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Computer Modeling and Virtual Reality for Stent Development and Case Planning in Congenital Heart Disease

Gareth J Morgan, MD & Jenny Zablah, MD

Introduction

Device development, pre-clinical, and clinical testing have traditionally relied heavily on iterative design, interrupted by prototype development and testing, followed by animal testing and then heavily regulated human implantation trials.[1] Although the objective of such labor intensive processes has been to produce a safe, marketable and efficient end-product, these regulatory mantras have continued despite the explosion in computer-based simulation, mathematical modelling and virtual and augmented reality environments through which many key device characteristics can be tested.[2]

Some of these computer-generated environments can also be used to perform risk-free trial and error device implantation; guiding the clinical team towards a safer and more efficient human implantation and minimizing resource use by coning down on the number of device sizes and variations which may need to be made available for complex cases.

The need for improvement in the balloon-expandable covered stent portfolio for the treatment of Congenital Heart Disease is clear. The covered CP stent has facilitated improved procedural safety and broadened the range of defects which can be treated percutaneously.[3,4] However, the intrinsic drawbacks with this stent continue to cause uncertainty and concern during stent selection and deployment, particularly with respect to shortening at larger diameters. After brainstorming alterations to the design and manufacturing some initial prototypes, we used finite element analysis (FEOPS Inc. Belgium) and extensive bench-testing to create new shortening charts and also to confirm that radial strength, fracture resistance, apposition characteristics and recoil were not negatively affected by the re-design.[5,6] Designs for various lengths in 8Zig and 10Zig confirmations were then evaluated in conjunction with the FDA, leading to approval for use in Coarctation and RVOT stenting just one year after initial data submission.

The G-ARMOR stent represents a significant redesign of the Cheatham-Platinum (CP) Stent (NuMED Inc, Hopkinton NY), maintaining the traditional benefits of the covered CP whilst significantly decreasing shortening and allowing controlled flaring at the ends through its combination of larger and standard sized cells **(Figure 1)**. The redesign was inspired by two questions asked by the late Doug Villenave, Chief Engineer at NuMED. What performance characteristics about the CP stent are undesirable? What achievable physical changes could be made to the stent to address some of the undesirable behaviour? We decided that reducing the degree of stent shortening on large caliber dilation and improving the ability to predictably flare the ends of the stent across a range of diameters could be tackled by changing the configuration of the rows of Zigs at either end of the stent. Once we recognised that this change was achievable, we were able to produce prototypes with a rapid design hold.

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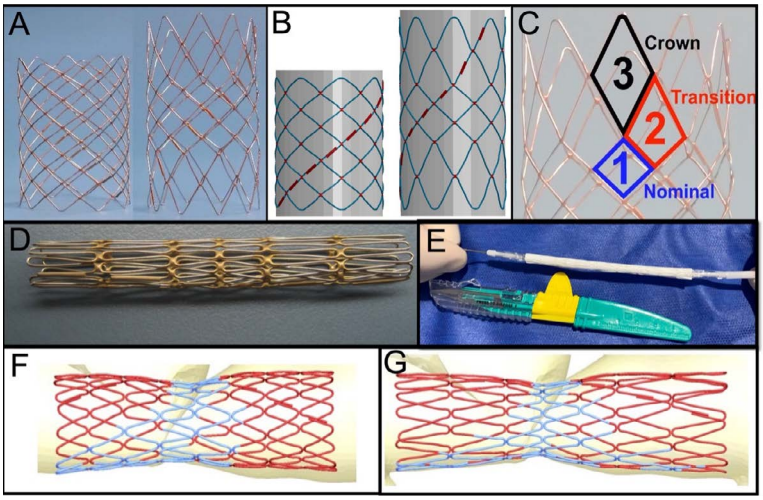

Figure 1 *Schematics and photography illustrating the changes made to create the G-ARMOR. Panel **A** Bare metal 10Zig versions of the original Cheatham-Platinum (CP) stent and the G-ARMOR stent. The difference in shortening between the stents is obvious and illustrated further in schematic panels **B** and **C**. Panel **C** illustrates how changing the length of the wires used to form the distal 2 rows of the stent, creates three different cell morphologies. The originally shaped "nominal" cell (1); the asymmetric "transition" cell (2) and the uniform but larger "crown" cell (3) are marked in panel **A, B, C**. The modification can also be seen in Panel **D**, showing a neutral, unboxed bare metal G-ARMOR stent. Panel **E** shows the covered version of the G-ARMOR, crimped on a BiB balloon and ready to implant. Panels **F** and **G** show FEA analysis of an 8Zig version of both the CP Stent, **F,** and a G-ARMOR, **G,** stent dilated on the same virtual balloon in the same simulated aortic coarctation. The decreased shortening experienced by the G-ARMOR is readily visible.*

The design, which uses a combination of different cell sizes to minimize shortening and allow controlled flaring of the proximal and distal ends while maintaining all the positive mechanical properties and familiar preparation and deployment processes is specifically aimed towards procedures where stent shortening is undesirable. Hence, coarctation of the aorta as well as stent implantation in preparation for percutaneous pulmonary valve placement are obvious use areas, as well as the growing body of evidence supporting percutaneous treatment of sinus venosus defects.

