Bioprosthetic Valve Fracturing: 
In vitro Testing of Edwards PERIMOUNT Model P 2900

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Background: Bioprosthetic valve fracturing (BVF) results in low gradients following valve-in-valve transcatheter aortic valve replacement (ViV-TAVR). For the commonly used Edwards PERIMOUNT valve data from bench-testing are lacking to provide technical specifications for successful BVF during ViV-TAVR.

Methods: Using four Perimount 19- and 21-mm valves, in-vitro high-pressure balloon valvuloplasty with the True Dilatation Balloon Valvuloplasty Catheter and Atlas Gold PTA Dilatation Catheter was performed to analyze balloon-over sizing and pressure-thresholds to successfully achieve BVF.

Results: High-pressure balloons one millimeter larger than the labeled valve size and pressure rates of 20 atm (for Perimount 19-mm) and >22 atm (for Perimount 21-mm) were required to achieve BVF. Caliper measurements demonstrated 2.5 mm (Perimount 19-mm) and 1.5 mm (Perimount 21-mm) enlarged inner prosthetic diameters after BVF. The Atlas TM Gold PTA Dilatation Catheter achieved BVF with the Perimount 21-mm, whereas the True TM Dilatation Balloon Valvuloplasty Catheter failed in the Perimount 21-mm either for balloon-rupture or pinhole-defect.

Conclusion: Both 19-mm and 21-mm Perimount P 2900 are amendable to BVF, thereby increasing the inner prosthetic diameter. High-pressure balloons 1 mm larger than the labeled valves are essential for this purpose, and the Atlas Gold PTA Dilatation Catheter alone should ensure success in the 21-mm prosthetics.

Keywords: bioprosthetic valve fracturing, valve-in-valve transcatheter aortic valve replacement, in-vitro, balloon rupture, transprosthetic gradient

INTRODUCTION

Valve-in-valve transcatheter aortic valve replacement (ViV-TAVR) is an established therapy for failing surgical bioprostheses in patients with higher operative risks (1, 2). One-year survival after ViV-TAVR is 83%, but mean transprosthetic pressure gradients are determined by the size of bioprosthetics previously implanted (2). In a cohort with small-sized surgical valves (<21 mm inner prosthetic diameter), higher gradients and poor 8-year survival have resulted from ViV-TAVR procedures (1). Bioprosthetic valve fracturing (BVF) is intended to lower transprosthetic
gradients in this setting, especially in patients with small surgical valves (3–5). Although technical specifications (ie, balloon types, sizes, and pressure ratings) needed for successful BVF have been documented for various surgical valves through in vitro testing (6–8), there is limited clinical data on BVF utilization frequency or success rates (4, 9). PERIMOUNT surgical valves (Edwards Lifesciences, Irvine, CA, USA), models 2800 and 2900 in particular, have demonstrated inconsistent BVF success (9). Data from in vitro studies of Magna and Magna Ease valves (Edwards Lifesciences) have served to guide clinicians in terms of balloon type and sizing, enabling successful BVF during TIV- TAVR procedures (6). However, the PERIMOUNT model 2700 is known for its resistance to BVF. Between 2012 and 2018, Edwards PERIMOUNT valves (models 2800 and 2900) have been commonly deployed surgical valves, used in 15,000–20,000 implantations annually throughout Europe and the US (personal communication with Edwards Lifesciences). The present in vitro study was undertaken to better understand the amenability of a model 2900 PERIMOUNT valve to BVF attempts, determining pressure rates and balloon oversizing metrics required for successful BVF implementation.

**METHODS**

**Materials**

The Edwards PERIMOUNT (model P2900) 19- and 21-mm valves used for study came from institutional stock. The P2900 valve has three pericardial leaflets mounted on a cobalt-chromium-nickel alloy stent frame. Its sewing ring has a silicone rubber core and a polytetrafluoroethylene (PTFE) skirt.

For in vitro BVF testing, two distinctly different high-pressure balloons were engaged: (1) the True Dilatation Balloon Valvuloplasty Catheter (Bard Peripheral Vascular Inc, Temp, AZ, USA), burst-pressure rating of 6 atm, and (2) the Atlas Gold PTA Dilatation Catheter (Bard Peripheral Vascular Inc), burst-pressure rating of 14 atm. The Edwards Inflation Device (Edwards Lifesciences) allows inflation pressures up to 30 atm.

**Bioprosthetic Valve Fracturing**

Balloons for BVF were sized 1–3 mm beyond true inner diameters of surgical valves, using the Valve in Valve App (UBQO Ltd. [London, UK] and Dr. Vinayak Bapat [Minneapolis, MN, USA]). True inner diameters were obtained before and after BVF by caliper. In the course of BVF, a high-pressure balloon was connected via high-pressure stopcock (Marquis; Merit Medical Systems Inc., South Jordan, UT, USA) to a 50-ml syringe containing dilute contrast and to a high-pressure indeflator (Figure 1). Once the balloon filled with contrast, the stopcock was turned, allowing incremental indeflator pressurization to the point of valve fracture or balloon rupture (Supplementary Video 1). The corresponding pressure level was then recorded.

