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Review Paper

Managing patients in the post-HVAD era: Clinical and surgical realities of HeartMate 3 exchanges

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Abstract

Introduction: Durable mechanical circulatory support (MCS) is a key therapy for advanced heart failure. In 2021, the HeartWare HVAD (HVAD) – one of the primary devices used for MCS – was globally withdrawn due to high rates of pump thrombosis and neurological adverse events. This established the HeartMate 3 (HM3) as the current standard of care.

Aim: This review synthesizes the biomechanical differences between the HVAD and HM3. It also provides a clear overview of the clinical consensus and the surgical strategies needed for device exchange.

Material and methods: For this narrative review, a comprehensive literature search of the PubMed/MEDLINE database was conducted to find peer-reviewed articles on the biomechanics, clinical outcomes, and surgical exchange protocols for the HVAD and HM3 systems.

Results and discussion: The narrow-gap design of the HVAD causes higher shear stress than the fully magnetically levitated HM3. Because device exchange carries an approximate 10% 30-day mortality rate, STS-INTERMACS registry data support a conservative "for cause" exchange strategy rather than elective replacement. During emergency exchanges, surgeons face hardware incompatibility and severe mediastinal adhesions. Managing these challenges requires off-label techniques, such as removing the retained apical sewing ring or using extra-anatomic outflow graft anastomoses.

Conclusions: Although the HM3 improves survival, losing the smaller HVAD creates a treatment gap for patients with limited chest space, affecting both adult and pediatric populations. Until new compact devices are available, clinicians must focus on strict medical management of retained devices and refine high-risk surgical exchange strategies.

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1. INTRODUCTION

For patients with advanced heart failure, heart transplantation remains the definitive therapeutic standard.[1] In practice, severe organ shortages limit this option; for instance, recent Polish registry data (Poltransplant, 2024) reveal that only half of listed candidates underwent transplantation, with elective wait times exceeding 490 days.[2] Organ shortages and transplant contraindications make mechanical circulatory support (MCS) a crucial therapy.

MCS strategies range from short-term stabilization systems to durable devices, such as left ventricular assist devices (LVADs), utilized for prolonged support or destination therapy.[1]

The HeartWare HVAD (HVAD; Medtronic, Minneapolis, MN, USA) and HeartMate 3 (HM3; Abbott, Abbott Park, IL, USA) emerged as the primary third-generation centrifugal continuous-flow pumps for durable support.[3,4] Following the 2021 HVAD market withdrawal due to neurological complications and malfunctions, the HM3 remains the sole option for pump exchange.[5]

2. AIM

This narrative review aims to synthesize the biomechanical vulnerabilities of the HVAD system – specifically its restrictive narrow-gap architecture generating excessive shear stress – and contrast them with the fully magnetically levitated HM3. Furthermore, this paper seeks to provide a comprehensive overview of the current clinical consensus and the complex surgical strategies required to safely navigate device replacement.

3. MATERIAL AND METHODS

To fulfill the objectives of this narrative review, a comprehensive literature search was conducted utilizing the PubMed/MEDLINE database to identify peer-reviewed articles published between January 2010 and March 2026. The search strategy incorporated the following keywords and Medical Subject Headings (MeSH) terms: "HeartWare HVAD", "HeartMate 3", "pump thrombosis", "device exchange", and "left ventricular assist device".

The selection process involved an initial screening of titles and abstracts for relevance, followed by a full-text review of the selected articles. Selection criteria prioritized English-language articles, including multi-center observational studies, clinical registries (e.g., STS-INTERMACS), and surgical case series that directly addressed the biomechanics, clinical outcomes, and surgical exchange protocols for the HVAD and HM3 systems. Single-case reports were included only if they detailed novel surgical techniques. Additionally, official manufacturer documentation and regulatory press releases were analyzed to establish an accurate historical context regarding the 2021 HVAD market withdrawal.