The first-in-man use of the G-ARMOR stent was performed at our institution in Denver in a 40-year-old male who was referred after a routine echocardiogram revealed a large superior sinus venosus defect with severe right ventricular and atrial enlargement. The patient had mild desaturation on exercise (90% on room air) and had noted increasing fatigue on exercise associated with the decrease in his oxygen saturations. He and his family had significant concerns regarding the need for an open-heart operation, and a particular desire to avoid an emergency procedure of any kind. He directed us to use any custom devices and experimental approaches which we felt would optimize the chances of success of a minimally invasive approach. The medical team had concerns that his particular anatomy may be worrying with respect to stent instability and embolization, which encouraged us to use a novel stent design rather than a regular CP covered stent. An ECG-gated cardiac CT scan was then used to create a 3D printed model to facilitate discussion with the patient and a virtual reality (VR) rendering of his heart to allow for both device selection and procedural simulation and preparation (**Figure 2**). STL (expand) files of the proposed stents can either be obtained under license from the manufacturers or can be created in-house. We create our own

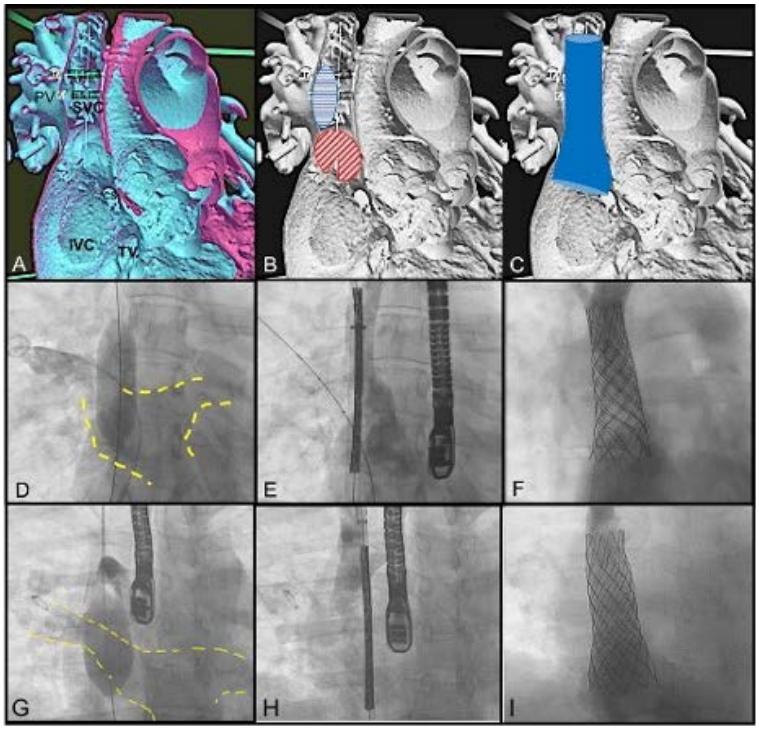

Figure 2 *G-ARMOR in SVASD. Panel **A** Pre-procedural planning using a 3D reconstruction in virtual reality using Elucis TM (Realize Medical, ON, Canada). Panel **B** highlights particularly relevant anatomy with the atrial communication overlayed by a red diagonal striped shape and the area of entry of the anomalous pulmonary veins highlighted by a blue horizontal overlay. Panel **C** is a mock-up of pre-procedural planning with the expected shape and position of the G-ARMOR stent (solid blue overlay) within the VR environment. A right pulmonary vein angiogram demonstrating anomalous drainage channeled behind the SVC into the LA (LA outline highlighted in yellow dashes). There is no PV flow obstruction with a 20mm balloon inflated across the defect, **D**. The 8.5cm long G-ARMOR 8Zig covered stent, mounted on a 9cm long BiB (20mm diameter) is seen in place with check angiography prior to deployment. An uninflated "rescue" balloon has been positioned in the right pulmonary veins, **E**. 3D-rotational angiogram after deployment and flaring of the inferior end of the balloon demonstrating satisfactory stent placement without evidence of a residual atrial shunt, **F**. Panels **G**, **H** and **I** show the same stages of imaging from patient 2. Here we did not opt to position the rescue balloon for pulmonary vein protection in the anomalous veins as we felt that the chances of obstruction in patient 2's particular anatomy were very low. IVC: Inferior Vena Cava; SVC: Superior Vena Cava; PV: Pulmonary Veins; CS: Coronary Sinus; TV: Tricuspid Valve orifice; LA: Left Atrium.*

STL files by performing a 3DRA of the device under scrutiny, then the 3D DICOM files can be imported into a variety of 3DD CAD software to produce an STL file (**Movie 1 VR Code**). The VR system used with this STL file is Elucis (Realize Medical) and can be used to virtually implant the stent and adjust to various sizes in various positions in the SVC RA junction. Using this tool or volumetric segmentation with software like VMersive (Movie 2 VR Code), we can confidently select a single stent length and diameter, tailored to the patient anatomy.

