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Review Article

A Review of Current Trends in Implantable Textile Materials

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Abstract

The article reviews some significant current trends in implantable textile materials. The complication of stent graft-induced new entry (SINE) after thoracic endovascular aortic repair (TEVAR) may be caused by the spring-back force of both ends of the stent grafts. Spring-back force, which is exerted by the curvature and ends of stent grafts on the greater wall of the aorta, suggests poor flexibility. Research on stent graft flexibility via design optimization has been widely disregarded. Thus, this study investigates the relationship between stent graft structure and flexibility by measuring bending and spring back forces. Stent spacing, apex angle and strut configuration were considered for the structural parameters. The overall tendency of spring back and bending forces were similar. The Z-stented graft obtained a lower force than the M stented graft with the same number of struts per hoop. Consequently, optimal flexibility was obtained when the structural design was characterized by long stent spacing, big stent apex angle, and Z-type strut configuration. The study is the first large-scale analysis of new generations of textile endoprostheses. A tendency foraging consisting mainly of compression and abrasion of the fabric with time associated with abrasion of stitches was demonstrated. These lesions might lead to surfaces of cumulated small holes, the consequences of which should be more deeply explored, mainly to explain endotension. Various ageing related phenomena on commercial textile endoprostheses were identified and classified. Main damaging mechanisms were related to compression and abrasion leading to tears and holes in the fabric and rupture of stitches.

Keywords: Aortic Endoprosthesis; Degradation; Endovascular; Graft Flexibility; Stent Grafts; Textile

Introduction

With the advent of effective thoracic stent graft device application, thoracic endovascular aortic repair (TEVAR) technology for thoracic dissection and aneurysm treatment has witnessed fast development [1]. In comparison with open surgery, short and midterm clinical trials appear prospective [2]. But, all long-term results have not been completely fulfilled [3,4]. Hence, more work is required in order to decrease incidences of long-term complications.

One of the major developments in vascular surgery during recent years is the endovascular therapy for thoracic aortic aneurysms, thoraco abdominal aortic aneurysm and abdominal aortic aneurysm [5,6]. The practicability of the procedure has been demonstrated and across the world, this technique has now developed in an increasing number. Though 50% of patients undergo endovascular procedures, the real impact on mortality and morbidity is still uncertain [7,8].

Chanllenges in evaluation of the flexibility of endovascular stent grafts

Despite the effectiveness of rigid thoracic stent grafts for descending thoracic aorta, they are not entirely compatible with the anatomy of the aortic arch [9]. The morphological complexity of aorta arch can result in incompatibility between thoracic aorta and stent grafts, and therefore, pose great problems of bird beak-leading to possible occurrence of endoleak and stent graft collapse [10]. Further, it is necessary that the short angulated necks of abdominal aortic aneurysms have agreat degree stent graft flexibility, stent graft displacement, and kinking can cause limb occlusions [11-13]. Hence, stent grafts need to have flexibility and should be compatible with the host artery [14-18].

Stent graft-induced new entry (SINE) is a new tear formed by the rigid stent graft itself when ends spring back to the preliminary form after they are passively bent along the aorta arch [19,20]. It can either be proximal or distal. Dong *et al.* [19] posited that spring-back force could potentially cause SINE, especially in the proximal end. Proximal SINE was noticed when the oversizing rate was only 3%, and this could decline radial force to the maximum extent. Hence, radial force was disassociated with proximal SINE and instead was considered as the main factor of distal SINE. In general, spring-back force is the force exerted by stent grafts acting on the greater curve when placed in a tortuous arterial anatomy, such as aorta arch and popliteal artery. Till now, no single term measure is used to measure the flexibility of stent graft. Various assessment indexes, like percentage change in diameter, bending force, and spring-back force have been discussed [21,22]. Bending force is the force to bend a stent graft, whereas spring-back force is the force to recover a straight stent graft after bending. Finite element analysis (FEA) or in vitro experimental studies can be used for flexibility evaluation [23].

Flexibility of some seven commercial aortic grafts and luminal reduction rate was assessed using FEA by Demanget *et al* [13]. Most of the FEA studies have focused on stents alone and limited number of studies were conducted on the mechanics of stent grafts.The reasons may be attributed to the complexity of the stent graft, which is a combination of a rigid stent and a soft textile tubular graft [24]. Too many assumptions were proffered to simplify numerical work during the study, but they tend to decrease the result accuracy.

Qualitative and quantitative in vitro experimental studies were also conducted. Singh and Wang related the bending behavior of segmented and plain knit stents by bent configuration observation immediately and bending moment with the free-bending end of the stents at 90° from the stent axis [12]. Percentage change in the diameter at 90°, which correspond to the flexibility of weft-knitted and braided stents was measured by Freitas *et al* [25]. It was suggested by Hirdes et al that measuring the force exerted by the stent from bending to straightening (i.e., spring-back force in this study) is much more meaningful than the force to bend it (i.e., bending force) [26]. Spring-back force was measured by recording the force required to keep the stent at the bending angle of 20° at 20mm from the bending point. However, as load cell foot was not placed vertical to the sample, the force tested was not the real spring-back force. Isayama et al. and Zouet al. used a similar method in the vertical orientation to test the spring-back force of stents and stent grafts [27,28]. However, only the forces under limited curving angles were tested.

