Understanding Different Inflated Balloon Catheter Behaviours via Computational Modelling

Junke Yao, Giorgia Bosi, Gaetano Burriesci and Helge Wurdemann

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J. Yao[1], G.M. Bosi[1], G. Burriesci[1,2], and H. Wurdemann[1]

[1]*Mechanical Engineering, University College London, UK*
[2]*Bioengineering at Ri.MED Foundation, Palermo, Italy*
junke.yao.19@ucl.ac.uk

INTRODUCTION

Balloon aortic valvuloplasty (BAV), a minimally invasive intervention, uses a balloon catheter to dilate the narrowed aortic valve as pre-dilatation or post-dilatation during the treatments of aortic stenosis. However, the instability of the inflated balloon by blocking the pulsating blood flow and the cardiac contraction causes the risk of tissue damage. Although a technique named rapid ventricle pacing (RVP) has been introduced to reduce the cardiac output for balloon stabilisation during its inflation, RVP is still associated with several complications. Several studies have introduced new balloon designs with considering non-occlusive configuration to improve the stability of the balloon catheter [1], [2], but sufficient data and understanding of their clinical outcome is still required. Therefore, using a commercially available valvuloplasty balloon catheter to achieve stability and avoid the use of RVP is worth to be investigated. In this study, to study the level of balloon inflation that allows for its stabilization during heart systole, a Finite Element (FE) model of the balloon catheter is created to simulate inflation and deflation procedures. Then, a Fluid-Structure Interaction (FSI) model is used to simulate how the displacement of the balloon along the aortic root varied by the different internal volumes under the blood flow.

MATERIALS AND METHODS

A. Simulation Models

The numerical model was created based on an Edwards 9350BC23 balloon catheter (Edwards Lifesciences, Irvine, USA), which is a standard shape balloon catheter. The inflated unstretched balloon diameter was 20.75 mm with a total length of 79.6 mm, whose tapered ends were attached to the catheter shaft. The 2.8 mm catheter was curved to the upper wall of the aortic arch (Fig. 1). The materials of the balloon and the catheter were modelled as isotropic, linear elastic with Young's modulus of 600 MPa and 1 GPa, Poisson ratio of 0.45 and 0.4 and density of 1256 kg/m^3 and 1100 kg/m^3, respectively[3]. The idealised aortic arch was designed with a diameter of 25 mm and a thickness of 1.5 mm, where a 100 mm straight section was regarded as ascending aorta ending with an arch of 50 mm radius, assumed as a rigid body. The blood flow was assigned as a Newtonian incompressible fluid having a density of 1060 kg/m^3 and a dynamic viscosity of 4.0×10^{-3} Pa $\cdot$ s.

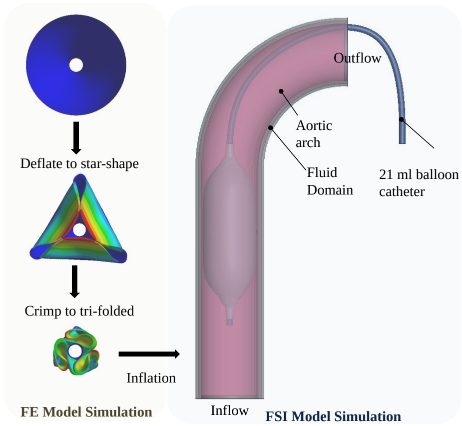

Fig. 1 Simulations of FE model and FSI model

B. Simulations of Balloon FE Model

To describe the deflation and inflation procedures, the balloon was crimped to a tri-folded configuration and then inflated to its nominal internal volume (21 ml). Suction pressure (1 atm) was applied on the surface of the balloon to form a star-shaped configuration and then an iris mechanism was used to crimp the balloon into a tri-folded state as shown in Fig. 1. Subsequently, the unloaded deflated balloon model was imported to investigate the inflation process by applying pressure until reaching its nominal volume. During the whole procedure, the ends of the balloon were constrained in three directions.

C. Fluid-Structure Interaction Simulation

The unloaded balloon models with different internal volumes were imported into an FSI model, where the inlet boundary as a parabolic velocity profile with 1.3 m/s maximum value at the systole peak and zero pressure outlet boundary are used for the fluid domain. The simulation time was set to 0.2 seconds, which was close to the time of systole.

