# Sutureless aortic valve replacement with the Trilogy Aortic Valve System: Multicenter experience

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**Objective:** To evaluate the modular sutureless Arbor Trilogy Aortic Valve System (Arbor Surgical Technologies, Irvine, Calif), designed for minimally invasive aortic valve replacement.

**Methods:** In a prospective multicenter study, 32 patients with severe aortic valve stenosis underwent aortic valve replacement with the Trilogy valve between 2006 and 2008. Concomitant coronary artery bypass grafting was performed in 6 patients. Transthoracic echocardiography was performed at baseline, at discharge, at 4 to 6 months, at 11 to 14 months, and annually thereafter.

**Results:** Valve implantation was successful in 30 patients. The procedure was converted to conventional aortic valve replacement in 2 patients. Mean bypass time was 111 ± 42 minutes, and crossclamp time was 70 ± 23 minutes. Valve implantation took 21 ± 7 minutes. The transvalvular gradients at discharge were 10 ± 3 mm Hg (mean) and 20 ± 7 mm Hg (peak), and the effective orifice area was 1.9 ± 0.4 $cm^2$. At 2-year follow-up, gradients were 7 ± 3 mm Hg (mean) and 14 ± 4 mm Hg (peak), and the effective orifice area was 1.9 ± 0.3 $cm^2$. There was no intraoperative mortality: Two patients died of causes unrelated to the valve during follow-up. One redo aortic valve replacement was performed at 22 months for prosthetic valve endocarditis.

**Conclusions:** Sutureless aortic valve replacement is feasible and safe with the Trilogy System. After an initial learning curve, the modular valve design allows a more rapid and simple implantation compared with conventional stented tissue valves. The simplicity may also facilitate a greater adoption of minimally invasive aortic valve replacement by a broader spectrum of surgeons. (J Thorac Cardiovasc Surg 2010;140:878-84)

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The current treatment of choice for severe aortic valve stenosis remains valve replacement using biological or mechanical valves, which are hand sewn to the aortic annulus with a series of stitches.[1] As minimally invasive techniques have become more popular, there is a growing demand for a prosthesis that can be easily implanted via minimal access under direct or endoscopic view.[2] In addition to the transapical or transfemoral devices that are available only for high-risk patients, minimally invasive access aortic valve replacement (AVR) using standardized sutureless valve implantation techniques can be applied in a greater variety of patients. With the advantages of minimally invasive access AVR, such as improved cosmesis, less postoperative pain, reduced risk of infection, shortened convalescence, and decreased length of hospital stay, it has the potential to evolve into the standard surgical technique for AVR.[3-5]

More than 40 years after the implantation of the first sutureless valve by George Magovern, this technology is becoming more important.[6] In the last few years, many sutureless aortic valves have been designed.[7-9] The Trilogy Aortic Valve System (Arbor Surgical Technologies, Irvine, Calif) differs from these in its modular valve technology, consisting of 2 parts: the valve crown and SecuRing (Figure 1, *A*). The valve crown is a trilobal bovine pericardial valve on a nitinol frame allowing independent leaflet suspension, which potentially optimizes stress distribution on the leaflets and consequently reduces leaflet calcification. This represents a modification of currently available stented pericardial tissue valves, with its promising and proven long-term durability.[10,11]

The second part of the system, the Trilogy SecuRing, is similar to a standard sewing ring incorporating a nitinol ring, providing a perfectly round inflow orifice from the left ventricular outflow tract and elevating the valve crown

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**Abbreviations and Acronyms**

AVR = aortic valve replacement
EOA = effective orifice area
TAC = Trilogy Attachment Clip
TCAT = Trilogy Crown Anchoring Tool
TSIT = Trilogy SecuRing Insertion Tool

into a high supra-annular position within the aortic root. This allows all of the valve hardware to reside in the sinuses of Valsalva and out of the blood flow path.

The modular design may simplify the surgical procedure and result in a faster implantation as rapid-firing Trilogy Attachment Clips (TACs) affix the SecuRing into the annulus under direct view. These TACs, in addition to the nitinol ring incorporated in the sewing ring, are expected to provide a safe and competent fixation of the SecuRing to the annulus. The valve crown is then locked to the SecuRing, obviating the need for sutures. This study presents the multicenter experience with this valve system implanted in the first 32 patients.

## MATERIAL AND METHODS

### Study Design

After approval of their institutional ethics committee (No. 4355), 6 centers in Europe joined a pilot project to assess the Trilogy Aortic Valve System. Between November 2006 and November 2008, 32 patients (18 female, mean age 71.7 ± 6.5 years, body surface area 1.88 ± 0.27 $cm^2$, ejection fraction 54% ± 6%) underwent AVR with the Trilogy System according to the inclusion and exclusion criteria as shown in Table 1 and after they had given informed consent. During the procedure bypass time, crossclamp time and implantation time were recorded. Intraoperative transesophageal echocardiography was performed after cardiopulmonary bypass to confirm adequate valve performance.

