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DELIVERABILITY REDEFINED. TAVI REIMAGINED.



PORTICO™ WITH FLEXNAV™ TAVI SYSTEM



Real-world case reports illustrating the benefits of the Portico with FlexNav TAVI system.

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Portico With FlexNav TAVI System: Enhancing Innovative Technology to Optimize Patient Outcomes and Physician Experience

BY MIKE MORRISSEY

The original Portico transcatheter aortic valve implantation (TAVI) system (Abbott) comprises a transcatheter valve and a delivery system used to navigate and deploy the valve into position at the native aortic annulus. Throughout the initial clinical experience with the Portico system, several aspects were identified as major strengths. These included the low profile and overall flexibility of the delivery system; ease of tracking the system over the aortic arch; intra-annular valve positioning for hemodynamic stability during deployment; recapturability, repositionability, and retrievability of the valve; and large-cell geometry for easy coronary access postimplantation.

Over time, additional areas for improvement were identified as physicians expressed a need for sheathless vascular access, valve placement accuracy, and overall improvements in ease of use.

LATEST-GENERATION TAVI SYSTEM

As a response to these customer requests, the FlexNav delivery system (Abbott; Figure 1) was developed to address improvement needs while maintaining the positive performance aspects of the original Portico system (see the *Technology Design Goals Met By the FlexNav Delivery System* sidebar). The FlexNav delivery system incorporates a stability layer to the catheter, reducing the amount of manipulation required at the access site and providing predictable, accurate, and stable implantation of the valve at the annulus. The addition of an integrated sheath onto the catheter allows easy, sheathless access into the vasculature and maintains a low insertion profile,

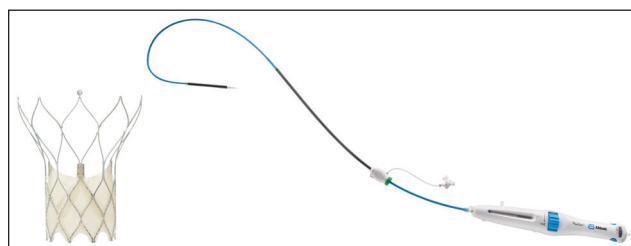


Figure 1. Portico with FlexNav TAVI system.

allowing access into vessels as small as 5 mm for the small system and 5.5 mm for the large system. Additionally, the hydrophilic coating on the inserted length of the delivery system significantly reduces the surface frictional properties of the catheter and augments easy tracking through tortuous vessels. Lastly, ease-of-use improvements are accomplished through a redesigned handle with automation of the deployment lock mechanism, increased mechanical advantage (less force per turn), and the addition of a dedicated macro slide feature, all serving to simplify the user interface and provide a streamlined workflow. In total, the FlexNav delivery system represents a significant advancement and greatly simplifies and improves implantation of the Portico valve.

IMPROVED PLACEMENT ACCURACY AND STABILITY

Improvements in placement accuracy and stability were achieved with the addition of a stability layer to the main catheter assembly (Figure 2). This additional layer encapsulates the primary outer shaft, which contains the

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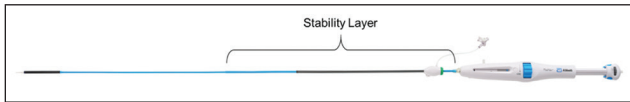


Figure 2. Stability layer.

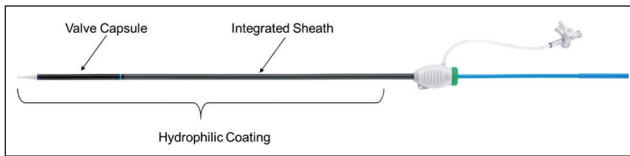


Figure 3. Integrated sheath and hydrophilic coating.

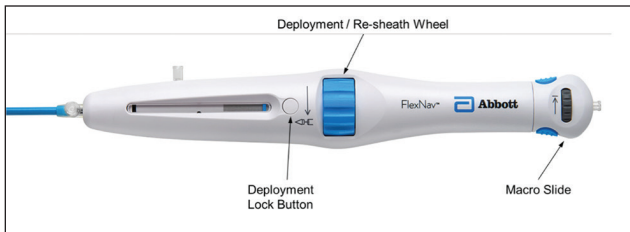


Figure 4. FlexNav control handle.

valve capsule and thus eliminates all motion of the delivery system at the vessel access site during deployment. By eliminating this motion, the user does not need to manipulate the delivery system at the access site to obtain valve placement accuracy because there is no tendency for the valve to “dive” into the left ventricle during implantation.

LOW INSERTION PROFILE

To maintain a low insertion profile, an integrated introducer sheath is incorporated into the delivery system proximal to the valve capsule (Figure 3). This integrated sheath has the same outer diameter as the delivery catheter, offering 14-F (6 mm) and 15-F (6.3 mm) equivalent sheath diameters for the two delivery system sizes (small size for 23- and 25-mm valves and large size for 27- and 29-mm valves) and allowing for insertion of the delivery system without the use of a separate introducer sheath. Additionally, the hydrophilic coating enhances tracking of the delivery system into the access vessel.

EASE OF USE

The last main area of focus for the FlexNav delivery system was an overall improvement in ease of use, which was largely achieved through a redesign of the control handle (Figure 4). The primary deployment wheel mechanism was maintained; however, mechanical design improvements were made to give the deployment wheel an increased mechanical advantage and smoother

TECHNOLOGY DESIGN GOALS MET BY THE FLEXNAV DELIVERY SYSTEM

- Maintains the positive performance aspects of the original Portico system: low profile and overall flexibility of the delivery system; ease of tracking; intra-annular valve positioning for hemodynamic stability during deployment; recapturability, repositionability, and retrievability of the valve; and large-cell geometry for easy coronary access postimplantation.
- The addition of the stability layer to the catheter offers predictable, accurate, and stable valve implantation.
- The integrated sheath reduces the insertion profile of the delivery system from a max of 7.3 mm to a max of 6.3 mm, allowing for a reduction in the indicated minimum vessel size from 6 mm to 5 mm, thus offering a low profile.
- The hydrophilic coating on the inserted length of the delivery system significantly reduces the surface frictional properties of the catheter and may lead to reduced vascular complications during insertion and removal of the delivery system.
- Ease-of-use improvements were largely accomplished through a redesign of the control handle. Automation of the deployment lock mechanism, increased mechanical advantage, and the addition of a dedicated macro adjustment dial feature all serve to simplify the user interface and provide for a simplified workflow for valve implantation.

action, providing a more consistent tactile feel during deployment and, if necessary, the ability to recapture the valve. In addition to the improved deployment mechanisms, the deployment lock button was redesigned to automatically engage during use, eliminating the need to manually engage the lock during device preparation and resheathing, thus reducing the overall number of steps to use the device. Lastly, a pullback handle (macro slide) was incorporated to clearly delineate the device closure mechanism from the deployment/recapture wheel and allow for atraumatic recapture of the distal tip of the catheter into the valve capsule after final valve release.

