Conformational changes during in vitro balloon fracture of internal aortic annuloplasty ring

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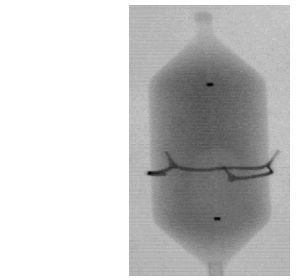
ABSTRACT

Objective: HAART 300 300 (BioStable Science and Engineering, Inc) aortic annuloplasty rings restore physiologic annular geometry during aortic valve repair. Transcatheter valve-in-ring implantation is appealing for recurrent valve dysfunction but may necessitate balloon fracture of downsized annuloplasty rings. We characterized the feasibility of ring fracture and changes in ring geometry preceding fracture.

Methods: The 19-mm, 21-mm, and 23-mm HAART 300 annuloplasty rings were obtained, and 23-mm, 24-mm, 25-mm, and 26-mm valvuloplasty balloons were obtained. Under continuous fluoroscopy and video recording, a 23-mm balloon was inflated within a 19-mm ring at 1 atm/s until ring fracture or balloon failure occurred. If balloon failure occurred, experiments were sequentially repeated with 1-mm upsized balloons until ring fracture occurred or no larger-sized balloons were available.

Results: Upon balloon inflation, all rings exhibited an irreversible conformational change from an elliptical, annular geometry to a circular shape with ring posts flaring outward. A 23-mm balloon burst at 21 atm without fracturing the 19-mm ring. The 24-mm balloon fractured the 19-mm ring at 15 atm. Likewise, a 24-mm balloon ruptured at 18 atm without fracturing the 21-mm annuloplasty ring. A 25-mm balloon fractured the 21-mm ring at 18 atm. Finally, a 26-mm balloon burst at 20 atm without fracturing a 23-mm annuloplasty ring, but it did elicit the confirmational changes described. All fractures occurred along the upslope of a ring post. The exposed metal frame was visible after the 21-mm ring fracture.

Conclusions: Fracture of HAART 300 aortic annuloplasty rings is possible with an oversized, high-pressure balloon. However, the geometrical changes in the ring and subsequent rupture of its fabric covering may be obstacles to safe, in vivo ring fracture. (JTCVS Techniques 2023;20:24-9)



Conformational changes may prohibit safe fracture of HAART 300 annuloplasty rings in vivo.

CENTRAL MESSAGE

HAART 300 aortic annuloplasty rings can be fractured with oversized, high-pressure balloons. However, changes in ring geometry and rupture of its fabric covering may prohibit ring fracture in vivo.

PERSPECTIVE

HAART 300 internal aortic annuloplasty rings can restore annular geometry during valve repair. However, outcomes of transcatheter valve-in-ring implantation in downsized rings are unknown. We demonstrated ring fracture is possible with available oversized True Dilation balloons. However, changes in ring geometry preceding fracture and rupture of its fabric covering may prohibit safe, in vivo HAART ring fracture.

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Abbreviations and Acronyms
AR = aortic regurgitation
BVF = bioprosthetic valve fracture

Video clip is available online.

Aortic valve repair for aortic regurgitation (AR) is increasingly favored over valve replacement given its low operative mortality, fewer valve-related complications, and improved survival.[1,2] The downfall of valve repair versus replacement remains recurrence of valve dysfunction, and prediction of which patients will develop recurrence of AR is an ongoing effort.[3] Annulus stabilization has been shown to be a key protective factor against AR recurrence and has led to the development of the HAART 300 (BioStable Science and Engineering, Inc) internal aortic annuloplasty ring, which has been shown to enhance repair by restoring physiologic annular geometry and reducing the risk of recurrent aortic annular dilation.[4,5] Most recently, HAART rings have even demonstrated good early outcomes in reconstruction of bicuspid aortic valves with proximal aortic aneurysms.[6] Most rings are 23 mm or less to treat the annulo-aortic ectasia component of the AR and in accordance with sinus sizing using the manufacturer's ball sizer. We have previously demonstrated survival benefit of valve-sparing approaches with or without valve repair, and other reports have shown mean gradients with the small HAART 300 rings to be favorable (typically < 10 mm Hg).[2,7,8]

Transcatheter valve-in-ring approaches are an appealing option for patients with recurrent valve dysfunction after HAART ring implantation. However, balloon fracture of undersized annuloplasty rings may be needed to facilitate larger transcatheter valve placement to avoid patient–prosthesis mismatch. Balloon valve fracture is well studied in the valve-in-valve space; however, there are no published data on balloon fracture of HAART rings. We characterized valvuloplasty balloon sizes and pressures necessary to fracture HAART 300 rings and the associated changes in ring geometry leading up to ring fracture.

