Although biodegradable materials have been used in medicine for several decades, these materials only recently have been utilized for pediatric transcatheter and surgical vascular and cardiac devices. Most devices used to repair congenital heart lesions only need to serve as temporary scaffoldings; ideally, they would ultimately disappear.

Biodegradable implants have many potential advantages over conventional devices. The interest in these materials for pediatric applications is primarily to accommodate growth. Lesions such as coarctation of the aorta and pulmonary artery stenosis could be temporarily augmented with a bioresorbable stent, allowing time for remodeling. As the patient grows and the vessel regains adequate functionality, the stent is slowly resorbed. Eventual complete resorption of the stent avoids the complications associated with traditional stents and eliminates the possible need to remove the device in the future.

Biodegradable implants for congenital heart patients can also facilitate other interventions at the same site. Biodegradable stents and devices will completely avoid these “full metal jacket” situations and may even preserve side branches near the site of intervention. These devices also will allow for improved radiographic imaging of lesions with MRI or CT.

“Biodegradable implants have many potential advantages over conventional devices. The interest in these materials for pediatric applications is primarily to accommodate growth.”

Reduction or avoidance of late stent restenosis has been ascribed, at least to some degree, to inflammation around metallic struts after coronary stenting. Replacement of the conventional metallic scaffold with an absorbable biopolymer, therefore, theoretically should decrease the rate of restenosis. This has been the impetus for the maturation of biodegradable stent technology and currently a variety of biodegradable coronary stents are now being tested in the adult population. As many bioresorbable stents are embedded with drug-eluting agents, they may even provide an opportunity to improve results in stenting difficult lesions such as pulmonary vein stenoses.
SIZING UP THE FUTURE

X™ Line PTV Balloon Dilatation Catheters
Braided inner tubing and radiopaque marker bands for maintaining strength & trackability

PTS® Sizing Balloon Catheters
For accurate measurement of selecting the appropriately sized occluder device

NuCLEUS-X™
PTV Balloon Dilatation Catheters
Variable waist expansion in the center of the balloon for accurate placement

B.BRAUN
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
Tel: 1-877-VENA CAV (836-2228)
Fax: 610-266-3982

www.bisusa.org
Biodegradable Stents

Biodegradable stents have been the most heavily investigated biodegradable cardiovascular devices to date. These devices have been hypothesized to cause a decreased incidence of late thrombosis, since they are eventually completely resorbed. The new generation of fully absorbable stents will, hopefully, minimize or completely eliminate late restenosis.

Like other drug-eluting stents (DES), biodegradable stents have the ability to deliver antiproliferative medications, such as sirolimus, directly to the site of disease. In the pediatric population, such devices may be particularly valuable for systemic or pulmonary vein stenting, as restenosis in this setting is extremely common.

Several biodegradable stents that have undergone clinical trials are discussed below (Table 1).

**Igaki-Tamai Stent**

The Igaki-Tamai stent was the first absorbable stent to be implanted in a human. It is made from poly(L-lactic acid) (PLLA). Strut thickness and vessel coverage by the struts both are larger than conventional metal stents (Figure 1a). Absorption is by bulk erosion and results in release of lactic acid, which is metabolized through the Krebs cycle.

A first-in-man prospective nonrandomized clinical trial of the stent was performed in 50 patients with a low complication rate. Although no further human coronary implants have been performed with this stent, it is being explored for peripheral applications and is clearly the predecessor to the current generation of coronary and peripheral biodegradable stents.

**REVA Stent**

The REVA stent is made from an absorbable tyrosine-derived polycarbonate polymer, configured in a slide and lock (ratchet) structure that allows for expansion without deformation (Figure 1b). This design may allow for increased radial force in stents designed for pulmonary artery and coarctation stenting. The RESORB first-in-man trial was a prospective nonrandomized safety study with a non-drug-eluting version of the REVA stent. Poor outcomes were noted with higher-than-anticipated target lesion revascularization due mainly to reduced stent diameter. A subsequent iteration of this stent, the ReZolve stent, includes an antiproliferative agent and soon will be undergoing clinical testing in the RESTORE trial.

![Figure 1: Biodegradable Stents. (a) The Igaki-Tamai stent, (b) the REVA stent, (c) the BTI Stent.](image-url)
BTI Stent

The BTI stent is a bioabsorbable sirolimus-eluting stent. This device incorporates a polymer backbone made from repeating salicylate molecules (Figure 1c). Resorption of the device releases salicylic acid, which is anticipated to decrease the inflammation associated with PCI. The Whisper first-in-man trial of patients implanted with the BTI stent showed higher-than-expected neointimal hyperplasia. Thus, the design is currently being revised to include thinner struts, decreased wall coverage, and a higher dose of sirolimus.

