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NEWS RELEASE

September/October 2010



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

Dear Colleagues

A lot has happened over the past two months. We have an addition to our Board of Directors, and two highly distinguished Cardiologists have joined our Medical Advisory Board. We have presented the ValveXchange story at AdvaMed, at the TCT and at the PCR London Valves meeting, and have done two transapical implants of our Vanguard™ exchangeable valve prototype in animal studies. In September, my [invited review article on transcatheter valves was published in the Journal of Heart Valve Disease](#), and I've been invited to contribute a chapter to a book on heart valves. Our new NIH / SBIR Fast Track grant, entitled "*Beating Heart Surgery for Heart Valve Replacement*" became active in September, allowing us to accelerate the development of our transapical implant technologies. Details on all of these new developments can be found below.

For those new to this Newsletter, ValveXchange is an emerging technology 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, we believe that the ValveXchange system will offer the best combination of least-invasive techniques and greatest valve longevity and durability.

Press Release

Noted Cardiologists, Drs. Carlos Ruiz and Blase Carabello, join ValveXchange Medical Advisory Board.

September, 2010. Denver - ValveXchange Inc. is pleased to announce that Carlos Ruiz, M.D., Ph.D., has joined the VXi Medical Advisory Board. Dr. Ruiz was born and raised in Barcelona, Spain. He obtained his Masters of Science from La Salle Bonanova in 1968, and his Medical Degree from the University of Barcelona in 1972. He completed a residency in Pediatrics and Medicine, as well as his training in Cardiology at the University of Barcelona. He earned a PhD from the Mayo Clinic and completed a fellowship in Critical Care Medicine at the University of Southern California. He is Board Certified in Internal Medicine and Cardiovascular Disease. He is a founding member of the Pediatric and Congenital Heart Disease Committee of the Society for Cardiac Angiography and Interventions. In 1991 Dr. Ruiz was named the Director of the Pediatric and Adult Catheterization Labs at Loma Linda University Medical Center and Children's Hospital. In 1999 he moved to Chicago where he was Chief of Pediatric Cardiology at the University of Illinois, Chicago until 2006. He currently holds the position of Director of Cardiac Intervention for Structural Heart Disease at Lenox Hill Heart and Vascular Institute of New York. Dr. Ruiz has authored over 200 peer reviewed medical publications, and holds patents for multiple medical devices. He is a member of the Editorial Board of the European Heart Journal, Circulation, JACC: Cardiovascular Interventions and several other prestigious journals. He has been a Visiting Professor at the University of Madrid, the University of Pittsburgh, in Saudi Arabia, Singapore, Venezuela, Chile, and Spain. Dr. Ruiz holds a number of different positions in national and international professional organizations including the American College of Cardiology, the Society for Cardiac Angiography and Interventions, the American Heart Association, the Society for Heart Valve Disease, and the New York State Cardiac Advisory Committee among others. Dr. Ruiz is a leading authority on structural and congenital cardiovascular interventions.



September, 2010. Denver - ValveXchange Inc. is pleased to announce that Blase Carabello, M.D., has joined the VXi Medical Advisory Board. Dr. Carabello is listed as one of the best doctors in the nation in the field of cardiovascular disease. He received his medical degree from Temple University in 1973 and completed his internal medicine residency and cardiology fellowship at Harvard Medical School in 1978. Since 2001, Carabello has served as a member of the Cardio/Renal Advisory Committee for the Food and Drug Administration in Washington, D.C. He is a member of American Society for Clinical Investigation. He is on the



editorial board and serves as an editorial consultant of a number of peer-reviewed journals including the Journal of the American College of Cardiology, the Journal of the American College of Cardiology the Journal of Heart Valve Disease, Journal of Cardiac Failure, and Current Cardiology Reports. Dr. Carabello is the author of more than 350 peer-reviewed and invited publications and the recipient of numerous awards for excellence in teaching. Most recently, he received the 2003 Alumnus of the Year Award from Temple University and served as the president of the Society for Heart Valve Disease and of the Association of University Cardiologists, completing his term in January of 2009. In the spring of 2010, he was selected to receive the Distinguished Scientist Award from the American College of Cardiology (ACC), the college's most prestigious research honor. He has served as an author of the 1998 and 2006 AHA/ACC Guidelines for the Management of Patients with Valvular Heart Disease. He is currently the Medical Careline Executive at the Michael E DeBakey VA Medical Center and Vice Chairman of Medicine at the Baylor College of Medicine in Houston Texas. Dr. Carabello has been acting as an informal advisor to ValveXchange since 2006, and has recently formalized his relationship with VXI.

