

ELECTRICAL PERFORMANCE OF A NOVEL ENTIRELY EXTRAVASCULAR TEMPORARY PACING SYSTEM: INITIAL PILOT STUDY EXPERIENCE

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Electrical Performance of a Novel Entirely Extravascular Temporary Pacing System: Initial Pilot Study Experience

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ABSTRACT

Background

A completely extravascular cardiac temporary pacing system has been developed that includes a lead positioned within the anterior mediastinum, through a parasternal skin incision using a custom delivery tool (Figure 1, top). This novel system may provide clinical advantages over existing device alternatives that require intravascular, endocardial, or epicardial contact.

Objective

The purpose of this study was to evaluate electrical performance of an EV lead used for temporary pacing.

Methods

In this single-center study, patients who underwent a transvenous (TV) permanent pacemaker implant or replacement were simultaneously implanted with the temporary extravascular lead. Electrical performance was evaluated through analysis of capture thresholds, impedance, and R-wave amplitudes at implant, 1 and 2 days post implant.

Results

Lead insertions with acute capture were successful in all 11 patients (36% female, 67.7 ± 9.4 years, BMI 25.9 ± 3.5 kg/m²). Mean acute measurements, including threshold @ 1.5 ms, impedance and R-wave amplitude were 3.9 V, 580 Ω, 4.3 mV, respectively. A trend in rising thresholds with decreasing impedance and R-waves was observed, although capture remained possible over the follow-up period. (Figure 1, bottom)

Conclusions

A completely extravascular pacing lead can facilitate effective temporary bradycardia pacing. Although capture generally remained possible over time, further investigations to minimize threshold increases are warranted.

Disclosures: **W. van der Stuijt:** None **A.F. Quast:** None **N.E.G. Beurskens:** None **M.C. Burke:** Boston Scientific Corp., AtaCor Medical, Inc., Medtronic, Inc., St. Jude Medical. **A. Ebner:** None **M. Husby:** AtaCor Medical, Inc. **R. Sanghera:** AtaCor Medical, Inc. **R. Sanghera:** AtaCor Medical, Inc. **R.E. Knops:** Boston Scientific Corp., Medtronic, Inc., St. Jude Medical.

INTRODUCTION

The AtaCor EV Temporary Pacing System (AtaCor Medical, San Clemente, CA) is a completely extracardiac temporary pacing system that provides potential clinical advantages over existing temporary pacing alternatives that require intravascular, endocardial or epicardial contact. Included in these potential clinical advantages are the avoidance of risks historically associated with temporary pacing (systemic infection, thrombo-embolism, cardiac perforation, pericardial effusion and tamponade) and the elimination of bedrest restrictions while the temporary lead is inserted. The Subcostal Temporary Extracardiac Pacing (STEP) Study (n=12) represents the first human data collected with development versions of the AtaCor Medical custom extracardiac temporary pacing lead (“StealthTrac Lead”) and custom delivery tool (“MACH I Delivery Tool”).

METHODS

Subjects undergoing a standard-of-care procedure provided written informed consent in order to participate in the study. All subjects were required to have a market-released pacing system (e.g., transvenous) to provide backup clinically necessary pacing during the study.

StealthTrac Leads were placed in the anterior mediastinum using the custom MACH I Delivery Tool, as depicted **Figure 1**.

