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NEWS RELEASE

August / Sept. 2009



[From the Desk of Ivan Vesely, Ph.D.](#)

Dear Colleagues

August and September witnessed continued progress on the exchange tools and techniques. We have now done 4 exchanges and also demonstrated that the VXi valves can survive 5 months in the orthotopic sheep model.

In August, we submitted two new NIH grant applications and in September we attended the [TCT \(Transcatheter Cardiovascular Therapeutics\)](#) meeting in San Francisco. While transcatheter valves continue to capture the attention of conference delegates, a cold air of skepticism has blown in to the San Francisco meeting - serious concerns are now being raised regarding their potential for long-term durability. Noted physicians that used to proclaim that transcatheter valves have signaled an end of the surgical valve era, are now urging for caution and clinical trials, citing the good long-term outcomes of conventional valves. Later in this newsletter in the Reality Check section, I cite independent evidence of what transcatheter delivery does to valve geometry, and show how that leads to reduced to long-term durability of the deployed valve.

In October, we will be attending the [EACTS](#) meeting in Vienna, Austria, and will have a booth right beside St.Jude and Sorin - [booth 63b](#). This will make for a great comparison of product features!

Our Medical Advisory Board continues to expand with noted cardiac surgeons. We are particularly excited to announce that [Dr. Michael Mack](#) has recently joined our MAB. Dr. Mack is an expert in minimally invasive surgery and prominent voice in the arena of transcatheter valve development.

For those new to this Newsletter, ValveXchange is a start-up company based in Colorado. We call ourselves "The Lifetime Tissue Valve Company" and are developing the first-of-its-kind "serviceable" bioprosthetic valve. By offering periodic, minimally invasive exchange of the worn-out leaflet set, young and physically active patients can avoid the use of a mechanical valve and the associated Coumadin® anticoagulation therapy. By adhering to the time-proven design tenets of conventional bovine pericardial valves, the ValveXchange system offers the best combination of least-invasive reoperation and greatest longevity and durability.

Press Release

Michael Mack joins VXi Medical Advisory Board

September, 2009. Denver - ValveXchange Inc. is pleased to announce that Michael Mack M.D., has joined the VXi Medical Advisory Board. Michael J. Mack, M.D. was born in 1947 in Syracuse, New York. He obtained his undergraduate degree in Philosophy from Boston College in 1969 and his Medical Degree from St. Louis University in 1973. He completed a residency in Internal Medicine at the University of Minnesota in 1976, and completed his training in General Surgery and Thoracic Surgery at the University of Texas Southwestern Medical School in Dallas, Texas in 1982.



He is Board Certified in Internal Medicine, General Surgery, and Thoracic Surgery. He began practice in cardiothoracic surgery in 1982 in Dallas, Texas, being a founding member of Cardiothoracic Surgery Associates of North Texas (CSANT). The practice currently has 60 physicians in the fields of cardiac surgery, thoracic surgery, cardiology, and vascular surgery. He also co-founded the Cardiopulmonary Research Science and Technology Institute (CRSTI), a not for profit research organization in 1996. He currently holds the position of Director of Cardiovascular Research and Cardiovascular Medicine of the Heart Hospital Baylor Plano. He is Director of Cardiovascular Surgery for the Baylor Healthcare System.

Dr. Mack has over 250 peer reviewed medical publications. He is a member of the Editorial Board of the Annals of Thoracic Surgery and is a reviewer for over 10 medical journals. His current areas of interest include minimally invasive surgery and percutaneous heart valve therapy. He has been a Visiting Professor at the Cleveland Clinic Foundation, Northwestern University, Emory University, and the University of Virginia. He has performed surgery in over 10 foreign countries including China, Egypt, Taiwan, Sweden, Germany, and Brazil. Dr. Mack holds a number of positions in national organizations. He is the President of the Thoracic Surgery Foundation for Research and Education (TSFRE) and is currently the President of the Southern

Thoracic Surgical Association (STSA). He is Second Vice President (President-elect 2011) of the Society of Thoracic Surgeons (STS) and is Secretary of the Board of Directors of the Joint Committee for Thoracic Surgical Education (JCTSE). He is also the Co-Chairman of the Industry Alliance Committee of the STS/AATS.

Dr. Mack is a founding organizer of the [Dallas-Leipzig International Valve Conference](#) and is considered today to be the most noted authority on the emerging field of transcatheter valves.

