

# Self-Expanding Percutaneous Aortic Valve Implantation

An update on the CoreValve system.

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Since the principle of transcatheter aortic valve implantation (TAVI) was first applied in an early animal study by Danish cardiologist Anderson in his garage in 1992,<sup>1</sup> approximately 8,000 patients have now been treated with this technology worldwide. The procedures have been predominantly performed using two different devices with almost equal frequency: the Edwards Lifesciences (Irvine, CA) Sapien systems and the Medtronic, Inc. (Minneapolis, MN) CoreValve system. Although both systems have been shown to be safe and clinically effective, albeit with a limited duration of follow-up thus far, the principal difference in design is that the Edwards systems have employed a balloon-expandable concept, whereas the CoreValve device is self-expanding.<sup>2</sup> The CoreValve device and TAVI procedure will be discussed in this article, with its story traced from the first use in animal studies to its contemporary applications.

## DEVICE DESIGN

The CoreValve device consists of a long, self-expanding nitinol stent frame that houses a porcine pericardial tissue valve in its proximal/mid portion, which is fixed to the frame in a surgical manner with polytetrafluoroethylene sutures (Figure 1). The stent frame has differential properties of expansion as a result of varying pretreatment processes: the higher part (proximal) expands gently with the purpose of anchoring the system in the proximal ascending aorta; the middle part is constrained to avoid the coronary arteries and carries the valve; and the lower (distal) part has a high radial force for fixation at the annulus and leaflets and pushes aside the calcified

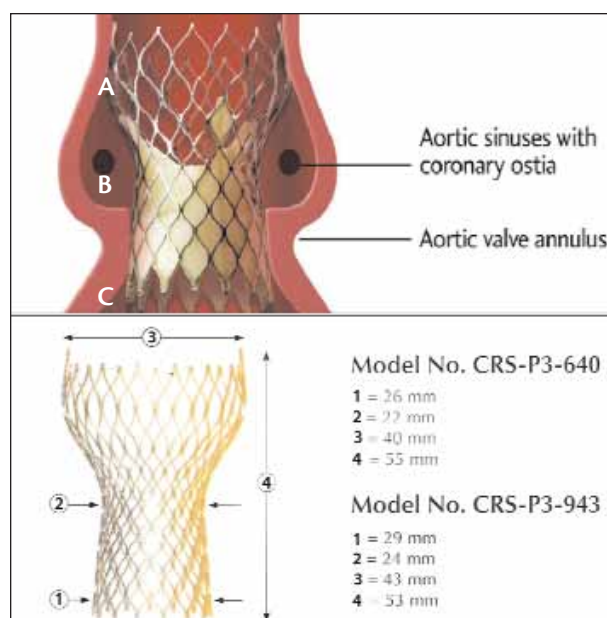


Figure 1. CoreValve device design (top panel). This system is a porcine pericardial tissue valve fixed to a nitinol stent frame in a surgical manner with polytetrafluoroethylene sutures. The stent frame consists of three parts: the higher (proximal) part is positioned across the left ventricular outflow tract and expands firmly to minimize paravalvular leak (A), the middle part of the stent frame carries the valve and is constrained to avoid compromise to coronary blood flow (B), and the lower (distal) part gently expands to make contact with the proximal ascending aorta (C). A smaller 26-mm inflow (CRS-P3-640) and larger 29-mm inflow (CRS-P3-943) device and dimensions (bottom panel).

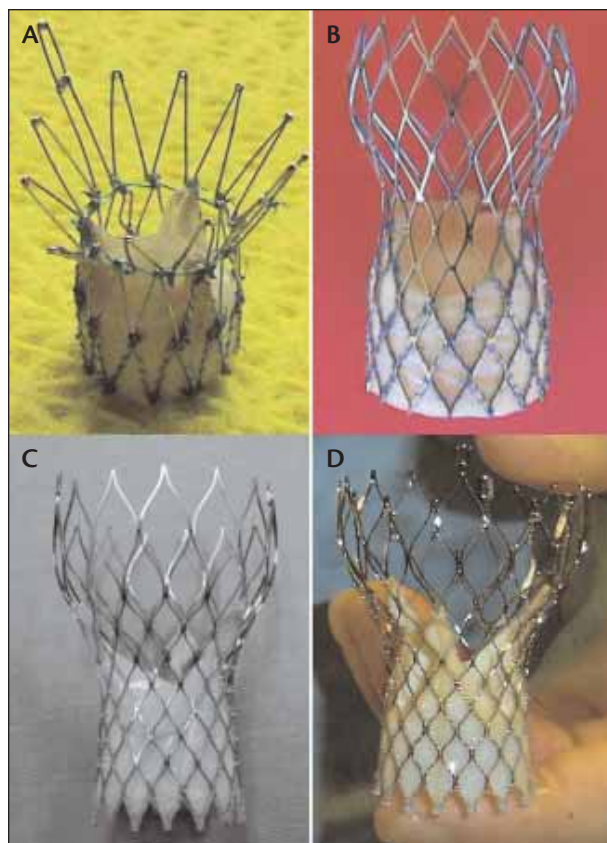
leaflets to avoid recoil and minimize the possibility of paravalvular leaks.