BVS Everolimus-Eluting Stent

The Bioresorbable Vascular Scaffold (BVS) everolimus-eluting stent is the first biodegradable stent to have comparable clinical and imaging outcomes to metallic DES 2 years after implantation (Figure 2a). The BVS stent is composed of a PLLA backbone with a coating of poly(D,L-lactic acid) (PDLLA) and the antiproliferative drug everolimus. A larger version of this stent – possibly one designed for peripheral interventions – could be the first stent widely used for palliation of congenital heart disease.

The ABSORB trials studied two different revisions of the stent. The ABSORB cohort, a first-in-man trial, was a prospective nonrandomized study of BVS stent revision 1.0. At 3 years post-implantation the ischemia-driven major adverse cardiac event rate was very favorable and there were no stent thromboses. No vessel shrinkage was seen at 6 months; however, angiographic late loss was similar to some metallic DES (Figure 3). Despite this shrinkage, the stent resisted negative remodeling well. In fact, between 6 months and 2 years lumen enlargement was detected. Vasoactivity in the stented segment was also noted in the small number of patients who were tested. These vessels showed vasoconstriction induced by methylergonovine maleate and vasodilatation induced by nitroglycerin. This observation suggests that the return of a physiologic response to vasoactive stimuli and the potential for arterial dilation in response to local ischemia is possible with bioresorbable stents.

The ABSORB cohort B trial is a prospective nonrandomized study of BVS stent revision 1.1. Based on results seen with BVS 1.0, modifications were made to maintain the mechanical integrity of the stent up to 6 months with the goal of reducing scaffold shrinkage and eventual late luminal loss, and to reduce acute and late recoil. The overall performance of BVS 1.1 at 6 months was significantly improved over BVS 1.0.
A perfect melody of compassionate hearts, innovative minds and skilled hands.

Melody®
TRANSCLATHETER PULMONARY VALVE (TPV) THERAPY

Worldwide, over 3,000 congenital heart disease patients have benefited from Melody TPV therapy. We remain committed to providing innovative options for your clinical management of these patients over their lifetime.

Visit www.Melody-TPV.com and restore hope for your patients.

Indications: The Melody TPV is indicated for use in a dysfunctional Right Ventricular outflow Tract (RVOT) conduit (≥16mm in diameter when originally implanted) that is either regurgitant (≥moderate) or stenotic (mean RVOT gradient ≥35 mm Hg).

Contraindications: None known.

Warnings/Precautions/Side Effects:
- 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: 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, and pain at the catheterization site.
- Potential device-related adverse events that may occur following device implantation include: stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, and hemolysis.
- For additional information, please refer to the Instructions for Use provided with the product or call Medtronic at 1-800-328-2516 and/or consult Medtronic’s website at www.medtronic.com.
- Melody and Ensemble are trademarks of Medtronic, Inc.
- Humanitarian Device. Authorized by Federal law (USA) for use in patients with a regurgitant or stenotic Right Ventricular Outflow Tract (RVOT) conduit (≥16mm in diameter when originally implanted). The effectiveness of this system for this use has not been demonstrated.

© Medtronic, Inc. 2012 UC UC201205149 EN

Melody® Transcatheter Pulmonary Valve
Ensemble® Transcatheter Valve Delivery System
The ABSORB EXTEND trial is a single-arm study currently enrolling patients throughout Europe, Asia, Canada, and Latin America. The trial will include patients with more complex coronary artery disease than those in the previous ABSORB cohorts.

**Biocorrodible Materials**

Corrosion is a design consideration that must be taken into account for any metallic implant. It can lead to premature device failure and can affect biocompatibility by releasing metal ions/particles. While typically a hindrance that must be carefully combated, this property is now being investigated for positive uses. Biocorrodible metallic implants have the mechanical advantages of stainless steel, while also incorporating the benefits of a temporary scaffold like the previously described biodegradable devices.

**Absorbable Magnesium Stent**

The absorbable magnesium stent (AMS) was the first metallic bioabsorbable stent to be implanted in a human. The device is laser cut from tubular magnesium WE-43 (Figure 4). Arterial wall coverage is comparable to that of conventional BMS. Initial radial strength is similar to stainless steel stents. It is radiolucent and lacks radio-opaque markers. Absorption is by surface erosion, so strut thickness decreases as the stent is absorbed.

