CAIR EXPRESS

Fall 2018

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Dr. Jason Wong

President's Blog

Dear CAIR members,

The CAIR organization has been busy on many fronts. At the annual meeting, we voted in two new board members, Dr. Véronique Caty (Montreal, Quebec) and Dr. Darren Ferguson (St. John, New Brunswick). Welcome to the CAIR board and thanks in advance for your valuable contributions.

This fall, we are rolling out a new member recruitment campaign, led by Bob Cook, Remon Elyas, Véronique Caty and Daniel Lapointe. The theme is "There has never been a better time to join CAIR". As a friendly reminder, all physician MOC activity can now be obtained through CAIR (cases of the month, annual meeting, and our smaller M&M style meeting – "Grand Slams and Catastrophe's").

Membership offers many additional benefits including automatically being a corresponding member of CIRSE. This allows access to CIRSE's electronic IR learning platform, which is the largest online platform currently available. So, if you have colleagues who are not CAIR members, please spread the word of the advantages of CAIR membership.

Amol Mujoomdar, Tara Graham, and David Valenti, and our CAMRT partners are currently busy planning the annual meeting to be held in Toronto next year. They have already lined up a fantastic group of international faculty, and I know Toronto will be a huge success.

Myself and Andrew Benko have been busy organizing the "Grand Slams and Catastrophe's" meeting to be held in Lake Louise. We have also "locked down" a fantastic dynamic guest speaker, Dr. John Kaufman.

The entire board is also engaged and working on various facets of the CAIR Initiative. We will be firing on all cylinders this fall. As always, please feel free to drop me a line with any comments, questions, or concerns.

Take CAIR!

Yours truly,

CAIR

Catching up with... Dr. Robert Abraham

Introduction

Dr. Robert (Bob) Abraham is a Professor of Radiology at the Dalhousie University and is a well-known interventional radiologist across Canada. He is the lead IR for several programs and established the Uterine Fibroid Embolization program as well as the 90Y Radioembolization program at the QEII Hospital. Dr. Abraham frequently speaks at national and international IR meetings and his research in imageable embolic agents and minimally invasive bone augmentation systems has been supported by large grants. He has a track record of licensed catheter innovations, granted patents and is actively engaged in funded research projects with funding to date, totalling in excess of $4 million. Dr. Abraham is a recognized leader in Canada and recently completed his tenure as Chair of the Royal College of Physicians and Surgeons of Canada Examination in Diagnostic Radiology and as President of the Canadian Association for Interventional Radiologists (CAIR, formerly called CIRA)."

Dr. Robert Abraham

"Practice models that prioritize clinical earnings over research and development can indeed be problematic and a major hindrance to innovation. "

CAIR Interview Question & Answers

1.The current practice model in Canada is quite heavily focused on clinical work. In this scenario, what do you think is the future of innovation in IR?

Practice models that prioritize clinical earnings over research and development can indeed be problematic and a major hindrance to innovation. I was very lucky to have a supportive clinical group who at least allowed me to reduce my clinical commitment in order to pursue my ideas. However, that of course meant that I had to accept a significant reduction in income. The sacrifice my family and I made in order for me to pursue innovation may not be something most IRs would be willing to accept.

"There is much less appetite for risk here in Canada when compared to the US or even most other countries. "

I am hopeful there are sites where clinical groups do support IRs financially for their time in research to develop and commercialize a product but I fear it is rare. Increasing this type of support would make a major difference and perhaps some form of profit-sharing arrangement with the clinical group could help but I am not sure if these groups would be willing to take on the capital risks involved. It would indeed require a major shift in thinking and culture but perhaps it is time for us to start the conversation!

2. What resources are available at institutional, provincial and national levels that could be leveraged by Canadian IRs to develop new products in IR?

There is support from federal and provincial governments for innovation and commercialization as it is known that successful ventures improve the local economy. The team I formed here in Halifax have had great support from Federal Government through innovation grants and also through provincial funding organizations. I would recommend any IR interested in commercialization to approach local government to understand what support is available. A simple internet search on "Innovation" and the name of your province will usually lead you to a suitable contact that can help guide you. The National Research Council also has innovation grants through their IRAP and other great programs. Universities and Hospitals also have Industry liaisons and Innovation Offices that could be a source of information. However, I would strongly recommend first exploring your Hospital and your University policies, if you are at an academic site, to ensure you understand the implications of an institutional invention and IP (intellectual property) rights.

