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FDA Approval of the Alterra Adaptive Prestent™ and Sapien 3 Valve: A Unique Transcatheter Solution for the Large Dilated Right Ventricular Outflow Tract (RVOT)

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Introduction

Patients who have undergone previous surgery or catheter-based intervention on the right ventricular outflow tract (RVOT) such as transannular patch repair of Tetralogy of Fallot or balloon pulmonary valvotomy commonly experience significant pulmonary regurgitation requiring pulmonary valve placement.[1] Transcatheter pulmonary valve placement was first described over two decades ago by Bonhoeffer[2]; however current balloon expandable valves are better suited to the size and geometry of surgical conduits and bioprosthetic valves limiting their use to only an estimated 15-20% of patients requiring pulmonary valve replacement. The more complex "native" RVOT, characterized by variable and dynamic morphology, large diameters and unpredictable compliance often precludes transcatheter valve replacement with balloon expandable valves.[3,4] The Alterra Adaptive Prestent™ was designed to internally remodel a wide variety and sizes of RVOT morphologies, thereby creating a suitable "landing zone" for implantation of a 29 mm Sapien 3 transcatheter valve. On December 20, 2021 the U.S. Food and Drug Administration (FDA) approved the use of the Edwards SAPIEN 3 transcatheter valve with the Alterra Adaptive Prestent™ (SAPIEN 3 with Alterra) for patients with severe pulmonary regurgitation. Herein, we describe this unique device and delivery system, clinical trial results and present a typical case.

The Device

The Alterra Adaptive Prestent™ is designed to be used as a docking adaptor for the 29 mm SAPIEN 3 THV within the RVOT (**Figure 1**). It is comprised of a self-expanding, radiopaque,

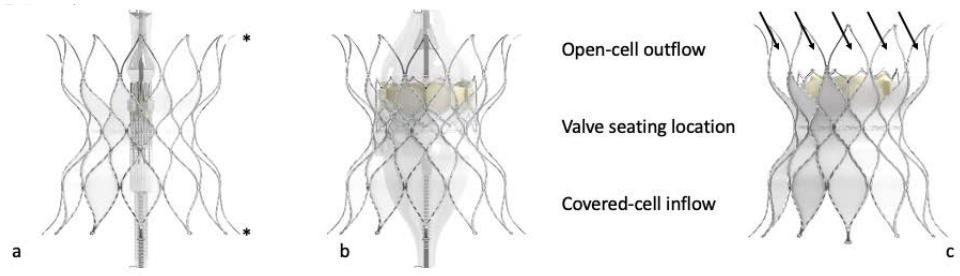

FIGURE 1 *Stylized image of a transparent Alterra Adaptive Prestent™ (a, b) demonstrating implantation of a 29 Sapien 3 valve within the central landing zone. The distal and proximal flares (*) aid in device stability. The uncovered distal row of cells (arrows) allows for placement of the device into the orifice of the branch pulmonary arteries without causing obstruction to flow (c).*

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nitinol frame assembly and polyethylene terephthalate (PET) fabric covering and has designated inflow and outflow ends. The inflow section is identifiable by the presence of two triangular tabs that are attached to the delivery system and circumferential covering of all cells. The outflow section is distinguished by open cells designed to facilitate blood flow into the branch pulmonary arteries should the device need to extend into the orifice of one or both of these structures. The PET fabric is attached by sutures to the inside surface of the frame to create a seal at the inflow section. The device has a symmetrical frame design with the inflow and outflow diameters equal to 40 mm and the central section 27 mm to provide a rigid landing zone for a SAPIEN 3 THV (29 mm). While the total unconstrained device length is 47 mm, the non-fabric coated row of cells at the outflow results in a completely covered length of only 30 mm, allowing for the treatment of shorter RVOT by placing the distal apices across the orifice of the branch pulmonary arteries if needed. Currently, suitable anatomy is deemed to have a landing zone diameter > 27 mm and <38 mm with a length > 35 mm. Importantly, the Alterra Adaptive Prestent™ can be recaptured within the delivery system after up to 50% deployment, allowing for multiple attempts at placement if required.

Delivery System Description

The Alterra Adaptive Prestent™ comes fully loaded in a custom delivery system consisting of a handle, retractable outer shaft, inner delivery shaft (upon which the stent sits), prestent connector and a tapered tip meant to facilitate tracking through the vasculature (**Figure 2**). The delivery handle consists of a single knob that ergonomically allows for a one-handed, slow, controlled deployment and potential recapture and a flush port to flush the guidewire lumen (consistent with a 0.035" guide wire). The entire system fits through a 16F eSheath (Edwards Life Sciences, Irvine, CA) or comparable 22 or 24 Fr commercial sheath.