The PROGRESS-AMS trial was a prospective nonrandomized study of 63 patients with simple de novo native coronary artery lesions in whom magnesium stents were implanted. Angiographic results immediately after implantation were similar to those seen with conventional BMS. Radial support, however, was lost very early, and accordingly there was a high restenosis rate of almost 50% at 4 months.

While the AMS stent is clearly not ideal for use in coronary applications, it may be well suited for pediatric applications. The AMS was successfully implanted in two newborns for emergency off-label uses. Its first use was in a 6 week-old female baby who had been born prematurely at 26 weeks gestation. In this case, the AMS was used to correct an accidental ligation of the left pulmonary artery. At 5 months, after the stent had been completely degraded, left lung perfusion remained adequate. The second pediatric application of the AMS was in a 3 week-old male baby with a postsurgical long-segment recoarctation. This patient also did well with the stent and did not require further intervention until 3 months later.
Summary

Because of their use in coronary stents, biodegradable polymers have been developed for use in medical devices. Biodegradable stents and closure devices are in clinical trials. The chemistry and mechanical properties of these materials are well known. It is possible to engineer devices with very predictable degradation times, biology and radial force. Biodegradable materials are likely to replace many of the conventional metals in the current surgical and transcatheter pediatric devices. In general, the ideal material will always need to be non-toxic, non-thrombogenic, and will need to have appropriate strength, elasticity, and degradation rate. Because the ideal biodegradable material will need to be tailored from device to device, there is unlikely to ever be one “ideal” biodegradable material. Nonetheless, many challenges remain for the development of devices in the pediatric community. A wide range of potential biodegradable devices can be realized in the pediatric community if the significant biological, regulatory, and financial issues in bringing new pediatric biodegradable devices to market can be overcome.

REFERENCES


Biographical Sketch of Principal Author

Daniel S. Levi, MD is an Interventional Pediatric Cardiologist who has served on the UCLA School of Medicine faculty since 2003. His primary clinical role involves the use of catheters and devices to help children with congenital heart disease. He is internationally known for his laboratory and clinical research. He is also the director of the adult congenital interventional catheterization program and director of the fellowship program in pediatric cardiology, and is a member of the pediatric heart transplantation team.

Dr. Levi earned his B.S. in Biology from Stanford (1992) and his M.D. from UCSF (1997). He was in the Medical Scientist Training Program at UCSF from 1992-1995. After Pediatrics internship and residency were completed at UCSF, Dr Levi completed his pediatric cardiology fellowship and pediatric interventional cardiology subspecialization at UCLA. He is board certified in Pediatric Cardiology by the American Academy of Pediatrics, he is the recipient of the Gerd Hausdorf Scientist Training Program at UCSF (1997). He was in the Medical Scientist Training Program at UCSF, Dr. Levi completed his pediatric cardiology fellowship and pediatric interventional cardiology subspecialization at UCLA. He is board certified in Pediatric Cardiology by the American Academy of Pediatrics, he is the recipient of the Gerd Hausdorf Pediatric Research Award and is director of the Congenital Program of the Society for Cardiac Angiography and Interventions (SCAI) annual program. His laboratory research centers on the development of novel pediatric stents and other devices made from nano-synthesized “smart” materials such as thin film nitinol. Dr. Levi is been the recipient of grants from the National Institute of Health (NIH), National Science Foundation (NSF), the American Heart Association (AHA), the Paige Foundation and multiple other foundations and agencies.

Coming in the August issue

FDA Clearance of Cardiac Devices for Children: A Primer and Call to Action
By Robert H. Beekman, III, MD
The Pediatric/Congenital Interventional Cardiology Early-Career Society (PICES) held its inaugural breakout sessions at both the PICS/AICs and SCAI conferences in 2012. PICES was established in July of 2011, and is currently a task force under the umbrella of the Congenital Heart Disease council of SCAI. The group was established to support and advance the careers of young interventionalists in structural heart disease. The PICES group has several goals including: clinical education, multi-center research collaboration, improving transcatheter treatment of congenital heart disease in developing countries, and creation of a social network. The PICES executive board is composed of president Daniel H. Gruenstein, MD, from University of Minnesota, Amplatz Children’s Hospital; clinical chair Brent M. Gordon, MD, from Loma Linda University Children’s Hospital; research chair Michael A. Bingler, MD, from Children’s Mercy Hospital, Kansas City; and secretary John S. Lozier, MD, from Pediatric Cardiology PC, Mercy Medical Center, Des Moines, Iowa.

