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Suture Forces in Undersized Mitral Annuloplasty: Novel Device and Measurements

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Abstract

Purpose: Demonstrate the first use of a novel technology for quantifying suture forces on annuloplasty rings to better understand the mechanisms of ring dehiscence.

Description: Force transducers were developed, attached to a size 24 Physio™ ring, and implanted in the mitral annulus of an ovine animal. Ring suture forces were measured after implantation and for cardiac cycles reaching peak left ventricular pressures (LVP) of 100, 125, and 150 mmHg.

Evaluation: After implanting the undersized ring to the flaccid annulus, the mean suture force was 2.0±0.6 N. During cyclic contraction, anterior ring suture forces were greater than posterior ring suture forces at peak LVPs of 100 mmHg (4.9±2.0 N vs. 2.1±1.1 N), 125 mmHg (5.4±2.3 N vs. 2.3±1.2 N), and 150 mmHg (5.7±2.4 N vs. 2.4±1.1 N). The largest force was 7.4 N at 150 mmHg.

Conclusions: Preliminary results demonstrate trends in annuloplasty suture forces and their variation with location and LVP. Future studies will significantly contribute to clinical knowledge by elucidating the mechanisms of ring dehiscence while improving annuloplasty ring design and surgical repair techniques.

Keywords

restrictive mitral annuloplasty; dehiscence; functional mitral regurgitation; suture; forces

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Introduction

The preferred reconstructive surgery for functional mitral regurgitation (FMR) is undersized complete rigid ring annuloplasty. While effective in the majority of patients, postoperative complications can lead to short-term repair failure [1]. One increasingly acknowledged short-term failure is annuloplasty ring dehiscence [1-6]. In FMR, ring dehiscence commonly occurs along the posterior annulus [1-4] with select cases resulting in complete separation of the ring from the annulus [5,6]. While these failures are often attributed to surgical technique, no studies have identified whether suture failure, knot failure, or annular tissue tearing is the primary cause of dehiscence.

The inability to identify the mechanisms of ring dehiscence has contributed to large uncertainty for the conditions under which it is most likely to occur. One route towards addressing this challenge is to measure suture forces at ring implantation and during cyclic contraction of the heart. Quantifying these forces and comparing them to the forces associated with suture failure or tissue tearing will significantly contribute to our clinical understanding of dehiscence and developing new ring designs and surgical approaches to reduce its occurrence. Thus, the aim of this study was to demonstrate the first use of a novel technology capable of quantifying suture forces for an undersized mitral annuloplasty ring.

Technology

Suture Force Transducers

Novel transducers were designed to isolate the tensile forces in individual sutures along an annuloplasty ring.These devices are strain gage based and manufactured from biocompatible stainless steel (316L) (Figure 1A). Mounting holes in the transducer's frame allow each device to be directly sutured to an annuloplasty ring (Figure 1A and B).During implantation, mattress sutures are passed directly through each transducer then tied to the top of each device in the exact method used to secure sutures to a ring's suture cuff (Figure 1C and D).

Based on previous studies, all transducers were calibrated from 0-10 N [7]. Following calibration, the accuracy and precision of each transducer were evaluated. The mean relative error between true and measured forces was less than 1% with a minimal measurable force of 0.05 N. This accuracy is similar to previous strain gage transducers used to quantify forces within the mitral apparatus [7].

Ten calibrated suture force transducers were attached to a size 24 Physio™ ring (Edwards Lifesciences, Irvine, CA). Transducers were placed at each trigonal location and at near symmetric locations around the ring (Figure 1B). In this configuration, 4 transducers were placed on the anterior portion of the ring with the remaining 6 on the posterior circumference. Since the transducers sit external to the ring's suture cuff, the outer dimensions of the annuloplasty ring were increased to a size 26 Physio™ ring.

Technique

Experimental Protocol

The animal used in this work received care in compliance with the protocols approved by the Institutional Animal Care and Use Committee at the University of Pennsylvania in accordance with the guidelines for humane care (National Institutes of Health Publication 85-23, revised 1996).

