First-in-Man Transcervical Surgical Aortic Valve Replacement Using the CoreVista System

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Objective: This study aimed to evaluate a novel device system for surgical aortic valve replacement (SAVR) using a unique new less invasive access approach. The hypothesis is that SAVR can be performed through a short transverse incision in the neck, similar to that used for transcervical thymectomy avoiding chest disruption.

Methods: A new device system was developed to provide retraction, step-by-step illumination, and on-screen visualization for the new approach. Preliminary feasibility studies were performed in cadavers. Comprehensive risk analysis was performed, and training was implemented in Thiel preserved cadavers. For the first-in-man clinical case, a 63-year-old woman with symptomatic critical aortic stenosis (The Society of Thoracic Surgeons risk, 11%) and heavily calcified aortic valve was selected. A short transverse incision was made in the neck; the device was introduced, and the sternum was elevated; femorofemoral cardiopulmonary bypass was established; substernal dissection was guided by the sequenced illumination, and high-definition visualization was provided by the device, allowing for optimal exposition of the aorta and aortic valve; and a 23-mm Medtronic ENABLE sutureless valve prosthesis was implanted. Procedure success was evaluated according to the standardized composite end point definition of "device success" proposed by the Valve Academic Research Consortium.

Results: Access, delivery, and deployment of the valve prosthesis were successful. The correct position and intended performance of the valve were demonstrated (mean gradient, 6 mm Hg; aortic valve area, 2.5 cm^2) with the absence of moderate or severe prosthetic aortic regurgitation. Only one valve prosthesis was used.

Conclusions: Transcervical SAVR with sutureless valve is feasible using this novel access system. The new approach has potential to offer patients substantially shorter stay and fewer, less serious complications, as has been observed in transcervical thymectomy. Further studies are merited.

Key Words: Aortic valve replacement, Minimally invasive cardiac surgery, Transcervical approach, Rapid deployment aortic valves.

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Approaches to surgical aortic valve replacement (SAVR) have changed little for well more than a decade.[1,2] Initially, Cosgrove and Sabik[1] described a parasternal approach for SAVR as an alternative to median sternotomy. A couple of years later, in 1998, Gundry et al[2] proposed a partial sternotomy in a reverse "J" fashion from the sternal notch into the fourth right intercostal space. The parasternal approach was associated with lung herniation and wound complications such as chest wall instability and paradoxical chest movement requiring reoperation[3] and was progressively abandoned.[4] The ministernotomy incision originally described was further reduced to a slightly shorter incision extending into the third right intercostal space rather than the fourth space, but still, these minimally invasive (MIS) approaches failed to reach the revolutionary achievements and the clinical significance in terms of patient recovery, hospital stay, and complication rate, which accompanied the advent of laparoscopic surgery in general surgery, for example. Indeed, the initial enthusiasm regarding the idea of turning a major cardiac operation into a day-case procedure, similar to the revolution that occurred in the treatment of gallbladder disease with laparoscopic cholecystectomy, was tempered by the disappointing and sometimes contradictory results obtained in clinical trials on MIS SAVR. Meta-analysis of studies comparing full sternotomy and ministernotomy showed a general improvement in clinical outcomes such as mortality, complication rates, and blood loss,[5,6] but failed to reveal a major impact on the outcome variables reflecting actual early recovery from surgery, such as hospital length of stay (LOS) or intensive care unit stay.[7,8] A careful reading of the data generated from these meta-analyses showed a reduction of less than a day in the intensive care unit stay and of just a single day for the total LOS in the hospital,[8] suggesting limited overall improvement in the real-life surgical scenario and prompting reconsideration of the clinical advantage of SAVR MIS approaches even by surgeons mastering the necessary skills.[7]

However, the increasing pressure for optimization of clinical outcomes of cardiac surgical patients and for a cost-effective

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management of their postoperative care has stimulated renewed interest in MIS among the surgical community and given new impulse to the development of alternative strategies with the aim of obtaining better outcomes in terms of length of hospital stay, recovery, and return to work activities, similar to those achieved in the context of day surgery laparoscopic procedures.

Taking inspiration from the parasternal approach firstly described by Cosgrove et al, a 5- to 7-cm right anterior thoracotomy (RAT) in the line of the ribs has been proposed to achieve access to the aortic valve without splitting the sternum.[9] Continuous improvements in the technique along with advancements in the design and industrial development of surgical tools and prosthetic valve technologies have brought this approach to the edge of the current state of the art in the field.[4] However, a step change in outcomes after RAT has still not been forthcoming with reported median LOS of 5 days, which does not represent a major improvement when compared with 6 days normally required for standard procedures.[4] Neither RAT nor ministernotomy has been able to produce the expected benefit in clinical outcomes that would have made them comparable with an MIS procedure with the potential to be performed as day case or with single overnight stay, such as has been observed in laparoscopic general surgery. Reasons underlying these unsatisfactory results might be related to the biological response to stress involving chest wall disruption associated with ministernotomy or minithoracotomy[10,11] and postoperative pain as it is well-known that these incisions are intrinsically painful and take time to heal.

