

Novel mitral/tricuspid annuloplasty sizing device and technique: Proof of concept using a cadaveric porcine heart model



Nikola Dobrilovic, MD

From the Division of Cardiac Surgery, Department of Surgery, NorthShore University Hospital System, Chicago, Ill.

IRB: N/A.

Informed consent: N/A.

Read at the American Association for Thoracic Surgery Mitral Conclave Workshop 2023, New York, New York, May 4-5, 2023.

Received for publication April 19, 2023; revisions received May 12, 2023; accepted for publication May 19, 2023; available ahead of print July 5, 2023.

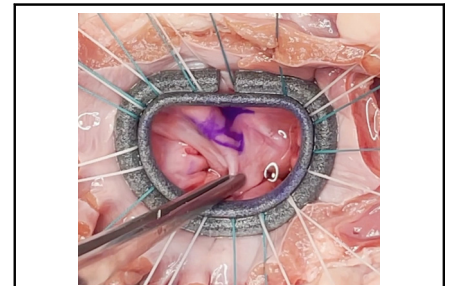
Address for reprints: Nikola Dobrilovic, MD, Division of Cardiac Surgery, Department of Surgery, NorthShore University Hospital System, 2650 Ridge Ave, Walgreens Building, Suite 3507, Evanston, IL 60201 (E-mail: ndobrilovic@northshore.org).

JTCVS Techniques 2023;21:74-7

2666-2507

Copyright © 2023 The Author(s). Published by Elsevier Inc. on behalf of The American Association for Thoracic Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.jtc.2023.05.025>



Paired-ring annuloplasty sizer holds the mitral annulus in a fixed position for testing.

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 3-dimensional shape of the sizer.

Video clip is available online.

For more than half a century, the method for mitral annuloplasty ring sizing has remained essentially unchanged.¹ During this time, debate has pitted science against 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 surgeons are 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 and colleagues.² 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.”²

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 surgeons 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 surgeons 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 surgeons in producing more precise valve repairs, safely and efficiently. Key features of the proposed technique include direct measurement of coaptation length and early simulation of valve physiology, with the ability

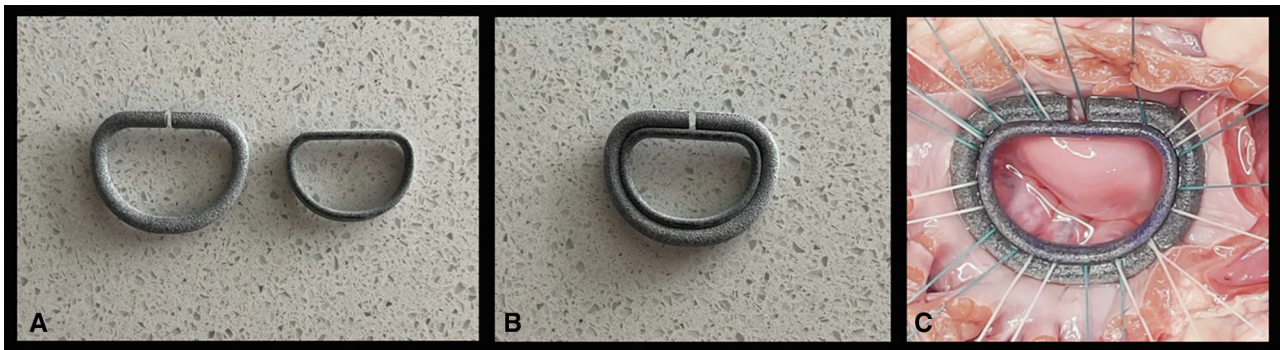


FIGURE 1. First-generation paired-ring annuloplasty ring sizing prototype. A and B, Each specific sizer consists of 2 paired components. C, Sizer system in use previewing repair conditions under saline pressure test.

to preview and iterate the entire process using several different sizers before final ring selection.

SURGICAL TECHNIQUE AND DISCUSSION

Introduced is an early prototype of a paired-ring sizing system that 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 and 2, Video 1, and Appendix E1). 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 a surgeon to rapidly preview the potential contributions offered by multiple ring options before 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 also complementary to, all existing sizing strategies, whether one relies on manufacturer-provided sizers, estimation, surgeon experience, or predictive formulae.⁴ Even adjustable rings require correct initial sizing.⁵

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 implementation of better clinical guidelines sooner.