MATERIALS AND METHODS

The HAART 300 ring is an elliptical aortic annuloplasty ring with a 2:3 major-to-minor axis ratio and 3 commissural posts angled 10° outwards from the ring. The 19-mm, 21-mm, and 23-mm HAART 300 aortic annuloplasty rings were provided by BioStable Science and Engineering, Inc (Figure 1). The 23-mm, 24-mm, 25-mm, and 26-mm True Dilatation Valvuloplasty Balloons (BD) were also obtained. The noncompliant True Dilatation balloon was chosen because it is one of the most common balloons used for balloon valve fracture and is the standard balloon used for valve fracture in our institution. Balloon sizes for attempted fracture were chosen based on a diameter calculated from the circumference of the ring (rather than the elliptical ring's long axis). Starting with the 19-mm ring, ring fracture was attempted by inflating a 23-mm balloon at a rate of 1 atm/s within the ring until either ring fracture or balloon failure occurred. If balloon failure occurred, the balloon was upsized by 1 mm, and the experiment was repeated. If ring fracture occurred, the maximum pressure recorded on the balloon indeflator was recorded. This protocol was repeated for all ring sizes until ring fracture occurred or no larger-sized balloons were available (Table 1). All experiments were carried out under continuous fluoroscopy and video recording to better study changes in ring conformation leading up to fracture.

FIGURE 1. Standard, elliptical 21-mm HAART 300 (BioStable Science and Engineering, Inc) internal aortic annuloplasty ring.

RESULTS

Upon valvuloplasty balloon inflation, all rings exhibited an irreversible conformational change from an elliptical, physiologic annular geometry to a more circular shape with ring posts flaring outward (Figure 2). These changes were maintained after balloon rupture or removal for upsizing. The maximal angle of outward flaring of the posts was not measured. Circular deformation was noted in all rings before reaching manufacturer-specified rated bust pressure, whereas all ring fractures were achieved at pressures above rated burst pressures.

The 19-mm and 21-mm HAART rings were both able to be fractured with valvuloplasty balloons 4 to 5 mm greater in size. A 23-mm balloon was unable to fracture the 19-mm annuloplasty ring and burst at 21 atm. The 24-mm balloon was able to fracture the 19-mm ring when inflated to 15 atm (Figure 3). The 19-mm ring exhibited a controlled fracture along the upslope of a post with no metallic frame exposed through the Dacron covering on the ring.

Likewise, a 24-mm balloon was unable to fracture the 21-mm annuloplasty ring and ruptured at 18 atm. A 25-mm balloon, however, was able to fracture the 21-mm ring when inflated to 18 atm (Video 1). Of note, both the balloon and ring failed at 18.0 atm. The 21-mm ring also fractured along the upslope of a post, but unlike the 19-mm ring, it left an exposed sharp metal tip protruding through the Dacron ring covering (Figure 4). The exposed metal conformed with the new ring shape and did not frankly point inward or outward from the ring.

Fracture of the 23-mm HAART 300 ring was also attempted but failed. A 26-mm balloon was first trialed and

TABLE 1. In vitro results of valvuloplasty balloon inflation within HAART 300 internal aortic annuloplasty ring: Fracture of internal aortic annuloplasty rings is possible with an oversized, high-pressure balloon

Ring size (mm)	Balloon size (mm)	Result	Pressure (atm)
19	23	Balloon failure	21
19	24	Ring fracture	15
21	24	Balloon failure	18
21	25	Ring fracture	18
23	26	Balloon failure	20

burst at more than 20 atm. Subsequently, a remaining 24-mm balloon was used on the "predilated" ring and burst at more than 20 atm, leaving the ring intact.

DISCUSSION

Bioprosthetic valve fracture (BVF) has quickly become a well-studied procedure to facilitate placement of larger transcatheter valves within certain prosthetic valve models with recurrent dysfunction. Extensive literature on this topic has provided key insight into preprocedural and intraprocedural predictors of success.