After IRB and FDA compassionate use approval, the patient was brought to the catheterization laboratory. The intervention itself was guided using a combination of Vessel Navigator (Philips Medical Systems, The Netherlands) fusion imaging, 3D transesophageal echocardiography and traditional angiography and fluoroscopy.

The procedural steps we use have been described by the team at Evelina London Children's Hospital, but with the addition of the CT fusion using Vessel Navigator (Philips medical systems, The Netherlands).[9,10,11] Access was gained in the LFV, the RFV and the RIJ with three 8French sheaths. The ACT was kept at >250 throughout the procedure. We fused the 3D rendering of the CT data set onto the fluoroscopic image, allowing guidance of the position of the testing balloons, wires and eventually the stent landing zone, minimizing fluoroscopic and angiographic acquisition (**Figure 2**).

Movie 1 QR Code
(scan or click to view)

Movie 2 QR Code
(scan or click to view)

Inflated Balloon Diameter	G-ARMOR 10Z 63 (Stent length after expansion) Percentage Shortening	CP 10Z 60 (Stent length after expansion) Percentage Shortening
26mm	(5.3cm) 15%	(4.8cm) 20%
28mm	(5. 1cm) 18%	(4.4cm) 28%
30mm	(4.9cm) 21%	(4.1cm) 33%

Table 1 *Shortening chart comparing the 10Zig 63mm G-ARMOR stent with the 10Zig 60mm CP stent. At larger diameters there is a significant improvement in the shortening behaviour of the G-ARMOR over the CP stent. By the time 30mm diameter is reached the G-ARMOR has lost a fifth of its length, whereas the CP has lost one third of its length. These figures where achieved under controlled circumstances in the manufacturers testing facility using BiB balloons.*

The LFV was used to perform a transeptal puncture in the Foramen Ovale, allowing unhindered access to the aberrant right-sided pulmonary veins before, during and after stent deployment. An externalized wire rail was achieved from RFV to RIJ over which balloon interrogation with a compliant 30mm diameter PTS sizing balloon (NuMED Inc, Hopkinton, NY) and then a 20mm Zmed balloon (NuMED Inc, Hopkinton, NY) was performed with simultaneous multimodality assessment of the pulmonary vein flow, the inter-atrial communication, and the SVC. These maneuvers ratified our choice of an 8.5cm long G-ARMOR 8Zig covered stent, mounted on a 9cm long x 20mm Diameter BiB (Numed Inc, Hopkinton, NY) (**Figure 1 and Figure 2**). Our preprocedural planning predicted that this stent would shorten to between 7.5cm and 8cm after flaring at the bottom (atrial) end (**Figure 2**). We used the entry of the azygous vein into the SVC as both an imaging marker and as a supportive structure into which to allow some flaring of the top cell of the stent, and we aimed to keep at least 1cm of stent below the superior crest of the interatrial septum to promote apposition and increase the chances of a complete seal. The hemodynamic, angiographic and echocardiographic parameters at the end of the procedure suggested a minimal L-R shunt with no evidence of pulmonary vein stenosis, or SVC stenosis and complete stability of the stent (**Figure 2**). Follow-up at two weeks, including a negative bubble study, was equally satisfactory. We prescribed 81mg of Aspirin and 75mg of Clopidogrel for 6wks, then a single antiplatelet agent for the foreseeable future.

The long-term clinical result has been excellent with no obstruction to pulmonary venous return and no visible L-R shunt on the transthoracic echo now through one year follow-up.

Discussion

The application and acceptance by industry, physicians and regulatory bodies of modern computer-based design and bench testing techniques, facilitating approved clinical use without the need for animal studies and human trials has obvious benefits. Aside from the ethical arguments related to animal testing and resource use; the ability to provide necessary devices to the chronically under-resourced field of congenital heart disease in a timely, safe and pragmatic manner could be a reality, based on our experience. The spectrum of device novelty, risk and hence the level of testing required is paramount and many new devices will still require the utmost scrutiny but, evidence of pragmatism and a measured response to design proposals has existed before this project.[12] As well as this modern approach to testing and regulatory scrutiny, this was the first published case to combine the clinical application of VR technology and CT fusion imaging to improve the efficiency and accuracy of both the preplanning and execution of an exciting new interventional technique.[13]

We hope that FDA approval of the G-ARMOR stent, moreover the techniques used to achieve FDA approval, will provide confidence to those with great ideas, but who are incumbered

by the concept of entering into a regulatory maze. In a similar vein, we are conscious that VR and fusion imaging are still seen by many as a gimmick and as future technology. This case report is, however, representative of the day-to-day practice in the congenital cath lab at University of Colorado. We hope that it soon becomes the normal practice in other institutions as we provide more evidence of its substantial benefits to patient care.

