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Mitral annuloplasty ring flexibility preferentially reduces posterior suture forces

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ABSTRACT

Annuloplasty ring repair is a common procedure for the correction of mitral valve regurgitation. Commercially available rings vary in dimensions and material properties. Annuloplasty ring suture dehiscence from the native annulus is a catastrophic yet poorly understood phenomenon that has been reported across ring types. Recognizing that sutures typically dehisce from the structurally weaker posterior annulus, our group is conducting a multi-part study in search of ring design parameters that influence forces acting on posterior annular sutures in the beating heart. Herein, we report the effect of ring rigidity on suture forces. Measurements utilized custom force sensors, attached to annuloplasty rings and implanted in normal ovine subjects via standard surgical procedure. Tested rings included the semi-rigid Physio (Edwards Lifesciences) and rigid and flexible prototypes of matching geometry. While no significant differences due to ring stiffness existed for sutures in the anterior region, posterior forces were significantly reduced with use of the flexible ring (rigid: 1.95 ± 0.96 N, semi-rigid: 1.76 ± 1.19 N, flexible: 1.04 ± 0.63 N; $p < 0.001$). The ratio of anterior to posterior F_C scaled positively with increasing flexibility ($p < 0.001$), and posterior forces took more time to reach their peak load when a flexible ring was used ($p < 0.001$). This suggests a more rigid ring enables more rapid/complete force equilibration around the suture network, transferring higher anterior forces to the weaker posterior tissue. For mitral annuloplasties requiring ring rigidity, we propose a ring design concept to potentially disrupt this force transfer and improve suture retention.

1. Introduction

Mitral valve regurgitation (MR) is the most common heart valve disease (Nkomo et al., 2006). Dilation and/or distortion of the mitral annulus inhibits mitral leaflet closure, and is common in MR occurring both organically and secondarily to ventricular disease (Grewal et al., 2010; Piérard and Carabello, 2010). Surgical correction using ring or band annuloplasty is commonly used in the management of MR (Acker et al., 2014; Adams et al., 2010; Braun and Klautz, 2012; De Bonis et al., 2012). Annuloplasty aims to re-establish normal valve function by correcting annulus geometry and/or preventing its further degeneration. All currently available annuloplasty devices are implanted surgically, using sutures that anchor them to the annulus.

Mitral annuloplasty is usually successful. However, one form of post-operative failure is suture dehiscence, in which one or more sutures detaches from the annulus. It has been shown through several large retrospective clinical studies that 13–42% of reoperations for failed annuloplasty are attributable to suture dehiscence (Cerfolio et al., 1996; Dumont et al., 2007; Gillinov et al., 1997). The consequences of dehiscence are severe, including hemolysis, endocarditis, device migration, acute recurrent MR, and excessive patient morbidity (Ciobanu et al., 2014; Jones-Haywood et al., 2013; Kronzon et al., 2009; Tsang et al., 2009).

Although conventional thinking may tend to dismiss reports of annuloplasty ring dehiscence as a series of mere surgical errors (MacArthur and Boyd, 2018), our group and others have recently explored the potential impacts of systematic factors affecting dehiscence likelihood (Paul et al., 2017; Pierce et al., 2018; Pierce et al., 2016b; Spratt et al., 2012; Wong et al., 2012). Complex mechanics of annulus-suture interaction have been observed. It has been shown in an ovine model that heterogeneous collagen

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distribution imparts non-uniform suture holding strength (i.e. pullout force) around the annular circumference (Paul et al., 2017; Pierce et al., 2016b). Similarly, in the beating heart, the forces that sutures endure vary by position (Pierce et al., 2018; Pierce et al., 2016b). Although the forces applied during suture tie-down have been shown to differ between surgeons, tie-down forces show no correlation to the eventual cyclic forces in the beating heart (Pierce et al., 2018).

Following these studies, combined with the ongoing development of transcatheter-based annular repair devices (which rely on novel anchor types, implanted without direct visual access), interest is growing in identifying strategies to systematically improve anchor retention (MacArthur and Boyd, 2018; McCarthy, 2017; Spratt et al., 2016). The need for an annuloplasty approach that reduces loading on posterior annular sutures has been established (Pierce et al., 2016b), but such a solution remains elusive. This study therefore explored the capacity for annuloplasty ring stiffness to modulate posterior suture forces in the beating ovine heart.

2. Methods

2.1. Annuloplasty rings

The Physio ring (Edwards Lifesciences, Irvine, CA) is a common, nearly planar annuloplasty ring, which is generally regarded as semi-rigid. It is constructed from layered Elgiloy and plastic strips, which are covered in polyester fabric. This study investigated the comparative suture force dynamics among the Physio ring and in-house prototyped rigid and flexible counterparts.

Rigid and flexible ring prototypes were manufactured in sizes 24, 26, and 28, using a novel pipeline presented in Fig. 1. These rings are not approved for human use or for sale in any jurisdiction, and were manufactured solely for use in this study. First, Physio rings of each size were imaged by micro-computed tomography (μCT). Imaging used a Siemens Inveon scanner (Siemens Medical Solutions USA, Inc., Malvern, PA) tuned for metal visualization at 43.29 μm isotropic voxel resolution. Image segmentation yielded a surface mesh of each ring's core (InVesalius, São Paulo, Brazil); the closely packed Elgiloy strips were reconstructed as a single, hollow tube. The mesh was smoothed using Geomagic Studio (3D Systems, Cary, NC), and the tube's centerline was computed using the Vascular Modeling Toolkit (www.vmtk.org). After additional smoothing in Geomagic, the centerlines were used as the basis for reconstructing the Physio ring's three-dimensional geometry.