The breakout session at PICS began with a welcome from Dan Gruenstein, followed by a guest lecture from Henri Justino, MD, from Texas Children's Hospital entitled, “Creating a Career Niche-Revascularization of Thrombosed Vasculature in Pediatric Patients.” Dr. Justino profiled several truly remarkable outcomes in neonates and children with life-threatening vascular thromboses and discussed several modalities available to treat this difficult subset of patients. The talk concluded with suggestions and philosophies that young interventionalists may utilize to help establish a career niche for themselves. This was followed by case presentations from Bryan Goldstein, MD, and Nathaniel Taggart, MD. Dr. Goldstein discussed a case of severe aortic coarctation with associated aneurysmal involvement of the left subclavian artery that was treated with a covered CP stent, while Dr. Taggart presented an example of transcatheter Fontan completion. The cases generated healthy discussion from the audience and lent themselves to numerous teaching points.

The PICES group has several goals including: clinical education, multi-center research collaboration, improving transcatheter treatment of congenital heart disease in developing countries, and creation of a social network.”

The PICS meeting also featured the inaugural selection of the Young Leadership Program for early career interventionalists. Christopher Petit, MD, from Texas Children’s Hospital and a PICES member, was selected as the initial recipient. Dr. Petit was designated a faculty member for the meeting and had the opportunity to chair several sessions throughout the meeting while participating with the other faculty. PICES was very involved in creating the Young Leader Program and congratulates Dr. Petit on all of his accomplishments.

The PICES group also had a significant presence at SCAI that culminated in a breakout session on Friday afternoon. The session began with a talk by Lynn Peng, MD, from Lucille Packard Children’s Hospital at Stanford University on the Emerging Leadership Mentoring (ELM) Program. The ELM program, of which Dr. Peng is currently the only pediatric interventional representative, was created by SCAI to pair young interventionalists with senior mentors, with the ultimate goal of training younger faculty to become the leaders of tomorrow in the treatment of structural heart disease. The next series of ELM applications will be due in the fall of 2012. Please see the SCAI website for further information.

The breakout session continued with several interesting case presentations. Jeffery Zampi, MD from University of Michigan discussed transcatheter Fontan fenestration creation, Luke Lamers, MD from Phoenix Children’s Hospital showed a coronary artery fistula case with some bonus operator chest pain, and Michael Bingler, MD discussed the utility of balloon angioplasty in the treatment of discrete subaortic membrane. After a close vote, Dr. Lamer’s case was deemed the best presentation and he received the inaugural PICES case presentation award, which he will watch over until the next meeting. Congratulations Dr. Lamers for a job well done.

The PICES membership is now approaching 80 people with representatives from the United States and several other countries around the world. We plan to have a link to our website operational within the next few months and are excited to initiate some multi-center studies before the end of summer. The next formal meeting will be in January 2013 at PICS in Miami. Nominations for future board members will be accepted at that time with elections to follow at SCAI in Orlando. For further information or to be added to the PICES list-serve please contact John Lozier at: john.lozier@gmail.com.
The Children’s Cardiomyopathy Foundation’s Grant Announcement

The Children’s Cardiomyopathy Foundation (CCF) is pleased to announce the availability of one-year research grants for studies focused on pediatric cardiomyopathy. The purpose of CCF’s Annual Research Grant Program is to advance knowledge of the basic mechanism of the disease and to develop more accurate diagnostic methods and improved therapies for children affected with cardiomyopathy. Please visit CCF’s website www.childrenscardiomyopathy.org (click on Research/Grants & Awards) for guidelines and to view past grant awards.

Eligibility: Principal investigator must hold an MD, PhD or equivalent degree and reside in the United States or Canada. The investigator must have a faculty appointment at an accredited US or Canadian institution and have the proven ability to pursue independent research as evidenced in publications in peer-review journals.

Funding: Funding is available in the range of US$25,000 to US $50,000 for one year of total direct costs. Following the completion of the proposed study, a second year of funding may be an option for relevant study extensions.

Application Process: CCF grant guidelines and application forms are downloadable off the website at www.childrenscardiomyopathy.org/site/grants.php. The 2012 deadline for application submission is Friday, September 7, 2012 with final award decisions to be made by January 2013.

Selection Process: Grant award decisions are made through a careful peer-review process led by CCF’s Medical Advisors and reviewed by CCF’s Board of Directors. Scientific excellence and relevance to primary forms of pediatric cardiomyopathy are the main criteria for selecting research projects to support.

