Feature | [Heart Failure](#) | **May 04, 2022 | By Jean-Luc Boulnois, Ph.D.**

Effectively Treating Heart Failure: New Technology on the Horizon

With the increase of patients experiencing heart failure and clinical challenges to manage advanced heart failure conditions, therapies with implantable devices have become an essential treatment method

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The current standard of care for [heart failure](#) (HF) is guideline-directed medical therapy combined with device-based interventions in eligible patients. However, many patients experience progressive deterioration in their HF status that warrants additional intervention.

Consequently, each year, the lack of efficient treatment options for more than 75% of new heart failure patients leaves about 200,000 waiting for their disease to worsen while their health and quality of life deteriorate. While there have been many advances over the years, it is becoming increasingly clear that medical devices, including [mechanical circulatory support](#) (MCS), will enhance HF management and improve patient outcomes.

The development of new device technologies associated with tailored medical management will likely play a significant role in extending and saving patient lives while improving their quality of life.

Heart Failure Disease

HF is a chronic, long-term cardiac condition that, over time, worsens and is exacerbated with no or inappropriate treatments. The American College of Cardiology (ACC) and the American Heart Association (AHA) define HF as "a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood."[1] As the condition worsens, the heart muscle pumps less blood to organs, precluding them from receiving the oxygen and nutrients they need to thrive. Over time, the quality of life of patients with HF deteriorates inexorably.

A standard functional classification of the severity of HF patients' symptoms as they limit their physical activity was introduced by the New York Heart Association (NYHA). As patients with severe heart failure (NYHA functional class III and IV) lose their exertional capabilities and potentially become critically ill, the current practice supports initial management using a combination of medications, temporary or permanent mechanical support devices, or heart transplantation in eligible patients. The challenges faced by existing device options are vast — they limit mobility, cardiac output is fixed, and are fraught with complications and adverse events both in the early post-operative period and in the long term.

In the 1940s and '60s, the understanding of HF was significantly advanced by the introduction of several new diagnostic modalities: electrocardiography (ECG), which records the heart's electrical signals as a function of time and checks the heart's condition and rhythm using electrodes placed on the patient's chest; cardiac catheterization, a procedure used to diagnose and treat specific cardiovascular pathologies; and echocardiography, an ultrasound technology that images heart structures as well as blood flow through the heart. These diagnostic tests allowed the characterization of many forms of structural and functional heart diseases, which were further transformed by the emergence of modern cardiac surgery.

These advances, however, did not solve the clinical and pathological challenges of HF. Further complicating the disease was the emergence of ischaemic HF, valvular diseases and hypertension, together with genetic or acquired cardiomyopathies as major HF causes.[2]

Before the 1980s, the main effort to explain the changes occurring in HF was related to how the disease was treated: bed rest, inactivity and fluid restriction. Only digitalis and diuretics were prescribed at the time, and research concentrated on kidney issues rather than the heart itself.

The emergence of remarkable imaging technologies in the late 1980s and early 1990s enabled a much-improved characterization of the causes of cardiac insufficiency. The computed tomography (CT) scanner and cardiac magnetic resonance imaging (MRI), which uses powerful magnetic fields, radio waves and computer algorithms, produced detailed anatomical images of structures inside the heart.

In parallel, pharmacopeia was enriched by the availability of medications that revolutionized the medical treatment of cardiac insufficiencies, such as beta-blockers and renin-angiotensin inhibitors. These medications, which regulate the destructive effects of catecholamines (the stress hormones) and the peripheral and renal vascular functions, freed patients from invalidating oedemas. These two major cardiac medication classes have enabled the retreat of disease worsening while improving patient survival.

Mortality

Despite significant advances in prevention and medical treatments, heart failure remains a degenerative disease with no cure and has high morbidity and mortality. It is a global epidemic affecting at least 26 million people worldwide and increasing in prevalence and incidence; it is the second leading cause of death in the United States and Europe, although incidence has stabilized

in these countries. In 2018, in the U.S. alone, it was estimated that 6.2 million individuals were affected by HF,[3] with 915,000 new cases diagnosed every year.[4] Additionally, HF affects an aging population most, and, in men, rates approximately double while tripling for women with each ten-year-age increase from 65 to 85 years.[4]

The Centers for Disease Control and Prevention (CDC) estimates that one in nine deaths is attributable to heart failure. With approximately 380,000 deaths caused by HF each year,[2] it accounts for 8.5% of cardiovascular-related deaths.[4]

Implantable Heart Device Therapies

With the rapid increase of patients experiencing heart failure and challenges in clinical practice to manage advanced heart failure syndromes, therapies with an implantable device have become an essential treatment method. Such therapies fall into two main categories according to the nature of HF: as a standard of care, patients afflicted with ventricular dyssynchrony, a disorder of the heart rhythm, are treated by cardiac resynchronization therapy (CRT), whereas hemodynamically compromised patients, i.e., whose heart has a reduced ability to adequately pump and/or fill with blood without ventricular dyssynchrony are not candidates to CRT, and are treated with MCS when indicated.

