SensorART

A remote controlled Sensorized ARTificial heart enabling patients empowerment and new therapy approaches

Grant Agreement number: 248763

Project acronym: SensorART

Project title: A remote controlled Sensorized ARTificial heart enabling patients empowerment and new therapy approaches

Funding scheme: Large-scale integrating project (IP), FP7-ICT-2009.5.1: Personal Health Systems Heart Failure

Project website address: www.sensorart.eu

D1.2
Publishable Summary

Due date of deliverable: 30/04/2011

Actual submission date: 01/07/2011

Start date of project: 01/03/2010 Duration: 48 months

Organisation name of lead contractor for this deliverable: CNR

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Deliverable contributors: ALL

Version: Revision

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Service)	
RE	Restricted to a group specified by the consortium (including the Commission Service)	
CO	Confidential, only for members of the consortium (including the Commission Service)	

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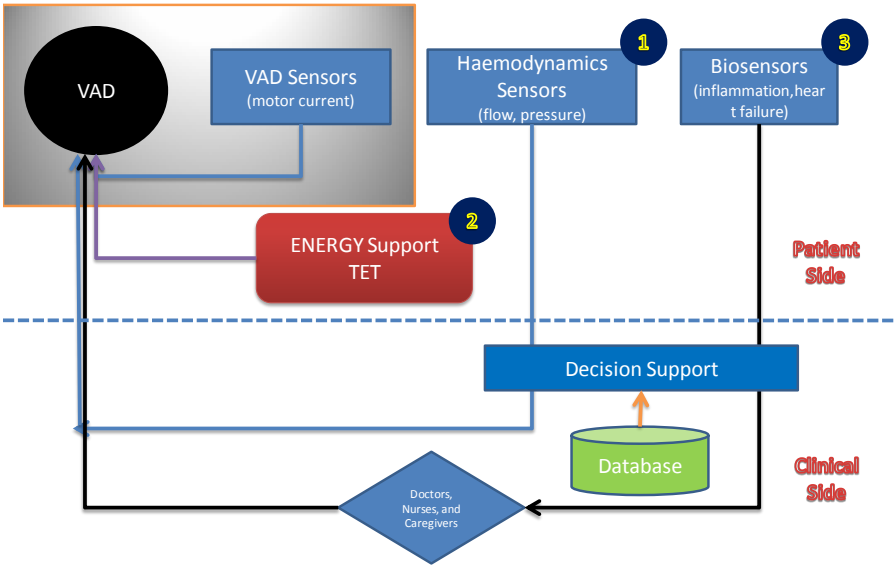
1 Publishable summary

SensorART - A remote controlled Sensorized ARTificial heart enabling patient empowerment and new therapy approaches (Project Identifier: FP7-2009-ICT-248763) - is a large-scale integrated project, funded by the European Union in the Seventh Framework Programme, (ICT, Challenge 5.1: Personal Health Systems for monitoring and point-of-care diagnostics). The project started in March 1st, 2010 and will be completed in February 28th, 2014. The consortium consists of 13 partners – 4 research centres, 4 universities, 3 SMEs, and 2 large enterprises - from 10 European countries: Consiglio Nazionale delle Ricerche (Italy), Scuola Superiore di Studi Universitari e di Perfezionamento Sant'Anna (Italy), Katholieke Universiteit Leuven (Belgium), Azienda Ospedaliera Ospedale Niguarda Ca' Granda (Italy), Implemental Systems SL (Spain), Foundation for Research and Technology Hellas (Greece), CircuLite GmbH (Germany), Université Claude Bernard Lyon 1 (France), Datasel Bilgi Sistemleri A.S. (Turkey), Institute of Biocybernetics and Biomedical Engineering – Polish Academy of Sciences (Poland), Velti Anonymos Etairia Proionton Logismikou & Synafon Proionton & Ypiresion (Greece), Intrarom S.A. (Romania) and Bangor University (United Kingdom). The project coordinator is Maria Giovanna Trivella, from CNR Consiglio Nazionale delle Ricerche (Italy).

Current treatment of heart failure, in severe end-stage patients, consists of ventricular assist devices (VADs) i.e mechanical pumps implanted in the patient's body used to restore blood circulation. These devices, whose large majority is constituted by continuous-flow pumps, are nowadays mainly used to provide temporary support (from a few to several months) to bridge heart transplantation. All of these systems suffer from common limitations since they are operated as standalone systems, with no or little regulation capability and substantially unable to interact with the patient and the physicians.

