

Energetic Independence in Implanted Bioelectronics: First-in-Human Results of the *Embedix* Metabolic Fuel Cell System

Benny Manor, M.D.^{1,2}, Hila Brosh, Ph.D.², Leonid Semyonov² and Ehud Levi²

1. Cardiac Radiology Dept., Neve Refua Hospital, Tel-Aviv, Israel

2. *Embedix* Ltd., Research and Development Division, Rehovot, Israel

Long-term power supply remains the primary constraint for active medical implants. Current pacemaker technologies rely on lithium-based batteries with a finite lifespan of 7–10 years, necessitating invasive replacement surgeries. Here, we report the first-in-human (FIH) trial of the *Embedix* system, a revolutionary bioelectronic platform that achieves full energetic independence by harvesting energy directly from host blood glucose. Our study involved 10 human subjects who underwent implantation of a four-component system: a simplified cellular controller, a bone-conduction earpiece, and a metabolic charger module, in addition to an off-the-shelf pacemaker. Over a 90-day follow-up period, the system demonstrated continuous power generation averaging 40–56 milliwatts (mW), sufficient to power both cardiac pacing and a voice-activated communication interface. These results indicate a shift from passive monitoring toward perpetual, self-sufficient implanted systems.

Introduction

The human body consumes approximately 2,000 Kilocalories per day, yet modern medical implants struggle to harness even a fraction of this metabolic energy. While enzymatic and abiotic fuel cells have demonstrated potential in animal models (Cinquin et al., 2010; Zebda et al., 2013), they have historically produced only microwatts (μ W) of power, insufficient for high-drain applications.

The *Embedix* technology mimics mitochondrial function, utilizing a proprietary electron cascade process based on the Krebs Cycle to burn glucose as fuel (Brosh et al., 2020). By integrating this metabolic fuel cell into a standard cardiac pacing circuit, we hypothesized that the requirement for repeat battery replacement could be eliminated entirely (Maity et al., 2023). Furthermore, the surplus energy produced allows for the integration of auxiliary functions, such as cellular communication and continuous glucose monitoring (Rapoport et al., 2012).

Materials and Methods

The *Embedix* System: The system consists of three primary hardware modules.

Controller: A matchbook-sized unit containing a cellular network interface, processor, memory, and additional hardware (e.g. GPS antenna).

Earpiece: A miniature transparent microphone / speaker positioned adjacent to the patient's eardrum,

utilizing bone conduction for discreet audio input and output.

Metabolic Charger: A two-inch tube attached directly to a major blood vessel (in our trial, the Cervical vein), allowing glucose-rich blood to flow through an integrated energy-harvesting module.

In addition, all patients except for patient no. 1 received a standard off-the-shelf pacemaker device (model XK-7016, manufactured by Chicago Scientific).

Surgical Protocol: Ten volunteers (ages 47 – 58) were recruited, including nine patients with documented bradycardia and one healthy subject. Procedures were performed under general anaesthesia, taking approximately four hours to facilitate the implantation of the charger to the vascular system, placing the controller outside the ribcage and the earpiece in the right ear of the subject and connecting the required wiring between all system components.

Data Collection: System telemetry was downloaded via a 10cm induction device placed against the chest. Parameters monitored included power output (mW), usage hours, and heart-rate stability.

Results

Power Generation: The metabolic charger exceeded initial estimations, providing a continuous average of

Patient ID	Age	Gender	Clinical Indication	Avg. Power Gen. (mW)	Daily Usage (Hours)	Heart-Rate Stability	Serious Adverse Events
1	58*	M	Healthy Control	48.2	4.5	N/A	None
2	52	M	Bradycardia	41.5	2.1	Stable	None
3	61	F	Bradycardia	44.8	3.5	Stable	None
4	55	M	Bradycardia	42.0	2.0	Stable	None
5	55	F	Bradycardia	56.1	7.2	Stable	None
6	49	F	Bradycardia	43.7	4.8	Stable	None
7	57	M	Bradycardia	40.2	3.1	Stable	None
8	53	M	Bradycardia	45.9	5.4	Stable	None
9	50	F	Bradycardia	41.3	2.6	Stable	None
10	47	M	Bradycardia	42.8	3.0	Stable	None
Mean	53.7	—	—	44.6	3.8	—	—

Table 1: Clinical and Operational Summary of the *Embedix* First-in-Human Cohort (90-Day Follow-Up)

***Note:** Patient 1 underwent implantation of the controller, earpiece, and metabolic charger only, without a pacing lead.

40-50 mW across the cohort. Notably, one patient (Patient No. 5) achieved a record average of 56 mW, likely due to a diet high in simple sugars and high metabolic efficiency. This power level is several orders of magnitude higher than ceramic-electrolyte fuel cells reported in recent literature (Simons et al., 2022).

Operational Stability: The system supported an average of 5–7 hours of active voice-interface use per day. The installed voice assistant, (“*DEBRA*”, Version 1.0.93), successfully performed tasks including bi-directional conversation with the patient, phone calls, GPS navigation, language translation, and text messaging.

Safety and Biocompatibility: No serious adverse events (SAEs) were reported. While early abiotic cell research highlighted risks of tissue fibrosis (Xiao et al., 2019), the *Embedix* charger maintained stable integration with the blood vessel throughout the 90-day trial, with no interference between the metabolic charger and the Chicago Scientific pacing lead.

Discussion

This study represents the “First in Human” milestone for metabolically powered electronics. The transition from lithium-dependency to glucose-harvesting effectively grants the device an unlimited lifespan.

While the current procedure requires invasive surgery, development is already underway for a second-generation system.

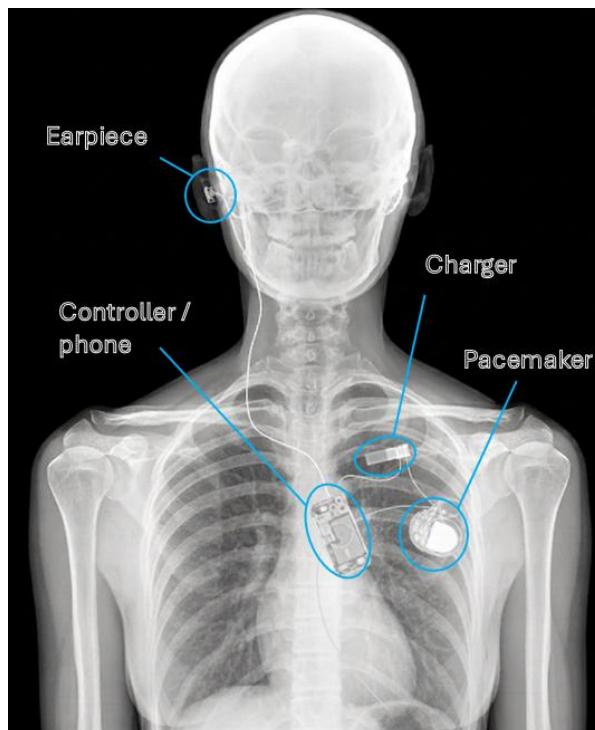


Image 1: X-ray image of patient #5, (F, 56.1), demonstrating the system implantation

This miniaturized version is designed for transcatheter delivery under local anaesthesia, which is expected to significantly enhance patient recruitment and market adoption. Future applications include integration of continuous glucose monitoring

For automated insulin regulation, potentially functioning as an artificial pancreas (augmenting Maity et al., 2023).

Conflict of Interest: The authors are shareholders or employees of *Embedix* Ltd.

References

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