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A review of clinical ventricular assist devices

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ABSTRACT

Given the limited availability of donor hearts, ventricular assist device (VAD) therapy is fast becoming an accepted alternative treatment strategy to treat end-stage heart failure. The field of mechanical ventricular assistance is littered with novel and unique ideas either based on volume displacement or rotary pump technology, which aim to sufficiently restore cardiac output. However, only a select few have made the transition to the clinical arena.

Clinical implants were initially dominated by the FDA approved volume displacement Thoratec HeartMate I, IVAD, and PVAD, whilst Berlin Heart's EXCOR, and Abiomed's BVS5000 and AB5000 offered suitable alternatives. However, limitations associated with an inherently large size and reduced lifetime of these devices stimulated the development and subsequent implantation of rotary blood pump (RBP) technology. Almost all of the reviewed RBPs are clinically available in Europe, whilst many are still undergoing clinical trial in the USA. Thoratec's HeartMate II is currently the only rotary device approved by the FDA, and has supported the highest number of patients to date. This pump is joined by MicroMed Cardiovascular's Heart Assist 5 Adult VAD, Jarvik Heart's Jarvik 2000 FlowMaker and Berlin Heart's InCOR as the axial flow devices under investigation in the USA. More recently developed radial flow devices such as WorldHeart's Levacor, Terumo's DuraHeart, and HeartWare's HVAD are increasing in their clinical trial patient numbers. Finally CircuLite's Synergy and Abiomed's Impella are two mixed flow type devices designed to offer partial cardiac support to less sick patients.

This review provides a brief overview of the volume displacement and rotary devices which are either clinically available, or undergoing the advanced stages of human clinical trials.

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1. Introduction

Ventricular assist devices are employed clinically to help ease the rising demand for heart donors. These devices may be used to support a failing left and/or right ventricle, whilst being implemented as abridge to decision (BTD), bridge to myocardial recovery (BTR), bridge to heart transplantation (BTT), or indeed as a longer term destination therapy (DT) for patients in need of circulatory support.

History has witnessed the development of many types of circulatory assist devices. Efforts were initially focused on devices that reproduce the pulsatile outflow delivered by the native heart [1,2]. Despite the improved one-year survival observed when treated with these devices over optimal medical therapy [3], these types were inherently flawed with reliability and durability problems, by virtue of their mode of operation. These issues led to a push to develop continuous flow devices based on a rotating impeller [4–6], which has resulted in improved outcomes for patients treated with these devices [7].

Mechanical circulatory assist devices are generally classified according to their characteristic outflow (pulsatile/volume displacement or continuous) as described in Table 1, with details relating to their operational characteristics categorising them further into first, second or third generation designs [8]. Another additional classification is emerging which categorises the devices as either providing partial or full circulatory support for short or long-term durations. The distinction indicates the target patient population, with partial support devices, often implanted via minimally invasive techniques, intended for use in less sick patients.

This review provides an overview of the various types of mechanical ventricular assist devices which enable patient mobility for greater than 30 days, and are either clinically available or undergoing clinical trials to gain food and drug administration (FDA) approval.

2. Volume displacement pumps

Although pumps that deliver a pulse to the circulatory system produce a similar physiologic outflow to that of the human heart, they are generally volume displacement type devices that incorporate pneumatically or electrically actuated sacs, diaphragms or pusher plates. These pumps, classified as 'first generation', have an inherently large tissue and blood contacting surface and have multiple moving mechanical parts including prosthetic valves. Despite advancements in affiliated technologies, these features limit the effectiveness of first generation devices as they are both difficult to fit into many patients and are prone to mechanical failure due to wear inside two or three years [9]. Furthermore, they present a high risk of infection, thrombus formation and blood trauma, which also contribute to poor patient outcomes [10].

Despite these limitations, pulsatile pumps were aggressively developed in the last century and as a result, many of these devices became clinically available to provide full mechanical circulatory support. These more commonly known and commercially available pumps are produced by companies such as Thoratec, Berlin Heart and Abiomed.

Fig. 1. HeartMate I XVE.

2.1. Thoratec "HeartMate I"

The HeartMate I LVAS series evolved from the discontinued implantable pneumatic (IP) model to the vented electric VE and finally the XVE (Fig. 1) [11,12]. Both devices are medium to long term first generation volume displacement pumps. They rely on the actuation of a pusher plate that interfaces with a flexible plastic diaphragm to induce pulsatile blood flow from the left ventricular apex to the ascending aorta [13]. However, as the name suggests, the HeartMate IP was pneumatically powered, whilst the XVE utilises an electric power source to shift the pusher plate. It is for this reason that the XVE replaced its predecessor as the model of choice, since the electric supply reduces the size of the skin penetrating driveline to just ⌀ 12 mm, whilst eliminating the requirement for an external compressed air source.

With a size of ⌀ 110 × 40 mm and weight of 1190 g, the device exhibits a somewhat restricted ability for intra-corporeal implantation into patients with a body surface area (BSA) smaller than 1.5 m^2. However, full support of up to 10 l/min is achievable at a maximum beat rate of 120 BPM. The sintered titanium blood contacting surfaces reduce the requirement for anticoagulation therapy by promoting the formation of a pseudo neo-intima lining [14].

The HeartMate XVE was involved in a randomised study (REMATCH) which demonstrated that patients exhibited an 81% improvement in two year survival with this device as opposed to

Table 1
Types of clinical ventricular assist devices.

Volume displacement	Thoratec 'HeartMate I XVE/IP'
	Thoratec 'IVAD/PVAD'
	Abiomed 'BVS5000/AB5000'
Rotary – Axial Flow	Thoratec 'HeartMate II'
	Jarvik Heart 'Jarvik 2000 FlowMaker'
	MicroMed 'Heart Assist 5 Adult VAD'
	Berlin Heart 'InCOR'
Rotary – Radial Flow	WorldHeart 'Levacor'
	Terumo 'DuraHeart'
	HeartWare 'HVAD'
Rotary – Mixed Flow	Abiomed 'Impella'
	CircuLite 'Synergy'