Conformational Changes During In-Vitro Balloon Fracture of Internal Aortic Annuloplasty Ring

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Objectives

Fig 1. 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.

HAART 300 aortic annuloplasty rings restore physiologic annular geometry during aortic valve repair. Transcatheter valve-in-ring approaches are appealing for recurrent valve dysfunction following HAART ring implantation, however, balloon fracture of undersized annuloplasty rings may be necessary. Balloon valve fracture (BVF) is well studied in the valve-in-valve space, however, there is no published data on balloon fracture of HAART annuloplasty rings.

Methods

HAART 300 aortic annuloplasty rings of sizes 19 mm through 23mm were provided by BioStable Science and Engineering, Inc. (Figure 1). True Dilatation Valvuloplasty Balloons (BD, Franklin Lakes, NJ), commonly used for balloon valve fracture, were also obtained in sizes ranging from 23 to 26 mm. Balloon sizes were chosen using diameters calculated from ring circumference (rather than the elliptical ring's long axis). Balloons of increasing sizes were inflated within each HAART ring at 1 atm/second until either ring fracture or balloon failure occurred (Figure 2). If balloon failure occurred, the balloon was upsized by 1 mm, and the experiment was repeated. If ring fracture occurred, maximum balloon pressure was recorded. All experiments were performed under continuous fluoroscopy and video recording to better study changes in ring conformation leading up to fracture.

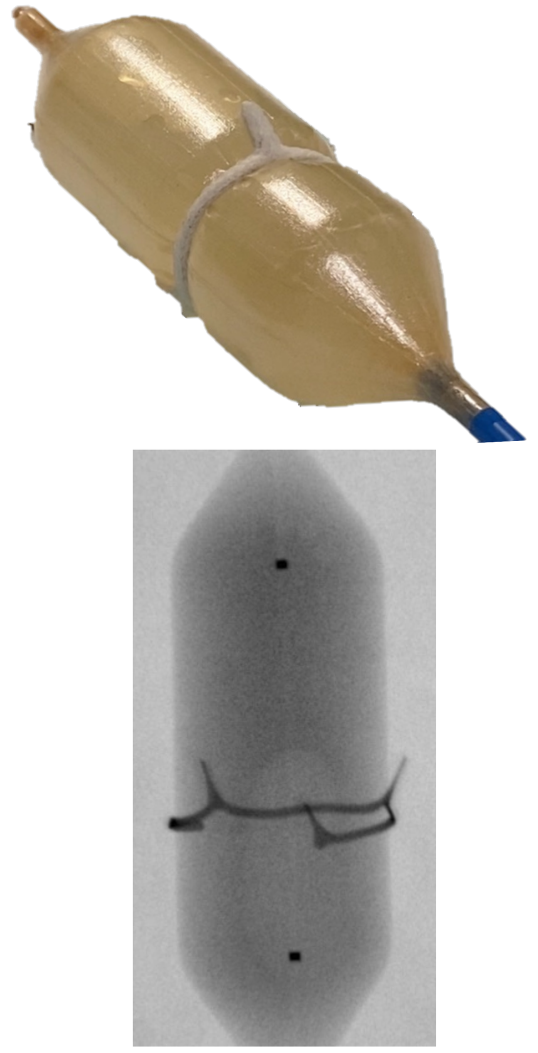

Fig 2. (Upper) Bard True Dilatation Valvuloplasty Balloons of increasing sizes were inflated within 19mm, 21mm, and 23mm HAART rings to elicit ring fracture. (Lower) Experiments were performed under continuous fluoroscopy.

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Results - Quantitative

HAART Ring Size	True Dilatation Balloon Size	Pressure	Outcome	Other findings
19 mm	23 mm	21 atm	Balloon Failure	Circular Deformation
19 mm	24 mm	15 atm	Ring Fracture	Controlled Fracture
21 mm	24 mm	18 atm	Balloon Failure	Circular Deformation
21 mm	25 mm	18 atm	Ring Fracture and Balloon Failure	Uncontrolled Fracture, Exposed metal tip
23 mm	26 mm	> 20 atm	Balloon Failure	Circular Deformation

Table 1. Outcomes of attempted HAART ring fracture with balloons of various sizes.