Distinguished Colorado Executive Joins VXI Board of Directors

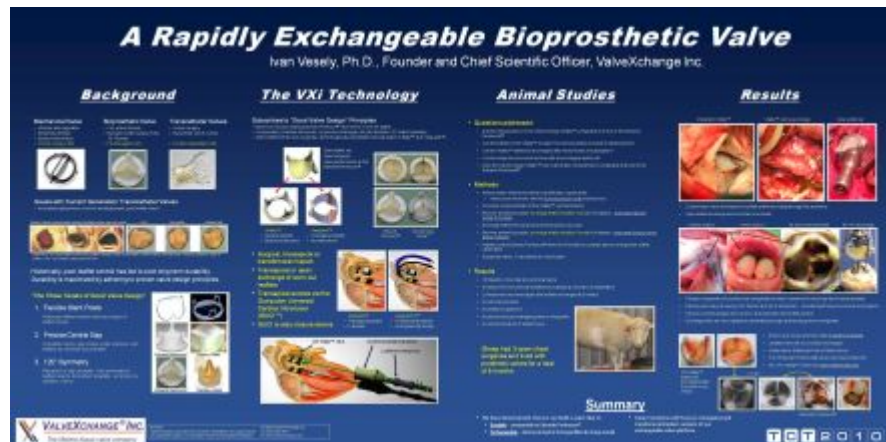
October, 2010. Denver - ValveXchange Inc. is pleased to announce that Bonnie Vivian has joined the VXI Board of Directors. Ms. Vivian is an accomplished Medical Device professional and a significant early investor in ValveXchange. Bonnie Vivian has spent over 25 years in the healthcare market, specifically focused on medical devices including equipment, disposables and implants. Most recently, she served as the President / CEO of Denver Biomedical, growing the company ten-fold over 8 years and then selling it, providing her equity partner with the highest percentage return on their investment. She began her career in medical product



sales with IBM, building a strong customer focused bias. At IBM she exceeded sales quota every year, was selected to IBM's top honor for sales staff, the Golden Circle, and then as Director of IBM's One Hundred Percent Club. She then moved into marketing and product management at COBE Laboratories where she led an equipment redesign effort that ultimately quadrupled the unit's mean time to failure. She joined Denver Biomedical in 1991 as Director of Marketing and Sales and grew through Vice President of Marketing to VP and General Manager. She ultimately led a buyout of the company in 2000, became its CEO and then sold Denver Biomedical to Cardinal Healthcare in 2006. She graduated Summa Cum Laude from Purdue University with a B.A. with a focus on organizational communications.

Other News

The most recent TCT conference was a resounding success for VXi. Getting on the program at the TCT is not easy - this year we were there twice. At this year's TCT 1,085 abstracts were submitted and a total of 107 peer-reviewed oral abstracts and 417 poster were presented, giving a rejection rate greater than 51%. Besides passing the criteria for a peer-reviewed poster, we were also pleased that [Dr. Joseph Sabik](#), Chairman of Thoracic and Cardiovascular Surgery at the Cleveland Clinic, and member of the [VXi Medical Advisory Board](#), was invited by the TCT organizing committee to deliver a presentation on the ValveXchange technology. As expected, Dr. Sabik delivered an outstanding presentation to a full-house audience. The poster also received good exposure and lots of visits at the main poster session. A copy of the poster can be downloaded by clicking [here](#), or on the image below.



The broad industry attendance at the TCT also gave us the opportunity to continue due diligence discussions with two potential strategic partners.

The [PCR London Valves](#) was also a very interesting meeting. Unlike the TCT, it was a much smaller meeting, lasting only two days, but like others in the PCR family of meetings, it was exceptionally well organized, complete with a theatrical opening to the beat of Euro-rock music! As at the [EuroPCR](#) meeting in Paris earlier this year, ValveXchange was part of the Innovation Session that featured most of the current valve technologies in various states of development (see image below and [link](#) to full session program)

Technology	Company	Device Name	Access Route	Target Market	US Status	OUS Status	# Trials
Valve Replacement	Direct Flow	DFM	Transfemoral	Aortic valve disease			7
	JenaValve	JenaValve Transfemoral	Transfemoral	Aortic valve disease		Unknown	2
		JenaValve Transapical	Transapical	Aortic valve disease	Unknown		3
	Sadra	Lotus	Transfemoral	Aortic valve disease			4
	Shelhigh	IPVC	Surgical-Less Invasive	Pulmonary valve disease			3
	Symetis	Acurate TA	Transapical	Aortic valve disease	Unknown		3
	ValveXchange	Vitality Valve and Docking Station	Transapical	Aortic valve disease		Unknown	3
Embolic Protection	Embrella	Embrella Embolic Deflector	Transfemoral & Transapical	Aortic valve disease			3
	SMT R&D	SHEF	Transfemoral & Transapical	Aortic valve disease			1
Mitral Repair	ReCor	Therapeutic Ultrasound	Percutaneous	Mitral annulus re-shaping			2

