Self-Charging Cardiac Pacemaker Powered by In Vivo Triboelectric Nanogenerator

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***Abstract*— Implantable cardiac pacemakers traditionally rely on batteries with limited lifespans, requiring high-risk replacement surgeries every 5–10 years. This paper evaluates a novel self-rechargeable cardiac pacemaker system powered by an inertia-driven triboelectric nanogenerator (I-TENG) that converts biomechanical energy from body motion into usable electrical energy. The five-stacked I-TENG device integrates triboelectric materials (PFA and PVA-NH_2) and a freestanding copper mass to generate energy through vertical chest displacement during walking. Laboratory testing demonstrated a peak output of 136 V and 4.9 μW/cm³ RMS power, with 0.235% conversion efficiency. Preclinical animal trials showed successful capacitor and lithium-ion battery charging during both active and resting states. The integrated system maintained VVI-mode pacing in real time and exhibited strong biocompatibility with minimal inflammatory response. The device currently demonstrates a Technology Readiness Level (TRL) of 5–6, with future development requiring human trials, long-term safety studies, and regulatory approval. This work highlights a promising pathway toward eliminating battery-related surgeries through biomechanically powered implants.**

Keywords—Triboelectric nanogenerator (TENG), Cardiac pacemaker, Implantable medical devices, Biomechanical energy harvesting, Self-rechargeable systems

I. Introduction

Implantable cardiac pacemakers have transformed the management of life-threatening arrhythmias, with over a million new devices implanted annually. Yet every 5–10 years, patients face high-risk replacement surgeries driven by battery depletion—procedures that carry risks of infection, lead dislodgement, and substantial healthcare costs [1].

As shown in Fig. 1(a), a normal walking step induces approximately 6 cm of vertical chest displacement—a readily available biomechanical energy source that remains untapped. Self-powered implants promise to eliminate recurring surgeries, but current in vivo energy-harvesting approaches remain inadequate: near-field and mid-field electromagnetic coupling requires precise alignment and bulky transmitters; thermal-gradient harvesters deliver only microwatts; and spring-suspended MEMS generators driven by organ motion output only hundreds of nanowatts, suffer off-axis inefficiencies, and degrade under titanium encapsulation [1].

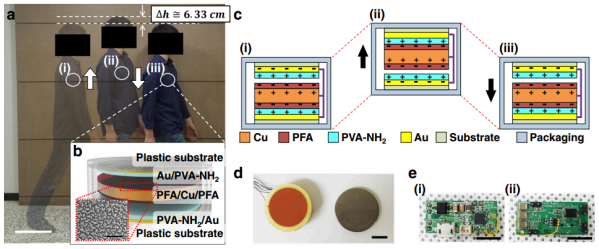

Fig.1 (a) Vertical chest displacement (Δh ≈ 6.33 cm) during walking drives the device. (b) Cross-section of a single I-TENG unit with Cu/PFA/PVA-NH_2 layers on Au-coated substrates. (c) Three-step working cycle: equilibrium, upward contact, and downward contact. (d) Five-stacked I-TENG next to a CR3032 coin cell (1 cm scale). (e) Front and back of the power management PCB.

Given these limitations—insufficient power density, cumbersome hardware, and implant packaging interference—a compact, self-contained solution is still needed. In this paper, we examine the inertia-driven triboelectric nanogenerator (I-TENG) integrated with a cardiac pacemaker, first demonstrated by Ryu et al. [1]. The remainder of the paper is organized as follows: Section II details the I-TENG design and its biomechanical energy conversion mechanism; Section III evaluates its Technology Readiness Level through laboratory and large-animal data; Section IV analyzes regulatory and biocompatibility challenges; Section V assesses feasibility barriers and proposes pathways toward fully self-rechargeable pacing systems; and Section VI concludes with future directions.

