

Start-Up Innovation: Device to stop sternal bleeding

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Singapore: Dr Randall Moshinsky, a cardio-thoracic surgeon in Australia, was frustrated by bleeding from the cut edge of the sternum since he was a surgical trainee. Surgeons have tried to address the problem of sternal bleeding during heart operations, but none of the attempts have been able to negotiate the very significant variability in size and shape of adult breastbones (sternums), nor to make a device that is quickly and easily fitted to the sternum by the surgeon.

Surgeons have to deal with continued bleeding during surgery or use products such as bone wax, a product made from beeswax which is pressed into the bone marrow to stem bleeding, which remains in the body post-operatively, and which has been associated with impaired healing of the sternum and could be a contributor to post-operative sternal infections.

Dr. Moshinsky's desperation to stop sternal bleeding during a surgery guided him with the idea to invent a sternal protection technology that overcomes the challenge of excess bleeding during cardiothoracic surgery.

After a chance meeting and later forming association with Dr Ingmar Wahlqvist, a medical doctor who is investment manager

at Brandon Capital Partners and also the manager of Medical Research Commercialisation Fund (MRCF), Dr. Moshinsky founded Protego Medical in 2013 along with Dr. Silvana Marasco, a cardiac surgeon at Alfred Health who leads the clinical investigation of the new device at the Alfred Hospital.

The use of sternal retractors to hold back the edges of the sternum in cardiac surgery leads to trauma to the sternum and sometimes sternal fractures resulting in increased post-operative pain and morbidity. The device developed by Dr. Moshinsky protects the sternum from trauma and also reduces blood loss from the sternum, both of which are associated with significant patient morbidity. The technology will shortly enter a preliminary clinical trial at the Alfred Hospital, Melbourne.

With the invention of sternal protection technology, surgeons would have immediate benefit, says Dr. Moshinsky. "Additionally, in many patients the marrow is very soft, and not sufficiently strong to hold the beeswax, rendering it ineffective. By contrast, if the surgeon elects to let the sternum bleed, the blood frequently obscures the surgeon's work, and complicates the picture when establishing whether bleeding is coming from other sources. Blood loss is in itself correlated with poorer outcomes in cardiac surgery, driven by a range of factors. Therefore any mechanism to address this has the potential to contribute to better overall outcomes in these patients," he elaborated.

"My involvement in Protego Medical and the technology we are developing arose in response to a need I perceived in current clinical practice. As surgeons we are always trying to find ways to improve our practice so that we can offer better patient care. Every operation we perform involves numerous small steps and the efficiency of each one of these steps contributes to the overall success of the operation and the patient's outcome. It seems natural to me that we should constantly refine each of these steps through ever improving medical devices and surgical techniques. Surgery is an evolving art and where I see that a patient's well-being could be enhanced it is imperative to problem solve to arrive at increasingly better solutions," he believes.

Money Matters

MRCF has committed USD2 million in a tranching investment to advance the prototype design to a proof-of-concept trial at the Alfred Hospital in Melbourne, progressing to a larger clinical trial program and ultimately registration and market launch. Dr. Moshinsky has conceived the idea to develop the technology and is now in the process to finalise the design and to demonstrate that the device will deliver the anticipated benefits to surgeons and patients.

"This needs to be achieved in a short timeframe as we are a start-up with very limited resources. The next major challenge is to commercialise the device in major markets, normally a very draining activity, in terms of resources, for any small company," stressed Dr. Moshinsky.

Dr. Moshinsky is now wearing the cap of a surgeon as well as an entrepreneur. He expressed, "it is extremely exciting to see the development of an idea in my head, to drawings and prototypes of a medical device that will hopefully one day deliver improved patient care. The main challenge has been balancing the demands of clinical practice with the demands of a newly formed medical device company. My role in the development of this technology has been very rewarding, and it is very exciting developing a device in which we have great confidence."