4. RESULTS

4.1. Evolution of continuous-flow devices

Durable MCS technology has transitioned from first-generation pulsatile pumps to continuous-flow devices. This transition has been crucial, facilitating device miniaturization while simultaneously enhancing mechanical durability and improving long-term patient survival.

Contemporary CF devices are stratified by their rotor mechanism into axial-flow and centrifugal-flow systems.[6] The axial-flow configuration is exemplified by the HeartMate II (HMII; Abbott).[7] Functioning as a continuous-flow rotary pump, HMII features an axial configuration that directs blood flow parallel to the rotor's axis, allowing for a significantly lighter and more compact design than its first-generation predecessors.[8]

Conversely, the field has advanced toward centrifugal-flow technologies, most notably the HM3 and the HVAD.[7] The HM3 is distinguished by a fully magnetically levitated rotor designed to minimize blood trauma.[6] Although the HMII was never subjected to a market withdrawal, clinical preference decisively shifted toward the HM3 following the MOMENTUM 3 trial. The final analysis of this study established the clinical superiority of the HM3 over the HMII, demonstrating significantly higher rates of survival free from debilitating strokes and a reduced need for surgical pump replacement due to technical faults.[9] Currently, the HM3 stands as the sole FDA-approved LVAD in active manufacturing, thereby representing the predominant standard of care for new implantations.[6]

4.2. The HVAD system

The HVAD system was a key device in MCS therapy, frequently serving as the device of choice for anatomically challenging patient cohorts due to its distinctively compact architecture. This miniaturized profile rendered it the preferred option for patients with limited intrathoracic geometry – such as those with smaller body surface areas (BSA) or cachexia – and facilitated surgical implantation in high-complexity scenarios, including congenital heart disease or cases requiring concomitant mechanical support.[3,4]

The HVAD System, following its European certification in 2009 and subsequent FDA approvals for both bridge-to-transplantation (2012)[10] and destination therapy (2017),[11] was permanently withdrawn from the global market in 2021.[12]

4.3. Reasons for HVAD market withdrawal

The decision to withdraw the HVAD System from the market on June 3, 2021, was driven by mounting observational evidence indicating a higher frequency of mortality and neurological adverse events, including stroke, compared to other available devices.[12] The withdrawal was precipitated by technical investigations identifying a critical malfunction involving the pump's internal impeller, which could lead to a delay or complete failure to restart. Initially isolated to specific manufacturing lots, reports of this failure mode subsequently expanded, with an estimated occurrence rate of 0.4%, rendering the root cause indeterminable in all cases.[13]

Beyond these technical failures, clinical data explicitly positioned the HVAD as inferior to its main competitor, the HM3. A comprehensive meta-analysis identified the HM3 as the superior device across six key clinical outcome categories, including substantially lower risks of mortality and neurological events.[14] For instance, a propensity-matched analysis by Numan et al. found that HVAD support was linked to a statistically higher frequency of hemorrhagic stroke,[15] while a separate multi-center study by the same group confirmed a reduction in ischemic stroke rates with the HM3.[16] These findings are reinforced by single-center experiences, such as that of Shin et al., who reported a complete absence of stroke cases in their HM3 cohort in contrast to the HVAD group.[3]

Furthermore, the risk of pump thrombosis appears markedly elevated with the HVAD; several studies, including a Polish registry analysis, observed zero clotting events in HM3 patients compared to distinct occurrences in the HVAD population.[4,17,18] Consequently, these complications contribute to the significantly higher mortality observed with the HVAD, as evidenced by inferior short-term and long-term survival rates in comparative analyses.[17,19] It should be acknowledged that most comparative data between HVAD and HM3 originate from retrospective analyses and registry-based studies, which are inherently subject to selection bias. Direct randomized comparisons beyond the MOMENTUM 3 trial are limited.