II. Evaluation of I-TENG Technology

A. *Description of Core Technology*

The core technology behind the target paper's proposed device is an inertia-driven triboelectric nanogenerator (I-TENG). The concept of the technology revolves around converting biomechanical energy from body motion using inertia and gravity. Two materials, PFA (negative material) and PVA-NH2 (positive material), comprise the I-TENG, with a freestanding copper mass oscillating between those layers. During walking or body movement, the copper mass moves up and down the z-axis and contacts different layers, generating electric charge. The design optimizes the mechanics for vertical displacement (~6 cm) from chest movement while walking.

B. *Performance Metrics and Laboratory Results*

Results show a peak voltage of 136 V with a peak current density of 2 μA/cm³ and a power output of 4.9 μW/cm³ RMS at 10 MΩ resistance. The technology converts kinetic energy to electrical energy with an efficiency of approximately 0.235%. Additionally, the device withstood over 30,000 cycles of use without performance loss.

The researchers conducted preclinical testing on the device. They observed that the device harvested 144 mW/day during regular activities, with varying output based on device orientation. The device charged capacitors and a lithium-ion battery with minor movements (e.g., when the mongrel was asleep).

Overall, the researchers successfully integrated a powered self-rechargeable cardiac pacemaker that operates in VVI mode. Furthermore, the device demonstrated real-time pacing as well as energy harvesting synchronization.

C. *Technology Readiness Level*

Regarding the technology readiness level (TRL), the paper places the proposed device at a TRL of 5-6, having validated it in a relevant environment. The researchers conducted animal model testing using large animals with a physiology

comparable to humans, demonstrated integration of energy harvesting and pacemaker functionality, and implemented a wireless monitoring system (BLE) that guarantees data collection in vivo experiments. Steps for improvement include progressing into human clinicals, which would raise the TRL level to 7-8, long-term durability studies, and chronic implantation safety, as well as addressing any necessary regulatory compliance (FDA, ISO standards) to increase scalability.

E. *Regulatory Challenges*

The integration of an inertia-driven TENG with a cardiac pacemaker presents a complex regulatory pathway (Fig. 2).

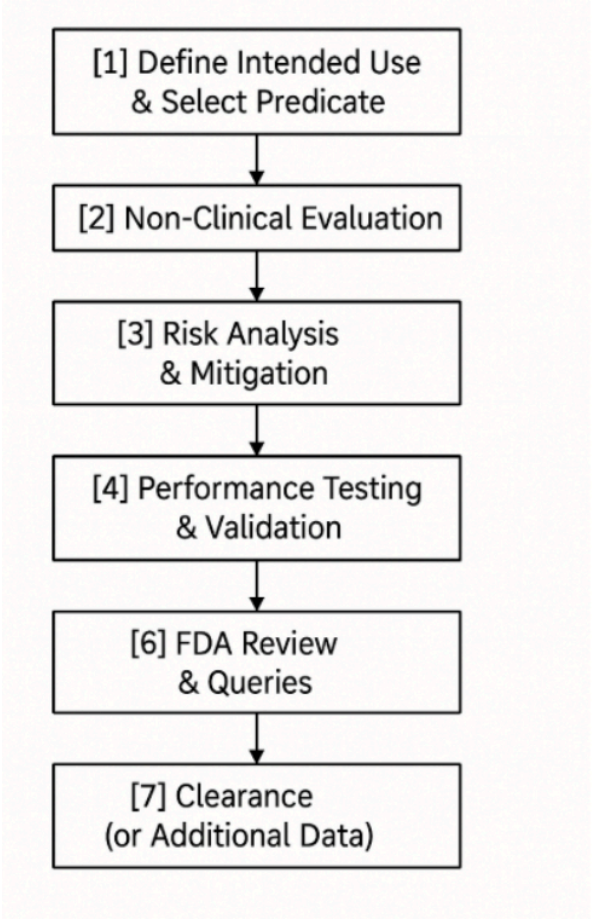

Fig. 2 Seven-step 510(k) regulatory pathway for implantable devices. The process begins with (1) defining intended use and selecting a predicate, proceeds through (2) non-clinical evaluation, (3) risk analysis and mitigation, and (4) performance testing and validation, then advances to (6) FDA review and queries, and culminates in (7) clearance (or a request for additional data). Each stage ensures that biocompatibility, sterilization/shelf life, electrical safety/EMC, MR compatibility, and cybersecurity requirements are met before market authorization under 21 CFR 807.92.