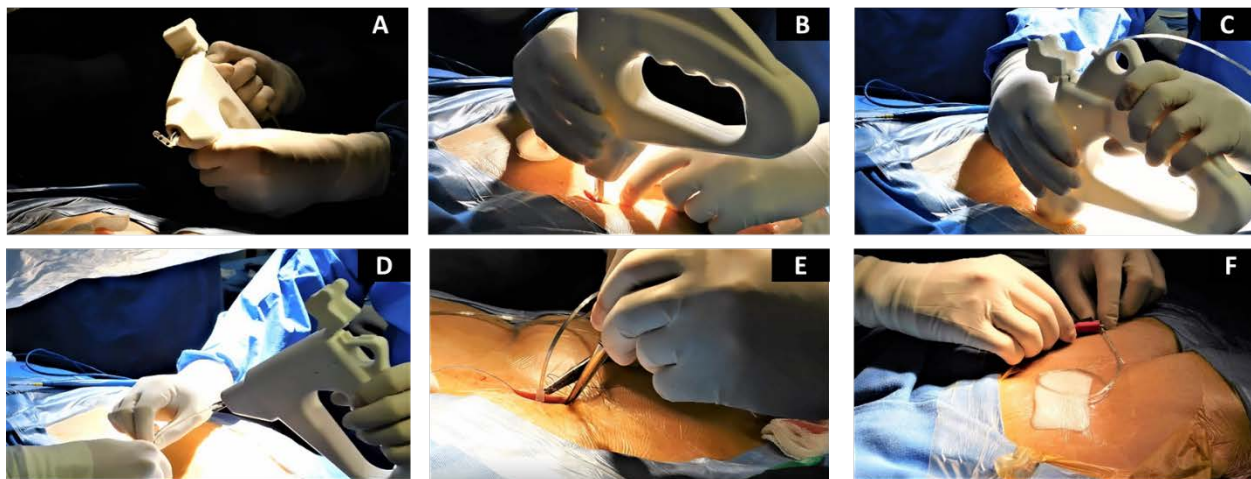


FIGURE 1: (A) Loading the StealthTrac Lead into the Mach I Delivery Tool (AtaCor Medical, San Clemente, CA); (B) The Mach I Delivery Tool tips inserted through a 2-3 cm skin incision; (C) The Mach I Delivery Tool tips inserted through the intercostal muscle to access the mediastinal space; (D) Removal of the MACH I Delivery Tool over the proximal end of the StealthTrac Lead; (E) Fixation of the StealthTrac Lead with a suture sleeve; (F) Connection between the terminal pin of the StealthTrac Lead to an external pacing system analyzer.

The distal end of the pacing lead contains two electrodes that reside in the extracardiac tissue in the area of the cardiac notch of the left lung above the pericardium. The proximal end of the pacing lead contains electrical contacts that allow for connection to a pacing system analyzer or temporary pacemaker.

Pacing capture thresholds, pacing impedance and R-wave amplitudes were assessed at four timepoints: 1) During the procedure (peri-procedure); 2) after the procedure (post-procedure); 3) one (1) day after the procedure; 4) two (2) days after the procedure.

Pacing capture and sensing were achieved by connecting the StealthTrac Lead to a commercially available pacing system analyzer, temporary pacemaker or externalized implantable pacemaker, as shown below in **Figure 2**.