Although 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.

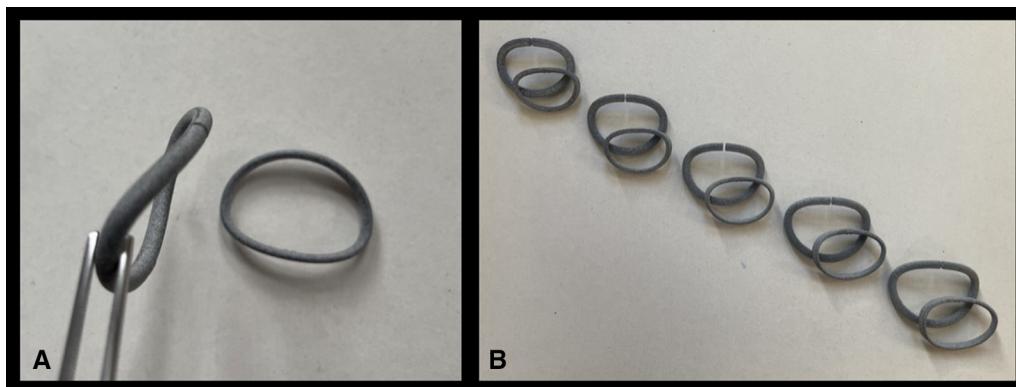
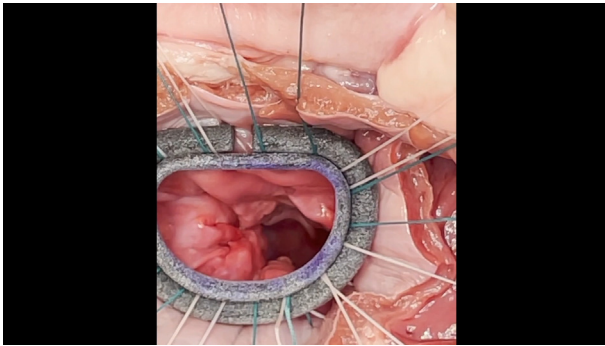


FIGURE 2. Second-generation prototype, which is fully functional and designed to correspond exactly to popular, commercially available annuloplasty ring products. Pictured sizers are 3-dimensionally printed and of nylon and glass fiber composition. A, Views demonstrating preservation of each sizer's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



VIDEO 1. 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 <1 minute of time. Video available at: [https://www.jtcvs.org/article/S2666-2507\(23\)00204-3/fulltext](https://www.jtcvs.org/article/S2666-2507(23)00204-3/fulltext).

CONCLUSIONS

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 surgeons with immediate, actionable feedback before a final commitment to any particular size/shape of ring. Additional studies are in progress and will be required to further develop this technology.

Conflicts of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

References

1. Carpentier A. Cardiac valve surgery—the “French correction.” *J Thorac Cardiovasc Surg.* 1983;86:323-37.
2. Bothe W, Miller DC, Doenst T. Sizing for mitral annuloplasty: where does the science stop and the voodoo begin? *Ann Thorac Surg.* 2013;95:1475-83.
3. Anyanwu AC, Adams DH. The intraoperative “ink test”: a novel assessment tool in mitral repair. *J Thorac Cardiovasc Surg.* 2007;133:1635-6.
4. McCarthy PM, Herborn J, Kruse J, Liu M, Andrei AC, Thomas JD. A multiparameter algorithm to guide repair of degenerative mitral regurgitation. *J Thorac Cardiovasc Surg.* 2022;164:867-76.
5. Maisano F, Falk V, Borger MA, Vanermen H, Alfieri O, Seeburger J, et al. Improving mitral valve coaptation with adjustable rings: outcomes from a European multicentre feasibility study with a new-generation adjustable annuloplasty ring system. *Eur J Cardio Thorac Surg.* 2013;44:913-8.

Key Words: mitral, tricuspid, valve, repair, annuloplasty, sizing, ring, band, ink test, saline test, saline pressure test, coaptation length, paired ring, 2 ring

APPENDIX E1. RING-SIZING TECHNIQUE DESCRIBED IN A STEP-BY-STEP MANNER

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 the 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 the “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 the 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) because 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.