In fact, the only approach to aortic valve replacement (AVR) that currently provides a realistic prospect of day-case or next-day discharge is transcatheter aortic valve implantation (TAVI). However, despite the rapid evolution of TAVI and the progressive widening of its indications, the transcatheter approach is not suitable for every patient and is restricted by both anatomical and pathological factors. Extensive calcification,[12] eccentric annulus geometry,[13] and bicuspidy, especially in young patients, are considered contraindications to TAVI because of risk of paravalvular leaks and major complication.[14–16] Infective endocarditis is also considered a purely surgical indication, as complete excision of infected leaflet tissue is required in these cases. In addition, TAVI devices, mainly designed for the treatment of calcific aortic stenosis, have numerous limitations for the treatment of native pure aortic regurgitation (AR).[17] In addition, when considering that AR occurs at a younger age, these patients tend to be more likely considered as surgical candidates.[17] Therefore, although effective and providing a real less invasive day-case approach, TAVI is not suitable for all patients, and alternative strategies need to be found if pursuing the idea of a next-day discharge in the totality of patients requiring AVR.

Against this background, we sought to develop a radically less invasive approach to SAVR that avoids any kind of chest disruption in the expectation that this would bring about a step change in the speed of recovery from surgery and minimize complications.

The inspiration for this approach comes from an operation "borrowed" from thoracic surgery, that of transcervical thymectomy (TCT).[18] The thymectomy operation has traditionally been performed by full median sternotomy with a postoperative course similar to those of patients undergoing heart surgery via the same approach, including a potential for deep sternal wound complications, chest and respiratory morbidity, and bleeding with consequent reflection in prolonged hospital stay.[19,20] However, in 1988, Cooper et al[18] proposed a much less invasive approach to thymus excision and developed the TCT procedure. Transcervical thymectomy is performed using a simple, unlit retractor with the surgeon wearing a headlight and looking through a small transverse incision in the neck. Evidence that TCT can be performed with short LOS and with relatively low risk of largely nonserious adverse events has been demonstrated in several large series.[21,22] Indeed, after excluding myasthenic crisis (not relevant to the population of patients undergoing SAVR), the next most frequent complication across these studies was pleural effusion, closely followed by wound seroma/other minor wound problem, and simple pneumothorax, all occurring with a cumulative incidence ranging between 2% and 6%.[21]

Cooper's achievements have been reproduced by many other surgeons worldwide[21] with a mean LOS currently ranging between 1 and 2 days[22–25] and some series reporting discharge of patients on the day of surgery as a routine.[26] Hence, Cooper's vision of being able to create a radically less invasive procedure simply by moving from full sternotomy approach to a short transverse incision in the neck, changing nothing else, has been realized for this procedure.

We hypothesize that if SAVR can be performed through the same incision adopted by Cooper, then SAVR patients will also experience much shorter LOS and related benefits.

METHODS

Development of Novel Access Device

Existing device systems used for TCT were found to be unsuitable for transcervical AVR, a much more complex procedure than TCT. Absence of an effective system for illumination inside the chest cavity and adequate visualization of mediastinal structures were identified as particular problems. A novel access system was developed to address these deficiencies and facilitate the new procedure (CoreVista; CardioPrecision Ltd, Glasgow, UK). The device comprises a robust lifting frame that attaches to each side of the table; a retractor equipped with a set of lights sequenced to illuminate different zones of the operative field in step with the surgical procedure, the light sequence being delivered through an optical switch mounted on the rear surface of the retractor; and a high-definition (HD) surgical monitor that is positioned immediately above the incision (behind a sterile cover) in the natural line of sight of the surgeon. The device is designed to create a comfortable operating environment for transcervical surgery to be performed from a seated position through a perfect combination of retraction, illumination, and visualization at every stage of the procedure (Figs. 1 and 2).

Surgical Procedure Development

The surgical procedure was developed and iteratively improved through repeated experimentation and practice on

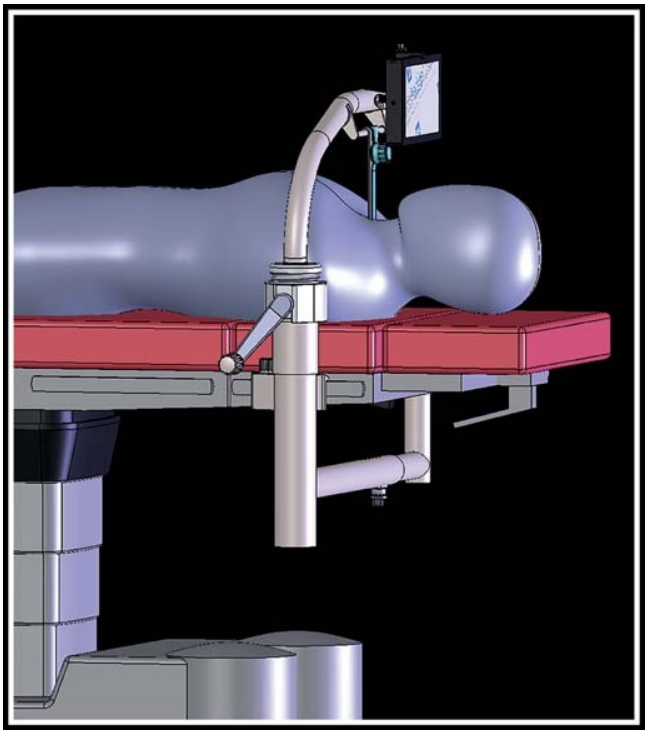

FIGURE 1. Schematic diagram of the CoreVista system (CardioPrecision Ltd, Glasgow, United Kingdom), which comprises a lifting frame that attaches to each side of the operating table, an illuminated retractor blade to elevate the sternum and programmed to deliver illumination to different zones of the operative field in sequence, and a high-definition surgical monitor positioned immediately above the incision in the natural line of sight of the surgeon for optimal hand-eye coordination.

cadavers starting from a simple transverse (skin crease) incision in the neck. The Thiel embalming technique[27] of soft cadaver fixation was explored as a suitable model for training.

