

Shore OO Hardness Measurement of Bovine Aorta and Mock Vessel Materials for Endovascular Device Design

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Abstract. Endovascular stent-grafts must seal in order to successfully exclude an aneurysm and prevent rupture. This sealing is dependent on how well the self-expanding stent-graft devices embed within the tissue of the vessel wall. The degree of embedding in the vessel wall is dependent on the hardness, or resistance to indentation, of the material. However, while a recognised experimental test procedure involves deploying the device into a mock vessel which is representative of human aorta, the hardness of the mock vessels is not considered and the hardness of healthy aorta has not been determined. This may lead to incorrect design decisions being made regarding the strength of the devices necessary to form a seal. The present work presents the results of Shore OO hardness testing carried out on healthy bovine aortic tissue samples and a comparison with the mock vessel materials silicone sponge rubber and room-temperature-vulcanising rubber. The results show that healthy bovine aorta has a mean Shore OO hardness of 41, in comparison with silicone sponge rubber (sheet) - 48, silicone sponge rubber (tube) - 56 and room-temperature vulcanising rubber - 82.

Introduction

Endovascular stent-graft devices have emerged as a less-invasive alternative to open surgical repair in the treatment of aortic aneurysms [1]. These devices, consisting of superelastic nitinol stents attached to polyester or PTFE graft material, are compacted into a small sheath and advanced to the aneurysm site within the aorta through a cut in the femoral artery. The devices are then positioned at a healthy “sealing neck” of vessel and deployed, with the superelastic nitinol enabling the stents to self-expand. If the device successfully embeds within the healthy vessel then a seal is formed which channels the blood flow through the graft, away from the diseased tissue and prevents the aneurysm from rupturing. Therefore, the hardness, or resistance to indentation [2], of a vessel is a key parameter in determining whether or not a device will seal.

The current trend in endovascular devices is a move towards lower profile delivery systems, which are less invasive to patients and can be advanced through narrower arteries [3,4]. However, straining the nitinol to a higher level can result in the onset of plasticity and a loss of radial force [5], which may result in the device not embedding sufficiently to form a seal. Testing of new devices is often carried out using bovine aorta, due to its similar material characteristics to less freely available human aorta [6]. Nevertheless, bovine vessel can be difficult to size appropriately and can degrade during testing at body temperature, leading to difficulty in isolating the effect of device design changes. Therefore, development of the next generation of endovascular devices requires information on the material characteristics of aortic tissue, including hardness, so that a suitable vessel material for testing can be found.

This present work details the characterisation of the Shore OO hardness properties of bovine aorta and a range of synthetic materials which are commonly used in the testing of endovascular devices, with the aim that the data be used in finding an alternative material to animal or human tissue for experimental testing.

Materials

Bovine aorta was sourced from a local abattoir and cleaned and prepared prior to testing. All testing was carried out within an hour of harvesting the aorta to prevent spoiling. Silicone sponge in flat and tubular extrusion form was obtained with a density of $200 \pm 40 \text{ kg/m}^3$, along with Ditto® Clear Mold Rubber, a castable room-temperature-vulcanising (RTV) rubber material commonly used in the creation of mock vessel models. The bovine aorta and tubular sponge samples were cut to produce samples suitable for hardness testing. Eight samples of each material were prepared, and as per ASTM D2240 [7], samples with thicknesses greater than 6mm were chosen for testing.

Methodology

The hardness testing was carried out using a Checkline® AD-100 Precision Shore OO Durometer and RX-OS-4H-E test stand, pictured in Fig. 1. Test samples were held flat by applying a small amount of glue at the edges of the test sample, on the face opposite the test face. The distance, D, from the samples to the presser foot of the durometer was set for each sample such that the durometer could fully contact the sample (Fig. 1). Following ASTM D2240 [7] guidelines, 5 determinations of hardness were made for each test piece, at a distance of 6mm apart. The hardness value was noted at 1s, 5s and 15s to determine any viscoelastic effect, with the values at 15s used to calculate a mean, maximum and minimum Shore OO value for each material.



Figure 1 – Left: Checkline® AD-100 Precision Shore Durometer and RX-OS-4H-E test stand, Right: Distance from test piece to presser foot

Results

The results of the hardness testing are summarised in Table 1.

Material	Thickness Range [mm]	Min. Shore OO Hardness [units]	Max. Shore OO Hardness [units]	Av. Shore OO Hardness [units]	Viscoelastic Creep [Y/N]
Bovine aorta	6.29-7.31	39	46	41	N
Silicone sponge (sheet)	6.02-6.15	46	50	48	Y
Silicone sponge (tube)	6.06-6.58	52	59	56	Y
Ditto® Clear Mold Rubber	6.41-7.80	77	84	82	N

Table 1 - Shore OO Hardness Testing Results

Discussion

The Shore OO hardness of the rubber materials is higher than that of healthy bovine aorta. Of the synthetic alternatives, the sponge rubber was found to be the closest to the hardness of healthy bovine aorta. Therefore, a stent deployed within silicone sponge of density $200\pm 40 \text{ kg/m}^3$ will embed most similarly to a stent deployed within healthy bovine aorta. The sponge material exhibited viscoelastic creep, reducing 1-2 units in the 15s measurement window before stabilising, while the other materials tested showed no viscoelastic response to the indenter test.

Conclusion

The hardness of healthy bovine aorta, which has similar material characteristics to human aorta, lies in the Shore OO range. Meanwhile, the RTV rubber material, commonly used in endovascular device testing, is harder and provides an unrepresentative environment for seal testing. Silicone sponge rubber, however, is significantly closer to the hardness of bovine aorta and is therefore more suitable for use in endovascular device testing. A limitation of this study is the absence of samples of harder diseased or calcified aorta which would commonly be found in-vivo and would represent worst case conditions for device testing. This is considered to be an area of future work.

References

- [1] The United Kingdom EVAR Trial Investigators: *Endovascular versus Open Repair of Abdominal Aortic Aneurysm*, The New England Journal of Medicine, Vol. 362, No. 20 (2010), p.1863-1871.
- [2] J. Hannah and M.J. Hillier: *Applied Mechanics*, Third Edition, Pearson United Kingdom (1995).
- [3] G. F. Torsello, M. Austermann, H. K. Van Aken, G. B. Torsello and G. Panuccio: *Initial Clinical Experience with the Zenith Alpha Stent-Graft*, Journal of Endovascular Therapy, Vol. 22, No. 2 (2015), p. 153-159.
- [4] M. Mehta, F.E. Valdés, T. Nolte, G. J. Mishkel, W. D. Jordan, B. Gray, M. K. Eskandari and C. Botti: *One-Year Outcomes from an International Study of the Ovation Abdominal Stent Graft System for Endovascular Aneurysm Repair*, Journal of Vascular Surgery, Vol.59, No. 1 (2014), p.65-73.
- [5] N. Rebelo, X. Y. Gong, A. Hall, A. R. Pelton and T. W. Duerig: *A Material Model for the Cyclic Behaviour of Nitinol*, Proceedings of the International Conference on Shape Memory and Superelastic Technologies SMST-2010 (Springer), ISBN 978-1-4614-0197-1, p. 605 – 612.
- [6] J.A. Kratzberg, J. Golzarian and M.L. Raghavan: *Role of Graft Oversizing in the Fixation Strength of Barbed Endovascular Grafts*, Journal of Vascular Surgery, Vol.49, No. 6 (2009), pp.1543-1553.
- [7] ASTM D2240-15: *Standard Test Method for Rubber Property – Durometer Hardness*.