In vitro testing of 19- and 21-mm surgical aortic valves has demonstrated increases in internal diameter of 3 to 4 mm after BVF. This should be accounted for during patient selection when calculating valve-to-coronary distance (>6 mm distance classified as low risk).[9] During the procedure, balloon fracture of surgical aortic valves may be performed either before or after valve-in-valve deployment; however, performing BVF after valve-in-valve TAVR was an independent predictor of lower postprocedure mean gradients in one study.[10] Intraprocedural confirmation of valve fracture may be challenging because observing release of the waist of the balloon and listening for a snap are unreliable; observing for a sudden decrease in indeflator pressure near the valve fracture threshold while feeling for a vibration in the balloon shaft is the best confirmation of successful valve fracture.[9] With successful fracture, published series have shown additional reductions of postprocedure gradients of 16.5 mm Hg and increases in valve effective orifice area by 0.8 cm^2.[11,12] It is possible that balloon fracture of aortic annuloplasty rings may provide similar benefits during transcatheter valve-in-ring procedures. We performed bench testing to determine feasibility and any potential safety concerns of this approach.

The valve-in-ring approach, which avoids the risks of redo sternotomy, was initially described in preclinical porcine models by Andreas and colleagues,[13] who successfully implanted three 23-mm Medtronic Evolut R valves within pigs with 19-mm annuloplasty rings and one 26-mm Evolut R valve in a pig with a 21-mm annuloplasty ring; postprocedure gradients were, on average, 7.6 ± 4.0 mm Hg. To evaluate the effect of valve oversizing, a 29-mm Evolut R valve was also placed within a 19-mm ring within a porcine model; this model showed postprocedural migration of the valve to a higher position. After Andreas' experiments, groups at Duke University Medical Center and in Europe have both successfully performed valve-in-ring procedures in humans, both placing a 26-mm Medtronic Evolut R valve into a 21-mm HAART 300 ring with reported postprocedure gradients of "none" and 6 mm Hg, respectively.[14,15] Our institution has also successfully implanted a 23-mm Evolut FX valve within a 19-mm HAART 300 ring with a postprocedure mean gradient of 12 mm Hg.

These measurements seem consistent with reported measurements on the widely used "Aortic ViV" mobile application, which reports that a 23-mm Evolut R valve can fit within a 19-mm HAART 300 ring and that an a 26-mm Evolut R valve can fit within a 21-mm ring.[16] These measurements must be used with caution, however, because implantable valve size greatly depends on where the valve is deployed relative to the HAART device and the patient's native anatomy. As observed during the first

FIGURE 2. A 21-mm ring demonstrating circular deformation with posts flaring outward after dilation with a 24-mm balloon.

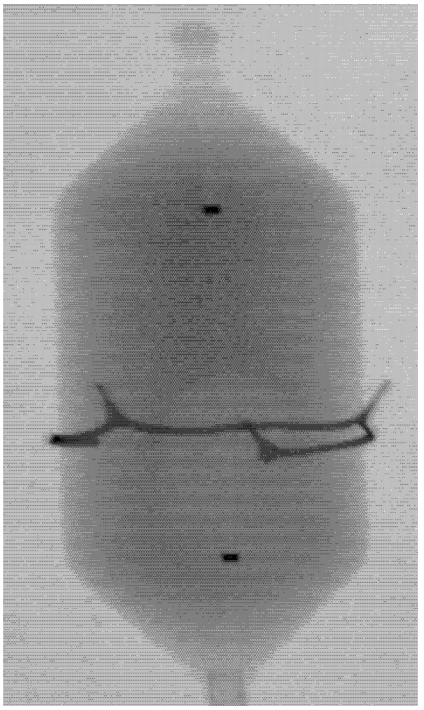
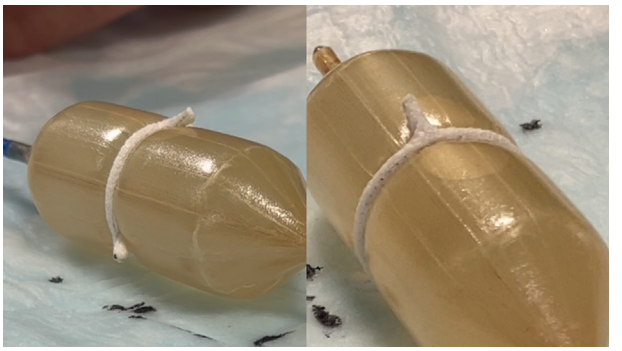


FIGURE 3. A 19-mm HAART 300 ring viewed just after fracture with a 24-mm valvuloplasty balloon at 15 atm. The 19-mm ring exhibited a controlled fracture with no exposed metal ring frame after ring fracture.



