A WIRELESS PACING SYSTEM MINIATURIZED FOR VASCULAR IMPLANTATION

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INTRODUCTION

- Cardiac pacemakers are the primary non-pharmacologist therapy for patients with bradyarrhythmias and conduction disorders

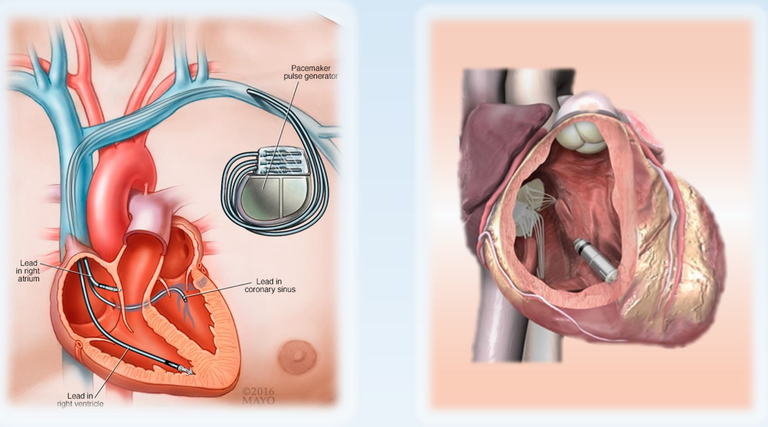

Figure 1: (a) traditional cardiac pacemaker and (b) Micra leadless pacemaker

- ~10% of all pacemaker implants have lead-related complications
- Although the recent FDA approval of the leadless Micra has eliminated some of these risks, the device carries new complications

TRADITIONAL PACEMAKER [1][2]	MICRA LEADLESS PACEMAKER [3]
Lead Dislodgement	Large Delivery Catheter
Myocardial Perforation	Difficult Implantation
Valvular Damage	Long Fluoroscopy Time
Pericarditis	Single-Chamber Only
Cardiac Temponade	Limited Battery Life
Vascular Stenosis	Fixation Mechanism
Extracardiac Stimulation	
Coil Fracture & Hemorrhaging	
Insulation Breaks	
Dangerous Lead Removal	
Twiddler Syndrome	

- Almost all of these limitations arise from the continued need to integrate a battery in pacer packaging that is fixated inside the myocardium.

SYSTEM DESIGN

- A miniature wireless pacing system was developed in which power transmission to the receiver antenna and stimulation electrodes were provided in intermittent pulses controlled by the transmitter circuitry [4].

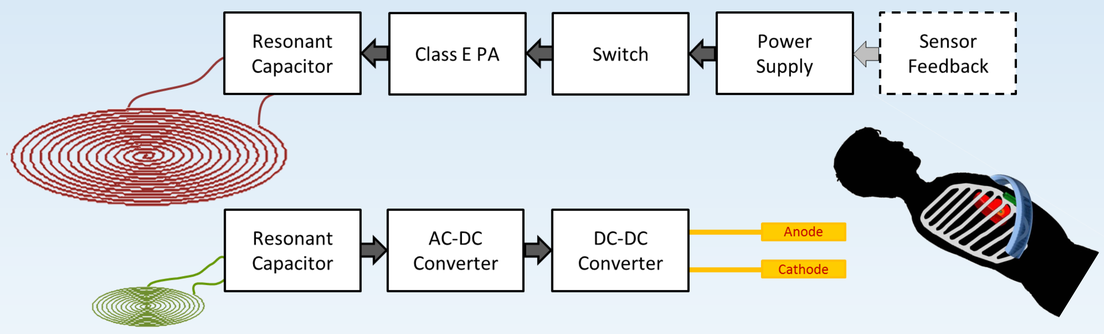

Figure 2: remote-controlled stimulation system

- Advantages of remote-control stimulation:
  - Reduction in size ➔ removal of complex logic circuitry.
  - Reduction in size ➔ removal of a battery.
  - Reduction in power ➔ use of wired over wireless transmission.
  - Reduction in power ➔ delivery of several short-pulse wireless transmissions as opposed to a single long transmission.
  - Reduction in SAR ➔ decreased time of transmission.
- Pacer was fabricated as follows (Figure 3):
  - 40x40x2 mm transmitter
  - 2.8x2x20 mm receiver ➔ packaged in 9 Fr catheter for delivery