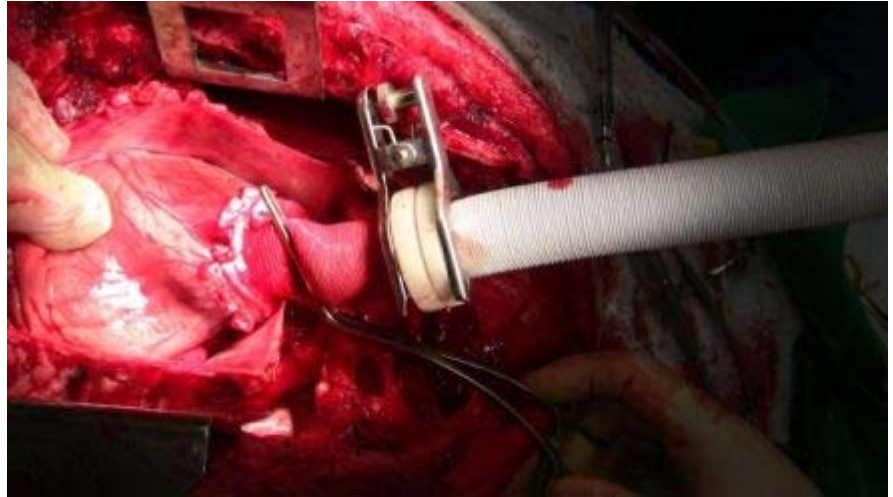
The VXi presentation can also be downloaded by clicking [here](#).

Our CEO, Mr. [Larry Blankenship](#), was invited to present at the [2010 Sessions of AdvaMed](#) held at the Washington Convention Center. This year's sessions set a new attendance record of over 1,700 delegates from Industry, Academia, Government and the Investment Community. Mr. Blankenship presented as part of the [Invited Company Presentation session](#) and his presentation can be downloaded by clicking [here](#).

Technology Report

The Transapically Implantable Vanguard™ Docking Station

During September, we performed two implants of the Vanguard™ transapically implantable docking station and leaflet set. Both were acute animal studies, allowing us to examine the position of the valve following implantation. These early implant studies have enabled us to test both the anchoring mechanism of the Vanguard™, the sizing of the introducer and the function of the transapical implant tools. In particular, these early studies have enabled us to work towards the next generation version that will be half the diameter of the current one, making transapical implant possible with the conventional [Sedlinger approach](#) as is done today with transfemoral implants.



Reality Check

Prosthesis - Patient Mismatch:

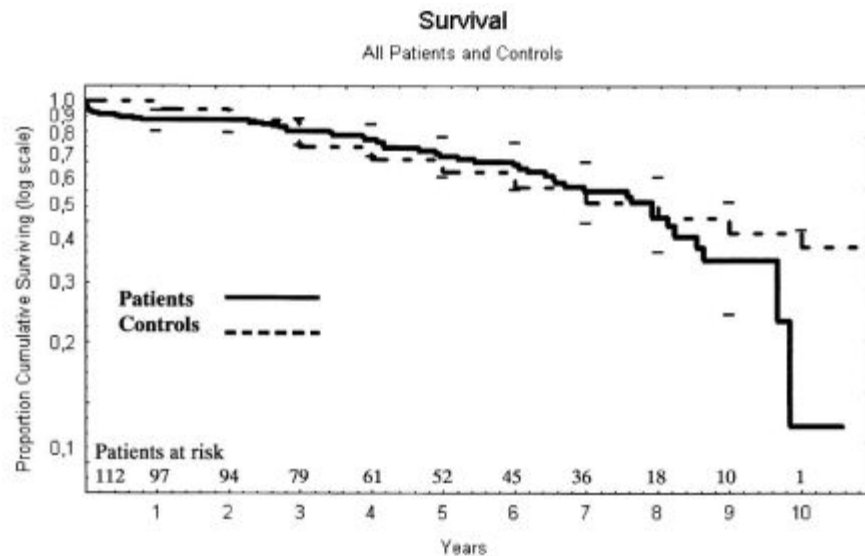
An important factor to consider in prosthetic heart valve technology is one that has always been there, but one that has taken a back seat to the transcatheter valve revolution - Prosthesis-Patient Mismatch.

