

# First successful transcatheter valve-in-valve implantation into a failed mechanical prosthetic aortic valve facilitated by fracturing of the leaflets: a case report

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## Background

Degenerated and failed bioprosthetic cardiac valves can safely be treated with transcatheter valve-in-valve implantation in patients at high risk for reoperation. So far, non-functional mechanical valves must be treated with a surgical redo. Breaking the carbon leaflets before implanting a transcatheter valve into the remaining ring has never been described before.

## Case summary

Here, we present the case of a 65-year-old male patient with severe heart failure, poor left ventricular function based on a fully immobile disc of his mechanical bileaflet aortic valve implanted 7 years ago. After the heart team declined to reoperate the patient due to his extremely high risk, we considered a transcatheter valve-in-valve implantation as the ultimate treatment approach. After successful interventional cracking of the leaflets *in vitro*, this approach, together with implanting a balloon-expandable transcatheter aortic valve replacement (TAVR) into the remaining ring, was performed under cerebral protection. The intervention resulted in a fully functional TAVR, improvement of heart function, and early discharge from the hospital.

## Discussion

This case demonstrates the possibility to implant a transcatheter valve successfully into a non-functional mechanical bileaflet aortic prosthesis after fracturing the carbon discs while the brain is protected by a filter system. Critical steps of the procedure were identified. This new therapeutic approach might be offered to a limited patient cohort who is not eligible for a surgical redo.

## Keywords

Transcatheter valve-in-valve implantation • Degenerated mechanical valve • Valve fracture • Cerebral protection • Bileaflet mechanical valve • Case report

## Learning points

- Until now, non-functional mechanical prosthetic valves must be treated with a surgical valve replacement.
- Transcatheter aortic valve implantation after fracturing the discs can be successfully performed with cerebral protection and hemodynamic management.
- So, far it remains an individual approach as a bail-out strategy accompanied by a critical discussion in the heart team.

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## Introduction

In 2002, Cribier *et al.*<sup>1</sup> published the first human percutaneous transcatheter implantation of an aortic valve prosthesis for a calcified aortic stenosis using a transseptal approach. Meanwhile, retrograde implantation can be performed with exceptionally low complications and excellent functional results. In 2007, Wenaweser *et al.*<sup>2</sup> demonstrated for the first time that percutaneous aortic valve replacement in a degenerated bioprosthesis is feasible. Bioprosthetic valve fracture in the undersized prosthesis is also feasible in selected patients undergoing valve-in-valve transcatheter aortic valve replacement (TAVR).<sup>3</sup> Meanwhile transcatheter valve-in-ring implantation has been also established in mitral, pulmonary, and tricuspid position.<sup>4,5</sup> Up to now valve-in-valve TAVR has been limited to degenerated bioprosthesis in all positions. So far, a non-functioning mechanical aortic valve can only be treated with surgical reoperation which is associated with doubled mortality compared to first-time surgical aortic valve replacement (4.7% vs. 2.2%).<sup>6</sup> One quarter of patients with acute valve dysfunction die before the intervention, with an overall mortality rate of 33%.<sup>7</sup>

In this case report, we present clinical and procedure-related issues in the first in-human intended fracturing of a dysfunctional mechanical bileaflet valve and successful transcatheter implantation of a balloon-expandable aortic valve as ultimate intervention.

## Timeline

Presentation	A 65-year-old patient presented with severe dyspnoea, cardiac decompensation, and hypotension.
Seven years ago	The patient received a mechanical bileaflet aortic valve.
Transthoracic echocardiogram and transoesophageal echocardiography	Revealed poor left ventricular function (left ventricular ejection fraction 15%) and a mean pressure gradient of 45 mmHg above the mechanical aortic prosthesis.
Heart team meeting	Open surgery due to extremely high risk denied.
Preclinical <i>in vitro</i> testing	Fracturing of carbon discs found to be feasible with high-pressure balloon.
Decision	Valve-in-valve implantation.
Intervention	Successful valve-in-valve procedure under cerebral protection.
Discharge 7 days after intervention	The patient left the hospital walking without neurological deficiency and improved heart function.