Contact: Lisa Yue, President, Children’s Cardiomyopathy Foundation; 866-808-CURE ext. 901 or lyue@childrenscardiomyopathy.org.

Medical News, Products and Information

ACC President Comments on Congress’s Vote Passing FDA User Fee Bill

“The American College of Cardiology supports Congress’s decision to reauthorize FDA’s user fees for devices and prescription drugs. Appropriate funding allows the FDA to provide oversight and to review and approve new treatments in a timely manner,” said ACC President William Zoghbi, MD, FACC in a statement.

Transplant Cardiologist
Assistant or Associate Professor
(In Residence, Adjunct, or Clinical)

THE UNIVERSITY OF CALIFORNIA, SAN DIEGO, DEPARTMENT OF PEDIATRICS (http://www-pediatrics.ucsd.edu) AND CHILDREN’S SPECIALISTS OF SAN DIEGO (http://childrensspecialists.com) are committed to academic excellent and diversity within the faculty, staff, and student body and are jointly recruiting a Medical Director of Cardiac Transplantation for the unified Division of Pediatric Cardiology at Rady Children’s Hospital, San Diego. This 220-bed facility serves as a major regional tertiary care hospital for children and is the major teaching facility for the Department of Pediatrics of the UCSD School of Medicine.

The Director position is a unique opportunity to develop an exceptional Cardiac Transplantation Program in San Diego. The successful candidate must have training and experience in a UNOS certified pediatric cardiac transplant center and should possess the qualifications for academic appointment at the rank of Assistant or Associate Professor. The academic series will be determined based on the background and qualifications of the successful candidates. Candidates must be Board Certified in Pediatric Cardiology and licensed or licensable to practice medicine in the State of California. This appointment will require demonstrated administrative capabilities, excellent skills in clinical care and teaching, and research accomplishment.

The Division provides a full range of Pediatric Cardiology services. It currently has six pediatric cardiologists, two cardiothoracic surgeons, and an ACGME approved fellowship program. The Division supports a program with approximately 400 surgical procedures yearly. Extensive opportunities to perform clinical, epidemiologic or basic science research exist at UCSD and Children’s Hospital, San Diego.

Salary commensurate with qualifications and based on University of California pay scales.

Applications received by July 1, 2011 or until the position is filled, will receive full consideration.

Please send Curriculum Vitae, the names and e-mail addresses for three references, and a personal statement summarizing your demonstrable commitment to promoting and enhancing diversity and equality, or your potential to make contributions in the field.

Please apply to UCSD’s application collection system, Recruit at: https://apol-recruit.ucsd.edu/apply (preferred method) or by e-mail to: John Moore, M.D. - jmoore@rchsd.org or by mail to: 3020 Children’s Way, MC 5004 San Diego, CA 92123

UCSD is an Affirmative Action/Equal Opportunity Employer with a strong institutional commitment to excellence through diversity.

"Innovative treatments have played a pivotal role in reducing deaths due to cardiovascular disease in recent decades. It is important to support a system that encourages the development of new medications and devices. The College commends Congress for taking steps to improve post-market surveillance of medical devices and increase the use of data registries to improve patient care and device safety. The agreement is excellent for patient health, the future of medical science and continued advances in the field of cardiology."
Pediatric Cardiac Critical Care Physician
Chicago Area

Advocate Medical Group (AMG), a physician-led multi-specialty team of over 900 physicians, seeks an experienced board certified/board eligible Pediatric Cardiac Critical Care specialist to join The Heart Institute for Children at Advocate Hope Children's Hospital. Located in suburban Chicago this unique, thriving, dynamic clinical practice includes 16 Pediatric Cardiologists.

Position includes the opportunity to educate residents and fellows from multiple area institutions. The program has over 8000 clinic visits per year, 4500 on-site echocardiograms, 300 cardiac catheterizations, and 350-450 surgeries/year at our main campus alone. Our surgical group averages 700+ surgeries per year at multiple sites. Our outcomes are among the best in the nation. We have an accredited cardiology fellowship program with 6 fellows. We have a dedicated 9 bed Pediatric Surgical Heart Unit, an additional 15 bed Pediatric Intensive Care Unit, and a 4 bed step down unit.

Candidates must be BC/BE in Pediatric Cardiology or Pediatric Critical Care. Board Certification in both subspecialties is preferred but not required. This is an outstanding opportunity for the right individual who is interested in both cardiology and critical care. Additional training can be provided on-site dependent upon needs (with consideration for a fourth year training period for recent graduates). Numerous opportunities for research and professional growth exist. Excellent benefit package is offered.

