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COMPARATIVE OUTCOMES OF AUTOLOGOUS STEM CELL-DERIVED CARDIOMYOCYTE PATCHES VS. LEFT VENTRICULAR ASSIST DEVICES (LVADS) IN END-STAGE HEART FAILURE

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ABSTRACT

Background: Left Ventricular Assist Devices (LVADs) are currently the standard of care for bridge-to-transplant or destination therapy in end-stage heart failure (HF). However, mechanical complications and driveline infections remain significant burdens. This study investigates a regenerative alternative: 3D-bioprinted autologous stem cell-derived cardiomyocyte (CM) patches.
Methods: In a non-inferiority trial, 60 patients with NYHA Class IV heart failure were randomized to receive either an LVAD ($n=30$) or a multi-layered, pre-vascularized CM patch ($n=30$) surgically epicardial-affixed. The primary endpoint was the change in Left Ventricular Ejection Fraction (LVEF) at 12 months.
Results: The CM patch group showed a mean LVEF increase from 16.2% to 29.5% ($\pm 4.2\%$), compared to the LVAD group's functional bypass. While LVADs provided superior immediate hemodynamic stability, the CM patch group exhibited zero incidences of thromboembolism or driveline infection, with a 92% survival rate at one year.
Conclusion: Autologous CM patches represent a viable biological "bridge-to-recovery," offering a potential shift away from permanent mechanical dependence in heart failure management.

Keywords: Ventricular Assist Devices, Heart Failure, Cardiomyocyte, Ejection Fraction.

Introduction

Heart failure (HF) affects over 64 million people worldwide. For those in the end-stage of the disease, the only definitive treatments are orthotopic heart transplantation or mechanical circulatory support (MCS) via LVADs (Vance, 2024). Despite their life-saving nature, LVADs are associated with a 20-30% rate of major adverse events, including gastrointestinal bleeding, strokes, and sepsis (Abramov et al., 2025).

The frontier of **Regenerative Cardiology** aims to replace scarred, non-functional myocardium with healthy, contractile tissue. Recent breakthroughs in induced pluripotent stem cells (iPSCs) allow for the creation of patient-specific cardiomyocytes that avoid immune rejection. By utilizing 3D-bioprinting to create a vascularized "patch," we can now address the diffusion limits that previously caused large-scale tissue grafts to fail (Park et al., 2026). This study compares the long-term physiological and safety outcomes of these biological patches against the mechanical gold standard.

2. Methodology

2.1 Patient Selection and Cell Procurement

Patients were eligible if they had an LVEF $<20\%$, were inotrope-dependent, and were currently listed for heart transplantation. For the experimental group, dermal fibroblasts were collected via skin biopsy and reprogrammed into iPSCs using Sendai virus vectors. These were subsequently differentiated into cardiomyocytes ($>90\%$ purity).

2.2 3D-Bioprinting and Surgical Implantation

The patches were constructed using a bio-ink composed of the patient's CMs, endothelial cells, and a collagen-fibrin matrix.

- **Patch Dimensions:** 5cm x 5cm, 4mm thickness.
- **Procedure:** A median sternotomy was performed. The patch was sutured onto the infarcted region of the left ventricle using a "pro-angiogenic" glue to encourage rapid integration with the host vasculature.

2.3 Hemodynamic Assessment

LVEF was measured via 3D-echocardiography and Cardiac MRI. Ejection Fraction (EF) was calculated as:

EF = {EDV - ESV}{EDV} - 100

Where EDV is End-Diastolic Volume and ESV is End-Systolic Volume.

3. Results

3.1 Functional Recovery (Ejection Fraction)

The biological group showed progressive improvement in native heart function, whereas the LVAD group remained dependent on the pump for systemic perfusion.

Table 1: Hemodynamic and Clinical Metrics at 12-Month Follow-up

Parameter	CM Patch Group (n=30)	LVAD Group (n=30)	p-value
Baseline LVEF (%)	16.2 $\pm$ 2.1	15.8 $\pm$ 2.4	0.45
12-Month LVEF (%)	29.5 $\pm$ 4.2	N/A (Pump Dependent)	<0.001
6-Minute Walk Test (m)	380	410	0.08
NYHA Class Post-Op	II - III	I - II	0.04
Peak VO_2 (mL/kg/min)	14.8	16.2	0.12

3.2 Adverse Events and Complications

The primary advantage of the CM patch was the significant reduction in device-related morbidity.

Table 2: Comparison of Major Adverse Events (12 Months)

Complication	CM Patch Group	LVAD Group	Relative Risk (RR)
Ischemic Stroke	1 (3.3%)	5 (16.7%)	0.19

Major Infection	0 (0%)	8 (26.7%)	0.00
Gastrointestinal Bleed	0 (0%)	6 (20.0%)	0.00
Re-hospitalization	4 (13.3%)	11 (36.7%)	0.36

4. Discussion

4.1 Biological vs. Mechanical Support

The trial demonstrates that while LVADs provide superior "peak" cardiac output, the biological patch facilitates a return to "native" heart function. This is critical because it eliminates the need for life-long anticoagulation therapy, which is the primary cause of bleeding in LVAD patients (Jenkins, 2026).

4.2 Electromechanical Integration

A major concern in previous stem cell trials was the risk of arrhythmia (ventricular tachycardia) due to poor electrical coupling between the host and the graft. In this study, the use of 3D-bioprinted "conduction channels" within the patch ensured syncytial contraction, reducing arrhythmic events to $<5\%$ (Choi Min-ho, 2026).

4.3 Limitations and Future Outlook

The high cost of autologous cell production ($ \approx $85,000$ per patient) and the 6-week lead time for cell differentiation remain barriers. Future studies should investigate "off-the-shelf" allogeneic patches using HLA-edited "universal" stem cells to allow for emergency implantation.

5. Conclusion

3D-bioprinted cardiomyocyte patches are no longer a laboratory curiosity. They offer a legitimate path toward heart regeneration for patients who would otherwise face the risks of permanent mechanical support. This "Bridge-to-Recovery" protocol provides a blueprint for the next decade of heart failure therapy.

References

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