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ORIGINAL ARTICLES

Freestyle Bioprosthetic Valves: Clinical Outcomes, Surgical Techniques, and Future Directions

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Abstract

Introduction: The Freestyle® stentless porcine aortic root (Medtronic, Minneapolis, MN) has emerged as a valuable option for aortic valve replacement (AVR), offering superior hemodynamics compared to stented bioprostheses and eliminating the need for lifelong anticoagulation required with mechanical valves. Derived from a porcine aortic root, the Freestyle valve allows for versatile implantation techniques, including subcoronary, root inclusion, and full root replacement. While the Freestyle valve demonstrates excellent hemodynamics and benefits, as well as acceptable long-term survival, challenges remain regarding structural valve deterioration (SVD) in younger patients and technical complexities during implantation. These technical complexities include the need for precise surgical expertise, the stentless nature of the prosthesis, dense adhesions, and circumferential calcification of the porcine root. Emerging technologies, such as advanced anti-calcification treatments and tissue engineering, may further enhance its durability. In this article, we present two illustrative cases from our institution to highlight these challenges and discuss surgical strategies, as well as synthesize current evidence and discuss future directions for stentless bioprosthetic valves.

Conclusion: The Medtronic Freestyle stentless bioprosthetic valve offers significant hemodynamic benefits and acceptable durability in appropriately selected patients. However, late failure of the Freestyle stentless aortic root bioprosthetic can present as catastrophic pseudoaneurysm formation or severe leaflet degeneration with rupture. Prosthesis excision requires complex surgical strategies, including the need for root replacement and tailored coronary reimplantation.

Keywords: Freestyle valve, bioprosthetic valve, aortic valve replacement, stentless valve, structural valve deterioration.

Introduction

Aortic valve disease, including stenosis, regurgitation, and mixed pathologies, remains a leading cause of cardiovascular morbidity and mortality, often necessitating surgical intervention. Diseases of the aortic valve account for 61% of all valvular heart disease deaths [1].

While mechanical valves offer durability, they require lifelong anticoagulation, making bioprosthetic valves a preferred choice for older patients and those seeking to avoid the risks of warfarin therapy [2].

The use of bioprostheses for aortic valve replacement (AVR) is recommended by international guidelines in patients aged more than 65 years, also due to the decreased risk of device structural deterioration [3].

Among bioprostheses, the Medtronic Freestyle stentless aortic valve has garnered attention due to its unique design, which mimics the native aortic root, providing superior hemodynamic performance compared to traditional stented valves [4].

Introduced in the 1990s, the Freestyle valve is constructed from a porcine aortic root treated with alpha-amino oleic acid (AOA) to mitigate calcification. Its stentless configuration allows for greater effective orifice

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area (EOA), reducing transvalvular gradients and improving left ventricular mass regression post-AVR [5]. However, its implantation is technically demanding, requiring precise surgical expertise. Additionally, long-term durability, particularly in younger patients, remains a topic of ongoing research.

Objective

This review aims to present two illustrative cases from the Cardiac Surgery Department in "Mother Teresa University Hospital" and German Hospital International to highlight challenges met during redo operations of Freestyle bioprosthesis and discuss surgical strategies, clinical outcomes, long-term durability of the Medtronic Freestyle valve, and to explore future advancements that may improve the performance and broaden the indications for stentless bioprosthetic valves. These future advancements include but are not limited to, advanced anti-calcification treatments, tissue engineering, and the potential use of novel biomaterials in valve construction.

Materials and Methods

This review was conducted through a comprehensive search of PubMed, Scopus, and Google Scholar databases for English-language articles published between 1995 and 2025.

The search was thorough, and priority was given to clinical studies, meta-analyses, case series, and review articles that reported long-term outcomes, comparative analyses with stented valves or mechanical valves, and technical aspects of surgical implantation. Articles about future innovations in tissue engineering were also included.

The inclusion of studies from a variety of geographic regions and institutional experiences minimized selection bias, ensuring the validity of the presented information.

