

QUANTIFICATION OF AORTIC VALVULOPLASTY CATHETER SIZE USING A METROLOGY SYSTEM BASED ON BRIGHTFIELD MICROSCOPY

R. Aviles-Espinosa^{1, *}, H. Dore¹, T. Williams², and E. Rendon-Morales¹

¹University of Sussex – School of Engineering and Informatics, BN1 9QT, United Kingdom

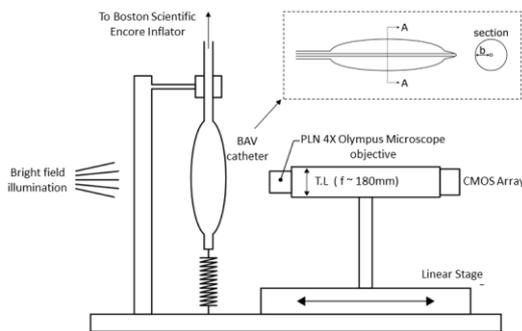
²Brighton and Sussex Medical School, BN1 9PX, United Kingdom

* R.Aviles-Espinosa@sussex.ac.uk

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1. ABSTRACT

Balloon aortic valvuloplasty (BAV) has been employed [1] as a simple and low-cost treatment method for patients with severe aortic stenosis, for symptom palliation in patients considered inoperable, for aortic valve replacement and to select the proper transcatheter heart valve (THV) size. During THV implantation choosing the correct balloon size is paramount for minimizing the risks of coronary occlusion, annular damage or THV embolization. Current methods for selecting the proper balloon dimensions are based on transesophageal



echocardiography and computed tomography requiring trained staff for image interpretation, expensive equipment and high doses of patient radiation exposure. Alternative methods propose the use of BAV to determine the correct THV size before its implantation [2]. The strategy is based on determining the BAV aortic anulus using a sterile caliper. Any slight pressure to the balloon may compromise the measurement accuracy.

In this paper, we present a non-contact metrology system for BAV measurement based on bright field microscopy (BFM). The balloons under test (MedTek-22 and TrueDilation-22) were clamped vertically, employing a tension spring to restrict movement and ensure perpendicularity to the microscope optical axis. The BFM is based on an Olympus PLN 4X WD~18.5mm, NA 0.1, a tube lens (f~180mm) and a FL3-U3-13S2M-CS camera mounted on top of a custom-made linear stage having a coarse resolution of ~ 3.3 μ m. Balloon expansion was performed using a Boston scientific Encore 26 inflation device. The balloons are made up of an outer shell with an internal catheter tube (\varnothing ~2mm). By focusing the microscope on the internal tube, then moving the linear stage to refocus on the balloon outer wall, the inner tube to outer wall dimension (see figure inset) can be accurately measured using the linear stage digital readout. The balloon was inflated up to six times recording the pressure and radius at each stage of inflation (twice the amount required for THV). Our non-contact method preserves the catheter sterile conditions and allows the accurate measurement of the BAV anulus showing: a) repeatability of the achieved balloon radius within all the inflation rounds, b) accurate measurements with a standard error of ± 200 μ m c) and a variation of 1.38 ± 0.0387 mm from the manufacturer data. Knowing the exact balloon dimensions is crucial for avoiding the adverse consequences of THV oversizing. Our method may potentially improve the safety and efficacy of THV implantation.

2. REFERENCES

- [1] Criber et al, "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis," *Circulation*, **106**, 3006-3008 (2002).
- [2] Babaliaros et al, "Use of balloon aortic valvuloplasty to size the aortic anulus before implantation of a balloon-expandable transcatheter heart valve," *JACC*, **3**, 114-118 (2010).