4.4. HVAD design and biomechanical limitations

The HVAD System was a third-generation, continuous-flow LVAD.[20] Within the pericardial cavity, the device occupies a fully intrathoracic position, and blood is drawn into the system through an inflow cannula that opens directly into the left ventricle. Blood leaves the device through a flexible, gel-coated outflow graft, which is surgically anastomosed to the ascending aorta. Instead of relying on an abdominal pump pocket, all core components remain confined to the thorax.[21]

The rotor, which is the pump's only moving structure, remains suspended without physical contact due to the combined effects of magnetic stabilization and hydrodynamic forces, allowing high-speed rotation with minimal friction. Operating speeds typically fall between 2,000 and 3,000 rpm, enabling the pump to deliver flows that may reach 10 L/min.[22] A driveline routed through the subcutaneous tissue to the abdominal surface links the intrathoracic pump to its external controller. This external unit supplies power, adjusts operational parameters, continuously evaluates device performance, and issues alerts whenever abnormal conditions arise.[21]

The HVAD relies on a four-bladed, tapered impeller for hydrodynamic levitation, necessitating a highly restrictive axial clearance of approximately 40 μm (comparable to ten blood cells). In contrast, the HM3 features a significantly wider gap of 1000 μm, accommodating hundreds of erythrocytes. This narrow geometry in the HVAD induces elevated hydraulic forces, yielding peak scalar shear stresses of 2000 Pa – four times greater than the 500 Pa maximum observed in the HM3.[22] However, it is crucial to avoid overinterpreting these in vitro biomechanical models. While these computational findings explain the mechanisms behind blood trauma, translating them directly to clinical events requires caution. Although experimental data showed a six-fold higher hemolysis rate for the HVAD,[22] the clinical manifestation of this hemocompatibility profile is complex and influenced by multifactorial patient-specific variables, not solely by pump shear stress.

4.5. The HM3 system design

The HM3 utilizes a fully magnetic system to suspend and rotate the impeller, relying on forces generated between the casing's coils and the permanent magnets. By replacing mechanical bearings with this active magnetic levitation, the design eliminates friction, heat generation, and dynamic sealing, while functioning without the need for a liquid working fluid. Building on this bearingless design, the previously described wider rotor housing mitigates the risk of shear-induced blood damage.[21] Functionally, the system incorporates an artificial pulse that promotes effective fluid washout under dynamic physiologic conditions.[22] Ultimately, the combination of this artificial pulse, the wide rotor

Table 1. Key differences between the HVAD and HM3 systems.

	HVAD	HM3
Market status	Withdrawn (2021)	Gold standard (active)
Levitation	Magnetic-hydrodynamic	Fully magnetic
Gap width	40 μm	1000 μm
Peak shear stress	2000 Pa	500 Pa
Complications	6-fold higher hemolysis, frequent thrombosis	Minimized hemolysis, minimal reported thrombosis risk
Size / Weight	50 ml / 160 g	80 ml / 200 g
Sintered surface	11.7 mm (inflow cannula)	22 mm (inflow cannula)
Patient profile	Adults and children with smaller BSA	Requires larger intrathoracic geometry

Legend: BSA, body surface area; g, grams; HM3, HeartMate 3; HVAD, HeartWare ventricular assist device; mm, millimeters; ml, milliliters; Pa, Pascal; μm, micrometer.