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Apart from the redesigned control handle, additional ease-of-use improvements arise from the previously mentioned stability layer, which eliminates the need for manipulation to maintain implant position and reliable release of the valve from the delivery system on full deployment.

DELIVERABILITY

Excellent deliverability of the FlexNav system is achieved by leveraging the highly flexible shaft design of the original Portico delivery system as well as the Portico valve, which has less metal by design. This delivery system shaft was optimized for reliable resheathability without the need for significant metallic support structures, resulting in a very trackable system. For FlexNav, the addition of the

integrated sheath and hydrophilic coating is intended to optimize deliverability even further. These features together are designed to easily traverse tortuous anatomy leading up to the aortic arch as well as horizontal aortas.

SUMMARY

The Portico transcatheter valve system has been used to treat nearly 15,000 patients with aortic stenosis and continues to gain momentum in an increasingly crowded market. ■

Mike Morrissey
Staff R&D Engineer
Abbott

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CASE REPORT

Achieving Accurate Valve Deployment in Complex Anatomies

BY GIULIA COSTA, MD, AND LARS SØNDERGAARD, MD, DMSc

The Portico valve (Abbott) is a transcatheter, self-expanding, resheathable device with intra-annular positioning of the bovine leaflets, which has proven safety and performance in several studies.^{1,2} The major advantages of this device include its low profile and flexibility, making it easier to overcome potential challenges related to tortuous and calcified vessels, as well as horizontal aortic anatomy. The next-generation delivery system (FlexNav, Abbott) recently took its first step into the clinical arena, offering additional improvements in deliverability and accurate valve deployment in complex anatomies.

PATIENT PRESENTATION

An 81-year-old woman was referred for evaluation of a severe symptomatic aortic stenosis that was detected several months ago but her symptoms rapidly progressed. The patient reported exertional dyspnea (New York Heart Association [NYHA] class III) that limited daily activities that she had previously undertaken without problems. Her clinical history included systemic hypertension, chronic obstructive pulmonary disease, recurrent pyelonephritis, and previous deep vein thrombosis and stroke. Moreover, the patient had undergone left mastectomy and radiation therapy for breast cancer and subsequent reoperation for relapse.

Her physical examination revealed obesity (body mass index, 31.1 kg/m²) but no signs of cardiac decompensation or renal impairment. An electrocardiogram (ECG) showed normal sinus rhythm. A transthoracic echocardiogram confirmed the diagnosis of severe calcific aortic stenosis (peak gradient, 95 mm Hg; mean gradient, 64 mm Hg; aortic valve area, 0.6 cm²)

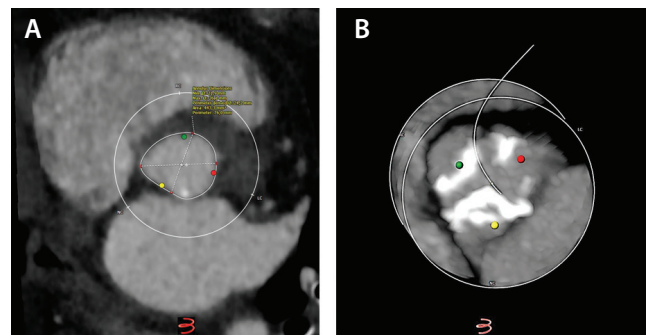


Figure 1. Aortic annulus dimensions (A) and “hockey-puck” view of valvular calcifications (B).

with preserved left ventricular ejection fraction but concentric left ventricular hypertrophy. The coronary arteries showed mild atherosclerotic disease without obstructive lesions.

TREATMENT SELECTION

The case was discussed in the multidisciplinary heart team meeting. Taking into consideration the overall risk profile (age, obesity, lung disease, previous thoracic radiation therapy), the patient was scheduled for transcatheter aortic valve implantation (TAVI).

The preprocedural CT scan showed an elliptical aortic annulus with a perimeter-derived diameter of 24.2 mm, valvular calcifications (Figure 1), and horizontal aortic angulation (Figure 2). The abdominal aorta and aortic arch were calcified, but the iliofemoral vessels were otherwise deemed suitable for a transfemoral approach (Figure 3). Due to the calcified aortic arch and horizontal aorta, the flexible Portico transcatheter heart valve (THV) was chosen and delivery was planned with the FlexNav system.

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Figure 2. Aortic root angulation.



Figure 3. A three-dimensional volume-rendering reconstruction of the aorta and iliofemoral vessels.

PROCEDURE DESCRIPTION AND RESULTS

The procedure was performed using local anesthesia and without sedation. The right femoral artery was chosen as the access route for the THV system. After establishing vascular access in the common femoral artery, a 14-F sheath was inserted over a stiff guidewire. The aortic valve was then crossed with an Amplatz left 2 catheter and a straight standard guidewire. Next, a preshaped stiff guidewire (Safari2, Boston Scientific Corporation) was placed in the left ventricle and predilatation was

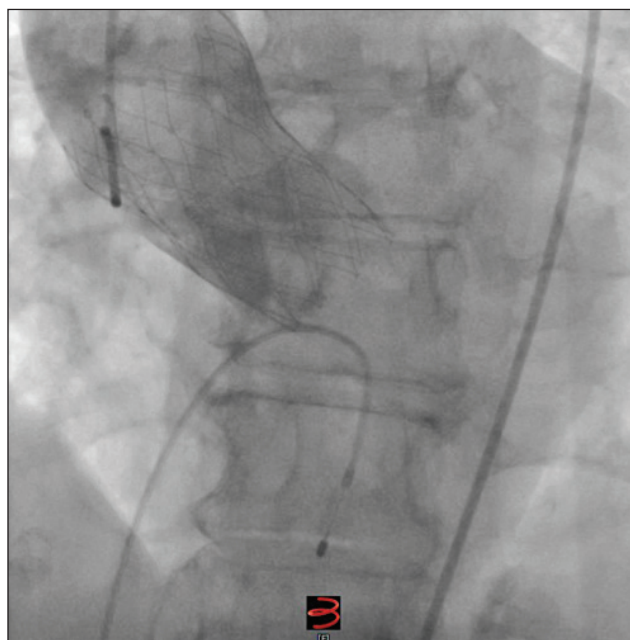


Figure 4. Final aortogram after implantation of the Portico THV.

performed with a 22-mm True balloon (BD Interventional). Subsequently, a 27-mm Portico THV was loaded in the FlexNav delivery system, the 14-F sheath was removed, and the FlexNav delivery system was introduced using the integrated sheath. The flexibility of the delivery system allowed safe passing of the calcified aortic arch, as well as coaxial alignment in the aortic annulus. The Portico THV was successfully deployed without the need for pacing or repositioning. The final aortogram showed only trace paravalvular leak (Figure 4). The ipsilateral arterial access site was successfully closed with a Manta device (Teleflex). An ECG revealed unchanged normal sinus rhythm, and the temporary pacing lead was therefore removed at the end of the procedure. No procedural complications occurred, and the total procedural time was 90 minutes, including 45 minutes of skin-to-skin time.