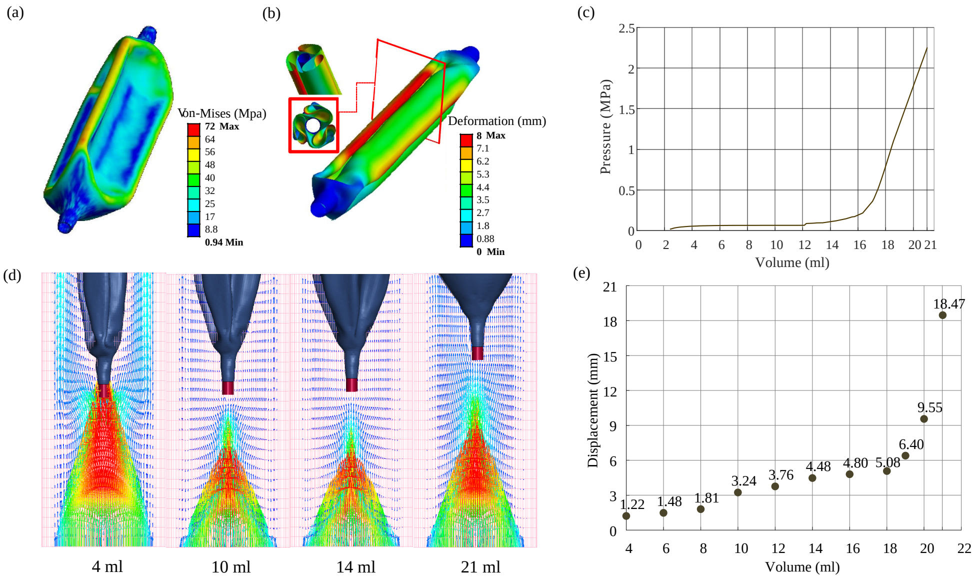

Fig. 2 Simulation results. (a)The von Mises stress distribution of deflation via pressurization; (b)The deformation of the tri-folded configuration; (c)The pressure-volume curve of the inflation simulation; (d)The velocity distribution with different internal volume; (e)The change of the maximum displacement by the increase of the internal volume.

RESULTS

During the deflation simulation, the ratio of kinetic energy to the total internal energy remained lower than 5%, which ensured that the internal forces were negligible and no unrealistic dynamic effect occurred. The balloon model was firstly deflated to a star shape with maximum von Mises stress 72 MPa at the end of the simulation (Fig. 2(a)). Then the balloon was crimped as tri-folded with 9 mm diameter in Fig. 2(b), which had an internal volume of 2.16 ml as the potential residual fluid. For the inflation procedure, the internal volume balloon reached 21 ml at the end with a diameter of 23.3 mm. The internal volume varied with the applied pressure is shown in Fig. 2(c), where the volume increased during a low value of the pressure until it reached 12 ml and it required higher applying pressure to have the same increment of the volume after 16 ml. FSI simulation has ten inflation levels simulated: 4 to 20 ml with 2 ml increment, and 21 ml. In Fig. 2(d), it shows the velocity distribution from the inlet section to the middle of the aortic straight part at 0.9 s, where the flow velocity reaches the highest value of 1.225 m/s and the displacement of 21 ml balloon is obviously larger than others. The maximum displacement verse volume is plotted in Fig. 2(e), where the displacements are 1.22, 1.48 and 1.81 mm for 4 to 8 ml and shows a jump from 8 to 10 ml (3.24 mm). For the 20 ml balloon, the maximum value jumps to 9.55 mm and increases to 18.47 mm for the 21 ml balloon.

DISCUSSION

A successful process for the FE model of balloon catheter deflation and inflation operations, as well as FSI simulations for the interaction between a balloon catheter and blood flow, were described in the current study. The pressure-volume curve of the numerical balloon model inflation shows a similar trend with experimental data in a previous study [4]. For the FSI model, the maximum displacement has two jumps when increasing the inflation level from 8 to 10 ml and 18 to 20 ml. These sudden increases in balloon displacement show that there is a volume threshold permitting the balloon to cause considerable displacement and another amount that forces the balloon's displacement to expand abruptly in Fig. 2(e). The small value (<1.5 mm) of the displacement can be inferred that the balloon in this situation is relatively stable. Therefore, by regularly deflating the balloon to a 'safe volume' (i.e. <10 m) during systole and inflating it to the nominal volume to induce valve expansion during diastole several times until successful dilatation, it is possible to achieve stabilisation while avoiding the complications associated with RVP. To the authors' knowledge, this model is the first attempt to use FSI modelling with two-way strong coupling to simulate a balloon catheter and aorta under realistic loading conditions. In the future, incorporating the aortic sinus and leaflets to give the different blood pressure on the balloon will allow the simulation to be more accurately represented.

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