Suture Forces in Undersized Mitral Annuloplasty: Novel Device and Measurements

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Purpose. To 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 mm Hg.

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

Conclusions. The 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.


The preferred surgical reconstructive procedure for functional mitral regurgitation (FMR) is undersized complete rigid ring annuloplasty. Although undersized annuloplasty is 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 with select cases resulting in complete separation of the ring from the annulus [1–6]. Although these failures are often attributed to surgical technique, no studies to our knowledge 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 much uncertainty for the conditions under which it is most likely to occur. One route toward addressing this challenge is to measure suture forces at ring implantation and during cyclic contraction of the heart. Quantifying these forces and comparing them with the forces associated with suture failure or tissue tearing will significantly contribute to our clinical understanding of dehiscence and to the development of 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 gauge–based and are manufactured from biocompatible stainless steel (316L) (Fig. 1A). Holes mounted in the transducer’s frame allow each device to be directly sutured to an annuloplasty ring (Figs. 1A, 1B). During implantation, mattress sutures are passed directly through each transducer and then tied to the top of each device in the exact method used to secure sutures to a ring’s suture cuff (Figs 1C, 1D).

On the basis of previous studies, all transducers were calibrated from 0 to 10 N [7]. After 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 that of previous strain gauge 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 nearly symmetric locations around the ring (Fig 1B). In this configuration, four transducers were placed on the anterior portion of the ring and the remaining six on the posterior circumference. Given that 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 [8]. A Dorset hybrid sheep (72 kg) was intubated, anesthetized, and ventilated with isoflurane (1.5% to 2%) and oxygen. Surface electrocardiogram and arterial blood pressure were monitored. After the 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 (Fig 1C). Before the ring was lowered and secured 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 with 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 implantation of the ring, the suture forces on the flaccid mitral annulus were recorded.

After 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. On the establishment of baseline hemodynamics (100 mm Hg peak LVP, 4.0 L/min cardiac output), cyclic suture forces were measured within the postcardioplegic heart. To evaluate the effects of increasing afterload, suture forces were recorded continuously for cardiac cycles exhibiting a peak LVP of 125 and 150 mm Hg. Elevated LVP was achieved by a continuous infusion of neosynephrine and dobutamine. After successful force measurement, the animal was 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 by use of a compact data acquisition system (cDAQ 9174), strain gauge bridge modules (NI 9237), and analog voltage module (NI 9215) (National Instruments, Austin, TX). Suture forces and LVP were monitored and recorded with a custom-built LabVIEW program (National Instruments, Austin, TX). Recorded data were processed offline with a custom MATLAB program (Mathworks, Natick, MA). Suture forces after 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 ten 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 cardiopulmonary bypass and valve exposure were established, the mitral annulus was sized to a 30-mm Physio ring. Implantation of 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). The mean suture forces on the anterior ring (2.3 ± 0.5 N) were observed to be of similar magnitude to that of the 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.

After ring implantation, the animal was successfully weaned from cardiopulmonary bypass (Fig 1D). Fifty-nine minutes passed between defibrillation and our reported measurements at 100 mm Hg peak LVP. At baseline and elevated levels of peak LVP, suture forces were seen to increase from ventricular diastole and peak near midsystole. The distribution of cyclic suture forces occurring over ten consecutive cardiac cycles was measured for peak LVPs of 100, 125, and 150 mm Hg (Fig 2). Overall, cyclic suture forces were observed to increase with increasing levels of peak LVP.

The sutures located on the anterior portion of the annuloplasty ring exhibited cyclic force characteristics that differed from those of the sutures on the posterior ring. The suture force maximums and their corresponding cyclic ranges (maximum to 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 o’clock and 3 to 9 o’clock positions. We believe this trend could have been caused by suture implantation order, mitral annular anatomic variation, or both. 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. Although the annulus was undersized by two sizes, the similarity between anterior and posterior suture forces was likely caused by a normal LV. With LV dilatation, we hypothesize that posterior sutures will carry a proportionally greater load. Future studies will aim to use an ovine model with FMR to evaluate this hypothesis.

