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Bioresorbable wireless battery-free pacemaker for transient electrical stimulation of the heart

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The goal of this project is to demonstrate the feasibility of a fully implantable, battery-free biodegradable pacemaker for acute and chronic transient applications.

INTRODUCTION

Temporary pacemakers are implanted into patients for short-term pacing of the heart as a bridge to therapy or when arrhythmias are expected to be temporary. However, the standard hardware is often the focus for infection where bacteria form biofilms along wires or seed in the blood, resulting in pathological tissue reactions. Due to the short-term nature of these devices, the generator that powers the pacemaker is external, which increases chances of infection at the venous access sites of the hardware. Patients face physiological distress associated with re-operation and increased chances of infection during the removal of the temporary pacemaker leads. Few pacemakers can both deliver cardiac electrotherapy while also addressing the physiological complications of the removal of mechanical hardware. A biodegradable pacemaker would utilize more biocompatible materials to minimize adverse pathological reactions, and its biodegradable mechanism eliminates the need for device removal procedures.

Figure 1: Previous generation of miniature pacemakers. *Our lab previously developed a wireless implantable pacemaker for mice (Laughner et al., 2013).*

METHODS

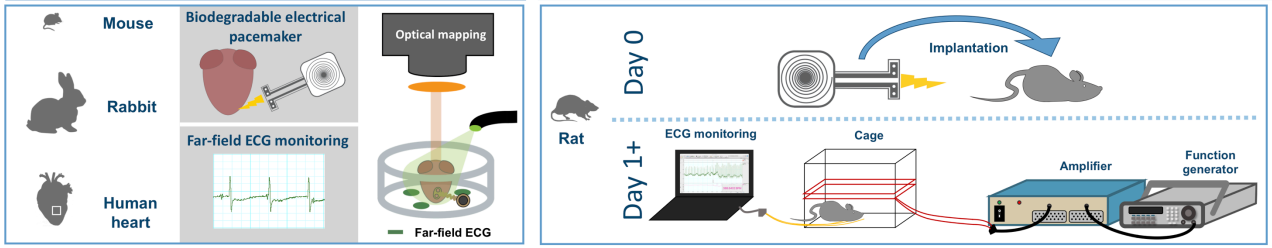
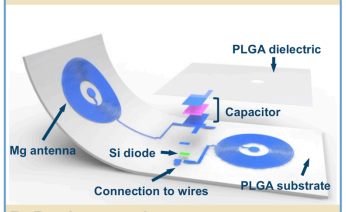
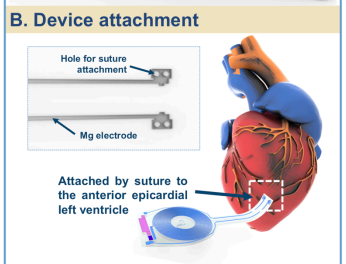
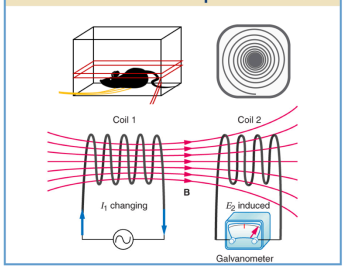


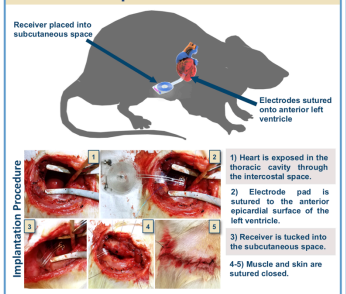
Figure 2: Validation and verification methods. ***(a)*** *Electrical pacing capabilities of the device were confirmed with far-field ECG monitoring and optical mapping of ex vivo mouse and rabbit whole hearts, as well as human ventricular slices.* ***(b)*** *For long-term electrical pacing, miniature pacemakers were implanted into rats by suturing the electrodes onto the anterior epicardial surface of the left ventricle and placing the receiver in the subcutaneous space. Devices were powered by wireless inductive power transfer. Successful pacing for capture of the heart was verified by ECG. Pacing and capture of the heart was monitored daily by ECG until device failure.*