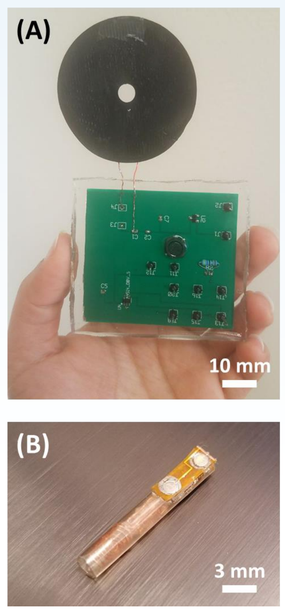

Figure 3: Tx and Rx

METHODS

- Magnetic Resonance Imaging of the thorax over a full cardiac cycle was used to estimate anatomical range for antenna
- Power transfer efficiency was then tested using ANSYS Maxwell and PSPICE simulation software.
- Bench tests validated simulation results.
- Ex vivo and in vivo experiments were performed by deploying the receiver into the anterior cardiac vein of Yorkshire pigs.

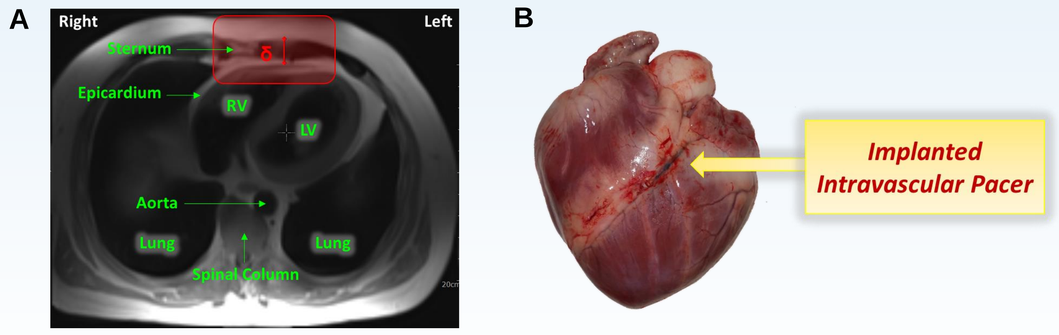

Figure 4: (A) MRI measurements, (B) pacer implant in pig experiments

RESULTS

- Simulation and bench test results are shown in Figure 5:

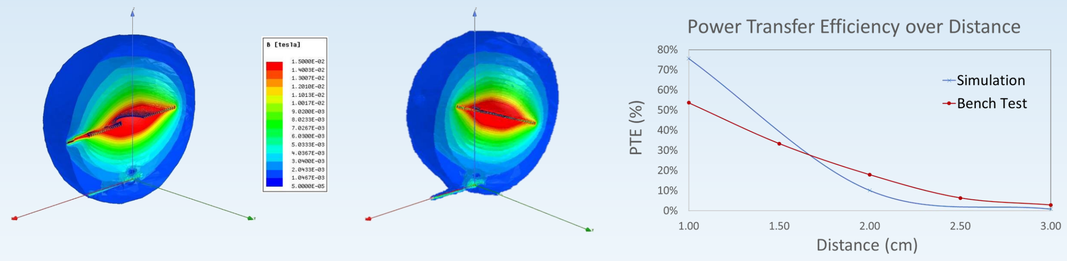

Figure 5: Simulation and bench test results

- EKG tracings demonstrating pacing are shown in Figure 6:

Figure 6: EKG from (A) ex vivo and (B) in vivo pig experiments

DISCUSSION & CONCLUSION

- The miniaturization of a wirelessly powered pacing system allows for implantation into the anterior cardiac vein.
- This minimizes the mechanical failure points associated with a cardiac chamber implant which experiences dramatic shifts in applied force and position during cyclical cardiac contractions.
- The presented study provides a basis for the development of a long-term wireless implantable pacemaker

ACKNOWLEDGEMENTS

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