Fifteen cadavers underwent transcervical AVR. Successful valve implantation was defined as secure location of a prosthetic valve (mechanical, biological, or sutureless) in the aortic root, unrestricted opening and closure of the valve leaflets, patent coronary ostia, and secure closure of the aortotomy as dynamic modes of valve assessment were not possible in the cadaver model.

The experience achieved in cadavers was transferred into a comprehensive step-by-step guide to the procedure, taking account of the real-life scenario in living patients and the requirements of an on-pump cardiac operation. The main goal was to identify key steps of the procedure and optimize illumination settings. In addition, a comprehensive hazard analysis and adverse scenario planning was undertaken.

Training on Cadavers

Once the effectiveness and feasibility of this approach were confirmed and detailed step-by-step operative plan capturing every step of the new procedure was developed, a training program for the surgical team was implemented, and two surgeons were extensively trained before embarking on first human case.

In parallel, theater setup, materials, and human resource allocation within the operating room were identified and used to inform anesthesiologists and theater personnel before first clinical case.

First Clinical Case

A 63-year-old woman with symptomatic critical aortic stenosis (The Society of Thoracic Surgeons risk, 11%) was selected to undergo the procedure. Coronary angiography showed normal coronary arteries but heavily calcified aortic valve. Transesophageal echocardiography demonstrated a mean gradient of 47 mm Hg, valve area of 0.5 cm^2, and mild AR. Computed tomography showed extensive calcification of the valve leaflets, especially noncoronary leaflet and a functionally bicuspid valve, owing to fusion between right and left coronary cusps demanding surgical AVR (Fig. 3). Computed tomographic scan with Multi-Planar Reconstruction 3D planar reconstructions was also used to define spatial an anatomical relation between the neck and cardiac structures. According to our previous experimental cadaveric work, a distance of 12 to 15 cm from the neck incision to the aortic valve plane over a straight line was suitable to easily perform the procedure. In this patient, neck incision–to–aortic valve distance was measured as 13 cm. Ethics committee approval and informed consent were obtained.

Surgery was performed through a skin crease incision in the neck, using the novel access device and surgical procedure outlined earlier. Initial dissection was directed under the

FIGURE 2. Magnified view of the CoreVista Retractor and high-definition display. The retractor can be operated with three different illumination modes (A, B, and C) for optimal illumination of different zones of the operative field as described in Table 1. Light beams from the various illumination modes are superimposed for illustrative purposes.

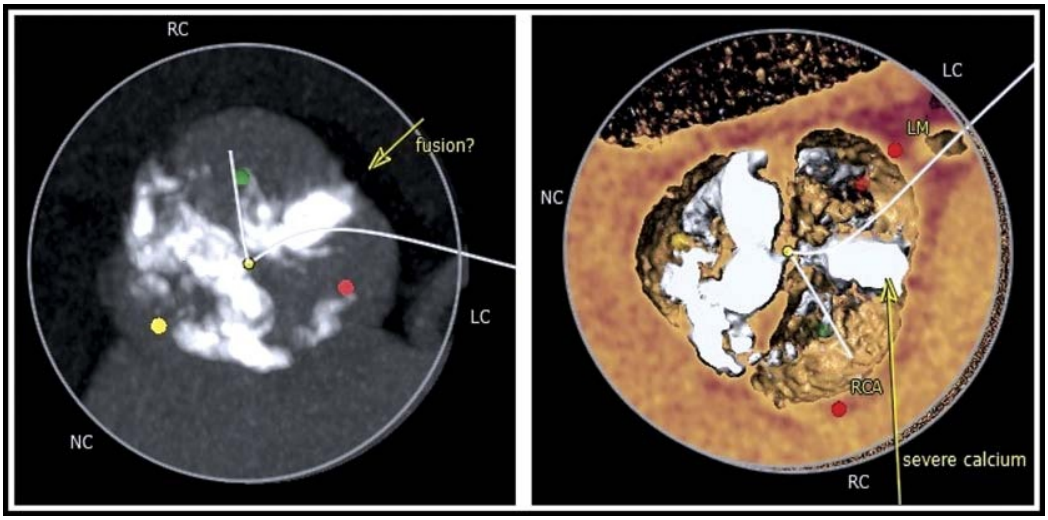

FIGURE 3. Computed tomographic scan reconstruction of the stenosed native aortic valve showing distribution of calcification in the leaflets and aortic annulus; severe calcification is observed in the area between the left and right cusps with possible leaflet fusion. LC, left cusp; LM, left main stem; NC, noncoronary cusp; RC, right cusp.

sternum, anterior to the left brachiocephalic (innominate) vein, and the pericardium was opened to expose the ascending aorta using the sequenced illumination and HD visualization provided by the device. Cardiopulmonary bypass (CPB) was established by femorofemoral cannulation, and the aorta was cross-clamped using transthoracic (Chitwood) clamp inserted percutaneously at the third intercostal space. The clamping maneuver was performed under vision, and cardioplegia was given through the aortic root. The aorta was transversely opened, the native valve was excised, and a 23-mm Medtronic ENABLE sutureless valve prosthesis was selected and implanted according to the manufacturer's instructions. Unfolding and deployment of the ENABLE valve was facilitated by HD visualization of the operative field on the screen. The aorta was closed, the heart was deaired, and the procedure was completed, as planned. Procedure success was evaluated according to the standardized composite end point definition of "device success" proposed by the Valve Academic Research Consortium (VARC) 2011.

