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Review

A Rise in Devices: An Overview of the Current Ventricular Support Devices and Future Prospects

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Abstract

The field of mechanical circulatory support devices has experienced remarkable progress, addressing critical challenges in managing heart failure and related cardiovascular conditions. Both temporary and durable ventricular assist devices have transformed therapeutic strategies, improving survival rates and enhancing the quality of life for individuals with acute and chronic heart failure. However, challenges such as device longevity, biocompatibility, and patient-specific optimization remain significant barriers. Therefore, advances in bioengineering and device miniaturization present promising opportunities to optimize device performance and minimize complications. By emphasizing key innovations and outlining future pathways, this review aims to discuss current developments in mechanical support devices and explore future directions for innovation in the field.

Keywords

ventricular assist device; temporary mechanical circulatory support; left ventricular assist device; heart failure; total artificial heart

Introduction

Heart failure is a growing health issue in the United States, currently affecting approximately 6.7 million Americans aged over 20 years. Moreover, this prevalence is expected to double during the next 25 years, with an estimated lifetime risk of 1 in 4 individuals developing heart failure [1]. Managing heart failure continues to evolve as new technology and research are conducted. While inotropes provide temporary circulatory support, patients with advanced heart failure often require more robust interventions involving either mechanical circulatory support or heart transplantation [2]. Since the first clinical use of a circulatory support device in 1963, evolutions in device technology and production have continued to expand the usage of mechanical devices and improve outcomes for patients with advanced heart failure [3]. This paper aimed to describe the current developments in mechanical support devices and explore future directions for innovation in the field.

Durable Circulatory Support Devices

Heartmate

Ventricular assistance devices (VADs) are the foundation of circulatory support for end-stage heart failure patients refractory to inotropic treatment. The Heartmate series (Abbott, Abbott Park, IL, USA) are left ventricular assistance devices (LVADs) that are the standard for durable support. The first-generation Heartmate device, the Heartmate XVE, was used as a pulsatile pump to pump blood and mimic the native heart flow [4]. This device originally received Food and Drug Administration (FDA) approval as a bridge to transplant (BTT) in 1998. Heartmate devices have been used as a destination therapy after the results of the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial. This trial, published in 2001, demonstrated an increased survival of 8 months when using the Heartmate XVE (1st generation) compared to medical therapy for transplant-ineligible patients. The study also showed poor longer-term survival due to high rates of device complications, including bleeding, infection, and device malfunction [5].

The second-generation Heartmate II device used an axial continuous flow pump. Unlike the previous generation, Heartmate II provided continuous flow, which resulted in the patient having little to no pulse. Due to the mechanics of constant flow, these devices were capable of both partial and full circulatory support with greater capabilities for customization of flow rate and the ability to adjust to changes in preload. The Heartmate II was also smaller and quieter [6]. A randomized control trial published in 2009 demonstrated significantly better outcomes when using the Heartmate II than with Heartmate XVE. Heartmate II had an improved

two-year survival rate (58% vs. 24%) and improvements in most adverse events except stroke [7], ultimately ending the Heartmate XVE era.

The availability of the third-generation Heartmate III device led to the current LVAD era. The Heartmate III was created to address the major limitations of the Heartmate II: high rates of thrombosis, stroke, and bleeding due to its mechanical rotor having direct contact with the pump, leading to high shear stress. The Heartmate III uses a centrifugal, continuous flow through a magnetically levitated rotor to address these issues. This prevents rotor contact with the pump, creates wide blood-flow gaps, and is made of textured blood-contacting surfaces. These mechanisms reduce shear stress and allow for greater control of flow. Subsequently, the Heartmate III can rapidly change its flow rate, creating an artificial pulse that allows routine device washing to prevent thrombus formation. Furthermore, the Heartmate III is much smaller than the Heartmate II [8], which allows for the device to be implanted in patients with a smaller body habitus than is permitted with the Heartmate II.