It goes without saying that Chicago is indeed a wonderful place to live. It is a beautiful city that boasts a diverse cultural and historic background.

Interested candidates should send their resume to:

Donna C. Kutka, R.N., M.S.
Director, Physician Recruitment
708.684.5009
donna.kutka@advocatehealth.com

Andrew Van Bergen, MD
Director, Pediatric Cardiac Critical Care
The Heart Institute for Children
Advocate Hope Children’s Hospital

The American College of Cardiology is transforming cardiovascular care and improving heart health through continuous quality improvement, patient-centered care, payment innovation and professionalism. The College is a 40,000-member nonprofit medical society comprised of physicians, surgeons, nurses, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care. More information about the association is available online at www.cardiosource.org/ACC.

The China California Heart Watch Looking for Participants for Several Internships

The China California Heart Watch is a not-for-profit public charity whose missions include medical research, teaching and clinical care in rural Yunnan Province, China. They invite students, particularly those interested in future careers in medicine, public health or related fields to participate in one of several internships this year. These internships involve first-hand exposure to medical problems – particularly cardiovascular problems – and care in impoverished communities, where access to high-quality medical services is very limited.

Objective: The objective of the internship program is to create awareness of the problems of healthcare in rural China, and encourage students to pursue a career in public health and/or medicine focused on the underserved in developing countries.

Students: China Cal will have three internship programs for the remainder of 2012. Each is open to 5-15 students. Candidates will be interviewed to determine suitability. To intern at China Cal, you must have an interest in pursuing a career involving public health or health-related care in underserved populations. Some knowledge of Mandarin is desirable, although this is not a strict requirement.

August-December 2012 upcoming Internship dates: August 4th – 26th; September 1st – 23rd; and December 14th – 30th.

Programs: Upon arrival in Yunnan (Kunming or Dali), students will undergo three days of training and certification. Students will learn about how to assist in a program focuses on screening and treatment of adults and school children living in rural towns, who have high blood pressure and heart disease. We then travel to surrounding areas to begin clinics among rural populations. Interns will travel and work alongside with faculty members from Kunming and Dali Universities, as well as receiving training from Dr. Robert C. Detrano, MD, PhD, Professor of Radiological Sciences at the University of California at Irvine and a board-certified cardiologist. Interns will also have the opportunity to help conduct a clinical research program while staying in villages in Yunnan. To read experiences of recent interns, please visit: www.chinacal.org.

Logistics: Students will travel to Yunnan Province, where several China Cal staff will meet the students at the airport. China Cal will arrange all accommodations, as well as any local travel (by bus, train or air as needed). Students will be living in hotels, community centers and, occasionally while in remote areas, the homes of farmers.

Archiving Working Group
International Society for Nomenclature of Paediatric and Congenital Heart Disease
ipccc-awg.net
Women Undergoing TAVI Using the Medtronic CoreValve® System Have Similar Survival Benefit as Men

Rigorous Trial Design and Monitoring Provides New Insight to Outcomes for Men and Women with Aortic Stenosis

PARIS--(BUSINESS WIRE)--May. 17, 2012-- Medtronic, Inc. (NYSE: MDT) has announced new results from the Medtronic CoreValve ADVANCE Study, which found that women and men benefitted similarly from the Medtronic CoreValve® System. The study, presented at EuroPCR 2012, evaluated patients who were at high-risk for surgical aortic valve replacement. The Medtronic CoreValve System is currently limited to investigational use in the United States.

The gender analysis, a secondary-endpoint evaluation in the real-world CoreValve ADVANCE Study, found that survival rates were nearly identical between genders, with no statistical differences in 30-day and 6-month all-cause mortality, cardiovascular mortality or the 30-day MACCE endpoint (Major Adverse Cardiac & Cerebrovascular Events, a composite of all-cause mortality, myocardial infarction, emergent cardiac surgery or percutaneous re-intervention, and stroke).

Overall, patients experienced low 30-day stroke rates (2.9%), with the combined stroke rates of major and minor strokes being very low (major 1.2%, and minor 1.7%). However, female patients experienced a statistically higher rate of strokes (4.4% vs. 1.4%; p-value <0.01), major vascular complications (14.1% vs. 7.1%; p-value <0.01) and major bleeding (5.0% vs. 3.1%; p-value <0.01). For minor stroke between genders, and for major strokes between genders, differences were not significant, though there was a trend for women to have more minor strokes than men.