Physicians who dedicate their practice to heart valve surgery have a unique perspective on the prosthetic valve field that comes about by their long and careful follow-up of their patients. Throughout my nearly 25 years of attending heart valve conferences, I found it most interesting to see surgeons presenting a paper with a title something like *"My 12-year experience with the Valvetronic supra-annular bioprosthesis"*. They would show up at the same conference next year with a paper entitled *"My 13-year experience with the Valvetronic ..."*, and the following year with *"My 14-year experience with the Valvetronic ..."* As a young skeptical scientist with a fairly broad research program, my first impressions of these repeat visits were *"Oh no, not again! Give me something new!"* Indeed there were a lot of "new things" at these early conferences and many of these pioneering presentations ended up winning awards for innovations that were presumably poised to change the entire field of prosthetic heart valves. I remember seeing an amazing presentation about growing cells on chemically passivated bovine pericardial leaflets that won the Carpentier Award for Innovation. This was at one of my first international clinical meetings. As a young scientist, I thought to myself *"Well, I really picked a dead field to pursue my career in. They just solved all the problems!"* But I went to the same conference next year and guess what? That group wasn't there, that topic wasn't even mentioned and the whole project ended with one publication and then complete silence. Over the next 20 some years in my career as an academic research scientist studying heart valves, I had two, maybe three such moments, when I thought to myself *"My career is over. They just solved all the problems with prosthetic heart valves..."*. Well, clearly, the death of innovation in the heart

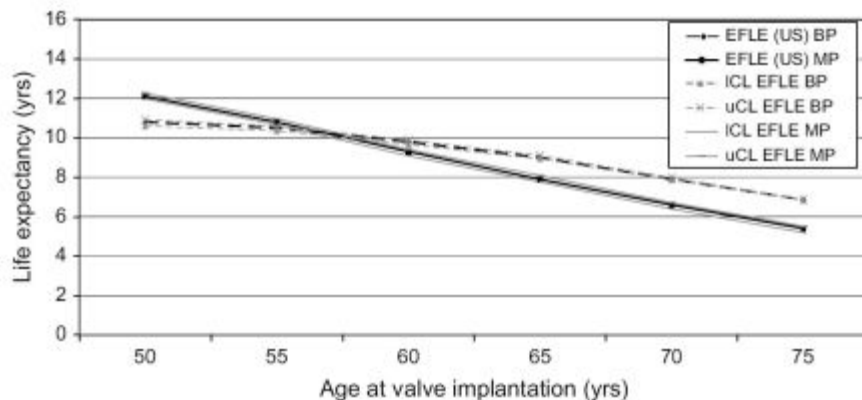
valve space has been greatly exaggerated! Innovations rise and fall and every product has its niche, be it large or small. Some products live but most die. Indeed, few of those [valve concepts under development that I tabulated](#) in the [January - February edition of this newsletter](#) are still alive.

But through all these innovations, the same surgeons show up at the clinical meeting with a presentation entitled "*My 20-year experience with Valvetronic supra-annular bioprosthesis*". The physicians are a little older but the data is solid and years later some amazing revelations are made and great insight into the patient-prosthesis relationship emerges.

Prosthesis-Patient Mismatch (PPM) has recently been recognized as one of these ultra-long-term findings that could not have existed were it not for the patience and perseverance of these academically-inclined physicians. I had not truly appreciated the significance of PPM until recently, primarily because one of the most touted benefits of having a bioprosthetic heart valve is the nearly identical survival history of patients with bioprostheses and those of the otherwise healthy population. One specific example is that of the Biocor stentless valve which, if done right, offers the greatest effective orifice area and shows that the [9-year survival of patients with the prosthesis is within the error bars of an age- and gender-matched control population](#) without aortic stenosis (see graph below).