3. We as IRs (and our radiology colleagues) are not particularly trained in business development. How does one go about learning relevant skills?

It is of course best if you have an interest in finance as I do. This has

been very helpful for me and has reduced the learning curve. However, I never took course on it. I learned by simply reading great books available that were written by individuals who have been through the process before. These books are all available at your local library! In addition, it goes to perseverance, hard work and for me, the ability to find and partner with great people who are a lot smarter than me and who are willing to share their knowledge!

4. Do you think it is important that Canadian IRs spend time learning skills and involve themselves in product development?

Medical device product development is complex, multifactorial and can frankly be overwhelming. You have to learn and understand Finance, Intellectual Property, Design Control, Quality Assurance, Manufacture, Supply Chain, Regulatory, HR and much more. You can pursue innovation and commercialization either by establishing a start-up company or by working for or with larger established companies in the medical device space. It requires focus, tremendous passion and dedication beyond what any of us have done to date. I will tell you that it is the hardest thing I have ever done in my career. Researchers could simply license their novel technology and if so do not need to get into a lot of what I have mentioned as the licensee would be responsible for all of the rest. However, these individuals should have a strong understanding of the market need for their product and the regulatory strategy for approval in order to ensure the work they do will result in a product that will eventually succeed in the market and will also be enticing for a large company to take on. In those instances, it is best to have IP locked up with at least a provisional patent and also have a working prototype that demonstrates the value of your product. Word of warning though; working to get a large company interested is not easy and can be very slow and frustrating. A lot of IRs have many great ideas that remain sitting on the shelf at these companies. If you do choose to go down this road, ensure you have a non-disclosure agreement in place. In fact, never discuss your ideas with anyone without an NDA in place. I can share some NDA templates if anyone is interested but in the end it is best to partner with a strong law firm.

5. What were some of the major challenges you faced during the development of your product?

Though I have had great support for seed investment from family, friends and local angel investors that then allowed leveraging of the innovation grants we received, the next level of investment was extremely difficult to find in Canada. There is much less appetite for risk here in Canada when compared to the US or even most other countries. One of my companies, ABK Biomedical Inc., was able to successfully clear this hurdle by obtaining investment from the United States and from Asia. Without this, we would not have succeeded.

Another major challenge was to find individuals with skillsets required to develop, manufacture and eventually commercialize high quality medical devices as I do not live in a medical technology "Hub". However, I have been very lucky at ABK, to now have 18 employees who are highly skilled and who are all dedicated to taking our products to market but creating this great team took a lot of effort and determination! We were able to attract great people from outside our province and hopefully this will be the start of a cascade!

6. Could you enumerate the various regulatory steps needed in Canada and what your experience was dealing with some of the bureaucratic procedures? Also, could you say a few words on how easy/difficult it is in Canada compared to elsewhere (US)?

Health Canada is a distinct organization from FDA and requires completely independent product approvals. Both organizations are necessarily thorough and comprehensive. Health Canada requires ISO certification of Quality Systems before consideration of a new device approval whereas FDA will approve medical devices through 510K Clearance or Pre-Market Approval and will then audit quality system and production facilities for compliance with FDA's Quality System Regulations (QSR) and Good Manufacturing Practices (GMP) requirements soon after a product is cleared or approved and ready for sale. However, there is a lot of work being done to harmonize requirements for approvals globally and we will start to see more commonality in these requirements. So, one is not easier than the other and in fact, both are plain old hard! Rightfully so though, as the public does need to be assured that products are safe and effective as they enter the market.

We are seeing more and more of our clinical colleague specialties spending time doing laboratory research, technology development and bench-top testing. Is there a need for IRs to do the

Medical device product development is complex, multifactorial and can frankly be overwhelming.

same and if so, what in your opinion is the best way to integrate this into our practice models, which are fee for service at most Canadian sites?