Conclusion

The G-ARMOR stent is a substantially modified version of the CP stent. After extensive bench testing and FEA assessment, it has now had its first in man use. We have demonstrated that it can help with predictability and success in performing SVASD closure. Our use of VR and fusion imaging also facilitates this excellent new technique for this group of patients with Congenital Heart Disease.

Acknowledgements

Dr Joseph Kay (Head of ACHD at University of Colorado) for referring his patient and supporting the process. Dr Salvador Franco for his assistance with IRB and FDA approval applications for this case. Dr Pei Ni Jone and Dr Dale Burkett, 3D TEE attendings at CHCO and the staff of the Congenital Cath Lab at CHCO. Thanks to the team at Numed Inc. and in particular posthumous thanks to Dougie Villeneuve who facilitated the design and development of the G-ARMOR stent.

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PICS Istanbul - Where East Meets West, March 2023

Kamel Shibbani, MD

We recently had the pleasure of chatting with Drs. Ziyad Hijazi (ZH), Damien Kenny (DK), Ahmet Celebi (AC), and Mario Carminati (MC), as well as Mr. Burak Zengi (BZ), about the upcoming PICS Istanbul meeting set to take place from **March 15th - 18th, 2023, in Istanbul, Turkey**! We cannot be more excited about this first-of-its-kind meeting, and we wanted to share the details of our conversation with the meeting's course directors.

KS: Thank you all for your time, we greatly appreciate the opportunity to chat with all of you! Can you tell us how this meeting came to be?
ZH: The origin of this meeting dates back several years. We were in Istanbul for another meeting, and we couldn't help but appreciate how ideally located Istanbul is to bridge East and West! Just before the pandemic started, we talked with Drs. Ahmet Celebi and Mario Carminati about doing a joint meeting in Istanbul, and both were very enthusiastic. Unfortunately, everything was postponed due to COVID. However, we stayed committed to this goal and as soon as the opportunity arose, we collaborated with Dr. Mario Carminati's IPC meeting, as well as the Turkish Society of Cardiology under the leadership of Dr. Ahmet Celebi and his distinguished colleagues, to get the collaborative meeting organized. I strongly believe that a collaborative meeting will benefit everyone. We hope to continue with this effort and perhaps alternate between Milan and Istanbul.

KS: This meeting seems to represent the coming together of three great societies - Dr. Carminati, can you tell us a little bit about IPC?
MC: IPC, or Interventional Pediatric Cardiology, started approximately 25 years ago! We organize meetings every two years in Milan, where we focus on transcatheter interventions for both children and adults with Congenital Heart Disease. Just before COVID, Drs. Hijazi, Celebi and myself all agreed that a joint meeting would be mutually beneficial. There were academic, logistic, and economic benefits to creating such a meeting. I am very happy about this collaboration because the atmosphere of cooperation between us is very strong - and we hope that this will be reflected in PICS Istanbul.

KS: Dr. Celebi, can you tell us a little bit about the Turkish Society of Cardiology?
AC: As the previous president of the Turkish Society of Pediatric Cardiology and the Interventional Pediatric Cardiology working group, we helped set up yearly interventional meetings in Turkey, to which we invited Drs. Hijazi, Kenny, Carminati, as well many other international cardiologists. This time however, we are incredibly happy to host PICS and IPC in a joint interventional meeting in Istanbul. The location of Turkey will hopefully facilitate attendance from all over the world including Europe, Asia, Middle East, America, and Africa! We have a fantastic academic program as well as a great social program, and we hope people can learn about the most up-to-date topics in interventional cardiology and enjoy our beautiful city.

K.S: Dr. Kenny, how does this meeting differ from the yearly PICS meetings?
DK: We have tried to keep the format somewhat similar to PICS, in the sense that we have our morning live sessions followed by afternoon breakout sessions in a variety of interesting subjects! An aspect of this meeting that is somewhat different is the plenary sessions, which are sessions where we all come together in the evening to discuss topics of interest not only for interventional cardiologists, but also for adult structural interventionalists. We also plan to have a PDA symposium at this meeting that will involve international speakers as well as our collaborators from the Turkish Society of Neonatology. What I would say is unique to this meeting is our deliberate choice to focus on topics that we felt would be pertinent to our colleagues from Europe, Asia, the Middle East, and other parts of the world, in-line with the "East meets West" theme and our location in Istanbul. This includes topics like coronary artery fistula occlusion, PDA closure in adults, and many other such topics.