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However, evaluating flexibility as a design parameter of stent grafts was not discussed in detail. It is found that the structures of stent grafts and their effects on flexibility have not yet been tested via animal trials. Many perplexities are encountered in designing flexible stent grafts [32]. Hence, a feasibility study on the relationship between the structural parameters and flexibility of stent grafts is necessitated. Findings of the above studies may particularly help to improve Z-stented devices, which is currently a common design of several commercial products. In another study, bending force and spring-backforce were tested by employing a newly designed device under a continuous curving angle. The force tester foot was placed vertical to the surface of the sample. The two forces (bendingand spring-back) served as indicators of stent graft flexibility. Both forces were estimated and compared using stent grafts with different structural characteristics. As a result, the optimal design factor that may affect the flexibility of stent grafts was established.

Proximal SINE as a form of TEVAR complication has engrossed a wide attention. SINE formation can be attributed to stent graft inflexibility. In this study, bending force and spring-back force were used to characterise the flexibility of endovascular stent grafts. The relationship between structural design factors and flexibility was also established. New generation stent grafts can be designed based on the above results. According to findings, long stent spacing, large apex angle, and Z-stented strut configuration are potential structural designs of stent grafts. The results can help engineers to design and improve stent graft structures and guide clinicians on the best types of stent grafts. The best stent grafts are those with excellent comprehensive performance, particularly, high levels of flexibility.

3 New generation endoprosthesis

The objective of the method has been to prevent the risk of rupture by excluding the aneurysmal wall from the systemic arterial pressure. The preliminary study of endovascular aneurysm repair has shown that incomplete seal of the aneurysm is to be taken as a failure of the method,as, in particular cases, it can result in further expansion of the aneurysm having rupture risk. "Endoleak" is the term used to name the this incomplete seal of the aneurysm [33]. The graft-related endoleaks characterized by blood flow into the aneurysmal sac from within or around the graft have been differentiated and termed as type I and III, from nongraftrelated endoleaks characterized by blood flow coming from patent collateral arteries, which have been termed as type II [34,35]. Type IV, oozing through the fabric, and type V, call edendotension, were more questionable concepts.

Devices having various concepts, types of connection, materials for the stents, and the fabrics, have been developed. But, clinical trials on first generation of endoprostheses (EPs) have proved unsatisfactory, with a high rate of graft-related failures [36]. These first observations demonstrated the important role played by the stability of the device on the outcome of the technique.

In early 1990s, the European Collaborative Retrieval Program (ECRP) was initiated in order to analyze the degenerative phenomena occurring on explanted aortic EPs. Researches carried out on the first generation of EPs demonstrated that continuous movements of a grafted aorta and blood pressure enforce permanent stress on the stent frame and the polyester fabrics resulting in frame dislocation of body middle rings in first-generation endovascular stent tubegrafts [37]. It was also found that Nitinol stent degradation and mainly corrosion, was a factor of long-term stability of the EPs [38]. Finally, it was demonstrated that an optimal choice of a woven textile was mandatory for the construction of an EP as the textile properties, such as saturation index, may contribute to the macroscopic lesions observed on the explanted EPs [39].

First-generation EPs have now been replaced by new generation EPs that overcome early graft-related complications [40,41]. However, to date, there are no records available regarding the aging curve of these new implants. Hence, in another study, the mechanisms of degradation of polyethylene terephthalate (PET) textile structure in new-generation EPs explanted from humans was identified and classification of these mechanisms was established.

A preliminary classification of EP degradation mechanisms have been proposed that permits objective assessment of the aging of textile-covered EPs. Aging phenomena related to compression and abrasion resulting in tears, holes and rupture of stitches has been observed [42]. The proposed classification may be modified if further researches on aging increases along with increasing number of explanted devices. Further studies must be performed to better understand factors enhancing delayed textile lesions and EP degradation. This would help to improve material durability and long-term stability.

Conclusion

Problems like endoleaks and SINE cause stent collapse due to incompatibility between thoracic aorta and stent grafts. Research on stent graft flexibility via design optimization has been widely overlooked. Few studies investigated the relationship between stent graft structure and flexibility by measuring bending and spring-back forces. Stent spacing (5, 10, and 15 mm), apex angle (30° and 45°), and strut configuration (Z- and M-stented) were considered for the structural parameters. optimal flexibility was obtained when the structural design was characterized by long stent spacing, big stent apex angle, and Z-type strut configuration. Finite element analysis (FEA) and in vitro experimental studies were used for flexibility evaluation. First-generation EPs have been replaced by new generation EPs that overcome early graft-related complications because of continuous trials.

Sixty-four percent of the samples demonstrated at least one defect caused by compression damage potentially related to the insertion of the EP within the delivery system, which promoted holes and tears. Ninety-five percent of all EPs demonstrated at least one type of abrasion on the stitches. The degradation of the stitches and the number of ruptures increased with duration of implantation. Stent degradation was uncommon and consisted of corrosion and rupture. Cumulated holed surface area increased with time and was measured up to 13.5 mm^2 [42]. Various aging-related phenomena on commercial textile EPs were identified and classified. Main damaging mechanisms were related to compression and abrasion leading to tears and holes in the fabric and rupture of stitches.

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