## Case presentation

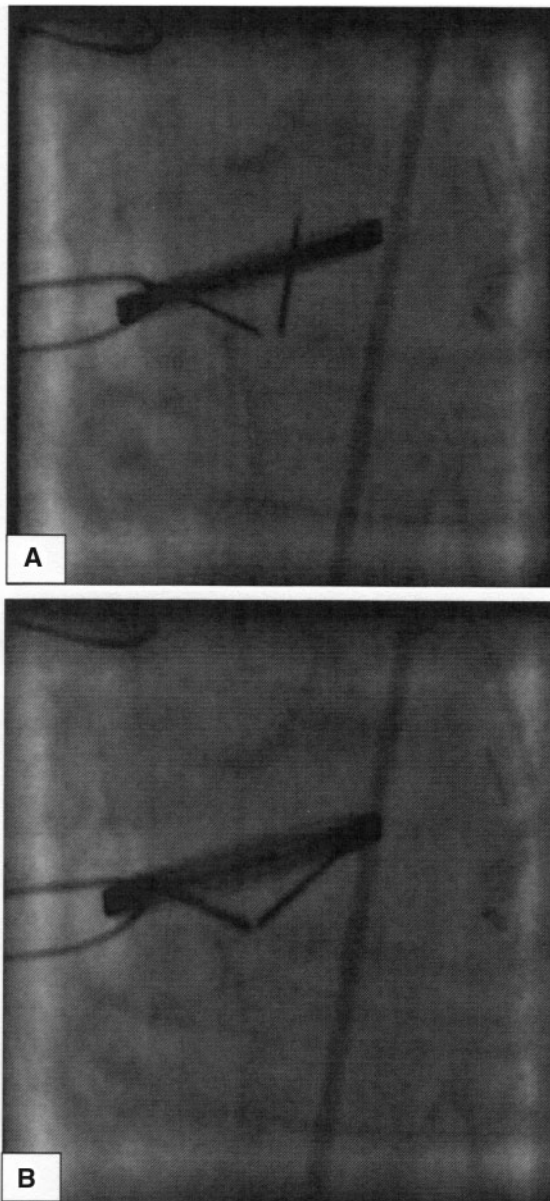
A 65-year-old male patient in reduced general condition (52 kg/180 cm/BMI 16) presented with severe dyspnoea, cardiac decompensation, and hypotension and was referred to our cardiac centre. The risk of mortality was 36.1% using EuroScore II and 10.6% using Society-of-Thoracic-Surgeons (STS) Score. Cardiovascular comorbidities included chronic obstructive pulmonary disease (COPD) with pulmonary hypertension, chronic kidney disease, severe peripheral artery disease, and a cerebral stroke. Since several years, the patient received permanent supplemental oxygen due to COPD GOLD IV (according to the Global initiative of Obstructive Lung Disease criteria). In 2013, he received a surgical mechanical bileaflet aortic valve St. Jude Medical (SJM AHPJ) 23 mm (inner diameter 20.4 mm) made from pyrolytic carbon coated and tungsten impregnated graphite substrate (Figure 1A,B). In addition, a left internal mammary artery (LIMA) graft to the left anterior descending coronary artery (LAD) was made.

Transthoracic echocardiography and transoesophageal echocardiography confirmed extremely poor left ventricular function with left ventricular ejection fraction (LVEF) of 15% and a mean pressure gradient of 45 mmHg above the mechanical aortic prosthesis and moderate regurgitation. The aortic valve region presented with a hyperdense mass and only minor movement of probably one tilting disc and no paravalvular leakage. There was no evidence for an acute thrombosis being responsible for the pressure gradient. Also, the patient was under well-adjusted oral vitamin K antagonist anticoagulation. Fluoroscopy and coronary angiography confirmed the fixation of one tilting disc in 33° position with nearly full movement of the second disc (opening angle 40°). Right coronary artery (RCA) left main artery and left circumflex artery showed no critical stenosis and left internal mammary (LIMA)-graft on left anterior descending artery (LAD) was fully functioning.