Register for PICS Istanbul

March 15th – 18th, 2023

www.picsistanbul.com

KS: Can you tell us a little bit more about other sessions that participants can expect?
DK: Our program includes: two sessions on TPVR, a VSD session, a session on aortic interventions, another on access in complex procedures, and a session about interventions in the single ventricle patients, among others. For our adult interventional colleagues, we have sessions about paravalvar leak, PFO, and left atrial appendage occlusion. In addition to all of that, we plan to have plenary sessions in the evening where we come together to discuss topics that are relevant to both audiences including RVOT interventions, branch PA interventions, and the impact of imaging on our procedures, including the role of 3DI3. We also plan to have a lymphatics session on Saturday in collaboration with Dr. Yoav Dori and our ever popular "Nightmare in the Cath Lab."

KS: Will there be sessions that target an audience beyond interventional cardiologists?
MC: Of course! We must take into account the importance that our allied health professionals play in every aspect of our work.
ZH: Absolutely! We plan to have a parallel session for our allied health professionals.
MC: In addition to that, a lot of the sessions will necessarily involve non-interventional cardiologists. The PDA session, for example, highlights the importance of the involvement of our neonatal colleagues. Similarly, our adult congenital heart disease colleagues play a very important role in our field.
DK: Another example would be our surgical and our imaging colleagues. Realistically, we cannot discuss interventional management without the involvement of all the stakeholders. While this meeting will have an interventional flavor, it will definitely include non-interventional faculty and points of view.

KS: Dr. Celebi, what are some aspects of the meeting that you think participants can take back home with them?
AC: Participants can look forward to learning from global experts in the field on various topics! I think the central location of this meeting will allow for easier access for participants from all over the world.

Course Directors Drs. Ahmet Çelebi, Mario Carminati, Ziyad Hijazi and Damien Kenny

Top row: Mr. Norm Linsky (PICS Executive Director), Dr. Kamel Shibbani (PICS Senior Editor, Public Communications), Dr. Ahmet Çelebi (Course Director)
Center row: Drs. Damien Kenny and Mario Carminati (Course Directors), Mr. Burak Zengi (Managing Partner, Z Event Congress Organization Service)
Bottom row: Dr. Ziyad M. Hijazi (Course Director)

KS: Dr. Carminati, what do you think participants can take away from this meeting?
MC: There is no doubt that the participants can expect to learn a tremendous amount from this meeting. The format is somewhat similar to other meetings, but what sets this meeting apart, in addition to what was mentioned, is the makeup of the participants. Not everyone can travel to the US or Europe for the PICS meetings. So, organizing a meeting with the same format as PICS in different locations around the world will enhance the attendance of the meeting and will facilitate learning within our international community.

KS: Who can we expect to be the faculty at this PICS Istanbul meeting?
ZH: We have been very deliberate in selecting faculty from all over the globe. This includes expert faculty from the US, Italy, Germany, UK, France, Turkey, as well as Middle East, Asia, and Africa. In fact, we have over 110 global faculty members, all of them experts in our fields.
DK: Absolutely! We've tried hard to work in collaboration with Drs. Celebi and Carminati to make use of the excellent meetings that they already have in place. The coming together of these three entities - the PICS Society, the IPC, and the Turkish Society of Cardiology – will hopefully produce greater access for our colleagues worldwide.

KS: Will there be a chance for participants to interact with and learn from industry?
DK: There has been a lot of interest from industry in this meeting. We will have an exhibit hall for people to visit the booths of various vendors and experience the latest devices and technologies. We are also very cognizant of the potential effects that MDR will have on device availability in Europe and the world, and this meeting will provide an opportunity for us to get together with industry to tackle this new challenge together.

KS: Dr. Celebi, can you talk to us about the live cases at PICS Istanbul?
AC: Our live sessions will be coming from all over the globe! We'll have sessions from Qatar, Saudi Arabia, two different centers in Istanbul, Dublin, Milan, as well as other locations. We also plan to have guest operators join us in our cath lab in Istanbul for specific live cases.
ZH: This year, the Saudi Arabian Cardiac Interventional Society is partnering with PICS, IPC, and the Turkish Society of Cardiology to sponsor a session from their society at PICS Istanbul. I think this really highlights one of the themes of this meeting, which is collaboration between societies. Collaborations like this will only enhance our field and improve not just our meetings, but the care we provide our patients. We hope to build on this in future meetings, and we hope to have more international societies co-sponsoring this meeting with us.