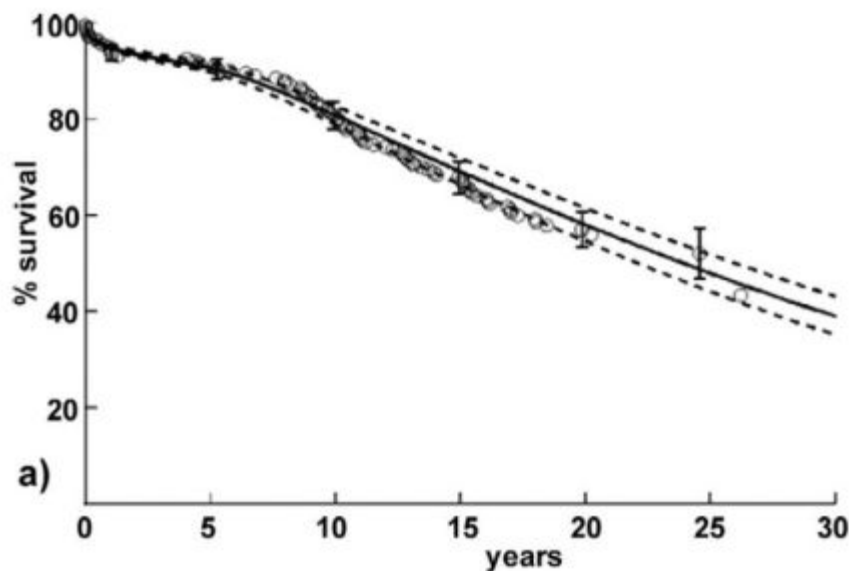


Interestingly, not many studies compare survival after valve surgery with survival of the entire population, most likely because other comparative studies, like between valve types, may be more interesting. This is where the tenacity and intense data-focus of heart valve surgeons comes into play, as any differences in patient survival tend to manifest not much sooner than 10 years post implantation. Even then, the differences tend to be minor. For example, [one monumental study](#) followed nearly 4,000 patients for over 20 years and statistically analyzed the different life expectancies of patients receiving mechanical vs. tissue valves. As seen from the plot below, the confidence intervals were very tight, and the difference in life expectancy between the two valves was less than two years.



While minimal, the differences are real and the data is sound statistically. Particularly interesting is that if one is in their 50's, one can get a slightly longer life expectancy if one chooses a mechanical valve, whereas if one is over 60, a longer life expectancy can be had with a bioprosthesis. These differences lie in the types of complications that one can expect with each valve type. With mechanical valves, one can expect bleeding complications resulting from the anticoagulation regimen, whereas with the bioprosthesis, one can expect reoperation. However, even for a 60-year old, the lifetime risk of reoperation for structural valve degeneration is only 22%, according to this paper.

With this kind of statistical power and age discrimination made possible by the long follow-up times that surgeons are capable of, one can begin to get a sense of how patients of different age do with different types of prosthetic valves. The aortic allograft is generally considered to be the most long-lived tissue valve. In rare cases, even the early [antibiotic-sterilized allografts lasted 30 years](#) (see image below), something that not even the best porcine or bovine bioprostheses can claim.



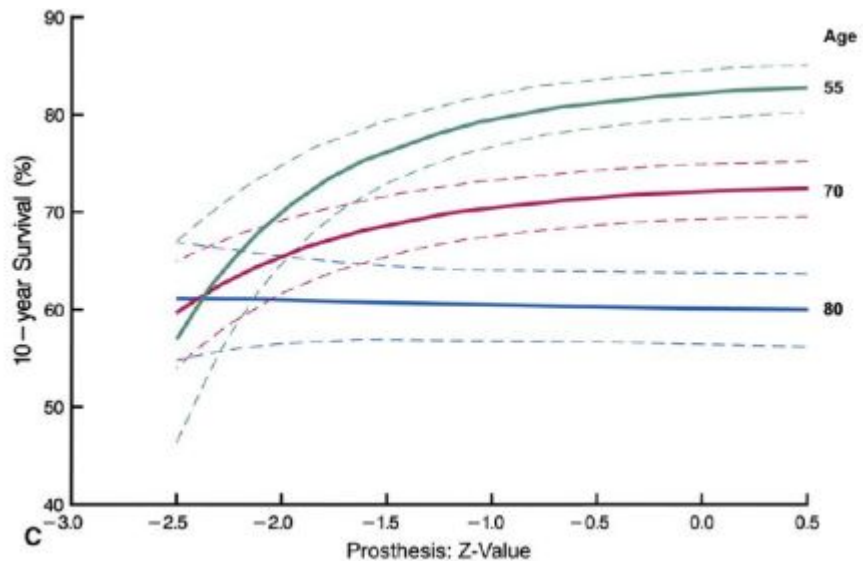
While durability is the main feature of the aortic allograft, it is truly a

stentless valve, and it can also claim the best effective orifice area, and thus be free of any hint of prosthesis-patient mismatch. The concept of Prosthesis-Patient Mismatch was first introduced by [Rahimtoola in 1978](#), as a condition of "*effective stenosis*", even if the prosthetic valve is functioning normally. It is an issue not of absolute valve size, but of gradients which come about due to a relationship between the effective orifice area of a given valve, and the cardiac output needs of the patient. The requirements for cardiac output are proportional to body surface area, so a PPM is represented as some critical value of valve area / body surface area or cm^2/m^2 . Over the years, the critical value that determines the presence of moderate PPM has been set at less than $0.85 \text{ cm}^2/\text{m}^2$, and has been reported by some as occurring in between [19% and 70% of patients undergoing aortic valve replacement](#). Severe PPM is set at less than $0.65 \text{ cm}^2/\text{m}^2$ and occurs less frequently.