VIDEO 1. Fracture of HAART 300 annuloplasty rings is possible with oversized, high-pressure balloons. Changes in ring geometry and stability surrounding fracture remain concerning. The 19-mm ring exhibited controlled fracture with a 24-mm balloon, and the 21-mm ring exhibited an uncontrolled fracture with a 25-mm balloon. Video available at: https://www.jtcvs.org/article/S2666-2507(23)00107-4/fulltext.

and only reported implantation of a balloon-expandable valve within a HAART ring, a group from Germany successfully implanted a 26-mm Edwards Sapien 3 (Edwards Lifesciences) valve within a 21-mm ring, despite the valve-in-valve application suggesting 23-mm valve implantation at most.[17]

In cases where patients may require larger transcatheter aortic valve sizes, our work shows that HAART ring fracture is possible using valvuloplasty balloons 4 to 5 mm larger than the ring size. However, the safety of ring fracture within live models warrants further testing. The fracturing pressures of all rings (15 atm for 19-mm ring and 18 atm for 21-mm ring) were above the rated burst pressure of the balloons but comparable to the 18 atm reported pressure for balloon valve fracture of the Edwards MagnaEase transcatheter valve. Ring fracturing pressures were greater than previously reported fracturing pressures for the St Jude Biocor Epic (8 atm), Medtronic Mosaic (10 atm), and Sorin Mitroflow (12 atm) transcatheter valves and less than reported fracturing pressures for the Edwards Magna valve (24 atm).[18]

The level of HAART ring implantation in the subannular plane compared with supra-annular implantation of prosthetic valves is an important consideration. Oversized balloon expansion and valve fracture during valve-in-valve procedures pushes the fractured valve against aortic tissue and empty sinuses surrounding the aortic root. However, HAART ring fracture would transmit force to the annular and subannular planes, risking rupture of the

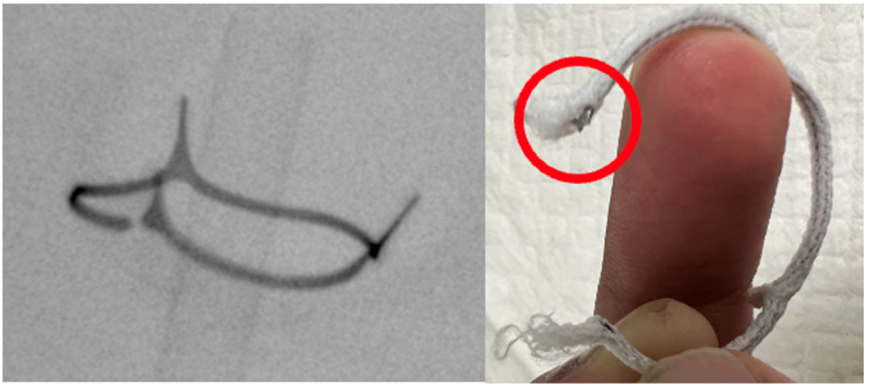


FIGURE 4. *Left*: Fractured 21-mm HAART 300 annuloplasty ring viewed under fluoroscopy. *Right*: Fractured 21-mm HAART 300 annuloplasty ring with exposed metal ring frame visible (*red circle*).