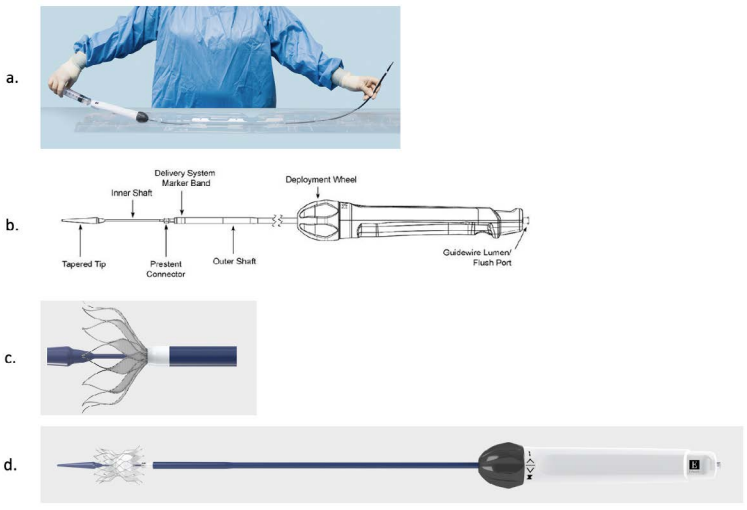

FIGURE 2 *(a) The Alterra delivery system comes pre-packaged with the device loaded and covered by the outer shaft and requires only a saline flush for preparation prior to introduction into the bloodstream. (b) Schematic diagram showing the Alterra prestent delivery system components. (c) Enlarged image of the distal end of the delivery system with approximately 50% of the Alterra prestent deployed. At this point, recovering, recapture and subsequent redeployment are possible. (d) With the outer shaft completely withdrawn the Alterra prestent is completely deployed.*

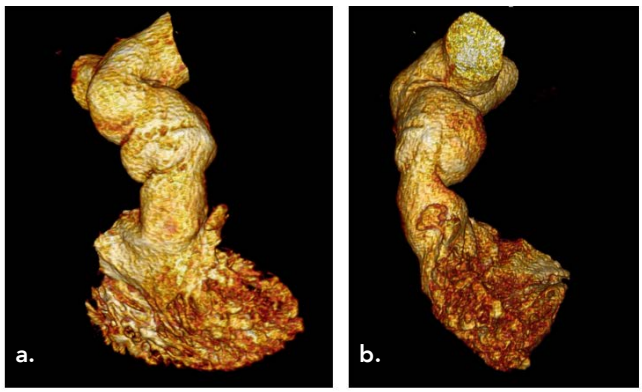

FIGURE 3 *Surface rendered 3D images constructed from a gated cardiac CT demonstrating a large aneurysmally dilated RVOT in simulated frontal (a) and lateral (b) projections.*

Case Report

A 24-year-old man who was born with tetralogy of Fallot and underwent operative repair at 18 months of age utilizing a transannular patch, was referred for treatment of severe pulmonary regurgitation. Pre-procedural testing (MRI and CT) revealed severe pulmonary regurgitation (regurgitant fraction = 49%) without RVOT obstruction, an irregular and aneurysmally dilated RVOT associated with a markedly dilated right ventricle (RV end diastolic volume = 219 ml/m2) with preserved systolic function (ejection fraction = 55%) (**Figure 3**). Diameter and perimeter plots of the patient's RVOT in both systole and diastole were created in 5 mm increments from the bifurcation of the branch pulmonary arteries down to contractile right ventricular

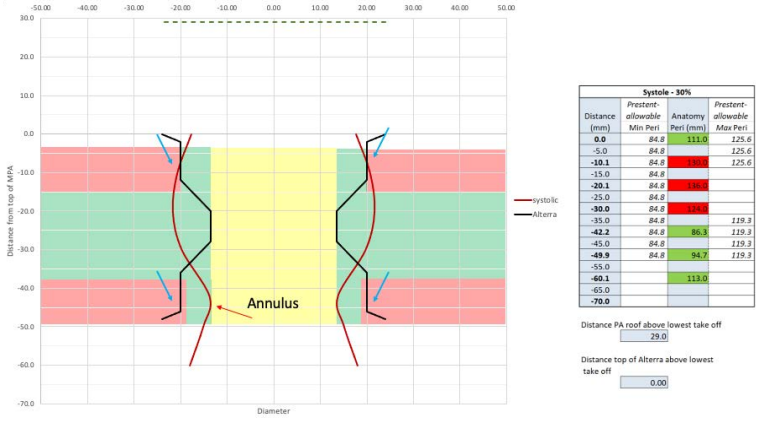

FIGURE 4 *Preimplantation perimeter plot (a) of the patients RVOT (red lines) in systole with an Alterra Adaptive Prestent™ prestent (black lines) superimposed upon the anatomy. The distal and proximal ends of the device extend outside the anatomy (blue arrows) corresponding to suitable device tissue interference predicting a stable implant with good proximal and distal sealing despite the large central aneurysmal section of the RVOT.*

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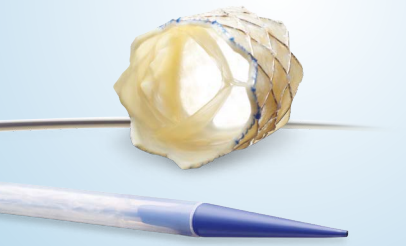
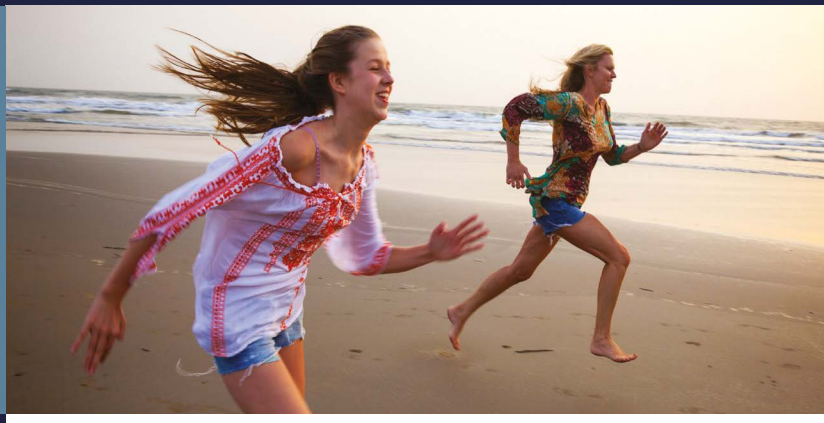


Melody™

Transcatheter Pulmonary Valve (TPV) System



Not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances. Melody TPV is not suitable for all patients and ease of use, outcomes, and performance may vary. See the Instructions for Use for indications, contraindications, precautions, warnings, and adverse events.

