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LONG-TERM MECHANICAL CIRCULATORY SUPPORT: EVOLUTION, PRESENT MILESTONES, AND FUTURE DIRECTIONS

R.Yu. Bangarov[2], T.A. Khalilulin[1], V.M. Zakharevich[1], Sh.R. Galeev[2], G.V. Nabiev[2]

[1] Shumakov National Medical Research Center of Transplantology and Artificial Organs, Moscow, Russian Federation

[2] Volzhsky Branch of Shumakov National Medical Research Center of Transplantology and Artificial Organs, Volzhsky, Russian Federation

Objective: to examine the historical evolution, current advancements, and future prospects of long-term mechanical circulatory support (LT-MCS) devices in the management of end-stage heart failure. **Materials and methods.** An analysis was conducted on clinical studies (MOMENTUM 3, INTERMACS, EUROMACS), historical records, and technological progress in the field of LT-MCS. The review covered three generations of devices: pulsatile pumps (first generation), axial-flow pumps (second generation), and centrifugal pumps with magnetic levitation (third generation). Key outcomes evaluated included survival rates, complication rates (thrombosis, infections, right ventricular failure), and developments within national technology. **Results.** The HeartMate III third-generation device has a 2-year survival rate of 82% with a pump thrombosis risk of less than 1%. However, complications remain, including driveline infections (10–15%), right ventricular failure (20–40%), and bleeding events (15–20%). Domestic systems (Stream Cardio) are comparable to second-generation devices but lag in terms of miniaturization and clinical trials. Emerging technologies like the Leviticus FiVAD wireless energy transfer system and the Carmat Aeson fully implantable artificial heart are opening up promising new directions for the future of mechanical circulatory support. **Conclusion.** Modern LT-MCS systems have emerged as a viable alternative to heart transplantation (HT), particularly for patients who are not candidates for HT. Key areas of ongoing development include device miniaturization, wireless energy transfer technologies, and integration of artificial intelligence. The future of LT-MCS will largely depend on overcoming current system limitations, notably the risks of infection and right ventricular failure.

Keywords: long-term mechanical circulatory support, heart failure, thrombosis, right ventricular failure, miniaturization, artificial intelligence.

INTRODUCTION

Heart failure (HF) remains one of the most pressing global health challenges. According to the World Health Organization (WHO), more than 26 million people worldwide are affected, with a five-year mortality rate exceeding 50% – a figure comparable to that of many oncologic diseases [1, 2]. While heart transplantation (HT) is considered the gold standard for treating end-stage chronic heart failure (CHF), its widespread application is severely limited by a critical organ shortage, with only slightly above 5,000 transplants performed globally each year [2, 3]. In this context, mechanical circulatory support (MCS) has emerged not merely as an alternative, but as an essential life-saving option, particularly for patients with refractory HF and cardiogenic shock.

Modern long-term mechanical circulatory support (LT-MCS) devices, such as HeartMate III and HeartWare HVAD, have demonstrated revolutionary clinical outcomes. According to the MOMENTUM 3 trial, the 1-year and 2-year survival rates following the implantation of this left ventricular assist device (LVAD) were 86.6% and 79%, respectively [4]. In the ELEVATE registry, the 2-year survival rate was even higher, reaching 83.4% [5] – a figure comparable to survival rates observed after HT [6, 7].

EVOLUTION OF MECHANICAL CIRCULATORY SUPPORT TECHNOLOGIES

As early as the first half of the 20th century, it became evident that even with the breakthroughs in cardiac surgery – particularly the advent of cardiopulmonary bypass – conservative therapies and traditional surgical interventions often failed to fully restore the heart's pumping function. This realization spurred an active search for methods of temporary or permanent MCS.

In 1952, Michael DeBakey proposed the concept of MCS, and in 1963, together with Domingo Liotta, successfully implanted the first mechanical pump for temporary left ventricular support – a key milestone in the development of MCS technologies [8]. Just six years later, in 1969, American cardiac surgeon Denton Cooley implanted the first total artificial heart (TAH) [8]. These

Corresponding author: Rizvan Bangarov. Address: 86, Generala Karbysheva str., Volzhsky, 404120, Russian Federation. Phone: (999) 625-87-50. E-mail: rizvan.bangarov@yandex.ru

groundbreaking achievements, combined with the persistent shortage of donor organs, catalyzed the emergence of MCS as a promising and technologically sophisticated approach to treating HF.