ValveXchange reports another successful exchange procedure in the sheep model

September 30, 2009. Denver - A fourth sheep underwent an open exchange procedure in the Experimental Surgery Laboratories of Prof. Richard Bianco at the University of Minnesota. Multiple valve exchange procedures have been done during the spring and summer of this year to continually refine the valve exchange tool set. The valve works extremely well, before and after the exchange procedure.

The sheep model, however, is challenging from a surgical point of view. The aortic tissue is very delicate and friable and closing the aortotomy without rupture and stenosis is difficult. Moreover, the ascending aorta of the sheep is very short which results in difficult exposure and access to the aortic valve. Therefore, "...sheep surgery in some aspects is tougher than operating on children", says [Prof. Bianco of the University of Minnesota](#). Although the sheep model is considerably more challenging than human patients, from a technology development point of view, it is the model preferred by the FDA for the assessment of new or modified cardiac valves.

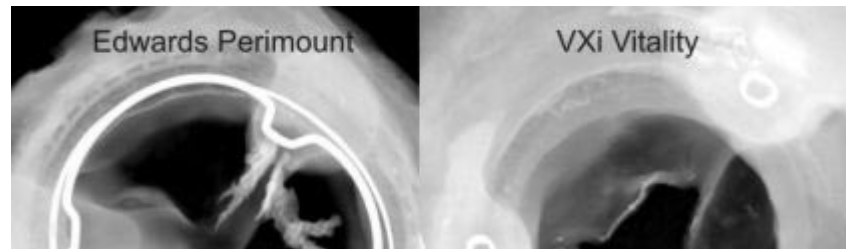
"We could separate the tool development and the valve performance between two animal models. We could develop the tools in the calf model, for example, where the anatomy is easier to deal with." noted Dr. Vesely. "However, by sticking to the sheep model, by doing what is hard, not what is easy; we will achieve a greater confidence that the procedure and the tools will take less effort to transition to the human condition, and that ultimately the whole package will be safer for patients. If we can pull this off in sheep and have a living, surviving sheep, like we have today, we know we can make it safe for patients. I'm not interested in going through a learning curve like transcatheter valves had, when we start doing our first-in-man studies."

Other News

The VXi valve survives for 5 months in the sheep model

We have recently kept one of our valves in the sheep for the full 5-month time frame required by the FDA for preclinical testing. This was not to prove that our valve is clinically ready, but rather to get a sense of how our valve will likely do when subjected to full-scale durability and animal

testing. Alongside our valve, we also implanted several Edwards Perimount valves, two of which have also been explanted. As expected, the Edwards valves did very well, showing only modest calcification and structural damage (see x-ray images below). The VXi Vitality valve did remarkably well, also exhibiting only minor calcification and no commissural leaflet distortion that would be indicative of potential design or fabrication flaws.



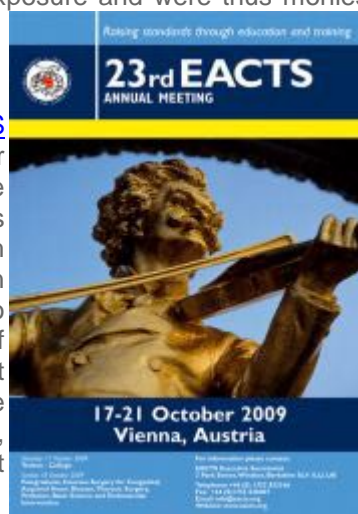
In hind sight, this is to be expected, as the VXi Vitality valve was designed to mimic the geometry and fabrication principles of the off-patent Edwards Perimount valve. By using a support frame with well-controlled geometry and leaflet symmetry, leaflet stresses are minimized and so is mineralization. Similarly, making use of leaflet clamping in the highly stressed commissural regions, instead of sewing, we avoid commissural leaflet damage and leaflet stretching. All evidence thus indicates that our valve will perform just as well as the Edwards valve, as intended.

ValveXchange Inc. to Display at EACTS meeting in Vienna

The famous car builder, Henry Ford, was quoted as saying *"I know that half of my advertising dollars are completely wasted! The problem is that I don't know which half."* For a start-up company, like VXi, cash is king. This is particularly true during these difficult financial times when Venture Capital is scarce and likely to be for a few more months. VXi is supporting its operations from private investment capital and from an NIH Phase II SBIR grant. Clearly, there is very little money set aside for marketing and promotional activities.