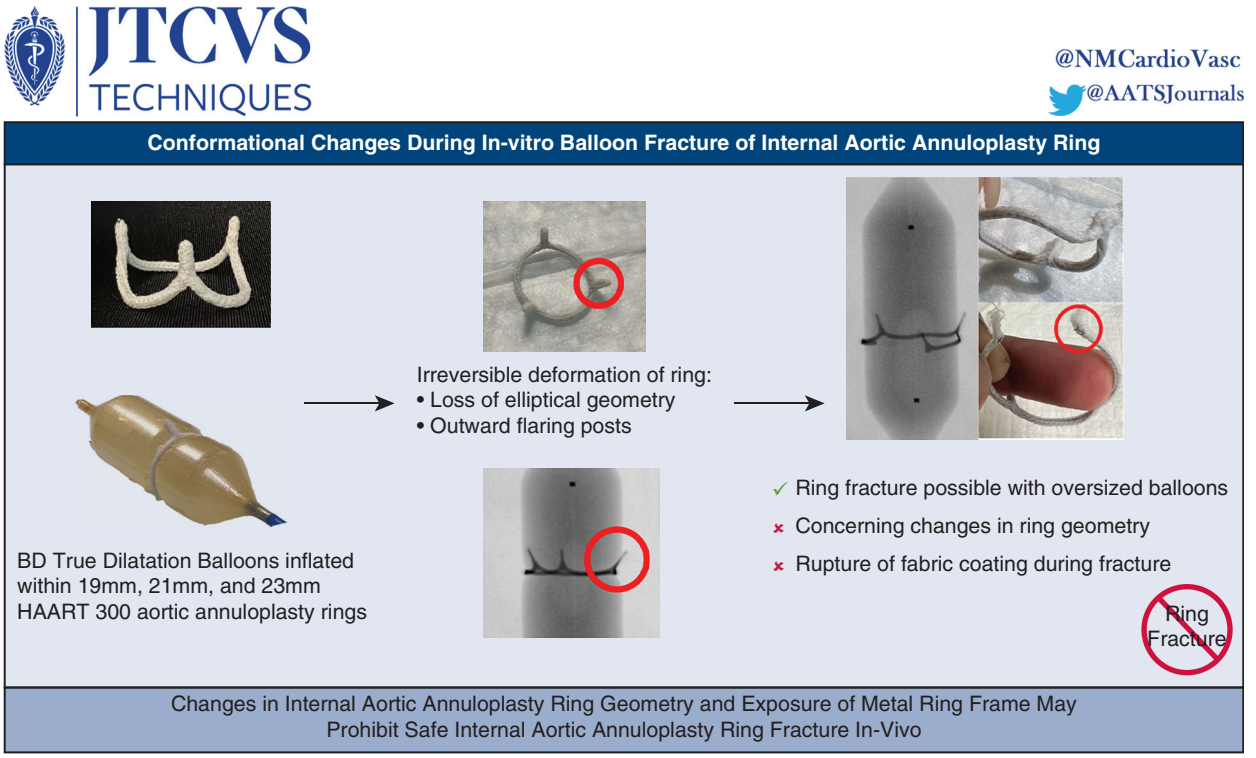


FIGURE 5. Conformational changes in HAART ring geometry preceding fracture may prohibit application of ring fracture in vivo.

membranous septum, conduction system damage, and possible damage of the aorto-mitral fibrous continuity. At this location, the force of instantaneous 5-mm expansion of an oversized balloon transmitted onto annular tissue via a newly fractured ring remains a safety concern. The uncontrolled nature of the 21-mm ring fracture in our study further elevates these concerns. Additionally, the conformational changes the HAART rings exhibit upon dilation remain worrisome (Figure 5). Outward flaring of the ring posts to increasingly perpendicular angles to the aortic wall theoretically risks rupture of the subcommissural triangles as the posts spear against the aortic wall. Finally, the loss of elastic recoil and retention of the distorted ring geometry even after balloon deflation and removal may prove problematic should valvuloplasty balloons be oversized or overinflated.

The location of ring fracture at the upslope near the posts fits expected results. However, it remains unknown whether an exposed tip of the ring's inner metal frame would be worrisome, especially should the fractured frame tip be positioned near the conduction system.

Study Limitations

Limitations of our work include testing on a small number of HAART rings. We would recommend replicating experiments with larger numbers of rings and assessing mean fracture pressures to improve reliability. Additionally, further investigation is needed to determine whether the inward force of a fractured ring would prohibit adequate transcatheter valve expansion or injure a newly implanted transcatheter valve. Further changes in ring shape after transcatheter valve expansion would also be of interest. Future directions should also include elucidating the effect of other balloon models in fracturing HAART rings. We speculate that the conformational changes exhibited by the ring would remain unchanged given that most balloon models exert similar radial force as the True dilatation balloons used. Finally, we acknowledge that our results reflect an in vitro model of ring fracture and that the results and feasibility may vary in vivo.

CONCLUSIONS

Our study is the first of its kind to characterize the requirements for and geometry of aortic annuloplasty ring fracture. We demonstrate that fracture of HAART 300 internal aortic annuloplasty rings is possible with an oversized, high-pressure balloon. However, the geometrical changes in the metal frame of the ring and subsequent rupture of the fabric covering may be obstacles to safe, in vivo fracture of aortic annuloplasty rings.