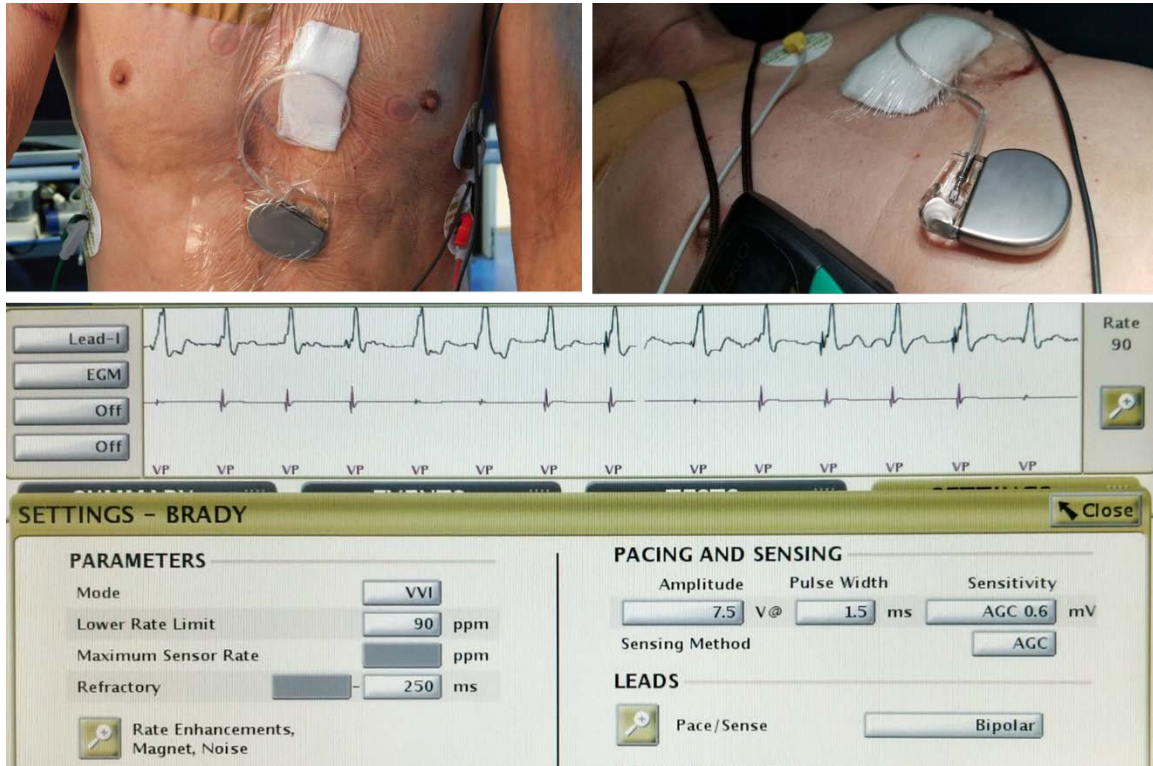


FIGURE 2: Example of pacing and sensing with an externalized implantable pacemaker

The pacing threshold was determined by setting the pulse width to 1.5 ms and decreasing the voltage output until at least two (2) consecutive paced beats failed to capture. The assessment of capture was made by observing an ECG monitor and documenting the threshold that demonstrated loss of cardiac capture, defined as two consecutive non-captured pacing pulses (see **Figure 3**).

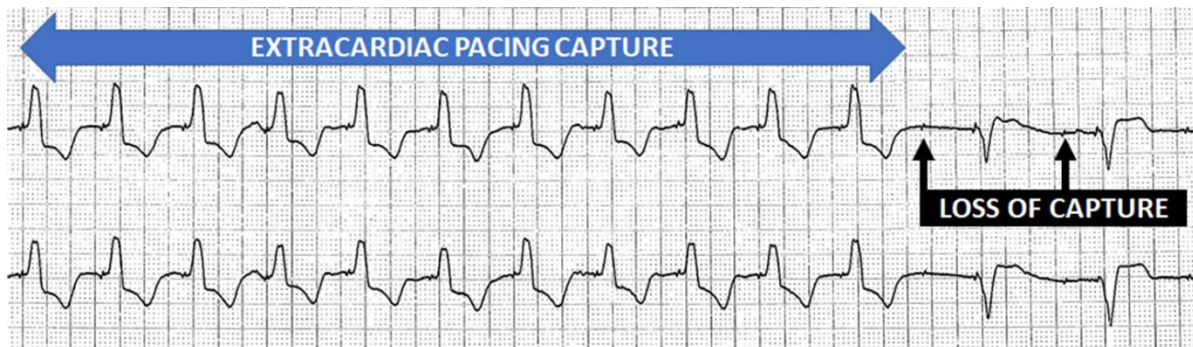


FIGURE 3: Sample of loss of cardiac capture during pacing threshold evaluation

RESULTS

Twelve (12) subjects were enrolled at Sanatorio Italiano in Asuncion, Paraguay (Adrian Ebner, MD, Principal Investigator) and inserted with the StealthTrac Lead on 27-Aug-2019 and 08-October-2019.

Eleven (11) subjects underwent a successful STEP procedure temporary pacing study extravascular pacing lead implant. One (1) subject was withdrawn due to pericardial tamponade caused by the market-released transvenous lead, which precluded any attempt to insert the StealthTrac Lead. Baseline demographic characteristics of the study subjects are summarized in **Table 1**.