The Multicenter Study of Maglev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with Heartmate III (MOMENTUM) Trial was a randomized controlled trial that compared Heartmate III with Heartmate II. The first set of results was published in 2019 and demonstrated the superiority of the Heartmate III to the previous generation in terms of pump replacement and survival free of disabling stroke. This study showed that over 2 years, the third-generation Heartmate devices had significantly fewer instances of stroke, thrombosis, and bleeding than the Heartmate II device, demonstrating the effectiveness of the magnetic centrifugal flow design in addressing the complications of the older device generations [9]. A subsequent long-term analysis published in 2022 showed that Heartmate III had a higher 5-year survival than Heartmate II due to the decreased incidences of stroke, bleeding, thrombosis, and need for device exchange (54.0% vs. 29.7%) [10]. A similar long-term, multicenter trial in Europe, the CE Mark Trial, demonstrated further evidence of the superiority of Heartmate III to the previous generations regarding hemocompatibility adverse events and survival. However, this trial found a greater risk of stroke for the Heartmate III device than was reported in the MOMENTUM Trial [11]. Both devices required a driveline, and the trials found no significant difference in device infection rates between the Heartmate III and Heartmate II devices [9,11]. Overall, these trials demonstrate an improvement in the Heartmate III device compared to the previous generations, making Heartmate III the first-choice device within the Heartmate series.

Hemocompatibility-related events remain the burden of durable LVAD technology. During its early adoption, the Heartmate III required management with antiplatelet (aspirin) and anticoagulation (warfarin) drugs. Meanwhile, due to the continuous flow technology, bleeding events have increased. The ARIES Trial was an international, randomized, placebo-controlled trial aimed at assessing the non-inferiority of a placebo compared to aspirin therapy for Heartmate III implanted patients. The trial had 628 participants across 51 centers in nine different countries. The results demonstrated the placebo group had a reduced risk of nonsurgical bleeds with no increase in thromboembolic events or stroke when compared with aspirin therapy [12]. Thus, the study demonstrated evidence for discontinuing aspirin therapy after Heartmate III implantation. Following the results of the ARIES Trial, the U.S. FDA approved the elimination of aspirin therapy following Heartmate III implantation in April 2024 [13].

Warfarin remains the foundation of anticoagulation for patients in support of the Heartmate III device. However, there is a growing series of patients who are supported on the Heartmate III after discontinuation of warfarin due to severe complications. A retrospective, multi-center study published in 2022 included eight patients who discontinued warfarin. This was conducted due to a major bleeding event in five patients and non-adherence in the remaining three. Half of all the patients were on aspirin therapy. This study found no subsequent thromboembolic events in these patients after discontinuation [14]. Another series published in 2024 included 22 Heartmate III patients with subtherapeutic or no warfarin compared to twenty-two Heartmate III patients with warfarin therapy. This study showed no significant difference in thromboembolic events between the two groups, but the group with minimal/no warfarin experienced fewer bleeding events [15].

Current research into the Heartmate III device primarily focuses on real-world data and applications. One such study evaluated the application of the Heartmate III Risk Score (HM3RS). The HM3RS system developed in the MOMENTUM Trial sought to predict 1- and 2-year mortality using clinical variables, such as age, serum blood urea nitrogen, and left ventricular end-diastolic dimension. The trial internally validated this scoring system. A recent study demonstrated the continued effectiveness of the INTERMACS registry in real-world patients. However, it did note reduced predictability in patients who did not meet the original MOMENTUM trial criteria [16]. Multiple Heartmate III database registries, such as INTERMACS in the United States, the ELEVATE registry, and EuroMACS, provide further opportunities for prospective analysis of Heartmate III in a real-world setting [17].

Novel Durable Circulatory Support Devices

In addition to advancements in the Heartmate series, numerous innovations in other VADs aim to overcome the limitations of current technologies. One such innovation is centered around the power supply. A major limitation of current VADs is the need for a percutaneous driveline

to charge and power the device. This driveline greatly increases the risk for device infections, a major adverse event that has had minimal improvement with newer generations of VADs. While battery technology has improved, creating a reliable and strong transcutaneous/wireless energy transfer method is the main goal. Magnetic wireless energy transfer carries risks of increased heat transfer, thermal damage, and poor charging from unstable energy transfer [18]. However, advancements in wirelessly charged VADs are limited due to these challenges.