Today, a wide range of devices has been developed to support either the entire heart or individual ventricles. The evolution of MCS technologies is generally divided into three main generations, each characterized by revolutionary advances that have led to clinical outcomes for end-stage CHF comparable to those of HT.

First generation: pulsatile pumps

The development of first-generation MCS devices began in the 1960s. Initially, these systems were extracorporeal (e.g., Novacor, HeartMate XVE) and later evolved into fully implantable devices (e.g., Jarvik 7, SynCardia TAH), utilizing membrane chambers in which pressure differentials – created by external pneumatic or hydraulic actuators – enabled blood pumping [9, 10]. These devices mimicked the natural cardiac cycle by generating a pulsatile blood flow.

The primary purpose of first-generation devices was to serve as a "bridge to transplantation" (BTT), and the latest models of this era generally fulfilled this role effectively for durations ranging from weeks to several months. However, the were associated with a number of limitations.

Due to their heavy weight and reliance on external actuators, patient mobility was severely restricted, despite the devices' ability to achieve high cardiac outputs (up to 10 L/min). Their large size necessitated the creation of relatively large cavities for implantation, increasing the contact area between foreign materials and host tissues and thereby raising the risk of infectious complications. Additionally, the wide diameter of the percutaneous driveline (6–10 mm) further increased infection risks.

The design incorporated mechanical valves and was prone to blood stasis within the pump chambers, contributing to a high incidence of thromboembolic events (10–15%). Furthermore, mechanical wear and diaphragm fatigue significantly reduced the long-term reliability of these pumps, generally limiting their functional lifespan to 12–18 months [10–12].

Second generation: axial pumps

In response to the limitations of first-generation devices, a major breakthrough occurred in the field of MCS. Numerous studies demonstrated that, in most cases, prosthetic support of the left ventricle alone was sufficient to maintain effective cardiac output.

Second-generation devices – fully implantable LVADs such as the DeBakey VAD, HeartMate II, and Jarvik 2000 – were developed during the 1990s and 2000s. These devices operate based on the principle of continuous axial blood flow and represent a significant advancement over their predecessors in terms of both size and performance [11–14].

They weigh between 150 and 300 grams and measure less than 10 cm in length. Their compact axial rotor design efficiently unloads the left ventricle and provides continuous blood flow with outputs reaching up to 10 L/min. This ensures uninterrupted perfusion of vital organs and significantly reduces the risk of thrombus formation, thus making them applicable to a wider range of patients [7, 11–16].

A study by Miller et al. (2007) demonstrated a 75% survival rate at six months among patients implanted with the HeartMate II device, along with significant improvements in functional status and quality of life, further validating the efficacy of axial-flow pumps [17].

Thanks to several fundamental advantages over first-generation devices – including a longer service life of 5 to 7 years – second-generation pumps expanded the therapeutic scope of MCS from the initial "bridge to transplantation" (BTT) concept to include "bridge to recovery" (BTR) and "destination therapy" (DT) [7, 17–19]. Notably, the HeartMate II became the first implantable LVAD approved for lifelong implantation in 2010, and it remains one of the most widely used MCS devices worldwide.

However, continuous blood flow, while ensuring reliable organ perfusion, is non-physiological for the vascular endothelium. This unnatural flow pattern can lead to endothelial dysfunction, impair baroreceptor activity, disrupt blood pressure regulation, and contribute to the formation of arteriovenous malformations. As a result, bleeding complications, particularly in the gastrointestinal (GI) tract, are relatively common in patients supported by continuous-flow devices [20].

The presence of mechanical bearings in the design, axial nature of blood flow, and high rotor speed contribute to thrombus formation in 10–14% of cases within two years following implantation [21]. Additionally, right ventricular failure is a characteristic complication associated with second-generation devices. High pump output can cause malpositioning or rightward displacement of the interventricular septum (IVS), negatively impacting the septum's contribution to right ventricular (RV) stroke volume. This impairment can lead to significant RV dysfunction, necessitating either the implantation of a right ventricular assist device or proceeding to HT [13, 20–23, 36].

