The Development of In Vitro Abrasion Test Method for Textile and Metal Components of Endovascular Stent Grafts

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Statement of Purpose: Abdominal aortic aneurysms (AAA) and thoracic aortic aneurysms (TAA) are localized dilations of the abdominal aorta and thoracic aorta respectively. They are the thirteenth leading cause of death in the United States [1]. Implantable endovascular stent-grafts have become routine devices for the treatment of abdominal and thoracic aneurysms [2]. The endovascular stent-graft consists of a tubular flexible non-permeable graft fabric or membrane and a rigid stent [3]. Given that such devices are permanent implants, the question of long-term biostability needs to be addressed. Examples of explanted specimens indicate that in certain cases premature failure is caused by the abrasive action that can occur between the textile graft fabric and the metallic stent [4-6].

Methods: An *in vitro* abrasion test method for the graft fabric and metal stent material of an endovascular device has been developed in this research study. This modified abrasion tester enables a stent wire abradant to abrade against a strip of graft fabric material under either a wet or a dry environment to mimic *in situ* abrasive motion.

Three endpoints, number of abrasive holes, number of broken yarns and the loss of breaking strength, were established to determine the fabric's abrasion resistance after a certain number of abrasion cycles. Two types of graft fabric materials, multifilament polyester fabric and monofilament polyester fabric, and two types of stent materials, laser cut nitinol stent and regular round section nitinol stent wire, were evaluated under dry and wet environments using the developed abrasion tester.

Results: Firstly, the number of holes and broken yarns of the multifilament polyester fabric under wet conditions were the same as in the dry state, while more of these defects were observed for the monofilament polyester fabric when wet compared to the dry condition (Fig. 1). Secondly, the breaking strength of both fabrics were lower when wet (Fig. 2). Thirdly, the number of broken yarns created in the multifilament polyester fabric was smaller than that for the monofilament polyester fabric. Additionally, the strength loss of the multifilament polyester fabric was smaller than that of the monofilament polyester fabric (Fig. 2). Finally, the laser cut nitinol stent created more holes and broken yarns in both fabrics than the regular nitinol stent wire. However, as the same time both fabrics unexpectedly lost more strength when abraded by the regular stent wire rather than the laser cut nitinol stent.

Conclusions: In conclusion, this test method was useful in testing abrasion resistance of the components in endovascular stent grafts. The abrasion resistance of both fabrics was lower in a wet environment compared to being tested dry. Additionally, the multifilament polyester fabric had better abrasion resistance than the monofilament polyester fabrics. The laser cut nitinol stent was more aggressive in creating holes and broken yarns in both fabrics, while the regular nitinol stent wire caused more fabric strength loss. These conclusion have led to the recommendation of a new in vitro stent-graft abrasion test method for endovascular devices which include the use of this abrasion tester operating for 7,200 cycles (1 hour) under wet conditions and using the three endpoints described above.

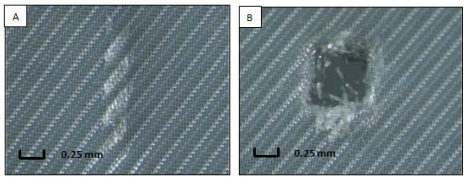

Figure 1. Stereomicroscopic images of abrasion holes after 7,200 cycles: monofilament polyester sample tested with a laser cut nitinol stent under dry conditions , A: 40x, and wet conditions, B:40x.

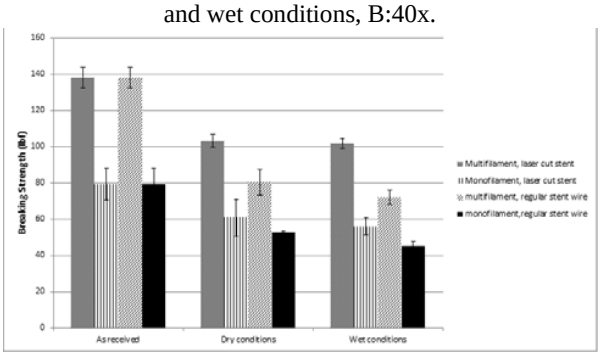

Figure 2 Mean breaking strengths for the multifilament and monofilament polyester samples before and after 7,200 abrasion cycles under dry and wet conditions

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