The patient was discharged to home 48 hours after the procedure. A predischARGE echocardiogram showed favorable prosthesis performance (mean gradient, 6 mm Hg; effective orifice area, 2.5 cm²) and absence of paravalvular leakage.

At 30-day follow-up, the patient reported a marked improvement in clinical symptoms (NYHA class I), with progressive resumption of normal everyday activities.

DISCUSSION

TAVI is currently playing an increasing role in the treatment of symptomatic severe aortic stenosis. During

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the last decade, the technological evolution and increased learning experience has facilitated streamlining the procedures and simplifying the overall clinical course. This even applies to high-risk patients with diseased peripheral vessels, horizontal aorta, and aortic annulus with unfavorable anatomy. Particularly in these often elderly patients with several comorbidities, it is mandatory to avoid complications that may not only prolong the hospital stay but also trigger a vicious cycle of clinical deterioration. Historically, vascular complications and bleeding have confounded the TAVI journey, leading to increased morbidity and mortality.³ The presence of a horizontal aorta represents a challenge for accurate THV placement, especially with less flexible systems.⁴ Finally, the presence of an elliptic aortic annulus may represent an additional challenge in the setting of self-expandable heart valves.⁵

This high-risk case demonstrates how the development of a new-generation THV system with a low insertion profile and high flexibility allows a simple and safe procedure with accurate THV placement, even in cases with challenging anatomic features. Thus, the Portico THV system allows passage even through severely tortuous and calcified peripheral vessels and overcomes the challenges of unfavorable aortic root angulations. The next-generation FlexNav delivery system promises further enhancement of such features, offering an integrated sheath and a hydrophilic coating. The outcomes of the ongoing FlexNav European Union CE Mark study (NCT03724812) and FlexNav arm of the Portico United States investigational device exemption

trial (NCT02000115) will provide information about the safety and efficacy of the new-generation Portico delivery system in larger patient cohorts. ■

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Giulia Costa, MD

Department of Cardiology, Rigshospitalet
University of Copenhagen
Copenhagen, Denmark
giulia.costa@regionh.dk

Disclosures: None.

Lars Søndergaard, MD, DMSc

Department of Cardiology, Rigshospitalet
University of Copenhagen
Copenhagen, Denmark
lars.sondergaard.01@regionh.dk

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CASE REPORT

Transfemoral TAVI in the Horizontal Aorta

BY FRANCESCO BEDOGNI, MD

Over the last decade, transcatheter aortic valve implantation (TAVI) has become an established treatment option for patients with severe aortic stenosis. Nowadays, transcatheter valves are approved across the entire spectrum of risk, from patients ineligible for surgery to those at low risk.^{1,2} However, extending TAVI indications to even lower-risk and younger patients necessitates safer and more accurate devices, even in those with unfavorable anatomy (ie, horizontal aorta, tortuosity, elliptic annuli). The FlexNav delivery system (Abbott), encompassing a reduced insertion profile, improved placement accuracy, and enhanced ease of use, aims to further improve procedural outcomes and expand the applicability of transfemoral TAVI to a greater proportion of patients. The following case report illustrates the utility of this newly designed delivery system.

PATIENT PRESENTATION

An 84-year-old woman presented to the outpatient clinic with a history of previous syncope and dyspnea for mild exertion due to severe calcific aortic stenosis (mean gradient, 45 mm Hg; effective orifice area, 0.76 cm²). Given her advanced age, frailty, and multiple comorbidities and a Society of Thoracic Surgeons predicted risk of mortality of 8%, the heart team considered the patient to be at high risk for surgery and recommended TAVI.

Preprocedural multislice CT revealed a moderately calcified tricuspid aortic valve (perimeter, 61.4 mm; area, 293.6 mm²) with horizontal aortic root anatomy (58°; Figure 1) and favorable bilateral iliofemoral arteries with some degree of tortuosity and mild-to-moderate calcification at the aortic bifurcation (Figure 2).

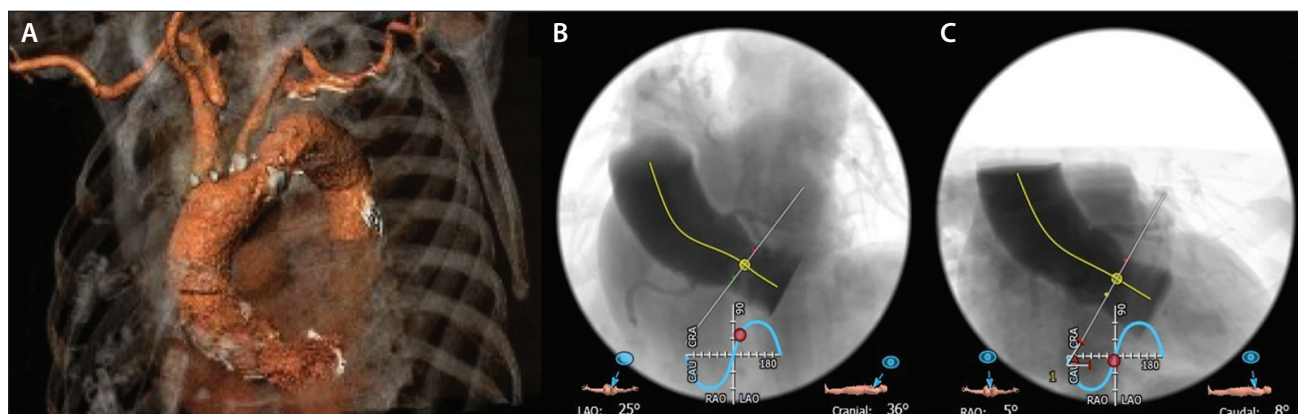


Figure 1. Preprocedural CT scan: three-dimensional rendering of aortic arch (A), left cranial (B), and right caudal (C) projections showing a 58° horizontal aorta.