Composite end point criteria for "device success" are defined as follows:

- Successful vascular access, delivery, and deployment of the device and successful retrieval of the delivery system.
- Correct position of the device in the proper anatomical location.
- Intended performance of the prosthetic heart valve (aortic valve area > 1.2 cm^2 and mean aortic valve gradient < 20 mm Hg or peak velocity < 3 m/s, without moderate or severe prosthetic valve AR).
- Only one valve implanted in the proper anatomical location.

RESULTS

Surgical Procedure Development

The Thiel method of embalming provided a convenient fixation of cadavers with optimal preservation of color, consistency, and flexibility of tissues. This method allowed to accurately simulate every step of the procedure including mediastinal dissection, exposure, as well as removal and replacement of an aortic valve through the mentioned transcervical access.

Valve implantation was completed successfully in all 15 cadavers according to the criteria earlier defined with no need of sternotomy. Although replacement with conventional sutured valve prosthesis was clearly achievable in cadavers, the procedure seemed particularly well suited to use with one of the new sutureless valve technologies.

A total of 25 key procedural steps were identified as necessary to accomplish SAVR using this approach. Key steps of the procedure, device settings, and modes of use optimized according to the temporal progression of the surgical phases of the operation are listed in (Table 1).

In addition, the hazard analysis and adverse scenario planning led to the addition of a safety feature to the device that allows the surgeon to quickly remove the retractor, swing the lifting arm to the side, and revert to open surgery should a problem arise.

Training

The operative steps were subjectively classified for training purposes into (i) operative maneuvers that are routinely practiced in MIS cardiac surgery or entail only minor variation from standard surgical practice and (ii) major variations from normal practice that merit specific training. Examples of major departures from standard practice include the initial setup and installation of the device system on the operating table; the incision, mobilization of soft tissues, and insertion of the specialized retractor device; intrathoracic dissection and exposure of the ascending aorta; and importantly, the use of sequenced illumination on the CoreVista Retractor to optimize illumination of different zones of the surgical field at different stages of the operative procedure.

TABLE 1. Device Operation Modes and Operative Steps in Association to the Specific Training Requirements

Training Requirements	Operative Step	Device Setting
Operative maneuver entailing major variation from normal practice (specific training required)	• Device installation on the operating table	
	• Short transverse (skin crease) incision in the neck	
	• Mobilization of soft tissues around the entrance of the wound	
	• Insertion of the CoreVista Retractor	
	• Elevation of the CoreVista Retractor	
	Turn to first illumination setting	Mode A illumination
	• Dissection in the immediate vicinity of the incision	
	• Intrathoracic dissection and mobilization of fatty thymic remnants	
	Turn to second illumination setting	Mode B illumination
	• Identification of left brachiocephalic vein and arterial trunks	
	• Opening of the pericardium and exposure of the ascending aorta	
	• Insertion and application of transthoracic (Chitwood) aortic cross-clamp at third intercostal space	
	• Insertion of vent catheter, if required	
	• Instillation of carbon dioxide into the field	
	• Purse string placement in aortic root and cardioplegia delivery	
	• Opening of aorta	
Operative maneuver requiring standard minimally invasive skills or minor variation	Turn to third illumination setting	Mode C illumination
	• Excision of native aortic valve leaflets	
	• Sizing of the aortic annulus using standard sizers	
	• Placing sutures [guiding suture(s) or valve securing sutures]	
	• Deployment of prosthetic valve into annular location	
	• Tying and trimming of suture(s) with knot pusher and scissors	
	• Closure of aortotomy	
	• Deairing and release of aortic cross-clamp	
	• Attachment of pacing wire to surface of right ventricle	
	• Establishing cardiopulmonary bypass via the femoral artery and vein	
	• Placing of drains in the pericardial space from the neck and closure of soft tissues and skin.	

Training of the surgeon encompassed the use of the device and all steps of the new procedure but placed particular emphasis on the steps of the procedure that were considered major variations from normal surgical practice, as outlined earlier and identified in Table 1. No step was considered too difficult to be learned or taught to an accomplished cardiac surgeon of average skill. The training conferred to surgeons the skills and confidence to perform the first-in-man case.

Surgeon training and simulation of the procedure allowed the development of a protocol for organization of theater setup and human resource allocation in the operating room, which was used to train anesthesiologists and theater personnel before the human case. The CoreVista system is secured to the operative table, and the theater setup was organized to have the surgeon at the head of table and the assistant on his left side. The ventilator and anesthesiologist stand aside of the surgeon with eventual second assistant at the top left of the table. Scrub nurse and the instruments table are conveniently located at the right side of the patient, whereas the perfusion machine and its operator are situated along the left side of the patient, with the aim to allow ample space of maneuver around the patient's right side for unobstructed passage of instruments from scrub nurse to surgeon and vice versa, or in case the surgeon needs to rapidly move to convert the procedure in a full median sternotomy, the operator has free access to the patient's right side. In fact, a built-in safety feature of the system allows the retractor to be swiftly removed, and the lifting apparatus swings easily out of the way for conventional access (Fig. 4).

