SWAN-iCare: Smart wearable and autonomous negative pressure device for wound monitoring and therapy

Context and Objectives

More than 10 million people in Europe suffer from chronic wounds, a number which is expected to grow due to the aging of the population. The EU FP7 SWAN-iCare project aims at developing an integrated autonomous device for the monitoring and the personalized management of chronic wounds, mainly diabetic foot ulcers and venous leg ulcers. Most foot and leg ulcers are caused by diabetes and vascular problems respectively but a remarkable number of them are also due to the co-morbidity influence of many other diseases, e.g. kidney disease, congestive heart failure, high blood pressure, inflammatory bowel disease.

The core of the project is the fabrication of a conceptually new wearable negative pressure device equipped with Information and Communication Technologies (ICT). SWAN-iCare novel idea focuses on the pioneering provision of two-line therapy at home:

- a first line based on a negative pressure device, which provides a moist environment, reduces bacterial colonization, localized oedema and dead space, and promotes localized blood flow, granulation and epithelialization.

- a second line based on a smart interface at the direct contact of the wound in order txo continuously release bioactive compounds to improve wound healing.

Such device will allow users to: (a) accurately monitor many wound parameters via non-invasive integrated micro-sensors, (b) early identify infections and (c) remotely provide an innovative personalized two-line therapy via non-invasive micro-actuators to supplement the negative pressure wound therapy.

The physician's analysis of the collected data will be the basis for the decision and the remote control of the therapy. The closed-loop approach offered by SWAN-iCare project provides unprecedented levels of care, improves the patient's health condition and significantly lowers the costs and need of hospitalisation, with obvious advantages for both the patient and health care services. Future statistical analysis of recorded patients' histories will help advance the wound management science and clinical practice.

Concluded and ongoing project activities

SWAN-iCare has currently completed its second year. In the first year, the project specified the requirements of all stages of the full innovation chain, starting from user requirements to business aspects that must be addressed for launching a competitive solution in the market. More specifically, user and medical requirements were identified taking into account all stakeholders in the full value innovation chain of the project, workshops have been organized by CHURG and UNIPI, the medical partners of the project, in order to gather requirements from patients for the Diabetes Foot Ulcer (DFU) and the Venus Leg Ulcer (VLU) applications which are addressed within the scope of this project. In total, 102 patients were informed about the scope of SWAN-iCare and filled questionnaires, whose results were analysed to derive conclusions. A number of external to the project doctors and nurses specializing in WP3 worked in collaboration with WP2 to define the requirements and the list of sensors for both Venous Leg Ulcer (VLU) and Diabetic Foot Ulcer (DFU) use cases. Within the second year, the project defined the system architecture, taking into account the user and medical requirements and the regulations and standards applicable to the scope of the envisaged SWAN-iCare system.

The project worked on the design and implementation of sensors both for the mainstream and the high risk streams of development. The mainstream development delivered progress on the MMP sensor, the Trans Epidermal Water Loss device, the durable pump head, collagen-containing dressings compatible with the use of Negative Pressure Wound Therapy (NPWT) and an Insole pressure device.

The high risk components were also progressed. Specifically, the project worked on the delivery of the Protein sensors (CRP and TNFα), the pH sensor (high risk), the Wound impedance device, the Bacteria sensor. It also worked on the development of new collagen-based biomaterials for the delivery of chemical or biochemical therapeutics, vectorized by lipid nanoparticles and of the disposable pump head.

The project defined the schematic block diagrams for the components of the main stream development. It designed the SNPD enclosure and the layered firmware architecture. It also delivered the first prototypes of SWAN–iCare's data fusion algorithms, the embedded software running on the SNPD device, the Hub application for managing the external devices, the Personal mobile application for the patient and the Medical Gateway application for healthcare professionals and administrators.

The first version of the integration plan has been devised. The integration tasks were defined to integrated components in the form of the main stream prototype (i.e. prototype integrating the "main stream" sensors") to be delivered within the third year for approval for clinical trials.

The two clinical partners (Pisa and Grenoble hospitals) worked on the collection of wound exudate samples in VLU and DFU to familiarize with the technique and towards achieving a preliminary in vitro model for testing with the project's diagnostics tools. Furthermore, the project worked towards business models of the envisaged commercial product taking into account the market size and the competition. The consortium devoted substantial time to identify which sensors and actuators would provide the greatest return in relationship to cost of goods.

Expected final results and potential impact

The project is expected to have significant impact, with positive effects in the patients' quality of life, healing time and also reduction of healthcare costs. Scientific and business impact is also expected. The impact of the project - on four different dimensions - is summarized below.

Patient: Continuous efficient monitoring of a number of wound parameters at the patient's home will help providing an additional data set for assessing the treatment progress. Personalised and improved therapy initiated by the physician remotely and adapted to the daily measurements will provide a tailored solution to the patients' needs that can lead to a faster healing outcome: wound deterioration can be identified early and acted upon, therefore leading to reduced morbidity and amputation rates. Furthermore, the patient will benefit from reduced need for hospitalisation due to early identification of wound deterioration. Better quality of life with better mobility, more comfort and less stress from reassurance of being continuously monitored and an anticipated healing trajectory will be key benefits to patients.

Society and Healthcare: Reduced healthcare costs are expected as a result of reduced need for hospitalisation and clinician/nursing visits through increased remote monitoring. Reduced costs to the social system and manufacturing productivity as a result of enabling the patient to return to work earlier from faster wound healing. Increased access to best practice wound care for patients living in remote geographical locations.

Medical science: The project is expected to advance current wound care best practices towards provisioning of more effective would care protocols at a European and at international levels. A database (not available in the past) will be formulated to provide a greater understanding of the wound healing processes. Continuous objective measurement will contribute to the evaluation of wound progress and the effectiveness of the treatment, also giving the potential for new wound healing research by correlating measurements and outcomes from multiple patients.

ICT science and Business: The interdisciplinary expertise available in the SWAN-iCare consortium, is the basis for the development of business relationships between companies and research institutes from different industrial domains and will allow bringing forward a really multidisciplinary approach for wound management. The current Negative Pressure Devices market is unevenly split between USA, Europe and ROW, with more than 75% of the global market (estimated at 1.25billion euro) being localized in US. Europe is currently lagging behind this market, but this innovative project strives to offer the possibility to fill the technology gap and to take the lead in this sector.

Consortium and contact point

The SWAN-iCare consortium consists of the following industrial, academic and research partners:

- EXUS S.A. (Greece, Project Coordinator)
- Commissariat à l'Energie Atomique et aux Energies Alternatives (France)
- Centre Suisse d'Electronique et de Microtechnique SA (Switzerland)
- Università di Pisa (Italy)
- CHU Grenoble (France)
- Euroresearch (Italy)
- Heamopharm Biofluids (Italy)
- European Wound Management Association Secretariat (Denmark)
- Institute of Communications and Computer Systems (Greece)
- Smith & Nephew (United Kingdom)
- SWISSINNOV (Switzerland)

For more information on the project, please contact the project coordinator Dr Leonidas Lymberopoulos (lelym@exus.co.uk), or visit the project's web site:

http://www.swan-icare.eu