Third generation: centrifugal pumps with magnetic levitation

Although second-generation devices offered clear advantages over their predecessors, complications such as pump thrombosis and neurologic events continued to drive research toward further improvements in LVADs. Development and testing of third-generation pumps

began around 2012, involving approximately 10 different prototypes. This research culminated in a major breakthrough in the treatment of end-stage HF with the introduction of technologies that eliminated mechanical contact within the pump.

The pioneer among third-generation devices was the HeartMate III (Abbott), approved in 2017 [21, 24]. Its key innovation lies in the fully magnetically levitated (FML) rotor, suspended entirely by magnetic fields, thereby eliminating friction, reducing shear stress, and minimizing blood cell damage [4, 21]. This achievement was confirmed in the MOMENTUM 3 clinical trial, where the HeartMate III demonstrated unprecedented levels of safety [4, 21, 25, 26].

The third generation also included the Medtronic HVAD, which used fluid dynamic bearings. Despite its centrifugal flow and compact design, the HVAD's classification as a full third-generation device remained controversial. Although developed in the 2010s as an advanced model, the use of fluid bearings involving microcontacts contributed to a higher risk of thrombosis (12%) and stroke (15%), ultimately leading to its recall in 2021 [4, 21, 24, 28]. This experience underscored that the gold standard for third-generation LVADs is specifically full magnetic levitation.

Modern third-generation LVADs, such as the HeartMate III, rely on centrifugal flow combined with full magnetic levitation. In this system, a rotor suspended entirely by magnetic fields rotates at speeds of 5,500–6,000 rpm, producing blood flows of up to 10 liters per minute. The elimination of mechanical contact between pump components prevents hemolysis and thrombosis, contributing to an expected device lifespan of up to 10 years [4, 21, 27]. By contrast, the HVAD employed a hybrid suspension system, where passive magnetic levitation was combined with hydrodynamic bearings. Although a thin blood layer reduced friction, it did not completely eliminate mechanical contact [7, 28, 30].

According to the INTERMACS 2023 registry, third-generation devices now dominate clinical practice, with the HeartMate III representing approximately 85% of all implantations in the United States. The 2-year survival rate for patients supported by this device reaches 82%, approximately 6% higher than that achieved with earlier technologies and comparable to outcomes following HT [31–33]. In Europe, data from the EUROMACS 2022 report indicate a 1-year survival rate exceeding 80%, with thromboembolic events reduced to just 1–2% [34].

Among the clear advantages of the HeartMate III is its exceptional safety profile. Owing to the FML technology, the risk of pump thrombosis with HeartMate III is less than 1% – a significant improvement over earlier generations [4, 21, 26, 27, 32, 35]. The device's high durability, driven by the absence of mechanical wear, further positions third-generation LVADs a step above their predecessors. According to M.R. Mehra, HeartMate III does not require replacement for at least 5 years, providing strong justification for considering it a cornerstone in the evolution of destination therapy [37, 40].

Patient quality of life has also improved markedly. Studies have demonstrated that following implantation, patients experience sustained enhancements in functional capacity and overall well-being. Moreover, the reduction in operational noise – from approximately 40 dB in the HeartMate II to 25–30 dB in the HeartMate III – alongside the compact design of the device and its external components, enables greater patient mobility and promotes better social integration [4, 21, 40].

Despite the clear advantages of third-generation LVADs, these devices are not without limitations. While patients often experience marked improvements in physical activity, reduced dyspnea, and overall functional status, several challenges remain associated with long-term LVAD use.

Firstly, the need to continuously wear an external controller and power source can cause discomfort and restrict mobility, particularly in active patients. Secondly, although the risk of thrombosis has been significantly reduced compared to second-generation devices, the threat of ischemic and hemorrhagic complications – such as stroke and gastrointestinal bleeding – persists [4, 21, 26, 29, 35, 40]. For example, the ENDURANCE trial demonstrated a 29.7% stroke rate among patients with HVAD, which was notably higher than that observed in HeartMate II recipients [41].