This is a great question. I strongly believe Canadian IRs should be involved in bench top research and product development however, the infrastructure to do this is limited and expensive. One needs to have "buy in", literally, from university, hospital and from government for a successful program and of course there are donors who may step up to support. Problem of course is the difficulty in our fiscal environment for such an investment. One of the best ways to deal with this is collaboration. Working with other groups that may have the infrastructure in place can be very successful. So, if there are individuals in other specialties in your institution that are involved in product development, talk to them to see if there is interest in combining forces to apply for grants and collaborate in your research and development ideas.

In Halifax, we had great collaboration and we started our projects in research labs at Dalhousie University. We initially used grant funding but when it came time to do more extensive testing for product approvals, we had to create new infrastructure and seek the funding to complete the R&D. We took the option of creating a Start Up company and set out to find private investment. I have been very lucky in raising over $12,000,000 from private and institutional investors over the past 5 years which has resulted in us now having our own 6000 sq. ft. manufacturing and R&D facility complete with clean rooms and with 18 employees working together to revolutionize the future of Y-90 Radioembolization! I do have to emphasize that it took a lot of effort and perseverance to get to this point but I really look forward to the day when IRs will be using our products to successfully treat their patients!

Dr. Robert (Bob) Abraham,
MD, FRCPC, FSIR

Hot off the Press : The Heli-FX

Interview with Mark L. Stiger (Sr. Principal Engineer – Research & Product Development) and Nicole E. Hurley, Ph.D. (Product Consultant, Endo Global Marketing), MEDTRONIC.

1. How did the idea for the Heli-FX device originate?

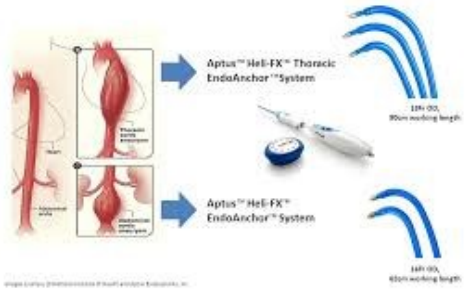
The origin of the Heli-FX EndoAnchor can be traced back to an Endovascular pioneer and innovator, Dr. Juan Parodi. Dr. Parodi patented the endosuturing concept in 2002 and continued to disclose and patent improvements for several years after the original patent was granted. The founder and engineers of APTUS Endosystems later collaborated with Dr. Parodi to expand the original ideas to a broad portfolio of claims around the original endosuturing concept as well as to device concepts intended to treat vascular aneurysms.

2. What were the key concerns during development of the device and how were they addressed?

⇒ *Adequate fixation and resistance to pull-out.* The geometry of the EndoAnchor (length – 4.5mm/diameter – 3mm/wire diameter – 0.5mm) was engineered based on relationships between the anchored stent graft and the parent vessel (aorta). These relationships were used to simulate user conditions with computer modelling and then proven with bench testing. The EndoAnchor helical pitch was specifically designed such that it would not unwind or back out of its implanted position.

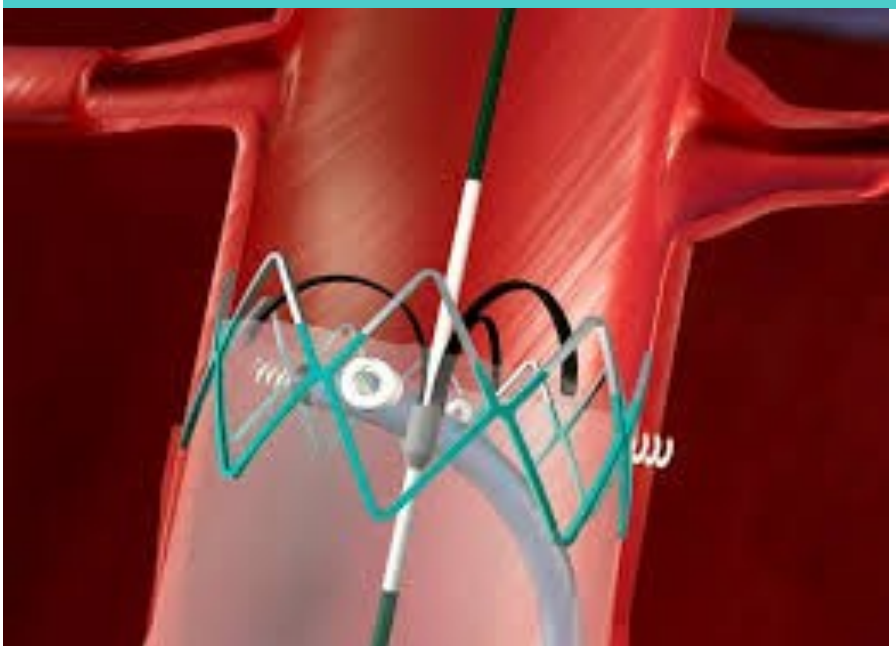
⇒ *Fatigue life.* The cyclic nature of the physiologic environment is a concern for any chronic implant. Computer simulations were used to engineer the EndoAnchor to withstand a minimum life of 10 years in this cyclic environment. The EndoAnchor was then fatigue tested to the 10-year equivalent to support the computer simulations. Once any implant reaches this level of fatigue life there is little risk that it will fail due to cyclic fatigue after the 10-year mark.

