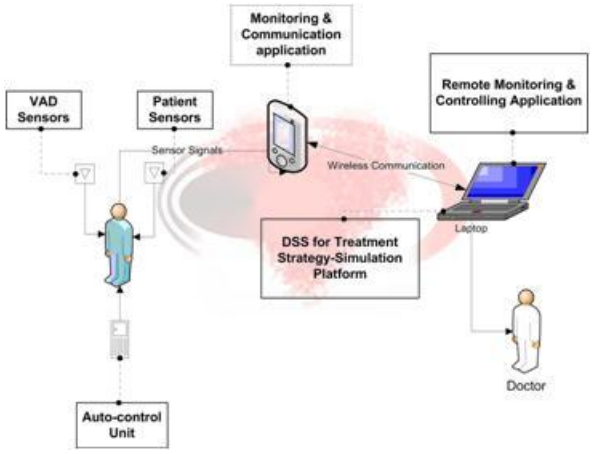
SensorART: A remote controlled Sensorized Artificial heart enabling patient empowerment and new therapy approaches

SensorART aims at sensorizing Ventricular Assistive Devices (VADs), in order to turn VADs from mechanical devices into intelligent systems allowing patients suffering from heart failure to conduct normal lives and help healthcare professionals to monitor patient status remotely and in real-time. The ambitious objective of SensorART is to develop VADs not only as bridges to transplant, but also as definitive devices. Furthermore, if cellular readouts of natural heart recovery are identified, SensorART could be proposed as a transient therapeutic platform. SensorART is a good example of how ICT can meet basic research.

Objectives of the project

Current treatment of heart failure consists of ventricular assistive devices (VADs), mechanical pumps implanted in the patient's body used to restore blood circulation. At present, however, VADs are used mainly to bridge heart transplantation. The SensorART project intends to turn VADs from mechanical devices to intelligent systems, by endowing them with dedicated sensors (i.e. flow, pressure). In this way, VADs could adjust autonomously to the patients' physical needs and monitor his/her status. Most importantly, intelligent VAD systems could be used not only as a bridge to transplant, but also as destination therapy.



Project: Among the expected results of the SensorART project are:

- Monitor and control patient – device interactions
- Therapeutic intervention optimization
- Increase device acceptability
- Patient training and empowerment
- Impact on healthcare delivery
- Reduce hospitalization time
- Increase applicability of VADs as bridge to transplant and as destination therapy
- Modeling and simulation of cardiac and circulatory dynamics of individual patient's status across different conditions
- Specific training of health care providers

The project will also aim at providing scientists with new knowledge of heart recovery.

Scenario

Patient with implanted sensorized artificial heart: the device is linked wirelessly to an external control unit, applied to the waist by means of a belt. The artificial heart will be powered wirelessly by an innovative system for energy transfer via the skin. Thanks to different assembled sensors, as well as to special algorithms, the control unit can monitor the patient's physiological condition and optimize support from the pump. In this way, the empowered patient can lead a normal life. Moreover, via wireless Internet communication the control unit will allow doctors to monitor the patient's status in real-time and remotely, and to take immediate action when required.

Project Description:

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 heart function. 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 (despite their functioning systems, i.e. continuous or pulsatile flow) in order to:

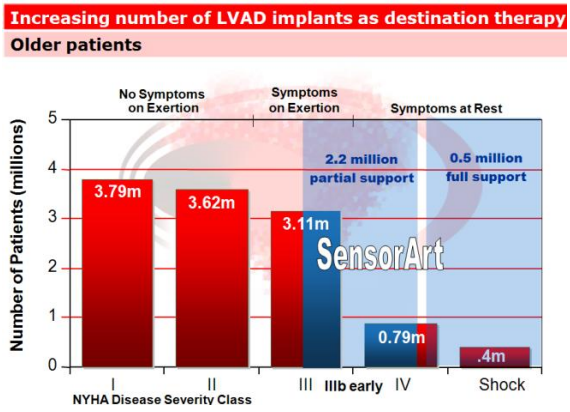
- personalize and optimize the degree of heart unloading
- understand biohumoral signals during assistance, and possible cellular changes before and after the assisting therapy
- measure the capacity of the natural heart to develop major or minor delivery capacity according to the assisting time
- identify 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 contribution of the native heart.

Telemetric wireless sensors integrated in the SensorART platform will allow monitoring of patients after implants.

SensorART: bridge to recovery strategy. There is important evidence that patients assisted by VADs can recover their natural heart function and leave the transplant waiting list, especially if the natural history of the disease is not longer than 5 years.

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 alterations of variables preceding the events, it would be possible to define new "disease specific" sensors by considering a possible further implementation of the devices with specific chemical and/or biological sensors.



Data from US. Adding Europeans will double the numbers.

Expected Results & Impact

Please keep the following in mind when writing:

- Shift the application from bridge to transplantation to definitive device also for elderly people
- Abolish power supply cables by Transcutaneous Energy Transfer with improved outcomes and increased patient acceptance
- Extend the use of VADs to less severe state of heart failure with a possibility of application in more than 5 million people
- Understand the natural heart recovery mechanism
- Extend the application of intelligent artificial heart devices for transient therapeutic treatment
- Empower patients by means of user-friendly ICT devices

Keywords: ventricular assistance devices, heart recovery, sensors and biosensors, transcutaneous energy transfer, advanced telemonitoring system, patient empowerment, decision support system, patient device simulation, health care personnel training

Administrative information:

SensorART

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

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