Cardiac resynchronization therapy uses an implantable biventricular pacemaker (CRT-P) to send electric signals to the heart's left and right ventricles to synchronize contractions and improve cardiac output. CRTs are an admirable therapeutic option but are limited to patients whose HF is worsened by electrical dyssynchrony, typically from a left bundle branch block. The CRT system consists of an implantable pulse generator and insulated lead wires designed to deliver electrical charges to the heart, which help restore the normal timing pattern of the heartbeat.

Today, CRT devices combine pacing capability with implantable cardioverter-defibrillator (ICD). Implanted in the chest, an ICD is a small device that continually monitors the heart's rhythm, detecting abnormal heartbeats. In the event it senses a dangerous erratic heart rhythm, or when arrhythmias lead to sudden cardiac arrest, it delivers an internal electric shock to the heart with the intent of restoring a normal heart rhythm (CRT-D).

Complementing the use of ICDs, techniques of severe heart rhythm disorders based on radio-frequency ablation provide renewed hope of comfort and survival.

Left Ventricular Assist Devices

Left Ventricular Assist Devices (LVAD) are not a recent technology. The first successful clinical use of mechanical circulatory support (MCS) device was in 1953 for a cardiopulmonary bypass.[5]

In 1984, LVADs emerged as bridge-to-transplant (BTT) therapy for patients suffering from advanced heart failure who were waiting for an acceptable donor heart. Early devices' bulky size limited patient selection to larger individuals and required implantation into the abdominal cavity. In addition, these pumps were pneumatically driven to deliver a pulsatile flow profile creating a loud sound that affected patients' quality of life. The design required multiple moving parts, which reduced device durability leading to increased frequency of device failure and need for replacement. With the exponential explosion of heart failure and the limitations of first-generation LVADs, smaller, continuous flow, more durable second-generation devices were developed, but the general concept remained the same. LVADs pump blood from the left ventricle by bypassing the heart and discharging it out the aorta to the rest of the body.[6]

Legacy LVAD technology was largely influenced by the belief that heart failure is a mechanical problem. Devices were developed as continuous flow pumps designed to assist non-functioning ventricles necessary to supply blood to end organs. The operative procedure requires a midline

incision of the sternum to access the diseased heart. The patient is placed on a heart and lung bypass machine while the LVAD is implanted in the space below the apex of the heart: LVADs are an intrusive means of assisting a weakened or failing heart.

LVADs are also designed in a way that is counterintuitive to how the heart works. Oxygenated blood flows down the left ventricle; then, blood is pumped out of the LVAD through an outflow valve and up through an aortic graft into the aorta, completely bypassing the left ventricular outflow tract and aortic valve. Counter to the physiologic approach, blood is pulled opposite to the natural direction out the left ventricular apex before being redirected up toward the aorta. In 25-35% of patients, blood propelled into the aorta streams back down into the left ventricle due to a leak in the aortic valve, which leads the left ventricle to steadily become LVAD dependent and reducing the likelihood of cardiac recovery.

Current LVADs consume significant power (up to 15 W) and require a percutaneous driveline to receive power from external batteries or an electrical outlet. As a result of the driveline protruding through the patients' skin, these patients remain susceptible to driveline infections that frequently lead to re-hospitalizations, sepsis, traumatic damage, poor quality of life, increased caregiver burden and ultimately a lower survival rate. Complications are numerous, particularly the destruction of red blood cells (hemolysis) and the loss of coagulation factors caused by a state of chronic inflammation and blood element damage, which explains the occurrence of digestive or cerebral hemorrhages.

Previous attempts to wirelessly power LVADs using transcutaneous energy transfer systems (TET) have not been successful without burning the patients' skin due to these high-power requirements. Additionally, restrictions on using wireless power have been limited by separation distance and alignment between the transmit and receive coils.

There are electrophysiologists (EP) with a different perspective on the requirements for a HF device. A surgeon or engineer would take a mechanical focus. EPs treat heart arrhythmias and other heart rhythm disorders, including tachycardia, bradycardia and atrial fibrillation. The overall approach to providing a solution for improving the quality of life for heart failure patients would be different. It would consider the heart's electrical and rhythmic patterns, which ebbs and flows as its four chambers alternately contract and dilate, and in turn, open and close valves. Blood does not move in a continuous flow throughout the body; instead, there are specific pulsatile patterns to the way it is delivered based on the requirements of end organs and vessels through which blood is transported. The synchronization of the heart's natural rhythm with the workings of an adjunctive LVAD is integral to its success and ability to minimize adverse events like bleeding and clotting.