At the same time, attendance at prominent clinical meetings is crucial for keeping abreast of new clinical data and of the successes and failures of our competitors. Equally important is the interface with prominent surgeons that can offer critical feedback on our approach and guidance for our future technological development activities, and for introducing our future customers to our product. VXi has presented at three prominent meetings this year - The [Dallas/Leipzig International Valve Conference](#) hosted by Dr. Michael Mack, the [ACTS2009 Conference](#) in New York hosted by Dr. Subramanian, and the Biennial Meeting of the [Society of Heart Valve Disease in Berlin](#). At that meeting, Prof. Bianco presented our technology at a [keynote address about experimental animal models for the development of novel heart valves](#). All three of these conference gave us outstanding exposure and were thus monies well-spent!

We are now looking forward the [EACTS Meeting](#) (European Association for Cardio-Thoracic Surgery) in Vienna, to be held October 17 to 21. Like at previous meetings, VXi will have a booth at which to present its products and entertain inquiries. We are particularly pleased to have our booth right next to those of St.Jude and Sorin, two very prominent heart valve companies. For those that are planning to attend the EACTS meeting, we would be happy to receive you at [booth 63b](#).



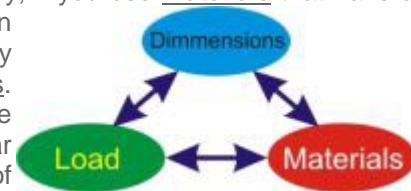
Reality Check

How Long Will PIVs Last - Part II

Not long. That is the current word on the street - the Streets of San Francisco, anyway. We just came back from the TCT meeting, frankly astonished at what has happened in less than a year. A year ago, transcatheter valves were the darling of the TCT. Back when transcatheter valves were introduced, a prominent physician at the TCT pronounced that these devices herald to valve surgery what intracoronary stenting did to CABG. Well apparently the death of valvular surgery has been greatly exaggerated. This is for two reasons; (i) surgeons are working side-by-side with cardiologists in "hybrid" OR/Cath lab suites to develop these new valvular implant procedures, and (ii) treatment of aortic valve stenosis with a transcatheter valve has been far more complex than initially anticipated.

The procedural complications of TVI (Transcatheter Valve Implantation) have been steadily dropping. However, concerns about the valves' long-term durability remain, and have recently come to the forefront.

Indeed, in his opening address to the transcatheter valve session, Dr. Martin Leon made a comment to the effect that *"Unless their durability equals that of surgical valves, transcatheter valves will never be used on anyone except the inoperable patient"*. This theme of limited durability was subsequently echoed many times for the balance of the TCT meeting. In the last session on transcatheter valves, [Dr. Ajit Yoganathan](#) of Georgia Tech outlined the history of surgical valves and described the *"triad of load, dimensions and materials"* as a basis for predicting the likely durability of a new valve design. In a nutshell, if you reduce the dimensions of a valve component but subject the valve to the same loads, the strength of materials needs to increase in order to get the same durability. The use of thinner pericardium is a good example of a design compromise present in transcatheter valves - the pericardium is thinner, but not any stronger. Similarly, if you use materials that have a poor fatigue resistance when subjected to high loads, then they need to have greater dimensions. Nitinol, which is known to have fatigue problems in some vascular applications, is another example of why there is such concern with new transcatheter valve designs.



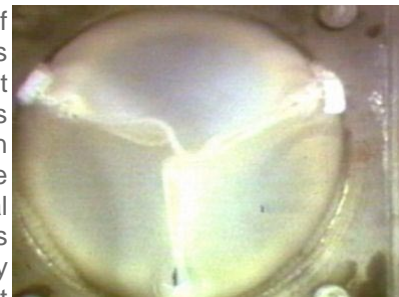
Even when making use of conventional materials with the appropriate dimensions, departure from the time proven design tenets of bioprosthetic valves leads to reduced valve longevity. In my Reality Check segment in the [April/May issue](#) of this newsletter, I introduced some guiding principles of valve design that need to be followed. They are restated here as the following three tenets:

1. maintain a precise central gap to prevent leaflet pinwheeling during closure
2. maintain 120 degree symmetry between leaflet commissures
3. maintain absolute circular precision in the supporting stent

Although these are but a few of the features that make for a good valve design, they are perhaps the easiest to visualize and also to support with real clinical data.

