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Biomechanical implications of excessive endograft protrusion into the aortic arch after thoracic endovascular repair

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ABSTRACT

Endografts placed in the aorta for thoracic endovascular aortic repair (TEVAR) may determine malappositioning to the lesser curvature of the aortic wall, thus resulting in a devastating complication known as endograft collapse. This premature device failure commonly occurs in young individuals after TEVAR for traumatic aortic injuries as a result of applications outside the physical conditions for which the endograft was designed. In this study, an experimentally-calibrated fluid–structure interaction (FSI) model was developed to assess the hemodynamic and stress/strain distributions acting on the excessive protrusion extension (PE) of endografts deployed in four young patients underwent TEVAR. Endograft infolding was experimentally measured for different hemodynamic scenarios by perfusion testing and then used to numerically calibrate the mechanical behavior of endograft PE. Results evinced that the extent of endograft can severely alter the hemodynamic and structural loads exerted on the endograft PE. Specifically, PE determined a physiological aortic coarctation into the aortic arch characterized by a helical flow in the distal descending aorta. High device displacement and transmural pressure across the stent-graft wall were found for a PE longer than 21 mm. Finally, marked intramural stress and principal strain distributions on the protruded segment of the endograft wall may suggest failure due to material fatigue. These critical parameters may contribute to the endograft collapse observed clinically and can be used to design new devices more suitable for young individuals to be treated with an endoprosthesis for TEVAR of blunt traumatic aortic injuries.

1. Introduction

Thoracic endovascular aortic repair (TEVAR) has emerged over the last decade as the preferential minimally invasive therapeutic modality for a variety of thoracic aortic pathologies, including traumatic thoracic aortic injuries [1–3]. TEVAR for traumatic injuries is effective but its outcome remains a concern especially in young patients [4,5]. In these individuals, the endograft is often implanted “off-label”, and device oversizing is essential for fixation at the level of the proximal landing zone [6]. This may ultimately induce to premature device failure and endograft collapse/infolding, which usually requires a secondary intervention by means of re-do TEVAR or conversion to open surgery with attendant high morbidity and mortality [7–10]. The incidence rates of endograft collapse after TEVAR for traumatic injuries are not well defined [8,11], although collapses usually present in the early post-operative period (median time of 15 days) [12]. It has been recently reported that the Gore TAG thoracic endoprosthesis (W. L. Gore and Assoc, Flagstaff, Ariz) accumulated a 0.4% frequency rate of device collapse among 33,000 endografts distributed worldwide [6]. However, collapse rates likely differ for other available endografts.

A number of anatomic- and device-related factors may contribute to endograft infolding including a young healthy aorta with tight aortic arch and marked pulsatility, excessive stent-graft oversizing and material fatigue [8,12,13]. Endograft infolding–related mortality rates of 16.9% for asymptomatic patients and 27.3% for symptomatic patients within 3 years of diagnosis [11,13,14]. Collapses are most often observed when the proximal extent of the endograft is in the transverse arch with malapposition of the

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endograft wall along the lesser curvature of the aorta (the so-called "bird-beak" phenomenon) [9–11,14]. Bird-beaking is not desirable because it exposes the graft undersurface to the force of the bloodstream. However, the bird-beak configuration is not the only determinant of stent-graft collapse, because this phenomenon has not been observed with high frequency in patients with thoracic aneurysms (10.1% of 139 TAG collapses), many of whom can present a proximal bird-beaking in the aortic arch [6].

Although the bird-beak effect is often observed after TEVAR of traumatic injuries in young patients [11], collapses do not occur in all of them. It would be also desirable if these individuals with increased risk for developing such a complication would benefit of ad-hoc endografts to tailor their tight and elastic aortic arch. However, the mechanics of endograft collapse has not been clearly defined yet. The understanding of the mechanisms underlying endograft collapse may lead to the design of new devices for TEVAR in young patients. Therefore, we developed an experimentally-calibrated computational model to study the hemodynamic, wall stress and strain acting on the bird-beak configuration observed in four patients underwent TEVAR. Initially, endograft infolding was measured for different perfusion conditions and bird-beak configurations in a patient-specific phantom model. Then, infolding measurements were used as input for a fluid–structure interaction (FSI) model to tune the endograft mechanical property and then the displacement of the proximal protruded wall of the endograft. Finally, computational simulations were performed to estimate the intramural wall stress and principal strain distributions on the bird-beaking of four young patients underwent TEVAR for traumatic thoracic aortic injuries. The possible causes of endograft collapse are discussed.

2. Methods

The role of hemodynamic loads on the infolding resulting from the bird-beak configuration of a thoracic endograft was explored using a case of a male patient who underwent TEVAR for a traumatic aortic injury, and subsequently developed stent-graft collapse with neurologic complications, as previously investigated by our group [14]. Once a phantom model of the patient aortic anatomy was obtained, the infolding resulting from the endograft deployment was assessed by perfusion testing and then used to calibrate the global mechanical behavior of the endograft implanted in this patient. Finally, the hemodynamic and the strain/stress distributions on the protruded stent-graft wall were predicted for four young patients with mean age of 32 ± 9 years.

