

Biomedical Innovation Competitor #5

SmartForceps System

Presented by Dr. Hamidreza Hoshyarmanesh, PhD and Dr. Sanju Lama, MD, PhD

Video: <https://w21cinnovationacademy.com/competitors/#Competitor9>

Authors: Dr. Sanju Lama, MD, PhD, Dr. Hamidreza Hoshyarmanesh, PhD, Mohammad Saleh Razmi, Dr. Amir Baghdadi, PhD, Fang Wei Yang, Starr Tze, Dr. Garnette Sutherland, MD

The SmartForceps System is a sensorized surgical bipolar forceps linked to an Intelligent Module (software) for real time display and record of tool-tissue interaction forces during surgery! The data uploaded to a secure server is used for performance feedback and machine-learning algorithm for automated analyses and error warning. Based on force variability and error, the innovation has already shown surgeon discrimination by their skill level. Emulating the aerospace industry, the SmartForceps system, uniquely establishes a digital footprint of surgery for standardized surgical performance and training, providing a distinct advantage over conventional tools towards increased patient safety.

It has been shown using virtual reality simulators that ~50% of surgical errors occur from use of excessive force. Currently, the ability to apply optimal force of tool-tissue interaction during surgery is only mastered through years of apprenticeship. This knowledge remains largely qualitative, as none of the commercially available surgical instruments provide real-time measurement of intra-operative surgical forces. There is no objective means of assessing detectable amount of force applied to delicate tissues until obvious injuries have occurred. The SmartForceps System is the innovative solution that links surgeons' intra-operative force data for measurable performance metrics to patient's surgical care.

Optimal use of tool-tissue forces during surgery remains an ongoing quest as the skill is largely gained through years of hands-on training. Learning from the neuroArm neurosurgical robot equipped with force sensors, our team set-off on the journey of sensorizing conventional surgical tools, the bipolar forceps, used commonly for surgical dissection and coagulation. The SmartForceps is the first of its kind integrated with strain gauge force sensors for real-time sensing and monitoring of tool-tissue interaction forces during surgery. The innovation includes a calibration station, signal conditioning unit, and a unique software platform for intra-operative force monitoring and recording. Following pre-clinical evaluation, the prototype has been clinically validated in 27 patients with a spectrum of neurosurgical disease, such as brain tumour, vascular malformations and epilepsy. In addition, it was discovered that the force profiles and error analysis precisely discriminate surgeons by skill level and experience, thus establishing a novel metric for surgical skill assessment and education. Towards value creation, the innovation already has one patent application, two pre-clinical and two clinical publications, and an application to Health Canada. The IP resides in OrbSurgical Ltd., a Calgary based start-up that was created to translate new IP spinning out of Project neuroArm-University of Calgary for successful commercialization. By partnering with Bissinger GmbH Germany (SmartForceps manufacturing), and Quadrus Development Inc. Calgary (intelligent software), the team has just completed development of medical grade SmartForceps System. A custom developed Signal Conditioning Unit now deployed for mass printing (Canadian Circuits, Surrey BC) and state-of-the-art Calibration Station v3.0 now residing at Bissinger facility in Teningen Germany, further ensures product manufacturability. The team has also

begun the clinical testing of the technology at Foothills Medical Centre (REB19-0114). Submission to Health Canada for Investigational Testing Authorization has just been completed. Technology launch to neurosurgical community is anticipated in October 2019 at Congress of Neurological Surgeons Annual Meeting in San Francisco, USA. For this innovative R&D, the team has obtained grants from the German Canadian Centre for Innovation & Research (GCCIR) and the Canadian Institutes for Health Research (CIHR) (Technology Commercialization).

The SmartForceps System is unique as it leads the entry of sensors and smart technology into the operating theatres. As bipolar forceps is one of the most common surgical tools (world market size ~47 million/yr.), the innovation will reach multiple hospitals and surgeons worldwide. The technology represents a major advance in sensitive and reliable metric for surgical performance and skill assessment currently not available, it will invariably transform the training and practice of neurosurgery/surgery to an era of competency-based big data mining evolution. Similar to aerospace industry, this will lead to standardized, and perhaps cost-efficient, patient care and services.