BVF was confirmed under fluoroscopy (Figure 2), with visual inspection after removal of the sewing ring (Figure 3). The ratio of balloon diameter to inner prosthetic diameter was calculated.

**Failure of High-Pressure Balloons**

Balloon failures were attributed to either ruptures (Supplementary Video 2) or pinhole defects (Supplementary Video 3). In the latter events, inflated balloon volumes remained visibly stable, but further pressure increase failed due to inherent microlesions.

**RESULTS**

**In vitro Bioprosthetic Valve Fracturing**

Both the 19- and 21-mm PERIMOUNT P2900 valves were amenable to in vitro BVF, requiring balloons 1 mm larger than labeled valve sizes for procedural success. Applied pressures of 19–20 atm were sufficient to fracture the 19-mm valve, whereas pressures of 22–25 atm were needed for the 21-mm valve (Table 1). Fluoroscopy confirmed frame dehiscence in all valves tested. Caliper measurements also indicated increases in inner diameters after BVF, relative to baseline determinations (19-mm valve: 17.5 mm → 20 mm; 21-mm valve: 20 mm → 21.5 mm).

**High-Pressure Balloon Performance**

In the four 19-mm PERIMOUNT P2900 valves that were tested, BVF was consistently achieved using 20-mm True Dilatation Balloon Valvuloplasty Catheters at pressures of 19–20 atm (Table 1). One pinhole defect surfaced within this test series. An 18-mm Atlas Gold PTA Dilatation Catheter inflated to 30 atm remained intact but failed to achieve BVF.

Four 21-mm PERIMOUNT P2900 valves were similarly tested. BVF was consistently achieved using 22-mm Atlas Gold PTA Dilatation Catheters at pressures of 22–25 atm (Table 1). True Dilatation Balloon Valvuloplasty Catheters at 20-, 21-, and 22-mm sizes failed to achieve BVF due to ruptures or pinhole defects. A 20-mm Atlas Gold PTA Dilatation Catheter inflated to 30 atm remained intact but failed to achieve BVF.

**High-Pressure Balloon Defects**

During in vitro BVF testing, the high-pressure balloons displayed two modes of failure. There were four ruptures of True Dilatation Balloon Valvuloplasty Catheters at pressures of 18–22 atm (mean, 20 atm), whereas all Atlas Gold PTA Dilatation Catheter remained intact. In the True Dilatation Balloon Valvuloplasty Catheters, pinhole defects undermined balloon pressurization, leading to three failed BVF attempts.

**DISCUSSION**

During in vitro testing of the Edwards PERIMOUNT P2900 valve (both 19- and 21-mm sizes), fracturing of its bioprosthetic ring was fully achievable. However, a balloon 1 mm larger than the labeled valve size (ie, 3 mm beyond inner prosthetic diameter) was required for success. In the 21-mm valve, higher pressure levels were required to achieve BVF. Only the Atlas Gold PTA Dilatation Catheter was capable of doing so, the True Dilatation Balloon Valvuloplasty Catheter failing entirely. Balloon failures resulted from true ruptures or pinhole defects.
In-vitro BVF Studies
Recent in-vitro BVF studies have reported technical specifications and feasibility data for various surgical valves other than the PERIMOUNT P2900 (6, 7). Higher pressure levels (ie, 18–24 atm) were required for BVF of surgical bioprostheses with metal rings (e.g., Magna, Magna Ease [Edwards Lifesciences]).
as opposed to those with polymer rings (e.g., Epic [Abbott Laboratories, Chicago, IL, USA], Mosaic [Medtronic, Dublin Ireland], Mitroflow [LivaNova, London, UK]) where 8–12 atm sufficed (5–7). Based on bench testing of analogous devices, balloon oversizing of 1 mm beyond stated valve dimension is recommended (6, 7). For the 19- and 21-mm PERIMOUNT Magna valves, the feasibility of BVF using either an Atlas Gold PTA Dilatation Catheter or a True Dilatation Balloon Valvuloplasty Catheter has been proven at high (24-atm) pressure levels (6). Although the PERIMOUNT P2900 and the Magna have similar fluoroscopic appearances, results of our in vitro test series differed. Pressure required (19–20 atm) for the 19-mm PERIMOUNT P2900 was lower than that required (24 atm) for the 19-mm Magna. Also, successful BVF of the 21-mm Magna has been reported at 24 atm, whether by Atlas Gold PTA Dilatation Catheter or True Dilatation Balloon Valvuloplasty Catheter (6). We did not achieve BVF in 21-mm P2900 valves using True Dilatation Balloon Valvuloplasty Catheters. Table 2 summarizes the currently available data on in-vitro BVF studies.

Causes of BVF Failure
Existing clinical data on BVF failure rates are sparse (9). Although balloon ruptures during ViV-TAVR procedures are quite evident by fluoroscopy, pinhole balloon defects are more likely signaled indirectly. For instance, manometer readings may indicate pressure loss or stagnation during full fluoroscopic balloon inflation. In such circumstances, balloons should be deflated, and attempts at BVF terminated. Balloon undersizing also precludes successful BVF.