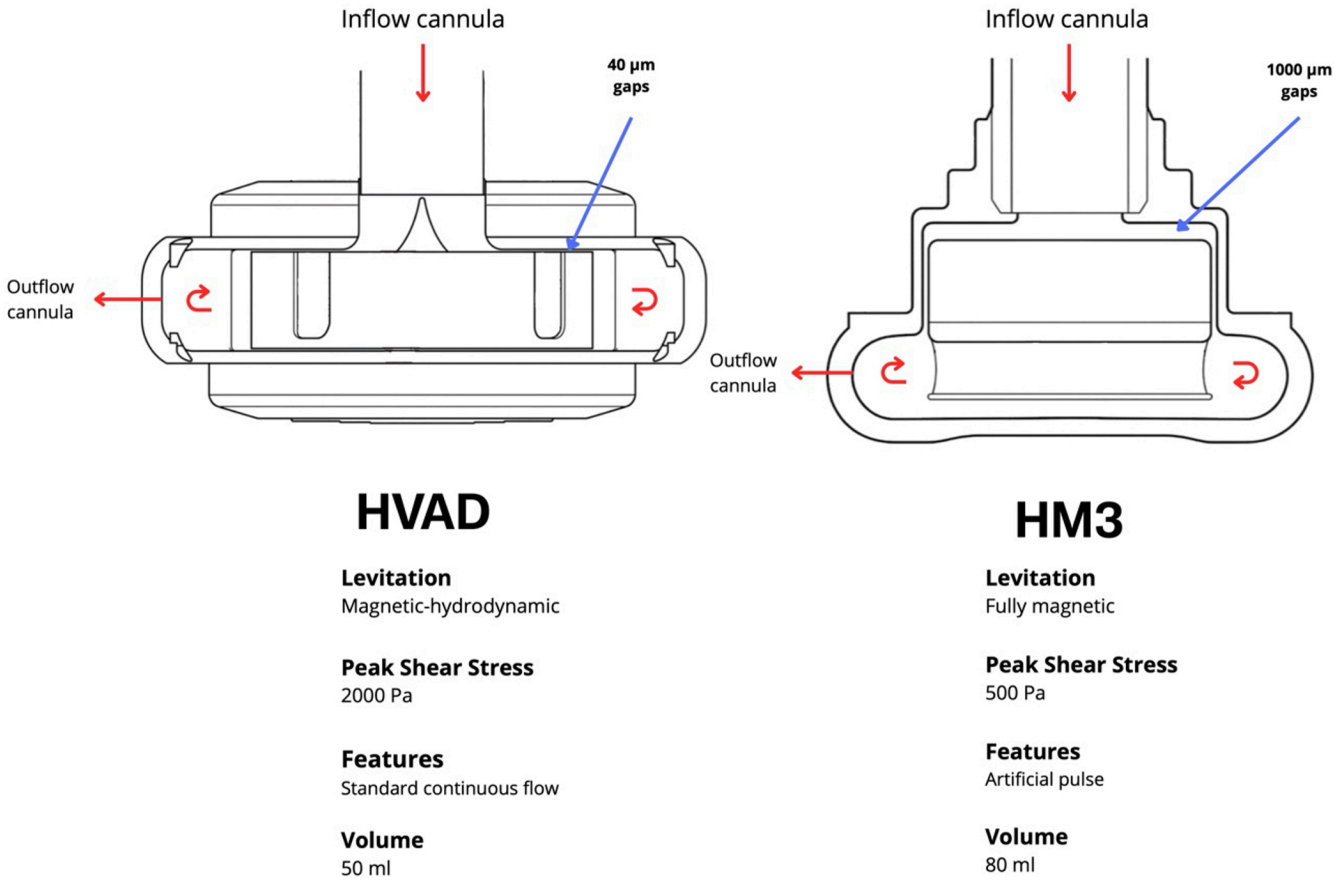

Figure 1. Working principles of the HVAD and HM3. The HVAD's narrow gap (40 μm) generates high shear stress, whereas the HM3's wide gap (1000 μm) and artificial pulse minimize blood trauma.

Legend: HM3, HeartMate 3; HVAD, HeartWare ventricular assist device; ml, milliliters; Pa, Pascal; μm, micrometer.

housing, and the fully magnetically levitated rotor is credited with the clinically observed reduction in pump thrombosis rates.[15] In terms of physical characteristics, the HM3 is a larger and heavier pump than the HVAD, with a volume of 80 ml and a weight of 200 g, compared to 50 ml and 160 g for the HVAD system. The fundamental biomechanical differences and working principles of both systems are visualized in Figure 1 and Table 1. Notwithstanding these increased dimensions, the device remains suitable for intrapericardial implantation. However, to successfully accommodate the larger pump housing and guarantee precise inflow cannula alignment, specific surgical modifications may be necessary; these can include extending the pericardial incision, opening the left pleura, or creating a preperitoneal space at the level of the left ventricular apex.[5]