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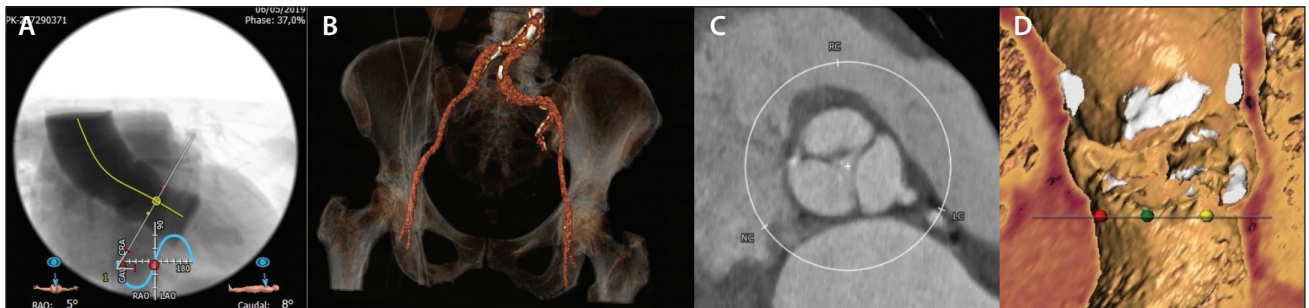


Figure 2. Preprocedural CT scan showing a 58° aortic angle (A), mild degree of tortuosity with moderate aortic bifurcation calcification (B), and a tricuspid aortic valve with moderate annular calcification (C, D).

PROCEDURE DESCRIPTION AND RESULTS

TAVI was planned via a right transfemoral approach using the new FlexNav delivery system and a 23-mm Portico valve (Abbott). The procedure was performed under local anesthesia. After echo-guided right common femoral artery access (Figure 3) and preclosure with two Perclose ProGlide devices (Abbott), a 14-F sheath was inserted and a preshaped 0.035-inch stiff wire was placed into the left ventricle. Aortic valve valvuloplasty with an 18-mm Cristal balloon (Balt) was performed. Afterward, the 14-F sheath was removed and the Portico valve was successfully advanced via the right femoral artery using the FlexNav delivery system and the integrated sheath. Slow and controlled release of the Portico device was performed, starting at the ideal depth under the annulus on the noncoronary cusp side. The increased placement accuracy of the FlexNav delivery system was instrumental in achieving optimal placement of the Portico device in the slightly horizontal aortic root, minimizing the need for repositioning and catheter manipulation (Figure 4).

Balloon postdilatation with a 20-mm Cristal balloon was performed to optimize the implant, achieving excellent angiographic and hemodynamic results. The postimplantation mean transvalvular aortic gradient measured by transthoracic echocardiography was satisfyingly low (6 mm Hg), with only a trivial amount of paravalvular leak (PVL). Access site hemostasis was successfully achieved using the preclosure sutures, and the right iliofemoral angiogram showed no dissection and normal antegrade contrast flow (Figure 3C).

DISCUSSION

Many factors affect TAVI procedural outcomes, including the presence of calcifications, elliptic annuli, bicuspid aortic valve, vascular access, as well as a horizontal aorta, as this poses a degree of technical challenge for self-expanding devices. Indeed, extreme aortic angulation (AA) > 70° has been previously reported as an absolute exclusion criterion from a

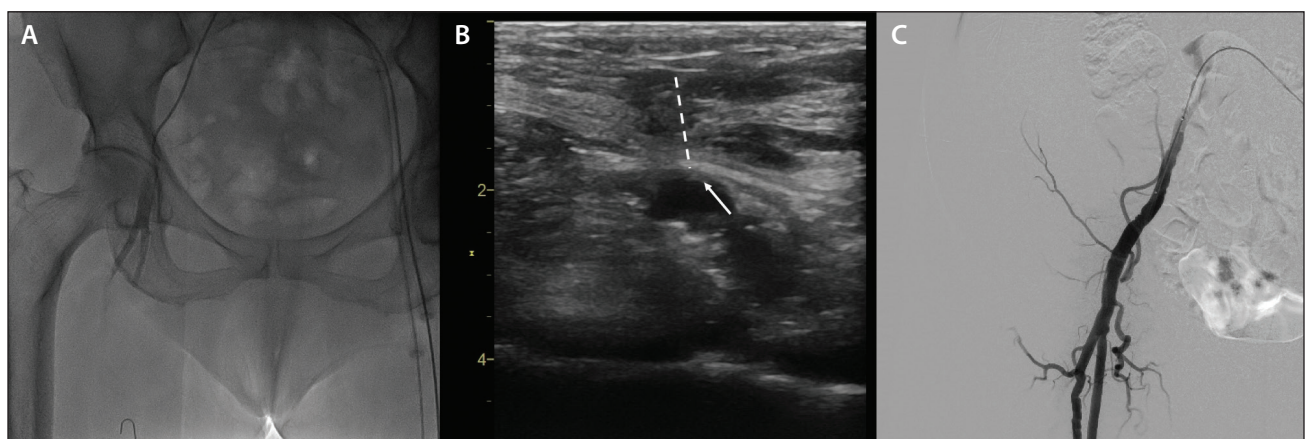


Figure 3. Basal iliofemoral angiogram (A), right femoral echo-guided puncture (dashed line indicates needle trajectory; arrow indicates puncture side) (B), and postprocedural iliofemoral angiogram (C).

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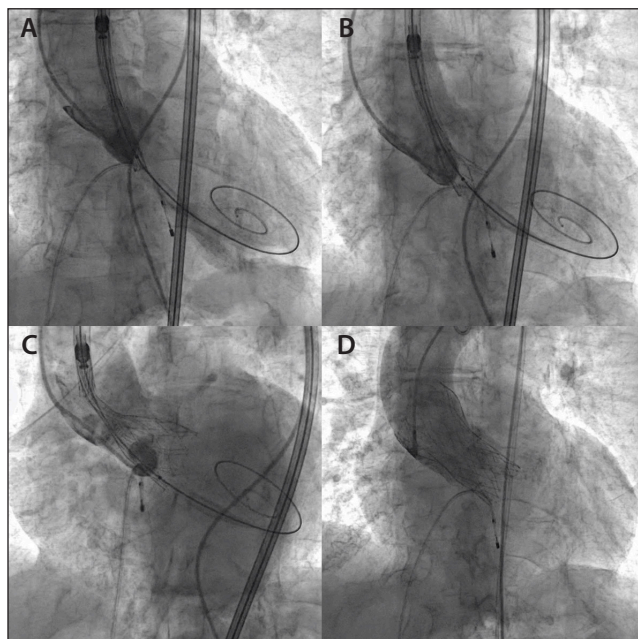


Figure 4. Portico valve positioning and deployment (A, B). The flexibility and adaptability of the Portico valve can be appreciated in difficult anatomy, including a horizontal aorta (C). Final result with trivial PVL (D).

clinical trial of a self-expandable valve.³ Moreover, several studies identify AA as a factor influencing the procedural outcome. Sherif et al found that a greater AA, measured using left ventriculography, was associated with a greater risk of PVL.⁴ Abramowitz et al showed that patients with an AA $\geq 48^\circ$ who underwent TAVI with a self-expandable device, when compared with those who underwent TAVI with a balloon-expandable device, had an increased risk of valve embolization, need for a second valve, and postprocedural paravalvular regurgitation.⁵ The authors suggest that differences between self-expandable and balloon-expandable devices in stent frame length, stent deformation, radial force, and flexion control of the delivery system may be responsible for these findings.