The device started as a 25-F animal prototype and subsequently evolved into 24-F and then 21-F systems (Figure 2). It is now in an 18-F form. The nitinol stent frame used in all human models initially housed a bovine pericardial valve for the first-generation 24-F device. However, it was soon determined that using a porcine pericardial valve allowed for reduction of the profile to the second-generation 21-F device. Further improvements in both the device itself and the delivery system have allowed development of the present, third-generation 18-F device.

CoreValve's success in minimizing device profile is as much a function of the catheter loading system and process as the device itself. The catheter loading system has slow-release and fast-release mechanisms that can deliver the valve in vivo, but can also act to slowly load the valve onto the delivery system ex vivo. Device loading is performed on iced water and utilizes the unique memory properties of nitinol: at cold temperatures the stent frame can be compressed into a narrower profile, and at body temperature, when delivered in vivo, it assumes its original fully expanded form.

## THE COREVALVE REVALVING PROCEDURE

The present day CoreValve TAVI procedure uses the third-generation 18-F system with no cardiopulmonary bypass support required (Figure 3). At the start of the procedure, a second arterial access is established either by a contralateral femoral approach or radially (as in our practice). This access is used to perform contrast injections, usually at 10 mL/s, to identify the plane of the aortic annulus and to guide device implantation. The optimal view is established first, with an optimal projection to view all three leaflets aligned; computed tomography scanning can help find this optimal projection. After femoral arterial access is achieved and before closing with the Prostar XL device (Abbott Vascular, Santa Clara, CA), the native aortic valve is crossed using an Amplatzer left 1 or 2 catheter or Judkins right catheter and a straight 0.035-inch (usually nonhydrophilic) wire. Once the catheter is in place in the left ventricle, the wire is exchanged for a specially shaped Amplatzer Super Stiff guidewire (Boston Scientific Corporation, Natick, MA). The curved shape of the Super Stiff wire is critical to the TAVI procedure; it not only minimizes the risk of left ventricular perforation, but it also allows, through careful alteration of the wire's position and stored tension, subtle reorientation of the prosthesis frame during deployment to conform to aortic angulation. After positioning the Super Stiff wire, the native aortic valve is predilated. If



**Figure 2.** The rapid evolution of the CoreValve device from 2005 to 2006. A 25-F device used in the initial animal study (A). The 24-F first-generation clinical device (B). The 21-F second-generation device (C). The 18-F third- (present-) generation device (D).

necessary, a pigtail may be used to further optimize wire position in the left ventricular apex before predilatation.

In contrast to the Edwards procedure, rapid pacing is not mandatory during valve dilation or the TAVI deployment (although it can be used). The pacing has been used by some operators at a rate of 120 to 180 bpm rather than at 180 to 220 bpm, as is required when using the Sapien device. Movement of the balloon during inflation or deflation is minimized with use of the Nucleus balloon (NuMed Canada, Inc., Cornwall, Ontario, Canada), which is a dog-bone-shaped balloon that is designed to anchor on the calcium of the native aortic valve during inflation.

After valvuloplasty is performed, the CoreValve device is deployed through an 18-F sheath, with progressive expansion usually using the slow-release system. The primary operator pulls and pushes the delivery catheter during this process to optimize positioning using the wire if necessary to optimize axial orientation. Within the mid