Case Reports

Case 1: Acute Freestyle Valve Failure Presenting as Cardiogenic Shock

A 53-year-old male with a history of Freestyle valve implantation (29 mm) 13 years earlier for aortic root aneurysm and severe aortic regurgitation was admitted with acute onset of dyspnea, orthopnea, and rapidly progressing pulmonary edema. He reported low-grade fever, bilateral pleuritic chest pain, and productive cough for two weeks prior to admission.

Clinical evaluation revealed signs of left-sided heart failure with rales across both lung fields and bilateral pleural effusions on chest X-ray. Transthoracic echocardiography (TTE) revealed severe aortic regurgitation with flail leaflet motion but no clear evidence of vegetation.

A transesophageal echocardiogram (TEE) showed massive central regurgitation through a dysfunctional prosthetic valve. Blood cultures were drawn, and empiric broad-spectrum antibiotic therapy was initiated, although the patient remained hemodynamically unstable despite medical management.

Surgical Findings and Procedure:

Emergency surgery was indicated due to cardiogenic shock. Through a median re-sternotomy, dense fibrous adhesions were encountered surrounding the Freestyle root. Cardiopulmonary bypass was established via peripheral femoral venous and aortic graft cannulation.

After aortotomy, an inspection of the prosthesis showed torn and prolapsing cusps with no visible vegetation. The prosthesis was densely adhered to the aortic wall, necessitating meticulous dissection to avoid injury to surrounding structures.

The valve was explanted in total. The native annulus was sized, and a 21 mm stented bovine pericardial bioprosthesis was implanted. Postoperative transesophageal echocardiography confirmed excellent valve function with no paravalvular leak.

All cultures, including blood and explanted tissue, were negative. The patient was extubated on the first postoperative day and discharged on postoperative day 7 with complete resolution of symptoms. He continued long-term follow-up under clinical surveillance with periodic echocardiography and CT angiography.

Case 2: Silent Pseudoaneurysm and Leaflet Rupture 16 Years Post-Implantation

A 79-year-old man, who had undergone Freestyle valve implantation (27 mm) 16 years earlier for severe aortic stenosis, presented with progressively worsening dyspnea on exertion and fatigue over several months. Her medical history included permanent atrial fibrillation managed with anticoagulation. Notably, she had no fever or systemic signs of infection.

Fig 1. CT-scan images showing rupture and pseudoaneurysm - aortic dissection

On examination, she had an irregularly irregular pulse, mild peripheral edema, and a decrescendo diastolic murmur over the left sternal border.

TTE demonstrated moderate to severe aortic regurgitation. TEE confirmed a flail leaflet and mobile echo-dense masses suggestive of vegetation. CT angiography was ordered for further evaluation and unexpectedly revealed a large pseudoaneurysm arising from the noncoronary sinus and extending into the periaortic space. There was also radiological suspicion of a localized type A aortic dissection originating near the porcine aortic wall, with involvement of the proximal ascending aorta.

Surgical Findings and Procedure:

Redo sternotomy was performed under moderate hypothermia (32°C) and complete cardiopulmonary bypass via right atrial and aortic arch cannulation. Intraoperatively, a large pseudoaneurysm cavity was identified at the noncoronary sinus, in continuity with the degenerated Freestyle root. There was partial disruption of the aortic wall and early signs of root dissection.

The Freestyle prosthesis was calcified and fused to the native aortic annulus and sinuses, requiring sharp dissection for extraction. Given the extensive damage to the root and coronary buttons, a complete root replacement using a 25 mm mechanical valved conduit was performed. The right coronary artery was reimplanted directly (Bentall technique), while the left coronary artery required a Cabrol extension graft due to inadequate tissue mobility and calcific involvement of the ostium.

The patient had an uneventful postoperative course. He was extubated on postoperative day 2 and transferred to the ward by day 4. A repeat CT scan at 3 months showed normal conduit position and no residual pseudoaneurysm. The patient was continued on warfarin and maintained on outpatient follow-up with stable, functional status.