In our case, despite a 58° AA, the improved placement accuracy of the FlexNav delivery system with the new stability layer and the enhanced flexibility and

trackability allowed for optimal prosthesis positioning and deployment. There was no need for repositioning or the valve diving into left ventricular outflow tract, with an excellent procedural outcome.

Aside from the delivery system, the Portico valve has self-centering properties due to a reduced amount of metal and larger stent cells. Furthermore, due to the sheath integrated into the FlexNav system (14–15 F), the valve can be delivered without the requirement for a separate introducer, reducing the delivery sheath-to-femoral artery ratio, which has been found to be a strong predictor of major vascular complications.⁶

CONCLUSION

The redesigned FlexNav delivery system, with its improved valve placement accuracy and reduced insertion profile, may significantly improve daily practice by extending the possibility of transfemoral TAVI with the Portico valve to a greater proportion of patients. This novel technology has the potential to improve procedural outcomes by reducing the number of recaptures, risk of major vascular complications, malpositioning, or need for second valves. ■

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Francesco Bedogni, MD

Department of Clinical and Interventional Cardiology
IRCCS Policlinico San Donato
Milan, Italy

francesco.bedogni@grupposandonato.it

Disclosures: Consultant to Abbott.

CASE REPORT

TAVI in a Patient With Tortuous Iliac Anatomy and Calcification

BY ANTONY WALTON, MBBS, FRACP, FCSANZ

PATIENT PRESENTATION

An 85-year-old man presented with progressive symptomatic aortic stenosis (New York Heart Association class II) and reported progressive dyspnea and angina. His clinical history included coronary artery bypass grafting (left internal mammary artery [LIMA] to left anterior descending [LAD] artery, saphenous vein graft [SVG] to LAD-D1, and SVG to posterior descending artery [PDA]), peripheral vascular disease treated with an endovascular stent graft (left femoral artery aneurysm repair), as well as hypertension and atrial fibrillation. There was moderate renal impairment with an estimated glomerular filtration rate of 41 mL/min/1.73 m².

The patient was cognitively intact with no strokes. He had a clinical frailty score of 1 out of 4, a Society of Thoracic Surgeons score of 12.6, and a morbidity/mortality risk of 34.7%. An electrocardiogram revealed sinus bradycardia with inferior Q waves. An echocardiogram demonstrated preserved left ventricular function with an ejection fraction of 61%. His aortic valve mean pressure gradient was 38 mm Hg, with a valve area of 0.48 cm², peak aortic jet velocity of 4.3 m/s, and a trileaflet valve. There was moderate aortic and mitral regurgitation.

A coronary angiogram demonstrated complete occlusions of the left main and right coronary arteries. The LIMA-to-LAD artery graft was patent and there were vein grafts to the PDA and the obtuse marginal artery. The SVG to LAD-D1 had failed.

Results of CT included a perimeter of 80.2 mm with an area of 495.5 mm² (Figure 1), heavy sinotubular junction calcification (Figure 2), aortic root angulation of 46°, and left and right coronary heights of 11.6 mm and 15.2 mm, respectively. The eccentricity ratio was 0.78. There was

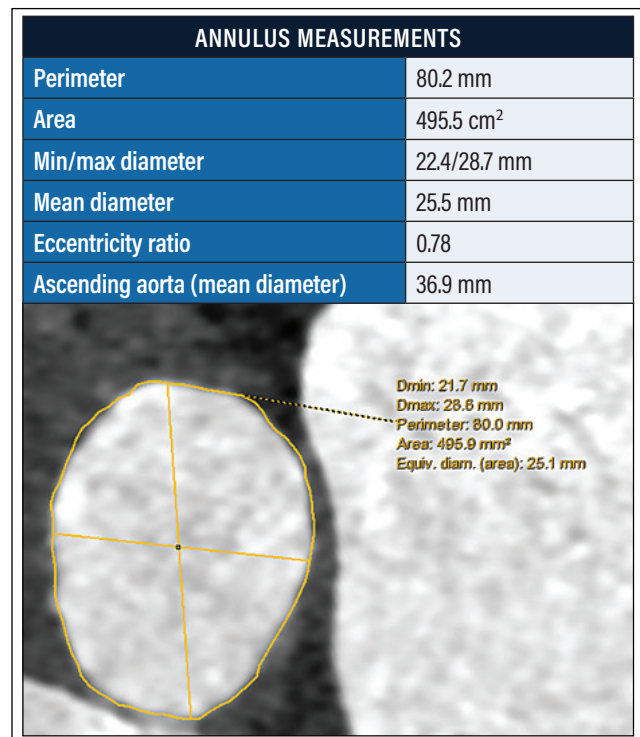


Figure 1. Annulus measurements.

heavy calcification and significant tortuosity of the iliofemoral system (Figure 3). Femoral artery access was considered acceptable. Subclavian access was suboptimal due to angulation and small size.

TREATMENT SELECTION

The patient was discussed in our multidisciplinary meeting and was decided to be most suitable for transcatheter aortic

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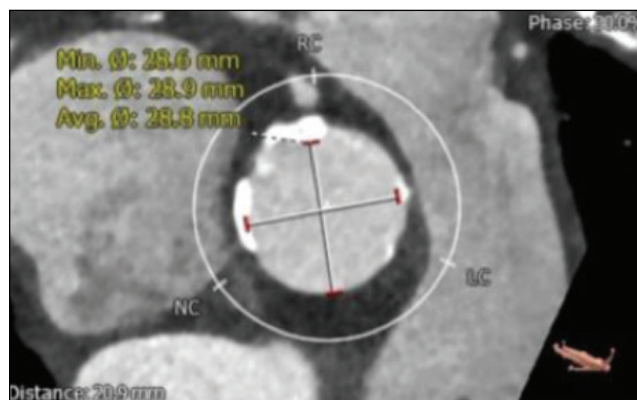


Figure 2. Heavy calcification of the sinotubular junction.

valve implantation (TAVI) in view of the extreme risk for surgery. Despite the heavy iliofemoral disease, we believed right femoral access would be successful. Next, the choice of valve was considered. The sinotubular junction calcification was concerning for a balloon-expandable system, and because the iliac tortuosity and calcium would not be ideal for use of the Evolut system (Medtronic), we chose the Portico with FlexNav system (Abbott).