"This study is an important contribution to the growing base of research on TAVI, and sheds light on the unique needs for managing severe aortic stenosis in women," said Patrizia Presbitero, MD, Director of Interventional Cardiology at Hospital Humanitas Rozzano in Milan and an investigator in the CoreValve ADVANCE Study, and a professional development co-chair and member of the Leadership Council of WIN (Women in Innovations/Society for Cardiovascular Angiography and Interventions, SCAI). "We need to know more about gender differences to effectively treat patients with heart disease in a more specific way, taking into account those differences that can affect treatment."

Women and men benefitted similarly from the CoreValve System even though women (51% of patients) and men (49% of patients) had different risk profiles. Specifically, at the time of enrollment, women as compared to men were:
- Older than males (82.2 years vs. 79.9 years; p-value <0.001);
- Had higher average gradients (47.6 vs. 43.5 mmHg; p-value <0.001) and peak gradients (79.0 vs. 72.5 mmHg; p-value <0.001), a measure of blood flow across the valve;
- Had less coronary artery disease (46% vs. 70%; p-value <0.001); and
- Were prescribed fewer cardiovascular medications, including cholesterol-lowering medications (p-value 0.002) and statins (p-value 0.013).

"The robust ADVANCE trial provides a compelling discovery that the CoreValve System is an excellent therapeutic option for both men and women, and it helps us begin to consider how men and women
The ADVANCE study is one of the largest multicenter transcatheter aortic valve implantation (TAVI) trials to date, with 1,015 patients consecutively treated at 44 experienced TAVI centers in 12 countries. Clinical endpoints were calculated according to Valve Academic Research Consortium (VARC) standardized definitions. All data were independently monitored, all adverse events related to the primary endpoints were adjudicated by an independent Clinical Events Committee (CEC) consisting of experienced cardiac surgeons and interventional cardiologists, and all cerebrovascular events (including stroke and other events) were adjudicated by an independent neurologist using neuroimaging and systematic NIH Stroke Scale assessments.

The Medtronic CoreValve System received CE (Conformite Europeenne) Mark in 2007 for the treatment of patients deemed at high or extreme risk for surgery. Since then, it has been implanted in more than 27,000 patients in more than 50 countries outside the US. The CoreValve System is available in three sizes (26mm, 29mm and 31mm), and is the only transcatheter aortic valve implantation system approved for direct aortic or subclavian access. For more information visit Medtronic, Inc. at www.medtronic.com.

Worldwide, approximately 300,000 people have been diagnosed with symptomatic, severe aortic stenosis, and approximately one-third of these patients are deemed at too high a risk for open-heart surgery (Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Bernard Iung et al. Eur Heart J (December 2005) 26(24): 2714-2720.)

Pediatric Cardiologists

The Division of Pediatric Cardiology at the University of Utah School of Medicine and based at Primary Children’s Medical Center is recruiting board eligible/board certified pediatric cardiologists with major interests in 1) Heart Transplant/Heart Failure and 2) Adult Congenital Heart Disease. The Pediatric Cardiologists will join a 25-member division and established Heart Transplant and Adult Congenital Heart Disease Programs. There will be protected time and mentoring available within the Division for clinical research. The Division has a very active clinical research program and is one of the participating centers in the Pediatric Heart Disease Clinical Research Network funded by the NIH.

The successful candidates will receive a faculty appointment at the University of Utah on the clinical or tenure track. Rank will be dependent on qualifications. The University of Utah offers an excellent benefits package that includes 20.2% retirement contributions that vest immediately, and excellent health care choices. Salt Lake City is a diverse major metropolitan area with outstanding restaurants, arts and music. Recreation is unparalleled with 6 ski resorts within 30 minutes and 5 national parks within an easy 4 hour drive. It is serviced by a convenient international airport with direct flights to most major cities.

To read more about each opportunity and to apply, please go to:

Heart Transplant/Heart Failure Position
http://utah.peopleadmin.com/postings/13074

Adult Congenital Heart Disease Position
http://utah.peopleadmin.com/postings/8177

For additional information, please contact Lloyd Y. Tani, MD: lloyd.tani@imail.org.

The University of Utah Health Sciences Center is an equal opportunity employer and educator. Minorities, women and persons with disabilities are strongly encouraged to apply. Veterans preference. Reasonable accommodations provided. For additional information: http://www.regulations.utah.edu/humanResources/5-106.html.

