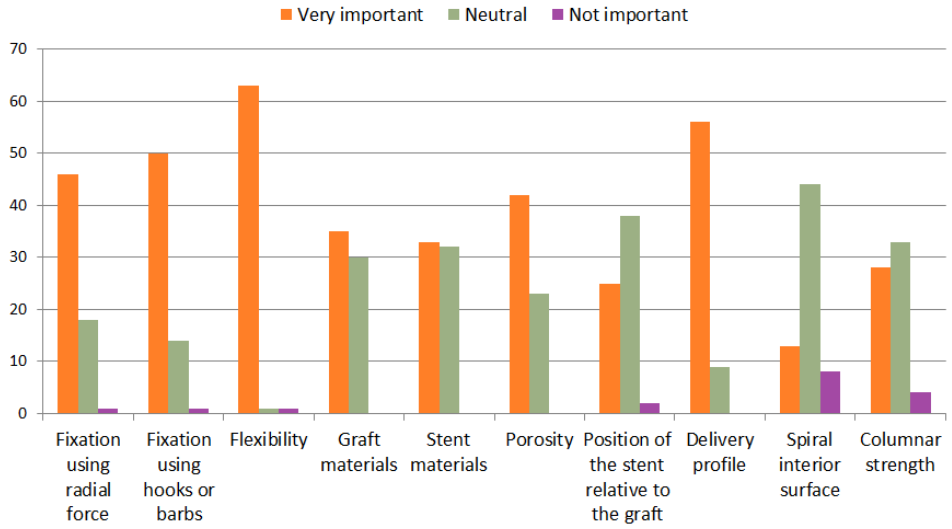

Fig. 3: Valuation of the stent-graft's characteristics.
(Question: What do you value in a stent-graft?; Total answers: 65)

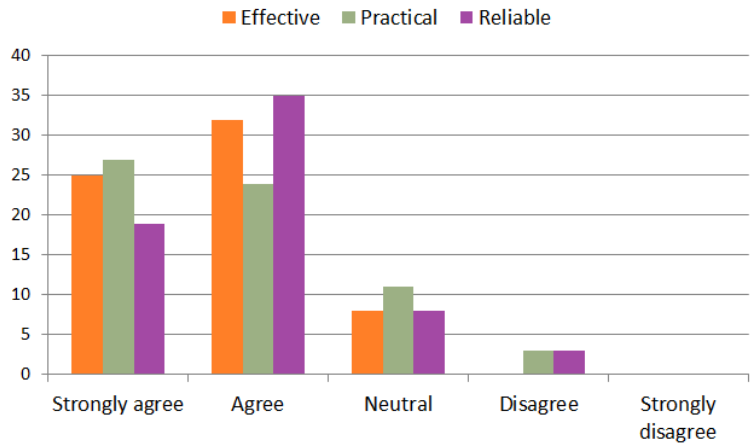

Fig. 4: Description of the EVAR follow-up protocol.
(Question: How would you describe the exam process?; Total answers: 65)

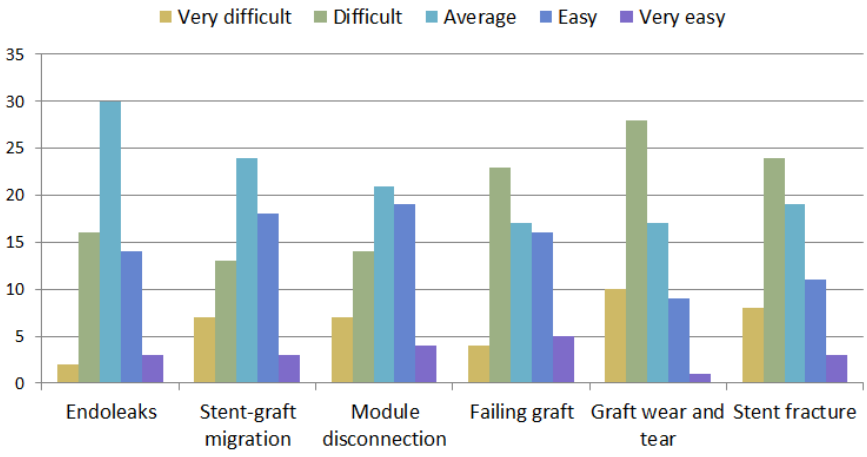

Fig. 5: Difficulty in the detection of complications.
(Question: How would you classify the identification of the following problems?; Total answers: 65)

The requirements gather during the literature review and the surveys were then classified in accordance with the Kano Model [8], [9]; the results are summarized in Table 3.