Leviticus Cardio

The Leviticus Cardio (Leviticus Cardio, Petach Tikva, Israel) device is a promising new VAD at the forefront of wireless charging technology. This device uses a coplanar energy transfer system by utilizing two large rings and a coil-within-coil topology. This system allows for reliable energy charging and greater than 6 hours of wireless VAD operation. A successful implantation and use of this technology in humans was published in 2019. Two patients were implanted with the device: One patient had pump thrombosis after 35 days, while the other had the device for 2 months until he was transplanted. No device complications related to the wireless charging or malfunction were noted [19]. This successful preliminary use of the device contributed to Leviticus Cardio receiving a Breakthrough Device Designation by the FDA in 2019. The device is undergoing continued technological developments to meet milestones before a formal clinical trial [20].

EvaHeart2

Other new devices are being developed to continue the trend of minimizing hemocompatibility-related adverse events in VADs. The EvaHeart2 (EvaHeart, Bellaire, TX, USA) is a centrifugal-flow VAD similar to the Heartmate III. The device has numerous unique design features to reduce complications associated with the Heartmate III device. One feature is an inflow cannula that does not protrude into the ventricle, which is hypothesized to reduce areas of blood stasis and turbulence and reduce the risks of stroke, thrombosis, arrhythmia, and low ventricular output [21,22]. Another feature is a wide cross-sectional area throughout the device designed for higher flow rates and pulsatility compared to Heartmate III [22].

Comparisons of the EvaHeart2 with the Heartmate III device via *in vitro* analyses demonstrated the potential superiority of EvaHeart2 in addressing hemocompatibility issues. EvaHeart2 caused less hemolysis, decreased destruction of von Willebrand factor multimers, and lowered coagulation activation *in vitro* compared to Heartmate III [23]. Animal studies with EvaHeart2 demonstrated device functionality and adverse event improvements compared to an earlier model [24]. Currently, no animal studies have compared EvaHeart2 to Heartmate III.

Due to the promising preclinical results of EvaHeart2, a formal clinical trial is ongoing. The COMPETENCE Trial is a prospective, multicenter study that compares Evaheart2 (EVA2) and Heartmate III (HM3). The study has proposed 2:1 (EVA2:HM3) randomization to conduct a non-inferiority analysis using short-term (6-month) and long-term (24-month) end-points. The trial is being performed, and it is estimated that 399 patients will have been analyzed at its conclusion; 25 patients were enrolled as of January 2023, with no further results being published [22].

BrioVAD

Another device currently approved by the FDA for clinical trial is the BrioVAD (BrioHealth Solutions, Burlington, MA, USA). The BrioVAD is a centrifugal flow pump that is more compact with additional adjustments in the pump rotor aimed at minimizing hemocompatibility issues. The device has a smaller pump size than the Heartmate III device, allowing it to be placed in smaller thoracic cavities with potentially easier implantation. The BrioVAD also has a flexible driveline and mimics a physiological pulse. Studies conducted *in vivo* in bovine calves showed minimal thrombosis, embolism, and hemolysis [25,26]. A preliminary trial in humans was conducted in China from 2017 to 2023. In total, 50 patients were implanted with the device during this period. The trial showed 93% survival after one year and 89% survival after three years. The trial demonstrated low hemocompatibility complication rates with three non-disabling strokes and one instance of a gastrointestinal bleed. Device infections were the most significant adverse event, with a 16% rate in the trial [27]. Due to these promising results, the device gained FDA approval for a clinical trial in the United States in 2024. The INNOVATE trial aims to enroll about 800 patients for implantation with either the BrioVAD or alternative LVAD to compare survival, complication rates, and hospital stay. The trial is currently recruiting participants and has not released any results [28].