First Clinical Case

The surgeon operated through the cervical incision using on-screen HD visualization (Fig. 5). Key steps of the procedure observed by the surgeon on the screen during the operation are shown in Figures 6 and 7. Access to the aorta and aortic valve entails the opening of the pericardium just caudal to the left brachiocephalic vein at the pericardial reflection, placement of a purse string suture in the ascending aorta, insertion of cardioplegia delivery cannula for instillation of cold blood cardioplegia, and opening of the aorta by transverse aortotomy using MIS instruments (the aortic cross-clamp is seen just cranial to the cardioplegia cannula) (Fig. 6). Surgical replacement of the valve entails excision of the native aortic valve leaflets, which is easily achieved using MIS instruments; sizing of the aortic annulus with the Medtronic sizer; delivery of the folded 23-mm Medtronic ENABLE sutureless valve prosthesis into the aortic root; and final unfolding and inspection of the implanted valve prosthesis, all performed by the surgeon on the screen with the benefit of HD (Fig. 7). Cross-clamp time was 63 minutes; total CPB time was 87 minutes.

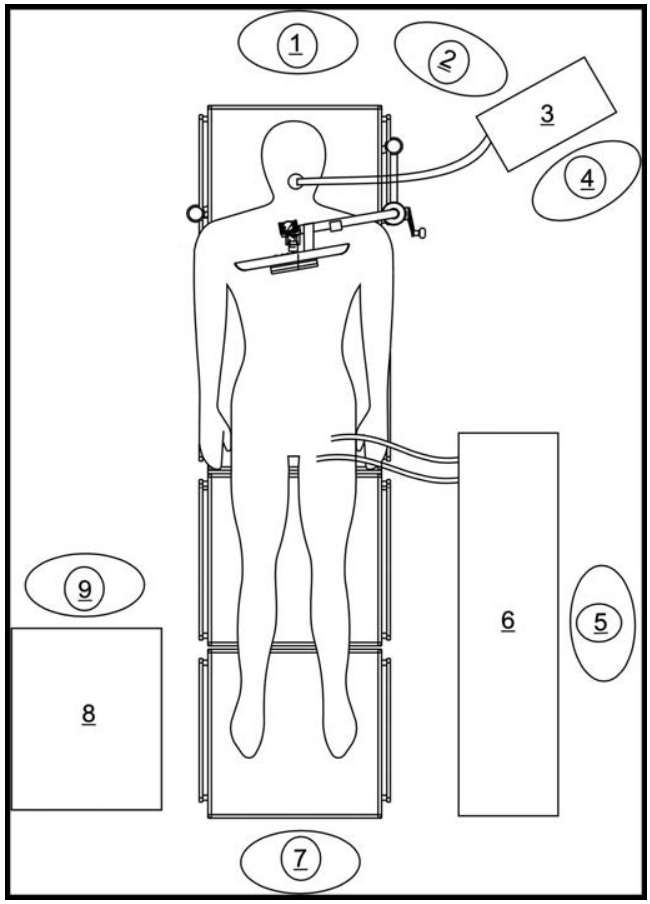

FIGURE 4. Schematic drawing of theater setup showing the surgeon (1) at the head of table with the assistant (2) on his left side; the ventilator (3) and the anesthesiologist (4) stand aside of the surgeon at the top left of the table; the scrub nurse (9) and the instruments table (8) are conveniently located at the right side of the patient; the perfusion machine (6) and its operator (5) are situated along the left side of the patient, allowing ample space of maneuver around the patient's right side for passage of instruments and in case of emergency conversion to median sternotomy; the running nurse (7) is ideally located at the patient's feet.

The purpose of this study was to evaluate effectiveness of this approach according to the updated VARC criteria published by the VARC, which is considered the current standard reference to assess device success parameters. The criteria of VARC for device success entail an uneventful access, delivery, and deployment of the device with successful retrieval of the delivery system; demonstration of the achievement of a correct position of the device in the proper anatomical location and the use of only one valve implanted in the correct position; demonstration of satisfactory performance of the prosthetic heart valve, namely, aortic valve area of greater than 1.2 cm^2 and mean aortic valve gradient of less than 20 mm Hg or peak velocity of less than 3 m/s, without moderate or severe prosthetic valve AR. In our case access, delivery and deployment of a single valve prosthesis was successfully achieved using the novel access system and surgical procedure. Transesophageal echocardiography (Fig. 8) confirmed correct position of the valve in the proper anatomical location with a mean gradient of 6 mm Hg, aortic valve area of 2.5 cm^2, and a mild prosthetic AR as defined in the VARC criteria. The patient experienced an uncomplicated course in the immediate postoperative period.