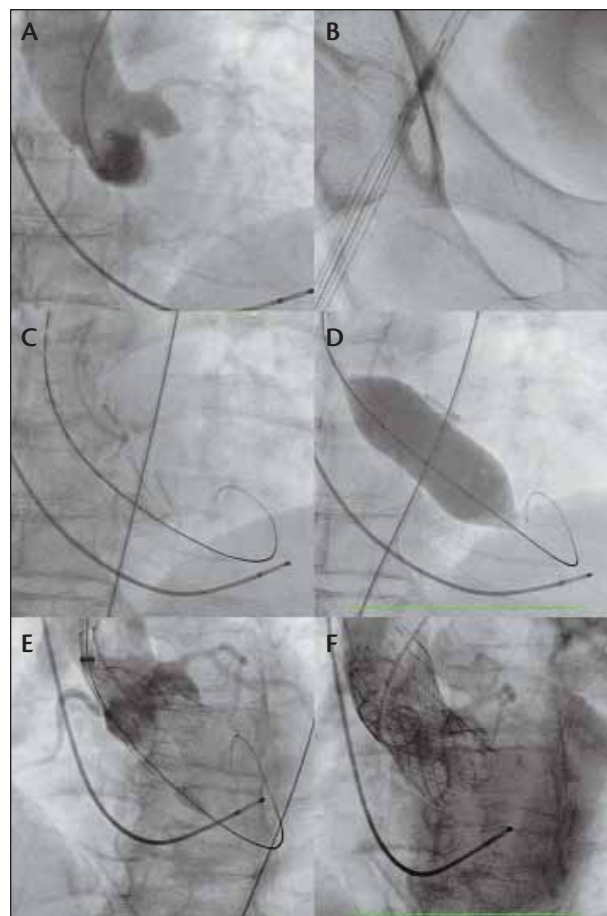
third of device expansion, there is a momentary occlusion of blood flow; for this portion, expansion should be rapid, but thereafter, even though the stent frame is not fully deployed, the prosthetic leaflets are fully functional in situ and the device position may be carefully and gradually altered further before final release. Final release must be carefully verified fluoroscopically, with release of both distal anchoring hooks, or retrieval of the delivery system may result in distal displacement of the deployed valve. A final gradient is measured by exchanging the Super Stiff wire for a pigtail catheter; a final angiogram is also obtained to evaluate any potential paravalvular leaks (Figure 4). The Prostar sutures are then secured. A lack of access site bleeding is routinely confirmed angiographically at the end of the procedure with an iliofemoral contrast injection via contralateral femoral or radial access.

### ALTERNATIVE APPROACHES

Recently, limited experience with the CoreValve device and the apical approach with a reversed delivery system has been performed.<sup>3</sup> However, due to technical difficulties with device expansion in reverse, this experience has been superseded by the transaxillary approach as an alternative for those in whom the transfemoral approach is unsuitable or challenging.<sup>4,5</sup> The transaxillary approach is usually performed on the left side, but it has also been done on the right side (always with open surgical access<sup>4,5</sup> following the basic principle that one should not use a closure device where one cannot compress manually). An open surgical approach has also been used to facilitate CoreValve deployment via the abdominal and thoracic aorta in a slightly more invasive, albeit beating heart, approach in the absence of other access.<sup>6</sup> Moreover, the presence of localized peripheral vascular disease, and even abdominal aneurysms, may be addressed with endovascular therapies even before successful CoreValve implantation via transfemoral access.<sup>7</sup>

### PROSTAR SUTURE-MEDIATED VESSEL CLOSURE

One of the key aspects in aiding the evolution of TAVI with the CoreValve bioprosthesis in a true catheterization lab procedure has been the approach to femoral artery access closure. Whereas early cases were performed with surgical cut down, percutaneous access with preclosing using the Prostar XL 10-F device has subsequently dominated. Although initially designed for 10-F access closure, this device has a long history of success in closing up to 24-F holes in the setting of transcatheter aortic stent graft procedures.<sup>8</sup> It employs a delivery system that allows delivery of four needles that carry two nonbraided sutures from the femoral arterial internal surface to the



**Figure 3.** The CoreValve revalving procedure was performed under conscious sedation. Transvenous temporary wire placement via the right internal jugular vein and a 5-F radial or contralateral femoral arterial access for aortograms (A). Femoral artery preclosing with Prostar XL and subsequent positioning of a 14-F sheath (B). The native aortic valve was crossed using an Amplatz left 2 catheter (Boston Scientific Corporation) and straight wire and then exchanged in the left ventricle for a specially curved Amplatz Super Stiff wire (C). The native valve was predilated and femoral access was changed for 18 F (D). The CoreValve was loaded on the delivery catheter and positioned retrograde via the transfemoral route across the aortic annulus with progressive expansion and optimized positioning using fluoroscopy (E). Final deployment and removal of delivery catheter and wires (F).

