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Effects of annular contraction on anterior leaflet strain using an *in vitro* simulator with a dynamically contracting mitral annulus

Thomas F. Easley [a,b], Charles H. Bloodworth IV [a,b], Vinay Bhal [c], Ajit P. Yoganathan [a,c,*]

[a] *Parker H. Petit Institute for Bioengineering and Bioscience, Georgia Institute of Technology, Atlanta, GA 30332, USA*
[b] *George W. Woodruff School of Mechanical Engineering, Georgia Institute of Technology, Atlanta, GA 30332, USA*
[c] *Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology, Atlanta, GA 30332, USA*

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ABSTRACT

Using *in vitro* models, the mechanics as well as surgical techniques for mitral valves (MV) and MV devices can be studied in a more controlled environment with minimal monetary investment and risk. However, these current models rely on certain simplifications, one being that the MV has a static, rigid annulus. In order to study more complex issues of imaging diagnostics and implanted device function, it would be more advantageous to verify their use for a dynamic environment in a dynamic simulator. This study provides the novel design and development of a dynamically contracting annulus (DCA) within an *in vitro* simulator, and its subsequent use to study MV biomechanics. Experiments were performed to study the ability of the DCA to reproduce the MV leaflet mechanics *in vitro*, as seen *in vivo*, as well as investigate how rigid annuloplasties affect MV leaflet mechanics. Experiments used healthy, excised MVs and normal hemodynamics; contractile waveforms were derived from human *in vivo* data. Stereophotogrammetry and echocardiography were used to measure anterior leaflet strain and the change in MV geometry. In pursuit of the first *in vitro* MV simulator that more completely represents the dynamic motion of the full valvular apparatus, this study demonstrated the successful operation of a dynamically contracting mitral annulus. It was seen that the diseased contractile state increased anterior leaflet strain compared to the healthy contractile state. In addition, it was also shown *in vitro* that simulated rigid annuloplasty increased mitral anterior leaflet strain compared to a healthy contraction.

1. Introduction

Moderate to severe mitral valve regurgitation (MR) affects 1.7% of adults in the US (Mozaffarian et al., 2015). In MR, the mitral valve (MV) leaflets do not completely coapt, leading to backward flow of blood from the ventricle to the atrium. Currently, *in vivo* large animal and patient studies do not offer ways to quickly evaluate MV and MV device mechanics, or to do so without higher monetary investment and risk. For functional MR (FMR), the MV maintains a normal anatomy with pathological structure/geometry (Schmitto et al., 2010). This allows *in vitro* models to be more advantageous due to their ability to use readily-accessible, healthy MVs and easily modify their geometry for different experiments, all while maintaining the valve's subvalvular anatomy (Siefert and Siskey, 2015).

Using *in vitro* models, the solid and fluid mechanics of FMR, as well as surgical treatments, can be studied in a more controlled environment than in animal models, with the ability to focus on individual parameters of interest. This environment provides better physical and optical access to the MV, enabling the use of measurement techniques with better spatial and temporal resolution. However, these models are not perfectly representative of *in vivo* MV performance and rely on certain simplifications, one being that the MV is mounted to a static, rigid annulus (leaflet attachment to the myocardium). This simplification of the annulus is justified for investigations where systolic annular geometry is held constant to assess MR repairs during systole (Jimenez et al., 2006; Rabbah et al., 2014). However, in order to study more advanced issues of imaging diagnostics and implanted device function, it would be more powerful to verify their use for a dynamic environment (i.e. the MV) in a dynamic simulator. This extends to the needs of future MR quantification techniques to account for a moving MR jet orifice, the testing of valvular and perivalvular hemodynamics of transcatheter mitral valve replacements, advancing computational

* Corresponding author at: Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology, 387 Technology Circle NW, Suite 200, Atlanta, GA 30313, USA.
E-mail address: ajit.yoganathan@bme.gatech.edu (A.P. Yoganathan).

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models for surgical planning, and further investigation of MV repair procedures.

Restrictive annuloplasty MV repair is the treatment of choice for patients with FMR (Carpentier, 1983; Carpentier et al., 1980). The annuloplasty ring is implanted into the MV to bring the MV leaflets closer together by reducing the annular area; this provides better leaflet coaptation during systole and reduces MR (Braun et al., 2008). Implantation of an annuloplasty ring restricts the motion of the mitral annulus throughout the cardiac cycle, with stiffer rings imparting greater restriction. Although this surgical repair is an effective treatment, studies have shown MR recurrence as high as 30% in patients with ischemic MR (a major type of FMR) within the first 6 months after operation (McGee et al., 2004). Previous studies have shown that a flat annuloplasty ring can alter anterior leaflet strain with the potential to decrease repair durability (Amini et al., 2012). Assessment of how changes in annular dynamics effect MV leaflet mechanics could help in further understanding long-term outcomes post-annuloplasty.

