



## Early Valve Dysfunction of Bioprosthetic Valves: Review of Reports

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### Abstract

**Background:** Early tissue failure has been reported in the bioprosthetic valve.

**Method and Results:** We reviewed studies written in English on PubMed, and we have reached six case reports indicating early structural dysfunction of the Trifecta valve and some showing leaflet tear in other bioprosthetic valves. Four cases showed leaflet tear within four years after the implantation of the Trifecta. The others include leaflet calcification and pannus formation around the valve.

**Conclusions:** Mid-term durability of the Trifecta is acceptable, but early tissue failure can be recognized. The early tissue failure should be overcome.

**Keywords:** Trifecta valve; Bioprosthetic heart valve; Primary tissue failure; Leaflet tear; Aortic valve replacement; Prosthetic valve dysfunction

### Introduction

Primary tissue failure could occur after heart valve implantation with a bioprosthesis. The Trifecta bioprosthetic valve consists of a bovine pericardial sheet externally mounted on a titanium stent, and it is implanted for Aortic Valve Replacement (AVR). Some unpredictable primary tissue failure has been reported in the bioprosthetic valve. The complication consists of early onset after surgery associated with cusp leaflet tear without calcification or a leaflet attached to the Valsalva sinus causing valve dysfunction. Herein, we review early Structural Valve Dysfunction (SVD) of the Trifecta valve.

### Methods

We reviewed studies written in English published after 2011 when the Trifecta valve was approved for commercial use in USA, including studies written in non-English with English abstracts as of the end of 2017. Studies were searched for using following key words: bioprosthesis, Trifecta, structural dysfunction aortic valve replacement, and leaflet tear. We have reached six case reports indicating early structural dysfunction of the Trifecta valve after 2014 in PubMed searching and some showing leaflet tear in other bioprosthetic valves.

### Results

Sexena reported the first case with an early structural dysfunction in 2014 [1]. A 67-year-old woman presented with heart failure after four years after AVR with a Trifecta prosthetic valve. Echocardiographic examination showed aortic valve stenosis. Operative findings revealed degenerative changes of the valve with calcification like primary tissue failure long after prosthetic valve replacement.

Two cases with different pathologic changes were shown by Campisi [2]. Both cases presented with severe aortic valve regurgitation three and eight months after AVR. The former revealed that the noncoronary leaflet of the bioprosthesis was tightly attached to the corresponding Valsalva sinus, leading to incomplete leaflet coaptation. The latter showed a partial tear on the stent of the bioprosthesis.

The other case with early leaflet tear occurred in 71-year-old woman three years after AVR with a Trifecta valve [3]. Operative findings consisted of a para-stent tear in the non-coronary cusp without infective changes.

A tear was also noted in the valve leaflet between the non- and right coronary cusps in a 77-year-

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old woman 19 months after AVR with a Trifecta valve for combined heart valve diseases [4]. Zhu and colleagues reported a case of early and acute structural deterioration (stent-post leaflet rupture) of the Trifecta valve, explanted after 33 months, in a 76-year-old male [5].

Kalra and colleagues reported early Trifecta valve failure in seven patients [6]. The mean duration of valve durability was  $32 \pm 21$  months, and the most common lesion was prosthetic regurgitation, and the most common pathologic finding in the explanted valves included the presence of a circumferential, homogeneous, tan-yellow, fibro-fatty membrane adherent to the inflow portion of the valves and leaflet calcification concentrated around the stent-posts in the outflow portion of the valves, leading to restricted leaflet mobility manifesting as prosthetic valve dysfunction.

## Discussion

Newly developing tissue valves such as the Trifecta valve provide excellent hemodynamics and extremely low incidence of SVD [7-15]. Mid-term clinical results show that freedom from reoperation because of structural dysfunction is almost 98% up to five years after operation [8,9,11]. The causes of early SVD could be related to patient factors, valve size and design, surgical technique, anticoagulation strategies, or a combination of the above [16]. Most early SVD is the result of sub-annular pannus leading to prosthetic valve dysfunction [17,18]. Leaflet calcification with/without cusp laceration long after implantation also leads to prosthetic valve dysfunction [19]. However, unpredictable primary leaflet tear has been reported in the Trifecta bioprosthetic heart valve since it was commercially available. The cause of the early tear has been still unknown.

Some investigators have reported similar complications to this valve dysfunction. Other bioprosthetic valves include Carpentier-Edwards, Freestyle ones [20-22]. The complications occurred within two years after implantation. In the Mitroflow valve, structural valve deterioration was observed in 100% of the valves that had been in place for more than 2 years with the high rate of cusp tears, calcification, and tissue degeneration [19]. Explanation in detail for these early primary tissue failure remains still unresolved. Manufacture analysis of the complication should be inevitable.

Leaflet adhesion to the aortic wall was also observed in the Freedom Solo [23]. Approximation of the prosthetic valve and the aortic wall might lead to the complication. Anatomical aspects might be considered in specific patients with a narrow aortic valve annulus in case of implantation of a bioprosthesis.

A lot of articles endorse the usefulness of a different type of bioprosthetic heart valves. However, some rare cases such as early leaflet tear are unpredictably observed. Limited healthcare costs require longer durability of bioprosthetic heart valves. We believe the complication will be overcome with scientific progress in medical technology.

## Conclusions

Early tissue failure has been reported in the bioprosthetic valve. We reviewed studies written in English on PubMed, and we have reached six case reports indicating early structural dysfunction of the Trifecta valve and some showing leaflet tear in other bioprosthetic valves. Four cases showed leaflet tear within four years after the implantation of the Trifecta. The others include leaflet calcification and pannus formation around the valve. The early tissue failure should be overcome.

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