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Harvesting the Lotus: A Tale of Two Transcatheter Aortic Valve Implantations

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Abstract

Transcatheter Aortic Valve Replacement (TAVR) emerged as a minimally invasive alternative to Surgical Aortic Valve Replacement (SAVR) and is on the rise. Given the expansion of TAVR in the current era to young and low-to-intermediate risk patients, it is important to anticipate that this population will likely outlive their TAVR valves. Those who are unable to undergo redo-TAVR will likely require surgical explantation and a SAVR instead. Therefore, it is imperative to be familiar with the surgical techniques and pitfalls needed for explantation of these failed valves.

Keywords: Lotus; Transcatheter Aortic Valve Replacement (TAVR); SAVR

Introduction

With two decades of data from randomized controlled trials and registries [1,2], the use of TAVR has rapidly expanded from its original indication in patients with high surgical risk [3] to patients with lower risks [4]. However, an increasing number of patients are requiring treatment for failed TAVR valves (0.22% incidence) [5]. It is important to understand the techniques used to extract these valves.

Boston Scientific's mechanically expandable LOTUS system was first cleared by the Food and Drug Administration (FDA) in April 2019, thereby becoming the third TAVR valve to enter the United States market. Designed to rival other TAVR valves on the market such as the SAPIEN and core valve, it provided interventionalists with the ability to reposition and retrieve the valve after deployment. Due to its braided Nitinol wire frame and adaptive seal which allowed the valve to conform to the anatomy of the patient's native aortic valve, the LOTUS valve had one of the lowest incidences of Paravalvular Leaks (PVL) [6].

The LOTUS Edge was introduced next which included radiopaque markers and Depth Guard technology [7]. Depth Guard was a modification to the prior delivery system which attempted to reduce the interaction between the valve frame and the LVOT by anchoring the valve early to prevent elongation during unsheathing. This change reduced the valve height from 40 mm to 19 mm. We report on two cases of surgical LOTUS Edge explantation.

Case Series

Case 1

A 90-year-old man has undergone TAVR with a 27 mm LOTUS Edge valve that was complicated with heart block requiring PPI two years prior to his presentation with dyspnea and heart failure. Transthoracic Echocardiogram (TTE) showed severely decreased Left Ventricle Ejection Fraction (LVEF) 20%, prosthetic valve stenosis (aortic valve area =0.49 cm^2), moderate-to-severe mitral regurgitation, and severe pulmonary hypertension. After medical optimization, the decision was made to proceed with surgical explantation of the Lotus Edge valve. The Society of Thoracic Surgeons (STS) risk was 9.020%. Preoperative Cardiac CT scan confirmed migration of the prosthesis in to the Left Ventricular Outflow Tract (LVOT) (Video 1).

Intraoperatively, migration of the LOTUS valve into the ventricle was confirmed on Transesophageal Echocardiogram (TEE) (Video 2), creating significant LVOT obstruction (Video 3), and after opening the ascending aorta (Figure 1). The distal rim of the valve was adhered to the native aortic valve annulus, while the body and proximal rim were adhered to the anterior leaflet of the Mitral Valve (MV). The Nitinol stent was softened with ice, and a freer elevator was used to separate the valve from the endocardium. The valve was removed from the surrounding structures (Figure 2A, 2B) with the aid of an incision in the left atrium. However, upon explantation of the

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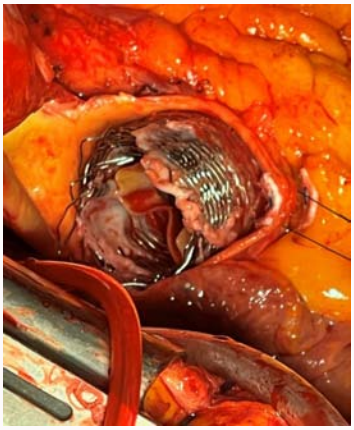

Figure 1: Intraoperative photo with the opened aorta on cardiopulmonary bypass showing the LOTUS Edge prosthesis.

valve, an erosion of the anterior mitral leaflet from the prosthesis was identified. A decision was made to replace the MV with a 31 mm bioprosthesis (Video 4). The native aortic valve was then excised and was replaced with a 21 mm bioprosthesis. Cardiopulmonary bypass and Aortic Cross Clamp (AXC) times were 173 and 145 min respectively. The postoperative course was uneventful and he was discharged six days after his surgery.

Case 2

A 73-year-old male underwent TAVR (27 mm LOTUS Edge valve) followed by PPI three years prior to his recent presentation with progressively worsening dyspnea, and bilateral lower extremity edema. Follow up TTEs revealed a paravalvular leak which progressed from mild to severe, with worsening LVEF. Cardiac catheterization showed depressed cardiac index 1.7 l/min/m^2, elevated pulmonary capillary wedge pressure (30 mmHg), and 99% occlusion of the distal right coronary artery. Following medical optimization, surgical explantation of the prosthetic aortic valve followed by SAVR was planned. His STS risk calculator for isolated AVR was 2.304%.

