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

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Abstract-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). 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 core of the project is the fabrication of a conceptually new wearable negative pressure device equipped with Information and Communication Technologies. 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. This paper describes the main components of the SWAN-iCare system and its potential impact in the area of wound management.

Keywords—SWAN-iCare, wound monitoring, sensors, actuators, medical software, embedded software

I. Introduction

The swan-icare projects aims at improving the monitoring and management of chronic wounds: venous leg ulcers mainly originating from vascular problems, and diabetic foot ulcers. As previously described, “chronic venous insufficiency and leg ulcers affect approximately 1-2 people per 1000 of the general population, with approximately 10-20 people per 1,000 ever affected. Ulcer healing rates can be poor with up to 50% of venous ulcers open and unhealed for 9 months. Ulcer recurrence rates are worrying with up to one third of treated patients on their fourth or more episodes. In the UK leg ulcer treatment accounts for 1.3% of the total healthcare budget and up to 90% are treated in the community. In the United States, venous ulcers have been estimated to cause the loss of 2 million working days and to incur treatment costs of approximately $3 billion per year” [1]. On the other hand, approximately 1-4% of those with diabetes will develop a foot ulcer annually, and approximately 15% of those with diabetes will develop at least one foot ulcer during their lifetime [5]. The prevalence of diabetic foot ulcers has been estimated to be 3-8% in the diabetes population [6]. The annual incidence of foot ulcers in the US population has been estimated at 1.9% in type 1 and 2 diabetic patients. Various European studies suggest the incidence to be 2.1% and 3.6% [7], respectively.
This relatively high incidences impact a growing population, since by the year 2025, it is estimated that 300 million people will have diabetes [2] and by 2030 nearly 438 million will be affected by diabetes [3], [4].

Most foot and leg ulcers are caused by diabetes and vascular problems respectively, but a remarkable number of them are due to the collateral damage of many other diseases such as kidney disease, congestive heart failure, high blood pressure, inflammatory bowel disease and others. An aging European population and a high incidence of wound recurrence stress the need to efficiently take in charge these pathologies. Clearly a large population is affected, the diabetes population worldwide is estimated about 250 million [8].

The Negative Pressure Wound Therapy (NPWT) is increasingly applied in hospitals to treat this kind of chronic wound and performs by removing exudate and potentially infectious material. It also promotes the formation of granulation tissue by applying a negative pressure healing system, thus accelerating the wound healing. At the moment, the healthcare costs due to the application of this promising technique are relatively high since it necessitates hospitalization and medical acts. Recently, portable systems - including ‘PICO™’ of partner Smith & Nephew were developed and commercialized with several advantages for the patients: such as portability, discreetness and ease-of-operation. Some of the commercial devices are even used outside the hospital. However, they are all still offering the single service of negative pressure on the wound.

To address the above, SWAN-iCare is an ambitious project aiming at providing a major leap forward in the management of chronic wounds, mainly diabetic foot ulcers (DFU) and venous leg ulcers (VLU). Specifically, the project aims at developing a next generation integrated autonomous solution for monitoring and personalized therapy for foot and leg ulcers. The goal is to provide an objective continuous evaluation of the wound condition as opposed to the current subjective evaluation by the clinician. ‘Autonomous solution’ means that the device will have integrated battery to work autonomously.

At the core of the SWAN-iCare project is the fabrication of a conceptually new wearable negative pressure device equipped with Information and Communication Technologies. Such a device will allow clinicians to:

- accurately monitor many wound parameters via non-invasive integrated micro-sensors;
- early identify infections;
- remotely provide an innovative personalized two-line therapy associating active ingredient delivery 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 the SWAN-iCare system provides unprecedented levels of care, improves the patient’s health condition and significantly lowers the costs and need of hospitalization, 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.