KS: Is there any role for early career interventionalists to get involved in this meeting?
MC: The education of our junior colleagues and early career interventionalists is one of the most important goals in our society. This goal is one that we try to focus on during all our meetings. In the past, we have dedicated satellite sessions to our junior attendees.
DK: I absolutely agree. The education of our junior colleagues is always in the forefront of our meetings. At this meeting, we plan to have an abstract session with prizes for best abstract, and that is something that tends to attract our younger investigators. For future meetings, we plan to have dedicated sessions for junior faculty/a fellow course that can attract an international audience.

KS: Burak, can you talk to us about your role in this meeting?
BZ: I run "Z Event," a company that organizes national and international medical meetings in Turkey and outside of Turkey. We will be organizing PICS Istanbul and we couldn't be more excited! We anticipate that this will be a fantastic meeting!

KS: Thank you so much to all of you for taking some time to chat with us today!

LINQ II™ Insertable Cardiac Monitor

The LINQ II™ ICM is the first insertable cardiac monitor now available for pediatric patients two years and older.

Medtronic is excited to announce that the LINQ II insertable cardiac monitor is now available to help you find answers for your younger patients. The LINQ II ICM is the world's most accurate ICM[1-13] featuring advanced artificial intelligence technology, making it the optimal choice for pediatric patients who need cardiac monitoring. Insertion of the device typically takes less than five minutes and has a low infection rate, per published data.[14-18]

The device delivers 24/7 heart monitoring with no patches or wires in the way, letting kids be kids and granting peace of mind for parents and caregivers.

Medtronic remains committed to expanding patient access for insertable cardiac monitors and is excited to announce that the LINQ II ICM is now available for patients as young as two years old. Insertion of a LINQ II ICM typically takes less than five minutes. It involves making a small < 1 cm incision with a preloaded insertion tool.

The LINQ II ICM is the smallest[19] insertable cardiac monitor, making it the optimal choice for pediatric patients who need cardiac monitoring. The device reassures parents their child's heart is being properly monitored 24/7 and allows the child to play freely, without patches or wiring in the way. The LINQ II ICM can help your pediatric patients enjoy a better quality of life and get back to their active lifestyle.

Insertable cardiac monitors are useful for monitoring arrhythmias in pediatric patients. As part of a retrospective study, it was reported ICM monitoring led to a change in management in one-third of patients.[20] To learn more, visit: **https://www.medtronic.com/us-en/healthcare-professionals/products/cardiac-rhythm/cardiac-monitors/linq-ii.html**

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ACHA Continues Commitment to Research, Including Additional Focus on Neurocognitive Studies

The Adult Congenital Heart Association (ACHA) is proud to announce its third round of research grants to fund four new projects across the United States. The total commitment for ACHA's research program now totals $400,000 since 2019, which has funded 14 scientific research projects.

As the only national patient advocacy organization specifically funding Adult Congenital Heart Disease (ACHD) research, ACHA emphasizes the importance of partnership between patients, their families and the medical field. According to ACHA Medical Advisory Board Chair Arwa Saidi, MB, BCh, MEd, it is this collaborative partnership that will continue to improve long-term survival and quality of life in adult patients with Congenital Heart Disease (CHD).

"Research has always brought about progress in medicine, and this has led to the great success in the survival and outcome of the children born with CHD," Dr. Saidi said. "The awards highlight some of the important issues where questions remain, such as lifestyle concerns, patient-reported outcomes, and Fontan management."

In addition to the three traditional research grants, this year ACHA is excited to introduce the inaugural Meil Family Foundation Research Award for Neurocognitive Studies.

"We are becoming increasingly more aware of neurocognitive issues, and that living with CHD often leads to related challenges for many individuals," said ACHA President and CEO Mark Roeder. "The field is just starting to do organized research around this, and ACHA wants to take a leadership role by funding research in areas such as cognition, anxiety, stress, and more—as we have begun funding in prior rounds. Now, with designated funding, we will be able to ensure we continue to focus on these studies for many years to come."

Roeder gives credit to Barry and Wendy Meil of the Meil Family Foundation, who in 2019 were the first funders to step up with a leadership gift when ACHA announced it would be funding emerging research. Through the years, they have continued to increase their investment. As the ACHA research program continues to grow, it remains an integral part of the organization's five pillars, along with awareness, accreditation, advocacy, and education.