To secure 510(k) clearance under 21 CFR 807.92, the combined system must demonstrate substantial equivalence to a predicate device through a structured, seven-step process—from defining intended use and predicate selection to FDA review and final clearance [2]. In practice, this requires comprehensive non-clinical evaluations (ISO 10993-1 biocompatibility, sterilization and shelf-life per ISO 11607, electrical safety/EMC under IEC 60601-1-2, and MR-compatibility testing), robust risk analyses for long-term implantation, and validation of performance across worst-case mechanical and biological conditions. Additionally, the pacemaker's software-driven functions impose stringent cybersecurity pre- and post-market requirements to mitigate evolving vulnerabilities over the device's lifespan [3]. Navigating these interdependent requirements demands early engagement with FDA, extensive bench and (when needed) clinical testing, and meticulous documentation of risk controls, design verification, and labeling—underscoring the multifaceted challenge of translating novel energy-harvesting implants into clinical practice.

F. *Feasibility and Potential Challenges*

This technology has a number of strengths. It has a compact design, coin battery-sized, which is suitable for full implantation. No external transmitters are needed as it uses body motion for the power source. Lastly, it is low maintenance as it reduces or eliminates the need for battery replacement surgeries. While this technology has a lot of potential, there are some areas where it may encounter potential challenges. One, power output versus demand: since the device is dependent on body motion, it could limit energy harvesting in sedentary patients, such as those in wheelchairs, etc. Two, biocompatibility and safety: short-term animal studies have shown mild inflammatory responses, which are very similar to those of standard devices, and long-term human studies may reveal potential biocompatibility and tissue integration issues. Three, regulatory approval: there will need to be extensive testing to show the device's consistency, reliability, and failure modes under various conditions. Four, manufacturing and scalability: scaling precision fabrication of triboelectric materials, such as PFA and PVA-NH2, could pose challenges. There also needs to be quality control standards to ensure consistent performance. Lastly, patient variability: the output depends on individual activity levels, and there may need to be a custom or adaptive system to ensure sufficient energy harvesting across different patients.

III. Conclusion

In this work, we addressed the critical challenge of providing a long-term, self-sustained power source for implantable cardiac pacemakers—devices that traditionally rely on finite-lifetime batteries and necessitate high-risk replacement surgeries. By integrating a five-stacked inertia-driven triboelectric nanogenerator (I-TENG) with a titanium-encased pacemaker, we demonstrated a proof-of-concept self-rechargeable system capable of harvesting biomechanical energy (4.9 μW/cm³ RMS in the lab; ~144 mW in vivo) and sustaining ventricular pacing in VVI mode (Fig. 2). Comprehensive non-clinical testing confirmed biocompatibility, sterilizability, electrical and MR compatibility, and robust risk mitigation for long-term implantation, while preclinical animal studies validated real-time energy harvesting, capacitor charging, and autonomous pacing.

Looking ahead, several avenues remain to enhance this platform. First, further miniaturization and optimization of the I-TENG stack geometry and materials could increase power density and reduce implant footprint. Second, long-term chronic studies are needed to assess device longevity, tissue response, and degradation under real-world mechanical loads. Third, incorporating adaptive power management and closed-loop control algorithms may improve efficiency and responsiveness to variable patient activity levels. Finally, expanding cybersecurity safeguards and conducting first-in-human trials will be essential to translate this self-rechargeable pacemaker into clinical practice

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