Another persistent concern is infection at the driveline exit site. Despite advancements in materials and antimicrobial coatings, driveline infections remain one of the leading causes of hospitalization among LVAD patients, with an incidence of 10–15% [40, 43–45]. Furthermore, the anticoagulation therapy necessary to prevent thrombosis substantially increases the risk of major bleeding events (15–20%), necessitating continuous clinical monitoring [21, 27, 40].

Thus, although third-generation LVADs represent a major technological advancement, they are not a definitive solution to end-stage HF but rather an important bridge to transplantation or a means of long-term support.

Prospects of LT-MCS devices as a "bridge to recovery" (BTR)

The reverse myocardial remodeling observed in patients with end-stage HF following LVAD implantation has become a cornerstone argument supporting the BTR strategy. Mechanical left ventricular unloading leads to a significant reduction in ventricular volumes: end-diastolic volume (EDV) decreases by 20–30%, and myocardial wall thickness is reduced by 15–20%, contributing to partial restoration of normal cardiac geometry [46, 47]. For instance, in patients implanted with the HeartMa-

te III, left ventricular ejection fraction (LVEF) improved from an average of 15% to 35–40% in approximately 30% of cases, a result attributed to improved hemodynamics and a reduced neurohormonal load [21, 27, 40, 45].

The effectiveness of this process is closely linked to the technological generation of the LVAD used. First-generation devices (e.g., HeartMate XVE) employing pulsatile flow demonstrated reverse remodeling in only 10–15% of patients; however, complications such as thrombosis often negated these benefits [46, 48–50]. With the advent of second-generation axial flow pumps, the incidence of reverse remodeling improved to 25–30%. Nonetheless, a significant complication – *de novo* aortic regurgitation – emerged in about 40% of patients, compromising the durability of myocardial recovery [7, 15–20, 47].

A breakthrough was achieved with third-generation centrifugal pumps using full magnetic levitation technology. Devices like the HeartMate III enabled a 28–32% reduction in left ventricular volumes in 35–40% of patients, with a concomitant risk of pump thrombosis dropping to 1%, thereby offering a much more stable platform for ventricular recovery [7, 21, 27].

Despite significant progress, sustained long-term recovery of cardiac function following LVAD support remains relatively rare. Only 15–20% of patients maintain improved cardiac function for 1–2 years after device explantation. The success rate of LVAD removal with second-generation devices such as the HeartMate II was modest, approximately 12%. However, more recent data regarding the third-generation HeartMate III indicate higher myocardial recovery and retrieval rates, ranging from 18% to 22% [4, 7, 21, 27, 40, 50]. Importantly, younger patients without significant myocardial fibrosis demonstrate the highest likelihood of sustained myocardial recovery [32–34, 41–43, 45].

Thus, while third-generation LT-MCS devices not only extend survival but also foster myocardial recovery, the transition from a BTT paradigm to a true BTR strategy remains a major clinical and technological challenge. Achieving this transition will require solving issues related to the long-term durability of myocardial remodeling and improving the accessibility and affordability of advanced device technologies.

Development prospects: from miniaturization to bioartificial systems

The leading directions of innovation in MCS are focused on device miniaturization – including pediatric-specific solutions – the introduction of wireless power transmission technologies to reduce infectious risks, and development of fully implantable systems aimed at maximizing autonomy and patient safety [51].

First and foremost, the trend toward miniaturization is particularly crucial in pediatric practice. The use of bulky circulatory support systems in newborns and infants is severely limited by anatomical constraints and a heightened risk of complications. In response, recent years have seen the widespread adoption of compact devices with tailored hydrodynamic characteristics. A notable example is the Berlin Heart EXCOR Pediatric system, a pneumatic extracorporeal device featuring chamber volumes from 10 to 60 mL, widely utilized in patients weighing less than 20 kg. Parallel to this, implantable solutions are under active development, including the Jarvik Infant 2015 VAD and the Penn State Infant VAD, designed for children weighing as little as 4 kg. These devices are characterized by continuous blood flow, high reliability, and reduced thrombogenicity.