Clinical Data on BVF
Some clinical case series addressing ViV-TAVR have demonstrated lower transvalvular gradients through BVF, compared with its non-use or with postdilatation, respectively (4, 9). As defined by the Valve Academic Research Consortium (VARC), device success is reportedly higher after ViV-TAVR procedures if BVF is performed (93 vs. 68%; p < 0.001) (4); and transvalvular gradients seem to be lower (10). Midterm data
on ViV-TAVR with BVF are scant. Immediate postoperative transvalvular gradients in 139 patients treated thusly were low (9.4 ± 5.8 mmHg) but increased significantly (14.6 ± 7.5 mmHg; p < 0.001) at 30 days and remained stable for up to 1-year of follow-up (11). BVF-related complications, such as stroke, annular rupture, and coronary obstruction,
TABLE 1 | In vitro fracturing studies of PERIMOUNT model P2900 bioprosthetic valve.

| Valve Model | Labeled Valve Size (mm) | Atlas Gold Fracture Pressure (atm) | True Dilatation Fracture Pressure (atm) | Source Data Reference |
|-------------|-------------------------|-----------------------------------|----------------------------------------|-----------------------|
| Perimount P2900 | 19 | 20 | Not tested | 20 | 19 |
| Magna Ease 19 | 20 | 20 | 19 | Not tested | (7) |
| Magna Ease 19 | 20 | 18 | 20 | 18 | (6) |
| Magna Ease 21 | 22 | 21 | Not tested | (7) |
| Magna Ease 21 | 22 | 18 | 22 | 18 | (6) |
| Mosaic 19 | 20 | 24 | 20 | 24 | (6) |
| Mosaic 21 | 22 | 24 | 22 | 24 | (6) |
| Mosaic 19 | 20 | 10 | Not tested | (7) |
| Mosaic 19 | 20 | 10 | 20 | 10 | (6) |
| Mosaic 21 | 22 | 8 | Not tested | (7) |
| Mosaic 21 | 20 | 10 | 20 | 10 | (6) |
| Mitroflow 19 | 20 | 12 | 20 | 12 | (6) |
| Mitroflow 21 | 22 | 10 | Not tested | (7) |
| Mitroflow 21 | 22 | 12 | 22 | 12 | (6) |
| St. Jude Epic | 22 | 8 | 22 | 8 | (6) |

Color-coded outcomes of bioprosthetic valve fracturing attempts:

- **Successful BVF**
- **Balloon undersizing, no effect**
- **Pinhole defect**
- **Balloon rupture**

TD, true dilatation balloon; AG, atlas gold balloon.

have been rare, not exceeding rates cited for ViV-TAVR only (9, 12).

Technical Specifications for BVF Procedure

The present study provides technical specifications for BVF of PERIMOUNT P2900 bioprosthetic valves. Models P2900 and P2800 differ only in their pericardial leaflet treatments. Hence, we presume that the findings herein are applicable to the P2800 model as well.

We do suggest that balloons 1 mm larger than labeled valves be applied in this setting. In vitro BVF of the 21-mm PERIMOUNT P2900 also requires use of an Atlas Gold PTA Dilatation Catheter. Because pinhole defects seemed to account for nearly one-half of our balloon failures, we advise continuous monitoring of manometers during any BVF attempts to clearly identify such defects and abort all non-productive efforts.

Randomized clinical studies of ViV-TAVR procedures conducted alone or in conjunction with BVF are needed to verify the hemodynamic benefit of BVF and to establish protocols for its utilization.

CONCLUSION

Both 19- and 21-mm PERIMOUNT P2900 valves are amenable to BVF, thereby increasing inner prosthetic diameters. High-pressure balloons 1 mm larger than labeled valve sizes are essential for this purpose, and the Atlas Gold PTA Dilatation Catheter alone should ensure success in 21-mm prosthetics.

LIMITATIONS

Despite the limited number of valves tested, results were quite consistent. Still, an in vitro study may not entirely simulate in vivo BVF during transcatheter replacement of a degenerated surgical valve.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

HR is responsible for the study design, data collection, data analysis, data interpretation, and writing the manuscript. HA-C, OD, and ZA contributed in the in-vitro testing and manuscript
supplementary video. KV revised the manuscript. RL revised the manuscript and supervised the project. All authors contributed to the article and approved the submitted version.

ACKNOWLEDGMENTS

The manuscript has been copy edited by native English speakers with related biomedical background in BioMed Proofreading® LLC.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fcvm.2022.859088/full#supplementary-material

Supplementary Video 1 | Successful bioprosthetic valve fracturing.
Supplementary Video 2 | High-pressure balloon rupture causing failure of bioprosthetic valve fracturing attempt.
Supplementary Video 3 | With pressure increase microlesion with volume loss undermine bioprosthetic valve fracturing attempt.

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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