The eccentricity ratio of 0.78 was considered acceptable, with the recommendation being > 0.73 .

PROCEDURE DESCRIPTION AND RESULTS

The patient was admitted and elective TAVI was performed under conscious sedation with local anesthesia. Vascular access was achieved using ultrasound guidance via

the right femoral artery with a preplaced Prostar XL closure device (Abbott) and a femoral venous balloon-tipped pacing wire. Contralateral access was gained in the left femoral artery.

Aortography was performed, and baseline aortic pressure gradients were obtained. A 14-F sheath was placed in the right femoral artery over a Confida guidewire (Medtronic). Balloon aortic valvuloplasty was performed with a 20- X 40-mm Nucleus-X balloon (B. Braun Interventional Systems, Inc.) with rapid pacing at 180 bpm. A 29-mm Portico valve was chosen. The valve was delivered via the 14-F integrated sheath with its hydrophilic coating.

The valve was very stable during deployment and was placed on the first attempt at a depth of 0 mm (Figure 4). Although a little higher than the target depth, the valve was very stable. No pacing was required during valve positioning. There was trivial paravalvular leak on aortography, and final valve deployment occurred. There was no new conduction disturbance.

The valve performed well, with an on-table echocardiogram revealing only trivial regurgitation. The mean hemodynamic pressure gradient was 6 mm Hg. A predischarge echocardiogram revealed excellent valve function with trivial paravalvular leak. The patient was discharged from the hospital 3 days later without complication.

DISCUSSION

A key advantage of the Portico system is its excellent trackability in tortuous vessels, including the iliac arteries and the aortic arch, which was particularly relevant in this

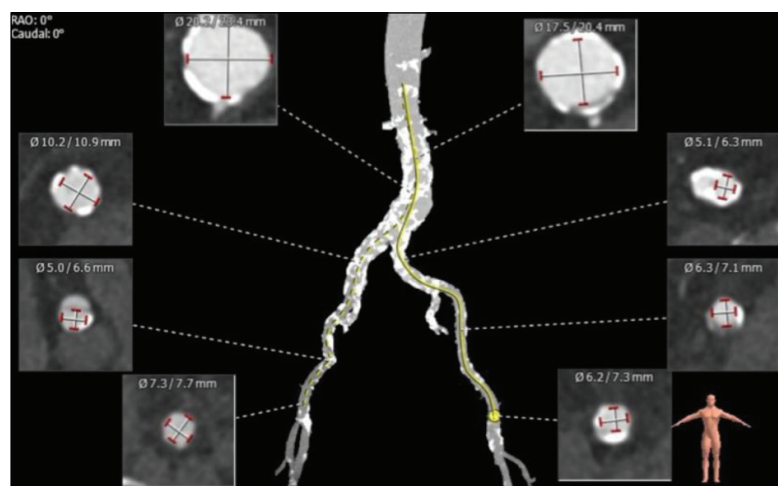


Figure 3. CT imaging showing heavy iliofemoral calcification and tortuosity.

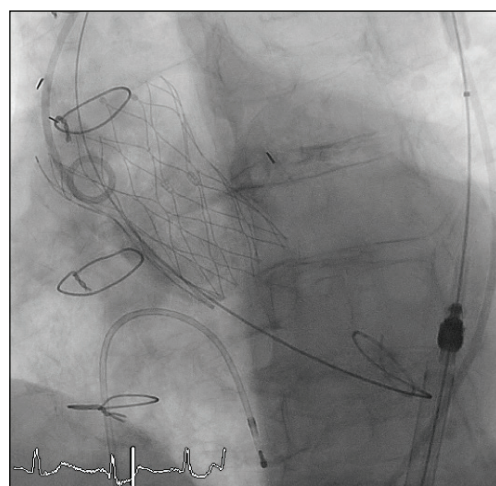


Figure 4. Valve position after implantation.

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case. The lower-profile integrated sheath allows treatment with the FlexNav delivery system in patients with previous femoral artery contraindications.

The FlexNav delivery system allows the valve to remain very stable during deployment. There is little need for pacing during deployment. The new stability layer has significantly improved the ease of placement with very little adjustment required. It is important to deploy slowly and wait several minutes after valve expansion to ensure that the position is stable and the valve can be finally deployed. The target depth is 2 to 5 mm below the annulus. The release mechanism of the FlexNav delivery system is easy to use and intuitive.

Coronary access is generally straightforward due to the intra-annular valve position and the large cell design. The system has a lower profile from the integrated sheath with hydrophilic coating. Blood pressure remains stable during deployment due to the early function of the Portico valve.

Predilatation of the valve is highly recommended prior to delivery system insertion. The balloon size should not

exceed the minimum annulus diameter as derived by CT.

CONCLUSION

As demonstrated by this case, significant improvements have been made in the delivery system of the Portico valve. Primarily, the system is smaller with markedly improved stability during valve deployment. The flexibility in the iliofemoral system is excellent in more challenging anatomies. The next-generation Navitor with FlexNav TAVI system (Abbott), which is currently undergoing trial, may further add to the ease of use and effectiveness of this valve. ■

Antony Walton, MBBS, FRACP, FCSANZ

Associate Professor

Alfred Health

Melbourne, Victoria, Australia

a.walton@alfred.org.au

Disclosures: Proctor for Abbott.

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CASE REPORT

Implantation of the Portico With FlexNav TAVI System in a Patient With Aortic Stenosis, Severe Renal Impairment, and Diffuse Iliac Atherosclerosis

BY SINNY DELACROIX, MD, PhD; RAMESH G. CHOKKA, MD;
AND STEPHEN G. WORTHLEY, MBBS, PhD, FRACP

PATIENT PRESENTATION

This case describes a 90-year-old woman with comorbidities that included type 2 diabetes, morbid obesity, hypertension, mixed mitral valve disease, chronic kidney disease, and hyperlipidemia, as well as a history of transient ischemic attack, pacemaker implantation for trifascicular block, breast cancer with right lumpectomy, and bilateral total knee replacement. She presented with worsening shortness of breath over several months and was assessed for transcatheter aortic valve implantation (TAVI) considering the high surgical risk due to her medical history. She lived alone, was independent with her activities of daily living, and was mobile with the use of a four-wheeled walker and an electric wheelchair. She had a Mini-Mental State Examination score of 28/30 and a Society of Thoracic Surgeons score of 7.9%.