Motivated by these needs, this study provides the novel design and development of a dynamically contracting annulus (DCA) within an *in vitro* left heart simulator and subsequent use to study MV biomechanics. Experiments were performed to study the ability of the DCA to reproduce MV leaflet mechanics *in vitro*, as seen *in vivo*, as well as investigate how rigid annuloplasties affect MV leaflet mechanics. This was done by comparing anterior leaflet strains of healthy and diseased contractile annulus states, and a comparison of anterior leaflet strains between healthy contraction and static annulus states (modeling rigid annuloplasties).

2. Methods

2.1. Mitral valve annulus plate design and development

The dynamically contracting MV annulus (DCA) was designed to fit within our existing modular left heart simulators to maintain the current imaging capabilities (Fig. 1a) (Bloodworth et al., 2017; Siefert et al., 2013). A spring was embedded within a Dacron cuff to which the MV annulus is sutured. A wire was fed through the center of the spring and attached to the piston heads of two linear actuators (HAD2-2, RobotZone, Winfield, KS) (Fig. 1b). The wire facilitated contraction of the annulus using the motors, while the spring provided an improved means for relaxation. Two different annulus plates were fabricated; a larger to better accommodate the size of porcine MVs (porcine DCA) and a smaller for ovine (ovine DCA).

The linear actuators were displacement driven and controlled individually using a proportional-integral-derivative (PID) controller with the addition of a feed-forward loop written in LabVIEW (2015, National Instruments, Austin, TX), and H-bridge controllers (DeviceCraft, Fitchburg, MA) with power supplies (Allied Electronics) to provide voltage to the motors. The positions of the motors were measured using their built-in potentiometers.

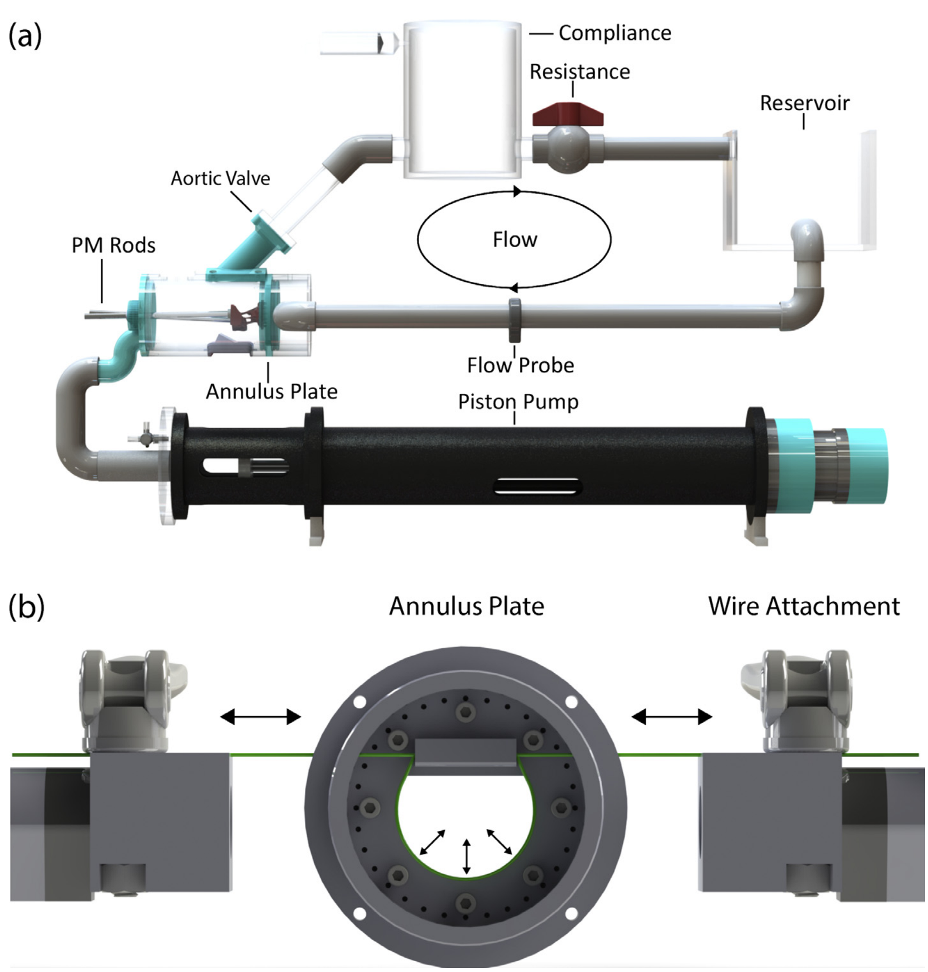

Fig. 1. (a) Schematic of left heart simulator complete flow loop with cylindrical chamber for ovine valves. (b) Simplified diagram of the ovine dynamically contracting annulus setup with the annulus plate centered between the wire attachments at the ends of the linear actuators. Cam levers were used to secure the steel wire.

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