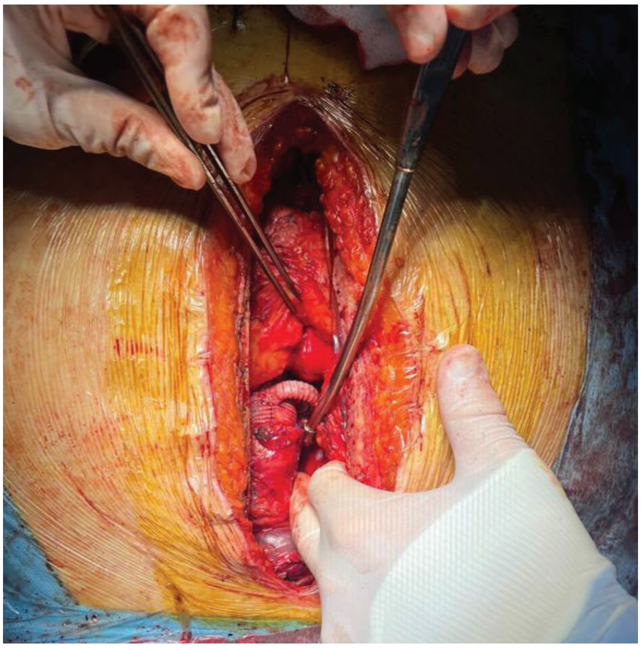

Fig 3. In-op images showing the view at the end of the Cabrol procedure.

Discussion

The Freestyle valve's hemodynamic benefits are among its most significant advantages, primarily attributed to the absence of a supporting stent frame. This design enables a larger effective orifice area (EOA), which translates into lower transvalvular gradients and better flow dynamics [6].

The improved hemodynamics are particularly beneficial in patients with small aortic roots, as they help mitigate the risk of patient-prosthesis mismatch (PPM) and support more effective left ventricular unloading. The favorable pressure gradients associated with the Freestyle valve have also been correlated with improved left ventricular mass regression and recovery of diastolic function [7, 14, 15].