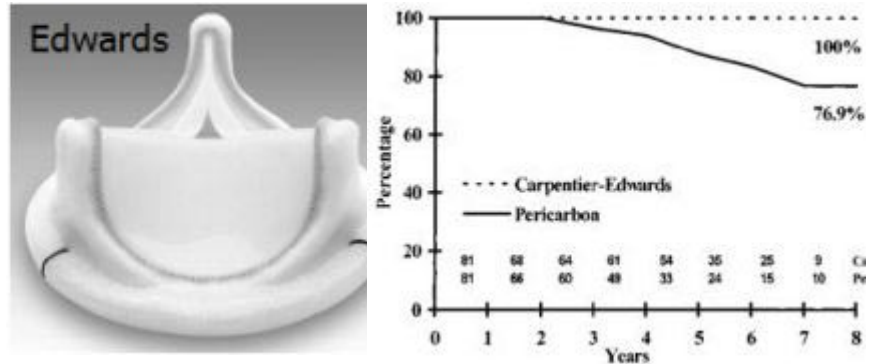
Importance of Central Gap

The central gap is a unique feature of the Edwards Perimount® valve, and its derivatives, and not found on most other pericardial valves. Its purpose is to accommodate the inward deflection of the compliant stent posts and the slight distension of the pericardial leaflets during valve closure. This central gap is intended to close fully under maximal loading with the stent posts slightly bent inward. Without the gap, the leaflets will bunch up together as the valve is loaded, wrinkle and pinwheel when the valve is



Without the gap, the leaflets will bunch up together as the valve is loaded, wrinkle and pinwheel when the valve is

fully closed. A classic example of this type of pinwheeling was the [Ionescu-Shiley](#) valve (see image above) which had very poor durability, with [75% of the valves failing at seven years](#). When viewing this short [video loop](#) please note how the leaflets are wrinkled in the central coaptation point and twisted clockwise. The Ionescu-Shiley valve, however, had additional design problems that are beyond the scope of this example. Perhaps a better example of how the lack of a central gap contributes to diminished longevity is a direct comparison of the clinical experience with the Edwards Perimount valve and the Sorin Pericarbon valve.



As shown in the images above, the Edwards Perimount valve (left) has the familiar central gap whereas the Sorin Pericarbon (right) does not. In patients with a mean age of 70 years for both groups, the Edwards valve had 100% freedom from structural failure at 8 years post implant, whereas the [Sorin valve had only a 77% freedom from failure](#) (see actuarial curve above). While other design differences between the Edwards and Sorin valves may be at play here, the similarity of the above two examples suggests that there is a direct link between the presence or absence of a central gap and long term durability - certainly the mechanistic linkage between leaflet deformation and durability is consistent with the greater experience in the bioprosthetic valve field.

Importance of Geometrical Precision and Symmetry.

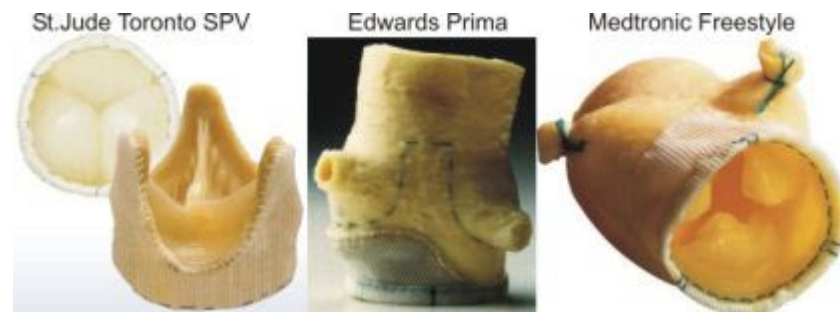
Some assume that just because the native semilunar valves are not perfectly symmetrical (see image right), leaflet symmetry in bioprosthetic valves is not all that important. It is true that native aortic valves have nowhere near the perfect 120 degree symmetry of the bovine pericardial valve. But unlike manufactured valves, native biological valves also have structural and mechanical variations between the three leaflets that work in concert with the geometrical variations.