A Dorsett hybrid sheep (72 kg) was intubated, anesthetized, and ventilated with isofluorane (1.5% to 2%) and oxygen. Surface electrocardiogram and arterial blood pressure was monitored. After establishment of cardiopulmonary bypass, a left atriotomy was performed. Ten 20 mm Y-31 Ti·Cron™ sutures (Covidien, Mansfield, MA) were placed in the mitral annulus and through the mounting holes of the transducers' measurement arms (Figure 1C). Prior to lowering and securing the ring into the mitral annulus, each of the transducers was zeroed to establish a zero force baseline. The annular mattress sutures were then secured to the ring using five surgeon's knots in the following order: left fibrous trigone, right fibrous trigone, then each remaining suture proceeding clockwise from the left fibrous trigone. After implanting the ring, the suture forces on the flaccid mitral annulus were recorded.

Following left atrial closure and weaning from cardiopulmonary bypass; a high-fidelity pressure transducer (SPR-3505; Millar Instruments, Houston, TX) was passed through the carotid artery to the left ventricle (LV) for continuous measurement of LV Pressure (LVP). Surface electrocardiogram, LVP, and arterial pressure (Hewlett-Packard 78534C monitor; Hewlett-Packard Inc, Santa Clara, CA) were simultaneously monitored. Upon establishing baseline hemodynamics (100 mmHg peak LVP, 4.0 L/min cardiac output), cyclic suture forces were measured within the post-cardioplegic heart. Continuous wave To evaluate the effects of increasing afterload, suture forces were recorded continuously for cardiac cycles exhibiting a peak LVP of 125 and 150 mmHg. Elevated LVP was achieved via continuous infusion of neosynephrine and dobutamine. After successful force measurement, animals were euthanized with an injection of 80 mEq KCl. The heart was removed and opened to verify secure anchoring of the device to the annulus.

Data Acquisition and Analysis

Suture forces and LVP were continuously acquired using a compact Data Acquisition System (cDAQ 9174), strain gage bridge modules (NI 9237), and analog voltage module (NI 9215) (National Instruments, Austin, TX). Suture forces and LVP were monitored and recorded using a custom-built LabVIEW program (National Instruments, Austin, TX). Recorded data were processed offline using a custom MATLAB program (Mathworks, Natick, MA). Suture forces following implantation in the flaccid mitral annulus were averaged over 1 minute of continuous recording. During cyclic contraction of the heart, the distribution of each suture force over 10 consecutive cycles was analyzed for its minimum, 25th percentile, median, 75th percentile, and maximum values. Averaged values are expressed as a mean ± 1 standard deviation.

Clinical Experience

After establishing cardiopulmonary bypass and valve exposure, the mitral annulus was sized to a 30 mm Physio™ ring. Implanting the instrumented ring undersized the annulus by two sizes (size 26 Physio™). Among all sutures, the mean implantation suture force was 2.0±0.6 N (Table 1). Mean suture forces on the anterior ring (2.3±0.5 N) were observed to be of similar magnitude to mean suture forces on the posterior ring (1.8±0.6 N). The largest force measured at implantation was 3 N at the 1 o'clock position.

Following ring implantation, the animal was successfully weaned from cardiopulmonary bypass (Figure 1D). 59 minutes passed between defibrillation and our reported measurements at 100 mmHg peak left ventricular pressure. At baseline and elevated levels of peak LVP, suture forces were seen to increase from ventricular diastole and peak near mid-systole. The distribution of cyclic suture forces occurring over 10 consecutive cardiac cycles was measured for peak LVPs of 100, 125, and 150 mmHg (Figure 2). Overall, cyclic suture forces were observed to increase with increasing levels of peak LVP.

Sutures located on the anterior portion of the annuloplasty ring exhibited cyclic force characteristics that differed from sutures on the posterior ring. The suture force maximums and their corresponding cyclic ranges (maximum-minimum) were greater along the anterior portion of the ring (Table 2). Interestingly, peak suture forces were observed to increase from the 11 to 1 and 3 to 9 o'clock positions. We believe this trend could be due to suture implantation order and/or mitral annular anatomical variation. Future studies are necessary to determine the impact of these variables on the magnitude of annuloplasty ring suture forces.

Comment

After ring implantation, suture forces measured in the flaccid mitral annulus were of similar magnitude regardless of ring position. While the annulus was undersized by 2 sizes, the similarity between anterior and posterior suture forces was likely due to the presence of a normal LV. With LV dilatation, we hypothesize posterior sutures will carry a proportionally greater load. Future studies will aim to utilize a FMR ovine model to evaluate this hypothesis.

