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Novel Mitral/Tricuspid Annuloplasty Sizing Device and Technique: Proof of Concept Using a Cadaveric Porcine Heart Model

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GLOSSARY OF ABBREVIATIONS

None

KEY WORDS

mitral; tricuspid; valve; repair; annuloplasty; sizing; ring; band; ink test; saline test; saline pressure test; coaptation length, paired ring, two ring

CENTRAL PICTURE

Paired-ring annuloplasty sizer holds mitral annulus in fixed position for testing preview

CENTRAL MESSAGE

A paired-ring annuloplasty sizing system provides an early preview of function by engaging annular sutures and requiring the mitral annulus to conform to the exact three-dimensional shape of the sizer
INTRODUCTION

For over half a century the method for mitral annuloplasty ring sizing has remained essentially unchanged. During this time, debate has pitted science versus art in trying to analyze how mitral repair is actually accomplished. It is well known that annuloplasty sizing is critical to achieving successful valve repair. Yet, many have observed that to this day the surgeon is left without a reliable method to accomplish this elusive task. It is increasingly being recognized that intraoperative ring selection is actually driven by surgeon experience – art – and likely has little to do with proven, consistent methodology that could be construed as science. As a consequence, valve repair outcomes can suffer when operative methods are imprecise.

The most comprehensive examination of the annuloplasty sizing issue was performed by Bothe et al. in their article Sizing for Mitral Annuloplasty: Where does the Science Stop and Voodoo Begin? The authors determined that science is, in fact, not driving successful annuloplasty ring selection. After completing a tour de force review of the relevant literature, they humorously suggest that “Current sizing strategies are closer to voodoo than to science.” Upon completion of their exhaustive investigation, the authors define what the field requires: “We hypothesize that improvements in the approach to determine the size of an annuloplasty ring could make the procedure safer, more reproducible, and ultimately, help to further improve outcomes after surgical mitral valve repair.”

OBJECTIVE

This study aims to evaluate the feasibility and utility of a novel, paired-ring, annuloplasty sizing technique using a cadaveric porcine heart model as proof of concept. With regard to mitral (tricuspid) repair, current annular sizing methods for annuloplasty ring selection are
varied. They guide the surgeon with an estimate, but none provide a precise, true measurement and an opportunity for early physiologic evaluation. No current sizing system is able to instruct the surgeon regarding the number of millimeters change in coaptation length that will occur should a particular ring be selected for implantation.

It is hypothesized that the use of a paired-ring annular sizing system will provide immediate, actionable information to aid the surgeon in producing a more precise valve repair, safely and efficiently. Key features of the proposed technique include 1) direct measurement of coaptation length, and 2) early simulation of valve physiology, with the ability to preview and iterate the entire process using several different sizers prior to final ring selection.

**SURGICAL TECHNIQUE AND DISCUSSION**

Introduced is an early prototype of a paired-ring sizing system which engages the annuloplasty sutures and requires the valve annulus to conform to the exact size and shape of the specific sizer being tested (Figures 1&2, Video, Supplement). The described technique can potentially produce an early preview of any commercially available ring/band undergoing evaluation. The ability to perform rapid, subsequent iteration between several varying ring sizes/shapes is a valued feature of the technique. Both, precise anatomic measurement of coaptation length, as well as, early physiologic saline pressure testing can be performed while the annulus is under the influence of the sizer being evaluated. The opportunity to immediately iterate allows the surgeon to rapidly preview the potential contributions offered by multiple ring options prior to selecting the optimal one.

The described technique is noninvasive to both patient and surgeon. It is best utilized in conjunction with the saline pressure and ink³ tests. It is not only fully compatible with, but is
complementary to, all existing sizing strategies, whether one relies on manufacturer provided
sizers, estimation, surgeon experience, or predictive formulae. Even adjustable rings require
correct, initial sizing.

The ability to predict, and as a result dictate, specific repair features such as coaptation
length should allow our field to more deliberately control key parameters in future studies.
Doing so would hopefully translate into the implementation of better clinical guidelines sooner.

Though beyond the scope of this brief report, the presented paired-ring system forms the
foundation of a larger platform that not only provides sizing information, but also supports
applications that facilitate more efficient annuloplasty ring implantation. While offering modest
efficiencies in sternotomy cases, there exists the potential for significant advantages in minimally
invasive and robotic operations.

CONCLUSION

Proof of concept evaluation of the proposed mitral/tricuspid annuloplasty sizing
technique demonstrated correct function and ease of use in a cadaveric porcine heart model.
Early physiologic evaluation during the sizing portion of an annuloplasty procedure is critical
because it provides the surgeon with immediate, actionable feedback prior to a final commitment
to any particular size/shape of ring. Additional studies are in progress and will be required to
further develop this technology.
REFERENCES


LEGENDS

Figure 1: First generation paired-ring annuloplasty ring sizing prototype. A,B) Each specific sizer consists of two paired components. C) Sizer system in use previewing repair conditions under saline pressure test.

Figure 2: Second generation prototype which is fully functional and designed to correspond exactly to popular, commercially available annuloplasty ring products. Pictured sizers are 3-D printed and of nylon and glass fiber composition. A) Views demonstrating preservation of each sizer’s unique, three-dimensional “saddle” shape. B) Multiple, paired-ring sizers displayed in progression.

Supplement: Ring sizing technique described in a step-by-step manner.

Video: The video documents (subjective) evaluation of an early annuloplasty ring sizing prototype using an isolated, cadaveric, porcine heart model. After placement of annuloplasty sutures in standard fashion, use of a paired-ring sizing technique/device is introduced. The outer ring is used to encircle annuloplasty sutures and is then "snapped" together with its corresponding inner ring. The paired sizer complex is then advanced along the sutures until it sits in direct contact with the valve annulus. In this position, the potential contribution of the annuloplasty ring is temporarily simulated for evaluation. Saline pressure testing provides subjective repair information and the objective ink test previews an exact, potential leaflet coaptation length. The second portion of the video demonstrates the iterative process and the
interaction of sizer rings with annular sutures. Rings were able to slide smoothly along the annuloplasty sutures without injury or fraying. Positioning and exchange of sizers is relatively quick, usually requiring less than one minute of time.
SUPPLEMENT

**Technical Suggestions - Step-by-Step Process**

- Place annuloplasty sutures in standard fashion
- Encircle annuloplasty sutures using outer ring (facilitated by gap at 12 o’clock)*
- Couple (snap) inner ring together with outer ring to capture and hold sutures in position
- Seat ring down onto annulus circumferentially, confirming that no gaps remain between sizer and annulus
- Perform standard saline pressure test (with sizer in place) for initial, subjective evaluation
- Consider temporary removal of sizer if additional valve repair work needs to be completed
- Perform "ink-test" (with sizer in place)**
- Assess coaptation length through direct measurement or by subjective estimation
- Remove sizer and iterate process with sizer representing a different size and/or shape of ring
- Once optimal size/shape has been identified, remove sizer and complete implantation of corresponding commercially available ring in standard fashion

* If a suture organizer or similar system is being used, it is recommended to keep the sutures slightly loose to facilitate this step.

** It is recommended that a minimal amount of ink is used initially (such as a dot or a single vertical line) as the surgeon may wish to make additional markings if multiple sizers are evaluated. A different color ink can also be used for a subsequent test with a different sizer. This approach will facilitate the comparison of multiple coaptation lengths with initial ink marks in side-by-side fashion.