The Effects of Pulsatile Fatigue on *in Situ* Fenestrated Endovascular Stent Grafts Deployed inside a Phantom of an Aortic Aneurysm

[1]Tong Yao, [1]Alicia Ruthrauff, [2]Mark A. Farber, [3]Leonard W. Tse, [4]KT Tan, [5]Gilles Soulez, [1]Martin W. King.
1. College of Textiles, North Carolina State University, Raleigh, NC, 2. School of Medicine, University of North Carolina, Chapel Hill, NC, 3. Division of Vascular Surgery and 4. Division of Vascular & Interventional Radiology, Toronto General Hospital, Toronto, Canada, 5. Département de radiologie, Hôpital Notre-Dame, CHUM, Université de Montréal, Canada.

Statement of Purpose: A fenestration technique is used to treat complex aortic aneurysms when the aneurysm involves visceral arteries such as the renal arteries and deployment of a conventional stent-graft would block blood flow to the kidneys [1,2]. The objective of the present study is to investigate the long term fatigue properties of this technique, by monitoring the performance of stent grafts after being fenestrated by RF puncture and ballooning in an aneurysmal phantom which was then attached to a pulsatile fatigue tester.

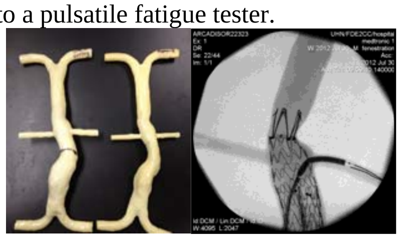

Fig.1 Polyurethane phantoms (left) and stent graft being fenestration under fluoroscopy (right)

Methods: Two Cook Zenith® and two Medtronic Endurant® devices were deployed supra-renally into polyurethane phantoms (Fig.1) based on an actual abdominal aortic aneurysm (AAA) so that the renal arteries were covered. They were then fenestrated under fluoroscopy (Fig.1) at the renal arteries using a radiofrequency puncture device and dilated by either a conventional angioplasty balloon or a cutting balloon. Atrium® covered stents were deployed through the fenestrations. The phantom containing the deployed and fenestrated device were then fatigued on a pulsatile fatigue tester (Fig.2) for 40 million cycles or the equivalent of one year *in vivo*. After fatiguing the stent grafts were examined for evidence of loss of integrity of the graft fabric and enlargement of the fenestrations.

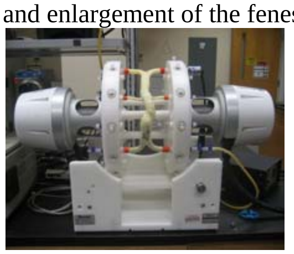

Fig.2 Bose Enduratec Pulsatile Fatigue Tester™ with phantom attached

Results: A significant waist was observed on the Atrium® extensions when a conventional angioplasty balloon was used. All devices showed signs of melted and fused fibers at the edge of the fenestrations (Fig.3). The size of the fenestrated areas was found to be dependent on the stent-graft and the type of balloon catheter (Fig.4). After fatigue testing the extent of fraying was greater with the use of a cutting balloon. None of the fenestration sizes or dimensions increased during fatiguing.

Fig.3 Fenestrated areas

Conclusions: There were changes in the structure due to both fenestration and fatigue but they did not impact the overall integrity of the devices. The type and extent of change were dependent on the material selection, fabric structure, and the fenestration technique. There was no enlargement of the fenestrations due to fatiguing.

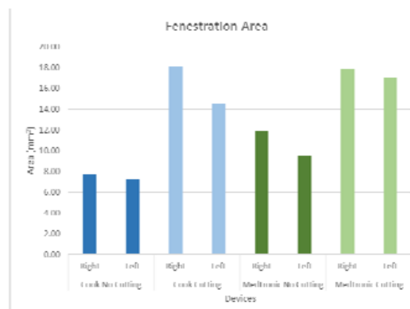

Fig.4 Area after fenestration

Future work: A similar pulsatile fatigue study to evaluate the fenestration technique of thoracic aortic aneurysms (TAA) will be carried out to further investigate the long term stability of using a fenestration technique. Additionally, chimney and sandwich techniques which involve the depolyment of more than one stent-graft in the same aneurysm, are alternative approaches to treating complex aneurysms in the aortic arch or the thoracoabdominal aorta (TAAA)[3]. Similar fatigue tests will be conducted to monitor the long term stability of these techniques.

References:

1. Chuter, T. A. (2007). Fenestrated and branched stent-grafts for thoracoabdominal, pararenal and juxtarenal aortic aneurysm repair. Seminars in Vascular Surgery, 20(2), 90-96.
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3. Lobato A. Sandwich technique for aortoiliac aneurysms extending to the internal iliac artery or isolated Common/Internal iliac artery aneurysms: A new endovascular approach to preserve pelvic circulation. J Endovasc Therapy. 2011;18(1):106-11.