New Pacemaker Paradigm: a Novel Single Conduit Lead for AV Sequential Pacing and Unique Conduction System Capture

Michael V. Orlov, MD, PhD*; Pugazhendhi Vijayaraman, MD§; Maxim V. Gorev, MD¶; Daniel L. Makharinsky, BS;* Lyubov Mitrofanova, MD, DSci★; Dmitry S. Lebedev, MD, DSci★; Andrei Starostin, MSci+; Leonid E. Makharinsky, MSci, PhD*



Background

Current tools for physiologic pacing (PHP) are limited. No innovative leads are in development. Leadless devices for PHP are not available. There is a need for better tools. A single conduit lead providing multiple options for dual chamber PHP would be highly desirable.

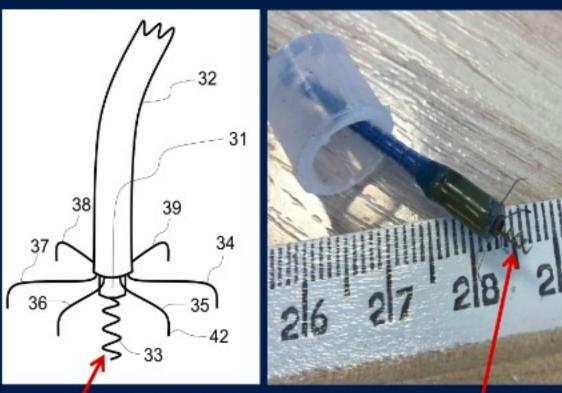


Fig.1 Concept and Prototype 2.0. Single conduit lead with central active helix (red arrow) and multiple active prong electrodes.

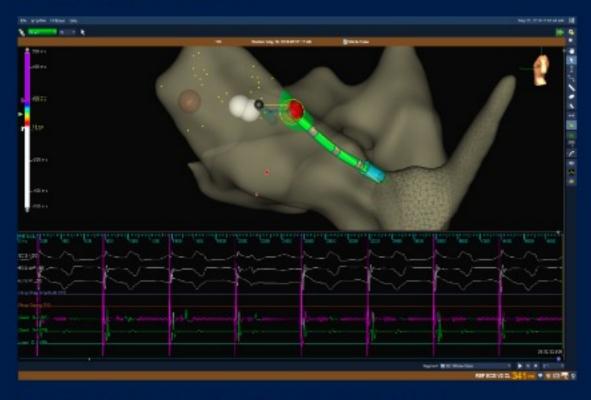


Fig.2 AV septum in left lateral view, electroanatomical mapping. Atrial capture site (red dot) is 8 mm away from LBBB correction site (white dots)

Methods

A new concept for PHP consists of a multipronged single conduit lead (MPL) (Fig.1) to be implanted into Koch's triangle followed by selection of the best electrode subsets. Prototypes 1.0 and 2.0 have been produced. Open chest (Prototype 1.0) and transvenous (Prototype 2.0) experiments have been performed in 9 pigs. Acute prototype lead placement was guided by EGM's, electro-anatomical mapping and X-ray. Modified standard delivery sheaths were used. A subacute experiment was attempted in 1 animal.

Results

- Distance between atrial tissue and conduction system is short (Fig.2)
- The prototype lead was successfully implantable into Koch's triangle via a transvenous route; it remained in place for the duration of the acute and subacute experiments. Pathology shows tissue penetration of the distal screw and individual prongs of MPL (Fig. 3)
- Differential capture of atrial tissue or His bundle is possible from a single implant location from different individual electrodes of a single conduit MPL thus providing sequential dual chamber pacing capabilities (Fig. 4)

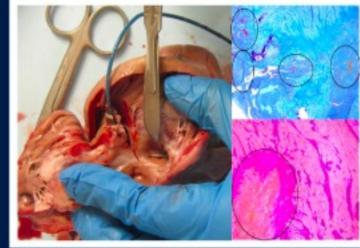
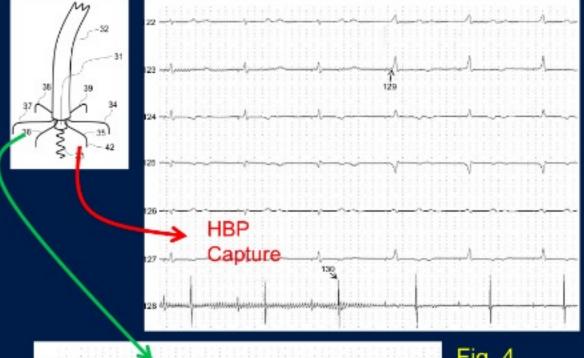


Fig.3 Lead implanted at the septal commissure of the tricuspid valve (left). Subacute experiment, 10 days post implant. Microscopy showing necrosis from the anchoring screw (bottom right) and from the prongs of the MPL (top right).

Different variants of His bundle capture with different capture thresholds and atrial capture from individual electrodes are achievable with MPL (Fig. 4)



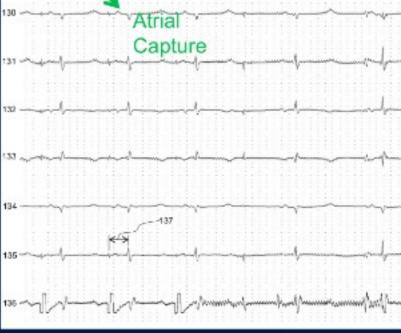


Fig. 4 Selective and nonselective PHP (top) and atrial capture (bottom) from different prongs of MPL implanted in Koch triangle

Conclusion

- MPL allows for PHP with AV sequential capabilities from a single location.
- This technology may obviate the need for two leads to be implanted separately so as to simplify the implant procedure.
- Leadless concepts can be pursued.
- Chronic animal and human studies are planned to prove these potential capabilities.