

# First-in-Human Experience with a Novel Active Fixation Temporary Pacing Lead: Safety and Feasibility of the Tempo<sup>®</sup> Lead

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## Background

Complications associated with current temporary pacing leads include dislodgement causing loss of capture, arrhythmias and ventricular perforation. The need for temporary pacing has increased with the rapid evolution of transcatheter aortic valve replacement (TAVR), both for rapid pacing during balloon aortic valvuloplasty (BAV) and valve deployment, and for post-procedure bradyarrhythmias. This investigational first-in-human study evaluated a novel temporary pacing technology, the Tempo Lead (BioTrace Medical, San Carlos, CA), with features including a soft tip to mitigate perforation and a novel fixation mechanism designed to provide lead stability.

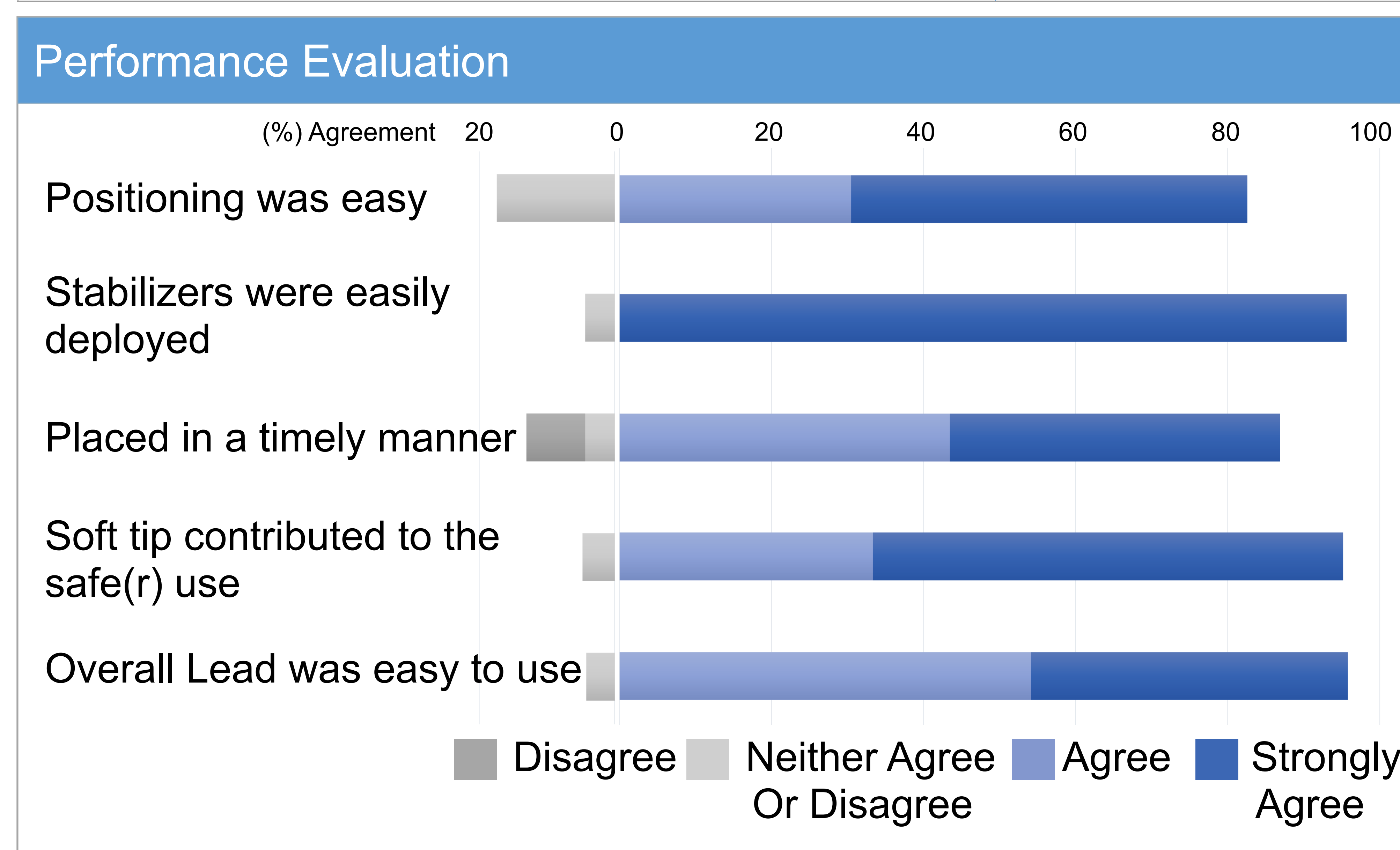
## Methods

Patients were eligible for prospective study enrollment in this Ethics Committee and government approved study if they required temporary pacing for TAVR, BAV or electrophysiology (EP) procedures. Transthoracic echocardiograms were obtained at baseline and 24 hours after lead removal. The device was evaluated for safety (freedom from pericardial effusion requiring intervention and/or echocardiographic evidence of tamponade) and technical feasibility (intracardiac delivery and pace capture). Additional evaluations included pace capture thresholds (PCT), success of rapid pacing, and incidence of dislodgement or sustained ventricular arrhythmias (>30 seconds). Follow up was to 30 days.

Baseline	Value
Number of patients (n)	25
Age (years)	64.6 ± 17
Gender (% Female)	60
Height (range, cm)	147-184
Weight (range, kg)	36 to 125
Tricuspid Valve Disease (% ≥ Moderate)	12

Safety Results	Value
Freedom from Pericardial Effusion (%)	100
Freedom from Cardiac Tamponade (%)	100
Device Related Adverse Events (%)	0
Lead Dislodgements (%)	0
Sustained Arrhythmias (%)	0

Pacing Performance Results	Value
Final Pace Capture Threshold (Mean±SD, mA)	0.70 ± 0.53
Post Procedure Pace Capture Threshold (Mean±SD, mA)	0.75 ± 0.56
Pace Capture Threshold 24h (Mean±SD, mA) (n=4)	1.15 ± 0.40
Sensitivity Threshold (mV)	9.4 ± 6.5
Rapid Pacing Success (%)	100



## Results

Twenty five (25) patients (60% female, mean age 64±19 years) underwent 13 TAVR (7 Edwards Sapien 3, 4 Medtronic Evolut<sup>™</sup> R, 2 Boston Scientific Lotus<sup>™</sup>), 11 EP procedures and 1 BAV at two New Zealand centers. The Tempo Lead was successfully positioned in 23 cases (92%); two patients had unsuitable anatomy. The safety endpoint was met in all patients, with no device-related adverse events. No patient had a sustained ventricular arrhythmia or lead dislodgement. Average final procedural PCT was 0.7±0.5mA. Rapid pacing was successful in all cases, with no loss of pace capture. In 5 patients the lead was used post-procedure, between 9 hours and 5 days. The patient with the five day duration was pacing dependent and ambulated with stable pace capture thresholds and a final PCT of 1.5mA.

## Conclusion

This first-in-human study demonstrates that the Tempo Lead is safe and feasible for temporary cardiac pacing, and provides stable peri- and post-procedural pacing support.