Cardiothoracic computed tomography (CT) scan revealed 3 mm between the ring of the mechanical valve and the ostium of the RCA, probably due to the supra-annular implantation of the prosthesis. After the heart team declined open surgery due to extremely high surgery-associated mortality, we discussed a new approach to fracture the tilting discs and implanting a transcatheter aortic valve. We discussed with the patient all potential complications caused by the embolization of the fragments such as stroke, bowel infarction, acute kidney injury, acute limb ischaemia, and death.

## Preclinical *in vitro* testing

In a preclinical testing, we were able to fracture the discs either from the central or the lateral opening with high-pressure balloon (Atlas Gold 20 mm BARD—RBP 16 atm) success with 4 atm (Figure 2A–C). Balloon dilatation resulted in two major carbon pieces, but also several tiny pieces, which were judged to cause a relevant risk of cerebral embolism. We considered a direct implantation of a S3 model, but we have not been able to fracture the discs just by pushing even with high force. Thus, direct S3 model implantation was denied for use in our patient.

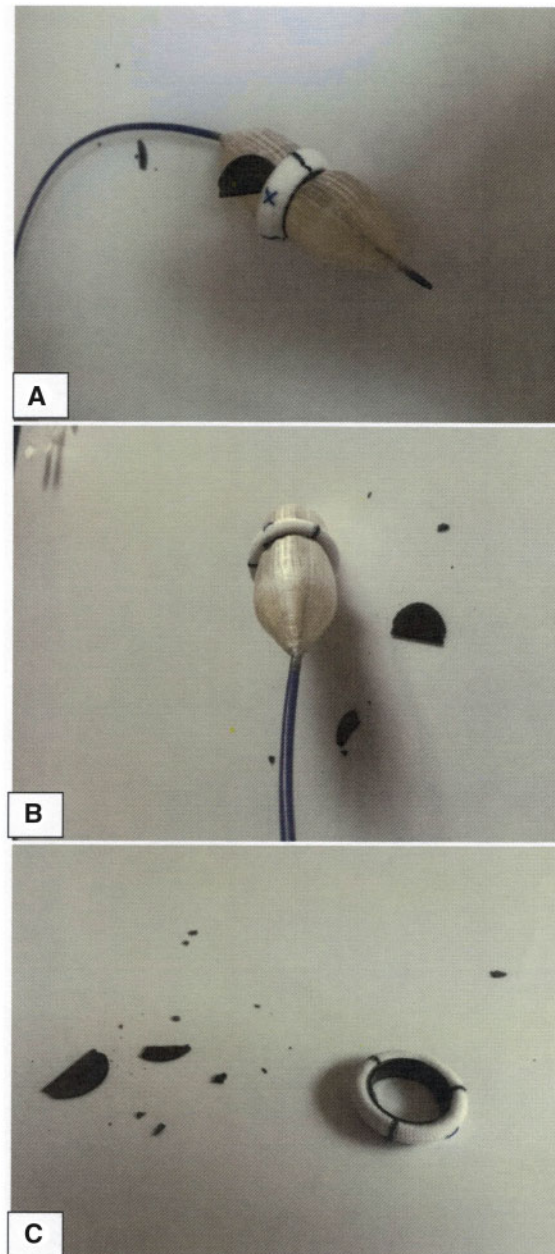


**Figure 1** Fluoroscopy in systole and diastole. (A) Bileaflet mechanical aortic prosthesis (SJM AHPJ) in systole. (B) Left tilting disc is fixed over the heart cycle in diastole (opening angle is 38°).

## Procedure

The patient consented to transcatheter valve-in-valve implantation into his failed mechanical prosthetic aortic valve facilitated by fracturing of the leaflets knowing it would be the first-in-men human procedure.