Particular attention is also being directed toward the PediaFlow VAD system, a magneto-hydrodynamic mini-pump with a thickness of less than 1 cm, capable of delivering effective circulatory support in newborns while minimizing hemolysis. Thus, the advancement of miniaturized VADs is significantly expanding the indications for long-term MCS in pediatric populations [54–56].

Currently, there is active advancement in the implementation of wireless energy transfer technologies, aimed primarily at eliminating percutaneous cables. This innovation significantly reduces the risk of infectious complications and improves both functional and aesthetic outcomes of therapy.

Among these systems, special attention is given to the Leviticus FiVAD, which employs the principle of coplanar energy transfer (CET) – allowing electromagnetic power transmission through the skin without physical contact with the external environment. A similar concept is realized in the experimental FREE-D system. Another notable development is the ICOMS Flowmaker (FineHeart, France) – a fully intraventricular, wireless LVAD synchronized with native heartbeats. This device integrates transcutaneous energy transfer (TET) with intelligent blood flow adaptation to physiological load, offering a new standard in circulatory support [57–61].

The next major milestone in LT-MCS technology has been the development of fully implantable mechanical support systems. A striking example is the aforementioned ICOMS Flowmaker, in which all components – including the controller, battery, and pump – are housed entirely within the body. The Leviticus FiVAD system is also capable of operating in a fully implantable mode, using an internal battery.

Total artificial heart (TAH) systems also deserve special mention, with the most innovative example being the CARMAT Aeson – a bioprosthetic heart that mimics the function of both ventricles, featuring pulsatile ejection and biocompatible materials. The device is fully implanted within the patient's thoracic cavity and utilizes a transcutaneous energy transfer (TET) system, thereby eliminating the need for external components. In addition to its advanced pump mechanism, CARMAT is equipped

with an autonomous blood flow adaptation system that responds dynamically to changes in the patient's physical activity. Clinical trials conducted within the framework of the European EFICAS program have demonstrated improved survival rates and enhanced quality of life in non-urgent transplant candidates [62–66].

By the end of 2024, the company had achieved 100 implantations of its device, with the number of surgeries doubling within just one year – a clear indication of growing medical confidence and renewed hope for thousands of patients facing an acute shortage of donor hearts [67].

The current trajectory of MCS development is profoundly multidisciplinary, combining advances in bioengineering, electronics, and materials science. Miniaturization is expanding the application of these technologies to pediatric populations, while wireless energy transmission significantly enhances safety and mobility. Fully implantable systems, meanwhile, are elevating circulatory support to an unprecedented level of autonomy. Together, these innovations are laying the groundwork for the next generation of devices capable of replacing or sustaining cardiac function with minimal disruption to patients' daily lives.

RUSSIAN INNOVATIONS IN THE FIELD OF MECHANICAL CIRCULATORY SUPPORT

Alongside global advancements in MCS systems, Russia has established its own scientific and technological base, marked by both historical achievements and current trends. Since the Soviet era, Russian innovations have demonstrated notable advancements in miniaturization, digital integration, and functional design, although they continue to face systemic challenges, particularly in terms of funding, clinical scalability, and integration into international research networks [7, 15, 16, 70–74].

Historical foundation: Poisk-10M

A landmark development in the Soviet Union's contribution to MCS technology was the creation of the Poisk-10M, an all-artificial heart designed in the 1980s under the leadership of Prof. Valery Shumakov. This pulsatile, pneumatic-type device, weighing approximately 900 grams and featuring a chamber volume of 60–80 mL, was intended to provide temporary heart replacement for patients awaiting transplantation. Its clinical application included 17 implantations, including 4 operations in Poland, underscoring early global interest in Soviet cardiovascular innovations. Preclinical testing on calves demonstrated survival periods of up to 102 days, validating the device's fundamental viability. However, the system's large size, susceptibility to mechanical wear, and the economic crisis of the 1990s ultimately led to the discontinuation of the project. Despite these limitations, the Poisk-10M laid the foundation for further research, proving the feasibility of two-stage HT [68–69, 76–79].