DISCUSSION

This study was undertaken to demonstrate the feasibility of transcervical SAVR using the CoreVista system. In particular, the main goals of surgical access to the aortic valve, excision of calcified leaflets, and satisfactory implantation of an aortic valve prosthesis were achieved. Furthermore, the AVR procedure was completed without conversion to open surgery, and only one prosthesis was used. The intended performance criteria and other criteria for "device success" were met as judged by VARC standardized end point definitions.[28]

Complete excision of the native valve was achieved in this patient, and a 23-mm sutureless aortic valve prosthesis was deployed in the aortic annulus, thereby preserving the basic principles of conventional surgical approach to the aortic valve. In particular, this patient had a heavily calcified, functionally bicuspid native aortic valve. Surgical AVR allowed excision of the calcified valve leaflets and implantation of a bioprosthesis with a significant increase in the orifice area. In this case, valve area increased from 0.5 to 2.5 cm^2, which represents a substantially greater increase in valve area than seen with either conventional stented valve or TAVI prostheses of similar size after implantation. It may be postulated that the hemodynamic benefit carried by surgical valve excision and prosthetic replacement might warrant a superior outcome in young active

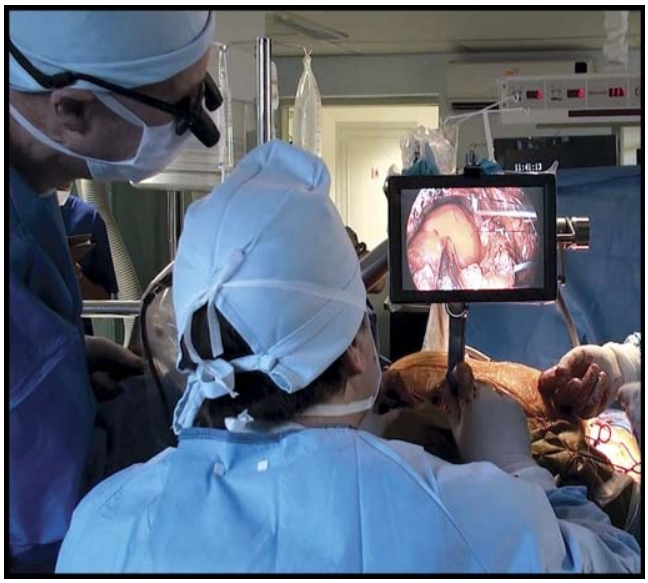

FIGURE 5. Photograph of the operative procedure, actual real-life surgical scenario with the surgeon operating at the top of the table, high-definition screen in line of sight of the surgeon showing the aorta and the assistant surgeon standing at the left side.

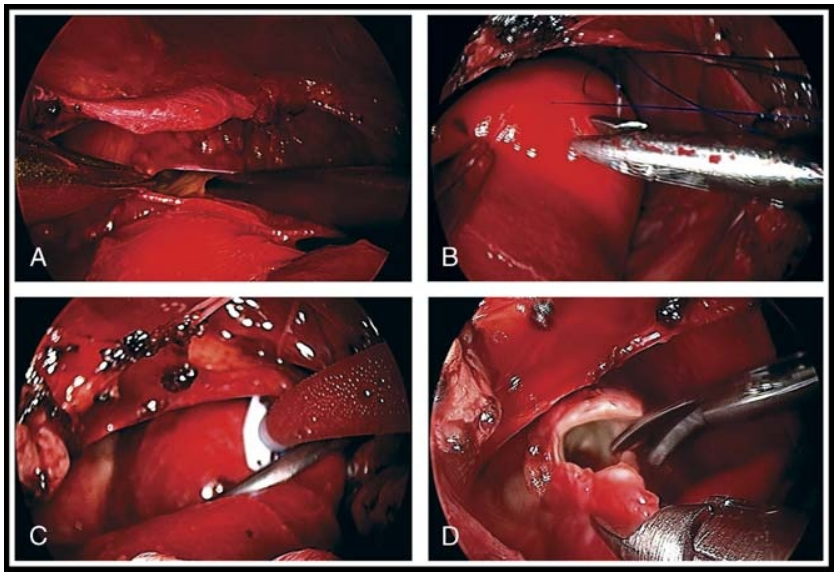

FIGURE 6. Intraoperative steps of the procedure (access to the aorta and aortic valve) seen by the surgeon on screen. A, Opening of the pericardium. B, Placement of the purse string for cardioplegia delivery cannula. C, Instillation of cold blood cardioplegia. D, Opening of the ascending aorta by transverse aortotomy.

patients or in patients with heavily calcified native valve because sutureless valves enable larger effective orifice area[29] in comparison with transcatheter valves.[30,31] Indeed, a recent study from Biancari et al[32] comparing large cohorts of patients undergoing sutureless valve implantation versus TAVI patients matched for age and preoperative clinical characteristics demonstrated significantly reduced in-hospital mortality, incidence of mild-to-moderate paravalvular leaks, and a need for permanent pacemaker in the sutureless group. However, when considering hospital stay, time for surgical recovery, and effective return of the patient to normal activities, TAVI has until now been the least invasive procedure and the only approach able to deliver a day-case perspective in AVR. From these standpoints and with the aim to offer an early discharge procedure to patients unsuitable for TAVI and virtually to all patients candidate to AVR, the concept of a truly MIS surgical approach was ideated and developed. The rationale inspiring our effort relies on the fact that one of the principal determinants affecting the postoperative course in cardiac surgery and causing complications is the degree of invasiveness of the procedure and of chest