Restoring lives for

13

years and counting.

The only transcatheter pulmonary valve specifically designed for RVOT conduits and bioprosthetic valves. The longest studied transcatheter valve, with the largest body of clinical evidence at over 10 years.* More than 16,000 patients' lives have been changed over 13 years, and counting.

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*Melody Transcatheter Pulmonary Valve Study: Post Approval Study of the Original IDE Cohort.

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Important Labeling Information for the United States

Indications: The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥ 35 mm Hg.

Contraindications: None known.

Warnings/Precautions/Side Effects

- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Important Labeling Information for Geographies Outside of the United States

Indications: The Melody™ TPV is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture.* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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tissue and analyzed in relation to the diameter and perimeter of the unconstrained device (**Figure 4**). Patients were felt to be suitable candidates when the distal and proximal portions of the device were circumferentially opposed to the RVOT wall. Cardiac catheterization entailed hemodynamic assessment, intracardiac echocardiography, 3-dimensional rotational angiography and 2-dimensional biplane axial angiography. Angiographic findings at catheterization confirmed the multiplanar imaging findings, as well as the dynamic nature of the RVOT in relation to the cardiac cycle. The Alterra Adaptive Prestent™ was then advanced over a 0.035" Lunderquist Extra-Stiff Wire Guide (Cook Medical, Bloomington, IN) into position within the RVOT (**Figure 5**). Serial angiograms were performed during deployment to optimize positioning using a second catheter in the right ventricle. The device was deployed using a slow, controlled turning of the deployment wheel until it was fixed in the intended location. A 29 SAPIEN 3 THV was prepared in the usual fashion, mounted on the new pulmonic delivery system, advanced to the desired location within the Alterra Adaptive Prestent™ and deployed with balloon inflation. Post deployment hemodynamics, intracardiac echocardiography and pulmonary angiography confirmed an excellent result (**Figure 6**) with no pulmonary regurgitation or stenosis and well-functioning pulmonary valve leaflets. The patient was discharged the following morning and continues to have no pulmonary regurgitation or RVOT obstruction four years following implant.

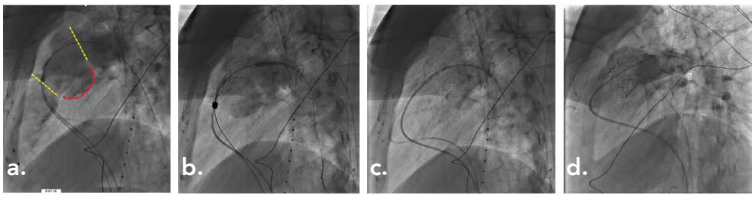

FIGURE 5 *Lateral angiographic projections of the Alterra Adaptive Prestent™ and Sapien 3 implant. Pre-intervention angiogram (a) confirming the large posterior RVOT aneurysm (red line) and intended location of the distal and proximal apices of the device (yellow lines). RVOT angiogram (b) with the Alterra Adaptive Prestent™ 50% deployed. Note the precise positioning of the distal apices. At this point the device can still be recaptured and removed/repositioned. The Alterra Adaptive Prestent™ completely deployed (c). Pulmonary angiogram (d) following placement of the Sapien 3 within the Alterra Adaptive Prestent™ demonstrating no pulmonary regurgitation.*

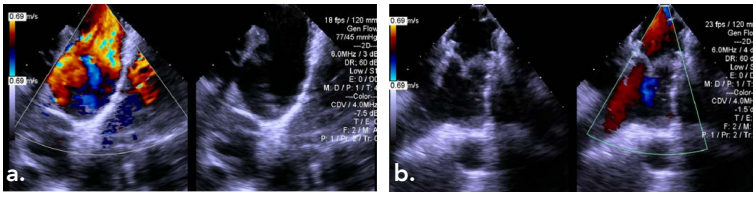

FIGURE 6 *Intracardiac echocardiographic images of the RVOT before and after the intervention. Note the absence of leaflet tissue and free regurgitation (a) as indicated by color flow Doppler prior to placement of the Alterra Adaptive Prestent™ and Sapien 3 valve compared to following the implant (b).*

Baseline Characteristics	Median (IQR) or % (n)
	Patients N=60
Age, years	21.5 (16.0, 44.0)
≤ 21 years	50.0 (30)
Female	43.3 (26)
Weight, kg	69.5 (58.8, 83.7)
MPA regurgitation fraction	46.2 (40.7, 54.7)*
RVEDVi, mL/m²	159.5 (136.3, 177.9)*
RVEF, %	45.2 (39.8, 51.0)*

FIGURE 7 *Baseline subject demographics for the Alterra Pivotal trial subject cohort.*

Primary Diagnosis	% (n)
	Patients N=60
Tetralogy of Fallot	70.0 (42)
Pulmonary atresia (intact septum)	5.0 (3)
Isolated pulmonary regurgitation*	1.7 (1)
Pulmonary valve stenosis	23.3 (14)
Balloon valvuloplasty	42.9 (6)
Surgical valvuloplasty	35.7 (5)
Pericardial/transannular patch	21.4 (3)

