James Joye, DO

Dr. James Joye, inventor of cryoplasty, discusses his experiences developing the procedure, bias in medicine, and the latest initiatives of VIVA Physicians.

Among your many noteworthy achievements, you are perhaps best known for conceiving and developing cryoplasty. What inspired this idea? The "light bulb" for cryoplasty actually came from cryotherapy work in the field of oncology that I was exposed to in the early stages of my cardiovascular fellowship. At that time, we had no coronary stents, and restenosis was a much larger problem than it is currently. Numerous methods, drugs, and devices had been tried and had failed to make an impact on the problem of neointimal hyperplasia, but nobody had tried cryotherapy.

In the late 1960s, cryoablation of tumors was being investigated as a minimally invasive means of debulking tumor load. Because many tumors are highly vascularized, there were concerns as to how the vascular tissue would behave when exposed to cold. Andrew Gage and his colleagues performed an elaborate series of animal studies to answer that question and found that arteries exposed to even extremely cold temperatures maintained their conduit function and had no late sequelae.

What caught my attention was that the healing process that followed freezing of the vessel demonstrated trivial evidence of neointimal proliferation. The vascular idea was thus to superimpose the benign healing process of cryotherapy on the aggressive, proliferative response to angioplasty in a manner that would limit smooth muscle cell growth and limit restenosis.

How would you describe the early days of design and development? The entire life cycle of cryoplasty as a medical device endeavor has been an incredible experience. The early years were filled with tremendous highs and lows as we tried to develop a device that worked as well as the science to support it. Although the physics underlying cryoplasty were quite simple, creating a safe, disposable catheter that simultaneously dilates and freezes was no simple task.

Fortunately, I met Ron Williams, who cofounded the venture with me. Ron had already enjoyed success in the device field, and aside from being a clever engineer, he knew the people and the processes that were vital to an early-stage company. The project truly started in a garage, and I can readily recall the excitement and frustrations that accompanied each hurdle we encountered. The experience has left me with a much greater appreciation for what it takes to bring a product to market. We were ultimately very fortunate to have a great team, sage advisors, and incredibly understanding spouses.

As the inventor of the technology, how often do you use it in your everyday practice? Is it difficult to be unbiased about using a product so closely linked to your name? My interventional practice is currently about 20% cardiac and 80% peripheral, and a significant proportion of my endovascular work is femoropopliteal and limb salvage. As such, I use cryoplasty regularly, and it has transformed my approach to infrainguinal disease and improved outcomes for my patients.

Bias is inherent in any endeavor for which one has passion. We all have our biases about what works best in a particular location on any given day of the week. How one manages bias is the key. In my situation, I have to routinely disclose my relationships, and I always strive to keep my patients' well-being foremost. My VIVA colleagues have been particularly helpful in keeping my interests balanced. At the end of the day, the professional satisfaction I receive from being affiliated with cryoplasty far outweighs any financial consideration.

You were also instrumental in pioneering the percutaneous bypass technique. What has the early work with this procedure been like, and how has the reception from the endovascular community been?
Percutaneous bypass of the lower extremities is still very much in the "early work" phase even though we treated our first patients over 3 years ago. Much has been learned from cadaver and animal studies, and each clinical case has identified new challenges. In essence, the procedure is designed to offer a minimally invasive alternative to femoropopliteal bypass grafting. Given the challenges and limitations of *(continued on page 105)*

(continued from page 106) long-segment stenting (strut fractures, high restenosis rates, and external compression of endografts), this approach may offer a more viable endovascular option for TASC D lesions.

Thus far, patient outcomes with this procedure have been excellent, and the peripheral vascular community certainly seems interested. What has become clear is that in order to pursue the procedure effectively, we need devices that are specifically designed for the task, and we need more data.

As one of the organizers of the VIVA meeting, what can you tell us about how you and the other founders came up with the idea to start the program? The concept of VIVA has always been about developing a better way to educate in the field of endovascular intervention. Several of us who had pre-existing regional meetings believed that there were simply too many "live-case" courses and that we were not able to do alone what might be better accomplished together. We quickly learned that other leaders in the field had a similar impression and formed a working group of 10 endovascular specialists who comprise an amiable balance between academia, private practice, and the various disciplines involved. Together we formed VIVA: The National Education Course for Endovascular Interventions.

I have to credit my wife, Carolyn Bing, for much of the formative strategic and operational insights needed in designing the meeting, and Medical Media Communications for their ability to execute our vision. The success of VIVA thus far can be traced to its interactive format (using Laptop Learning), its "turf-neutral" environment, and the high-quality faculty that we have recruited. Entering our 4th year in Las Vegas this September, the untold success story behind VIVA may be the unity and focus that has developed amongst my fellow founders Gary Ansel, Mike Dake, Tony Das, Michael Jaff, John Laird, Jon Matsumura, Krishna Rocha-Singh, Kenny Rosenfield, and Tim Sullivan. I am honored to be affiliated with these gentlemen.

What are some of the upcoming research projects you are involved in, such as the below-the-knee stenting protocol that VIVA Physicians is sponsoring? We all recognize that the one element that prevents endovascular medicine from gaining broader-based acceptance is the lack of good quality data. Although the situation is slowly improving, the VIVA group has dedicated significant resources to try to expedite the execution of trials that will ultimately support standards of practice. Our first venture into this arena is the XCELL Trial, which will rigorously test the use of self-expanding small vessel stenting in the setting of critical limb ischemia. This is a unique trial in that it is a physician-sponsored effort, and it has multiple core lab analyses that will set the stage for future evaluation of more aggressive infrapopliteal therapies such as drug elution.

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VIVA is also deeply involved in an effort to develop objective performance criteria in the areas of limb salvage and femoropopliteal intervention that will potentially pave the way for more rapid and reliable assessment of technologies that target infrainguinal disease. This effort has been led by Krishna Rocha-Singh and Michael Jaff, and if successful, will help all of us to work "on-label" and will expedite the trials that are necessary to support many of the procedures that we perform on a daily basis.

Other VIVA initiatives in process range from strategies to deal with in-stent restenosis, drug-elution platforms in the femoropopliteal space, and acute stroke intervention.

Although you are already considered one of the foremost innovators in endovascular care, you still have many years ahead of you. What will characterize the next 10 years of your career? I am hopeful that the next 10 years will hold many of the things that fulfill me currently. I truly enjoy early device development and hope to continue in my current capacity as a consultant and early evaluator of emerging endovascular and cardiovascular devices. Although many are not yet real or imagined, some current efforts include the PATRIOT Trial to evaluate the Crosser (FlowCardia, Inc., Sunnyvale, CA) for peripheral occlusions, the PARACHUTE Trial to study the ventricular partitioning device for heart failure (Cardiokinetix Inc., Redwood City, CA), and a percutaneous bypass venture with Rich Heuser.

I also hope to continue to expand my clinical capabilities in the direction of acute stroke intervention, as I feel this is the next frontier that we must embrace. I will undoubtedly continue to devote a significant amount of my time to the evolution of VIVA and its expanding agenda. Finally, I hope that the next 10 years will be characterized by personal and professional balance. I cherish my free time with family and friends, and I will always play at least as hard as I work! ■