5. DISCUSSION

5.1. HVAD to HM3 exchange: Clinical and surgical considerations

The HVAD system was permanently withdrawn in June 2021 due to a significantly higher risk of mortality and major neurologic adverse events compared to the HM3. Consequently, the HM3 has become the sole remaining option for long-term mechanical circulatory support.[5]

However, this paradigm shift must be viewed with a nuanced perspective. As previously noted, the comparative superiority of the HM3 is predominantly based on indirect comparisons and observational registry data, which carry inherent limitations. Furthermore, while the HM3 effectively mitigates pump thrombosis, it is not without limitations. Patients supported with the HM3 remain susceptible to significant LVAD-related morbidities, including severe gastrointestinal bleeding, right ventricular failure, and driveline infections.[7,9] Additionally, the larger physical dimensions of the HM3 pose considerable anatomical challenges for pediatric and small-statured adult populations—a demographic previously reliant on the compact HVAD design. Thus, while the HM3 represents the current standard of care, it does not universally resolve all clinical challenges associated with continuous-flow support.

5.2. Clinical decision-making: Defining "For Cause" vs. elective criteria

The discontinuation of the HVAD has necessitated a choice between two clinical pathways (Figure 2): clinicians must

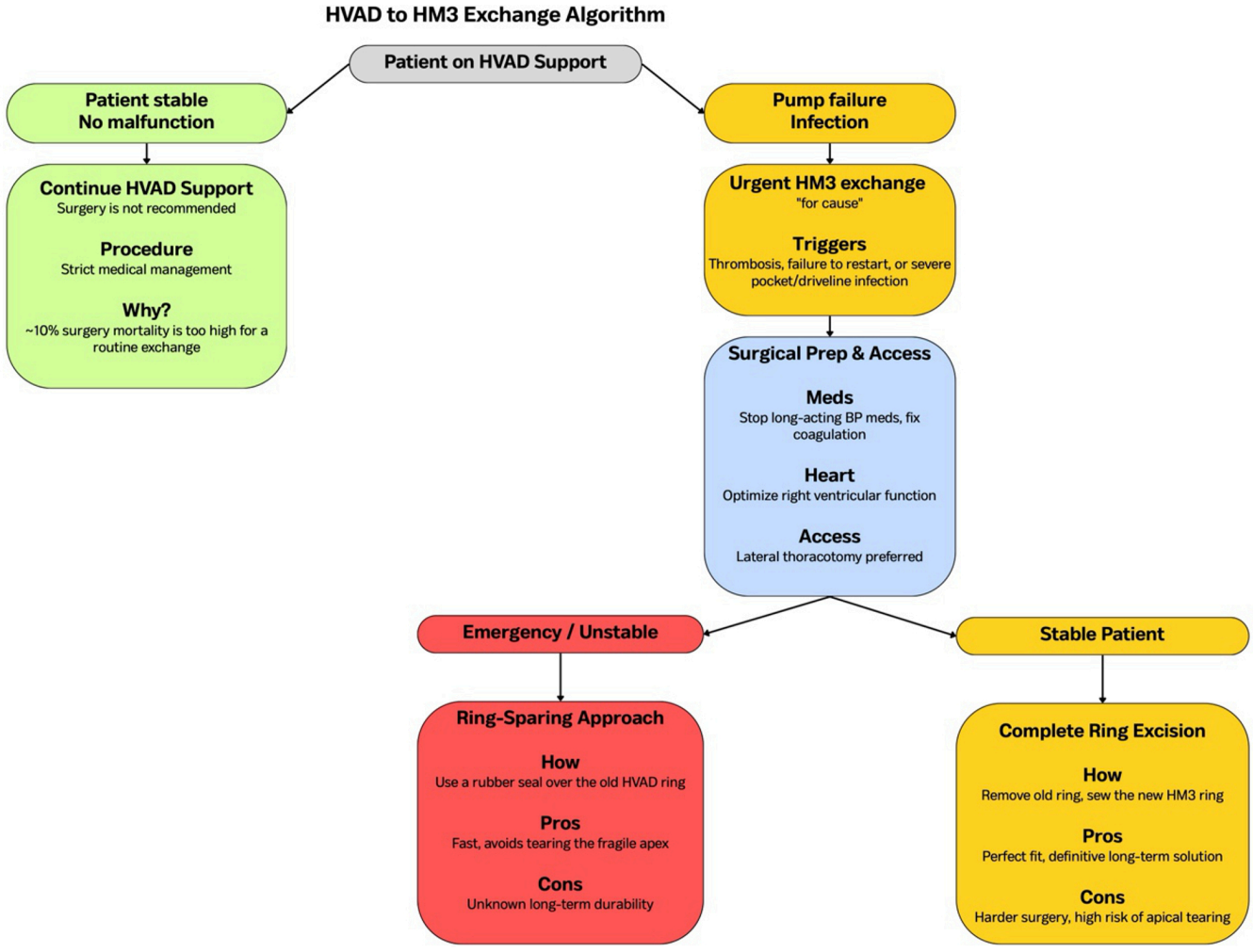

Figure 2. Clinical and surgical algorithm for HVAD to HM3 exchange, outlining "for cause" indications and tailored surgical strategies based on patient stability.

Legend: BP, blood pressure; HM3, HeartMate 3; HVAD, HeartWare ventricular assist device; Prep, preparation.

decide between maintaining the current device until a complication necessitates a "for cause" exchange or performing an elective prophylactic switch to the HM3 to mitigate future device failure risks.[14] Reviewing the available evidence, Medtronic and registry analyses endorse the "for cause" strategy as the standard of care. This recommendation stems from evidence that elective surgery carries a higher cumulative risk than continued functional pump support. Therefore, prophylactic exchange is strongly discouraged absent specific device malfunction or clinical deterioration.[23]