external surface. These two sutures can each be closed with a sliding knot to seal the artery at the end of the procedure. After a slight learning curve, this can be performed with a high procedural success as part of the TAVI procedure under local anesthesia with conscious sedation. Some centers prefer the use of ultrasound to optimize arterial puncture, whereas others use a pigtail

**TABLE 1. CASE SELECTION**

| Anatomy                                         | Noninvasive    |            | Angiography     |           |                       |                   | Selection Criteria                               |                              |                               |
|-------------------------------------------------|----------------|------------|-----------------|-----------|-----------------------|-------------------|--------------------------------------------------|------------------------------|-------------------------------|
|                                                 | Echocardiogram | CT/<br>MRI | LV<br>Angiogram | Aortogram | Coronary<br>Angiogram | Aortic<br>Runoffs | Preferred                                        | Borderline                   | Not<br>Acceptable             |
| Atrial or ventricular thrombosis                | x              |            |                 |           |                       |                   | Not present                                      |                              | Present                       |
| Mitral regurgitation                            | x              |            |                 |           |                       |                   | ≤ Grade 1                                        | Grade 2                      | > Grade 2                     |
| LV ejection fraction                            | x              |            | x               |           |                       |                   | > 50%                                            | 30%–50%                      | < 20%                         |
| LV hypertrophy (wall thickness)                 | x              |            |                 |           |                       |                   | Normal to mild (0.6–1.3 cm)                      | Moderate (1.4–1.6 cm)        | Severe (≥ 1.7 cm)             |
| Subaortic stenosis                              | x              | x          |                 |           |                       |                   | Not present                                      |                              | Present                       |
| Annulus (width)                                 | x              | x          |                 |           |                       |                   | 20–23 mm → 26-mm device; 24–27 mm → 29-mm device |                              | < 20 mm or > 27 mm            |
| Annulus-to-aorta (angle) <sup>a</sup>           |                | x          | x               | x         |                       |                   | < 30°                                            | 30°–45°                      | > 45°                         |
| Aortic root (width)                             |                | x          | x               | x         |                       |                   | ≥ 30 mm                                          | 27–29 mm                     | < 27 mm (if sinus < 15 mm)    |
| Sinuses of Valsalva (height)                    |                | x          | x               | x         | x                     |                   | ≥ 15 mm                                          | 10–14 mm                     | < 10 mm                       |
| Coronary ostia position (takeoff)               |                |            |                 |           | x                     |                   | High                                             | Midsinus level               | Low                           |
| Coronary disease                                |                |            |                 |           | x                     |                   | None                                             | Mid or distal stenosis < 70% | Proximal stenosis ≥ 70 %      |
| Ascending aorta (width)                         |                | x          | x               | x         |                       |                   | ≤ 40 mm → 26-mm device; ≤ 43 mm → 29-mm device   |                              | > 43 mm                       |
| Aortic arch angulation                          |                | x          |                 | x         |                       | x                 | Large-radius turn                                |                              | High angulation or sharp bend |
| Aorta and runoff vessels (disease) <sup>b</sup> |                | x          |                 |           |                       | x                 | None                                             | Mild                         | Moderate to severe            |
| Iliac and femoral vessels (diameter)            |                | x          |                 |           |                       | x                 | ≥ 7 mm                                           | Nondiabetic ≥ 6 mm           | < 6 mm                        |

<sup>a</sup>Within the first 7 cm of the ascending aorta versus a perpendicular line across the aortic valve.

<sup>b</sup>Evaluate for evidence and degree of calcification, obstruction, tortuosity, and ulceration.

Abbreviations: CT, computed tomography; LV, left ventricular; MRI, magnetic resonance imaging.