At present, however, VADs are mechanical devices, working in a closed loop, used mainly to bridge heart transplantation.
The SensorART project moves from the idea of realizing an "upgraded device", starting from a mechanical VAD, with the objective of developing an intelligent device, based on an open, interoperable, modular platform.



As shown in the scheme, the state of art of VADs is represented by the grey area: VADs have motor current sensors and act as "black boxes", in a small, closed loop working in the

clinical application. The project has the objective of adding other loops, by including hemodynamic sensors in order to evaluate patient-device interactions and optimize the heart unloading and support. A second objective is substituting the cables, which are the cause of inflammation and sepsis, unfavourably affecting patient's outcome. Replacement of cable connections with telemetric wireless systems for power and signal transmission will increase the patient acceptability. In order to early detect inflammation and to monitor heart failure, the research area of biosensors will be investigated. Finally to obtain a more efficient loop, a decision support system will be implemented, by taking information from physiological sensors, biosensors and existing data base.

The aim of SensorART project can be summed up in three main objectives:
1) sensorize VADs
2) allow patients suffering from severe heart failure to conduct normal lives
3) allow healthcare professionals to monitor patient status remotely and in real-time.
In addition, two more ambitious goals can be identified:
1) develop VADs not only as bridges to transplant, but also as definitive devices
2) to propose the SensorART platform as a transient therapeutic platform, provided that signals and/or cellular readouts of natural heart recovery will be identified.
In fact, the project will also aim at providing scientists with new knowledge of heart recovery.
Mechanical artificial hearts are currently used as a bridge to heart transplantation and more recently, as "destination therapy" due to the shortage of heart donors as well as increasing pathology in the aging society.
There is experimental evidence that chronic unloading of the heart leads to improved function of the failing heart. Clinical experiences report the possibility of improving cardiac function to the extent that the patient could be weaned from the device and transplantation avoided. Heart recovery mechanisms and related time are still unknown since today assistance devices are mainly implanted in patients with end-stage heart failure.
The clinical significance of such bridge-to-recovery strategy is emerging. It allows the implant of the devices:

- as an alternative to heart transplantation
- in case of life-threatening device-related complications (e.g. recurrent thromboembolism or device infection)
- when urgent transplantation is unfeasible.

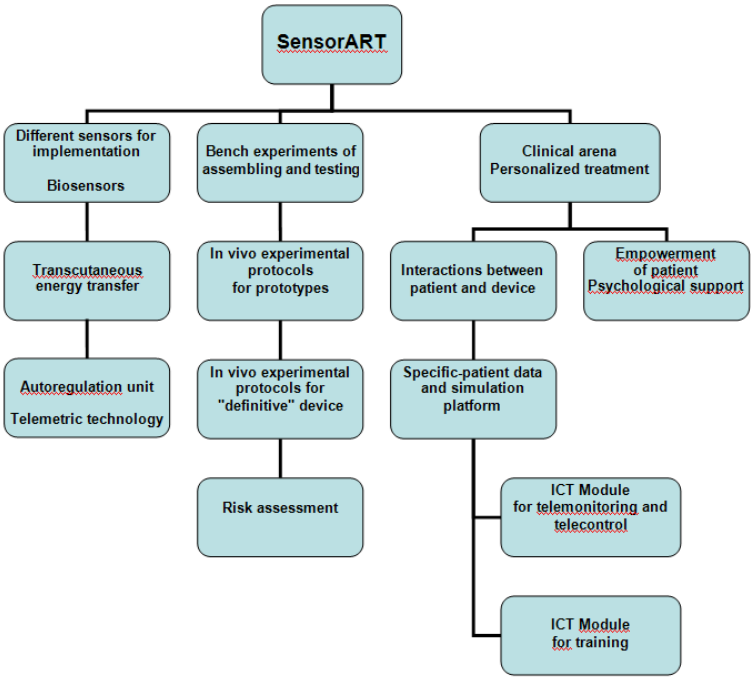
Moreover, there is evidence that patients have better quality of life following recovery as compared to heart transplantation and bridge-to-transplantation patients. Heart recovery merits study even in younger patients in whom support allowed good functional recovery, but with low probability of being transplanted and high probability of long-term assistance.
In order to facilitate such a revolutionary approach, the SensorART project aims at better understanding of patient-device interactions by a remote monitoring strategy supported by implantable miniaturized sensors (nano- and microsensors) of flows and pressures on VADs (irrespective of their functioning systems, i.e. continuous or pulsatile flow) in order to:

- personalize and optimize the degree of heart unloading
- understand biohumoral signals during assistance, and possible cellular changes before and after the assisting therapy
- measure the capacity of the natural heart to develop major or minor delivery capacity according to the assisting time
- identify recovery times and mechanisms as well as biohumoral signals in assisted patients in order to understand potential outcomes
- steer and optimize pump function without interaction of a caretaker and thus
- improve the patient's independence and quality of life
- reduce the cost in personnel to realize home support.