The present paper is describing the SWAN-iCare concept. It is structured as follows. Section II presents the overall architecture of the SWAN-iCare system. Section III describes the sensors and actuators to be developed for wound monitoring. Section IV overviews the medical applications and section V the embedded software that will be developed to provide data fusion support to the sensors implemented within the system. Finally, section VI discusses the potential impact of the SWAN-iCare system in the area of wound management.

II. Architecture of the SWAN-iCare system

SWAN-iCare will develop an integrated autonomous solution for diagnosis, monitoring and personalized therapy of foot and leg ulcers. SWAN-iCare exploits a closed-loop approach with the following characteristics:

- Remote monitoring and analysis by the physician of patient sensor data, these being used for remote configuration of the ulcer therapy;
- Wider level feedback that incorporates the statistical/intelligent analysis of the therapy policies and patient data also enhanced by the potential of future correlation of multiple patients’ measurements.

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 to continuously release bioactive compounds to improve wound healing.

The project will follow a dual approach for the sensors/actuators development, to ensure the delivery of proven prototypes by the end of the project. ‘Mainstream’ development will rely on sensors/actuators with already quite mature technologies, for which further development is straightforward and will lead to more secure results. ‘High risk’ development will focus on sensors/actuators based on very innovative technologies, which implies that considerable research and development effort is required.

In more details, the overall SWAN-iCare solution, as depicted in Fig. 1, will incorporate:

A- A Smart Negative Pressure Device (SNPD) for continuous, accurate monitoring and therapy of ulcers enabled by smart configuration of Micro-Nano Bio Systems MNBS and ICT components, including:
A1. A negative pressure cartridge containing:
• A negative pressure system which will remove the exudate in order to accelerate the foot and leg ulcers healing,

• A power management module consisting of batteries integrated in a complete recharge controller and their health and capacity monitoring for autonomous device operation,

• Wireless connectivity networks,

• Novel embedded electronics & software: including Real Time Operating System (RTOS),

• Integrated sensors to provide information on the patient’s global health status and wound healing,

• Integrated display on the durable cartridge for information visualization, alarm and basic control by the patient.

A2. Disposable interface parts for measuring and treating the wound and containing:

• A transparent occlusive layer (film) to avoid vacuum leaks,

• Integrated sensors to provide information on the patient’s global health status and wound healing,

• An innovative dressing designed in smart biomaterial to provide continuous infusion of active ingredients to improve the wound healing process.

B- Commercially available and wearable (non-commercial) sensors to monitor the patient and complement above measurements, including glucose monitoring, body temperature, bending of the ankle joint, local-on-feet pressure sensor.

C- A Medical Staff Gateway Application in the clinic, for collecting and analyzing the multi-parametric data of each individual patient.

D- A Patient’s Personal Station Application, for his/her handheld device, which provides appropriate interfaces for:

• the management of the SNPD, local collection of the data signal processing, display of the results including alarms, malfunctions advices, etc.

• the remote reconfiguration of the therapy by physicians.

This application will be offered over a smartphone, which must be equipped with wireless short-range interface like Bluetooth LE [9], ANT+ Ecosystem [10], or ZigBee [11]. For reasons of interoperability, an available standard will be preferred rather than proprietary solutions.

The overall system developed in the SWAN-iCare project will be validated in a series of tests sessions in vitro and in vivo on a small group of humans. The comfort aspect will also be evaluated. The overall process will follow a very detailed methodology considering all legal and ethical issues, ensuring no risk for patient’s health.

A detailed impact analysis and business plan will be conducted including impact and cost/benefit analysis, leading to the roadmap for adoption strategies and identification of business opportunities for SWAN-iCare. The business aspects of the successful commercial placement of such a product, the involved players and value chain will also be considered.

The project will document a medical shift in the clinical practice and this imposes education and training requirements for patients and healthcare personnel, which will also be provided by the project.

III. Sensors/Actuators of the SWAN-iCare System

The SWAN-iCare sensors and actuators are designed to provide clinically useful information and act on the wound at multiple levels. Figure 2 displays photographs of commercial devices or prototypes of sensors and actuators that could be included in the SWAN-iCare system.