Evaluating perioperative risks during device transitions, systematic reviews report an approximate 30-day mortality rate of 10%, subject to variation depending on the specific pump models.[19] Although the surgical risk of an HVAD-to-HM3 exchange is comparable to historical HVAD-to-HVAD replacements, STS-INTERMACS data strongly advocate for a conservative 'for cause' protocol. Current clinical consensus establishes that the immediate mortality risk of elective surgery substantially outweighs the dangers of continuing support with a fully operational HVAD.[5]

To enhance the clinical applicability of this review, it is critical to delineate the exact criteria for a "for cause" exchange. Based on current clinical consensus, an urgent transition to the HM3 is strictly indicated in the presence of: 1) recurrent or refractory pump thrombosis, 2) catastrophic hardware or electrical malfunctions (e.g., the recognized "failure to restart" fault), and 3) severe, intractable device-related infections (such as ascending driveline infections or pump pocket infections) that fail to respond to aggressive medical therapy and debridement.[5]

5.3. Preoperative management and hemostasis

Preoperative preparation involves three key steps. First, clinicians should discontinue long-acting blood pressure medications to lower the risk of vasoplegia. Second, right ventricular function must be optimized using inotropes or diuretics. Finally, it is essential to ensure the patient's coagulation profile is optimized before surgery.[5] In patients supported with LVADs, achieving adequate hemostasis prior to surgery is challenging due to the need for continuous

anticoagulation and antiplatelet therapy. Typically, vitamin K antagonists are discontinued several days before surgery and bridged with intravenous unfractionated heparin, which can be stopped shortly before the procedure. Antiplatelet agents may be temporarily withheld depending on bleeding risk. In urgent cases, reversal strategies such as administration of prothrombin complex concentrates or vitamin K may be required. Careful monitoring of INR and coagulation parameters is essential to balance bleeding and thrombotic risks.[5,7]

