# Historical Development of Durable Ventricular Assist Devices

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Heart transplantation is the most effective treatment for end-stage heart failure; however, the shortage in donor hearts constrains the undertaking of transplantation. Mechanical circulatory support (MCS) technology has made rapid progress, providing diverse therapeutic options and alleviating the dilemma of donor heart shortage. The ventricular assist device (VAD), as an important category of MCS, demonstrates promising applications in bridging heart transplantation, destination therapy, and bridge-to-decision. VADs can be categorized as durable VADs (dVADs) and temporary VADs (tVADs), according to the duration of assistance. With the technological advancement and clinical application experience accumulated, VADs have been developed in biocompatible, lightweight, bionic, and intelligent ways.

heart failure mechanical circulatory support durable ventricular assist devices

## 1. Introduction

Cardiovascular diseases (CVDs) are ranked as the first killer in the United States [1]. Heart failure (HF) is the end-stage symptom of various kinds of chronic CVDs, resulting from the accumulating cardiac impairments of the heart's structure [2][3]. The prevalence of HF is continually increasing and reaches approximately 4.5 million cases in China [4]. Heart transplant is regarded as the gold standard therapy, but the lack of donor hearts severely limits the application [5]. Recent advancements in mechanical circulatory support (MCS) technology have significantly broadened the range of therapeutic choices available. This progress shows this technology is an instrumental tool in managing severe heart conditions, offering alternative solutions for patients with advanced HF, bridging the gap between medical therapy and heart transplantation [6]. The application of ventricular assist devices (VADs) has revolutionized the management of heart failure, particularly for patients ineligible for heart transplantation or awaiting a donor heart.

According to the duration of application, VADs could be divided into temporary VADs (tVADs) and durable VADs (dVADs) [7]. tVADs are commonly used for acute HF patients to maintain the stability of circulation in a short time, no more than several weeks and months in most cases. Several systems, including Hemopump™ (Johnson&Johnson), ABIOMED, and Impella, in recent practice, have received great attention and have considerable efficacy [8][9]. dVADs can be implanted into the thoracic cavity of patients and support cardiac function in the long term, with its duration ranging from several months to several years.

The initial strategy towards end-stage HF centered around complete heart replacement, focusing on total artificial hearts (TAHs). However, the launch of the United States' Artificial Heart Program in 1962 illustrated a dramatic shift in therapeutic approach [10]. The focus was pivoted on augmenting the heart's existing capabilities, leading to the development of single-chamber pump assist devices and eventually VADs [11].

The inception of VAD technology was marked by the implantation of the first gas-energized, synchronized, hemispherical pump by DeBakey and Liotta on 19 July 1963 in Houston [12]. However, the significant milestone in VAD history was the successful execution of the first VAD-Bridge to Transplant (VAD-BTT) surgery practiced with the Novacor device in 1984 [11].

## 2. First-Generation dVADs

The first generation of dVADs partially inherited the idea of artificial heart replacement therapies, whereby a pulsatile blood flow was generated by a pneumatic or electric drive to assist ventricular function, being represented by the Pierce–Donachy VAD (conducted by Thoratec Laboratories Corporation in California from 1985), Novacor LVAS (conducted by Baxter Healthcare Division in 1988), and HeartMate VEX (also known as HeartMate I, approved by the FDA in 1994) [13][14]. The Thoratec PVAD followed a similar way of design and was put into practice in 1995 [15]. Despite being innovative, its technological immaturity brought constraints in application. More than the expected performance, the first-generation dVADs had significant issues, such as large size, uncontrollable noise, and malfunction due to the tearing of the power unit envelope or degradation of valves [16]. These drawbacks led to various complications, severely reducing the quality of life of patients after implantation and notably increasing the risk of post-discharge from the hospital, making the use of first-generation dVADs highly hospital-dependent.

## 3. Second-Generation dVADs

The second generation of dVADs used axial flow centrifugation to generate a continuous flow (CF) for circulation, being represented by the HeartMate II, JARVIK 2000, and Debakey by MicroMed Cardiovascular Inc. from Houston, TX, USA [17][18]. The reduced size and increased biocompatibility effectively improved patient prognosis, and the application of impeller mechanics and magnetic fixation combining technology in this generation significantly increased the device durability [19]. Moreover, the significantly reduced noise level improved the quality of life of patients after discharge. The HeartMateII, the most widely used device of second-generation dVADs, was approved by the FDA for use in BTT in 2008 and later for use in DT in 2010. Data from a clinical study comparing first- and second-generation dVADs showed that the use of the continuous flow (CF) technology of second-generation dVADs had a significant advantage over first-generation dVADs using a pulsatile flow technology in terms of improved postoperative survival and reduced complication rates [20]. As of 2017, the share of CF-dVAD implanted devices, including third-generation dVADs, has exceeded 95% [20].

However, the second generation also suffered from some design defects. The continuous flow pump of the second-generation dVAD used a rigid bladed rotor shaft, although it was able to meet the ejection demands by rotating at high speeds; the high-speed rotor shaft was prone to heat production when in contact with the bloodstream, which caused the destruction of blood components and the formation of blood clots, increasing the risk of thromboembolism. With the widespread use of the HeartMate III, the HeartMate II was retired from the market in 2019.

## 4. Third-Generation dVADs

In the third generation of dVADs, represented by the EvaHeart and HeartMate III, the use of magnetic or hydrodynamic levitation fixation technology was merged with higher pumping efficiencies, allowing the third-generation dVADs to meet the pumping demands at lower rotational speeds, significantly reducing the destruction of blood components.

The EVAHEART design was initiated in 2002 and was later approved for clinical use for BTT by the Ministry of Health, Labor, and Welfare of Japan for manufacturing and sale in 2010. It was the first to utilize an open-impeller fluid dynamic suspension system and retrieved excellent clinical outcomes domestically. The significant lower occurrence of complications, including right heart failure and gastrointestinal bleeding, enabled its acquisition by the U.S. Medical Device Investigational Device Exemption (IDE) and European Conformity (CE) regulations.

HeartMate III is the world's first artificial heart with full magnetic levitation technology. The first clinical implantation was launched in 2014, approved for BTT in 2017, and approved for DT in 2018. It is at present the most widely used VAD in the world, with 80% of the market in the U.S. [21]. The unique FullMagLev magnetic levitation technology of HeartMate III effectively reduces wear and heat generation, and this "no wear-out" technology makes it last for more than a decade. The continuous rotation of the levitated rotor avoids the stagnation of blood flow within the ventricle, and the non-contact design of the rotor and the mechanical ventricle significantly reduces the disruption of blood components, which in turn reduces the risk of hemorrhagic or thrombotic complications [22]. In 2022, a multicenter study (MOMENTUM 3) on the use of magnetic levitation technology for patients receiving HeartMate mechanical circulatory support therapy compared the five-year prognosis of HeartMate II and III on the line. The results revealed that the latter had significant advantages in BTT, DT, and BTD and a lower incidence of serious adverse events, such as strokes, hemorrhage, and thrombosis [23].

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