Graft Durability and Fatigue after In Situ Fenestration of Endovascular Stent Grafts Using Radiofrequency Puncture and Balloon Dilatation

L.A. Eadie [a], **G. Soulez** [b], **M.W. King** [a,c], **L.W. Tse** [d,*]

[a] College of Textiles, North Carolina State University, Raleigh, NC, USA
[b] Department of Radiology, Centre Hospitalier de l'Université de Montréal (CHUM), CHUM Research Centre, Department of Radiology, Radiation-Oncology and Nuclear Medicine, Université de Montréal, QC, Canada
[c] College of Textiles, Donghua University, Songjiang District, Shanghai, China
[d] Division of Vascular Surgery, Toronto General Hospital, PMCC, UHN, University of Toronto, Toronto, ON, Canada

WHAT THIS PAPER ADDS

As the technique of in situ fenestration of endovascular stent grafts becomes more frequently used, it is important to understand and characterize the effect of puncture and dilatation on the textile graft material. This manuscript represents the first study of textiles after in situ fenestration techniques that uses a large number of textile specimens, and applies formal textile materials analysis, including fatigue testing. This study demonstrates that the choice of device, and hence textile material, has a significant impact on the effects of in situ fenestration.

Objectives: In situ fenestration of endovascular stent grafts is a technique that is becoming more common, as it has the advantages of decreased cost, increased availability, and more anatomic configuration than other methods of branch revascularization. However, a significant concern is the short- and long-term durability of the stent graft fabric during and after fenestration.
Methods: This study utilizes the textiles analysis techniques of macro- and microscopic imaging, tear strength testing, burst strength testing, and accelerated cyclic fatigue testing on the fabrics of the Cook Zenith, Medtronic Talent, and Medtronic Endurant stent grafts (three polyester grafts), as well as two different expanded polytetrafluoroethylene (ePTFE) membranes. Specimens were punctured using radiofrequency, and serially dilated with angioplasty balloons (3, 5, and 7 mm). For each type of fabric, three groups were analyzed: control, radiofrequency (RF) puncture only, and balloon dilated.
Results: A total of 110 specimens were analyzed, with 80 of them having been fenestrated. The Zenith fabric had the greatest strength after fenestration, but was limited by the inability to fully dilate the fenestration with the conventional balloons, which only achieved 26—29% of their nominal balloon diameter. While the Talent and Endurant grafts could be dilated with balloons, the orifices were markedly elliptical not circular. After accelerated fatigue testing, there was an increase in the size of fenestrations of the Talent fabric. There was no increase in fenestration size for the Endurant fabric, Zenith fabric, or the ePTFE fabrics, after fatigue testing.
Conclusions: While the Zenith fabric was the strongest both before and after fenestration, it requires further study with cutting balloons to achieve full-sized fenestrations. All fenestrations remained stable during fatigue testing except for the Talent fabric. This study serves as the baseline for future studies that will include stent grafts, branch stents, and cutting balloons.

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INTRODUCTION

In situ fenestration is a technique that enables a conventional aortic stent graft to be used in locations where branches arise that cannot be sacrificed. The technique involves deploying the main aortic device, then puncturing the graft fabric in situ adjacent to the target branch. This puncture is then stretched to the desired size using angioplasty balloons. This has been used with good success in a "retrograde" fashion for the great vessels of the aortic arch.[1–6] It is also being developed for antegrade fenestration for repair of juxtarenal aortic aneurysms.[7–9] While off-the-shelf fenestrated devices are being developed, their clinical use is still very early and limited. When compared to custom fenestrated devices, the technique has much lower cost, much greater availability, no waiting period, and possibly more accurate fenestrations. When compared to