Results - Qualitative

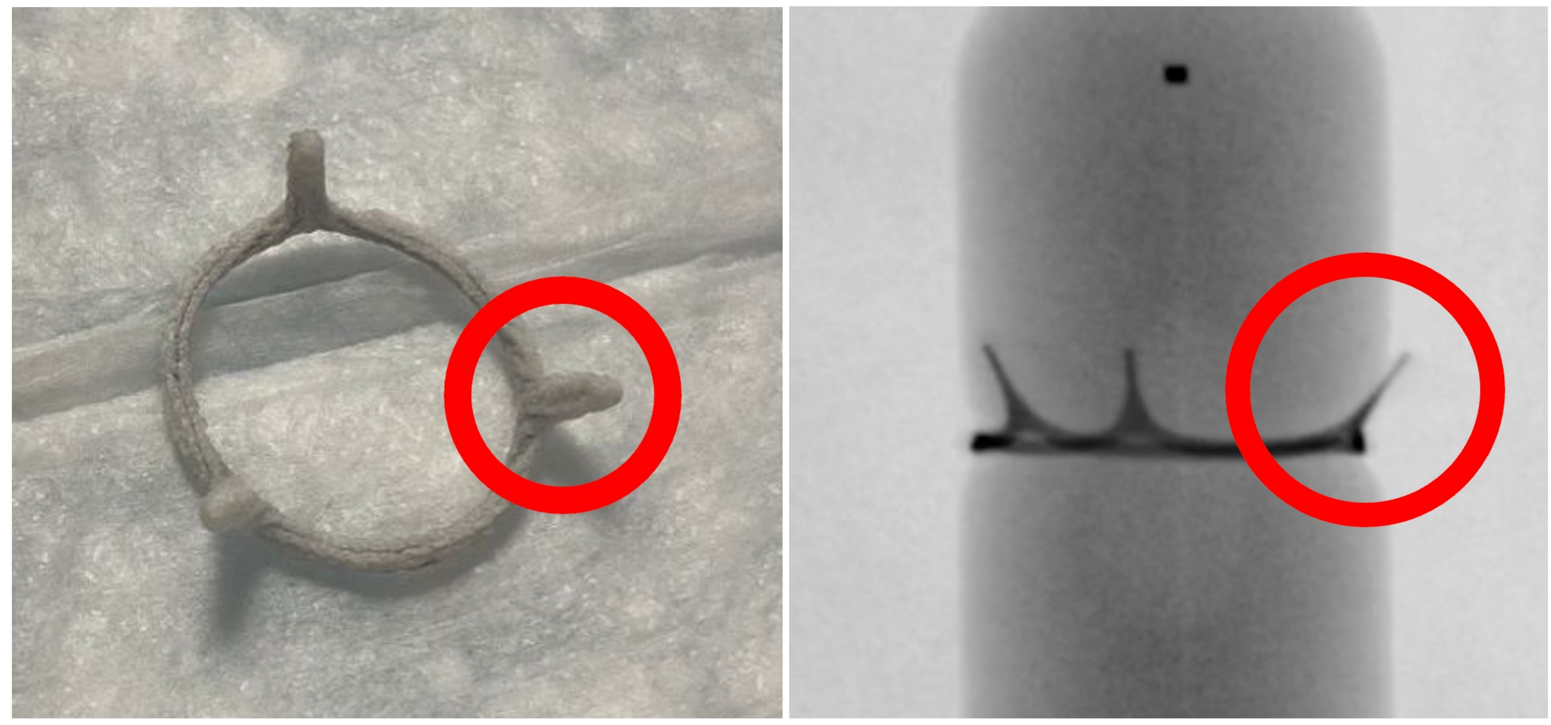
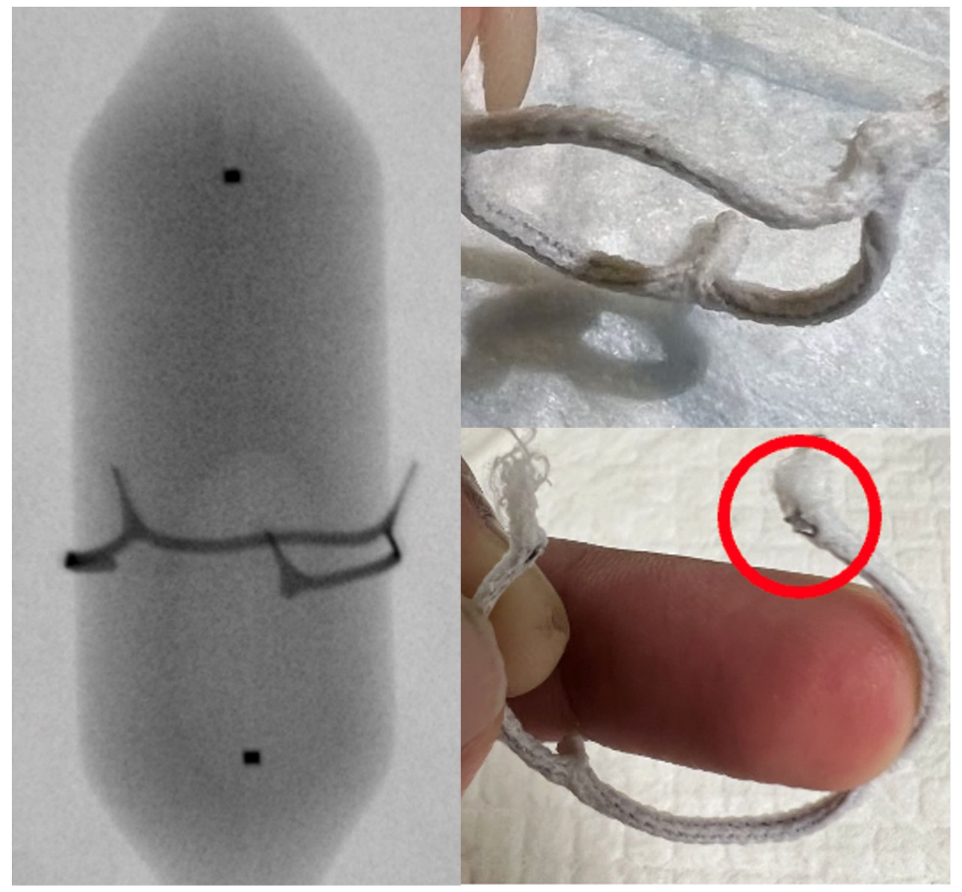