2.1. Phantom and flow circuit

To reconstruct the aortic geometry after TEVAR, the post-operative patient's CT scan was segmented using the vascular modeling toolkit VMTK as previously described [15]. Thus, the reconstructed patient-specific aortic geometry was transferred to the Metal Professional (River Road, WI, USA) in order to manufacture a compliant and transparent silicone phantom model. The latter represents a scale 1:1 of the patient's aortic anatomy after endovascular repair. Under no perfusion conditions, scissor-handle forceps were utilized to deploy a 26 mm × 10 cm Gore TAG thoracic endoprosthesis (TAG v1.5, W. L. Gore and Assoc, Flagstaff, Ariz) with partial coverage of left-subclavian artery (LSA) into the phantom aortic arch, as shown by post-operative CT imaging (Fig. 1). Phantom diameter just distal the LSA was 23.6 mm so that an 11% endograft oversizing was obtained according the instruction of use (IFU) provided by Gore. Device deployment determined an excessive stent protrusion into the aortic arch (i.e., bird-beak configuration), which was characterized by a protrusion extension (PE) of 19 mm and an angle (θ) of 24° between the lesser curvature of the aorta and the protruded segment of the stent-graft wall (Fig. 1B). To better explore the endograft mechanical behavior, two additional configurations were investigated with PEs of 13 mm and 24 mm, respectively.

A dynamic flow circuit, which is similar to that developed by Tsai et al. [16] to study aortic dissection, was adopted to evaluate device infolding under controlled hemodynamic conditions. In brief, the flow circuit consisted of four components: (1) a custom-made pulsatile pump, (2) the phantom model with the endograft, (3) a compliance chamber, and (4) a fluid collector, all connected by silicone tubes and plastic connectors (Fig. 1A). Two valves placed at inlet and outlet of the pulsatile pump controlled the flow from the fluid collector to the mock's loop. Stroke volume was imposed through a sinusoidal waveform with stroke time depending on systolic and diastolic duration. The perfusion fluid was a solution of 36% glycerin by volume in water to mimic blood viscosity and density. Systemic pressure was obtained varying the resistance of two adjustable valves (5) placed proximal and distal from the compliance chamber. Pressure was continuously measured at LSA by a pressure transducer (X5072 Druck, GE Measurement and Control) connected to 20 G catheters (6), and thus recorded with LabVIEW software (National Instruments, Austin, TX, USA). For flow measurements, an electromagnetic flow-meter (7) (Optiflux 5300 C, Krohne, Duisburg, Germany) was placed on the plastic tube after the pulsatile pump to estimate inlet flow. Flow was also measured at innominate artery and left common carotid artery by temporarily moving the flow meter from the original position and placing it on the plastic tube of these vessels. During perfusion, endograft infolding was monitored using a high resolution CMOS camera (8) (Evo8050, SVS-Vistek, Seefeld, Germany) with a Nikon Micro-Nikkor lens (AF Micro-Nikkor 60 mm f/2.8D) located on the front of the phantom. Image acquisition and post-processing were performed with the Matlab Image Acquisition Toolbox (The MathWorks, Natick, MA, USA).

2.2. Perfusion settings

To estimate endograft infolding as input for computational modeling, three different hemodynamic scenarios with cardiac outputs of 3, 5 and 7 L/min were investigated for each bird-beak configuration (i.e., PE = 13, 19 and 24 mm). This was performed due to the fact that patient-specific flow and pressure were not available. For the cardiac output of 5 L/min, a physiological flow waveform was imposed with a systemic pressure of 120/80 mmHg, systolic duration of 330 ms and heart rate of 60 bpm. Pump stroke and velocity were varied to simulate the other hemodynamic scenarios: (a) a cardiac output of 3 L/min with heart rate of 60 bpm and systemic pressure of 90/55 mmHg; and (b) a cardiac output of 7 L/min with 70 bpm and 170/100 mmHg. Fig. 1C and D shows flow and pressure profiles measured during perfusion testing. Endograft infolding was evaluated by the device displacement as defined by the displacement change of the bird-beak apex from systole to diastole. This parameter was then used to tune the computationally-derived displacement of the bird-beak configuration.

2.3. FSI computational modeling

The reconstructed patient-specific aortic geometry was exported to GAMBIT v2.3.6 (ANSYS Inc., Canonsburg, PA) for meshing the fluid domain (i.e, the lumen) with ~1 million of tetrahedral elements and the structural domain (i.e, the aorta and bird-beak endograft) with ~300000 quadrilateral elements. Reconstructions and meshing of the aortic anatomy were also performed for the other patients underwent TEVAR. Thus, the proximal bird-beaking