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Original Research Article

A portable system for autoregulation and wireless control of sensorized left ventricular assist devices

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ABSTRACT

End stage heart failure patients could benefit from left ventricular assist device (LVAD) implantation as bridge to heart transplantation or as destination therapy. However, LVAD suffers from several limitations, including the presence of a battery as power supply, the need for cabled connection from inside to outside the patient, and the lack of autonomous adaptation to the patient metabolic demand during daily activity. The authors, in this wide scenario, aim to contribute to advancement of the LVAD therapy by developing the hardware and the firmware of a portable autoregulation unit (ARU), able to fulfill the needs of sensorized VAD in terms of physic/physiological data storing, continuous monitoring, wireless control from the external environment and automatic adaptation to patient activities trough the implementation of autoregulation algorithms. Moreover, in order to answer the rules and safety requirements for implantable biomedical devices, a user control interface (UCI), was developed and associated to the ARU for an external manual safe control. The ARU and UCI functionalities and autoregulation algorithms have been successfully tested on bench and on animal, with a response time of 1 s for activating autoregulation algorithms.

Animal experiments showed as the presence of the ARU do not affect the animal cardiovascular system, giving a proof of concept of its applicability in vivo.

1. Introduction

It is recognized that more than 20 million people suffer from heart failure (HF) worldwide, in particular, end-stage HF is the most increasing cause of mortality and morbidity [1,2].

The International Society of Heart and Lung Transplantation registry has shown that after a decline between 1993 and 2004, the number of performed heart transplants remained stable for several years. In the last years a slowly increasing is noted, in particular in North America [3]. This is principally due to the shortage of heart donors in comparison to the

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growing number of patients who have the risk of heart failure. Therefore, this has led to rapidly accept the left ventricular assist devices (LVAD or VADs) therapy as an alternative strategy for treating end-stage heart failure although heart transplantation remains the gold standard therapy [2,4,5].

The generation of VADs has evolved from the pulsatile-flow pumps of the 1990s to today's non-pulsatile, rotary pumps [6]. The implantable rotary blood pumps (IRBPs), continuous flow VADs, currently used or in advanced development are today preferred to the pulsatile-flow pumps [7–10], for their minimal blood trauma, smaller size, lighter weight, easier implantation, simpler design and construction, much longer and more reliable duty life [1,11,12]. Most of these devices have been approved as a bridge to transplant (e.g., Debakey [13], Jarvik [14], Ventrasist [15], and most recently the Heartware HVAD [16], HeartMate II [17]), or to myocardial recovery while others are currently in trials for destination therapy [6,18,19].

Besides the VAD implantation as destination therapy, the need of a long-term VAD therapy starts mainly from the long time before heart transplantation (HTx) in the context of donors shortage. By this awareness, the European SensorART project envisaged an e-health program with a telemedicine platform, in order to reduce patients dependence on clinical management, allow them to be treated as soon as possible at home, improve their quality of life and reduce the hospitalization costs project [20].

At present most commercially continuous flow VADs work at constant speed adjusted manually by the clinicians or by the technical people of device manufacturers in order to match pump output to her/his own physiology and level of activity, as the Jarvik 2000 (Jarvik Heart Inc., NY, USA). Studies confirm that operation at fixed speed can increase the risk of over-pumping or under-pumping during changes in the patient's circulatory state, caused by the low preload detection of IRBPs in comparison to the natural heart. This implies the regular monitoring by clinicians to ensure the correct VADs operation [21]. In addition other studies on the relationship between pump speed and exercise capacity during assist device support seems to show that the modulation of LVAD speed during exercise could be of benefit to LVAD implanted patients [22–24]. Therefore the implementation of an automatic, robust and adaptive physiological control and monitoring platform, able to adjust pump output according to real patient status changes, joined to a data remote management system, could be useful to improve life quality of implanted VAD patients.

Several control techniques of heart assist devices have been proposed in literature but never implemented on real system [25–30].

In this paper, a novel, portable and flexible autoregulation unit (ARU) for enhancing VADs applicability as a long-term solution to heart failure is presented, thus enabling new therapeutic approaches as alternative to heart transplantation. The ARU functionalities and autoregulation algorithms have been implemented and tested on bench and on animal extensively with respect to other works [31,32].

The system overview, including the description of the ARU functionalities, hardware and firmware, is described in the following sections. Furthermore, the interfacing of the ARU with the User Control Interface (UCI), developed for an external local safe intervention, as required by implantable biomedical device safety regulations is also reported, as well as the wearable system integration and the wireless data management. Finally, the experimental tests on bench and in vivo are presented.

2. Materials and method

2.1. System overview

The main features of a future generation VAD, can be summarized as reported in the block diagram in Fig. 1. They include: embedded sensors, automatic regulation, local safe and remote control, wireless powering, compactness, and wearable system integration.

In this work, the attention is focused mainly on the automatic regulation feature which, together with continuous monitoring of patient's data, lead to the implementation of autoregulation algorithms in a novel portable device, the ARU, paving the way to the delivery of an advanced sensorized device into the clinical practice. Secondly, on safety control feature obtained with the UCI, for an external local safe intervention by the clinician or VADs a dedicated technician and a local real-time display of VAD parameters. The ARU and the UCI are represented by blocks of Fig. 1.

Moreover, a wireless interface was implemented in the ARU (working as by-pass for the VAD), for a preliminary demonstration of the feasibility to control the VAD remotely (Fig. 1, remote control feature). In the same way, a wearable system integration was performed and a sensorized on bench VAD based platform was conceived and implemented to simulate the VAD embedded sensors and to test the ARU functionalities and algorithms (Fig. 1, wearable system and embedded sensors features).

In summary, the ARU, interfaces a sensorized VAD, a dedicated UCI, a commercial wearable system for the monitoring of additional physiological parameters, and a laptop, tablet or Smartphone for the wireless VAD control and data monitoring of patient. The ARU and the UCI will be part of the VADs of future generation for managing the sensorized VAD and further functionalities (e.g. autoregulation algorithms based on signals from wearable systems). For sake of clarity, a block diagram of the presented architecture is shown in Fig. 2.

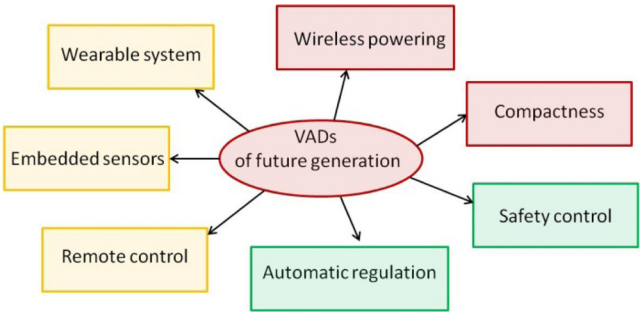

Fig. 1 – VADs of future generation: main features.