While only a few devices, such as the HeartMate II and HeartMate 3, are the only commercially FDA-approved adult options in North America, the field of MCS is undergoing significant technological improvements based on innovative engineering concepts which have already resulted in various approvals for clinical use in other other parts of the world such as Europe.[6]

In general, new generations of MCS devices intend to improve patient survival while reducing adverse events. The main design focus is on miniaturization, less invasiveness and increased durability. New LVADs also introduce pulsatility and even some LV systolic-based synchronization features based on pressure changes at the bypassing pump inlet during contraction. However, absent heart rhythm monitoring and pump synchronization may be delayed, affecting the filling phase of the cardiac cycle.

Other significant developments have also occurred with total artificial hearts (TAH), including prosthetic devices or double rotary pumps, which are implanted in select patients with biventricular HF.[6]

Beyond LVADs, percutaneous MCS are efficacious, but temporary solutions used in intensive care settings, such as Abiomed's Impella device, a percutaneous miniaturized heart pump technology indicated for patients with severe coronary artery disease requiring high-risk PCI or acute myocardial infarction (AMI) related cardiogenic shock, prove that after implantation, patients often experience relief from heart failure symptoms. However, they are costly, run the risk of hemolysis and thrombus, and only serve as a temporary solution for acute heart failure patients — less than two months. For long-term solutions, LVADs currently remain the standard of care.

Implantable Cardiac Output Management System
Recognizing that, fundamentally, heart failure is a hemodynamic problem, designed by EPs, a device has recently been developed called the ICOMS Flowmaker. The Implantable Cardiac Output Management System (ICOMS) is intended to address the unmet need of patients suffering from severe heart failure (NYHA-IV).

An innovative hybrid between a pacemaker and a mechanical cardiac assist device, the ICOMS technology was derived on a similar premise of cardiac resynchronization therapy (CRT) by increasing the instantaneous cardiac flow by a few milliliters at each natural ventricular ejection and targeting the much larger patient population whose heart failure is of a mechanical origin.

Only requiring a standard minimally invasive thoracic surgery (without incision of the sternum or breastbone or a heart-lung bypass machine), ICOMS is the first fully intraventricular flow accelerator providing pulsatile, physiologic support of the native heart function without bypassing the aortic valve. It respects the natural pulsatile blood flow within the left ventricle and is synchronized with the native heart's contractions, using the same tracking technology as a pacemaker. The ICOMS is powered to help the blood ejection through the aortic valve when the aortic valve opens. No more than four inches long, ICOMS is the first miniaturized device with adjustable flow, allowing a cardiologist to modify the device's blood flow based on the patient's heart failure severity and fluctuating body demands (e.g., when exercising).

Like LVADs, ICOMS Flowmaker does not cure the heart, but the two technologies' differences are profound, particularly in the long term. The entire ICOMS system is fully implanted in the left ventricle. It is powered by a miniaturized internal battery rechargeable by transcutaneous energy transfer (TET), eliminating the risk of driveline infection, a significant determinant of post-VAD morbidity and mortality. The TET-induced skin burns encountered in past experiences are nonexistent since the system requires very little energy. Maintaining trans-aortic flow increases left ventricular unloading, improving myocardial recovery chances and faster device weaning possibilities and limiting the rate of aortic valve regurgitation. As observed with CRT, beat after beat, muscle oxygenation is expected to improve together with cardiac compliance, enabling long-term native recovery. The wireless device is programmable, like a pacemaker, and operating modes can be customized for individual hemodynamic requirements, preserving pump efficiency in case of increased cardiac demand during exercise.

From the patient perspective, ICOMS is designed to deliver improved quality of life by providing untethered freedom and supporting the patients' return to daily activities such as exercising or simply enjoying a shower without the worry of protecting an external driveline. The device also decreases a large number of complications since it induces significantly less hemolysis and hemorrhage.

With current minimally invasive technologies only offering temporary solutions, the ICOMS device fills a void in the management of patients suffering from the complications of severe heart failure. The ICOMS Flowmaker can be initiated as a temporary MCS device and "morph" into lasting MCS if recovery doesn't happen in the immediate term, and can also be explanted at a later time if there is myocardial recovery.

In addition, promising therapeutic strategies focused on managing and treating comorbidities have proven beneficial for HF patients. Providing robust and long-term cardiac support, the ICOMS could facilitate clinicians' ability to prescribe high doses of guideline-directed medical therapies. This modern approach, using ICOMS to assist high dose medical therapy, can drive higher recovery rates and provide more favorable cardiac reverse remodeling than what is seen in current practice with LVADs and temporary MCS devices or with limited medical treatment without hemodynamic support.

Advances in Treating Heart Failure

Heart failure is a degenerative disease leading to poor quality of life, frequent, costly hospitalizations and early mortality. Severe heart failure requires device-based therapy to enhance the left ventricle's pumping capacity. Several new devices are being added to the clinical arsenal to fight against the disease, and advances in implantable HF technologies offer new approaches to more effectively treat heart failure.

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