During cyclic contraction, anterior ring sutures experienced a greater range and maximum force than sutures located along the posterior ring. The increased forces measured along the anterior annulus are likely the result of a blunting of the normal annular saddle shape caused by the placement of a flat annuloplasty ring. During systole the saddle shape of the anterior annulus is accentuated with the mid-anterior annulus being "elevated" toward the atrium by the filling of the aortic root and the fibrous trigones being "depressed" toward the ventricle by LV contraction. A flat annuloplasty ring prevents this normal accentuation. The increased forces measured along the anterior annulus and fibrous trigones are likely the result of the annulus pulling away from the flat ring in these regions. The posterior annulus likely produces lower forces and small forcer variations throughout systole because its relatively flatter geometry is more stable throughout the cardiac cycle and similar to the flat annuloplasty ring.

These data provide preliminary insight and implications for annuloplasty ring design. The salutary effect of saddle shape annuloplasty on leaflet geometry and leaflet stress have been described [7]. The data presented here also suggest saddled rings may potentially reduce suture forces on the anterior annulus. To fully understand these effects, future studies will evaluate the difference in suture forces between flat and saddled annuloplasty rings. These studies will additionally evaluate if regional LV distortions associated with FMR can exacerbate posterior ring suture forces. These data will provide critical knowledge for patient-ring selection and understanding ring dehiscence.

To better understand what may contribute the most to ring dehiscence, careful comparison of observed forces to those which may cause suture failure, knot failure, or annular tissue tearing is required. A previous study evaluated the strength of surgeon knots thrown from 3-0 Ti·Cron [8]. Five suture throws decreased the ultimate suture holding strength from 27 to 17.8 N. While 2-0 sutures are expected to exhibit a larger holding strength, results from 3-0 sutures are approximately 140% greater than the maximum force measured in this study (7.4 N at 150 mmHg peak LVP).

In comparison to suture and suture knot failure, annular tissue tearing may be a more likely failure mechanism in ring dehiscence. Among patients with varying MV disease, single sutures have been shown to tear from MV annular tissue with a mean force of 6.0 ± 4.5 N [9]. While this study used only 10 sutures to implant the undersized ring (∼16-20 used for a FMR patient), the magnitude of annular tissue tearing forces is within the range of forces measured herein. Future studies are required to understand the effects of suture number on measured forces and the resulting potential for annular-tissue tearing. Future studies should additionally evaluate if the suture holding strength of the aorto-mitral curtain may be greater than that of the posterior mitral annulus. This will provide additional insight to ring implantation and to why dehiscence is more commonly observed on the posterior annulus.

Despite the advantages of the present study, several limitations exist. Measured forces were likely affected by suture bite width, bite depth, suture securing order, and use of anesthetic isoflurane. While isoflurane has been demonstrated to depress LV contractility [10], measurements at elevated LVP provide insight to the range of forces which may be anticipated in the awake, extubated, and ambulating animal. The use of dobutamine to achieve elevated levels of LVP increased the subject’s heart rate from 97 to 110 and 150 beats/min. Future studies will additionally evaluate the effects of heart rate on observed suture forces.

This study was successful in utilizing a novel technology to quantify mattress suture forces for an undersized annuloplasty ring implanted in an ovine model. Preliminary results demonstrate trends in annuloplasty suture forces and their variation with ring location and LVP. The developed methods and technology provide the means to evaluate how patient-ring selection, ring geometry, implantation technique, tie-down order, and left heart geometry affect mattress suture forces and how their magnitudes relate to potential for suture dehiscence. The determination of these endpoints will significantly contribute to improved clinical knowledge and improve annuloplasty ring design and surgical repair techniques.