Perhaps the most well-studied group of individuals with reference to Prosthesis-Patient Mismatch have been those with some form of ventricular dysfunction. Exhaustive studies by [Ruel](#) show that in those patients who had impaired left ventricles, the incidence of PPM led to a decrease in survival 3 years postoperatively. Patients with normal ventricles preoperatively had less than 2% chance of dying from heart failure, whereas those with bad ventricles and PPM had a 12% chance of dying from heart failure, with an odds ratio of 5.1. Clearly, PPM prevents the [regression of ventricular mass](#) that otherwise occurs after surgery for aortic stenosis with good quality heart valves - patients with PPM don't get better.

This reduction in longevity associated with PPM is a function of patient size, or body surface area, as is currently measured. As reported by [Moon et al.](#) larger patients do significantly worse in cases where they have PPM, than do smaller patients, possibly because of the greater pumping requirements of the hearts of larger, potentially obese patients.

Those that are the most significantly affected by PPM, however, are the young, active individuals that receive prosthetic valves. In a study of over 3,000 patients, [Mihaljevic et al.](#) developed a statistical model that enabled them to test the effects of various patient factors on their longevity and survival after Aortic Valve Replacement (AVR). The most telling was the diagram below that shows three patient groups of different ages.



The vertical axis shows the probability of the patient surviving for 10 years after AVR and the horizontal axis is the Z-value, a measure of the severity of PPM. More specifically, Z represents the number of standard deviations that the prosthesis orifice deviated from the mean annulus diameter of the patient. The lower the negative Z value, the greater the PPM. As can be seen from this graph, patients in their 80's do not live any less long in the presence of PPM. Those in their 50's however, clearly have a diminished life expectancy when their prosthesis causes PPM. Those that can benefit the most from AVR are also those that suffer the most if it is not done right.

Besides longevity, Prosthesis-Patient Mismatch also has negative impact on the [quality of life and survival](#) after AVR. In the elderly, this results largely from a perception of reduced physical activity. This phenomenon has been editorialized by [Pibarot](#) recently. While PPM is clearly a factor in the survival and quality of life of younger patients, Pibarot argues that *"Older people also deserve a good quality of life"*. The elderly are now more active than ever, and are likely to consent to open-heart surgery if there are expectations that their quality of life and activity can be maintained. This can be done only by implanting the best, most hemodynamically-efficient prosthesis available.

What is fascinating about the entire PPM story, is how subtle details of the design of the sewing cuff of the prosthesis have on the likelihood that a recipient of the device will have PPM. [Wagner et al.](#) compared 4 current-generation supra-annular valves, measured their hemodynamics and also the incidence of PPM in 192 patients. The Edwards Magna and the Sorin Soprano had the lowest incidence of PPM, whereas the Medtronic Mosaic had the worst (see image below).

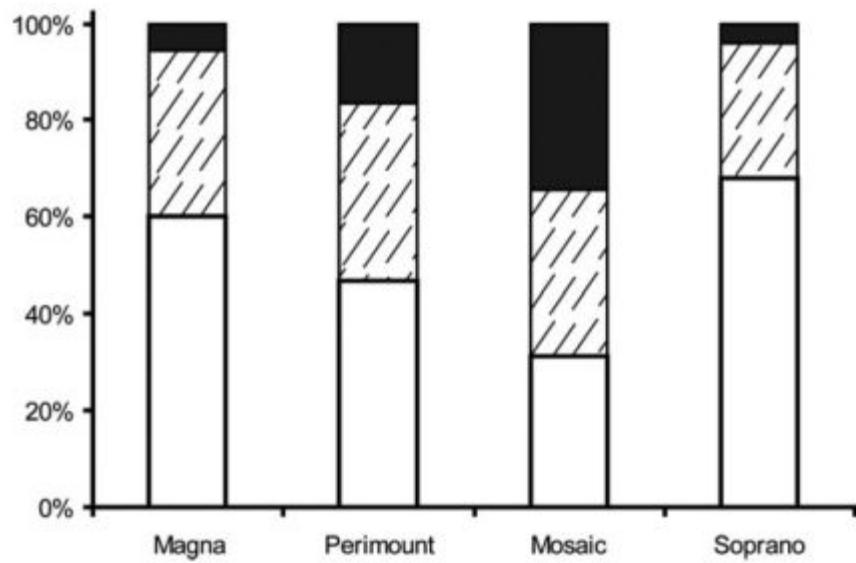


Figure 3. Incidence of PPM calculated with the Doppler-derived EOA 6 months postoperatively. ■ severe PPM ▨ moderate PPM □ no PPM. PPM, Patient–prosthesis mismatch; EOA, effective orifice area.

The authors conclude that while the design of the sewing cuff is clearly a contributing factor, patient anatomy may also play a role. For example, if the Sinuses of Valsalva are small, even a fully supra-annular valve can project slightly into the flow stream, causing Prosthesis-Patient Mismatch. The example given in the report (see image below) shows a supra-annular valve of a particular design, positioned in a patient where the Sinuses of Valsalva can accommodate the sewing cuff (right image).