Physical sensors could also allow assessing the patient/device hemodynamics relationship during assistance, in order to detect the actual and potential contribution of the native heart.
Telemetric wireless sensors integrated in the SensorART platform will allow monitoring of patients after implant.
Patient evaluation can help in adjusting output of the assistance device, by considering the residual cardiac output of the natural heart and the changed needs of the assisted patient (worsening phase and/or acute phase, stabilized clinical state, normal life needs in chronic conditions). From a careful observation of Serious Adverse Events or of the variables changes preceding the events, it would be possible to define new "disease specific" sensors and further implement the devices with specific chemical and/or biological sensors.
The expected results and impact of SensorART project are:

- shift the application of VAD from bridge to transplantation to definitive device also for elderly people
- abolish power supply cables by Transcutaneous Energy Transfer (TET) with improved outcomes and higher patient acceptance
- extend the use of VADs to less severe heart failure extending its possible application to more than 5 million people
- understand the biological of mechanisms of natural heart recovery
- extend the application of VAD to short-term treatment of cardiac failure
- empower patients by means of user-friendly ICT devices.

The activities of the project, due to the different areas of disciplines and required competences, are organized in modules, as represented in the flow chart.



The modules on the left are representing bioengineering laboratories working on sensors, wearable and/or implantable, biosensors, TET, autoregulation unit and telemetric technology. In the experimental laboratories, bioengineering and preclinical research experts work on the implementation of different components, bench testing, experimental protocol definition and carrying out. The module of risk assessment has the prerequisite of

regulatory affairs knowledge and requires a careful evaluation of potential risk in terms not only of implemented device failure, but mainly of its interaction with recipient, i.e. exclusion of lesions of any degree.
Within the clinical arena there are different actions relative to clinical requirements definition, data collection from patients, psychological support and personalized empowerment plans.
Data from implanted patient with VAD are analyzed for interactions and utilized for simulation platform, in order to define the ICT modules (telemonitoring, telecontrol, training). Also data from experimental laboratories are collected and processed for ICT modules.
A wide dissemination activity has been obtained at national and international levels. The dissemination results included not only the announcement of the project, the interviews relatives to the project program, but also an initial technical work within scientific conferences.
The main achievements of the SensorART project in the first year are summarised in the followings.
A preliminary analysis of the requirements of specific user groups has been defined: the different users can be divided into clinicians (cardiac surgeons, cardiologists, nurses...) and patients. Each group has specific requirements regarding information which might be obtained from the SensorART platform.
For biosensors, an extensive work of fabrication by micro technology has been done, followed by testing of sensitivity and reproducibility on cytokines.
A collaboration for detection of specific markers on human blood has been established among HONIG, CNR and UCBL, in order to define the clinical relevance of selected biosensors.
On TET, two main options have been studied and are currently under evaluation:

- A system using TET as main power source and a small implanted back up battery
- A system relying on a large implanted battery, which is charged on demand by a TET system.

Two sets of sensors, both implantable and wearable, have been selected and their implementation is ongoing. It is important to underline that pressure and flow feedbacks are considered crucial by the medical arena to monitor the VAD operation. The possibility of interconnecting the sensors wirelessly in a star network have been studied both for the implanted and wearable nodes.
A simulation station (EndoVascular Evaluator, EVE simulator by Fain Biomedical) has been assembled by SSSA for testing the "sensorized" Synergy pump (Circulite) in different conditions, by implementing the cardiovascular circulatory system of the simulator with different sensors and actuators. The station allows the evaluation of autoregulation unit, when working as data acquisition station as well as VAD controller.
Furthermore, various approaches and technologies for sensors interoperability have been investigated. In line with the Continua Health Alliance guidelines, effort was concentrated on the Bluetooth technology and the Health Device Profile (HDP/IEEE-11073), which are new application standards that defines the requirements for qualified Bluetooth Healthcare and Fitness device implementations and utilization.
More information on the project, including results achieved, current activities and dissemination material are available in the project website: www.sensorart.eu. The contact person is Maria Giovanna Trivella, Tel: +39 050 3152730 - Fax: +39 050 3152166 - Email: trivella@ifc.cnr.it

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