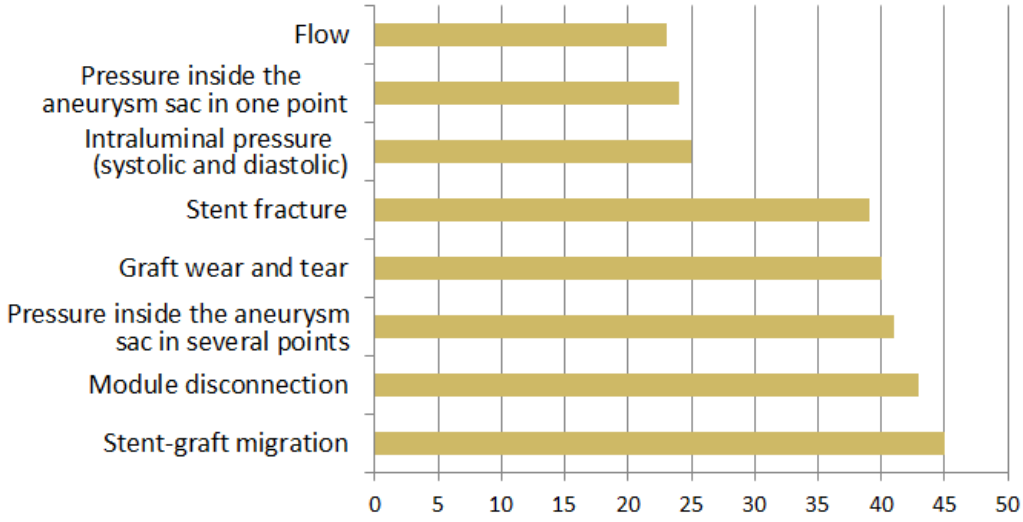

Fig. 6: Information provided by a smart stent-graft.
(Question: Which information would you like to obtain from a stent-graft?; Total answers: 65)

Table 3. Requirements for the smart stent-graft

Must-be	Biocompatible and biostable
	Non toxic, allergic and carcinogenic
	Not cause thrombosis and hemolysis
	Not cause inflammatory reaction or foreign body reaction
	Exceed patient life expectancy
	Flexible, ductile and fatigue resistant
	Stable configuration
	Resistant to corrosion, wear and tear
	Radial force enough to ensure fixation and avoid leaks
	Radiopaque
	Sterilizable
	Storable as an "off-the-shelf" product
	Manufacture environmentally accepted
Satisfier	Zero porosity
	Predictable behavior
	Wide range of diameters and lengths
	Low profile
Delighter	Minimizes flow resistance and pressure drops
	Indicates the intraluminal pressure (systolic and diastolic)
	Indicates the pressure inside the aneurysm sac at several points
	Indicates if stent-graft migrates
	Indicates if module disconnects
	Indicates stent fractures
	Indicates if graft tears
	Indicates blood flow

4. Summary

Although the follow-up costs of EVAR represent a disadvantage to the procedure, they also signify an opportunity to develop a new stent-graft; namely, one that has some in-device mechanism to perform a given function with communication capabilities to an external element. So, the development of the novel device was planned using a product development methodology.

To identify the desired features of the novel device, a literature review was performed, and both patients and physicians were interviewed. Although the patients are the users, they are not usually

involved in the selection of the device adopted; physicians are to the ones that decide which device should be employed.

Physicians are looking for stent-grafts with better flexibility and fixation. As far as the information they would like to receive from the stent-graft, they are interested to know if the device is migrating.

5. Acknowledgement

The first author wishes to thank Fundação para a Ciência e Tecnologia (FCT), in Portugal, for its financial support provided by the grant SFRH/BD/42967/2008.
We would like to thank both the healthcare professionals and the patients that answered our surveys.

References

[1] K. W. Johnston, B. R. Robert, M. D. Tilson, M. S. Dhiraj, H. Larry, and C. S. James, Suggested standards for reporting on arterial aneurysms, *Journal of Vascular Surgery*, vol. 13, pp. 452-458, 1991.

[2] J. J. Ricotta, R. D. Malgor, and G. S. Oderich, Endovascular abdominal aortic aneurysm repair: part I, *Annals of vascular surgery*, vol. 23, pp. 799-812, 2009.

[3] R. Milner, K. Kasirajan, and E. L. Chaikof, Future of endograft surveillance, *Seminars in Vascular Surgery*, vol. 19, pp. 75-82, 2006.

[4] B. T. Katzen and A. A. MacLean, Complications of endovascular repair of abdominal aortic aneurysms: A review, *CardioVascular and Interventional Radiology*, vol. 29, pp. 935-946, 2006.

[5] K. C. Young, N. A. Awad, M. Johansson, D. Gillespie, M. J. Singh, and K. A. Illig, Cost-effectiveness of abdominal aortic aneurysm repair based on aneurysm size, *Journal of Vascular Surgery*, vol. 51, pp. 27-32, 2010.

[6] K. Ulrich and S. Eppinger, Product design and development, 5th ed. McGraw-Hill/Irwin, 2011, p. 432.

[7] I. C. T. Santos, A. Rodrigues, L. Figueiredo, L. Rocha, and J. M. R. S. Tavares, Mechanical properties of stent-graft materials, *Proceedings of the Institution of Mechanical Engineers, Part L: Journal of Materials: Design and Applications*, *in press*.

[8] A. M. M. Sharif Ullah and J. Tamaki, Analysis of Kano-model-based customer needs for product development, *Systems Engineering*, vol. 14, pp. 154-172, 2011.

[9] Q. Xu, R. Jiao, X. Yang, M. Helander, H. Khalid, and A. Opperud, An analytical Kano model for customer need analysis, *Design Studies*, vol. 30, pp. 87-110, 2009.