Aptus Heli-FX Product Offerings



Impact to the Endograft. We also studied the impact of the EndoAnchor to the Endograft to ensure that the EndoAnchor did not negatively impact the ability of the Endograft to perform as intended.

⇒ *Safe and consistent implantation.* The Heli-FX catheter system was engineered to facilitate EndoAnchor implantation despite anatomic variations and user specific handling. The shape and deflection angles of the



Heli-FX Guide were engineered to suit both AAA and TAA work and to support repeated deflections needed support multiple EndoAnchor implantations.

⇒ *Usability.* The system employs minimal controls, as well as visual and audible alerts, that allow the operator to intuitively carry-out all the steps needed to complete an endosuturing case.

⇒ 3. Could you enumerate the specific materials/components of the device relevant to use?

⇒The Heli-FX EndoAnchor itself is composed of a Cobalt-Chromium alloy called MP35N-LT. MP35N has become the standard material of choice for many coronary stents due to its strength, corrosion resistance and resistance to fatigue. These properties are also required characteristics of the EndoAnchor, so MP35N was a logical choice.

⇒4. What are the indications for use and which are the ideal patients/ cases?

⇒ Intended to provide fixation and sealing between aortic stent grafts and native artery;

⇒ Indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications and in patients needing augmented radial fixation and/ or sealing to maintain adequate aneurysm exclusion

⇒ Can be placed at the time of the initial stent graft placement, or during a secondary procedure and approved for use with a wide variety of stent grafts.

5. Are there any specific points of consideration during usage, any tips to IRs while using this device?

⇒ Off-label use of endo-anchors is not recommended. The following are limitations of the device:

⇒ Not recommended in proximal necks where thrombus, calcification and/or plaque is greater than 180° in target area

⇒ Irregular or eccentric thrombus, calcification and/or plaque that may compromise EndoAnchor implant penetration

⇒ Bridging an endoleak gap if the native aorta has dilated beyond the max diameter of the endograft

⇒ Attaching multiple components and/ or layered endografts without aortic wall penetration

6. What complications have been reported with the Heli-Fx device?

⇒ The complications associated with the EndoAnchors themselves are extremely low due to the relatively simple function of the device. Once secured through the endograft and into the adventitia, the resultant composite nature of the EndoAnchors, stentgraft, and the vessel create a stable structure.

⇒ Most of the complications reported have been acute or observed at the time of implantation. The Heli-FX system requires that the operator have a complete understanding of the purpose and intent of each of the implantation steps. Subtle mis-steps in the implantation process, can lead to premature failure of the delivery system or incomplete EndoAnchor implantation.

The Heli-FX device was developed, investigated, and commercially marketed by APTUS Endosystems (Sunnyvale, CA) which was acquired by Medtronic in June of 2015 .