Transthoracic echocardiography (TTE) revealed severe aortic stenosis with a left ventricular ejection fraction (LVEF) of 55%. Mild mitral and tricuspid regurgitation was also noted. Coronary angiography revealed mild-to-moderate disease in the dominant left coronary artery and no disease in the nondominant right coronary artery. A coronary height of 8.7 mm in the diseased left coronary artery added to the complexity of the case. The aortic valve area was 0.8 cm², with a mean gradient of 36 mm Hg, Vmax of 4 m/s, and a dimensionless performance index of 0.2, which is indicative of severe aortic stenosis.

CT assessments using 3mensio software (Pie Medical Imaging) showed an annular area of 543 mm² and a perimeter of 83.5 mm. The left and right coronary artery heights were 8.7 mm and 20.4 mm, respectively. Vascular access was challenging due to the relatively small femoral diameters of 5.4 mm and 6.1 mm. Diffuse minor atherosclerosis was also noted in the iliac arteries, which were quite tortuous as well (Figure 1).

PROCEDURE DESCRIPTION AND RESULTS

A 29-mm Portico valve (Abbott) was deployed under local anesthesia and conscious sedation using the FlexNav delivery system (Abbott) via a transfemoral access route (Figure 2A and 2B). Immediately after the procedure, the patient had no residual aortic valve gradient or paravalvular aortic regurgitation on cine aortography



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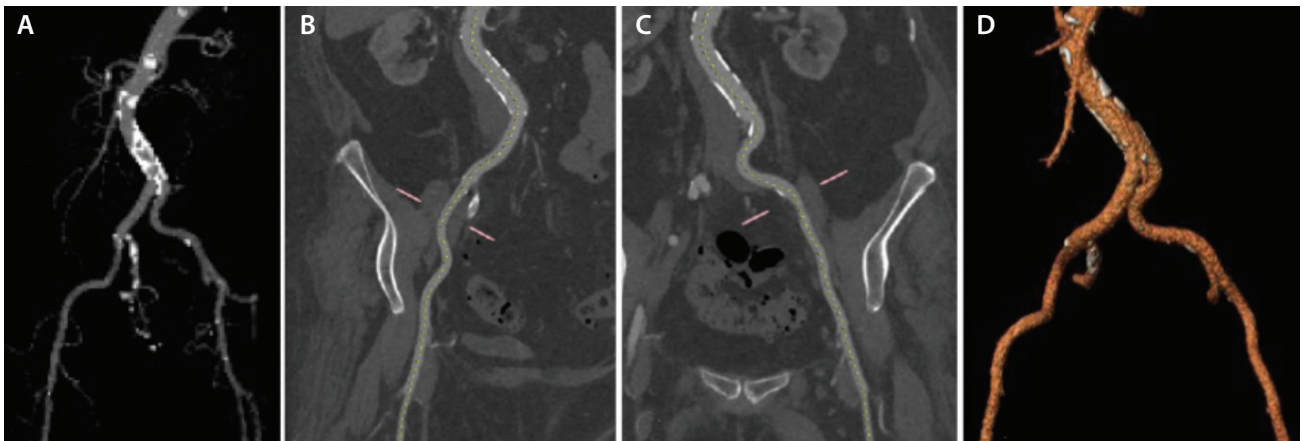


Figure 1. Contrast CT image of the iliofemoral arteries (A), snake view of the right iliac (B), snake view of left iliac (C), and three-dimensionally rendered image of the iliofemoral arteries (D).

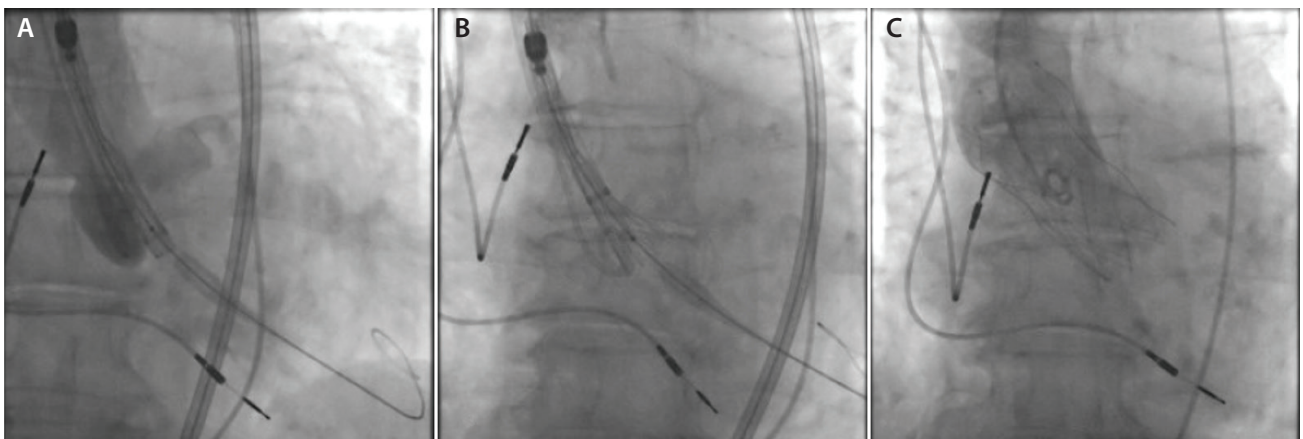


Figure 2. FlexNav delivery system across the aortic valve (A). Initial stages of Portico valve deployment (B). The Portico valve in position (C).

and TTE. Access was achieved without complication using 6- and 14-F sheaths in the left and right femoral arteries, respectively, and the access was preclosed with two Perclose ProGlide devices (Abbott). The aortic valve was crossed with a 6-F Amplatzer left 1 guide catheter followed by a 6-F pigtail catheter. Valvuloplasty with a 23-mm Cristal balloon (Balt) was performed under rapid pacing via the existing pacemaker. The 14-F sheath was then removed and the FlexNav delivery system with its 15-F integrated sheath was introduced. This was performed quite easily, despite the tortuous iliac artery anatomy. A 29-mm Portico valve was then deployed without pacing. The frictionless sheath permitted stable delivery of the valve without movement into the ventricle

during valve release, and thus we were able to achieve a stable high position with an excellent result (Figure 2C). The final position of the ventricular aspect of the valve frame was 0 mm below the noncoronary cusp and 2 mm below the left coronary cusp. Hemostasis was obtained with the Perclose ProGlide devices.

The postoperative course was uneventful with pre-discharge TTE showing a well-seated Portico valve and no aortic regurgitation. The patient was discharged 1 day after the procedure on a regimen of aspirin and clopidogrel.