The University of Utah Health Sciences Center is a patient focused center distinguished by collaboration, excellence, leadership, and respect. We value candidates who are committed to fostering and furthering the culture of compassion, collaboration, innovation, accountability; diversity, integrity, quality, and trust that is integral to the mission of the University of Utah Health Sciences Center.
Watch over 300 Live Case Videos, Presentations and Workshops Online from Leading Congenital and Structural Medical Meetings from Around the World - www.CHDVideo.com

- Transseptal Access Workshop from Cook Medical
- Workshop: Past Present and Future of Pediatric Interventions Cardiology - St. Jude & AGA Medical
- Symposium on Prevention of Stroke Clinical Trials at the Heart of the Matter - WL Gore Medical
- Imaging in Congenital & Structural Cardiovascular Interventional Therapies
- Morphology of The Atrial Septum
- Morphology of The Ventricular Septum
- Pre-Selection of Patients of Pulmonic Valve Implantation and Post-Procedural Follow-up
- Echo Paravalvular Leakage (PVL)
- ICE vs TEE ASD Closure in Children - PRO & CON ICE
- 3D Rotational Angiography - Why Every Cath Lab Should Have This Modality
- PICS Doorway to the Past - Gateway to the Future
- Follow-up From PICS Live Cases 2010 Presentation
- Intended Intervention - Transcatheter TV Implantation - Live Case
- Intended Intervention - LAA Closure Using Amplatzer Cardiac Plug Under GA & Real Time 3D
- Provided Intervention - LPA Stenting / Implantation of a Sapien Valve
- Intended Intervention - PV Implantation
- Intended Intervention - COA Stent Using Atrium Advanta V12 Covered Stent - Live Case
- Intended Intervention - ASD Closure - Live Case
- Intended Intervention - Transcatheter VSD Device Closure - Live Case
- Intended Intervention - COA Stenting Using Premounted Advanta V12 Covered Sten - Live Case
- Stunning Revelation - The Medical System is Changing - What Can You Do To Show Patients That Your Practice Does It Right? Patient Perspective
- Percutaneous Paravalvular Leak Closure Outcomes
- Intensive Management of Critically Ill Infants Undergoing Catheterization
- Off Label Device Usage - Careful!
- Evolving Hybrid Programs Communications is the Key
- Anti-Coagulation in Pediatric Interventions - Evidence Please! Are we Flying Blind?
- Shaping Your Structural Heart Interventional Career: How Do I Get the Necessary Training and Start a Program?
- Closure of Post-Infarct VSDs Limitations & Solutions
- Percutaneous Interventions During Pregnancy
- Percutaneous PVL Closure Techniques & Outcomes
- Percutaneous Therapy for MR
- Update on Percutaneous Aortic Valve Replacement: Time to Open the Flood Gates?
- 2011 PICS/AICS Achievement Achievement Award Presented To Horst Sievert, MD.
- The Cases I Learn The Most From
- If I was Starting Now I Would... Contemplating the Question.
- 10 Tips for the Trainee
- The Perfect CV
- Why I Left The Cath Lab
- Intended Intervention Occlude Right High Flow Superior Segment PAVM
- Intended Intervention Edwards Sapien XT Transcatheter Heart Valve - 3D Guidance - Live Case
- Closure of the Silent PDA - Indicated or Not
- Transcatheter Tricuspid Valve Replacement
- Recommendations For Device Closure of MVSDs
- Intended Intervention Diagnostic Angio/First Intervention Occlude Left Lower Lobe - Live Case
- Intended Intervention PFO Closure using Gore Helex Septal Occluder Under GA and TEE Guidance - Live Case
- Pulmonary Valvuloplasty - Pulmonary Oedema Presentation
- Intended Intervention LAA Closure Using the Amplatzer Cardiac Plug - Live Case
- Transcatheter Alternatives in Sick Neonates With Coartation of the Aorta; Balloon Angioplasty vs Surgery for Native Coartation of the Aorta in Newborns
- and many more.... Plus, live cases from other major meetings

Presented by CONGENITAL CARDIOLOGY TODAY

TINY HEARTS inspired

HYBRID LABS WITH ACCESS FOR BIG TEAMS.

Fixing a heart from birth through adulthood takes big teams working together. So we examined the needs of leading clinicians when designing our hybrid solutions. The result: our Infinix™-i with 5-axis positioners and low profile detectors, stays out of the way, but right where needed, providing the best possible access to patients. To lead, you must first listen. medical.toshiba.com