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 cm². 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 cm². 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)

Supplemental material is available online.

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 transap-

ical 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 cm², ejection fraction $54\% \pm 6\%$) 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 echocardiograms 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 $\pm$ 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

FIGURE 1. A, Survey of the Trilogy Aortic Valve System (Arbor Surgical Technologies, Irvine, Calif). After affixing the SecuRing (1) with the TACs (2) to the aortic annulus, the valve crown (3) is locked to the SecuRing using a guiding and locking mechanism (4). B, SecuRing (1) mounted onto the TSIT (2) after folding by closing the TSIT handle. C, TAC tool (1) and TACs in their unstressed parent shape (2). When loaded into the tool, TACs are U-shaped (3) for insertion into annular tissue. After release, the clip legs cross over in the parent shape, capturing the tissue and cloth (4). D, TCAT (1) with the inserted rails (2) from the SecuRing guided through the valve crown and affixed on the receptacles of the TCAT (3).

deployment is complete. After implantation, the aortotomy is closed in the regular fashion. Correct positioning of the valve without paravalvular leakage is assessed intraoperatively using transesophageal echocardiography.

RESULTS

AVR was performed using the Trilogy Aortic Valve System in 32 patients, 11 of whom received the 21-mm valve and 21 of whom received the 23-mm valve. Concomitant

coronary artery bypass grafting was performed in 6 patients. There were no intraoperative deaths. Valve implantation was successful in 30 patients. The valve had to be explanted intraoperatively in 2 patients. The SecuRing design was not versatile enough to effectively seal to the valve crown in 1 patient, and a severe leakage between the gasket and the crown was detected on intraoperative echocardiography. In the other patient, shield manipulation caused damage to

TABLE 1. Inclusion and exclusion criteria

Inclusion	Patient must be aged ≥ 18 y.
	Patient required AVR with or without concomitant surgical procedure, except other valve replacements.
	Patient is a candidate for bioprosthetic heart valve.
	Patient signed an approved informed consent form before enrollment.
Exclusion	Congenital bileaflet aortic valve.
	Patient requires concomitant valve surgery.
	Any disease with a poor 2-y prognosis that may interfere with the ability to conduct follow-up.
	Valve replacement on an emergency basis that does not permit performance of the complete preoperative evaluation.
	Acute neurologic deficit, myocardial infarction, or cardiac event within 30 d before surgery.
	Renal dialysis.
	Acute fungal or bacterial endocarditis.
	Any abnormality, such as aortic aneurysm, that might put the patient at high risk for surgical complications.
	Pregnancy or nursing.
	Documented history of substance abuse within 1 y.
	Currently participating in another study of an unapproved device or drug.

the rails and prevented crown locking. In both patients, the valve was explanted and the procedure was converted to conventional AVR. The patients had an uneventful postoperative course.

The mean bypass time in the remaining 30 patients was 111 ± 42 minutes, the crossclamp time was 70 ± 23 minutes, and the implantation time was 21 ± 7 minutes. In

the last 3 patients, implantation time could be reduced to 10 ± 1 minutes.

Detailed echocardiographic results are shown in Table 2. At discharge, regurgitation between the SecuRing and the gasket (intravalvular) was detected in 4 patients ($n = 2$ moderate, $n = 1$ mild, $n = 1$ trivial). Trivial central regurgitation was found in 1 patient. One patient died of pulmonary embolism confirmed by computed tomography scan. As a result, discharge examination could be completed in 29 patients.

At the 3- to 6-month visit, 29 patients were examined. One of the moderate intravalvular regurgitations was reduced to mild regurgitation, and one disappeared. The cases of trivial and mild regurgitation were still present.

At the 11- to 14-month follow-up, 27 patients were examined. Two patients were lost to follow-up. The patient with the regurgitation at 3 to 6 months showed no more regurgitation. The other intravalvular regurgitations were still present.

At the 2-year follow-up, 12 of the expected 27 patients were examined until now. The intravalvular regurgitation present in patients at the 1-year follow-up was not detected at the 2-year follow-up. Trivial central regurgitation was still present in 1 patient. The New York Heart Association class improved over the follow-up period (Figure 2).

During the follow-up period, 1 patient died of lung cancer. One patient was referred back to the hospital after 22 months because of pyrexia and dyspnea. Echocardiography showed a vegetation of 1.5 cm at the noncoronary cusp with abscess formation below the SecuRing. Re-do surgery was performed. Prosthetic valve endocarditis was confirmed

