Mitral annuloplasty ring suture forces: Impact of surgeon, ring, and use conditions

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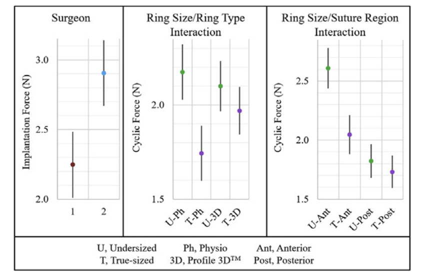
ABSTRACT

Objective: The study objective was to quantify the effect of ring type, ring-annulus sizing, suture position, and surgeon on the forces required to tie down and constrain a mitral annuloplasty ring to a beating heart.

Methods: Physio (Edwards Lifesciences, Irvine, Calif) or Profile 3D (Medtronic, Dublin, Ireland) annuloplasty rings were instrumented with suture force transducers and implanted in ovine subjects ($N = 23$). Tie-down forces and cyclic contractile forces were recorded and analyzed at 10 suture positions and at 3 levels of increasing peak left ventricular pressure.

Results: Across all conditions, tie-down force was 2.7 ± 1.4 N and cyclic contractile force was 2.0 ± 1.2 N. Tie-down force was not meaningfully affected by any factor except surgeon. Significant differences in overall and individual tie-down forces were observed between the 2 primary implanting surgeons. No other factors were observed to significantly affect tie-down force. Contractile suture forces were significantly reduced by ring-annulus true sizing. This was driven almost exclusively by Physio cases and by reduction along the anterior aspect, where dehiscence is less common clinically. Contractile suture forces did not differ significantly between ring types. However, when undersizing, Profile 3D forces were significantly more uniform around the annular circumference. A suture's tie-down force did not correlate to its eventual contractile force.

Conclusions: Mitral annuloplasty suture loading is influenced by ring type, ring-annulus sizing, suture position, and surgeon, suggesting that reports of dehiscence may not be merely a series of isolated errors. When compared with forces known to cause suture dehiscence, these in vivo suture loading data aid in establishing potential targets for reducing the occurrence of ring dehiscence. (J Thorac Cardiovasc Surg 2017;■:1-9)



Annuloplasty suture forces are affected by device characteristics, surgeon, and anatomy.

Central Message

Forces experienced by mitral annuloplasty sutures are modulated by ring type, ring-annulus sizing, suture position, and surgeon, establishing potential targets for reducing the incidence of dehiscence.

Perspective

Reports of suture dehiscence may not be merely a series of unrelated surgical errors. Repeatable differences in suture force according to ring selection, suture position, and surgeon suggest suture retention may be improved by novel ring designs or increased attention to knot-tying technique. Further, regulation of valvular implants may benefit from verification of tolerable in vivo anchor loads.

See Editorial Commentary page xxx.

Surgical repair is a common approach to correct ischemic mitral regurgitation (IMR), and its optimal use is the subject of active investigation.[1-3] Ring or band annuloplasty is central to mitral valve repair.[4,5] With more than 20 commercially available devices in the United States, surgeons performing annuloplasty must select from

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Abbreviations and Acronyms

ANOVA = analysis of variance
F_C = cyclic contractile force
F_{TD} = tie-down force
IMR = ischemic mitral regurgitation
LVP_{max} = maximum left ventricular pressure

among a range of shapes, stiffnesses, and sizes. Undersized rigid or semi-rigid ring annuloplasty has been the favored approach for IMR repair.[4]

Although favored, IMR repair durability is generally poor.[6,7] One increasingly recognized adverse event after IMR repair is annuloplasty suture dehiscence. Among studies of reoperation after failed annuloplasty-based mitral repair, the proportion of failures attributed to annular suture dehiscence is 13% to 42%.[8-10] A range of reports[11-15] reveal that suture dehiscence is a pressing challenge across device types. Its consequences may be severe, including device migration, embolization, endocarditis, recurrent regurgitation, and increased patient mortality.[14-16]

The factors contributing to annuloplasty suture dehiscence remain largely unclear. Although clinical reports may be naturally attributed to surgical error, multiple groups have questioned the extent to which dehiscence likelihood is determined systematically.[17-20] Quantification of such systematic factors would offer 2 principal benefits. First, in a review of recent literature (with mean patient follow-up >1 year), Khamooshian and colleagues[21] found insufficient evidence to establish any superior ring type, in terms of New York Heart Association class and ventricular function. Amidst such uncertainty, differences in anchoring performance would constitute a basis to discriminate among existing rings. Second, data describing the factors contributing to suture dehiscence would be instrumental in the development of controls to prohibit its occurrence.