CorWave

The CorWave (Corwave, Clichy, France) VAD is a wave-membrane pump currently in development. The CorWave uses a flexible polymer that moves in a wave motion instead of a traditional rotor. This technology was created to improve the mimicking of the physiological pulse. While blood flows on a traditional rotor at a rate near 5 m/s, the CorWave boasts a 1–2 m/s flow rate on its wave membrane, miming the physiological rate and limiting shear stress. The design also boasts a high-fidelity pulsatality [29]. Device trials performed *in vivo* and *in vitro* showed a 95% synchronization rate with left ventricle contraction. Moreover, these trials reported minimal hemocompatibility adverse events [30]. The CorWave is planned for an early feasibility trial in humans, aiming to enroll up to 15 patients in

Asia, Europe, and Australia to investigate survival, adverse events, and quality of life [31].

Innovations in Surgical Techniques for Durable Circulatory Support Device Implantation

Along with advancements in LVAD technology, modifications to VAD implantations are occurring. The standard surgical method of LVAD implementation is a medial sternotomy. LVAD implantation via less invasive procedures, such as a lateral thoracotomy, has gained popularity. A meta-analysis investigating the lateral thoracotomy approach to LVAD implementation showed a significant reduction in surgical bleeding, post-operative RVAD implementation, intensive care unit (ICU) and hospital stays, and post-operative inotrope usage compared to the conventional sternotomy approach [32].

The Multi-Center Implantation of the Heartmate III in Subjects with Heart Failure Using Surgical Techniques Other Than Full Median Sternotomy (HM3 SWIFT) study is the first prospective study comparing thoracotomy to sternotomies for LVAD placement. This trial enrolled 102 patients in a non-inferiority study of the thoracotomy-based approaches. No significant differences were observed for surgical approaches in event-free survival, blood product utilization, adverse events, including infection, functional status, or quality of life. This study also showed increased hospital stay for the thoracotomy approach. Overall, the study demonstrated less clinical benefit from the thoracotomy approach than prior retrospective and observational studies [33]. Although it is important to note that the study included patients who received either a bilateral thoracotomy or a partial sternotomy with left thoracotomy in the thoracotomy-based group. A pure lateral thoracotomy approach has been described in the literature but is limited due to the current LVAD size [34]. Therefore, one key direction in LVAD innovation has been to decrease its size while maintaining hemodynamic function. As this development occurs, further minimally invasive surgical approaches with more clinical benefit may become evident.

Total Artificial Heart

An LVAD is insufficient for circulatory support in patients with severe biventricular failure. These patients can use biventricular assist devices (BiVADs) or a total artificial heart (TAH). TAH implantation consists of performing a ventriculostomy and implanting two polyurethane ventricle chambers containing two tilting disc valves. This method is currently used for temporary circulatory support as a bridge-to-transplantation. When analyzed, post-transplantation outcomes are similar to using a TAH or BiVAD as a bridge-to-transplant [35].

Syncardia

Currently, the SynCardia (SynCardia Systems, Tucson, AZ, USA) device is the only TAH that is FDA-approved for clinical use. The SynCardia device is approved and used as a bridge-to-transplant only; however, there is a preliminary trial investigating its use as a destination therapy, for which 19 patients were recruited. This study was expected to be completed in 2022, but the last update in 2021 stated the study was still recruiting. No further results from this trial are available [36].

The Syncardia device is bulky with many structural limitations similar to early-generation LVADs, such as a mechanical rotor with high part-to-part direct contact and high shear stress. The bulk of the device limits its implantation to people with a large enough body habitus, making it not feasible for smaller patients [37]. Next-generation TAHs aim to address these limitations.

BiVACOR

The BiVACOR (BiVACOR Inc., Huntington Beach, CA, USA) device is a novel TAH that uses a magnetic centrifugal pump similar to the Heartmate III. However, the BiVACOR device is more compact than Syncardia, allowing it to be used in smaller patients. While the Syncardia device requires a body surface area (BSA) of at least 1.7 m^2, the BiVACOR is designed to fit into individuals with a BSA >1.4 m^2 [38,39]. The first anatomical fitting into humans was conducted in 2020 and showed a good fit into six individuals with an average body mass index (BMI) of 28 kg/m^2 [40].