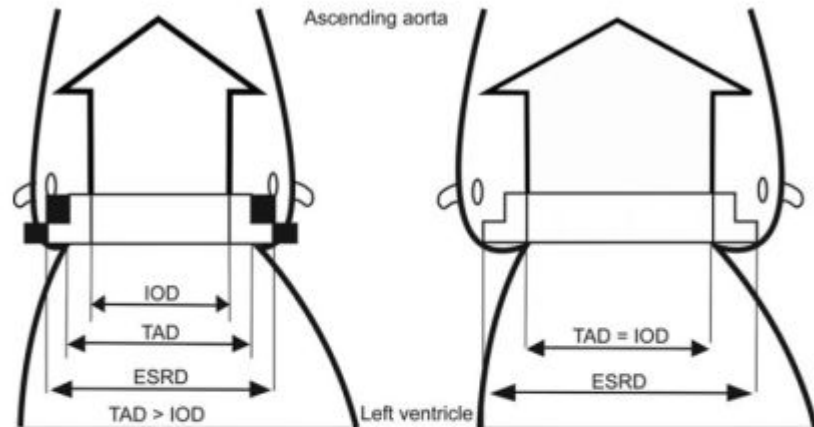


Figure 4. Two aortic root anatomies with an identical TAD. A more bulbar-shaped root (*right*). This is the ideal situation for completely supra-annular placement in which the tissue annulus diameter corresponds to the internal orifice diameter of the prosthesis ($TAD = IOD$). Small aortic root (*left*). Despite the same tissue annulus diameter, the valve of the same size (*black*) does not fit. Thus, the surgeon has to choose a smaller valve (*white*),

However, if the patient has small sinuses, the same sewing cuff cannot fit (black outline in left image), and the surgeon has to choose a smaller size valve (white outline). This is not the fault of the valve, per-se, but rather a phenomenon of the patient anatomy. Again, PPM results because of the unique relationship between a given patient and a given valve design.

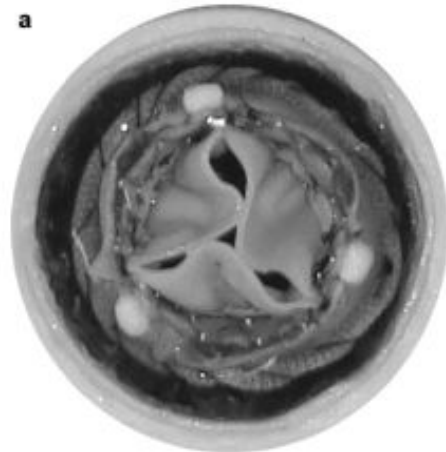
Turning now to the specific designs of transcatheter valves, we know that some are cylindrical and some have the pinched-waist, "Coke-bottle" look (image right). The extent to which these designs push aside the native leaflets will thus affect the incidence of significant PPM. Of course, this is in the context of being implanted into younger people, where the presence of PPM is expected to have the greatest impact. Nevertheless, given the tremendous costs of developing a given valve design, it would be prudent to look towards the future of eventually transitioning the design into younger patients IF the design is durable and IF it does not induce significant PPM or cause other risks or complications that would not be tolerated in younger patients. Mechanical expansion mechanisms, like the balloons used in the Edwards Sapien® valve or the pull-cords of the Sadra Lotus™ valve and the VXi Vanguard™ are capable of generating the greatest expansion forces. Self-expanding Nitinol valves, like CoreValve, Ventr, JenaValve, Symetis and the new St.Jude transcatheter valve, which looks similar to the CoreValve, offer lower expansion forces.



Indeed, the CoreValve, having extensive use in the elderly population, has already been reported as having issues with Prosthesis-Patient Mismatch. [Jilaihawi from the UK](#) reports that in the 50 patients studied, sixteen of them or 32%, had incidence of moderate or severe PPM. While these authors comment that the 32% incidence of PPM in the CoreValve is consistent with that of surgical valves, that is not confirmed in other studies, such as those of [Mihaljevic](#) who reported 15% incidence of PPM, and [Flameng](#), who reported 20% incidence of moderate PPM and 0.2% of severe PPM. Moreover, another [TAVI PPM paper by Tzikas](#) reports that sever PPM with the CoreValve occurred in 16% of their patients and moderate PPM was in 23% of patients. This is clearly greater than what typically occurs with surgically implanted valves. Whether transcatheter valves induce significantly more PPM than surgical valves is thus still up for debate. However, their restricted use in the inoperable elderly patients could may make the PPM debate a non-issue.