FIGURE 8 *Cardiac diagnoses for the Alterra Pivotal trial subject cohort.*

Results of the FDA Multicenter Pivotal Clinical Trail

Recently the one-year outcomes of the Alterra Adaptive Prestent™ and Sapien 3 transcatheter heart valve were presented at the PICS-AICS meeting in September 2021. Patients with greater than moderate pulmonary regurgitation were prospectively evaluated for entry into this single arm, multicenter trial. Eleven sites from across the United States participated. One hundred patients were evaluated and 60 patients were enrolled following the screening process, resulting in a screen pass rate of 60%. Patient demographics and cardiac history are shown in **Figures 7 and 8**. The Alterra Adaptive Prestent™ and Sapien valve were implanted in the intended location in 100% of patients during a single procedure in all but one patient in which the procedure was staged. Fluoroscopy time averaged 37 minutes. There were no instances of device migration, embolization or death at implant or in follow-up. Transient arrhythmias were reported in 28% of the patients within the first month after implant, but no arrhythmias were noted after 30 days out to one year. New or worsening tricuspid regurgitation was noted in 10% of patients believed most likely secondary to chordal damage sustained with use of the Commander delivery system in the right heart. In patients where paired one-year MRI data was available for core lab comparison, significant improvement in pulmonary regurgitant fraction and right ventricular and diastolic volume were noted (**Figure 9**) and the mean echocardiographic Doppler RVOT gradient remained stable for the group through one year (**Figure 10**). Minor type one frame fractures of the Alterra Adaptive Prestent™ were noted in 12 patients at one year with no apparent clinical impact at this time. There were no reported cases of bacterial endocarditis and all patients remained with the device in place at one year.

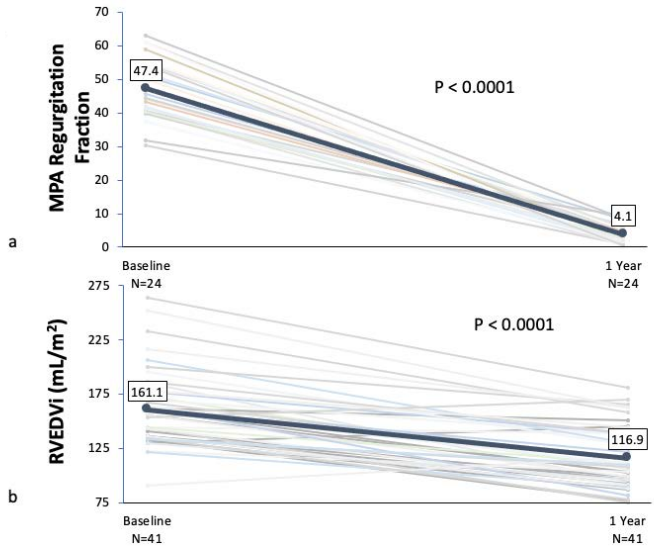

FIGURE 9 *Paired pre-implant and one-year MRI core lab data comparing pulmonary regurgitant fraction (a) and right ventricular end diastolic volumes (b) showing significant improvement following Alterra Adaptive Prestent™ and Sapien implant.*

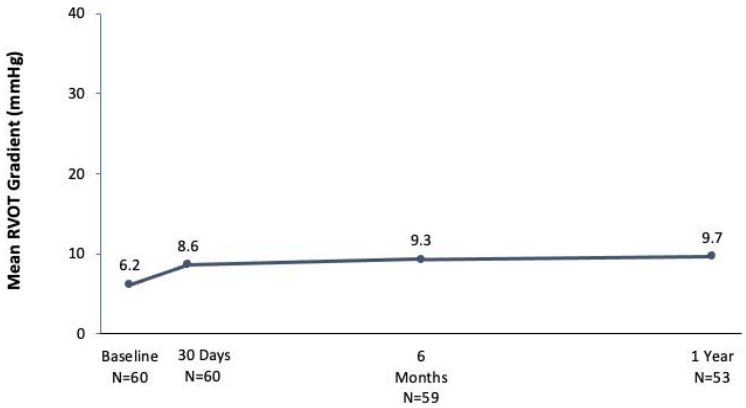

FIGURE 10 *Mean echocardiographic Doppler RVOT gradient rose slightly after implant and remained stable throughout the first year of follow-up.*

Discussion

Patients who have undergone surgical or catheter-based procedures addressing RVOT obstruction (e.g. transannular patch, pulmonary valvotomy, etc.) commonly develop significant pulmonary regurgitation. As the long-term outcomes of these patients become more clearly defined, it appears that the majority will ultimately benefit from placement of a competent, non-obstructive pulmonary valve.[1] While surgical valve placement remains a viable option, it comes with all the attendant risks, morbidities and discomfort associated with repeat open-heart surgical procedures.[5] Currently available balloon expandable transcatheter heart valves have been successfully placed in selected patients with "native" RVOT, however, the majority are not suitable anatomic candidates due to the large and irregular size and compliant nature of these RVOT types.[6,7] To address this need, several innovative devices are in various stages of development and implementation around the world.[8-10]

The Alterra Adaptive Prestent™ was designed to facilitate internal RVOT remodeling providing a predictable landing zone for a balloon expandable valve through a simple catheter-based approach. The concept of preparing the RVOT for a transcatheter valve implant with a prestent is well ingrained in the congenital interventional community and has been shown to have numerous benefits including providing a stable and safe "landing zone" for valve placement, protection of valve components from extrinsic forces which could lead to valve dysfunction and longer freedom from re-intervention.[11] We feel there are numerous potential advantages of this design and approach worth considering:

1. Expansion of currently treatable anatomies
2. Out-of-the-box deliverability with minimal table preparation
3. Simple and consistent trackability to the target zone
4. Precise and predictable positioning
5. Ability to recapture the device
6. Use of proven valve technology (Sapien valves have been placed in > 660,000 patients worldwide)
7. Large valve platform allowing for future valve-in-valve

The requirement to place the prestent and the valve independently (typically during the same procedure) may add another step to the procedure but looking at the fluoroscopy and procedural times in comparison to those of other devices designed to treat this patient population suggests no important differences with this approach. Certainly, using the Commander delivery system in the right heart without the assistance of a long sheath (such as the Gore DrySeal sheath), as was done for the majority of patients in the Alterra Adaptive Prestent™ clinical trial presented numerous challenges as this delivery system was never designed to do this. We are optimistic that the newly designed, covered Edwards pulmonic delivery system, designed specifically to navigate a Sapien valve through the right heart, will greatly simplify this procedure and minimize risk of tricuspid valve damage (**Figure 11**).

FIGURE 11 *The new Edwards Pulmonic Delivery system featuring a covered balloon assembly which protects the Sapien valve and cardiac structures from one another during navigation through the right heart.*

Conclusions

The recent FDA approval of the Alterra Adaptive Prestent™ and Sapien valve add another valuable tool to the growing armamentarium of devices designed for percutaneous pulmonary valve placement in this highly variable and complex group of patients. While the early results are quite encouraging, a larger

experience and longer follow-up will be needed to determine the ultimate role that this novel device will play in the ongoing lifetime care of congenital heart patients with pulmonary regurgitation.

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PICS Society News & Views

If you are a specialist in minimally invasive treatment of Congenital Heart Disease, the PICS Society is **your** professional home. Our vision: A world where anyone who can benefit from minimally invasive techniques to treat CHD has access to safe, effective and affordable care… Here's the latest news from **your** Society!

PICS Symposium 2022 September 7-10 in Chicago

Our flagship event again will spotlight "the best of the best": live cases, hands-on workshops, news you can use, abstracts and state-of-the-science talks from global leaders. PICS Society members receive a significant registration discount. We have also negotiated an extremely low room rate for our world class hotel, the Marriott Chicago Downtown. Immediately preceding the Symposium, we will offer our highly popular fellows-in-training/early career course. New this year: PICS Committee day, where members of our 20+ committees and working groups will meet & collaborate in-person. **Save these dates!**

Global Partnerships with National Societies

As the long-desired global voice of the CHD interventional cardiology community, the PICS Society is dedicated to growth of the many distinguished national societies in your field. In late 2021, this goal became reality in two countries, with more planned for 2022.

India: Thank you Professor S. Ramakrishnan, Conference Chair, and Professor Snehal Kulkarni, President of the Pediatric Cardiac Society of India (PCSI), for inviting PICS to co-organize a joint session at the excellent PCSI 21st Annual Conference in October 2021. Drs. Kulkarni, Nageswara Rao and Ziyad Hijazi chaired the joint session, "Expanding the Horizon of Pediatric Cardiac Interventions." Thanks also to the session's faculty: Drs. Bharat Dalvi (who also served as PICS Society Coordinator), Daniel Levi, Shabana Shahanavaz, K. Sivakumar, Lee Benson, Matthew Gillespie, and Younes Boudjemline. For information about the archived content or about membership in PCSI, visit www.pcsi2021.com.

Brazil: A few days later PICS was privileged to present a similar session during the Brazilian Society of Interventional Cardiology (SBHCI) Scientific Congress 2021. Dr. Juliana Neves, Coordinator of the SBHCI Congenital Department and Congress Organizer, worked closely with PICS Board member Dr. Carlos Pedra to plan this session. Drs. Shabana Shahanavaz, K. Sivakumar, Dan Levi, Ziyad Hijazi, Carlos Pedra, Matt Gillespie, Lee Benson and Younes Boudjemline all participated in this excellent session. Thank you all! For information about the recent Congress or membership in SBHCI visit www.sbhci.org.

Dr. Juliana Neves

Opportunities for Volunteer Service

The PICS Society has many committees and working groups offering opportunities to serve your profession and grow professionally. If you have already expressed an interest in committee service, we are working hard to match your interests with those opportunities. Interested? Email nlinsky@CHDinterventions.org today.

Committees & Working Groups, a Partial List

Adult CHD, Budget & Finance, Industry Relations, Early Career, Education, Guidelines Membership, Annual Symposium, Fellows/Early Career Course, Advocacy & Policy, Quality Improvement, Nurses/Allied Health Professionals, Diversity, Website & Communications, Lymphatics, "Tips & Tricks," Website, Communication/PR. Have an idea for a critically needed group? We'd like to hear from you.