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Disclosures and Freedom of Investigation

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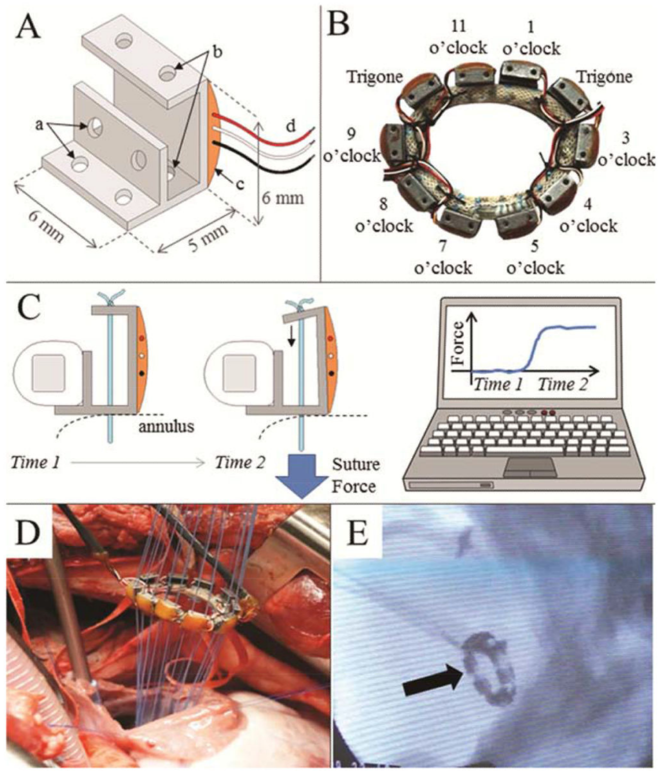

Figure 1.
(A) Schematic of transducer with (a)mounting holes for ring mounting, (b)mattress suture passages, (c)strain gage for force measurement, and (d)exiting wires. (B) Completed transducer. (C) Schematic of implanted ring with suture induced transducer deformation and force measurement. (D) Device implantation. (E) Implanted transducer imaged using fluoroscopy.

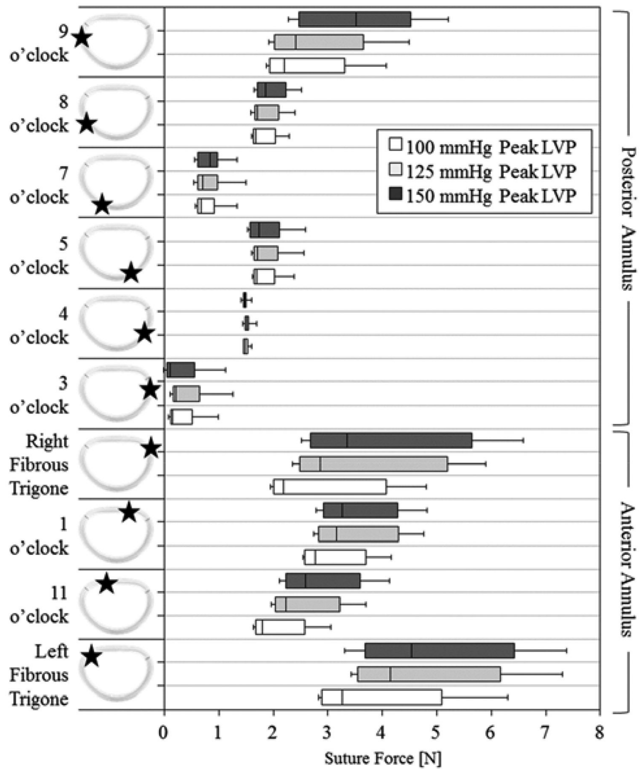

Figure 2.

Box and whisker plot exploring the distribution of suture forces occurring over 10 consecutive cardiac cycles for each level of LVP.

Table 1

Implantation suture forces

	Anterior				**Posterior**					
Suture Position	Left Fibrous Trigone	11 o'clock	1 o'clock	Right Fibrous Trigone	3 o'clock	4 o'clock	5 o'clock	7 o'clock	8 o'clock	9 o'clock
Implantation Force [N]	2.2	1.8	3.0	2.2	0.8	2.2	2.2	1.1	2.1	2.3

Table 2

Variation in cyclic force range and maximums by ring location

	Range of Forces [N]			Peak Forces [N]		
Location of Sutures	**100 mmHg**	**125 mmHg**	**150 mmHg**	**100 mmHg**	**125 mmHg**	**150 mmHg**
Anterior Ring	2.3 ± 0.9	2.8 ± 1.0	3.0 ± 1.2	4.9 ± 2.0	5.4 ± 2.3	5.7 ± 2.4
Posterior Ring	0.9 ± 0.6	1.1 ± 0.7	1.2 ± 0.9	2.1 ± 1.1	2.3 ± 1.2	2.4 ± 4.5