

Innovative Resuscitation System Saves Lives In Critical Patient Care

British Columbia Inst of Tech (BCIT)











Seconds can mean the difference between life and death in medical emergencies. Trauma patients in car accidents, life-threatening situations at home, on battlefields, or on ambulance crash carts and in hospitals, need life-saving medicine and fluids, and they need them fast. But sometimes administering intravenous (IV) drugs and fluids rapidly and reliably is not possible.

When Veins Collapse

When patients receive serious injuries, or experience health emergencies such as cardiac arrest, the body starts to shut down and the person's veins become smaller and more difficult to access. Even with the most skilled provider, it can take precious time to thread a catheter into a peripheral vein in the arm or leg before the vein becomes flat and inaccessible. The FAST1™ technology, invented by Pyng Medical with the support of British Columbia Institute of Technology (BCIT), allows drugs and fluids to be administered directly into the sternum through the intraosseous (IO) space, which acts as a non-collapsible route to the heart. It is the only device able to provide access within seconds to

get drugs and fluids to the heart of someone who is critically injured. For that reason the FAST1 is used in the battlefields of Iraq and Afghanistan when access to the peripheral veins is not a fast and efficient option.

Jason LeMoine, a fifth-generation firefighter and paramedic at a 21-station fire department in the San Francisco Bay area, and who also works as a registered nurse at a local medical emergency center says, "I have seen patients die when time was not on our side. It was frustrating when we couldn't get IV access to them faster."

But on one particular September day in the San Francisco Bay area, where fiery sunsets and wind-swept beaches are part of the landscape, something even more stunning appeared.

LeMoine, along with a team of firefighters, responded to a report that an 18-year-old was having a seizure. When they arrived, they found the patient was not having a seizure but he was in cardiac arrest. Two bystanders, who were performing CPR, reported that the downtime of the patient was between five and seven minutes. When the fi re department arrived, the patient was unconscious and had "fl at-lined." "He didn't have a heart rhythm," he says.

Never were the words "time is of the essence" more apparent. Instead of taking valuable time to use traditional IV access when the patient was pulseless, LeMoine, 36, used FAST1™ technology to administer lifesaving medication to the patient. "We were able to revive him within five to six minutes," says LeMoine. "When the patient was transported to the hospital, he had a pulse."

Development of Intraosseous Access

While timing and technology saved the life of this patient, this is just one of many successful outcomes due to FASTI™. Numerous stories like this one can be attributed to research conducted by the Health Applied Research and Development group at British Columbia Institute of Technology (BCIT). Judy Findlay and David L. Johnson Ph.D., were the principal inventors of the technology. Technology transfer also was handled by the Health Applied Research and Development group led by Dr. Johnson. Findlay, now the director of BCIT's Health Technology Research Group, says, "This has been a successful collaboration between BCIT and Pyng Medical Corp. The company's flagship product, which has been adopted worldwide, has already saved many lives."

The collaboration between Pyng Medical Corp., based in Richmond, British Columbia, and BCIT began when Michael Jacobs, founder of Pyng, came to BCIT for assistance. Specifically, Pyng needed BCIT's scientific and engineering expertise in helping develop a product that could be used in medical emergencies when IV lines failed or peripheral IVs were difficult to access.

Developing technology that can save lives takes an enormous amount of time, patience, and teamwork. FAST1™ development involved in-depth research of adult sternal and vascular anatomy as well in-depth research into the skills, attitudes, and training of users and the unique challenges of pre-hospital environments.

Findlay explains, "It is often assumed that an invention coming out of a university is ready to be manufactured, but that is seldom the case. The invention is really just step one. The solution needs a significant amount of development which may entail a huge risk for the company licensing the product. This is where professional product development comes into play — including developing and meeting design requirements, verification and validation testing, achieving regulatory approvals (in this case by the FDA and Health Canada), and eventually manufacturing, distribution and product launch."

The progression from research to product commercialization for FAST1™ had to do with its unique set of variables. A brilliant idea, as in the case of FAST1™, needs a significant amount of professional product development before it can be

commercialized. With FAST1™, Findlay says, "The first invention that Pyng hoped to market met only five of about 20 necessary top-level design requirements. Once these had been established, BCIT worked with Pyng to develop a product that ultimately met all the necessary performance, safety and regulatory requirements."

Funding for the development of the technology came from Pyng's parent company, Pyng Technologies, from Canadian Federal Government funding sources and from the Science Council of British Columbia. In 1998, the first patent was assigned to Pyng for the "Apparatus for Intraosseous Infusion or Aspiration," followed by a 2004 patent for the "Method and Apparatus for the Intraosseous Introduction of a Device Such as an Infusion Tube."

Pyng's President and CEO David Christie comments, "It takes a bold vision to turn an invention into a business, and entrepreneurial energy and tenacity to get the idea to market. People don't often realize the amount of blood, sweat and tears it takes from research to commercialization of products. It took us more than seven years to develop the product, another three years to develop the market, and three more years to secure true profitability and a sustaining business." From the time Pyng came to BCIT in early 1993, it took until 2001 before the company sold its first product. Christie says, "Today, we have sold over 120,000 units. FAST1™ has likely saved tens of thousands of lives on the battlefield of Iraq and Afghanistan, in motor vehicle accidents, in cases of violent or accidental trauma, and in situations involving cardiac arrests." The company, which has eight patents in eight countries, has 17 employees and annual sales of \$4.8 million.

Combat medics and the people they treat in Iraq and Afghanistan have benefited from the FAST1™ technology. Since the late 1970s, many American troops have worn the Kevlar flak vest which protects a person's "body core," that is, the heart, lungs and abdominal area. Battlefield injuries often involve the peripheral areas — a person's arms and legs. Many lives on battlefields have been saved thanks to FAST1™ rapid resuscitation access through the sternum.

Victims of civilian emergencies around the world are also benefiting from the FAST1™. Paramedic LeMoine, who has used FAST1™ with about 15 individuals over two years, says, "It is a fast way to get venous access. It only takes about 60 to 90 seconds to gain vascular access as opposed to standard IV access in a person's limb which typically takes three to 12 minutes, and that's if you even can get access."

66 IO devices like FAST1™ are now recognized as the first-in-line, safe and effective alternative when IV access is not an available route to deliver lifesaving drugs and medicine.

Recently, the American Heart Association made a historic recommendation when it revised its guidelines for Advanced Cardiac Life Support (ACLS) and recommended IO devices, which include FAST1™, as the first alternative for adults in cardiac arrest. At the same time the International Liaison Committee on Resuscitation (ILCOR) recommended IO access be used for adults and pediatric patients as a first alternative in life-threatening situations. Since FAST1™ was first developed, other IO devices have entered the marketplace.

Today, Pyng has started the development of the next generation of FAST1™, and complementary devices.

"In the face of the ever-changing role of emergency medical service and the evolution of our medical products, we anticipate an even broader use of FAST1™ technology," says Christie.

LeMoine adds, "FAST1™ has saved numerous lives and will save many more. The first few minutes during a medical emergency can mean the difference between life and death, which is why this is an excellent advancement in prehospital care."

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