Conflict of Interest Statement

K.B.A.: Edwards, Medtronic, Abbott, Zimmer Biomet: research support, speaker bureau, proctoring with all payments to the institution and none to me personally. C.K.M.: Gore: Funding and speaking fees. S.C.M.: Edwards Lifesciences, Medtronic, Terumo Aortic, Artivion:

consultant and research. All other 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. Boodhwani M, El Khoury G. Aortic valve repair: indications and outcomes. *Curr Cardiol Rep*. 2014;16:490.
2. Collins JD, Semaan E, Barker A, McCarthy PM, Carr JC, Markl M, et al. Comparison of hemodynamics after aortic root replacement using valve-sparing or bioprosthetic valved conduit. *Ann Thorac Surg*. 2015;100:1556-62.
3. Yanagawa B, Mazine A, El-Hamamsy I. Predictors of aortic valve repair failure. *Innovations*. 2019;14:199-208.
4. Zeeshan A, Idrees JJ, Johnston DR, Rajeswaran J, Roselli EE, Soltesz EG, et al. Durability of aortic valve cusp repair with and without annular support. *Ann Thorac Surg*. 2018;105:739-48.
5. Baker JN, Klokocovnik T, Miceli A, Glauber M, Wei LM, Badhwar V, et al. Minimally invasive aortic valve repair using geometric ring annuloplasty. *J Card Surg*. 2022;37:70-5.
6. Gerdisch MW, Reece TB, Emerson D, Downey RS, Blossom GB, Singhal A, et al. Early results of geometric ring annuloplasty for bicuspid aortic valve repair during aortic aneurysm surgery. *JTCVS Tech*. 2022;14:55-65.
7. Malaisrie SC, Kislitsina ON, Wilsbacher L, Mendelson M, Puthumana JJ, Vassallo P, et al. Valve-sparing versus valve-replacing aortic root replacement in patients with aortic root aneurysm. *J Card Surg*. 2022;37:1947-56.
8. Mazzitelli D, Fischlein T, Rankin JS, Choi YH, Stamm C, Pfeiffer S, et al. Geometric ring annuloplasty as an adjunct to aortic valve repair: clinical investigation of the HAART 300 device. *Eur J Cardiothorac Surg*. 2016;49:987-93.
9. Allen KB, Chhatriwalla AK, Saxon JT, Huded CP, Sathananthan J, Nguyen TC, et al. Bioprosthetic valve fracture: a practical guide. *Ann Cardiothorac Surg*. 2021;10:564-70.
10. Allen KB, Chhatriwalla AK, Saxon JT, Cohen DJ, Nguyen TC, Webb J, et al. Bioprosthetic valve fracture: technical insights from a multicenter study. *J Thorac Cardiovasc Surg*. 2019;158:1317-28.e1311.
11. Brinkmann C, Abdel-Wahab M, Bedogni F, Bhadra OD, Charbonnier G, Conradi L, et al. Bioprosthetic valve fracture: predictors of outcome and follow-up. Results from a multicenter study. *Catheter Cardiovasc Interv*. 2021;98:756-64.
12. Chhatriwalla AK, Allen KB, Saxon JT, Cohen DJ, Aggarwal S, Hart AJ, et al. Bioprosthetic valve fracture improves the hemodynamic results of valve-in-valve transcatheter aortic valve replacement. *Circ Cardiovasc Interv*. 2017;10:e005216.
13. Andreas M, Russo M, Kuwata S, Cesarovic N, Wang C, Guidotti A, et al. Transcatheter aortic valve-in-ring implantation: feasibility in an acute, preclinical, pilot trial. *Interact Cardiovasc Thorac Surg*. 2019;28:908-15.
14. Takayuki G, Volker H, Axel H, Dirk F. Transfemoral transcatheter aortic valve implantation after aortic valve repair with HAART 300 device. *Catheter Cardiovasc Interv*. 2019;94:856-8.
15. Chung MJ, Ganapathi AM, Vora AN, Schroder JN, Kiefer TL, Hughes GC. Valve-in-ring transcatheter aortic valve replacement after left ventricular assist device therapy. *Ann Thorac Surg*. 2020;109:e163-5.
16. Bapat V. HAART 300. ViV digital application. Accessed September 22, 2022. https://mplsheart.org/valve-in-valve-digital-application
17. Vogt F, Marianowicz J, Jessl J, Eckner D, Fischlein T. Balloon transcatheter aortic valve replacement after aortic valve repair with HAART 300 device. *Ann Thorac Surg*. 2020;110:e375-6.
18. Allen KB, Chhatriwalla AK, Cohen DJ, Saxon JT, Aggarwal S, Hart A, et al. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation. *Ann Thorac Surg*. 2017;104:1501-8.

Key Words: aortic annuloplasty ring, aortic valve repair, HAART 300 annuloplasty ring, ring fracture, valve-in-ring