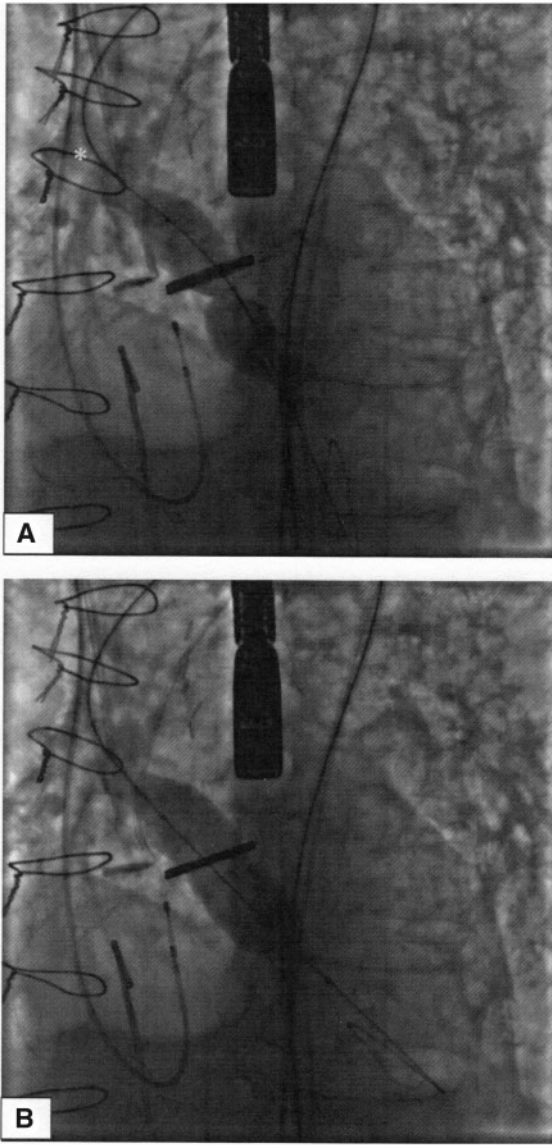
While passing the centre of the bileaflet mechanical valve, an immediate drop of systemic blood pressure occurred due to fixation of the formerly movable disc. Due to hemodynamic instability, the wire was removed. After placing the balloon (Atlas Gold 20 mm BARD—RBP 16 atm) in the centre of the bileaflet valve, simultaneous inflation



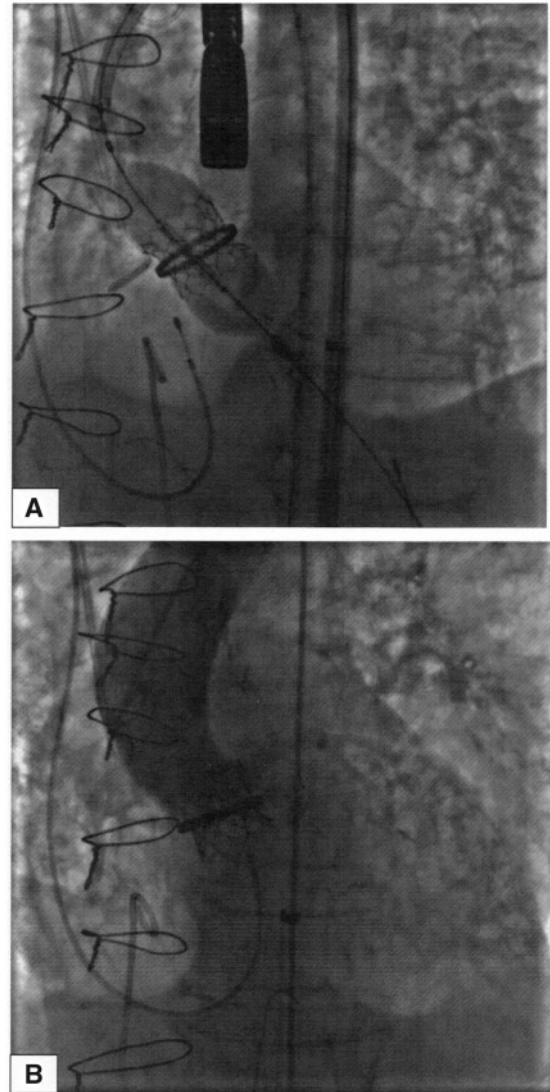
**Figure 2** Preclinical *in vitro* testing. (A) A 20 mm TRUE Dilatation balloon (Loma VISTA) fractured a SJM AHPJ 23. (B) Different sized fragments are resulting, the tiny fragments probably generated from the hinge-joints. (C) The ring is finally completely free of remaining material.

of the protection balloon in the right coronary artery (RCA) and in the aortic valve (Figure 3A,B) resulted in a second episode of blood pressure drop. The Atlas Gold balloon needed submaximal pressure (15 atm) to crack the discs. Overall, it took 127 s from cracking, loading the S3 until correct implantation and full function (Figure 4A,B). This was followed by 70 s of chest compression and pharmacological support to re-establish circulation. Removal of cerebral protection





**Figure 3** Placement of balloons. (A) Simultaneous inflation of protection balloon in right coronary artery (\*) and waisted high-pressure balloon in mechanical valve. (B) High-pressure balloon is fully expanded and leaflets fractured.