Many years ago, I studied the [regional mechanical differences within porcine aortic valve cusps](#) and between the three leaflets and demonstrated the presence of this structural-mechanical-geometrical

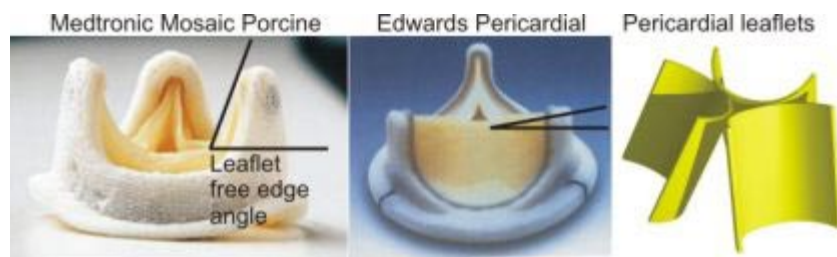
linkage. While this structural-mechanical linkage may be an adaptation to asymmetrical growth during morphogenesis in the developing embryo, or during the physical growth of the organism, such mechanical variations between leaflets simply cannot be controlled in the manufacture of bioprosthetic valves. Once fixed in glutaraldehyde, much of micromechanical function of the valve leaflet material is altered and the best that one can do is maintain the geometry of the leaflets as is by way of the supporting stent. This is particularly the case in bioprosthetic valves fabricated from glutaraldehyde-fixed porcine aortic valves, also called the "porcine xenografts". Indeed, once properly mounted on a fixed geometry frame, the long-term [durability of the porcine xenograft](#) can approach that of the bovine pericardial valve. Conversely, if the geometry is compromised and leaflet asymmetry ensues, the long-term durability of the valve is significantly reduced.

A good historical example of this has been the stentless valves, introduced in the mid 80's. Stentless valves were constructed from a whole porcine aortic root fixed in glutaraldehyde, but not mounted on any synthetic supporting stent, like most other valves (see image below).



Stentless valves were adopted readily by surgeons because they offered greater effective orifice area (EOA) for the patient, even at the expense of increased surgical challenges and longer implantation time. They were promoted as having greater durability because of more "physiological function", as the leaflets were not "constrained" by a stent. The aortic wall component of the stentless valve calcified within a few years, however, making it rigid and eliminating any cyclic compliance and hence the theoretically better physiological function. The more technically demanding surgical implant resulted in minor misalignments in leaflet apposition and led to the earlier failure through leaflet tearing due to increased leaflet stresses. On average, [stentless valves required reoperation at only 8 years](#) - a very disappointing outcome, particularly since their greater EOA made them the ideal choice for the younger, more active patient. The prognosis for patients who have had stentless valves implanted and who now face redo surgery is not good. Reoperation for early failure of stentless valves requires complete aortic root reconstruction, including reattachment of coronary buttons to the Dacron graft. This is not a trivial procedure. It takes many hours to complete and has an [operative mortality of 11%](#). Accordingly, many surgeons are no longer implanting stentless valves in their younger patients who are expected to outlive these valves.

While the distortion example has been demonstrated in the stentless valve product based on the glutaraldehyde fixed porcine xenografts, it also applies to valves fabricated from bovine pericardium. Because glutaraldehyde-fixed bovine pericardium is far less compliant than similarly fixed porcine aortic valve tissue, the leaflet geometry of pericardial valves is quite different from that of porcine xenografts (see images below). Leaflet shape and free edge angle are the two most obvious differences. The leaflets of the bovine pericardial valve (center) are much flatter, less spherical than those of the porcine xenografts (left), and also have a much shallower leaflet free edge angle. With the much lower radial leaflet compliance, the only way to make the leaflets of bovine valves coapt and seal against backpressure is to make the leaflets almost parallel in the coaptation region - hence the low coaptation angle and their almost cylindrical in shape (right).



Clearly, this works very well in practice. However, the limitation of low compliance leaflets and shallow leaflet angle is that pericardial valves are even less forgiving to geometrical distortions than porcine xenograft valves. Indeed, even a small geometrical or material asymmetry between the valve leaflets can lead to early failure by way of single leaflet prolapse. As an example, the valve shown above became highly regurgitant and failed roughly 3 years after implantation from the functional asymmetry of adjacent leaflets. Note that the free edges of the left and right leaflets (arrows) sit below that of the posterior leaflet (*). Pericardial valves thus tolerate only very small margins of error in leaflet misalignment and the symmetry must be controlled by a precise circular stent structure.