* Corresponding author. L.W. Tse, Division of Vascular Surgery, Toronto General Hospital, PMCC, UHN, Eaton Building 6—220, 200 Elizabeth Street, Toronto, ON M5G 2C4, Canada.
E-mail address: leonard.tse@utoronto.ca (L.W. Tse).
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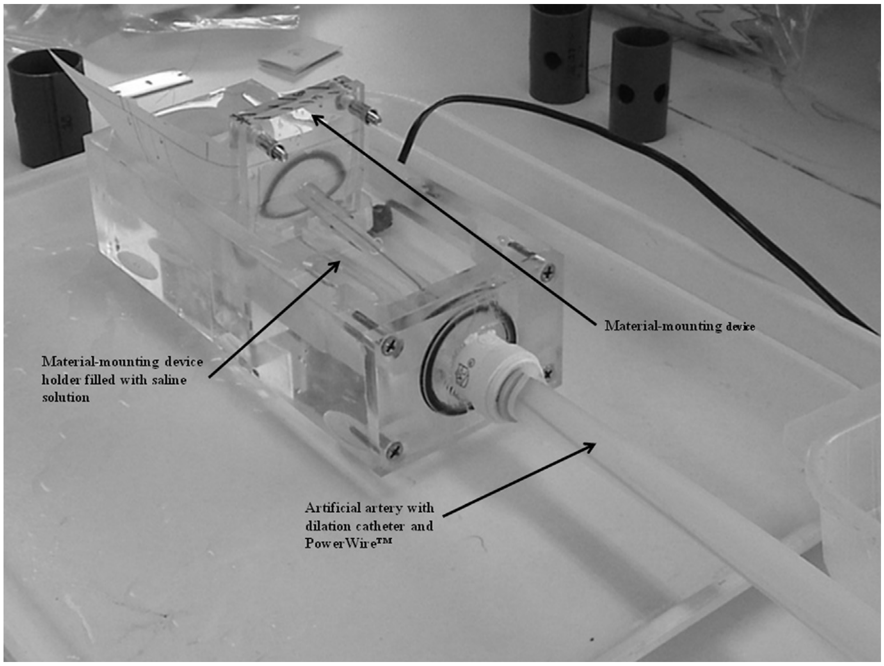

Figure 1. Radiofrequency puncture set-up used on flat material specimens.

hybrid techniques, the technique maintains an anatomical configuration and can decrease the operative time. The physician also has the option to use the aortic stent graft device with which they are familiar, or use the technique as a bailout for inadvertent branch coverage.

While the feasibility of in situ fenestration has been demonstrated,[1–9] a comprehensive assessment of the changes to, and the durability of, the fabric graft component as a result of this technique has not yet been undertaken. The goal of this study was to assess the mechanical integrity and fatigue resistance of these fenestrated fabrics.

METHODS

Materials

Five different endovascular stent graft materials were studied: (a) the multifilament tubular woven polyester fabric used in the Cook Zenith device (Atex Technologies, Pinebluff, NC, USA); (b) the multifilament plain woven tubular polyester material used in the Medtronic Endurant device (Medtronic, Ontario, Canada); (c) the monofilament twill woven polyester material used in the Medtronic Talent device (Sefar, Depew, NY, USA); and two different types of expanded polytetrafluoroethylene (ePTFE) membranes referred to as (d) conventional and (e) prototype (Zeus Inc., Orangeburg, SC, USA). The “conventional” ePTFE membrane was equivalent to the material used to construct the W.L. Gore Excluder device.

Fenestration technique and equipment

The woven fabrics were radiofrequency (RF) punctured, at a standard 90-degree angle to the graft, using the Baylis Medical Research RF generator (Baylis Medical, Mississauga, Canada) in conjunction with the PowerWire Radiofrequency Guidewire (Baylis Medical) as proposed previously.[9] The generator had the following settings: modulation, 1 Hz; duration, 1 s; duty cycle, 100 ms; and voltage, 270 V_{rms}. Although the same settings were attempted on the ePTFE membranes, these materials required RF puncture using a Valleylab Force FX RF generator (Covidien, Boulder, CO, USA) in conjunction with the same PowerWire Radiofrequency Guidewire. While needle and laser puncture have been described, we have found radiofrequency puncture to be the easiest and most versatile.[9] All RF puncture procedures were performed in a 0.9% saline solution at room temperature in a customized flat material mounting device designed and built specifically for this procedure. Subsequent to RF puncture, the samples designated for dilation were sequentially balloon expanded using 2.5 mm, 5 mm, and 7 mm nominal diameter Medtronic Sprinter Legend angioplasty balloons (Medtronic, Santa Rosa, CA, USA) (Fig. 1). Inflation was by manometer to a pressure of 1 MPa (10 atm) (above nominal pressure and below rated burst pressure for each balloon).

Macroscopic and microscopic analysis

The fenestrated specimens were examined macroscopically for changes to the fabric and membrane structure. Photographs were taken using a Pentax Optio P70 camera. Microscopic evaluation of the areas surrounding the fenestration sites was performed using a stereoscopic zoom microscope (Nikon SMZ1000) at magnifications in the range 8–80×. Scanning electron microscopy (SEM) was performed on the unfenestrated ePTFE membranes to characterize their surfaces and to determine their internodal distances (INDs). The IND helps describe the structure of an ePTFE membrane, and is the length, in micrometers, between clumps (nodes) that are connected by