The magnetic rotor is aimed to drastically improve hemocompatibility compared to the Syncardia device. The design difference resembles the difference between first- and third-generation Heartmate devices. Early *in vivo* trials conducted in bovine show good hemodynamics with minimal hemocompatibility issues despite minimal anticoagulation [41]. Currently, BiVACOR is approved by the FDA for an early feasibility study. This study aims to recruit five patients to test the feasibility of using BiVACOR as a bridge-to-transplant. The trial is ongoing, with the first human implantation and device use conducted in July 2024; meanwhile, no further results from the trial are currently available [39].

Aeson

The Aeson TAH (CARMAT, Vélizy-Villacoublay, France) is another novel TAH that aims to address the limitations presented by the Syncardia device. The Aeson TAH is more compact and has an external system for improved patient mobility. Moreover, the Aeson TAH device utilizes a bioprosthetic surface made from bovine pericardium to help improve biocompatibility and reduce hemocompatibility issues. A study of ten patients implanted with the Aeson

TAH showed minimal modification of the von Willebrand factor multimer profiles and low blood shear stress [42]. The Aeson TAH also has an autoregulation feature where the device can automatically adjust to changes in preload and hemodynamics. This feature has led to minimal need for clinician adjustments to device settings and greater reactions to exercise and patient movement [43].

This device was first implanted into a European adult in 2013. Since this implementation, more than 100 patients have been implanted in total. Forty-two of these implantations were conducted in 2024, showcasing a recent expansion of interest in the Aeson TAH [44]. The first U.S. implantation occurred in a 39-year-old adult male in 2021. This patient was successfully bridged to transplant after 8 months on the device. This implantation was a part of an early feasibility trial by the FDA. However, the trial was temporarily suspended due to quality issues with the prosthetics. Although the quality defects were identified and corrected, the trial has not yet restarted [45]. Currently, the Aeson TAH is primarily implanted in the European Union. Moreover, the implantation of the Aeson TAH is being studied in 52 patients in the prospective EFICAS trial. The goal of the study is to examine the outcomes and safety profiles of the device. As of January 6th, 2025, approximately 70% of the recruitment for this study was complete. No results are available, but CARMAT expects results to be published at the end of 2025 [44].

Temporary Circulatory Support Devices

Impella 5.5

The Impella (Abiomed, Danvers, MA, USA) series are micro-axial flow pumps that provide temporary left ventricular circulatory support. The newest generation of the device is the Impella 5.5, released in 2019. Compared to the prior generation, Impella 5.0, the latest Impella 5.5 generation has a sturdier cannula and a smaller motor and lacks the thrombogenic pigtail at the tip of the device. These changes aim to make the device more compact, functional, and capable of providing longer support. An FDA-mandated study comparing these two devices demonstrated that Impella 5.5 has a significantly higher survival rate than the prior generation despite similar rates of adverse events [46].

The Impella Protected Cardiac Surgery Trial (IMPACT Trial) aims to assess the safety and efficacy of Impella 5.5 use perioperatively in patients with severe LV dysfunction undergoing cardiac surgery. The study is a multicenter prospective trial that aims to enroll 100 patients. The study is ongoing and expected to be completed in 2025; however, no results are currently available [47].

CentriMag

CentriMag (Abbott, Abbott Park, IL, USA) is a temporary circulatory support device that can offer right ventricular, left ventricular, or biventricular support and compatibility with an extracorporeal membrane oxygenator (ECMO). The CentriMag device uses a magnetically levitating rotor to generate flows up to 10 L/min. The inflow and outflow cannula locations can be adjusted to provide left or right ventricular support [48].

Two pilot trials approved by the FDA were conducted using this device. These trials evaluated the efficacy of the CentriMag in relation to cardiogenic shock and right-ventricular failure after LVAD implantation. A total of 38 patients were included in these trials, with 26 in the cardiogenic shock trial and 12 in the post-LVAD implantation trial. The cardiogenic shock trial had a 17-day mean duration of support and 30-day post-explant survival of 50% for post-acute myocardial infarction cardiogenic shock. The six-month survival post-explant for these patients was 17%. Post-cardiotomy cardiogenic shock patients had a mean support duration of 8 days with a 20-day post-explant survival of 33%. The post-LVAD implantation trial patients had a mean support duration of 14 days with a 58% 30-day post-explant survival and 33% 6-month post-explant survival. These trials show evidence that the CentriMag provides adequate temporary circulatory support but poor long-term survival rates [48]. An *in vitro* analysis of Impella 5.5 versus CentriMag demonstrated that both devices have similar hemocompatibility issues. However, CentriMag had slightly more platelet degradation and microparticle activation despite Impella having a higher rotational speed [49].