TABLE 2. Echocardiographic data

Time interval	Valve size	Mean gradient	Peak gradient	EOA	LVOT diameter	Aortic regurgitation
Discharge	21 mm ($n = 10$)	10 ± 3 mm Hg (7–14 mm Hg)	21 ± 8 mm Hg (12–33 mm Hg)	1.8 ± 0.3 cm ² (1.5–1.9 cm ²)	1.8 ± 0.2 cm (1.6–1.9 cm)	–
	23 mm ($n = 19$)	10 ± 4 mm Hg (5–22 mm Hg)	19 ± 6 mm Hg (9–35 mm Hg)	2.0 ± 0.3 cm ² (1.5–2.6 cm ²)	1.9 ± 0.1 cm (1.8–1.9 cm)	$n = 2$ moderate iv $n = 1$ mild iv $n = 1$ trivial iv $n = 1$ trivial central
3–6 mo	21 mm ($n = 10$)	11 ± 6 mm Hg (4–24 mm Hg)	21 ± 8 mm Hg (8–35 mm Hg)	1.9 ± 0.2 cm ² (1.7–2.1 cm ²)	1.7 ± 0.1 cm (1.6–1.7 cm)	–
	23 mm ($n = 19$)	8 ± 4 mm Hg (4–16 mm Hg)	15 ± 7 mm Hg (7–31 mm Hg)	2.0 ± 0.3 cm ² (1.5–2.4 cm ²)	1.8 ± 0.1 cm (1.6–1.8 cm)	$n = 2$ mild iv $n = 1$ trivial iv $n = 1$ trivial central
11–14 mo	21 mm ($n = 8$)	10 ± 4 mm Hg (6–13 mm Hg)	17 ± 6 mm Hg (9–25 mm Hg)	1.9 ± 0.3 cm ² (1.6–2 cm ²)	1.7 ± 0.1 cm (1.7–1.8 cm)	–
	23 mm ($n = 19$)	9 ± 4 mm Hg (5–18 mm Hg)	16 ± 6 mm Hg (9–30 mm Hg)	2.1 ± 0.3 cm ² (1.6–2.6 cm ²)	1.8 ± 0.1 cm (1.8–2.0 cm)	$n = 1$ mild iv $n = 1$ trivial iv $n = 1$ trivial central
2 y	21 mm ($n = 1$)	5 mm Hg	10 mm Hg	1.8 cm ²	1.7 cm	–
	23 mm ($n = 11$)	8 ± 3 mm Hg (4–10 mm Hg)	14 ± 5 mm Hg (7–18 mm Hg)	2.0 ± 0.4 cm ² (1.6–2.4 cm ²)	1.9 ± 0.1 cm (1.8–1.9 cm)	$n = 1$ trivial central

EOA, Effective orifice area; iv, intravalvular (between the SecuRing and the valve crown); LVOT, left ventricular outflow tract. Data are reported as mean $\pm$ standard deviation. Data ranges are reported in parentheses.

FIGURE 2. New York Heart Association class improvement over the follow-up period. *NYHA*, New York Heart Association.

intraoperatively. In addition to the vegetation, a small abscess formation was detected below the SecuRing. The valve crown was removed, and the TACs were removed using a forceps. The SecuRing was incorporated into the annular tissue; nevertheless, a dissection plane was found and it was removed with no more difficulties. After aggressive debridement, redo-AVR using an aortic homograft was performed successfully. The patient had an uneventful postoperative course.

Redesign of the SecuRing

Because of the severe intravalvular leakages that were detected intraoperatively, resulting in a conversion to conventional AVR, and the occurrence of initial intravalvular regurgitation, the SecuRing was redesigned adding a collar

that perfectly seals the SecuRing to the valve crown (Figure 3). After implanting the valve using the redesigned SecuRing (n = 19), no more intravalvular regurgitation could be detected.

DISCUSSION

AVR with biological or mechanical prostheses using the median sternotomy as conventional access is still the gold standard for treatment of severe aortic stenosis.¹ In the past few years, minimally invasive techniques found their way into cardiac surgery because of their many advantages. For high-risk patients, avoiding sternotomy by using lateral right minithoracotomy results in early postoperative extubation, less pain, and rapid mobilization after operation and therefore shortens the time to return to normal activities.¹⁴⁻¹⁶ In

FIGURE 3. A, Original SecuRing. B, Redesigned SecuRing with the additional collar (1) to seal the SecuRing to the valve crown and prevent intravalvular regurgitation.

addition, improved cosmesis and lower infection rates made the access attractive to many patients.¹⁴⁻¹⁶

When using standard biological or mechanical valves, the prostheses are hand sewn into the annulus with many stitches. Minimally invasive approaches limit the view of the surgeon and the operative field. As a result, the surgeon requires more refined surgical abilities to accomplish the same quality compared with the conventional procedure.⁴ Sutureless valves may simplify these techniques and facilitate the adoption of minimally invasive approaches by a broader spectrum of surgeons.

Although many efforts have been taken in this field, only 2 biological valves in addition to the Trilogy Valve System found their way into clinical practice, whereas many other valves remained in preclinical testing.^{1,7-9}

The 3F-Enable valve (ATS Medical, Minneapolis, Minn) is constructed from a self-expandable nitinol-based stent with an equine pericardial trileaflet valve sewn within the stent,⁸ and the Perceval-S valve (Sorin, Milan, Italy) has a functional component of bovine pericardium fixed in a metal cage in a superelastic alloy of nitinol, allowing the device to be compressed and subsequently released in the annulus.⁹ The Trilogy Valve System has a modular configuration, enabling the surgeon to perform the entire procedure under direct view, and all surgical manipulations are performed extracorporeally using special equipment (TCAT and TSIT).