The prototype Physio geometry was designed using SolidWorks (Dassault Systèmes, Waltham, MA). A 3 mm diameter circular profile was swept around the ring centerline. Pairs of grooves (approximately 0.2 mm deep) were positioned at the sites where each suture force sensor would later be attached. These grooves, which occupied only the atrial/inner quadrant of the ring's minor circumference, facilitated repeatable, secure sensor attachment (see Section 2.2. below).

Rigid rings were rapid prototyped from polycarbonate (tensile modulus: approximately 1.95 MPa) at 0.13 mm resolution (Fortus 360 mc, Stratasys, Eden Prairie, MN). Flexible rings were cast from a fast-setting silicone (shore hardness: 40 A) using a mold that was designed in SolidWorks and rapid prototyped at 0.016 mm resolution from VeroWhite (Objet350 Connex3, Stratasys). The mold's cavity matched the rigid ring's geometry.

Rings were characterized through mechanical compression in their septal-lateral directions. Compression testing was performed using an ElectroForce3200 uniaxial tester (Bose Corporation, Eden Prairie, MN) with in-line load cell (SMT1-22; Interface, Scottsdale, AZ) and custom holders. Compression ended when the ring's most septal and lateral points moved to within 75% of one their nominal distance (5 mm total deflection) or a load of 7.5 N was reached. Each of these limits are conservative representations of *in vivo* annular function (Rausch et al., 2011; Siefert et al., 2012).

2.2. Suture force sensors and ring instrumentation

Previously developed and demonstrated force sensors were employed in this study (Fig. 2A) (Siefert et al., 2014). Each sensor utilized two strain gages (Fig. 2A, arrow a), orthogonally aligned and wired in a half-bridge configuration (062TZ, Micro Measurements, Wendell, NC). Gages were bonded to a custom, bracket-shaped spring element, which was laser sintered from biocompatible stainless steel. Each sensor was fixed to the annuloplasty ring of interest using dedicated sutures. These were first passed through the sensor's fixturing holes (Fig. 2A, arrow b) and then passed and tied either *through* the suture cuff of the commercial (semi-rigid) ring or *around* the minor circumference of the prototype rigid/flexible rings. The small grooves in the prototype rings (Fig. 1, inset) enabled repeatable, secure positioning of fixturing sutures.

Wires (Fig. 2A, arrow c) connected sets of sensors to data acquisition hardware and custom LabVIEW-based software (all from National Instruments, Austin, TX). Once a suture was passed through a sensor's implantation holes (Fig. 2A, arrow d), any force on that suture elastically deformed the strain gage and generated a detectable voltage response. The minimum detectable force and the sampling rate were 0.1 N and 0.6 ms, respectively. Each sensor was calibrated before and after all experiments, using forces in excess of those anticipated *in vivo*. This process demonstrated a highly linear voltage-force relationship ($R^2 > 0.99$ in all cases).

The total size of each sensor was $6 \times 6 \times 6$ mm. This was sufficiently small to fix 10 sensors to annuloplasty rings as small as size 24. Sensors were positioned at the left trigone (LT), right trigone (RT), and at evenly spaced positions around the ring's remaining outer circumference. This amounted to four anterior and six posterior sutures (Fig. 2B). Given the sensors' implantation holes sat radially outward from the ring's suture cuff, the apparent ring size was 2 mm (one ring size) larger in its fully instrumented form.

2.3. Experimental protocol

The present work included N = 16 healthy Dorsett hybrid sheep (cohorts receiving the rigid, semi-rigid, and flexible annuloplasty rings respectively numbered N = 6, N = 5, and N = 5). Animals received care according to protocols approved by the Institutional Animal Care and Use Committee at the University of Pennsylvania, and in compliance with the guidelines for humane care (National Institutes of Health Publication 85–23, revised 1996). The animal protocol has been previously described in detail (Pierce et al., 2018; Pierce et al., 2016a; Pierce et al., 2016b). In the present studies, once cardiopulmonary bypass was established and the mitral valve was exposed, the valve was sized and a ring was selected to *undersize* the valve by two sizes. To implant the instrumented ring, one 2–0 mattress suture (braided polyester) was passed through and tied to each transducer (i.e. ten total sutures), via the same method normally used to tie sutures to a ring's suture cuff.

Upon reestablishing baseline hemodynamics after cardiopulmonary bypass (4.0 L/min cardiac output, 100 mmHg LVP_{max}), Doppler, 3D and 2D echocardiography were performed to verify normal ventricular function and transvalvular pressure gradient. Suture forces were recorded during cardiac cycles with peak left ventricular pressure (LVP_{max}) of 100 mmHg, and subsequently under increased afterload (namely, LVP_{max} = 125 and 150 mmHg). Elevated LVP_{max} was achieved using a continuous infusion of