At the 30-day postoperative follow-up, the patient was significantly less short of breath than she was prior to the procedure but remained in New York Heart Association

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class II. Her TTE findings, from an aortic valve perspective, remained unchanged from discharge with a well-seated valve, no paravalvular leaks, and normal hemodynamics. There were no significant issues after discharge.

At the 6-month follow-up, the patient expressed that although her exertional dyspnea had significantly improved, she continued to experience some shortness of breath with exertion that could be due to her obesity and lack of physical fitness. TTE demonstrated a well-seated Portico valve with trivial paravalvular leak and a normal LVEF of 55%. She had no other complaints. Clopidogrel was ceased, but she continued to take aspirin.

DISCUSSION

Over the last decade, evidence from several clinical trials has propelled the evolution of TAVI in the treatment of severe aortic stenosis.¹⁻⁷ It is currently the preferred treatment modality for patients with severe symptomatic aortic stenosis, and studies have shown that the procedure is noninferior or even superior to standard therapies in intermediate-risk patients.^{8,9} More recently, based on the results of the PARTNER 3 trial, the FDA has approved an expanded indication for several transcatheter heart valves to include patients with severe aortic stenosis, even at low surgical risk.⁵

The Portico valve consisting of a self-expanding nitinol frame started its clinical use in 2012 and has gained regulatory approval in Europe for sheathless introduction of the valve, providing physicians with the ability to use the valve in patients with complex anatomies. The large stent cell sizes of the valve with minimal flaring and the valve's intra-annular design provide the added advantages of improved valve positioning and hemodynamic stability. The new FlexNav delivery system provides the added advantage of stable, controlled deployment of the valve, which permits very accurate placement of the valve frame. By permitting safe, accurate deployment, the valve can be more reliably deployed at a target depth of 3 mm, which potentially reduces risk of pacemaker implantation and may also reduce paravalvular leak. The smaller French size (14-F equivalent for the 23/25-mm valves and 15-F equivalent for the 27/29-mm valves) may reduce the vascular

complication rate and could potentially treat patients with some compromise of the iliac and femoral arteries that would not be accessible with traditional TAVI delivery systems. ■

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Sinny Delacroix, MD, PhD

Royal Adelaide Hospital
Adelaide, South Australia, Australia
GenesisCare
Alexandria, New South Wales, Australia
Disclosures: None.

Ramesh G. Chokka, MD

Royal Adelaide Hospital
Adelaide, South Australia, Australia
GenesisCare
Alexandria, New South Wales, Australia
Disclosures: None.

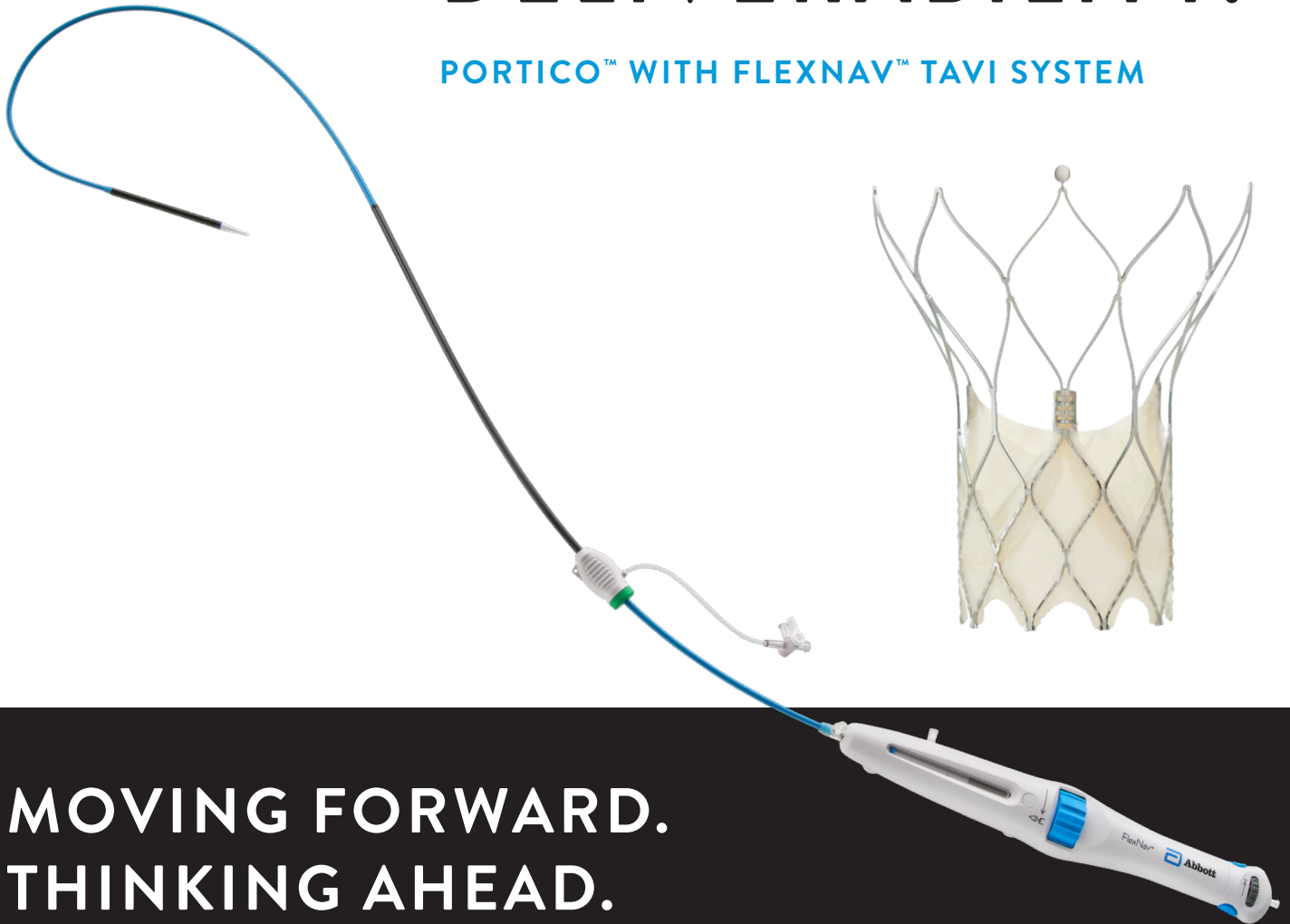
Stephen G. Worthley, MBBS, PhD, FRACP

Royal Adelaide Hospital
Adelaide, South Australia, Australia
GenesisCare
Alexandria, New South Wales, Australia
stephen.worthley@genesiscare.com
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Abbott
Park Lane, Culliganlaan 2b, 1831 Diegem, Belgium, Tel: +32 2 714 14 11
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