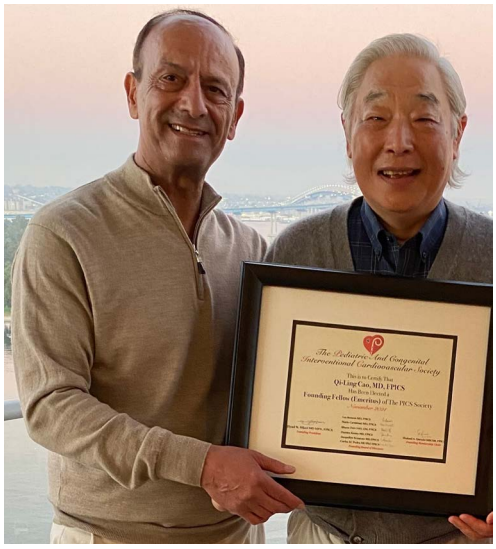
Spotlight on Quality Improvement

The Quality Improvement Committee (Dr. Ralf Holzer, Chair, Drs. Lisa Bergersen and John Thomson, Co-Chairs) has the critical mission of preparing guidance & recommendations regarding quality measurement, public reporting, cath lab standards, CQI, accreditation and much more. Through his leadership, Dr. Holzer is working closely with Drs. Bergersen and Thomson (valued leaders as well) coordinating a global coalition of seven professional societies and 25 co-authors to write the Standards for Cardiac Catheterization of Pediatric Patients and Patients with CHD. Watch for more details in a column later this year.

PICS Patient Advocacy

In the October 2021 issue of CCT, you met PICS Senior Patient Advocate Natalie Poli, Ed.S. In "A Survivor's Story" Natalie movingly described her journey from a stroke at age 29 (due to an undiagnosed ASD), through recovery and a fulfilling career as an educator, parent and recent crowning as Mrs. Midwest International 2022. Natalie is a voice on behalf of adult CHD patients everywhere and will compete for the national title in the July 2022 Mrs. International Pageant. Natalie's platform is "Stroke of Insight." Since she believes in "giving forward," the designated charity of her platform, www.nataliepoli.com, is the PICS Society. Thank you, Natalie!

We need your help! Do you know a patient who could be an effective advocate in partnership with PICS? Provider/patient teams are highly effective in educating policymakers and payors about the importance of your profession. If you know a patient or parent who might welcome participating in PICS advocacy efforts, please contact us at the email address below.



Drs. Ziyad M. Hijazi & Qi-Ling Cao

PICS Society Founding Fellow Emeritus Elected

While the PICS Society is relatively new, your profession's history runs deep. Following recommendation by the Membership Committee (Dr. Shakeel Qureshi, Chair, Drs. Allison Cabalka and Jae Yong Choi, Co-Chairs), the Board recently elected the first

FPICS Emeritus members. All are distinguished leaders of our profession and will be properly recognized in future editions of this newsletter. Recently PICS President Dr. Ziyad Hijazi had the opportunity to present the FPICS Emeritus certificate to one of these "Best of the Best" colleagues, Dr. Qi-Ling Cao. Congratulations Dr. Cao and thank you for your service!

Coming soon: Tips & Tricks!

Suffering from Zoom overload? Not enough time to see (read, hear, view) even a fraction of what you need to stay clinically sharp? Good news: two of your colleagues have come up with something that can help. Drs. Gurumurthy "Guru" Hiremath (University of Minnesota) and Sarosh "Shawn" Batlivala (Cincinnati Children's) have designed a new "Tips & Tricks" section for the PICS website;

Dr. Gurumurthy Hiremath

Dr. Sarosh Batlivala

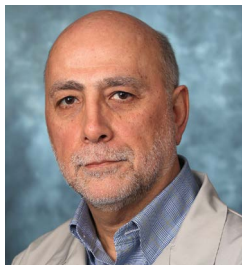
Dr. Jacqueline Kreutzer will serve as the initial consulting editor. Coming soon, this new section will include short "news you can use" items highlighting practical approaches to challenges in the cath lab. Have a tip you would like to contribute? Let us know. Thank you Drs. Hiremath and Batlivala for your initiative!

New PICS Membership Benefit, FREE Online Subscription to *Pediatric Cardiology*

We are pleased to announce that ***Pediatric Cardiology*** Journal (Springer Media) is now the official peer-reviewed scientific journal of the PICS Society. A subscription to the online version is FREE to PICS members. PICS is responsible for the interventional component of the Journal and encourages you to submit articles of interest. ***Pediatric Cardiology's*** Editor-in-Chief Dr. Karim A. Diab and Senior Editor Dr. Ra-id Abdulla welcome original articles, review articles and letters to the editor for consideration.

Dr. Diab commented that "Dr. Abdulla, our Editorial Board, Springer and I are proud to have this new partnership with the PICS Society, a partnership which will dramatically accelerate the growth of our profession." Dr. Diab encourages you to submit manuscripts via https://www.springer.com/journal/246/.

Dr. Karim A. Diab



Dr. Ra-id Abdulla

In a recent statement Springer recognized Dr. Abdulla's leadership for the past three decades: "Thank you Dr. Abdulla, MD, Editor-in-Chief of Pediatric Cardiology, whose vision and editorial guidance for over thirty years has established the Journal as a comprehensive source of information that sets the standard of care for diagnosis and management."

How you can Become a PICS Member

Support YOUR professional society by filling out an application form today. Go to **www.CHDinterventions.org** and click on "PICS Society." PICS is the long-envisioned voice of the global CHD interventional community. Members receive the complimentary Pediatric Cardiology journal subscription, discounts on Annual Symposium, opportunities for committee service **plus one VERY big benefit being finalized at press time** (sorry we can't say more today: watch for a major announcement soon!).

Thank you *Congenital Cardiology Today (CCT)*, our Official News & Information Partner

PICS is proud to partner with CCT in communicating with you on a regular basis. CCT Founder & Senior Editor Tony Carlson has been a valued colleague and friend from the earliest years of our profession. We are honored to continue that tradition working with Publisher & Editor-in-Chief Mrs. Kate Baldwin now and for many years to come. Thank you! Be sure to forward this issue to your colleagues--they can and should sign up for a complimentary subscription.