Implications for Transcatheter Valves

Reoperation for a failed transcatheter valve will not be easy. First of all, the patient is inoperable to begin with - hence a transcatheter valve, so redo surgery for a failed prosthetic valve is likely to have even greater contraindications. Like stentless valves, transcatheter valves have a large surface area that adheres to the native aortic root, making them difficult to remove. The only option is to do a valve-in-valve procedure, placing a new valve inside the old one. In the early days of transcatheter valves, this was considered a viable option. That may be so for the end-stage, inoperable patient who is relatively sedentary, but not for anyone that intends to make use of full cardiac output. Remember that the gradients reported for transcatheter valves are low because they are

measured as a function of flow velocity through the valve by Doppler. This gradient is low because of the cardiac output of these sick, sedentary individuals is also low. When cardiac output goes up, so will the transvalvular gradient. Judging from the opinions and comments at the recent TCT meeting, valve-in-valve procedures are not expected to be a solution for the majority of otherwise healthy, prosthetic valve recipients.

So if multiple revalving is not a likely to be a good solution for failed transcatheter valves, and reoperations to replace them are going to be just as tough as they are for stentless valves, there must be some indication that transcatheter valves have some reasonable expectations of longevity. If not, it is difficult to imagine that transcatheter valves will be used in anyone except the inoperable patient. Unfortunately, the 40+ years experience from the surgical valve field implies that transcatheter valves will have very poor durability. This is because of the "triad of load, dimensions and materials" proposed by Dr. Yoganathan, and by the "three tenets of valve design" proposed by myself - (i) central gap, (ii) 120 degree symmetry, and (iii) circularity.

The first evidence that transcatheter valves are likely to have serious durability issues due to geometry came to light by a [paper by Rachid Zegdi of Paris, France](#). After obtaining informed consent from patients undergoing conventional, open-heart surgery to implant a prosthetic valve, the investigators inserted empty Nitinol transcatheter valve stents into the orifice of native calcified, stenotic aortic valves and photographed their expanded shape (see images below).



Because of the presence of the calcified leaflets noncircular deployment of the stent occurred in 86% of all deployments into bicuspid valves and in 32% of all tri-leaflet valves. However, even when deployed in tri-leaflet valves to a circular shape, the range of deployed diameters was 17-20 mm - this for a valve designed for a nominal deployed geometry of 20 mm. A visible gap between the expanded stent and the adjacent tissue was noted in 49% of all cases and the protrusion of calcific nodules through the Nitinol cage was found in the majority of cases. To visualize the impact of the non-circular and under-deployed geometry on the shape of the leaflets, the investigators then inserted transcatheter valves into plastic forms that mimicked the geometries observed during the open-heart procedures. The range of leaflet distortion is shown in the images below.



As can be seen from these photos, distortions in leaflet geometry are profound in these simulations and lead one to question if such grossly distorted valves could have durability beyond just a few years. The reasons for non-circular deployment are quite simple. The final size and shape of the deployed valve is determined by the elastic balance between the expanding Nitinol stent and the asymmetric resistance of the calcified leaflets of the native aortic valve. Depending on exactly how the native valve is diseased, where the calcific nodules are and how asymmetrically positioned they may be, will determine whether the final shape of the self expanding valve will be triangular, circular or elliptical, and also what the final diameter will be even in the unlikely event that it will be perfectly circular. Self-expanding valves, like CoreValve and Ventor, are likely to be most vulnerable to such geometrical abnormalities because their shape is determined primarily by the elastic balance between the expansion of the Nitinol cage and the recoil of the stenotic valve. Balloon distensible valves, such as the Sapien valve, are likely to be less prone because their metal stent has less spring-back than Nitinol, but they are unlikely to be completely free of geometrical uncertainty - particularly the central gap. Experience with conventional, current generation, state of the art pericardial valves, like the Edwards Perimount, indicate that even a 1 mm departure from absolute geometrical symmetry will lead to rapid leaflet degeneration and early valve failure.

Unfortunately, the geometry of the valve after deployment in the patient cannot be fully visualized with current imaging technologies. Transesophageal echocardiography does not have resolution sufficient to show the pinwheeling and leaflet distortion shown in the images above. All that can be shown echocardiographically is that the valve "works" (i.e., opens and closes) after deployment. This is what has been reported in the clinical literature and this is what gives the supporters of transcatheter valves their false sense of comfort. Transcatheter valves will function well for the first several years, but with leaflets so grossly misshapen, experience dictates that they cannot function well beyond that. Indeed, the valve shown above failed in 3 years with leaflet distortion far less severe than what the Zegdi study has shown for transcatheter valves.