But as noted by [Pibarot](#), even the elderly can suffer from PPM, in terms of their quality of life, if not in their ultimate survival. As the indications for TAVI start to creep down to the lower risk patient, PPM will become just as important with transcatheter valves as it is with surgical valves. The fact that the leaflets of native valves are not cut out prior to the insertion of a transcatheter valve and their intra-

annular positioning, make the presence of PPM highly likely. Accordingly, the wide-spread use of valve-in-valve applications for TAVI are unadvisable since the majority of previously implanted bioprostheses are of the 19-21 mm size. This would create serious problems with PPM if these failed bioprostheses are [revalved with TAVI](#). Indeed, the impact of revalving an existing bioprosthesis is shown visually in an elegant study by [Azadani et al.](#) (see image at right). As TAVI applications begin to penetrate



into patients with a broader spectrum of clinical conditions, PPM is likely to manifest more severely, and even in less active patients. Time will tell.

Closing:

In closing, I have just come across an interesting government-sponsored investment program. Details can be found through our [banker](#) at Morgan Joseph, or on the following link ([Section 1202](#)). But in a nutshell, if you invest in a small company between now and the end of the year, and then hold the stock for 5 years, you will not be required to pay any capital gains tax on the stock once you sell it 5 years later. Yes, 0% capital gains tax on your investment. Food for thought....

Sincerely,

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

Recent News Releases

August 19, 2010. Denver - ValveXchange Inc. is pleased to announce the receipt of a \$1.3 million Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) under the Fast Track program. The Fast Track program is reserved for highly innovative and competitive projects with a short time-line to commercialization. This is VXi's 5th NIH SBIR Grant.

June, 2010. Denver - ValveXchange Inc. is pleased to announce that Lars G. Svensson, MD, PhD, has joined the VXi Medical Advisory Board. [Read More.](#)

April 13, 2010. Minneapolis - Dr. Ivan Vesely, the founder of ValveXchange Inc., presented a review paper entitled "The Three Tenets of Good Valve Design: Where transcatheter Valves Fail", at the 2010 [Design of Medical Devices conference](#) in Minneapolis, Minnesota. Other noted invited speakers were Manny Villafona, the founder of St.Jude Medical, and Dr. Robert Levy, a pioneer in understanding prosthetic valve calcification. Dr. Vesely's presentation can be viewed [here](#).

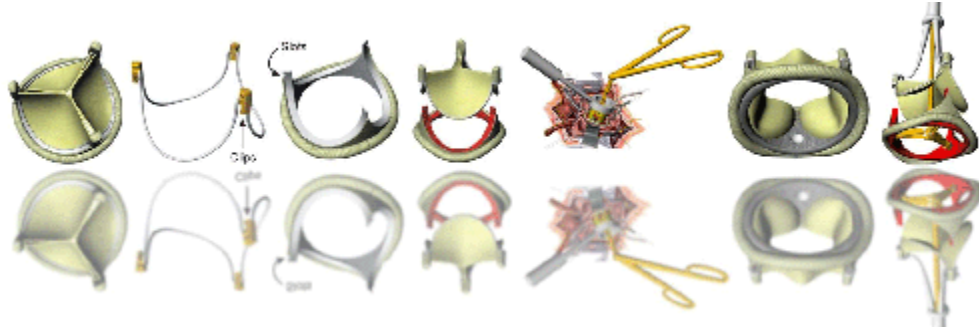
January, 2010. Denver - ValveXchange Inc. is pleased to announce that it has received a \$250,000 grant from the State of Colorado under the Bioscience Discovery Evaluation Grant Program (BDEGP). [Read More.](#)

November 19, 2009. Aurora, CO - ValveXchange Inc. recently executed a license agreement with the University of Colorado for a process to transform cardiac imaging data into high-quality three-dimensional models used for heart valve product development, clinician training, and pre-procedure planning. [Read More.](#)

October, 2009. Denver - ValveXchange Inc. is pleased to announce that Dr. Antonio Calafiore has joined the VXi Medical Advisory Board. Dr. Calafiore is recognized internationally for pioneering off-pump coronary artery bypass grafting and the "Calafiore technique" of myocardial preservation. Dr. Calafiore has recently moved from Italy to Riyadh, Saudi Arabia as the director of the Prince Sultan Cardiac Center. [Read More.](#)

September, 2009. Denver - ValveXchange Inc. is pleased to announce that Michael J. Mack, M.D., has joined the VXi Medical Advisory Board. Dr. Mack is Director of Cardiovascular Research and Cardiovascular Medicine of the Heart Hospital Baylor Plano and Director of Cardiovascular Surgery for the Baylor Healthcare System. He is considered to be the most noted authority on the emerging field of transcatheter valves. [Read More.](#)

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.](#)



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