Want to know more? Have an announcement to share? Interested in participating in any of these activities? Email info@CHDinterventions.org

PICS Society
Pediatric *and Congenital* Interventional Cardiovascular Society

3D IMAGING I3

Edwards Announces Six-Month Data From Transcatheter Tricuspid Replacement Program

PRNewswire -- Edwards Lifesciences Corporation announced that results from a clinical trial of the company's EVOQUE transcatheter tricuspid valve replacement system demonstrated that favorable patient outcomes were sustained at six months. Results from the TRISCEND study, treating patients with tricuspid regurgitation, were presented during the late-breaking clinical science session at the 33rd Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

Patients enrolled in the TRISCEND study had symptomatic, moderate or greater functional or degenerative tricuspid regurgitation (TR), despite optimal medical therapy. Following positive 30-day outcomes that were presented earlier this year, the 6-month results (n=56) demonstrated significant TR reduction by core laboratory assessment. Specifically, at six months, the study revealed:

- Significant reduction in TR severity, with 100 percent of patients with none/trace or mild TR in 43 patients with paired echocardiographic data available
- Significantly improved functional and quality-of-life outcomes, including 89% of patients in NYHA Class I or II, and a 27-point increase in KCCQ score over baseline
- High survival rate of 96%, and freedom from heart failure hospitalization of 94%

"Severe tricuspid regurgitation is becoming increasingly recognized to have a significant impact on quality of life and may be a predictor of increased mortality. Unfortunately, most patients with TR are at high risk for conventional surgery and there currently are no approved transcatheter options in the US," said Susheel Kodali, MD, Columbia University Irving Medical Center and TRISCEND Study Principal Investigator. "The six-month results that we have seen with patients enrolled in the TRISCEND study who received the EVOQUE tricuspid valve replacement are truly remarkable and very promising for patients who suffer from tricuspid regurgitation."

"We are quite encouraged by these data, not only related to the therapy and procedural success rates demonstrated by the EVOQUE system, but also for the significant TR reduction and sustained improvements in quality-of-life measures experienced by patients," said Bernard J. Zovighian, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. "Our goal is to lead the transformation of treatment for this diverse and expansive population of tricuspid valve disease patients. We are committed to building a strong body of evidence to support emerging therapies like the EVOQUE system, which will continue with our randomized pivotal trial, TRISCEND II, currently underway."

The TRISCEND study is a prospective, single-arm, multicenter study, designed to evaluate the safety and performance of the transfemoral EVOQUE tricuspid valve replacement system in TR. Results were reported on 132 patients enrolled, with 6-month follow-up results on 56 patients. The study continues to enroll, and additional patient follow-up will take place at one year and annually up to five years. The trial endpoints are device and procedural success, a composite of major adverse events (MAEs) at 30 days and TR reduction.

The EVOQUE valve replacement system is an investigational device and is not available for sale in any country.

MARCH

15-17

ALICE 2022 – Advanced Live Interventional Course of Essen
Essen, Germany
https://alice-the-course.info/

26-27

CSI Focus LAA & PFO
Tokyo, Japan
https://www.csi-congress.org/laa-pfo

APRIL

02-04

ACC22
Washington, D.C., USA
https://accscientificsession.acc.org/

03-05

EHRA 2022
Copenhagen, Denmark
https://www.escardio.org/Congresses-&-Events/EHRA-Congress

29-01

Heart Rhythm 2022: Bringing the World of EP Together
San Francisco, California, USA
https://heartrhythm.com/

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HeartVista Receives FDA 510(k) Clearance to Deliver One Click MRI™ on Siemens Healthineers MRI Scanners

- FDA 510(k) Clearance Creates Multi-Vendor, One Click MRI™ Automation Platform to Increase Real-Time MRI Imaging Access and Accuracy for Patients
- New AHA and ACC Guidelines, Making Cardiac MRI a Class I Recommendation for Chest Pain, Will Increase CMR Use to Widely Impact the Practice of Cardiology

Business Wire -- HeartVista, a pioneer in AI-assisted MRI solutions, today announced it has received 510(k) Clearance from the U.S. Food and Drug Administration, to deliver its AI-assisted One Click MRI™ acquisition software on Siemens Healthineers MRI scanners.

Despite many advantages, the use of cardiac MRI, also known as cardiac magnetic resonance (CMR), has been largely limited due to a lack of trained technologists, high cost, long scan time and difficulty of use. With HeartVista's AI-assisted solutions, CMR exams on Siemens' MRI scanners are simpler, significantly faster, and achieve more consistent results.

Siemens is a global leader in Magnetic Resonance (MR), and clinical decision-making. One Click MRI™ clearance on Siemens Healthineers MRI scanners advances HeartVista's mission of improving and increasing patient access to real-time MRI imaging, to enable better treatment decisions for physicians. Beyond compatibility with Siemens Healthineers MRI scanners, the newly FDA-cleared One Click MRI™ software includes product-wide speed and scan accuracy enhancements, as well new real-time automated analysis of regional wall motion as part of cardiac function assessment, new registration of perfusion images for easier visual defect detection, enhanced T1-mapping for cardiomyopathy analysis, and dedicated septal T1-mapping for myocarditis.

"We're excited to receive FDA 510(k) Clearance for One-Click MRI™ with Siemens scanners, which positions us as a multi-vendor platform for global CMR deployment. This groundbreaking achievement was a result of our hardworking R&D team's efforts. The team dedicated over 5,000 hours to the clearance process during a pandemic, and evaluated our software by scanning a broad array of patients and volunteers on multiple MRI machines across three countries," said Itamar Kandel, CEO of HeartVista. "By expanding our cardiac MRI compatibility to include Siemens Healthineers' scanners, some of the world's most popular MRI machines, we have taken a major leap forward to enable cardiac MRI access for all."