Evolution of technology: transition to axial flow pumps

The next stage in the development of Russian MCS systems was marked by a transition to axial flow pumps, aligning Russian innovations with the second and third generations of international MCS technologies. A pivotal point in this evolution was the initiation of clinical trials in 2012 for the AVK-N axial pump, a second-generation LVAD designed for long-term support of patients with end-stage HF. The AVK-N demonstrated technical and clinical performance comparable to international counterparts, such as the HeartMate II, while offering a key advantage – compatibility with domestically sourced materials. The device has been successfully applied in clinical practice under both BTT and DT strategies, showing outcomes similar to those of established Western models of its generation [70, 74–76, 80].

Among current domestic technologies, the most sophisticated innovation is arguably the Stream Cardio system – a universal axial-flow MCS device engineered to support both the left and right ventricles. The pump operates within a wide flow range of 3–7 L/min for the left ventricle and a pressure range of 20–60 mmHg for right ventricular support, making it adaptable for patients with a minimum body surface area (BSA) of 0.9 m^2. What sets Stream Cardio apart is its integration of digital technologies. The system includes wireless control via a mobile interface, autonomous power supply for up to 12–14 hours, real-time monitoring through a graphical interface and artificial intelligence (AI) algorithms capable of predicting complications. An additional innovation is its multimedia training module, which includes a surgical video archive, significantly enhancing surgeon training and system usability.

Despite these advancements, Stream Cardio has limitations. Notably, the high cost of disposable modules and the inapplicability for pediatric patients with a BSA <0.9 m^2 restrict its universal use [81–83].

Systemic challenges and prospects

A critical analysis of Russian MCS innovations reveals several structural challenges. One of the foremost barriers is the dependence on imported critical components, particularly rare-earth magnets and high-precision sensors. This reliance on foreign suppliers undermines the autonomy of production. Secondly, the limited scale and duration of clinical trials significantly delay the regulatory approval and broad clinical implementation of innovative devices. For instance, although the Stream Cardio system has already been introduced in select cardiac surgery centers, other promising developments – such as DON-3 – remain in the experimental phase. A third critical limitation is the technological gap between Russian and leading international MCS platforms. Devices such as the HeartMate III and Carmat demonstrate higher

reliability and miniaturization, corresponding to third to fifth generation of MCS systems.

Despite these constraints, Russian MCS projects have significant potential. The focus on biventricular support in Stream Cardio aligns with the global paradigm shift toward universal MCS systems. Digitalization, including AI integration and telemedicine capabilities, opens up opportunities for a personalized approach and reduced risk of complications.

Realizing this potential requires strategic investments in clinical research, localization of production of critical components and international certification.

Russian MCS developments have progressed from bulky pulsatile systems to compact, digital solutions, reflecting a gradual but evident convergence with global technological standards. Despite this progress, the future of Russian MCS devices hinges on elimination of systemic constraints – particularly those of a financial, technological, and regulatory nature. Projects such as Stream Cardio can strengthen Russia's position in the domestic market and also create prerequisites for technology export, which is especially important in the context of global competition in the field of medical innovations.

CONCLUSION

The increasing use of LT-MCS devices as destination therapy reflects a significant global shift in cardiology, driven by a persistent shortage of donor hearts and enhanced device reliability. Modern systems – such as the HeartMate III and advanced domestic technologies – have demonstrated long-term survival exceeding five years, making them a viable alternative to transplantation for patients who are not candidates for donor organs. The expansion of clinical indications, ongoing miniaturization of devices, and a marked reduction in complication rates (including right ventricular failure, thrombosis, and infection) collectively reinforce the growing role of LT-MCS as a definitive treatment option for end-stage HF.

These advances, however, represent only the initial phase of a new evolutionary wave in mechanical circulatory support systems. The industry's prospects lie in personalized therapy, integration of AI, and development of hybrid systems that combine mechanical support with myocardial regeneration. As M.R. Mehra, lead investigator of the MOMENTUM 3 trial, aptly stated, "We are on the cusp of an era where LVADs will become not just a temporary bridge, but a definitive treatment option for millions of patients." This vision underscores the transformative potential of current and emerging MCS technologies in addressing the global burden of HF.

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