### Follow-up

After discharge examination, all patients were followed up at 4 to 6 months, at 11 to 14 months, and annually thereafter. The follow-up was performed by an experienced cardiologist and included a clinical examination, a New York Heart Association evaluation using a standardized questionnaire, and transthoracic echocardiography. Data were recorded in case report forms at each site and then entered into a database by means of double-data entry. Queries were generated for any discrepancies. Half-year monitor visits took place at each site to control case report forms. Monitor visits were performed by independent clinical research organization (Medpass International, Paris, France).

### Echocardiography

All echocardiograms were performed according to the recommendations of the American Society of Echocardiography.[12] Three beats were measured for each variable. Mean and peak gradient were measured according to the recommendations for quantification of Doppler echocardiography from the American Society of Echocardiography, and effective orifice area (EOA) was measured using the continuity equation.[13] Whenever more than trivial aortic insufficiency was found by Doppler, the severity was assessed using (1) the width of the regurgitant jet in the left ventricular outflow tract relative to the left ventricular outflow diameter; (2) the pressure half-time of the regurgitant jet recorded with the continuous-wave Doppler; and (3) the magnitude and duration of the retrograde diastolic velocity in the upper descending aorta with pulse-wave Doppler according to the guidelines.[12,13]

All echocardiographic measurements were confirmed by an independent core echocardiography laboratory (Cardiovascular Imaging and Clinical Research Core Laboratory, Washington University School of Medicine, St Louis, Mo). The core laboratory had information of the implantation date and the implanted valve size and was blinded to other clinical data.

Experienced cardiologists who had extensive echocardiography experience performed the echogardiograms at each site. All echocardiograms (baseline and follow-up) were performed by the same person. The echocardiographers had to complete an echocardiography certification process before the enrollment of their first study patient. The certification entitled each echocardiographer to perform 3 test echocardiograms according to core laboratory protocol specifications. Echocardiographers were allowed to perform echocardiography on study patients only if they met the protocol requirements. The core laboratory judged the quality of the performed echocardiograms. Those examinations found to be inadequate required completion of a repeat echocardiogram within the fixed time frame.

### Statistical Analysis

All data are reported as mean ± standard deviation. Additional data ranges are reported for the echocardiographic results.

### Operative Technique

After median sternotomy, cardiopulmonary bypass, and cardioplegic arrest, a transverse or oblique aortotomy 2 cm above the sinotubular junction was performed. After confirmation of the tricuspid nature of the valve, the leaflets were excised and the annulus was debrided. The annular size was assessed using the Arbor sizer, of which one end is cylindric corresponding to the annular diameters of 21 or 23 mm. The opposite side of the tool has a replica of the overall Arbor Trilobal-shaped valve to allow the surgeon to verify fit without obstructing the coronary ostia before implantation. After sizing, the SecuRing is first mounted onto the Trilogy SecuRing Insertion Tool (TSIT) (Figure 1, *B*). The prongs of the TSIT are aligned with the slots in the SecuRing gasket package, and then the gasket is folded in a clover shape by closing the TSIT handle. Then, the SecuRing is inserted into the aortic root and the 3 highest points of the ring are aligned with the native commissures. The depth of the gasket in the aortic root is adjusted using depth markers in the TSIT. With the release button on the TSIT, the gasket is delivered. Proper fitting into the annulus is visually confirmed using a dental mirror before permanent attachment with the TACs begins. These specialized clips made of superelastic Nitinol are crossed U-shape with a length of 3.3 mm, width of 7.6 mm, and diameter of 0.4 mm (Figure 1, *C*). They are stored in their unstressed parent shape in the TAC Tool (Figure 1, *C*). When loaded into the air-powered TAC Tool by stepping on a foot pedal, the TACs are spread in a ''U'' shape for insertion into annular tissue. After releasing the TAC by pressing a trigger in the handle, the TACs are driven into the SecuRing and the underlying annular tissue and the clip legs cross over, capturing the tissue and cloth. For optimal fixation, 12 TACs usually were used (1 for each commissure and 3 for each cusp). If necessary, the surgeon used 1 or 2 additional TACs.

In the meantime, the valve crown is prepared for implantation by rinsing for 3 minutes in physiologic saline to remove the glutaraldehyde-based storage solution. The valve crown is designed to lock into the implanted SecuRing. The SecuRing commissures have guiding rails pre-sewn onto them. There are corresponding receptacles for the rails on the outside rim of the valve crown. During implantation, the valve crown is attached to the Trilogy Crown Anchoring Tool (TCAT) (Figure 1, *D*). The rails from the gasket are inserted through the receptacles of the valve crown, and the valve is guided through the shield for proper placement onto the SecuRing. There is a specialized portion of the guiding rail that mechanically locks when engaging the crown receptacles. The TCAT secures the rails during implantation and then cuts and removes the rails, crown cap, and shield after crown