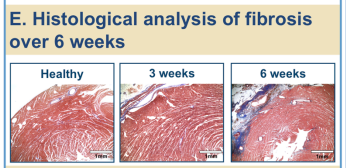
RESULTS

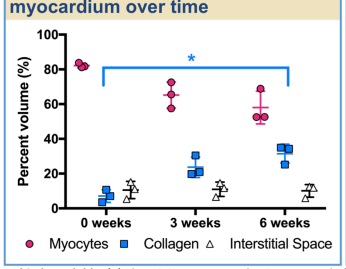


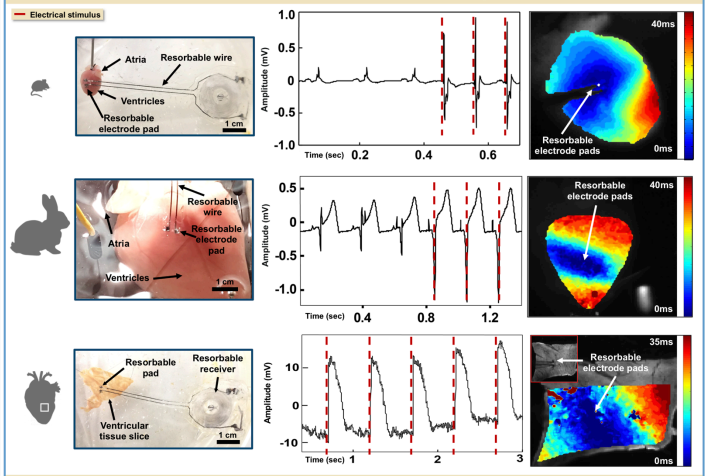


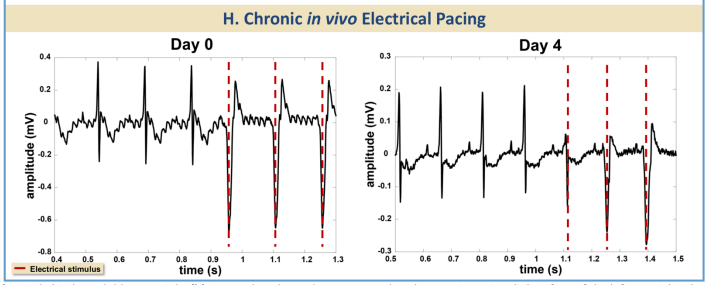












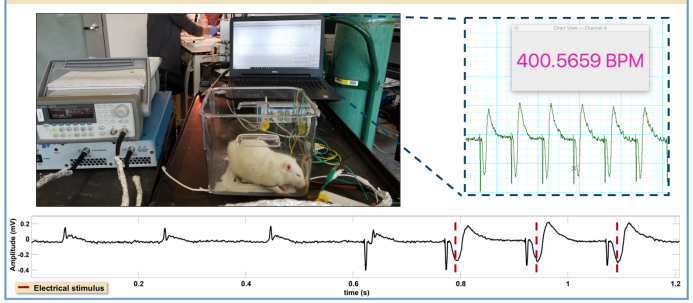


Figure 3: Acute and chronic electrical pacing using the miniature biodegradable. ***(a)*** *The miniature pacemaker is composed of entirely biodegradable materials.* ***(b)*** *Pacemaker electrodes are sutured to the anterior epicardial surface of the left ventricle. The receiver is implanted into the subcutaneous space.* ***(c)*** *Miniature pacemaker is powered by wireless inductive power transfer.* ***(d)*** *(Top) Anatomical placement of the device in relation to the heart. (Bottom) Pacemaker implantation procedure.* ***(e)*** *Histological analysis of myocardium at 0 weeks (left), 3 weeks (middle), and 6 weeks (right) post-surgery.* ***(f)*** *No significant difference in fibrotic tissue volume in myocardium except between 0 and 6 weeks post surgery. (* = p<0.05).* ***(g)*** *(Left column) Device can pace different scales of hearts from mouse to rabbit to human ventricular slices. (Center column) Far-field ECG trace or optical action potential shows capture of sinus rhythm. (Right column) Activation map of transmembrane potential shows that initial activation originates from electrode location, thus the device is driving the activation of propagation.* ***(h)*** *In vivo electrical pacing captures rat sinus rhythm up to 4 days post-surgery.* ***(i)*** *(Top) A conscious rat with an implanted miniature pacemaker is monitored via ECG. (Bottom) With an implanted miniature pacemaker, the ECG shows that the rat heartbeat is captured during live stimulation.*

CONCLUSIONS

These fully biodegradable pacemakers can deliver acute electrical stimulation with size scalability and can be fully implanted for chronic electrical stimulation for up to 4 days. The device is powered by wireless inductive power transfer and is therefore battery-free, thus allowing for its miniaturized nature. The full implantability minimizes complications such as infection that are common to external temporary pacemakers. The combination of the miniature geometry and the biodegradability make the device highly suitable for cases where temporary pacemakers and pediatric pacemakers are used because it eliminates a need for a second surgery to remove the device. This miniature biodegradable pacemaker serves as the basis for an alternative technology for temporary pacemakers.

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