Transcatheter valves are an important life-extending option for the aged, inoperable patient. They will not become an option for the otherwise healthy, operable patient who expects 15-year longevity from their bioprosthetic valve. To assure that type of longevity in a new valve

design, leaflet geometry must be controlled to the same precision as in the Edwards Perimount valve.

Postscript:

The ValveXchange concept was first introduced as a surgically implantable valve with a transapically exchangeable leaflet core. We believe that this approach is the safest for the patient, as it lends itself to the design and fabrication of a valve that lasts 15-18 years between off-pump exchanges. However, we have made considerable advances in our initial designs and licensed some key technologies, such as the [GUICI \(Guiraudon Universal Cardiac Introducer\)](#), and now have designed a version of our exchangeable valve that can be inserted transapically even the first time. This means that with this design, there is no need for open heart surgery ever. Not during the initial implant nor during the subsequent exchanges every 15 years. As such, we are the only valve company that can bring the "transcatheter valve approach" to the younger, operable patient. With our pediatric product that has a resizable docking station for the growing patient, we have a full spectrum of tissue valve technologies that spans the full range from "pediatric to geriatric". I look forward to sharing details of these technologies with you in the coming months.

Sincerely,

Ivan Vesely, Ph.D.
Founder and Chief Scientific Officer
ValveXchange Inc.
vesely@valveXchange.com

Recent News Releases

June, 2009. Denver - ValveXchange Inc. announces that Walter Randolph "Randy" Chitwood, Jr., M.D., FACS, FRCS has joined the VXi Medical Advisory Board. Dr. Chitwood was the principal investigator of the FDA robotic mitral valve trials that led to approval for this use in the United States. Today, he is the world's leader in robotic mitral valve surgery. [Read More.](#)

May 15, 2009. Denver - ValveXchange Inc. is pleased to announce that it has signed an option agreement with Dr. Gerard Guiraudon to license his Universal Cardiac Introducer technology. Unlike rigid trocars, the Guiraudon Universal Cardiac Introducer (GUICI) is a flexible, collapsible system that facilitates intracardiac surgery and off-pump exchange of the VXi valve. [Read More.](#)

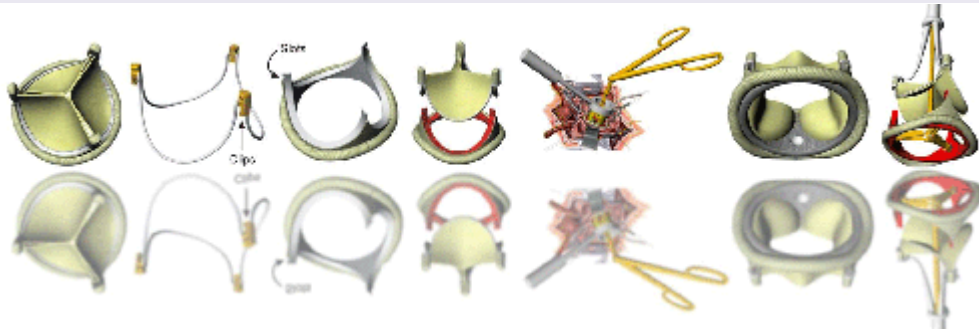
March, 2009. Denver - ValveXchange Inc. announced that Dr. Tirone E. David has joined the VXi Medical Advisory Board. Dr. David is recognized world-wide for his pioneering work in valve sparing surgery.

his remarkable surgical skills and his commitment to teaching. [Read More.](#)

March 30, 2009. Denver - ValveXchange licensed its exchangeable valve technology patents from the Cleveland Clinic. The Clinic and ValveXchange have now entered into an arrangement whereby the Cleveland Clinic will in the future receive an equity position in ValveXchange, Inc. [Read More.](#)

February, 2009. Denver - ValveXchange Inc. announced that of Dr. Joseph Sabik, Chair of Cardiothoracic Surgery, The Cleveland Clinic Foundation, will serve as the Chair of the VXi Medical Advisory Board. [Read More.](#)

January 30, 2009. Denver - ValveXchange Inc. announced that it has begun animal testing of its proprietary exchangeable valve technology, working with the College of Veterinary Medicine at the Colorado State University, Fort Collins, CO, and with Experimental Surgical Services, University of Minnesota, Minneapolis, MN. Both Institutions are well-recognized for their expertise in animal surgery. [Read More.](#)



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