The following one-year ACHD early investigator grants, which began October 1st, 2022, are jointly funded by ACHA, the Meil Family Foundation, the Dale Amorosia Heart Fund, and the Brad's Heart of a Jayhawk Research Fund:

- Impact of a Home-Based Healthy Lifestyle Program on Body Composition and Exercise Capacity in Adult Congenital Heart Disease Patients with Heart Failure, Tracey Thompson, MD, Salil Ginde, MD, Medical College of Wisconsin, https://www.achaheart.org/media/3678/researchthompsonginde.pdf.
- REHAB Fontan Failure: RCT of the Effects of Cardiac Rehabilitation versus Tadalafil Among Patients with Fontan Failure, Jonathan Menachem, MD, Daniel Clark, MD, MPH, Vanderbilt University, https://www.achaheart.org/media/3677/researchmenachemclark.pdf.
- Validating a Patient-Reported Outcomes Tool in Adults with Congenital Heart Disease, R. Thomas Collins II, MD, Alexander Sandhu, MD, Jennifer Woo, MD, Stanford University, https://www.achaheart.org/media/3679/researchcollinssandhuwoo.pdf.

The Meil Family Foundation Research Award for Neurocognitive Studies also began on October 1st, 2022, and was awarded to:

- Exploring Mind/Body Resilience and Coping/Cognitive Exercises-(EMBRACE): A Psychoeducational Intervention for Adult Congenital Heart Disease, a Randomized Control Trial, Vicki Freedenberg, PhD, RN, Children's National Hospital, https://www.achaheart.org/media/3680/researchfreedenberg.pdf

These four studies were chosen through a double-blind process with two teams of reviewers—one comprised of Medical Advisory Board members, including ACHD cardiologists and nurses, and the other of patients and family members across the country, including peer mentors, board members, fundraisers, and more.

"We received many excellent research proposals and critically reviewed each application based on its scientific merit and relevance to our patient population," added Dr. Saidi. Scoring included areas such as significance and innovation, approach and methodology, and investigator track record and qualifications.

To learn more about ACHA's research program and research projects, visit: https://www.achaheart.org/your-heart/programs/research/.

ACHA is the only nonprofit in the country dedicated solely to the unique needs of nearly 2 million adults born with heart defects, the most common birth defect in the United States, diagnosed in one in 100 births. These adults are living longer today with one of the many varying types of congenital heart defects that range among simple, moderate, and complex—which was not a reality 20 years ago.

First-In-Human Use of the ŌNŌ Retrieval System for Percutaneous Removal of an Embolized Leadless Pacemaker from the Right Pulmonary Artery

GLOBE NEWSWIRE--The ŌNŌ endovascular retrieval system was recently used to remove a malpositioned leadless pacemaker (LPM) that embolized to the right pulmonary artery in a 52- year-old patient, ŌNŌCOR LLC announced today. The team at UCLA Medical Center, Los Angeles, California, percutaneously removed the wayward device from the patient using a combination of ŌNŌ, commercially available endovascular snares and a large bore sheath.

"Our patient was referred in from a hospital outside of UCLA, where unfortunately, they experienced an embolization of the LPM device from the right ventricle into the right pulmonary artery, where it became entrapped in a small segmental branch," said Dr. Zach Haber, a UCLA Interventional Radiologist. "The LPM, which looks like an AA battery with hooks on it, was noted to be out of position at a recent follow-up appointment. Removal was initially deemed too risky by the referring hospital, so it was left in the pulmonary artery for several weeks," said Dr. Haber.

"Our team at UCLA reviewed the case and thought that using ŌNŌ, we could safely capture and remove the LPM from the pulmonary artery in an atraumatic fashion. Fortunately, that is exactly what we were able to accomplish," said Dr. Aron Bender, a UCLA Electrophysiologist.

"Leadless pacemakers convey many advantages over the older lead-based systems," said Dr. Bender, the patient's electrophysiologist at UCLA. "However, embolization and misplacement of such devices, though rare, is an unavoidable risk. It is incumbent upon us as clinicians to be able to manage this complication safely, and preferably without surgery," said Dr. Bender.

"I think the ŌNŌ represents a significant advancement in bailout technology, and as we saw here today, ŌNŌ will be very helpful in helping us to avoid urgent/emergent surgery moving forward," said Dr. Jamil Aboulhosn, head of the UCLA Adult Congenital Heart Disease program.

"I'd say that the game has just changed significantly thanks to ŌNŌ and ŌNŌCOR," added Dr. Daniel Levi, a Pediatric Cardiologist who assisted Dr. Haber in the procedure.

ŌNŌCOR

The ŌNŌ is a novel device designed to receive, align, compress, and remove material (non-biologic and biologic) from the vascular system. ŌNŌ is intuitive to use and is compatible with commercially available vascular sheaths, endovascular snares and other graspers. ŌNŌ received FDA clearance in May 2022 and is available at select sites throughout the United States.*

"ŌNŌ was designed to add an extra layer of security to advanced endovascular procedures," said Mark Piper, CEO of ŌNŌCOR. "Thanks to the team at UCLA, we can now clearly see that ŌNŌ's reach extends into the world of electrophysiology."

