

ISCHEMSURG: minimally-invasive microsensors for detection and control of tissue ischemia

The Challenge

Monitoring tissue ischemia is key to avoid irreparable damage or even tissue loss due to blood perfusion impairment. Tissue ischemia control is commonly required on reconstructive surgery units, where microsurgical anastomosis of tissue flap vessels is routinely performed by clinical observation of general symptoms; as well as in trauma units, where compartmental syndrome (i.e. raise of tissue pressure due to severe trauma and consequent loss of blood perfusion) is a main concern.

Currently, the control of tissue ischemia is based on the clinical observation of subjective symptomology (e.g. skin color or turgence). Therefore, microcirculatory complications are normally detected after 5-8 days post-surgery, when tissue salvage rate is very low. Thus, reliable methods for earlier detection of tissue ischemia are required.

The Market

As an average, 20 persons per each 100,000 habitants undergo flap surgery in the developed countries every year (i.e. 100,000 cases per year in the EU). The control of such patients to avoid secondary surgeries due to primary tissue loss, could save to the EU Health Care system 222M€ per year, as well as decreasing patient morbidity and serious health risks.

Compartment syndrome can be acute or chronic, and can be a life- or limb-threatening condition. Acute condition is closely related to severe trauma in large bones or the abdominal compartment. Only for tibial fractures, one of the main causes of compartment syndrome, already presents an incidence of 406-1,693 patients per 100,000 habitants per year. The cost assumed by the EU Health Care systems for the 1st year treatment of the compartment syndrome's consequences is estimated to be 390 M€.

The Asset

ISCHEMSURG is a disposable and miniaturized array of electrochemical sensors for the minimally invasive monitoring of tissue ischemia. ISCHEMSURG technology is based on the detection of physiological changes that occur under ischemia conditions, which are analyzed by means of potentiometry and bioimpedance. This wireless sensor permits the continuous control of deep tissues, whose blood perfusion may be compromised. Ischemia control by means of ISCHEMSURG technology can be carried out by both physicians and caregiver professionals. Moreover, the small dimensions of the sensor as well as the probe design, permits ISCHEMSURG to be easily removed from the site of insertion with minimal pain and risk. Thus, in case of ischemia complications, ISCHEMSURG will permit an immediate surgical response before irreversible tissue damage occurs.

Product Opportunity

Early recognition of tissue compromise is a primary aim of every microsurgical and trauma unit. The standard monitoring method is based on subjective clinical observations, which depend on the professional experience. Moreover, early tissue compromise is often asymptomatic, increasing ischemic times and reducing successful salvage rates. Moreover, deep tissues are very complex to monitor by clinical observation. On the market, only two options have been proposed to overcome this trouble: flap micro dialysis and the Cook-Swarts implantable

Scientific Project Leader

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Stage of Development

Large-scale prototype tested on stomach pig-model. Micro-sized prototype under development.

Multi-sensing integration achieved.

Intellectual Property Status

Patent application on-going.

Exploitation Plan

Licensing or co-development

Contact

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