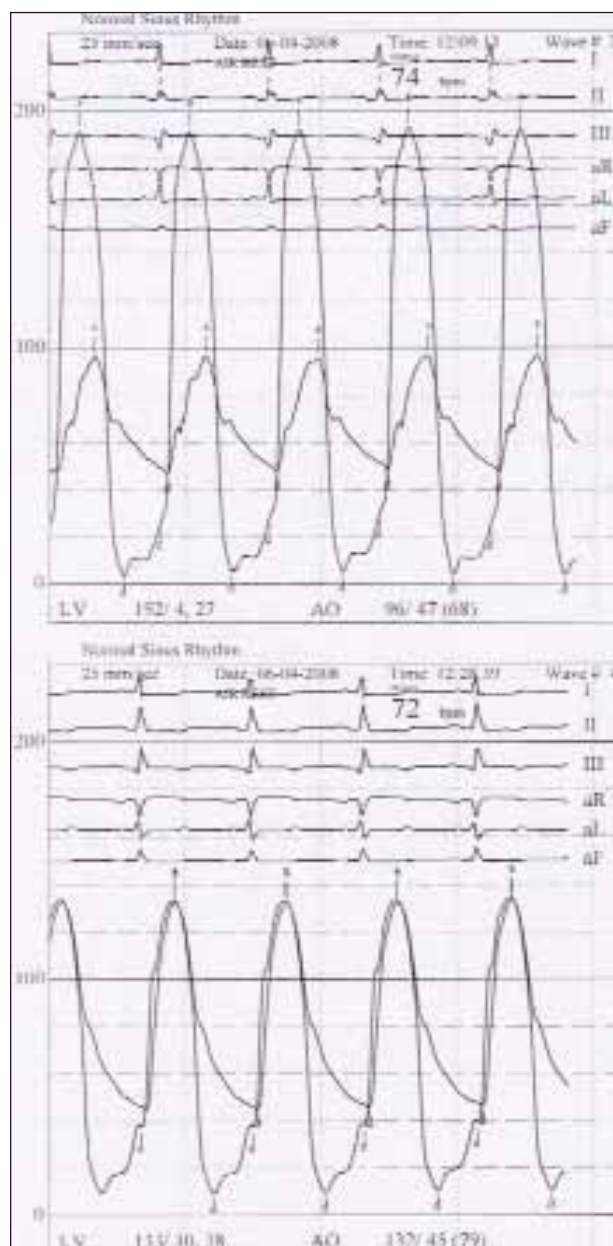


Figure 4. Hemodynamic pressure tracings before and after CoreValve implantation.

from the contralateral side or a long pigtail from the radial side; the pigtail can be positioned within the common femoral artery at the level of the midfemoral head and used with fluoroscopy to guide puncture precisely.

#### CASE SELECTION AND ANATOMICAL CONSIDERATIONS

As for all TAVI procedures, successful CoreValve implantation is dictated by rigorous case selection. For now, TAVI should only follow clinical determination of

high surgical risk by combined cardiosurgical evaluation, with incorporation of quantitative scores to assist this assessment including Society of Thoracic Surgeons score and logistic EuroSCORE. The present CoreValve device is available in two sizes that are defined by its inflow portion to treat aortic annuli of 20- to 27-mm: 20- to 23-mm annuli are treated with the smaller 26-mm inflow device, and 24- to 27-mm annuli are treated with the larger 29-mm inflow device (both are 18-F devices). For the femoral approach, iliofemoral dimension on at least one side that is  $\geq 6$  mm is mandated in the absence of excessive tortuosity in nondiabetic patients; an iliofemoral dimension of  $\geq 7$  mm is recommended in diabetic patients due to putative reduced vascular compliance. Other important anatomical factors that may preclude successful CoreValve implantation include excessive aortic root angulation, low coronary artery ostia, shallow aortic sinuses, and severe septal hypertrophy. All of these factors are evaluated systematically, often using the CoreValve selection matrix as a guide (Table 1).

#### FIRST ANIMAL STUDY

Although it was performed much earlier, the first animal study for a CoreValve prototype was reported by Laborde et al in 2005,<sup>9</sup> approximately 3 years after the first-in-man Edwards TAVI implant by Alain Cribier, MD, and colleagues in 2002.<sup>10</sup> This prototype consisted of a bovine pericardial valve sutured onto a self-expanding Conichrome wire stent frame with 5-0 polypropylene sutures. The self-expanding stent frame consisted of wire bent in a zigzag shape. It was tested in 14 adult sheep and achieved procedural success in eight of 14 animals. The primary initial difficulty was the regulation of the radial force of expansion of the stent frame, and this posed initial difficulties for device stability and paravalvular aortic regurgitation, which were addressed successfully in later models.

#### INITIAL REPORTS IN HUMANS

From early animal studies, the CoreValve procedure was translated rapidly to humans and was first reported in man in 24-F form by Grube and colleagues.<sup>11</sup> The first successful case was a 73-year-old woman with severe aortic stenosis and comorbidities in the form of left ventricular dysfunction, previous coronary artery bypass grafting, renal impairment, and breast cancer. There had been earlier unsuccessful attempts in four patients in India and South America, with one in the setting of predominant aortic regurgitation.