**Figure 4** Transcatheter valve implantation. (A) Implantation of the balloon-expandable Sapien S3 – 23 mm. (B) Supra-aortic angiogram showing no aortic regurgitation. Both coronary ostia are patent.

device showed tiny carbon fragments captured in both filters (Figure 5).

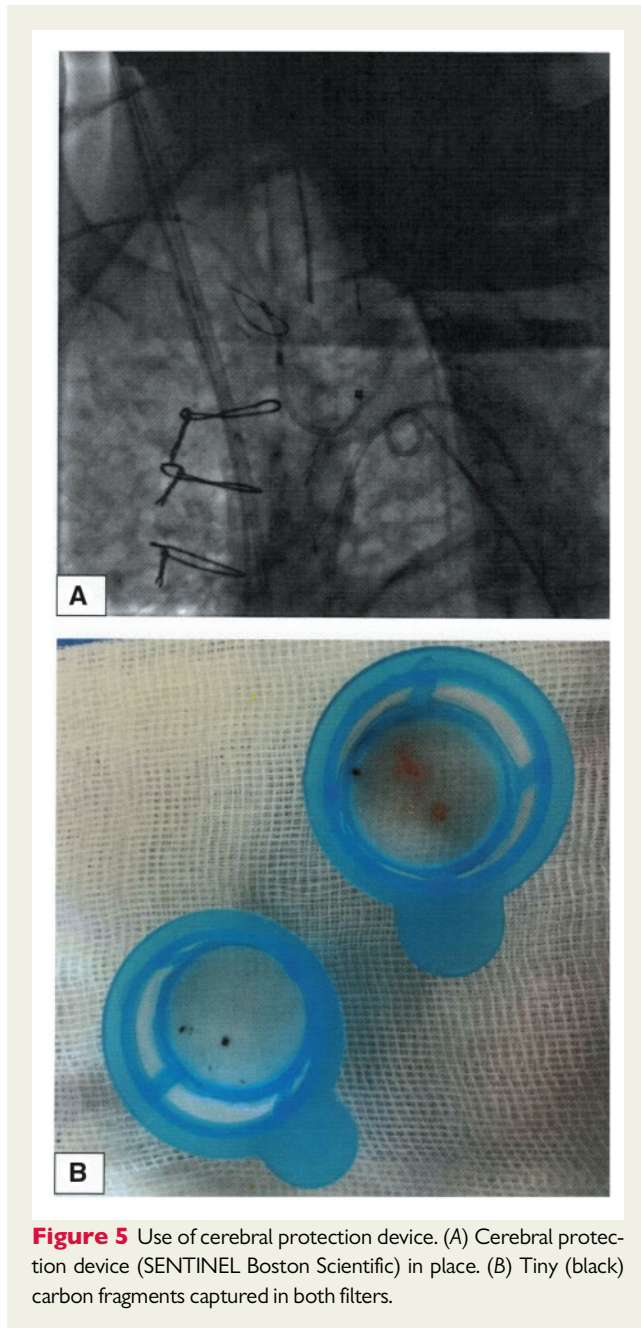
The patient was extubated directly in the hybrid operation room, stayed for two days in the intensive care unit with norepinephrine and supplemental oxygen (4 L/min). He showed no signs of embolic or neurological events. Transthoracic echocardiography showed a normal function of the TAVR with a remaining mean gradient of 14 mmHg and no regurgitation. Left ventricular ejection fraction slightly increased to 25%. N-terminal prohormone of brain natriuretic peptide decreased continuously from pre-interventional 21 400 ng/mL to 13 540 ng/mL to 8300 ng/mL (normal < 220 ng/mL) at hospital discharge 7 days after the procedure and 5500 ng/mL at 4 months follow-up. A full body low dose CT scan performed at 4 months follow-

up detected 3 disc fragments in the iliac arteries causing no symptoms at all. We decided to continue oral anticoagulation with a vitamin K antagonist to prevent any thrombus formation at the TAVR prosthesis.

