



The Pioneer of Spray Cryotherapy

Mark H. Johnston, MD
pictured above with his
family in Kenya

In the mid-1990s, Mark H. Johnston, MD, was a practicing physician with the U.S. Navy. Board certified in Internal Medicine and Gastroenterology, he was highly respected by patients and peers alike, having treated Members of Congress and the Supreme Court and serving as gastroenterology consultant to the White House.

Dr. Johnston's patients typically presented with esophageal diseases like Barrett's Esophagus, dysplasia and esophageal cancer. Curious by nature, he was never one to accept the status quo and was growing increasingly dissatisfied with some of the conventional approaches to treating esophageal disease at the time. Often, care

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involved watchful waiting until disease progressed significantly enough to require esophagectomy, a painful procedure in which some or all of the patient's esophagus is removed. The procedure had a long recovery, permanently altered what the patient could eat and significantly impacted quality of life.

Inspired to find a better approach, Dr. Johnston attended medical conferences and studied scientific literature about new developments in heat-based treatments that aimed to destroy the diseased tissue lining of the esophagus so that the healthy tissue could grow back. He knew that burning-based methods had complications and wondered if cryotherapy, the use of extreme cold (e.g. liquid nitrogen) to freeze diseased tissue, might be a better option to trigger the body to naturally regenerate healthy tissue. Cryotherapy was a well-known and accepted treatment approach for dermal lesions, including skin cancer, and was used in other specialties such as gynecology. The challenge was that the existing cryotherapy devices being used inside the body had limited cooling power and required contact with the diseased tissue through a probe, which made it difficult to treat large surface areas. After a quick literature search, Dr. Johnston found that no one had tried using a non-contact, low-pressure spray cryogen that could deliver extreme cold consistently and reach larger segments of bumpy, hard-to-reach tissue.

Driven by this idea, Dr. Johnston went to work building a prototype in his garage using a thermos, a compressor, discarded equipment from the hospital and epoxy resin

purchased at Home Depot. His “cryoblaster” delivered liquid nitrogen through a catheter connected to an endoscope that could be placed in the esophagus and sprayed on diseased tissue. When his prototype was complete, Dr. Johnston approached the National Institutes of Health (NIH) for a grant for a protocol in pigs to assess the feasibility and safety of the new device. He received the grant and found that his invention worked as intended in the animal studies and that the depth of treatment could be controlled by the amount of time the spray cryogen was applied to the tissue.

With Dr. Johnston’s spray cryotherapy device showing great promise, a friend advised him to patent his invention. As a naval officer, everything Dr. Johnston did technically belonged to the government, so he filed a determination of rights and after several months the Navy determined that he owned the intellectual property and could pursue his own patent. However, as inventor of the device, Johnston learned that it would be a conflict of interest to continue to be involved with research and development associated with the device if he also earned royalties from any market success. He had to make a choice between earning potential royalties and having a role in the research studies.

“I knew that this technology could help people find relief from suffering and I wanted to see my idea through and play an active role in early feasibility work and ongoing spray cryotherapy research and development,” said Johnston.

Johnston’s family was actively involved with charitable missions and had previously established a nonprofit Christian charity, called Johnston’s Hope Foundation, which performs medical missions work in developing countries. Johnston elected to arrange for any potential royalties that derived from his spray cryotherapy device to be put to work helping less fortunate people through his mission work. *“This just felt like the right decision and I hoped that one day we’d take the spray cryotherapy device on a mission to help patients abroad.”*

For the next few years, Dr. Johnston worked to define a pathway to bring his device to the market. He signed away licensing rights to an early stage medical device company and, immersed himself in developing a second prototype and began work on a human protocol. Roughly 18 months later, he initiated a human trial and achieved favorable results. He presented data at clinical meetings in Paris and Boston and confirmed that spray cryotherapy was a very promising and unique approach that had significant and far-reaching clinical relevance.

In 2005, after 20 years of service, Dr. Johnston retired as a Captain from the U. S. Navy and joined a gastroenterology practice in Lancaster, PA. In the summer of 2007, CSA Medical, Inc. of Baltimore, Maryland released the first commercial version of the spray cryotherapy device that Dr. Johnston invented. Subsequently, CSA Medical conducted multicenter trials at major U.S. medical centers, with Dr. Johnston as a participating investigator.

Dr. Johnston has since performed spray cryotherapy more than 1,000 times and has helped hundreds of patients find relief from their symptoms. He has also trained numerous physicians on use of the device in the U.S. and abroad through Johnston’s Hope Foundation. In particular, Dr. Johnston focused a significant effort bringing the technology to Tenwek Hospital in Kenya, a nation with one of the highest incidences of squamous cell cancer of the esophagus in the world.

After the Johnston’s Hope Foundation prepared and submitted a research protocol that was approved by the Kenyan Government, CSA Medical donated a spray cryotherapy system to Tenwek Hospital and Dr. Johnston and his family traveled to Africa so that he could train the Kenyan clinicians on proper use of the device. Royalties from spray cryotherapy have also funded a small mission hospital in Togo West Africa and the Albanian Health Fund.

In recognition of his entrepreneurial, clinical and philanthropic achievements, Dr. Johnston has received numerous military, academic, research and humanitarian awards, including the state of Maryland’s Innovator of the Year Award, American College of Physicians Navy Chapter Volunteer of the Year Award and being named winner of the National Navy Medical Center Research Competition.

“This has been a long journey, but I am pleased that CSA Medical is leading the way to train physicians and invest in research and development so that we can bring the benefits of spray cryotherapy to more patients,” said Johnston. *“I’ve seen this technology provide relief and significant improvements to quality of life for many patients. It isn’t possible to put a value on witnessing this transformation and bringing new hope to patients. I feel blessed that I’ve been able to turn my idea into a reality, and at the same time support our family charity with the royalties, this is my personal measure of success.”*