Figure 3: Circular flattening with outward flaring of posts (compare to Fig 1) seen upon balloon inflation within HAART rings.

Stage 1:
- Circular flattening of ring with loss of elliptical geometry (Figure 3)
- Outward flaring of posts
- Irreversible deformation of ring
- Findings consistent across all rings

Results – Qualitative (cont'd)



Stage 2:
- Controlled vs uncontrolled fracture (ring flying off valvuloplasty balloon upon fracture)
- Rupture of Dacron coating exposes sharp metal frame tip (Figure 4)
- Retention of altered ring geometry

Figure 4: (Left) 19 mm HAART ring fracture seen on fluoroscopy, (Right upper) 21 mm HAART ring following uncontrolled fracture with retention of altered geometry, (Right lower) Exposure of sharp metal frame tip through Dacron covering upon 21 mm HAART ring fracture

Conclusions

HAART ring fracture is possible with valvuloplasty balloons 4-5 mm larger than ring size. Conformational changes preceding ring fracture remain worrisome for 3 reasons:

1. Balloon ring fracture transmits instantaneous force and expansion to the annular and sub-annular planes, risking injury to the membranous septum, conduction system, and aorto-mitral continuity. This contrasts with BVF, which pushes fractured valves against aortic tissue and empty sinuses around the aortic root.

2. Flaring of ring posts to increasingly perpendicular angles to the aortic wall persists after balloon deflation and risks rupture of the subcommissural triangles as posts spear against subannular structures.

3. The uncontrolled nature of 21mm ring fracture and exposure of the ruptured, sharp metal frame tip further raise concerns for injury and unpredictability of fracture.