TABLE 1: Demographic Characteristics

VARIABLE	N (%) OR MEAN (SD)	RANGE (MIN, MAX)
Age (years)	67.7 (9.4)	49, 82
Female Gender	4 (36%)	.
Height (cm)	165.0 (8.8)	156, 187
Weight (kg)	69.5 (9.6)	56, 86
BMI (kg/m ²)	25.9 (3.5)	21.3, 31.9

Pacing capture was obtainable in all eleven (11) subjects who underwent a StealthTrac Lead insertion procedure. Peri-procedural mean pacing threshold @ 1.5 ms, mean impedance and mean R-wave amplitude were 3.9 V, 580 Ω , 4.3 mV, respectively (**Figure 4**).

On Day 1 post insertion, a single subject experienced an apparent lead dislodgement, precluding further testing; therefore, measurements on Day 1 and Day 2 post insertion were taken on ten (10) subjects. By Day 2 post insertion, the mean pacing threshold increased to 7.0 V, the mean impedance decreased to 266 Ω and the mean R wave amplitude decreased to 2.6 mV.

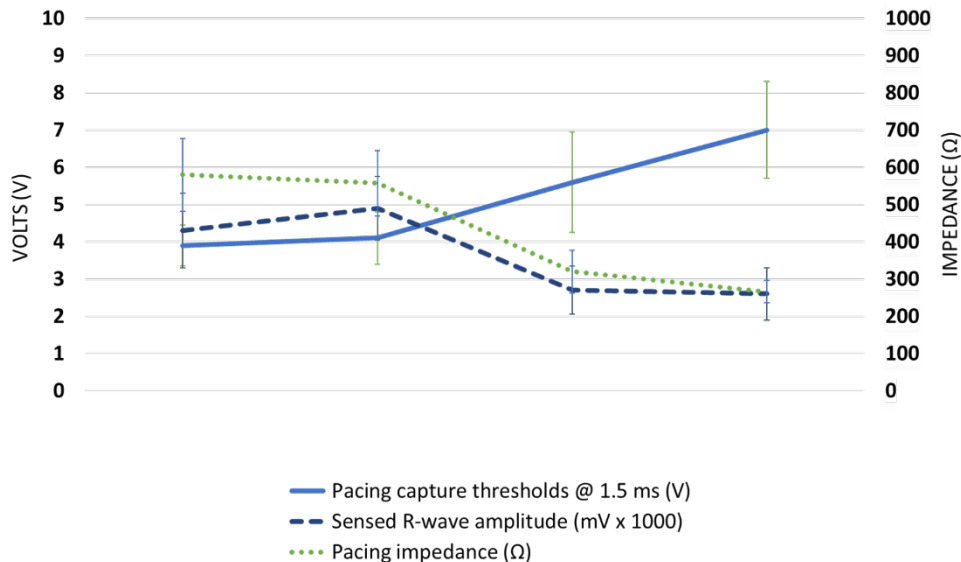


FIGURE 4: Mean pacing capture threshold (n=11), pacing impedance (n=11) and R-wave amplitudes (n=4)

CONCLUSION

The STEP Study represents the first human use with development versions of the StealthTrac Lead and MACH I Delivery Tool, custom devices intended to provide extravascular/extracardiac temporary pacing when connected to an external pacemaker.

These initial results confirm that the StealthTrac Lead can provide consistent pacing and sensing without fixation to the heart over 48 hours. The StealthTrac Lead provided consistent capture and sensing in all but a single case, where a suspected lead dislodgement prevented capture.

Notably, appropriate sensing and pacing were maintained over two (2) days during which time subjects had no bedrest restrictions and performed short walks as part of the study protocol.

Learnings from this pilot study are being used to guide improvements in extracardiac lead electrical performance through iterative device designs, new accessories and improved instructions for use.

The STEP Study underscores the potential of the AtaCor EV Temporary Pacing System, providing a completely extravascular/extracardiac approach to rapid initiation of temporary pacing without bed rest restrictions.