INTRODUCTION

Surgical treatment of severe functional mitral regurgitation (MR) often involves mitral annuloplasty, a procedure where a flexible or rigid annuloplasty ring is used to downsize the dilated mitral valve annulus (MA) and improve leaflet apposition by posterior annular correction. Recently various minimally invasive percutaneous transvenous mitral annuloplasty (PTMA) devices have been tested in patients who are not suitable candidates for a surgical procedure involving a thoracotomy. The approach is based on the concept that by utilizing the parallel location of the coronary sinus (CS) to the mitral annulus, a device, that can reshape the annulus, can be percutaneously deployed within the coronary sinus (CS) and the great cardiac vein (GCV). When the implanted device deforms, it shortens the MA anterior-posterior dimension and decreases mitral regurgitation (MR) (Fig. 1). Although the approach has been shown to be promising, PTMA device dysfunction and fatigue fracture have been reported in several first-in-human clinical trials (1). We hypothesize that quantitative understanding of the biomechanical interaction between the venous tissue, the mitral apparatus, and the PTMA device can improve the efficacy of the PTMA treatment of MR. In this study, we aim to model interactions between the PTMA proximal anchor and the CS using computational tools.

MATERIALS & METHODS

**Modeling of proximal anchor stent of PTMA device.** Details of the proximal anchor design in 2D drawings and 3D crimped geometry were reported previously (2). Multiple steps of expansion-annealing, to expand the anchoring stent from its initial laser-cut tube (~2.0 mm in diameter) to a final diameter of about ~15.0 mm (Fig. 1-a), are simulated. Two types of Nitinol materials adopted from Kleinstreuer et al. (3) are utilized in the simulations. The Nitinol material parameters are listed in Table 1. It can be seen that Nitin-1 is stiffer than Nitin-2.

**Modeling of the CS.** Mechanical properties of coronary sinus are obtained from the pressure-inflation test data of human coronary sinus that were obtained in our lab (unpublished data). To reduce the computational cost, we choose to implement the following Ogden constitutive model to characterize the experimental data of the CS.

![Table 1 – Two Nitinol material parameters (3)](image)

**Figure 2 – A) expanded proximal anchor for Nitin-1 material, B) a typical Nitinol stress-strain curve, and C) the human CS stress-stretch curve fitted with the Ogden model.**

![Image](image)
The Goodman diagrams are plotted in Fig. 5 for the stent fatigue analysis under the cyclic blood pressure loading of 0 – 10 mmHg. Because the strain amplitude or oscillating strain has a greater effect on fatigue life than the mean strain, with higher strain amplitude in the Nitin-2 stent, the Nitin-2 may have a shorter fatigue life than the Nitin-1 stent. Using the 0.4 strain amplitude delineated by the constant life line (4), one can predict the stent fatigue safety factor using the equation: safety factor = 0.4%/strain amplitude. Thus the Nitin-1 stent has a safety factor of about 4, whereas the Nitin-2 stent has a safety factor of about 2.

In conclusion, this study provides quantitative evaluation of the biomechanical responses involved in the deployment of PTMA stent into the CS. Comparison between two different stent materials may offer insights on optimal PTMA stent design.