Intraoperatively, the LOTUS Edge valve had migrated as well (Video 5). Ice was used to soften the Nitinol wire material, and a freer elevator was used to gently detach the prosthesis from the surrounding endocardium. Following valve explantation, a 23 mm bioprosthesis was then implanted (Video 6). Right atriotomy was then performed to evaluate the mechanism of tricuspid regurgitation and it was related to pacemaker lead adherence to the leaflet, thus interfering with the valve competence. The Tricuspid Valve (TV) was repaired with a 34 mm annuloplasty ring (Video 7). The total bypass and AXC times were 142 and 86 min respectively. The patient had an uneventful postoperative course and was discharged on post-operative day five.

Discussion

While surgical explantation of failed TAVR valves is uncommon, it carries significant risks [8], especially when considering that TAVR was initially created for patients who were deemed to be not good surgical candidates. The expansion into younger and low-risk groups would increase the likelihood of need for reoperation. Therefore, it is imperative to be familiar with techniques used for surgical explantation of these valves.

The two cases we presented show the technical aspects we used for explantation of the LOTUS Edge. These valves failed, two and three years after their implantation and both migrated from their original implant position. This represents the only report of explantation of the LOTUS Edge valve to the best of our knowledge.

The morbidities that were associated with these transcatheter valves have to be strongly considered when making the decision to proceed with such procedures. The first patient required concomitant MV replacement, and the second require TV repair. It also confirms the point that the STS risk calculator is not an absolute accurate way of assessing who should be turned down for surgery. The need for permanent pacemaker secondary to heart block after implantation of transcatheter valves should not be underestimated and this can be associated with further new problems such as tricuspid regurgitation as occurred in the second case. This will be even of paramount importance when considering TAVR for younger and lower surgical risks-patients.

Conclusion

We have to accept that there will be a percentage of TAVR patients who will require explantation of these prostheses for one reason or another. These patients will have different morbidity profiles that may impose higher surgical risks and will be associated with further morbidities and/or mortalities.

Surgical explantation of these valves is not a straightforward procedure and will most likely be associated with a variety of concomitant procedures that were not planned if these patients offered SAVR from the beginning [9]. Surgeons need to be familiar with the different pitfalls and tips used to explant these valves and more importantly a frank discussion with patients prior to TAVR need to include these possible outcomes to ensure their thorough and complete understanding of the procedure.

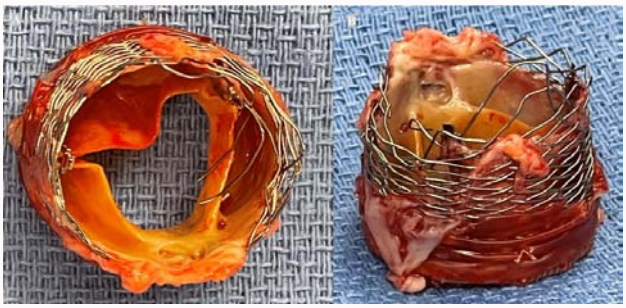

Figure 2: The extracted LOTUS Edge prosthesis, top (A), and (B) side views.

Video Links

Link 1: https://youtu.be/2gLnpdx4dGQ

Video 1: Intraoperative transesophageal echocardiogram in case 1, showing the migrated LOTUS Edge prosthesis in the left ventricular outflow tract.

Link 2: https://youtu.be/EDMpeUn5uAY

Video 2: Intraoperative transesophageal echocardiogram in case 1, showing the migrated LOTUS Edge prosthesis in the left ventricular outflow tract causing significant left ventricular outflow tract obstruction and the associated moderate-severe mitral valve regurgitation.

Link 3: https://youtu.be/zOhQes2vXMs

Video 3: Preoperative computed tomography scan of case 1, showing the migrated LOTUS Edge prosthesis.

Link 4: https://youtu.be/OkCAMWKq4oA

Video 4: Postoperative transesophageal echocardiogram of case 1, showing well-seated mitral and aortic bioprostheses with good leaflets mobility and no periprosthetic regurgitation.

Link 5: https://youtu.be/Ul58nQKxHzA

Video 5: Case 2 preoperative transesophageal echocardiogram showing displaced LOTUS Edge valve in the left ventricular outflow tract.

Link 6: https://youtu.be/kLaoJu-lD28

Video 6: Case 2 postoperative transesophageal echocardiogram showing well-seated aortic bioprosthesis with no periprosthetic regurgitation and good leaflet mobility.

Link 7: https://youtu.be/lTU-0Vk2X8U

Video 7: Case 2 postoperative transesophageal echocardiogram showing the repaired tricuspid valve with no significant regurgitation. Notice the pacemaker lead appears in view.

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