Sensors will be used to obtain information on the global patient conditions and activity, the possible presence of an inflammation or an infection, as well as the condition of the wound and the perilesional skin. Both optical and electrochemical sensors will be designed, according to the monitored parameters.

A glucometer, a body temperature sensor and a pedometer provide an overview of the patient’s general condition. The glucometer data are only important in the case of diabetic patients.

Inflammation is the first stage of the wound-healing process and is characterised by redness, pain, increased temperature and fever. Its function is to neutralise and destroy any toxic agents at the site of injury and to restore the tissue homeostasis. Since inflammation is associated with increased temperature values, wearable temperature sensors will be included in the wound dressing to allow a real-time remote monitoring of this parameter. Inflammation status will also be assessed by quantification of biomarkers, such as metalloproteases.

A certain level of bacterial burden is normal in every wound, but when it becomes excessive an infection develops that requires antibiotic treatment. The proliferation of bacteria in the wound leads to increased pH values. For example, in chronic venous leg ulcers and in pressure ulcers, alkaline or neutral pH value, compared with the normal surrounding skin, is considered a sign of infection [12]. In the project, we will also focus on the detection of the most encountered antibiotic-resistant bacteria strains, requiring tailored medical treatments. The early identification of bacterial infections based on sensor monitoring could help removing some of the errors and misinterpretations which are common in the clinical practice, currently based on the visual observation of the wound colour and the viscosity or volume of the exudate.

The evaluation of the permeability of the skin to water can help the assessment of the conditions of the perilesional skin.
Trans-epidermal water loss (TEWL) is commonly accepted to assess structural damages of the epidermis and a specific sensor can thus add relevant information for the physician about the evolution and recovery of chronic wounds or the efficacy of treatments.

Smart dressings will also be designed for continuous delivery of active ingredients known to promote wound healing [13].

The overall concept of the SWAN-iCare sensing and therapy system is to achieve a miniaturized, low power and wearable device where each sensor/actuator is biocompatible and sterilizable, and disposable due to its low cost.

Therefore, technological developments will be aimed at targeting easy to implement and produce sensors and actuators, while achieving the sensitivity and technical specifications required for wound monitoring and healing application.

IV. Medical software components

The SWAN-iCare novel software applications elevate the services offered to ulcer patients by this personalized, patient-centric service. Such service will allow the physicians to be continuously and remotely aware of patient’s condition, and to receive alerts highlighting situations requiring instant actions and emergencies. Figure 3 depicts all the software components, which will be integrated in the complete SWAN-iCare system. In this way, the loop of diagnosis, processing and feedback to therapy will be closed. In fact, the measurements have three different applications, related to user interfaces and data-fusion mechanisms to be implemented:

- **The embedded application** within the Negative Pressure Device, which will be responsible for the local sensor data fusion. Data fusion will be the basis for any local alerts sent to the patient’s personal station (Smart phone or similar) as well as for communicating the regular measurements to the smart phone and medical staff gateway application. More information about the embedded software will be given in the next section of the paper.
- **The smartphone application** which will allow for local data processing of sensors for the patient’s information as well as running all device management processes, including the remote configuration of the negative pressure therapy.
- **The medical staff gateway application** which will provide innovative, efficient data processing rules, combining the patient’s conditions and pathology with the actual monitoring data, comparing with clinical workflows and thus alerting when an emergency occurs. This application will also incorporate novel and user friendly interfaces to visualize with the measured data over time and correlate measurements when necessary. For example the level of wound exudates will be correlated between the clinical aspect of wound bed and surrounding skin and the monitored data from the interfaces during treatment.
The data fusion design of all the three applications will require understanding and modeling of the relationships and patterns of the data measured and determine what procedure algorithms and protocols need to be modeled and developed. New unexploited multi-parametric sources of data will be combined to achieve inferences that could not be obtained from a single sensor, neither by regular patient examination in the clinic.