The *American Heart Association (AHA)*, the American College of Cardiology (ACC), and other groups issued new guidelines, making cardiac magnetic resonance (CMR) a Class I recommendation as a front-line testing strategy for the diagnosis of chest pain.

"Chest pain is one of the most important and most common symptoms our patients complain about. On the basis of the diagnostic accuracy of cardiac MRI for coronary artery disease and myocarditis, the test is now recommended as a Class I recommendation for the evaluation of chest pain," said Bob S. Hu, MD, HeartVista's Chief Medical Officer. "This recent FDA 510(k) Clearance will enable increased access to HeartVista's AI-assisted One Click MRI™ acquisition software, enabling physicians to make better treatment decisions for patients."

About HeartVista

HeartVista believes in leveraging artificial intelligence with the goal of improving access to MRI and improved patient care. The company's One Click™ software platform enables real-time MRI for a variety of clinical and research applications. Its AI-driven, one-click cardiac localization method received first place honors at the International Society for Magnetic Resonance in Medicine's Machine Learning Workshop in 2018. The company's innovative technology originated at the Stanford Magnetic Resonance Systems Research Laboratory. HeartVista is funded by Khosla Ventures, and the National Institute of Health's Small Business Innovation Research program.

For more information, visit www.heartvista.ai

BJC HealthCare Becomes First Health Care System in Midwest to Adopt Latest Robotic Technology for Arrhythmia Treatment

Globe Newswire -- Stereotaxis, the global leader in innovative robotic technologies for the treatment of cardiac arrhythmias, announces today that BJC HealthCare has become the first health care system in the Midwest to offer the Genesis RMN system, advancing electrophysiology patient care and expanding access to advanced robotic technology for the treatment of cardiac arrhythmias in the greater St. Louis region.

BJC HealthCare, one of the largest nonprofit healthcare organizations in the U.S., serving patients primarily in the greater St. Louis, southern Illinois, and mid-Missouri regions, has installed the latest Genesis Robotic Magnetic Navigation (RMN) system at its Missouri Baptist Medical Center. Plans are underway for a second installation at BJC's Barnes-Jewish Hospital on the Washington University Medical Campus. With this equipment, BJC becomes the first hospital system in the midwest providing the latest robotic technology to treat cardiac arrhythmia, and Missouri Baptist Medical Center becomes the first hospital to successfully treat patients with the Genesis RMN system in the region.

Tens of millions of individuals worldwide suffer from arrhythmias – abnormal heart rhythms that result when the heart beats too quickly, too slowly, or with an irregular pattern. When left untreated, certain arrhythmias can significantly increase the risk of stroke, heart failure, and sudden cardiac arrest. Robotic Magnetic Navigation introduces the benefits of robotic precision and safety to cardiac ablation, a common, minimally invasive procedure to treat arrhythmias.

The Genesis RMN system consists of two robotically controlled magnets, a flexible catheter with a magnetic tip, and an operating console. The system creates magnetic fields which can be finely manipulated to steer catheters with an unprecedented degree of precision and control. Because the catheter is controlled from the tip, it is flexible and gentle. With RMN, physicians can safely and effectively treat patients with complex arrhythmias, reaching areas of the heart that cannot be treated using traditional, manual techniques.

The clinical benefits of robotic cardiac ablation are well-documented with hundreds of publications describing, on average, fewer adverse events, better procedure success, and reduced radiation to patients with robotics when compared with manual cardiac ablation.

Today's announcement continues the consistent collaboration in advancing clinical science, physician training, patient awareness, and patient access to robotic cardiac ablation procedures. Located less than one mile from Stereotaxis' headquarters, Barnes-Jewish Hospital was among the first in the world to offer Robotic Magnetic Navigation to patients in 2005. Since then, over 1,000 patients have been treated for cardiac arrhythmias with the benefits of robotic precision and safety at Barnes-Jewish Hospital and Missouri Baptist Medical Center.

"We appreciate the opportunity to serve the patients of BJC HealthCare at Barnes-Jewish Hospital and Missouri Baptist Medical Center," said David Fischel, Chairman and CEO of Stereotaxis. "This strengthens and renews a long-term relationship that has been instrumental for technological progress and clinical care. We look forward to expanding the success of BJC's robotic ablation practices and access to the benefits of robotics for patients suffering from arrythmias in St. Louis and the entire midwestern region."

About Stereotaxis

Stereotaxis is the global leader in innovative robotic technologies designed to enhance the treatment of arrhythmias and perform endovascular procedures. Its mission is the discovery, development and delivery of robotic systems, instruments, and information solutions for the interventional laboratory. These innovations help physicians provide unsurpassed patient care with robotic precision and safety, improved lab efficiency and productivity, and enhanced integration of procedural information. Stereotaxis' Robotic Magnetic Navigation technology is used in the United States, Europe, Asia, and elsewhere.

For more information, please visit www.Stereotaxis.com or follow us on Facebook https://www.facebook.com/Stereotaxis/, Twitter https://twitter.com/stereotaxis, LinkedIn https://www.linkedin.com/company/stereotaxis/, Instagram https://www.instagram.com/stereotaxisrmn/ and YouTube https://www.youtube.com/channel/UCk8ez-lUDfdDkmVgHDdQcrQ.

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