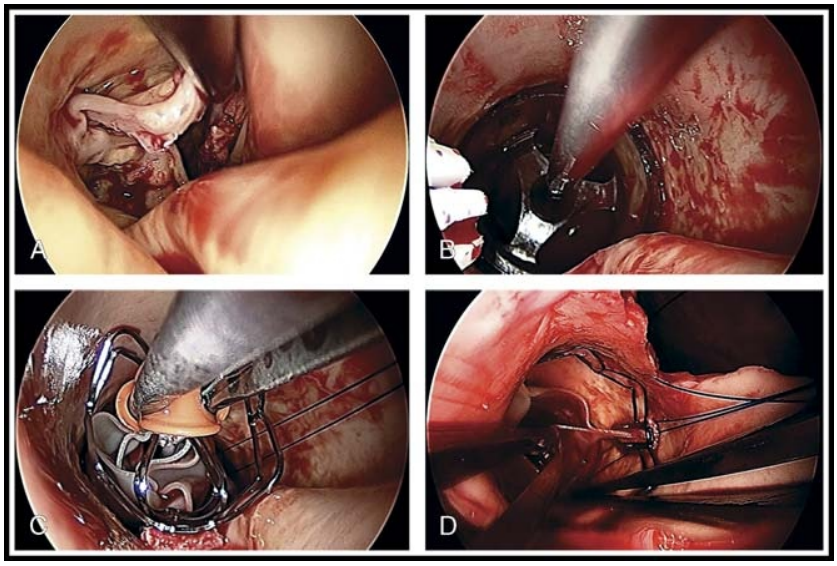

FIGURE 7. Intraoperative steps of the procedure (surgical valve replacement) seen by the surgeon on screen. A, Excision of aortic valve leaflets. B, Sizing of the aortic annulus. C, Deployment of folded Medtronic ENABLE sutureless valve. D, Final inspection of deployed valve prosthesis.

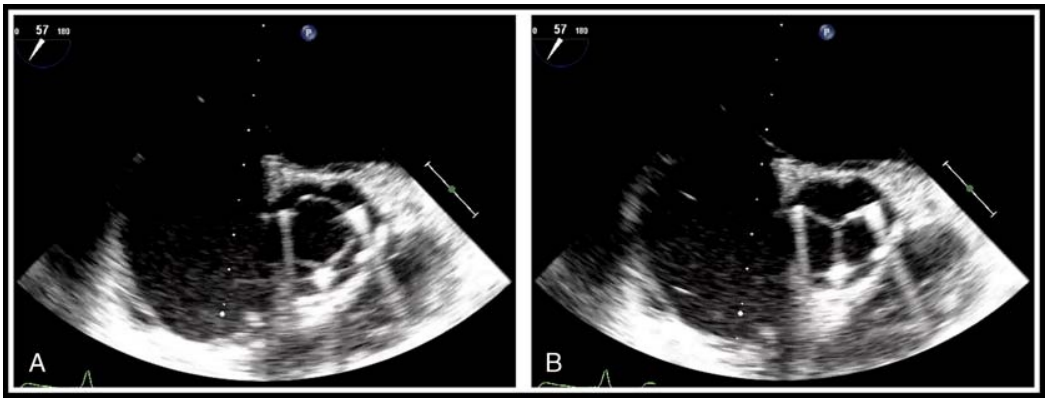

FIGURE 8. Transesophageal echocardiograph of the aortic valve at the end of the procedure in systole (A) and diastole (B) in short axis.

disruption. Although RAT is increasingly gaining consensus as providing an MIS approach for SAVR through a small thoracic access, rib spreading, occasional need for surgical rib dislocation to obtain suitable exposure, thoracic and lung complications along with postoperative pain associated to the chest access harness the actual benefit expected from the avoidance of median sternotomy.[4] Interestingly, a recent randomized trial comparing clinical outcomes between median sternotomy and lateral thoracotomy in cardiac surgery showed quicker discharge times in the sternotomy group, worse lung function at discharge in the thoracotomy group, and no clinical advantage in terms of analgesia requirements, quality of life, and surgery costs of minithoracotomy over full median sternotomy.[33] From these standpoints, we thought of a procedure that would completely avoid any kind of chest disruption but provide access to the thoracic cavity through its natural cranial inlet.

The technique to achieve this goal and perform SAVR as here described was borrowed and actually originated from the basic principles of transcervical surgery adopted for the excision of the thymus gland through the use of a specially designed novel access device system that provides safe and comfortable exposure of both mediastinal and cardiac structures. The operative strategy is to avoid any type of chest disruption, while maintaining the effectiveness and advantages of a real surgical approach to AVR. Indeed, illumination of the field in steps sequenced with the three key stages of the procedure and on-screen visualization provides a much enhanced view of anatomy inside the chest, thus permitting thorough and accurate anatomical dissection, assessment of the native valve pathology, and a safe and controlled implantation of the prosthesis.

There is a large body of evidence supporting the use of transcervical approach for thymectomy,[21] and such procedure is associated with dramatically reduced LOS and risk of complications when compared with traditional sternotomy approaches.[34] Hence, it is hypothesized that similar benefits will follow for patients undergoing SAVR by this route. Interestingly, although this novel access device system was designed for AVR (either SAVR or transcatheter AVR), it may also be suitable for TCT as the device addresses all of the problems previously identified with respect to TCT.[20]

Clearly, given the learning curve required for suturing within a confined space, the developing technology of sutureless valves was considered ideally suited to this new approach. The progressive maturation of sutureless valve designs, as testified by the number of commercially available options in the market, has virtually eliminated the need to secure a valve prosthesis with sutures,[35] making these bioprostheses optimal candidates for this approach. However, the experience in cadaveric models also demonstrated the feasibility of a conventional suturing approach through this access, making the technology equally suitable for patients desiring a mechanical prosthesis.