The SWAN-iCare medical staff gateway application in the clinic will be integrated in a novel way with the workflows of the existing clinical practice or new ones will be designed when necessary, since such remote monitoring is not currently happened for therapy of ulcers. This process will be designed to ensure that the clinical practice will enhance the care provisioning through more efficient electronic workflows and use of SWAN-iCare applications. This innovative practice of ulcers remote monitoring and therapy will be specifically designed for the management of these remote patients and will outline the elements that capture, document and communicate the new clinical targets and the actions that are required based on them.

Additionally, the collection of SWAN-iCare historical data from multiple patients when this service is in full usage, will allow for providing new knowledge and scientific data that result out of the correlation of stored data within the clinic. New potential for the monitoring and therapy may be in the future derived by adopting Decision Support Systems (DSS).

V. Embedded software

Novel embedded software will be designed and integrated in the Negative Pressure device, regarding the device local data fusion actions, the control of the electronics, sensor and actuator parts, the user interface communication and the wireless communication with the rest of the system components. The embedded software to
be developed will advance state-of-the-art regarding the new algorithms and mathematical models.

The use of computing systems technology is essential to improve healthcare. The need for reduced power consumption for smarter and smaller sensors and diagnostic tools for medical devices is evident. In the software community, much literature is available about software power optimizations [15-17], memory management implementations and policies [18] to be used in general-purpose systems. In the context of SWAN-iCare, an RTOS is going to be used, running on the device where data fusion and device control and interface algorithms are to be executed as well. Typical design constraints in embedded systems the power consumption and the limited resources, including memory and processing elements. In particular, an efficient memory management strategy implies the use and development application specific and eventually, platform specific design techniques and methodologies. Consequently, in the embedded platform emphasis implementation we will study the interrelationship between RTOS and data management. Although it is a well known design problem and several initiatives have addressed aspects of this interrelationship, the dynamic behavior and the complexity of the whole SWAN system makes very challenging the study of a such problem.

VI. Expected impact

SWAN-iCare brings together multidisciplinary European research teams for the development of a product addressing real business opportunities as evidenced by the industrial partners involved who are major players in the current wound management markets.

In summary, the expected impact of SWAN-iCare revolves around four aspects and can be summarized in the following:

Patient
• Continuous efficient monitoring of a number of wound parameters at the patients home,
• Personalized and improved therapy initiated by the physician remotely and adapted to the daily measurements,
• Faster wound healing due to the early identification and therapy of potential problems,
• Wound deterioration can be identified early and acted upon, therefore leading to reduced morbidity and amputation rates,
• Reduced need for hospitalization, better quality of life with better mobility, more comfort and less stress.

Society and Healthcare
• Reduced need for hospitalization, results in reduced healthcare costs, and better therapy for an increased remotely monitored number of patients,
• Less losses due to patient remaining away from work,
• Less burden over the relatives and carers who may help and support the patient,
• More accessible care for patients living in remote geographical places,
• Lower nursing involvement allows for more patients’ treatments,
• More intelligent and effective prescription leading to faster wound healing, thus lower healthcare costs.

Medical science
• New ways of patient monitoring by correlating continuous measurements not available before,
• Continuous objective measurement contributing to evaluation of wound progress, and treatment effectiveness,
• New remote therapeutic approaches with innovative products,
• New potential for research by correlating measurements and outcomes of multiple patients when these become available in the future.

ICT science and Business
• Novel solutions incorporating multidisciplinary research providing services of unparalleled quality,
• Fresh business models in the wound management market and closer business relationships between the various disciplines and between the players of the potential value chain in the wound management market,
• Reinforced leadership and innovation in the area of convergence of Bio-micro-ICT system, gained by knowledge and skills and improving the competitiveness of the involved industries.

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References