*The ŌNŌCOR LLC ŌNŌ retrieval device is indicated for use in the cardiovascular system to retrieve foreign objects using minimally invasive procedures. For complete instructions and other important safety information for ŌNŌ, please refer to the Instructions for Use.

About ŌNŌCOR

ŌNŌCOR LLC is a medical technology company dedicated to developing essential safety tools and other facilitating technologies for the modern-day catheterization lab. For more information, please go to www.onocorvascular.com.

Contact: Mark Piper, mpiper@onocorvascular.com

Beaumont Health Genetics and Artificial Intelligence Research Discovers Blood Test to Prenatally Identify Dangerous Fetal Heart Defects

Early Detection Could Help Reduce Infant Mortality

Royal Oak, Michigan – Researchers at Beaumont Hospital, Royal Oak, have discovered a blood test for pregnant women that uses artificial intelligence and genetic-related biomarkers to accurately detect fetal congenital heart defects, well before birth.

"We know that when congenital heart defects are diagnosed early – ideally before birth – outcomes can improve significantly and mortality and morbidity reduced," said Dr. Ray Bahado-Singh, System Chief of Obstetrics and Gynecology, Beaumont Health, and lead author of, "Accurate Prenatal Detection of Fetal Congenital Heart Defects," which appears in a recent issue of the leading journal, American Journal of Obstetrics and Gynecology.

Bahado-Singh, his team from Beaumont and researchers from three other institutions, harnessed the power of Artificial Intelligence to identify and evaluate fetal DNA that circulates in the mother's bloodstream.

Dr. Bahado-Singh cautions that larger, prospective studies are needed to validate these findings. However, he said this minimally invasive detection method is an important, first step in establishing an effective, postnatal action plan that quickly puts at-risk infants on track to receive the intensive medical and surgical attention they need.

"Once confirmed, these results could lead to exciting new protocols and, most importantly, improved outcomes for newborns and their families," Dr. Bahado-Singh said. "The next steps after a positive test would include performing an echocardiogram prenatally and repeated after birth to confirm the presence and nature of a cardiac defect."

Currently, ultrasound which images the fetal heart, is the only available screening tool for early (prenatal) detection of congenital heart defects, Dr. Bahado Singh said. Unfortunately, in the United States, only about half of fetal congenital heart defects are identified on prenatal ultrasound. Because of this limitation, it is now the standard of care to screen and monitor newborn oxygen levels, via pulse oximetry. Regrettably, pulse oximetry still misses about 10% of critical newborn heart defects, leading to increased deaths and severe complications.

Birth defects, particularly ones that stem from heart disease, are a leading cause of infant mortality. These include a hole in the heart, the most common, and other potentially deadly cardiac birth defects, that might affect oxygen levels and blood flow at birth; valve and other abnormalities. Smoking, alcohol use, environmental toxins and vitamin deficiency are all known contributors to the development of congenital heart defects. These agents cause chemical ('epigenetic') changes in DNA which can affect the function of genes critical to the development of the heart," Dr. Bahado Singh explained, "by turning genes on or off," he continued. "You need a certain group of genes turned on and others turned off, for example, to make sure the chambers of the heart are fully developed. Switching the wrong genes on or off in this normally perfectly orchestrated symphony can cause mal-development leading to major heart defects."

Artificial intelligence analysis of the circulating (including fetal) DNA extracted from the mother's blood, Dr. Bahado-Singh explained, "enables us to efficiently review potentially billions of pieces of information in the genome. This includes swiftly identifying specific predictors of a possible fetal heart defect and separating those that need continued monitoring."

Ultimately, Dr. Bahado-Singh would like to see all pregnant women achieve ready access to screening - through a blood test, which requires no advance appointments or significant time off from work. Those who test positive could then be referred for detailed fetal and newborn cardiac ultrasounds and appropriate early intervention, as needed.

"We are still a ways away from that," he said. "But it's exciting to contemplate the possibilities."

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FEBRUARY

16-18

The 7th Annual Advances in Congenital Heart Disease Summit: Transposition of the Great Arteries: The Master Class
Orlando, FL, USA
https://www.clevelandclinicmeded.com/live/courses/CongenitalHeart23/

25-28

CRT23 – Cardiovascular Research Technologies
Washington, DC, USA
https://www.crtmeeting.org/Default.aspx

MARCH

15-18

PICS Istanbul 2023
Istanbul, Turkey
https://www.picsistanbul.com/

MAY

18-20

SCAI 2023 Scientific Sessions
Phoenix, AZ, USA
https://scai.org/scai-2023-scientific-sessions

JUNE

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ASE 2023 – Foundations and the Future of Cardiovascular Ultrasound
National Harbor, MD, USA
https://www.asescientificsessions.org/

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CSI Frankfurt
Frankfurt, Germany
https://www.csi-congress.org/conferences-courses/conferences/csi-frankfurt

Program Directory 2022-2023

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