The actual valve prosthesis selected was the Medtronic 3f ENABLE prosthesis. However, a sutureless valve from any of the other main manufacturers in the field would be equally well suited to this approach.

Another technical consideration is aortic cross-clamping during the procedure. Although it is possible to clamp through the neck incision, presently available clamps obstruct the view and hinder the conduct of the remainder of the operation. Therefore, we adopted a percutaneous approach entailing the use of transthoracic (Chitwood) clamp through a small incision at the level of third or fourth intercostal space in the right chest in accordance to the level of the aorta. The clamp is advanced through the right chest and a small fenestration above the superior vena cava is needed to enter the pericardium. The maneuver is performed analogous to the one performed during MIS mitral surgery, but in our approach, the jaws of the clamp progressively come into the surgical sight from the neck access and on the HD screen provided by the device, allowing for positioning of the clamp under direct vision. This overcomes the limits and the risk of complications such as injury to the left atrial appendage or pulmonary artery previously reported.[36] In our setting, because the clamp is not placed until CPB is established and is removed well before weaning from CPB, a double-lumen endotracheal tube to deflate the right lung is not required. The entry site of the clamp can then be used to position the chest drain. In addition, once the aorta is opened, the clamp may be gently levered with handle upward to depress the aorta and further facilitate exposure of the aortic valve. However, the presence of right chest pleural adhesions or previous surgery of

the right lung needs to be considered as a potential contraindication. In this context, the development of a dedicated instrument might be advocated; however, in our previous cadaveric experience, we were able to clamp the aorta from the neck using a long angled clamp.

Cardiopulmonary bypass was established peripherally through cannulation of the femoral vessels as previously described using minimal skin crease groin incision, avoiding tissue extensive mobilization and dissection around vascular structures and lymphatic disruption.[37] Retrograde perfusion with femoral CPB is generally considered safe and has been recently proposed by Drews et al[38] as a valid adjunct also in high-risk TAVI patients, normally affected by peripheral vascular disease (70% in the reported study). In our setting, relative contraindications such as aortic aneurysm, atherosclerotic plaques, intimal flaps, or dissection could be ruled out within the preoperative workup using computed tomographic scan. Alternatively, we have developed a central cannulation strategy at the level of the aortic arch. Purse string suture is easily placed between the origins of the brachiocephalic and left common carotid with the arterial cannula exiting the neck wound to the left side and secured out of the way of the surgeon. In this context and in the general economy of the procedure itself, the preoperative measurement of the distance between the neck incision and the aortic valve plane was useful to plan the surgical strategy. Previous cadaveric studies indicated a distance between 12 and 15 cm as suitable to perform easily the procedure. For the first case, a favorable anatomy (13 cm) has been selected even if additional degree of access and visualization is normally provided by the intrinsic mobility of the aortic root. Further imaging studies and surgical experience might elucidate additional details on the angle between the neck access and the valve to optimize preoperative planning; however, neck extensibility plays a fundamental role in this extent.

The technical skills required to perform this procedure are those of a cardiac surgeon with experience in MIS surgery and techniques of implantation of sutureless valve. These skill sets are increasingly familiar to young surgeons trained in the modern era.[39] A detailed training plan was developed before embarking on the clinical case. In retrospect, the soft fix cadaver by the Thiel method provided a useful training model,[27] but proctoring on live case(s) will likely also be required for a surgeon to safely embark on a first case independently as the technology becomes more widely adopted. In addition, although relatively uncommon, complications of this access need to be taken into account. Potential complications include the ones reported for TCT[40] and mainly concern simple pneumothorax and pleural effusion. Other complications may become apparent as the technology moves into widespread use.

Even if in need of more confirmatory results and larger clinical trial, the overall satisfactory outcome of this feasibility study allows one to reliably speculate that this device and approach might constitute a realistic surgical alternative to TAVI. However, the exposure provided by the described device is also suitable for direct aortic TAVI as well, making the surgeon comfortable to select the best approach to use according to technical considerations such as the degree of calcification of the valve itself and the individual clinical needs of the patient.

The preliminary nature of this study, regarding a single case and a single surgeon experience, clearly prevents any further speculation regarding the future application of this approach, but considering the positive outcome and the achievement of the expected goals, we can reliably hypothesize that, if supported by further evidence and validation, this device and approach might become a cornerstone in the treatment of aortic valve disease, offering a valid alternative to percutaneous approaches and revolutionizing the existing surgical ones.

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CLINICAL PERSPECTIVE

This interesting report from Professor Dapunt of the Medical University of Graz, Austria, and colleagues describes a novel device system for surgical aortic valve replacement using a transcervical approach. This approach was popularized for thymectomy and avoids a thoracic incision. This new system provided sternal retraction, illumination, and endoscopic high-definition visualization for the approach. The procedure was first developed and perfected through animal experimentation and practice on cadavers. They then used the system to implant a rapid deployment aortic valve prosthesis in a 63-year-old woman. The case was successful.

This case report shows the feasibility of this new approach. If this initial result is verified in further studies, this approach has the potential to further limit the morbidity of surgical aortic valve replacement. Combined with the new sutureless aortic valve prostheses, this may represent another advance toward the goal of creating a less invasive surgical approach.