5.4. Surgical strategies: Navigating anatomical challenges

Key technical considerations include addressing the incompatibility of apical connectors and the varying diameters of the outflow grafts. Furthermore, selecting the appropriate incision is critical; an anterolateral thoracotomy is often safer than a sternotomy for avoiding damage to retrosternal adhesions, provided the surgeon is proficient in this approach.[24] During complex reoperations, the ascending aorta frequently proves unsuitable for anastomosis due to severe calcifications or impenetrable pericardial adhesions. Encountering such adverse anatomical conditions necessitates the utilization of atypical target vessels for the outflow graft. Routing the outflow cannula to the descending thoracic aorta or the innominate artery offers a highly effective alternative. These unconventional anastomoses perfectly complement a lateral thoracotomy approach, allowing surgeons to safely bypass a hostile mediastinum.[25]

5.5. Apical mismatch: Stable vs. emergency patient scenarios

Consistent with general principles of cardiac surgery, the optimal timing and method of intervention depend primarily on the patient's hemodynamic stability.[26] A distinct anatomical challenge arises from the dimensional discrepancies between the two pump designs. While the inflow cannula diameters are similar, the sintered surface measures 22 mm on the HM3 compared to only 11.7 mm on the HVAD.[5] Consequently, the HM3 inflow cannula cannot achieve a hemostatic seal within the retained HVAD sewing ring.

Addressing this mismatch requires critical surgical decision-making, tailored to the patient's hemodynamic status, presenting two distinct scenarios:

- **Emergency cases (hemodynamically unstable):** In critical salvage operations, such as patients in cardiogenic shock bridged with extracorporeal membrane oxygenation (ECMO), surgeons often utilize an improvised rubber seal (e.g., a sterile surgical glove-tip gasket) over the retained HVAD ring.[27,28] This ring-sparing approach is highly advantageous because it significantly reduces operative time and minimizes manipulation of a fragile left ventricular apex. However, its unproven long-term durability raises theoretical concerns regarding future device thrombosis or migration.
- **Stable cases (hemodynamically controlled):** For patients undergoing a "for cause" exchange who are hemodynamically stable and possess favorable local tissue integrity, complete excision of the retained HVAD ring is the preferred strategy.[29] Suturing the new HM3 ring directly into the fibrotic tissue ensures a secure, manufacturer-compliant fit. While this strategy is technically demanding, markedly increases cardiopulmonary bypass time, and carries a high risk of catastrophic apical tearing, it provides the most definitive long-term solution.

Table 2. Surgical challenges and strategies in HVAD to HM3 exchange.

Surgical Challenge	Strategy / Solution
Vasoplegia risk	Stop long-acting BP medications
Right heart dysfunction	Inotropes or diuretics
Hostile mediastinum	Anterolateral thoracotomy
Calcified aorta	Outflow to descending or innominate artery
Cannula mismatch	Improvised rubber seal or excise HVAD ring

Legend: BP, blood pressure; HM3, HeartMate 3; HVAD, HeartWare ventricular assist device.

5.6. Limitations

This review has several limitations. Due to the relatively recent and abrupt withdrawal of the HVAD system, the current literature regarding HVAD-to-HM3 exchanges lacks large-scale randomized controlled trials. Consequently, our synthesis relies primarily on retrospective registry analyses, single-center case series, and expert consensus statements. Furthermore, while immediate surgical outcomes of off-label modifications (such as ring adapters) have been documented, long-term follow-up data regarding their structural integrity and hemocompatibility remain scarce.

6. CONCLUSIONS

The withdrawal of the HVAD system has left the HM3 as the sole durable mechanical circulatory support option, creating significant technical challenges during pump exchanges. Given the considerable perioperative mortality associated with these procedures – estimated at approximately 10% – current evidence strongly supports a strict "for cause" exchange strategy rather than elective, prophylactic replacement. When an emergent exchange is necessitated by device failure, surgical teams must critically balance the risks of off-label, ring-sparing techniques, which are highly advantageous for unstable salvage operations, against the hazards of complete apical ring excision, a strategy preferable for anatomically stable patients. Ultimately, the obsolescence of the compact HVAD has created a critical therapeutic gap for pediatric and small-statured adult populations. This anatomical mismatch underscores an urgent clinical need for the development of next-generation, miniaturized devices.

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