The gradient above the TAVR is unchanged with 14 mmHg, the patient feels much better than before the intervention and can perform his daily tasks in his domestic surroundings.

## Discussion

Transcatheter aortic valve implantation was initially introduced for patients who were unable to undergo open surgery, but showed superior results in high-risk patients and meanwhile even in low-risk



**Figure 5** Use of cerebral protection device. (A) Cerebral protection device (SENTINEL Boston Scientific) in place. (B) Tiny (black) carbon fragments captured in both filters.

patients it seems to be an acceptable option with favourable results. Valve-in-valve transcatheter aortic valve replacement in patients with failed bioprosthetic aortic valves has become an established and successful interventional therapy in patients unable to undergo a redo operation. A recent meta-analysis confirmed high procedural success rates and favourable short-term to midterm outcomes when performed by experienced operators.<sup>8</sup>

So far, dysfunctional mechanical heart valves could only be treated with a cardiac surgical reoperation. We report the first successful implantation of a balloon-expandable transcatheter aortic valve into a stenosed mechanical bileaflet aortic prosthesis after fracturing the discs and protecting the cerebral arteries in a patient without a surgical re-do option. Right coronary artery was protected from

obstruction and embolism by wiring and inflated balloon. We identified several critical steps, which are (i) uncontrolled embolization of fragments of unknown size, (ii) small distance of the RCA to the ring and (iii) haemodynamic consequence of a fully open aortic valve in an extremely low LVEF. We assumed that we would only have a very short period to restore full function of the implantable valve, which was confirmed in the procedure. Within 2 min, the valve was implanted followed by a short period of pump failure requiring chest compression. Existing experience with cerebral protection devices during TAVR showed a significant higher rate of stroke-free survival compared with unprotected TAVR,<sup>9</sup> whereas a change in neurocognitive function and a reduction in the number and new lesion volume on magnetic resonance scans were not fully conclusive yet, despite the fact, that in 99% embolic debris was captured.<sup>10,11</sup>

In our case, several tiny carbon pieces were found in the cerebral filter system. Two larger disc fragments, temporarily seen floating in the left ventricle, could eventually not be located. However, we could not detect any related clinical problem, but for safety reasons, we continued the oral anticoagulation. At 4 months follow-up, three fragments were detected in the iliac vessels in full-body low dose CT scan causing no symptoms yet. With a higher pre-procedural ejection fraction, the intervention may have been less dramatic given more time to manage hemodynamic instability before acute pump failure occurs. This consideration should be taken into account if such a procedure will be considered as a 'bail out' strategy in the future. Finally, the transcatheter replaced aortic valve showed no dysfunction. Left ventricular function improved before the patient left the hospital with his walking frame. This early improvement has been described in the literature and is correlated with outcome<sup>12-14</sup>

## Conclusion

Non-functional mechanical prosthetic valves might be successfully treated with a transcatheter valve-in-valve implantation given this procedure is performed in an experienced centre and the critical issues are identified before. Potential impediments of the procedure include the distance from the remaining ring to the coronary arteries, cerebral protection from disc fragments, and haemodynamic instability between the fracture and successful implantation of the new valve.

## Lead author biography



Prof. Christian Butter is Head of the Department of Cardiology at the Heart Center Brandenburg in Bernau/Berlin (Germany). In 2015, he was appointed professor for cardiology at the Brandenburg Medical School. At the beginning of his clinical and scientific career he focused on device therapy and heart failure. Today, he is deeply involved in the development and interventional therapy of structural and valvular heart disease.

## Supplementary material

Supplementary material is available at *European Heart Journal—Case Reports* online.

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**Slide sets:** A fully edited slide set detailing this case and suitable for local presentation is available online as [Supplementary data](#).

**Consent:** The authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient in line with COPE guidelines.

**Conflict of interest:** None declared.

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