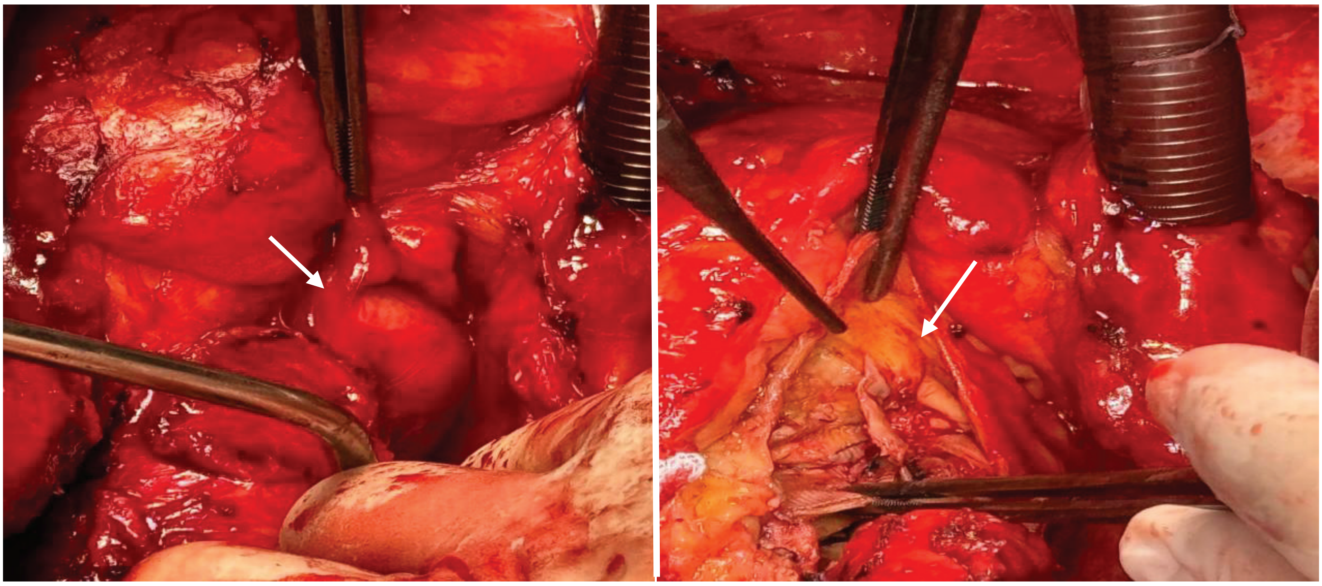

Fig 2. In-op images (left) show the pseud-aneurysm formation, and (right) show the Freestyle prosthesis structural deterioration.

The implantation techniques for the Freestyle valve: sub-coronary, root inclusion, and full root replacement - offer flexibility to the operating surgeon but require considerable technical skill. Each method presents distinct advantages and limitations. Sub-coronary implantation, while less invasive and preserving the native root, is more sensitive to suture technique and alignment and may be associated with an increased risk of aortic insufficiency over time.

Root inclusion serves as a compromise, offering better annular support and less distortion of valve geometry. Complete root replacement, the most comprehensive of the three techniques, is often associated with the most favorable long-term outcomes but demands a high level of surgical precision, particularly in reimplanting the coronary arteries and managing cross-clamp time [3,8].

In terms of durability, the Freestyle valve has demonstrated strong mid-term and long-term outcomes, particularly in elderly patients, with freedom from structural valve deterioration (SVD) reported in over 85% of cases at ten years [9-15]. However, durability concerns become more prominent in younger patient populations, where the early onset of calcific degeneration and valve failure has been observed.

This xenograft also carries unique late structural risks not commonly associated with other valve types. The mechanisms of failure typically involve leaflet calcification and tearing, but in root replacement procedures, dilation of the porcine aortic root (pseudoaneurysm formation) has also been noted as a contributing factor [16]

The presented case series illustrates two of the most clinically relevant complications following Freestyle implantation: acute valvular failure secondary to leaflet degeneration and spontaneous rupture of the aortic root wall, resulting in a pseudoaneurysm.

These findings are not isolated. Mohammadi et al. found that among 608 patients implanted with the Freestyle valve, leaflet tears accounted for over 80% of structural valve deterioration (SVD), often occurring with minimal calcification and presenting acutely. [17]

Perhaps more concerning are the pseudoaneurysms arising from the porcine sinus wall. Ozaki et al. first described spontaneous rupture of the noncoronary sinus in patients with Freestyle valves, which led to pseudoaneurysm formation and even death in one case [18]. Later reports confirmed these failures occurred not at the suture lines but within the native porcine tissue itself—suggesting intrinsic material degeneration rather than technical failure [19].

Sakaguchi and colleagues echoed this in their case report of a patient who developed a large pseudoaneurysm due to rupture of the noncoronary sinus 12 years after complete root implantation [20].

Mizuno also documented a pseudoaneurysm that compressed the pulmonary artery, causing cardiogenic shock, and traced the rupture to a tear just above the Dacron collar—again implicating native porcine tissue degeneration rather than suture dehiscence [21].

An extensive retrospective analysis by *Dagnégard et al.,* including 1,030 patients from six centers, reported a pseudoaneurysm rate of 5.2%, with reinterventions most frequently prompted by endocarditis and wall rupture [22].

This was further supported by Hughes' editorial commentary, which reviewed both registry data and institutional series, concluding that pseudoaneurysm formation may affect up to 13% of patients, often presenting silently and detectable only through advanced imaging modalities such as 4D-CT or MR angiography [9].

The diagnostic challenge is underscored by the poor sensitivity of transthoracic echocardiography (TTE) in detecting early structural degeneration and the formation of pseudoaneurysms. In many of the reviewed cases—including our own—computed tomography angiography (CTA) was required for accurate diagnosis. Hughes and others have advocated for life-long surveillance using CTA or MRA in all patients with Freestyle valves [9].