Evidence is mounting that suture dehiscence likelihood can be targeted in this way. For example, using a deterministic simulation, Wong and colleagues[20] noted differences between 2 commercial rings in terms of virtual suture force in each posterior annulus segment (with peak difference >0.5 N at end diastole). By using a live ovine model coupled to in vitro imaging, we recently found that the clinical tendency for dehiscence from the posterior annulus[12-14,22] likely derives from this region's reduced collagen density.[18] We further observed a stark redistribution of force after a single suture's tear-out to its 2 adjacent sutures, highlighting a potential dehiscence cascade mechanism.[17] These initial findings now motivate our pursuit to understand the impact of ring type, ring-annulus sizing, suture position, surgeon, and left heart hemodynamic conditions on suture loading. To this end, the present study sought to quantify suture forces required to tie-down and constrain true-sized and undersized Physio (Edwards Lifesciences, Irvine, Calif) and Profile 3D (Medtronic, Dublin, Ireland) rings within the ovine heart.

MATERIALS AND METHODS

A video description of the methodology used herein is provided in Video 1.

Suture Force Measurement

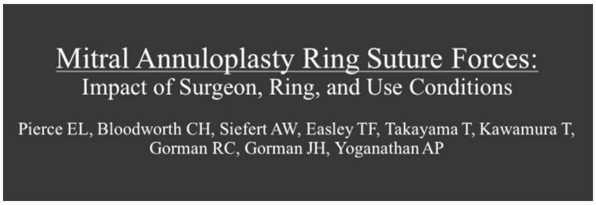
To measure tension in individual annuloplasty sutures, novel transducers were previously developed and demonstrated (Figure 1, *A*).[19] Transducers were designed to report suture tension as a positive force. As previously described, transducers were calibrated with known forces exceeding those anticipated in vivo. Sets of transducers (N = 10) were affixed to Physio or Profile 3D annuloplasty rings. Transducers were positioned at the left trigone, right trigone, and at evenly spaced locations around the remaining circumference (Figure 1, *B-D*). The flaccid annulus was sized using the sizer set corresponding to either ring type; either an undersized (2 sizes down) or true-sized ring of that type was selected. Transducer signals were zeroed before implantation in the cardioplegic heart. To implant the instrumented ring, one 2-0 Ti•Cron mattress suture (Medtronic) was passed through and tied to each transducer (ie, 10 total sutures) via a method analogous to normal attachment to a ring's suture cuff (Figure 1, *E*).

Data were collected from 23 healthy Dorsett hybrid sheep. All animals received care in compliance with protocols approved by the Institutional Animal Care and Use Committee at the University of Pennsylvania, in accordance with the guidelines for humane care.[23] Surgical protocols were performed by experienced mitral surgeons. For additional details on force transducer technology and experimental procedures, see Supplemental Materials and Methods or our previous publications.[18,19]

Tie-Down and Cyclic Contractile Force Analyses

For each suture, tie-down force (F_{TD}) was computed as the difference in force immediately before and after its tie-down (Figure 2, *A*). Cyclic contractile force (F_C) was computed as the difference between the minimum and the maximum force recorded within a cardiac cycle (Figure 2, *B*), averaged across 10 consecutive cardiac cycles. These forces were computed for 3 levels of maximum left ventricular pressure (LVP_{max}), namely, 100, 125, or 150 mm Hg. F_C represents the tensile force to which a suture is subjected in the beating heart. It may be attributable to a range of factors, including annular bending out-of-plane or contraction in-plane, myocardial fiber dimension change, and aortic root expansion.

Averages are reported as mean ± standard deviation. Statistical analyses included Levene's test for differences in variance between ring types (SPSS, IBM Corporation, Armonk, NY), correlation analyses on



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Impact of Surgeon, Ring, and Use Conditions

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VIDEO 1. A summary of the study's overall goal and approach, highlighting key tools, experimental procedures, and data types. Video available at: http://www.jtcvsonline.org.