During cyclic contraction, anterior ring sutures showed a greater range and maximum force than did 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 midanterior 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 smaller variations throughout systole because its relatively flatter geometry is more

Table 1. Implantation Suture Forces

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<thead>
<tr>
<th>Suture position</th>
<th>Anterior</th>
<th>Posterior</th>
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<tbody>
<tr>
<td>Implantation force (N)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left fibrous trigone</td>
<td>2.2</td>
<td>0.8</td>
</tr>
<tr>
<td>11 o’clock</td>
<td>1.8</td>
<td>2.2</td>
</tr>
<tr>
<td>1 o’clock</td>
<td>3.0</td>
<td>1.1</td>
</tr>
<tr>
<td>Right fibrous trigone</td>
<td>2.2</td>
<td>2.1</td>
</tr>
<tr>
<td>3 o’clock</td>
<td></td>
<td>2.3</td>
</tr>
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stable throughout the cardiac cycle and similar to the flat annuloplasty ring. These data provide preliminary insight into, 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 that saddled rings may potentially reduce suture forces on the anterior annulus. To enable full understanding of these effects, future studies will evaluate the difference in suture forces between flat and saddled annuloplasty rings. These studies will additionally evaluate whether regional LV distortions associated with FMR can exacerbate posterior ring suture forces. These data will provide critical knowledge for patient-ring selection and to the understanding of ring dehiscence. To enable a better understanding of what may contribute the most to ring dehiscence, careful comparison of observed forces to those that may cause suture failure, knot failure, or annular tissue tearing is required.

A previous study evaluated the strength of surgeon’s knots thrown from 3-0 Ti-Cron [9]. Five suture throws decreased the ultimate suture holding strength from 27 to 17.8 N. Although 2-0 sutures are expected to exhibit a larger holding strength, the results from 3-0 sutures are approximately 140% greater than the maximum force measured in this study (7.4 N at 150 mm Hg peak LVP).

In comparison with 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 [10]. Although this study used only ten sutures to implant the undersized ring (approximately 16 to 20 used for an FMR patient), the magnitude of annular tissue tearing forces is within the range of the forces measured herein. Future studies are required to enable an understanding of the effects of suture number on measured forces and the resulting potential for annular tissue tearing. Future studies should additionally evaluate whether the suture holding strength of the aortomitral curtain may be greater than that of the posterior mitral annulus. This will provide additional insight to ring implantation and to the reason why dehiscence is more commonly observed on the posterior annulus.

Despite the advantages of the present study, several limitations exist. The measured forces were likely affected by suture bite width, bite depth, suture securing order, and use of anesthetic isoflurane. Although isoflurane has been demonstrated to depress LV contractility [11], measurements at elevated LVP provide insight to the range of forces that 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 using a novel technology to quantify mattress suture forces for an undersized annuloplasty ring implanted in an ovine model. The 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 the effect of patient-ring selection, ring geometry, implantation technique, tie-down order, and left heart geometry on mattress suture forces and the relationship of their magnitudes to the 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.

![Fig 2. Box-and-whisker plot exploring the distribution of suture forces occurring over ten consecutive cardiac cycles for each level of left ventricular pressure (LVP).](image)

Table 2. Variation in Cyclic Force Range and Maximums by Ring Location

<table>
<thead>
<tr>
<th>Location of Sutures</th>
<th>Range of Forces (N)</th>
<th>Peak Forces (N)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>100 mm Hg</td>
<td>125 mm Hg</td>
</tr>
<tr>
<td>Anterior ring</td>
<td>2.3 ± 0.9</td>
<td>2.8 ± 1.0</td>
</tr>
<tr>
<td>Posterior ring</td>
<td>0.9 ± 0.6</td>
<td>1.1 ± 0.7</td>
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Disclosures and Freedom of Investigation

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References


Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and The Annals of Thoracic Surgery neither endorse nor discourage use of the new technology described in this article.