Upcoming Events & Latest News

— CAIR RECRUITMENT CAMPAIGN —

There has never been a better time to join CAIR

We recently launched a member recruitment campaign under the theme There has never been a better time to join CAIR. The benefits of membership have never been more interesting. Here's why:

1) Members can now obtain all the CME credits they need (section 1, 2 and 3) through CAIR activities;
2) Members now have automatic access to the benefits of membership with CIRSE, including CIRSE's online resources;
3) Members have access to improved CAIR resources, such as the quarterly newsletter, the Cases of the Month and the CAIR online community forum;
4) Members have a reduced registration fee for the CAIR Annual Meeting, which promises to be particularly outstanding and well attended in 2019 in Toronto.

Pass the word around and convince your peers who are not yet members to join the CAIR. I am personally convinced that there has never been a better time to join CAIR.

Bob Cook,
CAIR Board member responsible for the 2019 member recruitment campaign.

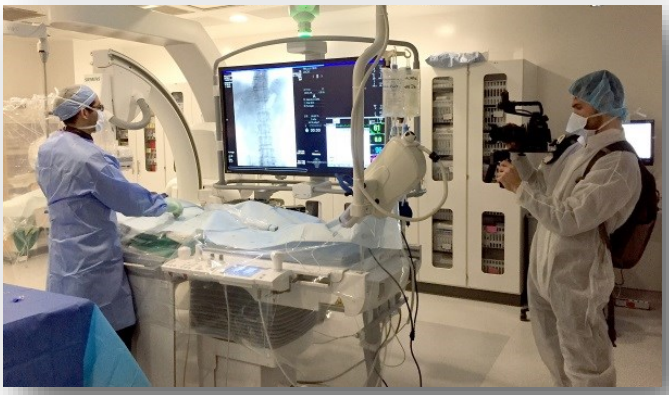
— New videos —

To help patients better understand IR procedures

I am happy to announce that the CAIR has produced six new short videos (three in English and three in French) that you can find on the CAIR website.
These videos aim to help patients better understand three very common IR procedures, namely Uterine Fibroid Embolization, Chemoembolization and Tumor Ablation and Venous Access.

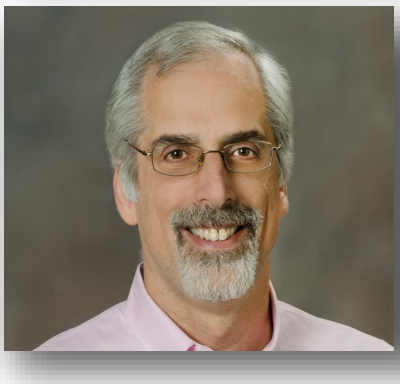
I want to thank Dr. Marie-France Giroux and Dr. Patrick Gilbert of the Centre hospitalier universitaire de Montréal (CHUM) who are the stars of these videos.

Daniel Lapointe,
CAIR Executive Director



CAIR Grand Slams & Catastrophes 2019

Don't forget to get your membership to benefit a preferential rate!



Dr. John Kaufman will be the guest speaker of the Grand Slams & Catastrophes course in Lake Louise (AB).

John A. Kaufman, MD**,** MS is the inaugural Chair of the Department of Interventional Radiology, Director of the Dotter Interventional Institute and the Frederick S. Keller Professor of Interventional Radiology at the Oregon Health & Science University in Portland. He also has appointments as Professor of Diagnostic Radiology, Surgery and Medicine at OHSU.

CAIR Annual Meeting 2019

This year, the Annual Meeting will take place in Toronto (ON), at the Hilton hotel.

The faculty of guest speakers will be revealed soon.

Don't forget to get your membership to enjoy a special rate.

LOOKING FORWARD TO SEEING YOU THERE!

Corporate Partners News

New publication on Drug Coated Balloon Angioplasty in Failing AV Fistulae!
https://cjasn.asnjournals.org/content/early/2018/07/23/CJN.14231217.full

Learn more about Merit Medical's Prostatic Artery Embolization Course (2019 dates will soon be announced) here.
https://www.merit.com/education/think-pae/

Pioneer Plus - the only re-entry device with IVUS and ChromaFlo.
https://www.usa.philips.com/healthcare/product/HCIGTDPPLUS/pioneer-plus-ivus-guided-re-entry-catheter

Terumo Medical Canada Inc. will open its doors in January 2019, this new facility will offer best in class service to our Canadian customers with a combined office, warehouse and distribution facility in Vaughan, ON.