Surgically, the explanation of the Freestyle valve is especially challenging due to circumferential calcification and fusion of the porcine root to native tissue. Our second case, which required a complex Cabrol–Bentall procedure, is consistent with reports that reoperations often necessitate full root replacements, often accompanied by creative coronary reimplantation strategies [18, 20].

Although there is a lack of studies that directly compare Freestyle valves to conventional stented prostheses, a large number of studies that compare stent-less to stented bio-prostheses suggest that the Freestyle valve offers superior hemodynamics to the stented ones. However, long-term survival and reoperation rates may be similar [6, 7].

In comparison to mechanical valves, the Freestyle valve eliminates the need for anticoagulation, thereby reducing the risk of bleeding complications and improving the quality of life for patients, particularly those over 65 years old. Furthermore, a study by *Silberman et al.* [23] showed that stentless valves behave similarly to normal aortic valves in that there is almost no increase in gradient at exercise.

Mechanical valve groups showed increased gradients at exercise, suggesting that stentless valves are hemodynamically superior to mechanical valves in the aortic position. Still, mechanical valves continue to offer unmatched durability, especially in younger patients where bioprosthetic degeneration is a notable concern.

A significant limitation to the broader adoption of the Freestyle valve lies in its technical complexity and the steep learning curve associated with its implantation. This has led many institutions to prefer stented alternatives that are easier to implant and less prone to intraoperative complications.

However, studies such as one published by *Ennker et al.* [24] suggest that the Freestyle stentless bioprosthesis can be safely implanted without increased operative risk, even during the learning phase. Nevertheless, exceptional surgeon training is recommended to achieve optimal hemodynamic performance.

Looking to the future, several innovations promise to enhance the utility and performance of stentless valves. Improved anti-calcification treatments are under development, aimed at extending the durability of bioprosthetic leaflets and minimizing early structural valve deterioration (SVD) [25].

Additionally, tissue engineering approaches, such as decellularized scaffolds and regenerative tissue constructs, may offer more robust and longer-lasting valve solutions [26]. In patients with failed Freestyle valves, the emergence of transcatheter valve-in-valve (ViV) technologies provides a less invasive alternative to reoperation, significantly lowering the risk profile for high-risk surgical candidates.

Ultimately, the Freestyle valve remains a valuable option in the AVR landscape, particularly for older patients who prioritize optimal hemodynamics and anticoagulation-free outcomes, as well as for young patients with small roots or complex infective endocarditis. However, the emerging body of literature demands caution.

The potential for catastrophic complications years after implantation mandates stringent long-term imaging protocols and high clinical suspicion for subtle presentations of SVD or pseudoaneurysm formation. As surgical experience accumulates and bioengineering advances continue to unfold, the potential to further refine and extend the lifespan of stentless valves, such as the Freestyle, grows increasingly promising.

Conclusion

The Medtronic Freestyle stentless bioprosthetic valve offers significant hemodynamic benefits and acceptable durability in appropriately selected patients. However, late failure of the Freestyle stentless aortic root bioprosthesis can present as catastrophic pseudoaneurysm formation or severe leaflet degeneration with rupture.

Prosthesis excision requires complex surgical strategies, including the need for root replacement and tailored coronary reimplantation. Lifelong surveillance with advanced imaging is mandatory to detect complications early and plan optimal reintervention. Despite these limitations and the demand for a high level of surgical expertise, AVR remains an attractive option, especially in patients with small aortic roots or contraindications to anticoagulation.

Future research and technological innovation are expected to enhance its long-term performance and expand its indications, reaffirming its place in the evolving field of aortic valve replacement.

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Abbreviations

AVR - Aortic Valve Replacement; SVD - Structural Valve Deterioration; AOA - Amino Oleic Acid; EOA Effective Orifice Area; TTE - Transthoracic echocardiography; PPM - Patient-Prosthesis Mismatch; SVD - Structural Valve Deterioration; CTA - Computed Tomography Angiography; ViV - Valve-in-Valve;

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