Temporary Circulatory Support Devices for Right Heart Failure

Impella RP

In addition to left ventricular support, the Impella devices also have the option for right ventricular support. The Impella RP is a temporary right-sided heart pump inserted through the femoral vein that is FDA-approved to treat acute right heart failure following a heart transplant, LVAD implantation, myocardial infarction, or open-heart surgery [50]. The RECOVER RIGHT trial was a single-arm multicenter study involving 30 patients with right heart failure refractory to medical management. The study found improved hemodynamics with Impella RP usage and a 30-day survival rate of 73.3% [51]. The FDA did a post-approval study investigating the 30-day survival rates of patients with an Impella RP implant in a real-world setting. This study found similar survival rates to the RECOVER RIGHT trial in patients who met the trial inclusion criteria. However, survival rates were lower in patients excluded from the trial.

This led to the update on the FDA recommendations for Impella RP use to exclude device use in 2022 in patients with "severe cardiogenic shock, end-organ failure, or acute neurological injury" [50]. More recently, the Impella RP Flex has been FDA-approved because it offers the advantage of being placed via the internal jugular vein, facilitating patient mobility. Early results suggest improved delivery issues, bleeding, and vascular complications with the Impella RP Flex compared to the Impella RP [52].

ProtekDuo

The ProtekDuo (LivaNova, London, UK) device is similar to the Impella RP Flex as it is implanted through the femoral vein. However, an oxygenator can also be added to the ProtekDuo device, which allows the device to function as a veno-venous extracorporeal membrane oxygenator (VV-ECMO) [53]. Several studies that compare ProtekDuo to Impella RP showed minimal differences in survival, although one report suggested greater survival in patients with ProtekDuo support [54–56]. Further research is needed to compare the devices; however, current data suggest that the ProtekDuo is an effective alternative to the Impella RP, especially for patients who may be contraindicated to femoral access or have severe hypoxic respiratory failure.

Conclusions

The evolution of mechanical circulatory support devices represents a shift in managing advanced heart failure and related cardiovascular conditions. Over the previous decades, significant strides in device technology, biocompatibility, and miniaturization have improved patient survival and quality of life and expanded the applicability of these devices to a diverse patient population. Temporary and durable ventricular assist devices have proven efficacy in both acute and chronic heart failure, providing vital circulatory support and bridging patients to recovery, transplantation, or destination therapy. However, challenges related to device durability, thromboembolic complications, infection risk, and patient-specific optimization persist.

Emerging advancements in bioengineering, such as biomaterials, enhanced flow dynamics, and sensor technologies, hold great promise for addressing these limitations. Furthermore, integrating artificial intelligence and machine learning into device monitoring systems may pave the way for personalized therapy and predictive maintenance. Future innovation must also improve the accessibility and affordability of mechanical circulatory support devices to ensure equitable healthcare outcomes.

By embracing these advancements, the field of mechanical circulatory support is poised to redefine the landscape of heart failure treatment. However, continued collaboration between clinicians, researchers, and industry partners is crucial to developing next-generation circulatory support systems that meet the evolving needs of heart failure patients.

Author Contributions

BF and RR are both co-first authors of this manuscript and contributed equally to its preparation. Conceptualization, BF, RR, JW, MU and TS; writing—original draft preparation, RR; writing—review and editing, BF, RR, JW, MU, TS; supervision, TS; All authors have participated sufficiently in the work. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

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Conflict of Interest

The authors declare no conflict of interest. Tadahisa Sugiura is serving as one of the Editorial Board members of this journal. We declare that Stefano De Servi had no involvement in the peer review of this article and has no access to information regarding its peer review.

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