Compared with other sutureless valves, the Trilogy valve has a large EOA, even at 21- and 23-mm valve sizes, because of its sinusoidal shape and modular design allowing high supra-annular implantation (Figure E1). Compared with the Perceval-S valve, the EOA of the Trilogy valve was larger. Shrestha and coworkers⁹ reported an EOA of 1.3 (1–1.7) cm², resulting in mean gradients of 18 (10–25) mm Hg and peak gradients of 25 (14–35) mm Hg at 1 month in a mixed collective in which 9 patients obtained a 23-mm Perceval-S valve and 6 patients received a 21-mm Perceval-S valve. Compared with these series, the Trilogy valve showed an EOA of 1.9 ± 0.2 cm² with mean gradients of 11 ± 6 mm Hg and peak gradients of 21 ± 8 mm Hg at 3 to 6 months follow-up. The 23-mm valves are even better, with an EOA of 2.0 ± 0.3 cm², a mean gradient of 8 ± 4 mm Hg, and a peak gradient of 15 ± 7 mm Hg.

The hemodynamic performance of the 3F-Enable bioprosthesis lags behind that of the Trilogy valve. Martens and coworkers⁸ reported an EOA of 1.4 ± 0.3 cm² for the 21-mm valve, resulting in mean gradients of 10 ± 3 mm Hg at 6 months (EOA for the 23 mm valve of 1.9 ± 0.4 cm² resulting in mean gradients of 11 ± 2 mm Hg).

In using the Trilogy valve, we expect a positive impact of the obtained lower gradients and the larger EOA on long-term survival and valve durability, as reported by other groups.¹⁷

The initial implantation series showed 4 cases of intra-valvular regurgitation between the SecuRing and the valve

crown. This regurgitation completely disappeared during the follow-up period. This may be attributed to the progradient epithelialization of the valve components, especially the SecuRing and the incorporation into the annular tissue. Nevertheless, after the initial implantation series, the SecuRing was redesigned to avoid early intra-valvular regurgitation. After the changes, the intra-valvular regurgitation was effectively avoided, and no regurgitation was detected in the following 19 patients. The implantation time of the Trilogy Aortic Valve System was 21 ± 7 minutes. However, a detailed analysis of the implantation times showed that after a learning curve, the initial implantation time of 25 minutes was reduced to 9 to 11 minutes. These learning curves are similar to these of other novel implantation techniques.⁷⁻⁹ To shorten this initial learning curve, we used the median sternotomy as access in these initial series. In the future, we are planning the implantation of the Trilogy Aortic Valve System via a right lateral minithoracotomy and port access or a partial upper sternotomy to increase the benefit for the patients and to reduce blood loss.^{18,19}

CONCLUSIONS

AVR using the Trilogy Aortic Valve System is feasible and safe. We expect a simpler and faster implantation if used in minimally invasive AVR. The extreme supra-annular implantation leads to a favorable hemodynamic performance. At early follow-up, it remains unclear whether long-term durability will be better than currently available stented pericardial tissue valves.

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Discussion

Dr Nawwar Al-Attar (*Paris, France*). In the conclusion of your talk you described a faster implantation time, but when you showed us the crossclamping times, they had an average of 71 minutes. Does this compare favorably with what you do with conventional AVR or do you really see a gain in time?

Dr Breitenbach. If you had a closer look at our results, you would see that we performed concomitant coronary artery bypass grafting in 6 patients; this explains the higher crossclamping time.

Dr Al-Attar. What would be the average crossclamping time then of a standard conventional AVR versus your new technique, this new valve?

Dr Breitenbach. I think conventional AVR crossclamping time ranges from 40 to 50 minutes, depending on the experience of the surgeon. With this new technique, we could reduce the crossclamping time by 10 to 15 minutes.

Dr Al-Attar. Crossclamping time?

Dr Breitenbach. Yes, crossclamping time.

Dr Bryan Fitch Meyers (*St Louis, Mo*). I am always interested in the downstream consequences of these novel techniques, and you had to remove 2 of these valves, but you did them immediately, apparently, in the same operation. Do you have any experience on what it would be like to remove one of these valves after it is fully healed in or does that change the nature of a redo operation based on the securing system that is involved?

Dr Breitenbach. It was very easy to explant this valve because the TACs could be easily removed without any difficulties by using a forceps and you don't need to cut and remove any kind of knotted sutures as in conventional AVR.

Dr Meyers. With an immediate removal, but once it is healed in, have you removed any 3 or 6 months later?

Dr Breitenbach. We had to remove 1 valve because of endocarditis at 22 months, and we did that without any difficulties.

Dr Wolfgang Harringer (*Braunschweig, Germany*). I have been the principal investigator of this multicenter trial. Just a brief comment on the last question. The animal studies in which we performed chronic implantation and removal of the valve demonstrated that it is extremely easy to take the valve out because there is a clear dissection plane.

FIGURE E1. Anatomic position of the Trilogy Aortic Valve System showing the high supra-annular position of the valve crown within the aortic root.

ET/BS