As well as differing from Cribier's design in its self-expandable nature (as opposed to balloon-expandable), the CoreValve device employed a retrograde approach as opposed to the antegrade approach that was initially

developed for the Cribier-Edwards design. At the outset, it was unclear whether the device could be implanted with stability retrograde in a beating ventricle, so the initial procedures were performed using full cardiopulmonary bypass, and later, a percutaneous form of cardiac assist (TandemHeart system [CardiacAssist, Inc., Pittsburgh, PA]).<sup>12,13</sup> It was not long before percutaneous aortic valve replacement with CoreValve and coronary artery revascularization were performed as a combined procedure.<sup>14</sup>

## CLINICAL SERIES

The first clinical series described for TAVI using the CoreValve bioprosthesis was in the Siegburg first-in-man study,<sup>13</sup> which reported results in a series of 25 consecutive patients on cardiopulmonary bypass using the first- and second-generation devices. The investigators reported an 88% success rate, with a 20% in-hospital mortality rate, a 24% major bleeding rate, and a 4% stroke rate. A combined multicenter 86-patient series using the second- and third-generation devices reported a 74% success rate, with a procedural mortality rate of 6%, a 30-day mortality rate of 12%, and a stroke rate of 10%.<sup>12</sup>

Results have since improved with simplification of the procedure and no requirement for cardiac assist, with a 97% procedural success rate. This outcome was reported from a 646-patient multicenter proctored series 1-year after CE Mark approval of the 18-F device, and the authors reported a 30-day mortality rate of 8% and a stroke rate of 0.6%.<sup>15</sup> Interestingly, a surgical team without the assistance of interventional cardiologists (aside from initial proctorship) have reported a 137-patient series predominantly using the CoreValve with a 12.4% 30-day mortality rate and a 5.1% rate of neurological events.<sup>5</sup> The latest series of 1,243 patients from the 18-F CoreValve expanded registry displayed a procedural success of 98%, a 30-day mortality of 6.7%, a stroke or transient ischemic attack rate of 1.7%, and a myocardial infarction rate of 3.9%.<sup>16</sup>

A series of 77 proctored transaxillary cases was recently described by Laborde,<sup>17</sup> and there was a 100% procedural success rate and a 9.4% mortality rate at 30 days in a cohort with a mean logistic EuroSCORE of 28.2%. Although the access bleeding complications were stated to be 1.9%, brachial plexus and subclavian injury were also emphasized as potential complications, however, the frequency of their occurrence is unknown.

The issue of permanent pacing with CoreValve has been frequently highlighted and has varied widely in the published literature at a 9.3% to 33.3%.<sup>5,15,18,19</sup> requirement for a permanent pacemaker. The clinical threshold for and timing of pacing appears to be critical in these reported frequencies. At least by indirect cross-series

comparisons, the requirement for pacemaker implantation after the CoreValve procedure appears to be higher than the 8.5% reported in octogenarians after open aortic valve replacement<sup>20</sup> and the 0% to 5.9% reported with the Edwards device.<sup>21-23</sup>

Although some regard this as a major adverse event, others regard it as a precaution in this high-risk population. The potential of recovery of the conduction system and its timeframe is poorly elucidated, but there are some preliminary data to suggest temporal improvements.<sup>18</sup> The incidence of new left bundle branch block is a more uniform phenomenon in published series and appears to be approximately 40% or more;<sup>18,19</sup> this is much greater than the 15.6% reported after open aortic valve replacement.<sup>24</sup> The established value of new left bundle branch block in predicting complete heart block, syncope, or sudden cardiac death after open aortic valve replacement has led to some centers practicing a strategy of prophylactic pacemakers when a new left bundle branch block is seen after CoreValve implantation. This remains a topic of great debate and will require a greater understanding to be resolved.

## NOVEL THERAPEUTIC TARGETS AND FUTURE DIRECTIONS

Today, the CoreValve device has been implanted in more than 4,000 patients in 157 centers spanning 26 countries worldwide. The device received CE Mark approval for severe symptomatic calcific stenosis in tricuspid native aortic valves. It has been successfully used for so-called off-label indications, including valve-in-valve to treat failing bioprostheses<sup>25</sup> and as a bailout for device malposition,<sup>26</sup> and to treat (in isolated cases) native aortic regurgitation.

## CONCLUSION

The applicability and simplification of the CoreValve TAVI procedure have paralleled progressive improvements in the device itself. The recent acquisition of CoreValve, Inc. by Medtronic, a company with well established prosthetic valve technology, will be significant in further refinements in the device, procedure, and post-operative care. ■

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